# DC-80/DC-80S/DC-80 PRO/DC-80 EXP/DC-85

**Diagnostic Ultrasound System** 

**Operator's Manual** 

[Basic Volume]

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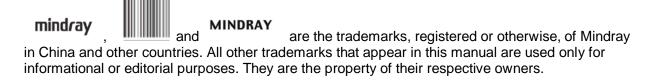
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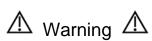
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Mindray is responsible for the effects on safety, reliability and performance of this product, only if:

- 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.



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



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. It is the physician's responsibility for 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 always be alert to dangers other than those indicated as well. Mindray shall not be liable for damage or loss that results from negligence or from ignoring the precautions and operating instructions described in this operator's manual.
- 10. If the manager for this system is changed, be sure to hand over this operator's manual to the new manager.

#### **About This Manual**

This operator's manual describes the operating procedures for this diagnostic ultrasound system and the compatible probes. To ensure safe and correct operations, 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 (refer to "Safety Precautions"). Please read this operator's manual before using the system.

**NOTE:** Indicates information of interest to users of this system as to 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 in compact disc or paper. Please refer to English manual for latest information and register 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 upon 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 quick guide for basic operations of the system.

# **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 English manuals, refer ONLY to the corresponding English manuals.

The accompanying manuals may vary depending upon 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, these conventions are used to describe the buttons on the control panel, the items in menu, buttons in dialog box and some basic operations:

- <Buttons>: the angular bracket indicates buttons, knobs and other controls on control
  panel or on the keyboard.
- [Items in menu or buttons in dialog box]: the square bracket indicates items in menu, on the touch screen or buttons in dialog box.
- Click [Items or Buttons]: move the cursor to the item or button and press <Set>.
- Touch [Items or Buttons]: touch the item on the touch screen.
- [Items in Menu] → [Items in Submenu]: select a submenu item following the path.

# **1** Safety Precautions

## 1.1 Safety Classification

- According to the type of protection against electric shock:
  - **CLASS I EQUIPMENT**
- According to the degree of protection against electric shock:
  - Type-BF applied part
- According to the disinfection and sterilization method(s) recommended by manufacturer:
  - The devices recommended by the manufacturer.
- The device equipped with the applied part of defibrillation protection:
  - The device is not equipped with the applied part of defibrillation protection.
- Persistent installation or non-persistent installation:
  - Non-persistent installation
- According to the degree of protection against harmful ingress of water:
  - The main unit and ECG belong to IPX0
  - Probes belong to IPX7
  - Footswitch belongs to IP68
- 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**

## 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  |
|------------------|--|
| ⚠DANGER          | Indicates an imminently hazardous situation that, if not avoided, will result in death or serious injury.  |
| <b>∆</b> WARNING | Indicates a potentially hazardous situation that, if not avoided, could result in death or serious injury. |
| <b>△</b> CAUTION | Indicates a potentially hazardous situation that, if not avoided, may result in minor or moderate injury.  |
| NOTE             | Indicates a potentially hazardous situation that, if not avoided, may result in property damage.           |
| Description      | Important information that helps you use the system more effectively.                                      |

# 1.3 Meaning of Safety Symbols

| Symbol      | Description  |
|-------------|--|
| <b>★</b>    | Type-BF applied part The ultrasound probes connected to this system are type-BF applied parts.                                 |
| [K]         | The ECG leads applied on this system are type-BF applied parts.  |
| $\triangle$ | Caution!   |
| <u>^</u>    | General warning sign.  |
| <b>S</b>    | Patient/user infection due to contaminated equipment. Be careful when performing the cleaning, disinfection and sterilization. |
|             | Patient injury or tissue damage from ultrasound radiation. It is required to practice ALARA when operating 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:

- Do connect the power plug of this system to wall receptacles that meet the ratings indicated on the rating nameplate. If adapters or multifunctional receptacles are used, it may cause the leakage current to exceed the safety requirement.
- 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 IEC 60601-1 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 IEC 60601-1), and the responsibility is held by the user.
- Connect the grounding conductor before turning ON the system.
   Disconnect the grounding cable after turning OFF the system.
   Otherwise, electric shock may result.
- 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. Otherwise, system failure and electric shock may result.
- 8. This system is not water-proof. Do not use this system in any place where water leakage may occur. If any water is sprayed on or into the system, electric shock may result. If water is accidentally sprayed on or into the system, contact Mindray Customer Service Department or sales representative.
- DO NOT use a probe that has a damaged, scratched surface, or exposed wiring of any kind. Immediately stop using the probe and contact Mindray Customer Service Department or sales representative. There is risk of electric shock if using a damaged or scratched probe.

- 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 probes to knocks or drops. Use of a defective probe 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 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.
- 15. Only use the ECG leads provided with the physiology module; otherwise, electric shock may be resulted.
- 16. 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.
- 17. 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 limitation may be exceeded and failure may be resulted. Maximum output power of the outlet is 240VA.
- 18. 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 IEC 60601-1. 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 IEC 60601-1. If you have any questions regarding these requirements, please consult your sales representative.
- 19. 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.
- 20. When using intra-cavity probes, do not activate the probe outside the patient's body.
- 21. DO NOT touch the Signal I/O ports if in contact with the patient; otherwise patient injury may result.

## **A**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 make sure 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 probe to exceed the body temperature of a patient due to environmental temperature and exam type combinations. Do not apply the probe to the same region on the patient for a long time. Apply the probe 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. 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 be harmful to the human body, but also damage the accessory.

- 8. It is necessary to press <End Exam> 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 hard disk or system failure.
- 11. Do not use a USB memory device (e.g., a USB flash drive, a 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 agents 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.
- 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 the <Freeze> key to freeze an image or turn off the power of the system before connecting or disconnecting a probe. Otherwise, the system and/or probe can be damaged.
- 7. Remove the ultrasound gel from the face of the probe when the examination is completed. Water in the gel may enter the acoustic lens and adversely affect the performance and safety of the probe.
- 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 feature constructs a single extended image from a series of individual image frames. The quality of the final image is user-dependent and requires skill to efficiently apply the feature and technique. Exercise caution when measurements are performed from an iScape image.
- 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.



- 1. The probe is only for use with the specified ultrasonic diagnostic system. Please refer to the "2.5.2 Probes and Needle-guided Brackets Available" to select the proper probe.
- 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 probe sheath must be installed over the probe before performing intra-cavity or intra-operative examination.

## **△ CAUTION:**

- 1. When using the probe, wearing sterile gloves can help 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 probe. If the carrying case is used for storage, it may become a source of infection.
- It is required to practice ALARA when operating ultrasound system.
   Minimize the acoustic power without compromising the quality of images.
- 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 singleuse 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 probe may be caused by the contact of improper gel or cleaner:
  - DO NOT soak or saturate probes in the strong polar solution of ethanol, chloride of lime, ammonium chloride, acetone or formaldehyde.
  - DO NOT contact the probe with solutions or ultrasound gels containing oily medium such as mineral oil or lanoline.

**NOTE:** Read the following precautions to prevent the probe from malfunction:

- Before connecting or disconnecting the probe, freeze or turn off the diagnostic ultrasound system.
- Clean and disinfect the probe before and after each examination.
- After the examination, wipe off the ultrasound gel thoroughly. Otherwise, the ultrasound gel may solidify and the image quality would be degraded.

Ambient conditions:

To prevent the probe from being damaged, do not use it where it will be exposed to:

- Direct sunlight or X-rays
- Sudden changes in temperature
- Dust
- Excessive vibration
- Heat generators

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

#### 1.5 Latex Alert

When choosing a probe sheath, it is recommended that you directly contact CIVCO for obtaining probe sheath, pricing information, samples and local distribution information. For CIVCO information, please contact the following:

**CIVCO Medical Instruments** 

Tel: 1-800-445-6741 WWW.civco.com



Allergic reactions in latex (natural rubber) sensitive patients may range from mild skin reactions (irritation) to fatal anaphylactic shock, and may include difficulty in breathing (wheezing), dizziness, shock, swelling of the face, hives, sneezing or itching of the eyes (FDA Medical Alert on latex products, "Allergic Reactions to Latexcontaining 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 symbol  $\triangle$  on the warning labels indicates safety precautions.

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:

| No. | Warning Labels                              | Meaning  |
|-----|---|--|
| 1.  | a d c                                       | <ul> <li>a. Do not place the device on a sloped surface. Otherwise the device may slide, resulting in personal injury or the device malfunction. Two persons are required to move the device over a sloped surface.</li> <li>b. Do not sit on the device.</li> <li>c. DO NOT push the device. When the casters are locked.</li> <li>d. Caution! please carefully read this manual before use system</li> </ul> |
| 2.  | ETL CLASSIFIED  C  LISTED  Intertek 3179617 | Conforms to ANSI Std. ES60601-1, IEC Std. 60601-2-37, IEC Std. 60601-2-18 and IEC Std. 60601-2-37 Certified to CAN/CSA Std. C22.2 No.60601-1, No.60601-1-6,No.60601-2-18 and No.60601-2-37   |

# 2 System Overview

#### 2.1 Intended Use

The DC-80/DC-80 PRO/DC-80 EXP/DC-85 Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, intra-operative, pediatric, small organ (breast, thyroid, testes), neonatal cephalic, adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), cardiac adult, cardiac pediatric, peripheral vessel, urology and transesophageal (Cardiac) exams.

## 2.2 Contraindication

The diagnostic ultrasound system is not intended for ophthalmic use.

#### 2.3 Product and Model Code



NOTE: 1. The functions described in the operator's manual may vary depending upon the specific system you purchased.

2. Differences between models:

| Model     | B-hist | B-profile | Color Vel |
|-----------|--------|-----------|-----------|
| DC-80     | √      | √         | √         |
| DC-80S    | √      | √         | ×         |
| DC-80 PRO | ×      | √         | √         |
| DC-80 EXP | √      | ×         | √         |
| DC-85     | √      | ×         | ×         |

## 2.4 Product Specifications

**NOTE** The functions described in the operator's manual may vary depending upon the specific system you purchased.

#### 2.4.1 Imaging Mode

B Mode B

Anatomical M: Free Xros M, Free Xros CM

C Mode Color

Power

DirPower

D Mode PW CW

Special imaging Smart 3D

Static 3D

4D

Color 3D Color M

iScape (panoramic imaging)

Contrast Imaging Contrast Imaging QA Strain Elastography

STE/STQ

TDI (Tissue Doppler imaging)

Stress Echo

Tissue Tracking QA

iPage+ STIC SCV+

**Smart Volume** 

Niche iLive

**Smart Planes CNS** 

## 2.4.2 Power supply

 Voltage
 220−240 V~

 Frequency
 50/60Hz

 Power consumption
 800VA

#### 2.4.3 Environmental Conditions

|                      | Operating conditions               | Storage and transportation conditions |
|----------------------|------------------------------------|---------------------------------------|
| Ambient temperature  | 0°C∼40°C                           | <b>-20</b> ℃~55℃                      |
| Relative humidity    | $30\%{\sim}85\%$ (no condensation) | $30\%{\sim}95\%$ (no condensation)    |
| Atmospheric pressure | 700hPa∼1060hPa                     | 700hPa∼1060hPa                        |

⚠WARNING: Do not use this system in the conditions other than those specified.

## 2.4.4 Dimensions and Weight

Dimension: 1355~1800mm (H) ×920mm (D) ×580mm (W)

Net weight: about 120Kg

## 2.5 System Configuration

## 2.5.1 Standard Configuration

- Main unit
- System software
- UltraView
- Accessories
  - Control panel overlay
  - Operator's manual
  - Ge
  - Basic accessories (holders and cables etc.)
  - Dust-proof cover and dust-proof cover of a probe socket
  - Endocavity probe bracket

For UltraView information, please refer to the user guide of the UltraView.

## 2.5.2 Probes and Needle-guided Brackets Available

| Probe<br>model | Probe Type | Intended Use   | Region<br>Applied |
|----------------|------------|--|-------------------|
| L12-3E         | Linear     | Abdominal, Pediatric, Small Organ (breast, thyroid, testes), Neonatal Cephalic, Musculo-skeletal (Conventional), Musculo-skeletal (Superficial), Peripheral vessel | Body surface      |
| L9-3E          | Linear     | Abdominal, Pediatric, Small Organ (breast, thyroid, testes), Neonatal Cephalic, Musculo-skeletal (Conventional), Musculo-skeletal (Superficial), Peripheral vessel | Body surface      |
| L14-6NE        | Linear     | Abdominal, Pediatric, Small Organ (breast, thyroid, testes), Neonatal Cephalic, Musculo-skeletal (Conventional), Musculo-skeletal (Superficial), Peripheral vessel | Body surface      |

| Probe<br>model | Probe Type   | Intended Use  | Region<br>Applied |
|----------------|--------------|---|-------------------|
| L14-6WE        | Linear       | Abdominal, Pediatric, Small Organ (breast, thyroid, testes), Neonatal Cephalic, Musculo-skeletal (Conventional), Musculo-skeletal (Superficial), Peripheral vessel  | Body surface      |
| L14-5WE        | Linear       | Abdominal, Pediatric, Small Organ (breast, thyroid, testes), Neonatal Cephalic, Musculo-skeletal (Conventional), Musculo-skeletal (Superficial), Peripheral vessel  | Body surface      |
| L16-4HE        | Linear       | Abdominal, Intra-operative (abdominal, thoracic, and vascular), Pediatric, Small Organ (breast, thyroid, testes), Neonatal Cephalic, Musculoskeletal (Conventional), Musculoskeletal (Superficial), Peripheral vessel | Body surface      |
| P7-3E          | Phased       | Abdominal, Pediatric, Neonatal Cephalic, Adult<br>Cephalic, Musculo-skeletal (Conventional), Cardiac<br>Adult, Cardiac Pediatric  | Body surface      |
| P10-4E         | Phased       | Abdominal, Pediatric, Neonatal Cephalic, Adult<br>Cephalic, Cardiac Adult, Cardiac Pediatric  | Body surface      |
| P4-2NE         | Phased       | Abdominal, Pediatric, Adult Cephalic, Cardiac<br>Adult, Cardiac Pediatric   | Body surface      |
| P7-3TE         | Phased       | Trans-esoph. (Cardiac)  | Transesophagel    |
| SP5-1E         | Phased       | Abdominal, Pediatric, Adult Cephalic, Cardiac<br>Adult, Cardiac Pediatric   | Body surface      |
| V11-3E         | Convex       | Fetal, Trans-rectal, Trans-vaginal, Urology   | Transvaginal      |
| V11-3BE        | Convex       | Fetal, Trans-rectal, Trans-vaginal, Urology   | Transvaginal      |
| V11-3HE        | Convex       | Fetal, Trans-rectal, Trans-vaginal, Urology   | Transvaginal      |
| C7-3E          | Convex       | Fetal, Abdominal, Pediatric, Peripheral vessel  | Body surface      |
| C11-3E         | Convex       | Abdominal, Pediatric, Neonatal Cephalic, Cardiac Adult, Cardiac Pediatric, Peripheral vessel  | Body surface      |
| C5-1E          | Convex       | Fetal, Abdominal, Pediatric, Musculo-skeletal (Conventional), Peripheral vessel   | Body surface      |
| SC5-1E         | Convex       | Fetal, Abdominal, Pediatric, Musculo-skeletal (Conventional), Peripheral vessel   | Body surface      |
| C6-2GE         | Convex       | Fetal, Abdominal, Pediatric   | Body surface      |
| D6-2NE         | Volume       | Fetal, Abdominal, Pediatric   | Body surface      |
| D7-2E          | Convex (4D)  | Fetal, Abdominal  | Body surface      |
| D8-2E          | Convex (4D)  | Fetal, Abdominal  | Body surface      |
| DE10-3E        | Convex (4D)  | Fetal, Trans-rectal, Trans-vaginal  | Transvaginal      |
| DE11-3E        | Convex (4D)  | Fetal, Trans-rectal, Trans-vaginal  | Transvaginal      |
| CW2s           | Pencil probe | Pediatric, Adult Cephalic, Cardiac Adult, Cardiac Pediatric   | Body surface      |

| Probe<br>model | Probe Type                       | Intended Use  | Region<br>Applied |
|----------------|----------------------------------|---|-------------------|
| CW5s           | Pencil probe                     | Pediatric, Adult Cephalic, Cardiac Adult, Cardiac Pediatric | Body surface      |
| CB10-4E        | Bi-plane<br>(convex &<br>convex) | Trans-rectal, Urology                                       | Transrectal       |

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<br>Model                                  | Biopsy<br>angle/depth<br>(±1°) | Applicable Biopsy Needle   |
|------------------------------|---|--------------------------------|--|
| V11-3E/ V11-<br>3BE/ CB10-4E | NGB-004<br>metal/needle un-detachable                           | /                              | 16G, 17G, 18G  |
| L14-6NE/ L12-<br>3E/ L14-6WE | NGB-007<br>plastic/needle detachable<br>metal/needle detachable | 40°, 50°, 60°                  | Metal: 14G, 16G, 18G, 20G, 22G<br>Plastic: 13G, 15G, 16G, 18G, 20G |
| P4-2NE/ SP5-<br>1E           | NGB-011<br>metal/needle un-detachable                           | 11°, 23°                       | 13G, 15G, 16G, 18G, 20G  |
| C11-3E                       | NGB-018<br>Metal/needle detachable                              | 15°, 25°, 35°                  | 14G, 16G, 18G, 20G, 22G  |
| C7-3E                        | NGB-019<br>metal/needle detachable                              | 20°, 30°, 40°                  | 14G, 16G, 18G, 20G, 22G  |
| DE10-3E                      | NGB-021 metal/needle un-detachable                              | 2°                             | 16G, 17G, 18G  |
| C5-1E                        | NGB-022<br>metal/needle detachable                              | 25°, 35°, 45°                  | 14G, 16G, 18G, 20G, 22G  |
| C6-2GE                       | NGB-024<br>metal/needle detachable                              | 7°, 25°, 35°                   | 14G, 16G, 18G, 20G, 22G  |
| V11-3HE                      | NGB-025<br>metal/needle un-detachable                           | 1.6°                           | 16G, 17G, 18G  |
| DE11-3E                      | NGB-027<br>metal/needle un-detachable                           | 1.7°                           | 16G, 17G, 18G  |
| SC5-1E                       | NGB-031 metal/needle detachable                                 | 25°, 35°, 45°                  | 14G, 16G, 18G, 20G, 22G  |
| L9-3E                        | NGB-034<br>metal/needle detachable                              | 40°, 50°, 60°                  | 14G, 16G, 18G, 20G, 22G  |
| L14-5WE                      | NGB-035<br>metal/needle un-detachable                           | 40°, 50°, 60°                  | Metal: 14G, 16G, 18G, 20G, 22G<br>Plastic: 13G, 15G, 16G, 18G, 20G |
| D8-2E                        | NGB-040<br>metal/needle detachable                              | 20°, 30°, 40°                  | 14G, 16G, 18G, 20G, 22G  |

NOTE: Mindray does not offer the biopsy needle, please purchase it according to your own needs.

# **2.5.3** Options

| No. | Item  | Remarks   |
|-----|---|---|
| 1.  | Physiology module   | Contains ECG, PCG and pencil probe socket assembly. |
| 2.  | DC-IN cable   | Physiology module should be configured.             |
| 3.  | ECG cable   | Physiology module should be configured.             |
| 4.  | PCG module  | Physiology module should be configured.             |
| 5.  | 4D module   | Consists of 4D board and 4D software kit.           |
| 6.  | CW module   | /   |
| 7.  | Gel Warmer  | /   |
| 8.  | Wireless Adapter (built-in)   | /   |
| 9.  | Built-in Battery  | /   |
| 10. | Qwerty keyboard assembly  | /   |
| 11. | DICOM Basic (including: Verify (SCU, SCP), task management, DICOM storage, DICOM print, DICOM storage commitment, DICOM media storage (including DICOM DIR) etc.) |   |
| 12. | DICOM Worklist  |   |
| 13. | DICOM Query/Retrieve  |   |
| 14. | DICOM MPPS  |   |
| 15. | DICOM OB/GYN SR   | DICOM Basic should be configured.                   |
| 16. | DICOM Cardiac SR  |   |
| 17. | DICOM Vascular SR   |   |
| 18. | DICOM Breast SR   |   |
| 19. | Abdomen/General Package   | /   |
| 20. | Obstetrics Package  | /   |
| 21. | Gynecology Package  | /   |
| 22. | Cardiology Package  | /   |
| 23. | Small Parts Package   | /   |
| 24. | Urology Package   | /   |
| 25. | Vascular Package  | /   |
| 26. | Pediatrics Package  | /   |
| 27. | Smart OB  | Obstetrics Package should be configured.            |
| 28. | Emergency Medicine Package  | /   |
| 29. | Nerve Package   | /   |
| 30. | IMT   | Vascular Package should be configured.              |

| No. | Item                                 | Remarks  |
|-----|--------------------------------------|--|
| 31. | IVF                                  | Gynecology Package should be configured                |
| 32. | iWorks                               | /  |
| 33. | Free Xros M                          | /  |
| 34. | Free Xros CM                         | /  |
| 35. | Tissue Doppler Imaging               | Cardiology Package should be configured.               |
| 36. | TDI QA                               | Tissue Doppler Imaging should be configured.           |
| 37. | Contrast Imaging                     | /  |
| 38. | Contrast Imaging QA                  | Contrast Imaging should be configured.                 |
| 39. | LVO (Left Ventricular Opacification) | Cardiology Package should be configured.               |
| 40. | iScape View                          | /  |
| 41. | Smart 3D                             | /  |
| 42. | iPage+                               |  |
| 43. | SCV+                                 |  |
| 44. | STIC                                 |  |
| 45. | Color 3D                             | 4D module should be configured.                        |
| 46. | Niche                                |  |
| 47. | Smart Volume                         |  |
| 48. | Smart Planes CNS                     |  |
| 49. | Smart FLC                            | 4D module and Gynecology Package should be configured. |
| 50. | Strain Elastography                  | /  |
| 51. | STE                                  | /  |
| 52. | STE(DE, FR, NA)                      | /  |
| 53. | STQ                                  | /  |
| 54. | STQ(DE, FR, NA)                      | /  |
| 55. | iNeedle                              | /  |
| 56. | Smart NT                             | Obstetrics package should be configured.               |
| 57. | Stress Echo                          | Cardiology package should be configured.               |
| 58. | Tissue Tracking QA                   | Cardiology package should be configured.               |
| 59. | iLive                                | Smart 3D module or 4D module should be configured.     |
| 60. | AutoEF                               | Cardiology package should be configured.               |
| 61. | DVR Module                           | /  |

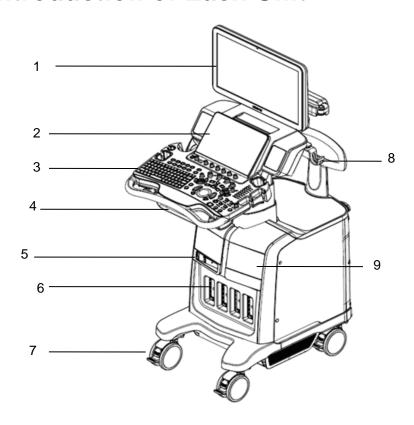
## 2.5.4 Peripherals Supported

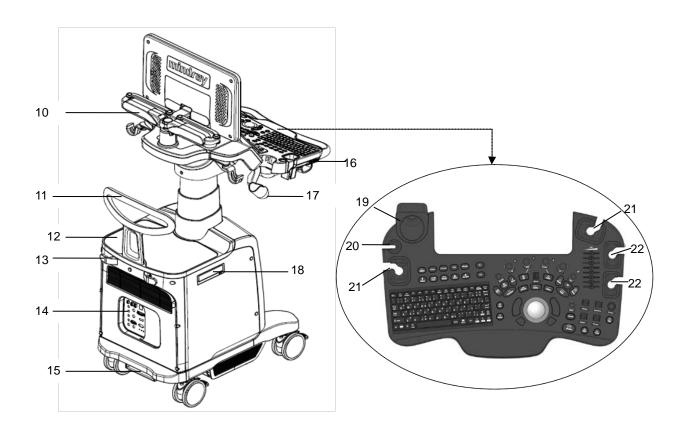
| Item  | Model                                       |
|---|---|
| Black/white video                                       | Digital: SONY UP-D898MD, MITSUBISHI P95DW-N |
| printer   | Analog: SONY UP-X898MD                      |
| Color digital printer SONY UP-D25MD, CANON SELPHY CP800 |   |
|   | USB port: FS-81-SP-2 (1-pedal)              |
| Footswitch  | USB port: 971-SWNOM (2-pedal)               |
|   | USB port: 971-SWNOM (3-pedal)               |
| Bar code reader   | SYMBOL LS2208-SR, DS6707                    |



This system complies with IEC60601-1-2: 2014, and its RF emission meets the requirements of CISPR11 Class B. In a domestic environment, the customer or the user should guarantee to connect the system with Class B peripheral devices; otherwise RF interference may result and the customer or the user must take adequate measures accordingly.

## 2.6 Introduction of Each Unit

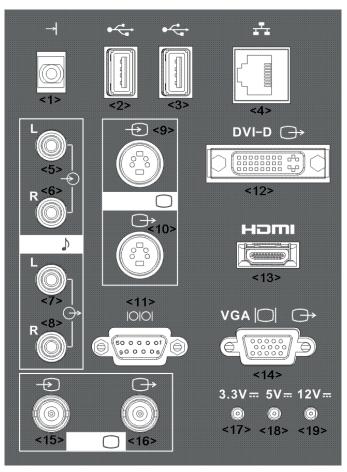




| No. | Name                              | Function  |  |
|-----|-----------------------------------|---|--|
| 1.  | Monitor                           | Displays the images and parameters during scanning.                         |  |
| 2.  | Touch screen panel                | Operator-system interface or control.                                       |  |
| 3.  | Main control panel                | Operator-system interface or control.                                       |  |
| 4.  | Storage compartment               | Used for placing small objects.   |  |
| 5.  | Physio panel                      | Used for connecting the ECG leads external ECG device and etc.              |  |
| 6.  | Probe port                        | Sockets connecting transducers and the main unit.                           |  |
| 7.  | Caster                            | Used for securing or moving the system.                                     |  |
| 8.  | Probe cable hook                  | Used for fixing the probe cable.  |  |
| 9.  | Compartment                       | Used for placing B/W video printer.   |  |
| 10. | Monitor support arm               | Supports the monitor, for adjusting the height and position of the monitor. |  |
| 11. | Rear handle                       | Used for pushing and moving the system.                                     |  |
| 12. | Color video printer placing table | Used for placing the color video printer.                                   |  |
| 13. | Hanger                            | /   |  |
| 14. | I/O Panel                         | Interface panel used for inputting and outputting signals.                  |  |

| No. | Name                                 | Function  |  |
|-----|--------------------------------------|---|--|
| 15. | Power supply panel                   | Electrical port panel.  |  |
| 16. | USB_MIC port                         | USB port and MIC port.  |  |
| 17. | Intracavitary probe holder           | Used for fixing the intracavitary probe.                          |  |
| 18. | DVD-RW                               | DVD-RW drive.   |  |
| 19. | Ultrasound gel holder/<br>gel warmer | Used for placing the ultrasound gel or installing the gel warmer. |  |
| 20. | Pencil probe holder                  | Reserved.   |  |
| 21. | Probe holder                         | Used for placing general probe or 4D volume probe.                |  |
| 22. | Probe holder                         | Used for placing general probe.                                   |  |

## 2.7 I/O Panel



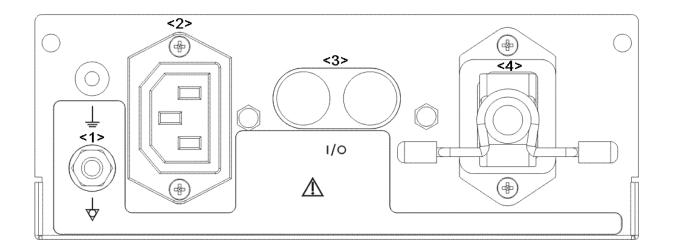
| No. | Symbol                                  | Function  |
|-----|---|---|
| <1> | $\rightarrow$                           | Connects the control port of the video printer. |
| <2> | • | USB ports.                                      |
| <3> | •~                                      | COD ports.                                      |

| No.  | Symbol        |               | Function                                       |
|------|---------------|---------------|--|
| <4>  | <b>2</b> 5    |               | Network port.                                  |
| <5>  | -0            |               | Audio signal input port, left channel.         |
| <6>  | -€)           |               | Audio signal input port, right channel.        |
| <7>  | $\rightarrow$ |               | Audio signal output port, left channel.        |
| <8>  |               |               | Audio signal output port, right channel.       |
| <9>  | S VIDEO       | <b>→</b>      | Used for separate video input.                 |
| <10> | S-VIDEO       |               | Used for separate video output.                |
| <11> | IOIOI         |               | Serial port, connects the serial port devices. |
| <12> | DVI−D⊕        |               | Used for DVI-D signal output.                  |
| <13> | HDMI          |               | High definition multimedia interface.          |
| <14> | VGA I□I→      |               | VGA signal output.                             |
| <15> | VIDEO 🗍       | <b>→</b>      | Used for composite video input.                |
| <16> | VIDEO         | $\Rightarrow$ | Used for composite video output.               |
| <17> | /             |               | 3.3V power indicator.                          |
| <18> | /             |               | 5V power indicator.                            |
| <19> | 1             |               | 12V power indicator.                           |

#### **NOTE:** 1. S-VIDEO port performs better in analog video print.

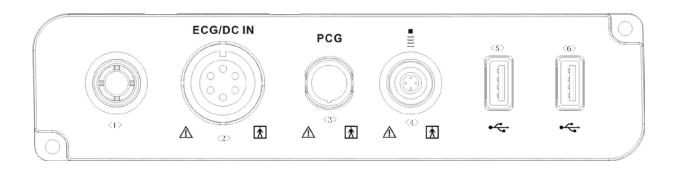
2. When connecting an external video device (HDMI/VGA), please make sure the display setting for resolution is 1920\*1080, otherwise the image quality may be degraded.

# 2.8 Power Supply Panel



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

# 2.9 Physio Panel (ECG)



| No.  | Name                  | Function  |  |
|--|-----------------------|---|--|
| <1>  | Reserved port         | Port for reserved function.   |  |
| ECG lead signal in port / external ECG signal input port | ECG lead signal input | Connects to ECG leads, to directly obtain the ECG signals of the patient. |  |
|  |                       | Connects the signal output port of external ECG monitoring device.        |  |
| <3>  | PCG signal input port | Reserved.   |  |
| <4>  | Pencil probe port     | Used for connecting a pencil probe.                                       |  |
| <5>/<6>  | USB ports             | Connects USB devices.   |  |

# 2.10 Operation Panel



#### **Exam Operation**

| Symbol        | Name                   | Control<br>Type   | Function                             |
|---------------|------------------------|-------------------|--------------------------------------|
| End Exam      | End Exam               | Functional button | End the current exam.                |
| Patient       | Patient<br>Information | Functional button | Enter/ exit Patient Info screen.     |
| Probe         | Probe/Exam<br>switch   | Functional button | Switch probe and exam mode.          |
| (라니<br>Review | Review                 | Functional button | Enter/ exit the Review screen.       |
| Report        | Report                 | Functional button | Open/ close the exam report.         |
| F2            | /                      | Functional button | Enter/ exit the Patient Info system. |

## **Cursor Operation**

| Symbol | Name       | Control<br>Type             | Function  |
|--------|------------|-----------------------------|---|
|        | /          | Trackball<br>Confirm<br>key | Move the trackball to change the cursor position.  Select functions. The left/right kidney shaped key is the <set> key.</set> |
| Cursor | Cursor     | Functional button           | Show/ hide the cursor.  |
| Nav.   | Navigation | Pressable knobs             | Multifunctional knob  |

# Image operations

| Symbol   | Name | Control<br>Type | Function  |
|----------|------|-----------------|---|
| 8        | 1    | Pressable knobs | Press to enter B mode; Rotate to adjust B mode gain.  |
|          | /    | Pressable knobs | Press to enter M mode, and rotate to adjust M gain; while in 3D/4D mode, rotate the knob to make the 3D image to rotates around X axis.                 |
| Color    | /    | Pressable knobs | Press to enter Color mode, and rotate to adjust Color or Power gain; while in 3D/4D mode, rotate the knob to make the 3D image to rotate around Z axis. |
| Power    | /    | Key             | Enter Power mode.   |
| PW       | /    | Pressable knobs | Press to enter PW mode, and rotate to adjust PW or CW gain; while in 3D/4D mode, rotate the knob to make the 3D image to rotate around Y axis.          |
| CW       | /    | Key             | Enter CW mode.  |
| Elasto   | /    | Key             | Enter Elastography.   |
| Contrast | /    | Key             | Enter contrast imaging.   |
| TDI      | /    | Key             | Enter TDI imaging.  |
| iScape   | /    | Key             | Enter iScape.   |
| 30       | 1    | Key             | Enter 3D imaging function: Smart 3D or Static 3D.   |

| Symbol | Name | Control<br>Type | Function  |  |
|--------|------|-----------------|---|--|
|        | 1    | Pressable knobs | Press to enter 4D function; rotate to make the 3D image rotation. |  |

| Symbol   | Name              | Control Function    |   |
|--|-------------------|---------------------|---|
| P1   | 1                 | Undefined<br>Button | Undefined Button, set by the user in preset.  |
| P2   | 1                 | Undefined<br>Button | Undefined Button, set by the user in preset.  |
| (s,ro)   | /                 | Functional button   | Enter single window in multiple window mode.  |
| Colins of the Co | /                 | Functional button   | Enter Dual mode in Non-Dual mode;<br>Switch between the two display windows in Dual<br>mode.                        |
| PR   | /                 | Functional button   | Enter Quad mode in Non-Quad mode; Press to switch among the display windows in Quad mode.                           |
| Update   | 1                 | Functional button   | Switching key: Press to change the currently active window.  Start/ stop image acquisition in iScape or 3D/4D mode. |
| Cine   | Cine<br>Review    | Functional button   | Enter/ exit the Cine Review status.   |
| Save1  | Save 1/<br>Save 2 | Functional button   | Save images in a way as preset.   |

# **Parameter Adjustment**

| Symbol   | Name  | Control<br>Type   | Function  |  |
|----------|-------|-------------------|---|--|
| TGC      | /     | Slide bar         | Adjust the depth gain.  |  |
| Scale    | /     | Deflector<br>rod  | Adjust scale parameter.   |  |
| Baseline | /     | Deflector<br>rod  | Adjust baseline parameter.  |  |
| Zoom     | Zoom  | Pressable knobs   | Rotate to enter the pan zoom mode, and press to enter the spot zoom mode. |  |
| Depth    | Depth | Deflector<br>rod  | Adjust depth in real-time imaging.  |  |
| Focus    | /     | Deflector<br>rod  | Change the focus position.  |  |
| Angle    | Angle | Functional button | Adjust angle.   |  |
| Steer    | 1     | Deflector<br>rod  | Activate the steer function for linear probe.                             |  |
| iTouch   | /     | Functional button | Optimize the image.   |  |

# Measurement, Comment, and Body Mark Operations

| Symbol            | Name        | Control<br>Type      | Function  |
|-------------------|-------------|----------------------|---|
| Caliper           | Caliper     | Functional button    | Enter or exit the general measurement mode.   |
| Wegente<br>huming | Measurement | Functional button    | Enter/ exit the application measurement mode.   |
| (Heri             | Comment     | Functional<br>button | Enter/ exit the textual comment status.   |
| Arrow             | Arrow       | Functional button    | Enter/ exit the arrow comment status.   |
|                   |             |                      | Clear the measurement caliper, comments and body mark.  |
| Clear )           | Delete      | Functional button    | Press <clear> to clear the selected item, return to the previous operation or to delete the last project.</clear> |
|                   |             |                      | Long press <clear> to delete the mode related elements or all elements on the screen.</clear>                     |
| Body Walk         | Body Mark   | Functional button    | Enter/ exit Body Mark.  |

### **Other Operations**

| Symbol | Name   | Control<br>Type   | Function                        |
|--------|--------|-------------------|---------------------------------|
| Physio | /      | Functional button | Enter/ exit ECG control screen. |
| Print  | Print  | Functional button | Print.                          |
| Freeze | Freeze | Functional button | Freeze/ unfreeze the image.     |

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.  | Back space             | 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 Text            | 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  |

### ■ 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.  | $\rightarrow$ | End         | Move the cursor to the end of the row, or the rightmost side of an edit unit. |
| 2.  | <b>←</b>      | Home        | Home  |
| 3.  | <b>↑</b>      | Pg Up       | Turn pages upward.  |
| 4.  | <b>\</b>      | Pg Dn       | Turn pages downward.  |
| 5.  | Home          | Set<br>Home | Activate the Set Home function: set the start point of comment.               |

# 2.11 Symbols

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

| Symbol                      |               | Description   |  |
|-----------------------------|---------------|---|--|
| <b>†</b>                    |               | Type-BF applied part                                |  |
| $\triangle$                 |               | Caution   |  |
| A                           |               | Dangerous voltage                                   |  |
| $\sim$                      |               | AC (Alternating current)                            |  |
| <u></u>                     |               | Functional grounding                                |  |
| ~<br>                       |               | Equipotentiality                                    |  |
|                             |               | protective earth                                    |  |
| 1/0                         |               | Circuit breaker ON/OFF                              |  |
| <b>•</b> / <b>•</b>         |               | Power button  |  |
| <u>⊙/</u> <u>≥</u> <u>=</u> |               | Footswitch  |  |
| )))                         |               | Transducer sockets                                  |  |
| <b>-</b>                    |               | Network port  |  |
| IOIOI                       |               | Serial port   |  |
| •                           |               | USB port  |  |
| DVI-D (→                    |               | Used for DVI-D signal output.                       |  |
| VGA →                       |               | Used for VGA input.                                 |  |
| S-VIDEO                     | <b>(</b>      | Reserved, used for separate video input             |  |
| 3-41020                     | $\Rightarrow$ | Reserved, used for separate video output            |  |
| AUDIO .                     | <b>⊕</b>      | Reserved, used for stereo audio input.              |  |
| AUDIO J                     | $\rightarrow$ | Reserved, used for stereo audio output.             |  |
| VIDEO (                     | <b>→</b>      | Reserved, used for composite video input            |  |
| VIDEO ☐ →                   |               | Reserved, used for composite video output           |  |
| D                           |               | Microphone input jack                               |  |
| SN                          |               | Product serial number                               |  |
| سا                          |               | Manufacture date                                    |  |
| EC REP                      |               | Authorized representative in the European Community |  |

# **3** System Preparation

# **△WARNING**:

- Do not connect the three-wire cable of the system with a twowire plug without protective grounding; otherwise, electric shock may result.
- 2. Do connect the power plug of this system to wall receptacles that meet the ratings indicated on the rating nameplate. If adapters or multifunctional receptacles are used, it may cause the leakage current to exceed the safety requirement.
- 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 IEC 60601-1 or the power input of the same safety level.
- 4. DO NOT use power supply of different phases to power peripherals.
- 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 IEC 60601-1), and the responsibility is held by the user.

# 3.1 Move / Position the System

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

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

# $\triangle$ CAUTION:

- 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 10°-sloped plane to avoid system toppling.

# 3.2 Connecting Power Cord & Protective Grounding

# 3.2.1 Connecting Power

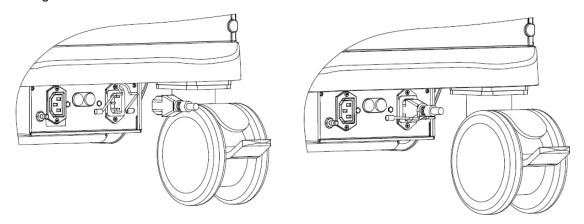
■ The power system must meet the following requirements:

Voltage:220-240V

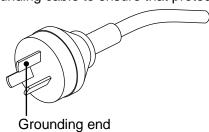
Power supply frequency: 50/60Hz

Power consumption: greater than 800VA

- The connection method is described as follows:
- 1. Push the retaining clamp upward, and insert the power plug into the receptacle, as shown in the figure below.



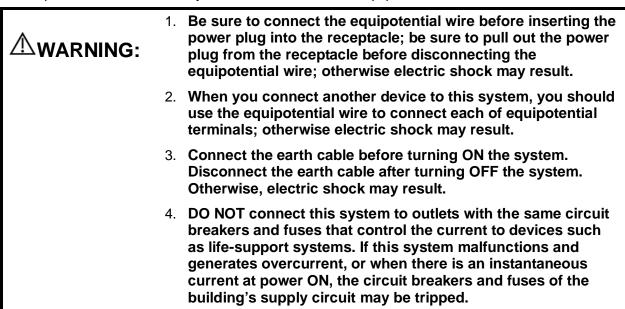
- 2. Pull the retaining clamp downward to lock the power cord, as shown in the figure below.
- 3. Plug the other end power plug into an appropriate outlet. The grounding terminal should be connected with a power grounding cable to ensure that protective grounding works normally.



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

# 3.2.2 Equipotential terminal

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



# 3.2.3 Power 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.

Check 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. See "2.4.3 Environmental Conditions " for details.             |
| 2   | There shall be no condensation.   |
|     | There shall be no distortion, damage or dirt on the system and peripheral devices.      |
| 3   | If any dirt is found, cleaning shall be performed as illustrated in section "17 System  |
|     | Maintenance".   |
| 4   | There shall be no 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 "13 Probes and Biopsy" chapter for details of probe cleaning and disinfection.      |
| 7   | No miscellaneous odds and ends are allowed to be attached or affixed to the control     |
| •   | panel.  |

| No. | Check Item  |
|-----|---|
|     | Ensure that all connections are free from damage and remain clear of foreign object |
| 8   | 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.                           |
| 11  | The locking mechanism of casters can work normally.                                 |

Before turning on the system, check if the system is plugged in – verify that the system circuit breaker is at "On". After the power indicator at the touch panel turns green, press the power button (on the left of the touch panel) to power on the system.

■ Check the system after it is powered on

To check the system after the system is powered 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.  |

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

# 3.2.4 Power 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 before the power indicator is off.

■ 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 in a direct way. It may destroy the data.

2. After the system is upgraded, using "Shut Down" to power off the system to make the upgraded data effective.

# 3.2.5 Standby

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

Standby condition: only 5V\_STB power are available, and the standby indicator turns orange.

To enter standby:

Open [Setup]  $\rightarrow$  [System Preset]  $\rightarrow$  "General" to set the time for screensaver and standby. If there is no operation to the system, the system enters screensaver after the waiting time set for screensaver, and if there is still no operation, the system enters standby after the waiting time for standby.

■ To exit standby:

Press the power button.

Under the standby status:

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

**NOTE:** If you will not use the system for a long period of time, you shall disconnect the power adapter; disconnect the mains power; turn off powers of all peripherals connected to the system.

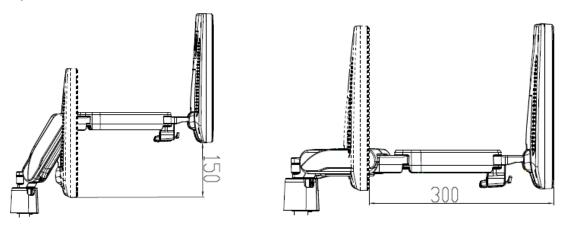
# 3.3 Monitor Adjustment

# 3.3.1 Monitor Position Adjustment

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

Height and displacement adjustment

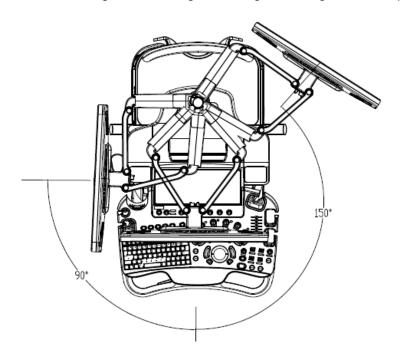
Move the monitor support arm up or down to adjust the height, back and forth to adjust the displacement



**NOTE:** Take care of your hands when adjusting the monitor up and down, back and forth.

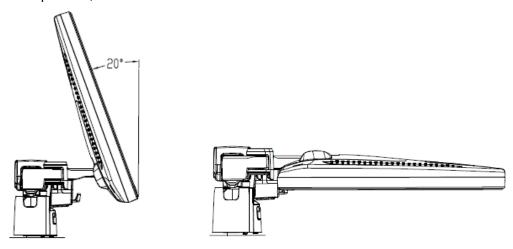
### Rotate the monitor

The monitor can turn left 90 degrees to the right 150 degrees along with the support arm.



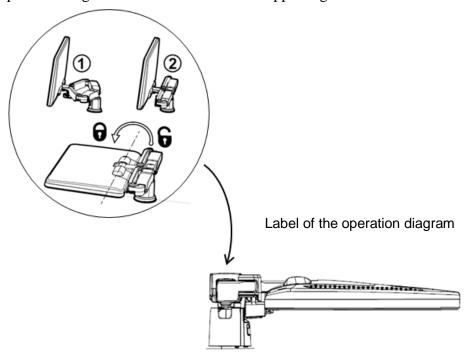
### ■ Tilt the monitor

When positioned vertically, the monitor can be tilted for 20°backward and to the horizontal position forward. In the process of transportation or moving the system, keep monitor in the horizontal position, shown as follows:



#### 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

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

■ Brightness adjustment:

Press <F10 Setup>. Click [System]→[General]→ [LCD] and tap the brightness adjustment on the touch screen. Tap to reduce and to enhance the brightness.

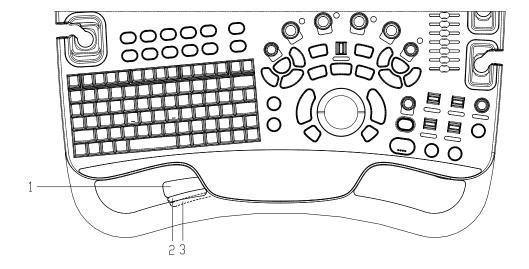
■ Contrast adjustment:

Press <F10 Setup>. Click [System]→[General]→ [LCD] and tap the contrast adjustment on the touch screen. Tap to reduce and to enhance the contrast.

**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 lever at the side of control panel handle to position 2, the control panel can be rotated ±90°; press the lever to position 3, the control panel can be move upwards or downwards.



# 3.5 Connecting a Probe

# **∆**CAUTION:

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

NOTE:

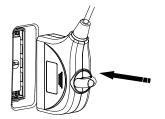
If a probe port is not used for a long period of time, please use the dustproof cover to protect the probe port from dust; otherwise bad contact may result.

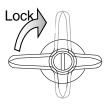
# 3.5.1 Connecting a Probe

# **≜**WARNING:

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

- 1. Keep the cable end of the transducer to the right side of the system, and insert the connector into the port of the system, and then press in fully. (Shown as the left figure)
- 2. Turn the lock handle 90° clockwise to lock it securely. (Shown as the right figure)
- 3. Place the probe properly to avoid being treaded or wrapping with other devices. DO NOT allow the probe head to hang free.



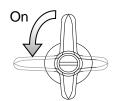


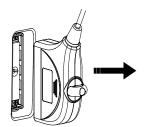
NOTE:

Before inserting the connector into the probe port, inspect the connector pin. If the pin is bent, do not use the probe until it has been inspected / repaired / replaced.

# 3.5.2 Disconnecting a probe

- 1. Turn the locking lever 90° counterclockwise to the horizontal position. (Shown in the left figure)
- 2. Pull the transducer connector straight out vertically (Shown in the figure below).





# 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 system may be damaged.

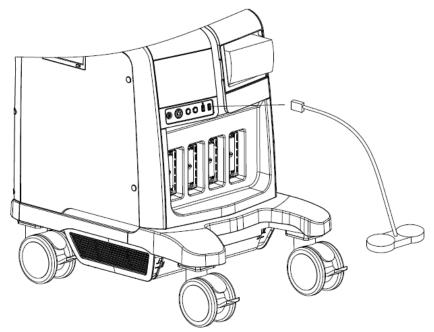
- When connecting a USB memory device to the ultrasound system via a USB port, you can hear a sound if it is connected successfully and the symbol will appear in the lower right corner of the screen.
- To remove the USB device: Click to open the [Remove USB Device] screen. Select the device to be removed and click [OK]. There will be sound feedback when removing the USB memory device.

# 3.6.2 Connecting a Footswitch

The system supports 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 "12.1.6 Key Configuration".

# 3.6.3 Installing a Graph/Text Printer

A graph / text printer is connected to the system via the USB port.

- Connect the data cable to the USB port on the ultrasound system.
- 2. Plug the printer power cord to an appropriate outlet.
- 3. Power on the system and the printer.
- 4. Install the printer driver (drivers of printers listed in the "2.5.4 Peripherals Supported" chapter are installed already):
  - 1)Press <F10> to enter the Setup menu.
  - 2) Click [Print] to enter the screen.
  - 3)Click [Add Printer] to enter the driver installation screen, you can select to install a local printer or network printer.
    - Add a local printer

Select "Local printer attached to this computer", and click [Next] to search the connected printer.

Add network printer

Select "A network printer, or a printer attached to another computer" and click [Next] to enter the browse screen, select the printer to install.

When you install the printer's driver, you must specify the specific path for installation; otherwise, vague path may result in longer time for searching.

- 5. When the printer is successfully installed, you can see the printer in the list.
- 6. Select "Report Print" in the printer list, and then select the installed graph/text printer in the "Property" box.
- 7. Click [Save] to confirm the setting and exit the preset page.

#### NOTE:

The installed printer drivers may be incompatibility with the Doppler system, which may lead to the incorrectness of cursor status during printer, you can press the <Cursor> button to get the cursor if the cursor status is incorrect.

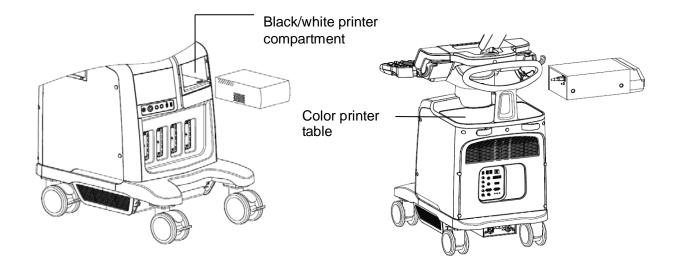
### **NOTE:** Check the settings of the target PC if adding the shared printer fails:

In Windows XP operating system, select [Start]→[Run], input gpedit.msc, enter [Local Group Policy Editor], select [Computer Configuration]→ [Windows Settings]→ [Security Settings]→ [Local Policies]→ [Security Options], and set [Network access: Sharing and security model for local accounts] to [Guest only].

In Windows 7 operating system, enter [Control Panel]→ [Network and Sharing Center]→ [Change advanced sharing settings], turn on File and Printer Sharing, and select [turn off password protected sharing] in current profile. If there is no such item, you can also enter the [Local Group Policy Editor] and check the setting item as described in Windows XP system.

### 3.6.4 Position the Printer

As shown in the following figure, you can place the black/white analog video printer in the video printer compartment, and place the color printer on the table at the rear side of the machine.



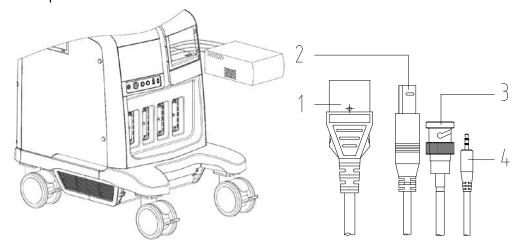
# 3.6.5 Installing Analog Video Printer

- 1. Plug the printer power cord to an appropriate outlet.
- 2. Put the printer in a proper place.
- 3. Cable connection:
  - B / W analog video printer

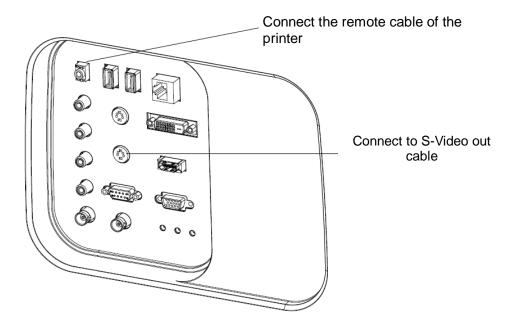
The printer compartment under the control panel provides the following cables:

- (1) power cord, (2) USB cable (used for connecting digital video printer), (3) video signal cable,
- (4) Remote control cable, as shown in the figure.

Connect the remote cable to the remote port of the printer, and video signal cable to VIDEO IN port of the printer.



 Color analog video printer: use the I/O panel at the rear side of the machine to connect the printer, as shown in the following figure:



- 4. Load a paper roll, and turn on the system and printer.
- 5. Modify print service:
  - Add a print service:
  - (1) Open the [Setup]-> [Print]->[Print Service] 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 Printer Service page.
  - (5) Select the printer model, and then you can set the properties in the Property box.
  - (6) Click [Save] to complete the setting.
  - Modify print service:
  - (1) Select an existed printer service in the list.
  - (2) Select the printer model, and then you can set the properties in the Property box.
  - (3) Click [Save] to complete the setting.

# 3.6.6 Installing Digital Video Printer

- 1. Put the printer in a proper place.
- 2. Plug the printer power cord to an appropriate outlet.
- 3. Use a USB cable to connect between the USB port of the system and the USB port of the printer.
- 4. Load a paper roll, and turn on the system and printer.
- 5. See section "3.6.5 Installing Analog Video Printer" for driver installation procedure (drivers of printers listed in the "2.5.4 Peripherals Supported" chapter are installed already).
  - Add a print service:
  - (1) Open the [Setup]-> [Print]->[Print Service] 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 Printer Service page.
  - (5) Set printing properties.
  - (6) Click [Save] to complete the setting.
  - Modify print service:
  - (1) Select an existed printer service in the list.
  - (2) Select the printer model, and then you can set the properties in the Property box.
  - (3) Click [Save] to complete the setting.

# 3.7 Basic Screen & Operation

# 3.7.1 Monitor Display

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

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

|                  | Logo                  | Hospital Name |      | Patient<br>Name | Exam<br>Mode                          | Probe<br>Model | Freeze icon  |            |
|------------------|-----------------------|---------------|------|-----------------|---------------------------------------|----------------|--------------|------------|
|                  |                       | Date          | Time | Operator        | ID                                    | Age            | Gender       | Clip Board |
|                  | Transducer Parameter  |               |      |                 |                                       |                | /Thumbnails  |            |
| Menu             | Image Area            |               |      |                 | Grayscale/<br>Color Bar/<br>Parameter |                |              |            |
|                  | ECG                   |               |      |                 |                                       |                |              |            |
|                  | Cine Review           |               |      |                 |                                       |                |              |            |
|                  | Parameter Window Hint |               |      |                 |                                       |                | meter<br>dow |            |
| Help Information |                       |               |      |                 | System I                              | con            |              |            |

#### ■ Patient/ Exam information

Information area consists of manufacture logo, hospital name, exam time, freeze icon, patient information, probe model, exam mode and etc. To preset whether gender, age or operator is displayed: open the [Setup]  $\rightarrow$  [System]  $\rightarrow$  [General] screen, and check [Gender], [Age] or [Operator] in the "Patient Info" box in the upper left corner of the screen.

### Probe parameter area

- Probe model
  - Displays the currently-used probe model, or the default model.
- Probe parameter area
   Displays the acoustic power. Including the acoustic power, MI (Mechanical Index) and TI (Thermal Index), for the setting, please refer to "15.4.2 MI/TI Display".

### ■ Menu area

Include image menu, measurement menu, comment menu, body mark menu and so on.

### ■ Image area

The image area displays the ultrasound images, ECG waveforms, probe mark (or activating window mark), time line (in M or PW mode), coordinate axis (including depth, time, velocity/frequency), focal position (located at depth axis in the form of annotation, body mark, measurement calipers, color bar/grayscale bar are also display here.

#### ■ Parameter area

Displays the image parameters for the active window. If there are more than one imaging modes, the parameters are displayed by each mode.

### ■ Cine Review area

Displays the cine review progress bar to indicate the cine replay progress.

### ■ ECG curve

**ECG** Display

Tip: amplitude and position of ECG waveforms can be changed.

#### ■ Help information area

The help information area displays various help information or progress bar in the current status.

Tips: in terms of help information, "TB" refers to "Trackball", "Knob" refers to "Multifunction knob".

Press <Help> to open the Help Info manual.

### ■ Thumbnail

Displays the thumbnail images stored under the current patient.

#### ■ Grayscale/ color bar

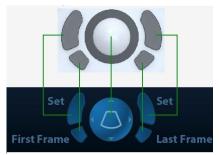
Displays the grayscale/ color bar corresponding to the current mode.

#### ■ Soft Menu area

The monitor soft menu area displays the items that simultaneously appear at the bottom of the touch screen.

#### ■ Trackball function hint area

Displays the current functions of trackball and keys, as shown in the following figure:



The left/right kidney shaped key is the <Set> key, to confirm the operation, similar to the left-button of the mouse. Press to confirm an operation, same as the left-button of a mouse.

### System status icon

This area displays the relevant system icons, such as USB memory device, printer, network, Chinese / English entry, and current system time, etc.

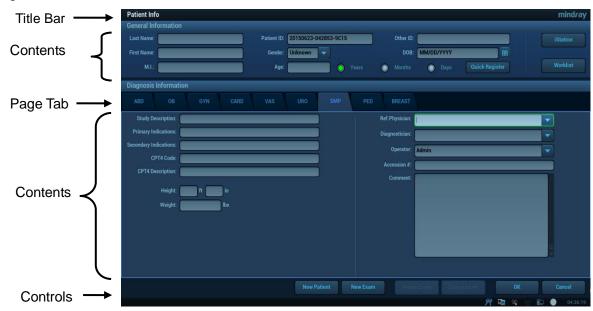
### Other Operations

Position of areas illustrated here are not fixed, you can move them by the trackball within a certain area on the monitor.

- Result window
- Comment area
- Body mark area

# 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:



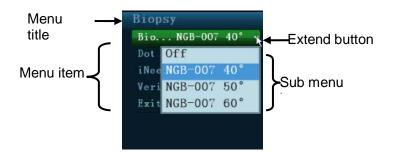
| Composition        | Description   |  |
|--------------------|---|--|
| Title Bar          | The title bar is used to give a description for the content and function of the screen.   |  |
| Page Tab           | For some screens, contents are distributed into several pages. Use the <set> key to open/close the available pages.</set>             |  |
|                    | ■ Radio box: click to select the item.  |  |
| Contents           | ■ Check box: click to check or uncheck the item.  |  |
| Contents           | ■ Entry box: enter characters manually via the keyboard.  |  |
|                    | ■ Drop-down list box: click ▼ to show the list and select an item.  |  |
| Functional buttons | 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 ♣; press the <Set> key.
- 2. Roll the trackball and posit the rectangular graphic to the new desired location.
- 3. Release the <Set> key, and the dialogue box is moved to the desired position.

# 3.7.3 Menu Operation

Use the trackball or the multifunctional knob to operate on the menu.

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



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

- For a commanding item or command optional item: press the knob to directly activate the item.
- For a parameter item or ON/OFF item: press the knob to lock and select the item (the item turns green in active status), then rotate the knob to switch among the available values; press the knob again to release and deselect the item.
- For a parameter optional item: press the knob to lock the item (the item turns green in active status) and meanwhile the available parameter list is extended, the cursor is positioned on the list. Rotate to view the parameters, and press the knob again to confirm the parameter, then close the list and release the previous parameter.
- Operate the menu by the trackball and left/right <Set> key.
- 1. Press <Cursor> to show the cursor.
- 2. Roll the trackball to locate the cursor onto the item to be adjusted.
  - For a commanding item or command optional item: press <Set> to directly activate the item.
  - For a parameter item or ON/OFF item: press <Set> to activate the item (the item turns green in active status), 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.

# 3.7.4 Touch Screen Display and Operation

Refer to the relevant chapters for details about touch screen display and operation.

# 4 Exam Preparation

You can start a patient exam in the following situations:

- New patient information: to start a new patient exam, you have to enter the patient information first
- New exam: to start a new exam for an already registered patient; the recorded information can be obtained either through iStation or Worklist.
- Activate exam: select an exam that is ended within 24 hours; continue the exam with the imported patient information and exam data.
- Continue an exam: select an exam that is paused within 24 hours; continue the exam with the 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 enter 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.



Before examining a new patient, press the <End Exam> key to end the exam of the previous patient, and update the patient ID and information, to avoid mixing data of the next new patient.

- To enter the Patient Info screen
  - Press <Patient>, or,
  - Move the cursor onto the patient information area on the main screen and press <Set> to open the screen.
- To exit the Patient Info screen
  - Click [OK] on the Patient Info screen, press <Patient> on the control panel again, or touch [OK] on the touch screen to save the settings and exit the screen.
  - Click [Cancel] on the Patient Info screen, touch [Cancel] on the touchscreen; or press <Esc> on the control panel to exit the screen without saving any of the entered patient data
  - Press <B> or <Freeze> to return to the current exam mode with the entered information being saved.
- Click [Quick Register] on the screen to save the patient information quickly and return to the main screen.

### 4.1.1 New Patient Information

The Patient Info screen is shown as follows:



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. Once you enter the ID and confirm it, you are not allowed to change it."\" is 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.

DOB (Date of birth):

You can either enter the birth date of a patient manually;

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

- Age
  - Auto generated age: once the DOB is obtained, the system can display an autogenerated 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.

**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** To enter the primary indications (reason to perform the exam.)

indications:

**Secondary** To enter the secondary indications.

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  |  |  |  |
|--------------------|-------------------------------|--|--|--|--|
|                    | Height                        | /  |  |  |  |
|                    | Weight                        | /  |  |  |  |
| ABD<br>(Abdomen)   | BSA (body<br>surface<br>area) | ace calculate the BSA based on the formula which is set via "[Setup]   |  |  |  |
| (Abdolliell)       | ВМІ                           |  |  |  |  |
|                    | Fasting                       | /  |  |  |  |
|                    | ALT                           | Alanine transaminase.  |  |  |  |
|                    | Calculation index             | Calculate gestation age (GA) and estimated delivery date (EDD) based on last menstrual period (LMP), date of conception (DOC), in vitro fertilization (IVF), basic body temperature (BBT), previous exam date (PRV). Select LMP, DOC, IVF, PRV, BBT, or EDD from the drop-down list; or, calculates GA and LMP according to the EDD and entered date.  • LMP: After you enter LMP, the system will calculate and |  |  |  |
| OB<br>(Obstetrics) |                               | <ul> <li>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</li> </ul>   |  |  |  |
|                    |                               | <ul><li>will calculate a new GA and EDD.</li><li>BBT: input BBT, the system will calculate the GA and EDD.</li></ul>   |  |  |  |
|                    |                               | <ul> <li>EDD: after you enter EDD, the system will calculate and<br/>display GA and LMP.</li> </ul>  |  |  |  |

| Exam Type  | Information                   | Description  |
|--|-------------------------------|--|
|  | Gravida                       | Times of pregnancy.  |
|  | Ectopic                       | Times of abnormal pregnancy. e.g. extrauterine pregnancy   |
|  | Gestations                    | Number of embryos (1, 2, 3, 4)   |
|  | Para                          | Times of delivery.   |
|  | Aborta                        | Times of abortion.   |
|  | LMP                           | Last menstrual period.   |
|  | Gravida                       | Times of pregnancy.  |
| GYN  | Para                          | Times of delivery.   |
| (Gynecology)   | Ectopic                       | Times of abnormal pregnancy. E.g. extrauterine pregnancy.  |
| CARD (Cardiology)  VAS (Vascular)  URO (Urology)  SMP (Small   | Aborta                        | Times of abortion.   |
|  | IVF Info                      | Female hormone basic level and drugs inducing the ovulation.   |
|  | Height                        | /  |
|  | Weight                        | /  |
| -  | BSA (body<br>surface<br>area) | After the height and weight are inputted, the system will automatically calculate the BSA based on the formula which is set via "[Setup] →[System Preset] → [General] ". |
| (Cardiology)   | BP                            | Blood pressure.  |
|  | HR                            | /  |
|  | RA Press                      | Right Atrium Pressure.   |
| Gestations Number of embryos (1, 2, 3, 4)  Para Times of delivery.  Aborta Times of abortion.  LMP Last menstrual period.  Gravida Times of pregnancy.  Para Times of delivery.  Ectopic Times of abortion.  IVF Info Female hormone basic level and drugs  Height /  Weight /  BSA (body surface area) Via "[Setup] →[System Preset] → [General Pressure]  Height /  RA Press Right Atrium Pressure.  Height /  RAPICS Right Atrium Pressure.  Height /  Weight /  RAPICS Right Atrium Pressure.  Height /  Weight /  RAPICS Right Atrium Pressure.  Height /  Weight /  BP(L) (blood pressure) Input left blood pressure.  URO (Urology)  Serum PSA /  PPSA coefficient: / | Height                        | /  |
|  | /                             |  |
|  | Input left blood pressure.    |  |
|  |                               | Input right blood pressure.  |
| LIBO   | Serum PSA                     | /  |
|  | _                             | /  |
|  | None                          | /  |
|  | None                          | /  |
| Breast   | Height                        | /  |
| URO (Urology)  SMP (Small Parts)  PED (Pediatrics)   | 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.

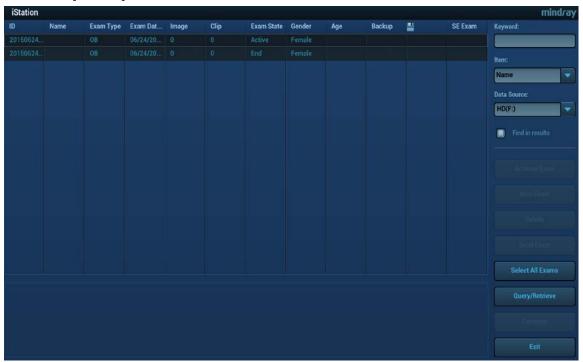
- [New Patient]: click to clear the current patient information in the patient information screen in order to input new patient information.
- [New Exam]: click to clear the current exam information in order to create a new exam for the current patient.
- [OK]: click to save the patient data entered 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 <iStation> on the control panel; or,
  - Click [iStation] in the Patient Info screen; or
  - 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 and Exam Date, the default one is name; then enter a keyword 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:



| Button | Function               | Description  |
|--------|------------------------|--|
|        | Review an Image        | Click to enter the Review screen.  |
|        | Patient<br>Information | Click to enter the Patient Info screen.  |
|        | Review<br>Report       | Click to enter diagnostic report screen.   |
|        | Delete Exam            | Click to delete the selected record.   |
|        | Backup Exam            | Click to back up the selected patient record to media supported.                             |
| 6      | Restore<br>Exam        | Click to import the patient data from an external media.                                     |
|        | Send Exam              | Click to send the selected patient data to external device, DICOM storage server or printer. |
|        | Activate exam          | Click to continue an exam that has been finished within 24 hours.                            |
|        | Resume<br>Exam         | Click to continue an exam that has been paused within 24 hours.                              |

### 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 DICOM Worklist/HL7 Enquiry

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

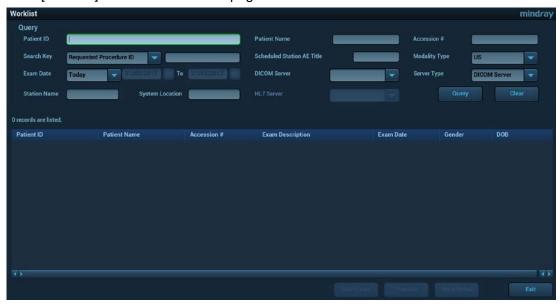
When the DICOM basic package is configured and the Worklist server has been set, click [Worklist] in the Patient Info screen to query or import the patient data. (For details about Worklist server setting, please refer to the DICOM chapter.)

The system supports: DICOM and HL7.

**Basic Operations:** 

1. Tap [Patient] to enter the patient information page.

2. Click [Worklist] to enter the Worklist page.



- 3. Guarantee the data source: after select the service type, select the worklist server from the corresponding server (DICOM and HL7 server).
- 4. Input the searching condition:
  - a) Input the searching condition:
    - Select "DICOM server". You can search via patient ID, accession #, 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.
- 5. 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. Edit the
    patient information in the Patient Info screen, and click [OK] to start a new exam.
  - Click [Show Detail] to see details of patient data.
- 6. Click [Exit] to exit the Worklist.

### 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.

- Selecting exam mode
- 1. Connect proper probes to the system, and press <Probe> on the control panel, the touchscreen displays the following dialog box:



- 2. Click to select the probe type and exam mode, and the system exits the dialogue box to enter the selected exam mode and probe.
  - Click [Exit] or press <Probe> again to cancel the selection and exit the screen.
- Using the Bi-plane Endocavity Probe (CB10-4E)

When activating the probe, system displays sagittal plane B-mode image by default, you can switch the plane by clicking [Select Plane] on the touch screen or pressing the plane select key on the probe (yellow button) to select the plane. Available selections are: S (sagittal) Plane, T (transverse) Plane, S&T. An intuitive reference image will show the S plane and T plane on the lower left side of the screen.

In S&T displaying mode, click [Display Format] on the touch screen to set the image display format.

Biopsy line is displayed on both planes when the system enters biopsy in S&T displaying mode. Of which, the biopsy line on S plane is displayed as a dotted-line, while on T plane the biopsy line is displayed as a dot. When moving the biopsy line, the lines on both planes will be moved.

# 4.3 Select the Imaging Mode

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

# 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 [Activate Exam] in iStation or Review screen to activate the exam.

Tips:

- The system can automatically load the patient information and exam data to continue the exam.
- If you want to continue an exam with data 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 activated exam, you can modify patient ID.

### 4.4.2 Continue 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.

# 4.5 Pause & End an Exam

### 4.5.1 Pause Exam

- Sometimes, you have to stop an uncompleted exam due to some special reasons. When the exam is paused, the system can begin other exams.
- 1. Press <Patient> to enter Patient Info screen.
- 2. Click [Pause Exam].
- If the system is powered off during scanning, the exam status turns "paused" after the system restart.

When an exam is paused, the system will:

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

### **4.5.2** End Exam

Before examining a new patient, press <End Exam> 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:

- Press <End Exam> on the control panel.
- Click [New Patient] on the Patient Info screen to end the last patient exam and clear the patient information.

| Click [New Exam] on the Patient Info screen (or iStation screen, or Review screen) to end the last exam and clear the exam data. |  |
|--|--|
|  |  |
|  |  |
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# 5 Image Optimization

# **△WARNING**:

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

In Dual-B imaging mode, the measurement results of the merged image may be inaccurate. Therefore, the results are provided for reference only, not for confirming a diagnosis.

# 5.1 Imaging Mode

### 5.1.1 Switching Between Imaging Modes

Switch among the imaging modes according to the actual situation.

### 5.1.2 Image Adjustment

- Adjust through image menu:
  For details about menu adjustment, please refer to "3.7.3 Menu Operation" Chapter.
- Adjust through the touch screen

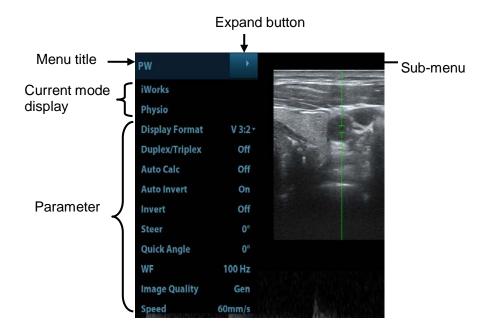


1. Mode displaying area (or main functional tabs): displays the current modes, touch the tab to enter the mode.

- 2. Other application mode entrance: displays the available application modes related; touch to enter the modes.
- 3. Parameter adjusting area: displays the parameters in the current imaging mode or function.
  - Parameter magnitude setting: touch ▶ 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 green.
  - Page selection: if there is more than 1 page for the current mode, touch turn the pages.
  - 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.

- Adjust through the touch screen (image mapping mode)
- 1. Enter the mapping mode to open the mapping menu. See Chapter 3.7.4 Touch Screen Display and Operation for details.



#### 2. 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.
- b) Other application mode entrance: displays the available application modes related, click to enter the corresponding mode. Such as, iWorks, Physio.
- c) 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 decrease 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 green.
- 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, control panel key, deflector rod, knob or slider.

### 5.1.3 Quickly Saving Image Setting

Press <F7> to enter the image data saving dialogue box.



Save image parameter adjustment:

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

■ Create a new exam data (using current image parameter setting):

Enter the name in the box after the "Save As" to assign a name for a user-defined exam mode, and click [Create] to save the current image parameters, measurements, comments, body mark settings to the exam mode.

Restore factory setting:

Settings of the current exam mode and the probe can be restored to factory data by clicking [Restore].

- View image parameter
  - Tap [Show Parameter] to view the image parameter of the current exam mode and the probe.
  - Tap [Advanced]. The value to TIC/TIB/TIS can be set.
  - Tap [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.

# **5.2** B Mode Image Optimization

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

### 5.2.1 Basic Procedures for B Mode Imaging

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

### 5.2.2 B Mode Parameters

In B mode scanning, the image parameter area in the upper right corner of the screen displays the real-time parameter values as follows:

| Parameter | F         | D     | G    | FR            | DR               | iClear                              | iBeam | iTouch  | Zoom | Echo<br>Boost |
|-----------|-----------|-------|------|---------------|------------------|-------------------------------------|-------|---------|------|---------------|
| Meaning   | Frequency | Depth | Gain | Frame<br>Rate | Dynamic<br>Range | Display when the function is turned |       | ned on. |      |               |

### 5.2.3 B Mode Image Optimization

### **Image Quality**

**Description** 

To switch between the fundamental frequency and harmonic frequency, and select the corresponding frequency type. The real-time value of frequency is displayed in the image parameter area in the upper right corner of the screen, and if harmonic frequency is used, "F H" is displayed as harmonic frequency value.

Harmonic frequency

Press the knob under the [Image Quality] on the touch screen to be "Harmonic On" to turn on the function.

Rotate the knob under the [Image Quality] on the touch screen to select the different frequency values.

The adjusting range of frequency values can be divided into 6 levels, penetration preferred, (HPen), general mode (HGen), resolution preferred (HRes), the mode between penetration preferred and general mode (HPen-Gen), the mode between general mode and high FR(HGen-FFR), high FR with resolution preferred(HRes-FFR).

Fundamental frequency

Press the knob under the [Image Quality] on the touch screen to be "Harmonic Off" to use the fundamental frequency.

The adjusting range of frequency values can be divided into 3 levels, penetration preferred, (Pen), general mode (Gen), resolution preferred (Res).

Rotate the knob under the [Image Quality] on the touch screen to select the different frequency values.

**Impacts** 

The system provides an imaging mode 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 right corner of the

screen.

**Operations** Rotate the <B> knob clockwise to increase the gain, and anticlockwise to

decrease.

The adjusting range is 0-100.

**Effects** 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 sampling depth, the real-time value of which is

displayed in the image parameter area in the upper right corner of the screen.

**Operations** Use the <Depth> deflector rod on the lower right part of the control panel to adjust

the depth.

The adjustable depth values vary depending upon the probe types.

Effects Increase the depth to see tissue in deeper locations, while decrease the depth to

see tissue in shallower locations.

**TGC** 

**Description** The system compensates the signals from deeper tissue by segments to optimize

the image.

There are 8-segment TGC sliders on the control panel corresponding to the areas

of the image.

**Operations** 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.

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

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

**Acoustic Power** 

**Description** Refers to the power of ultrasonic wave transmitted by the probe, the real-time

value of which is displayed in the upper part of the screen.

**Operations** Use the <A.Power> knob to adjust the acoustic power. The adjusting range is 3.2-

100%.

Effects Generally, increasing the acoustic power will increase the brightness and contrast

of the image and the force of penetration.

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

Principle.

**Focus** 

**Description** Refers to adjustment of focus of the ultrasonic beams, symbols as "◀" of which

are displayed on the right of the image.

**Operations** Adjust the focus number through the [Focus Number] item on the touch screen.

Use the <Focus> deflector rod on the lower right part of the control panel to adjust

the focus position.

In B mode, available focus number can be switched among 1-4.

**Effects** The area that is focused will be of a higher contrast and resolution.

**Impacts** The greater the number of focal zones, the slower the frame rate to image.

### **Imaging Adjustment**

**Description** More information can be obtained without moving the probe or changing the

sampling position.

FOV (Field of View)

1. To change the scan range, touch [FOV] on the touch screen to enter the FOV range and FOV position adjustment status.

2. Press <Set> to switch between FOV range/position changing according to the hint region display.

3. Rotate the trackball to adjust FOV position or the 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.

Frame rate decreases when using a larger FOV.

**B Steer** Use the <Steer> deflector rod on the control panel to adjust the steer angle.

ExFOV (Extended FOV) Touch [ExFOV] on the touch screen to turn on/off the function.

For linear probes, the ExFOV function displays as trapezoid imaging. For convex probes, the ExFOV function displays as extending the scanning angle.

**Impacts** The FOV position/range is available only for convex and phase probes.

The B Steer function is available only for linear probes.

**Line Density** 

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

**Operations** Adjust the line density through the [Line Density] item on the touch screen.

There are four levels of line density available: UH, M, H, L.

**Effects** The higher the line density, the higher the resolution.

**Impacts** The higher the line density, the lower the frame rate.

**Dynamic Range** 

**Description** This function is used to adjust the B image resolution to compress or expand the

gray display range. And the real-time value displays in the image parameter area

in the upper right corner of the screen.

**Operations** Rotate the knob under the [Dyn Ra.] item on the touch screen to adjust the

dynamic range.

Rotate the knob clockwise to increase the value; rotate the knob counterclockwise

to decrease the value.

**Impacts** The more the dynamic range, the more specific the information, and the lower the

contrast with more noise.

**iClear** 

**Description** The function is used to enhance the image profile so as to distinguish the image

boundary for optimization.

**Operations** Adjust through the [iClear] item on the touch screen.

The system provides 7 levels of iClear adjustment, off represents no iClear effect,

and the bigger the value the stronger the effect.

**Impacts** It may cause noise increasing.

**Persistence** 

**Description** This function is used to superimpose and average adjacent B images, so as to

optimize the image and remove noise.

**Operations** Rotate the knob under the [Persistence] item on the touch screen to adjust the

value.

The system provides 7 levels of frame average adjustment, the bigger the value

the stronger the effect.

**Effects** Persistence can remove image noise to make details to be clearer.

**Impacts** Persistence increasing may lead to signal missing.

Rotation /Invert (U/D Flip and L/R Flip)

**Description** The function provides a better observation for image display.

**Rotation** Rotate the image through the [Rotation] item on the touch screen.

Image can be rotated in the manners of angles of 0°, 90°, 180° and 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.

Invert (U/D Flip and L/R To invert the image horizontally or vertically.

Flip)

Touch [U/D Flip] or [L/R Flip] on the touch screen to invert the image

**Effects** You can identify image orientation through the "M" mark on the screen; by default,

the M mark is located in the upper left corner of the imaging area.

iBeam (Spatial Compound Imaging)

**Description** This function is used to superimpose and average images of different steer angles

to obtain image optimization.

**Operations** Adjust through the [iBeam] item on the touch screen.

The system provides 4 levels of iBeam adjustment in single B mode; Off

represents no iBeam.

Effects Images can be optimized with less spot noise and higher resolution, so that more

details for the structure are revealed.

**Impacts** iBeam is valid for linear and convex probes, and it is not available when ExFOV

function is turned on.

**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 the magnification factor, the system

will merge the two images so as to extend the field of vision.

**Operations** Turn on or off the function through the [Auto Merge] item on the touch screen.

**Impacts** The function is valid only for linear probes.

**Gray Map** 

**Description** This function applies the gray correction to obtain the optimum images.

**Operations** Select among the maps by rotating the knob under the [Gray Map] item on the

touch screen. The system provides 10 different gray effect maps.

**Tint Map** 

**Description** This function provides an imaging process based on color difference rather than

gray distinction.

**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.

**TSI (Tissue Specific Imaging)** 

**Description** The TSI function is used to optimize the image by selecting acoustic speed

according to tissue characteristics.

**Operations** Select among the TSI modes through the [TSI] item on the touch screen.

The system provides four ways of optimization for specific tissues: general,

muscle, fluid and fat.

iTouch (Auto Image Optimization)

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

image effect.

**Operations** 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

right corner of the screen once press <iTouch>.

Select different levels of iTouch effect through [iTouch] on the touch screen.

Long press the <iTouch> key to exit the function.

#### H Scale

**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. When image is turned up/down, the H Scale will also be inverted.

**Operations** Touch [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** Touch [Dual Live] on the touch screen to turn on/off the function, and dual-split

window of images are displayed on the main screen.

Two pages of adjustable parameters are displayed in 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 right corner of the main screen,

parameters of the both windows are displayed.

**Impacts** Image magnification is available in dual live mode.

#### **LGC**

**Description** Adjust gain of scan lines to increase the image lateral resolution.

**Operation** Touch [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.

Touch the 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** This function can improve contrast and decrease noises, so that a much clearer

boundary can be seen.

**Operation** Touch [Echo Boost] on the touch screen to turn on the function (when the function is

turned on, the [Echo Boost] button is highlighted in green and the system has "Echo

Boost" status indicating on the image parameter area).

**Impacts** This function is available only using phased probe in cardiac exam mode (P7-3TE

probe does not support this function) and linear probe.

# 5.3 M Mode Image Optimization

### 5.3.1 Basic Procedures for M Mode Imaging

- 1. Select a high-quality image during B mode scanning, 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.

### 5.3.2 M Mode Image Parameters

■ In M mode scanning, the image parameter area in the upper right corner of the screen displays the real-time parameter values as follows:

| Parameter | F         | D     | G      | V       | DR              |
|-----------|-----------|-------|--------|---------|-----------------|
| Meaning   | Frequency | Depth | M Gain | M speed | M Dynamic Range |

- During M mode imaging, menus 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.
- During M mode scanning, frequency and acoustic power of the probe are synchronous with that of B mode.
- Adjustment of the depth, focus position or TGC to the B mode image will lead to synchronous 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 the upper right corner of the screen.

**Operations** Rotate the <M> knob clockwise to increase the gain, and anticlockwise to

decrease.

The adjusting range is 0-100.

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 M mode image and B mode image.

**Operations** Touch the different display format radio buttons on the touch screen to adjust.

There are 5 formats available for image display: H2:3, V2:3, V3:2, V3:1, Full.

Effects Select different format types according to the actual situation and obtain a desired

analysis through comparison.

Speed

**Description** This function is used to set the scanning speed of M mode imaging, and the real-

time speed value is displayed in the image parameter area in the upper right

corner of the screen.

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

There are 6 levels of scan speed available, the smaller the value the faster the

speed.

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

Tint Map

**Description** This function provides an imaging process based on color difference rather than

gray distinction.

**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.

**Gray Map** 

**Description** This function applies the gray correction to obtain the optimum images.

**Operations** To select among the maps, turn the knob under [Gray Map] on the touch screen.

The system provides 10 different gray effect maps.

### **Edge Enhance**

**Description** This function is used to enhance image profile so as to distinguish image

boundary for optimization.

**Operations** Adjust through the [Edge Enhance] item on the touch screen.

There are 3 levels of edge enhance adjustment available, the bigger the value the

stronger the effect.

**Impacts** Larger edge enhance may lead to noise increasing.

### **Dynamic Range**

**Description** This function is used to adjust the M image resolution to compress or expand the

gray display range.

The real-time dynamic range value is displayed in the image parameter area in the

upper right corner of the screen.

**Operations** Rotate the knob under the [Dyn Ra.] item on the touch screen.

**Effects** The more the dynamic range, the more specified the information.

M Soften

**Description** This feature is used to process the scan lines of M images to reject noise, making

the image details clearer.

**Operations** Adjust through the [M Soften] item on the touch screen.

The system provides 4 levels of M Soften adjustment, the bigger the value the

stronger the effect.

# 5.4 Color Mode Image Optimization

The Color mode is used to detect color flow information, 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, the faster the flow speed, while the darker the color, the slower the flow speed.

### 5.4.1 Basic Procedures for Color Mode Imaging

- 1. Select a high-quality image during B mode scanning, and adjust to place the area of interest in the center of the B mode image.
- 2. Press <Color> to enter B + Color mode. Roll the trackball to change position and size of the Region of Interest (ROI) and press the <Set> key to set.
- 3. Adjust the image parameters during scanning to obtain optimized images.
- 4. Perform other operations (e.g. measurement and calculation) if necessary.

### 5.4.2 Color Mode Image Parameters

■ In Color mode scanning, the image parameter area in the upper right corner of the screen displays the real-time parameter values as follows:

| Parameter | F         | G          | PRF                              | WF                |
|-----------|-----------|------------|----------------------------------|-------------------|
| Meaning   | Frequency | Color Gain | Pulse Repetition Frequency (PRF) | Color Wall Filter |

- During Color mode imaging, menus of image optimizing for B mode and Color 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 to the B mode image will lead to corresponding changes in Color mode image.

### 5.4.3 Color Mode Image Optimization

#### **Color Gain**

**Description** Refers to the overall sensitivity to flow signals, and this function is used to adjust

the gain in Color mode. The real-time gain value is displayed in the image

parameter area in the upper right corner of the screen.

**Operations** Rotate the <Color> knob clockwise to increase the gain, and anticlockwise to

decrease.

The adjusting range is 0-100.

**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.

### **ROI Adjustment**

**Description** This function is to adjust the width and position of ROI in Color mode.

**Operations** When the ROI box is dotted line, roll the trackball to change the size.

When the ROI box is solid line, roll the trackball to change the position.

Press <Set> to switch between the solid line and the dotted line.

**Impacts** The larger the ROI box, the lower the frame rate, and the lower the resolution and

color sensitivity.

### **Image Quality**

**Description** Refers to the operating frequency in Color mode of the probe, the real-time value

of which is displayed in the image parameter area in the upper right corner of the

screen.

**Operations** Rotate the knob under the [Image Quality] on the touch screen to select the

different frequency values.

The adjusting range of frequency values can be divided into 3 levels, penetration

preferred, (Pen), general mode (Gen), resolution preferred (Res).

Values of frequency vary by probe types. Select the frequency according to the

need of the detection depth and the current tissue characteristics.

**B/C Align** 

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

ROI.

**Operations** Turn on or off the function through the [B/C Align] item on the touch screen.

**Impacts** Frame rate increases when the function is turned on.

**Dual Live** 

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

**Operations** Turn on or off the function through the [Dual Live] item on the touch screen.

When the function is turned on, the window will be automatically switched to the

dual windows (one for B image, and the other for Color image).

Steer

**Description** The feature is used to adjust the ROI of color flow of different angles with

immobility of the linear probe.

**Operations** Adjust through the <Steer> deflector rod on control panel.

Effects This function is used to adjust the scan angle of linear probes, so as to change the

angle between the transmitting beam and flow direction.

**Impacts** Steer is valid only for linear probes.

**Line Density** 

**Description** Line density determines the quality and information of the image.

**Operations** Adjust through the [Line Density] item on the touch screen.

There are 4 levels of line density provided: H, L, UH, M.

**Effects** The higher the line density, the higher the resolution. **Impacts** The higher the line density, the lower the frame rate.

**Packet Size** 

**Description** This function is an indication of the ability to detect flow, which is used to adjust the

accuracy of color flow.

**Operations** Rotate the knob under the [Packet Size] item on the touch screen to adjust the

value.

There are 3 levels of packet size available, 0 represents no packet size control and

the bigger the value the higher the sensitivity.

**Effects** The higher the packet size, the more sensitive indication for low-velocity flow.

**Impacts** Adjusting the packet size may lead to frame rate changing.

Flow State

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

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

There are 3 levels provided to adjust: L, M, H.

**Persistence** 

**Description** This function is to adjust the temporal smooth in Color mode to optimize the

image.

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

The system provides 6 levels of persistence adjustment, 0 represents no

persistence and the bigger the value the stronger the effect.

Smooth

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

**Operations** Adjust through the [Smooth] item on the touch screen.

The system provides 6 levels of smooth function, the bigger the value the higher

the smooth.

iTouch (Auto Image Optimization)

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

image effect.

**Operations** Press <iTouch> on the control panel to turn on the function.

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 upper right corner of the screen.

**Operations** Use the <Scale> deflector rod on the control panel to adjust.

The adjusting range varies by frequency, probe and depth; adjust according to the

actual situation.

**Effects** To provide a much clearer color flow image.

Use low PRF to observe low-velocity flows, and 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.

**Operations** Use the <Baseline> deflector rod on the upper right part of the control panel to

adjust.

Positive value means to increase the signals above the baseline, and negative

value means to increase the signals below the baseline.

Invert

**Description** To set the display mode of color flow and the color scale will be inverted when the

function is turned on.

**Operations** Turn on or off the function through the [Invert] item on the touch screen.

Select "Auto Invert" in the "[Setup] (F10)  $\rightarrow$  [System]  $\rightarrow$  [Image]", then the color bar can automatically invert when the color flow is steered to a certain angle to

accommodate operator's habit of distinguishing flow direction.

**Color Map** 

**Description** This function is a combination of several image parameters, which indicates the

display effect of color image.

**Operations** Rotate the knob under the [Color Map] item on the touch screen to select among

the maps.

The system provides 21 different maps to be selected among, where the V group

provides 11 ordinary maps and the VV group provides 10 2-D maps.

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 is displayed in the image

parameter area in the upper right corner of the screen.

**Operations** Select through the [WF] item on the touch screen.

There are 8 levels of wall filter function available. Select the value according to the

actual situation.

**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.

Impacts The probe L12-3E/L9-3E/L14-5WE/L14-6NE/L14-6WE for Upper Ext Artery,

Upper Ext Vein, Lower Ext Artery, Lower Ext Vein, carotid, IMT, EM Vascular exam

supports the smart track.

### **Priority**

**Description** This function is used to set levels of the flow display, to display the grayscale

signal or color signal.

**Operations** Rotate the knob under the [Priority] item on the touch screen to select the value.

The adjusting range of the priority is 0-100%.

The higher the value, color signals are prior to be displayed; while the lower the

value, grayscale signals are prior to be displayed.

### 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
 Touch [Velocity Tag] on the touch screen to enter the velocity marking status, and green mark appears on the color bar.

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.

Press <Set> to switch between marking position and marking range.

### HR Flow (High Resolution Flow)

**Description** This function enhances micro vessel imaging effect, can be used to analyze tissue

blood supply condition.

**Operations** Touch [HR Flow] on the touch screen to turn on HR Flow status ([HR Flow] button is

highlighted in green when turning the status.)

Parameters in HR Flow mode are independent from those in Color mode.

# 5.5 Power Mode Image Optimization

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

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

# 5.5.1 Basic Procedures for Power Mode Imaging

- 1. Select a high-quality image during B mode or B + Color scanning, and adjust to place the area of interest in the center of the image.
- 2. Press <Power> to enter B + Power mode. Roll the trackball to change position of the Region of Interest (ROI) and press the <Set> key to set. Roll the trackball to change the size and position of ROI.
- 3. Adjust the image parameters during B + Power mode scanning to obtain optimized image.
- 4. Perform other operations (e.g. measurement and calculation) if necessary.

### **5.5.2** Power Mode Image Parameters

■ In Power mode scanning, the image parameter area in the upper right corner of the screen displays the real-time parameter values as follows:

| Parameter | F         | G          | PRF                                 | WF                |
|-----------|-----------|------------|-------------------------------------|-------------------|
| Meaning   | Frequency | Power Gain | Pulse Repetition<br>Frequency (PRF) | Power Wall Filter |

- 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 clicking the mode tabs.
- In Power 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 Power mode image.

Parameters consistent with those in Color mode and B mode are not described, please refer to relevant sections of the Color mode and B mode, while special items of the Power mode are introduced in the following.

# 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 in the upper

right corner of the screen.

**Operations** Rotate the <Color> knob clockwise to increase the gain, and anticlockwise to

decrease.

The adjusting range is 0-100.

**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 the Power mode image are grouped into two categories: Power maps

and Directional Power maps.

**Operations** To select among the maps, turn the knob under [Color Map] on the touch screen.

There are 8 kinds of maps provided: P0-3 belong to Power mode maps, while

Dp0-3 belong to Directional Power mode maps.

The Power maps provide information of blood flow, which are highly sensitive to

the low-velocity flows.

The Directional Power maps provide information of flow direction.

### **Dynamic Range**

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

Operations Rotate the knob under the [Dyn Ra.] item on the touch screen to adjust the

dynamic range.

**Effects** Increasing dynamic range will lead to higher sensitivity to low-power signals, thus

enhances the range of signals to display.

# 5.6 PW/CW Doppler Mode

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

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

CW imaging is an option.

Adjustment items, such as SV, steer, Duplex, Triplex, iTouch and HPRF, are not available in the CW mode.

### 5.6.1 Basic Procedures for PW / CW Mode Exam

- 1. Select a high-quality image during B mode or B + Color (Power) mode scanning, and adjust to place the area of interest in the center of the image.
- 2. Press <PW>/<CW> to adjust the sampling line,
  - The sampling status will be displayed in the image parameter area in the upper right corner of the screen as follows:

| <u>PW</u> |
|-----------|
| F 2.0     |
| WF 200    |
| G 50      |
| SVD 77.7  |
| SV 5.0    |
| PRF 2.9k  |
| Angle 0°  |
|           |

| <u>CW</u> |
|-----------|
| F 2.0     |
| WF 600    |
| G 50      |
| SVD 84.7  |
| PRF 17.4k |
| Angle 0°  |

| PW Sampling Line | SV    |
|------------------|-------|
| Adjustment       | Angle |
|                  | SVD   |
| CW Sampling Line | Angle |
| Adjustment       | SVD   |

- 3. Set the position of the sample line by moving the trackball left and right, and set the SVD by moving the trackball up and down, adjust the angle and SV size according to the actual situation.
- 4. Press <PW>/ <CW> or <Update> again to enter PW/CW mode and perform the examination. You can also adjust the SV size, angle and depth in real-time scanning.
- 5. Adjust the image parameters during PW/CW mode scanning to obtain optimized image.
- 6. Perform other operations (e.g. measurement and calculation) if necessary.

### 5.6.2 PW/CW Mode Image Parameters

In PW/CW mode scanning, the image parameter area in the upper right corner of the screen displays the real-time parameter values as follows:

| PW | Parameter | F         | G    | PRF | WF             | SVD            | SV      | Angle |
|----|-----------|-----------|------|-----|----------------|----------------|---------|-------|
|    | Meaning   | Frequency | Gain | PRF | Wall<br>Filter | SV<br>Position | SV Size | Angle |

| CW | Parameter | F         | G    | PRF | WF          | SVD         | Angle |
|----|-----------|-----------|------|-----|-------------|-------------|-------|
|    | Meaning   | Frequency | Gain | PRF | Wall Filter | SV Position | 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.
- When you adjust the depth of the B 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 parameters of the both are combined together to be introduced here.

NOTE: The P4-2NE, P7-3E, P10-4E, SP5-1E, P7-3TE CW5s and CW2s probes support CW mode.

### 5.6.3 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 upper right corner of the

screen.

**Operations** Rotate the [PW] knob clockwise to increase the gain, and anticlockwise to

decrease.

The adjusting range is 0-100.

Effects Increasing the gain will brighten the image and you can see more received

signals. However, noise may also be increased.

SV

**Description** To adjust 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 upper right corner

of the screen.

**SV size** Rotate the knob under [SV] on the touch screen to adjust the SV size.

Value: 0.5-20mm.

**SVD** Roll the trackball to select the SV depth.

Effects The smaller the SV size, the more accurate the result; and more details are

obtained when selecting large SV size.

### **CW Focus Position**

**Description** To adjust the CW mode SVD. The real-time focus position value is displayed on

the image parameter area in the upper right corner of the screen.

**Operation** Roll the trackball to select the focus depth.

### **Image Quality**

**Description** Refers to the operating frequency in PW mode of 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 knob under the [Image Quality] on the touch screen to select the

different frequency values.

The adjusting range of frequency values can be divided into 3 levels, penetration

preferred, (Pen), general mode (Gen), resolution preferred (Res).

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

features.

**Effects** The higher the frequency, the better the resolution and sensitivity, and the worse

the force of penetration.

Scale

**Description** This function is used to adjust the speed range of flow, which is adjusted through

PRF in the system.

The real-time PRF value is displayed in the image parameter area in the upper

right corner of the screen.

**Operations** Adjust through the <Scale> deflector rod on the control panel.

**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.

**Operations** Press <iTouch> on the control panel to turn on the function.

**Auto Calculation** 

**Description** This function is used to trace the spectrum and calculate parameters of PW/CW

mode image, and the results of which are displayed in the result window.

Auto Turn on or off the auto calculation function through the [Auto Calc] item on the Calculation

touch screen.

Calculation **Parameter** 

Auto

Select parameters in the dialogue box prompted by touching [Auto Calc Param] on

the touch screen.

**Auto Calc** Cycle

To set the number of heart cycle for auto calculation.

Touch [Auto Calc Cycle] on the touch screen to select the cycle number.

**Operations** In real-time scanning, the results displayed are derived from the calculation of

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.

**Operations** Turn on or off the function through the [Invert] item on the touch screen.

Select "Auto Invert" in the "[Setup] (F10) → [System] → [Image]", thus the

spectrum can automatically invert when the color flow is steered to a certain angle

to accommodate operator's habit of distinguishing flow direction.

Speed

**Description** This function is used to set the scanning speed of PW mode imaging.

**Operations** Rotate the knob under [Speed] item on the touch screen.

**Effects** Changing the speed makes it easier to identify the cardiac cycles and to detect

more details.

T/F Res

**Description** This function is used to adjust for a balance between time resolution and spatial

resolution.

**Operations** Adjust through the [T/F Res] item on the touch screen.

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 is displayed in the image

parameter area in the upper right corner of the screen.

**Operations** Select through the [WF] item on the touch screen.

**Impacts** Signals of low-velocity flow may be missing.

Tint Map

**Description** This function provides an imaging process based on color difference rather than

gray distinction.

**Operations** Rotate the knob under the [Tint Map] item on the touch screen to select the map.

Press the knob under the [Tint Map] item on the touch screen to turn on/off the

function.

Trace

**Trace Smooth** To set the smooth level of tracing.

The smooth level can be adjusted through the [Trace Smooth] item on the soft

menu.

**Trace** To set the sensitivity of the spectrum tracing.

**Sensitivity** The smooth sensitivity can be adjusted through the [Trace Sensitivity] item on

the soft menu.

The system provides 5 levels of trace sensitivity adjustment. The bigger the

value is, the higher the smooth sensitivity becomes.

**Trace Area** To set the trace area of the Doppler wave in the spectrum map, applicable for

auto calculation.

Change the trace area through the [Trace Area] item on the touch screen.

The available selections are: Above, Below, All.

**Gray Map** 

**Description** This function applies the gray correction to obtain the optimum images.

**Operations** To select among the maps, turn the knob under [Gray Map] on the touch screen.

**Display Format** 

**Description** To set the display format of PW mode image with B mode image.

**Operations** Touch the different display format radio 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 (B + Color image) and PW image are

displayed synchronously.

**Operations** Click [Duplex]/ [Triplex] on the touch screen to turn on or off the synchronization.

**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 selected PW Doppler scale.

**Operations** Turn on or off the function through the [HPRF] item 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.

**Operations** Adjust through the <Baseline> deflector rod on the control panel.

**Effects** To change the range of flow velocity to optimize the image.

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 right part of the spectrum

map.

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

The adjustable angle range is -89~89°, in increments of 1°.

**Quick Angle** 

**Description** To adjust the angle faster, in increments 60°, and the real-time value of which is

displayed on the right part of the spectrum map.

**Operations** Adjust through the [Quick Angle] item on the touch screen.

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

**Dynamic Range** 

**Description** The dynamic range conveys the information that being transformed from echo

intensity to gray scale.

**Operations** Adjust through the [Dyn Ra.] item on the touch screen.

Effects The more the dynamic range, the more specific the information, and the lower the

contrast with more noise.

Audio

**Description** This function is used to adjust the output audio in spectrum map.

**Operations** Rotate the <Volume> knob on the left of the touch panel to adjust the volume.

Press <Volume> knob to open or shut down the volume.

The adjusting range of the audio is 0-100%.

**Effects** Utilizing the output audio helps to identify the feature and status of flow.

**PW Steer** 

**Description** This function provides adjustment on angles for sampling line.

**Operations** Adjust through the <Steer> deflector rod on the control panel.

Effects This feature is used to steer the direction of the beam so as to change the angle

between the beam and flow direction with immobility of the linear probe.

Values of steer angles vary by probe.

**Impacts** The PW Steer function is available only for linear probes.

### 5.7 Color M Mode

Color M mode provides information of color flow or tissue on the M mode images to indicate cardiac motion state. It is highly sensitive to the flow or tissue movement.

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

### 5.7.1 Enter Color M Mode

- Color Flow M Mode
  - In B + M mode, press <Color> on the control panel to enter sampling line adjustment status, and press <M> again.
  - In B + Color, B + Color + PW or B + Color + CW mode, press <M> twice on the control panel.
- Color Tissue M Mode (TVM)
  - In B + TVI/TVD, or B + TVI + TVD mode, press <M> twice on the control panel.
  - In Color Flow M mode, press <TDI> on the control panel to enter sampling line adjustment status, and press <M> again.

### 5.7.2 Exit Color M Mode

- Press <Color> or <M> on the control panel to exit Color M mode.
- Or, press <B> on the control panel to return to B mode.

### 5.7.3 Color M Mode 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 TVI modes; please refer to relevant sections of B, M and TVI mode for details.
- In Color M mode scanning, the image parameter area in the upper right corner of the screen displays the real-time parameter values.
- ROI Adjustment
  - ROI determines 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, and set the ROI
    position by moving the trackball up and down.
  - Set the ROI size by moving the trackball up and right.
  - Press <Set> to switch the cursor status between the ROI position adjustment and ROI size adjustment.
- Press <Update> on the control panel to switch between the real-time mode and freeze mode.

### 5.8 Anatomical M Mode

 $\triangle$ CAUTION:

Anatomical M Mode and Color Anatomical M mode images are provided for reference only, not for confirming a diagnosis. Please compare the image with that of other machines, or make diagnosis using none-ultrasound methods.

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

Shortcut key setting

You can preset a user-defined key for entering Free Xros M mode: [Setup] (F10)  $\rightarrow$  [System]  $\rightarrow$  [Key Config], Refer to "12.1.6 Key Configuration" for details.

Free Xros M imaging and Free Xros CM imaging are options.

### 5.8.1 Free Xros M Imaging (Anatomical M-Mode)

### 5.8.1.1 Basic Procedures for Free Xros M Imaging

- 1. In real-time 2D mode or M mode, adjust the probe and image to obtain the desired plane. Or select the desired 2D cine files.
- 2. Click [Free Xros M] on the touch screen of the B mode tab to enter Free Xros M mode, or press the user-defined key.
- 3. Adjust the M-mark (single or multiple) line to obtain optimized images and necessary information.
- In Dual-split or Quad-split mode, it is the current activated window that enters the Free Xros M mode.

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

### **5.8.1.2** Free Xros M Image Parameters

- During Free Xros M mode imaging, menus of image optimizing for B mode and Free Xros M mode are displayed on the touch screen at the same time. You can switch between the 2 modes by clicking the mode tabs.
- While imaging in freeze mode, menus of image optimization for B mode and Free Xros M mode are displayed on the touch screen at the same time. You can switch between the 2 modes by clicking the mode tabs.
- Parameters consistent with those in M mode are not to be introduced, please refer to relevant section of the M mode, while special items of the Free Xros M mode will be introduced in the following.

### Display/ Hide the M-mark Line

**Description** There are 3 M-mark lines available, each with a symbol of "A", "B" or "C" at the one

end as identification and an arrow at the other end as a mark for direction.

M-mark Line Selection

Perform the selection through the [Show A], [Show B] or the [Show C] item on the touch screen, and the corresponding image will be displayed on the screen once

the related item is selected.

Display current

Touch [Display Cur.] or [Display All] on the touch screen to select whether to

display the image of the current M-mark line or all.

**Impacts** When there is only one M-mark line on the screen, you cannot hide it.

### Switching between the M-mark Lines

**Description** To switch between the M-mark lines in Free Xros M mode.

**Operations** Press <Set> to switch between the M-mark lines and press <Cursor> to show the

cursor.

The activated M-mark line will be green and the inactivated one will be white.

### Adjustment of the M-mark Line

Description

To adjust the position and angle of the M-mark line.

**Operations** 

Position Adjustment

When the M-mark line is activated, move the trackball left and right to adjust the position. The direction is recognized by the arrow at the end of the line.

Angle Adjustment

When the M-mark line is activated, move the trackball to adjust the fulcrum of the line, and adjust through the [Angle] deflector rod on the control panel.

The adjusting angle range is 0-180, in increments of 1.

#### 5.8.1.3 Exit Free Xros M

In Free Xros M mode, touch [Free Xros M] or press B or the user-defined Free Xros M key to exit Free Xros M mode.

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

**A**CAUTION:

Free Xros CM images are provided for reference only, not for confirming a diagnosis. Please compare the image with that of other machines, or make diagnosis using none-ultrasound methods.

In Free Xros CM mode, distance/time curve is generated from the sample line manually depicted at anywhere on the image. Free Xros CM mode can be entered through B, Color, Power and TVI modes.

Only phased probe supports Free Xros CM

#### 5.8.2.1 Basic Procedures for Free Xros CM

- 1. In 2D real time imaging mode, adjust the probe and image to get the desired image, and then fix the probe.
- 2. Press <TDI> to enter TDI imaging; acquire necessary images.
- 3. Tap [Free Xros CM] on the touch screen or the user-defined key to enter Free Xros CM mode.
- 4. Roll the trackball to define the start point of the sample 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 (touch [Undo] to cancel the current point and activate the preview point), the system updates the time-motion curve in real time. The sample line is displayed in green, and each point is marked with a number in sequence.
- 7. Repeat Step 6 to finish the sample line.
- 8. Double click the <Set> key to end the editing, and the sample line is displayed in white.
- 9. Adjust the image parameters to optimize the image, obtain the interested tissue image for data analysis, and then save the image if necessary.
- 10. Press [Free Xros CM] again to exit Free Xros CM mode.

#### **Sample Line Modification**

- 1. To enter curve (sample line) modification status:
  - For a finished sample line, set [Edit] as "On", the sample line is editable.
- 2. Anchor the cursor on a certain point, press the <Set> key to activate the point, then roll the trackball to drag the point for a desired sample line.
- 3. Double click the <Set> key to end the edit; and the sample line is displayed in white.

### **Delete the Sample Line**

Tap [Delete] on the touch screen to delete the selected line and you can re-depict a new sample line.

Tips:

Parameters of Free Xros M mode and Free Xros CM mode are independent from each other, but their functions are the same, parameters of Free Xros CM are not to be introduced, please refer to relevant sections of the M mode and Free Xros M mode.

### 5.9 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 probe, while the cool color indicates the movement away from the probe.
- Tissue Energy Imaging (TEI): This imaging mode reflects the status of cardiac movement by displaying the intensity of tissue, the brighter the color the less the intensity.
- Tissue Velocity Doppler Imaging (TVD): This imaging mode provides direction and velocity information of the tissue quantificationally.
- Tissue Velocity M Imaging (TVM): This function assists to observe the cardiac motion through a direct angle. TVM mode is also called Color Tissue M mode which has been introduced in Color M mode chapter, please refer to "5.7 Color M Mode" for details.

TDI imaging and TDI QA are options.

TDI

The P4-2NE, P7-3E, P10-4E, SP5-1E and P7-3TE probes support TDI function.

### 5.9.1 Basic Procedures for TDI Imaging

- Press
- on the control panel in real-time scanning to enter the modes:
- ➤ 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.
- ➤ In PW mode: to enter TVD Mode, parameters of TVD mode will be displayed on the touch screen.
- ➤ In M mode: to enter TVM Mode, parameters of TVM mode will be displayed on the touch screen.
- Switching among the TDI sub modes

In TDI mode, press <Color>, <Power>, <M> or <PW> to switch between the modes.

- Exit TDI
  - Press <TDI> to exit TDI mode and enter general imaging modes.
  - Or, press <B> on the control panel to return to B mode.

### 5.9.2 TDI Image Parameters

- In TDI mode scanning, the image parameter area in the upper right corner of the screen displays the real-time parameter values as follows:
  - TVI/TEI

| Parameter | F         | G    | PRF | WF          |
|-----------|-----------|------|-----|-------------|
| Meaning   | Frequency | Gain | PRF | Wall Filter |

TVD

| Parameter | F         | G    | PRF | WF          | SVD         | SV      | Angle       |
|-----------|-----------|------|-----|-------------|-------------|---------|-------------|
| Meaning   | Frequency | Gain | PRF | Wall Filter | SV Position | SV Size | Angle value |

### 5.9.3 TDI Image Optimization

In each TDI mode, parameters that can be adjusted are similar to those in the color flow modes (Color, PW, and Power); please refer to the relevant sections for details. The following is to introduce the specific items in TDI mode.

### **Tissue State**

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

**Operations** Adjust through the [Tissue State] item on the touch screen.

There are 3 levels provided to adjust: L, M, H.

### 5.9.4 TDI Quantitative Analysis (QA)

CAUTION:

TDI Quantitative Analysis results are provided for reference only, not for confirming a diagnosis. Please compare the results with that of other machines, or make diagnosis using none-ultrasound methods.

NOTE:

For a better analysis result, please perform strain or strain rate analysis based on images with ECG curves.

NOTE: TDI Quantitative Analysis is option.

TDI QA is applied for TVI original data analysis, for evaluating the velocity change of the same cardiac muscle with cardiac cycles.

The system provides 3 kinds of curves for quantitative analysis:

- Speed 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. |

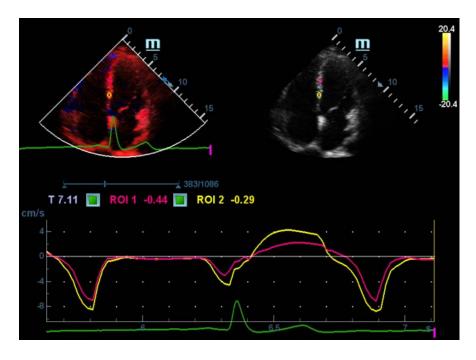
### Workflow of TDI QA:

1. Perform image scanning on cardiac muscle, freeze the image and select a range of images for analysis; or select a desired cine loop from the stored images.

#### Tips:

- Images from the current scan session (already in freeze mode) or from a saved image loop can be used for TDI QA.
- TDI QA is only available if the user has selected an image loop. If the user has selected a saved still image (just one frame), TDI QA function is not available.
- 2. Click [TDI QA] on the TVI touch screen page to activate TDI QA function.
- 3. Mark out the interesting part.
- 4. Select quantitative analysis curve: touch [Speed] / [Strain Rate] / [Strain] to select.
- 5. Save the curved image, export the data and do parameter analysis.
- 6. Exit TDI QA function.
  - Press <Freeze> or <B> on the control panel.

### 5.9.4.1 TDI QA Screen Description



TDI QA Screen (take Speed – Time curve as an example)

#### 1---TVI 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

### Tips:

- Images in the TVI cineloop window and B cineloop window are the frozen image of the same moment; roll the trackball to review the images in the two cineloop windows.
- Sample areas are linked in the TVI cineloop window and B cineloop window.

#### 3---Displays analysis curve

- Y axis represents the speed (unit: cm/s). [In Strain Rate Time curve, Y axis represents strain rate (1/s). In Strain Time curve, Y axis represents strain (%).]
- while X axis represents the time (unit: s).
- Frame marker: a white line that 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.
- 4---Displays ECG trace (no ECG trace displayed here).

### 5.9.4.2 Basic Procedures of TDI 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 TDI QA 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 with the same color.

#### 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. Roll the trackball to one cine review window.
- 3. 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

Use touch screen selections [Std. Height], [Std. Width], [Std. Angle] to adjust the height, the width and the tilt angle of the standard ROI for the undergoing or afterward ROIs.

#### **Strain Distance**

Sampling distance for calculating deformation. Use 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

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

#### 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.
- 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 choose different value, so that the X scale display manner will be changed. This function can be used to track detailed tissue information.

#### Smooth

Use this function to smooth the curve, and 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.

### 5.10 3D/4D

NOTE: 3D/4D imagin

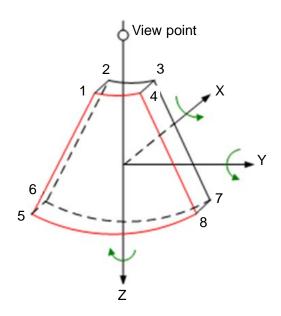
3D/4D imaging is largely environment-dependent, so the images obtained are provided for reference only, not for confirming a diagnosis.

### 5.10.1 Overview

Ultrasound data based on three-dimensional imaging methods can be used to image any structure where a view can't be achieved by standard 2D-mode to improve understanding of complex structures.

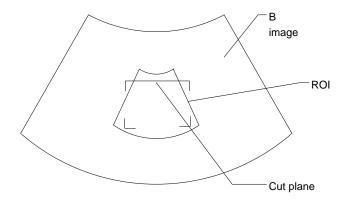
#### Terms

- 3D image Volume Rendering (VR): the image displayed to represent the volume data.
- 4D: Continuous-sweep volume acquisition.
- View point: a position for viewing volume data/3D image.
- MultiPlaner Rendering (MPR): The three sectional planes of the volume acquisition. As shown in the figure below, XY-paralleled plane is C-section, XZ-paralleled plane is B-section, and YZ-paralleled plane is A-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 size and position

Roll the trackball to change the ROI size and position, press the <Set> key to toggle between setting the size (dotted line) and position (solid line).

### Curved VOI adjustment

Roll the trackball to change the curved VOI position, press the <Set> key to switch among the state of changing ROI and curved VOI.

This function is to change the curved shape of the nearest VOI section, to facilitate observation for the interested volume data.

It can be adjusted both in acquisition preparation status, and in A, B, C sections of review/ 4D imaging status, while a triangle of control point on the curved VOI is displayed.

Depending on the view direction, the orientation and the shape (line or dot) of curved VOI vary:

| View | Curved VOI                      |
|------|---------------------------------|
| U/D  | At the upper part of curved VOI |
| D/U  | At the lower part of curved VOI |
| L/R  | At the left part of curved VOI  |
| R/L  | At the right part of curved VOI |
| F/B  | Displays as a dot               |
| B/F  | Displays as a dot               |

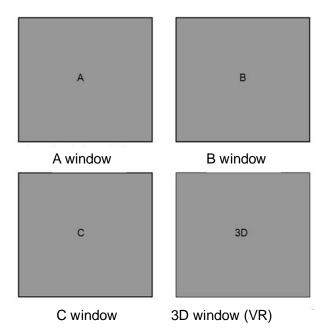
### ■ About the probes

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

The principle of 3D imaging is to render a 3D image from multiple 2D image information. The following describes the spatial relation of 3 MPRs (A, B and C) and the 3D image (VR).

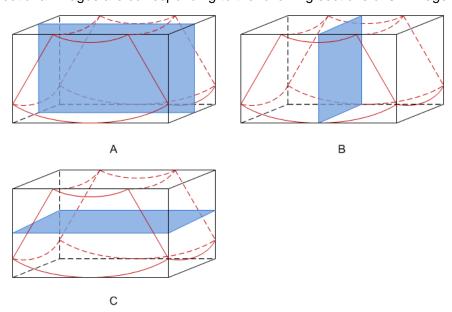
In the quad display format view, the screen displays 3 MPRs (A, B and C) and the 3D image.



On the touch screen, the current window's icon is highlighted; as shown in the following, A window is the current 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 touching [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 (Free View Imaging)

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 [Angle] can be adjusted on B image touch screen for probe angle adjusting.

Range:  $-45^{\circ} \sim +45^{\circ}$ ; 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. To help, the system displays a three-dimensional drawing to illustrate the orientation. 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. See the graphic below:



Wire Cage

# 5.10.2 Note before Use

# 5.10.2.1 3D/4D Image Quality Conditions

5.10.2.1 3D/4D image Quality Conditions

to shorten the sweeping time after a good 3D imaging is obtained.

The quality of images rendered in the 3D/4D mode is closely related to the fetal condition, angle of a B tangent plane and scanning technique (only for Smart 3D). The following description uses the

In accordance with the ALARA (As Low As Reasonably Achievable) principle, please try

■ Fetal Condition

NOTE:

(1) Gestational age

Fetuses of 24~30 weeks old are the most appropriate for 3D imaging.

fetal face imaging as an example, the other parts imaging are as the same.

(2) Fetal body posture

Recommended: cephalic face up (Figure a) or face aside (Figure b); NOT recommended: cephalic face down (Figure c).







b

(3) Amniotic fluid(AF) isolation

The region desired is isolated by amniotic fluid adequately.

The region to imaging is not covered by limbs or umbilical cord.

- (4) The fetus keeps still. If there is a fetal movement, you need a rescanning.
- Angle of a B tangent plane

The optimum tangent plane to the fetal face 3D/4D 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/4D capture, optimize the B mode image to assure:

- High contrast between the desired region and the AF surrounded.
- Clear boundary of the desired region.
- Low noise of the AF area.
- Scanning technique (only for Smart 3D)
  - Stability: body, arm and wrist must move smoothly, otherwise the restructured 3D image distorts.
  - Slowness: move or rotate the probe slowly.
  - Evenness: move or rotate the probe at a steady speed or rate.

NOTE:

- A region with qualified image in B mode may not be optimal for 3D/4D imaging. E.g. adequate AF isolation for one MPR doesn't mean the whole desired region is isolated by AF.
- 2. More practices are needed for a high success rate of qualified 3D/4D imaging.
- 3. Even with good fetal condition, to acquire an approving 3D/4D image may need more than one scanning.

# 5.10.3 Static 3D

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

Only probe D7-2E, D8-2E, D6-2NE, DE10-3E and DE11-3E support Static 3D imaging.

# 5.10.3.1 Basic Procedures for Static 3D Imaging

To perform Static 3D imaging:

- 1. Select the appropriate probe and exam mode. Make sure there is sufficient gel on the probe for scanning.
- 2. Obtain a 2D image.

Make sure:

- High contrast between the desired region and the AF (amniotic fluid) surrounded.
- Clear boundary of the desired region.
- Low noise of the AF area.

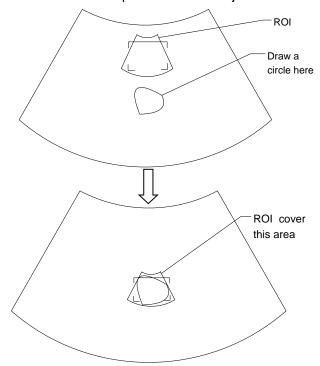


3. Press to enter Static 3D mode, and define the ROI as well as curved VOI.

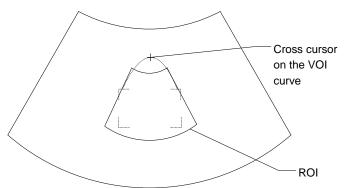
Methods to adjust the ROI:

- 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 size, position or curved VOI. Press the left <set> key to adjust VOI angle.
- Enter touch screen mapping mode. See Chapter 3.7.4 Touch Screen Display and Operation for details.

Draw a circle on the desired area. Move ROI over the circle to adjust the size and position of ROI. RoII 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 a render mode on the touch screen, set parameters like [Angle], [Image Quality] on the touch screen accordingly.
- 5. Press <Update> on the control panel to start the 3D image acquisition.

The system enters into 3D image viewing status when the acquisition is completed.

In image viewing status, you can perform VOI setting, image editing and other operations. For details, please refer to "5.10.3.3 Static 3D Image Viewing".

6. Exit Static 3D.



Press <B> or

to enter B mode.

# 5.10.3.2 Static 3D Acquisition Preparation

Parameters description:

| Туре                   | Parameter | Description   |  |  |  |
|------------------------|-----------|---|--|--|--|
| Parameter<br>adjusting | Angle     | Function: to set the range for imaging. Range: 10-80°.  |  |  |  |
|                        | 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, the longer the time.  |  |  |  |
|                        |           | Range: Low2, Low1, Mid, High1, High2  |  |  |  |
|                        |           | Function: set Surface as 3D image rendering mode.   |  |  |  |
|                        | Surface   | This is helpful for surface imaging, such as fetus face/hand or foot.   |  |  |  |
|                        |           | Tips: 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.  |  |  |  |
| Render Mode            | Min       | Function: set Min as 3D image rendering mode, displays the minimum echo intensity in the observation direction.   |  |  |  |
|                        |           | density. Image quality can affect the imaging speed that the better the image quality, the longer the time.  Range: Low2, Low1, Mid, High1, High2  Function: set Surface as 3D image rendering mode.  This is helpful for surface imaging, such as fetus face/hand or foot.  Tips: you may have to adjust the threshold to obtain a clear body boundary.  Function: set Max as 3D image rendering mode, displays the maximum echo intensity in the observation direction.  This is helpful for viewing bony structures.  Function: set Min as 3D image rendering mode, displays the   |  |  |  |
|                        | V mou     |   |  |  |  |
|                        | X-ray     | Range: 10-80°.  Function: to adjust the image quality by changing the line density. Image quality can affect the imaging speed that the better the image quality, the longer the time.  Range: Low2, Low1, Mid, High1, High2  Function: set Surface as 3D image rendering mode.  This is helpful for surface imaging, such as fetus face/hand or foot.  Tips: you may have to adjust the threshold to obtain a clear body boundary.  Function: set Max as 3D image rendering mode, displays the maximum echo intensity in the observation direction.  This is helpful for viewing bony structures.  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.  Function: set X-ray as 3D image rendering mode. Displays the average value of all gray values in the ROI.  X Ray: used for imaging tissues with different structure inside or tissues with tumor.  Function: add the light rendering effect based on the general rendering effect. It supports the global illumination and local |  |  |  |
|                        | iLive     | rendering effect. It supports the global illumination and local   |  |  |  |

# 5.10.3.3 Static 3D Image Viewing

# **Enter/Exit Image Viewing**

■ To enter image viewing:

The system enters image viewing when image acquisition is finished.

■ Exit

To return to 3D/4D image acquisition preparation status, you can,

Press < Update > or < Freeze >.

### **Activate MPR**

Touch [A], [B], [C] or [VR] to activate MPR or 3D image (VR).

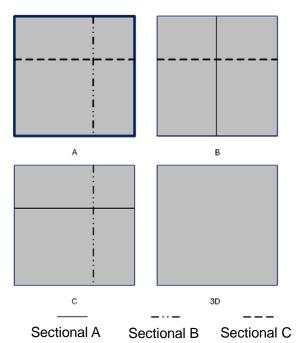


# **MPR Viewing**

In actual display, different colors of the window box and the section line are used to identify the MPR A. B and C.

- The color of window A is blue, and the color of the lines (representing MPR 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 MPR 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 MPR C) displayed in the other two windows is orange as well.

Positions of the other two MPRs are indicated in the selected plane. You can roll the track ball to change the position.



#### MPR Only

Touch on the touch screen to display MPR only. And the adjustable image parameters are changed into MPR parameters automatically.

Only A, B and C MPR are displayed, and VR is not displayed.

MPR Only function is available in image acquisition status.

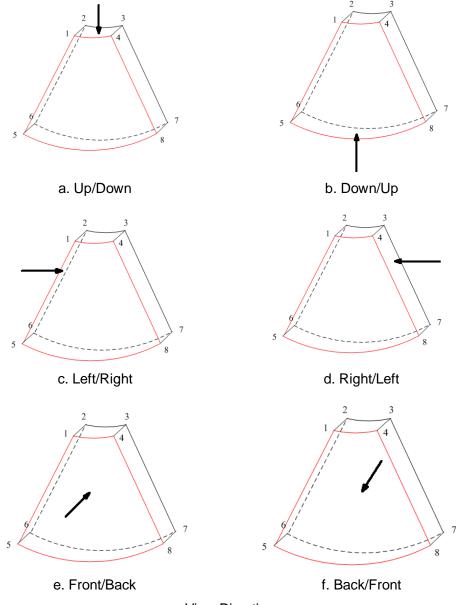
#### **Asymmetric**

Touch on the touch screen to display MPR along with VR. It will represent you with a larger VR image along with 3 small MPR images.

#### **View Direction**

The Region of Interest (ROI), also referred to as the Render Box in rendering, contains the section of the volume you want to render. Therefore, objects that are not inside of the box are not included in the render process and are cut out (this is important in surface mode to allow a free line of sight). This may or might not be the entire VOI.

You can adjust the view direction of the ROI.



View Direction

Touch [Up/Down], [Left/Right] or [Front/Back] on the second page of the touch screen to select the direction of the above Figure a, c and e.

Touch [Flip] on the touch screen to observe by the converse direction of the current direction, as shown in the Figure b, d and f.

### **Adjust VOI**

### ■ VOI On

VR image displays VOI information.

- 1. In image viewing status, touch [VOI] to be "On".
- 2. Select a desired window by touching [A], [B] or [C] or [VR].
- 3. Roll the trackball to adjust VOI position, size and curved VOI, and press <Set> to switch among the adjusting status; or you can rotate <4D> knob on the control panel to adjust relative position of MPRs so as to slice through the VR.

#### ■ VOI Off

VR image displays ROI information.

Touch [VOI] to be "Off", then the ROI image is displayed on the screen, roll the trackball to observe MPR.

#### Accept VOI

- 1. This function is usually used for MPR observation and to determine the relative position of the MPR to the VR.
- 2. Touch [Accept VOI] on the touch screen.
- 3. Select a desired MPR by touching [A], [B] or [C] or [VR].
- 4. Roll the trackball to view the current active MPR, and the other two MPRs change correspondingly. Or you can rotate the <4D> knob to adjust the relative position of MPRs so as to slice through the VR.

In Accept VOI status, when the VR is active or the MPR which is perpendicular to the view direction is active, center point of the VR displays, and you can adjust the position using the trackball.

### **Image Rendering Parameters**

In image viewing status, you can render the image by adjusting the relevant parameters. Render setting parameters description:



Touch or on the touch screen to select parameter adjustments of VR or MPR.

- When the [VR] is highlighted in green, parameter adjustment is performed on VR image.
- When the [MPR] is highlighted in green, parameter adjustment is performed on MPR.

Adjustable parameters are as follows:

| Parameter  | Description  |  |  |
|------------|--|--|--|
| Threshold  | Function: to set the threshold for VR rendering. VR is rendered using the signal between the high and low thresholds.  |  |  |
|            | When signals are received, from small to large, they are divided into different levels assigned within the range of 0-100%. The threshold is a selected range when the system filters out signals below it and select signals above it to render the VR image. |  |  |
|            | Lower threshold can eliminate lower range noises and echo, which will contribute to a clearer and smoother image.  |  |  |
|            | Range: 0%-100%.  |  |  |
|            | Available in Surface render mode only.   |  |  |
|            | Function: to set the transparency value for VR rendering.  |  |  |
| Opacity    | Range: 0%-100%.  |  |  |
|            | The lower the number, the more transparent the gray scale information.   |  |  |
|            | Function: to set the smoothness of VR.   |  |  |
| Smooth     | Selection: 0-10. 0 refers to no smooth effect, 1-10 present 10 effects in incremental order.   |  |  |
|            | Tips: insufficient smoothness can result in a fuzzy image; however, over smoothness will lead to image distortion.   |  |  |
|            | Function: to set the brightness of VR.   |  |  |
| Brightness | Range: 0%-100%. 0% presents the minimum brightness, while 100% the maximum.  |  |  |

| Parameter       | Description  |  |  |
|-----------------|--|--|--|
| Contrast        | Function: to set the contrast of VR.   |  |  |
| Contrast        | Range: 0%-100%.  |  |  |
| Tint            | Switch on/off tint map, selection: Off, 1-8.   |  |  |
| VR Orientation  | To quickly rotate the VR.  |  |  |
| VIX Offertation | Selection: 0°, 90°, 180°, 270°.  |  |  |
| iClear          | Enhances B mode image profile for better boundary details.   |  |  |
|                 | Range: Off, 1-7.   |  |  |
| VR Refine       | Function: used to increase 2D image profile for better boundary details.                                       |  |  |
|                 | Selection: OFF, 1-7.   |  |  |
| MagiClean       | Function: the bigger the value is, the clearer the boundary of the image is.                                   |  |  |
| Magiolean       | Selection: only enabled in rendering mode Off, Low, Mid, High and Max.   |  |  |
| Depth VR        | Function: VR image becomes more stereoscopic. The render color in the VR image corresponds to the depth color. |  |  |
|                 | Selection: Off, Black, Cyna, Blue, Rose  |  |  |
| Thickness       | Selection: 0-30mm.   |  |  |

# ■ Reset Curve

| Parameter   | Description  |
|-------------|--|
| Reset Ori   | To reset the volume rotation, shifting and zooming to original status. |
| Reset Curve | To reset the curve to be the beeline.                                  |
| Reset All   | To reset volume to original orientation and original parameters.       |

# ■ Render Mode

| Parameter      |         | Description  |  |  |  |
|----------------|---------|--|--|--|--|
|                | Surface | Function: set Surface as VR rendering mode.  |  |  |  |
|                |         | This is helpful for surface imaging, such as fetus face/hand or foot.  |  |  |  |
|                |         | Tips: you may have to adjust the threshold to obtain a clear body boundary.  |  |  |  |
|                | Max     | Function: set Max as VR rendering mode, displays the maximum echo intensity in the observation direction.  |  |  |  |
|                |         | This is helpful for viewing bony structures.   |  |  |  |
| Gray/Inversion | Min     | Function: set Min as VR rendering mode, displays the minimum echo intensity in the observation direction.  |  |  |  |
| ,              |         | This is helpful for viewing vessels and hollow structures.   |  |  |  |
|                | V       | Function: set X-ray as VR rendering mode. Displays the average value of all gray values in the ROI.  |  |  |  |
|                | X-ray   | X Ray: 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. It supports global lighting mode as well as partial scattering mode, allowing human tissue texture to be revealed more clearly. |  |  |  |

| Parameter |   | Description |  |  |
|-----------|---|-------------|--|--|
|           | The above five rendering manners can be applied to both gray and inversion modes.  Where, inversion is to inverse the grayscale of the 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 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 currently activated image around the X, Y or Z axis.

- Procedures
  - a) Select the current image.
  - b) Rotate the corresponding knobs to make the image rotate, here,
  - 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 <Color> button on the control panel clockwise, the image rotates right along the Z-axis, and rotate the button anticlockwise, the image rotates left.

#### Auto rotation

- (1) In 3D viewing mode, tap [Auto Rot.] tab on the touch screen, system enters into auto rotation preparation state.
- (2) Touch [Left/Right] or [Up/Down] to set the auto rotation direction.
- (3) 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 "Set End" according to the trackball hint area.

- (4) Touch to activate rotation.
- (5) Touch [Step] to set the rotate step.
- (6) Set rotation mode: touch for single direction rotation, and touch bidirectional rotation.

**NOTE:** You can view the back of the VR by rotating it 180°, but the back view image may not as vivid as the front. (Here we call the initial view of the VR you see as "front"). It's recommended to re-capture than to rotate the VR remarkably if a certain region desired is blocked in the VR.

#### Inversion

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

### 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**

To adjust the zoom factor of VR; the sectional images will be zoomed in/out accordingly.

■ 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.

■ Range:

0.2 - 4 times.

### **Comment and Body Mark**

■ Function:

Add comment and body mark to the MPR and VR.

Operation:

The operation is the same as adding comment and body mark in B image mode.

# Sync

This function is to switch the view direction which is perpendicular to the current active plane, so as to get a better observation of VR.

In the following graph, the current active plane is MPR A and after performing Sync on Figure A, you can see a same fetal face profile in VR.



Figure A



Figure B

#### ■ Procedures

- 1. Enter image editing status by taping "Tool" tab page.
- 2. Select an edit/erase tool:
  - Polygon
    - a) Press <Set> to position the start point, roll the trackball to set a region and press <Set> to trace the region.

- b) When the start point and the end point coincide, the region is selected or you can press <Set> twice to finish tracing.
- c) Move the cursor to the region you want to cut and press <Set> again to cut.

#### Contour

- a) Press <Set> to position the start point, roll the trackball to trace the region.
- b) When the start point and the end point coincide, the region is selected or you can press <Set> twice to finish tracing.
- c) Move the cursor to the region you want to cut and press <Set> again to cut.

#### Rectangle

- a) Press <Set> to fix the rectangle position, roll the trackball to change the size, and press <Set> again to finish rectangle drawing
- b) Move the cursor to the region you want to cut and press <Set> again to cut.

#### Line

- a) 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.
- b) Move the cursor to the region you want to cut and press <Set> again to cut.
- Soft/ hard eraser
  - a) Press <Set> to position the start point and roll the trackball to select the region.
  - b) Press <Set> when ends are required. You can repeat the step to erase all parts blocking the interesting region.
- To undo the last cutting, touch [Undo] on the touch screen. To undo all cuttings, touch [Undo All].
- Section image (MPR) measurement.

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

Measurement is not available in acquisition preparation status.

# 5.10.3.4 Image Saving and Reviewing in Static 3D

- Image saving
  - In the 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 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 do in VR viewing mode.

# 5.10.3.5 Color Static 3D (Color 3D)

The system also supports color Static 3D flow image function. For details, please refer to "5.10.10 Color 3D".

## 5.10.4 4D

4D provides continuous, high volume acquisition of 3D images. During the scanning, the probe performs the scanning automatically.

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.

4D imaging is an option.

Only probe D7-2E, D8-2E, D6-2NE, DE10-3E and DE11-3E support 4D imaging.

## 5.10.4.1 Basic Procedures for 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 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 a render mode, set quality and angle parameters.
- 6. Press < Update > to enter the 4D imaging mode.
- Press <Freeze> on the control panel to freeze the image. Do image cutting, rotation, annotation, image saving if necessary.
- 8. Exit 4D.

Press < Update > to return to 4D image acquisition preparation;



Or, press <B> or

key to enter B mode.

### 5.10.4.2 4D Acquisition Preparation

Parameters are the same as that of Static 3D, for details; please refer to "5.10.3.2 Static 3D Acquisition Preparation".

## 5.10.4.3 4D Real-time Display

In 4D real-time display status, operations are similar to those in Static 3D. For the details, please refer to the corresponding contents in Static 3D.

#### 4D Real-time Editing

You can remove unnecessary information from the VR in real-time scanning by using a line tool.

- 1. Tap [Tool] to enter editing mode in 4D real-time review state.
- 2. Press <Set>to place the start position of the editing.
- 3. Roll the trackball to adjust the orientation, and then press <Set> to confirm the boundary.
- 4. Move the cursor to the area to be edited. Press <Set> to finish editing.

Tap [Undo] or [Undo All] to return to the previous step.

# **5.10.4.4 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.

# 5.10.4.5 3D/4D Fast Switching

During 4D viewing mode, press to switch to VR viewing status quickly, where you can obtain the same image of a better quality.

During 3D viewing mode, press to switch to 4D image real-time status quickly, where you can obtain the same image of dynamic mode.

## 5.10.5 Smart 3D

The operator manually moves the probe to change its position/angle when performing the scanning. After the scanning, the system carries out image rendering automatically, and then displays a frame of 3D image.

Smart 3D is an option.

4D probe does not support Smart 3D.

## 5.10.5.1 Basic Procedures for Smart 3D Imaging

NOTE:

In Smart 3D image scanning, if the probe orientation mark is oriented to the operator's finger, please perform the scanning from right to left in linear scan; or rotate the probe from left to right in rocked scanning; otherwise, the VR direction is 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 <3D> 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 viewing status when the acquisition is completed; or, you can finish the acquisition ahead by pressing <Freeze> or <Update> on the control panel.

In image viewing status, you can perform operations like VOI setting, parameter adjustment, comments, image saving, image cutting, etc. For details, please refer to "5.10.3.3 Static 3D Image Viewing".

7. Exit Smart 3D.

Press <Update> or <Freeze> to return to Smart 3D image acquisition preparation; or, press



<B> or

to enter B mode.

# 5.10.5.2 Smart 3D Acquisition Preparation

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

| Parameter | NOTE  |  |  |  |
|-----------|---|--|--|--|
|           | Function: to select the probe moving method.  |  |  |  |
|           | Selection: Fan, Linear.   |  |  |  |
|           | Fan mode: during the sweep, the probe may not be moved parallel, the speed at which you scan should be constant, about 2cm/s.   |  |  |  |
| Method    | Fan 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 degrees 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. The speed is about 10°/s~15°/s. |  |  |  |
|           | Tips: the scan speed is determined by scan angle or distance.   |  |  |  |
| Distance  | 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.  |  |  |  |
| Anglo     | Function: to set the motion angle the probe covered during a fan sweep.   |  |  |  |
| Angle     | Range: 10~80°, in increments of 2°.   |  |  |  |

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

# 5.10.5.3 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 involve the whole region desired. See the above figure.

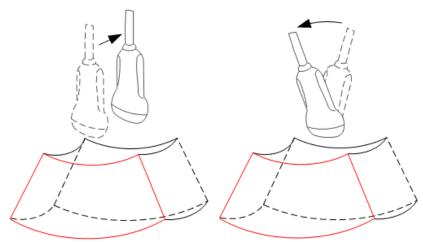
## 5.10.5.4 Smart 3D Image Viewing

In VR viewing, the system supports the following functions:

- Render setting.
- B-mode parameters adjustment.
- Set the display format.
- View MPR.
- Image zooming.
- Rotation.
- Image edit.
- VR parameters adjustment.
- Scanning plane and the probe movement

Move the probe across the body surface.

Arrow in the figure below indicates the movement of the probe (you can move the probe in the contrary direction of the arrow.).



# 5.10.5.5 Image Saving and Reviewing in Smart 3D

- Image saving
  - In the 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 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 do in VR viewing mode.

### 5.10.5.6 Color Smart 3D

The system also supports color Smart 3D flow image function. For details, please refer to "5.10.10 Color 3D".

# 5.10.6 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.

Only probe D7-2E, D8-2E and D6-2NE support STIC function.

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.



- 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.

riangleWARNING:

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!

#### 5.10.6.1 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 or 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 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, touch [Reject All] to perform the acquisition again. Touch [Accept HR] to accept the result and go to image review, or touch [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.

# **5.10.6.2 Operation Controls**

Controls consistent with those in 3D/4D mode are not to be introduced here; only the special controls of STIC mode will be introduced here.

Acquiring Time

The time required for a whole acquisition.

Range: 7.5~17.5s.

### ■ Angle

The range from acquisition beginning to acquisition end.

Range: 10~75°.

### 5.10.6.3 Color STIC 3D

The system also supports color STIC 3D flow image function. For details, please refer to "5.10.10 Color 3D".

# 5.10.7 3D Layout

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

This function is provided by [Niche] option, and it does not support Smart 3D imaging. Only probe D7-2E, D8-2E, D6-2NE, DE11-3E and DE10-3E support Niche function.

#### **Niche**

- 1. Tap [Tools] → [3D Layout] on the touch screen, and then touch [Niche]. .
- 2. Touch [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 touch screen: from the front of the reference image or from the back.
- 4. Roll the trackball to view sectional images as necessary; you can rotate <M>, <PW>, <Color> to perform axial rotation or rotate <4D> knob to adjust the nearest VOI section (cut plane) position.

Click [Reset Ori] to reset the rotation, the center point position, as well as the position of the MPR.

### 3Slice

- 1. Tap [Tools] → [3D Layout] tab on the touch screen, and then touch [3Slice]...
- 2. Touch [A] / [B] / [C] / [3Slice] on the touch screen to select the reference plane.
- Roll the trackball to view sectional images as necessary; you can rotate <M>, <PW>, <Color>
  to perform axial rotation or rotate <4D> knob to adjust the nearest VOI section (cut plane)
  position.

Click [Reset Ori] to reset the rotation, the center point position, as well as the position of the MPR.

# 5.10.8 iPage+

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 Contras View) function is turned on, the system expands the parallel section images into a slice region with a specified thickness, and draw this region with 3D rendering effect to enhance the image.

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

Only probe D7-2E, D8-2E, D6-2NE, DE11-3E and DE10-3E support iPage+ function.

## 5.10.8.1 Operating Procedures

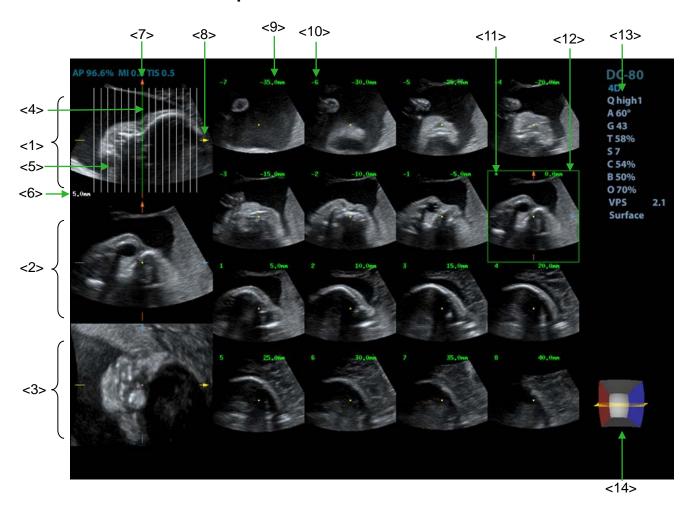
- iPage operation
- 1. Acquire necessary 3D/4D data.
  - Single-frame VR:
    - > STIC/4D mode: freeze the system, and then roll the trackball to select the image.
    - > Static 3D: a frame of image is acquired after the acquisition is finished automatically.
  - Multi-frame 3D images: acquire multiple 3D images in 4D imaging mode.
- 2. Perform operations like rotation, VOI adjusting to the image to find the interested region.
- 3. Touch [iPage+] 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 can't be observed even after image rotation and shifting, touch [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.

# 5.10.8.2 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 <                   |     | Central slice mark | <12> | Active slice be highlighted in green  |
| <13> | Image parameter <14>                     |     | Wire cage          |      |                                       |

## 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

Touch [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.

- Touch 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 right side of the slice, unit: mm. Adjust it through touch screen selection [Spacing].

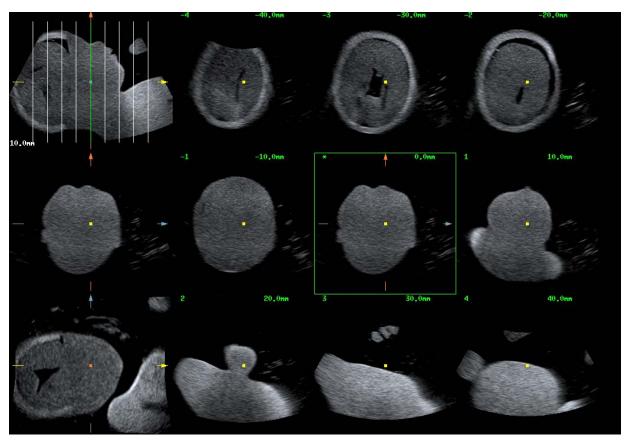
#### ■ Slices number

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

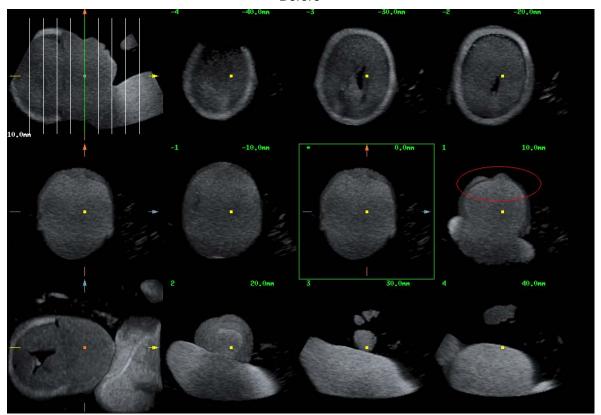
#### Thickness

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 cannot 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.







After

### Image rotation

Rotate <M>, <PW>, <Color> 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; touch 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.

Touch [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.

## 5.10.9 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.

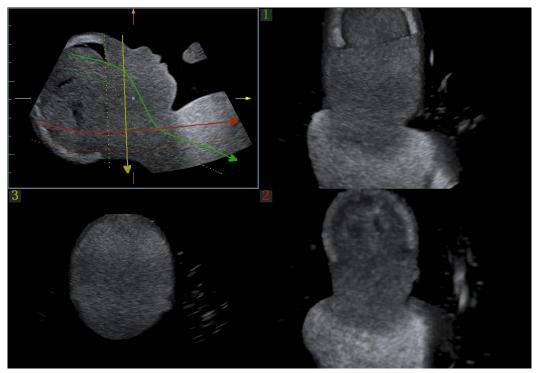
Only probe D7-2E, D8-2E, D6-2NE, DE11-3E and DE10-3E support SCV+ function.

Note: SCV<sup>+</sup> imaging is an option, and it is not available in Smart 3D mode.

#### 5.10.9.1 Basic Procedures

- SCV operation
- 1. Acquire necessary 3D/4D data.
- 2. Touch [SCV<sup>+</sup>] tab on the touch screen to enter SCV imaging, and the system displays three section image in A, B and C window.
- 3. Rotate the knob under [Thickness] on the touch screen to adjust imaging thickness.
- 4. Save images as necessary.
- SCV+CMPR operation
- 1. Enter SCV+.
- 2. Touch [A Plane], [B Plane] or [C Plane] on touch screen to select current window.
- Touch [CMPR] on touch screen to turn on the CMPR function. Window A on main screen displays the current window and three other windows are blank.
- 4. Select reference section, perform rotation and shifting operations to adjust image.
- 5. Touch [1], [2], or [3] button in Active Quadrant on touch screen.
- 6. Select trace options: touch [Line], [Trace] or [Spline] on the touch screen.

7. Draw on the reference image. You can draw three curves at most and the CMPR imaging for the curve are displayed in the selected [1], [2] or [3] window respectively as shown in figure below.



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

# 5.10.9.2 Operation Controls

### SCV

- Current Quadrant
  - Touch [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. Touch [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.
- 3. After line is finished, press left <Set> key to change line position.

Touch [Reset Curve] to cancel current drawing.

- Trace
- 1. Touch [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.

Touch [Reset Curve] to cancel current drawing.

- Spline
- 1. Touch [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.

Touch [Reset Curve] to cancel current drawing.

### Single image zoom

Press <Single> to view single SCV image.

Zoom

Same as Static 3D 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 MPR. For details, please refer to [Advanced Volume].

# 5.10.10 Color 3D

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

Color 3D is an option, which includes color Smart 3D, color STIC and color static 3D flow imaging. Only probe D7-2E, D8-2E, D6-2NE, DE11-3E and DE10-3E support Color 3D (except color STIC) imaging. And only probe D7-2E, D8-2E and D6-2NE support color STIC.

### 5.10.10.1 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 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.

# 5.10.10.2 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, 2D, C, 2D&C.  |  |  |
| Priority               | Function: to determine color information displayed on gray scale images.  |  |  |
|                        | Range: 0-100.   |  |  |
|                        | Function: to eliminate color noise and motion artifacts.  |  |  |
| Threshold              | Range: 0%-100%.   |  |  |
|                        | Affects MPR as well as VR.  |  |  |
| Opacity                | Function: to set the transparency value for VR rendering.   |  |  |
|                        | Range: 0%-100%.   |  |  |
|                        | Function: to smooth the Color image and erase artifacts by time averaging.  |  |  |
| Smooth                 | 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<br>Mark | Operations are the same as those in the other modes.  |  |  |
| MPR<br>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.   |  |  |

# 5.10.11 Smart Volume

The system provides a fast volume calculation method, using computer technology to define and enclose a boundary of the target within the VOI area (the computer technology allows the ultrasound system to fit an ellipsoid that can be most approximate to the target) and then calculating this volume. It can be used to measure the volume of mass, gestational sac or fetus. Smart Volume is an option, and it is not available in Smart 3D mode.

CAUTION: Smart Volum a diagnosis.

Smart Volume result is provided for reference only, not for confirming

### 5.10.11.1 Basic Procedure for Smart Volume

- 1. Acquire necessary 3D/4D data.
- 2. Touch [Smart-V] tab on the touch screen to enter Smart Volume, and the system is in the "Edit VOI" status ([Edit ROI] button is highlighted in green);
- 3. Set ROI position and size, and touch [Calc] (after touching the button, the button is highlighted in green to indicate the status);
- 4. The system starts to calculate;
- 5. Auto calculation is finished:
  - There are green solid curves enclosing target region on each MPR image (A, B, C) window.
  - 3D image (VR) displays image of the target region in red;
  - Parameter area on the right upper screen displays the calculation result.

**NOTE:** To ensure the accuracy of the result, please make sure that the VOI position and size setting has entirely enclosed the target and is approximate to the target before using the Smart Volume function.

# 5.10.11.2 Result Display

After calculation, the following result will be displayed on the upper right part of the screen.



Whereas, L, W and H represent 3 diameter lengths of the fitting ellipsoid.

V represents calculated volume value.

# 5.10.11.3 Operation Controls

## **Edit ROI (Region of Interest)**

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

- (1) Touch [Edit ROI] on the touch screen to be on (green highlighted status).
- (2) Select a desired MPR image by touching [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.

#### Calculation

After touching [Calc] to be on, the system starts calculation.

#### **Reset Curve**

| Parameter   | Description  |
|-------------|--|
| Reset Ori   | To reset the volume rotation, shifting and zooming to original status. |
| Reset Curve | /  |
| Reset All   |  |

#### 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].

## 5.10.12 iLive

iLive brings you a better imaging experience by adding light rendering effect to the traditional way. It supports global lighting mode as well as partial scattering mode, allowing human tissue texture to be revealed more clearly.

iLive is an option, it is available under Smart 3D. Static 3D and 4D mode. To use iLive function, you also have to firstly configure Smart 3D module or 4D module.

- To Activate iLive
- 1. Enter 3D/4D image viewing status: or double-click the saved 3D/4D cine file in iStation or Review screen.
- 2. Touch the [iLive] on the second page of the touch screen to turn on the function, adjust parameters.
- Imaging using iLive
- 1. Select the imaging mode:
  - Use 2D ordinary probe and press



to enter Smart 3D;

Or, use D7-2E, D8-2E, D6-2NE, DE11-3E or DE10-3E probe and press



to enter 4D mode or Static 3D mode.



- 2. Select render mode to be iLive by touching the touch screen, and set related parameters (quality and angle etc.).
- 3. Press <Update> to start acquisition. The system finishes acquisition and enters image viewing screen.
- 4. In image review status, you can perform operations like VOI setting, image editing, comment adding, body mark adding and etc. For details, please refer to "5.10.3.3 Static 3D Image Viewing".



5. Or press <B> or

to exit the mode.

## 5.10.12.1 Operation Controls

Adjustable parameters for iLive are placed on the second page of the touch screen.

Shading

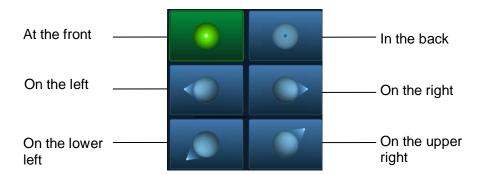
Adjusts the effect of shadowing and scattering. When the level is selected as 0, the rendered image will be bright and sharp, and the border of shadow will be clear while the extent of shadow will be relatively small. As the level increases, the rendered image will become warmer but the details remain the same. Also, the border of shadow will be smoother while the extent of shadow will be large



Light source adjustment

This function is to adjust the position of the light source as VR is considered.

Select the direction by touching the buttons under "Light Position" box.



- You can also make fine adjustments after touching [Move Light] and roll 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 under 3D/4D mode.

### **Other Operation**

iLive does not support Inversion mode.

■ Zoom

Same as those in 3D/4D mode.

■ Rotation

Roll the trackball to view sectional images as necessary; you can rotate <M>, <PW>, <Color> to perform axial rotation or rotate <4D> knob to adjust the nearest VOI section (cut plane) position.

Comments and Body Marks

Same as those in other modes.

# 5.10.13 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.

The probe D7-2E, D8-2E, D6-2NE, DE11-3E and DE10-3E support the Smart FLC function.

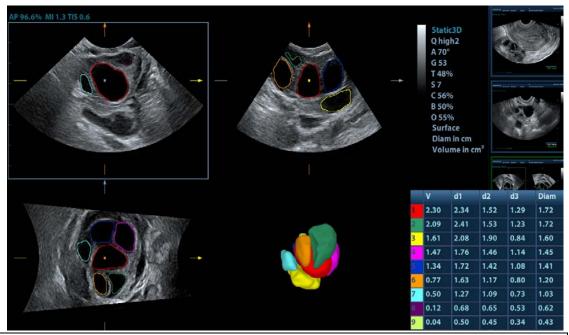
### 5.10.13.1 Basic Procedures

- 1. Acquire necessary 3D/4D data and freeze.
- 2. Touch [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. Touch [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. Includes:

V: volume

d1, d2, d3: diameters of the follicle

MD: mean diameter of the follicle



**NOTE:** To ensure the correctness of the results, please select an image with clear follicle boundary when entering Smart FLC.

# **5.10.13.2 Operation Controls**

#### **Edit ROI**

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

#### **Edit/Undo**

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

Touch [Undo], [Redo] or [Undo All] on touch screen to undo, redo or cancel previous editing.

#### Zoom

Same as those in 3D/4D mode.

### **Comments and Body Marks**

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.

## 5.10.14 Smart Planes CNS

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

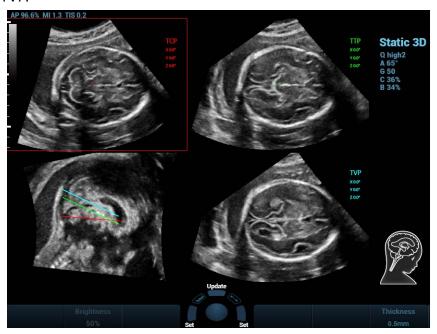
Taking the sagittal features from 3D data of fetus's intracranial, Smart Planes CNS is a mode-wise technology, which detects the middle of the fetus's sagittal view, transverse plane of thalami, transverse plane of lateral ventricles and transverse plane of cerebellum. It helps the doctors find the sagittal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

Only D7-2E, D8-2E and D6-2NE supports Smart Planes CNS in OB2 and OB3 exam mode.

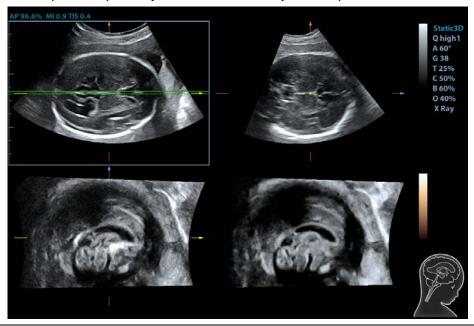
### 5.10.14.1 Basic Procedures for Smart Planes CNS

- 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 select a clear sectional image.

- 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 appears 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 5.10.14.2 Other Operations for details.
- 8. Tap [Auto Measure]. Tap [Edit] to edit the measurements. See Chapter 5.10.14.2 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 5.10.14.2 Other Operations for details.
- 10. Add the comment and body mark on the plane. Perform the measurement, and save the single frame/multi-frame image.

# 5.10.14.2 Other Operations

### Parameter adjusting

Brightness

**Description** Adjusting the brightness of the images.

**Operation** Rotate [Brightness] to adjust the parameter.

The adjusting range is: 0-100% in increment of 2%.

Thickness

**Operation** Rotate [Thickness] to adjust the parameter.

The adjusting range is: 0-30 in increment of 1.

**Impacts** The bigger the value is, the more the thickness information

appears.

3D iClear

**Operation** Tap [3D iClear] to adjust the parameter.

The adjusting range is: off, 1-7 in increment of 1.

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

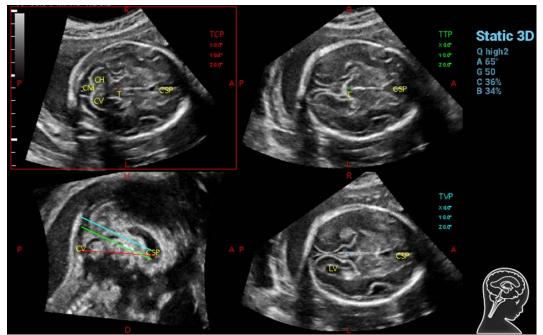
#### **Auto Comment**

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. See 9.1 Comments for adding, moving, editing or deleting the comments.
- 4. Save the single-frame and multi-frame image.
- 5. 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 single frame/multi-frame 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 upwards. 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, 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.

#### **Automatic Measurement**

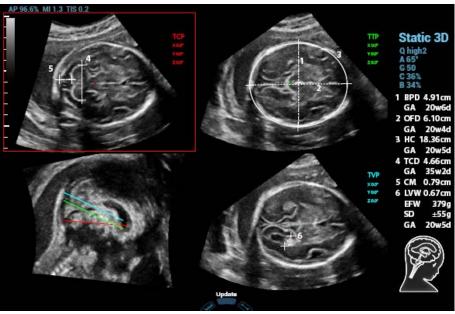
There are 6 measurements:

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 [Smart 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.

The measurement result is saved only for single-frame image, not for multi-frame image.

#### Reset

### All planes

Acquire 3D data. Tap [Smart 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 [Smart Planes CNS] to enter the automatic detection of the mode. Reset the following operations:

- ➤ Tap [Current Plane] to reset the plane. The position of the current plane returns to the initial condition. The angle of the current plane returns to 0°.
- ➤ Tap [Current Plane] to reset the current plane. The position and the angle to the current plane returns to the last MSP condition.

### Other related Operations

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** 

between the single and quad-split display.

# 5.11 iScape View (Real-time Panoramic Imaging)

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, you move the probe linearly and acquire a series of B images, the system pieces these images together into single, extended B image in real time. Besides, the system supports out-and-back image piecing.

After you obtain 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 also provides color iScape function, so that you can get more information from extended images.

iScape imaging is an option.

# **⚠**CAUTION:

- iScape panoramic imaging constructs an extended image from individual image frames. The quality of the resulting image is userdependent 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 the iScape mode. Smooth even speed will help produce optimal image results.
- 2. Color iScape images are provided for reference only, not for confirming a diagnosis.

### Tips:

- iScape is an optional.
- The display of the biopsy guideline is not allowed in iScape mode.

# 5.11.1 Basic Procedures for iScape Imaging

To perform iScape imaging:

i Scape

- 1. Connect an appropriate iScape-compatible probe. Make sure that there is enough coupling gel along the scan path.
- 2. Press on the control panel to enter iScape (To acquire color iScape image, please enter iScape mode from B + Power mode):
- 3. Optimize the B mode (Power mode) image:
  - In the acquisition preparation status, touch [B] ([Power]) page tab to go for the B mode (color) image optimization. Do measurement or add comment/body mark to the image if necessary.
- 4. Image acquisition:

Tap [iScape] page tab to enter the iScape acquisition preparation status. Tap [Start Capture] or press <Update> on the control panel to begin the acquisition. For details, please refer to "5.11.2 Image Acquisition".

The system enters into image viewing status when the acquisition is completed. You can perform operations like parameter adjusting. For details, please refer to "5.11.3 iScape Viewing".

- 5. Exit iScape:
  - Press <B> button to return to B mode. Image Acquisition

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

- 1. Press the <Update> key or touch [Start Capture] on the touch screen to start the iScape image capture.
- 2. Scan slowly to obtain a single extended field of view image; you can also perform erasing and retracing if the image is not satisfied.
- 3. End image capture:

To end the image capture:

- Click [Stop Capture] on the touch screen; or,
- Press the <Update> key; or,
- Wait until the acquisition is finished automatically.

After the acquisition is completed, the panoramic image will be displayed. And the system enters iScape viewing mode.

#### Tips:

- During the image acquisition, no parameter is adjustable, and functions like measurement, comment and body mark are not available.
- ROI: a green box on the image indicating the boundary between the merged images and the unfinished images.
- Tips about the probe speed: during image slicing, the system gives feedbacks about the probe moving speed in the form of color and words, the relations are listed as follows:

| Status         | ROI Color | Tips                                   |
|----------------|-----------|--|
| 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 uniform motion:

- Make sure that 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. Don't lift the probe from the skin surface.
- Always keep the probe perpendicular to the skin surface. Don't rock, rotate or tilt the probe during the scan.
- The system accommodates a reasonable range of motion velocity. Don't make abrupt changes in speed of motion.
- Deeper scans generally require reduced acquisition speed.

# 5.11.3 iScape Viewing

After completing the image acquisition, the system performs image splicing and then enters the iScape viewing mode.

In iScape viewing mode, you can perform the following functions:

- Image parameters setting, for details, please refer to "5.11.3.1 Image Parameters".
- Image zooming, for details, please refer to "5.11.3.2 Image Zooming".
- Image rotation, for details, please refer to "5.11.3.3 Rotating the Image".
- Measurement, comment, and body mark, for details, please refer to "5.11.3.4 Measurement, Comment, and Body Mark".

# 5.11.3.1 Image Parameters Adjusting

In image viewing 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 map

Press the knob under [Tint Map] to activate the function, and then change the effect by rotating the knob.

#### ■ Ruler

Touch [Ruler] on the touch screen to hide or show the ruler around the image.

■ Color Display (in Power iScape)

Touch [Color Disp] on the touch screen to display or hid the color image.

■ Color Map (in Power iScape)

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

# 5.11.3.2 Image Zooming

Press <Zoom> button on the control panel to enter image zooming mode. Rotate the button to zoom in/out the panoramic image.

- Rotate the button clockwise to zoom in the image.
- Rotate the button anticlockwise to zoom out the image.
- Roll the trackball to change position of the magnified image.
- Press the <Zoom> key again to exit the zoom mode.
- When image displayed is bigger than the image area, the thumbnail is automatically displayed.

# 5.11.3.3 Rotating the Image

For the convenience of viewing the image, you can rotate the image by rotating the knob under [Rotation] on the touch screen.

# 5.11.3.4 Measurement, Comment, and Body Mark

In iScape image viewing status, you can perform measurement, comment, and body mark. The operations are the same as that of B mode.

#### NOTE:

- 1. The measurement accuracy for the spliced image may be degraded, exercise caution when measurements are performed on an iScape image.
- 2. If there is a trace during the retracing, please don't perform measurement across the trace.

# 5.11.3.5 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.

NOTE:

iScape panoramic imaging is intended for well-trained ultrasound operators or physicians. The operator must recognize image artifacts that will produce a sub-optimal or unreliable image.

The following artifacts may produce a sub-optimal image. If the image quality cannot meet the following criteria, you shall delete the image and do image acquisition 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 is no large black area in the image.

# 5.11.4 Cine Review

Click [Review Cine] on the touch screen in panoramic image viewing status to enter cine reviewing mode. In cine reviewing mode, there is a green frame marker indicating the sequence of currently reviewed image in the panoramic image on the left 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, touch [Auto Play] on the touch screen; or, press/rotate the
  corresponding knob to change the play speed. When the speed is 0, 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 [Return] item on the touch screen to exit the cine review mode, and there displays the panoramic image.
- In cine review mode, press <Freeze> on the control panel to return to the acquisition preparation status.

# 5.12 Contrast Imaging

2D 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. Only the following probes support contrast imaging:

The probes C5-1E/SC5-1E/C7-3E/C6-2GE support abdominal contrast imaging for liver.



- 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.

# 5.12.1 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
- 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.
- 5. 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.
- 6. 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 touching [Destruct] as "ON" to destruct the microbubbles left by the last contrast imaging; or to observe the reinfusion effect in a continuous agent injecting process.
- 7. Exit contrast imaging.



Press to exit the contrast imaging mode; or, press <B> button to return to B mode.

# 5.12.2 Left Ventricular Opacification

Basic Procedures for LVO:

- 1. Acquire ECG signal;
- 2. Press to open Probe/Exam Mode selecting dialogue box;
- 3. Select P4-2NE or SP5-1E probe and LVO exam mode;
- 4. Workflow of LVO is similar to abdomen contrast imaging. For details, please refer to "5.12.1 Basic Procedures for Contrast Imaging".

# **5.12.3 Contrast Image Parameters**

# 5.12.3.1 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 "D") and tissue image (marked with "D") are displayed (the two window position can be changed). Parameter area displays as follows:



| Туре     | Parameter | Description          |
|----------|-----------|----------------------|
| Contrast | F         | Contrast frequency.  |
|          | D         | Depth.               |
|          | G         | Gain.                |
|          | FR        | Frame rate.          |
| Contrast | DR        | Dynamic Range.       |
|          | Z         | Magnification factor |
|          | iTouch    | iTouch status        |
|          | iClear    | iClear status        |
| Tissue   | G         | Gain                 |
|          | DR        | Dynamic Range.       |
|          | Z         | Magnification factor |
|          | iTouch    | iTouch status        |
|          | iClear    | iClear status        |

| Туре                      | Parameter | Description   |
|---------------------------|-----------|---|
| Timing (If timer is "ON") | /         | In real time mode, the time displayed is the elapsed time. In freeze mode, the timer stops working, the frozen time is displayed. |

# 5.12.3.2 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.

#### 5.12.3.3 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 right 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, the timer stops working, and there displays the elapsed time. For example, 00:00:09, it means the elapsed time between begin timing and freeze the image is 9s.
- Set [Timer 1] or [Timer 2] as "OFF", the timer discontinues its work.

### 5.12.3.4 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: touch [Destruct] on the touch screen to enable the micro-bubble destruction function.
- Parameters: set the parameters through the touch screen/menu.
  - DestructAP: adjust the destruct acoustic power by the touch screen/menu item.
  - DestructTime: adjust the destruct time by the touch screen/menu item.

Use the contrast imaging according to the residual level of the microbubbles, using contrast imaging continuously may result in human harm.

#### 5.12.3.5 **Dual Live**

In live mode or freeze mode, set touch screen item [DualLive] as "ON" to enable dual live function.

Both the contrast image (marked with "••") and tissue image (marked with "••") are displayed (the position can be changed). Meanwhile, you can switch to [Contrast] or [Tissue] page to adjust the corresponding parameters.

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.

# 5.12.3.6 Mix Map

This function is to mix the contrast image with the tissue image, so that interested contrast regions can be located.

Touch [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.

### 5.12.3.7 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 right corner of the screen once press <iTouch>.

Select different levels of iTouch effect through [iTouch] on the touch screen.

■ Long press the <iTouch> key to exit the function.

# **5.12.3.8 Image Saving**

■ Live capture

In live mode, you can save the interested images by touching [Pro Capture] and [Retro Capture].

Cine saving

In live mode, press the <Freeze> key on the control panel to enter cine review status.

# 5.12.4 Measurement, Comment and Body Mark

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

# 5.12.5 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 micro bubbles.

#### MFE switch

During real-time scanning, touch [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.

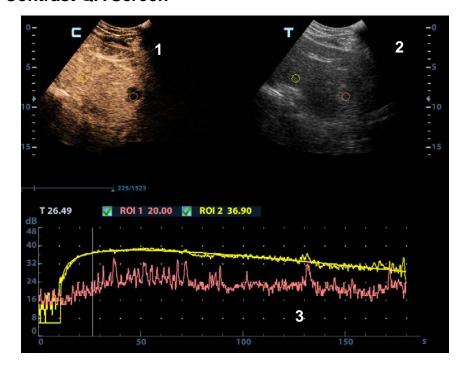
# 5.12.6 Contrast Imaging QA

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.
  - Images from the current scan session (already in freeze mode) or from a saved image loop can be used.
- 2. Tap [Contrast QA] on the touch screen page to activate the function.
- 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.

### 5.12.6.1 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.

# 5.12.6.2 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. Touch [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 the <Set> key to fix the starting point.
- 5. Press the <Set> key, and roll the trackball to depict the ROI. When a suitable ROI has been drawn, confirm the ROI by double clicking <Set> key, press <Clear> key 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. Touch [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.
- Press the <Set> key 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> key to cancel the last point.
- Delete ROI

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

### **Motion Tracking**

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. Touch [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.
  - 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.

- Touch [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.
- Touch [Raw Curve] to hide/display raw curve, when the button is highlighted in green, raw curve is displayed.
- Touch [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.

**NOTE:** 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.

# 5.13 Elastography

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

# 5.13.1 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. Only the following probes support the strain elastography:

- The L12-3E/L14-6WE/L14-6NE/L14-5WE/L9-3E probes support the strain elastography under the thyroid, breast exam modes.
- The V11-3E/V11-3BE/V11-3HE/DE10-3E/DE11-3E probe supports the strain elastography under GYN and Prostate exam modes.

NOTE:

- Make sure the transducer surface of the intra-cavity probe is well contacted with the tissue during Elasto imaging.
- 2. If all arrays of the transducer surface of intra-cavity probe cannot contact completely with the tissue, please select the ROI in the region of contacting (normal B image region).
- 3. In Elasto dual imaging of intra-cavity probe, there is a part of image is overlapped between two B images. Please adjust the ROI position and size to the visible region.

# 5.13.1.1 Basic Procedure for Elastography

1. Perform B scan to locate the region.



- Press to enter the mode, adjust ROI according to the actual situation.
  - Select the probe according to the experiences and actual situation.
  - Adjust the image parameters to obtain optimized image and necessary information.
  - Adjust ROI on the frozen image if necessary.
  - Adjust the image parameters to obtain optimized image.
  - Save the image or review the image if necessary.
  - 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.

# 5.13.1.2 Enter/ Exit

■ Enter

Press <Elasto> on the control panel to enter the mode.

After entering the mode, the system displays two windows in real-time on the screen, the left one is 2D image, and the right one is Elasto image.

#### ■ Exit

Press <B> or <Elasto> on the control panel to exit and enter the mode.

#### 5.13.1.3 Pressure Hint Curve

The screen displays the pressure curve in real-time:



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

# 5.13.1.4 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** To adjust the image smooth, adjust through the [Smooth] item on the touch

screen.

Opacity

**Description** To adjust the opacity feature of the Elasto image.

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

Invert

**Description** To invert the E color bar, thus to invert the color of benign and malignant tissue

can be inverted.

**Operation** Click [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.

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.

Map

**Description** To select different maps for observation.

**Operation** Rotate the knob under [Map] item on the touch screen to select the map.

The system provides 6 maps, including 1 grayscale map and 5 color maps.

#### 5.13.1.5 Mass Measurement

Press < Measure > to enter measurement status.

You can measure shell thick, strain ratio, strain-hist and etc.

For details, please refer to [Advanced Volume].

### **5.13.1.6 Cine Review**

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

# 5.13.2 STE Imaging (Sound Touch Elastography)

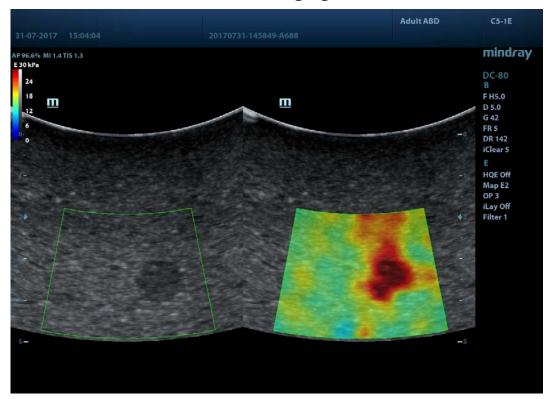
Keep the probe still to produce the elastography image in real-time 2D mode. The tissue hardness of the mass can be determined by the image color and brightness. Besides, the relative tissue hardness is displayed in quantitative manners.

STE imaging provides you real elasto modulus for quantification analysis without relying on technique.

STE imaging is an option.

The SC5-1E and C5-1E probes support the STE imaging in Adult ABD, Ped-ABD, ABD-Difficult, EM ABD, EM FAST exam modes.

# 5.13.2.1 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 <Elasto> 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.
- Perform the measurement or add comment/body mark to the image if necessary.
- 7. Save the single-frame and multi-frame image.
- Acquire high-quality image if necessary (for details, refer to "5.13.2.2 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.

# 5.13.2.2 STE Mode Image Optimization

#### **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), 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.

Note: the operation description of the STE in the manual may differ from the real display of the system because of the configuration variability, please refer to the

system the user purchased.

#### 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 Rotate the knob under [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 Rotate the knob under the [Map] on the touch screen to select the map.E1 is a gray

map; E2 and E3 are color maps.

### **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 enable the function (the soft key is highlighted). The quality map

appears on the left side of the image.

With both real-time ultrasound image and elasto image displaying, the real-time

ultrasound image is replaced with the quality image.

With only elasto image displaying, the elasto image is replaced with the quality

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.

**HFElasto** 

**Description** This feature is used to improve the frame rate (FR).

Operations Tap [HFElasto] 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.

**Filter** 

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

**Operation** Rotate the knob under [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.

# **5.13.2.3 Measuring**

Press < Caliper> to enter general measurements.

Press <Measure> to enter application measurement.

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

#### **5.13.2.4 Cine Review**

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

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

# 5.13.3 STQ Imaging (Sound Touch Quantification)

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

The SC5-1E and C5-1E probes support the STQ imaging in Adult ABD, Ped-ABD, ABD-Difficult, EM ABD, EM FAST exam modes.

### 5.13.3.1 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 key (set the user-defined key via [Preset] → [System] → [Key Config]) to enter the STQ imaging mode.

The "Depth", at the right bottom of the screen, shows the depth value of the ROI center (marked with a +).



- 3. Adjust the ROI based on the lesion size and the position, and rotate [Fixed ROI] knob or move the trackball to adjust the ROI 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.

Elasto modulus inside the ROI of the current frame;

The mean value, maximum value, minimum value, SD value of STQ velocity;

Depth value of the active elasto modulus.

- 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. Reacquire the image if necessary.
- 9. Press <B> on the control panel or tap [STQ] on the touch screen to exit the elastography imaging mode, and return to B mode.

# 5.13.3.2 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 wave velocity Cs

(unit: m/s).

Note: the operation description of the STQ in the manual may differ from the real display of the system because of the configuration variability, please refer to the

system the user purchased.

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.

The adjusting range is: off, 2-10.

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.

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** Rotate the knob under the [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.

**HFElasto** 

**Description** This feature is used to improve the frame rate (FR).

**Operations** Tap [HFElasto] on the touch screen to enable the function and the button will be

highlighted.

Lesion

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

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

# 5.14 Stress Echo

CAUTION: Stress echo data are provided for reference only, not for confirming a diagnosis.

Stress Echo is an option, only the phased probes support stress echo function under the cardiac mode.

# 5.14.1 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 motion of a whole heart cycle or from beginning systole to 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 be selected only in the configured order. Acquisition is retrospective; when you touch [Save Clip] on the touch screen or press <Save1> (<Save2>) key 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 <Save1> (<Save2>) key on the control panel, the system
  starts saving newly acquired images. With this workflow, you assign view labels to the
  loops after acquisition is complete, using controls on the Stress Echo screen to select the
  "preferred" loop for each view.

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 continuous stage.

# 5.14.2 Stress Echo Acquisition Procedure

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

- 1. Touch [Stress Echo] on the touch screen or press the customized key.
- 2. The system displays the Select Protocol window with protocol selections. Select the desired protocol and then touch [Select].
  - The system displays the real-time imaging screen.
  - If the Stress Echo manual ROI option is selected in the Maintenance dialog box, then 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; for details, please refer to "5.14.5 Maintenance and Protocol".
- 3. If an ROI is displayed, adjust the ROI size and position, touch [Fix ROI] or press <Update> key on the control panel to confirm the ROI.
  - Tips: When you confirm the ROI size by pressing <Update> or touch [Fix ROI], you cannot adjust the ROI size during acquisition but only adjust ROI position through trackball.
- 4. Press <Save1> (<Save2>) key 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 views of the first phase (Phases are stages). The system selects the first view for acquisition by default, indicating view selection by placement of a red mark to the right of the view name.
- 5. Proceed through each view in each stage using the following instructions:

- Non-continuous stages:
  - To save acquired images for the selected view, touch [Save Clip] on the touch screen or press <Save1> (<Save2>) key on the control panel, and the system goes to the next view for acquisition by default, saved views are marked by green "√".
  - Rotate the knob under [Stages] or [Views] on the touch screen to select the stage and view for image acquisition (or reacquisition), press <Save1> (<Save2>) key to start acquisition.

Tips: views can be re-acquired until you click [End Acquisition].

- If the protocol contains continuous stages (for alternative workflow), then proceed through each continuous stage using the following instructions:
  - To begin saving acquired images for the selected stage, press <Save1> (<Save2>) key
    on the control panel or touch [Save Clip] on the touch screen.
    - The system displays a percentage marker below the selected stage indicating the progress of the continuous capture.
  - To stop saving acquired images for the selected stage, press the knob under [Pause Acquisition] on the touch screen or press <Freeze> directly, the percentage stops to increase.
  - Press the [Continue Acquisition] knob or press <Freeze> key again to continue.
  - To end the current acquisition, press <Save> on the control panel.
  - To select another continuous stage, position the trackball pointer over the stage and then
    press the <Set> key on the control panel, or rotate the knob under [Stages] on the touch
    screen.

At completion of acquisition for each stage, the system advances to the next stage. If the stage is non-continuous, then the system displays the views of the stage. When image acquisition is completed for all views and continuous stages, the system shifts the red mark to the [End Acquisition] selection in the Protocol window.

- 6. To start or restart the timer, touch [Stage Timer] / [Exam Timer] on the touch screen to turn on. Stage time is displayed at the right side of each stage in the protocol list, while Exam time is displayed on the left side of the monitor.
  - Each saved image will be marked with two times T1 and T2, T1 refers to the total time of the whole acquisition, while T2 means the time the acquisition lasted for a certain stage.
- 7. To review loops before ending acquisition, touch [Review/WMS] on the touch screen. You can redisplay the real-time imaging screen to continue acquisition by clicking [Acquire] in the toolbar on the upper part of the screen.
- 8. To end acquisition and review the acquired images, touch [End Acquisition] or press <End Exam>.

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

# 5.14.3 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 for the selection of the best loops of the examination.

When 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 [Stages] or [Views] 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 fullscreen.
  - 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 pertinent controls:

| Selection                       | Description   |
|---------------------------------|---|
| Stages                          | Rotate the corresponding knob under the button to select a stage.   |
| Views                           | Rotate the corresponding knob under the button to select a view.  |
| Acquire/ Select/<br>Review/WMS  | To switch the mode status.  |
| 1. Clip/2. Clip/3. Clip/4. Clip | For selecting views in the selected stage.  |
| Next                            | Next four Clips.  |
| Previous                        | Previous four Clips.  |
| First                           | Go to "first" Clips.  |
| Last                            | Go to "last" Clips.   |
| Prev/Next/First/Last frame      | See previous/next/first/last frame of the cine file.  |
| Speed decrease/Speed increase   | Decreases or increases playback speed.  |
| Text                            | Function that turns on screen graphic text "On"/"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, name of level, 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.   |

| Selection         | Description  |
|-------------------|--|
| Bookmark          | For continuous acquisition, when bookmark is set "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           | Pause the stress echo exam but not end the stress echo exam.  When stress echo exam is suspended, the user can perform image acquisition of all other imaging modes, or perform operations like measurement. |
| End SE exam       | End the stress echo exam.  |

# 5.14.4 Review/WMS Mode

Review/WMS mode is used by cardiologist to evaluate clips for cardiac wall motion abnormalities. Different views, from different stages, will be selected to display to compare in a wide variety of combinations. The most common workflow is to compare "same views" but at "different stages" of the exam (Example: PSLA view, Rest stage compared to PSLA view, Post exercise stage).

### **5.14.4.1 Review Mode**

- 1. Select [Review/WMS].
- 2. Select the label of the phase or view 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 exclude a phase or view from display, select the box to the left of each required phase and/or view.

The system inserts a red X into each selected box, like

2. 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, Long Axis).
  - 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.

# 5.14.4.2 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 to score each segment to evaluate the degree of abnormality using the motion of the walls of entire left ventricle from the sum of scores in each segment. Scoring is displayed in the report.

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.

ASE 16 and ASE 17 two methods of chamber segments divisions are supported. In addition, each segment can be done 4, 5 and 7 points scoring.

To assign a wall motion score (WMS):

1. Select a colored number in the bottom-right area of the screen.

The signification and color used in segments are listed in the table below.

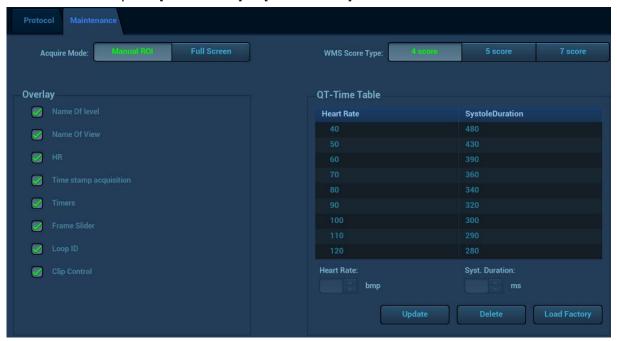
| Score | Signification     | Color  |
|-------|-------------------|--------|
| 1     | Normal            | Green  |
| 2     | Hypokinesis       | Yellow |
| 2.5   | SevereHypokinesis | Khaki  |
| 3     | Akinesis          | Blue   |
| 4     | Dyskinesis        | Red    |
| 5     | Aneurysm          | 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 loops: Select [Set All Normal] on the touch screen.
- To assign a normal wall motion score (WMS) to the currently selected loop: Select [Set Current Normal] on the touch screen.

# 5.14.5 Maintenance and Protocol

### 5.14.5.1 Maintenance

Select "<F10 Setup $> \rightarrow$  [Stress Echo]  $\rightarrow$  [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.   |  |

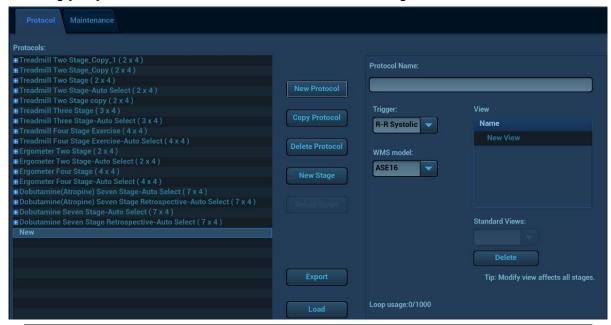
### **QT-Time Table Operation:**

- 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].
- To load the factory defaults:
  - Select the [Factory Settings] button.

### 5.14.5.2 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 methods of chamber segments division.                              |
| Loop usage      | Displays the acquired loop number as well as the total usable loop number. |
| View            | Set the views for the each stage.  |
| Standard views  | 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.                                |
| Delete protocol | Delete the protocol.   |
| New stage       | Create a stage for the current protocol.                                   |
| Delete stage    | Delete the stage.  |

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

To create a stress echo protocol:

- 1. Click [New Protocol] button on the right of the Protocol Editor dialog box.
- 2. Enter the protocol name in the Protocol Name box at the top.
- 3. For each phase in the protocol:
  - (a) Select "new" in the Stage list.
  - (b) Enter a phase name in the Description box.
  - (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.
- 4. 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.
- 5. Click [Save] to save changes.

### **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.

# 5.14.6 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.

# 5.14.7 Exiting the Stress Echo Feature

To exit the Stress Echo feature:

Press <End Exam> on the control panel or click [End SE exam] on the screen.

# 5.14.8 Measurement and Report

Suspend the stress echo exam by touching [Suspend Exam] on the touch screen, press measurement related keys or buttons to enter cardiology measurement. For details, please refer to 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. Press <Report> on the control panel to open the report.

Use the keyboard to enter text in the Indication dialog box and then click [OK].

# 5.15 Tissue Tracking Quantitative Analysis (QA)

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.

**△ CAUTION**:

Tissue Tracking Quantitative Analysis images are provided for reference only, not for confirming a diagnosis.

Tissue tracking quantitative analysis is an option.

Only use the following probes matched with corresponding exam modes to start Tissue Tracking QA function.

- P4-2NE: adult cardiac/ cardiac-difficult (car-penetration)/ pediatric cardiac
- P7-3E: neonatal cardiac/ pediatric cardiac;
- P10-4E: neonatal cardiac.
- SP5-1E: adult cardiac/ cardiac-difficult (car-penetration)/ pediatric cardiac/LVO(B mode)

# 5.15.1 Basic Procedures for Tissue Tracking QA

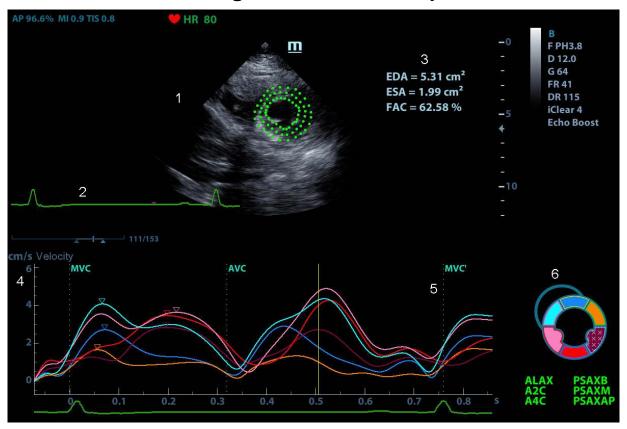
- 1. Select a saved B mode cardiac cine file (a cin. Format file which contains more than 1 cardiac cycles (with 2 R waves) and ECG signal).
- 2. Touch [TT QA] on the touch screen to activate the function:
  - a) You can determine the interested image by a preview of the image;
  - b) To find the interested image, roll the trackball or rotate the knob under [Cycle] on the touch screen to select.
- 3. Select corresponding section name on the touch screen, and press <Cursor> to show the cursor; use the cursor to set reference point (for details, please refer to "5.15.4 Myocardial Boundary Tracing" chapter):
  - Long axis section: use "3-point" method or "Manual" method to set;
  - Short axis section: enter multiple points (at least 6 points) by cursor manually to set.
- 4. After reference points are set, the system will display boundary of the endocardium and epicardium, adjust the thickness if necessary.

If traced result is not good, touch [Reload] on the touch screen to re-trace the reference points, or you can make fine adjustment to the points by cursor;

If the cycles are not enough to provide the information, switch another cycle to trace.

- 5. Touch [Start Tracking] on the touch screen to start tracking function, adjust parameters if necessary.
  - Touch [Edit] on the touch screen to display free cursor, roll the trackball and press <Set> to reselect trace reference points, move the cursor to exact boundary position and press <Set> again to set the right place. Click [Start Tracking] to start tracking again.
- 6. Touch [Accept & Compute] on the touch screen to calculate and display the curve. Adjust parameters if necessary.
- 7. Touch on the touch screen to turn to the other page, touch [Bull's Eye] to see the result.
- 8. Touch [Data Export] on the touch screen to export analyzed data.
- 9. Touch [Exit] on the touch screen.

# 5.15.2 Tissue Tracking QA Screen Description



- 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:** Fractional Area Change= (EDA — ESA)/EDA.

This parameter is available under short axis section.

**EF:** Ejection fraction.

This parameter is available under long axis section.

**HR:** Heart rate.

GS: Global Strain

Also on Bull's Eye graph, the system displays TPSD value: Time to Peak Standard Deviation (TPSD):

$$TPSD = \sqrt{\frac{\sum_{1}^{N} \left(TP_{i} - \overline{TP}\right)^{2}}{N}}$$

Where, standardized value of time to peak data:  ${TP_i \mid i \in [1,N]}$ . (N is the number of time to peak data) Average value of standardized value of time to peak data:  $\overline{TP}$ 

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, ✓ points out the peak position of the curve.
- Click 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.

# 5.15.3 Select Image and Cardiac Cycle

You can select images with a better image quality to get a better analysis result.

- Switch the cine file
- 1. Tap <Review> on the control panel to enter review status;
- 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.

# 5.15.4 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 clockwise 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.

At least 6 points should be determined by you before the system generates automated trace.

- 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;

- 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 step 2-3 to finish all points that need adjustment.

Under tracking status, touch [Edit] on the touch screen to enter the status.

# 5.15.5 Operation Controls

### Switch the operation controls

- [Start Tracking]: touch to start tracking.
- [Accept & Compute]: touch to start calculation and display the curve.
- [Exit]: touch 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 button to select for the view.

- [A4C]: apical four chamber view.
- [A2C]: apical two chamber view.
- [ALAX]: Apical long axis view.
- [PSAX B]: Short axis base view.
- [PSAX M]: Short axis mid view.
- [PSAX AP]: Short axis apex view.

### **Parameter Adjustment**

- [Thickness]: adjust tracing thickness that is the distance between endocardium wall and the tracking points on the epicardium.
- [Tracking Points]: adjusts number of points within the segment.
- [Cycle]: rotate clockwise to select the next cycle, and vice versa.
- [Smooth]: adjusts smooth effect of the curve.
- [Display Effect]: Turns on/ off the arrow vector graphics display of the myocardial movement.

#### Image display

According to the status of the current section, touch the corresponding button on the touch screen to check the matching time.

- [AVO]: displays aortic valve open time.
- [AVC]: displays aortic valve close time.
- [MVO]: displays mitral valve open time.
- [MVC]: displays mitral valve close time.

# 5.15.6 Bull's Eye Display

You can acquire:

After tracking, the system can display Bull's Eye graph, for judging the reverse movement or scope of myocardium.

- Touch [Bull's Eye] on the touch screen to turn on the function:
  - Time to peak value and peak value of the 17 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.



<sup>&</sup>quot;-" will display in the table to indicate those segments that are not well tracked.

# 5.15.7 Measurement/ Comment

Under tissue tracking QA mode, only Time measurement is available. For details, please refer to Operator's Manual [Advance Volume].

Comments and Body Mark operations are the same as in other modes.

# 5.15.8 Data Export

The system provides data exporting function, so that you can export calculation result for analysis (for instance, SPSS analysis).

Touch [Data Export] on the touch screen, to export analyzed data of each segment in .csv format.

# 6 Display & Cine Review

# 6.1 Splitting Display

The system supports dual-split and quad-split display format. However, only one window is active.

- Dual-split: press key on the control panel to enter the dual-split mode, and using the key to switch between the two images; press <B> on the control panel to exit.
- Quad-split: press key on the control panel to enter the quad-split mode, and using the key to switch among the four images; press <B> on the control panel to exit.

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 filed. As a result, the MI may change.

## 6.2.1 Spot zoom



To use the function, use the **Zoom** knob on the control panel.

- 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 sample volume is set, press <Zoom> key again to enter spot zoom status.
- 3. Rotate the <Zoom> knob to change the magnification factor.
- 4. Press <Zoom> again to exit spot zoom.

Tips:

- Spot zoom can only be achieved on real-time image.
- The size and position of sample volume box change along with scanning depth and area.

### 6.2.2 Pan zoom



To use the function, use the Zoom knob on the control panel.

- 1. Rotate <Zoom> knob to directly enter the pan zoom status. Image-in-image is displayed.
- 2. Magnification factor adjustment: rotate the [Zoom] knob to change the magnification factor.
- 3. Press <Zoom> to exit pan zoom.

## 6.2.3 iZoom (Full Screen View)

Function: to magnify the image in full screen.

Procedures:

- 1. Press **F8 (iZoom)** to zoom in the image; the zooming area includes image area, parameter area, image banner, thumbnail area and so on.
- 2. Press **F8 (iZoom)** again to zoom in the image area only.
- 3. Press **F8 (iZoom)** again to exit iZoom.

## 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:  $[Setup] \rightarrow [System] \rightarrow [Image]$ )

Press <Freeze> in freeze mode to unfreeze the image, and the system continues image scanning.

## 6.3.1 Imaging Mode Switching When Frozen

Imaging mode switching in freeze mode follows the following principles:

- In splitting display B mode, press <Dual>/<Quad> to switch among the windows; press <Single> to exit splitting display mode and enter the image of the currently activated window in full screen.
- In freeze 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 <Color> 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.

## 6.3.2 Imaging Display Format Switching When Frozen

Image display format switching in freezing mode follows the following principles:

- 2D + PW (Press <Freeze> in 2D + PW imaging mode)
  - If the imaging mode before frozen is 2D (frozen) +PW (real time) or 2D (real time) +PW (frozen), then in freeze mode, you can switch between 2D (frozen) +PW (activated) or 2D (activated) +PW (frozen) by pressing <Update> key on the control panel.
- Dual/quad splitting display mode (Press <Freeze> key in dual/quad splitting display mode)
  - When entering freezing mode, the default activated window is the real time window before frozen. Other image windows display the corresponding cine memories, if a certain cine memory is empty, then no image is displayed.
  - Press [Dual] / [Quad] to switch between dual-splitting and quad-splitting mode.
  - Press <Single> on the control panel to enter the single display format, which displays the currently activated window. In single display format, press <Dual>/<Quad> to return to splitting display mode.
  - Unfrozen: in splitting display status, when you unfreeze the image you can only unfreeze
    the image in the activated window, other images still keep frozen. In single-window display
    status, the system displays single image after being unfrozen.

## 6.4 Cine Review

After you press the <Freeze> key, 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 after the <Freeze> key is pressed, 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 waveforms, if the detection of physiological waveforms is performed.

Cine Review images can be inadvertently combined in-between separate patient scans. The Cine Review memory must be cleared at the end of the current patient and the onset of the next new patient by pressing the <End Exam> key on the control panel.

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
  - 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.

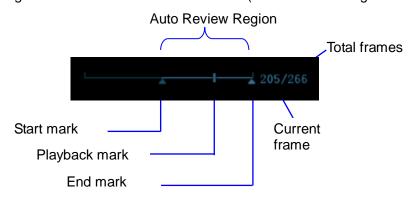
# 6.4.2 Cine Review in 2D Mode (B/B+Color/B+Power/B+TVI/B+TEI)

Manual Cine Review:

After entering the cine review of 2D mode, roll the trackball or slide the screen to review the cine images on the screen one by one.

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 left, 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] in the touch screen to adjust the review speed. When the speed is changed to 0, the system exits the auto cine review.
  - c) In auto play status, press the knob again, or roll the trackball to exit auto play.
- Setting Region of Auto Review
  - a) Set 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 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 the [Auto Play] in the touch screen; the system plays the auto review region automatically.
  - d) Rotate the knob under the [Auto Play] to increase/decrease the auto play speed.
  - 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.

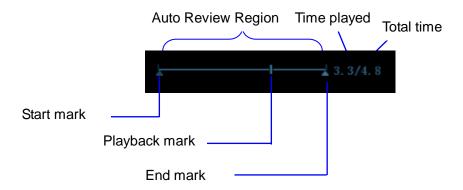
Tips: you can perform cine review on each image window in the dual/ quad splitting mode, and set auto review region for each window.

## 6.4.3 Cine Review in M/ PW/ CW/ TVD Mode

Enter cine review in M/PW/CW/TVD mode, and 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 you review the images until the earliest or the latest 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):



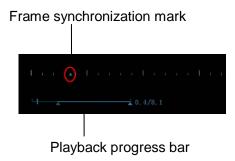
Cine review operations are the same as those of 2D mode.

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 ×1.

### 6.4.4 Linked Cine Review

The linked cine review refers to review of the images captured at the same moment.

- Dual live mode(B+C)
- B+M
- B/B Dual liveDuplex mode
- Triplex mode



The frame mark on the time mark of M/PW image indicates the corresponding 2D image. In the statuses rather than the dual live, you can only review images in the currently active window.

# 6.5 Image Compare

## 6.5.1 Image Compare in Review Mode

- 1. Tap [Image 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 left 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> or <Quad> to toggle between the 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. Rotate the knob under [Mode 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, touch [Frame Compare] in "Cine" page on the touch screen to enter frame compare 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. Click [Frame Compare] again to return to image frozen status; press <Freeze> to enter real-time imaging.

Tips: cine compare can only be performed on single-format 2D images only.

# 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.

#### Tips:

- 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 tapping [Prospective] as the start time. The system proceeds saving the cine.

Procedures:

With the ECG disabled: tap [Cine] tab, and rotate [Time (Post)] knob to adjust it.

With the ECG enabled: tap [Cine] tab. Tap [Saving type (Post)] to choose the type of the saving time and the cardiac cycles. Rotate [Time (Post)] or [Cycle (Post)] to adjust it.

Retrospective Cine Length:

Retrospective cine duration: set the time that user tapping [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 [Saving 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 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 Chapter 2.9 Physio Panel (ECG).

- 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**:

- 1. DO NOT use the physiological traces for diagnosis and monitoring.
- 2. To avoid electric shock, the following checks shall be performed prior to an operation:
  - The ECG electrode cable shall not be cracked, frayed or show any signs of damage or strain.
  - The ECG electrode cable shall be correctly connected.
  - You should use the ECG leads provided with the physiological module. Otherwise it 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.
- 4. DO NOT place the ECG electrodes directly in contact the patient's heart; otherwise it may lead to stop of the patient's heartbeat.
- 5. DO NOT apply the ECG electrodes if the voltage exceeds 15 volts. This could produce an electric shock.
- 6. Before using high frequency electric surgical unit, high frequency therapeutic equipment or defibrillator, be sure to remove the ECG electrode from the patient, in order to prevent electric shock.
- 7. Conductive parts of electrodes and associated connectors for ECG should not contact other conductive parts including earth/grounding.
- 8. 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.
- 10. 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.

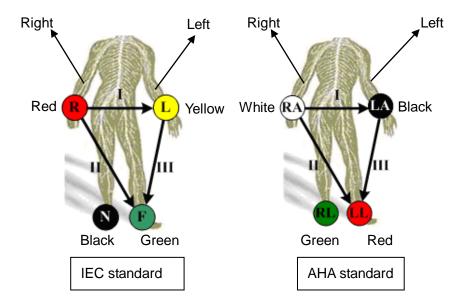
**NOTE:** When abnormality is detected in physio trace, please check if ECG leads are properly connected with the system.

## **7.1 ECG**

## 7.1.1 ECG Operation Basic Procedures

- 1. Connect the device.
  - Turn off the power supply of the system, and connect the ECG cable to the corresponding interface on the physiological module.
  - Turn on the power supply of the system.

Place the ECG electrodes on the patient's body (as shown in the following figures).



- 2. Press < Physio> key on the control panel to enter physio operation status.
- 3. Switch the imaging modes and display formats, adjusting the parameters to get an optimized image.
- 4. Parameter adjustment: On the Physio page, you can adjust [Speed], [ECG Gain], [Position] and [Invert].
- 5. Trigger:

Select the trigger mode, or switch on [Real & Trig], set the trigger time.

- 6. Freeze the images and review the images.
- 7. Press < Physio> to exit ECG mode, and remove ECG electrodes from the patient.

## 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. In most cases, the triggered images are 2D-mode images.

For single/dual trigger, when ECG triggering occurs, a mark appears on the ECG waveform, indicating the time points when the B images are captured (corresponding to the delay time from R curve started).

#### Tips:

- The trigger mark is displayed in both freeze mode and live mode.
- The marks in Dual trigger are different in color.
- Trigger function is unavailable if the ECG trace is disappeared. Only the live 2D image can be triggered.
- No delay time or time interval shall less than the time required to scan a single image.
- If the delay time is longer than a heart cycle, then the heart cycle between 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, the image will be triggered after delay time T1. The value of T1 can be changed in triggering status.
- Dual Trigger: when an R waveform is detected, the image will be triggered respectively after delay time T1 and T2. The value of T1 and T2 can be changed in triggering status.
- Timer Trigger: an image will be triggered after a certain interval. The time interval can be changed in triggering status.

The image trigger 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 on the soft menu according to actual situation.

### 7.1.2.3 Real & Trigger

Tap [Real & Trigger] to enable or disable the real trigger function.

After the [Real & Trigger] is turned on, 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 Parameter Description

| Parameter   | Description   |  |  |
|---|---|--|--|
| ECG Source  | Select ECG source.  |  |  |
| ECG Gain  | Function: to set the amplitude of ECG trace.                                    |  |  |
| ECG Gaiii   | Value: 0-30, in increments of 1.  |  |  |
| Position  | Function: to set the vertical position of the both traces on the image display. |  |  |
|   | Value: 0%-100%, in increments of 5%.  |  |  |
| Speed   | Function: change the speed of the physio trace.                                 |  |  |
| Speed   | Value: 15-120mm/s   |  |  |
| Trig Mode   | Select the trig mode.   |  |  |
| mg wode   | Value: Off, Single, Dual, Timer   |  |  |
| Real &Trigger   | Turn on/off the real-trigger  |  |  |
| Invert  | To invert the display.  |  |  |
| 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.                            |  |  |
| In timer triggering mode, set the time interval for Timer triggering. |   |  |  |

## **7.2 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.

## 7.2.1 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.

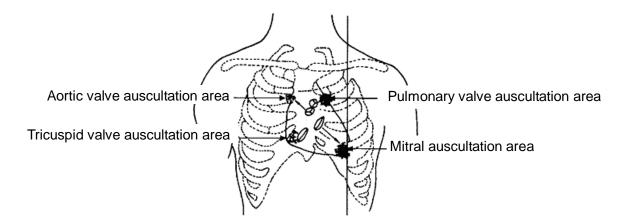
The position is shown below:

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.

## 7.2.2 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.   |  |

# 7.3 Respiratory Wave

## 7.3.1 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. Press < Physio> to enter Physio screen.
- 3. Switch the imaging modes and display formats, adjusting the parameters to get an optimized image.
- 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. Press < Physio > to exit physio mode.

# **8** Measurement

There are general measurements and application measurement. You can perform measurements on a zoomed image, cine reviewing image, real-time image, or frozen image. For measurements 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 Exam> is pressed during a measurement, the data not saved will be lost.
- 3. In dual-B imaging mode, the measurement results of the merged image can be inaccurate. Therefore, the results are provided for reference only, not for confirming a diagnosis.

## 8.1 Basic Operations

■ To enter/exit measurement

To enter: press <Caliper> on the control panel to enter general measurement; press <Measure> key to enter application measurement.

To exit: 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.
  - Move the cursor to the target position, press <Set> again, the result window has already been places in the target position.

## 8.2 General Measurements

## 8.2.1 2D General Measurements

2D general measurements refer to general measurements on images of B, Color, Power, or iScape imaging modes. The measurements listed below can be performed:

| Measurement<br>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,<br>Trace, Cross,<br>Spline)        | Measures the area and perimeter of a closed region.  |  |  |
| Volume (Ellipse),<br>Volume (Ellipse<br>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,<br>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.   |  |  |
| 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   |  |  |
| 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   |  |  |

## 8.2.2 M General Measurements

M general measurements refer to general measurements on M-mode, CM-mode, AM-mode images. The measurements listed below can be performed:

| Measurement<br>Tools   | Function  |  |  |
|--|---|--|--|
| Distance   | The vertical distance between two points.                                   |  |  |
| Time   | The time interval between any two points.                                   |  |  |
| Slope  | Measures the distance and time between two points and calculates the slope. |  |  |
| HR Measures the time of n (n≤8) cardiac cycles and calculates the heart roughly mode image.      |   |  |  |
| Velocity  Calculates the average velocity by measuring the distance and time between two points. |   |  |  |

## 8.2.3 Doppler General Measurements

Doppler general measurements refer to general measurements on PW/CW-mode images. The measurements listed below can be performed:

| Measurement<br>Tools | Function  |  |  |
|----------------------|---|--|--|
| Time                 | The time interval between any two points.   |  |  |
| HR                   | N intervals (n≤8) are measured to calculate a PW mode derived HR value in Beats Per Minute (BPM).                                     |  |  |
| Velocity             | On the Doppler mode image, velocity and PG (pressure gradient) of a poin on the Doppler spectrum waveform are measured.               |  |  |
| Acceleration         | Velocity and time interval between two points are measured to calculate speed difference and acceleration.                            |  |  |
| D Trace              | On the PW mode image, one or several Doppler waveforms are traced to obtain speed and PG, etc.  |  |  |
| PS/ED                | Velocity and PG between two peaks on the Doppler spectrum to calculate RI (resistance index) and PS/ED (peak systolic/end diastolic). |  |  |
| Volume Flow          | Blood flow through some vascular cross section per unit time.   |  |  |
| Ratio (Vel)          | Measures D velocity and calculate ratio value for blood analysis.   |  |  |
| Ratio (VTI)          | Measures VTI values from the spectrum and then calculate ratio value.   |  |  |

# 8.3 Application Measurement

- 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 fetal growth indexes (including EFW) as well as GA and EDD calculations. The fetus can be evaluated through growth graph analysis and fetal biophysical profile.
- Cardiac measurements Used for left ventricle function measurements and measurements of main artery and vein 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.
- Vascular measurements Used for carotid, cerebral, upper and lower extremities vessels, etc.
- EM measurements Used for EM related full functional measurement.

# 8.4 Measurement Accuracy

Table 1 Error of 2D Images

| Parameter                        | Value Range | Error                                   |  |  |
|----------------------------------|-------------|---|--|--|
| Distance                         | Full screen | Within ±3%.                             |  |  |
| Area                             | Full screen | Within ±7%.                             |  |  |
| Circ                             | Full screen | Within ±10%                             |  |  |
| Angle Full screen Within ±3%.    |             | Within ±3%.                             |  |  |
| Volume Full screen Within ±10 %. |             | Within ±10 %.                           |  |  |
| Distance (iScape)                | Full screen | Within ±5 % (all probes except CB10-4E) |  |  |
|                                  | Full screen | Within ±10 % (CB10-4E probe)            |  |  |

Table 2 Time/Motion Measurements

| Parameter   | Value Range   | Error   |  |
|---|---|---|--|
| Distance  | Full screen   | Within ±3 %.                                      |  |
| Time  | Timeline Display  | Within ±2%.                                       |  |
| Heart rate  | Timeline Display  | Within ±4%.                                       |  |
| Velocity (PW<br>mode)   | TCI: 10-300cm/s (for P7-3E, P10-4E, SP5-1E, P4-2NE)   | When angle≤60°, ≤5%.<br>(C11-3E: angle≤60°, ≤7%)  |  |
|   | Other application: 10-200cm/s (for L12-3E, L14-6NE, L14-6WE, DE10-3E, C11-3E, V11-3BE, CB10-4E, SC5-1E, L16-4HE, D6-2NE, DE11-3E, L14-5WE, L9-3E, V11-3E, V11-3HE, D8-2E, D7-2E, C5-1E, C5-2E, C7-3E, C6-2GE, P7-3TE) |   |  |
| Velocity (CW mode)  TCI: 10-300cm/s (for P4-2NE, P7-3E, P10-4E, SP5-1E)  Other application: 10-200cm/s (for P7-3TE) |   | When angle≤60°, ≤5%. (not including pencil probe) |  |

Table 3 Contrast Performance

| Probe   | Max. Depth |
|---------|------------|
| V11-3HE | ≥4         |
| C7-3E   | ≥7         |
| SC5-1E  | <i></i> ≥7 |
| L12-3E  | <i>≥</i> 4 |
| C6-2GE  | ≥10        |
| P4-2NE  | ≥12        |
| V11-3E  | ≥4         |
| V11-3BE | ≥4         |
| SP5-1E  | ≥12        |
| C5-1E   | ≥8.5       |
| L9-3E   | ≥4         |

Table 4 Elastography Performance

| Probe<br>Type | Max.<br>Depth(cm) | Spatial<br>Resolution | Accuracy of<br>Geometric for the<br>Lateral | Strain Deviation of<br>Strain ratio | Repetition rate of Strain ratio |
|---------------|-------------------|-----------------------|---|-------------------------------------|---------------------------------|
| L12-3E        | ≥30mm             | ≤10.5mm               | within ±20%                                 | within ±70%                         | within ±20%                     |
| L14-6WE       | ≥30mm             | ≤10.5mm               | within ±20%                                 | within ±70%                         | within ±20%                     |
| L14-6NE       | ≥30mm             | ≤10.5mm               | within ±20%                                 | within ±70%                         | within ±20%                     |
| L14-5WE       | ≥30mm             | ≤10.5mm               | within ±20%                                 | within ±70%                         | within ±20%                     |
| L9-3E         | ≥30mm             | ≤10.5mm               | within ±20%                                 | within ±70%                         | within ±20%                     |
| V11-3E        | ≥30mm             | ≤10.5mm               | within ±30%                                 | within ±70%                         | within ±20%                     |
| V11-3BE       | ≥30mm             | ≤10.5mm               | within ±30%                                 | within ±70%                         | within ±20%                     |
| V11-3HE       | ≥30mm             | ≤10.5mm               | within ±30%                                 | within ±70%                         | within ±20%                     |
| DE11-3E       | ≥30mm             | ≤10.5mm               | within ±30%                                 | within ±70%                         | within ±20%                     |
| DE10-3E       | ≥30mm             | ≤10.5mm               | within ±30%                                 | within ±70%                         | within ±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 Marks

## 9.1 Comments

Comments can be added to an ultrasound image to bring attention, notate or communicate information observed during the examination. You can add comments to: zoomed image, cine review image, real-time image, frozen image. You can type the character as comments; insert the pre-defined comments from the comment library; or insert arrow markers. The system supports recording voice comment as well.

 $\triangle$ WARNING:

You must ensure that the entered comments are correct. Incorrect comments may cause misdiagnosis!

## 9.1.1 Comment Basic Procedures

To perform a comment:

1. Enter comment status:



- Press : o
- Press any alphanumeric key or the space bar to enter the comment status; Or,



- Press to enter the arrow-adding status.
- 2. Place the cursor to the desired place to set the comment location.
- 3. Add new comment to the image according to actual situation. Here, you can modify, move or delete a completed comment.
- 4. To exit comment status:



In the comment status, press



- In the arrow-adding status, press
- Press <ESC> or other operating mode keys to exit.

## 9.1.2 Touch Screen Display in Comment

The system can be configured with comment text libraries including Abdomen, Cardiology, GYN (Gynecology), OB (Obstetrics), Urology, SMP (Small Part), Vascular, PED (Pediatric), Nerve Blocks and emergency medicine. In comment status, you can enter the comment text using the screen menu or touch screen.

To set home of comments.

Roll the trackball to move the cursor to the desired location for the comment and press <Set Home> on the touch screen.

Return the cursor to the set home location.

Press <Fn>+<Home> on the control panel to return the cursor to the set home location.

Grab/Del

Rotate the knob under the [Grab/Del] button on the touch screen, to select the entered comment items; press the knob to delete the selected item.

Navigate through comment libraries

To select the comment library, rotate/ press the knob under the [Library] button on the touch screen.

Change Font Size/Arrow Size

To change font size of comment text, rotate the knob under the [Font Size] button on the touchscreen to select among Small, Medium and Large.

To change arrow size, rotate the knob under the [Arrow Size] button on the touchscreen to select among Small, Medium and Large.

Comment display/hide

Tap [Hide]/[Display] 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 navigate to the other pages by touching on the touchpad.

User-defined comments

You can customize comments if necessary, including adding/deleting comments and adjust comment display on touch screen menu.

Trace

Touch [Trace] on the touch screen to enter the trace commenting status.

## 9.1.3 Adding Comments

- Typing comment 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:

You can enter the characters through the keyboard or the soft keyboard on the touchpad.

- Type the alphanumeric characters through the qwerty or soft keyboard (The default characters are uppercase).
- 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 added turns to 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.
- Touch 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.
- Add combined comment: Rotate the multifunctional knob to view the comments one by one; press the knob again to add the selected item onto the image (comment added in an editable state); rotate the multifunctional knob to search for the next part, and press the knob again to add the second part of the combined comment. Repeat procedures to add other parts of a combined comment. Press <Set> to complete the comment.

#### 2. Exit comment edit status

In comment edit status, press <Set> or <Enter> key, or roll the trackball to confirm the added comment text and exit the edit status, the comment changes into yellow.

#### Adding an arrow

You can add an arrow to a location where you want to pay attention.

To add an arrow:

- (1) Press the <Arrow> key, and an arrow will appear in the default position.
- (2) Adjust the arrow in shape and position:
  - > To posit the arrow to the area of interest: roll the trackball to the desired position.
  - ➤ To change the orientation of the arrow: Rotate the <Angle> knob to change the arrow orientation (in increments of 15°).
  - Adjust the arrow size: rotate the knob under the [Arrow Size] button on the touch screen to change the size.
- (3) Press <Set> or <Enter> to anchor the arrow position, and then the arrow turns yellow. Repeat the above steps to add more arrows.
- (4) Press <Arrow> on the control panel to exit the arrow comment status.

#### Tracing

(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 operation:
  - 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 anticlockwise, to cancel trace of 1 pixel.
  - ➤ Rotate the <Angle> knob clockwise, to restore trace of 1 pixel.
  - Press <Clear> to delete trace (s).
    - c) Press <Set> to finish a tracing.

### Touch screen operation:

- a) Trace around the ROI by touching the touch screen image using your finger.
- b) Remove your finger to finish the tracing.
- ➤ [Clear]: touch to delete the trace in reverse order one by one.
- ➤ [Clear All]: touch 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 the <Set> key to anchor the comment at the new position.

## 9.1.5 Modifying (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 turns to yellow.
  - If there are already comments in the screen, press the space bar to enter editing status.
- Modifying (Editing) Arrows
- 2. Rotate the <Angle> knob to modify the arrow direction.
- 3. Press <Set> or <Enter> key to complete the operation.

## 9.1.6 Deleting Comments

- Deleting Comment Characters, Texts or Arrows
- 1. Move the cursor to the comment to be deleted.
- 2. Press the <Set> key to select the comment.
- 3. Press the <Back>, <Del.>, <Delete Text> or <Clear> key to delete the comment.
- Deleting a recently-added character, text or arrow In comment status, pressing <Clear> can delete the recently-added or recently-edited comment.
- 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 "|".

■ Delete All Comments

Press < Delete Text> key or long press < Clear> key to delete all the comments.

**NOTE:** When no object is selected, long pressing the <Clear> key will clear all comments and all measurements calipers.

After powering off, the system will clear all comments on the image.

## 9.1.7 Comment Setting

- See Chapter 12.4 Comment Preset for comments preset.
- Comment Setting

Enter the "[Setup]  $\rightarrow$  [System]  $\rightarrow$  [Application]" screen to perform the following setting:

- 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.
- Set if the voice comment is enabled.

## 9.2 Voice Comment

The system supports adding voice comment to the frozen images.

## 9.2.1 Voice Comment Panel

After the system enters the voice comment status, the voice comment panel will be displayed on the lower left corner of the screen.



## 9.2.2 Adding Voice Comment

- To perform voice comment adding, the function should be enabled through the path: [Setup] →
  [System] → [Application].
- 2. Connect the microphone to the mic port of the physic unit panel the microphone icon appears highlighted.
- 3. Acquire the necessary images and press <Freeze> to freeze the image.
- 4. Press <Cursor> and roll the trackball to move the cursor onto the voice comment panel; click to start recording, and the icon turns 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.

## 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 Abdomen, Cardiology, GYN, OB, Urology, Small Part and Vascular applications. In addition, the system supports user-defined body marks, and body marks can be imported.

## 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 of the body marks, tap



to turn pages.

■ Save Probe

Under the condition that the probe mark direction and position is determined for the current adding body mark, touch [Save Probe] to save the current direction and position for the probe mark of the current body mark.

## 9.3.2 Adding Body Mark

- 1. Enter the Body Mark status; use the knob under [Library] to select the body mark category.
- 2. Adding Body Marks:
  - Adding body marks 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 multifunctional knob
     Rotate the knob to view the body mark one by one, and press the knob to add the body mark.
  - Adding the body mark using the touch screen.
     Touch 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 the <Angle> knob to adjust the orientation.
  - Touch [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 Mark

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 changes into , indicating you can move the pictogram to a new position.
- 2. Press the <Set> key to select the body mark.
- 3. Roll the trackball to move the Body Mark graphic to the desired position.
- 4. Press <Set> to anchor and confirm the new graphics position.

**NOTE:** In Dual B Mode, a body mark cannot be moved between the separated image windows.

## 9.3.4 Deleting Body Mark

- 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.

**NOTE:** If no object is selected, long pressing the [Clear] key will clear all comments, body marks and general measurements from the screen.

## 9.3.5 Body Mark Setting

Powering off, preset returning, switching the exam/ patient/ mode/ probe will clear the body marks.

# 10 Patient Data Management

An exam record consists of all information and data of one exam.

An exam record consists of the following information:

- Patient basic information and exam data
- Image files
- Report

**NOTE:** DO NOT use the internal hard drive for long-term image storage. Daily backup is recommended. External storage media is recommended for image archive.

The system patient database space is limited, please back up or clear patient data in time.

Mindray is not responsible for lost data if you DO NOT follow suggested backup procedures.

# 10.1 Patient Information Management

## 10.1.1 Enter Patient Information

The general patient information and exam information are entered through the Patient Info screen, for details; please refer to "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 saved image, you can perform operations like image reviewing, analyzing and demonstration (iVision).

## 10.2.1 Memory 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 two types of image file formats: system-relevant and PC-compatible.

- System-relevant formats:
  - Single-frame image file (FRM)
     Refers to single-frame static image files not to be compressed; you can perform measurements and comments adding on this type of files.
  - Cine file (CIN)
     System-defined multi-frame file format; you can perform manual or auto cine review, and perform measurements or add comments for the reviewed images. After you open a stored CIN file, the system automatically enters cine review status.

The system can save FRM files as BMP, JPG, TIFF or DCM files, or save CIN files as AVI, DCM files.

- PC-compatible formats:
  - Screen file (BMP)

Single-frame file format, used to save the current screen, non-compressed format;

- JPG: Single frame export format.
- TIFF: Single frame export format.
- Multi-medium file (AVI)
   Multi-frame export format.
- DICOM file (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 Preset

Set image size

You can set the image size via "[Setup]  $\rightarrow$  [System]  $\rightarrow$  [Image]":



Set cine saving length (clip length)

For details, please refer to "6 Display & Cine Review".

Set send/ print image after end exam

Open "[Setup]  $\rightarrow$  [System]  $\rightarrow$  [General]", check "Sending/ printing after End Exam" in exam setting area. Then every time you press <End Exam>, 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:
- 1. Set the user-defined key through the path: [Setup] → [System] → [Key Config]. Select a key in the Key Function field on the left side and select "Save Image to hard drive" in the Output page of Function field on the right side.
- 2. Press the user-defined key to save the image.
  - In the image screen, the image is saved in the FRM format.
  - When a dialog box is displayed on the current screen, save the screen in the BMP format.
- To save cineloop image to the system quickly:
- 1. Set the user-defined key through the path: [Setup] → [System] → [Key Config]. Select a key in the Key Function field on the left side and select "Save Clip (Retrospective) to hard drive" or "Save Clip (Prospective) to hard drive" in the Output page of Function field on the right side.
- 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 the 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.

You can set clip saving length in the path: [Setup]-[System]-[General].

## 10.2.5 Quickly Saving Full Screen Image to the System

- Set user-defined key: select one key from [Preset] → [System] → [Key Config] 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 key to quickly save the single-frame to USB flash drive.

- (1) The image file is stored in the directory: X (USB flash drive name): patient name+ ID\exam type + exam time \ image ID. Set the user-defined key through the path: [Setup] → [System] → [Key Config].
  - Select a key in the Key Function page on the left side and select "Send Image to USB disk" in the Output page of Function field on the right side. Click [Save] to exit setup.
- (2) Press the user-defined key to save the image to the USB flash drive.

## 10.2.7 Thumbnails

The stored images are displayed in the form of thumbnails on the screen:

- During image scanning, thumbnails of the current exam display at 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.
- In the Review screen, 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.
- In the Review screen, open an image to enter the image analyzing status, and all the thumbnails belong to the exam will be displayed on the right.

## 10.2.8 Image Review and Analysis

You can review and analyze the stored images (only refer to the images stored in the system default path).

## 10.2.8.1 Review an Image

You can review all images stored in an exam, and send, delete or analyze the stored images.

- To enter image review:
  - During image scanning, saved image thumbnails will display at right part 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.
  - Press <Review> to enter the Review screen. Images of the current exam and the current patient are displayed.
  - Select an exam of a patient in the iStation screen, and press <Review> or double-click the
    exam to enter the Review screen to review the images of the patient.

The Review screen is shown as follows:



### To exit Review:

- Click [Exit] on the Review screen
- Press <ESC>.
- Basic operations

Select an exam from the "Exam History" drop-down list.

Double-click a thumbnail to view and 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 images.

- 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 and

etc. Or, select the image and click the image 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.

Other operations:

- ➤ [New Exam]: click to create a new exam for the selected patient and open the Patient Info screen.
- ➤ [Activate Exam]: activate the currently selected exam (ended already) and enter the image scanning screen.
- > [iStation]: click to enter the iStation screen.
- ➤ [Exit]: click to exit the Review status, and return to the main screen.

## 10.2.8.2 Image Analysis

In the image analysis status, you can view, zoom, perform post processing and measurements, add comments and perform cine (multi-frame) 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 image analysis:
  - Press <Freeze> to exit and enter the real-time scanning status.
  - Press <Review> or click [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 below the thumbnail.
- Other operations

You can perform operations of cine review in image analysis status, for details, please refer to "6 Display & Cine Review".

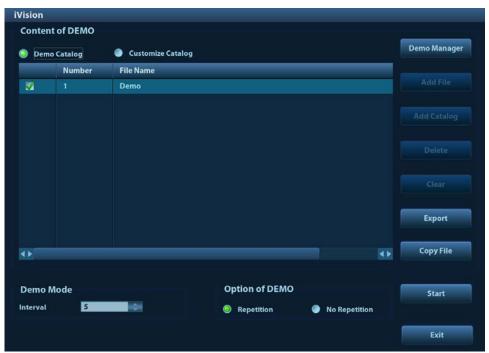
### 10.2.9 iVision

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] → [Key Config])
- 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 catalog

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 performing demonstration.

The system supports importing, deleting or clearing the data in demo catalog.

Click [Demo Manager] to operate:

to import data to demo catalog.

: 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 performing demonstration.

Operate the catalog or the files by the buttons on the right:

[Add File]: to add files to the file list.

[Add Catalog]: to add catalog of the files to the 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] to pop up the Browse dialogue box, select the path, and click [OK].

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.

## 10.2.10 Sending Image File

**NOTE:** Data saved this way can only be reviewed on the PC and cannot be restored to the ultrasound system.

- In the iStation screen, click ⇒; or, in Review screen, click [Send To] to send patient data to an external memory device, you can choose if reports are exported with images.
  - For external memory devices (e.g. USB memory devices or DVD-RW) or iStorage:
    - a) PC format transfer: JPG/ AVI, BMP/ AVI, TIFF/ AVI. Where a single-frame image is exported as JPG, TIFF or BMP, and the cine file exported as AVI.
    - b) DCM format transfer: DCM (including single-frame DCM and multi-frame DCM).
    - c) Cine zoom mode can be changed.
    - d) You can also select if to export report and select the report type.
  - For DICOM server, select the DICOM Storage or Print server.
  - For a video printer, send images to the video printer connected with the system. For a graph/ text printer, send the images to the default graph/ text printer.
  - Send the image to MedTouch/MedSight as necessary.

NOTE: the file sent to MedTouch/MedSight is transferred into PNG format, and the cine file is transferred into AVI format.

## 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

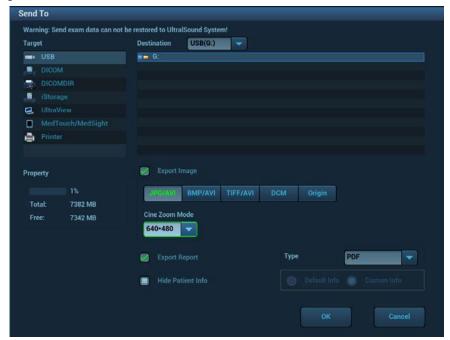
In iStation screen, select patient data, click or in the popped up menu to import or export patient information, images and reports from or to an external memory device. See the following figure:



You can select the destination and select whether to remove local data.

#### Export report via Send To

In iStation or Review screen, click [Send Exam] in the popped up menu to send patient data to an external memory device or iStorage, you can choose if reports are exported with images. See the figure below.



To export the report:

- (1) Check "Export Report" on the screen.
- (2) Select report type to be exported.
- (3) Click [OK] to confirm.

You can select paper size for the report print in the path: [Setup]-[Print].

#### Report printing

Use a connected graph/text printer to print a report.

For details on report relevant operations, please refer to [Advanced Volume].

# 10.4 iStation - Patient Data Management

The patient data include basic patient information, exam information, image files and reports. You can search, view, backup, send, restore or delete 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.

# 10.4.1 Viewing Patient Information

■ Data Source

Select the data source of patient data, and 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 [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].

# 10.4.2 Searching a Patient

- 1. Select the data source.
- 2. Set search conditions of Name, ID, DOB, Exam Date in the "Item" drop-down list.
- 3. Enter the keyword in accordance with the "Item" selected, and the system searches and displays the results in the patient list.
- 4. When you select a patient in the patient list, 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 an exam record, click [Delete Exam] to delete the record. However, you cannot delete patient data being printed, exported or sent, or delete the current exam.
- To delete an image, select the image first and then click in on the upper right side.

### ■ Backup/ Restore

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.

- [Backup Exam]: click to back up the selected patient data to the system-supported media.
- [Restore Exam]: click to import the patient data from an external media.

#### Send Exam

The system supports to send data to external memory devices, print or iStorage.

- Select the patient record, click [Send Exam] in the menu to send exam data or images of the selected record.
  - Send patient exam data to USB devices, DVD-RW/DVD+RW drive.
  - Send images to USB devices, disc, DICOM storage server, DICOM printer, video printer, text/ graph printer.
  - Send exam data with report to USB devices, DVD-RW/DVD+RW drive.
  - ➤ Format transfer is available when sending images to USB devices or disk.
  - Send to DICOMDIR: you can change the cine compression mode, and JPEG compression mode.
  - Press <Control> or <Shift> with <Set> key on the control panel to select more than one exam or image at one time.

#### 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 Exam

Select an exam that is paused within 24 hours, click [Continue 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 the deleted patient data, exam data and images. The system supports recovery of those 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.

- a) Select items to be recovered in the list.
- b) 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 Recycle Bin screen.

# 10.5 iStorage

iStorage is used to save image files and measurement reports to the remote PC server.

Open "[Setup]  $\rightarrow$  [Network]  $\rightarrow$  [iStorage]" to do the setting for iStorage.

- 1. Enter iStation screen, select one (or more than one) patient data or image in the local data source.
- 2. Click [Send Exam].
- 3. Select [iStorage] in the Send To dialogue box, and select the PC server on the right side.
- 4. Select PC transfer format if to send the report.
- 5. Click [OK] to start the sending.

# **10.6** Print

# 10.6.1 Print Setting

- Print Service Setting
- 1. Open the [Setup] → [Print], select an existed printer service in the list.
- 2. Select the printer type in the Property box.
- 3. Set printing properties.
- 4. Click [Save] to confirm the setting and exit the preset page.
- User-defined shortcut key for printing

To use <Print> key on the control panel of the system, you may need to:

- 1. Press the <Setup> key to show the Setup menu, click [System] item to open the [System Preset] screen, and click [Key Config] tab.
- 2. Click to select "Print" on the left side. Click to select desired print key on the right side.
- 3. Click [Save] to exit the preset and make the settings effective. Press the <Print> key on the control panel to print.
- Video output settings:

Open [Setup]  $\rightarrow$  [System]  $\rightarrow$  [Output], then select the image output mode: PAL or NTSC.

Open [Setup]  $\rightarrow$  [System]  $\rightarrow$  [General], then select the image storage area: image area and standard area.

# 10.6.2 Image Print

Image printing is mainly achieved by video printer, and for DICOM image printing, refer to DICOM chapter.

- 1. Select the desired image in iStation or Review screen.
- 2. Click printer in the upper right side of the image, and select the printer in the popped up dialogue box.
- 3. Click [OK] to start printing.

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

# 10.6.3 Report Print

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

- 1. Press <Report> to enter the report dialog box.
- 2. Select [Print] to print the report.

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

#### **Backup Files through DVD Drive** 10.7

The system supports DVD-RW/DVD+RW drive to write data in CD/DVD and to read data from CD/DVD in 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 [Backup Exam] in the popped up menu. Select the target drive in the Send To or Backup Patient Record dialogue box.
  - (3) Click [OK] or [Backup] to begin writing with the symbol displays



to pop up the Disc Option dialogue box. (4) After the writing process is completed, click and select [Eject] to eject the CD/DVD.

#### Tips:

- Writing data using "Send To" supports PC format transfer function, while CD/DVD written by "Backup" supports only system-relevant formats.
- symbol indicates that the input CD/DVD is damaged or with data of wrong The format.

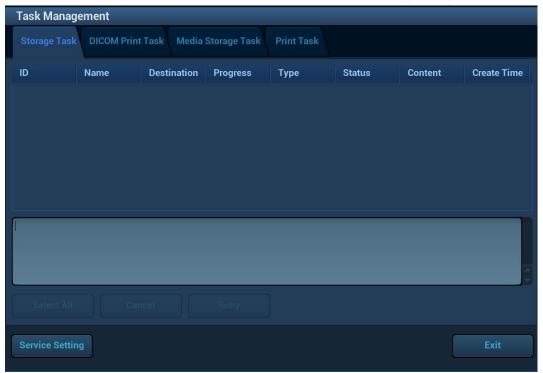
You can check the data writing procedure in patient task manager, for details, please refer to "10.8" Patient Task Management".



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 at the lower right corner of the screen to pop up the following dialogue box:



The system supports four 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)
  - Backup task (system-relevant format): select the exam to be backed up in iStation and click [Backup Exam].
  - Send to external devices (including disc and USB devices): select exam data or images in iStation or Review screen, click [Send Exam] or of the image.
  - iStorage task.
  - MedTouch/MedSight task.
- Print Task: displays image or report printing task.

In the Task Management dialogue box, patient ID, name, destination, progress, type, contents and task created time are displayed.

You can do the following operations:

- Click [Delete] to delete the task.
- Click [Retry] to retry the failed task.
- Click [Select All] to select all the tasks.
- Task Status

When there is/are task(s) undergoing, the task management icon displays as likely, you car click the icon to check the process.

When there is/are task(s) failed, the task management icon displays as \_\_\_\_\_, you can click the icon to check the failure reason.

When the task management icon displays as , it means no task is undergoing or failure.

■ DICOM Service Setting

In the Storage Task and DICOM Print Task page, click [Service Setting] to enter the DICOM service setting screen. For details, please refer to DICOM chapter.

Troubleshooting

If any serious error occurred like network disconnection or operation timeout, the system can try to reconnect the network. The interval time and maximum retries can be set, for details, please refer to DICOM chapter.

# 10.9 Administration

# 10.9.1 Access Setting

The system support two types of users: the system administrator and operator.

■ Administrator

The system administrator can view all patient data, such as patient information, image and report, etc.

Operator

The operator can only view the exam information saved in the system and operated by himself or herself, such as patient information, image and report, etc. The operator cannot view the exam data operated by others.

# 10.9.2 Setting Access Control

The system administrator can preset the access control, that is, if an operator has the right to access to the data in the system.

The access control only can be set by the system administrator.

Setting access control:

- 1. Open the "Admin" page through the path: [Setup]  $\rightarrow$  [System]  $\rightarrow$  [Admin].
- 2. If Enable User Account Control is selected, you need to have the authority before accessing the data. If unselected, you can access all the data without the authority.

# 10.9.3 System Login

If access control has been set by the system administrator, you can access the data in the system only after you log on the system.

You need to enter user name and password in the following cases:

- Before entering the system
- Changing user

You need to login again after system restart or dormancy.

- Log on the system:
- 1. The following dialogue box pops up:



- 2. Select the user name in the drop-down list of User Name.
- 3. Enter password and click [Login].
- To change user:
- 1. To log out the current user and change to another user, click at the lower right corner of the screen to pop up the dialogue box:
- 2. Click [Change User] to pop up the Login dialogue box.
- 3. Enter the user name and password in the field box.
- Lock the system
- 1. Click the at the lower right corner of the screen to pop up the dialogue box.
- 2. Select [Lock Machine], and the system is locked; you have to log on before using the system.

## 10.9.4 Add/ Delete a User

The system administrator can add and delete a user, while the operator can't.

#### Add a User

Premise: you must log on the system as the system administrator. If not, you will be required to enter administrator name and password before the setting.

- 1. Open the "Admin" page through the path: [Setup] → [System] → [Admin].
- 2. Click [Add] to pop up the following dialogue box.



- 3. Enter user name.
- 4. Enter the password and the confirmed password.
- 5. Set the user role in the drop-down list: administrator or operator.
- 6. Click [OK] to confirm the setting and exit the dialogue box, then the new user will appear on the User List.

#### Delete a User

Premise: you must log on the system as the system administrator. If not, you will be required to enter administrator name and password before the setting.

- 1. Open the "Admin" page through the path: [Setup]  $\rightarrow$  [System]  $\rightarrow$  [Admin].
- 2. Select the user to be deleted in the User List, click [Delete] to delete the selected user.

# 10.9.5 Modify Password

The system administrator can modify password of all users. The administrator password by factory is empty; you can set the password for it.

The operator can only modify his/her own password. There are two ways to modify password: modify it on "Admin" page or on "Session Manage" dialogue box.

- "Admin" page (administrator can modify the password)
- 1. Open the "Admin" page through the path: [Setup] → [System] → [Admin].
- 2. Select the user name to be modified in User List, click [Change Password] to open the dialogue box (see the figure below).



- 3. Enter new password and confirm the password, then click [OK].
- Session Manage page (general operator and administrator can modify the password).

When the user has logged on the system, you can see at the lower right corner of the screen.

- 1. Click at the lower right corner to pop up the Session Manage dialogue box, on which you can see the current user's information.
- 2. If you want to modify the current password, click [Change Password] to pop up the Change Password dialogue box.
- 3. Enter the previous and the new password in the dialogue box.
- 4. Click [OK] to exit.

# 11 DICOM/HL7

**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.

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                            |

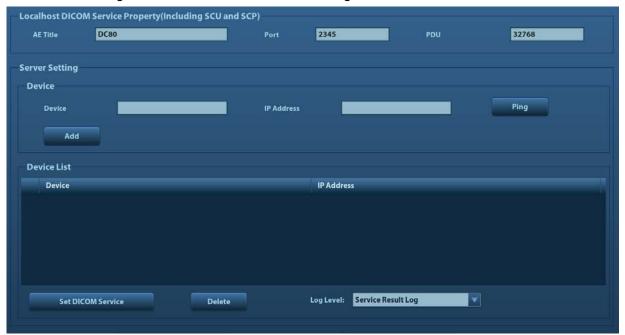
# 11.1 DICOM Preset

## 11.1.1 Network Preset

Refer to "12.9 Network Preset" for details.

## 11.1.2 DICOM Local Preset

- 1. Enter the DICOM local preset screen through the path: [Setup]->[DICOM/HL7].
- 2. Enter AE Title, Port, and PDU according to the actual situation, and then click [Save] to exit the screen, setting items are introduced in the following.



| Name      |   | Description   |
|-----------|---|---|
|           | AE Title  | Application Entity title.   |
| DICOM     | Port  | DICOM communication port.   |
| Local PDU | Maximum PDU data package size, 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. |   |
|           | Device  | Name of the device supporting DICOM services.   |
|           | IP Address  | IP address of the server.   |
|           | Ping  | You can ping the other machines after you entered the correct IP address.                       |
| Server    |   | Besides, you can select a server in the Device list to ping it.                                 |
| Setting   | Device List   | Displays the added device.  |
|           | Set DICOM<br>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.                                     |

## ■ 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.

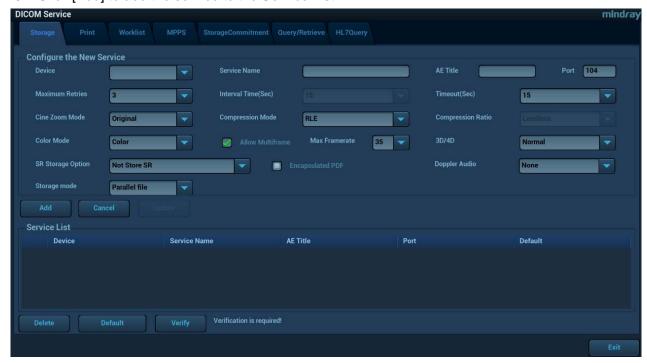
## 11.1.3 Service Preset

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 DICOM Service screen, click [Storage] page tab to enter the Storage page.
- 2. Select device, enter the right 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   |
|-----------------------------|------------------|---|
|                             | 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.  |
| Configure<br>New<br>Service | AE Title         | Application Entity title, here, it should be consistent with that of the storage server.  |
| Gervice                     | 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.  |
|                             | Interval Time(s) | Interval time that the system retries a connection.   |

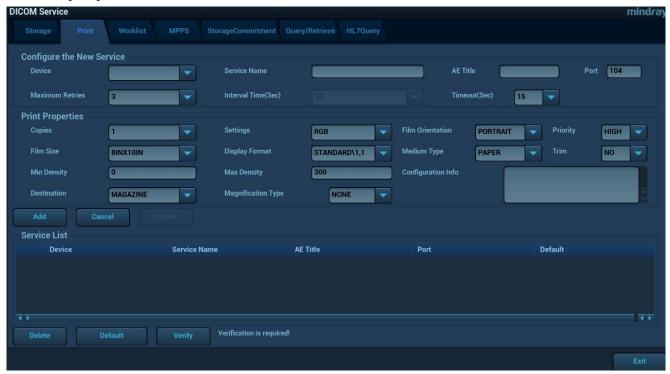
|              | Name              | Description   |
|--------------|-------------------|---|
|              | Timeout           | Refers to the amount of time after which the system will stop trying to establish a connection to the service.                          |
|              | Cine Zoom Mode    | Select the cine zoom mode during image file storage.  |
|              | Compression Mode  | Select the compression mode: uncompressed, RLE, JPEG, and JPEG2000.   |
|              | Compression Ratio | Select the JPEG compression ratio: lossless, low, medium, and high.   |
|              | Color Mode        | Select the color mode.  |
|              | Allow Multiframe  | If SCP supports this function, then select it.  |
|              | Max Frame Rate    | Set the frame range of transferring cin file into DCM multi-<br>frame file.   |
|              | 3D/4D             | Set the 3D/4D image transfer mode.  |
|              | SR Storage Option | To enable or disenable structured reporting sending.  |
|              | Encapsulated PDF  | Select if to encapsulate PDF format report in DICOM standard.   |
|              | Doppler audio     | Set to save the audio of PW mode.   |
|              |                   | Set the storage mode for image and cine file:   |
|              | Storage mode      | Parallel file: save the current file, and is ready for the storage of the next file.  |
|              |                   | Parallel frame: send the current frame, and is ready for sending the next frame.  |
|              | 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. |
|              | Delete            | Click to delete the selected service in the service list.   |
| Service List | 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.   |

## Tips:

- 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. Please refer to the electronic file DICOM CONFORMANCE STATEMENT of the SCP to check whether SCP supports or not. Do not select these compression modes if the storage server doesn't support them.

## 11.1.3.2 Print Service Preset

- 1. On DICOM Service screen, click [Print] page tab to enter the Print page.
- 2. Select device, enter the right 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   |
|---------------------|-------------------|---|
|                     | Device            | After you set the server (s) in DICOM Preset screen, the name (s) will appear in the drop-down list, select the name of the print server. |
|                     | Service Name      | Default is xxx-Print, user-changeable.  |
| Configure<br>New    | AE Title          | Application Entity title, here, it should be consistent with that of the print server.  |
| Service             | Port              | DICOM communication port, 104 is default. Here, the port should be consistent with that of the print server port.                         |
|                     | Maximum Retries   | Set the maximum retries.  |
|                     | Interval Time (s) | Interval time that the system retries a connection.   |
|                     | Timeout           | Refers to timeout during association establishment.   |
|                     | Copies            | Refer to copies of printed files. You can select among 1 through 5, or directly enter the numeral.  |
| Print<br>Properties | 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.   |

|                 | Name               | Description   |
|-----------------|--------------------|---|
|                 | 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).                                   |
|                 |                    | Select how the printer magnifies an image to fit the film.  |
|                 |                    | Replicate: interpolated pixels belong to duplicate of adjacent pixels);   |
|                 | Magnification Type | Bilinear: interpolated pixels are generated from bilinear interpolations between adjacent pixels;   |
|                 |                    | Cubic: interpolated pixels are generated from cubic interpolations between adjacent pixels;   |
|                 |                    | None: without interpolation.  |
|                 | 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.           |
|                 | Delete             | Click to delete the selected service in the service list.   |
| Service<br>List | Default            | Select an item in the service list, click [Default] and you can see "Y" in the Default column.  |
| -5-             | Verify             | Click to verify if the two DICOM application entities are normally connected.   |

### 11.1.3.3 DICOM Worklist Preset

- 1. On DICOM Service screen, click [Worklist] page tab to enter the Worklist page.
- 2. Select device, enter the right AE Title, port, etc.
- 3. Click [Add] to add the service to the Service List.

DICOM Worklist service parameters are similar to those described in DICOM Storage Preset, please refer to "11.1.3.1 Storage Service Preset" for details.

## 11.1.3.4 MPPS Preset

- 1. On DICOM Service screen, click [MPPS] page tab to enter the MPPS page:
- 2. Select device, enter the right AE Title, port, etc.
- 3. Click [Add] to add the service to the Service List.

DICOM MPPS service parameters are similar to those described in DICOM Storage Preset, please refer to "11.1.3.1 Storage Service Preset" for details.

## 11.1.3.5 Storage Commitment Preset

- 1. On DICOM Service screen, click [Storage Commitment] page tab to enter the Storage Commitment page.
- 2. Select device, enter the right AE Title, port, etc.
- 3. Click [Add] to add the service to the Service List.

Special setting item for DICOM Storage Commitment service is Associated Storage Service, as described in the following; other parameters are similar to those described in DICOM Storage Preset, please refer to "11.1.3.1 Storage Service Preset" for details.

| Name                          | Description   |
|-------------------------------|---|
| Associated Storage<br>Service | The associated storage server should be preset before storage commitment, only after the exam is sent out, can storage commitment be created. |

## 11.1.3.6 Query/Retrieve Preset

- 1. On DICOM Service screen, click [Query/Retrieve] page tab to enter the Query/Retrieve page.
- 2. Select device, enter the right AE Title, port, etc.
- 3. Click [Add] to add the service to the Service List.
- 4. Click [Exit] to confirm the preset and exit the page.

DICOM Query/Retrieve service parameters are similar to those described in DICOM Storage Preset, please refer to "11.1.3.1 Storage Service Preset" for details.

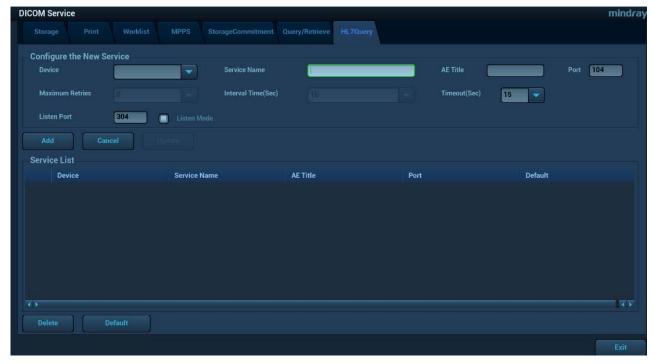
## 11.1.3.7 HL7 Query Service Preset

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]→[HL7] 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   |
|--------------------------|--------------------|--|
|                          | 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. |
|                          | DICOM 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.   |
| Configure<br>New service | Port               | DICOM communication port, 104 by default. Here, the port should be consistent with that of the HL7 server port.                                      |
|                          | Maximum Retries    | Reserved feature.  |
|                          | Interval Time(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.   |

| Name         |                       | NOTE   |
|--------------|-----------------------|--|
|              | Monitoring mode       | The ultrasound device starts using the monitoring port to receive the date after the monitoring mode is enabled.   |
|              |                       | In monitoring mode, the ultrasound system sends the information as the user end; it monitors the result via the port as the service end.                                   |
|              |                       | In non-monitoring mode, the ultrasound system sends the query information and receives the query result as the user end; the monitoring mode is not chosen by default.     |
|              | Monitoring port       | It is the port to receiving the data for the ultrasound system after the monitoring mode is enabled. Here, the port should be consistent with that of the HL7 server port. |
|              |                       | See the server settings for the monitoring port.   |
|              | 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.                                    |
|              | Delete                | Click to delete the selected service in the service list.  |
| Service list | To set default server | Select an item in the service list, click [Default] and you can see "Y" in the Default column.   |

# 11.2 Verify Connectivity

If you want to verify connectivity (it is not a must), you can click [Verify] button on Storage, Print, Worklist, MPPS, Storage Commitment, and Query/Retrieve pages respectively.

If the verification succeeded, the system prompts "xxx Verify Succeed". Otherwise, it prompts "xxx Verify Failed".

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

#### Tips:

Not all the SCPs can support verification; please consult SCP belongings to confirm whether SCP can support this service. If not, the verification won't pass.

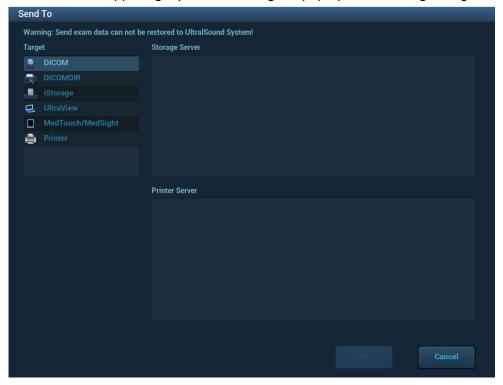
# 11.3 DICOM Services

If you completed all DICOM presets on DICOM Service Preset screen. Now you are ready for Storage, Print, Worklist, MPPS, Storage Commitment, and Query/Retrieve applications.

# 11.3.1 DICOM Storage

DICOM Storage is used to send image (s) to DICOM storage server for storage.

- Send image on iStation/Review/main screens
  - (1) Select image(s)
  - Press <iStation> on the control panel to open the iStation screen, 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, then click to select a thumbnail or several thumbnails. Or,
  - Press <Review> on the control panel to enter the Review screen, click to select a thumbnail or several thumbnails. Or,
  - On the main screen, select a thumbnail or several thumbnails.
  - (2) Click at the upper right part of the image to pop up the following dialogue box.



- (3) 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.
- (4) Click [OK] to start the sending.
- To send images by shortcut key

You can save single frame image or multi-frame images to DICOM server while saving to hard drive by shortcut key. Procedures are described as follows:

- (1) Define the key:
  - a) Open Key Config page via "[Setup] → [System] → [Key Config]".
  - b) Assign functions to the desired keys: in Key Config page, select a free key or footswitch at the left side, then select the corresponding key on the right side:
  - c) Click [Save] to confirm the preset and exit.
- (2) Set a default storage server:
  - a) Enter the DICOM Service Preset screen via "[Setup] → [DICOM] → [Set DICOM Service]".
  - b) Select a storage server in the Service List and click [Default]; you can see "Y" is marked in the Default column.
  - c) Click [Exit] to exit the page and return to Setup menu, then click [Save] on the Setup menu to make the preset to take effect.
- (3) Press the key to send DICOM storage.
- To send image for storage after an exam ends
  - (1) Open "[Setup] → [System] → [General]", and then check
     Sending/printing after End Exam in the Patient Info area.
  - (2) Set a default storage server as steps above.
  - (3) After finishing resets, you can perform image scanning, each time you press <End Exam> on the control panel, the system will send the image to the default DICOM storage server for storage.

## 11.3.2 DICOM Print

DICOM Print is used to send image(s) to DICOM print server for printing.

- Print image in iStation/Review/main screens
- 1. Select image(s), operations are the same with DICOM storage.
- 2. In the Send To dialogue box, select a DICOM print server. (For the dialogue box, please refer to DICOM Storage).
- 3. Click [OK] to begin the printing.
- To send images by shortcut key

You can send single frame image to DICOM print server while saving to hard drive by shortcut key.

- 1. Define the short key:
  - a) Open Key Config page via "[Setup] → [System] → [Key Config]".
  - b) Assign functions to the desired keys: in Key Config page, select a free key or footswitch at the left side, then select "Save Image to Hard Disk and Send to DICOM Printer" on the right side.
  - c) Click [Save] to confirm the preset.
- 2. Set a default printer server. For details, see Chapter 11.1.3.2 Print Service Preset.
- 3. Press Key1 (defined as shortcut key for Save Image to Hard Disk and Send to DICOM Printer), the system captures the current screen and sends it to the print server.

- To print image for storage after an exam ends
  - (1) Open "[Setup] → [System] → [General]", and then check
     Sending/printing after End Exam in the Patient Info area.
  - (2) Set a default print server. For details, see Chapter 11.1.3.2 Print Service Preset.
  - (3) After finishing presets, you can perform image scanning, each time you press <End Exam> on the control panel, 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 DICOM Worklist/HL7 Enquiry.

## 11.3.4 MPPS

MPPS is used to send exam state information to the configured server. This will facilitate the other systems to obtain 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 to the DICOM storage server.

Before storage commitment, you should set the default storage commitment server.

- Storage commitment after sending images on iStation screen.
- 1. Open iStation screen.
- Select an exam (a suspended exam or an exam not active) (image (s) is/are stored in the exam record), click [Send Exam] button in the popped up menu to open the Send To dialogue box.
- 3. 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.
- 4. Click [OK] to start the sending. The system will send all the images stored in the exam record to the storage server, meanwhile, it will send storage commitment to storage commitment server.
- To send storage commitment after an exam ends
- Open [Setup] → [System] → [General], and then check
   Sending/printing 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. After finishing presets, you can perform image scanning, each time you press <End Exam> on the control panel, the system will send the image to the default DICOM storage server for storage and send storage commitment to storage commitment server.

If images are successfully sent to the storage server, the storage commitment server will return information about the successful image storage. In the iStation screen, you will see there is a tick " $\sqrt{}$ " marked in the list below.

Tips:

Storage commitment is confined to the whole exam; not each image sending can be indicated.

NOTE:

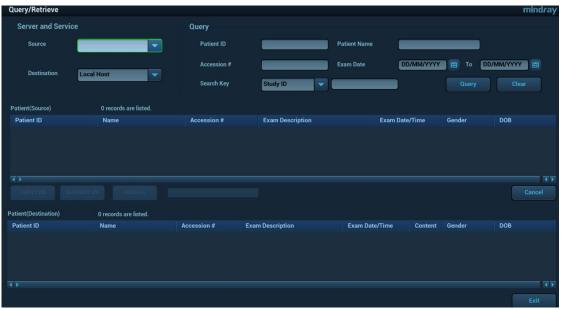
Multi-frame storage is not allowed if "Allow Multiframe" is not selected ([Setup]  $\rightarrow$  [DICOM/HL7]  $\rightarrow$  [Set DICOM Service]  $\rightarrow$  "Storage"). Even if there is multi-frame file in the exam to be sent, only single-frame image storage will be performed, and after the storage is completed, there is no " $\sqrt{}$ " marked in the list of the iStation screen.

## 11.3.6 Query/Retrieve

The query/retrieve function is employed to query and retrieve the patient exam records in a designated server.

After setting the DICOM query/retrieve server, you can perform the query/retrieve function in iStation screen.

- 1. Open iStation screen: press <iStation> on the control panel; or, press <Info> on the control panel, and then click [iStation] on the Patient Info screen.
- 2. Click [Query/Retrieve] to open the screen.



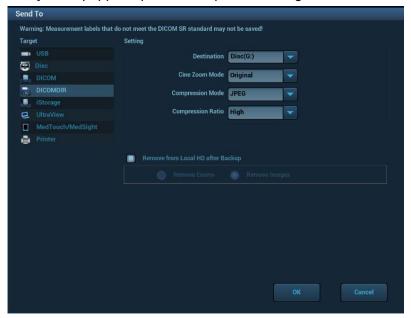
- 3. Select the server in "Server and Service" area (both the source and the destination).
- 4. Enter the query information, such as Patient ID, Patient Name, Accession #, Exam Date, or key words.
  - Click [Clear] to empty the entered query information.
- 5. Click [Query], the system performs the query and lists out the results into the patient (source) list
  - You can perform further guery basing on the results by entering new guery 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 into the local machine.
- 8. Click [Exit], you can see the retrieved patient records are listed in the iStation screen.

# 11.4 DICOM Media Storage

Patient data in the ultrasound system can be saved into the external media in the format of DCM; meanwhile, DCM files can be accessed in the ultrasound system.

## **Media Storage**

- 1. Select patient record (s) in the iStation screen.
- 2. Click [Send Exam] in the popped up menu to open the dialogue box.



- 3. Select DICOMDIR from the [Target] volume. Select destination, DICOM Format as well as compression mode in DICOMDIR.
- 4. Click [OK] to begin the storage.

There should be no DICOMDIR/DCMIMG/IHE\_PDI files in the external storage media of the same name with the one being backed up; otherwise, the backup can't be preceded. Besides, make sure there is enough storage space; otherwise, the backup may fail due to space shortage.

## 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 DICOM format data are saved to external media, you can restore the data to the ultrasound system.

- 1. Connect the external media with DCM files to the system.
- 2. In iStation, review the data stored in the external media.
- 3. Select the data to be restored in iStation.
- 4. Click in the iStation screen.

NOTE: Only the system accessible media can be selected.

# 11.5 Structured Report

DICOM OB/GYN Structured report, Cardiac Structured report, Vascular Structured report and Breast Structured report are supported by this system, they can be sent together with the exam only.

- Send image and structured report for storage in iStation screen
  - (1) Select "Attach SR When Store Images" in the DICOM Storage preset page, for details; please refer to "11.1.3.1 Storage Service Preset".
  - (2) Create new patient information or load scheduled the patient information.
  - (3) Perform measurements.
  - (4) Save the image (s).
  - (5) End the exam.
  - (6) Open the iStation screen, select the patient exam, and click the corresponding [Send Exam] button in the popped up menu to open the Send To dialogue box.
  - (7) 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.
  - (8) Click [OK], you can check for the result in the DICOM Task Management dialogue box. After successful storage of both image and structured report, you can see the storage commitment mark "√" in the list below in the iStation screen.

**NOTE:** Only PACS system from Medstreaming company (http://www.medstreaming.com/default.aspx) supports the function of sending self-defined measurements by DICOM SR.

# 11.6 DICOM Task Management

DICOM Task Management is used to view task progress or manage tasks after sending images for storage, printing, or media storage. For details, please refer to "10.8 Patient Task Management".

# 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 devices.

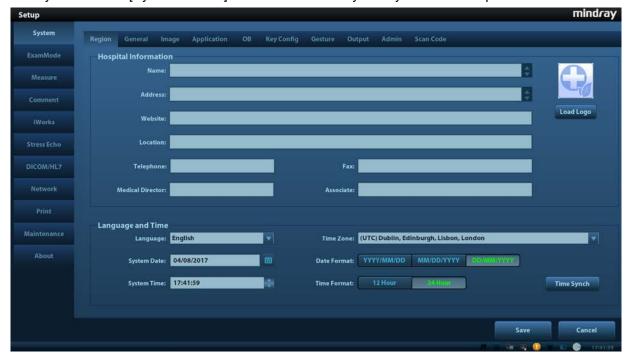
**△ CAUTION**:

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 the preset data.

- To enter Setup:
  - Press the <F10> key on the keyboard to enter setup menu.
- To exit Setup:
  - Select [Save] on the Setup menu, and parameter settings is saved.
  - Select [Cancel] on the Setup menu or press <ESC> to close the Setup menu.

# 12.1 System Preset

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



| Page    | Description  |
|---------|--|
| Region  | To set the hospital name, language, time zone, time format and system date/time. |
| General | To set patient information, exam setup, system dormancy, display and so on.      |
| Image   | To set general parameters in imaging modes.                                      |

| Page        | Description   |
|-------------|---|
| Application | To set the measure ruler, measure setting, follicle method, comment setting and so on.              |
| ОВ          | To set the relevant information about fetal gestational age, fetal growth formula and fetal weight. |
| Key Config  | To assign functions to footswitch and the user-defined keys.  |
| Gesture     | Preset the gesture on the touch screen.   |
| Output      | Set the output format, the range and the resolution for the image.                                  |
| Admin       | To set the user account control relevant information.   |
| Scan Code   | To set the code parameters for barcode reader.  |

# 12.1.1 Region

| Item                 | Description  |
|----------------------|--|
|                      | To set the hospital relevant information like name, address, telephone and so on.  |
| Hospital Information | Logo loading:  |
|                      | NOTE: For a better display effect, please try to use a BMP image with 400*400 pixels and 8/24/32 bit depth.  |
| Language             | To select a language for the system.   |
| Time Zone            | To select the time zone.   |
| Time Format          | To select the time format.   |
| Date Format          | To set the date format.  |
|                      | To set the date for the system.  |
| System Date          | Posit the cursor into the "System Date" field, and enter the   |
| System Date          | data through the keyboard; or, click the icon to select the date.  |
| System Time          | Move the cursor onto the corresponding field, enter the time manually through the keyboard; or, move the cursor onto the time segment and press <set>, then increase or decrease the certain value by rotating the multifunctional knob or clicking the icons at the right side.</set> |
| Time Sync            | To assign a time server and make the time of the ultrasound machine to be consistent with the server.  |

## **12.1.2** General

Open the page via [Setup] -> [System] -> [General].

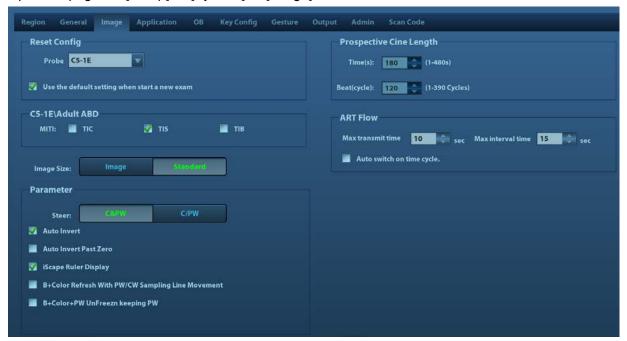


| Туре                  | Item                            | Description   |
|-----------------------|---------------------------------|---|
|                       | Info displays in image banner   | To select if to display the available patient information items on the screen.                      |
| Patient Info          | H&W Unit                        | To set the unit for patient height and weight.  |
|                       | Surface Formula                 | To set the surface formula.   |
| Freeze<br>Setting     | Enter after the freeze          | To set the system state after the image is frozen.  |
| Exam Setup            | Status after exam ends          | To set the system status when an exam ends.   |
| Patient<br>Management | Sending/printing after End Exam | Select if to automatically archive the exam data to DICOM server for storage/print.                 |
| Display               | Main screen preset              | 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. |
|                       | Touch screen preset             | After selection, the system restores the touch screen settings back to factory.                     |

| Туре            | Item         | Description  |
|-----------------|--------------|--|
|                 | Screen Saver | Select the different saver methods to the system.  |
| Screen<br>Saver |              | After enabling the screen saver, check "Mindray" to select the image from the system. Or click [Review] 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.                            |
|                 |              | The system enters screen saver automatically if the system waiting time exceeds the screen saver already set and standby time.           |

# 12.1.3 Image Preset

Open the page via [Setup] -> [System] -> [Image].



| Туре          | 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 Use the default setting when start a new exam. |
| MITI          | /          | To set the TIC, TIS and TIB value of the selected probe.   |
| Image storage | Image size | Set the standard for saving the image or using the digital/graph printer.                                      |

| Туре  | Item  | Description   |
|-------|---|---|
|       | Steer   | To set the steer mode in B+ Color +PW imaging mode. C&PW: select to adjust the sample volume in color mode and sample line in PW mode together. C/PW: select to adjust the sample volume in color mode and sample line in PW mode individually. |
|       | Auto Invert                                       | The spectrum can automatically invert when the color flow is steered to a certain angle, thus accommodating operator's habit of distinguishing flow direction.  |
| Image | Auto Invert Past Zero                             | Set smart invert mode of Color Map.   |
|       | 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.   |
|       | B+Color+PW UnFreezn keeping PW                    | To set whether to retain PW images when unfreezn under B+Color+PW mode.   |
|       | iScape Ruler Display                              | To set if to display the iScape ruler on iScape imaging mode.   |

# 12.1.4 Application

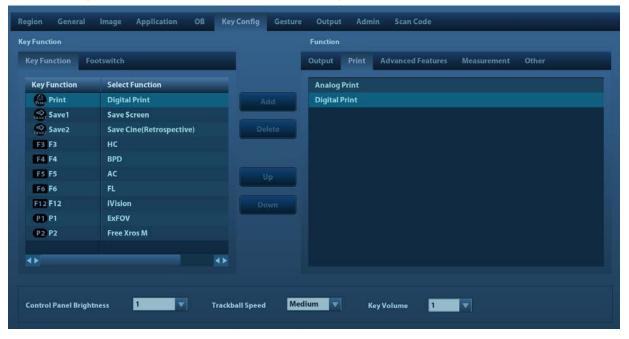
Open the page via [Setup] -> [System] -> [Application]. Through the page, you can set the measure ruler and relevant information. For details, please refer to the Operator's Manual [Advanced Volume]

## **12.1.5 OB Preset**

Open the page via "[Setup] -> [System] -> [OB]". Through the page, you can set the gestational age formula, fetal growth formula, fetal weight formula and the relevant information. For details, please refer to the Operator's Manual [Advanced Volume].

# 12.1.6 Key Configuration

Open the page via "[Setup] -> [System] -> [Key Config]".



## Key function setting

You can set the functions for <Print>, <Save1>, <Save2>, F3-F6, F12, P1 and P2.

To assign a function to a key:

- a) Click to select the desired key in the Key Function column at the left side of the page.
- b) Click to select a function in Function area. You can see the available functions selected at the right side.
- c) Click [Save] to complete function setting.

### ■ Footswitch function setting

You can assign a function to the left/mid/right key of footswitch. Setting method is similar to key function setting, please refer to the above steps for setting.

#### Other Settings

| Item            | Description   |
|-----------------|---|
| Key Brightness  | To set the brightness for the keys.                   |
| Key Volume      | To set the key volume in 3 levels, 0 means no sound.  |
| Trackball Speed | To set the trackball speed when moving the trackball. |

## **12.1.7 Gesture**

The gesture setting is the same with the settings of other keys. See Chapter 12.1.6 Key Configuration for details.

# 12.1.8 Output



| Туре               | Item  | NOTE   |
|--------------------|---|--|
| AVI encode         | Image quality   | Set the image quality of unloaded AVI. The system unloads 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 unloading format of the AVI. The system unloads according to the settings.   |
|                    |   | If checking "Mac OS", saving CIN files to USB flash drive as "MP4 Video".  |
| Analog output mode | Select the format to output/separate the video format: NTSC or PAL. |  |

## 12.1.9 Admin

For details of access control, please refer to 10.9 Administration.

## 12.1.10 Scan Code

For details of scan code preset, please refer to 17.2Appendix E Barcode Reader

## 12.2 ExamMode Preset

Open "[Setup] → [ExamMode]" to enter the screen.



You can assign available exam modes for probes.

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

On the right side of the screen, you can view the current exam modes supported by the probe. On the left side, you can view all the available exam modes in the exam library for 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.</li>
- Click [Delete] to delete a user-defined exam in the Exam Mode Library area.
- Click [Default] to set a selected exam mode as the default exam mode. The default exam mode is marked by a " $\sqrt{\ }$ " in the top-left corner.

# 12.3 Measure Preset

For details about Measure Preset, please refer to the [Advanced Volume].

## 12.4 Comment Preset

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



- Add comments: directly enter user-defined comment texts, or select comment texts for the comment library.
  - 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 in the drop-down list beside "Available Items", all items 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 userdefined 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 [<].

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

# 12.5 iWorks Preset

For details, please refer to Appendix D iWorks.

# 12.6 Stress Echo

For details, please refer to Chapter 5.14 Stress Echo.

## **12.7 DICOM/HL7**

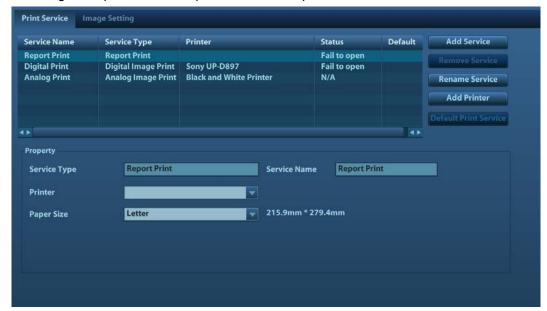
For details, please refer to Chapter 11 DICOM/HL7.

# 12.8 Print Preset

The screen is used to set up for printer and image print.

Printer setting

The settings of a printer include print service and print driver.



- Print Service Setting
  - Add Service: click to begin print service adding.
  - > 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 the property of print services.

For details about adding printer, please refer to "3.6.3 Installing a Graph/Text Printer".

Image Settings

You can set brightness, contrast and saturation of image printing, or you can use the default value.

# 12.9 Network Preset

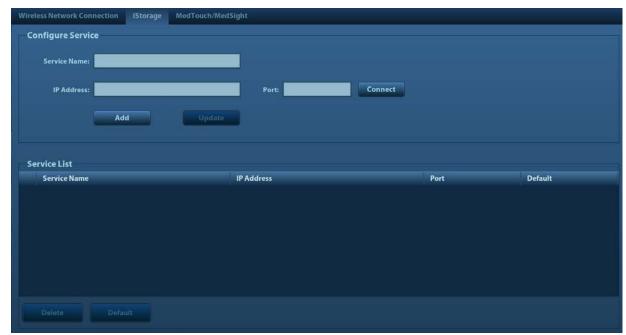
## 12.9.1 Wireless Network Connection

You can set the ultrasound system as a hotspot. When other devices (with available wireless network function) are connected to the system, DICOM, iStorage and network print function can be implemented this way.

Turn on hosted network function:

- 1. Select [Wireless Network Connection] page in Network preset screen.
- 2. Confirm the Wi-Fi is enabled: you see [Disable Wifi] in the screen.
- 3. Enter the name and password for this hotspot in the Hosted Network box.
- 4. Click [Start] to enable the function.
- 5. Use other devices to search and connect to this network.

# 12.9.2 iStorage Preset



| 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 in the service list. |  |

- Add a 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.

# 12.9.3 MedTouch/MedSight Preset

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

# 12.10 Maintenance

In the Setup menu, select [Maintenance] enter the screen.

# 12.10.1 Option

Press [Option] to enter the option page. In Option list, the system lists out all the system supported options and the installation status (Not installed or installed).

- Install and uninstall
  - Click [Install] to begin the installation of a disabled option.
  - Click [Uninstall] to begin the un-installation of an already installed option.

Please contact Mindray Customer Service Department or 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 Other Settings

|       | Item                   | Description   |
|-------|------------------------|---|
|       | Export Log             | Export the log.   |
|       | Self-Test              | Perform system self-test and restart the machine.   |
| Setup | 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<br>Installment  | Entrance of prepay of payment function.   |
|       | Start/Stop<br>WinProxy | Cursor debug interface.   |

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

# 12.11 System Information

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

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

The "About Detail" screen displays the system software version and versions of other devices. You cannot edit the information but only view them. The information varies depending upon the system configurations and version.

# 13 Probes and Biopsy

## 13.1 Probes

**NOTE:** For details of storage time and condition for disinfected probes and brackets, please refer to Technical standard for Disinfection of Medical and Health Structures.

The system supports the following probes:

|         | cappoint and remonning proposit |         |  |
|---------|---------------------------------|---------|--|
| C7-3E   |                                 | CB10-4E |  |
| L12-3E  |                                 | V11-3E  |  |
| L14-6NE |                                 | SC5-1E  |  |
| L14-6WE |                                 | C11-3E  |  |
| V11-3BE |                                 | DE10-3E |  |

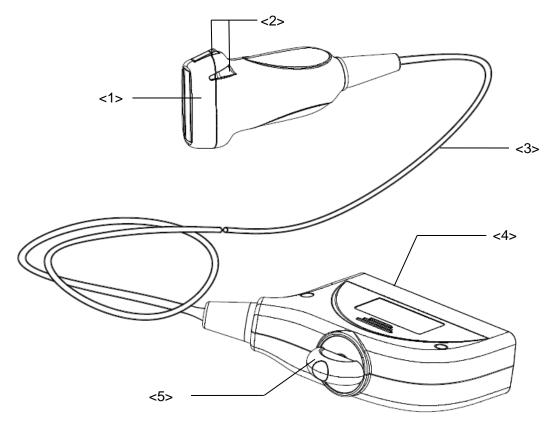
| P4-2NE | P10-4E  |  |
|--------|---------|--|
| P7-3E  | P7-3TE  |  |
| CW2s   | CW5s    |  |
| SP5-1E | L16-4HE |  |
| D6-2NE | DE11-3E |  |

| D7-2E   | C6-2GE  |  |
|---------|---------|--|
| C5-1E   | V11-3HE |  |
| L14-5WE | L9-3E   |  |
| D8-2E   |         |  |

For details of probe P7-3TE, please refer to P7-3TE accompanying manual

## 13.1.1 Probe Functions by Part

The basic structures and corresponding functions of probes are basically the same; the following will take probe L14-6NE as an example.



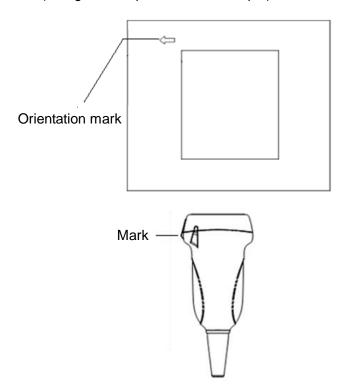
| No. | Name                                       | Function  |
|-----|--|---|
| <1> | Probe head                                 | Converts the electrical signal into an ultrasonic signal, focusing the sound beams in a given direction; meanwhile, it receives the reflected ultrasonic signal and converts 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.   |
| <5> | Lock handle                                | Locks the connector 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

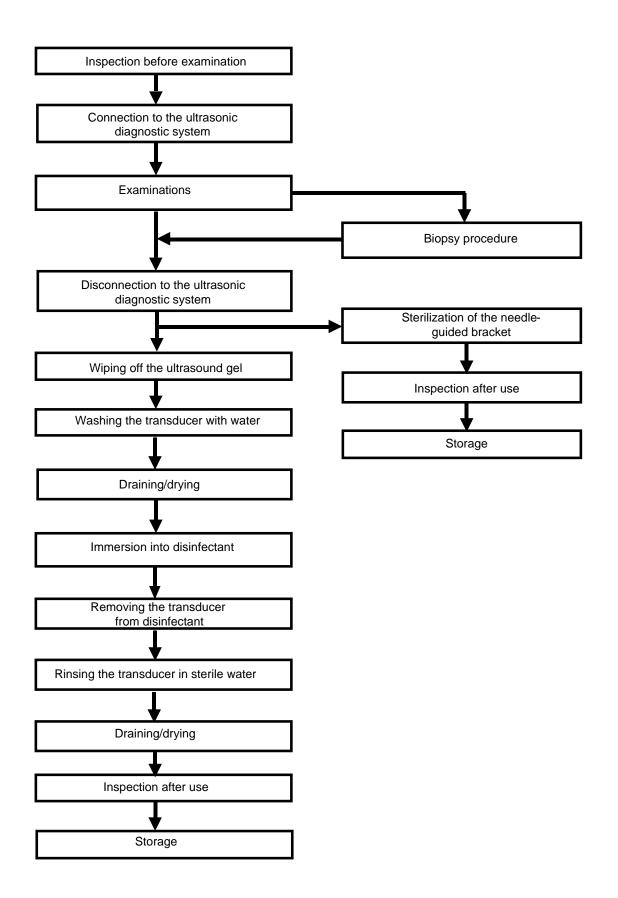
The orientation of the ultrasound image and the probe are shown as below. The "Mark" side of the ultrasound image on the monitor corresponds to the mark side of the probe. Check the orientation before the examination (Using a linear probe as an example).



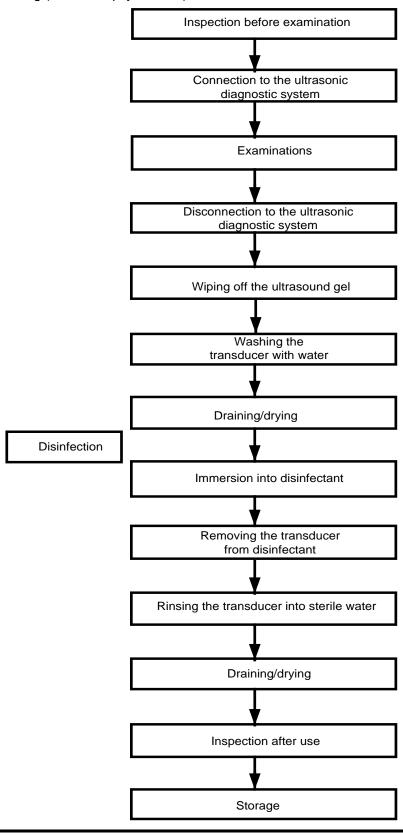
## 13.1.3 Procedures for Operating

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):



 $\triangle$ WARNING:

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 become a source 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

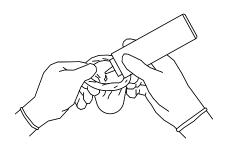
E-mail: info@civco.com http://www.civco.com

## CAUTION:

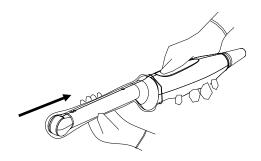
- 1. Be sure to cover the probe with a new (unused) probe sheath to prevent infection during examination. If the package of a probe sheath is open or broken, the sterilization of the probe sheath may not be sufficient. DO NOT use such a probe sheath.
- 2. The cover contains natural rubber latex and talc that can cause allergic reactions in some individuals.
- 3. DO NOT use an expired probe sheath. Before using a probe sheath, verify whether the term of validity has expired.

Method (for reference only):

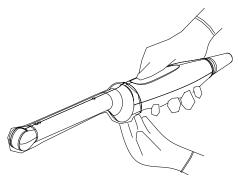
 Place an appropriate amount of gel inside the sheath or on the probe acoustic lens. Poor imaging may result if no gel is used.



 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.



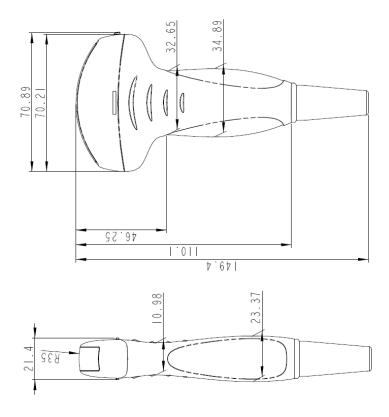
3. Secure the sheath with the enclosed elastic bands.



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.

| Model   | Length(mm) | Width(mm) | Height(mm) | Cable Length(mm) |
|---------|------------|-----------|------------|------------------|
| C5-1E   | 109.5      | 76.7      | 28         | 1950±50          |
| C6-2GE  | 115        | 39.4      | 21         | 2730±50          |
| C7-3E   | 110        | 71        | 23         | 1950±50          |
| C11-3E  | 94         | 33        | 25         | 1950±50          |
| SC5-1E  | 110        | 81        | 28         | 2200±50          |
| CB10-4E | 324        | 39        | 35         | 2260±50          |
| V11-3E  | 317        | 41        | 33         | 1950±50          |
| V11-3BE | 319        | 64        | 32         | 1950±50          |
| V11-3HE | 320        | 38        | 33         | 1950±50          |
| L9-3E   | 101        | 58        | 23         | 1950±50          |
| L12-3E  | 102        | 61        | 24         | 1950±50          |
| L14-5WE | 98         | 66.4      | 25.5       | 1950±50          |
| L14-6NE | 102        | 61        | 24         | 1950±50          |
| L14-6WE | 102        | 70        | 25         | 1950±50          |
| L16-4HE | 77.8       | 34.6      | 11.5       | 2730±50          |
| P4-2NE  | 102        | 38        | 30         | 1950±50          |
| P7-3E   | 102        | 38        | 30         | 1950±50          |
| P7-3TE  | 1402       | 59        | 60         | 1600±50          |
| P10-4E  | 83         | 29        | 20         | 1950±50          |
| SP5-1E  | 102        | 38        | 30         | 2200±50          |
| D6-2NE  | 122.7      | 73.1      | 51.5       | 2400±50          |
| D7-2E   | 117.4      | 68.4      | 45         | 1950±50          |
| D8-2E   | 103.6      | 76.8      | 49         | 2135±50          |
| DE10-3E | 294        | 52        | 43         | 2260±50          |
| DE11-3E | 323.6      | 37        | 46.7       | 1950±50          |
| CW2s    | 120        | 80        | 18         | 2100±50          |
| CW5s    | 123        | 11        | 11         | 2050±50          |



The above is a dimension illustration of the C7-3E probe.

You can select the probe sheath according to the actual application situation.

## 13.1.5 Probes Cleaning and Disinfection

After completing each examination, clean and disinfect (or sterilize) the probes as required. When biopsy procedures have been performed, be sure to sterilize the needle-guided bracket. Fail to do so may result in the probe and the needle-guided bracket to becoming sources of infection. Please follow the instructions in the manual for cleaning.

Never immerse the probe connector into liquid such as water or **WARNING:** disinfectant. Immersion may cause electrical shock or malfunction.

When performing cleaning and CAUTION: disinfection of the probe to prevent

infection, wear sterile gloves.

After disinfection, rinse the probe thoroughly with sterile water to remove all chemical residues. Chemical residues on the probe may be harmful to the human body.

No cleaning and disinfecting may result in the probe becoming a source of infection.

NOTE: After the examination, wipe off the ultrasound gel thoroughly. Otherwise, the ultrasound gel may solidify and degrade the image quality of the transducer.

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

Please refer to the instructions in the manual and follow your hospital policy and procedures for cleaning.

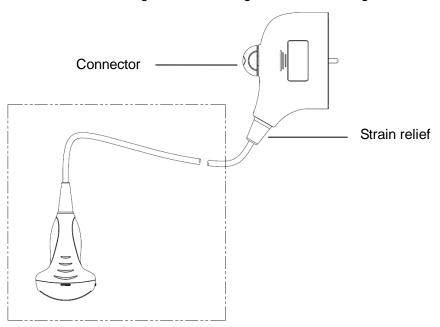
- 1. Disconnect the probe from the system.
- 2. Wear sterile gloves to prevent infection.
- 3. Wash the transducer with clean water or soapy water to remove all the foreign matters, or, wipe the transducer with a soft ethyl carbamate sponge. Avoid using a brush, because it may damage the transducer.
- 4. Dry the transducer using a sterile cloth or gauze after rinsing. Do not dry the transducer by heating it.

#### **Disinfecting with Sprays or Wipes**



Use protective eyewear when disinfecting using sprays.

- 1. Wear sterile gloves to prevent infection.
- 2. After you have finished cleaning, spray or wipe the transducer 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 transducer.
- 4. Wipe off water on the transducer using sterile cloth or gauze after washing.

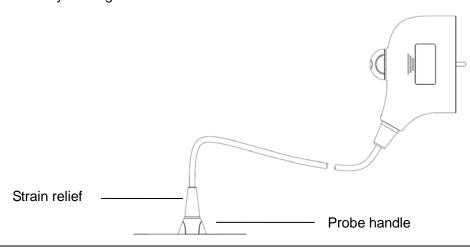


**NOTE**: Observe the graph here carefully to perform disinfection. Do not spray the strain relief on the connector end or the connector.

#### **Disinfecting by Immersion**

- 1. Wear sterile gloves to prevent infection.
- Clean the transducer before disinfecting it. MINDRAY recommends the following solutions to disinfect the transducer.

- Refer to the instructions provided by the chemical manufacturer concerning concentration
  of the disinfectant solution, method of disinfection and dilution and cautions during use.
  Do not soak the transducer connector or the cable near it into water or any solution.
- Soak the transducer 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 transducer 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 transducer.
- 4. Wipe off the water on the transducer with sterile cloth or gauze after rinsing it. Do not dry the transducer by heating.



#### NOTE:

- 1. Observe the graph here carefully to immerse the transducer. Only soak parts of the transducer below the strain relief.
- 2. Repeated disinfection will eventually damage the probe, please check the probe performance periodically.

Before the probe's safety and performance is affected, the minimum number of disinfection times for the probe is as follows:

| NO. | Trade Name                | Manufacturer                       | Number of Test Cycles |
|-----|---------------------------|------------------------------------|-----------------------|
| 1   | Sani-Cloth® Plus          | PDI                                | 5200                  |
| 2   | Surfa'safe                | Anios Laboratoires                 | 1560                  |
| 3   | Wip'Anio, premium         | Anios Laboratoires                 | 1560                  |
| 4   | IODOCLEAN                 | Anios Laboratoires                 | 1560                  |
| 5   | SALVANIOS pH7             | Anios Laboratoires                 | 1560                  |
| 6   | SALVANIOS pH10            | Anios Laboratoires                 | 1560                  |
| 7   | ANIOXYDE 1000             | Anios Laboratoires                 | 5200                  |
| 8   | Oxivir <sup>TMMC</sup> Tb | Diversey                           | 2600                  |
| 9   | SONO™ ULTRASOUND WIPES    | Advanced Ultrasound Solutions Inc. | 5200                  |

| NO. | Trade Name   | Manufacturer              | Number of Test Cycles |
|-----|--|---------------------------|-----------------------|
| 10  | Protex <sup>™</sup> Disinfectant Wipes/                                | Parker laboratories Inc   | 5200                  |
| 11  | Protex <sup>™</sup> Disinfectant Spray                                 | Parker laboratories Inc   | 5200                  |
| 12  | TRANSEPTIC   | Parker Laboratories Inc.  | 5200                  |
| 13  | CIDEX OPA  | ASP                       | 5200                  |
| 14  | Cidex Activated Glutaraldehyde Solution                                | ASP                       | 1560                  |
| 15  | Ster-bac   | Ecolab Inc.               | 5200                  |
| 16  | Minncare® Cold Sterilant   | Minntech Corporation      | 2600                  |
| 17  | MetriZyme  | Metrex                    | 5200                  |
| 18  | CLEANISEPT® WIPES  | DR.SCHUMACHER GMBH        | 10400                 |
| 19  | DESCOTON extra   | DR. SCHUMACHER            | 1560                  |
| 20  | Triacid-N  | ANTISEPTICA               | 5200                  |
| 21  | gigasept®FF(neu)   | SCHÜLKE                   | 1560                  |
| 22  | gigasept®PAA concentrate   | SCHÜLKE                   | 1560                  |
| 23  | UNIVERSAL WIPES  | GAMA HEALTHCARE           | 5200                  |
| 24  | PI-SPRAY II  | PHARMACEUTICAL INNOV      | 2600                  |
| 25  | Tristel Surface Wipes  | Tristel Solutions Limited | 5200                  |
| 26  | Tristel Pre-Clean Wipes  | Tristel Solutions Limited | 5200                  |
| 27  | Tristel Trio Wipes System ( Including Sporicidal Wipes,Activator Foam) | Tristel Solutions Limited | 5200                  |
| 28  | Tristel Rinse Wipes  | Tristel Solutions Limited | 5200                  |
| 29  | Tristel Solo   | Tristel Solutions Limited | 5200                  |
| 30  | Tristel Duo  | Tristel Solutions Limited | 5200                  |
| 31  | mikrozid®AF Wipes Jumbo  | SCHÜLKE                   | 1560                  |
| 32  | mikrozid®Sensitive Wipes   | SCHÜLKE                   | 1560                  |
| 33  | Trophon Sonex-HL (used with Trophon EPR Ultrasound Probe Disinfector)  | Nanosonics Limited        | 4000                  |
| 34  | ultrasound probe cleaning wipes  | Nanosonics Limited        | 5200                  |

#### **Compatible Disinfectants**

For details about compatible disinfectants, please refer to the Cleaning & Disinfection Guide. For details about P7-3TE disinfection, please refer to the P7-3TE accompanying manual.

| Disinfection Type                         | Probe  |
|---|--|
| Low level disinfection                    | L14-5WE, P7-3E, P10-4E, CW2s, CW5s, D6-2NE, D7-2E  |
| High level disinfection                   | P7-3TE, V11-3E, V11-3BE, V11-3HE, CB10-4E, DE10-3E, DE11-3E                                  |
| High level disinfection (for biopsy exam) | C5-1E, C6-2GE, C7-3E, C11-3E, SC5-1E, L9-3E, L12-3E, L14-6NE, L14-6WE, P4-2NE, SP5-1E, D8-2E |

For details about additional infection control procedures or disinfection information, contact Mindray North America Customer Service [Tel: (1-800) 288 2121, (1-201) 995 8000].

#### Sterilization

For intra-operative probes, they have to be sterilized after completing each examination.

- 1. Wear sterile gloves to prevent infection.
- 2. Clean the probe before sterilizing it. MINDRAY recommends the following solutions to sterilize the probe.

Glutaraldehyde-based sterilization solution

| Trade Name                 | Chemical Name        | Procedures   |
|----------------------------|----------------------|--|
| Cidex Activated Dialdehyde | 2.4% Glutaraldehyde  | Soak the transducer into the activated solution for 10 hours (20-25℃)                      |
| Solution                   | 2.4% Glutaralueriyue | Please refer to the instructions provided by the manufacturer of the solution for details. |

Before safety and performance is affected, probe L16-4HE can be sterilized by Cidex Activated Glutaraldehyde Solution for at least 217 times (10 hours for one time).

- Refer to the instructions provided by the chemical manufacturer concerning concentration of the sterilization solution, method of sterilization and dilution and cautions during use.
- Do not soak the probe connector or the cable near it into water or any solution.
- Follow local regulations when selecting and using the sterilization solution.
- 3. Rinse the probe 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 sterilization solution manufacturer to rinse the probe.
- 4. Wipe off the water on the probe with sterile cloth or gauze after rinsing it. Do not dry the probe by heating.



Immerse the probe in the solution (take 7LT4s as an illustration)

**NOTE:** Repeated disinfection may degrade the performance and safety of the probe.

## 13.1.6 Environment

#### **Working condition**

Use the probes in the following ambient conditions:

| Probe    | Ambient temperature | Relative humidity | Atmospheric pressure   |
|----------|---------------------|-------------------|--|
| CD10 4E  | 0°C ~ 40°C          | 30%~85%RH ( no    | 700hDa 1060hDa   |
| CB10-4E  | 0 C ~ 40 C          | condensation )    | 700NPa ~ 1000NPa   |
| D7-2E    | 10°C ~ 40°C         | 25%~90%RH ( no    | •  |
| D7-2E    | 10 C ~ 40 C         | condensation )    | 70011Fa ~ 100011Fa   |
| L14-6NE  | 0°C ~ 40°C          | 30%~85%RH ( no    | 700hPa ~ 1060hPa   |
| LI4-OINL | 0 0 740 0           | condensation )    | 70011178 100011178   |
| L12-3E   | 0°C ~ 40°C          | 30%~85%RH ( no    | 700hPa ~ 1060hPa   |
|          | 0 0 740 0           | condensation )    | 70011178 100011178   |
| C7-3E    | 0°C ~ 40°C          | 30%~85%RH ( no    | 700hPa ~ 1060hPa   |
|          | 0 0 40 0            | condensation )    | 700111 a 1000111 a   |
| L14-6WE  | 0°C ~ 40°C          | 30%~85%RH ( no    | 700hPa ~ 1060hPa   |
|          | 0 0 40 0            | condensation )    | 700111 a 1000111 a   |
| P10-4E   | 0°C ~ 40°C          | 30%~85%RH ( no    | 700hPa ~ 1060hPa   |
| 110 46   | 0 0 40 0            | condensation )    | 700111 a 1000111 a   |
| C11-3E   | 0°C ~ 40°C          | 30%~85%RH ( no    | 700hPa ~ 1060hPa   |
|          | 0 0 0 0 0           | condensation )    |  |
| V11-3E   | 0°C ~ 40°C          | 30%~85%RH ( no    | 700hPa ~ 1060hPa  700hPa ~ 1060hPa |
|          | 0 0 10 0            | condensation )    |  |
| V11-3BE  | 0°C ~ 40°C          | 30%~85%RH ( no    | 700hPa ~ 1060hPa   |
|          | 0 0 10 0            | condensation )    | 700111 0 1000111 0   |
| P4-2NE   | 0°C ~ 40°C          | 30%~85%RH ( no    | 700hPa ~ 1060hPa   |
|          | 0 0 10 0            | condensation )    | 700111 0 1000111 0   |
| C5-1E    | 0°C ~ 40°C          | 30%~85%RH ( no    | 700hPa ~ 1060hPa   |
|          | 0 0 10 0            | condensation )    | 700111 0 1000111 0   |
| SP5-1E   | 0°C ~ 40°C          | 20%~85%RH ( no    | 700hPa ~ 1060hPa   |
|          | 0 0 10 0            | condensation )    | 700111 0 1000111 0   |
| DE11-3E  | 18℃~30℃             | 20%~85%RH ( no    | 700hPa ~ 1060hPa   |
|          |                     | condensation )    |  |
| C6-2GE   | 0°C ~ 40°C          | 20%~85%RH ( no    | 700hPa ~ 1060hPa   |
|          |                     | condensation )    | 7 00 0 2000 0  |
| V11-3HE  | 0°C ~ 40°C          | 20%~85%RH ( no    | 700hPa ~ 1060hPa   |
|          |                     | condensation )    | 2000111 4  |
| L9-3E    | 0°C ~ 40°C          | 20%~85%RH ( no    | 700hPa ~ 1060hPa   |
|          | 0 0 40 0            | condensation )    | 1 2000111 0  |

| Probe     | Ambient temperature | Relative humidity | Atmospheric pressure |
|-----------|---------------------|-------------------|----------------------|
| 144 514/5 | •                   | 20%~85%RH ( no    | 700   D              |
| L14-5WE   | 0°C ~ 40°C          | condensation )    | 700 hPa ~ 1060 hPa   |
| P7-3E     | 10°C ~ 40°C         | 30%~85%RH ( no    | 700hPa ~ 1060hPa     |
| P/-3E     | 10 C ~ 40 C         | condensation )    | 700NPa ~ 1000NPa     |
| DE10-3E   | 18℃~30℃             | 30%~85%RH ( no    | 700hPa ~ 1060hPa     |
| DE10-3E   | 16 C~ 30 C          | condensation )    | 70011Pa ~ 100011Pa   |
| L16-4HE   | 10°C ~ 40°C         | 30%~85%RH ( no    | 700hPa ~ 1060hPa     |
| L10-4ПE   | 10 C ~ 40 C         | condensation )    | /00nPa ~ 1060nPa     |
| SC5-1E    | 0°C ~ 40°C          | 30%~85%RH ( no    | 700hPa ~ 1060hPa     |
| <u></u>   | 0 0 ~ 40 0          | condensation )    | 70011Pa ~ 100011Pa   |
| D6-2NE    | 15°C ~ 40°C         | 30%~85%RH ( no    | 700hPa ~ 1060hPa     |
| D0-ZINE   | 13 C~40 C           | condensation )    | 70011Pa ~ 100011Pa   |
| D8-2E     | 18°C ~ 30°C         | 10%~90%RH ( no    | 700hPa ~ 1060hPa     |
|           | 18 C~ 30 C          | condensation )    | 70011Fa ~ 100011Fa   |
| CW2s      | 0°C ~ 40°C          | 30%~85%RH ( no    | 700hPa ~ 1060hPa     |
|           | 0 0 ~ 40 0          | condensation )    | 70011Fa ~ 100011Fa   |
| CW5s      | 0°C ~ 40°C          | 30%~85%RH ( no    | 700hPa ~ 1060hPa     |
| CVV 35    | 0 0 ~ 40 0          | condensation )    | 70011Fa~100011Fa     |

#### **Storage and transportation Condition**

When all examinations for the day have been completed, confirm that the probe is in good condition. After disinfecting the probe, confirm that the probe is in good condition and stored in a suitable place.

Store and transport the probes in the following ambient conditions:

| Probe    | Ambient      | Relative       | Atmospheric    |
|----------|--------------|----------------|----------------|
| FIODE    | temperature  | humidity       | pressure       |
| CB10-4E  | -20°C ~ 55°C | 30%~95%RH ( no | 700 hPa ~ 1060 |
| CB10-4E  | -20 C ~ 33 C | condensation ) | hPa            |
| D7-2E    | 10°C 60°C    | 30%~95%RH ( no | 700 hPa ~ 1060 |
| D7-2E    | -10°C ~ 60°C | condensation ) | hPa            |
| L14-6NE  | -20°C ~ 55°C | 30%~95%RH ( no | 700 hPa ~ 1060 |
| L14-OINE | -20 C ~ 33 C | condensation ) | hPa            |
| 112.25   | -20°C ~ 55°C | 30%~95%RH ( no | 700 hPa ~ 1060 |
| L12-3E   | -20 C ~ 55 C | condensation ) | hPa            |
| C7-3E    | -20°C ~ 55°C | 30%~95%RH ( no | 700 hPa ~ 1060 |
| C7-3E    | -20 C ~ 55 C | condensation ) | hPa            |
| 114 6\45 | 20°C FF°C    | 30%~95%RH ( no | 700 hPa ~ 1060 |
| L14-6WE  | -20°C ~ 55°C | condensation ) | hPa            |

|         | Ambient      | Relative       | Atmospheric    |
|---------|--------------|----------------|----------------|
| Probe   | temperature  | humidity       | pressure       |
| D10 45  | -20℃~55℃     | 30%~95%RH ( no | 700 hPa ~ 1060 |
| P10-4E  |              | condensation ) | hPa            |
| 611.35  | 2006 5506    | 30%~95%RH ( no | 700 hPa ~ 1060 |
| C11-3E  | -20℃~55℃     | condensation ) | hPa            |
| V11-3E  | -20℃~55℃     | 30%~95%RH ( no | 700 hPa ~ 1060 |
|         |              | condensation ) | hPa            |
| V11 2DE | -20℃~55℃     | 30%~95%RH ( no | 700 hPa ~ 1060 |
| V11-3BE |              | condensation ) | hPa            |
| D4 2NE  | -20℃~55℃     | 30%~95%RH ( no | 700 hPa ~ 1060 |
| P4-2NE  |              | condensation ) | hPa            |
| CF 1F   | 2006 5506    | 30%~95%RH ( no | 700 hPa ~ 1060 |
| C5-1E   | -20℃~55℃     | condensation ) | hPa            |
| CDE 1E  | -20°C ~ 55°C | 20%~95%RH ( no | 700 hPa ~ 1060 |
| SP5-1E  | -20 C ~ 55 C | condensation ) | hPa            |
| DE11-3E | -10°C ~ 50°C | 30%~95%RH ( no | 700 hPa ~ 1060 |
| DEII-3E | -10 C ~ 50 C | condensation ) | hPa            |
| C6-2GE  | 20°C 55°C    | 20%~95%RH ( no | 700 hPa ~ 1060 |
|         | -20℃~55℃     | condensation ) | hPa            |
| V11-3HE | -20°C ~ 55°C | 20%~95%RH ( no | 700 hPa ~ 1060 |
| VII-3HE | -20 C ~ 33 C | condensation ) | hPa            |
| L9-3E   | -20℃~55℃     | 20%~95%RH ( no | 700 hPa ~ 1060 |
|         |              | condensation ) | hPa            |
| L14-5WE | -20°C ~ 55°C | 20%~95%RH ( no | 700 hPa ~ 1060 |
|         |              | condensation ) | hPa            |
| P7-3E   | -20°C ~ 55°C | 30%~95%RH ( no | 700 hPa ~ 1060 |
| F7-5L   |              | condensation ) | hPa            |
| DE10-3E | -10°C ~ 50°C | 30%~95%RH ( no | 700 hPa ~ 1060 |
|         |              | condensation ) | hPa            |
| L16-4HE | 0°C ~ 60°C   | 30%~95%RH ( no | 700 hPa ~ 1060 |
|         |              | condensation ) | hPa            |
| SC5-1E  | -10°C∼60°C   | 20%~95%RH ( no | 700 hPa ~ 1060 |
|         |              | condensation ) | hPa            |
| D6-2NE  | -10°C∼60°C   | 5%~95%RH ( no  | 700 hPa ~ 1060 |
|         |              | condensation ) | hPa            |
| D8-2E   | -10°C ~ 50°C | 10%~90%RH ( no | 700 hPa ~ 1060 |
|         |              | condensation ) | hPa            |
| CW2s    | -20°C ~ 55°C | 30%~95%RH ( no | 700 hPa ~ 1060 |
|         |              | condensation ) | hPa            |

| Probe | Ambient<br>temperature | Relative<br>humidity | Atmospheric pressure |
|-------|------------------------|----------------------|----------------------|
| CW5s  | -20°C ~ 55°C           | 30%~95%RH ( no       | 700 hPa ~ 1060       |
|       |                        | condensation )       | hPa                  |

- 1. 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
- 2. When the probe is sent to MINDRAY Customer Service Department or sales representative for repair, be sure to disinfect it and keep it in the carrying case to prevent infection.
- 3. Sterilize the carrying case as necessary.

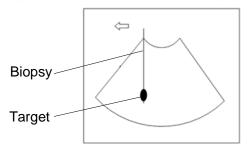
## 13.2 Biopsy Guide

## **△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.
- 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

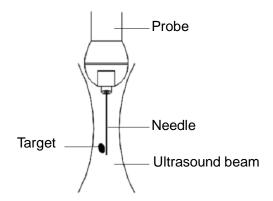
direction of the probe. (That is to say, the information shown in the images consist all the information scanned in the thickness direction of the probe.) So, even though the biopsy needle appears to have penetrated the target object in the image, it may not actually have done so. When the target for 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 CB10-4E, misoperation may occur when the scan range is not set to "W".

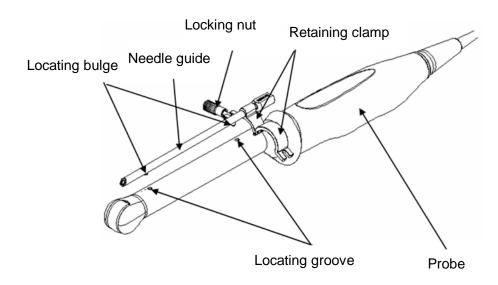
## 13.2.1 Needle-guided Brackets

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).

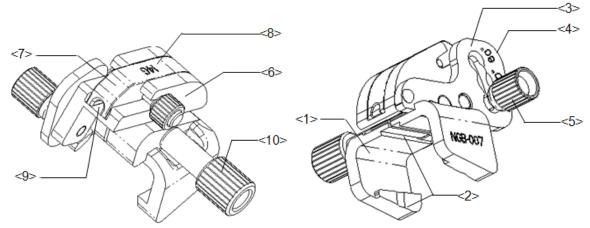
#### **Names of Parts**

This section describes the parts and corresponding functions of each needle-guided bracket. Here, we take a matched probe as an example.



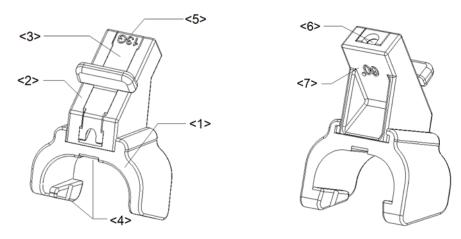
#### ■ NGB-007/NGB-035

Metal/needle detachable needle-guided bracket:

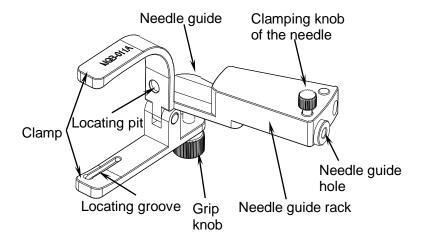


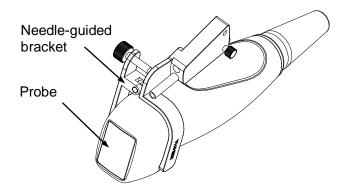
| No.  | Name  | Description  |
|------|---|--|
| <1>  | Support of needle-<br>guided bracket        | Used for installing the needle-guided bracket on the probe.  |
| <2>  | Groove and tab of the needle-guided bracket | Respectively matched with the tab and groove of the probe.   |
| <3>  | Angle adjusting base                        | There are 3 types of angles available to be adjusted.  |
| <4>  | Angle shift sign (40°,50°,60°)              | Matched with the biopsy angle (40°, 50°, and 60°).   |
| <5>  | Angle pinch nut                             | Used for fixing the angle lock at a chosen angle.  |
| <6>  | Angle block                                 | Used for determining the angle of the biopsy; different specifications of blocks can be used.                    |
| <7>  | Guiding block                               | Used for installing biopsy needle; there are five specifications of guiding blocks for different biopsy needles. |
| <8>  | Specification of guiding block (14G)        | Matched with the corresponding biopsy needle (14G).  |
| <9>  | Needle guide hole                           | Used for installing the biopsy needle.   |
| <10> | Pinch nut of needle-<br>guided bracket      | Used for locking the needle-guided bracket and the probe.  |

### Plastic/needle detachable needle-guided bracket:

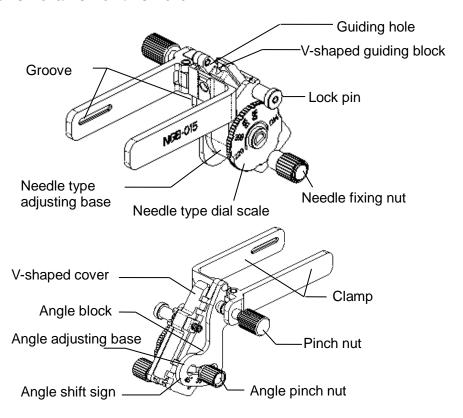


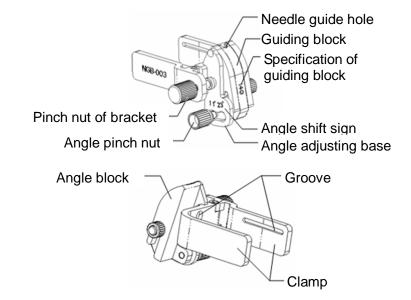
| No. | Name  | Description  |
|-----|---|--|
| <1> | Support of needle-<br>guided bracket        | Used for installing the needle-guided bracket on the probe.  |
| <2> | Angle block                                 | Used for determining the angle of the biopsy; there are three specifications of blocks of angle.                 |
| <3> | Guiding block                               | Used for installing biopsy needle; there are five specifications of guiding blocks for different biopsy needles. |
| <4> | Groove and tab of the needle-guided bracket | Respectively matches with the tab and groove of the probe.   |
| <5> | Specification of guiding block (13G)        | Matched with the corresponding biopsy needle (13G).  |
| <6> | Guiding hole of the biopsy needle           | Used for installing the biopsy needle.   |
| <7> | Specification of angle block (60°)          | The corresponding biopsy angle is 60°.   |



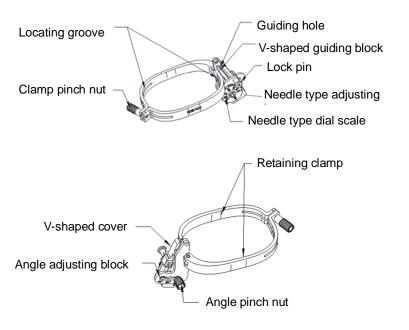


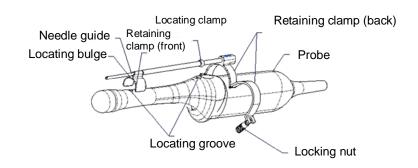
#### ■ NGB-015/NGB-019/NGB-022/NGB-023

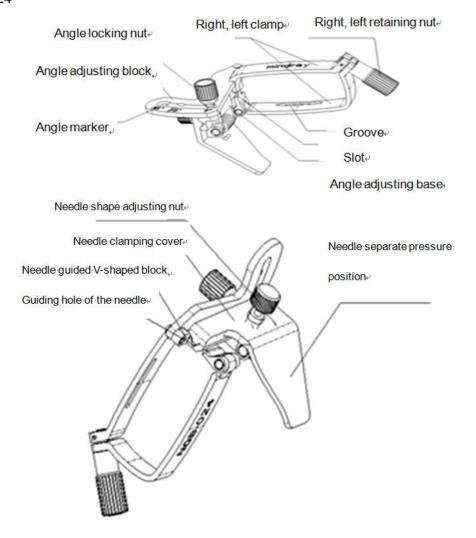


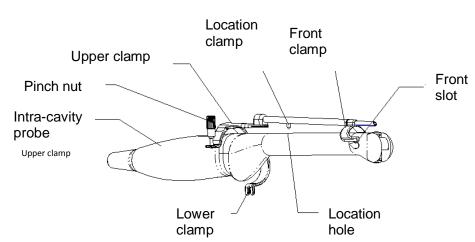


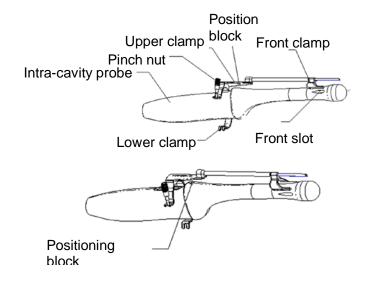
#### ■ NGB-020/NGB-040

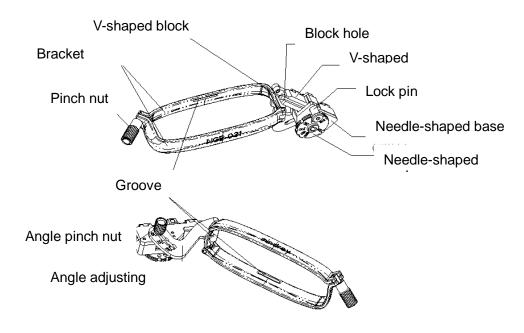


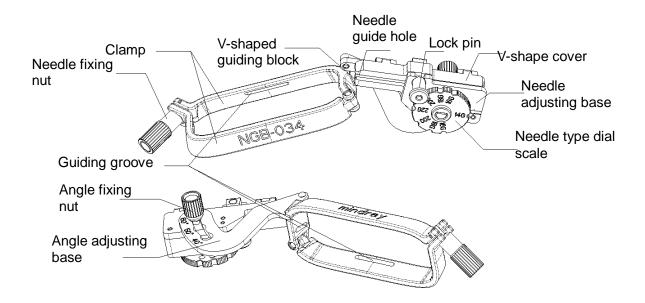












## 13.2.2 Basic Procedures for Biopsy Guiding

- 1. Select the right needle-guided bracket and needle, install them properly. For details, please refer to "13.2.3 Needle-guided Bracket Inspection and Installation".
- 2. Verify the biopsy guide line.
- 3. Press <F11 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 hidden before image frozen, then you can't enter Biopsy menu.
- Before entering Biopsy menu, the system will prompt you "Please verify guidelines before biopsy".
- 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 guide zone 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. To exit Biopsy menu: press the <Esc> key; or press <Biopsy>.
- 9. Disassemble the items and properly dispose of these items as required.



Fail to match the guide zone displayed to the guide may cause the needle to track a path outside the zone.

It is extremely important that when using the adjustable angle biopsy guides, the angle displayed on the screen matches the angle set on the guide, otherwise the needle will not follow the displayed guide zone which could result in repeated biopsies or patient injury.

## 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.

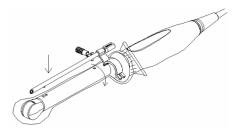
- 1. Sterilize the needle-guided bracket before and after use.
- 2. Confirm that the needle-guided bracket is free of damage, deformation, stripping, malfunction, loose, or missing parts.
- 3. Confirm that the needle-guided bracket is securely mounted in the correct position.

#### 13.2.3.2 Installing the Needle-guided Bracket

- NGB-004
  - (1) Put on the sterile probe sheath.



(2) Open the retaining clamp, align the needle-guided bracket with the probe to locate the locating bulge on the needle guide to the locating grooves on the probe, and then turn the retaining clamp to match it with the probe (See the figure below).



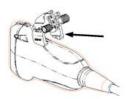
(3) When the retaining clamp is turned to the right position, the locking nut will lock the retaining clamp and the needle-guided bracket is then mounted to the right position.



#### ■ NGB-007/NGB-035

Metal/needle detachable needle-guided bracket:

- (1) Put on the sterile probe sheath.
- (2) Hold the probe by one hand, select the proper needle-guided bracket, and hold it with the other hand. Match the groove and tab with the tab and groove of the probe respectively. Amount the bracket onto the probe.



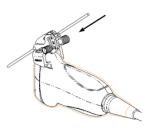


- (3) Screw the pinch nut of the needle-guided bracket to confirm that the needle-guided bracket is properly installed on the probe.
- (4) Select a proper guiding block and push it into the groove above the angle block, and clamp it tightly.



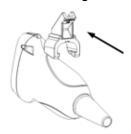


- (5) Screw the nut of the block to secure the block.
- (6) Insert a biopsy needle with the same specification as that of the guiding block into the hole of the guiding block.

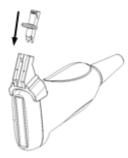


#### Plastic needle-guided bracket:

- (1) Put on the sterile probe sheath.
- (2) Hold the probe by one hand, select the proper needle-guided bracket, and hold it with the other hand. Align the narrow end tab of the needle-guided bracket with the groove of the probe, then push the needle-guided bracket forward, making the tabs and the grooves of the needle-guided bracket to match with the grooves and tabs of the probe.



- (3) Check manually to confirm that the needle-guided bracket is securely installed on the probe.
- (4) Select a proper guiding block and push it into the groove above the angle block, and clamp it tightly.



(5) Insert a biopsy needle with the same specification as that of the guiding block into the hole of the guiding block.

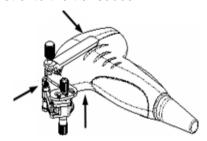


#### ■ NGB-011

- (1) Inosculate 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) Turn the grip knob at the tail of the needle-guided bracket tightly.

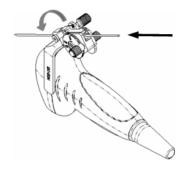
#### ■ NGB-015/NGB-019/NGB-022/NGB-023

- (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.



- (1) Put on the sterile probe 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.



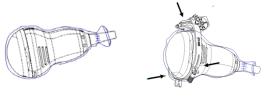
- (3) Screw the pinch nut of the needle-guided bracket to confirm that the needle-guided bracket is properly installed on the transducer.
- (4) Select a proper guiding block and push it into the groove above the angle block.



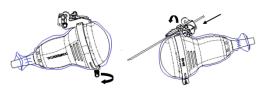
- (5) Screw the nut of the block to secure the block.
- (6) Insert a biopsy needle with the same specification as that of the guiding block into the hole of the guiding block.

#### ■ NGB-020/NGB-040

(1) Put on the sterile transducer sheath.

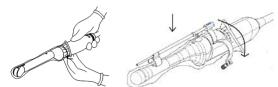


- (2) Select a proper needle-guided bracket, and match the locating groove with the tab of the transducer. Mount the bracket onto the transducer. Screw the pinch nut of the needle-guided bracket to confirm that the needle-guided bracket is properly installed on the transducer.
- (3) Adjust the dial scale to the required needle type shift.

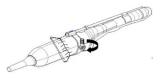


(4) Pull the lock pin and close the V-shaped cover to fix the lock pin in the groove of the needle type adjusting base, so as to install the needle into the guiding hole.

- (1) Put on the sterile transducer sheath.
- (2) Loose the retaining clamp, align the needle-guided bracket with the transducer to locate the locating clamp on the needle guide to the locating grooves on the transducer, and then press the retaining clamp (front) to match the locating clamp and the locating bulge on the front retaining clamp to the corresponding groove.



(3) Screw the retaining clamp to match with the transducer structure. When the clamp is turned to the right position, the locking nut will lock the retaining clamp and the needleguided bracket is then mounted to the right position.



#### ■ NGB-024

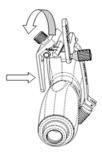
- (1) Put on the sterile transducer sheath.
- (2) Select a proper needle-guided bracket, and match the groove with the tab of the transducer. Mount the bracket onto the transducer.



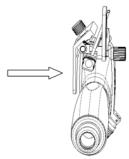
(3) Rotate the clamping nuts of the guided bracket on right and left side to fix the bracket and the transducer. Rotate the needle-type adjusting nut to the ultimate position as shown in the figure.



(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 needletype adjusting nut manually (following the direction of the arrow). The needle moves smoothly at the vertical direction due to its gravity.



#### ■ NGB-025

(1) Put on the sterile probe sheath.

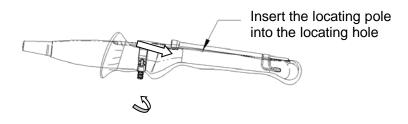


(2) Open the clamp. Insert the front clamp to the front groove.

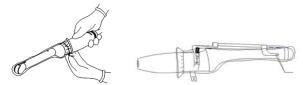


Align front clamp with front groove

(3) Push the needle-guided bracket 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).



(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).

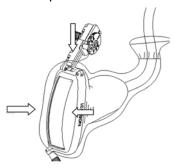


#### ■ NGB-031

(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 pinch nut of the needle-guided bracket (following the arrow's direction) to confirm that the needle-guided bracket is properly installed on the probe.



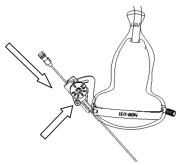
(4) Adjust the dial scale to the required needle type shift.



(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).

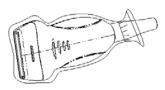


(6) Pull the lock pin and close the V-shaped cover to fix the lock pin in the groove of the needle type adjusting base, so as to install the needle into the guiding hole.

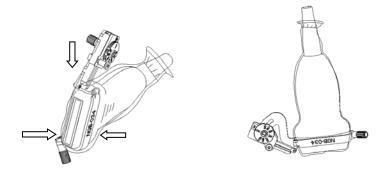


#### ■ NGB-034

(1) Put on the sterile probe sheath.



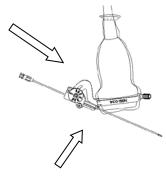
(2) Select a proper needle-guided bracket, and match the locating groove with the tab of the transducer. Mount the bracket onto the transducer.



- (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.



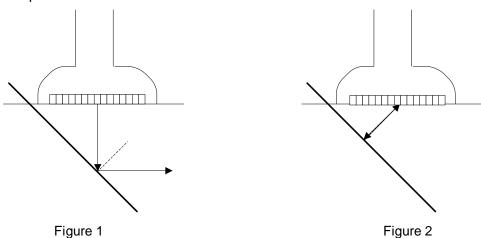
CAUTION: Ensure that all guide parts are seated properly prior to performing a biopsy.

## 13.2.4 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 angel can be chosen by users.

iNeedle is an option.



#### To enter/exit iNeedle

■ To enter iNeedle

Touch [iNeedle] item in B page on the touch screen.

Or, you can assign a user-defined key for entering iNeedle.

- 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

Press the user-defined key or touch [iNeedle] to exit the status and enter B mode.

#### **Needle Steer**

**Description** This function adjusts the biopsy needle angle via changing the steer angle of the

scan line. The iNeedle affecting region changes correspondingly.

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

#### B/iNeedle

**Description** This function is used to display B image and iNeedle image synchronously.

**Operation** To turn on or off the function, touch [B/iNeedle] on the touch screen.

Tips: iZoom (full-screen magnification) is available on iNeedle status.

## 13.2.5 Verifying the Biopsy Guide Line

Adjusting the needle mark is necessary before every 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 get a biopsy needle into 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.

## $\triangle$ WARNING:

- 1. Prior to each biopsy procedure, be sure to verify the guide line.
- 2. 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 biopsy bracket angle
  - If the needle-guided bracket supports more than one biopsy angle, select the angle/guideline by touching the [Kit: NGB-XXX-XX] on the touch screen.
- Select guide line dot size

Tap [Dot Size] to select the dot size among Small, Medium and Large.

Tips:

- 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.
- When the imaging depth and area are changed, the guide line will be adjusted.

#### Verification

You can also operate on the touch screen. Use menu operation as an example.

Click [Verify] in the Biopsy menu to open the Biopsy Verify menu, as shown in the figure below.

■ Adjust guide line position

Move the cursor onto [Position], press the <Set> key to move it linearly. This is operative when there is only one guide line displayed.

Adjust angle

Move the cursor onto [Angle], press the <Set> key to change the guide line angle. This is operative when there is only one guide line displayed.

Save verified settings

After the position and angle of the guide line are adjusted, click [Save], and the system will save the current settings of the guide line. If enter biopsy again, the displayed Position and Angle are the verified value.

Restore the factory default settings

Click [Load Factory], and the position and angle of the guide line will be restored to the factory default settings.

■ Exit the biopsy verify status

Click [Exit], and the system will exit the verification status of the guide line.

## 13.2.6 Removing the Needle-guided Bracket

#### ■ NGB-004

Hold the probe in the left hand, unscrew the locking nut with the right hand to open the retaining clamp, and then raise the needle-guided bracket to separate the locating bulge from the locating grooves.

#### ■ NGB-007/NGB-035

Metal needle-guided bracket:

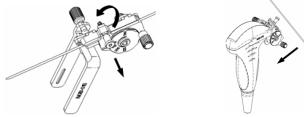
- (1) Screw the nut of the guiding block and remove the guiding block slightly along the direction of the needle's tail.
- (2) Separate the residual part of the needle-guide bracket and the probe from the needle.
- (3) Screw the pinch nut of the bracket, and remove the needle-guided bracket from the probe. Plastic needle-guided bracket:
- (1) 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 probe from the needle.
- (3) Remove the support of needle-guided bracket from the probe.

#### ■ NGB-011

Hold the probe and the needle-guided bracket, and then open the grip knob of the needle-guided bracket.

#### ■ NGB-015/NGB-019/NGB-022/NGB-023

(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-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-quide bracket and the transducer from the needle.
- (3) Screw the pinch nut of the bracket, and remove the needle-guided bracket from the transducer.

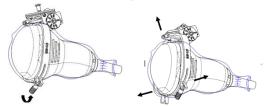


#### ■ NGB-020/NGB-040

(1) Pull the lock pin out 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 transducer and the needle-guided bracket.

#### ■ NGB-021

Hold the transducer in the left hand, unscrew the locking nut with the right hand to loose the retaining clamp. Raise the needle-guided bracket to separate the locating clamp/ bulge from the locating grooves.

#### ■ NGB-024

(1) Hold the transducer. Press the biopsy needle to separate the needle from pressure position of the needle.



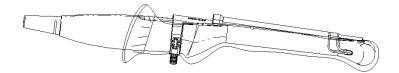


- (2) Separate the bracket and the transducer from the needle.
- (3) Rotate the clamping nuts of the needle guided-bracket on right and left side (following the direction of the arrow). The needle guided-bracket is separate from the transducer. Hold the transducer and take out the bracket.



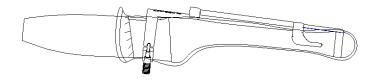
#### ■ NGB-025

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.



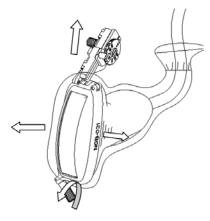
#### ■ NGB-027

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.

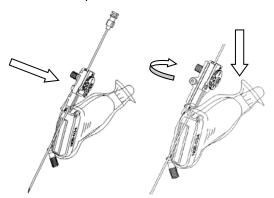


#### ■ NGB-031

Unscrew the pinch nut to separate the needle-guided bracket from the probe. Release the needle-guided bracket from the probe.

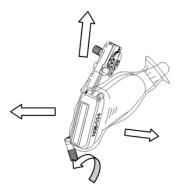


- NGB-034
- Separation of the needle in the operation
- 1. Pull the lock pin out until the V-shaped cover can be turned and opened up.



- 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.



## 13.2.7 Clean and Sterilize the Needle-guided Bracket

#### Cleaning

Please follow the instructions in the manual for cleaning.

- 1. Wear sterile gloves to prevent infection.
- 2. Wash the needle-guided bracket with water or soap water to remove all the external matters. Or, clean the needle-guided bracket with urethane sponge.
- 3. Wipe off the water on the needle-guided bracket using sterile cloth or gauze after washing it.

#### Sterilization

- 1. Wear sterile gloves to prevent infection.
- 2. Clean the needle-guided bracket before sterilizing it. MINDRAY recommends the following solution or sterilizing system to sterilize the needle-guided bracket.
- 3. Follow local regulations when selecting and using the disinfectant.
- Glutaraldehyde-based sterilant:

| Chemical name                | Trade name                              | Procedures   |
|------------------------------|---|--|
| Glutaraldehyde<br>(2.2-2.7%) | Cidex Activated Glutaraldehyde Solution | Please refer to the instructions provided by the manufacturer of the solution for details. |

Before safety and performance is affected, plastic bracket NGB-007 can be sterilized by Cidex Activated Glutaraldehyde Solution for at least 233 times (10 hours for one time).

■ Hydrogen Peroxide and Peroxyacetic Acid -based sterilant:

| Trade Name                              | Chemical Name                                   | Procedures   |
|---|---|--|
| Minncare <sup>®</sup> Cold<br>Sterilant | 22% Hydrogen Peroxide<br>4.5% Peroxyacetic Acid | Dilute the sterilant with sterilized purified water (1:20).  Immersed time: 11 hours.  Temperature: 20°C-25°C.  Please refer to the instructions provided by the manufacturer of the solution for details. |

Before safety and performance is affected, plastic bracket NGB-007 can be sterilized by Minncare COLD STERILANT for at least 245 times (11 hours for one time).

- Refer to the instructions provided by the chemical manufacturer concerning concentration
  of the solution, and method of disinfections and dilution. Note that the glutaraldehyde
  disinfectant solution needs an activating solution.
- Rinse the needle-guided bracket thoroughly with sterile water to remove all chemical residues on it.
- Wipe off the water on the needle-guided bracket with sterile cloth or gauze after rinsing it.
- STERRAD 100S low-temperature hydrogen peroxide gas plasma sterilization system

| Chemical name                      | Trade name                 | Procedures   |
|------------------------------------|----------------------------|--|
| Hydrogen<br>peroxide gas<br>plasma | Hydrogen<br>peroxide vapor | Please refer to the instructions provided by the producer of the solution for details. |

- Refer to the instruction of STERRAD 100S sterilizing system provided by the manufacturer for operation instructions and cautions.
- The STERRAD 100S low-temperature hydrogen peroxide gas plasma sterilization system is available for metal needle-guided brackets.
- High-pressure steam sterilization (only applicable for metal guided-bracket)

Autoclaving (moist heat) 121°C for 20 minutes.

#### NOTE:

- Repeated sterilization may degrade the safety and performance of the needle-guided bracket.
- 2. The high-pressure steam/ immersion sterilization do not affect the bracket duration life, and the duration life is affected by the daily application of the bracket. Please check the appearance of the bracket before using.

## 13.2.8 Storage and Transportation

- 1. Don't 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-quided 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 bracket under the following ambient conditions:
  - Ambient temperature: -20°C to 55°C
  - Relative humidity: 20% to 95% (no condensation)

## 13.2.9 Disposal

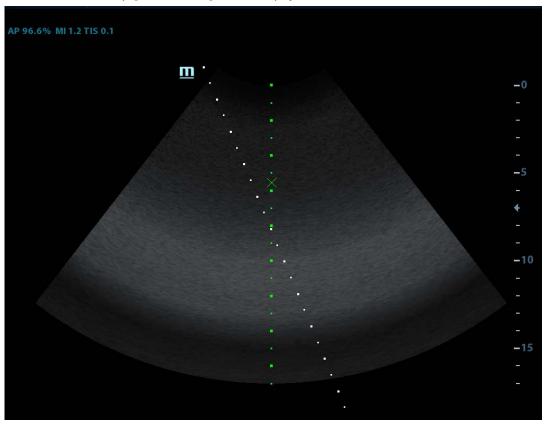
Be sure to dispose the needle-guided bracket only after sterilizing it.

Contact your MINDRAY representative when disposing of this device.

## 13.3 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 menu



- 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

#### NOTE:

Strictly observe the procedures described here to perform the recording and replaying operations; otherwise it may result in data loss or system malfunction.

Accidental exposure to strong electromagnetic fields 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: Local/USB/CDROM;
- 3. Click [Close] to enter recording status;
- 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:\dvr.
    In the patient task management screen, click [Media Storage Task] tab to check transferring

## 14.2 Send Image

status.

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;
- 2. Select the destination and the target file, click [Send] to send the file to the selected path.

During sending progress, the icon displays as

## 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 and select desired playing type: Local/USB/CDROM;
- 2. Click [Play] to open the dialogue box;
- 3. Select the path and name for the file and then click [OK] to replay the file, or double-click the file name directly.

# 15 Acoustic Output

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 ≤28.5%, TI≤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. <u>Once you perform preset settings, default setting values of the system may be changed and invalid.</u> It is the user's responsibility for any change to the default settings.

Adjusting range

Initial power: 3.2% 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.

NOTE:

This system automatically returns to the settings whenever changes are made to the values (when you turn on the power, switch between probes, press <End Exam>, or select OK or Cancel in the Setup menu). In the factory default settings, the Acoustic Output is limited below 100%. Following the ALARA restriction, you are allowed to increase the acoustic power under FDA 510(k) Guidance-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: 2007, FDA 510(K) GUIDANCE, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment (NEMA UD-2 2004) and the Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment (AIUM and NEMA UD-3 2004).

## 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<sub>SPTA.3</sub> of 720 mW/cm² 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 l<sub>atten</sub> is the attenuated intensity, l<sub>water</sub> is the intensity measured in a water tank (at distance z), fc is the center frequency of the ultrasound wave (as measured in water), and z is the distance from the probe. The equation for attenuating pressure values is similar except that the attenuation coefficient is 0.15 dB/cm/MHz, or one-half the intensity coefficient. The intensity coefficient is double the pressure coefficient because intensity is proportional to the square of pressure.

Although the attenuation coefficient chosen, 0.3 dB/cm/MHz, is significantly lower than any specific solid tissue in the body, this value was chosen to account for fetal examinations. In early trimester ultrasound fetal examinations, there may be a significant fluid path between the probe and the fetus, and the attenuation of fluid is very small. Therefore the attenuation coefficient was lowered to account for this case.

## 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 <sub>spta.3</sub> (mW/cm <sup>2</sup> ) | I <sub>sppa.3</sub> (W/cm <sup>2</sup> ) |    | MI    |
|-----------------------|---|--|----|-------|
| Regions (except eyes) | ≤720                                      | ≤ 190                                    | or | ≤ 1.9 |

## 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 than0.3 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 proscribed 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:

| Ispta                              | 28.5%   |
|------------------------------------|---|
| I <sub>sppa</sub>                  | 28.5%   |
| Center frequency (f <sub>C</sub> ) | 2%  |
| Total power (W)                    | 28.5 % (5.1% for Scan-mode and Combined-mode) |
| Rarefactional pressure (pr)        | 14.7%   |

## 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. "Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, Revision 3" issued by AIUM/NEMA in 2004
- 4. "Standard for real-time display of thermal and mechanical acoustic output indices on diagnostic ultrasound equipment, Revision 2" issued by AIUM/NEMA in 2004
- 5. "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" issued by FDA in 2008
- 6. "Medical electrical equipment Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment" issued by IEC in 2007

# **16** EMC Guidance and Manufacturer's Declaration

The system complies with the EMC standard IEC 60601-1-2: 2014.

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.
- 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.
- 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 the system,including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

#### NOTE: 1

- 1 The system needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.
- 2 Other devices may interfere with this system even though they meet the requirements of **CISPR**.
- 3 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.
- 4 Portable and mobile RF communications equipment can affects system. See tables 1, 2, 3, and 4 below.

If the system is operated within the electromagnetic environment listed in Table 2 and Table 3, the system will remain safe and will provide the following basic performances:

- Imaging;
- Doppler acoustic spectral displaying;
- Taking measurements;
- Patient information;
- Date/time information.

#### TABLE 1

| GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC EMISSIONS  |            |   |  |
|---|------------|---|--|
| The system is intended for use in the electromagnetic environment specified below. The customer or the user of system should assure that it is used in such an environment. |            |   |  |
| EMISSIONS TEST  | COMPLIANCE | ELECTROMAGNETIC ENVIROMENT—<br>GUIDANCE   |  |
| RF emissions<br>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<br>CISPR 11  | Class B    | The system is suitable for use in all   |  |
| Harmonic Emissions<br>IEC 61000-3-2   | Class A    | establishments including domestic<br>establishments and those directly<br>connected to the public low-voltage   |  |
| Voltage Fluctuations/ Flicker<br>Emissions<br>IEC 61000-3-3   | Compliance | power supply network that supplies buildings used for domestic purposes   |  |

TABLE 2

## **GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC IMMUNITY**

The system is intended for use in the electromagnetic environment specified below. The customer or the user of system should assure that it is used in such an environment.

| IMMUNITY TEST  | IEC 60601<br>TEST LEVEL   | COMPLIANCE<br>LEVEL  | ELECTROMAGNETIC ENVIRONMENT-GUIDANCE  |
|--|---|--|---|
| Electrostatic<br>Discharge(ESD)<br>IEC 61000-4-2   | ±8 kV contact;<br>±15 kV air  | ±8 kV contact;<br>±15kV 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<br>Transient / burst<br>IEC 61000-4-4  | ±2 kV for power<br>supply lines;<br>±1 kV for<br>input/output<br>lines  | ±2 kV for power<br>supply lines;<br>±1 kV for<br>input/output lines  | Mains power quality should be that of a typical commercial or hospital environment.   |
| Surge<br>IEC 61000-4-5   | ±1 kV line(s) to line(s); ±2 kV line(s) to  | ±1 kV line(s) to<br>line(s);<br>±2 kV line(s) to   | Mains power quality should be that of a typical commercial or hospital environment.   |
| Voltage dips,<br>Short interruptions<br>and voltage<br>variation on power<br>supply input<br>voltage<br>IEC 61000-4-11 | earth  0 % UT; 0,5 cycle  At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°  0 % UT; 1 cycle 70% UT for 25/30 cycle at 0°  0 % UT; 250/300 cycle | earth  0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°  0 % UT; 1 cycle 70% UT for 25/30 cycle at 0°  0 % UT; 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<br>(50/60 HZ)<br>magnetic field<br>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.   |

#### TABLE 3

#### GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC IMMUNITY

The system is intended for use in the electromagnetic environment specified below. The customer or the user of system should assure that it is used in such an environment.

| IMMUNITY<br>TEST                          | IEC 60601 TEST<br>LEVEL  | COMPLIANCE<br>LEVEL  | ELECTROMAGNETIC<br>ENVIRONMENT-GUIDANCE  |
|---|--|--|--|
| Conduced RF<br>IEC 61000-4-6              | 3 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz | 3 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz | Portable and mobile RF communications equipment should be used no closer to any part of system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \ x \ \sqrt{P}$ |
| Radiated RF<br>IEC 61000-4-3              | 10 V/m<br>80MHz - 2.7GHz   | 10 V/m<br>80MHz -<br>2.7GHz  | d = 1.2 x $\sqrt{P}$ 80 MHz to 800 MHz<br>d = 2.3 x $\sqrt{P}$ 800 MHz to 2.7GHz<br>Where, P is the maximum output<br>power rating of the transmitter in<br>watts (W) according to the<br>transmitter manufacturer and d is  |
| Proximity fields                          | 27 V/m<br>380–390 MHz  | 27 V/m   | the recommended separation distance in meters (m).  Field strengths from fixed RF  |
| from RF wireless communications equipment | 28 V/m<br>430–470 MHz,<br>800–960 MHz,<br>1700–1990 MHz,<br>2400–2570 MHz                  | 28 V/m   | transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.  Interference may occur in the vicinity of equipment marked with the  |
| IEC 61000-4-3                             | 9 V/m<br>704–787 MHz,<br>5100–5800 MHz   | 9 V/m  | 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.

**a** 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 system is used exceeds the applicable RF compliance level above, system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the system.

**b** Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.

#### TABLE 4

## RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATION DEVICE AND THE SYSTEM

The system is intended for use in an electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and system as recommended below, according to the maximum output power of the communication equipment.

| Rated Maximum Output power of | Separation Distance According to Frequency of Transmitter (m) |              |               |  |
|-------------------------------|---|--------------|---------------|--|
| Transmitter                   | 150kHz -80MHz   | 80MHz-800MHz | 800MHz-2.7GHz |  |
| (W)                           | d=1.2√P   | d=1.2√P      | d=2.3√P       |  |
| 0.01                          | 0.12  | 0.12         | 0.23          |  |
| 0.1                           | 0.38  | 0.38         | 0.73          |  |
| 1                             | 1.2   | 1.2          | 2.3           |  |
| 10                            | 3.8   | 3.8          | 7.3           |  |
| 100                           | 12  | 12           | 23            |  |

For transmitters at a maximum output power not listed above, the recommended separation distanced in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

If system image distortion occurs, it may be necessary to position system further from sources of conducted RF noise or to install external power source filter to minimize RF noise to an acceptable level.

Note 1 At 80 MHz and 800 MHz, the separation distance for 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.

#### Cable sample

| 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        | 4.0m             | Shielding     | /       |
| 4   | Probe Cable      | <3.0m            | Shielding     | /       |
| 5   | Footswitch Cable | 2.9m             | Shielding     | /       |

# 17 System Maintenance

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.

## $\Delta$ WARNING:

- 1. Only an authorized Mindray service engineer can perform maintenance not specified in this operator's manual.
- 2. For the sake of the system performance and safety, you should perform periodical checks for the system.

## 17.1 Daily Maintenance

You are responsible for daily maintenance.

## 17.1.1 Cleaning the System

## **△WARNING**:

Before cleaning the system, be sure to turn off the power and disconnect the power cord from the outlet. If you clean the system while the power is "On", it may result in electric shock.

DO NOT directly spray solution onto the monitor, system control panel or hard surfaces that is under pressure or pumped. Ingress fluid leakage into the monitor or system can damage the monitor or system, causing possible electric shock or system failure.

 $\Lambda$ CAUTION:

Do not spill water or other liquid into the system while you perform the cleaning. Otherwise it may result in malfunction or electric shock.

#### NOTE:

DO NOT use hydrocarbon glass cleaner or cleaner for OA (Office Automation) equipment to clean the monitor. These substances may cause deterioration of the monitor.

Please clean the control panel periodically, otherwise the button may be blocked by dirt and the system will be buzzing while the button makes no response.

- Cleaning the probe
  - Tools: mild soapy water , dry soft cloth, soft brush
  - Method:
    - a) Wipe out the dust attached to surface of probe head, connector and cable.
    - b) Use soft brush to brush the dust inside probe connector gently.
    - c) Remained stain or dust attached to surface of cable or surface of connector should be washed out by cloth with a little soapy water, and then air-dry.

**NOTE:** Don't use cloth with water to clean the probe connector.

#### Cleaning the probe cable

- a) Use soft dry cloth to wipe off stains from the probe cable.
- b) If it is difficult to clean the stains thoroughly, use soft cloth dipped with mild detergent, and then let the cable air dry.

#### Cleaning holders

- Tool: dry soft cloth, soapy water, soft brush
- Method:

Surface of power button should be cleaned by dry soft cloth. Remained stain should be washed out by cloth with clear water or soapy water (NOTE: cloth should not be dipped with too much water, which may cause electric shock), and then air-dry the surface.

- a) Use dry soft cloth to wipe off the dust attached to inside, outside or gap of probe holder or gel holder. As to small intra-cavity probe holder or its gap, use the soft brush to brush the dust or stain.
- b) Remained stain attached to inside, outside of holder should be washed out by cloth with a little soapy water and then air-dry after take it out.
- c) Gel warmer: Take the gel warmer out after pull out the power supply cable, use dry soft cloth to wipe off the dust attached to inside and outside, then brush the dust in the gel warmer or brush the stain with a little soap water and air-dry at last.
- Cleaning the monitor and the touch screen
  - Tool: soft dry cloth ,clear water or soapy water
  - Method:

Surface of monitor and touch screen should be cleaned with soft dry cloth directly. Remained stain should be washed out by cloth with a little clear water or soapy water, and then air-dry the surface.

- Cleaning the main panel
  - Tools: dry soft cloth, soapy water
  - Method:

Use dry soft cloth to clean the surface of control panel (including keystrokes, encoders and sliders). If the control panel is dirty, moisten the soft cloth with a little mild soapy water and wipe off any stains. Use another dry soft cloth to remove any moisture and allow all hard surfaces to completely air-dry. If it is difficult to clean the control panel, disassemble the encoder caps first and then use mild soapy water to clean it.

**NOTE:** Keyboard on the control panel should be cleaned periodically; otherwise, keys maybe blocked by dirt and buzzer dings, keys don't work.

#### Cleaning cover

- Tools: dry soft cloth, soapy water
- Method:

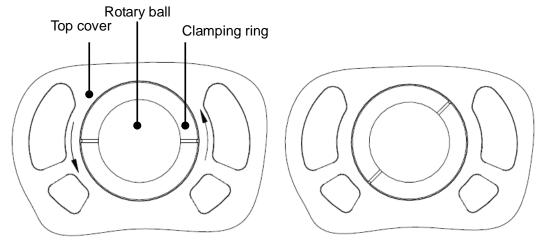
Use dry soft cloth to clean the cover of the system. If the system is dirty, moisten the soft cloth with mild soapy water and wipe off any stains, then air-dry.

#### Cleaning the trackball

- Tools: Paper, dry cloth or mild soapy water
- Method:

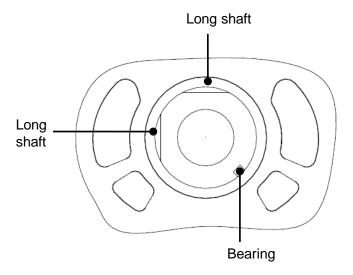
#### 1. Disassembling the trackball:

Press the bulges on the clamping ring by both hands and turn the ring about 45° counterclockwise until it lifts. Take out the ring and the rotary ball. Be careful not to drop the ball. As shown in figure below.



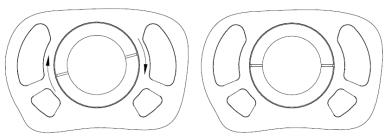
#### 2. Cleaning

Clean the two long shafts, the bearing and the rotary ball with clean soft dry cloth or paper.



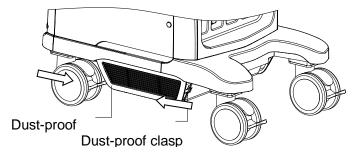
## 3. Installing the trackball

Put the rotary ball back in the trackball mechanism and put the clamping ring back in (with the bulge direction of 15 ° deviated from the horizontal line), turn the ring clockwise until the bulges are flush with the top cover, and the ring clicks and locks, which means the ring is secured. See figure below.



- Clean dust-proof cover
  - Tool: Soft brush
  - Method:
    - a) Disassemble dust-proof cover before cleaning.

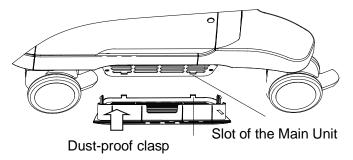
System dust-proof cover: Grab the lower side of the dust net frame, and then pull out the net.



Probe port dust-proof cover: there are 4 probe ports at the front of the system, on which there is a dust-proof cover. Pull it out.

- b) Cleaning: with soft brush and then wipe off the dust.
- c) Assemble dust-proof covers.

Input the dust-proof clasp into the slot of the main unit, push the dust-proof inward until the dust-proof clasp is stuck in the slot.



**∆**CAUTION:

Please clean all dust-proof covers of the system periodically (1 time per month); otherwise, system damage may result. Cleaning times can be increased when the system is used in the open air or somewhere dust is more.

**NOTE:** Be sure to use soft brush to brush the dust attached to all the sockets or interfaces which can be seen (such as probe sockets, sockets or interfaces in IO panel and power supply panel),not the cloth with water.

#### Cleaning the peripherals

Do the cleaning maintenance according to your actual peripheral configuration; items which are not configured can be skipped.

| Content                     | Description  |
|-----------------------------|--|
| Color and B/W video printer | First wipe off dust or stain attached to the cover of printer with soft dry cloth, then clean the inside of printer. Be sure to do the cleaning maintenance according to the operation manual if is necessary. |
| Graph / text<br>printer     | First wipe off dust or stain attached to the cover of printer with soft dry cloth, then clean the inside of printer. Be sure to do the cleaning maintenance according to the operation manual if is necessary. |
| Footswitch                  | Use soft dry cloth with a little mild soap water to wipe off the dust or stain attached to the pedals or cable of foot switch.   |
| Barcode reader              | First use soft dry cloth to wipe off dust attached to glass panel of the reader, then the dust or strain attached to cable and bracket. Refer to Appendix E Barcode Reader for details.                        |

## 17.1.2 Checking the Probe

- Visually check to confirm that there is no crack and expansion to probe head.
- Visually check to confirm that there is no deterioration or desquamation to probe cable.
- Visually check to confirm that there is no bend, destroyed or falling off pins to the connector.

## 17.1.3 Checking the Power Cable and Plug

- Visually check to confirm that there is no wrinkles, crack or deterioration; No crack and expansion to the surface of adapter.
- Manually check to confirm that there is no looseness or rupture. The connection of plug is reliable.

## 17.1.4 Checking the Circuit Breaker

Manually check to confirm that the circuit breaker can be turned on or off normally.

## 17.1.5 Checking Appearance

Check if there is any crack in the covers:

- Ultrasound system covers
- Probe appearance
- External appearance of ECG lead

## 17.1.6 Backup of the System Hard Drive

To prevent deterioration or loss of data stored in the system hard drive data (including patient info data, preset data and etc.), create a backup copy of the hard drive at regular intervals.

## 17.2 Troubleshooting

If any persistent system malfunction is experienced, e.g. an onscreen error message, blank imaging screen, absent menus, please refer to the table below. If the failure can't be eliminated, please contact Mindray Customer Service Department or sales representative.

**Troubleshooting Table** 

| No. | Failure   | Cause  | Measure   |
|-----|---|--|---|
| 1   | After the AC power input is connected, the power indicator does not light on. | <ul> <li>Abnormal power system<br/>or incorrect connection of<br/>the power cord.</li> </ul>   | <ul> <li>Check if the system is plugged in.</li> <li>Check if the system circuit breaker is in the Up position.</li> <li>Check if the plug has not become loosened or dislodged from the back of the system.</li> </ul> |
| 2   | The power indicator of the monitor is light on, but image is blank.           | <ul> <li>The interval between turning off and restarting the system is too short – wait a minimum time of 20 seconds.</li> <li>The monitor brightness or contrast may be improperly set.</li> </ul>      | <ul> <li>Turn off the system and wait a minimum time of 1 minute, and then restart the system.</li> <li>Adjust the monitor brightness and contrast back to factory defaults.</li> </ul>                                 |
| 3   | The monitor displays the characters and menus but no images.                  | <ul> <li>The transmission power, overall gain or TGC controls are improperly set.</li> <li>Check if a probe is connected and/or fully connected.</li> <li>The system is in the frozen status.</li> </ul> | <ul> <li>Adjust the transmission power, gain or TGC control.</li> <li>Ensure proper probe connection.</li> <li>Unfreeze the image.</li> </ul>   |
| 4   | The image quality is degraded   | <ul> <li>The exam mode is not correct.</li> <li>The settings of the image post processing are not correct.</li> <li>The image presets are inappropriate.</li> </ul>                                      | <ul> <li>Select an appropriate exam mode.</li> <li>Adjust the settings of the image via post processing or reset the post processing to the default values.</li> <li>Reset the factory default presets.</li> </ul>      |
| 5   | The button is responseless with the system buzzing                            | ■ There is too much dirt blocking the button   | <ul> <li>Check the control panel for the button being blocked and press it several times to release it.</li> <li>Clean the button.</li> </ul>   |

## Appendix A Wireless LAN

The system provides wireless net adapter configuration, so as to assist information query and unlimited network service.

## **MARNING**

It is prohibited to use the wireless LAN function in an airplane, as this may violate the relevant provisions in the aviation regulations.

Use the wireless LAN function prudently in emergency ambulances (or other vehicles) as other devices or communication signals may be interfered with.

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 ≥300M
  - Use AP (access point) setting;
  - Number of the devices connected to the same router ≤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 IEC60601-1-2: 2014 standard.

## A.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 after successful connection.

#### IP Config

**NOTE:** When the system background is processing network task (DICOM sending for example), please do not enter network setting to change the IP, otherwise the background task may fail. You can check if there are tasks undergoing in the task manager.

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.
  - Click [Refresh] to check current IP address.
- 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.

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).

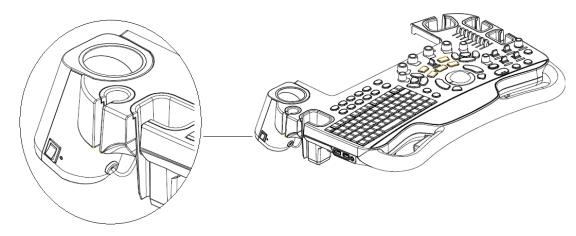
2. Click [Apply] to save current setting. Click [Close] to exit.

**NOTE:** 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.

## **Appendix B Ultrasound Gel Warmer**

Ultrasound gel warmer is an option of the system, used for heating the ultrasound gel.

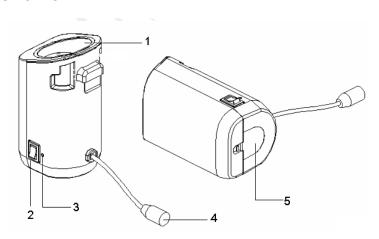
## **B.1** Overview



As shown in the figure above, the warmer is installed at left side of the control panel, the position that is used for placing the ultrasound gel.

To install the warmer, you should remove the ultrasound gel holder first.

## **B.2** Structure



| No. | Name                   | Function   |
|-----|------------------------|--|
| 1.  | Ultrasound gel box     | Used for placing ultrasound gel.   |
| 2.  | Warming control switch | Set the gel warmer to the temperature of 37 $^{\circ}\mathrm{C}$ /40 $^{\circ}\mathrm{C}$ , or turn off. |
| 3.  | Status indicator       | Working normally: green. Failure: blink in orange.   |
| 4.  | Power cable            | Connect to the power socket under the control panel.   |
| 5.  | Bottom cover           | /  |

## **B.3** Specifications

#### Power supply

| Voltage           | 12V <sup></sup> |
|-------------------|-----------------|
| Power consumption | 12W             |

#### Environmental conditions

|                      | Operating conditions               | Storage and transportation conditions |
|----------------------|------------------------------------|---------------------------------------|
| Ambient temperature  | 5℃~40℃                             | -20℃~55℃                              |
| Relative humidity    | $35\%{\sim}85\%$ (no condensation) | $30\%{\sim}85\%$ (no condensation)    |
| Atmospheric pressure | 700hPa∼1060hPa                     | 700hPa∼1060hPa                        |

## **B.4** Function and Requirement

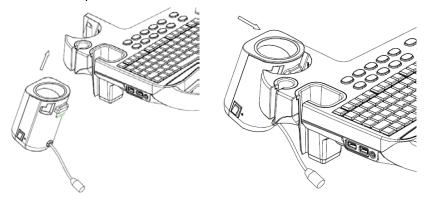
When the gel is put inside the warmer, the time it takes to heat from environmental condition of  $18^{\circ}$ C to 28  $^{\circ}$ C should be no more than 0.5 hours.

The ultrasound gel warmer can work continuously over 12 hours.

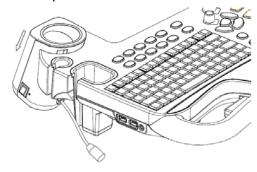
| NOTE: | When the environment temperature is higher than the requirement temperature of the warmer, the warmer does not function. |
|-------|--|
|       | The warmer can heat only one bottle of gel at one time.  |

## **B.5** Install the Warmer

1. As shown in the figure, install the gel warmer as per the arrow direction, to fix the tab of the warmer to the groove in the control panel.



2. Push the warmer as per the arrow direction until it is tightly fixed, and connect the power cable to the power socket under the control panel.



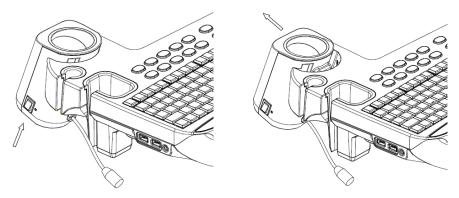
- 3. Insert the power plug of the warmer into the jack in the back side of the control panel.
- 4. Put the gel inside the warmer, and press the warming control switch, the gel warmer starts to work. There are three levels of the switch:
  - II: sets the warmer to 40 °C.
  - I: Sets the warmer to 37℃.
  - O: turn the warmer off.

NOTE:

If the status indicator is off or blinks in orange after connecting the power cord, it means the gel warmer is not working normally, please turn it off and contract the service engineer.

## **B.6** Remove the Warmer

- 1. Pull out the power cable from the control panel jack.
- 2. Push the warmer as per the arrow direction.



3. Remove the warmer as shown in the following figure.

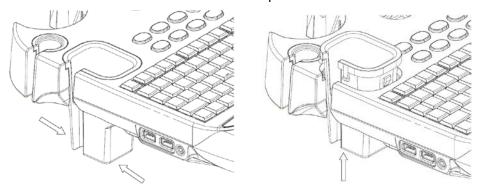


# **B.7** Mount/Remove Probe Holder

To install the gel warmer, you have to remove the probe holder first.

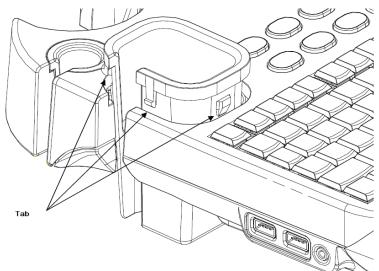
#### **B.7.1** Remove the Holder

Push towards the arrow direction on the bottom and lift upwards to remove the holder.



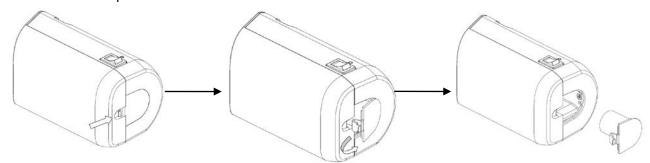
### **B.7.2** Mount the Holder

Match the tab with the groove inside the control panel, and push the holder downwards to mount the holder.



# **B.8** Cleaning

1. Press the clasp of the bottom cover to release the cover.



2. Remove the cover and clean the cover.

# **Appendix C Battery**

 $\Delta$ WARNING:

The battery is inside the machine; only technical professionals from Mindray or engineers authorized by Mindray after training can perform battery installation and uninstallation.

If you need to change the battery or buy a new one, please contact your sales representative.

## C.1 Overview

The built-in battery is an 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 8 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.

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

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.

# C.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 nearly empty.
- Indicates the battery capacity is full.

# Appendix D iWorks (Auto Workflow Protocol)

#### D.1 Overview

The major objective of ultrasound workflow automation (iWorks) is to speed up exam time and reduce the excessive number of user interface manual key strokes that can lead to repetitive motion injuries over time. It automates a clinical work flow in common exam protocols in a logical, "step by step" manner. It also prevents missing an important part of an examination as well as decreases exam time.

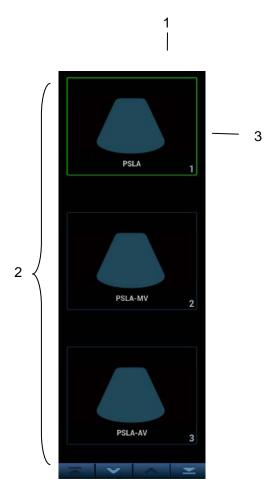
A Protocol Event contains series workflow events (annotation comments, body mark and measurements) and image modal commands to assist the user in routine ultrasound examinations.

The system provides different protocol events based on the different application regions. iWorks is an option.

# D.2 Normal iWorks Basic Procedure

- 1. Enter the patient information.
- 2. Touch [iWorks] on the touch screen 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 right part of the screen, perform the scanning and saving according to the screen prompt.
  - Perform measurements or add comment/body mark to the image according to the screen prompt.
- 4. After one view scanning is completed, press the user-defined save key (usually <Save1> or <Save2>) to switch to the next view according to the screen prompt.
- 5. Repeat step 3 and step 4 to acquire all necessary images.
  - If any pathology is discovered, touch [Insert] to select a protocol out of normal routine to start scanning.
  - Tap [Repeat] to add a copy of the selected view to operate if necessary.
  - Tap [Next] or [Previous] to skip to a certain view you are interested.
  - Tap [Replace] to delete images and operations of the selected view and restart operations on that view.
  - Tap [Delete] to delete current activated view.
  - Tap [Suspend] to start a manual scanning when unusual or atypical workflow is required, and touch [Resume iWorks] to restart iWorks procedure.
- 6. After all views are finished, the system will prompt you if to exit iWorks, touch [Yes] to exit.

# D.3 Screen Display



| Name | Description   |
|------|---|
| 1    | Displays the protocol name, and the number of views contained.    |
| 2    | Displays the view steps in the protocol.                          |
| 3    | The current active view, with green solid frame around the image. |

# **D.4** View Operation

In iWorks status, you can perform view selection, repeat, replacement and delete operations by 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 lower left corner of the image, ready for you to scan the specified anatomy.

#### D.4.1 View Selection

Tap [Previous] / [Next] to select the view to be scanned. The current view is surrounded by a solid green frame.

## **D.4.2** View Operation

In the current active view, you can perform image scanning, measurements, and adding comments and body mark, etc. Operations are the same as those in manual operation. See the relevant chapters for details.

## D.4.3 Repeat View

If necessary, touch [Repeat] to insert another template of the current view. You can then perform an extra examination.

## **D.4.4** View Replacement

The previous image will be deleted and replaced by the new image.

#### D.4.5 Delete View

Tap [Previous]/ [Next] to select the view to be deleted. Tap [Delete] to delete the selected view.

# **D.5** Check Undone Section

You can quickly check and select an incomplete view using [Incomplete Section] on the touch screen.

Tap [Incomplete] on the screen to enter the selecting dialog box on the touch screen and touch the desired view to enter the status.

# **D.6** 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.

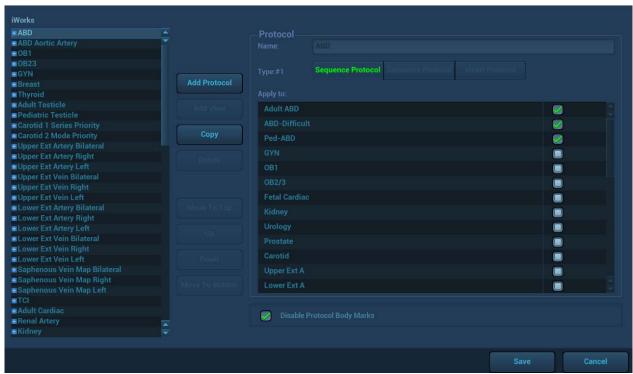
## D.7 Insert

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.

# D.8 iWorks Setting

Enter the iWorks preset screen through the path: "[Setup]  $\rightarrow$  [iWorks]". Here you can customize the protocols and views:



## **D.8.1** Protocol Management

- 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 "Apply 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 "copy of XXX" is created with the copied views, which can be customized.
- 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.

# **D.8.2** View Management

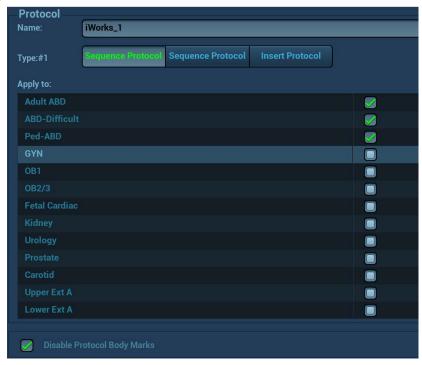
- Click to select the views in the list. The image, annotation, body mark and measurement settings can be checked on the right.
- Click to select a user-defined protocol in the list. Click [Add View] to add a view template to the protocol.

#### **D.8.3** Create New Protocol

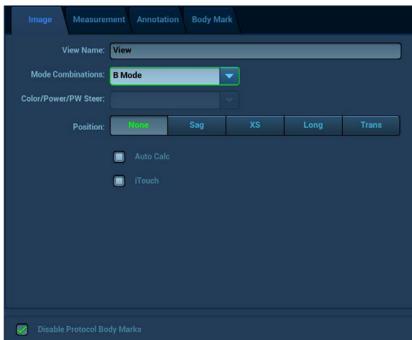
You can create user-defined protocols and customize the automated procedure.

1. In the iWorks preset screen, click [Add Protocol] to create a new protocol, enter the protocol name, type and select the application region.

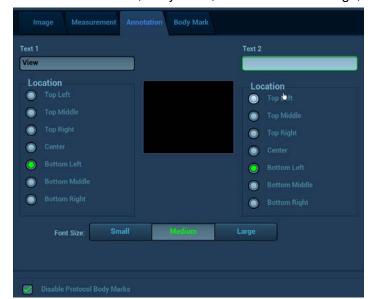
Or you can select an existed protocol and click [Copy] to customize the protocol based on the previous template.



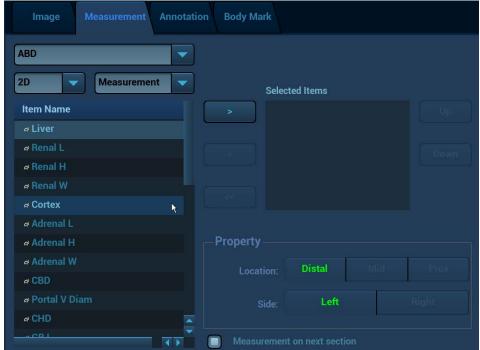
2. Click [Add View] to enter the view name, and perform image settings, as shown in the following figure.



3. Perform comments, body mark, 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, and one of the two sections will include the measurement result.

4. Use the check box for auto OB measurement and body mark display settings.

Disable Protocol Body Marks

5. Click [Save] to complete the setting and exit.

# Appendix E Barcode Reader

The product supports reader for logging data as patient ID: 1-D barcode reader (SYMBOL LS2208). The laser transmitted by the reader is Class 2 laser.

 $\triangle$ 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.

**CAUTION:** Ensure the information acquired by barcode reader is consistent with the actual information.

There are 2 operation modes:

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.

**NOTE:** The reader does not support decoding of Multilanguage.

## E.1 1-D Barcode Reader

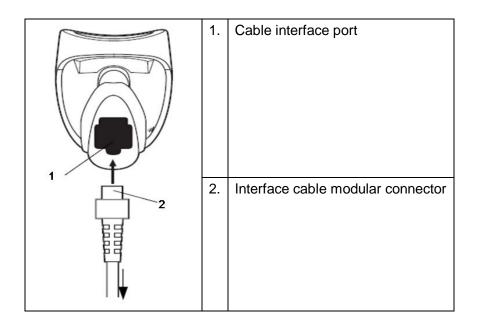
#### E.1.1 Overview



| 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  |

## E.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.



# E.1.3 Setting

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 codebar scanning:

To enable or disable Code 93, scan the appropriate barcode below.



Enable Code 93

To enable Codebar, 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

■ 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.

















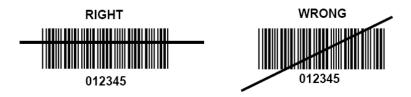




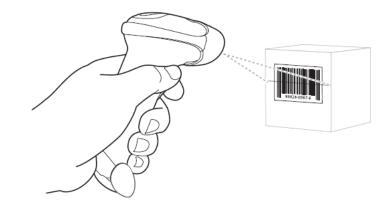
## E.1.4 Scanning in Hand-Held Mode

- 1. Ensure all connections are secure.
- 2. Aim the reader at the barcode. Press the trigger.

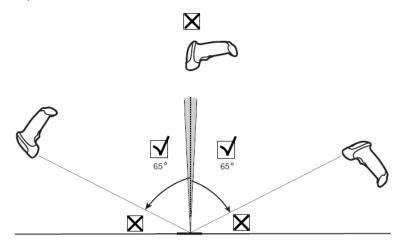
**NOTE:** Ensure the scan line crosses every bar and space of the symbol, see the figure below.



3. Upon successful decode, the reader beeps and the LED turns green.

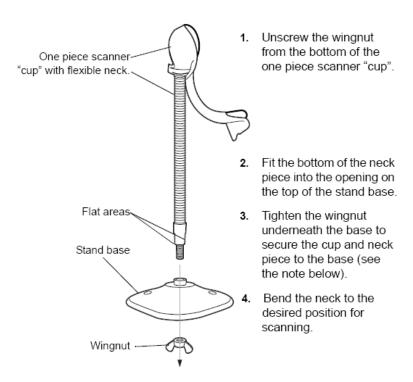


Tips: Do not hold the reader directly over the barcode. Laser light reflecting *directly* back into the reader from the barcode is known as specular reflection. This specular reflection can make decoding difficult. You can tilt the reader up to 55 forward or back and achieve a successful decode



## E.1.5 Scanning in Hands-Free Mode

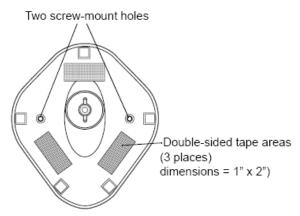
#### Assembling the Intellistand



**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.

#### **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).

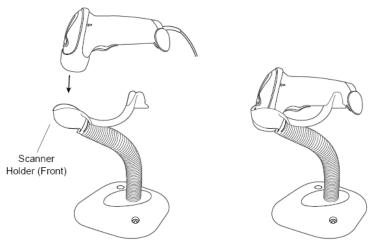


- Screw Mount
- 1. Position the assembled base on a flat surface.
- 2. Screw one #10 wood screw into each screw-mount hole until the base of the stand is secure
- Tape Mount
- 1. Peel the paper liner off one side of each piece of tape and place the sticky surface over each of the three rectangular tape 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.

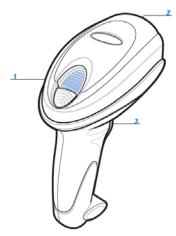
#### Scanning in Hands-Free Mode

When the reader is seated in the stand's "cup", the reader's built-in sensor places the reader in handsfree mode. When you remove the reader from the stand it operates in its normal hand-held mode.



# E.2 2D Barcode Reader (Take DS6707 as an example)

#### E.2.1 Overview

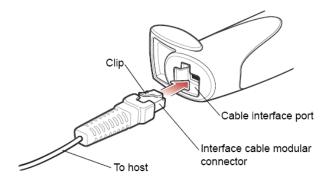


| 1. | LED         | Green: A barcode was successfully decoded.                     |
|----|-------------|--|
|    |             | Red: A data transmission error or reader malfunction occurred. |
| 2. | Scan window | Scan the barcode.  |
| 3. | Trigger     | Press to decode  |

# E.2.2 Setting Up the Digital Imager Reader

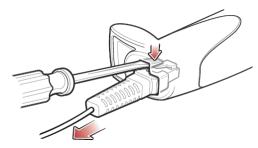
#### **E.2.2.1** Installing the Interface Cable

- 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



#### E.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.

## E.2.3 Setting

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 (02h)



Medium Volume (01h)



High Volume (00h)

#### code 93 and codebar setting

To enable Code 93, scan the appropriate barcode below.



Enable Code 93 (01h)

To enable Codebar, scan the appropriate barcode below.



Enable Codabar (01h)

#### 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 (01h)



Disable Code 39 Full ASCII (00h)

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.















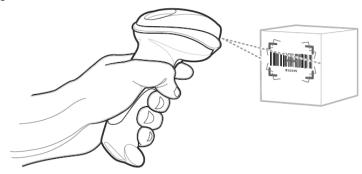
Carriage Return/Line Feed setting

Scan the barcode below to set Carrige Return/Line Feed.

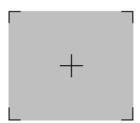


# E.2.4 Scanning in Hand-Held Mode

- 1. Ensure all connections are secure (see the appropriate host chapter.)
- 2. Aim the digital imager reader at the barcode.

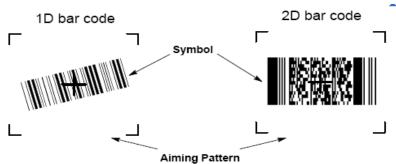


3. When the digital imager reader senses movement, in its default **Auto Aim** trigger mode, it projects a red laser aiming pattern which allows positioning the barcode or object within the field of view.



If necessary, the digital imager reader turns on its red LEDs to illuminate the target barcode.

4. Center the symbol in any orientation within the aiming pattern. Be sure the entire symbol is within the rectangular area formed by the brackets in the pattern.



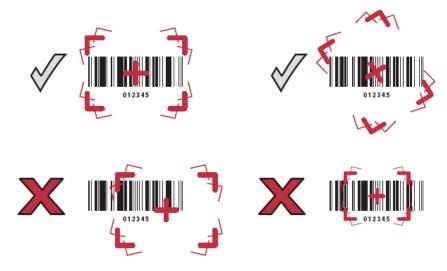
5. Hold the trigger until the digital imager reader beeps, indicating the barcode is successfully decoded.

NOTE: Steps 2 - 4 may be required to repeat on poor quality or difficult barcodes.

Tips: Hold the digital imager reader between two and nine inches (depending on symbol density) from the symbol, centering the aiming pattern cross hairs on the symbol.

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 pattern but not centered. The top examples in show acceptable aiming options, while the bottom examples cannot be decoded.



# E.2.5 Scanning in Hands-Free Mode

The optional Intellistand adds greater flexibility to scanning operation. When the digital imager reader is seated in the stand's "cup," the digital imager reader's built-in sensor places the digital imager reader in hands-free mode. When the digital imager reader is removed from the stand it operates in its normal hand-held mode.

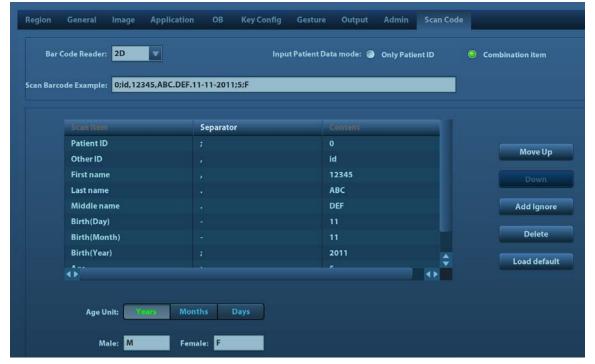
Use the Intellistand's adjustment knobs to adjust the height and angle of the digital imager reader.



Reader holder (cup)
 Angle adjustment knob
 Height adjustment knob

# **E.3** Setting in Ultrasound System

Open the Scan Code page via [Setup]  $\rightarrow$  [System]  $\rightarrow$  [Scan Code].



Setting items are described as follows:

| Parameter                  | Description  |
|----------------------------|--|
| Bar Code<br>Reader         | Select type: 1D or 2D.   |
|                            | Select type: Only Patient ID or Combination Items.   |
| Input Patient<br>Data mode | Only Patient ID: Only Patient ID is acquired from barcode reader. If this function is selected, patient ID can be acquired via barcode reading in Worklist or QR screen. |
|                            | Combination Items: patient ID, patient name and other information can be acquired from barcode. (available only in 2-D barcode reader)                                   |
| Scan Barcode<br>Example    | When 2-D barcode reader is adopted, you should first scan a sample barcode here and then set the parts definition for the information.                                   |

#### **Parameter Description** Set the start and end position of each item via separators. Swipe the screen downwards to see all parameter settings. The following items are displayed on the right side of the screen: Patient ID, Other ID, First Name, Last Name, Middle Name, Birth(Day), Birth(Month), Birth(Year), Age, and Gender. Separator **Patient ID** 0 Other ID 12345 First name **ABC** Last name Middle name DEF 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.) Move up: move up the selected item by one line. Parameter Down: move down the selected item by one line. Add Ignore: add one line below the selected item to hide unimportant patient information. Delete: delete the selected item. The item deletion operation does not delete the corresponding information in the barcode. Load default: restore the parameter value to the default value. Select an age unit from the drop-down list of the Age Unit: Year, Month, or Day. Input the customized gender symbol besides the Male and Female filed box. such as Male (M) or Female (F). 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.

# **E.4** Parameter Defaults

Refer to the following table for parameter defaults of LS2208.

| Parameter  | Defaults         |
|--|------------------|
| 1-D Symbologies                                    |                  |
| UPC/EAN  |                  |
| 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          |
| Code 128   |                  |
| Code 128   | Enable           |
| UCC/EAN-128  | Enable           |
| ISBT 128   | Enable           |
| Code 39  |                  |
| Code 39  | Enable           |
| Trioptic Code 39                                   | Disable          |
| Convert Code 39 to Code 32 (Italian Pharmacy Code) | Disable          |
| Code 32 Prefix                                     | Disable          |
| Set Length(s) for Code 39                          | 2 to 55          |
| Code 39 Check Digit Verification                   | Disable          |
| Transmit Code 39 Check Digit                       | Disable          |
| Code 39 Full ASCII Conversion                      | Disable          |

| Parameter                         | Defaults |
|-----------------------------------|----------|
| Buffer Code 39                    | Disable  |
| Code 93                           |          |
| Code 93                           | Enable   |
| Set Length(s) for Code 93         | 4 to 55  |
|                                   |          |
| Interleaved 2 of 5 (ITF)          |          |
| Interleaved 2 of 5 (ITF) Enable   | Enable   |
| Set Lengths for I 2 of 5          | 14       |
| 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  |
|                                   |          |
| Codabar (NW - 7)                  |          |
| Codabar                           | Enable   |
| Set Lengths for Codabar           | 5 to 55  |
| CLSI Editing                      | Disable  |
| NOTIS Editing                     | Disable  |

# E.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 F 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 complying with IEC 60601-1 used in Europe such as Fluke, Metron, or Gerb may require modifications to the procedure. Follow the instructions of the analyzer manufacturer.

The electrical safety inspection should be periodically performed every two years. The safety analyzer also proves to be an excellent troubleshooting tool to detect abnormalities of line voltage and grounding, as well as total current loads.

# F.1 Power Cord Plug

# F.1.1 The Power Plug

| Test Item      |                     | Acceptance Criteria   |
|----------------|---------------------|---|
| The power plug | The power plug pins | No broken or bent pin. 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 for device 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 at the device.        |
|                |                     | For devices with non-detachable power cords, inspect the strain relief at the device. |

# F.2 Device Enclosure and Accessories

# F.2.1 Visual Inspection

| Test Item                     | Acceptance Criteria  |
|-------------------------------|--|
|                               | No physical damage to the enclosure and accessories.                 |
| The enclosure and accessories | No physical damage to meters, switches, connectors, etc.             |
|                               | No residue of fluid spillage (e.g., water, coffee, chemicals, etc.). |

| Test Item | Acceptance Criteria  |
|-----------|--|
|           | No loose or missing parts (e.g., knobs, dials, terminals, etc.). |

# F.2.2 Contextual Inspection

| Test Item                     | Acceptance Criteria   |
|-------------------------------|---|
|                               | No unusual noises (e.g., a rattle inside the case).                                     |
| The enclosure and accessories | No unusual smells (e.g., burning or smoky smells, particularly from ventilation holes). |
|                               | No taped notes that may suggest device deficiencies or operator concerns.               |

# F.3 Device Labeling

Check the labels provided by the manufacturer or the healthcare facility are present and legible.

- Main unit label
- Integrated warning labels

# F.4 Protective Earth Resistance

- a. Plug the probes of the analyzer into the device's protective earth terminal and protective earth terminal of the AC power cord.
- b. Test the earth resistance with a current of 25 A.
- c. Verify the resistance is less than limits.

#### **■ LIMITS**

ALL COUNTRIES R =  $0.2 \Omega$  Maximum

# F.5 Earth Leakage Test

Run an Earth Leakage test on the device being tested before performing any other leakage tests.

The following outlet conditions apply when performing the Earth Leakage test.

- normal polarity( Normal Condition);
- reverse polarity( Normal Condition);
- normal polarity with open neutral(Single Fault Condition);
- reverse polarity with open neutral(Single Fault Condition).

#### ■ LIMITS

For UL60601-1,

- 300 µA in Normal Condition.
- 1000 μA in Single Fault Condition.

For IEC60601-1,

- 500 µA in Normal Condition.
- 1000 μA in Single Fault Condition.

# F.6 Enclosure Leakage Test

The following outlet conditions apply when performing the Enclosure Leakage test.

- normal polarity( Normal Condition);
- reverse polarity( Normal Condition);
- normal polarity with open neutral(Single Fault Condition);
- reverse polarity with open neutral(Single Fault Condition);
- normal polarity with open earth(Single Fault Condition);
- reverse polarity with open earth(Single Fault Condition).

#### LIMITS

For UL60601-1,

- 100µA in Normal Condition.
- 300 µA in Single Fault Condition.

#### For IEC60601-1:

- 100µA in Normal Condition.
- 500 µA in Single Fault Condition.

# F.7 Patient Leakage Current

Patient leakage currents are measured between a selected applied part and mains earth. All measurements have a true RMS only.

The following outlet conditions apply when performing the Patient Leakage Current test.

- normal polarity( Normal Condition);
- reverse polarity( Normal Condition),
- normal polarity with open neutral(Single Fault Condition);
- reverse polarity with open neutral(Single Fault Condition).
- normal polarity with open earth(Single Fault Condition);
- reverse polarity with open earth(Single Fault Condition).

#### ■ LIMITS

For BF applied parts,

- 100µA in Normal Condition.
- 500μA in Single Fault Condition.

# F.8 Mains on Applied Part Leakage

The Mains on Applied Part test applies a test voltage, which is 110% of the mains voltage, through 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) to 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 μA.

# F.9 Patient Auxiliary Current

Patient Auxiliary currents are measured between any selected Applied Part connector and the remaining Applied Part connectors. All measurements may have a true RMS only 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



- 100µA in Normal Condition.
- 500μA in Single Fault Condition.

**NOTE:** Make sure the safety analyzer is authorized comply with requirement of IEC61010-1. Follow the instructions of the analyzer manufacturer.

P/N: 046-011355-01 (1.0)