# Resona 7/Resona 7CV/Resona 7EXP/ Resona 7OB/Resona 7S/Resona 7PRO/ Resona R9 Exp/Resona R9 Pro/Resona R9S/Resona R9/Resona R9W/Resona R7W/Nuewa R9/Nuewa R9 Exp/Nuewa R9 Pro/Nuewa R9S/Imagyn 7/Nuewa R9W/ Nuewa R7W/Resona Y

# **Diagnostic Ultrasound System**

**Operator's Manual** 

[Basic Volume]

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- the product is used in accordance with the instructions for use.

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This warranty shall not extend to:

- Malfunction or damage caused by improper use or man-made failure.
- Malfunction or damage caused by unstable or out-of-range power input.
- Malfunction or damage caused by force majeure such as fire and earthquake.
- Malfunction or damage caused by improper operation or repair by unqualified or unauthorized service people.
- Malfunction of the instrument or part whose serial number is not legible enough.
- Others not caused by instrument or part itself.

#### **Customer Service Department**

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Address:	Mindray Building, Keji 12th Road South, High-tech industrial park, Nanshan, Shenzhen 518057, P.R.China
Website:	www.mindray.com
E-mail Address:	service@mindray.com
Tel:	+86 755 81888998
Fax:	+86 755 26582680

Manufacturer:	Mindray DS USA, Inc.	
Address:	800 MacArthur Blvd. Mahwah, NJ 07430-0619 USA	
Tel:	+1(201) 995-8000	
Toll Free:	+1 (800) 288-2121	
Fax:	+1 (800) 926-4275	

# **Important Information**

- It is the customer's responsibility to maintain and manage the system after delivery.
- The warranty does not cover the following items, even during the warranty period:

- Damage or loss due to misuse or abuse.
- Damage or loss caused by Acts of God such as fires, earthquakes, floods, lightning, etc.
- Damage or loss caused by failure to meet the specified conditions for this system, such as inadequate power supply, improper installation or environmental conditions.
- Damage or loss due to use of the system outside the region where the system was originally sold.
- Damage or loss involving the system purchased from a source other than Mindray or its authorized agents.
- This system shall not be used by persons other than fully qualified and certified medical personnel.
- DO NOT make changes or modifications to the software or hardware of this system.
- In no event shall Mindray be liable for problems, damage, or loss caused by relocation, modification, or repair performed by personnel other than those designated by Mindray.
- The purpose of this system is to provide physicians with data for clinical diagnosis. The physician is responsible for the results of diagnostic procedures. Mindray shall not be liable for the results of diagnostic procedures.
- Important data must be backed up on external memory media.
- Mindray shall not be liable for loss of data stored in the memory of this system caused by operator error or accidents.
- This manual contains warnings regarding foreseeable potential dangers, but you shall also be continuously alert to dangers other than those indicated. Mindray shall not be liable for damage or loss resulting from negligence or ignorance of the precautions and operating instructions described in this operator's manual.
- If a new manager takes over this system, be sure to hand over this operator's manual to the new manager.

# **About This Manual**

This operator's manual describes the operating procedures for this diagnostic ultrasound system and the compatible probes. To ensure safe and correct operation, carefully read and understand the manual before operating the system.

## **Meaning of Signal Words**

In this manual, the signal words  $\triangle$  **DANGER**,  $\triangle$  **WARNING**,  $\triangle$  **CAUTION**, **NOTE** and **TIP** are used regarding safety and other important instructions. The signal words and their meanings are defined as follows. Please understand their meanings clearly before reading this manual.

Signal word	Meaning
	Indicates an imminently hazardous situation that, if not avoided, will result in death or serious injury.
MarningIndicates a potentially hazardous situation that, if not avoided result in death or serious injury.	
	Indicates a potentially hazardous situation that, if not avoided, may result in minor or moderate injury.
NOTE	Indicates a potentially hazardous situation that, if not avoided, may result in property damage.

Signal word	Meaning		
TIP	Important information that helps you to use the system more effectively.		

### **Operator's Manuals**

You may receive multi-language manuals on compact disc or paper. Please refer to the English manual for the latest information and registration information.

The content of the operator manual, such as screens, menus or descriptions, may be different from what you see in your system. The content varies depending on the software version, options and configuration of the system.

### **Hardcopy Manuals**

• Operator's Manual [Basic Volume]

Describes the basic functions and operations of the system, safety precautions, exam modes, imaging modes, preset, maintenance and acoustic output, etc.

- Operator's Manual [Advanced Volume]
- Operator's Manual [Acoustic Power Data and Surface Temperature Data] Contains data tables of acoustic output for transducers.
- Quick Reference Guide Contains a quick reference guide for basic system operations.

#### NOTE:

- Manuals on CD are the manuals translated into languages other than English, according to the English manuals.
- If you find that the contents of the manuals on CD are NOT consistent with the system or the English manuals, refer ONLY to the corresponding English manuals.
- The accompanying manuals may vary depending on the specific system you purchased. Please refer to the packing list.

## Software Interfaces in this Manual

Depending on the software version, preset settings and optional configuration, the actual interfaces may be different from those in this manual.

#### Conventions

In this manual, the following conventions are used to describe the buttons on the control panel, items in the menus, buttons in the dialog boxes and some basic operations:

- <Keys>: angular brackets indicate keys, knobs and other controls on the control panel or on the keyboard.
- [Items in menu or buttons in dialog box]: square brackets indicate items in menus, on the soft menu or buttons in dialog boxes.
- Click [Items or Buttons]: move the cursor to the item or button and press <Set> or use the soft key corresponding to the soft menu.
- [Items in menu] > [Items in submenu]: select a submenu item following the path.

### **Notification of Adverse Events**

As a health care provider, you may report the occurrence of certain events to SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD., and possibly to the competent authority of the Member state in which the user and / or patient is established.

These events, include device-related death and serious injury or illness. In addition, as part of our Quality Assurance Program, SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. requests to be notified of device failures or malfunctions. This information is required to ensure that SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. provides only the highest quality products.

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# 1.1 Meaning of Safety Symbols

Symbol	Description
	Type-BF applied part The ultrasound probes connected to this system are type-BF applied parts. The PCG leads within this system is type-BF applied part. The ECG leads within this system is type-BF applied part.
	General warning sign.
	Patient injury or tissue damage from ultrasonic radiation. The ALARA principle must be practiced when operating the ultrasound system.

# 1.2 Safety Precautions

Please observe the following precautions to ensure patient and operator's safety when using this system.

## **A**DANGER

Do not operate this system and probes in an atmosphere containing flammable gases or liquids such as anesthetic gases, hydrogen, and ethanol, because there is danger of explosion.

# **WARNING**

- Do connect the power plug of this system to wall receptacles that meet the ratings indicated on the rating nameplate. If adapters or multifunctional receptacles are used, it may cause the leakage current to exceed the safety requirement.
- In the environment that patient is 1.5 meters around, connect peripherals to the auxiliary power outlet, or power the peripherals by auxiliary output cable or isolation transformer complied with IEC60601-1 or the power input of the same safety level.
- DO NOT use power supply of different phases to power peripherals, like power supply of air-conditioning.

- When using peripherals not powered by the auxiliary output of the ultrasound system, or using peripherals other than permitted by Mindray, make sure the overall leakage current of peripherals and the ultrasound system meets the requirement of the local medical device electrical regulation (like enclosure leakage current should be no more than 500 uA of IEC60601-1), and the responsibility is held by the user.
- Connect the grounding conductor before turning ON the system. Disconnect the grounding cable after turning OFF the system. Otherwise, electric shock may result.
- For the connection of power and grounding, follow the appropriate procedures described in this operator's manual. Otherwise, there is risk of electric shock. Do not connect the grounding cable to a gas pipe or water pipe; otherwise, improper grounding may result or a gas explosion may occur.
- Before cleaning the system, disconnect the power cord from the outlet. System failure and electric shock may result.
- This system is not water-proof designed. Do Not use this system in any place where water or any liquid leakage may occur. If any water is sprayed on or into the system, electric shock may result or the system may be damaged. If water is accidentally sprayed on or into the system, contact Mindray Customer Service Department or sales representative.
- DO NOT use a probe that has a damaged, scratched surface, or exposed wiring of any kind. Immediately stop using the probe and contact Mindray Customer Service Department or sales representative. There is risk of electric shock if using a damaged or scratched transducer.
- Do not allow the patient to contact the live parts of the ultrasound system or other devices, e.g. signal I/O ports. Electric shock may occur.
- Do not use an aftermarket probe other than those specified by Mindray. The probes may damage the system causing a profound failure, e.g. a fire in the worst case.
- Do not subject the transducers to knocks or drops. Use of a defective transducer may cause an electric shock.
- Do not open the covers and front panel of the system. Short circuit or electric shock may result when the system hardware is exposed and powered on.
- Do not use the system with the patient when the system is being serviced or maintained.
- Do not use this system when any digital device such as a high-frequency electrotome, high-frequency therapeutic device or defibrillator is applied already. Otherwise, there is a risk of electric shock to the patient.
- Only use the ECG leads provided with the physiology module; otherwise, electric shock may be resulted.
- When moving the system, you should hold the handle; otherwise, damage may be resulted by abnormal force. Do not push the system from the left/ right side, otherwise, it may be toppled over.

- The auxiliary power output outlet in the system is used to supply power for the recommended peripheral devices. Do not connect other devices to the outlet, otherwise, the rated output power may be exceeded and failure may be resulted.
- Accessory equipment (analog or digital) connected to the ultrasound system must comply with the relevant IEC standards (e.g., IEC 60950 information technology equipment safety standard and IEC 60601-1 medical equipment standard). Furthermore, all configurations must comply with the standard IEC60601-1. It is the responsibility of the person, who connects additional equipment to the signal input or output ports and configures a medical system, to verify that the system complies with the requirements of IEC60601-1. If you have any questions regarding these requirements, consult your vendor.
- Prolonged and repeated use of keyboards may result in hand or arm nerve disorders for some individuals. Observe the local safety or health regulations concerning the use of keyboards.
- It is not allowed for the operator to have contact with other patients and the electronic parts (such as the input/output terminal of the signal) of other devices that are connected to the system. Otherwise, it may produce the electrical shock to the patient.
- When using a probe, pay attention to the status of the ultrasound image. Do not use the probe to perform image acquisition when the image is frozen.
- Do not modify this equipment without authorization of the manufacturer.
- An additional multiple socket-outlet or extension cord shall not be connected to the system.
- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

## 

- Precautions concerning clinical examination techniques:
  - This system must be used only by qualified medical professionals.
  - This operator's manual does not describe clinical examination techniques. The clinician should select the proper examination techniques based on specialized training and clinical experience.
- Malfunctions due to radio wave:
  - If a radio wave emitting device is used in the proximity of this system, it may interfere with operations. Do not use or take any devices transmitting RF signals (such as cellular phones, transceivers and radio controlled products) in the room placing the system.
  - If a person brings a device that generates radio waves near the system, ask him/her to immediately turn OFF the device.
- Precautions concerning movement of the system:

- Please install the system on a flat plane with casters locked. Otherwise, damage may be resulted by accidental moving.
- Do not move the system laterally, which may result in damage in case of toppling.
- Move the system slowly on the slope by two people and make sure that the support arm is not extended, otherwise, damage may result in case of unexpected sliding.
- Do not sit on the system, which may result individual falling in case of system moving.
- Object placed on the monitor may fall and injure an individual.
- Fasten and fully secure any peripheral device before moving the system. A loose peripheral device may fall and injure an individual.
- When moving the system on the steps, please take care to prevent the system from toppling.
- If the circuit protector is tripped, it indicates that the system or a peripheral device was improperly shut down and the system is unstable. You cannot repair the system under this circumstance and must call the Mindray Customer Service Department or sales representative.
- There is no risk of high-temperature burns during normal ultrasound examinations. It is possible for the surface temperature of the transducer to exceed the body temperature of a patient due to environmental temperature and exam type combinations. Do not apply the transducer to the same region on the patient for a long time. Apply the transducer only for a period of time required for the purpose of diagnosis.
- Do not use the system to examine a fetus for a long period of time.
- Except accessories that have been stated as sterile, the system and its accessories are not disinfected or sterilized prior to delivery. The operator is responsible for the cleaning and disinfection of probes and sterilization of biopsy brackets according to the manuals, prior to the use. All items must be thoroughly processed to completely remove harmful residual chemicals, which will not only harmful to the human body, but also damage the accessory.
- It is necessary to end the current exam that is in progress and clear the current Patient Information field. Otherwise, new patient data may be combined with the previous patient data.
- Do not connect or disconnect the system's power cord or its accessories (e.g., a printer or a recorder) without turning OFF the system power first. This may damage the system and its accessories or cause electric shock.
- If the system is powered off improperly during operation, it may result in data damage of the system's hard disk or system failure.
- Do not use a USB memory device (e.g., a USB flash drive, removable hard disk) which has unsafe data. Otherwise, system damage may result.
- It is recommended to only use the video devices specified in this manual.

- Do not use gel, disinfectant, probes, probe sheath or needle-guided brackets that are not compatible with the system.
- The applied contrast agency should be compliant with the relevant local regulations.
- Read the Acoustic Output Principle in the operation manual carefully before operating this system on clinical examination.
- The cover contains natural rubber that can cause allergic reactions in some individuals.
- Please use the ultrasound gel compliant with the relevant local regulations.
- Normal operation may be affected by unstable mains power supply; it is recommended that our product be powered from an uninterruptible power supply.
- DO NOT expose the system to excessive vibration through transportation. Mechanical damage may result.
- Always keep the system dry. Avoid transporting this system quickly from a cold place to a warm place; otherwise condensation or water droplets may form allowing a short circuit and possible electric shock.

#### NOTE:

- DO NOT use the system in the vicinity of strong electromagnetic field (such as a transformer), which may affect the performance of the system.
- Do not use the system in the vicinity of high-frequency radiation source (e.g. cellular phones), which may affect the performance of the system or even lead to failure.
- When using or placing the system, keep the system horizontal to avoid imbalance.
- To avoid damaging the system, do not use it in following environment:
  - Locations exposed to direct sunlight.
  - Locations subject to sudden changes in environmental temperature.
  - Dusty locations.
  - Locations subject to vibration.
  - Locations near heat generators.
  - Locations with high humidity.
- Turn ON the system only after the power has been turned OFF for a while. If the system is turned ON immediately after being turned OFF, the system may not be rebooted properly and could malfunction.
- Select "Freeze" to freeze an image or turn off the power of the system before connecting or disconnecting a probe.
- Remove the ultrasound gel from the face of the transducer when the examination is completed. Water in the gel may enter the acoustic lens and adversely affect the performance and safety of the transducer.
- You should properly back up the system to a secure external storage media, including system configuration, settings and patient data. Data stored to the system's hard drive may be lost due to system failure, improper operation or accident.
- Do not apply external force to the control panel. Otherwise, the system may be damaged.

- If the system is used in a small room, the room temperature may rise. Please provide proper ventilation and free air exchange.
- To dispose of the system or any part, contact Mindray Customer Service Department or sales representative. Mindray is not responsible for any system content or accessories that have been discarded improperly.
- Electrical and mechanical performance may be degraded due to long usage (such as current leakage or distortion and abrasion); the image sensitivity and precision may become worse too. To ensure optimal system operations, it is recommended that you maintain the system under a Mindray service agreement.
- To replace the fuse, contact Mindray Customer Service Department or sales representative.
- Do not turn OFF the power supply of the system during printing, file storage or invoking other system operations. An interrupted process may not be completed, and can become lost or corrupted.
- The iScape feature constructs a single extended image from a series of individual image frames. The quality of the final image is user-dependent and requires skill to efficiently apply the feature and technique. Exercise caution when measurements are performed from an iScape image.
- Ensure that the current exam date and time are the same as the system date and time.
- Use detachable power supply cord as mains power breaking device. DO NOT set equipment in place where difficult for disconnection of detachable power supply cord.

Please read the following precautions carefully to ensure the safety of the patient and the operator when using the probes.

#### 

- The ultrasound probe is only for use with the specified ultrasound diagnostic system.
- The ultrasound probe must be used only by qualified professionals.
- Confirm that the transducer and probe cable are normal before and after each examination. A defective probe may cause electric shock to the patient.
- Do not subject the probe to shock. A defective probe may cause electric shock to the patient.
- Do not disassemble the probe to avoid the possibility of electric shock.
- Never immerse the probe connector into liquids such as water or disinfectant because the connector is not waterproof. Immersion may cause electric shock or malfunction.
- A transducer sheath must be installed over the transducer before performing examination.

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• When using the probe, wear sterile gloves to prevent infection.

- Be sure to use sterile ultrasound gel. Please use the ultrasound gel compliant with the relevant local regulations. And manage the ultrasound gel properly to ensure that it does not become a source of infection.
- In normal diagnostic ultrasound mode, there is no danger of a normaltemperature burn; however, keeping the probe on the same region of the patient for a long time may cause such a burn.
- Do not use the carrying case for storing the transducer. If the carrying case is used for storage, it may become a source of infection.
- It is required to practice ALARA when operating ultrasound system. Minimize the acoustic power without compromising the quality of images.
- The probe and accessories supplied with it are not delivered disinfected or sterilized. Sterilization (or high-level disinfect) before use is required.
- Disposable components should be packaged sterile and for single-use only. Do not use if integrity of packaging violated or if expiration date has passed. Please use the disposable components compliant with the relevant local regulations.
- Please use the disinfection or sterilization solution recommended in this operator's manual; otherwise Mindray will not be liable for damage caused by other solutions. If you have any questions, please contact Mindray Customer Service Department or sales representative.
- Do not use pre-lubricated condoms as a sheath. Lubricant may not be compatible with the probe material and damage may result.
- The damage of the transducer may be caused by the contact of improper gel or cleaner:
  - DO NOT dip the transducer in the strong polar solution of ethanol, chloride of lime, ammonium chloride, acetone and formaldehyde.
  - DO NOT contact the transducer with solution or ultrasound gel containing oily medium such as mineral oil or lanoline.

#### NOTE:

- Read the following precautions to prevent the probe from malfunction:
  - Before connecting or disconnecting the probe, freeze or turn off the diagnostic ultrasound system.
  - Clean and disinfect the probe before and after each examination.
  - After the examination, wipe off the ultrasound gel thoroughly. Otherwise, the ultrasound gel may solidify and the image quality would be degraded.
- To prevent the probe from being damaged, do not use it where it will be exposed to:
  - Direct sunlight or X-rays
  - Sudden changes in temperature
  - Dust
  - Excessive vibration
  - Heat generators

• Repeated disinfection will eventually damage the probe, please check the probe performance periodically.

## 1.3 Latex Alert

When choosing a probe sheath, it is recommended that you directly contact CIVCO for obtaining information regarding probe sheaths, pricing, samples and local distribution.

For CIVCO information, please contact the following:

CIVCO Medical Instruments

Tel: 1-800-445-6741

www.civco.com

## **MWARNING**

Allergic reactions in patients sensitive to latex (natural rubber) may range from mild skin reactions (irritation) to fatal anaphylactic shock, and may include difficulty breathing (wheezing), dizziness, shock, swelling of the face, hives, sneezing, or itching of the eyes (FDA Medical Alert on latex products, "Allergic Reactions to Latex-containing Medical Devices", issued on March 29, 1991).

# 2.1 Intended Use

#### NOTE:

The system is not intended for central cardiovascular or central nervous system use.

Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, Intra-operative, pediatric, small organ (breast, thyroid, testes), neonatal and adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), adult and pediatric cardiac, trans-esoph. (Cardiac), peripheral vessel, urology exams.

This device is a general purpose diagnostic ultrasound system intended for use by qualified and trained healthcare professionals for ultrasound imaging, measurement, display and analysis of the human body and fluid, which is intended to be used in a hospital or medical clinic.

Modes of operation include: B, M, PWD (Pulse wave Doppler), CWD (Continuous wave Doppler), Color Doppler, Amplitude Doppler, Combined mode (B+M, PW+B, Color+B, Power+B, PW+Color+B, Power+PW+B), Tissue Harmonic Imaging, Smart 3D, 4D (Real-time 3D), iScape View, TDI (Tissue Doppler Imaging), Color M, Strain Elastography, Contrast imaging (Contrast agent for LVO (Left Ventricular Opacification), V Flow (Vector Flow), STE (Sound Touch Elastography), STQ (Sound Touch Quantification), Contrast imaging (Contrast agent for Liver)

# 2.2 Contraindication

The diagnostic ultrasound system is not intended for ophthalmic use.

# 2.3 Safety Classifications

- According to the type of protection against electric shock: Externally powered CLASS I EQUIPMENT
- According to the degree of protection against electric shock: TYPE-BF APPLIED PART
- According to the degree of protection against harmful ingress of water or particulate matter:
  - The main unit is classified as IPX0
  - The probe is classified as IPX7
  - The footswitch (can be used in the operating room) is classified as IPX8
- According to the disinfection and sterilization method(s) recommended by manufacturer: The devices recommended by the manufacturer.
- According to the degree of safety of application in the presence of a FLAMMABLE ANESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE:

EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE.

- According to the mode of operation: CONTINUOUS OPERATION
- The device equipped with the applied part of defibrillation protection: The device is not equipped with the applied part of defibrillation protection.
- According to the signal input and output parts of the device: The device is equipped with signal input and output parts
- Permanently installed or non-permanently installed: Non-permanently installed

# 2.4 Product Specifications

#### NOTE:

The functions described in the operator's manual may vary depending on the specific system purchased.

## 2.4.1 Power Supply

#### **Power input**

- Voltage: 220-240 V~
- Frequency: 50/60 Hz
- Power consumption: 1000 VA

#### **Power output**

Voltage: 220-240 V~

Frequency: 50/60 Hz

Power consumption: 300 VA (note: this is the maximum auxiliary output power of the outlet. When the peripheral device is connected to the outlet, ensure that the maximum auxiliary output power does not exceed this threshold. Otherwise, the system may be damaged.)

### 2.4.2 Environmental Conditions

#### **MWARNING**

Do not use this system in conditions other than those specified.

- Operating conditions
  - Ambient temperature:  $0 \degree C \sim 40 \degree C$
  - Relative humidity:  $20\% \sim 85\%$  (no condensation)
  - Atmospheric pressure: 700 hPa ~ 1060 hPa
- Storage and transportation conditions
  - Ambient temperature: -20 °C  $\sim$  55 °C
  - Relative humidity: 20% ~ 95% (no condensation)
  - Atmospheric pressure: 700 hPa ~ 1060 hPa

### 2.4.3 Dimensions and Weight

- Dimensions (the monitor and the control panel are kept to a minimum position):
  - Dual-wing floating arm and 21.5-inch monitor
     Depth: 945±10 mm
     Width: 545±10 mm (main unit)/510±10 mm (control panel)
     Height: 1368±10 mm (with the display vertically stands)
     Dual wing floating arm and 23.8 inch monitor
  - Dual-wing floating arm and 23.8-inch monitor
     Depth: 945±10 mm
     Width: 545±10 mm (main unit)/510±10 mm (control panel)
     Height: 1390±10 mm (with the display vertically stands)
- Weight (net weight, standard configured but not including probes): <134.4kg.

# 2.5 **Product Differences**

Model	B-Hist (Ellips e)	B-Hist (Trace )	B-Hist (Splin e)	B-Hist (Recta ngle)		Veloci ty	Cross	Doubl e dist.	PCG
Resona 7	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	×	×	$\checkmark$
Resona 7CV	×	$\checkmark$		$\checkmark$	$\checkmark$	$\checkmark$	×	×	$\checkmark$
Resona 7EXP	$\checkmark$	×	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	×	×	$\checkmark$
Resona 70B	$\checkmark$	$\checkmark$	×	$\checkmark$	$\checkmark$	$\checkmark$	×	×	$\checkmark$
Resona 7S	$\checkmark$	$\checkmark$	$\checkmark$	×	$\checkmark$	$\checkmark$	×	×	$\checkmark$
Resona 7PRO		$\checkmark$	$\checkmark$	$\checkmark$	×	$\checkmark$	×	×	$\checkmark$
Resona R9 Exp	$\checkmark$	×	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$
Resona R9 Pro	$\checkmark$	$\checkmark$	×	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$
Resona R9S	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	×	$\checkmark$	$\checkmark$	$\checkmark$
Resona R9	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$
Resona R9W	$\checkmark$	×	$\checkmark$	$\checkmark$	$\checkmark$	×	$\checkmark$	$\checkmark$	$\checkmark$
Resona R7W	$\checkmark$	×	$\checkmark$	$\checkmark$	$\checkmark$	×	$\checkmark$	$\checkmark$	×
Nuewa R9		$\checkmark$		$\checkmark$	$\checkmark$	$\checkmark$	×	$\checkmark$	$\checkmark$
Nuewa R9 Exp	$\checkmark$	×	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	×	$\checkmark$	$\checkmark$
Nuewa R9 Pro		$\checkmark$	×	$\checkmark$	$\checkmark$	$\checkmark$	×	$\checkmark$	

Model	B-Hist (Ellips e)	B-Hist (Trace )	B-Hist (Splin e)	B-Hist (Recta ngle)	Profile	Color Veloci ty	Cross	Doubl e dist.	PCG
Nuewa R9S	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	×	$\checkmark$
Imagyn 7	×	×	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	×	×	$\checkmark$
Nuewa R9W	$\checkmark$	×	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	×	
Nuewa R7W	$\checkmark$	×		$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	×	×
Resona Y	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	×	$\checkmark$	×	$\checkmark$

# 2.6 System Configuration

### 2.6.1 Standard Configuration

- Main unit
- System software
- Hard disk drive (HDD)
- Solid state disk (SSD)
- Built-in DVD recorder
- Accessories
  - Ultrasound gel
  - Dust-proof cover
  - Printer tray
  - Probe holders
  - Cable hook
  - Leak-proof cap for the ultrasound gel
  - Cables
  - Operator's Manual

### 2.6.2 Probes and Needle-guided Brackets Available

Please see "17 Probes and Biopsy".

### 2.6.3 Options

No.	Item	Remarks
1.	CW Module	Including 2 CW modules
2.	Linear CW function package	Should be configured with CW module
3.	Pencil probe cable	/
4.	Built-in wireless adapter	/

No.	Item	Remarks	
5.	Intra-cavity probe holder (with screws)	<ul><li>The left holder should be configured in preference.</li><li>The left and right holders cannot be configured at the same time.</li></ul>	
6.	Battery	/	
7.	Ultrasound gel warmer	Should be configured with the ultrasound gel warmer holder.	
8.	Ultrasound gel warmer holder	Should be configured with the ultrasound gel warmer.	
9.	Storage Tray Kit	/	
10.	ECG module	/	
11.	ECG cable	The ECG module should be configured.	
12.	DC-IN cable	The ECG module should be configured.	
13.	PCG	The ECG module should be configured.	
14.	Fusion imaging module	Contains 1 magnetic navigation controller, 1 magnetic generator, and 2 fusion imaging sensors. Fusion imaging should be configured.	
15.	Fusion imaging module (including trolley)	Contains 1 magnetic navigation controller, 1 magnetic generator, 2 fusion imaging sensors, and 1 trolley for the magnetic generator. Fusion imaging should be configured.	
16.	Fusion Control Unit Container	Used for carrying the magnetic navigation controller. Fusion imaging module or fusion imaging module (including trolley) should be configured.	
17.	Trolley for magnetic generator	/	
18.	Motion sensor support	Fusion RESP Component should be configured.	
19.	NB-011	SP5-1U	
20.	NB-022	SC6-1U/C5-1U	
21.	NB-024	C6-2Gs/C6-2GU	
22.	NB-025	V11-3HU	
23.	NB-026	L11-3U	
24.	NB-028	SC5-1U	
25.	NB-029	SC8-2U	
26.	NB-035	L14-5WU	
27.	NB-036	C4-1U	
28.	NB-051	ELC13-4U	
29.	NB-054	L14-3WU/L13-3WU/L15-3WU	
30.	NB-058	SC9-2U	

No.	Item	Remarks
31.	Probe extend module PCM- SU01	The P8-2Ts, P7-3Ts, P8-3Ts, C6-2Gs, 7LT4s and L16-4Hs probes can be connected to the ultrasound system through the probe adapter.
32.	iClear <sup>+</sup> Dongle	iClear <sup>+</sup> should be configured.
33.	Barcode reader (1D or 2D)	/
34.	Footswitch (1-pedal, 2- pedal, or 3-pedal)	USB interface
35.	iScape View	/
36.	Free Xros M	/
37.	Free Xros CM	/
38.	Tissue Doppler Imaging	Cardiology Package should be configured.
39.	TDI QA	Tissue Doppler Imaging should be configured.
40.	Contrast Imaging	/
41.	Contrast Imaging QA	Contrast Imaging should be configured.
42.	LVO	Cardiology Package should be configured.
43.	Volume CEUS	4D function and Contrast Imaging should be configured.
44.	HiFR CEUS	Contrast Imaging should be configured.
45.	CEUS Chrono-Parametric Mode	Contrast Imaging or Volume CEUS should be configured.
46.	TCMR (Tissue-Contrast Mix Rendering)	Volume CEUS should be configured.
47.	Strain Elastography	/
48.	STE	Not including Endocavity STE
49.	STE(DE, FR, NA)	Not including Endocavity STE
50.	STQ	/
51.	STQ(DE, FR, NA)	/
52.	Endocavity STE	/
53.	High frame rate STE	STE, STE(DE, FR, NA) or Endocavity STE should be configured.
54.	STE-HiRE	STE, STE(DE, FR, NA) or Endocavity STE should be configured.
55.	Stress Echo	Cardiology Package should be configured.
56.	Tissue Tracking QA	Cardiology Package should be configured.
57.	FH Tissue Tracking QA	Obstetrics Package should be configured.
58.	Smart 3D	/
59.	4D Function	/
60.	iPage <sup>+</sup>	4D Function should be configured.
61.	STIC	4D Function should be configured.
62.	SCV <sup>+</sup>	4D Function should be configured.

No.	ltem	Remarks	
63.	Smart Volume	4D Function should be configured.	
64.	Smart V Trace	Smart Volume should be configured.	
65.	Color 3D	4D Function should be configured.	
66.	Niche	4D Function should be configured.	
67.	iLive	4D Function or Smart 3D should be configured.	
68.	Smart Planes CNS	4D Function and Obstetrics Package should be configured.	
69.	Smart Planes FH	4D Function and Obstetrics Package should be configured.	
70.	Smart Face	4D Function and Obstetrics Package should be configured.	
71.	Smart ICV	Smart Planes CNS should be configured.	
72.	Smart Scene 3D	4D Function should be configured.	
73.	Ultrasound Fusion Imaging	<ul> <li>Fusion imaging module or Fusion imaging module (including trolley) should be configured.</li> <li>Not including Endocavity Fusion Imaging.</li> </ul>	
74.	Endocavity Fusion Imaging	Fusion imaging module or Fusion imaging module (including trolley) should be configured.	
75.	Fusion RESP	Ultrasound Fusion Imaging and motion sensor support should be configured.	
76.	Needle Navigation	Ultrasound Fusion Imaging should be configured.	
77.	V Flow	Vascular Package should be configured.	
78.	Ultra-Micro Angiography	/	
79.	Glazing Flow	/	
80.	iClear <sup>+</sup>	iClear <sup>+</sup> Dongle should be configured.	
81.	USAT (UltraSound ATtenuation analysis)	/	
82.	HRI <sup>+</sup> (HepatoRenal Index Plus)	USAT should be configured.	
83.	M-Ref. E Compare	Strain Elastography and STE/STE(DE, FR, NA) should be configured.	
84.	M-Ref. C&E	Contrast Imaging and STE/STE(DE, FR, NA) should be configured.	
85.	DICOM Basic	Including: Verify (SCU, SCP), task management, DICOM storage, DICOM print, DICOM storage commitment, DICOM media storage (including DICOM DIR) etc.	
86.	DICOM Worklist	DICOM Basic should be configured.	
87.	DICOM MPPS	DICOM Basic should be configured.	
88.	DICOM Query/Retrieve	DICOM Basic should be configured.	
89.	DICOM OB/GYN SR	DICOM Basic should be configured.	

No.	Item	Remarks
90.	DICOM Vascular SR	DICOM Basic should be configured.
91.	DICOM Cardiac SR	DICOM Basic should be configured.
92.	DICOM Breast SR	DICOM Basic should be configured.
93.	DICOM Abdomen SR	DICOM Basic should be configured.
94.	DICOM Small Parts SR	DICOM Basic should be configured.
95.	DICOM Pediatric SR	DICOM Basic should be configured.
96.	DICOM Urology SR	DICOM Basic should be configured.
97.	Abdomen/General Package	/
98.	Obstetrics Package	/
99.	Smart OB	Obstetrics Package should be configured.
100.	Smart NT	Obstetrics Package should be configured.
101.	Smart Fetal HR	Obstetrics Package should be configured.
102.	Gynecology Package	/
103.	Smart FLC	Gynecology Package should be configured. Can be accessed in 2D or 3D mode.
104.	Cardiology Package	/
105.	Small Parts Package	/
106.	Urology Package	/
107.	Vascular Package	/
108.	Pediatrics Package	/
109.	Nerve Package	/
110.	Emergency&Critical Package	/
111.	Pelvic Floor Package	Gynecology Package should be configured.
112.	IVF	Gynecology Package should be configured.
113.	IMT	Vascular Package should be configured.
114.	RIMT	Vascular Package should be configured.
115.	AutoEF	Cardiology Package should be configured.
116.	Smart Pelvic	Pelvic Floor Package should be configured.
117.	R-VQS	Vascular Package should be configured.
118.	Smart Hip	Pediatrics Package should be configured.
119.	Smart HRI	Abdomen/General Package should be configured.
120.	Smart Caliper	/
121.	Smart Trace	/
122.	СРР	/
123.	iWorks	/
124.	iNeedle	/

No.	ltem	Remarks
125.	DVR Module	/
126.	McAfee	Anti-virus software
127.	iScanHelper	Instructional software of Ultrasound techniques
128.	3D-Print Format	/

### 2.6.4 Peripherals Supported

Item	Model
Graph/text printer	HP OFFICEJET PRO 8100 (the printer driver requires manual installation.)
Black/white video printer (digital)	MITSUBISHI P95DW-N
Black/white video printer (digital& analog)	SONY UP-X898MD
Digital color video printer	SONY UP-D25MD
Barcode reader	<ul><li>LS2208</li><li>DS4308</li></ul>
Footswitch	<ul> <li>FS-81-SP-2 (1-pedal)</li> <li>971-SWNOM (2-pedal)</li> <li>971-SWNOM (3-pedal)</li> </ul>

## **MWARNING**

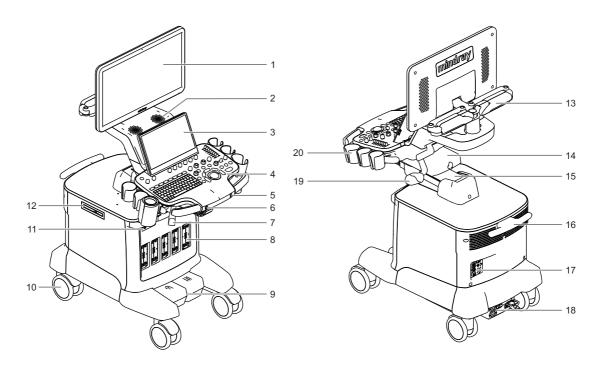
This system complies with IEC60601-1-2: 2014, and its RF emissions meet the requirements of CISPR11 Class B. In a domestic environment, the customer or user should ensure the system is connected to Class B peripheral devices, otherwise RF interference may occur, and the customer or user must take adequate measures accordingly.

### 2.6.5 Parts that can be used within patient environment

- Main unit
- Probes
- Footswitch
- Printers

# 2.7 Introduction of Each Unit



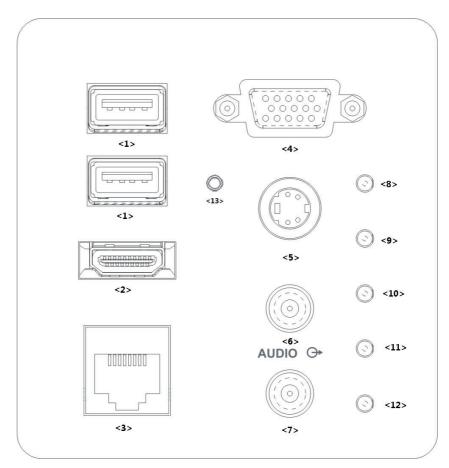


No.	ltem	Description
1.	Monitor	Used for displaying the images and parameters during scanning.
2.	Speaker	Used for outputting the audio.
3.	Touch Screen	Screen-touching operator-system interface or control.
4.	Control panel	Key-pressing operator-system interface or control.
5.	Ascending/descending button	Used for ascending or descending the system electrically.
6.	Control panel moving control button	Used for locking or unlocking the move of the control panel.
7.	Cable hook	Used for hanging the probe cables.
8.	Probe port	Used for connecting transducers and the main unit.
9.	Central brake	<ul> <li>Used for securing the system by stepping down the left pedal.</li> <li>Used for moving the system straight forward by stepping down the right pedal.</li> </ul>
10.	Caster	Used for moving the system.
11.	Input panel	Used for connecting ECG leads and USB drive, etc.
12.	DVD	Used for DVD reading and writing.
13.	Monitor support arm	Used for supporting and adjusting the LCD monitor angle.

No.	Item	Description	
14.	The control panel moving mechanism	Used for stretching or rotating the control panel.	
		Available only after the Moving Assembly of the Control Panel is configured.	
15.	Ascending/descending mechanism	Used for adjusting the height of the control panel, in conjunction with the electrical system.	
16.	Handle of main unit	Used for winding the cables up and moving the system.	
17.	I/O Panel	Used for input and output signals.	
18.	Power supply assembly for the system	Used for providing the power to the system.	
19.	Intra-cavity probe holder	Used for placing the intra-cavity probe.	
20.	Transducer & gel holder	Used for placing transducers and gel temporarily.	

# 2.8 I/O Panel

Figure 2-2 I/O Panel

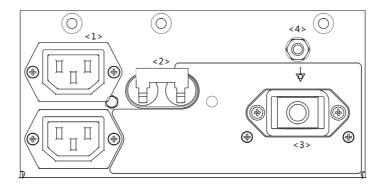


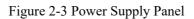
No.	Name	Function		
1.	ऽङर् <sub>न</sub>	High speed USB port. Used for connecting storage device such as USB disk, Fusion imaging module, bar code reader, printer, footswitch, DVD recorder, etc.		
2.	HDMI	High definition multimedia interface. Used for connecting TV, projector, ultrasound workstation video capture card, etc.		
3.	格	Network port. Used for connecting router, ultrasound workstation, server, etc.		
4.		VGA signal output. Used for connecting TV, Projector, ultrasound workstation video capture card, etc.		
5.	S-VIDEO G→	S-Video signal output. Used for separating video output, and connecting projector, ultrasound workstation video capture card, etc.		
6.	$\ominus$	Audio signal output port, left channel.		
7.	-	Audio signal output port, right channel.		
8.	/	12 V indicator		
9.	/	5 V indicator		
10.	/	3.3 V indicator		
11.	/	PC_LVDS indicator		
12.	/	Preserved function, PHV_OP protection indicator.		
13.	Ē	<ul> <li>Preserved function, PHV_OP protection indicator.</li> <li>Battery status indicator: <ul> <li>Charging status:</li> <li>It illuminates in green when batteries are charged fully.</li> </ul> </li> <li>Discharging status: <ul> <li>It illuminates in green when the power of the batteries is more than 20%;</li> <li>It blinks in orange when the power of the batteries is lower than 20%.</li> <li>It blinks quickly in orange when the power of the batteries is lower than 5%.</li> </ul> </li> </ul>		

### NOTE:

S-VIDEO port performs better in analog video print.

# 2.9 Power Supply Panel

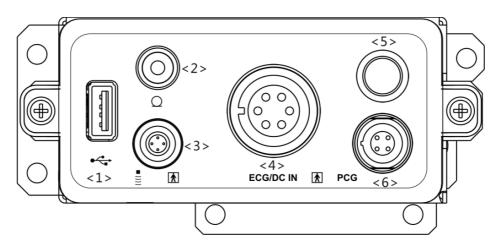




No.	Name	Function
1.	Alternative current auxiliary output	Supply power for optional peripheral devices.
2.	Circuit breaker	Used for switching off/ on the power supply.
3.	Power inlet	AC power inlet
4.	Equipotential terminal	Used for equipotential connection, that balances the protective earth potentials between the system and other electrical equipment.

# 2.10 Physio Unit Panel (ECG)

Figure 2-4 Physio Unit Panel (ECG)



No.	Name	Function
1.	•~+	Connects USB devices.Used for connecting storage device such as USB disk, Fusion imaging module, bar code reader, printer, footswitch, DVD recorder, etc.
2.	Q	Microphone input. Used for connecting a microphone.
3.	•	Used for connecting a pencil probe.
4.	ECG/DC IN	• Connects to ECG leads, to directly obtain the ECG signals of the patient.
		• Connects the signal output port of ECG monitoring device.
5.	Reserved port	Reserved feature.
6.	PCG (Reserved)	Connects to PCG transducer, to directly obtain the PCG signals of the patient.

# 2.11 Control Panel

### Figure 2-5 Control Panel



No.	Name	Description	
1.	Ċ	<ul> <li>Power button</li> <li>Press the button to turn on the system, the system enters the work status and the indicator becomes green.</li> <li></li></ul>	
2.	A.power	Adjust the acoustic power.	
3.	Volume	Adjust the volume.	
4.	/	Adjust the corresponding functions on the touch screen.	
5.	P1-P3	Undefined Button, set by the user in preset. see "4 Setup".	
6.	iWorks	Enter iWorks.	
7.	Fusion	Enter the fusion.	
8.	Elasto	Enter the elastography.	
9.	Contrast	Enter the contrast imaging.	
10.	Body Mark	Enter the body mark status.	
11.	/	<ul> <li>Press: to adjust the angle in increments of 60°.</li> <li>Toggle to adjust the Baseline.</li> <li>C : Rotate to adjust the angle.</li> <li>Slide to adjust the steer.</li> </ul>	
12.	PW	Press to enter PW mode, and rotate to adjust PW (in PW mode) or CW gain (in CW mode); while in 3D/4D mode, rotate the knob to make the 3D image rotate around Y axis.	
13.	С	Press to enter Color mode, and rotate to adjust Color (in color mode) or Power gain (in Power mode); while in 3D/4D mode, rotate the knob to make the 3D image rotates around Z axis.	
14.	/	<ul> <li>Press to enter 3D</li> <li>4D/4D : Slide right to enter 4D.</li> <li>☆ : Slide upwards to enter quad-split display.</li> <li>3D/2 : Slide downwards to enter dual-split display.</li> <li>☆ C: Rotate to switch the view.</li> </ul>	
15.	TGC	Slide to adjust the depth gain. <b>TGC</b> : Indicates the control or indicator to increase or decrease a parameter.	
16.	Cursor	Display/hide the cursor.	
17.	Clear	Remove the comments or measurement caliper.	
18.	M	Enter M mode, and rotate to adjust M mode gain. While in 3D/4D mode, rotate the knob to make the 3D image rotate around X-axis.	
19.	CW	Enter CW mode.	

No.	Name	Description	
20.	Power	Enter Power mode.	
21.	Dual	Enter Dual mode in Non-Dual mode.	
		Press to switch between the two interfaces in the Dual mode.	
22.	В	Press: to enter B mode; Rotate: to adjust B mode gain.	
23.	Depth	Adjust the depth in real-time imaging.	
24.	Zoom	Rotate to enter the pan-zoom mode, and press to enter the spot-zoom mode.	
25.	Measure	Enter/exit the application measurement mode.	
26.	Update	Switching key: Press to change the currently active window.	
		Start/stop image acquisition in iScape or 3D/4D mode.	
27.	Caliper	Enter/exit the general measurement mode.	
28.	/	Confirm an operation. The function is same with the left- button of the mouse.	
29.	/	Move the trackball to change the cursor position.	
30.	/	Confirm an operation. The function is same with the left- button of the mouse.	
31.	iTouch	Press to optimize the images.	
32.	Save	Save the image; user-defined key.	
33.	Print	Print; user-defined key.	
34.	Freeze	Freeze/unfreeze the image.	

### TIP:

 $^{\prime\prime}\!/^{\prime\prime}$  means the key / knob has no silk-printed name.

# 2.12 Keyboard

Figure 2-6 QWERTY keyboard

Esc F1 F2 Help Station	F3 F4 F5 F6	F7 F8 F9 F10 F11 F12 Save izoom DVR Setup Biopsy Physio Set Home Delete Word
~         !         1         @           .         1         i         2         2	# \$ % ^ 3 3 4 £ 5 € 6	$ \begin{array}{cccccccccccccccccccccccccccccccccccc$
$\begin{bmatrix} I \\ Tab \end{bmatrix} \begin{bmatrix} A \\ Q \end{bmatrix} \begin{bmatrix} A \\ W \end{bmatrix} \begin{bmatrix} A \\ W \end{bmatrix}$	A E R ® T Y	$ \begin{array}{c} 0 \\ \mathbf{U} \\ \mathbf{U} \\ \mathbf{I} \\ \end{array} \begin{array}{c} \mathbf{i} \\ \mathbf{O} \\ \mathbf{O} \\ \mathbf{P} \\ \mathbf{I} \\ \mathbf{i} \\ \mathbf{V} \\ \mathbf{i} \\ \mathbf{N} \\ \mathbf{i} \\ \mathbf{i} \\ \mathbf{N} \\ \mathbf{i} \\ \mathbf{N} \\ \mathbf{i} \\ \mathbf{i}$
Caps Á Lock A S	§ D S Z F G F	$ \begin{array}{c} c \\ I \\ I \\ \end{array} \begin{bmatrix} \dot{Y} \\ J \\ \end{bmatrix} \begin{bmatrix} S \\ K \\ \end{bmatrix} \begin{bmatrix} \emptyset \\ L \\ \vdots \\ 1 \\ \end{bmatrix} \begin{bmatrix} \cdot \\ \cdot \\ \cdot \\ \end{bmatrix} \begin{bmatrix} \cdot \\ I \\ \vdots \\ Enter \end{bmatrix} $
<pre></pre>	X C © V B	N N N V V V V V V V V V V V V V V V V V
Ctrl Fn Alt Gr D	Del ABC Comment	Image: Sedy Mark     Image: Sedy Mark </th

### Common functional keys

NO	Кеу	Description
1.	<b>↓</b> Enter	Confirms the input data; or moves the cursor to the head of next row of the text or the input field.
2.	Esc	Cancel the operation or exit.
3.	ı <del>⊆</del> Tab	Go to the next operable item.
4.	Comment	Press to enter or exit the comment status.
5.	Caps Lock	Switch the upper/ lower case.
6.	Home	Activate the Home function: return to start position of the comment.
7.	Set Home	Activate the Home function, move the cursor to the target position, then press <set home=""> to set the start position of the comment</set>
8.	Delete Word	Delete all comments on the screen.
9.	Direction keys	Move the cursor one letter each time; or, select the ambient one in a selectable area.
10.	Arrow	Press the key to turn to the symbol of arrow.
11.	Body Mark	Press the key to enter the body mark.
12.	Back Space	Delete the character before the cursor
13.	Del	Delete the character after the cursor

### Functions of the Keys F1 to F12

No.	Key	Description	Function
1.	F1 Help	Help	Open or close the accompanying help documents.
2.	F2 iStation	iStation	Enter or exit patient information system.
3.	F3~F6	F3~F6	User-defined keys, functions of which can be defined in preset.
4.	F7 QSave	QSave	Save the current image parameters quickly.
5.	F8 iZoom	iZoom	Enter/switch/exit full-screen zoom status.
6.	F9 DVR	DVR	Enter VCR/DVR mode.
7.	F10 Setup	Setup	Enter/exit setup.
8.	F11 Biopsy	Biopsy	Display/hide the guide line.
9.	F12 Physio	F12 Physio Unit	Enter the physio Unit interface.

For functions of undefined buttons or keys, see "4.1.6 Key Configuration" for details about function setting if necessary.

### Functions of key combinations

The system supports multi-language input using key combinations. Key combinations include [Shift], [Alt Gr], [Ctrl], [Fn] and some alphabet keys.

- Shift> key
  - <Shift> + key: enter the top left letter on the key.
  - For the alphabet keys (<A>~<Z>), press <Shift> + key to enter the current letter in a different case.
- [Alt Gr] key
  - Combined with other letter keys, [Alt Gr] can be used for entering other languages.
  - Press [Alt Gr] and a letter key simultaneously. The letter in the top-right corner of the key is entered.
- [Ctrl] key combined keys

On the iStation or Review screen, use <Ctrl> and <Set> to select more than one patient or more than one image.

• [Fn] key

For these combination keys, press  ${<\!\!\!\rm Fn\!\!>}+$  key to use the functions indicated with a frame on the key.

No.	Fn+	Name	Function
1.	$\rightarrow$	End	Move the cursor to the end of the row, or the rightmost side of an edit unit.
2.	←	Home	Activate the Home function: return to start position of comment.

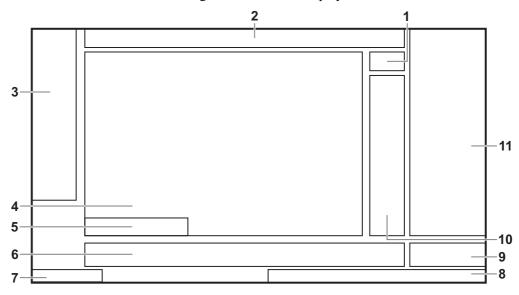
# 2.13 Basic Screen & Operation

## 2.13.1 Monitor Display

The system monitor displays ultrasound images, parameters, menus and measurement results window.

The following diagram maps out the different areas, such as patient information, image parameter & menu, image area, thumbnail, help information, soft menu, and system status.

### Figure 2-7 Monitor Display



No.	Item	Description
1.	System Information Area	Displays the manufacturer's logo and product model.
2.	Patient Information Area	Displays the hospital name, the exam time, patient information, the probe model, the exam mode, etc.
3.	Menu Area	Displays the image menu, measurement menu, comment menu, body mark menu and so on.
4.	Image Area	Displays the ultrasound images, ECG waveforms, probe mark (or active window mark), time line (in M or PW mode), coordinate axis (including depth, time, velocity/frequency), acoustic power (including the acoustic power, MI (Mechanical Index) and TI (Thermal Index), besides, the comment, bodymark, measurement calipers, color bar/grayscale bar are also displayed here.
5.	Cine Review Area	Displays the cine review progress bar to indicate the cine replay progress.
6.	Hint (trackball and <set> key function indications)/Soft Menu Area</set>	<ul> <li>Displays the current functions of trackball and <set> keys.</set></li> <li>Displays the items that simultaneously appear at the bottom of the touch screen.</li> </ul>
7.	Help Information Area	Displays various help information items.
8.	System Icons Area	Displays the relevant system icons, such as USB memory device, printer, network, and current system time, etc.
9.	User-defined Key Area Displays the functions for the user-defined keys. see "Configuration".	
10.	Parameters Area	Displays the image parameters for the active window. If there are more than one imaging modes, the parameters are displayed by each mode.

No.	Item	Description
11.	Thumbnails Area	Displays the thumbnail images stored under the current patient.

### 2.13.2 Dialog Box

A dialog box screen consists of title, page tabs, contents and buttons, etc.



#### Figure 2-8 Dialog Box

No.	ltem	Description	
1.	Title bar	The title bar is used to give a description for the content and function of the screen.	
2.	Page Tab	For some screens, contents are distributed into several pages. Use <set> to open/close the available pages.</set>	
3.	Contents	<ul> <li>Radio box: click to select the item.</li> <li>Check box: click to check or uncheck the item.</li> <li>Entry box: enter characters manually via the keyboard.</li> <li>Drop-down list: click ▼ to show the list and select an item.</li> </ul>	
4.	Controls	When the operation of a screen is completed, save or cancel the operation, and close the screen.	

### To reposition a dialog box

1. Use the trackball to move the cursor onto the title bar of the dialog box.

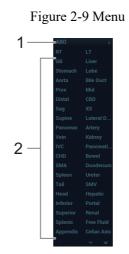
At this time the cursor becomes a  $\clubsuit$ , then press  $\langle \text{Set} \rangle$ .

- 2. Use the trackball and position the rectangular graphic to the new desired location.
- 3. Release <Set>, and the dialog box is moved to the desired position.

### 2.13.3 Menu Operation

Use the cursor to operate on the menu.

Menus of different modes display in real-time at the upper left corner of the screen.



No.	Item
1.	Menu title
2.	Menu item

Operate the menu by the trackball and left/right <Set> key.

- 1. Press <Cursor> to show the cursor.
- 2. Roll the trackball to locate the cursor onto the item to be adjusted.
  - For a commanding item or command optional item: press <Set> to directly activate the item.
  - For a parameter item or ON/OFF item: press <Set> to activate the item, and press <Set> to switch among the available values.
  - For a parameter optional item: press <Set> to extend the available parameter the cursor is
    positioned onto the list. Roll the trackball to locate the cursor onto the item to be adjusted,
    and press <Set> to set the value.

For details about menu operation of measurements, please refer to the [Advanced Volume].

## 2.13.4 The Display of Touch Screen and Its Operation

### Mapping mode of touch screen

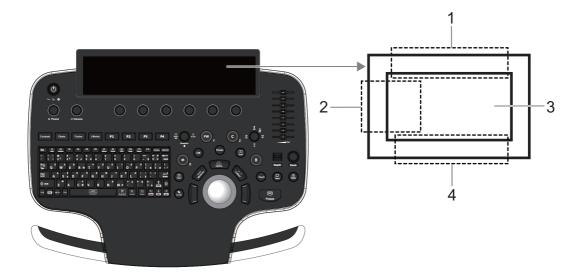


Figure 2-10 Mapping Mode

Operation area	Operations	
1.	Flick the edge downwards to enter the mapping mode.	
2.	Sweep to right to open the menus under the mapping mode.	
3.	The mapping menu, and toolbar are displayed. It is available to perform the image adjustment, measures, image review, etc. see "6.1.1 Image Adjustment".	
	Under mapping or non-mapping mode, you can do fast operation using the two-finger gesture according to the gesture hints on the bottom-right of the screen. see "4.1.7 Gesture".	
4.	Flick the edge upwards to exit.	

#### NOTE:

If there is a dialog box in the screen, the mapping mode is unavailable.

• Enter the mapping mode

Flip the touch screen from top to bottom (area 1). The image on the control screen maps on the touch screen. The mapping mode appears.

Mapping menu operations

Swipe the touch screen from left to right (area 2) under the mapping mode. The mapping menu appears on the touch screen. Tap or sweep right or left to adjust the image parameter, measures, etc. see "6.1.1 Image Adjustment".

Tap the blank area on the touch screen. The menu of the mapping mode hides.

• Soft menu operations

Rotate the knob below the touch screen under the mapping mode. The soft menu is displayed. Rotate the knob below the soft menu to adjust the parameters.

• Two-finger gesture

Two-finger gesture can be configured with varied functions. see "4.1.7 Gesture". According to the two-finger gesture under mapping or non-mapping mode, perform the operations on the touch screen (area 3).

- Enter the preview mode
  - Method 1:

Swipe right to review the saved image under the mapping mode (area 3). Tap the saved image (area 3), and the tool bar is displayed on the top of the touch screen. It is available to review, send or delete the image, and also available to access the review page...

No.	Description	
	Enters the review page.	
₩	Review the previous image.	
•••	Send the image.	
<b>→</b>	Review the next image.	
莭	Delete the current image.	

– Method 2:

Tap the real-time image on the touch screen (area 3) under mapping mode. The tool bar is displayed in real-time.

Tap to enter the preview mode. Swipe right or left to view the image. If tapping one image, the only selected one image appears on the touch screen; tap the image again, the touch screen enters four images display mode on each page. Check the box on the top right of the image or click [Select All] to send or delete the image. Click [Exit] to exit the preview mode.

Exit the mapping mode

Flip from the edge to the top or tap  $\bigotimes$  on the top right corner of the touch screen to exit the mapping mode (area 4) under the mapping mode.

#### Non-mapping mode of touch screen

The layout of the touch screen varies with the applications or modes. Flip the touch screen to go to another page. Learn the interface display and operations by referring to related chapters.

#### NOTE:

You cannot enter the stage from cine review mode or when there is a dialogue box on the screen. This stage cannot switch to mapping mode.

• Controls on the touch screen

Tap and hold the screen to enter control editing stage.

Function	Operations
Add a control	Tap 🖶 to select a button to add and tap [Confirm].

Function	Operations
Add a user-defined control	In comment and body mark editing status, tap  and then tap [Custom] to bring out the dialogue box for adding user-defined controls. Enter the control name and tap [OK].
Delete a control	Tap 🐼 of the target control and tap [Confirm] to delete.
Change the control position	Tap and drag the control to the desired position.

Moving tabs on 3D/4D viewing status

On 3D/4D viewing status, tap and hold the desired tab on the touch screen, and then drag the tab to adjust its position.

# 2.14 Warning Labels

The warning labels are attached to this system in order to call your attention to potential hazards.

The warning labels use the same signal words as those used in the operator's manual. Read operator's manual carefully before using the system.

The name, pattern and meaning of each warning label are described as follows:

Warning Labels	Meaning
1 2 2 2 2 3	<ol> <li>Do not place the system on a sloped surface. Otherwise the system may slide, resulting in personal injury or the system malfunction. Move the system slowly on the slope by two people and make sure that the support arm is not extended.</li> <li>DO NOT sit on the system.</li> <li>DO NOT push the system when the casters are locked.</li> <li>Read this information carefully before using the system.</li> </ol>
	Warning; Crushing of hands

The general meaning assigned to geometric shapes, safety colors and contrast colors for safety signs are as follows:

Geometric shape	Meaning	Safety color	Contrast color	Graphical symbol color
$\bigcirc$	Prohibition	Red	White	Black
	Mandatory action	Blue	White	White
$\bigtriangleup$	Warning	Yellow	Black	Black

# 2.15 Symbols

This system uses the symbols listed in the following table. Their meanings are explained as follows:

Symbol	Description	
<b>*</b>	Type-BF applied part	
Ŵ	Caution!	
$\sim$	AC (Alternating current)	
	Protective earth (ground)	
	Pencil probe port	
	Equipotentiality	
2	Footswitch	
	Probe socket	
S-VIDEO ⊕	Separate video output	
VGA O G+	VGA output	
器	Network port	
HDMI	HDMI port	
<b>\$\$~~</b> •~-	High speed USB port	
•	USB port	
Q	Microphone input jack	
$\ominus$	Stereo audio output	
ĒŦ	Battery indicator	
Ĩ	When the probe locking lever points to , you can remove the probe.	
1	<ul> <li>When the probe locking level points to 1, it means that the probe is locked and you can not remove the probe.</li> <li>Central brake locking symbol</li> </ul>	
\$	Central brake straight forward moving symbol	
€	Atmospheric pressure limitation	

Symbol	Description
<u>j</u>	Humidity limitation
X	Temperature limit
SN	Product serial number
$\sim$	Manufacture date
	Manufacturer
Rx Only	Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner (USA).
UDI	Unique Device Identifier
SGS c 710285 US	Conforms to ANSI Std. ES60601-1, IEC Std. 60601-2-37, IEC Std. 60601-2-18 and IEC Std. 60601-2-37 Certified to CAN/CSA Std. C22.2 No.60601-1, No.60601-1-6,No.60601-2-18 and No.60601-2-37
	MR Unsafe - The system is not intended to be used within magnetic resonance (MR) environment.

## **WARNING**

- Do not connect the three-wire cable of the system with a two-wire plug without protective grounding; otherwise, electric shock may result.
- Do connect the power plug of this system to wall receptacles that meet the ratings indicated on the rating nameplate. If adapters or multifunctional receptacles are used, it may cause the leakage current to exceed the safety requirement.
- In the environment that patient is 1.5 meters around, connect peripherals to the auxiliary power outlet which is capable of isolation protection, or power the peripherals by auxiliary output cable or isolation transformer complied with IEC60601-1 or the power input of the same safety level.
- DO NOT use power supply of different phases to power peripherals, like power supply of air-conditioning.
- When using peripherals not powered by the auxiliary output of the ultrasound system, or using peripherals other than permitted by Mindray, make sure the overall leakage current of peripherals and the ultrasound system meets the requirement of the local medical device electrical regulation (like enclosure leakage current should be no more than 500uA of IEC60601-1), and the responsibility is held by the user.

# 3.1 Moving/Positioning the System

Please read and understand the safety precautions before placing the system to ensure safety for both operator and devices.

- 1. Switch off the power, and pull out the plug.
- 2. Disconnect all cables from the off-board peripheral devices (printer, recorder, etc.)
- 3. Unlock the right and the left pedal brakes; hold the handle to move the system.
- 4. When you move the system to a desired location, press down the pedal brake to lock the four casters.

# 

- Maintain a generous free air flowing space around the back and both sides of the system; failure may result due to increased rise in system operating temperature.
- Pay extra attention when moving the system on a sloping ground, do not move it on a more than 10°-sloped plane to avoid system toppling.

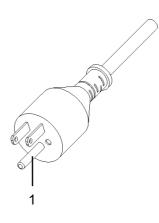
# 3.2 Connecting the Power Cord

This system can work normally only when it is connected to the external power supply.

## 3.2.1 Connecting Power

The connection method is described as follows:

- 1. Plug the power cable in the socket of the ultrasound system.
- 2. Plug the other end power plug into an appropriate outlet. The grounding terminal should be connected with a power grounding cable to ensure that protective grounding works normally.



I Grounding terminal		1	Grounding terminal
----------------------	--	---	--------------------

#### NOTE:

Make sure to allow sufficient slack in the cable so that the plug is not pulled out of the wall if the system is moved slightly. If the plug is pulled out accidentally, data may be lost.

### 3.2.2 Powered by Batteries

The battery cannot support the ultrasound system for normal working, but only standby function.

When the system is working, the battery charges when its capacity is not full, and the indicator turns green when the capacity is full.

When the battery capacity is charged to the full capacity, the standby time of the system is no less than 24 hours.

### **AWARNING**

- The battery is inside the machine; only technical professionals from Mindray or engineers authorized by Mindray after training can perform battery installation and uninstallation.
- If you need to change the battery or buy a new one, please contact your sales representative.
- The lithium-ion battery has a service life of five years. Replace your battery when it reaches the end of its service life.

#### NOTE:

- Power off the system if you will not use the system for a long period of time (including storage/ transportation condition), and you should not allow the system in standby status, otherwise the batteries will be out of power and permanently damaged.
- When you need to move the ultrasound system in a hurry, you can first make the system enter the standby mode, pull off the power plug to power the machine in standby status when moving the machine, and then press the power button to exit standby after you move the machine to the target position and connect the AC power.

## 3.2.3 Equipotential Terminal

The symbol  $\checkmark$  represents the equipotential terminal that is used for balancing the protective earth potentials between the system and other electrical equipment.

# **WARNING**

- Be sure to connect the equipotential wire before inserting the power plug into the receptacle; be sure to pull out the power plug from the receptacle before disconnecting the equipotential wire; otherwise electric shock may result.
- When you connect another device to this system, you should use the equipotential wire to connect each of equipotential terminals; otherwise electric shock may result.
- Connect the earth cable before turning ON the system. Disconnect the earth cable after turning OFF the system. Otherwise, electric shock may result.
- DO NOT connect this system to outlets with the same circuit breakers and fuses that control the current to devices such as life-support systems. If this system malfunctions and generates overcurrent, or when there is an instantaneous current at power ON, the circuit breakers and fuses of the building's supply circuit may be tripped.

# 3.3 Powering ON/OFF

## 

To ensure safe and effective system operation, you must perform daily maintenance and checks. If the system begins to function improperly, immediately stop scanning. If the system continues to function improperly, fully shut down the system and contact the Mindray Customer Service Department or a sales representative. If you use the system in a persistent improperly functioning state, you may harm the patient or damage the equipment.

## 3.3.1 Checking Before Powering ON

Check before the system is powered on:

- The temperature, relative humidity and atmospheric pressure meet the requirements of the operating conditions. For details, see "2.4.2 Environmental Conditions".
- There is no condensation.
- There is no distortion, damage or dirt on the system and peripheral devices. If any dirt is found, cleaning shall be performed. For details, see "19 System Maintenance".
- There are no loose screws on the monitor, control panel.
- There is no cable damage (e.g., power cord). Maintain secure connections to the system at all times.
- The probes and probe cables are free from damage or stains.
   For details of probe cleaning and disinfection, see "17.1.5 Probes Cleaning and Disinfection/ Sterilization".
- No miscellaneous odds and ends are attached or affixed to the control panel.
- Ensure that all connections are free from damage and remain clear of foreign object blockages. There are no obstacles around the system and its air vent.
- Probe cleaning and disinfection.
- The entire scanning environment and field must be clean.
- The locking mechanism of the casters can work normally.

### 3.3.2 Powering the System ON

Before getting the system started, check if the system is plugged in – verify that the system circuit breaker is at "On". After the power indicator on the control panel turns on, press the power button to power the system on. The system image appears.

If access control has been set by the system administrator, you can access data in the system only after logging onto the system. For details, see "4.1.9 Access Control".

#### NOTE:

You must log in again after system restart or dormancy.

#### To Login onto the System

Perform the following procedure:

- 1. Select the login type (Local or LDAP), and user name in the drop-down list.
- 2. Enter the password and click [Login].

When the user has logged onto the system,  $\Re$  is visible in the bottom-right corner of the screen.

#### **To Change Users**

Perform the following procedure:

- 1. Click  $\mathbf{F}$  in the bottom-right corner of the screen.
- 2. Click [Change User] to bring up the Login dialog box.
- 3. Select the login type (Local or LDAP), and user name in the drop-down list.
- 4. Enter the password and click [Login].

#### **To Modify Password**

General operators and administrators can modify the password. Perform the following procedure:

- 1. Click **F** in the bottom-right corner to bring up the Session Manage dialog box where you can see the current user's information.
- 2. If you want to modify the current password, click [Change Password].
- 3. Enter both the previous and new passwords, and confirm the new password in the dialog box.
- 4. Click [OK] to exit.

#### To Lock the System

Perform the following procedure:

- 1. Click the  $\Re$  in the bottom-right corner of the screen to bring up the dialog box.
- 2. Select [Lock Machine] and the system is locked.

You must log on before using the system.

### 3.3.3 Checking After Powering On

Check after the system is powered on:

- There are no unusual sounds or smells indicating possible overheating.
- There are no persistently displayed system error messages.
- There is no evident excessive noise, or discontinuous, absent or black items in the B mode image.
- Check whether there is abnormal heat on the surface of the probe during an ultrasound procedure.
- The control panel keys and knobs are fully functional.
- The date and time are displayed correctly.
- The touch screen and the main monitor screens display normally depending on the system modes and image status.

## **MWARNING**

- If you use a probe giving off excessive heat, it may burn the patient.
- If you find anything not functioning properly, this may indicate that the system is defective. In this case, shut down the system immediately and contact Mindray Customer Service Department or sales representative.

#### NOTE:

If there is over loading to the system, the breaker will switch into OFF to discontinue the power supply. If the breaker cannot be set as On, or returns to OFF after being switched on, please disconnect the power cables, and contact your sales representative.

## 3.3.4 Powering the System Off

You must follow the correct procedures to power the system off. Also, after you upgrade the software or when the system is down, you need to power off and restart it.

### NOTE:

- DO NOT directly shut down the system. It may make the data corrupted.
- Do not turn off the breaker while the power indicator is on. Otherwise, the data may lose or the system software may be damaged.

• If you will not use the system for a long period of time, you shall turn off the circuit breaker and disconnect the power to all other peripheral devices.

#### To power off your system normally

- 1. Press the power button to see the option:
  - Shutdown: To power off the system normally.
  - Standby: To enter standby status.
  - Cancel: To cancel the operation.
- 2. Select [Shutdown] to power the system off.

### 3.3.5 Standby

### NOTE:

- If you will not use the system for a long period of time, you shall disconnect the power adapter; disconnect the mains power; turn off powers of all peripherals connected to the system.
- If the system is disconnected from the AC power, make sure not to press the power button in the standby status. In this circumstance, to exit standby status or power off the system, connect the system to the AC power before pressing the power button.

#### **To Enter Standby**

- Open [Setup] > [System] > [General] to set the time for screensaver and standby. The system goes into the screen saving status if without the operating. The system then goes into the standby status if without the operation during expiring the standby time.
- Press the power button to select [Standby]. The system enters standby status.

#### To Exit Standby

Press the power button.

#### TIP:

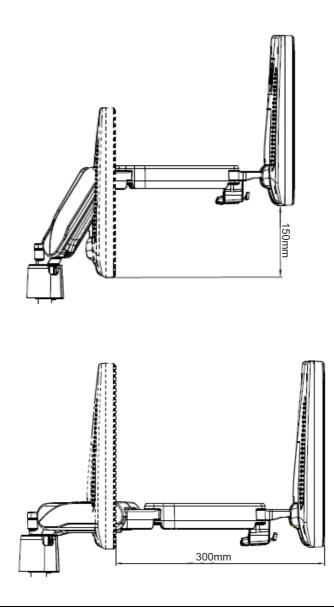
When the system enters the standby status, and you need to power off: Press the power button to exit the standby status and then power off the system.

## 3.4 Adjusting Monitor Position

Gently hold the bottom edge of the monitor when adjusting its position.

### 3.4.1 Adjusting Height and Displacement

Move the monitor support arm up or down to adjust the height, back and forth to adjust the displacement.

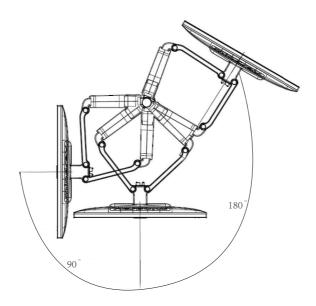


### NOTE:

Take care not to trap your hands when adjusting the monitor up and down.

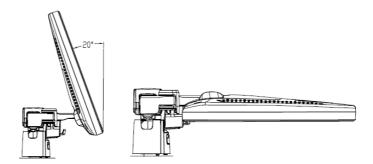
## 3.4.2 Rotating the Monitor

The monitor can be rotated  $90^{\circ}$  to the left and  $180^{\circ}$  to the right along with the supporting arm.



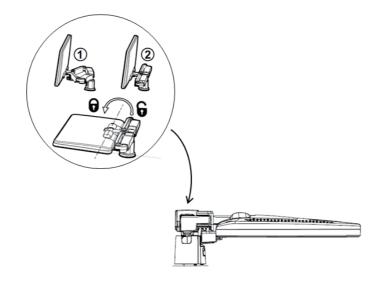
### 3.4.3 Tilting the Monitor

When positioned vertically, the monitor can be tilted 20° backward and can be tilted forward to a horizontal position. When transporting or moving the system, keep the monitor in the horizontal position, as shown below:



### 3.4.4 Locking the Monitor

If the ultrasound system is required to be moved within a short distance (for example: move to other department), turn the monitor to the horizontal level, push it to the locking structure, and then the monitor can be locked. For more details, please refer to the operation diagram that is attached to the supporting arm.



# 3.5 Adjusting Monitor Brightness/Contrast

Monitoring the brightness and contrast adjustment is one of the most important factors for proper image qualities. If set incorrectly, the gain, TGC, dynamic range or even acoustic output have to be changed more often than necessary to compensate.

- Brightness adjustment
   Press <F10 Setup>, and then select [System] > [General] > [LCD]/[TouchPanel].
- Contrast ratio adjustment
   Press <F10 Setup>, and then select [System] > [General] > [LCD]/[TouchPanel].
- Automatic brightness adjustment

Press <F10 Setup>, and then select [System] > [General] > [Brightness auto adjustment]. The system will automatically adjust the brightness/contrast ratio of the main screen and touch screen according to the surrounding environment.

### NOTE:

On the monitor, the brightness adjustment comes before contrast. After readjusting the monitor's contrast and brightness, adjust all preset and peripheral settings.

# 3.6 Adjusting the Control Panel Position

### NOTE:

Make sure that the Ultrasound System is powered on.

1. Press and hold the  $\bigcirc$  button on the control panel to rotate the control panel  $\pm 90^{\circ}$ .

If you purchase the stretching assembly of the control panel, the control panel can be stretched back and forth.

2. Press and hold the  $\bigcirc$  button on the control panel to ascend or descend the control panel.

# 3.7 Connecting/Disconnecting a Probe

## 

- Press <Freeze> to freeze an image or turn off the power of the system before connecting/disconnecting the probe. Otherwise, system or probe failure may occur.
- When connecting or disconnecting a probe, place it in a proper position, to prevent the probe from falling off or becoming damaged.
- Hang the probe cable to the hanger located under the control panel to avoid excessively bending and damaging the cable.
- Only use the probes provided by Mindray. Aftermarket probes may result in damage or cause a fire.

## 3.7.1 Connecting a Probe

### **WARNING**

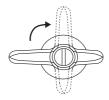
The probes, cables and connectors should be in proper operating order and free from surface defects, cracks and peeling. Otherwise, this may lead to electrical shock.

Perform the following procedure:

1. Turn the knob horizontally. Keep the cable end of the transducer upwards, and insert the connector into the port of the system, and then press in fully.



2. Turn the lock handle  $90^{\circ}$  clockwise to lock it securely.

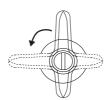


3. Place the probe properly to avoid being treaded or wrapping around other devices. DO NOT allow the probe head to hang free.

## 3.7.2 Disconnecting a Probe

Perform the following procedure:

1. Turn the locking lever 90° counterclockwise to the horizontal position.

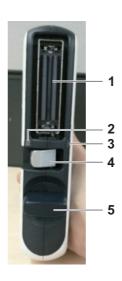


2. Pull the probe connector straight out vertically.



## 3.7.3 Installing a Probe Adapter

Figure 3-1 Probe Adapter Illustration



NO.	Description
1.	Probe socket
2.	: Probe socket unlock position
3.	: Probe socket lock position
4.	Probe locking lever
5.	Probe adapter locking lever

Perform the following procedure:

1. Firstly, move the probe adapter locking lever to horizontal direction and keep the probe locking lever to unlock position. Then, push probe adapter to probe port slowly and carefully while keeping the socket position upward.



2. Rotate the probe adapter locking lever  $90^{\circ}$  clockwise to the vertical position to lock it.



3. Stick the probe connector to probe socket and keep the cable upward, then move the probe locking lever to the lock position in order to lock the probe, finishing installation of probe adapter and probe.



# 3.8 Connecting Peripheral Devices

### 3.8.1 Connecting USB Devices

## **MWARNING**

DO NOT directly remove a USB memory device, as the USB device and/or the system may become damaged.

- When connecting a USB memory device to the ultrasound system via a USB port, a sound is heard if it is connected successfully and the symbol **R** appears in the bottom-right corner of the screen.
- To remove the USB device: click **C** to open the [Remove USB Device] screen. Select the device to be removed and click [OK]. A sound is heard when removing the USB memory device.
- The diagnostic ultrasound system supports USB 3.0.

## 3.8.2 Connecting a Footswitch

## **AWARNING**

Do not connect two or more footswitches to the main unit; otherwise, it may lead to the malfunction to the system.

The system supports USB port-type footswitch.

Directly insert the USB port of the footswitch to the system applicable USB ports.

Function Setting: The function of the foot switch can be preset. For details, see "4.1.6 Key Configuration"

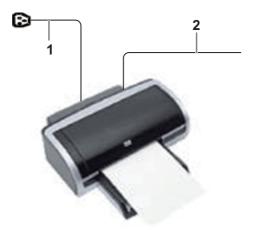
## 3.8.3 Connecting a Graph/Text Printer

#### NOTE:

- Unless otherwise specified, printers listed in Chapter "2.6.4 Peripherals Supported" have drivers installed already.
- Please refer to the accompanying manuals of the printers for more details.

### To add a local printer

As shown in the figure below, a graph/text printer has a power cord and data cable. The power cord shall be directly connected to a wall receptacle as required.



1	Power supply cable	Connect to power supply.
2	Data cable	Connect to the USB port of this system.

Perform the following procedure:

- 1. Connect the data cable to USB port of the ultrasound device.
- 2. Power on the system and the printer.
- 3. Put the installation optical disk of the printer driver into the drive.
- 4. Install the printer driver: Select [Setup] > [Print] > [Add Printer].

All the operations are finished with right <Set> button.

- 5. Select [The printer that I want isn't listed].
- 6. Select [Add a local printer or network printer with manual settings] and click [Next] to enter the following screen.

See the printer's operation manual to select the port, or use the default port of the system.

- 7. Click [Have Disk] to find the driver path (the installation type should be WIN64), and then click [Next] to install the driver.
- 8. Complete the operation according to the tips on the screen. Click [Finish] to end the installation.

#### To Add network printer

Perform the following procedure:

- 1. As the system is connected into a LAN, open [Setup] > [Print] screen.
- 2. Click [Add Printer] and select [The printer that I want isn't listed] > [Add a Bluetooth, wireless or network discoverable printer].

- 3. The system starts to search all available printers within the network. Select the target printer and click [Next], the system tries to connect to this printer.
- 4. When the connection is successful, the system prompts the dialogue box, click [Next] according to the screen tips and then click [Finish]. The printer is installed successfully.

#### NOTE:

- The network printer functions depending on the configured network environment in the hospital, please consult the network configuration administrator in case of failure.
- When you install the printer's driver, you must specify the specific path for installation; otherwise, vague path may result in longer time for searching.

#### To print

Both report and image can be printed on a graph/text printer. Set the default report printer and its attribute:

- 1. In [Setup] > [Print] screen, select the "Report Print" column in the service list.
- 2. You can select printer from the driver list next to "Printer" in the lower screen and set the items in the "Property" box.
- 3. Click [Save] after you have finished setting.

### 3.8.4 Connecting a Video Printer

#### NOTE:

- Unless otherwise specified, printers listed in Chapter "2.6.4 Peripherals Supported" have drivers installed already.
- Please refer to the accompanying manuals of the printers for more details.

The digital video printers that system supports consist of the B/W printers and color printers.

Perform the following procedure:

- 1. Connect the data cable to USB port of the ultrasound device.
- 2. Power on the system and the printer.
- 3. Add a print service:
  - a. Open the [Setup] > [Print] screen.
  - b. Click [Add Service] to enter the page.
  - c. Select the service type and enter the service name manually.
  - d. Click [OK] to return to the page.
  - e. Select the target printer from the drop-down list in the "Property" box and set other printing properties.
  - f. Click [Save] to complete.

### 3.8.5 Connecting a Wireless Printer

The system supports the wireless graph/text printer for the report print.

Perform the following procedure:

- 1. Power on the system and the printer.
- 2. Make sure the ultrasound machine and the printer are connected to a same LAN, and turned on the Wi-Fi function of the printer.

- 3. Add wireless printer by following the procedures of adding a Graph/Text printer. see "3.8.3 Connecting a Graph/Text Printer" for details.
- 4. Press <F10>, select [Print] to choose the report to be printed. Select the printer from the wireless printer list, and set the printer.
- 5. Click [Save] to exit the preset and make the settings effective.

### 3.8.6 Rectangle Caps

In order to use the defined-function key more conveniently, user can replace the key freely.

The Ultrasound System is equipped with five rectangle caps (iScape, RIMT, TDI, V Flow, S-Planes) by factory default. It is designed for replacing the rectangle caps by the user.

Insert the paper clip or pen into the slot around the rectangle buttons (P1, P2, P3, iWorks, Fusion, Elasto, Contrast, Body Mark) to remove them.

### NOTE:

It is unnecessary to disassemble the control panel to remove the rectangle caps.



NO.	Description
1.	Slot
2.	Rectangle cap (8)

### 3.8.7 Installing Storage Tray Kit

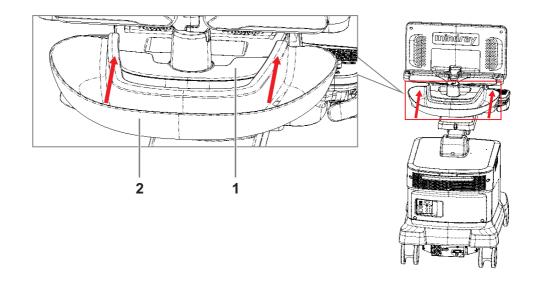
The storage tray kit consists of a storage tray of control panel base, a storage tray of main unit top cover, and an intra-cavity probe holder connector.

The installation procedures of the two storage trays are described in this section.

For details on installing the intra-cavity probe holder connector, contact Mindray Customer Service Department or sales representative.

### Storage Tray of Control Panel Base

Hold the storage tray of control panel base with both hands, with the U-shaped opening facing the control panel base, make the upper edge of the storage tray lap on the control panel base, and push it into place along the plane.



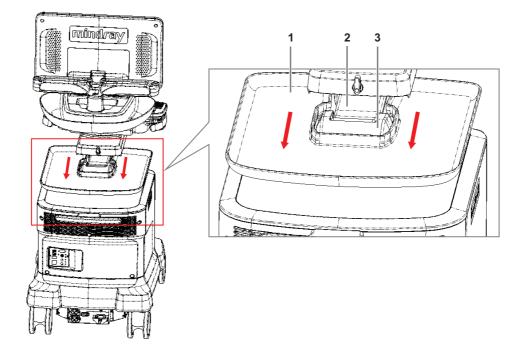
NO.	Description
1.	Control panel base
2.	Storage tray of control panel base

#### NOTE:

Keep the center of the U-shaped opening of the tray align with the center of the control panel base, and make the upper edges of the tray lap on the control panel base.

### Storage Tray of Main Unit Top Cover

Hold the two sides of the storage tray with both hands, and make the U-shaped opening facing the base arm so that the opening in the middle of the storage tray is right above the protective cover of the turbine. Then place the storage tray vertically to make it sleeve on the protective cover of the turbine.



NO.	Description
1.	Main unit top cover storage tray
2.	Base arm
3.	Turbine protective cover

The Setup function is designed to set the configuration parameters of operating the system and maintaining user workflow setup data. The setup data of the user and system are stored to the hard drive, and should be backed up to CD/DVD or USB memory device.

# 

When the preset data is changed, be sure to save the preset data according to the methods described in this chapter. Mindray is not responsible for the loss of preset data.

• To enter Setup:

Press <F10 Setup> on the keyboard to enter the setup menu.

- To exit Setup:
  - Select [Save] in the Setup menu. The parameter settings are saved.
  - Select [Cancel] in the Setup menu or press <ESC> to close the Setup menu.

When you change the system language and click [OK] in the Setup menu, the system automatically shuts down to make the modification effective.

Basic operations

The commonly-used setting types are:

- Text box: position the cursor over the corresponding field box. Enter the desired value using the keyboard or soft keyboard on the soft menu.
- Radio button: click the button to select an item.
- Check box: click the checkbox to select one or more options.
- Drop-down list: click the arrow beside the list to select an item.

# 4.1 System Preset

The system automatically enters the [System] screen after you enter Setup.

ltem	Description		
Region	To set the hospital name, language, time zone, time format and system date/time.		
General	To set patient information, exam setup, patient management, storage, ystem dormancy, display and so on.		
Image	To set general parameters in imaging modes.		
Application	To set the measurement ruler, measurement setting, follicle method, comment setting and so on.		
OB	To set the relevant information regarding the fetal gestational age, fetal growth formula and fetal weight.		

ltem	Description	
Key Config	To assign functions to the F keys of the key board.	
Gesture	Preset the gesture on the touch screen.	
Output	Set the output format, the range and the resolution for the image.	
Access Control	To set the user account control relevant information.	
Scan Code	To set the code parameters for barcode reader.	
Key Probe	To assign the functions to the buttons on the probe.	
Biopsy	To set the Biopsy grid parameters.	

# 4.1.1 Region

Set the hospital name, language, time zone, time format and system date/time.

ltem	Description
HOSPITAL INFORMAT ION	To set the hospital-relevant information such as name, address, telephone, and so on.
Load Logo	Import image for logo loading.
	NOTE:
	For a better display effect, please try to use an BMP image with 400*400 pixels.
Language	To select a language (input) for the system.
Time Zone	To select the time zone.
System Date	To set the date for the system.
Date Format	To set the date format.
System Time	Move the cursor over the corresponding field and enter the time manually using the keyboard, or, move the cursor over the time segment and press <set>, then increase or decrease the required value by clicking the icons on the right side.</set>
Time Format	To select the time format.
Time Synch	To assign a time server and make the time of the ultrasound machine consistent with the server.

# 4.1.2 General

Set patient information, exam setup, display, screen saver and so on.

Туре	ltem	Description
Patient Info	Patient Banner Display Content	To select whether to display the available patient information items on the screen.
	H&W Unit	To set the unit for calculating patient height and weight.
	BP Unit	To set the blood pressure unit.
	Surface Formula	To set the surface formula.
	Font Size (For Storage)	To set the font size in the Patient Banner Display Content for storage.
Status after Freeze To set the system state after the image		To set the system state after the image is frozen.
	Storage Beep Volume	Set the key volume for saving single /multi-frame image.

.

Туре	ltem	Description	
Exam Setup	Status After Ending Exams	To set the system status when an exam ends.	
	Auto Screenshot of Report Page by Page	After selected, perform measure application and save single frame image, then end the patient exam, the system will save the report image in iStation.	
	Auto Screenshot of Report Preview Page by Page	Select whether to automatically save screenshots of the report preview pages to iStation after ending exams.	
	Sending/printing Image After Ending Exams	Select whether to automatically archive the exam data to the DICOM server for storage/print.	
	Sending SR After Ending Exams	Select whether to automatically send structure report to the DICOM server.	
	Save Patient Info Dialog After Ending Exams	Select whether to automatically save the screenshot of patient information after ending exams.	
	Disable Recycle Bin	After checking this option, the deleted data will not go to the recycle bin.	
		<b>NOTE:</b> After disabling the recycle bin, the deleted data cannot be recovered.	
	Speed up the export of exams	Select whether to speed up the export of exams after prospective saving the cine.	
	Remind exams backup after	To set number of days to remind the operator of exam backup.	
	Maximum number of exams to be kept	To set the maximum number of exams to be kept. If the actual number is larger than the preset number, the latest exam will replace the earliest exam.	
		NOTE:	
		The patient exams which exceed the preset maximum will be deleted and unrecoverable. It is recommended to perform patient data backup before enabling this function to avoid data loss.	
	Exam cannot be activated after	To set the number of days that allows the exams to be activated.	

Туре	Item	Description			
Screen Saver	Screen Saver	<ul> <li>Select the different saver methods to the system.</li> <li>After enabling the screen saver, check "Mindray" to select the image from the system. Or click [Preview] to select the image on your own.</li> <li>To set the waiting time before the system enters dormancy status in the drop-down list beside "Wait".</li> <li>The system enters screen saver automatically if the system waiting time exceeds the screen saver already set.</li> </ul>			
	Standby	The system enters screen saver automatically if the system waiting time exceeds the screen saver already set and standby time.			
		To set the brightness/contrast of the main screen and the touch screen according to the conditions.			
	LCD	To set the brightness and the contrast of the main screen, or restore to the default.			
	TouchPanel	After selection, the system restores the touch screen settings back to factory.			

# 4.1.3 Image Preset

Туре	ltem	Description		
Reset Config	Probe	<ul><li>To set the default probe model for the system from the dr down list.</li><li>The default parameters are applied to the new probe if checking "Use the default setting when start a new exam</li></ul>		
	Image Size	Set the standard for saving the image or using the digital/ graph printer.		
	Default Elasto	Set the default elastography mode.		
ART Flow	Max transmit time	Set the maximum duration time. Enter Color mode and enable ART Flow; the penetrability of color image is enhanced in this time period.		
	Max interval time	Set the maximum interval time. Enter Color mode and enable ART Flow; the ART Flow is enabled again until the interval is finished.		

Type Item		Description		
Parameter	Steer	<ul> <li>To set the steer mode in B + Color + PW/CW imaging mode.</li> <li>C&amp;(PW/CW): select to adjust the sample volume in color mode and sample line in PW or CW mode together.</li> <li>C/(PW/CW): select to adjust the sample volume in color mode and sample line in PW or CW mode separately.</li> </ul>		
	Auto Invert	The spectrum can automatically invert when the color flow is steered to a certain angle, thus accommodating the operator's wish to distinguish the flow direction.		
	iScape Ruler Display	To set whether to display the iScape ruler in iScape imaging mode.		
	B+Color Refresh With PW/CW Sampling Line Movement	To set whether to turn on the function that when moving PW/CW sampling line, B+Color image is activated under B+Color+PW/CW mode.		
	Uninterruptible image saving when preprocessing parameters are changed	Adjusting preprocessing parameters will not interrupt image/ cine saving.		
	Color And PW/CW Synchronize Invert	To set whether to invert Color Map and PW/CW spectrum synchronously		
	Display Transducer SN	To set whether to display the transducer SN.		
	B+Color+PW Unfreeze keeping PW	To set whether to retain PW images when unfrozen under B+Color+PW mode.		
FreeHand Cine Length	Time(s)	To set the freehand cine storage length.		
Fusion	Power Line Frequency	Select the power frequency.		
Tissue Tracking QA	LV Segment Model	To set the cardiac segment model: 16 or 17.		

# 4.1.4 Application

Set the measurement ruler, measurement setting, follicle method, left ventricular setting, comment setting and so on.

#### **Measure Parameter**

Controls are as follows:

Item	Description		
Cursor Type	Type of cursor displayed on the measurement caliper and results window. Value options:		
	• Number: the cursor always displays as "+" while different measurements are marked with numbers.		
	• Symbol: the cursor displays sequentially in 8 symbols to identify different measurements.		
Cursor Size	The size of the cursor.		
Heart Beat	The number of cardiac cycles in the heart rate calculation. (In heart rate measurement, the number of cardiac cycles should match the preset number.)		
Ellipse's style	To set the style of ellipse calipers.		
Trace line style	To set the style of trace line calipers.		
Cursor Line Display	If unselected, the connecting line between the measuring ends will be hidden after measurement.		
Ellipse CrossLine Display	If unselected, the measuring axis within the ellipse area will be hidden after measurement.		
Clear results while deleting caliper	Uncheck. The image is unfrozen or the image mode is changed after the measurement is completed. The measurement results are saved if the caliper is cleared.		
Unit Setting	To set the measurement unit.		

#### **Trace Cursor Speed**

Set the cursor speed during tracing.

#### LV Cube/Teichholz/Gibson

Set the tools used in the Cube/Teichholz/Gibson study.

### Comment

Set whether to clear comments and bodymark:

Item	Description
Clear comments while unfreezing image or changing probe/exam	To set whether to clear comments while unfreezing image or changing probe/exam.
Clear Bodymark upon Unfreeze	To set whether to clear bodymark whiling unfreezing image.
Voice comment enabled	To set whether to enable voice comment feature.

#### Follicle

Set the method for calculating the follicle.

#### **PW Measure**

PW Velocity Measure Displays Absolute Value: All measurement results in PW mode are absolute values based on the unit of velocity after checking this item.

### Intelligent Input

Set to enable the Input Method Association.

#### ICA/CCA && RAR

Set the measurement properties of ICA, CCA, Renal A and Aorta.

#### Cardiac Value Range Display

Set whether to display value range of EMINCA Study for cardiac measurement results.

### 4.1.5 OB

Set the relevant information regarding the fetal gestational age, fetal growth formula and fetal weight.

#### To set the default formula

Perform the following procedure:

- 1. On the [Fetal Gestational Age], [Fetal Growth] or [Fetal Calc] page, select an OB Item in the left column.
- 2. Select a formula in the right column.
- 3. Click [Default]. The default formula is marked with a  $\sqrt{.}$ 
  - On the [Fetal Gestational Age] page, select whether to display the SD or EDD in the obstetric result.
  - On the [Fetal Gestational Age] page, select whether to display the EFW derived GA in the report.

### To set the fetal weight display

Perform the following procedure:

- 1. Enter the [Fetal Calc] page.
- 2. Select the [Fetal Weight Unit].

Select Metric, English or English & Metric from the drop-down list.

3. Select the formula for calculating the weight percentile.

Select the formula from the drop-down list of [EFW-GP].

4. Click [Save] to confirm.

### To import/export an OB Table or Formula

#### NOTE:

Only imported user-defined tables can be exported.

Perform the following procedure:

- 1. Select [Import] or [Export] on the [Fetal Gestational Age] or [Fetal Growth] page.
- 2. Select the drive and file path where the data is located.
- 3. Select the data file to load or export, click [OK] to confirm.

The imported user-defined table for FG and GA must be a \*.csv file. The format of the \*.csv file is described as follows:

#### • FG table

Table Type	Author Name	SD Type	Meas. Value Unit	SD Unit
FG	The author name	Value of standard deviation	Unit of the measurement value	Unit of the standard deviation
Row Num.	Row number (N) of the table			
No.	GA	Min	Meas. Value	Мах
1	GA value	Minimum value	Measurement value	Maximum value
2				
N				

• GA table

Table Type	Author Name	SD Type	Meas. Value Unit	
GA	The author name	Value of standard deviation	Unit of the standard deviation	
Row Num.	Row number (N) of the table			
No.	Meas Value	SD(-)	GA	SD(+)
1	Measurement value	Standard deviation (-)	GA value	Standard deviation (+)
2				
N				

#### NOTE:

- Fill in the table according to the actual clinical values, except for those cells with bold text.
- Value of standard deviation. Select from one of the following: None, ±1SD, ±2SD, 3%~97%, 5%~95%, 10%~90%.
- Unit of the measurement value: according to the table to import, select from mm, cm, g, kg, cm<sup>2</sup> or mm<sup>2</sup>.
- Row number (N) of the table: the maximum row number N in the column "No."
- The third row is empty.
- GA value, Minimum value, Measurement value, Maximum value: enter the number of days without the unit.

• Measurement value, Standard deviation (-), GA value, Standard deviation (+): enter the number of days without the unit.

### **User-defined OB Items**

### NOTE:

The calculation results of the user-defined OB formula are used for reference rather than clinical diagnosis.

You can add user-defined formula for items (obstetric tools) that are not included in the GA and FG table.

- 1. Select [More OB Items] on the [Fetal Gestational Age] or [Fetal Growth] page.
- 2. Select an item and click [OK].

The new item appears in the left column and the system asks if to add a formula.

3. Click [OK] to select the \*.csv file (formula file) for the item. Or add a formula for the new item by clicking [Import].

#### **Measure Result**

EDD Display: the EDD is displayed in the result window after checking.

#### GA Cycle For EDD

- Normal Cycle: GA is calculated according to 40 weeks after checking (EDD=LMP+287(40 weeks)).
- French Cycle: GA is calculated according to 41 weeks after checking (EDD=LMP+287(41 weeks)).

### **Display EFW GA in Report**

Estimate GA according to EFW data after checking.

#### **Reference Value/Range**

You can select whether to display obstetrics reference value or range of certain measurement items in the measurement result window and report page, so as to acquire diagnosis reference. The reference value or range changes with the growing of GA.

The options are as follows:

Item	Description	
Show Reference Value/Range	To select whether to display the reference value or range of all measurement items.	
Meas Item	Obstetrics measurement item.	
Value/Range Type	<ul> <li>To select whether to display the reference value or range of a specific measurement items in the drop-down list.</li> <li>Off: Cancels display of reference value or range.</li> <li>MOM (Multiple of Median): indicates the multiple of the measured value against the median (of the same GA in the statistical data column).</li> <li>P (Percentage): it is a statistical term that indicates the position of the current value in the statistical data.</li> <li>SD (Standard Deviation): it is a statistical term. Values between -SD to SD or -2SD to 2SD are normal.</li> </ul>	

ltem	Description
References	To display the reference information of a specific measurement item.

#### NOTE:

Before starting measurement, ensure that the GA data is acquired by manually entering the LMP in the "Patient Info" page.

### 4.1.6 Key Configuration

Assign functions to the foot switch and user-defined keys.

#### Key function setting

You can set the functions for <Save>, <Print>, user-defined keys (including F3, F4, F5, F6, K1 to K8). To assign a function to a key:

- 1. Click to select the desired key in the Key Function column on the left side of the page.
- 2. Click to select a function in the Function area. You can see the available functions selected on the right side.
- 3. Click [Save] to complete the function setting.

The rectangle key from the left to right are the user defined keys K1 to K8 on the control panel.



#### Foot switch function setting

You can assign a function to the left/middle/right key of the foot switch. The method is similar to setting key functions.

#### **Other Settings**

Item	Description
Key Preview	To preview the user-defined key layout of the control panel.
Control Panel Brightness	To set the brightness for control panel key.
Trackball Speed	To set the speed of the trackball when moving the trackball.
Key Volume	To set the key volume at 3 levels, 0 means no sound.
Touch Screen Volume	To set the touch screen volume at 3 levels, Off means no sound.
Trackball Cine Play Speed	To set the cine playing speed when moving the trackball.

### 4.1.7 Gesture

The gesture setting is the same with the settings of other keys. see "4.1.6 Key Configuration". see "2.13.4 The Display of Touch Screen and Its Operation" for the operation to two-figure gesture on the touch screen

## 4.1.8 Output

Set the output format, the range and the resolution for the image.

Туре	Item	Description	
Send To	BMP/TIFF/JPG	To set the image parameters when sending to other locations.	
	AVI/MP4/WMV		
	DCM		
	DICOMDIR	-	
Digital Output	Output Size:	To select the VGA, HDMI output size.	
Size	Resolution:	To select the VGA, HDMI output image resolution.	
DVR Output	Output Size:	To select DVR recording area.	
	Output Format:	To select the DVR output format.	
Clipboard	Clipboard Reload Save	To set whether to overwrite or save a copy of the original image after editing.	
	Copy Position	To select the position to save a copy.	
Retrospective Cine Length	Time(s)	To set the time duration of the retrospective cine saving with ECG disabled.	
	Beat(heart cycle)	To set the heart cycle of the retrospective cine saving with ECG enabled.	
Prospective Cine Length	Time(s)	To set the time duration of the prospective cine saving with ECG disabled.	
	Beat(heart cycle)	To set the heart cycle of the prospective cine saving with ECG enabled.	
/	Analog Output Mode:	Select the format to output/separate the video format: NTSC or PAL.	
	Text Enhancement Mode:	Click [Yes], and the text in stored image is in white.	

## 4.1.9 Access Control

The system supports three types of users: System Admin, administrator, and operator.

### NOTE:

Only one System Admin is configured by default.

• System Admin

The System Admin can access all function modules, and view all patient data, such as patient information, images and reports, etc. The System Admin can add or delete administrators or operators.

Administrator

The administrator can only access the function modules with assigned privileges, and view all patient data, such as patient information, images and reports, etc. The administrator can add or delete administrators or operators.

• Operator

The operator can only access the function modules with assigned privileges. The operator can only view exam information saved in the system and operated by him or herself, such as patient information, images and reports, etc.

#### **Enabling Access Control**

The System Admin or administrator can preset the access controls, that is, whether an operator has the right to access data in the system.

Access control only can be set by the System Admin or administrator.

- If "Enable User Account Control" is selected, you must be authorized before accessing the data, and you can configure password policy and LDAP, and change password. If unselected, you can access all the data without authorization, and you cannot configure password policy and LDAP, and change password.
- If "Enable Emergency User" is selected, the administrator can edit privileges for emergency users. If unselected, the administrator cannot edit privileges for emergency users.

#### Adding a User/Assigning privilege

Turn on the access control function and log in to the system as System Admin or administrator before you add the user.

- 1. Click [Add] to bring up the dialog box.
- 2. Enter the user name and password, confirm password.
- Select or deselect the check box from the privilege list.
   Users can only access the function module with assigned privilege.

4. Select the user type from the drop-down list.

5. Click [OK] to confirm the setting and exit the dialog box.

The new user and the privilege will appear in the User List.

#### **Deleting a User**

Turn on the access control function and log in to the system as System Admin or administrator before you delete the user.

Select the user to be deleted in the User List. Click [Delete] to delete the selected user.

#### **Editing Privilege**

Turn on the access control function and log in to the system as System Admin or administrator before you edit privileges.

- 1. Select a user, click [Edit Privilege] to enter the "Edit user privilege" dialog box.
- 2. Select or deselect the check box from the privilege list.
- 3. Click [OK] to confirm the editing and exit the dialog box.

The edited privileges will appear in the User List.

#### Modify Passwords

#### NOTE:

The account password needs to be changed every 3 months.

The System Admin can modify all user passwords. The System Admin password is empty by factory default. You can set this password. The administrator can modify all user passwords except for the System Admin.

An operator can only modify his/her own password.

- 1. Select the user name to be modified in User List.
- 2. Click [Change Password] to open the dialog box.
- 3. Enter current password, new password and confirm new password, then click [OK].

#### **Configure Password Policy**

Turn on the access control function and log in to the system as Administrator before you configure the password policy.

Click [Password Policy Config]:

ltem	Description	Remark	
Lockout Threshold	Set the maximum time that a user can input the wrong password. If you exceed the maximum times, your account will be locked.	For example, assume that the "Lockout Threshold" is set to 5, the "Reset Account	
Reset Account Lockout Threshold after	Set the duration allowed for a user to continuously input the wrong password.	Lockout Threshold after" is set to 60, and the "Lockout Duration" is set to 60. That is, a user inputs the wrong	
Lockout Duration	Set the duration after an account is locked.	password for 5 times within 60 minutes, the account is locked, and the user can log in to the system only after 60 minutes. Other users with unlocked accounts can still log in to the system normally.	
Reset all lockout	Reset all locked accounts.	/	
Enable strong password(The password length must be 6-64)	<ul> <li>Enable strong password to improve security.</li> <li>If the strong password is enabled and you log in to the system with the account that is added before the strong password is enabled, the system prompts a warning message to inform you whether your password conforms to the password policy. The administrator can change password for administrator or operator.</li> </ul>		
	• If the strong password is enabled and you add a new user account, the system prompt an error message to inform you that the password is too weak. Modify the password according to the error message.		

#### LDAP Privilege Management

Turn on the access control function and log in to the system as Administrator before you edit privileges for the LDAP (Lightweight Directory Access Protocol) users. Click [LDAP Config].

Item	Description
Select LDAP type	Select AD or LDAP.

Item	Description		
Server Address	Enter the server address in the field box after accessing the network. If LDAP type is selected, enter "Root DN" at the same time, and you can also import SSL certificates if needed by checking "SSL".		
Test LDAP Server	Enter the User name and password in the field boxes of the Authentication test area, and click [Test LDAP Server] to test whether the LDAP server is accessible. If the LDAP is accessible, the system prompts the following message "Server test succeeded."		
Days to keep cached password	<ul> <li>Set days to keep the cached passwords in the local system.</li> <li>Users can log in to the server even without accessing the network within the setting days.</li> <li>Empty: the passwords are kept in the local system permanently.</li> <li>0: no passwords are kept in the local system.</li> <li>&gt;1: for example, if it is set to 5, the passwords are kept in the local system for 5 days.</li> </ul>		
Clear Cache	If the cached passwords is kept in the local system, click [Clear Cache] to remove cached data of authentication from the local system.		
Member and privileges	<ul> <li>Adding a user: Enter the member name, and select or deselect privileges from the drop-down list of "Privilege". Click [Add], and the new members and privileges will appear in the list above.</li> <li>Deleting a user: Select a member to be deleted, and click [Delete].</li> <li>Modifying the member name or privileges: Select a member to be modified, modify the member name, and select or deselect privileges from the drop-down list of "Privilege". Click [Modify], and the modified member name and privileges will appear in the Member of filter list.</li> </ul>		
Logon Test	<ol> <li>Enter the User name and password in the field boxes of the Authentication test area.</li> <li>Click [Logon Test] to test whether the user is authenticated. After successful authentication, the system prompts a successful authentication message.</li> </ol>		

### **Auto Lock Machine**

To set the waiting time before the system enters locked status in the drop-down list beside "Wait". The system will be locked automatically if the system waiting time exceeds the duration already set.

### 4.1.10 Scan Code

Set the code parameters for barcode reader.

### 1-dimension barcode reader (1D)

Item	Description
Scan Item	After scanning 1D bar code, the regular expression is matched in the priority order: "Patient ID > Other ID > First name > Last name > Middle name > Accession # > Operator > Diagnostician". If the regular expression is matched successfully, the data of 1D bar code will be displayed in this item in Patient page automatically. Example: The data of the bar code is 123 after scanning 1D bar code. The regular expression is matched in the priority order: "Patient ID > Other ID > First name > Last name > Middle name > Accession# > Operator > Diagnostician". If the regular expression of "Other ID" is matched successfully, "123" will be displayed in "Other ID" item in Patient page automatically.
Regular Expression	Set the regular expression according to the bar code format.
Move Down	Move up or Move down a selected item.
Move Up	
Delete	Add or delete a selected item. (Only the default item can be added or deleted.)
Add	
Load default	Restore the parameter value to the default value.

### 2-dimension barcode reader (2D)

• General Analysis Mode

Select "General" from "Analysis Mode" drop-down list: The scan codes consist of Patient ID, Other ID, Patient Name, Birth, etc.

ltem	Description	
Scan Barcode Example	Input a barcode example, barcode example is separated by separators (the separator is used to set the start and end position of each item), and the barcode data is displayed in the following items in turn.	
Parameters	• Input a barcode example, and you can change the information of Patient ID, Other ID, First Name, Last Name, Middle Name, Birth (Day), Birth (Month), Birth (Year), Age, Gender and etc. in the "Content" list.	
	Note:	
	Ignore item is used to add one line below the selected item to hide unimportant patient information.	
	• Set the start and end position of each item via separators. After inputting a barcode example, you can select item separators from the drop-down list of the Separator. (Only separators that are input in the field box of the Scan Barcode Example can be displayed in the drop-down list of the Separator.)	
	NOTE:	
	You can customize the age unit of Birth (Day), Birth (Month), Birth (Year) in the Content column. If the DOB provided by the patient contains only digit, the system displayed an auto-generated age.	

ltem	Description	
Move Down	Move up or Move down a selected item.	
Move Up		
Delete	Add or delete a selected item. (Only the default item can be added or deleted.)	
Add		
Load default	Restore the parameter value to the default value.	
Age Unit	Select an age unit from the drop-down list of the "Age Unit": Year, Month, or Day.	
Female	Input the customized gender symbol besides the Male and Female field box, such as Male (M) or Female (F).	
Male		

Advanced Analysis Mode

Select "Advanced" from "Analysis Mode" drop-down list: user enters scan barcode example and regular expression and click [Match], the system will match scan barcode example with regular expression automatically, and if which is matched successfully, the scan item will display the barcode by separators.

#### **Append Options**

The information of operator or diagnostician can be appended after selecting the check box. For example, after scanning a 1D barcode of an operator or diagnostician, the obtained data is A, and A will be displayed in "Operator" or "Diagnostician" item in Patient page automatically. After scanning a 1D barcode of an operator or diagnostician for a second time, the obtained data is B, and A will be appended by B in "Operator" or "Diagnostician" item in Patient page automatically.

#### **Default Item**

If the default item is set to "No", and both the 2D and 1D barcodes fail to be matched, the obtained data of the barcode is input as a string of characters. After selecting a default item from the drop down list of "Default Item", the obtained data of the scanned barcode will be displayed in the corresponding selected default item.

For example, if the default item is set to "Patient ID", and both the 2D and 1D barcodes fail to be matched, the obtained data is displayed in the "Patient ID" item in Patient page automatically.

#### Import/Export

Set the barcode by importing/exporting configure file. You can contact Mindray service engineer also.

#### **Worklist Options**

- Select "Worklist Server" from the drop-down list, and the system searches the Worklist server according to the scanned data.
- Select "No" from the drop-down list, and the system creates a new exam in the Patient page according to the scanned data.

#### Worklist Default

- Select a default item for searching the Worklist server.
  - For example, users select "Patient ID" from the drop down list of "Worklist Default", and the system searches Patient ID in the Worklist server.

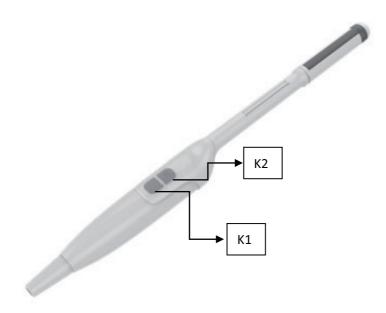
 Select "No", and the system searches the Worklist server in the priority order: "Patient ID" > "Last name" > "Accession #".

#### NOTE:

The matching priority order is 2D item, 1D item, and Default Item, after the 1D/2D and default items are configured.

### 4.1.11 Key Probe

This page is used to set the functions of keys on the key probe by Short Press, Long Press, and Double Click.



## 4.1.12 Biopsy

This page is used to set the biopsy grid parameters, such as Guide Line Dot Type, Grid Size, and Grid Type.

# 4.2 Exam Mode Preset

You can assign available exam modes for probes.

Perform the following procedure:

- 1. To select a probe, move the cursor over the Probe column and select the probe model using the drop-down list.
- 2. Select/delete exam modes:

On the left side, you can view all the available exam modes in the exam library for the probe.

On the right side of the screen, you can view the current exam modes assigned to the probe.

- Click [>]: add a selected exam mode in the [Exam Mode Library] to the [Probe and Exam mode] list.
- Click [<]: add a selected exam mode in the [Probe and Exam Mode] to the [Exam Mode Library] list.

- Click [>>]: add all exam modes in the library to the [Probe and Exam Mode] list.
- Click [<<]: add all probe and exam modes in the library to the [Exam Mode Library] list.
- Click [Delete] to delete a user-defined exam in the Exam Mode Library area.
- Click [Default] to set a selected exam mode as the default exam mode. The default exam mode is marked by a " $\sqrt{}$ ".

# 4.3 Measurement Preset

"Exam Mode XX" on the upper left side refers to the currently configured exam mode. The configured general/application menus are only related to the current exam mode.

There are three kinds of measurement items.

#### Measurement

Results of measurements are directly obtained via the measurement tools, which are indicated by "

For example, "Distance" in the 2D general measurement or "HC" in the OB measurement.

On the touch screen, measurement tools are displayed using square button.

### Calculation

Results of calculations are automatically derived by the system using other measured or calculated values as parameters, they are indicated by " $\blacksquare$ " in the preset screen.

For example, EFW (Estimated Fetal Weight) in the OB measurement.

If all measurements related to a calculation tool are completed, the system will automatically calculate the result. If some measurement tools are performed again, the system will automatically update the calculation result using the latest measurement results.

On the touch screen, calculation tools are displayed using square button.

#### Study

A group of measurements and/or calculations for a specific clinical application, which are indicated by "\_\_\_\_\_" in the preset screen.

For example, AFI in the OB measurement.

Fold/unfold the study to hide/show the measurement or calculation items included.

On the touch screen, study items are displayed with an arrow indicating the tools to be selected.

### 4.3.1 General Measurement Preset

You can preset the General Measurement packages for 2D (B/Color/Power Mode), M Mode, or Doppler (PW/CW) Mode respectively.

Perform the following procedure:

- 1. Select the [Caliper] on the [Measure] page.
- 2. Select the [2D], [M] or [Doppler] tab to go to the corresponding preset menu.
  - [Available Items]: general measurement tools configured by the system in the current scanning mode which are available but not assigned yet.
  - [Selected Items]: displays the tools to be added to the menu.
- 3. Add/Remove the general measurement item using the following buttons:
  - [>]: To add the selected tool from the [Available Items] to the [Selected Items].
  - [>>]: To add all tools in the [Available Items] to the [Selected Items].

- [<]: To remove the selected tool from the [Selected Items] to the [Available Items].
- [<<]: To remove all tools from the [Selected Items] to the [Available Items]. You do not need to select any items before removing.
- 4. Set the default item.

Select an item from the [Selected Items], then click [Default]. The item is marked with a  $\sqrt{.}$ 

The default item is activated automatically when entering this general measurement menu.

5. Adjust the item position.

Select an item from the right column and click [Move Up]/[Move Down] to adjust the sequence in which the items are arranged in the corresponding general measurement menu (touch screen display).

6. Modify the properties of a measurement item.

The following takes D Trace as an example to show how to set the properties of a measurement tool.

- a. Select the [Doppler] tab to go to the corresponding preset menu.
- b. Select [D Trace] from the [Selected Items] and click [Property] to bring up the following dialog box.

Item Name	Result	Unit	CalcMethod
PS		cm/s	Last
ED		cm/s	Last
TAMAX		cm/s	Last
TAMEAN		cm/s	Last
PI			Calc after Mean
RI			Calc after Mean
S/D			Calc after Mean
HR		Bpm	Last
Vel		cm/s	Last
PV		cm/s	Last
MD		cm/s	Last

Descriptions of the attributes are shown in the following table:

Item	Description	
Item Name	Results obtained from D Trace are listed. The selected items will be	
Result	<ul> <li>displayed in the results window after measurement.</li> <li>If PV is selected, other results become deselected (except the temporary result "velocity").</li> <li>Some results, such as PS and ED, can be derived via a simple method (e.g., Velocity), but others, such as TAMAX, can only be derived via complicated methods such as Manual, Spline, Auto, etc. Only Vel. is available in [Method] if only PS or ED is selected. Methods for obtaining PS and TAMAX simultaneously (trace, spline and auto) should be chosen if both PS and TAMAX are selected (TAMEAN should use auto method).</li> </ul>	

ltem	Description
Unit	Select the measurement unit. Click "Unit" column of each item to select.
CalcMethod	Select the measurement method for the tool. Click "CalcMethod" column of each item to select.

- c. Click [OK] to confirm the setting.
- 7. Select the measurement sequence.
  - [Repeat]: after the current measurement is completed, the system automatically activates the current tool again.
  - [Next]: after the current measurement is completed, the system automatically activates the next tool in the menu.
  - [None]: after the current measurement is completed, the cursor can be moved over the whole screen. And the cursor will automatically return to the menu of the corresponding measurement.
- 8. Click [Save] to confirm.

### 4.3.2 Application Measurement Preset

#### **Measurement Package Preset**

During measurement, the preset package displays on the touch screen. Items in the package can be preset and may belong to different application regions.

You may configure more than one measurement package for current exam mode. Under actual measurement status, switch the measurement library if necessary (by rotating the knob under the [Library] button on the touch screen or clicking the menu title.)

Click [Advanced] on the [Measure] page to enter the "Add New Package" page.

- [Available Items]: shows application packages configured in the system but not yet assigned to the current mode.
- [Selected Items]: shows application packages assigned to the current exam mode. If more than one package is assigned to the current exam mode, you can rotate the knob under the [Library] button on the touch screen or clicking menu title in the measuring status.

Package editing includes Creating Packages, Add/Remove Items, Deleting Measurement Packages, Setting Default Packages, Adjusting Package Positions.

- Creating Packages: Click [New] and enter a name for the new package in the dialog box popup. Click [OK] to confirm, the new package displays in the [Available Items] list.
- Adding/Removing Packages: Add/remove the package by clicking [>], [>>], [<] and [<<].
- Deleting Packages: Select a package from the [Available Items] list, click [Delete]. To delete an item from [Selected Items], you need to move it to the [Available Items] first.
- Setting Default Packages: Select a package from the [Selected Items] list, then click [Default]. The default package is marked with a √.

The default package displays when entering the [Measure] page.

The measurement menu of the default package (corresponding to the exam mode) displays when entering the measuring status.

• Adjusting Package Positions: Select a package from the [Selected Items] and click [Move Up]/ [Move Down] to adjust the sequence that the packages in the menu are arranged in.

#### **Measurement Menu Preset**

The following operations are available.

- Adding/Removing Items: Add/Remove the general measurement item using the [>], [>>], [<] and [<<].
- Setting Default Items: Select an item from the [Selected Items] list, click [Default]. The defaulted item is marked with a  $\sqrt{}$ .

To deselect the default tool, select it and click [Default] or set another item as the default.

If a particular item is set as the default item, it automatically displays the submenu of the study when entering this measurement menu.

• Adjusting Item Positions: Select an item from the [Selected Items], click [Move Up]/[Move Down].

The order in the list is also the item position in the menu.

#### **User-defined Measurement**

Perform the following procedure:

- 1. Select the [Measure] tab page.
- 2. Click [New].

The "Measurement Custom Wizard" dialog box appears.

Measurement Custom Wizard
Step 1: Input new item name and select type
Name Custom1
Туре
Add Meas
The measurement is a caliper that measures distance, area, velocity, and etc.
O Add Calc
A calculation is a formula that uses some parameters to calculate a result
Add Study
A study is a group of calipers that measures volumes, three diam, ratio, stenosis, etc.
Prev Next Complete Cancel

3. Enter the Name in the "Measurement Custom Wizard" dialog box, select "Add Meas", then select [Next].

4. Select the [Tool Type], [App Region] and the Measurement Result.

Measureme	nt Custom Wizard		
Step 2: Set the	e attribute for the measure		
Name			Has Left-Right
App Region	ОВ		Has Prox-Mid-Dist
Tool Type	Dist		Has Multi-Fetus
Measure	Result:		
Result	Item Name	Unit	
	Custom1 Distance		
	Prev	Co	mplete Cancel

Descriptions of the attributes in the dialog box are shown in the following table.

Attributes	Descriptions
App Region	Select the application region for the user-defined item.
Tool Type	General measurement tool type of the user-defined item. E.g. Select Dist. if you want to add a new item to measure the distance.
Has Left-Right	If selected, you can choose left or right side in the measurement menu.
Has Multi-Fetus	If selected, you can choose different fetuses in the measurement menu (available in the Obstetric application region only).
Has Prox-Mid-Dist	If selected, you can choose proximal, middle or distal in the measurement menu.
Measurement Result	Choose the results to be displayed in the results window. The result name can be changed. Move the cursor over an item and press <set>, then enter the name in the text box.</set>
Unit	Select the measurement unit. Click "Unit" column of each item to select.

5. Click [Complete] to finish setting. The user-defined measurement item is listed in the "Selected Items" menu and in the "User-defined" category of "Available Items". An asterisk appears after the user-defined item for identification.

The user-defined measurement item will be added automatically to the "Selected Items" in the Report template. If the item is completed in an exam, the results will be displayed in the report.

#### **User-defined Calculations**

#### NOTE:

- Please ensure the correctness and validity of the defined formula, otherwise Mindray will not be liable for damage caused by improper definition of the formula.
- Trigonometric functions are in degrees, not radians.

• PI is accurate to 7 digits.

User-defined calculations are derived from arithmetic operations in which the parameters are measurement, calculation or study results obtained in measurement items which exist in the system or are user-defined.

Perform the following procedure:

- 1. Select the [Measure] tab page.
- 2. Click [New].

The "Measurement Custom Wizard" dialog box appears.

Measurement Custom Wizard
Step 1: Input new item name and select type
Name Custom1
Туре
Add Meas
The measurement is a caliper that measures distance, area, velocity, and etc.
Add Calc
A calculation is a formula that uses some parameters to calculate a result
Add Study
A study is a group of calipers that measures volumes, three diam, ratio, stenosis, etc.
Prev Next Complete Cancel

- 3. Enter the Name in the "Measurement Custom Wizard" dialog box, select "Add Calc", then select [Next].
- 4. Select the [App Region] and edit the formula.

Measurement Custom Wizard						
Step 2: Set the	attribute	for the	calc			
Name	2					
App Region	ABD		-		UnitType	
Formula						Verify
2D		Neasure	ment 🥃			Calculator
Item Name		Res	ult Name	Unit		F41 51 61 F1
Liver		Liv	er	cm		<b>610 (2) (3) (-)</b>
Renal L						
Renal H						-Function
Renal W						sin cos tan atan
Cortex						min max sqrt pow
Adrenal L						exp In log avg
Adrenal H						() () abs (P)
			Pr	ev	Next	Complete Cancel

Descriptions of the attributes in the dialog box are shown in the following table.

Attributes	Descriptions	
Formula	Displays the user-defined formula.	
Verify	Used to verify if the formula is valid.	
App Region	Select the application region for the user-defined item.	
Measurement Item	All available measurement items of the application region selected in the previous step.	
Calculator	You can select from measurement/calculation/study items in 2D/M/	
Function	Doppler mode.	
Unit	Used to enter numbers and functions in the formula.	

For example, to create a user-defined measurement item (HC/AC):

- a. Enter name for the item, such as "calculation 1."
- b. In Region select "Obstetric," then select the measurement tool sources "2D" and "Measurement".
- c. Find HC in the "Item Name" list, click to select it, then double-click HC in the Result Name box on the right side. The index is added to the formula.
- d. In the Calculator, click "/" and it is added to the formula.
- e. Find AC in the "Item Name" list, click to select it, then double-click AC in Result Name box on the right side. The index is added to the formula.

The function description is as follows:

Function	Method	Number of Parameters	Function Description
sin	sin(a)	1	Sine (the ratio of the opposite to the hypotenuse)
cos	cos(a)	1	Cosine (the ratio of the adjacent to the hypotenuse)
tan	tan(a)	1	Tangent (the ratio of the opposite to the adjacent)
atan	atan(a)	1	Arctangent (the result is expressed in radian.)
min	min(a,b,)	≥2	Minimum
max	max(a,b,)	≥2	Maximum
sqrt	sqrt(a)	1	Square root
pow	pow(a,b)	2	Calculate b power of a
exp	exp(a)	1	Exponential function with natural constant e as the base
ln	ln(a)	1	Logarithm with natural constant e as the base
log	log(a)	1	Logarithm with 10 as the base
avg	avg(a,)	≥1	Average value
abs	abs(a)	1	Absolute value

Function	Method	Number of Parameters	Function Description
PI	PI	/	Constant π, 3.1415926

#### NOTE:

The letter "a" and "b" in the "Method" Column are parameters.

The following physiological indicators can be added to the formula.

Name	Definition	Unit
Age	Age	day
BSA	Body surface area	m <sup>2</sup>
PSA	Prostate specific antigen	ng/ml
PPSA Coefficient	PPSA Coefficient	ng/ml <sup>2</sup>
RAP	Right atrial pressure	mmHg
GA	Gestational age	day
Height	Height	cm
Weight	Weight	kg
Heart Rate	Heart rate	bpm
High BP(CAR)	High blood pressure (Cardiac)	mmHg
Low BP(CAR)	Low blood pressure (Cardiac)	mmHg
High BP(VAS Left)	High blood pressure (Left Vessel)	mmHg
Low BP(VAS Left)	Low blood pressure (Left Vessel)	mmHg
High BP(VAS Right?	High blood pressure (Right Vessel)	mmHg
Low BP(VAS Right)	Low blood pressure (Right Vessel)	mmHg

5. Verify the formula, select the unit of the result, then click [Complete]. The user-defined calculation item is listed in the "User-defined" category of "Available Items".

In the meantime, the user-defined calculation item will be added automatically to the "Selected Items" in the Report template. If the item is completed in an exam, the results will be displayed in the report.

#### Add a Study

You can add or remove user-defined study items in the [Selected Items] column.

Perform the following procedure:

- 1. Select the [Measure] tab page.
- 2. Click [Add Study] on the right.
- 3. Enter the study name in the dialog box that appears.
- 4. Click [OK] and the item will be added to the "Selected Items".
- 5. Select a measurement/calculation item from the "Available Items" and click [>] to add the item to the user-defined study.
- 6. Repeat the step 5 to add more items if necessary.
- 7. Move the cursor to click on the study and click [Property] on the right to edit the measure sequence.

### Edit User-defined Items

#### NOTE:

- Adding B-Hist or B-Profile to the study is not supported.
- Click [Export Custom] in the measurement preset window to export the user-defined measurement.

Select the target defined item in the "Available Items", and click [Edit].

### **Remove User-defined Items**

- Remove Measurement/Calculation
  - a. Select "User-defined" in the "Available Items", and select the desired item.
  - b. Click [Delete].
- Remove Study

Select a user-defined study, and click [<].

# 4.3.3 Report Preset

#### NOTE:

- Deleting is not supported in IVF, IMT and EM reports.
- Watch the layout when setting the patient information layout of the report template. Do not set too many characters in one line; otherwise it may affect the display of the report.

### **Creating Report Templates**

Perform the following procedure:

- 1. Select the [Report] on the [Measure] page.
- 2. Click [New].
- 3. Select template: click the drop-down list under "Application Region" to select the template and click [OK] to confirm the template layout and exit the dialog box.
- 4. Enter the name for the user-defined report template in the box after "Report Template Name".
- 5. Click [Measurement] to select measurement results to be displayed in the report:
  - a. Select an application category from the drop-down list beside "Available Items".
  - b. Select Measurement, Calculate, Study or All from the drop-down list beside "Available Items". The corresponding items appear in the list.
  - c. Use the [>] or [>>] buttons to add items to the "Selected" list.

Only tools which appear in the right column and are completed in the ultrasound exam can be displayed in the report.

In cardiac mode, if result items of only one formula are selected, only results of that one formula will be displayed after measurement. (For e.g., if only items suffixed with Teicholz are selected, not with Gibson or Cube, then only results suffixed with Teicholz after measurement are displayed.)

Add the study.
 Click [Add Study] and enter the study name in the dialog box which appears, then click [OK].

The new added study appears in the "Selected" list.

e. Adjust the item position.

Select an item from the "Selected" list, click [Up]/[Down] to adjust the position of the item in the list, as well as in the report template.

- f. Click [OK] to save the settings and exit the dialog box.
- 6. Set the module display in the report: click [Settings] to make a selection;
  - Tick the check box in front of the module name to display the module in the report;
  - Click [OK] to save the setting and exit.
- 7. Change the patient information layout in the report template:
  - Change the template used in the report layout: click [New Layout] to select another template.
  - Double click the information lines to be edited in "Report body". The dialog box of font setting appears. Set the font size, font weight or hidden key words.
  - Double click the blank of a module in "Report Body". The dialog box of editing the content appears. Select the content to be displayed at current position.
  - Press left <Set> on the blank of a module in "Report Body". Choose to add or delete the line, or add the table, etc.
- 8. Click [Save] to save the setting.
- 9. Click [Close] to quit the template.

### **Deleting Report Templates**

Perform the following procedure:

- 1. Select the [Report] on the [Measure] page.
- 2. Select the template to be deleted from the list.
- 3. Click [Delete] > [Yes] to delete the selected template.
- 4. Click [Save] to confirm the settings.

#### **Editing Report Templates**

Perform the following procedure:

- 1. Select the [Report] on the [Measure] page.
- 2. Select the template to be modified from the list.
- 3. Select [Edit] to enter the report editing page.
- 4. Click [Save] to confirm the settings.

### **Setting Default Templates**

Perform the following procedure:

- 1. Select the [Report] on the [Measure] page.
- 2. Select a report template from the list.
- 3. Click [Default].
- 4. Click [Save] to confirm.

### **Editing Anatomy Information**

Anatomy information items can be added or deleted from the Report page. Perform the following procedure:

- 1. Select the [Report] on the [Measure] page.
- 2. Select a report template from the list.
- 3. Click [AnatomyInfo].

- 4. Click the drop-down list besides "Application Region" to select the application.
- 5. Use the [>], [>>], [<] and [<<] buttons to add or delete items.

You can click [New] to add user-defined items.

6. Click [OK] to confirm.

### **Setting Analysis Model**

The measurement parameters in different clinical diagnostic scenarios that are used for reproductive function evaluation are integrated into a dedicated report template, and a user-defined diagnostic model is supported.

Perform the following procedure:

- 1. Select the [Report] on the [Measure] page.
- 2. Select the report template that supports Analysis Model from the list.
- 3. Click [Analysis Model].
- 4. Add a new model.
  - a. Click [New Model], and enter the model name in the filed box.
  - b. Click [OK] to confirm.
    - You can rename, delete, clear, import or export a model.
- 5. Add a new item.
- 6. Click [New Item], and select an item type.
- 7. Set the parameters as needed.

Attributes	Descriptions
Standard Item	<ul> <li>Provides a set of default measurement items and sets relevant parameters.</li> <li>1. Select a measurement item from the drop-down list, and set the grade segment. The unit is provided by default.</li> <li>2. Enter the measurement value and scores.</li> </ul>
Custom Item	<ul> <li>3. Click [OK] to confirm.</li> <li>Adds user defined measurement items and sets relevant parameters.</li> <li>1. Select a result type.</li> </ul>
	For the Numerical type, the measurement value is numbers and the unit needs to be defined. For the Text type, the measurement value is text and the unit is not available to be defined.
	<ol> <li>2. Enter a user-defined measurement item, and set the grade segment.</li> <li>3. Enter the measurement value and scores.</li> <li>4. Click [OK] to confirm.</li> <li>Check "Always display in report" to display the custom item in the report.</li> </ol>
Summary Item	<ul> <li>Sets the Summary of all items.</li> <li>1. Set the grade segment.</li> <li>2. Enter the scores and assessment. The score is the total sum of all items, and the assessment is given on this basis.</li> </ul>
	3. Click [OK] to confirm.

You can move, add, delete, or edit the item.

8. Click [OK] to confirm.

# 4.4 Comment Preset

You can preset the custom comments library for current exam mode. The comments in the library are provided by the system or user-defined ones.

# 4.4.1 Comment Configure

### Add comments

Directly enter user-defined comment texts, or select available items (select comment texts for the comment library or select comment in groups).

- Directly enter user-defined comment texts: posit the cursor in the field box above [Add Comment], enter the text comment through the keyboard, and then click [Add Comment]. Then the directly-entered comment will be added to the Available Items and Selected Items.
- Select available items: First select a comment library and "Comment" from the drop-down lists beside "Available Items", and then all items will be displayed below "Available Items". Or Select "Group" from the drop-down list beside "Available Items", all groups will be displayed below "Available Items".
  - Click [>] to add the item in Available Items on the left into Selected Items on the right.
  - Click [>>] to add all items in Available Items on the left into Selected Items on the right.

### Change position of the selected items

Select an item on the right side box and click [Up], [Down], [Left] or [Right] button to change the position of the item.

### Withdraw or delete a user-defined comment

- Withdraw an item (from the library or user-defined) in the Selected Items list:
  - Click [<] to withdraw selected Items to the Available Items list.
  - Click [<<] to withdraw all items in Selected Items.</li>
- Delete a user-defined item in the Available Items box: You can only delete the user-defined items rather than the items in the system library. After a user-defined item is deleted, it will not be available.

Select a user-defined item in the Available Items box, and click [<].

### **List Config**

Select a desired group from the drop-down list.

## 4.4.2 Comment Group Define

You can add user-defined comment group for current exam mode. The groups in the library are provided by the system or user-defined ones.

### NOTE:

You can rename, delete, add comment to, delete comment from, or change position of the selected items in the user-defined groups, while system standard groups cannot be modified.

- Add groups: click [Add Group], position the cursor in the field box near [Lists Name], enter the group name through the keyboard, and then click [Confirm]. Then the entered group will be added to the Group Lists.
- Rename groups: select a user-defined group, click [Rename], enter the group name through the keyboard, and then click [Confirm]. Then the new group name will be displayed in the group lists.
- Delete groups: select a user-defined group, click [Delete Group]. After a user-defined group is deleted, it will not be available.
- Add comments to groups: the operation is the same to that of the "Comment Configure" tab.
- Delete comments: select an item from the selected items and click [Delete].
- Change position of the selected items: the operation is the same to that of the "Comment Configure" tab.

After you customize groups, click [Save] to confirm and exit the screen.

# 4.5 iWorks Preset

You can customize the protocols and views in the iWorks preset screen.

## 4.5.1 Protocol Management

- Click [Multi Select] and you can select multiple views to be copied in the list on the left.
- Click to select the protocol in the list. The protocol type can be checked on the right.
- Click [Add Protocol] to create a new protocol. It can be customized.
- Click to select a protocol in the list on the left and click [Copy]. A protocol named "XXX Copy1" is created with the copied views, which can be customized.
- Select a view with "Left", "Lt", "Right" or "Rt" in its name in the list on the left, and click [Copy L <> R]. The selected view is copied onto a new view in which bodymarks, annotations and measurement items are reversed to the opposite side.
- Click [Delete] to delete a user-defined protocol.
- Click [Up] or [Down] to move the selected protocol.
- Click [Move to Top]/[Move to Bottom] to move the selected protocol to the top or bottom of the list.
- Click [Disable Protocol Body Marks] to set whether to display the body marks in iWorks.
- Click to select the key from the drop-down list of "Caliper Trigger" to start basic measurement function.

## 4.5.2 View Management

- Click to select the views in the list. The image, annotation, body mark and measurement settings can be checked on the right.
- Click to select a user-defined protocol in the list. Click [Add View] to add a view template to the protocol.

## 4.5.3 Create a New Protocol

You can create user-defined protocols and customize the automated procedure.

Perform the following procedure:

1. In the iWorks preset screen, click [Add Protocol] to create a new protocol.

Or, select an existing protocol and click [Copy] to customize the protocol based on the previous template.

- 2. Enter the protocol name, type and select the application region.
- 3. Click [Add View] to enter the view name and perform image settings.
  - In the measurement setting, if "Image without measurement(s) stored together" is selected, the system will save two images after finishing the section operation. One of the two image will include the measurement result.
  - In the measurement setting, if "Store image with measurement(s) first and then store image without measurement(s)." is selected, the system will store the image in order.
- 4. Click [Save] to complete the setting and exit.

# 4.6 Stress Echo Preset

### 4.6.1 **Protocol Edit**

You can create, edit, delete, copy, export and load the Stress Echo protocols using the Protocol Editor dialog box.

ltem	Description
Protocol Name	Enter the protocol name.
Trigger	Set the trigger type.
WMS model	Set the chamber segment division method.
Loop usage:	Displays the acquired loop number as well as the total usable loop number.
View	Set the views for each stage.
Standard Views:	Set the standard view.
Export	Import/Export a protocol.
Load	
New Protocol	Create a new protocol.
Copy Protocol	Create a new protocol with an existing one.
Delete Protocol	Delete the protocol.
New Stage	Create a stage for the current protocol.
Delete Stage	Delete the stage.

#### **Creating a Stress Echo Protocol**

Perform the following procedure:

- 1. Click the [New Protocol] to the right of the Protocol Editor dialog box.
- 2. Enter the protocol name in the Protocol Name box at the top.
- 3. For each view (all views display for each phase):
  - a. Select [New View] in the View list.
  - b. Select a standard view from the Standard View list. Or you can customize the view name.
- 4. For each phase in the protocol:
  - a. Select [New Stage] in the Stage list.

- b. Enter a phase name.
- Select [Auto Select], the system jumps to Select Mode after retrospective acquisition.
- Select the required option from the Clip Capture drop-down list.
- Select the number of loops to acquire (per view in the selected phase) in the Loops list (for non-continuous stages).
- Select the type: exercise or drug.
- 5. Click [Save] to save changes and quit.

### Editing a Stress Echo Protocol

Perform the following procedure:

- 1. Click an available protocol on the Select Protocol screen.
- 2. Click [Edit] to enter the Protocol Editor screen.
- 3. Edit the protocol as described in the create protocol.

### **Deleting a Stress Echo Protocol**

Click an user-defined protocol on the Select Protocol screen, click [Delete Protocol].

### 4.6.2 Maintenance

Item	Description	
Acquire Mode	Set the type of ROI: manual ROI or full-screen.	
Overlay	Select the items to be labeled on each loop.	
Acquire timer	Set whether to automatically start the timer when starting continuous image acquisition.	
WMS Score Type	Set the chamber segment division method.	
QT-Time Table	To customize the length of systolic duration acquired for a specific heart rate, it will store the clip duration. You can add and remove entries in this table. You can also load the factory defaults.	
Heart rate	Enter the heart rate.	
Syst. Duration:	Enter the systolic duration.	
Load Factory	To reset the QT time table.	
Update	Enter a heart rate and the referring systolic duration and then click [Update].	
Delete	Select the required heart rate and systolic duration pair from the QT – Time Table and then click [Delete].	

# 4.7 DICOM/HL7

## 4.7.1 DICOM Local Preset

### NOTE:

• AE Title should be the same with the SCU AE Title preset in the server (PACS/RIS/HIS), for example, if the AE Title of the server preset in the storage server is Storage, and the AE Title of

the accepted SCU is preset as Machine, then in the figure above, the AE Title of Local should be Machine, and the AE Title of storage server should be Storage.

- The device name is random. If the server name is same with that in the DICOM server list, the information "the server added already exits", click [OK] to retype the name.
- 4001, 6000, 3001, 6555 cannot be set as the port.
- IP address should be the address of the remote server.

DICOM local preset items are described as follows:

Item		Description
Local host DICOM Service Property (Including SCU and SCP)	AE Title	Application Entity title.
	Port	Communication port, DICOM communication port.
	PDU	Maximum PDU data package size (not need to change), ranging from 16384 to 65536; if the value is less than 16384 or greater than 65536, the system automatically sets it to the value 32768.
	Resume tasks upon restart	Resume unfinished sending tasks after system reboot.
	Max	The maximum number of tasks that can be resumed.
	TLS Port	Set the TLS port.
	TLS Server Setting	Import the encryption key/certificate.
	TLS Client Setting	<ul> <li>After importing TLS certificates, and selecting Verify Certificate check box, the system verifies the effectiveness of the TLS function in the DICOM storage, print, and worklist services.</li> <li>Import trusted certificates, or delete certificates.</li> </ul>
Server Setting	Device	Name of the device supporting DICOM services.
	IP Address	IP address of the server.
	Ping	You can ping the other machines after you entered the correct IP address. Besides, you can select a server in the Device list to ping it.
	Add	Click to add server (s) to the Device List.
	Device List	Displays the added device.
	Delete	Click to delete the selected server (s) in the device list.
	Set DICOM Service	Provides server settings of DICOM service. For details, please refer to the following chapters.
	Set DICOM Strategy	Provides strategy settings of DICOM service. For details, please refer to the following chapters.
	Log Level	Select the log display level: No Log, Service Result Log, Service Process Log, All Log.

### Adding a Server

Perform the following procedure:

1. Enter the server device name and IP address.

- 2. Click [Ping] to check the connection.
- 3. Click [Add] to add the server to the device list, and its name and address are displayed in the list.

### Setting DICOM Strategy

#### NOTE:

- The DICOM strategy must be configured by qualified personnel with good knowledge of DICOM standards.
- The qualified personnel must ensure the validity of the DICOM strategy.

Perform the following procedure:

- 1. Click [Set DICOM Strategy].
- 2. Edit the DICOM strategy:
  - Add: Enter strategy name and description, and click [Add] to add a new strategy. Then the added strategy will be added to the Strategy List.
  - Delete: Select a strategy from the Strategy List, and click [Delete].
  - Update: Select a strategy from the Strategy List, re-enter strategy name or description, and click [Update].
- 3. Configure the item:

Select a strategy name from the Strategy List, and assign strategy items to the selected strategy.

- Add: Set the function from the drop-list box, enter the parameter 1 and parameter 2, and click [Add]. Then the added strategy item will be added to the Strategy Items List.
- Delete: Select a strategy item from the Strategy Items List, and click [Delete].
- Update: Select a strategy from the Strategy Items List, reselect the function or re-enter the parameter 1/2, and click [Update].
- 4. Import/Export strategy:
  - Import: Click [Import], browse the desired strategy file and operate according to the screen prompts to import.
    - The imported file for DICOM strategy must be a \*.xml file.
  - Export: Select a strategy from the Strategy List, click [Export] and then select the export path and type the file name.

E drive is default, and the file type is .xml.

You can click [Import SR Configuration], [Export SR Configuration], [Reset SR Configuration] to import, export or reset structure report configuration.

## 4.7.2 DICOM Service Preset

The DICOM Service screen is used to set attributes for DICOM service.

When the system is configured with DICOM basic function module, and installed with DICOM modules, the corresponding preset can be found in DICOM Service screen.

### TIP:

Not all SCPs can support verification. See the SCP properties to confirm whether the SCP can support this service. If not, the verification will not be successful.

Perform the following procedure:

- 1. Click [Set DICOM Service] on the DICOM/HL7 screen.
- 2. Select the DICOM service tab to enter the corresponding settings screen.
- 3. Enter the correct AE Title, port, etc.
  - Click [Add] to add the service to the Service List.
  - Select an item in the service list, change the parameters in the above area, and click [Update] to update the item in the service list.
  - Click to delete the selected service in the service list.
  - Select an item in the service list, click [Default] and you can see "Y" in the Default column.
- 4. Click [Verify] to verify that the two DICOM application entities are properly connected.

If the verification is successful, the system displays "xxx Verify Succeed." Otherwise, it displays "xxx Verify Failed."

If verification failed, possible causes may be: wrong IP address, not able to access IP address, remote DICOM server is not running, wrong port, incorrect application name.

#### **Storage Service Preset**

DICOM storage preset items are described as follows:

Item	Description		
Device	After you set the server (s) in DICOM Preset screen, the name (s) will appear in the drop-down list, select the name of the storage server.		
Service Name	Default is xxx-Storage, user-changeable.		
AE Title	Application Entity title, here, it should be consistent with that of the storage server.		
Port	DICOM communication port, 104 is default. Here, the port should be consistent with that of the storage server port.		
Maximum Retries	Set the maximum retries (0-9). The default value is 3. If the DICOM task sending to the server fails, the retry times should be 3.		
Interval Time(Sec)	Interval time.		
Timeout(Sec)	Refers to the amount of time after which the system will stop trying to establish a connection to the service.		
TLS	Transport Layer Security. Select whether to encrypt the data during network transportation.		
Cine Zoom Mode	Select the cine zoom mode during image file storage.		
Compression Mode	Select the compression mode: original data (uncompressed), RLE (the image not compressed), JPEG, and JPEG2000.		
Compression Ratio	Select the JPEG compression ratio: lossless, low, medium, and high. The compression ratio is inversely proportional to the image quality (reserved function).		
Color Mode	Select the color mode. If you choose the mix or the grey, RLE/JPEG is unavailable. The image uses 24 bit when sending the image from the ultrasound device to the server; it depends on the image when choosing the mix. The image use 8 bit if the image is captured in color mode or the image has the tint. All images use 8 bit when choosing the grey.		

ltem	Description	
Allow Multiframe	If SCP supports this function, then select it.	
Max Framerate	Set the frame range of transferring cin file into DCM multi-frame file. It is editable to the user.	
Window Width	Set the window width of images.	
Window Center	Set the window center of images.	
3D/4D	<ul> <li>Set the 3D/4D image transfer mode.</li> <li>Set the transfer mode for the 3D/4D cine sending.</li> <li>Normal: use the way that 2D image adopts to send;</li> <li>Volume: use Enhanced US Volume Storage IOD to send;</li> <li>Data source: used to obtain 3D/4D image for 4D Viewer.</li> </ul>	
SR Storage Option	To enable or disable structured reporting sending.	
Send All SR	Select whether to send all the structured reports for different application parts of the same exam mode.	
Encapsulated PDF	Select if to encapsulate PDF format report in DICOM standard. It becomes available if SCP supports the function.	
Doppler Audio	Set to save the audio of PW mode.	
Measurement	<ul> <li>If "All" is selected, the structured report will contain all the latest measurement values displayed on the measurement report.</li> <li>If "Single" is selected, the structured report will contain only the final measurement value.</li> </ul>	
SR Compatibility	Select the structure report format: Mindray or ViewPoint	
Storage mode	<ul> <li>Set the storage mode for image and cine file:</li> <li>Parallel file: save the current file, and is ready for the storage of the next file.</li> <li>Parallel frame: send the current frame, and is ready for sending the next frame.</li> </ul>	
TransducerTracking	Files of images that are saved in DCM format through DICOM or DICOMDIR contain transducer serial number information.	
Strategy Name	Set the DICOM strategy.	

#### NOTE:

- If the server software supports the compression algorithm, select JPEG, RLE, JPEG2000. Otherwise, original data should be used (RLE is the default method).
- RLE, JPEG and JPEG2000 are not supported by all SCPs. Refer to the SCP's DICOM CONFORMANCE STATEMENT electronic file to check whether SCP supports it or not. Do not select these compression modes if the storage server does not support them.
- Images of PW/M/TVM/TVD mode (B image is not frozen) and images other than PW/M/ TVM/TVD mode: if "Max Frame rate" is not "Full" and the actual frame rate is larger than the set value, the system will save the image files in a frame rate of the set value, and transfer in a frame rate of B mode.
- Images of PW/M/TVM/TVD mode (B image is frozen), the system will save/transfer the images files in frame rate of 6.

### **Print Service Preset**

DICOM print preset items are described as follows:

ltem	Description	
Device	After you set the server (s) in DICOM Preset screen, the name (s) will appear in the drop-down list, select the name of the print server.	
Service Name	Default is xxx-Print, user-changeable.	
AE Title	Application Entity title, here, it should be consistent with that of the print server.	
Port	DICOM communication port, 104 is default. Here, the port should be consistent with that of the print server port.	
Maximum Retries	It starts retrying if it fails to send DICOM task to the server. The retry entry times should be this value.	
Interval Time(Sec)	Reserved time.	
Timeout(Sec)	Refers to the amount of time after which the system will stop trying to establish a connection to the service.	
TLS	Transport Layer Security. Select whether to encrypt the data during network transportation.	
Copies	Refer to copies of printed files. You can select among 1 through 5, or directly enter the numeral.	
Settings	The system supports RGB (color printing) and MONOCHROME2 (black and white printing). Please select the type the printer supports.	
Film Orientation	Select between LANDSCAPE and PORTRAIT.	
Priority	Specify printing task priority among HIGH, MED and LOW.	
Film Size	Select film size among the selections listed in the drop-down list.	
Display Format	Specify quantity of printed files, e.g. STANDARD\2, 3 indicates 6 images are printed for each page.	
Medium Type	Specify print medium: Paper, Clear Film, Blue Film; select Blue Film or Clear Film for black and white printing; select Paper for color printing.	
Trim	Specify whether you want a trim box to be printed around each image on the film: Yes or No.	
Configuration Info	Enter configuration information in the field.	
Min Density	Enter the minimum density of the film.	
Max Density	Enter the maximum density of the film.	
Destination	Specify where the file is exposed: MAGAZINE (stored in the magazine), or, PROCESSOR (exposed in the processor).	
Magnification Type	<ul> <li>Select how the printer magnifies an image to fit the film.</li> <li>Replicate: interpolated pixels belong to duplicate of adjacent pixels);</li> <li>Bilinear: interpolated pixels are generated from bilinear interpolations between adjacent pixels;</li> <li>Cubic: interpolated pixels are generated from cubic interpolations between adjacent pixels;</li> <li>None: without interpolation.</li> </ul>	
Strategy Name	Set the DICOM strategy.	

### **Worklist Setting**

DICOM service setting for Worklist is described as follows:

ltem	Description	
Device	After you set the server (s) in DICOM Server Setting screen, the name (s) will appear in the drop-down list, select the name of the Worklist server.	
Service Name	Default is server-Worklist, and it can be modified.	
AE Title	Application Entity title. It is consistent with that of the Worklist server.	
Port	DICOM communication port, 104 by default. The port should be consistent with that of the Worklist server port.	
Maximum Retries	Reserved feature.	
Interval Time(Sec)	Reserved feature.	
Timeout(Sec)	Refers to time after which the system will stop trying to establish a connection to the service.	
TLS	Transport Layer Security. Select whether to encrypt the data during network transportation.	
Strategy Name	Set the DICOM strategy.	
Remove Attribute	Set what DICOM element(s) that will not be used in worklist query.	

#### **MPPS Preset**

MPPS setting items are described as follows:

ltem	Description	
Device	After you set the server (s) in DICOM Server Setting, the name (s) will appear in the drop-down list, select the name of the MPPS server.	
Service Name	Default is server-MPPS, and it can be modified.	
AE Title	Application Entity title. It should be consistent with that of the MPPS server.	
Port	DICOM communication port, 104 by default. The port should be consistent with that of the MPPS server.	
Maximum Retries	It starts retrying if it fails to send DICOM task to the server. The retry entry times should be this value.	
Interval Time(Sec)	Reserved feature.	
Timeout(Sec)	Refers to the amount of time after which the system will stop trying to establish a connection to the service.	
TLS	Transport Layer Security. Select whether to encrypt the data during network transportation.	

### NOTE:

Set the MPPS service as the default when using the MPPS.

#### Storage Commitment Setting

DICOM storage commitment setting items are described as follows:

Name	NOTE	
Device	After you set the server (s) in DICOM Server Setting, the name (s) will appear in the drop-down list, select the name of the storage commitment server.	
Service Name	Default is server-SC, and it can be modified.	
AE Title	Application Entity title. Here, it should be consistent with that of the storage commitment server.	
Port	DICOM communication port, 104 by default. Here, the port should be consistent with that of the storage commitment server port.	
Maximum Retries	Reserved feature.	
Interval Time(Sec)	Reserved feature.	
Timeout(Sec)	Refers to the amount of time after which the system will stop trying to establish a connection to the service.	
Associated Storage Service	The associated storage server is preset before storage commitment, only after the exam is sent out, can storage commitment be created.	
TLS	Transport Layer Security. Select whether to encrypt the data during network transportation.	

#### NOTE:

- Set the related server before performing the storage commitment service.
- Save SCP port and the IP on SCP corresponds to the port and the IP on DICOM preset page.

#### **Query/Retrieve**

DICOM query/retrieve setting items are described as follows:

Item	Description	
Device	Select the name of a device that can be added (including the local).	
Service Name	Default is server-queryRetrieve, and it can be modified.	
AE Title	Application Entity title.Here, it should be consistent with that of the storage commitment server.	
Port	DICOM communication port, 104 by default.Here, the port should be consistent with that of the storage commitment server port.	
Maximum Retries	Reserved feature.	
Interval Time(Sec)	Reserved feature.	
Timeout(Sec)	Refers to the amount of time after which the system will stop trying to establish a connection to the service.	
TLS	Transport Layer Security. Select whether to encrypt the data during network transportation.	

#### **HL7 Query Service Preset**

The protocol version that the ultrasound system supports: V2.3, V2.4, V2.5, V2.6.

HL7 service setting for Worklist is described as follows:

Item	Description	
Device	After you set the server (s) in DICOM Server Setting screen, the name (s) will appear in the drop-down list, select the name of the Worklist server.	
Service Name	Default is server-HL7Query, and it can be modified.	
AE Title	Application Entity title.here, it should be consistent with that of the HL7 server.	
Port	DICOM communication port, 104 by default.Here, the port should be consistent with that of the HL7 server port.	
Maximum Retries	Reserved feature.	
Interval Time(Sec)	Reserved feature.	
Timeout(Sec)	Refers to the amount of time after which the system will stop trying to establish a connection to the service.	
Listen Mode	This function enables the ultrasound system to use the listen port for data receiving.	
Listen Port	Port for ultrasound system to receive data after the listen mode function is activated. Here, the port should be consistent with that of the HL7 server port. For details of listen port setting, refer to settings in the server.	

# 4.8 Network Preset

# 4.8.1 Network Settings

#### **Transmission Encryption**

After accessing the network, click [VPN Config] to enter the "VPN Config" interface.

ltem	Description
Status	<ul> <li>No driver: click [SetupDriver] to enter the "TAP-Windows 9.21.2 Setup" interface, and do as instructed.</li> <li>Ready: the VPN is ready for use.</li> <li>Advance: VPN Advance Configuration</li> <li>Connected: VPN is successfully connected.</li> <li>Disconnected: VPN is disconnected.</li> <li>Error: error connection.</li> </ul>
Server IP	/
Select Group	/
User Name	/
Password	/
Hide characters	The password is displayed as *.
Disconnect	Connect or disconnect VPN.
Connect	]

ltem	Description	
Advance	<ul> <li>Enters the "VPN Advance Config" interface.</li> <li>Reset: if the system does not respond after you click [Config], click [Reset].</li> <li>Config: enters the "OpenConnect-GUI VPN client" interface. For details about the settings, please refer to the TAP manual.</li> </ul>	
	<b>NOTE:</b> After exiting the "VPN Advance Config" interface, you need to reboot the system; otherwise, you cannot connect VPN normally.	
Close	Close the "VPN Advance Config" interface.	

#### **Turning on Wi-Fi function**

Perform the following procedure:

- 1. Select [Network Settings] page in Network Preset screen.
- 2. Click [Enable Wi-Fi] in the screen.

After Wi-Fi function is enabled, [Disable WIFI] appears on the screen.

#### Turning on hosted network function

Reserved.

### 4.8.2 iStorage Preset

You can send exam data or images to the iStorage server and perform analysis using UltraAssist. For details about this feature, see the UltraAssist manual.

ltem	Description	
Service Name	The name of the iStorage service.	
IP Address	IP address of the iStorage service device.	
Port	Port for transmitting.	
Connect	Click to verify connection.	
Add	Click to add the Network service to the service list.	
Update	To save the changed parameters.	
Delete	Click to delete the selected service from the service list.	

#### Adding an iStorage service

Perform the following procedure:

- 1. Set the iStorage server properties as described above.
- 2. Click [Add] to add the service to the Service list.

#### Editing a network service

Perform the following procedure:

- 1. Select the service to be updated in the service list.
- 2. You can see properties in the Configure Service area.
- 3. Modify the parameters and click [Update] to update the setting.

# 4.8.3 MedTouch/MedSight Preset

You can set environment for MedTouch/MedSight here and then use the MedTouch/MedSight function by mobile phone or tablet computers. See MedTouch/MedSight manual for details.

#### **Remote Maintenance**

#### NOTE:

- After the remote maintenance permission is enabled, it indicates that the ultrasound equipment permits remote access from the remote controller to upgrade the equipment, transmit files, or check and download logs.
- Once enabled, the remote maintenance permission is enabled by default after restarting the ultrasound equipment.
- For detailed operation information, see the Remote Maintenance manual.

Perform the following procedure:

- 1. Select [Remote Maintenance Permission].
- 2. Select [Upload logs to remote server] to upload logs to the remote server, Mindray service engineers can acquire and handle those log.

# 4.8.4 Q-Path Preset

This screen is used to set the Q-Path parameters.

Perform the following procedure:

- 1. Check "Enable Q-Path",
- 2. Enter the website, account and password of the target service.
- 3. Click [Save] to confirm.

## 4.8.5 Route Settings

Reserved.

# 4.9 Print Preset

This screen is used to set up the printer and image printing.

# 4.9.1 Print Setting

ltem	Description	
Add Service	Click to begin adding print services.	
Remove Service	Click to delete the selected print service.	
Rename Service	Click to rename the selected print service.	
Add Printer	Click to install printers.	
Default Print Service	Click to set the selected print service as the default one.	
Property	Preset print service properties.	

# 4.9.2 Image Settings

Click [Image Setting] to enter the page, you can set the brightness, contrast and saturation of image printing, or you can use the default values.

# 4.10 Maintenance

The [Maintenance] function is designed for you to import or export user data, restore factory setting and export log. You may also execute self-test and option installation/trial through the maintenance menu. Furthermore, you can set the factory preset, export the register data, and etc.

If you require other maintenance functions, please contact Mindray Customer Service Department or sales representative.

# 4.10.1 Option

The system enters the Option page after entering the Maintenance screen. In the Option list, the system lists all the system-supported options and their installation status (not install or installed).

Please contact the Mindray Customer Service Department or a sales representative for details.

# 4.10.2 Exporting Setup Data

This function is used to write all setup data of the system into a disk for backup. The format of the data file is .PDP.

You can select 2 types of preset data to export from the system:

- General module preset data: including "All Preset", "Image Preset", "iWorks Preset" and "DICOM/HL7" data.
- Exam mode related preset data, including all image setting, comment and body mark setting and measurement setting data.

Perform the following procedure:

- 1. Select the target module.
- 2. Click [Export].
- 3. Select the path to save the data.
- 4. Select the exported file and type as PDP and click [OK].

### 4.10.3 Importing Setup Data

This function is used to import the existing setup data to the setup data memory of the system. The system will reset and operate according to the setup preferences that were imported.

Perform the following procedure:

- 1. Click [Import].
- 2. Select the imported file.
- 3. Click [OK], a progress bar will appear and the setup data is imported to the specified path.

### 4.10.4 Load Factory

To restore the factory setup data, click [Load Factory] on the right side of the screen.

## 4.10.5 Probe Check

This function enables users to check if a transducer element is in malfunction, so as to evaluate the transducer performance.

Before performing the probe check, ensure the probe head must be clean and the probe is in nonscanning state.

Click [Probe Check] to open the Probe Check screen. The system automatically performs probe check to the element of the currently activated probe.

- If a transducer element is in malfunction, it is displayed as a red spot.
- If a transducer element functions well, it is displayed as a green spot.

You can export the result image to the external device.

## 4.10.6 Other Settings

Other preset settings are described as follows:

	ltem	Description
Setup	Export Log	Export the log.
	Self Test	Perform system self-test and restart the machine.
	Recover	To recover the system.
	Prepay Installment	Display the prepay installment information.
	Enter Windows	For this function, you need a one-time password, please contact the service engineer or your agent.
	Stop WinProxy	Cursor debug interface.
	Start WinProxy	-
	Fast Startup	To speed up the startup process.
		NOTE:
		After installing McAfee, please disable the Fast Startup function to avoid McAfee failure.
	Sound	To enter the sound configuration tab of the operating System.

If you have any questions, please contact the service engineer or your sales representative.

# 4.11 Security

## 4.11.1 Drive Encryption/Secure Data Wipe

Encrypt the patient data stored in the hard disk. The system provides two encryption methods: Factory Default and User Define.

- Factory Default: the system is in factory state by default.
- User Define: add a user-defined password.

Perform the following procedure:

- 1. Select [User-defined].
- 2. If no patient data are stored in the hard disk, click [Confirm], input the password and click [Confirm] to finish the password setting

If the patient data are already stored in the hard disk, the system will pop-up prompts, follow the steps below:

- a. Click [OK].
- b. Click [Wipe] or [Secure Wipe] and operate according to the screen prompts to clear patient data.

If [Secure Wipe] is selected, the deleted patient data cannot be restored with restoration tools. Perform this operation with caution.

- c. Select [User-defined] again, and click [Confirm].
- d. Input the password and click [Confirm] to finish the password setting.

#### NOTE:

- If you want to switch to Factory Default, perform steps above again. The password is the same as that of the User Define.
- When you set password, multi-language and Chinese characters are not supported.

### 4.11.2 Anti-Virus

The system provides two pieces of anti-virus software: Windows Defender and McAfee. They can effectively prevent the ultrasound system from being attacked by virus, spyware, or other malware.

- Windows Defender is already installed on the system.
- The McAfee software is an option. If the McAfee software is installed, the system displays "McAfee is running". If you want to buy McAfee, contact Mindray representatives.

#### NOTE:

- McAfee cannot be uninstalled after successful installation.
- After the option is installed, the system will be restarted. And after restart, the system installs McAfee automatically, which needs about one hour.
- If McAfee is improperly installed due to power-off, shut-down, closing of cmd.exe, or any other abnormal operation during the installation, please contact the Mindray service engineers.

# 4.12 System Information

Click [About] on the Setup menu to enter the system information screen.

About

The "About" shows the information about the product type, manufacturer, configuration type, ECN/TCN, version number, MAC address, etc.

You cannot edit the information, but only view them. The information varies depending on the system configurations and version.

Statistics

Log onto the system as Administrator, and click [Statistics] to enter the statistics screen, which shows the total exam numbers of each probe, application and operator.

Open Source

The "Open Source License" and "Open Source Info." pages display the license and declaration of open sources.

You can start a patient exam in the following situations:

- New patient information: to start a new patient exam, patient information must first be entered.
- New exam: to start a new exam for patient who is already registered, the recorded information can be obtained through either iStation or Worklist.
- Activate exam: to select an exam that has been completed within 24 hours, continue the exam with imported patient information and exam data.
- Continue an exam: to select an exam that has been paused within 24 hours, continue the exam with imported patient information and exam data.

# 5.1 Patient Information

## 5.1.1 New Patient Information

# 

Before examining a new patient, tap the [End] on the touch screen to end the exam of the previous patient, update the patient ID and information, to avoid mixing data of the next new patient.

To start a new patient exam, it is better to type the detailed patient information. The system will set up a unique information database for each patient based on the patient information entered, so that the information of one patient will not be confused with that of another patient.

#### NOTE:

The system supports image scanning and measurement without patient information.

1. Tap [Info] on the touch screen to enter the patient information page.

Place the cursor onto the targeted box. The field box is highlighted and a flashing cursor appears. Information can be entered or selected from the options.

#### NOTE:

- Patient ID is generated automatically by the system after starting a new patient, and can be modified manually. The characters "\", "\*", "?" are not permitted.
- You can either enter the patient's date of birth manually, or click  $\overset{\text{manually}}{=}$  to select the date, and click [Confirm] to finish.
- The age unit can be "Years", "Months" or "Days." If the age is less than one year, the system will automatically calculate the age in months or days.
- When you enter the date manually, please enter it in the format as that of the system.

2. Select the exam type tab to enter general information/operating information, and exam-specific information.

	ltem	Description	
General	Study description	To enter description for each exam.	
information	Primary indications	To enter the primary indications (reason to perform the exam.)	
	Secondary indications	To enter the secondary indications.	
	CPT4 code	To enter the CPT4 code.	
	CPT4 description	To enter the CPT4 description.	
Operating	Accession #	Refers to exam number used in DICOM.	
information	Diagnostician	People who is responsible for the exam.	
	Operator	People who is responsible for images collection and scanning.	
	Ref. Physician	People who requires the operator to do the ultrasound operation.	
Exam specified information	BSA body surface area	After the height and weight are inputted, the system will automatically calculate the BSA and BMI (Body Mass Index) based on the formula.	
	ALT	Alanine transaminase.	
	1	<ul> <li>To enter fatty liver related parameters:</li> <li>Waistline</li> <li>BP: Blood pressure</li> <li>TG: Triglycerides</li> <li>HDL: High density lipoproteins</li> <li>Fasting Blood Glucose</li> <li>Glucose(2h after meal): 2-hour after meal Blood glucose level</li> <li>HbA1c: Hemoglobin A1c</li> </ul>	
	Tumor marker	To enter tumor markers: AFP: Alpha-fetoprotein CEA: Carcinoembryonic antigen CA: Carbohydrate antigen Fer: Ferritin	

Item	Description
Calculation index	<ul> <li>Calculate gestation age (GA) and estimated delivery date (EDD) based on last menstrual period (LMP), in vitro fertilization (IVF), basic body temperature (BBT), previous exam date (PRV). Select LMP, IVF, PRV, BBT, or EDD from the drop-down list; or, calculates GA and LMP according to the EDD and entered date.</li> <li>LMP: After you enter LMP, the system will calculate and display GA and EDD.</li> <li>DOC: After you enter DOC, the system will calculate the GA and EDD.</li> <li>BBT: input BBT, the system will calculate the GA and EDD.</li> <li>EDD: after you enter EDD, the system will calculate and display GA and LMP.</li> <li>IVF: After you enter IVF, the system will calculate and display GA and LMP.</li> <li>PRV: input the date and GA of the last exam, the system will calculate a new GA and EDD.</li> </ul>
Gravida	Times of pregnancy.
Gestations	Number of embryos (1, 2, 3, 4).
Para	Times of delivery.
Abort	Times of abortion.
Ectopic	Times of ectopic pregnancies. e.g. extrauterine pregnancy
V Delivery	Times of vaginal delivery
AV Delivery	Times of instrumental vaginal delivery
C Section	Times of cesarean delivery
IVF information	Essential female hormone and ovulation.
HR	Heart Rate
RA Press	Right Atrium Pressure
BP	Blood pressure
BP(L) (blood pressure)	left blood pressure.
BP(R) (blood pressure)	Right blood pressure.
Serum PSA	Serum prostate-specific antigen
PPSA coefficient	Predicted prostate specific antigen coefficient

### NOTE:

If the name of the operating information has been entered before, then it can be memorized by the system, you can select it in the drop-down list.

- 1. Functional keys.
  - [Pause Exam]: to pause the current exam due to some special causes or system power off.

- [Cancel Exam]: to cancel the current exam.
  - The canceled exam can't be restored.
- [New Patient]: click to clear the current patient information in the patient information screen in order to input new patient information.
- [New Exam]: click to clear the current exam information in order to create a new exam for the current patient.
- [OK]: click to save the patient data entered and exit the screen.
- [Cancel]: click to cancel the patient data entered and exit the screen.
- [Quick Register]: click to save the patient information quickly and return to the main screen.
- 2. To exit the Patient Info screen
  - Exit and save the settings: click [OK] on patient information page, tap [OK], or tap [Info] on the touch screen.
  - Exit without saving the information: click [Cancel] on patient information page or tap [Cancel] on the touch screen.
  - Press <B> or <Freeze> to return to the current exam mode.

### 5.1.2 Retrieve Patient Information

#### iStation

The patient data can be obtained in iStation from the system hardware or USB memory device. You can enter the searching conditions for the patient.

- 1. Do one of the following to enter iStation screen:
  - Press <F2 iStation> on the control panel;
  - Click [iStation] in the "Patient Info" screen;
  - Click [iStation] in the Review screen.
- 2. Select the data source.

Select the data source in the drop-down list of "Data Source".

- 3. Search for patient information.
  - a. Select [Item] to set up search options.

The search options include Name, ID, DOB, Exam Date, Exam Type, Study Description, Gender, Operator, Diagnosis (comments in the report) and Annotation, the default one is name.

b. Enter the keyword corresponding to the search type in the search box. The system will display all exam records immediately.

Select "Find in results", the system will search the keyword based on the existed searched results.

4. Select the desired patient information in the list, and the system pops up the shortcut menu.

Review Image	Click to enter the Review screen.
Patient Info	Click to enter the Patient Info screen.
Review Report	Enter diagnostic report screen.
Delete Exam	Delete the selected record.
Backup Exam	Click to back up the selected patient record to media supported.

Restore Exam	Click to import the patient data from an external media.
Send Exam	Click to send the selected patient data to external device, storage server or printer.
Activate Exam	Click to continue an exam that has been finished within 24 hours.
Resume Exam	Click to continue an exam that has been paused within 24 hours.
Annotation Exam	Click to add annotations to the selected exam, or view the history annotations of the selected exam.
Statistic Export	Click to export the fatty liver quantitative data, such as patient information, serum parameters, and measurement results etc.

5. Click [New Exam] to enter the Patient Info screen.

The corresponding patient information is also imported to the new exam simultaneously. After editing the patient information in the Patient Info screen, select [OK] to start a new exam.

#### WorkList

#### NOTE:

Configure DICOM Basic and DICOM WorkList first.

Click [Worklist] in the "Patient Info" screen to query or import the patient data.

# 5.2 Select Exam Mode and Probe

### 

If the exam mode is changed during a measurement, all measurement calipers on the image will be cleared. The data of general measurements will be lost, but the data of application measurements will be stored in the reports.

- 1. Connect proper probes to the system, and tap [Probe] on the touch screen.
- 2. Tap to select the probe type and exam mode, and the system exits the dialogue box to enter the selected exam mode and probe.

#### Quickly switch to recently used probes and exam modes

The recently used probes and exam modes are displayed on the left side of the touch screen. Select an appropriate probe and exam mode for quick switch.

#### IP (Image Process) switch

For the application that supports IP switch, a set of exam modes that corresponds to different IPs are displayed on the touch screen. You can select to switch to the corresponding IP.

#### NOTE:

• The exam modes that correspond to switchable IPs should belong to the same application. For example, ABD generic, ABD Difficult, and ABD vascular all belong to the abdomen application.

- IP switch will not cause the system to return to real-time B mode. After the IP is switched, only the image parameter is switched at the same time. Measurements, comments, and bodymarks remain the same as those before switching.
- IP switch can not be performed in the frozen mode.
- For details about IP preset manager, see "6.1.2 Quickly Saving Image Settings".

## 5.2.1 Dual-probe Switch

A user-defined key for dual-probe switch can be defined in preset, by which you can fast switch the probe under B/Color/Power mode.

#### NOTE:

This function applies only to probes with the same exam modes.

- 1. Scan to obtain the image by current probe.
- 2. Tap [Probe] on the touch screen. The probe types appear.
- 3. Choose the probes to be compared. The system enters dual-probe mode. The image from previous probe is frozen.
- 4. Scan and obtain the required image from the current probe.
- 5. Press the user-defined key to switch the images of two probes.

### 5.2.2 Bi-plane Probe Switch

For the probe ELC13-4U, after selecting the exam mode, enter B mode, and tap [C] or [L] on the touch screen to select the convex plane or linear plane.

## 5.2.3 Selecting Imaging Mode

Select the imaging mode via the functional buttons on the control panel.

# 5.3 Activate& Continue an Exam

### 5.3.1 Activate an Exam

In iStation screen, select the exam record finished within 24 hours, and click [Activate Exam] from the menu popped up; or, click [Activate Exam] in iStation or Review screen to activate the exam.

#### NOTE:

- The system can automatically load the patient information and exam data to continue the exam.
- If you want to continue an exam which data lies in an external memory database, you have to first allow the system to load the patient data to the system's patient database.
- For an only one re-activated exam, you can modify patient ID.

### 5.3.2 Continue an Exam

In iStation screen, select an exam record paused within 24 hours, click [Resume Exam] from the menu popped up to continue the exam.

If you want to select a patient data in an external memory database, you have to first allow the system to load the patient data to the system's patient database.

The patient ID can be modified for the exam only with one exam record and being activated again.

# 5.4 Pause & End an Exam

### 5.4.1 Pause an Exam

Sometimes, you have to stop an uncompleted exam due to some special causes. When the exam is paused, the system can begin other exams.

- 1. Tap [Info] on the touch screen to enter the patient information page.
- 2. Click [Pause Exam].

If the system is powered off during scanning, the exam status turns "paused" after the system restart.

When an exam is paused, the system will:

- Save the exam-related images, reports and measurement data, modify the status as "Paused".
- Save the exam information, including report, imaging mode, exam mode, image parameters, operation mode, and imaging/measurement data and so on.

## 5.4.2 End an Exam

Before examining a new patient, tap [End] to end the exam of the previous patient, update the patient ID and information, to avoid mixing data of the next new patient.

To end an exam, do one of the following:

- Tap [End] on the touch screen to finish the current exam.
- Click [New Patient] on the Patient Info screen to end the last patient exam and clear the patient information.
- Click [New Exam] on the Patient Info screen (or iStation screen, or Review screen) to end the last exam and clear the exam data.

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# **MWARNING**

- The images displayed in this system are only reference for diagnosis. Mindray is not responsible for the correctness of diagnostic results.
- In Dual-B imaging mode, the measurement results of the merged image may be inaccurate. Therefore, the results are provided for reference only, not for confirming a diagnosis.

# 6.1 Imaging Mode

### Switching Between Image Modes

Refer to "2.11 Control Panel" for image mode switch.

# 6.1.1 Image Adjustment

#### Touch screen displays (Non-mapping mode)



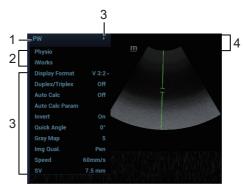
No.	ltem	Description
1.	Mode displaying area (or main functional tabs)	Displays the current modes, click the tab to enter the mode.

No.	ltem	Description
2.	Other application mode entrance	Displays the available application modes related, click to enter the modes.
3.	Parameter adjusting area	<ul> <li>Displays the parameters in the current imaging mode or function.</li> <li>Parameter magnitude setting: Click ▶ or ◀ to increase/ decrease the value.</li> <li>ON/OFF setting: some of the parameters only can be set at ON or OFF, ON is to activate the function, and when the function is activated, the key is highlighted.</li> <li>Page selection: if the parameters cover more than one pages, slide left and right to turn pages.</li> <li>Parameter submenu: for the parameter with ▼ icon, tap to display the submenu to select the desired value.</li> <li>Functional item: tap to go to the corresponding function.</li> </ul>
4.	Knob-adjusting area	Displays the knob-controlled parameters.

#### Touch screen displays (image mapping mode)

There are six knobs at the bottom of the touch screen; their functions vary with the current menu. Press or rotate the knobs to adjust the corresponding parameters.

Enter the mapping mode to open the mapping menu. Tap the menus to operate.



No.	Item	Description
1.	Menu title	Displays the current image mode. Click the expand button to show the image modes. Select the image mode if necessary.
2.	Other application mode entrance	Displays the available application modes related, click to enter the corresponding mode.
3.	Parameter adjusting area	Displays the parameters in the current imaging mode or function. Parameter magnitude setting: Click or to increase/ decrease the value. ON/OFF setting: some of the parameters only can be set at ON or OFF, ON is to activate the function, and when the function is activated, the key is highlighted. Page selection: if the parameters cover more than one pages, slide left and right to turn pages. Parameter submenu: for the parameter with icon, tap to display the submenu to select the desired value. Functional item: tap to go to the corresponding function.

No.	ltem	Description
4.	Expand button	/
5.	Sub-menu	/

## 6.1.2 Quickly Saving Image Settings

Tap [QSave] on the probe and exam mode selection page, press <F7> or the user-defined key to QSave to enter the page.

#### To save image parameters

Click [Save] to save the current image values for the current exam mode of the certain probe.

#### **New Exam**

Click [Create] to save the current image parameters, measurements, comments, body mark settings to the exam mode. The system will ask for a new name of the exam.

#### Restore the factory default settings:

Click [Restore] to restore the probe and exam mode to factory settings.

#### View image parameter

Click [Show Parameter] to view the image parameter of the current exam mode and the probe.

- Click [Advanced]. The value to TIC/TIB/TIS can be set.
- Click [Advanced], and then enable [Sampling Line Displaying]. The sampling line always appears after being set when entering PW/M/TVM mode for once. Press <PW>/<M>to enter the corresponding mode one time.
- Click [Advanced], and then enable "High Frame Rate STE" (it is an option) to improve the image effect.

#### **IP Preset Manager**

Click [IP Preset Manager] to save, create, restore, or delete the IP.

#### TIP:

It is unavailable for frozen dual-probe mode.

# 6.2 B Mode

B mode is the basic imaging mode that displays real-time views of anatomical tissues and organs.

### 6.2.1 B-mode Image Scanning

- 1. Enter the patient information, and select the appropriate probe and exam mode.
- 2. Press <B> on the control panel to enter B mode.
- 3. Adjust parameters to optimize the image.
- 4. Perform other operations (e.g. measurement and calculation) if necessary.

### 6.2.2 B-mode Image Parameters

In B Mode scan, the image parameter area on the right part of the screen will display the real-time parameters:

Items	Remark
F	Frequency
D	Depth
G	Gain
FR	Frame Rate
DR	B Dynamic Range
TSI	Tissue characteristics
iClear	Display when the function is activated.
iBeam	
iTouch	
Zoom	
Echo Boost	

#### **Image Quality**

Used for switching B/THI and adjusting the frequency. The real-time value of frequency is displayed in the image parameter area, and if harmonic frequency is used, "F H" is displayed as harmonic frequency value.

The system provides a THI function using harmonics of echoes to optimize the image. Harmonic imaging enhances near field resolution and reduces low-frequency and large amplitude noise, so as to improve Small Parts imaging.

Please select the frequency according to the detection depth and current tissue features.

#### Gain

To adjust the gain of the whole receiving information in B mode. The real-time gain value is displayed in the image parameter area.

#### Depth

This function is used to adjust the display depth of sampling, the real-time value of which is displayed in the image parameter area.

Depth increase will cause a decrease in the frame rate.

#### TGC

The system compensates the signals from deeper tissue by segments to optimize the image.

There are 8-segment TGC sliders on the touch screen corresponding to the areas in the image.

Adjust the signal gain for the certain image area to get a balanced image.

#### Acoustic Power (A.Power)

Refers to the power of ultrasonic wave transmitted by the probe, the real-time value of which is displayed in the upper left corner of the screen.

#### NOTE:

You should perform exams according to actual situation and follow the ALARA Principle.

#### Scan range and FOV position

More information can be obtained without moving the probe or changing the sampling position.

#### NOTE:

- The FOV position/range is available only for the convex and phased probes.
- When the scan range is adjusted to the widest, the FOV position cannot be changed.

#### **B** Steer

To steer the beam the probe transmits.

#### TIP:

Steer is available only for linear probes.

#### **ExFov**

For linear probes, the ExFOV function displays as trapezoid imaging.

For convex and phase probes, the ExFOV function displays as extending the scan angle.

#### Line Density

The function determines the quality and information of the image.

#### Dynamic Range (Dyn Ra.)

Adjusts contrast resolution of an image, compresses or expands gray display range.

#### Smooth

This feature is used to reject the noise and smooth the image.

#### iClear

The function is used to enhance the image profile so as to distinguish the image boundary for optimization.

#### iClear<sup>+</sup>

This function is the advanced version of iClear. It can better enhance image quality, reject noise, and provide better contrast resolution.

If iClear<sup>+</sup> is configured, iClear will be replaced by iClear<sup>+</sup>.

#### Persistence

Used to superimpose and average adjacent B images, so as to optimize the image and remove noises.

#### Rotation/Flip

This function provides a better observation for image display.

The "M" mark indicates the orientation of the image; the M mark is located on the top of the imaging area by default.

#### iBeam

This function is used to superimpose and average images of different steer angles to obtain image optimization.

#### TIP:

The phased probe does not support iBeam.

#### **Auto Merge**

In the Dual-split mode, when the images of the two windows have the same probe type, depth, invert status, rotation status and magnification factor, the system will merge the two images so as to extend the field of vision.

#### TIP:

Only for linear probes.

#### **Gray Map**

Adjusting grayscale contras to optimize the image.

#### **Tint Map**

This function provides an imaging process based on color difference rather than gray distinction.

#### TSI

The TSI function is used to optimize the image by selecting acoustic speed according to tissue characteristics.

#### HDScope

The image inside the ROI is clearer than these outside when the function is enabled.

#### TIP:

The function is disabled in frozen state.

#### iTouch

To optimize image parameters as per the current tissue characteristics for a better image effect. It is available for all real-time imaging in B mode.

#### **H** Scale

Display or hide the width scale (horizontal scale).

The scale of the horizontal scale is the same as that of vertical scale (depth), they change together in zoom mode, or when the number of the image window changes. The H Scale will be inverted when image is turned upwards/downwards.

#### **Dual Live**

Display different image effects of one probe for a better observation.

Two pages of adjustable parameters are displayed on the touch screen as well; where, shared parameters and left window parameters are displayed in the B (L) page, while right window parameters are displayed in the B(R) page.

In the image parameter area, parameters of the both windows are displayed.

It supports the magnification of the image.

#### LGC

Adjust the gain along the scan line to improve the lateral resolution of the image.

#### TIP:

The system provides several preset parameters for imaging.

#### **Echo Boost**

The contrast is increased and the noise is decreased with the clear boundary after generating the function.

#### TIP:

Use phased probe to activate the function in cardiac mode.

#### **Ref Lines**

A reference line and a help line meeting the probe icon side 45° display on the 2D image under GYN and Pelvic Floor exam mode. This helps to locate midsagittal plane of pelvic floor precisely and define the reference line for measurement.

#### TIP:

- Ref Lines can be adjusted by pressing <Set> in frozen state.
- Use intra-cavity probe to activate the function in GYN or Pelvic Floor exam mode.

#### Dehaze

This function can restrain noise, so as to enhance the contrast resolution of the image.

#### V 1:1

This function is to display images in vertical format in the dual-split mode. After the feature is enabled, one image appears above, and the other image appears below.

#### TIP:

Only linear probes support this function.

#### Extend Image (ExtImage)

This function is to extend image area and hide menu area and thumbnails.

#### Edge Enhance

This function is used to increase image profile, so as to distinguish the image boundary.

# 6.3 Color Mode

The Color mode is used to detect color flow, and the color is designed to judge the direction and speed of blood flow.

Generally, the color above the color bar indicates the flow towards the probe, while the color below the color bar indicates the flow away from the probe; the brighter the color is, the faster the flow speed becomes; while the darker the color is, the slower the flow speed becomes.

#### NOTE:

- During color mode imaging, menus of image optimizing for B-Mode and C-Mode are displayed on the touch screen at the same time. You can switch between the 2 modes by clicking the mode tabs.
- In Color Mode, acoustic power is synchronous with that of B Mode. Adjustment of the depth or zoom to the B Mode image will lead to corresponding changes in Color Mode image.

# 6.3.1 Color Mode Image Scanning

Perform the following procedure:

- 1. Select a premium image during B mode scan, and adjust to place the area of interest in the center of the image.
- 2. Press <C> to enter B+Color mode.
- 3. Use the trackball and <Set> to change position and size of the Region of Interest (ROI).
- 4. Adjust the image parameters during scan to obtain optimized images.

### 6.3.2 Color Mode Image Parameters

In Color mode scan, the image parameter area on the right side of the screen displays the real-time parameter values as follows:

Items	Meaning
F	Frequency
G	Color Gain
WF	Color wall filter
PRF	Pulse Repetition Frequency PRF

#### **ROI Adjustment**

To adjust the width and position of ROI in Color mode.

- When the ROI box is solid line, roll the trackball to change its position.
- When the ROI box is dotted line, roll the trackball to change the size.
- Press <Set> to switch between the solid line and the dotted line status.

The larger the ROI box is, the lower the frame rate becomes, and the lower the resolution and color sensitivity will be.

#### **Color Gain**

Refers to the overall sensitivity to flow signals. The real-time gain value is displayed in the image parameter area.

Increasing the gain will increase the flow signal presented as well as noise, while the signals may be missing when the gain is adjusted too low.

#### **Image Quality**

Refers to the transmitting frequency in Doppler mode of the probe, the real-time value of which is displayed in the image parameter area.

#### **B/C Align**

To set and constrain the maximum width of the B mode image to that of the Color ROI.

#### **Dual Live**

This function is used to display B image and Color image synchronously.

#### Steer

The feature is used to adjust the ROI of color flow with different angles with immobility of the probe.

This function is used to adjust the scan angle of linear probes, so as to change the angle between the transmitting beam and flow direction.

#### TIP:

Steer is available only for linear probes.

#### Line Density

The function determines the quality and information of the image.

The higher the line density is, the higher the resolution becomes.

#### Packet Size

This function is an indication of the ability to detect flow, which is used to adjust the accuracy of color flow.

The higher the sensitivity is, the more sensitive indication for low-velocity flow becomes. It affects the frame.

#### **Flow State**

Refers to optimizing the various flow states.

#### Persistence

This function is to adjust the temporal smooth to optimize the image.

#### Smooth

This feature is used to reject the noise and smooth the image.

#### Scale

This function is used to adjust the speed range of color flow, which is adjusted through PRF in the system. The real-time PRF value is displayed in the image parameter area.

Aliasing may occur if low velocity scale is used and high velocities are encountered.

Low velocities may not be identified when a high velocity scale is used.

#### **Baseline**

Refers to the area where the velocity is zero in the scale. Adjust according to the actual situation so as to get an optimum flow display.

#### Invert

To set the display mode of the color flow, the color scale will be inverted when the function is activated.

#### TIP:

It is available only for linear probes.

#### **Color Map**

This function is a combination of several image parameters, which indicates the display effect of color image.

#### Wall Filter (WF)

It filters out low-velocity signals to provide effective information, and this function is used to adjust the filtered frequency. The real-time value (WF) is displayed in the image parameter area.

#### Smart Track

To optimize image parameters as per the current tissue characteristics for a better image effect. The angle and the position of the ROI are adjusted after the function is enabled. The area is tracked without being affected by the dynamic moves.

#### **Priority**

This function is used to set levels of the flow display, to display the grayscale signal or color signal. The color image is preferred with higher value; while grayscale signals are displayed with the lower value.

#### **Velocity Tag**

This function is used to mark the specified velocity range in flow to check the flow function or specific flow velocity value.

Enable this function, the green mark appears on the color scale. Use trackball and <Set> to set the marking range and marking position.

#### iTouch

To optimize image parameters as per the current tissue characteristics for a better image effect.

#### **HR Flow**

Enhance tiny vessel display to analyze the blood supply of the vessel in pathological organ.

#### **ART Flow**

Enhance the blood sensitivity and penetrability in time period.

ART Flow Duration appears at the right bottom of the screen after the function is enabled. The penetrability of color image is enhanced during this time period.

After ART Flow Duration is finished, the ART Flow interval appears at the right bottom of the screen. The ART Flow is enabled again until the interval is finished.

#### **Glazing Flow**

This function applies glazing effect to the vessel flow, so as to make it more stereoscopic.

The color codes of the vessel velocity and power will change after the Glazing Flow function is enabled. During diagnosis, users should exam the ROI without using the Glazing Flow function. Otherwise, misdiagnosis may occur.

#### UMA (Ultra-Micro Angiography)

This function filters out low-velocity tissue signals so as to optimize the display of blood flow of low velocity in capillary vessels.

After entering UMA, select the sub-mode:

• cUMA (Color UMA): it is the velocity sub-mode of Color mode, used to observe color flow and provide flow direction and velocity information.

- pUMA (Power UMA): it is the power sub-mode of Color mode, used to display the density and power of the red blood cells in the blood flow for a certain period of time, and express it with different brightness colors, providing perfusion information of the blood flow, but not velocity information.
- sUMA (Subtraction UMA): the function of sUMA is the similar to pUMA. Compared with pUMA, sUMA displays more flow information and focus more on the tiny flow.

#### TIP:

UMA provides a set of parameters for quick adjustment predefined for different organs in different scenes, such as Placenta and Fetal Head.

#### Background

This function is used to adjust the rejection degree of the internal B image background of the color ROI. The display of tiny blood flow is enhanced, by not displaying or reducing displaying the B image, and only displaying the color flow energy signal.

#### TIP:

This parameter is only applicable to sUMA.

#### C ExFov

The C ExFOV function displays as trapezoid imaging in color mode.

Only for linear probes. It can only be displayed after the "ExFov" parameter in B mode is enabled and cannot be adjusted together with "Steer".

# 6.4 Power Mode

Power mode provides a non-directionally display of blood flow in the form of intensity as opposed to flow velocity.

DirPower (Directional Power Mode) provides the additional information of flow direction towards or away from the probe.

#### NOTE:

- During Power mode imaging, menus of image optimizing for B mode and Power mode are displayed on the touch screen at the same time. You can switch between the 2 modes by tapping the mode tabs.
- In Power mode, the acoustic power is synchronous with that of B mode. Adjustment of the depth to the B mode image will lead to corresponding changes in Power mode image.

### 6.4.1 Power Mode Image Scanning

Perform the following procedure:

- 1. Select a premium image during B mode or B+ Color scan, and adjust to place the area of interest in the center of the image.
- 2. Press <PD> to enter B+Power mode.
- 3. Use the trackball and <Set> to change position and size of the Region of Interest (ROI).
- 4. Adjust the image parameters during scan to obtain optimized images.

# 6.4.2 Power Mode Image Parameters

In Power mode scan, the image parameter area on the right side of the screen displays the real-time parameter values as follows:

Items	Meaning
F	Frequency
G	Color Gain
WF	Color Wall Filter
PRF	Pulse Repetition Frequency PRF

Because both are based on Doppler color imaging, the adjustments of Power mode are same with these of Color mode's. Hence, only the adjustments of Power mode are introduced.

#### **Power Gain**

Refers to the overall sensitivity to flow signals, and this function is used to adjust the gain in Power mode. The real-time gain value is displayed in the image parameter area.

#### **Color Map**

This feature indicates the display effect of power image. The maps in Power mode image are grouped into two categories: Power maps and Directional Power maps.

- The Power maps provide information of blood flow, which are highly sensitive to the low-velocity flows.
- The Directional Power maps provide information of flow direction.

#### Dynamic Range (Dyn Ra.)

This function is to adjust the transformation of echo intensity into color signal.

Increasing dynamic range will lead to higher sensitivity to low-power signals, thus enhances the range of signals to display.

# 6.5 V Flow (Vector Flow)

V Flow shows the blood direction and velocity via the arrow. The arrow length represents the velocity, and the arrow orientation represents the direction of the blood flow. The blood flow is displayed according to the updates of the arrow position and the velocity.

V Flow shows the blood situation on vortex flow, turbulent flow, regurgitation, etc.

#### NOTE:

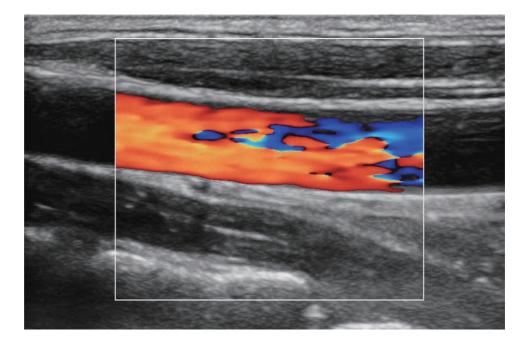
- You can enter V Flow on B/Color real-time scan mode.
- It only supports single-window display, but does not support dual-window display and quadwindow display.
- V Flow image does not support the image magnification.
- The parameters on B mode and Color mode are same with these on V Flow mode during V Flow scan.
- During V Flow scan, menus of image optimizing for B mode, Color mode and V Flow are displayed on the touch screen at the same time. You can switch among them by tapping the mode tabs.

• In Color Mode, acoustic power is synchronous with that of B Mode. Adjustment of the depth to the B mode image will lead to corresponding changes in V Flow mode image.

## 6.5.1 Basic Operations

Perform the following procedure:

- 1. Scan the carotid artery on the real-time B/Color mode; adjust the probe and the image to locate the desired region at the center of the B/Color mode image.
- 2. Tap [V Flow] or user-defined key to enter V Flow mode. Roll the trackball to locate the ROI, and press <Set> and roll the trackball to adjust the ROI position and the size.



- 3. To optimize the image, adjust the parameters during the image scan.
- 4. Tap [Start Capture] or press <Update>, and keep the probe still. The image shows the change of the blood flow over a period of time.



- 5. The image is frozen after completing the capture. Review the single-frame or cine file.
- 6. Measure speed, volume flow and WSS. Click [Data Export] to import result window and velocity curve data.
- 7. Press <B> on the control panel or the user-defined key to quit V Flow mode.

### 6.5.2 Image Optimization

#### Quality

The filling, smoothness and the image effect have slight change after completing the v flow adjustment.

#### **V** Flow Map

This function is a combination of several image parameters, which indicates the display effect of color image. The blood flow information is displayed via switching among the different spectrums. The color of the arrow changes after completing the adjustment.

#### Gain

Used for adjusting the sensitivity of the blood flow signal.

The filling of the blood becomes more with the value becoming larger, and the arrows becoming more.

The filling of the blood becomes less with the value becoming smaller and the arrows becoming less.

#### **Arrow Density**

Used for adjusting the arrows' number in the unit area.

The arrow becomes more with the density becoming more compacted.

The arrow becomes less with the density becoming fewer.

#### Persistence

Used for adjusting the temporal smooth to optimize the image.

#### WF (Wall Filter)

It filters out flow noise. The bigger the value, the more the filtered noise. The real-time value (WF) is displayed in the image parameter area.

#### **Flow Brightness**

Used for adjusting the blood brightness of the grey background.

The grey background of the blood flow effect becomes brighter with the value becoming larger.

#### **Colorbar Scale**

The maximum velocity of the color map.

The velocity on the color bar becomes larger with the value becoming larger and the arrow's color changing.

The velocity on the color bar becomes smaller with the value becoming smaller and the arrow's color changing.

#### **Edge Smooth**

The blood against the edge becomes smooth with the value being larger.

#### **Arrow Lifetime**

The arrow appears longer with the value becoming larger.

#### **Arrow Size**

The end point of the arrow does not change with the value becoming larger, but the arrow length becomes longer.

The end point of the arrow does not change with the value becoming smaller, but the arrow length becomes shorter.

#### **Trig Type**

Set trigger type.

Under V Flow mode, turn on ECG and select "Manual" or "R" or "R100/200/300/400" trigger mode. Image will be captured in 100/200/300/400ms after R wave and ECG wave will be marked by red at that time.

#### **ROI Size**

Adjust the size of ROI.

#### **Acquire Time**

Adjust the acquisition time.

#### Sensitivity

This function is an indication of the ability to detect flow, which is used to adjust the accuracy of color flow.

The higher the sensitivity is, the more sensitive indication for low-velocity flow becomes. It affects the frame.

### 6.5.3 Vector Flow Quantitative Analysis

#### Single point-time curve

Perform the following procedure:

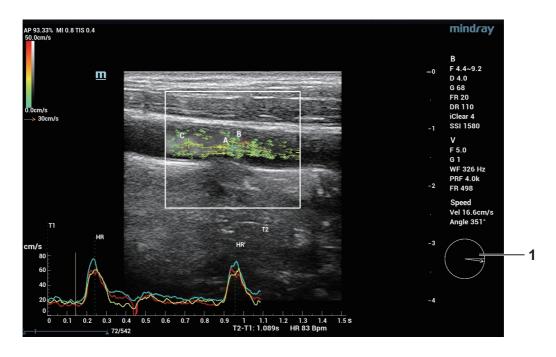
1. Capture the image. Follow steps 1-5, see "6.5.1 Basic Operations".

2. Tap [Velocity A/B/C] on the touch screen. The single point-time curve appears at the bottom of the screen. (The speed of either point changes with the time. Besides, horizontal axis represents the time; vertical axis represents the speed. Single point-time curve appears in white.)

The starting point and the end point of heart rate cycle and heart rate are also displayed at the bottom of the screen. If necessary, you can tap [Edit HR] to adjust the starting point and the end point by using the trackball and <Update> button. Press <Set> key to confirm the position, and the measurement result of HR is updated.

The speed vector graphics appears below the parameter area. Here, Vel and Angle refer to the absolute velocity and angle of the blood flow at this position. The white arrow indicates the speed direction of the cursor.

Move the cursor to any position of the blood vessel; the single speed-time curve and the vector graphics are updated in real time (click [Velocity A/B/C], adjust [Velocity A/B/C] again by rotating the track ball and pressing <set> key, or press <Clear> key to clear Velocity A/B/C).



1	Vector graphics
---	-----------------

3. Press <Cursor>. The trackball indication changes to cine-play indication. Move the trackball to replay the V Flow cine. The speed and the direction of the vector graphics changes with the time.

#### **ROI speed-time curve**

After the V Flow capturing is completed, a smaller ROI appears inside the original ROI to calculate the arrangement of spatial speed and the maximum speed-time curve.

Perform the following procedure:

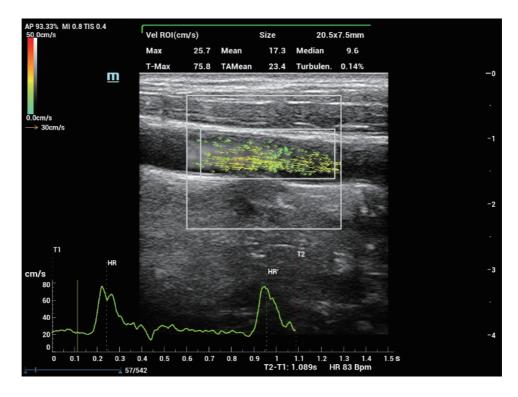
- 1. Capture the image. Follow steps 1-5, see "6.5.1 Basic Operations".
- 2. Tap [Velocity ROI] on the touch screen, rotate the knob under the [ROI Size] on the touch screen, or rotating the track ball and pressing <Cursor> key to adjust ROI size and position.

A purple dot appears inside the smaller ROI indicating the maximum speed position. The maximum speed-time curve appears at the bottom of the screen. (The speed of purple dot changes with the time. Besides, horizontal axis represents the time; vertical axis represents the speed. The ROI speed-time curve appears in purple.)

The starting point and the end point of heart rate cycle and heart rate are also displayed at the bottom of the screen. If necessary, you can tap [Edit HR] to adjust the starting point and the end point by using the trackball and <Update> button. Press <Set> key to confirm the position, and the measurement result of HR is updated.

The result box shows the speed values of the smaller ROI. Max, T-Max, Mean, TAMean, Median, Turbulen and Size refer to maximum speed of the current frame, maximum speed of all the frames during T1~T2 time, average speed of the current frame, average speed of all the frames during T1~T2 time, median speed of the current frame, blood flow dispersion of the current frame and ROI size.

Move the smaller ROI. The ROI speed-time curve and the values in the result box are updated in real time.



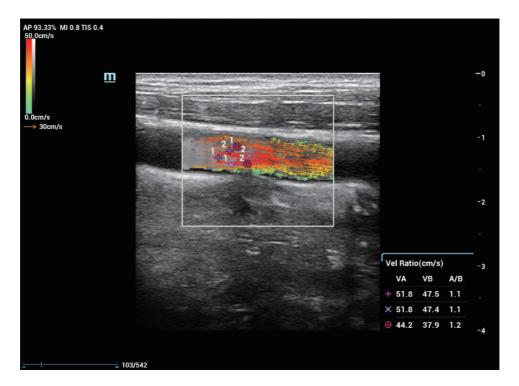
3. Press <Cursor>. The trackball indication changes to cine-play indication. Move the trackball to replay the V Flow cine.

#### **Velocity Ratio**

Perform the following procedure:

- 1. Capture image as described in steps 1-5, see "6.5.1 Basic Operations".
- 2. Tap [Velocity Ratio] on the touch screen to see number 1 and a cross.
- 3. Roll the trackball to replay the cine and select a target frame. Press <Cursor> to see the indication area switch to status.
- 4. Move the cursor onto the target position in the vessel and press <Set> to anchor. The Velocity Ratio result window on top of the image then displays the corresponding velocity and dotted line and another cursor appears.

Move the cursor to other locations and press <Set> to anchor continuously. Corresponding velocities and velocity ratio of the two adjacent points are displayed on the Velocity Ratio result window.



5. Tap [Velocity Ratio] again and repeat step 4 to measure the 2nd and 3rd velocity ratio measurement.

Press <Update> to switch the velocity ratios.

6. Press <Save> to save the cine file.

#### **Delete velocity ratio**

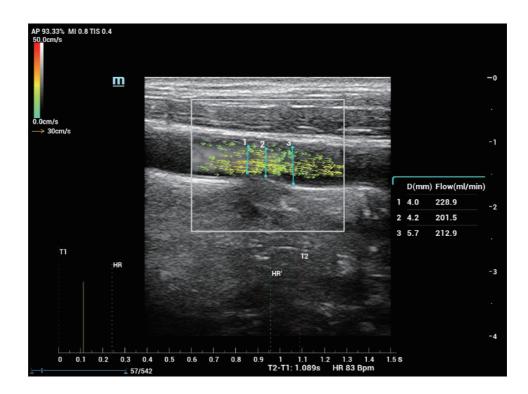
After three results are acquired, you can delete the result by pressing <Update> to activate it and press <Clear>.

### 6.5.4 Volume Flow Calculation

Perform the following procedure:

- 1. Capture image as described in steps 1-5, see "6.5.1 Basic Operations".
- 2. Roll the trackball to replay the cine and select a target frame. Press <Cursor> to see the indication area switch to status.
- 3. Tap [Volume Flow] to see a green dot on the image.
- 4. Roll the trackball to drag the first green dot onto the vessel wall and press <Set>. The green dot is anchored and another dotted line and dot appear.

The dotted line is perpendicular to the vessel. Drag the dot onto the other vessel wall and press <Set> to anchor. Flow and Diam results are displayed then in the Volume Flow result window.



5. Tap [Volume Flow] again and repeat step 4 to measure the 2nd and 3rd volume flow measurement.

Press <Update> to switch the volume flow results.

6. Set the range for VF and VF' measurement.

Press <Cursor> to see the indication area switch to status.

Roll the trackball to review the cine. Tap [VF] to set the starting point for measurement and [VF'] to set end point. Due to different range of the measurement, result of the volume flow may be slightly different.

7. Press <Save> to save the cine file.

#### Delete a volume flow result

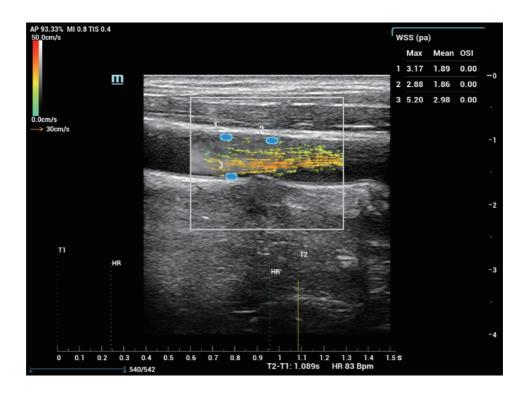
After 3 results are acquired, you can delete the result by pressing <Update> to activate it and press <Clear>.

### 6.5.5 WSS (Wall Shear Stress)

Perform the following procedure:

- 1. Capture image as described in steps 1-5, see "6.5.1 Basic Operations".
- 2. Roll the trackball to replay the cine and select a target frame. Press <Cursor> to see the indication area switch to status.
- 3. Tap [WSS] to see a green ellipse on the image.
- 4. Roll the trackball to drag the first green ellipse onto the vessel wall and press <Set>. The ellipse is anchored and another dotted line and dot appear.

Move the green solid line to drag the dotted line along the vessel wall and press <Set> to anchor the position and orientation of stress point. WSS result window displays maximum and average shear stress and oscillatory shear index of the location.



5. Tap [WSS] again and repeat step 4 to add more stress points.

Press <Update> to switch the stress points.

Press <Set> to select WSS points, then move the track ball to adjust the position and direction of WSS point.

6. Press <Save> to save the cine file.

#### Wall shear stress indices

Wall shear stress indices change linearly with wall shear stress. The higher wall shear stress, the higher the indices value.

Tap [Blood Viscosity] to change Wall shear stress indices.

#### Delete wall shear stress point

After 3 stress points are added, you can delete the point by pressing <Update> to activate it and press <Clear>.

### 6.6 M Mode

#### NOTE:

- During M mode imaging, menus of image optimizing for B mode and M mode are displayed on the touch screen at the same time. You can switch between the 2 modes by tapping the mode tabs.
- During M mode scanning, the frequency, depth, and acoustic power of the probe are synchronous with that of B mode.
- Adjustment of the depth or TGC to B Mode image will lead to corresponding changes in M Mode image.

### 6.6.1 M Mode Image Scanning

Perform the following procedure:

- 1. Select a premium image during B mode or B+ Color scan, and adjust to place the area of interest in the center of the image.
- 2. Press <M> on the control panel, and use the trackball to adjust the sampling line.
- 3. Press <M> on the control panel again or <Update> to enter M mode, and then you can observe the tissue motion along with anatomical images of B mode. During the scanning process, you can also adjust the sampling line accordingly when necessary.
- 4. Adjust the image parameters to obtain optimized images.

#### TIP:

The sampling line is displayed for one procedure operation. Press <M> to enter M mode.

### 6.6.2 M Mode Image Parameters

In M mode scan, the image parameter area on the right side of the screen displays the real-time parameter values as follows:

Items	Meaning
F	Frequency
D	Depth
G	M Gain
V	M Speed
DR	M Dynamic Range

#### Gain

To adjust the gain of M mode image, the real-time gain value is displayed in the image parameter area.

Increasing the gain will brighten the image and you can see more received signals. However, noise may also be increased.

#### **Display Format**

To set the display format of B mode image and M mode image.

Adjust according to the actual situation and obtain a desired analysis through comparison.

#### Speed

This function is used to set the scan speed of M mode imaging, and the real-time speed value is displayed in the image parameter area.

#### **Tint Map**

This function provides an imaging process based on color difference rather than gray distinction.

#### **Gray Map**

Adjusting grayscale contrast to optimize the image.

#### **Edge Enhance**

This function is used to increase image profile, so as to distinguish the image boundary.

#### Dynamic Range (Dyn Ra.)

Adjusts contrast resolution of an image, compresses or expands gray display range. The real-time dynamic range value will be displayed on the image parameter area.

#### M Soften

This feature is used to process the scan lines of M images to reject noise, making the image details to be clearer.

## 6.7 Color M Mode (CM)

To know the cardiac motion state, CM is overlaid with flow based on M mode, which is more sensitive to the instantaneous signal changes. Then, it shows the diagnosis information in detail.

The Color M mode includes Color Flow M mode and Color Tissue M mode.

TIP:

- Linear probe does not support Color M mode.
- Only phased probe supports color tissue M mode.

### 6.7.1 CM Image Scanning

Perform the following procedure:

- 1. To enter Color Flow M mode:
  - In B+M mode, press <C>.
  - In B+Color, press <M>.
- 2. To enter Color Tissue M mode:
  - Press <TDI>, or tap [TDI] on the touch screen, and then press <M> or <Update>.
  - In B+TVI/TVD, or B+TVI+TVD mode, press <M>.
- 3. Adjust the image parameters to obtain optimized images.
- 4. Exit Color M Mode

Press <C> or <M> on the control panel to exit Color M mode.

Or, press <B> on the control panel to return to B mode.

### 6.7.2 CM Image Parameters

In Color Flow M mode, parameters that can be adjusted are in accordance with those in B, M and Color modes; please refer to relevant sections of B, Color and M mode for details.

In color tissue M mode, parameters that can be adjusted are in accordance with those in B, M and Color modes; please refer to relevant sections of B, Color and M mode for details.

The ROI size and position determine the size and position of the color flow displayed in the color M mode image.

- Set the position of the sampling line by moving the trackball left and right.
- Press <Set> to switch the cursor status between the ROI position adjustment and ROI size adjustment.

## 6.8 Anatomical M Mode

For an image in the traditional M mode, the M-mark line goes along the beams transmitted from the probe. Thus it is difficult to obtain a good plane for difficult-to-image patients who cannot be moved easily. However, in the Anatomical M mode, you can manipulate the M-mark line and move it to any position at desired angles. The system supports anatomical M scanning (including Free Xros M mode and Free Xros CM mode) in 2D imaging modes (B, Color, Power and TVI mode).

## 

Anatomical M Mode and Color Anatomical M mode images are provided for reference only, not for confirming diagnoses. Compare the image with those of other machines, or make diagnoses using non-ultrasound methods.

### 6.8.1 Free Xros M

Free Xros M imaging is supported on frozen B image, B+M image and B+Power/Color/TVI image. Perform the following procedure:

1. Adjust the probe and image to obtain the desired plane in real-time B mode or M mode.

Or select the B mode cine file to be observed.

2. Tap [Free Xros M] on the touch screen to enter Free Xros M mode or press the user-defined key to enter Free Xros M mode.

There are 3 M-mark lines available, each with a symbol of "A", "B" or "C" at one end as identification.

- 3. Adjust the sampling line (single line or couple of lines) to obtain optimized images and necessary information.
  - Tap [Show A], [Show B] or [Show C] on the touch screen to adjust the sampling line. The corresponding sampling line and the Free Xros M image appear on the screen. Then, activate the sampling line.
  - Tap [Display Cur.] or [Display All] on the touch screen to select whether to display the image of the current M-mark line or all.

You can choose to display the sampling line on the current image or all.

- Press <Set> to switch among the sampling lines and press <Cursor> to show the cursor.
- Position Adjustment: When the sampling line is activated, move the trackball to adjust the
  position. The direction is recognized by the arrow at the end of the line.
- Angle Adjustment: When the sampling line is activated, move the trackball to adjust the fulcrum of the line, and rotate the <Angle> knob to adjust the angle.
- 4. Adjust the image parameters to obtain optimized images.
- 5. Press <B> to return to real-time B mode.

### 6.8.2 Free Xros CM (Curved Anatomical M-Mode)

In Free Xros CM mode, the distance/time curve is generated from the sample line manually depicted anywhere on the image. Free Xros CM is used for TVI and TEI modes.

### 

Curved anatomical M image in the operator's manual that it is provided for reference, not for confirming a diagnosis. Generally it should be compared with other device or make a diagnosis by non-ultrasonic methods.

#### NOTE:

Only phased probe supports Free Xros CM.

Perform the following procedure:

- 1. In real-time 2D mode, adjust the probe and image to obtain the desired plane.
- 2. Tap [TDI] on the touch screen or the user-defined TDI key to obtain the image.
- 3. Tap [Free Xros CM] on the touch screen or the user-defined key to enter the mode.
- 4. Use the trackball to define the start point of the sampling line on the 2D image.

The cursor displays as +, and can be moved within the 2D image only.

- 5. Press <Set> to fix the start point, and the digital number "1" is marked beside the point.
- 6. Define the next point using the trackball and <Set> key (tap [Undo] on the touch screen to cancel the current point and activate the preview point). The system updates the time-motion curve in real time, and each point is marked with a number in sequence.
- 7. Repeat Step 6 to finish the sampling line. Double press <Set> to finish the editing.
- 8. You can edit the curve if needed:
  - a. After finishing the sampling line, tap [Edit] on the touch screen. The cursor becomes the icon  $\square$ .
  - b. Move the cursor over the curve, press <Set> to activate the spot.
  - c. Move the cursor to change the shape of the curve.
  - d. Double press <Set> to finish the editing.

#### NOTE:

Tap [Delete] on the touch screen to remove the curve, and tap [Edit] to re-edit the curve.

- 9. Adjust the parameters to obtain the desired tissue of Free Xros CM image. Then, save the image.
- 10. Press  $\langle B \rangle$  to exit.

## 6.8.3 Anatomical M Mode Parameters

In anatomical M mode, adjustable parameters are similar with these in M mode.

## 6.9 PW/CW Mode

PW (Pulsed Wave Doppler) mode or CW (Continuous Wave Doppler) mode is used to provide blood flow velocity and direction utilizing a real-time spectral display. The horizontal axis represents time, while the vertical axis represents Doppler frequency shift.

PW mode provides a function to examine flow at one specific site for its velocity, direction and features; while CW mode proves to be much more sensitive to high velocity flow display. Thus, a combination of both modes will contribute to a much more accurate analysis.

- During PW/CW mode imaging, menus of image optimizing for B Mode and PW/CW mode are displayed on the touch screen at the same time; if there is also Color mode (Power mode) working, menus of certain modes will also be displayed on the touch screen synchronously, and you can switch by clicking the mode tabs.
- In PW/CW mode, acoustic power of the transducer is synchronous with that of B mode.
- When you adjust the depth or TGC of the PW/CW-Mode image, related changes will occur in PW/CW mode image as well.

### 6.9.1 PW/CW Mode Image Scanning

Perform the following procedure:

- 1. Select a premium image during B mode or B+ Color (Power) scan, and adjust to place the area of interest in the center of the image.
- 2. Press <PW>/<CW> to set the position of the sample line by moving the trackball left and right. Set the SVD by moving the trackball up and down, and adjust the angle and SV size according to the actual situation.
- 3. Press <PW>/<CW> again or <Update> to enter PW/CW Mode and perform the examination. Observe and calculate the data based on B mode or Color mode image. You can also adjust the SV size, angle and depth in the real-time scan.
- 4. Adjust the image parameters during PW/CW mode scan to obtain optimized images.

#### TIP:

The sampling line is displayed for one procedure operation. Press <PW>/<CW> to enter M mode.

### 6.9.2 PW/CW Mode Image Parameters

In PW/ CW mode scan, the image parameter area on the right side of the screen shows the real-time parameter values as follows:

Items	Meaning
F	Frequency
G	PW/CW gain
WF	WF (Wall Filter)
PRF	Pulse Repetition Frequency PRF
SVD	SV depth
SV	SV Size
Angle	Angle

#### Gain

This function is intended to adjust the gain of spectrum map. The real-time gain value is displayed in the image parameter area.

Increasing the gain will brighten the image and you can see more received signals. However, noise may also be increased.

#### **PW Sampling Gate**

Adjusts the SV position and size of sampling in PW mode, the real-time value of SV and SVD are displayed in the image parameter area, in which SV represents the size of the sampling gate, and SVD represents the sampling depth.

- SV size: Rotate the knob under [SV] on the touch screen to adjust the SV size.
- SVD: Roll the trackball to select the SV depth.

The smaller the SV size becomes, the more accurate the result is; and more information can be obtained when selecting large SV size.

#### **CW Focus Position**

To adjust the focus position of CW mode. The real-time focus position value is displayed on the image parameter area in SVD.

Roll the trackball to select the focus depth.

#### **Image Quality**

Refers to the transmitting frequency in Doppler mode of the probe, the real-time value of which is displayed in the image parameter area.

#### Scale

This function is used to adjust the speed range of color flow, which is adjusted through PRF in the system. The real-time PRF value is displayed in the image parameter area.

Aliasing may occur if low velocity scale is used and high velocities are encountered.

Low velocities may not be identified when a high velocity scale is used.

#### iTouch

To optimize image parameters as per the current tissue characteristics for a better image effect.

#### **Auto Calculation**

This function is used to trace the spectrum and calculate the PW/CW mode image parameters. The results are displayed in the results window.

In real-time scanning, the results displayed are derived from the calculation of the latest cardiac cycle.

In the freeze and cine status, the results displayed are calculated from the current selected area.

- Auto Calc Param: To set the calculation results to display.
- Auto Calc Cycle: To set the heart cycle number for auto-calculation.
- Auto Calc Loop: Freeze the image, turn the knob under [Auto Calc Loop] on the touch screen.
  - Rotate the knob clockwise to select the next loop.
  - Rotate the knob anticlockwise to select the last loop.
- Trace Area: To set the trace area of the Doppler wave in the spectrum map, applicable for auto calculation, V Max and V Mean display.
- Trace Smooth: To set the smooth level when tracing.
- Trace Sensitivity: This function is used to set the sensitivity of tracing in the spectrum.

#### Invert

This function is used to set the display manner of spectrum.

It is available only for linear probes.

#### Speed

This function is used to set the scan speed of PW mode imaging.

Changing the speed makes it easier to identify the cardiac cycles and to detect more details.

#### T/F Res

Adjusts for a balance between time resolution and spatial resolution.

#### WF (Wall Filter)

To display the image accurately, it adjusts the cut-off used in the wall filter, and filters out the flow noise which is produced by vessel wall vibration. The real-time value is displayed in the image parameter area.

#### **Tint Map**

This function provides an imaging process based on color difference rather than gray distinction.

#### **Gray Map**

Selects among post processing map curves to optimize grayscale images.

#### **Display Format**

Sets the display proportion of PW mode image and B mode image.

#### **Duplex/Triplex**

This function is used to set if B image or B+Color image (Power) is scanned synchronously.

#### HPRF

HPRF mode is used when detected velocities exceed the processing capabilities of the currently selected PW Doppler scale or when the selected anatomical site is too deep for the selective PW Doppler scale.

HPRF enhances the range of detecting high-velocity flow.

#### **Baseline**

Refers to the area where the velocity in zero in the spectrum. The map changes after being edited. To optimize the image, adjust baseline according to the actual situation to change the range of flow velocity.

#### Angle

This function is used to adjust the angle between Doppler vector and flow to make the velocity more accurate.

The real-time adjusting angle value is displayed in the image parameter area.

#### **Quick Angle**

Adjusts the angle faster in increments of  $60^{\circ}$ , and the real-time value of which is displayed in the image parameter area.

The function is available in real-time imaging, freeze or cine review status.

#### Dynamic Range (Dyn Ra.)

The dynamic range conveys the information that being transformed from echo intensity to gray scale.

With the contrast range, dynamic range, information displayed more, the noise increases more as well.

#### Volume

Adjusts the output audio in spectrum Doppler.

Utilizing the output audio helps to identify the feature and status of flow.

#### Steer

Adjusts the scan angle in PW mode, so as to change the angle between the transmitting beam and flow direction.

Obtain more information with immobility of the probe.

Values of steer angles vary with the probe.

#### NOTE:

Steer is available only for linear probes.

## 6.10 TDI (Tissue Doppler Imaging)

TDI mode is intended to provide information of low-velocity and high-amplitude tissue motion, specifically for cardiac movement.

There are 4 types of TDI mode available:

- Tissue Velocity Imaging (TVI): This imaging mode is used to detect tissue movement with direction and speed information. Generally the warm color indicates the movement towards the transducer, while the cool color indicates the movement away from the transducer.
- Tissue Energy Imaging (TEI): This imaging mode reflects the status of cardiac movement by providing the energy information, the larger the energy is, the brighter the color becomes.
- Tissue Velocity Doppler Mode (TVD): This imaging mode provides direction and speed information of the tissue.
- Tissue Velocity M Mode (TVM): This function assists to observe the cardiac motion through a direct angle.

### 6.10.1 TDI Mode Image Scanning

Perform the following procedure:

- 1. Tap <TDI> on the screen or the user-defined <TDI> key to enter the TDI mode.
  - In B or B+Color mode: to enter TVI Mode, parameters of TVI mode will be displayed on the touch screen.
  - In Power mode: to enter TEI Mode, parameters of TEI mode will be displayed on the touch screen.
  - PW mode: Tap <TDI> on the screen or the user-defined <TDI> key and then press <PW> or <Update> to enter TVD. The parameters of TVD are displayed on the touch screen.
  - M mode: Tap <TDI> on the screen or the user-defined <TDI> key and then press <M> or
     <Update> to enter TVM. The parameters of TVM are displayed on the touch screen.
  - In TDI mode, press <C>, <PD>, <M> or <PW> to switch among the modes.

- 2. Adjust the image parameters to obtain optimized images.
- 3. Tap <TDI> on the screen or the user-defined <TDI> key to exit from TDI mode and enter general imaging modes.

Or, press <B> on the control panel to return to B mode.

## 6.10.2 TDI Mode Image Parameters

In TDI mode scan, the image parameter area in the right corner of the screen will show the real-time parameter values as follows:

• TVI/TEI

Items	Meaning
F	Frequency
G	Gain
WF	Color Wall Filter
PRF	Pulse Repetition Frequency PRF

• TVD

Items	Meaning
F	Frequency
G	Gain
WF	WF (Wall Filter)
PRF	Pulse Repetition Frequency PRF
SVD	SV depth
SV	SV Size
Angle	Angle

• TVM

Image parameters combine the parameters of TVI mode and M mode.

In each TDI mode, the parameters that can be adjusted are similar to those in the color flow modes (Color, PW, and Power). See the relevant sections for details. The following introduces the specific items in TDI mode.

#### **Flow State**

This function is used for fast image optimization. Adjust using the [Flow State] item on the touch screen.

### 6.10.3 TDI Quantitative Analysis

## 

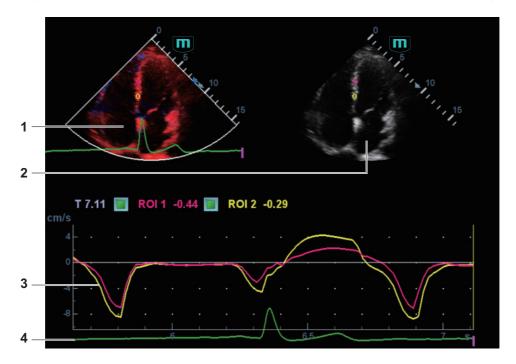
TDI is provided for reference, not for confirming a diagnosis.

To perform the strain and strain curve, the ECG curve is in need in case of the deviation in curve.

It is about analyzing the data of TVI imaging and measuring the velocity of the myocardium with the cardiac cycle.

Here are three types of curves to perform the quantitative analysis:

- Velocity-time curve
- Strain-time curve
- Strain rate-time curve
  - Strain: Deformation and displacement of the tissue within the specified time.
  - Strain rate: speed of the deformation, as myocardial variability will result in velocity gradient, strain rate is used commonly to evaluate how fast the tissue is deforming.



1	TDI review	Sampling area: indicates the sampling position of the curve. The sampling lines are marked with color numbers. It can mark 8 ROIs at most.	
2	2D grey image review	• Use the trackball; the images in TDI review window and 2D review window are reviewed synchronously, since the two images are frozen at the same time.	
		• ROI movement is linked between the TDI (Tissue Doppler Imaging) review window and the 2D imaging reviewing window.	

3	Display analysis curve	<ul> <li>Y-axis represents the velocity (unit: cm/s) [in strain-time curve, Y-axis represents the strain (%); in strain-time curve, Y-axis represents the strain (unit: 1/s)].</li> <li>X-axis represents time (s);</li> <li>Frame mark: a white straight line perpendicular to the X-axis, and can be moved left and right by using the trackball.</li> <li>Click the check box in front of the ROI to display or hide the analysis curve.</li> <li>You can get the current X/Y axis value by moving the cursor onto one point on the curve; and if you press <set> at this time, the frame marker will move to the spot.</set></li> </ul>
4	ECG display area	/

Perform the following procedure:

1. Scan the image with the moves of myocardium on, freeze the image and select the scan scope, or open the image which includes the myocardium moves already.

#### NOTE:

- The current image (in frozen state) and the saved image can be used in the quantitative analysis.
- Only after the user chooses the image review, the quantitative analysis is available. If the user chooses the static image (only one frame), the quantitative analysis is not available.
- 2. Tap [TDI QA] or press the user-defined key <TDI QA> to enable the function.
- 3. Mark the interested myocardium area.

One image can save 8 ROIs at most, and draw the corresponding curve in image area. Each ROI has different color; the corresponding curve is painted with each color.

**ROI** settings:

a. Tap [Standard ROI]/[Ellipse ROI] to select a ROI method.

The cursor moves into the review area (TDI review window or 2D grey review window.

- b. Review to the desired frame.
- c. Move the cursor to one cine review window.
- d. Add a ROI.

When selecting "Standard ROI": Add ROI automatically after capturing the area. ROI size is decided by "Standard Height/Width/Angle".

When selecting "Ellipse ROI": Press <Set> to confirm the start point, and use the trackball and press <Set> to confirm the next point; then use the trackball to adjust the size and press <Set> to complete the drawing.

You can press <Clear> to remove the last ROI.

4. Select the curve: Tap [Speed], [Strain] or [Strain Rate].

For [Strain] or [Strain Rate], rotate the knob under [Strain Dist.] on the touch screen to select the corresponding value for Strain – Time curve or Strain Rate – Time curve.

If needed, tap [ROI Tracking] to enable the function. This function provides a motion compensated ROI as precise time-intensity information can be acquired using active tracking. It can enhance the calculation accuracy as reducing the impact of probe or patient respiratory movement.

- Elliptical ROIs can be positioned in any manner that keeps their center within the image boundaries. In the case that part of the ROI is outside the image boundary, only data from within the image boundary is used for calculating the mean intensity value.
- When the user repositions an ROI, the old trace data is erased from the plot and the trace data for the new position re-plotted.
- 5. Adjust the curve display:
  - X Scale: Rotate the knob under [X Scale] on the touch screen to select the different value to change the display of X scale. The tissue information can be located precisely.
  - Smooth: Adjust the smooth feature of the curves.
- 6. Save the curves, and export the curve data, parameter data.
  - a. Tap [Export] on the touch screen. The dialog box appears.
  - b. Select the storage path and type the file name. E drive is default; and the file type is .CSV.
  - c. Click [OK] to complete the export.

After being exported successfully, a BMP. file shows on the thumbnail area.

The exported data include:

- Current image;
- Analysis curve data;
- Analysis parameter.
- 7. Tap [Exit] to exit the quantitative analysis.

## 6.11 iScape View

The iScape panoramic imaging feature extends your field of view by piecing together multiple B images into a single, extended B image. Use this feature, for example, to view a complete hand or thyroid.

When scanning, move the probe linearly and acquire a series of B images. The system pieces these images together into a single, extended B image in real time. The system also supports out-and-back image piecing.

After obtaining the extended image, you can rotate it, move it linearly, magnify it, add comments or body marks, or perform measurements on the extended image.

The system provides a color iScape function, so you can get more information from extended images.

### 

- It is provided for reference, not for confirming a diagnosis.
- iScape panoramic imaging constructs an extended image from individual image frames. The quality of the resulting image is user-dependent and requires operator skill and additional practice to become fully proficient. Therefore, the measurement results can be inaccurate. Exercise caution when you perform measurements in iScape mode. A smooth and even speed will help produce optimal image results.

- Guidance and precautions for even movement:
  - Make sure there is enough coupling gel along the scan path.
  - Always move the probe slowly and steadily.
  - Continuous contact is required throughout the length of the extended image. Do not lift the probe from the skin's surface.
  - Always keep the probe perpendicular to the skin's surface. Do not rock, rotate or tilt the probe during the scan.
  - The system accommodates a reasonable range of motion velocity. Do not make abrupt changes in motion speed.
  - Deeper scans generally require reduced acquisition speed.
- Needle mark cannot be displayed in iScape imaging mode.

### 6.11.1 Basic Procedures

Perform the following procedure:

- 1. Connect an appropriate iScape compatible probe. Make sure there is enough coupling gel along the scan path.
- 2. Press the user-defined key for <iScape View> or tap [iScape] on the touch screen (it is available after enter Power/Color mode).
- 3. Optimize the 2D mode image:

In the capture preparation status, tap [B] ([Power]/[Color]) page tab to go for the B mode image optimization. Do measurement or add comment/bodymark to the image if needed.

- 4. Tap [Start Capture] or press <Update> on the control panel to begin the capture.
- 5. Scan slowly to obtain a single extended field of view image. You can also erase and retrace if the image is not satisfactory.
  - During image acquisition, none of the parameters are adjustable, and functions such as measurement, comments and body marks are not available.
  - A green box on the image indicating the boundary between the merged images and the unfinished images.
  - During image slicing, the system gives feedback on the probe's moving speed in the form of colors and words. The meanings are as follows:

Status	ROI Color	Тір
Speed too low	Blue	Moving speed of the probe is too low.
Appropriate	Green	/
Speed too high	Red	Moving speed of the probe is too high.

- 6. The system enters into image review status when the acquisition is completed. You can perform operations such as parameter adjusting.
- 7. Do one of following to end image capture:
  - Tap [Stop Capture] on the touch screen.
  - Press <Update>.
  - Wait until the acquisition completes automatically.

After the acquisition is completed, the panoramic image will be displayed and the system enters iScape viewing mode.

### 6.11.2 Image Review

After the acquisition is completed, the panoramic image will be displayed and the system enters iScape viewing mode.

In image reviewing mode, you can adjust the following parameters.

#### **Image Parameters Settings**

- Image size
  - Tap [Actual Size] to display the image in its actual size.
  - Tap [Fit Size] to display the image in an appropriate size according to the current window.
- Tint and Tint map

Press the knob under [Tint Map] to activate the function, then change the effect by rotating the knob.

• Ruler

Tap [Ruler] on the touch screen to hide or show the ruler around the image.

• Color Display (in Power iScape)

Tap [Color Display] on the touch screen to display or hide the color image.

• Color Map (in Power iScape)

Rotate the knob under [Color Map] on the touch screen to select the map, as in Power mode.

#### Image Zooming

- Rotate <Zoom> to zoom in or zoom out the image.
- Rotate the button clockwise to zoom in the image, the max factor is 10;
- Rotate the button anticlockwise to zoom out the image.
- Roll the trackball to change position of the magnified image.
- Press <Zoom> again to exit zoom mode.
- When the image displayed is bigger than the image area, the thumbnail is automatically displayed.

#### **Rotating the Image**

For the convenience of image viewing, you can rotate the image by rotating the knob under [Rotation] on the touch screen in increments of  $5^{\circ}$ .

#### Measurement, comments, and body mark

In iScape image review status, you can perform measurement, comment, and body mark.

### 6.11.3 Evaluate image quality

Many variables may affect the overall image quality. It is important to evaluate the image content and quality before an image is used for diagnosis or measurements.

#### NOTE:

• iScape panoramic imaging is intended for use by well-trained ultrasound operators or physicians. The operator must recognize image items that will produce a sub-optimal or unreliable image.

- If the image quality cannot satisfy the following criteria, you shall remove the image and capture it again.
  - The Image must be continuous (no part of an image moves suddenly or disappears.)
  - No shadow or absent signal along the scan plane.
  - Clear profile of anatomy through the entire scan plane without distortion.
  - Skin line is continuous.
  - The images are captured from the same plane.
  - There are no large black areas in the image.

### 6.11.4 Cine Review

Tap [Review Cine] on the touch screen in panoramic image viewing status to enter cine reviewing mode. In cine reviewing mode, a frame marker indicates the sequence of the currently reviewed images in the panoramic image on the left-hand side of screen.

In cine review status:

- Use the trackball to review the captured images frame by frame.
- Tap [Auto Play] to start or end auto play.
- In auto play mode, tap [Auto Play] on the touch screen to change the play speed. When the speed is off, the system exits auto play mode.
- Review to a certain image. Tap [Set Begin] to set the start point. Review to another image. Tap [Set End] to set the end point. In auto play mode, the review region is confined to the set start point and end point.
- Tap [iScape] > [Overview] to exit cine review mode. The panoramic image displays.
- In cine review mode, press <Freeze> on the control panel to return to the acquisition preparation status.

## 6.12 R-VQS

R-VQS (RF-data based quantification on arterial stiffness) tracks movements of the upper and lower vessel walls and measures vessel diameter, displacement, coefficient of hardness and PWV (dimensionless pulse wave velocity).

Hardness coefficient: Arterial stiffness is changed with the blood pressure changing. The bigger the value the higher the stiffness.

PWV (dimensionless pulse wave velocity) represents the transmit speed of pulse wave. The bigger the stiffness parameter the higher the PWV.

#### NOTE:

Only linear probe under Carotid exam mode supports this feature.

Perform the following procedure:

- 1. Select a probe and carotid exam mode. Perform B real-time imaging and search for carotid vessel. Try to place the vessel on the image horizontally.
- 2. Tap [R-VQS] and use the trackball to locate the ROI box on the target area.

Dotted line of the ROI lies in the middle of the vessel and divides the vessel upper wall and lower wall. Use <Set> key and trackball to change ROI size and position.

Note that ROI should include the upper and lower wall of the vessel.

3. Tap [Start Calc] to start tracking. Upper wall and lower wall are marked by the line in the ROI box.

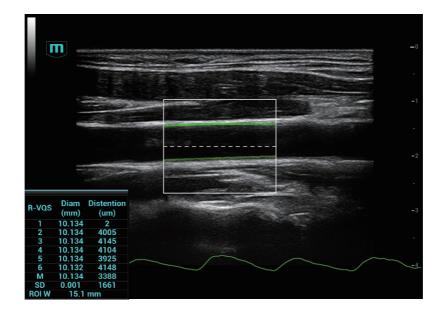
Motion curve of vessel walls display under the image in real time. 6 cardiac cycles are calculated in total with each results display in the result window on the left synchronously.

Where,

Dist = [maximum diameter within 1 s] - [minimum diameter within 1 s]

Diam: Vessel diameter refers to maximum diameter within 1 s.

6 R-VQS (RF-data based quantification on arterial stiffness) values (6 cardiac cycles are calculated in total), standard deviation SD and ROI length will be displayed in the result window on the left.



- 4. Adjust parameters.
  - Speed: Adjust refresh speed of vessel wall motion curve.
  - Position: Adjust the location of the motion curve upwards and downwards.
  - Curve Disp (Min)/Curve Disp (Max): Adjust amplitude of vessel wall motion curve.
- 5. Tap [Stop Calc] or press <Freeze> to freeze the image and stop updating motion curve and result data.
- 6. Use the trackball to review the cine file and select desired frame.
  - Tap [Accept Result] to update the result window data to the report.
     Save the single-frame and multi-frame image if necessary.
  - Tap [Cancel Result] to recalculate and perform step 3-5 if necessary.
- 7. Tap [Report] to check report.

Only the last result data will be saved.

If pressure is entered in the patient information page or the report page, Hardness coefficient and PWV result will be displayed on the report.

For details about report operation, refer to "Advanced Volume".

## 6.13 RIMT (Real-time Intima-Media Thickness)

RIMT detects the changes of the vascular intima in real time, and monitors and calculates the thickness of the carotid intima automatically.

#### NOTE:

- It is merely available to enter RIMT imaging mode in B single window and dual window when adopting linear probe for carotid exam.
- Do not press the probe after entering RIMT imaging mode when scanning the image in real time.
- RIMT inside ROI is highlighted in red, yellow and green. There is no gap between the filling area and the vascular wall. The green color indicates the normal acceptable value. The red color or yellow color indicates the abnormal unacceptable value.

Perform the following procedure:

- 1. Select the probe first. Perform B mode in carotid exam mode. Detect the patient's carotid in B mode. Keep the acoustic beam vertical with the anterior and the posterior of the vascular and make the anterior and the posterior of the intima visible at the carotid stenosis to obtain a premium image.
- 2. Tap [RIMT] to activate the function. Rotate the knob under [Side] to select left or right carotid.
- 3. Use the trackball to locate ROI over the target area. The dotted line of the ROI is in the middle of the blood vessel. Press <Set> to confirm the position and size of the ROI.
- 4. Tap [Start Calc] to measure RIMT of left carotid and right carotid. 6 RIMT values (each RIMT value represents maximum IMT value within one cardiac cycle), RIMT average value (arithmetic mean value of the 6 RIMT values), SD (standard deviation of the 6 RIMT values) and ROI length are displayed in the result pane.
- 5. Tap [Accept Result] or press <Set>, the image is frozen. You may save single frame image and results to the result pane.

Tap [Cancel Result] to recalculate RIMT. Perform step 4 to reset the RIMT.

6. Tap [Report] to view the report. Only last acceptable data, including RIMT on left and right carotid, is in the data sheet.

You can perform:

- Deleting data: select RIMT data from the data sheet. Tap [Delete Rows] to remove the RIMT data of the left and the right carotid.
- Viewing graphic: tap [IMT Trend] to view the RIMT graphic. The data on the graphic is same with these in data list. The RIMT average value, SD and ROI length of the exams are displayed at the bottom of the graphic (including the current exam).
- Previewing the report: tap [Preview] to show IMT. The RIMT average value, SD and ROI length of the exams are displayed.

For details about report operation, refer to "Advanced Volume".

7. Tap [RIMT] again to exit.

## 6.14 **Tissue Tracking Quantitative Analysis**

## 

Tissue Tracking Quantitative Analysis images are provided for reference only, not for confirming diagnoses.

Apart from TDI imaging function, the system also provides tissue tracking QA function for myocardial movement evaluation.

By tissue tracking QA function, the ultrasound system will scan each pixel position by frame within the cardiac cycle, and then use region matching method and auto-correlation searching method to trace each spot and calculate the movement, so as to determine myocardial motion in a more quantitative way.

#### NOTE:

Only use the probes that support stress echo function under the cardiac mode to start Tissue Tracking QA function.

## 6.14.1 Basic Procedures for Tissue Tracking QA

Perform the following procedure:

1. Open a saved B mode cardiac cine file.

A cin. format file which contains more than 1 cardiac cycle (with 2 R waves) and ECG signal.

- 2. Tap [TTQA] or press the user-defined key to activate the function:
  - You can determine the image of interest by previewing the image.
  - Use [Cycle] to select and find the image of interest.
- 3. Select the corresponding section name and locate one frame image with good image effect by cine play. Use the cursor to set the reference point:
  - Long axis section: use the "3-point" method or "Manual" method to set.
  - Short axis section: enter multiple points (at least 6 points) using the cursor manually to set.
- 4. After reference points are set, the system will display the boundary of the endocardium and epicardium. Adjust the thickness if necessary.

If the traced result is poor, tap [Reload] to re-trace the reference points, or make fine adjustments to the points using the cursor.

If the cycles are not adequate to provide the information, switch to another cycle to trace.

5. Tap [Start Tracking] on the soft menu to start the tracking function. Adjust the parameters if necessary.

Tap [Edit] on the soft menu to display the cursor. Use the trackball and press <Set> to re-select the trace reference points (inner dots of the curve). Move the cursor to the exact boundary position and press <Set> again to set the right place. Tap [Start Tracking] to start tracking again.

6. Tap [Accept & Compute] to calculate and display the curve.

Adjust the parameters if necessary.

- 7. Tap [Bull's Eye] to see the result.
- 8. If necessary, press <Save> key to save the result.

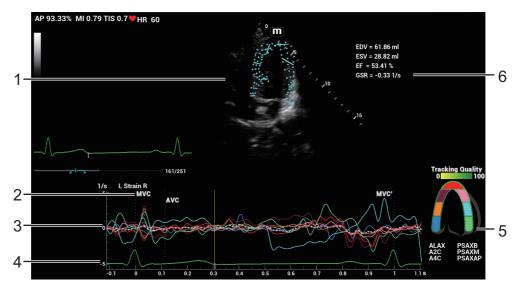
9. If necessary, repeat steps 3-8 to track the next section.

#### NOTE:

The screen displays the result of the current section, and the bull's eye graph shows the average value of all the tracked sections.

- 10. Tap [Data Export] to export analyzed data.
- 11. Tap [Exit] to exit.

## 6.14.2 Screen Display of Tissue Tracking QA



1	Displays image used to generate trace curve	/
2	Displays corresponding time of AVO (aortic valve open)/AVC (aortic valve close)/MVO (mitral valve open)/MVC (mitral valve close).	/
3	Display curve: Velocity/ Displacement/Strain/Strain Rate.	<ul> <li>Each curve on the image is matched with a certain segment in the cardiac segmentation model (6), identified by different colors.</li> <li>Velocity curve: X-axis represents time (s); Y-axis represents velocity (cm/s).</li> <li>Displacement curve: X-axis represents time (s); Y-axis represents displacement (mm).</li> <li>Strain curve: X-axis represents time (s); Y-axis represents deformation of the tissue (%).</li> <li>Strain-rate curve: X-axis represents time (s); Y-axis represents strain by time (s<sup>-1</sup>).</li> </ul>
4	Displays ECG trace	/

n	Displays cardiac segmentation nodel, and each segment name s illustrated beneath the model.	<ul> <li>In the figure,   marks the peak position of the curve.</li> <li>Under tracking status, click on a segment in the cardiac segmentation model. The segment has "X" mark and its corresponding calculating is eliminated.</li> <li>Tap certain segment in the cardiac segmentation model, the segment will turns grey and its corresponding curve no longer displays.</li> <li>You can get the current X/Y axis value by moving the cursor onto one point on the curve; and if you press <set> at this time, the frame marker will move to the spot.</set></li> </ul>
	Displays measurement and alculation results	<ul> <li>EDV: Maximum value of the end diastolic volume during the trace.</li> <li>EDA: Maximum value of the end diastolic area (Left Ventricular) during the trace.</li> <li>ESV: Maximum value of the end systolic volume (Left Ventricular) during the trace.</li> <li>ESA: Maximum value of the end systolic area (Left Ventricular) during the trace.</li> <li>FAC (for short axis section): Fractional Area Change= (EDA — ESA)/EDA</li> <li>EF (for long axis section): Ejection fraction</li> <li>HR: Heart rate</li> <li>Global strain of all segments.</li> <li>Displays when strain rate curve is acquired.</li> <li>Global strain rate of all segments.</li> <li>Displays when strain rate curve rate is acquired.</li> <li>Also on Bull's Eye figure, the system displays TPSD value: Time to Peak Standard Deviation (TPSD):</li> <li>Where, standardized value of time to peak data: {TP<sub>i</sub>   i ∈ [1, N]}. (N is the number of time to peak data) Average value of standardized value of time to peak data:</li> <li>TPSD = √ ((TP<sub>i</sub> - TP)<sup>2</sup>)/(N)</li> </ul>

## 6.14.3 Select Image and Cardiac Cycle

You can select images with a better image quality so as to guarantee the analysis result.

#### Switch the cine file

- 1. Tap [Review] to enter the review state on touch screen.
- 2. Double-click the target file.
- 3. The system closes current displayed file and switch to the newly selected file.

#### Switch cardiac cycle within the cine file

Tap [Cycle] to select when opening a cine which includes multiple cardiac cycles.

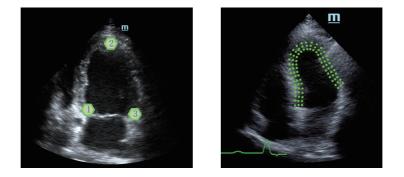
### 6.14.4 Myocardial Boundary Tracing

#### Tracing

The system provides 2 kinds of tracing method for 2 kind of sections. Long axis section (A4C, A2C, ALAX): 3-point method and manual tracing method are both available. Short axis section (PSAX B, PSAX M, PSAX AP): only manual tracing is available.

• 3-point method

As shown in the following figure, after operation by pressing <Set> to place 3 points on the image, the system generates the trace automatically.



• Manual trace method

Press <Set> and move the cursor by using the trackball along the boundary to add the trace points gradually, after trace is finished, press <Set> twice to finish tracing.

#### NOTE:

At least 6 points should be determined by you before the system generates automated trace. Press <Set> to make the traces on the image clockwise or anticlockwise.

#### Retracing

If current trace is not satisfactory, tap [Reload] on the touch screen to clear the trace and to start another tracing.

During the tracing drawing, press <Clear> to clear already traced drawing.

#### Make fine adjustment to the trace

You can make fine adjustments to the trace after it is completed.

Perform the following procedure:

- 1. Under tracing curve adjusting status, the cursor turns into  $\Box$ .
- 2. Move the cursor to the editable point, press <Set>.
- 3. Use the trackball to drag the curve to desired position, press <Set> again to set the point to the new position.
- 4. Repeat step  $2 \sim 3$  above to finish all points that need adjustment.

#### NOTE:

Under tracking status, tap [Edit] on the touch screen to enter the status.

## 6.14.5 Basic Operations of TTQA

#### Switch among the operation controls

- [Start Tracking]: tap to start tracking.
- [Accept & Compute]: tap to start calculation and display the curve.
- [Exit]: tap to exit tissue tracking.
- [Parameter]: rotate to select the curve type.
- [Bull's Eye]: touch to turn on/off bull's eye and peak data table.
- [Auto Play]: change the speed of the play.

#### **View Selection**

Before tracing, touch the corresponding keys to select for the view.

- [A4C]: apical four chamber.
- [A2C]: apical two chamber.
- [ALAX]: apical long-axis view, also called 3-chamber view.
- [PSAXB]: short axis view of base section, short axis view of mitral valve.
- [PSAXM]: short axis view of base section, short axis view of papillary muscle.
- [PSAXAP]: short axis view of apex.

#### **Parameter Adjustment**

- [Thickness]: adjusts the tracing thickness, i.e., the distance between the endocardium wall and the tracking points on the epicardium.
- [Track Point]: adjusts the number of points within the segment.
- [Cycle]: select the next cycle.
- [Display Effect]: turns on/off the arrow vector graphical display of the myocardial movement.
- [Velocity Scale]: adjust the scale length of the velocity.
- [Display Style]: display the endometrial, the epicardium, the myocardial or all.
- [Tracking Cycles]: select the cycles to be tracked.
- [Average Cycles]: obtain the average parameter curves of the tissue.
- [Cycle Select]: select among different cycles.

#### **Time Mark**

According to the status of the current section, tap the corresponding key on the touch screen to check the matching time.

- [AVO]: displays aortic valve open time.
- [AVC]: displays aortic valve closure time.
- [MVO]: displays mitral valve open time.
- [MVC]: displays mitral valve closure time.

#### **Curve Display**

Select [Parameter], the system provides different curves of different segments for observation.

- General
  - Speed curve: The X-axis represents time (s); the Y-axis represents velocity (cm/s).
  - Displacement curve: The X-axis represents time (s); the Y-axis represents displacement (cm).
- Long axis section

- Volume: The X-axis represents time(s); the Y-axis represents volume (ml).
- Strain curve (Longitudinal, Transversal): The X-axis represents time (s); the Y-axis represents strain deformation of the tissue (%).
- Strain-rate curve (Longitudinal, Transversal): The X-axis represents time (s); the Y-axis represents strain by time (s<sup>-1</sup>).
- Short axis section
  - Area curve: The X-axis represents time(s); the Y-axis represents area (cm2).
  - Strain curve (Radial, Circumferential): The X-axis represents time (s); the Y-axis represents strain deformation of the tissue (%).
  - Strain-rate curve (Radial, Circumferential): The X-axis represents time (s); the Y-axis represents strain by time (s<sup>-1</sup>).
  - Circumferential Rotation curve: The X-axis represents time (s); the Y-axis represents rotation of the tissue (Deg).
  - Circumferential Rotation Rate curve: The X-axis represents time (s); the Y-axis represents rotation by time (Deg/s).

#### **Torsion & Torsion Rate Curve**

The system provides left ventricular torsion data based on short axis sections of PSAX AP and PSAX B. Torsion is acquired by calculating difference of apex and base of the heart.

Torsion = PSAX AP Rot. - PSA XB Rot.

- The X-axis represents time (s).
- The Y-axis represents tortion by time (Deg/s).

### 6.14.6 Bulleye

After tracking, the system can display Bull's Eye graph, so as to judge reverse movement or scope of myocardium.

1. Tap [Bull's Eye] on the touch screen to turn on the function:

You can acquire:

- Time to peak value and peak value of the 17 segments (similar to 16 segments);
- Display measurement result EDV/ESV/EF/TPSD.
- 2. Rotate the knob under [Parameter] on the touch screen to see different parameter bull's eye graph.

"-" will display in the table to indicate those segments that are not well tracked.

### 6.14.7 Measurement/Comment

Under tissue tracking QA mode, only Time measurement is available. For details, please refer to Operator's Manual "Advanced Volume".

Comments and Body Mark operations are the same as in other modes.

#### 6.14.8 Data Export

The system provides data exporting function, so that you can export calculation result for analysis (for instance, SPSS analysis).

Tap [Data Export] on the touch screen, to export analyzed data of each segment in .csv format.

## 6.14.9 FH Tissue Tracking QA

FH Tissue Tracking QA (Fetal Heart Tissue Tracking and Quantitative Analysis) is a quantitative assessment tool specifically made for fetal heart analysis based on the speckle tracking method. This tool is used to automatically track the motion of the left ventricular wall in a 4-chamber view cardiac cine and calculate the long-axis strain, strain rate, and other relevant parameters that reflects the contractile function of the left ventricle. It is an offline and semi-automatic tool that requires the user to manually define the cardiac cycle and manually mark the left ventricular myocardium before automatic tracking process starts.

#### NOTE:

FH Tissue Tracking QA does not support Bull's eye.

- 1. Open a saved B mode fetal echo cine file. Or press <Freeze> under fetal echo related exam mode (the frame rate should be higher than 40).
- 2. Tap [TTQA] on the touch screen:

You can determine the image of interest by previewing the image, set the ROI and zooming the image.

- 3. You can tap [Free Xros M] to enter Free Xros M mode and adjust the sampling line to help you observe the image and determine the heart rate cycle.
- 4. If necessary, use the trackball to move the frame mark, and tap [MVC] or [MVC'] to set the frame as the starting tracking point or ending tracking point of a needed cardiac cycle.
- 5. Use the cursor to set the reference point:

Manually enter multiple points (at least 6 points) clockwise using the cursor to set and double press the <Set> key to confirm the last reference point.

6. After reference points are set, the system will display the boundary of the endocardium, myocardium, and epicardium. Adjust the thickness if necessary.

If the traced result is poor, tap [Reload] on the touch screen to re-trace the reference points, or make fine adjustments to the points using the cursor.

7. Tap [Start Tracking] on the touch screen to start the tracking function. Adjust the parameters if necessary.

Tap [Edit] on the touch screen to display the cursor. Roll the trackball and press <Set> to reselect the trace reference points. Move the cursor to the exact boundary position and press <Set> again to set the right place. Click [Start Tracking] to start tracking again.

- 8. Tap [Accept & Compute] on the touch screen to calculate and display the curve. Adjust the parameters if necessary.
- 9. Tap [Data Export] on the touch screen to export analyzed data.
- 10. Tap [Exit] on the touch screen.

## 6.15 Fusion Imaging

### 6.15.1 Overview

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The Fusion Imaging is contraindicated to the person wearing the internal pacemaker, cochlear implant or nerve stimulator. People wearing the implant or

# intra-corporeal devices should keep one-meter away when the magnetic generator starts working.

Ultrasound Fusion Imaging completes the matching of multiple modalities and overlapping for ultrasound images and 3-dimensional data, such as pre-operative computed tomography (CT)/ magnetic resonance imaging (MRI) 3-dimensional data/position emission computed tomography (PET) 3-dimensional data/ultrasound 3-dimensional data, etc. With the benefits of high spatial resolution, wide field of view and free-interference of the air, it offers adequate diagnostic information to the doctor.

Spatial Positioning: Import CT/MR/PET/freehand volume data to the Ultrasound System. CT/MR/ PET/freehand volume data will be set as a CT/MR/PET/freehand 3-dimensional cubic image. After the doctor registers the ultrasound real-time image with a certain plane of CT/MR/PET/freehand image, the Ultrasound System receives the probe position information from "positioning (probe) sensor". The Ultrasound System shows the CT/MR/PET/freehand image aligned with the ultrasound image on account of the magnetic spatial navigation function.

Lesion Viewing and Marking: to show the lesions marked on the ultrasonic planes, the ultrasound image and CT/MR/PET/freehand image are displayed simultaneously via the spatial positioning device based on the old lesion marks on CT/MR/PET/freehand image. The lesion marks on CT/MR/PET/freehand image appear on the ultrasound image in real time. It helps the doctor spot the old lesion mark and perform the surgical plan to the tumor ablation.

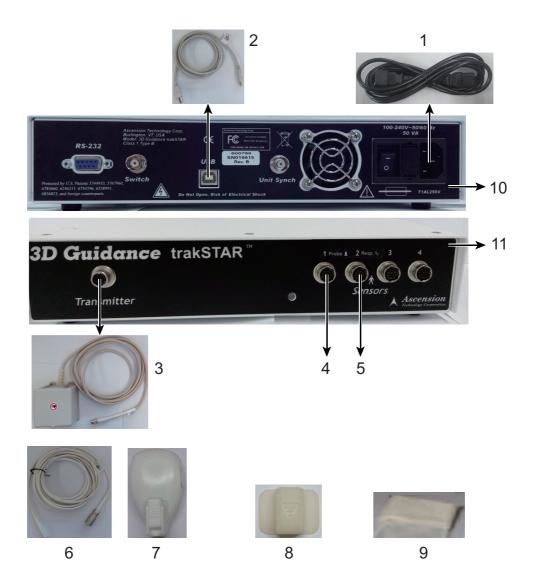
Clinical applications: the lesions not-easily-detected in the ultrasonic exams; the panorama of the large lesion not-fully-displayed in therapeutic ultrasound; surgical operations to tumor ablation; biopsy and ablation to the liver neoplasms (enabled in the biopsy to renal tumor, lung neoplasms and prostate).

### 6.15.2 Magnetic Navigator

#### NOTE:

- Place the set of the magnetic navigator away from the electromagnetic interference sources, such as power filter, signal indication, magnetically activated metal materials, cell phone in the use of the devices.
- Connect the magnetic navigator when the magnetic navigation controller is OFF.
- Exit Fusion imaging before reconnecting/disconnecting sensor from the magnetic navigation controller. Turn off the magnetic navigation controller before connecting/disconnecting magnetic generator.
- Mindray does not provide the sterile sheath. Users should prepare it according to the own needs.

Plug the auxiliary output power supply cable, USB data cable, magnetic generator and sensor(s) to the magnetic navigator respectively following the arrow's guide.



1	Auxiliary output power supply cable	2	USB Data cable
3	Magnetic generator	4	Positioning (probe) sensor port
5	Motion (abdomen) sensor port	6	Sensor (2)
7	Positioning (probe) navigation support	8	Motion (abdomen) sensor support
9	sterile sheath	10	Magnetic navigator (rear)
11	Magnetic navigator (front)	•	•

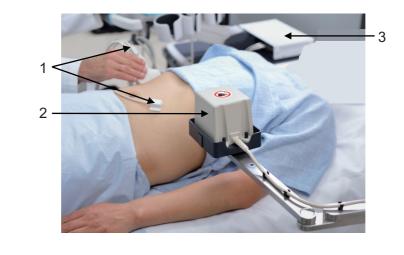
The description of the magnetic navigator is given in details. See the table below.

No.	Device Name	Port	Description
1	Auxiliary output power supply cable	Power supply port	Plug the auxiliary output power supply cable to the port of the magnetic navigator, and connect the power supply. <b>NOTE:</b> Please use the auxiliary output power supply cable equipped with the Ultrasound System.
2	USB data cable	USB port	Plug one end of the USB data cable to the USB port of the magnetic navigator, and another end to the USB port of the Ultrasound System.
3	Magnetic generator	Transmitter port	Plug the magnetic generator to the Transmitter port. Place it around the patient's shoulder or two sides of the patient's abdomen. The magnetic generator should be frontal-faced with the lesion. The frontal face of the magnetic generator keeps 15-60 cm from the target within the scope 30 cm up/ down and towards probe.
			NOTE:
			Keep the magnetic generator away from the metal devices or electromagnetic interference.
4-9	/	Positioning (probe) sensor port Motion (abdomen) sensor port	1. Plug two sensors to positioning (probe) sensor port

No.	Device Name	Port	Description
4-9	/	Positioning (probe) sensor port Motion (abdomen) sensor port	<ul> <li>2. Positioning (probe) navigation support: fix the support to the probe. See the method below:</li> <li>The plastic markers on the probe (1 in the figure) and on the positioning (probe) navigation support (2 in the figure) must be on the same side.</li> </ul>
			• The silk prints on the probe (1 in the figure) and the navigation support (2 in the figure) must be on the same side.
			• Push the navigation support fastened following the arrow's guide and lock it in the position shown in Figure 1

No.	Device Name	Port	Description
4-9		Positioning (probe) sensor port Motion (abdomen) sensor port	3. Positioning (probe) sensor: fix the positioning (probe) sensor (2 in the figure) which is already plugged in positioning (probe) sensor port to the cavity of the positioning (probe) navigation support (1 in the figure) following guide.
			<b>NOTE:</b> Note: if failed to plug the positioning (probe) sensor
			<ul> <li>following guide, it may lead to non-correlation of spatial positioning.</li> <li>4. Positioning (probe) sensor sterile sheath: wear the probe sterile sheath after probe sensor and positioning (probe) navigation support are installed.</li> </ul>
			5. Motion (abdomen) sensor: fix the motion (abdomen) sensor which is already plugged in motion (abdomen) sensor port to the cavity of the motion (abdomen) sensor support following $\blacksquare$ guide.
			6. Motion (abdomen) sensor sterile sheath: wear the sterile sheath after abdomen sensor and positioning (probe) navigation support are installed.
			7. Motion (abdomen) sensor support: stick the sensor support against the top left of the patient's abdomen with the medical plasters (below left costal arch, right above the navel, the area where the skin moves apparently with the respiration).
10	Magnetic navigator	/	Place the magnetic navigator behind the Ultrasound System. Power on the navigator to enable the positioning function.

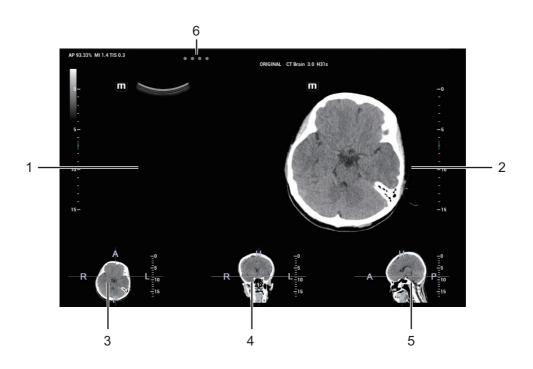
#### Magnetic devices positioning:



1	Sensor	2	Magnetic generator	3	Magnetic navigator
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## 6.15.3 Screen Description

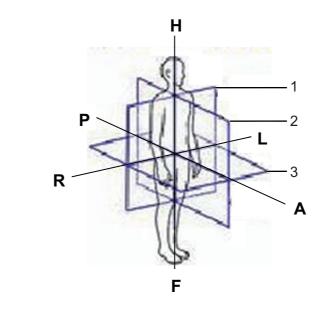
You should connect the magnetic devices, and then enter Fusion Imaging. The Fusion Imaging screen appears.



No.	Image	Description
1.	Ultrasound Display	When Fusion Ratio is among -1 to 0, the Ultrasound System registers CT/MR/PET/freehand image to ultrasound image. The fusion display appears then.
2.	Fusion Display	When Fusion Ratio is among 0 to 1, the Ultrasound System registers ultrasound image to CT/MR/PET/freehand image. The fusion display appears then.

No.	Image	Description
3.	Transverse plane	R, L, A, and P imply the right, left, anterior and posterior of the patient.
4.	Coronal plane	R, L, H, and F imply the right, left, head and foot of the patient.
5.	Sagittal plane	H, F, A, and P imply the head, foot, anterior and posterior of the patient.
6.	Indicator	<ul> <li>Four indicators (1<sup>st</sup> indicator is on positioning (probe) sensor and 2<sup>nd</sup> indicator is on motion (abdomen) sensor. 3<sup>rd</sup> indicator is on Needle Navigation Guiding sensor. 4<sup>th</sup> indicator are reserved functions.)</li> <li>Check the indicator becomes green in use.</li> <li>Different indicator color: <ul> <li>Blinks green: excellent.</li> <li>Blinks yellow: mediocre.</li> <li>Blinks red: poor.</li> </ul> </li> <li>Stays grey: no signal activated. (Magnetic navigation is not enabled.)</li> </ul> NOTE: <ul> <li>If the signal of the sensor becomes poor, check the connections of the magnetic devices. Reset the distance/orientation among the magnetic generator, sensors and the patient. Exclude the interference from the metal devices (ward beds made of metal materials) or the electromagnetic devices.</li> </ul>

The position for each plane is shown below:



1	Coronal plane	2	Sagittal plane	3	Transverse plane
---	---------------	---	----------------	---	------------------

## 6.15.4 Basic Procedures

Perform the following procedure:

1. Select a proper probe and a correct exam. Enter real-time B/Color/Power/Contrast mode (non-cardiac Contrast Imaging mode).

- 2. Get magnetic devices prepared. Connect the magnetic devices. Power on the magnetic navigator.
- 3. Activating the magnetic positioning:
  - a. Tap [Fusion] on the touch screen or user-defined key to enter Fusion Imaging mode (see also Chapter 12 Setup for key preset operations). Tap [Tracking System] on the touch screen. The magnetic navigation positioning is activated when the soft key becomes highlighted (it is usually activated by default).
  - b. Checking indicator. The Fusion Imaging works when the indicator becomes green.
- 4. Acquire/import CT/MR/PET/freehand volume data. XX

You can load PET volume data and CT volume data, and tap [Multi Data Regi] to register the PET image with CT image. Tap [Mark on Multimodality] to make marks on CT and PET images. Tap [Exit]. Then tap [Multi Data] to select "PET-CT". The PET-CT volume data will be used in later registering with ultrasound image.

#### NOTE:

- The Ultrasound System sets CT/MR/PET/freehand volume data to 3-dimensional display automatically. One of anatomical planes (2-dimensional image) appears on the screen.
- After freehand volume data is imported or acquired, the system registers freehand volume data with the ultrasound plane automatically. Do not move the magnetic generator and the patient for any circumstances after the freehand volume data is imported or acquired. Otherwise, the registration display for freehand image and the ultrasound image is affected.
- 5. The brightness and the grey level of loaded data can be completed via Window Width and Window Level. Set Window W and Window L.
- 6. Obtain an optimum plane as the registration plane from CT/MR/PET image.

#### NOTE:

Registered with the ultrasound plane). (For freehand volume data, skip steps 6-8.

It is suggested that the plane concentrated with blood vessels, organs, tissue margins, lesions is optimum for registering.

Tap [View Type] to change CT/MR/PET plane (transverse plane/coronal plane/sagittal plane). The pan (using the trackball), the shift or the rotation (along Z-axis) can be completed on CT/MR/PET plane until an optimum plane for registering appears.

See XX for CT/MR/PET image operations.

7. Obtain an ultrasound plane consistent with CT/MR/PET plane (taking as the registration plane) from human body in ultrasonic scan.

#### NOTE:

- It is usually easier to obtain an optimum plane when the probe sweeps.
- The registration is only approved when the image is frozen after pressing <Freeze>.
- 8. Data registering (first time registering).
  - a. Tap [Registration] to activate the registration. Tap [View Type] to select.
  - b. To register the ultrasound image with the CT/MR/PET image, perform the following procedures to set CT/MR/PET image.
    - The icons for different plane operations appear after pressing <Set> for multiple times.

- Tap [View Type] to change the active plane of CT/MR/PET image (sagittal plane, transverse plane, coronal plane). Varied planes can be panned, scrolled or rotated through the axis.
- Rotate CT/MR/PET image axially (rotate the <C> knob to cycle through Z-axis). See XX for operations.
- Rotate [Fusion Ratio] to adjust the display ratio that the ultrasound image registers with the CT/MR/PET image. The ultrasound image and CT/MR/PET image are displayed well.
- Rotate <Zoom> on the control panel to zoom in or zoom out CT/MR/PET image;
- Rotate the knobs beneath [Offset X] and [Offset Y]. Pan the CT/MR/PET image.

- After tapping [Registration] each time, Tap [View Type]. It is convenient for panning or scrolling CT/MR/PET image.
- Do not move the magnetic generator and the patient for any circumstances after the registration accomplished. Otherwise, the registration display for CT/MR/PET image and the ultrasound image is affected.
- c. Tap [Confirm Registration] to complete registering. The ultrasound image and CT/MR/ PET image appear synchronously after the registration accomplishment.
- 9. Checking registration effect:

After completing 8th step (first registration), move the probe and adjust the probe scan angle and position. View the synchronous effect of varied planes (coronal plane, sagittal plane, transverse plane) from the ultrasound image and CT/MR/PET/freehand image.

Synchronous display effect: The Ultrasound System represents the ultrasound image and CT/MR/PET/freehand image synchronously after the ultrasound image and CT/MR/PET/freehand image are registered first time with the magnetic spatial positioning and in the aid of positioning (probe) sensor receiving the spatial message from the probe.

10. Fine tuning (second time registering):

If the ultrasound image and CT/MR/PET/freehand image are not registered precisely after first-time registering, perform the fine tuning operations below:

- a. Tap [Fine Tuning] on the touch screen. Press <Freeze> or tap [Freeze US] and [Freeze MPR] to freeze the image.
  - Unfreeze the ultrasound image (tapping [Freeze US] to dim the soft key).
  - For CT/MR/PET/freehand image is frozen, whereas the ultrasound image is not, take CT/MR/PET/Freehand image as the comparison reference (keeping CT/MR/PET/ freehand image still); tune the probe scan orientation and position to obtain the ultrasonic plane which is identical with that on the CT/MR/PET/freehand image (the ultrasonic plane moved).
  - Or, unfreeze the CT/MR/PET/freehand image (tapping [Freeze MPR] to dim the soft key).
  - For the ultrasound image is frozen, whereas the CT/MR/PET/freehand image is not, take the ultrasound image as the comparison reference (keeping ultrasonic plane still); tune the probe scan orientation and position to obtain the CT/MR/PET/
     Freehand plane which is identical with that on the ultrasound image (the CT/MR/PET/PET/Freehand plane moved).
- b. Tap [Confirm Registration] to complete the fine tuning.

- Use the plane concentrated with the patient's lesions to perform the fine tuning.
- The adjusting levels of the CT/MR/PET/Freehand plane and the ultrasound plane become finer after entering the fine-tuning. The ultrasound image and CT/MR/PET/ Freehand image can precisely be registered after several times of fine tuning.
- Freeze the ultrasound image and CT/MR/PET/freehand image simultaneously after the fine tuning. Tap [Confirm Registration] to make the fine tuning work.
- 11. Respiration compensation (it is suggested that the respiration compensation should be operated according to your demands).

The respiration compensation can possibly enhance the fusion accuracy of the ultrasound image and CT/MR/PET/Freehand image, and reduce the aspiration motion effects to the image.

See XX.

- 12. Conduct the ultrasonic exam and operation after the registration is completed.
- 13. Freeze the ultrasound image to save the single frame image or multi-frame cine.

#### **Contrast Fusion Imaging**

Contrast Fusion Imaging increases the possibility of diagnosing the difficult lesions in the preoperation; improves the accuracy to ablating the lesion in the intra-operation; estimates the therapeutic effect of the target in the post-operation.

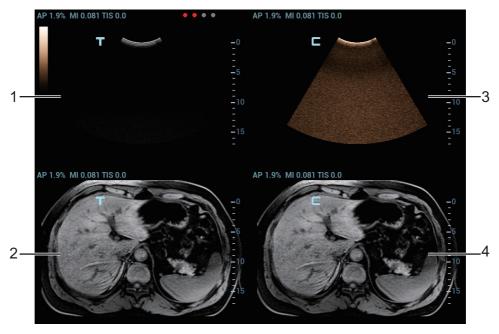
Perform the following procedure:

1. Tap [Contrast] to enter Contrast Fusion Imaging after the Fusion Imaging is registered.

Set fusion ratio. Adjust the display ratio of two split windows that the contrast image registers with CT/MR/PET/freehand image.

2. Contrast Fusion Dual Live:

Select [Contrast] > [Dual Live] to adjust the fusion ratio. Adjust the display ratio that tissue image registers with CT/MR/PET/freehand image (see Window 1 and window 2). Adjust the display ratio that contrast image registers with CT/MR/PET/freehand image (see window 3 and window 4).



3. Inject the contrast agent. Enable the timer, and save the dynamic image. Refer to "9 Contrast Imaging".

### Data registration of same patient/body part in different phases

When different phases of CT/MR/PET data from the same patient/body part exist and one CT/MR/ PET data has been registered already, system will register the data by previous information if other phases data are imported.

# 6.15.5 Acquiring/Importing Volume Data

### NOTE:

- Only support DICOM CT/MR/PET volume data, and cine format freehand volume data.
- The following CT/MR/PET volume data not accepted:
  - Slices less than 2.
  - Discontinuous or corrupted data.
  - Slice space not equal.
  - Slice distance is 0.
  - Data from varied alignment (tissue, plane).
- The liver enveloped in CT/MR/PET/freehand volume data.
- The registration effect will be better if the CT/MR/PET volume data already bears the data of Contrast Imaging with the ultrasound image.

## **Acquiring Volume Data**

• Acquiring volume data from network server

#### NOTE:

- It is only applied to the Ultrasound System that is configured with DICOM software package.
- The storage path should be short and clear for network server obtaining. Space or Chinese character is not allowed.
- Refer to "15 DICOM/HL7" to configure DICOM.

Perform the following procedure:

- a. Configure DICOM service and Query/Retrieve service.
- b. Load volume data to iStation.
- Acquiring volume data from external storage medium. Perform the following procedure:
  - a. Save volume data to USB disk, portable hard disk, optical disk, etc.
  - b. Press <F2 iStation> to enter the iStation page. Select from the drop-down list of the data source, such as USB.

c. Select the volume data disk from the drive drop-list (or portable hard disk, optical disk). Click [OK]. The icon appears after the volume data is acquired successfully.

Select DCM Files				
Drive	: G: USB			
Path				
	File Name	Туре	Date Modified	Size(KB)
		Folder		
			2021-01-08 17:11	
			2021-01-08 17:03	
				4 >
			ОК	Cancel

### NOTE:

- The icon i at the right lower corner of the screen shows the progress of the task. Click the icon to see the progress.
- The icon appears after all tasks are completed, which implies that the patient data are loaded to the ultrasound system successfully.
- The dialog box does not appear for:

If any file (Ultrasound patient data) is named with "LV" in the external storage medium, please rename the file, and conduct step 2. The dialog box given above appears then. If DICOMDIR volume data or backup file of the Ultrasound patient data is in the root directory of USB disk (portable hard disk, optical disk), the Ultrasound System does not pop up the path. However, volume data or patient data is loaded to iStation database.

d. Press <Esc> to return to iStation page. Press <F2 iStation> again to enter the iStation page. You can see the volume data which is loaded successfully.

### **Importing Volume Data**

Acquire volume data to iStation. Then, import the data to Fusion exam with the procedures below.

- 1. Press <Fusion> or user-defined <Fusion> key to enter Fusion Imaging mode. Tap [Load Volume Data]. The page appears as shown below. Select the CT/MR/PET/Freehand volume data, and click [OK].
- 2. Check "US--Patient Information" and "CT/MR--Patient Information". The information should be from same one patient (the name, the gender and DOB also should be from same one patient). Click [Accept] to load volume data.

P 93.33% MI 1.4 TIS 0.3 П

Volume data is loaded to Fusion Imaging exam. The page is given below:

### **Acquiring Freehand Volume Data**

Except importing existing volume data, the operator can also acquire freehand 3D cine on fusion imaging mode.

# 6.15.6 Marks

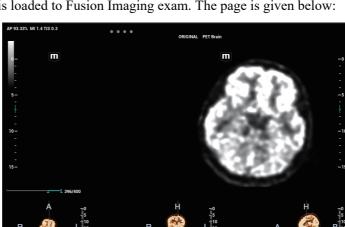
Mark tumor position, lesion position on CT/MR/PET/Freehand image. Be sure of the lesion appearing on US and CT/MR/PET/Freehand image at the same time after the registration is completed.

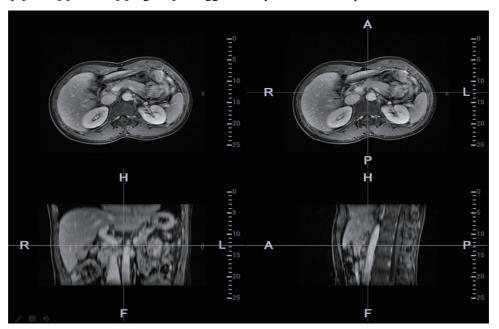
# TIP:

Mark the tumor or lesion on CT/MR/PET/Freehand image after CT/MR/PET/Freehand data is loaded. Generally, it is available to mark the tumor or lesion before/during/after the registration.

Perform the following procedure:

1. Tap [Mark on Volume Data] to enter the page. Select [Add Marks]>[Display Marks] to activate the mark.





Tap [Axial]/[Coronal]/[Sagittal] to toggle the top-left reference plane.

2. Press <Cursor> to show the cursor. Mark on the axial plane (top-right)/coronal plane (bottom-left)/sagittal plane (bottom-right). The procedures to make marks are given below:

#### NOTE:

- The Ultrasound System adds 3-dimesnsional sphere mark to CT/MR/PET/Freehand volume data. Set the target mark based on your sphere center and sphere radius.
- At least two CT/MR/PET/Freehand planes should be marked when performing manual tracing.
- a. Select "Manual tracing" or "Circle tracing" in the "Mark" drop-down list.

Circle tracing: Press <Set> to locate the center at the core of the lesion. Roll the trackball to adjust the radius. Envelop the tumor or the lesion with the circle. Double press <Set> to complete adding the mark.

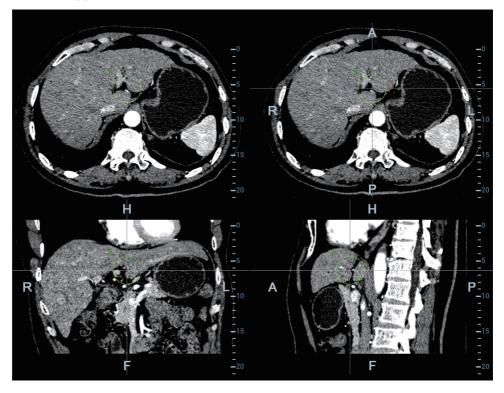
Manual tracing: roll the trackball to manually envelop the lesion. Rotate the <4D> key to scroll the CT/MR/PET/Freehand image and continue to mark the lesions. After lesions of all the desired CT/MR/PET/Freehand planes are marked, tap [Accept Slice Trace] to add marks.

b. Rotate [Ablative Margin] to add the ablative margin for this mark. See also "Ablative Margin" description below.

#### NOTE:

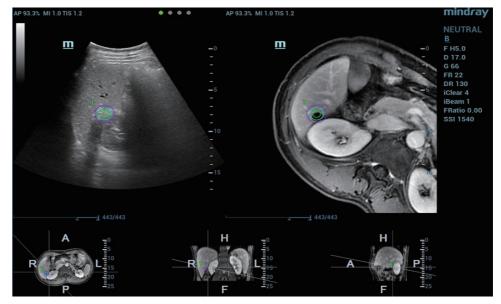
- The tumor infiltrates the neighboring organs, which leads to the tumor boundary unclear. The ablation scope is larger than practical tumor boundary's. The enlargement scope is called ablative margin.
- The ablative margin is about setting a safe boundary on the lesion which is already marked. It also implies another boundary mark outside the lesion mark on image.
- The ablative margin reminds of the narrowest boundary for surgical ablation. It takes significant effect on ablating the tumor.

c. Mark the tumor (a maximum of 20 tumors can be marked). The color of the mark can be green, blue, or red in turn. These colors appear in circle. The sphere diameter and ablative margin appear in the result window.



3. Click [Esc] to exit. Enter Fusion Imaging page. Move the probe to view the mark situation in varied planes.

The mark in the following figure is enveloped with three circles. There are real-time tumor, mark tumor (completed in step 3), and ablative margin from inside to outside.



## TIP:

It is not allowed to conduct other operations, such as, freezing, measuring, adding body mark, at the exception of adding the mark on the plane.

# Saving/Loading the Mark

Saving the mark

Enter tumor mark page. Mark varied tumors on CT/MR/PET/Freehand image. Tap [Save Marks] to type the mark name. Click [OK].

Save the tumor mark of the patient. It is convenient to load the tumor mark when conducting the tumor ablation for the patient.

### NOTE:

"Mark Group Name" is not permitted to have same name in all exams (including the exam ended) of one patient.

• Loading the mark

Tap [Load Marks]. All mark groups of previous exams of this patient are displayed. Select the mark group. Click [Import]. The marks are loaded to the CT/MR/PET/Freehand plane (in general, the marks saved in one week are loaded).

### Moving the mark

Select one tumor mark from the result window (the cross appearing in the circle). Move the cursor inside the circle. The cursor becomes arrow-shaped. Press <Set> to select the mark. Move the mark to the desired position. Press <Set> to relocate the mark.

### Removing the mark

- Select one mark from the result window (the cross appearing in the circle). Tap [Delete Cur.] to remove the tumor mark.
- Tap [Delete All] to remove all tumor marks.

### NOTE:

The button <Clear> is disabled when tumor mark is activated.

### **Displaying/Hiding the mark**

- Tap [Display Marks] to activate it. All tumor marks appear on CT/MR/PET/Freehand image.
- Tap [Display Marks] to dim it. All tumor marks hide on CT/MR/PET/Freehand image.

### Adding the comment

It is available to add the comment before adding tumor mark or after tumor mark is added.

# 6.15.7 Respiratory Compensation

#### TIP:

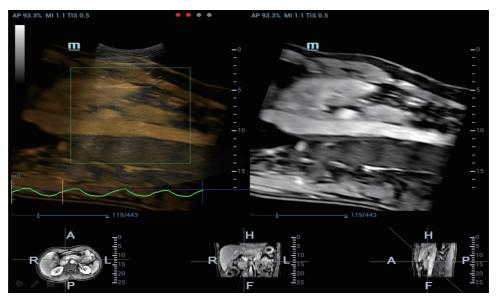
Stick respiration sensor to the patient's abdomen before entering Fusion Imaging mode.

Respiration Compensation sets a motion model for the movement regularities of the liver, and compensates the CT/MR/PET/freehand image in real time. The fusion dynamic accuracy is enhanced apparently.

Perform the following procedure:

- 1. Enter Fusion Imaging mode. Tap [Display Resp Curve] to activate it (it is highlighted by default). The respiratory curve appears on the image.
- 2. Keep the patient breathing regularly. Tap [Capture US & Resp] to capture the cine until the respiration curve becomes stable. Keep the probe still when capturing the cine. The progress

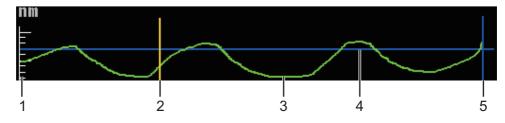
bar appears on the screen. The ultrasound cine plays automatically after the capturing is finished.



### NOTE:

The Ultrasound System selects one premium phase of respiration curve automatically after the capturing is finished. It is prepared for the motion modeling. You can set the start frame and end frame to select one phase of the respiration curve.

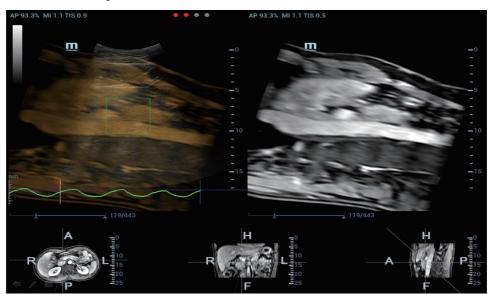
Respiration Curve Description:



No. Description	
1.	Respiration Curve Scale (respiration depth).
2.	Set Modeling start (start point of motion modeling of the respiration curve).
3.	The green curve is the respiration depth in real-time respiration.
4.	The blue curve is the respiration depth at last registration.
5.	Set Modeling End (end point of motion modeling of the respiration curve).

3. Tap [Set Modeling ROI] to highlight it (it is activated by default). Move the trackball to set ROI position and size.

Set ROI position and size. Envelope the liver with the ROI.



Press <Set> again to adjust ROI position and size, and to set the start frame and end frame of the motion modeling.

4. Tap [Motion Modeling]. If modelling succeeds, the system will play the cineloop automatically, and ROI moves along with the motion of the respiration curve.

### NOTE:

- RMQF scale is 0~1. 0 represents the poor motion modeling; 1 represents the premium motion modeling.
- Conduct step 3~4 repeatedly based on your demands. Set motion modeling repeatedly until a premium one appears.
- 5. Tap [Motion Compen] to activate it. Move the probe. The Ultrasound System shows the CT image which is processed by respiration compensation (Fusion Imaging with the respiration compensation).



6. Save multi-frame cine.

### **Respiration Range**

The aspiration curve appears due to the active respiration depth. The respiration curve beyond the scale becomes the straight line.

Rotate the knob beneath [Resp Range]. Respiration curve scale and the unit appear on the right-axis.

# 6.15.8 Freehand 3D

## NOTE:

The effect of freehand 3D image acquisition is dependent on the technique of the operator. Thus, there is a risk of low registration accuracy.

Perform the following procedure:

- 1. Select a proper probe and correct exam. Enter real-time B/Contrast mode (non-cardiac Contrast Imaging mode).
- 2. Get magnetic devices prepared. Connect the magnetic devices. Power on the magnetic navigator, and check if the indicator becomes green.
- 3. Tap [Freehand 3D] on B-mode/Fusion-mode/Contrast-mode tab of the touchscreen.

Entering freehand 3D mode under fusion imaging mode is preferred.

- 4. Capture images using linear scan or rocked scan.
  - Linear scanning

Move the probe across the surface slowly at a constant speed.



Rocked scanning

Rotate the probe once from the left to the right side (or from the right to the left) slowly at a constant speed to include the entire desired region.



5. After the acquisition is completed, the freehand 3D cine is automatically saved.

If the freehand 3D cine is captured under fusion imaging mode, the system automatically registers the ultrasound image with the freehand volume data after the acquisition is completed. Do not move the magnetic generator and the patient for any circumstances after the freehand 3D cine is captured. Otherwise, the registration display for freehand image and the ultrasound image is affected.

# 6.15.9 Parameter Settings

The parameters of the Fusion Imaging are described below:

## Nav System

Tap [Tracking System] to enable or disable the function.

CT/MR/PET/freehand image and the ultrasound image build up the coordinate relation. The sensor indicator becomes green (navigation signal state indicator).

## **Fusion Ratio**

Adjust the display ratio that the ultrasound image registers with the CT/MR/PET/freehand image. Rotate the knob beneath [Fusion Ratio] to set the ratio.

The adjusting range is  $-1 \sim 1$  in increments of 0.1.

• 0~1 represents that the ultrasound image registers with the CT/MR/PET/freehand image; the change of the fusion ratio appears on the right window side.

The larger the value is, the better the display effect becomes for the ultrasound image registering with the CT/MR/PET/freehand image; and vice versa. 0 only relates to CT/MR/PET/freehand image on the right window side and 1 only relates to ultrasound image on the right window side.

• -1~0 represents that the CT/MR/PET/freehand image registers with the ultrasound image; the change of the fusion ratio appears on the left window side.

The larger the value is, the poorer the display effect becomes for the CT/MR/PET/freehand image registering with the ultrasound image; vice versa. -1 only relates to CT/MR/PET/ freehand image on the left window side and 0 only relates to ultrasound image on the left window side.

## **Image Magnification**

The lesion or tumor ultrasound and CT/MR/PET/freehand image becomes clearer and easier to register via <Zoom> key.

Rotate <Zoom> to zoom in or zoom out the image. The parameter "Z" on the right side of the image refers to the magnification value.

## Toggling CT/MR/PET/Freehand Anatomical Plane

The Ultrasound System sets CT/MR/PET/freehand volume data to 3-dimensional image automatically after importing CT/MR/PET/freehand volume data. There are transverse plane, coronal plane, sagittal plane displaying from left to right at the bottom of the screen.

It is available to toggle and register among three planes.

Tap [View Type] to select the CT/MR/PET/freehand anatomical planes (among the sagittal plane, transverse plane, coronal plane).

## Window Width (Window W)/Window Level (Window L)

It is available to set CT/MR/PET/freehand image contrast via the window width.

It is available to set CT/MR/PET/freehand image grey scale via the window level.

• Window Width

Rotate [Window W] to set the value in increment of 1.

The larger the window width is, the poorer the image contrast becomes.

Window Level

Rotate [Window L] to set the value in increment of 1.

The darker image on CT/MR/PET/freehand image may be missed if the window level becomes larger. The image with brighter grey scale may appear then.

The darker scale on CT/MR/PET/freehand image may appear on the screen if the window level becomes smaller.

Tap [Window W/L Set by Trackball]. Move the trackball to set the window width and window level.

Move the trackball left; the window width becomes smaller, and the window level becomes larger; the image contrast becomes more visible.

Move the trackball right; the window width becomes larger, and the window level becomes smaller; the image contrast becomes poorer.

### Reset Width (Reset W)/Reset Level (Reset L)

It initializes the window width and window level of the CT/MR/PET/freehand image.

Tap [Reset Window W/L] to initialize the width/level of the CT/MR/PET/freehand image.

### **Reset CT/MR/PET/Freehand**

It initializes CT/MR/PET/freehand image when CT/MR/PET/freehand image is cycled axially, panned, scrolled or zoomed, etc., after CT/MR/PET/freehand volume data is imported to Ultrasound System.

Tap [Reset CT/MR] to initialize the CT/MR/PET/freehand image.

#### Tint Map

This function provides an imaging process based on color difference rather than gray distinction for CT/MR/PET/freehand image.

Rotate the knob under the [Tint Map] item on the touch screen to select the map. The system provides 8 different color effect maps.

Press the knob under the [Tint Map] item on the touch screen to turn on/off the function.

#### Single Window

If the feature is enabled, only the image at the upper left is displayed on the image area. Tap [Single Window].

#### Rotate 180°

This function is to rotate CT/MR/PET volume data 180 degrees before registration. Tap [Rotate 180°].

#### **B** Display

This function is to set whether to display B-mode image under Color fusion imaging mode.

Tap [B Display].

- If [B Display] is highlighted, the B-mode image is displayed.
- If [B Display] is not highlighted, the B-mode image is hidden.

# 6.15.10Rotating/Scrolling CT/MR/PET/Freehand Image

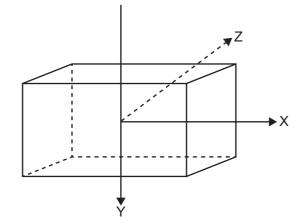
The Ultrasound System sets the CT/MR/PET/freehand volume data to 3-dimensional image after the CT/MR/PET/freehand image is imported to iStation.

Each of any CT/MR/PET/freehand anatomical planes (2-dimensional) appears on the screen via rotating or scrolling the CT/MR/PET/freehand image.

### Rotating CT/MR/PET/Freehand Cubic Image

Rotate the knob <M>, the knob <PW>, the knob <C> to cycle the CT/MR/PET/freehand cubic image through X-axis, Y-axis and Z-axis. The 2-dimensional CT/MR/PET/freehand anatomical plane cycles simultaneously.

The relations of X-axis, Y-axis and Z-axis are given below:



- Rotate the knob <M> clockwise to cycle CT/MR/PET/freehand image clockwise through Xaxis.
- Rotate the knob <PW> clockwise to cycle CT/MR/PET/freehand image clockwise through Yaxis.
- Rotate the knob <C> clockwise to cycle CT/MR/PET/freehand image clockwise through Zaxis.

### Offset X/Offset Y CT/MR/PET/Freehand Image

- It is available to offset CT/MR/PET/Freehand image through X-axis and Y-axis and obtain a proper position to register.
- Rotate [Offset X]/[Offset Y] to offset the CT/MR/PET image.

### Scrolling CT/MR/PET/Freehand Image

It is available to scroll one certain plane (sagittal/transverse/coronal) of CT/MR/PET/Freehand image on the Ultrasound System and obtain a desired CT/MR/PET/Freehand plane to register.

- Rotate the <4D> key clockwise. The transverse plane moves towards the patient's head. The R~L axis and A~P axis on the transverse plane move towards the patient's head.
- R~L axis, A~P axis correspond with the axe of coronal plane and sagittal plane. R~L axis of coronal plane and A~P axis of sagittal plane move towards the cephalosome.

# 6.15.11Measuring

It is available to conduct the general measurements on the image that the ultrasound image registers with the CT/MR/PET/freehand image.

# 6.15.12Comment and Body Mark

It is available to conduct the comment and the body mark on the image that the ultrasound image registers with the CT/MR/PET/freehand image.

# 6.16 Smart Fetal HR (Heart Rate)

## NOTE:

• This feature is available only under Fetal Echo (High Flow), OB1 Fetal Echo, Fetal Echo (Low Flow) exam modes.

• During image acquisition, the user is recommended to stably hold the ultrasound probe to acquire fetal heart ultrasound video. If the Smart Fetal HR measurement is not satisfactory (e.g., the heart rate cycles are not marked accurately on the M-mode image), the user can manually modify the sampling lines of heart rate cycles on the M-mode image or change the number of heart rate cycles. The fetal heart rate measurement result will be updated simultaneously.

This feature is to measure the fetal heart rate automatically on M mode.

Perform the following procedure:

- 1. Perform B-mode scanning under Fetal Echo (High Flow), OB1 Fetal Echo, Fetal Echo (Low Flow) exam mode.
- 2. Tap [Smart FHR], and the button is highlighted.
- 3. Press <M> on the control panel, and the system acquires M-mode image automatically. The M mode image and the sampling line are displayed on the screen.

If necessary, tap [Smart FHR Cycle] to set the number of heart rate cycle.

4. Press <Freeze> on the control panel. The heart rate cycles are marked on the M-mode image. And the fetal heart rate measurement result is displayed on the screen.

If necessary, tap [Smart FHR Cycle] to set the number of heart rate cycle, and the measurement result is updated simultaneously.

# 6.16.1 iPage

### **Operation Procedures**

Perform the following procedure:

- 1. Tap [iPage] on the touch screen.
- 2. Check A/B/C sectional planes, and select the reference image. Confirm if the slices displayed are the target planes, if not, re-select the reference image again.
  - If [Ref MPR] is set to A, and [Vertical Dir] is selected, B sectional planes are displayed on the right.
  - If [Ref MPR] is set to A, and [Horizontal Dir] is selected, C sectional planes are displayed on the right.
  - If [Ref MPR] is set to B, and [Vertical Dir] is selected, A sectional planes are displayed on the right.
  - If [Ref MPR] is set to B, and [Horizontal Dir] is selected, C sectional planes are displayed on the right.
  - If [Ref MPR] is set to C, and [Vertical Dir] is selected, B sectional planes are displayed on the right.
  - If [Ref MPR] is set to C, and [Horizontal Dir] is selected, A sectional planes are displayed on the right.
- 3. Observe the interested structure through multiple slices and perform parameter settings.

### Layout

The system supports several types of displaying layout: 2\*2, 4\*4 and 5\*3, touch the corresponding icon on the touch screen to select.

### Slice and slice line

• Central slice: the central slice line corresponding plane are the central slice.

- Tap [Vertical Dir] to place the slice lines vertically, and touch [Horizontal Dir] to place the slice lines horizontally.
- Active slice: the green slice line corresponding plane is the active slice, which is marked with a green box. The default active slice is the central slice.
- Slice order number: indicating the order of the slices, the order of central slice is "0", the slices before the central slice are marked with negative integral numbers, and the slices after the central slice are marked with positive integral numbers.
- Slice position (to the central slice): displayed at the upper left corner of each image, indicating the position of each image (such as -6mm, -3mm, 3mm, 6mm).
- Coordinate axis: indicated on the A, B, C three reference images, match together with the central slice line, and will move accordingly with the central slice line.

### Slice shifting

Tap [Translation] to enable slice-shifting feature. Roll the trackball to shift the crossing point of central axis up/down, left/right, and the slice lines will shift accordingly with the crossing point.

### **Slice position**

Rotate the knob under [Slice Position] to move the active slice line (red) either forward or backward within the range, then the corresponding slice will be highlighted in red.

### Spacing

The value is displayed at the upper right side of the slice, unit: mm. Adjust it through touch screen selection [Spacing].

# 6.17 iWorks (Auto Workflow Protocol)

The main objective of ultrasound workflow automation (iWorks) is to speed up exam times and reduce the excessive number of user interface manual key strokes that can lead to repetitive strain injuries over time. It automates a clinical workflow in common exam protocols in a logical "step by step" manner. It also prevents missing important parts of examinations as well as decreasing exam times.

A Protocol Event contains series workflow events (annotation comments, body marks and measurements) and image modal commands to assist the user in routine ultrasound examinations.

### NOTE:

- The system provides different protocol events based on the different application regions.
- You can press the user-defined keys for iWorks operations.

Perform the following procedure:

- 1. Input the patient information.
- 2. Tap [iWorks] on the touch screen or press the user-defined key for "iWorks" to enter the protocol selection screen, and tap the corresponding protocol button to enter the status.

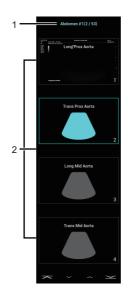
After the system enters the iWorks screen, the available protocol is displayed on the right of the screen.

- 3. Perform the scanning and saving according to the screen prompt.
- 4. Perform measurements or add comments/body marks to the image according to the screen prompt.

- 5. After a view scanning is complete, press the [Next] on the touch screen to switch to the next view according to the screen prompt.
- 6. Repeat steps 3 to 5 to acquire all the necessary images.
- 7. After all views are finished, the system will prompt you to exit iWorks. Tap [Yes] to exit.

# 6.17.1 Screen Display

The monitor displays the following screen:



1	Displays the protocol name, and the number of views contained.
2	Displays the view steps in the protocol. The current active view with a solid frame around the image.

# 6.17.2 View Operation

In iWorks status, you can perform view selection, repeat, replacement and delete operations using the touch screen.

For some views, the system switches to the relevant imaging modes if necessary.

The comment for the current view has been automatically added to the bottom-left corner of the image, ready for you to scan the specified anatomy.

### **View Selection**

Tap [Prev]/[Next] to select the view to be scanned. The current view is surrounded by a solid frame.

### **View Operation**

In the current active view, you can perform image scanning, measurements, and adding comments and body marks, etc. Operations are the same as those for manual operation. See the relevant chapters for details.

### **Repeat View**

If the current view has been performed, you can touch [Repeat] to insert another template of the current view and then perform an extra examination. If the current view has not been performed, you can touch [Repeat] to insert another template of the previous view.

## **View Replacement**

The previous image will be deleted and replaced by the new image.

## **Delete View**

Tap [Prev]/[Next] to select the view to be deleted. Tap [Delete] to delete the selected view.

# 6.17.3 Manual Examination

Suspend - Exit the protocol so the user can run the system manually. This is used when an unusual or atypical workflow is required.

- Start manual examination: tap [Suspend] to pause the current iWorks protocol. The system enters manual examination status.
- Return to iWorks: tap [Resume iWorks] to return to automated status. You can continue the previous iWorks scan.

# 6.17.4 Insert

Insert is a specialized protocol event within iWorks and iWorks OB. It assists with the workflow for documenting and measuring common pathological (disease) states (i.e. Mass, Cyst, Stenosis, Thrombus) that occurs outside a routine, normal examination.

Perform the following procedure:

- 1. Tap [Insert] on the touch screen to enter the status.
- 2. Select the necessary protocol and the system adds the protocol events to the current protocol.
- 3. Perform measurements or add comments/body marks to the image if necessary.

# 6.17.5 Create

The ultrasound system supports creating a user-defined iWorks protocol based on user's habits.

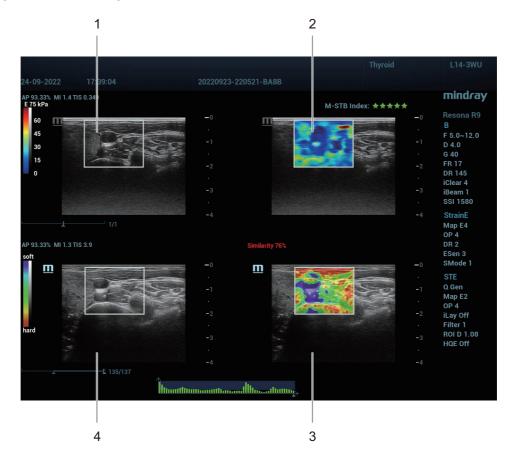
- 1. Tap [Create] on the touch screen.
- 2. Press the knob under [Start] to start creating an iWorks protocol.
  - During creating, the red button of REC on the touch screen is blinking.
  - Press the knob under [New Group] to add more groups.
  - Press the knob under [Pause] to pause the creating.
  - Press the knob under [Continue] to continue the creating.
- 3. Press the knob under [Stop] to enter Protocol Setup and Review page.
  - You can rename Groups, Views, or Protocols.
  - Select type from the drop-down list as Sequence, Random, or Insert Protocol.
  - Tap or click [Save] to temporarily save the creating.
- 4. Tap or click [Generate Protocol] to generate a user-defined iWorks protocol.

# 6.18 M-Reference

# 6.18.1 M-Ref. E Compare

It is used to analyze the tissue stiffness by STE and StrainE jointly in the same screen.

# E Compare (Non Real Time)



1.	B mode image
2.	STE image
3.	StrainE image
4.	B mode image

Perform the following procedure:

1. Open a saved STE single frame image or cine file. Or perform STE imaging and freeze the image. For details, see "8.2.1 Basic Procedures for STE Imaging".

#### NOTE:

The image should be saved under an appropriate probe and exam mode.

2. Select [E Compare].

The quad windows of B+STE and B+StrainE images are displayed. The depth and ROI of StrainE are automatically matched to those of STE.

3. Move the probe to find the plane of high similarity between StrainE and STE, and adjust the StrainE ROI size.

The similarity value between StrainE and STE is displayed in real time.

- 4. Press the probe gently and stably to acquire the StrainE image.
- 5. Freeze the image.

- 6. Play the cine file to select an image with good similarity, and then perform measurement.
- 7. Save a single frame image or cine file.

# E Compare Live (Real Time)

## NOTE:

- You can enter E Compare Live from STE or StrainE. Entering from STE is taken as an example.
- You can enter E Compare Live in elasto acquisition preparation mode or after acquisition. Entering after acquisition is taken as an example.



1.	StrainE image
2.	STE image

Perform the following procedure:

- 1. Select a proper probe. Perform 2D scan to locate the region.
- 2. Tap [Elasto] > [STE] on the touch screen. Or press the user-defined <STE> key to enter the STE mode.

The dual windows of B+STE images are displayed.

- 3. Adjust the ROI size and position, and press <Update> to start acquisition.
- 4. Select [E Compare Live].

The dual windows of StrainE+STE images are displayed. The depth and ROI of StrainE are automatically matched to those of STE.

5. Press the probe gently and stably to acquire the image.

- 6. Freeze the image.
- 7. Play the cine file to select a high quality image, and then perform measurement.
- 8. Save a single frame image or cine file.

### **Display B**

It is used to select whether to display the B mode images in a quad window.

### Similarity

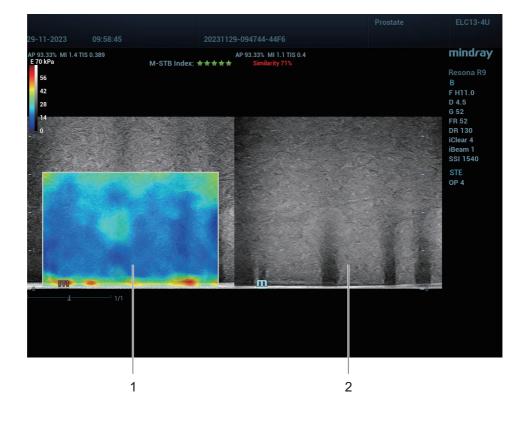
It is used to indicate the similarity between STE and StrainE images based on plane matching condition of tissue form. The higher the matching degree of the STE and StrainE planes, the larger the value.

### NOTE:

Other parameters are the same as those of the Elasto or STE/STQ modes.

# 6.18.2 M-Ref. E Biopsy

It is used to guide the plane of the systematic prostate biopsy based on the STE plane with the plane matching method, so that the biopsy plane is consistent with the STE plane.



1.	STE image
2.	B mode image

Perform the following procedure:

- 1. Select the ELC13-4U probe and prostate exam mode, and then switch to the linear plane.
- 2. Perform 2D scan to locate the region.

3. Tap [Elasto] > [STE] on the touch screen. Or press the user-defined <STE> key to enter the STE mode.

The dual windows of B+STE images are displayed.

- 4. Adjust the ROI size and position, and press <Update> to start acquisition.
- 5. Freeze the image and save a single frame image.
- 6. Unfreeze the image, and repeat steps 4-5 to acquire images of all necessary planes for systematic prostate biopsy.
- 7. Open the saved single frame image and select [M-Ref. E Biopsy].

The dual windows of STE+B images are displayed.

8. Move the probe to find the plane of high similarity between B and STE.

The similarity value between B and STE is displayed in real time.

- 9. Perform biopsy procedure and save the biopsy images.
- 10. Select the single frame image of other planes in the touch screen in turn.

The STE images in the left window is updated synchronously.

- 11. Repeat steps 8-10 to finish the biopsy procedure for all planes.
- 12. Freeze the image and exit M-Ref. E Biopsy.

### Similarity

It is used to indicate the similarity between STE and B images based on plane matching condition of tissue form. The higher the matching degree of the STE and B planes, the larger the value.

### NOTE:

Other parameters are the same as those of the Elasto or STE/STQ modes.

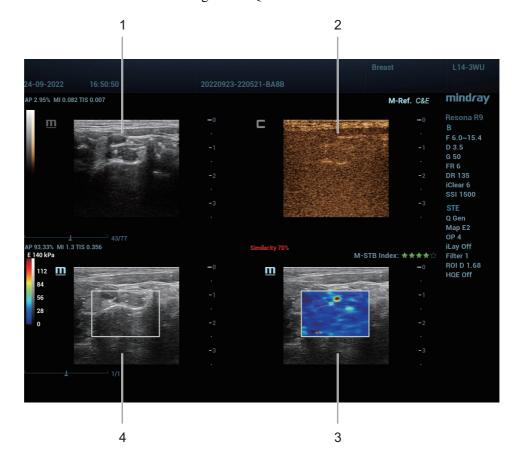
# 6.18.3 M-Ref. C&E

This function is used to display planes of Contrast images and STE images in real time. Based on the matching information, the system acquires Contrast images and STE images of the same plane respectively in turn and displays them at the same time. Also, it performs synchronous quantitative measurement to acquire Contrast imaging and STE imaging parameters of the target tissue in the same region.

#### NOTE:

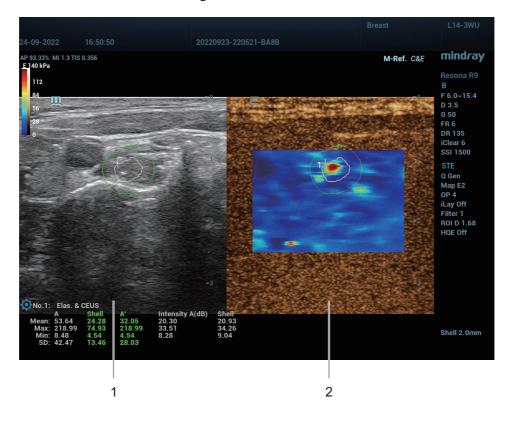
You can either enter M-Ref. C&E from Contrast image or Contrast Imaging QA images. Entering from Contrast imaging is taken as an example.

### Figure 6-1 Quad Window



1.	Tissue image
2.	Contrast image
3.	STE image
4.	B mode image

#### Figure 6-2 Mix Window



1.	B mode image
2.	Mixed image of Contrast and STE

Perform the following procedure:

1. Open a saved Contrast single frame image or cine file. Or perform Contrast imaging to acquire images. For details, see "9.1 Basic Procedures for Contrast Imaging".

### NOTE:

The image should be saved under an appropriate probe and exam mode.

- 2. Play the multi-frame images and move the cursor to select a frame.
- 3. Select [M-Ref.C&E] to enter acquisition preparation status.

The quad windows of Tissue+Contrast and B+STE images are displayed.

- 4. Move the probe to find the plane of high similarity between Contrast and STE images, and adjust the STE ROI size.
- 5. Press <Update> to start acquisition.

The similarity value between Contrast and STE is displayed in real time.

- 6. Freeze the image and enter measurement.
- 7. Tap [Elas. & CEUS] to perform measurement for Contrast and STE at the same time.
- 8. Save a single-frame image or cine file.
- 9. Exit the measurement status, and tap [Mix] on the touch screen.

The quad window is switched to dual window. Adjust the parameters if necessary.

- 10. Save a single-frame image or cine file. Tap [Mix] again to exit the Mix mode.
- 11. Repeat the above steps for other Contrast multi-frame images.

### Mix

It is used to enable or disable mix mode. In mix mode, the left window is the B mode image and the right window is the mixed image of Contrast and STE.

# NOTE:

Other parameters are the same as those of the Contrast imaging mode.

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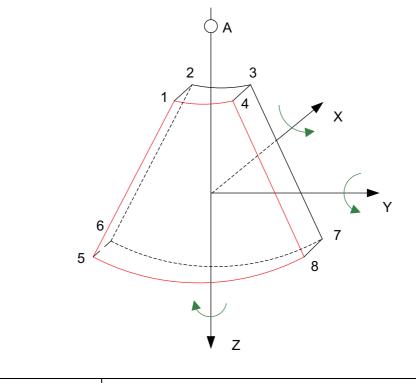
# NOTE:

3D/4D imaging is largely environment-dependent, so the images obtained are provided for reference only, not for confirming a diagnosis.

# 7.1 Overview

The ordinary 2D imaging has the limitations on viewing the overall structure and different planes of the target. However, 3D imaging can obtain the reference information by overall observation.

# 7.1.1 Terms



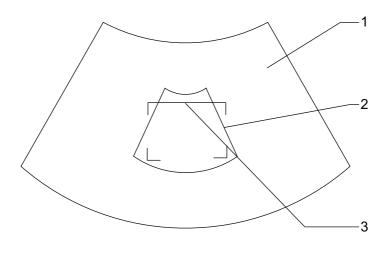
A View point

- Volume data: to obtain the data collection of three-dimensional object via the sequence reconstruction to two-dimensional object.
- 3D image Volume Rendering (VR): the 3D image on the screen.
- View point: the position for viewing volume data/3D image.
- MultiPlaner Rendering (MPR): a tangent plane of the 3D image that obtained by algorithm.Of which, XY-paralleled plane is C-plane, XZ-paralleled plane is B-plane, and YZ-paralleled plane is A-plane.YZ-paralleled plane is B-section. The probe is moved along the X-axis.

- ROI (Region of Interest): a volume box used to determine the height and width of scanning volume.
- VOI (Volume of Interest): a volume box used to display 3D image (VR) by adjusting interesting region in MPR.

# 7.1.2 ROI and VOI

After the system enters 3D/4D imaging, a B image with ROI displays on the screen. A line (shown in the following figure) that shows the upper edge position of VOI is inside ROI.



1	B image	2	ROI
3	Cut plane		

- ROI adjustment: roll the trackball to change the ROI size and position, press <Set> to toggle between setting the size (dotted line) and position (solid line).
- Curved VOI adjustment: change the curved shape of the nearest VOI section (front section), to facilitate observation for the interested volume data. It can be adjusted both in acquisition preparation status, and in A, B, C sections of review/ 4D imaging status, while a triangle of control point on the curved VOI is displayed.

Depending on the view direction, the orientation and the shape (line or dot) of curved VOI vary:

View	Curved VOI	
U/D	At the upper part of curved VOI	
D/U	At the lower part of curved VOI	
L/R	At the left part of curved VOI	
R/L	At the right part of curved VOI	
F/B	Displays as a dot	
B/F	Displays as a dot	

# NOTE:

To define a ROI, please remove the useless data as to reduce the volume data and shorten the time for image storing, processing and reconstruction.

# 7.1.3 About the probes

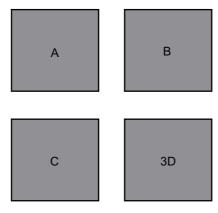
A 2D imaging probe can be applied for Smart 3D imaging, however, to realize Static 3D imaging, 4D imaging, STIC, iPage, SCV, CMPR, Color 3D or Niche, a volume probe should be selected.

A 2D imaging probe can be applied for Smart 3D imaging, however, to realize Static 3D imaging, 4D imaging, iPage, SCV, CMPR, Color 3D or Niche, a volume probe should be selected.

# 7.1.4 MPR

MPR represents three different views of 3D image.

In the quad display format view, the screen displays 3 MPRs (A, B and C) and the 3D image.

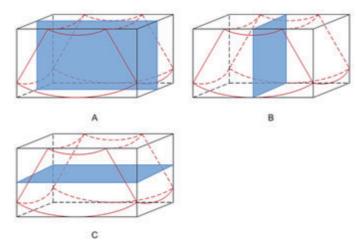


А	A window	В	B window
С	C window	3D	3D window (VR)

On the touch screen, the current window's icon is highlighted; as shown in the figure below, A window is the currently activated window.



A, B, C sectional images are corresponding to the following sections of 3D image.



- Section A: corresponds to the 2D image in B mode. Section A is the sagittal section in fetal face up posture, as shown in the figure A above.
- Section B: it is the horizontal section in fetal face up posture, as shown in the figure B above.
- Section C: it is the coronal section in fetal face up posture, as shown in the figure C above.

The upper part of the 3D image in the 3D window is corresponding to the orientation mark on the probe, if the fetal posture is head down (orientating the mother's feet), and the orientation mark is orientating the mother's head, then the fetus posture is head down in the 3D image, you can make the fetus head up by rotating the 3D image by taping  $[180^\circ]$  on the touch screen.

# **ACAUTION**

The ultrasound images are provided for reference only, not for confirming a diagnosis. Please use caution to avoid misdiagnosis.

# 7.1.5 Free View

With this function, probe scanning direction can be controlled just by changing the probe scanning angle, the interested image can be easily found without any actual probe position and direction change. It not only reduces the operations, but most importantly, it decreases the discomfort of patients resulted from probe moving.

When the intra-cavity 4D probe is activated, the parameter [Free View] can be adjusted on the B image touch screen for adjusting the probe angle.

Range:  $-45^{\circ}$  to  $+45^{\circ}$ .

In increments of 5°.

# 7.1.6 Wire cage

When you view a 3D image on the display monitor, it's sometimes difficult to recognize the orientation. The system displays a three-dimensional drawing to illustrate the orientation for help. Of which, the blue plane presents the image acquisition where started, while the red plane presents the image acquisition where ended. Besides, a yellow plane in the wire cage presents the position of the MPR.

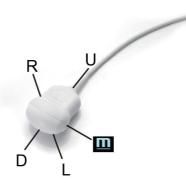


# 7.1.7 Orientation Assistance

With this function, the relative position of the target and the probe is indicated on the image, which is a convenience for the operator to understand the relative position of the target, MPR images and the VR image.

Tap [Orientation Assist] on the 3D/4D acquisition status, and the orientation marks are shown on the image.

Take a volume probe as example, the meanings of orientation marks are as follows.



M: the front of the probe, when the operator holds the probe and the probe mark points forward.

U: the side of the probe cable.

D: the side of the probe head.

R: the right of the probe, when the operator holds the probe and the probe mark points forward.

L: the left of the probe, when the operator holds the probe and the probe mark points forward.

# 7.2 Note before Use

The quality of images reconstructed in the freehand 3D mode is closely related to the fetal condition, angle of a B tangent plane and scanning technique. The following Smart 3D description uses the fetal face imaging as an example, the other parts imaging are same as 3D/4D imaging.

### NOTE:

- In accordance with the ALARA (As Low As Reasonably Achievable) principle, please try to short the sweeping time after a good 3D imaging is obtained.
- A region with qualified image in B mode may not be optimal for 3D imaging. E.g. adequate AF isolation for one section plane of 2D image doesn't mean the whole desired region is isolated by AF for 3D imaging.
- More practices are needed for a high success of qualified 3D imaging.
- Even with good imaging condition, to acquire an approving 3D image may need more than one scanning.

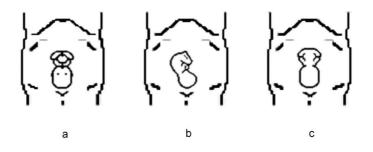
## **Fetal Condition**

Gestational age

Fetuses of 24~30 weeks old are the most appropriate to 3D imaging.

• Fetal body posture

Recommended: Cephalic face up (figure a) or face aside (figure b); NOT recommended: Cephalic face down (figure c).



- Amniotic fluid (AF) isolation
  - The region desired is isolated by amniotic fluid adequately.
  - The region for imaging is not covered by limbs or umbilical cord.
- The fetus keeps still. If there is a fetal movement, you need a rescan when the fetus is still.

### Angle of a B tangent plane

The optimum tangent plane to the fetal face 3D imaging is the sagittal section of the face. To ensure high image quality, you'd better scan maximum face area and keep edge continuity.

## Image quality in B mode (2D image quality)

Before entering 3D capture, optimize the B mode image to ensure:

- High contrast between the desired region and the amniotic fluid surrounded.
- Clear boundary of the desired region.
- Low noise of the amniotic fluid area.

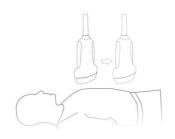
# Scanning technique (only for Smart 3D)

- Stability: body, arm and wrist must move smoothly, otherwise, the restructured 3D image distorts.
- Slowness: Move or rotate the transducer slowly. The speed of linear scan is about 2 cm/s and the rotation rate of the fan scan is about  $10^{\circ}/s \sim 15^{\circ}/s$ .
- Evenness: move or rotate the transducer at a steady speed or rate.
- Method

Capture images using Linear scan or Rocked scan.

– Linear scanning

Move the probe across the surface.



Rocked scanning

Rotate the probe once from the left to the right side (or from the right to the left) to include the entire desired region.

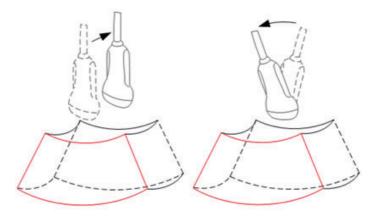


• Scanning plane and probe movement

Move the probe across the body surface.

The arrow in the figure below indicates the movement of the probe.

You can move the probe in the opposite direction to the arrow.



# 7.3 Static 3D

Static 3D provides single frame image acquisition of 3D images. During the scanning; the probe performs the scanning automatically.

# 7.3.1 Basic Procedures for Static 3D Imaging

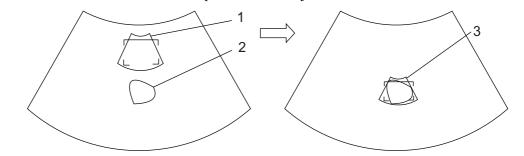
Perform the following procedure:

- 1. Select the proper probe and exam mode; make sure there is sufficient gel on the probe for scanning.
- 2. Obtain a 2D image, and optimize the image if necessary.
- 3. Press 🖫 🌑 🛱 to enter Static 3D mode, and define the ROI and curved VOI.

Methods to adjust the ROI:

- Under acquisition preparation status: Roll the trackball to change the ROI size, position
  and curved VOI, press the right <Set> key to toggle among setting the ROI position, size
  or curved VOI. Press the left <set> key to adjust VOI angle.
- Tap [Flip VOI] to flip VOI. Tap [Reset VOI] to reset the angle of VOI to the original status.
- Enter touch screen mapping mode.

Draw a circle on the desired area. Move ROI over the circle to adjust the size and position of ROI. Roll the trackball or press <Set> to adjust ROI.



-	1	ROI	2	Draw a circle here
-	3	ROI cover this area		

			2	
1	Cross cursor on the VOI curve	2	ROI	

Move the cursor over the VOI, and move the cursor to the desired area to adjust the VOI curve.

To setting the ROI, make sure:

- Set ROI on the 2D image with the largest section area of the fetal face.
- Set ROI a little larger than the fetal head.

#### NOTE:

To define a ROI, please try to cut the useless data as to reduce the time for image storing, processing and reconstruction.

- 4. Select the render mode, and set the quality and angle parameter.
- 5. Press <Update> to start capturing 3D.

During the acquisition, a progress bar is displayed to indicate the acquisition progress.

The system enters into 3D image review status when the acquisition is completed.

In image review status, you can perform operations like VOI setting, parameter adjustment, comments, image saving, image cutting, etc. For details, please see "7.3.3 Static 3D Image Viewing".

6. Exit static 3D.

Press <B> or press 2 to exit Static 3D mode. It returns to B mode.

# 7.3.2 Static 3D Acquisition Preparation

Use the touch screen to select render mode in acquisition preparation status.

Parameters of Static 3D Acquisition Preparation

Туре	Parameter	Description
Parameter adjusting	3D/4D Scenario Setting	Select 3D/4D scenario based on different scenario application.
	Quality	To adjust the image quality by changing the line density. Image quality can affect the imaging speed that the better the image quality is, the longer the time needs. Tap [Quality] on the touch screen, or, rotate the
	Angle	corresponding knob below the touch screen.To set the motion angle the probe covered during a fan sweep.
	Mix	Set the Mix ratio of main render to sub render.

Туре	Parameter	Description	
Main/Sub Render	Surface	Set Surface as 3D image rendering mode. Applicable for surface imaging, such as fetus face/hand or foot.	
		NOTE:	
		You may have to adjust the threshold to obtain a clear body boundary.	
	Max	Set Max as 3D image rendering mode, displays the maximum echo intensity in the observation direction. This is helpful for viewing bony structures.	
	Min	Set Min as 3D image rendering mode, displays the minimum echo intensity in the observation direction. This is helpful for viewing vessels and hollow structures.	
	X ray	Set X-ray as 3D image rendering mode. Displays the average value of all gray values in the ROI. This is used for imaging tissues with different structure inside or tissues with tumor.	
	iLive	Add the light rendering effect based on the general rendering effect. iLive cannot be selected as sub render mode. When it is set as main render mode, the sub render mode is disabled.	
STIC		novements of the fetus, rebuilt and show the anatomical structure cal movement by using the interconnection between the time and	

# 7.3.3 Static 3D Image Viewing

## To enter/exit image viewing

- Enter: The system enters image viewing when 3D image acquisition is finished.
- Exit: Press <Freeze> or <Update> to return to image acquisition preparation status and to exit image reviewing.

## Activate MPR

Tap [A], [B], [C] or [VR] to activate sectional plane image (MPR) or 3D image (VR).

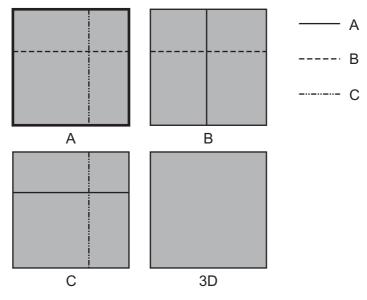


### **MPR Viewing**

In actual display, different colors of the window box and the section line are used to identify the section A, B and C.

- The color of window A is blue, and the color of the lines (representing section A) displayed in the other two windows is blue as well.
- The color of window B is yellow, and the color of the lines (representing section B) displayed in the other two windows is yellow as well.
- The color of window C is orange, and the color of the lines (representing section C) displayed in the other two windows is orange as well.

Positions of the other two sectional planes are indicated in the selected plane. You can roll the track ball to change the position.



# **MPR Only**

Tap **\_\_\_\_\_** on the touch screen to display section images. And the adjustable image parameters are changed into MPR parameters automatically.

Only A, B and C section images are displayed, and 3D image is not displayed.

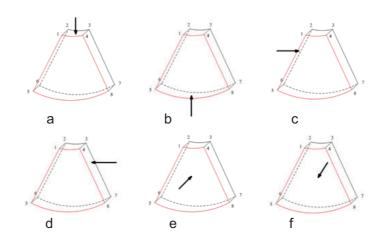
# Asymmetric

Tap on the touch screen to display section images along with 3D image.

### **View Direction**

The Region of Interest (ROI) contains the section of the volume you want to render. You can adjust the view direction of the ROI.

The system supports the observation of 3D/4D image from 6 directions.



a Up/Down	b Down/Up	c Left/Right
d Right/Left	e Front/Back	f Back/Front

Select [Up/Down], [Left/Right] or [Front/Back] on the second page to select the direction of the figure a, c and e.

Tap [Flip] on the first page to observe by the converse direction of the current direction, which is equivalent of the 180° rotarion of current VOI.

## **Adjust VOI**

Adjusting the VOI box size and position is to select the volume data needed to restructure the 3D image and improve the reconstruction effect.

• VOI On

3D image (VR) image displays VOI information.

- a. In image viewing status, set [VOI] to be "On".
- b. Select a desired section plane by tapping [A], [B] or [C] or [VR].
- c. Roll the trackball to adjust VOI position, size and curved VOI, and press <Set> to toggle among the adjusting status; or you can rotate <4D> knob on the control panel to adjust section image position.
- VOI Off

3D image (VR) image displays ROI information.

set [VOI] to be "Off", then the ROI image is displayed on the screen, roll the trackball to observe section images.

## Accept VOI

This function is usually used for section image observation and to determine the relative position of the section image to the VR.

- 1. Set [VOI] to be "Fixed".
- 2. Select a desired MPR image by taping [A], [B] or [C].
- 3. Roll the trackball to view the current active section image, and the other section images change correspondingly. Or you can rotate the 4D knob to adjust the relative position of section image.

In Accept VOI status, when the 3D image is active or the section image which is perpendicular to the view direction is active, center point of the 3D image displays, and you can adjust the position by rolling the trackball.

# The adjustment of Rendering Parameters

In image viewing status, you can render the image by adjusting the relevant parameters.

Tap [VR] or [MPR] on the touch screen to select the VR parameter or MPR parameter.

- When [VR] button is highlighted in green, adjust parameters of 3D image (VR).
- When [MPR] button is highlighted in green, adjust parameters of sectional image.

You can adjust:

Parameter	Description
Threshold	<ul> <li>To set the threshold for 3D image rendering.3D image is rendered on the signal above thresholds by eliminating noise via the Threshold parameter. Lower threshold can eliminate lower range noises and echo, which will contribute to a clearer and smoother image.</li> <li>Available only in Surface rendering mode.</li> </ul>
Opacity	<ul> <li>To adjust the transparency value for 3D image rendering. It implies the transparency of the light. The higher the value is, the tougher the surface becomes.</li> <li>The lower the number is, the more transparent the gray scale information will be.</li> <li>Available only in Surface rendering mode.</li> </ul>
Smooth	<ul><li>To set the smoothness of 3D image.</li><li>0 refers to no smooth effect.</li></ul>
	NOTE:
	Insufficient smoothness can result in a fuzzy image; however, too much smoothness will lead to image distortion.
Brightness	To set the brightness of image.
	• 0% represents the minimum brightness, while 100% represents the maximum.
	NOTE:
	The adjustment for 3D (VR) and MPR.
Contrast	• Set the contrast scale of the image (contrast).
	• As long as the contrast becomes larger, the bright spot and dark spot on the image change as well.
	NOTE:
	The adjustment for 3D (VR) and MPR.
Tint	Enable/disable tint map. The color of image changes according the tint value.
Quick Rotation	Tap $[0^\circ]$ , $[90^\circ]$ , $[180^\circ]$ , or $[270^\circ]$ to rotate the 3D image quickly.

Parameter	Description			
3D iClear	• Function: Use the 3D self-adaptation filter to strengthen the space continuity of the tissue structure, and provide speckle noise suppression, and improve the image contrast effect, so as to optimize the volume image data.			
	• Select VR image. Adjust 3D iClear to optimize VR image.			
	Select MPR image. Adjust 3D iClear to optimize MPR image.			
Face <sup>+</sup>	Optimize the signal of the face area to reduce the noise of the AF area and improve the signal-noise ratio of the face area, make the face more fullness to easily obtain the image of fetal face.			
VR Refine	Optimize the signal-noise ratio and the contrast of VR image.			
MagiClean	Reduce the noise and keep the boundary of the image more clearly.			
	Available only in Surface rendering mode.			
Depth VR	Superimpose the tint map basic on the VR image to improve the stereoscopic sensation and the contrast of the image.			
Hyaline	• Function: Improve the transparency in iLive rendering mode to observe the tissue, such as cyst.			
	• Adjust method: The merging ratio of two render modes between Hyaline and iLive is 100%.			
	• Effect: Adjust the merging ratio of two render modes between Hyaline and iLive			
Thickness	Adjust the rendering thickness of the section.			

# **Reset Curve**

Parameter		Description			
Reset	Ori	To reset the volume rotation, shifting and zooming of 3D image to original status.			
	All	To reset the parameters, rendering rotation, VOI and image effect.			
	Curve	To reset the curve to be the original beeline.			

### **Render Mode**

The rendering manners can be applied to both gray and inversion modes.

Function: to inverse the echo of the 3D image, so as to enhance observation for low-echo region, applicable for vessel, cyst and etc.

When the function is turned on, the rendering mode parameters change into the corresponding inverse parameters.

For details, see "7.3.2 Static 3D Acquisition Preparation".

# Rotate the Image

## NOTE:

You can view the back of the VR by rotating it 180°. The back view image may not be as vivid as the front. (Here we call the initial view of the VR the "front"). It is recommended to re-capture rather than rotate the VR if a certain desired region is obscured in the VR.

#### Axial rotation

Axial rotation is to rotate the 3D image around the X, Y or Z axis.

Rotate the corresponding knobs to make the image rotate:

- To rotate along X-axis: rotate <M> button on the control panel clockwise, the image rotates right along the X-axis, and rotate the button anticlockwise, the image rotates left.
- To rotate along Y-axis: rotate <PW> button on the control panel clockwise, the image rotates right along the Y-axis, and rotate the button anticlockwise, the image rotates left.
- To rotate along Z-axis: rotate <C> button on the control panel clockwise, the image rotates right along the Z-axis, and rotate the button anticlockwise, the image rotates left.

Or, enter the touch screen mapping mode and hide the tool bar. Rotate the image by touching the image window and move slowly.

- To rotate along the X-axis: flip from top to bottom and the image rotates right along the X-axis. Swipe from bottom to top and the image rotates to the left.
- To rotate along the Y-axis: swipe from left to right and the image rotates right along the Y-axis. Swipe right to left and the image rotates to the left.
- Auto Rotation
- 1. In 3D viewing mode, tap [Auto Rotation] tab on the touch screen, system enters into auto rotation preparation state.
- 2. Select [Left/Right] or [Up/Down] to set the auto rotation direction.
- 3. Select the angle under rotation range to set the auto rotation range.
- 4. Set Start position and End position:
  - Start position: roll the trackball to view to a certain position, tap [Set Start].
  - End position: roll the trackball to view to a certain position, tap [End Start].
- Set rotation mode: tap for single direction rotation; tap = for bidirectional rotation.
   Select [Step] to set the auto rotation increment.
- 6. Tap b to start auto rotation. Select [Speed] to adjust the rotation speed.

#### Inversion

Function: vessel shape is correct with the capture target. The vessel wall is smooth and clear.

### Surface Enhancement

This function is to make the edge structure of the image and surface details clearer, so as to enhance the overall contrast.

Operation: Select [Surf. ENH] to adjust the enhancement level.

The higher the level is, the clearer the edge structure of the image is.

When the level is higher than 0 and [Move Light] is highlighted, image close to the light source is clearer, and image away from the light source is darker.

### Move the light

This function is to adjust the position of the light source as VR is considered. The image becomes clearer as keeping closer to the light.

Adjustment: roll the trackball and change the light position to make fine adjustments after tapping [Move Light].

### Image Zooming

Adjust the zoom factor of 3D image, the section images will be zoomed in/out accordingly.

Switch the current window to 3D window.

- Rotate <Zoom> to change the magnification factor.
- Zoom in or out by pinching or stretching in mapping mode.

### Sync

This function is to switch the direction of the image to the direction that is perpendicular to the current active plane, so as to get a better observation.

## **Comments and Comments**

Add comments and comments on MPR and 3D image.

The operations are the same with these in B mode.

## **Image Editing**

Image cutting is a more elaborate function than VOI adjusting to optimize the 3D by clipping (removing) the part blocked the region of interests.

### NOTE:

- In image cutting status, image parameter cannot be edited. There displays a cutting cursor +, and the system enters "Accept VOI" status.
- The editing function is only available on 3D image.

Perform the following procedure:

- 1. Enter image cutting status by taping [Tools] tab page.
- 2. Select an edit/erase tool:
  - Polygon: Press <Set> to position the start point, roll the trackball to set a region and press
     <Set> to trace the region. When the start point and the end point coincide, the region is selected or you can press <Set> twice to finish tracing. Move the cursor to the region you want to edit and press <Set> again to edit.
  - Contour: Press <Set> to position the start point, roll the trackball to trace the region.
     When the start point and the end point coincide, the region is selected or you can press
     <Set> twice to finish tracing. Move the cursor to the region you want to edit and press
     <Set> again to edit.
  - Rectangle: Press <Set> to fix the rectangle position, roll the trackball to change the size, and press <Set> again to finish rectangle drawing.
  - Line: Press <Set> to position the start point and the system will display a reference line, roll the trackball to set the line orientation and press <Set> to start drawing, press <Set> when ends are necessary; press <Set> twice to finish drawing. Move the cursor to the region you want to edit and press <Set> again to edit.
  - Rubber: Press <Set> to position the start point and roll the trackball to select the region.
     Press <Set> when ends are required. You can repeat the step to erase all parts blocking the interesting region.

You can select [Eraser Diam.] to adjust the eraser diameter.

To undo one operational step, tap [Undo] on the touch screen and to undo all operational steps, tap [Undo All] and start a new editing operation.

### Measurement

2D related measurement can be performed. For details, please refer to "Advanced Volume".

# NOTE:

Capturing preparation does not support the measurement.

# **Image Saving**

- Image saving:
  - In the 3D Review mode, press <Save> (with user-defined saving function) to save the current image and volume data to the patient information management system in the set format.
  - Save cine: in 3D viewing mode, press the user-defined save key to save CIN-format clip to the hard drive.
- Image review:

Open an image file to enter the image review mode. In this mode, you can perform the same operations as what you can in review mode.

# 7.4 Color 3D

Color 3D imaging provides more visualized flow information, especially in heart and kidney application, which helps in observing cardiovascular diseases.

# 7.4.1 Basic Procedures for Color 3D

- 1. Enter into color 3D image acquisition preparation status:
  - a. Obtain a feasible Power/Color image with the volume probe.
  - b. Press 🖫 🌑 📽 knob to enter 3D/4D image acquisition preparation status.
- 2. Set the acquisition, displaying related parameters, select acquire mode.
- 3. Press <Update> to begin image acquisition.
- 4. After the acquisition is completed, the system enters into image view status; you can perform operations like image edit and storage.
- 5. Save image as necessary.

# 7.4.2 Operation Controls

### Display

You can choose to display only color images or gray scale images, or to mix them.

### **Priority**

To determine color information displayed on gray scale images.

### Threshold

To eliminate color noise and motion artifacts. Affects MPR as well as VR.

### Opacity

To set the transparency value for VR rendering.

### Smooth

To smooth the Color image and erase artifacts by time averaging.

### Mix

To adjust mix percentage of gray scale information and color information. When display format is 2D&C, you can adjust this parameter.

### Image Zooming

Same as in 3D/4D mode.

## **Comment & Body Mark**

Operations are the same as those in the other modes.

### **MPR Measurement**

2D related measurement can be performed on MPR. For details, please refer to "Advanced Volume".

# NOTE:

You cannot perform measurement on acquisition preparation status.

# 7.5 4D

4D provides continuous, high volume acquisition of 3D images.

The probe performs the scan and renders the image automatically without the move of the probe.

Image acquisition operations of 4D are basically similar with that of Static 3D, the only difference is: in static 3D mode, only a single frame 3D image captured, while in 4D mode, continuous, high volume acquisition of 3D images are provided.

# 7.5.1 4D Procedures

Perform the following procedure:

- 1. Select the proper probe and exam mode; make sure there is sufficient gel on the probe for scanning.
- 2. Obtain a 2D image, and optimize the image if necessary.
- 3. Toggle 2 💭 2 knob right to enter 4D image acquisition preparation status.
- 4. Adjust ROI size and position and the VOI. The operations are same with these in static 3D mode.

# NOTE:

To define a ROI, please try to cut the useless data as to reduce the time for image storing, processing and reconstruction.

- 5. Select the render mode, and set the quality and angle parameter.
- 6. Press <Update> to enter the 4D real-time imaging status.
- 7. Press <Freeze> to freeze the image, you can perform image editing, rotation, comment and body mark adding and etc.
- 8. Exit 4D imaging.
  - Press <Update>. The system returns to 4D image preparation state.
  - Or press <B> to exit 4D mode.

# 7.5.2 4D Acquisition Preparation

Set the parameters before the acquisition. The settings for 4D mode are same with static 3D's.

# 7.5.3 4D Image Review

The settings for 4D mode are same with static 3D's.

## 4D image Review on Frozen State

In 4D real-time display mode, press <Freeze> on the control panel to enter the frozen mode.

Tap [Auto Play] to switch between auto play cine or manual play cine on cine page. Rotate the knob under [Auto Play] to select the play speed. Move the track ball to select the frame, tap [Start Frame] and [End Frame] to set the start frame and end frame, tap [Start Frame] to jump to the first frame.

## NOTE:

The operation of 4D image on frozen state is same with these in static 3D.

# 4D Image Saving

- In the 4D Review mode, press <Save> (with user-defined saving function) to save the current image to the patient information management system in the set format.
- Save cine: in 4D viewing mode, press the user-defined save key to save CIN-format clip to the hard drive.

## **3D/4D Fast Switching**

Press the user-defined <3D> key to enter 3D acquisition. After completing the acquisition, the image is obtained.

Press the <4D> key to enter 4D review mode. The active image can be obtained.

# 7.6 Smart 3D

The operator moves the probe to change its position/angle when performing the scanning. After the scanning, the system carries out image reconstruction, and then displays a single frame of 3D image.

If the system is only set up with Smart 3D module, press the user-defined <3D> key to enter Smart 3D imaging mode.

## NOTE:

- 4D probe does not support Smart 3D imaging.
- In Smart 3D image scanning, if the probe orientation mark is oriented to the operator's finger, perform the scan from right to left in linear scan, or rotate the probe from left to right in rocked scanning. Otherwise, the VR direction will be wrong.

# 7.6.1 Smart 3D Procedures

Perform the following procedure:

- 1. Select the proper probe and exam mode; make sure there is sufficient gel on the probe for scanning.
- 2. Obtain a 2D image, and optimize the image if necessary.
- 3. Press 🖞 🌑 🛱 to enter Smart 3D image acquisition preparation status.

- 4. Adjust ROI size and position and the position of VOI.
- 5. Select the render mode. Set the scan method and the movement of the probe (angle and distance).
- 6. Press <Update> to start 3D imaging.
- 7. The system enters into 3D image review status when the acquisition is completed; or, you can finish the acquisition ahead by pressing <Freeze> or <Update>.

NOTE:

In image review status, you can perform the same operations as in Static 3D.

- 8. Exit Smart 3D
  - Press <Update> or <Freeze> to return to Smart 3D acquisition preparation status.
  - Or press  $\langle B \rangle$  to exit the mode.

# 7.6.2 Smart 3D Acquisition Preparation

Parameter	NOTE
3D/4D Scenario Setting	Select 3D/4D scenario based on different scenario application.
Method	Select the image acquisition method. The speed is related to scanning distance or angle.
Distance	To set the distance the probe covered from one end to the other end during the linear sweep.
Angle	To set the motion angle the probe covered during a fan sweep.
Acquiring Time	To set the acquiring time of the Smart 3D acquisition.

The smart 3D acquisition preparation is same with these in Static 3D and 4D.

# 7.7 STIC (Spatio-Temporal Image Correlation)

# **MWARNING**

Diagnoses made only by assessing this 3D/4D acquisition are not permitted. Every diagnostic finding has to be evaluated in 2D as well.

STIC function provides sectional images of high spatial resolution as well as good time resolution, which is mainly used in fetal heart observation and cardiac hemodynamic exams.

Acquired images are post processed to calculate a Volume Cine sequence representing one complete heart cycle.

In order to achieve a good result, try to adjust the size of the volume box and the sweep angle to be as small as possible. The longer the acquisition time, the better the spatial resolution will be.

The user must be sure that there is minimal movement of the participating persons (e.g., mother and fetus), and that the probe is held absolutely still throughout the acquisition period.

Movement will cause a failure of the acquisition. If the user (trained operator) clearly recognizes a disturbance during the acquisition period, the acquisition has to be canceled.

# 

- One or more of the following artifacts in the data set indicate a disturbance during acquisition. In all of the following cases the data set has to be discarded and the acquisition has to be repeated.
  - Sudden discontinuities in the reference image B: These are due to motion of the mother, the fetus or fetal arrhythmia during acquisition.
  - Sudden discontinuities in the color display: Motion of the mother, the fetus or fetal arrhythmia affects the color flow in the same way it affects the gray image.
  - Fetal heart rate far too low or far too high: After acquisition the estimated fetal heart rate is displayed. If the value does not match the estimations based on other diagnostic methods at all, the acquisition failed and has to be repeated.
  - Asynchronous movement in different parts of the image: e.g., the left part of the image is contracting and the right part is expanding at the same time.
  - The color does not match the structure in the display format of grey mode: The color displays above or beneath the actual vessels.
  - Color "moves" through the image in a certain direction: This artifact is caused by a failure in detecting the heart rate due to low acquisition frame rate.
  - Use higher acquisition frame rate for better result.
- It is not allowed to perform the STIC fetal cardio acquisition if there is severe fetal arrhythmia.

# NOTE:

The system also supports color STIC 3D flow image function.

Perform the following procedure:

1. Obtain a feasible 2D image (fetus heart).

To observe a small structure, zoom in the interested part (Usually Res Zooming is applied for good image quality).

- 2. Toggle 2 🕐 x knob to enter 3D/4D acquisition preparation mode.
- 3. Tap [STIC] to enter STIC acquisition preparation mode.
- 4. Set the acquisition, displaying related parameters.
  - Select the parameter package.
  - Set the acquiring time and angle according to the target size and the motion conditions.
     For fetus of 20-30 weeks, the acquisition time range are: 10 12.5s, and the angle range are: 10-20°.

For gestation age of more than 20-30 weeks, the acquisition time should be about 15s, and the angle should be about  $30^{\circ}$ .

5. Adjust the size and position of the sample box to contain the interested region within the sample box.

However, the box should be small enough to contain only the heart, not the whole thorax.

In order to archive a good result, try to adjust the volume box and the sweep angle to be as small as possible. The longer the acquisition time, the better the spatial resolution will be.

- 6. Press <Update> to begin image acquisition.
  - Keep the probe still, the volume acquisition proceeds automatically and the acquired images are displayed.
  - To avoid external interference to the image, make sure that there is minimal movement of the mother.
  - In case of motion of the mother, the fetus or probe position change, cancel the current acquisition and begin for a new acquisition.

After the calculation, the estimated heart rate is shown on the screen.

- 7. Judge if the shown estimated heart rate is reasonable.
  - If the result is not reasonable, tap [REJECT HR] to perform the acquisition again.
  - Tap [ACCEPT HR] to accept the result and go to image review.
  - Tap [REJECT HR] to reject the HR but save the volume data.

Operations in review mode are the same as that of 4D cine review mode; please refer to the details in 4D chapter.

After STIC acquisition, press <Set> to switch between cine auto play mode and manual mode.

# 7.8 iLive

iLive brings you a better imaging experience by adding a light rendering effect to the traditional method. It supports the point lighting mode, parallel lighting mode as well as the torch lighting mode, allowing human tissue texture to be revealed more clearly.

### NOTE:

iLive is available under Smart 3D, Static 3D and 4D modes.

### To Activate iLive

Perform the following procedure:

- 1. Enter 3D/4D image viewing status, or double-click the saved 3D/4D cine file in the iStation or Review screen.
- 2. Tap [iLive] under the [Adv.] page on the touch screen to turn the function on, and adjust the parameters.

### Imaging using iLive

Perform the following procedure:

- 1. Select the imaging mode:
  - Use the ordinary probe and press  $\frac{3}{2}$   $\bigcirc$   $\frac{4}{3}$  to enter Smart 3D.
  - Or, use 4D probe and press 📱 🌑 🛫 to enter 4D mode or Static 3D mode.
- 2. Select the render mode to be iLive by touching the touch screen, and set the related parameters (quality and angle, etc.).
- 3. Press <Update> to begin acquisition.

4. The system finishes acquisition and enters the image viewing screen.

In image review status, you can perform operations such as VOI setting, image editing, comment adding, body mark adding, etc.

5. Or press  $\langle B \rangle$  or toggle  $\frac{\alpha}{2}$  ( a)  $\alpha$  to exit the mode.

# **Operation Controls**

Adjustable parameters for iLive are on the [Adv.] tab.

Shading

Adjusts the effect of shadowing and scattering. When the selected level is 0, the rendered image will be bright and sharp, and the shadow border will be clear while the area of the shadow will be relatively small. As the level increases, the rendered image will become warmer but the details remain the same. Also, the shadow border will be smoother while the shadow area will be large.

Light source adjustment

You can make fine adjustments by tapping [Move Light] and rolling the trackball to adjust.

Grad View

After this function is activated, VR details will be revealed and enhanced.

Other operation controls and adjusting methods are similar to those in 3D/4D mode.

#### Lighting Mode

- 1. Tap 🔁 on the [iLive] item to enter the iLive settings interface.
- 2. Tap the desired lighting mode.

If necessary, adjust parameters for the selected lighting mode.

3. Tap [Return] to apply the selected lighting mode.

Operation Controls for Lighting Mode Settings

Parameter	Description				
VL Sat.	Adjust the saturation for light $1/2/3$ .				
VL Hue	Adjust the color for light 1/2/3.				
VL Dis.	Adjust the distance for light 1/2/3 when the light source is set to torch or point. The larger the distance, the more the illuminated part on the surrounding area of the image; vice versa.				
VL Angle	Adjust the angle for light 1/2/3 when the light source is set to torch. The larger the angle, the larger the scope of light beam, and the larger the illuminated area; vice versa.				
Copy to	Copy the lighting mode to customized lighting mode "User 1" or "User 2".				
Reset Classic/ IntPoint/ ExtPoint/ Parallel/ Torch/ 3-Light/ User 1/ User 2	Reset the lighting mode to the original status.				
Rotation	Roll the trackball to view sectional images as necessary. Rotate <m>, <pw>, <c> to perform axial rotation or rotate the &lt;4D&gt; knob to adjust the nearest VOI section (cut plane) position.</c></pw></m>				

# 7.9 3D Layout

The function compiles the 3 MPRs together according to their relative positions, to provide a much clearer interior anatomical structure.

# NOTE:

This function is provided by the [Niche] option, and does not support Smart 3D image data.

# Niche

Perform the following procedure:

- 1. Select the [Tools] > [3D Layout] tab on the touch screen, then tap [Niche].
- 2. Tap [A]/[B]/[C]/[Niche] to select the reference plane as Plane A, Plane B, Plane C or Niche.
- 3. Set the view direction for niche display mode using the touch screen: from the front of the reference image or from the back.
- 4. Roll the trackball to view sectional images as necessary. Rotate <M>, <PW>, <C> to perform axial rotation or rotate the <4D> knob to adjust the nearest VOI section (cut plane) position.

## **3Slice**

Perform the following procedure:

- 1. Select [Tools] > [3D Layout] tab on the touch screen, then tap [3Slice].
- 2. Tap [A]/[B]/[C]/[3Slice] on the touch screen to select the reference plane.
- 3. Roll the trackball to view sectional images as necessary. Rotate <M>, <PW>, <C> to perform axial rotation or rotate the <4D> knob to adjust the nearest VOI section (cut plane) position.

# 7.10 3D Reference Point

The function enables operators to define one or more reference points on MPRs, which are then projected to VR image. It is helpful for operators to better understand the corresponding spatial relations of VR image and MPRs.

- 1. Select the [VR] > [3D Ref] tab on the touch screen.
- 2. Tap [Input] on the touch screen, and a green cross mark appears on the screen.
- 3. Move the mark to the desired point and press the <Set> key to set the reference point.

You can move the cursor onto the reference point and use the trackball and the <Set> key to move the reference point.

- 4. Tap [Display] to select the display mode.
  - [Point]: only the reference point is displayed.
  - [H Line]: The reference point and the horizontal line crossing the reference point are displayed.
  - [V Line]: The reference point and the vertical line crossing the reference point are displayed.
- 5. If necessary, tap [Delete] to delete the corresponding reference point.
- 6. After the four reference points are defined, you can Tap [Delete All] or [Hide All] to delete or hide all the reference points.
- 7. Tap [Return] to exit.

# 7.11 3D-Print Format

It is used to export 3D facial and limb data to external storage devices through 3D print format. Users can view the 3D contour model of the fetus on the external electronic devices at any time. Users can also send the 3D print file to the 3D printing vendor to print the physical model.

# 

The result is provided for reference only, not for confirming diagnoses.

# NOTE:

- You can store, print, and re-open the saved cine file.
- Physical/3D printed models generated from the digital output files are not for diagnostic use.

Perform the following procedure:

1. Obtain 3D single volume data. Select [3D-Print Format] in the "Tools" tab.

The main screen switches to the dual-window mode. The left window is VR and the right window is the grid model.

When you enter 3D print for the first time, the system will automatically generate a grid model.

2. Select [Quality] to generate models with low, medium and high quality.

After changing the printing quality, select [Generate Mesh] to generate a grid model again.

- 3. After the grid model is generated, the system supports rotating, translating, and zooming VR and grid models simultaneously.
- 4. Select [File Format] to choose a file format.

The following formats are supported:

- .stl: STL Format
- .obj: Stanford Polygon Format
- .ply: Alias Wavefront Format
- .off: Point Cloud Format
- .3mf: 3D Manufacturing Format
- 5. Select [Save mesh to USB] and export the 3D print files.

### NOTE:

- If you want to view the 3D print files on the mobile phone, please download and install "EMB3D" application program first.
- The Windows 10 computer supports viewing 3D print files directly (except files in .off format).

# 7.12 Smart Volume

# 

The Smart Volume result is provided for reference only, not for confirming diagnoses.

The system provides three fast volume calculation methods that can be used to calculate the volume of tissue structure or lesions. The methods are as follows.

- Smart-V ROI: The method uses computer technology to define and enclose a boundary of the target within the ROI area (the computer technology allows the ultrasound system to fit an ellipsoid that can be most approximate to the target) and then calculate this volume. It can be used to measure the volume of mass, gestational sac, bladder or gall bladder.
- Smart-V Trace: The method uses computer technology to enclose a boundary of the target traced by the operator and then calculate this volume. It can be used to measure the volume of endometria or cerebellum.
- Smart-V Vocal: The operator traces the boundary of the target on planes generated by rotation. Then the system fits a 3D contour based on the contours traced by the operator, and calculate this volume. It can be used to measure the volume of targets except for those in long and thin shape.

# NOTE:

- To ensure the accuracy of the result, ensure that the VOI position and size setting has entirely enclosed the target and is approximate to the target before using the Smart Volume function.
- Smart Volume is not available for Smart 3D image.

# 7.12.1 Basic Procedure

# **Smart-V ROI**

Perform the following procedure:

- 1. Acquire necessary 3D/4D data.
- 2. Tap [Smart-V] > [Smart V ROI] on the touch screen to enter Smart V ROI interface, and the system is in the "Adjust ROI" status ([Edit ROI] button is highlighted).
- 3. Set ROI position and size.
  - a. Select a desired MPR image by tapping [A], [B] or [C].
  - b. Roll the trackball to adjust ROI position and size, and press <Set> to switch between the adjusting status.
- 4. Tap [Calc], the system starts to calculate.
- 5. Auto calculation is finished:
  - There are yellow solid curves enclosing target region on each MPR image (A, B, C) window.
  - 3D image (VR) displays image of the target region in red;
  - The calculation result is displayed on the lower left part of the screen.
- 6. Modify the contour of the calculated area and recalculate its volume, if necessary.
- 7. Calculate the volume of the shell.

Tap [Shell] and rotate the knob under [Thickness] to set the shell of the contour and its thickness. The calculation result is displayed on the lower left part of the screen.

#### NOTE:

To ensure the accuracy of the result, please make sure that the ROI position and size setting has entirely enclosed the target and is approximate to the target before using the Smart Volume function.

## **Smart V Trace**

- 1. Acquire necessary 3D/4D data.
- 2. Tap [Smart-V] > [Smart V Trace] on the touch screen to enter Smart V Trace interface, and the system is in the "Trace On MPRs" status.
- 3. Rotate the knob under [Trace Mode] to select the desired trace mode.
- 4. Tap [Calc], and the system starts to calculate.
- 5. Auto calculation is finished:
  - There are yellow solid curves enclosing target region on each MPR image (A, B, C) window.
  - 3D image (VR) displays image of the target region in red;
  - The calculation result is displayed on the lower left part of the screen.
- 6. Modify the contour of the calculated area and recalculate its volume, if necessary.
- 7. Calculate the volume of the shell.

Tap [Shell] and rotate the knob under [Shell Thickness] to set the shell of the contour and its thickness. The calculation result is displayed on the lower left part of the screen.

# NOTE:

To ensure the accuracy of the result, please make sure that the traced contour has entirely enclosed the target and is approximate to the target before using the Smart Volume function.

## **Smart-V Vocal**

- 1. Acquire necessary 3D/4D data.
- 2. Tap [Smart-V] > [Smart V Vocal] on the touch screen to enter Smart V Vocal interface, and the system is in the "Reference Line" status.
- 3. Use [Slice Num] to set the number of slices.
- 4. Set the reference line on one of the three MPRs by using the trackball and the set keys.
- 5. Rotate the knob under [Trace Mode] to select the desired trace mode.
- Trace the contour on slices. The trace should cross the two round points of the reference line. Tap [Next Slice]/[Previous Slice] to go to the next or previous slice.
- 7. After contours are traced on all the slices, tap [Calc Vol], and the system starts to calculate.
- 8. Auto calculation is finished:
  - There are yellow solid curves enclosing target region on each MPR image (A, B, C) window.
  - 3D image (VR) displays image of the target region in red;
  - The calculation result is displayed on the lower left part of the screen.
- 9. Modify the contour of the calculated area and recalculate its volume, if necessary.

10. Calculate the volume of the shell.

Tap [Shell] and rotate the knob under [Shell Thickness] to set the shell of the contour and its thickness. The calculation result is displayed on the lower left part of the screen.

# NOTE:

To ensure the accuracy of the result, please make sure that the traced contour has entirely enclosed the target and is approximate to the target before using the Smart Volume function.

# 7.12.2 Result Display

After calculation, the following result will be displayed on the lower left part of the screen.

Whereas, L, W and H represent 3 diameter lengths of the fitting ellipsoid.

V represents calculated volume value.

MG represents Mean gray value; VI represents Vascularization Index; FI represents Flow Index; VFI represents Vascularization Flow Index.

# 7.12.3 Operation Controls

#### Edit

After the calculation, you can modify the contour of the calculated area and recalculate its volume.

- For Smart-V ROI and Smart-V Trace:
  - Tap [Edit off] to enable the editing function.
  - Tap [Add] and then trace an enclosed area manually, and the area to be calculated will be enlarged to include the traced area.
  - Tap [Delete] and then trace an enclosed area manually in the already calculated area, and the area to be calculated will be narrowed down to exclude the traced area.
  - Rotate the knob under [ROI Range] to set ROI range. The operator can only trace the contour inside the ROI.
  - Tap [Undo] or [Redo] on touch screen to undo or redo previous editing. Tap [Undo All] to undo all editing steps.
  - Tap [ReCalc] to calculate the volume based on the new contour.
- For Smart-V Vocal:
  - Tap [Edit off] to enable the editing function. Then you can modify the contour on each slice.
  - Use [Win Format] to select the display format of slices.
  - Tap [Update Vol] to calculate the volume based on the new contour.

#### MPR Thickness

Rotate the knob under [Thickness] to adjust the thickness of MPRs. The bigger the value is, the more the thickness information appears.

### Trace Mode

- Trace
  - a. Rotate the knob under [Trace Mode] to select [Trace].
  - b. Rotate the trackball to place the cursor and press right <Set> key to fix the starting point, move the cursor along the target to trace the outline, and press right <Set> twice to finish

tracing. During tracing, press left <Set> to cancel a series of tracing, or you can roll the trackball backwards to delete latest tracing.

Press <set> key to display "Cancel" status on the track ball region, move the track ball to cancel the trace.

- Spline
  - c. Rotate the knob under [Trace Mode] to select [Spline].
  - d. Rotate the trackball to place the cursor and press right <Set> key to fix the starting point, move the cursor along the area of interest and press right <Set> to anchor several reference points; or press left <Set> to cancel a series of lines.
  - e. Press <Set> twice to set the end point of the spline.

Press <set> key to display "Cancel" status on the track ball region, move the track ball to cancel the spline.

- Smart Trace
  - f. Rotate the knob under [Trace Mode] to select [Smart Trace].
  - g. Rotate the trackball to place the cursor and press right <Set> key to fix the starting point, move the cursor along the target to trace the outline, and press right <Set> key twice to finish tracing. During tracing, press left <Set> to cancel a series of tracing, or you can roll the trackball backwards to delete latest tracing.
- Control Point

This mode can be used only after tracing is finished, and not support Smart-V ROI method.

- h. Rotate the knob under [Trace Mode] to select [Control Point].
- i. Rotate the trackball to place the cursor on the finished trace and press right <Set> key to select the point, move the cursor to the desired position, and press right <Set> key to fix the point. During tracing, press left <Set> to cancel the point moving.

Press <set> key to display "Cancel" status on the track ball region, move the track ball to cancel the trace.

### **Display 2D or Color 3D**

Tap [Display] to select 2D display or 2D+Color 3D display.

### Calculation

After tapping [Calc] or [ReCalc] to be on, the system starts calculation.

### **Reset Curve**

Tap [Smart-V Reset Ori] to reset the volume rotation, shifting and zooming to original status.

# 7.13 iPage<sup>+</sup>

iPage<sup>+</sup> is iPage+SCV function. iPage (Multi-Slice Imaging) is a "Visualization" mode for displaying sectional images. The data is presented as slices through the data set, which are parallel to each other. When SCV (Slice Contrast View) function is turned on, the system expands the parallel section images into a slice region with a specified thickness, and draws this region with 3D rendering effect to enhance the image.

## NOTE:

iPage<sup>+</sup> imaging is not available in Smart 3D mode.

# 7.13.1 Operating Procedures

# iPage operation

- 1. Acquire necessary 3D/4D data.
  - Single-frame VR:
    - 4D mode: freeze the system, and then roll the trackball to select the image.
    - Static 3D: a frame of image is acquired after the acquisition is finished automatically.
  - Multi-frame 3D images: acquire multiple 3D images in 4D imaging mode.
- 2. Perform operations like rotation, VOI adjusting to the image to find the interested region.
- 3. Tap [iPage<sup>+</sup>] on touch screen.
- 4. Check A/B/C sectional planes, and select the reference image.
- 5. Confirm if the slices displayed are the target planes, if not, re-select the reference image again.
- 6. Observe the interested structure through multiple slices.

Select the proper image layout and space according to the size of the target structure.

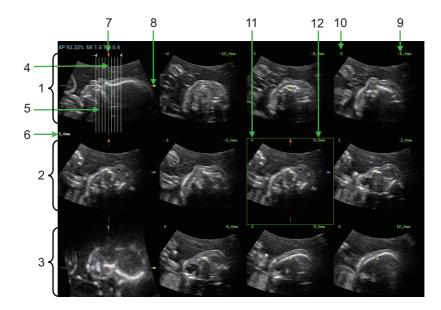
To observe the details or the tiny part of the interested region, do image zooming please.

- Rotate the 3D image to observe the slices of other orientations. Repeat step 6 if necessary. If the target orientation and region cannot be observed even after image rotation, tap [Reset Ori] to reset the 3D image.
- 8. Do operations like comment to the interested region.
- 9. Save images as necessary.

# iPage+SCV operation

Adjust the parameter [Thickness] when SCV imaging is needed.

# 7.13.2 Basic Screen & Operation



1 A plane (the reference im	```	B plane	3	C plane
-----------------------------	-----	---------	---	---------

4	Central slice line (Current active slice)	5	Slice line	6	Space between two slice lines
7	Y-axis	8	X-axis	9	Slice position (to the central slice)
10	Slice order number	11	Central slice mark	12	Active slice be highlighted in green

## Layout

The system supports several types of displaying layout: 2\*2, 3\*3, 4\*4 and 5\*5, touch the corresponding icon on the touch screen to select, and the selection [Slices Number] changes accordingly.

### **Reference image**

Tap [A], [B], or [C] to select the reference image.

### Slice and slice line

- Central slice: the central slice line corresponding plane are the central slice, which is marked with a green "\*" at the upper left corner of the image.
- Tap  $\blacksquare$  to place the slice lines vertically, and touch  $\blacksquare$  to place the slice lines horizontally.
- Active slice: the green slice line corresponding plane is the active slice, which is marked with a green box. The default active slice is the central slice.
- Slice order number: indicating the order of the slices, the order of central slice is "0", the slices before the central slice are marked with negative integral numbers, and the slices after the central slice are marked with positive integral numbers.
- Slice position (to the central slice): displayed at the upper left corner of each image, indicating the position of each image (such as -6mm, -3mm, 3mm, 6mm).
- Coordinate axis: indicated on the A, B, C three reference images, match together with the central slice line, and will move accordingly with the central slice line.

## Slice shifting

Roll the trackball to shift the crossing point of central axis up/down, left/right, and the slice lines will shift accordingly with the crossing point.

Rotate the knob under [Range Pos] on the touch screen to fine-tune slice lines horizontally.

#### Slice position

Rotate the knob under [Slice Position] to move the active slice line (green) either forward or backward within the range, then the corresponding slice will be highlighted in green.

#### Spacing

The value is displayed at the upper left side of the slice, unit: mm. Adjust it through touch screen selection [Spacing].

### Slices number

Change slices number as necessary using the knob under [Slices Number] on the touch screen.

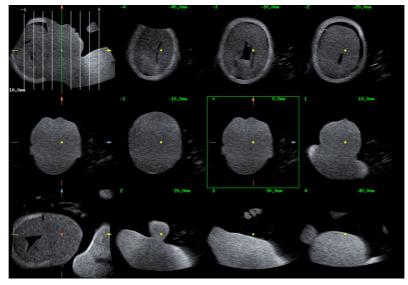
# Thickness

# TIP:

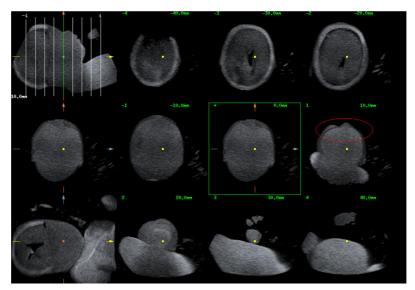
Thickness can not be larger than Spacing.

Rotate the knob under [Thickness] to adjust the SCV thickness. When the thickness value is larger than zero, the SCV function is on.

Figures below are the effect before and after the SCV function is turned on. You can see the body structure within the range of the thickness is added to the image after the SCV function is on.



Before



After

# Image rotation

Rotate <M>, <PW>, <C> to perform axial rotation or rotate <4D> knob to adjust the nearest VOI section (cut plane) position.

### Hide/show reference image

The system displays 3 standard sectional images (A plane, B plane, C plane) on the left side indicating the position of the slice lines; tap **to** hide the 3 reference images, and then slices are displayed on the whole image area.

## Quick switch to single display

Select a certain slice, double click <Set> to see the slice full screen, and double click <Set> again to return to the original display format.

### Reset Ori.

Tap [Reset Ori] to reset the orientation and zoom status of the image.

# 7.14 SCV<sup>+</sup>

SCV<sup>+</sup> is SCV (Slice Contrast View) +CMPR (Curved MPR).

SCV imaging can reduce speckle noise and improve contrast resolution as well as enhance signalnoise ratio, which helps in discovering diffuse pathology in organs.

The curved MPR function allows straightening of a curved surface/anatomy. In clinical application, this is usually used for imaging fetal spine.

# NOTE:

SCV<sup>+</sup> imaging is not available in Smart 3D mode.

# 7.14.1 Basic Procedures

### **SCV** operation

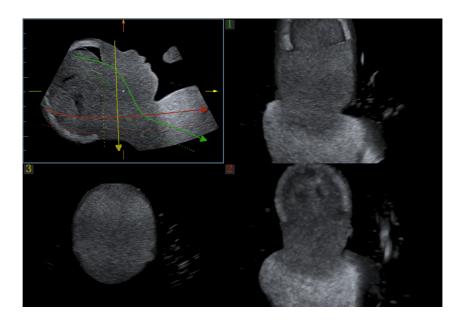
Perform the following procedure:

- 1. Acquire necessary 3D/4D data.
- 2. Tap [SCV<sup>+</sup>] tab on the touch screen to enter SCV imaging, and the system displays three section images in A, B and C window.
- 3. Rotate the knob under [Thickness] on the touch screen to adjust imaging thickness.
- 4. Save images as necessary.

### **SCV+CMPR** operation

Perform the following procedure:

- 1. Enter  $SCV^+$ .
- 2. Tap [A], [B] or [C] to select current window.
- 3. Tap [CMPR] to turn on the CMPR function. Window A on main screen displays the current window and three other windows are blank.
- 4. Select reference section, perform rotation and shifting operations to adjust image.
- 5. Tap [1], [2], or [3] button in [Active Quadrant].
- 6. Select trace options: tap [Line], [Trace] or [Spline].
- 7. Draw on the reference image. You can draw three curves at most and the CMPR imaging for the curve are displayed in the selected [1], [2] or [3] window respectively as shown in figure below.



- 8. Perform rotation and shifting operation to reference line.
- 9. Save images as necessary.

# 7.14.2 Operation Controls

## SCV

Current Quadrant

Tap [A Plane], [B Plane] and [C Plane] to select current active section image.

• Reset

Click [All] in Reset field to reset parameters, orientation and zooming status.

### CMPR

Trace Options

• Line

Perform the following procedure:

- a. Tap [Line] on the touch screen.
- b. Rotate the trackball to place the cursor and press right <Set> key to fix the starting point, rotate the trackball to extend the line and press right <Set> key again to finish drawing; or you can press left <Set> key to reset starting point.
- c. Rotate the knob under [Line Extension] on the touch screen to adjust the line length.
- d. After line is finished, press left <Set> key to change line position.
- e. Tap [Reset Curve] to cancel current drawing. Press <set> key to display "Cancel" status on the track ball region, move the track ball to cancel the line.
- Trace

Perform the following procedure:

- f. Tap [Trace] on the touch screen.
- g. Rotate the trackball to place the cursor and press right <Set> to fix the starting point, move the cursor along the target to trace the outline, and press right <Set> again to finish tracing. During tracing, press left <Set> to cancel a series of tracing, or you can roll the trackball backwards to delete latest tracing.

- h. After tracing, press left <Set> key to change tracing outline position.
- i. Tap [Reset Curve] to cancel current drawing. Press <set> to display "Cancel" status on the track ball region, move the track ball to cancel the trace.
- Spline
  - Perform the following procedure:
  - j. Tap [Spline] on the touch screen.
  - k. Rotate the trackball to place the cursor and press right <Set> to fix the starting point, move the cursor along the area of interest and press right <Set> to anchor several reference points; or press left <Set> to cancel a series of lines.
  - 1. Press <Set> twice to set the end point of the spline.
  - m. After tracing, press left <Set> to change tracing outline position.
  - n. Tap [Reset Curve] to cancel current spline. Press <set> to display "Cancel" status on the track ball region, move the track ball to cancel the spline.

## **SCV** Fusion

Tap [SCV Fusion] and rotate the knob under [SCV Fusion] to set the render modes and mix ratio. Only when [Thickness] is on, [SCV Fusion] can be adjusted.

#### Other Operations

• Single image zoom

Toggle <3D> to view single SCV image.

- Zoom in Same as these in 3D/4D mode.
- Rotation

Rotate <M>, <PW>, <C> to perform X/Y/Z rotation or rotate <4D> knob to adjust the nearest VOI section (cut plane) position.

• Comment and Body Mark

Same as these in other modes.

• Section image (MPR)/CMPR measurement.

2D related measurement can be performed on MPR/CMPR. For details, please refer to "Advanced Volume".

# 7.15 Smart Planes CNS

The doctor finds fetus's sagittal view by judgments on image features, and then makes an observation. The fetus's s sagittal view is hard to be detected or cannot be detected sometimes because of the fetus's move inside.

Taking the key anatomical tissues and organs' features from 3D data of fetus's intracranial, Smart Planes CNS is a mode-wise technology, which detects the middle of the fetus's sagittal view, transverse plane of thalami, transverse plane of lateral ventricles and transverse plane of cerebellum. It helps the doctors find the sagittal view rapidly and is easy for doctors accessing the anatomical structure on sagittal view. (such as corpus callosum, cerebellar vermis, etc.).

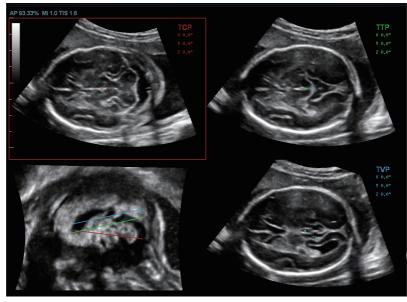
# NOTE:

Smart Planes CNS does not support smart 3D mode.

# 7.15.1 Basic Procedures for Smart Planes CNS

Perform the following procedure:

- 1. Acquire necessary 3D data.
- 2. Tap [S-Planes CNS]. There are four views detected by the system, which includes TCP, TTP, MSP and TVP.



- 3. Adjust the parameters to obtain the image.
- 4. Tap [MSP]. There are A/B/C images appearing on the screen. The sagittal plane of the fetus appears on window C.

Rotate A, B or C plane respectively, or rotate <4D> to adjust each plane.



### NOTE:

To ensure the correctness of the result, please make sure the cerebral midline on the anatomical plane is displayed clearly and ROI enclose the whole cranial region.

5. Tap [OK] to accept the edit to the MSP. The system recalculates the TCP, TTP and TVP according to MSP's position. The position and the angle for TCP, TTP and TVP appear on MSP plane.

- 6. Tap [TCP]/[TTP]/[TVP] to select the plane, and rotate <M>, <PW> or <C> knob to rotate the image plane along with X/Y/Z axis. The angle value appears on the right of the image.
- 7. Rotate the reference line on the MSP plane.
  - a. Press <Cursor> to show the cursor. Move the cursor over the red line of the MSP plane. Press left <Set> to select the red reference line after the cursor becomes hand-shaped. Then, the red reference line becomes dotted line.
  - b. Move the trackball left or downwards. The reference line rotates anticlockwise along the center. TCP image rotates clockwise along the Y-axis, and the value of Y-axis becomes bigger.
  - c. Move the trackball right or downwards. The reference line rotates clockwise along the center. TCP image rotates anticlockwise along the Y-axis, and the value of Y-axis becomes smaller.
  - d. The operations to green reference line and blue reference line are the same. TTP rotates along Y-axis when green reference line rotating. TVP rotates along Y-axis when blue reference line rotating.
- 8. Tap [Auto Measure] to show the caliper and the measurement number. The measurement results appear on the right of the screen.

#### NOTE:

- There are 6 measurements:
  - TCP supports the measurements on TCD, cerebral fossa pool.

TTP supports the measurements on BPD, OFD, HC.

TVP plane supports the measurement on LVW.

- The automatic measurement results appear only for these having the same characteristics on the planes.
- Once the automatic measurements are completed, the operations to axial rotation, reference line rotation, parameter adjustment, MSP editing, zooming/panning, dual/ quad-split display will remove the measurement results.
- a. Tap [Edit] to modify the measurements. The caliper becomes green.

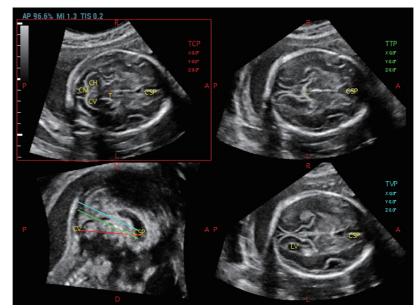
Or, press <Set> to activate the caliper (becoming green).

- b. Move the trackball and press <Update> to modify the length and the position of the caliper.
- c. Press <Set> to confirm the caliper. The caliper becomes white. [Edit] is off.
- 9. Tap [Auto Comment], the system adds the orientation and the organ comments to the desired area according to the active ultrasound image.

### NOTE:

• The orientation comments describe the location of the plane, referring to A (anterior), P (posterior), L (Left), R (right), U (up), D (down).

• Organ comments describe the position of the organ, referring to CSP (cavum septum pellucidum), T (thalamus), CH (cerebellar hemisphere), CV (cerebellar vermis), CM (cisterna magna), LV (lateral ventricles).



- a. Rotate [Font Size] knob to adjust the font size of the comment.
- b. see "14.2 Comments" for adding, moving or deleting the comments.
- c. Save the image.
- d. Tap [Auto Comment] again to clean them.
- 10. Tap [Save to Report] to save the measurements to the report.
- 11. Add the comment and body mark on the plane. Perform the measurement, and save the single frame/multi-frame image.

# 7.15.2 Smart ICV

Smart ICV is used to measure fetal cerebral volume.

# NOTE:

To ensure the accuracy of the result, please make sure that the traced contour has entirely enclosed the target and is approximate to the target before using the Smart ICV function.

Perform the following procedure:

- 1. Acquire necessary 3D/4D data.
- 2. Tap [Smart ICV] to enter Smart ICV interface, and the system measures the volume of fetal cerebral automatically.
- 3. If necessary, calculate the volume of the shell.

Tap [Shell] and rotate the knob under [Shell Thickness] to set the shell of the contour and its thickness.

- 4. If necessary, modify the contour of the calculated area and recalculate its volume.
  - a. Tap [Edit] to enable the editing function.
  - b. Use [Trace Mode] to select the desired trace mode. Trace the contour on slices. The trace should not cross the reference line.
  - Tap [Win Format] to select the display format of slices.

- Tap [Next Slice]/[Previous Slice] to go to the next or previous slice.
- Tap [Undo], [Redo] or [Undo All] to undo, redo or cancel previous editing.
- c. Tap [Update Vol] to calculate the volume based on the new contour. If necessary, tap [Undo], [Redo] or [Undo All] to undo, redo or cancel previous measurement.
- 5. Tap [Accept Result], and the measurement results are saved in the report.

# 7.15.3 Other Operations

## **Parameter adjusting**

- Brightness
  - Adjusting the brightness of the images.
  - Rotate [Brightness] to adjust the parameter.
- Thickness
  - Rotate [Thickness] to adjust the parameter.
  - The bigger the value is, the more the thickness information appears.
- 3D iClear
  - Tap [3D iClear] to adjust the parameter.
  - The bigger the value of iClear is, the less the noise becomes.

### Reset

All planes

Acquire 3D data. Tap [S-Planes CNS] to enter the automatic detection of the mode. Reset the following operations:

- Tap [All Planes] to reset the planes. The position and the angle to TCP, TTP, TVP, MSP and reference line return to the initial condition.
- Tap [All Planes] to reset the planes. The position to TCP, TTP, TVP, MSP and reference line returns to the last MSP condition. The angle to CP, TTP, TVP, MSP and reference line returns to 0°.
- Current plane

Acquire 3D data. Tap [S-Planes CNS] to enter the automatic detection of the mode. Reset the following operations:

- Tap [Current Plane] to reset the plane. The position of the current plane returns to the initial condition. The angle of the current plane returns to 0°.
- Tap [Current Plane] to reset the current plane. The position and the angle to the current plane returns to the last MSP condition.

# **Other related Operations**

- Hiding the reference
  - Tap to hide or show the reference line.
- Hiding the measurement Tap to hide or show the measurement.
- Switching between the single and quad-split display
   Tap [Single]or [Quad] between the single and quad-split display.

# 7.16 Smart FLC (Smart Follicles Calculation)

# 

- Smart FLC result is provided for reference only, not for confirming a diagnosis.
- Smart FLC is not available in Smart 3D mode.

# 7.16.1 Basic Procedures

Perform the following procedure:

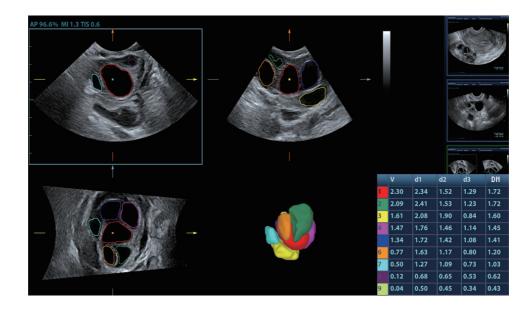
- 1. Acquire necessary 3D/4D data and freeze.
- 2. Tap [Smart FLC] tab to enter Smart FLC, and the system is in the "Edit ROI" status ([Edit ROI] button is highlighted).
- 3. Set the position and size of the ROI box.
- 4. Tap [Calc] on the touch screen.
- 5. Auto calculation is finished:
  - Section image (A, B, C) is enclosed with colored lines and the color corresponds to the follicle in VR window.
  - 3D image (VR);

- Results on the right of the screen are displayed in a table.

V: Volume

d1, d2, d3: diameters of the follicle

MD: Follicle Diam



# NOTE:

To ensure the correctness of the results, please select an image with clear follicle boundary when entering smart FLC.

# 7.16.2 Operation Controls

# Edit ROI

Same as the operation in ROI editing in Smart-V.

# Edit/ Undo

Select the button in the [Edit] area to turn on the editing function. It supports dividing, merging, adding and deleting of the follicle.

Tap [Undo], [Redo] or [Undo All] to undo, redo or cancel previous editing.

## Zoom

Same as those in 3D/4D mode.

# Annotation and Body Mark

Same as those in other modes.

## Measurement

2D related measurement can be performed on MPR. For details, please refer to "Advanced Volume".

# Save the image

The Smart FLC supports saving single-frame image only, does not support saving multi-frame cine file.

# 7.17 Smart Planes FH (Smart Planes on Fetal Heart)

By using this fetal heart automatic recognition feature, you can observe anatomical structures of fetal heart quickly.

## TIP:

Smart Planes FH is an option and not available under STIC or Smart 3D mode.

# 7.17.1 Basic Procedures

Perform the following procedure:

- 1. Acquire necessary 3D/4D data of fetal heart and save the file. Open the saved cine file.
- Tap [S-Planes FH] and [Navigate] to enter the screen. The system detects aorta and displays A/ B/C plane automatically. A refers to four-chamber view, B refers to aortic horizontal section and C refers to aortic vertical section.
- 3. Change the A plane slightly for a better observation by rotating X/Y/Z-axis or shifting operation.
- 4. Select the crossing in the four-chamber view.

Refer to the four-chamber view on the left as an example. The red "+" symbol represents the crossing point. Press <Cursor> to acquire the cursor and move the cursor onto the crossing in A plane and press <Set>. The system then displays four-chamber view, left ventricular outflow tract view, right ventricular outflow tract view, LAV-DA view, 3VV-T view and stomach bubble view.

- 5. Adjust the view if necessary, you can perform shifting, axis rotation or quick adjustment.
- 6. Adjust image parameters such as brightness, contrast and slice.

7. Save the file.

# 7.17.2 Operation Controls

## Axis rotation and shifting

Rotate <M>/<PW>/<C> knob to rotate the view along X/Y/Z-axis.

Rotate the  $\frac{1}{2}$  (**b**)  $\frac{1}{2}$  knob to scroll the view.

### Quick adjustment

After corresponding views are displayed, select the view and tap [Quick Adjust] to adjust the view. If four-chamber view, 3VV-T view or stomach bubble view is selected, tap [Quick Adjust] to scroll the view along Z-axis.

If current view is left ventricular outflow tract view (LVOT), tap [Quick Adjust] to move the view along Y-axis.

If current view is LAV-DA view or right ventricular outflow tract view (RVOT), tap [Quick Adjust] to move the view along X-axis.

### Reset

[Reset All]: tap to undo all operations on A/B/C plane and go back to status in step 4.

[Reset Ori]: tap to undo all orientation adjustments on A/B/C plane and go back to status in step 4. [Reset All/Current View]: tap to restore operations on all views or current view and go back to status in step 4.

## **Parameter adjusting**

Parameters under Smart Plane FH are similar to those under Static 3D mode.

# 7.18 Smart Face

## NOTE:

Smart Face is only used for obtaining fetal face features, not for confirming a diagnosis.

This feature allows the system to recognize fetal face and remove the shading obstacle data automatically, then display the face in a recommended viewing angle.

Perform the following procedure:

- 1. Acquire Static 3D image or frozen 4D single-frame image of fetal face.
- 2. Tap [Smart Face] to enter the function and the system adjust fetal face angle (fetal head facing up) automatically and remove the shading obstacle data.

# 7.18.1 Parameter adjusting

Parameters under Smart Face are similar to those under Static 3D mode. Tap  $\equiv$  to enter Setup screen.

# MixRender/SubTint

# NOTE:

This function is available only under "Surface" mode.

The higher the merge value, the clearer the shading obstacles on the image.

Tap [MixRender] to select the levels between 0-3. Tap [SubTint] to select the obstacle display color. If the value is set 0, no obstacle data will be displayed.

# Eraser

### NOTE:

This function is available only under "Surface" mode.

Clearing effect in the center of the eraser sphere is strongest, and this effect weakens along the sphere center to the edge.

Tap [For-Rubber] to erase existing data on the screen.

Tap [Re-Rubber] to restore those removed shading data.

- Use [EraseSize] to select the size: Small, Middle, Large.
- Tap [Undo] to undo the operation in sequence and tap [Undo All] to undo all erase effects.

#### AutoDirect

This feature allow you to optimize to a best observing angle of view within one step.

The recommended angle: fetal head is facing up and the face is at the front with [Direction] to be up/down.

## FaceContact

The higher the value, the more adjacent the VR image is to the fetal face, and the more obstacles cleared.

The lower the value, the further the VR image is to the fetal face, and the less obstacles cleared.

Rotate [FaceContact] to adjust the parameter.

### **VR** Orientation

Rotate the image quickly. Adjust in VR Orientation: 0°, 90°, 180°, 270°.

# 7.19 Volume CEUS

It is only to view the microbubbles injection of a certain plane once in the 2D ultrasound contrast imaging, however it is possible to view stereo microbubbles injection in the 3D ultrasound contrast imaging.

3D contrast injection imaging is used to characterize focal liver lesions. 3D ultrasound contrast imaging shows the arrangement of the tumor blood vessels from early phase enhancement to late phase enhancement and displays the changes of the enhancement type in multi-plane way. There is also another significant clinical application for 3D ultrasound contrast imaging. It is applied in the oviduct to judge its clearness.

Perform the following procedure:

- 1. Choose the volume probe and the exam mode. Scan the image. Optimize the image. Ensure the tumor, the lesion, ovary inside the image.
- 2. Tap [Contrast] to enter contrast imaging in 2D scan mode. Adjust the parameter to obtain the premium image.
- 3. Press 2 2 2 to enter the acquisition preparation of the volume CEUS. Set the ROI position/ size and VOI. Select the rendering mode. Set the scan angle/quality, etc.

Inject the contrast agent in step 2 or step 3. Turn the timer on. Obverse the contrast image.

4. Press <Update> to start capturing volume CEUS image.

During the acquisition, a progress bar is displayed to indicate the acquisition progress.

The system saves the single frame image when the acquisition is completed and enters the review status of 3D image. Tap [Contrast]/[Tissue] on the touchscreen. The image on the main monitor is switched between the contrast image and the tissue image.

It is available to perform operations on VOI setting, parameter adjustment, image editing, image comment, image measure and image saving, etc. in image review. see "7.3.3 Static 3D Image Viewing" for details.

5. Repeat step 2-4 to obtain the contrast images if necessary.

# 7.20 Smart Scene 3D

# NOTE:

- Smart Scene 3D is not available in Smart 3D mode.
- This feature is available only under GYN, OB2 or OB3 exam mode.

In 3D/4D acquisition preparation status, this feature can adjust ROI size and position automatically and activate appropriate render modes according to the recognized anatomical structure of some organs.

For OB2/OB3 exam mode, spine, brain, long bone and face can be recognized. For GYN exam mode, endometrium can be recognized.

Perform the following procedure:

- 1. Enter 3D/4D acquisition preparation status.
- 2. Tap [Smart Scene 3D] under 3D/4D Scenario Setting to enable the feature.
  - If necessary, select the desired organ type manually.
  - If necessary, tap [Refresh] to reset the ROI.
  - If necessary, adjust the ROI size and position manually.
- 3. Press <Update> to begin 3D/4D acquisition.

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# 

It is provided for reference, not for confirming a diagnosis.

# 8.1 Strain Elastography

It is produced based on the slight manual-pressure or human respiration in 2D real-time mode. The tissue hardness of the mass can be determined by the image color and brightness. Besides, the relative tissue hardness is displayed in quantitative manners.

# 8.1.1 Basic Procedure for Strain Elastography

Perform the following procedure:

- 1. Perform 2D scan to locate the region.
- 2. Tap [Elasto] > [StrainE] on the touch screen or press the user-defined key for <StrainE> to enter the elastography mode.

The system displays two dual B+E windows in real time. The left one is 2D image, and the right one is elasto image.

3. Adjust ROI according to the lesion size.

Press <Set> to switch between the solid line and the dotted line status.

- When the ROI box is solid line, use the trackball to change its position.
- When the ROI box is dotted line, use the trackball to change the size.
- 4. Press the probe according to the experiences and actual situation.

The screen displays the pressure curve in real-time:



Where, the X-axis represents time and Y-axis represents pressure.

- 5. Adjust the image parameters to obtain optimized image and necessary information.
- 6. Press <B> or tap [Elasto] to exit, and then return to B mode.

# 8.1.2 Image Parameters

### Smooth

Tap [Smooth] on the touch screen to adjust the parameters. The bigger the value is, the higher the smooth becomes.

# Opacity

Adjust the opacity feature of the Elasto image.

Turn the knob under [Opacity] on the touch screen to complete the adjustment. The bigger the value the stronger the effect.

#### Invert

Invert the E color bar and therefore invert the colors of benign and malignant tissue. Tap [Invert] on the touch screen.

#### **Display Format**

Adjust the display format of ultrasound image and the Elasto image.

Tap [H 1:1], [V 1:1], [Full] on the touch screen to adjust.

The system provides 3 types of display format:

- H 1:1: Right and left display (the real-time ultrasound image appears on the left, and the elasto image appears on the right);
- V 1:1: Up down display (the elasto image appears above, and the real-time ultrasound image appears below).
- Full: The elasto image only displayed.

#### Мар

Select different maps for observation.

Rotate the knob under the [Map] item on the touch screen or adjust through the mapping-menu item to select the map.

#### Strain mode

Affect the display effect of adjusting dynamic range.

Tap [Strain Mode] on the touch screen to adjust the parameters.

Strain mode is set to 0, adjust dynamic range, the image difference changes obviously.

#### Dynamic Range (Dyn Ra.)

Adjust contrast resolution of an image.

The real-time dynamic range value is displayed on the image parameter area in the upper left corner of the screen.

Rotate the knob below [Dyn Ra.] to adjust the parameters.

The more the dynamic range, the more specified the information, and the lower the contrast with more noise.

## **E** Sensitivity

Increase the image palpability.

Rotate the knob under the [E Sensitivity] item on the touch screen to adjust the value.

The higher the sensitivity, the higher the image palpability.

#### Strain Scale

Adjust the bar height of the pressure hint curve to keep the average height of the hint bar on proper position.

Rotate the knob under the [Strain Scale] item to adjust.

## **Map Position**

Adjust the up/down position of the map.

Tap [Map Position] on the touch screen to adjust the parameter.

When the E Average function is enabled or disabled, the elasto curve is displayed based on different statistical amounts.

# 8.1.3 Mass Measurement

Press <Measure> to enter measurement status. You can measure shell thick, strain ratio, strain-hist, etc. For details, see "Advanced Volume".

# 8.1.4 Cine Review

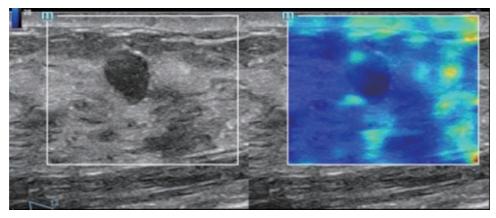
Press <Freeze> or open an elastography imaging cine file to enter cine review status.

# 8.2 STE Imaging (Sound Touch Elastography)

Keep the probe still to produce the elastography image in real-time STE mode. The tissue hardness of the mass can be determined by the image color and brightness. Besides, the relative tissue hardness is displayed in quantitative manners. STE imaging provides you real elasto modulus for quantification analysis.

# 8.2.1 Basic Procedures for STE Imaging

- 1. Select a proper probe. Perform 2D scan to locate the region.
- 2. Tap [Elasto] > [STE] on the touch screen. Or press the user-defined <STE> key to enter the STE mode.



- 3. Adjust the ROI based on the lesion size, and press <Set> to adjust the ROI size and the position. To compare the hardness between the lesion and the normal tissue, the ROI should include the lesion and the normal tissue.
- 4. Keep the probe still to imaging, and adjust the parameter to obtain premium image.
- 5. Freeze the image, and replay the image if necessary.
- 6. Perform the measurement or add comment/body mark to the image if necessary.
- 7. Save the single-frame and multi-frame image.
- 8. Acquire high-quality image if necessary.
- 9. Press <B> on the control panel or tap [Elasto] on the touch screen to exit the shear wave elastography mode, and return to B mode.

# 8.2.2 Image Parameters

# **E Quality**

Used to select the transmitting frequency of the current probe, the real-time value of which is displayed in the image parameter area in the upper left side of the screen.

Rotate the knob under [E Quality] on the touch screen to select the different THI frequency value.

Please select the frequency according to the detection depth and current tissue features.

### **Elas Metric**

Used to adjust the elastography metric.

Rotate the knob under [Elas. Metric] to adjust the value on the touch screen.

The metric includes Young's modulus E (unit: kPa), shear modulus G (unit: kPa), and shear wave velocity Cs (unit: m/s).

The current elastic modulus or the shear wave velocity (including the unit) appears on the top of the color bar.

#### Scale

Used to change the maximum scale to make the map related to the color at the top of the bar. Optimize the elasto modulus, or mirror the elasto wave velocity to the map.

Rotate the knob under [Scale] on the touch screen. The value on the top of the Map changes as the Scale changes.

Parts which exceed maximum elasto modulus or shear wave velocity will be mapped onto the color on top of the color bar at top-left part of the image. Thus if the color in the ROI is mainly the color on top of the color bar, you need to increase the metric range.

### Opacity

Used to adjust the opacity feature of the Elasto image.

Tap [Opacity] on the touch screen. The adjusting range: 0 to 5 in increment of 1.

### Мар

Used to adjust the color map to achieve the switch between the gray map and the color map. Tap [Map] on the touch screen to select the map.

## **ROI Adjustment**

This feature is used to adjust the ROI position and scale of the lesion detected in STQ imaging.

Rotate the knob under the [Fixed ROI] item on the touch screen to adjust the fixed size of the ROI, or press the <Set> key and roll the trackball to adjust the ROI position and scale. The ROI includes lesions and surrounding normal tissues.

The "+" sign indicates the ROI center, and the Depth value of the ROI center is displayed at the bottom right corner of the screen.

### **Display Format**

Used to adjust the display format of ultrasound image and the Elasto image, and return to the previous state.

Tap each soft key on the touch screen to complete the adjustment.

More accurate result is obtained based on the actual situation.

### **HQElasto**

Turn on high-quality scanning mode to optimize penetration.

Tap [HQElasto] to enable the function and the button will be highlighted.

When the feature is activated, the system turns into single-frame scanning mode. Pressing <Update> acquires one frame image of B and Elasto.

#### **RLB Map**

Used to help the user judge the region where it is suitable for elasto measurements based on the distinctive colors in elasto image in quality map.

The RLB Index shows the signal reliability of the STE inside the ROI, and it helps the user judge the effectiveness of the current elasto measurement.

Tap [RLB Map] to select the display mode of the RLB map, B-mode image and elasto image.

- The higher the RLB Index is, the more reliability the signal becomes; vice versa.
- There are three colors showing the RLB Index: Red (low reliability), Yellow (medium reliability) and White (high reliability).
- The color in High area is suitable for the imaging of shear wave elastography.
- The color in Low area is not suitable for the imaging of shear wave elastography (liquid, gas, bone, etc). It can be used as a tool to detect the tissue or the lesion.

#### **RLB View**

This feature supports the less qualified region or the region that fails to receive shear waves of the gas or liquid to be displayed in hollow.

Tap [RLB View] on the touch screen to enable the function and the button will be highlighted.

After the RLB View function is enabled, the less qualified region is displayed in hollow. The hollow region can be seen in B images. The hollow region corresponds to the purple region in the reliability image.

#### M-STB Index/Sensi.

The STE imaging can easily be affected by respiration, pulse of the main artery, or transducer movement, which may cause uncertainty and unreliability. The M-STB Index helps users judge whether the current elasto image is captured in stable state. Based on the judgment, capturing method, capturing part, and patient cooperation can be adjusted accordingly.

Tap [M-STB Index] on the touch screen to enable the function and the button will be highlighted. Then the M-STB Index is displayed at the upper side of the image.

- Grading definition of the M-STB Index: 1 star indicates that the motion interference is extremely strong, and it is not recommended to use the elasto image; 2 stars indicates that the motion interference is relatively strong, and it is not recommended to use the elasto image; 3 stars indicates that the motion interference is general, and it is not recommended to use the elasto image; 4 stars indicates that the motion interference is not strong, and the image can be used; 5 stars indicates that the motion interference is few or slight, and it is recommended to use the elasto image.
- Users can determine the interference degree of the currently-captured elasto image according to the M-STB Index.

Tap [M-STB Sensi.] on the touch screen to set the grading threshold of the M-STB Index.

The stronger the sensibility of the motion stability is, the higher the judgment accuracy of the motion interference becomes.

#### Smooth

This feature is used to reject the noise and smooth the image.

Tap [Smooth] on the touch screen to adjust the parameter.

The bigger the level is, the higher the smooth effect achieves.

#### Persistence

This feature is used to superimpose and average adjacent elasto images, so as to optimize the image.

Tap [Persistence] on the touch screen to adjust the parameter.

The bigger the value is, the higher the frame optimization effect achieves.

The persistence function can remove image noise and optimize image effect to gain a more detailed image.

#### FS Mode

This feature is used to improve the frame rate. Tap [FS Mode] on the touch screen to enable the function and the button will be highlighted.

#### Invert

Invert the map to satisfy the different doctors to define the benign lesion or malignant lesion. Tap [Invert] to enable the function (the soft key is highlighted).

#### iLayering

To increase the layer display in elasto images. Tap [iLayering] to enable the function.

#### Filter

To filter the noise of the elasto image.

Tap [Filter]. The higher the level is, the smaller the noise of the elasto image becomes, and the clearer the edge of the field target appears.

The system restarts scanning B image and E image after the filtering is completed.

#### **Map Position**

This feature is used to adjust the up/down position of the map.

Tap [Map Position] on the touch screen to adjust the parameter.

#### Select/Bad

It is used to remove the desired frame from stress curve. The removed frame will not be calculated in STE indices.

Rotate the knob under [Select/Bad] to select the desired frame, and press the knob to set the desired frame to "On".

#### HiRE ROI (High Resolution ROI, STE-HiRE)

It is used to improve the resolution of STE image by acquiring more intensive data with smaller ROI.

Tap [HiRE ROI] on the touch screen to enable the function in acquisition preparation mode or after acquisition.

- After the HiRE ROI function is enabled, you can rotate or press the knob under [HiRE ROI Size] to adjust the ROI size.
- Tap [Scale Adapt] to automatically adjust the map scale to a proper range. You can repeat tapping this item for more adaption.

## 8.2.3 Measuring

Press <Caliper> to enter general measurements. You can perform the measurements of Elastography, Elas. Ratio, Directional Ratio, Elas. Hist and etc.

Press <Measure> to enter application measurement. You can perform measurements on Isthmus and Mass, etc.

For details, see "Advanced Volume".

## 8.2.4 Cine Review

Press <Freeze> to freeze the image and enter cine review state.

Or, click the cine to enter the cine review state.

## 8.2.5 PZ Tracking (Peripheral Zone Tracking)

It is used to automatically recognize the peripheral zone boundary of the prostate, as well as automatically measure the prostate, and hardest/softest point of the prostate.

- 1. Select the ELC13-4U probe and prostate exam mode, and then switch to the linear plane.
- 2. Perform 2D scan to locate the region.
- 3. Tap [Elasto] > [STE] on the touch screen. Or press the user-defined <STE> key to enter the STE mode.

The dual windows of B+STE images are displayed.

- 4. Tap [PZ Tracking] on the touch screen to enable the function in acquisition preparation mode.
- 5. Turn on [Auto ROI] to automatically adjust the ROI position and size to cover the prostate. Tap [PZ Opacity] to adjust the opacity feature of the Elasto image if necessary.
- 6. Press <Update> to start acquisition.
- 7. Freeze the image or save a single-frame image or cine file.

If the tracking result is not satisfactory, you can manually edit the boundary.

- a. Tap [PZ Edit] in the freezing mode or by opening a saved single-frame image or cine file.
- b. Use the trackball and <Set> key to manually edit the boundary of the peripheral zone.
- 8. Press <Measure> to enter application measurement and perform measurement under the "Prostate AutoElas." item.
- 9. Save a single image to save the data to report.

# 8.3 STQ Imaging (Sound Touch Quantification)

## 8.3.1 Basic Procedures for the STQ Imaging

10. Select a proper probe. Perform 2D scan to locate the lesion.

11. Tap [Elasto] > [STQ] on the touch screen. Or press the user-defined <STQ> key to enter the STQ mode.



- 12. Adjust the ROI based on the lesion size and the position.
- 13. Press <Update> to generate the acquisition. Place the probe still with stable force (not pressing, sweeping or moving the probe) to acquire the image. Adjust the B image parameters to obtain a premium image.

The stress curve shows at the bottom of the screen after entering the real-time acquisition.

The following indices display besides end of the curve in real-time:

- Elasto modulus inside the ROI of the current frame;
- The mean value, maximum value, minimum value, SD value of shear velocity;
- Depth value of the active elasto modulus.
- 14. Freeze the image, and replay the image if necessary.
- 15. Save the single-frame and multi-frame image.
- 16. Reacquire the image if necessary.
- 17. Press <B> on the control panel or tap [Elasto] on the touch screen to exit the elastography imaging mode, and return to B mode.

### 8.3.2 Image Parameters

#### **ROI Adjustment**

Used to adjust the ROI position and scale in STQ imaging.

Rotate [Fixed ROI] knob to adjust the ROI fixed size.

The cross "+" shows the center of the ROI, and the depth appears at the right bottom of the screen.

#### Elas. Metric

Display the changes of elasto metric's average value inside the ROI by elasto curve. It is convenient to the doctor to choose the stable measurement result.

The square height of the elasto curve (Y-axis represents elasto metric; X-axis represents the time) represents the average value of the elasto metric for current frame.

Rotate [Elas. Metric] knob to adjust the value of the elasto metric.

The metric includes Young's modulus E (unit: kPa), and shear modulus G (unit: kPa).

#### E Avg

Used to optimize the measurement result via equalizing the elasto metric of the current frames and the previous frames. Decrease the image noise.

Rotate [E Avg] knob to adjust the value.

Off represents the E Avg is disabled. The larger the scale is, the more the frames of the elasto metric are equalized.

Decrease the image noise.

#### E Bar

This feature supports the elasto curve to be displayed based on different statistical amounts.

#### M-STB Index/Sensibility

The STE imaging can easily be affected by respiration, pulse of the main artery, or transducer movement, which may cause uncertainty and unreliability. The M-STB Index helps users judge whether the current elasto image is captured in stable state. Based on the judgment, capturing method, capturing part, and patient cooperation can be adjusted accordingly.

Tap [M-STB Index] on the touch screen to enable the function and the button will be highlighted. Then the M-STB Index is displayed at the upper side of the image.

- Grading definition of the M-STB Index: 1 star indicates that the motion interference is extremely strong, and it is not recommended to use the elasto image; 2 stars indicates that the motion interference is relatively strong, and it is not recommended to use the elasto image; 3 stars indicates that the motion interference is general, and it is not recommended to use the elasto image; 4 stars indicates that the motion interference is not strong, and the image can be used; 5 stars indicates that the motion interference is few or slight, and it is recommended to use the elasto image.
- Users can determine the interference degree of the currently-captured elasto image according to the M-STB Index.

Tap [M-STB Sensi.] on the touch screen to set the grading threshold of the M-STB Index.

The stronger the sensibility of the motion stability is, the higher the judgment accuracy of the motion interference becomes.

#### Scale

Used to optimize the display effect of the elasto average metric inside ROI via changing the Y-axis size.

Rotate [Scale] knob to adjust the value.

If elasto metric average value inside ROI of a certain frame image exceeds the maximum scale on the elasto curve, elasto metric will display in the maximum scale value.

#### HQElasto

Enable the high-quality scan mode and optimize the penetrability.

Tap [HQElasto] to enable the function. The soft key becomes highlighted.

Press <Update> to acquire the high-quality image. It produces single-frame B image and ROI elasto metric data.

The measurement, comment and body mark is not available in HQElasto status.

#### Filter

This feature is used to filter the noise of the elasto image.

Tap [Filter] item on the touch screen.

The higher the level is, the smaller the noise of the elasto image becomes, and the clearer the edge of the field target appears.

The system restarts scanning B image and E image after the filtering parameter is adjusted.

#### Smooth

This feature is used to reject the noise and smooth the image.

Tap [Smooth] on the touch screen to adjust the parameter.

The bigger the level is, the higher the smooth effect achieves.

#### Persistence

This feature is used to superimpose and average adjacent elasto images, so as to optimize the image.

Tap [Persistence] on the touch screen to adjust the parameter.

The bigger the value is, the higher the frame optimization effect achieves.

The persistence function can remove image noise and optimize image effect to gain a more detailed image.

#### Map Position

This feature is used to adjust the up/down position of the map.

Tap [Map Position] on the touch screen to adjust the parameter.

When the E Average function is enabled or disabled, the elasto curve is displayed based on different statistical amounts.

#### Lesion

It is used to distinguish elastography data of the different lesion region.

Rotate the knob under [Lesion] on the touch screen to adjust.

#### Select/Bad

It is used to remove the desired frame from stress curve. The removed frame will not be calculated in STQ indices.

Rotate the knob under [Select/Bad] to select the desired frame, and press the knob to set the desired frame to "On".

## 8.4 Fatty Liver Lab

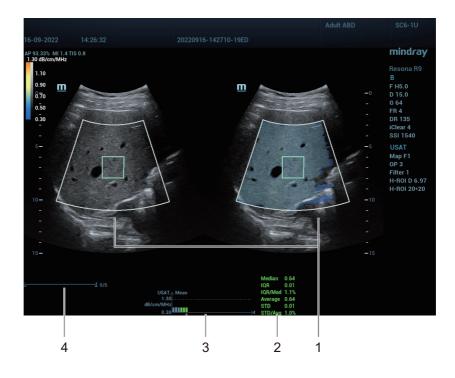
Fatty Liver Lab is a tool kit specifically designed for fatty liver applications, including USAT, HRI<sup>+</sup>.

#### NOTE:

- Input the fatty liver related parameters in the Abdomen tab of the patient information page. For details, see "5.1.1 New Patient Information".
- Keep the patient breathing smoothly.

# 8.4.1 USAT (UltraSound ATtenuation analysis)

It is used to measure the acoustic attenuation coefficient value of the target liver region and display its 2D spatial distribution, according to the ultrasonic echo signal.



1.	The left window is the B mode image, and the right window is the USAT image.			
2.	Measurement result window			
	Single frame			
	Mean: indicates the mean value.			
	Max: indicates the maximum value.			
	Min: indicates the minimum value.			
	SD: indicates the standard deviation value.			
	Multiple frames			
	Median: indicates the middle value.			
	IQR (Interquartile Range): indicates the 1st quartile subtracted from the 3rd			
	quartile.			
	Average: indicates the average value.			
	STD: indicates the standard deviation value.			

3.	Histogram area				
	• The horizontal axis represents time, while the vertical axis represents USAT value.				
	• The rectangle histogram above the horizontal axis represents the USAT value of every frame. The metric unit can be adjusted through "Att.Metric".				
	• The triangle icon under the horizontal axis indicates the histogram of the current frame.				
	• The dotted line that is parallel to and above the horizontal axis represents the maximum USAT value. The maximum value can be adjusted through "Scale".				
	• When the measured USAT value exceeds the maximum USAT value, the maximum USAT value is displayed. The value type can be adjusted through "E bar".				
4.	Progress bar to play the frames.				

Perform the following procedure:

- 1. Select an appropriate probe and exam mode.
- 2. In B mode, move the probe and adjust the parameters to acquire the image of the target area.
- 3. Tap [USAT] to enter the USAT mode by default.

The dual-split window with a square ROI is displayed.

- 4. Adjust the ROI position and size to the target area, as well as the scan time if necessary.
- 5. Press <Update> to start acquisition.
- 6. After the acquisition is completed, the system calculates and displays the measurement curve and statistic results. The image is in freezing mode.
- 7. Rotate the knob under [Frame Average] to select the number of frames. The system calculates and updates the measurement curve and statistics results in real time.

The histograms of the selected frames for statistics are displayed in green, while the histograms of the unselected frames are displayed in blue.

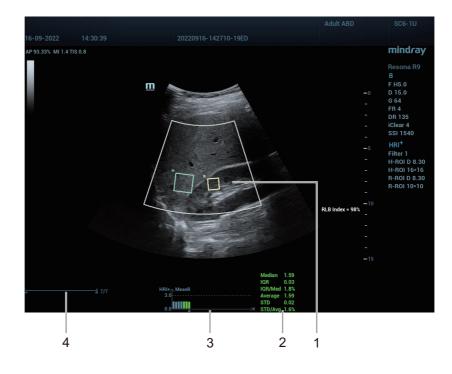
- 8. In the freezing mode, you can press the <Set> key to activate the ROI and adjust the ROI position and size again. The system calculates and updates the measurement curve and statistics results synchronously. Press the <Set> key again to confirm the results.
- 9. Rotate the knob under [Select/Bad] to select the current frame, or delete an invalid frame from calculation.

The histogram of the deleted frame is displayed in gray.

- 10. Perform measurement, or add annotations or body marks if necessary.
- 11. Save the single frame image or cine.
- 12. Press <B> on the control panel to return to B mode.

# 8.4.2 HRI<sup>+</sup> (HepatoRenal Index Plus)

It is used to manually calculate the brightness ratio of the hepatic parenchyma and renal cortex based on the radio frequency data. After the ROI of the hepatic parenchyma and renal cortex areas are located and confirmed by the doctor, the HRI<sup>+</sup> calculates and displays the echo signal intensity ratio of the selected areas, and then determines the brightness ratio.



1.	One is renal ROI, with the letter R in the upper left corner, and the other one is hepatic ROI, with the letter H in the upper left corner.
2.	<ul> <li>Measurement result window:</li> <li>Single frame MeanR: indicates ratio of the mean hepatic brightness value to mean renal brightness value.</li> <li>H-Mean: indicates the mean hepatic brightness value.</li> <li>R-Mean: indicates the mean renal brightness value.</li> <li>Multiple frames The parameters of the multiple frames are the same as those of the USAT function.</li> </ul>
3.	The histogram area parameters are the same as those of the USAT function.
4.	Progress bar to play the frames.

Perform the following procedure:

- 1. Select an appropriate probe and exam mode.
- 2. In B mode, move the probe and adjust the parameters to acquire the image of the target area.
- 3. Tap  $[USAT] > [HRI^+]$  to enter the HRI<sup>+</sup> function.

A single window with two square ROIs are displayed.

4. Adjust the ROI position and size to the target area.

The renal ROI is activated by default.

- a. Adjust the renal ROI position and size to the target area. In this case, the depth of the hepatic ROI is adjusted together.
- b. Press the <Set> key to switch to the hepatic ROI.

- c. Adjust the hepatic ROI position and size to the target area. In this case, the depth of the renal ROI is adjusted together.
- 5. Adjust the scan time if necessary.
- 6. Press <Update> to start acquisition.
- 7. After the acquisition is completed, the system calculates and displays the measurement curve and statistic results. The image is in freezing mode.
- 8. Rotate the knob under [Frame Average] to select the number of frames. The system calculates and updates the measurement curve and statistics results in real time.

The histograms of the selected frames for statistics are displayed in green, while the histograms of the unselected frames are displayed in blue.

- 9. In the freezing mode, you can press the <Set> key to activate the ROI and adjust the ROI position and size again. The system calculates and updates the measurement curve and statistics results synchronously. Press the <Set> key again to confirm the results.
- 10. Rotate the knob under [Select/Bad] to select the current frame, or delete an invalid frame from calculation.

The histogram of the deleted frame is displayed in gray.

- 11. Perform measurement, or add annotations or body marks if necessary.
- 12. Save the single frame image or cine.
- 13. Press <B> on the control panel to return to B mode.

The contrast imaging is used in conjunction with ultrasound contrast agents to enhance imaging of blood flow and microcirculation. Injected contrast agents re-emit incident acoustic energy at a harmonic frequency much more efficient than the surrounding tissue. Blood containing the contrast agent stands out brightly against a dark background of normal tissue.

# 

- Set MI index by instructions in the contrast agent accompanied manual.
- Read contrast agent accompanied manual carefully before using contrast function.

#### NOTE:

- Make sure to finish parameter setting before injecting the agent into the patient to avoid affecting image consistency. This is because the acting time of the agent is limited.
- The applied contrast agency should be compliant with the relevant local regulations.

# 9.1 Basic Procedures for Contrast Imaging

Perform the following procedure:

- 1. Select an appropriate probe, and perform 2D imaging to obtain the target image, and then fix the probe.
- 2. Tap [Contrast] or press <Contrast> to enter the contrast imaging mode.
- 3. Adjust the acoustic power experientially to obtain a good image.

Tap [Dual Live] to activate the dual live function. Observe the tissue image to find the target view.

- 4. Inject the contrast agent, and tap [Timer1] to start the contrast timing. When the timer begins to work, the time will be displayed on the screen.
- 5. Observe the image, tap [Pro Capture] and [Retro Capture] or the user-defined key to save the images. Press <Freeze> to enter cine review status.

Perform several live captures if there are more than one interested sections.

6. At the end of a contrast imaging, tap [Timer1] to exit the timing function. Perform steps 3-5 if necessary.

For every single contrast imaging procedure, use [Timer2] for timing.

If necessary, activate destruction function by tapping [Destruct] at "ON" to destruct the microbubbles left by the last contrast imaging; or to observe the reinfusion effect in a continuous agent injecting process.

7. Exit contrast imaging.

Press <B> button to return to B mode.

# 9.2 LVO (Left Ventricular Opacification)

Perform the following procedure:

- 1. Acquire ECG signal.
- 2. Select an appropriate probe and LVO exam mode.
- 3. Workflow of LVO is similar to abdomen contrast imaging, see "9.1 Basic Procedures for Contrast Imaging".

# 9.3 CEUS Chrono-Parametric Mode

It is used to visually display the recorded contrast agent arriving time by different tint colors in a color image through color coding method. It assists in observing the spatial distribution and time sequence of blood perfusion of the micro-vessels in the target area.

## 9.3.1 2D

Perform the following procedure:

- 1. Select an appropriate probe.
- 2. Enter the Contrast imaging mode.
- 3. Inject the contrast agent, and freeze the image after the contrast agent reaches the target area. Or open a saved Contrast imaging cine file.
- 4. Select [CCPM] to enter CCPM mode.

Set the start and end frames, and adjust the threshold and other parameters if necessary.

5. Select [CCPM Calc] to start calculation. The system codes and displays the color map of each frame according to the arriving time of the contrast agent.

You can adjust the starting time.

- a. Activate the cursor and move the cursor to the contrast image.
- b. Select a desired point as the new starting time
- c. Press the right <Set> key to confirm.

The arriving time of each point is updated. You can repeat adjusting the starting time. You can press the left <Set> key to restore the starting time to the original value.

6. Save images and exit the CCPM mode.

#### Background

It is used to set the background image for the color coding of arriving time.

#### **Motion Tracking**

It is used to enable or disable motion tracking compensation.

#### Transparency

It is used to adjust the transparency for the color coding of arriving time.

#### Threshold

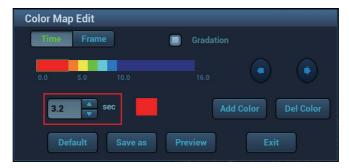
It is used to adjust the threshold of the contrast agent arriving time.

#### **Color Map**

Color map is used during color coding of the contrast agent arriving time in the contrast image. It consists of multiple color blocks. Different color blocks indicate different arriving time points/

image frames of the contrast agent and are separated by each scale. Tap [Color Map Edit] in the touch screen to enter the editing dialogue.

- Time/Frame: Select the horizontal axis of the color map from Time or Frame.
- Gradation: Set the display format of the color map to Gradation or non-Gradation.
- Add Color/Del Color: Add color to or delete color from the provided color map.
- Adjust the scale length of the currently selected color block.



• Adjust the color of the currently selected color block.

Color Map Edit	
Time Frame	Gradation
0.0 5.0 10.0	
3.2 sec	Add Color Del Color
Default Save as Pr	review Exit

Adjust the length of the entire color map.

Color Ma	p Edit					
Time	Frame			Gradatio		
0.0						
3.2	s s	ec		A	dd Color	Del Color
De	fault	Save as	Pre	eview	Exit	

- Preview: Preview the color map after re-calculating the arriving time.
- Save as: Save the adjusted color map as the user-defined settings.
- Default: Restore the color map to the default settings.

## 9.3.2 4D

#### Entry 1

Perform the following procedure:

- 1. Open a saved volume CEUS cine file.
- 2. Select [CCPM] to enter CCPM mode. The system starts calculating. Adjust length, tint, and other parameters if necessary.
- 3. Perform measurement, or add annotations or body marks if necessary.

4. Save images and exit the CCPM mode.

#### Entry 2

Perform the following procedure:

- 1. Select a volume probe.
- 2. Select Contrast, and then toggle <sup>3D</sup>/<sub>→</sub> to the right to enter volume CEUS imaging mode.
- 3. Inject the contrast agent, and press <Update>.
- 4. Freeze the image after the contrast agent reaches the target area.
- 5. Select [CCPM] to enter CCPM mode. The system starts calculating.

Adjust length, tint, and other parameters if necessary.

- 6. Perform measurement, or add annotations or body marks if necessary.
- 7. Save images and exit the CCPM mode.

# 9.4 TCMR (Tissue-Contrast Mix Rendering)

It is used to mix the rendering of 3D/4D Contrast Imaging and tissue data, and display them together (completely obscured, translucent display). Also, it is used to observe the dynamic perfusion process of Contrast Imaging, and display the relationship with the stereo structure and spatial position of the tissue.

#### Entry 1

Perform the following procedure:

- 1. Select a volume probe.
- 2. Select Contrast, and then press or toggle <sup>3D</sup>/<sub>→</sub> to the right to enter volume CEUS imaging mode.

The "Scan Modes" parameter is set to "Contrast+Tis" by default. You can only enter TCMR in "Contrast+Tis" mode.

- 3. In the acquisition preparation mode, press <Update> to start the acquisition.
- 4. Select [TCMR] under the "Display" item to enter TCMR mode.
  - The "FixTissue" parameter is enabled by default. In this status, you can fix the VOI and switch active windows.
  - Adjust mix color, mix ratio, tissue render, and other parameters if necessary.
- 5. Save images and exit the TCMR mode.

#### Entry 2

Perform the following procedure:

- 1. Select a volume probe.
- 2. Select Contrast, and then press or toggle <sup>3D</sup>/<sub>→</sub> to the right to enter volume CEUS imaging mode.

The "Scan Modes" parameter is set to "Contrast+Tis" by default. You can only enter TCMR in "Contrast+Tis" mode.

- 3. In the acquisition preparation mode, select [TCMR].
- 4. Press <Update> to start the acquisition.

- The "FixTissue" parameter is enabled by default. In this status, you can switch active windows.
- Adjust mix color, mix ratio, tissue render, and other parameters if necessary.
- 5. Save images and exit the TCMR mode.

#### Entry 3

Perform the following procedure:

- 1. Open a saved volume CEUS cine file.
- 2. Select [TCMR] under the "Display" item to enter TCMR mode.
  - The "FixTissue" item is enabled by default. In this status, you can switch active windows.
  - Adjust mix color, mix ratio, tissue render, and other parameters if necessary.
- 3. Save images and exit the TCMR mode.

# 9.5 Image Parameters

When entering contrast imaging mode, the screen displays the contrast image, and if [Dual Live] item on the touch screen is "ON", both the contrast image (marked with ) and tissue image (marked with ) are displayed (the two window position can be changed).

Parameters in Contrast mode are similar to those in B mode; please refer to B chapter for details, special Contrast imaging parameters are introduced in the following.

Туре	Parameter	Description			
Contrast	FC	Contrast frequency.			
	D	Depth.			
	G	Gain.			
	FR	Frame rate.			
	DR	Dynamic Range.			
	iTouch	iTouch status			
Tissue	G	Gain			
	DR	Dynamic Range.			
	iTouch	iTouch status			
Zoom	Ζ	Magnification factor			
Timing (If timer is "ON")	/	In real time mode, the time displayed is the elapsed time. Freezing status:			
		Timer 1 continues timing and two times will be displayed on the screen: frozen time and time duration after the image is frozen.			
		Timer 2 stops timing and the screen displays the frozen time.			

#### Timer

#### NOTE:

The starting time displayed may be inconsistent with the actual one due to system error or some other man-made mistakes; please check the agent-injecting time.

The two timers are used to record total time of contrast imaging and single time of one contrast exam.

After the image is frozen, Timer 1 is still timing, and after unfreezing the image, the corresponding time can be seen.

Timer 2 stops timing when one contrast exam is frozen, and after unfreezing the image, the Timer 2 is off.

Tap [Timer1] to start the timing at the moment you inject the contrast agent. Here, the screen displays the times at the lower corner.

- The time begins at 0.
- In live mode, there displays the elapsed time. For example, 00:00:08, it means the elapsed time is 8s.
- Freeze the image during the timing, timer 1 continues timing and two times will be displayed on the screen: frozen time and time duration after the image is frozen; the timer stops working, and there displays the elapsed time. After unfreezing, the timer 1 restarts working, and the timer 2 exits.
- Set [Timer1] or [Timer2] as "OFF", the timer discontinues its work.

#### **Micro-bubble Destruction**

### A CAUTION

Use the contrast imaging according to the residual level of the micro-bubbles. Using contrast imaging continuously may result in human harm.

Destruct the micro-bubbles left by the last contrast imaging; or to observe the reinfusion effect in a continuous agent injecting process.

Tap [Destruct] to enable the micro-bubble destruction function:

- DestructAP: Adjust the destruct acoustic power via the touch screen.
- Destruct Time: Adjust the destruct time via the touch screen.

#### **Dual Live**

In live mode or freeze mode, set touch screen item [Dual Live] as "ON" to enable dual live function. Both the contrast mode and tissue mode are displayed. The THI and B image are displayed on the screen if the [Dual Live] is enabled.

#### TIP:

- In dual live mode, the screen displays the contrast image and tissue image
- In freeze mode, there displays only one cine review progress bar as the contrast image and tissue image are reviewed synchronously.

#### Mix Map

This function is to mix the contrast image with the tissue image, so that interested contrast regions can be located.

Tap [Mix] to select different mixing modes, and select different maps by knobs under [Gray Map]/ [Tint Map]/[Mix Map] on the touch screen.

- When dual live function is on, you can see the mixed effect on the contrast image.
- When dual live function is off, you can see the mixed effect on the full screen image.

Select the map through the [Mix Map] item.

#### iTouch

On contrast status, you can also get a better image effect by using iTouch function.

1. Press <iTouch> on the control panel to turn on the function.

The symbol of iTouch will be displayed in the image parameter area in the upper left corner of the screen once press <iTouch>.

Select different levels of iTouch effect through [iTouch] on the touch screen.

2. Long press or double press <iTouch> to exit the function.

#### **High Frame Rate CEUS**

This function is used to improve the frame rate (FR) for contrast imaging. Tap [HiFR CEUS] to turn on the function.

#### **Contrast Enhancement**

Tap [Enhance] to suppress the noise of contrast imaging.

#### Mark Line

Tap [Markline] to enable this feature. Mark lines appear on the tissue image and contrast image. Use trackball to adjust the mark lines and mark the target with the larger circle.

#### Image Saving

Live capture

In live mode, you can save the interested images by tapping [Pro Capture] and [Retro Capture].

 Cine saving In live mode, press <Freeze> on the control panel to enter cine review status.

#### Measurement, Comment and Body Mark

The system supports image measurement, comment and body mark functions. For the details, please refer to the relevant sections.

## 9.5.1 Micro Flow Enhancement

#### NOTE:

- In MFE status, patient should lie down and hold breath, and transducer should be kept still.
- MFE imaging is available only for real-time imaging or cine file of auto review mode. If a MFE cine is reviewed manually, MFE effect cannot be displayed.

MFE superimposes and processes multiple frames of contrast image during the cycle; it indicates tiny vessel structures in detail by recording and imaging microbubbles.

#### **MFE Switch**

During real-time scanning, tap [MFE] on the touch screen to start MFE imaging (MFE key is highlighted in green).

#### **MFE Period**

Rotate the knob under [MFE Period] on the touch screen to select different imaging period suitable for current flow. Where, MAX is the maximum superimposing effect.

# 9.6 Contrast Imaging QA

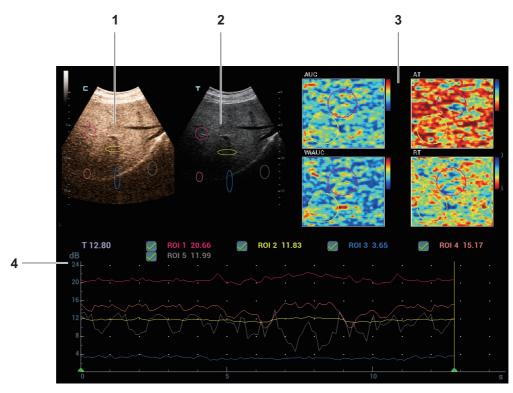
# 

Contrast Imaging QA images are provided for reference only, not for confirming a diagnosis.

#### NOTE:

- In case of inaccuracy of the data, do not adjust the depth and the pan-zoom when saving the cine. Also, during image scanning, ask the patient to hold breath for several seconds, and keep the probe still until the image is frozen.
- If the contrast signal inside the selected ROI does not meet the requirements of gamma fitting condition, that is the bulleting injection, curve fitting may not be available.

Contrast Imaging QA adopts time-intensity analysis to obtain perfusion quantification information of velocity flow, identify minor differences and control the overall perfusion trend to obtain perfusion analysis parameters and quantify the perfusion process. This is usually performed on both suspected tissue and normal tissue to get specific information of the suspected tissue.



1.	Contrast cineloop window	Sample area: indicates sampling position of the analysis curve. The sample area is color-coded. A maximum of 8 ROIs can be set.
2.	B cineloop window	The images in the contrast cincloop window and B cincloop window are the frozen images at the same time. Use the trackball to move the progress bar, and the images in the two windows are played simultaneously. Sample areas are linked in the contrast cincloop window and B cincloop window.

3.	Parameter Image Map	<ul><li>Tap [Para. Image Page] on the touch screen to turn pages of Parameter</li><li>Image Map.</li><li>Parameter Image Map can be displayed in single or quad image layout on</li><li>a page. Tap [Quad Para. Image] to switch the layout of Para. Image Map.</li></ul>
4.	Time-intensity curve	<ul> <li>Y axis represents the intensity (unit: dB), while X axis represents the time (unit: s).</li> <li>Frame marker: a yellow line that is perpendicular to the X axis, can be moved horizontally left to right (right to left) by using the trackball.</li> <li>Click the check box beside the ROI to set if to hide or to display the QA curve.</li> <li>You can get the current X/Y axis value by moving the cursor onto one point on the curve; and if you press <set> at this time, the frame marker will move to the spot.</set></li> </ul>

Perform the following procedure:

1. Perform image scanning, freeze the image and select a range of images for analysis; or select a desired cine loop from the stored images.

The system sets the starting time and ending time of the cine to be the first frame and last frame of QA analysis range.

- 2. Review the image to a desired frame.
- 3. Tap [Contrast QA] to activate the function. Trend curve is displayed on the screen by default.

You can mark and remove unreliable image frames if necessary. The unreliable image frames thus are excluded from time-intensity analysis.

- a. Tap [Mark Frames] on the touch screen.
- b. In the curve analysis area, move the cursor and press the left <Set> key to set the begin frame.
- c. Press the right <Set> key to set the end frame.

You can mark several image frames to exclude them from quantitative analysis.

- <Delete Current>: Delete the current marked frame.
- <Delete All>: Delete all the marked frames.
- <Reset Mrk Frm>: Restore the deleted frames.
- 4. Draw an Global ROI.
  - a. Rotate the knob under [Global ROI] item on the touch screen to select the shape of the sample area: "SquareROI" or "Ellipse ROI".
  - b. Roll the trackball to position the cursor to the contrast image display area. The cursor is displayed as a "+" mark.
  - c. Press <Set> to set the starting point of an ROI.
  - d. Use the trackball and the <Set> key to set the end point of an ROI.

To draw an Ellipse ROI, double-press <Set> to confirm the end point.

After the Global ROI is drawn, the system automatically calculates the parameters and displays Parameter Image Map on the right side of the image display area.

You can select to show or hide a certain parameter on the Parameter Image Map area or parameter table. The corresponding image will update synchronously.

Rotate the knob under [Para. Image List] item to select a parameter. Then press the knob to show or hide a certain parameter.

Click the color bar right beside the Parameter Image Map area and adjust it by rotating the knob under [Para. Image Map] item on the touch screen. You can press to select Auto, Min, and Max items.

5. Draw local ROIs respectively for the suspicious tissue and the normal tissue within the global ROI.

Up to 8 ROIs can be saved on the reference image, with the corresponding eight curves displayed simultaneously on the Time-intensity curve area. Each ROI display has a different color, and its corresponding curve data uses that same color.

Select formulas to fit the time-intensity curve if necessary.

The system automatically starts calculations after the local ROIs are drawn. The time-intensity curves consistent with the ROI color are displayed along the axis. The curve within the marked frame area is displayed as a straight line.

a. Use [ROI Type] to select the method for drawing the shapes of the sample area: Trace ROI and Ellipse ROI.

The cursor is displayed as a "+" mark.

b. Review the image to a desired frame.

Roll the trackball to position the cursor to the image review area and draw ROIs according to the selected drawing method.

Trace ROI	Follow the steps below:			
	1. Press <set> key to set the starting point.</set>			
	2. Use the trackball and <set> key to set the next point.</set>			
	Press <clear> to cancel the last point.</clear>			
	3. Set more trace points if necessary.			
	4. When a suitable ROI has been drawn, confirm the ROI by double pressing <set>.</set>			
Ellipse ROI	Follow the steps below:			
	1. Use the trackball to position the caliper on the reference image at the start point.			
	Press <set> to set the starting point of an axis of the ellipse.</set>			
	2. Use the trackball and <set> key to set the next point.</set>			
	3. Use the trackball and <set> key to set the other axis of the ellipse and confirm the ROI.</set>			

- Press <Clear> key to delete the last ROI.
- Tap [Delete Current] to delete the current selected ROI.
- Tap [Delete All] to delete all ROIs.
- Tap [Copy ROI] to create a new ROI same as the currently selected or latest added ROI.
- Adjust the ROI position: Move the cursor to the inside of an ROI, press the <Set> key to select the ROI, drag the ROI to the target position, and press the <Set> key.
- 6. Tap [Motion Tracking] to enable the Motion Tracking function.

This function provides a motion compensated ROI as precise time-intensity information can be acquired using active tracking. It can enhance the calculation accuracy as reducing the impact of probe or patient respiratory movement.

#### NOTE:

Elliptical ROIs can be positioned in any manner that keeps their center within the image boundaries. In the case that part of the ROI is outside the image boundary, only data from within the image boundary is used for calculating the mean intensity value.

7. If necessary, tap [Fit Curve] to perform curve fitting on the time-intensity curve, where color of the fitted curve is consistent with color of the current ROI curve.

The system can calculate characteristic parameters according to curve fitting formula and data, display fit curve for time-intensity curve, and perform data analysis on time-intensity curve for data table.

- Tap [Raw Curve] to hide/display raw curve.
- Tap [Table display] to check parameters:

Item	Description
РКІ	Peak intensity
AUC	Area under TIC
AT	Arrival time
WiAUC	Wash-in area under TIC
RT	Rising time
ТТР	Time-to-peak
WoAUC	Wash-out area under TIC
AS	Ascending slope
DS	Descending slope
SR	Slope ratio (D/A)
FT	Falling time
mTT	Mean transition time
AREA	ROI area
mTIC	Mean Time Intensity Curve

You can set range for the fit curve. After the range is set, the system displays fit curve within the range only. Use the trackball to the time-intensity curve to move the frame marker position.

- a. Set the starting of the fit curve: Use the trackball to select the starting time and tap [Set Fit Start].
- b. Set the end of the fit curve: Use the trackball to select the end time and tap [Set Fit End].
- 8. Rotate the knob under [X Scale] on the touch screen to choose different value, so that the X scale display manner will be changed.

This function can be used to track detailed tissue information.

- 9. Save the curve image, export the data and perform parameter analysis.
  - a. Tap [Export] on the touch screen.
  - b. Select the drive and enter the file name in the displayed window. The default format is .CSV.
  - c. Select [OK] to save the data and return to the QA Analysis screen.

After Exported successfully, the image thumbnail area on the screen displays the image for quantitative analysis.

The exported data includes Current Display image, analysis curve data and analysis parameters.

10. Tap [Exit] to exit Contrast QA.

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# **10** Physiological Unit Signal

The physiological unit signal waveform is used for checking ultrasound image in ultrasound exam (cardiac exam mainly).

The system provides the physiological unit input panel, on which ECG and other signals can be input.

The system is equipped with physiological unit signal module. Tap [Physio] to enable the function. The image area shows ECG curves.

Support ECG and external ECG.

Only one port is on the ECG module, which transfers to ECG source via DC-IN.

# AWARNING

- Do not use the physiological traces for diagnosis and monitoring.
- To avoid electric shock, the following checks shall be performed prior to an operation:
  - The ECG electrode cable must not be cracked, frayed or show any signs of damage or strain.
  - The ECG electrode cable must be correctly connected.
  - You must use the ECG leads provided with the ECG module. Failure to do so may result in electric shock.
- The ECG electrode cable must be connected to the system first. Only after the cable is connected to the system, can the patient be connected to the ECG electrodes. Failure to follow these instructions may subject the patient to electric shock.
- Do not place the ECG electrodes directly in contact the patient's heart; otherwise it may lead to stop of the patient's heartbeat.
- Do not apply the ECG electrodes if the voltage exceeds 15 volts. This could produce an electric shock.
- Do not use this system when any digital device such as a high-frequency electrotome or high-frequency therapeutic device is applied already.
- Only ECG can be used with defibrillator and anti-defibrillation ECG cable should be used when defibrilation is required for a patient.
- Conductive parts of electrodes and associated connectors for ECG should not contact other conductive parts including earth/grounding.
- Frequent trampling or squeezing on the cables may result in cable breakdown or fracture.
- Display effect of respiratory curve depends on the patient breathing status. While a very slow or smooth breathing may lead to an inapparent respiratory curve, breathing in a large amplitude may cause an incomplete display of the respiratory curve. Display effect is linked to the connected

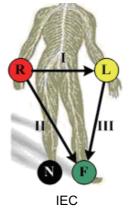
parts of the body. Generally, signals by connecting to limbs are stronger than by connecting to the chest.

• When abnormality is detected in physio trace, please check if ECG leads are properly connected with the system.

# 10.1 ECG

Perform the following procedure:

- 1. Connect the device and place ECG electrodes.
  - a. Turn off the power supply of the system, and connect the ECG cable to ECG port.
  - b. Turn on the power supply of the system.
  - c. Place the ECG electrodes on the patient's body.



- 2. Tap [Physio] or press the user-defined <Physio> key to enter physio operation interface.
- 3. Switch the imaging modes and display formats, adjusting the parameters to get an optimized image.
- 4. Parameter adjusting:

Tap [ECG] to enable or disable ECG waveform curve. Adjust the [Speed], [ECG Gain], [Position] and [Invert].

5. Trigger:

Select the trigger mode, or tap [Real & Trigger] to set the trigger time, triggering delay time and image display format.

- 6. Freeze the triggering image and the curve, and then review them.
- 7. Tap [Physio] or press the user-defined <Physio> key to exit ECG mode, and remove ECG electrodes from the patient.

## 10.1.1 ECG Triggering

ECG triggering means that image scanning is activated at some time points of ECG signals, thus obtaining B images at these time points. The triggering image should be in 2D-mode.

When ECG triggering occurs, some marks (frame triggering mark) appear on the ECG waveform (relative R wave, the time for delay set), indicating the time points when the 2D images are captured.

#### NOTE:

• The triggering mark is displayed in both freeze mode and live mode.

- The marks in Dual trigger are in different colors.
- Triggering function is unavailable if the ECG trace is disappeared. Only the live 2D image can be triggered.
- No delay time or time interval shall be less than the time required to scan a single image.
- If the delay time is longer than a heart cycle, then the heart cycle in the delay time is omitted, that is to say no trigger is occurred when R waveform is detected in the duration.

#### **Triggering Mode**

There are three triggering modes available: Single, Dual, and Timer.

- Single Trigger: When an R waveform is detected, an image will be triggered after delay time T1. The time of T1 can be edited in single mode.
- Dual trigger: when an R waveform is detected, two images in two windows will be triggered respectively after delay time T1 and T2. The time of T1 and T2 can be edited in dual mode.
- Timer Trigger: an image will be triggered after a time interval. The time interval can be edited in triggering status.

The image triggering operation is described as follows (Take single trigger as an example):

- 1. Select exam mode.
- 2. Tap [Trig Mode] to enable the trigger.
- 3. Select [Single].
- 4. Set the delay time (or use the T1 by default).

#### **Real & Trigger**

Tap [Real & Trigger] to enable or disable the real trigger function.

After the [Real & Trigger] is enabled, two images are displayed respectively in two windows. One is triggered by ECG, and the other is non-triggered real time image.

## 10.1.2 ECG Review

#### **Review Principle**

When an image is frozen, the ECG waveform where the image is triggered will be frozen at the same time. In the Dual triggering mode, the two window images are frozen at the same time. When images are reviewed with the ECG electrodes connected, the ECG trace is the reference for time.

After the images are frozen, all real time images are in the status of linked review.

#### Linked Review of ECG Waveforms, M/D Images and 2D Images

If the physio unit signal, time curve and 2D image are frozen at the same time, the replay of them is displayed at the same time.

## 10.2 Respiratory Wave

Perform the following procedure:

- 1. Connect the ECG lead and position the ECG electrodes.
- 2. Tap [Physio] or press the user-defined <Physio> key to enter Physio screen.
- 3. Switch the imaging modes and display formats, adjusting the parameters to get an optimized image.
- 4. Parameter adjusting:

- a. Tap [RESP].
- b. Adjust [Speed], [RESP Gain], [Position] and [Invert].
- 5. Exit Respiratory display mode, and remove ECG electrodes from the patient.
- 6. Tap [Physio] or press the user-defined <Physio> key to exit physio mode.

# 10.3 PCG

#### NOTE:

- Check PCG each time before use. If there are any cracks or scratch, please contact the sales representative.
- If there is no ECG signal (PCG waveform is flat) after entering ECG mode, please check whether the sensor plug is connected well.
- Do not hot unplug the PCG sensor.
- To satisfy the PCG sensor's receiving performance, do not rub the acoustic window hard because of the vulnerability of the silicone.

## **10.3.1 PCG Operation Basic Procedures**

Perform the following procedure:

- 1. Connect PCG sensor.
  - a. Connect the PCG sensor to the corresponding interface on the physiological module.
  - b. Power on the system.
  - c. Place PCG transducer on the patient.

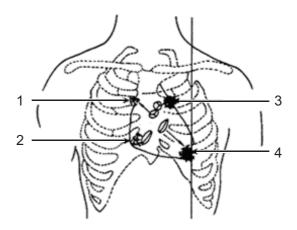
The position is shown below:

Auscultation area of the mitral valve: the fifth intercostal space on the left, the interior of clavicle's middle line.

Auscultation area of tricuspid valve: the right of the sternum.

Auscultation area of aortic valve: the second intercostal space of the right sternum.

Auscultation area of pulmonary valve: the second intercostal space of the left sternum.



1	Aortic valve auscultation area	2	Tricuspid valve auscultation area
---	--------------------------------	---	-----------------------------------

3	Pulmonary valve auscultation area	4	Mitral auscultation area

- 2. Tap [Physio] or press the user-defined <Physio> key. Tap [PCG] on. The PCG wave appears.
- 3. Press the different mode buttons to change the imaging mode. Adjust the parameter to obtain the optimized image.
- 4. Adjust [PCG Gain] and [PCG Smooth].
- 5. Freeze the image and the curve, and then review them.
- 6. Tap [Physio] or press the user-defined <Physio> key to disable PCG wave. Then exit the PCG, and unplug PCG sensor.

## 10.3.2 PCG Sensor Cleaning

#### NOTE:

- Disconnect the sensor with the ultrasound system before cleaning the PCG sensor.
- Do not rub PCG sensor hard in case of the damage to the sensor.

Clean the PCG sensor after each time use in case of the cross-infection.

- The check after the exam of general patient: Wipe the sensor with soft cloth dipping with medicinal alcohol, and then air dry the senor or clean the sensor with dry cloth.
- The check after the exam of patient with cutaneous infection:

Use the cover for the sensor. The cover should be against the appearance of the acoustic window.

Use the appropriate cover. To order the cover, contact:

CIVCO Medical Instruments Co.

102 First Street South, Kalona, IA 52247-9589 USA

Tel: 1-319-656-4447

E-mail: info@civco.com

http://www.civco.com

# **10.4 Parameter Description**

The physio parameters are described as follows:

Туре	Parameter	Description
ECG parameter	ECG Source	Select ECG source.
	Gain	Set the amplitude of the trace.
	Position	Set the vertical position of the both traces on the image display.
	Speed	Change the speed of the physio trace.
	T1	Set the delay time T1 in Single trigger or Dual trigger.
	T2	Set the delay time T2.
	Interval	Set the time interval for Timer.
	Invert	Invert the display.

Туре	Parameter	Description
PCG parameter	PCG	Control the display of PCG trace.
	PCG gain	Set the amplitude of PCG trace.
	PCG smooth	Smoothen PCG trace.

# **11** Stress Echo

Only the phased probes support stress echo function under the cardiac mode.

# 

Stress echo data are provided for reference only, not for confirming diagnoses.

The Stress Echo feature allows you to capture and review cardiac loops for multiple-phase (multiple-stage) Stress Echo protocols.

Stress Echo data consists of Stress Echo loops, wall motion scores, and all other information pertaining to the Stress Echo portion of a patient examination.

A loop is a clip that displays the motion of an entire heart cycle, or from the beginning systole to the end systole, as indicated by the R-wave of the ECG trace and determined by the QT – Time Table.

The loops in a given protocol are acquired by stages (phases), according to stage configuration (continuous (prospective) or retrospective (non-continuous)).

- Loops in non-continuous stages are limited to a specified loop-per-view maximum (such as four). View labels can only be selected in the configured order. Acquisition is retrospective when you press <Save> on the control panel, the system saves the previously acquired images.
- Loops in continuous stages are limited by time rather than a maximum number of loops the system stops acquisition after two minutes. Acquisition is prospective when you select the stage label and then press <Save>, the system starts saving newly acquired images. In some protocols, the system will jump to Select Mode after retrospective saving.

When images are saved, the system places a green checkmark to the right of the view or continuous stage and then shifts the red mark to the next view or next stage.

# 11.1 Stress Echo Acquisition Procedure

To acquire Stress Echo loops, you must enable the ECG function.

Perform the following procedure:

1. Use the proper probe and cardiac-related exam mode, tap [Stress Echo] or press the userdefined <Stress Echo> key to enter stress echo imaging.

The system displays the "Select Protocol" window with the protocol selections.

2. Select the desired protocol and then tap [OK].

The system displays the real-time imaging screen.

- If the Stress Echo manual ROI option is selected in the Maintenance dialog box, the system also displays a region of interest (ROI).
- If Acquire Mode is set as Full-screen in Maintenance, then no ROI box is displayed.
- 3. According to the help information in the bottom of the screen, if an ROI is displayed, adjust the ROI size and position. Press <Update> to confirm the ROI.

When you confirm the ROI size by pressing <Update>, you cannot adjust the ROI size during acquisition. You can only adjust the ROI position using the trackball.

4. Press <Save> to start acquisition.

The system displays the Protocol window on the screen, listing the phases for the selected protocol along with the first phase views (phases are stages). The system selects the first view for acquisition by default.

5. Proceed through each view in each stage according to the following instructions:

Non-continuous stages:

- To save acquired images for the selected view, press <Save>. The system goes to the next view for acquisition by default, saved views are marked with a green " $\sqrt{.}$ "
- Rotate the knob under [Stages XXX] or [Views XXX] to select the stage and view for image acquisition (or reacquisition). Press <Save> key to start acquisition.

Views can be re-acquired until you tap [End Acquisition].

If the protocol contains continuous stages (for alternative workflows), then proceed through each continuous stage according to the following instructions:

- To begin saving acquired images for the selected stage, press <Save>.
- The system displays a percentage marker below the selected stage indicating the progress of the continuous capture.
- To halt saving acquired images for the selected stage, rotate the knob under [Pause] on the touch screen or press <Freeze> directly. The percentage stops increasing.
- Select [Continue] or press <Freeze> again to continue.
- To end the current acquisition, press <Save>.
- To select another continuous stage, rotate the knob under [Stage XXX] on the touch screen.
- Suspending is not allowed under continuous exam.

When acquisition is complete for each stage, the system advances to the next stage. If the stage is non-continuous, the system displays the stage views. When image acquisition is completed for all views and continuous stages, the system switch to Select Mode.

6. To start or restart the timer, tap [Stage Timer]/[Exam Timer] to turn it on.

The Stage time is displayed to the right side of each stage in the protocol list, while the Exam time is displayed in the left side of the screen.

Each saved image will be marked with two times T1 and T2. T1 refers to the total time of the whole acquisition, while T2 indicates the time the acquisition lasted for a certain stage.

- 7. To review loops before ending acquisition, tap [Review/WMS]. You can redisplay the realtime imaging screen to continue acquisition by selecting [Acquire].
- 8. To end the acquisition and review the acquired images, tap [End Acquisition].

When the acquisition is ended, no stress echo image acquisition can be performed for the same exam.

# 11.2 Selecting Preferred Stress Echo Loops (Select Mode)

The selected clips are used for analysis in the review mode and wall motion scoring mode. Select Mode is used to select the best loops of the examination.

When the acquisition is ended, select mode is enabled automatically.

In Select Mode, you can select the representative loop ("preferred" loop) for each view.

To select "preferred" loops:

- 1. Use the <Update> key according to tips in the trackball hint area or select [Select] to enter the Select Mode, or the system enters the Select Mode directly after the acquisition is finished.
- 2. Select the loop. Use the buttons displayed during Select Mode to designate another loop or another view for display.
  - Use [Stages XXX] or [Views XXX] to select the target stage/view.
  - Single-click a clip to select the clip for current stage/view and zoom in the clip to the fullscreen.
  - Double-click a clip. The clip will be magnified.
  - Tap [First/Last] or [Previous/Next] to display another loop in the current view.
- 3. Select the stage and view to display all loops for the view and then continue designating the "preferred" loop for each displayed view until all views are completed.

Description of select mode controls:

Selection	Description	
Stages XXX	To select a stage.	
Views XXX	To select a view.	
Acquire/Select/ Review/ WMS	To switch the mode status.	
1. Clip/2. Clip/3. Clip/4. Clip	For selecting views in the selected stage.	
Next	Next four Clips.	
Previous	Previous four Clips.	
First	Go to "first" Clips.	
Last	Go to "last" Clips.	
Play	Click to play/stop cine play.	
Prev frame	See previous frame of the cine file.	
Next frame	See next frame of the cine file.	
First frame	See first frame of the cine file.	
Last frame	See last frame of the cine file.	
Speed decrease/Speed increase	Decreases or increases playback speed.	
Text	Function that turns the screen graphic text "On" or "Off". Information includes: name of level, name of view, heart rate, time stamp acquisition, timers, frame slider, loop ID, clip control. For the cine without distributed view, the name of level and name of view are displayed in "".	
Apply edit all	Clip edit applied to all clips taken.	
Clip Length	Specify the clip segments: systole, diastole, full cycle or user-defined.	
Bookmark	For continuous acquisition, when the bookmark is set to "On", only the selected loops for the current view can be displayed.	
Delete Unselected	Delete clips that are not selected. If selected, the system will delete all clips that are not selected after the exam is ended.	

Selection	Description
Suspend exam	Pauses the stress echo exam but does not end the stress echo exam. When a stress echo exam is suspended, the user can perform image acquisition of all other imaging modes, or perform operations such as measurement.
End SE exam	End the stress echo exam.

# 11.3 Review/WMS Mode

Review/WMS mode is used by cardiologists to evaluate clips for cardiac wall motion abnormalities. Different views from different stages are selected for comparison across a wide variety of combinations. The most common workflow is to compare "same views" but at "different stages" of the exam (e.g., PSLA view, Rest stage compared to PSLA view, Post-exercise stage).

## 11.3.1 Enter review mode

Select [Review/WMS] to enter review mode, and then select the label of the phase or view (for example, Rest or Long Axis), the system displays all loops that represent the selected phase or view.

#### To display phases for the selected view(s)

Perform the following procedure:

1. To include a phase or view for display, select the leftmost, gray box to the left of each required phase and/or view.

The system inserts a checkmark into each selected gray box.

2. To exclude a phase or view from display, select the blue box to the left of each required phase and/or view.

The system inserts a X into each selected box, like  $\mathbf{X}$ .

3. Select [Display Selected] on the touch screen.

The system displays the selected phases for each selected view side by side.

#### To display all views for a specific phase

Select the phase label (for example, Rest).

#### To display all phases for a specific view

Select the view label (for example, PLAX).

The system displays all phases for the selected view.

#### To display a loop in full-screen format

- 1. Double-click the loop to display in full-screen format.
- 2. Double-click the loop again to display the loop in its initial size, select the loop again.

ltem	Description	
Review/WMS	Perform side-by-side comparison of the same views at different stages (PLAX, PSAX, A4C, A2C at "Rest" compared to PLAX, PSAX, A4C, A2C "Post-Exercise"). Clips are synchronized.	
	• Under [Text] "Off" status, when you select one stage, all view loops are displayed on the screen; when you select one view, all loops of the same view in different stages will be displayed on the screen.	
	• Set [Text] to "On", the system will select loops of first two views of the first two stages to display automatically. If you choose [Previous], then loops of the next two views of the first stages will be displayed. If you choose [Next], loops of the first two views in the 3rd and 4th stage will be displayed.	
	In the meantime, if you choose one stage, loops of all views under this stage will be displayed on the screen (4 at most), and choosing one view will lead to loops of this view in different stages be displayed (4 at most).	
Display Selected	Displays loops of all the stages and views selected.	

Description of review/WMS mode keys (keys with the same function as in select mode are not described below):

## 11.3.2 Wall Motion Scoring

The WMS-Report lists user-assigned wall motion scores and associated data.

The Wall Motion Score (WMS) measurement is an application prepared for assisting in stress echo semi-quantitative evaluations of abnormalities with left ventricular wall motion or changes in wall thickness. The left ventricle is divided into segments for scoring to evaluate the degree of abnormality from the sum of the scores in each segment using the motion of the walls of the entire left ventricle.

You can assign wall motion scores to specific portions within each view (representative loop). You can also assign a normal wall motion score (WMS) to the currently selected view or to all displayed views.

Two methods of chamber segment division, ASE 16 and ASE 17, are supported. In addition, each segment has 3 kinds of scoring method: 4, 5 and 7 points. Select through the [Scoring] control on the touch screen.

To assign a wall motion score (WMS):

1. Select a colored number.

The meanings and colors used in segments are listed in the table below.

Score	Meaning	Color
1	Normal	Green
2	Hypokinesis	Yellow
2.5	Severe Hypokinesis	Khaki
3	Akinesis	Blue
4	Dyskinesis	Red
5	Aneurysm	Purple

2. Use the trackball to select the value and then click the target segments, then the segment is assigned with a value.

- 3. Repeat step 2 to perform value assign for all segments.
  - To assign a normal wall motion score (WMS) to all currently displayed views:
     Select [Set All Normal] on the touch screen.
  - To assign a normal wall motion score (WMS) to the currently selected view: Select [Set Current Normal] on the touch screen.

# 11.4 Saving Stress Echo Data

Stress Echo data consists of Stress Echo loops, wall motion scores, and all other information pertaining to the Stress Echo portion of a patient examination.

When the exam is ended, the system will save all images within the exam.

## 11.5 Exiting the Stress Echo Feature

Tap [End SE Exam] to exit the Stress Echo feature.

## 11.6 Measurement and Report

Suspend the stress echo exam by selecting [Suspend Exam]. Press the measurement related keys or buttons to enter cardiology measurement.

Reports contain the entered indication, if any, and also any entered comments that are specific to the report. You can include or exclude data from specific phase(s). You can preview and print the report for the currently selected mode. You can also enable colored report printing in Maintenance.

For details, see the "Advanced Volume".

# **12** Smart Pelvic Floor (Smart Pelvic)

The Smart Pelvic Floor function is used to Automatically measure distances and angles of anterior, central and posterior compartments according to the feature point inputs on 2D images of rest and stress, and then calculate BND and URA; Automatically measure the size of levator hiatus etc. according to the axial plane automatically obtained from volume data; Automatically measure the size of levator hiatus, levator urethra gap etc. according to the "open-closing-closed" planes automatically obtained from volume data.

# 12.1 Two Dimensional Image

- 1. Perform scanning under GYN or pelvic floor exam mode. Press <Freeze>, tap [Smart Pelvic].
- 2. Roll the trackball to select the target frame in the frozen cine file and tap [Rest] to set rest frame.
- 3. Tap [Measure] and press <Set> to anchor measurement calipers of location S/P/U/E/R/V by the indications on the screen. The system then calculates corresponding parameters.

S- Symphysis Pubis bottom, P- Central axis of Symphysis pubis, U- Uretha-Bladder joint, E-Uretha proximal, R- Bladder posterior wall near uretha, V- Bladder posterior wall bottom, SP-Pubic symphysis.

Following results are obtained: BSD (Bladder Neck – Symphyseal Distance), PVA (Pubovesical Angle), PUA (Pubourethral Angle), RVA (Retrovesical Angle), BND(Bladder Neck Descent), UTA (Urethral Tilt Angle), URA (Urethral Rotation Angle), BPW-SP Dist.(Bladder Post Wall - Symphysis Publis Distance), Cx-SP Dist.(Cervix - Symphysis Publis Distance)(Only measured under Ref Coord C1), RA-SP Dist.(Rectal Ampulla - Symphysis Publis Distance) (Only measured under Ref Coord C1).

- 4. Set Valsalva frame as described in step 2-3 and finish measurements.
- 5. Tap [Jump to Rest] / [Jump to Valsalva] to review the corresponding measurement results.

Tap [Rest] / [Valsalva] again to delete marks of rest frame and Valsalva and corresponding measurement results.

Tap [Meas Parameters] to select measurement tool and perform step 3 to measure. Result window displays only selected measurement results.

Tap [Ref Coord C1] / [Ref Coord C2] / [Ref Coord C3] for different measurement methods when necessary.

Tap [Edit] to edit the calipers, and corresponding measurement results changes.

Tap [Hide], and tick measurement tools to be displayed, and the result window will hide results of unchecked measurement tools.

Add comments and body marks if necessary.

6. Save the cine file.

# 12.2 3D/4D image data

#### **VR Mode**

Perform the following procedure:

- 1. Select probe and GYN/pelvic floor exam mode.
- 2. Enter 3D/4D preparation status, and then acquire 3D/4D image to enter Smart Pelvic.
  - a. Auto: Select [Pelvic] under the [Smart Scene 3D] scenario, and then press <Update>. The system enters [Smart Pelvic] tab automatically.
  - b. Manual: select a non-pelvic subpreset under the [Smart Scene 3D] scenario, press <Update>, and tap [Smart Pelvic] tab.
- 3. On image-frozen mode, adjust image parameters.

On 4D imaging mode, if necessary, tap [Timer] to turn on the timer, and freeze the image as needed.

- 4. Tap [Auto Measure] to start automatic measurement.
- 5. If necessary, tap [Edit], points are uniformly distributed on VR image automatically. Roll the trackball to drag the points. Tap [Edit] again to exit. After editing, tap [Auto Measure] to update the measurement result.

During the editing, tap [Undo] to undo last operation, and tap [Undo All] to undo all operations.

6. Tap [Rest]/[Valsalva]/[Contraction] to mark current image status.

Tap [Hide] to hide measurement results if necessary.

#### **CMPR Mode**

Perform the following procedure:

1. Tap [Multi-plane Mode] on smart pelvic VR mode to enter CMPR mode.

The reference line with an arrow and the other two sampling lines generated by the system are displayed on the screen. With the reference line being the start line, the three lines correspond to Open/Closing/Closed images in turn.

- 2. If necessary, perform the following operations.
  - Tap [Ref. Image] to switch between MPRs, and tap [Open]/[Closing]/[Closed] to switch activated window.
  - Tap [Set Ref. Lines] to set the reference line.

  - Rotate the knob under [Line Extension] on the touch screen to adjust the line length.
  - Rotate the knob under [Rotate RL] on the touch screen to adjust the line angle.
  - Rotate the knob under [Spacing] on the touch screen to adjust the spacing between the three lines.
  - Rotate the knob under [Thickness] on the touch screen to adjust the imaging thickness.
  - Rotate the <4D> knob to scroll CMPR image.
  - Tap [Auto Measure] to start automatic measurement.
- 3. Tap [Back] to go back to VR mode.

#### **Parameter Settings**

VOI Thickness

Rotate the knob under [VOI Thickness] to adjust the thickness of VOI.

- Measurement Parameter Tap [Meas Parm.] to set the automatic measurement items for Rest, Valsalva, and Contraction frame.
- Orientation Refresh

Tap [Refresh Ori], and the system adjusts the current image automatically to display the minimum levator ani muscle gap slice.

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## 13.1 Splitting Display

The system supports dual-split and quad-split display format. However, only one window is active. The multi-window display can complete the image and multi-frame image comparison.

#### **Dual-split**

 $\label{eq:press} $$ Press < Dual > on the control panel to enter the dual-split mode, and use < Dual > / < Update > key to switch between the two images; press < B > to exit.$ 

Modes support dual-split display: B mode, Color mode, Power mode, PW mode, CW mode, M mode and Color M mode.

#### Quad-split

Press the user-defined <Quad> key to enter the quad-split mode, and use the user-defined key to switch among four images; press <B> to exit.

Modes support quad-split display: B mode, Color mode and Power mode.

## 13.2 Image Magnification

#### NOTE:

Zooming an image changes the frame rate which tends to change thermal indices. The position of the focal zones may also change which may cause the peak intensity to occur at a different location in the acoustic filed.As a result, the MI may change.

## 13.2.1 Res Zoom

#### NOTE:

- Res Zoom only can be realized on a scanning image.
- The size and position of ROI will be changed along with scanning depth and area.

Perform the following procedure:

- 1. Press <Zoom> to enter the sample volume definition status.
- 2. Roll the trackball to change the box size and position. Press <Set> to toggle between setting the size and position, or rotate the <Zoom> knob to adjust the size. After the sample volume is set, press <Zoom> / <Update> again to enter Res zoom status.
- 3. Rotate the <Zoom> knob or to change the magnification factor. Or enter the touch screen mapping mode, and zoom the image by pinching two fingers on the touch screen. The image magnification factor value will display in real time in the image parameter area.
- 4. Press <Zoom> to exit Res zoom.

## 13.2.2 Pan Zoom

Perform the following procedure:

- 1. Rotate the <Zoom> knob to directly enter the pan zoom status. Or enter the touch screen mapping mode, and zoom the image by pinching the two fingers on the touch screen. Image-in-image is displayed.
  - Magnification factor adjustment: rotate the <Zoom> knob or pinch two fingers under mapping mode to change the magnification factor. The image magnification factor value will display in real time in the image parameter area. For example, Z1.3 indicates that the magnification factor is 1.3.
  - Shifting the image: roll the trackball or touch and translate the image.
- 2. Press <Zoom> to exit pan zoom.

## 13.2.3 Spot Zoom

Perform the following procedure:

- 1. Press <Freeze> to freeze the image and press <Zoom> to enter magnification status.
- 2. ROI adjustment: press <Set> to switch between size and position status; roll the trackball to change the size/position. You can also change ROI size by rotating <Zoom>.
- 3. Press <Zoom>/<Update> to enter magnification status and ROI area is displayed in full screen. Image-in-image displays in bottom-left part of the screen.
  - Roll the trackball to change ROI position and the screen image displays accordingly.
  - Rotate <Zoom> to change the magnification factor. Or enter mapping-mode and use twofinger gesture to change the magnification factor.
- 4. Press <Zoom> again to exit magnification.

## 13.2.4 iZoom (Full-screen Zooming)

Perform the following procedure:

- 1. Press <F8> to zoom in the image; the zooming area includes image area, parameter area, image banner, thumbnail area and so on.
- 2. Press <F8> again to zoom in the image area only. The image goes to full-screen.
- 3. Press <F8> again to exit.

## **13.3 Freeze/Unfreeze the Image**

Press <Freeze> on the control panel to freeze a scanning image. In freezing mode, the probe stops transmitting acoustic power, and all images as well as the parameters are kept still.

Press <Freeze> in frozen mode to unfreeze the image, and the system continues image scanning.

#### TIP:

After freezing an image, the system may enter cine review, measure, comment adding, or body mark mode, which is dependent upon preset. (Setting path: [Setup]>[System]>[General]>"Status After Freeze")

### Imaging Mode Switching When Frozen

Imaging mode switching in frozen mode follows the following principles:

- In splitting display B mode, press <Dual>/user-defined <Quad> key to switch among the windows; press <B> to exit splitting display mode and enter the image of the currently activated window in full screen.
- In frozen mode, the system supports imaging mode switching between the sub-modes (only for the activated window). For example, if the frozen image is of B+C+PW mode, then the system supports imaging mode switching between B+C+PW, B+C, B+PW and B by pressing <C> or <PW>.
- The imaging mode and parameters of an unfrozen image is the same as the corresponding one that before frozen; but the display format is the same as the one before unfrozen.

## 13.4 Cine Review

The system allows you to review and edit the images prior to the image frozen. This function is called as cine review. The magnified images can also be reviewed, and the operating method is the same. You can perform zoom, measurements, add comments and body marks on the images being reviewed.

The system supports manual review as well as automatic review. The default setup is Manual Cine, but you can switch between Auto Cine and Manual Cine.

In addition, the system supports the images reviewed along with physiological unit waveforms, if the detection of physiological unit waveforms is performed.

## 

- The cine memory must be cleared at the end of the current patient and the onset of the next new patient by tapping [End].
- Cine files stored in the system's hard drive shall contain patient information, to avoid the selection of an incorrect image file and potential misdiagnosis.

## **13.4.1 Entering/Exiting Cine Review**

#### **To Enter Cine Review**

- The system enters the manual cine review status once press <Freeze> to freeze the image.
- Open cine files in thumbnail, iStation or Review. The system enters automatic cine review status.
- Swipe the touch screen left or right under the mapping mode to review the cine.

#### **To Exit Cine Review**

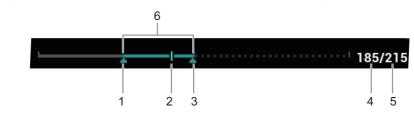
Press <Freeze> or <B>, the system will return to image scanning and exit cine review.

## 13.4.2 2D Cine Review

#### **Manual Cine Review**

Enter the cine mode in 2D imaging mode. Roll the trackball, or slide the screen to view the cine.

If you move the playback mark to the left by using the trackball, the review sequence is reversed to the image-storing sequence, thus the images are displayed in descending order. Whereas, if you move the playback mark to the right by using the trackball, the review sequence is the same as the image-storing sequence, thus the images are displayed in ascending order. When you review images until the first or the last frame, further using the trackball will display the last or first frame.



The cine progress bar at the bottom of the screen (as shown in the figure below):

-	1	Start mark	2	Playback mark
-	3	End mark	4	Current frame
-	5	Total frames	6	Auto Review Region

#### **Reviewing all of Auto Review**

Perform the following procedure:

1. In the manual cine review status, use the [Auto Play] to set the review speed to activate auto cine review.

In the auto cine review status, rotate the knob under the [Auto Play] on the touch screen to adjust the review speed.

2. Exit: Tap [Auto Play] on the touch screen, or use the trackball, the auto review state becomes manual cine review.

#### Setting scope of Auto Review

You can set a segment of cine loop which can be reviewed automatically. After the auto review scope is set, the auto cine review can only be performed within this scope; but the manual cine review can be performed beyond this scope. When the cine file is saved, only the images within this scope are saved.

#### NOTE:

You can perform cine review on each image window in the dual/quad splitting mode, and set auto review region for each window.

Perform the following procedure:

1. Set the start frame:

Rotate the knob under [Start Frame] in the touch screen to manually review the images for the frame you want to set as the start point; or manually review the cine file by trackball and touch [Set Begin] on the touch screen to set current frame to be the start point.

2. Set the end frame:

Rotate the knob under [End Frame] in the touch screen to manually review the images for the frame you want to set as the end point; or manually review the cine file by trackball and touch [Set End] on the touch screen to set current frame to be end.

- 3. Press the knob under [Auto Play] on the touch screen or use the mapping menu. The system plays the auto review region automatically.
- 4. Rotate the knob under [Auto Play] to increase/decrease the auto play speed or use the mapping menu.
- 5. In the auto cine review, press the knob under the [Auto Play] on the touch screen or rolling the trackball will stop the auto cine review and enter the manual cine review.
- 6. Click [Jump to First]/ [Jump to Last] to review the first or last image.

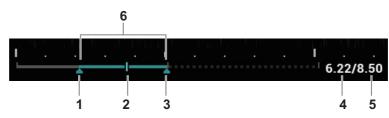
7. Rotate the knob under [Adjust Frame] to review the cine frame by frame.

## 13.4.3 Cine Review in M/PW/CW/TVD Mode

Enter cine review in M mode, PW mode, CW mode TVD mode, and then use the trackball the cine images are displayed on the screen one by one.

Move the playback mark to the left by using the trackball. The review progress slider moves to the left, the images moves to the right, and the earlier stored images are invoked. Whereas move the playback mark to the right by using the trackball, the review progress slider moves to the right, and the images move to the left, the recently stored images are invoked. When the image goes to the first/last frame, the cine is played in loop with the trackball moving left or right.

The cine progress bar at the bottom of the screen (as shown in the figure below):



1	Start mark	2	Playback mark
3	End mark	4	Time played
5	Total time	6	Auto Review Region

Cine review operations are the same as these of 2D mode.

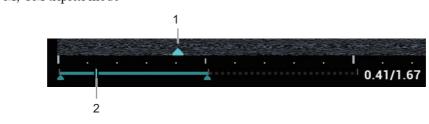
#### NOTE:

There is no audio when the spectrum is reviewed in manual status but audio synchronization can be realized in auto review status with speed of  $\times 1$ .

## 13.4.4 Linked Cine Review

The linked cine review refers to review of the images captured at the same moment.

- B/Color/Power/TVI/TEI dual live
- B/B dual live
- B+M synchronization mode
- B+PW/TVD duplex mode
- TVM, CM triplex mode



1	Frame synchronization mark	2	Playback progress bar
---	----------------------------	---	-----------------------

The frame synchronization mark  $\blacktriangle$  on the time mark of M/PW image indicates the corresponding 2D image and M/PW image. In statuses other than dual live status, you can only review images in the currently active window.

## 13.5 Image Compare

## 13.5.1 Image Compare in Review Mode

#### NOTE:

For B/B+COLOR/B+TVI/B+POWER/B+TEI mode image, you can select at most 4 images; for PW/M/CW/TVD mode image, you can select at most 2 images.

Perform the following procedure:

- 1. Tap [Compare] on iStation screen or Review screen.
- 2. Select the images for comparison.

Click to select the image, and the icon appears on the image, which indicates the image is to be compared.

If select the wrong image, click the image again to cancel the selection.

- Select image size display on "Thumbnail Size" bar to display more images at a time.
- Image compare of different exams for the same patient: Select "all" in the drop-down list of "Exam History" to see all exam files, then you can select different images of different exams to compare.
- 3. Repeat the step 2 above to add the image to be compared.

There is "Display" column you can filter the images by selecting "All Items", "Selected", "Unselected".

Click [Clear Selected] to clear all selected images.

- 4. Click [OK] to enter image comparison.
- 5. Switch the multi-frame cine among the windows to review (single-frame image cannot be reviewed).
  - Press <Dual> to toggle between the two images.
  - Press the user-defined key for "Quad" to switch among 3-4 images.

The window with the highlighted "M" mark is the current activated window.

You can select the image to be reviewed at synchronous time when the multi-frame image is reviewed by using [Sync Play].

- 6. Save the image if necessary.
- 7. Click [Return] on the screen or press <Freeze> to exit image compare.

## 13.5.2 Frame Compare

#### NOTE:

Cine compare can only be performed for B/C mode image only. The image on dual/quad window cannot be compared.

Perform the following procedure:

- 1. Freeze the image in B/C mode, tap [Frame Compare] in "Cine" page on the touch screen to enter frame comparison mode.
- 2. Review the images of different image windows (cine replaying can't be performed for single-frame image file), press <Update> or <Dual> key to switch the active image window.

3. Save the image if it is necessary.

Measurements, adding comments and body marks are allowed.

4. Tap [Frame Compare] again to return to image frozen status; press <Freeze> to enter real-time imaging.

## 13.5.3 iCompare

#### NOTE:

iCompare can only be performed on B, Color, Power, PW, CW, or M mode for FRM/CIN/PNG/ DCM files.

Perform the following procedure:

- 1. Set the user-defined key to enter iCompare.
- 2. In live mode or freeze mode, press the user-defined key for iCompare.
- 3. Select a single-frame image, multi-frame image, or screenshot in the iStation screen, Review screen, or thumbnail area in the main screen.
- 4. Press the <Dual> key to switch between the left and right windows. Roll the trackball to review the cine image on the screen one by one.

The window with the highlighted "M" mark is the current activated window.

When the left window is a screenshot, you cannot switch windows.

5. Save the image if it is necessary.

Measurements, adding comments and body marks are allowed.

6. Press <B>, user-defined <Single> key, or the user-defined key to exit iCompare.

## 13.6 Cine Saving

#### Live Capture

Live capture refers to saving the images or cines in image scanning status; after the storage, the system continues image scanning.

Live capture can be divided into 2 kinds: retrospective and prospective.

- Retrospective saving is to save the specified images before the current moment; to save the images stored in the cine memory to the system hard disk.
- Prospective saving is to save the specified images later than the current moment; to save the images to both the cine memory and the system hard disk.

The live capture time can be set in "Cine" page on the touch screen.

In imaging mode, tap [Pro Capture]/[Retro Capture] on the touch screen or press the user-defined key for "Save Cine (Prospective)/Save Cine (Retrospective)" on the control panel.

#### NOTE:

- Press the save key again or <Freeze> to stop saving.
- When a saving is completed, a thumbnail is showed in the Thumbnail area.

#### Frozen Image Storage

In frozen mode, tap [Pro Capture] / [Retro Capture] on the touch screen or press the user-defined key (The key has already been assigned the function as "Save Cine (Prospective)/Save Cine (Retrospective)").

After the cine is successfully saved, there is a thumbnail displayed on the screen.

## 13.7 Setting Cine Length

#### NOTE:

The system ends up saving if the cine length goes beyond the maximum value.

## 13.7.1 Live capture

#### **Prospective Cine Length**

Prospective cine duration: set the time that the user taps [Prospective] as the start time. The system proceeds saving the cine.

- With the ECG disabled: tap [Cine] tab, and rotate [Time(Pro)] knob to adjust it.
- With the ECG enabled: tap [Cine] tab. Tap [Loop Type(Pro)] to choose the type of the saving time and the cardiac cycles. Rotate [Time(Pro)] or [Cycles(Pro)] to adjust it.

#### **Retrospective Cine Length**

Retrospective cine duration: set the time that user taps [Retro] when playing the first frame of the image. It also refers to saving the cine or cycles retrospectively.

- With the ECG disabled: tap [Cine] tab, and use [Time(Retro)] to adjust it.
- With the ECG enabled: tap [Cine] tab. Tap [Saving type (Retro)] to choose the type of the saving time and the cardiac cycles. Use [Time(Retro)] or [Cycles(Retro)] to adjust it.

## 13.7.2 Freeze Storage Setting

The first frame of the image starts when the user presses <Freeze> at the first time. The system saves the cine in the auto review scope retrospectively.

Press <Freeze> to freeze the image. Use [Time(Retro)] to set the cine time of retrospective saving in frozen status under Cine page, or mark the start frame in the auto review scope to set the cine time of retrospective saving in frozen status.

#### NOTE:

It is only available to save the cine retrospectively in the frozen status.

## **14** Measurement, Comments and Body Mark

## 14.1 Measurement

There are general measurements and application measurement. You can perform measurements on a zoomed image, cine reviewing image, real-time image, or frozen image. For measurement details, please refer to the "Advanced Volume".

## **WARNING**

- Be sure to measure areas of interest from the most optimal image plane to avoid misdiagnosis from inaccurate measurement values.
- To obtain accurate Doppler flow measurement values, make sure the transmitting beam is not perpendicular to the flow, otherwise false readings and potential misdiagnosis may result.

## 

- If an image is unfrozen or the mode is changed during a measurement, the calipers and measurement data will be cleared from the screen, but the measurement data will be stored in the report.
- If the system is turned off or [End] is selected during a measurement, the data not saved will be lost.
- In Dual-B imaging mode, the measurement results of the merged image may be inaccurate. Therefore, the results are provided for reference only, not for confirming a diagnosis.

### **Measurement Accuracy**

• Error of 2D Images

Parameter	Value Range	Error
Distance	Full screen	Within ±3%
Area	Full screen	Within ±7%.
Circ	Full screen	Within ±10%
Angle	Full screen	Within ±3%.
Volume	Full screen	Within ±10%.

Parameter	Value Range	Error
Distance (iScape)	Full screen	Within $\pm 5\%$ (for linear, wide-convex, and phased probes)
	Full screen	Within $\pm 10\%$ (for micro-convex probes)

## • Error of 3D Images

Parameter	Value Range	Error
Distance	A/B/C sectional plane image (MPR), CMPR sectional plane image	Within $\pm$ 5%. (not including Smart 3D)
Area	A/B/C sectional plane image (MPR), CMPR sectional plane image	Within $\pm$ 7%. (not including Smart 3D)
Circ	A/B/C sectional plane image (MPR), CMPR sectional plane image	Within $\pm 10\%$ . (not including Smart 3D)
Angle	A/B/C sectional plane image (MPR), CMPR sectional plane image	Within $\pm$ 5%. (not including Smart 3D)
Volume	A/B/C sectional plane image (MPR)	Within ±20%. (not including Smart 3D)

#### Time/Motion Measurements

Parameter	Value Range	Error
Distance	Full screen	Within ±3%
Time	Timeline Display	Within 2%
Heart rate	Timeline Display	Within ±4%
Velocity (PW mode)	10-200 cm/s (for non-transcranial application)	When angle $\leq 60^\circ$ , $\leq \pm 5\%$
	10-300 cm/s (for transcranial application)	Within ±5%
Velocity (CW mode)	10-200 cm/s (for non-transcranial application)	When angle ≤ 60°, within ±5% (not including pencil probe) Within ±15% (pencil probe)
	10-300 cm/s (for transcranial application)	Within ±5% (not including pencil probe) Within ±10% (pencil probe)

#### • Auto Measurements

Measurement Item	Error
Smart Volume	Within ±20%
Smart V Trace	Within ±20%
Smart OB	Within ±10%
Smart NT	Within ±10%
Smart FLC	Within ±20%
Smart Fetal HR	Within ±10%

Measurement Item	Error
Smart ICV	Within ±20%
Smart Hip	Within ±5%
Smart HRI	Within ±5%
Smart Trace	Within ±20%
Smart Caliper	Within ±5%
AutoEF	Within ±10%
IMT	Within ±10%
RIMT	Within ±10%
TTQA	Within ±20%
FH Tissue Tracking QA	Within ±20%
Smart Planes CNS	Within ±20%
Smart Pelvic	Within ±20%
R-VQS	Within ±10%

• Fatty Liver related functions Performance

ltem	Value	
USAT	• Measurement range: 90 dB/m-450 dB/m	
	• Measurement accuracy: $\leq 5\%$	
	• Measurement repetition rate: $\leq 5\%$	
HRI <sup>+</sup>	Measurement error: Within ±10%	

• Contrast Performance

Transducer	Maximum Depth	Repetition Rate
SC5-1U	≥7cm	Within±10%
C5-1U	≥8.5cm	Within±10%
SC9-2U	≥7cm	Within±10%
L11-3U	≥4cm	Within±10%
SP5-1U	≥12cm	Within±10%
L9-3U	≥6.5cm	Within±10%
L14-5WU	≥4.5cm	Within±10%
C6-2GU	≥10cm	Within±10%
D8-4U	≥6cm	Within±10%
SC6-1U	≥8.5cm	Within±10%
C4-1U	≥10cm	Within±10%
D8-2U	≥6cm	Within±10%

Transducer	Maximum Depth	Repetition Rate
SC8-2U	≥7cm	Within±10%
C11-3U	≥5cm	Within±10%
SD8-1U	≥8cm	Within±10%
L14-3WU	≥5.4cm	Within±10%
L13-3WU	≥5.4cm	Within±10%
L15-3WU	≥5.4cm	Within±10%
C6-2Gs	≥10cm	Within±10%

• Elastography Performance

Transducer	Maximum Depth	Spatial Resolution	Accuracy of Geometric	Strain Deviation	Repetition Rate
L11-3U L14-6WU L9-3U L14-5WU L20-5U L16-4HU L14-3WU L13-3WU L15-3WU	≥30mm	≤10.5mm	Within ±20%	Within ±70%	≤0.2
L16-4Hs 7LT4s	≥30mm	≤10.5mm	Within ±20%	Within ±70%	≤0.2
V11-3HU DE10-3U DE10-3WU ELC13-4U	≥30mm	V11-3HU, DE10-3U, DE10-3WU: <7.5mm; ELC13-4U: ≤10.5mm	Within ±30%	V11-3HU, DE10-3U, DE10-3WU: Within ±40%; ELC13-4U: Within ±70%	≤0.2

• STE Performance

Transducer	Maximum Depth	Spatial Resolution	Accuracy of Geometric	Velocity Accuracy	Repetition Rate
L11-3U	≥30mm	≤10.5mm	Within $\pm 70\%$	Within $\pm 70\%$	≤20%
L14-6WU					
L9-3U					
L14-5WU					
SC5-1U					
C5-1U					
SC6-1U					
C6-2GU					
C4-1U					
L14-3WU					
V11-3HU					
DE10-3WU					
ELC13-4U					
L13-3WU					
L15-3WU					
L20-5U	≥20mm	≤10.5mm	Within ±70%	Within ±70%	≤20%
C6-2Gs	≥30mm	≤10.5mm	Within ±70%	Within ±70%	≤20%

### NOTE:

Within the selected field range, the measurement accuracy is ensured within the range mentioned above. The accuracy specifications are performance in the worst conditions, or based on the real test for the system, regardless of acoustic speed error.

## 14.2 Comments

Comments can be added to an ultrasound image to bring attention, notate or communicate information observed during the examination. You can add comments to: zoomed image, cine review image, real-time image, frozen image. You can type the character as comments; insert the pre-defined comments from the comment library; insert arrow markers or add the trace.

## **AWARNING**

You must ensure that the entered comments are correct. Incorrect comments may lead to misdiagnosis.

## 14.2.1 Touch Screen Displaying

- Set the start point of the comment cursor.
   Move the cursor to the desired position. Select the comment type to the image.
- Return the cursor to the set home location.
   Press <Home> on the control panel; the cursor returns to the start position.
- Grab/Del

Rotate the knob under the [Grab/Del] button on the touch screen, to select the entered comments items; press the knob to delete the selected item.

• Navigate through comments libraries

To select the comment library, rotate/press the knob under the [Library] button on the touch screen.

• Set comments

Tap [Settings] to enter

- Change active text color/fix text color: select a desired color block to change the active text color or fix text color. The default active text color is green and fix text color is yellow.
- Change Arrow style: Select 
  , 
  , 
  , 
  or
- Change Arrow Size: Drag the slider or tap the -/+ button to select arrow size.
- Change text size: Drag the slider or tap the -/+ button to select text size.
- Comment Display

Tap [Hide Text]/[Show Text] to display or hide the comments.

• User-defined

Adjust comments display on touch screen menu, including adding/deleting comments.

• Page-turning

If there is more than one page of comment texts for the current exam mode, you can slide to view more.

• Quickly select a comment in a group

Configure groups to List 1, List 2, and List 3. Select a comment in a group by pressing or rotating the Knob under the [List 1], [List 2], or [List 3] button on the touch screen. The selected comment is displayed in the main screen synchronously.

## 14.2.2 Adding Comments

#### Adding an Comments Text

Perform the following procedure:

- 1. Press <ABC> to enter the comment status.
- 2. Use the trackball or press direction-control keys on the keyboard to move the cursor to the desired location for comments.
- 3. Do one of the following to add a comment:
  - Tap the desired comment text on the touch screen, the system adds the selected comment text onto the screen where the cursor is anchored, you can edit the comment directly.
  - Type the alphanumeric characters through the keyboard.

In the edit status, press <Enter> to move the cursor to the new line, and the location of the cursor is aligned with that of the first line

4. In comments edit status, press <Set> or move the cursor to confirm the added comments text and exit the edit status.

#### Adding an Arrow

You can add an arrow to a location where you want to pay attention.

Perform the following procedure:

1. Press <Arrow> or tap [Arrow] on the touch screen, and an arrow will appear in the default position.

- 2. Adjust the arrow in shape and position.
  - Adjust the position and orientation of the arrow: roll the trackball to the desired position and rotate the trackball to decide the orientation of the arrow.
  - To change the orientation of the arrow: rotate the <Angle> knob to change the arrow's orientation (in increments of 15°).
  - Adjust the arrow size: rotate the knob under the [Arrow Size] button on the touch screen to change the size.
- 3. Press <Set> or <Enter> to anchor the arrow position, and then the arrow becomes yellow.
- 4. Press <Arrow> or tap [Arrow] on the touch screen to exit the arrow comment status.

#### Trace

In comment status, tap [Trace] on the touch screen to activate trace function, and the current image is also displayed on the touch screen.

Using the control panel:

- 1. Use the trackball to move the cursor to a desired position, and press <Set> to confirm the start point.
- 2. Use the trackball to move the cursor along the edge of the desired region and trace the outline of the region.
  - Rotate the <Angle> knob counter-clockwise to cancel 1 pixel of trace.
  - Rotate the <Angle> knob clockwise to restore 1 pixel of trace.
  - Short press <Clear> to clear last trace. Long press <Clear> to delete all tracing.
- 3. Press <Set> to finish the tracing.

Using the touch screen:

- 1. Trace around the ROI by taping the touch screen image using your finger.
- 2. Remove your finger to finish the tracing.
  - [Clear]: tap to delete the trace in reverse order one by one.
  - [Clear All]: tap to delete all traces.
- 3. Tap [Exit] to exit the tracing.

## 14.2.3 Moving Comments

#### NOTE:

If image size and position changed due to display format switching, then the position of the comment can be changed, too.

Perform the following procedure:

- 1. Select the comment to be moved.
- 2. Use the trackball to move the comment to the new position.
- 3. Press <Set> to anchor the comment in the new position, and the comment-moving operation is complete.

## 14.2.4 Editing Comments

#### **Modifying characters**

Perform the following procedure:

1. In comment status, move the cursor onto the comments to be modified.

- Press alphabetic keys to enter the character to the cursor position directly.
- Or, double press <Set> to enter comment editing status, and use the direction-control keys to move the cursor to the desired location to insert/delete characters; you can either type characters by pressing the corresponding keys or select the new comment text from the menu.
- 2. Press <Del> on the keyboard to delete the comment character or text on the right side of the cursor; press <Back> to delete the comment character or text on the left side of the cursor.
- 3. Press <Set>, or move the cursor to confirm the added comments text and exit the edit status.

If there are already comments on the screen, press the space bar to enter editing status.

#### **Modifying Arrows**

Perform the following procedure:

- 2. Rotate the <Angle> knob to modify the arrow's direction.
- 3. Press <Set> to complete the operation.

## 14.2.5 Deleting Comments

#### **Deleting Comments Characters, Texts or Arrows**

Perform the following procedure:

- 1. Move the cursor to the comments to be deleted.
- 2. Press  $\leq$  Set> to select the comment.
- 3. Press <Back>, <Del>, <Delete Word> or <Clear> to complete the deletion.

Or, rotate the knob under [Grab/Del] on the touch screen to select the comment, then press the knob to delete the comment.

#### Deleting a recently-added character, text or arrow

Perform the following procedure:

- 1. In comment status, press <Clear> to delete the latest added/modified comment unit.
- 2. Enter letters by pressing the alphanumeric key on the keyboard and use blank key to divide the letters. Press user-defined key for "Delete Word" or <Delete Word> to delete latest added/ modified comment unit and enter comment status.

#### Delete letters one by one

In comment editing status, press <Back> on the keyboard to delete letters before cursor "|".

In comment editing status, press <Del> on the keyboard to delete letters after cursor "|".

In comment status, enter letters by pressing the alphanumeric key on the keyboard. Press userdefined key for "Delete Word" to delete letters before cursor "|".

#### **Erase All Text**

#### NOTE:

- When no item is selected, press <Clear> will clear all comments and all measurements calipers.
- After powering off, the system will clear all comments on the image.

Press user-defined key for "Delete Text" or long press <Clear> key to delete all the comments.

In dual-window mode, press user-defined key for "Delete Text" once to delete the all the comments for one window, and press twice to delete all the comments for both windows.

## 14.3 Voice Comments

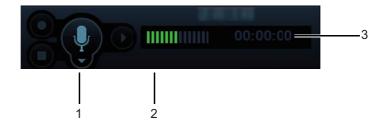
The system supports adding voice comment to the frozen images.

#### NOTE:

- To perform voice comments adding, the function should be enabled through the path: [Setup] > [System] > [Application]. Check "Voice comment enabled". The voice comment panel appears on the right corner of the screen.
- It only supports the vocal input from the wired microphone.

## 14.3.1 Voice Comment Panel

After the system enters the voice comment status, the voice comment panel will be displayed on the lower right corner of the screen.



1	Start/Stop Recording	2	Recording
3	Duration		

## 14.3.2 Adding Voice Comments

#### NOTE:

- In voice comment recording status, you can perform measurements, comments adding, body marks adding, print tasks and DICOM tasks.
- If you press <Freeze> during the recording course, the already recorded voice comment cannot be saved.
- 1. Connect the microphone to the mic port of the front I/O panel. The microphone icon appears highlighted.
- 2. Press <Freeze> after obtaining the image. Press <Cursor> and roll the trackball to move the cursor onto the voice comment panel; tap (•) to start recording and the icon (•) becomes red.
- 3. After the voice recording ends, tap the icon 💿 to end recording.
- 4. Save the cine.

## 14.3.3 Voice Comment Review

Click to open a cine file with voice comment, and during the cine review mode, voice comments are played as well.

## 14.4 Body Mark

#### NOTE:

After powering off, the system will clear all comments on the image.

The Body Mark feature is used for indicating the exam position of the patient and transducer position and orientation.

You can preset the system configured general body marks for each exam mode. The system supports the import of user-defined body marks.

## 14.4.1 Touch Screen Display in Body Mark

The body mark touch screen displays the settings for the current mode:

#### Library

Rotate the knob under the [Library] button on the touch screen or press the knob to switch the body mark library, the corresponding body marks are shown on the left.

#### Page-turning

If there is more than one page, slide the touch screen to turn the page.

#### Save Probe

Under the condition that the probe mark direction and position is determined for the current adding body mark, tap [Save Probe] to save the current direction and position for the probe mark of the current body mark.

## 14.4.2 Adding Body Mark

Perform the following procedure:

- 1. Press <Body Mark> to enter the Body Mark status, tap [Library] to select the body mark category.
- 2. Adding Body Marks:
  - Adding the body mark using the trackball and <Set> key.

Move the cursor onto the desired body mark to highlight your choice, and press <Set> to add the body mark.

- Adding the body mark using the touch screen.

Tap the desired body mark on the touch screen directly.

- 3. To adjust the probe position and orientation marker.
  - Use the trackball to place the probe marker at the correct position.
  - Rotate <Angle> to adjust the mark's direction.
  - Tap [Save Probe] to save the current direction and position for the probe mark of the current body mark.
- 4. Press <Set> to confirm the position and orientation of the probe marker and exit the body mark mode.

## 14.4.3 Moving Body Marks

You can move the body mark graphics to any desired position within the image area.

#### NOTE:

In Dual B Mode, a Body Mark cannot be moved between the separate image windows.

Perform the following procedure:

- 1. Press <Cursor> and move the cursor onto the body mark. The cursor then becomes ↔, indicating you can move the Body Mark graphic to a new position.
- 2. Press <Set> to select the body mark.
- 3. Move the Body Mark graphic to the desired position.
- 4. Press <Set> to anchor and confirm the new graphic position.

## 14.4.4 Deleting Body Marks

#### NOTE:

- Preset returning, switching the exam mode/patient/probe will clear the body marks.
- Set if body mark is erased when the image is unfrozen, see "4.1.4 Application".

Perform the following procedure:

- 1. Press <Cursor> and move the cursor onto the body mark. The cursor then becomes .
- 2. Press <Clear> to delete the body mark.

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# 15 DICOM/HL7

## NOTE:

- Before using DICOM, please read the electronic file DICOM CONFORMANCE STATEMENT along with the device.
- The DICOM package is optional, so the description here is only applicable for the system configured with the DICOM package.

The chapter is confined to the preset, connection verification and DICOM services of the DICOMconfigured ultrasound machine, not including SCP configurations like PACS/RIS/HIS.

This system supports the following DICOM functions:

- Verify Connectivity
- DICOM Storage
- DICOM Print
- DICOM Worklist
- MPPS (Modality Performed Procedure Step)
- Storage Commitment
- Query/Retrieve
- Structured Report
- DICOM Medium Storage (DICOMDIR Review)
- DICOM Task Management

If all the DICOM presets on the DICOM Service Preset screen are completed, you are ready for the Storage, Print, Worklist (HL7 Query), MPPS, Storage Commitment and Query/Retrieve applications. For detailed information about DICOM presets, see "4.7 DICOM/HL7". Terms:

Abbreviations	Description
DICOM	Digital Imaging and Communications in Medicine
AE	Application Entity
MPPS	Modality Performed Procedure Step
PDU	Protocol Data Unit
SCU	Service Class User (DICOM client)
SCP	Service Class Provider (DICOM server)
SOP	Service-Object Pair
TLS	Transport Layer Security

## 15.1 DICOM Storage

DICOM Storage is used to send images (single-frame or multi-frame) or structured report to the DICOM storage server for storage.

## 15.1.1 Send images on iStation/Review/Main screens

Perform the following procedure:

- 1. Do one of the following to select images:
  - Press <F2 iStation> to enter the iStation page. Click to select a patient or an exam record in the list. Thumbnails are displayed in the thumbnail area in the lower part of the screen, and then click to select a thumbnail or the cine. Or, select an exam or exams from the patient list (there should be images for this exam).
  - Tap [Review] on the exam main screen to enter the Review screen. Click to select a thumbnail or the cine.
  - On the main screen, select a thumbnail or the cine.
- 2. Click  $\bigcirc$  in the top-right part or [Send To] to bring up the Send To dialog box.
- 3. Click to select "DICOM" in the Target box on the left side, then select the DICOM storage server in the Storage Server box on the right side, and click [OK].

## 15.1.2 To send images using a shortcut key

You can save single-frame images or multi-frame images to a DICOM server while saving to hard drive using a shortcut key.

#### NOTE:

To define the shortcut key, for details see "4.1.6 Key Configuration".

Start the ultrasound exam scan. Press the user-defined key to send the image or the cine to DICOM storage.

## **15.1.3** To send images to storage after an exam ends

#### NOTE:

To preset Sending/printing after End Exam, for details see "4.1.2 General".

Start the ultrasound exam scan. Tap [End] to send the image or the cine to DICOM storage automatically.

## 15.1.4 Structured Report (SR)

The system supports OB/GYN structured report, Cardiac structured report, Breast structured report, Abdomen structured report, Small Parts structured report, Pediatric structured report, Vascular structured report, and Urology structured report.

The SR can be sent when meeting the following procedures.

- DICOM structured report installed with the corresponding exam mode;
- The exam mode is: OB, GYN, cardiac, Abdomen, vascular, Small Parts, pediatric, breast and urology;
- Send in the unit of single exam;
- Unable to sending the SR if the state is Cancel or Pause.

• Set the storage option to Attach SR When Store Images, or Only Store SR.

Send SR on iStation.

- 1. Choose the storage option to Attach SR When Store Images, or Only Store SR.
- 2. Create new patient information or load the patient information.
- 3. Perform obstetric (gynecology, cardiac, Abdomen, Small Parts, breast, vascular, urology) measurements:
- 4. Save the image or the cine.
- 5. End an exam
- 6. Click [Send Exam] on iStation page.
- 7. Select DICOM in the storage server list, and select a server in the "Storage Server" list.
- Click [OK], the status of sending task can be viewed in DICOM task management. After successful storage of both image and structured report; you can see the storage commitment mark "√" in the list below □□ in the iStation screen.

## 15.1.5 Encapsulate PDF

Encapsulate PDF refers to the PDF file is encapsulated in DICOM IOD.

Encapsulated PDF is sent by following the procedures below:

- Send in the unit of single exam.
- The exam with the state of End, Cancel or Stop cannot be sent as encapsulated PDF.
- Check "Encapsulate PDF" in the storage service preset.
- If there is an exam result in the report template, this type of exam should be performed.

Sending the exam or archiving the exam can send the encapsulated PDF file.

## 15.1.6 Unload DCM file

The image can be unloaded to DCM format and send to the storage media, iStorage.

Perform the following procedure:

- 1. Select the image, and  $click \ominus$ .
- 2. Select [Target] > [iStorage] to export the image in DCM format.
- 3. Click [OK] to send DCM format file to the external media

## 15.2 DICOM Print

DICOM Print is used to send images to the DICOM print server for printing.

#### Print images on iStation/Review/Main screens

Perform the following procedure:

- 1. Do one of the following to select images:
  - Press <F2 iStation> to enter the iStation page. Click to select a patient or an exam record in the list. Thumbnails are displayed in the thumbnail area in the lower part of the screen, and then click to select a thumbnail. Or, select an exam or exams from the patient list (there should be images for this exam).
  - Tap [Review] on the exam main screen to enter the Review screen. Click to select a thumbnail.
  - On the main screen, select a thumbnail or the cine.

- 2. Click  $\ominus$  in the top-right part or [Send To].
- 3. Click to select "DICOM" in the Target box on the left side, then select the DICOM print server on the right side, and click [OK].

#### To send images using a shortcut key

You can send single-frame images to a DICOM print server while saving to hard drive using a shortcut key.

- 1. Define the short key.
- 2. Set a default printer server.
- 3. Press the shortcut key to send the image to the hard disk; the system also sends the single-frame file to the printer server.

#### To send images to DICOM Print after an exam ends

#### NOTE:

Preset Sending/printing after End Exam, for details see "4.1.2 General".

Start the scan and obtain the image. Each time [End] is tapped, the system will send the image to the default DICOM print server for printing.

## 15.3 Worklist

When the DICOM basic package is configured and the Worklist server has been set, click [Worklist] in the "Patient Info" screen to query or import the patient data.

The system supports: DICOM and HL7.

Perform the following procedure:

- 1. Tap [Info] on the touch screen to enter the patient information page.
- 2. Click [Worklist] to enter the Worklist page.

Patient ID		-		Patient Name		Accession	#		
Search Key	Requested Pro	ocedure ID		Scheduled Station AE Title		Modality T	ype US		<b>~</b>
Exam Date	Today	▼ 23/11/2022 Ⅲ To		DICOM Server		Server Typ	e DICC	OM Server	-
Station Name		System Location				Query	Clear	Worklist	t setting
0 records are listed.									k
Patient ID		Patient Name	Accession #	Exam Description	Exam	Date	Gender	DOB	
								_	
									Exit

- 3. Guarantee the data source: after select the service type, select the worklist server from the corresponding server.
- 4. Input the searching condition:

- DICOM server: Search via patient ID, accession #, key words, AE title, worklist server or exam date.
- Select HL7 server: Search via patient ID, patient name.
- eGateway server: Search via patient ID, patient name, exam date, and so on.
- 5. Click [Query]. The scheduled patients, which meet the criteria, are displayed in the lower part of the screen.
  - After the first query, you can perform the second query based on the preview results. The scheduled patients in the list will update in real time.
  - Enter patient ID, patient name, accession # and exam date, the system affords the result in real-time.
  - Select the keyword type, enter the keywords and then click [Query] to search.

To reset the criteria, click [Clear] button.

- 6. Select the desired patient from the list.
  - Click [Start Exam], the patient information is imported into the system and then an exam is started.
  - Click [Transfer], the patient information is imported into the "Patient Info" screen and it is opened. After you edit the patient information in the "Patient Info" screen, click [OK] to start a new exam.
  - Click [Show Detail] to see details of patient data.
- 7. Click [Exit] to exit the Worklist.

## 15.4 MPPS

MPPS is used to send exam state information to the configured server. This facilitates the other systems in obtaining the exam progress in time.

After you preset the Worklist server and MPPS server, if the system obtains the patient information from Worklist server to begin the exam, it will send exam status information to MPPS server of when the exam is undergoing or ended. If the sending fails, the system resends automatically.

## 15.5 Storage Commitment

Storage commitment is used to confirm whether the images or structured reports are successfully stored on the DICOM storage server.

Before using storage commitment, set the associated storage service

If images are successfully sent to the storage server, the storage commitment server will return to the information about the successful image storage. In the iStation screen, you will see a tick " $\sqrt{}$ " marked in the list below  $\square$ .

#### NOTE:

Multi-frame storage is not allowed if "Allow Multiframe" is not selected. Even if there is a multi-frame file in the exam to be sent, only single-frame image storage will be performed. After the storage is complete, there is no " $\sqrt{}$ " marked in the list of the iStation screen.

## 15.5.1 Storage commitment after sending images on the iStation screen

Select the image, the cine or the data, and send it, see "15.1 DICOM Storage".

The system will send all the images stored in the exam record to the storage server. Meanwhile, it will send storage commitment to the storage commitment server.

## 15.5.2 To send storage commitment automatically after an exam ends

#### NOTE:

- Preset Sending/printing after End Exam, for details see "4.1.2 General".
- Set the default storage server, and click "Storage Commitment" to connect to the storage server, see "4.7.2 DICOM Service Preset".

Start the scan and obtain the image. Tap [End] each time; the system will send the image to the default DICOM storage server for storage and send storage commitment to the storage commitment server.

Storage commitment is confined to the whole exam. Not each image sending can be indicated.

## 15.6 Query/Retrieve

The query/retrieve function is used to query and retrieve patient exam records in a designated server.

After setting the DICOM query/retrieve server, you can perform the query/retrieve function in the iStation screen.

- 1. Press <F2 iStation> on the control panel.
- 2. Select [Query/Retrieve] to open Query/Retrieve screen.
- 3. Select the server in the "Server and Service" area (both the source and the destination) and query level.

#### NOTE:

- If the level is set to "Study", all images and cines under this "Study" level will be retrieved.
- If the level is set to "SERIES", all results under the "series" level will be retrieved.
- 4. Enter the query information, such as Patient ID, Patient Name, Accession #, Exam Date or key words.

Select [Clear] to empty the entered query information.

- 5. Select [Query]. The system performs the query and lists the results in the patient (source) list. You can perform further queries based on the results by entering new query information.
- 6. Select one or more patient records according to the actual situation.
  - Select [Select All] to select all the patient records in the list.
  - Select [Deselect All] to deselect all the patient records in the list.
- 7. Select [Retrieve] to retrieve the patient records in the DICOM query/retrieve server to the local machine.
- 8. Select [Exit]. The retrieved patient records are listed in the iStation screen.

## 15.7 DICOM Media Storage (DICOMDIR Review)

Patient data in the ultrasound system can be saved on external media in DCM format, while DCM files can be accessed in the ultrasound system.

DICOM media storage and DICOMDUR review should meet the following conditions:

- There is a DVD disk in the ultrasound device, and it works well.
- File system format of CD/ DVD optical file should be ISO9660, and the optical disk should not be damaged.
- File system format of DVD optical file should be UDF, and the optical disk should not be damaged.
- Normally read/write data from the USB ports on the ultrasound system.
- File system format of removable device (USB flash drive) is FAT32 and the media should not be damaged.

## 15.7.1 Media Storage

Perform the following procedure:

- 1. Select patient records in the iStation screen.
- 2. Select [Send Exam] in the menu which appears to open the dialog box.
- 3. Select the destination to "DICOMDIR" and DICOM Format as well as compression mode. You can select to delete the exam or the image after the backup, and select to hide patient information.
- 4. Select [OK]. The image from the current exam is sent to the external storage media in DICOM format.

If the backup is successful, a tick will appear in the Backup list in the iStation screen. If not, there will be no tick.

#### NOTE:

There must be no DICOMDIR/DCMIMG/IHE\_PDI files on the external storage media of the same name as the one being backed up. Otherwise, the backup cannot proceed. Ensure there is enough storage space, or the backup may fail due to shortage of space.

## 15.7.2 Media review

Perform the following procedure:

- 1. Connect the external media with DCM files to the system.
- 2. Select the data source in iStation screen, and the visible data will be shown.

If there are several types of data on the media, the system will ask you to select the format. Then, click [DICOMDIR].

## 15.7.3 Data Restore

#### NOTE:

Only system-accessible media can be selected.

After the DICOM format data are saved to external media, restore the data to the ultrasound system. Connect the external media containing DCM files to the system.

- 1. In iStation, review the data stored on the external media.
- 2. Select the data to be restored in iStation.
- 3. Click [Restore Exam] on the iStation screen.

## 15.8 Showcase Recording

#### NOTE:

To view the DCM files successfully, it is suggested to install NET Framework (Visual Studio.Net) of a version later than 2.0, if your computer was installed with TortoiseSVN.

Showcase software can be employed for DICOM image file viewing.

When files and structured reports are saved in DCM format through DICOMDIR and sent to storage devices, the showcase can be sent to the storage devices together. Connect the storage device, and the user can view files in DCM format through showcase.

# **16** Patient Data Management

An exam record consists of all information and data of one exam.

An exam record consists of the following information:

- Patient basic information and exam data
- Image files
- Report

### NOTE:

- DO NOT use the internal hard drive for long-term image storage. Daily backup is recommended. External storage media is recommended for archiving images.
- The system patient database space is limited, please back up or clear patient data in time.
- Compression type for image compression and storage may cause loss of image data.
- Mindray is not responsible for lost data if you DO NOT follow suggested backup procedures.

## 16.1 Image File Management

You can store the image files either in the patient database in the system, or to external memory devices. For a save image, you can perform operations like image reviewing, analyzing and demonstration.

## 16.1.1 Storage Media

System supported memory media including:

- System hard disk
- USB memory devices: USB flash drive, removable USB hard disk
- Optical disk

## 16.1.2 Image File Formats

The system supports file formats which belong to the system and file formats which are PC-compatible.

### System-relevant formats

Single-frame image file (FRM)

Refers to single-frame static image files not to be compressed; you can perform measurements and comments adding on this type of files.

• Cine file (CIN)

System-defined multi-frame file format; you can perform manual or auto cine review, and perform measurements or add comments for the reviewed images. After you open a stored CIN file, the system automatically enters cine review status.

The system can save FRM files as BMP, JPG, TIFF or DCM files, or save CIN files as AVI, DCM files.

### PC-compatible formats

- Screen file (BMP) Single-frame file format, used to save the current screen, non-compressed format;
- JPG: Single frame export format.
- TIFF: Single frame export format
- Multi-medium files: Multi-frame export format.
- DICOM files

DICOM standard files format, single-frame or multi-frame format, used to record patient information and images; you can only open DCM files to view rather than to edit.

## 16.1.3 Image Storage Setting

- Set user-defined key and auxiliary output function.
- Set the image size.
- Set cine saving length.
- Set send/print image after end exam. Then every time you tap [End], the system will send images of the exam to the connected default DICOM server.

## 16.1.4 Saving Images to the System

The image is saved to the default path with the default name. The thumbnail of this image will appear in the thumbnail area on the right side of the screen. When you move the cursor onto the thumbnail, its filename with suffix will be displayed.

#### To save a single-frame image to the system quickly

Press the user-defined <Save Image> key to save the image.

- The image format is FRM in the imaging interface.
- When a dialog box is displayed on the current screen, press the user-defined key to save the screen in the BMP format.

#### To save cineloop image to the system quickly

Press the user-defined <Save Cine (Retrospective)/Save Cine (Prospective)> key to save the cine file in the default file directory in the CIN format.

### **Quickly Saving Full Screen Image to the System**

Press the user-defined <Save Screen> key to save the image. The format of the image is PNG.

## 16.1.5 Saving Images/Cines File to USB Flash Drive

- Press the user-defined <Save Image to USB Disk> key to save the image to the USB flash drive.
- Press the user-defined <Send Cine to USB Disk> key to save the images to the USB flash drive.

## **16.1.6 Auxiliary Output Function**

For the following three functions, the system provides auxiliary output function setting: "Save Image", "Save Cine (Retrospective)" and "Save Cine (Prospective)". When the corresponding userdefined key is pressed, the ultrasound system can perform multiple operations one by one as per the preset.

Save the single-frame image:

- Send image to DICOM Storage
- Send image to DICOM Printer
- Send image to USB Disk
- Send image to iStorage
- Send image to local default Printer
- Send image to Workstation
- Send image to Workstation Cache

Retrospective/prospective saving cine:

- Send cine to DICOM Storage
- Send cine to USB Disk
- Send cine to iStorage
- Send image to Workstation
- Send image to Workstation Cache

Taking "Save Image" as an example, add the auxiliary functions "Send Image to DICOM Storage" and "Send Image to USB disk", press the user-defined key, then the system will perform three steps:

- 1. Save the image to the local hard disk.
- 2. Send image to DICOM Storage server.
- 3. Send the image to USB disk.

## 16.1.7 Thumbnails

The stored images or cineloops are displayed in the form of thumbnails on the screen:

- During image scanning, thumbnails of the current exam display in the Clip board/Thumbnails Area of the screen.
- In the iStation screen, the thumbnails of the current selected patient display at the bottom of the screen. When you move the cursor onto a thumbnail, its name and format will display.
- On the [Review] page, the thumbnails refer to the images stored in the same exam. When you move the cursor onto a thumbnail, its name and format will display.
- On the Review page, open images to enter the image analyzing status, all the thumbnails belong to the exam are displayed.

## 16.1.8 Image Review

The system supports the image review and analysis to the saved patient image. You can review all images stored in an exam, and send, delete or analyze the stored images.

#### To enter image review

- Tap [Review] to enter review page. Images of the current exam and the current patient are displayed.
- During mapping mode, slide to left or right on the touch screen to review the image.
- Select an exam of a patient in the iStation screen, and click <Review> or double-click the exam to enter the Review screen to review the images of the patient.

During image scan, saved image thumbnails will display on the right of the screen. Move the cursor onto a thumbnail, and press <Set> twice to open the image; if the stored image is a cine file, double-click the thumbnail to enter the auto cine review.

#### Exit the review

Click [Exit] on the Review screen; or, Press <ESC> or tap [Review] to exit.

#### **Basic Operations**

Select an exam from the [Exam History] drop-down list.

Double-click the image thumbnail to analyze an image.

The function buttons are described as follows:

Exam History

You can select one certain exam from the exam directory to review the image.

- If entered from iStation, the screen displays the record(s) selected in the iStation.
- If entered from the imaging status, the Review screen displays the images of the current exam, and the default selected image is the one displayed on the preview main screen.
- Info

Click to enter the Patient Info screen, you can review or edit the currently-selected patient information.

• Report

Click to review or edit the currently-selected patient report.

- Image operations
  - [Select All]: click to select all images in the thumbnail window.
  - [Deselect All]: after clicking the [Select All], the button changes into [Deselect All], you can cancel all the selections by clicking [Deselect All].
  - [Send To]: click to send the selected image to other location, DICOM server, printer, MedTouch/MedSight, DVD, etc.
  - [Delete]: click to delete the selected image.
  - [Image Compare]: Image Comparison.
- Thumbnail Size

To change the thumbnail size.

- Switching operations:
  - [New Exam]: click to create a new exam for the selected patient and open the Patient Info screen.
  - [Activate Exam]: activate the ended exam, and enter the image scan interface.
  - [iStation]: click to enter the iStation screen.
  - [Exit]: click to exit the Review status, and return to the main screen.

## 16.1.9 Image Analysis

In the image analysis status, you can view, zoom, perform post processing and measurements, add comments and perform cine review for a stored image (FRM or CIN format). The operation steps are the same as those for real-time scanning; please refer to relevant sections for details.

#### To enter image analysis

- In the image scanning or freeze status, double-click a thumbnail stored in this exam to enter the image analysis status; or
- In the image review status, double-click the selected thumbnail to open the image.

#### To exit the image analysis

- Press <Freeze> to exit and enter the real-time scan status.
- Press [Return] to exit from the image analysis to the Review status. In image analysis status, the selected image is displayed on the screen, and the thumbnails of the same exam are displayed on the thumbnail area, you can turn pages using the buttons on the right side of the thumbnail.

## 16.1.10Sending Image File

#### NOTE:

Data saved this way can only be reviewed on the PC and cannot be restored to the ultrasound system.

Perform the following procedure:

- 1. Do one of the following to bring up the "Send To" screen:
  - In the main screen, select a stored image thumbnail and click 

     → on the upper right corner of the image.
  - In the iStation screen, select a stored image and click  $\bigcirc$ .
  - In Review screen, click  $\bigcirc$  to send patient data to an external memory device.
  - In the Review screen, select a image and click [Send To].
- 2. Select from the destination:

Item	Description			
USB/iStorage	For external memory devices (e.g. USB memory devices, DVD recorder) or network storage server, you can set:			
	• PC format transfer.			
	• DCM format transfer			
	Cine Zoom Mode.			
	• Export the report or the report format.			
	• Hide patient information.			
DICOM/Print/eGateway	Select the DICOM Storage, Print server or eGateway server.			
MedTouch/MedSight	Send the image to MedTouch/MedSight as necessary.			
	NOTE:			
	The file sent to MedTouch/MedSight is transferred into PNG format, and the cine file is transferred into AVI format.			

#### NOTE:

- If the transferred AVI file cannot be played normally on PC, please try to transfer the multi-frame cine file in MP4 format and try Send To function again, or use a VLC media player.
- You can select whether to hide patient info: if "Default Info" is selected, the patient name is hidden after backup; if "Custom Info" is selected, the system prompts a message requiring you to input the patient name, which will be displayed after backup.

## 16.2 Report Management

## 16.2.1 Report storage

The exam reports are stored under the directory of the exam of the patient.

## **16.2.2** Importing, exporting and sending a report

#### Import/export report via Backup

In iStation screen, select patient data, click [Restore Exam] or [Backup Exam] in the popped up menu to import or export patient information, images and reports from or to an external memory device.

Perform the following procedure:

- 1. Select the destination.
- 2. Select whether to remove from local HD after Backup:
  - If "Remove Exams" is selected, the patient information and images are removed.
  - If "Remove Images" is selected, only the patient images are removed.
- 3. Select whether to hide the patient information.
  - Default Info: the patient name is hide after backup.
  - Custom Info: the system prompts a message requiring you to input the customed patient name, which will be displayed after backup.
- 4. Select whether to encrypt backup exams for USB only: input the password and confirm password in the field box. Click [Backup], a "Patient.7z" compressed package is backed up to the USB device, and you need to input the password to open the package.

#### NOTE:

- If the password is forgotten, you cannot open the backup package.
- The password cannot be multi-language or Chinese characters.

#### Export report via Send To

In the iStation or Review screen, click [Send Exam] or [Send To] to send patient data to an external memory device (USB disk or disc) or network storage, you can choose if reports are exported.

Perform the following procedure:

- 1. Select [Export Report].
- 2. Select report type to be exported.
- 3. Select whether to hide the patient information.
  - Default Info: the patient name is hide after backup.
  - Custom Info: the system prompts a message requiring you to input the customed patient name, which will be displayed after backup.
- 4. Click [OK] to confirm.

The size of the report can be set, see "4.9 Print Preset".

## 16.3 Patient Data Management (iStation)

The patient data include basic patient information, exam information, image files and reports. You can search, view, backup, send, restore, delete or export patient data in iStation.

Do one of the following to enter iStation:

- Press <F2 iStation> key on the control panel
- Select [iStation] in the Patient Info screen.
- Click [iStation] in the Review screen.

### 16.3.1 Searching a Patient

Perform the following procedure:

1. Select the data source.

Click [Data Source] to select the data source of patient data, the system patient database is default.

- 2. Set search conditions.
- 3. Enter the key word. The matching patient information is displayed in the patient list.
- 4. When you select a patient in the patient list, the images of this patient will be displayed at the bottom of the screen.

### 16.3.2 Patient Data View & Management

Select the desired patient information in the list.

Item	Description		
Review an image	Select an exam of a patient, click [Review Image] to enter Review screen.		
Patient Information	Select an exam of a patient, click [Patient Info] to check the patient information of this exam.		
Review Report	After you select an exam of a patient, click [Review Report] to view the report of this exam for this patient.		
Delete Exam	<ul> <li>Select the patient record. Click [Delete Exam] to delete the exam. However, you cannot delete patient data being printed, exported or sent, or delete the current exam.</li> </ul>		
	• To delete an image, select the image and click i on the right side.		
Backup Exam	<ul> <li>You can back up the selected patient data to the system-supported media in order to view it on PC, or restore the patient data to the system from an external media. The exam after being backed up can be restored to the system for another review. Click to back up the selected patient data to the system-supported media.</li> <li>Original format: to back up the data in original format.</li> <li>DICOM format: you can change the cine compression mode, and JPEG compression mode.</li> <li>You can select whether to remove images or the whole exam record from the system.</li> </ul>		
Restore Exam	Click to import the patient data from an external media.		
Send Exam	<ul> <li>You can use this function to export the exam data to external devices (in PC data or DICOMDIR data format) and then import to PC or restore to the ultrasound system to review the data.</li> <li>Select the patient record, click [Send Exam] in the menu to send exam data or images of the selected record.</li> <li>Select from the destination, and set related settings.</li> </ul>		

Item	Description
Activate an Exam	After you select an exam, which has been performed within 24 hours, click [Activate Exam] to activate the exam and load the basic patient information and measurement data to continue the exam.
	If you want to select a patient data in an external memory database to start a new exam or recover the exam, you have to first allow the system to load the patient data to the system's patient database.
Continue an Exam	Select an exam that is paused within 24 hours, click [Resume Exam] to activate the exam and load the basic patient information and measurement data to continue the exam.
	If you want to select a patient data in an external memory database, you have to first allow the system to load the patient data to the system's patient database.
Annotation an exam	Select an exam and click [Annotation Exam] to add annotation. In the popped-up screen, you can also review the history annotations for the selected exam.

# 16.4 Recycle bin

The recycle bin is used to store deleted patient data, exam data and images.

The system supports recovery of these data from the recycle bin.

Click 🗑 at the lower right corner of the screen (when the button is gray, the operation is unavailable) to enter the Patient Recycle Bin screen.

#### To recover the deleted patient data

#### NOTE:

If the capacity of the recycle bin exceeds 200. The system reminds the user to clean. Follow the procedures below to clean the recycle bin.

Perform the following procedure:

- 1. Select items to be recovered in the list.
- 2. Select operations:
  - Click [Restore Items] to restore the item back to iStation.
  - Click [Delete] to delete the item permanently, and the item can never be restored again;
  - Click [Restore All Items] to restore all the items back to iStation;
  - Click [Empty Recycle Bin] to empty the recycle bin and all items can never be restored again.
  - Click [Exit] to exit the recycle bin.

#### To set maximum number of days or deleted data to be kept in the recycle bin

#### NOTE:

The patient exams which exceed the preset maximum will be deleted and unrecoverable, it is recommended to perform patient data backup before enabling this function to avoid data loss.

Perform the following procedure:

1. Input the desired number besides "Maximum number of days to be kept".

If the input box is left blank, the feature will not be enabled.

Only the whole number ranging from 1 to 365 can be input.

2. Click [Modify].

# 16.5 iStorage

#### NOTE:

To use iStorage function, you need UltraAssist software in 2.0 version (with V1.0 network protocol); consult Mindray service engineer for details.

Network storage is used to save image files and measurement reports to the remote PC server. For network storage setting, see "4.8.2 iStorage Preset".

- 1. Enter iStation, select one (or more than one) patient data or image in the local data source.
- 2. Click [Send Exam].
- 3. Select [iStorage] in the Send To dialog box, and select the PC server of the right side.
- 4. Select PC transfer format and check whether to send report.
- 5. Click [OK] to start sending.

# 16.6 Print

For printer connection, see "3.8 Connecting Peripheral Devices".

For user-defined key for printing and video output settings, see "4.1 System Preset".

### 16.6.1 Image Print

For DICOM image printing, refer to relevant chapters. Video printer is applied in image print service.

Perform the following procedure:

- 1. Select the desired image in iStation or Review screen.
- 2. Click  $\ominus$  icon on the upper right side of the image, and select the printer in the popped up dialog box.
- 3. Click [OK] to start printing.

Please refer to the accompanying manuals of the printers for more details.

### 16.6.2 Report Printing

Both reports and images can be printed on a graph/text printer. For detailed information about the report printing, see *Advanced Manual*.

# 16.7 Back up Files using the DVD Drive

### 

During the backup process, if a CD/DVD is forcibly taken out or you perform other operations, the backup process will fail or the system may malfunction.

#### NOTE:

- Writing data using "Send To" supports the PC format transfer function, while CD/DVD writing using "Backup" supports only system-relevant formats.
- The symbol indicates that the input CD/DVD is damaged or contains data in an incorrect format.

The system supports writing data to CD/DVD using the DVD-RW/DVD+RW drive and reading data from CD/DVD on the PC.

Perform the following procedure:

- 1. Put a CD/DVD in the tray.
- 2. Select the data to be backed up. Select [Send Exam] or [Backup Exam] in the menu which appears. Select the target drive in the Send To or Back Up Patient Record dialog box.
- 3. Click [OK] or [Backup] to begin writing when the 🔊 symbol displays.
- 4. After the writing process is complete, click 💿 to bring up the Disc Option dialog box, and select [Eject] to eject the CD/DVD.

# 16.8 Patient Task Management

Click in the bottom-right corner of the screen to bring up the Task Management dialog box.

#### Storage Task

Displays the DICOM storage task.

#### **DICOM Print Task**

Displays the DICOM print task.

#### Media Storage Task

- DICOM media storage task (including disc and USB devices): In iStation screen, select the target exam and click [Send Exam], then click DICOMDIR in the menu which appears.
- Back up task (system-relevant format): Select the exam to be backed up in iStation and click [Backup Exam].
- Send to external devices (including disc and USB devices): Select exam data or images in the iStation or Review screen. Click [Send Exam] for the image.
- iStorage task: In iStation screen, select the target exam and click [Send Exam], then click iStorage in the menu which appears.
- MedTouch/MedSight storage task:
  - In iStation screen, send exam to MedTouch/MedTouch devices.
  - In Review screen, iStation screen, thumbnail area, send the image(s) to MedTouch/ MedSight devices.

#### Log Upload

Displays log uploading tasks.

#### **Print Task**

Displays image or report printing tasks.

In the Task Management dialog box, the patient ID, name, destination, progress, type, contents and task created time are displayed.

You can perform the following operations:

- Click [Delete] to delete the task.
- Click [Retry] to retry the failed task.
- Click [Select All] to select all the tasks.
- Click [Priority] to set priority for tasks.

#### **Task Status**

When there are tasks underway, the task management icon displays as **1** Click the icon to check the process.

When tasks have failed, the task management icon displays as  $\overline{\mathbf{L}}$ . Click the icon to check the reason for the failure.

When the task management icon displays as  $\mathbf{I}$ , it means no task is underway or has failed.

#### **DICOM Service Setting**

On the Storage Task and DICOM Print Task page, click [Service Setting] to enter the DICOM service setting screen. For details, see "4.7 DICOM/HL7".

#### Troubleshooting

If a serious error occurs, such as network disconnection or operation timeout, the system can try to reconnect the network. The interval time and maximum retries can be set as desired. For details, see "4.7.2 DICOM Service Preset".

### 16.9 Q-Path

You can use the ultrasound system to check data on browser directly. After you have ordered storage service of a network website service, you can check data using the website, authorized account and password (provided by the service vendor). You can open the browser to review previously sent DICOM data. For Q-Path settings, see "4.8.4 Q-Path Preset".

Perform the following procedure:

- 1. Send stored images or worksheet reports from iStation/Review/thumbnail area to the Q-Path server.
- 2. In iStation screen, click [Q-Path] to enable the function.
- 3. Log in to the Q-Path server through the Q-View browser to check the stored images and worksheet reports.
- 4. Click [Esc] to exit the Q-View browser.

### 16.10 V-Access

The ultrasound system can be used to log on to a remote server to check or modify patient data on the server.

- 1. Press the user-defined key to use the function.
- 2. The system brings up a dialog box for entering the IP address of the remote server.
- 3. Enter the IP address and click [OK].
- 4. Log on with the server account and password.
- 5. Check the data transferred and carry out operations as necessary.

#### NOTE:

After logging in to the remote server, you can switch from the Ultrasound System and the remote server as follows: click [Minimize] to exit the remote server and enter the Doppler interface, and press the user-defined key for V Access to enter the remote server again.

# 17.1 Probes

Model	Region Applied	Probe Figure
C5-1U	Body surface	
SC6-1U	Body surface	

Model	Region Applied	Probe Figure
SC5-1U	Body surface	A market and a m
C4-1U	Body surface	
SC9-2U	Body surface	
C11-3U	Body surface	
C6-2Gs	Body surface	

Model	Region Applied	Probe Figure
C6-2GU	Body surface	
L9-3U	Body surface	
L20-5U	Body surface	
V11-3HU	Trans- vaginal, Trans- rectal	Ca III

Model	Region Applied	Probe Figure
SP5-1U	Body surface	
SD8-1U	Body surface	
D8-4U	Body surface	
D8-2U	Body surface	

Model	Region Applied	Probe Figure
DL14-3U	Body surface	
DE10-3U	Trans- vaginal, Trans- rectal	
DE10- 3WU	Trans- vaginal, Trans- rectal	
CW5s	Body surface	
CW2s	Body surface	O B D
P7-3TU	Trans- esophage al	
P7-3Ts	Trans- esophage al	
P8-3Ts	Trans- esophage al	

Model	Region	Drobo Figuro
woder	Applied	Probe Figure
P8-2Ts	Trans- esophage al	
SC8-2U	Body surface	
L14-6WU	Body surface	
L15-3WU	Body surface	

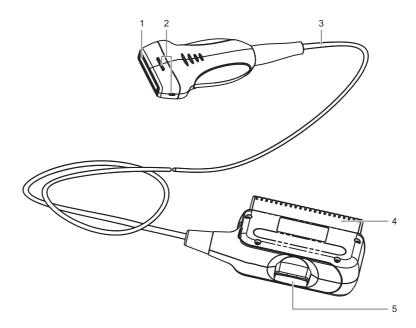
Model	Region Applied	Probe Figure
L14-5WU	Body surface	
L14-3WU	Body surface	
L13-3WU	Body surface	

Model	Region Applied	Probe Figure
L11-3U	Body surface	
ELC13- 4U	Trans- rectal	
7LT4s	Body surface, Intra- operative	
L16-4Hs	Body surface, Intra- operative	
L16-4HU	Body surface, Intra- operative	

Model	Region Applied	Probe Figure
P10-4U	Body surface	
P7-3U	Body surface	
P8-2U	Body surface	

# 17.1.1 Probe Functions by Part

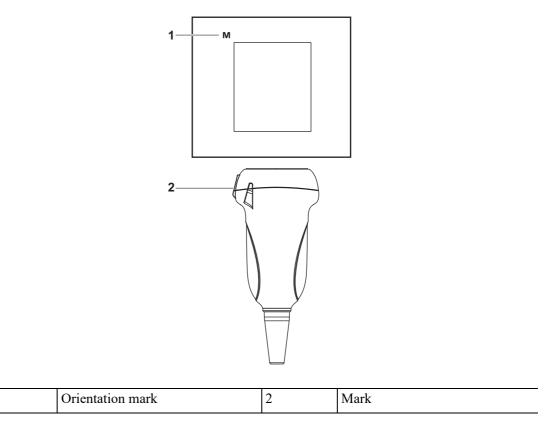
The basic structures and corresponding functions of probes are basically the same; take the following probe as an example.



No.	Item	Description
1.	Probe head	Converts the electrical signal into an ultrasonic signal, focusing the sound beams in a given direction; meanwhile, it receives the reflected ultrasonic signal and converts it into an electrical signal for transmission over the cable. The lens on the surface is the acoustic lens. Apply ultrasound gel on the acoustic lens for correct operation.
2.	Needle-guided bracket fix tabs and grooves	Provides mounting support of the needle-guided bracket. <b>NOTE:</b> This structure of probes in the figure above may vary with the matched needle-guided brackets.
3.	Probe cable	Transmits electrical signals between the probe head and connector.
4.	Probe connector	Connects the probe to the ultrasonic diagnostic system.
5.	Lock handle	Locks the connector to the ultrasonic diagnostic system.

# 17.1.2 Orientation of the Ultrasound Image and the Probe

The orientation of the ultrasound image and the probe are shown as below. The "M" side of the ultrasound image on the monitor corresponds to the mark side of the probe. Check the orientation before the examination (Using a linear probe as an example).



### **17.1.3 Procedures for Operating**

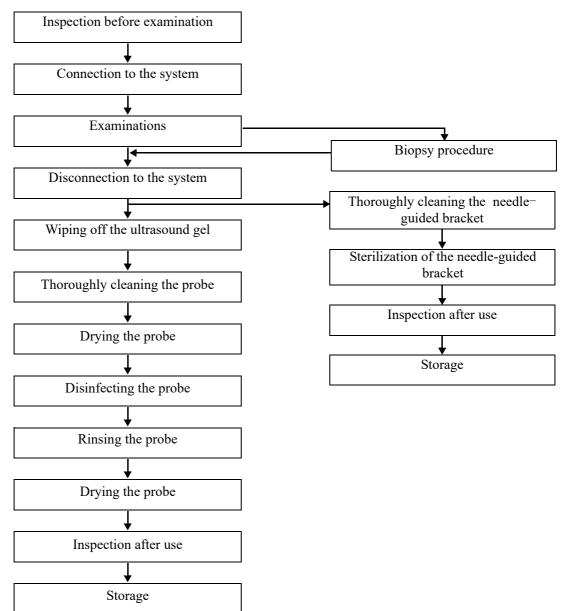
### **MWARNING**

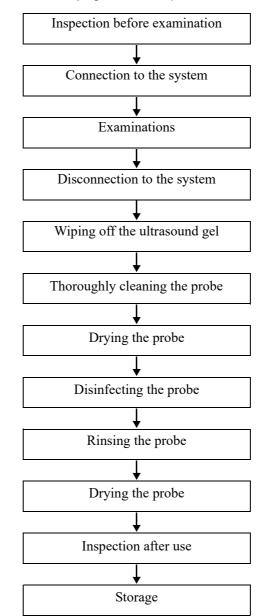
1

Disinfect the probe and sterilize the needle-guided bracket before and after an ultrasound-guided biopsy procedure is performed. Failure to do so may cause the probe and the needle-guided bracket becomes a source of infection.

This section describes general procedures for operating the probe. The proper clinical technique to be used for operating the probe should be selected on the basis of specialized training and clinical experience.

#### Procedures for operating (with biopsy function)





#### Procedures for operating (with no biopsy function)

### 17.1.4 Wearing the Probe Sheath

### 

- Be sure to cover the probe with a new (unused) probe sheath to prevent infection during examination. If the package of a probe sheath is open or broken, the sterilization of the probe sheath may not be sufficient. DO NOT use such a probe sheath.
- The cover contains natural rubber latex and talc that can cause allergic reactions in some individuals.
- DO NOT use an expired probe sheath. Before using a probe sheath, verify whether the term of validity has expired.

A legally marketed probe sheath must be installed over the probe before performing intra-cavitary and intra-operative examination. Protective barriers may be required to minimize disease transmission. Probe sheaths are available for use with all clinical situations where infection is a concern.

To order probe sheath, contact:

CIVCO Medical Instruments Co.

102 First Street South, Kalona, IA 52247-9589 USA

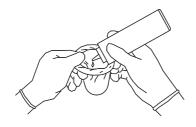
Tel: 1-319-656-4447

E-mail: info@civco.com

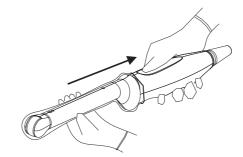
http://www.civco.com

Perform the following procedure to install the probe sheath:

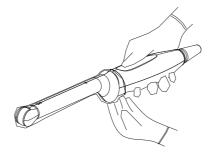
1. Place an appropriate amount of gel inside the sheath or on the probe acoustic lens. Poor imaging may result if no gel is used.



2. Insert the probe into the sheath; make sure to use proper sterile technique. Pull cover tightly over probe acoustic lens to remove wrinkles and air bubbles, and taking care to avoid puncturing the sheath.



3. Secure the sheath with the enclosed elastic bands.



4. Inspect the sheath to ensure there is no hole or tear.

### 17.1.5 Probes Cleaning and Disinfection/Sterilization

Before and after completing each examination, clean and disinfect (or sterilize) the probes as required. When biopsy procedures have been performed, be sure to sterilize the needle-guided

bracket. Fail to do so may result in the probe and the needle-guided bracket to becoming sources of infection. Please follow the instructions in the manual for cleaning.

### **AWARNING**

Never immerse the probe connector into liquid such as water or disinfectant. Immersion may cause electrical shock or malfunction.

# 

- When performing cleaning and disinfection of the probe to prevent infection, wear sterile gloves.
- After disinfection, rinse the probe thoroughly with sterile water to remove all chemical residues. Chemical residues on the probe may be harmful to the human body.
- No cleaning and disinfecting may result in the probe becoming a source of infection.
- Please follow the disinfectant manufacturer's manual for performing cleaning and disinfection, including preparing sterile water and cleaning and disinfection time.

#### NOTE:

- After the examination, wipe off the ultrasound gel thoroughly. Otherwise, the ultrasound gel may solidify and degrade the image quality of the probe.
- DO NOT make the probe to become overheated (more than 55 °C) during cleaning and disinfections. High temperature may cause the probe to become deformed or damaged.
- Observe the graph here carefully to immerse the probe. Only soak parts of the probe below the strain relief.
- Repeated disinfection will eventually damage the probe, please check the probe performance periodically.

#### **Cleaning and Disinfection/Sterilization Overview**

Cleaning and disinfection refer to two distinct processes. According to the Centers for Disease Control and Prevention (CDC) "Guideline for Disinfection and Sterilization in Healthcare Facilities" (2008):

- Cleaning is the removal of visible soil (e.g. organic and inorganic material) from objects and surfaces and normally is accomplished manually or mechanically using water with detergents or enzymatic products. Thorough cleaning is essential before high-level disinfection and sterilization because inorganic and organic material that remains on the surfaces of instruments interfere with the effectiveness of these processes.
- Disinfection describes a process that eliminates many or all pathogenic microorganisms, except bacterial spores.
  - Low-Level Disinfection—Destruction of most bacteria, some viruses, and some fungi.
     Low-level disinfection will not necessarily inactivate Mycobacterium tuberculosis or bacterial spores.

- High-Level Disinfection (HLD)—Destruction/removal of all microorganisms except bacterial spores.
- Sterilization describes a process that destroys or eliminates all forms of microbial life and is carried out in healthcare facilities by physical or chemical methods.

#### Selecting a Microbicidal Method

Probes can be divided into three categories based on their intended use. Some probes may fall into more than one category (e.g. probes use for biopsy procedures). When selecting a disinfectant, determine the required level of disinfection based on intended use and possibility of cross-contamination.

- Contacts intact skin: Probes that only come into contact with clean, intact skin are considered noncritical devices and require cleaning after every use. Cleaning may be followed by a low-level disinfectant spray or wipe.
- Contacts mucous membranes and non-intact skin: This category includes all endocavity probes

   intravaginal, transrectal, and transesophageal (TEE) and probes use for biopsy procedures.
   These semi-critical probes must be cleaned with an appropriate cleaner after use followed by
   high-level disinfection.
- Contacts otherwise sterile tissue or body-space: These probes are considered critical and include all intraoperative probes. These probes must be cleaned with an appropriate cleaner after each use, followed by a sterilization process.

#### Cleaning

Please refer to the instructions in the manual and follow your hospital policy and procedures for cleaning.

Perform the following procedure:

- 1. Wear a pair of gloves to prevent infection.
- 2. Disconnect the probe from the system. If the sheath is used, take off the sheath and discard it.
- 3. Wipe off the ultrasound gel or other visible dirt on the surface of the probe by using a damp piece of disposable lint-free soft cloth or tissue.
- 4. Choose an appropriate cleaning agent including mild detergents, enzymatic cleaners and specially designed enzymatic sponges.
- 5. Immerse the probe fully in the cleaning fluid for at least 1 minute or according to manufacturer's instructions. Lightly mechanical clean the probe with a piece of lint-free soft cloth or soft sponge until no dirt is visible. When necessary, clean the seams or biopsy guide features by using disposable cotton swabs. Avoid using a brush to wash the lens because it may damage the probe.
- 6. Rinse the probe thoroughly by using a large amount of clean water (about 7.5 L/2 gallons) at room temperature for about 30 s to remove the residual dirt and cleaning solvent. Repeat the rinsing operation twice.
- 7. Dry the probe by wiping with a piece of disposable lint-free soft cloth or tissue.

Do not dry the probe by heating.

- 8. Inspect the probe. If visible dirt still exists, repeat the preceding steps to wash the probe until it is all clean.
- 9. Check whether the probe has defects such as peeling, rifts, bumps, cracks, or liquid spill. If such defects exist, the probe has reached the end of its service life. In this case, stop using it and contact the Mindray service department.

#### Low-level disinfection of a non-critical probe

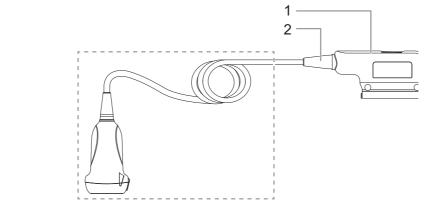
### 

Use protective eyewear when disinfecting using sprays.

Perform the following procedure:

- 1. Wear a pair of gloves to prevent infection.
- 2. Clean the probe thoroughly in accordance with the cleaning procedure before disinfection.
- 3. Disinfect the probe by using an appropriate low-level disinfectant. Follow the disinfection agent manufacturer's instructions for preparation and use of the disinfectant.
  - Wipes: Wipe all the surface of the probe according to the wiping duration specified in the operator's manual provided by the manufacturer.
  - Spray: Spray the disinfectant directly on the surface of the probe or spray the disinfectant on a piece of disposable lint-free soft cloth and wipe the probe according to the wiping duration in the operator's manual provided by the manufacturer.

Observe the graph here carefully to perform disinfection. Do not spray the strain relief on the connector end or the connector.



1     Connector     2     Strain relief	
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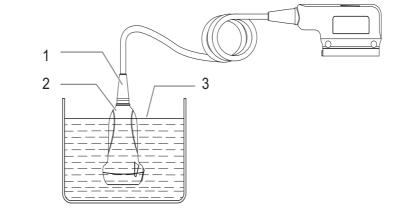
- 4. Wipe away the residual disinfectant on the probe by using a piece of lint-free soft cloth soaked with clean water. Wipe three times. Or rinse the probe thoroughly by using a large amount of clean water (about 7.5 L/2 gallons) at room temperature.
- 5. Dry the probe by wiping with a piece of disposable lint-free soft cloth. Do not dry the probe by heating.
- 6. Check whether the probe has defects such as peeling, rifts, bumps, cracks, or liquid spill. If such defects exist, the probe has reached the end of its service life. In this case, stop using it and contact the Mindray service department.
- 7. Store the probe in a cool, clean and dry environment. And repeat the cleaning and disinfection process before the next use.

#### High-level disinfection of a semi-critical probe

- 1. Wear a pair of gloves to prevent infection.
- 2. Clean the probe thoroughly in accordance with the cleaning procedure before disinfection.

- 3. Disinfect the probe by using an appropriate high-level disinfectant or system. For how to use a high-level disinfectant or system, see the operator's manual provided by the manufacturer. Prepare a disinfectant by using sterile distilled or softened water when necessary.
  - Soaking: Immerse the probe head in the disinfectant and shake the probe appropriately to remove any bubbles on the probe surface. For details about the probe immersion duration, see the operator's manual provided by the manufacturer.

Observe the graph here carefully to immerse the probe. Only soak parts of the probe below the strain relief.



1	Strain relief	2	Probe handle	3	Fluid level

- Wiping: Use a market disinfection wipe product or sterile disposable lint-free soft cloth wetted with disinfection spray and wipe all surfaces of the probe for a duration according to the manufacturer instructions.
- 4. Rinse the probe thoroughly by using a large amount of clean water (about 7.5 L/2 gallons) at room temperature for about 30 s to remove the residual disinfectant. Repeat the operation twice. Or follow the disinfectant manufacturer's instructions regarding rinsing.
- 5. Dry the probe by wiping with a piece of clean disposable lint-free soft cloth. Do not dry the probe by heating.
- 6. Check whether the probe has defects such as peeling, rifts, bumps, cracks, or liquid spill. If such defects exist, the probe has reached the end of its service life. In this case, stop using it and contact the Mindray service department.
- 7. Store the probe in a cool, clean and dry environment. And repeat the cleaning and disinfection process before the next use.

#### Sterilization of a critical probe

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Repeated sterilization will eventually damage the probe, please check the probe's performance periodically.

For intra-operative probes, they have to be thoroughly cleaned and sterilized after completing each examination.

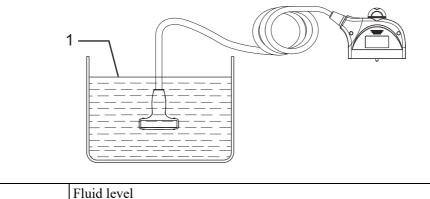
- 1. Wear a pair of gloves to prevent infection.
- 2. Clean the probe thoroughly in accordance with the cleaning procedure before sterilization.
- 3. Sterilize the probe by using an appropriate sterilant or system.

For how to use a system, see the operator's manual provided by the manufacturer.

When using a sterilant, follow the following steps:

- a. Prepare a sterilant by using sterile distilled or softened water when necessary.
- b. Immerse the probe head in the sterilant and shake the probe appropriately to remove any bubbles on the probe surface.

For details about the probe immersion duration, see the operator's manual provided by the manufacturer.



c.	Rinse the probe thoroughly by using a large amount of sterile distilled or softened water
	(about 2 gallons) at room temperature for about 30 s to remove the residual disinfectant.
	Repeat the operation twice. Or follow the sterilant manufacturer's instructions regarding
	rinsing.

- d. Dry the probe by wiping with a piece of sterile disposable lint-free soft cloth. Do not dry the probe by heating.
- 4. Check whether the probe has defects such as peeling, rifts, bumps, cracks, or liquid spill. If such defects exist, the probe has reached the end of its service life. In this case, stop using it and contact the Mindray service department.
- 5. Store the probe in a cool, clean and dry environment. And repeat the cleaning and sterilization process before the next use.

#### **Compatible Cleaners and Disinfectants**

For the detailed information about cleaners and disinfectants, see *Recommended Transducer Cleaner and Disinfectant*.

For TEE probes, refer to accompanied manual for disinfection and sterilization.

### 17.1.6 Cleaning the probe cable and connector

#### NOTE:

1

Do not use cloth with water to clean the probe connector.

- 1. Wipe out the dust attached to surface of probe connector and cable.
- 2. Use soft brush to brush the dust inside probe connector gently.
- 3. Remained stain or dust attached to surface of cable or surface of connector should be washed out by cloth with a little soapy water, and then air-dry.

# **17.1.7 Probe Environmental Conditions**

### **Operating Conditions**

Use the probes in the following ambient conditions:

Probe	Ambient temperature	Relative humidity	Atmospheric pressure
C5-1U	0°C - 40°C	30% - 85%RH (no condensation)	700hPa - 1060hPa
SC8-2U	0°C - 40°C	30% - 85%RH (no condensation)	700hPa - 1060hPa
V11-3HU	0°C - 40°C	20% - 85%RH (no condensation)	700hPa - 1060hPa
D8-4U	18°C - 30°C	30% - 75%RH (no condensation)	700hPa - 1060hPa
DE10-3U	18°C - 30°C	30% - 85%RH (no condensation)	700hPa - 1060hPa
L14-6WU	0°C - 40°C	30% - 85%RH (no condensation)	700hPa - 1060hPa
L11-3U	0°C - 40°C	20% - 85%RH (no condensation)	700hPa - 1060hPa
SP5-1U	0°C - 40°C	20% - 85%RH (no condensation)	700hPa - 1060hPa
SC6-1U	0°C - 40°C	20% - 85%RH (no condensation)	700hPa - 1060hPa
L14-3WU	0°C - 40°C	20% - 85%RH (no condensation)	700hPa - 1060hPa
SC5-1U	0°C - 40°C	30% - 85%RH (no condensation)	700hPa - 1060hPa
L20-5U	0°C - 35°C	15% - 80%RH (no condensation)	700hPa - 1060hPa
L9-3U	0°C - 40°C	20% - 85%RH (no condensation)	700hPa - 1060hPa
L14-5WU	0°C - 40°C	20% - 85%RH (no condensation)	700hPa - 1060hPa
P10-4U	0°C - 40°C	30% - 85%RH (no condensation)	700hPa - 1060hPa
C6-2GU	0°C - 40°C	20% - 85%RH (no condensation)	700hPa - 1060hPa
C11-3U	0°C - 40°C	30% - 85%RH (no condensation)	700hPa - 1060hPa
P7-3U	10°C - 40°C	30% - 85%RH (no condensation)	700hPa - 1060hPa
L16-4HU	10°C - 40°C	30% - 85%RH (no condensation)	700hPa - 1060hPa
L16-4Hs	10°C - 40°C	30% - 85%RH (no condensation)	700hPa - 1060hPa
C4-1U	0°C - 35°C	15% - 90%RH (no condensation)	700hPa - 1060hPa
DE10-3WU	18°C - 30°C	10% - 90%RH (no condensation)	700hPa - 1060hPa
CW5s	0°C - 40°C	30% - 85%RH (no condensation)	700hPa - 1060hPa
CW2s	0°C - 40°C	30% - 85%RH (no condensation)	700hPa - 1060hPa
D8-2U	18°C - 30°C	10% - 90%RH (no condensation)	700hPa - 1060hPa
ELC13-4U	0°C - 40°C	20% - 85%RH (no condensation)	700hPa - 1060hPa
C6-2Gs	0°C - 40°C	20% - 85%RH (no condensation)	700hPa - 1060hPa
7LT4s	0°C - 40°C	25% - 90%RH (no condensation)	550hPa - 1060hPa
DL14-3U	15°C - 40°C	20% - 85%RH (no condensation)	700hPa - 1060hPa
L13-3WU	0°C - 40°C	20% - 85%RH (no condensation)	700hPa - 1060hPa
L15-3WU	0°C - 40°C	20% - 85%RH (no condensation)	700hPa - 1060hPa
P8-2U	0°C - 40°C	20% - 85%RH (no condensation)	700hPa - 1060hPa

Probe	Ambient temperature	Relative humidity	Atmospheric pressure
SD8-1U	18°C - 30°C	20% - 85%RH (no condensation)	700hPa - 1060hPa
SC9-2U	0°C - 40°C	20% - 85%RH (no condensation)	700hPa - 1060hPa

#### **Storage and Transportation**

When all examinations for the day have been completed, confirm that the probe is in good condition. After disinfecting the probe, confirm that the probe is in good condition and stored in a suitable place.

- To prevent the probe from being damaged, DO NOT store it in locations where it may be exposed to:
  - Direct sunlight or X-rays
  - Sudden changes in temperature
  - Dust
  - Excessive vibration
  - Heat generators
- When the probe is sent to MINDRAY Customer Service Department or sales representative for repair, be sure to disinfect it and keep it in the carrying case to prevent infection.

Store and transport the probes in the following ambient conditions:

Probe	Ambient temperature	Relative humidity	Atmospheric pressure
C5-1U	-20°C - 55°C	30% - 95%RH (no condensation)	700 hPa - 1060 hPa
SC8-2U	-10°C - 60°C	20% - 95%RH (no condensation)	700 hPa - 1060 hPa
V11-3HU	-20°C - 55°C	20% - 95%RH (no condensation)	700 hPa - 1060 hPa
D8-4U	-10°C - 50°C	10% - 85%RH (no condensation)	700 hPa - 1060 hPa
DE10-3U	-10°C - 50°C	30% - 95%RH (no condensation)	700 hPa - 1060 hPa
L14-6WU	-20°C - 55°C	30% - 95%RH (no condensation)	700 hPa - 1060 hPa
L11-3U	-20°C - 55°C	20% - 95%RH (no condensation)	700 hPa - 1060 hPa
SP5-1U	-20°C - 55°C	20% - 95%RH (no condensation)	700 hPa - 1060 hPa
SC6-1U	-20°C - 55°C	20% - 95%RH (no condensation)	700 hPa - 1060 hPa
L14-3WU	-20°C - 55°C	20% - 95%RH (no condensation)	700 hPa - 1060 hPa
SC5-1U	-10°C - 60°C	20% - 95%RH (no condensation)	700 hPa - 1060 hPa
L20-5U	-20°C - 60°C	15% - 90%RH (no condensation)	700 hPa - 1060 hPa
L9-3U	-20°C - 55°C	20% - 95%RH (no condensation)	700 hPa - 1060 hPa
L14-5WU	-20°C - 55°C	20% - 95%RH (no condensation)	700 hPa - 1060 hPa
P10-4U	-20°C - 55°C	30% - 95%RH (no condensation)	700 hPa - 1060 hPa
C6-2GU	-20°C - 55°C	20% - 95%RH (no condensation)	700 hPa - 1060 hPa
C11-3U	-20°C - 55°C	30% - 95%RH (no condensation)	700 hPa - 1060 hPa
P7-3U	-20°C - 55°C	30% - 95%RH (no condensation)	700 hPa - 1060 hPa
L16-4HU	0°C - 60°C	30% - 95%RH (no condensation)	700 hPa - 1060 hPa

Probe	Ambient temperature	Relative humidity	Atmospheric pressure
L16-4Hs	0°C - 60°C	30% - 95%RH (no condensation)	700 hPa - 1060 hPa
C4-1U	-20°C - 60°C	15% - 90%RH (no condensation)	700 hPa - 1060 hPa
DE10-3WU	-10°C - 50°C	10% - 90%RH (no condensation)	700 hPa - 1060 hPa
CW5s	-20°C - 55°C	30% - 95%RH (no condensation)	700 hPa - 1060 hPa
CW2s	-20°C - 55°C	30% - 95%RH (no condensation)	700 hPa - 1060 hPa
D8-2U	-10°C - 50°C	10% - 90%RH (no condensation)	700 hPa - 1060 hPa
ELC13-4U	-20°C - 55°C	20% - 95%RH (no condensation)	700 hPa - 1060 hPa
C6-2Gs	-20°C - 55°C	20% - 95%RH (no condensation)	700 hPa - 1060 hPa
7LT4s	-20°C - 60°C	10% - 95%RH (no condensation)	500 hPa - 1060 hPa
DL14-3U	-10°C - 60°C	20% - 95%RH (no condensation)	700 hPa - 1060 hPa
L13-3WU	-20°C - 55°C	20% - 95%RH (no condensation)	700 hPa - 1060 hPa
L15-3WU	-20°C - 55°C	20% - 95%RH (no condensation)	700 hPa - 1060 hPa
P8-2U	-20°C - 55°C	20% - 95%RH (no condensation)	700 hPa - 1060 hPa
SD8-1U	-10°C - 50°C	20% - 95%RH (no condensation)	700hPa - 1060hPa
SC9-2U	-20°C - 55°C	20% - 95%RH (no condensation)	700 hPa - 1060 hPa

#### NOTE:

For details of the TEE probes, refer to TEE Ultrasonic Transducer manual.

### **17.1.8 Storage and Transportation**

When all examinations for the day have been completed, confirm that the probe is in good condition. After disinfecting the probe, confirm that the probe is in good condition and stored in a suitable place.

- To prevent the probe from being damaged, DO NOT store it in locations where it may be exposed to:
  - Direct sunlight or X-rays
  - Sudden changes in temperature
  - Dust
  - Excessive vibration
  - Heat generators
- When the probe is sent to MINDRAY Customer Service Department or sales representative for repair, be sure to disinfect it and keep it in the carrying case to prevent infection.

### 17.1.9 Sensor (Fusion Imaging) Support Cleaning and Disinfection

Before performing the fusion imaging exam, clean and disinfect (or sterilize) the fusion sensor support as required.

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- When performing cleaning and disinfection of the sensor support to prevent infection, wear sterile gloves.
- After disinfection, rinse the sensor support thoroughly with sterile water to remove all chemical residues. Chemical residues may be harmful to the human body.
- No cleaning and disinfecting may result in the sensor support becoming a source of infection.

The efficacy of disinfectants and sterilizing solutions is not guaranteed by MINDRAY. Contact the manufacturers for information on the activity of the products.

#### Cleaning

Perform the following procedure:

- 1. Disconnect the sensor support from the system.
- 2. Wear sterile gloves to prevent infection.
- 3. Wash the sensor support (fusion) with clean water or soapy water to remove all the foreign matters, or, wipe the sensor support with a soft ethyl carbamate sponge. Avoid using a brush, because it may damage the transducer.
- 4. Dry the sensor support using a sterile cloth or gauze after rinsing. Do not dry the sensor support by heating it.

#### **Disinfecting with Sprays or Wipes**

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Use protective eyewear when disinfecting using sprays.

Perform the following procedure:

- 1. Wear sterile gloves to prevent infection.
- 2. After you have finished cleaning, spray or wipe the sensor support (fusion) with a disinfectant. Follow the disinfectant manufacturer's recommended contact time and mode.
- 3. Remove any residue with a water-moistened soft cloth on the sensor support.
- 4. Wipe off water on the sensor support using sterile cloth or gauze after washing.

#### **Disinfecting by Immersion**

- 1. Wear sterile gloves to prevent infection.
- 2. Clean the sensor support before disinfecting it. MINDRAY recommends the following solutions to disinfect the sensor support (fusion).
  - Refer to the instructions provided by the chemical manufacturer concerning concentration of the disinfectant solution, method of disinfection and dilution and cautions during use.
  - Soak the sensor support into the disinfectant solution for the shortest time the manufacturer recommends (for example, the shortest time recommended by the manufacturer for soaking Cidex OPA is 12 minutes).

- Follow local regulations when selecting and using the disinfectant.
- 3. Rinse the sensor support with plenty of sterile water (about 2 gallons) for at least 1 minute to remove all chemical residues on it. Or, follow the rinsing method recommended by the disinfectant manufacturer to rinse the sensor support.
- 4. Wipe off the water on the sensor support with sterile cloth or gauze after rinsing it.

#### **Compatible Disinfectants**

Manufacturer	Trade Name	Procedures	Туре
Metrex	MetriZyme	Please refer to the instructions provided by the manufacturer of the solution for details.	Solution
ASP	Cidex Activated Glutaraldehyde Solution	Please refer to the instructions provided by the manufacturer of the solution for details.	Solution
ASP	Cidex OPA	Please refer to the instructions provided by the manufacturer of the solution for details.	Solution
Ecolab Inc.	Ster-Bac	Please refer to the instructions provided by the manufacturer of the solution for details.	Solution
Advanced Ultrasound Solutions Inc.	SONO Ultrasound Wipes	Please refer to the instructions provided by the manufacturer of the solution for details.	Wipe
Professional Disposables International, Inc.	Sani-Cloth	Please refer to the instructions provided by the manufacturer of the solution for details.	Wipe

### 17.1.10Storage and Transportation for Sensor Support (Fusion)

When all examinations for the day have been completed, confirm that the sensor support is in good condition. After disinfecting the sensor support, confirm that the sensor support is in good condition and stored in a suitable place.

- To prevent the sensor support from being damaged, DO NOT store it in locations where it may be exposed to:
  - Direct sunlight
  - Sudden changes in temperature
  - Dust
  - Excessive vibration
  - Heat generators
- Store and transport sensor support under following ambient conditions:
  - Ambient temperature:  $-20^{\circ}C \sim 55^{\circ}C$
  - Relative humidity: 20% ~95% (no condensation)
  - Atmospheric pressure: 700 hPa ~1060 hPa

## 17.1.11Sensor (Fusion Imaging) Cleaning and Disinfection

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- When performing cleaning and disinfection of the sensor to prevent infection, wear sterile gloves.
- After disinfection, rinse the sensor thoroughly with sterile water to remove all chemical residues. Chemical residues may be harmful to the human body.
- No cleaning and disinfecting may result in the sensor becoming a source of infection.
- The efficacy of disinfectants and sterilizing solutions is not guaranteed by MINDRAY. Contact the manufacturers for information on the activity of the products.

#### **Disinfecting with Sprays or Wipes**

# 

Use protective eyewear when disinfecting using sprays.

Perform the following procedure:

- 1. Wear sterile gloves to prevent infection.
- 2. Spray or wipe the sensor (fusion) with a disinfectant. Follow the disinfectant manufacturer's recommended contact time and mode.
- 3. Remove any residue with a water-moistened soft cloth on the sensor.
- 4. Wipe off water on the sensor using sterile cloth or gauze after washing.

#### **Compatible Disinfectants**

Manufacturer	Disinfectants Name	Disinfect times	Procedures	Туре
Advanced Ultrasound Solutions Inc.	SONO Ultrasound Wipes	5200 times, 3 min/ time	Please refer to the instructions provided by the manufacturer of the solution for details.	Wipe
Professional Disposables International,Inc.	Sani-Cloth	5200 times, 4min/ time	Please refer to the instructions provided by the manufacturer of the solution for details.	Wipe

Clean and disinfect eTRAX needle using disinfectant and sterilant such as ani-cloth® HB, CIDEX OPA® (Johnson & Johnson), ENZOL® (Johnson & Johnson), T-Spray<sup>TM</sup>, Protex<sup>TM</sup> or ethanol.

# 17.2 Biopsy Guide

### **WARNING**

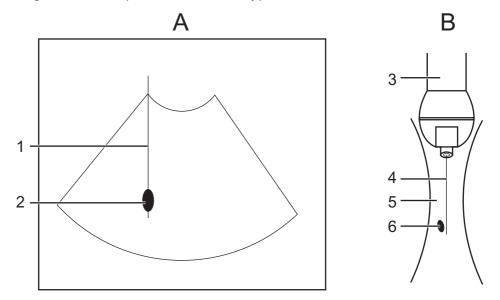
- The person performing biopsy procedures must understand diagnostic ultrasound thoroughly and have been trained adequately, otherwise, side effects may be caused to the patient.
- In situations listed below, the biopsy needle may fail to penetrate the target. The incorrect biopsy may cause various side effects in the patient.
  - Use a needle-guided bracket other than that provided.
  - Mount the needle-guided bracket incorrectly.
  - Use a biopsy needle that is unsuitable for the type of biopsy being performed.
  - Use a biopsy needle that is unsuitable for the needle guide.
- Before and after a biopsy procedure is performed, confirm that the needleguided bracket is normal. Manually confirm that the parts of the needleguided bracket do not slip off or move from their proper positions. If the needle-guided bracket is used when parts are not securely and correctly installed, the patient may be injured. If an abnormality is found on the needle-guided bracket, immediately stop using it and contact MINDRAY Customer Service Department or sales representative.
- DO NOT use a needle-guided bracket when scanning is performed. The needle may advance in an incorrect direction and possibly injure the patient.

Never perform a biopsy during image scanning.

- DO NOT freeze an image while performing biopsy procedure.
- During biopsy procedures, the needle may deviate from the desired course due to the tissue characteristics or the type of needle. In particular, needles of small diameters may deviate to a greater degree.
- Disinfect the probe and sterilize needle-guided bracket before and after each ultrasound-guided biopsy procedure is performed. Fail to do so may cause the probe and the needle-guided bracket become sources of infection.
- The needle mark displayed on the ultrasound image does not indicate the actual position of the biopsy needle. Therefore, it should only be used as a reference. Always monitor the relative positions of the biopsy needle during the procedures.
- Adjust the needle mark before the biopsy procedure is performed.
- When performing biopsy procedures, use only sterile ultrasound gel that is certified to be safe. And manage the ultrasound gel properly to ensure that it does not become a source of infection.
- When performing the operation concerning biopsy, wear sterile gloves.
- Image of the biopsy target and the actual position of the biopsy needle:

Diagnostic ultrasound systems produce tomographic plane images with information of a certain thickness in the thickness direction of the probe. (That is to say, the information shown in the images consist all the information scanned in the thickness direction of the probe.) So, even though the biopsy needle appears to have penetrated the target object in the image, it may not actually have done so. When the target for biopsy is small, dispersion of the ultrasound beam may lead to image deviate from the actual position. Pay attention to this.

If the target object and the biopsy needle appear in the image as shown in the figures below (For reference only):



A	The biopsy needle appears to reach the target object in the image	В	Dispersion of the ultrasound beam
1	Biopsy	2	Target
3	Probe	4	Needle
5	Ultrasound beam	6	Target

The biopsy needle may not have actually entered the target object even though it appears to have done so in the image. To avoid this, note the points below:

- Do not rely only on the needle tip in the image. Pay careful attention to the fact that when the biopsy needle enters the target object or comes into contact with it, the object should shift slightly.
- Before performing the biopsy, evaluate the size of the object and confirm whether the biopsy can be carried out.

During biopsy of the probe, misoperation may occur when the scan range is not set to "W".

# 17.2.1 Needle-guided Brackets Available

Some of the probes have matched needle-guided brackets for biopsy, the available probes and the corresponding needle-guided brackets are listed as follows.

Probe Model	Needle-guided Bracket Model	Biopsy angle/ depth (±1°)	Applicable Biopsy Needle
L14-6WU	<ul> <li>NGB-007</li> <li>Plastic-needle detachable</li> <li>Metal-needle detachable</li> </ul>	40°, 50°, 60°	<ul> <li>Plastic: 13G, 15G, 16G, 18G, 20G</li> <li>Metal: 14G, 16G, 18G, 20G, 22G</li> </ul>
7LT4s	NGB-010 Metal-needle detachable	30°, 40°, 50°	13G, 15G, 16G, 18G, 20G
SP5-1U	NGB-011 Metal-needle undetachable	11°, 23°	13G, 15G, 16G, 18G, 20G
C11-3U	NGB-018 Metal-needle detachable	15°, 25°, 35°	14G, 16G, 18G, 20G, 22G
DE10-3U/DE10- 3WU	NGB-021 Metal-needle undetachable	2°	16G, 17G, 18G
SC6-1U/C5-1U	NGB-022 Metal-needle detachable	25°, 35°, 45°	14G, 16G, 18G, 20G, 22G
C6-2GU/C6-2Gs	NGB-024 Metal-needle detachable	7°, 25°, 35°	14G, 16G, 18G, 20G, 22G
V11-3HU	NGB-025 Metal-needle undetachable	1.6°	16G, 17G, 18G
L11-3U	NGB-026 Metal-needle detachable	40°, 50°, 60°	14G, 16G, 18G, 20G, 22G
SC8-2U	NGB-029 Metal-needle detachable	20°, 30°, 40°	14G, 16G, 18G, 20G, 22G
SC5-1U	NGB-031 Metal-needle detachable	25°, 35°, 45°	14G, 16G, 18G, 20G, 22G
L9-3U	NGB-034 Metal-needle detachable	40°, 50°, 60°	14G, 16G, 18G, 20G, 22G
L14-5WU	NGB-035 Metal-needle detachable	47°, 53°, 59°, 65°	14G, 16G, 18G, 20G, 22G
C4-1U	NGB-036 Metal-needle detachable	7°, 25°, 35°	14G, 16G, 18G, 20G, 22G
SD8-1U	NGB-039 Metal-needle detachable	21°, 26°, 33°	14G, 16G, 18G, 20G, 22G

Probe Model	Needle-guided Bracket Model	Biopsy angle/ depth (±1°)	Applicable Biopsy Needle
D8-2U	NGB-040 Metal-needle detachable	21°, 26°, 33°	14G, 16G, 18G, 20G, 22G
D8-4U	NGB-042 Metal-needle detachable	28°	16G, 18G
ELC13-4U	NGB-051 Metal-needle detachable	5mm, 10mm, 15mm, 20mm, 25mm, 30mm, 35mm, 40mm, 45mm, 50mm	14G, 16G, 18G, 20G
L14-3WU/L13- 3WU/L15-3WU	NGB-054 Metal-needle detachable	15mm (65°), 23.7mm (55°), 35mm (45°)	11G ~ 23G
SC9-2U	NGB-058 Metal-needle detachable	20°, 30°, 40°	11G ~23G

### Disposable Bracket

Probe Model	Needle-guided Bracket Model
V11-3HU	CIVCO 610-543
	CIVCO 610-1274
L14-5WU	CIVCO 698-007
	CIVCO 698-012
C4-1U	CIVCO 698-013
	CIVCO 698-019
SC6-1U/C5-1U	CIVCO 658-004-1
	CIVCO 658-004-2
	CIVCO 658-004-3
	CIVCO 658-004-4
	CIVCO 658-004-5

#### **Biopsy Grid**

Probe Model	Needle-guided Bracket Model
ELC13-4U	CIVCO 658-007 EX3 Stepper
	NOTE:
	• It is used to correctly position the needle insertion coordinate in the prostate biopsy operation, in conjunction with the positioning grid bracket.
	• Mindray does not offer the biopsy grid; please purchase it according to your own needs. For more information about the biopsy grid, refer to the manufacturer's accompanying manual.

#### NOTE:

Mindray does not offer the biopsy needle; please purchase it according to your own needs.

### 17.2.2 Needle-Guided Bracket Installation and Removal

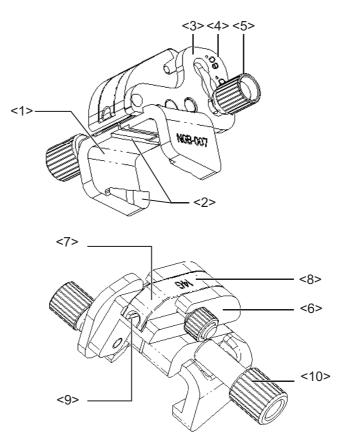
A needle-guided bracket is available for purchase as an optional accessory; it is used in combination with the probe. Some of the probes have matched needle-guided bracket and needles. To order needle-guided brackets, contact MINDRAY Customer Service Department or sales representative.

For biopsy or treatment, ultrasound-guided biopsy procedures can be performed using the probe in combination with a needle-guided bracket (optional accessory) and a biopsy needle (provided by the user).

Be sure to perform inspections before and after use of the needle-guided bracket. If an abnormality is found on the needle-guided bracket, immediately stop using it and contact MINDRAY Customer Service Department or sales representative.

- Sterilize the needle-guided bracket before and after use.
- Put on the sterile probe sheath before installing to the probe.
- Confirm that the needle-guided bracket is free of damage, deformation, stripping, malfunction, loose, or missing parts.
- Confirm that the needle-guided bracket is securely mounted in the correct position.
- Select the proper needle according to the specification above, and adjust the needle shift to the same specification of the selected needle.

# NGB-007 (Metal)

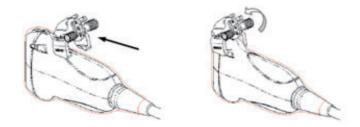


1	Support of needle- guided bracket	Used for installing the needle-guided bracket on the probe.
2	Groove and tab of the needle-guided bracket	Respectively matched with the tab and groove of the probe.
3	Angle adjusting base	There are 3 types of angles available to be adjusted.
4	Angle shift sign (40°, 50°, 60°)	Matched with the biopsy angle (40°, 50°, and 60°).
5	Angle pinch nut	Used for fixing the angle lock at a chosen angle.
6	Angle block	Used for determining the angle of the biopsy; different specifications of blocks can be used.
7	Guiding block	Used for installing biopsy needle; there are five specifications of guiding blocks for different biopsy needles.
8	Specification of guiding block (14G)	Matched with the corresponding biopsy needle (14G).
9	Needle guide hole	Used for installing the biopsy needle.
10	Pinch nut of needle- guided bracket	Used for locking the needle-guided bracket and the probe.

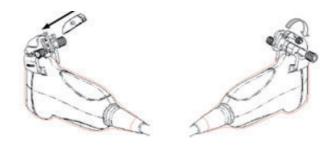
Perform the following procedure:

1. Install the needle-guided bracket:

- a. Put on the sterile probe sheath.
- b. Hold the probe by one hand, select the proper needle-guided bracket, and hold it with the other hand. Match the groove and tab with the tab and groove of the probe respectively. Amount the bracket onto the probe.



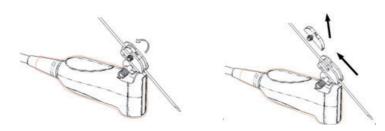
- c. Screw the pinch nut of the needle-guided bracket to confirm that the needle-guided bracket is properly installed on the probe.
- d. Select a proper guiding block and push it into the groove above the angle block, and clamp it tightly.



- e. Screw the nut of the block to secure the block.
- f. Insert a biopsy needle with the same specification as that of the guiding block into the hole of the guiding block.

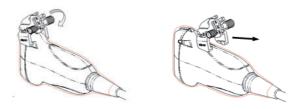


- 2. Remove the needle-guided bracket:
  - a. Screw the nut of the guiding block and remove the guiding block slightly along the direction of the needle's tail.



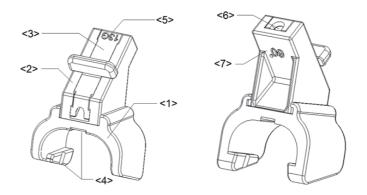
b. Separate the residual part of the needle-guide bracket and the transducer from the needle.

c. Screw the pinch nut of the bracket, and remove the needle-guided bracket from the transducer.



d. Separate the transducer and the needle-guided bracket.

### NGB-007 (Plastic)



1	Support of needle-guided bracket	Used for installing the needle-guided bracket on the probe.
2	Angle block	Used for determining the angle of the biopsy; there are three specifications of blocks of angle.
3	Guiding block	Used for installing biopsy needle; there are five specifications of guiding blocks for different biopsy needles.
4	Groove and tab of the needle- guided bracket	Respectively matches with the tab and groove of the probe.
5	Specification of guiding block (13G)	Matched with the corresponding biopsy needle (13G).
6	Guiding hole of the biopsy needle	Used for installing the biopsy needle.
7	Specification of angle block (60°)	The corresponding biopsy angle is 60°.

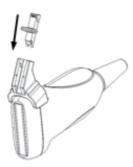
Perform the following procedure:

- 1. Install the needle-guided bracket:
  - a. Put on the sterile probe sheath.
  - b. Hold the probe by one hand, select the proper needle-guided bracket, and hold it with the other hand. Align the narrow end tab of the needle-guided bracket with the groove of the

probe, then push the needle-guided bracket forward, making the tabs and the grooves of the needle-guided bracket to match with the grooves and tabs of the probe.



- c. Check manually to confirm that the needle-guided bracket is securely installed on the probe.
- d. Select a proper guiding block and push it into the groove above the angle block, and clamp it tightly.



e. Insert a biopsy needle with the same specification as that of the guiding block into the hole of the guiding block.



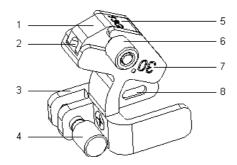
- 2. Remove the needle-guided bracket:
  - a. Remove the guiding block slightly along the direction of the needle's tail.
  - b. Separate the residual part of the needle-guide bracket and the transducer from the needle.



c. Remove the support of needle-guided bracket from the transducer.



## NGB-010



1.	Guiding block	Used for installing biopsy needle; there are five specifications of guiding blocks for different biopsy needles.			
2.	Guiding hole of the biopsy needle	Used for installing the biopsy needle.			
3.	Support of needle-guided bracket	Used for installing the needle-guided bracket on the probe.			
4.	Knob of fixing needle-guided bracket	Used for fixing the needle-guided bracket on the probe.			
5.	Specification of guiding block (13G)	Matched with the corresponding biopsy needle (13G).			
6.	Knob of fixing the guiding block	Used for fixing the guiding block.			
7.	Needle guide angle	The needle guide angle of this needle-guided bracket.			
8.	Grooves of the needle-guided bracket	Matched with the tabs of the probe.			

Perform the following procedure:

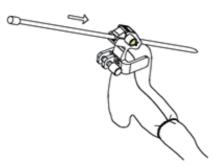
- 1. Install the needle-guided bracket:
  - a. Put on the probe cover.
  - b. Hold the probe by one hand, select proper needle-guided bracket, and hold it with the other hand, and align the grooves of the needle-guided bracket with the tabs of the probe, then push the needle-guided bracket forward, making the grooves of the needle-guided bracket to match with the tabs of the probe. Set the needle-guided bracket at the desired position, turn tightly the knob of fixing needle-guided bracket to fix the needle-guided bracket.



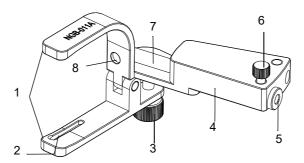
- c. Check manually to confirm the needle-guided bracket is securely installed on the probe.
- d. Select a proper guiding block and push it into the groove above the support of needleguided bracket, then turn tightly the knob of fixing the guiding block to fix the guiding block on the support of needle-guided bracket.



e. Insert a biopsy needle with the same specification as that of the guiding block into the hole of the guiding block.



- 2. Remove the needle-guided bracket:
  - a. Remove the guiding block slightly along the direction of the needle's tail, and separate the residual part of the needle-guide bracket and the probe from the needle.
  - b. Remove the support of needle-guided bracket from the probe.



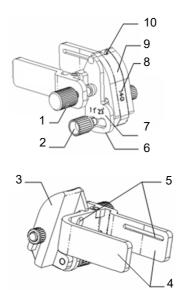
1	Clamp	2	Locating groove
3	Grip knob	4	Needle guide rack
5	Needle guide hole	6	Needle guide clamping knob
7	Needle guide	8	Locating pit

Perform the following procedure:

- 1. Install the needle-guided bracket:
  - a. Put on the sterile probe sheath.
  - b. Connect the locating groove on the clamp with the two raised edges on the probe head and align the locating pit of the clamp with the convex point on the probe head.
  - c. Turn the grip knob at the tail of the needle-guided bracket tightly.
- 2. Remove the needle-guided bracket:

Hold the probe and the needle-guided bracket, then open the grip knob of the needle-guided bracket.

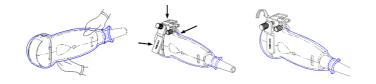
### NGB-018



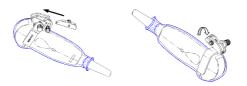
1	Pinch nut of bracket	2	Angle pinch nut
3	Angle block	4	Clamp
5	Groove	6	Angle-adjusting base
7	Angle shift sign	8	Guiding block specification
9	Guiding block	10	Needle guide hole

Perform the following procedure:

1. Install the needle-guided bracket:



- a. Put on the sterile probe sheath.
- b. Select a suitable needle-guided bracket and match the groove to the tab of the probe. Mount the bracket onto the probe.
- c. Screw the pinch nut of the needle-guided bracket to ensure that the needle-guided bracket is properly installed on the probe.
- 2. Adjust the needle angle to the proper shift as required:
  - a. Loosen the angle pinch nut.
  - b. Adjust the angle block to the desired level.
  - c. Tighten the angle pinch nut.
- 3. Install the guiding block:

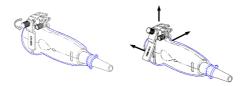


- a. Select a suitable guiding block and push it into the groove above the angle block
- b. Screw the block's nut to secure the block.
- c. Insert a biopsy needle with the same specification as that of the guiding block into the guiding block hole.
- 4. Release the needle from the bracket:

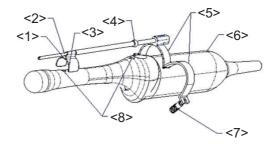


a. Loosen the guiding block's nut and slightly move the guiding block in the direction of the needle's tail.

- b. Separate the residual part of the needle-guide bracket and the probe from the needle.
- 5. Remove the needle-guided bracket:



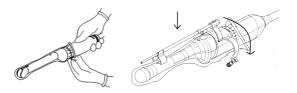
- a. Screw the pinch nut to release the needle-guided bracket
- b. Separate the bracket and the probe.



1	Locating bulge	2	Needle guide
3	Retaining clamp (front)	4	Locating clamp
5	Retaining clamp (back)	6	Probe
7	Locking nut	8	Locating groove

Perform the following procedure:

- 1. Install the needle-guided bracket:
  - a. Put on the sterile probe sheath.
  - b. Loose the retaining clamp, align the needle-guided bracket with the transducer to locate the locating clamp on the needle guide to the locating grooves on the transducer, and then press the retaining clamp (front) to match the locating clamp and the locating bulge on the front retaining clamp to the corresponding groove.



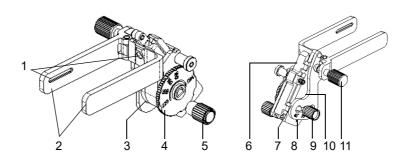
c. Screw the retaining clamp to match with the transducer structure. When the clamp is turned to the right position, the locking nut will lock the retaining clamp and the needle-guided bracket is then mounted to the right position.



2. Remove the needle-guided bracket:

Hold the transducer in the left hand; unscrew the locking nut with the right hand to loosen the retaining clamp. Raise the needle-guided bracket to separate the locating clamp/ bulge from the locating grooves.

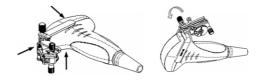
### NGB-022



1	Groove	2	Clamp
3	Needle type adjusting base	4	Needle type dial scale
5	Needle fixing nut	6	V-shaped cover
7	Angle adjusting base	8	Angle shift sign
9	Angle pinch nut	10	Angle block
11	Pinch nut		

Perform the following procedure:

- 1. Install the needle-guided bracket:
  - a. Put on the sterile probe sheath.
  - b. Hold the probe by one hand, select the proper needle-guided bracket, and hold it with the other hand. Match the groove of the bracket with the tab of the probe. Amount the bracket onto the probe.

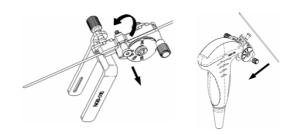


- c. Screw the pinch nut of the needle-guided bracket to confirm that the needle-guided bracket is properly installed on the probe.
- 2. Adjust the needle angle to the proper shift as required:
  - a. Loosen the angle pinch nut.

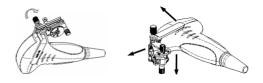
- b. Adjust the angle block to the desired level.
- c. Tighten the angle pinch nut.
- 3. Insert the biopsy needle:



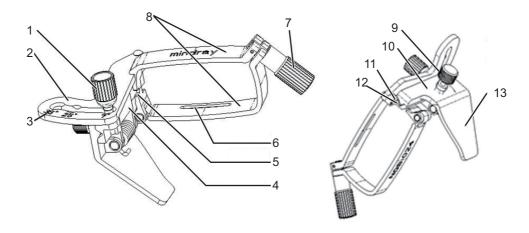
- a. Adjust the dial scale to the required needle type shift, and then screw the needle fixing nut to lock the dial scale. (To adjust the dial scale you have to loosen the needle fixing nut first.)
- b. Pull the lock pin and close the V-shaped cover to fix the lock pin in the groove of the needle type adjusting base, so as to install the needle into the guiding hole.
- 4. Release the needle from the bracket:



- a. Pull the lock pin and open up the V-shaped cover to expose the needle.
- b. Separate the bracket and the probe from the needle.
- 5. Remove the needle-guided bracket:



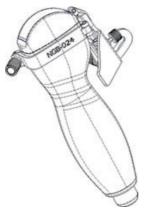
- a. Screw the pinch nut to release the needle-guided bracket.
- b. Separate the bracket and the probe.



1	Angle locking nut	2	Angle adjusting block	3	Angle marker
4	Angle adjusting base	5	Slot	6	Groove
7	Right, left retaining nut	8	Right, left clamp	9	Needle shape adjusting nut
10	Needle clamping cover	11	Needle guided V-shaped block	12	Guiding hole of the needle
13	Needle separate pressure	positic	n		1

Perform the following procedure:

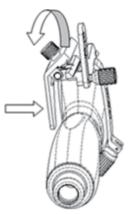
- 1. Install the needle-guided bracket:
  - a. Put on the sterile transducer sheath.
  - b. Select a proper needle-guided bracket, and match the groove with the tab of the transducer. Mount the bracket onto the transducer.



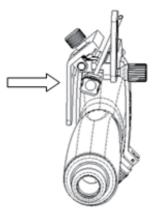
c. Rotate the clamping nuts of the guided bracket on right and left side to fix the bracket and the transducer. Rotate the needle-type adjusting nut to the ultimate position as shown in the figure.



d. Hold the transducer. Press the biopsy needle to separate needle guided V-shaped block from pressure position of the needle.



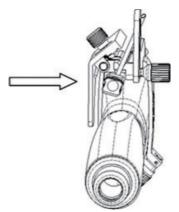
e. Put the needle into the needle guided-bracket, and the needle leans to V-shaped block.



f. Hold the transducer, and release the pressure position of the needle. Adjust the needletype adjusting nut manually (following the direction of the arrow). The needle moves smoothly at the vertical direction due to its gravity.

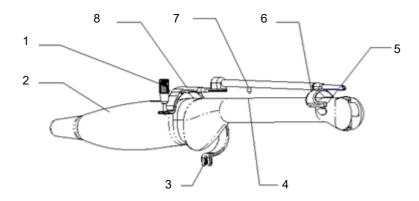


- 2. Remove the needle-guided bracket:
  - a. Hold the transducer. Press the biopsy needle to separate the needle from pressure position of the needle.



- b. Separate the bracket and the transducer from the needle.
- c. Rotate the clamping nuts of the needle guided-bracket on right and left side (following the direction of the arrow). The needle guided-bracket is separate from the transducer. Hold the transducer and take out the bracket.





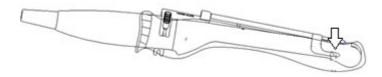
1	Pinch nut	2	Intra-cavity probe
3	Lower clamp	4	Location hole
5	Front slot	6	Front clamp
7	Location clamp	8	Upper clamp

Perform the following procedure:

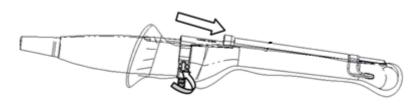
- 1. Install the needle-guided bracket:
  - a. Put on the sterile probe sheath.



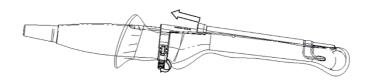
b. Open the clamp. Insert the front clamp to the front groove, and align front clamp with front groove.



c. Push the biopsy forward (arrow's direction) until the locating pole inserting into the location hole. Turn the lower clamp against the intra-cavity probe. Tighten the nut to lock the biopsy (arrow's direction)

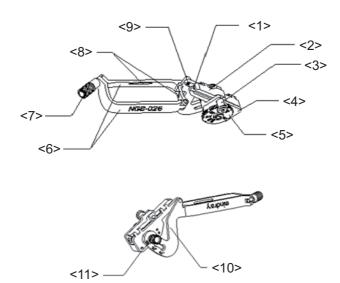


2. Remove the needle-guided bracket:



- a. Hold the prober in the left hand; unscrew the locking nut with the right hand to loose the clamp (arrow's direction).
- b. Lift the biopsy up (towards arrow's direction). The locating pole, front clamp, the locating hole and the front clamp become loose.

NGB-026



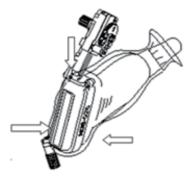
1	Guiding hole	2	V-shaped cover
3	Lock pin	4	Adjusting base
5	Dial scale	6	Clamp of needle-guided bracket
7	Pinch nut	8	Locating groove
9	V-shaped guiding block	10	Angle adjusting block
11	Angle pinch nut		

Perform the following procedure:

- 1. Install the needle-guided bracket:
  - a. Put on the sterile probe sheath.



b. Select a proper needle-guided bracket, and match the locating groove with the tab of the transducer. Mount the bracket onto the transducer.



c. Tighten the pinch nut of the needle-guided bracket to confirm that the needle-guided bracket is properly installed on the transducer.



d. Adjust the dial scale to the required needle type shift.



e. Adjust the needle angle to the proper shift as required (loosen the nut first, and then tighten the nut based on the shift you need).

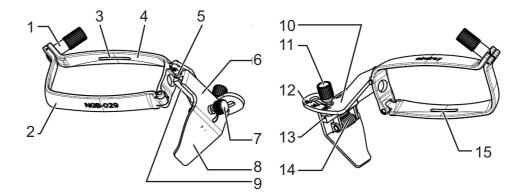


f. Pull the lock pin and close the V-shaped cover to fix the lock pin in the groove of the needle type adjusting base, so as to install the needle into the guiding hole.



Remove the needle-guided bracket:
 Screw the pinch nut to release the needle-guided bracket.

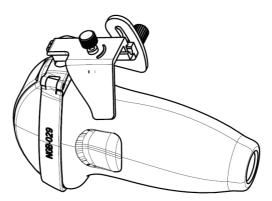




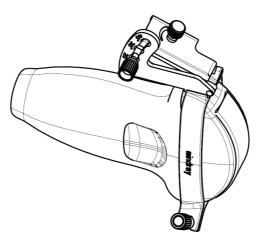
1	Fixing nut of clamps	2	Clamp	3	Groove
4	Clamp	5	Needle guide hole	6	Needle clamp cover
7	Pinch nut	8	Needle separation pressure position	9	V-shaped guiding block
10	Angle adjusting block	11	Angle fixing nut	12	Needle mark
13	Angle adjusting base	14	Torsion spring of the needle pressure cover	15	Groove

Perform the following procedure:

- 1. Install the needle-guided bracket:
  - a. Put on the sterile probe sheath.
  - b. Select a proper needle-guided bracket, and match the locating groove with the tab of the probe. Mount the bracket onto the probe.



2. Tighten the fixing nut of clamps of the needle-guided bracket to confirm that the needle-guided bracket is properly installed on the probe. And tighten the pinch nut (following the arrow's direction).



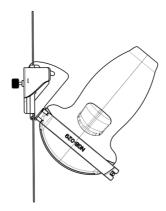
a. Hold the transducer. Press the pressure position of the needle to separate needle guided V-shaped block from pressure position of the needle.



b. Put the needle into the needle guided-bracket, and the needle leans to V-shaped block.



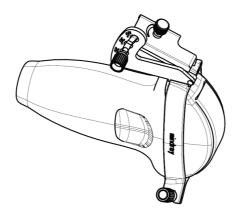
c. Hold the transducer, and release the pressure position of the needle. Adjust the needletype adjusting nut manually (following the direction of the arrow). The needle moves smoothly at the vertical direction due to its gravity.

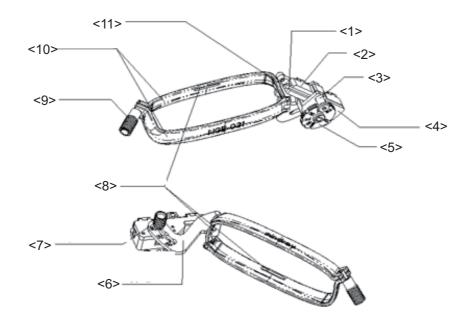


- 3. Remove the needle-guided bracket:
  - a. Hold the transducer. Press the biopsy needle to separate the needle from pressure position of the needle.



- b. Separate the bracket and the transducer from the needle.
- c. Rotate the clamping nuts of the needle guided-bracket (following the direction of the arrow). The needle guided-bracket is separate from the transducer. Hold the transducer and take out the bracket.

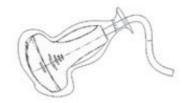




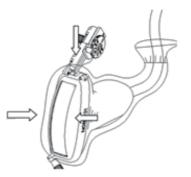
1	Block hole	2	V-shaped cover
3	Lock pin	4	Needle-shaped base
5	Needle-shaped scale	6	Angle adjusting block
7	Angle fixing nut	8	Groove
9	Pinch nut	10	Bracket clamp
11	V-shaped block		

Perform the following procedure:

- 1. Install the needle-guided bracket.
  - a. Put on the sterile probe sheath.



b. Select a proper needle-guided bracket, and match the locating groove with the tab of the probe. Mount the bracket onto the probe.



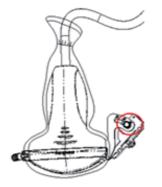
c. Tighten the pinch nut of the needle-guided bracket (following the arrow's direction) to confirm that the needle-guided bracket is properly installed on the probe.



d. Adjust the dial scale to the required needle type shift.



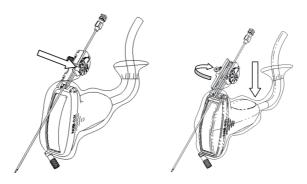
e. Adjust the needle angle to the proper shift as required (loosen the nut first, and then tighten the nut based on the shift you need).



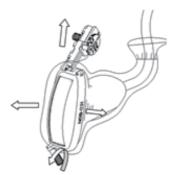
f. Pull the lock pin and close the V-shaped cover to fix the lock pin in the groove of the needle type adjusting base, so as to install the needle into the guiding hole.



- 2. Separate the needle in the operation.
  - a. Open the block pin until the V-shaped cover can be rotated.

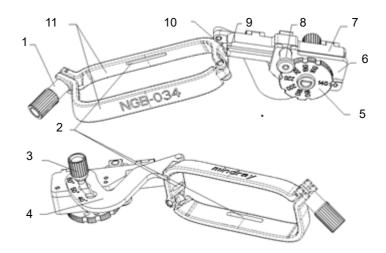


b. Rotate V-shaped cover until the needle is separate from it. Remove the probe and the bracket.



3. Remove the needle-guided bracket:

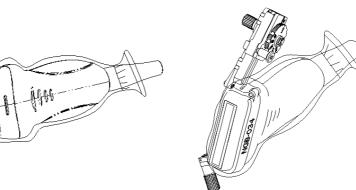
Unscrew the pinch nut to separate the needle-guided bracket from the probe. Release the needle-guided bracket from the probe.



1	Needle fixing nut	2	Guiding groove
3	Angle fixing nut	4	Angle adjusting base
5	Needle type dial scale	6	Needle adjusting base
7	V-shape cover	8	Lock pin
9	Needle guide hole	10	V-shaped guiding block
11	Clamp	ŀ	

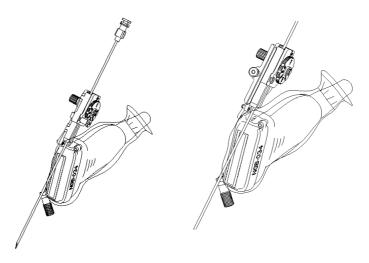
Perform the following procedure:

1. Install the needle-guided bracket:

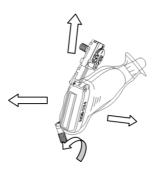


- a. Put on the sterile probe sheath.
- b. Select a proper needle-guided bracket, and match the locating groove with the tab of the probe. Mount the bracket onto the probe.
- c. Tighten the pinch nut of the needle-guided bracket to confirm that the needle-guided bracket is properly installed on the probe.
- 2. Adjust the needle angle to the proper shift as required:
  - a. Loosen the angle pinch nut.
  - b. Adjust the angle block to the desired level.
  - c. Tighten the angle pinch nut.

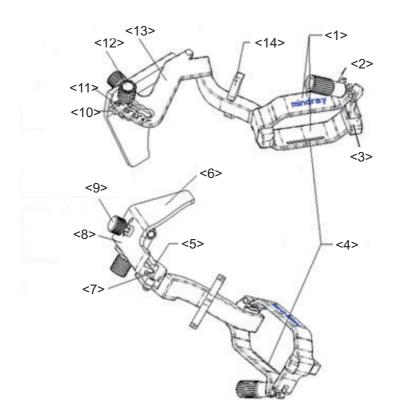
- 3. Insert the biopsy needle:
  - a. Adjust the dial scale to the required needle type shift.
  - b. Pull the lock pin and close the V-shaped cover to fix the lock pin in the groove of the needle type adjusting base, so as to install the needle into the guiding hole.
- 4. Release the needle from the bracket:



- a. Pull the lock pin out until the V-shaped cover can be turned and opened up.
- b. Turn over the V-shaped cover to expose the needle. Remove the probe and bracket.
- 5. Remove the needle-guided bracket:



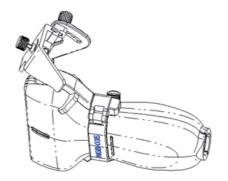
- a. Unscrew the pinch nut to release the needle-guided bracket.
- b. Hold the probe and take out the bracket.



1	Clamp	2	The clamping nut of left/right clamp
3	The locating position block	4	Groove
5	V-shaped guiding block	6	The pressing block for separating needle
7	Needle guide hole	8	Needle clamping cover of needle- guided bracket
9	Needle adjusting nut of needle guided bracket	10	Angle adjusting base
11	Angle mark	12	Angle locking nut
13	Angle adjusting block	14	Buckle

Perform the following procedure:

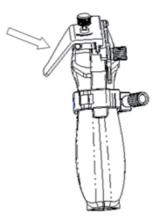
- 1. Install the needle-guided bracket:
  - a. Put the sterile sheath on the probe.
  - b. Select a proper needle-guided bracket, and match the locating groove with the tab of the transducer. Mount the bracket onto the transducer.



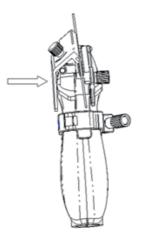
c. Tighten the pinch nut of the needle-guided bracket to confirm that the needle-guided bracket is properly installed on the probe. Loosen the angle adjusting nut.



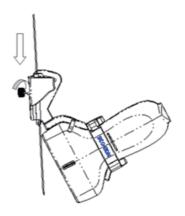
d. Hold the probe and press the pressing block to separate V-shaped guiding block from the pressing block.



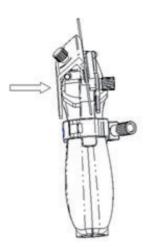
e. Insert the needle into V-shaped guided block.



f. Release the pressing block, adjust the angle adjusting nut to confirm that the needle can freely slide in a vertical direction.

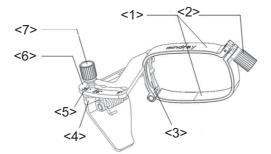


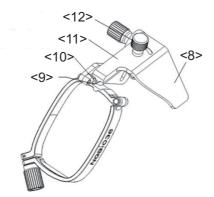
- 2. Remove the needle-guided bracket:
  - a. Hold the probe and press the pressing block to separate V-shaped guiding block from the pressing block.



- b. Remove the needle.
- c. Rotate the clamping nut to separate the bracket from the probe.







1	Left/right clamp	2	Left/right clamp pinch nut
3	Tab	4	Angle adjusting base
5	Angle shift sign	6	Angle adjusting block
7	Angle pinch nut	8	Separation pressure position
9	Guiding hole	10	V-shaped guiding block
11	Needle clamp cover	12	Needle type adjusting nut

Perform the following procedure:

- 1. Install the needle-guided bracket:
  - a. Put on the sterile probe sheath.
  - b. Select a proper needle-guided bracket, and match the tab with the groove of the transducer. Mount the bracket onto the transducer.



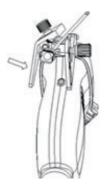
c. Rotate the clamping nuts of the guided bracket on the right and left side to fix the bracket and the transducer. Rotate the needle-type adjusting nut to the ultimate position as shown in the figure.



d. Hold the transducer. Press the biopsy needle pressure position to separate it from needle guided V-shaped block.



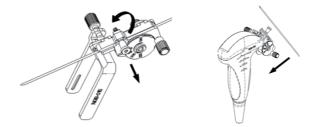
e. Put the needle into the needle guided-bracket, and the needle leans to V-shaped block.



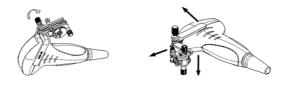
f. Hold the transducer, and release the pressure position of the needle. Adjust the needletype adjusting nut manually (following the direction of the arrow). The needle moves smoothly at the vertical direction due to its gravity.



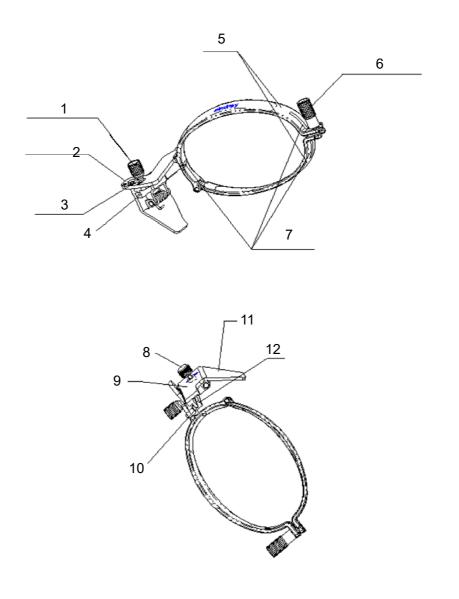
- 2. Remove the needle-guided bracket:
  - a. Pull the lock pin and open up the V-shaped cover to expose the needle.



- b. Separate the bracket and the transducer from the needle.
- c. Screw the pinch nut to release the needle-guided bracket.



d. Separate the bracket and the transducer.



1	Angle blocking nut	2	Angle adjusting block
3	Angle mark	4	Angle adjusting base
5	Clamp	6	The clamping nut
7	Groove	8	Needle-guided bracket adjusting nut
9	Needle clamping cover	10	Needle guide hole
11	The pressing block for separating needle	12	V-shaped guiding block

Perform the following procedure:

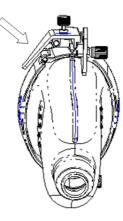
- 1. Install the needle-guided bracket:
  - a. Put the sterile sheath on the probe.
  - b. Select a proper needle-guided bracket, and match the locating groove with the tab of the probe. Mount the bracket onto the probe.



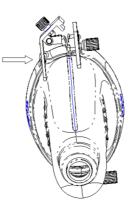
c. Tighten the pinch nut of the needle-guided bracket to confirm that the needle-guided bracket is properly installed on the probe. Loosen the angle adjusting nut.



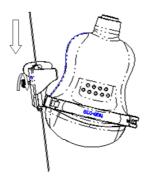
d. Hold the probe and press the pressing block to separate V-shaped guiding block from the pressing block.



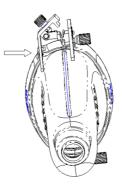
e. Insert the needle into V-shaped guided block.



f. Release the pressing block, adjust the angle adjusting nut to confirm that the needle can freely slide in a vertical direction.

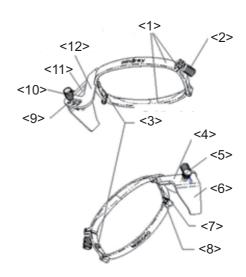


- 2. Remove the needle-guided bracket:
  - a. Hold the probe and press the pressing block to separate V-shaped guiding block from the pressing block.



- b. Remove the needle.
- c. Rotate the clamping nut to separate the bracket from the probe.





1	Left/right clamp	2	Left/right clamp pinch nut
3	Guiding bulges	4	Needle clamp cover
5	Needle type adjusting nut	6	Separation pressure position
7	Guiding hole	8	V-shaped guiding hole
9	Angle shift sign	10	Angle pinch nut
11	Angle adjusting base	12	Angle adjusting block

Perform the following procedure:

- 1. Install the needle-guided bracket:
  - a. Put on the sterile probe sheath.
  - b. Hold a needle-guided bracket, and match the tab with the groove of the transducer. Mount the bracket onto the transducer.



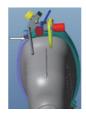
c. Rotate the clamping nuts of the guided bracket on the right and left side to fix the bracket and the transducer. Rotate the needle-type adjusting nut to the ultimate position as shown in the figure.



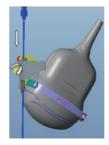
d. Hold the transducer. Press the biopsy needle pressure position to separate it from needle guided V-shaped block.



e. Put the needle into the needle guided-bracket, and the needle leans to V-shaped block.



f. Hold the transducer, and release the pressure position of the needle. Adjust the needletype adjusting nut manually (following the direction of the arrow). The needle moves smoothly at the vertical direction due to its gravity.



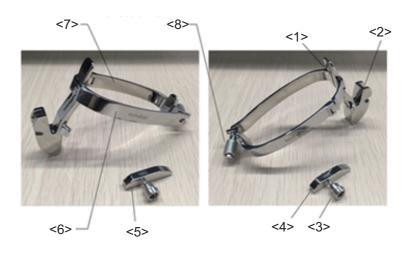
- 2. Remove the needle-guided bracket:
  - a. Hold the transducer, and press the pressure position of the needle to separate the biopsy needle from the biopsy needle pressure position.



- b. Remove the transducer and the needle-guided bracket to separate the biopsy needle.
- c. Rotate the clamping nuts of the guided bracket on the right and left side to release the bracket and the transducer. Remove the bracket from the transducer.



### NGB-042



1	Needle-guided bracket grooves	2	Guiding block fixing frame
3	Left/right clamp pinch nut	4	Needle guiding hole
5	Guiding block	6	Left clamp
7	Right clamp	8	Left/right clamp pinch nut

Perform the following procedure:

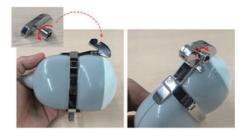
- 1. Install the needle-guided bracket:
  - a. Put the sterile sheath on the probe.
  - b. Needle-guided bracket groove corresponds to the convex point of the probe, and install the needle-guided bracket onto the probe.



c. Tighten left/right clamp pinch nut to confirm that the needle-guided bracket is properly installed on the probe.



d. Loosen left/right clamp pinch nut, and put it onto the guiding block fixing frame, then tighten left/right clamp pinch nut.



e. Hold the probe, and insert the needle into guided hole.



- 2. Remove the needle-guided bracket:
  - a. Hold the probe and remove the needle.



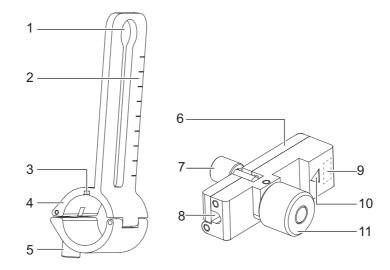
b. Loosen left/right clamp pinch nut, and remove it from the guiding block fixing frame.



c. Loosen left/right clamp pinch nut, and remove the needle-guided bracket.



### NGB-051



No.	Name	Description
1.	Support of needle-guided bracket	Used for installing the needle-guided bracket on the transducer.
2.	Knob of fixing needle- guided bracket	Used for fixing the needle-guided bracket on the transducer.
3.	Groove	Match with the tab on the transducer.
4.	Hole for installing guiding block	Used for installing the knob of fixing needle-guided bracket.
5.	Needle distance scales	Indicate distance between needle and the transducer head surface.
6.	Guiding block	Used for installing biopsy needle; there are five specifications of guiding blocks for different needles.
7.	Knob of fixing the needle	Used for fixing the needle.
8.	Guiding hole of the needle	Used for installing the biopsy needle.
9.	Specification of guiding block	Matched with the corresponding biopsy needle.
10.	Mark of indicating scales	Indicating needle distance scales.
11.	Knob of fixing the guiding block	Used for fixing the guiding block.

Perform the following procedure:

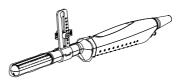
- 1. Install the needle-guided bracket:
  - a. Put on the transducer cover.



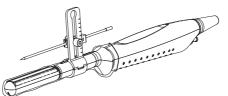
b. Cover the support of needle-guided bracket on the transducer, making the groove of the needle-guided bracket to match with the tab of the transducer. Set the needle-guided bracket at the desired position, turn tightly the knob of fixing needle-guided bracket to fix the needle-guided bracket.



c. Select a proper guiding block and thread the knob of fixing the guiding block through the hole of installing guiding block, move the guiding block to the desired position, then turn tightly the knob of fixing the guiding block to fix the guiding block on the support of needle-guided bracket.

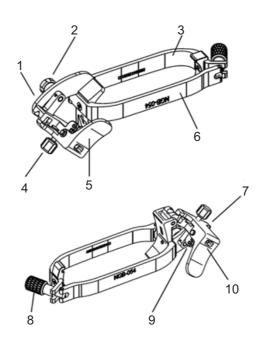


d. Insert a biopsy needle with the same specification as that of the guiding block into the hole of the guiding block and turn tightly the knob of fixing the needle.



- 2. Remove the needle-guided bracket:
  - a. Turn on the knob of fixing the needle and separate the needle from the needle-guided bracket.
  - b. Turn on the knob of fixing guiding block and remove the guiding block from the hole of installing guiding block.
  - c. Turn on the knob of fixing needle-guided bracket and remove the needle-guided bracket.

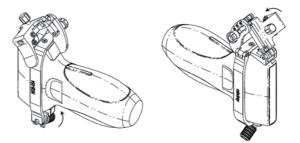
#### NGB-054



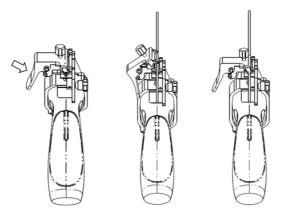
1	Angle adjusting block		Angle locking nut
3	Right clamp of the bracket		Needle-shaped adjusting nut
5	Needle clamping cover	6	Left clamp of the bracket
7	Angle adjusting base	8	Locking nuts of the guided bracket at the right and left sides
9	Torsion spring of the needle pressure cover	10	Biopsy needle pressure position

Perform the following procedure:

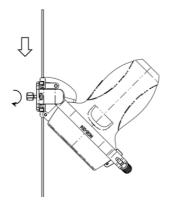
- 1. Install the needle-guided bracket:
  - a. Put on the sterile probe sheath.
  - b. Hold the probe in one hand, select the correct needle-guided bracket and hold it with the other hand. Match the inside of the bracket with the outside of the probe respectively. Mount the bracket onto the probe. Rotate the locking nuts of the guided bracket at the right and left sides to fix the bracket and the probe. Rotate the needle-shaped adjusting nut to the ultimate position as shown in the figure.



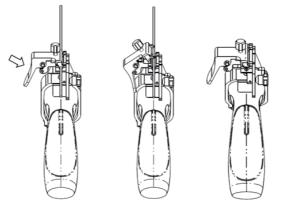
c. Hold the probe. Press the biopsy needle pressure position to separate it from the V-shaped guiding block. Put the needle into the V-shaped guiding block of the needle guided-bracket.



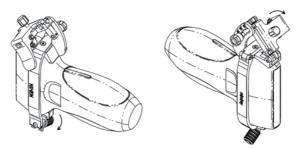
d. Hold the probe, and release the pressure position of the needle. Adjust the needle-shaped adjusting nut manually (following the direction of the arrow). The needle moves smoothly at the vertical direction due to its gravity.

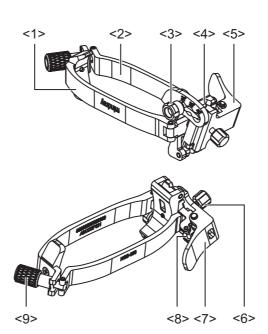


- 2. Remove the needle-guided bracket:
  - a. Hold the probe. Press the biopsy needle pressure position to separate the biopsy needle from the pressure position. Separate the bracket and the probe from the needle.



b. Rotate the locking nuts of the needle guided-bracket at the right and left sides (following the direction of the arrow). The needle guided-bracket is separate from the probe. Hold the probe and take out the bracket.



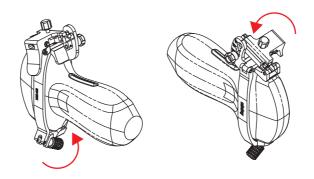


1	Right clamp of the bracket	2	Left clamp of the bracket
3	Angle locking nut	4	Angle adjusting block
5	Needle clamping cover	6	Angle adjusting base
7	Biopsy needle pressure position	8	Torsion spring of the needle pressure cover
9	Locking nuts of the guided bracket at the right and left sides		

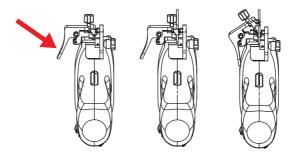
Perform the following procedure:

- 1. Install the needle-guided bracket:
  - a. Put on the sterile probe sheath.
  - b. Hold the probe in one hand, select the correct needle-guided bracket and hold it with the other hand. Match the inside of the bracket with the outside of the probe respectively. Mount the bracket onto the probe. Rotate the locking nuts of the guided bracket at the right and left sides to fix the bracket and the probe. Rotate the needle-shaped adjusting nut to the ultimate position as shown in the figure.

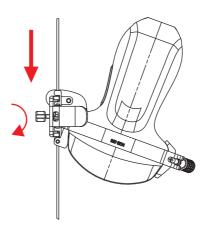
NGB-058



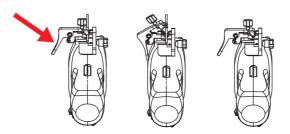
c. Hold the probe. Press the biopsy needle pressure position to separate it from the needle guided V-shaped guiding block. Put the needle into the V-shaped guiding block of the needle guided-bracket.



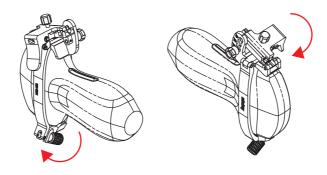
d. Hold the probe, and release the pressure position of the needle. Adjust the needle-shaped adjusting nut manually (following the direction of the arrow). The needle moves smoothly at the vertical direction due to its gravity.



- 2. Remove the needle-guided bracket:
  - a. Hold the probe. Press the biopsy needle pressure position to separate the biopsy needle from the pressure position. Separate the bracket and the probe from the needle.



b. Rotate the locking nuts of the needle guided-bracket at the right and left sides (following the direction of the arrow). The needle guided-bracket is separate from the probe. Hold the probe and take out the bracket.



## 17.2.3 Verifying the Biopsy Guide Line

# **WARNING**

- Prior to each biopsy procedure, be sure to verify the guide line.
- If the needle is not consistent with the guide line, DO NOT perform the biopsy procedure.

### NOTE:

You can perform guide line verification on a single live B/C image, and all biopsy-irrelevant operations are forbidden.

Adjusting the needle mark is necessary before each biopsy procedure.

Perform the following procedure:

- 1. Confirm that the needle-guided bracket has been installed securely in the correct position.
- 2. Prepare a container filled with sterile water.
- 3. Place the head of the probe in the sterile water and place a biopsy needle in the needle guide.
- 4. When the biopsy needle appears on the image, confirm that the biopsy needle is displayed at almost the same position as the selected needle mark.
- 5. Press <F11 Biopsy> to enter Biopsy.
  - Select the biopsy bracket angle/guide line: If the needle-guided bracket supports more than one biopsy angle, select the angle/guideline by using [Biopsy Kit].
  - Select the guide line dot size: Tap [Dot Size] to select the dot size.

#### NOTE:

- The guide line is a dotted line which consists of two kinds of dots. The distance between two dots is depth-dependent. Move the cursor over the big dot and a numeral, representing the biopsy depth, is displayed.
- The biopsy guide zone adjusts along with image adjustments, such as image inversion/ rotations, zoom and depth changes.
- When the imaging depth and area are changed, the guide line is adjusted.
- Tap [Biopsy] or press <F11 Biopsy> to exit.

#### NOTE:

In real-time status, press <F11 Biopsy> to exit biopsy status; in frozen status, press <F11 Biopsy> to hide/show the guide line if biopsy function is enabled.

- 6. Tap [Verify] in the Biopsy tab to open the Biopsy Verify menu.
  - Adjust the guide line position: Rotate the knob under [Position] on the touch screen to change the position of the guide line.
  - Adjust the angle: Rotate the knob under [Angle] on the touch screen to change the guide line angle.
  - Biopsy guide grid

Tap [C-L] on the touchscreen or press the user-defined keys for "Switching Probe" on the probe to switch the probe plane.

For ELC13-4UC (convex plane), the biopsy needle appears as a spot on the image. On the image, find and select the guide grid point corresponding to the biopsy needle insertion point of the template grid, and then adjust the parameters of the menu on the screen to make sure that the biopsy needle is displayed at almost the same position as the selected guide grid point.

For ELC13-4UL (linear plane), select one grid point in the D column of the template grid to insert the needle, and the biopsy needle appears as a line on the image. On the image, find and select the guide grid line corresponding to the biopsy needle insertion line of the template grid, and then adjust the parameters of the menu on the screen to make sure that the biopsy needle is displayed at almost the same position as the selected guide grid line.

- Save the verified settings: After the position and angle of the guide line are adjusted, touch [Save] and the system saves the current guide line settings. If biopsy is entered again, the displayed Position and Angle are the verified value.
- Restore the factory default settings: Tap [Load Factory] and the position and angle of the guide line are restored to the factory default settings.
- Exit biopsy verify status: Tap [Exit] and the system exits the guide line verification status.

## 17.2.4 Starting the biopsy procedure

## 

- Ensure that all guide parts are properly fixed prior to performing a biopsy.
- If you changed the probe or needle-guided bracket during the biopsy, verify the guide line again.
- Failure to match the guide zone displayed to the guide may cause the needle to track a path outside the zone.
- It is extremely important that when using the adjustable angle biopsy guides, the angle displayed on the screen matches the angle set on the guide, otherwise the needle will not follow the displayed guide zone and this could result in repeated biopsies or patient injury.

Perform the following procedure:

- 1. Select the correct needle-guided bracket and needle and install them properly.
- 2. Press <Biopsy> to enter the biopsy. Before biopsy guiding, you can preset bracket model, biopsy display and guide line dot type.

If the current probe has no corresponding bracket, or the image is frozen and the guide line was hidden before the image was frozen, then you cannot enter the Biopsy menu.

3. Select the bracket and guide line according to the actual situation.

Tap [Verify] to enter Biopsy Verify menu to fine tune the guide line if needed.

- 4. If available, use iNeedle function to help enhance the needle visualization when the needle display is not clear.
  - a. Tap [iNeedle] in B menu.

The parameters that can be adjusted appear on the menu:

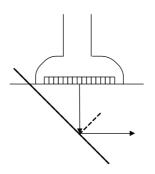
[B/iNeedle]: tap to display B image and iNeedle image synchronously.

[Needle Dir.]: select to adjust the needle direction display according to actual direction of needle insertion. The iNeedle affecting region changes correspondingly.

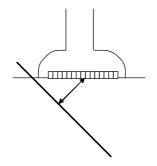
- b. Tap [iNeedle] again to exit iNeedle.
- 5. Scan to locate the target. Center the target in the electronic guidezone path.
- 6. Direct the needle into the area of interest for specimen.
- 7. After extracting the biopsy sample is complete, gently remove the probe from the body.
- 8. Press <F11 Biopsy> in non-frozen state to exit; press <F11 Biopsy> in frozen state to hide/ show the biopsy.
- 9. Disassemble the items and properly dispose of these items as required.

## 17.2.5 iNeedle (Needle Visualization Enhancement)

In the course of biopsy, the metal needle attached to the probe is punctured into the tissue with a certain angle; because of the needle acoustic impedance, the ultrasonic beam cannot penetrate the metal needle, a reflecting boundary is formed. As in figure below, If the deflection angle is very large, the needle display is not clear.

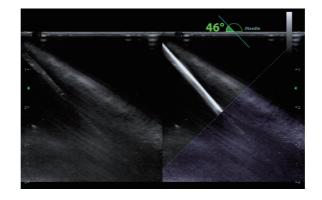


In the condition of deflected ultrasonic transmission, the beam direction is perpendicular to the needle direction, and the reflection direction will be the same with the needle, as shown in figure below, when the needle display in the ultrasound image is very clear. The system provides an additional deflection transmission that is approximately perpendicular to the metal needle, as the normal transmission (perpendicular to the transducer surface) is contained as well. And the deflection angle can be chosen by users.



### Premium angle display

The premium angle appears on the screen after entering iNeedle. The appropriate angle is  $30^{\circ}$  as shown in the figure below.



#### **Needle Direction**

This function adjusts the biopsy needle direction according to actual direction of needle insertion. The iNeedle affecting region changes correspondingly.

Tap [Needle Dir.] to select the direction.

#### **B/iNeedle**

This function is used to display B image and iNeedle image synchronously.

To disable or enable the function, tap [B/iNeedle] on the touch screen.

#### TIP:

iZoom (full-screen magnification) is available on iNeedle status.

## 17.2.6 Clean and Sterilize the Needle-Guided Bracket

## 

- Needle-guided brackets whose name starts with NGB are reusable, and need thorough cleaning and sterilization before and after each biopsy.
- Follow local regulations when selecting and using the disinfectant.
- Repeated sterilization may degrade the safety and performance of the needle-guided bracket. Before use, please check whether the needle-guided bracket has defects such as deformation and rusting. If such defects exist, the bracket has reached the end of its service life. In this case, stop using it and contact the Mindray service department.

- It is recommended to use immersion sterilization for plastic needle-guided brackets and high-pressure steam sterilization for metal needle-guided brackets.
- For detailed operations about the cleaning solvent, sterilant and hightemperature steam sterilizer, see the respective operator's manuals provided by the manufacturer.

#### NOTE:

Disposable components are packaged sterile and are single-use only. Do not use if integrity of packaging is violated or if expiration date has passed. Please use the disposable components compliant with the relevant local regulations.

#### Cleaning

Perform the following procedure:

- 1. Wear a pair of gloves to prevent infection.
- 2. After use, immerse the needle-guided bracket in distilled water immediately to prevent dirt from drying. Wipe the entire surface of the needle-guided bracket by using a piece of disposable lint-free soft cloth to remove coarse dirt.
- 3. Prepare a cleaning solvent (enzymatic or neutral pH detergent, e.g., liquinox, MetriZyme) by using distilled or softened water in accordance with the operator's manual provided by the manufacturer.
- 4. Detach all the detachable parts of the needle-guided bracket and immerse the needle-guided bracket and all its parts fully in the cleaning solvent for at least 1 minute or a period specified by the manufacturer.
- 5. Immerse the needle-guided bracket and all its parts fully in the cleaning solvent. Wipe and wash the surface and connecting parts of the needle-guided bracket gently by using a soft brush until no dirt is visible. Place the needle-guided bracket inside an ultrasonic cleaner and perform ultrasonic cleaning for 3–5 minutes.
- 6. Rinse the needle-guided bracket thoroughly by using a large amount of distilled or softened water (about 2 gallons) at room temperature for about 30 s to remove the residual dirt and cleaning solvent. Repeat the operation twice.
- 7. Wipe away the water on the needle-guided bracket by using a piece of disposable lint-free soft cloth.
- 8. Inspect the needle-guided bracket. If visible dirt still exists, repeat the preceding steps to wash the bracket until it is all clean.

#### Sterilization with a sterilant

Perform the following procedure:

- 1. Wear a pair of gloves to prevent infection.
- 2. Clean thoroughly in accordance with the cleaning procedure before sterilization.
- 3. Prepare a sterilant by using sterile distilled water when necessary.

Chemical name	Trade name	Procedures
Glutaraldehyde (2.4%)	Cidex Activated Dialdehyde Solution (applicable for FDA region only)	Refer to the instructions provided by the solution manufacturer for details.
Glutaraldehyde (2.6%)	Metricide	
22% Hydrogen Peroxide 4.5% Peroxyacetic Acid	MINNCARE LIQUID DISINFECTANT (applicable for Canada region only)	

4. Immerse the needle-guided bracket fully in the sterilant and shake the bracket appropriately to remove any bubbles on the surface. Use a syringe to draw an appropriate amount of sterilant and inject the sterilant into the hole to remove the bubbles inside the hole if necessary.

For details about the immersion duration, see the operator's manual provided by the manufacturer.

- 5. After sterilization, wash the needle-guided bracket thoroughly by using a large amount of sterile distilled water (about 2 gallons) at room temperature for about 30 s to remove the residual sterilant. Repeat the operation twice.
- 6. Dry the needle-guided bracket by using a piece of sterile disposable lint-free soft cloth.
- 7. Store the needle-guided bracket in a cool, clean and dry environment.

#### High-pressure steam sterilization

Perform the following procedure:

- 1. Wear a pair of gloves to prevent infection.
- 2. Clean thoroughly in accordance with the cleaning procedure before sterilization.
- 3. Package the needle-guided bracket in accordance with the sterilization requirements of surgical instruments using the sterilization wrap or pouch cleared by FDA.
- 4. Place the packaged needle-guided bracket inside a high-temperature steam sterilizer and perform sterilization.

The sterilization parameters are 121 °C and 30 minutes for a gravity displacement steam sterilizer and are 132 °C and 4 minutes for a dynamic-air-removal steam sterilizer.

5. Take out the sterilization package after sterilization and dry it in an oven at 60 °C for 20 minutes to 30 minutes.

Keep the sterilization package together with other sterilized surgical instruments in a sterile item storage area.

## 17.2.7 Storage and Transportation

- Do not use the carrying case for storing the needle-guided bracket. If the carrying case is used for storage, it may become a source of infection.
- Between examinations, keep the needle-guided bracket in a sterile environment.
- If the needle-guided bracket is sent to your MINDRAY representative for repair, be sure to disinfect or sterilize it and keep it in the carrying case to prevent infection.
- Sterilize the carrying case as necessary.
- Store or transport the needle-guided bracket under the following ambient conditions:
  - Ambient temperature: -20 °C to 55 °C

- Relative humidity: 20% to 95% (no condensation)
- Atmospheric pressure: 700hPa-1060hPa

## 17.2.8 Disposal

Be sure to sterilize the needle-guided bracket before disposing of it. Contact your MINDRAY representative when disposing of this device.

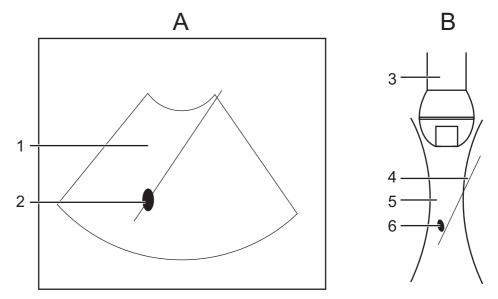
# 17.3 Needle Navigation Guiding

# AWARNING

- The person performing needle navigation guiding procedures must understand diagnostic ultrasound thoroughly and have been trained adequately, otherwise, side effects may be caused in the patient.
- Wear sterile gloves before performing the needle navigation.
- Clean and disinfect the navigation device by instructions in the device accompanied manual before and after needle navigation.
- Please read the warning information by instructions in the device before needle navigation.
- Disinfect the probe and sterilize the bracket. For details, refer to chapter "17.2.6 Clean and Sterilize the Needle-Guided Bracket". Otherwise, cross-infection may be caused.
- When performing needle navigation procedures, use only sterile ultrasound gel that is certified to be safe. And manage the ultrasound gel properly to ensure that it does not become a source of infection.
- Needle navigation on patients with implants or with intracavity electro, magnetic, mechanical device are prohibited. When the magnetic navigator is working, previously described patients should be at least 1 meter away from the working area. Bent or damaged needle are forbidden in the operation.
- Perform accuracy verification before conducting needle navigation. You can use the needle-guided bracket to anchor the needle before needle navigation for a better result.
- Needle guidance on the ultrasound image is for reference only and cannot provide as sole guidance for diagnosis basis.
- The needle mark displayed on the ultrasound image does not indicate the actual position of the needle. Therefore, it should only be used as a reference. Always monitor the relative positions of the biopsy needle during the procedures.
- Stop operation immediately when incorrect installation or improper working status of the magnetic device is observed. Contact the device manufacturer for further action. Do not freeze an image while performing biopsy procedure. Image of the biopsy target and the actual position of the biopsy needle: Diagnostic ultrasound system produces tomographic plane images

with information of a certain thickness in the thickness direction of the transducer. (The information shown in the images consist all the information scanned in the thickness direction of the probe.) So, even though the needle appears to have penetrated the target object in the image, it may not actually have done so.

 When the target for biopsy is small, dispersion of the ultrasound beam may lead to image deviate from the actual position. Pay attention to this. Image deviation is shown as the figures below:



А	The biopsy needle appears to reach the target object in the image	В	Dispersion of the ultrasound beam
1	Needle	2	Target
3	Probe	4	Needle
5	Ultrasound beam	6	Target

To avoid this problem, note points below:

- Do not rely only on the echo of the needle tip on the image. Pay careful attention to the target object, which should shift slightly when the biopsy needle comes into contact with it.
- Before you perform the biopsy, please evaluate the size of the object and confirm if the biopsy can be carried out successfully.

### NOTE:

- Refer to navigation device accompanied manual about installation, operation and disinfection of navigation device. Contact navigation device manufacturer if necessary.
- During needle navigation guiding procedure, please keep the navigation device, ultrasound system and the probe away from electromagnetic interference, such as: power filter, signal indication, magnetic materials, cellphone and metal instruments. Otherwise, navigation may be interfered.

- Frontal side of the magnetic navigator should directly face the lesion. Distance between the magnetic navigator front part and the target should reaches 20-66cm within the scope of 30cm from left to right, up to down. Otherwise, magnetic signal is unstable for navigation precisely.
- Check stability of magnetic navigator before conducting needle navigation.
- The Fusion Imaging is contraindicated to the person wearing the internal pacemaker, cochlear implant or nerve stimulator. People wearing the implant or intra-corporeal devices should keep one-meter away when the magnetic generator starts working.
- Mindray does not provide the sterile sheath. Users should prepare it according to the own needs.

Needle navigation feature combines technology of real-time imaging and mini-magnetic locating to provide GPS real-time guiding biopsy. Based on the sensors attached to the probe and needle, magnetic navigator provides the related 3-dimentional orientation of the needle and the ultrasound image plane.

There are two types of needle navigation: in-plane and out-plane. In-plane navigation applies to needle path inside the ultrasound image plane and out-plane navigation applies to needle path not inside the ultrasound image plane.

## **17.3.1 Basic Procedures for Needle Navigation Guiding**

#### Needle navigation guiding biopsy procedure under non-Fusion mode

Perform the following procedure:

- 1. Connect all accessories of magnetic navigator. Refer to chapter "6.15.2 Magnetic Navigator" and "17.3.2 Installation" for details.
- 2. Activate needle navigation guiding feature and select needle type and length. Perform accuracy verification. For details, refer to chapter "17.3.3 Accuracy Verification".
- 3. Perform ultrasound image scanning and confirm position/size/structure of tumor/lesion. Mark the lesion. For details, refer to chapter "17.3.4 Mark".

Tap [SSC] to perform acoustic speed correction.

4. Place the needle next to the probe and adjust the biopsy guideline on the image for recommended needle position and angle.

The guideline turns green if it is able to reach the lesion mark.

5. Perform biopsy by the guideline.

The distance indicating box shrinks by the time needle tip goes towards the lesion mark. When the tip reaches the lesion mark, the box turns green and merges with the tip.

For detailed procedure description, refer to chapter "17.3.5 Screen Display in the Guiding".

6. Save the single-frame and multi-frame image if necessary.

#### Needle navigation guiding biopsy procedure under Fusion mode

Perform the following procedure:

- 1. Connect all accessories of magnetic navigator. Refer to chapter "6.15.2 Magnetic Navigator" and "17.3.2 Installation" for details.
- 2. Activate needle navigation guiding feature and select needle type and length. Perform accuracy verification. For details, refer to chapter "17.3.3 Accuracy Verification".
- 3. Enter Fusion imaging and load CT/MR/PET/freehand data. Refer to step 1-5 in chapter "6.15.4 Basic Procedures" for details.

4. Mark the tumor/lesion on CT/MR/PET/freehand image. For details, refer to chapter "6.15.6 Marks".

Tap [SSC] to perform acoustic speed correction.

- 5. Register CT/MR/PET/freehand data. For details, refer to chapter "6.15.4 Basic Procedures".
- 6. Place the needle next to the probe and adjust the biopsy guideline on the image for recommended needle position and angle.

The guideline turns green if it is able to reach the lesion mark.

7. Perform biopsy by the guideline.

The distance indicating box shrinks by the time needle tip goes towards the lesion mark. When the tip reaches the lesion mark, the box turns green and merges with the tip.

For detailed conversion procedure description, refer to chapter "17.3.5 Screen Display in the Guiding".

8. Save the single-frame and multi-frame image if necessary.

### 17.3.2 Installation

## AWARNING

- Do not bend the needle during installation.
- Improper installation of the magnetic navigator leads to incorrect space navigation.

#### NOTE:

- Dispose needle, sensor support, and sterile cover by requirements of the manufacturer. Keep the bracket sensor.
- Clean and disinfect the sensor by requirements of the manufacturer and do not bend the sensor.
- Refer to the manufacturer manual for magnetic navigation installation and other information.
- Make sure the dimensions of sensor and eTRAX needle is basically the same, or magnetic navigation may be incorrect.
- eTRAX needle sensor is matched with eTRAX needle and trocar.

### vTRAX



1	Needle	2	Needle bracket
3	Needle sensor	4	Sterile cover

Specifications:

Biopsy needle

10~17G hard needle (vTRAX). Diameter: 2.0-3.3mm. Needle should be of non-inference to the sensor. Refer to manual provided by manufacturer for disinfection information.

- Needle sensor
  - Manufacturer: CIVCO.
  - Product number: 610-1080
- Needle sensor support and sterile cover (disposable)
  - Manufacturer: CIVCO

Product number: 610-1059

- Probe sterile sheath
   Manufacturer: CIVCO
- Magnetic navigator

Magnetic controller, generator and probe sensor. Refer to "6.15.2 Magnetic Navigator" for details. Abdomen sensor is necessary under Fusion imaging mode.

Refer to manufacturer manual for details about installation and disinfection of the magnetic navigator. Contact the magnetic navigator if necessary.

To order needle sensor and needle sensor support, contact:

- CIVCO Medical Instruments Co.
- 102 First Street South, Kalona, IA 52247-9589 USA
- Tel: 1-319-656-4447
- E-mail: info@civco.com
- http://www.civco.com

Perform the following procedure:

1. Refer to "6.15.2 Magnetic Navigator" for installation of magnetic controller, auxiliary power line, USB cable, and magnetic generator and probe sensor. Abdomen sensor is necessary under Fusion imaging mode.

- 2. Wear the probe sterile sheath after probe sensor and bracket are installed.
- 3. Connect the needle sensor to the 3rd port on the magnetic controller.



4. Put on the sterile cover onto the needle sensor.

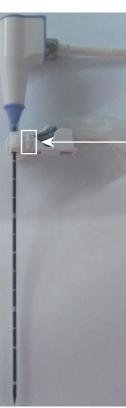


5. Connect needle sensor to the bracket.



6. Loose the knob on the bracket anti-clockwise and insert the vTRAX needle into the bracket by the arrow direction. Anchor the bracket at the bottom of the needle and then tighten the knob.





7. Turn on the magnetic navigator power and perform needle navigation guiding operation after the signal is stabilized.

#### eTRAX

eTRAX needle is used to biopsy, melt, drainage, administere, vascular access, local anaesthetic.



1	eTRAX needle sensor	2	eTRAX neeedle
3	Sterile sheath		

Specifications:

- Needle sensor
  - Manufacturer: CIVCO.
  - Product number: 610-1112
  - Wear sterile sheath for sensor.
- eTRAX needle and sterile sheath (disposable)
  - Manufacturer: CIVCO
  - Product number: 16G eTRAX needle
  - eTRAX needle model: 610-1057, 610-1606-10, 610-1608-10, 610-1610-10, 610-1613-10, 610-1615-10
- Biopsy/melt needle
  - 16G biopsy/melt needle
  - Refer to manual provided by manufacturer for disinfection information.
- Probe sterile sheath
  - Manufacturer: CIVCO
  - Wear sterile sheath for probe, refer to "6.15.2 Magnetic Navigator" for details.
- Magnetic navigator
- Magnetic controller, generator and probe sensor. Refer to "6.15.2 Magnetic Navigator" for details. Abdomen sensor is necessary under Fusion imaging mode.
- Refer to manufacturer manual for details about installation and disinfection of the magnetic navigator. Contact the magnetic navigator if necessary.

To order needle sensor and needle sensor support, contact:

- CIVCO Medical Instruments Co.
- 102 First Street South, Kalona, IA 52247-9589 USATel: 1-319-656-4447
- E-mail: info@civco.com
- http://www.civco.com

Perform the following procedure:

- 1. Refer to "6.15.2 Magnetic Navigator" for installation of magnetic controller, auxiliary power line, USB cable, magnetic generator and probe sensor. Abdomen sensor is necessary under Fusion imaging mode.
- 2. Connect the needle sensor to the 3rd port on the magnetic controller.



3. Put on the sterile sheath onto the needle sensor.



4. Insert the sensor into the needle.



5. Tighten the knob, and make sure not to break the sterile sheath.



- 6. Turn on the magnetic navigator power and perform needle navigation guiding operation after the signal is stabilized. Refer to "6.15.3 Screen Description" for details.
- 7. Perform needle navigation guiding; refer to "17.3.1 Basic Procedures for Needle Navigation Guiding" for details.
- 8. Anticlockwise eTRAX needle interface to take out the needle from trocar after the eTRAX needle access the target tissue.



9. Select the proper Biopsy/melt needle according to the actual situation.

## 17.3.3 Accuracy Verification

## AWARNING

• This manual describes simple accuracy verification only. Perform elaborate accuracy verification procedure based on clinical scenario if necessary.

- If the needle is bent, projective line of the needle and projective point of the tip will not suit the actual situation.
- Be sure to conduct accuracy verification before needle navigation. Perform needle navigation when the measured result is in the acceptable range.

Accuracy error is measured by comparing actual biopsy depth and the measured depth in the ultrasound image. Needle navigation guidance feature should be activated only when the error is acceptable.

Perform the following procedure:

- 1. Connect all accessories of magnetic navigator.
- 2. Precisely measure the distance between tip to the bottom.



#### NOTE:

- Use disinfected tool to measure the distance.
- Precise length data of the needle is important to the space magnetic navigation.
- 3. Tap [Needle Navigation] on the touch screen to turn on the feature. Select needle type and set needle length.

Tap [Edit Needle] and enter "Needle name" "Length" (measured in the step 1) and "needle size (needle model)". Tap [Add] to add vTRAX/eTRAX information in the system. You can update vTRAX/eTRAX needle data.

You can also adjust by rotating the knob under [Needle Length] on the touch screen.

- 4. Put the needle tip against the middle part of probe surface and press <Freeze>. Press <Caliper> to enter general measurement and measure the distance between the tip and the probe surface.
- 5. Put the needle body on the probe surface horizontally and press <Freeze>. Press <Caliper> to enter general measurement and measure the distance between the needle and the probe surface.

## 17.3.4 Mark

#### Marking procedure under non-Fusion mode

You can mark the tumor/lesion on the ultrasound image as indication for real-time biopsy.

#### NOTE:

• Keep the magnetic navigator and patient still after mark is added. Otherwise, space navigation GPS result is affected.

• Make sure only one mark is left on the ultrasound image during needle navigation guidance procedure. If there are multiple marks on the image, hide the marks.

Perform the following procedure:

- 1. Connect all accessories of magnetic navigator. Perform accuracy verification procedure.
- 2. Perform ultrasound image scanning and confirm position/size/structure of tumor/lesion. Switch to the section with maximum size of the lesion.
- 3. Mark the lesion: Tap [Tissue Mark] and press <Cursor> to acquire the cursor. Roll the trackball to move the cross onto the center of the lesion and press <Set> to anchor the center. Roll the trackball until the whole lesion is enveloped and double-click <Set> to add the mark.

Rotate the knob under [Ablative Margin] to add a safe boundary for the mark. Refer to chapter "6.15.6 Marks" for details.

#### NOTE:

Be sure to use the section displaying the maximum of the lesion for marking.

- 4. The lesion is enveloped by 3 circles from the inside and out: real-time mark, maximum diameter mark and safety boundary.
  - Perform the marking steps repeatedly for multiple marks. Marked color are displayed in green, red and blue in cycle and result window displays the diameter of the marked circle.
  - Refer to chapter "6.15.6 Marks" for details about moving/deleting/displaying/hiding marks.

#### Marking procedure under Fusion imaging mode

Tap [Register CT/MR] and tap [Add Mark]->[Display Marks] to turn on the mark function. Refer to chapter "6.15.6 Marks" for details.

## 17.3.5 Screen Display in the Guiding

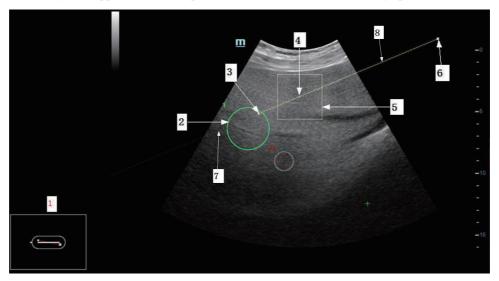
#### In-plane biopsy

In-plane navigation applies to needle path inside the ultrasound image plane.



### Out-plane biopsy

Out-plane navigation applies to needle path not inside the ultrasound image plane.



No	Image	Description
1.	Orientation indication	<ul> <li>Orientation of the needle to the surface of the acoustic lens.</li> <li>Needle color turns green if the needle is inside the real-time ultrasound image plane.</li> <li>Needle color turns brown if the needle is not inside the real-time ultrasound image plane.</li> </ul>
2.	Mark	Mark the lesion/tumor.
3.	Intersection	Intersection displays if the needle navigation is conducted in out-plane status. Intersection is the cross point of the needle and the ultrasound image plane.
4.	Tip projecting point	Projecting point of the needle tip on the ultrasound image plane.
5.	Indicating box	<ul> <li>Image with mark: the box indicates the needle tip projecting point to the mark.</li> <li>Image with no mark: the box indicates the needle tip projecting point to the intersection in out-plane status.</li> <li>The distance indicating box shrinks by the time needle tip goes towards the lesion mark or intersection. When the tip is 3mm away from the lesion mark or intersection, the box turns green.</li> </ul>
6.	Needle end projecting point	Projecting point of the needle end on the ultrasound image plane.
7.	Projected line	<ul> <li>Projected line of the needle on the ultrasound image plane.</li> <li>Solid line in the middle is the projected line of the needle central part.</li> <li>Dotted line on the both sides are top and bottom parts of the needle.</li> <li>Needle projected line turns green if the needle is inside the real-time ultrasound image plane.</li> <li>Needle projected line turns brown if the needle is not inside the real-time ultrasound image plane.</li> </ul>

No	Image	Description
8.	Guideline	Virtual line.
		• Image with mark: guideline turns green if it can cross the mark. Otherwise, the guideline turns brown.
		<ul> <li>Image with no mark: guideline displays in brown.</li> <li>Tap [Guideline] to display or hide the guideline.</li> </ul>

## 17.3.6 Disposal

Dispose needle, sensor support, sterile cover by requirements of the manufacturer. Contact the manufacturer for details.

Dispose the bracket after sterilization. Contact Mindray for bracket disposal.

# 17.4 Middle Line

Middle Line helps to locate and observe the focus point of lithotripsy wave during lithotripsy treatment. By means of providing information for the lithotripsy machine as well as a tool for watching the procedure of lithotripsy in real-time, you can adjust the intension and frequency of the lithotripsy wave through lithotripsy machine.

Tap [Middle Line] in the biopsy tab or preset a shortcut key for middle line function.

- The middle line is a vertical dotted line located in the middle of the screen, the position and direction of which cannot be changed.
- There is a mark icon of "×" located on the middle line which can be moved up and down along the line by using the trackball.
- To use the Middle Line function of the ultrasound system:
  - a. Use the trackball to change the mark position and by adjusting lithotripsy machine tools or patient posture to locate the stone center at the mark.
  - b. Read the depth of the mark by observing the depth caliper on the screen.
  - c. After the stone is located, refer to lithotripsy machine manuals to perform the lithotripsy.
- The depth of the mark is displayed in the image parameter area of the screen.

### NOTE:

- Strictly observe the procedures described here to perform the recording and replaying operations; otherwise it may result in data loss or system malfunction.
- Set the PAL or NTSC in the setup and this shall be consistent with that in the DVR.
- Accidental exposure to strong electromagnetic fields or mishandling of the video cassette may result in image and data loss, so check if the recording is successful as soon as possible. Mindray is not responsible for any data loss.

The system provides built-in DVR recording function. You can use the DVR to record and replay videos and audios that can be stored in DVD disc or hard disc.

The recorded video is AVI format; you can save it in the hard disk drive, burn to the DVD or export to the USB disk.

When the built-in DVR is in normal status, the 🕅 displays at the lower right corner of the screen.

# 18.1 Start Recording

After recording, the system will save the recording file automatically, you can select to save in local disk, U disk or optical disk.

- 1. Perform ultrasound exams, select appropriate views and adjust parameters to prepare for recording.
- 2. Click 😤 to open the dialog box and select desired recording type: Hard disk/USB/CDROM.
- 3. Click [Close] to enter recording status.
- 4. Press  $\langle F9 \rangle$  to record, and the DVR icon displays as  $\bigotimes$  in recording status.

During the recording process, you can perform imaging mode switching, comments adding, body mark adding and measurements.

- 5. Press <F9> again to stop recording, the DVR icon in the lower right corner turns into data transfer status 😥.
  - If USB/CDROM is selected, the system sends the recorded file to the target storage media (USB disk or DVD optical disk drive) in the meantime.
  - If "Hard disk" is selected, the system saves the file to the path: D/LV/DVR.

In the task management screen, click [Media Storage Task] tab to check transferring status.

# 18.2 Send Image

The system also supports exporting recorded images that are saved in the local disk.

1. Click 🔁 to open the dialog box, and click [Local Video Manage] to enter the managing dialog box.

Click [Rename] to rename the video file.

2. Select the destination and the target file, click [Send] to send the file to the selected path. During sending progress, the icon displays as  $\bigotimes$ .

# 18.3 DVR Video Replay

You can replay the video and audio record.

## 18.3.1 Replay on PC

Connect the USB disk or optical disk with the file to the PC, open the file directly.

## 18.3.2 Replay on the ultrasound system

Perform the following procedure:

- 1. Click 😵 to open the dialog box and select desired playing type: Hard disk/USB/CDROM.
- 2. Click [Play] to open the dialog box.
- 3. Select the path and name for the file and then click [OK] to replay the file, or double-click the file name directly.

Routine system maintenance shall be carried out by the user. System maintenance after the warranty has expired is the full responsibility of the owner/operator.

The responsibility for maintenance and management of the product after delivery resides with the customer who has purchased the product.

If you have any questions, please contact Mindray Customer Service Department or sales representative.

# **WARNING**

- Only an authorized Mindray service engineer can perform maintenance not specified in this operator's manual.
- For the sake of the system performance and safety, you should perform periodical checks for the system.

# 19.1 Daily Maintenance

You are responsible for daily maintenance.

# 19.1.1 Cleaning the System

## **WARNING**

- Before cleaning the system, be sure to turn off the power and disconnect the power cord from the outlet. If you clean the system while the power is "On", it may result in electric shock.
- DO NOT directly spray solution onto the monitor, system control panel or hard surfaces that is under pressure or pumped. Ingress fluid leakage into the monitor or system can damage the monitor or system, causing possible electric shock or system failure.

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Do not spill water or other liquid into the system while you perform the cleaning. Otherwise it may result in malfunction or electric shock.

### NOTE:

Please clean the control panel periodically, otherwise the button may be blocked by dirt and the system will be buzzing while the button makes no response.

### **Cleaning probes**

Cleaning the probe

Tools: mild soapy water, dry soft cloth, soft brush

Method:

- 1. Wipe out the dust attached to surface of probe head, connector and cable.
- 2. Use soft brush to brush the dust inside probe connector gently.
- 3. Remained stain or dust attached to surface of cable or surface of connector should be washed out by cloth with a little soapy water, and then air-dry.

#### NOTE:

Don't use cloth with water to clean the probe connector.

#### Cleaning the probe cable

- 1. Use soft dry cloth to wipe off stains from the probe cable.
- 2. If it is difficult to clean the stains thoroughly, use soft cloth dipped with mild detergent, and then let the cable air dry.

#### **Cleaning holders**

Tool: dry soft cloth, soapy water, soft brush

Method:

Surface of power button should be cleaned by dry soft cloth. Remained stain should be washed out by cloth with clear water or soapy water (NOTE: cloth should not be dipped with too much water, which may cause electric shock), and then air-dry the surface.

- 1. Use dry soft cloth to wipe off the dust attached to inside, outside or gap of probe holder or gel holder. As to small intra-cavity probe holder or its gap, use the soft brush to brush the dust or stain.
- 2. Remained stain attached to inside, outside of holder should be washed out by cloth with a little soapy water and then air-dry after take it out.
- 3. Gel warmer: Take the gel warmer out after pull out the power supply cable, use dry soft cloth to wipe off the dust attached to inside and outside, then brush the dust in the gel warmer or brush the stain with a little soap water and air-dry at last.

### Cleaning the monitor and the touch screen

#### NOTE:

DO NOT use hydrocarbon glass cleaner or cleaner for OA (Office Automation) equipment to clean the monitor. These substances may cause deterioration of the monitor.

Tool: soft dry cloth, clear water or soapy water

Method:

Surface of monitor and touch screen should be cleaned with soft dry cloth directly. Remained stain should be washed out by cloth with a little clear water or soapy water, and then air-dry the surface.

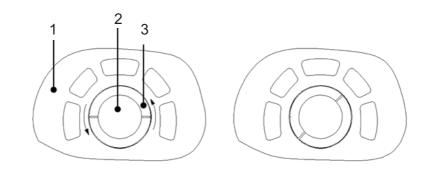
### **Cleaning the trackball**

Tools: Paper, dry cloth or mild soapy water

Method:

1. Disassembling the trackball:

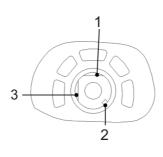
Press the bulges on the clamping ring by both hands and turn the ring about 45° anticlockwise until it lifts. Take out the ring and the rotary ball. Be careful not to drop the ball. As shown in figure below.



1.	Keyboard cover
2.	Trackball
3.	Clamp ring

#### 2. Cleaning

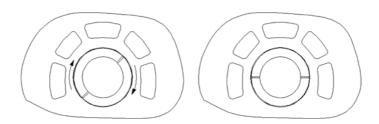
Clean the two long shafts, the bearing, the plastic cover, the internal of the ring and the rotary ball with clean soft dry cloth or paper.



1.	Long shaft
2.	Bearing
3.	Long shaft

3. Installing the trackball

Put the rotary ball back in the trackball mechanism and put the clamping ring back in (with the bulge direction of  $15^{\circ}$  deviated from the horizontal line), turn the ring clockwise until the bulges are flush with the top cover, and the ring clicks and locks, which means the ring is secured. See figure below.



### **Cleaning the cover**

Tools: soft dry cloth, soapy water

Method:

Use a soft dry cloth to clean the system's cover. If the system is dirty, moisten the soft cloth with mild soapy water, wipe away any stains, then air dry.

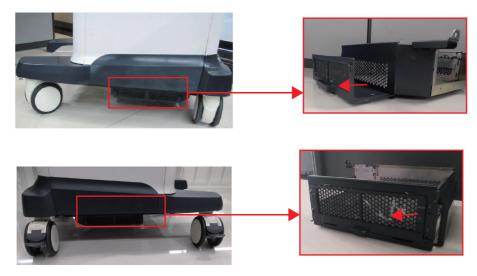
### **Cleaning dust-proof cover**

Tool: Soft brush

Method:

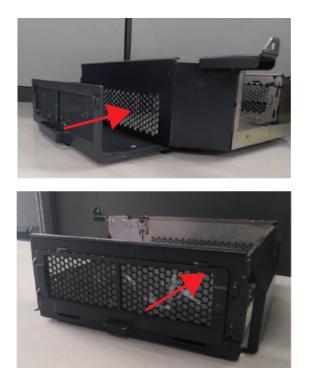
1. Disassemble dust-proof cover before cleaning.

Pull out the dust-proof cover.



- 2. Cleaning: with soft brush and then wipe off the dust.
- 3. Assemble dust-proof covers.

Insert the bottom dust-proof cover into the slot of the main unit, and push the dust-proof towards the arrow's direction. Align the side of the dust-proof cover to the magnetic suction position and absorb the magnets to the four corner in place.



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Please clean all dust-proof covers of the system periodically (1 time per month); otherwise, system damage may result. Cleaning times can be increased when the system is used in the open air or somewhere dust is more.

### **Cleaning the peripherals**

Do the cleaning maintenance according to your actual peripheral configuration; items which are not configured can be skipped.

Content	Description	
Color and B/W video printer	First wipe off dust or stain attached to the cover of printer with soft dry cloth, then clean the inside of printer. Be sure to do the cleaning maintenance according to the operation manual if is necessary.	
Graph / text printer	First wipe off dust or stain attached to the cover of printer with soft dry cloth, then clean the inside of printer. Be sure to do the cleaning maintenance according to the operation manual if is necessary.	
Footswitch	Use soft dry cloth with a little mild soap water to wipe off the dust or stain attached to the pedals or cable of foot switch.	
Barcode reader	First use soft dry cloth to wipe off dust attached to glass panel of the reader, then the dust or strain attached to cable and bracket. For detail, see "A Barcode Reader".	

## **19.1.2 Checking the Probe**

- Visually check to confirm that there is no crack and expansion to probe head.
- Visually check to confirm that there is no deterioration or desquamation to probe cable.
- Visually check to confirm that there is no bend, destroyed or falling off pins to the connector.

## 19.1.3 Checking the Power Cable and Plug

- Visually check to confirm that there is no wrinkles, crack or deterioration; No crack and expansion to the surface of adapter.
- Manually check to confirm that there is no looseness or rupture. The connection of plug is reliable.

## **19.1.4 Checking Appearance**

Check if there is any crack in the covers:

- Ultrasound system covers
- Probe appearance
- External appearance of ECG lead

Probe	<ul> <li>Visual estimation, check whether there are any cracks and distention to probe head;</li> <li>Visual estimation, check whether there is aging or peeling;</li> <li>Visual estimation, check whether there is bending, damage or missed stitch to the probe's connector.</li> </ul>	
Power supply cable and socket	<ul> <li>Visual estimation, check whether there are creases, cracks or aging to the power supply cable;</li> <li>Manual operation, check whether the plug of the power supply is fixed enough. No loose or crack occurs to it. The retaining clamp of</li> </ul>	
Circuit breaker	power supply cable works well.         Manual operation, check whether the breaker works well.	

## 19.1.5 Backup of the System Hard Drive

To prevent deterioration or loss of data stored in the system hard drive data (including patient info data, preset data and etc.), create a backup copy of the hard drive at regular intervals.

# 19.2 Troubleshooting

If any persistent system malfunction is experienced, e.g. an onscreen error message, blank imaging screen, absent menus, please refer to the table below. If the failure can't be eliminated, please contact Mindray Customer Service Department or sales representative.

Troubleshooting Table

No.	Failure	Cause	Measure
1.	After the AC power input is connected, the power indicator does not light on.	Abnormal power system or incorrect connection of the power cord.	<ul> <li>Check if the system is plugged in.</li> <li>Check if the system circuit breaker is in the Up position.</li> <li>Check if the plug has not become loosened or dislodged from the back of the system.</li> </ul>

No.	Failure	Cause	Measure
2.	The power indicator of the monitor is light on, but image is blank.	<ul> <li>The interval between turning off and restarting the system is too short – wait a minimum time of 20 seconds.</li> <li>The monitor brightness or contrast may be improperly set.</li> </ul>	<ul> <li>Turn off the system and wait a minimum time of 1 minute, and then restart the system.</li> <li>Adjust the monitor brightness and contrast back to factory defaults.</li> </ul>
3.	The monitor displays the characters and menus but no images.	<ul> <li>The transmission power, overall gain or TGC controls are improperly set.</li> <li>Check if a probe is connected and/or fully connected.</li> <li>The system is in the frozen status.</li> </ul>	<ul> <li>Adjust the transmission power, gain or TGC control.</li> <li>Ensure proper probe connection.</li> <li>Unfreeze the image.</li> </ul>
4.	The image quality is degraded	<ul> <li>The exam mode is not correct.</li> <li>The settings of the image post processing are not correct.</li> <li>The image presets are inappropriate.</li> </ul>	<ul> <li>Select an appropriate exam mode.</li> <li>Adjust the settings of the image via post processing or reset the post processing to the default values.</li> <li>Reset the factory default presets.</li> </ul>
5.	The button is responseless with the system buzzing	There is too much dirt blocking the button.	Check the control panel for the button being blocked and press it several times to release it. Clean the button.

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The system supports logging data as patient ID by using the barcode reader.

The laser transmitted by SYMBOL LS2208 is Class 2 laser.

SYMBOL DS4308 is classified as "EXEMPT RISK GROUP" according to IEC 62471:2006 and EN 62471:2008.

# **WARNING**

- Class 2 laser adopts low power, visible LED. DO NOT stare into beam because of unknown hazards of transient radiation provided by class 2 laser.
- DO NOT stare into beam emitted by SYMBOL DS4308 for more than 10s.

# 

Ensure the information acquired by barcode reader is consistent with the actual information.

#### NOTE:

The reader does not support decoding of Multi-language.

# A.1 1-D Barcode Reader

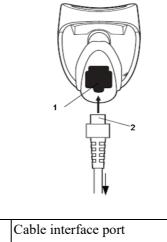
There are 2 operation modes for 1-D barcode readers:

- Hand-held mode: press the trigger to decode.
- Hands-free mode: seat the reader in the stand to enter the mode, the reader decodes automatically.



1	LED	<ul><li>Green: A barcode was successfully decoded.</li><li>Red: A data transmission error or reader malfunction occurred.</li></ul>	
2	Scan window	Scan the barcode.	
3	Trigger	Press to decode.	

## A.1.1 Setting Up the Reader (Take LS2208 as an example)



	1
2	Interface cable modular connector

Perform the following procedure:

- 1. Plug the interface cable modular connector into the cable interface port on the bottom of the reader handle, and ensure the connector is properly secured.
- 2. Connect the other end of the interface cable to the host.

1

# A.1.2 Setting

The reader has factory settings. For details, please see "A.3 Parameter Defaults".

The reader supports some user-defined functions as introduced below.

For more details, please contact the SYMBOL reader agents or Mindray Customer Service Department.

#### Volume setting

Scan the following barcode to set the volume parameter.

• Low Volume:



• Medium Volume:

High Volume:





#### Code 93 and codebar scanning

• To enable or disable Code 93, scan the appropriate barcode below.



• To enable Codebar, scan the appropriate barcode below.



#### Code 39 full ASCII scanning

Code 39 Full ASCII is a variant of Code 39 which pairs characters to encode the full ASCII character set.

• To enable Code 39 Full ASCII, scan the appropriate barcode below.



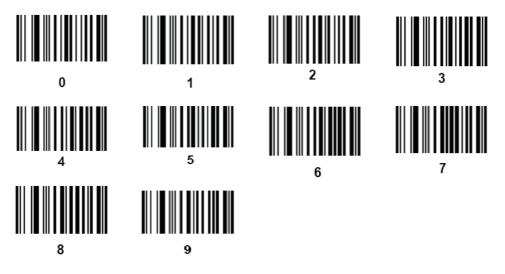
• To disable Code 39 Full ASCII, scan the appropriate barcode below.



I 2 of 5 symbols setting:



Select this option to decode only I 2 of 5 symbols containing a selected length. Select the length using the numeric barcodes below. For example, to decode only I 2 of 5 symbols with 8 characters, scan I 2 of 5 - One Discrete Length, then scan 0 followed by 8.



## A.1.3 Scanning in Hand-Held Mode

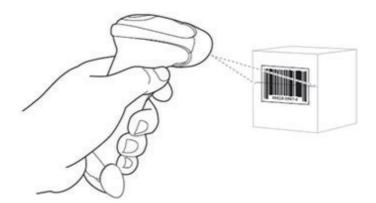
Perform the following procedure:

- 1. Ensure all connections are secure.
- 2. Aim the reader at the barcode. Press the trigger.

Ensure the scan line crosses every bar and space of the symbol, see the figure below.

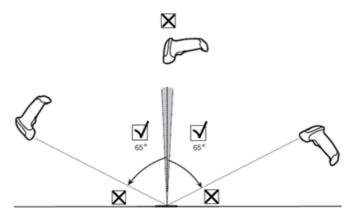


3. Upon successful decode, the reader beeps and the LED turns green.



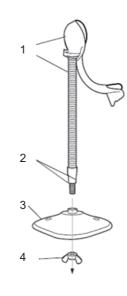
Do not hold the reader directly over the barcode. Laser light reflecting directly back into the reader from the barcode is known as specular reflection. This specular reflection can make

decoding difficult. You can tilt the reader up to  $55^{\circ}$  forward or back and achieve a successful decode.



## A.1.4 Scanning in Hands-Free Mode

Assembling the Intellistand



1	One piece scanner "cup" with flexible neck	2	Flat areas
3	Stand base	4	Wingnut

Perform the following procedure:

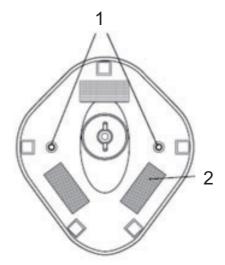
- 1. Unscrew the wingnut from the bottom of the one piece scanner "cup".
- 2. Fit the bottom of the neck piece into the opening on the top of the stand base.
- 3. Tighten the wingnut underneath the base to secure the cup and neck piece to the base.

Before tightening the wingnut under the base, ensure that the flat areas on the flexible neck fit securely in the grooves in the base.

4. Bend the neck to the desired position for scanning.

#### Mounting the Stand (optional)

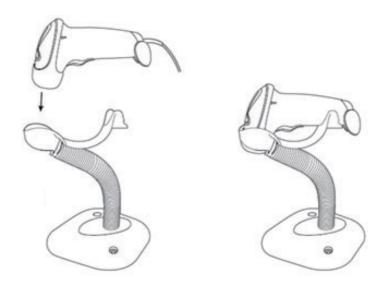
You can attach the base of the reader's stand to a flat surface using two screws or double-sided tape (not provided).



1	Two screw-mount holes	For Screw Mount, follow the steps below:
		1. Position the assembled base on a flat surface.
		2. Screw one #10 wood screw into each screw-mount
		hole until the base of the stand is secure
2	Double-side tap areas	For Tape Mount, follow the steps below:
	(3 places, dimensions: 1"×2")	1. Peel the paper liner off one side of each piece of
		tape and place the sticky surface over each of the
		three rectangular tape holders.
		2. Peel the paper liner off the exposed sides of each
		piece of tape and press the stand on a flat surface
		until it is secure.

#### Perform Scanning in Hands-Free Mode

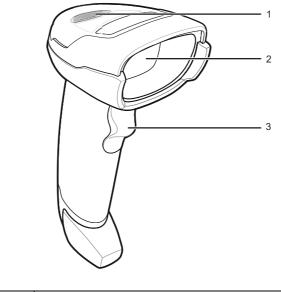
When the reader is seated in the scanner cup, the reader's built-in sensor places the reader in handsfree mode. When you remove the reader from the stand it operates in its normal hand-held mode.



# A.2 2D Barcode Reader (Take DS4308 as an example)

The 2-D barcode reader supports hand-held operation mode. Hand-held mode: press the trigger to decode.

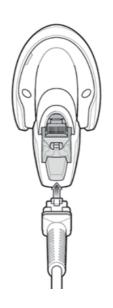
## A.2.1 Overview



1	LED	• Green: A barcode was successfully decoded.	
		• Red: A data transmission error or reader malfunction occurred.	
2	Scan window	Scan the barcode.	
3	Trigger	Press to decode.	

# A.2.2 Setting Up the Digital Imager Reader

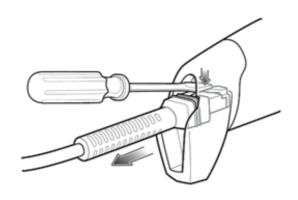
Installing the Interface Cable



Perform the following procedure:

- 1. Plug the interface cable modular connector into the cable interface port on the bottom of the reader handle and ensure the connector is properly secure.
- 2. Connect the other end of the interface cable to the host.

#### **Removing the Interface Cable**



Perform the following procedure:

- 1. Using the tip of a screwdriver or some other tools with a sharp head, depress the cable's modular connector clip.
- 2. Carefully slide out the cable.

### A.2.3 Setting

The reader has factory settings, for details see "A.3 Parameter Defaults".

The reader supports some user-defined functions as introduced below.

For more details, please contact the SYMBOL reader agents or Mindray Customer Service Department.

#### Volume setting

Scan the following barcode to set the volume parameter.

Low Volume



Medium Volume



High Volume



#### Code 93 and codabar setting

• To enable Code 93, scan the appropriate barcode below.



• To enable Codabar, scan the appropriate barcode below



#### Code 39 full ASCII setting

Code 39 Full ASCII is a variant of Code 39 which pairs characters to encode the full ASCII character set.

• To enable Code 39 Full ASCII, scan the appropriate barcode below.



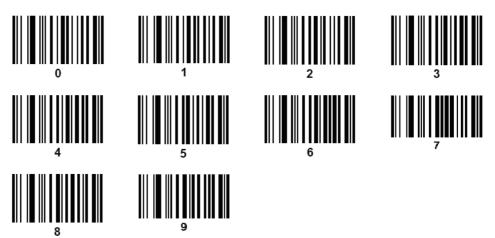
• To disable Code 39 Full ASCII, scan the appropriate barcode below.



#### I 2 of 5 symbols setting



Select this option to decode only I 2 of 5 symbols containing a selected length. Select the length using the numeric barcodes below. For example, to decode only I 2 of 5 symbols with 8 characters, scan I 2 of 5 - One Discrete Length, then scan 0 followed by 8.

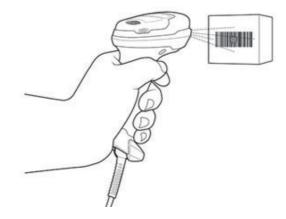


## A.2.4 Scanning in Hand-Held Mode

Perform the following procedure:

1. Ensure all connections are secure (see the appropriate host chapter.)

2. Aim the digital imager reader at the barcode.



3. When the digital imager reader senses movement, in its default Auto Aim trigger mode, it projects a red LED dot which allows positioning the barcode within the field of view.



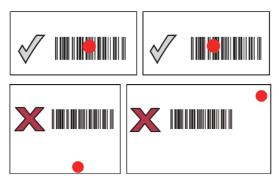
If necessary, the digital imager reader turns on its red LEDs to illuminate the target barcode.

- 4. Center the symbol. Be sure the entire symbol is within the rectangular area formed by the illumination LEDs.
- 5. Hold the trigger until the digital imager reader beeps, indicating the barcode is successfully decoded.

Steps 2 - 4 above may be required to repeat on poor quality or difficult barcodes.

The aiming pattern is smaller when the digital imager reader is closer to the symbol and larger when it is farther from the symbol. Scan symbols with smaller bars or elements (mil size) closer to the digital imager reader, and those with larger bars or elements (mil size) farther from the digital imager reader.

The digital imager reader can also read a barcode presented within the aiming dot not centered. The top examples in show acceptable aiming options, while the bottom examples cannot be decoded.



# A.3 Parameter Defaults

Refer to the following table for parameter defaults of LS2208 and DS4308.

Parameter	Defaults	Parameter	Defaults
1-D Symbologies	ļ	Interleaved 2 of 5 (ITF)	
UPC/EAN		Interleaved 2 of 5 (ITF) Enable	Enable
UPC-A	Enable	Set Lengths for I 2 of 5	14
UPC-E	Enable	I 2 of 5 Check Digit Verification	Disable
UPC-E1	Disable	Transmit I 2 of 5 Check Digit	Disable
EAN-8/JAN 8	Enable	Convert I 2 of 5 to EAN 13	Disable
EAN-13/JAN 13	Enable	Codabar (NW - 7)	
Bookland EAN	Disable	Codabar	Enable
Decode UPC/EAN/JAN Supplementals (2and 5 digits)	Ignore	Set Lengths for Codabar	5 to 55
UPC/EAN/JAN Supplemental Redundancy	10	CLSI Editing	Disable
Transmit UPC-A Check Digit	Enable	NOTIS Editing	Disable
Transmit UPC-E Check Digit	Enable		
Transmit UPC-E1 Check Digit	Enable	2-D Symbologies	
UPC-A Preamble	System Character	PDF417	Enable
UPC-E Preamble	System Character	MicroPDF417	Disable
UPC-E1 Preamble	System Character	Code 128 Emulation	Disable
Convert UPC-E to A	Disable	Data Matrix	Enable
Convert UPC-E1 to A	Disable	Maxicode	Enable
EAN-8/JAN-8 Extend	Disable	QR Code	Enable
UCC Coupon Extended Code	Disable		
Code 128			
Code 128	Enable		
UCC/EAN-128	Enable		
ISBT 128	Enable		
Code 39			
Code 39	Enable		
Trioptic Code 39	Disable		
Convert Code 39 to Code 32 (Italian Pharmacy Code)	Disable		
Code 32 Prefix	Disable		
Set Length(s) for Code 39	2 to 55		

Parameter	Defaults	Parameter	Defaults
Code 39 Check Digit Verification	Disable		
Transmit Code 39 Check Digit	Disable		
Code 39 Full ASCII Conversion	Disable		
Buffer Code 39	Disable		
Code 93	·		
Code 93	Enable		
Set Length(s) for Code 93	4 to 55		

The system provides wireless net adapter configuration, so as to assist information query and unlimited network service. The ultrasound system can be connected to router, mobile phone, tablet, ultrasound workstation, server network device and so on via wireless network.

# **WARNING**

- Use the wireless LAN function prudently in OR/ICU/CCU as it may interfere with other devices.
- When the wireless LAN function is turned on, the ultrasound system may suffer interference from other equipment, even if that other equipment complies with CISPR EMISSION requirements.
- Keep at least 20 cm away from the ultrasound system when the wireless LAN function is in use.

#### NOTE:

- DO NOT connect devices other than specified into the LAN.
- Medical devices within the same LAN may interfere with each other, the operator should be cautious. (Do not connect devices that may cause strong interference. For example, life-supporting devices should not be connected in the same LAN.)
- Other non-medical devices in the same frequency band may cause interference, please be cautious.
- Wireless network designing, deploying, debugging, and maintenance should be executed by Mindray service personnel or authorized technicians.
- Always set the wireless network according to local wireless regulations.
- Keep network authentication information, for example password, safe, protecting the network from being accessed by unauthorized users.
- If the wireless signal is poor, the ultrasound machine may fail to send data to the server.
- RF interference may result in wireless network disconnection.
- Disconnecting from the network may result in send data to server failure. Solve the network problem as soon as possible.
- Ensure that the ultrasound device IP address setting is correct. Changing the network settings may result in network disconnection. Contact your service personnel if you have any problems on setting the IP address.
- To make sure that the ultrasound system works well, the ultrasound system can coexist with Wi-Fi as the interfering network operating at maximum throughput and maximum transmit power when a separation distance of 1m is maintained.
- Wi-Fi function is not affected when the system is imposed with radiation interference complied with IEC 60601-1-2: 2014 standard.

For a better wireless LAN transmission effect, please take the following settings:

- SSID > 80% with stable WLAN network.
- Wireless router and the server are in the same network segment.
- Router setting:
  - Wireless standard IEEE 802.11 ac/a/b/g/n.
  - Maximum transmission speed 300 Mbps.
  - Number of the devices connected to the same router  $\leq 5$ .
- Target server setting:
  - Network is stable and not under overloading state (e.g. high CPU/memory usage, fast HDD speed, limited HDD space).
  - Level other than the highest level of firewall is adopted.
  - Operating system is Windows 10 or higher versions and it supports a Gigabit Ethernet.

# **B.1 Use the Wireless Feature**

Perform the following procedure:

- 1. Press <Cursor> to show the cursor, click < in the bottom bar to open the wireless network manager.
- 2. Move the cursor to the target network and press <Set> to select it, then click [Connect] to connect to the network.

When connecting an encrypted network, enter the password in the box first. You can select to hide password characters or not.

- 3. The system tries to connect and the wireless manager icon turns into reference turns into
- 4. Click [Refresh] to refresh the "Wireless Network Connection" list.

# B.2 IP Configure

#### NOTE:

- When the system background is processing network task (DICOM sending for example), please do not enter network setting to change the IP, otherwise the background task may fail. You can check if there are tasks undergoing in the task manager.
- If the IP address displays as 0.0.0, this means that the network is abnormal. The reason for the failure may be disconnection or the system cannot obtain the IP address.

IP Config is used for setting local network parameters, which is also applied to DICOM connection. Perform the following procedure:

- 1. In Wireless network manager screen, click [IP Config] to open the configuration page.
  - If "DHCP" is selected, the IP address will be automatically obtained from the DNS server.
  - If "Static" is selected (using a static IP address), enter the IP address.
     IP address of the system should be in the same network segment with the server.
     The name of the device is saved under the service name by default. The system remembers the service name of the ultrasound system when sending the image, the report

to DICOM server. Open the file (DCM Editor Tool, eZDicom.exe) to view the service name (iStation Name).

- 2. Click [OK] to save current setting.
- 3. Click [Cancel] to exit.

# **B.3 EAP Network**

For setting EAP network, contact Mindray Customer Service Department or the sales representatives.

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By providing the referential information, such as, the ultrasonic image, the anatomic graphic, scanning pictures/other scanning tips or diagnosis comments, the system helps the doctors to operate the scanning by iScanHelper. Furthermore, it is a good platform for the self-learning and training of ultrasound scanning technique for doctors. The system also plays a role in the assistant software system in fulfilling training and education.

#### NOTE:

- THIS "iScanHelper" IS FOR REFERENCE OR TUTORIAL PURPOSES ONLY, AND THE MANUFACTURER WILL NOT BE LIABLE FOR DAMAGES AND/OR OTHER UNDESIRABLE CONSEQUENCE IN ANY KIND THAT MAY OCCUR TO THE PATIENT OR THE USERS BY USING THE SOFTWARE.
- iScanHelper feature is available under Abdomen, gynecological, urological, obstetrical, Small Parts and nerve block area.

# C.1 Use iScanHelper for Reference

Perform the following procedure:

- 1. Perform ordinary scanning procedure.
- 2. Tap [iScanHelper] or press the user-defined <iScanHelper> key to enter iScanHelper status.
- 3. Select the desired section.
- 4. Perform scanning according to information displayed on the help information area.

Click  $\bigcirc$  to back to the section selection interface.

You can synchronize the help information to the main screen or read the scanning skills as needed. see "C.3 Basic Screen and Operation" for more details.

5. Tap  $\mathbf{X}$  to exit iScanHelper.

# C.2 Use iScanHelper for Learning or Training

Perform the following procedure:

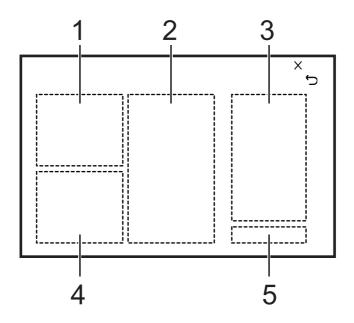
- 1. Switch to the exam modes that support iScanHelper.
- 2. Tap [iScanHelper] or press the user-defined <iScanHelper> key to enter iScanHelper status.
- 3. Learn and practice views by system defaulted sequence according to the information displayed on help information area; or select unfamiliar views to practice.

Click  $\bigcirc$  to back to the section selection interface.

You can synchronize the help information to the main screen or read the scanning skills as needed. see "C.3 Basic Screen and Operation" for more details.

4. Tap  $\mathbf{X}$  to exit iScanHelper.

# C.3 Basic Screen and Operation



1.	Ultrasonic image	It is used to compare with images scanned by the operator.	
2.	Anatomic graphic	Related anatomical tissue information are provided here.	
3.	Scanning tips	You can read tissue related anatomical information and adjacent tissue information here.	
4.	Scanning picture	Ordinary scanning tips can be observed here, including posture, probe mark, probe swing/sweep techniques.	
5.	Button	<ul> <li>After clicking the button, the system reads scanning tips.</li> <li>After clicking the button, you can adjust reading volume or put it on silent.</li> <li>After clicking the button, the standard ultrasound images will be synchronized to the main screen and zoomed in.</li> <li>After clicking the button, iScanHelper information will be synchronized to the left side of the main screen.</li> </ul>	

# **D** iVision

The iVision function is used to demonstrate the stored images. Image files are played one by one according to file names (including system-relevant and PC-compatible format images).

Perform the following procedure:

- 1. Press the user-defined *<*iVision*>* key to enter the iVision screen.
- 2. Add the contents to be played and select demo mode.
- 3. Select an item in the list and click [Start] to begin the demonstration.
- 4. Click [Exit] or press <ESC> to exit iVision status.

#### **Demonstration Item**

Demonstration items are image files in formats supported by the system. You can add exam data from the patient database or system-supported image files and folders to the demonstration list. For files and folders in the demonstration list, the images in the directory and subdirectory are played one by one, and the system will automatically skip files that cannot be opened.

#### **Demonstration Catalog**

There are two kinds of catalog: Demo Catalog and Customize Catalog.

Demo Catalog

The demo catalog is a folder on the hard disk where the factory DEMO is stored. The system plays the images in this folder when performing demonstrations.

The system supports importing, deleting or clearing the data in the demo catalog.

Click [Demo Manager] to operate:

- [>]: to import data into the demo catalog.
- [<]: to delete selected data.
- [<<]: to delete all data.
- Customize Catalog
- The catalog of the displayed images is saved here. The system plays the images in the catalog when performing demonstrations.
- Operate the catalog or the files using the buttons on the right:
  - [Add Exam]: to add exam to iStation. Click [Add Exam], and select the desired exam in the pop-up menu, and click [Restore Exam] to add the selected exam to iStation.
  - [Add File]: to add files to the file list.
  - [Add Catalog]: to add a catalog of files to the list.
  - [Delete]: to delete selected files or catalogs from the file list.
  - [Clear]: to clear all the files or catalogs in the file list.
  - [Export]: to export selected directories/files to external storage devices. Click [Export] to bring up the Browse dialog box, select the path and click [OK].

#### Copy the File

Transfer files between the mobile hard disk and the ultrasound system.

Perform the following procedure:

- 1. Plug the USB disk, and click [Copy File].
- 2. Select the path of the source file from the "Drive" and "File Name".
- 3. Click [Choose Catalog]. Select the path of the source file from the "Drive" and "File Name", and then click [OK].
- 4. Click [OK] again to complete the task.

#### **Promotion Video**

Click to play exhibition video.

#### **Demonstration Mode**

The system automatically plays all the image files in the list one by one.

The time interval between images played is same and can be changed.

#### **Option of Demo**

You can choose whether to repeat the demonstration or exit after a demonstration is completed.

This section of the operator's manual applies to the overall system including the main unit, probes, accessories and peripherals. This section contains important safety information for operators of the device, pertaining to acoustic output and how to control patient exposure through use of the ALARA (as low as reasonably achievable) principle. Also this section contains information regarding the acoustic output testing and the real-time output display.

Read this information carefully before using the system.

# E.1 Concerns with Bioeffects

Diagnostic ultrasound is recognized as being safe. In fact, there have been no reports of injuries to patients caused by diagnostic ultrasound.

It cannot be stated categorically that ultrasound is 100% safe. Studies have revealed that ultrasound with extremely high intensity is harmful to body tissues.

Diagnostic ultrasound technology has made a great leap forward during the last several years. This rapid advance has generated concerns about the potential risk of bioeffects when new applications or diagnostic technologies become available.

# E.2 Prudent Use Statement

Although there are no confirmed biological effects on patients caused by exposures from present diagnostic ultrasound instruments, the possibility exists that such biological effects may be identified in the future. Thus ultrasound should be used in a prudent manner to provide medical benefit to the patient. High exposure levels and long exposure times should be avoided while acquiring necessary clinical information.

# E.3 ALARA Principle (As Low As Reasonably Achievable)

It is required to practice ALARA when using ultrasound energy. Practicing ALARA ensures that the total energy level is controlled below a low enough level at which bioeffects are not generated while diagnostic information is being accumulated. The total energy is controlled by output intensity and total radiation time. The output intensity necessary for examinations differs depending on the patient and the clinical case.

Not all examinations can be performed with an extremely low level of acoustic energy. Controlling the acoustic level at an extremely low level leads to low-quality images or insufficient Doppler signals, adversely affecting the reliability of the diagnosis. However, increasing the acoustic power more than necessary does not always contribute to an increase in quality of information required for diagnosis, rather increasing the risk of generating bioeffects.

Users must take responsibility for the safety of patients and utilize ultrasound deliberately. Deliberate use of ultrasound means that output power of ultrasound must be selected based on ALARA.

Additional information regarding the concept of ALARA and the possible bioeffects of Ultrasound is available in a document from the AIUM (American Institute of Ultrasound Medicine) title "Medical Ultrasound Safety".

# E.4 MI/TI Explanation

## E.4.1 Basic Knowledge of MI and TI

#### **Mechanical Bioeffect and Thermal Bioeffect**

The relationship of various ultrasound output parameters (frequency, acoustic pressure and intensity, etc.) to bioeffects is not fully understood presently. It is recognized that two fundamental mechanisms may induce bioeffects. One is a thermal bioeffect with tissue absorption of ultrasound, and another one is a mechanical bioeffect based on cavitations. Thermal Index (TI) gives the relative index of temperature increase by thermal bioeffect, and Mechanical Index (MI) gives the relative index of mechanical bioeffect. TI and MI indices reflect instantaneous output conditions, so they DO NOT consider the cumulative effects of the total examination time. TI and MI models contain practical simplifications to complex bioeffects interaction. Then the operator should be aware that the actual worst case temperature rise may be up to several times higher than the displayed TI value.

#### **MI (Mechanical Index)**

The mechanical bioeffects are the result of compression and decompression of insonated tissues with the formation of micro bubbles that may be referred to as cavitations.

MI is an index that shows the possibility of the cavitations generation based on acoustic pressure, and the value in which the peak-rarefactional acoustic pressure is divided by the square root of the frequency. Therefore MI value becomes smaller when the frequency is higher or the peak-rarefactional acoustic pressure is lower, it becomes difficult to generate the cavitations.

$$MI = \frac{P_{r, \alpha}}{\sqrt{f_{awf}} \times C_{MI}}$$

 $C_{MI} = 1 (\text{MPa} / \sqrt{MHz})$ 

For the frequency 1 MHz and the peak rarefactional acoustic pressure 1 MPa, MI becomes 1. It is possible to think MI to be one threshold of the cavitations generation. Especially, it is important to keep MI value to be low when both gases and the soft tissues exist together, for such as lung exposure in cardiac scanning and bowel gas in Abdomen scanning.

#### TI (Thermal Index)

TI is determined by the ratio of the total acoustic power to the acoustic power required to raise the tissue temperature by 1 degree C. In addition, because the temperature rises is greatly different according to tissue structures, TI is divided three kinds: TIS (Soft-tissue Thermal Index), TIB (Bone Thermal Index) and TIC (Cranial-bone Thermal Index).

- TIS: Thermal index related to soft tissues, such as Abdomen and cardiac applications.
- TIB: Thermal index for applications, such as fetal (second and third trimester) or neonatal cephalic (through the fontanel), in which the ultrasound beam passes through soft tissue and a focal region is in the immediate vicinity of bone.
- TIC: Thermal index for applications, such as pediatric and adult cranial applications, in which the ultrasound beam passes through bone near the beam entrance into the body.

Although the output power is automatically controlled for the selected applications, high TI values should be kept to a minimum or avoided in obstetric applications. WFUMB (World Federation for Ultrasound in Medicine and Biology) guidelines: state that temperature increase of 4 degree C for 5 min or more should be considered as potentially hazardous to embryonic and fetal tissue.

The smaller the MI/TI values, the lower the bioeffects.

### E.4.2 MI/TI Display

TI and MI values are displayed in the upper part of the screen in real-time. The operator should monitor these index values during examinations and ensure that exposure time and output values are maintained at the minimum amounts needed for effective diagnosis.

#### NOTE:

If there is a value of MI or TI exceeds 1.0, you must be careful to practice the ALARA principle.

The display precision is 0.1.

Real-time Display accuracy: MI  $\leq$  28.5%, TI  $\leq$  38.7%

# E.5 Acoustic Power Setting

#### Acoustic power adjustment

Use the <A.power> to adjust the acoustic power percentage, and its value is displayed on the corresponding item, as well as at the top of the screen. The greater the acoustic power percentage, the greater the current acoustic output. When the image is frozen, the system stops transmitting acoustic power.

#### Default setting of acoustic power

Selection of diagnostic applications is the most important factor for controlling ultrasound output. The permissible level of intensity of ultrasound differs depending on the region of interest. For fetal examinations, in particular, much care must be exercised.

In this system, imaging setups can be created using the ultrasound output set by you.

Once you perform preset settings, default setting values of the system may be changed and invalid. It is the user's responsibility for any change to the default settings.

#### Adjusting range

Initial power: 0.1% to 100%\*

Definition of 100%: The maximum acoustic power of a probe determined by the increase in probe surface temperature in the selected mode and the acoustic power restrictions specified by the FDA.

Default settings of acoustic power value refer to the best image quality of the probe. The larger the acoustic power value, the better the image quality.

In this product, to obtain optimum images for applications under the requirements of safety and ALARA principle, we set acoustic power default values in factory to be maximum 93.33% in all exam modes for a better image quality. The user can make adjustments according to the imaging effect in practical use.

#### NOTE:

This system automatically returns to the settings whenever changes are made to the values (when you turn on the power, switch between probes, end the exam, or select OK or Cancel in the Setup menu). In the factory default settings, the Acoustic Output is limited below 100%.

Following the ALARA restriction, you are allowed to increase the acoustic power under FDA 510 (k) Guidance-Track 3 limits and to set it in the image preset screen.

The acoustic output of the system has been measured and calculated in accordance with IEC60601-2-37: 2015, FDA 510(K) GUIDANCE, IEC 62359: 2017, Ultrasonics-Field characterization-Test methods for the deter mination of thermal and mechanical indices related to medical diagnostic ultrasonic fields.

# E.6 Acoustic Power Control

The qualified operator may use the system controls to limit the ultrasound output and to adjust the quality of the images. There are three categories of system controls relative to output. They are,

- Controls that have direct effect on the output
- Controls that indirectly control output
- Controls that are receiver controls

#### **Direct controls**

It is possible to control, if necessary, the acoustic output with the "A.power" item. In this case, the maximum value of the acoustic output never exceeds an MI of 1.9 and an  $I_{SPTA.3}$  of 720 mW/cm<sup>2</sup> in any mode of operation.

#### **Indirect controls**

The controls that indirectly affect output are the many imaging parameters. These are operating modes, frequency, focal point positions, overall depth, and PRF.

The operating mode determines whether the ultrasound beam is scanning or non-scanning. Thermal bioeffect is closely connected to M mode, Doppler and Color mode. Acoustic attenuation of tissue is directly related to probe frequency. The focal point is related to active aperture of probe and beam width. For the higher PRF (pulse repetition frequency), the more output pulses occur over a period of time.

#### **Receiver controls**

The receiver controls (for example, gain, dynamic range, and image post-processing, etc.) won't affect output. These controls should be used, when possible, to improve the image quality before using controls that directly or indirectly affect output.

## E.7 Acoustic Output

## E.7.1 Derated Ultrasonic Output Parameters

In order to determine the relevant Ultrasonic Output Parameters, a method is used which allows for the comparison of ultrasound systems which operate at different frequencies and are focused at different depths. This approach, called "derating" or "attenuating", adjusts the acoustic output as measured in a water tank to account for the effect of ultrasound propagation through tissue. By convention, a specific average intensity attenuation value is used, which corresponds to a loss of 0.3 dB/cm/MHz. That is, the intensity of ultrasound will be reduced by 0.3 dB/MHz for every centimeter of travel from the probe. This can be expressed by the following equation:

$$I_{atten} = I_{water} \times 10^{((-0.3)/10 \times f_c \times z)}$$

Where  $I_{atten}$  is the attenuated intensity,  $I_{water}$  is the intensity measured in a water tank (at distance z), fc is the center frequency of the ultrasound wave (as measured in water), and z is the distance from the probe. The equation for attenuating pressure values is similar except that the attenuation coefficient is 0.15 dB/cm/MHz, or one-half the intensity coefficient. The intensity coefficient is double the pressure coefficient because intensity is proportional to the square of pressure.

Although the attenuation coefficient chosen, 0.3 dB/cm/MHz, is significantly lower than any specific solid tissue in the body, this value was chosen to account for fetal examinations. In early trimester ultrasound fetal examinations, there may be a significant fluid path between the probe and the fetus, and the attenuation of fluid is very small. Therefore the attenuation coefficient was lowered to account for this case.

### E.7.2 Limits of Acoustic Output

In accordance with the FDA Track 3 requirements, the derating (or attenuated) approach was incorporated into the FDA Acoustic Output Limits, as listed below. The maximum acoustic output level from any probe in any operating mode is expected to fall below these limits.

FDA Maximum Acoustic Output Limits for Track 3 (Attenuated Values)

Application:	$I_{spta.3} (mW/cm^2) \le 720$	$I_{sppa.3} (W/cm^2) \le 190 \text{ or } MI \le 1.9$
Regions (except eyes)		

### E.7.3 Differences between Actual and Displayed MI and TI

In operation, the system will display to the operator the Acoustic Output Parameters Thermal Index, TI, or Mechanical Index, MI (or sometimes both parameters simultaneously). These parameters were developed as general indicators of risk from either thermal or mechanical action of the ultrasound wave. They serve to indicate to the operator whether a particular setting of the system increases or decreases the possibility of Thermal or Mechanical effect. More specifically, they were designed to assist in the implementation of the ALARA principle. As an operator changes a given system control, the potential effect of the change in output will be indicated. However, the Thermal Index is not the same as temperature rise in the body, for several reasons. First of all, in order to provide a single display index to you, a number of simplifying assumptions had to be made. The biggest assumption was the use of the attenuating formula described above, which is much lower than the actual value for most tissues within the body. Scanning through muscle or organ tissue, for example, will produce much higher attenuation than 0.3 dB/cm/MHz. There were also significant simplifications made for the thermal properties of tissue. Therefore, scanning through highly perfused tissue, such as the heart or vasculature, will produce significantly less thermal effect than that suggested by the Thermal Index.

Similarly, the Mechanical Index was derived to indicate the relative possibility of mechanical (cavitation) effects. The MI is based on the derated peak-rarefactional pressure and the center frequency of the ultrasound wave. The actual peak-rarefactional pressure is affected by the actual attenuation caused by tissue in the path between the probe and the focal point. Again, all solid tissues within the body have higher attenuation than the prescribed 0.3 dB/cm/MHz value, and therefore, the actual peak-rarefactional pressure will be lower. Further, the actual peak-rarefactional pressure will change depending upon the region of the body being scanned.

For these reasons, the TI and MI displays should only be used to assist the operator in implementing ALARA at the time of the patient examination.

# E.8 Measurement Uncertainty

The total estimated measurement uncertainty (where the total uncertainty includes the uncertainties in hydrophone response, measurement, calculation, and positioning) are:

Acoustic Quantities	Total Uncertainties (Standard)
Power	26.48% for non-scan modes; 6.03% for scan modes.
Frequency	0.22%
Pressure	13.01%
I <sub>ta</sub>	26.48% for non-scan modes; 26.95% for scan modes.
I <sub>pa</sub>	26.5%
Mechanical Index	13.01%
Total Uncertainty for TIS	Non-scan Modes: 26.48%; Scan-Modes: 6.03%
Total Uncertainty for TIB	Non-scan Modes: 26.48% or 18.72%; Scan-Modes: 6.03%
Total Uncertainty for TIC	Non-scan Modes: 26.48%; Scan-Modes: 6.03%

# E.9 References for Acoustic Power and Safety

- "Bioeffects and Safety of Diagnostic Ultrasound" issued by AIUM in 1993
- "Medical Ultrasound Safety" issued by AIUM in 1994
- Marketing Clearance of Diagnostic Ultrasound Systems and Transducers, June 27, 2019. Center for Devices and Radiological Health.
- Medical electrical equipment-Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment issued by IEC in 2015
- IEC 62359, Ultrasonics-Field characterization-Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields, 2017.

The following electrical safety tests are recommended as part of a comprehensive preventive maintenance program. They are a proven means of detecting abnormalities that, if undetected, could prove dangerous to either the patient or the operator. Additional tests may be required according to local regulations.

All tests can be performed using commercially-available safety analyzer test equipment. These procedures assume the use of a 601PROXL International Safety Analyzer or equivalent safety analyzer. Other popular testers which comply with IEC 60601-1 and are used in Europe, such as Fluke, Metron or Gerb, may require modifications to the procedure. Follow the analyzer manufacturer's instructions.

An electrical safety inspection should be periodically performed every two years. The safety analyzer is also an excellent troubleshooting tool for detecting abnormalities in line voltage and grounding, as well as total current loads.

#### NOTE:

Make sure the safety analyzer is authorized and complies with the requirements of IEC 61010-1. Follow the analyzer manufacturer's instructions.

# F.1 Power Cord Plug

Test Item		Acceptance Criteria
The power plug	The power plug pins	No broken or bent pins. No discolored pins.
	The plug body	No physical damage to the plug body.
	The strain relief	No physical damage to the strain relief. No plug warmth when device is in use.
	The power plug	No loose connections.
The power cord		No physical damage to the cord. No deterioration to the cord.
		For devices with detachable power cords, inspect the connection with the device.
		For devices with non-detachable power cords, inspect the strain relief at the device.

# F.2 Device Enclosure and Accessories

# F.2.1 Visual Inspection

Test Item	Acceptance Criteria
The enclosure and accessories	No physical damage to the enclosure and accessories.
	No physical damage to meters, switches, connectors, etc.
	No residue of fluid spillage (e.g., water, coffee, chemicals, etc.).
	No loose or missing parts (e.g., knobs, dials, terminals, etc.).

# F.2.2 Contextual Inspection

Test Item	Acceptance Criteria
The enclosure and accessories	No unusual noises (e.g., rattles inside the case).
	No unusual smells (e.g., burning or smoky smells, particularly from ventilation holes).
	No taped notes that may suggest device deficiencies or operator concerns.

# F.3 Device Labeling

Check that the labels provided by the manufacturer or the healthcare facility are present and legible.

- Main unit label
- Integrated warning labels

# F.4 Protective Earth Resistance

- 1. Plug the analyzer probes into the device's protective earth terminal and the protective earth terminal of the AC power cord.
- 2. Test the earth resistance with a current of 25 A.
- 3. Verify the resistance is less than the limits.

#### LIMITS

ALL COUNTRIES  $R = 0.2 \Omega$  Maximum

# F.5 Earth Leakage Test

Run an Earth Leakage test on the device being tested before performing any other leakage tests. The following outlet conditions apply when performing the Earth Leakage test.

- normal polarity (Normal Condition).
- reverse polarity (Normal Condition).

- normal polarity with open neutral (Single Fault Condition).
- reverse polarity with open neutral (Single Fault Condition).

#### LIMITS

- For UL 60601-1:
  - 300 μA in Normal Condition.
  - 1000 μA in Single Fault Condition.
- For IEC 60601-1:
  - 500 μA in Normal Condition.
  - 1000 μA in Single Fault Condition.

# F.6 Enclosure Leakage Test

The following outlet conditions apply when performing the Enclosure Leakage test.

- normal polarity (Normal Condition).
- reverse polarity (Normal Condition).
- normal polarity with open neutral (Single Fault Condition).
- reverse polarity with open neutral (Single Fault Condition).
- normal polarity with open earth (Single Fault Condition).
- reverse polarity with open earth (Single Fault Condition).

#### LIMITS

- For UL 60601-1
  - 100 μA in Normal Condition.
  - 300 μA in Single Fault Condition.
- For IEC 60601-1:
  - 100  $\mu$ A in Normal Condition.
  - 500 μA in Single Fault Condition.

# F.7 Patient Leakage Current

Patient leakage currents are measured between a selected applied part and mains earth. All measurements have a true RMS only.

The following outlet conditions apply when performing the Patient Leakage Current test.

- normal polarity (Normal Condition).
- reverse polarity (Normal Condition).
- normal polarity with open neutral (Single Fault Condition).
- reverse polarity with open neutral (Single Fault Condition).
- normal polarity with open earth (Single Fault Condition).
- reverse polarity with open earth (Single Fault Condition).

#### LIMITS

For BF **†** applied parts:

- 100 µA in Normal Condition.
- 500 µA in Single Fault Condition.

# F.8 Mains on Applied Part Leakage

The Mains on Applied Part test applies a test voltage, which is 110% of the mains voltage using a limiting resistance, to selected applied part terminals. Current measurements are then taken between the selected applied part and earth. Measurements are taken with the test voltage (110% of mains) on applied parts in the normal and reverse polarity conditions.

The following outlet conditions apply when performing the Mains on Applied Part test.

- Normal Polarity;
- Reversed Polarity.

#### LIMITS

For BF  $\mathbf{\dot{\pi}}$  applied parts: 5000  $\mu$ A.

# F.9 Patient Auxiliary Current

Patient Auxiliary currents are measured between any selected Applied Part connector and the remaining Applied Part connectors. All measurements may have a true RMS response.

The following outlet conditions apply when performing the Patient Auxiliary Current test.

- normal polarity (Normal Condition);
- reverse polarity (Normal Condition);
- normal polarity with open neutral (Single Fault Condition);
- reverse polarity with open neutral (Single Fault Condition);
- normal polarity with open earth (Single Fault Condition);
- reverse polarity with open earth (Single Fault Condition).

#### LIMITS

For BF 🗼 applied parts:

- 100 µA in Normal Condition.
- 500 µA in Single Fault Condition.

# **G** EMC Guidance and Manufacturer's Declaration

The system complies with the EMC standard IEC60601-1-2:2014+A1:2020.

Intended Environments: HOME HEALTHCARE ENVIRONMENT (except for near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging).

# **AWARNING**

- The use of unapproved accessories may diminish system performance.
- Use of components, accessories, probes, and cables other than those specified may result in increased emission or decreased immunity of system.
- The system needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.
- Use of the system adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the system and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of the system could result in increased electromagnetic emissions or decreased electromagnetic immunity of the system and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Operation of system, in the case that the patient physiological signal is lower than the minimum amplitude or value specified in the product specifications, results may not be obtained (results can be obtained when the HR is in the range of 30-250 bmp or when the QRS wave amplitude is between 0.5-5 mV.)
- When the Ultrasound diagnostic system works with Fusion Imaging function, the system is not intended for use in residential environments and can possibly not provide adequate protection to radio reception in such environments.
- Preventing conducted RF immunity. Due to technological limitations, the conducted RF immunity level are limited to 3Vrms level, conducted RF

interference above 3Vrms may cause wrong diagnosis and measurements. We suggest that you position system further from sources of conducted RF noise.

- The system should be away from RFID, MRI, diathermy, and electrocautery testing, wireless power transfer, 5G cellular and security equipment (such as electromagnetic anti-theft system and metal detector). If the devices are near and are interfered by the concealed and undiscovered RF transmitter (for example, scanning mode changes or image disturbances affecting diagnosis), the user should immediately take mitigation measures, such as redirecting, repositioning or shielding the RF transmitter.
- This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
  - Reorient or relocate the receiving antenna.
  - Increase the separation between the equipment and receiver.
  - Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
  - Consult the dealer or an experienced radio/TV technician for help.

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

• This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

If the system is operated within the electromagnetic environment listed in Table G-3, Table G-4, Table G-5, Table G-6, and Table G-7, the system will remain safe and will provide the following basic performances:

- Imaging;
- Doppler acoustic spectral displaying;
- Taking measurements;
- Patient information;

• Date/time information.

#### Table G-1

#### GUIDANCE AND MINDRAY DECLARATION-ELECTROMAGNETIC EMISSIONS

The system is intended for use in the electromagnetic environment specified below. The customer or the user of system should assure that it is used in such an environment.

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIROMENT – GUIDANCE
RF Emissions CISPR 11	Group 1	The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The system is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Compliance	

Table G-2

#### **GUIDANCE AND MINDRAY DECLARATION-ELECTROMAGNETIC EMISSIONS**

When the Ultrasound diagnostic system works with Fusion Imaging function, the system was declared to the category of CISSPR11 Group1 Class A. The system is intended for use in the electromagnetic environment specified below. The customer or the user of system should assure that it is used in such an environment.

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIROMENT - GUIDANCE
RF Emissions CISPR 11	Group 1	The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The system is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Compliance	

## GUIDANCE AND MINDRAY DECLARATION-ELECTROMAGNETIC IMMUNITY

The system is intended for use in the electromagnetic environment specified below. The customer or the user of system should assure that it is used in such an environment.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT- GUIDANCE
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact; ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact; ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast Transient / burst IEC 61000-4-4	±2 kV for power supply lines; ±1 kV for input/output lines	±2 kV for power supply lines; ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	$\pm 0,5 \text{ kV}, \pm 1 \text{ kV line(s)}$ to line(s); $\pm 0,5 \text{ kV}, \pm 1 \text{ kV}, \pm 2 \text{ kV}$ line(s) to earth	$\pm 0,5 \text{ kV}, \pm 1 \text{ kV line(s)}$ to line(s); $\pm 0,5 \text{ kV}, \pm 1 \text{ kV}, \pm 2 \text{ kV}$ line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, Short interruptions and voltage variation on power supply input voltage IEC 61000-4-11	0% $U_T$ ; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% $U_T$ ; 1 cycle 70% $U_T$ for 25/30 cycle at 0° 0% $U_T$ ; 250/300 cycle	0% $U_T$ ; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% $U_T$ ; 1 cycle 70% $U_T$ for 25/30 cycle at 0° 0% $U_T$ ; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If you require continued operation during power mains interruptions, it is recommended that our product be powered from an uninterpretable power supply or a battery.
Power frequency (50/60 HZ) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

### NOTE:

 $U_T$  is the A.C. mains voltage prior to application of the test level.

#### **GUIDANCE AND MINDRAY DECLARATION-ELECTROMAGNETIC IMMUNITY**

The system is intended for use in the electromagnetic environment specified below. The customer or the user of system should assure that it is used in such an environment.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT-GUIDANCE
Conduced RF IEC 61000-4-6	3 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM <sup>a</sup> and amateur radio bands between 0,15 MHz and 80 MHz	3 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \times \sqrt{P}$ $d = 2 \times \sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80MHz - 2.7GHz	10 V/m 80MHz - 2.7GHz	d = $1.2 \times \sqrt{P} 80$ MHz to $800$ MHz d = $2.3 \times \sqrt{P} 800$ MHz to $2.7$ GHz Where, P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey <sup>b</sup> , should be less than the compliance level in each frequency range <sup>c</sup> . Interference may occur in the vicinity of equipment marked with the following symbol:

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

#### **GUIDANCE AND MINDRAY DECLARATION-ELECTROMAGNETIC IMMUNITY**

The system is intended for use in the electromagnetic environment specified below. The customer or the user of system should assure that it is used in such an environment.

IMMUNITY	IEC 60601 TEST	COMPLIANCE	ELECTROMAGNETIC
TEST	LEVEL	LEVEL	ENVIRONMENT-GUIDANCE

a: The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

b: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device. c: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

#### Table G-5

#### **GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC IMMUNITY** The system is intended for use in the electromagnetic environment specified below. The customer or the user of system should assure that it is used in such an environment. **IMMUNITY TEST IEC 60601** COMPLIANCE ELECTROMAGNET **IC ENVIROMENT – TEST LEVEL** LEVEL **GUIDANCE** Proximity magnetic 8 A/m 8 A/m fields 30 kHz 30 kHz IEC 61000-4-39 CW CW 65 A/m 65 A/m 134.2 kHz 134.2 kHz Pulse modulation Pulse modulation 2,1 kHz 2,1 kHz 7.5 A/m 7.5 A/m 13,56 MHz 13,56 MHz Pulse modulation Pulse modulation 50 kHz 50 kHz

Table G-6 Test specifications and minimum distances

#### Recommended separation distances between portable and mobile RF communications equipment and system

The system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the system as recommended below, according to the maximum output power of the communications equipment. Portable and mobile radio communications equipment (e.g. two-way radio, cellular/ cordless telephones and similar equipment) should be used no closer to any part of this system, including cables, than determined according to the following method:

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximu m power (W)	Distance (m)	Immunity test level (V/m)
385	380 - 390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430 -470	GMRS 460 FRS 460	FM ±5 kHz deviation 1 kHz sine	2	0.3	28
710	704 - 787	LTE Band	Pulse	0.2	0.3	9
745		13,17	modulation 217 Hz			
780	-		217 112			
810	800 - 960	GSM 800/900,	Pulse	2	0.3	28
870		tetra 800,	modulation 18 Hz			
930		iDEN 820, 18 Hz CDMA 850, LTE Band 5				
1720	1700 -1990	GSM 1800,	Pulse	2	0.3	28
1845	-	CDMA 1900,	modulation 217 Hz			
1970		GSM 1900, DECT, LTE Band 1, 3, 4, 25, UMTS	217 nz			
2450	2400 -2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240	5100 - 5800	WLAN,	Pulse	0.2	0.3	9
5500		802.11 a/n	modulation 217 Hz			
5785	1		21/11Z			

#### RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATION DEVICE AND THE SYSTEM

The system is intended for use in an electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and system as recommended below, according to the maximum output power of the communication equipment.

Rated	Separation Distance According to Frequency of Transmitter				
Maximum Output power of Transmitter (W)	150kHz -80MHz Out ISM and amateur radio bands d=1.2 √P	150kHz -80MHz in ISM and amateur radio bands d=2 √P	80MHz-800MHz d=1.2 √P	800MHz-2.7GHz d=2.3 $\sqrt{P}$	
0.01	0.12	0.2	0.12	0.23	
0.1	0.38	0.64	0.38	0.73	
1	1.2	2	1.2	2.3	
10	3.8	6.4	3.8	7.3	
100	12	20	12	23	

For transmitters at a maximum output power not listed above, the recommended separation distanced in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

If system image distortion occurs, it may be necessary to position system further from sources of conducted RF noise or to install external power source filter to minimize RF noise to an acceptable level.

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

No.	Name	Cable length (m)	Shield or not	Remarks
1.	Power input	2.5m	Not shielded	/
2.	ECG Cable	2.9m	Shielding	/
3.	ECG Lead	1.0m	Shielding	/
4.	SIP/SOP	< 3.0m	Shielding	/
5.	Probe Cable	< 3.0m	Shielding	/
6.	Footswitch Cable	2.9m	Shielding	/

Table	G-8	Cable	sample
raute	U-0	Cable	sample

## **Radio Regulatory Compliance**

RF parameter

Features	2.4GHz	5GHz
Frequency Rage	2.412 - 2.472 GHz	5.180 - 5.825 GHz
Modulation	DSSS and OFDM	OFDM
Output Power	≤20dBm	

## NOTE:

Keep a distance of at least 20cm away from the monitor when Wi-Fi function is in use.

# H Ultrasound Gel Heater

## NOTE:

Ultrasound gel heater is a system option used for heating the ultrasound gel.

# H.1 Structure



No.	Name	Description	
1.	Ultrasound gel box	Used for placing the gel.	
2.	Indicator	• The indicator is off when switching off the heater.	
		• Set the heater temperature to low; one indicator on the right becomes white.	
		• Set the heater temperature to med; two indicators on the right become white.	
		• Set the heater temperature to high; three indicators on the right become white.	
3.	Warming control switch	Open the switch to get gel heater worked. Set the temperature of the heater.	
4.	Power supply indicator	The power supply indicator becomes green after the power supply accessing.	
5.	Power supply cable	Connect to the power socket under the control panel.	
6.	Bottom cover	/	

# H.2 Specifications

- Power supply
  - Voltage: 10-20V (±5%)
  - Power consumption: 12W±10%W
- Operating conditions

- Ambient temperature: 0°C~40°C
- Relative humidity: 20%~85% (no condensation)
- Atmospheric pressure: 700hPa~1060hPa
- Storage and transportation conditions
  - Ambient temperature: -20°C~55°C
  - Relative humidity: 20%~95% (no condensation)
  - Atmospheric pressure: 700hPa~1060hPa

# H.3 Function and Requirement

### NOTE:

- When the ambient temperature is higher than the required temperature of the heater, the heater does not function.
- The heater can only heat one bottle of gel at a time.

The gel heater can make the gel reach 40°C. There are four levels for the temperature: 34°C, 37°C, 40°C and off.

When the gel is placed inside the heater, the time it takes to heat from an ambient temperature of 18°C to the desired temperature should be no more than 0.5 hours.

The ultrasound gel heater can work continuously over 12 hours.

## H.4 Install the Heater

Perform the following procedure:

1. Push the gel heater into the gel heater bracket.



- 2. Plug the gel heater into the slot lying beneath the control panel.
- 3. Put the gel inside the heater, and press the power button of the gel heater.

# Software and Hardware Specification

# I.1 Operating Environment

## Hardware Configuration

CPU: Intel X86, 2.3GHz Hard disk: 128G SSD + 1T HDD Monitor: 21.5 or 23.8 inches

## Software Environment

Windows 10, 64bit

## **Network Condition**

Cable network: 10M/100M/1000M adaption

Wireless network:

- Protocol compatible with IEEE 802.11 ac/a/b/g/n standard
- Working frequency: 2.4G/5G
- Data security/Encryption mode: WPA, WPA2

## NOTE:

The operating environment listed above is the minimum requirements for the system.

# I.2 Off-the-Shelf Software

The OTS (off-the-shelf) Software of the ultrasound system are as follows:

ltem	Description	Version/Kernel Version	Supplier	Operating Environment
Operating System	Windows 10	Windows 10	Microsoft	Windows 64bit
Database	Sqlite Database	3.6.16	Open Source	Windows 64bit
Cyber Security	McAfee	Version 8.0.2-125	McAfee	Windows 64bit

# I.3 Electronic Interface

The technical descriptions of the ultrasound system, with a wireless or wired electronic interface, are as follows:

Electronic Interface	Specification	
VGA	D-sub interface, complied with RS343 level standards.	
HDMI	<ul><li>Type A interface, complied with HDMI 2.1 standard.</li><li>Clock synchronization.</li></ul>	
Wi-Fi	<ul> <li>TCP/IP protocol bottom layer.</li> <li>DICOM/HL7 protocol application layer.</li> <li>Wireless network, complied with the IEEE 802.11 ac/a/b/g/n standard.</li> <li>NTP/SNTP Calibration protocol of TCP/IP.</li> <li>The intended information flow is from the ultrasound system in the client site to the workstation server.</li> </ul>	
USB	<ul><li>Type A interface, complied with USB 3.0 standard.</li><li>Fixed time synchronization pulse specified by the USB protocol.</li></ul>	
Network port	<ul> <li>TCP/IP protocol bottom layer.</li> <li>DICOM/HL7 protocol application layer.</li> <li>RJ45 interface, supporting wired network 10 M/100 M/1000 M, and complied with IEEE802.3 technical standard.</li> <li>NTP/SNTP Calibration protocol of TCP/IP.</li> <li>The intended information flow is from the ultrasound system in the client site to the workstation server.</li> </ul>	
S-Video	4-core 2-component separate video interface.	
ECG	<ul> <li>Mindray ECG interface, using USB communication, and complied with Mindray internal standard.</li> <li>Time stamp of packet definition.</li> </ul>	
PCG	Mindray PCG interface, complied with Mindray internal standard.	
MIC	3.5 mm interface, used for transmitting analog signal, and complied with CTIA international standard.	

# I.4 Wireless Specification

The wireless QoS (Quality of Service) related parameters are as follows:

No.	ltem	Specifications
1.	Data rate	802.11a: up to 54 Mbps @ 5 GHz
		802.11b: up to 11 Mbps @ 2.4 GHz
		802.11g: up to 54 Mbps @ 2.4 GHz
		802.11n: up to 300 Mbps @ 2.4 GHz and 5 GHz
2.	Data security	WEP/WPA/WPA2

No.	ltem	Specifications
3.	Vision Distance Communications	<ul> <li>The ultrasound diagnostic system can be connected within 3 meters of the wireless network, and the system can perform the following operations and realize its intended use:</li> <li>Support DICOM transferring patient data through the wireless network (Wi-Fi).</li> <li>Support the remote network storage of patient data to the PC server (iStorage).</li> <li>Support MedSight, the interaction between the ultrasound system and mobile terminal, the ultrasound</li> </ul>
4.	Application-layer delay	data management, and data query and browsing.
5.	Application-layer reliability	If the connection fails, the user will be prompted by the Wi-Fi icon.
6.	System capacity	When the ultrasound system is used as the hotspot AP, no more than 1 access device is allowed.
7.	System anti-interference	It is allowed to coexist with multiple Wi-Fi devices.
8.	Network interruption alarm	<ul> <li>Wireless signal not connected</li> <li>Strong wireless signal</li> <li>Normal wireless signal</li> <li>Weak wireless signal</li> <li>If DICOM or other data transfer fails, a window will pop up for alarm and LOG recording.</li> </ul>
9.	Coexist & EMC test process	Wi-Fi function is not affected when the system is imposed with radiation interference complied with AAMI TIR69:2017 &IEC60601-1-2:2014 standard.

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N= new indication; P= previously cleared by FDA;
Additional comments: Combined modesB+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.
*Intraoperative includes abdominal, thoracic, and vascular.
**Small organ-breast, thyroid, testes.
***Other use includes Urology.
Note 1: Tissue Harmonic Imaging.
Note 2: Smart 3D
Note 3:4D(Real-time 3D)
Note 4: iScape View
Note 5: TDI
Note 6: Color M
Note 7: Strain Elastography
Note 8: Contrast imaging (Contrast agent for LVO)
Note 9: V Flow
Note10: STE
Note11: STQ
Note12: Contrast imaging (Contrast agent for Liver)

Intended Use:	Diagnostic ultrasound ima	iging	or flu	uid flov	v analy	sis of the	human bo	dy as follow	/s:
Clinical				Мо	de of (	Operation			
Application									
General(Track 1	Specific (Track 1 & 3)	В	Μ	PWD	CWD	Color	Amplitude	Combined	Other (Specify)
Only)						Doppler	Doppler	(specify)	
Ophthalmic	Ophthalmic								
Fetal Imaging &	Fetal	Ρ	Р	Р	Р	Р	Р	Р	Note 1, 2,3, 4,
Other									5, 6
	Abdominal	Ρ	Р	Р	Р	Р	Р	Р	Note 1, 2, 3,4,
									6, 10,11,12
	Intra-operative (Specify*)	Ρ	Ρ	Р		Р	Р	Р	Note1,2,4,6,7
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	Ρ	Р	Р	Р	Р	Р	Р	Note 1, 2,3,4, 6

	Small Organ (Specify**)	Р	Р	Р	Р	Р	Р	Р	Note
	ennan organ (opeeniy )		· ·			•			1,2,3,4,6,7,10,
									11
	Neonatal Cephalic	Р	Р	Р	Р	Р	Р	Р	Note 1, 2, 4,6
	Adult Cephalic	Р	Р	Р	Р	Р	Р	Р	Note 1, 2, 4, 6
	Trans-rectal	Р	Р	Ρ		Р	Р	Р	Note 1, 2, 3,4, 6, 7, 10,11
	Trans-vaginal	Р	Р	Ρ		Р	Р	Р	Note 1, 2, 3,4, 6, 7,10,11
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	Ρ	Ρ	Ρ	Р	Р	Р	Р	Note 1, 2, 4, 6, 7,10,11
	Musculo-skeletal (Superficial)	Р	Р	Ρ	Р	Р	Р	Р	Note 1, 2, 4,6, 7,10,11
	Intravascular								
Cardiac	Cardiac Adult	Р	Р	Ρ	Р	Р	Р	Р	Note 1, 2, 4, 5, 6,8
	Cardiac Pediatric	Ρ	Р	Ρ	Р	Р	Р	Р	Note 1, 2, 4, 5, 6
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)	Р	Р	Р	Р	Р	Р	Р	Note 1,5,6
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	Р	Р	Ρ	Р	Р	Р	Р	Note 1, 2,3,4, 6, 7,9,10,11
	Other (Specify***)	Р	Р	Ρ	N	Р	Р	Р	Note 1, 2, 3,4, 6, 7,10,11

Transducer:	C5-1U								
Intended Use:	Diagnostic ultrasound ima	iging	or flu	uid flov	v analy	sis of the	e human bo	dy as follow	/S:
Clinical				Мо	de of (	Operation	1		
Application							-		
	Specific (Track 1 & 3)	В	М	PWD	CWD	-			Other (Specify)
Only)						Doppler	Doppler	(specify)	
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	Ρ	Ρ	Р		Р	Р	Р	Note 1, 2, 4, 6
	Abdominal	Р	Р	Р		Р	Р	Р	Note 1, 2, 4, 6,10,11,12
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal	Ρ	Р	Р		Р	Р	Р	Note 1, 2, 4, 6
	(Conventional)								
	Musculo-skeletal								
	(Superficial)								
	Intravascular								

Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
Peripheral vessel	Peripheral vessel	Р	Р	Ρ	Р	Р	Р	Note 1, 2, 4, 6
	Other (Specify***)	Ρ	Р	Р	Р	Р	Р	Note 1, 2, 4, 6

Transducer:	SC8-2U											
Intended Use:	Diagnostic ultrasound ima	iging	or flu	uid flov	v analy	sis of the	e human bo	dy as follow	/S:			
Clinical				Мо	de of (	Operation	1					
Application					1			r	•			
	Specific (Track 1 & 3)	В	М	PWD	CWD				Other (Specify)			
Only)						Doppler	Doppler	(specify)				
Ophthalmic	Ophthalmic											
5 5 5	Fetal	Ρ	Ρ	Р	Ν	Р	Р	Р	Note 1, 2, 4, 5,			
Other									6			
	Abdominal	Ρ	Ρ	Р	N	Р	Р	Р	Note 1, 2, 4, 6, 12			
	Intra-operative (Specify*)											
	Intra-operative (Neuro)											
	Laparoscopic											
	Pediatric											
	Small Organ (Specify**)											
	Neonatal Cephalic											
	Adult Cephalic											
	Trans-rectal											
	Trans-vaginal											
	Trans-urethral											
	Trans-esoph. (non-Card.)											
	Musculo-skeletal (Conventional)											
	Musculo-skeletal (Superficial)											
	Intravascular											
Cardiac	Cardiac Adult											
Cardiac	Cardiac Adult Cardiac Pediatric											
	Intravascular (Cardiac)											
	Trans-esoph. (Cardiac)											
	Intra-cardiac											
Peripheral vessel	Peripheral vessel	Ρ	Ρ	Р		Р	Р	Р	Note 1, 2, 4, 6			
	Other (Specify***)	Ρ	Ρ	Р	Ν	Р	Р	Р	Note 1, 2, 4, 6			

Transducer:	V11-3HU										
Intended Use:	Diagnostic ultrasound ima	aging	or fl	uid flov	v analy	sis of the	human bo	dy as follow	'S:		
Clinical				Мо	de of (	Operation					
Application											
General (Track 1	Specific (Track 1 & 3)	pecific (Track 1 & 3)   B   M   PWD   CWD   Color   Amplitude   Combined   Other (Specify)									
Only)						Doppler	Doppler	(specify)			
Ophthalmic	Ophthalmic										
Fetal Imaging &	Fetal	Р	Р	Р		Р	Р	Р	Note 1, 2, 4, 6		
Other											
	Abdominal										

	Intra-operative (Specify*)							
	Intra-operative (Neuro)							
	,							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify**)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	Р	Р	Р	Р	Р	Р	Note 1, 2, 4, 6,7,10,11
	Trans-vaginal	Р	Р	Ρ	Р	Р	Р	Note 1, 2, 4, 6, 7,10,11
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal							
	(Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
Peripheral vessel	Peripheral vessel							
	Other (Specify***)	Ρ	Р	Р	Р	Р	Р	Note 1, 2, 4, 6, 7,10,11

Transducer:	D8-4U								
Intended Use:	Diagnostic ultrasound ima	iging	or flu	uid flov	v analy	sis of the	e human bo	dy as follow	/S:
Clinical				Мо	de of (	Operation	1		
Application									
	Specific (Track 1 & 3)	В	М	PWD	CWD				Other (Specify)
Only)						Doppler	Doppler	(specify)	
Ophthalmic	Ophthalmic								
Fetal Imaging &	Fetal	Ρ	Р	Р		Р	Р	Р	Note 1, 3, 4, 5,
Other									6
	Abdominal	Ρ	Ρ	Р		Р	Р	Р	Note 1, 3, 4, 6,12
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
-	Pediatric								
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								

	Intravascular				
Cardiac	Cardiac Adult				
	Cardiac Pediatric				
	Intravascular (Cardiac)				
	Trans-esoph. (Cardiac)				
	Intra-cardiac				
Peripheral vessel	Peripheral vessel				
	Other (Specify***)				

Transducer:	DE10-3U								
Intended Use:	Diagnostic ultrasound ima	iging	or fl	uid flov	v analy	sis of the	e human bo	dy as follow	/S:
Clinical				Мо	de of (	Operation	1		
Application									
	Specific (Track 1 & 3)	В	М	PWD	CWD				Other (Specify)
Only)						Doppler	Doppler	(specify)	
Ophthalmic	Ophthalmic								
Fetal Imaging &	Fetal	Ρ	Ρ	Р		Р	Р	Р	Note 1, 3, 4, 6
Other	Abdominal								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	Ρ	Р	Р		Р	Р	Р	Note 1, 3, 4, 6, 7
	Trans-vaginal	Ρ	Р	Р		Р	Р	Р	Note 1, 3, 4, 6, 7
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult			1					
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)			1	1				
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)	Ρ	Р	Р		Р	Р	Р	Note 1, 3, 4, 6, 7

Transducer:	L14-6WU									
Intended Use:	Diagnostic ultrasound ima	aging	or flu	uid flov	v analy	sis of the	human bo	dy as follow	/s:	
Clinical		Mode of Operation								
Application		·								
General (Track 1	Specific (Track 1 & 3)	В	Μ	PWD	CWD	Color	Amplitude	Combined	Other (Specify)	
Only)		Doppler Doppler (specify)								
Ophthalmic	Ophthalmic									

Fetal Imaging &	Fetal							
Other								
	Abdominal	Ρ	Р	Р	Р	Р	Р	Note 1, 2, 4
	Intra-operative (Specify*)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	Ρ	Р	Р	Р	Р	Р	Note 1, 2, 4
	Small Organ (Specify**)	Ρ	Ρ	Ρ	Р	Р	Р	Note 1, 2, 4,7,10,11
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal	Ρ	Р	Р	Р	Р	Р	Note 1, 2,
	(Conventional) Musculo-skeletal	Р	Р	Р	Р	P	P	4,7,10,11 Note 1, 2,
	(Superficial)	Р	Р	Р	Р	P	P	4,7,10,11
	Intravascular							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							1
Peripheral	Peripheral vessel	Ρ	Р	Р	Р	Р	Р	Note 1, 2, 4
vessel	Other (Specify***)							

Transducer:	L11-3U								
Intended Use:	Diagnostic ultrasound ima	iging	or fl	uid flov	v analy	sis of the	e human bo	dy as follow	/S:
Clinical Application				Мо	de of (	Operation	I		
General (Track 1 Only)	Specific (Track 1 & 3)	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	Ρ	Ρ	Р	Р	Р	Р	Р	Note 1, 2, 4
-	Abdominal	Ρ	Ρ	Р	Р	Р	Р	Р	Note 1, 2, 4, 12
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	Ρ	Ρ	Р	Р	Р	Р	Р	Note 1, 2, 4
	Small Organ (Specify**)	Ρ	Р	Р	Р	Р	Р	Р	Note 1,2,4,7,10,11
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	Ρ	Р	Р	Р	Р	Р	Р	Note 1,2,4,7,10,11

	Musculo-skeletal	Р	Р	Р	Р	Р	Р	Р	Note
	(Superficial)								1,2,4,7,10,11
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	Р	Р	Р	Р	Р	Р	Р	Note 1, 2, 4, 9
	Other (Specify***)				1				

Transducer:	SP5-1U											
Intended Use:	Diagnostic ultrasound ima	iging	or flu	uid flov	v analy	sis of the	e human bo	dy as follow	/S:			
Clinical				Мо	de of (	Operation	1					
Application												
•	Specific (Track 1 & 3)	В	Μ	PWD	CWD		Amplitude		Other (Specify)			
Only)						Doppler	Doppler	(specify)				
Ophthalmic	Ophthalmic											
Fetal Imaging &	Fetal											
Other	Abdominal	Р	Р	Р	Р	Р	Р	Р	Note 1, 2, 4,6			
		Г	F	Г	г	Г	F	F	Note 1, 2, 4,0			
	Intra-operative (Specify*)											
	Intra-operative (Neuro)											
	Laparoscopic											
	Pediatric											
	Small Organ (Specify**)											
	Neonatal Cephalic											
	Adult Cephalic	Р	Р	Р	Р	Р	Р	Р	Note 1, 2, 4,6			
	Trans-rectal											
	Trans-vaginal											
	Trans-urethral											
	Trans-esoph. (non-Card.)											
	Musculo-skeletal (Conventional)											
	Musculo-skeletal (Superficial)											
	Intravascular											
Cardiac	Cardiac Adult	Ρ	Ρ	Р	Р	Р	Р	Р	Note 1, 2, 4, 5, 6,8			
	Cardiac Pediatric	Ρ	Р	Р	Р	Р	Р	Р	Note 1, 2, 4, 5, 6			
	Intravascular (Cardiac)											
	Trans-esoph. (Cardiac)		<u> </u>									
<u> </u>	Intra-cardiac											
Peripheral	Peripheral vessel											
vessel												
	Other (Specify***)											

Transducer:	SC6-1U										
Intended Use:	Diagnostic ultrasound ima	aging	or flu	uid flov	v analy	sis of the	human bo	dy as follow	s:		
Clinical		Mode of Operation									
Application		·									
General (Track 1	Specific (Track 1 & 3)	В	Μ	PWD	CWD	Color	Amplitude	Combined	Other (Specify)		
Only)						Doppler	Doppler	(specify)			

Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	Ρ	Ρ	Ρ	N	Р	Р	Р	Note 1, 2, 4, 5
	Abdominal	Р	Р	Р	N	Р	Р	Р	Note 1, 2,
									4,6,10,11,12
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal	Р	Р	Р		Р	Р	Р	Note 1, 2, 4,6
	(Conventional)								
	Musculo-skeletal								
	(Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral	Peripheral vessel	Ρ	Ρ	Ρ		Р	Р	Р	Note 1, 2, 4,6
vessel	Other (Specify***)	Р	Р	Р	N	Р	Р	Р	Note 1, 2, 4,6

Transducer:	SC5-1U								
Intended Use:	Diagnostic ultrasound ima	aging	or fl	uid flov	v analy	sis of the	e human bo	dy as follow	/S:
Clinical				Мо	de of (	Operation	l		
Application									
•	Specific (Track 1 & 3)	В	М	PWD	CWD	-	Amplitude		Other (Specify)
Only)	<b>•</b> • • • • •					Doppler	Doppler	(specify)	
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	Ρ	Р	Р		Р	Р	Р	Note 1, 2, 4, 5, 6
	Abdominal	Ρ	Ρ	Р		Р	Р	Р	Note 1, 2, 4,6,10,11,12
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	Ρ	Ρ	Р		Р	Р	Р	Note 1, 2, 4,6

	Musculo-skeletal							
	(Superficial)							
	Intravascular							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
Peripheral	Peripheral vessel	Р	Р	Р	Р	Р	Р	Note 1, 2, 4,6
vessel								
	Other (Specify***)	Р	Р	Р	Р	Р	Р	Note 1, 2, 4,6

Transducer:	L20-5U								
Intended Use:	Diagnostic ultrasound ima	iging	or fl	uid flov	v analy	sis of the	e human bo	dy as follow	'S:
Clinical				Мо	de of (	Operation	1		
Application								- ·· ·	
	Specific (Track 1 & 3)	В	М	PWD	CWD				Other (Specify)
Only)						Doppler	Doppler	(specify)	
Ophthalmic	Ophthalmic								
Fetal Imaging &	Fetal								
Other	Abdominal	Р	Р	Р	Р	Р	Р	Р	Note 1, 2, 4
	Intra-operative (Specify*)	Г					F	Г	11010 1, 2, 4
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)	Ρ	Ρ	Р	Р	Р	Р	Р	Note 1, 2, 4,7,10,11
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	Ρ	Ρ	Р	Р	Р	Р	Р	Note 1, 2, 4,7,10,11
	Musculo-skeletal (Superficial)	Ρ	Ρ	Р	Р	Р	Р	Р	Note 1, 2, 4,7,10,11
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac		<u> </u>						
Peripheral vessel	Peripheral vessel	Ρ	Ρ	Р	Р	Р	Р	Р	Note 1, 2, 4,10,11
	Other (Specify***)								

Transducer:	L9-3U										
Intended Use:	Diagnostic ultrasound ima	aging	or flu	uid flov	/ analy	sis of the	e human bo	dy as follow	s:		
Clinical				Мо	de of (	Operation					
Application											
General(Track 1	Specific(Track 1 & 3)	В	М	PWD	CWD	Color	Amplitude	Combined	Other (specify)		
Only)						Doppler	Doppler	(specify)			
Ophthalmic	Ophthalmic										

Fetal Imaging &	Fetal	Р	Р	Р	Р	Р	Р	Р	Note 1,2, 4
Other						_	_	_	
	Abdominal	Ρ	Ρ	Р	Р	Р	Р	Р	Note 1,2,
									4,10,11,12
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	Р	Р	Р	Р	Р	Р	Р	Note 1,2, 4
	Small Organ (Specify**)	Ρ	Ρ	Ρ	Р	Р	Р	Р	Note 1,2, 4,7,10,11
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	Р	Р	Р	Р	Р	Р	Р	Note 1,2, 4,7,10,11
	Musculo-skeletal (Superficial)	Ρ	Ρ	Ρ	Р	Р	Р	Р	Note 1,2, 4,7,10,11
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral	Peripheral vessel	Ρ	Ρ	Р	Р	Р	Р	Р	Note 1,2,
vessel									4,7,9,10,11
	Other (Specify***)								

Transducer:	L14-5WU								
Intended Use:	Diagnostic ultrasound ima	aging	or flu	uid flov	v analy	sis of the	human bo	dy as follow	/S:
Clinical Application				Мо	de of (	Operation			
General (Track 1 Only)	Specific (Track 1 & 3)	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	Ρ	Ρ	Р	Р	Р	Р	Р	Note 1, 2, 4,12
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	Ρ	Ρ	Р	Р	Р	Р	Р	Note 1, 2, 4
	Small Organ (Specify**)	Ρ	Р	Р	Р	Р	Р	Р	Note 1, 2, 4, 7,10,11
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								

	Musculo-skeletal	Р	Р	Р	Р	Р	Р	Р	Note 1, 2, 4,
	(Conventional)								7,10,11
	Musculo-skeletal	Р	Р	Р	Р	Р	Р	Р	Note 1, 2, 4,
	(Superficial)								7,10,11
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral	Peripheral vessel	Р	Р	Р	Р	Р	Р	Р	Note 1, 2, 4,
vessel									7,10,11
	Other (Specify***)								

Transducer:	P10-4U								
Intended Use:	Diagnostic ultrasound ima	iging	or fl	uid flov	v analy	sis of the	e human bo	dy as follow	/S:
Clinical				Мо	de of (	Operation	1		
Application									
	Specific (Track 1 & 3)	В	М	PWD	CWD		-		Other (Specify)
Only)						Doppler	Doppler	(specify)	
Ophthalmic	Ophthalmic								
00	Fetal								
Other	Abdominal	Р	Р	Р	Р	Р	Р	Р	Note 1, 2, 4, 6
		Г	Г	Г	г	Г	F	F	Note 1, 2, 4, 0
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	Ρ	Р	Р	Р	Р	Р	Р	Note 1, 2, 4, 6
	Small Organ (Specify**)								
	Neonatal Cephalic	Р	Р	Р	Р	Р	Р	Р	Note 1, 2, 4, 6
	Adult Cephalic	Р	Р	Р	Р	Р	Р	Р	Note 1, 2, 4, 6
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal								
	(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult	Р	Р	Р	Р	Р	Р	Р	Note 1, 2, 4, 5,
Cardiac		г		Г	F	Г	Г	Г	6
	Cardiac Pediatric	Ρ	Ρ	Р	Р	Р	Р	Р	Note 1, 2, 4, 5, 6
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral	Peripheral vessel								
vessel									
	Other (Specify***)								

Transducer:	C6-2GU
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:
Clinical	Mode of Operation
Application	

General (Track 1	Specific (Track 1 & 3)	В	М	PWD	CWD	Color	Amplitude	Combined	Other (Specify)
Only)						Doppler	Doppler	(specify)	
Ophthalmic	Ophthalmic								
Fetal Imaging &	Fetal	Р	Р	Р		Р	Р	Р	Note1,2,4,6
Other			_						
	Abdominal	Ρ	Р	Р		Р	Р	Р	Note1,2,4,6,10 11,12
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
-	Pediatric	Ρ	Р	Р		Р	Р	Р	Note1,2,4,6
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal								
	(Conventional)								
	Musculo-skeletal (Superficial)								
	(Superiiciai) Intravascular								
Cardiac	Cardiac Adult								
Caldiac	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral	Peripheral vessel								
vessel	r enpiteral vesser								
	Other (Specify***)	Р	Р	Р		Р	Р	Р	Note1,2,4,6

Transducer:	C11-3U								
Intended Use:	Diagnostic ultrasound ima	aging	or flu	uid flov	v analy	sis of the	e human bo	dy as follow	'S:
Clinical				Мо	de of (	Operation			
Application									
	Specific (Track 1 & 3)	В	М	PWD	CWD	-	Amplitude		Other (Specify)
Only)						Doppler	Doppler	(specify)	
Ophthalmic	Ophthalmic								
Fetal Imaging &	Fetal								
Other									
	Abdominal	Р	Р	Р		Р	Р	Р	Note 1, 2,
									4,6,12
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	Р	Р	Р		Р	Р	Р	Note 1, 2, 4,6
	Small Organ (Specify**)								
	Neonatal Cephalic	Ρ	Р	Р		Р	Р	Р	Note 1, 2, 4,6
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								

	Musculo-skeletal							
	(Conventional)							
	Musculo-skeletal							
	(Superficial)							
	Intravascular							
Cardiac	Cardiac Adult	Р	Р	Р	Р	Р	Р	Note 1, 2, 4,6
	Cardiac Pediatric	Р	Р	Р	Р	Р	Р	Note 1, 2, 4,6
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
Peripheral	Peripheral vessel	Р	Р	Р	Р	Р	Р	Note 1, 2, 4,6
vessel								
	Other (Specify***)							

Transducer:	P7-3U								
Intended Use:	Diagnostic ultrasound ima	iging	or fl	uid flov	v analy	sis of the	e human bo	dy as follow	/s:
Clinical				Мо	de of (	Operation	1		
Application									
	Specific (Track 1 & 3)	В	М	PWD	CWD				Other (Specify)
Only)						Doppler	Doppler	(specify)	
Ophthalmic	Ophthalmic								
5 5 5	Fetal								
Other	Abdominal	Р	Р	Р	Р	Р	Р	Р	Note 1, 2,4,6
	Intra-operative (Specify*)		•		•	•			1010 1, 2,4,0
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	Ρ	Р	Р	Р	Р	Р	Р	Note 1, 2,4,6
	Small Organ (Specify**)								
	Neonatal Cephalic	Ρ	Р	Р	Р	Р	Р	Р	Note 1, 2,4,6
	Adult Cephalic	Ρ	Р	Р	Р	Р	Р	Р	Note 1, 2,4,6
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	Ρ	Р	Р	Р	Р	Р	Р	Note 1, 2,4,6
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult	Ρ	Ρ	Р	Р	Р	Р	Р	Note 1, 2,4,5,6
	Cardiac Pediatric	Ρ	Ρ	Р	Р	Р	Р	Р	Note 1, 2,4,5,6
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac			1	1				
Peripheral	Peripheral vessel						ĺ		
vessel									
	Other (Specify***)								

Transducer:	P7-3TU
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:
Clinical	Mode of Operation
Application	

General (Track 1	Specific (Track 1 & 3)	В	М	PWD	CWD	Color	Amplitude	Combined	Other (Specify
Only)						Doppler	Doppler	(specify)	
Ophthalmic	Ophthalmic								
Fetal Imaging &	Fetal								
Other									
	Abdominal								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)	Ρ	Ρ	Р	Р	Р	Р	Р	Note 1,5,6
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)								

Transducer:	P7-3Ts								
Intended Use:	Diagnostic ultrasound ima	aging	or fl	uid flov	v analy	sis of the	e human bo	dy as follow	/S:
Clinical Application				Мо	de of (	Operation			
General (Track 1 Only)	Specific (Track 1 & 3)	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								

	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)	Р	Р	Р	Р	Р	Р	Р	Note 1,5,6
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)								

Transducer:	L16-4HU								
Intended Use:	Diagnostic ultrasound ima	iging	or fl	uid flov	v analy	sis of the	e human bo	dy as follow	'S:
Clinical Application				Мо	de of (	Operation			
General (Track 1 Only)	Specific (Track 1 & 3)	В	М	PWD	CWD	Color Doppler	-	Combined (specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	Ρ	Ρ	Р		Р	Р	Р	Note1,2,4
	Intra-operative (Specify*)	Ρ	Р	Р		Р	Р	Р	Note1,2,4,7
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	Ρ	Ρ	Р		Р	Р	Р	Note1,2,4
-	Small Organ (Specify**)	Ρ	Ρ	Р		Р	Р	Р	Note1,2,4,7
	Neonatal Cephalic	Ρ	Ρ	Р		Р	Р	Р	Note1,2,4
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	Ρ	Р	Р		Р	Р	Р	Note1,2,4,7
	Musculo-skeletal (Superficial)	Ρ	Ρ	Р		Р	Р	Р	Note1,2,4,7
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	Ρ	Р	Р		Р	Р	Р	Note1,2,4,7
	Other (Specify***)								

Transducer:	L16-4Hs										
Intended Use:	Diagnostic ultrasound ima	aging	or flu	uid flov	v analy	sis of the	e human bo	dy as follow	S:		
Clinical				Мо	de of (	Operation					
Application											
General (Track 1	Specific (Track 1 & 3)	Specific (Track 1 & 3)   B   M   PWD   CWD   Color   Amplitude   Combined   Other (Specify)									
Only)						Doppler	Doppler	(specify)			
Ophthalmic	Ophthalmic										
Fetal Imaging &	etal										
Other											

	Abdominal	Р	Р	Р		Р	Р	Р	Note1,2,4
	Intra-operative (Specify*)	Ρ	Ρ	Ρ		Р	Р	Р	Note1,2,4,7
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	Ρ	Р	Р		Р	Р	Р	Note1,2,4
	Small Organ (Specify**)	Ρ	Р	Р		Р	Р	Р	Note1,2,4,7
	Neonatal Cephalic	Р	Р	Р		Р	Р	Р	Note1,2,4
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	Ρ	Р	Р		Р	Р	Р	Note1,2,4,7
	Musculo-skeletal	Р	Р	Р		Р	P	Р	Note1,2,4,7
	(Superficial)	-	-	-			-		,,,,,,
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								1
Peripheral vessel	Peripheral vessel	Ρ	Р	Р		Р	Р	Р	Note1,2,4,7
	Other (Specify***)								

Transducer:	C4-1U												
Intended Use:	Diagnostic ultrasound ima	iging	or fl	uid flov	v analy	sis of the	e human bo	dy as follow	/s:				
Clinical				Мс	de of (	Operation	ı						
Application			_			-							
•	Specific (Track 1 & 3)	В	М	PWD	CWD	-			Other (Specify				
Only)						Doppler	Doppler	(specify)					
Ophthalmic	Ophthalmic												
Fetal Imaging & Other	Fetal	Ρ	Ρ	Р		Р	Р	Р	Note 1, 2, 4,6				
	Abdominal	Ρ	Ρ	Р		Р	Р	Р	Note 1, 2, 4,6,10,11,12				
	Intra-operative (Specify*)												
	Intra-operative (Neuro)												
	Laparoscopic												
	Pediatric	Ρ	Ρ	Р		Р	Р	Р	Note 1, 2, 4,6				
	Small Organ (Specify**)												
	Neonatal Cephalic												
	Adult Cephalic												
	Trans-rectal												
	Trans-vaginal												
	Trans-urethral												
	Trans-esoph. (non-Card.)												
	Musculo-skeletal (Conventional)	Ρ	Ρ	Р		Р	P	Р	Note 1, 2, 4,6				
	Musculo-skeletal (Superficial)												
	Intravascular												
Cardiac	Cardiac Adult	Ρ	Р	Р		Р	Р	Р	Note 1, 2, 4,6				

	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
Peripheral vessel	Peripheral vessel	Р	Р	Ρ	Р	Р	Р	Note 1, 2, 4,6
	Other (Specify***)	Ρ	Р	Р	Р	Р	Р	Note 1, 2, 4,6

	DE10-3WU								
Intended Use:	Diagnostic ultrasound ima	aging	or fl	uid flov	v analy	sis of the	e human bo	dy as follow	/s:
Clinical				Мо	de of (	Operation	1		
Application									
	Specific (Track 1 & 3)	В	М	PWD	CWD				Other (Specify
Only)						Doppler	Doppler	(specify)	
Ophthalmic	Ophthalmic	-							
Fetal Imaging &	Fetal	Ρ	Ρ	Р		Р	Р	Р	Note 1, 3,4,6
Other	Abdominal								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	Ρ	Р	Р		Р	Р	Р	Note 1, 3,4,6,7,10,11
	Trans-vaginal	Р	Р	Р		Р	Р	Р	Note 1,
									3,4,6,7,10,11
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal								
	(Conventional)								
	Musculo-skeletal								
	(Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac		-						
Peripheral	Peripheral vessel								
vessel									
	Other (Specify***)	Ρ	Р	Р		Р	Р	Р	Note 1, 3,4,6,7,10,11

Transducer:	D8-2U										
Intended Use:	Diagnostic ultrasound ima	aging	or flu	uid flov	v analy	sis of the	human bo	dy as follow	'S:		
Clinical				Мо	de of C	Operation					
Application											
General (Track 1	Specific (Track 1 & 3)	Specific (Track 1 & 3)   B   M   PWD   CWD   Color   Amplitude   Combined   Other (Specify)									
Only)						Doppler	Doppler	(specify)			
Ophthalmic	Ophthalmic										
Fetal Imaging &	Fetal	tal P P P P P P P Note 1, 3, 4, 5,									
Other	6										

	Abdominal	Ρ	Р	Р	Р	Р	Р	Note 1, 3, 4, 6,
								12
	Intra-operative (Specify*)							
	Intra-operative (Neuro)							
	Laparoscopic							-
	Pediatric							
	Small Organ (Specify**)							
	Neonatal Cephalic							
	Adult Cephalic				-		-	
	Trans-rectal							_
	Trans-vaginal							_
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
Peripheral vessel	Peripheral vessel							
	Other (Specify***)							

Transducer:	CW5s								
Intended Use:	Diagnostic ultrasound ima	iging	or fl	uid flov	v analy	sis of the	e human bo	dy as follow	/S:
Clinical				Мо	de of (	Operation			
Application									
•	Specific (Track 1 & 3)	В	М	PWD	CWD	-			Other (Specify)
Only)						Doppler	Doppler	(specify)	
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric				Р				
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic				Р				
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal								
	(Conventional)								
	Musculo-skeletal								
	(Superficial)								
	Intravascular								
Cardiac	Cardiac Adult				Р				

	Cardiac Pediatric		Р		
	Intravascular (Cardiac)				
	Trans-esoph. (Cardiac)				
	Intra-cardiac				
Peripheral vessel	Peripheral vessel		Р		
	Other (Specify***)				

Transducer:	CW2s								
Intended Use:	Diagnostic ultrasound ima	iging	or fl	uid flov	v analy	sis of the	e human bo	dy as follow	'S:
Clinical Application				Мо	de of (	Operatior			
General (Track 1 Only)	Specific (Track 1 & 3)	В	М	PWD	CWD	Color Doppler	-	Combined (specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
-	Abdominal								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric				Р				
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic				Р				
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult				Р				
	Cardiac Pediatric				Р				
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)								

Transducer:	ELC13-4U											
Intended Use:	Diagnostic ultrasound ima	iging	or flu	uid flov	v analy	sis of the	human bo	dy as follow	S:			
Clinical	4			Мо	de of (	Operation						
Application												
General (Track 1	Specific (Track 1 & 3)											
Only)	Doppler Doppler (specify)											
Ophthalmic	Ophthalmic											
Fetal Imaging &	Fetal											
Other												
	Abdominal											
	Intra-operative (Specify*)											
	Intra-operative (Neuro)	ntra-operative (Neuro)										

1	Laparoscopic							
	Pediatric							
	Small Organ (Specify**)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	Ρ	Р	Р	Р	Р	Р	Note 1,2,4,6,7,10,11
	Trans-vaginal	N	N	N	N	N	N	Note 1,2,4,6,7,10,11
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
Peripheral vessel	Peripheral vessel							
	Other (Specify***)	Ρ	Р	Ρ	Р	Р	Р	Note 1,2,4,6,7,10

Transducer:	L14-3WU											
Intended Use:	Diagnostic ultrasound ima	iging	or fl	uid flov	v analy	sis of the	e human bo	dy as follow	/S:			
Clinical				Мо	de of (	Operatior	1					
Application												
•	Specific (Track 1 & 3)	В	М	PWD	CWD	-			Other (Specify			
Only)	<b>•</b> • • • • •					Doppler	Doppler	(specify)				
Ophthalmic	Ophthalmic											
Fetal Imaging & Other												
	Abdominal	Ρ	Р	Р	Ν	Р	Р	Р	Note 1,2,4,12			
	Intra-operative (Specify*)											
	Intra-operative (Neuro)											
	Laparoscopic											
	Pediatric	Р	Р	Р	Ν	Р	Р	Р	Note 1,2,4			
	Small Organ (Specify**)	Ρ	Ρ	Р	N	Р	Р	Р	Note 1,2,4,7,10,11			
	Neonatal Cephalic											
	Adult Cephalic											
	Trans-rectal											
	Trans-vaginal											
	Trans-urethral											
	Trans-esoph. (non-Card.)											
	Musculo-skeletal (Conventional)	Ρ	Р	Р	N	Р	Р	Р	Note 1,2,4,7,10,11			
	Musculo-skeletal (Superficial)	Ρ	Ρ	Р	N	Р	Р	Р	Note 1,2,4,7,10,11			
	Intravascular											

Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	Р	Р	Р	N	Р	Р	Р	Note 1,2,4,7,9,10,11
	Other (Specify***)								

Transducer:	P8-3Ts								
Intended Use:	Diagnostic ultrasound ima	iging	or fl	uid flov	v analy	sis of the	e human bo	dy as follow	/s:
Clinical Application				Мо	de of (	Operatior			
General (Track 1 Only)	Specific (Track 1 & 3)	В	М	PWD	CWD	Color Doppler		Combined (specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)	Ν	Ν	Ν	Ν	N	N	Ν	Note 1,5,6
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)								

Transducer:	C6-2Gs										
Intended Use:	Diagnostic ultrasound ima	aging	or flu	uid flov	v analy	sis of the	human bo	dy as follow	'S:		
Clinical				Мо	de of (	Operation					
Application											
General (Track 1	Specific (Track 1 & 3)	В	Μ	PWD	CWD	Color	Amplitude	Combined	Other (Specify)		
Only)						Doppler	Doppler	(specify)			
Ophthalmic	Ophthalmic										
Fetal Imaging &	Fetal	al P P P P P P Note 1,2,4,6									
Other											

	Abdominal	Ρ	Р	Р	Р	Р	Р	Note 1,2,4,6,10,11,1
	Intra-operative (Specify*)							2
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	Ρ	Р	Р	Р	Р	Р	Note 1,2,4,6
	Small Organ (Specify**)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral			-				
	Trans-esoph. (non-Card.)							
	Musculo-skeletal							
	(Conventional)							
	Musculo-skeletal							
	(Superficial)							
	Intravascular							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
Peripheral vessel	Peripheral vessel							
	Other (Specify***)	Ρ	Р	Р	Р	Р	Р	Note 1,2,4,6

7LT4s												
Diagnostic ultrasound ima	iging	or flu	uid flov	v analy	sis of the	e human bo	dy as follow	/S:				
			Мо	de of (	Operation							
Specific (Track 1 & 3)	В	М	PWD	CWD	Color	Amplitude	Combined	Other (Specify)				
					Doppler	Doppler	(specify)					
Ophthalmic												
Fetal		l										
Abdominal	Ρ	Р	Р		Р	Р	Р	Note 1,2,4				
Intra-operative (Specify*)	Ρ	Р	Р		Р	Р	Р	Note 1,2,4,7				
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	Ρ	Р	Р		Р	Р	Р	Note 1,2,4				
Small Organ (Specify**)	Ρ	Р	Р		Р	Р	Р	Note 1,2,4,7				
Neonatal Cephalic	Ρ	Р	Р		Р	Р	Р	Note 1,2,4				
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal	Р	Р	Р		Р	Р	Р	Note 1,2,4,7				
(Conventional)								, , . , .				
, Musculo-skeletal	Р	Р	Р		Р	Р	Р	Note 1,2,4,7				
(Superficial)								,				
Intravascular												
	Diagnostic ultrasound ima Specific (Track 1 & 3) Ophthalmic Fetal Abdominal Intra-operative (Specify*) Intra-operative (Neuro) Laparoscopic Pediatric Small Organ (Specify**) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-rectal Trans-rectal Trans-urethral Trans-urethral Trans-esoph. (non-Card.) Musculo-skeletal (Conventional) Musculo-skeletal (Superficial)	Diagnostic ultrasound imaging Specific (Track 1 & 3) B Ophthalmic Fetal P Intra-operative (Specify*) P Intra-operative (Neuro) Laparoscopic Pediatric P Small Organ (Specify**) P Neonatal Cephalic P Adult Cephalic P Adult Cephalic Trans-rectal Trans-rectal Trans-vaginal Trans-urethral Trans-esoph. (non-Card.) Musculo-skeletal P (Conventional) P	Diagnostic ultrasound imaging or flu         Specific (Track 1 & 3)       B         M         Ophthalmic         Fetal         Abdominal       P         Intra-operative (Specify*)       P         Intra-operative (Neuro)         Laparoscopic         Pediatric       P         Small Organ (Specify**)       P         Neonatal Cephalic       P         Trans-rectal       I         Trans-vaginal       I         Trans-esoph. (non-Card.)       I         Musculo-skeletal       P         Musculo-skeletal       P         Superficial)       P	Diagnostic ultrasound imaging or fluid flow         Mo         Specific (Track 1 & 3)       B       M       PWD         Ophthalmic       Imaging or fluid flow       Mo         Pophthalmic       Imaging or fluid flow       Imaging or fluid flow         Abdominal       P       P         Abdominal       P       P         Intra-operative (Specify*)       P       P         Intra-operative (Neuro)       Imaging or fluid flow       Imaging or fluid flow         Laparoscopic       Imaging or fluid flow       Imaging or fluid flow       Imaging or fluid flow         Pediatric       P       P       P       P         Small Organ (Specify**)       P       P       P         Neonatal Cephalic       P       P       P         Adult Cephalic       Imagenetic       Imagenetic       Imagenetic         Trans-rectal       Imagenetic       Imagenetic       Imagenetic         Trans-esoph. (non-Card.)       Imagenetic       Imagenetic       Imagenetic         Musculo-skele	Diagnostic ultrasound imaging or fluid flow analy         Mode of (         Specific (Track 1 & 3)       B       M       PWD       CWD         Ophthalmic       I       I       I       I       I         Fetal       I       I       I       I       I       I         Abdominal       P       P       P       I <td< td=""><td>Diagnostic ultrasound imaging or fluid flow analysis of the         Mode of Operation         Specific (Track 1 &amp; 3)       B       M       PWD       CWD       Color         Doppler         Ophthalmic       I       I       I       I         Fetal       I       I       I       I       I         Abdominal       P       P       P       P         Intra-operative (Specify*)       P       P       P       P         Intra-operative (Neuro)       I       I       I       I       I         Laparoscopic       P       P       P       P       P         Small Organ (Specify**)       P       P       P       P       P         Adult Cephalic       P       P       P       P       P         Trans-rectal       I       I       I       I       I       I         Trans-esoph. (non-Card.)       I       I       I       I       I       I       I         Musculo-skeletal       P       P       P       P       P       P       P         Musculo-skeletal       P       P       P       P       P       P       I       <t< td=""><td>Diagnostic ultrasound imaging or fluid flow analysis of the human bo         Mode of Operation         Specific (Track 1 &amp; 3)       B       M       PWD       CWD       Color Doppler       Amplitude Doppler         Ophthalmic       I       I       I       I       I       I       Diagnostic ultrasound imaging or fluid flow analysis of the human bo         Specific (Track 1 &amp; 3)       B       M       PWD       CWD       Color Doppler       Amplitude Doppler         Ophthalmic       I       I       I       I       I       Diagnostic ultrasound imaging or fluid flow analysis of the human bo         Ophthalmic       I       I       I       I       Diagnostic ultrasound imaging or fluid flow analysis of the human bo         Ophthalmic       I</td><td>Diagnostic ultrasound imaging or fluid flow analysis of the human body as follow         Mode of Operation         Specific (Track 1 &amp; 3)       B       M       PWD       CWD       Color       Amplitude Doppler       Combined (specify)         Ophthalmic       I       I       I       I       I       Image: Specific (Track 1 &amp; 3)       B       M       PWD       CWD       Color       Amplitude Combined (specify)         Ophthalmic       Image: Specific (Track 1 &amp; 3)       B       M       PWD       CWD       Color       Amplitude (specify)         Ophthalmic       Image: Specific (Track 1 &amp; 3)       P</td></t<></td></td<>	Diagnostic ultrasound imaging or fluid flow analysis of the         Mode of Operation         Specific (Track 1 & 3)       B       M       PWD       CWD       Color         Doppler         Ophthalmic       I       I       I       I         Fetal       I       I       I       I       I         Abdominal       P       P       P       P         Intra-operative (Specify*)       P       P       P       P         Intra-operative (Neuro)       I       I       I       I       I         Laparoscopic       P       P       P       P       P         Small Organ (Specify**)       P       P       P       P       P         Adult Cephalic       P       P       P       P       P         Trans-rectal       I       I       I       I       I       I         Trans-esoph. (non-Card.)       I       I       I       I       I       I       I         Musculo-skeletal       P       P       P       P       P       P       P         Musculo-skeletal       P       P       P       P       P       P       I <t< td=""><td>Diagnostic ultrasound imaging or fluid flow analysis of the human bo         Mode of Operation         Specific (Track 1 &amp; 3)       B       M       PWD       CWD       Color Doppler       Amplitude Doppler         Ophthalmic       I       I       I       I       I       I       Diagnostic ultrasound imaging or fluid flow analysis of the human bo         Specific (Track 1 &amp; 3)       B       M       PWD       CWD       Color Doppler       Amplitude Doppler         Ophthalmic       I       I       I       I       I       Diagnostic ultrasound imaging or fluid flow analysis of the human bo         Ophthalmic       I       I       I       I       Diagnostic ultrasound imaging or fluid flow analysis of the human bo         Ophthalmic       I</td><td>Diagnostic ultrasound imaging or fluid flow analysis of the human body as follow         Mode of Operation         Specific (Track 1 &amp; 3)       B       M       PWD       CWD       Color       Amplitude Doppler       Combined (specify)         Ophthalmic       I       I       I       I       I       Image: Specific (Track 1 &amp; 3)       B       M       PWD       CWD       Color       Amplitude Combined (specify)         Ophthalmic       Image: Specific (Track 1 &amp; 3)       B       M       PWD       CWD       Color       Amplitude (specify)         Ophthalmic       Image: Specific (Track 1 &amp; 3)       P</td></t<>	Diagnostic ultrasound imaging or fluid flow analysis of the human bo         Mode of Operation         Specific (Track 1 & 3)       B       M       PWD       CWD       Color Doppler       Amplitude Doppler         Ophthalmic       I       I       I       I       I       I       Diagnostic ultrasound imaging or fluid flow analysis of the human bo         Specific (Track 1 & 3)       B       M       PWD       CWD       Color Doppler       Amplitude Doppler         Ophthalmic       I       I       I       I       I       Diagnostic ultrasound imaging or fluid flow analysis of the human bo         Ophthalmic       I       I       I       I       Diagnostic ultrasound imaging or fluid flow analysis of the human bo         Ophthalmic       I	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follow         Mode of Operation         Specific (Track 1 & 3)       B       M       PWD       CWD       Color       Amplitude Doppler       Combined (specify)         Ophthalmic       I       I       I       I       I       Image: Specific (Track 1 & 3)       B       M       PWD       CWD       Color       Amplitude Combined (specify)         Ophthalmic       Image: Specific (Track 1 & 3)       B       M       PWD       CWD       Color       Amplitude (specify)         Ophthalmic       Image: Specific (Track 1 & 3)       P				

Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
Peripheral vessel	Peripheral vessel	Р	Р	Р	Р	Р	Р	Note 1,2,4,7
	Other (Specify***)							

Transducer:	DL14-3U								
Intended Use:	Diagnostic ultrasound ima	iging	or fl	uid flov	v analy	sis of the	e human bo	dy as follow	/S:
Clinical Application				Мо	de of (	Operation	1		
General (Track 1 Only)	Specific (Track 1 & 3)	В	М	PWD	CWD	Color Doppler		Combined (specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	Ρ	Ρ	Р		Р	Р	Р	Note 1,3,4
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	Ρ	Ρ	Р		Р	Р	Р	Note 1,3,4
	Small Organ (Specify**)	Ρ	Ρ	Р		Р	Р	Р	Note 1,3,4
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	Ρ	Ρ	Р		Р	Р	Р	Note 1,3,4
	Other (Specify***)								

Transducer:	L13-3WU										
Intended Use:	Diagnostic ultrasound ima	aging	or flu	uid flov	v analy	sis of the	human bo	dy as follow	'S:		
Clinical				Мо	de of (	Operation					
Application											
General (Track 1	Specific (Track 1 & 3)										
Only)		Doppler Doppler (specify)									
Ophthalmic	Ophthalmic	phthalmic									
Fetal Imaging &	Fetal										
Other											
	Abdominal	dominal         P         P         P         P         P         Note 1,2,4,12									
	Intra-operative (Specify*)										

Intra-operative (Neuro)								
Laparoscopic								
Pediatric	Ρ	Р	Р		Р	Р	Р	Note 1,2,4
Small Organ (Specify**)	Р	Р	Р		Р	Р	Р	Note
								1,2,4,7,10,11
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph. (non-Card.)								
Musculo-skeletal	Р	Р	Р		Р	Р	Р	Note
(Conventional)								1,2,4,7,10,11
	Ρ	Р	Р		Р	Р	Р	Note
								1,2,4,7,10,11
Intravascular								
-								
-								
Intravascular (Cardiac)								
Trans-esoph. (Cardiac)								
Intra-cardiac								
Peripheral vessel	Ρ	Р	Р		Р	Р	Р	Note
								1,2,4,7,9,10,11
	Pediatric         Small Organ (Specify**)         Neonatal Cephalic         Adult Cephalic         Trans-rectal         Trans-vaginal         Trans-urethral         Trans-esoph. (non-Card.)         Musculo-skeletal (Conventional)         Musculo-skeletal         (Superficial)         Intravascular         Cardiac Adult         Cardiac Pediatric         Intravascular (Cardiac)         Trans-esoph. (Cardiac)	LaparoscopicPediatricPSmall Organ (Specify**)PSmall Organ (Specify**)PNeonatal CephalicAdult CephalicTrans-rectalTrans-vaginalTrans-vaginalTrans-esoph. (non-Card.)Musculo-skeletal (Conventional)PMusculo-skeletal (Superficial)PIntravascularCardiac AdultCardiac Pediatric Intravascular (Cardiac)Trans-esoph. (Cardiac)	LaparoscopicPPediatricPPSmall Organ (Specify**)PSmall Organ (Specify**)PNeonatal CephalicIAdult CephalicITrans-rectalITrans-vaginalITrans-vaginalITrans-vaginalPNesculo-skeletalP(Conventional)PMusculo-skeletalP(Superficial)PIntravascularICardiac AdultICardiac PediatricIIntravescular (Cardiac)ITrans-esoph. (Cardiac)I	LaparoscopicIPediatricPPSmall Organ (Specify**)PPSmall Organ (Specify**)PPNeonatal CephalicIAdult CephalicITrans-rectalITrans-vaginalITrans-vaginalITrans-urethralITrans-esoph. (non-Card.)IMusculo-skeletalPP(Conventional)PPMusculo-skeletalPP(Superficial)IntravascularICardiac AdultIICardiac PediatricIIIntravascular (Cardiac)ITrans-esoph. (Cardiac)I	LaparoscopicImage: scalar	LaparoscopicImage: scalar	LaparoscopicPPPPPediatricPPPPPSmall Organ (Specify**)PPPPPNeonatal CephalicIIIIAdult CephalicIIIITrans-rectalIIIITrans-vaginalIIIITrans-vaginalIIIITrans-vethralIIIITrans-esoph. (non-Card.)IIIMusculo-skeletal (Conventional)PPPPMusculo-skeletal (Superficial)PPPPIntravascularIIIIICardiac AdultIIIIIIntravascular (Cardiac)IIIIIIntra-cardiacIIIIIIntra-cardiacIIIII	LaparoscopicImage: scalar

Transducer:	P8-2Ts								
Intended Use:	Diagnostic ultrasound ima	aging	or fl	uid flov	v analy	sis of the	e human bo	dy as follow	/s:
Clinical				Мо	de of (	Operation	1		
Application					0.115				
•	Specific (Track 1 & 3)	В	М	PWD	CWD				Other (Specify)
Only)						Doppler	Doppler	(specify)	
Ophthalmic	Ophthalmic								
Fetal Imaging &	Fetal								
Other	Abdominal								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal								
	(Conventional)								
	Musculo-skeletal								
	(Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric			1					
	Intravascular (Cardiac)								

	Trans-esoph. (Cardiac)	Ν	Ν	Ν	Ν	N	N	N	Note 1,5,6
	Intra-cardiac								
Peripheral	Peripheral vessel								
vessel									
	Other (Specify***)								

Transducer:	P8-2U										
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:										
Clinical				Мо	de of (	Operation	1				
Application	Specific (Track 1 & 3)   B   M   PWD   CWD   Color   Amplitude   Combined   Other (Specify)										
``	Specific (Track 1 & 3)	В	Μ	PWD	CWD				Other (Specify)		
Only)						Doppler	Doppler	(specify)			
Ophthalmic	Ophthalmic										
5 5 5	Fetal										
Other	Abdominal	N	N	N	N	N	N	N	Note 1, 2,4,6		
	Intra-operative (Specify*)					N		N	1010 1, 2,4,0		
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric	Ν	Ν	Ν	Ν	Ν	N	Ν	Note 1, 2,4,6		
	Small Organ (Specify**)										
	Neonatal Cephalic	Ν	Ν	Ν	Ν	N	N	Ν	Note 1, 2,4,6		
	Adult Cephalic	Ν	Ν	N	N	N	N	Ν	Note 1, 2,4,6		
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skeletal (Conventional)	N	N	N	N	N	N	N	Note 1, 2,4,6		
	Musculo-skeletal (Superficial)										
	Intravascular										
Cardiac	Cardiac Adult	Ν	N	N	N	N	N	N	Note 1, 2,4,5,6		
	Cardiac Pediatric	Ν	N	N	N	N	N	N	Note 1, 2,4,5,6		
	Intravascular (Cardiac)										
	Trans-esoph. (Cardiac)										
	Intra-cardiac										
Peripheral	Peripheral vessel										
vessel											
	Other (Specify***)										

Transducer:	L15-3WU										
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:										
Clinical	Mode of Operation										
Application											
General (Track 1	Specific (Track 1 & 3)	Specific (Track 1 & 3) B M PWD CWD Color Amplitude Combined Other (Speci									
Only)						Doppler	Doppler	(specify)			
Ophthalmic	Ophthalmic										
Fetal Imaging &	Fetal										
Other											
	Abdominal	Ν	Ν	Ν	Ν	N	N	N	Note 1,2,4,12		
	Intra-operative (Specify*)										
	Intra-operative (Neuro)										

	Laparoscopic								
	Pediatric	Ν	Ν	Ν	Ν	Ν	Ν	N	Note 1,2,4
	Small Organ (Specify**)	Ν	Ν	Ν	Ν	Ν	Ν	N	Note
									1,2,4,7,10,11
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal	Ν	Ν	Ν	Ν	Ν	Ν	N	Note
	(Conventional)								1,2,4,7,10,11
	Musculo-skeletal	Ν	Ν	Ν	Ν	Ν	Ν	N	Note
	(Superficial)								1,2,4,7,10,11
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral	Peripheral vessel	Ν	Ν	Ν	N	Ν	N	N	Note
vessel									1,2,4,7,9,10,11
	Other (Specify***)								
			1		1				

Transducer:	SD8-1U											
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:											
Clinical Application	Mode of Operation											
General (Track 1	Specific (Track 1 & 3)	В	М	PWD	CWD	Color	Amplitude	Combined	Other (Specify)			
Only)						Doppler	Doppler	(specify)				
Ophthalmic	Ophthalmic											
Fetal Imaging & Other	Fetal	Ν	N	N	N	N	N	N	Note 1, 3, 4, 5, 6			
	Abdominal	Ν	N	N	N	N	N	N	Note 1, 3, 4, 6, 12			
	Intra-operative (Specify*)											
	Intra-operative (Neuro)											
	Laparoscopic											
	Pediatric											
	Small Organ (Specify**)											
	Neonatal Cephalic											
	Adult Cephalic											
	Trans-rectal											
	Trans-vaginal											
	Trans-urethral											
	Trans-esoph. (non-Card.)											
	Musculo-skeletal											
	(Conventional)											
	Musculo-skeletal (Superficial)											
	Intravascular											
Cardiac	Cardiac Adult											
	Cardiac Pediatric											

	Intravascular (Cardiac)				
	Trans-esoph. (Cardiac)				
	Intra-cardiac				
Peripheral vessel	Peripheral vessel				
	Other (Specify***)				

Transducer:	SC9-2U										
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:										
Clinical	Mode of Operation										
Application							A 111 1				
•	Specific (Track 1 & 3)	В	М	PWD	CWD		Amplitude		Other (Specify)		
Only) On bits a line in	Ora hatha a Inni a					Doppler	Doppler	(specify)			
Ophthalmic	Ophthalmic	N1	N	N	N	N	N	NI			
Fetal Imaging & Other	Fetal	Ν	IN	IN	IN	IN	IN	N	Note 1, 2, 4, 5, 6		
	Abdominal	N	N	N	N	N	N	N	Note 1, 2, 4, 6, 12		
	Intra-operative (Specify*)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric										
	Small Organ (Specify**)										
	Neonatal Cephalic										
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skeletal (Conventional)										
	Musculo-skeletal (Superficial)										
	Intravascular										
Cardiac	Cardiac Adult										
	Cardiac Pediatric										
	Intravascular (Cardiac)										
	Trans-esoph. (Cardiac)										
	Intra-cardiac										
Peripheral vessel	Peripheral vessel	Ν	N	N		N	N	N	Note 1, 2, 4, 6		
	Other (Specify***)	Ν	Ν	Ν	Ν	N	N	N	Note 1, 2, 4, 6		

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