

**Resona I9/Resona I9 Exp/Resona I9S/Resona  
I9T/Resona I9 Easi/Resona I9 Nasa/Resona  
IV/Imagyn I9/Imagyn I9S/Imagyn I9 Easi/Nuewa  
I9/Nuewa I9S/Nuewa I9 Easi/Anesus I9/Anesus I9  
Easi/Eagus I9/Nuewa I9T/Nuewa I9 Exp/Resona  
I9W/Recho R9W/Recho R9/Recho R9 Pro/Recho  
R9 Exp/Recho R9S/Recho R9T/Recho R9 Super**

## **Diagnostic Ultrasound System**

### **Operator's Manual**

**[Basic Volume]**



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Mindray is responsible for the effects on safety, reliability and performance of this product, only if:

- all installation operations, expansions, changes, modifications and repairs of this product are conducted by Mindray authorized personnel;
- the electrical installation of the relevant room complies with the applicable national and local requirements; and
- the product is used in accordance with the instructions for use.

### NOTE

This equipment must be operated by skilled/trained clinical professionals.

### Warning

It is important for the hospital or organization that employs this equipment to carry out a reasonable service/maintenance plan. Neglect of this may result in machine breakdown or personal injury.

# Warranty

THIS WARRANTY IS EXCLUSIVE AND IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE.

## Exemptions

Mindray's obligation or liability under this warranty does not include any transportation or other charges or liability for direct, indirect or consequential damages or delay resulting from the improper use or application of the product or the use of parts or accessories not approved by Mindray or repairs by people other than Mindray authorized personnel.

**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.**

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# Important Information

1. It is the customer's responsibility to maintain and manage the system after delivery.
2. The warranty does not cover the following items, even during the warranty period:
  - (1) Damage or loss due to misuse or abuse.
  - (2) Damage or loss caused by Acts of God such as fires, earthquakes, floods, lightning, etc.
  - (3) Damage or loss caused by failure to meet the specified conditions for this system, such as inadequate power supply, improper installation or environmental conditions.
  - (4) Damage or loss due to use of the system outside the region where the system was originally sold.
  - (5) Damage or loss involving the system purchased from a source other than Mindray or its authorized agents.
3. This system shall not be used by persons other than fully qualified and certified medical personnel.
4. DO NOT make changes or modifications to the software or hardware of this system.
5. 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.
6. 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.
7. Important data must be backed up on external memory media.
8. Mindray shall not be liable for loss of data stored in the memory of this system caused by operator error or accidents.
9. 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.
10. If a new manager takes over this system, be sure to hand over this operator's manual to the new manager.
11. According to the conclusion of clinical evaluation and residual risk evaluation, for the intended patients, there is no known side effects that can occur during or after the use of the medical device. And there is no need for the operator to make extra preparations. Thus, no residual risk associated with using the medical device should be disclosed.

## 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.

## Notation Conventions

In this operator's manual, the following words are used besides the safety precautions (see "Safety Precautions"). Please read this operator's manual before using the system.

<b>NOTE:</b> Indicates information of interest to users of this system regarding exceptional conditions or operating procedures.
--

**CAUTION:**

The diagnostic ultrasound system is not intended for ophthalmic use. Its use in this clinical specialty is contraindicated.

U.S.A. Federal Law restricts this device to sale by or on the order of a physician.

## 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.

### Operation NOTE

Contains a quick 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:

- <Buttons>: angular brackets indicate buttons, 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.

# Product Differences

Model	B-Hist (Ellipse)	B-Hist (Trace)	B-Hist (Spline)	B-Hist (Rectangle)	Profile	Spline Length	Color Vel	Cross	Double dist
Resona I9	√	√	√	√	√	√	√	√	√
Resona I9 Exp	√	×	√	√	√	√	√	√	√
Resona I9S	√	√	√	√	√	√	×	√	√
Resona I9T	×	√	√	√	√	√	×	√	√
Resona I9 Easi	√	√	√	√	√	√	×	×	√
Resona I9 Nasa	×	√	√	√	√	√	×	×	√
Resona IV	×	√	√	√	×	√	×	√	√
Imagyn I9	√	√	√	√	√	√	√	×	√

Model	B-Hist (Ellipse)	B-Hist (Trace)	B-Hist (Spline)	B-Hist (Rectangle)	Profile	Spline Length	Color Vel	Cross	Double dist
Imagyn I9S	√	√	√	√	√	√	√	√	×
Imagyn I9 Easi	√	×	√	√	√	√	×	×	√
Nuewa I9	×	×	√	√	√	√	√	×	√
Nuewa I9S	√	√	√	√	×	√	√	√	×
Nuewa I9 Easi	√	√	√	×	√	√	×	×	√
Nuewa I9T	×	×	√	√	√	√	√	√	×
Nuewa I9 Exp	×	√	√	×	√	√	√	×	√
Anesus I9	×	√	×	√	√	√	√	√	√
Anesus I9 Easi	×	√	√	×	√	√	×	×	√
Eagus I9	×	×	√	√	√	√	√	√	√
Resona I9W	√	×	√	√	√	√	√	×	√
Recho R9W	√	√	√	√	√	×	×	√	√
Recho R9	×	√	√	√	√	×	×	√	√
Recho R9 Pro	√	×	√	√	√	×	×	√	√
Recho R9 Exp	√	√	×	√	√	×	×	√	√
Recho R9S	√	√	√	×	√	×	×	√	√
Recho R9T	√	√	√	√	×	×	×	√	√
Recho R9 Super	×	×	√	√	√	×	×	√	√

# 1 Safety Precautions

---

## 1.1 Safety Classification

According to the type of protection against electric shock:

CLASS I EQUIPMENT + INTERNALLY POWERED 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 2-pedal or 3-pedal footswitch (can be used in the operating room) is classified as IPX8

The 1-pedal 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

## 1.2 Meaning of Signal Words

In this manual, the signal words  **DANGER**,  **WARNING**,  **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
 <b>DANGER</b>	Indicates an imminently hazardous situation that, if not avoided, will result in death or serious injury.
 <b>WARNING</b>	Indicates a potentially hazardous situation that, if not avoided, could result in death or serious injury.
 <b>CAUTION</b>	Indicates a potentially hazardous situation that, if not avoided, may result in minor or moderate injury.
<b>NOTE</b>	Indicates a potentially hazardous situation that, if not avoided, may result in property damage.
Description	Important information that helps you to use the system more effectively.

## 1.3 Meaning of Safety Symbols

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

## 1.4 Safety Precautions

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



### **DANGER:**

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



### **WARNING:**

1. Do not 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.
2. 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.
3. **DO NOT** use power supply of different phases to power peripherals, like power supply of air-conditioning.
4. 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.
5. Connect the grounding conductor before turning **ON** the system. Disconnect the grounding cable after turning **OFF** the system. Otherwise, electric shock may result.
6. 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.
7. Before cleaning the system, disconnect the power cord from the outlet. System failure and electric shock may result.
8. 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.
9. **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.

10. **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.**
11. **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.**
12. **Do not subject the transducers to knocks or drops. Use of a defective transducer may cause an electric shock.**
13. **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.**
14. **Do not use the system with the patient when the system is being serviced or maintained.**
15. **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.**
16. **Only use the ECG leads provided with the physiology module; otherwise, electric shock may be resulted.**
17. **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.**
18. **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.**
19. **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.**
20. **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.**
21. **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.**
22. **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.**



**23. To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.**



**Caution:**

1. **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.
2. **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.
3. **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, 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.
4. **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.**
5. **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.**
6. **Do not use the system to examine a fetus for a long period of time.**
7. **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.**
8. **It is necessary to press [End] to end the current scan that is in progress and clear the current Patient Information field. Otherwise, new patient data may be combined with the previous patient data.**

9. 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.
10. If the system is powered off improperly during operation, it may result in data damage of the system's hard disk or system failure.
11. 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.
12. It is recommended to only use the video devices specified in this manual.
13. Do not use gel, disinfectant, probes, probe sheath or needle-guided brackets that are not compatible with the system.
14. The applied contrast agency should be compliant with the relevant local regulations.
15. Read the Acoustic Output Principle in the operation manual carefully before operating this system on clinical examination.
16. The cover contains natural rubber that can cause allergic reactions in some individuals.
17. Please use the ultrasound gel compliant with the relevant local regulations.
18. Normal operation may be affected by unstable mains power supply; it is recommended that our product be powered from an uninterruptible power supply.
19. DO NOT expose the system to excessive vibration through transportation. Mechanical damage may result.
20. 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:**
1. DO NOT use the system in the vicinity of strong electromagnetic field (such as a transformer), which may affect the performance of the system.
  2. 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.
  3. When using or placing the system, keep the system horizontal to avoid imbalance.
  4. 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.
  5. 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.
  6. Press <Freeze> key to freeze an image or turn off the power of the system before connecting or disconnecting a probe.

7. 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.
8. 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.
9. Do not apply external force to the control panel. Otherwise, the system may be damaged.
10. If the system is used in a small room, the room temperature may rise. Please provide proper ventilation and free air exchange.
11. 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. Mindray is not responsible for any system content or accessories that have been discarded improperly.
12. 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.
13. The replaceable fuse is inside the chassis. Refer replacing job to Mindray service engineers or engineers authorized by Mindray only.
14. 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.
15. The iScape View 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 View image.
16. Ensure that the current exam date and time are the same as the system date and time.
17. Use the pluggable power supply as the net power supply breaking facility.

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



**WARNING:**

1. The ultrasonic probe is only for use with the specified ultrasonic diagnostic system. See Chapter 2.4.2 Probes and Needle-guided Brackets Available for details.
2. The ultrasonic probe must be used only by qualified professionals.
3. Confirm that the transducer and probe cable are normal before and after each examination. A defective probe may cause electric shock to the patient.
4. Do not subject the probe to shock. A defective probe may cause electric shock to the patient.
5. Do not disassemble the probe to avoid the possibility of electric shock.
6. 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.

**7. A transducer sheath must be installed over the transducer before performing examination.**



**Caution:**

1. **When using the probe, wear sterile gloves to prevent infection.**
2. **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.**
3. **In normal diagnostic ultrasound mode, there is no danger of a normal-temperature burn; however, keeping the probe on the same region of the patient for a long time may cause such a burn.**
4. **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.**
5. **It is required to practice ALARA when operating ultrasound system. Minimize the acoustic power without compromising the quality of images.**
6. **The probe and accessories supplied with it are not delivered disinfected or sterilized. Sterilization (or high-level disinfect) before use is required.**
7. **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.**
8. **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.**
9. **Do not use pre-lubricated condoms as a sheath. Lubricant may not be compatible with the probe material and damage may result.**
10. **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 probe 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 an examination, wipe the ultrasound gel off thoroughly. Failure to do so may result in the ultrasound gel solidifying and the image quality being 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. Check the probe's performance periodically.

## 1.5 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




**⚠️ WARNING:** 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).

## 1.6 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
<p>a</p>  <p>b</p>	<p>d</p> <p>c</p>	<p>a) Do not place the system on a sloped surface. Otherwise the system may slide, resulting in personal injury or the system malfunction. Two persons are required to move the system over a sloped surface.</p> <p>b) Do not sit on the system.</p> <p>c) DO NOT push the system when the casters are locked.</p> <p>d) Please carefully read this manual before use system.</p>
		Warning; Crushing of hands
		No heavy load

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
	Prohibition	Red	White	Black
	Mandatory action	Blue	White	White
	Warning	Yellow	Black	Black

# 2 System Overview

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## 2.1 Intended Use

Resona I9 series Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, 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 and Thoracic/Pleural exams.

Modes of operation include: B, M, PWD, CWD, Color Doppler, Amplitude Doppler, Combined mode(B+M, PW+B, Color+B, Power+B, PW+Color+B, Power+PW+B), Tissue Harmonic Imaging, Smart3D, 4D(Real-time 3D), iScape View, TDI, Color M, Strain Elastography, Contrast imaging (Contrast agent for LVO), V Flow, STE, STQ, Contrast imaging (Contrast agent for Liver).

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.

## 2.2 Contraindication

The diagnostic ultrasound system is not intended for ophthalmic use.

## 2.3 Product Specifications

<b>NOTE</b>	The functions described in the operator's manual may vary depending upon the specific system you purchased.
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### 2.3.1 Power Supply

Power input

Voltage	100-240 V~
Frequency	50/60 Hz
Power consumption	650 VA

Power output

Voltage	100-240 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.)

## 2.3.2 Environmental Conditions

	Operational Conditions	Storage and Transportation Conditions
Ambient temperature	0°C-40°C	-20°C-55°C
Relative humidity	20%-85% (no condensation)	20%-95% (no condensation)
Atmospheric pressure	700 hPa-1060 hPa	700 hPa-1060 hPa



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

### **WARNING:**

## 2.3.3 External Dimensions and Weight

Item	Specification	Remark
External Dimensions	Length: 1020±20mm; Width: 550±10mm; Height: 1000±20mm.	The monitor and the control panel are kept to a minimum position
Weight	105kg ± 4kg	Standard configuration without probes

## 2.4 System Configuration

### 2.4.1 Standard Configuration

Main unit

System software

Hard disk drive (HDD)

Solid state disk (SSD)

Accessories

- Ultrasound gel
- Dust-proof cover
- Storage bin
- Cable hook
- Probe holders
- Leakage-proof cap for the ultrasound gel
- Cables
- Dust-proof cover for the probe socket
- Small keyboard
- Operator's manual

### 2.4.2 Probes and Needle-guided Brackets Available

For details about the probes and needle-guided brackets, please refer to "13 Probes and Biopsy".



### 2.4.3 Options

No.	Item	Remarks
1.	Pencil probe cable	/
2.	CW Module	/
3.	4D module	/
4.	Built-in wireless adapter	/
5.	Battery assembly	/
6.	Ultrasound gel warmer	Should be configured with the bracket of the ultrasound gel warmer.
7.	Ultrasound gel warmer holder	Should be configured with the ultrasound gel warmer.
8.	Intra-cavity probe holder (with screws)	/
9.	ECG module	/
10.	ECG cable (configured with the ECG)	The ECG module should be configured.
11.	PCG module	The ECG module should be configured.
12.	DC-IN cable (configured with the ECG)	The ECG module should be configured.
13.	Fusion imaging module	Contains 1 magnetic navigation controller, 1 magnetic generator, 2 fusion imaging sensors, and 1 motion sensor support. Fusion imaging should be configured.
14.	Fusion imaging module (including trolley)	Contains 1 magnetic navigation controller, 1 magnetic generator, 2 fusion imaging sensors, 1 trolley for the magnetic generator, and 1 motion sensor support. Fusion imaging should be configured.
15.	Magnetic navigation controller box	Used for carrying the magnetic navigation controller. Fusion imaging module or fusion imaging module (including trolley) should be configured.
16.	Probe Adapter PCM-ES01	The SD8-1E, P7-3TE, SC6-1E, or SP5-1E probe should be configured.
17.	Probe Adapter PCM-US01	The P7-3TU or SP5-1U probe should be configured.
18.	iClear+ Dongle	iClear+ should be configured.
19.	1D Barcode reader (1D or 2D)	/
20.	Footswitch (1-pedal, 2-pedal, or 3-pedal)	USB interface
21.	DVD assembly	/
22.	iVocal Microphone Package	iVocal should be configured.

No.	Item	Remarks
23.	Wipes box bracket	/
24.	iScape View	/
25.	Free Xros M	/
26.	Free Xros CM	/
27.	Tissue Doppler Imaging	Cardiology Package should be configured.
28.	TDI QA	Tissue Doppler Imaging should be configured.
29.	Contrast Imaging	/
30.	Contrast Imaging QA	Contrast Imaging should be configured.
31.	LVO	Cardiology Package should be configured.
32.	Volume CEUS	4D module should be configured.
33.	Strain Elastography	/
34.	STE	/
35.	STQ	/
36.	Endocavity STE	/
37.	High frame rate STE	STE or Endocavity STE should be configured.
38.	Stress Echo	Cardiology Package should be configured.
39.	Tissue Tracking QA	Cardiology Package should be configured.
40.	FH Tissue Tracking QA	Obstetrics Package should be configured.
41.	Smart 3D	/
42.	iPage <sup>+</sup>	4D module should be configured.
43.	STIC	4D module should be configured.
44.	SCV <sup>+</sup>	4D module should be configured.
45.	Smart Volume	4D module should be configured.
46.	Smart V Trace	Smart Volume should be configured.
47.	Color 3D	4D module should be configured.
48.	Niche	4D module should be configured.
49.	iLive	4D module or Smart 3D should be configured.
50.	Smart Planes CNS	4D module and Obstetrics Package should be configured.
51.	Smart Planes FH	4D module and Obstetrics Package should be configured.

No.	Item	Remarks
52.	Smart Face	4D module and Obstetrics Package should be configured.
53.	Smart ICV	Smart Planes CNS should be configured.
54.	Smart Scene 3D	4D module should be configured.
55.	Ultrasound Fusion Imaging	Fusion imaging module or Fusion imaging module (including trolley) should be configured.
56.	Endocavity Fusion Imaging	Fusion imaging module or Fusion imaging module (including trolley) should be configured.
57.	Fusion RESP	Ultrasound Fusion Imaging should be configured.
58.	Needle Navigation	Ultrasound Fusion Imaging should be configured.
59.	V Flow	Vascular Package should be configured.
60.	Glazing Flow	/
61.	iClear+	iClear+ Dongle should be configured.
62.	DICOM Basic	/
63.	DICOM Worklist	DICOM Basic should be configured.
64.	DICOM MPPS	DICOM Basic should be configured.
65.	DICOM Query/Retrieve	DICOM Basic should be configured.
66.	DICOM OB/GYN SR	DICOM Basic should be configured.
67.	DICOM Vascular SR	DICOM Basic should be configured.
68.	DICOM Cardiac SR	DICOM Basic should be configured.
69.	DICOM Breast SR	DICOM Basic should be configured.
70.	DICOM Abdomen SR	DICOM Basic should be configured.
71.	DICOM Small Parts SR	DICOM Basic should be configured.
72.	Abdomen/General Package	/
73.	Obstetrics Package	/
74.	Smart OB	Obstetrics Package should be configured.
75.	Smart NT	Obstetrics Package should be configured.
76.	Smart Fetal HR	Obstetrics Package should be configured.
77.	Gynecology Package	/
78.	Smart FLC	4D module and Gynecology Package should be configured.

No.	Item	Remarks
79.	Cardiology Package	/
80.	Small Parts Package	/
81.	Urology Package	/
82.	Vascular Package	/
83.	Pediatrics Package	/
84.	Nerve Package	/
85.	Emergency&Critical Package	/
86.	Pelvic Floor Package	Gynecology Package should be configured.
87.	Smart Pelvic	Pelvic Floor Package should be configured.
88.	IVF	Gynecology Package should be configured.
89.	IMT	Vascular Package should be configured.
90.	RIMT	Vascular Package should be configured.
91.	AutoEF	Cardiology Package should be configured.
92.	R-VQS	Vascular Package should be configured.
93.	Smart Hip	Pediatrics Package should be configured.
94.	Smart HRI	Abdomen/General Package should be configured.
95.	Smart Caliper	/
96.	Smart Trace	/
97.	CPP	/
98.	Smart IVC	Cardiology Package or Abdomen/General Package should be configured.
99.	Smart VTI	Cardiology Package should be configured.
100.	Smart B-line	/
101.	V-Mapping	Vascular Package should be configured.
102.	iWorks	/
103.	iNeedle	/
104.	DVR Module	/
105.	McAfee	/
106.	iVocal	/

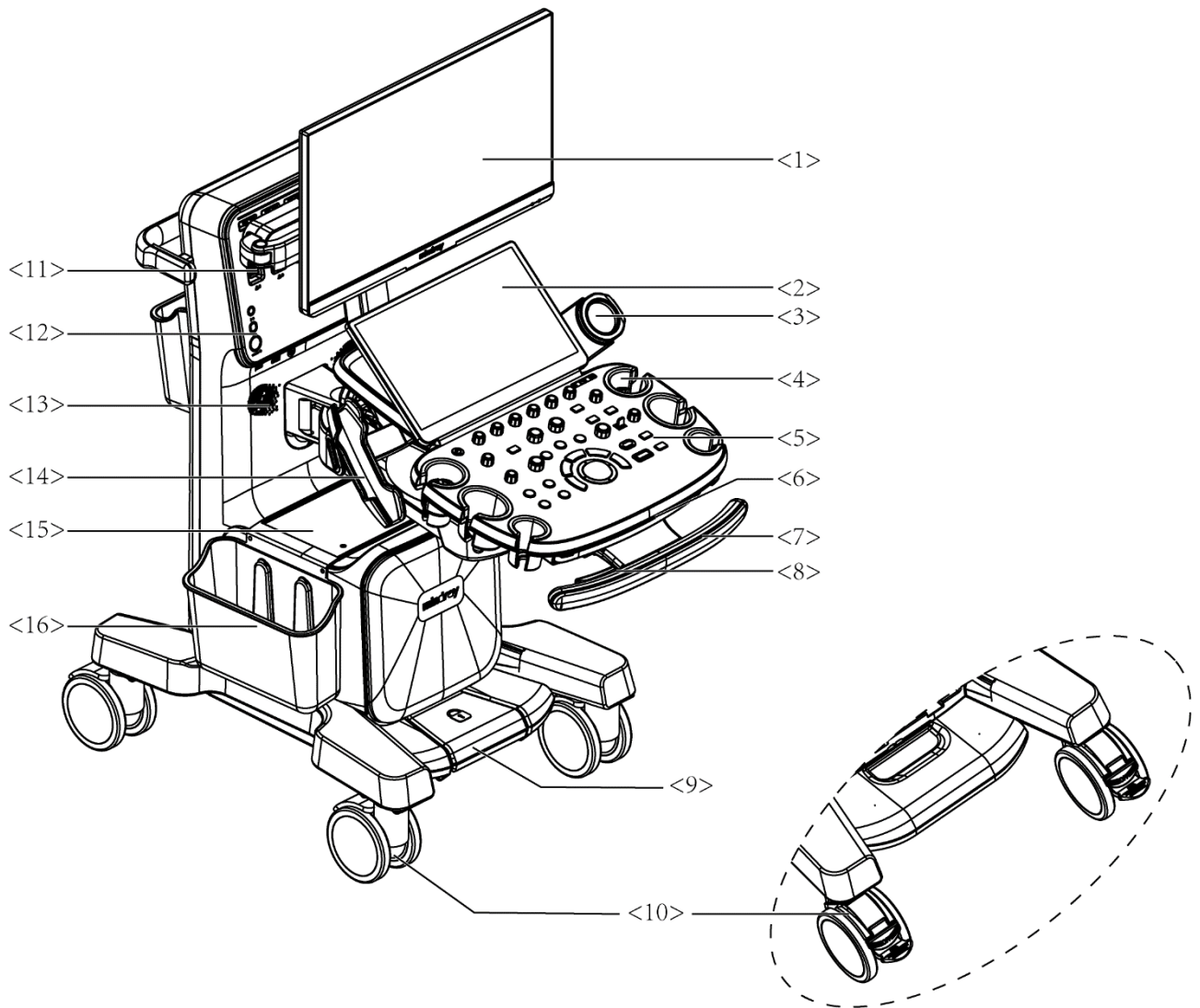
## 2.4.4 Peripherals Supported

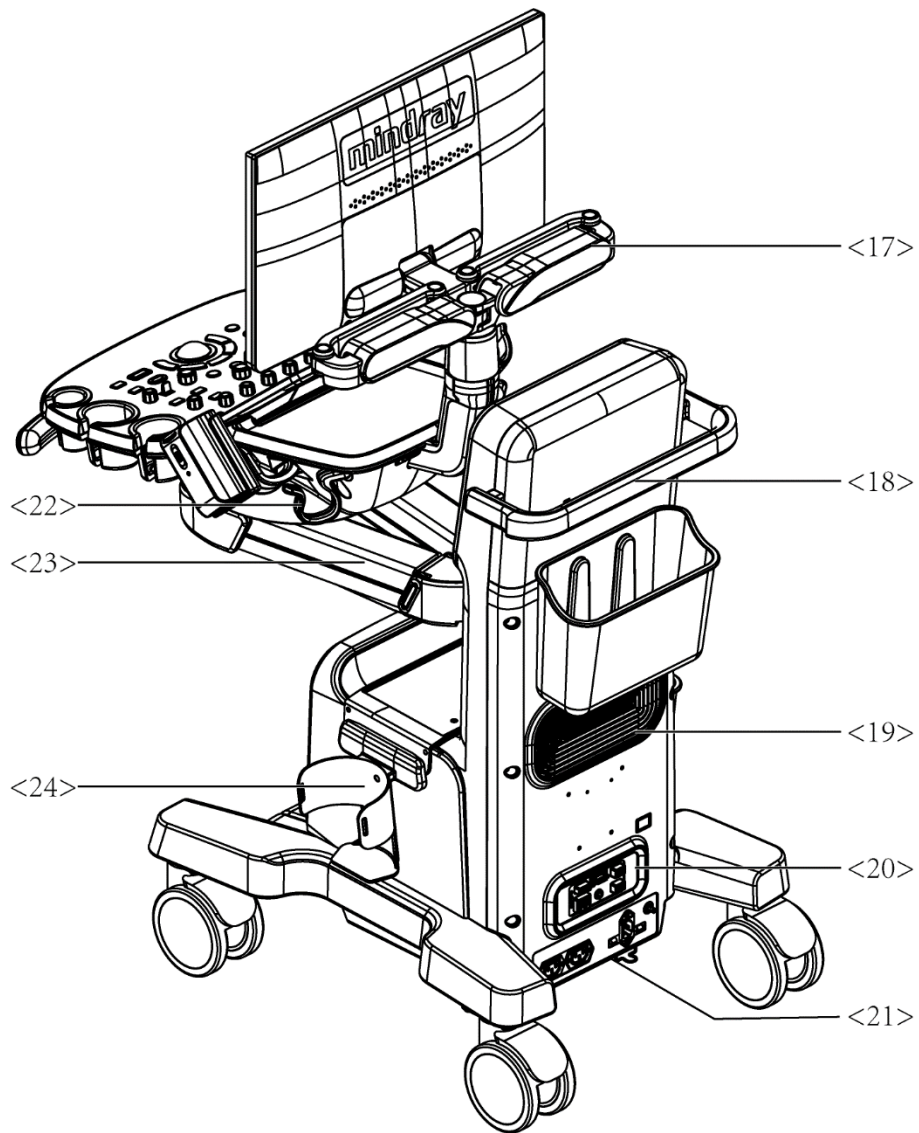
Type	Model
Graph/text printer	HP OFFICEJET PRO 8100 (the printer driver requires manual installation.)
Black/white video printer (digital)	MITSUBISHI P95DW-N
Black/white video printer (analog)	SONY UP-X898MD
Digital color video printer	SONY UP-D25MD
Barcode reader	LS2208, DS4308
Footswitch	FS-81-SP-2 (1-pedal) 971-SWNOM (2-pedal) 971-SWNOM (3-pedal)
iVocal Microphone	SAMSON XPD2 (iVocal should be configured)

Parts that can be used within patient environment:

- Main unit.
- Probes.
- Footswitch.
- Printers

## 2.5 Introduction of Each Unit





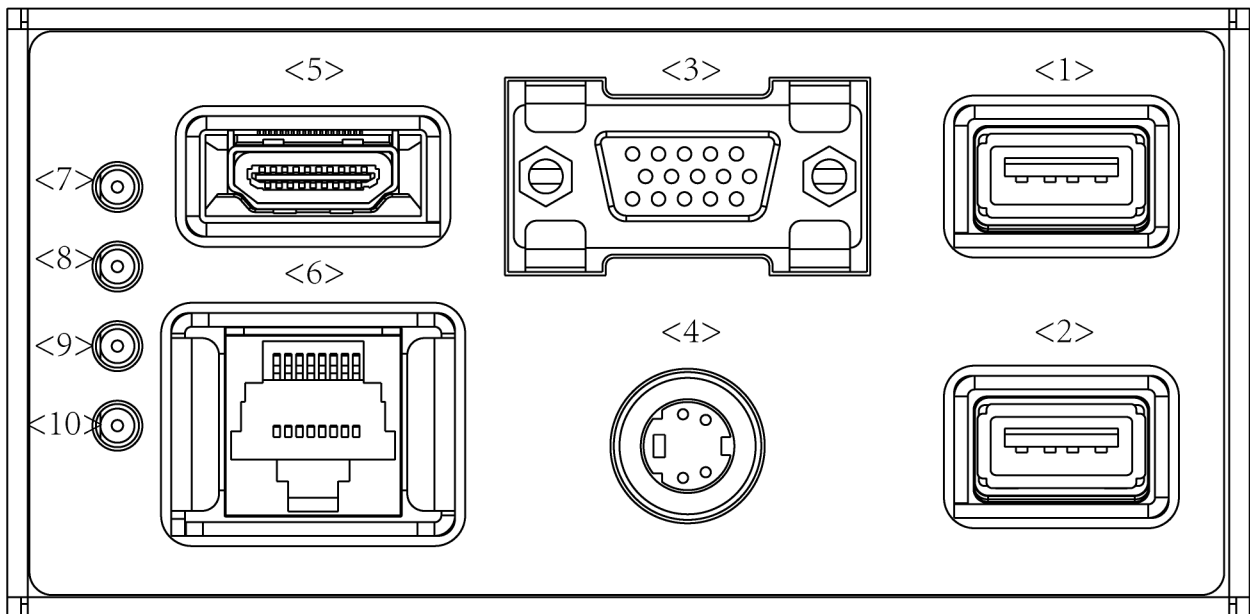
No.	Name	Function
1.	Monitor	Displays the images and parameters during scanning.
2.	Touch Screen	Screen-touching operator-system interface or control.
3.	Ultrasound gel warmer	Used for heating the ultrasound gel.
4.	Transducer& ultrasound gel holder	Used for placing transducers or ultrasound gel temporarily.
5.	Control panel	Key- pressing operator-system interface or control.
6.	Qwerty keyboard	Used for typing characters or entering some functions.




No.	Name	Function
7.	Touch control handle	Holding the right part of the handle to display the battery indicator on the control panel. <b>NOTE:</b> Available only after the battery assembly is configured.
8.	Control panel adjusting lever	Used for lifting or swiveling the control panel.
9.	Central brake	Used for locking the 3 full-lock casters. <b>NOTE:</b> Available only after the central brake is configured.
10.	Caster	With central brake: <ul style="list-style-type: none"> <li>● Press the central brake pedal (used for locking the 3 full-lock casters): press the red pedal of the double-lock caster to lock the system.</li> <li>● Release the central brake pedal (used for locking the 3 full-lock casters): press the off pedal of the double-lock caster to freely move the system; press the green pedal of the double-lock caster to move the system straight.</li> </ul> Without central brake: <ul style="list-style-type: none"> <li>● 3 full-lock casters: press the “ON” pedal to lock the system, and press the “OFF” pedal to move the system.</li> <li>● 1 double-lock caster: press the red pedal to lock the system, press the green pedal to move the system straight, and press the “OFF” pedal to reset the green and red pedals.</li> </ul>
11.	Probe port	Sockets connecting transducers and the main unit.
12.	Front I/O panel	Connecting to ECG leads, CW, USB drive, audio input and output etc.
13.	Speaker	Outputs the audio.
14.	Intracavitary probe holder	Used for placing the intracavitary probe.
15.	Placing table	Used for placing the B/W video printer, storage bin, and wipes box bracket.




No.	Name	Function
16.	Storage bin	Used for temporal storage
17.	Monitor support arm	Supports the LCD display and adjusts the position and angle of the LCD display.
18.	Rear handle	Used for pushing and moving the system.
19.	Cooling vent	Used for cooling the main unit.
20.	Back I/O panel	Interface panel used for inputting and outputting signals.
21.	Power supply panel	Electrical port panel.
22.	Hanger	Used for hanging the probe cables.
23.	Control panel support arm	Supports the control panel and adjusts the position of the control panel.
24.	Wipes box bracket	Used for placing the wipes box.

## 2.6 Back I/O Panel

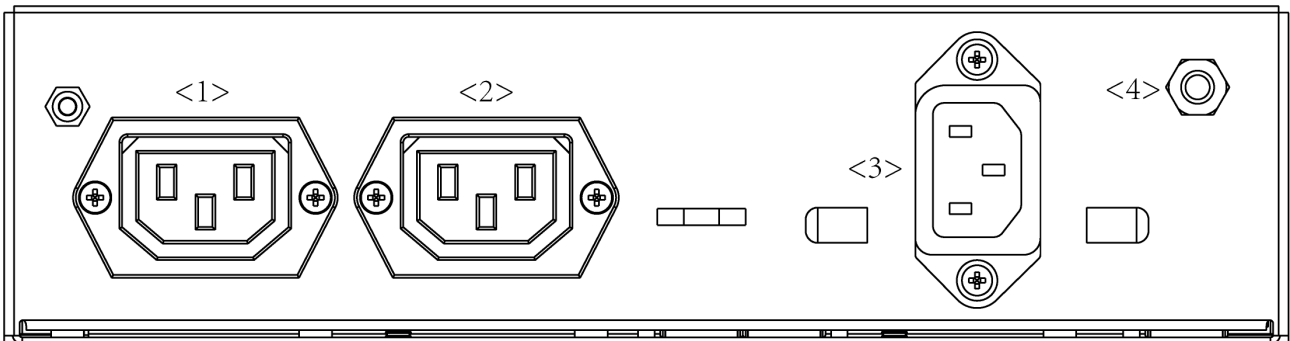



No.	Symbol	Function
<1>		High speed USB port
<2>		High speed USB port
<3>		VGA signal output

No.	Symbol	Function
<4>	S-Video	S-Video signal output
<5>	HDMI	High definition multimedia interface
<6>		Network port
<7>	/	12 V indicator
<8>	/	24 V indicator
<9>	/	5V_STB indicator
<10>	/	DBG_FLAG indicator

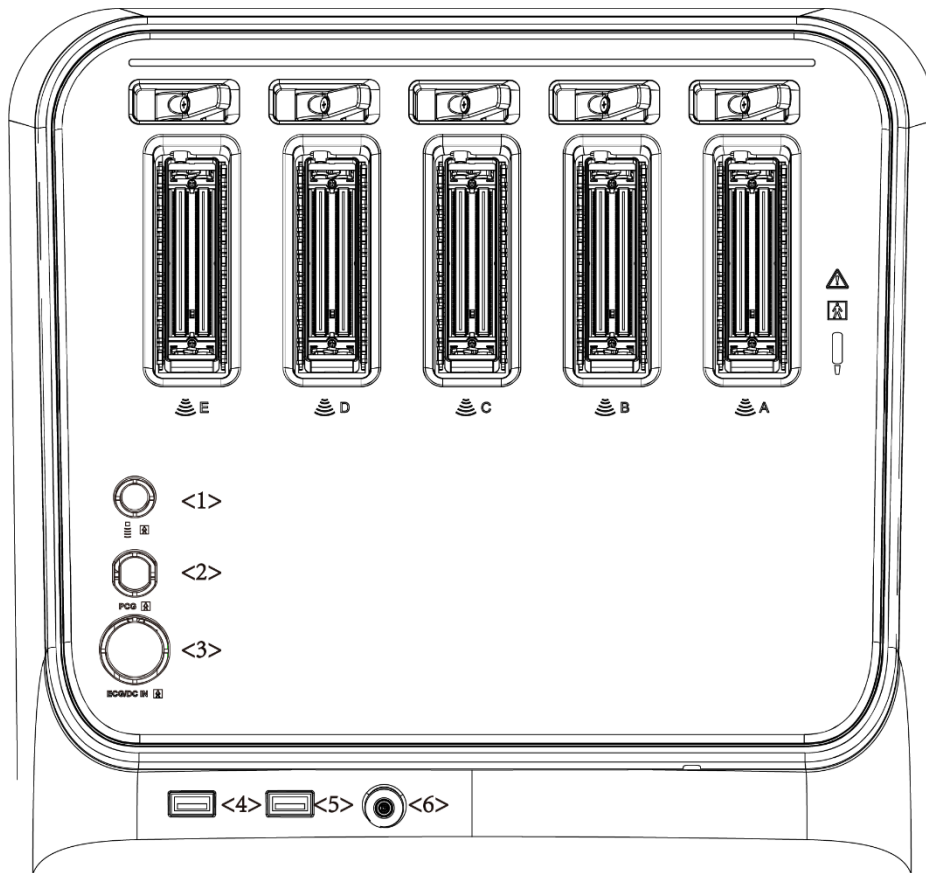
**NOTE:** S-VIDEO port performs better in analog video print.





## 2.7 Power Supply Panel



No.	Name	Function
<1>	Alternative current auxiliary output 1	Supply power for optional peripheral devices.
<2>	Alternative current auxiliary output 2	Supply power for optional peripheral devices.
<3>	AC 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.

## 2.8 Front I/O Panel





No.	Name	Function
<1>		Used for connecting a pencil probe.
<2>	<b>PCG</b>	PCG signal input port
<3>	<b>ECG/DC IN</b>	ECG lead signal input port/external ECG signal input terminal
<4>		High speed USB port
<5>		High speed USB port
<6>		Audio input and output

## 2.9 Control Panel



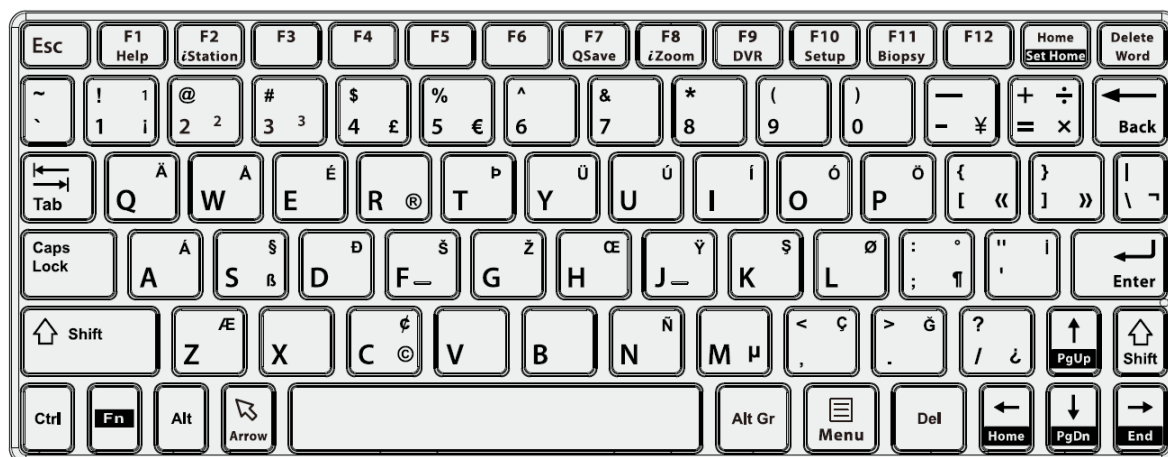
No.	Name	Description
<1>	/	<p>Power button Turn on/turn off the system.</p> <p>~ AC (Alternating current). It turns on at AC supply.</p> <p>☾ Standby. It blinks in orange in standby status.</p> <p>💡 Hard disk indicator. It blinks when reading the disk.</p>
<2>	A.power	<ul style="list-style-type: none"> <li>● Press the button to switch from A.Power and Volume.</li> <li>● Rotate the button to adjust the acoustic power or volume.</li> </ul>
<3>	Soft menu key (1-6)	<ul style="list-style-type: none"> <li>● Press the button to enable or disable the corresponding functions on the touch screen.</li> <li>● Rotate the button to adjust the parameter on the touch screen.</li> </ul>
<4>	P1	User defined key. Press the button to enable or disable the user-defined function. E-ink Supported. Set by the user in the Preset.
<5>	PW/Y	<ul style="list-style-type: none"> <li>● Press to enter or exit the PW mode. When the PW mode is enabled: If the Mark is not displayed, then press to display the Mark line; If the Mark is displayed, then press to enter PW mode.</li> <li>● Rotate to adjust PW/CW gain; while in 3D/4D mode, rotate the knob to make the 3D image rotate around Y axis.</li> </ul>

No.	Name	Description
<6>	C/Z	<ul style="list-style-type: none"> <li>● Press to enter or exit Color mode</li> <li>● Rotate to adjust Color/Power gain; while in 3D/4D mode, rotate the knob to make the 3D image rotates around Z axis.</li> </ul>
<7>	M/X	<ul style="list-style-type: none"> <li>● Press to enter or exit the M mode. When the M mode is enabled: If the Mark is not displayed, then press to display the Mark line; If the Mark is displayed, then press to enter M mode.</li> <li>● Rotate to adjust M gain; while in 3D/4D mode, rotate the knob to make the 3D image rotate around X axis.</li> </ul>
<8>	CW	Press to enter or exit the CW mode. When the CW mode is enabled: If the Mark is not displayed, then press to display the Mark line; If the Mark is displayed, then press to enter PW mode.
<9>	PD	Press to enter or exit the Power mode.
<10>	B	Press to enter the B mode; Rotate to adjust the B or 3D/4D gain.
<11>	3D	Press to enter or exit the 3D mode. E-ink Supported. Set by the user in the Preset.
<12>	4D	Press to enter or exit the 4D mode.
		Rotate to adjust the slice position of the 3D/4D mode.
<13>	Dual	<ul style="list-style-type: none"> <li>● In non-dual split mode, press to enter the dual split mode.</li> <li>● In dual split mode, press to switch the active window.</li> </ul>
<14>	Single	Press to enter the single window mode. E-ink Supported. Set by the user in the Preset.
<15>	Quad	In non-dual split mode, press to enter the quad split mode. In quad split mode, press to switch the active window. E-ink Supported. Set by the user in the Preset.
<16>	Depth	Slide upward to increase the depth by 1 unit in real-time imaging until reaching the threshold. Slide downward to decrease the depth by 1 unit in real-time imaging until reaching the threshold.
<17>	Zoom	<ul style="list-style-type: none"> <li>● Rotate clockwise to zoom in the image; rotate anticlockwise to zoom out the image.</li> <li>● Press to enter the spot-zoom mode, press again to enter pan-zoom mode, and press for the third time to exit the zoom mode.</li> </ul>
<18>	iTouch	<ul style="list-style-type: none"> <li>● Press to optimize the images, and keep pressing to further optimize the image.</li> <li>● Long press to exit iTouch.</li> </ul>

No.	Name	Description
<19>	Save	E-ink Supported. Set by the user in the Preset. Supports 3 kinds of save mode: <ol style="list-style-type: none"> <li>1. Save single-frame image.</li> <li>2. Save multi-frame image;</li> <li>3. Select save mode based on different situations: <ol style="list-style-type: none"> <li>a) Real time: Auto cine replay: save multi-frame image</li> <li>b) Freeze: save single-frame image.</li> </ol> </li> </ol>
<20>	Freeze	Press to freeze/defreeze the image.
<21>	Print	Press to print the image. E-ink Supported. Set by the user in the Preset.
<22>	Angle	Rotate to adjust the angle. Press to switch to the maximum steer angle.
<23>	Bodymark	Press to enter or exit Bodymark status.
<24>	ABC	Press to enter or exit Comment status.
<25>	Clear	<ul style="list-style-type: none"> <li>● Press to clear in the sequence of “the selected measurement and comment information”, “screen information of the current application mode”, and then “all measurement and comment information”</li> <li>● Long press to clear all the measurement and comment information on the screen.</li> </ul>
<26>	Cursor	Press to display/hide the cursor.
<27>	/	Set key. The function is determined based on the actual situation. For example, next one or previous one; or special command of some special modes.
<28>	/	
<29>	Measure	Press to enter/exit the application measurement mode, and start default measurement.
<30>	Caliper	Press to enter/exit the general measurement mode, and start default measurement.
<31>	Update	<ul style="list-style-type: none"> <li>● Switch the current active window in multi-windows mode.</li> <li>● Complete the image acquisition in iScape View/3D/4D mode etc..</li> </ul>
<32>	/	<ul style="list-style-type: none"> <li>● Move the trackball to change the cursor position or repaly multi-frame image.</li> <li>● Adjust or move the VOI.</li> <li>● Move the comment or body mark.</li> <li>● Adjust the probe orientation of the body mark</li> </ul>
<33>	/	 Battery indicator: displays the battery indicator <b>NOTE:</b> Available only after the battery assembly is configured.

Tip: “/” means the key / knob has no silk-printed name.

## Keyboard



### Common functional keys

No.	Key	Function
1.	Enter	Confirm 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.	Tab	Jump to the next operable item.
4.	Space key	Insert a space.
5.	Caps Lock	Switch the upper/ lower case.
6.	Home	Activate the Home function: return to start position of comment.
7.	Delete Word	Delete all comments on the screen.
8.	Direction-control keys	Move the cursor one letter each time; or, select the ambient one in a selectable area.
9.	Del	Delete the character after the cursor
10.	Back Space	Delete the character before the cursor
11.	Menu	Display or hide the parameter menu on the upper right corner of the screen.

### 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 Info 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/ 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	F12	User-defined keys, functions of which can be defined in preset.

## Functions of key combination

The system supports multi-language input; you can use the key combinations. The key combinations include [Shift], [Alt Gr], [Ctrl] and some alphabet keys.

- <Shift> key

<Shift> + key: input the upper left letter of the key.

For the alphabet keys (<A>~<Z>), press <Shift>+key to input the letter of different case with the current state.

- [Alt Gr] key

Combined with other letter keys, [Alt Gr] can be used for entering other languages.

Press [Alt Gr], and meanwhile press a letter key, the letter on the upper-right corner of the key can be entered.

- [Ctrl] key combined keys

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











- [Fn] key

For those combination keys, press <Fn>+key to use the functions indicated with a frame on the key.

















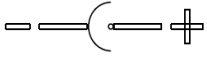


No.	Fn+	Name	Function
1.	→	End	Move the cursor to the end of the row, or the rightmost side of an edit unit.
2.	←	Home	Home
3.	↑	Pg Up	Turn pages upward.
4.	↓	Pg Dn	Turn pages downward.
5.	Home	Set Home	Activate the Set Home function: set the start point of comment.


## 2.10 Symbols

This system uses the symbols listed in the following table, and their meanings are explained as well.

No.	Symbol	Description
1.		Type-BF applied part
2.		Caution
3.		AC (Alternating current)
4.		Protective earth (ground)
5.		Pencil probe port
6.		Equipotentiality
9.		Probe socket
10.		Network port
11.		High speed USB port
12.		VGA output



No.	Symbol	Description
13.	S-VIDEO 	Reserved, used for separate video output
14.	AUDIO 	Audio input and output
15.	HDMI	High definition multimedia interface
16.		Microphone input jack
17.		When the probe locking lever points to  , you can remove the probe.
18.		<ul style="list-style-type: none"> <li>- When the probe locking level points to , it means that the probe is locked and you can not remove the probe.</li> <li>- Central brake locking symbol</li> </ul>
19.		Product serial number
20.		Manufacture date
21.		Manufacturer
22.		Temperature limit
23.		Humidity limitation
24.		Atmospheric pressure limitation
25.		Standby
26.		Direction of the probe cable
27.		Battery status indicator
28.		Positive inside and negative outside
29.		Unique Device Identifier
30.	<p>ETL CLASSIFIED</p>  <p>Intertek 3179617</p>	<p>CONFORMS TO AAMI STD ES 60601-1, IEC STD 60601-1-6, 60601-2-37</p> <p>CERTIFIED TO CSA STD C22.2 NO. 60601-1, NO. 60601-1-6, NO. 60601-2-37</p>

No.	Symbol	Description
31.	<b>Rx Only</b>	Caution: Federal Law restricts this device to sale by or on the order of a physician.
32.		MR Unsafe – the system is not intended to be used within magnetic resonance (MR) environment.

# 3 System Preparation

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## **WARNING:**

1. Do not connect the three-wire cable of the system with a two-wire plug without protective grounding; otherwise, electric shock may result.
2. Do not 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.
3. 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.
4. **DO NOT** use power supply of different phases to power peripherals, like power supply of air-conditioning.
5. 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/Position the System

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

If the ultrasound system is configured with the central brake system:

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 central brake pedal and reset the green pedal of the double-lock caster; hold the handle to move the system.
4. When you move the system to a desired location, press down the central brake pedal and red pedal of the double-lock caster to lock the four casters.

If the ultrasound system is not configured with the central brake system:

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 four casters; hold the handle to move the system.
4. When you move the system to a desired location, lock the four casters.



**CAUTION:**

1. **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.**
2. **Pay extra attention when moving the system on a sloping ground, do not move it on a more than 5°-sloped plane to avoid system toppling.**

## 3.2 Connecting Power Cord & Protective Grounding

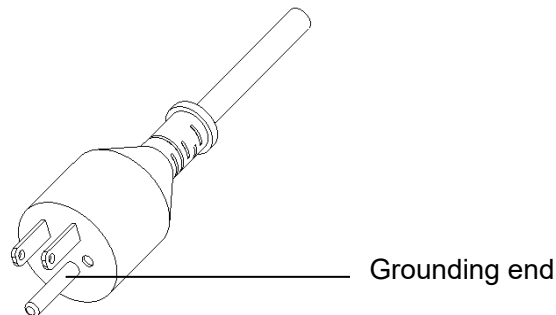
This system can work when it is connected to the external power supply or the battery capacity is sufficient.

**NOTE:** When the system is powered by the batteries, self-test is not supported.

### 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.



**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 Battery

The battery can support the ultrasound system for normal working for no less than 90 minutes.

- When connected to the external power supply, the system is powered by the external power. The batteries inside it are in the charging status.
- When disconnected from the external power supply, the system is powered by the batteries. Refer to Appendix F Battery” for the detailed operations and precautions.

### 3.2.3 Equipotential terminal



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

**WARNING:**

1. **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.**
2. **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.**
3. **Connect the earth cable before turning ON the system. Disconnect the earth cable after turning OFF the system. Otherwise, electric shock may result.**
4. **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.**

### 3.2.4 Powering on the System

**CAUTION:**

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 Mindray Customer Service Department or sales representative. If you use the system in a persistent improperly functioning state – you may harm the patient or damage the equipment.

#### Checking before Power ON

Check the system before the system is powered on:

No.	Check Item
1	The temperature, relative humidity and atmospheric pressure shall meet the requirements of operating conditions. For details, please refer to “2.3.2 Environmental Conditions”
2	There shall be no condensation.
3	There shall be no distortion, damage or dirt on the system and peripheral devices. If any dirt is found, cleaning shall be performed.
4	There shall be loose screws on the monitor or control panel.
5	There shall be no cable damage (e.g. power cord). Maintaining secure connections to the system at all times.
6	The probes and probe cables shall be free of damage or stains. See Chapter 13 Probes and Biopsy for details of probe cleaning and disinfection.
7	No miscellaneous odds and ends are allowed to be attached or affixed to the control panel.
8	Ensure that all connections are free from damage and remain clear of foreign object blockages. There shall be no obstacles around the system and its air vent.
9	Probe cleaning and disinfection.
10	The overall scanning environment and field must be clean.

No.	Check Item
11	The locking mechanism of casters can work normally.

To check the system after it is turned 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 touch panel becomes green, press the power button to power on the system. The system image appears.

To check the system after the system is turned on:

No.	Check Item
1	There shall no unusual sounds or smells indicating possible overheating.
2	There shall be no persistently displayed system error message.
3	There shall no evident excessive noise, discontinuous, absent or black artifacts in the B Mode image.
4	Check if there is abnormal heat on the surface of the probe during an ultrasound procedure. If you use a probe giving off excessive heat, it may burn the patient.
5	The control panel keys and knobs are fully functional.
6	The touch screen and the main monitor screens display normally depending on the system modes and image status.
7	The exam date and time are the same as the system date and time, and are displayed correctly.



**WARNING:**

1. **The patient may get burnt if using an excessive heated probe.**
2. **The system is defective if any malfunctioning happens. 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.

### 3.2.5 Powering off the System

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

To power off your system normally

Press the power button on left of the touch panel to see the option:

- Shut down: To power off the system normally.
- Standby: To enter standby status.
- Cancel: To cancel the operation.

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

**NOTE:** Do not turn off the breaker while the power indicator is on. Otherwise, the data may lose or the system software may be damaged.

To shut down the system in a direct way if you cannot do it normally:

Directly turn off the circuit breaker or unplug the power cord.

- NOTE:**
1. DO NOT rush shutdown of the system or switch off the breaker in a direct way. It may make the data corrupted. DO NOT directly shut down the system. It may make the data corrupted.
  2. After the system is upgraded, using "Shut Down" to power off the system to make the upgraded data effective.

## 3.2.6 Standby

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

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.

When the system enters the standby status, if need to power off:

Press the power button to exit the powering-off status and then power off the system.

- NOTE:**
1. 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.
  2. 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.

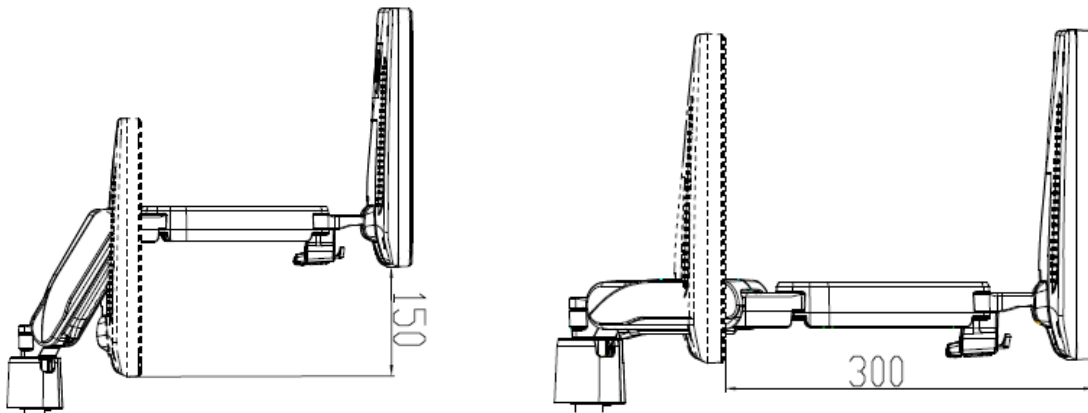
## 3.3 Monitor Adjustment

### 3.3.1 Monitor Position Adjustment

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

### Height and displacement adjustment

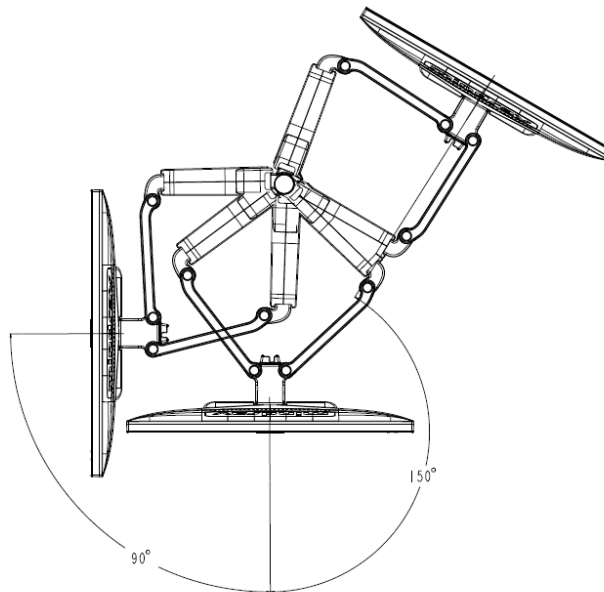
Move the monitor support arm up or down to adjust the height, back and forth to adjust the displacement.



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

### Rotate the monitor

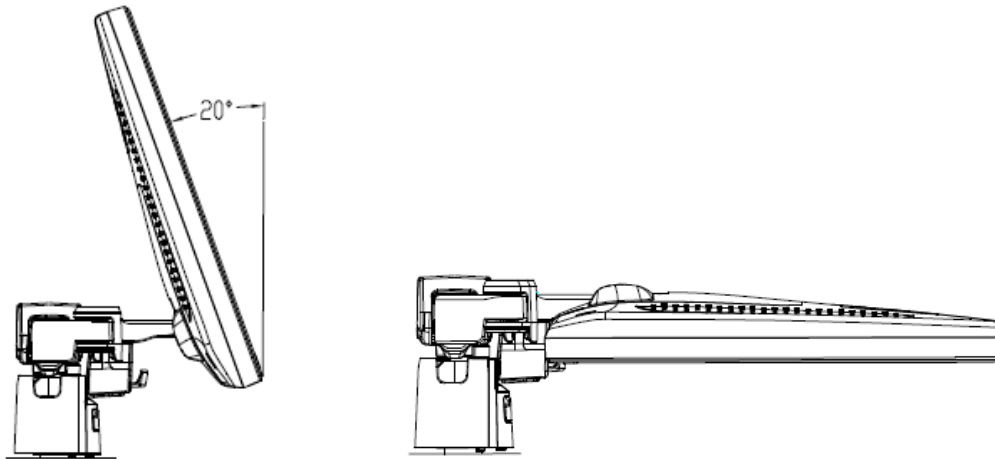
The monitor can be rotated 90° to the left and 150° to the right along with the supporting arm.



### Tilt the monitor

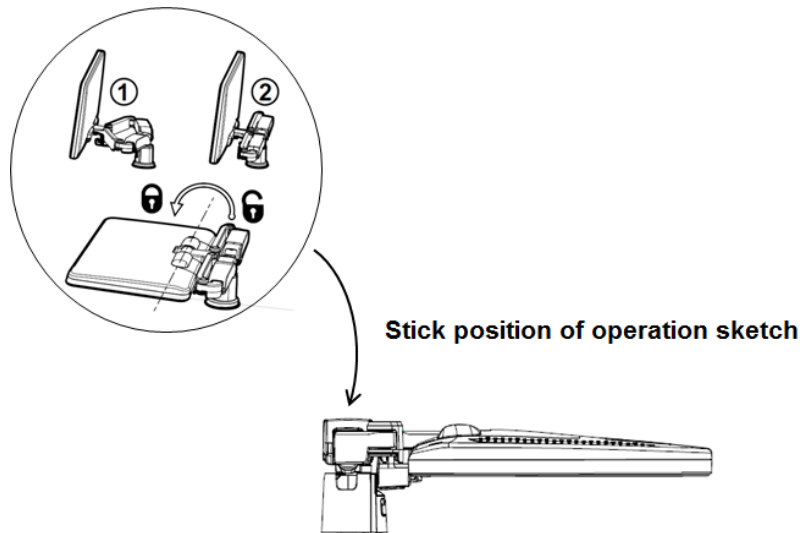
When positioned vertically, the monitor can be tilted 20° backward and can be tilted forward to a horizontal position. When transporting or moving the system, keep the monitor in the horizontal position, as shown below:





### Lock 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.



## 3.3.2 Monitor Brightness/Contrast Adjustment

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.

The adjusting buttons are shown as follows:

Brightness adjustment:

Press <F10 Setup>, and then select [System] > [General] > [LCD]/[TouchPanel]

Contrast adjustment:

Press <F10 Setup>, and then select [System] > [General] > [LCD]/[TouchPanel].

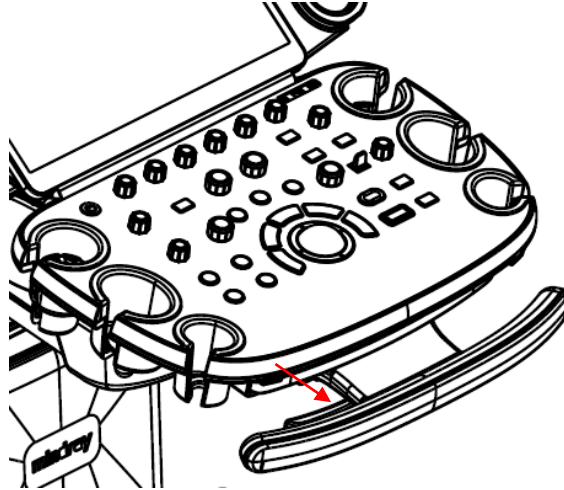
Automatic brightness adjustment

Press <F10 Setup>, tap [System] > [General], and then select [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.

## 3.4 Control Panel Position Adjustment

Press the control panel lever in the direction as shown in the following figure. The control panel can be rotated left and right in  $\pm 90^\circ$ . The control panel can be moved back and forth in 200mm, left and right in 270mm, and up and down in 300mm. The control panel can be locked at any position.



## 3.5 Connecting/Disconnecting a Probe



### CAUTION:

1. 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.
2. When connecting or disconnecting a transducer, place it in a proper position, to prevent the transducer from falling off or becoming damaged.
3. Hang the probe cable to the hanger located under the control panel to avoid excessively bending and damaging the cable.
4. Only use the transducers provided by Mindray. Aftermarket transducers may result in damage or cause a fire.

### 3.5.1 Connecting a Probe

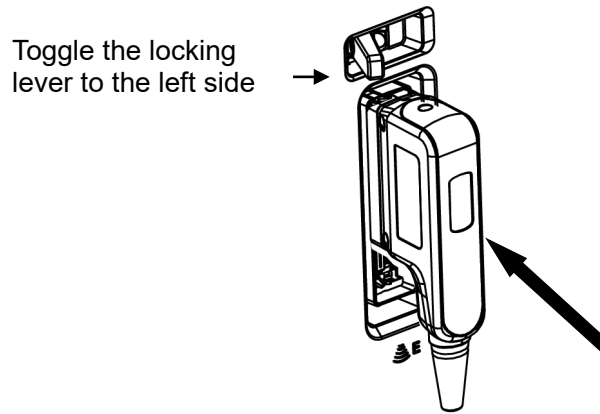


### WARNING:

The transducers, cables and connectors are in proper operating order and free from surface defects, cracks and peeling. Otherwise, electrical shock may result.

Perform the following procedure:

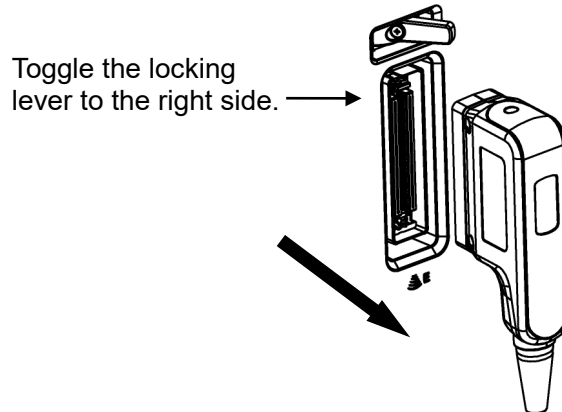
1. Keep the cable of the transducer downward, insert the connector into the system port.
2. Toggle the locking lever to the left side to lock the transducer connector.
3. Position the probe properly to avoid it being treaded on or becoming wrapped around other devices. DO NOT allow the probe head to hang free.



### 3.5.2 Disconnecting a Probe

Perform the following procedure:

1. Toggle the locking lever to the right side.
2. Pull the transducer connector straight out vertically.



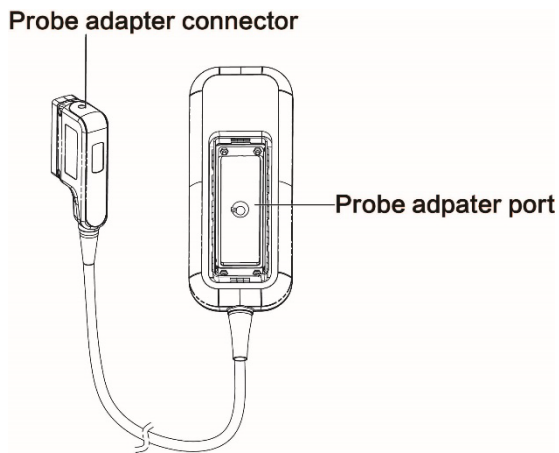
### 3.5.3 Probe Adapter Installation

Probe adapter is an option.

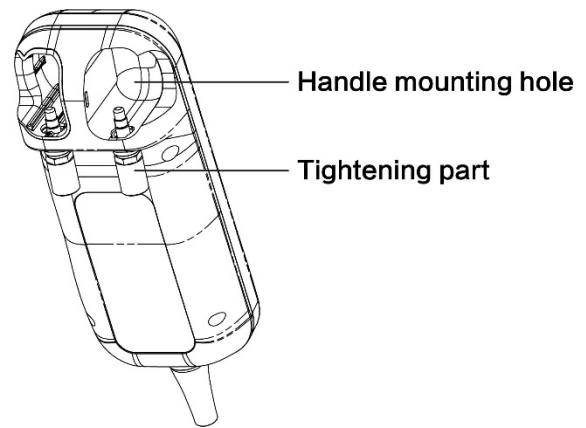
The following probes can be connected to the ultrasound system through probe adapter installation.

Probe Adapter	Probe
PCM-ES01	SD8-1E
	P7-3TE
	SC6-1E
	SP5-1E
PCM-US01	P7-3TU
	SP5-1U

■ **Probe Adapter Illustration**



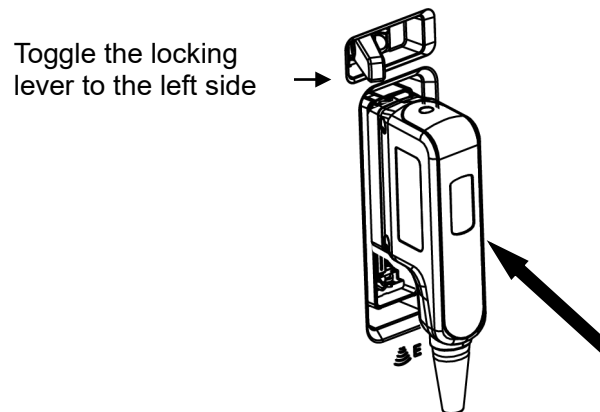
**Front View of the probe adapter**



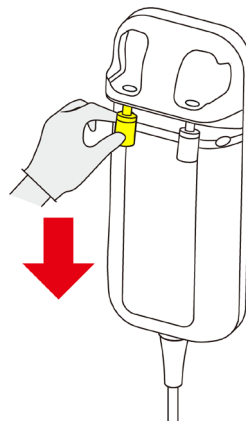
**Back View of the probe adapter**

■ **Installation steps are as follows:**

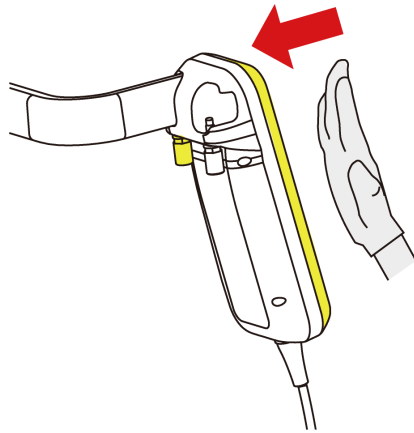
1. Keep the cable of the transducer downward, insert the connector into the system port.
2. Toggle the locking lever to the left side to lock the probe adapter connector.



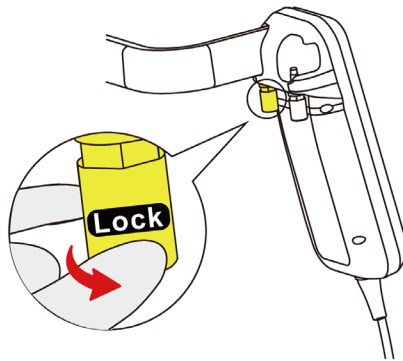
3. Pull down the tightening part of the probe adapter.



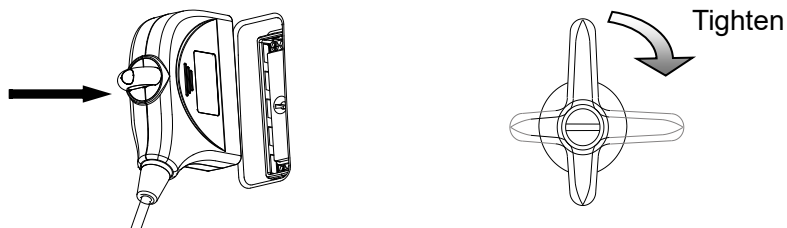
4. Aim the mounting hole to the handle end of the ultrasound system, and push the probe adapter slowly and carefully.



5. Turn the tightening part to the right.



6. Insert the probe connector into the probe adapter port, and turn the lock handle 90° clockwise to lock it securely.




## 3.6 Connecting Peripheral Devices


### 3.6.1 Connecting USB Devices



#### **WARNING:**

**DO NOT** directly remove a USB memory device; otherwise, the USB device and/or the ultrasound system may be damaged.

When connecting a USB memory device to the ultrasound system via a USB port, you can hear a sound if it is connected successfully and the icon  will appear in the lower right corner of the screen.

To remove the USB memory device: Click the icon  to open the [Remove USB Device] screen. Select the memory device to be removed. Click [OK] and you can hear a sound. Remove the USB memory device. A sound is heard when removing the USB memory device.

The diagnostic ultrasound system supports USB 3.0.

## 3.6.2 Connecting a Footswitch

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

The system supports the wired footswitch of USB port type.

Connection

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

Function Setting

The function of the footswitch can be preset, for details, please refer to Chapter “12.1.7 iConsole&Footswitch”

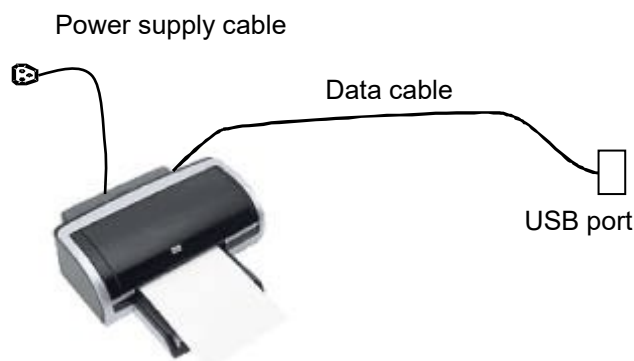
## 3.6.3 Installing a Graph/Text Printer

Add a local printer

NOTE: Unless otherwise specified, printers listed in Chapter 0

Peripherals Supported have drivers installed already.

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. Connect the data cable to USB port of the ultrasound device.
2. Power on the system and the printer.
3. Install the printer driver. For details, please contact the Mindray service engineer.

Print

Both report and image can be printed on a graph/text printer.

Set the default report printer and its attribute:

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

Please refer to the accompanying manuals of the printers for more details.

### 3.6.4 Connecting a Video Printer

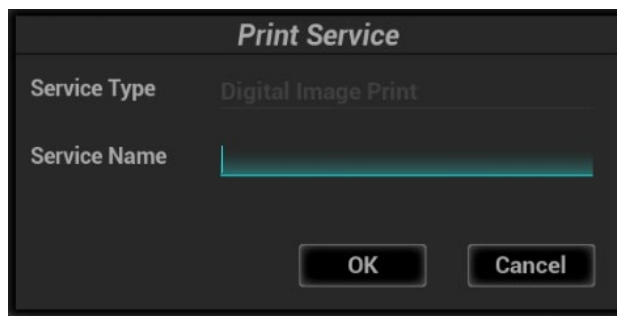
The digital video printers that system supports consist of the B/W printers and color printers.

NOTE: Unless otherwise specified, printers listed in Chapter 0

Peripherals Supported have drivers installed already.

Install a local printer

1. Place the printer appropriately.
2. Connect the power cord of the printer to a receptacle. Connect the USB port of the system to the USB port of the printer with USB cable.
3. Load a paper roll and turn on the system and printer.
4. Install the printer driver. For details, please contact the Mindray service engineer.
5. Add a print service:
  - (1) Open the "[Setup] → [Print]" screen.
  - (2) Click [Add Service] to enter the page.



- (3) Select the service type and enter the service name manually.
- (4) Click [OK] to return to the page.
- (5) Select the target printer from the drop-down list in the "Property" box and set other printing properties.
- (6) Click [OK] to complete.

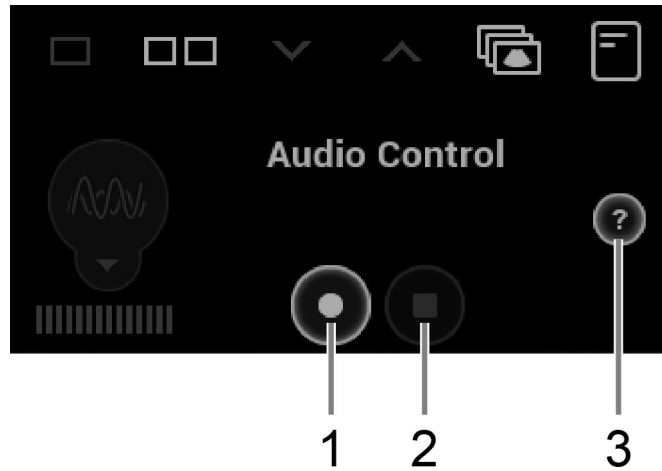
### 3.6.5 Installing Wireless Printer

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

1. Plug the printer power cord to an appropriate outlet.
2. Power on the system and the printer.
3. Make sure the ultrasound machine and the printer are connected to a same LAN, and turned on the W-LAN function of the printer.
4. Add wireless printer by following the procedures of adding a network printer. See Chapter 3.6.3 Installing a Graph/Text Printer for details.
5. Select <Preset> ([F10]-<Print>), select "Report Print" from the printer list, select the printer, and set properties.
6. Click [Save] to exit the preset and make the settings effective.

### 3.6.6 iVocal

Insert the iVocal microphone device to the USB port of the ultrasound system. The system automatically enters the following page.



No.	Description
1	Click to speak to the microphone (the system recognizes the vocal order). The system conducts the operations after recognizing the voice.
2	Click to stop the voice Recognition.
3	Click to open the help information.

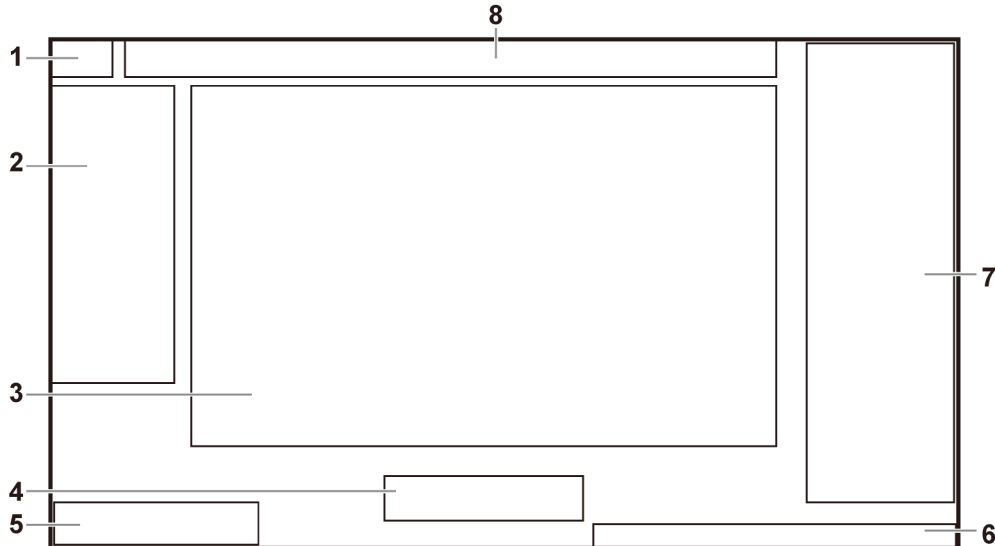
For details about iVocal command. Please refer to Appendix G List of Vocal Commands



## 3.7 Basic Screen & Operation

### 3.7.1 Monitor Display

The following diagram maps out the different areas, such as System Information Area, Parameters Area/Menu, Image Area, Hint (trackball and <Set> key function indications), Help Information Area, System Icons Area, Thumbnails Area, Patient Information Area.

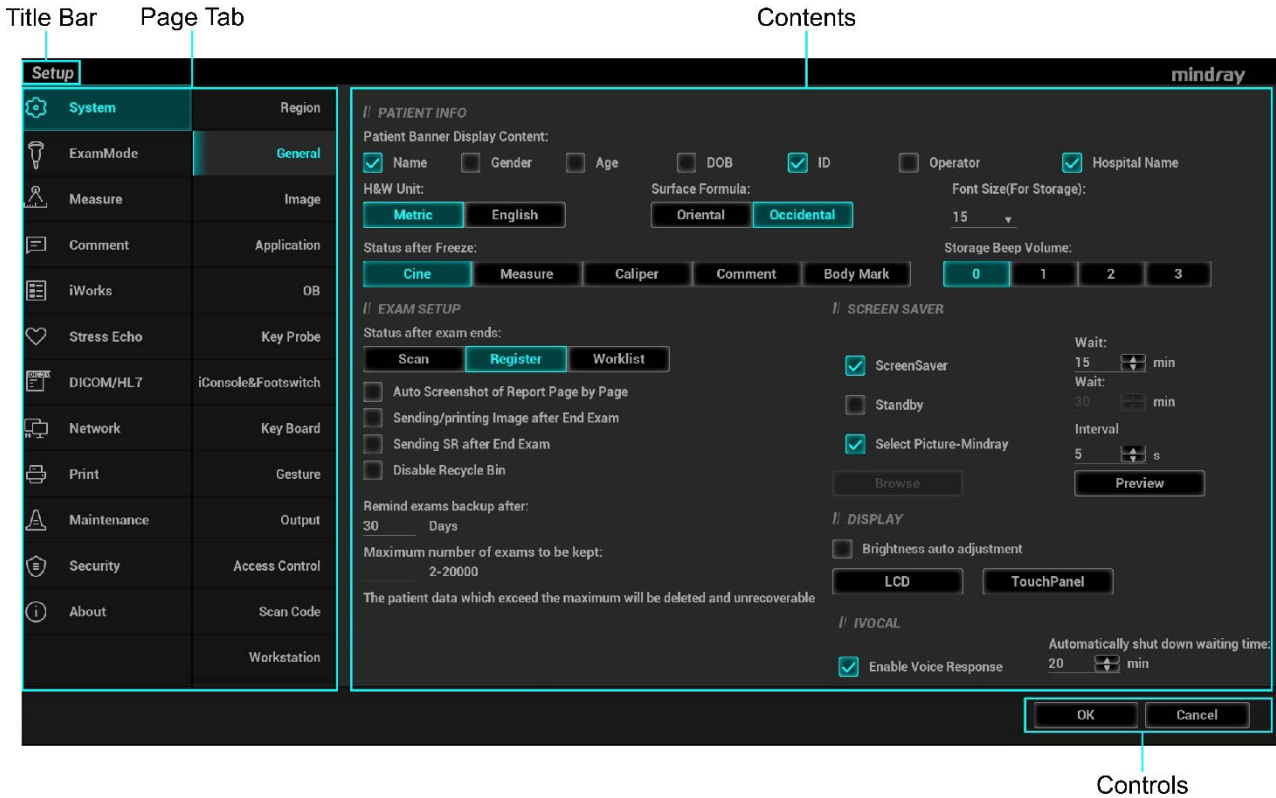


NO.	Item	Description
1.	System Information Area	Displays the manufacturer's logo and product model.
2.	Parameters Area/Menu	<ul style="list-style-type: none"> <li>● Displays the image parameters for the active window. If there are more than one imaging modes, the parameters are displayed by each mode.</li> <li>● Menu: Measurements, Comments and bodymarks. The menu is not displayed by default. Press the &lt;Menu&gt; key on the small keyboard to display or hide the parameter menu.</li> </ul>
3.	Image Area	Displays the ultrasound images, ECG waveforms, probe mark (or active window mark), time line (in M or PW mode), coordinate axis (in the top left corner of the image area, 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.
4.	Hint (trackball and <Set> key function indications)	Displays the current functions of trackball and <Set> keys.
5.	Help Information Area	Displays various help information items or the progress bar in the current status.
6.	System Icons Area	This area displays the relevant system icons, such as USB memory device, printer, network, Chinese/English entry, recorder, current system time, etc.
7.	Thumbnails Area	Displays the thumbnail images stored under the current patient.

NO.	Item	Description
8.	Patient Information Area	Displays the hospital name, patient name, exam mode, probe model, exam time, date, operator, patient ID, DOB, age and GA etc..

### 3.7.2 Basic Operations of Dialogue Box

A dialogue box screen consists of title, page tabs, contents and buttons, as shown in the following figure:



Component	Description
Title Bar	The title bar is used to give a description for the content and function of the screen.
Page Tab	For some screens, contents are distributed into several pages. Use <Set> to open/close the available pages.
Content	Radio box: click to select the item. Check box: click to check or uncheck the item. Entry box: enter characters manually via the keyboard. Drop-down list: click ▼ to show the list and select an item.
[OK] and [Cancel]	When the operation of a screen is completed, click the [OK] or [Cancel] button to save or cancel the operation, and close the screen.

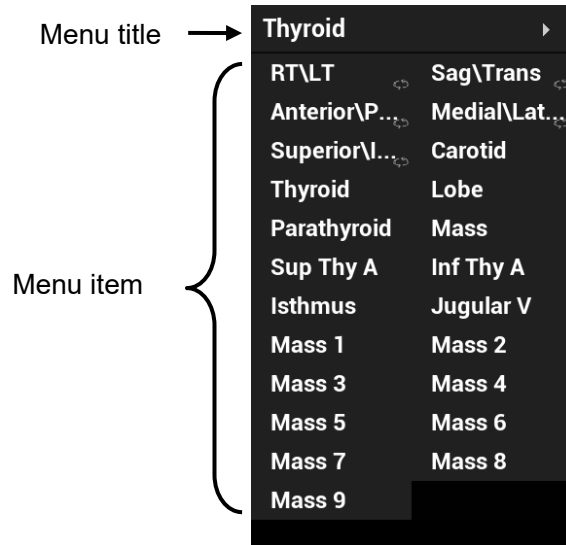
To reposition a dialogue box:

1. Roll the trackball to move the cursor onto the title bar of the dialogue box. At this time the cursor becomes a  $\updownarrow$ ; press <Set> key.
2. Roll the trackball and posit the rectangular graphic to the new desired location.
3. Release <Set> key, and the dialogue box is moved to the desired position.

### 3.7.3 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.



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

Press <Cursor> to show the cursor.

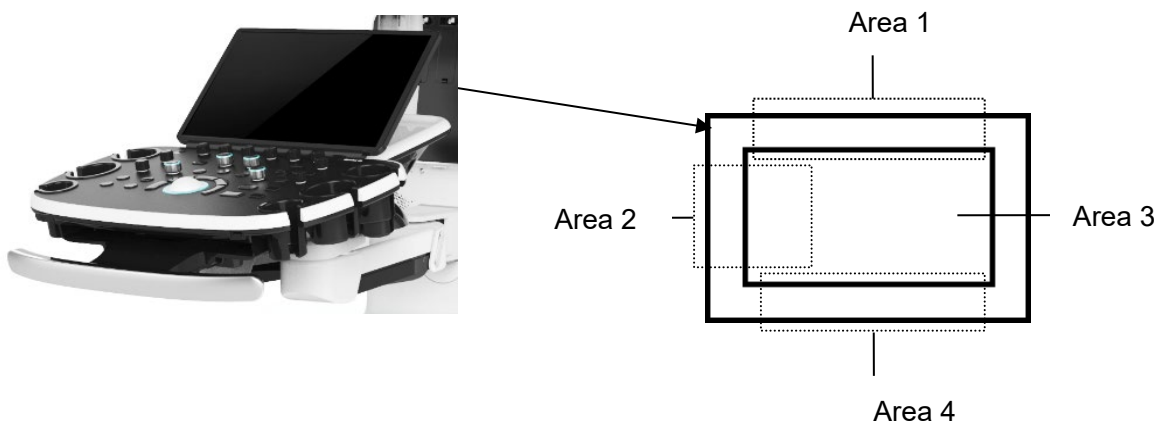
Roll the trackball to locate the cursor onto the item to be adjusted.


- 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].

### 3.7.4 The Display of Touch Screen and Its Operation

- Mapping mode of touch screen

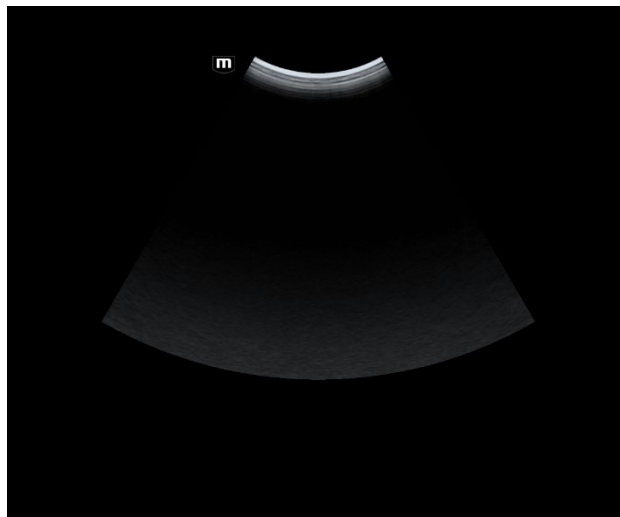


Operation area	Operations
1	Flick the edge downwards to enter the mapping mode.
2	Sweep to right to open the menus under the mapping mode.
3	The mapping menu, and toolbar are displayed. It is available to perform the image adjustment, measures, image review, etc. For details, see Chapter 5.1.2 Image 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-left of the screen. See Chapter "12.1.9 Gesture" for details.
4	Flick the edge upwards to exit.

- 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. See the figure below.

Tips: if there is a dialog box in the screen, the mapping mode is unavailable.




- 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. See the figure below: Tap or sweep right or left to adjust the image parameter, measures, etc. See Chapter 5.1.2 Image Adjustment for details.

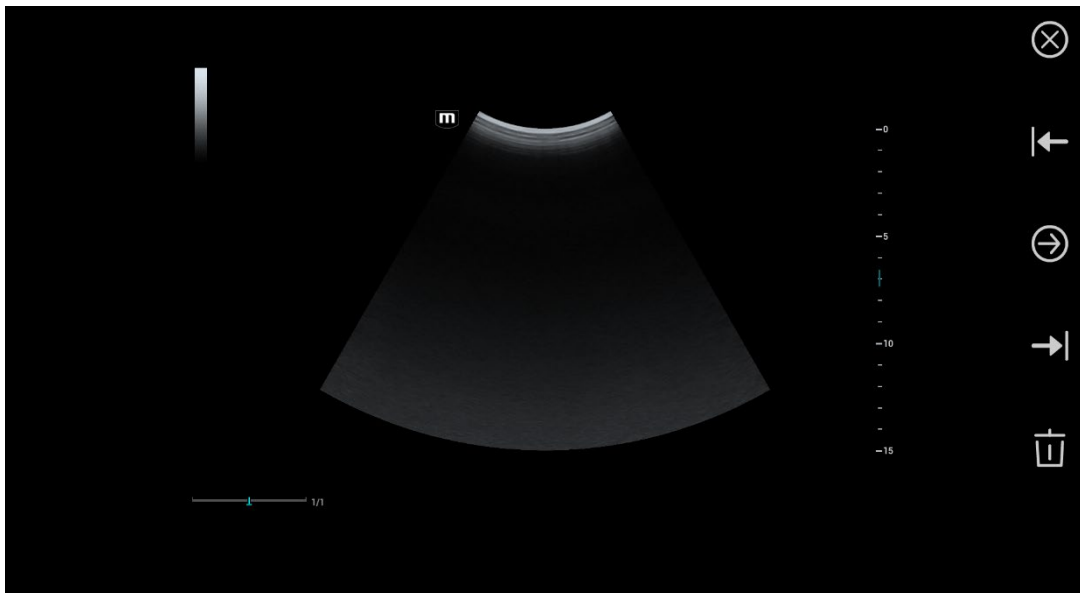
Tap the blank area on the touch screen. The menu of the mapping mode hides.







- Two-finger gesture  
Two-finger gesture can be configured with varied functions. See Chapter “12.1.9 Gesture” for details.

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



Icon	Description
	Review the previous image.
	Send the image. See Chapter 10.2.12 Sending Image File for details.
	Review the next image.

Icon	Description
	Delete the current image.

- Exit the mapping mode

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

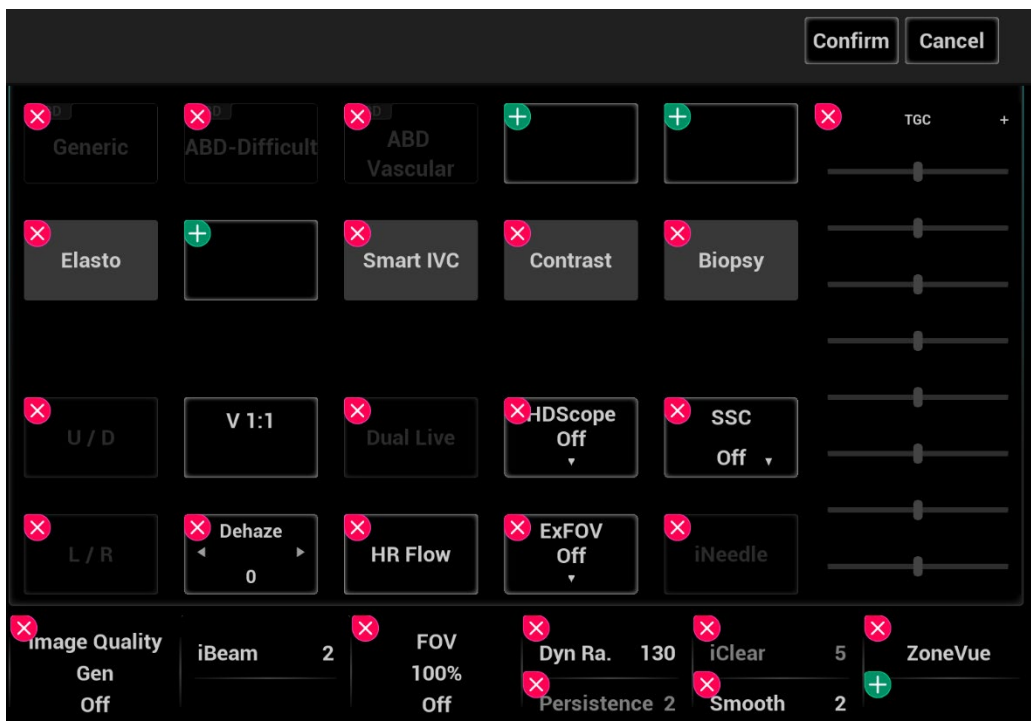
- Non-mapping mode of touch screen




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.

#### Controls on the touch screen:

Tap and hold the screen to enter control editing stage.

Tips: 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.



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

# 4 Exam Preparation

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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.

**General procedure for an exam:**

Enter the patient information → select an exam mode and probe → Choose an imaging mode → Start the exam.

The system supports image scanning and measurement without patient information.

## 4.1 Patient Information

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.



**CAUTION:**

**Before examining a new patient, tap the [End] key 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 enter the "Patient Info" screen

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

To exit the Patient Info screen

- Exit and save the settings: click [Save] 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.

Click [Quick Register] on the screen to save the patient information quickly and return to the main screen.

The system supports image scan and measurement without patient information.

## 4.1.1 New Patient Information

The Patient Info screen is shown as follows:

The screenshot shows the 'Patient info' screen with the following sections:

- Navigation:** Arrows labeled <1>, <2>, <3>, and <4> are positioned above and to the right of the screen.
- Patient info (GENERAL INFORMATION):** Fields for Last Name, First Name, M.I., Patient ID (20201209-165640-44DB), Gender (Unknown), Age (Years | Months | Days), and DOB (DD/MM/YYYY).
- DIAGNOSIS INFORMATION:** Fields for Study Description, Primary Indications, Secondary Indications, CPT4 Code, CPT4 Description, Height (cm), Weight (kg), LMP (DD/MM/YYYY), Gestations (1), Para, Abort, Ectopic, and V Delivery/AV Delivery/C Section.
- Ref. Physician, Diagnostician, Operator, Accession #:** Fields with dropdown menus.
- mindray:** Buttons for New Patient, New Exam, Pause Exam, Cancel Exam, iStation, Worklist, Quick Register, Save, and Cancel.

A red box highlights the 'New Patient' button, and a red arrow labeled <4> points to it from the right.

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.

You can also change the cursor position by [Tab], [Enter] or up/down controls.

Information includes:

### 1. General information

- Patient ID

Patient ID is generated automatically by the system after starting a new patient, and can be modified manually. The characters “\”, “\*”, “?” are not permitted.

The ID can be obtained by the bar code reader as well.

- Name

Enter patient name through the keyboard.

- Gender

Select Male, Female or Unknown for patient gender in the drop down list.

- Date of Birth

Or, click  to select the date and click [Confirm] to finish.

- Age

- Auto generated age: once the DOB is obtained, the system can display an auto-generated age in the field box, the 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.

- Also, you can manually enter the age.

If the entered patient ID or Last name already exists in the system, the related history patient records will be displayed on the pop-up window. You can select the desired patient record and click [OK] to load data, and the general information is auto-filled.

**NOTE:** When you enter the date manually, please enter it in the format as that of the system.

### 2. Exam Type



### Exam Application Type

You can select among: ABD (Abdomen), OB (Obstetrics), GYN (Gynecology), CARD (Cardiac), VAS (Vascular), URO (Urology), SMP (Small Part), PED (Pediatrics) and BREAST (Breast).

Select the exam type tab to enter the exam-specific information.

### General information:

- Study description: to enter description for each exam.
- 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.
- Remarks Exam-specific explanation or remarks.

### Exam specified information:

Exam Type	Information	Description
Abdomen	Height	/
	Weight	/
	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.
	Fasting	/
	ALT	Alanine transaminase.
Obstetric	Height	/
	Weight	/
	Calculation index	<p>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.</p> <ul style="list-style-type: none"> <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>● IVF: After you enter IVF, the system will calculate GA and EDD.</li> <li>● PRV: input the date and GA of the last exam, the system will calculate a new 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> </ul>
	Gravida: times of pregnancy.	/

Exam Type	Information	Description
	Ectopic: times of abnormal pregnancy.	Times of abnormal pregnancy. e.g. extrauterine pregnancy
	Gestations	Number of embryos (1, 2, 3, 4)
	Para: times of delivery	/
	Abort: times of abortion	/
	Ectopic	/
	V Delivery: times of vaginal delivery	/
	AV Delivery: times of instrumental vaginal delivery	/
	C Section: times of cesarean delivery	/
GYN (Gynecology)	Height	/
	Weight	/
	LMP (last menstrual period)	/
	Gravida: times of pregnancy.	/
	Para: times of delivery	/
	Ectopic: times of abnormal pregnancy.	Extrauterine pregnancy
	Abort: times of abortion	/
	Ectopic	/
	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	
Cardiology	Height	/
	Weight	/

Exam Type	Information	Description
	BSA body surface area	After the height and weight are input, the system will automatically calculate the BSA based on the formula.
	BP (blood pressure)	/
	HR	/
	RA Press (Right Atrium Pressure)	/
VAS (Vascular)	Height	/
	Weight	/
	BP(L) (blood pressure)	Input left blood pressure.
	BP(R) (blood pressure)	Input right blood pressure.
URO (Urology)	Height	/
	Weight	/
	Serum PSA	/
	PPSA coefficient	/
Small Parts	Height	/
	Weight	/
	N/A	/
PED (Pediatrics)	Height	/
	Weight	/
	N/A	/
Breast	Height	/
	Weight	/

### 3. Operating Information

- Accession #: refers to exam number used in DICOM.
- Diagnostician: people who is responsible for the exam.
- Operator: people who is responsible for images collection and scanning.
- Ref. Physician: the people who requires the operator to do the ultrasound operation.

Tip: if the name has been entered before, then it can be memorized by the system, you can select it in the drop-down list.

### 4. Functional key

- [Pause Exam]: to pause the current exam due to some special causes or system power off.
- [Cancel Exam]: to cancel the current exam.  
NOTE: The cancelled 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.
- [Save]: click to save the patient data entered and exit the screen.

- [Cancel]: click to cancel the patient data entered and exit the screen.

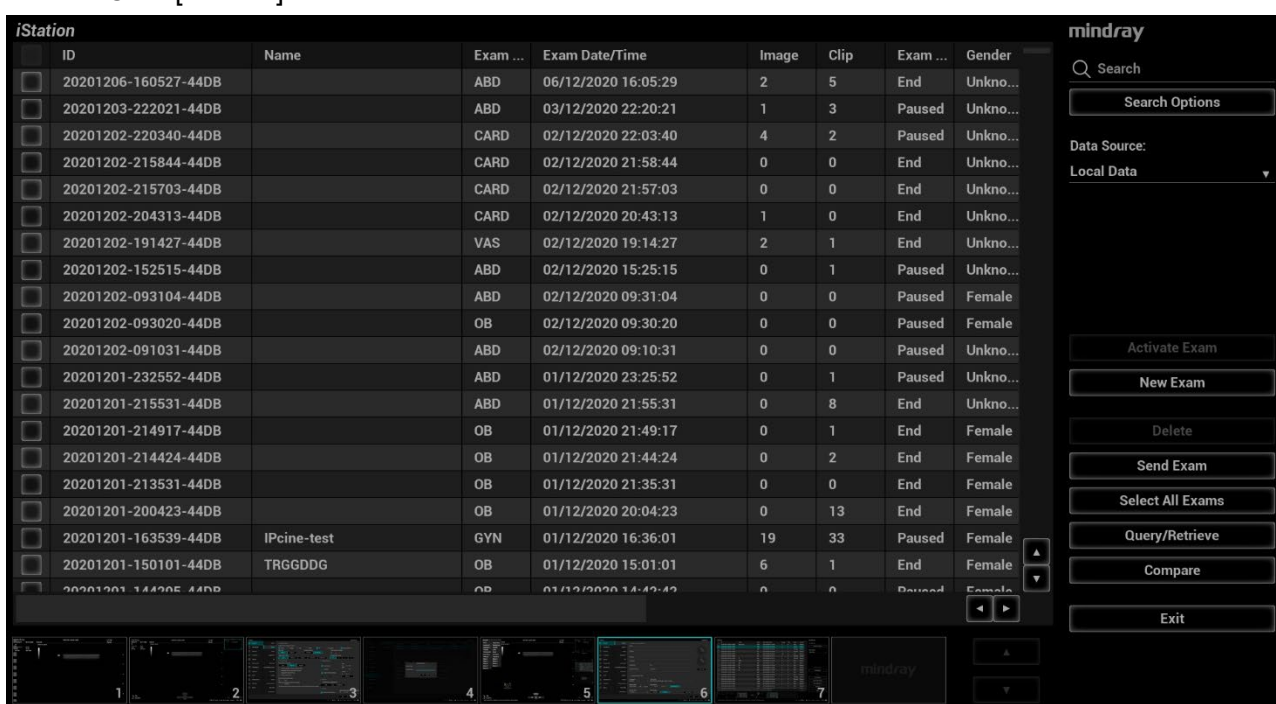
## 4.1.2 Retrieve Patient Information

### 4.1.2.1 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. To enter iStation screen (the screen is shown as follows):

- Press <F2 iStation> on the control panel;
- Click [iStation] in the "Patient Info" screen;
- Click [iStation] in the Review screen.



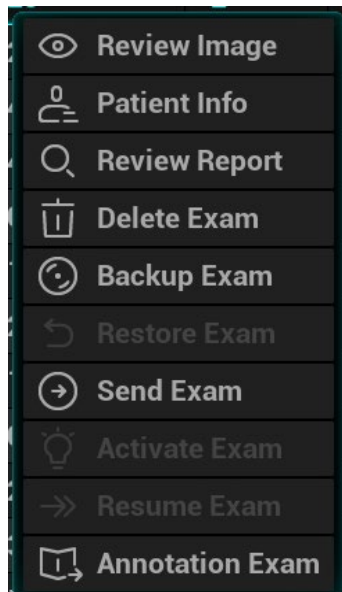
2. Select the data source

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

3. Input the searching condition:

- Item: including Name, ID, DOB, Exam Date, Exam Type, Study Description, Gender, Operator, Diagnosis (comments in the report) and Annotation, the default one is name; then enter a keyword or select the period in accordance with the Item selected.
- 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 following menu.



Description	Description
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 an annotation for the selected exam or check the history annotation.

Other buttons:

- [New Exam]: Click to enter Patient Info screen, meanwhile, the corresponding patient information is also imported to the new exam. After you edit the patient information in the Patient Info screen, select [OK] to start a new exam.
- [Select All Exams]: click to select all records.
- [Exit]: click to exit iStation.

#### 4.1.2.2 WorkList/HL7 Enquiry

Tips: Worklist is an optional function. Configure DICOM Basic and DICOM WorkList first.

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 (For details about Worklist server setting, please refer to the DICOM chapter.)

The system supports: DICOM and HL7.

Basic Operations:

- Tap [Information] on the touch screen to enter the patient information page.
- Click [WorkList] to enter the WorkList page.

Worklist

mindray

// QUERY

Patient ID: \_\_\_\_\_

Patient Name: \_\_\_\_\_ Accession #: \_\_\_\_\_

First Name: \_\_\_\_\_ Station Name: \_\_\_\_\_

M.I.: \_\_\_\_\_ System Location: \_\_\_\_\_

Admit Date: DD/MM/YYYY \_\_\_\_\_ Unit: \_\_\_\_\_

Scheduled Station AE Title: \_\_\_\_\_

DICOM Server: \_\_\_\_\_

Modality Type: \_\_\_\_\_

Server Type: \_\_\_\_\_

DICOM Server: \_\_\_\_\_

Search Key: \_\_\_\_\_

Requested Procedure ID: \_\_\_\_\_

Exam Date: Today \_\_\_\_\_ From: 09/12/2020 \_\_\_\_\_ To: 09/12/2020 \_\_\_\_\_

Query Clear Setting

0 records are listed.

Patient ID	Patient Name	Accession #	Exam Description	Exam Date	Gender	DOB
------------	--------------	-------------	------------------	-----------	--------	-----

Charset option: ISO\_IR 109

Start Exam Transfer Show Detail Exit

- Guarantee the data source: after select the service type, select the worklist server from the corresponding server (DICOM and HL7 server).
- Input the searching condition:
  - a) Input the searching condition:
    - Select "DICOM server". You can search via patient ID, accession #, station name, system location, key words, AE title, worklist server or exam date.
    - Select HL7 server. Search via patient ID, patient name.
  - b) 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.
- Or select the keyword type, enter the keywords and then click [Query] to search.
- To reset the criteria, click [Clear] button.
- Select the character set from the drop-down list of "Charset option".

The system converts the character set of retrieved patient records to current system character set from the selected character set in "Charset option".
- 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.
- Click [Exit] to exit the Worklist.

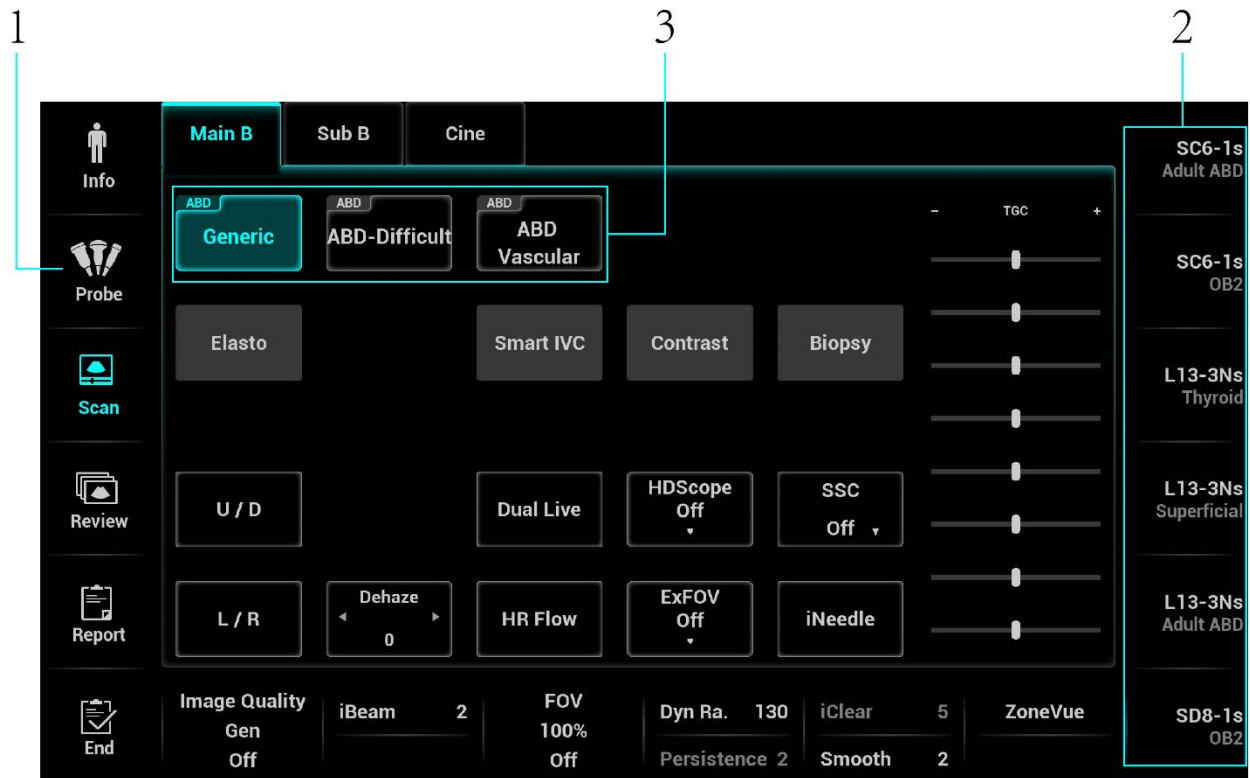
#### 4-8 Exam Preparation

## 4.2 Select Exam Mode and Probe



### CAUTION:

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. Regularly selecting probes and exam modes
  - a) Connect proper probes to the system, and tap <Probe> on the touch screen.
  - b) Tap to select the probe type and exam mode, and the system exits the dialogue box to enter the selected exam mode and probe. The activation indicator of the selected probe on the front I/O panel lights in blue.

Click [Exit] to cancel the selection and exit the screen.

2. Quickly switch to recently used probes and exam modes
 

The recently used probes and exam modes are displayed on the right side of the touch screen. Select an appropriate probe and exam mode for quick switch.
3. 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 click to switch to the corresponding IP.

- Note:
1. 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.
  2. 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.

For details about IP preset manager, please refer to “5.1.3 Quickly Saving Image Settings”.

## 4.2.1 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.

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.

The path for setting the keys: [F10 Setup]→[System]→[iConsole&Footswitch]/[Key Board].

1. Select the key to be defined to enter key setting page.
2. Select [Image]→[Dual Probe].
3. Click [OK] to confirm the setting or exit. The setting comes into effect then.

## 4.2.2 Bi-plane Probe Switch

For the probe ELC13-4s, 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.

## 4.3 Selecting Imaging Mode

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

For detailed operations in each imaging mode, please refer to Chapter 5 Image Optimization.

## 4.4 Activate& Continue an Exam

### 4.4.1 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 [Active 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.

### 4.4.2 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.



## 4.5 Pause & Continue an Exam

### 4.5.1 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 [Information] 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:

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

### 4.5.2 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, you can 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.

### 4.5.3 Annotation 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.



# 5 Image Optimization

**WARNING:**

1. The images displayed in this system are only reference for diagnosis. Mindray is not responsible for the correctness of diagnostic results.
2. 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.

## 5.1 Imaging Mode

### 5.1.1 Switching Between Image Modes

Refer to Chapter 2.9 Control Panel for image mode switch.

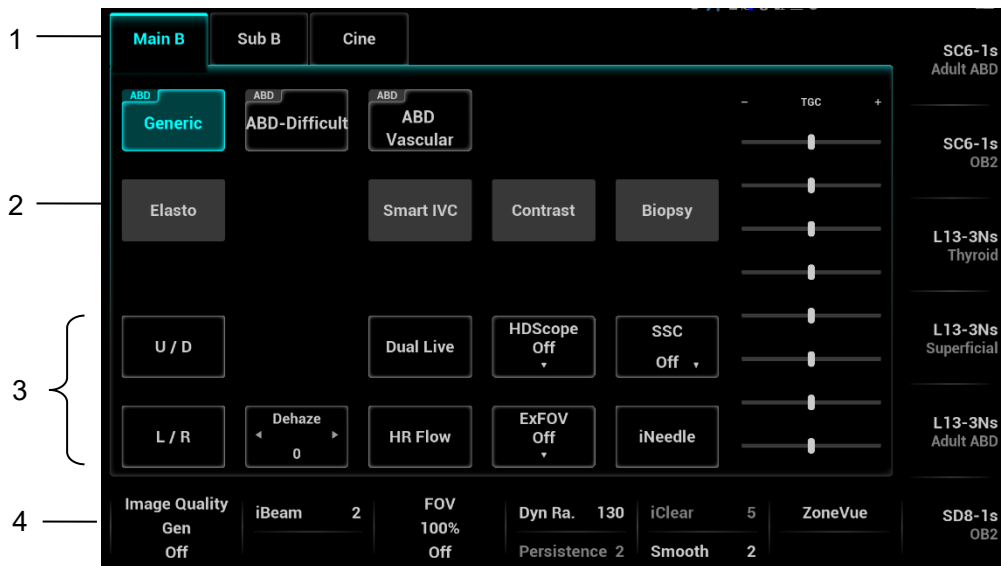
Quickly switch imaging mode

Press the <Menu> key on the small key board to quickly switch to the special mode. The available special modes are displayed on the top left corner of the screen. Press the <Menu> key again to close the special menu.




### 5.1.2 Image Adjustment

Touch screen:

Touch screen displays:

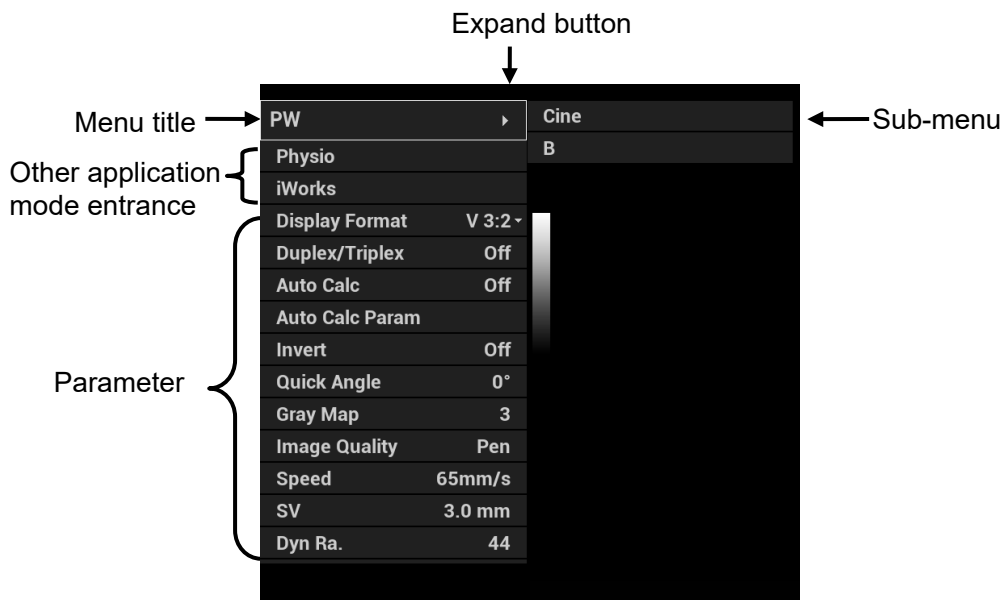



1. Mode displaying area (or main functional tabs): displays the current modes, click the tab to enter the mode.
2. Other application mode entrance: displays the available application modes related, click to enter the modes.

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 in blue.
  - Page selection: if the parameters cover more than one pages, tap the Main tab or Sub tab to find more.
  - Parameter submenu: for the parameter with  icon, tap to display the submenu to select the desired value.
  - Functional item: touch to go to the corresponding function.
4. Knob-adjusting area: displays the knob-controlled parameters.
 

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.

  - Touch screen adjustment (image mapping mode)
  - Enter the mapping mode to open the mapping menu. See Chapter 3.7.4 The Display of Touch Screen and Its Operation for details.



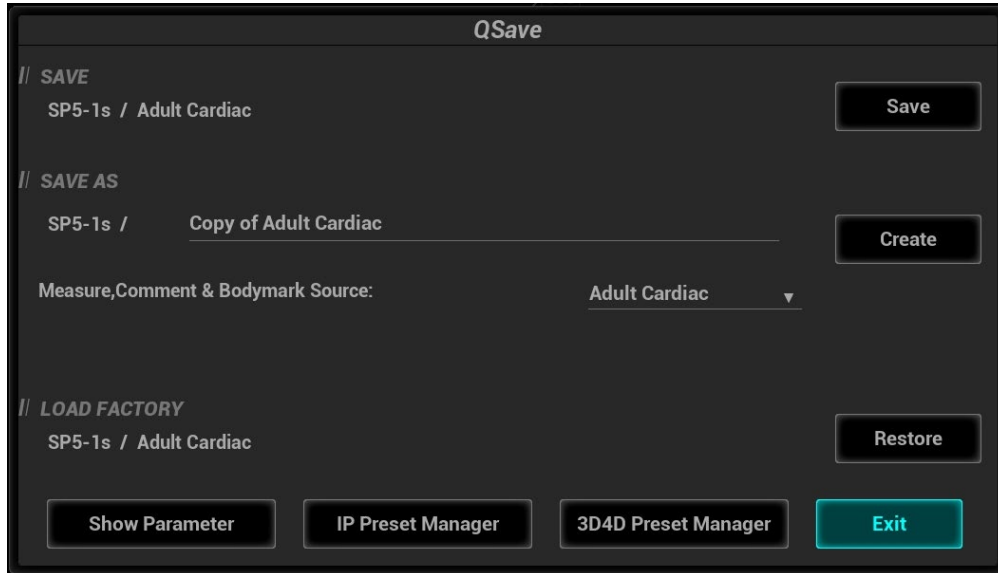
- Tap the menus to operate:
- Menu title: displays the current image mode. Click the expand button to show the image modes. Select the image mode if necessary.
- Other application mode entrance: displays the available application modes related, click to enter the corresponding mode. Such as, iWorks, physio.
- Parameter adjusting area: displays the parameters in the current imaging mode or function.
- Value adjustment: click the parameter item. The value increases as swiping from left to right; the value decreases as swiping from right to left.
- 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 in blue.
- Parameter submenu: for the parameter with  icon, tap to display the submenu to select the desired value.
- Functional item: touch to go to the corresponding function.
- Scrollbar operation: scroll to view all items.

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

Control Panel

Adjust through trackball, deflector rod, or knob.

### 5.1.3 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 the M-mark line. The M-mark 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.

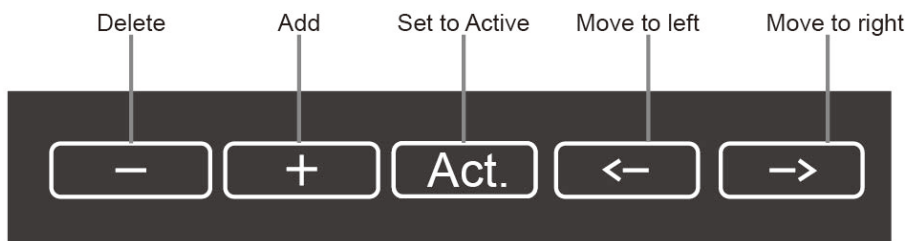
IP Preset Manager

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

3D4D Preset Manager

Click [3D4D Preset Manager].

- Level: displays the scenario and subpreset item of the currently activated probe and exam mode. The scenario and subpreset item can be renamed or restored to factory settings.
- Scenario and Subpreset: the item can be deleted, added, and set to default active item, and the position can be adjusted.



- Delete: delete a selected scenario or subpreset.
- Add: click a blank button, and select a desired scenario or subpreset under the currently activated probe and exam mode.
- Set to active: set a scenario or subpreset to the default active item.
- Move to left/right: move a scenario or subpreset to the left or right.
- Click [Show Scenario Parameters] and [Show Subpreset Parameters] to view the Scenario and Subpreset parameters.

Tips: it is unavailable for frozen dual-probe mode.

## 5.2 B-mode Image Optimizing

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

### 5.2.1 B Mode Exam Protocol

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.

### 5.2.2 B Mode Parameters

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

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

### 5.2.3 B Mode Image Optimization

#### Image quality

- Description** Used for switching B/THI and adjusting the frequency. The real-time value of frequency is displayed in the image parameter area in the upper left corner of the screen, and if harmonic frequency is used, "F H" is displayed as harmonic frequency value.
- Operation** Press the knob under the [Image Quality] on the touch screen to switch B/THI.  
Rotate the knob under the [Image Quality] on the touch screen to select the different frequency values.

The adjusting range of THI frequency values can be divided into penetration preferred (HPen), general mode (HGen), resolution preferred (HRes).

Under cardiac and cardiac-difficult mode, the values for SP5-1s can be arranged from penetration preferred (HPen), general mode (HGen), between general mode and high frame (HGen-FFR), resolution preferred (HRes), between the resolution and the high frame (HRes-FFR).

The adjusting range of basic frequency values can be divided into penetration preferred (Pen), general mode (Gen), resolution preferred (Res).

**Impacts** 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

**Description** To adjust the gain of the whole receiving information in B mode. The real-time gain value is displayed in the image parameter area in the upper left corner of the screen.

**Operation** Rotate <B> knob clockwise to increase the gain, and anticlockwise to decrease.

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

## Depth

**Description** This function is used to adjust the display depth of sampling, the real-time value of which is displayed on the image parameter area in the upper left corner of the screen.

**Operation** Use the <Depth> deflector rod on the control panel to adjust.  
The adjustable depth values vary depending upon the probe types.

**Impacts** Increase the depth to see tissue in deeper locations, while decrease the depth to see tissue in shallower locations.

**Impacts** Depth increase will cause a decrease in the frame rate.

## TGC

**Description** 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.

**Operation** To increase the gain compensation at an area of interest, move the TGC slider to the right. To decrease the gain compensation at the corresponding area of interest, move the TGC slider to the left. Double click anywhere of the TGC screen, the slider will return to the original status.


About 1.5s after the adjustment is finished, the TGC curve disappears.

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

## Quick TGC Adjustment

- Description** The system provides “User preset” or “Standard preset” to quickly adjust the TGC sliders.
- Operation** Touch the desired icon in the “User preset” or “Standard preset” column on the touch screen to adjust TGC sliders.
- Touch the  icon on the touch screen to restore TGC to the original status.

## TGC User Preset

- Description** Users can preset the TGC sliders to the desired position.
- Operation** Touch the  icon on the touch screen to enter TGC user preset screen. Select the desired slider position in the “Standard preset” or “User Preset” column, make adjustment of the sliders manually if necessary, and then touch [Save as] to select among Save as User1, Save as User2, and Save as User3.

## Acoustic power

- Description** Refers to the power of ultrasonic wave transmitted by the probe, the real-time value of which is displayed in the image parameter area in the upper left corner of the screen.
- Operation** Rotate the [A.power] knob to adjust the parameters.
- Generally, increasing the acoustic power will increase the brightness and contrast of the image as well as the force of penetration.
- Impacts** You should perform exams according to actual situation and follow the ALARA Principle.

## Image display adjustment

- Description** More information can be obtained without moving the probe or changing the sampling position.
- Scan range and FOV position** To change the scan range, press the knob under the [FOV] on the touch screen to enter or exit the FOV range and FOV position adjustment status.
- Press <Set> to switch the FOV range and FOV position.
- Rotate the trackball to adjust FOV position or the FOV range. Or, rotate the knob under [FOV] to adjust FOV range.
- When the scan range is adjusted to the widest, the FOV position cannot be changed.
- You can get a much larger field of view when selecting a larger FOV, but the frame rate will decrease.
- PW Steer** To steer the beam the probe transmits.
- Use the <Angle> knob to complete the adjustment.
- ExFov** Tap [ExFov] on the touch screen to turn on/off the function.
- For linear probes, the ExFOV function displays as trapezoid imaging.
- For convex and phase probes, the ExFOV function displays as extending the scan angle.



**Impacts** The FOV position/range is available for the convex, linear and phased probes. Steer is available only for linear probes.

## Line Density

**Description** The function determines the quality and information of the image.

**Operation** Tap [Line Density] on the touch screen to adjust the parameters.  
Levels of line density: UH/H/M/L.

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

## Dynamic Range

**Description** Adjusts contrast resolution of an image, compresses or expands gray display range. The real-time dynamic range value is displayed on the image parameter area in the upper left corner of the screen.

**Operation** Rotate the knob below [Dyn Ra.] to adjust the parameters.  
Rotate the knob clockwise to increase the value; rotate the knob counterclockwise to decrease the value.

**Impacts** The more the dynamic range, the more specified the information, and the lower the contrast with more noise.

## Smooth

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

**Operation** Rotate the knob under [Smooth] to adjust the parameter.  
The bigger the value is, the higher the smooth becomes.

## iClear

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

**Operation** Rotate the knob under [iClear] to adjust the parameters.  
*Off* represents iClear is disabled, and the bigger the value is the stronger the effect becomes.

## iClear<sup>+</sup>

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

**Operation** Rotate the knob under [iClear<sup>+</sup>] on the touch screen to adjust the parameters.  
*Off* represents iClear<sup>+</sup> is disabled, and the bigger the value is, the stronger the effect becomes.

**Impacts** iClear<sup>+</sup> is an option. If iClear<sup>+</sup> is configured, iClear will be replaced by iClear<sup>+</sup>.

## Persistence

- Description** Used to superimpose and average adjacent B images, so as to optimize the image and remove noises.
- Operation** Rotate the knob under the [Persistence] item on the touch screen to adjust the value. The bigger the value is the stronger the effect becomes.
- Impacts** Persistence can remove image noise to make image clearer.  
Persistence increase may lead to signal missing.

## Rotation/Invert

- Description** This function provides a better observation for image display.
- Invert** To invert the image horizontally or vertically.  
Tap [U/D] or [L/R] on the touch screen to adjust the parameters, and identify the image orientation through the "M" mark on the screen.
- Rotation** Tap [Rotation] on the touch screen to adjust the parameters.  
Image can be rotated by the manners in angle of 0°, 90°, 180°, 270°.  
When the image is rotated in the angle of 90° or 270°, the depth scale is displayed on the upper part of the screen.

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

## iBeam

- Description** This function is used to superimpose and average images of different steer angles to obtain image optimization.
- Operation** Rotate the knob under [iBeam] to adjust the parameters.  
The system provides various iBeam in B mode. iBeam is disabled when it is off.  
Images after iBeam processing can be optimized with less spot noise and higher resolution, so that more details for the structure are revealed.
- Impacts** The phased probe does not support iBeam.

## Image Merge

- Description** 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.
- Operation** Tap [Auto Merge]] on the touch screen to enable/disable the function.
- Impacts** Only for linear probes.

## Gray map

- Description** Adjusting grayscale contrast to optimize the image.
- Operation** Tap [Gray Map] on the touch screen to complete the adjustment.

## Tint Map

- Description** This function provides an imaging process based on color difference rather than gray distinction.
- Operations** Tap [Tint Map] on the touch screen to select the map.

## TSI

- Description** The TSI function is used to optimize the image by selecting acoustic speed according to tissue characteristics.
- Operation** Tap [TSI] on the touch screen to select.  
The system provided 4 ways of optimization for specific tissues: general, muscle, fluid and fat.

## Smooth

- Description** This feature is used to reject the noise and smooth the image.
- Operation** Rotate the knob under [Smooth] to adjust the parameter.  
The bigger the value is, the higher the smooth becomes.

## Optimize Speed

- Description** It refers to adjusting the acoustic speed according to tissue characteristics.
- Operation** Tap [SSC] on the touch screen to optimize the speed. SSC status and SSI value is displayed in real time.
- Impacts** The function is disabled in frozen state.

## HD Scope

- Description** The image inside the ROI is clearer than these outside when the function is enabled.
- Operation** Tap [HDScope] on the touch screen, the ROI appears. The image inside the ROI is clearer than the outside.  
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.  
Tap [HDScope]. The image effect increases as the value changes.  
Off represents the disable. The larger the value is, the clearer the image becomes.
- Impacts** The function is disabled in frozen state.

## iTouch

- Description** 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.

**Operation** Press <iTouch> on the control panel to enter the iTouch status, the symbol of which will be displayed in the image parameter area of the screen.  
Long press <iTouch> to exit.  
Tap [iTouch] on the touch screen to adjust the parameters.

## HScale

**Description** 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 HScale will be inverted when image is turned upwards/downwards.

**Operation** Click [H Scale] on the touch screen to display or hide the scale.

## Dual Live

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

**Operation** Tap [Dual Live] on the touch screen to enable/disable the function, and dual-split window of images are displayed.  
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 on the upper left corner of the main screen, parameters of the both windows are displayed.

**Impacts** It supports the magnification of the image.

## LGC

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

**Operation** Tap [LGC] on the touch screen to enter the adjusting dialogue box.  
The 8 rods displayed on the touch screen indicate the corresponding image areas on the main screen.  
Tap the slider to adjust the gain, move downwards to decrease the gain, while move upwards to increase the gain.  
In addition, the system provides several preset parameters for imaging.

## Echo Boost

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

**Operation** Tap [Echo Boost] on the touch screen. Echo Boost value appears on the parameter area.

**Impacts** Use phased probe to activate the function in cardiac mode.

## Ref. Line

<b>Description</b>	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.
<b>Operation</b>	Tap [Ref Lines] in the B tab on the touch screen: Roll the trackball to move the reference line; Rotate the <Angle> to rotate the reference line around the intersection point. NOTE: Ref. Line can be adjusted by pressing <Set> in frozen state.
<b>Impacts</b>	Use intra-cavity probe to activate the function in GYN or Pelvic Floor exam mode.

## Dehaze

<b>Description</b>	This function can restrain noise, so as to enhance the contrast resolution of the image.
<b>Operations</b>	Tap the [Dehaze] item on the touch screen to adjust the value.

## V 1:1

<b>Description</b>	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.
<b>Operations</b>	In the dual-split mode, tap [V 1:1] to enable this function.
<b>Impacts</b>	Only linear probes support this function.

## Extend Image

<b>Description</b>	This function is to extend image area and hide menu area and thumbnails.
<b>Operations</b>	Tap [ExtImage] on the touch screen or press user-defined key to enable this function

## ZoneVue

<b>Description</b>	Image within the zone range is clearer.
<b>Operations</b>	Rotate the knob under [Zone Vue] to adjust the zone range. The real-time zone range is displayed on the screen.

# 5.3 M Mode Image Optimization

## 5.3.1 M Mode Exam Operation

1. Select a premium image during B mode scan, and adjust to place the area of interest in the center of the B mode image.
2. Press <M> on the control panel, and roll 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.

5. Perform other operations (e.g. measurement and calculation) if necessary.

Tips: the M-mark line is displayed for one procedure operation. Press <M> to enter M mode.

## 5.3.2 M Mode Parameters

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

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

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.

## 5.3.3 M Mode Image Optimization

### Gain

**Description** To adjust the gain of M mode image, the real-time gain value is displayed in the image parameter area in left corner of the screen.

**Operation** Rotate <M> knob clockwise to increase the gain, and anticlockwise to decrease.

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

### Display Format

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

**Operation** Tap the different display format ratio keys on the touch screen to adjust.  
There are 5 formats available for image display: H2:3, V2:3, V3:2, V3:1, Full.

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

### Speed

**Description** 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 in the left corner of the screen.

**Operation** Turn the knob under [Speed] on the touch screen to complete the adjustment.  
The smaller the value is, the slower the speed becomes.

**Effects** Speed changing makes it easier to identify disorders in cardiac cycles,

### Tint Map

**Description** Tint map function provides an imaging process based on color difference rather than gray distinction.

**Operation** Tap [Tint Map] on the touch screen to select the map.

## Gray map

- Description** Adjusting grayscale contrast to optimize the image.
- Operation** Tap [Gray Map] on the touch screen to complete the adjustment.

## Edge Enhance

- Description** This function is used to increase image profile, so as to distinguish the image boundary.
- Operation** Rotate the knob under [Edge Enhance] on the touch screen to adjust the parameters. 0 represents no edge enhance is turned on, and the bigger the value is, the stronger the effect becomes.
- Impacts** Larger edge enhance may lead to noise increase.

## Dynamic Range

- Description** 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 on the top of the screen.
- Operation** Rotate the knob under [Dyn Ra.] on the touch screen to complete the adjustment.
- Impacts** The more the dynamic range is, the more specified the information appears.

## M Soften

- Description** This feature is used to process the scan lines of M images to reject noise, making the image details to be clearer.
- Operation** Rotate the knob under [M Soften] to adjust the parameters on the touch screen. 0 represents the function is disabled. The bigger the value is, the stronger the effect becomes.

# 5.4 Color Mode Image Optimization

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.

## 5.4.1 Color Mode Exam Protocol

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. Use the trackball and <Set> to change position and size of the Region of Interest (ROI).
3. Adjust the image parameters during scan to obtain optimized images.
4. Perform other operations (e.g. measurement and calculation) if necessary.

## 5.4.2 Color Mode Image Optimization

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

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

During color 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 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.

## 5.4.3 Color Mode Image Parameter

### Color Gain

**Description** Refers to the overall sensitivity to flow signals. The real-time gain value is displayed in the image parameter area in the left corner of the screen.

**Operation** Rotate the <C> knob clockwise to increase the gain, and anticlockwise to decrease.

**Impacts** 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.

### ROI Adjustment

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

**Operation** 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.

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

### Image quality

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

**Operation** Rotate the knob under the [Image Quality] on the touch screen to select the different fundamental wave value.

The adjusting range of basic frequency values can be divided into penetration preferred (Pen), general mode (Gen), resolution preferred (Res). Please select the frequency according to the detection depth and current tissue features.

### B/C Align

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

**Operation** Tap [B/C Align] on the touch screen.



## Dual Live

- Description** This function is used to display B image and Color image synchronously.
- Operation** Tap [Dual Live] on the touch screen to enable or disable the function. When the function is activated, the window will be automatically switched to the dual windows (one for B image, and another for Color image).

## Steer

- Description** The feature is used to adjust the ROI of color flow with different angles with immobility of the probe.
- Operation** Rotate the knob under the [Steer] on the control panel to adjust the steer angle.
- Effects** This function is used to adjust the scan angle of the probes, so as to change the angle between the transmitting beam and flow direction.
- Impacts** Only for linear probes.

## C ExFov

- Description** The C ExFOV function displays as trapezoid imaging in color mode.
- Operation** Tap [C ExFov] on the touch screen to turn on/off the function.
- Impacts** 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".

## Line Density

- Description** The function determines the quality and information of the image.
- Operation** Tap [Line Density] on the touch screen to adjust the parameters.  
Levels of line density: UH/H/M/L.
- Impacts** The higher the line density is, the higher the resolution becomes.

## Sensitivity

- Description** This function is an indication of the ability to detect flow, which is used to adjust the accuracy of color flow.
- Operation** Rotate the knob under the [Packet Size] item on the touch screen to adjust the value.  
0 represents no packet size control and the bigger the value is, the higher the sensitivity becomes.
- Effects** The higher the sensitivity is, the more sensitive indication for low-velocity flow becomes.
- Impacts** It affects the frame.

## Flow State

- Description** Refers to optimizing the various flow states.
- Operation** Tap [Flow State] on the touch screen to adjust the parameters.

## Persistence

- Description** This function is to adjust the temporal smooth to optimize the image.
- Operation** Rotate the knob under [Persistence] on the touch screen to adjust the parameters. 0 represents no persistence. The bigger the value is, the stronger the effect becomes.

## Smooth

- Description** This feature is used to reject the noise and smooth the image.
- Operation** Rotate the knob under [Smooth] on the touch screen to adjust the parameters. The bigger the value is, the higher the smooth becomes.

## Scale

- Description** 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 in the left corner of the screen.
- Operation** Rotate the knob under [Scale] on the touch screen to complete the adjustment.
- Effects** To provide a much clearer color flow image.  
Use low PRF to observe low-velocity flows, and use high PRF to observe high-velocity flows.
- Impacts** 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

- Description** 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.
- Operation** Rotate the knob under [Baseline] to complete the adjustment. Positive value means to increase the signals below the baseline, and negative value means to increase the signals above the baseline.

## Invert

- Description** To set the display mode of the color flow, the color scale will be inverted when the function is activated.
- Operation** Tap [Invert] on the touch screen to complete the adjustment.  
Then the color bar can automatically invert when the color flow is steered to a certain angle to accommodate operators' habit of distinguishing flow direction. Select [Auto Invert] via [Setup]→[System Preset]→[Image].  
It is available only for linear probes.

## Color map

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

**Operation** Tap the [Color Map] item on the touch screen to select the map.

## WF (Wall Filter)

**Description** 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 in the left corner of the screen.

**Operation** Rotate the knob under [WF] on the touch screen to adjust the parameters.  
Adjust the parameter according to the actual situation and the transducer.

**Impacts** Flow signals may be missing.

## Smart Track

**Description** 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.

**Operation** Tap [Smart Track] on the touch screen under Color/Power mode. The vessels lay in the middle of the ROI.

Enable the function under B+Color/Power+PW mode. The PW sampling line, SV size and SV position are adjusted automatically.

## Priority

**Description** This function is used to set levels of the flow display, to display the grayscale signal or color signal.

**Operation** Rotate the knob under [Priority] on the touch screen to complete the adjustment.  
The color image is preferred with higher value; while grayscale signals are displayed with the lower value.

## Velocity Tag

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

**Operation**

1. Tap [Velocity tag] on the touch screen to adjust the parameters. The green mark appears on the color scale.
2. Roll the trackball upwards and downwards to select the marking velocity.
3. Press <Set> to enter the tag range selection status, roll the trackball upwards and downwards to select the range.
4. Press <Set> to switch between marking position and marking range.

## iTouch

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

**Operation** Complete the image optimization via <iTouch>.

### HR Flow

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

**Operation** Tap [HR Flow] on the touch screen or press the user-defined key to complete the adjustment ([HR Flow] is highlighted after it being enabled).

### ART Flow

**Description** Enhance the blood sensitivity and penetrability in time period.

**Operation** Tap [ART Flow] on the touch screen (the soft key is highlighted when the function is enabled).

**Impacts** 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

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

**Operation** Tap the [Glazing Flow] item on the touch screen.

**Impacts** 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.

## 5.5 Power Mode Image Optimization

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.

### 5.5.1 Power Mode Protocol

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. Use the trackball and <Set> to change position and size of the Region of Interest (ROI).
3. Adjust the image parameters to obtain optimized images.
4. Perform other operations (e.g. measurement and calculation) if necessary.

## 5.5.2 Power Mode Image Parameters

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

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

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, 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 Power mode image.

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.

## 5.5.3 Power Mode Image Optimization

### Power Gain

**Description** 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 on the top of the screen.

**Operation** Rotate <C> knob clockwise to increase the gain, and anticlockwise to decrease.

**Effects** 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.

### Color map

**Description** 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.

**Operation** Tap [Color Map] on the touch screen to complete the adjustment. 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

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

**Operation** Rotate the knob under [Dynamic Range] on the touch screen to adjust the parameters.

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

## 5.6 V Flow

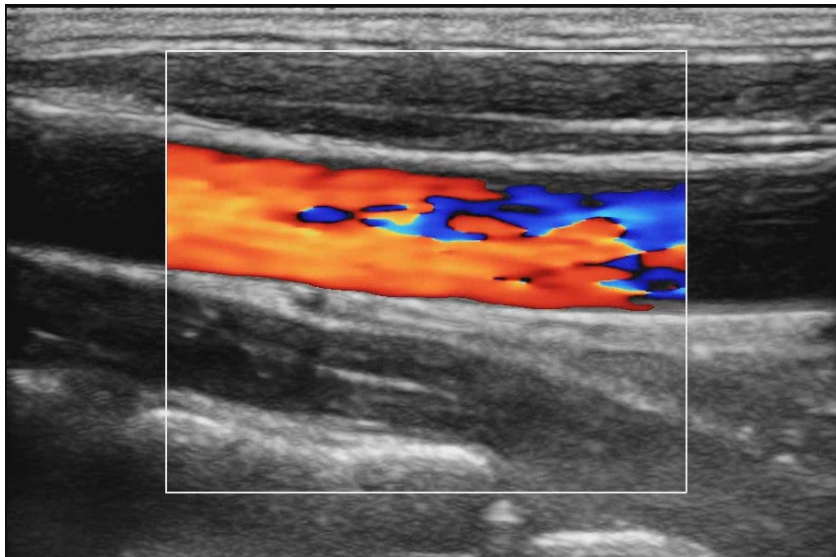
V Flow shows the blood direction and velocity via the arrow. The arrow length represents the velocity, and the arrow orientation represents the direction of the blood flow. The blood flow is displayed according to the updates of the arrow position and the velocity.

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

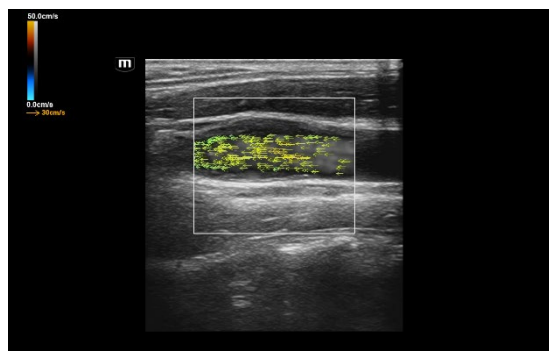
- |                    |  |
|--------------------|--|
| <b>Description</b> | <ol style="list-style-type: none"><li>1. V Flow imaging is an option.</li><li>2. You can enter V Flow on B/Color real-time scan mode.</li><li>3. It only supports single-window display, but does not support dual-window display and quad-window display.</li><li>4. V Flow image does not support the image magnification.</li></ol> |
|--------------------|--|

### 5.6.1 V Flow Basic Operations

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. See Chapter 5.12.3 Cine Review for details.
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 [Import data] 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.

## 5.6.2 V Flow Mode Image Parameter

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.

## 5.6.3 V Flow Mode Image Optimization

### Quality

- Description** To adjust the image quality
- Operation** Tap [Quality] to adjust the parameter.  
There are seven values of the spectrum.
- Impacts** The filling, smoothness and the image effect have slight change after completing the v flow adjustment.

### V Flow Map

- Description** 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.
- Operation** Tap [V Flow Map] to adjust the parameter.  
There are four values of the spectrum.
- Impacts** The color of the arrow changes after completing the adjustment.

### Gain

- Description** Used for adjusting the sensitivity of the blood flow signal.
- Operation** Rotate the knob under [Gain] to adjust the parameter.
- Impacts** 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

- Description** Used for adjusting the arrows' number in the unit area.
- Operation** Rotate the knob under [Arrow Density] item on the touch screen.
- Impacts** The arrow becomes more with the density becoming more compacted.  
The arrow becomes less with the density becoming fewer.

## Persistence

**Description** Used for adjusting the temporal smooth to optimize the image.

**Operation** Rotate the knob under [Persistence] on the touch screen.

0 represents no persistence. The bigger the value is, the stronger the effect becomes.

## WF (Wall Filter)

**Description** 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 in the left corner of the screen.

**Operation** Rotate the knob under [WF] on the touch screen to adjust the parameters.

**Impacts** Flow signals may be missing.

## Flow Brightness

**Description** Used for adjusting the blood brightness of the grey background.

**Operation** Rotate the knob under [Brightness] item on the touch screen.

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

The grey background of the blood flow effect becomes darker with the value becoming smaller.

## Colorbar Scale

**Description** The maximum velocity of the color map.

**Operation** Rotate the knob under [Colorbar Scale] item on the touch screen.

**Impacts** 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

**Operation** Tap [Edge Smooth] to adjust the parameter.

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

The blood against the edge becomes tough with the value being smaller.

## Arrow Lifetime

**Description** Used for adjusting the frame of the arrow.

**Operation** Rotate the knob under [Arrow Lifetime] to adjust the parameter.

**Impacts** The arrow appears longer with the value becoming larger.

The arrow appears shorter with the value becoming smaller.



## Arrow Size

- Description** Used for adjusting the arrow size.
- Operation** Rotate the knob under [Arrow Size] to adjust the parameter.
- Impacts** 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

- Description** Set trigger type.
- Operation** 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.
- Impacts** Tap [Trig Type] to select the levels: manual, R, R100, R200, R300 and R400.

## ROI Size

- Description** Adjust the size of ROI.
- Operation** Tap [ROI Size] on the touch screen to adjust.

## Acquire Time

- Description** Set the acquisition time.
- Operation** Tap [Acquire Time] on the touch screen to adjust the acquisition time.

## Sensitivity

- Description** This function is an indication of the ability to detect flow, which is used to adjust the accuracy of color flow.
- Operation** Rotate the knob under the [Packet Size] item on the touch screen to adjust the value.  
0 represents no packet size control and the bigger the value is, the higher the sensitivity becomes.
- Effects** The higher the sensitivity is, the more sensitive indication for low-velocity flow becomes.
- Impacts** It affects the frame.

## 5.7 PW/CW Mode Optimization

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.

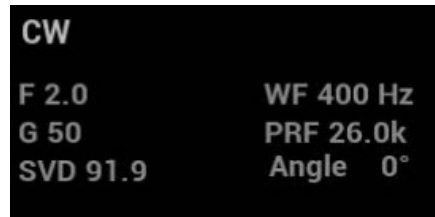
PW mode provides a function to examine flow at one specific site for its velocity, direction and features; while CW mode proves to be much more sensitive to high velocity flow display. Thus, a combination of both modes will contribute to a much more accurate analysis.

CW module is optional.

### 5.7.1 PW/CW Mode Exam Operation

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.

The parameter area appears in the left of the screen, see the figure below:



PW Sampling Line Adjustment	SV	SV Size
	Angle	Angle
	SVD	SV depth
CW Sampling Line Adjustment	Angle	Angle
	SVD	Focus depth

4. Adjust the image parameters during PW/CW mode scan to obtain optimized images.
5. Perform other operations (e.g. measurement and calculation) if necessary.

Tips: the M-mark line is displayed for one procedure operation. Press <PW>/<CW> to enter M mode. For details, please refer to Chapter 5.1.3 Quickly Saving Image Settings.

### 5.7.2 PW/CW Mode Image Parameters

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

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

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.

Most of the parameters are the same for the PW Mode and CW Mode, so the both are combined together to be introduced here.

## 5.7.3 PW/CW Mode Image Optimization

### Gain

- Description** This function is intended to adjust the gain of spectrum map. The real-time gain value is displayed in the image parameter area in the left corner of the screen.
- Operation** Rotate <PW> knob clockwise to increase the gain, and anticlockwise to decrease.
- Effects** Increasing the gain will brighten the image and you can see more received signals. However, noise may also be increased.

### PW Sampling Gate

- Description** 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 the left corner of the screen, 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.
- Effects** 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

- Description** To adjust the focus position of CW mode. The real-time focus position value is displayed on the image parameter area in the left corner of the screen in SVD.
- Operation** Roll the trackball to select the focus depth.

### Image quality

- Description** Refers to the transmitting frequency in Doppler mode of the probe, the real-time value of which is displayed in the image parameter area in the left corner of the screen.
- Operation** Rotate the knob under the [Image Quality] on the touch screen to select the different fundamental wave value.
- The adjusting range of basic frequency values can be divided into penetration preferred (Pen), general mode (Gen), resolution preferred (Res).
- Please select the frequency according to the detection depth and current tissue features.

### Scale

- Description** 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 in the left corner of the screen.
- Operation** Rotate the knob under [Scale] on the touch screen to complete the adjustment.
- Effects** To provide a much clearer color flow image.
- Use low PRF to observe low-velocity flows, and use high PRF to observe high-velocity flows.

**Impacts** 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

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

**Operation** Complete the image optimization via <iTouch>.

## Auto-Calculation

**Description** This function is used to trace the spectrum and calculate the PW/CW mode image parameters. The results are displayed in the results window.  
Tap [Auto Calc] on the touch screen to turn the auto calculation function on or off.

**Auto Calculation Parameter** Tap [Auto Calc Param] on the Auto Calculation page.

**Auto Calculation Cycle** To set the heart cycle number for auto-calculation.  
Tap [Auto Cycle] on the touch screen to select the cycle number.

**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.  
To change the trace area, adjust through [Trace Area] item on the touch screen.  
The available selections of trace area are: Above, Below, All.

**Trace Smooth** To set the smooth level when tracing.  
To change the trace area, adjust through [Smooth] item on the touch screen.  
The bigger the value, the higher the smooth processing.

**Trace Sensitivity** This function is used to set the sensitivity of tracing in the spectrum.  
To change the trace area, adjust through [Sensitivity] item on the touch screen.  
The bigger the value the higher the sensitivity.

**Operations** 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.

## Invert

- Description** This function is used to set the display manner of spectrum.
- Operation** Tap [Invert] on the touch screen to complete the adjustment.  
Then the color bar can automatically invert when the color flow is steered to a certain angle to accommodate operators' habit of distinguishing flow direction. Select [Auto Invert] via [Setup]→[System Preset]→[Image].  
It is available only for linear probes.

## Speed

- Description** This function is used to set the scan speed of PW mode imaging.
- Operation** Tap [Speed] on the touch screen to adjust the parameters.  
The smaller the value is, the slower the speed becomes.
- Effects** Changing the speed makes it easier to identify the cardiac cycles and to detect more details.

## T/F Res

- Description** Adjusts for a balance between time resolution and spatial resolution.
- Operation** Rotate the knob under [T/F Res] on the touch screen to adjust the parameters.  
Adjust according to the actual situation and the transducer.

## WF (Wall Filter)

- Description** 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 in the left corner of the screen.
- Operation** Rotate the knob under [WF] on the touch screen to adjust the parameters.  
Adjust the parameter according to the actual situation and the transducer.
- Impacts** Flow signals may be missing.

## Tint Map

- Description** This function provides an imaging process based on color difference rather than gray distinction.
- Operation** Tap [Tint Map] on the touch screen to complete the adjustment.

## Gray map

- Description** Selects among post processing map curves to optimize grayscale images.
- Operation** Tap [Gray Map] on the touch screen to complete the adjustment.

## Display Format

- Description** To set the display proportion of PW mode image and B mode image.

**Operation** Tap the different display format ratio buttons on the touch screen to adjust.  
There are 5 formats to display the images: H2:3, V2:3, V3:2, V3:1, Full.

### Duplex/Triplex

**Description** This function is used to set if B image or B+Color image (Power) is scanned synchronously.

**Operation** Tap [Duplex/Triplex] on the touch screen.

### HPRF

**Description** 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.

**Operation** Tap [HPRF] on the touch screen.

**Effects** HPRF enhances the range of detecting high-velocity flow.

### Baseline

**Description** Refers to the area where the velocity is zero in the spectrum. The map changes after being edited.

**Operation** Rotate the knob under [Baseline] to complete the adjustment.

**Effects** To optimize the image, adjust baseline according to the actual situation to change the range of flow velocity.

### Angle

**Description** 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 on the left part of the spectrum map.

**Operation** Rotate the <Angle> knob on the control panel to adjust.

### Quick Angle

**Description** To adjust the angle faster in increments of 60°, and the real-time value of which is displayed on the left part of the spectrum map.

**Operation** Press the <Angle> knob on the control panel to adjust the parameters.

There are 3 angles for quick adjustment: -60° , 0° , 60°.

**Impacts** The function is available in real-time imaging, freeze or cine review status.

### Dynamic Range

**Description** The dynamic range conveys the information that being transformed from echo intensity to gray scale.

- Operation** Turn the knob under [Dyn Ra.] on the touch screen or on the touchpad to complete the adjustment.
- Effects** With the contrast range, dynamic range, information displayed more, the noise increases more as well.

## Volume

- Description** This function is used to adjust the output audio in spectrum Doppler.
- Operation** Rotate the <Volume> knob on the control panel to adjust the volume.  
Press the <Volume> knob to turn on/off.
- Effects** Utilizing the output audio helps to identify the feature and status of flow.

## Steer

- Description** This function is used to adjust the scan angle in PW mode, so as to change the angle between the transmitting beam and flow direction.
- Operation** Rotate the knob under [Steer] to complete the adjustment.
- Effects** Obtain more information with immobility of the probe.  
Values of steer angles vary with the probe.
- Impacts** Only for linear probes.

# 5.8 Color M Mode (CM)

To know the cardiac motion state, CM is overlaid with flow and tissue movements 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.

## 5.8.1 Enter Color M Mode

Color Flow M mode

- In B+M mode, press <C>.
- In B + Color, press <M>.

Color Tissue M mode

- Press <TDI> which can be defined (via [F10 Preset]→[System]→[iConsole&Footswitch]/[Key Board]) on color flow M mode, or tap [TDI] on the touch screen, and then press <M> or <Update>.
- In B+TVI/TVD, or B+TVI+TVD mode, press <M>.

NOTE: only phased probe supports color tissue M mode.

## 5.8.2 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.

## 5.8.3 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.

ROI Adjustment

The ROI size and position determine the size and position of the color flow or color tissue 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.

## 5.9 Free Xros M Mode

Free Xros M mode analyzes the arbitrary part and direction of 2D image to obtain cardiac movements in a period of time, which can be fulfilled via the comparison of various sampling lines, thus to complete the estimate of the tissue accurately. The system supports Free Xros M (including linear anatomical M and curved anatomical M) scan for B mode, color mode, power mode and TVI mode.

Free Xros M mode is optional.



**CAUTION:**

**Free Xros M 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.**

User-defined key for Free Xros M mode

Assign a user-defined key for Free Xros M via: [Setup]→[System Preset]→  
[iConsole&Footswitch]/[Key Board].

### 5.9.1 Linear Anatomical M (Free Xros M)

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.
3. Adjust the sampling line (single line or couple of lines) to obtain optimized images and necessary information.

Free Xros M imaging is supported on frozen B image, B+M image and B+Power/Color/TVI image.



### 5.9.1.1 The Adjustment of Linear Anatomical M

In Free Xros 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.

In linear anatomical M mode, adjustable parameters are similar with these in M mode, as a result, specific parameters of linear anatomical M mode will be introduced as follows.

#### Display or Hide the M-mark Line

<b>Description</b>	There are 3 M-mark lines available, each with a symbol of "A", "B" or "C" at one end as identification.
<b>Sampling line selection</b>	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.
<b>Sampling line display</b>	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.
<b>Impacts</b>	When there is only one sampling line on the image, you cannot hide it.

#### Switching between the M-mark Lines

<b>Description</b>	To switch among the sampling lines in Free Xros M mode.
<b>Operation</b>	Press <Set> to switch among the sampling lines and press <Cursor> to show the cursor. The active sampling line becomes blue and the inactive one is white.

#### Adjustment of the sampling line

<b>Description</b>	To adjust the position and angle of the sampling line.
<b>Operation</b>	<ul style="list-style-type: none"><li>● 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.</li><li>● Angle Adjustment When the sampling line is activated, move the trackball to adjust the fulcrum of the line, and rotate the &lt;Angle&gt; knob to adjust the angle. The adjusting angle range of the sampling line is 0-180 degrees in the increment of 1.</li></ul>

### 5.9.1.2 Exit Linear Anatomical M Mode

Tap [Free Xros M] or the user-defined key to exit linear anatomical mode.

Press <B> to return to real-time B mode.


## 5.9.2 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.


**CAUTION:**

**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.**

### 5.9.2.1 Operations

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. Roll 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. The sampling line is displayed in blue, and each point is marked with a number in sequence.
7. Repeat Step 6 to finish the sampling line.
8. Double click <Set> to finish the editing, and the sample line is displayed in white.
9. Adjust the parameters to obtain the desired tissue of Free Xros CM image. Then, save the image.
10. Press the user-defined key for Free Xros CM, or press <B> to exit.

#### Editing the curve

1. To enter:  
After finishing the sampling line, tap [Edit] on the touch screen. The cursor becomes the icon .
2. Move the cursor over the curve. Press <Set> to activate the spot. Move the cursor to change the shape of the curve.
3. Double click <Set> to finish the editing, and the sample line is displayed in white.

#### Removing the curve

Tap [Delete] on the touch screen to remove the curve.

NOTE: the way to adjusting the parameters is same with that in M mode in Free Xros CM.

## 5.10 TDI

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.

NOTE: TDI is optional.

The phase probes support the TDI mode under the cardiac exam.

### 5.10.1 TDI Exam Protocol

Enter TDI

- Tap [TDI] to enter the TDI mode. Or set the key via [Preset]→[System]→[iConsole&Footswitch]/[Key Board] 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: Press 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: Press user-defined <TDI> key, and then press <M> or <Update> to enter TVM. The parameters of TVM are displayed on the touch screen.

#### Switching between the TDI modes

In TDI mode, press <C>, <PD>, <M> or <PW> to switch among the modes.

#### Exit TDI

- Press 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.

### 5.10.2 TDI Image Parameters

In TDI mode scan, the image parameter area in the left corner of the screen will show the real-time parameter values as follows:

- TVI/TEI

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

- TVD

Items	F	G	WF	PRF	SVD	SV	Angle
Meaning	Frequency	Gain	WF (Wall Filter)	Pulse Repetition Frequency PRF	SV depth	SV Size	Angle

- TVM

Image parameters combine the parameters of TVI mode and M mode.

### 5.10.3 TDI Image Optimization


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

**Description** This function is used for fast image optimization.

**Operations** Adjust using the [Flow State] item on the touch screen.

### 5.10.4 TDI Quantitative Analysis

 **CAUTION:** TDI is provided for reference, not for confirming a diagnosis.

**NOTE:** To perform the strain and strain curve, the ECG curve is in need in case of the deviation in curve.

TDI quantitative analysis is an option.

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.

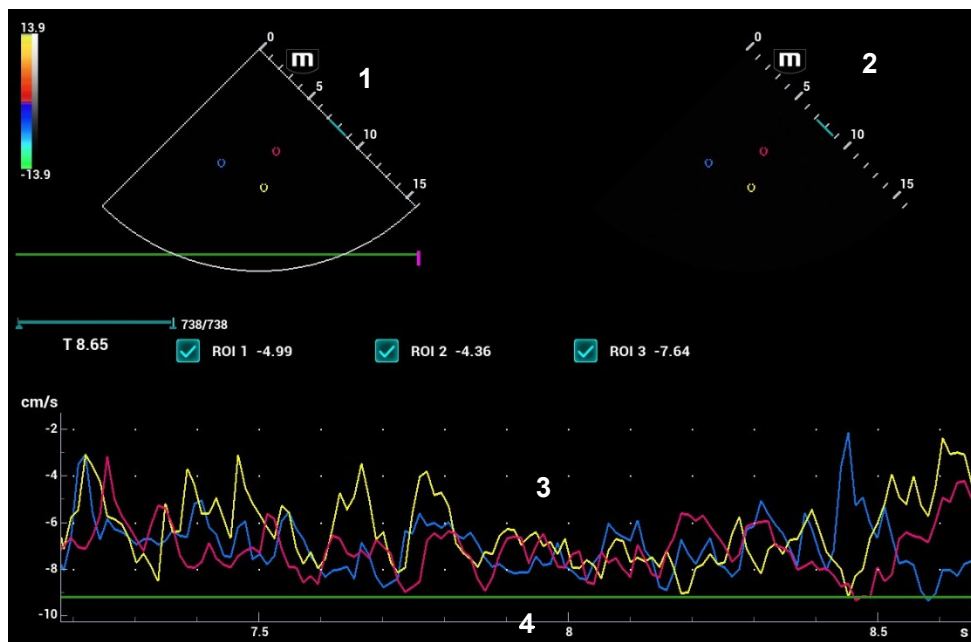
Procedures:

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.
  4. Select the curve: tap [Speed], [Strain] or [Strain Rate].
  5. Save the curves, and export the curve data, parameter data.
  6. Exit the quantitative analysis.  
Tap [Exit].

### 5.10.4.1 Screen Display of TDI Quantitative Analysis



Quantitative analysis display (taking velocity-time curve as the example)

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

#### NOTE:

- Move 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

- 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)].
- X-axis represents time (s);
- Frame mark: a white straight line perpendicular to the X-axis, and can be moved left and right by rotating the track ball.
- Click the check box in front of the ROI to display or hide the analysis curve.
- 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.

#### 4—ECG display area

### 5.10.4.2 Basic Operations of TDI Quantitative Analysis

#### ROI Settings

It is the sampling scope of the quantitative analysis.

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.

Procedures:

- Standard ROI: add ROI automatically after capturing the area. ROI size is decided by “Standard Height/Width/Angle”.
- Ellipse ROI: roll the trackball to perform the ellipse ROI after capturing the area.

#### Standard ROI

1. Tap [Standard ROI]. The standard ROI is displayed when the cursor moves into the review area (TDI review window or 2D grey review window).
2. Review to the desired frame.
3. Roll the trackball to one cine review window.
4. Press <Set>. The system updates the analysis curve and the data instantly.

Press <Clear> to remove the last ROI.

#### Ellipse ROI

1. Tap [Ellipse ROI]. The ellipse ROI is displayed when the cursor moves into the review area (TDI review window or 2D grey review window).
2. Review to the desired frame.
3. Roll the trackball to one cine review window.
4. Press <Set> to confirm the start point, and roll the trackball and press <Set> to confirm the next point. Press <Set> to complete the drawing. Press <Clear> to cancel the active ROI.

Press <Clear> to remove the last ROI.

#### Standard Height/Standard Width/Standard Angle

Adjust the hard key below the touch screen to adjust the ROI size: standard height, standard width and standard angle.

#### Strain Distance

Sample distance for calculating deformation. Rotate the knob under [Strain Dist.] on the touch screen to select the corresponding value for Strain – Time curve or Strain Rate – Time curve.

## ROI Tracking

Tap [ROI Tracking] to be On to start tracking.

This function provides a motion-compensated ROI as precise time-intensity information can be acquired using active tracking.

Tip:

- Elliptical ROIs can be positioned in any way that keeps their center within the image boundaries. If 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.

## 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

It is for smoothening the curve. The system provides 7 levels of smooth effect.

## Export curve (save curve data)

1. Tap [Export] on the touch screen.
2. The dialog box appears. Then select the storage path and type the file name. E drive is default; and the file type is .CSV.
3. Tap [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.

## 5.11 3D/4D

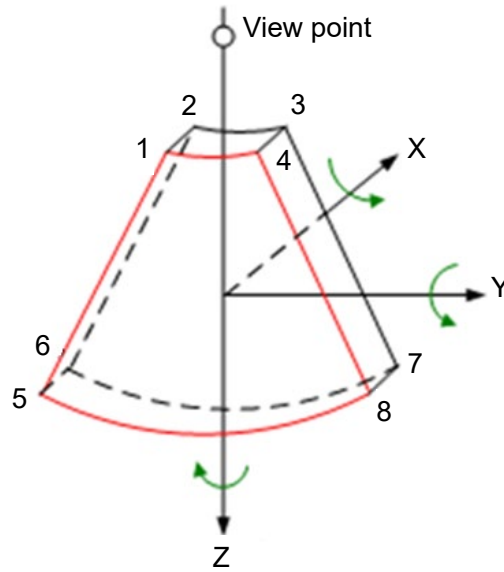
**NOTE:** 3D/4D imaging is largely environment-dependent, so the images obtained are provided for reference only, not for confirming a diagnosis.

### 5.11.1 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.

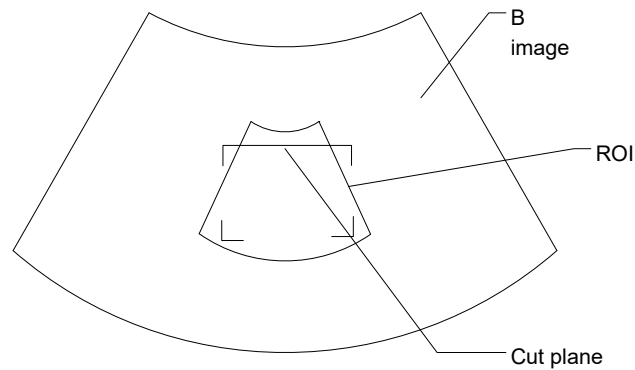
Terms (see the graphics below)

- 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.



### 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.



- 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

View	Curved VOI
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.

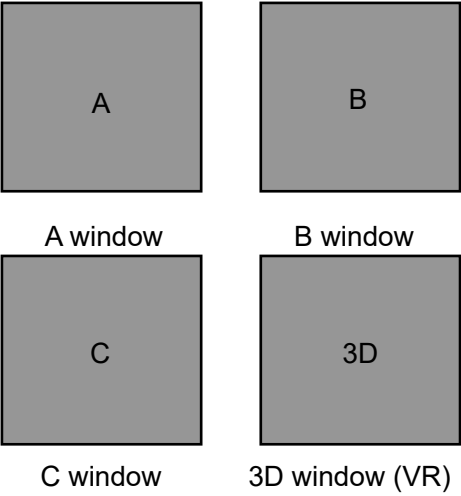
About the probes

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.

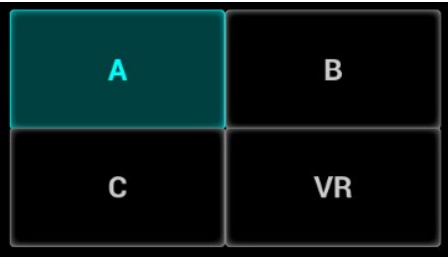
MPR

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.

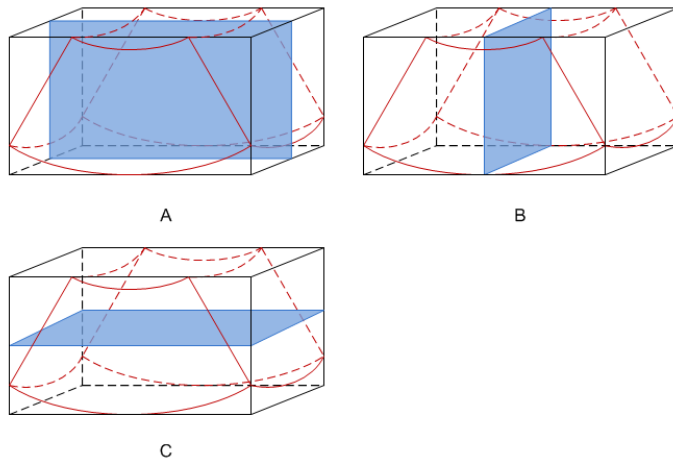


On the touch screen, the current window's icon is highlighted; as shown in the following, A window is the currently activated window.



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.

Tips: the upper part of the 3D image in the D 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 tapping [180°] on the touch screen.



**CAUTION:**

**The ultrasound images are provided for reference only, not for confirming a diagnosis. Please use caution to avoid misdiagnosis.**

**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.

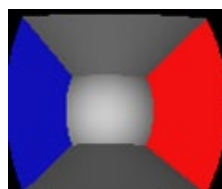
When the intra-cavity 4D probe is activated, the parameter [Free View] can be adjusted on the B image touch screen for adjusting the probe angle.

Range: -45° to +45°.

In increments of 5°.

**Wire cage**

When you view a 3D/4D 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.



Wire Cage

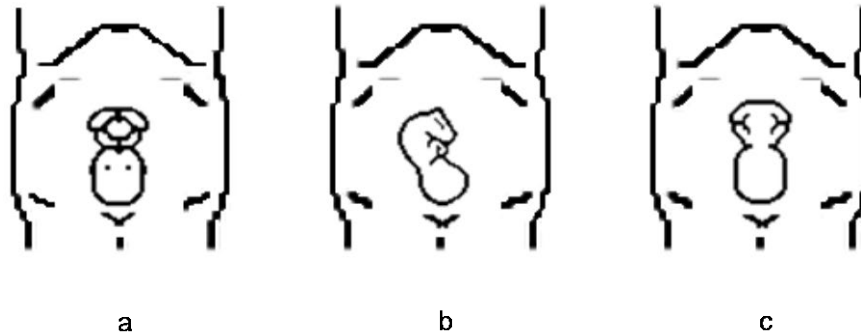
**5.11.2 Note before Use**

**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.

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.

#### 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 reconstructed 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°/s ~ 15°/s.
- Evenness: move or rotate the transducer at a steady speed or rate.

**NOTE:**

1. 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.
2. More practices are needed for a high success of qualified 3D imaging.
3. Even with good imaging condition, to acquire an approving 3D image may need more than one scanning.

### 5.11.3 Static 3D

Static 3D provides single frame image acquisition of 3D images. During the scanning; the probe performs the scanning automatically.

### 5.11.3.1 Basic Procedures for Static 3D Imaging

To perform static 3D imaging:

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.

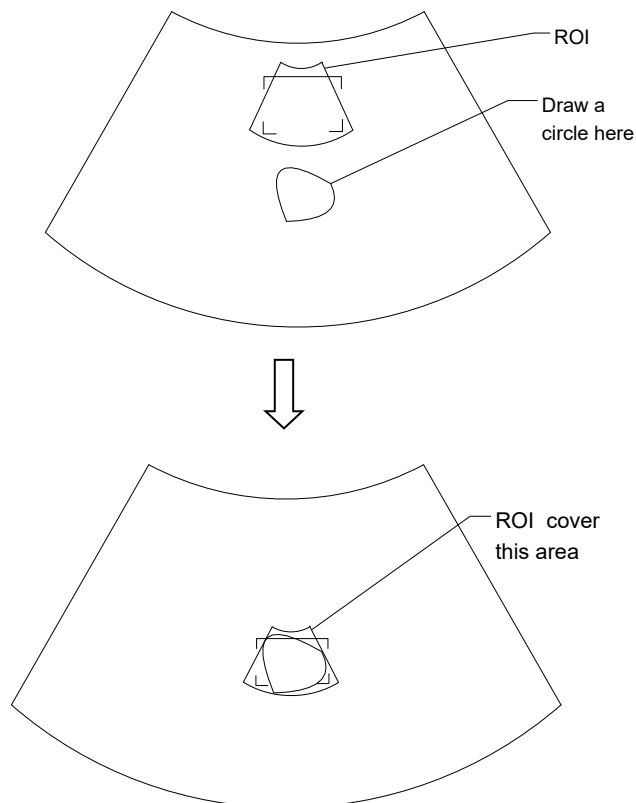
The imaging conditions should be:

- High contrast between the desired region and the AF (amniotic fluid) surrounded.
  - Clear boundary of the desired region.
  - Low noise of the AF area.
3. Press the user-defined <3D> key to enter Static 3D mode, and define the ROI and curved VOI.

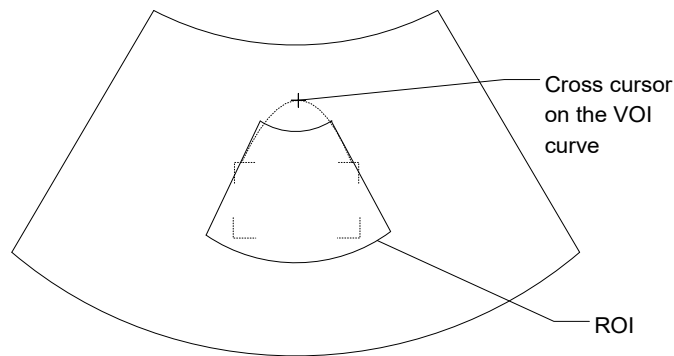
Methods to adjust the ROI:

- 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. See Chapter 3.7.4 The Display of Touch Screen and Its Operation for details.

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.



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.

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 refer to Chapter 5.11.3.3 Static 3D Image Viewing.

6. Exit static 3D.

Press <B> or press user-defined <3D> key to exit Static 3D mode. It returns to B mode.

### 5.11.3.2 Static 3D Acquisition Preparation

Press user-defined <3D> key to enter Static 3D status, the system enters Static 3D acquisition preparation status.

Use the touch screen to select render mode in acquisition preparation status.

Parameters of Static 3D Acquisition Preparation

Type	Parameter	Description
Parameter adjusting	3D/4D Scenario Setting	Select 3D/4D scenario based on different scenario application.
	Quality	Function: 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. Method: tap [Quality] on the touch screen, or, rotate the corresponding knob below the touchpad. Range: Low2, Low1, Mid, High1, High2.
	Angle	Function: to set the motion angle the probe covered during a fan sweep. Range: 10~85°, in increments of 2°.
	Mix	Set the Mix ratio of main render to sub render.
Main/Sub Render	Surface	Function: set Surface as 3D image rendering mode. Applicable for surface imaging, such as fetus face/hand or foot. Tip: you may have to adjust the threshold to obtain a clear body boundary.

Type	Parameter	Description
	Max	Function: set Max as 3D image rendering mode, displays the maximum echo intensity in the observation direction. This is helpful for viewing bony structures.
	Min	Function: 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	Function: 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	Function: 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		Based on the movements of the fetus, rebuilt and show the anatomical structure within a physical movement by using the interconnection between the time and the space.

### 5.11.3.3 Static 3D Image Viewing

#### Entering/ Exiting Image Viewing

To enter image viewing

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.

#### 3D/4D Scenario

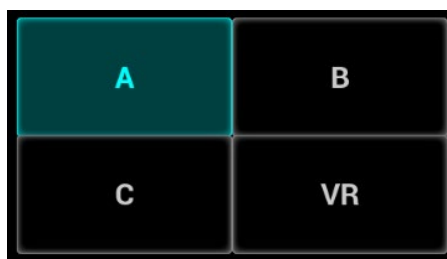
This function provides users multiple groups of preset 3D/4D parameters based on different application scenarios to quickly obtain expected image effect.

Tap [3D/4D scenario] to select a desired scenario and subpreset (rendering mode) under each scenario to view images. The parameters of each rendering mode are preset to different values.

Default scenarios and rendering modes of each probe and exam mode are different. You can customize the 3D/4D scenario in QSave. For details, please refer to “5.1.3 Quickly Saving Image Settings”.

#### Activate MPR

On the [VR] subtab, tap [A], [B], [C] or [VR] to activate sectional plane image (MPR) or 3D image (VR).

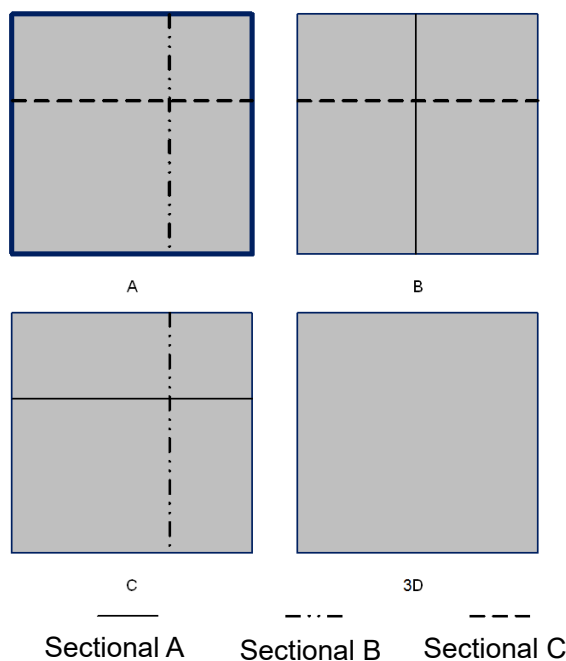


## MPR Viewing

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 the [MPR] subtab 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.

Tap the [MPR] subtab again to exit MPR only display mode.

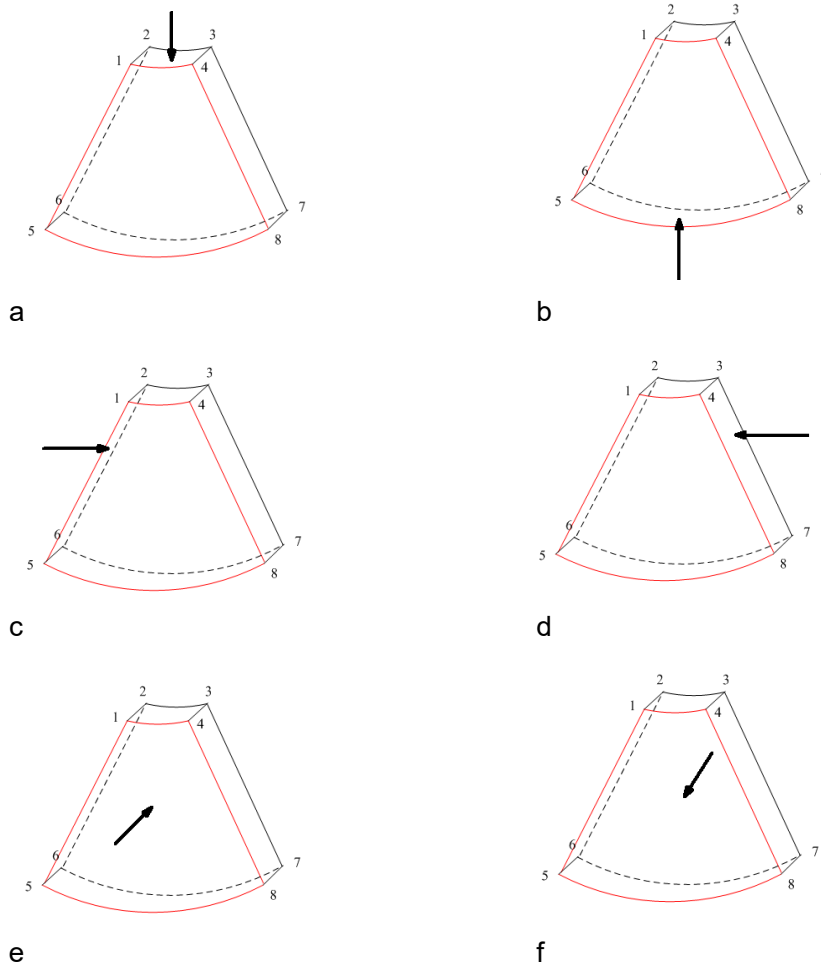
## Asymmetric

Tap  on the [Adv.] subtab 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.



View Direction		
a. Up/Down	b. Down/Up	c. Left/Right
d. Right/Left	e. Front/Back	f. Back/Front

Tap [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° rotation of current VOI, as shown in the figure b, d, e and f.

### 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.

1. In image viewing status, tap [VOI] to be "On".
2. Select a desired section plane by tapping [A], [B] or [C] or [VR].
3. 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.

Tap [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. Tap [Accept VOI], or tap [VOI Fixed] under 3D/4D contrast imaging.
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 blue, adjust parameters of 3D image (VR).
- When [MPR] button is highlighted in blue, adjust parameters of sectional image.

You can adjust:

Parameter	Description
Threshold	<p>Function: 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.</p> <p>Range: 0% to 100%.</p> <p>Available only in Surface rendering mode.</p>
Opacity	<p>Function: 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.</p> <p>Range: 0% to 100%.</p> <p>The lower the number is, the more transparent the gray scale information will be.</p> <p>Available only in Surface rendering mode.</p>
Smooth	<p>Function: to set the smoothness of 3D image.</p> <p>Range: 0 to 10.0 refers to no smooth effect; 1-10 provides 10 effects in incremental order.</p> <p>Tip: insufficient smoothness can result in a fuzzy image; however, too much smoothness will lead to image distortion.</p>
Brightness	<p>Function: to set the brightness of image.</p> <p>Range: 0%-100%, in increments of 2%. 0% represents the minimum brightness, while 100% represents the maximum.</p> <p>NOTE: the adjustment for 3D (VR) and MPR.</p>



Parameter	Description
Contrast	Function: 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. Range: 0%-100%, in increments of 2%. NOTE: the adjustment for 3D (VR) and MPR
Tint	Function: enable/disable tint map. The color of image changes according the tint value. Selection: OFF, 1-8.
Quick Rotation	Function: to rotate the 3D image quickly. Range: 0°, 90°, 180°, 270°.
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. Selection: OFF, 1-7. Select VR image. Adjust 3D iClear to optimize VR image. Select MPR image. Adjust 3D iClear to optimize MPR image.
Face+	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. Range: OFF, 1-3.
VR Refine	Function: Optimize the signal-noise ratio and the contrast of VR image. Selection: OFF, 1-7.
MagiClean	Function: Reduce the noise and keep the boundary of the image more clearly. Selection: Off, Low, Mid, High and Max. Available only in Surface rendering mode.
Depth VR	Function: Superimpose the tint map basic on the VR image to improve the stereoscopic sensation and the contrast of the image. Selection: Off, Black, Cyna, Blue, Rose
Hyaline	Function: Improve the transparency in iLive rendering mode to observe the tissue, such as cyst. Adjust method: Click [Hyaline] under iLive render mode, the merging ratio of two render modes between Hyaline and iLive is 100%; or, rotate the knob under [Hyaline] and adjust hyaline range. Effect: Adjust the merging ratio of two render modes between Hyaline and iLive
Thickness	Selection: 0-30mm.

### Reset Curve

Parameter	Description	
Reset	Ori	To reset the volume rotation, shifting and zooming of 3D image to original status.
	Reset All	To reset the parameters, rendering rotation, VOI and image effect.
	Reset Curve	To reset the curve to be the original beeline.

## Render Mode

Parameter	Description	
Main/Sub Render Mode (Gray/Inversion)	Surface	Function: set 3D image rendering mode as Surface. This is helpful for surface imaging, such as fetus face/hand or foot. Tip: you may have to adjust the threshold to obtain a clear body boundary.
	Max	Function: set Max as 3D image rendering mode, displays the maximum echo intensity in the observation direction. This is helpful for viewing bony structures.
	Min	Function: set Min as 3D image rendering mode. Display the minimum echo intensity in the observation direction. This is helpful for viewing vessels and hollow structures.
	X ray	Function: set X-ray as 3D image rendering mode. Display 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	iLive brings you a better imaging experience by adding lighting rendering effect to the traditional way, allowing human tissue texture to be revealed more clearly.  iLive cannot be selected as sub render mode. When it is set as main render mode, the sub render mode is disabled.
	The above five 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.	

## Rotate the Image

The system supports the following rotation modes:

- Axial rotation
- Auto Rotation




Axial rotation

Axial rotation is to rotate the 3D image around the X, Y or Z axis.

a) 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 the [Auto Rotation] subtab under [Tool] tab on the touch screen, system enters into auto rotation preparation state.
- 2) Tap [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, press the trackball function key of “Set Start” according to the trackball hint area.
  - End position: roll the trackball to view to a certain position, press the trackball function key of “End Start” according to the trackball hint area.
- 5) Set rotation mode: tap  for single direction rotation; tap  for bidirectional rotation. Set the auto rotation increment: rotate the knob under the [Step].
- 6) Tap  to start auto rotation. Rotate [Speed] to adjust the rotation speed.

**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.

## Inversion

Function: vessel shape is correct with the capture target. The vessel wall is smooth and clear.

## Surface Enhancement

Description: This function is to make the edge structure of the image and surface details clearer, so as to enhance the overall contrast.

Operation: Touch [Surf. ENH] to adjust the enhancement level.

Effect: 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

Function:

Adjust the zoom factor of 3D image, the section images will be zoomed in/out accordingly.

Operation:

Switch the current window to 3D window.

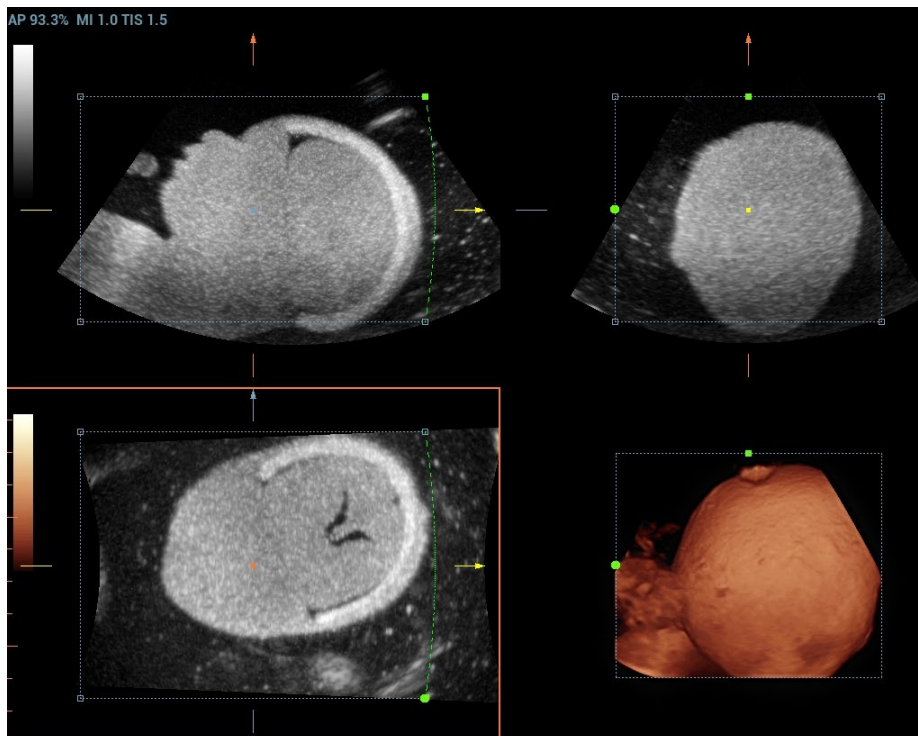
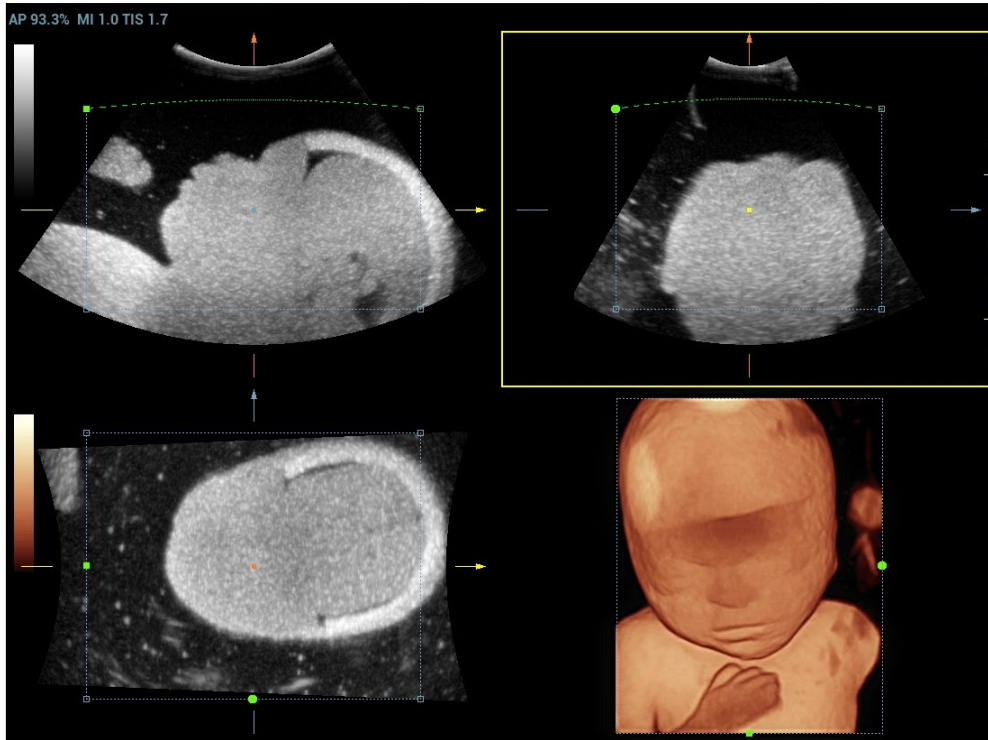
- Rotate <Zoom> to change the magnification factor.
- Zoom in or out by pinching or stretching in mapping mode.

Range:

0.2 – 4 times.

## 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


- Function:  
Add comments and comments on MPR and 3D image.
- Specific operation:  
The operations are the same with these in B mode.

## Image Editing

### ■ Function:

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:

- Tip: 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.

### ■ Procedures:

1. Enter image cutting status by taping "Tool" 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.
  - Soft/ hard eraser
    - 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.

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.

Parameters are described as follows:

Type	Parameters	Description	
Edit Type	Contour	Allows you to trace the portion of the image you want to cut.	
	Rect	Displays a box which can be used to define the portion of the image you want to cut.	
	Rubber		Applies to softer or smoother boundary within a small range of the image.
			Applies to a distinct boundary of within a wider range of the image.
	Polygon	Allows you to trace a polygon on the image you want to cut.	
	Line	Use a multi-point line to trace the boundary quickly.	
	Eraser Diam.	As the eraser erases the image by means of sphere, you can adjust the size so as to adjust the erased area and depth. The eraser sphere center has a more distinct effect of clearing compared to other parts.	

Type	Parameters	Description
Other Operations	Undo	To undo the last cut only.
	Undo All	To undo all cuts since you entered image edit mode.

## Measurement

2D related measurement can be performed. For details, please refer to [Advanced Volume].

NOTE: capturing preparation does not support the measurement.

### 5.11.3.4 Image Saving in Static 3D

- Image saving:
  - In the 3D Review mode, press <Save> key (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.

### 5.11.3.5 Color Static 3D (Color 3D)

NOTE: the system supports color Static 3D flow imaging function. See Chapter 5.11.4 Color 3D.

## 5.11.4 Color 3D

Color 3D imaging provides more visualized flow information, especially in heart and kidney application, which helps in observing cardiovascular diseases.

NOTE: Color 3D is an option, which includes color Smart 3D, color STIC and static 3D flow imaging.

### 5.11.4.1 Basic Procedures for Color 3D

1. Enter into color 3D image acquisition preparation status:
  - (1) Obtain a feasible Power/Color image with the volume probe.
  - (2) Press the user-defined <3D> key, or <4D> key 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.

### 5.11.4.2 Operation Controls

Parameter	Description
Display	Function: you can choose to display only color images or gray scale images, or to mix them. Range: VR, MPR, B, C, B&C.
Priority	Function: to determine color information displayed on gray scale images. Range: 0-100.

Parameter	Description
Threshold	Function: to eliminate color noise and motion artifacts. Range: 0%-100%. Affects MPR as well as VR.
Opacity	Function: to set the transparency value for VR rendering. Range: 0%-100%.
Smooth	Function: to smooth the Color image and erase artifacts by time averaging. Range: 0-10. Affects MPR as well as VR.
Mix	Function: to adjust mix percentage of gray scale information and color information. When display format is 2D&C, you can adjust this parameter. Range: 0-100%.
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]. Tips: you cannot perform measurement on acquisition preparation status.

## 5.11.5 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.

### 5.11.5.1 4D Procedures

To perform 4D imaging:

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 the <4D> key to enter 4D imaging mode.
4. Adjust ROI size and position and the VOI. The operations are same with these in static 3D mode.  
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> on the control panel to exit 4D mode.

### 5.11.5.2 4D Acquisition Preparation

Set the parameters before the acquisition. The settings for 4D mode are same with static 3D's.

### 5.11.5.3 4D Image Review

The settings for 4D mode are same with static 3D's.

### 5.11.5.4 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.

### 5.11.5.5 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.

### 5.11.5.6 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.

## 5.11.6 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.

If the ultrasound system is equipped with Smart 3D module, press the user-defined <3D> key to enter Smart 3D imaging.

Smart 3D is an option. 4D probe does not support Smart 3D imaging.

### 5.11.6.1 Smart 3D Procedures

**NOTE:** 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.

To perform Smart 3D imaging:

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 the user-defined <3D> key on the control panel to enter Smart 3D mode.
4. Adjust ROI size and position and the position of VOI.

**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.

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.

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> on the touchpad.

In image review status, you can perform operations like VOI setting, parameter adjustment, comments, image saving, image cutting, etc. For details, please refer to Chapter 5.11.6.4 Smart 3D Image Viewing.

7. Exit Smart 3D

Press <Update> or <Freeze> to return to Smart 3D acquisition preparation status.

Or press <B> or user-defined <3D> key to exit the mode.

### 5.11.6.2 Smart 3D Acquisition Preparation

Press <3D> to enter Smart 3D mode.

Parameter	NOTE
3D/4D Scenario Setting	Select 3D/4D scenario based on different scenario application.
Method	<p>Function: select the image acquisition method.            Selection: Rocked, Linear.</p> <p>Linear mode: during the sweep, the probe must be kept parallel. The scanning speed should be constant.</p> <p>Rocked mode: in this mode, the probe must be moved to a position where you can clearly see a middle cut of the object you want to scan and render. Tilt the probe to about 30° until the object you want to scan disappears. Start the acquisition and tilt the probe over a distance of around 60 degrees until the object disappears again. During the sweep, the probe may not be moved parallel, just tilted.</p> <p>Tip: the speed is related to scanning distance or angle.</p>
Distance	<p>Function: to set the distance the probe covered from one end to the other end during the linear sweep.            Range: 10~200 mm, in increments of 10mm.</p>
Angle	<p>Function: to set the motion angle the probe covered during a fan sweep.            Range: 10~80°, in increments of 2°.</p>
Acquiring Time	Function: to set the acquiring time of the Smart 3D acquisition.

The smart 3D acquisition preparation is same with these in Static 3D and 4D.

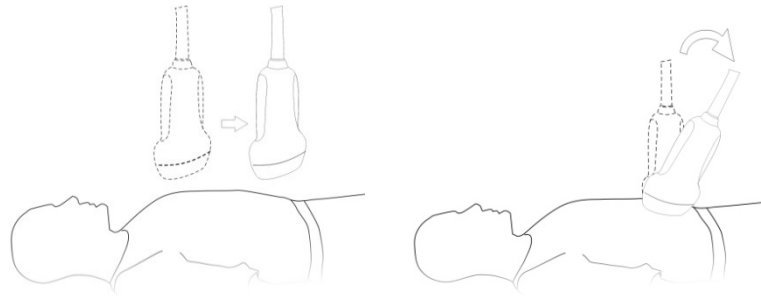
### 5.11.6.3 Smart 3D Image Acquisition

In Smart 3D mode, you need to set the scan method in addition to the other items in Static 3D mode. The other parameters are the same as those for Static 3D.

Method

Capture images using Linear scan or Rocked scan.

- Linear scanning
  - Move the probe across the surface. See the following figure.



- 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. See the figure.

#### 5.11.6.4 Smart 3D Image Viewing

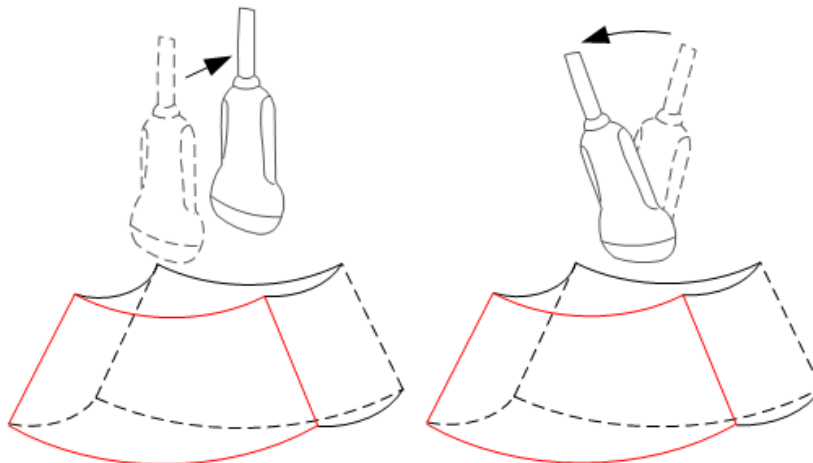
In VR viewing, the system supports the following functions:

- Render setting.
- B-mode parameter adjustment.
- Setting the display format.
- Viewing MPR.
- Image zooming.
- Rotation.
- Image editing.
- VR parameter adjustment.
- Scanning distance or angle

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.)



#### 5.11.6.5 Image Saving and Reviewing in Smart 3D

Image saving

- In 3D viewing mode, press the single image Save key (Save Image to hard drive) to save the current image to the patient information management system in the set format and image size.
- Save clip: in 3D viewing mode, press the user-defined Save key (Save Clip (Retrospective) to hard drive) to save a 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 in VR viewing mode.

### 5.11.6.6 Color Smart 3D

The system also supports the color Smart 3D flow image function.

## 5.11.7 STIC (Spatio-Temporal Image Correlation)

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.

STIC is an option.

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 cancelled.

One or more of the following artifacts in the data set indicate a disturbance during acquisition:

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.



**CAUTION:**

1. In all of the above cases the data set has to be discarded and the acquisition has to be repeated.
2. It is not allowed to perform the STIC fetal cardio acquisition if there is severe fetal arrhythmia.



**WARNING:**

Diagnoses made only by assessing this 3D/4D acquisition are not permitted. Every diagnostic finding has to be evaluated in 2D as well.

**NOTE:** The user must be sure that no one of the participating persons (mother, fetus, and user) moves during the acquisition. A movement of anyone will cause a failure of the acquisition. If the user recognizes a movement during the scan, the acquisition has to be cancelled!

### 5.11.7.1 Basic Procedures for STIC

1. Obtain a feasible 2D image (fetus heart).  
To observe a small structure, zoom in the interested part (Usually Spot zooming is applied for good image quality).
2. Press the user-defined <3D> key, or <4D> key 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°.
  - 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.

**NOTE:** 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.

5. Place the sample box over the region of interest.
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 All] to perform the acquisition again. Tap [Accept HR] to accept the result and go to image review, or 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.

Tips: after STIC acquisition, press <Cine> to switch between cine auto play mode and manual mode.

### 5.11.7.2 Operation Controls

#### Acquiring Time

The time required for a whole acquisition.

#### Angle

The range from acquisition beginning to acquisition end.

Other control operations are same with these in 3D/4D mode.

### 5.11.7.3 Color STIC 3D

The system also supports color STIC 3D flow image function.

## 5.11.8 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.

iLive is an option, and is available under Smart 3D, Static 3D and 4D modes. To use the iLive function, you must configure the Smart 3D module or the 4D module.

To Activate iLive

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

1. Select the imaging mode:
  - Use the ordinary probe and press the user-defined <3D> key to enter Smart 3D.
  - Or, use 4D probe and press the user-defined <3D> key, or <4D> key 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 <B>, the user-defined <3D> key, or <4D> key to exit the mode.

### 5.11.8.1 Operation Controls

Adjustable parameters for iLive are on the touch screen.

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

Basic Procedures

1. Tap  on the [iLive] item to enter the iLive settings interface.
2. Tap the desired lighting mode.
  - a) If necessary, tap  on the lighting mode to adjust parameters for the selected lighting mode.

- b) After parameter settings, tap [Exit XXX] to exit the lighting mode settings.
  - c) Tap [Refresh] to refresh the thumbnails on the iLive settings interface.
3. Tap [Return] to apply the selected lighting mode.

Operation Controls for Lighting Mode Settings

Parameter	Description
VL Saturation	Adjust the saturation for light 1/2/3.
VL Hue	Adjust the color for light 1/2/3.
VL Distance	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.
Reset Classic/ IntPoint/ ExtPoint/ Parallel/ Torch/ 3-Light/ User 1/ User 2	Reset the lighting mode to the original status.
Copy to	Copy the lighting mode to customized lighting mode "User 1" or "User 2"

**Other Operations**

Zoom

Same as in 3D/4D mode.

Rotation

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.

Comments and Body Marks

Same as in other modes.

**5.11.9 3D Layout**

The function compiles the 3 MPRs together according to their relative positions, to provide a much clearer interior anatomical structure.

This function is provided by the [Niche] option, and does not support Smart 3D image data.

**Niche**

1. Select the [Tool]→[3D Layout] tab on the touch screen, then tap [Niche].
2. Tap [A]/[B]/[C]/[Niche] on the touch screen 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

1. Select [Tool]→[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.

### 5.11.10 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: 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.

### 5.11.11 Smart Volume

The system provides three fast volume calculation methods that can be used to calculate the volume of tissue structure or lesions. The three 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.

Smart Volume and Smart V Trace are optional, and not available in Smart 3D mode.



#### **CAUTION:**

**Smart Volume result is provided for reference only, not for confirming a diagnosis.**

### 5.11.11.1 Smart V ROI

#### Basic 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 in blue);
3. Set ROI position and size, and tap [Calc] (after touching the button, the button is highlighted in blue to indicate the status);
4. 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.  
For details, see 5.11.11.6 Operation Controls.
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.

### 5.11.11.2 Smart V Trace

#### Basic Procedure

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, and trace the contour on at least two MPRs.
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.  
For details, see 5.11.11.6 Operation Controls.
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.



### 5.11.11.3 Smart V Vocal

#### Basic Procedure

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. Rotate the knob under [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.
6. 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.  
For details, see 5.11.11.6 Operation Controls.
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.

### 5.11.11.4 Smart V Parallel

The operation of Smart V Parallel is the same as those of Smart V Vocal.

### 5.11.11.5 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.

### 5.11.11.6 Operation Controls

#### Edit ROI (Only for Smart-V ROI)

Adjusting the ROI box size and position is to select the volume data needed for calculation.

1. Tap [Edit ROI] on the touch screen to be on (blue highlighted status).
2. Select a desired MPR image by tapping [A], [B] or [C].
3. Roll the trackball to adjust ROI position and size, and press <Set> to switch between the adjusting status, or you can rotate <4D> knob on the control panel to adjust section image position.

## 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, and the item becomes “Edit On” in blue.
- Tap [Add] and then trace an enclosed area manually, and the area to be calculated will be enlarged to include the traced area. The original contour is yellow, and the new contour is blue.
- 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. The original contour is yellow, and the new contour is blue.
- 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, and the item becomes “Edit On” in blue. Then you can modify the contour on each slice.
- Tap [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
  1. Rotate the knob under [Trace mode] to select [Trace].
  2. 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
  1. Rotate the knob under [Trace mode] to select [Spline].
  2. 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.
  3. 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
  1. Rotate the knob under [Trace mode] to select [Smart Trace].
  2. 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.

Press <set> key to display “Cancel” status on the track ball region, move the track ball to cancel the trace.

- Control Point

This mode can be used only after tracing is finished, and not support Smart-V ROI method.

1. Rotate the knob under [Trace mode] to select [Control Point].
2. 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.

### Zoom

Same as 3D/4D image zooming.

### Comments and Body Marks

Operations are the same as those in the other modes.

### MPR measurement

2D related measurement can be performed on MPRs. For details, please refer to [Advanced Volume].

### Save the image

The Smart Volume supports saving single-frame image and multi-frame cine file.

## 5.11.12 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 an option, and it is not available in Smart 3D mode.

### 5.11.12.1 Operating Procedures

- iPage operation

1. Acquire necessary 3D/4D data.
  - Single-frame VR:
    - STIC/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.

7. 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.

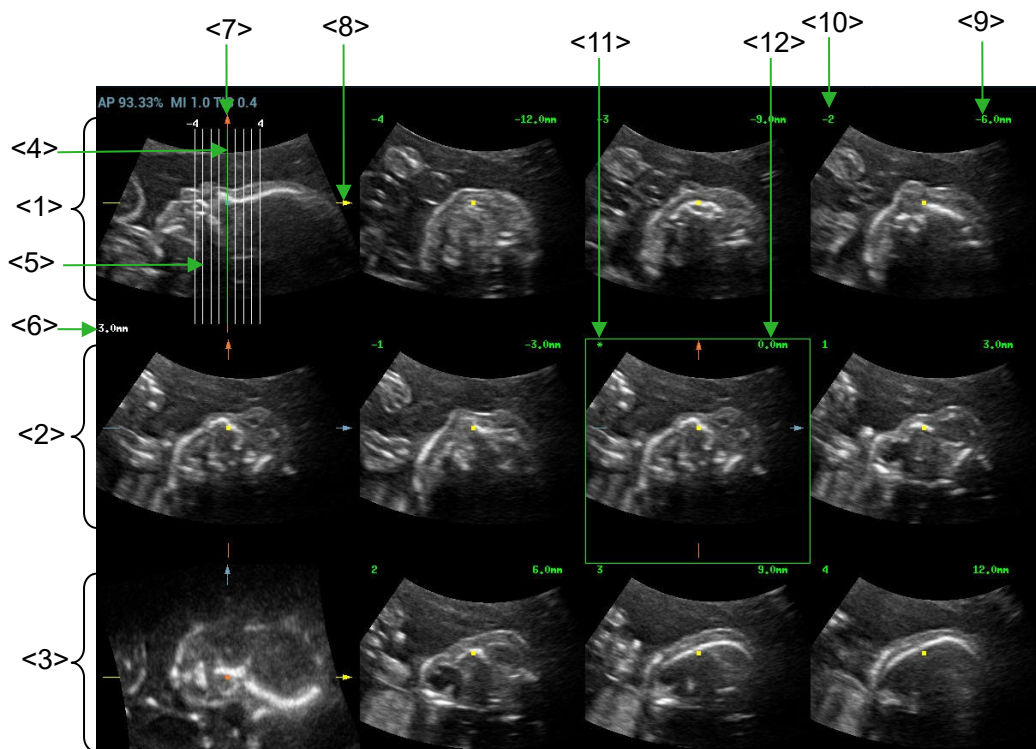
8. Do operations like comment to the interested region.

9. Save images as necessary.

iPage+SCV operation

Adjust the parameter [Thickness] in iPage+ screen when SCV imaging is needed.

### 5.11.12.2 Basic Screen & Operation



<1>	A plane (the current reference image)	<2>	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 [Slice 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  to place the slice lines vertically, and touch  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].

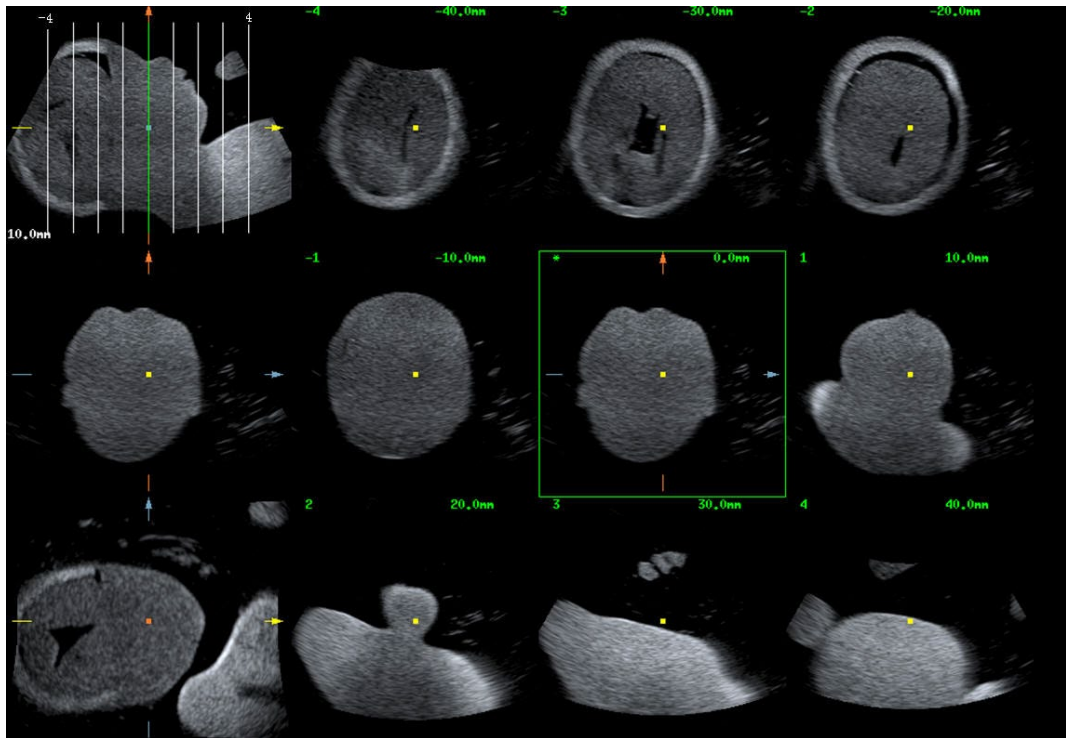
## ■ Slices number

Change slices number as necessary using the knob under [Slices Number] on the touch screen.

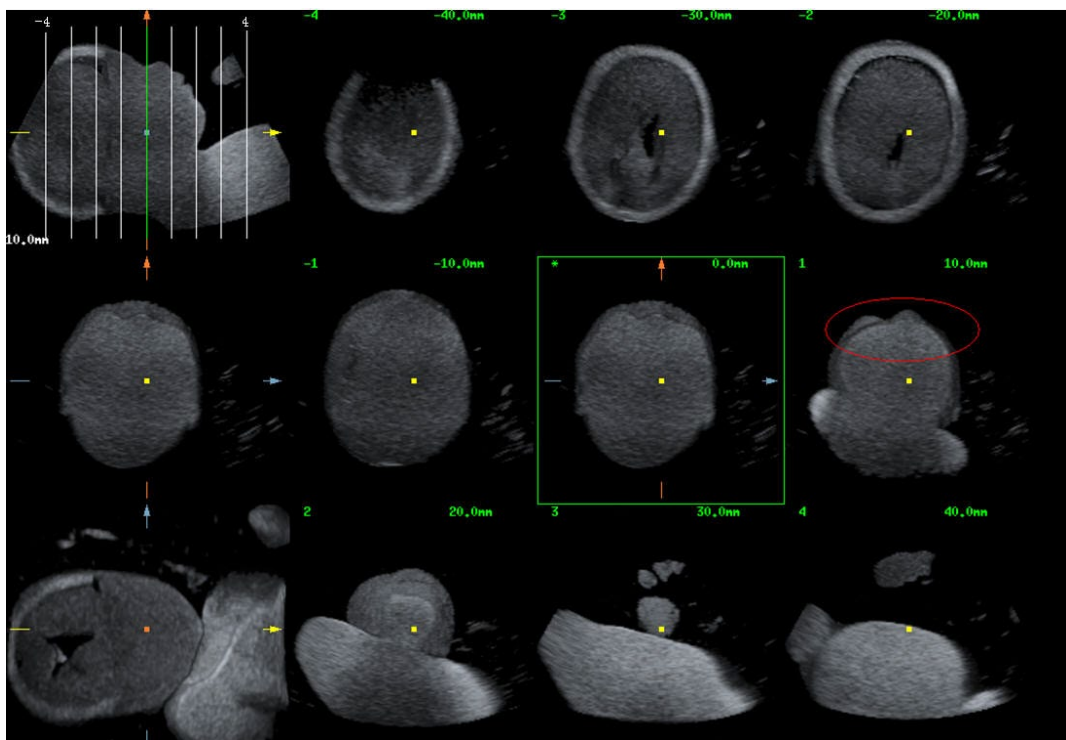
## ■ Thickness

Rotate the knob under [Thickness] to adjust the SCV thickness. When the thickness value is larger than zero, the SCV function is on. (NOTE: thickness can not be larger than Spacing)

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.  
 For details, refer to descriptions in Static 3D.
- Image zooming  
 Same as Static 3D image zooming.

- 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.

- Comment & Body Mark

Operations are the same as those in the other modes.

- Measurement

Measurement can be done on any slice when it is in the single format display.

## 5.11.13 SCV+

SCV+ is SCV (Slice Contrast View) +CMPR (Curved MPR).

SCV imaging can reduce speckle noise and improve contrast resolution as well as enhance signal-noise 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, as illustrated below.

NOTE: SCV+ imaging is an option, and it is not available in Smart 3D mode.

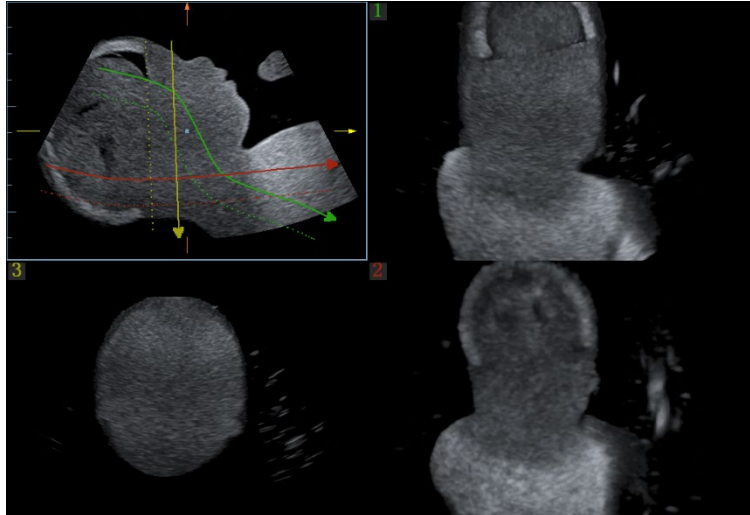
### 5.11.13.1 Basic Procedures

- SCV operation

1. Acquire necessary 3D/4D data.
2. Tap [SCV+] 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+CMR operation

1. Enter SCV+.
2. Tap [A Plane], [B Plane] or [C Plane] on touch screen to select current window.
3. Tap [CMR] on touch screen to turn on the CMR function. Window A on main screen displays the current window and three other windows are blank. Select reference section, perform rotation and shifting operations to adjust image.
4. Tap [1], [2], or [3] button in Active Quadrant on touch screen.
5. Select trace options: tap [Line], [Trace] or [Spline] on the touch screen.
6. Draw on the reference image. You can draw three curves at most and the CMR imaging for the curve are displayed in the selected [1], [2] or [3] window respectively as shown in figure below.



7. Perform rotation and shifting operation to reference line.
8. Save images as necessary.

### 5.11.13.2 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

1. Tap [Line] on the touch screen.
2. 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.  
Rotate the knob under [Line Extension] on the touch screen to adjust the line length.
3. After line is finished, press left <Set> key to change line position.

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

1. Tap [Trace] on the touch screen.
2. 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> 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.
3. After tracing, press left <Set> key to change tracing outline position.

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 trace.

- Spline

1. Tap [Spline] on the touch screen.



2. 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.
3. Press <Set> twice to set the end point of the spline.
4. After tracing, press left <Set> key to change tracing outline position.

Tap [Reset Curve] to cancel current spline. Press <set> key 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].

## 5.11.14 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.

NOTE:

Procedures:

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. See 5.13 Contrast Imaging for details.
3. Press the user-defined <3D> key, or <4D> key 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. See 5.11.3 Static 3D for details.  
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 5.11.3.3 Static 3D Image Viewing for details.

5. Repeat step 2-4 to obtain the contrast images if necessary.

### 5.11.15 Smart Planes CNS

The doctor finds fetus's sagittal view by judgments on image features, and then makes an observation. The fetus's sagittal view is hard to be detected or cannot be detected sometimes because of the fetus's move inside.

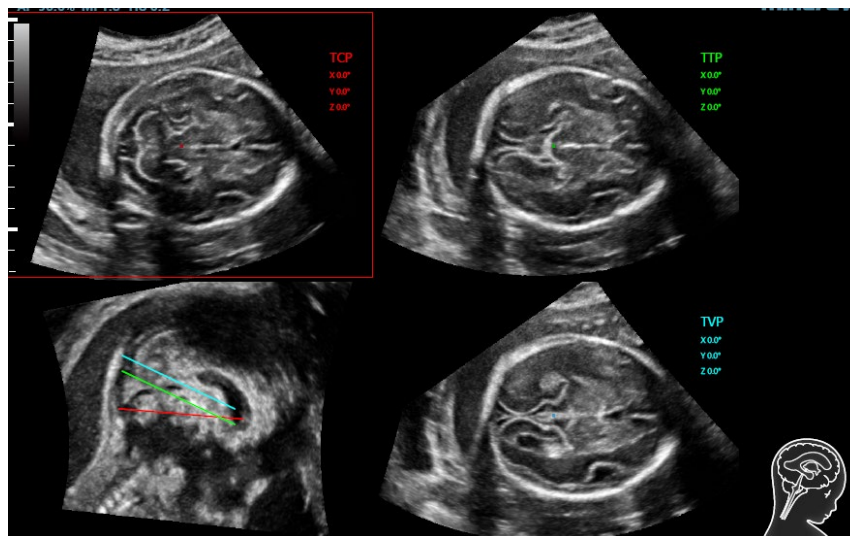
Taking the key anatomical tissues and organs' features from 3D data of fetus's intracranial, Smart Planes CNS is a mode-wise technology, which detects the middle of the fetus's sagittal view, transverse plane of thalami, transverse plane of lateral ventricles and transverse plane of cerebellum. It helps 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:

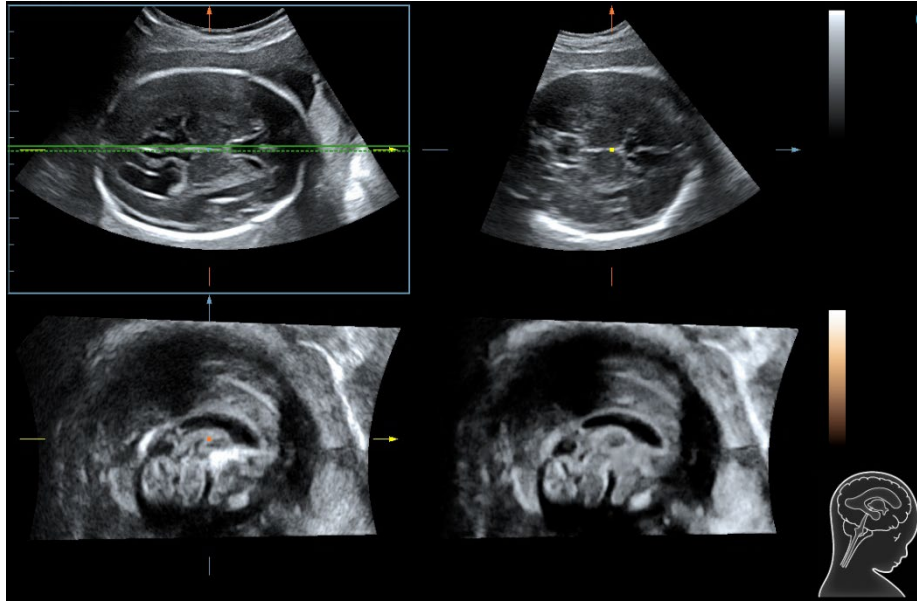
Smart Planes CNS is an option, which does not support smart 3D mode.

#### 5.11.15.1 Basic Procedures for Smart Planes CNS

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 brightness, 3D iClear and the thickness 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. See Chapter 5.11.15.2 Other Operations for details.
8. Tap [Auto Measure]. Tap [Edit] to edit the measurements. See Chapter 5.11.15.2 Other Operations for details.
9. Click [Auto Comment], the system adds the orientation and the organ comments to the desired area according to the active ultrasound image. See Chapter 5.11.15.2 Other Operations for details.
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.

## 5.11.15.2 Other Operations

### Parameter adjusting

- **Brightness**

<b>Description</b>	Adjusting the brightness of the images.
<b>Operation</b>	Rotate [Brightness] to adjust the parameter.
  
- **Thickness**

<b>Operation</b>	Rotate [Thickness] to adjust the parameter.
<b>Impacts</b>	The bigger the value is, the more the thickness information appears.
  
- **3D iClear**

<b>Operation</b>	Tap [3D iClear] to adjust the parameter.
------------------	--

## Impacts

The bigger the value of iClear is, the less the noise becomes.

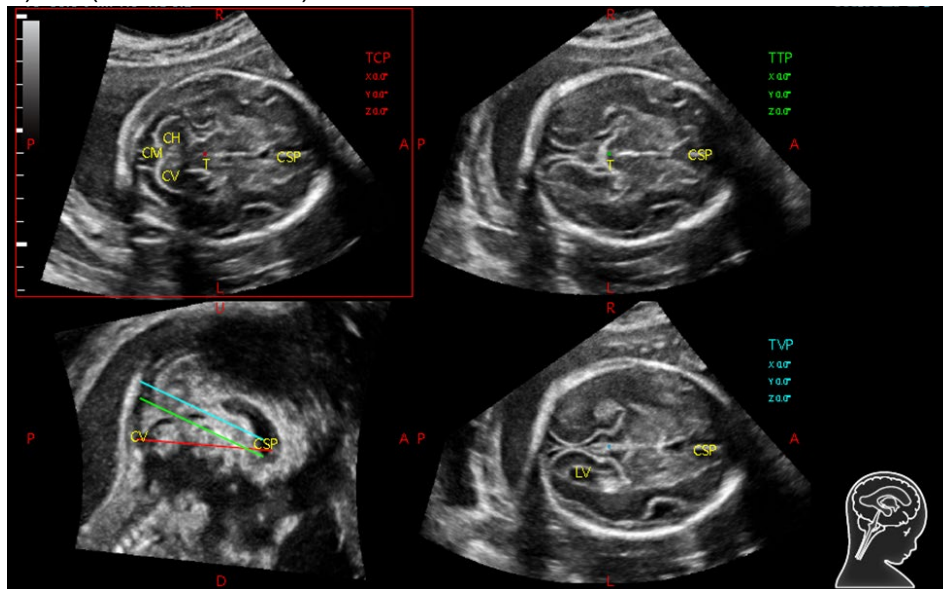
## Auto Comment

The system adds the orientation and the organ comments to the desired area according to the active ultrasound image.

1. Acquire 3D data. Tap [S-Planes CNS] to enter the automatic detection of the mode.
2. Click [Auto Comment]. The comments appear on the image automatically.

Each of them is:

- 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).



3. Rotate [Font Size] knob to adjust the font size of the comment.
4. See 9.1 Comments for adding, moving or deleting the comments.
5. Save the image.
6. Click [Auto Comment] again to clean them.

## Axis Rotation

1. Acquire 3D data. Tap [S-Planes CNS] to enter the automatic detection of the mode.
2. 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.

NOTE: it supports the rotation to the saved image.

## Reference line rotating

1. Acquire 3D data. Tap [S-Planes CNS] to enter the automatic detection of the mode.
2. 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.
3. 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.

4. 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.
5. 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.

### MSP editing

1. Acquire 3D data. Tap [S-Planes CNS] to enter the automatic detection of the mode.
2. Tap [MSP]. There are A, B and C views appearing on the screen, in which C plane refers to MSP, and A and B planes refer to MPR plane.
3. Rotate A, B or C plane respectively, or rotate <4D> to adjust each plane.
4. 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.
5. Click [Cancel] to cancel the editing result.

### Automatic Measurement

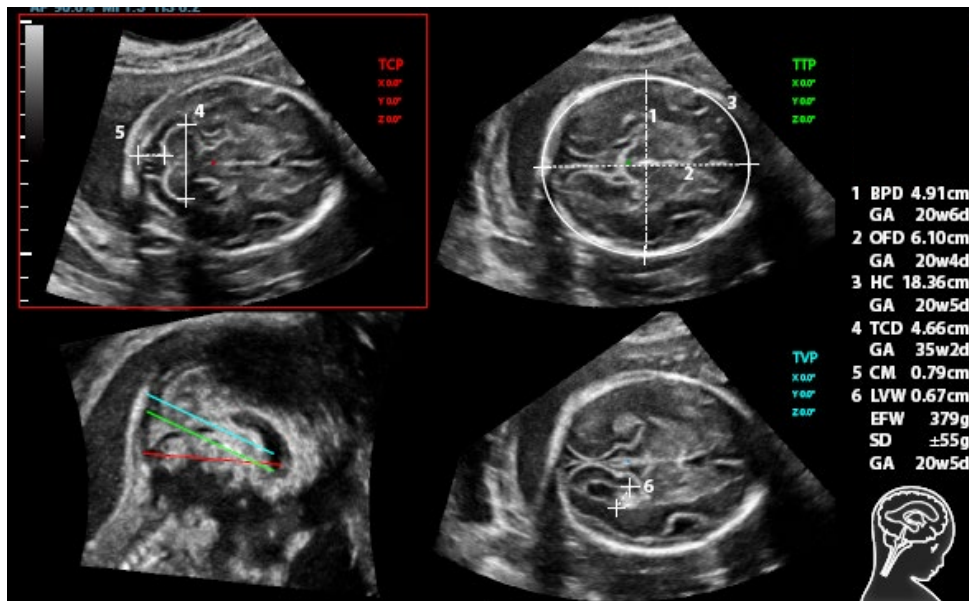
There are 6 measurements:

TCP supports the measurements on TCD, cerebral fossa pool;

TTP supports the measurements on BPD, OFD, HC;

TVP plane supports the measurement on LVW.

1. Acquire 3D data. Tap [S-Planes CNS] to enter the automatic detection of the mode.
2. Tap [Auto Measure] to show the caliper and the measurement number. The measurement results appear on the right of the screen.



**NOTE** The automatic measurement results appear only for these having the same characteristics on the planes.

3. Tap [Edit] to edit the measurements. The measurements on the right of the screen update in real time.
  - 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.

NOTE:

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.

## 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.

## Smart ICV

Smart ICV is used to measure fetal cerebral volume.

NOTE: Smart ICV is an option.

Basic Procedure:

1. Acquire necessary 3D/4D data.
2. Tap [Smart ICV] on the touch screen 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) Rotate the knob under [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] on touch screen 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] on touch screen to undo, redo or cancel previous measurement.
5. Tap [Accept Result], and the measurement results are saved in the report.

<p><b>NOTE:</b> 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.</p>
---

## Other related Operations

- Zooming/panning adjustment  
Same as these in 3D/4D mode.
- Measurement, comments, and body mark  
Same as these in other modes.
- 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  
Press <Dual> or the user-defined <Quad> key between the single and quad-split display.

## 5.11.16 Smart FLC (Smart Follicles Calculation)



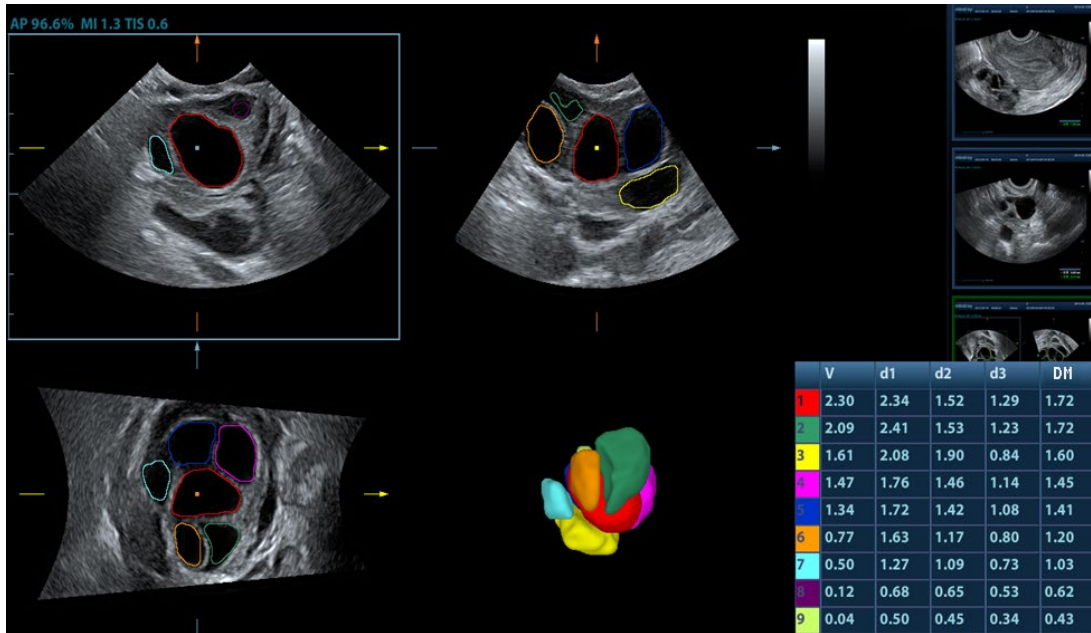
### CAUTION:

Smart FLC result is provided for reference only, not for confirming a diagnosis.

NOTE: Smart FLC is an optional function, and it is not available in Smart 3D mode.

### 5.11.16.1 Basic Procedures for Smart FLC

1. Acquire necessary 3D/4D data and freeze.
2. Tap [Smart FLC] tab on the touch screen to enter Smart FLC, and the system is in the “Edit ROI” status ([Edit ROI] button is highlighted in green);
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.

## 5.11.16.2 Operation Controls

### Edit ROI

Same as the operation in ROI editing in Smart-V.

### Edit/ Undo

Tap [Edit] on touch screen to turn on the editing function. It supports dividing, merging, adding and deleting of the follicle.

Tap [Undo], [Redo] or [Undo All] on touch screen 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.

## 5.11.17 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.

Tips: 4D and OB package should be installed first.

Smart Planes FH is an option and not available under STIC or Smart 3D mode.



## Basic Procedures

1. Acquire necessary 3D/4D data of fetal heart and save the file. Open the saved cine file.
2. 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.

## Axis rotation and shifting

Rotate <M>/<PW>/<C> knob to rotate the view along X/Y/Z-axis.

Rotate the <4D> key 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. For details, refer to "5.11.3.3 Static 3D Image Viewing".

## 5.11.18 Smart Face

<b>NOTE:</b> 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.


Note:

Tips: 4D module and OB package should be installed first.

Smart Face is an option.




## Basic Procedures

1. Acquire Static 3D image or frozen 4D single-frame image of fetal face.

2. Tap [SmartFace] to enter the function and the system adjust fetal face angle (fetal head facing up) automatically and remove the shading obstacle data.
3. Tap the  button to enter Setup screen. Adjust parameters as described below.

## Parameter adjusting

Parameters under Smart Face are similar to those under Static 3D mode. For details, refer to “5.11.3.3 Static 3D Image Viewing”.

- MixRender/SubTint
  - Description** The higher the merge value, the clearer the shading obstacles on the image. If the value is set 0, no obstacle data will be displayed.
  - Operation** Tap the  button to enter Setup screen, tap [MixRender] to select the levels between 0-3.  
Tap [SubTint] to select the obstacle display color.
  - Impacts** This function is available only under “Surface” mode.
  
- Eraser
  - Description** 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.
  - Operation** Tap the  button to enter Setup screen, tap [EraseSize] to select the size: Small, Middle, Large.  
Select different clearing manner: [For Rubber] / [Re-Rubber].  
Tap [Undo] to undo the operation in sequence and tap [Undo All] to undo all erase effects.
  - Impacts** This function is available under “Surface” mode.
  
- AutoDirect
  - Description** 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.
  - Operation** Tap the  button to enter Setup screen and select [AutoDirect].
  
- FaceContact
  - Description** 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.
  - Operation** Rotate [FaceContact] to adjust the parameter.
  
- VR Orientation
  - Description** Rotate the image quickly.

Operation Adjust in VR Orientation: 0° , 90° , 180° , 270° .

## 5.11.19 Smart Scene 3D

- |                    |   |
|--------------------|---|
| <b>Description</b> | <ol style="list-style-type: none"><li>1. Smart Scene 3D is not available in Smart 3D mode.</li><li>2. This feature is available only under GYN, OB2 or OB3 exam mode.</li></ol> |
|--------------------|---|

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.

### Basic Procedures

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.

## 5.12 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 View function, so you can get more information from extended images.



### **CAUTION:**

1. It is provided for reference, not for confirming a diagnosis.
2. 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 View mode. A smooth and even speed will help produce optimal image results.

iScape View is optional.

**NOTE:** Needle mark cannot be displayed in iScape View imaging mode.

### 5.12.1 Basic Procedures for iScape View Imaging

Basic procedures for iScape View:

1. Connect an appropriate iScape-compatible probe. Make sure there is enough coupling gel along the scan path.

2. Tap [iScape View] on the touch screen (it is available after enter Power mode).
  - Optimize the 2D (or Power) mode image:  
In the capture preparation status, tap [B] ([Power]) tab to go for the B mode image optimization. Do measurement or add comment/body mark to the image if necessary.
  - Image capture  
Tap [iScape View] page tab to enter the iScape View acquisition preparation status. Tap [Start Capture] or press [Update] on the control panel to begin the capture.  
The system enters into image review status when the acquisition is completed. You can perform operations such as parameter adjusting.
  - Exit iScape View  
Press <Freeze> or <Update>, or tap [Recapture] to return to the capturing state.  
Or, press <B> on the control panel to exit.

## 5.12.2 Capture Images

To create an iScape View image, start with an optimized 2D (color) image. The 2D image serves as the mid-line for the resulting iScape View image.

1. Press <Update> or tap [Start Capture] on the touch screen to start the iScape View image capture.
2. Scan slowly to obtain a single extended field of view image. You can also erase and retrace if the image is not satisfactory.
3. End image capture:  
To end the image capture:
  - Click [Stop Capture] on the touch screen, or,
  - Press <Update>, or,
  - Wait until the acquisition completes automatically.
 After the acquisition is completed, the panoramic image will be displayed and the system enters iScape viewing mode.

Tip:

- During image acquisition, none of the parameters are adjustable, and functions such as measurement, comments and body marks are not available.
- ROI: a green box on the image indicating the boundary between the merged images and the unfinished images.
- Tip on the probe speed: 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	Tip
Speed too low	Blue	Moving speed of the probe is too low.
Appropriate	Green	None.
Speed too high	Red	Moving speed of the probe is too high.

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.

### 5.12.2.1 Image Parameters Settings

In image reviewing mode, you can adjust the following parameters:

■ 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 View)

Tap [Color Disp.] on the touch screen to display or hide the color image.

Color Map (in Power iScape View)

Rotate the knob under [Color Map] on the touch screen to select the map, as in Power mode.

### 5.12.2.2 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.

### 5.12.2.3 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°.

### 5.12.2.4 Measurement, comments, and body mark

In iScape View image review status, you can perform measurement, comment, and body mark.

- |              |   |
|--------------|---|
| <b>NOTE:</b> | <ol style="list-style-type: none"><li>1. The measurement accuracy for the sliced image may be degraded, exercise caution when measurements are performed from an iScape View image.</li><li>2. If there is a trace during the retracing, do not perform measurement across the trace.</li></ol> |
|--------------|---|

### 5.12.2.5 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.

- |              |   |
|--------------|---|
| <b>NOTE:</b> | 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.

### 5.12.3 Cine Review

Click [Review Cine] on the touch screen in panoramic image viewing status to enter cine reviewing mode. In cine reviewing mode, a blue 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:

- Roll the trackball to review the captured images frame by frame.
- Click [Auto Play] to start or end auto play.
- In auto play mode, tap [Auto Play] on the touch screen, or press/rotate the corresponding knob to change the play speed. When the speed is off, the system exits auto play mode.
- Review to a certain image. Press the knob under [Set Begin] to set the start point. Review to another image. Press the knob under [Set End] to set the end point. In auto play mode, the review region is confined to the set start point and end point.
- Click [Review Cine] on the touch screen 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.

## 5.13 Contrast Imaging

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.

- Contrast imaging is an option.



**Caution:**

1. **Set MI index by instructions in the contrast agent accompanied manual.**
2. **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.

### 5.13.1 Basic Procedures for Contrast Imaging

To perform a successful contrast imaging, you should start with an optimized 2D image and have the target region in mind. To perform a contrast imaging:

1. Select an appropriate probe, and perform 2D imaging to obtain the target image, and then fix the probe.
2. Press user-defined <Contrast> key or tap [Contrast] to enter the contrast imaging mode.
3. Adjust the acoustic power experientially to obtain a good image.  
Tap [Dual Live] to be "On" to activate the dual live function. Observe the tissue image to find the target view.
4. Inject the contrast agent, and set [Timer 1] at "ON" to start the contrast timing. When the timer begins to work, the time will be displayed on the screen.

- Observe the image, use the touch screen button of [Pro Capture] and [Retro Capture] or the user-defined key (usually "Save1" and "Save2") to save the images. Press <Freeze> to end the live capture.

Perform several live captures if there are more than one interested sections.

- At the end of a contrast imaging, set [Timer 1] as "OFF" to exit the timing function. Perform procedures 3-5 if necessary.

For every single contrast imaging procedure, use [Timer 2] for timing.

If necessary, activate destruction function by tapping [Destruct] as "ON" to destruct the micro-bubbles left by the last contrast imaging; or to observe the reinfusion effect in a continuous agent injecting process.


- Exit contrast imaging.

Press <B> button to return to B mode.

### 5.13.1.1 Parameter Area Display

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). Parameter area displays as follows:

Type	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	Z	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.

### 5.13.1.2 Image Optimization

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.

### 5.13.1.3 Timer

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.

**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.

Set [Timer 1] as “ON” 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 [Timer 1] or [Timer 2] as “OFF”, the timer discontinues its work.

#### 5.13.1.4 Micro-bubble Destruction

Function: destruct the micro-bubbles left by the last contrast imaging; or to observe the reinfusion effect in a continuous agent injecting process.

Entering: Tap [Destruct] on the touch screen to enable the micro-bubble destruction function.

Parameters:

- DestructAP: adjust the destruct acoustic power via the touch screen.
- DestructTime: adjust the destruct time via the touch screen.



**Caution:**

**Use the contrast imaging according to the residual level of the micro-bubbles, using contrast imaging continuously may result in human harm.**

#### 5.13.1.5 Dual Live

In live mode or freeze mode, set touch screen item [DualLive] 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.

Tips:

- 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.
- Image position

The contrast appears on the left of the screen if the contrast image position is enabled.

#### 5.13.1.6 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 mode, 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.



### 5.13.1.7 iTouch

On contrast status, you can also get a better image effect by using iTouch function.

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.

Long press <iTouch> to exit the function.

### 5.13.1.8 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.

### 5.13.1.9 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.

## 5.13.2 Left Ventricular Opacification

Basic Procedures for LVO:

1. Acquire ECG signal.
2. Tap <Probe> on the touch screen to open Probe/Exam Mode selecting dialogue box.
3. Select a proper probe and LVO exam mode.
4. Workflow of LVO is similar to abdomen contrast imaging. For details, please refer to “5.13.1 Basic Procedures for Contrast Imaging”.

ECG triggering is supported under LVO mode. For details on operation procedures, refer to “7.1.2 ECG Triggering”.

## 5.13.3 Measurement, Comment and Body Mark

The system supports image measurement, comment and body mark functions. For the details, please refer to the relevant sections.

## 5.13.4 Micro Flow Enhancement

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).

Tips: 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 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.

**NOTE:** In MFE status, patient should lie down and hold breath, and transducer should be kept still.

## 5.13.5 Contrast Imaging QA

**CAUTION:** Contrast Imaging QA images are provided for reference only, not for confirming a diagnosis.

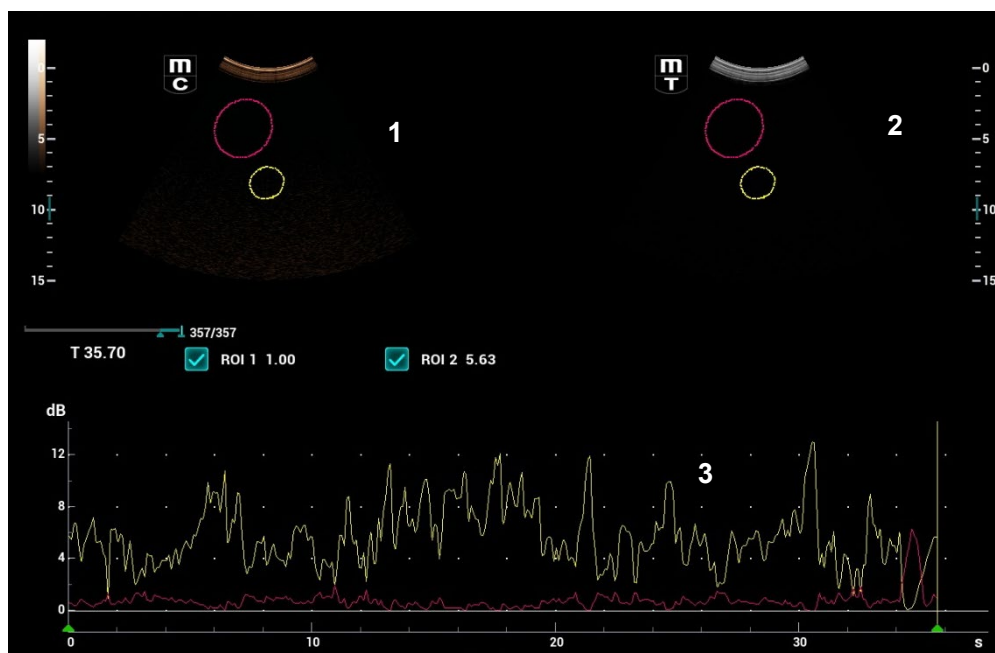
Contrast Imaging QA adopts time-intensity analysis to obtain perfusion quantification information of velocity flow. This is usually performed on both suspected tissue and normal tissue to get specific information of the suspected tissue.

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.

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.

2. Tap [Contrast QA] on the touch screen page to activate the function.
3. Mark out the interested part (ROI).
- If necessary, perform curve fitting on the time-intensity curve.
4. Analyze the parameters of the curve, or perform B measurement.
5. Save the curved image, export the data and do parameter analysis.

### 5.13.5.1 Contrast QA Screen



(For reference only)

1---Contrast cineloop window

Sample area: indicates sampling position of the analysis curve. The sample area is color-coded, 8 (maximum) sample areas can be indicated.

2---B Cineloop window

- Sample areas are linked in the contrast cineloop window and B cineloop window.

3---Time-intensity curve

- Y axis represents the intensity (unit: dB), while X axis represents the time (unit: s).
- Frame marker: a white line that is perpendicular to the X axis, can be moved horizontally left to right (right to left) by rolling the trackball.
- Click the check box beside the ROI to set if to hide or to display the QA curve.
- 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.

### 5.13.5.2 Basic Operations of Contrast QA

#### QA Analysis Image Range

The system set the starting time and ending time of the cine to be first frame and last frame of QA analysis range.

#### Setting ROI

This function is used for setting the target.

Up to eight ROIs can be saved on the reference image, with the corresponding eight traces plotted simultaneously on the graph. Each ROI display has a different color, and its corresponding trace data is plotted using that same color.

There are two different methods for determining the shapes of the sample area: Standard ROI and Freehand ROI.

##### Trace ROI

1. Tap [Trace ROI] on the touch screen.
2. Review the image to a desired frame.
3. Rotate the trackball to position the image display cursor over the reference image(s).
4. Press <Set> key to fix the starting point.
5. Press <Set> key, and roll the trackball to depict the ROI. When a suitable ROI has been drawn, confirm the ROI by double clicking <Set>, press <Clear> to cancel the last point.

The system automatically links the start point to the end point by drawing a straight line between them.

##### Ellipse ROI

1. Tap [Ellipse ROI] on the touch screen, when the cursor is evolved in the image review area, it displays as a color-coded ellipse.
2. Review the image to a desired frame.
3. Use the trackball to position the caliper on the reference image at the start point. Press <Set> to fix the start point.
4. Trace the outline of the desired ROI by moving the cursor with the trackball.
5. Press <Set> to fix the end point, and roll the trackball to depict the ROI. When a suitable ROI has been drawn, confirm the ROI by double pressing <Set> key, press <Clear> to cancel the last point.

##### Delete ROI

Press <Clear> key to clear out the last ROI; tap [Delete All] on the touch screen to clear out all ROIs.

The corresponding traces for the deleted ROIs are erased from the plot.

##### Copy ROI

Tap [Copy ROI] to create a new ROI similar to the current or latest added ROI.

#### Motion Tracking

Tap [Motion 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.

Tips: 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.

### **X Scale**

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.

### **Export/Save Trace Data**

1. Tap [Export] on the touch screen.
2. Select the drive and enter the file name in the displayed window.
3. Select [OK] to save the data and return to the QA Analysis screen.
  - All displayed ROI traces are saved in the exported file.
  - The parameters are included in the trace file if the user has fixed a ROI.
  - After the exporting is succeeded, a .BMP format image is displayed in the thumbnail area at the lower part of the screen.
  - Only data from the user selected image range is included in the exported trace file.

### **Curve Fitting**

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 [Fit Curve] on the touch screen to turn on the function, where color of the fitted curve is consistent with color of the current ROI curve.
- Tap [Raw Curve] to hide/display raw curve, when the button is highlighted in green, raw curve is displayed.
- Tap [Table Display] to check parameters.

Parameters calculated include the following:

- GOF (Goodness of Fit): to calculate the fit degree of the curve; range: 0-1, where 1 means the fit curve fits the raw curve perfectly.
- BI (Base Intensity): basic intensity of no contrast agent perfusion status.
- AT (Arrival Time): time point where contrast intensity appears, generally, the actual time value is 110% higher than the base intensity.
- TTP (Time To Peak): time when the contrast intensity reaches peak value.
- PI (Peak Intensity): contrast peak intensity.
- AS (Ascending Slope): ascending slope of contrast, the slope between the start point of lesion perfusion to the peak.
- DT/2: time when the intensity is half the value of the peak intensity.
- DS (Descending Slope): descending slope of the curve.
- AUC (Area Under Curve): to calculate the area under the time-intensity curves during contrast.
- MTT (Mean Transition Time): the mean time which a red blood cell (microbubble) needs to flow through the tissue mass.

<p><b>NOTE:</b> 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.</p>
--

## 5.14 Elastography



CAUTION:

It is provided for reference, not for confirming a diagnosis.

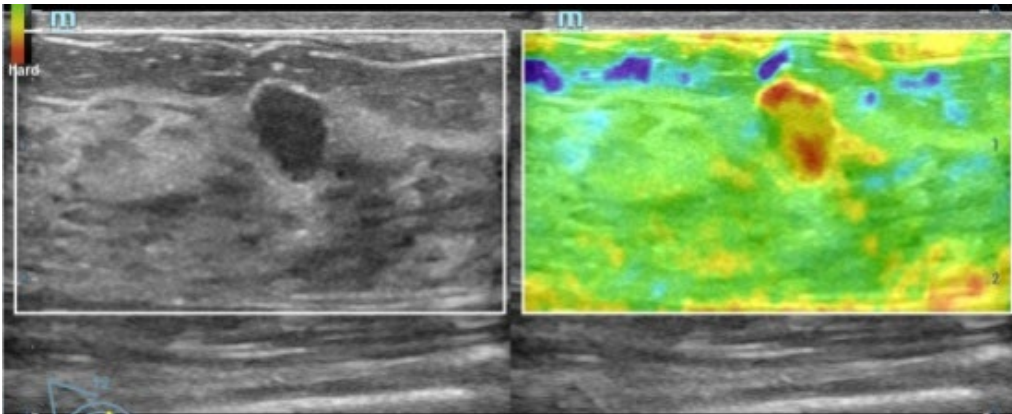
### 5.14.1 Strain Elastography

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.

The strain elastography is an option.

#### 5.14.1.1 Basic Procedure for Strain Elastography

1. Perform 2D scan to locate the region.
2. Tap [Elasto]→[StrainE] on the touch screen. Assign a user-defined key for Elastography via: [Setup]→[System Preset]→[iConsole&Footswitch]/[Key Board]. Adjust ROI according to the lesion size.



- Press the probe according to the experiences and actual situation.
  - Adjust the image parameters to obtain optimized image and necessary information.
  - Adjust the image parameters to obtain optimized image.
  - Do measurement or add comment/body mark to the image if necessary.
3. Evaluate the result based on the information above.
  4. Press <B> to return to B mode or another mode.

#### 5.14.1.2 Enter/Exit

##### ■ Enter

Select [Elasto]→[StrainE] on the touch screen to enter the mode.

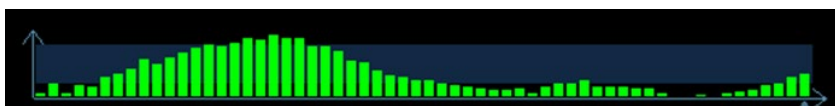
The system displays two dual B+E windows in real time. The left one is 2D image, and the right one is elasto image.

##### ■ Exit

Press <B> or tap [Elasto] to exit, and then return to B mode.

#### 5.14.1.3 Strain E Curve

The screen displays the pressure curve in real-time:



Where, the X-axis represents time and Y-axis represents pressure.

#### 5.14.1.4 Parameter adjusting

##### ROI Adjustment

- Description** To adjust the width and position of ROI in Elasto imaging.
- Operation** 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.

##### Smooth

- Description** To adjust the smooth feature of the Elasto image.
- Operation** Tap [Smooth] on the touch screen to adjust the parameters.  
The system provides 5 levels of smooth function. The bigger the value is, the higher the smooth becomes.

##### Opacity

- Description** To adjust the opacity feature of the Elasto image.
- Operation** Turn the knob under [Opacity] on the touch screen to complete the adjustment.  
The system provides 5 levels of opacity function: the bigger the value the stronger the effect.

##### Invert

- Description** To invert the E color bar and therefore invert the colors of benign and malignant tissue.
- Operation** Tap [Invert] on the touch screen.

##### Display Format

- Description** Adjust the display format of ultrasound image and the Elasto image.
- Operation** 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.
- Impacts** Adjust according to the actual situation and obtain a desired analysis through comparison.

##### Map

- Description** To select different maps for observation.

**Operation** Rotate the knob under the [Map] item on the touch screen or adjust through the mapping-menu item to select the map.  
The system provides 6 maps, including 1 grayscale map and 5 color maps.

### Strain mode

**Description** Affect the display effect of adjusting dynamic range.  
**Operation** Tap [Strain mode] on the touch screen to adjust the parameters.  
**Impacts** Strain mode is set to 0, adjust dynamic range, the image difference changes obviously.

### Dynamic Range

**Description** Adjusts 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.  
**Operation** Rotate the knob below [Dyn Ra] to adjust the parameters.  
**Impacts** The more the dynamic range, the more specified the information, and the lower the contrast with more noise.

### Sensitivity

**Description** Increase the image palpability.  
**Operation** Rotate the knob under the [E Sensitivity] item on the touch screen to adjust the value.  
**Impacts** The higher the sensitivity, the higher the image palpability.

### Strain Scale

**Description** Adjust the bar height of the pressure hint curve to keep the average height of the hint bar on proper position.  
**Operation** Rotate the knob under the [Strain Scale] item to adjust.

### Map Position

**Description** This feature is used to adjust the up/down position of the map.  
**Operations** Tap [Map Position] on the touch screen to adjust the parameter.  
**Effects** When the E Average function is enabled or disabled, the elasto curve is displayed based on different statistical amounts.

### 5.14.1.5 Mass Measurement

Press <Measure> to enter measurement status.  
You can measure shell thick, strain ratio, strain-hist, etc.  
For details, see [Advanced Volume].

### 5.14.1.6 Cine Review

Press <Freeze> or open an elastography imaging cine file to enter cine review status.

## 5.14.2 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.

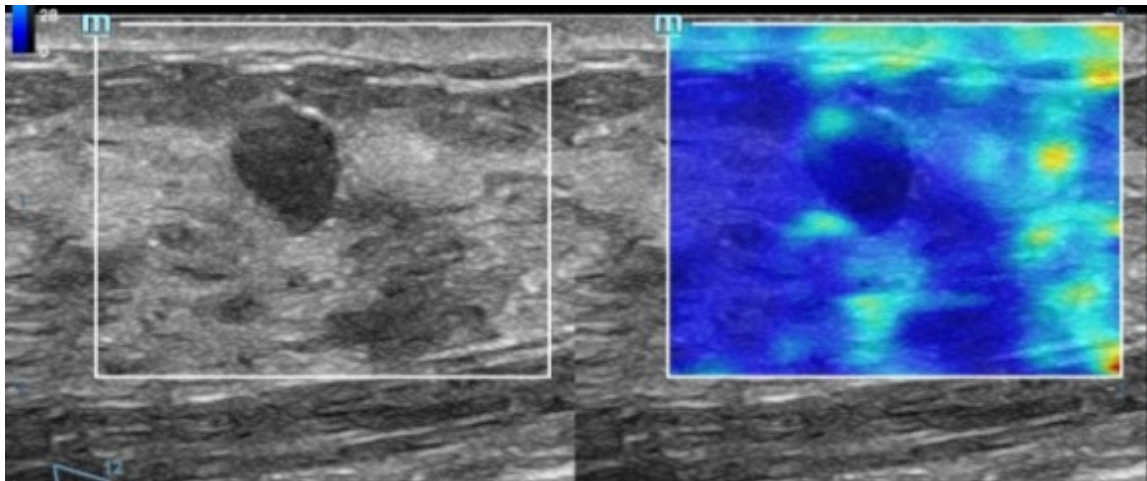
STE imaging is an option. The system supports STE imaging only when STE or Endocavity STE is configured.

The SC6-1s, C6-2Gs, L9-3s, L20-5s, L14-3Ws, L13-3Ns, and SC6-1E probes support STE imaging when STE is configured.

The V11-3Hs, DE11-3Ws, and ELC13-4s probes support STE imaging when Endocavity STE is configured.

### 5.14.2.1 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 (set the user-defined key via [Preset]→[System]→[iConsole&Footswitch]/[Key Board]) 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 (for details, refer to “5.14.2.2 STE Mode Image Optimization”).
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.

### 5.14.2.2 STE Mode Image Optimization

#### Image Quality

**Description** 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.



**Operation** Rotate the knob under [E Quality] on the touch screen to select the different THI frequency value.

The adjusting range of basic frequency values can be divided into penetration preferred (Pen), general mode (Gen), resolution preferred (Res). Please select the frequency according to the detection depth and current tissue features.

**Impacts** Used to optimize the resolution and the penetrability of the image.

## Elas Metric

**Description** Used to adjust the elastography metric.

**Operation** 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

**Description** 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.

**Operation** Rotate the knob under [Scale] on the touch screen. The value on the top of the Map changes as the Scale changes.

The adjusting range: 0 to 29 in increment of 1.

**Impacts** 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

**Description** Used to adjust the opacity feature of the Elasto image.

**Operation** Tap [Opacity] on the touch screen. The adjusting range: 0 to 5 in increment of 1.

## Map

**Description** Used to adjust the color map to achieve the switch between the gray map and the color map.

**Operation** Tap [Map] on the touch screen to select the map. E1 is a gray map; E2 and E3 are color maps.

## ROI Adjustment

**Description** This feature is used to adjust the ROI position and scale of the lesion detected in STQ imaging.

**Operation** 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

**Description** Used to adjust the display format of ultrasound image and the Elasto image, and return to the previous state.

**Operation** Tap each soft key on the touch screen to complete the adjustment.  
The system provides 3 types of display format:  
H 1:1; V 1:1; Full.

**Impacts** More accurate result is obtained based on the actual situation.

## HQElasto

**Description** Turn on high-quality scanning mode to optimize penetration.

**Operation** Tap [HQElasto] to enable the function and the button will be highlighted.

**Impacts** 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

**Description** 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.

**Operation** 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).

**Impacts** 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

**Description** 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.

**Operation** 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/Sensibility

- Description** 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.
- Operation** 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.  
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.
- Effects** Users can determine the interference degree of the currently-captured elasto image according to the M-STB Index.

## Smooth

- Description** This feature is used to reject the noise and smooth the image.
- Operations** Tap [Smooth] on the touch screen to adjust the parameter.
- Effects** The bigger the level is, the higher the smooth effect achieves.

## Persistence

- Description** This feature is used to superimpose and average adjacent elasto images, so as to optimize the image.
- Operations** Tap [Persistence] on the touch screen to adjust the parameter.  
The bigger the value is, the higher the frame optimization effect achieves.
- Effects** The persistence function can remove image noise and optimize image effect to gain a more detailed image.

## FS Mode

- Description** This feature is used to improve the frame rate.
- Operations** Tap [FS Mode] on the touch screen to enable the function and the button will be highlighted.

## Invert

- Description** Invert the map to satisfy the different doctors to define the benign lesion or malignant lesion.

**Operation** Tap [Invert] to enable the function (the soft key is highlighted).

### **iLayering**

**Description** To increase the layer display in elasto images.

**Operation** Tap [iLayering] to enable the function.

### **Filtering**

**Description** To filter the noise of the elasto image.

**Operation** Tap [Filter] on the touchpad.

The higher the level is, the smaller the noise of the elasto image becomes, and the clearer the edge of the field target appears.

**Impacts** The system restarts scanning B image and E image after the filtering is completed.

### **Map Position**

**Description** This feature is used to adjust the up/down position of the map.

**Operations** Tap [Map Position] on the touch screen to adjust the parameter.

### **Select/Bad**

**Description** It is used to remove the desired frame from stress curve. The removed frame will not be calculated in STE indices.

**Operations** Rotate the knob under [Select/Bad] to select the desired frame, and press the knob to set the desired frame to "On".

## **5.14.2.3 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.

Refer to Operator's Manual (Advanced Volume) for details.

## **5.14.2.4 Cine Review**

Press <Freeze> to freeze the image and enter cine review state.

Or, click the cine to enter the cine review state.

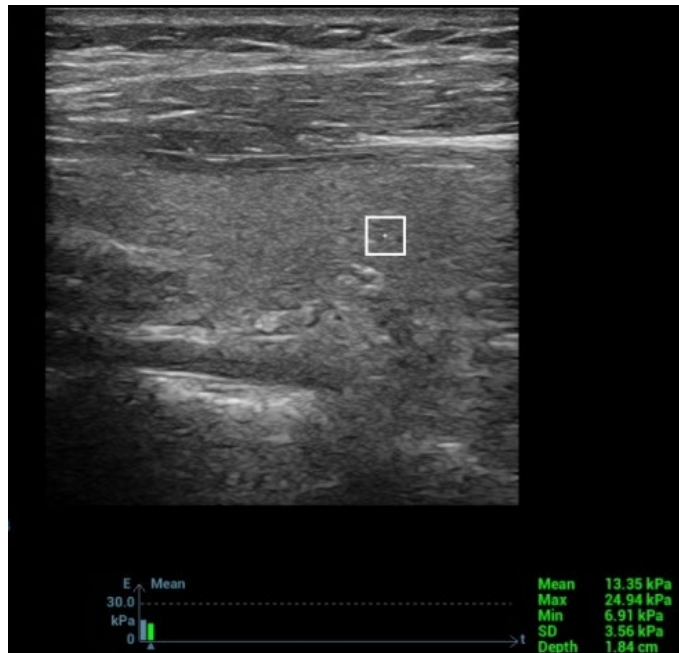
## **5.14.3 STQ Imaging (Sound Touch Quantification)**

The STQ imaging is an option. Probes support this function:

### **5.14.3.1 Basic Procedures for the STQ Imaging**

1. Select a proper probe. Perform 2D scan to locate the lesion.

2. Tap [Elasto]→[STQ] on the touch screen. Or press the user-defined <STQ> key (set the user-defined key via [Preset]→[System]→[iConsole&Footswitch]/[Key Board]) to enter the STQ mode.

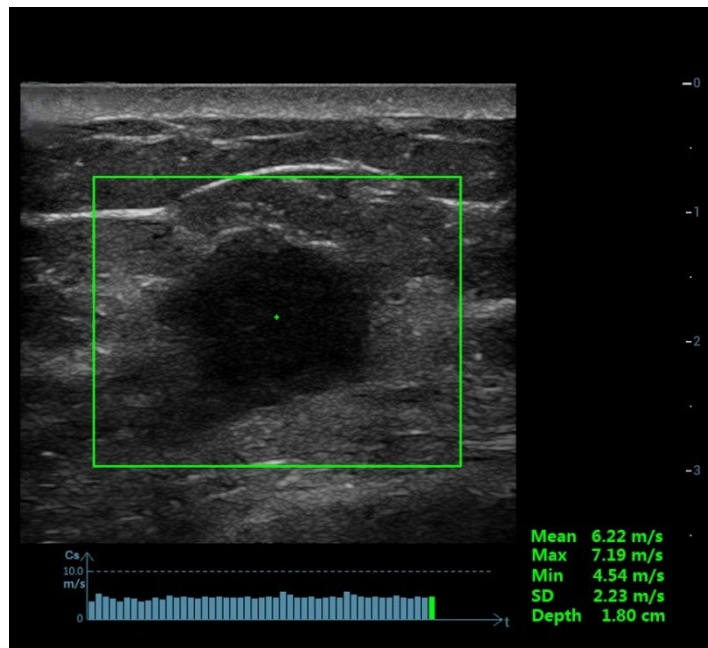


3. Adjust the ROI based on the lesion size and the position.
4. Press <Update> to generate the acquisition. Place the probe still with stable force (not pressing, sweeping or moving the probe) to acquire the image. Adjust the B image parameters to obtain a premium image.

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.



5. Freeze the image, and replay the image if necessary.
6. Save the single-frame and multi-frame image.
7. Reacquire the image if necessary.

8. Press <B> on the control panel or tap [STQ] on the touch screen to exit the elastography imaging mode, and return to B mode.

### 5.14.3.2 STQ Mode Image Optimization

#### ROI Adjustment

- Description** Used to adjust the ROI position and scale in STQ imaging.
- Operation** 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.

#### Elasto Curve and Metric

- Description** 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.
- Operation** 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

- Description** Used to optimize the measurement result via equalizing the elasto metric of the current frames and the previous frames.
- Operation** 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.
- Impacts** Decrease the image noise.

#### E bar

- Description** This feature supports the elasto curve to be displayed based on different statistical amounts.
- Operations** Tap [E bar] on the touch screen to adjust the parameter.

#### M-STB Index/Sensibility

- Description** 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.

**Operation** 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.

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.

**Effects** Users can determine the interference degree of the currently-captured elasto image according to the M-STB Index.

## Scale

**Description** Used to optimize the display effect of the elasto average metric inside ROI via changing the Y-axis size.

**Operation** Rotate [Scale] knob to adjust the value.  
The adjusting range is: 0-9 in increment of 1.

**Impacts** 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

**Description** Enable the high-quality scan mode and optimize the penetrability.

**Operation** 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.

**Impacts** The measurement, comment and body mark is not available in HQElasto status.

## Filtering

**Description** This feature is used to filter the noise of the elasto image.

**Operations** 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.

**Effects** The system restarts scanning B image and E image after the filtering parameter is adjusted.

## Smooth

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

**Operations** Tap [Smooth] on the touch screen to adjust the parameter.

**Effects** The bigger the level is, the higher the smooth effect achieves.

### **Persistence**

**Description** This feature is used to superimpose and average adjacent elasto images, so as to optimize the image.

**Operations** Tap [Persistence] on the touch screen to adjust the parameter.  
The bigger the value is, the higher the frame optimization effect achieves.

**Effects** The persistence function can remove image noise and optimize image effect to gain a more detailed image.

### **Map Position**

**Description** This feature is used to adjust the up/down position of the map.

**Operations** Tap [Map Position] on the touch screen to adjust the parameter.

**Effects** When the E Average function is enabled or disabled, the elasto curve is displayed based on different statistical amounts.

### **Lesion**

**Description** It is used to distinguish elastography data of the different lesion region.

**Operations** Rotate the knob under [Lesion] on the touch screen to adjust.

### **Select/Bad**

**Description** It is used to remove the desired frame from stress curve. The removed frame will not be calculated in STQ indices.

**Operations** Rotate the knob under [Select/Bad] to select the desired frame, and press the knob to set the desired frame to "On".

## **5.15 Stress Echo**

Stress Echo is an option.



**CAUTION:**

**Stress echo data are provided for reference only, not for confirming diagnoses.**

### **5.15.1 Overview**

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> on the control panel, 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.

## 5.15.2 Stress Echo Acquisition Procedure

To acquire Stress Echo loops, you must enable the ECG function.

1. Use the proper probe and cardiac-related exam mode, press the user-defined key for Stress Echo (Set the user-defined key for Stress Echo via the path: [Setup]→[System]→[iConsole&Footswitch]/[Key Board].) or touch [Stress Echo] on the touch screen to enter stress echo imaging.
2. The system displays the “Select Protocol” window with the protocol selections. Select the desired protocol and then click [OK].

The system displays the real-time imaging screen.

If the Stress Echo manual ROI option is selected in the Maintenance dialog box ([Setup]→[Stress Echo]→[Maintenance]), 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> on the control panel to confirm the ROI.

Tip: 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> on the control panel to start acquisition.

The system displays the Protocol window on the left of 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, indicating the selected view by placing a red mark to the right of the view name.

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> on the control panel. The system goes to the next view for acquisition by default, saved views are marked with a green “√.”
- 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.

Tip: Views can be re-acquired until you click [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> on the control panel. 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> on the control panel.
- 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, click [Stage Timer]/[Exam Timer] on the soft menu 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, select [Review/WMS] on the menu. You can redisplay the real-time imaging screen to continue acquisition by selecting [Acquire].
8. To end the acquisition and review the acquired images, click [End Acquisition].

**NOTE:** When the acquisition is ended, no stress echo image acquisition can be performed for the same exam.

### 5.15.3 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] on the menu 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 [Stage: XX] or [View: XX] on the soft menu 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 full-screen.
  - Double-click a clip. The clip will be magnified.
  - Tap [First/Last] or [Previous/Next] on the touch screen to display another loop in the current view.
  - Click buttons on the left side of the screen to view the cine files by frame.
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:

Touch screen controls:

Selection	Description
Stages: XX	Rotate the corresponding knob under the button to select a stage.
Views: XX	Rotate the corresponding knob under the button to select a view.
Acquire/ Select/ Review/WMS	To switch the mode status.

Selection	Description
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.
	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.
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.

## 5.15.4 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).

### 5.15.4.1 Enter review mode

1. Select [Review/WMS].
2. Select the label of the phase or view (for example, Rest or Long Axis) on the right part of the screen.  
The system displays all loops that represent the selected phase or view.

To display phases for the selected view(s)

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 red X into each selected box, like .

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.

Description of review/WMS mode keys (keys with the same function as in select mode are not described below):

Key	Description
Review/WMS	<p>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.</p> <p>Selection: On, Off</p> <p>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.</p> <p>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 click [Next], loops of the first two views in the 3<sup>rd</sup> and 4<sup>th</sup> stage will be displayed.</p> <p>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).</p>
Display Selected	Displays loops of all the stages and views selected.

### 5.15.4.2 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 in the bottom-right area of the screen.  
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. Roll 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.

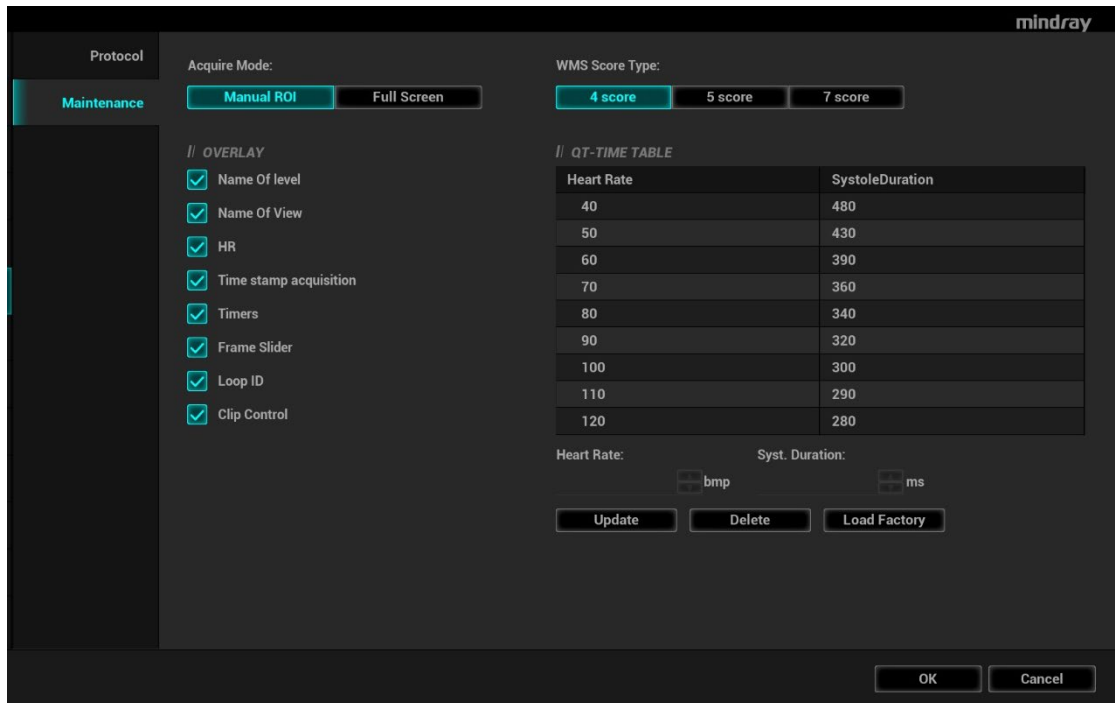
To assign a normal wall motion score (WMS) to the currently selected view:

Select [Set Current Normal] on the touch screen.

## 5.15.5 Maintenance and Protocol

### 5.15.5.1 Maintenance

Select "<F10 Setup>→[Stress Echo]→[Maintenance]" to enter the screen.



Item	Function Description
Acquire mode	Set the type of ROI: manual ROI or full-screen.
Overlay	Select the items to be labeled on each loop.

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.

### QT-Time Table Operation:

To add an entry:

Enter a heart rate and the referring systolic duration and then click [Update].

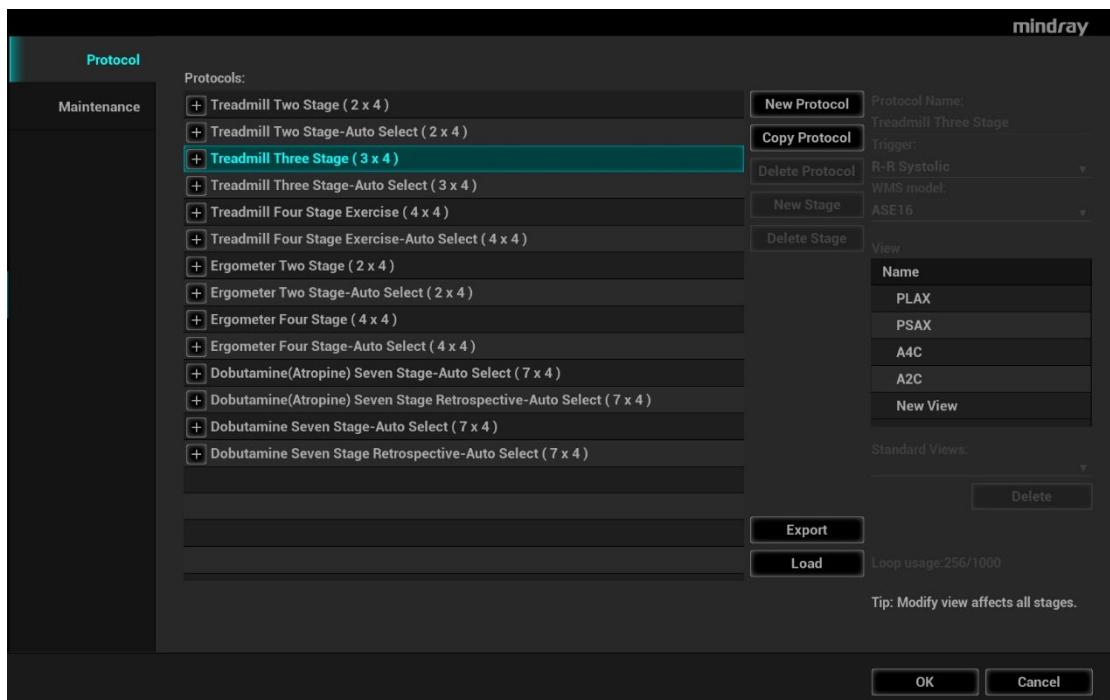
To delete an entry:

Select the required heart rate and systolic duration pair from the QT – Time Table and then click [Delete].

### 5.15.5.2 Protocol Edit

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

Access the Protocol Editor dialog box by clicking [Protocol] in [Setup]→[Stress Echo]→[Protocol], or clicking [Edit] on the Select Protocol screen as shown in the figure below:



Item	Function 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.

Item	Function Description
Standard view	Set the standard view.
Load	Import a protocol.
Export	Export a protocol.
New protocol	Create a new protocol.
Copy protocol	Create a new protocol with an existing one.
Load	Load an existing protocol.
Save	Save the changes to the protocol.
Delete protocol	Delete the protocol.
New stage	Create a stage for the current protocol.
Quit	Remove the Protocol Editor dialog box.

### Creating a Stress Echo Protocol

To create a stress echo protocol:

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

### Editing or Deleting a Stress Echo Protocol

To delete a protocol:

Select the protocol or one of its component phases or views and then click [Delete].

To Edit a Stress Echo Protocol:

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.

## 5.15.6 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.

## 5.15.7 Exiting the Stress Echo Feature

To exit the Stress Echo feature:

Tap [End] on the control panel or click [End SE exam] on the screen.

## 5.15.8 Measurement and Report

Suspend the stress echo exam by selecting [Suspend Exam] on the soft menu. Press the measurement related keys or buttons to enter cardiology measurement. For details, see the [Advanced Volume].

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.

Entering Indications or Comments for the Reports

You can enter an indication for display in Stress Echo reports.

To enter an indication:

1. Tap [Report] on the touch screen to open the report.
2. Use the keyboard to enter text in the Indication dialog box and then click [OK].

## 5.16 Tissue Tracking Quantitative Analysis



**CAUTION:**

**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.

Tissue tracking quantitative analysis is an option.

### 5.16.1 Basic Procedures for Tissue Tracking QA

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 [TT QA] on the touch screen:
  - a) You can determine the image of interest by previewing the image
  - b) To find the image of interest, tap [Cycle] on the touch screen to select.
3. Select the corresponding section name on the soft menu 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] on the touch screen 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 touch screen to start the tracking function. Adjust the parameters if necessary.



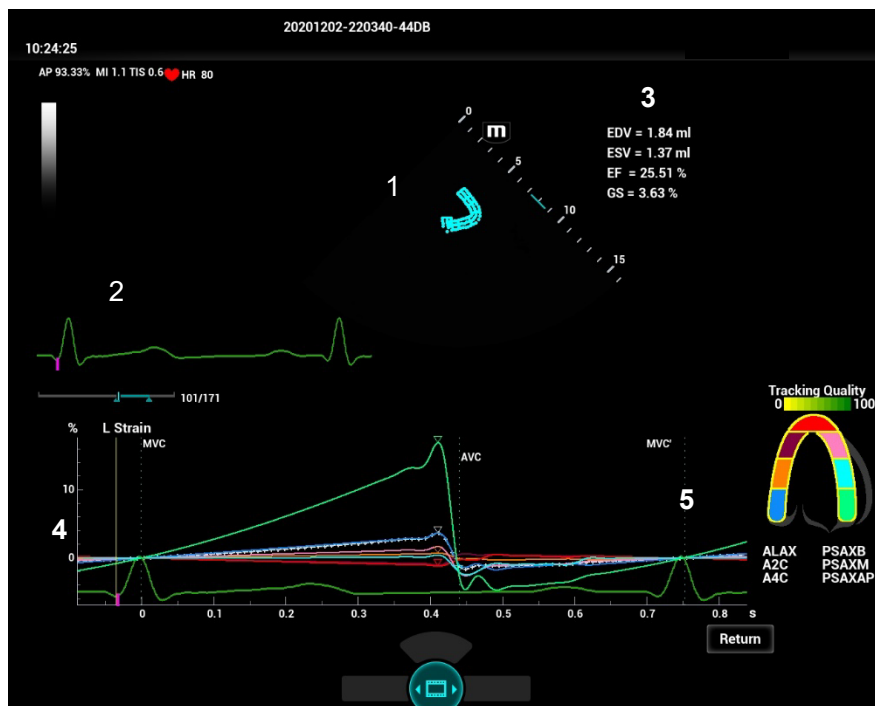
Tap [Edit] on the touch screen to display the cursor. Roll the trackball and press <Set> to re-select the trace reference points. Move the cursor to the exact boundary position and press <Set> again to set the right place. Click [Start Tracking] to start tracking again.

6. Tap [Accept & Compute] on the touch screen to calculate and display the curve. Adjust the parameters if necessary.
7. Tap [Bull's Eye] on the touch screen 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.

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] on the touch screen to export analyzed data.
11. Tap [Exit] on the touch screen.

## 5.16.2 Screen Display of Tissue Tracking QA



1—Displays image used to generate trace curve

2—Displays ECG trace

3—Displays measurement and calculation results:

- EDV: Maximum value of the end diastolic volume during the trace.
- EDA: Maximum value of the end diastolic area (Left Ventricular) during the trace.
- ESV: Maximum value of the end systolic volume (Left Ventricular) during the trace.
- ESA: Maximum value of the end systolic area (Left Ventricular) during the trace.
- FAC (for short axis section): Fractional Area Change= (EDA — ESA)/EDA
- EF (for long axis section): Ejection fraction
- HR: Heart rate
- Global strain of all segments. Displays when strain rate curve is acquired.
- Global strain rate of all segments. Displays when strain rate curve rate is acquired.

Also on Bull's Eye figure, the system displays TPSD value:

Time to Peak Standard Deviation (TPSD):

Where, standardized value of time to peak data:  $\{TP_i | i \in [1, N]\}$ . (N is the number of time to peak data) Average value of standardized value of time to peak data:  $\overline{TP}$ , and the standard deviation is

$$TPSD = \sqrt{\frac{\sum_1^N (TP_i - \overline{TP})^2}{N}}$$


4—Display curve: Velocity/Displacement/Strain/Strain Rate.

Each curve on the image is matched with a certain segment in the cardiac segmentation model (6), identified by different colors.

Velocity curve	X-axis represents time (s); Y-axis represents velocity (cm/s).
Displacement curve	X-axis represents time (s); Y-axis represents displacement (mm).
Strain curve	X-axis represents time (s); Y-axis represents deformation of the tissue (%).
Strain-rate curve	X-axis represents time (s); Y-axis represents strain by time (s <sup>-1</sup> ).

5—Displays corresponding time of AVO (aortic valve open)/AVC (aortic valve close)/MVO (mitral valve open)/MVC (mitral valve close).

6- Displays cardiac segmentation model, and each segment name is illustrated beneath the model.

In the figure,  marks the peak position of the curve.

Under tracking status, click on a segment in the cardiac segmentation model. The segment has “X” mark and its corresponding calculating is eliminated.

- Tap certain segment in the cardiac segmentation model, the segment will turns grey and its corresponding curve no longer displays.
- 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.
- The segment boundary color indicates the tracking quality.

### 5.16.3 Select Image and Cardiac Cycle

You can select images with a better image quality so as to guarantee the analysis result.

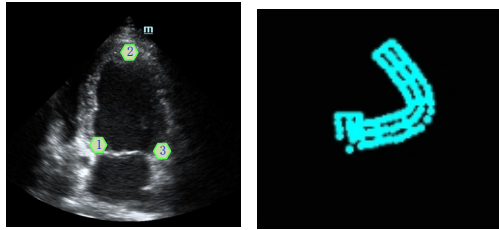
- Switch the cine file
  1. Tap [Review] to enter the review state on touch screen.
  2. Double-click the target file;
  3. The system closes current displayed file and switch to the newly selected file;
- Switch cardiac cycle within the cine file

Tap [Circle] to select when opening a cine which includes multiple cardiac cycles.

### 5.16.4 Myocardial Boundary 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.
    - ◆ 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 roll 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.

- Short axis section (PSAX B, PSAX M, PSAX AP): only manual tracing is available.


■ Retracing

If current trace is not satisfactory, touch [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;

1. Under tracing curve adjusting status, the cursor turns into .
2. Move the cursor to the editable point, press <Set>;
3. Roll the trackball to drag the curve to desired position, press <Set> again to set the point to the new position;
4. Repeat steps 2-3 to finish all points that need adjustment.

NOTE: under tracking status, tap [Edit] on the touch screen to enter the status.

## 5.16.5 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.

[PSAX B]: short axis view of base section, short axis view of mitral valve.

[PSAX M]: short axis view of base section, short axis view of papillary muscle.

[PSAX AP]: 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.

[Tracking Points]: 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] on the soft menu, 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 (cm <sup>2</sup> ).
	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).
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### 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.

$$\text{Torsion} = \text{PSAX AP Rot.} - \text{PSA XB Rot.}$$

- The X-axis represents time (s);
- The Y-axis represents torsion by time (Deg/s).

## 5.16.6 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.

## 5.16.7 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.

## 5.16.8 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.

## 5.16.9 FH Tissue Tracking QA

FH Tissue Tracking QA is used to analyze ventricular shape and contractility in a cardiac cycle, so as to realize fetal heart quantitative analysis.

- NOTE:**
1. FH Tissue Tracking QA is an option. It is supported only in Fetal Echo related exam modes.
  2. 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 re-select 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.

## 5.17 Fusion Imaging

### 5.17.1 Overview


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/positron 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).

<b>Note</b>	<ol style="list-style-type: none"><li>1. Fusion imaging is an optional function. Configure “Ultrasound Fusion Imaging or Endocavity Fusion Imaging (software optional)”, “Fusion RESP (software optional)”, “Fusion Imaging Kit (hardware optional)”, Motion Sensor Support (hardware optional) first before conduct the Fusion Imaging exam. See also Chapter “2.4.3 Options” for details.</li><li>2. The SC6-1s, C6-2Gs, SP5-1s, SC8-2s, L14-3Ws, L13-3Ns, SC6-1E, SP5-1E, and SP5-1U probes support Fusion Imaging when Ultrasound Fusion Imaging is configured. The V11-3Hs and ELC13-4s probes support Fusion imaging when Endocavity Fusion Imaging is configured.</li></ol>
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 <b>WARNING</b>	<b>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.</b>
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## 5.17.2 Magnetic Navigator

<b>Note:</b>	<p>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.</p> <p>Connect the magnetic navigator when the magnetic navigation controller is OFF.</p> <p>Exit Fusion imaging before reconnecting/disconnecting sensor from the magnetic navigation controller. Turn off the magnetic navigation controller before connecting/disconnecting magnetic generator.</p>
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
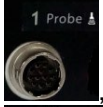

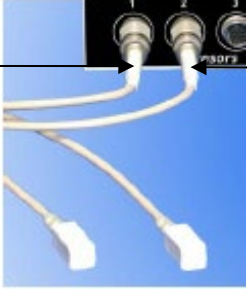


Plug the auxiliary output power supply cable, USB data cable, magnetic generator and sensor(s) to the magnetic navigator respectively following the arrow’s guide.






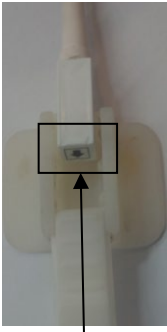
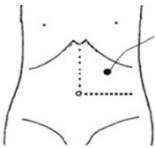

The description of the magnetic navigator is given in details. See the table below.

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. Note: 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.

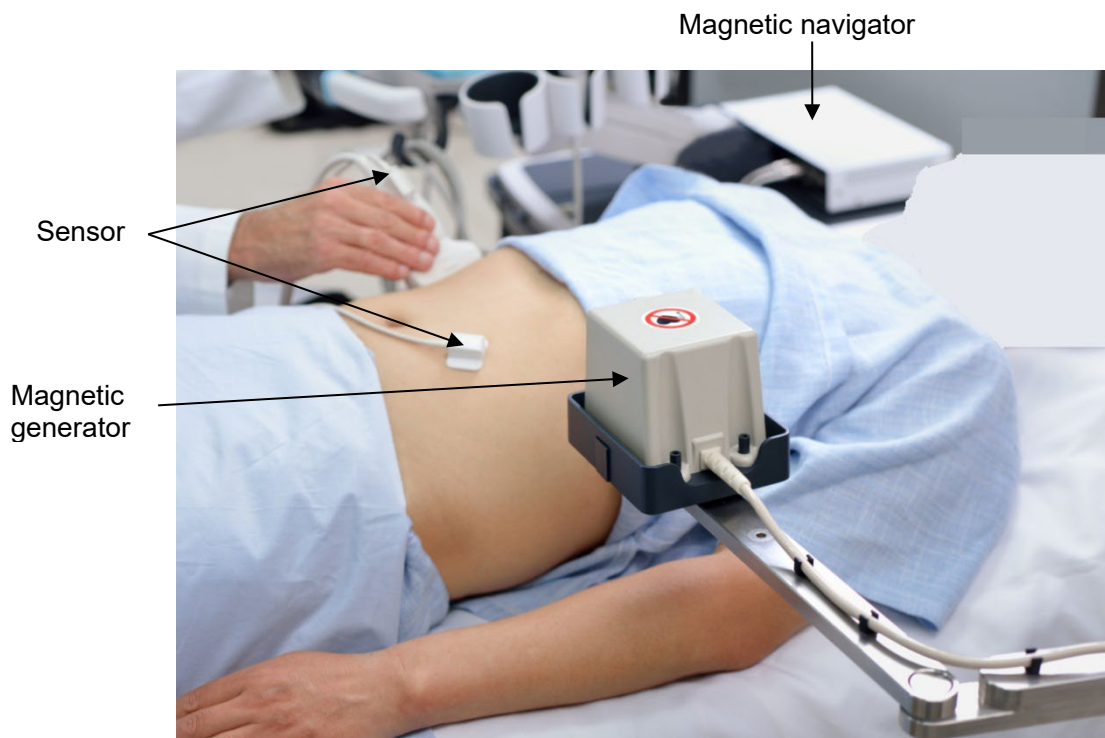


No.	Device Name	Port	Description
<3>	Magnetic generator	Transmitter port	<p>Plug the magnetic generator to the Transmitter port. Place it around the patient's shoulder or two sides of the patient's abdomen. The magnetic generator should be frontal-faced with the lesion. The frontal face of the magnetic generator keeps 15-60 cm from the target within the scope 30 cm up/down and towards probe.</p> <p style="text-align: center;">Front </p> <p>NOTE: keep the magnetic generator away from the metal devices or electromagnetic interference.</p>
<4>~<9>	Sensor (2), Positioning (probe) navigation support Motion (abdomen) sensor support	Positioning (probe) sensor port Motion (abdomen) sensor port	<p>1. Plug two sensors to positioning (probe) sensor port  and motion (abdomen) sensor port  respectively.</p> <p></p> <p>2. Positioning (probe) navigation support: fix the support to the probe. See the method below:</p> <ul style="list-style-type: none"> <li>The plastic markers on the probe and on the positioning (probe) navigation support must be on the same side.</li> </ul> <p style="text-align: center;">       Marker on the probe         Marker on the support  </p> <ul style="list-style-type: none"> <li>The silk prints on the probe and the navigation support must be on the same side.</li> </ul>

No.	Device Name	Port	Description
			<div data-bbox="884 344 1082 412" data-label="Text"> <p>Silk print on the probe</p> </div> <div data-bbox="884 461 1082 528" data-label="Text"> <p>Silk print on the support</p> </div> <div data-bbox="1129 275 1358 629" data-label="Image"> </div> <ul style="list-style-type: none"> <li data-bbox="791 645 1430 712">● Push the navigation support fastened following the arrow's guide.</li> </ul> <div data-bbox="868 763 1315 958" data-label="Image"> </div> <p data-bbox="730 976 1430 1155">3. Positioning (probe) sensor: fix the positioning (probe) sensor which is already plugged in positioning (probe) sensor port to the cavity of the positioning (probe) navigation support following  guide.</p> <div data-bbox="828 1249 943 1447" data-label="Image"> </div> <div data-bbox="804 1469 1002 1503" data-label="Text"> <p>Face downward</p> </div> <div data-bbox="1002 1301 1145 1424" data-label="Text"> <p>Positioning (probe) navigation support</p> </div> <div data-bbox="1198 1171 1369 1469" data-label="Image"> </div> <div data-bbox="1043 1503 1378 1536" data-label="Text"> <p>Positioning (probe) sensor</p> </div> <p data-bbox="791 1585 1430 1704">Note: if failed to plug the positioning (probe) sensor following  guide, it may lead to non-correlation of spatial positioning.</p> <ul style="list-style-type: none"> <li data-bbox="730 1715 1430 1805">4. Positioning (probe) sensor sterile sheath: wear the probe sterile sheath after probe sensor and positioning (probe) navigation support are installed.</li> <li data-bbox="730 1816 1430 1962">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  guide.</li> </ul>

No.	Device Name	Port	Description
			 <p data-bbox="999 607 1198 636">Face downward</p> <p data-bbox="730 674 1442 943">           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).         </p>  
<10>	Magnetic navigator	/	Place the magnetic navigator behind the Ultrasound System. Power on the navigator to enable the positioning function.

Magnetic devices positioning:

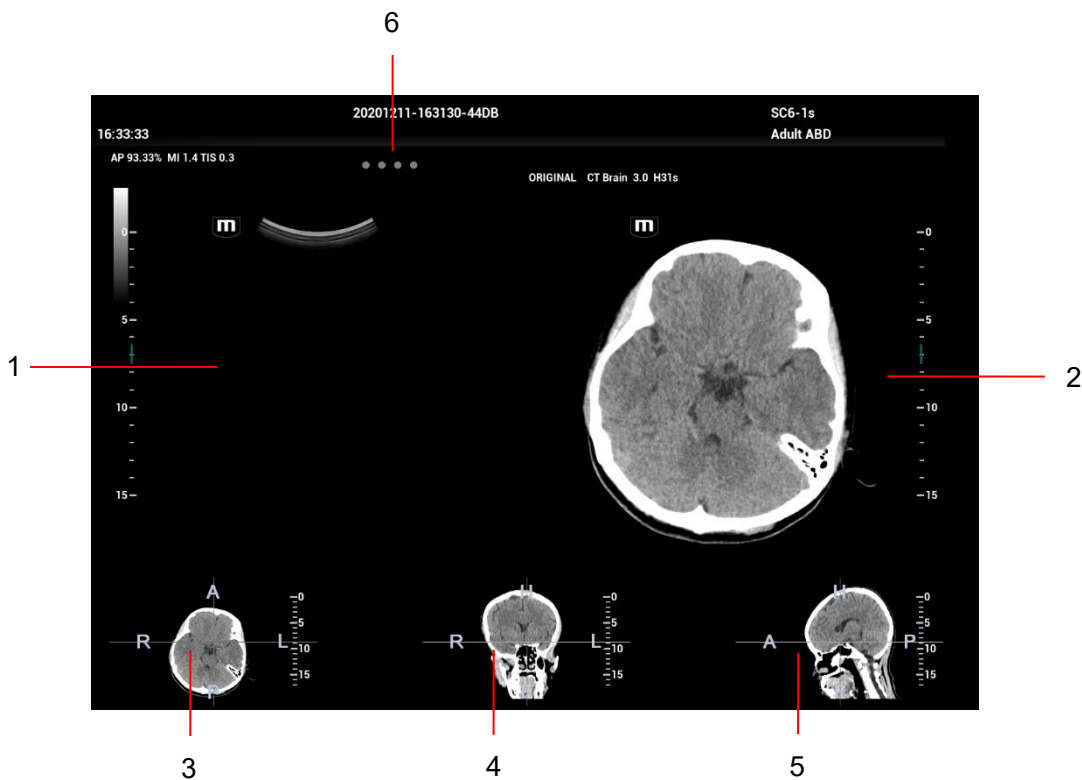


The navigation support equipped with the probe shows below:

Navigation Support	Probe Type
NB-011	SP5-1s, SP5-1E, SP5-1U
NB-022	SC6-1s, SC6-1E
NB-024	C6-2Gs
NB-025	V11-3Hs
NB-029	SC8-2s
NB-051	ELC13-4s
NB-053	L13-3Ns
NB-054	L14-3Ws

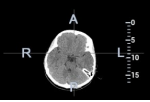


### 5.17.3 Screen Description

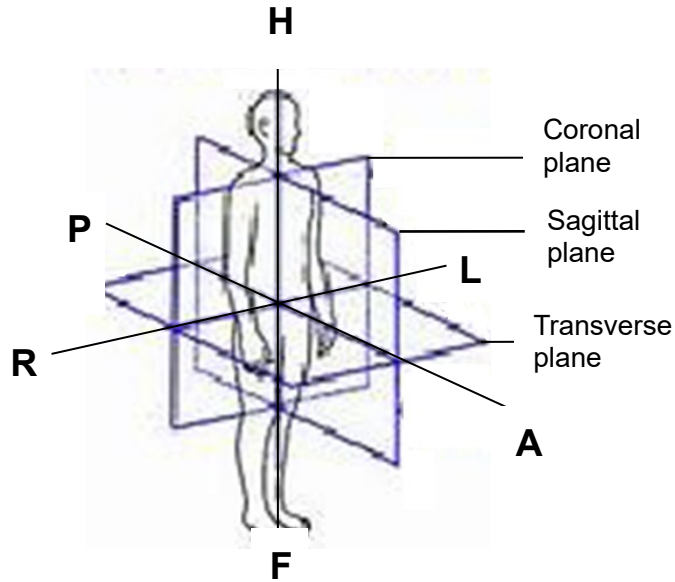
You should connect the magnetic devices, and then enter Fusion Imaging. The Fusion Imaging screen appears. See Chapter 5.17.2 Magnetic Navigator for details.



3, 4 and 5 windows show the three anatomical planes of CT/MR/PET/freehand 3-dimensional image (there are transverse plane, coronal plane and sagittal plane respectively). The position for each plane is shown below:

Each of them is:

R-L axis on transverse plane  , A-P axis on coronal plane  and H-F axis on sagittal plane  positioning in human body are shown below:



Five windows descriptions are given below:

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. See also Chapter 5.17.10 Parameter Setting for fusion parameter adjustment.
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. See also Chapter 5.17.10 Parameter Setting for fusion parameter adjustment.
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.

No.	Image	Description
6	Indicator	<p>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.)</p> <p>Check the indicator becomes green in use.</p> <p>Different indicator color:</p> <ul style="list-style-type: none"> <li>● Blinks green: excellent.</li> <li>● Blinks yellow: mediocre.</li> <li>● Blinks red: poor.</li> <li>● Stays grey: no signal activated. (Magnetic navigation is not enabled.)</li> </ul> <p>Note: 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.</p>

## 5.17.4 Basic Procedures

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 (see also Chapter 5.17.2 Magnetic Navigator). 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.

See also Chapter 5.17.2 Magnetic Navigator (table) for indicator descriptions.
4. Acquire/import CT/MR/PET/freehand volume data. See also Chapter 5.17.5 Acquiring/Importing Volume Data.
 

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 [Multidata] to select "PET-CT". The PET-CT volume data will be used in later registering with ultrasound image.

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.

**Note:** 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. See also Chapter 5.17.10 Parameter Setting.
6. Obtain an optimum plane as the registration plane from CT/MR/PET image (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 also Chapter 5.17.11 Rotating/Scrolling CT/MR/PET/Freehand Image 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.

<b>Note:</b> After tapping [Registration] each time, Tap [View Type]. It is convenient for panning or scrolling CT/MR/PET image.
--

- 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 also Chapter 5.17.11 Rotating/Scrolling CT/MR/PET/Freehand Image 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. See also Chapter 5.17.10 Parameter Setting for operations.
- 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. See also Chapter 5.17.10 Parameter Setting for operations.

- c) Tap [Confirm Registration] to complete registering. The ultrasound image and CT/MR/PET image appear synchronously after the registration accomplishment.

<b>Note:</b> 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.
--

9. Checking registration effect:

After completing 8<sup>th</sup> 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/Freehand plane moved).

b) Tap [Confirm Registration] to complete the fine tuning.

<b>Note:</b>	<ul style="list-style-type: none"><li>● Use the plane concentrated with the patient's lesions to perform the fine tuning.</li><li>● 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.</li><li>● Freeze the ultrasound image and CT/MR/PET/freehand image simultaneously after the fine tuning. Tap [Confirm Registration] to make the fine tuning work.</li></ul>
--------------	--

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 also Chapter 5.17.7 Respiratory Compensation.

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.

### **Marks (setting the mark based on your need)**

Mark the lesion position on CT/MR/PET/Freehand image. See also Chapter 5.17.6 Marks.

Note: mark the tumor on CT/MR/PET/Freehand image after CT/MR/PET/freehand data is loaded. Generally, it is available to mark the tumor before/during/after the registration.

### **Ultrasound Contrast Fusion (conducting the Contrast Fusion based on your need)**

Inject the contrast gel after the registration is completed. Enter Ultrasound Contrast Fusion imaging mode. See also Chapter 5.17.8 Contrast Fusion 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.



## 5.17.5 Acquiring/Importing Volume Data

- |             |  |
|-------------|--|
| <b>Note</b> | <ul style="list-style-type: none"><li>● Only support DICOM CT/MR/PET volume data, and cine format freehand volume data.</li><li>● The following CT/MR/PET volume data not accepted:<ul style="list-style-type: none"><li>Slices less than 2;</li><li>Discontinuous or corrupted data;</li><li>Slice space not equal;</li><li>Slice distance is 0;</li><li>Data from varied alignment (tissue, plane);</li></ul></li><li>● The liver enveloped in CT/MR/PET/freehand volume data.</li><li>● The registration effect will be better if the CT/MR/PET volume data already bears the data of Contrast Imaging with the ultrasound image.</li></ul> |
|-------------|--|

### Acquiring Volume Data

Two methods to obtain volume data:

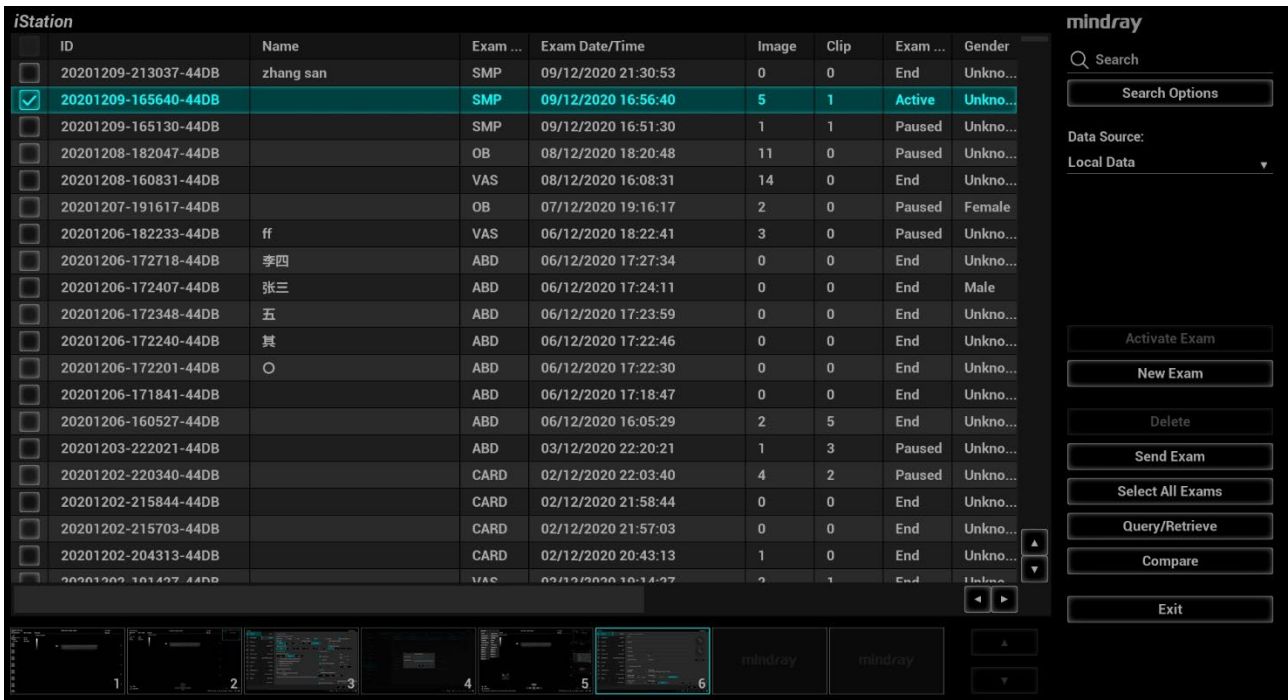
#### Method 1: acquiring volume data from network server.

- |              |   |
|--------------|---|
| <b>Note:</b> | <ul style="list-style-type: none"><li>● It is only applied to the Ultrasound System that is configured with DICOM software package. See also Chapter 2.4.3 Options.</li><li>● The storage path should be short and clear for network server obtaining. Space or Chinese character is not allowed.</li></ul> |
|--------------|---|

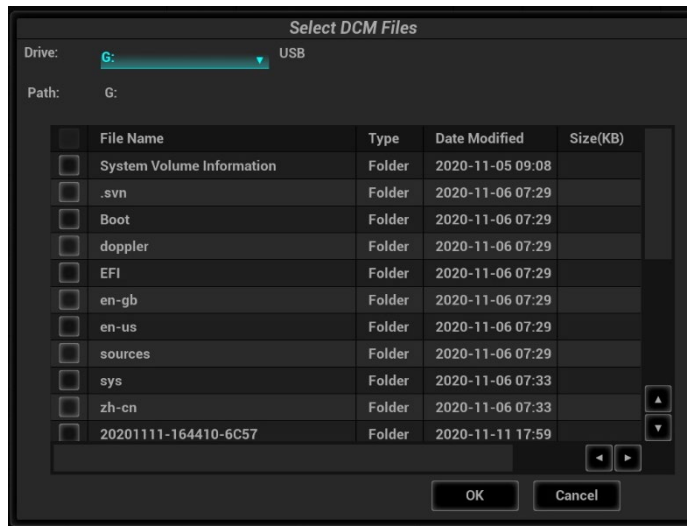
1. Configure DICOM service. See also Chapter 11.1.2 DICOM Local Preset.
2. Configure Query/Retrieve service. See also Chapter 11.1.3.6 Query/Retrieve.
3. Load volume data to iStation. See also Chapter 11.3.6 Query/Retrieve.

#### Method 2: acquiring volume data from external storage medium.


1. Save volume data to USB disk, portable hard disk, optical disk, etc.
2. Press <F2 iStation> to enter the iStation page. Select from the drop-down list of the data source, such as USB.



- 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.



Note:

- The icon  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.

**Note:** The dialog box does not appear for:

- If any file (Ultrasound patient data) is named with “DC9” 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.

- 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.

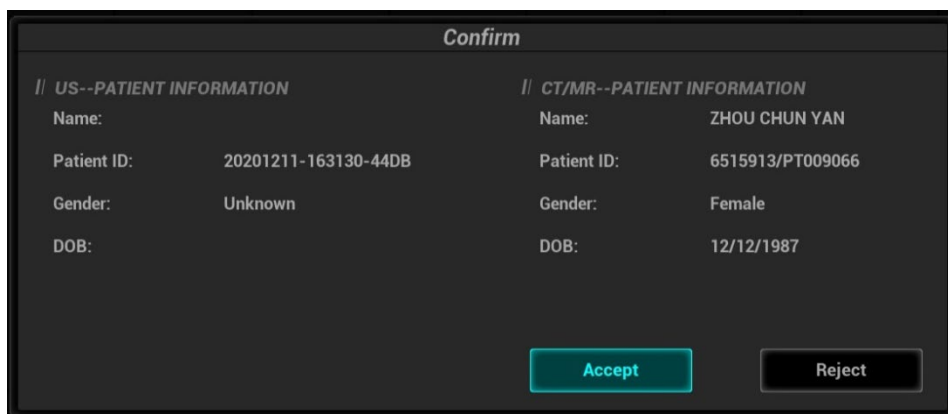
### Importing Volume Data

Acquire volume data to **iStation**. Then, import the data to Fusion exam with the procedures below.

- 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].



- 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.



Volume data is loaded to Fusion Imaging exam. The page is given below:



### Acquiring Freehand Volume Data

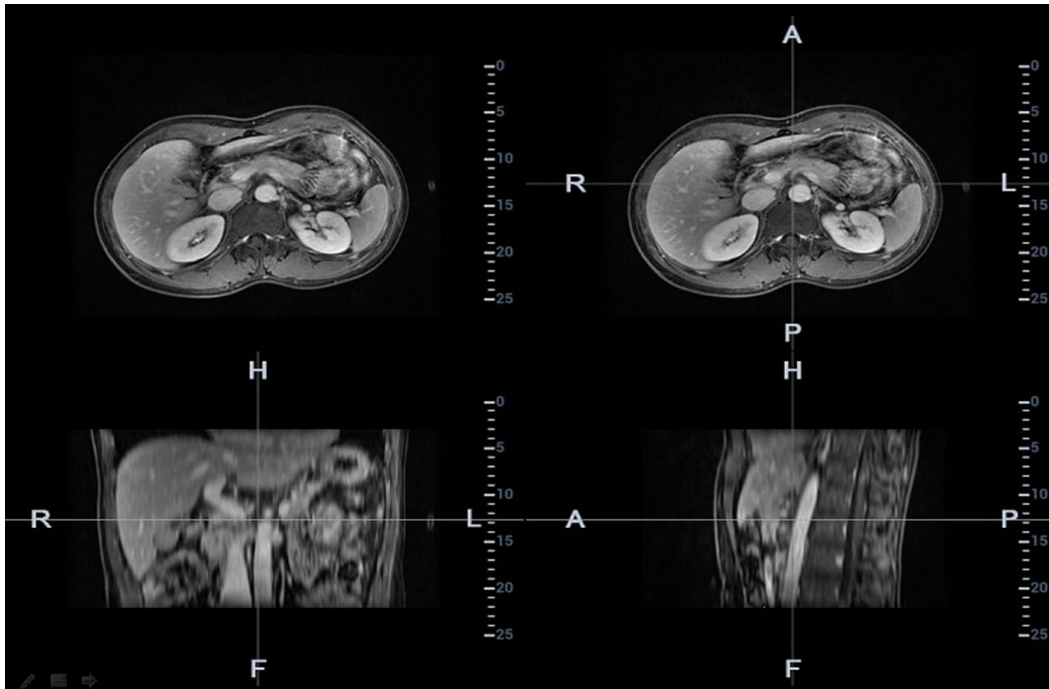
Except importing existing volume data, the operator can also acquire freehand 3D cine on fusion imaging mode. For details, refer to “5.17.9 Freehand 3D”.

### 5.17.6 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.

**Note:** 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.

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:

- Select “Manual tracing” or “Circle tracing” in the “Mark” drop-down list.

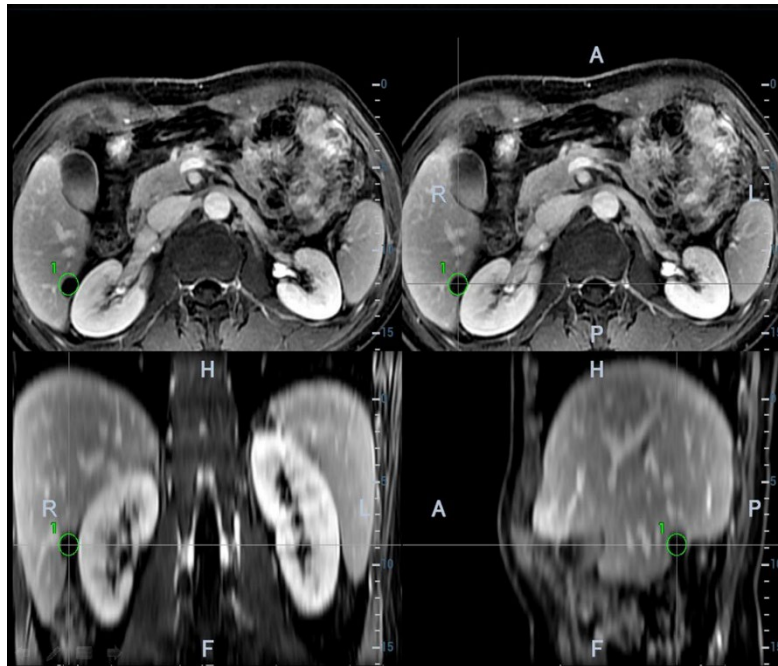
Circle tracing: Press <Set> to locate the center at the core of the lesion. Roll the trackball to adjust the radius. Envelop the tumor or the lesion with the circle. Double press <Set> to complete adding the mark.

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.

Tips: At least two CT/MR/PET/Freehand planes should be marked when performing manual tracing.

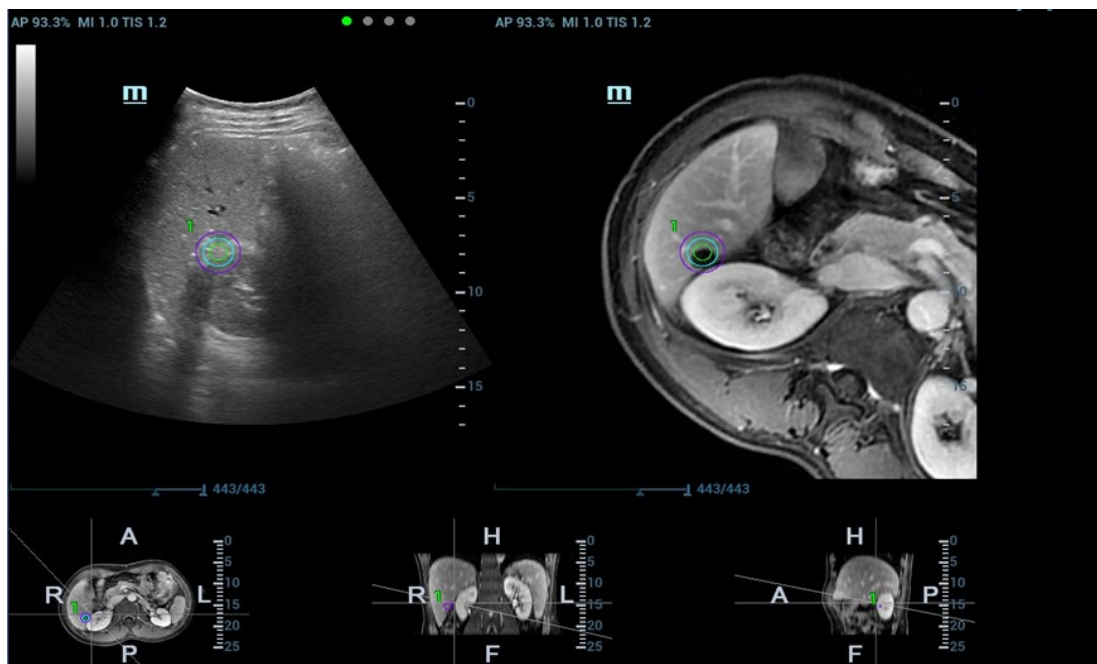
**Note:** The Ultrasound System adds 3-dimesnsional sphere mark to CT/MR/PET/Freehand volume data. Set the target mark based on your sphere center and sphere radius.

- Rotate [Ablative Margin] to add the ablative margin for this mark. See also “Ablative Margin” description below.
- 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.



- 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.



**Note:** 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 Mark] 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.

2. Loading the mark.

Tap [Load Marks]. All mark groups of previous exams of this patient are displayed. See the figure below. 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).

■ **Ablative Margin**

**Description** 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.

**Operation** Rotate [Ablative Margin] to adjust the value. The increment is 1. The adjusting range is 0~10 mm.

■ **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.

■ **Marking on the Fusion Image**

After the registration is completed, tap [Mark on Fusion Image] to mark on the fusion display.

■ **Adding the comment**

It is available to add the comment before adding tumor mark or after tumor mark is added. See also Chapter 9.1 Comments.

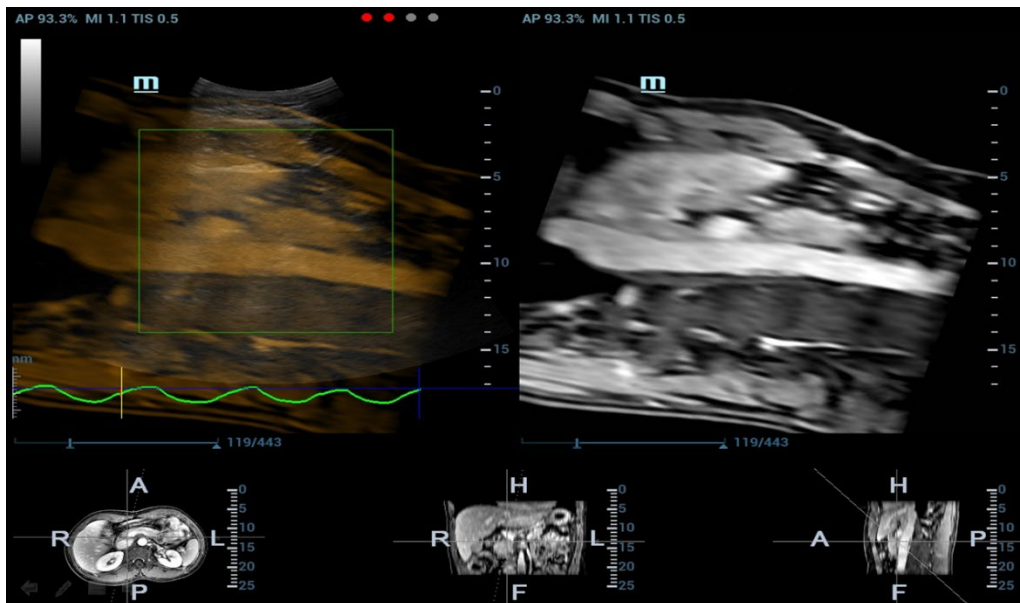
## 5.17.7 Respiratory Compensation

- Note**
- Fusion RESP Component (Fusion Respiration Component) is an option.
  - Configure Fusion RESP Component (optional software), one fusion imaging sensor, one motion sensor support (optional hardware) before enabling Fusion RESP Component. See also Chapter 2.4.3 Options. Stick respiration sensor to the patient's abdomen before entering Fusion Imaging mode.

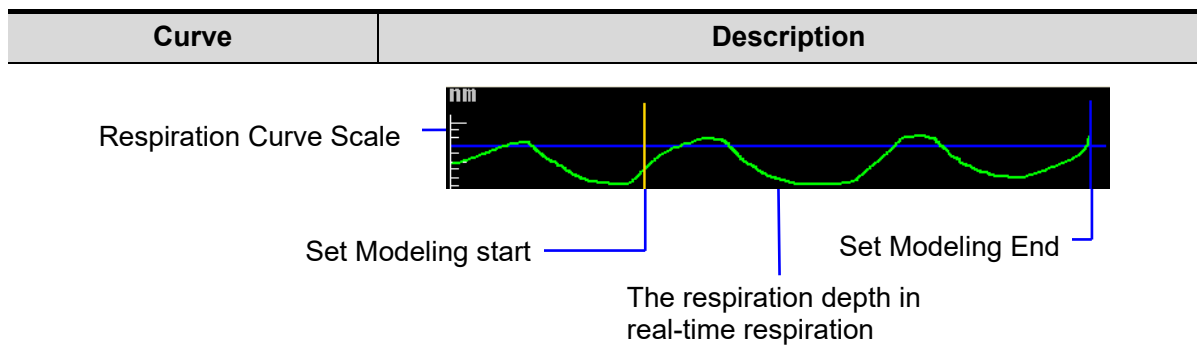
Respiration Compensation sets a motion model for the movement regularities of the liver, and compensates the CT/MR/PET/freehand image in real time. The fusion dynamic accuracy is enhanced apparently.

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 [Motion Modeling] 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.


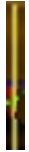


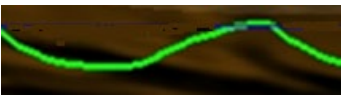
Note: the Ultrasound System selects one premium phase of respiration curve automatically after the capturing is finished. It is prepared for the motion modeling. You can set the start frame and end frame to select one phase of the respiration curve.



Respiration Curve Description:



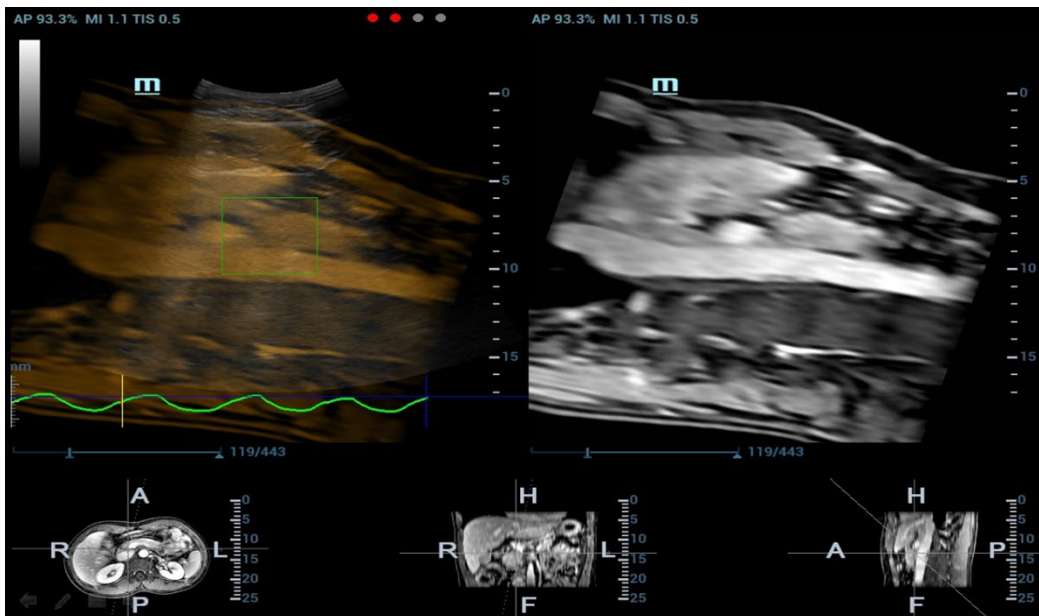


Curve	Description
	Respiration Curve Scale (respiration depth).
	Set Modeling start (start point of motion modeling of the respiration curve).
	Set Modeling End (end point of motion modeling of the respiration curve).
	The blue curve is the respiration depth at last registration.
	The green curve is the respiration depth in real-time respiration.

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

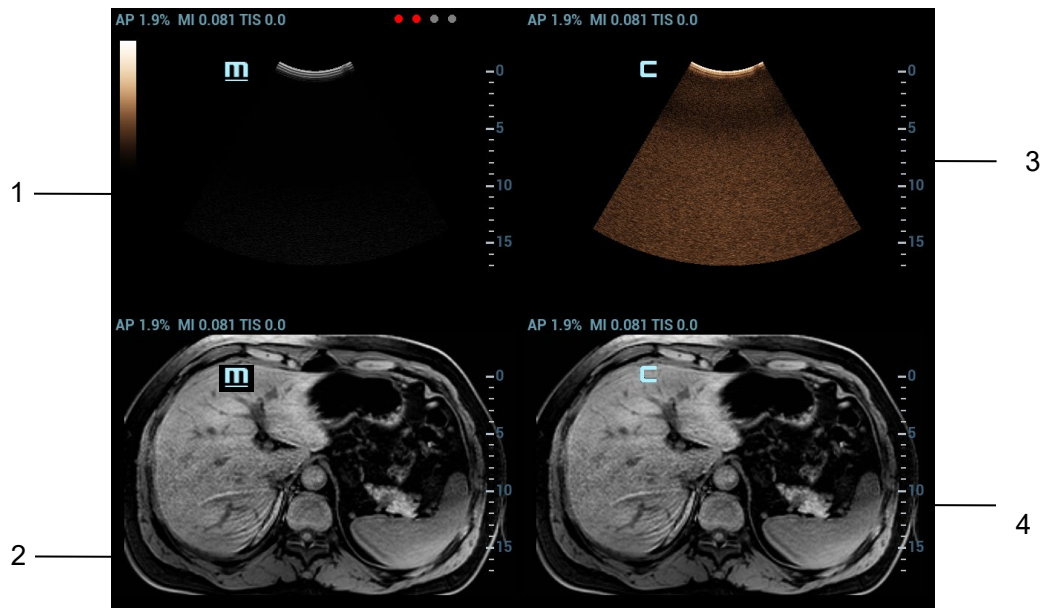
**Description** The aspiration curve appears due to the active respiration depth. The respiration curve beyond the scale becomes the straight line.

**Operation** Rotate the knob beneath [Resp Range].  
Respiration curve scale and the unit appear on the right-axis.

## 5.17.8 Contrast Fusion Imaging

Contrast Fusion Imaging increases the possibility of diagnosing the difficult lesions in the pre-operation; improves the accuracy to ablating the lesion in the intra-operation; estimates the therapeutic effect of the target in the post-operation.

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. (See also Chapter 5.17.10 Parameter Setting).
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. See also Chapter 5.13 Contrast Imaging.

### 5.17.9 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.

Operation Procedures:

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 (see also Chapter 5.17.2 Magnetic Navigator). 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. (To set freehand cine length, select "<F10 Setup>→[System]→[Image]")  
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.

## 5.17.10 Parameter Settings

The parameters of the Fusion Imaging are described below:

### Nav System

- Operation** 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

- Description** Adjust the display ratio that the ultrasound image registers with the CT/MR/PET/freehand image.
- Operation** Rotate the knob beneath [Fusion Ratio] to set the ratio.  
The adjusting range is -1 ~ 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

- Description** The lesion or tumor ultrasound and CT/MR/PET/freehand image becomes clearer and easier to register via <Zoom> key.
- Operation** 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. The adjusting scale is: 0.8-2.0.

### Toggling CT/MR/PET/Freehand Anatomical Plane

- Description** 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.
- Operation** Tap [View Type] to select the CT/MR/PET/freehand anatomical planes (among the sagittal plane, transverse plane, coronal plane).

### Cycling CT/MR/PET/Freehand Image Axially

- Description** Rotate X/Y/Z to rotate CT/MR/PET/Freehand image. Obtain the desired CT/MR/PET plane to register.
- Operation** Rotate <M>, <PW>, or <C> knob to cycle CT/MR/PET/freehand image through X-axis, Y-axis or z-axis in increment of 2°. The rotation range is 0° ~ 360° in increment of 2°. See also Chapter 5.17.11 Rotating/Scrolling CT/MR/PET/Freehand Image.

### Offset X/Offset Y CT/MR/PET/Freehand Image

- Description** It is available to offset CT/MR/PET/Freehand image through X-axis and Y-axis and obtain a proper position to register.
- Operation** Rotate [Offset X]/[Offset Y] to offset the CT/MR/PET image.

### Scrolling CT/MR/PET/Freehand Image

- Description** 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.
- Operation** Rotate the <4D> key to scroll CT/MR/PET/Freehand plane. See also Chapter 5.17.11 Rotating/Scrolling CT/MR/PET/Freehand Image for scrolling operations.

### Window Width (Window W)/Window Level (Window L)

- Description** 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.
- Effect** The larger the window width is, the poorer the image contrast becomes. The smaller the window width is, the better the image contrast becomes.
- Window Level** Rotate [Window L] to set the value in increment of 1.
- Effect** 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.
- Window W/Window L** Tap [Fast Adjust Window W/L]. 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)**

- Description** It initializes the window width and window level of the CT/MR/PET/freehand image.
- Operation** Tap [Reset W/L] to initialize the width/level of the CT/MR/PET/freehand image.

### **Reset CT/MR/PET/Freehand**

- Description** 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.
- Operation** Tap [Reset CT/MR] to initialize the CT/MR/PET/freehand image.

### **Tint Map**

- Description** This function provides an imaging process based on color difference rather than gray distinction for CT/MR/PET/freehand image.
- Operations** 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**

- Description** If the feature is enabled, only the image at the upper left is displayed on the image area.
- Operation** Tap [Single Window].

### **Rotate 180°**

- Description** This function is to rotate CT/MR/PET volume data 180 degrees before registration.
- Operations** Tap [Rotate 180°].

### **B Display**

- Description** This function is to set whether to display B-mode image under Color fusion imaging mode.
- Operations** 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.

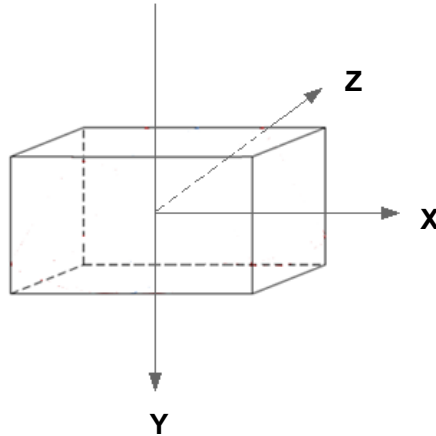
## **5.17.11 Rotating/Scrolling CT/MR/PET/Freehand Image**

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:

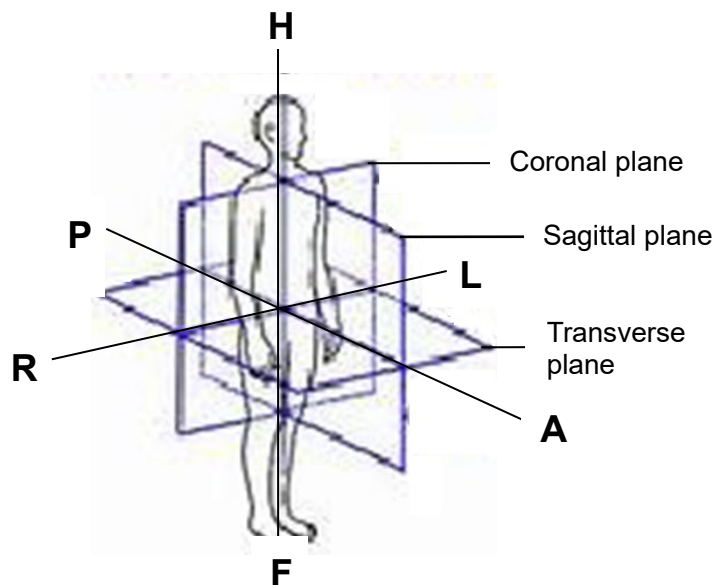


Rotate the knob <M> clockwise to cycle CT/MR/PET/freehand image clockwise through X-axis;  
 Rotate the knob <PW> clockwise to cycle CT/MR/PET/freehand image clockwise through Y-axis;  
 Rotate the knob <C> clockwise to cycle CT/MR/PET/freehand image clockwise through Z-axis;

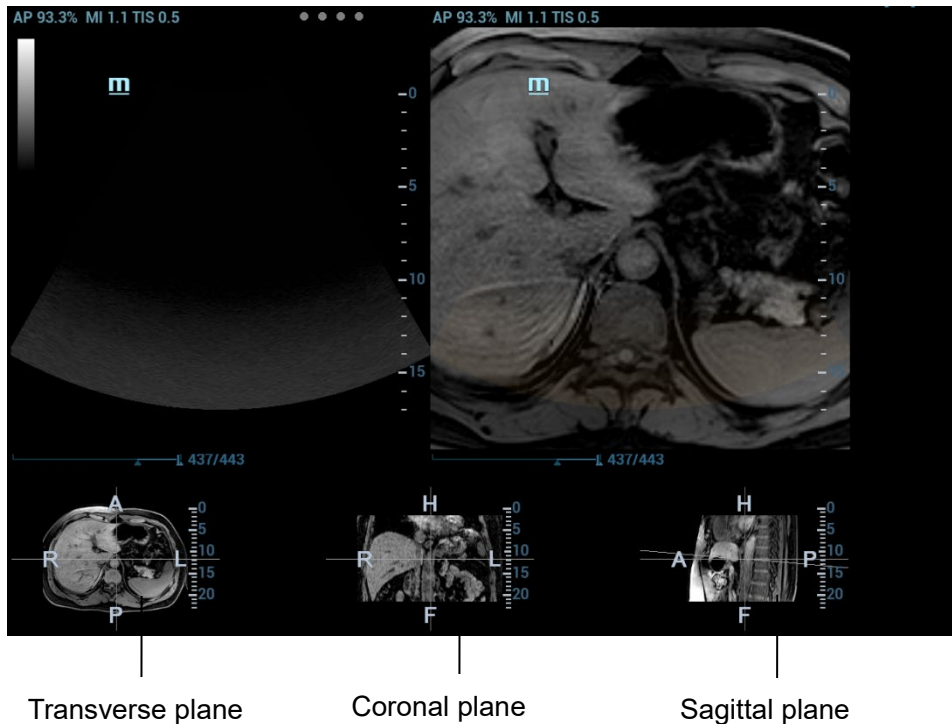
### Scrolling CT/MR/PET/Freehand Image

The description of “scrolling the transverse plane” is given below:

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.



### 5.17.12 Measuring

It is available to conduct the general measurements on the image that the ultrasound image registers with the CT/MR/PET/freehand image. See also Chapter 8.2 General Measurements.

### 5.17.13 Comment 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. See also Chapter 9.1 Comments.

## 5.18 RIMT (Real-time Intima-Media Thickness)

RIMT early detects and prevents coronary heart disease, artery vessel from being pathological, and estimates the therapeutic effects. RIMT detects the changes of the vascular intima in real time, and monitors and calculates the thickness of the carotid intima automatically.

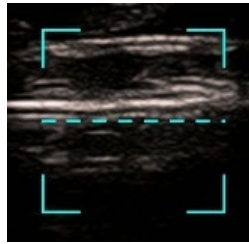
**Note**

- RIMT is an option.
- 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.

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 [Side] to select left or right carotid.
3. Roll 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.



**Note** 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.



4. Tap [Start Calc] to measure RIMT of left carotid and right carotid. Six 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 window.
  5. Tap [Accept Result] or press <Set>. The image is frozen. You may save single frame image and results of the result window.  
Tap [ReCalc] to recalculate 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.
- See Advanced Volume for setting, printing, saving or loading the report.
7. Tap again [RIMT] to exit.

## 5.19 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:

Vascular Package should be configured.

R-VQS is an option.

### Basic Procedures

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 roll the trackball to locate green 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> 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 green line in the ROI box.

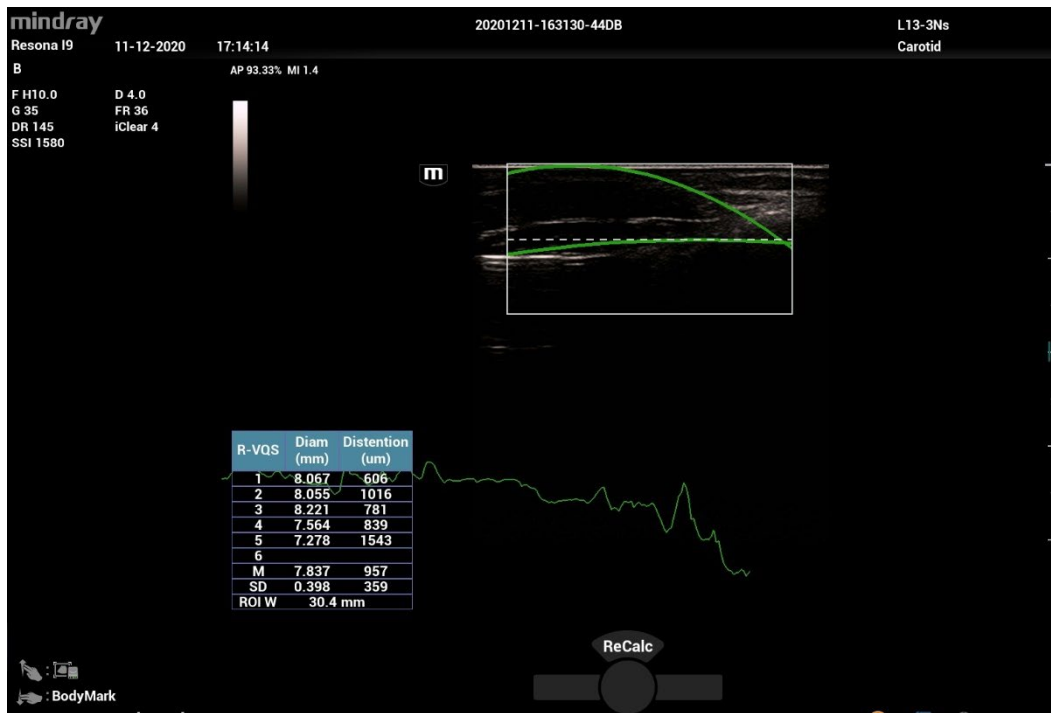
Motion curve of vessel walls display under the image in real time. 6 cardiac cycles are calculated in total with each results display in the result window on the left synchronously.

Where,

Dist = [maximum diameter within 1s] – [minimum diameter within 1s]

Diam: Vessel diameter refers to maximum diameter within 1s.

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. Tap [Stop Calc] or press <Freeze> to freeze the image and stop updating motion curve and result data.
5. Roll the trackball to review the cine file and select desired frame. Tap [Accept Result] to send the data in the result window to the report. Save the single-frame and multi-frame image if necessary. Tap [ReCalc] to recalculate R-VQS.
6. Tap [Report] on the touch screen to check report. Only 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].

#### Parameter adjusting

- **Speed**

**Description** Adjust refresh speed of vessel wall motion curve.

**Operation** Adjust through [Speed] on the touch screen.

There are 6 levels of scan speed available, the smaller the value is, the faster the speed becomes.

- **Position**

**Description** Adjust the location of the motion curve upwards and downwards.

**Operation** Adjust through [Position] on the touch screen.  
The adjusting range is: 0-100% in increment of 5%.

- Side

**Description** Mark the side of measured vessels.

**Operation** Adjust through [Side] on the touch screen.  
The measurement results in the report will be marked as the selected side.

## 5.20 Smart Pelvic Floor

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.

<b>Description</b>	1. Smart Pelvic Floor and Pelvic Floor Package is an option. 2. This feature is available only under GYN or pelvic floor exam mode.
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### 5.20.1 Two Dimensional Image

1. Perform scanning under GYN or pelvic floor exam mode. Press <Freeze> and tap [Smart Pelvic] tab.
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- Urethra-Bladder joint, E- Urethra proximal, R- Bladder posterior wall near urethra, 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).

During the measurement, if necessary, press the <Update> key to skip the current measurement caliper (S and P cannot be skipped).

During the measurement, if necessary, rotate the knob under [Select Frame] to continue measurement on other frames.

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. For details, refer to chapter “9 Comments and Body Mark”.

6. Save the cine file. See “6.6 Cine Saving” for details.

## 5.20.2 3D/4D image data

### ■ VR Mode

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

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.
  - Tap  to display the planes in 3\*3 mode.
  - 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 [return] 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.

For other parameter adjustments, refer to section “5.11 3D/4D” for details.

## 5.21 Smart Fetal HR (Heart Rate)

<b>Description</b>	This feature is available only under Fetal Echo (High Flow), OB1 Fetal Echo, Fetal Echo (Low Flow) exam modes.
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<b>Note</b>	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.
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This feature is to measure the fetal heart rate automatically on M mode.

Smart Fetal HR is an option.

Basic procedures:

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.

## 5.22 Smart VTI

Smart VTI (Velocity-Time Integral) is used to calculate the CO (cardiac output) of the LVOT (left ventricular output tract), so as to quickly evaluate the cardiac function.

<b>NOTE:</b>	<ol style="list-style-type: none"><li>1. The cardiac package should be configured in advance.</li><li>2. Smart VTI is an option.</li></ol>
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### 3. Smart VTI supports B mode image calculation in real time.

Perform the following procedure:

1. Select a phased probe and “Adult Cardiac” exam mode.
2. Move the probe to capture an appropriate image of the long axis view of the left ventricular near the sternum.
3. Press the <Measure> key to enter the application measurement. Select the “LVOT Diam” item and the measurement cursor is displayed on the main screen.
  - a. Move the cursor to the starting point and press <Set> to set the starting point.
  - b. Move the cursor to the end point.  
Press <Clear> to cancel setting the starting point for measurement and <Update> to switch the active end and fixed end of the caliper.
  - c. Press <Set> to set the end point.For more information about measurement, see Advanced Volume.
4. Press the <Freeze> key to unfreeze the image. Move the probe to capture an appropriate image of the apical five chamber view.
5. Tap [Smart VTI] on the touch screen or the user-defined key to enter the Smart VTI mode.  
The system will:
  - Automatically trace the color VOI, and PW sampling line and sampling volume.
  - Automatically recognize the cardiac cycle: when there are ECG inputs, the ECG signals are preferred; when there are no ECG signals, the system automatically starts calculation.
  - Trace the LVOT spectrum in a cardiac cycle in real time to gain the VTI, HR, and CO results of the LVOT.
6. If necessary, adjust the color VOI, and PW sampling line and sampling volume:
  - Use the trackball and <Set> keys to adjust the color VOI position and size, and the PW sampling line position.
  - Tap the PW tab to enter the PW mode, and adjust the PW sampling volume.After adjustment, the LVOT spectrum tracing and calculation results display in real time.
7. Press the <Freeze> key to freeze the image, and check the Smart VTI calculation results.  
If necessary, you can edit the LOVT spectrum manually:
  - a. Tap [Edit VTI] on the touch screen.
  - b. Press the <Cursor> key to activate the cursor.
  - c. Move the cursor to the spectrum tracing line and press the <Set> key.
  - d. Use the trackball to trace a line.After tracing, the calculation results display in real time.
8. Tap [Save VTI] to save the Smart VTI calculation results of the current cardiac cycle to the report.
9. Tap [Graph] to check the quantitative index trend curve.  
VTI, SV, and CO have different trend curves and are differentiated by colors. A maximum of 6 sets of Smart VTI results can be saved and displayed.
10. Tap [Report], and select “Fluid Management” from the drop list box of [Report Type] to check report.  
For details about report operation, refer to Advanced Volume.

## 5.23 Smart IVC

Smart IVC is used to automatically measure the IVC inner diameter and calculate the change rate in the B mode image. Measure the IVC (Inferior Vena Cava) in real time, and the system automatically tracks

and measures the changes of IVC inner diameter. It can be used to assist in treatments, such as volume estimation and fluid infusion.

- NOTE:**
1. The cardiac package should be configured in advance.
  2. Smart IVC is an option.
  3. Smart IVC supports calculation in both real time and freeze modes.
    - Enable Smart IVC in real time. The calculation starts from the current frame and ends after the image is frozen.
    - Enable Smart IVC in freeze mode or from the cine file. The calculation starts from the current frame and ends at the last frame. If the cine length is no longer than 10 seconds, it is allowed to calculate in retrospective from the current frame after the cine length reaches 10 seconds.

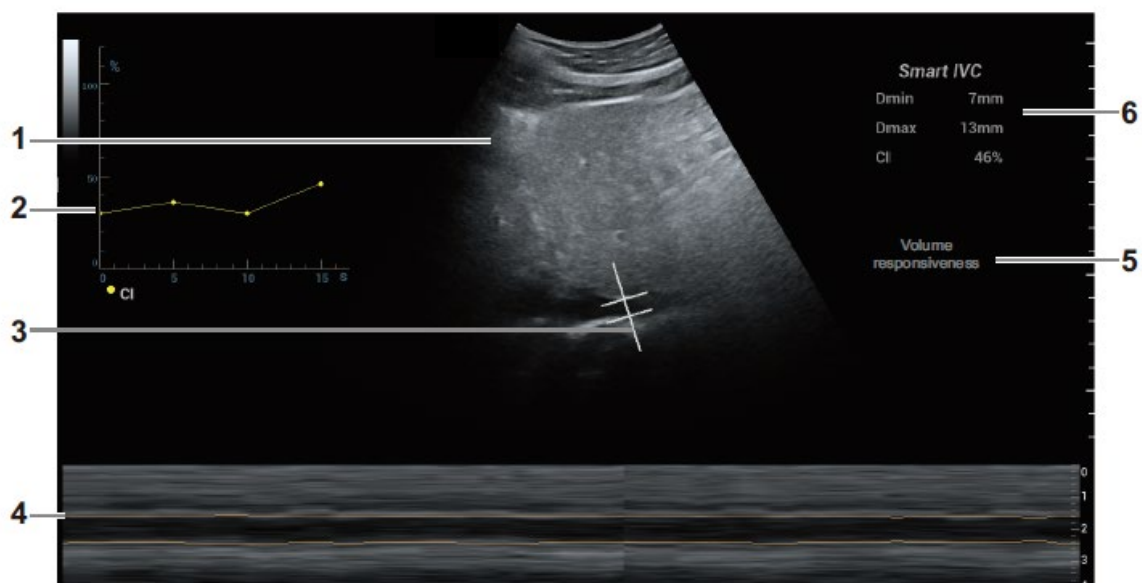
Perform the following procedure:

1. Select an appropriate probe and exam mode.
2. Move the probe to gain an appropriate IVC long axis image.
3. Tap [Smart IVC] on the touch screen or the user-defined key to enter Smart IVC mode and start calculation.
  - a) Tap to select a breath type: Spontaneous Breath or Mechanical Ventilation.
  - b) Select [Change Resp time] > [[Resp Time(rpm)]] to set a respiratory time.

The system measures the IVC inner diameter of the image in every frame, calculates the maximum and minimum IVC diameters, and draws a quantitative index change curve in real time.

4. If necessary, you can adjust the IVC sampling line manually:
  - a) Tap [Edit Line] on the touch screen.
  - b) Tap [Angle] on the touch screen to adjust the sampling line angle, and use the trackball to adjust the sampling line position.
  - c) Press the <Update> key to start calculating IVC again.
5. Press the <Freeze> key to freeze the image and finish calculating IVC.

The calculation results and quantitative trend curve are displayed on the main screen. Tap [Diagnostic Info] on the touch screen to add diagnostic information to the image quickly.



1.	B Mode Image	/
2.	IVC CI (Collapsibility Index), DI (Distensibility Index), IVCV trend curve	Corresponds to the selected breath type: <ul style="list-style-type: none"> <li>● Spontaneous Breath: displays the IVC CI curve.</li> <li>● Mechanical Vent: displays the IVC DI curve and IVCV curve.</li> </ul>
3.	IVC Sampling Line	/
4.	IVC Trending Line	The horizontal axis represents the time, which is displayed in the below Free Xros M image, and is traced along the IVC vessel wall.
5.	Diagnostic Information	Displays the added diagnostic information.
6.	Calculation Results Window	Displays the calculation results within the current calculation range. <ul style="list-style-type: none"> <li>● Dmax: indicates the maximum IVC inner diameter within a respiratory cycle.</li> <li>● Dmin: indicates the minimum IVC inner diameter within a respiratory cycle.</li> <li>● IVC CI = <math>(D_{max}-D_{min})/D_{max}</math></li> <li>● IVC DI = <math>(D_{max}-D_{min})/D_{min}</math></li> <li>● IVCV = <math>(D_{max}-D_{min})/[(D_{max}+D_{min})/2]</math></li> </ul>

6. Tap [Save Data] to save the calculating IVC results to the report.
7. Tap [Report], and select “Fluid Management” from the drop list box of [Report Type] to check report.

For details about report operation, refer to Advanced Volume.

## 5.24 Smart B-line

The lung acoustic impedance difference increases with the increase of lung liquids. The ultrasound waves produce strong reverberations in the lung at different depth. After multiple reflections, the comet tail sign is formed, which is perpendicular to the pleura plane. Starting from the pleura line, the comet tail sign moves along with the lung and extends to the far field. The reverberation line perpendicular to the pleura plane is called Smart B-line.

Smart B-line is used to detect the B line of the lung in B mode. It supports B-line detecting in both real-time and freeze modes.

- NOTE:**
1. Smart B-line is only available in Single B imaging mode.
  2. It supports single-frame and multi-frame image file detection in B mode.
  3. Smart B-line is an option.

### 5.24.1 Basic Procedures for Smart B-line

Perform the following procedure:

1. Select an appropriate probe and exam mode. The system enters the B mode by default.



2. Adjust the image parameters to obtain optimized images.  
For details about image parameter adjustment, see “5.2.3 B Mode Image Optimization”.
3. Tap [Smart B-line] on the touch screen or the user-defined key to enter Smart B-line mode.  
Tap [Scanning Areas] to select different zone combinations for examination.
4. Select a desired zone, and tap [Auto Calc].  
The system automatically starts tracing the B line sampling area, and automatically recognizes and traces the B line in frame.  
If necessary, use the trackball/trackpad and <Set> keys to adjust the B line sampling area.
5. Press the <Freeze> key to freeze the image.  
The system automatically calculates the quantitative index, and the calculation results are displayed on the screen.
  - B Lines: indicates the number of B lines of the current frame. The number can be 1, 2, 3, 4, or  $\geq 5$ . When the number is equal to or greater than 5, the system does not display a specific number.
  - Percent: indicates the percent of the B lines area against the total sampling area.
  - Score: the score is among 0 to 3.  
Normal: when there are a lung sliding sign and A line, or isolated B lines (<3), it is marked as N in the brackets and the score is 0.  
Moderate: when there are multiple clearly-distributed B lines, it is marked as B1 in the brackets and the score is 1.  
Severe: when there are intensively fused B lines, it is marked as B2 in the brackets and the score is 2.  
Lung consolidation: when the lung has a symptom that is similar to the liver lesion structure and air bronchogram, it is marked as C in the brackets and the score is 3. When the lung consolidation and pleural effusion occur at the same time, it is marked as C/P in the brackets and the score is 3.
  - Dist  $n$  (B Line distance): indicates the distance between the 2 neighboring lines and is measured in the pleura line area, among which,  $n$  corresponds to the number between the 2 B lines.
  - Avg Dist (B Line average distance): indicates the average distance of all B lines.
 According to the quantitative index calculated by the system, you can add image and diagnosis information. Tap the check box under the [Image] or [Diagnosis] tab to select items:
6. Press the <Save> key to save the single-frame image and B line calculation results.  
If necessary, press the <Freeze> key again to unfreeze the image. Repeat steps 4-6 to finish calculating other points.
7. Tap [Report], and select “Fluid Management” from the drop list box of [Report Type] to check report.  
For details about report operation, refer to Advanced Volume.

## 5.24.2 Overview

After capturing images, tap [Overview] to enter the Overview screen. The Smart B-line supports displaying two types of lung overviews in the main screen. You can switch the two lung overviews using the corresponding buttons on the touch screen.

- Image Map: Displays the ultrasound images of all zones, so as to check the overall lung condition. Ever lung zone displays the ultrasound image with the highest percent of the B line area by default.  
If a zone saves multiple ultrasound images, tap the point corresponds to this zone, and tap [Pre Item] and [Next Item] to switch the image.

- Color Map: Displays the color map of the lung and ultrasound image of a zone. The color map uses different colors to mark the ultrasound image analysis result of every lung zone. This analysis result is calculated from the ultrasound image with the highest percent of B line area.


Tap a point on the touch screen to check the calculation result of the zone related to this point.

# 6 Display & Cine Review

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## 6.1 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: press  on the control panel to enter the dual-split mode, and using <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 <Quad> user-defined key on the control panel to enter the quad-split mode, and using <Quad> user-defined key to switch among four images; press <B> to exit. For details about user defined key, please refer to 12.1.7 or 12.1.8.  
Modes support quad-split display: B mode, Color mode and Power mode.

For the detailed display format, please refer to the content of each imaging mode chapter.

## 6.2 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 field. As a result, the MI may change.

### 6.2.1 Spot Zoom

To use the function, use the  knob on the control panel.

There are two methods to zoom image:

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 spot 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.
  - Press <Zoom> again to exit spot zoom
  - The size and position of sample volume box change along with scan depth and area.

Another method:

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.
4. Image-in-image displays in bottom-left part of the screen. Roll the trackball to change ROI position and the screen image displays accordingly.

5. Rotate <Zoom> to change the magnification factor. Or enter mapping-mode and use two-finger gesture to change the magnification factor.
6. Press <Zoom> again to exit magnification.

## 6.2.2 Pan Zoom



To use the function, use the  knob on the control panel.

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.
2. 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.
3. Shifting the image: roll the trackball or touch and translate the image.
4. Press <Zoom> to exit pan zoom.

## 6.2.3 iZoom (Full-screen Zooming)

Function: to magnify the image in full screen.

Procedures:

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.

## 6.3 Freeze/Unfreeze the Image

Press [Freeze] key 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.

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")

Press <Freeze> in frozen mode to unfreeze the image, and the system continues image scanning.

### 6.3.1 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> to switch among the windows; press the user-defined <Single> key 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.

## 6.4 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.





### CAUTION:

1. **The cine memory must be cleared at the end of the current patient and the onset of the next new patient by tapping [End] on the control panel.**
2. **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.**

### 6.4.1 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.
- Tap the icon  or  to select the cine on the touch screen under the mapping mode. Or swipe the touch screen left or right to review the cine.

#### ■ To Exit Cine Review:

Press <Freeze> or <B>, the system will return to image scanning and exit cine review.

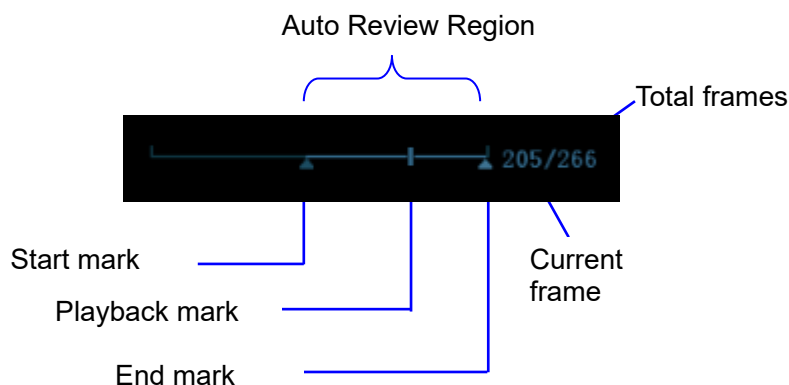
### 6.4.2 2D (B/B+Color/B+Power/B+TVI/B+TEI) Cine Review

#### ■ Manual Cine Review:

Enter the cine mode in 2D imaging mode. Roll the trackball, or slide the screen to view the cine.

If you roll the trackball left or slide the screen left, the review sequence is reversed to the image-storing sequence, thus the images are displayed in descending order. Whereas, if you roll the trackball right or slide the screen right, 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 rolling 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):



- Auto Review
- Reviewing all
  - a) In the manual cine review status, press the knob under the [Auto Play] in the touch screen to activate auto cine review.
  - b) Reviewing speed: In the auto cine review status, rotate the knob under the [Auto Play] on the touch screen to adjust the review speed.
  - c) Exit: set [Auto Play] to stop in auto review state, or tap [Auto Play] on the touch screen, or move the track ball, 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.

- a) 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.
- b) 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.
- c) Press the knob under [Auto Play] on the touch screen or use the mapping menu. The system plays the auto review region automatically.
- d) Rotate the knob under [Auto Play] to increase/decrease the auto play speed or use the mapping menu.
- e) 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.
- f) Click [Jump to First]/ [Jump to Last] to review the first or last image.
- g) Rotate the knob under [Adjust Frame] to review the cine frame by frame.

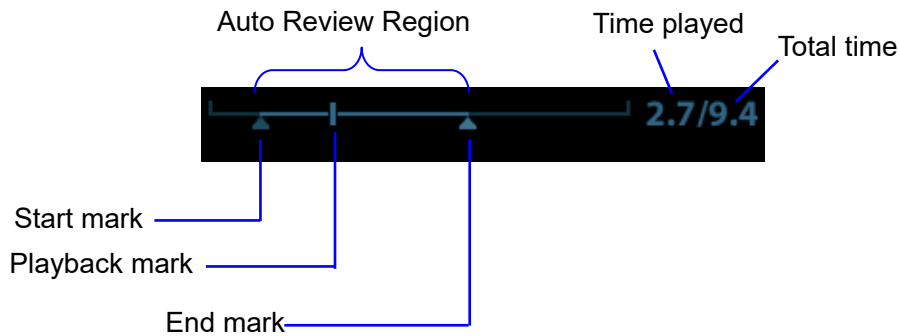
Tips: you can perform cine review on each image window in the dual/ quad splitting mode, and set auto review region for each window.

### 6.4.3 Cine Review in M/PW/CW/TVD Mode

Enter cine review in M mode, PW mode, CW mode TVD mode, and then roll the trackball, the cine images are displayed on the screen one by one.

Roll the trackball left or slide the screen left. The review progress slider moves to the left, the images moves to the right, and the earlier stored images are invoked. Whereas roll the trackball right or slide the screen right, 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 rolling left or right.

The cine progress bar at the bottom of the screen (as shown in the figure below):



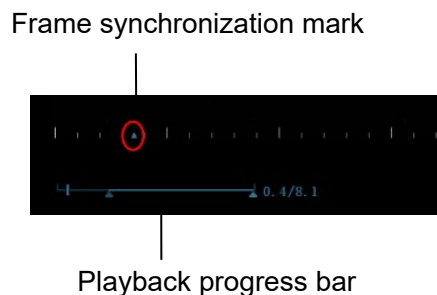
Cine review operations are the same as these of 2D mode.


Tips: 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  $\times 1$ .

## 6.4.4 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




The frame mark  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.

## 6.5 Image Compare

### 6.5.1 Image Compare in Review Mode

1. Tap [Compare] on iStation screen (press <F2 iStation>) or Review screen (tap [Review]).
2. Select the images for comparison.

Click to select the image, and the icon  appears on the right side of 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.

Tip: 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.

- 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 above to add the image to be compared.  
On the top-right corner, there is "Selection" 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 <Quad> key 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. Tap [SyncPlay] on the touch screen to display: synchronously, asynchronously.
6. Save the image if it is necessary.
7. Click [Return] on the screen or press <Freeze> to exit image compare.

## 6.5.2 Frame Compare

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.

Tips: cine compare can only be performed for B/C mode image only. The image on dual/quad window cannot be compared.

## 6.5.3 iCompare

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 (press <iStation> to enter), Review screen (tap <Review> to enter), 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.

Tips: iCompare can only be performed on B, Color, Power, PW, CW, or M mode for FRM/CIN/PNG/DCM files.



## 6.6 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. For details, please refer to preset chapter.

- In imaging mode, tap [Pro Capture] / [Retro Capture] on the touch screen or press the user-defined key for “Save Cine (Prospective)/(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 Clip retrospective or prospective”).

After the cine is successfully saved, there is a thumbnail displayed on the screen.

The live capture time can be set. For details, please refer to preset chapter.

## 6.7 Setting Cine Length

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.

Procedures:

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 [Cycle (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.

Procedures:

With the ECG disabled: tap [Cine] tab, and rotate [Time (Retro)] knob to adjust it.

With the ECG enabled: tap [Cine] tab. Tap [Loop Type (Retro)] to choose the type of the saving time and the cardiac cycles. Rotate [Time (Retro)] or [Cycle (Retro)] to adjust it.

Freeze storage setting:

The first frame of the image starts when the user pressing <Freeze> at the first time. The system saves the cine in the auto review scope retrospectively.

Press <Freeze> to freeze the image. Rotate [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.

NOTE: the system ends up saving if the cine length goes beyond the maximum value.



# 7 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. See Section 2.8 Front I/O Panel .

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.

## **⚠️WARNING:**

**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 physiological unit 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, high-frequency therapeutic device or defibrillator is applied already.**

**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 break-down or fracture.**

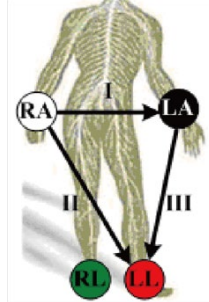
**Display effect of respiratory curve depends on the patient breathing status. While a very slow or smooth breathing may lead to an unapparent respiratory curve, breathing in a large amplitude may cause an incomplete display of the respiratory curve. Display effect is linked to the connected parts of the body. Generally, signals by connecting to limbs are stronger than by connecting to the chest.**

**NOTE:** When abnormality is detected in physio trace, please check if ECG leads are properly connected with the system.

# 7.1 ECG

## 7.1.1 ECG Operation Basic Procedures

1. Connect the device and place ECG electrodes.
  - Turn off the power supply of the system, and connect the ECG cable to ECG port.
  - Turn on the power supply of the system;
  - Place the ECG electrodes on the patient's body (as shown in the following figures).



2. Tap [Physio] on the touch screen or press the user-defined key for “Physio” on the control panel to enter physio operation interface.
3. Switch the imaging modes and display formats, adjusting the parameters to get an optimized image.
4. Parameter adjusting:  
In Physio unit menu, tap [ECG] on the touch screen to enable or disable ECG waveform curve. Adjust the [Speed], [ECG Gain], [Position] and [Invert].
5. Trigger:  
Select the trigger mode, or tap [Real & Trig] 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. Exit ECG mode, and remove ECG electrodes from the patient.  
Tap [Physio] or press the user-defined key for “Physio” to exit.

## 7.1.2 ECG Triggering

### 7.1.2.1 Overview

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.

### 7.1.2.2 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] on the touch screen to enable the trigger.
3. Select [Single].
4. Set the delay time (or use the T1 by default).

### 7.1.2.3 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.

## 7.1.3 ECG Review

### 7.1.3.1 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.

### 7.1.3.2 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.

## 7.2 Respiratory Wave

### 7.2.1 Respiratory Wave Operation Basic Procedures

1. Connect the ECG lead and position the ECG electrodes. For details of ECG lead connection, see “7.1.1 ECG Operation Basic Procedures”.
2. Tap [Physio] on the touch screen or press the user-defined key for “Physio” on the control panel to enter Physio screen.
3. Switch the imaging modes and display formats, adjusting the parameters to get an optimized image.
4. Parameter adjusting  
In Physio menu, click [RESP] on the touch screen. 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 key for “Physio” to exit physio mode.

### 7.2.2 Parameter Description

The physio parameters are described as follows:

Parameter	Description
ECG Source	Select ECG source.
Gain	Function: to set the amplitude of the trace. Method: click [Gain] on the soft menu, or press/rotate the corresponding knob. Each adjustment takes you to the next setting.
Position	Function: to set the vertical position of the both traces on the image display. Method: click [Position] on the soft menu. Each adjustment cycles you to the next setting.
Speed	Function: change the speed of the physio trace.
T1	Function: to set the delay time T1 in Single trigger or Dual trigger.
T2	Function: to set the delay time T2. Method: select a proper value in the drop-down list.
Interval	Function: to set the time interval for Timer. Method: select a proper value.
Invert	To invert the display.

## 7.3 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.

### 7.3.1 PCG Operation Basic Procedures

1. Connect PCG sensor.
  - 1) Connect the PCG sensor to the corresponding interface on the physiological module.
  - 2) Power on the system.
  - 3) Place PCG transducer on the patient.

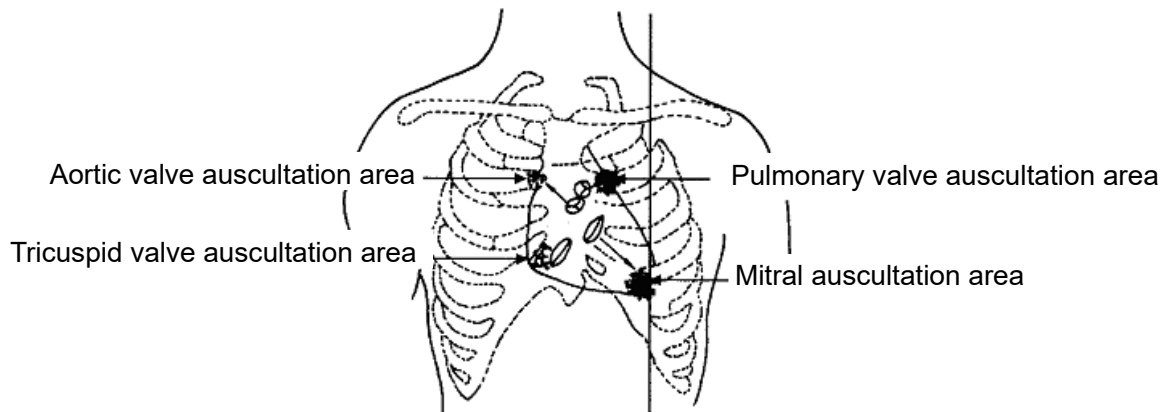
The position is shown below:

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;



2. Press <Physio> on the control panel. Tap [PCG] on. The PCG wave appears as the backlight becomes green.
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. Press <Physio> to disable PCG wave. Then exit the PCG, and unplug PCG sensor.

### 7.3.2 PCG Parameters Description

Type	Parameter	Description
PCG parameter	PCG	Function: to control the display of PCG trace. Adjustment value: ON/OFF, the trace appears when the backlight becomes green.
	PCG gain	Function: to set the amplitude of PCG trace.
	PCG smooth	Function: to smoothen PCG trace.





# 8 Measurement

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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:**

1. **Be sure to measure areas of interest from the most optimal image plane to avoid misdiagnosis from inaccurate measurement values.**
2. **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.**



## **CAUTION:**

1. **If an image is unfrozen or the mode is changed during a measurement, the calipers and measurement data will be cleared from the screen. The general measurement data will be lost (the application measurement data are stored in the report).**
2. **If the system is turned off or [End] is selected during a measurement, the data not saved will be lost.**
3. **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.**

## 8.1 Basic Operations

### ■ Entering/Exiting Measurement

Press <Caliper> key to enter general measurement status; Press <Measure> key to enter application measurement status.

To exit the measurement status: press [Caliper] key or [Measure] key again.

### ■ Measurement result and help information

The system displays and updates measurement results in the result window.

### ● To move the result window:

- a) Place the cursor on the title of result window (you can see the cursor becoming ).
- b) Press <Set> and move the trackball, the window moves together with the cursor.
- c) Move the cursor to the target position, press <Set> again, the result window has already been placed in the target position.

## 8.2 General Measurements

### 8.2.1 2D General Measurements

2D general measurements refer to general measurements on images like B, Color, Power, or iScape View.

Measurement Tools	Description
Distance(mm)	Measures the distance between two points on the image.
Depth	The distance between transducer surface and the probing point along ultrasound beam.
Angle	The angle between two intersected planes.
Area (Ellipse, Trace, Cross, Spline)	Measures the area and perimeter of a closed region.
Volume (Ellipse), Volume (Ellipse distance)	The volume of a target.
Double dist	Measures the length of two line segments perpendicular to each other.
Parallel Line	Measures the distance between every two line segments of five parallel line segments, namely, four distances in total.
Trace length, Spline length	Measures the length of a curve on the image.
Distance Ratio	Measures the lengths of any two line segments and the calculated ratio.
Area Ratio	The areas of any two regions and the calculated ratio.
B histogram	Measures and counts the gray distribution of ultrasonic echo signals within a closed region.
B profile	Measures the gray distribution of ultrasonic echo signals on a line.
B ratio	Measures gray statistics ratio of normal tissue to abnormal tissue.
Color Velocity	Color flow velocity (only valid for Color mode).
Volume Flow	Measures blood flow through some vascular cross section per unit time.
Strain Ratio	Measures the strain ratio.
Elasto ratio	Measure the elastography ratio
Directional Ratio	Measure the directional ratio
RAC	Calculates the Relative Anisotropy Coefficient
Strain-Hist	Display the strain value of the ROI in a histogram.
Elasto-Hist	Display the elasto value of the ROI in a histogram
IMT	Measure intima-media thickness
TSM	Tissue stiffness measurement
Smart Trace	Measures the lengths of major axis and minor axis, area and circumference of a closed region on the image semi-automatically
Smart Caliper	Measure lengths of the major axis and the minor axis semi-automatically

Measurement Tools	Description
Color Pixel Percentage	Measures the pixel proportion of blood flow signal in the region of interest

## 8.2.2 M General Measurements

M general measurements refer to general measurements on M-mode, AM-mode images. The measurements listed below can be performed:

Measurement Tools	Description
Distance	Measures the distance of the sampling line between two random points.
Time	The time interval between any two points on M mode image.
Slope	Measures the distance and time between two points and calculates the slope.
HR	Measures the time of n ( $n \leq 8$ ) cardiac cycles and calculates the heart rate on M mode image.
Velocity	Measures the distance and time between two points on the M Mode image and then calculates the average velocity between the two points.

## 8.2.3 Doppler General Measurements

Doppler general measurements refer to general measurements on PW/CW-mode images.

Measurement Tools	Description
Time	The time interval between any two points.
HR	Measure N interval ( $n \leq 8$ ) of the cardiac cycle on Doppler image and calculates the heart rate.
Velocity	On the Doppler mode image, measure velocity, PG (pressure gradient) and spectrum correction angle of a point on the Doppler spectrum waveform $\theta$ .
Acceleration	Measure the velocities of two points and their time interval on the Doppler image, and calculates the acceleration, pressure gradient, velocity difference and correction angle $\theta$ .
D Trace	On the PW mode image, one or several Doppler waveforms are traced to obtain speed and PG, etc.
PS/ED	Measure the velocities of Systolic Peak (PS) and Diastolic End (ED) on the Doppler image.
Volume Flow	Measure blood flow through some vascular cross section per unit time.
Velocity Ratio	Measure two D velocity values on one or two spectrum and calculate the ratio to analyze the flow information.
VTI Ratio	Measure two TVIs and the calculated ratio of the spectrum.

## 8.3 Application Measurements

The application includes the following items:

Abdomen measurements: used for measurements of abdominal organs (liver, gall bladder, pancreas and kidney, etc.) and large abdominal vessels.

OB measurements: used for measurements of GA and EDD, to calculate the growth indices, including the EFW. The growth estimation is determined by growth curve and fetal biophysical profile.

Cardiac measurements: used for cardiac measurements and measurements of other parameters, etc.

Gynecology measurements: used for the uterus, ovary and follicles, etc.

Small Part measurements: used for small parts such as thyroid.

Urology measurements: used for prostate, seminal vesicle, renal, adrenal, micturated and testicle volume.

Orthopedics measurements: used for hip joint measurement.

Peripheral vessel measurements: used for carotid, cerebral, upper and lower extremities vessels, etc.

EM measurements - used for EM-related full functional measurements.

## 8.4 Measurement Accuracy

Table 1 Error of 2D Images

Parameter	Value Range	Error
Distance	Full screen	Within $\pm 3\%$ .
Area	Full screen	Within $\pm 10\%$ .
Circ	Full screen	Within $\pm 10\%$
Angle	Full screen	Within $\pm 3\%$ .
Volume	Full screen	Within $\pm 10\%$ .
Distance (iScape)	Full screen	Within $\pm 5\%$ (for linear, wide-convex, and phased probes)
	Full screen	Within $\pm 10\%$ (for micro-convex probes)

Table 2 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 $\pm 20\%$ . (not including Smart 3D)

Table 3 Time/Motion Measurements

Parameter	Value Range	Error
Distance	Full screen	Within $\pm 3\%$ .
Time	Timeline Display	$\leq 2\%$ .
Heart rate	Timeline Display	Within $\pm 4\%$ .
Velocity (PW mode)	10-300cm/s (for transcranial application) 10-200cm/s (for non-transcranial application)	Within $\pm 20\%$ (for transcranial application) When angle $\leq 60^\circ$ , within $\pm 5\%$ (for non-transcranial application)
Velocity (CW mode)	10-300cm/s (for transcranial application) 10-200cm/s (for non-transcranial application)	For transcranial application: Within $\pm 20\%$ (not including pencil probe) Within $\pm 10\%$ (pencil probe) For non-transcranial application: When angle $\leq 60^\circ$ , within $\pm 5\%$ (not including pencil probe) Within $\pm 15\%$ (pencil probe)

Table 4 Automatic measurements

Parameter	Error
Smart V Trace	Within $\pm 20\%$
Smart Fetal HR	Within $\pm 10\%$
Smart Hip	Within $\pm 5\%$
Smart HRI	Within $\pm 5\%$
Smart Caliper	Within $\pm 5\%$
Smart ICV	Within $\pm 20\%$
Smart Trace	Within $\pm 20\%$

**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.

# 9 Comments and Body Mark

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## 9.1 Comments

Comments can be added to an ultrasound image to bring attention, annotate 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; add voice comment, insert arrow markers or add the trace.





### **WARNING:**

**You must ensure that the entered comments are correct. Incorrect comments may lead to misdiagnosis!**



### 9.1.1 Comments Basic Procedures

To perform a comment:

1. Enter comment status:
  - Press <ABC>; or,
  - Press any alphanumeric key to enter the comment status, and the corresponding letter or numeral is displayed besides the cursor; Or,
  - Press  to enter the arrow-adding status.
2. Place the cursor to the desired place to set the comments location.
3. Add a new comment to the image according to actual situation. Here, you can modify, move, delete, hide or display a completed comments.
4. To exit comments status:
  - In the arrow-adding status, press ; Or,
  - Press <ESC> or other operating mode keys to exit.

## 9.1.2 Touchscreen Displaying

The system can be configured with comment text libraries including ABD (Abdomen), CARD (Cardiology), GYN (Gynecology), OB (Obstetrics), URO (Urology), SMP (Small Part), VAS (Vascular), PED (Pediatric), Nerve Blocks and EM (emergency). In comment status, you can enter the comment text using the screen menu or touch screen.

- 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 or tap [Set Home] on the touch screen; the cursor returns to the start position.
- Crab/Del  
Rotate the knob under the [Crab/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 [Setting] 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  on the touch screen to select arrow style.  
Change Arrow Size: Drag the slider or tap the -/+ button on the touch screen to select arrow size.  
Change text size: Drag the slider or tap the -/ + button on the touch screen to select text size.
- Arrow  
Tap [Arrow] on the touch screen to add an arrow.
- Delete Text  
Tap [Del Text] on the touch screen to delete all the comments.
- Comment Display  
Tap [Hide Text]/[Show Text] on the touch screen to display or hide the comments.
- Page-turning  
If there is more than one page of comment texts for the current exam mode, you can slide to view more.
- User-defined  
Adjust comments display on touch screen menu, including adding/deleting comments. For details, please refer to Chapter 9.1.7 Comment Setting.
- Trace  
Tap [Trace] on the touch screen.
  - Trackball trace  
Move the trackball to position. Press <Set> to fix the start point.  
Press <Set> to confirm the end; or the trace curve will close automatically if the cursor is near the starting point.
  - Trace on touch screen  
Tap the touch screen to set the starting point and trace the curve, touch the touch screen again to set the end.
- Quickly select a comment in a group



Configure groups to List 1, List 2, and List 3. For details about group configuration, please refer to "12.4 Comment Preset". 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.

### 9.1.3 Adding Comments

#### Typing comments characters

- (1) To set the comment location:  
Roll the trackball or press direction-control keys on the keyboard to move the cursor to the desired location for comments.
- (2) To type the alphanumeric characters:  
Type the alphanumeric characters via the keyboard.
  - Type the alphanumeric characters through the qwerty or soft keyboard (The default characters are uppercase).
  - To type the upper characters, press [Shift] and the character key at the same time.
  - In the edit status (the characters are in green color), press [Enter] to move the cursor to the new line, and the location of the cursor is aligned with that of the first line.
- (3) In the edit status, press <Set> or <Enter> on the control panel to confirm the character added, and the color of the character becomes yellow.

#### Adding a comment Text

- (1) In comment status, select the comment to be added.  
You can add comment texts using the following methods:
  - Roll the trackball to move the cursor onto the desired comment text on the screen menu and press <Set>, and then the system adds the selected comment text onto the screen. Move the trackball to confirm the adding.
  - 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, and roll the trackball to confirm the adding.
- (2) Exit comments edit status  
In comments edit status, press <Set> or <Enter> key, or roll the trackball to confirm the added comments text and exit the edit status, the comments becomes yellow.

#### Adding an arrow

You can add an arrow to a location where you want to pay attention.

#### Adding an arrow

- (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°).
- (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

- (1) In comment status, touch [Trace] on the touch screen to activate trace function, and the current image is also displayed on the touch screen.
- (2) Control Panel:
  - a) Roll the trackball to a desired position, and press <Set> to confirm the start point.

- b) Roll 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.
- c) Press <Set> to finish the tracing.

Touch screen operation:

- a) Trace around the ROI by taping the touch screen image using your finger.
- b) 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.
- c) Click [Exit] to exit the tracing.

## 9.1.4 Moving Comments

1. Select the comment to be moved.
2. Roll the trackball to move the comment to the new position.
3. Press <Set> key to anchor the comment in the new position, and the comment-moving operation is complete.

Tip: if image size and position changed due to display format switching, then the position of the comment can be changed, too.


## 9.1.5 Editing Comments

Modifying (Editing) characters

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> to delete the comment character or text on the right side of the cursor; press <Backspace> to delete the comment character or text on the left side of the cursor.
3. Roll the trackball or press <Set> to confirm the modification and to exit the edit status, and the color of the comments becomes yellow.

If there are already comments on the screen, press the space bar to enter editing status.

Modifying (Editing) Arrows

1. Move the cursor on the arrow that needs to be modified. After the cursor becomes , press <Set>. The color of the current arrow becomes green, and there is green frame around the arrow, indicating the arrow can be edited. Move the cursor to change the arrow position.
2. Rotate the <Angle>knob to modify the arrow's direction.
3. Press <Set> or <Enter> key to complete the operation.

## 9.1.6 Deleting Comments

Deleting Comments Characters, Texts or Arrows

1. Move the cursor to the comments to be deleted.

2. Press <Set> to select the comments.
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

In comment status, press <Clear> to delete the latest added/modified comment unit.

Enter letters by pressing the alphanumeric key on the keyboard and use blank key to divide the letters. Press user-defined key (<F10> -> [System Preset] -> [iConsole&Footswitch]/[Key Board]) for "Delete Word" to delete latest added/modified comment unit and enter comment status.

Delete letters one by one

In comment editing status, press <Back> to delete letters before cursor "|".

In comment editing status, press <Del> to delete letters after cursor "|".

In comment status, enter letters by pressing the alphanumeric key on the keyboard. Press user-defined key for "Delete Text" to delete letters before cursor "|" (<F10> -> [System Preset] -> [iConsole&Footswitch]/[Key Board]).

Erase All Text

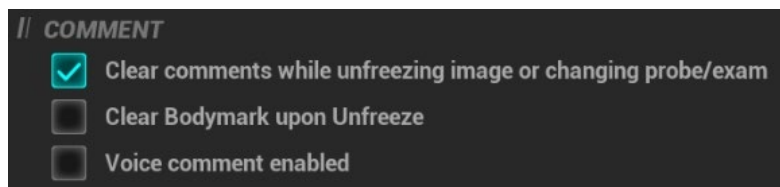
Press <Delete Word> key, long press <Clear> key, or tap [Del Text] on the touch screen to delete all the comments.

- NOTE:**
1. When no item is selected, press <Clear> will clear all comments and all measurements calipers.
  2. After powering off, the system will clear all comments on the image.

## 9.1.7 Comment Settings

- See Chapter 12.4 Comment Preset for comment preset.
- Comments Setting

Enter the "[System]->[Application]" screen to perform the following settings:



- Besides, you can preset whether to clear the comments when unfreezing the image or change the probe/ exam.
- Set if body mark is erased when the image is unfrozen.

## 9.2 Voice Comments

The system supports adding voice comment to the frozen images.

NOTE: it only supports the vocal input from the wired microphone.

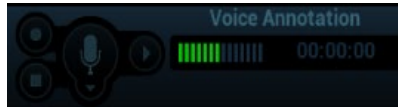
### 9.2.1 Voice Comment Panel

After the system enters the voice comment status, the voice comment panel will be displayed on the lower right corner of the screen.

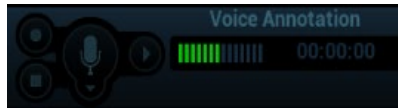


## 9.2.2 Adding Voice Comments

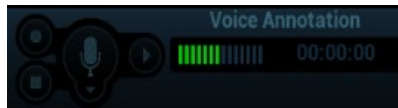
1. To perform voice comments adding, the function should be enabled through the path: [Preset]→[System]→[Application]. Check “Enable Voice Response”. Click [OK] to exit. The voice comment panel appears on the right corner of the screen.






2. Connect the microphone to the mic port of the front I/O panel. The microphone icon appears highlighted.



3. Acquire the necessary images and press <Freeze> to freeze the image.



4. Press <Freeze> after obtaining the image. Press <Cursor> and roll the trackball to move the cursor onto the voice comment panel; click  to start recording and the icon  becomes red.
5. After the voice recording ends, click the icon  to end recording. Press the user-defined key for saving the cine.

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.

## 9.2.3 Voice Comment Review

Click to open a cine file with voice comment, and during the cine review mode, voice comments are played as well.

For details about opening a cine file, please see Chapter 6 Display & Cine Review.

## 9.3 Body Mark

**NOTE:** After powering off, the system will clear all comments on the image.

The Body Mark (Pictogram) feature is used for indicating the exam position of the patient and transducer position and orientation.

The system supports body marks for ABD (Abdomen), CARD (Cardiology), GYN (Gynecology), OB (Obstetrics), URO (Urology), SMP (Small Part), Nerve, EM (Emergency) and VAS (Vascular) applications. You can preset the system configured general body marks for each exam mode. The system supports the import of user-defined body marks.

### 9.3.1 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.

### 9.3.2 Adding Body Marks

1. 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:
  - Roll 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.

### 9.3.3 Moving Body Marks

You can move the body mark graphics to any desired position within the image area.

1. Press <Cursor> and roll the trackball to move the cursor onto the body mark. The cursor then becomes , indicating you can move the pictogram to a new position.
2. Press <Set> key to select the body mark.
3. Roll the trackball to move the Body Mark graphic to the desired position.
4. Click <Set> key to anchor and confirm the new graphic position.

**NOTE:** In Dual B Mode, a Body Mark cannot be moved between the separate image windows.

### 9.3.4 Deleting Body Marks

1. Use the trackball to position the cursor on the body mark graphic and Press <Set> to select.
2. Press <Clear> to delete the selected body mark.

### 9.3.5 Comments Settings

Preset returning, switching the exam mode/ patient/ probe will clear the body marks.



# 10 Patient Data Management

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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

<p><b>NOTE:</b></p> <ol style="list-style-type: none"><li>1. DO NOT use the internal hard drive for long-term image storage. Daily backup is recommended. External storage media is recommended for archiving images.</li><li>2. The system patient database space is limited, please back up or clear patient data in time.</li><li>3. Mindray is not responsible for lost data if you DO NOT follow suggested backup procedures.</li></ol>
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## 10.1 Enter Patient Information

The general patient information and exam information are entered through the Patient Info screen, for details, see Chapter 4.1 Patient Information.

## 10.2 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.

### 10.2.1 Storage Media

System supported memory media including:

- System hard disk
- USB memory devices: USB flash drive, removable USB hard disk
- DVD+R, DVD+RW, DVD-R, DVD-RW, CD-RW, CD-R.

### 10.2.2 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. For details, see Chapter 10.2.12 Sending Image File.

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 (AVI)  
Multi-frame export format.
- DICOM files (DCM)  
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.

## 10.2.3 Image Storage Settings

Set image size

You can set the image size via "[Setup]→[System]→[Image]". The items are shown as follows:

"Image": only save the image on the main screen when saving the single-frame image.

"Classic": save the images on the left menu and scan image when saving the single-frame image.

"Standard": save the images on the left menu, scan image, left parameter area when saving the single-frame image.

Set cine saving length

Set sending/ printing image after end exam

Open "[Setup]→[System]→[General]", check "Sending/ printing Image after End Exam" in exam setting area. Then every time you tap [End], the system will send images of the exam to the connected default DICOM server.

## 10.2.4 Quickly Saving Images to the System

To save a single-frame image to the system quickly:

Specific operation:

1. Set user-defined key: select one key from [Preset]→[System]→[iConsole&Footswitch]/[Key Board] page. Select "Save Image" from "Output" column.
2. Press the user-defined key to save the image.

Format:

1. The image format is FRM in the imaging interface.
2. When a dialog box is displayed on the current screen, press the user-defined key to save the screen in the PNG format.

The single frame 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 cineloop image to the system quickly:

1. Set user-defined key: select one key from [Preset]→[System]→ [iConsole&Footswitch]/[Key Board] page. Select "Save Cine(Retrospective)" or "Save Cine (Prospective)" from "Output" column.
2. Press the user-defined key to save the image.

Press the user-defined key to save the cine file in the default file directory in the CIN format.

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 file name with suffix will be displayed.

Set the cine length via [Preset]→[System]→[Image].



## 10.2.5 Quickly Saving Full Screen Image to the System

### ■ Specific operation:

1. Set user-defined key: select one key from [Preset]→[System]→ [iConsole&Footswitch]/[Key Board] page. Select “Full Screen” from “Output” column.
2. Press the user-defined key to save the image. The format of the image is PNG.

The full screen image is saved to the default path with the default name. The thumbnail of this image will appear in the thumbnail area on the lower side of the screen. When you move the cursor onto the thumbnail, its file name with suffix will be displayed.

## 10.2.6 Quickly Saving Images to USB Flash Drive

Use user-defined keys to quickly save the single-frame or cine to USB flash drive.

1. Set the user-defined key via the path: [Setup]→ [System] →[iConsole&Footswitch]/[Key Board]. Select “Save Image to USB disk” from the “Output” column.
2. Press the user-defined key to save the image to the USB flash drive.

## 10.2.7 Quickly Exporting Cine File to USB Flash Drive

Use the user-defined key to export the cine to the USB flash drive (not saved to the local path).

The file is stored in the directory: X (USB flash drive name): patient name+ ID\exam type + exam time \ image ID.

1. Set the user-defined key through the path: [Setup]→[System Preset]→ [iConsole&Footswitch]/[Key Board]. Select “Send Cine to USB disk” from the “Output” column.
2. Perform the scan and freeze the image
3. Press the user-defined key to save the image to the USB flash drive.

## 10.2.8 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 user-defined 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

Setting method (taking “Save Image” as an example, add the auxiliary functions “Send Image to DICOM Storage” and “Send Image to USB disk”):

1. Set the user-defined key through the path: [Setup]→[System]→ [iConsole&Footswitch]/[Key Board]. Select “Save Image” in the Output column.

2. The system will automatically show the available auxiliary functions for current key. Select “Send Image to DICOM Storage” and “Send Image to USB Disk”.
3. Click [OK] to confirm.
4. Scan and freeze the image
5. 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.

Tips: repeat step 2 will continue adding auxiliary functions; you can add 6 functions at most.

## 10.2.9 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 on the right 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.



## 10.2.10 Image Review and Analysis

The system supports the image review and analysis to the saved patient image.

### 10.2.10.1 To review images

Image review: you can review all images stored in an exam, and send, delete or analyze the stored images.

To enter image review:

- During image scan, saved image thumbnails will be displayed 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.
- During mapping mode, tap  and  to review the last and next image, or slide to left or right on the touch screen to review the image
- Tap [Review] to enter review page. Images of the current exam and the current patient are displayed.
- Select an exam of a patient in the iStation screen, and click <Review Image> or double-click the exam to enter the Review screen to review the images of the patient.

The Review screen is shown as follows:



Exit the review:

To exit 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, MedSight, DVD, etc. Or, select the image and click the  icon on the upper right of the image.
  - [Delete]: click to delete the selected image.
  - [Image Compare]: see *Chapter 6.5* for details.
- 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.

### 10.2.10.2 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.

Other operations

You can perform cine review operations in image analysis status.

### 10.2.11 iVision

iVision function is used for demonstration of the images stored. Image files are played according to file names one by one (including the image of system-relevant and PC-compatible format).

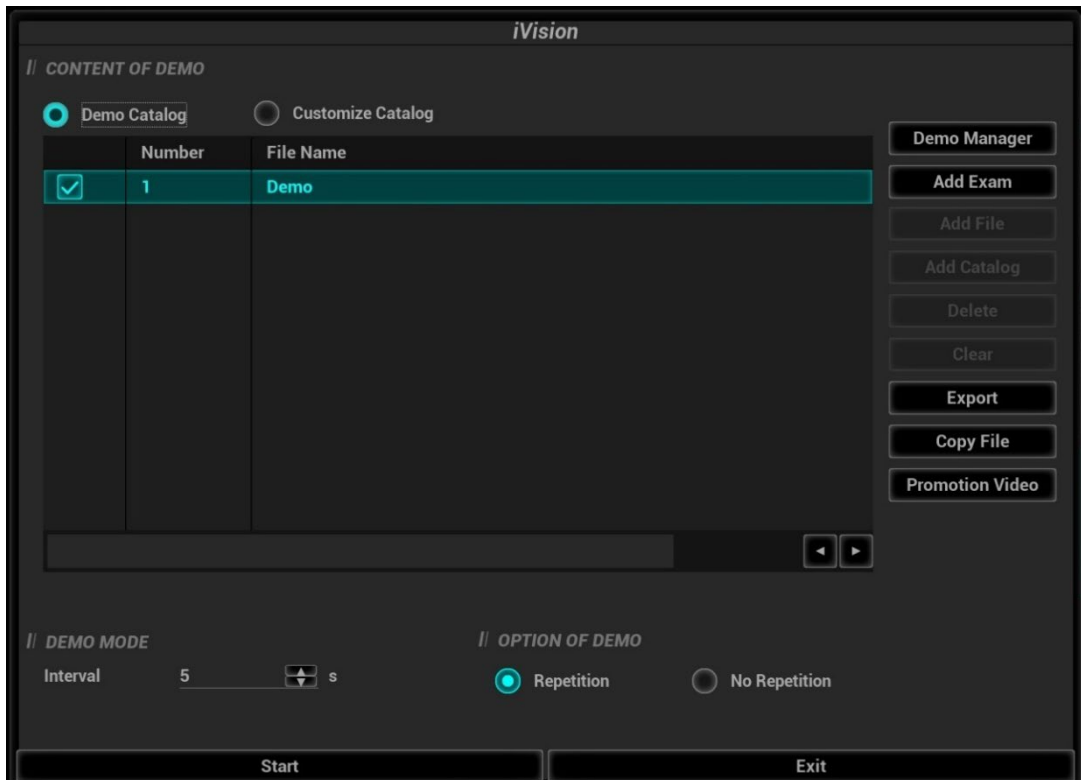
To perform image demonstration:

1. Enter iVision screen:

Press the user-defined key for iVision (setting path:  
[Setup]→[System]→[iConsole&Footswitch]/[Key Board]).

2. Add the contents to be played and select the demo mode.
3. Select an item in the list, and click [Start] to begin the demonstration.
4. Click [Exit] or press <ESC> to exit the iVision status.

The iVision screen is shown as follows:



#### Demonstration item

The demonstration items are the image files in the formats that the system supports. You can add the exam data in patient database or system supported image files and folders to demonstration list. For files and folders in demonstration list, the images in the directory and subdirectory are played one by one, and the system will automatically jump over the files that can't be opened.

#### Demonstration item


There are two kinds of catalogs: Demo Catalog and Customize Catalog.

- Demo Catalog: demo catalog is the folder in hard disk, where the factory DEMO is stored. The system plays the images in this folder when performs demonstration.

The system supports import, delete or clear the data in demo catalog.

Click [Demo Manager] to operate:

: to import data to demo catalog.

: to delete the selected data.

: to delete all data.

- Customize Catalog: what saved here is the catalog of the displayed image. The system plays the images in the catalog when performs demonstration.

Operate the catalog by 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 catalog to the file list.

[Delete]: to delete the selected file or catalog in the file list.

[Clear]: to clear all the files or catalogs in the file list.

[Export]: to export the selected directory/file to the external storage devices. Click [Export]. The review dialog box appears. Select the drive name and the path (the default name of the folder is DEMO), then, click [OK].

- Copy the file (file transmission between the mobile hard disk and the ultrasound system):  
Plug the USB disk, and click [Copy File].  
Select the path of the source file from the “Drive” and “File Name”.  
Click [Choose Catalog]. Select the path of the source file from the “Drive” and “File Name”, and then click [OK].  
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.

## 10.2.12 Sending Image File

**NOTE:** Data saved this way can only be reviewed on the PC and cannot be restored to the ultrasound system.

On the image screen, select a stored image thumbnail, click  on the upper right corner of the image, the image can be sent to the external device, DVD recorder, MedSight, DICOM storage server, DICOM print server, system connected printer and etc.

In the iStation screen, click ; or, in Review screen, click  to send patient data to an external memory device.

- For external memory devices (e.g. USB memory devices, DVD recorder) or network storage server:
  - a) PC format transfer: JPG/ AVI, BMP/ AVI, TIFF/ AVI, JPG/MP4, BMP/MP4, TIFF/MP4.  
Where a single-frame image is exported as JPG, TIFF or BMP, and the cine file exported as AVI (windows), MP4 (Mac OS).
  - b) DCM format transfer: DCM (including single-frame DCM and multi-frame DCM).
  - c) Cine zoom mode can be changed.
  - d) To select to export the report or the report format.
  - e) To select to hide patient information.
- For DICOM Storage or Print server, select the DICOM Storage or Print server.
- Select the printer service according to the printer you choose.
- Send the image to MedSight as necessary.

**NOTE:** The file sent to MedSight is transferred into PNG format, and the cine file is transferred into AVI or MP4 format.

If the transferred AVI file cannot be played normally on PC, please try to transfer the multi-frame cine file in MP4 format 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.



# 10.3 Report Management

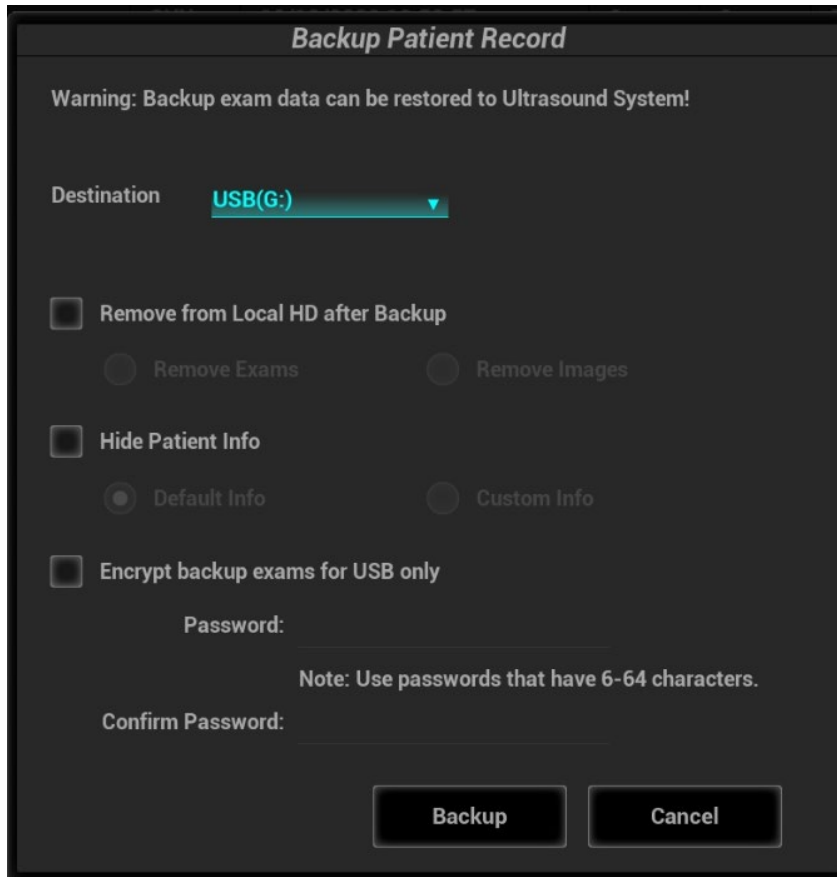
Report storage:

The exam reports are stored under the directory of the exam of the patient.

Importing, exporting and sending a report

- Import/export report via Backup

In iStation screen, select patient data, click  or  in the popped up menu to import or export patient information, images and reports from or to an external memory device. See the following figure:

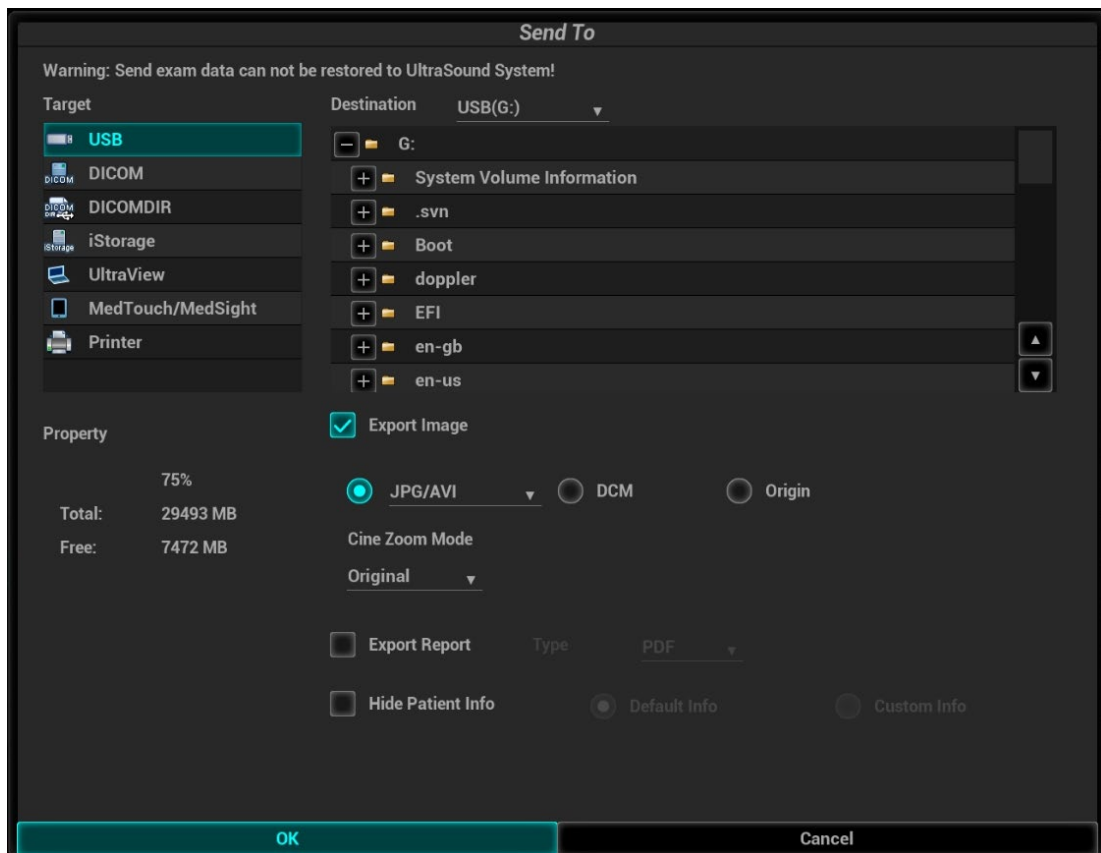


- 1) Select the destination.
- 2) Select whether to remove from local HD after Backup: if "Remove Exams" is selected, the patient information and images are removed; if "Remove Images" is selected, only the patient images are removed.
- 3) Select whether to hide patient info: if "Default Info" is selected, the patient name is hide after backup; if "Custom Info" is selected, the system prompts a message requiring you to input the customized 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, and then 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.

Notes:	1. If the password is forgotten, you cannot open the backup package.
	2. The password cannot be multi-language or Chinese characters.

- Export report via Send To

In the iStation or Review screen, click [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. See the figure below.



To export the report:

1. Check "Export Report" on the screen.
2. Select report type to be exported.
3. Select whether to hide patient info: if "Default Info" is selected, the patient name is hide after backup; if "Custom Info" is selected, the system prompts a message requiring you to input the customized patient name, which will be displayed after backup.
4. Click [OK] to confirm.

The size of the report can be set via [Preset]→[Print].

Printing report

Use a connected graph/text printer to print a report.

For details on report relevant operations, please refer to [Advanced Volume].

## 10.4 Patient Data Management (iStation)

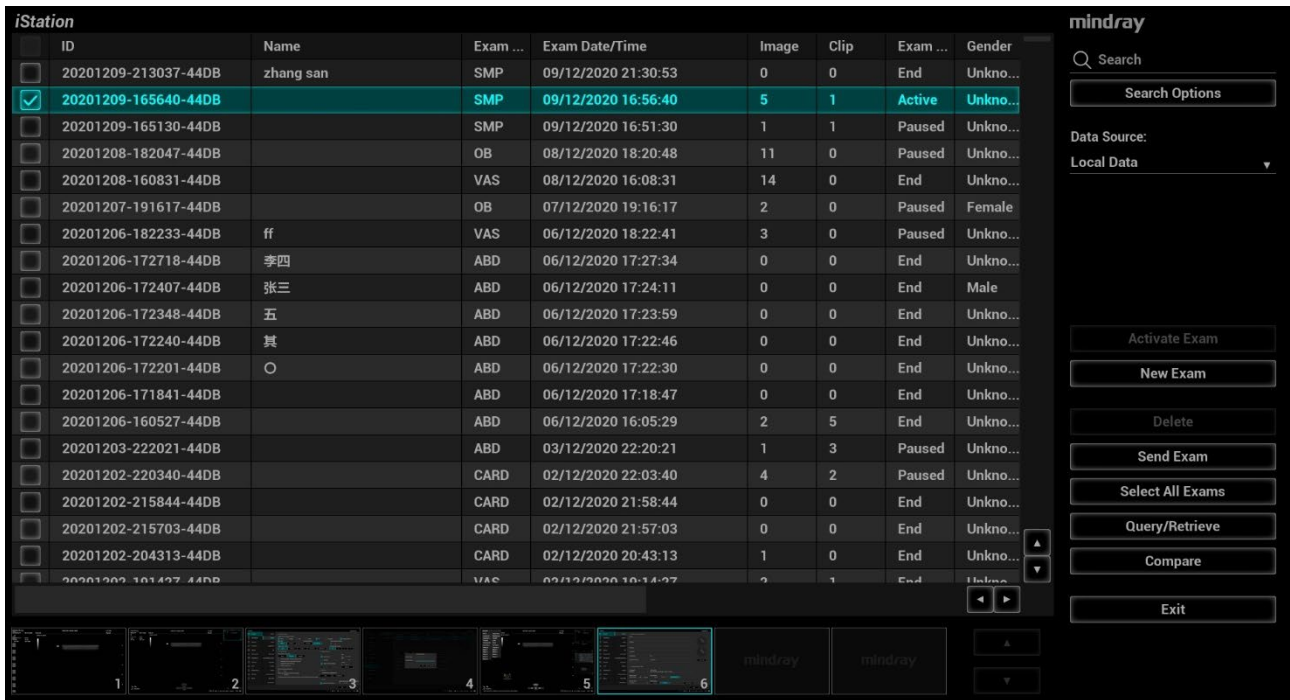
The patient data include basic patient information, exam information, image files and reports. You can search, view, backup, send, restore, delete or export patient data in iStation.

To Enter iStation

- Press <F2 iStation> key on the control panel; or
- Click [iStation] in the Patient Info screen; or
- Click [iStation] in the Review screen.

The iStation screen is shown as follows:





## 10.4.1 Viewing Patient Information

### Data Source

Select the data source of patient data, the system patient database is default.

### Patient list

Display patient information, exam mode, number of images and cines, exam state, backed up or not.

### New Exam

After you select a patient data or exam in the iStation screen, click the [New Exam] to enter the Patient Info screen, where you can select the exam mode and click [Save] to begin a new exam.

### Select All/Deselect All

Click [Select All] to select all the patient data listed. Then the button changes into [Deselect All], you can cancel all the selections by clicking [Deselect All].

## 10.4.2 Searching a Patient

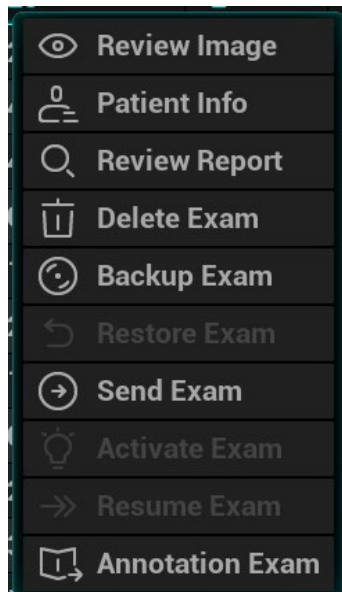
1. Select the data source.

Click [Data Source] to select the data source of patient data, the system patient database is default.

2. Set search conditions in the "Item" drop-down list.
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.

## 10.4.3 Patient Data View & Management

Select the desired patient information in the list. The following menu pops up:



#### 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

- 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.
- To delete an image, select the image and click  on the right side. Or tap the icon  on the mapping mode. See Chapter 3.7.4 *The Display of Touch Screen and Its Operation*.

#### Backup/Restore the exam

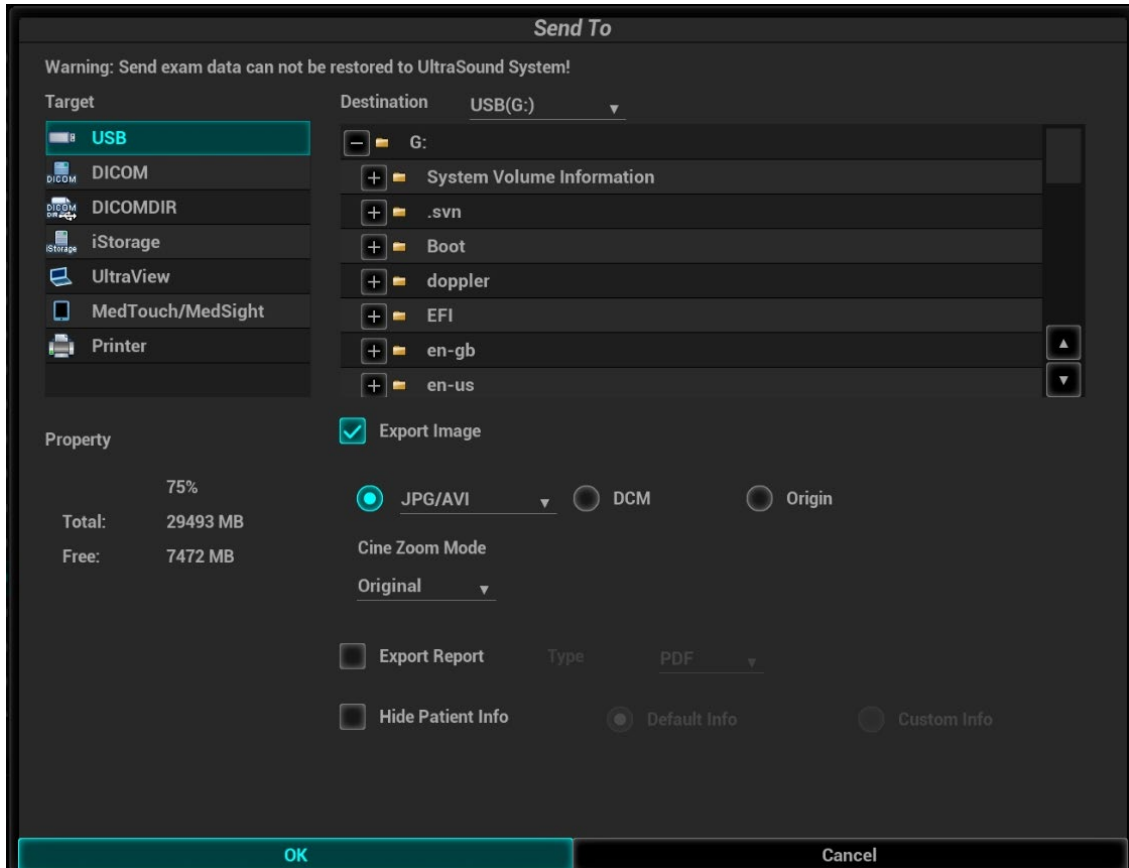
You can back up the selected patient data to the system-supported media in order to view it on PC, or restore the patient data to the system from an external media. The exam after being backed up can be restored to the system for another review.

[Backup Exam]: click to back up the selected patient data to the system-supported media;

- Original format: to back up the data in original format.
- DICOM format: you can change the cine compression mode, and JPEG compression mode.
- You can select whether to remove images or the whole exam record from the system.

[Restore Exam]: click to import the patient data from an external media.

## Send Exam



The system supports sending data to external memory devices, print or iStorage. 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.

1. Select the patient record, click [Send Exam] in the menu to send exam data or images of the selected record.

Press <Ctrl or <Shift> with <Set> key on the control panel to select more than one exam or image at one time.

2. Select from the destination:
  - DICOM: select the storage/print server to store or print DICOM.
  - DICOM format: use DICOMDIR format as the backup; you can change the cine compression mode, and JPEG compression mode.
  - USB disk or disc: send the exam to USB disk or disc.
    - The report format is selectable.
    - Format transfer is available when sending images to USB devices or disk.
  - Print: send the image to the video/graph printer.
  - MedSight: send the exam to MedSight.

## New Exam

After you select a patient data or exam in the iStation screen, click the [New Exam] to enter the Patient Info screen, where you can select the exam mode and click [OK] to begin a new exam.

## Select All/Deselect All

Click [Select All] to select all the patient data listed. Then the button changes into [Deselect All], you can cancel all the selections by clicking [Deselect All].

## 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.

## 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.

To recover the deleted patient data, 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.

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 Worklist.

To set maximum number of days for deleted data to be kept in the recycle bin:

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].

NOTE: if the capacity of the recycle bin exceeds 200. The system reminds the user to clean. Follow the procedures to clean the recycle bin.

# 10.5 iStorage

Network storage is used to save image files and measurement reports to the remote PC server.

Select [Setup]→[Network Preset]→[Network Storage] to perform network storage setting. (For details, please refer to Setup chapter.)

1. Enter iStation, select one (or more than one) patient data or image in the local data source;
2. Click [Send To].
3. Select [iStorage] in the Send To dialogue 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.

To use iStorage function, you need UltraAssist software in 2.0 version (with V1.0 network protocol); consult Mindray service engineer for details.

## 10.6 Print

### 10.6.1 Print Settings

For printer connection and driver installation, please refer to Chapter 3.6.3 *Installing a Graph/Text Printer*.

Print Service Setting

1. Select the [Setup]-[Print Preset], select an existed printer service in the list.
2. Select the printer type in the Property box.
3. Set printing properties.
4. Click [OK] to confirm the setting and exit the preset page.

User-defined shortcut key for printing

- Select the image to be printed on the iStation or Review screen, and click [Send To] to select the desired printer.
- Set shortcut keys (e.g. print): select [Setup]-[System]-[iConsole&Footswitch]/[Key Board]. Click [Output] to select the printer service.

Please refer to the accompanying manuals of the printers for more details.

Video output settings

Open [Setup] (<F10>)->[System]->[Output], then select the image output mode: PAL or NTSC.

Video output settings

Open [Setup] (<F10>)->[System Preset]->[Image], then select the image output mode: image area or standard area.


### 10.6.2 Image Print

For DICOM image printing, refer to relevant chapters. Video printer is applied in image print service.

Modify print service:

1. Select an existed printer service from [Print Service].
2. Select the printer type in the Property box.
3. Print property: print paper, print orientation, layout, etc.
4. Click [OK] to save the settings.

Send to print

1. Select the desired image in iStation or Review screen.
2. Click  icon on the upper right side of the image, and select the printer in the popped up dialogue box.  
On the pop-up dialogue box, you can modify print property, including paper orientation and layout.
3. Click [OK] to start printing.

Please refer to the accompanying manuals of the printers for more details.

### 10.6.3 Report Printing

Both reports and images can be printed on a graph/text printer.

1. Tap [Report] on the touch screen to enter the report dialog box.
2. Select [Print] to print the report.



See the accompanying printer manuals for more details.

## 10.7 Back up Files using the DVD Drive


The system supports writing data to CD/DVD using the DVD-RW/DVD+RW drive and reading data from CD/DVD on the PC.

The system supports the following media: DVD+RW, DVD+R, CD-RW, CD-R, DVD-R and DVD-RW.

To write data to a CD/DVD:

- (1) Put a CD/DVD in the tray.
- (2) Select the data to be backed up. Select [Send Exam] or [Back up 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 [Back up] 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.

Tip:

- Writing data using “Send To” supports the PC format transfer function, while CD/DVD writing using “Back Up” supports only system-relevant formats.
- The  symbol indicates that the input CD/DVD is damaged or contains data in an incorrect format.


You can check the data writing procedure in the patient task manager. For details, see Chapter 10.8 *Patient Task Management*.

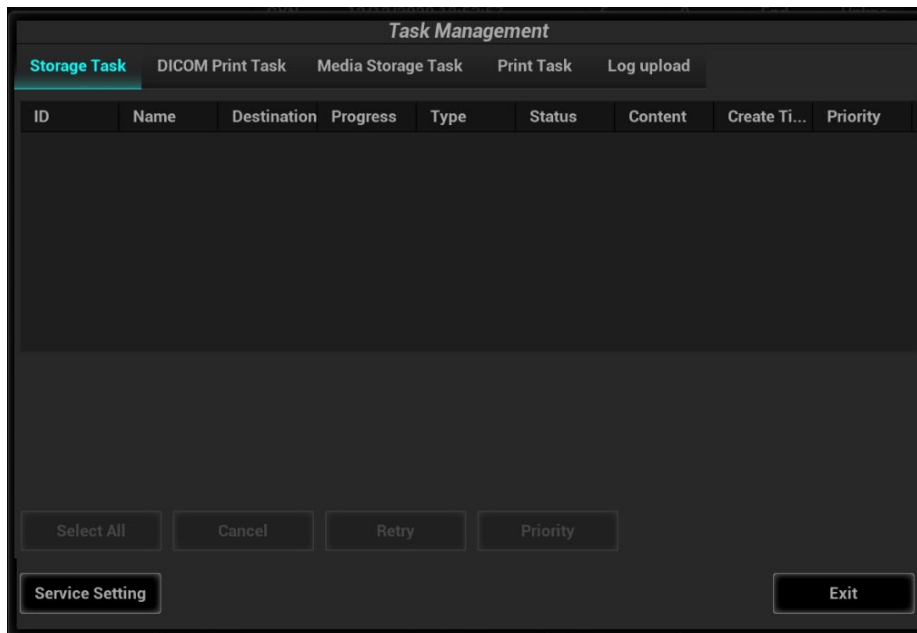


### CAUTION:

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.

## 10.8 Patient Task Management

Click  in the bottom-right corner of the screen to bring up the following dialog box:




The system supports following types of task management:

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 [Back Up Exam].
- Send to external devices (including disc and USB devices): select exam data or images in the iStation or Review screen. Click [Send Exam] or  for the image.
- iStorage task: in iStation screen, select the target exam and click [Send Exam], then click iStorage in the menu which appears.
- MedSight storage task:  
In iStation screen, send exam to MedSight devices.  
On review screen, iStation screen, thumbnail area, send the image(s) to 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 . Click the icon to check the process.

When tasks have failed, the task management icon displays as . Click the icon to check the reason for the failure.

When the task management icon displays as , 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 the DICOM/HL7 chapter.

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 the DICOM chapter.

## 10.9 Administration

### 10.9.1 Access Control

The system supports two types of users: system administrator and operator.

Administrator

The system administrator can access all function modules, and view all patient data, such as patient information, images and reports, etc. Only one administrator is configured by default. The administrator can add or delete operators.

## Operator

The operator can only access the function modules with assigned privileges (for details about privilege assignment, please refer to "10.9.4 Local Privilege Management" and "10.9.5 LDAP Privilege Management"). 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.

## 10.9.2 Enabling Access Control

The system 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 administrator.

Setting access control:

1. Open the "Access Control" page using the path: [Setup] → [System] → [Access Control].
2. 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.
3. If "Enable Emergency User" is selected, the administrator can edit privileges for emergency users. If unselected, the administrator cannot edit privileges for emergency users.

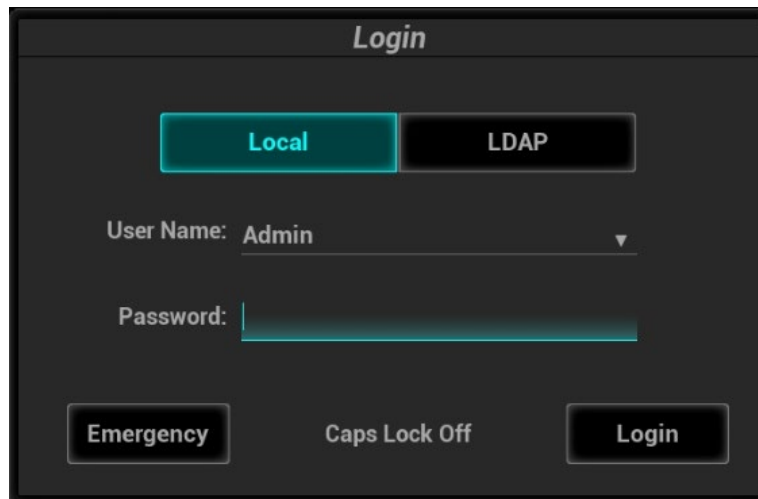
## 10.9.3 System Login

If access control has been set by the system administrator, you can access data in the system only after logging onto the system.

You must log in again after system restart or dormancy.


Logging onto the system:

1. The following dialog box appears:




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

To change users:

1. To log out the current user and change to another user, click  in the bottom-right corner of the screen to bring up the dialog box:
2. Click [Change User] to bring up the Login dialog box.
3. Select the login type, and user name in the drop-down list.
4. Enter the password and click [Login]



Lock the system

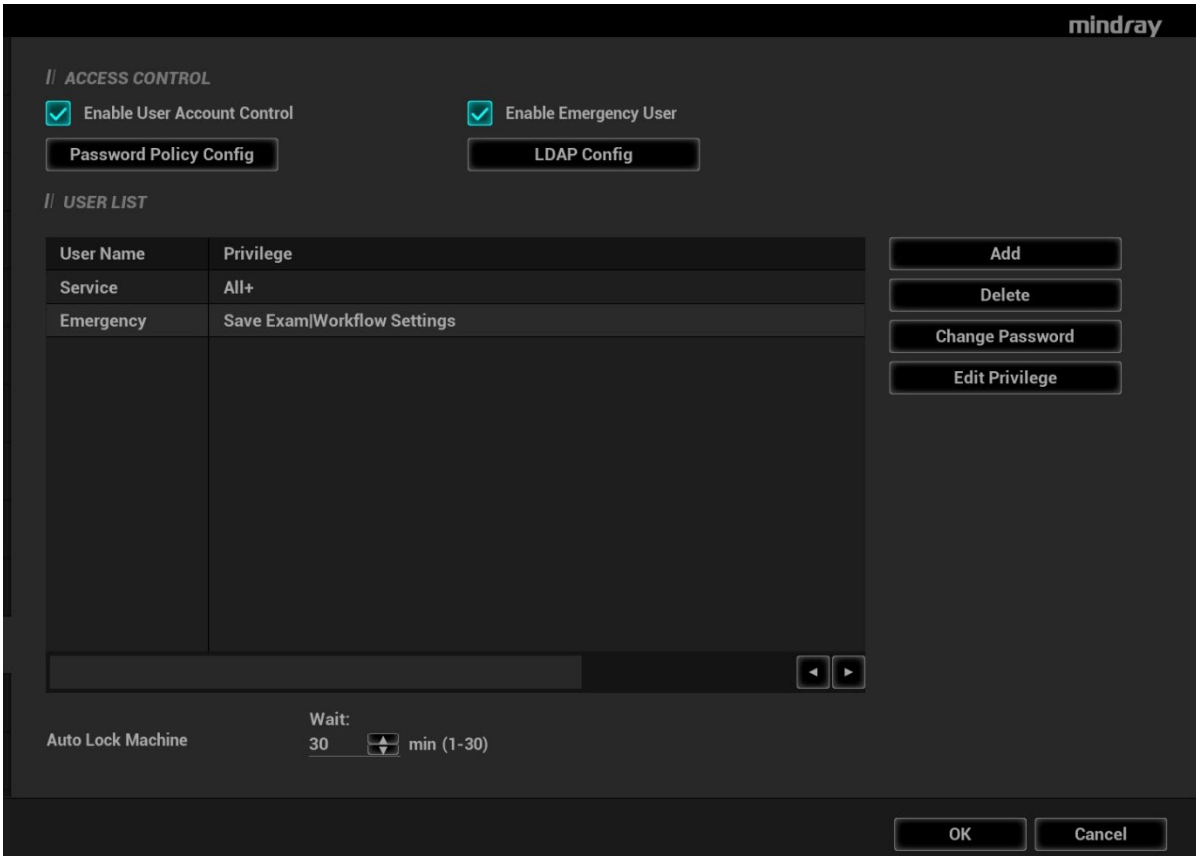
1. Click the  in the bottom-right corner of the screen to bring up the dialog box.
2. Select [Lock Machine] and the system is locked. You must log on before using the system.

## 10.9.4 Local Privilege Management

The system administrator can add and delete users, and assign privileges, while the operator cannot. The privileges can be assigned through the local system or LDAP server.

### Adding a User/ assigning privilege

Turn on the access control function and log in to the system as Administrator before you add the user.



**mindray**

// ACCESS CONTROL

Enable User Account Control       Enable Emergency User

Password Policy Config      LDAP Config

// USER LIST

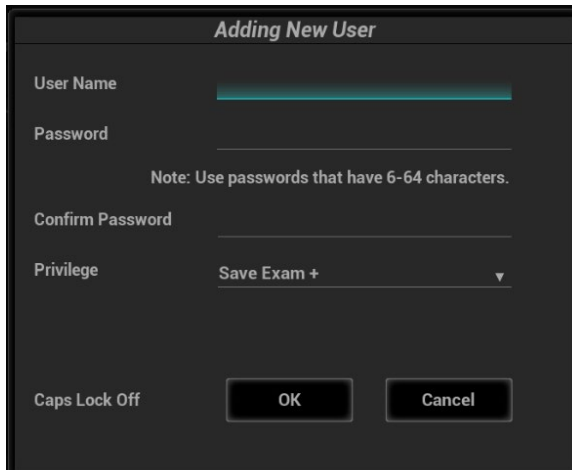
User Name	Privilege
Service	All+
Emergency	Save Exam Workflow Settings

Add  
Delete  
Change Password  
Edit Privilege

Auto Lock Machine      Wait: 30 min (1-30)

OK      Cancel

1. Open the “Access Control” page using the path: [Setup] → [System] → [Access Control].
2. Click [Add] to bring up the dialog box.



**Adding New User**

User Name \_\_\_\_\_

Password \_\_\_\_\_

Note: Use passwords that have 6-64 characters.

Confirm Password \_\_\_\_\_

Privilege Save Exam + ▾

Caps Lock Off      OK      Cancel

3. Enter the user name and password, confirm password, and select or deselect the check box from the privilege list. Users can only access the function module with assigned privilege.
4. 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

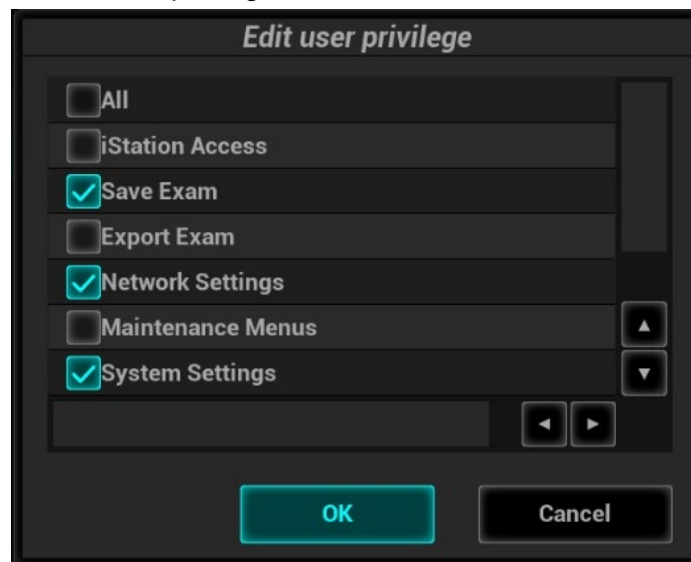
Turn on the access control function and log in to the system as Administrator before you delete the user.

1. Open the "Access Control" page using the path: [Setup] → [System] → [Access Control].
2. 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 Administrator before you edit privileges.

1. Open the "Access Control" page using the path: [Setup] → [System] → [Access Control].
2. Select a user, click [Edit Privilege] to enter the "Edit user privilege" dialog box, and 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

The system administrator can modify all user passwords. The administrator password is empty by factory default. You can set this password.

An operator can only modify his/her own password. There are two ways to modify passwords: on the "Access Control" page or in the "Session Manage" dialog box.


"Access Control" page (administrators can modify the password)

1. Open the "Access Control" page using the path: [Setup] → [System] → [Access Control].
2. Select the user name to be modified in User List. Click [Change Password] to open the dialog box.

3. Enter the new password and confirm the password, then click [OK].

Session Manage page (general operators and administrators can modify the password).

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

1. Click  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] to bring up the Change Password dialog box.
3. Enter both the previous and new passwords, and confirm the new password in the dialog box.
4. Click [OK] to exit.

### Configure password policy

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

1. Open the "Access Control" page using the path: [Setup] → [System] → [Access Control]. Click [Password Policy Config]:

**Password Policy Config**

Lockout Threshold  Times(3-20)

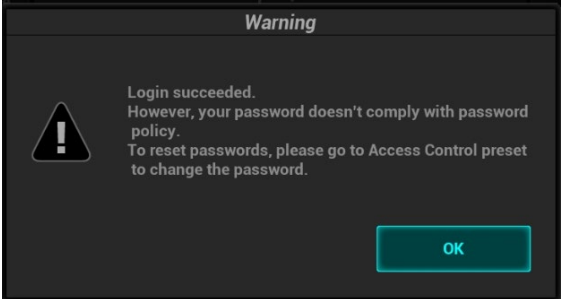
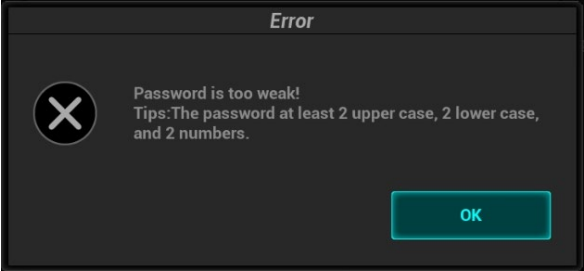
Reset Account Lockout Threshold after  Minutes(5-600)

Lockout Duration  Minutes(1-9999) Reset all lockout

Enable strong password(The password length must be 6-64)

Notes: strong password means at least 2 upper case, 2 lower case, and 2 numbers.

Parameter	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 Lockout Threshold after" is set to 60, and the "Lockout Duration" is set to 60. That is, a user inputs the wrong 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 Account Lockout Threshold after	Set the duration allowed for a user to continuously input the wrong password.	
Lockout Duration	Set the duration after an account is locked.	
Reset all lockout	Reset all locked accounts.	/

Parameter	Description	Remark
Enable strong password	<p>Enable strong password to improve security.</p> <ul style="list-style-type: none"> <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.</li> </ul>  <p>The administrator can change password for administrator or operator via [Setup] → [Access Control].</p> <ul style="list-style-type: none"> <li>If the strong password is enabled and you add a new user account, the system prompts an error message to inform you that the password is too weak:</li> </ul>  <p>Please modify the password according to the error message.</p>	/

## 10.9.5 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.

1. Enter [Setup] → [System] → [Access Control] → [LDAP Config].

2. Select LDAP type.

AD and LDAP configuration are almost the same. Here, LDAP configuration is taking as an example.

3. Enter the server address in the field box after accessing the network.

4. 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."

Parameter	Description
Root DN	It is automatically displayed after the server is successfully tested.

Parameter	Description
Default Domain	The default domain is the DC name in the Root DN. For example, if DC=security1, then input "security1" in the field box of the "Default Domain"
Days to keep cached password	<p>Set days to keep the cached passwords in the local system Users can log in to the server even without accessing the network within the setting days.</p> <ul style="list-style-type: none"> <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>

### Adding a user

1. Enter [Setup] → [System] → [Access Control] → [LDAP Config].
2. Enter the member name, and select or deselect privileges from the drop-down list of "Privilege".
3. Click [Add], and the new members and privileges will appear in the Member of filter list.

### Deleting a user

1. Enter [Setup] → [System] → [Access Control] → [LDAP Config].
2. Select a member to be deleted, and click [Delete].

### Modifying the member name or privileges

1. Enter [Setup] → [System] → [Access Control] → [LDAP Config].
2. Select a member to be modified, modify the member name, and select or deselect privileges from the drop-down list of "Privilege".
3. Click [Modify], and the modified member name and privileges will appear in the Member of filter list.

### Logon test

1. Enter [Setup] → [System] → [Access Control] → [LDAP Config].
2. Enter the User name and password in the field boxes of the Authentication test area.
3. Click [Logon Test] to test whether the user is authenticated. After successful authentication, the system prompts a successful authentication message.

## 10.9.6 User field name

The user field name corresponding to privileges are as follows:

Privilege	User field name
iStation Access	1
Save Exam	2
Export Exam	4
Network Settings	8
Maintenance Menus	16
System Settings	32
Workflow Settings	64

Privilege	User field name
Worklist Access	128

Note: the privilege items can be combined randomly. For example, if user A is assigned with all the above 8 privileges, the user field name for user A is  $1+2+4+8+16+32+64+128=255$ .

## 10.10 Q-Path

### 10.10.1 Overview

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.

Item	Description
Advanced	Sets the sub URLs of “QView full” and “QView lite”. The sub URL is set by default. Users can modify the sub URL and click [Apply] to exit the “QView sub URL setting” window.
Enable Direct Report	Sets whether to open the Q-Path server through the [Report] key.
Worksheet Only	Sets whether to directly enter the Worksheet interface after opening the Q-Path server.
Password On Worksheet	Sets whether to display the Signature field box in a worksheet. Tap [Report] > [WorkSheet] or tap [Review] > [Report] > [WorkSheet], enter the worksheet password in the field box, and click [OK]. Users can query the corresponding worksheet by searching the worksheet password in the Q-Path server.
Password On End Exam	Sets whether to input the worksheet password after ending an exam.
Password Visible	Sets whether the password is visible.
Import	Imports a user-defined worksheet template from the USB storage (downloaded from the Q-Path server).
Backup	Backs up worksheets to the USB storage.
Restore	Restores the backup worksheet template from the USB storage to the ultrasound system.
Delete	Deletes a worksheet template.
Load Factory	Restores the worksheet template to the default state.

### 10.10.2 Q-Path Basic Procedure

Perform the following procedure:

1. Select “Enable Q-Path”.
2. Enter the website, account and password of the target service.
3. Select user type: Personal User or Default User.

Personal User: the personal user needs to enter the user name and password in every-time login.

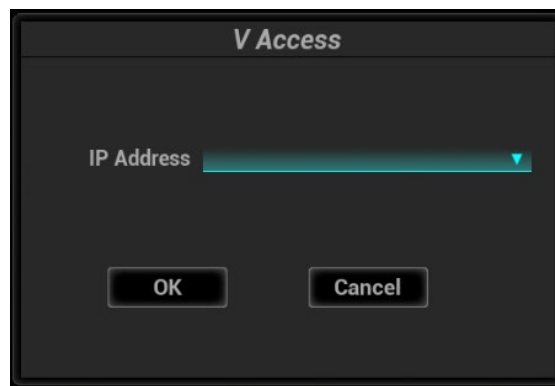
Default User: after the default user enters the user name and password in the field box of the “User Name” and “Password”, and click [OK], no login is required to access the QPath server later.

4. Select an appropriate item from the drop-down list of “Available Items”.
5. Select an exam mode in the left “Exam Mode” column.
6. Select a worksheet in the right “Worksheets” column.
7. Click [OK] to exit, and the system will shut down.

## 10.11 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. Set the user-defined key via the path: [Setup] → [System Preset] → [iConsole&Footswitch]/[Key Board]. Select a blank key, and select “V Access” in the “Other” column.
2. Press the user-defined key to use the function.
3. The system brings up a dialog box for entering the IP address of the remote server.



4. Enter the IP address and click [OK].
5. Log on with the server account and password.
6. 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.



# 11 DICOM/HL7

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**NOTE:** Before using DICOM, please read the electronic file DICOM CONFORMANCE STATEMENT along with the device.

The chapter is confined to the preset, connection verification and DICOM services of the DICOM-configured ultrasound machine, not including SCP configurations like PACS/RIS/HIS.

The DICOM package is optional, so the description here is only applicable for the system configured with the DICOM package.

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

Workflows of DICOM Preset and Applications are briefly described as follows:

1. DICOM preset (network property, DICOM local preset, server and service preset).
2. Verify connectivity.
3. Services application.
4. DICOM task management.

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

## 11.1 DICOM Preset

### 11.1.1 Network Preset

Refer to Appendix C Wireless LAN for details.

## 11.1.2 DICOM Local Preset

1. Enter the DICOM local preset screen using the path: [Setup] → [DICOM/HL7].
2. Enter AE Title, Port and PDU according to the actual situation, then click [Save] to exit the screen. Setting items are introduced in the following.

	Name	Description
DICOM Local	AE Title	Application Entity title.
	Port	Communication port, DICOM communication port. The general port of DICOM port is 2345 by default.
	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.
	DICOM output charasets	Select a character set for DICOM output according to the local PACS workstation
	TLS Port	Set the TLS port.
	TLS Server Setting	Import the encryption key/certificate.
	TLS Client Setting	<ul style="list-style-type: none"> <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>
	Resume tasks upon restart	Resume unfinished sending tasks after system reboot.
Server Setting	Device	Name of the device supporting DICOM services.
	IP Address	IP address of the server.

Name	Description
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.
Device List	Displays the added device.
Set DICOM Service	Provides server settings of DICOM service, for details, please refer to the following chapters.
Add	Click to add server (s) to the Device List.
Delete	Click to delete the selected server (s) in the device list.
Log Level	Select the log display level: No Log, Service Result Log, Service Process Log, All Log.
Set DICOM Strategy	Provides strategy settings of DICOM service, for details, please refer to the following chapters.

Server setting procedure:

1. Enter the server device name and IP address; click [Ping] to check the connection.
2. Click [Add] to add the server to the device list, and its name and address are displayed in the list.

Tips:

- 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 exists”, 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.

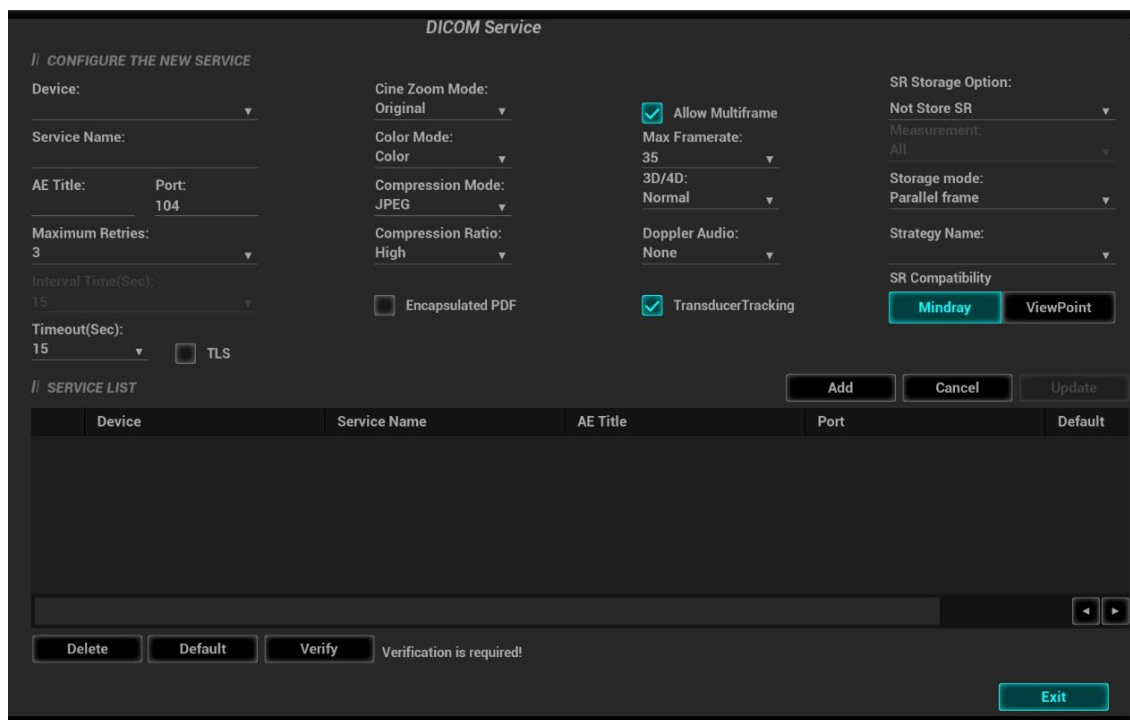
### 11.1.3 Service Preset

The DICOM Service screen is used to set attributes of Storage, Print, WorkList, MPPS, Storage Commitment, and Query/Retrieve.

When the system is configured with DICOM basic function module, and installed with DICOM WorkList, MPPS, DICOM structured report, and DICOM query/retrieve modules, the corresponding preset can be found in DICOM Service screen.

#### 11.1.3.1 Storage Service Preset

1. On the DICOM Service screen, click the [Storage] page tab to enter the Storage page.
2. Select a device and enter the correct AE Title, port, etc.
3. Click [Add] to add the service to the Service List.



DICOM storage preset items are described as follows:

	Name	Description
Configure New Service	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(s)	Interval time.
	Timeout	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).

Name	Description	
	<p>Select the color mode.</p> <p>If you choose the mix or the grey, RLE/JPEG is unavailable.</p> <p>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.</p>	
Allow Multiframe	If SCP supports this function, then select it.	
Max Frame Rate	Set the frame range of transferring cin file into DCM multi-frame file. It is editable to the user.	
3D/4D	<p>Set the 3D/4D image transfer mode.</p> <p>Set the transfer mode for the 3D/4D cine sending.</p> <ul style="list-style-type: none"> <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.	
Storage mode	<p>Set the storage mode for image and cine file:</p> <p>Parallel file: save the current file, and is ready for the storage of the next file.</p> <p>Parallel frame: send the current frame, and is ready for sending the next frame.</p>	
Add	Add the DICOM service to the service list.	
Cancel	Click to cancel parameter setting.	
Update	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.	
Advance Setting	<p>Encapsulated PDF</p> <p>Select if to encapsulate PDF format report in DICOM standard.</p> <p>It becomes available if SCP supports the function.</p>	
	Doppler audio	Set to save the audio of PW mode.
	Transducer Tracking	Files of images that are saved in DCM format through DICOM or DICOMDIR contain transducer serial number information.
	Measurement	<p>If "All" is selected, the structured report will contain all the latest measurement values displayed on the measurement report.</p> <p>If "Single" is selected, the structured report will contain only the final measurement value.</p>
	Manufacturer	Select the desired manufacturer, and the structured report will be in accordance with the regulations of the selected manufacturer.
	Strategy Name	Select the desired DICOM strategy.
Service List	Delete	Click to delete the selected service in the service list.

Name	Description
Default	Set the default server for the storage service. Select an item in the service list, click [Default] and you can see “Y” in the Default column.
Verify	Click to verify if the two DICOM application entities are normally connected.

Tip:

- 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.

### 11.1.3.2 Print Service Preset

1. On the DICOM Service screen, click the [Print] page tab to enter the Print page.
2. Select a device and enter the correct AE Title, port, etc.
3. Click [Add] to add the service to the Service List.

DICOM print preset items are described as follows:

Name	Description
Configure New Service	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.

Name	Description
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	Range: 0-9. It starts retrying if it fails to send DICOM task to the server. The retry entry times should be this value.
Interval Time (s)	Reserved time.
Timeout	Refers to timeout during association establishment.
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	<p>Select how the printer magnifies an image to fit the film.</p> <p>Replicate: interpolated pixels belong to duplicate of adjacent pixels);</p> <p>Bilinear: interpolated pixels are generated from bilinear interpolations between adjacent pixels;</p> <p>Cubic: interpolated pixels are generated from cubic interpolations between adjacent pixels;</p> <p>None: without interpolation.</p>
Strategy Name	Select the desired DICOM strategy.
Add	Add the DICOM service to the service list
Cancel	Click to cancel parameter preset.

Print Properties

Name		Description
	Update	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.
Service List	Delete	Click to delete the selected service in the service list.
	Default	Set the default server for the printer service Select an item in the service list, click [Default] and you can see "Y" in the Default column.
	Verify	Click to verify if the two DICOM application entities are normally connected.

### 11.1.3.3 Worklist Setting

1. Select [Setup]→[DICOM/HL7]→[Set DICOM Service]→[Worklist] to enter the "Worklist" page.
2. Select device in the drop-down list, the available devices are DICOM services already set in the system, enter the information about AE, Title and the port.
  - 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 [Cancel] to cancel changing.
  - Select an item in the service list, and click [Delete] to delete the service.
  - Select an item in the service list, and click [Default] to set the server to be the default service.
3. Select an item in the service list, and click [Verify] to verify the connection.

DICOM service setting for Worklist is described as follows:

Name		NOTE
Configure new service	Device Name	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.



Name		NOTE
	AE Title	Application Entity title. Here, it is consistent with that of the Worklist server.
	Port	DICOM communication port, 104 by default. Here, the port should be consistent with that of the Worklist server port.
	Maximum Retries	Reserved feature.
	Interval Time(s)	Reserved feature.
	Timeout	Refers to time after which the system will stop trying to establish a connection to the service. Value: 5—60s, in increments of 5, and 15 by default.
	TLS	Transport Layer Security. Select whether to encrypt the data during network transportation.
	Strategy Name	Select the desired DICOM strategy.
	Add	Click to add the Worklist service to the service list.
	Cancel	Click to cancel the parameter setting.
	Update	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.
Service list	Delete	Click to delete the selected service in the service list.
	Default	Set the worklist server as the default. Select an item in the service list, click [Default] and you can see “Y” in the Default column.
	Verify	Click to verify if the two DICOM application entities are normally connected.

#### 11.1.3.4 MPPS Preset

1. Select [Setup]→[DICOM/HL7]→[DICOM Service Setting]→[MPPS] to enter the MPPS page.
2. Select the device name, and type the information about the AE title, the port.
3. Click [Add]. The entry will be added in the service list.

**NOTE:**

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

**DICOM Service**

// CONFIGURE THE NEW SERVICE

Device:  Service Name:  AE Title:  Port:

Maximum Retries:  Interval Time(Sec):  Timeout(Sec):   TLS

// SERVICE LIST Add Cancel Update

Device	Service Name	AE Title	Port	Default

Delete Default Verify Verification is required! Exit

MPPS setting items are described as follows:

	Name	NOTE
Configure new service	Device Name	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. Here, 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(s)	Reserved feature.
	Timeout	Value: 5—60s, in increments of 5, and 15 by default. The connection is disabled if there is no message to be sent in 15 seconds after the MPPS being sent.
	Add	Add the DICOM service to the service list.
	Cancel	Click to cancel the parameter setting.
Service list	Update	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.
	Delete	Click to delete the selected service in the service list
	Default	Set the worklist server as the default. Select an item in the service list, click [Default] and you can see “Y” in the Default column.

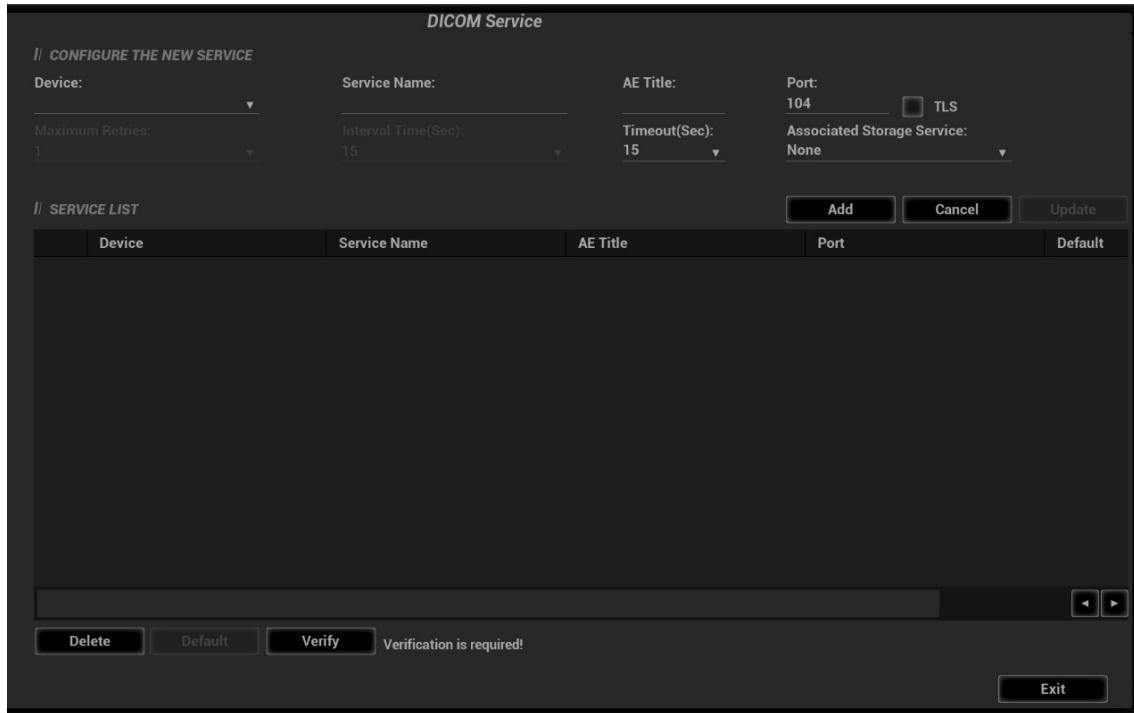
	Name	NOTE
	Verify	Click to verify if the two DICOM application entities are normally connected.
	Exit	Click to exit the screen.

**NOTE:**

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

### 11.1.3.5 Storage Commitment Setting

1. Select [Setup]→[DICOM/HL7]→[DICOM Service Setting]→[Storage] to enter the storage page.
2. Select the device name, and type the information about the AE title, the port.
3. Click [Add]. The entry will be added in the service list.



DICOM storage commitment setting items are described as follows:

	Name	NOTE
Configure new service	Device Name	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.
	DICOM 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(s)	Reserved feature.

	Name	NOTE
	Timeout	Value: 5-60s, in increments of 5, and 15 by default. After image storage commitment is sent, the system will close the connection with the server.
	Associated Storage Service	The associated storage server is preset before storage commitment, only after the exam is sent out, can storage commitment be created.
	Add	Add the DICOM service to the service list.
	Cancel	Click to cancel the parameter setting.
	Update	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.
Service list	Delete	Click to delete the selected service in the service list
	Default	Reserved feature.
	Verify	Click to verify if the two DICOM application entities are normally connected.
	Exit	Click to exit the screen.

**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.

### 11.1.3.6 Query/Retrieve

1. Select [Setup]→DICOM/HL7]→[DICOM Service Setting]→[Query/ Retrieve] to enter query/retrieve page.
2. Select the device name. The select device is from the DICOM server. Type the information about AE Title and the port.
  - 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 [Cancel] to cancel changing.
  - Select an item in the service list, and click [Delete] to delete the service.
  - Select an item in the service list, and click [Default] to set the server to be the default service.
3. Select an item in the service list, and click [Verify] to verify the connection.

**DICOM Service**

*// CONFIGURE THE NEW SERVICE*

Device:  Service Name:  AE Title:  Port:

Maximum Retries:  Interval Time(Sec):  Timeout(Sec):   TLS

*// SERVICE LIST* Add Cancel Update

Device	Service Name	AE Title	Port	Default

◀ ▶

Delete Default Verify Verification is required! Exit

DICOM query/retrieve setting items are described as follows:

	Name	Description
Configure new service	Device Name	Select the name of a device that can be added (including the local).
	Service Name	Default is server-query/Retrieve, 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(s)	Reserved feature.
	Timeout	Value: 5-60s, in increments of 5, and 15 by default. The connection is disabled if there is no image and information retrieving in 15 seconds after the user receiving the information or the image.
	Add	Add the DICOM service to the service list.
	Cancel	Click to cancel parameter preset.
	Update	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.
Service list	Delete	Click to delete the selected service in the service list
	Verify	Click to verify if the two DICOM application entities are normally connected.
	Default	Set the query/retrieve server as the default. Select an item in the service list, click [Default] and you can see "Y" in the Default column.

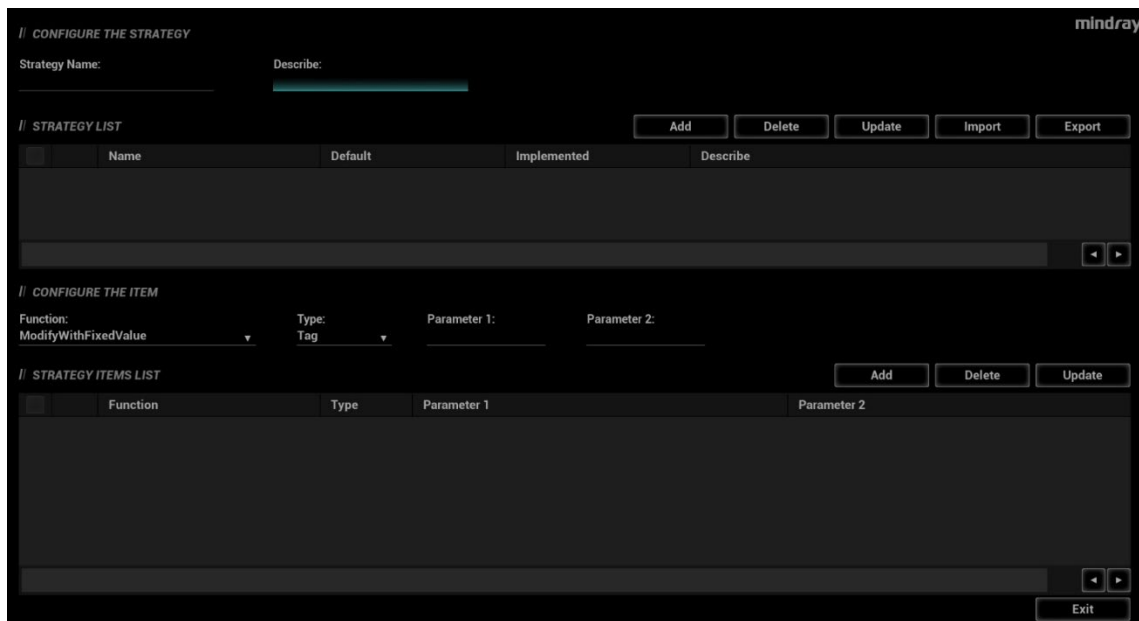
Name	Description
Exit	Click to exit the setup screen.

### 11.1.3.7 HL7 Query Service Preset

HL7 refers to the medical information exchange protocol on the seventh layer (application layer) of the Model of the Open System Interconnection published by ISO. It is established by Health Level Seven International in 1987. HL7 is mainly used for standardizing the communication between HIS/RIS system and the other devices, reducing the information interconnection costs among hospitals, and improving the data usability for hospital information system.

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

1. Select [Setup]→[DICOM/HL7]→[DICOM Service Setting]→[HL7Query] to enter the page.
2. Select device in the drop-down list, the available devices are services already set in the system, enter the information.
  - 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 [Cancel] to cancel changing.
  - Select an item in the service list, and click [Delete] to delete the service.
  - Select an item in the service list, and click [Default] to set the server to be the default service.



HL7 service setting for Worklist is described as follows:

Name	NOTE	
Configure New service	Device Name	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.

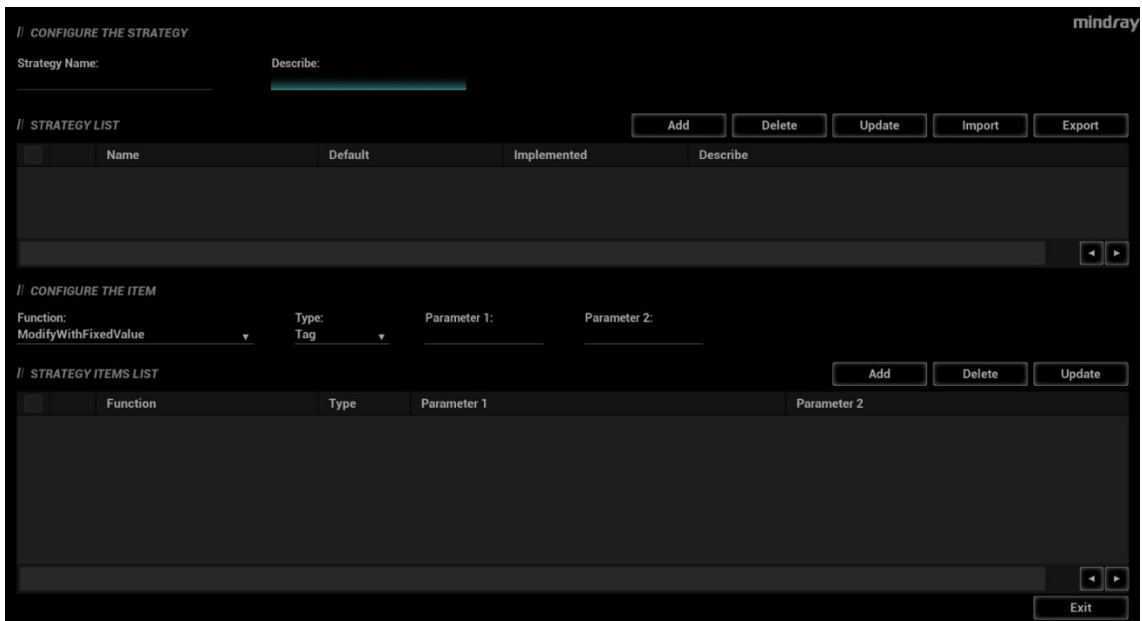
Name		NOTE
	Interval Time(s)	Reserved feature.
	Timeout	Refers to time after which the system will stop trying to establish a connection to the service. Value: 5—60s, in increments of 5, and 15 by default.
	Listen Mode	This function enables the ultrasound system to use the listen port for data receiving.
	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.
	Add	Click to add the Worklist service to the service list.
	Cancel	Click to cancel the parameter setting.
	Update	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.
Service list	Delete	Click to delete the selected service in the service list.
	To set default server	Select an item in the service list, click [Default] and you can see “Y” in the Default column.

### 11.1.3.8 Others

You can configure different type of DICOM services in different scenarios.

## 11.1.4 DICOM Strategy Preset

On the DICOM/HL7 preset screen, click [Set DICOM Strategy] to enter the strategy preset screen.



DICOM strategy preset items are described as follows:

	Name	Description
Configure The Strategy	Strategy Name	The strategy name is limited to 32-100 characters. Cases including duplication of name, comma and leaving a blank are forbidden.
	Describe	Description of the strategy.
	Add	Add the DICOM strategy to the strategy list
	Delete	Click to remove the DICOM strategy from the strategy list.
	Update	Select an item in the strategy list, change the parameters in the above area, and click [Update] to update the item in the strategy list.
	Import	Import DICOM strategy.
	Export	Export DICOM strategy.
Configure The Item	Function	Select function of strategy item.
	Type	Select type of strategy item.
	Parament 1	Set the parameter according to needs. The maximum character length is 64.
	Parament 2	Set the parameter according to needs. The maximum character length is 64.
	Add	Add the DICOM strategy item to the strategy item list
	Delete	Click to remove the DICOM strategy item from the strategy item list.
	Update	Select an item in the strategy item list, change the parameters in the above area, and click [Update] to update the item in the strategy item list.

## 11.2 DICOM Verifying

To verify connectivity (not essential), click the [Verify] button on the Storage, Print, Worklist, MPPS, Storage Commitment and Query/Retrieve pages respectively.

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.

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.

## 11.3 DICOM Services

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.

### 11.3.1 DICOM Storage

DICOM Storage is used to send images (single-frame or multi-frame) or structured report to the DICOM storage server for storage.



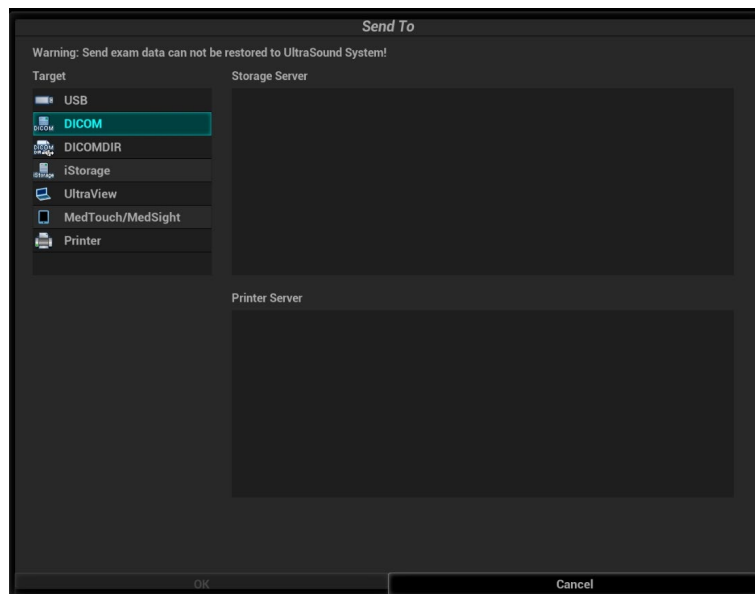
Follow the procedures below when setting DICOM storage.

Send images on iStation/Review/main screens

(1) 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).
- Press <Review> to enter the Review screen. Click to select a thumbnail or the cine. (press <Ctrl> or <Shift> to choose more).
- On the main screen, select a thumbnail or the cine.

(2) Click  in the top-right part or [Send to] to bring up the following 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].

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. The procedure is as follows:

- (1) Define the key. For details, see Chapter 10.2.8 Auxiliary Output Function.
- (2) Set a default storage server:
  - a) Enter the DICOM Service Preset screen via “[Setup]→[DICOM/HL7] → [Set DICOM Service].”
  - b) Select a storage server in the Service List and click [Default]. You will see “Y” marked in the Default column.
  - c) Click [Exit] to exit the page and return to the Setup menu, then click [OK] on the Setup menu to make the preset take effect.
- (3) Press the key to send the image or the cine to DICOM storage.

To send images to storage after an exam ends

- (1) Open “[Setup]→[System] →[General]” and then check “Sending/printing Image After End Exam” in the Patient Info area.
- (2) Enter DICOM preset page. Click “Storage” to preset the default storage server.
- (3) Start the ultrasound exam scan. Click [End] to send the image or the cine to DICOM storage automatically.

## Structured Report (SR)

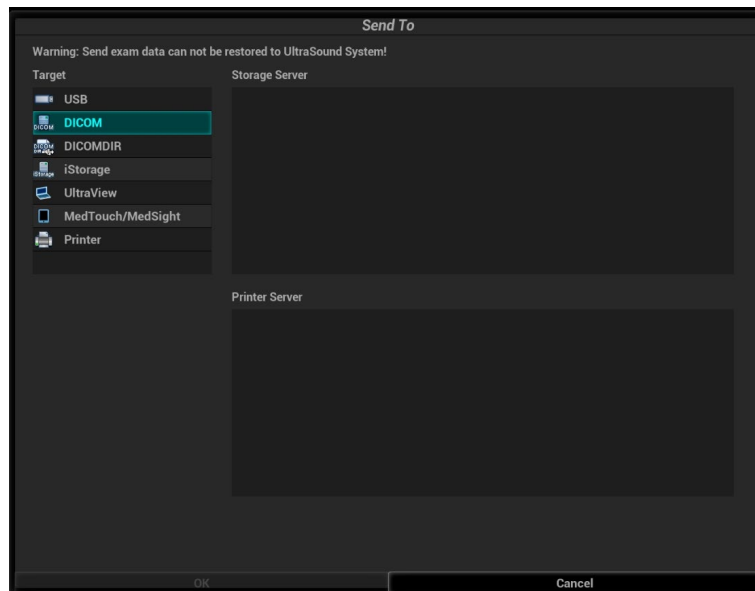
The system supports OB/GYN structured report, Cardiac structured report, Breast structured report, Abdomen structured report, Small Parts structured report and Vascular structured report.


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 and breast;
- 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 OB/GYN/Cardiac/Vascular/Abdomen/Breast/Small Parts 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 or vascular) measurements:
4. Save the image or the cine.
5. End an exam
6. Click [Send Exam] on iStation page. The following figure appears:



7. Select DICOM in the storage server list, and select a server in the “Storage Server” list.
8. 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.

## Encapsulate PDF

Encapsulate PDF refers to the PDF file is encapsulated in DICOM IOD.

Encapsulated PDF is sent by following the procedures below:

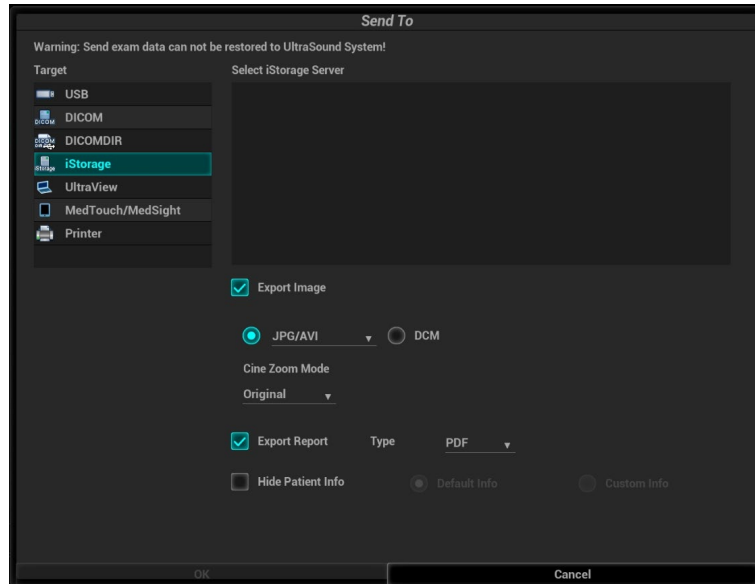
- Send in the unit of single exam;
- The exam with the state of *End*, *Cancel* or *Stop* cannot be sent as encapsulated PDF.
- Check “Encapsulate PDF” in the storage service preset;
- If there is an exam result in the report template, this type of exam should be performed.

Sending the exam or archiving the exam can send the encapsulated PDF file.

## Unload DCM file

The image can be unloaded to DCM format and send to the storage media, iStorage.

1. Select the image, and click  to enter the page.
2. Select "iStorage" to export the image in DCM format. See the figure below:



3. Click [OK] to send DCM format file to the external media.

## 11.3.2 DICOM Print

DICOM Print is used to send images to the DICOM print server for printing.

Perform the following procedures after configuring DICOM print.

Print images on iStation/Review/main screens

1. Select the image, the cine and the exam and send them. Operations are the same as for DICOM storage.
2. In the *Send To* dialog box, select a DICOM print server. (For the dialog box, see DICOM Storage).
3. Click [OK] to send the image and begin printing.

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. For details, see Chapter 10.2.8 Auxiliary Output Function.
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 print images for storage after an exam ends

- (1) Open "[Setup]→[System] →[General]" and then check "Sending/printing Image After End Exam" in the Patient Info area.
- (2) Set a default print server.
- (3) 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.

## 11.3.3 DICOM Worklist/HL7 Query

For details, see Chapter 4.1.2.2 WorkList/HL7 Enquiry.

## 11.3.4 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 resend automatically.

## 11.3.5 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.

Storage commitment after sending images on the iStation screen.

1. Select the image, the cine or the data, and send it.
2. Click to select "DICOM" in the Target box on the left side, and then select the DICOM storage server in the Storage Server box on the right side.
3. Click [OK] to start sending. 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.

To send storage commitment automatically after an exam ends

1. Open [Setup] → [System] → [General], then check "Sending/printing Image After End Exam" in the Patient Info area.
2. Select "DICOM Service Preset"---"Storage". Set the storage server to the default, and click "Storage Commitment" to connect to the storage server.
3. 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.

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 "√" marked in the list below .

Tip:

Storage commitment is confined to the whole exam. Not each image sending can be indicated.

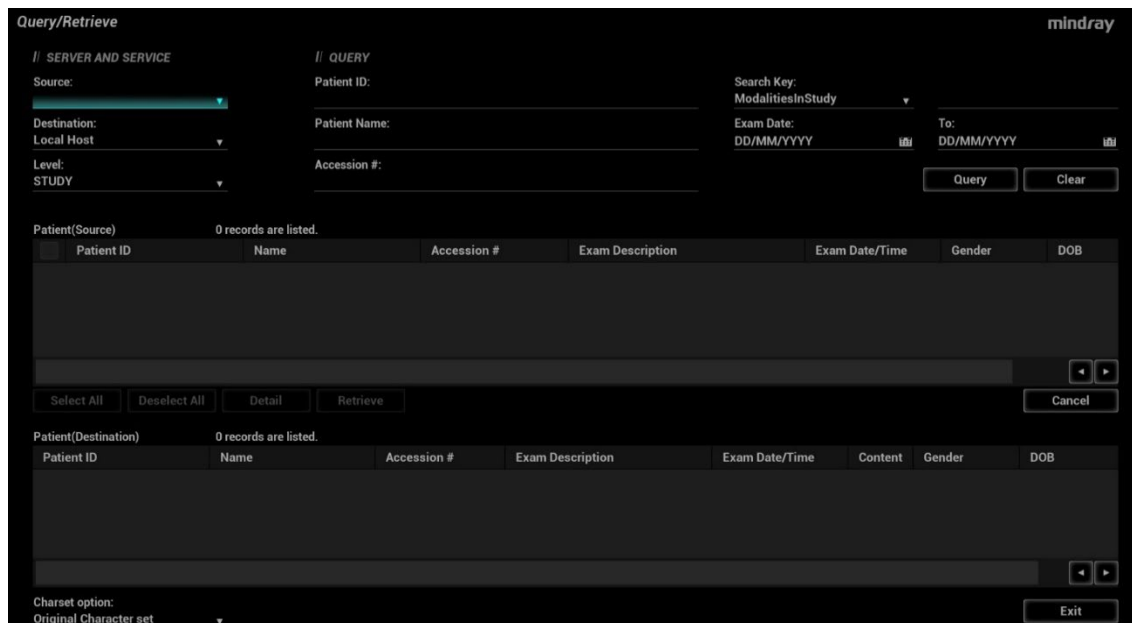
**NOTE:** Multi-frame storage is not allowed if "Allow Multiframe" is not selected ([Setup]→ [DICOM/HL7] → [Set DICOM Service] →"Storage"). Even if there is a multi-frame file in the exam to be sent, only single-frame image storage will be performed. After the storage is complete, there is no "√" marked in the list of the iStation screen.

## 11.3.6 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. Open the iStation screen: press <F2 iStation> on the control panel.
2. Click [Query/Retrieve] to open the screen.



3. Select the server in the “Server and Service” area (both the source and the destination) and query level.  
 Tips: 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.  
 Click [Clear] to empty the entered query information.
5. Click [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.  
 Click [Select All] to select all the patient records in the list.  
 Click [Deselect All] to deselect all the patient records in the list.
7. Click [Retrieve] to retrieve the patient records in the DICOM query/retrieve server to the local machine.
8. Click [Exit]. The retrieved patient records are listed in the iStation screen.

## 11.4 DICOM Media Storage (DICOMDIR Review)

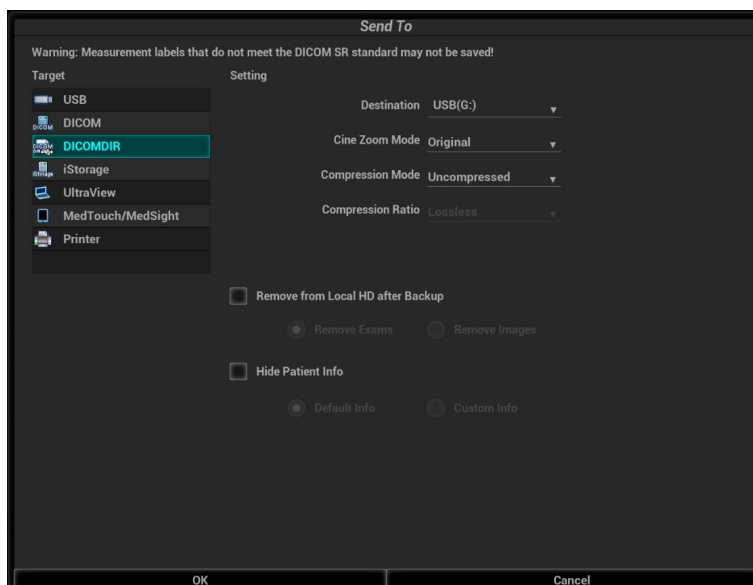
Patient data in the ultrasound system can be saved on external media in DCM format, while DCM files can be accessed in the ultrasound system.

DICOM media storage and DICOMDIR 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

### Media Storage

1. Select patient records in the iStation screen.
2. Click [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. Click [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.

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.


Media review:

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].

### Data Restore

After the DICOM format data are saved to external media, restore the data to the ultrasound system.

1. Connect the external media containing DCM files to the system.
2. In iStation, review the data stored on the external media.
3. Select the data to be restored in iStation.
4. Click  on the iStation screen.

**NOTE:** Only system-accessible media can be selected.

## 11.5 Showcase Recording

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.

**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.

# 12 Setup

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.

**CAUTION:** 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 [OK] 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.

## 12.1 System Preset

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

The screenshot displays the Mindray Setup interface. On the left is a navigation menu with categories like System, Measure, Comment, iWorks, Stress Echo, DICOM/HL7, Network, Print, Maintenance, Security, and About. The 'System' category is selected, showing sub-options: Region, General, Image, Application, OB, Key Probe, iConsole&Footswitch, Key Board, Gesture, Output, Access Control, Scan Code, and Workstation. The main area is titled 'HOSPITAL INFORMATION' and contains fields for Name, Address, Website, Location, Telephone, Fax, Medical Director, and Associate. Below this is the 'LANGUAGE AND TIME' section, which includes Language (English), Time Zone (UTC Dublin, Edinburgh, Lisbon, London), System Date (14/12/2020), Date Format (DD/MM/YYYY), System Time (19:46:49), and Time Format (24 Hour). There are also 'Load Logo', 'Time Synchron', 'OK', and 'Cancel' buttons.

Page	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, system 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.
Key Probe	To assign the functions to the buttons on the probe.
iConsole&Footswitch	To assign functions to the foot switch and user-defined keys.
Key Board	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.
Workstation	To set the Workstation quick key

## 12.1.1 Region

Open the Region page via [Setup] → [System] → [Region].

Item	Description
Hospital Information	To set the hospital-relevant information such as name, address, telephone, and so on.
Language	To display the language.
Hospital Logo	Import image for logo loading. Or. Delete imported image. <b>NOTE:</b> For a better display effect, please try to use an image with 400*400 pixels.
Time Zone	To select the time zone.
Time Format	To select the time format.
Date Format	To set the date format.
System Date	To set the date for the system.
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.
Time Sync	To assign a time server and make the time of the ultrasound machine consistent with the server.



## 12.1.2 General

Open the page via [Setup] → [System] → [General].

Type	Item	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 patient height and weight.
	Surface Formula	To set the surface formula.
	Font size (for Storage)	To set the font size of the patient information on saved images.
Freeze Setting	Status after freeze	To set the system state after the image is frozen.
Storage Volume	Storage Beep Volume	Set the key volume for saving single / multi-frame image.
Exam Setup	Status after exam ends	To set the system status when an exam ends.
	Auto Screenshot of Report Preview Page by Page	After selected, perform measure application and save single frame image, and then end the patient exam, the system will save the report preview image in iStation.
	Auto Screenshot of Report Page by Page	After selected, perform measure application and save single frame image, and then end the patient exam, the system will save the report image in iStation.
	Sending/printing after End Exam	Select whether to automatically archive the exam data to the DICOM server for storage/print.
	Sending SR after End Exam	To send the structured report when an exam ends.
	Disable Recycle Bin	After checking this option, the deleted data will not go to the recycle bin. Note: after disabling the recycle bin, the deleted data cannot be recovered.
	Maximum number of exams to be kept	To set the maximum number of exams to be kept in iStation.
	Remind exams backup after	To set number of days to remind the operator of exam backup.
Display	LCD	To set the brightness and the contrast of the main screen, or restore to the default.
	Brightness auto adjustment	To set the brightness/contrast of the main screen and the touch screen according to the conditions.
	TouchPanel	After selection, the system restores the touch screen settings back to factory.

Type	Item	Description
Screen Saver	Enable Screensaver	Select the different saver methods to the system. After enabling the screen saver, check “Mindray” to select the image from the system. Or click [Preview] to select the image on your own. To set the waiting time before the system enters dormancy status in the drop-down list beside “Wait”. The system enters screen saver automatically if the system waiting time exceeds the screen saver already set.
	Enable Standby	The system enters standby status automatically if the system waiting time exceeds the screen saver already set and standby time.
iVocal	Enable Voice Response	To enable the voice response function.
	Automatically shut down waiting time	To automatically disable the voice response function after the setting time.

### 12.1.3 Image Preset

Open the page via [Setup] → [System] → [Image].

Type	Item	Description
Reset Config.	Probe	To set the default probe model for the system from the drop-down list. The default parameters are applied to the new probe if checking <i>Use the default setting when start a new exam.</i>
	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.
Parameter	Steer	To set the steer mode in B + Color + PW/CW imaging mode. C&(PW/CW): select to adjust the sample volume in color mode and sample line in PW or CW mode together. C/(PW/CW): select to adjust the sample volume in color mode and sample line in PW or CW mode separately.
	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.

Type	Item	Description
	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 synchronize the invert status of PW/CW mode with that of Color mode.
	Display Transducer SN	To set whether to display the transducer SN in the imaging screen.
	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 imaging	Power line frequency	Select the power frequency.
Tissue Tracking QA	Segment model	Set the cardiac segment model: 16 or 17.
Image Parameter Display	/	To select the parameters under each mode to be displayed in the real-time imaging screen
ZoneVue	ZoneVue	To set whether to display "ZoneVue" parameter in the parameter adjusting area.

## 12.1.4 Application

Open the page via [Setup] → [System] → [Application].

Type	Item	Description
Comment	Clear comments while unfreezing image or changing probe/exam	To set whether to clear comments after unfreezing image or changing probe or exam.
	Clear bodymark upon unfreeze	To set whether to clear body marks after unfreezing image.
	Voice comment enabled	To set whether to enable voice comment feature.
Intelligent Input	Input Method Association	To set whether to enable intelligent input method.
Preview Thumbnail Image	Preview Thumbnail Image	To set whether to magnify the thumbnail image when the cursor is within the scope of the thumbnail image.

On this page, you can also set the measurement ruler and relevant information. For details, see the Operator's Manual [Advanced Volume].

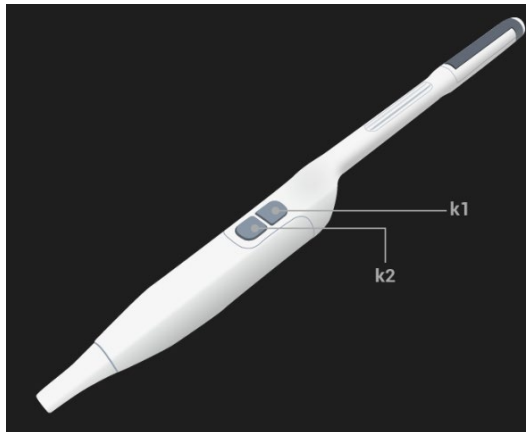
## 12.1.5 OB Preset

Open the page via “[Setup] → [System] → [OB].” On this page, you can set the gestational age formula, fetal growth formula, fetal weight formula and relevant information. For details, see the Operator’s Manual [Advanced Volume].

## 12.1.6 Key Probe Preset

Open the page via “[Setup] → [System] → [Key Probe].”

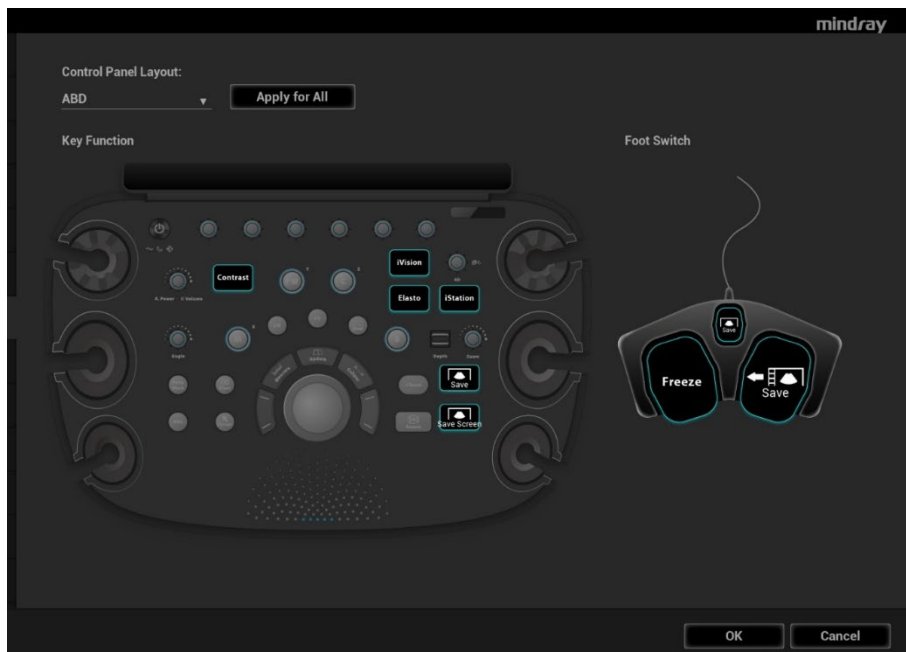
On the page, you can preset the functions of buttons on the probe ELC13-4s.



Type	Item	Description
Probe Key Function	K1	To set the function of K1 button.
	K2	To set the function of K2 button.

## 12.1.7 iConsole&Footswitch

Open the page via “[Setup] → [System] → [iConsole&Footswitch].”



Select the application from the drop-down list of the “Control Panel Layout”. Different applications have different set of key configurations by default.

Click [Apply for All] to apply the key configuration of the current application to all applications.

### Key function setting

You can set the functions for the 6 blank keys.

To assign a function to a key:

- a) Click to select a desired key. The system enters the function assignment page.
- b) Click to select a function in each column.
- c) Click [OK] to complete the function setting.

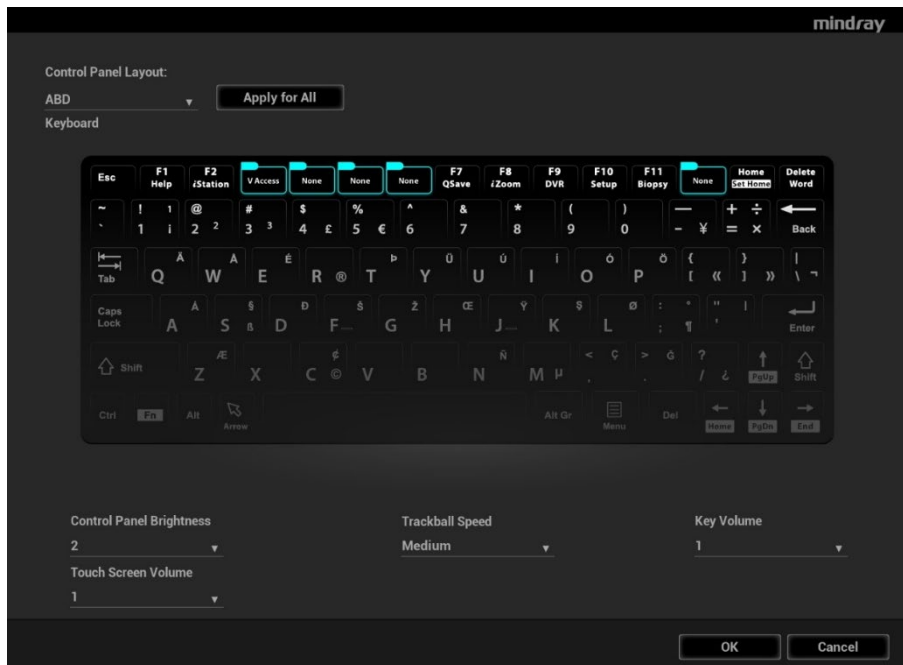
### Foot switch function setting

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

After completing the configuration, each of the footswitch can be used according to its function.

## 12.1.8 Key Board

Open the page via “[Setup] → [System] → [Key Board]”.



Select the application from the drop-down list of the “Control Panel Layout”. Different applications have different set of key configurations.

Click [Apply for All] to apply the key configuration of the current application to all applications.

You can set the functions for the F keys of the key board. The method is similar to setting iConsole&Footswitch.

### Other Settings

Item	Description
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.
Trackball Speed	To set the speed of the trackball when moving the trackball.
Control Panel Brightness	To set the brightness for control panel key.

## 12.1.9 Gesture

Select [System]→[Gesture] to enter the page.

1. Click to select the desired gesture 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 [OK] to complete the function setting.

See Chapter 3.7.4 The Display of Touch Screen and Its Operation for the operation to two-figure gesture on the touch screen

## 12.1.10 Output

Select [System]→[Output] to enter the page.

Type	Item	NOTE
AVI encode	Encode quality	Set the image quality of uploaded AVI. The system uploads according to the settings. The higher the image quality is, the clearer the unloaded image is. The unloading speed become slower with the larger space.
	Operating System Compatibility	Set the uploading format of the AVI. The system uploads according to the settings. If checking "Mac OS", saving CIN files to USB flash drive as "MP4 Video".
	SendTo Frame Rate	Set whether to compress AVI file when uploading AVI file.
Analog output	Output Size	Select the output size: Classic or Standard.
	Output Mode	Select the format to output/separate the video format: NTSC or PAL.
Digital output size	Output size	Select VGA, HDMI output image size.
	Resolution	Select VGA, HDMI output image resolution.
DVR Output	Output Size	Select DVR recording area.
Retrospective Time 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 Time 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.
Clipboard	Clipboard Reload Save	Set whether to overwrite or save a copy of the original image after editing.
	Copy Position	Select the position to save a copy.

## 12.1.11 Access Control

Open the page via “[Setup] → [System] → [Access Control].”

For access control details, see Chapter 10.9 Administration.

## 12.1.12 Scan Code Preset

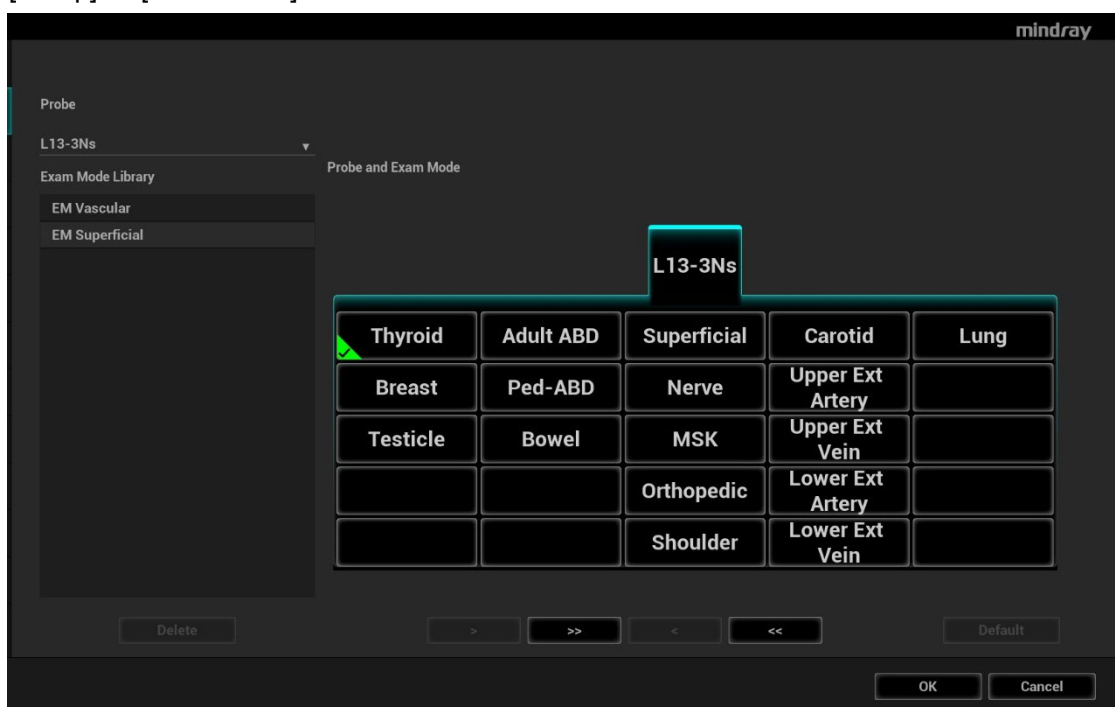
See Chapter Appendix A Barcode Reader for details.

## 12.1.13 WorkStation (Reserved)

This page is used to set the quick key for sending image or cine to Workstation.

# 12.2 Exam Mode Preset

Open “[Setup] → [ExamMode]” to enter the screen.



You can assign available exam modes for probes.

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 “√” in the top-left corner.

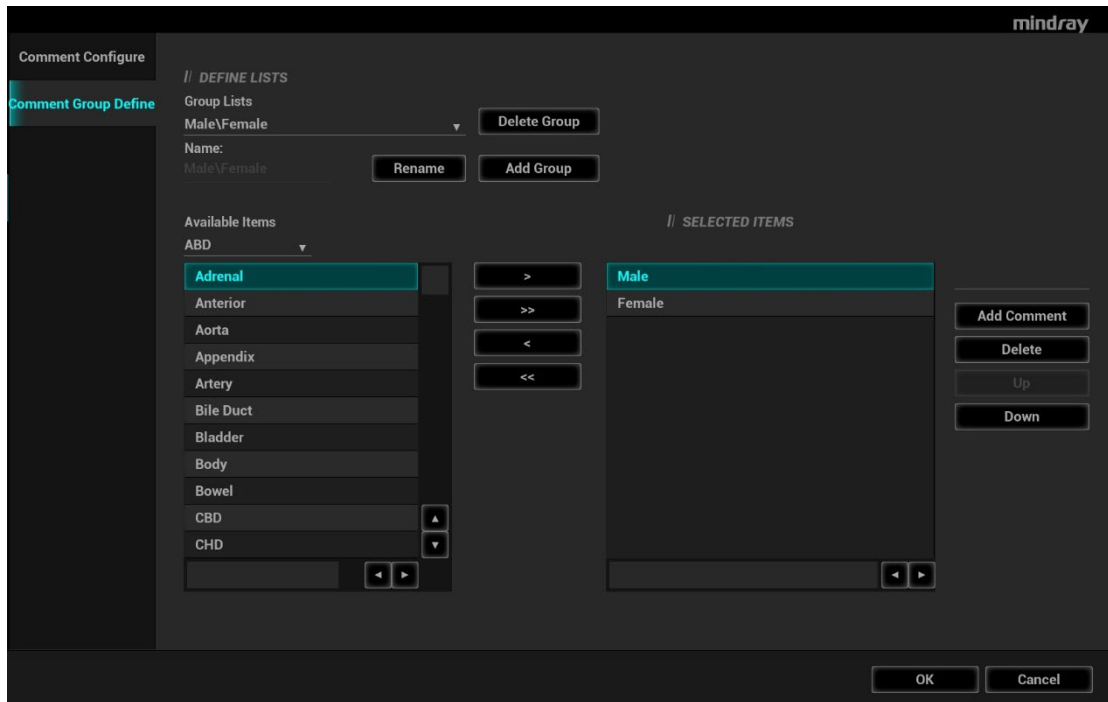
## 12.3 Measurement Preset

For details about Measurement Preset, see the [Advanced Volume].

## 12.4 Comment Preset

### Comment Configure

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.



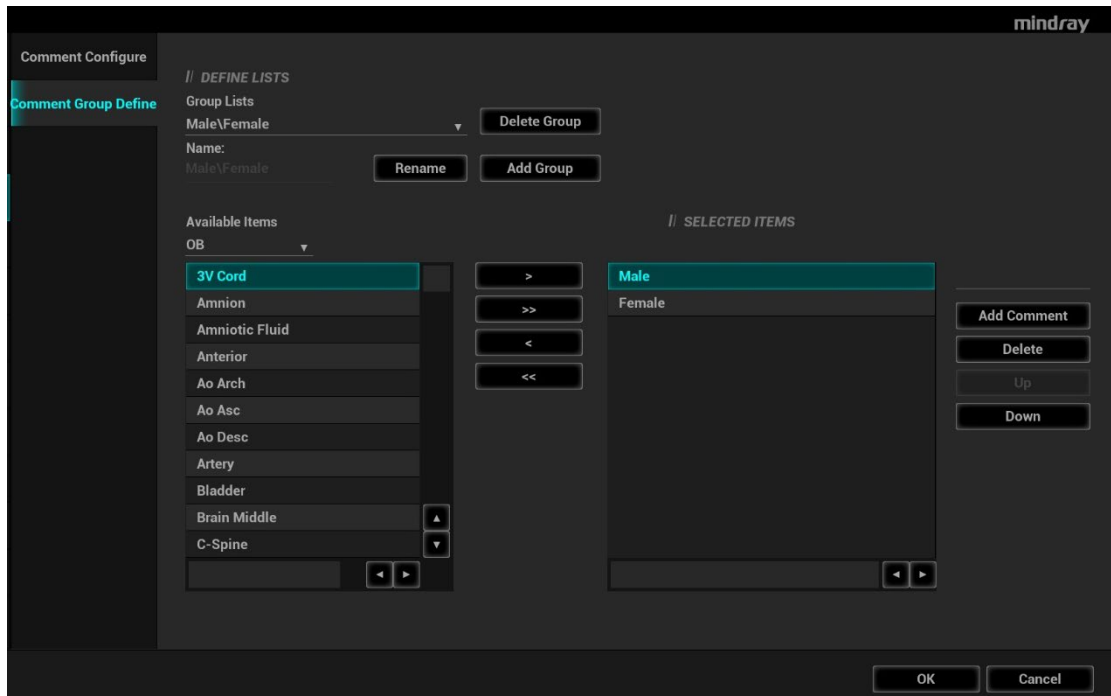
1. Add comments: directly enter user-defined comment texts, or select available items (select comment texts for the comment library or select comment in groups).
  - Directly enter user-defined comment texts: posit the cursor in the field box above [Add Comment], enter the text comment through the keyboard, 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.
2. 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.
3. 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.
  - 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.
- After you customize comments, click [OK] to confirm and exit the screen.

### 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.



- Add groups: position the cursor in the field box near [Lists Name], enter the group name through the keyboard, and then click [Add Group]. Then the entered group will be added to the Group Lists.
- Rename groups: select a user-defined group, enter the group name through the keyboard, and then click [Rename]. 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 [OK] to confirm and exit the screen.

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

## 12.5 iWorks Preset

For details, see Chapter Appendix B iWorks (Auto Workflow Protocol).

## 12.6 Stress Echo Preset

For details, see Chapter 5.15 Stress Echo.

## 12.7 DICOM/HL7 Preset

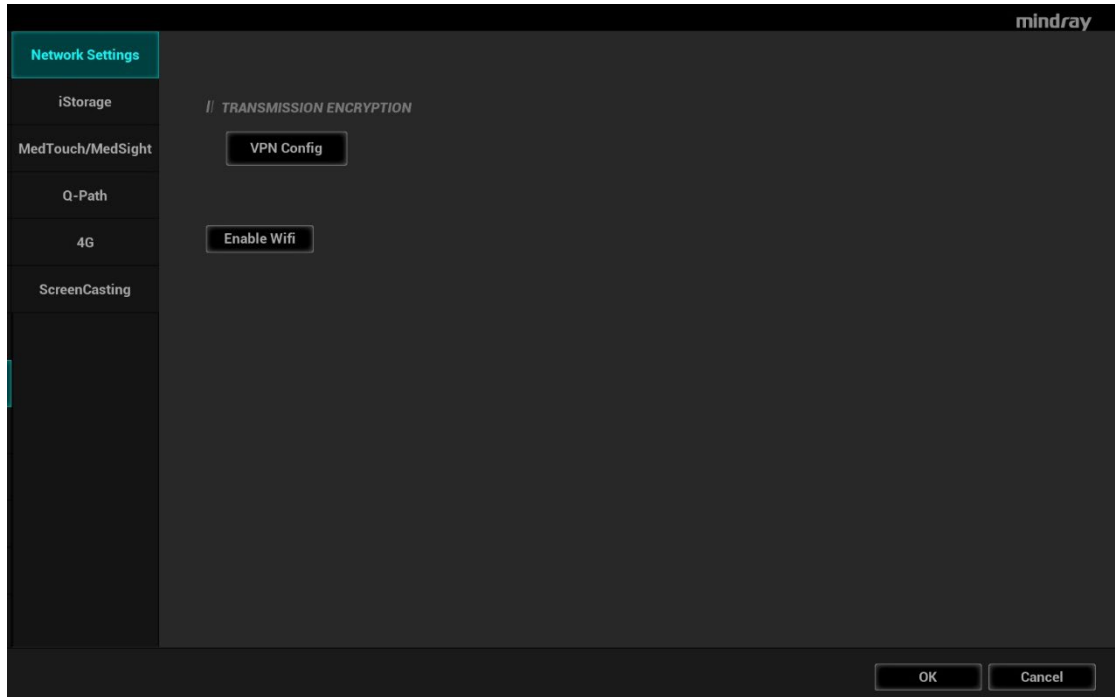
For details, see Chapter 11 DICOM/HL7.

## 12.8 Network Preset

Parameters for transferring are set here. For details of local IP setting, see Appendix C Wireless LAN.

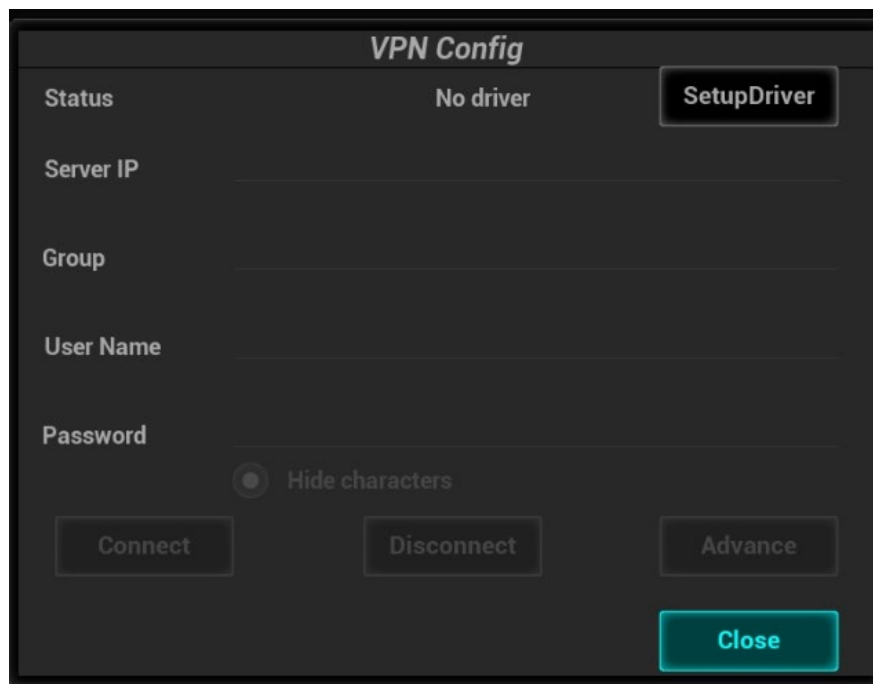
### 12.8.1 Network Settings

The Network Settings screen is as follows:



Transmission Encryption

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



Parameter	Description
Status	No driver: click [SetupDriver] to enter the "TAP-Windows 9.21.2 Setup" interface, and do as instructed. Ready: the VPN is ready for use. Advance: VPN Advance Configuration Connected: VPN is successfully connected. Disconnected: VPN is disconnected. Error: error connection.
Server IP	/
Group	
User Name	
Password	
Hide characters	The password is displayed as *.
Connect/ Disconnect	Connect or disconnect VPN.
Advance	Enters the "VPN Advance Config" interface. Reset: if the system does not respond after you click [Config], click [Reset]. Config: enters the "OpenConnect-GUI VPN client" interface. For details about the settings, please refer to the TAP manual. Note: after exiting the "VPN Advance Config" interface, you need to reboot the system; otherwise, you cannot connect VPN normally.
Close	Close the "VPN Config" interface.

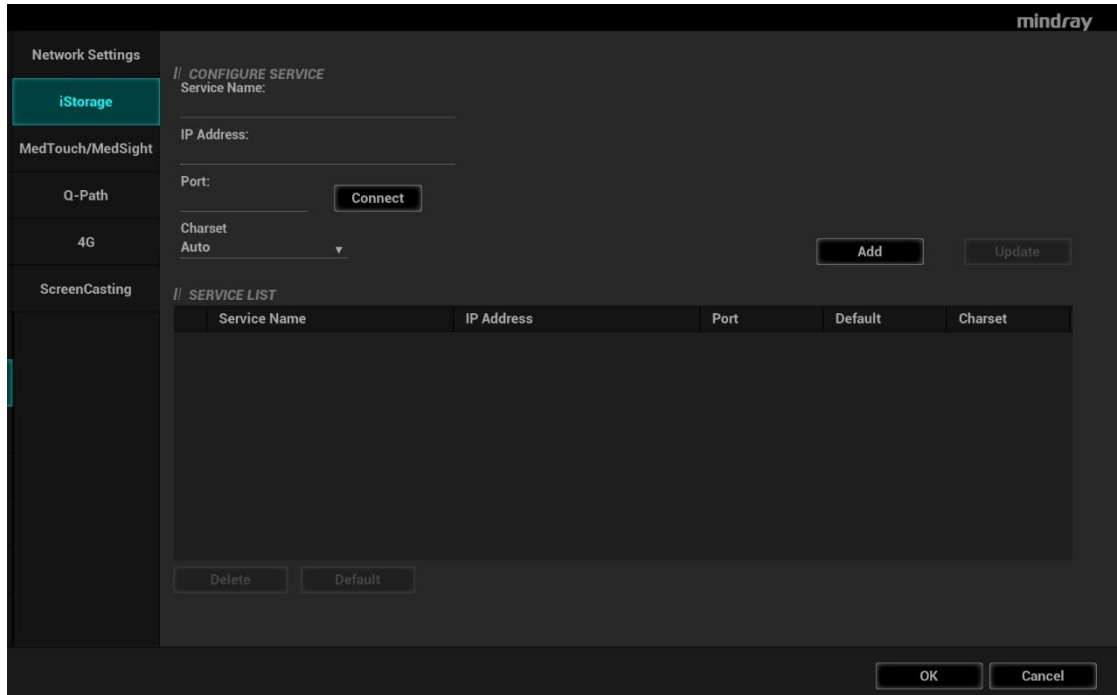
Turn on Wi-Fi function:

1. Select [Network Settings] page in Network Preset screen.
2. Click [Enable Wifi] in the screen.

## 12.8.2 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.

The iStorage screen is as follows:



Name	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.

Add an iStorage service

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

Modify a network service

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.

### 12.8.3 MedSight Preset

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

### 12.8.4 Q-Path Preset

See Chapter 10.10 Q-Path for details.

## 12.8.5 4G (Reserved)

The Ultrasound system can be connected to the 4G network.

The configuration steps are as follows:

1. Install the 4G device, and check that the 4G network icon is displayed on the bottom right corner.
2. Open the page via "[Setup] → [Network] → [4G]."
3. Click [Open] to enable the 4G function.

After opening the 4G function, the [GetInfo] button is highlighted. You can click [GetInfo] to check the 4G information of the current 4G device.

## 12.8.6 ScreenCasting

The screen of the ultrasound system can be casted on other devices in real time.

Before casting, ensure that the device is allowed to be casted, and the device and ultrasound system are connected to the same wireless network.

1. Open the page via "[Setup] → [Network] → [ScreenCasting]."
2. Click [ScreenCasting] to enter the searching interface.
3. Select the target device, and click [Connect].
4. In the pop-up window, click [Yes] to allow pair device. And then the screen of the ultrasound system is casting on the device.

If you have any question, please contact the Service Engineers.

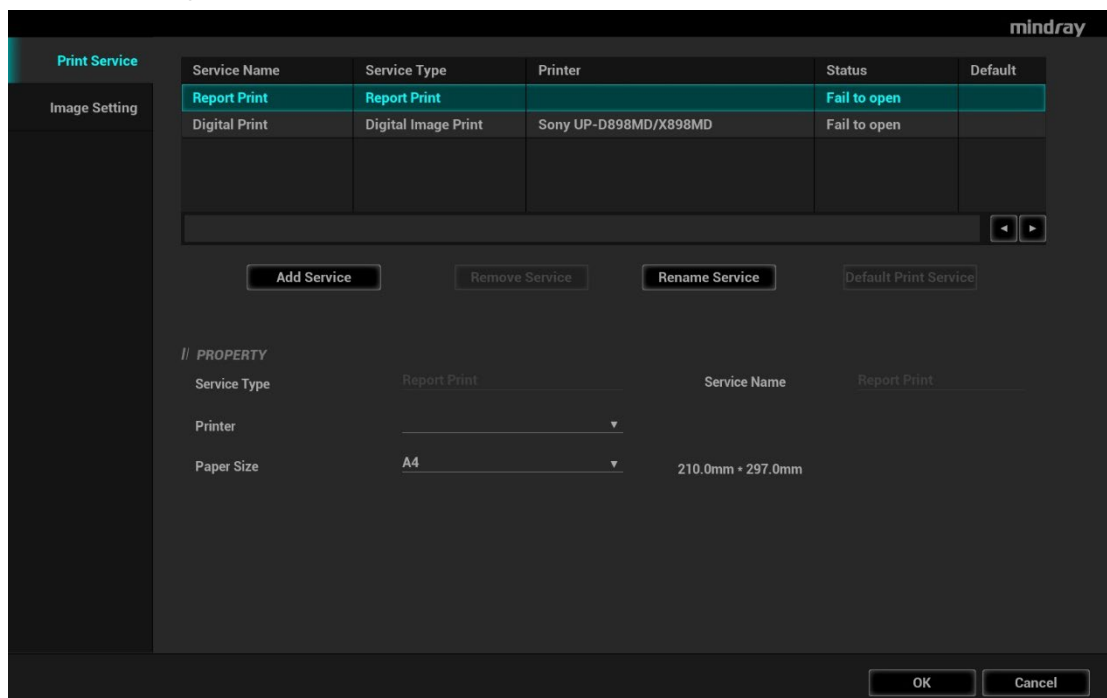
## 12.9 Print Preset

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

Click [Print] in the preset menu to enter.

Printer setting

The printer settings include print service and print driver.



- **Print Service Setting**
  - **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.
  - **Default print service:** click to set the selected print service as the default one.
  - **Property:** to preset print service properties.

For details about adding printers, see Chapter 3.6.3 Installing a Graph/Text Printer.

### 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.

## 12.10 Maintenance

In the Setup menu, select [Maintenance] to enter the screen.

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.

### 12.10.1 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 installed or installed).

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

### 12.10.2 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.

Procedures:

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

### 12.10.3 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.

Procedures:

1. Click [Import] to open the Load Data screen.
2. Select the imported file.
3. Click [OK], a progress bar will appear and the setup data is imported to the specified path.
4. To restore the factory setup data, click [Load Factory] on the right side of the screen.

## 12.10.4 Probe Check

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

- 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.

Notes: Each time a transducer is connected to the main system or activated, the users are recommended to implement probe check of transducer performance.

Before probe check, make sure the probe is clean and not being used for scan.

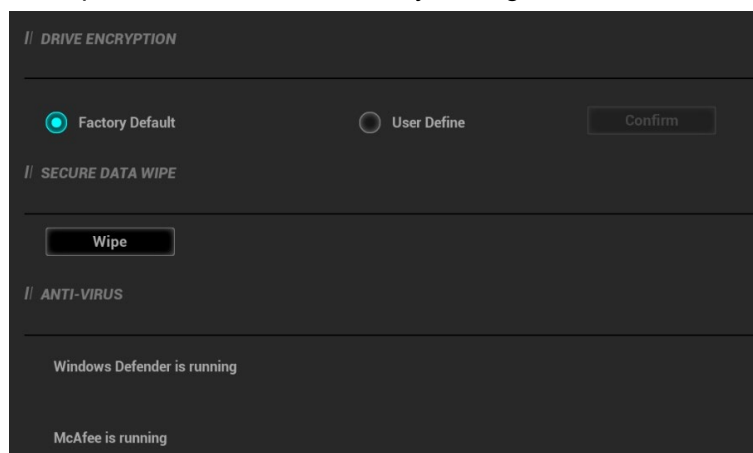
## 12.10.5 Other Settings

	Item	Description
Setup	Export Log	Export the log.
	Battery Manufacture State	Displays the battery state.
	Self-Test	Perform system self-test and restart the machine.
	Recover	Recover the ultrasound system (including Operating System and Doppler).
	Enter Windows	For this function, you need a one-time password, please contact the service engineer or your agent.
	Prepay Installment	Display the prepay installment information.
	Start/Stop WinProxy	Cursor debug interface.
	Fast Startup	To speed up the startup process. Note: After installing McAfee, please disable the Fast Startup function to avoid McAfee failure.

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

## 12.11 Security

Click [Security] on the Setup menu to enter the security-setting screen.



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.
- 1) Select [User Define]. If the patient data are already stored in the hard disk, the system prompts a message to inform you about the already existed patient data (if no patient data are stored in the hard disk, perform steps 5 to 6 directly).
  - 2) Click [OK] to return to the Security screen, click [Wipe], and the system prompts a confirmation message.
  - 3) Click [OK], and the system prompts a confirmation message.
  - 4) Click [Yes] to wipe the patient data.
  - 5) Select [User Define] and click [Confirm].
  - 6) Input the password and click [Confirm] to finish the password setting.

- Notes
1. If you want switch to Factory Default, perform steps 1 to 6 again. The password is the same as that of the User Define.
  2. When you set password, multi-language and Chinese characters are not supported.

## 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.

- Notes:
1. McAfee cannot be uninstalled after successful installation.
  2. After the option is installed, the system will be restarted. And after restart, the system installs McAfee automatically, which needs about one hour.
  3. 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.

## 12.12 System Information

Click [About] on the Setup menu to enter the system information screen. The "System Information" shows the information about the product type, manufacturer, configuration type, ECN/TCN, version number, MAC address, etc.


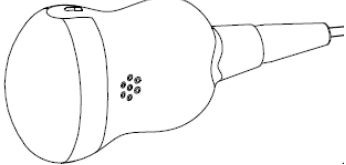

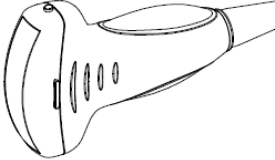
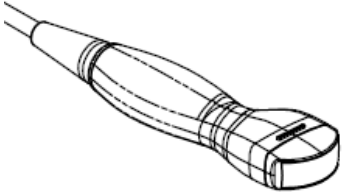

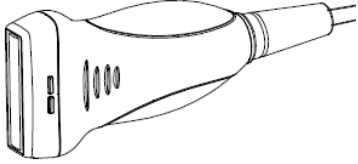

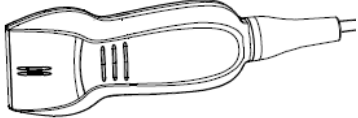

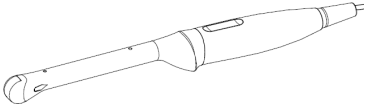
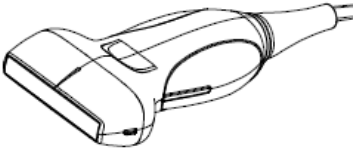
This screen displays the system software version, WLAN module FCC version and versions of other modules. You cannot edit the information, but only view them. The information varies depending on the system configurations and version.



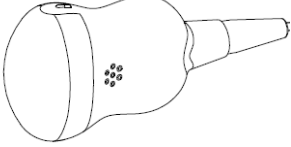
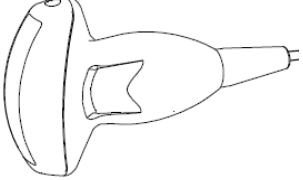
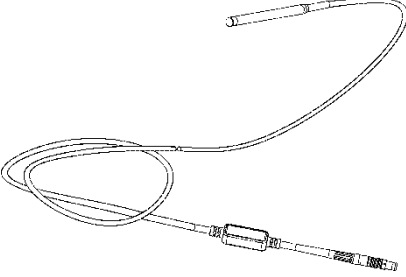
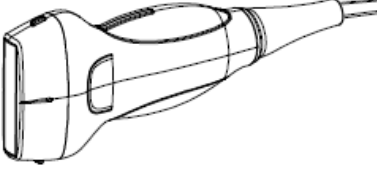
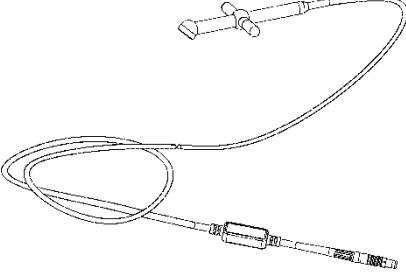
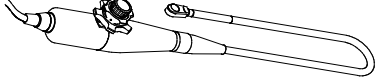
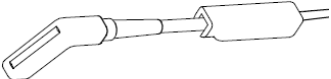
Log onto the system as Administrator, and click [Statistics] to enter the statistics screen, which shows the total exam numbers of each probe, application and operator.



# 13 Probes and Biopsy

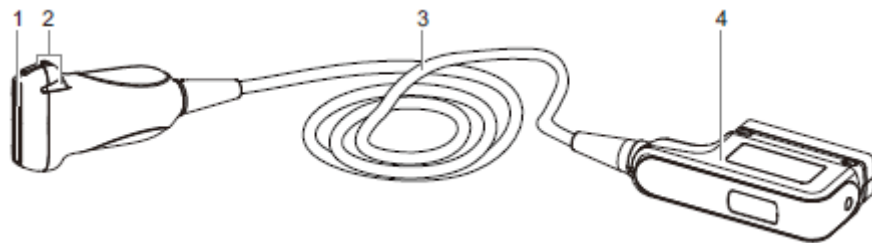
## 13.1 Probes

SC6-1s		SD8-1E	
C11-3s		SC6-1E	
C6-2Gs		SP5-1E	
L9-3s		SP5-1U	
L20-5s		DE11-3Ws	
V11-3Hs		L14-3Ws	

SP5-1s		ELC13-4s	
SD8-1s		SC8-2s	
CW5s		L13-3Ns	
CW2s		P7-3TU/P7-3Ts/P7-3TE	
L16-4Hs			

### 13.1.1 Probe Functions by Part

The basic structures and corresponding functions of probes are basically the same; take the following probe as an example.



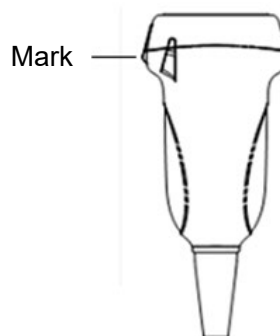
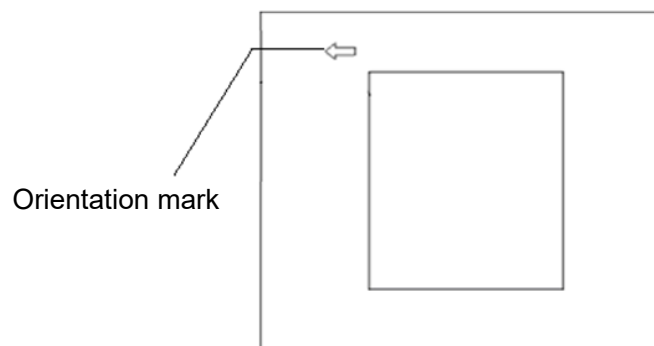
No.	Name	Function
<1>	Probe head	Converts the electrical signal into an ultrasonic signal, focusing the sound beams in a given direction; meanwhile, it receives the reflected ultrasonic signal and converts it into an electrical signal for transmission over the cable. The lens on the surface is the acoustic 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.
<3>	Probe cable	Transmits electrical signals between the probe body and connector.
<4>	Probe connector	Connects the probe and cable to the ultrasonic diagnostic system.

Tips:

The probes' structure marked <2> in the figure above may vary with the matched needle-guided brackets.

### 13.1.2 Orientation of the Ultrasound Image and the Probe Head

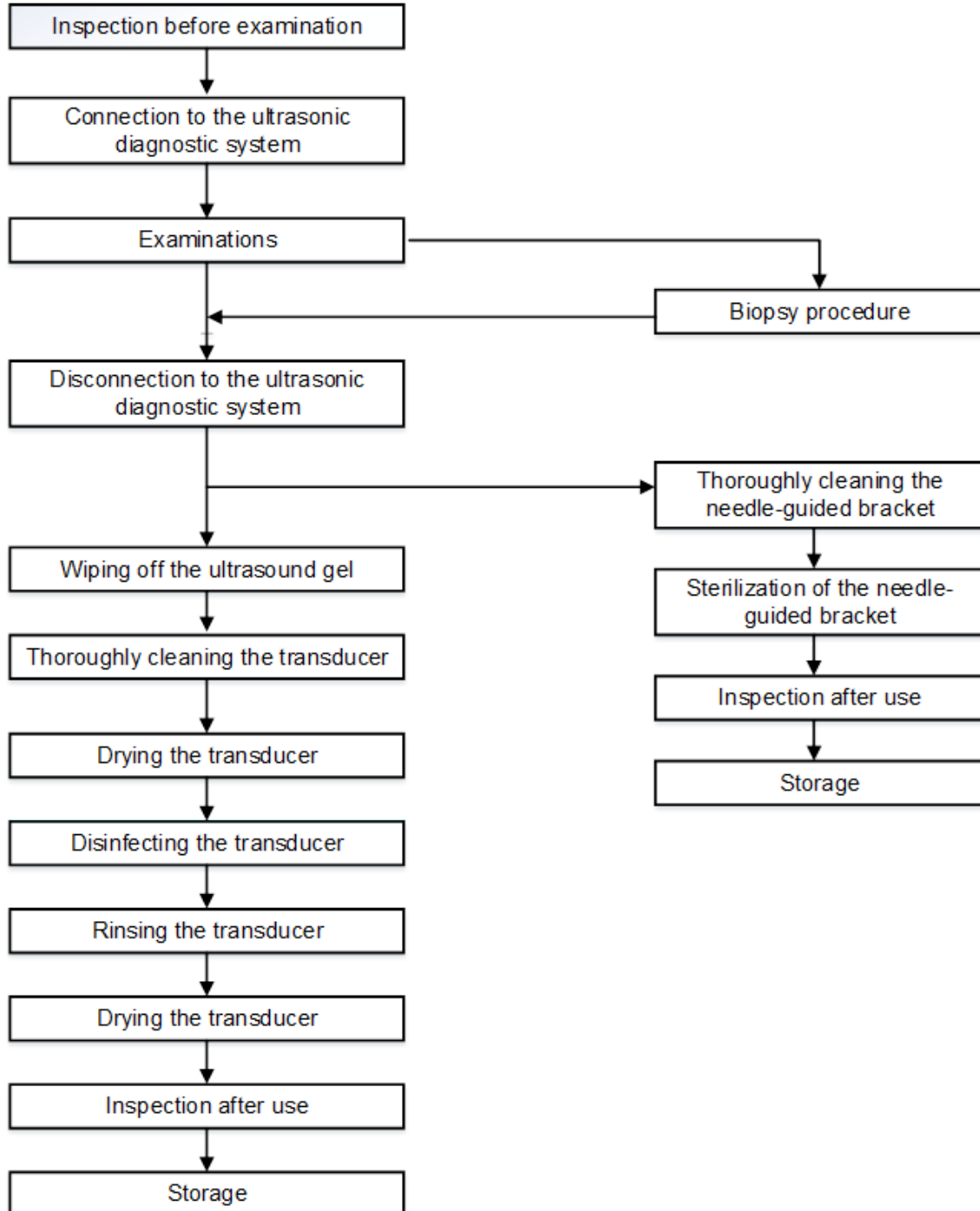
The orientation of the ultrasound image and the probe are shown as below. The "Mark" side of the ultrasound image on the monitor corresponds to the mark side of the probe. Check the orientation before the examination (Using a linear probe as an example).



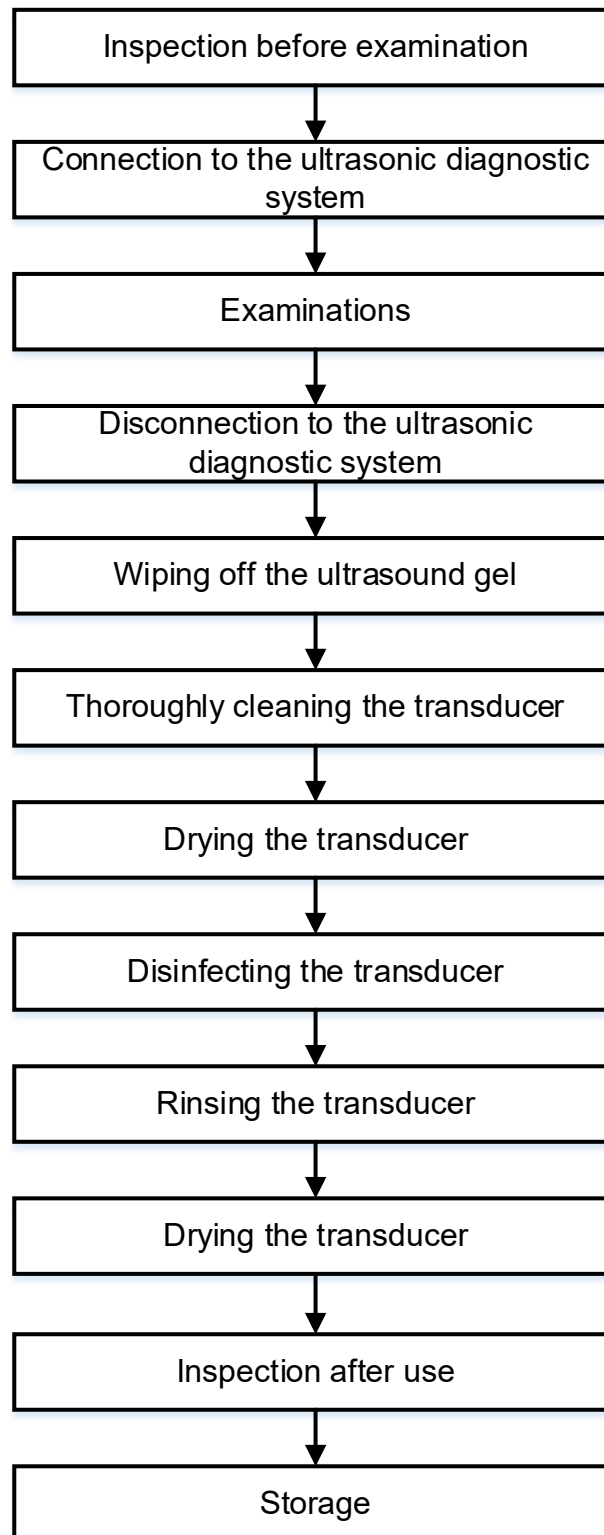
### 13.1.3 Procedures for Operating

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):



**WARNING:**

Thoroughly clean the probe and needle-guided bracket, then 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 to become sources of infection.

## 13.1.4 Wearing the Probe Sheath

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](mailto:info@civco.com)

<http://www.civco.com>



### CAUTION:

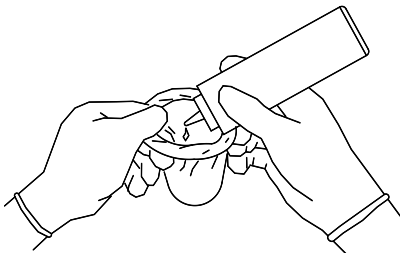
Be sure to cover the probe with a new (unused) probe sheath to prevent infection during examination. If the package of a probe sheath is open or broken, the sterilization of the probe sheath may not be sufficient. **DO NOT** use such a probe sheath.

The cover contains natural rubber latex and talc that can cause allergic reactions in some individuals.

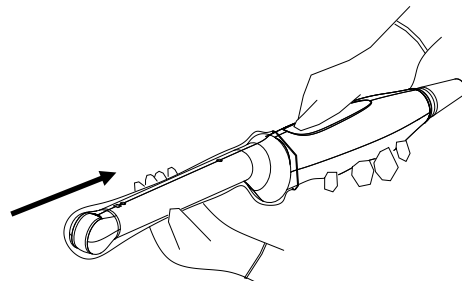
**DO NOT** use an expired probe sheath. Before using a probe sheath, verify whether the term of validity has expired.

Method (for reference only):

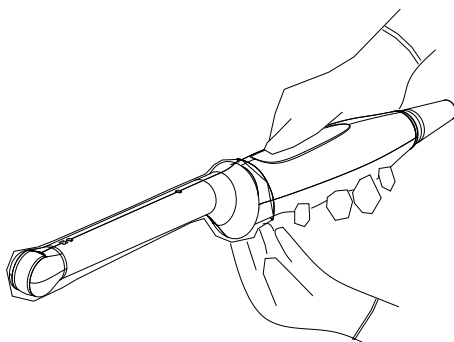
1. Place an appropriate amount of gel inside the sheath or on the probe acoustic lens. Poor imaging may result if no gel is used.



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.



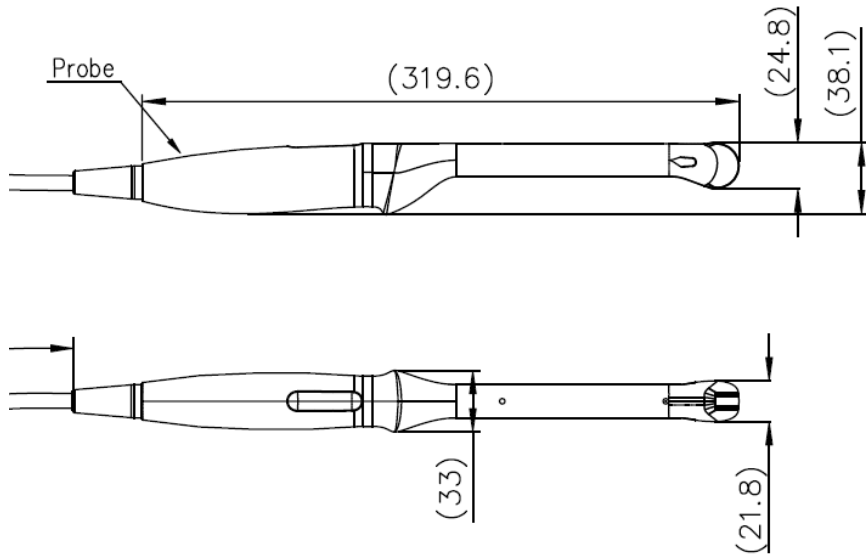
4. Inspect the sheath to ensure there is no hole or tear.

Refer to the following dimension table of all probes to choose the necessary probe sheath type.

Probe	Dimensions (mm)
C11-3s	L=96.4±10 W=32.8±3 H=25±2.5
C6-2Gs	L=117.4±11 W=39.4±4 H=21±2
CW2s	L=125±12 W=79.5±8 H=18.4±2
CW5s	L=98.3±10 W=11.2±2 H=11.2±2
DE11-3Ws	L=323.6±32 W=48±5 H=36.8±4
ELC13-4s	L=101.1±10 W=56.8±6 H=22±2
L13-3Ns	L=101.1±10 W=56.8±6 H=22±2
L14-3Ws	L=102.1±10 W=66.8±7 H=25.5±3
L20-5s	L=98±10 W=43±4 H=24.1±2
L9-3s	L=103.5±10 W=58.6±6 H=23.3±2
P7-3TE	L=1500±150 W=59.6±6 H=59.1±6
P7-3Ts	L=1500±150 W=59.6±6 H=59.1±6
P7-3TU	L=1500±150 W=59.6±6 H=59.1±6

Probe	Dimensions (mm)
SC6-1E	L=111.9±12 W=76.7±8 H=28±3
SC6-1s	L=111.9±12 W=76.7±8 H=28±3
SC8-2s	L=107±10 W=67.6±7 H=31±3
SD8-1E	L=122.4±12 W=77.6±8 H=53±5
SD8-1s	L=122.4±12 W=77.6±8 H=53±5
SP5-1E	L=102.6±10 W=38.2±4 H=30.4±3
SP5-1s	L=102.6±10 W=38.2±4 H=30.4±3
SP5-1U	L=102.6±10 W=38.2±4 H=30.4±3
V11-3Hs	L=319.6±32 W=33±3 H=38.2±4
L16-4Hs	L= 41.8 W=34.6 H=11.5







The above is a dimension illustration of the V11-3Hs probe.  
 You can select the probe sheath according to the actual application situation.


### 13.1.5 Probe Cleaning, Disinfection and Sterilization

Before and after 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.

 **WARNING:** Never immerse the probe connector into liquid such as water or disinfectant. Immersion may cause electrical shock or malfunction.

 **CAUTION:**

1. When performing cleaning and disinfection of the probe to prevent infection, wear sterile gloves.
2. 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.
3. No cleaning and disinfecting may result in the probe becoming a source of infection.
4. Please follow the disinfectant manufacturer's manual for performing cleaning and disinfection, including preparing sterile water and cleaning and disinfection time.



**NOTE:** 1. After the examination, wipe off the ultrasound gel thoroughly. Otherwise, the ultrasound gel may solidify and degrade the image quality of the transducer.

2. 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.

### 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

Transducers can be divided into three categories based on their intended use. Some transducers may fall into more than one category (e.g. transducers 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:** Transducers 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 transducers - intravaginal, transrectal, and transesophageal (TEE) and transducers use for biopsy procedures. These semi-critical transducers must be cleaned with an appropriate cleaner after use followed by high-level disinfection.

**Contacts otherwise sterile tissue or body-space:** These transducers are considered critical and include all intraoperative transducers. These transducers 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.

- 1 Wear a pair of gloves to prevent infection.
- 2 Disconnect the ultrasound probe from the ultrasound system. If the sheath is used, take off the sheath and discard it.

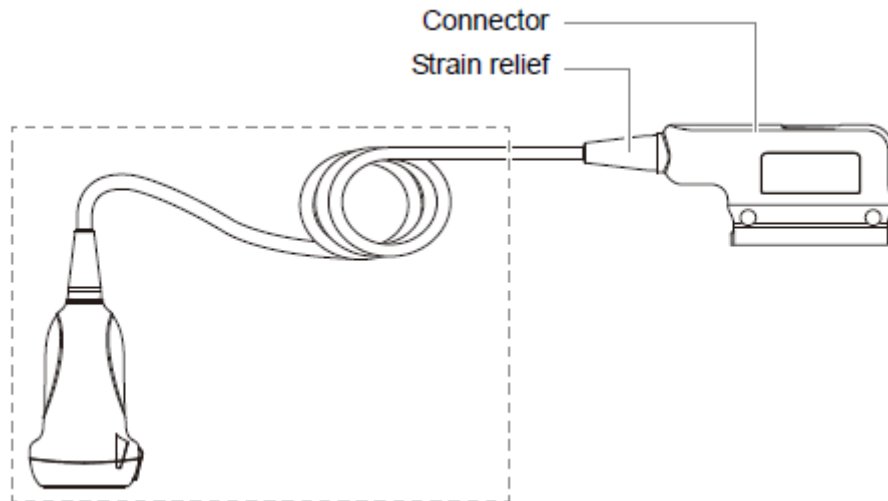
- 3 Wipe away the ultrasound gel or other dirt on the surface of the probe by using a piece of disposable lint-free soft cloth or tissue.
- 4 Prepare a cleaning solvent (enzymatic or neutral pH detergent, e.g., liquinox, MetriZyme) by using distilled or softened water in accordance with the operator's manual provided by the manufacturer.
- 5 Immerse the ultrasound probe fully in the cleaning solvent for at least 1 minute or a period specified by the manufacturer.
- 6 Wipe and wash the probe surface gently by using a piece of lint-free soft cloth or soft sponge until no dirt is visible. When necessary, wash the locating groove of the needle-guided bracket and other items by using disposable cotton swabs. Avoid using a brush to wash the lens because it may damage the probe.
- 7 Rinse the probe thoroughly by using a large amount of distilled or softened water (about 2 gallons) at room temperature for about 30s to remove the residual dirt and cleaning solvent. Repeat the operation twice.
- 8 Dry the probe by wiping with a piece of disposable lint-free soft cloth or tissue. Do not dry the probe by heating.
- 9 Inspect the probe. If visible dirt still exists, repeat the preceding steps to wash the probe until it is all clean.
- 10 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

**CAUTION:**

**Use protective eyewear when disinfecting using sprays.**

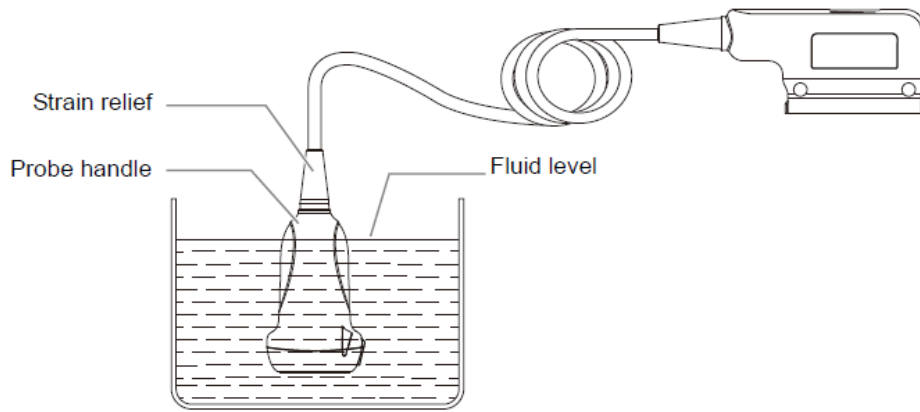
- 1 Wear a pair of gloves to prevent infection.
- 2 Clean the probe thoroughly in accordance with the cleaning procedure before disinfection.
- 3 Disinfect the probe by using an appropriate low-level disinfectant. Follow the disinfection agent manufacturer's instructions for preparation and use of the disinfectant.
- 4 If you use a wet wipe for disinfection, wipe all the surface of the probe according to the wiping duration specified in the operator's manual provided by the manufacturer. If you use a disinfectant 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.
- 5 Wipe away the residual disinfectant on the probe by using a piece of lint-free soft cloth soaked with distilled water. Wipe three times. Or rinse the probe thoroughly by using a large amount of distilled or softened water (about 2 gallons) at room temperature.
- 6 Dry the probe by wiping with a piece of disposable lint-free soft cloth. Do not dry the probe by heating.
- 7 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.
- 8 Store the probe in a cool, clean and dry environment. And repeat the cleaning and disinfection process before the next use.




**NOTE:** Observe the graph here carefully to perform disinfection. Do not spray the strain relief on the connector end or the connector.

### 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. For how to use a high-level disinfectant, see the operator's manual provided by the manufacturer. Prepare a disinfectant by using sterile distilled or softened water when necessary.
4. Immerse the probe head partially 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.
5. Rinse the probe thoroughly by using a large amount of distilled or softened water (about 2 gallons) at room temperature for about 30s to remove the residual disinfectant. Repeat the operation twice.
6. Dry the probe by wiping with a piece of disposable lint-free soft cloth. Do not dry the probe by heating.
7. 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.
8. Store the probe in a cool, clean and dry environment. Repeat the cleaning and disinfection process before the next use.



**NOTE:** Observe the graph here carefully to immerse the transducer. Only soak parts of the transducer below the strain relief.

**CAUTION:**  Repeated disinfection will eventually damage the transducer, please check the transducer's performance periodically.

**Compatible Cleaner and Disinfectants**

For the cleaner and disinfectants information, please refer to Mindray Transducer Disinfectant Recommendation.

For P7-3TU, P7-3Ts and P7-3TE, refer to accompanied manual for disinfection and sterilization.

**13.1.6 Environment**

NOTE: For details of the P7-3TU, P7-3Ts and P7-3TE probes, refer to TEE Ultrasonic Transducer manual.

**Working condition**

Use the probes in the following ambient conditions:

Probe	Ambient temperature	Relative humidity	Atmospheric pressure
C11-3s	0°C~40°C	30%~85%RH (no condensation)	700hPa~1060hPa
SP5-1E	0°C~40°C	20%~85%RH (no condensation)	700hPa~1060hPa
SP5-1s	0°C~40°C	20%~85%RH (no condensation)	700hPa~1060hPa
SP5-1U	0°C~40°C	20%~85%RH (no condensation)	700hPa~1060hPa
C6-2Gs	0°C~40°C	20%~85%RH (no condensation)	700hPa~1060hPa
SC6-1s	0°C~40°C	20%~85%RH (no condensation)	700hPa~1060hPa
SC6-1E	0°C~40°C	20%~85%RH (no condensation)	700hPa~1060hPa
V11-3Hs	0°C~40°C	20%~85%RH (no condensation)	700hPa~1060hPa
L9-3s	0°C~40°C	20%~85%RH (no condensation)	700hPa~1060hPa
SD8-1E	18°C~30°C	20%~85%RH (no condensation)	700hPa~1060hPa

Probe	Ambient temperature	Relative humidity	Atmospheric pressure
SD8-1s	18°C ~ 30°C	20% ~ 85%RH (no condensation)	700hPa ~ 1060hPa
L20-5s	0°C ~ 35°C	15% ~ 80%RH (no condensation)	700hPa ~ 1060hPa
SC8-2s	0°C ~ 40°C	30% ~ 85%RH (no condensation)	700hPa ~ 1060hPa
CW2s	0°C ~ 40°C	30% ~ 85%RH (no condensation)	700hPa ~ 1060hPa
CW5s	0°C ~ 40°C	30% ~ 85%RH (no condensation)	700hPa ~ 1060hPa
ELC13-4s	0°C ~ 40°C	20% ~ 85%RH (no condensation)	700hPa ~ 1060hPa
DE11-3Ws	18°C ~ 30°C	20% ~ 85%RH (no condensation)	700hPa ~ 1060hPa
L13-3Ns	0°C ~ 40°C	20% ~ 85%RH (no condensation)	700hPa ~ 1060hPa
L14-3Ws	0°C ~ 40°C	20% ~ 85%RH (no condensation)	700hPa ~ 1060hPa
L16-4Hs	10°C ~ 40°C	30% ~ 85%RH (no condensation)	700hPa ~ 1060hPa

### Storage and transportation Condition

When all examinations for the session 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.

Store and transport the probes in the following ambient conditions:



Probe	Ambient temperature	Relative humidity	Atmospheric pressure
C11-3s	-20°C ~ 55°C	30%~95%RH (no condensation)	700 hPa ~ 1060 hPa
SP5-1E	-20°C ~ 55°C	20%~95%RH (no condensation)	700 hPa ~ 1060 hPa
SP5-1s	-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
C6-2Gs	-20°C ~ 55°C	20%~95%RH (no condensation)	700 hPa ~ 1060 hPa
SC6-1s	-20°C ~ 55°C	20%~95%RH (no condensation)	700 hPa ~ 1060 hPa
SC6-1E	-20°C ~ 55°C	20%~95%RH (no condensation)	700 hPa ~ 1060 hPa
V11-3Hs	-20°C ~ 55°C	20%~95%RH (no condensation)	700 hPa ~ 1060 hPa
L9-3s	-20°C ~ 55°C	20%~95%RH (no condensation)	700 hPa ~ 1060 hPa
SD8-1E	-10°C ~ 50°C	20%~95%RH (no condensation)	700 hPa ~ 1060 hPa
SD8-1s	-10°C ~ 50°C	20%~95%RH (no condensation)	700 hPa ~ 1060 hPa
L20-5s	-20°C ~ 60°C	15%~90%RH (no condensation)	500 hPa ~ 1060 hPa
SC8-2s	-10°C ~ 60°C	20%~95%RH (no condensation)	700 hPa ~ 1060 hPa
CW2s	-20°C ~ 55°C	30%~95%RH (no condensation)	700 hPa ~ 1060 hPa
CW5s	-20°C ~ 55°C	30%~95%RH (no condensation)	700 hPa ~ 1060 hPa

Probe	Ambient temperature	Relative humidity	Atmospheric pressure
ELC13-4s	-20°C ~ 55°C	20%~95%RH (no condensation)	700 hPa ~ 1060 hPa
DE11-3Ws	-10°C ~ 50°C	20%~95%RH (no condensation)	700 hPa ~ 1060 hPa
L13-3Ns	-20°C ~ 55°C	20%~95%RH (no condensation)	700 hPa ~ 1060 hPa
L14-3Ws	-20°C ~ 55°C	20%~95%RH (no condensation)	700 hPa ~ 1060 hPa
L16-4Hs	0°C ~ 60°C	30%~95%RH (no condensation)	700 hPa ~ 1060 hPa

- 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 transducer 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.
- Sterilize the carrying case as necessary.

### 13.1.7 Sensor (Fusion Imaging) Support Cleaning and Disinfection

Before performing the fusion imaging exam, clean and disinfect (or sterilize) the fusion sensor support as required.

 <b>CAUTION:</b>	<ol style="list-style-type: none"> <li>When performing cleaning and disinfection of the sensor support to prevent infection, wear sterile gloves.</li> </ol>	
	<ol style="list-style-type: none"> <li>After disinfection, rinse the sensor support thoroughly with sterile water to remove all chemical residues. Chemical residues may be harmful to the human body.</li> </ol>	
	<ol style="list-style-type: none"> <li>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.</li> </ol>	

#### Cleaning

- Disconnect the sensor support from the system.
- Wear sterile gloves to prevent infection.
- 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.
- 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



**CAUTION:**

Use protective eyewear when disinfecting using sprays.

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	Type
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





### 13.1.8 Storage 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.

1. 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
2. Store and transport sensor support under following ambient conditions:
  - Ambient temperature: -20°C ~ 55°C
  - Relative humidity: 20% ~95% (no condensation)
  - Atmospheric pressure: 700 hPa ~1060 hPa

### 13.1.9 Sensor (Fusion Imaging) Cleaning and Disinfection

 <b>CAUTION:</b>	1. <b>When performing cleaning and disinfection of the sensor to prevent infection, wear sterile gloves.</b>	
	2. <b>After disinfection, rinse the sensor thoroughly with sterile water to remove all chemical residues. Chemical residues may be harmful to the human body.</b>	
	3. <b>No cleaning and disinfecting may result in the sensor becoming a source of infection.</b>	
	4. <b>The efficacy of disinfectants and sterilizing solutions is not guaranteed by MINDRAY. Contact the manufacturers for information on the activity of the products.</b>	

#### Disinfecting with Sprays or Wipes

 <b>CAUTION:</b>	<b>Use protective eyewear when disinfecting using sprays.</b>
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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	Procedures	Type
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

Clean and disinfect eTRAX needle using disinfectant and sterilant such as Sani-cloth® HB, CIDEX OPA® (Johnson & Johnson), ENZOL® (Johnson & Johnson), T-Spray™, Protex™ or ethanol.

### 13.1.10 Disposal of the Sensor Support

Be sure to dispose of the sensor support only after sterilizing it.  
Contact your MINDRAY representative when disposing of this device.

## 13.2 Biopsy Guide



### **WARNING:**

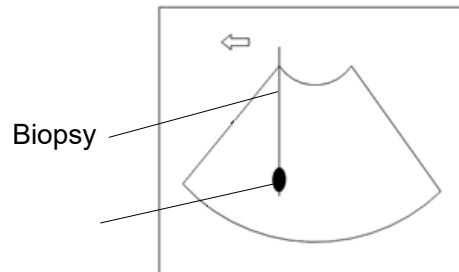
1. The person performing biopsy procedures must understand diagnostic ultrasound thoroughly and have been trained adequately, otherwise, side effects may be caused to the patient.
2. In situations listed below, the biopsy needle may fail to penetrate the target. The incorrect biopsy may cause various 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.
3. Before and after a biopsy procedure is performed, confirm that the needle-guided bracket is normal. Manually confirm that the parts of the needle-guided 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.
4. **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.
5. **DO NOT** freeze an image while performing biopsy procedure.
6. 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.
7. 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.
8. 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.
9. Adjust the needle mark before the biopsy procedure is performed.
10. 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.
11. When performing the operation concerning biopsy, wear sterile gloves.
12. 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

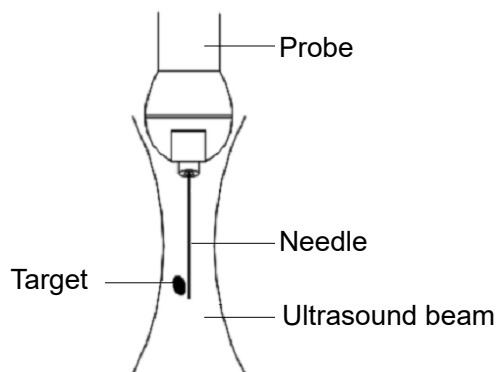
object in the image, it may not actually have done so. When the target for biopsy is small, dispersion of the ultrasound beam may lead to image deviate from the actual position. Pay attention to this.

If the target object and the biopsy needle appear in the image as shown in the figures below (For reference only):



The biopsy needle appears to reach the target object in the image

Dispersion of the ultrasound beam



The biopsy needle may not have actually entered the target object even though it appears to have done so on the image. To avoid this problem, note points below:

- Do not rely only on the needle tip on the image. Pay careful attention to that, when the biopsy needle comes into the target object or contacts with it, the object should shift slightly.
- Before you perform the biopsy, please evaluate the size of the object and confirm if the biopsy can be carried out.

During biopsy of the probe, misoperation may occur when the scan range is not set to "W".

## 13.2.1 Needle-guided Brackets

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 ( $\pm 1^\circ$ )	Applicable Biopsy Needle
SP5-1s/SP5-1E/SP5-1U	NGB-011 Metal-needle undetachable	11°, 23°	13G, 15G, 16G, 18G, 20G
C11-3s	NGB-018 Metal-needle detachable	15°, 25°, 35°	14G, 16G, 18G, 20G, 22G
SC6-1s/SC6-1E	NGB-022 Metal-needle detachable	25°, 35°, 45°	14G, 16G, 18G, 20G, 22G
C6-2Gs	NGB-024 Metal-needle detachable	7°, 25°, 35°	14G, 16G, 18G, 20G, 22G
V11-3Hs	NGB-025 Metal-needle undetachable	1.6°	16G, 17G, 18G
SC8-2s	NGB-029 Metal-needle detachable	20°, 30°, 40°	14G, 16G, 18G, 20G, 22G
L9-3s	NGB-034 Metal-needle detachable	40°, 50°, 60°	14G, 16G, 18G, 20G, 22G
SD8-1s/SD8-1E	NGB-039 Metal-needle detachable	21°, 26°, 33°	14G, 16G, 18G, 20G, 22G
DE11-3Ws	NGB-047 Metal-needle undetachable	1.7°	16G, 17G, 18G
ELC13-4s	NGB-051 Metal-needle detachable	5mm, 10mm, 15mm, 20mm, 25mm, 30mm, 35mm, 40mm, 45mm, 50mm	14G, 16G, 18G, 20G
L13-3Ns	NGB-053 (within the plane) Metal-needle detachable	15mm (60°), 23mm (50°), 34mm (40°)	11G ~ 23G
L14-3Ws	NGB-054 Metal-needle detachable	15mm (65°), 23.7mm (55°), 35mm (45°)	11G ~ 23G

## Disposable Bracket

Probe model	Needle-guided Bracket Model
V11-3Hs	CIVCO 610-543
	CIVCO 610-1274

NOTE: Mindray does not offer the biopsy needle; please purchase it according to your own needs.

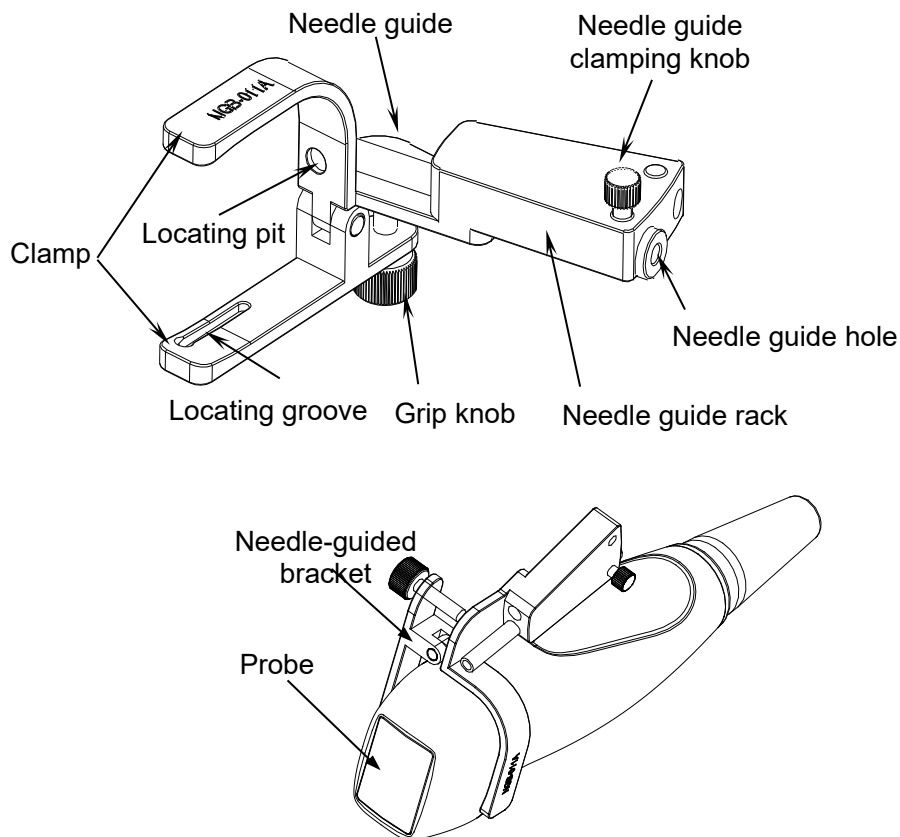
A needle-guided bracket is available for purchase as an optional accessory; it is used in combination with the probe. Some of the probes have matched needle-guided bracket and needles. To order needle-guided brackets, contact MINDRAY Customer Service Department or sales representative.

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).

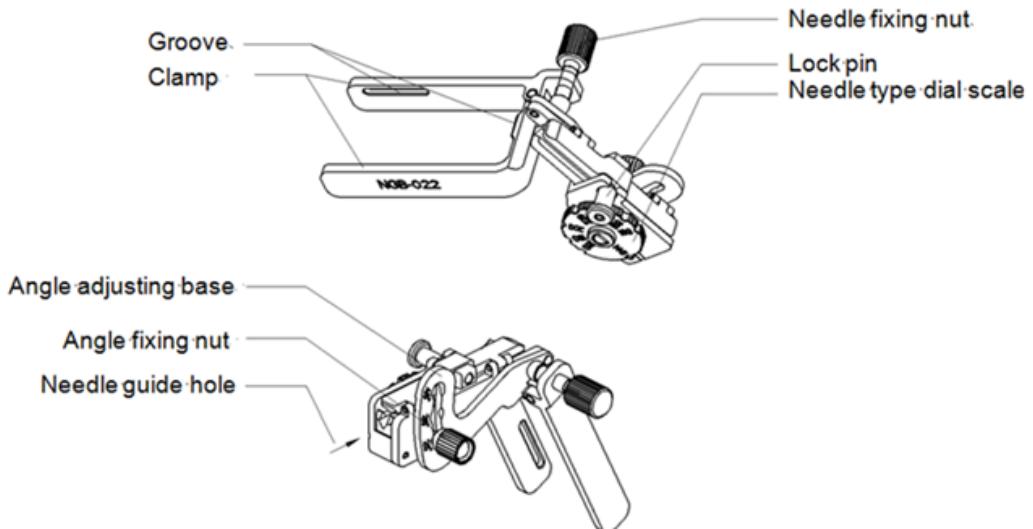
### Names of Parts

This section describes the parts and corresponding functions of each needle-guided bracket. Here, we take a matched probe as an example.

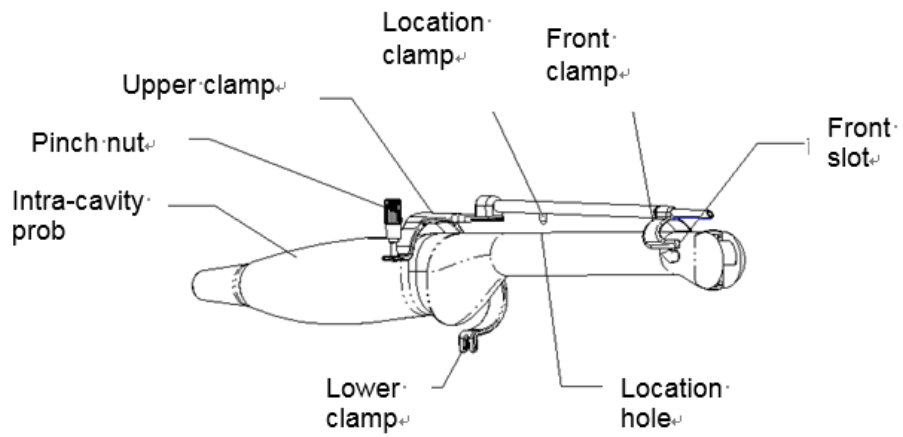
NGB-011 Metal/needle undetachable needle-guided bracket:



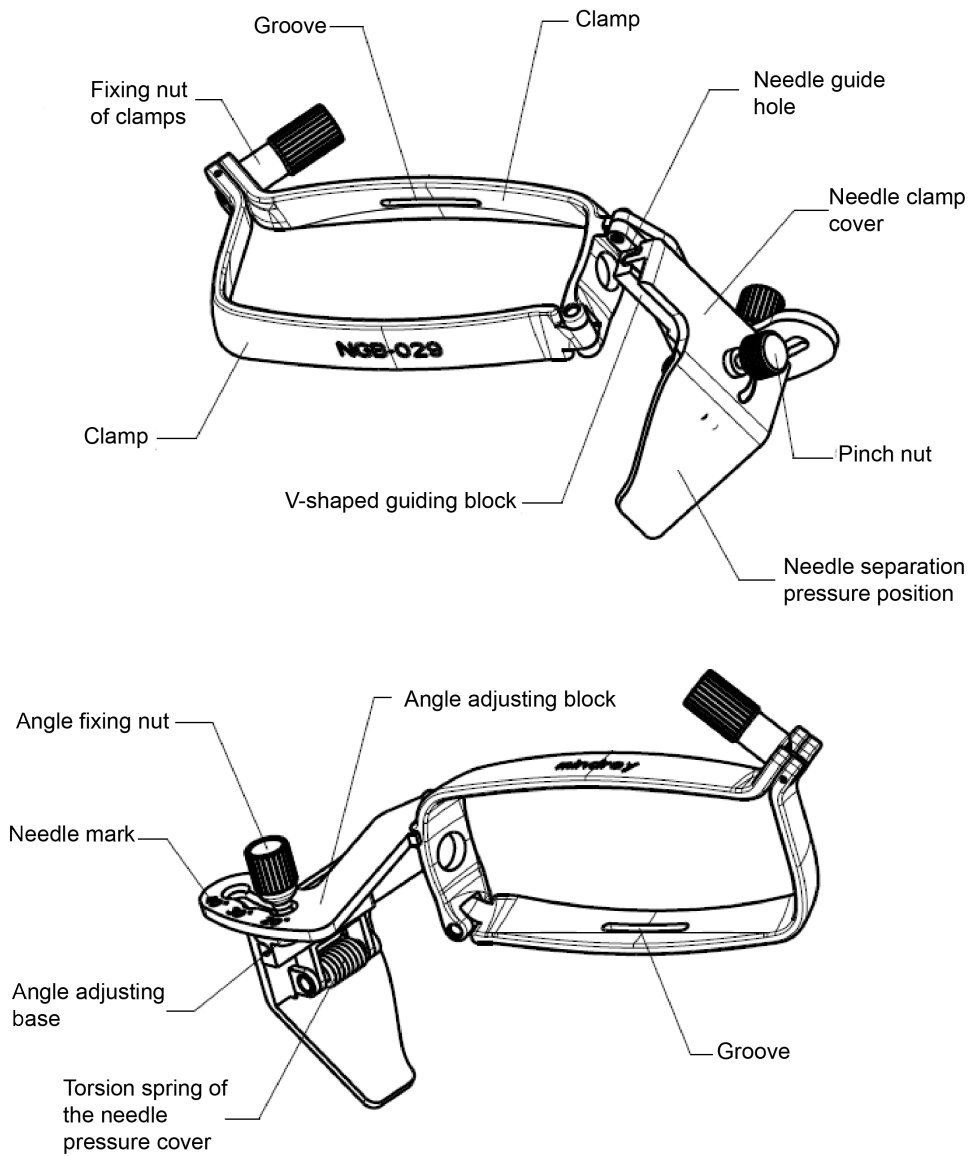
NGB-022 Metal/needle undetachable needle-guided bracket



NGB-025 Metal/needle undetachable needle-guided bracket:

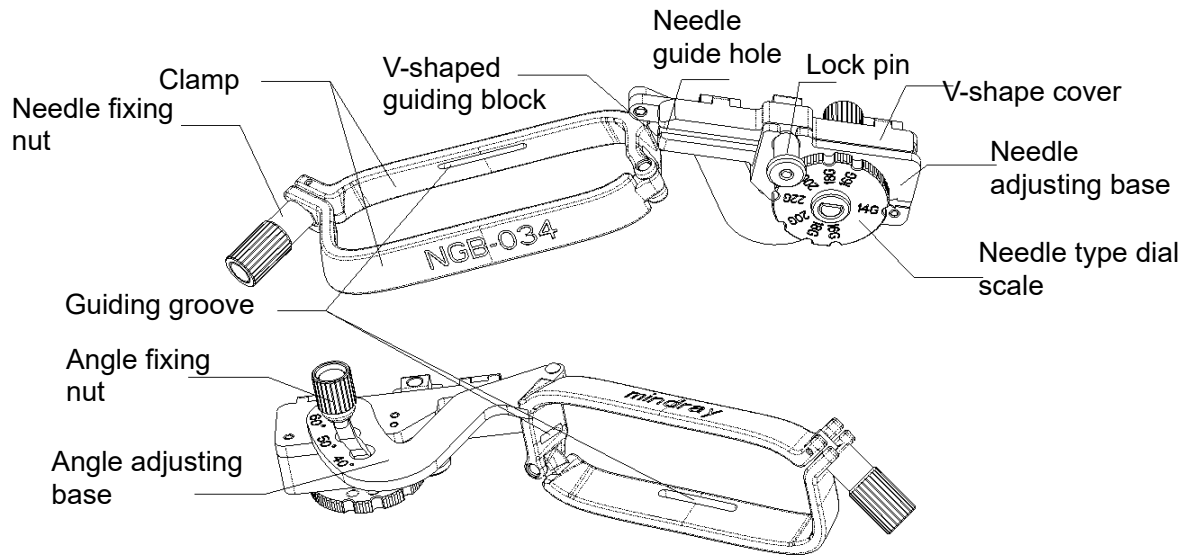


NGB-029 Metal/needle detachable needle-guided bracket:

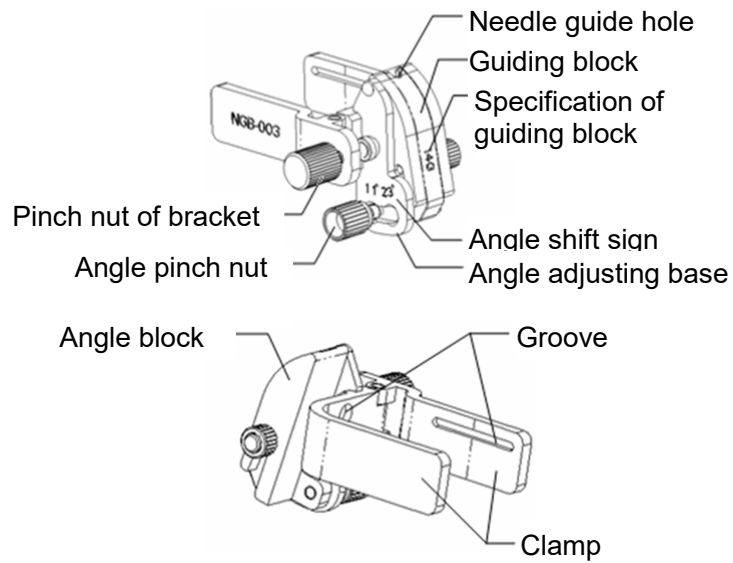




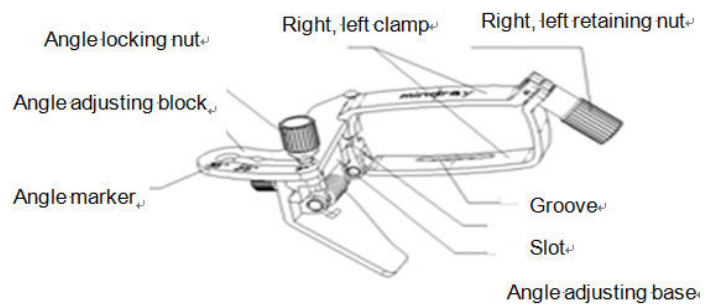
NGB-034

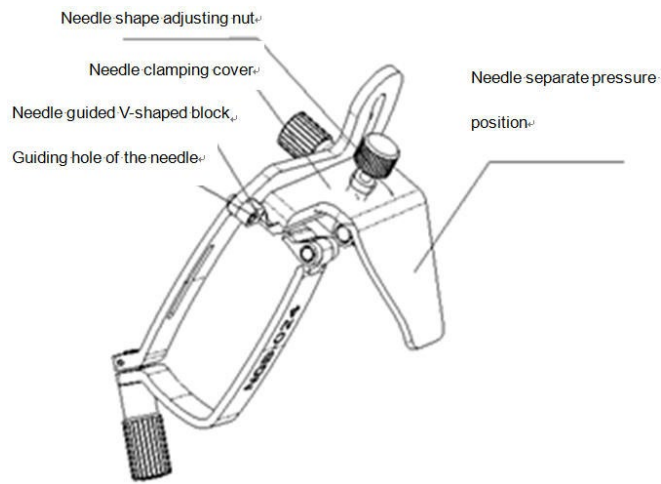


NGB-018

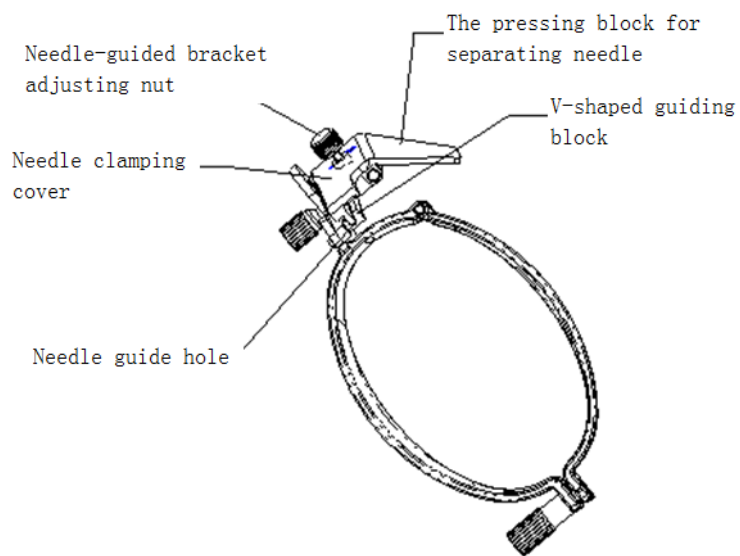
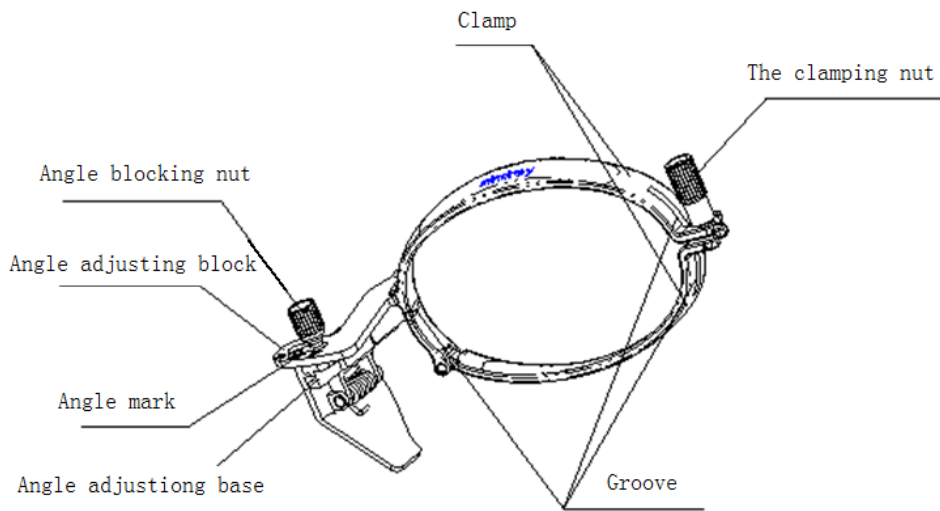


NGB-024

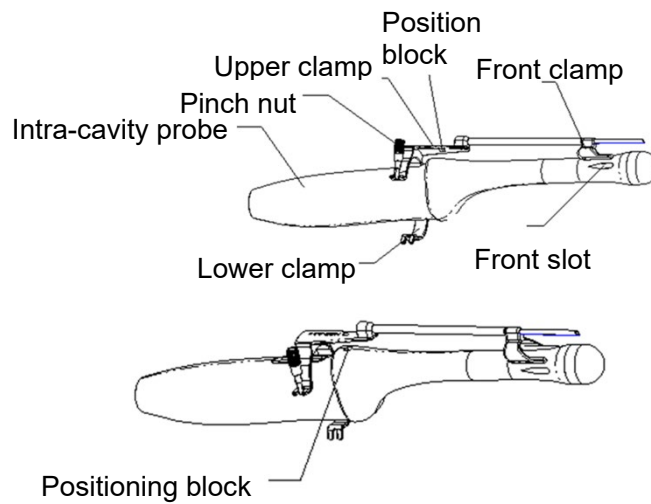




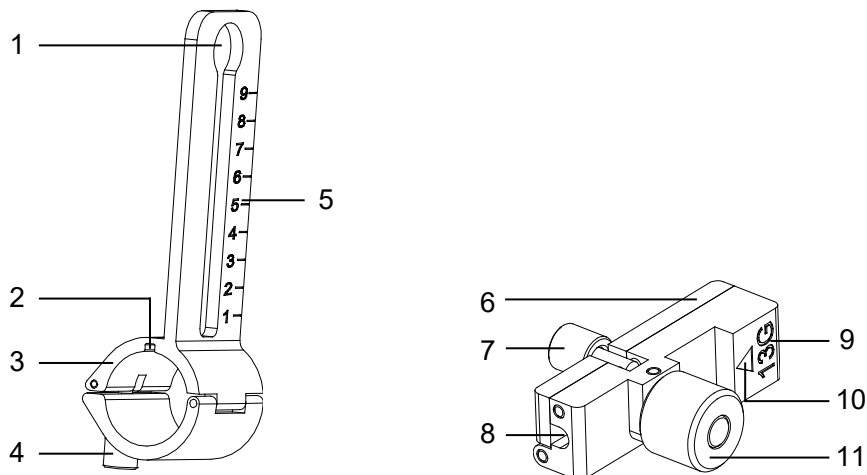
NGB-039



NGB-047



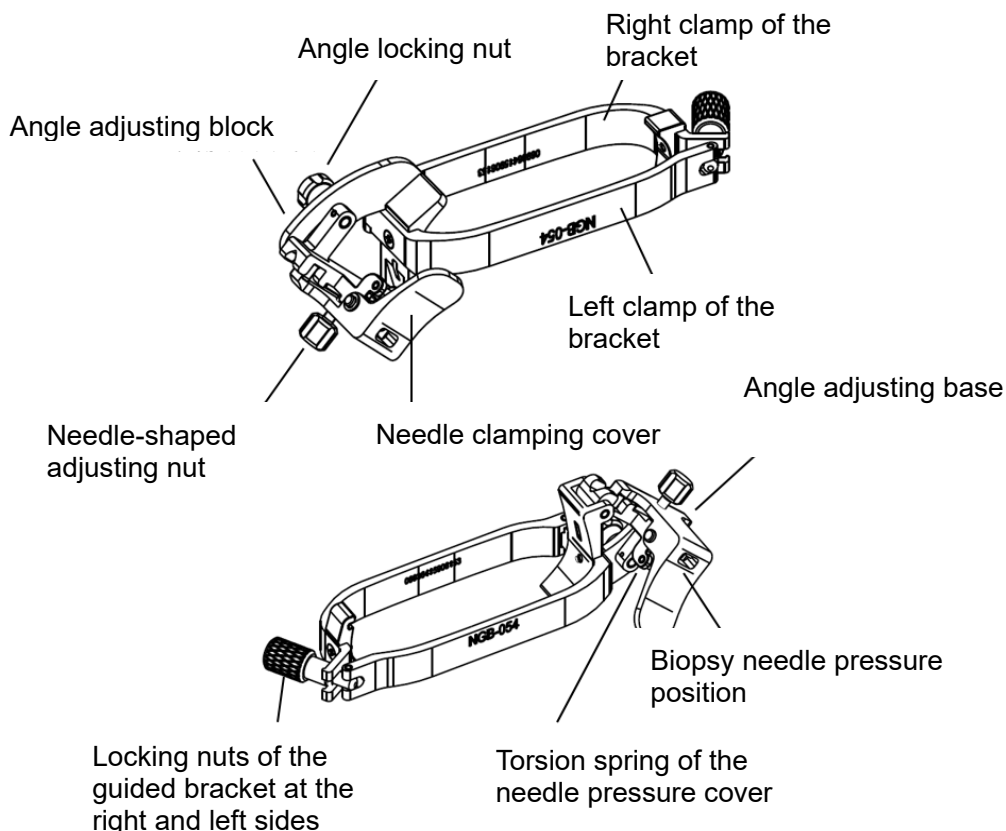
NGB-051



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.

NGB-053/NGB-054



## 13.2.2 Basic Procedures for Biopsy Guiding

1. Select the right needle-guided bracket and needle, install them properly. For details, please refer to Chapter 13.2.3 Needle-guided Bracket Inspection and Installation.
2. Verify the biopsy guide line.
3. Press <Biopsy> to enter the biopsy. Before biopsy guiding, you can preset bracket model, biopsy display and guide line dot type.

Tips:

- If the current probe has no matched bracket; or, the image is frozen and the guide line is off before image frozen, then you can't enter Biopsy menu.
4. Select the bracket and guide line according to actual situation.
  5. On the Biopsy menu, click [Verify] to enter the Verify menu to verify the guide line. After the verification, click [Save] on the menu to save the parameter setting. And then click [Exit] to return to Biopsy menu.

Tips:

- If you switched the probe or needle-guided bracket during the biopsy, please verify the guide line again.
  - When exiting the Verify menu without saving the setting, system will confirm with you “*Data have changes. Do you want to save the changes?*”. Click [Yes] to save the setting and return to Biopsy menu.
6. Scan to locate the target. Center the target in the electronic guidezone path.
  7. Direct the needle into the area of interest for specimen.
  8. After extraction of the biopsy sample is completed, gently remove the probe from the body.  
NOTE: 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.



### **Caution**

Ensure that all guide parts are seated properly prior to performing a biopsy.

## **13.2.3 Needle-guided Bracket Inspection and Installation**

### **13.2.3.1 Inspection of the Needle-guided Bracket**

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.

1. Sterilize the needle-guided bracket before and after use.
2. Confirm that the needle-guided bracket is free of damage, deformation, stripping, malfunction, loose, or missing parts.
3. Confirm that the needle-guided bracket is securely mounted in the correct position.

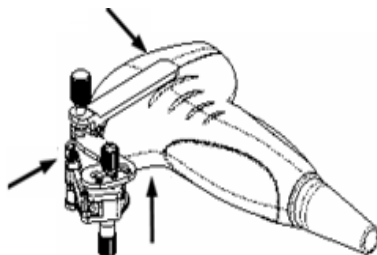
### **13.2.3.2 Installing the Needle-guided Bracket**

#### **NGB-011**

- (1) Inoculate the locating groove on the clamp with the two raised edges on the probe head and align the locating pit of the clamp to the convex point on the probe head.
- (2) Tighten the grip knob of the biopsy.
- (3) Pull the biopsy guide through the hole and tighten the knob..

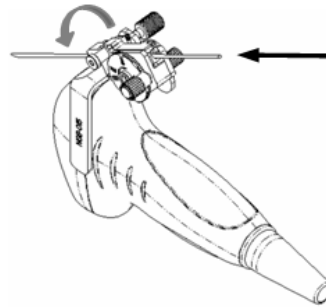
#### **NGB-022**

- (1) Put on the probe sheath.
- (2) Hold the transducer 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 transducer. Amount the bracket onto the transducer.



- (3) Screw the pinch nut of the needle-guided bracket to confirm that the needle-guided bracket is properly installed on the transducer.

- (4) 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 loose the needle fixing nut first.)
- (5) 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.

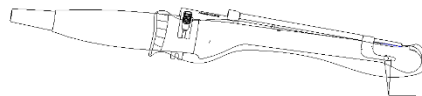


**NGB-025**

1. Put on the sterile probe sheath.

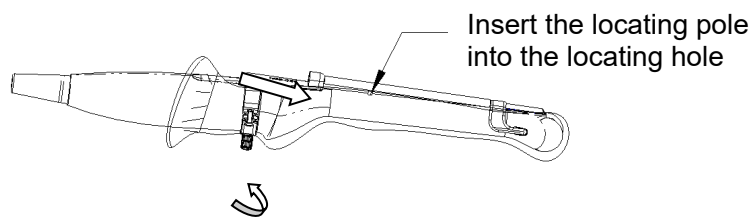


2. Open the clamp. Insert the front clamp to the front groove.



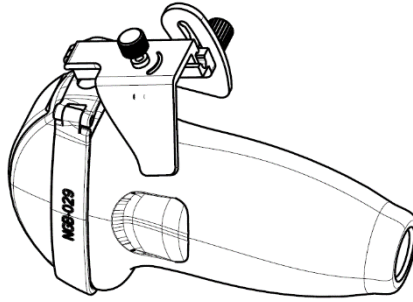
Align front clamp with front groove

3. 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).

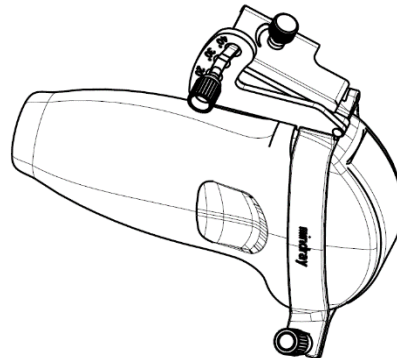


**NGB-029**

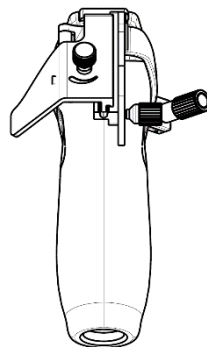
1. Put on the sterile probe sheath.
2. Select a proper needle-guided bracket, and match the locating groove with the tab of the probe. Mount the bracket onto the probe.



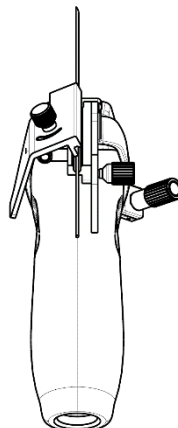
3. Tighten the fixing nut of clamps of the needle-guided bracket to confirm that the needle-guided bracket is properly installed on the probe. And tighten the pinch nut (following the arrow's direction).



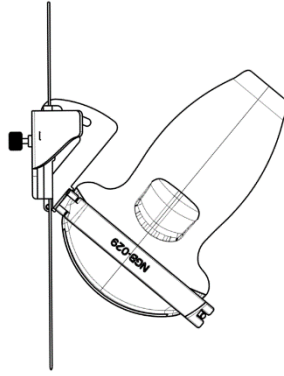
4. Hold the transducer. Press the pressure position of the needle to separate needle guided V-shaped block from pressure position of the needle.



5. Put the needle into the needle guided-bracket, and the needle leans to V-shaped block.

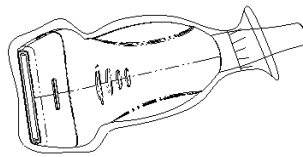


6. Hold the transducer, and release the pressure position of the needle. Adjust the needle-type adjusting nut manually (following the direction of the arrow). The needle moves smoothly at the vertical direction due to its gravity.

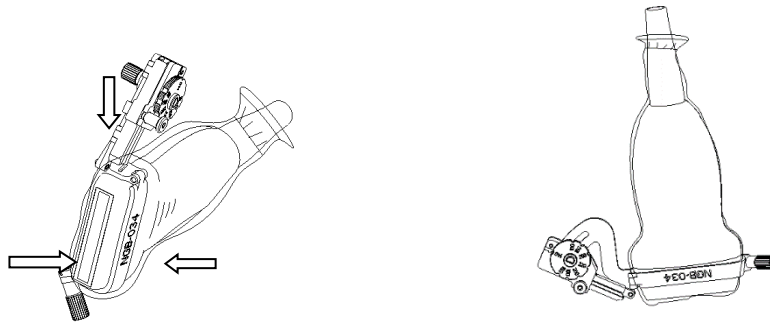


**NGB-034**

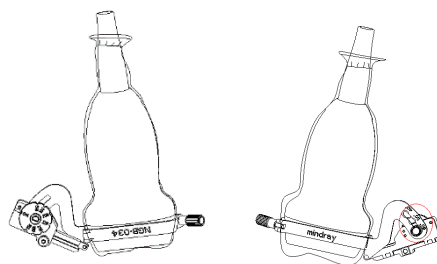
1. Put on the sterile probe sheath.



2. Select a proper needle-guided bracket, and match the locating groove with the tab of the transducer. Mount the bracket onto the transducer.

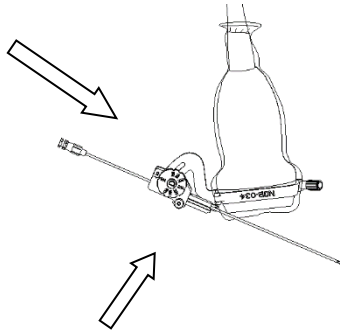


3. Tighten the pinch nut of the needle-guided bracket to confirm that the needle-guided bracket is properly installed on the transducer.
4. Adjust the dial scale to the required needle type shift.



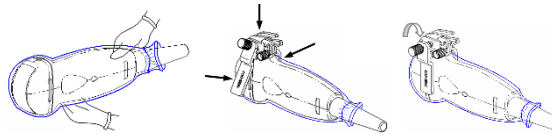
5. Adjust the needle angle to the proper shift as required (loosen the nut first, and then tighten the nut based on the shift you need).
6. Pull the lock pin and close the V-shaped cover to fix the lock pin in the groove of the needle type adjusting base, so as to install the needle into the guiding hole.



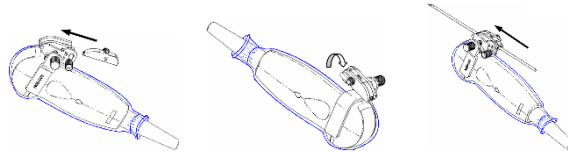


#### NGB-018

1. Put on the transducer sheath.
2. Select a proper needle-guided bracket, and match the groove with the tab of the transducer respectively. Mount the bracket onto the transducer. The needle-guided brackets may be different from each other, but the methods are the same.



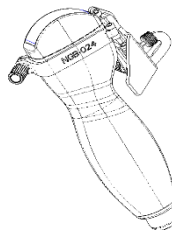
3. Screw the pinch nut of the needle-guided bracket to confirm that the needle-guided bracket is properly installed on the transducer.
4. Select a proper guiding block and push it into the groove above the angle block.



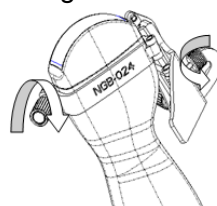
5. Screw the nut of the block to secure the block.
6. Insert a biopsy needle with the same specification as that of the guiding block into the hole of the guiding block.

#### NGB-024

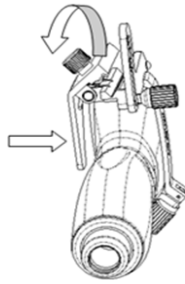
1. Put on the sterile transducer sheath.
2. Select a proper needle-guided bracket, and match the groove with the tab of the transducer. Mount the bracket onto the transducer.



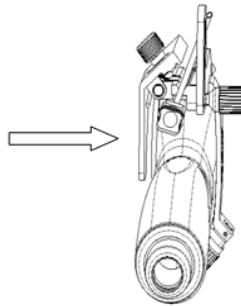
3. Rotate the clamping nuts of the guided bracket on right and left side to fix the bracket and the transducer. Rotate the needle-type adjusting nut to the ultimate position as shown in the figure.



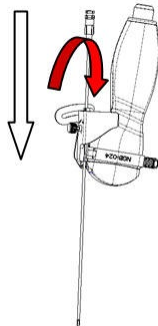
4. Hold the transducer. Press the biopsy needle to separate needle guided V-shaped block from pressure position of the needle.



5. Put the needle into the needle guided-bracket, and the needle leans to V-shaped block.

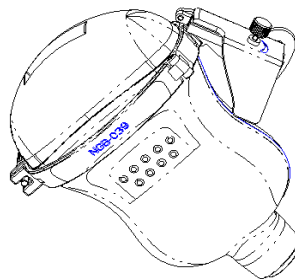


6. Hold the transducer, and release the pressure position of the needle. Adjust the needle-type adjusting nut manually (following the direction of the arrow). The needle moves smoothly at the vertical direction due to its gravity.

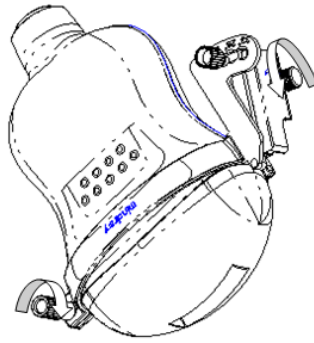


#### NGB-039

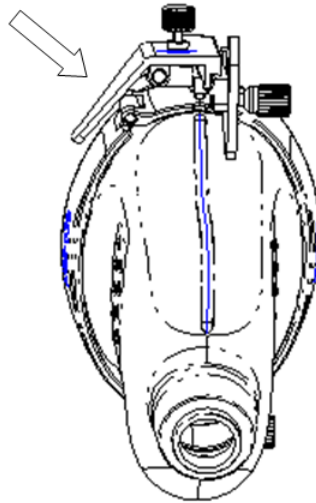
- (1) Put the sterile sheath on the probe.
- (2) Select a proper needle-guided bracket, and match the locating groove with the tab of the transducer. Mount the bracket onto the transducer.



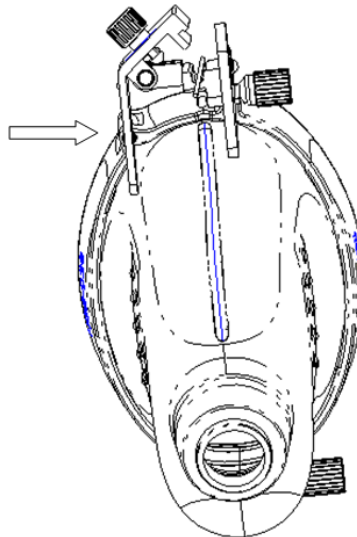
- (3) Tighten the pinch nut of the needle-guided bracket to confirm that the needle-guided bracket is properly installed on the probe. Loosen the angle adjusting nut.



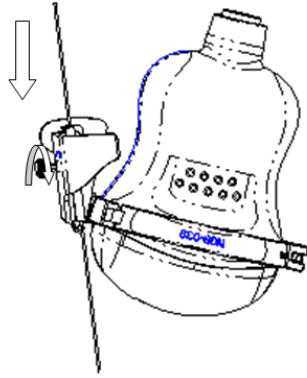
- (4) Hold the probe and press the pressing block to separate V-shaped guiding block from the pressing block.



- (5) Insert the needle into V-shaped guided block.

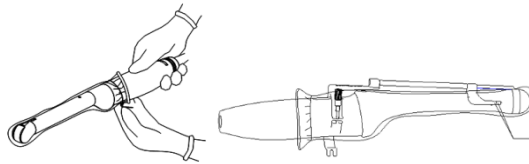


- (6) Release the pressing block, adjust the angle adjusting nut to confirm that the needle can freely slide in a vertical direction.

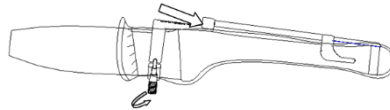


### NGB-047

1. Put on the sterile transducer sheath.

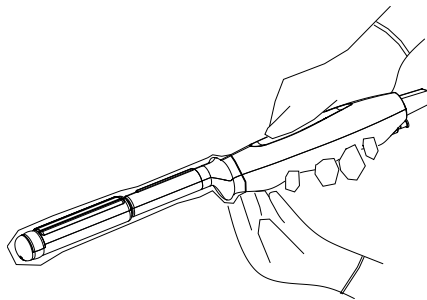


2. Open the clamp. Insert the front clamp to the front groove.
3. Push the biopsy forward (arrow's direction) until the locating pole inserting into the location hole. Turn the lower clamp against the intra-cavity probe. Tighten the nut to lock the biopsy (arrow's direction).

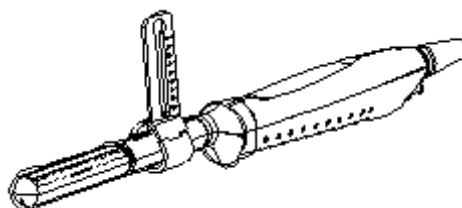


### NGB-051 metal/needle detachable needle-guided bracket

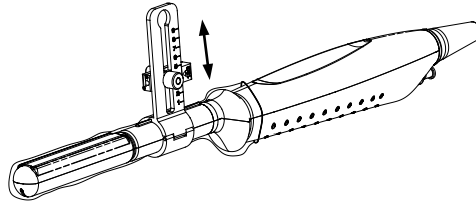
- (1) Put on the transducer cover.



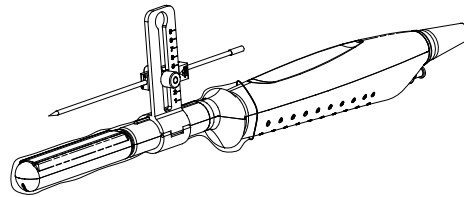
- (2) Cover the support of needle-guided bracket on the transducer, making the groove of the needle-guided bracket to match with the tab of the transducer. Set the needle-guided bracket at the desired position, turn tightly the knob of fixing needle-guided bracket to fix the needle-guided bracket.



- (3) 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.

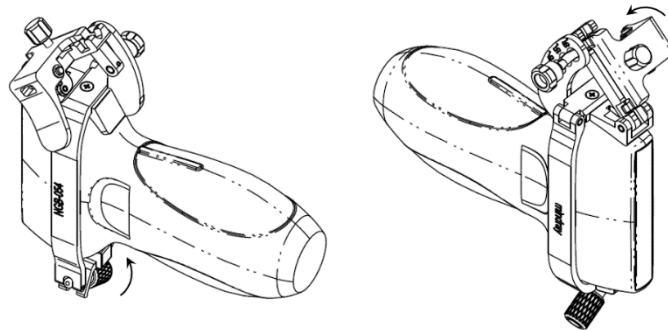


- (4) Insert a biopsy needle with the same specification as that of the guiding block into the hole of the guiding block and turn tightly the knob of fixing the needle.

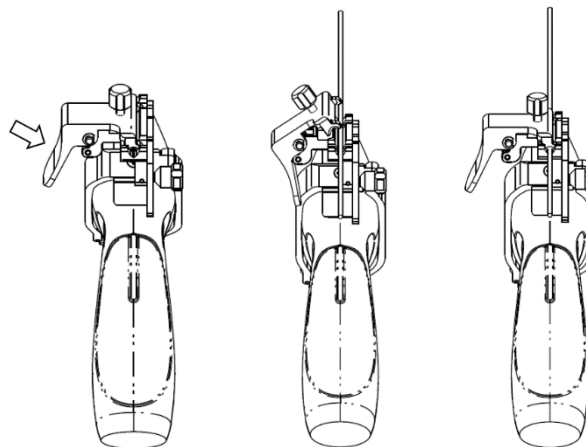


#### NGB-053/NGB-054

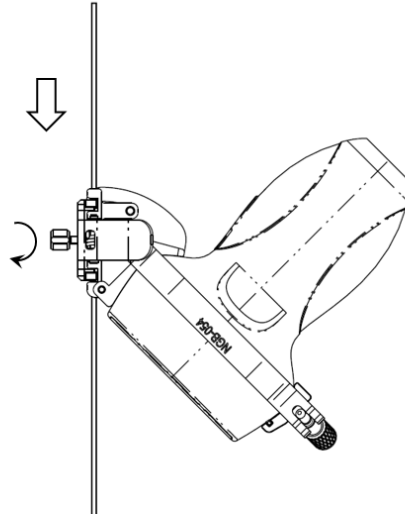
- (1) Put on the sterile transducer sheath.
- (2) Hold the transducer in one hand, select the correct needle-guided bracket and hold it with the other hand. Match the inside of the bracket with the outside of the transducer respectively. Mount the bracket onto the transducer. Rotate the locking nuts of the guided bracket at the right and left sides to fix the bracket and the transducer. Rotate the needle-shaped adjusting nut to the ultimate position as shown in the figure.



- (3) Hold the transducer. 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.



- (4) Hold the transducer, 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.



**CAUTION:**

Ensure that all guide parts are seated properly prior to performing a biopsy.

### 13.2.3.3 Selecting the Needle

Select the proper needle according to the specification above, and adjust the needle shift to the same specification of the selected needle.

### 13.2.4 Biopsy Menu

Press <F11 Biopsy> to enter the function. The menus are displayed on the touch screen;

Select biopsy bracket angle/guide.

If the needle-guided bracket supports more than one biopsy angle, you can select the angle from the menu (e.g., 25 refers to the angle or guide selected).

Select guide line dot size.

Click [Dot Size] to select the dot size of the guide line.

NOTE:

- The guide line is a dot line which consists of two kinds of dots, the distance between two dots is depth dependent. Move the cursor onto the big dot, a numeral, which represents the biopsy depth, is displayed.
- The biopsy guide zone adjusts along with image adjustments, such as image inversion/rotations, zoom and depth changes.

Verify

See 13.2.5 Biopsy Guideline Verification.

■ Exit

- Tap [Biopsy] on the touch screen to exit.
- Press <F11 Biopsy> to exit.

NOTE: press <F11 Biopsy> in non-frozen state to exit; press <F11 Biopsy> in frozen state to hide/show the biopsy.

## 13.2.5 Biopsy Guideline Verification

Adjusting the needle mark is necessary before each biopsy 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.



**Prior to each biopsy procedure, be sure to verify the guide line.**

### **WARNING:**

**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.

### **Biopsy Guideline**

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 touching the [Biopsy Kit: NGB-XXX-XX] on the touch screen.

Select the guide line dot size

Tap [Dot Size] to select the dot size.

Tip:

- 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.

Exit

- Tap [Biopsy] or press <F11 Biopsy> to exit.

Tips: 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.

### **Verification**

Tap [Verify] 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.

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.

## 13.2.6 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 1, 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 2, 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.

iNeedle is an option.

NOTE: only L14-3Ws, L20-5s, L9-3s, C6-2Gs, C11-3s, SC6-1s, SC6-1E, and L13-3Ns probes support the function.

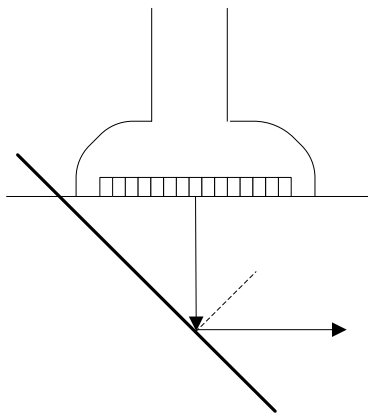


Figure 1

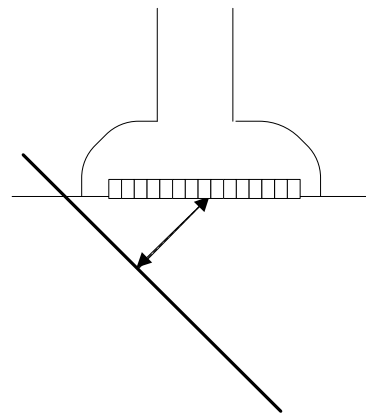


Figure 2

### To enter/exit iNeedle

To enter iNeedle

Tap [iNeedle] item in B page on the touch screen. The parameters that can be adjusted appear on the menu.

Open iNeedle in Biopsy status

1. Perform scanning and locate the target, press <Biopsy> (<F11>) to enter the screen.
2. Touch [iNeedle] to enter the status; available adjusting parameters are displayed on the menu.

To exit iNeedle

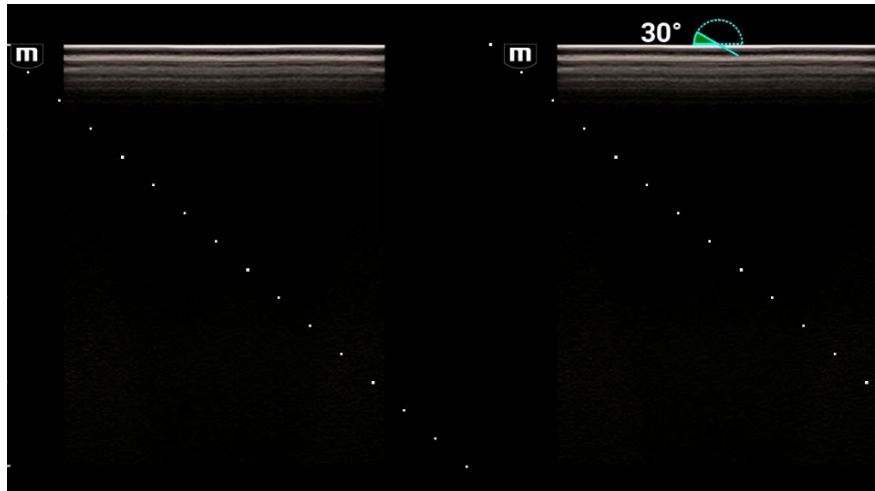
Tap [iNeedle] to exit the status and enter B mode.

Premium angle display

The premium angle appears on the screen after entering iNeedle.

The appropriate angle is 30° as shown in the figure below.





### Needle Direction

**Description** This function adjusts the biopsy needle direction according to actual direction of needle insertion. The iNeedle affecting region changes correspondingly.

**Operation** Tap [Needle Dir.] to select the direction.

### B/iNeedle

**Description** This function is used to display B image and iNeedle image synchronously.

**Operation** To disable or enable the function, tap [B/iNeedle] on the touch screen.

Tips: iZoom (full-screen magnification) is available on iNeedle status.

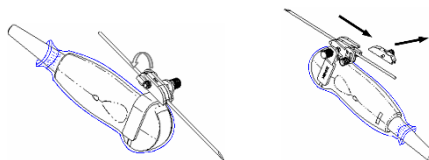
## 13.2.7 Removing the Needle-guided Bracket

### NGB-011

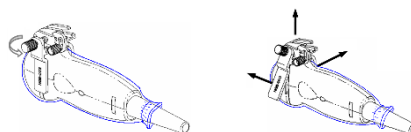
Hold the probe and the needle-guided bracket, and then open the grip knob of the needle-guided bracket.

### NGB-018

- (1) Screw the nut of the guiding block and remove the guiding block slightly along the direction of the needle's tail.

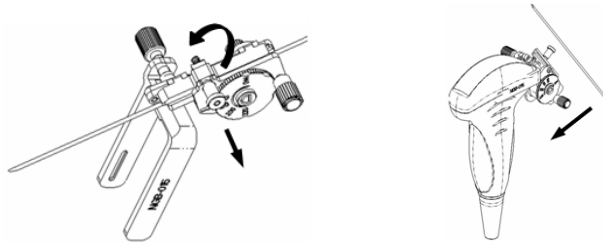


- (2) Separate the residual part of the needle-guide bracket and the transducer from the needle.
- (3) Screw the pinch nut of the bracket, and remove the needle-guided bracket from the transducer.

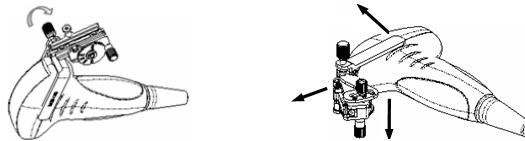


#### NGB-022

- (1) Pull the lock pin and open up the V-shaped cover to expose the needle.



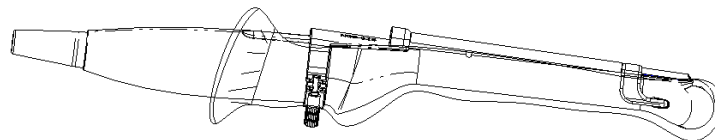
- (2) Separate the bracket and the transducer from the needle.
- (3) Screw the pinch nut to release the needle-guided bracket.



- (4) Separate the bracket and the transducer.

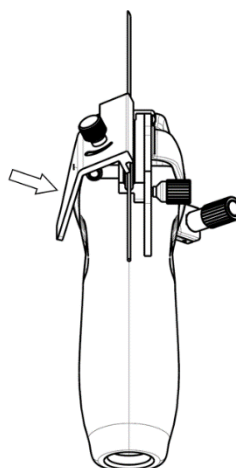
#### NGB-025

Hold the probe in the left hand; unscrew the locking nut with the right hand to loose the clamp (arrow's direction). Lift the biopsy up (towards arrow's direction). The locating pole, front clamp, the locating hole and the front clamp become loose.

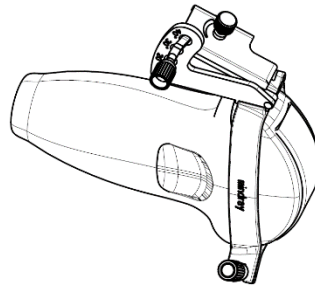


#### NGB-029

1. Hold the transducer. Press the biopsy needle to separate the needle from pressure position of the needle.

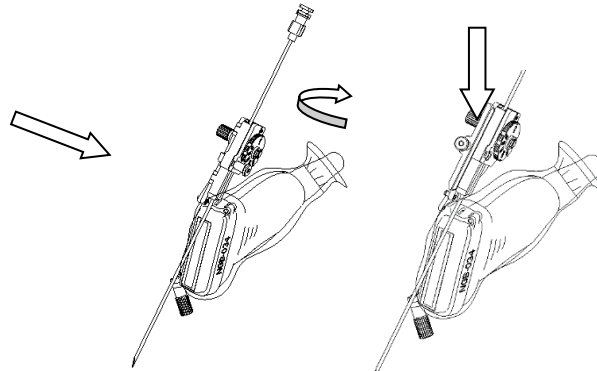


2. Separate the bracket and the transducer from the needle.
3. Rotate the clamping nuts of the needle guided-bracket (following the direction of the arrow). The needle guided-bracket is separate from the transducer. Hold the transducer and take out the bracket.

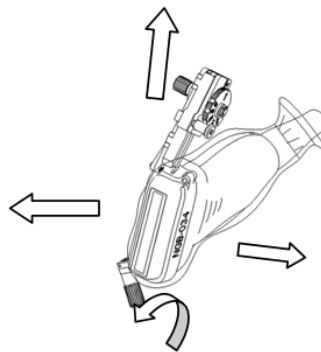


**NGB-034**

- Separation of the needle in the operation
1. Pull the lock pin out until the V-shaped cover can be turned and opened up.

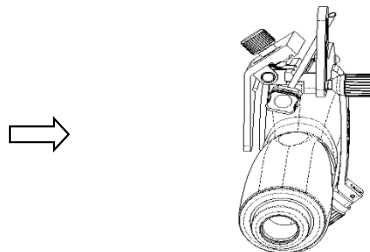


2. Turn over the V-shaped cover to expose the needle. Remove the probe and bracket.
- Removing the needle-guided bracket
- Screw the pinch nut to release the needle-guided bracket.



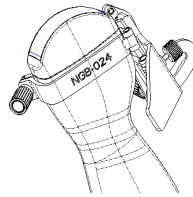
**NGB-024**

1. Hold the transducer. Press the biopsy needle to separate the needle from pressure position of the needle.



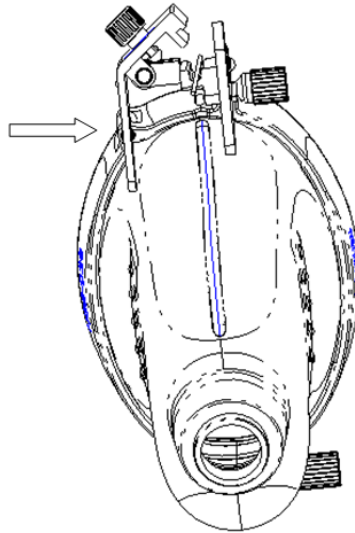
2. Separate the bracket and the transducer from the needle.

3. 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.

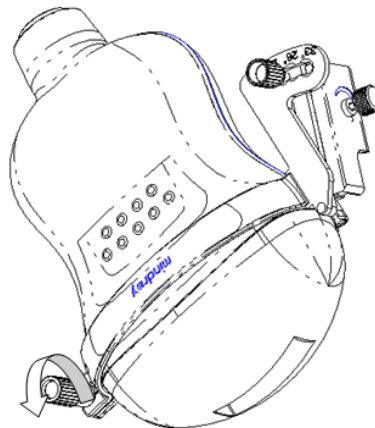


#### NGB-039

- (1) Hold the probe and press the pressing block to separate V-shaped guiding block from the pressing block.

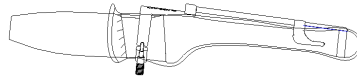


- (2) Remove the needle.
- (3) Rotate the clamping nut to separate the bracket from the probe.



#### NGB-047

Hold the prober in the left hand; unscrew the locking nut with the right hand to loose the clamp (arrow's direction). Lift the biopsy up (towards arrow's direction). The locating pole, front clamp, the locating hole and the front clamp become loose.

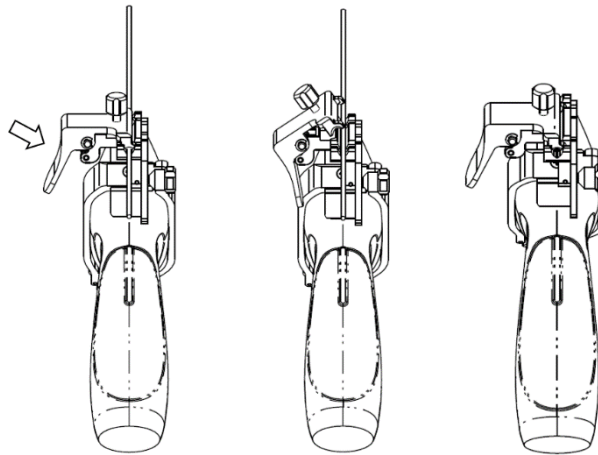


#### NGB-051

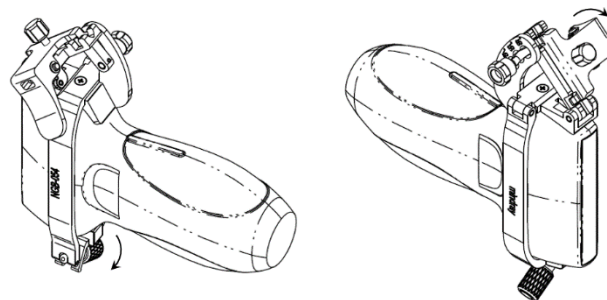
- (1) Turn on the knob of fixing the needle and separate the needle from the needle-guided bracket.
- (2) Turn on the knob of fixing guiding block and remove the guiding block from the hole of installing guiding block.
- (3) Turn on the knob of fixing needle-guided bracket and remove the needle-guided bracket.

#### NGB-053/NGB-054

- (1) Hold the transducer. Press the biopsy needle pressure position to separate the biopsy needle from the pressure position. Separate the bracket and the transducer from the needle.



- (2) 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 transducer. Hold the transducer and take out the bracket.



### 13.2.8 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.

#### Cleaning

Follow the cleaning instructions in the manual.

- 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 detached 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 30s 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.
- 9 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.

### High-pressure steam sterilization

High-pressure steam sterilization is preferred for the metal guided brackets.

- 1 Wear a pair of gloves to prevent infection.
- 2 Clean the needle-guided bracket 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.
- 5 Take out the sterilization package after sterilization and dry it in an oven at 60°C for 20–30 minutes.
- 6 Keep the sterilization package together with other sterilized surgical instruments in a sterile item storage area.
- 7 Check whether the needle-guided bracket has defects such as deformation and rusting before use. 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.

**NOTE:** 1. Repeated sterilization may degrade the safety and performance of the needle-guided bracket. Please check the needle-guided bracket's performance periodically.

2. Needle guided brackets are required to verified before each biopsy. If the verification fails, it indicates that the needle-guided brackets are out of service life.

## 13.2.9 Storage and Transportation

1. Don 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.
2. Between examinations, keep the needle-guided bracket in a sterile environment.
3. When 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.
4. Sterilize the carrying case as necessary.
5. Store or transport the needle-guided brackets under the following ambient conditions:
  - Ambient temperature: -20°C to 55°C

- Relative humidity: 20% to 95% (no condensation)  
Store or transport the needle-guided bracket NGB-024 under the following ambient conditions:
- Ambient temperature: -10°C to 60°C
- Relative humidity: 5% to 95% (no condensation)

### 13.2.10 Disposal

Be sure to dispose the needle-guided bracket only after sterilizing it.  
Contact your MINDRAY representative when disposing of this device.

## 13.3 Needle Navigation Guiding



### WARNING

**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 “13.2.8 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.**

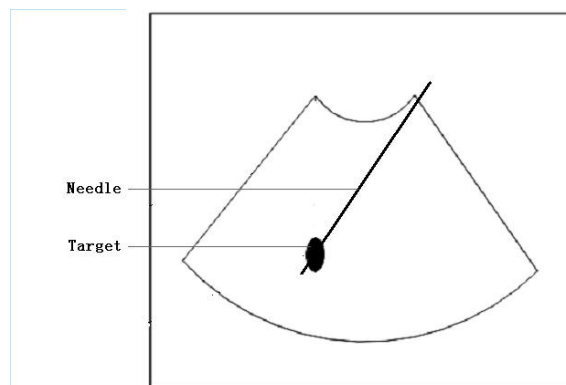
**Perform accuracy verification before conducting needle navigation. You can use the needle-guided bracket to anchor the needle before needle navigation for a better result.**

**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.**

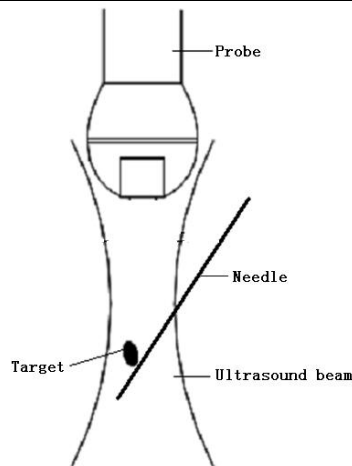
**When the target for biopsy is small, dispersion of the ultrasound beam may lead to image deviate from the actual position. Pay attention to this. Image deviation is shown as the figures below:**



**The biopsy needle appears to reach the target object in the image**

**Dispersion of the ultrasound beam**





### Dispersion of the ultrasound beam

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.

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.

## 13.3.1 Basic Procedures for Needle Navigation Guiding

### ■ Needle navigation guiding biopsy procedure under non-Fusion mode:


1. Connect all accessories of magnetic navigator. Refer to chapter "5.17.2 Magnetic Navigator" and "13.3.2 Installation" for details.
2. Activate needle navigation guiding feature and select needle type and length. Perform accuracy verification. For details, refer to chapter "13.3.3 Accuracy Verification".
3. Perform ultrasound image scanning and confirm position/size/structure of tumor/lesion. Mark the lesion. For details, refer to chapter "13.3.4 Mark".  
Tap [SSC] to perform acoustic speed correction. For details, refer to chapter "5.2.3 B Mode Image Optimization".
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 "13.3.5 Screen Display in the Guiding".
6. Save the single-frame and multi-frame image if necessary.

### ■ Needle navigation guiding biopsy procedure under Fusion mode:

1. Connect all accessories of magnetic navigator. Refer to chapter "5.17.2 Magnetic Navigator" and "13.3.2 Installation" for details.
2. Activate needle navigation guiding feature and select needle type and length. Perform accuracy verification. For details, refer to chapter "13.3.3 Accuracy Verification".
3. Enter Fusion imaging and load CT/MR/PET/freehand data. Refer to step 1-5 in chapter "5.17.4 Basic Procedures" for details.
4. Mark the tumor/lesion on CT/MR/PET/freehand image. For details, refer to chapter "5.17.6 Marks".  
Tap [SSC] to perform acoustic speed correction. For details, refer to chapter "5.2.3 B Mode Image Optimization".
5. Register CT/MR/PET/freehand data. For details, refer to chapter "5.17.4 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 "13.3.5 Screen Display in the Guiding".
8. Save the single-frame and multi-frame image if necessary.

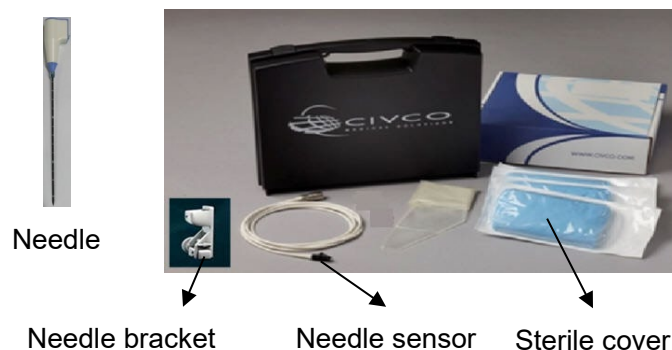
## 13.3.2 Installation

<b>Note:</b>	<p>Dispose needle, sensor support, and sterile cover by requirements of the manufacturer. Keep the bracket sensor.</p> <p>Clean and disinfect the sensor by requirements of the manufacturer and do not bend the sensor.</p> <p>Refer to the manufacturer manual for magnetic navigation installation and other information.</p> <p>Make sure the dimensions of sensor and eTRAX needle is basically the same, or magnetic navigation may be incorrect.</p> <p>eTRAX needle sensor is matched with eTRAX needle and trocar.</p>
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	<p><b>Do not bend the needle during installation.</b></p> <p><b>WARNING: Improper installation of the magnetic navigator leads to incorrect space navigation.</b></p>
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### vTRAX

Specifications:	
Biopsy needle	10~17G hard needle (vTRAX). Diameter: 2.0-3.3mm. Needle should be of non-interference to the sensor. NOTE: 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 "5.17.2 Magnetic Navigator" for details. Abdomen sensor is necessary under Fusion imaging mode.



NOTE: 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](mailto:info@civco.com)

<http://www.civco.com>

1. Refer to “5.17.2 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.



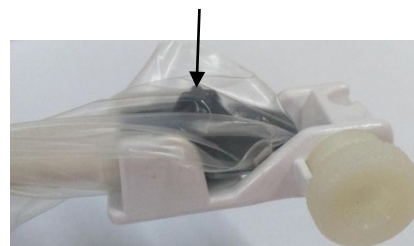
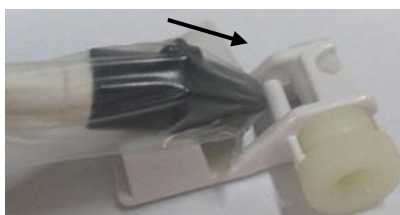
Biopsy needle sensor port

4. Put on the sterile cover onto the needle sensor.

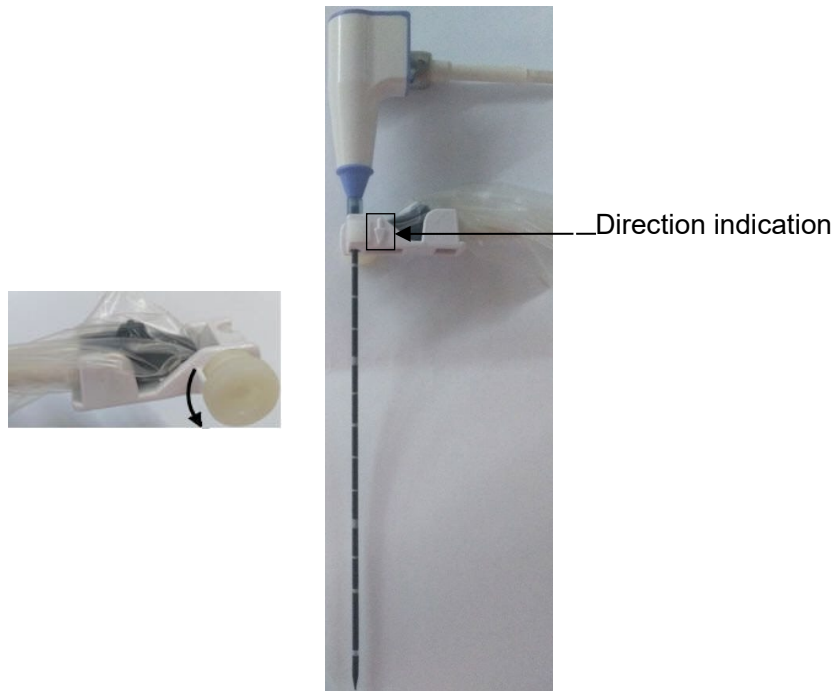


5. Connect needle sensor to the bracket.

Cross mark on the top



6. Loosen 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.

Specifications:	
Needle sensor	Manufacturer: CIVCO. Product number: 610-1112 Note: 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 NOTE: refer to manual provided by manufacturer for disinfection information.
Probe sterile sheath	Manufacturer: CIVCO Note: Wear sterile sheath for probe, refer to "5.17.2 Magnetic Navigator" for details.
Magnetic navigator	Magnetic controller, generator and probe sensor. Refer to "5.17.2 Magnetic Navigator" for details. Abdomen sensor is necessary under Fusion imaging mode.



eTRAX needle sensor      eTRAX needle      Sterile sheath

NOTE: 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](mailto:info@civco.com)  
<http://www.civco.com>

1. Refer to “5.17.2 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.



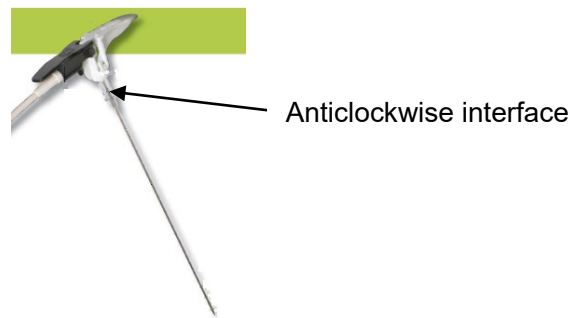
4. Insert the sensor into the needle.



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 “5.17.3 Screen Description” for details.
7. Perform needle navigation guiding; refer to “13.3.1 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.

### 13.3.3 Accuracy Verification



**WARNING:**

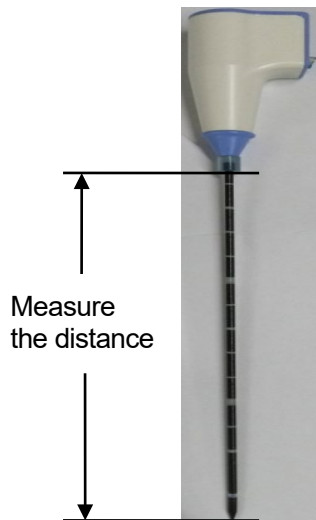
**This manual describes simple accuracy verification only. Perform elaborate accuracy verification procedure based on clinical scenario if necessary.**

**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.

1. Connect all accessories of magnetic navigator. Refer to “13.3.2 Installation” for details.
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.

### 13.3.4 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.

1. Connect all accessories of magnetic navigator. Perform accuracy verification procedure. Refer to chapter "13.3.2 Installation" and "13.3.3 Accuracy Verification" for details.
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 "5.17.6 Marks" for details.



**Note:** Be sure to use the section displaying the maximum of the lesion for marking.

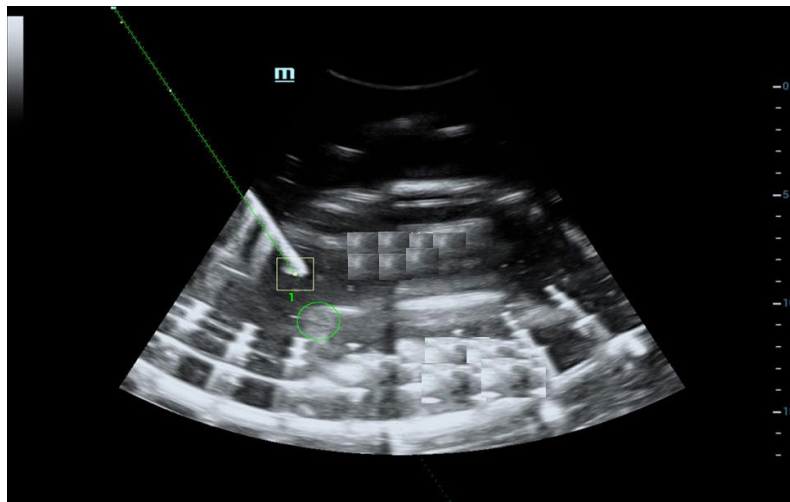
4. The lesion is enveloped by 3 circles from the inside and out: real-time mark, maximum diameter mark and safety boundary.
  - Perform the marking steps repeatedly for multiple marks. Marked color are displayed in green, red and blue in cycle and result window displays the diameter of the marked circle.
  - Refer to chapter “5.17.6 Marks” for details about moving/deleting/displaying/hiding marks.
  - Marking procedure under Fusion imaging mode:

Tap [Register CT/MR] and tap [Add Mark]->[Display Mark] to turn on the mark function. Refer to chapter “5.17.6 Marks” for details.

### 13.3.5 Screen Display in the Guiding

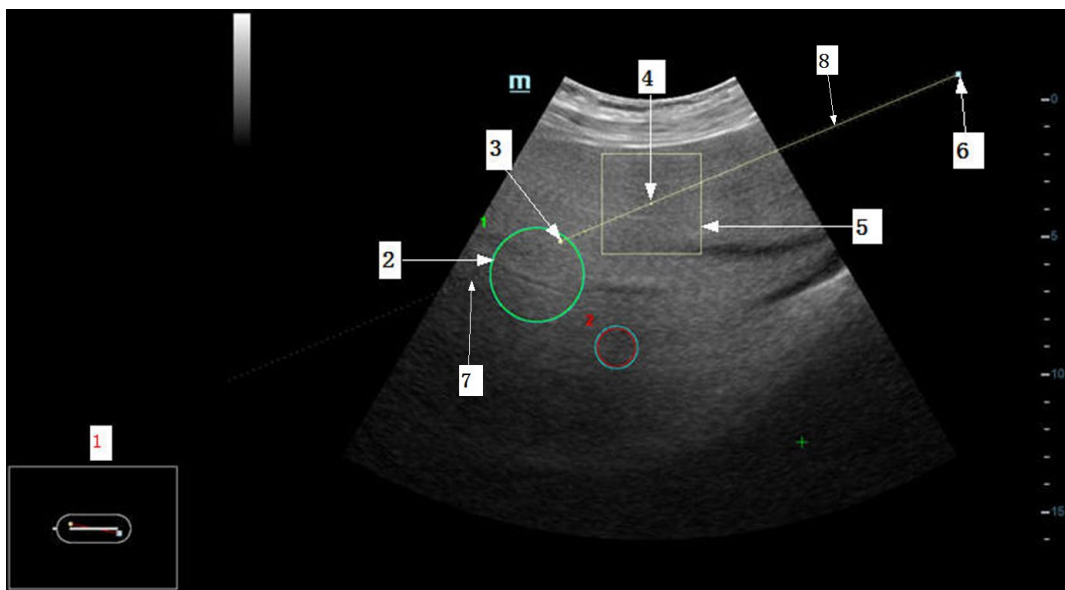
In-plane biopsy

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	<p>Orientation of the needle to the surface of the acoustic lens.</p> <ul style="list-style-type: none"> <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. For details, refer to chapter “13.3.4 Mark”.
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 style="list-style-type: none"> <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> </ul> <p>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.</p>
6	Needle end projecting point	Projecting point of the needle end on the ultrasound image plane.
7	Projected line	<p>Projected line of the needle on the ultrasound image plane.</p> <p>Solid line in the middle is the projected line of the needle central part. Dotted line on the both sides are top and bottom parts of the needle.</p> <ul style="list-style-type: none"> <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>
8	Guideline	<p>Virtual line.</p> <ul style="list-style-type: none"> <li>● Image with mark: guideline turns green if it can cross the mark. Otherwise, the guideline turns brown.</li> <li>● Image with no mark: guideline displays in brown.</li> </ul> <p>Tap [Guideline] to display or hide the guideline.</p>

### 13.3.6 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.

## 13.4 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.

To enter the mode: 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 “x” located on the middle line which can be moved up and down along the line by rolling the track ball.
- To use the Middle Line function of the ultrasound system:
- The depth of the mark is displayed in the image parameter area of the screen.



# 14 DVR Recording

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**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.

## 14.1 DVR 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 dialogue box and select desired recording type: Hard disk/USB/CDROM;
3. Click [Close] to enter recording status;
4. Press <F9> to record, and the DVR icon displays as  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 Local is selected, the system saves the file to the path: D/LV/DVR.

In the patient task management screen, click [Media Storage Task] tab to check transferring status.

## 14.2 Send Image

The system also supports exporting recorded images that are saved in the local disk.

1. Click  to open the dialogue box, and click [Local Video Management] to enter the managing dialogue box.  
Click [Rename] to rename the video file.
2. Select the destination and the target file, click [Send To] to send the file to the selected path. During sending progress, the icon displays as .


## 14.3 DVR Video Replay

You can replay the video and audio record.

Replay on PC

Connect the USB disk or optical disk with the file to the PC, open the file directly.

Replay on the ultrasound system

1. Click  to open the dialogue box.
2. Click [Play] to open the dialogue box;
3. Select the path and type for the file and then click [OK] to replay the file, or double-click the file name directly.

# 15 Acoustic Output

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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.

## 15.1 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.

## 15.2 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.

## 15.3 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".

## 15.4 MI/TI Explanation

### 15.4.1 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.

$$MI = \frac{P_{r, \alpha}}{\sqrt{f_{awf}} \times C_{MI}}$$

$$C_{MI} = 1 \text{ (MPa} / \sqrt{\text{MHz}} \text{)}$$

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 abdominal 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 abdominal 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.



## 15.4.2 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%

## 15.5 Acoustic Power Setting

Acoustic power adjustment

Rotate the [A.power] knob 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 the Resona I9 series 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 93.3% 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, tap [End], 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-Track3 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 determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields.

## 15.6 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 on the touch screen or the corresponding knob at the bottom of touch screen. 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.

## 15.7 Acoustic Output

### 15.7.1 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  $z$ ),  $f_c$  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.

### 15.7.2 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 <sup>2</sup> )	$I_{SPPA,3}$ (W/cm <sup>2</sup> )	or	MI
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Regions (except eyes)	$\leq 720$	$\leq 190$		$\leq 1.9$
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### 15.7.3 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.

## 15.8 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%	
$I_{ta}$	26.48% for non-scan modes; 26.95% for scan modes.	
$I_{pa}$	26.5%	
Mechanical Index	13.01%	
	Non-scan Modes	Scan-Modes
Total Uncertainty for TIS	26.48%	6.03%
Total Uncertainty for TIB	26.48% or 18.72%	6.03%
Total Uncertainty for TIC	26.48%	6.03%

## 15.9 References for Acoustic Power and Safety

1. "Bioeffects and Safety of Diagnostic Ultrasound" issued by AIUM in 1993
2. "Medical Ultrasound Safety" issued by AIUM in 1994
3. Marketing Clearance of Diagnostic Ultrasound Systems and Transducers, June 27, 2019. Center for Devices and Radiological Health.
4. 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
5. IEC 62359, Ultrasonics-Field characterization-Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields, 2017.

# 16 EMC Guidance and Manufacturer's Declaration

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Resona I9 series 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).

- WARNING:**
1. The use of unapproved accessories may diminish system performance.
  2. Use of components, accessories, probes, and cables other than those specified may result in increased emission or decreased immunity of system.
  3. 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.)
  4. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
  5. Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
  6. 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 Resona I9 series, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
  7. Keep a distance of at least 20 cm away from the monitor when WiFi function is in use.
  8. Resona I9 series needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.
  9. Other devices may interfere with this equipment even though they meet the requirements of CISPR.
  10. 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.

11. **Portable and mobile RF communications equipment could affect system. See below tables.**
12. **Resona I9 series 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.**
13. **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.**
14. **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.**

If Resona I9 series is operated within the electromagnetic environment listed in Table 3, Table 4, Table 5, Table 6, Table 7 Resona I9 series will remain safe and will provide the following basic performances:

Imaging;  
Doppler acoustic spectral displaying;  
Taking measurements;  
Patient information;  
Date/time information.

TABLE 1

<b>GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC EMISSIONS</b>		
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.		
<b>EMISSIONS TEST</b>	<b>COMPLIANCE</b>	<b>ELECTROMAGNETIC ENVIROMENT – GUIDANCE</b>
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 2


<b>GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC EMISSIONS</b>		
The Probe P7-3Ts/P7-3TE/P7-3TU and Fusion imaging function which integrated in 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.		
<b>EMISSIONS TEST</b>	<b>COMPLIANCE</b>	<b>ELECTROMAGNETIC ENVIROMENT – GUIDANCE</b>
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	

TABLE 3

<b>GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC IMMUNITY</b>			
Resona I9 series 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.			
<b>IMMUNITY TEST</b>	<b>IEC 60601 TEST LEVEL</b>	<b>COMPLIANCE LEVEL</b>	<b>ELECTROMAGNETIC ENVIRONMENT – GUIDANCE</b>
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	±0,5 kV, ±1 kV line(s) to line(s); ±0,5 kV, ±1 kV, ±2 kV line(s) to earth	±0,5 kV, ±1 kV line(s) to line(s); ±0,5 kV, ±1 kV, ±2 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 uninterruptible 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.			



TABLE 4

GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC IMMUNITY			
Resona I9 series 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 ENVIROMENT – GUIDANCE
Conduced RF IEC 61000-4-6	3 Vrms 0,15 MHz – 80 MHz  6 Vrms in ISM and amateur radio bandsa between 0,15 MHz and 80 MHz	3 Vrms 0,15 MHz – 80 MHz  6 Vrms in ISM and amateur radio bandsa 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 ~ 800 MHz $d = 2.3 \times \sqrt{P}$ 800 MHz ~ 2.7GHz 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.			

<sup>a</sup>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.

<sup>b</sup>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.

<sup>c</sup> Over the frequency ranges 150 kHz to 80 MHz, field strengths should be less than 3V/m.

TABLE 5

<b>GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC IMMUNITY</b>			
Resona I9 series 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.			
<b>IMMUNITY TEST</b>	<b>IEC 60601 TEST LEVEL</b>	<b>COMPLIANCE LEVEL</b>	<b>ELECTROMAGNETIC ENVIROMENT – GUIDANCE</b>
Proximity magnetic fields IEC 61000-4-39	8 A/m 30 kHz CW	8 A/m 30 kHz CW	/
	65 A/m 134,2 kHz Pulse modulation 2,1 kHz	65 A/m 134,2 kHz Pulse modulation 2,1 kHz	
	7,5 A/m 13,56 MHz Pulse modulation 50 kHz	7,5 A/m 13,56 MHz Pulse modulation 50 kHz	

TABLE 6 Test specifications and minimum distances

Recommended separation distances between portable and mobile RF communications equipment and system						
Resona I9 series 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 Resona I9 series 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	Maximum 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 $\pm 5$ kHz deviation 1 kHz sine	2	0.3	28
710	704 - 787	LTE Band 13,17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 - 960	GSM 800/900, tetra 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1720	1700 -1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3,4,25,UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
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, 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						

TABLE 7

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATION DEVICE AND THE SYSTEM				
Resona I9 series 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 Maximum Output power of Transmitter (W)	Separation Distance According to Frequency of Transmitter			
	150kHz -80MHz Out ISM and amateur radio bands $d=1.2\sqrt{P}$	150kHz -80MHz in ISM and amateur radio bands $d=2\sqrt{P}$	80MHz-800MHz $d=1.2\sqrt{P}$	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
<p>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.</p> <p>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.</p> <p>Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>				

TABLE 8

No.	Name	Cable length (m)	Shield or not	Remarks
1	Power input	2.5m	Not shielded	/
2	SIP/SOP	<3.0m	Shielding	/
3	ECG Cable	2.9m	Shielding	/
4	ECG Lead	1.0m	Shielding	/
5	Probe Cable	<3.0m	Shielding	/
6	Footswitch Cable	2.9m	Shielding	/

### Radio Regulatory Compliance

RF parameter

Features	2.4GHz	5GHz
Frequency Range	2412MHz~2483.5MHz	5.15~5.25GHz 5.25~5.35GHz 5.47~5.725GHz 5.725~5.850GHz
Modulation	DSSS and OFDM	OFDM
Output Power	$\leq 20\text{dBm}$	

**NOTE: Keep a distance of at least 20cm away from the monitor when Wi-Fi function is in use.**



# 17 System Maintenance

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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.

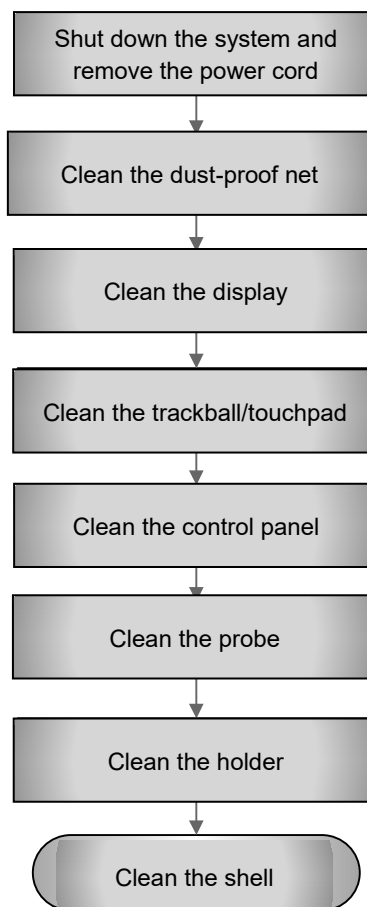
The responsibility for maintenance and management of the product after delivery resides with the customer who has purchased the product.

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.

## 17.1 Daily Maintenance

### Cleaning procedure



**WARNING:** Before cleaning the machine, turn off the power supply of the machine and remove the power cable. Cleaning the machine in power-on state may result in electric shock.

- Clean the dust-proof net of the main unit
  - Tool: soft brush
  - Method:
    1. Before cleaning, remove the dust-proof net. Remove the front cover assembly and the dust-proof net as shown below.
      - a) Lift the front cover outward from the groove (for the machine with the central brake structure, step on to lock the central brake, and then lift the cover outward).
      - b) Locate the dust-proof net handle on the upper part of the cover and pull out the dust-proof net.



2. Clean the dust-proof net: Gently brush off the dust from dust-proof net with a soft brush.
3. Install the dust-proof net: Install the dust-proof net by performing operations in reverse order of the dust-proof net removal procedure, and reinstall the front cover assembly back to the cover.

**CAUTION:**

Clean all the dust-proof nets of the machine regularly (once a month), otherwise it is easy to cause damage to the machine. When the machine is used outdoors or in other dusty places, increase the cleaning frequency.

- Cleaning the display (touch screen)
  - Tools: dry soft cloth, water or mild soapsuds
  - Method: Directly use a dry soft cloth to clean the surface of the display and touch screen. If there is still a stain, dip a dry soft cloth with a little water or mild soapsuds to wipe and then air dry the display.
- Cleaning the trackball

The trackball is a human-computer interaction component. It is easy for the trackball to bring dust from the outside into the module during use. Therefore, regular maintenance is needed to ensure



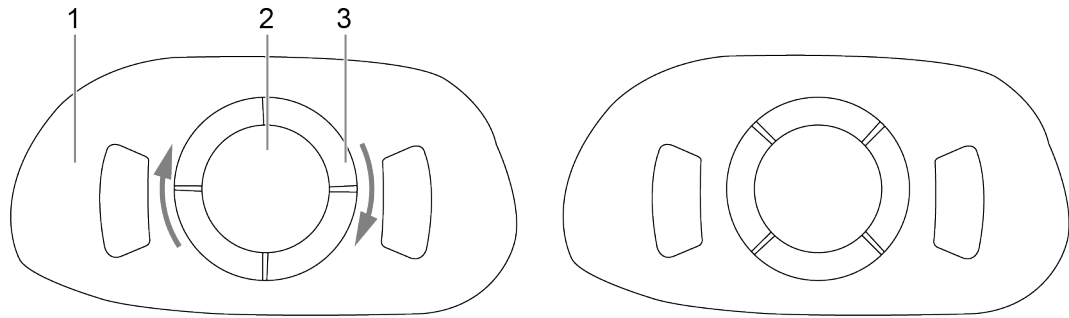
the system performance. When the cursor control is not flexible, it may be caused by dust pollution inside the trackball. In this case, remove the trackball and clean the dust inside.

- Tools: paper tissue, dry soft cloth, and mild soapsuds

- Method:

- Remove the trackball:

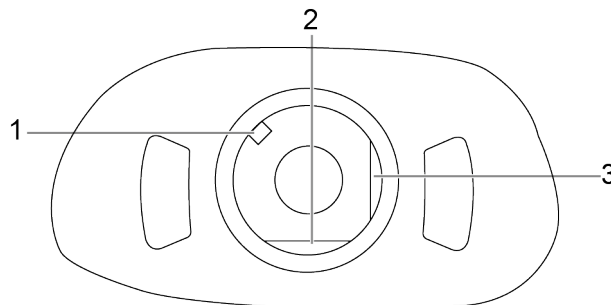
With two fingers, grab the convex strip on the trackball pressure ring and turn it clockwise for about 45 degrees. When the pressure ring rises with the rotation, take out the pressure ring and the ball (be careful that dropping the ball may cause damage to the ball). See the figure below:



1	Keyboard cover	2	Trackball
3	Trackball pressure ring		

- Cleaning:

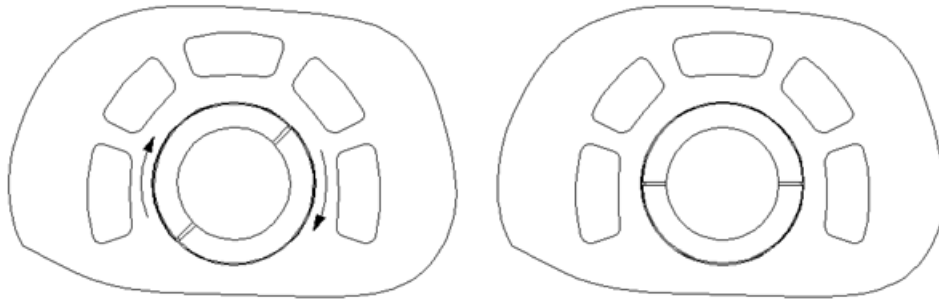
Use a clean soft cloth or dry paper tissue to clean the two main shafts inside the trackball, bearings, plastic housing, and inner part of the pressure ring, as shown below. Meanwhile, clean the ball.



1	Bearing	2	Main shaft
3	Main shaft		

- Re-installing:

Put the ball in. Then, put the pressure ring in (the convex strip on the pressure ring is about 15 degrees from the horizontal), and rotate counterclockwise until the convex strip on the pressure ring is horizontal. Then, the buckle is locked. At this time, the pressure ring can no longer be rotated, indicating that the pressure ring has been installed in place. See the figure below.



■ Cleaning the control panel

- Tools: mild soapsuds, and dry soft cloth
- Method: Use a dry soft cloth to wipe the dust from the surface of the control panel (including keys and encoder). Or, dip a soft cloth with a small amount of mild soapsuds to scrub away stubborn stains, and then use another soft cloth to dry or air dry the control panel. If it is difficult to clean the control panel, remove the encoder cap and clean the control panel with mild soapsuds.

**Note:** Clean the control panel and keyboard regularly; otherwise the dirt in the gaps between keys will jam the keys, causing long beeping of the buzzer and malfunction of keys.

■ Cleaning the holders

- Tools: mild soapsuds, dry soft cloth, and soft brush
- Method:
  1. Use a dry soft cloth to wipe the dust inside and outside the probe/medical ultrasound couplant holder and the gap of the holder. For the small cavity probe holder or gap, use a soft brush to gently brush off the dust and stains from the inner layer.
  2. If there are still stubborn stains, you can remove the holder, dip a dry soft cloth with a small amount of mild soapsuds to wipe off the stains attached to the external or internal layer of the holder, air dry the holder, and then install the holder.
  3. Medical ultrasound couplant heating cup: Disconnect the power cord of medical ultrasound couplant heating cup, remove the heating cup, dip a dry soft cloth with a small amount of soapy water to clean the inside and outside of the heating cup, use a soft brush to clean the dust in the holes at the bottom, dip a dry soft cloth with a small amount of soapy water to remove the residual stains, air dry the heating cup, and then install it.

■ Cleaning the coupling heater

- Tools: mild soapsuds, dry soft cloth, and soft brush
- Method:
  1. Disconnect the power cord of the coupler heater and remove the heater from its bracket.



2. Press the snap-fits of the bottom arm in the directions indicated by the arrows to remove the bottom cover.
3. Use a soft cloth dipped in soapy water or water to gently wipe the heater surface and the connection cable.
4. Remove the bottom cover for cleaning.

**Note:** Avoid liquid flowing into the gap of the heater. Do not use organic solvent to scrub the heater. Turn on and use the heater only after its surface is fully dried.

**Note:** Do not use strong solvent such as acetone. It is prohibited to use rough materials (such as steel velvet) to clean the surface of the heater.

Clean the bottom cover of the heater regularly. Remove the bottom cover during cleaning. After cleaning, re-install the bottom cover at the bottom of the heater after its surface is dried.

#### ■ Cleaning the machine shell

- Tools: mild soapsuds, and dry soft cloth
- Method: Use a dry soft cloth to wipe the dirt off the machine shell (the exposed part). Or, use with a dry soft cloth dipped in a small amount of mild soapsuds to remove stains, and air dry the shell.

**Note:** Use a soft brush to gently remove the dust from naked interfaces or sockets (such as probe sockets, IO panels, and power panels). Do not use a water cloth.

#### ■ Cleaning peripherals

Clean peripherals according to the actual conditions of the optional peripherals, and omit items that are not configured.

Item	Content	Method
1	Color or black and white video printer	Use a dry soft cloth to wipe off the dust or stains on the outer shell of the printer, and then open the outer shell to clean the inside of the printer. Make sure to follow instructions of the printer for cleaning and maintenance.
2	Graphic printer	Use a dry soft cloth to wipe off the dust or stains on the shell of the printer, and then open the shell to clean the inside of the printer. Make sure to follow instructions of the printer for cleaning and maintenance.
3	Footswitch	Use a dry soft cloth dipped with an appropriate amount of mild soapsuds to wipe off the dust and stains on the keys and cables of the footswitch.
4	Bar code scanner	Use a dry soft cloth to wipe the glass plate of the scanning window, and then wipe of the dust or stains on the cable and bracket. For special cleaning, make sure to follow the instructions of the scanner.

## 17.2 Common inspections

### Common inspections

Item	Content	Method
1	Probe	<p>Visually check the head of the probe for cracks or expansion.</p> <p>Visually check the probe cable for aging or peeling.</p> <p>Visually check the probe connector for bending, damage, or fallen stitches.</p>
2	Power cord and plug	<p>Visually check the power cord for wrinkles, cracks or aging.</p> <p>Manual check whether the connection of the power plug is reliable, check the power cord or plug is loosened or broken, and whether the anti-drop hook of the power cord is effective.</p>

Item	Content	Method
3	Battery	<p>Check battery performance regularly:</p> <p>Check whether the battery can be normally charged in startup state: If the current battery is 100% or the battery rises after a certain period of time, it indicates that the battery can be normally charged. When the general battery is less than 90%, the time needed to increase the battery power by 1% should be &lt; 5min; when the battery is greater than 90%, it takes more time to increase the battery power by 1%.</p> <p>In standby state, after disconnecting the AC power supply, check whether the battery can maintain normal standby status based on the standby status indicator.</p>

## 17.3 System Function Inspection

This inspection is an effective method to ensure product quality. When necessary, perform this inspection. Regular maintenance is not required.

**System function list**

SN.	Content	Method
1	B mode	Check the basic operations of the B mode. Check some of the basic software and hardware that affects operations related to the B mode.
2	Color mode	Check the basic operations of the color mode. Check some of the basic software and hardware that affects operations related to the color mode.
3	Doppler mode (PW/CW)	Check the basic operations of the Doppler mode. Check some of the basic software and hardware that affects operations related to the Doppler mode.
4	M mode	Check the basic operations of the M mode. Check some of the basic software and hardware that affects operations related to the M mode.
5	Measurement (2D, M, Doppler routine measurement; application measurement is optional)	Perform gray scale image scanning on the mannequin, use the measurement control to verify the accuracy of distance and area calculation. and verify the measurement accuracy based on the performance test results.
6	Keyboard test	Perform keyboard tests to verify that all control keys are working properly.

SN.	Content	Method
7	Custom key test	Verify that the user-defined functions of custom keys work properly.
8	Display	To check whether the display function and parameter adjustment of the display are normal, see the display test method.
8	Software menu check	Check the software menu display function, and verify that users can access various operation menus and screens normally.

## 17.4 Inspection of Peripherals and Optional Functions

If there are no modules or optional accessories in the system configuration, skip the relevant inspections.

### Inspection of optional functions, peripherals and accessories

Item	Content	Method
1	Color or black and white video printer	Check whether the output of the video printer is normal.
2	Graphic printer	Check whether the output of the graphic printer is normal.
3	Footswitch	Check whether the footswitch implements the configured functions according to the program.
4	DVD-R/W	Check if DVD-R/W is working properly (burning, reading and ejecting).
5	Bar code scanner	Check whether the scanner works normally and the output is correct.
6	DICOM	Check whether DICOM works normally. Send pictures and other data to DICOM server for verification.
7	ECG	Check the user's basic operations and verify the implementation of functions of the ECG module.

# Appendix A Barcode Reader

The product supports two kinds of readers for logging data as patient ID: 1-D barcode reader (SYMBOL LS2208) and 2-D barcode reader (SYMBOL DS4308).

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.**



## CAUTION:

**Ensure the information acquired by barcode reader is consistent with the actual information.**

**NOTE:** the reader does not support decoding of Multilanguage.

## 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.

### A.1.1 Overview

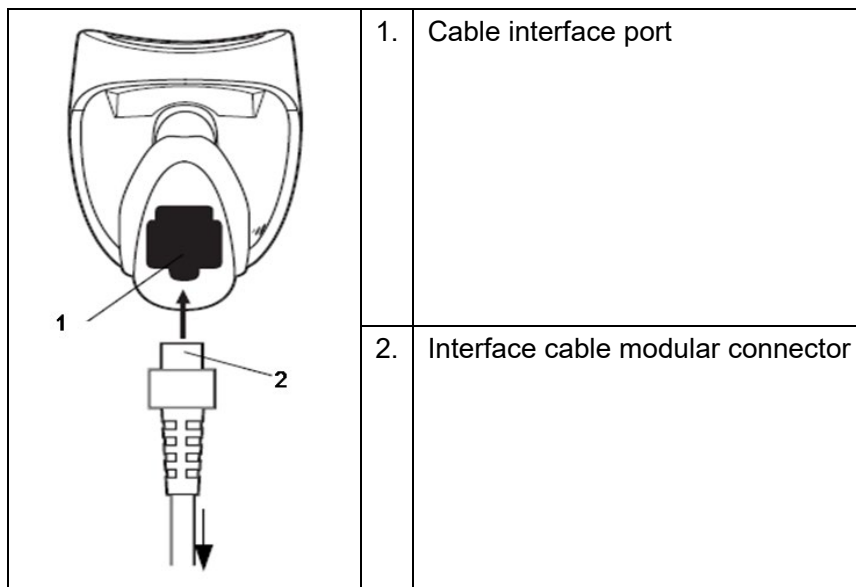


1.	LED	Green: A barcode was successfully decoded. Red: A data transmission error or reader malfunction occurred.
2.	Scan window	Scan the barcode.

3.	Trigger	Press to decode
----	---------	-----------------

## A.1.2 Setting Up the Reader (Take LS2208 as an example)

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.



## A.1.3 Settings

The reader has factory settings; please refer to A.4 for details.

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 scanning:

To enable or disable Code 93, scan the appropriate barcode below.



Enable Code 93

To enable Codabar, scan the appropriate barcode below.



Enable Codabar

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 or disable Code 39 Full ASCII, scan the appropriate barcode below.



Enable Code 39 Full ASCII



Disable Code 39 Full ASCII

1 2 of 5 symbols setting:



1 2 of 5 - One Discrete Length

Select this option to decode only 1 2 of 5 symbols containing a selected length. Select the length using the numeric barcodes below. For example, to decode only 1 2 of 5 symbols with 8 characters, scan **1 2 of 5 - One Discrete Length**, then scan **0** followed by **8**.



0



1



2



3



4



5



6



7



8



9

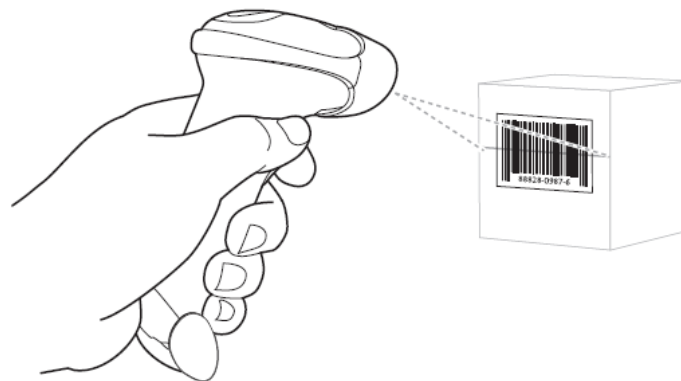
### A.1.4 Scanning in Hand-Held Mode

1. Ensure all connections are secure.
2. Aim the reader at the barcode. Press the trigger.

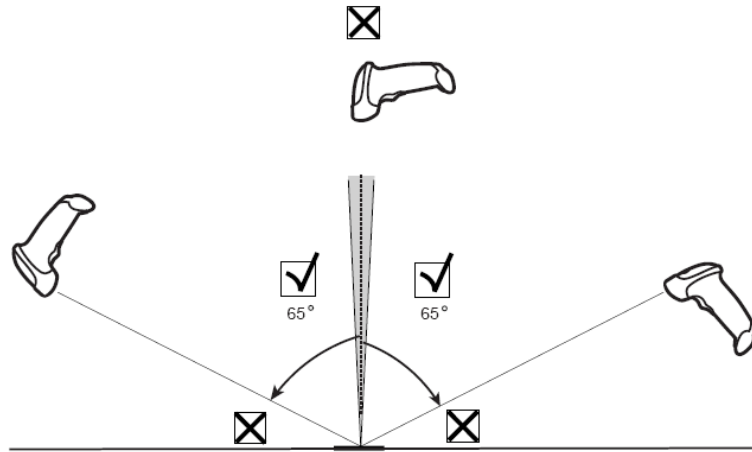
NOTE: Ensure the scan line crosses every bar and space of the symbol, see the figure below.



3. Upon successful decode, the reader beeps and the LED turns green.

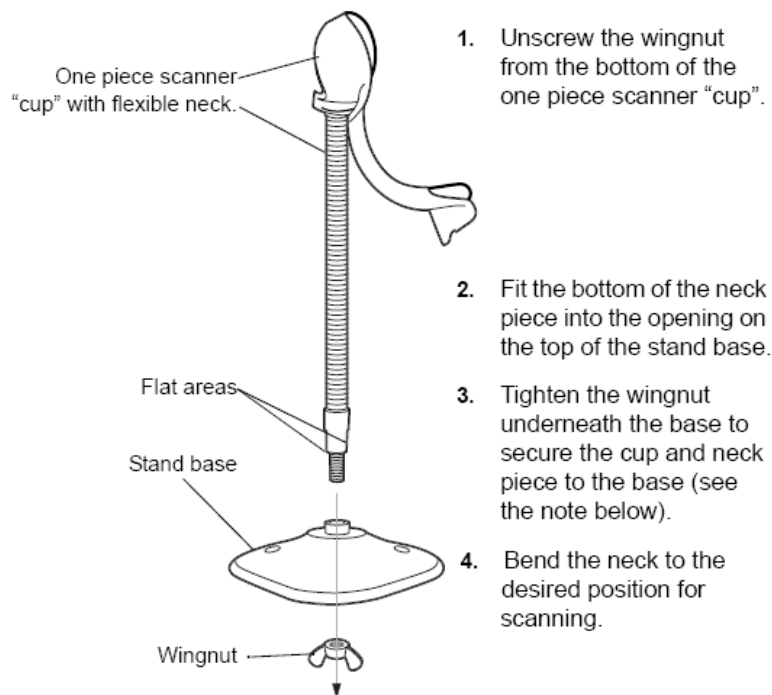


Tips: Do not hold the reader directly over the barcode. Laser light reflecting directly back into the reader from the barcode is known as specular reflection. This specular reflection can make decoding difficult. You can tilt the reader up to 55° forward or back and achieve a successful decode.



## A.1.5 Scanning in Hands-Free Mode

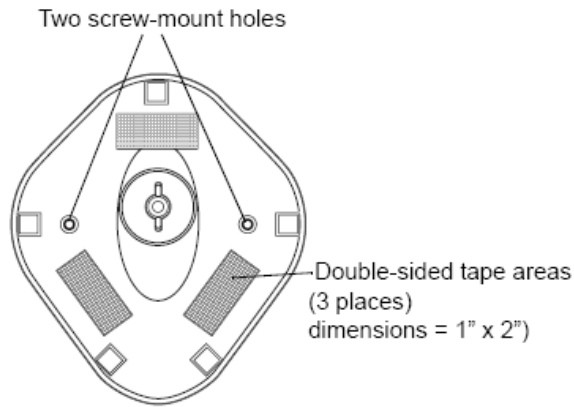
### A.1.5.1 Assembling the Intellistand



**NOTE** Before tightening the wingnut under the base, ensure that the flat areas on the flexible neck fit securely in the grooves in the base.

### A.1.5.2 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).



#### Screw Mount

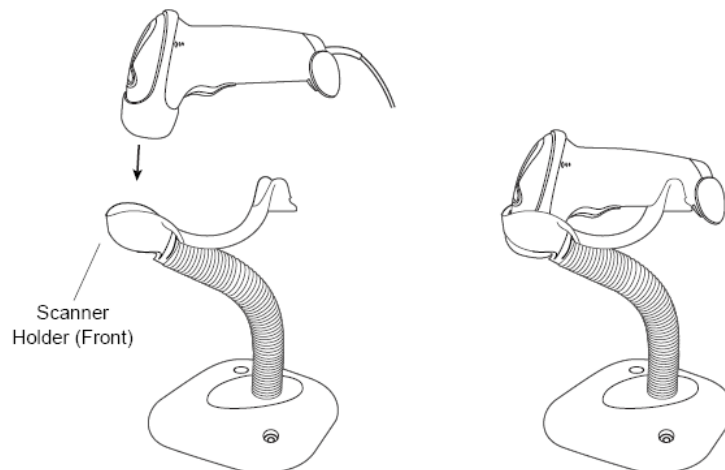
1. Position the assembled base on a flat surface.
2. Screw one #10 wood screw into each screw-mount hole until the base of the stand is secure

#### Tape Mount

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.

### A.1.5.3 Scanning in Hands-Free Mode

When the reader is seated in the stand's "cup", the reader's built-in sensor places the reader in hands-free mode. When you remove the reader from the stand it operates in its normal hand-held mode.

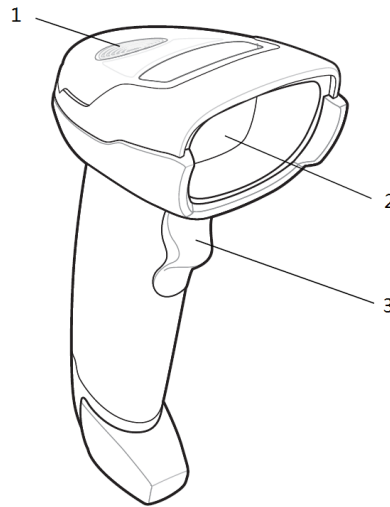


## A.2 2D Barcode Reader (Take DS4308 as an example)

The 2-D barcode reader supports hand-held operation mode.

Hand-held mode: press the trigger to decode.

## A.2.1 Overview

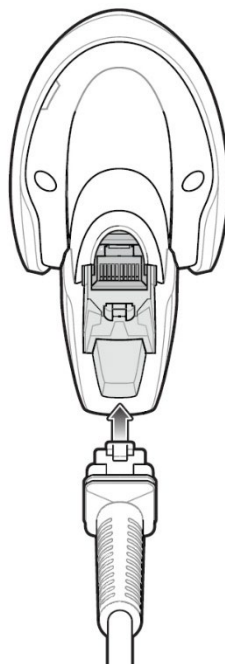


1.	LED	Green: A barcode was successfully decoded. Red: A data transmission error or reader malfunction occurred.
2.	Scan window	Scan the barcode.
3.	Trigger	Press to decode

## A.2.2 Setting Up the Digital Imager Reader

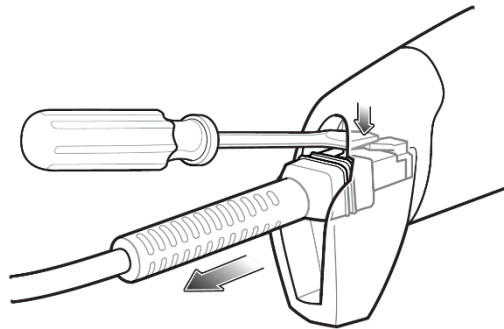
### A.2.2.1 Installing the Interface Cable

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.



### A.2.2.2 Removing the Interface Cable

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 Settings

The reader has factory settings; please refer to A.4 for details.

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**  
(2)



**Medium Volume**  
(1)



**\*High Volume**  
(0)

code 93 and codabar setting

To enable Code 93, scan the appropriate barcode below.



**\*Enable Code 93**  
(1)

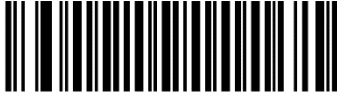
To enable Codabar, scan the appropriate barcode below.



**\*Enable Codabar  
(1)**

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 or disable Code 39 Full ASCII, scan the appropriate barcode below.



**Enable Code 39 Full ASCII  
(1)**



**\*Disable Code 39 Full ASCII  
(0)**

I 2 of 5 symbols setting



**I 2 of 5 - One Discrete Length**

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**.



**0**



**1**



**2**



**3**



**4**



**5**



**6**



**7**



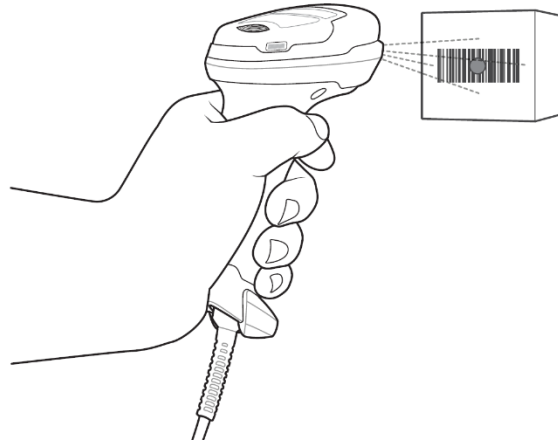
**8**



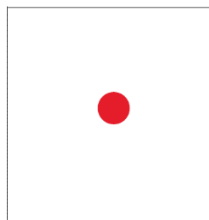
**9**

## A.2.4 Scanning in Hand-Held Mode

1. Ensure all connections are secure (see the appropriate host chapter.)
2. Aim the digital imager reader at the barcode.

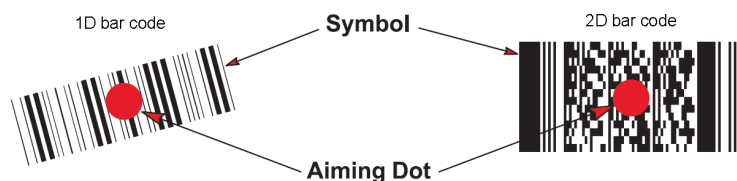


3. When the digital imager reader senses movement, in its default **Auto Aim** trigger mode, it projects a red LED dot which allows positioning the barcode within the field of view.



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.



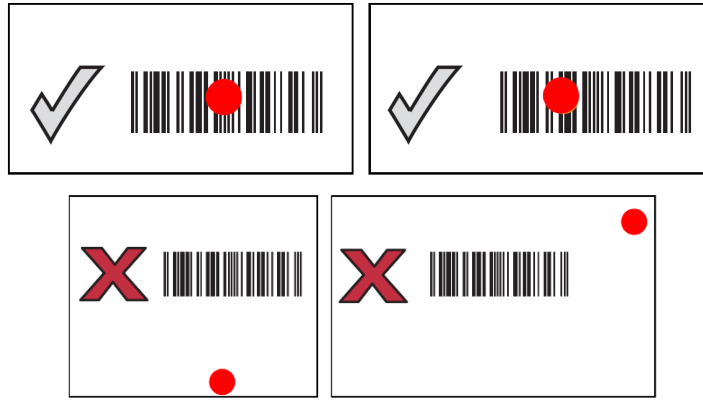
5. Hold the trigger until the digital imager reader beeps, indicating the barcode is successfully decoded.

NOTE: Steps 2 - 4 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.

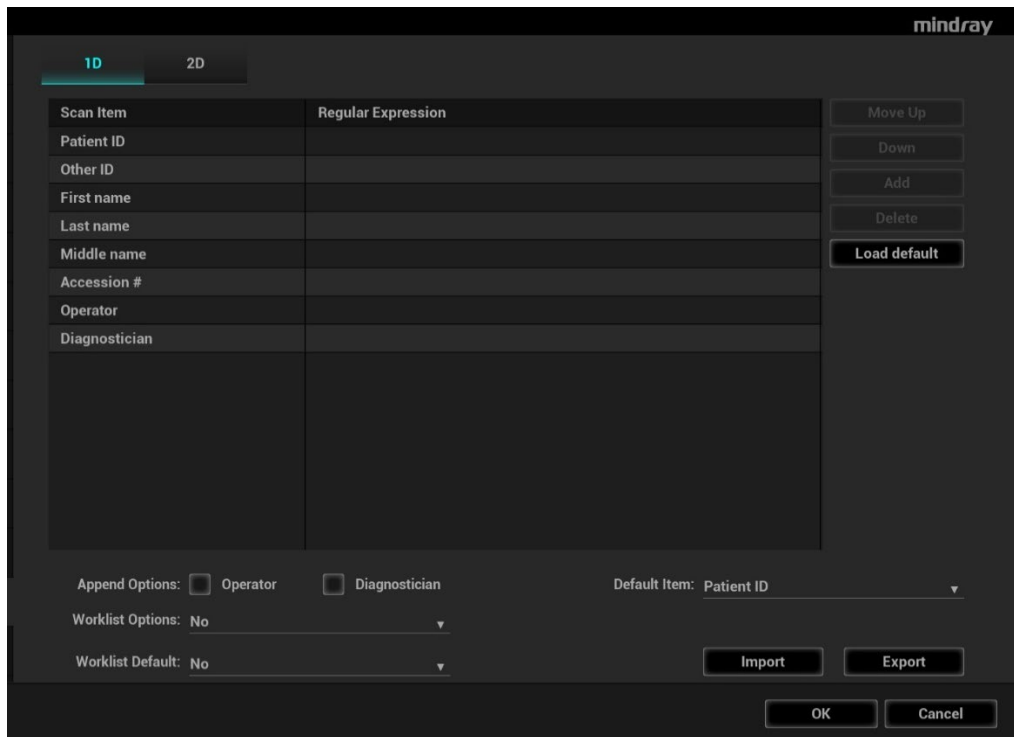
The digital imager reader can also read a barcode presented within the aiming dot not centered. The top examples in show acceptable aiming options, while the bottom examples cannot be decoded.





## A.3 Settings in Ultrasound System

Press <F10 Setup>, select [Setup] → [System] → [Scan Code] to set.  
1D bar code reader



Item	Description
Scan Item	<p>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 filled in this item in Patient page automatically.</p> <p>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 filled in "other ID" item in Patient page automatically.</p>

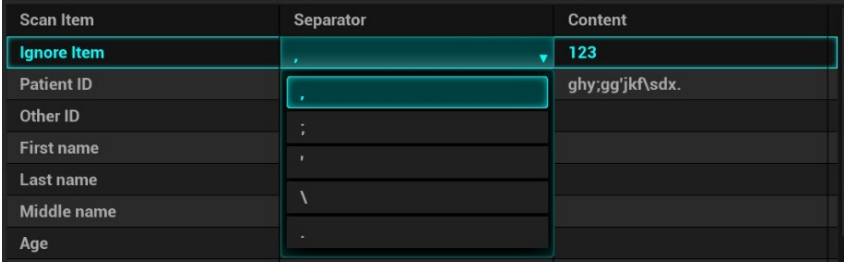
Item	Description
Regular Expression	Set the regular expression according to the bar code format.
Append Options	The information of operator or diagnostician can be appended after selecting append check box.

## 2D bar code reader

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

The screenshot shows the Mindray 2D bar code reader configuration window. At the top, there are tabs for '1D' and '2D', with '2D' being the active tab. Below the tabs is a 'Scan Barcode Example:' label. The main area contains a table with three columns: 'Scan Item', 'Separator', and 'Content'. The table lists various scan items such as 'Ignore Item', 'Patient ID', 'Other ID', 'First name', 'Last name', 'Middle name', 'Age', 'DOB', 'Birth(Year)', 'Birth(Month)', and 'Birth(Day)'. To the right of the table is an 'Analysis Mode:' dropdown menu set to 'General', with buttons for 'Move Up', 'Down', 'Add', 'Delete', and 'Load default'. Below the table, there are options for 'Age Unit' (Years, Months, Days), 'Male' and 'Female' checkboxes, 'Append Options' (Operator and Diagnostician checkboxes), 'Default Item' (Patient ID dropdown), 'Worklist Options' (No dropdown), and 'Worklist Default' (No dropdown). At the bottom, there are 'Import', 'Export', 'OK', and 'Cancel' buttons.

Parameter	Description
Scan Barcode Example	Input barcode example, barcode example is separated by separator.

Parameter	Description
Parameter	<ul style="list-style-type: none"> <li>Input barcode example, you can change the information of Patient ID, Other ID, First Name, Last Name, Middle Name, Birth(Day), Birth(Month), Birth(Year), Age, and Gender in the "content" list.</li> <li>Set the start and end position of each item via separators. You can select item separators from the drop-down list of the Separator, such as semicolon (;), hyphen (-), or comma (,) etc. (Note: 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.)</li> </ul>  <ul style="list-style-type: none"> <li>Move up: move up the selected item by one line.</li> <li>Down: move down the selected item by one line.</li> <li>Add Ignore: add one line below the selected item to hide unimportant patient information.</li> <li>Delete: delete the selected item. The item deletion operation does not delete the corresponding information in the barcode.</li> <li>Load default: restore the parameter value to the default value.</li> <li>Select an age unit from the drop-down list of the Age Unit: Year, Month, or Day.</li> <li>Input the customized gender symbol besides the Male and Female filed box, such as Male (M) or Female (F).</li> </ul> <p>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.</p>

- 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.

Default Item: after 2D and 1D barcode are matched unsuccessfully, the barcode will be filled as string when default item is no, otherwise, the barcode will be filled as selector.

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.

- (2) 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.

## A.4 Parameter Defaults

Refer to the following table for parameter defaults of LS2208 and DS4308.

Parameter	Defaults
<b>1-D Symbolologies</b>	
<b>UPC/EAN</b>	
UPC-A	Enable
UPC-E	Enable
UPC-E1	Disable
EAN-8/JAN 8	Enable
EAN-13/JAN 13	Enable
Bookland EAN	Disable
Decode UPC/EAN/JAN Supplementals (2and 5 digits)	Ignore
UPC/EAN/JAN Supplemental Redundancy	10
Transmit UPC-A Check Digit	Enable
Transmit UPC-E Check Digit	Enable
Transmit UPC-E1 Check Digit	Enable
UPC-A Preamble	System Character
UPC-E Preamble	System Character
UPC-E1 Preamble	System Character
Convert UPC-E to A	Disable
Convert UPC-E1 to A	Disable
EAN-8/JAN-8 Extend	Disable
UCC Coupon Extended Code	Disable
<b>Code 128</b>	
Code 128	Enable
UCC/EAN-128	Enable
ISBT 128	Enable
<b>Code 39</b>	
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
Code 39 Check Digit Verification	Disable
Transmit Code 39 Check Digit	Disable
Code 39 Full ASCII Conversion	Disable
Buffer Code 39	Disable
<b>Code 93</b>	
Code 93	Enable
Set Length(s) for Code 93	4 to 55
<b>Interleaved 2 of 5 (ITF)</b>	
Interleaved 2 of 5 (ITF) Enable	Enable
Set Lengths for I 2 of 5	14

<b>Parameter</b>	<b>Defaults</b>
I 2 of 5 Check Digit Verification	Disable
Transmit I 2 of 5 Check Digit	Disable
Convert I 2 of 5 to EAN 13	Disable
<b>Codabar (NW - 7)</b>	
Codabar	Enable
Set Lengths for Codabar	5 to 55
CLSI Editing	Disable
NOTIS Editing	Disable
<b>2-D Symbologies</b>	
<b>PDF417</b>	Enable
<b>MicroPDF417</b>	Disable
<b>Code 128 Emulation</b>	Disable
<b>Data Matrix</b>	Enable
<b>Maxicode</b>	Enable
<b>QR Code</b>	Enable

## A.5 Maintenance

Cleaning the exit window is the only maintenance required. A dirty window can affect scanning accuracy.

- Do not allow any abrasive material to touch the window.
- Remove any dirt particles with a damp cloth.
- Wipe the window using a tissue moistened with ammonia/water.
- Do not spray water or other cleaning liquids directly into the window.



# Appendix B iWorks (Auto Workflow Protocol)

## B.1 Overview

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.

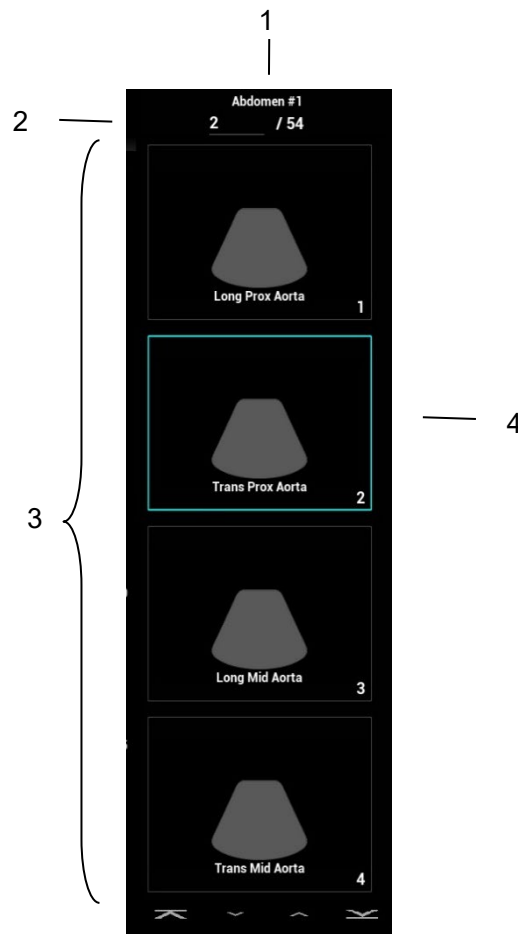
The system provides different protocol events based on the different application regions.

iWorks is an option.

## B.2 Normal iWorks Basic Procedure

1. Enter 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 touch the corresponding protocol button to enter the status.
3. After the system enters the iWorks screen, the available protocol is displayed on the touch screen. Perform the scanning and saving according to the screen prompt.  
Perform measurements or add comments/body marks to the image according to the screen prompt.
4. After a view scanning is complete, tap [Next] on the touch screen to switch to the next view according to the screen prompt.
5. Repeat step 3 and step 4 to acquire all the necessary images.
6. After all views are finished, the system will prompt you to exit iWorks. Tap [Yes] to exit.

## B.3 Screen Display



Name	NOTE
1	Displays the protocol name, and the number of views contained;
2	Go to the desired view by entering the view number.
3	Displays the view steps in the protocol.
4	The current active view, with green solid frame around the image.

## B.4 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.

### B.4.1 View Selection

Tap [Prev]/[Next] to select the view to be scanned. The current view is surrounded by a solid green frame.



## B.4.2 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.

## B.4.3 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.

## B.4.4 View Replacement

The previous image will be deleted and replaced by the new image.

## B.4.5 Delete View

Tap [Prev]/[Next] to select the view to be deleted. Tap [Delete] to delete the selected view.

## B.5 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.

You can run the system manually if necessary.

Start manual examination: touch [Suspend] to pause the current iWorks protocol. The system enters manual examination status.

Return to iWorks: touch [Resume iWorks] to return to automated status. You can continue the previous iWorks scan.

## B.6 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.

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.

## B.7 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.

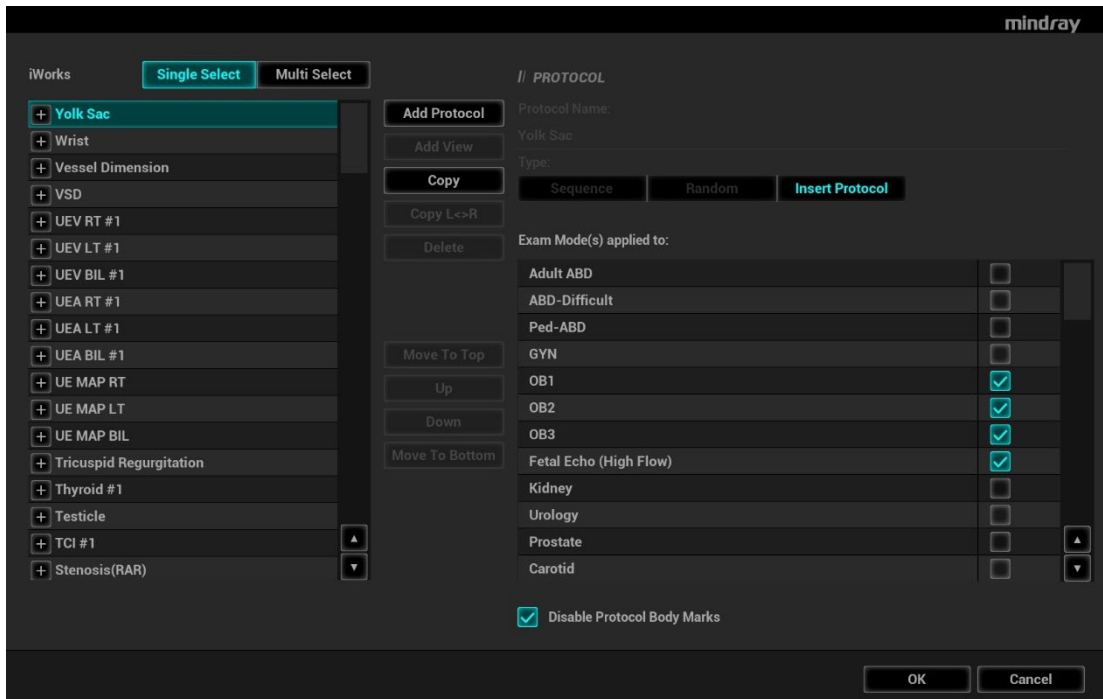
Select type from the drop-down list as Sequence, Random, or Insert Protocol.

Tap or click [Save] to temporarily save the creating.

4. Tap or click [Generate Protocol] to generate a user-defined iWorks protocol.

## B.8 iWorks Settings

Enter the iWorks preset screen using the path: “[Setup] → [iWorks].” Here you can customize the protocols and views:



### B.8.1 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. Check to select applied exam modes in the “Applied to” column.

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.

### B.8.2 View Management

Click to select the views in the list. The image, annotation, body mark and measurement settings can be checked on the right.

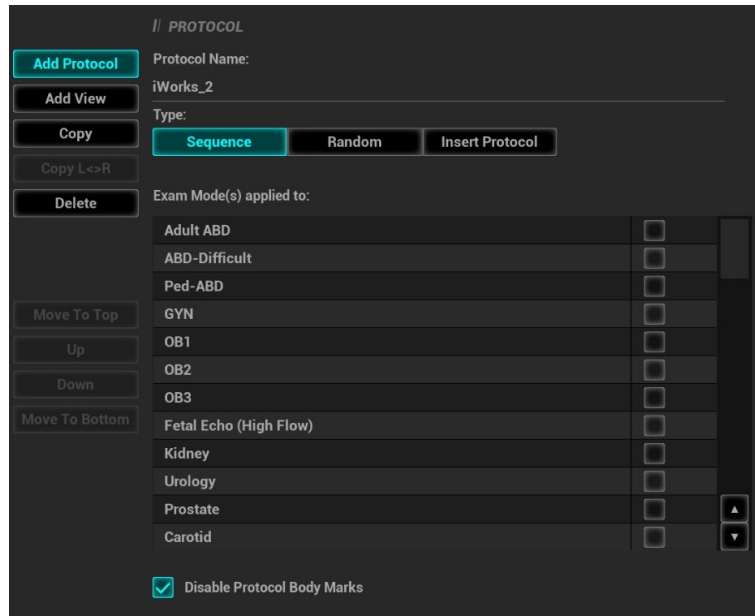
Click to select a user-defined protocol in the list. Click [Add View] to add a view template to the protocol.

## B.8.3 Create New Protocol

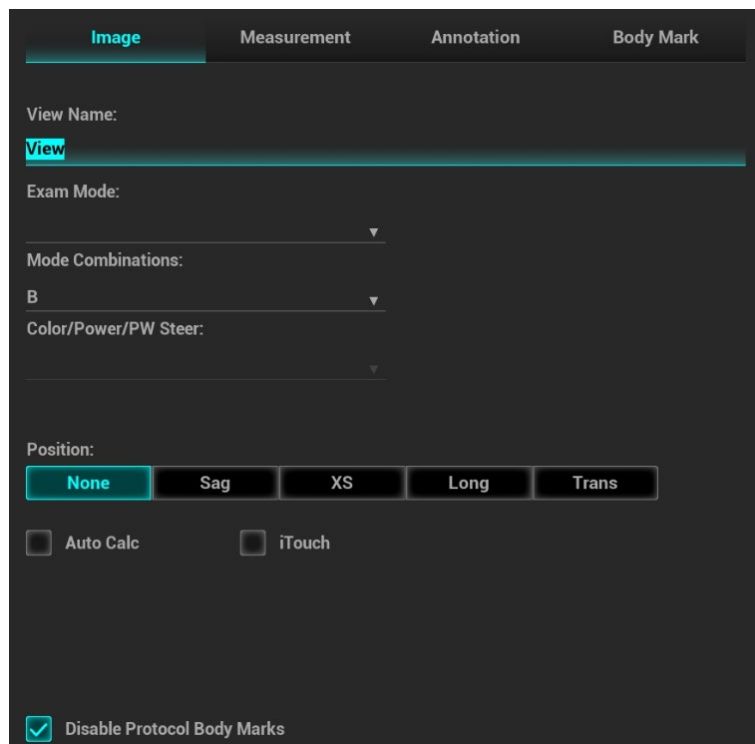
You can create user-defined protocols and customize the automated procedure.

1. In the iWorks preset screen, click [Add Protocol] to create a new protocol. Enter the protocol name, type and select the application region.

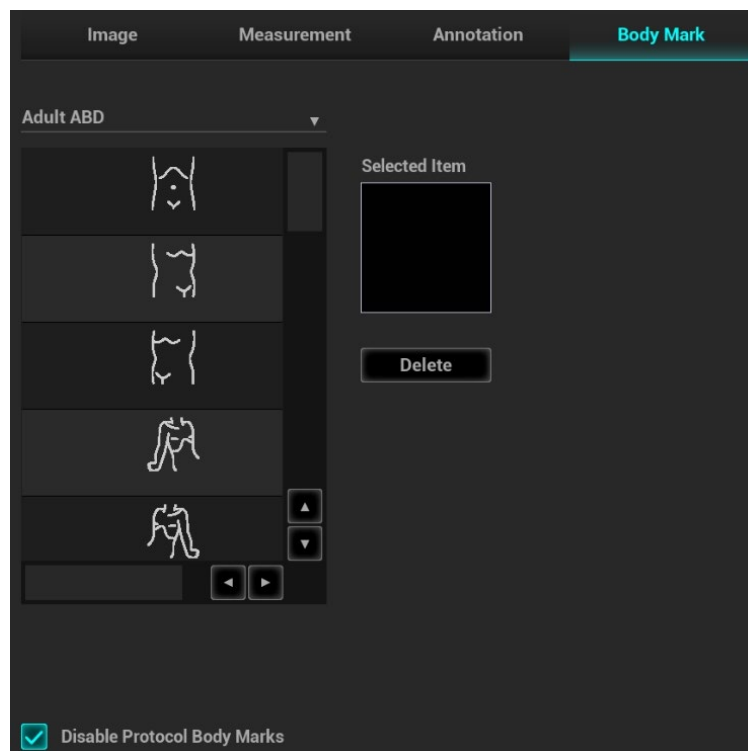
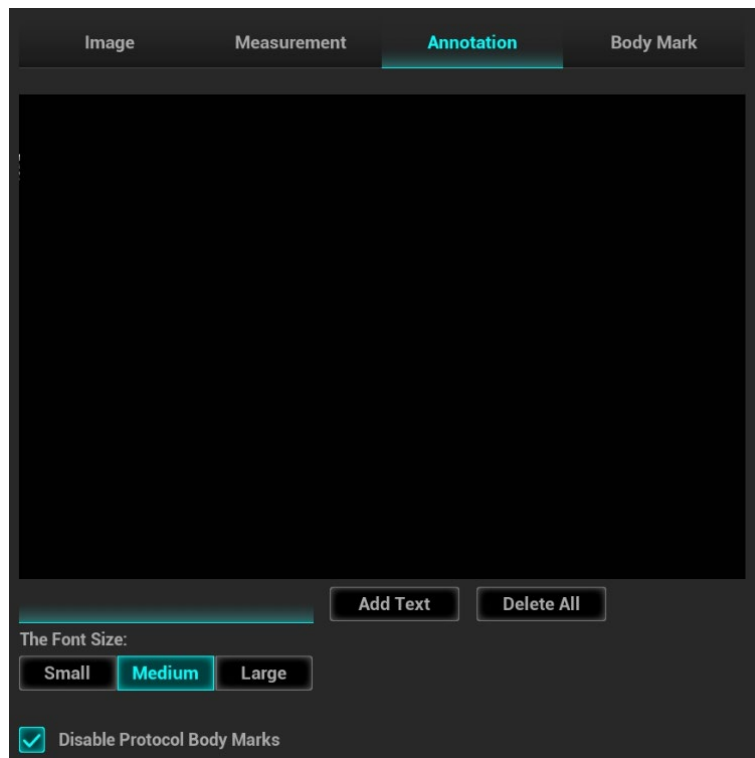
Or, select an existing protocol and click [Copy] to customize the protocol based on the previous template.

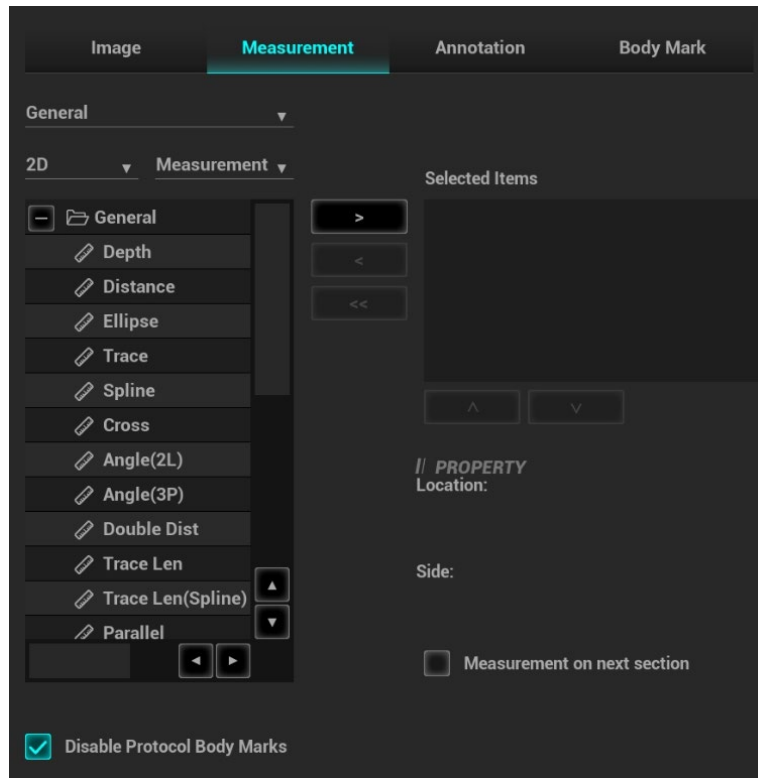


2. Click [Add View] to enter the view name and perform image settings as shown in the following figure.



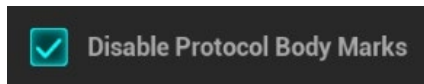
3. Add comments, body marks and perform measurement settings, as shown in the following figure:





In the image setting, if “Measurement on next section” is selected, the system will save two section images after finishing the section operation. One of the two sections will include the measurement result.

4. Select the checkbox for body mark display settings.



5. Click [Save] to complete the setting and exit.



# Appendix C Wireless LAN

The system provides wireless net adapter configuration, so as to assist information query and unlimited network service.

## **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:** 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 802.11n
  - Maximum transmission speed  $\geq 300\text{M}$
  - Use AP (access point) setting;
  - 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 Win8 or higher versions and it supports a Gigabit Ethernet.

Disconnection may be caused if the devices connected excess the router capacity (please refer to settings of the router, generally it should be  $\leq 5$ .)


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.

Wi-Fi function is not affected when the system is imposed with radiation interference complied with IEC 60601-1-2: 2014 standard.

## C.1 Use the Wireless feature

1. Press <Cursor> to show the cursor, click  in the bottom bar to open the wireless network manager.
2. Roll the trackball and press <Set> to select the target network, 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 . The icon turns into  or  after successful connection.

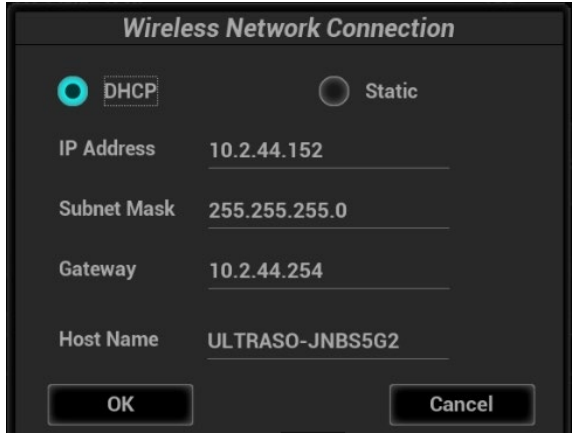


**NOTE:** When the system background is processing network task (DICOM sending for example), please do not enter network setting to change the IP or EAP, otherwise the background task may fail. You can check if there are tasks undergoing in the task manager.

### IP Config

IP config is used for setting local network parameters, which is also applied to DICOM connection.

1. In Wireless network manager screen, click [IP Config] to open the 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.
  - Subnet Mask: set different network segment.
  - Gateway: set the gateway IP.



- Host Name: automatically displayed.

NOTE: 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 [Apply] to save current setting. Click [Close] to exit.

<p><b>NOTE:</b> If the IP address displays as 0.0.0.0, this means that the network is abnormal. The reason for the failure may be disconnection or the system cannot obtain the IP address.</p>
---

#### EAP Network

For setting EAP network, contact Mindray Customer Service Department or the sales representatives.



# Appendix D Ultrasound Gel Heater

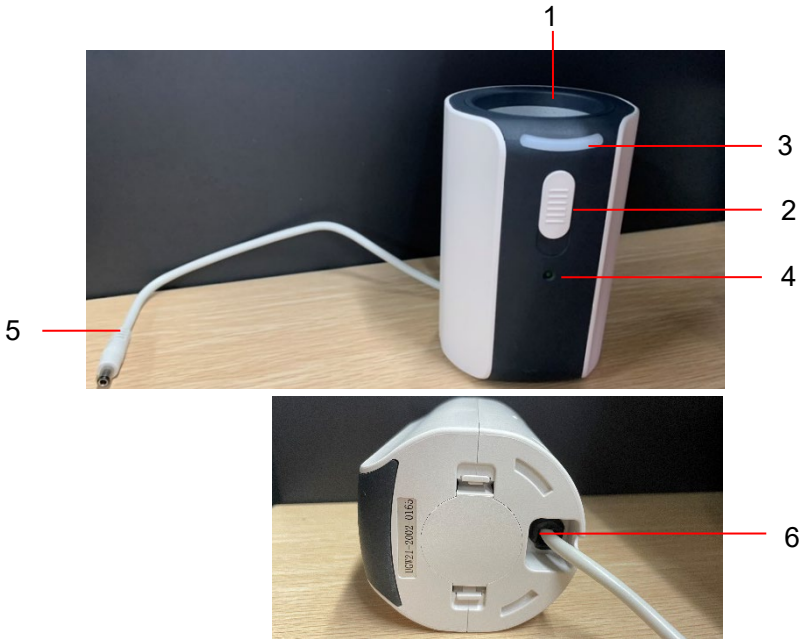
Ultrasound gel heater is a system option used for heating the ultrasound gel.

## D.1 Overview



As shown in the figure above, the heater is installed in the heater bracket, where the ultrasound gel is positioned.

## D.2 Structure



No.	Name	Description
1.	Ultrasound gel box	Used for placing the gel.
2.	Warming control switch	Open the switch to get gel heater worked. Set the temperature of the heater.
3.	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.
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	/

## D.3 Specifications

Power supply

<b>Voltage</b>	10-20V ( $\pm 5\%$ )
<b>Power consumption</b>	12W $\pm 10\%$ W

Environmental conditions

	Operating conditions	Storage and transportation conditions
<b>Ambient temperature</b>	0°C~40°C	-20°C~55°C
<b>Relative humidity</b>	20%~85% (no condensation)	20%~95% (no condensation)
<b>Atmospheric pressure</b>	700hPa~1060hPa	700hPa~1060hPa

## D.4 Function and Requirement

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.

<b>NOTE:</b>	1. When the ambient temperature is higher than the required temperature of the heater, the heater does not function.
	2. The heater can only heat one bottle of gel at a time.

## D.5 Install the Heater

1. Push the gel heater into the gel heater bracket as shown in the figure.



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.



# Appendix E Electrical Safety Inspection

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.

## E.1 Power Cord Plug

### E.1.1 The Power 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.

## E.2 Device Enclosure and Accessories

### E.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.).

### E.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.

## E.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

## E.4 Protective Earth Resistance

- Plug the analyzer probes into the device's protective earth terminal and the protective earth terminal of the AC power cord.
- Test the earth resistance with a current of 25 A.
- Verify the resistance is less than the limits.

LIMITS

ALL COUNTRIES R = 0.2  $\Omega$  Maximum



## E.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 UL60601-1:

- 300  $\mu\text{A}$  in Normal Condition.
- 1000  $\mu\text{A}$  in Single Fault Condition.

For IEC60601-1:

- 500  $\mu\text{A}$  in Normal Condition.
- 1000  $\mu\text{A}$  in Single Fault Condition.

## E.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 UL60601-1:

- 100  $\mu\text{A}$  in Normal Condition.
- 300  $\mu\text{A}$  in Single Fault Condition.

For IEC60601-1:

- 100  $\mu\text{A}$  in Normal Condition.
- 500  $\mu\text{A}$  in Single Fault Condition.

## E.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  $\mu\text{A}$  in Normal Condition.
- 500  $\mu\text{A}$  in Single Fault Condition.

## E.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  applied parts: 5000  $\mu\text{A}$ .

## E.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  $\mu\text{A}$  in Normal Condition.
- 500  $\mu\text{A}$  in Single Fault Condition.

**NOTE:** Make sure the safety analyzer is authorized and complies with the requirements of IEC61010-1.

Follow the analyzer manufacturer's instructions.

# Appendix F Battery



## WARNING:

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

## F.1 Overview

The built-in battery is an hardware option.

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

Generally, a completely discharged battery will fully charge in less than 6 hours.

**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.

## F.2 Battery Status Indicator

The battery status indicator is located in the lower right corner of the screen, indicating the battery capacity.



: Indicates the battery capacity is full.



: Indicates the battery capacity is less than 20%.



: Indicates the battery capacity is less than 10%.



: Indicates the battery capacity is 0.



: Indicates the battery is charging.



: Indicates the battery is not installed.



: Indicates the battery cannot be used. Please contact the Mindray service engineer.

# Appendix G List of Vocal Commands

The ultrasound system can automatically recognize some vocal commands. You can use a microphone device to input the vocal commands as shown in the following table. After the input command is recognized, the system automatically performs the corresponding operations.

Vocal command	Operation
Hello Mindray	Turn On Audio Control
Turn Off	Turn Off Audio Control
B Mode	Back to B Mode
CDI Mode	Turn on/off CDI Mode
Power Mode	Turn on/off Power Mode
M Mode	Turn on/off M Mode
PW Mode	Turn on/off PW Mode
3D	Turn on/off 3D Mode
Freeze	Freeze Image
UnFreeze	UnFreeze Image
Clear	Clear
Dual	Enter Dual Windows Format
Quad	Enter Quad Windows Format
QSave	QSave
Update	Update
Full Image	Turn on/off Full Image Mode
Middle Line	Display/Hide Middle Line
iNeedle	Turn on/off iNeedle Mode
iTouch	Turn on iTouch Mode
Depth Increase	Depth Increase One
Depth Decrease	Depth Decrease One
Gain Increase	Gain Increase One
Gain Decrease	Gain Decrease One
Gain Auto Increase	Gain Auto Increase
Gain Auto Decrease	Gain Auto Decrease
Gain Stop	Gain Stop Auto Increase/Decrease
Zoom In	Zoom In Image
Zoom Out	Zoom Out Image
Open Smart Track	Turn on Smart Track Mode
Close Smart Track	Turn off Smart Track Mode

<b>Vocal command</b>	<b>Operation</b>
Sound Volume Up	Turn Sound Volume Up
Sound Volume Down	Turn Sound Volume Down
Angle More	Angle More One
Angle Less	Angle Less One
Left Steer	Left Steer the Color ROI or Linear Image
Right Steer	Right Steer the Color ROI or Linear Image
BaseLine Down	Decrease the Baseline Position
BaseLine Up	Increase the Baseline Position
Save Image	Save Image
Save Clip	Save Clip
Save Screen	Save Screen
Adult Abdomen	Switch Exam Mode to Adult Abdomen
Abdomen Difficult	Switch Exam Mode to Adult Abdomen Difficult
Pediatric Abdomen	Switch Exam Mode to Pediatric Abdomen
Bowel	Switch Exam Mode to Bowel
Abdomen Vascular	Switch Exam Mode to Abdomen Vascular
Neonatal Abdomen	Switch Exam Mode to Neonatal Abdomen
Adult Cardiac	Switch Exam Mode to Adult Cardiac
Cardiac Difficult	Switch Exam Mode to Adult Cardiac Difficult
Pediatric Cardiac	Switch Exam Mode to Pediatric Cardiac
Left ventricular opacification	Switch Exam Mode to LVO
Neonatal Cardiac	Switch Exam Mode to Neonatal Cardiac
TEE Cardiac	Switch Exam Mode to TEE Cardiac
Gynecology	Switch Exam Mode to Gynecology
1st Trimester	Switch Exam Mode to 1st Trimester
Fetal Echo	Switch Exam Mode to Fetal Echo
Kidney	Switch Exam Mode to Kidney
Urology	Switch Exam Mode to Urology
Prostate	Switch Exam Mode to Prostate
Transcranial Imaging	Switch Exam Mode to Transcranial Imaging
Carotid	Switch Exam Mode to Carotid
Upper External Artery	Switch Exam Mode to Upper Ext Artery
Lower External Artery	Switch Exam Mode to Lower Ext Artery
Upper External Vein	Switch Exam Mode to Upper Ext Vein
Lower External Vein	Switch Exam Mode to Lower Ext Vein
Thyroid	Switch Exam Mode to Thyroid

<b>Vocal command</b>	<b>Operation</b>
Breast	Switch Exam Mode to Breast
Testicle	Switch Exam Mode to Testicle
Musculoskeletal	Switch Exam Mode to Musculoskeletal
Superficial	Switch Exam Mode to Superficial
Shoulder	Switch Exam Mode to Shoulder
Intraoperative	Switch Exam Mode to Intraoperative
Nerve Block	Switch Exam Mode to Nerve Block
Emergency Abdomen	Switch Exam Mode to Emergency Abdomen
Emergency FAST	Switch Exam Mode to Emergency Focused Assessment with Sonography for Trauma
Emergency Obstetrics	Switch Exam Mode to Emergency Obstetrics
Emergency Vascular	Switch Exam Mode to Emergency Vascular
Emergency Superficial	Switch Exam Mode to Emergency Superficial
Lung	Switch Exam Mode to Lung
Neonatal Head	Switch Exam Mode to Neonatal Head
Orthopedic	Switch Exam Mode to Orthopedic
Renal Artery	Switch Exam Mode to Renal Artery
IVF	Switch Exam Mode to IVF
NT	Switch Exam Mode to NT
Pelvic Floor	Switch Exam Mode to Pelvic Floor
Fetal Head	Switch Exam Mode to Fetal Head
Rectal	Switch Exam Mode to Rectal
OB2	Switch Exam Mode to OB2
OB3	Switch Exam Mode to OB3
HyCosy	Switch Exam Mode to HyCosy
Open Patient Info Dialog	Open Patient Info Dialog
Close Patient Info Dialog	Close Patient Info Dialog
Open Probe Dialog	Open Probe Dialog
Close Probe Dialog	Close Probe Dialog
Open Review Dialog	Open Review Dialog
Close Review Dialog	Close Review Dialog
Open Report Dialog	Open Report Dialog
Close Report Dialog	Close Report Dialog
Open Preset Dialog	Open Preset Dialog
Close Preset Dialog	Close Preset Dialog
Smart IVC	Smart IVC

Vocal command	Operation
Smart VTI	Smart VTI
Smart B-lines	Smart B-lines



# Appendix H Operating Environment

- Hardware Configuration

  - CPU: Intel X86, 3.7GHz

  - Hard disk: 128G SSD + 1T HDD

  - Monitor: 23.8 inch

- 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.



# Appendix I Indications For Use

N=new indication; P=previously cleared by FDA; E=added under Appendix E
Additional comments: Combined modes—B + 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
****For detection of fluid and pleural motion/sliding
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)

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

Transducer:	N/A								
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N	N	N	N	N	Note 1, 2, 3,4, 5, 6
	Abdominal	N	N	N	N	N	N	N	Note 1, 2,3, 4,6,10,11,12
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N	N	N	N	N	Note 1,2,4,6,
	Small Organ (Specify**)	N	N	N	N	N	N	N	Note 1, 2, 4,6,7,10,11
	Neonatal Cephalic	N	N	N		N	N	N	Note 1, 2, 4,6
	Adult Cephalic	N	N	N	N	N	N	N	Note 1, 2, 4,6
	Trans-rectal	N	N	N		N	N	N	Note 1, 2,3, 4, 6, 7,10,11
	Trans-vaginal	N	N	N		N	N	N	Note 1, 2,3, 4, 6, 7,10,11
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N	N	N	N	N	Note 1, 2,3, 4, 6, 7,10,11
	Musculo-skeletal (Superficial)	N	N	N	N	N	N	N	Note 1,2, 4,7,10,11
Intravascular									
Thoracic/Pleural (Specify****)	N	N	N		N	N	N	Note 1, 2, 4,6	
Cardiac	Cardiac Adult	N	N	N	N	N	N	N	Note 1, 2, 4, 5, 6, 7
	Cardiac Pediatric	N	N	N	N	N	N	N	Note 1, 2, 4, 5, 6
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)	N	N	N	N	N	N	N	Note 1,5,6
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N	N	N	N	N	Note 1, 2, 4,6,7,9,10,11
	Other (Specify***)	N	N	N		N	N	N	Note 1, 2, 4,6,7,10,11

Transducer:	SC6-1s								
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	Note 1, 2, 4, 5, 6
	Abdominal	N	N	N		N	N	N	Note 1, 2, 4,6,10,11,12
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)	N	N	N		N	N	N	Note 1, 2, 4,6
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	Note 1, 2, 4,6
	Musculo-skeletal (Superficial)								
	Intravascular								
Thoracic/Pleural (Specify****)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1, 2, 4,6
	Other (Specify***)	N	N	N		N	N	N	Note 1, 2, 4,6

Transducer:	C11-3s								
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N	N		N	N	N	Note 1, 2, 4,6,12
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	Note 1, 2, 4,6
	Small Organ (Specify**)								
	Neonatal Cephalic	N	N	N		N	N	N	Note 1, 2, 4,6
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
Intravascular									
Thoracic/Pleural (Specify****)									
Cardiac	Cardiac Adult	N	N	N		N	N	N	Note 1, 2, 4,6
	Cardiac Pediatric	N	N	N		N	N	N	Note 1, 2, 4,6
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1, 2, 4,6
	Other (Specify***)								

Transducer:	C6-2Gs								
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	Note1,2,4,6
	Abdominal	N	N	N		N	N	N	Note1,2,4,6,10,11,12
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	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)								
	Intravascular								
Thoracic/Pleural (Specify****)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)	N	N	N		N	N	N	Note1,2,4,6

Transducer:	L9-3s									
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:									
Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)	
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal	N	N	N	N	N	N	N	Note 1,2, 4	
	Abdominal	N	N	N	N	N	N	N	Note 1,2, 4, 10,11,12	
	Intra-operative (Specify*)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric	N	N	N	N	N	N	N	Note 1,2, 4	
	Small Organ (Specify**)	N	N	N	N	N	N	N	Note 1,2, 4,7,10,11	
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)	N	N	N	N	N	N	N	N	Note 1,2, 4,7,10,11
	Musculo-skeletal (Superficial)	N	N	N	N	N	N	N	N	Note 1,2, 4,7,10,11
Intravascular										
Thoracic/Pleural (Specify****)										
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
	Intravascular (Cardiac)									
	Trans-esoph. (Cardiac)									
	Intra-cardiac									
Peripheral vessel	Peripheral vessel	N	N	N	N	N	N	N	Note 1,2, 4,7,9,10,11	
	Other (Specify***)									



Transducer:	L20-5s								
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N	N	N	N	N	N	Note 1, 2, 4
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)	N	N	N	N	N	N	N	Note 1, 2, 4,7,10,11
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N	N	N	N	N	Note 1, 2, 4, 7,10,11
	Musculo-skeletal (Superficial)	N	N	N	N	N	N	N	Note 1, 2, 4, 7,10,11
Intravascular									
Thoracic/Pleural (Specify****)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N	N	N	N	N	Note 1, 2, 4,10,11
	Other (Specify***)								

Transducer:	V11-3Hs								
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application			Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	Note 1, 2, 4, 6
	Abdominal								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	N	N	N		N	N	N	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								
Thoracic/Pleural (Specify****)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)	N	N	N		N	N	N	Note 1, 2, 4, 6, 7,10,11

Transducer:	SP5-1s								
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N	N	N	N	N	N	Note 1, 2, 4,6
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic	N	N	N	N	N	N	N	Note 1, 2, 4,6
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Thoracic/Pleural (Specify****)	N	N	N			N	N	N	Note 1, 2, 4,6
Cardiac	Cardiac Adult	N	N	N	N	N	N	N	Note 1, 2, 4, 5, 6, 8
	Cardiac Pediatric	N	N	N	N	N	N	N	Note 1, 2, 4, 5, 6
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)								

Transducer:	SD8-1s								
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application			Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	Note 1, 3, 4, 6
	Abdominal	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								
Thoracic/Pleural (Specify****)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)								

Transducer:	CW5s								
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	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				N				
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic				N				
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Thoracic/Pleural (Specify****)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel				N				
	Other (Specify***)								

Transducer:	CW2s								
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	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				N				
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic				N				
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Thoracic/Pleural (Specify****)									
Cardiac	Cardiac Adult				N				
	Cardiac Pediatric				N				
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)								

Transducer:	P7-3Ts								
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	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								
	Thoracic/Pleural (Specify****)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)	N	N	N	N	N	N	N	Note 1,5,6
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)								

Transducer:	SC8-2s								
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	Note 1, 2, 4, 5, 6
	Abdominal	N	N	N		N	N	N	Note 1, 2, 4, 6
	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								
Thoracic/Pleural (Specify****)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1, 2, 4, 6
	Other (Specify***)	N	N	N		N	N	N	Note 1, 2, 4, 6



Transducer:	DE11-3Ws								
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	Note 1, 3,4,6
	Abdominal								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	N	N	N		N	N	N	Note 1, 3,4,6,7,10,11
	Trans-vaginal	N	N	N		N	N	N	Note 1, 3,4,6,7,10,11
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
Intravascular									
Thoracic/Pleural (Specify****)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)	N	N	N		N	N	N	Note 1, 3,4,6,7,10,11

Transducer:	L14-3Ws								
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N	N		N	N	N	Note 1,2,4,12
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	Note 1,2,4
	Small Organ (Specify**)	N	N	N		N	N	N	Note 1,2,4,7,10,11
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	Note 1,2,4,7,10,11
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	Note 1,2,4,7,10,11
Intravascular									
Thoracic/Pleural (Specify****)	N	N	N		N	N	N	Note 1,2,4	
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1,2,4,7,10,11
	Other (Specify***)								

Transducer:	ELC13-4s									
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:									
Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	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	N	N	N			N	N	N	Note 1,2,4,6,7,10,11
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
Intravascular										
Thoracic/Pleural (Specify****)										
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
	Intravascular (Cardiac)									
	Trans-esoph. (Cardiac)									
	Intra-cardiac									
Peripheral vessel	Peripheral vessel									
	Other (Specify***)	N	N	N			N	N	N	Note 1,2,4,6,7,10,11

Transducer:	L13-3Ns								
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N	N		N	N	N	Note 1,2,4,12
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	Note 1,2,4
	Small Organ (Specify**)	N	N	N		N	N	N	Note 1,2,4,7,10,11
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	Note 1,2,4,7,10,11
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	Note 1,2,4,7,10,11
Intravascular									
Thoracic/Pleural (Specify****)	N	N	N		N	N	N	Note 1,2,4	
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1,2,4,7,9,10,11
	Other (Specify***)								

Transducer:	SD8-1E								
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	Note 1, 3, 4, 6
	Abdominal	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								
Thoracic/Pleural (Specify****)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)								

Transducer:	P7-3TE								
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	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								
Thoracic/Pleural (Specify****)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)	N	N	N	N	N	N	N	Note 1,5,6
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)								

Transducer:	SC6-1E								
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	Note 1, 2, 4, 5, 6
	Abdominal	N	N	N		N	N	N	Note 1, 2, 4,6,10,11,12
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)	N	N	N		N	N	N	Note 1, 2, 4,6
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	Note 1, 2, 4,6
	Musculo-skeletal (Superficial)								
Intravascular									
Thoracic/Pleural (Specify****)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1, 2, 4,6
	Other (Specify***)	N	N	N		N	N	N	Note 1, 2, 4,6

Transducer:	SP5-1E								
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N	N	N	N	N	N	Note 1, 2, 4,6
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic	N	N	N	N	N	N	N	Note 1, 2, 4,6
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Thoracic/Pleural (Specify****)	N	N	N			N	N	N	Note 1, 2, 4,6
Cardiac	Cardiac Adult	N	N	N	N	N	N	N	Note 1, 2, 4, 5, 6,8
	Cardiac Pediatric	N	N	N	N	N	N	N	Note 1, 2, 4, 5, 6
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)								



Transducer:	P7-3TU								
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	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								
Thoracic/Pleural (Specify****)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)	N	N	N	N	N	N	N	Note 1,5,6
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)								

Transducer:	SP5-1U								
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N	N	N	N	N	N	Note 1, 2, 4,6
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic	N	N	N	N	N	N	N	Note 1, 2, 4,6
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Thoracic/Pleural (Specify****)	N	N	N			N	N	N	Note 1, 2, 4,6
Cardiac	Cardiac Adult	N	N	N	N	N	N	N	Note 1, 2, 4, 5, 6, 8
	Cardiac Pediatric	N	N	N	N	N	N	N	Note 1, 2, 4, 5, 6
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)								

Transducer:	L16-4Hs								
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	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	N	N	N		N	N	N	Note 1,2,4
	Small Organ (Specify**)	N	N	N		N	N	N	Note 1,2,4
	Neonatal Cephalic	N	N	N		N	N	N	Note 1,2,4
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	Note 1,2,4
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	Note 1,2,4
Intravascular									
Thoracic/Pleural (Specify****)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1,2,4
	Other (Specify***)								



