#### DC-N3S/DC-N3

# **Diagnostic Ultrasound System**

**Operator's Manual** 

[Basic Volume]

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This version of the manual applies to 01.00.00, 02.00.00, 03.00.00 and 04.00.00 software for the DC-N3S/DC-N3 ultrasound system.

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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.

#### **Customer Service Department**

**Manufacturer:** Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

Address: Mindray Building, Keji 12th Road South, High-tech industrial

park, Nanshan, Shenzhen 518057, P.R. China

Website: www.mindray.com

E-mail service@mindray.com

Address:

**Tel:** +86 755 81888998

**Fax:** +86 755 26582680

Mindray DS USA, Inc. 800 MacArthur Blvd. Mahwah, NJ 07430-0619 USA

Tel: +1(201) 995-8000

Toll Free: +1 (800) 288-2121 Fax: +1 (800) 926-4275

#### Important Information

- 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 DC-N3S/DC-N3 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.

**ACAUTION:** 

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.

#### Manuals on Paper

- 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]: Describes measurement preset, measurements and calculations, etc.
- 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:

- 1. The manuals in CD are the manuals translated into languages other than English according to English manuals.
- When you find that the contents of the manuals in CD are NOT consistent with the system or English manuals, please ONLY refer to the corresponding English manuals.
- 3. 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:

- <Button>: The angular bracket indicates buttons, knobs and other controls on control
  panel or keyboard.
- [Item in menu (soft menu) and button in dialog box]: The square bracket indicates items in menu or buttons in dialog box.
- Click [Item or Button]: Move the cursor to the item or button and press <Set>, or click it on the menu.
- [Item in Menu]→[Item in Submenu]: Select a submenu item following the path.
- [Dyn Rng (Value)]: Indicates menu items with parameter, (value) shows the current value of the item.

#### **Product Differences**

Ontion	Product Model	
Option	DC-N3	DC-N3S
B-Hist	V	×
B-Profile √ √		
NOTE: "√" means the option is configured on the product.		

NOTE: DC-N3S is not available in Canada.

# **1** Safety Precautions

#### 1.1 Safety Classification

- According to the type of protection against electric shock:
   Class I equipment powered by outer power & equipment powered by inner batteries
- According to the degree of protection against electric shock: Type-BF applied part
- According to the degree of protection against harmful ingress of water:

MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE

Main unit: IPX0 Probes: IPX7

Footswitch: 971-SWNOM (2-pedal or 3-pedal) belongs to IP68 and FS-81-SP (1-pedal) belongs to IPX8

- 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
- According to the mode of operation:

**CONTINUOUS OPERATION** 

According to the installation and use:

MOBILE EQUIPMENT

## 1.2 Meaning of Signal Words

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

Signal word	Meaning	
<b>≜</b> DANGER	Indicates an imminently hazardous situation that, if not avoided, will result in death or serious injury.	
<b>WARNING</b>	WARNING Indicates a potentially hazardous situation that, if not avoided, could result in death or serious injury.	
<b>A</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.	
Tips	Important information that helps you to operate the system more effectively.	

## 1.3 Meaning of Safety Symbols

Symbol	Description
	Type-BF applied part.
<u> </u>	The ultrasound probes connected to this system are type-BF applied parts.
$\triangle$	Caution.
	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 60601-1-1 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 60601-1-1), and the responsibility is held by the user.
- 5. Connect the grounding conductor before turning ON the system. Disconnect the grounding cable after turning OFF the system. Otherwise, electric shock may result.
- 6. For the connection of power and grounding, follow the appropriate procedures described in this operator's manual. Otherwise, there is risk of electric shock. Do not connect the grounding cable to a gas pipe or water pipe; otherwise, improper grounding may result or a gas explosion may occur.
- 7. Before cleaning the system, disconnect the power cord from the outlet. 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 and PCG transducer 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 may be exceeded and failure may be resulted. Maximum output power of the outlet is 240VA (including the auxiliary output port in the printer compartment).
- 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 60601-1-1. 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 60601-1-1. If you have any questions regarding these requirements, 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.

#### **⚠**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 move the system on the steps, please take care to prevent the system from toppling.

- 4. If the circuit protector is tripped, it indicates that the system or a peripheral device was improperly shut down and the system is unstable. You cannot repair the system under this circumstance and must call the Mindray Customer Service Department or sales representative.
- 5. There is no risk of high-temperature burns during normal ultrasound examinations. It is possible for the surface temperature of the 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, 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.

**NOTE:** 1. DO NOT use the system in the vicinity of strong electromagnetic field (such as a transformer), which may affect the performance of the system.

- 2. Do not use the system in the vicinity of high-frequency radiation source (e.g. cellular phones), which may affect the performance of the system or even lead to failure.
- 3. When using or placing the system, keep the system horizontal to avoid imbalance.

- 4. To avoid damaging the system, do not use it in following environment:
  - Locations exposed to direct sunlight;
  - Locations subject to sudden changes in environmental temperature;
  - Dusty locations;
  - Locations subject to vibration;
  - Locations near heat generators;
  - Locations with high humidity.
- 5. Turn ON the system only after the power has been turned OFF for a while. If the system is turned ON immediately after being turned OFF, the system may not be rebooted properly and could malfunction.
- 6. Press <Freeze> key to freeze an image or turn off the power of the system before connecting or disconnecting a probe. 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.
- 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.

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

#### **≜**WARNING:

- The probe is only for use with the specified ultrasonic diagnostic system. Please refer to the "2.5.2 Probes 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.
- 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.

#### $\Delta$ CAUTION:

- 1. When using the probe, wear sterile gloves to prevent infection.
- 2. Be sure to use sterile ultrasound gel. Please use the ultrasound gel compliant with the relevant local regulations. And manage the ultrasound gel properly to ensure that it does not become a source of infection.
- 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.
- 5. It is required to practice ALARA when operating ultrasound system. Minimize the acoustic power without compromising the quality of images.
- 6. The probe and accessories supplied with it are not delivered disinfected or sterilized. Sterilization (or high-level disinfect) before use is required.
- 7. Disposable components should be packaged sterile and for single-use only. Do not use if integrity of packaging violated or if expiration date has passed. Please use the disposable components compliant with the relevant local regulations.
- 8. Please use the disinfection or sterilization solution recommended in this operator's manual; otherwise Mindray will not be liable for damage caused by other solutions. If you have any questions, please contact Mindray Customer Service Department or sales representative.
- 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:

- 1. 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
- 2. Use the probes under the following ambient conditions (except D6-2 and D6-2A):
  - ambient temperature: 0°C to 40°C
  - relative humidity: 30% to 85% (no condensation)
  - atmospheric pressure: 700 hPa to 1060 hPa
- 3. Use the D6-2/D6-2A probe under the following ambient conditions:
  - ambient temperature: 10°C to 40°C
  - relative humidity: 25% to 90% (no condensation)
  - atmospheric pressure: 700 hPa to 1060 hPa

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 Latex-containing Medical Devices", issued on March 29, 1991).

## 1.6 Warning Labels

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

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

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

No.	Warning Labels	Meaning
1.	a d	a. Do not place the system on a sloped surface. Otherwise the system may slide, resulting in personal injury or the system malfunction. Two persons are required to move the system over a sloped surface.
	b (XI) c	b. Do not sit on the system.
		c. DO NOT push the system when the casters are locked.
		d. Caution! please carefully read this manual before use system.
2.	$((\bullet))$	Non-ionizing radiation
3.	No lifting	Please do not lift the hanger or try to push the ultrasound system by using it.
4.	Intertek 3179617	CONFORMS TO UL Std 60601-1, IEC Std 60601-1-1, IEC Std 60601-2-37 CERTIFIED TO CSA Std C22.2 No 601.1, CSA Std C22.2.60601.2.37, CSA Std C22.2 NO.60601-1-1
5.	When have wireless function, contain FCC ID:VQF-RT3091	WIFI module configured with the system has FCC certification. (ID: VQF-RT3091)

# **2** System Overview

#### 2.1 Intended Use

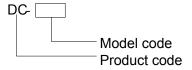
The DC-N3,DC-N3S Diagnostic Ultrasound System is applicable for adult, pregnant woman, pediatric patients and neonate.

It is intended for use in fetal, abdominal, pediatric, small organ (breast, thyroid, testes), cephalic (neonatal and adult), trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), cardiac (adult and pediatric), peripheral vascular and urology exam.

#### 2.2 Contraindication

This system is not intended for ophthalmic use.

#### 2.3 Product and Model Code



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

#### 2.4 Product Specifications

#### 2.4.1 Imaging Mode

B Mode B

М

M Mode Free Xros M

Free Xros CM

Color M Mode (CM)

C Mode Color

Power (Dirpower)

**D Mode** PW Doppler

CW Doppler

Special Imaging Smart 3D

Static 3D

4D

iScape/TDI

#### 2.4.2 Power supply

Voltage 100-240 V

Frequency 50/60Hz Power 600VA

consumption

**Fuse** 250V~ T10AH

#### 2.4.3 Environmental Conditions

Operational Conditions Storage and Transportation Conditions

Ambient  $0^{\circ}\text{C} \sim 40^{\circ}\text{C}$   $-20^{\circ}\text{C} \sim 55^{\circ}\text{C}$ 

temperature  $10^{\circ}\text{C} \sim 40^{\circ}\text{C}$  (for D6-2 and D6-2A)  $-10^{\circ}\text{C} \sim 60^{\circ}\text{C}$  (for D6-2 and D6-2A)

**Relative** 30%~85% (no condensation) 30%~95% (no cage ondensation)

humidity  $25\%\sim90\%$  (for D6-2 and D6-2A)

**Atmospheric** 700hPa $\sim$ 1060hPa 700hPa $\sim$ 1060hPa

pressure

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

#### 2.4.4 Size and Weights

■ External dimensions:

<sup>'!</sup>\WARNING:

• Highest: 1415mm (H)×500mm (W)×690mm (D)

Lowest: 1275mm (H)×500mm (W)×740mm (D)

■ Net weight: 62Kg (without batteries and 4D board)

## 2.5 System Configuration

#### 2.5.1 Standard Configuration

- Main unit
- Accessories
  - Operator's manuals
  - Ultrasound gel
  - Ultrasound gel holder
  - System power line
  - Dust-proof cover
  - Probe ports dust-proof cover
  - 4D probe port dust-proof cover
  - Grounding line
  - Video printer remote line
  - Hard disk (1T)

#### 2.5.2 Probes Available

No.	Probe Model	Intended Use	
1.	3C5A	Fetal, Abdominal, Pediatric, Musculo-skeletal Conventional, Peripheral Vascular	
2.	7L4A	Abdominal, Pediatric, Small organ(breast, thyroid, testes), Neonatal Cephalic, Musculo-skeletal Conventional, Musculo-skeletal Superficial, Peripheral Vascular	
3.	6C2	Abdominal, Pediatric, Neonatal Cephalic, adult Cephalic, Cardiac Adult, Cardiac Pediatric, Musculo-skeletal Conventional, Musculo-skeletal Superficial, Peripheral Vascular	
4.	L14-6	Abdominal, Pediatric, Small organ(breast, thyroid, testes),  Neonatal Cephalic, Musculo-skeletal Conventional, Musculo-skeletal Superficial, Peripheral Vascular	
5.	L12-4	Abdominal, Pediatric, Small organ(breast, thyroid, testes), Neonatal Cephalic, Musculo-skeletal Conventional, Musculo-skeletal Superficial, Peripheral Vascular	
6.	2P2	Abdominal, Pediatric, Neonatal Cephalic, Adult Cephalic, Cardiac Adult, Cardiac Pediatric	
7.	6CV1	Fetal, Trans-rectal, Trans-vaginal, Urology.	
8.	D6-2	Fetal, Abdominal	
9.	D6-2A	Fetal, Abdominal	
10.	V10-4B	Fetal, Trans-rectal, Trans-vaginal, Urology.	
11.	V10-4	Fetal, Trans-rectal, Trans-vaginal, Urology.	
12.	CB10-4	Trans-rectal, Trans-vaginal.	
13.	P7-3	Abdominal, Pediatric, Neonatal Cephalic, Adult Cephalic, Musculo-skeletal (Conventional), Cardiac Adult, Cardiac Pediatric.	
14.	L14-6N	Abdominal, Pediatric, Small organ(breast, thyroid, testes), Neonatal Cephalic, Musculo-skeletal Conventional, Musculo-skeletal Superficial, Peripheral Vascular.	
15.	L7-3	Abdominal, Pediatric, Small organ(breast, thyroid, testes), Neonatal Cephalic, Musculo-skeletal Conventional, Musculo-skeletal Superficial, Peripheral Vascular.	
16.	7L5	Abdominal, Pediatric, Neonatal Cephalic, Musculo- skeletal Conventional, Musculo-skeletal Superficial, Peripheral Vascular.	
17.	CW5s	Pediatric, Adult Cephalic, Cardiac Adult, Cardiac Pediatric.	

Some of the probes have matched needle-guided brackets for biopsy, the available probes and the corresponding needle-guided brackets are listed as follows:

V10-4/ V104B/6CV1/ CB10-4	NGB-004 Metal/needle un-detachable	1	16G, 17G, 18G
6C2	NGB-005 metal/needle un-detachable	12.7°, 24.2°	13G, 15G, 16G, 18G, 20G
3C5A	NGB-006 (plastic/needle detachable, metal/needle detachable)	25°, 35°, 45°	Plastic/needle detachable: 13G, 15G, 16G, 18G, 20G; Metal/needle detachable: 14G, 16G, 18G, 20G, 22G
7L4A/ L12-4/7L5/ 14-6N/L7-3	NGB-007 plastic/needle detachable metal/needle detachable	40°, 50°, 60°	Metal/needle detachable: 14G, 16G, 18G, 20G, 22G; Plastic/needle detachable: 13G, 15G, 16G, 18G, 20G
2P2	NGB-011 metal/needle un-detachable	11°, 23°	13G, 15G, 16G, 18G, 20G
L14-6	NGB-016 Metal/needle detachable	30°, 40°, 50°	14G, 16G, 18G, 20G, 22G
D6-2A	NGB-020 Metal/needle detachable	20°, 30°, 40°	14G, 16G, 18G, 20G, 22G

### 2.5.3 Options

No.	ltem
1	Free Xros M
2	Free Xros CM
3	TDI
4	TDI Quantitative Analysis
5	iScape View
6	CW module
7	Smart3D
8	Static 3D
9	4D
10	iPage
11	IMT
12	Smart NT
13	Smart Bladder
14	ECG module (including ECG lead)
15	Nerve Package

No.	Item			
16	Emergency Medicine Package			
17		DICOM Basic (including: task management, DICOM storage, I DICOM storage commitment, DICOM media storage (including etc.)		
18		DICOM Worklist	DICOM	
19	DICOM	DICOM MPPS	Basic should be	
20			DICOM Query/Retrieve	configured
21		DICOM OB/GYN Structured Report	first	
22		DICOM Vascular Structured Report		
23		DICOM Cardiac Structured Report		
24	Buit-in battery			
25	Footswitch: 971- SWNOM (two-pedal or three-pedal) FS-81-SP (one-pedal)			
26	Smart OB			
27	Built-in Wireless Adapter			

### 2.5.4 Peripherals Supported

No.	Item	Model		
		HP Desk	jet 1050	
		HP Desk	HP Deskjet Ink Advantage 2020hc	
		HP Desk	jet Ink Advantage 2010	
1.	Craph / toyt printer	HP Desk	jet Ink advantage Printer K109g	
1.	Graph / text printer	HP Office	ejet Pro 8100	
		HP Desk	jet 1000-J110a	
		EPSON	Stylus PHOTO R230	
		EPSON	Stylus PHOTO R270	
2.	Analog Color Video Printer	SONY UP-20		
		District.	SONY UP-D897	
3.		Digital:	SONY UP-D898MD	
	Black and White Video Printer	Analog:	SONY UP-897MD	
4.	riiilei		MITSUBISHI P93W-Z	
5.		SONY U	P-X898MD	
6.	Bar code reader	SYMBOL LS2208-SR		

All Graph/Text printers are not applied to softare version 01.00.00.

Parts that can be used within patient environment:

Main unit.

- Probes.
- Footswitch.
- Printers: SONY UP-20, SONY UP-D897, SONY UP-897MD, MITSUBISHI P93W-Z, SONY UP-D898MD, SONY UP-X898MD

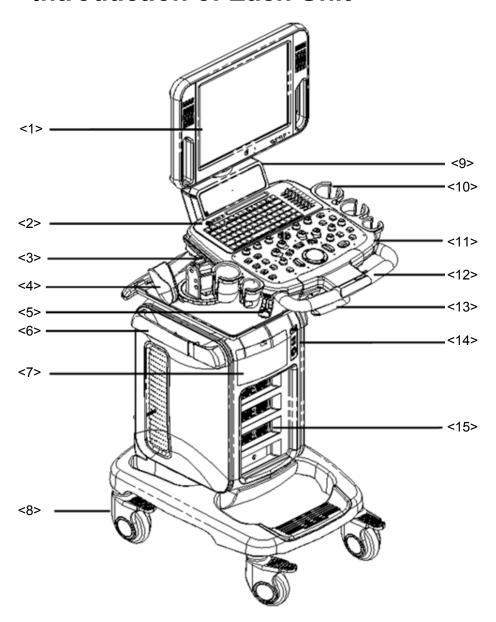
NOTE:

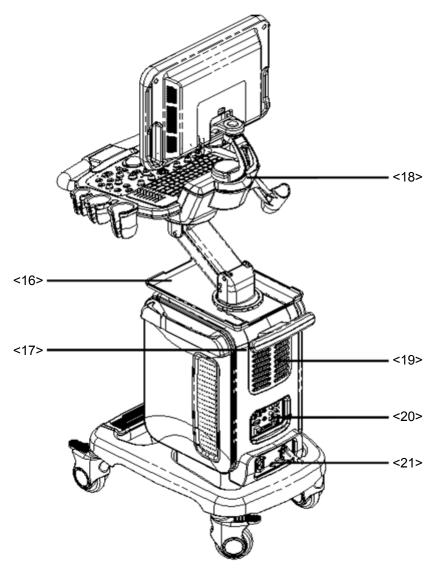
If the ultrasound system can not recognize the SONY UP-X898MD and SONY UP-D898MD printers automatically, you may need to change the settings on the printer: push <PUSH ENTER> to enter the main menu and select [DIGITAL]->[DRIVER], and select [897].

**⚠WARNING**:

This system complies with IEC60601-1-2:2007, 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



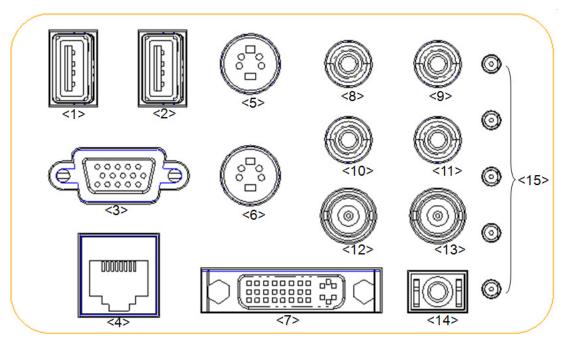


No.	Name	Function
<1>	Monitor	Displays the images and parameters during scanning.
		(Support optional 15-inch or 17-inch monitor)
<2>	Power button	Used for turning on/off the power supply (on the upper left corner of control panel).
<3>	DVD-RW	DVD-RW drive.
<4>	Intracavitary probe holder	Used for placing the intracavitary probe.
<5>	Probe cable hook	Used for fixing the probe cable.
<6>	Probe cable fixing bracket	Used for fixing the probe cable
<7>	Compartment	Used for placing B/W video printer.
<8>	Caster	Used for securing or moving the system.
<9>	Speaker	Audio output.

No.	Name	Function
<10>	Probe and ultrasound gel holder	Used for temporarily placing probes or ultrasound gel.
<11>	Control Panel	Operator-system interface or control.
<12>	Frontal handle	Used for pushing and moving the system.
<13>	Control table adjusting handle	Lift and hold the handle to lift/down the control table, or to turn the control table left / right.
<14>	Physiological-signal panel	Used for connecting the ECG leads, footswitch, and inputting ECG signal.
<15>	Probe ports	Sockets connecting probes and the main unit.  The lowest one is for 4D probes.
<16>	Table for placing peripherals	Placing peripherals.
<17>	Rear handle	Used for lifting the machine, or managing the probe cable.
<18>	Monitor support arm	Used for support and adjustment of height and position of LCD monitor.
<19>	Heat rejection panel	Main unit heat rejection.
<20>	I/O Panel	Interface panel used for inputting and outputting signals.
<21>	Power supply panel	Electrical port panel.

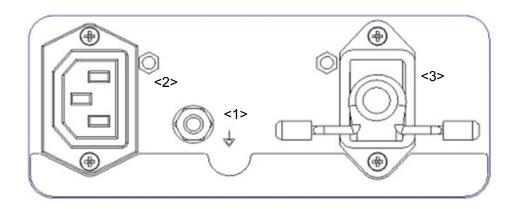
NOTE: Do not overexert to push down or lift up the control panel when operate the control table adjusting handle.

## 2.7 I/O Panel



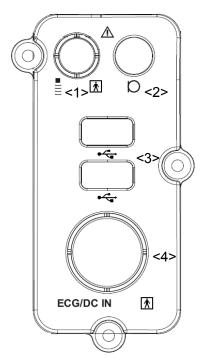
No.	Symbol	Function
<1><2>	•<	USB port, used for connecting USB devices.
<3>		VGA signal output; connects a monitor or projector.
<4>		Ethernet interface.
<5>	<b>→</b>	Separate video input (reserved).
<6>	$\Rightarrow$	Separate video output.
<7>	$\ominus$	DVI signal output.
<8><9>	-€)	Audio signal input port, left channel (reserved).
<10><11>	<b>→</b>	Audio signal output port, right channel.
<12>	<b>→</b>	Used for composite video input (reserved).
<13>	$\Rightarrow$	Used for composite video output.
<14>	<b>→</b>	Remote interface for connecting video printer.
<15>	Malfunction indication lights	Indicate the system's malfunction.

## 2.8 Power Supply Panel



No.	Name	Function
<1>	Equipotential terminal	Used for equipotential connection, balancing the protective earth potentials between the system and other electrical equipment.
<2>	AC Input	AC power inlet.
<3>	AC Auxiliary Output	Power supply port for peripherals.

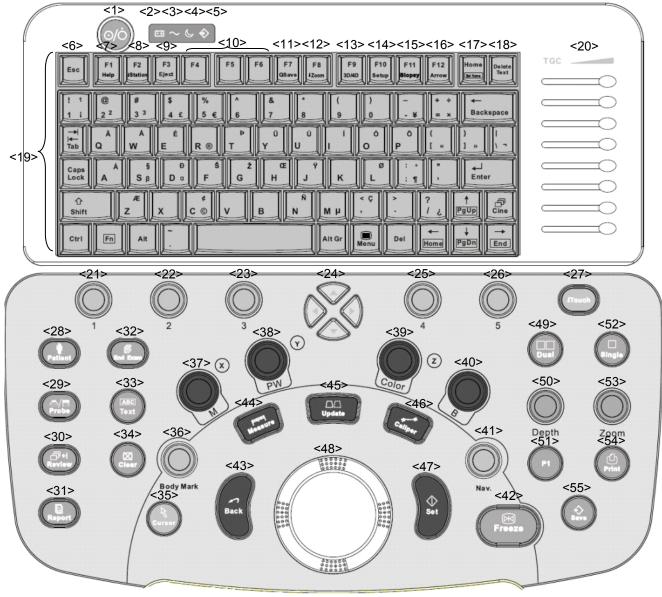
# 2.9 Physiological-signal Panel



No.	Name	Function
<1>	Pencil probe port	Pencil probe port (reserved).

<2>	Mic In port	Use for connecting microphone to record vocal comments (reserved)
<3>	Two USB ports ◆ ←	Used for connecting USB devices.
<4>	ECG lead signal input port/external ECG signal input port	Connects to ECG leads, to directly obtain patient electrocardiosignal/used for connecting the signal output port of ECG monitor.

### 2.10 Control Panel



No.	Name	Description	Function
<1>	/	Power button	It does not illuminate when the system is turned off.  Press the button to turn on the system, at the moment the indicator lights on and becomes green and flashes .When the system enters work status, the indicator turns in green.
<2>	1	Batteries	Indicates the current status of the batteries.

		-1-1	AMbaraha karantari da karantari		
<3>	1	AC power supply	<ul> <li>When the batteries are being charged, the indicator light is on and in orange.</li> <li>When the battery capacity is charged to full capacity, the indicator turns green.</li> <li>When the system is powered by the batteries and the power capacity is more than 20%, the indicator is green.</li> <li>When the system is powered by the batteries and the power capacity is lower than 20%, the indicator is orange and flashes.</li> <li>When the system is powered by the batteries and the power capacity is lower than 5%, the indicator is orange and flashes fleetly.</li> <li>In other statuses, the indicator light is off.</li> <li>Indicates if the main unit is connected to the AC power supply.</li> </ul>		
		status indicator	If not connected, the indicator does not illuminate.  If connected, the indicator illuminates in green color.		
<4>	1	Standby status indicator	When the system enters the standby status, the indicator turns orange and flashes. In other statuses, the indicator light is off.		
<5>	/	Hard disk status indicator	When the hard disk is operated, the indicator turns green and flashes. In other statuses, the indicator light is off. Note: When the indicator turns green, don't move the system. Otherwise, the hard disk may be damaged.		
<6>	Esc	Exit	Press to exit the current status to the previous status.		
<7>	F1 Help	Help	Press to open or close the accompanying help documents.		
<8>	F2 iStation	1	Press to enter or exit the patient information management system.		
<9>	F3 Eject	1	Press to eject the disc.		
<10>	F4-F6	User- defined key	You can assign a function to the key.		
<11>	F7 QSave	/	Save image.		
<12>	F8 iZoom	iZoom	Enter/exit iZoom mode.		
<13>	F9 3D/4D	3D/4D	Enter/exit 3D/4D.		
<14>	F10 Setup	Setup	Enter setup.		
<15>	F11 Biopsy	Biopsy	Enter/exit biopsy.		
<16>	F12 Arrow	Arrow	Enter/exit arrow comment status.		

<17>	Home	/	Set the default position of the comment/return to the default position.
<18>	Delete text	/	Press to delete the word in the reserved order.
<19>	/	Alphanumer ic keys	Same as those of PC.
<20>	TGC	Slide bar	Move to adjust time gain compensation.
<21>	/	Soft menu controls 1	Press or rotate to select the soft menu items displayed on the bottom of the screen.
	,		Refer to the subsequent contents for specific functions.
<22>	/	Soft menu controls 2	Press or rotate to select the soft menu items displayed on the bottom of the screen.
		CONTROIS 2	Refer to the subsequent contents for specific functions.
<23>	1	Soft menu controls 3	Press or rotate to select the soft menu items displayed on the bottom of the screen.
		CONTROLS 5	Refer to the subsequent contents for specific functions.
<24>	/	Directional soft menu controls	Up/down controls are used to turn pages up/down when there is more than one page for the soft menu.  Left/right keys are used to switch among the different modes.
<25>	/	Soft menu controls 4	Press or rotate to select the soft menu items displayed on the bottom of the screen.  Refer to the subsequent contents for specific functions.
<26>	1	Soft menu controls 5	Press or rotate to select the soft menu items displayed on the bottom of the screen.
		001111 010 0	Refer to the subsequent contents for specific functions.
<27>	iTouch	1	Press to optimize the image, serving as a one-key optimization.
<28>	Patient	Patient Information	Press to open the [Patient Info] screen.
<29>	Probe	Probe	Press to select the probe and exam mode.
<30>	Review	Review	To review the stored images.
<31>	Report	Report	Press to open or close the diagnosis reports.
<32>	End Exam	End Exam	Press to end an exam.
<33>	Text	ABC (Text)	Press to enter or exit the character comment status.
<34>	Clear	Clear	Clear the measurement caliper, comments and body mark.
			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>
<35>	Cursor	Cursor	Show/ hide the cursor.

while in 3D/4D mode, rotate the knob to make the image to rotate around X axis.  PW(Y) Pressable knob Press to enter PW mode, and rotate to adjust PV PW mode) or CW gain (in CW mode); while in 3I mode, rotate the knob to make the 3D image to rotate around Y axis.  Press to enter Color mode, and rotate to adjust Color color mode) or Power gain (in Power mode); while in 3D/4D mode, rotate the knob to make the 3D image rotate around Z axis.  Pressable knob Pressable knob Press to enter B mode, and rotate to adjust B gain.  Whavingation Multi-function knob.  Press to enter B mode, and rotate to adjust B gain.  Press to enter B mode, and rotate to adjust B gain.  Whavingation Multi-function knob.  Press to freeze or unfreeze the image.  Press to return to the previous operation or delete the previous item.  Wheasure Press to enter or exit the application measurement mode.  Press to change the currently active window.  Or start/stop image acquisition in iScape or 3D/4D.  Press to confirm an operation, same as the left-buttor of the mouse.  Press to confirm an operation, same as the left-buttor of the mouse.  Press to confirm an operation, same as the left-buttor of the mouse.  Press to confirm an operation, same as the left-buttor of the mouse.  Press to confirm an operation, same as the left-buttor of the mouse.  Press to confirm an operation, same as the left-buttor of the mouse.  Press to confirm an operation, same as the left-buttor of the mouse.						
while in 3D/4D mode, rotate the knob to make the image to rotate around X axis.    PW(Y)   Pressable knob   Press to enter PW mode, and rotate to adjust PV PW mode) or CW gain (in CW mode); while in 3I mode, rotate the knob to make the 3D image to rotate around Y axis.    Color(Z)   Pressable knob   Press to enter Color mode, and rotate to adjust Color color mode) or Power gain (in Power mode); while in 3D/4D mode, rotate the knob to make the 3D image rotate around Z axis.    Pressable knob   Press to enter B mode, and rotate to adjust B gain.	<36>		Body Marks	arks Press to enter or exit the Body Mark status.		
knob PW mode) or CW gain (in CW mode); while in 3I mode, rotate the knob to make the 3D image to rearound Y axis.  Color(Z) Pressable knob Press to enter Color mode, and rotate to adjust Color color mode) or Power gain (in Power mode); while in 3D/4D mode, rotate the knob to make the 3D image rotate around Z axis.  Press to enter B mode, and rotate to adjust B gain.  Nav. Navigation Multi-function knob.  Press to freeze or unfreeze the image.  Press to freeze or unfreeze the image.  Rack Back Press to return to the previous operation or delete the previous item.  Measure Measure Press to enter or exit the application measurement mode.  Press to change the currently active window. Or start/stop image acquisition in iScape or 3D/4D.  Caliper Caliper Press to enter or exit the general measurement mode.  Press to confirm an operation, same as the left-butt of the mouse.  Press to change the curror position.  Roll the trackball to change the cursor position.  Press Dual Enter Dual mode in Non-dual mode;  Switch between the two displaying windows in Dual mode.	<37>	M(X)		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 rotate around X axis.		
knob color mode) or Power gain (in Power mode); while in 3D/4D mode, rotate the knob to make the 3D image rotate around Z axis.  40> B Pressable knob Press to enter B mode, and rotate to adjust B gain.  41> Nav. Navigation Multi-function knob.  42> Freeze Freeze Press to freeze or unfreeze the image.  43> Back Back Press to return to the previous operation or delete the previous item.  44> Measure Measure Press to enter or exit the application measurement mode.  45> Update / Press to change the currently active window.  Or start/stop image acquisition in iScape or 3D/4D.  46> Caliper Caliper Press to enter or exit the general measurement mode.  47> Set Set Press to confirm an operation, same as the left-butte of the mouse.  48> / Trackball Roll the trackball to change the cursor position.  Enter Dual mode in Non-dual mode;  Switch between the two displaying windows in Dual mode.	<38>	PW(Y)		Press to enter PW mode, and rotate to adjust PW (in PW mode) or CW gain (in CW mode); while in 3D/4D mode, rotate the knob to make the 3D image to rotate around Y axis.		
Nav.   Navigation   Multi-function knob.	<39>	Color(Z)		Press to enter Color mode, and rotate to adjust Color (in color mode) or Power gain (in Power mode); while in 3D/4D mode, rotate the knob to make the 3D image to rotate around Z axis.		
<ul> <li>Freeze Freeze Press to freeze or unfreeze the image.</li> <li>Back Back Press to return to the previous operation or delete the previous item.</li> <li>Measure Measure Press to enter or exit the application measurement mode.</li> <li>Update / Press to change the currently active window. Or start/stop image acquisition in iScape or 3D/4D.</li> <li>Caliper Caliper Press to enter or exit the general measurement mode.</li> <li>Set Set Press to confirm an operation, same as the left-butte of the mouse.</li> <li>/ Trackball Roll the trackball to change the cursor position.</li> <li>Dual Enter Dual mode in Non-dual mode;</li> <li>Switch between the two displaying windows in Dual mode.</li> </ul>	<40>	В		Press to enter B mode, and rotate to adjust B gain.		
Set   Set   Press to return to the previous operation or delete the previous item.	<41>	Nav.	Navigation	Multi-function knob.		
previous item.    Measure	<42>	Freeze	Freeze	Press to freeze or unfreeze the image.		
<ul> <li>Update / Press to change the currently active window. Or start/stop image acquisition in iScape or 3D/4D.</li> <li>Caliper Caliper Press to enter or exit the general measurement mode.</li> <li>Set Press to confirm an operation, same as the left-buttor of the mouse.</li> <li>/ Trackball Roll the trackball to change the cursor position.</li> <li>Dual Enter Dual mode in Non-dual mode; Switch between the two displaying windows in Dual mode.</li> </ul>	<43>	Back	Back	Press to return to the previous operation or delete the previous item.		
Or start/stop image acquisition in iScape or 3D/4D.  46> Caliper Caliper Press to enter or exit the general measurement modes. 47> Set Set Press to confirm an operation, same as the left-buttor of the mouse. 48> / Trackball Roll the trackball to change the cursor position. 49> Dual Enter Dual mode in Non-dual mode; Switch between the two displaying windows in Dual mode.	<44>	Measure	Measure	···		
<46> Caliper Caliper Press to enter or exit the general measurement mode. <47> Set Set Press to confirm an operation, same as the left-buttor of the mouse. <48> / Trackball Roll the trackball to change the cursor position. Enter Dual mode in Non-dual mode; Switch between the two displaying windows in Dual mode.	<45>	Update	1	Press to change the currently active window.		
<ul> <li>Set</li> <li>Set</li> <li>Press to confirm an operation, same as the left-buttor of the mouse.</li> <li>/ Roll the trackball to change the cursor position.</li> <li>Dual</li> <li>Enter Dual mode in Non-dual mode;</li> <li>Switch between the two displaying windows in Dual mode.</li> </ul>				Or start/stop image acquisition in iScape or 3D/4D.		
of the mouse.  <48> / Trackball Roll the trackball to change the cursor position. <49> Dual Enter Dual mode in Non-dual mode; Switch between the two displaying windows in Dual mode.	<46>	Caliper	Caliper	Press to enter or exit the general measurement mode.		
Comparison of the control of the	<47>	Set	Set	Press to confirm an operation, same as the left-button of the mouse.		
Switch between the two displaying windows in Dual mode.	<48>	1	Trackball	Roll the trackball to change the cursor position.		
mode.	<49>	Dual		Enter Dual mode in Non-dual mode;		
			/	Switch between the two displaying windows in Dual mode.		
<50> Depth Depth Adjust depth in real-time imaging.	<50>	Depth	Depth	Adjust depth in real-time imaging.		
<51> P1 / User-defined key.	<51>	P1	1	User-defined key.		
<52> Single / Enter into single displaying window from splitting mo	<52>	Single	1	Enter into single displaying window from splitting mode.		
<53> Zoom Zoom Rotate to enter the pan mode, and press to enter the spot mode.	<53>	Zoom	Zoom	Rotate to enter the pan mode, and press to enter the spot mode.		
<54> Print Press to print, user-defined key.	<54>	Print	Print	Press to print, user-defined key.		
<55> Save Save Press to save image, user-defined key.	<55>	Save	Save	Press to save image, user-defined key.		

# 2.11 Symbols

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

No.	Symbol	Description		
1	<b>^</b>	Type-BF applied part		
2	$\triangle$	Caution		
3	A	Dangerous voltage		
4	⊙/Ċ	Power button		
5	))))	Probe port		
6	<del>-</del>	Network port		
7	•	USB port		
8	<b>\$</b>	S-VIDEO signal interface; VIDEO signal interface		
9	-+	Battery Status Indicator		
10	<b>-</b> [[[[	Pencil probe port (reserved)		
11	⊕ ⊕	Audio signal		
12	р	Microphone input jack		
13	$\rightarrow$	Remote control port		
14	•	System reset		
15	$\Leftrightarrow$	Hard disk status indicator		
16	0	Standby status indicator		
17	$\sim$	AC power supply status indicator		
18	SN	Product serial number		
19	سا	Manufacture date		
20	$((\overset{\bullet}{\bullet}))$	Non-ionizing radiation, RF emitting devices included in the device and system.		

# **3** System Preparation

# **MARNING:**

- 1. Do not connect the three-wire cable of the system with a two-wire plug without protective grounding; otherwise, electric shock may result.
- 2. Do 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 60601-1-1 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 60601-1-1), and the responsibility is held by the user.

# 3.1 Move/Posit the System

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

- 1. Switch off the power, unplug the power cord.
- 2. Disconnect all cables from the off-board peripheral devices (printer, recorder, etc.).
- 3. Release the four casters, and move the system by holding the handle.
- 4. When you move the system to a desired location, lock the four casters.
- 5. Leave at least 20cm at the back and both sides of the system.

# CAUTION:

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

# 3.2 Power Supply

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

# 3.2.1 Connecting AC Power Supply

The AC power system of the system must meet the following requirements:

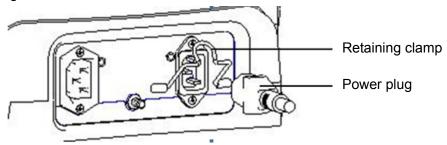
Voltage: 100-240V~;

Power supply frequency: 50/60Hz;

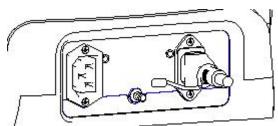
Power consumption: greater than 600VA.

The connection method is described as follows:

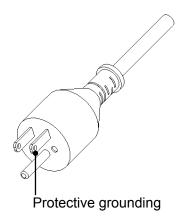
1. Push the retaining clamp upward, and insert the power plug into the receptacle, as shown in the figure below.



2. Push the retaining clamp downward, and lock the power cord, as shown in the figure below.



3. Plug the other end power plug into an appropriate power socket. 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 from the socket even if the system is moved slightly. If the plug is pulled out accidentally, data may be lost.

# 3.2.2 Powered by Batteries

- When connected to the external AC power supply, the system is powered by the external power. The lithium ion batteries inside it are in the charging status.
- When disconnected from the external power supply, the system is powered by the lithium ion batteries. Refer to Chapter 14 for the detailed operations and precautions.

# 3.2.3 Equipotential Terminal

The symbol represents the equipotential terminal that is used for balancing the protective earth potentials between the system and other electrical equipment. For the equipotential terminal location, please refer to "2.8 Power Supply Panel".

# riangleWARNING:

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

# 3.3 Power ON/OFF

# 3.3.1 Powering ON the System

 $\triangle$ CAUTION:

To ensure safe and effective system operation, you must perform daily maintenance and checks.

If the system begins to function improperly – immediately stop scanning. If the system continues to function improperly – fully shut down the system and contact Mindray Customer Service Department or sales representative.

If you use the system in a persistent improperly functioning state – you may harm the patient or damage the equipment.

### ■ Checking before Power ON

To check the system before the system is turned 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.
<3>	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 defined 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.
<b>\0</b> >	See "Chapter 13" for details on probe cleaning and disinfection.
<7>	No miscellaneous odds and ends are allowed to be attached or affixed to the control panel.
<8>	Ensure that all connections are free from damage and remain clear of foreign object blockages.
	There shall be no obstacles around the system and its air vent.
<9>	Probe cleaning and disinfection. (Please refer to "13 Probes and Biopsy" for details).
<10>	The overall scanning environment and field must be clean.
<11>	The locking mechanism of casters can work normally.

### ■ Turning on the Power

To turn on the system:

- (1) Press the power button in the upper left corner on the control panel
- (2) The system enters the work status.



When the battery capacity is sufficient, you can also press the power button directly to turn on the system.

To check the system after the system is turned on:

No.	Check Item
<1>	There shall be no unusual sounds or smells indicating possible overheating.
<2>	There shall be no persistently displayed system error message.
<3>	There shall be 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.
<5>	The control panel keys and knobs are fully functional.

No.	Check Item
<6>	The exam date and time are the same as the system date and time, and are displayed correctly.

# 3.3.2 Powering OFF the System

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

If you will not use the system for a long period of time, you shall:

- 1. Disconnect the mains power.
- 2. Turn off powers of all peripherals connected to the system.
- To power off your system normally:

Gently press the power button once on the upper left corner of the control panel. The Shutdown Confirm screen appears.

- Shut down: To power off the system normally.
- Standby: Click to enter the standby status. Press the power button to turn on the system.
- Cancel: To cancel the operation.
- To shut down the system in a direct way if you cannot do it normally:

Long press the power button and the system will power off without displaying the [Shutdown Confirm] screen. However, shutting down the system in this way may destroy the data.

NOTE: 1. DO NOT rush shutdown of the system in a direct way. It may destroy the data.
 2. After the software upgrade, please shut down the system in the normal way (using "Shut down" method) so as to guarantee a fully update.

# 3.3.3 Standby

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

- To enter standby:
  - Open [Setup]→[System Preset]→"General" to set the time for screensaver and standby mode. If there is no operation, 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.
  - Press the power button and select "Standby".
  - Disconnect the power plug, and select "Standby" in the prompted dialogue box.
     When the system enters the standby status, the standby status indicator blinks in orange.
- To exit standby
  - Press the power button.
- When the system enters the standby status, if need to power off:
  - Long press the power button for 5s.
  - Press the power button to exit the standby status and then power off the system.

# **NOTE:** 1. Power off the system if you will not use the system for a long period of time (including storage/ transportation conditions), and you should not allow the system in standby status, otherwise the batteries will be out of power and permanently damaged.

2. If you will not use the system for a long period of time, DO NOT leave the system in standby status, you should shut down the system, disconnect mains power, and turn off powers of all connected peripherals.

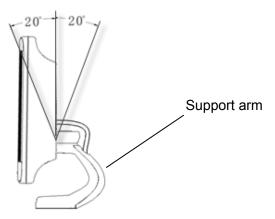
# 3.4 Monitor Adjusting

# 3.4.1 Monitor Position Adjusting

Grab the two sides of the monitor when adjusting its position.

Angle adjust

When posited vertically, the monitor can be tilted for  $\pm 20^{\circ}$  forward and backward respectively.

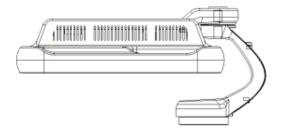


Rotate the monitor

The monitor can be rotated around its central pivot point for ±90°.

Tilt the monitor

In the process of transportation or moving the system, grab the two sides of the monitor, level the monitor, shown as follows:



# 3.4.2 Adjusting Brightness/Contrast on the Monitor

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

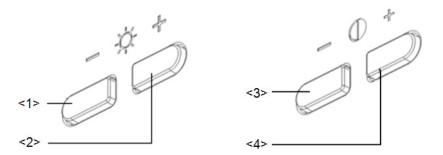
The adjusting buttons are shown as follows:

#### Brightness

<1>, <2> refer to the brightness control keys with a sun marked at the top side; key <1>, which marked a "-" on the top side, can be used to decrease the brightness; while key<2>, which marked a "+" on the top side, can be used to increase the brightness.

#### Contrast

<3>, <4> refer to the contrast control keys with a lune marked at the top side; key <3>, which marked a "-" on the top side, can be used to decrease the contrast, while key <4>, which marked a "+" on the top side, can be used to increase the contrast.



**NOTE:** On the monitor, the brightness adjustment comes before contrast. After readjusting the monitor's contrast and brightness, adjust all presets and peripheral settings.

# 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.
- 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 damaging the cable.
- 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

The system has four sockets for connecting probes. The lowest one is for 4D probes, and the other three are for the other probes.



Before connecting to the system, check if the probes, cables and connectors are in proper operating order and free from surface defects, cracks and peeling. Otherwise, electrical shock may result.

- 1. Keep the cable end of the probe 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 cable 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, don't use the probe until it has been inspected/repaired or 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 probe connector straight out vertically (Shown in the right figure).



#### Tips:

- If no effective probe is detected after the system is turned on, the system will show a warning "No valid transducer detected". And the system is frozen, no image is displayed.
- If you changed/disconnected the scanning probe after freezing the image and the system finds no other effective probe when the image is unfrozen, the system will show a warning "No valid transducer detected".
- In scanning mode, if the system suddenly detected no probe, it will show a
  warning "Abnormal connection of transducer". Image scanning can't be
  recovered until the right probe has been detected.
- If an ineffective probe is connected to the system, the system will show a warning "No valid transducer detected".
- Disconnect the idle probe when system is not frozen, the system will show a
  warning "Warning! It's illegal of pull out or insert the probe when system isn't
  frozen. It would damage the probe!"

# 3.6 Connecting Peripheral Devices

**NOTE:** Do not connect two or more than two peripherals at the same time to the printer room and IO panel.

# 3.6.1 Connecting the USB Devices

riangleWARNING:

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

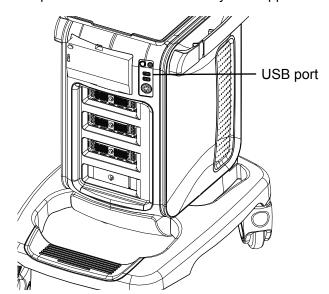
Available USB ports on the system:

- 1. Two USB ports on the physiological-signal panel.
- 2. Two USB ports on the I/O panel at the back of the system.
- 3. One USB port on the lower left corner of the control panel.
- 4. One USB port in the printer room, which is dedicated for digital video printer.
- When connecting a USB memory device to the ultrasound system via a USB port, you can hear a sound if it is connected successfully. You can see the symbol in the lower right corner of the imaging screen.
- To remove the USB memory device:
  - (1) Click to open the "Remove USB Device" dialogue box.
  - (2) Select the memory device to be removed.
  - (3) Click [OK] and you can hear a sound. There will be sound feedback when remove the USB memory device.

# 3.6.2 Connecting a Footswitch

Connection

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



Function setting

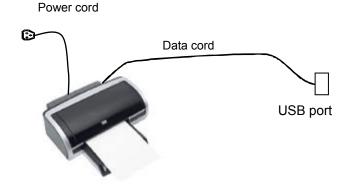
The function of the footswitch can be set, for details, please refer to "12.1.6 Key Configuration".

# 3.6.3 Graph /Text printer

The network printer, shared priner and iStorage UltraAssit Print are not applied on software version 01.00.00.

#### 3.6.3.1 Connecting a Local Printer

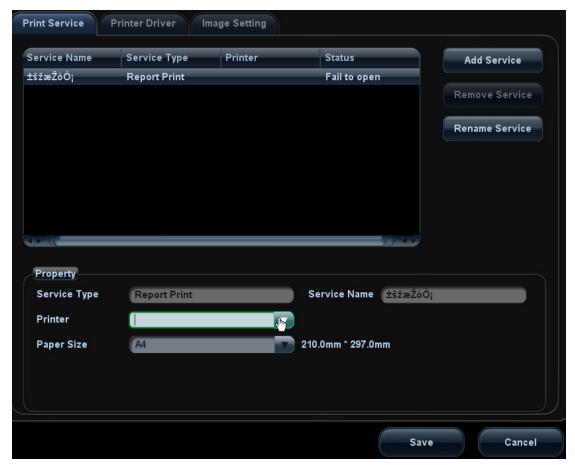
As shown in the figure below, a graph / text printer has a power cord and data cable. The power cord shall be directly connected to a wall receptacle as required.



- 1. Connect the data cable with the USB port on the ultrasound system.
- 2. Plug the other end power plug into an appropriate outlet.
- 3. Power on the system and the printer.
- 4. Check the printer status:
  - Enter [Setup]-> [Print Preset]-> "Printer Driver" page, printers that are installed automatically will be displayed in the list with the "Status" of "Ready".



- 5. Return to "Print Service" page, and select "Report Print" in the list, and set attributes in the Property box under the screen:
  - > Select the printer model from the drop-down list right to the "Printer";
  - Set Paper Size.



6. Click [Save] to finish the installation.

Tips: Drivers of some popular printers have already been integrated in the system, and will be installed automatically. You need to check the following information to check if the auto-installation fails:

- Model of the connected printer is not displayed in the "Printer Driver" list;
- Click "Printer Driver"->[Add Local Printer], the system will prompts you to update the ppd file.

At this time, you need to install the printer driver manually as described in the following:

- a) Download the ppd file from the printer manufacturer's official website (contact service engineer if necessary), and copy the ppd file to the storage device (USB disk as an example).
- b) Connect the USB disk to the ultrasound system, click [Setup]->[Print Preset]->"Printer Driver"->[Add Local Printer] to run the ppd file and finish the installation.

NOTE: All printer drivers integrated in the ultrasound system come from official website of each printer manufacturer (you can check models in the [Setup]->[Print Preset]->"Printer Driver"->[Supported Printer List]).Printer drivers may not be updated in time due to software version and region limitation, consult printer manufacturer for details.

#### 3.6.3.2 Add Network Printer

- 1. Make sure the target network printer and the ultrasound system are both connected into the same LAN.
- 2. Check the IP address of the network printer (for details, please refer to the accompanying documents of the printer).
- 3. Enter [Setup]->[Print Preset]->"Printer Driver" page, click [Add Network Printer] to enter the screen, type in the IP address of the network printer. (Port is 9100 in default).
- 4. Click [Verify Net Printer], the IP address, name and port information of the network printer will be displayed under the "Port" box. Change the port to match the verified printer information if necessary.
- 5. Click [OK] to enter the ppd installing screen:
  - Select PPD file from media: select the path from the external media and install.
  - Select PPD file from database: select the ppd. file integrated in the ultrasound system.
- 6. After the ppd. file is installed completely, enter the printer name to finish the installation.
- 7. After installation succeeds, the system returns to the "Printer Driver" page and displays the added network printer.

#### 3.6.3.3 Add Shared Printer

- Make sure the target computer or the server (to be connected to the ultrasound system with the shared printer) has set a shared printer (under Windows operating system, enter [Printers and Faxes] and right click the target printer and select "Share" to set).
- 2. As the system is connected into the LAN, open [Setup]-> [Print Preset]-> "Printer Driver" screen.
- 3. Click [Add Shared Printer], and input information of the printer (IP Address, User Name, Workgroup and password of the computer or server, and Shared Printer Name).
- 4. Click [Verify] to verify the connection, and click [OK] if the system prompts normally.
- 5. Select the ppd. file in the displayed dialogue box: you can either select from the ultrasound system integrated database, or media (USB disk).
- 6. Enter the name for the printer and click [OK], the system then starts installation. After installation succeeds, the system returns to the "Printer Driver" page and displays the added shared printer.

#### NOTE:

- 1. Before connecting the shared printer, make sure the ultrasound system and the computer or server (connected with shared printer) are in the same network domain, and the network is working normally.
- 2. The IP address and the server name should be valid, e.g. \\\\10.2.40.123 or \\\\5-HP\), otherwise, the system will fail to connect.
- 3. If the server has set accessing limitation, the system will prompt a dialogue box to identify the user. Enter the correct user name, domain name and password, and then click [OK].

### 3.6.3.4 iStorage UltraAssist Print

The system supports printing by iStorage function. Before using this function, please make sure that the iStorage server has configured a defaulted printer, and the ultrasound system has configured an iStorage server. For details, please refer to "12.5.2 iStorage".

- 1. Enter [Setup]->[Print Preset]->"Printer Driver" and check iStorage printer status, which should be AssistPrinter@IP address with "Ready" status.
- 2. Click "Print Service" to enter the screen, and select AssistPrinter@IP address to be the printer for the Report Print service.
- 3. Verify the status of the network connection.

Click the [Ping] button in the [Status] column of the iStorage printer list, and the system pops a dialog box to display whether the connection with the iStorage server is ready or not.

**NOTE:** Check if the iStorage printer is well connected with the server when the printing fails with the verification result being Ready,

4. Click [Save]

#### 3.6.3.5 Print Service

You can use a graph/ text printer to print report or images.

- To set the default report printer and its attribute:
   In "[Setup]-> [Print Preset]" screen, select the "Print Service", select "Report Print" column in the service list, set the items in the "Property" box.
- Report print:

Click [Print] in the report dialog box to print a report; or, use the user-defined key to print, see "12.1.6 Key Configuration" for details. Please refer to the accompanying manuals of the printers for more details.

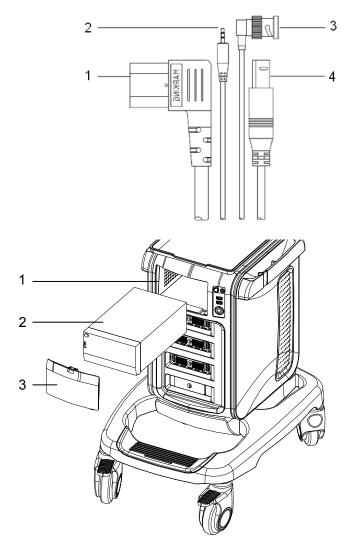
# 3.6.4 Installing Analog Video Printer

- 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:

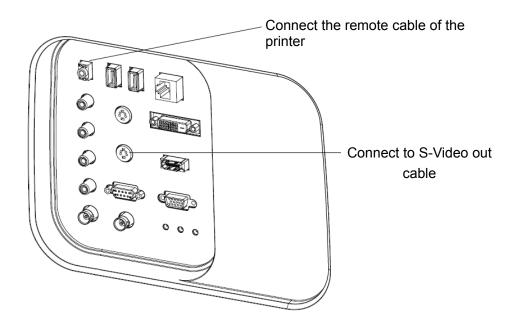
- (1) power cord;
- (2) USB cable (used for connecting digital video printer);
- (3) video signal cable;
- (4) Remote control cable, as shown in the figure.

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



1. Printer room window 2. Printer 3. Room cover

 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 Preset]→[Print Service].
  - (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 [OK] 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 [OK] to complete the setting.

# 3.6.5 Installing 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 "3.6.3 Graph /Text 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 Preset]→ [Print Service] screen.
  - (2) Click [Add Service] to enter the Print Service 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 [OK] 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 [OK] to complete the setting.

# 3.6.6 Installing the Barcode Reader

Directly insert the USB port of the barcode reader to the system applicable USB ports. Please refer to "Appendix A Barcode Reader" for operations of the barcode reader.

# 3.7 Basic Screen and Operation

### 3.7.1 Basic Screen

The following diagram maps out the different areas in the screen:

	Lo Ho		Hospital name		Patient name	Accession#	Freeze icon
	go	Operator	ID	DOB/age	Gender	Exam date&time	
		Probe&acoustic power					
Menu/exam mode/image parameter	Image area					Thumbnails	
Image-in-	ECG trace						Image manage
image Thumbnail	Cine Review						
Soft menu		Tips Soft me		enu			
Help Information Sys			System	Icon			

#### ■ Information Area

The information area displays manufacturer logo, hospital name, exam date & time, operator, probe, acoustic power & MI/TIS, freeze icon, patient information, ECG icon (if ECG module is configured), and accession #, etc.

To preset the patient banner display content: open the [Setup]  $\rightarrow$ [System Preset] $\rightarrow$ [General] screen, and check the content in the "Patient Info" box in the upper left corner of the screen.

Logo
 Manufacture logo, displayed in the upper left corner of the screen.

#### Hospital name

Display the hospital name. Hospital name can be set via "[Setup]  $\rightarrow$  [System Preset]  $\rightarrow$  [Region]".

#### Exam time

Displays the exam time, including date and time. Exam time format can be set via "[Setup]→[System Preset]→[Region]". Exam time will be frozen with the frozen image.

#### • Probe model

Displays the currently-used probe model, or the default model.

#### Acoustic power & MI/TIS

Displays the acoustic power, including the acoustic power, MI (Mechanical Index) and TIS.

#### Freeze icon

The freeze icon means the image is frozen.

#### Patient Information

Displays patient name, ID, gender and age etc. Enter the patient information through the "Patient Info" screen. Or, import the registered patient data from iStation or the DICOM Worklist server.

#### Operator

Displays the operator's name on the screen. This information is entered through the "Patient Info" screen.

#### ECG icon

Displays ECG icon, which consists of a heart icon and heart rate, e.g. "75bpm"

#### Accession#

Serial number used in DICOM or the manually entered serial number in "Patient Info" screen.

#### ■ Image Parameter and Menu Area

The image parameter and menu are both displayed in this area. When no menu is available; this area displays the image parameters of the current imaging mode. Current exam mode is also displayed here.

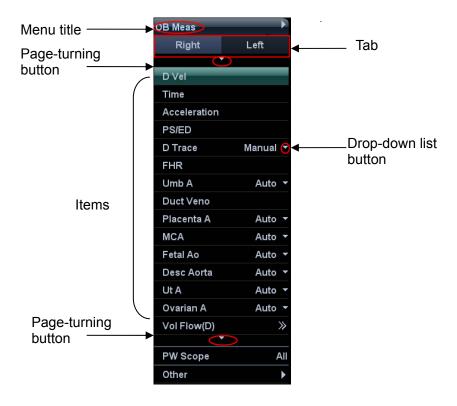
#### Menu area

When an image menu is displayed, the imaging parameters will be covered by the menu.

Include image menu, measurement menu, comment menu, body mark menu and so on. Use the trackball or the multifunctional knob to operate on the menu.

Use the <Menu> to show or hide the menu, or press the multifunctional knob.

The menu area consists of menu title, menu items and page-turning button. As shown in figure below.



#### Menu title

Displays the menu name.

#### ➤ Tab

Divide the menu items according to measurement conditions.

#### Page-turning button

When there are too many items in a menu, the items will be divided into more than one page.

You can turn pages by page-turning buttons, A and .

#### > Items

Refers to the items on a menu. For item that is applicable for more than one mode, the item appears as shared item in the certain mode. Items of image modes and measurement can be preset.

#### Down-drop list button

If there are several options available for one item, you can choose the options through the  $\blacksquare$  button.

#### > Return to previous menu

Click [Return] to return to the previous menu.

The multifunctional knob can be used to operate the menu. Press the knob to open the menu; rotate the knob to navigate through the items one by one, and press it to select the item.

Depending on the item types, the multifunctional knob can:

- 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, then rotate the knob to switch among the available values; press the knob again to release and deselect the item.

- ➤ For an item with sub-menu: press the knob to extend the sub-menu, and the cursor navigates to the first sub-item. Operate the sub-menu through the multifunctional knob.
- ➤ For tab items in the menu: e.g. the "Right" and "Left" items in the measurement menu. Rotate the multifunctional knob to navigate the tab, and press the knob to select the tab.

#### Parameter Area

Displays the image parameters for the activated image window. If there are more than one imaging modes, the system displays the parameters of each image mode respectively. For details, please refer to the corresponding imaging mode(s).

#### ■ 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 , besides, the annotation, body mark, measurement calipers, color bar/grayscale bar are also displayed here.

#### ■ Image-in-Image thumbnail area

In the zoom status, this area displays the thumbnail of a complete image, and a rectangular frame is used to highlight the currently magnified area. This feature is called image-in-image.

#### Cursor area

The status icon area indicates the current cursor status, such as in cineloop status.

#### ■ 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 "Multifunctional knob".

#### ■ Thumbnail area of images stored

Displays the thumbnail images stored under the current patient.

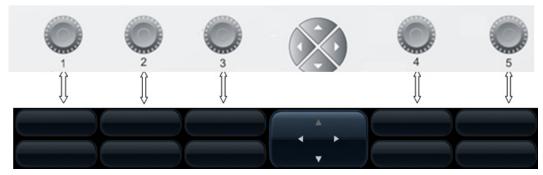
#### Image manage area

- Page up/down: when there are more than one page images have been stored, you can turn to the next or preview page by or respectively.
- Delete: select a thumbnail image, and click to delete it.
- Send to: select a thumbnail image, and click to send it to external devices.

#### ■ Soft Menu Area

The soft menu items displayed are corresponding to functions of soft menu controls in the control panel. The soft menu items are related to image mode and settings of each mode in preset.

The soft menu controls are located at the top of the control panel, shown in the following figure.



#### Page-turning:

Use the up/down keys in directional soft menu controls to turn pages up or down; you can operate the items only when they are highlighted.

#### Mode switching:

Left / right keys in directional soft menu controls are used to switch among the modes. The soft menu items vary depending on the mode. The menu navigation will cause the change of the menu, while the change of the menu will cause the menu navigation.

#### Soft menu control:

The soft menu items are operated respectively through the five knobs.

The soft menu items can also be adjusted by <Set> on the control panel. Move the cursor onto a soft menu item and press <Set> to change the parameter of the item.

#### System status area

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

#### None-fixing Area

Areas illustrated here are position-changeable; you can move them by the trackball within a certain area on the monitor.

#### Result window

The measurement result window displays the results of recently performed measurements.

To move the result window:

- a) Place the cursor on the title of result window (you can see the cursor changes into ⊕).
- b) Press <Set> and move the trackball, the window moves together with the cursor.
- c) Move the cursor to the target position, press <Set> again to anchor the result window in the target position.

#### Comment area

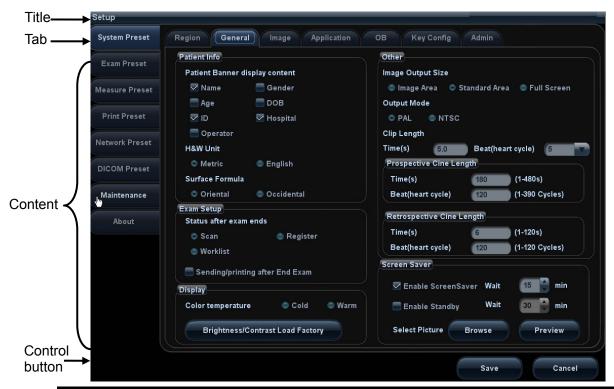
For details, please refer to "9 Comments and Body Marks".

#### Body mark area

For details, please refer to "9 Comments and Body Marks".

# 3.7.2 Basic Operations of Screens

A 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 across several pages. Click the tab by pressing <set> key to open/close the available pages.</set>		
	■ Radio button: click to select the item.		
	■ Check box: click to check or uncheck the item.		
Contents	Entry box: enter characters manually via the keyboard. Position the cursor into the box, and then enter the letters or characters.		
_	■ Drop-down list box: click "▼" to show the list and select an item.		
[Save] and [Cancel]	When the operation of a screen is complete, press the [Save] 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 <Set>.
- 2. Roll the trackball and reposition the rectangular graphic to the new desired location.
- 3. Press the <Set> key, and the dialogue box is moved to the desired position.

# 4 Exam Preparation

**△ CAUTION:** 

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.

### 4.1 To Start an Exam

You can start a patient exam in the following situations:

- New patient information: enter the patient information, if it is a new patient, refer to "4.2.1 New Patient Information" for details.
- New exam: to start a new exam for an already registered patient, the recorded information can be obtained either through iStation or Worklist, refer to "4.2.2.1 iStation" and "4.2.2.2 DICOM Worklist" for details.
- Activate an exam: select an exam that is ended within 24 hours, and continue the exam. For details, please refer to "4.5.1 Activate an Exam".

General procedure for an exam: Enter the patient information  $\rightarrow$  Select an exam mode and probe  $\rightarrow$  Choose an imaging mode  $\rightarrow$  Start the exam.

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.

# 4.2 Patient Information

- To enter the "Patient Info" screen
  - Press <Patient>, or,
  - Move the cursor onto the patient information area on the monitor and press <Set> to open the screen.
- To exit the "Patient Info" screen
  - Click [OK] on the "Patient Info" screen; or, press <Patient> on the control panel again, to save the settings and exit the screen.
  - Click [Cancel] or press <Esc> 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.

### 4.2.1 New Patient Information

The "Patient Info" screen is shown as follows (Take OB exam for example):

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 direction keys.



Detailed information is described as follows:

#### 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.

For details, please refer to "Appendix A Barcode Reader"

#### Name

Enter the patient name directly through the keyboard. Characters of A through Z and 0 through 9 and "." are allowed.

"\", "^", "=" and "," are not permitted.

#### 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 according to the format displayed in the field, or click to select the date. In the table, you can select the desired year (or enter it manually); month and day, then click [OK] to finish it.



#### Age:

- ➤ Auto generated age: once the DOB is entered, the system can display an auto-generated age in the field box; the unit can be "Years", "Months" or "Days". If the age is less than one year, the system will automatically calculate the age in months or days.
- ➤ Also, you can manually enter the age.

**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 9 types: ABD (Abdomen), OB (Obstetrics), GYN (Gynecology), CARD (Cardiac), VAS (Vascular), URO (Urology), SMP (Small Part), PED (Pediatrics), and Breast.

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

General information:

**Study description:** To enter description for each exam.

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

**Secondary indications:** To enter the secondary indications.

**CPT4 code:** To enter the CPT4 code.

**CPT4 description:** To enter the CPT4 description.

**Comment** Exam specific explanation or remarks.

#### • Exam specified information:

Exam Type	Information	Description
	Height	1
ABD	Weight	
(Abdomen)	BSA (body surface area)	After the height and weight are entered, the system will automatically calculate the BSA based on the formula which is set via "[Setup] → [System Preset] → [General]".

Exam Type	Information	Description	
OB (Obstetric)	Calculation index	According to the entered index (can be selected in the drop-down list); including LMP (last menstrual period), date of conception (DOC), IVF (in vitro fertilization), PRV (previous exam date), BBT (basic body temperature)), the system can automatically calculate GA and EDD (estimated delivery date); or, calculates GA and LMP according to the EDD and entered date.  • LMP: After you enter LMP, the system will calculate and display GA and EDD.  • DOC: after you enter the DOC, the system will calculate the GA and EDD.  • IVF: After you enter IVF, the system will calculate GA and EDD.  • PRV: input the date and GA of the last exam, the system will calculate a new GA and EDD.  • BBT: input BBT, the system will calculate the GA and EDD.  • EDD: after you enter EDD, the system will calculate and display GA and LMP.	
	Gravida	Times of pregnancy.	
	Ectopic	Times of abnormal pregnancy. e.g. extrauterine pregnancy.	
	Gestations	Number of embryos (1, 2, 3;4, 1 is default).	
	Para	Times of delivery.	
	Aborta	Times of abortion.	
	LMP	Last menstrual period.	
	Gravida	Times of pregnancy.	
	Para	Times of delivery.	
GYN (Gynecology)	Ectopic	Times of abnormal pregnancy. e.g. extrauterine pregnancy.	
	Aborta	Times of abortion.	
	IVF Info	Female hormone basic level and drugs inducing the ovulation.	
	Height	1	
	Weight	1	
Cardiology	BSA (body surface 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]".	
	BP	Blood pressure.	
	HR	1	
	RA Press	Right Atrium Pressure.	
VAS	Height	1	
(Vascular)	Weight	/	

Exam Type	Information	Description
	BP(L)	Input left blood pressure.
	BP(R)	Input right blood pressure.
URO	Serum PSA	1
(Urology)	PPSA coefficient	
SMP (Small Parts)	None	1
PED (Pediatrics)	None	
Breast	Height	1
	Weight	1

#### 3. Operating Information

- Accession #: exam number used in DICOM. It should be entered within 16 letters or characters; "\" is not permitted.
- Diagnostician: people who is responsible for the exam. "\", "^","=" and "," are not permitted.
- Operator: people who is responsible for images acquisition and scanning. "\", "^",
   "=" and "," are not permitted.
- Ref. Physician: the people who requires the ultrasound exam. "\", "^", "=" and "," are not permitted.

#### 4. Functional key

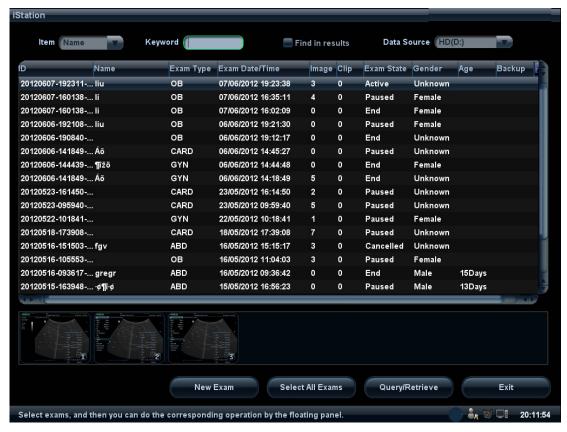
- [Pause Exam]: to pause the current exam.
- [Cancel Exam]: to cancel the current exam.
- [New Patient]: click to clear the current patient information in the patient information screen in order to input information of a new patient.
- [New Exam]: click to clear the entered exam information to start 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.

### 4.2.2 Retrieve Patient Information

#### 4.2.2.1 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,
  - Press the <Review> key on the control panel and click [iStation] in the screen.



2. Select the data source:

Select the data source in the drop-down list of "Data Source". The occupying space percentage of the selected data source will be displayed.

3. Set the searching condition

Define the searching item: Name, ID, BOD or Exam Date; and then enter the related keyword.

- 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.		
6	Patient Information	Click to enter the Patient Info screen.		

Button	Function	Description		
	Review 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.		
	Restore 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.		
	Export Teaching Files	Click to send the selected record to external devices as teaching file.		
	Activate exam	Click to continue an exam that has been finished within 24 hours.		
	Continue 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.

#### 4.2.2.2 DICOM Worklist

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

#### Procedure:

- 1. Select data source: choose a worklist server in the drop-down list of "Worklist Server", and then all the patient exam records in the server are listed out.
- 2. Set the searching condition:
  - Enter the period which includes the exam date, and click [Query] to search.
  - Enter patient ID, patient name, accession #, the system provides 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.
- 3. Select the desired patient from the list, and:
  - 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.
     After you edit the patient information in the "Patient Info" screen, click [OK] to start a new exam.
  - Click [Show Detail] to see details of patient data.
- 4. Click [Exit] to exit the Worklist.

# 4.3 Select an Exam Mode and Probe.

 $\triangle$ 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.

- Select the exam mode:
  - (1) Press < Probe > to open the probe and exam select dialog box.
  - (2) Roll the trackball and press <Set> to select the 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.

# 4.4 Select the Imaging Mode

Use the corresponding keys in the control panel to enter the imaging modes. For the detailed operations in each imaging mode, please refer to "5 Image Optimization".

# 4.5 Activate& Continue an Exam

#### 4.5.1 Activate an Exam

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

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.

#### 4.5.2 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.

# 4.6 Pause & End an Exam

### 4.6.1 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.

Only one exam can be paused every time.

When an exam is paused, the system will:

- (1) 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.

#### **4.6.2** 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.

# **5** Image Optimization

# riangleWARNING:

- The images displayed in this system are only reference for diagnosis. Mindray is not responsible for the correctness of diagnostic results. It is the responsibility of the clinician, who performs the exam, to capture the correct 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 Image Modes

Switch among the imaging modes according to the actual situation.

### 5.1.2 Image Adjustment

- Adjustment through image menu
  - Press <Menu> or multifunctional knob to open the menu; use the trackball and <Set> or the multifunctional knob to adjust.
- Adjustment through soft menu controls
  - The soft menu locates at the bottom of the screen, items of which are dependent upon image modes and preset. Take B mode adjustment as an example.
  - Image mode switching
    - Use left / right controls of the four-directional key to switch among the modes. The soft menu items vary depending on the mode. The menu navigation will cause the change of the menu, while the change of the menu will cause the menu navigation.
  - Page up/down
    - Use the up/down keys of the four-directional key to turn pages up or down; you can operate the items only when they are highlighted.
  - Soft menu controls operation
    - a) The soft menu items are operated respectively through the five groups of knobs.
    - b) You can also move the cursor to the certain soft menu item, and then press <Set> or rotate the multifunctional knob to adjust.
- Adjustment through image parameter area
  - The image parameter area is located in the upper left corner of the screen. The image parameters are displayed while the image menu is not available.

- (1) Move the cursor to the item on the parameter area, and a frame will be around the certain item, as DR65.
- (2) Press <Set> to adjust, and rotate the multifunctional knob to select the values.
- Adjustment through control panel
  - Trackball, control panel key, knob or sliders.

### 5.1.3 Quickly Saving Image Setting

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

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

# 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 left corner of the screen displays the real-time parameter values as follows:

Parameter	F	D	G	FR	DR	iClear	iBeam	iTouch	Zoom
Meaning	Frequency	Depth	Gain	Frame Rate	Dynamic Range	Displa	yed wher turne	_	ction is

# 5.2.3 B Mode Image Optimization

#### Gain

Description

To adjust the gain of the whole receiving information in B mode. The realtime gain value is displayed in the image parameter area in the upper left corner of the screen. **Operation** Rotate the <B> knob clockwise to increase the gain, and anticlockwise to

decrease.

Or adjust it in the image parameter area.

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 display depth of sampling, the real-time

value of which is displayed on the image parameter area in the upper left

corner of the screen.

**Operation** Rotate the "Depth" knob clockwise to increase the depth;

Rotate the "Depth" knob anticlockwise to decrease 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.

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

**TGC** 

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

optimize the image.

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

the areas in the image.

**Operation** To increase the gain compensation at an area of interest, move the TGC

slider to the right.

To decrease the gain compensation at the corresponding area of interest,

move the TGC slider to the left.

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.

Frequency

**Description** This function is used to select the operating frequency of the current

probe, the real-time value of which is displayed in the image parameter area in the upper left corner of the screen, where "F" represents B mode

frequency, and "FH" represents harmonic frequency.

**Operation** You can select a harmonic frequency or a B mode frequency.

Adjust the frequency value through the [Frequency] item in the soft menu,

"H" indicates harmonic frequency.

Values of frequency vary depending upon the probe types.

Select the frequency according to the detection depth and current tissue

characteristics.

Effects The higher the frequency the better the near field resolution but the worse

the force of penetration.

Harmonic imaging enhances near field resolution and reduces lowfrequency and large amplitude noise, so as to improve small parts

imaging.

#### **Acoustic Power**

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

time value of which is displayed in the image parameter area in the upper

left corner of the screen.

**Operation** Adjust through the [A. power] item in the soft menu.

The adjusting range is 7%-100%, in increments of 3%.

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

contrast of the image as well as the force of penetration.

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

ALARA Principle.

#### **Focus**

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

which are displayed on the right of the image.

**Operation** Adjust the focus number through the [Focus Number] in the soft menu.

Adjust the focus position through the [Focus Position] in the soft menu.

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

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

provide a much clearer image.

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

#### **Imaging Display 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, click [FOV] on the soft menu 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 (ExFOV function is turned on), the FOV position can not 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** Steer the transmitting beam through the [B Steer] item in the soft menu.

**ExFOV** Click [ExFOV] on soft menu 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.

**Operation** Adjust through the [Line Density] item in the soft menu.

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

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

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

area in the upper left corner of the screen.

**Operation** Adjust through the [Dyn Ra.] item in the soft menu.

Or adjust it in the image parameter area.

The adjusting range is 30-240dB in increments of 5dB.

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

lower the contrast with more noise.

#### iClear

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

image boundary.

**Operation** Adjust through the [iClear] item in the soft menu.

The system provides 5 levels of iClear effects adjustment, off represents no iClear is turned on, and the bigger the value the stronger the effect.

**Effects** The bigger the value the more clearly the profile of the image.

#### **Persistence**

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

as to optimize the image and remove noises.

**Operation** Adjust through the [Persistence] item in the soft menu.

The system provides 8 level 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 increase may lead to signal missing.

#### Invert /Rotation

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

**Invert(L/R** To invert the image horizontally or vertically.

**Flip)** Click [L/R Flip] in the menu or the soft menu to invert the image.

**Rotation** Rotate the image through the [Rotation] item in the menu or the soft menu.

Image can be rotated by the manners in angle of 0°, 90°, 180°, and 270°. When the image is rotated at the angle of 90° or 270°, the depth scale is

displayed on the upper part of the screen.

When you invert or rotate an image, the "M" mark will change its position correspondingly on the screen; the M mark is located in the upper left corner of the imaging area by default.

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

**iBeam** 

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

steer angles to obtain image optimization.

**Operation** Adjust through the [iBeam] item in the soft menu.

Effects Images after iBeam processing can be optimized with less spot noise and

higher resolution, so that more details for the structure are revealed.

**Impacts** When linear probe is being used, iBeam function is not available when

trapezoid function is turned on or B steer is adopted.

**Auto Merge** 

**Description** In the Dual-split mode, when the images of the two windows use the same

probe type, depth, invert status, rotation status and magnification factor, the system will merge the two images so as to extend the field of vision.

**Operation** Turn on or off the function through the [Auto Merge] item in the soft menu.

**Impacts** iBeam is available only for linear probes.

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

**Gray Map** 

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

**Operation** Select among the maps through the [Gray Map] item in the soft menu.

The system provides 8 groups of gray map.

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

**Tint Map** 

**Description** Colorize function provides an imaging process based on color difference

rather than gray distinction.

**Operation** Select the colorize map through the [Tint Map] item in the soft menu or

menu.

The system provides 16 (1-16) Tint Maps to be selected.

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

TSI (Tissue Specific Imaging)

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

speed according to tissue characteristics.

**Operation** Select among the TSI modes through the [TSI] item in the soft menu.

The system provided 4 ways of optimization for specific tissues: general,

muscle, fluid and fat.

iTouch

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

a better image effect.

Operation Press <iTouch> on the control panel to turn on the function, the symbol of

which will be displayed in the image parameter area of the screen.

Click [iTouch] on the menu to adjust the gain in iTouch, with the adjusting

range of -12-12dB.

Hold and press <iTouch> to exit iTouch mode.

**HScale** 

**Description** Display or hide the width scale (horizontal scale).

The scale of the horizontal scale is the same as that of vertical scale (depth), they change together in zoom mode, or when the number of the image window changes. When image is turned up/down, the HScale will

also be inverted.

**Operation** Click [HScale] on the soft menu to display or hide the scale.

**Tint Map** 

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

rather than gray distinction.

**Operations** Click [Gray Invert] on the image menu to change the color.

**Gray Invert** 

**Description** This function provides an imaging color inverting.

**Operations** Click [Gray Invert] on the image menu to change the color.

Lithority

**Description** "Lithotrity" helps to locate the focus point of lithotrity wave during lithotrity

treatment. By watching the procedure of lithotrity in real-time and adjusting the intension and frequency of the lithotrity wave, the harm to the patients

can be reduced to the least.

**Operations** Click [Lithority] on the image menu to hide or display the line.

# 5.3 M Mode Image Optimization

#### 5.3.1 M Mode Exam Protocol

- 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 left corner of the screen displays the real-time parameter values as follows:

Parameter	F	D	G	V	DR
Meaning	Frequency	Depth	M Gain	M velocity	M Dynamic Range

- During M mode imaging, menus for B mode and M mode are displayed at the same time. You can switch between the 2 modes through the soft menu of image parameter menu.
- 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 left corner of the screen.

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

decrease.

Or adjust it in the image parameter area.

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.

#### **Focus Position**

**Description** To change the focus position in M mode, symbols as "\" of which are

displayed on the right of the image.

**Operation** Adjust the focus position through the [Focus Position] item in the soft

menu.

#### **Display Format**

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

**Operation** Adjust through the [Display Format] item in the soft menu.

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

full.

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

through comparison.

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

**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 left corner of the screen.

**Operation** Change the speed through the [Speed] item in the soft menu.

Or adjust it in the image parameter area.

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** Colorize function provides an imaging process based on color difference

rather than gray distinction.

**Operation** Select the colorize map through the [Tint Map] item in the soft menu.

The system provides 16 different maps to be selected among.

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

**Gray Map** 

**Description** This function applies the gray correction to obtain the optimum image

through adjusting 3 parameters: curve, gray rejection and y.

**Operation** Select among the maps through the [Gray Map] item in the soft menu.

You can also adjust through the grayscale bar: move the cursor to the

grayscale bar and press <Set> on the control panel to adjust.

The system provides 8 groups of gray map.

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

**Edge Enhance** 

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

image boundary.

**Operation** Adjust through the [Edge Enhance] item in the soft menu.

The system provides 14 levels of edge enhance effects, off represents no edge enhance is turned on, and 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 B image resolution to compress or

expand the gray display range. The real-time dynamic range value will be displayed in the image parameter area in the upper left corner of the

screen.

**Operation** Adjust through the [Dyn Ra.] item in the soft menu.

Or adjust it in the image parameter area.

The adjusting range is 30-240dB in increments of 5.

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

lower the contrast with more noise.

M Soften

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

making the image details to be clearer.

**Operation** Adjust through the [M Soften] item in the soft menu.

The system provides 15 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 Color Mode Exam Protocol

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

# 5.4.2 Color Mode Image Optimization

■ In Color mode scanning, the image parameter area in the upper left 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 M mode are displayed on the soft menu. 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 left corner of the screen.

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

to decrease.

Or adjust it in the image parameter area.

The adjusting range is 0-100.

Impacts Increasing the gain will increase the flow signal presented as well as

noise, while the signals may be missing when the gain is adjusted too low.

**ROI Adjustment** 

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

**Operation** When the ROI box is dotted line, roll the trackball to change its 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 status.

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

resolution and color sensitivity.

**Frequency** 

**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

left corner of the screen.

**Operation** Select the frequency value through the [Frequency] item in the soft menu.

Or adjust it in the image parameter area.

Values of frequency vary by probes. Select the frequency value according to the need of the detection depth and the current tissue characteristics.

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

worse the force of penetration.

**B/C Align** 

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

the Color ROI.

**Operation** Turn on or off the function through the [B/C Align] item in the soft menu.

**Impacts** Frame rate will increase when the function is turned on.

**Dual Live** 

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

**Operation** Click [Dual Live] in the soft menu to turn on or off the function. 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).

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

Steer

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

with immobility of the linear probe.

**Operation** Adjust through the [Steer] item in the soft menu, or rotate the

multifunctional knob to adjust.

Values of steering angles vary by probes.

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 available only for linear probes.

#### **Line Density**

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

**Operation** Adjust through the [Line Density] item in the soft menu.

There are 2 levels of line density provided: UH, H, M, L.

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

**Impacts** The higher the line density, the smaller 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.

**Operation** Adjust through the [Packet Size] item in the soft menu.

There are 4 levels of packet size provided, 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** Increasing the packet size will lead to frame rate decrease.

#### **Persistence**

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

the image.

**Operation** Adjust through the [Persistence] item in the menu or the soft menu.

The system provides 5 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.

**Operation** Adjust through the [Smooth] item in the soft menu.

The system provides 5 levels of smooth function, the bigger the value the

higher the smooth.

#### 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 will be displayed in the image parameter area in the upper left corner of the

screen.

**Operation** Adjust the speed range through the [Scale] item in the menu or the soft

menu.

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.

**Operation** Adjust through the [Baseline] item in the soft menu.

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

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

Invert

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

inverted when the function is turned on.

**Operation** Turn on or off the function through the [Invert] item in the soft menu.

Select "Auto Invert" in the "[Setup]  $\rightarrow$  [System Preset]  $\rightarrow$  [Image Preset]", 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.

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

Map

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

indicates the display effect of color image.

**Operation** Select among the maps through the [Map] item in the soft menu.

You can also adjust through the color bar: move the cursor to the color bar

and press <Set> on the control panel to adjust.

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.

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

WF (Wall Filter)

**Description** It filters out low-frequency 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 left corner of the

screen.

**Operation** Select through the [WF] item in the soft menu.

Or adjust it in the image parameter area.

There are 8 levels of wall filter function, adjust according to the actual

situation and the probe.

**Impacts** Flow signals may be missing.

**Priority** 

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

grayscale signal or color signal.

**Operation** Select the value through the [Priority] item in the soft menu.

The adjusting range is 0-100%.

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

lower the value, grayscale signals are prior to be displayed.

iTouch

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

a better image effect.

**Operation** Press <iTouch> on the control panel to turn on the function, the symbol of

which will be displayed in the image parameter area of the screen.

Velocity tag

**Description** This function is used to mark the specified velocity range in flow to check

the flow function or specific flow velocity value.

**Operation** 1. Select [Velocity Tag] from the soft menu 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.

# 5.5 Power Mode Image Optimization

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

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

### 5.5.1 Power Mode Image Parameters

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

Parameter	F	G	PRF	WF
Meaning	Frequency	Power Gain	Pulse Repetition Frequency (PRF)	Power Wall Filter

- During Power mode imaging, menus of image optimizing for B mode and Power mode are displayed on the soft menu at the same time. You can switch between the 2 modes.
- 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 to be introduced, please refer to relevant sections of the Color mode and B mode, while special items of the Power mode are introduced in the following.

### 5.5.2 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 left corner of the screen.

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

to decrease.

Or adjust it in the image parameter area.

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.

Map

**Description** This feature indicates the display effect of power image. The maps in

Power mode image are grouped into two categories: Power maps and

Directional Power maps.

**Operation** Select the map through the [Map] item in the soft menu.

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.

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

**Dynamic Range** 

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

signal.

**Operation** Adjust through the [Dyn Ra.] item in the soft menu.

**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 Optimization

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

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

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

#### 5.6.1 PW / CW Mode Exam Protocol

- 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 left corner of the screen.

PW Sampling Line	SV
Adjustment	Angle
	SVD
CW Sampling Line	Angle
Adjustment	CW Focus Depth

- 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 left 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 Filter	SV Position	SV Size	Angle
CW	Parameter	F	G	PRF	WF	SVD		Angle

	Meaning	Frequency	Gain	PRF	Wall Filter	SV Position	Angle	l
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- During PW/CW mode imaging, menus of image optimizing for B mode and PW/CW mode are displayed on the soft menu at the same time; if there is also Color mode (Power mode) working, menus of certain modes will also be displayed synchronously, and you can switch by clicking the left/right arrow.
- 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.

Only phased probes support CW mode.

### 5.6.3 PW/CW Doppler Mode 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 left

corner of the screen.

**Operation** Rotate the <PW> knob clockwise to increase the gain, and anticlockwise

to decrease.

Or adjust it in the image parameter area.

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.

Frequency

**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** Select the frequency value through the [Frequency] item in the soft menu.

Or adjust it in the image parameter area.

Values of frequency vary depending upon the probe types.

Select the frequency according to the detection depth and current tissue

characteristics.

Effects The higher the frequency, the worse the axial resolution, and the better the

force of penetration.

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 will be displayed in the image parameter area in the upper left corner of the

screen.

**Operation** Adjust the speed range through the [Scale] item in the soft menu.

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 use high PRF to observe

high-velocity flows.

**Impacts** Aliasing may occur if low velocity scale is used and high velocities are

encountered.

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

#### **iTouch**

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

a better image effect.

**Operation** Press <iTouch> on the control panel to enter the iTouch status, the symbol

of which will be displayed in the image parameter area of the screen.

You can preset the mode for iTouch function.

#### **Auto Calculation and Auto Calculation Parameter**

**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.

**Operation** Click [Auto Calc] in the soft menu to turn on or off the function.

Select parameters in the dialogue box prompted by clicking [Auto Calc

Param].

In real-time scanning, the results displayed are derived from the

calculation of latest cardiac cycle.

In freeze and cine status, the results displayed are calculated from the

current selected area.

You can define user-defined key for auto calculation function in "[Setup] →

[System Preset] → [Key Config]".

**Impacts** Note: heart rate value obtained by auto calculation may be of deviation,

please adopt manual measurement or ECG function (optional) to get the

precise value.

#### **Auto Calc Cycle**

**Description** To set the number of heart cycle for auto calculation.

**Operations** Click [Auto Calc Cycle] on the soft menu or the menu.

Invert

**Description** This function is used to set the display manner of spectrum.

**Operation** Turn on or off the function through the [Invert] item in the soft menu.

Select "Auto Invert" in the "[Setup]  $\rightarrow$  [System Preset]  $\rightarrow$  [Image Preset]", 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.

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

**Speed** 

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

**Operation** Adjust the speed through the [Speed] item in the soft menu.

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

the speed.

**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.

**Operation** Adjust through the [T/F Res] item in the soft menu.

There are 5 levels of T/F Res values available, adjust according to the

actual situation and the transducer.

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 left corner of the

screen.

**Operation** Select through the [WF] item in the soft menu.

Or adjust it in the image parameter area.

There are 7 levels of wall filter function available, adjust according to the

actual situation and the transducer.

**Impacts** Flow signals may be missing.

**Tint Map** 

**Description** Colorize function provides an imaging process based on color difference

rather than gray distinction.

**Operation** Select the map through the [Tint Map] item in the soft menu.

The system provides 16 colorize maps to be selected among.

You can define user-defined key for colorize function in "[Setup] →

[System Preset] → [Key Config]".

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

**Trace** 

**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 menu.

The available selections are: Above, Below, All.

**Gray Map** 

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

**Operation** Select among the maps through the [Gray Map] item in the soft menu.

There are 8 different gray maps available.

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

#### **Display Format**

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

**Operation** Adjust through the [Display Format] item in the soft menu.

There are 5 formats to display the images: H2:3, V2:3, V3:2, V3:1, Full.

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

#### **Duplex/Triplex**

**Description** This function is used to set if B image (B+Color image) and PW image are

displayed synchronously.

**Operation** Turn on or off the function through the [Duplex] / [Triplex] in the soft menu.

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

**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.

**Operation** Turn on or off the function through the [HPRF] item in the soft menu.

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

**Baseline** 

**Description** Refers to the area where the velocity is zero in the spectrum.

**Operation** Adjust through the [Baseline] item in the soft menu.

**Effects** Adjust baseline according to the actual situation to change the range of

flow velocity to optimize the image.

Positive value means to enhance the signals above the baseline, and negative value means to enhance the signals below the baseline.

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

**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.

**Operation** Adjust through the [Angle] item in the soft menu.

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

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

#### **Quick Angle**

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

which is displayed on the right part of the spectrum map.

**Operation** Adjust through the [Quick Angle] item in the soft menu.

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

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

#### **Dynamic Range**

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

intensity to gray scale.

**Operation** Adjust through the [Dyn Ra.] item in the soft menu.

The adjusting range is 24-72dB in increments of 2dB.

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

lower the contrast with more noise.

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

**Audio** 

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

**Operation** Adjust through the [Quick Angle] item in the soft menu.

The adjusting range is 0-100%.

**Effects** Audio helps to identify the feature and status of flow.

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

**PW Steer** 

**Description** 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.

**Operation** Adjust through the [PW Steer] item in the soft menu.

Values of steering angles vary by probes.

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.

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 left corner of the screen.

**Operation** Adjust the SV size through the [SV] item in the soft menu.

Roll the trackball to adjust the SV depth.

Or adjust the SV directly in the image parameter area.

The adjusting range is 0.5-20.0mm.

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

information can be obtained when selected large SV size.

### 5.7 Anatomical M Mode

CAUTION:

Anatomical M images and Color Anatomical M 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.

### 5.7.1 Free Xros M Imaging

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 for Free Xros M mode

Assign a user-defined shortcut key for Free Xros M: [Setup] → [System Preset] →
[Key Config]. Please refer to "12.1.6 Key Configuration" for details.

#### 5.7.1.1 Basic Procedure

- 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 menu or press the user-defined key to enter Free Xros M mode.
- 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.

#### 5.7.1.2 Free Xros M Image Parameters

- During real-time Free Xros M mode imaging, menus for B mode, Free Xros M mode and other modes are displayed in the soft menu at the same time, use the left/right keys of soft menu directional controls to switch the menus.
- While imaging in freeze mode, menus of image optimization for B mode, Free Xros M mode and other modes are displayed in the soft menu at the same time. Use the left/right keys of soft menu directional controls to switch the menus.
- 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 or 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 on the other end as a mark for direction.

Operation Click [Show A], [Show B], [Show C] in the soft menu to display or hide the

sampling line, and the corresponding image will be displayed on the

screen once the related item is selected.

**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.

**Operation** 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.

#### Adjust the M-mark Line

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

Operation

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 the angle via the [Angle] in the soft menu or the multifunctional knob.

The adjusting angle range is 0-360 in increments of 1.

#### 5.7.1.3 Exit

■ In Free Xros M mode, click [Free Xros M] in the soft menu or press <B> or the user-defined key to exit.

### 5.7.2 Free Xros CM (Curved Anatomical M Mode)



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.

#### 5.7.2.1 Basic Workflow in Free Xros CM

- 1. In 2D real time scanning 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. Press the user-defined key for Free Xros CM 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 **a**, and can be moved within the 2D image only.

- 5. Press <Set> key 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 (press <Back> key to exit the operation; or, click [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 5 and 6 to finish the sample line.
- 8. Double click <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 the user-defined key again to exit Free Xros CM mode.

#### **Sample Line Modification**

- 1. To enter into curve (sample line) modification status:
  - When enter the Free Xros CM mode (not the first time after system started up), the sample line of the last Free Xros CM exam is displayed in edit status, and the cursor is displayed as
  - For a finished sample line, set [Edit] as "On", the sample line is editable.
- 2. Anchor the cursor on a certain point, press <Set> key to activate the point, then roll the trackball to drag the point for a desired sample line.
- 3. Double click <Set> key to end the edit, and the sample line is displayed in white.
- 4. Press the user-defined key again to exit Free Xros CM mode.

#### **Delete the Sample Line**

Click the sample line to select it, and click [Delete] 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 dependent 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.

# 5.8 TDI

TDI mode is intended to provide information of low-velocity tissue motion, specifically for cardiac movement.

There are 4 types of TDI mode:

- Tissue Velocity Imaging (TVI): This imaging mode is used to detect tissue movement with direction and speed information.
- 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 speed information of the tissue quantificationally with doppler spectrum.
- 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, refer to "5.9 Color M Mode" for details.

Only phased probe is valid for TDI function.

#### 5.8.1 TDI Exam Protocol

- Enter TDI
  - User-defined shortcut key
    - a) Assign a user-defined shortcut key for TDI: the setting path is "[Setup] →
       [System Preset] → [Key Config]". Please refer to "12.1.6 Key Configuration" for details.
    - b) Press the user-defined key in B mode to enter TVI mode.
  - In real-time mode, press the user-defined key to enter the corresponding TDI mode as follows:
    - ➤ In Color mode, click [TDI] to enter TVI mode, parameters of TVI mode will be displayed in the soft menu.
    - ➤ In Power mode, click [TDI] to enter TEI mode, parameters of TEI mode will be displayed in the soft menu.
    - ➤ In PW mode, click [TDI] to enter TVD mode, parameters of TVD mode will be displayed in the soft menu.
    - ➤ In M mode, click [TDI] to enter TVM mode, parameters of TVM mode will be displayed in the soft menu.
- Switching between the TDI modes
  In TDI mode, press <Color>, <Power>, <M> or <PW> to switch between the modes.
- Exit TDI
  - Press the user-defined key to exit TDI mode and enter general imaging modes.
  - Or, press <B> on the control panel to return to B mode.

# 5.8.2 TDI Image Parameters

■ In TDI mode scanning, the image parameter area in the upper left 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

# 5.8.3 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.

# 5.8.4 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 noneultrasound methods.

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

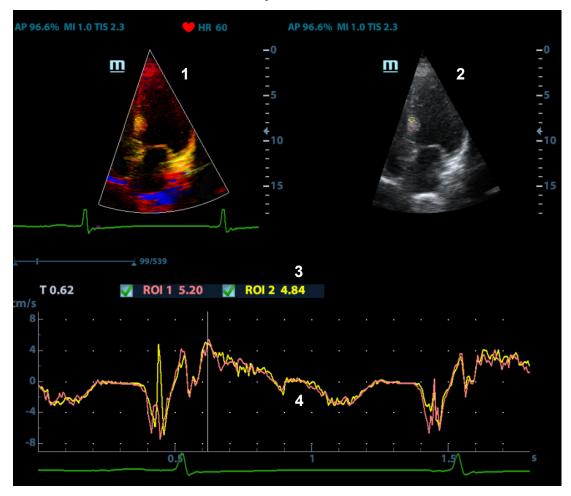
#### Workflow of TDI QA:

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 for cine files. If the user has selected a single-frame image, TDI QA function cannot be activated.
- 2. Click [TDI QA] on the TVI soft menu to activate TDI QA function.
- 3. Mark out the interesting part.
- 4. Save the curved image, export the data and do parameter analysis.
- 5. Exit TDI QA function.
  - Press <Freeze> key on the control panel or click [Exit] on the soft menu to exit TDI QA.

### 5.8.4.1 TDI QA Screen Description



#### 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 velocity (unit: cm/s), while X axis represents the time (unit: s).
- Frame marker: a 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 TIC curve.

#### 4---Displays ECG trace.

#### 5.8.4.2 Basic Operations of TDI QA

#### **Selecting TIC Analysis Image Range**

A range of frames is selected for the TDI quantitative analysis in Cine mode (before accessing TDI QA). Only the frames in this range are used for the TDI quantitative analysis. If a range is not selected prior to accessing the TDI QA, the system uses the default cine start and end frames as the default TDI QA start and stop frames.

- Move the cursor onto the desired start of the cineloop; click [Set First Frame] to set the start point.
- Move the cursor onto the desired end of the cineloop; click [Set End Frame] to set the end point.

#### **Setting ROI**

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.

#### Standard ROI

- (1) Click [Standard ROI] on the soft menu.
- (2) When the trackball positions the image display cursor over the reference image(s), an elliptical ROI is automatically generated and displays on the reference image(s).
- (3) The average intensity value inside the ellipse is calculated for every image in the image analysis range and plotted in the image display area.
- (4) The last generated or selected ellipse is considered the active ROI, and its trace plot automatically updates as the user repositions it on the reference image. Old traces are erased.
- (5) When scanning with an elliptical ROI, press <Set> to fix the ROI position and freeze its corresponding trace on the plot. A new active ROI is generated whose position is manipulated by the trackball and whose analysis curve traces will be plotted as before, while the previous ROI and trace remain fixed at the points where they were saved at.

#### Freehand ROI

- (1) Click [Freehand ROI] on the soft menu, when the cursor is evolved in the image review area (TVI image review window or 2D image review window), it displays as a color-coded ellipse.
- (2) Review the image to a desired frame.
- (3) Use the trackball to position the caliper on the reference image at the start point. Press <Set> to fix the start point.
- (4) Trace the outline of the desired ROI by moving the cursor with the trackball.
- (5) Press and hold <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 will update the graphics and the data as well.
- (6) Double click [Set] key to end ROI tracing.

The system automatically links the start point to the end point by drawing a straight line between them. The caliper is then free for repositioning for another freehand ROI.

You cannot go outside the image boundary when drawing a freehand ROI.

#### ■ Delete ROI

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

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

Deleting an ROI causes the ROIs to be deleted from all frames in the analysis loop.

Standard Height/Standard Width/Standard Angle

Click [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.

#### Tips:

- Once eight ROIs have been saved, the system does not automatically generate an active ROI when the cursor is positioned over the displayed reference image.
- The saved ROIs can be a mixture of elliptical and freehand ROIs.
- 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.

#### ROI tracking

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

#### Tips:

- The saved ROIs can be a mixture of elliptical and freehand ROIs.
- 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.

#### Hide/Show

Click [Hide] or [Show] on the soft menu to hide or display the analysis curve area.

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

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

# 5.9 Color M Mode

Color M mode provides information of color flow or tissue movement 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 (also known as TVM).

#### 5.9.1 Enter Color M Mode

- Color Flow M mode
  - In B+M Mode, press <Color>.
  - In B+Color, B+ Color+ Pw or B+ Color+ CW mode, press <M> twice or press <M> and press <Update>.
- Color Tissue M mode(TVM)
  - In B+TVI/TVD, or B+TVI+TVD mode, press <M> twice or press <M> and press <Update>.
  - In Color Flow M mode, click [TDI] in the soft menu or press the user-defined TDI key and press <Update>.

#### 5.9.2 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.

# 5.9.3 Image Parameters

- In Color Flow M mode, parameters that can be adjusted are in accordance with those in B, M and Color modes; please refer to relevant sections of B, Color and M mode for details.
- In Color Tissue M mode, parameters that can be adjusted are in accordance with those in B, M and 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 left corner of the screen displays the real-time parameter values as follows:
- 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.

# 5.10 3D/4D

**NOTE:** 3D/4D imaging is largely environment-dependent, so the images obtained are provided for reference only, not for confirming a diagnosis. Please compare the images with that of other machines, or make diagnosis using none-ultrasound methods.

#### 5.10.1 Note before Use

#### 5.10.1.1 3D/4D Image Quality Conditions

**NOTE:** In accordance with the ALARA (As Low As Reasonably Achievable) principle, please try to shorten the sweeping time after a good 3D imaging is obtained.

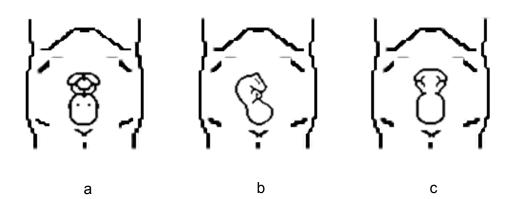
The quality of images rendered in the 3D/4D imaging is closely related to the fetal condition, angle of a B tangent plane and scanning technique (Smart3D). The following description uses the fetal face imaging as an example, the other parts imaging are as the same.

#### Fetal Condition

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

Fetal Body Posture
 Recommended: Cephalic face up (figure a) or face aside (figure b).

NOT recommended: Cephalic face down (figure c).



- Amniotic fluid(AF) isolation
   The region desired is isolated by amniotic fluid adequately.
   The region to imaging is not covered by limbs or umbilical cord.
- The best condition is that the fetus keeps still. If there is a fetal movement in Smart 3D or Static 3D imaging, you need a rescanning when the fetus is still.
- Angle of a B tangent plane

The optimum tangent plane to the fetal face 3D/4D imaging is the sagittal section of the face, or the coronal section. 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 Smart3D)
  - Stability: body, arm and wrist must move smoothly, otherwise the restructured 3D image distorts.
  - Slowness: move or rotate the probe slowly. The speed of linear scan is about 2 cm/s and the rotation rate of the fan scan is about 10°/s∼15°/s.
  - Evenness: move or rotate the probe at a steady speed or rate.

**NOTE:** 1. A region with qualified image in B mode may not be optimal for 3D/4D imaging.

E.g. adequate AF isolation for one sectional plane 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.

#### 5.10.2 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.

4D provides continuous, high volume acquisition of 3D images. 4D adds the dimension of "movement" to a 3D image by providing continuous, real-time displays.

#### Mode definition

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.

Static 3D

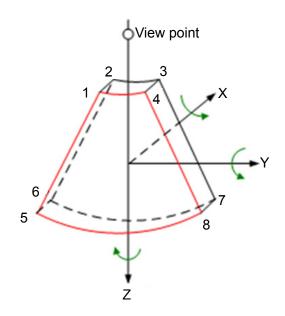
Posit the probe at a fixed place; the probe automatically performs the scanning. After the scanning is completed, the system carries out image rendering, and then displays a frame of 3D image.

4D

The probe performs the scanning automatically. During the scanning, the system renders 3D images in real time, and all 3D images are displayed in real time.

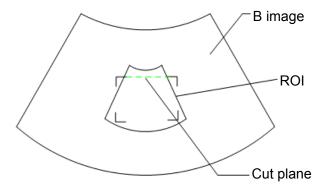
#### ■ Terms

- VR: a three-dimensional content.
- Volume data: the image data set of a 3D object rendered from 2D image sequence.
- 3D image: the image displayed to represent the volume data.
- View point: a position for viewing volume data/3D image.
- Section image: tangent planes of the 3D image obtained by algorithm. As shown in the figure below, XY-paralleled plane is C-section, XZ-paralleled plane is Bsection, and YZ-paralleled plane is A-section. The probe is moved along the Xaxis.
- 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 determine the area of a sectional plane for 3D imaging.



#### ■ ROI and VOI

Before image acquisition 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 cut plane 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, with a small box at each corner of ROI).

#### Curved VOI adjustment

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

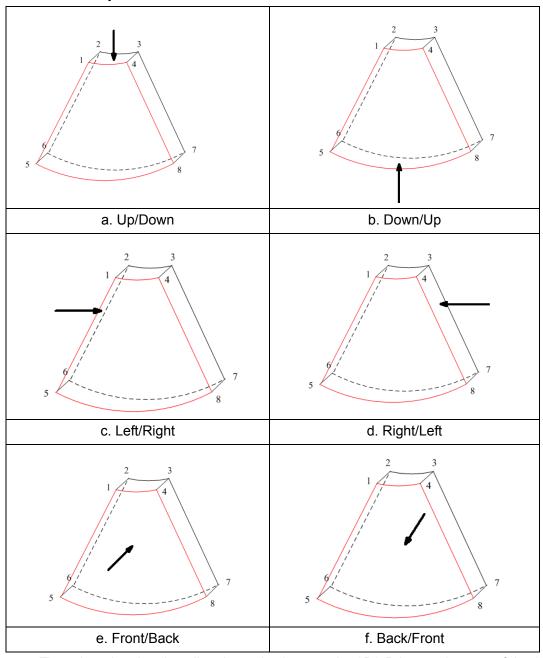
View	Curved VOI
U/D	At the upper part of curved VOI
D/U	At the lower part of curved VOI

View	Curved VOI
L/R	At the left part of curved VOI
R/L	At the right part of curved VOI
F/B	Displays as a dot
B/F	Displays as a dot

**NOTE:** To define a ROI, please try to cut the useless data as to reduce the volume data, shortening the time for image storing, processing and rendering.

#### ■ 3D view direction definition

You can adjust the view direction of the ROI.



Tips: changing the view direction only changes the 3D/4D image; images of the 3 sections do not change.

#### ■ Probe

A 2D imaging probe can be applied for Smart 3D imaging, however, to realize static 3D imaging or 4D imaging, a volume probe should be selected.

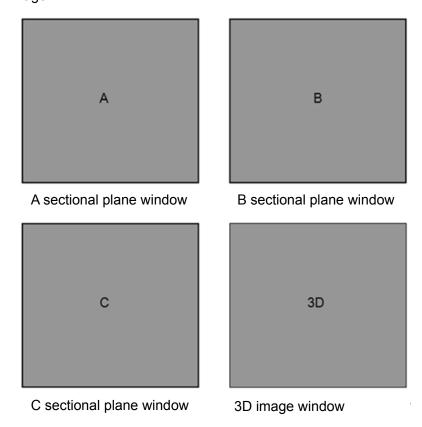
#### Sectional plane

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

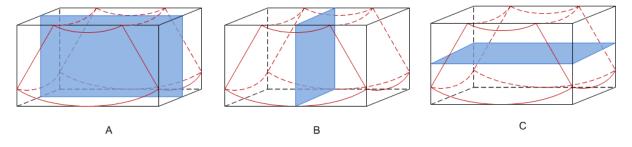
The sectional plane can be viewed in the following status:

- 3D image viewing status of Smart3D
- 3D image viewing status of Static 3D
- Real time 4D or frozen 4D status

In the quad display format view, the screen displays A, B, C 3 sectional planes and the 3D image.



A, B, C section images are illustrated as the following sections of 3D image.



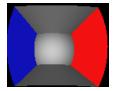
- Section A: corresponds to the 2D image in B mode. Section A is the sagittal section in fetal face up posture, as shown in the figure A above.
- Section B: it is the horizontal section in fetal face up posture, as shown in the figure B above.

 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 clicking [Quick Rot.] to be "180°" in the soft menu.

#### ■ 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 sectional plane. See the graphic below:



Wire Cage

 $\triangle$ CAUTION:

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

## 5.10.3 Static 3D

Static 3D provides single frame image acquisition of 3D images. Make sure to perform Static 3D imaging with an appropriate Static 3D-compatible probe—volume probe. Only if the current probe is an effective one, can the system enters Static 3D imaging mode. During the scanning, the probe performs the scanning automatically.

# 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 <F9> and select Static 3D sub-mode on the soft menu to enter Static 3D mode, and define the ROI as well as curved VOI.

To adjust the ROI: roll the trackball to change the ROI size, ROI position and curved VOI, press the <Set> key to toggle among setting the ROI size, ROI position and curved VOI.

For ROI setting, make sure:

- Set ROI on the 2D image with the largest section area of the fetal face.
- Set ROI a little larger than the fetal head.

**NOTE:** To define a ROI, please try to cut the useless data as to reduce the volume data, shortening the time for image storing, processing and rendering.

- 4. Select a render mode on the menu, set parameters like [Angle], [Image Quality] 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 <Update> to return to Static 3D image acquisition preparation; or, press <B> or <F9> to enter B mode.

# 5.10.3.2 Static 3D Acquisition Preparation

# ■ Parameters description:

Туре	Parameter	Description		
	Angle	Function: to set the range for imaging. Range: 10-70°, in increments of 5°.		
Parameter adjusting	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.		
Render Mode		This is helpful for viewing bony structures.		
	Min	Function: set Min as 3D image rendering mode, displays the minimum echo intensity in the observation direction.		
		This is helpful for viewing vessels and hollow structure		
	X-ray	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.		

## 5.10.3.3 Static 3D Image Viewing

## **Entering/Exiting Image Viewing**

To enter image viewing:

The system enters image viewing when image acquisition is finished. You can complete the acquisition by:

- Wait until the 3D acquisition automatically completed.
- Exit

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

Press <Update> or <Freeze>.

#### **Activate Sectional Plane**

Click [Cur. Win] to activate sectional plane image (MPR) or 3D image (VR).

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

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

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

### **MPR Only**

Set [MPR] as "On" to display section images. And the adjustable image parameters are changed into MPR parameters automatically.

Only A, B and C section images are displayed, and 3D image is not displayed.

MPR Only function is available in image acquisition status.

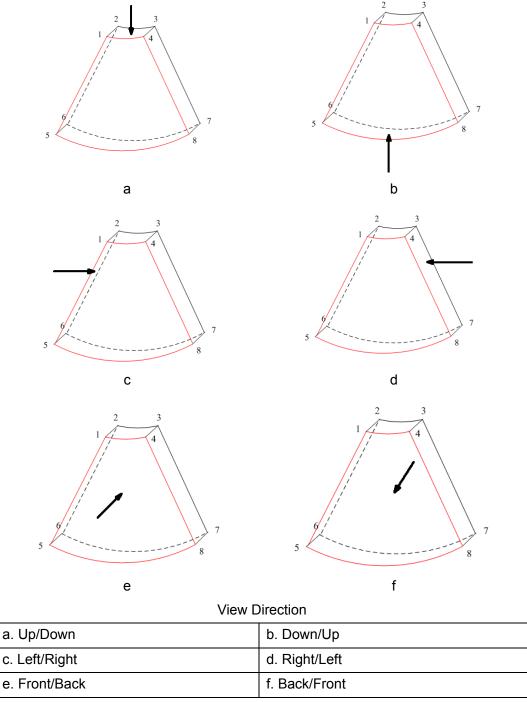
#### **Asymmetric**

Set [MPR] as "Off" to display section images along with 3D image.

# **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.



Click [Direct] on the soft menu to select the view direction.

Click [Flip] on the soft menu to observe by the converse direction of the current direction.

#### **Adjust VOI**

#### ■ VOI On

VR image displays VOI information.

- (1) In image viewing status, click [VOI] as "On".
- (2) Select a desired section plane by clicking [Cur. Win].
- (3) Roll the trackball to adjust VOI position, size and curved VOI, and press <Set> to switch among the adjusting status.

#### ■ VOI Off

VR image displays ROI information.

Click [VOI] as "Off", then the ROI image is displayed on the screen, roll the trackball to observe section images.

#### Accept VOI

This function is usually used for section image observation and to determine the relative position of the section image to the VR.

- (1) Click [Accept VOI] on the soft menu.
- (2) Select a desired section plane by clicking [Cur. Win].
- (3) Roll the trackball to view the current active section image, and the other section images change correspondingly.
- (4) In Accept VOI status, when the 3D image is active or the section image which is perpendicular to the view direction is active, center point of the 3D image displays, and you can adjust the position using the trackball.

## **Image Rendering Parameters**

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

Click [VR/MPR] on the menu to select parameter adjustments of VR or MPR.

- When VR is selected, parameter adjustment is performed on VR image.
- When [MPR is selected, parameter adjustment is performed on MPR image.

Adjustable parameters are as follows:

Parameter	Description		
	Function: to set the threshold for 3D image rendering. 3D image is rendered using the signal between the high and low thresholds.		
Threshold	Range: 0%-100%.		
	Available in Surface render mode only.		
	Function: to set the transparency value for 3D image rendering.		
Opacity	Range: 0%-100%.		
Opacity	The lower the number, the more transparent the gray scale information.		
	Function: to set the smoothness of 3D image.		
Smooth	Selection: 0-20. 0 refers to no smooth effect, 0-20 present 21 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 3D image.		
Brightness	Range: 0%-100%. 0% presents the minimum brightness, while 100% the maximum.		
Contrast	Function: to set the contrast of 3D image.		
Contrast	Range: 0%-100%.		
Tint	Switch on/off tint map, selection: Off, 1-8.		
Quick Rot.	To quickly rotate the 3D image.		
Quick Rot.	Selection: 0°, 90°, 180°, 270°.		
iClear	Enhances B mode image profile for better boundary details.		
iOleai	Range: Off, 1-4.		

#### ■ 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 original beeline.		
Reset All	To reset volume to original orientation and original parameters.		

## Render Mode

Parameter		Description		
		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.		
	Min	Function: set Min as 3D image rendering mode, displays the minimum echo intensity in the observation direction.		
Gray/Inversion		This is helpful for viewing vessels and hollow structures.		
	X-ray	Function: set X-ray as 3D image rendering mode. Displays the average value of all gray values in the ROI.		
		X Ray: used for imaging tissues with different structure inside or tissues with tumor.		
	The above four 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 parame change into the corresponding inverse parameters.				

#### Rotating 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, click [Rot.] on the soft menu, system enters into auto rotation preparation state.
- (2) Click [Direct] to set the auto rotation direction.
- (3) Set Start position and End position:

Start position: roll the trackball to view to a certain position, click [Set Start] to set the start position.

End position: roll the trackball to view to a certain position, click [Set End] to set the end position.

- (4) Set repeat mode: click [Repeat Mode] as "SE/SE" for single direction rotation, and click [Repeat Mode] as "SE/ES" for bidirectional rotation.
- (5) Click [Speed] to set the rotate speed.
- (6) Click [Step] to set the rotate step.
- (7) Click [Auto Rot.] as "Start" to activate rotation.

**NOTE:** You can view the back of the 3D image by rotating it 180°, but the back view image may not as vivid as the front. (Here we call the initial view of the 3D image you see as "front"). It's recommended to re-capture than to rotate the 3D image remarkably if a certain region desired is blocked in the 3D image.

#### **Image Zooming**

To adjust the zoom factor of 3D image; the sectional images will be zoomed in/out accordingly.

#### Operation

Set 3D image window as current window and rotate the <Zoom> knob to increase or decrease the magnification factor.

- Image relationship
  - In "Adjust VOI" status, both the VOI box size and position are fixed. In "Accept VOI" status, roll the trackball, the sectional planes are shifted along with it.

## Sync

This function is to switch the direction of 3D image to the direction that is perpendicular to the current active plane, so as to get a better observation.

As shown in the following, after performs Sync on Figure A, you can see the 3D image and section A from the same direction in Figure B.

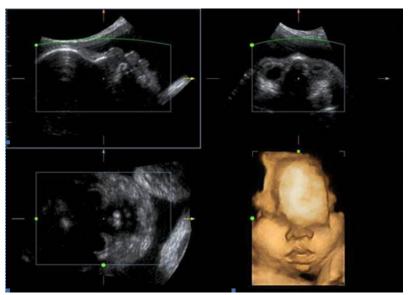


Figure A

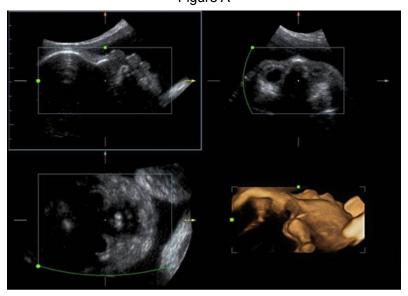


Figure B

## **Comment and Body Mark**

- Function:
  - Add comment and body mark to the sectional planes and 3D image.
- Operation:

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

#### **Image Edit**

#### ■ Function

Image editing is a more elaborate function than VOI adjusting to optimize the 3D by clipping (removing) the part blocked the region of interests.

#### Tips:

- In image edit status, no image parameter can be changed. There displays a cutting cursor ■, and the system enters "Accept VOI" status.
- The editing function is only available on a 3D rendered image.
- Editing of the 3D image does not affect the sectional plane of A, B and C window.

#### ■ Procedures

(1) Enter image editing status by clicking [Edit] on the menu or the left/right direction key on the soft menu.

When entered image editing mode, 3D image is automatically displayed on the screen.

- (2) Select an edit tool.
- (3) Roll the trackball and press the <Set> key to position the start point, roll the trackball to set a region and press the <Set> key again, the selected region will be cut from the 3D rendered image.

If the Inside Contour/Outside Contour/Inside Polygon/Outside Polygon is selected, the region that will be cut is defined when the start point and the end point coincide.

- To undo the last cutting, click [Undo];
- ➤ To undo all cuttings, click [Undo All];

The image cutting parameters are described as follows:

Туре	Parameters	Description		
	CTR. In	Allows you to trace the portion of the image you want to cut. Inside Contour removes all portions of the image that fall inside your traced region.		
	CTR.Out	Allows you to trace the portion of the image you want to cut. Outside Contour removes all portions of the image that fall outside your traced region.		
Edit Typo	Rect. In	Displays a box you can use to define the portion of the image you want to cut. Inside Rect removes all portions of the image that fall inside of the box.		
Edit Type	Rect. Out	Displays a box you can use to define the portion of the image you want to cut. Outside Rect removes all portions of the image that fall outside of the box.		
	Poly. In	Allows you to trace a polygon on the image you want to cut. Inside Polygon removes all portions of the image that fall inside your traced region.		
	Poly. Out	Allows you to trace a polygon on the image you want to cut. Outside Polygon removes all portions of the image that fall outside your traced region.		
Other	Undo	To undo the last cut only.		
Operations	Undo All	To undo all cuts since you entered image edit mode.		

# 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 3D image viewing mode.

## 5.10.4 4D

4D provides continuous, high volume acquisition of 3D images.

Make sure to perform 4D imaging with an appropriate 4D-compatible probe—volume probe. Only if the current probe is an effective one, can the system enters 4D imaging mode. 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 supported by probe D6-2 and D6-2A only.

## 5.10.4.1 Basic Procedures for 4D Imaging

- 1. Select the appropriate 4D-compatible probe and exam mode. Make sure there is sufficient gel on the probe for scanning.
- 2. Obtain a 2D image as described in Static 3D imaging procedure.
- 3. Press <F9> and then select 4D submode to enter 4D imaging preparation status. Define the ROI as well as curved VOI. For details, please refer to "5.10.3.1 Basic Procedures for Static 3D Imaging".
- 4. Select a render mode, set parameters.
- 5. Press <Update> on the control panel to enter the 4D image real-time displaying status.
- 6. Press <Freeze> key on the control panel to freeze the image. Do image cutting, rotation, annotation, image saving if necessary. For the detailed operations, please refer to "5.10.3.3 Static 3D Image Viewing".
- 7. Exit 4D.

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

Or, press <B> 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, the following operations can be performed (for the details, please refer to the corresponding contents in Static 3D.).

- Set [Quality] and [Angle].
- Set the image display format.

- Set 3D image view direction.
- Select sectional image to define the VOI.
- Set the brightness, contrast and tint map for 3D image.
- View sectional plane and 3D image.
- Image rendering setting.
- Save image.
- Other general operations like zooming, comment and body mark.

# **5.10.4.4 4D 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.

## 5.10.5 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 3D image direction is wrong.

When 4D module is configured, please select a non-volume probe to perform Smart3D imaging.

#### 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. Optimize the image as described in Static imaging procedure.
- 3. Press <F9> to enter Smart 3D imaging preparation status, and define the ROI as well as curved VOI.
- 4. Select a render mode, set parameters.
- 5. Press <Update> on the control panel to begin the 3D image acquisition.

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, image editing, for details, please refer to "5.10.3.3 Static 3D Image Viewing".

Exit Smart 3D.

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

# 5.10.5.2 Smart 3D Acquisition Preparation

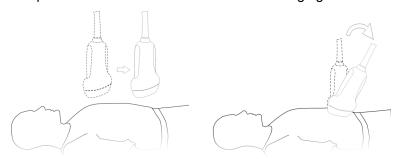
In Smart 3D mode, you may have to set scan method except all other items in Static 3D mode. Other parameters are the same as that of Static 3D, for details; please refer to "5.10.3.2 Static 3D Acquisition Preparation".

#### Method

You can capture images through 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 figure.

#### ■ Parameters description:

Parameter	Description			
	Function: select the image acquisition method.			
	Selection: Rocked, Linear.			
	Linear mode: during the sweep, the probe may not be moved parallel, the			
	speed at which you scan should be constant, about 2cm/s.			
	Rocked mode: in this mode, the probe must be moved to a position where			
Method	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 speed is related to scanning distance or angle.			
Distance	Function: to set the distance the probe covered from one end to the other end during a linear sweep.			
	Range: 10-200mm, in increments of 10mm.			
Anglo	Function: to set the angle the probe covered during a rock sweep.			
Angle	Range: 10-80°, in increments of 2°.			

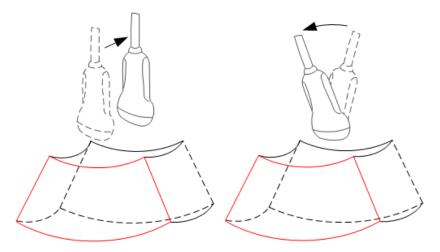
## 5.10.5.3 Smart 3D Image Viewing

In 3D image viewing, the system supports the following functions:

- Render setting.
- B-mode parameters adjustment.
- Set the display format.
- View sectional plane image.
- Image zooming.
- Rotation.
- Image edit.
- 3D image 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).



# 5.10.5.4 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 3D image viewing mode.

# 5.10.6 iPage

iPage is an option, if your system is not configured with this option, [iPage] selection is hidden.

iPage is a new "Visualization" mode for 3D and 4D data sets. The data is presented as slices through the data set, which are parallel to each other.



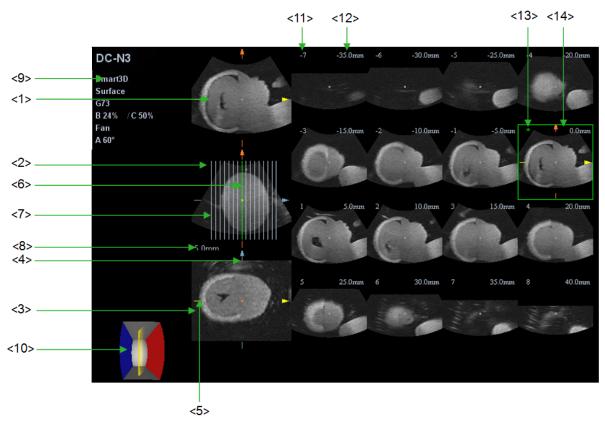
iPage imaging is provided for reference only, not for confirming a diagnosis. Please compare the image with that of other machines, or make diagnosis using none-ultrasound methods.

# 5.10.6.1 iPage Operation Procedure

- 1. Enter into 3D/4D image acquisition mode, acquire one or more 3D image (s) in Static 3D or 4D mode.
  - Single-frame 3D image:
     4D mode: freeze the system in 4D image scanning, roll the trackball to select the interested image.
    - Static 3D: a frame of 3D image is acquired after the acquisition is finished.
  - Multi-frame 3D images: acquire multiple 3D images in 4D imaging mode.
- 2. Perform operations like rotation, VOI adjusting on the image to find the interested region.
- 3. Click iPage on the menu to enter into iPage mode.

- 4. Select the reference image.
- 5. Confirm if the section planes displayed are the target planes, if not, re-select the reference image again.
- Observe the interested structure through multiple slices.
   Select the proper image layout and space according to the size of the target structure.
- Optimize the section plane by the post-process parameters.
   To observe the details or the tiny part of the interested region, do image zooming please.
- 8. Rotate the 3D image to observe the section planes of other orientations. Repeat step 6 if necessary.
  - If the target orientation and region can't be observed even after image rotation and shifting, click [Reset Ori.] to reset the 3D image.
- 9. Do operations like comment to the interested region.
- 10. Save the image.
- 11. Press < Update > to return to 4D imaging preparation status.

# 5.10.6.2 iPage Basic Functions and Operations



iPage Monitor Display Tour

<1>	A plane	<2>	B plane (the current reference image)	<3>	C plane
<4>	Y-axis	<5>	X-axis	<6>	Central section line (Current active section line)
<7>	Section line	<8>	Space between two planes	<9>	Image parameter
<10>	Wire cage	<11>	Section plane order number	<12>	Section plane position (to the central plane)
<13>	Central plane mark	<14>	Green box on the active image		

#### Display format

The system supports four types of displaying layout: 2\*2, 3\*3, 4\*4, 5\*5, click the corresponding selection to select.

#### ■ Reference image

Plane A, Plane B and Plane C are available, select [Ref. Plane] to set the reference image.

- Section plane and section line
  - The section plane is blank if the section plane has no intersection with the volume data.
  - Central section plane: the central section line corresponding plane are the central section plane, which is marked with "\*" in green at the upper left corner of the image.
  - The section line on the reference image can be vertical or horizontal, click [Line Direction] to set the section line as vertical or horizontal.
  - The section lines indicating the positions of the section planes one by one.
  - Active plane: the plane marked with green section line are the active section plane, it is marked with a green box. The default active plane is the central plane.
  - Section plane order number: indicating the order of the section planes, the order
    of central section plane is "0", the section planes before the central plane are
    marked with negative integral numbers, while the section planes after the central
    plane are marked with positive integral numbers.
  - Section plane position (to the central plane): displayed at the upper right corner of each image, indicating the position of each image (such as -10mm, -5mm, 5mm, 10mm).
  - Coordinate axis: indicated on the A, B, C three reference images, match together with the central section line, and will move together with the central section line.

#### Image shifting

Roll the trackball to shift the crossing point of central axis up/down, left/right, the section lines will shift together will the crossing point.

■ Adjust the position of the active image

Click [Adjust Slice] to adjust the spaces between the active image and the adjacent two images in a moderate way.

#### Spacing

The value is displayed at the lower left side of the reference image, unit: mm. Adjust it through [Spacing].

#### Image rotation

Take the selected reference image as X-Y plane, the rotation is the same as that of 3D/4D section plane.

- Image zooming
   Same as 3D/4D image zooming.
- Hide/show reference image

The system displays 3 standard sectional images (A plane, B plane, C plane) in the left side by default to indicate the position of the section lines; you can set [Ref. Img] as "Off" to hide the 3 standard sectional images, and other images are displayed on the whole image area.

Quick switch to single display

Select a certain image, double click <Set> key to enter into single display format, and double click <Set> key again to return to the original display format.

Reset Orientation

Click [Reset Ori.] to reset the orientation and zoom status of the image.

■ Comment

Operations are the same as those in the other modes.

# 5.11 iScape

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 piece 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.

You can perform the iScape panoramic imaging feature on B real time images using all types of probes. The system also provides color iScape function, so that you can get more information from extended images.



iScape panoramic imaging constructs an extended image from individual image frames. The quality of the resulting image is user-dependent and requires operator skill and additional practice to become fully proficient. Therefore, the measurement results can be inaccurate. Exercise caution when you perform measurements in the iScape mode. Smooth even speed will help produce optimal image results.

Color iScape images are provided for reference only, not for confirming a diagnosis.

Tips:

- iScape is an optional module, the function is available only if the module has been installed on the ultrasound system.
- The display of the biopsy guideline is not allowed in iScape mode.

# 5.11.1 Basic Procedures for iScape Imaging

To perform iScape imaging:

- 1. Connect an appropriate iScape-compatible probe. Make sure that there is enough coupling gel along the scan path.
- 2. Press the user-defined key on the control panel to enter iScape:

3. Optimize the B/Power mode image:

In the acquisition preparation status, click [B] (or [Power]) page tab to go for the B (color) mode image optimization.

Tips: in iScape mode, [FOV] is limited to "Off".

4. Image acquisition:

Click [iScape] page tab to enter the iScape acquisition preparation status. Click [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 <Freeze> to return to iScape preparation; or press <B> button to return to B mode.

# 5.11.2 Image Acquisition

#### Shortcut key preset

The system supports shortcut key to enter iScape mode. Assign a key as user-defined iScape key: [Setup]  $\rightarrow$  [System]  $\rightarrow$  [Key Config]. Refer to "12.1.6 Key Configuration" for details.

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 click [Start Capture] in the soft menu 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] in the soft menu; or,
- Press the <Update> key; or,
- Press <Freeze> 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:

- ROI: a 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 Setting

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

- Image size
  - Click [Actual Size] to display the image in its actual size.
  - Click [Fit Size] to display the image in an appropriate size according to the current window. Also this is the system default format.
- Tint map
  - Click [Tint Map] to activate the colorize function and change the effect.
- Ruler
  - Click [Ruler] to turn on or off the ruler display on the image.

#### 5.11.3.2 Image Zooming

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

- Rotate the knob clockwise to zoom in the image.
- Rotate the knob anticlockwise to zoom out the image.
- Roll the trackball to change position of the magnified image.
- Press the <Zoom> knob 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 clicking [Rotation] in the soft menu.

## 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:** iS

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] in the soft menu in panoramic image viewing status to enter cine reviewing mode.

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, click [Auto Play] in the soft menu; 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; click [Set First Frame] to set the start point. Review to another image; click [Set End Frame] 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 in the soft menu 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.

# 6 Display & Cine Review

# 6.1 Image Display

# 6.1.1 Splitting Display

The system supports dual-split and quad-split display format. However, only one window is active at one time.

- Dual-split: press <Dual> key on the control panel to enter the dual-split mode, and using <Dual> key to switch between the two images; press <B> on the control panel to exit.
- Quad-split: press user-defined <Quad> key on the control panel to enter the dual-split mode, and using user-defined <Quad> key to switch between the two images; press <B> on the control panel to exit.

For the detailed display format, please refer to the content of each imaging mode chapter.

# 6.1.2 Image Magnification

The system supports three magnifications: spot, pan and iZoom, which can be realized by different operations through the related keys.

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.

# 6.1.3 Spot

#### Procedures:

- 1. In image scanning mode, press <Zoom> knob to enter the sample volume definition status.
- 2. Define the sample volume: roll the trackball to change the box size and position, press <Set> to toggle between setting the size and position. And after sample volume is set, press <Zoom> knob again to enter spot zoom status.
  - Here, the sampled image is displayed, and meanwhile, image-in-image is displayed.
- 3. Rotate the <Zoom> knob to adjust the magnification factor. The system provides a zoom range of 0.8-10. Roll the trackball to move the magnified image.
- 4. Exit: in spot zooming status, press <Zoom> knob again or press <Esc> to exit image magnification.

#### Tips:

- Spot zooming only can be realized on a scanning image.
- The size and position of sample volume box will be changed along with scanning depth and area.

## 6.1.4 Pan

#### Procedures:

- 1. Rotate <Zoom> knob to directly enter the pan zooming status. Image-in-image is displayed.
- 2. Rotate the <Zoom> knob to change the magnification factor. The system provides a zoom range of 0.8-10.
- 3. Exit pan zooming: press <Zoom> knob.

# 6.1.5 iZoom (Full-screen Zooming)

- Function: to magnify the image in full screen.
  - According to the region to be zoomed, the system supports two types of full-screen zooming:
  - The first type is to zoom in the standard area, including image area, parameter area, image banner, thumbnail area and so on.
  - The second type is to zoom in the image area only.
- Manner:
  - (1) Open the image (or the under scanning image), press the <F8 >iZoom key once to zoom in image in the way of the first type, and then press the key again to zoom in the image in the way of the second type.
  - (2) Press <F8 > again to return to normal status.

# 6.1.6 Freeze/ Unfreeze the Image

Press <Freeze> on the control panel to freeze a scanning image. In freeze 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 Preset]  $\rightarrow$  [Image Preset]  $\rightarrow$  "Freeze Config")

Press <Freeze> in freeze mode to unfreeze the image, the system continues image scanning.

# 6.1.6.1 Imaging Mode Switching When Frozen

Imaging mode switching in freeze mode follows the following principles:

- In splitting display B mode, press <B> to exit splitting display mode and display the image of the currently activated window in full screen.
- In freeze mode, the system supports imaging mode switching between the submodes (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.

## 6.1.6.2 Imaging Display Format Switching When Frozen

Image display format switching in freeze mode follows the following principles:

- 2D+M/PW (Press <Freeze> in 2D+M/PW scanning mode)

  If the imaging mode before frozen is 2D (frozen) +M/PW (real time) or 2D (real time) +M/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 enters freeze 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> or user defined Quad key to switch between dual-splitting and quad-splitting modes.
  - Press <B> button on the control panel to enter the single display format, which
    displays the currently activated window. In single display format, press <Dual> or
    user defined Quad key to switch between dual-splitting and quad-splitting 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.

# 6.2 Cine Review

After you press <Freeze>, the system allows you to review and edit the images prior to the image frozen. This function is known as cine review. The magnified images can also be reviewed after <Freeze> is pressed, and the operating method is the same. You can perform post process operations, measurements, comments adding and body marks on the images being reviewed.

The system supports manual review as well as automatic review. The default mode 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.

# **△**CAUTION:

- Cine Review images can be inadvertently combined inbetween separate patient scans. The cine memory must be cleared at the end of the current patient and the onset of the next new patient by selecting the <End Exam> key on the control panel.
- 2. Cine files stored in the system's hard drive shall contain patient information, to avoid the selection of an incorrect image file and potential misdiagnosis.

# 6.2.1 Entering/ Exiting Cine Review

- To enter cine review:
  - Enter "[Setup] → [System Preset] → [Image Preset]" and set "Status after Freeze" to be "Cine". Press <Freeze> to freeze the image and enter the cine status, the <Cine> key indicator lights on automatically.
  - Open cine files in thumbnail, iStation or Review, the system enters automatic cine review status.

- To exit cine review:
  - Press <Freeze> key again, the system will return to image scanning and exit cine review.

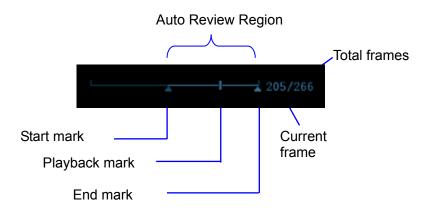
## 6.2.2 Cine Review in 2D Mode

#### Manual cine review

After entering the cine review of 2D mode, rolling the trackball or rotating the multifunctional knob will display the cine images on the screen one by one.

If you roll the trackball to the left, the review sequence is reversed to the imagestoring sequence, thus the images are displayed in descending order. Whereas, if you roll the trackball to the right, the review sequence is the same as the imagestoring sequence, thus the images are displayed in ascending order. When the reviewing image reaches 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, click [Auto Play] in the soft menu to activate auto cine review.
  - b) Reviewing speed: In the auto cine review status, click [Auto Play] in the soft menu to adjust the review speed.
  - c) In auto review status, Click [Auto Play], or roll the trackball to enter manual review.

#### Setting Region of Auto Review

You can set a segment of cine loop which can be reviewed automatically. After the auto review region is set, the auto cine review can only be performed within this region; but the manual cine review can be performed beyond this region. When the cine file is saved, only the images within this region are saved.

- a) Set first frame: Manually review the images until the frame which you want to set it as start point, and then click [Set First Frame] to set it as the start point.
- b) Set end frame: Manually review the images until the frame which you want to set it as end point, and then click [Set End Frame] to set it as the end point.
- Click [Auto Play] again or roll the trackball to enter manual review status; or press <Cine> to exit cine reviewing.

- d) Click [Skip to First]/ [Skip to Last] to review the first or last image.
- e) Click [Save Cine] in the soft menu to save the cine images of the set region.

Tips: you can perform cine review on each image window in the dual/ quad splitting mode.

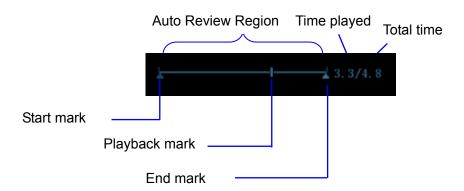
You can also press <Menu> to see the menu, and use the corresponding items to do the above settings.

## 6.2.3 Cine Review in M or D Mode

Enter cine review in M or D mode, and then roll the trackball or rotating the multifunctional knob, the cine images are displayed on the screen one by one.

Roll the trackball to the 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 to the 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.

## 6.2.4 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
- PW+B duplex mode
- PW+C+B 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.

# 6.3 Image Compare

# 6.3.1 Cine Compare

1. Press <Review> to enter Review screen, press <Ctrl>+<Set> to select files to be compared.

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.

- 2. Click [Compare] to enter image compare mode.
- 3. Review the images of different image windows (cine replaying can't be performed for single-frame image file), press <Dual> or <Quad> key to switch the active image window.

The window with the highlighted "M" mark is the current activated window.

Press < Cursor > and double click the image in the thumbnail area on the right side of the screen to change the current active window

- 4. Save the image if it is necessary.
- 5. Click [Return] on the screen or press <Freeze> to exit image compare.

Image compare of different exams for the same patient:

- (1) Select different exams in iStation screen, select [Review] in the popped up menu to enter Review screen.
- (2) In Review screen, click [History] to select the exam; click to select the image to be compared in different exams, and click [Image Compare].

# 6.3.2 Frame Compare

1. Freeze the image in B/C mode, click [Frame Compare] to be "On" to enter the windows of different frames. Besides, you can double click the cine file in the thumbnail area to go for same cine different images compare.

The two windows display the same image when initially enter into image compare.

- 2. Roll the trackball or rotate the multifunctional knob to review the images; switch the window by pressing <Update>.
- 3. Adjust the image parameters or do other operations (like image zoom in/zoom out, image saving, comment) if necessary.
- 4. Click [Frame Compare] again to return to freeze mode; press <Freeze> or click [Return] to go to image scanning.

Tips: image compare only can be performed on single-format B/C mode images only.

# 6.4 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.

To perform live capture:

• In scanning mode, press the <Save> key on the control panel (The key has already been assigned the function as "Save Clip (Prospective) to hard disk" or "Save Clip (Retrospective) to hard disk").

#### Tips:

- In retrospective saving, if any parameter is modified during saving, the changes will not be saved to the cine. While in prospective saving, any parameter modification before the saving finished can be saved into the cine.
- 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, press the <Save> key on the control panel (The key has already been assigned the function as "Save Clip (Retrospective) to hard disk").

After the cine is successfully saved, there is a thumbnail displayed on the screen.

The live capture time can be set.

# 6.5 Cine Memory

# 6.5.1 Cine Memory Setting

There are 2 ways of cine memory split: auto and split.

Setting path: select "Auto" or "Split" for cine memory in [Setup]  $\rightarrow$  [System Preset]  $\rightarrow$  [Image Preset].

#### Where.

- "Auto" for the cine memory indicates the system splits the cine memory as per the number of B image windows.
- "Split" indicates the system always splits the cine memory, even if in the single-B
  window, the system splits the cine memory into two as well. You can press <B>
  key to switch and display the images in either memory, so you can compare
  images in Split mode.

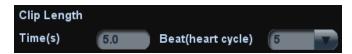
The memory capacity is evenly distributed as per splitting number, as shown in the following table (Taking B images in low density as an example, the capacity of B cine memory is N frames):

Imaging Mode	Single-B/ Color	Dual	Quad	
Split				
Auto	One memory, with capacity N frames.	The memory splits into two, with capacity N/2 frames each	The memory splits into four, with capacity N/4 frames each	
Split	The memory splits into two, with capacity N/2 frames each	The memory splits into two, with capacity N/2 frames each	The memory splits into four, with capacity N/4 frames each	

# 6.6 Cine Settings

You can set the cine length via "[Setup]  $\rightarrow$  [System Preset]  $\rightarrow$  [General]". The items are shown as follows:

■ Non-live storage (the items are shown as follows)



- For Time without ECG(s), 1~60s.
- For Time (with ECG Loop): the unit is Beat, 1~16.
- Live capture (the setting items are shown as follows)
  - Type: Retrospective, Prospective.
  - Cine length:



# 7 ECG

The system can be configured with the optional physio module. In that case, the ECG signal is displayed on the image, and can be reviewed simultaneously with the image.

- When the system is connected with the ECG module:
  - The Physio menu is available.
  - The ECG icon including heart-shaped symbol and heart rate symbol are displayed on the screen.
- The system supports ECG signal from ECG lead or external ECG signal devices.
  - Use DC-IN to connect to the external ECG signal devices.

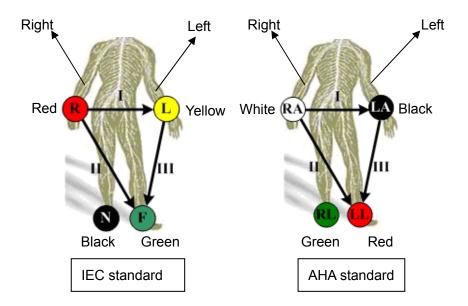
# **⚠WARNING**:

- 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 ECG 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.

**NOTE:** When abnormality is detected, please check if ECG leads are properly connected with the system.

# 7.1 ECG Operation Basic Procedures

- 1. Connect the ECG device.
  - Turn off the power supply of the system, and connect the ECG cable to the port in the system (For connection, please refer to "2.9 Physiological-signal Panel")
  - Turn on the power supply of the system
  - Place the ECG electrodes on the patient's body (as shown in the following figure)



- 2. Press ECG user-defined key (set in "[Setup] → [System Preset] →[Key Config]") to enter physio operation status.
- 3. Select [ECG] to be "On", and the heart-shaped symbol appears on the upper right part of the screen.
- 4. Switch the imaging modes and display formats, and adjust relevant parameters to optimize the image.
- Parameter adjustment:
   On the Physio page, you can adjust [Speed], [ECG Gain], [ECG Pos].
- 6. Freeze the images and review them. For details, please refer to "7.3 ECG Review"
- 7. Exit ECG mode, and remove ECG electrodes from the patient.

  In ECG mode, set [ECG] to be "Off", the ECG waveform disappears and the system exits ECG mode.

# 7.2 Parameter Description

Parameter	Description
ECG	Function: to control the display of ECG trace in live status.
	Value: On/Off, On is to display the trace, while Off is to hide the trace.
	In scanning mode, turn off ECG display will stop ECG signal acquisition.
	In freeze mode, this is used to show or hide the ECG trace.

Parameter	Description
ECG Source	Select ECG source.
	Function: to set the amplitude of ECG trace.
ECG Gain	Method: click [Gain] in the soft menu or menu.
	Value: 0-30, in increments of 1.
	Function: to set the vertical position of the ECG trace on the image display.
ECG Position	Method: click [ECG Pos] in the soft menu or menu.
1 00111011	Value: 0%-100%, in increments of 5%.
	Function: change the speed of the physio trace.
Speed	Value: 1-6
	The refresh speed of the physio signal on B image is independent from the refresh speed of timeline refresh speed (M mode, PW and CW mode)

# 7.3 ECG Review

When an image is frozen, the ECG waveform will be frozen at the same time. When images are reviewed with the ECG electrodes connected, the ECG waveform is the reference for time.

After the images are frozen, all real time images are in the status of linked review.

The frame position marker indicates the time relationship between the currently reviewed 2D image and the ECG trace or M/D image.

# **8** 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].

# **<b>△**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:

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

# 8.1 Basic Operations

- To enter/ exit measurement
  - Press <Caliper> to enter general measurement.
  - Press <Measure> key to enter application measurement.
  - Press <Caliper> or <Measure> again or <Esc> to exit.
- Measurement result and help information
  - The system displays and updates measurement results in the result window.
  - The help information concerning measurement and calculation is displayed in the Help Information area at the bottom of the screen.

# 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 Tools	Function	
Distance	Measures the distance between two points of interest.	
Depth	The distance between probe surface and the probing point along ultrasound beam.	
Angle	The angle between two intersected planes.	
Area	Measures the area and perimeter of a closed region.	
Volume	The volume of a target.	
Cross	The length of two line segments, which are perpendicular to each other.	
Parallel	The distance between each pair of parallel lines in a sequence.	
Trace Length	Measures the length of a curve on the image.	
Double Dist	Measures the length of two line segments, which are perpendicular to each other.	
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	The grayscale distribution of ultrasonic echo signals in a closed region.	
B profile	The grayscale distribution of ultrasonic echo signals across a line.	
Color Velocity	Color flow velocity (only valid for Color mode).	
Volume Flow	Blood flow through some vascular cross section per unit time.	
IMT	Measures the distance between LI (Lumen-Intima) and MA (Media-Adventia).	
Volume	Measures the volume of the target object.	

# 8.2.2 M General Measurements

M general measurements refer to general measurements on M mode, Color M mode, Free Xros M mode images. The measurements listed below can be performed:

Measurement Tools	Function	
Distance	The vertical distance between two points.	
Time	The time interval between any two points.	

Measurement Tools	Function	
Slope	Measures the distance and time between two points and calculates the slope.	
HR	Measures the time of n (n $\leq$ 8) cardiac cycles and calculates the heart rate in M 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 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).	
D Velocity	On the Doppler mode image, measure velocity, PG (pressure gradient) and spectrum correction angle of a point on the Doppler spectrum waveform and etc.	
Acceleration	Measure the velocities of two points and their time interval on the Doppler image, and calculates the acceleration, pressure gradient, velocity difference and correction angle.	
D Trace	On the PW mode image, one or several Doppler waveforms are traced to obtain speed and PG, etc.	
PS/ED	Measure the Peak Systolic (PS) velocity and End Diastolic (ED) velocity on the Doppler spectrum, and calculates resistance index (RI), S/D and correction angle.	
Vas Area	Measures the area of the vascular section of the blood flow.	

# 8.3 Application Measurement

The system can be configured with the following application measurement packages corresponding to the application packages:

- 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%.
Volume	Full screen	Within ±10 %

Table 2 iScape Measurements

Parameter	Probe Type	Error
Distance	Linear and convex-wide probe	Within ±5%
	Micro convex probe	Within ±10%

Table 3 Time/Motion Measurements

Parameter	Value Range	Error
Distance	Full screen	Within ±3 %.
Time	Timeline Display	Within ±2%.
Heart rate	Timeline Display	Within ±4%.
Velocity (PW mode)	L14-6 and L14-6N probe: 10-150cm/s;	When angle≤60°, ≤5%.
	Other probes: 10- 200cm/s	
Velocity (CW mode)	10-200cm/s	When angle≤60°, ≤5%.

Table 4 Doppler Velocity Measurements

Parameter	Value Range
Velocity (PW mode)	Min.≤2cm/s, Max.≥435cm/s
Velocity (CW mode)	Min.≤2cm/s, Max.≥28m/s
Velocity (Color mode)	Min.≤2cm/s, Max≥200cm/s

**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 (Annotations)

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.

**⚠WARNING**:

You must ensure that the entered comments are correct.

Incorrect comments may cause misdiagnosis!

### 9.1.1 To Add Comments

- 1. To enter comment status:
  - Press the <Text> key, and the cursor becomes "|".
  - Press any alphanumeric key, and the corresponding letter or numeral is displayed besides the cursor.
  - Press the <F12> (Arrow) key to enter the arrow-adding status.

Tips: when the system entered comment status, the default characters entered are uppercase. You can see the <Caps Lock> indicator lights on.

- 2. Place the cursor to the desired place to set the comment location. Add new comment to the image according to actual situation. Here, you can modify, move, delete, hide or display the completed comments.
- 3. To exit comment status:
  - In the comment status, press <Text> key.
  - Or press <Esc> or other operating mode keys, such as <Measure> key.
  - In the arrow-adding status, press the <F12> (Arrow) key.

### 9.1.2 Comment Menu

You can adjust relevant settings in comment status via menu or the soft menu.

- Display or hide the soft menu
  - After entering the comment status, pressing the <Menu> key or the multifunctional knob will show or hide the Comment Text Library menu.
- Home of comments

Move the cursor to the desired location for a comment and press <Home>. The current position of the cursor is set to be the default position of the comment adding. When press <Home>, the cursor will return to the default setting position.

- Change Font Size/Arrow Size
  - Click [Font Size] to change the font size of comment: Small, Mid, Big.
  - Click [Arrow Size] to change the arrow size of comment: Small, Mid, Big.
- Navigating through comment libraries
  - Press <Menu> to show the comment menu, and select the menu title to change the comment library (the available ones are those customized libraries for all the exams assigned to the current probe). See the screen below:



Click [Library] on the soft menu to change among comment text libraries (the
available ones are those customized libraries for all the exams assigned to the
current probe). The default is the customized comment text library in the current
exam mode.

When entered the comment status, the system displays the customized comment text library for the current exam. If there is no customized comment text library for the current exam, it will display the comment text libraries of all the exam modes assigned for the current probe. And if no text library for all the exam modes is customized, no comment text will be displayed.

- ABC Display
  - Click [ABC Display] as "On" to display or hide the added comments. Assign the user-defined key for the function in "[Setup]  $\rightarrow$  [System Preset]  $\rightarrow$  [Key Config]".
- Set comment language
  - Click [English] to turn on or off the English comments. If "English" is turned on, the comments will display in English; if turn off, the comments will display in the language you set.

If the current language is English, this selection is not available.

# 9.1.3 Adding Comments

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 EM (Emergency).

- Typing comment characters
  - (1) To set the comment location:
    - Roll the trackball or press directional keys on the control panel to move the cursor to the desired location for comments.
  - (2) To type the alphanumeric characters:

- > Type the alphanumeric characters through the qwerty (The default characters are uppercase).
- ➤ To type the upper characters, press <Shift> on the control panel and the character key at the same time.
- (3) Move to a new line:

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.

(4) In the edit status, move the trackball or press the multifunctional knob to confirm the character added, and the color of the character added turns yellow.

### Adding a comment text

Move the cursor onto the desired comment text in the menu and press <Set> or the multifunctional knob, and then the system adds the selected comment text on the set location. The added comment text is in the edit status, so you can edit the comment text added.

- Add combined comment
  - a) Press <Menu> or the multifunctional knob to show the menu.
  - b) Rotate the multifunctional knob to view the comments one by one
  - c) Press the knob again to add the selected item onto the image (comment added in an editable state)
  - d) Rotate the multifunctional knob to search for the next part, and press the knob again to add the second part of the combined comment.
  - e) Repeat procedures to add other parts of a combined comment.
  - f) Press <Set> to complete the comment.

### Adding an arrow

You can add an arrow to a location where you want to pay attention.

- (1) Press <F12> (Arrow) key, and an arrow will appear at the default position.
- (2) Adjust the arrow
  - ➤ Adjust the position and orientation of the arrow: roll the trackball to the desired position and use the multifunctional knob to change the orientation in 15° increments.
  - > Click the [Arrow Size] item on the soft menu to change the arrow size.
- (3) Press <Set> or <Enter> to anchor the arrow position, and then the arrow turns yellow.
- (4) Repeat the above steps to add more arrows if necessary.
- (5) Press <F12> (Arrow) key, <Esc> or to exit the arrow comment status.

# 9.1.4 Moving Comments

- 1. Move the cursor onto the comment that needs to be moved. Press <Set> to select it, and a highlighted box appears around the comment.
- 2. Roll the trackball to move the comment to the new position.
- 3. Press the <Set> key to anchor the comment in the new position, and the comment-moving operation is complete.

# 9.1.5 Modifying (Editing) Comments

- Modifying (Editing) characters
  - (1) In the comment status, move the cursor onto the comment that needs to be modified:
    - > Directly enter the character at the position that the cursor stays; or,
    - ➤ Double press the <Set> key to enter the edit status, use the to move the cursor to a location where needs to insert characters, and type characters.
  - (2) Press the <Del> key to delete the comment character or text on the right side of the cursor; Press the <Backspace> key to delete the comment character or text on the left side of the cursor.
  - (3) Roll the trackball or press the <Set> key or the multifunctional knob to confirm the modification and to exit the edit status, and the color of the comments turns yellow.
- Modifying (Editing) Arrows
  - (1) Move the cursor on the arrow that needs to be modified. After the cursor turns to press the <Set> key. The color of the current arrow turns green, and there is green frame around the arrow, indicating the arrow can be edited. Move the cursor to change the arrow position.
  - (2) Rotate the multifunctional knob to modify the arrow direction.
  - (3) Press the <Set> key or the <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 <Del> key to delete the selected comment.

Or,

- (1) Move the cursor to the comment to be deleted.
- (2) Press <Clear> to delete the selected comment.
- Deleting a recently-added character, text or arrow
   If no comment is selected, press <Clear> to delete the recently-added comment.
- Delete all comments (characters, texts or arrows)
   Press the <Clear> to delete all the comments.

**NOTE:** 1. When no object is selected, pressing the <Clear> key will clear all comments and all measurements calipers.

After powering off, the system will clear all comments on the image.

# 9.2 Body Marks (Pictograms)

The Body Mark (Pictogram) feature is used for indicating the exam position of the patient as well as probe position and orientation. The system can be configured with body mark

libraries including Abdomen, Cardiology, GYN (Gynecology), OB (Obstetrics), Urology, SMP (Small Part), Vascular, EM (Emergency) and Nerve.

# 9.2.1 Soft Menu for Body Marks

The body mark soft menu displays the settings for the current mode:

- Library
  - Click [Library] to switch the body mark library, the corresponding body marks are shown at the left of image.
- Display
  - Set [Display] to be "On" or "Off" to turn on or off the body mark display.
- Page-turning

If there is more than one page of the body marks, click the up/down arrow on the menu to turn pages.

# 9.2.2 Adding Body Marks

- 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 <Body Mark> knob
     Rotate the knob to view the body mark one by one, and press the knob to add the body mark.
- 3. To adjust the probe position and orientation marker:
  - Roll the trackball to place the probe marker at the correct position.
  - Rotate the <Body Mark > knob to adjust the orientation.
- 4. Press the <Body Mark> knob or the <Set> key to confirm the position and orientation of the probe marker and exit the body mark mode.

# 9.2.3 Moving Body Marks

You can move the body mark graphics to any desired position within the image area.

- 1. Roll the trackball to move the cursor onto the body mark. The cursor changes into indicating you can move the pictogram to a new position.
- 2. Press <Set> key to select the body mark, and a frame will appear around the graphics.
- 3. Roll the trackball to move the body mark 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.

# 9.2.4 Deleting Body Marks

- To delete a 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:** In the Body Mark mode, if no object is selected, pressing the [Clear] key will clear all comments, body marks and general measurements from the screen.

### Tips:

 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
- Reports

### 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.
- 2. The system patient database space is limited, please back up or clear patient data in time.
- 3. 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 "4.2.1 New Patient Information"

After completion of patient information entry, click [OK] to save the patient information to the patient data.

# 10.1.2 Patient Information Setting

Open "[Setup]  $\rightarrow$  [System Preset]  $\rightarrow$  [General]", and then set the following in the Patient Info area. Here, you can select if to display patient gender, age or operator in the screen; set the H&W applied unit and select the using surface formula.

- Image banner patient information displaying
- H&W Unit
- Surface formula setting



# 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
- CD-R/RW, DVD±RW

# 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-fran

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.

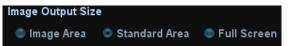
- PC-compatible formats:
  - Screen file (BMP)
     Single-frame file format, used to save the current screen, non-compressed format.
  - Screen file (JPG)
     Single-frame file format, used to save the current screen in the compressed format; you can set the compression ratio.
  - TIFF: Single-frame export format

- Multi-medium files (AVI)
   Multi-frame file format, general cine file format.
- DICOM files (DCM)
   DICOM standard files format, single-frame or multi-frame format, used to record patient information and images.

# 10.2.3 Image Storage Preset

Set image size

You can set the image size via "[Setup] →[System Preset] → [General]". The items are shown as follows:



Set cine saving length

For details, please refer to "6.2 Cine Review".

Storage image/clip linked operation

You can set to send image/clip to other media when you save/clip to hard disk (10.2.4 Saving Images to the System), the setting path is: [Setup]  $\rightarrow$  [System Preset]  $\rightarrow$  [General]  $\rightarrow$  "Image/clip storage"

- Image can be sent to: local default printer, DICOM storage, DICOM printer.
- Clip can be sent to DICOM storage.

# 10.2.4 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 Preset]→ [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, press the user-defined key to save the current single-frame image, and the image is saved with the default filename in the default file directory in the FRM 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.
  - When a dialog box is displayed on the current screen, press the user-defined key to save the screen in the BMP format.
- To save cineloop image to the system guickly:
  - (1) Set the user-defined key through the path: [Setup]→ [System Preset]→ [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 Preset]→[General].

# 10.2.5 Quickly Saving Full Screen Image to the System

- Set the user-defined key through the path: [Setup]→ [System Preset]→ [Key Config]. Select a key in the Key Function field on the left side and select "Save Full Screen 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, press the user-defined shortcut key to save the current screen image, and the image is saved with the default filename in the default file directory in the FRM 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.
  - When a dialog box is displayed on the current screen, press the user-defined key to save the screen in the BMP format.

### 10.2.6 Thumbnails

The stored images or cineloops are displayed in the form of thumbnails on the screen:

- In the iStation screen, the thumbnails refer to the images stored for the selected exam or the selected patient.
- In the scanning or freeze mode, the thumbnails refer to the images stored in the current exam. You can click or when there are more than one page.
- In the Review screen, the thumbnails refer to the images stored in the same exam.
- In the Review screen, open an image to enter the image analyzing status, all the thumbnails belong to the exam are displayed.
- When you move the cursor onto a thumbnail, its name and format will be displayed.

# 10.2.7 Image Review and Analysis

You can review and analyze the stored images (only refer to the images stored in the system default path).

### 10.2.7.1 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. Rotating the Multifunctional knob <Nav.> will navigate through thumbnails.

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, MedSight and etc. Or, select the image and click the icon on the upper left of the image.

[Delete]: click to delete the selected image.

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.

### 10.2.7.2 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, change image display format 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".

### 10.2.8 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:
  - Move the cursor onto [iVision] in the Other menu, and press <Set>.
  - Press the user-defined key (setting path: [Setup]→[System Preset]→[Key Config]→[Other]).
- 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 (D:\PatientData) or system supported image files and folders to demonstration item list. For files and folders in demonstration list, the images in the directory and subdirectory are played one by one, and the system will automatically jump over the files that can't be opened.

### Demonstration item

There are two kinds of catalogs: Demo Catalog and Customize Catalog.

 Demo Catalog: demo catalog is the folder in hard disk (E disc), where the factory DEMO is stored. The system plays the images in this folder when performs demonstration.

The system supports import, delete or clear the data in demo catalog.

Click [Demo Manager] to operate:

To import data to demo catalog.

: To delete the selected data.

: To delete all data.

 Customize Catalog: what saved here is the catalog of the displayed image. The system plays the images in the catalog when performs demonstration.

Operate the catalog by the buttons on the right:

[Add File]: to add files to the file list.

[Add Catalog]: to add catalog to the file list.

[Delete]: to delete the selected file or catalog in the file list.

[Clear]: to clear all the files or catalogs in the file list.

Select or deselect the directory/file by checking or un-checking the check box before the file list, only the selected directories/files will be replayed.

Demo mode

The system automatically plays all the image files in the list one by one. The time intervals between images played can be changed through the drop-down list of "Interval".

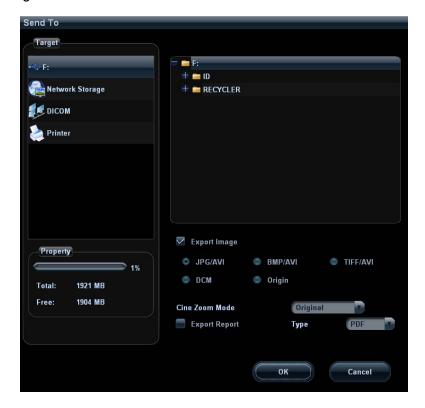
Option of Demo

You can choose whether to repeat the demonstration or exit after a demonstration is completed.

# 10.2.9 Sending Image File

- On the image screen, select a stored image thumbnail (press <Shift> to select more than one at the same time), click (Send To) on the lower right corner of the screen, the image can be sent to the external devices.
- In the iStation or Review screen, click [Send To] to send the selected image to the external devices.

See the figure below.



- For external memory devices (e.g. USB memory devices, DVD-RW or network storage server):
  - 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) You can also select to export report format.
  - d) Select the cine zoom mode.
- For DICOM Storage or Print 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.

 For MedSight devices, single-frame image will be saved in PNG format, and multi-frame image will be saved in 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

In the iStation screen, select patient data, click [Restore] or [Backup] to import or export patient information, images and reports from or to an external memory device or network storage server.

You can also select whether to remove local patient exams data or only images after backup.

See the following figure:



In the iStation or Review screen, click [Send To] to send patient data to an external memory device or network storage server, you can choose if reports are exported with images. See the figure below.



- To export the report
  - (1) Check "Export Report" on the screen, and select the exported format, RTF or PDF
  - (2) Click [OK] to confirm.
    You can select paper size for the report in the path: [Setup] → [Print Preset] → [Print Service].
- Printing report

Use a connected graph/text printer to print a report.

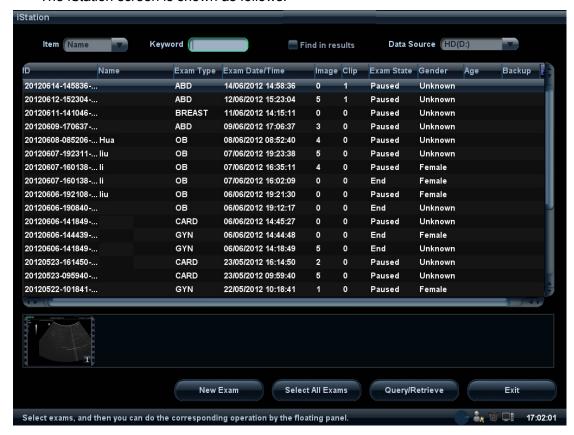
For details on report relevant operations, please refer to [Advanced Volume].

# 10.4 Patient Data Management (iStation)

The patient data include basic patient information, exam information, image files and reports. You can search, view, backup, send, restore or delete patient data in iStation.

- To Enter iStation
  - Press <iStation> key on the control panel; or
  - Click [iStation] in the Patient Info screen; or
  - Click [iStation] in the Review screen.

The iStation screen is shown as follows:



# 10.4.1 Viewing Patient Information

■ Data Source

Select the data source of patient data, 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 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 systemsupported media.
  - You can select whether to remove images or the whole exam record from the system.
- [Restore Exam]: click to import the patient data from an external media.

### Send Exam

The system supports to send data to external memory devices or print.

- 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: adjust the cine zoom mode, compression mode and JPEG compression size.
  - MedSight: send the exam to MedSight devices for review.
  - Press <Control> or <Shift> with <Set> key on the control panel to select more than one exam or image at one time.

### Export teaching file

Select the patient record, click [Export Teaching Files] in the menu to export exam data or images of the selected record.

- You can select to transfer image format.
- Select Patient Info to be "Default Info", the system deletes the patient name automatically of the exported file.
- Select Patient Info to be "Custom Info" and you can rename the patient name to keep the patient information safe.

### 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 (time lasts from deleting to system is powered off). The system supports recovery of those data from the recycle binate recycle bin will be cleared after the system is powered off.

To recover the deleted patient data, click at the lower right corner of the screen (when the button is gray, the operation is unavailable) to enter the Patient Recycle Bin screen.

- (1) Select items to be recovered in the list. 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.
- (2) Click [Exit] to exit Recycle Bin screen.

# **10.5** Print

# 10.5.1 **Setting**

- Print Service Setting
  - (1) Open the [Setup]→ [Print Preset], select an existed printer service in the list.
  - (2) Select the printer type in the Property box.
  - (3) Set printing properties.
  - (4) Click [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 should:

- (1) Press the [Setup] key to show the Setup menu, click [System Preset] item to open the [System Preset] screen, and click [Key Config] tab.
- (2) Click to select [Print] in the left side. Click to select desired print method in 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] →[System Preset]→[General], then select the image output mode.

Open [Setup] →[System Preset]→[General], then select the image storage size.

# 10.5.2 Image Print

Image printing is mainly performed by video printer, and for DICOM image printing, refer to DICOM chapter.

- 1. Select the desired image in iStation or Review screen.
- 2. Click → icon on the upper right side of the image, and select the printer in the popped up dialogue box.
- 3. Click [OK] to start printing.

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

# 10.5.3 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.

# 10.6 Backup and Erase Files through DVD Drive

The system supports CD-R/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: CD-R/RW, 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 as



- (4) After the writing process is completed, click to pop up the Disc Option dialogue box, and select [Eject] to eject the CD/DVD.
- To erase data from a CD/DVD
  - (1) Put the CD/DVD in the tray.
  - (2) Double-click the symbol to pop up the Disc Option screen.
  - (3) Click [Erase] to erase data from a CD/DVD;
  - (4) After the erasing process is completed, click [Eject] in the Disc Option dialogue box.

### Tips:

- Writing data using "Send To" supports PC format transfer function, while CD/DVD written by "Backup" supports only system-relevant formats.
- The symbol indicates that the input CD/DVD is damaged or with data of wrong format.

You can check the data writing procedure in patient task manager, for details, please refer to "10.7 Patient Task Management".



During the backup process, if a CD/DVD is forcibly taken out or if you perform other operations, the backup process will fail or the system may malfunction.

# 10.7 Patient Task Management

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].
  - 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.
- 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 you can click the icon to check the process.



When there is/are task(s) failed, the task management icon displays as can click the icon to check the failure reason.

or failure.

When the task management icon displays as , it means no task is undergoing

**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.

# 10.8 Administration

# 10.8.1 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 cann't view the exam data operated by others.

# 10.8.2 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]→[System Preset]→[Admin].
- 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.

# 10.8.3 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 corner of the screen to pop up the following dialogue box:



- (2) Click [Change User] to pop up the Login dialogue box.
- (3) Enter the user name and password in the field box.

NOTE: You have to exit the Preset screen before changing the user.

- 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.

### 10.8.4 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 Preset]→[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]→[System Preset]→[Admin].
- 2. Select the user to be deleted in the User List, click [Delete] to delete the selected user.

# 10.8.5 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 Preset]→[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

**NOTE:** Before using DICOM, please read the electronic file DICOM CONFORMANCE STATEMENT along with the device.

This chapter is confined to the preset, connection verification and DICOM services of the DICOM-configured ultrasound machine, not including SCP configurations like PACS/ RIS/ HIS.

The DICOM package is optional, so the description here is only applicable for the system configured with the DICOM package.

This system supports the following DICOM functions:

- Verify Connectivity
- DICOM Storage
- DICOM Print
- DICOM Worklist
- MPPS (Modality Performed Procedure Step)
- Storage Commitment
- Query/Retrieve
- Structured Report
- DICOM Medium Storage (DICOMDIR Review)
- DICOM Task Management

Workflows of DICOM Preset and Applications are briefly described as follows:

- 1. DICOM preset (network property, DICOM local preset, server and service preset).
- 2. Verify connectivity.
- 3. Services application.
- 4. DICOM task management.

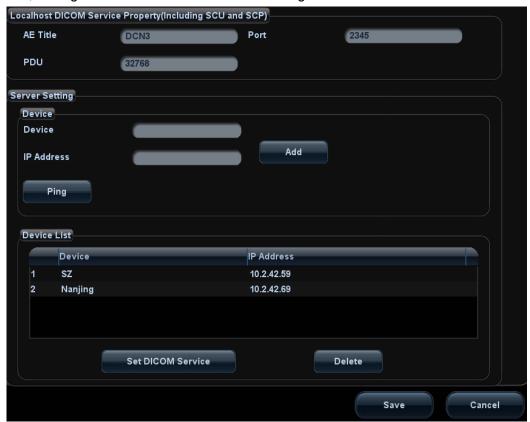
# 11.1 DICOM Preset

### 11.1.1 Network Preset

Refer to "12.5 Network Preset" for details.

## 11.1.2 DICOM Local Preset

- 1. Enter the DICOM local preset screen through the path: [Setup]→[DICOM Preset].
- 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 Local	Port	DICOM communication port.
	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	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 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.

To open the DICOM Service screen:

- 1. Press <F10> key to show the Setup menu.
- 2. Navigate to select [DICOM Preset], and click [Set DICOM Service] to open the DICOM Service preset 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.
	AE Title	Application Entity title, here, it should be consistent with that of the storage server.
	Port	DICOM communication port, 104 is default. Here, the port should be consistent with that of the storage server port.
	Maximum Retries	Set the maximum retries.
	Interval Time(s)	Interval time that the system retries a connection.
	Timeout	Refers to the amount of time after which the system will stop trying to establish a connection to the service.
Configure New Service	Compression Mode	Select the compression mode: uncompressed, RLE, JPEG, and JPEG2000.
Service	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- frame file.
	SR Storage Option	To enable or disenable structured reporting sending.
	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: 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.
New Service	AE Title	Application Entity title, here, it should be consistent with that of the print server.
	Port	DICOM communication port, 104 is default. Here, the port should be consistent with that of the print server port.
	Maximum Retries	Set the maximum retries.
	Interval Time (s)	Interval time that the system retries a connection.
	Timeout	Refers to timeout during association establishment.
Print Properties	Copies	Refer to copies of printed files. You can select among 1 through 5, or directly enter the numeral.
	Settings	The system supports RGB (color printing) and MONOCHROME2 (black and white printing). Please select the type the printer supports.

	Name	Description
	Film Orientation	Select between LANDSCAPE and PORTRAIT.
	Priority	Specify printing task priority among HIGH, MED and LOW.
	Film Size	Select film size among the selections listed in the drop down list.
	Display Format	Specify quantity of printed files, e.g. STANDARD\2, 3 indicates 6 images are printed for each page.
	Medium Type	Specify print medium: Paper, Clear Film, Blue Film; select Blue Film or Clear Film for black and white printing; select Paper for color printing.
	Trim	Specify whether you want a trim box to be printed around each image on the film: Yes or No.
	Configuration Info	Enter configuration information in the field.
	Min Density	Enter the minimum density of the film.
	Max Density	Enter the maximum density of the film.
	Destination	Specify where the file is exposed: MAGAZINE (stored in the magazine), or, PROCESSOR (exposed in the processor).
		Select how the printer magnifies an image to fit the film.
	Magnification Type	Replicate: interpolated pixels belong to duplicate of adjacent pixels);
		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 List	Default	Select an item in the service list, click [Default] and you can see "Y" in the Default column.
List	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

- 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 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.

# 11.2 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:

- The ultrasound machine can't communicate normally with the server. Please check if the cable is properly connected; or,
  - Check if the IP of the server is configured in the same segment with that of the ultrasound machine; or,
  - Check if the network adapter, the router, the exchanger or the HUB are normally working.
- The server does not support the verification. If the connection is normal, it can be concluded that the server does not support the verification.
- The server supports the verification, but this function is not activated. Please check if the verification function is activated.

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] (F10) → [System Preset] → [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.
  - > Save Image to Hard Disk and Send to DICOM Storage
  - Save Cine (Retrospective) to Hard Disk and Send to DICOM Storage.
  - Save Cine (Prospective) to Hard Disk and Send to DICOM Storage.
  - c) Click [Save] to confirm the preset and exit.
- (2) Set a default storage server:
  - a) Enter the DICOM Service Preset screen via "[Setup] (F10) → [DICOM Preset] → [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] (F10) → [System Preset] → [General]", and then check
     Sending/printing after End Exam in the Exam Setup area.
  - (2) Set a default storage server.

- a) Enter the DICOM Service Preset screen via "[Setup] (F10) → [DICOM Preset] → [Set DICOM Service]".
- b) Select a storage server in the Service List and click [Default]; you can see "Y" 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) When finished the 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.

### 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.

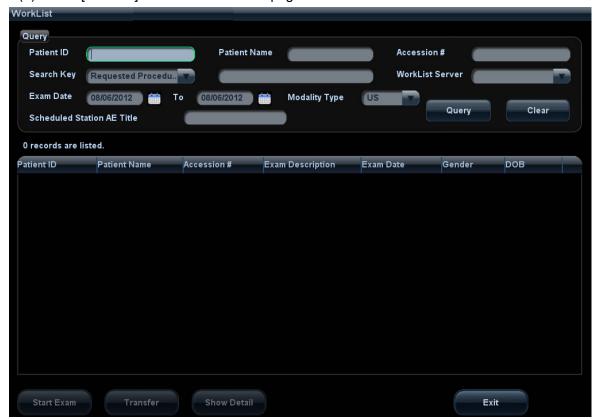
- (1) Define the short key:
  - a) Open Key Config page via "[Setup] (F10) → [System Preset] → [Key Config]".
  - b) Assign functions to the desired keys: in Key Config page, select a free key or footswitch at the left side, then select "Save Image to Hard Disk and Send to DICOM Printer" on the right side.
  - c) Click [Save] to confirm the preset.
- (2) Set a default printer server
  - a) Enter the DICOM Service Preset screen via "[Setup] (F10) → [DICOM Preset] → [DICOM Service]".
  - b) Click [Print] to open the Print page.
  - c) Select a Print server in the Service List and click [Default]; you can see "Y" is marked in the Default column.
  - d) 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 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] (F10) → [System Preset] → [General]", and then check
    - Sending/printing after End Exam in the Exam Setup area.
  - (2) Set a default print server.
    - a) Enter the DICOM Service Preset screen via "[Setup] (F10) → [DICOM Preset] → [DICOM Service]".
    - b) Click [Print] to open the Print page.
    - c) Select a Print server in the Service List and click [Default]; you can see "Y" is marked in the Default column.
    - d) 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) When finished the 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

After successfully connected DICOM Worklist server with ultrasound system, you can query patient records from Worklist server, and then import the desired information to your system.

- To query patient information via Worklist server
  - (1) Press the < Patient > key to open the Patient Info screen.
  - (2) Click [Worklist] to enter the Worklist page.



- (3) Query patient information:
  - a) Set query criteria among Patient ID, Patient Name, Accession #, Search Key, Scheduled Station AE Title, Worklist Server or Exam Date. The default exam date is the current date.
  - b) Click [Query].
  - c) The scheduled patients, which meet the criteria, are displayed in the lower part of the screen.
  - d) After you finished the first query, you can perform the second query basing on the previous results. The scheduled patients in the list will update in real time.
- (4) Select the desired patient record in the displayed patient list:
  - a) Select the desired patient and click [Start Exam], the patient information is imported into the system and then an exam is started.
  - b) Click [Transfer], the patient information is imported into the [Patient Info] screen. After you edited the patient information in the Patient Info screen, select [OK] to start a new exam.
- (5) To show patient information in details:

- a) Click to select a patient record.
- b) Click [Show Detail] button to view the detailed patient information and properties.
- To automatically query via Worklist server
  - (1) Enter DICOM Service Preset screen, click [Worklist] page tab to open Worklist page.
  - (2) Select an item in the service list and click [Default] to set it as default.
  - (3) Click [Exit] in the screen and click [Save] in the Setup menu.
  - (4) Press < Patient > key on the control panel to open Patient Info screen.
  - (5) Click [Worklist] button to open Worklist screen.
  - (6) The system automatically queries intraday patients via Worklist server and the patient records will appear in the list.

In the off-line status, you can:

- Perform the second query; or,
- Click [Show Detail] button in the Worklist screen to view the detailed patient information.

#### 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.

The status information is described as below:

- When you begin an exam or send image(s) during the exam, the system sends status information "Active" to MPPS server.
- When the exam is completed, the system sends status information "End" to MPPS server.
- When a paused exam is continued, the system sends status information "Active" to MPPS server.
- When an exam is cancelled, the system sends status information "Cancelled" to MPPS server.

## 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.
  - (2) 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
  - (1) Open [Setup] (F10) → [System Preset] → [General], and then check Sending/printing after End Exam in the Fixer Setup area
  - in the Exam Setup area.

    (2) Set the default storage server and storage commitment server.
    - a) Enter the DICOM Service Preset screen via "[Setup] (F10) → [DICOM Preset] → [Set DICOM Service]".

- b) Select a server in the Service List of Storage page and Storage Commitment page 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) When finished the 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 Preset]  $\rightarrow$  [Set DICOM Service]  $\rightarrow$  "Storage"). For example, if there is multiframe file in the exam to be sent, then only single-frame image storage will be performed, and after the storage is completed, there is no " $\checkmark$ " marked in the list below in 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 query basing on the results by entering new query information.
- 6. Select one or more patient records according to the actual situation.
  - Click [Select All] to select all the patient records in the list.
  - Click [Deselect All] to deselect all the patient records in the list.
- 7. Click [Retrieve] to retrieve the patient records in the DICOM query/retrieve server 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] in the popped up menu to open the dialogue box.
- 3. Select destination media, compression mode and size from DICOMDIR.
- Set whether to remove the patient data from local hard disk after backup (remove exams or just remove the images).
- 5. Click [OK].

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.

#### **Data Restore**

After DICOM format data are saved to external media, you can restore the data to the ultrasound system.

- 1. Review the data stored in the external media.
- 2. Select the data in iStation screen to be restored.
- 3. Click [Restore] in the iStation screen. If the data to be restored already existed in the system, the system will ask whether to overwrite the data or not.
- 4. After the data are restored, you can see they are listed out in the iStation screen.

**NOTE:** Only the system accessible media can be selected.

#### **DICOMDIR Update**

Data can be recorded to the disc which has backup data and free space.

# 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.

The structured report can be sent automatically, for details, please refer to "11.3.1 DICOM Storage".

Back up structured report

When record or store the exam that has a structured report to the external media (DICOMDIR), the structured report can be backed up together.

# 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 "10.7 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.

 $\triangle$ 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.

When you change the system language and click [Save] on the Setup menu, the system will automatically shut down to make the modification effective.

Basic operations

The commonly-used setting types are:

- Text box: posit the cursor into the corresponding field box; enter the desired value through keyboard.
- Radio button: click the button to select an item.
- Check box: click the check box to select one or several options.
- Drop-down list: click the arrow beside the list to select an item.

# 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, patient management, storage, system dormancy, display, operation log and so on.
Image	To set general parameters in imaging modes.
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.
Admin	To set the user account control relevant information.

# 12.1.1 Region

Open the Region page via [Setup]→[System Preset]→[Region].

Item	Description
Hospital Information	To set the hospital relevant information like name, address, telephone and so on.
Language	To select a language for the system, the available languages are Chinese, English, French, German, Italian, Portuguese, Russian, Spanish, Polish, Czech, Turkish (can be input only), Finnish (can be input only), Danish (can be input only), Icelandic (can be input only), Norwegian (can be input only), and Swedish (can be input only).
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 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]  $\rightarrow$  [System Preset]  $\rightarrow$  [General].

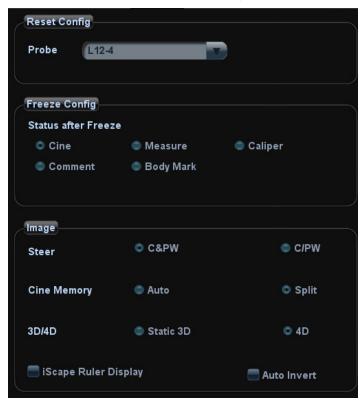


Туре	Item	Description
	Info displays in image banner	To select if to display the available patient information items on the screen.
Patient Info	H&W Unit	To set the unit for patient height and weight.
	Surface Formula	To set the surface formula.
Exam Setup	Status after exam ends	To set the system status when exam ends.
Patient Management	Sending/printing after End Exam	Select if to automatically archive the exam data to DICOM server for storage/print.
	Image size	To set the size for a stored image.
	Output Mode	To set the output format.
01	Clip Length	To set the cine length and heart cycle.
Storage	Prospective Cine Length	To set the cine length for prospective live capture.
	Retrospective Cine Length	To set the cine length for retrospective live capture.
Display	Brightness/Contrast Load Factory	To set if use the factory setting values of brightness and contrast.

Туре	Item	Description
		To select a system dormancy type.
Screen Saver	Screen Saver	After screen saver function is enabled, click [Browse] to select the figure used for screen saver, and click [Preview] to see the effect.
		To set the waiting time before the system enters dormancy/standby status in the drop-down list beside "Wait".

# 12.1.3 Image Preset

Open the page via [Setup]  $\rightarrow$  [System Preset]  $\rightarrow$  [Image].



Туре	Item	Description
Reset Config	Probe	To set the default probe model for the system.
Freeze Config	Status after Freeze	To set the system status after image is frozen.
Image	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.

Туре	Item	Description
	Cine Memory	To set the cine memory splitting type.
	3D/4D	To set the default status (Static 3D or 4D ) when entering 3D/4D.
	iScape Ruler Display	To set if to display the iScape ruler on iScape imaging mode.

## 12.1.4 Application

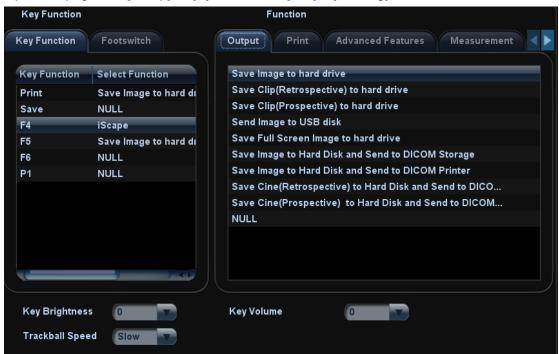
Open the page via [Setup]  $\rightarrow$  [System Preset]  $\rightarrow$  [Application]. Through the page, you can set the measure ruler and relevant information. For details, please refer to the Operator's Manual [Advanced Volume].

#### **12.1.5 OB Preset**

Open the page via "[Setup]  $\rightarrow$  [System Preset]  $\rightarrow$  [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]  $\rightarrow$  [System Preset]  $\rightarrow$  [Key Config]".



Key function setting

You can set the functions for <Print>, <Save>, F4, F5, F6, and P1.

To assign a function to a key:

(1) Click to select the desired key in the Key Function column at the left side of the page.

- (2) Click to select a function in Function area. You can see the available functions selected at the right side.
- (3) 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

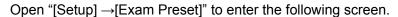
Item	Description
Key Brightness	To set the brightness for the keys.
Key Volume	To set the key volume, 0 means no sound.
Trackball Speed	To set the trackball speed when moving the trackball.

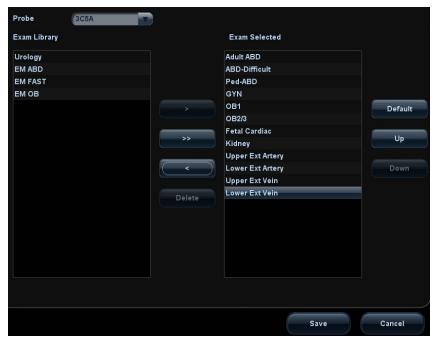
## 12.1.7 Admin

Open the page via "[Setup]  $\rightarrow$  [System Preset]  $\rightarrow$  [Admin].

For details of access control, please refer to "10.8 Administration".

## 12.2 Exam Preset





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.

- Select the exam from the Exam Library on the left and click to add it to the Exam Selected.
- Click to add the exams, which Exam Library has but Exam Selected doesn't have, from Exam Library to Exam Selected.
- To delete an exam supported by the current probe, select the exam first, and then click to delete it.
- Click [Delete] to delete the user-defined exam mode.
- Click [Default] to set a selected exam mode as the default exam mode, and the default exam mode is moved up to the first.

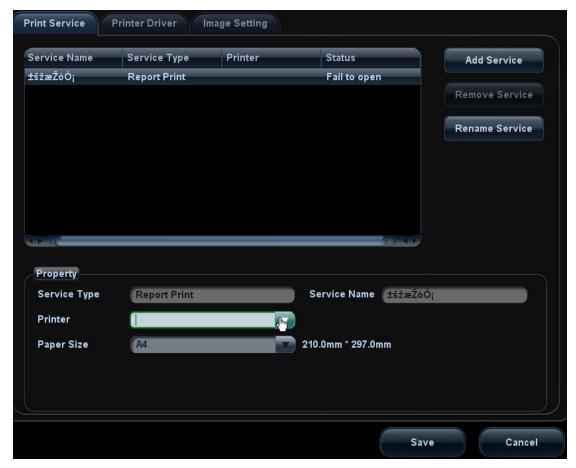
## 12.3 Measure Preset

For details about Measure Preset, please refer to the [Advanced Volume].

## 12.4 Print Preset

The settings of a printer include print service and print driver.

For details about print service and printer installation, please refer to "3.6.3 Graph /Text printer" chapter.



#### ■ 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.
- Property: to preset the property of print services.

#### ■ Printer Driver Setting

Printers listed in the operator's manual are all supported by the system, no drive is required.

Click [Printer Driver] page to enter printer driver setting screen:

- Display the printer name as well as print status.
- You can add printer including network printer.
- ➤ Click [Printer Attribute] to see the attributes of the printer, ppd. file source path, and you can select to update the ppd. file.

For details about DICOM print, please refer to "11 DICOM".

#### Image Settings

You can set brightness, contrast and saturation of image printing, or you can use the default value.

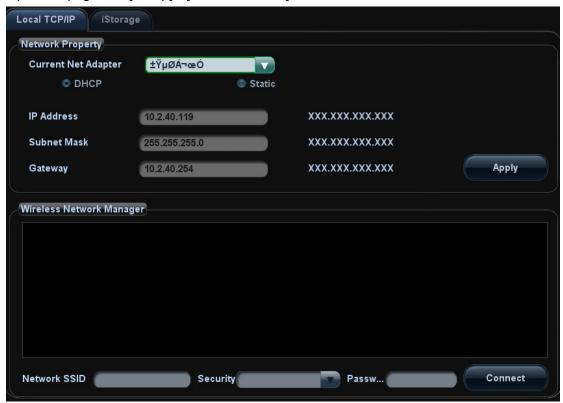
## 12.5 Network Preset

### 12.5.1 Local TCP/IP

**NOTE** DO Not edit IP address in Network Preset page as the network task is executed, otherwise it fails. View if there is any undergoing task in task manager of the system.

This page is used for setting network property of the ultrasound system, which is also applicable for DICOM function.

Open the page via "[Setup]->[Network Preset]".



Local TCP/IP setting items are described as follows:

Name	Description
Current Network Adapter	To choose the local connection or wireless adapter.
DHCP/ Static	DHCP/Static: If "DHCP" is selected, IP address will be automatically obtained from DNS server; if "Static" is selected (using static IP address), you need to enter the IP address.
IP Address	IP Address: IP address of the system should be at the same network segment with the service IP address.
Subnet Mask	Used to set different network segment.

Name	Description
Gateway	Used to set the gateway IP.
Apply	Click to make the settings effective.

Note: The IP address of the system should not be occupied by other devices in the LAN, otherwise DICOM function will fail.

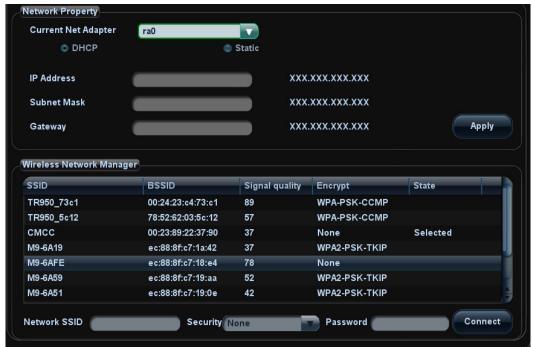
#### 12.5.1.1 Wireless LAN

-		
<b>≜</b> WARNING	1.	It is prohibited to use the wireless LAN function in airplane, as it may violate the relevant provisions in the aviation regulations.
	2.	Use the wireless LAN function prudently in the emergency ambulance (or other vehicles) as other devices or communication signals may be interfered with.
	3.	Be prudent to use the wireless LAN function in OR/ ICU/ CCU as it may interfere with other devices.
	4.	When wireless LAN function is turned on, the ultrasound system may be interfered with by other equipment, even if that other equipment complies with CISPR EMISSION requirements.

#### To Use the W-LAN Function

The system can be configured with built-in wireless net adapter, so as to assist information communication.

- 1. Press <Setup> to enter the Setup menu.
- 2. Enter [Network Preset] -> [Local TCP/IP].
- 3. Select the wireless net adapter from the [Current Net Adapter] list, and the hotspots being searched by the system are listed in the [Wireless Network Manager] box.



Tips: Usualy the DHCP is selected. If you select Static, please refer to 12.5.1 Local TCP/IP to set IP Adres, Subnet Mask and Gateway.

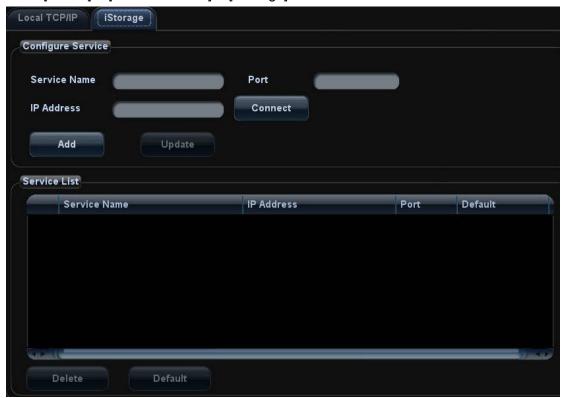
- 4. Select the desired hotspot from the [Wireless Network Manager]. The data display in the [Network SSID] and [Security] control. If the hotspot wanted is not in the list, you can input the data manually in the controls and click [Connect]. When connecting an encrypted network, enter the password in the box on the left first.
- 5. If the connection is successful, the will be displayed on the lower right corner of the screen.

**NOTE:** 1. You can refresh the W-LAN network by switching the current adapter.

- If the IP address displays as 0.0.0.0, this means that the network is abnormal, the reason may be failure disconnection or the system cannot obtain IP address.
- 3. The function of adding hotspot not displayed in the list by editing SSID, Security and Password manually is not applied on software version 01.00.00.

## 12.5.2 iStorage

Enter [Preset]-> [Network Preset]-> [iStorage].



Name	Description
Service Name	Name of the device, cannot be empty
IP Address	IP address of the PC installed with iStorage software, cannot be empty

Name	Description		
Connect	Press to verify connection with the PC server. On PC server, if the storage path has not been confirmed, a dialog box will pop up and guide the user to set it. If the storage path on PC has already been set, here it displays connection successful after clicking this button.		
Add	Click it to add the new service to the service list.		
Update	Update To save the changed parameters.		
Delete	Click to delete the selected service in the service list.		
Default	Click to set an selected item in the list as the default iStorage server.		

- Add a network service:
- 1. Set the network server properties as described above.
- 2. Click [Add] to add the service to the Service list;
- 3. Select the added service in the service list, you can delete it.
- 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 setting.

Tips: in order to make network storage function normally, setting of the sharing folder of the PC server in advance is a must, e.g. machine name, IP address, should be confirmed at first.

## 12.5.3 MedSight Preset

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

# 12.6 Maintenance

In the Setup menu, select [Maintenance] enter the screen.

## 12.6.1 **Option**

The system enters Option page after you enter the Maintenance screen. In Option list, the system lists out all the system supported options and the installation status (Disabled 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.
- Trial

Select the option item in the list to see the information on the Comment region on the right.

For functions that are not configured, you can use the function for free for 3 months.

Click to select the function(s) and click [Trial].

Tips: every trial option can be used only once.

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

## 12.6.2 Other Settings

Type Item		Description	
Log	Export Log	Export the operation log.	
Log	Upload Log	Upload the operation log.	
	Export	Export preset data to disk.	
Preset Manager	Import	Import the preset data into the system.	
	Load Factory	Local factory default settings.	

# 12.7 System Information

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

This 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

**Note:** For details of storage time and condition for disinfected probes or sterilized probes and brackets, please refer to Technical standard for Disinfection of Medical and Health Structures.

# 13.1 Probe

The system supports the following probes:

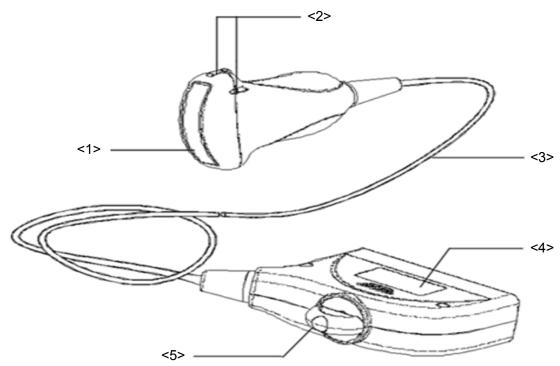
No.	Probe Model	Illustration
1.	3C5A	
2.	6C2	
3.	L14-6	
4.	6CV1	

No.	Probe Model	Illustration
5.	L12-4	
6.	7L4A	
7.	2P2	
8.	D6-2	
9.	V10-4B	
10.	V10-4	
11.	D6-2A	

No.	Probe Model	Illustration
12.	CB10-4	
13.	P7-3	
14.	L7-3	
15.	7L5	
16.	CW5s	
17.	L14-6N	

## 13.1.1 Name and Function of Each Part of the Probe

The basic structures and corresponding functions of probes are basically the same; the following will take probe 3C5A as an example.



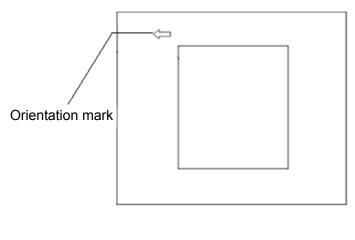
No.	Name	Function
<1>	Probe head	It converts the electrical signal into ultrasound signal, making the sound beams focus in the given direction; meanwhile, it will receive the ultrasound signal and then convert the received signal into electrical signal. The lens on the surface is the acoustic lens. Apply ultrasound gel on the acoustic lens.
<2>	Needle-guided bracket fix tabs and grooves	Used to mount the needle-guided bracket.
<3>	Probe cable	Used to transmit electrical signals between the probe body and connector.
<4>	Probe connector	Used to connect the probe to the ultrasonic diagnostic system.
<5>	Lock handle	Used to lock the connector to the ultrasonic diagnostic system.

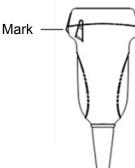
Tips:

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 (Here takes linear probe as an example).

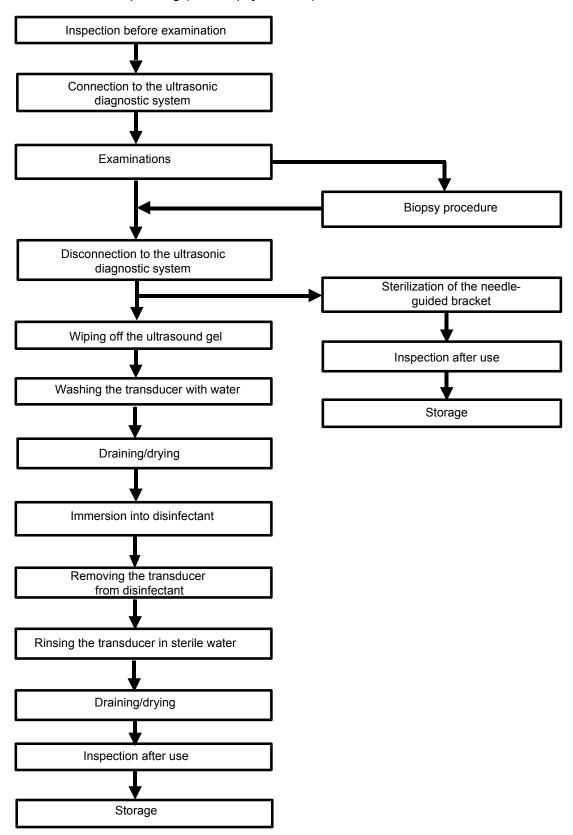




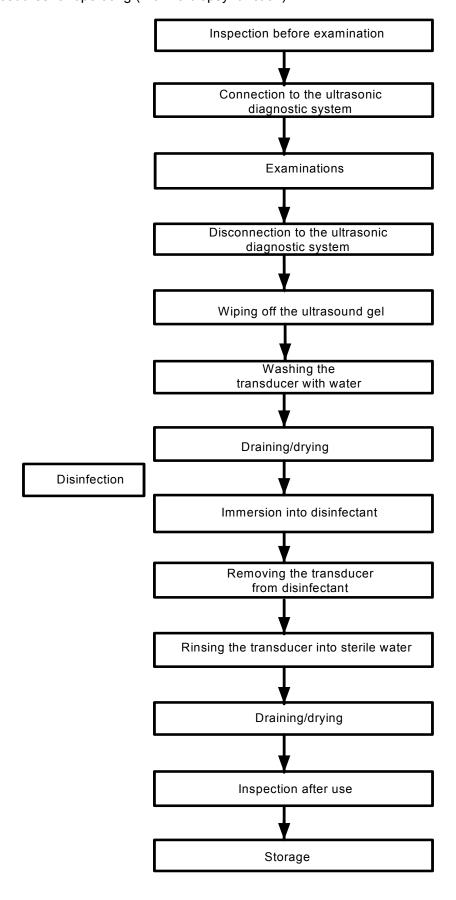
# 13.1.3 Procedures for Operating

This section describes general procedures for operating the probe. The proper clinical technique to be used for operating the probe should be selected on the basis of specialized training and clinical experience.

■ Procedures for operating (with biopsy function):



■ Procedures for operating (with no biopsy function):



**△**WARNING:

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 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

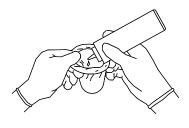
E-mail: info@civco.com http://www.civco.com



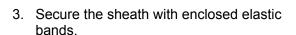
- 1. Be sure to cover the probe with a new (unused) probe sheath to prevent infection during examination. If the package of a probe sheath is open or broken, the sterilization of the probe sheath may not be sufficient. DO NOT use such a probe sheath.
- 2. The cover contains natural rubber latex and talc that can cause allergic reactions in some individuals.
- 3. DO NOT use an expired probe sheath. Before using probe sheaths, verify whether the term of validity has expired.

Method (for reference only):

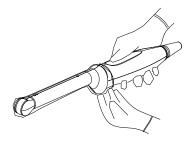
1. Place an appropriate amount of gel inside the sheath or on probe face. Poor imaging may result if no gel is used.



 Insert the probe into the sheath; make sure to use proper sterile technique. Pull cover tightly over probe face to remove wrinkles and air bubbles, taking care to avoid puncturing cover.

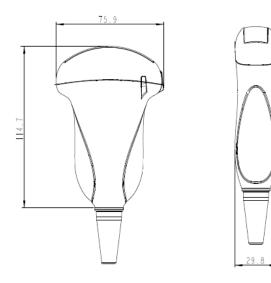


4. Inspect the sheath to ensure there are no holes or tears.



Refer to the following table of all probe dimensions to choose the necessary probe sheath type.

Model	Length(mm)	Width(mm)	Height(mm)	Cable Length(mm)
3C5A	114.7	75.9	29.8	2260±50mm
V10-4	315.84	40.95	31.85	2260±50mm
V10-4B	323	32.25	31.01	2260±50mm
6C2	95	33.5	24.8	2260±50mm
7L4A	101.6	61	25.7	2260±50mm
L11-4	101.6	61	25.7	2260±50mm
L12-4	101.6	61	25.7	2260±50mm
L14-6	91.4	47.1	22.8	2260±50mm
2P2	102.7	38.1	30.4	2260±50mm
D6-2	117.4	68.36	44.99	2260±50mm
D6-2A	128.0	79.0	56.0	2260±50mm
P7-3	79.5	34	25.2	2260±50mm
L7-3	102	61.1	25	2260±50mm
CW5s	105	13.7	13.7	2260±50mm
7L5	102.4	69.7	25.9	2260±50mm
L14-6N	101.6	61	25.7	2260±50mm
CB10-4	324.3	38.8	34.5	2260±50mm



The above is a dimension illustration of the 3C5A 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 disinfectant. Immersion may cause electrical shock or malfunction.

# $\Delta$ CAUTION:

- When performing cleaning and disinfection of the probe to prevent infection, wear sterile gloves.
- 2. After disinfection, rinse the probe thoroughly with sterile water to remove all chemical residues. Chemical residues on the probe may be harmful to the human body.
- 3 No cleaning and disinfecting may result in the probe becoming a source of infection.

#### NOTE:

- 1. After the examination, wipe off the ultrasound gel thoroughly. Otherwise, the ultrasound gel may solidify and degrade the image quality of the transducer.
- 2. DO NOT make the probe to become overheated (more than 55°C) during cleaning and disinfections. High temperature may cause the probe to become deformed or damaged.

#### Cleaning

Please refer to the instructions in the manual and follow your hospital policy and procedures for cleaning.

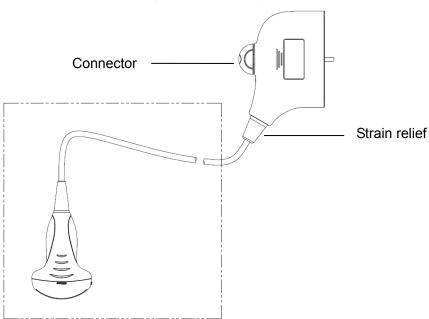
- 1. Disconnect the probe from the system.
- 2. Wear sterile gloves to prevent infection.
- 3. Wash the transducer with clean water or soapy water to remove all the foreign matters, or, wipe the transducer with a soft ethyl carbamate sponge. Avoid using a brush, because it may damage the transducer.
- 4. Dry the transducer using a sterile cloth or gauze after rinsing. Do not dry the transducer by heating it.

#### **Disinfecting with Sprays**

 $\Lambda$ CAUTION:

Use protective eyewear when disinfecting using sprays.

- 1. Wear sterile gloves to prevent infection.
- 2. After you have finished cleaning, spray 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.

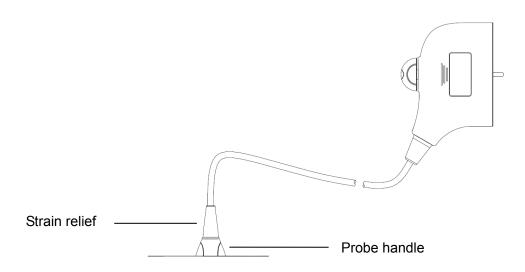


NOTE: Observe the graph here carefully to perform disinfection. Do not spray the strain relief on the connector end or the connector.

#### **Disinfecting by Immersion**

- 1. Wear sterile gloves to prevent infection.
- 2. 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:

Observe the graph here carefully to immerse the transducer. Only soak parts of the transducer below the strain relief.

#### **Compatible Disinfectants**

Please see the diainfectant compatible chart for the proper disinfectant for the probe of the Diagnostic Ultrasound System.

## 13.1.6 Storage and Transportation

When all examinations for the day have been completed, confirm that the probe is in good condition. After disinfecting the probe, confirm that the probe is in good condition and store it in a suitable place so that the next examination can be conducted smoothly.

- 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. Store and transport the probe under the following ambient conditions:
  - Ambient temperature: -20°C ∼ 55°C

- Relative humidity: 30%  $\sim$  95% (no condensation)
- ullet Atmospheric pressure: 700 hPa  $\sim$  1060 hPa

Store and transport the D6-2 probe under the following ambient conditions:

- Ambient temperature: -10°C ∼ 60°C
- Relative humidity: 30%  $\sim$  95% (no condensation)
- ullet Atmospheric pressure:700 hPa  $\sim$  1060 hPa

Store and transport the D6-2A probe under the following ambient conditions:

- Ambient temperature: -10°C ∼ 60°C
- Relative humidity: 30%  $\sim$  90% (no condensation)
- Atmospheric pressure:700 hPa ∼ 1060 hPa
- 3. 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.
- 4. Sterilize the carrying case as necessary.

# 13.2 Biopsy Guide

## **⚠WARNING**:

- The person performing biopsy procedures must understand diagnostic ultrasound thoroughly and have been trained adequately, otherwise, side effects may be caused to the patient.
- 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 or guiding block that is unsuitable for the needle guide.

- 3. Before and after a biopsy procedure is performed, confirm that the needle-guided bracket is normal. Manually confirm that the parts of the needle-guided bracket do not slip off or move from their proper positions. If the needle-guided bracket is used when parts are not securely and correctly installed, the patient may be injured. If an abnormality is found on the needle-guided bracket, immediately stop using it and contact MINDRAY Customer Service Department or sales representative.
- 4. DO NOT use a needle-guided bracket when scanning is performed. The needle may advance in an incorrect direction and possibly injure the patient.

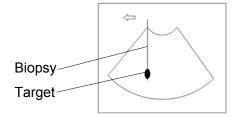
Never perform a biopsy during image scanning.

5. DO NOT freeze an image while performing biopsy procedure.

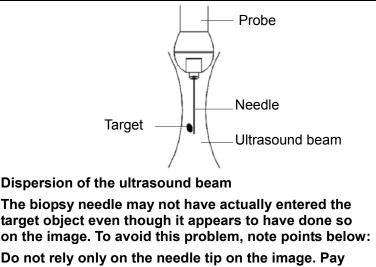
- 6. During biopsy procedures, the needle may deviate from the desired course due to the tissue characteristics or the type of needle. In particular, needles of small diameters may deviate to a greater degree.
- 7. Disinfect the probe and sterilize needle-guided bracket before and after each ultrasound-guided biopsy procedure is performed. Fail to do so may cause the probe and the needle-guided bracket become sources of infection.
- 8. Before clean and sterilize needle-guided bracket please remove the needle-guided bracket from the probe referring to chapter 12.
- 9. 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.
- 10. Adjust the needle mark before the biopsy procedure is performed.
- 11. 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.
- 12. When performing the operation concerning biopsy, wear sterile gloves.
- 13. 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



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.

 $\Delta$ CAUTION:

When using the needle-guided bracket wear sterile gloves to prevent infection.

## 13.2.1 Basic Procedures for Biopsy Guiding

- 1. Select the right needle-guided bracket and needle, install them properly. For details, please refer to "Needle-guided Bracket Inspection and Installation".
- 2. Verify the biopsy guide line.
- 3. Press <Biopsy> to enter the biopsy.

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. Set [Display] as "On" to display the guide line, 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 exit the Verify menu without saving the setting, system will confirm with you "Data have changes. Do you want to save the changes?". Click [OK] to save the setting and return to Biopsy menu.
- 6. Scan to locate the target. Center the target in the electronic guidezone path.
- 7. Direct the needle into the area of interest for specimen.

- 8. After extraction of the biopsy sample is completed, gently remove the probe from the body.
  - To exit Biopsy menu: press <Esc> key; or, navigate the cursor onto the other menu.
- 9. Disassemble the items and properly dispose of these items as required.
- 10. Click [Exit] on the menu to exit after finishing biopsy.

**⚠DANGER**:

Fail to match the guidezone 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 guidezone which could result in repeated biopsies or patient injury.

## 13.2.2 Needle-guided Brackets

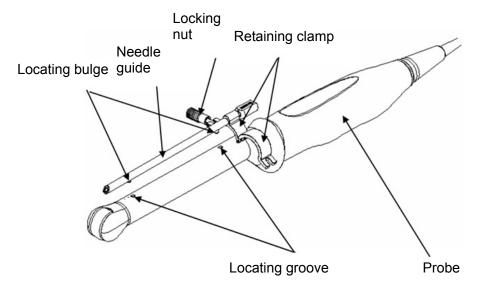
A needle-guided bracket is available for purchase as an optional accessory; it is used in combination with the probe. Some of the probes have matched needle-guided bracket and needles. To order needle-guided brackets, contact MINDRAY Customer Service Department or sales representative.

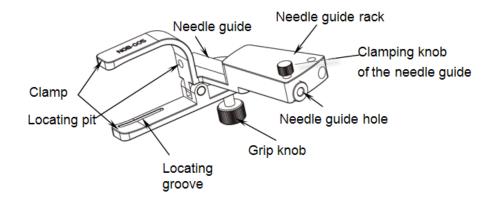
For biopsy or treatment, ultrasound-guided biopsy procedures can be performed using the probe in combination with a needle-guided bracket (optional accessory) and a biopsy needle (provided by the user).

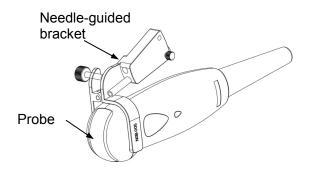
### **Names of Parts**

This section describes the parts and corresponding functions of each needle-guided bracket.

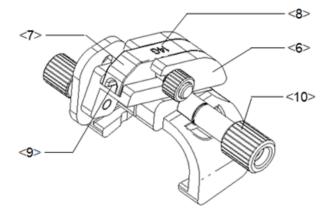
■ NGB-004

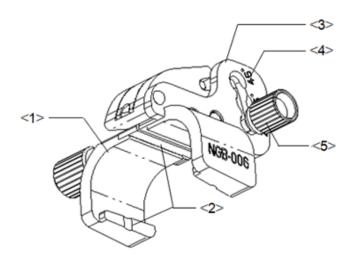






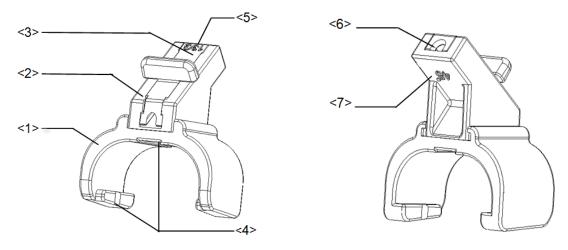
## NGB-006 Metal/needle detachable needle-guided bracket:





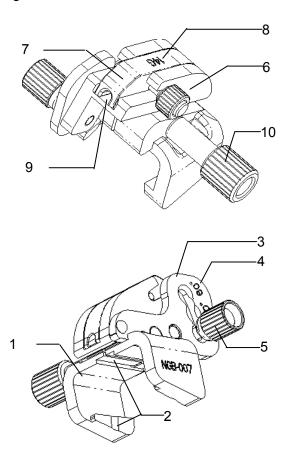
No.	Name	Description
<1>	Support of needle- guided bracket	Used for installing the needle-guided bracket on the probe.
<2>	Groove and tab of the needle-guided bracket	Respectively matched with the tab and groove of the probe.
<3>	Angle adjusting base	There are 3 types of angles available to be adjusted.
<4>	Angle shift sign (25°,35°,45°)	Matched with the biopsy angle (25°, 35°, 45°).
<5>	Angle pinch nut	Used for fixing the angle block at a chosen angle.
<6>	Angle block	Used for fixing the angle block at a certain angle.
<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>	Guiding hole of the biopsy needle	Used for installing the biopsy needle.
<10>	Pinch nut of needle-guided bracket	Used for locking the needle-guided bracket and the probe.

## Plastic/needle detachable needle-guided bracket:



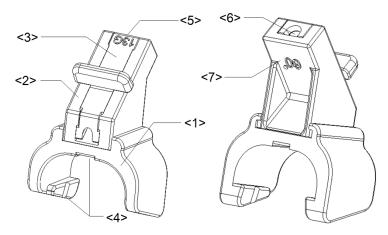
No.	Name	Description
<1>	Support of needle- guided bracket	Used for installing the needle-guided bracket on the probe.
<2>	Angle block	Used for determining the angle of the biopsy; there are three specifications of blocks of angle.
<3>	Guiding block	Used for installing biopsy needle; there are five specifications 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 (45°)	The corresponding biopsy angle is 45°.

Metal needle-guided bracket:

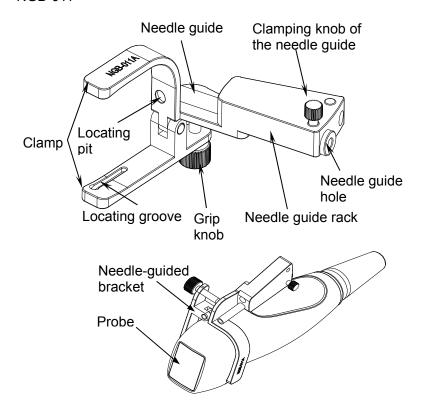


No.	Name	Description	
1.	Support of needle-guided bracket	Used for installing the needle-guided bracket on the probe.	
2.	Groove and tab of the needle-guided bracket	Respectively matches with the tab and groove of the probe	
3.	Angle adjusting base	There are 3 types of angles available to be adjusted.	
4.	Angle shift sign(40°, 50°, 60°)	Matched with the biopsy angle (40°, 50°, and 60°).	
5.	Angle pinch nut	Used for fixing the angle lock at a chosen angle.	
6.	Angle block	Used for determining the angle of the biopsy; different specifications of blocks can be used.	
7.	Guiding block	Used for installing biopsy needle; there are five specifications of guiding blocks for different biopsy needles.	
8.	Specification of guiding block (14G)	Matched with the corresponding biopsy needle (14G).	
9.	Needle guide hole	Used for installing the biopsy needle.	
10.	Pinch nut of needle- guided bracket	Used for locking the needle-guided bracket and the probe	

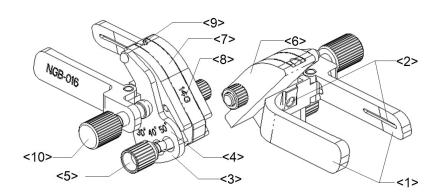
### Plastic needle-guided bracket:



No.	Name	Description	
<1>	Support of needle-guided bracket	Used for installing the needle-guided bracket on the probe.	
<2>	Angle block	Used for determining the angle of the biopsy; there are three specifications of blocks of angle.	
<3>	Guiding block	Used for installing biopsy needle; there are five specifications of guiding blocks for different biopsy needles.	
<4>	Groove and tab of the needle-guided bracket	Respectively matched with the tab and groove of the probe.	
<5>	Specification of guiding block (13G)	Matched with the corresponding biopsy needle (13G).	
<6>	Needle guide hole	Used for installing the biopsy needle.	
<7>	Specification of angle block (60°)	Corresponding to the size of the biopsy angle (60°).	

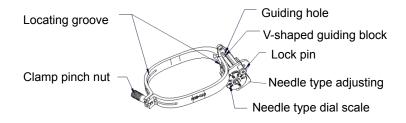


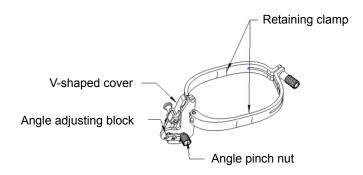
### ■ NGB-016



No.	Name	Description	
<1>	Clamp of needle-guided bracket	Used for installing the needle-guided bracket on the probe.	
<2>	Groove of the needle- guided bracket	Matches with the tab of the probe.	
<3>	Angle adjusting base	There are 3 types of angles available to be adjusted.	
<4>	Angle shift sign (30°, 40°, 50°)	Matches with the biopsy angle. (30°, 40°, 50°).	
<5>	Angle pinch nut	Used for fixing the angle lock at a chosen angle.	
<6>	Angle block	Determines the angle of the biopsy; different specifications of blocks can be used.	

No.	Name	Description	
<7>	Guiding block	Used for installing the needles of different specifications, 5 types of needles are available.	
<8>	Specification of guiding block (14G)	Matched with the corresponding biopsy needle (14G).	
<9>	Guiding hole of biopsy needle	Used for installing the needles.	
<10>	Pinch nut of needle- guided bracket	Used for locking the needle-guided bracket and the probe.	





## 13.2.3 Needle-guided Bracket Inspection and Installation

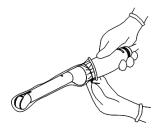
### Inspection of the Needle-guided Bracket

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, and malfunction, loose or missing parts.
- 3. Confirm that the needle-guided bracket is securely mounted in the correct position.

### 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-005

- (1) Inosculate the locating groove on the clamp with the two raised edges on the probe head and aligning 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-006

Metal needle-guided bracket:

- (1) Put on the sterile transducer cover.
- (2) Hold the transducer 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 transducer respectively. Amount the bracket onto the transducer.





- (3) Turn the pinch nut to secure the bracket and the transducer.
- (4) Select a guiding block of proper size, slightly push it into the groove on the support.





- (5) Screw the nut on the guiding block to secure the block and the needle-guided bracket.
- (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 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.

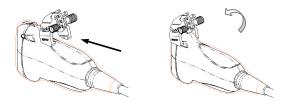


(5) Insert a biopsy needle with the same specification as that of the guiding block into the hole of the guiding block.

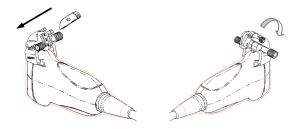


Metal needle-guided bracket:

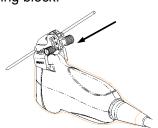
- (1) Put on the sterile probe sheath.
- (2) Select a proper needle-guided bracket, and match the groove and tab with the tab and groove of the probe respectively. Mount the bracket onto the probe.



- (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.

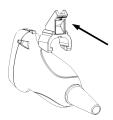


- (5) Screw the nut of the block to secure the block.
- (6) Insert a biopsy needle with the same specification as that of the guiding block into the hole of the guiding block.



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.

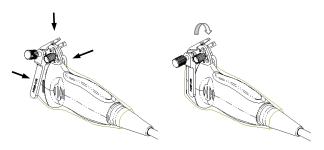


### ■ NGB-011

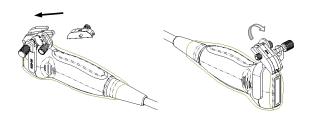
- (1) Inosculate the locating groove on the clamp with the two raised edges on the probe head and align the locating pit of the clamp to the convex point on the probe head.
- (2) Turn the grip knob at the tail of the needle-guided bracket tightly.

### ■ NGB-016

- (1) Put on the probe sheath.
- (2) Select a proper needle-guided bracket, and match the groove with the tab of the probe. Mount the bracket onto the probe.



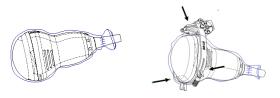
- (3) Screw the pinch nut of the needle-guided bracket to confirm that the needle-guided bracket is properly installed on the probe.
- (4) Select the appropriate guiding block, and fit it into the groove on the angle block.



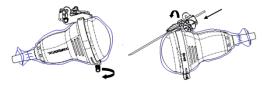
- (5) Screw the nut on the guiding block to secure the guiding block with the needle-guided bracket.
- (6) Insert the needle of the same specification with that of the guiding block into the guiding hole.



(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.

**⚠CAUTION:** 

Ensure that all guide parts are seated properly prior to performing a biopsy.

## 13.2.4 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.

## riangleWARNING:

- 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, you can select the angle from the drop-down list.

Select guide line dot size

Click [Dot Size] to select the dot size among Small, Medium and Big. 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 guidezone 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

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 <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 <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. When 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.

**NOTE:** For bi-planar probe applied biopsy, the verification is performed on the first guide line, the other guide lines can move together with the first one in parallel.

## 13.2.5 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-005

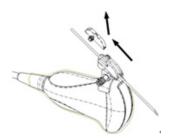
Hold the probe and the needle-guided bracket; open the grip knob of the needle-guided bracket.

■ NGB-006

Metal needle-guided bracket:

(1) Screw out the nut on the guiding block to loose the guiding block and the needle-guided bracket.





- (2) Take the guiding block away in the direction of the needle tail, and then separate the needle from the transducer and the residual parts of the needle-guided bracket.
- (3) Screw out the locking nut on the needle-guided bracket to loose the bracket with the transducer.

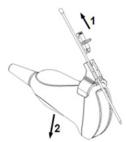




(4) Hold the transducer with one hand, and then separate the needle-guided bracket from the transducer.

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.

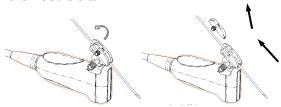


(3) Remove the support of needle-guided bracket from the probe.

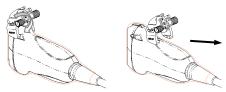
### ■ NGB-007

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.

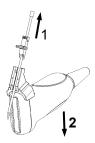


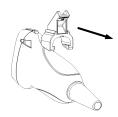
- (2) Separate the residual part of the needle-guided bracket and the probe from the needle.
- (3) Screw the pinch nut of the bracket, and remove the needle-guided bracket from the probe.



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.

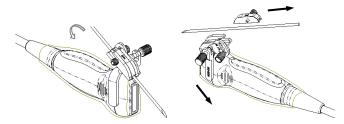




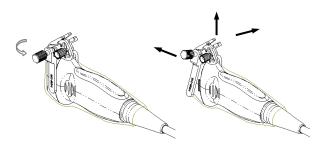
Hold the probe and the needle-guided bracket, and then open the grip knob of the needle-guided bracket.

### ■ NGB-016

(1) Screw out the nut on the guiding block to release the biopsy needle.



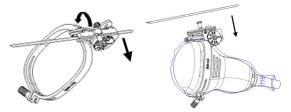
- (2) Remove the guiding block in the direction of the needle tail, and then remove the needle.
- (3) Screw the pinch nut of the bracket to release the needle-guided bracket.



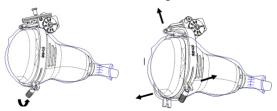
Separate the probe and the needle-guided bracket.

### ■ NGB-020

(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.

## 13.2.6 Clean and Sterilize the Needle-guided Bracket

### 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 (2.4%)	Cidex Activated Dialdehyde Solution	Please refer to the instructions provided by the manufacturer of the solution for details.  Soak the transducer into the activated solution for 10 hours (20-25°C)

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).

- 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 peroxide gas plasma	Hydrogen 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.

## 13.2.7 Storage and Transportation

- 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.
- Between examinations, keep the needle-guided bracket in a sterile environment.
- 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.
- Sterilize the carrying case as necessary.
- Store or transport the needle-guided bracket under the following ambient conditions:
  - Ambient temperature: -20°C to 55°C
  - Relative humidity: 30% to 85% (no condensation)

## 13.2.8 Disposal

Be sure to dispose the needle-guided bracket only after sterilizing it.

Contact your MINDRAY representative when disposing of this device.

## **14** Batteries

## riangleWARNING:

- The battery is inside the machine; only technical professionals from Mindray or engineers authorized by Mindray after training can perform battery installation and uninstallation.
- 2. If you need to change the battery or buy a new one, please contact your sales representative.

### 14.1 Overview

The battery charges when the system is connected to the AC power supply.

- Generally, a completely discharged battery will fully charge in less than 8 hours.
- When the battery capacity is charged to the full capacity, it can support a standby period of no less than 24 hours.

Note:

- 1. Charge the battery in time when the battery capacity is empty is necessary; otherwise, the performance of the batteries is degraded.
- Power off the system if you will not use the system for a long period of time (including storage/ transportation condition), and you should not allow the system in standby status, otherwise the batteries will be out of power and permanently damaged.

When the external power supply is not connected, two lithium-ion batteries will provide the power.

Fully charged battery can ensure a normal working condition of more than 1 hour (B mode with probe 3C5A probe).

 $\Delta$ CAUTION:

Only move the machine in the power off or standby status or damage may happen.

## 14.2 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 empty.
- Indicates the battery capacity is full.
- The battery icons other than the two icons above-mentioned indicate the capacity is between empty and full.

When the power capacity is not enough, the system will pop up a prompt:

"Warning! Battery is out of power! Please connect to AC power or system will be shut down in one minute." Connect to AC power to afford normal work.

## 14.3 One Full Discharge /Charge Cycle

Upon receipt of the system and before first time usage, it is recommended that you perform one full discharge /charge cycle. If the battery has not been used for over 2 months, you are recommended to perform one full discharge /charge cycle. It is also recommended that the battery is stored in the shady and cool area with FCC (full current capacity).

One Full Discharge / Charge Cycle:

- 1. Full discharge of the battery to let the system automatically shut down.
- 2. Charge the system to 100% FCC (full current capacity).
- 3. Discharge of the system for complete shutdown.

## 14.4 Checking Battery Performance

The battery performance may be degraded over time, so you need to check the battery performance periodically. The checking procedures are shown as follows:

- 1. Stop the ultrasound exam.
- 2. Connect the system to the AC power supply to charge the batteries until current capacity is full.
- 3. Disconnect the system from the AC power supply to power the system by the batteries until the system automatically shuts down.
- 4. The powering time of the batteries indicates the battery performance.

If the powering time of the battery is much shorter than that specified, you may replace the battery or contact the service personnel.

**NOTE:** The usage life of the battery is 300 charge / discharge cycles. If the battery is improperly used, its life may be shortened.

## 14.5 Battery Disposal

You need to dispose of the battery when it is damages or severely degraded.

**NOTE:** You should observe the local regulations when disposing of the battery.

## 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

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.

$$MI = P_{r, \alpha}$$

$$\sqrt{f_{awf}} \times C_{MI}$$

$$C_{MI} = 1 \text{ (MPa } / \sqrt{\text{MHz}} \text{ )}$$

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.

## 15.5 Acoustic Power Setting

Acoustic power adjustment

Click [A. power] in the soft menu or the menu 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. At this time, the default function is disabled. It is the user's responsibility for any change to the default settings.

Default choices

Initial power 7% to 100%\*

\*Definition of 100%: The maximum acoustic power of a transducer determined by the increase in transducer surface temperature in the selected mode and the acoustic power restrictions specified by the FDA.

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 Return 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, 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).

Display accuracy of MI is ±28.5%, and TI is ±38.7%.

## 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 and controls that are receiver controls.

### ■ Direct Controls

It is possible to control, if necessary, the acoustic output with the soft menu control on the control panel. In this case, the maximum value of the acoustic output never exceeds an MI of 1.9, TI of 6 and an I<sub>SPTA.3</sub> of 720 mW/cm<sup>2</sup> in any mode of operation.

### ■ Indirect Controls

The controls that indirectly affect output are many imaging parameters. These are operating modes, frequency, focal point positions, image depth and pulse repetition frequency (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 transducer frequency.

The focal point is related to active aperture of transducer 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.) do not 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 transducer. This can be expressed by the following equation:

$$I_{\mathit{atten}} = I_{\mathit{water}} \times 10^{(-0.3/10 \times f_c \times z)}$$

Where I<sub>atten</sub> is the attenuated intensity, I<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 transducer. 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 transducer 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 transducer 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 than 0.3 dB/cm/MHz. There were also significant simplifications made for the thermal properties of tissue. Therefore, scanning through highly perfused tissue, such as the heart or vasculature, will produce significantly less thermal effect than that suggested by the Thermal Index.

Similarly, the Mechanical Index was derived to indicate the relative possibility of mechanical (cavitation) effects. The MI is based on the derated peak-rarefactional pressure and the center frequency of the ultrasound wave. The actual peak-rarefactional pressure is affected by the actual attenuation caused by tissue in the path between the transducer 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

l<sub>spta</sub> 28.5%

l<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)

Peak-rarefactional pressure 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 2005.

# **16** Guidance and Manufacturer's Declaration

The system complies with the EMC standard IEC 60601-1-2: 2007.

## $\triangle$ 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.
- The system or its components should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the system or its components should be observed to verify normal operation in the configuration in which it will be used.
- 4. 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.)

### 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— GUIDANCE
RF emissions CISPR 11	Group 1	The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The system is suitable for use in all
Harmonic Emissions IEC 61000-3-2	Class A	establishments including domestic establishments and those directly connected to the public low-voltage
Voltage Fluctuations/ Flicker Emissions 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.

	<u> </u>		
IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT-GUIDANCE
Electrostatic Discharge(ESD) IEC 61000-4-2	±6 kV contact; ±8 kV air	±6 kV contact; ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast Transient / burst IEC 61000-4-4	±2 kV for power supply lines; ±1 kV for input/output lines	±2 kV for power supply lines; ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s); ±2 kV line(s) to earth	±1 kV line(s) to line(s); ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, Short interruptions and voltage variation on power supply input voltage IEC 61000-4-11	$ \begin{array}{l} <5\% \ U_T \ (>95\% \\ dip \ in \ U_T \ ) \ for \\ 0.5 \ cycle \\ \\ 40\% \ U_T \ (60\% \\ dip \ in \ U_T \ ) \ for \ 5 \\ cycle \\ \\ 70\% \ U_T \ (30\% \\ dip \ in \ U_T \ ) \ for \ 25 \\ cycle \\ \\ <5\% \ U_T \ (>95\% \\ dip \ in \ U_T \ ) \ for \ 5 \\ sec \\ \end{array} $	$ \begin{array}{l} <5\% \ U_T \ (>95\% \\ \text{dip in } U_T \ ) \ \text{for } 0.5 \\ \text{cycle} \\ \\ 40\% \ U_T \ (60\% \ \text{dip in } U_T \ ) \ \text{for } 5 \ \text{cycle} \\ \\ 70\% \ U_T \ (30\% \ \text{dip in } U_T \ ) \ \text{for } 25 \\ \text{cycle} \\ \\ <5\% \ U_T \ (>95\% \ \text{dip in } U_T \ ) \ \text{for } 5 \\ \text{sec} \\ \end{array} $	Mains power quality should be that of a typical commercial or hospital environment. If you require continued operation during power mains interruptions, it is recommended that our product be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 HZ) magnetic field IEC 61000-4-8	3 A/m	3 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 TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT-GUIDANCE
Conduced RF IEC 61000-4-6	3 Vrms 150 kHz - 80 MHz	<b>3</b> Vrms	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 IEC 61000-4-3	3 V/m 80MHz - 2.5GHz	3 V/m	d = $1.2 \times \sqrt{P}$ 80 MHz to 800 MHz d = $2.3 \times \sqrt{P}$ 800 MHz to $2.5$ GHz Where, P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

**Note 1** At 80 MHz and 800 MHz, the higher frequency range applies.

**Note 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- **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 (W)	150kHz -80MHz d=1.2√P	80MHz-800MHz d=1.2√P	800MHz-2.5GHz 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	AC inlet cable for the main unit	2.5	Not shielded	1
2	AC inlet cable for the trolley	2.5	Not shielded	1
3	ECG Lead	1.4	Shielded	1
4	Foot-switch control cable	2.8	Not shielded	1
5	Probe cable	2.2	Shielding	1

## 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.

## $\triangle$ 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.
- 2. 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.

**∆** 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 with dry soft cloth.
    - 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.

Please refer to "13.1.5 Probes Cleaning and Disinfection" to perform cleaning and disinfection.

■ Cleaning the probe cable

Use soft dry cloth to wipe off stains from the probe cable.

If it is difficult to clean the stains thoroughly, use soft cloth dipped with mild detergent, and then let the cable air dry.

- Cleaning the monitor
  - Tool: soft dry cloth ,clear water or soapy water
  - Method:

Surface of monitor and 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 airdry the surface.

- Clean the Control 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:** The control panel should be cleaned periodically; otherwise, keys maybe blocked by dirt and buzzer dings, keys don't work.

- Clean Holders
  - Tool: dry soft cloth, soapy water, soft brush
  - Method:
  - 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 after it was taken out, and then install the holder after air-dry.
- Clean Cover
  - Tools: dry soft cloth, soapy water
  - Method:

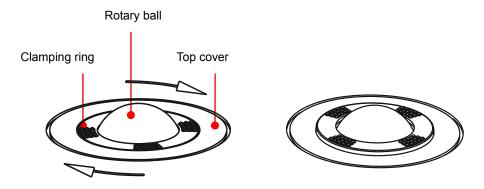
Use dry soft cloth to clean the cover of the system. If the system is dirty, moisten the soft cloth with mild soapy water and wipe off any stains, then air-dry.

**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 trackball

#### (1) Disassembling the trackball

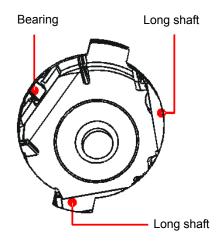
Press the bulges on the clamping ring by both hands and turn the ring about 45° clockwise until it lifts. Take out the ring and the rotary ball. Be careful not to drop the ball.



#### (2) Cleaning the trackball mechanism and rotary ball

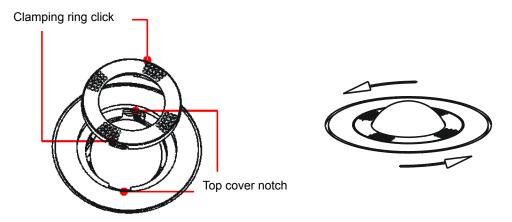
There can be a considerable buildup of finger oils and dirt on the internal trackball mechanisms. Use a cotton swab or soft dry cloth to clean the two long shafts and rotary bearing and to remove any accumulation.

Use the soft dry cloth to clean the rotary ball.



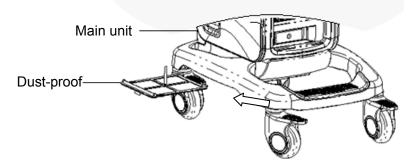
#### (3) Installing the trackball

Put the rotary ball back in the trackball mechanism and align the clamping ring with the top cover notches. Press the bulges on the ring with both hands and turn the ring about 45° counterclockwise until the ring clicks and locks. As the bulges are flush with the top cover, the ring is secured.



- Clean dust-proof covers
  - Tool: Soft brush
  - Method:
  - 1) 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 is a probe port dust-proof cover at the front of the system, Pull it out.

- 2) Cleaning: with soft brush and then wipe off the dust.
- 3) 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 blocked in the slot.



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.

### 17.1.2 Clean the Peripherals

Do the cleaning maintenance according to your actual peripheral configuration; items which are not configured can be skipped.

Content	Description
Color and	First wipe off dust or stain attached to the cover of printer with soft dry
B/W video	cloth, then clean the inside of printer. Be sure to do the cleaning
printer	maintenance according to the operation manual if is necessary.

Content	Description
Craph / toyt	First wipe off dust or stain attached to the cover of printer with soft dry
Graph / text	cloth, then clean the inside of printer. Be sure to do the cleaning
printer	maintenance according to the operation manual if is necessary.
Foot switch	Use soft dry cloth with a little mild soap water to wipe off the dust or stain
FOOL SWILCH	attached to the pedals or cable of foot switch.
	First use soft dry cloth to wipe off dust attached to glass panel of
Bar code	scanner, then the dust or strain attached to cable and bracket. Be sure to
scanner	do the especial cleaning maintenance according to the operation manual
	if is necessary.

#### 17.1.3 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.

#### 17.1.4 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.

#### 17.1.5 Checking the Circuit Breaker

Manually check to confirm that the circuit breaker can be turned on or off normally.

### 17.1.6 Checking Appearance

Check if there is any crack in the covers:

- Ultrasound system covers
- Probe appearance

#### 17.1.7 Backup of the System Hard Drive

To prevent deterioration or loss of data stored in the system hard drive, 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.

No.	Failure	Cause	Measure
1	After the power supply is turned on, the power indicator does not light on.	<ul> <li>Abnormal power system or incorrect connection of 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, 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 Barcode Reader

The product supports readers for logging data as patient ID: 1-D barcode reader (SYMBOL LS2208). The laser transmitted by the reader is Class 2 laser.

**≜**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.

 $\Delta$ 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.

#### A.1 1-D Barcode Reader

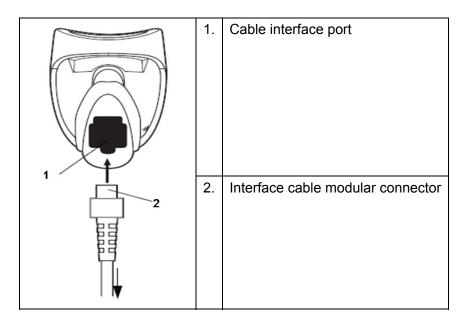
#### A.1.1 Overview



1.	LED	Green: A barcode was successfully decoded.		
		Red: A data transmission error or reader malfunction occurred.		
2.	Scan window	Scan the barcode.		
3.	Trigger	Press to decode		

## A.1.2 Setting Up the Reader (Take LS2208 as an example)

- 1. Plug the interface cable modular connector into the cable interface port on the bottom of the reader handle, and ensure the connector is properly secured.
- 2. Connect the other end of the interface cable to the host.



#### A.1.3 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.



0



1



Barcode Reader A-3











7

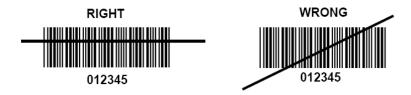




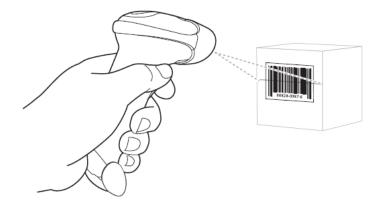
### A.1.4 Scanning in Hand-Held Mode

- 1. Ensure all connections are secure.
- 2. Aim the reader at the barcode. Press the trigger.

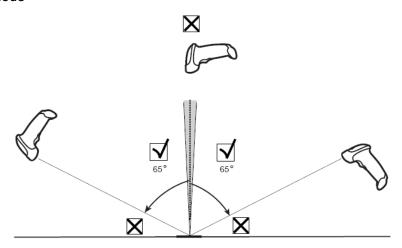
Tips: Ensure the scan line crosses every bar and space of the symbol, see the figure below.



3. Upon successful decode, the reader beeps and the LED turns green.

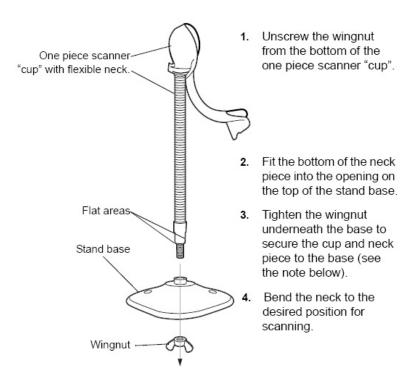


Tips: Do not hold the reader directly over the barcode. Laser light reflecting *directly* back into the reader from the barcode is known as specular reflection. This specular reflection can make decoding difficult. You can tilt the reader up to 55 forward or back and achieve a successful decode



#### A.1.5 Scanning in Hands-Free Mode

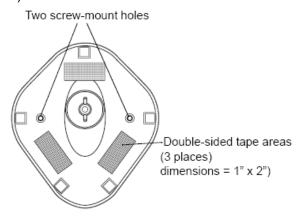
#### Assembling the Intellistand



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

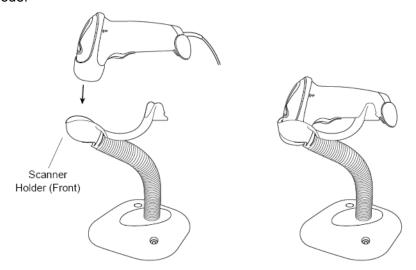
- (1) Position the assembled base on a flat surface.
- (2) Screw one #10 wood screw into each screw-mount hole until the base of the stand is secure.

#### ■ 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 hands-free mode. When you remove the reader from the stand it operates in its normal hand-held mode.



### A.2 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

Parameter	Defaults
Code 39 Full ASCII Conversion	Disable
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

### A.3 Maintenance

Cleaning the exit window is the only maintenance required. A dirty window can affect scanning accuracy.

- Do not allow any abrasive material to touch the window
- Remove any dirt particles with a damp cloth
- Wipe the window using a tissue moistened with ammonia/water
- Do not spray water or other cleaning liquids directly into the window.

# Appendix B 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.

### **B.1** Power Cord Plug

#### **B.1.1** The Power Plug

Test Item		Acceptance Criteria	
	The power plug pins	No broken or bent pin. No discolored pins.	
	The plug body	No physical damage to the plug body.	
The power plug	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	

### **B.2** Device Enclosure and Accessories

### **B.2.1 Visual Inspection**

Test Item	Acceptance Criteria	
The enclosure and	No physical damage to the enclosure and accessories.	
accessories	No physical damage to meters, switches, connectors, etc.	

No residue of fluid spillage (e.g., water, coffee, chemicals, etc.).
No loose or missing parts (e.g., knobs, dials, terminals, etc.).

#### **B.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.		

### **B.3** Device Labeling

Check the labels provided by the manufacturer or the healthcare facility are present and legible.

- Main unit label
- Integrated warning labels

#### **B.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 Ω Maximum

### **B.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

### **B.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

### **B.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

### **B.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

### **B.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**

For BF applied parts,

- 100µA in Normal Condition
- 500µA in Single Fault Condition

**NOTE:** Make sure the safety analyzer is authorized comply with requirement of IEC60601-1. Follow the instructions of the analyzer manufacturer.

### Appendix C Loading and **Transporting the DC-N3** Series Unit in a Van

#### **C.1 Overview**

When moving or transporting the unit without original packing materials, follow the instructions and precautions below to ensure maximum safety for personnel, the system and other equipment.

Minimum size for the vehicle door: 700mm (W)\*550mm (H)

Minimum size for the vehicle capacity (inside):700mm(L)\*550mm(W)\*1150mm(H)

Tools necessary: 048-002257-002122 LCD bumper, 1 peace

Strap, several peaces

#### **C.2** Securing the Unit

Use the strap, with one end tied to the front handle, the other end to a proper position of the vehicle.



Figure 1 Securing the Unit

Install the bumper onto the LCD monitor and the control panel, then strap the bumper together with the LCD monitor and control panel

Install the bumper onto the LCD monitor the control panel as shown in the figure



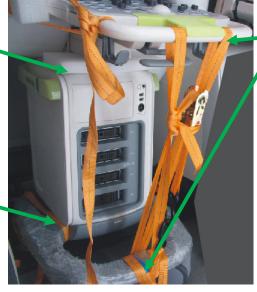
Tighten the

control table adjusting handle with the front handle using a strap

Figure 2 Securing the Unit (cont'd)

Put a bumper of 30mm in thickness (or use other soft material), adjust the support arm to anchor it on the bumper

Tighten the base to the proper position of the vehicle using the strap, making sure the unit can't be moved in any direction.



Tighten the front handle with the base using a strap

Figure 3 Securing the Unit (cont'd)

### **C.3** Details Description



Use a strap to fix the upper part of the unit

Figure 4 Details

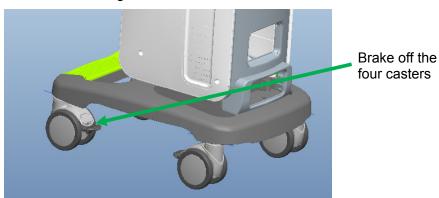
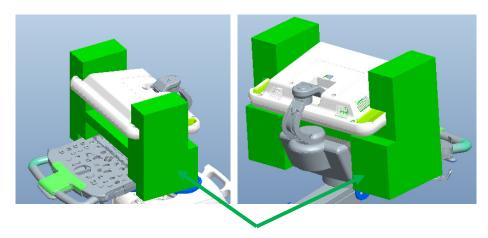


Figure 5 Details (cont'd)



LCD bumper position (front view and rear view)

Figure 6 Details (cont'd)

### Appendix D iScanHelper

By providing the referential information, such as, the ultrasonic image, the anatomic graphic, scanning pictures/other scanning tips or diagnosis comments, the system helps the doctors to operate the scanning by iScanHelper. Furthermore, it is a good platform for the self-learning and training of ultrasound scanning technique for doctors. The system also plays a role in the assistant software system in fulfilling training and education.

Tips: iScanHelper feature is available under abdominal, urological and small parts exam modes.

NOTE:

THIS "iScanHelper" IS FOR REFERENCE OR TUTORIAL PURPOSES ONLY, AND THE MANUFACTURER WILL NOT BE LIABLE FOR DAMAGES AND/OR OTHER UNDESIRABLE CONSEQUENCE IN ANY KIND THAT MAY OCCUR TO THE PATIENT OR THE USERS BY USING THE SOFTWARE.

#### D.1 Enter/ Exit

■ Enter

Press the user-defined key for entering iScanHelper (setting path: [Setup] (F10)  $\rightarrow$  [System]  $\rightarrow$  [Key Config.]).

■ Exit

Press the user-defined key again to exit iScanHelper.

### D.2 Use iScanHelper for Reference

- 1. Perform ordinary scanning procedure.
- 2. Press the user-defined key for entering iScanHelper to enter iScanHelper status.
- 3. Rotate the trackball to move the cursor onto the target view name in the view selecting box and then press <Set>.
- 4. Perform scanning according to information displayed on the help information area. You can zoom in a single window in the help information area to see the window more clearly. For details, please refer to "D.4.3 Single/quad-window Display".
- 5. Press the user-defined key for entering iScanHelper again to exit.

# D.3 Use iScanHelper for Learning or Training

- 1. Switch to the exam modes that support iScanHelper.
- 2. Press the user-defined key for entering iScanHelper to enter iScanHelper status.
- 3. Learn and practise views by system defaulted sequence according to the information displayed on help information area; or select unfamiliar views to practise.
  - You can zoom in a single window in the help information area to see the information. For details, please refer to "D.4.3 Single/quad-window Display".
- 4. Press the user-defined key for entering iScanHelper again to exit iScanHelper.

### D.4 Basic Screen and Operation

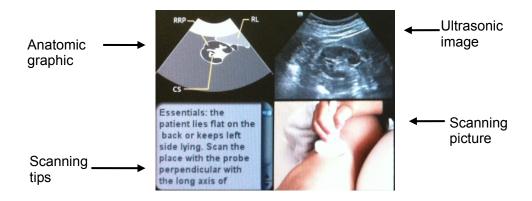


#### D.4.1 View Selecting Area

Rotate the trackball to move the cursor onto the target view and press <Set>, related information will be displayed on the help information area.

#### D.4.2 Help Information Area

Help information area displays on the lower right corner of the screen, providing ultrasonic image, anatomic graphic, scanning picture and scanning tips.



- Ultrasonic image
   It is used to compare with images scanned by the operator.
- Anatomic graphic
   Related anatomical tissue information are provided here.
- Scanning picture

Ordinary scanning tips can be observed here, including posture, probe mark, probe swing/sweep techniques.

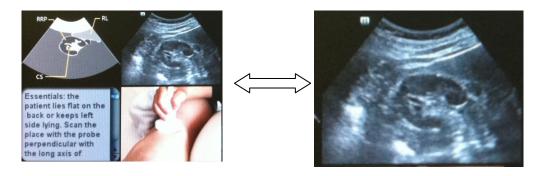
Scanning tips

You can read tissue related anatomical information and adjacent tissue information here.

#### D.4.3 Single/quad-window Display

You can zoom in the anatomic graphic, ultrasonic image as well as scanning picture to view those information more conveniently.

Press <Cursor> to obtain the cursor. Move the cursor on the anatomic graphic, the ultrasonic image or scanning tips. Double-click <Set> to go to the single window of each of them. Double-click single window again to return to quad-window display.



# D.5 Measurement, Comments, and Body Mark

Switching probe or exam, measurement, comments and the body mark are unavailable under iScanHelper status.

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