# DC-8 Diagnostic Ultrasound System

# **Operator's Manual**

[Basic Volume]

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This version of the manual applies to 01.01.00 and 01.02.00 software for the DC-8 ultrasound system.

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- the product is used in accordance with the instructions for use.
- MindrayVNC ver. 1.0 is free open source software, the performance of MindrayVNC ver. 1.0 is not guaranteed by MINDRAY.

#### <sup>▲</sup> Note <sup>▲</sup>

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

# **▲** Warning **▲**

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

#### Warranty

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

#### **Exemptions**

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

This warranty shall not extend to:

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

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#### **Important Information**

- 1. It is the customer's responsibility to maintain and manage the system after delivery.
- 2. The warranty does not cover the following items, even during the warranty period:
  - (1) Damage or loss due to misuse or abuse.
  - (2) Damage or loss caused by Acts of God such as fires, earthquakes, floods, lightning, etc.
  - (3) Damage or loss caused by failure to meet the specified conditions for this system, such as inadequate power supply, improper installation or environmental conditions.
  - (4) Damage or loss due to use of the system outside the region where the system was originally sold.
  - (5) Damage or loss involving the system purchased from a source other than Mindray or its authorized agents.
- 3. This system shall not be used by persons other than fully qualified and certified medical personnel.
- 4. DO NOT make changes or modifications to the software or hardware of this system.
- 5. In no event shall Mindray be liable for problems, damage, or loss caused by relocation, modification, or repair performed by personnel other than those designated by Mindray.
- 6. The purpose of this system is to provide physicians with data for clinical diagnosis. It is the physician's responsibility for diagnostic procedures. Mindray shall not be liable for the results of diagnostic procedures.
- 7. Important data must be backed up on external memory media.
- 8. Mindray shall not be liable for loss of data stored in the memory of this system caused by operator error or accidents.
- 9. This manual contains warnings regarding foreseeable potential dangers, but you shall always be alert to dangers other than those indicated as well. Mindray shall not be liable for damage or loss that results from negligence or from ignoring the precautions and operating instructions described in this operator's manual.
- 10. If the manager for this system is changed, be sure to hand over this operator's manual to the new manager.

#### **About This Manual**

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

#### **Notation Conventions**

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

**NOTE:** Indicates information of interest to users of this system as to exceptional conditions or operating procedures.

#### CAUTION: The diagnostic ultrasound system is not intended for ophthalmic use. Its use in this clinical specialty is contraindicated. U.S.A. Federal Law restricts this device to sale by or on the order of a physician.

#### **Operator's Manuals**

The operator's manuals consist of manuals for the main unit and manuals for transducers. The English manuals are provided on paper; however, the manuals, which are translated into languages other than English, are provided in CD (Compact Disc).

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]
- 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.

#### **Manuals in Compact Disc**

- Operator's Manual [Basic Volume]
- Operator's Manual [Advanced Volume]
- Operation Note

# NOTE:The manuals in CD are the manuals translated into languages other than English<br/>according to English manuals.When you find that the contents of the manuals in CD are NOT consistent with the<br/>system or English manuals, please ONLY refer to the corresponding English manuals.The accompanying manuals may vary depending upon the specific system you<br/>purchased. Please refer to the packing list.

#### **Software Interfaces in This Manual**

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

#### Conventions

In this manual, these conventions are used to describe the buttons on the control panel, the items in menu, buttons in dialog box and some basic operations:

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

# **1** Safety Precautions

# 1.1 Safety Classification

- According to the type of protection against electric shock: CLASS I EQUIPMENT
- According to the degree of protection against electric shock: Type-BF applied part
- According to the degree of protection against harmful ingress of water: The main unit belongs to IPX0
   Probes belong to IPX7
   Footswitch belongs to IP68
- According to the degree of safety of application in the presence of a FLAMMABLE ANESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE
- According to the mode of operation: CONTINUOUS OPERATION
- According to the installation and use: MOBILE EQUIPMENT

# **1.2 Meaning of Signal Words**

In this manual, the signal words **ADANGER**, **AWARNING**, **ACAUTION**, **NOTE** and Tip are used regarding safety and other important instructions. The signal words and their meanings are defined as follows. Please understand their meanings clearly before reading this manual.

Signal word	Meaning
	Indicates an imminently hazardous situation that, if not avoided, will result in death or serious injury.
	Indicates a potentially hazardous situation that, if not avoided, could result in death or serious injury.
	Indicates a potentially hazardous situation that, if not avoided, may result in minor or moderate injury.
Â	Indicates a high voltage, if not avoided, may result in electric shock.
NOTE	Indicates a potentially hazardous situation that, if not avoided, may result in property damage.
Description	Important information that helps you use the system more effectively.

#### **1.3 Meaning of Safety Symbols**

Symbol	Description
Ŕ	Type-BF applied part The ultrasound probes connected to this system are type-BF applied parts. The ECG leads and PCG transducer applied on this system are type-BF applied parts.
$\triangle$	General warning, caution, risk of danger.

# **1.4 Safety Precautions**

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

<b>▲DANGER</b> :	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.
	1. 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.
- 9. DO NOT use a probe that has a damaged, scratched surface, or exposed wiring of any kind. Immediately stop using the probe and contact Mindray Customer Service Department or sales representative. There is risk of electric shock if using a damaged or scratched 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.
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.

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.</end>
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.	Read the Acoustic Output Principle in the operation manual carefully before operating this system on clinical examination.
15.	The cover contains natural rubber that can cause allergic reactions in some individuals.
16.	Please use the ultrasound gel compliant with the relevant local regulations.
17.	Normal operation may be affected by unstable mains power supply; it is recommended that our product be powered from an uninterruptible power supply.
18.	The ultrasound system can be powered by connecting to mains power supply or powered by internal battery, if you have any doubt with stability of mains power protective grounding, please use internal battery.

**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.</freeze>
7.	Remove the ultrasound gel from the face of the probe when the examination is completed. Water in the gel may enter the acoustic lens and adversely affect the performance and safety of the probe.
8.	You should properly back up the system to a secure external storage media, including system configuration, settings and patient data. Data stored to the system's hard drive may be lost due to system failure, improper operation or accident.
9.	Do not apply external force to the control panel. Otherwise, the system may be damaged.
10.	If the system is used in a small room, the room temperature may rise. Please provide proper ventilation and free air exchange.
11.	To dispose of the system or any part, contact Mindray Customer Service Department or sales representative. Mindray is not responsible for any system content or accessories that have been discarded improperly. Mindray is not responsible for any system content or accessories that have been discarded improperly.
12.	Electrical and mechanical performance may be degraded due to long usage (such as current leakage or distortion and abrasion); the image sensitivity and precision may become worse too. To ensure optimal system operations, it is recommended that you maintain the system under a Mindray service agreement.
13.	The replaceable fuse is inside the chassis. Refer replacing job to Mindray service engineers or engineers authorized by Mindray only.
14.	Do not turn OFF the power supply of the system during printing, file storage or invoking other system operations. An interrupted process may not be completed, and can become lost or corrupted.
15.	The iScape feature constructs a single extended image from a series of individual image frames. The quality of the final image is user-dependent and requires skill to efficiently apply the feature and technique. Exercise caution when measurements are performed from an iScape image.
16.	Ensure that the current exam date and time are the same as the system date and time.

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

1.	The probe is only for use with the specified ultrasonic diagnostic system. Please refer to the "2.5.2 Probes and Needle-guided Brackets Available " to select the proper probe.
2.	The ultrasonic probe must be used only by qualified professionals.
3.	Confirm that the transducer and probe cable are normal before and after each examination. A defective probe may cause electric shock to the patient.
4.	Do not subject the probe to shock. A defective probe may cause electric shock to the patient.
5.	Do not disassemble the probe to avoid the possibility of electric shock.

- 6. Never immerse the probe connector into liquids such as water or disinfectant because the connector is not waterproof. Immersion may cause electric shock or malfunction.
- 7. A probe sheath must be installed over the probe before performing intra-cavity or intra-operative examination.

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

NOTE:	Read the following precautions to prevent the probe from malfunction:	
	<ul> <li>Before connecting or disconnecting the probe, freeze or turn off the diagnostic ultrasound system.</li> </ul>	
	<ul> <li>Clean and disinfect the probe before and after each examination.</li> </ul>	
	<ul> <li>After the examination, wipe off the ultrasound gel thoroughly. Otherwise, the ultrasound gel may solidify and the image quality would be degraded.</li> </ul>	

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:
  - ambient temperature: 0°C to 40°C
  - relative humidity: 30% to 85% (no condensation)
  - atmospheric pressure: 700 hPa to 1060 hPa
- 3. Use the D8-3E/D6-2E probe under the following ambient conditions:
  - ambient temperature: 10°C to 40°C
  - relative humidity: 30% to 85% (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

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

# 1.6 Warning Labels

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

The symbol  $\triangle$  on the warning labels indicates safety precautions.

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

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

No.	Warning Labels	Meaning
1.	1)	1) Do not sit on the system.
		2) General warning, caution, or risk of danger.
	2) 3)	<ol> <li>DANGER: There is explosion risk if the system is used in flammable anesthetics.</li> </ol>
2.	When the casters are locked, DONOT push the trolley.	When the casters are locked, DO NOT push the trolley.
3.	CAUTION           Do not place the system on a sloped surface. Otherwise the system may slide unexpectedly, resulting in personal nipury and the system margitunction. The system should be moved over a sloped surface by two persons to ensure safety.           Image: Comparison of the system of the system may be added over a sloped surface by two persons to ensure safety.	CAUTION: 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.
	High voltages inside may cause electric shock. Only service engineers should remove covers.	CAUTION: DO NOT open the system covers, because the high voltage inside may cause electric shock.
4.		Beware of excessive stress exerted to the system.
5.	ETL CLASSIFIED	CONFORMS TO UL 60601-1, IEC 60601-2-37 CERTIFIED TO CSA C22.2 No 601.1, CSA C22.2.60601.2.37
	Intertek	
	3191955	

**2** System Overview

# 2.1 Intended Use

The DC-8 diagnostic ultrasound system is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, pediatric, small organ (breast, thyroid, testes), neonatal cephalic, adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), cardiac adult, cardiac pediatric, peripheral vessel and urology exams.

### 2.2 Contraindication

The diagnostic ultrasound 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 M Mode	B M Anatomical M: Free Xros M, Free Xros CM
C Mode	Color Power
	DirPower
D Mode	PW CW
Special imaging	Smart 3D Static 3D
	4D
	iScape (panoramic imaging)
	Elastography
	TDI (Tissue Doppler imaging)

#### 2.4.2 Power supply

Voltage	100-127V $\sim$ or 220 $-$ 240 V $\sim$
Frequency	50/60Hz
Power consumption	800VA
Circuit breaker	250V~, 13A
Fuse	350V~T0.4AL
	250V~T6.3AH
	250V~T15AH

#### 2.4.3 Environmental Conditions

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

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

#### 2.4.4 Dimensions and Weight

Dimension: 1355~1800mm (H)×930mm (D)×585mm (W)Net weight: less than 120Kg.

#### 2.5 System Configuration

#### 2.5.1 Standard Configuration

- Main unit
  - Main unit with DSP chip
  - Main unit without DSP chip
- Accessories
  - Cover ground line
  - Probe holder
  - Gel holder
  - Stylus pen
  - Control panel overlay
  - Dust cover
  - Probe socket dust cover
  - Operator's manual
  - Operation note
  - Cables
  - Gel (made by Eco-Med Pharmaceuticals, model: Eco Gel 200, K955246)
  - Compact disk

#### 2.5.2 Probes and Needle-guided Brackets Available

Probe model	Probe Type	Intended Use	Region Applied
C5-2E	Convex	Fetal, abdominal, pediatric, musculo-skeletal (conventional), peripheral vessel	Body surface
C7-3E	Convex	Fetal, abdominal, pediatric, peripheral vessel	Body surface
L12-3E	Linear	Abdominal, pediatric, small organ(breast, thyroid, testes), neonatal cephalic, musculoskeletal (conventional, superficial), peripheral vessel	Body surface
L14-6NE	Linear	Abdominal, pediatric, small organ(breast, thyroid, testes), neonatal cephalic, musculoskeletal (conventional, superficial), peripheral vessel	Body surface
L14- 6WE	Linear	Abdominal, pediatric, small organ(breast, thyroid, testes), neonatal cephalic, musculoskeletal (conventional, superficial), peripheral vessel	Body surface
P4-2E	Phased	Abdominal, pediatric, adult cephalic, cardiac adult, cardiac pediatric, neonatal cephalic	Body surface
D6-2E	Volume	Fetal, abdominal, pediatric	Body surface
D8-3E	Volume	Fetal, abdominal, pediatric	Body surface
V11-3E	Convex	Fetal, trans-rectal, trans-vaginal, urology	Transvaginal

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

Probe model	Needle-guided Bracket Model	Biopsy angle/depth (±1°)	Applicable Biopsy Needle
V11-3E	NGB-004 metal/needle un- detachable	1	16G, 17G, 18G
L14-6NE / L12-3E / L14-6WE	NGB-007 plastic/needle detachable metal/needle detachable	40°, 50°, 60°	Metal: 14G, 16G, 18G, 20G, 22G Plastic: 13G, 15G, 16G, 18G, 20G
P4-2E	NGB-011 metal/needle un- detachable	11°, 23°	13G, 15G, 16G, 18G, 20G
C5-2E	NGB-015 metal/needle detachable	25°, 35°, 45°	14G, 16G, 18G, 20G, 22G
C7-3E	NGB-019 metal/needle detachable	20°、30°、40°	14G、16G、18G、20G、22G

#### 2.5.3 Options

No.	Item	Remarks
1.	Physiology module (including ECG, PCG, and the ECG leads)	1
2.	PCG transducer	1
3.	6 PIN three-cable lead	PCG should be configured first.
4.	Footswitch	USB port: 971-SWNOM (2-pedal) USB port: SP-997-350(3-pedal)
5.	4D module	The main unit with DSP chip should be configured.
6.	CW module	1
7.	Gel Warmer	1
8.	Wireless Adapter	1
9.	Built-in DVR	1
10.	DICOM Basic (including: Verify (SCU, SCP), task management, DICOM storage, DICOM print, DICOM storage commitment, DICOM media storage (including DICOM DIR) etc.)	/
11.	DICOM Worklist	DICOM Basic should be configured first.
12.	DICOM Query/Retrieve	DICOM Basic should be configured first.
13.	DICOM MPPS	DICOM Basic should be configured first.
14.	DICOM OB/GYN Structured Report	DICOM Basic should be configured first.
15.	DICOM Cardiac Structured Report	DICOM Basic should be configured first.
16.	DICOM Vascular Structured Report	DICOM Basic should be configured first.
17.	DICOM Breast Structured Report	DICOM Basic should be configured first.
18.	Abdominal Package	1
19.	Obstetrical Package	1
20.	Gynecological Package	1
21.	Cardiac Package	1
22.	Small Parts Package	1
23.	Urological Package	1
24.	Vascular Package	1
25.	Pediatric Package	1
26.	Smart OB	Obstetrical Package should be configured first.
27.	Emergency Medicine Package	1
28.	Nerve Package	1

No.	Item	Remarks
29.	IMT	Vascular Package should be configured first.
30.	iWorks	1
31.	Free Xros M (anatomical M module)	1
32.	Free Xros CM (Curved anatomical M module)	/
33.	TDI (including TVI/TVM/TVD)	1
34.	TDI QA	TDI should be configured first.
35.	iScape View	1
36.	Smart 3D	1
37.	Elastography	The main unit with DSP chip should be configured.
38.	iNeedle	1

#### 2.5.4 Peripherals Supported

Item	Model
Black/white digital video printer	SONY UP-D897, MITSUBISHI P93DC
Black/white analog video printer	SONY UP-897MD, MITSUBISHI P93W-Z
Color digital printer	SONY UP-D23MD, SONY UP-D25MD
Color analog printer	SONY UP-20, MITSUBISHI CP910E
Graph/text printer	HP Officejet J3600, HP Officejet6000, HP Color LaserJet CM1015 MFP, HP Deskjet1280, Epson office 85ND
Wireless printer	HPOTOSMART PLUS e-ALL-IN-ONE B 210a
Footswitch	USB port: 971-SWNOM (2-pedal)
	USB port: SP-997-350(3-pedal)
Bar code reader	SYMBOL LS2208

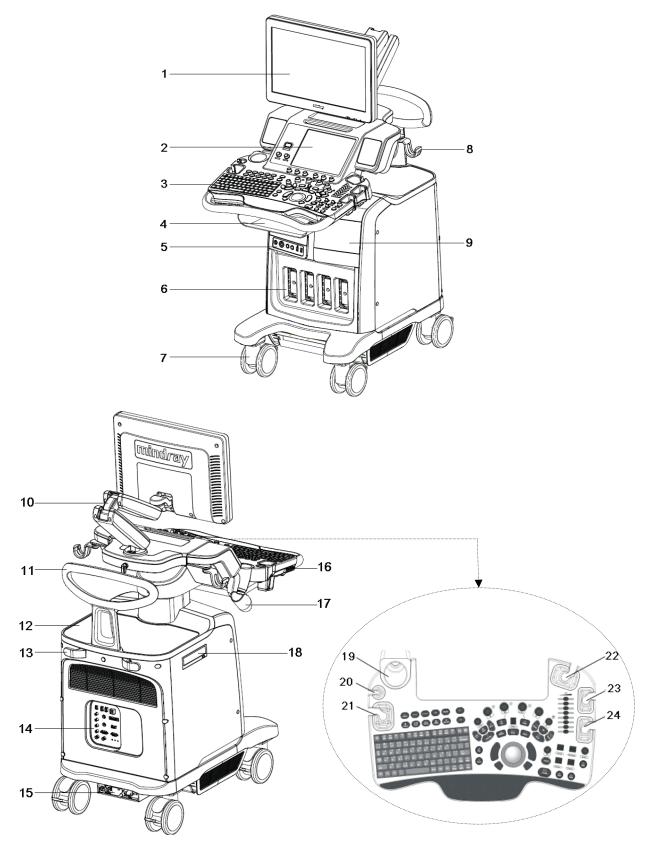
Parts can be used in patient environment:

- Main unit;
- Probes;
- Footswitch;
- Printers: SONY UP-D897, MITSUBISHI P93DC, SONY UP-897MD, MITSUBISHI P93W-Z, SONY UP-D23MD, SONY UP-D25MD, SONY UP-20, MITSUBISHI CP910E.



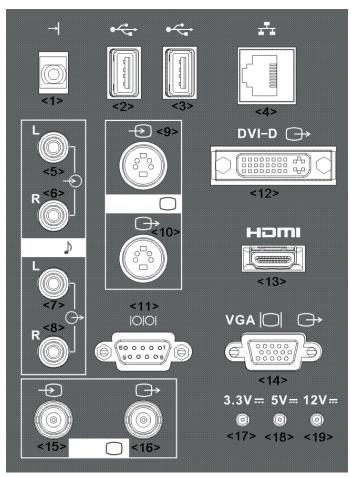
This system complies with IEC60601-1-2:2007, and its RF emission meets the requirements of CISPR11 Class B. In a domestic environment, the customer or the user should guarantee to connect the system with Class B peripheral devices; otherwise RF interference may result and the customer or the user must take adequate measures accordingly.

#### 2.6 Introduction of Each Unit



No. Name		Function		
1.	Monitor	Displays the images and parameters during scanning.		
2.	Touch screen panel	Operator-system interface or control.		
3.	Main control panel	Operator-system interface or control.		
4.	Storage compartment	Used for placing small objects.		
5.	Physio panel	Used for connecting the ECG leads, PCG transducer, external ECG device and PCG signal etc.		
6.	Probe port	Sockets connecting transducers and the main unit.		
7.	Caster	Used for securing or moving the system.		
8.	Probe cable hook	Used for fixing the probe cable.		
9.	Compartment	Used for placing B/W video printer.		
10.	Monitor support arm	Supports the monitor, for adjusting the height and position of the monitor.		
11.	Rear handle	Used for pushing and moving the system.		
12.	Color video printer placing table	Used for placing the color video printer.		
13.	Hanger	1		
14.	I/O Panel	Interface panel used for inputting and outputting signals.		
15.	Power supply panel	Electrical port panel.		
16.	USB_MIC port	USB port and MIC port.		
17.	Intracavitary probe holder	Used for fixing the intracavitary probe.		
18.	DVD-RW	DVD-RW drive.		
19.	Ultrasound gel holder/ gel warmer	Used for placing the ultrasound gel or installing the gel warmer.		
20.	Pencil probe holder	Reserved.		
21.	Probe holder	Used for placing general probe or 4D volume probe.		
22.	Probe holder	Used for placing general probe or 4D volume probe.		
23.	Probe holder	Used for placing general probe.		
24.	Probe holder	Used for placing general probe.		

# 2.7 I/O Panel

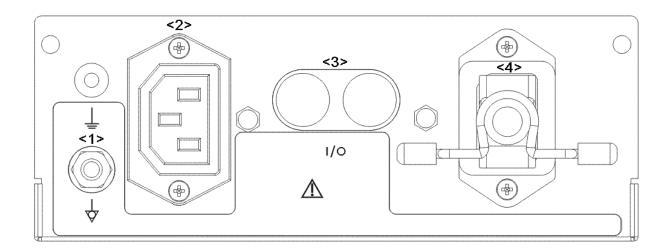


No.	Symbol		Function		
<1>	→		Connects the control port of the video printer.		
<2>	- •4		USB ports.		
<3>					
<4>	<b>₽</b> ₽		Network port.		
<5>			Audio signal input port, left channel.		
<6>	$\rightarrow$		Audio signal input port, right channel.		
<7>	- 🕀		Audio signal output port, left channel.		
<8>			Audio signal output port, right channel.		
<9>	S-VIDEO		Used for separate video input.		
<10>	3-VIDEO	$\ominus$	Used for separate video output.		
<11>	10101		Serial port, connects the serial port devices.		
<12>	DVI−D⊖→		Used for DVI-D signal output.		
<13>	HDMI		High definition multimedia interface.		
<14>			VGA signal output.		
<15>	VIDEO $\bigcirc$		Used for composite video input.		
<16>			Used for composite video output.		
<17>	1		3.3V power indicator.		
<18>	1		5V power indicator.		
<19>	1		12V power indicator.		

**NOTE:** 1. Hot-plug is not allowed on the ports including VGA IN, RGB IN, RGB OUT, parallel port, and DVI port (when DVI is used as VGA signal output).

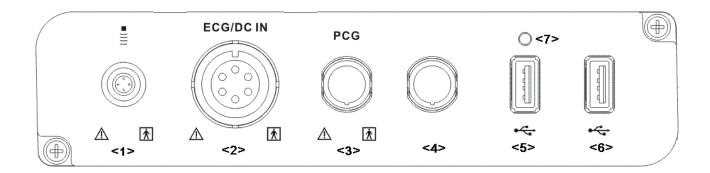
- 2. As the analog video output quality depends on the output image size, when using the video port for analog printing, try using smaller image size to get better print effect.
- 3. S-VIDEO port performs better in analog video print.

# 2.8 Power Supply Panel



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

# 2.9 Physio Panel (ECG & PCG)



No.	Name	Function		
<1>	Pencil probe port	Reserved (used for connecting a pencil probe).		
	ECG lead signal input	Connects to ECG leads, to directly obtain the ECG signals of the patient.		
<2>	port / external ECG signal input port	Connects the signal output port of external ECG monitoring device.		
<3>	PCG signal input port	Connects to PCG transducer, to directly obtain the PCG signals of the patient.		
<4>	Reserved port	Port for reserved function.		
<5>/<6>	USB ports	Connects USB devices.		
<7>	Indicator	Port for reserved function.		



#### Exam Operation

Symbol	Name	Control Type	Function	
End Exam	End Exam	Functional button	End the current exam.	
Patient Patient Functional Enter/ exit Patient Information		Enter/ exit Patient Info screen.		
Probe	Probe/Exam switch	Functional button	Switch probe and exam mode.	
문 Review	Review	Functional button	Enter/ exit the Review screen.	
Report	Report	Functional button	Open/ close the exam report.	
F2 iStation	1	Functional button	Enter/ exit the Patient Info system.	

#### **Cursor Operation**

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

### Image operations

Symbol	Name	Control Type	Function
8	/	Pressable knobs	Press to enter B mode; Rotate to adjust B mode gain.
() N X	/	Pressable knobs	Press to enter M mode, and rotate to adjust M gain; while in 3D/4D mode, rotate the knob to make the 3D image to rotates around X axis.
(Z)	/	Pressable knobs	Press to enter Color mode, and rotate to adjust Color or Power gain; while in 3D/4D mode, rotate the knob to make the 3D image to rotate around Z axis.
Power	1	Кеу	Enter Power mode.
PW	/	Pressable knobs	Press to enter PW mode, and rotate to adjust PW or CW gain; while in 3D/4D mode, rotate the knob to make the 3D image to rotate around Y axis.
CW	1	Кеу	Enter CW mode.
Elasto	1	Кеу	Enter elastography.
<i>i</i> Scape	1	Кеу	Enter iScape.
05	/	Кеу	Enter 3D imaging function: Smart 3D or Static 3D.
<b>1</b>	1	Pressable knobs	Press to enter 4D function; rotate to make the 3D image rotation.

ТОІ	1	Кеу	Enter TDI imaging.
P1	1	Undefined Button	Undefined Button, set by the user in preset.
P2	1	Undefined Button	Undefined Button, set by the user in preset.
Sinole	/	Functional button	Enter single window in multiple window mode.
	1	Functional button	Enter Dual mode in Non-Dual mode; Switch between the two display windows in Dual mode.
P B	/	Functional button	Enter Quad mode in Non-Quad mode; Press to switch among the display windows in Quad mode.
	/	Functional button	Switching key: Press to change the currently active window. Start/ stop image acquisition in iScape or 3D/4D mode.
년 Cine	Cine Review	Functional button	Enter/ exit the Cine Review status.
Save1 Save2	Save 1/ Save 2	Functional button	Save images in a way as preset.

### Parameter Adjustment

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

Symbol	Name	Control Type	Function
Caliper	Measurement	Functional button	Enter or exit the general measurement mode.
Measure	Caliper	Functional button	Enter/ exit the application measurement mode.
(LIEB)	Comment	Functional button	Enter/ exit the textual comment status.
Arrow	Arrow	Functional button	Enter/ exit the arrow comment status.
Ciest	Delete	Functional button	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. Long press <clear> to delete the mode related elements or all elements on the screen.</clear></clear>
Eody Wark	Body Mark	Functional button	Enter/ exit Body Mark.

#### Measurement, Comment, and Body Mark Operations

#### Other Operations

Symbol	Name	Control Type	Function
Physio	1	Functional button	Enter/ exit ECG, PCG control screen.
Print	Print	Functional button	Print.
Freeze	Freeze	Functional button	Freeze/ unfreeze the image.

#### Keyboard

Esc	F1 Help	F2 / Station	F3	F4	F5 I	F6 F Q\$a				F11 Blopsy	F12	Home Set Home	<b>Delete</b> Text
1 1 1 i	@ 2 <sup>2</sup>	# 3 <sup>3</sup>	\$ 4 £	% 5€	^ 6	&. 7	* 8	( 9	) 0	- - ¥	+ + = ×	← Back	space
-→I I← Tab	Ă Q	w	É	R®	Þ T	Û Y	Ú U	1	o	Ö P	{ [ «	} ] »	 \ 7
Caps Lock	A	§ Sβ	Ð <b>D</b> α	Š F	Ž G	Œ H	Ÿ J	к	ø L	: • ; ¶	11 /	لم Ente	r
습 Shift		Z Z	x	¢ C©	v	в	Ñ N	Μμ	< ç ,	>	? / ¿	∱ PgUp	仓 Shift
Ctrl	Fn	Alt	~					Alt Gr	Ctrl	Del	← Home	↓ PgDn	→ End

#### Common functional keys

No.	Key	Function
1.	Enter	Confirm the input data; or moves the cursor to the head of next row of the text or the input field.
2.	Esc	Cancel the operation or exit.
3.	Tab	Jump to the next operable item.
4.	Back space	Insert a space.
5.	Caps Lock	Switch the upper/ lower case.
6.	Home	Activate the Home function: return to start position of comment.
7.	Delete Text	Delete all comments on the screen.
8.	Direction-control keys	Move the cursor one letter each time; or, select the ambient one in a selectable area.
9.	Del	Delete the character after the cursor
10.	Back Space	Delete the character before the cursor

■ Functions of the Keys F1 to F12

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

■ Functions of key combination

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

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

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

- [Alt Gr] key Combined with other letter keys, [Alt Gr] can be used for entering other languages.
   Press [Alt Gr], and meanwhile press a letter key, the letter on the upper-right corner of the key can be entered.
- [Ctrl] key combined keys
   In iStation or Review screen, use <Ctrl> and <Set> to select more than one patient.
- [Fn] key

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

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

## 2.10.2 Touch Screen

The touch screen is mainly used for image parameters adjustment, as well as some commonlyused functions performed in each application mode.



No.	Name	Function
<1>	Power button	Power on/off the power supply.
<2>	Battery status indicator	Reserved.
<3>	AC power indicator	Indicates if the main unit is connected to the AC power supply. When connected, the indicator turns green.
<4>	Standby indicator	Reserved
<5>	Hard disk indicator	HDD status indicator.
<6>	Acoustic power	Rotate to adjust acoustic power value, and press to increase the value.
<7>	Volume	Rotate to adjust audio volume, and press to turn on/off the sound.
<8>	Pressable knobs	To adjust the corresponding functions on the touch screen.

#### 2.10.2.1 Touch Screen Brightness and Contrast Adjustment

- 1. Press [F10] to enter the Setup menu.
- 2. Click [Maintenance]->[Other] to enter the screen.
- 3. Click [Touch Screen Preset], contrast and brightness adjustment dialogue box will be displayed on the touch screen. Click "+" to increase the brightness or contrast, click "-" to decrease the brightness or contrast.
- Click [Accept] to finish the adjustment, and the system returns to preset status; press <ESC> to exit.

**NOTE:** Avoid operating under direct sunlight, or the touch screen could be blocked. Do not place anything on the touch screen, or the screen view will be blocked.

## 2.11 Symbols

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

Symbo	ol	Description				
<b>★</b>		Type-BF applied part				
$\triangle$		Refer to relevant content in the Operator's Manual, to avoid safety accidents				
A		Dangerous voltage				
$\sim$		AC (Alternating current)				
<u> </u>		Functional grounding				
~  ∳		Equipotentiality				
		protective earth				
I/O		Circuit breaker ON/OFF				
$\odot/\dot{\bigcirc}$		Power button				
		Footswitch				
((((		Transducer sockets				
		Network port				
10101		Serial port				
<b>→</b>		Connects the control port of the video printer				
●~~ <u></u>		USB port				
DVI−D⊖⇒		Used for DVI-D signal output.				
		Used for VGA input.				
S-VIDEO	$\widehat{\boldsymbol{\Phi}}$	Reserved, used for separate video input				
	ᠿ	Reserved, used for separate video output				
AUDIO 🕽	Ð	Reserved, used for stereo audio input.				
		Reserved, used for stereo audio output.				
	$\Rightarrow$	Reserved, used for composite video input				
$\ominus$		Reserved, used for composite video output				
HDMI		High definition multimedia interface.				
Ø		Microphone input jack				
1		When the lever located at the bottom of the monitor support arm points to $\widehat{\mathbf{I}}$ , you can move the monitor to the right and left.				

Symbol	Description
Ĩ	When the lever located at the bottom of the monitor support arm points to $\widehat{\mathbf{I}}$ , the supporting arm is fixed at the middle position.
SN	Product serial number
M	Manufacture date

# **3** System Preparation

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 devices.

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

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.

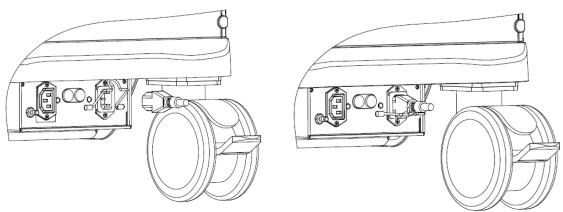
## 3.2 Connecting Power Cord & Protective Grounding

## 3.2.1 Connecting Power

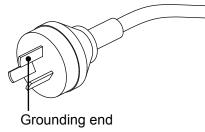
 The power system must meet the following requirements: Voltage:220-240V~or 100-127V~
 Power supply frequency: 50/60Hz

Power consumption: greater than 800VA

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



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



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

## 3.2.2 Equipotential terminal

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

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

## 3.2.3 Power ON the System

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

Check before Power ON

Check the system before the system is powered on:

No.	Check Item
1	The temperature, relative humidity and atmospheric pressure shall meet the requirements
	of operating conditions. See "2.4.3 Environmental Conditions " for details.
2	There shall be no condensation.
	There shall be no distortion, damage or dirt on the system and peripheral devices.
3	If any dirt is found, cleaning shall be performed as defined in section "17 System
	Maintenance".
4	There shall be loose screws on the monitor or control panel.
5	There shall be no cable damage (e.g. power cord). Maintaining secure connections to the
Ū	system at all times.
6	The probes and probe cables shall be free of damage or stains.
0	See "13 Probes and Biopsy" chapter for details of probe cleaning and disinfection.
7	No miscellaneous odds and ends are allowed to be attached or affixed to the control
1	panel.
	Ensure that all connections are free from damage and remain clear of foreign object
8	blockages.
	There shall be no obstacles around the system and its air vent.
9	Probe cleaning and disinfection.
10	The overall scanning environment and field must be clean.
11	The locking mechanism of casters can work normally.

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

• Check the system after it is powered on

To check the system after the system is powered on:

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

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

#### 3.2.4 Power OFF the System

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

To power off your system normally

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

- Shut down: To power off the system normally.
- Cancel: To cancel the operation.

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

**NOTE:** Do not turn off the breaker before the power indicator is off.

To shut down the system in a direct way if you cannot do it normally: Directly turn off the circuit breaker or unplug the power cord.

NOTE: 1. DO NOT rush shutdown of the system in a direct way. It may destroy the data.
2. After the system is upgraded, using "Shut Down" to power off the system to make the upgraded data effective.

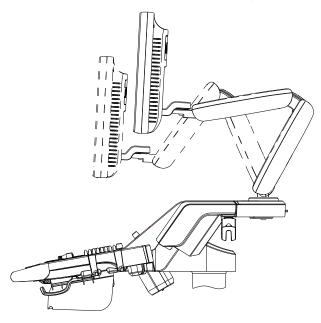
## 3.3 Monitor Adjustment

## 3.3.1 Monitor Position Adjustment

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

Height adjustment

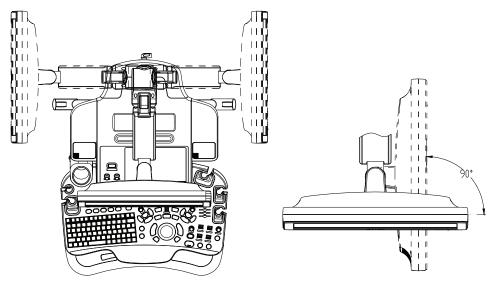
Move the monitor support arm up or down to adjust the height.



**NOTE:** Take care of your hands when adjust the monitor up and down.

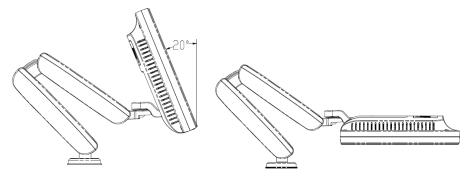
Rotate the monitor

The monitor can be rotated  $\pm 90^{\circ}$  along with the supporting arm; or fix the supporting arm; the monitor can be rotated  $\pm 90^{\circ}$  alone.



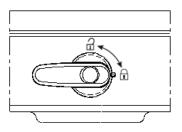
Tilt the monitor

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



Lock the monitor

To move the machine, first move the monitor and supporting arm to the middle position, and lock the locking lever to state to avoid crash.



## 3.3.2 Monitor Brightness/Contrast Adjustment

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

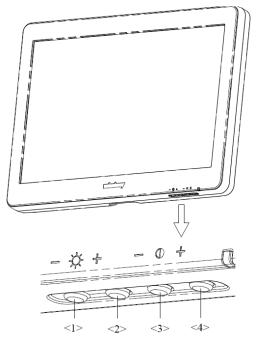
The adjusting buttons are shown as follows:

Brightness adjustment:

<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 adjustment:

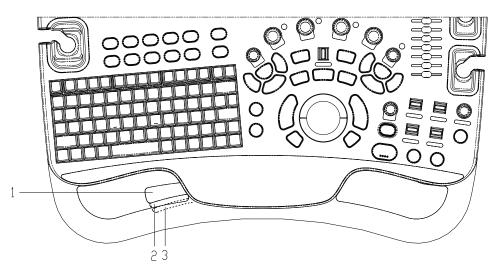
<3>, <4> refer to the contrast control keys with a lune marked at the top side; key <3>, which marked a "-" on the top side, can be used to decrease the contrast, while key <4>, which marked a "+" on the top side, can be used to increase the contrast.



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

## 3.4 Control Panel Position Adjustment

Press the control lever at the side of control panel handle to position 2, the control panel can be rotated  $\pm 90^{\circ}$ ; press the lever to position 3, the control panel can be move upwards or downwards.



## 3.5 Connecting a Probe

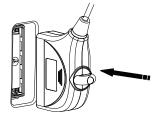
1.	Press <freeze> to freeze an image or turn off the power of the system before connecting / disconnecting the probe. Otherwise, system or probe failure may occur.</freeze>
2.	When connecting or disconnecting a probe, place it in a proper position, to prevent the probe from falling off or becoming damaged.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

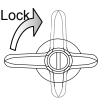
**NOTE:** If a probe port is not used for a long period of time, please use the dustproof cover to protect the probe port from dust; otherwise bad contact may result.

## 3.5.1 Connecting a Probe

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

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

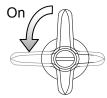


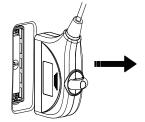


**NOTE:** Before inserting the connector into the probe port, inspect the connector pin. If the pin is bent, do not use the probe until it has been inspected / repaired / replaced.

## 3.5.2 Disconnecting a probe

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





## 3.6 **Connecting Peripheral Devices**

## 3.6.1 Connecting the USB Devices

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

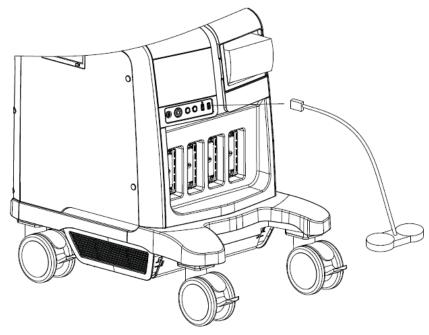
- When connecting a USB memory device to the ultrasound system via a USB port, you can hear a sound if it is connected successfully and the symbol will appear in the lower right corner of the screen.
- To remove the USB device: Click to open the [Remove USB Device] screen. Select the device to be removed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

## 3.6.2 Connecting a Footswitch

The system supports footswitch of USB port type.

Connection

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



Function setting

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

## 3.6.3 Installing a Graph/Text Printer

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

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

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

> Add network printer

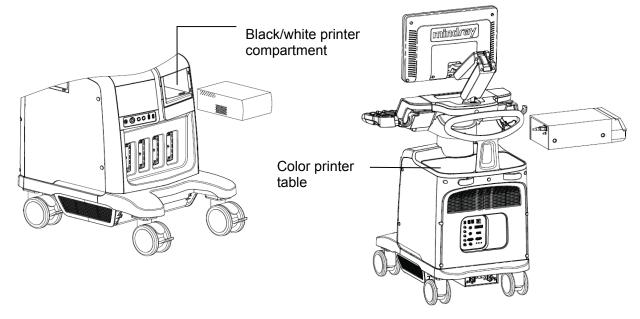
Select "A network printer, or a printer attached to another computer" and click [Next] to enter the browse screen, select the printer to install.

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

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

## 3.6.4 Posit the Printer

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



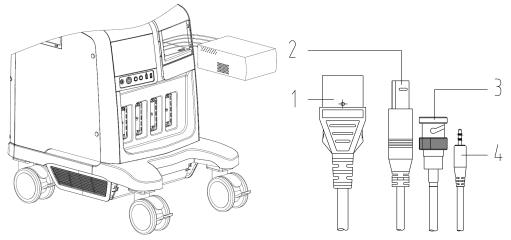
## 3.6.5 Installing Analog Video Printer

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

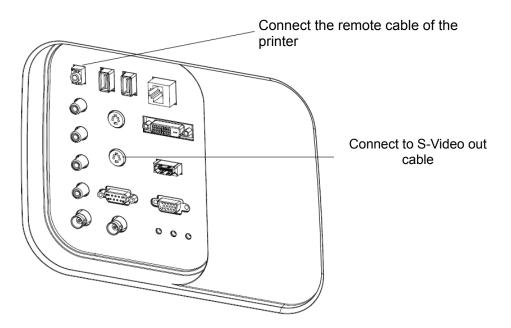
The printer compartment under the control panel provides the following cables:

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

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



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



- 4. Load a paper roll, and turn on the system and printer.
- 5. Modify print service:
  - Add a print service:
  - (1) Open the [Setup]-> [Print Preset]->[Print Service] screen.
  - (2) Click [Add Service] to enter the page.
  - (3) Select the service type and enter the service name manually.
  - (4) Click OK to return to the Printer Service page.
  - (5) Select the printer model, and then you can set the properties in the Property box.
  - (6) Click [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 Video Printer

- 1. Put the printer in a proper place.
- 2. Plug the printer power cord to an appropriate outlet.
- 3. Use a USB cable to connect between the USB port of the system and the USB port of the printer.
- 4. Load a paper roll, and turn on the system and printer.
- 5. See section 3.6.5 Install Analog Video Printer" for driver installation procedure (drivers of printers listed in the "2.5.4 Peripherals Supported" chapter are installed already).
  - Add a print service:
  - (1) Open the [Setup]-> [Print Preset]-> [Print Service] screen.
  - (2) Click [Add Service] to enter the page.
  - (3) Select the service type and enter the service name manually.
  - (4) Click OK to return to the Printer Service page.
  - (5) Set printing properties.
  - (6) Click [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.

## 3.6.7 Installing Wireless Printer

The system supports HP e-All-IN-ONE B210a wireless printer, usually for report printing.

- 1. Plug the printer power cord to an appropriate outlet.
- 2. Power on the system and the printer.
- 3. Make sure the ultrasound machine and the printer are connected to a same LAN, and turned on the W-LAN function of the printer.
- 4. Add wireless adapter, perform the steps as per steps described in add network printer; refer to "3.6.3 Installing a Graph/Text Printer".
- 5. Open the [Setup]→[Printer Preset] page, select "Report Print" in the printer list, and then select the printer to be HP e-All-IN-ONE B210a, and set properties.
- 6. Click [OK] to exit the preset and make the settings effective.

## 3.7 Basic Screen & Operation

## 3.7.1 Monitor Display

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

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

	Logo	н	ospital N	Name	Patient Name	Exam Mode	Probe Model	Freeze icon	
		Date	Time	Operator	ID	Age	Gender	Clip Board	
		Tr	ansduce	er Parameter	ſ			/Thumbnails	
Menu	Image Area					Colo	scale/ r Bar/ meter		
			E	CG					
	Cine Review								
	Parameter Window Hint Parameter Window								
	Help Information						System	con	

Patient/ Exam information

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

- Probe parameter area
  - Probe model

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

- Probe parameter area
   Displays the acoustic power. Including the acoustic power, MI (Mechanical Index) and TI (Thermal Index), for the setting, please refer to "MI/TI Display".
- Menu area

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

Image area

The image area displays the ultrasound images, ECG/PCG 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  $\square$ ), besides, the annotation, body mark, measurement calipers, color bar/grayscale bar are also display here.

Parameter area

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

Cine Review area

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

- ECG icon and ECG curve
  - ECG icon

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

 ECG curve ECG Display

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

Help information area

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

Press <Fn>+<Help>(F1) to enter the help information status. If the backlit of the key is on, it indicates that the key function is available at the current status. Press corresponding key on the control panel, and the screen displays the key-relevant information in the help information area, meanwhile, the system exits the key-help status.

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

Thumbnail

Displays the thumbnail images stored under the current patient.

Grayscale/ color bar

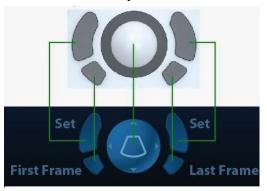
Displays the grayscale/ color bar corresponding to the current mode.

Soft Menu area

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

Trackball function hint area

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



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

#### System status icon

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

#### Other Operations

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

- Result window
- Comment area
- Body mark area

## 3.7.2 Basic Operations of Dialogue Box

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



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

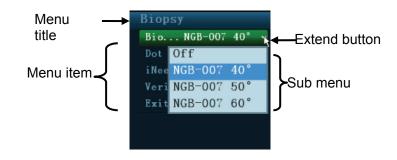
■ To reposition a dialogue box:

1. Roll the trackball to move the cursor onto the title bar of the dialogue box. At this time the cursor becomes a<sup>⊕</sup>; press the <Set> key.

- 2. Roll the trackball and posit the rectangular graphic to the new desired location.
- 3. Release the <Set> key, and the dialogue box is moved to the desired position.

## 3.7.3 Menu Operation

Use the trackball or the multifunctional knob to operate on the menu. Menus of different modes display in real-time at the upper left corner of the screen.



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

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

## 3.7.4 Touch Screen Display and Operation

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

## **4** Exam Preparation

You can start a patient exam in the following situations:

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

General procedure for an exam:

Enter the patient information-> Select an exam mode and probe -> Choose an imaging mode -> Start the exam. The system supports image scanning and measurement without patient information.

## 4.1 Patient Information

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

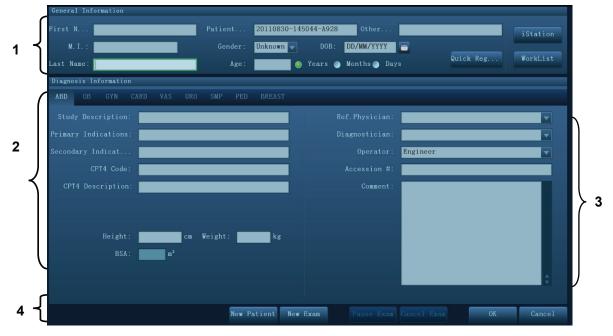


Before examining a new patient, press the <End Exam> key to end the exam of the previous patient, and update the patient ID and information, to avoid mixing data of the next new patient.

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

## 4.1.1 New Patient Information

The Patient Info screen is shown as follows:



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

You can also change the cursor position by <Tab>, <Enter> or up/down controls. Information includes:

- 1. General information
  - Patient ID

Patient ID is generated automatically by the system after starting a new patient, and can be modified manually. Once you enter the ID and confirm it, you are not allowed to change it."\" is not permitted.

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

• Name

Enter patient name through the keyboard.

Gender

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

• DOB (Date of birth):

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

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

1	Aug			2011		•
s	M	T	W	T	F	S
31	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31	1		
4		6				
	ſ		OK			

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

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

- 2. Exam Type
- Exam application type

You can select among: ABD (Abdomen), OB (Obstetrics), GYN (Gynecology), CARD (Cardiac), VAS (Vascular), URO (Urology), SMP (Small Part), PED (Pediatrics) and BREAST (Breast). Select the exam type tab to enter the exam-specific information.

General information:

Study description:	To enter description for each exam.
Primary indications:	To enter the primary indications (reason to perform the exam.)
Secondary indications:	To enter the secondary indications.
CPT4 code:	To enter the CPT4 code.
CPT4 description:	To enter the CPT4 description.
Remarks:	Exam-specific explanation or remarks.

#### Exam specified information:

Exam Type	Information	Description
	Height	1
ABD (Abdomen)	Weight	1
	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] $\rightarrow$ [System Preset] $\rightarrow$ [General] ".
	Calculation index	<ul> <li>Calculate gestation age (GA) and estimated delivery date (EDD) based on last menstrual period (LMP), in vitro fertilization (IVF), basic body temperature (BBT), previous exam date (PRV). Select LMP, IVF, PRV, BBT, or EDD from the drop-down list; or, calculates GA and LMP according to the EDD and entered date.</li> <li>LMP: After you enter LMP, the system will calculate and display GA and EDD.</li> <li>IVF: After you enter IVF, the system will calculate GA and EDD.</li> <li>PRV: input the date and GA of the last exam, the system</li> </ul>
OB (Obstetrics)		<ul> <li>will calculate a new GA and EDD.</li> <li>BBT: input BBT, the system will calculate the GA and EDD.</li> <li>EDD: after you enter EDD, the system will calculate and</li> </ul>
	Gravida	display GA and LMP. Times of pregnancy.
	Ectopic	Times of abnormal pregnancy. e.g. extrauterine pregnancy
	Gestations	Number of embryos (1, 2, 3; 1 is default)
	Para	Times of delivery.
	Aborta	Times of abortion.
	LMP	Last menstrual period.
	Gravida	· ·
	Para	Times of pregnancy. Times of delivery.
GYN (Gynecology)	Ectopic: times of abnormal pregnancy.	E.g. extrauterine pregnancy.
	Aborta	Times of abortion.
CARD (Cardiology)	Height	1
	Weight	1
	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.

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

3. Operating Information

Accession #: refers to exam number used in DICOM.

Diagnostician: people who is responsible for the exam.

Operator: people who is responsible for images collection and scanning.

Ref. Physician: the people who requires the operator to do the ultrasound operation.

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

- 4. Functional key
  - [Pause Exam]: to pause the current exam due to some special causes or system power off.
  - [Cancel Exam]: to cancel the current exam.

Note: The cancelled exam can't be restored.

- [New Patient]: click to clear the current patient information in the patient information screen in order to input new patient information.
- [New Exam]: click to clear the current exam information in order to create a new exam for the current patient.
- [OK]: click to save the patient data entered and exit the screen.
- [Cancel]: click to cancel the patient data entered and exit the screen.

## 4.1.2 Retrieve Patient Information

#### 4.1.2.1 iStation

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

- 1. To enter iStation screen (the screen is shown as follows):
  - Press <iStation> on the control panel; or,
  - Click [iStation] in the Patient Info screen; or
  - Click [iStation] in the Review screen.

Keyword:		Item: Name		Find in r	esults	Data	Source: HD	(D:)			
ID	Name	Exam Type	Exam Date,	/Time	Image	Clip	Exam State	Gender	Age	Backup	
20110826-15432 20110826-14413		ABD ABD	26/08/2011				Paused Paused	Unknown Unknown			
						Select	All Exams	Query/Ret	rieve	Exi	.t

2. Select the data source

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

3. Input the searching condition:

Item: including Name, ID, DOB and Exam Date, the default one is name; then enter a keyword in accordance with the Item selected.

- Select "Find in results", the system will search the keyword based on the existed searched results.
- 4. Select the desired patient information in the list, and the system pops up the following menu:



Button	Function	Description			
0	Review an Image	Click to enter the Review screen.			
2	Patient Information	Click to enter the Patient Info screen.			
	Review Report	Click to enter diagnostic report screen.			
$\otimes$	Delete Exam	Click to delete the selected record.			
٢	Backup Exam	Click to back up the selected patient record to media supported.			
$\bigcirc$	Restore Exam	Click to import the patient data from an external media.			

Button	Function	Description
ET)	Send Exam	Click to send the selected patient data to external device, DICOM storage server or printer.
E,	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.

### 4.1.2.2 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 are listed out.
- 2. Input the searching condition:
  - Enter the period which includes the exam date, and click [Query] to search.
  - Enter patient ID, patient name, accession #, the system affords the result in real-time.
  - Or select the keyword type, enter the keywords and then click [Query] to search.
  - To reset the criteria, click [Clear] button.
- 3. Select the desired patient from the list.
  - Click [Start Exam], the patient information is imported into the system and then an exam is started.
  - Click [Transfer], the patient information is imported into the Patient Info screen. Edit the patient information in the Patient Info screen, and click [OK] to start a new exam.
  - Click [Show Detail] to see details of patient data.
- 4. Click [Exit] to exit the Worklist.

# 4.2 Select Exam Mode and Probe

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

### 4.2.1 Selecting Exam Mode and Probe

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



- 2. Click to select the probe type and exam mode, and the system exits the dialogue box to enter the selected exam mode and probe.
- Click [Exit] or press <Probe> again to cancel the selection and exit the screen.

# 4.3 Select the Imaging Mode

Enter the period which includes the exam date, and click [Query] to search.

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

# 4.4 Activate& Continue an Exam

### 4.4.1 Activate an Exam

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

### 4.4.2 Continue Exam

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

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

# 4.5 Pause & End an Exam

### 4.5.1 Pause Exam

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

Press <Patient> to enter Patient Info screen.

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.

### 4.5.2 End Exam

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

To end an exam, you can do one of the following:

- Press <End Exam> on the control panel.
- Click [New Patient] on the Patient Info screen to end the last patient exam and clear the patient information.
- Click [New Exam] on the Patient Info screen (or iStation screen, or Review screen) to end the last exam and clear the exam data.

# **5** Image Optimization

1.	The images displayed in this system are only reference for diagnosis. Mindray is not responsible for the correctness of diagnostic results.
2.	In Dual-B imaging mode, the measurement results of the merged image may be inaccurate. Therefore, the results are provided for reference only, not for confirming a diagnosis.
3.	Tissue Harmonic Imaging does not use contrast agents.

# 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

Adjust through image menu:

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



Touch screen display

- 1. Mode displaying area (or main functional tabs): displays the current modes, click the tab to enter the mode.
- 2. Other application mode entrance: displays the available application modes related; touch to enter the modes.
- 3. Parameter adjusting area: displays the parameters in the current imaging mode or function.

- Parameter magnitude setting: touch ► or < to increase/ decrease the value.
- ON/OFF setting: some of the parameters only can be set at ON or OFF, ON is to activate the function, and when the function is activated, the key is highlighted in green.

to

- Page selection: if there is more than 1 page for the current mode, click turn the pages.
- Functional item: touch to go to the corresponding function.
- 4. Knob-adjusting area: displays the knob-controlled parameters.

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

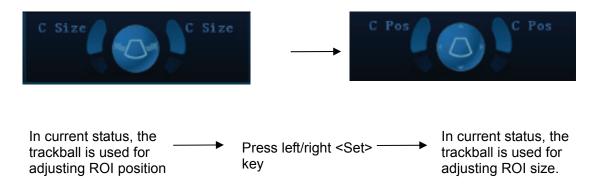
Control Panel

Adjust through trackball, control panel key, deflector rod, knob or sliders.

Trackball function keys

In some certain mode, you need to use both the trackball and the trackball function keys to adjust.

For instance, in Color mode, use the trackball and the trackball function keys to adjust ROI size/position.



### 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 right 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	Display v	when the fu	inction is tu	Irned on.

## 5.2.3 B Mode Image Optimization

### Image quality

Description Harmonic frequency	To switch between the fundamental frequency and harmonic frequency, and select the corresponding frequency type. The real-time value of frequency is displayed in the image parameter area in the upper right corner of the screen, and if harmonic frequency is used, "F H" is displayed as harmonic frequency value. Press the knob under the [Image Quality] on the touch screen to be "Harmonic On" to turn on the function.
	Rotate the knob under the [Image Quality] on the touch screen to select the different frequency values.
	The adjusting range of frequency values can be divided into 4 levels, penetration preferred, (HPen), general mode (HGen), resolution preferred (HRes), and the mode between penetration preferred and general mode (HPen-Gen).
Fundamental frequency	Press the knob under the [Image Quality] on the touch screen to be "Harmonic Off" to use the fundamental frequency.
	The adjusting range of frequency values can be divided into 3 levels, penetration preferred, (Pen), general mode (Gen), resolution preferred (Res).
	Rotate the knob under the [Image Quality] on the touch screen to select the different frequency values.
Impacts	The system provides an imaging mode using harmonics of echoes to optimize the image. Harmonic imaging enhances near field resolution and reduces low-frequency and large amplitude noise, so as to improve small parts imaging.
	Please select the frequency according to the detection depth and current tissue features.
Gain	
Description	To adjust the gain of the whole receiving information in B mode. The real-time gain value is displayed in the image parameter area in the upper right corner of the screen.
Operations	Rotate the <b> knob clockwise to increase the gain, and anticlockwise to decrease.</b>
	The adjusting range is 0-100.
Effects	Increasing the gain will brighten the image and you can see more received signals. However, noise may also be increased.
Depth	
Description	This function is used to adjust the sampling depth, the real-time value of which is displayed in the image parameter area in the upper right corner of the screen.
Operations	Use the <depth> deflector rod on the lower right part of the control panel to adjust the depth.</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.

Т	G	С

Description	The system compensates the signals from deeper tissue by segments to optimize the image.
	There are 8-segment TGC sliders on the control panel corresponding to the areas of the image.
Operations	To increase the gain compensation at an area of interest, move the TGC slider to the right.
	To decrease the gain compensation at the corresponding area of interest, move the TGC slider to the left.
	About 1.5s after the adjustment is finished, the TGC curve disappears.
Effects	Adjust the signal gain for the certain image area to get a balanced image.

#### **Acoustic Power**

Description	Refers to the power of ultrasonic wave transmitted by the probe, the real-time value of which is displayed in the upper part of the screen.
Operations	Use the <a.power> knob on the left part of the touch panel to adjust the acoustic power.</a.power>
Effects	Generally, increasing the acoustic power will increase the brightness and contrast of the image and the force of penetration.
Impacts	You should perform exams according to actual situation and follow the ALARA Principle.

### Focus

Description	Refers to adjustment of focus of the ultrasonic beams, symbols as "◀" of which are displayed on the right of the image.
Operations	Adjust the focus number through the [Focus Number] item on the touch screen.
	Use the <focus> deflector rod on the lower right part of the control panel to adjust</focus>

- the focus position. In B mode, available focus number can be switched among 1-4.
- **Effects** The area that is focused will be of a higher contrast and resolution.
- **Impacts** The greater the number of focal zones, the slower the frame rate to image.

### Imaging Adjustment

Description	More information can be obtained without moving the probe or changing the sampling position.		
FOV (Field of View)	<ol> <li>To change the scan range, touch [FOV] on the touch screen to enter the FOV range and FOV position adjustment status.</li> </ol>		
	<ol> <li>Press <set> to switch between FOV range/position changing according to the hint region display.</set></li> </ol>		
	3. Rotate the trackball to adjust FOV position or the FOV range.		
	When the scan range is adjusted to the widest, 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	Use the <steer> deflector rod on the control panel to adjust the steer angle.</steer>		
ExFOV	Touch [ExFOV] on the touch screen to turn on/off the function.		
	For linear probes, the ExFOV function displays as trapezoid imaging.		
	For convex probes, the ExFOV function displays as extending the scanning angle.		
Impacts	The FOV position/range is available only for convex and phase probes.		
	The B Steer function is available only for linear probes.		

### Line Density

Description	The function determines the quality and information of the image.
Operations	Adjust the line density through the [Line Density] item on the touch screen.
	There are four levels of line density available: UH, M, H, L.
Effects	The higher the line density, the higher the resolution.
Impacts	The higher the line density, the lower the frame rate.

### Dynamic Range

Description	This function is used to adjust the B image resolution to compress or expand the gray display range. And the real-time value displays in the image parameter area in the upper right corner of the screen.
Operations	Rotate the knob under the [Dyn Ra.] item on the touch screen to adjust the dynamic range.
	Rotate the knob clockwise to increase the value; rotate the knob counterclockwise to decrease the value.
	The adjusting range is 30-180dB, in increments of 5dB.
Impacts	The more the dynamic range, the more specific the information, and the lower the contrast with more noise.

iClear	
Description	The function is used to enhance the image profile, so as to distinguish the image boundary for optimization.
Operations	Adjust through the [iClear] item on the touch screen.
	The system provides 7 levels of iClear adjustment, off represents no iClear effect, and the bigger the value the stronger the effect.
Impacts	It may cause noise increasing.
Persistence	
Description	This function is used to superimpose and average adjacent B images, so as to optimize the image and remove noise.
Operations	Rotate the knob under the [Persistence] item on the touch screen to adjust the value.
	The system provides 7 levels of frame average adjustment, the bigger the value the stronger the effect.

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

Impacts Persistence increasing may lead to signal missing.

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

Description	The function provides a better observation for image display.			
Rotation	Rotate the image through the [Rotation] item on the touch screen.			
	Image can be rotated in the manners of angles of 0°, 90°, 180° and 270°.			
	When the image is rotated in the angle of 90° or 270°, the depth scale is displayed on the upper part of the screen.			
Invert (U/D	To invert the image horizontally or vertically.			
Flip and L/R Flip)	Touch [U/R Flip] or [L/R Flip] on the touch screen to invert the image			
Effects	You can identify image orientation through the "M" mark on the screen; by default, the M mark is located in the upper left corner of the imaging area.			

iBeam

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

- Operations Adjust through the [iBeam] item on the touch screen. The system provides 4 levels of iBeam adjustment in single B mode; off represents no iBeam.
- **Effects** Images can be optimized with less spot noise and higher resolution, so that more details for the structure are revealed.
- **Impacts** iBeam is valid only for linear probes, and it is not available when trapezoid function is turned on.

#### **Image Merge**

- **Description** In the Dual-split mode, when the images of the two windows have the same probe type, depth, invert status, rotation status and the magnification factor, the system will merge the two images so as to extend the field of vision.
- **Operations** Turn on or off the function through the [Img Merge] item on the touch screen.
- Impacts The function is valid only for linear probes.

#### **Gray Map**

- **Description** This function applies the gray correction to obtain the optimum images.
- **Operations** Select among the maps by rotating the knob under the [Gray Map] item on the touch screen.

#### **Tint Map**

- **Description** This function provides an imaging process based on color difference rather than gray distinction.
- **Operations** Rotate the knob under the [Tint Map] item on the touch screen to select the map. Press the knob under the [Tint Map] item on the touch screen to turn on/off the function.

#### **TSI (Tissue Specific Imaging)**

- **Description** The TSI function is used to optimize the image by selecting acoustic speed according to tissue characteristics.
- **Operations** Select among the TSI modes through the [TSI] item on the touch screen. The system provides four ways of optimization for specific tissues: general, muscle, fluid and fat.

#### iTouch

- **Description** To optimize image parameters as per the current tissue characteristics for a better image effect.
- OperationsPress <iTouch> on the control panel to turn on function.The symbol of iTouch will be displayed in the image parameter area in the upper<br/>right corner of the screen once press <iTouch>.Long press the <iTouch> key to exit the function.
- 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.
   Operations Touch [HScale] on the touch screen to display or hide the scale.

### **Dual Live**

Description	Display different image effects of one probe for a better observation.			
Operation	Touch [Dual Live] on the touch screen to turn on/off the function, and dual-split window of images are displayed on the main screen.			
	Two pages of adjustable parameters are displayed in the touch screen as well; where, shared parameters and left window parameters are displayed in the B(L) page, while right window parameters are displayed in the B(R) page.			
	In the image parameter area on the upper right corner of the main screen, parameters of the both windows are displayed.			
Impacts	Image magnification is available in dual live mode.			

### LGC

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

OperationTouch [LGC] on the touch screen to enter the adjusting dialogue box.The 8 rods displayed on the touch screen indicate the corresponding image areas on the main screen.

Touch the **second** to adjust the gain, move downwards to decrease the gain, while move upwards to increase the gain.

In addition, the system provides several preset parameters for imaging.

# 5.3 M Mode Image Optimization

### 5.3.1 Basic Procedures for M Mode Imaging

- 1. Select a high-quality image during B mode scanning, and adjust to place the area of interest in the center of the B mode image.
- 2. Press <M> on the control panel, and roll the trackball to adjust the sampling line.
- 3. Press <M> on the control panel again or <Update>to enter M mode, and then you can observe the tissue motion along with anatomical images of B mode. During the scanning process, you can also adjust the sampling line accordingly when necessary.
- 4. Adjust the image parameters to obtain optimized images.
- 5. Perform other operations (e.g. measurement and calculation) if necessary.

### 5.3.2 M Mode Image Parameters

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

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

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

### 5.3.3 M Mode Image Optimization

Gain

Description	To adjust the gain of M mode image. The real-time gain value is displayed in the image parameter area in the upper right corner of the screen.
Operations	Rotate the <m> knob clockwise to increase the gain, and anticlockwise to decrease.</m>
	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.
<b>Display Form</b>	nat
Description	To set the display format of M mode image and B mode image.
Operations	Touch the different display format ratio buttons on the touch screen to adjust. 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.
Speed	
Description	This function is used to set the scanning speed of M mode imaging, and the real- time speed value is displayed in the image parameter area in the upper right corner of the screen.
• •	

- OperationsRotate the knob under the [Speed] item on the touch screen to adjust.There are 6 levels of scan speed available, the smaller the value the faster the speed.
- Effects Speed changing makes it easier to identify disorders in cardiac cycles.

### Tint Map

- **Description** This function provides an imaging process based on color difference rather than gray distinction.
- **Operations** Rotate the knob under the [Tint Map] item on the touch screen to select the map. Press the knob under the [Tint Map] item on the touch screen to turn on/off the function.

### Gray Map

- **Description** This function applies the gray correction to obtain the optimum images.
- **Operations** To select among the maps, turn the knob under [Gray Map] on the touch screen.

### Edge Enhance

Description	This function is used to enhance image profile, so as to distinguish image boundary for optimization.
Operations	Adjust through the [Edge Enhance] item on the touch screen. There are 3 levels of edge enhance adjustment available, the bigger the value the stronger the effect.
Impacts	Larger edge enhance may lead to noise increasing.

### **Dynamic Range**

Description	This function is used to adjust the M image resolution to compress or expand the gray display range.			
	The real-time dynamic range value is displayed in the image parameter area in the upper right corner of the screen.			
Operations	Rotate the knob under the [Dyn Ra.] item on the touch screen.			
	The adjusting range is 30-180dB, in increments of 5dB.			
Effects	The more the dynamic range, the more specified the information.			
M Soften				

- **Description** This feature is used to process the scan lines of M images to reject noise, making the image details clearer.
- OperationsAdjust through the [M Soften] item on the touch screen.The system provides 4 levels of M Soften adjustment, the bigger the value the<br/>stronger the effect.

# 5.4 Color Mode Image Optimization

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

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

### 5.4.1 Basic Procedures for Color Mode Imaging

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

### 5.4.2 Color Mode Image Parameters

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

ſ	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 touch screen at the same time. You can switch between the 2 modes by clicking the mode tabs.
- In Color mode, acoustic power is synchronous with that of B mode. Adjustment of the depth to the B mode image will lead to corresponding changes in Color mode image.

### 5.4.3 Color Mode Image Optimization

**Color Gain** 

- **Description** Refers to the overall sensitivity to flow signals, and this function is used to adjust the gain in Color mode. The real-time gain value is displayed in the image parameter area in the upper right corner of the screen.
- **Operations** Rotate the <Color> knob clockwise to increase the gain, and anticlockwise to decrease.

The adjusting range is 0-100.

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

#### **ROI Adjustment**

Description	This function is to adjust the width and position of ROI in Color mode.
Operations	When the ROI box is dotted line, roll the trackball to change the size.
	When the ROI box is solid line, roll the trackball to change the position.
	Press <set> to switch between the solid line and the dotted line.</set>
Impacts	The larger the ROI box, the lower the frame rate, and the lower the resolution and color sensitivity.

#### **Image Quality**

- **Description** Refers to the operating frequency in Color mode of the probe, the real-time value of which is displayed in the image parameter area in the upper right corner of the screen.
- **Operations**Rotate the knob under the [Image Quality] on the touch screen to select the<br/>different frequency values.The adjusting range of frequency values can be divided into 3 levels, penetration<br/>preferred, (Pen), general mode (Gen), resolution preferred (Res).Values of frequency vary by probe types. Select the frequency according to the<br/>need of the detection depth and the current tissue characteristics.
- **B/C Align** Description To set and constrain the maximum width of the B mode image to that of the Color ROI. Operations Turn on or off the function through the [B/C Align] item on the touch screen. Impacts Frame rate increases when the function is turned on. **Dual Live** Description This function is used to display B image and Color image synchronously. Operations Turn on or off the function through the [Dual Live] item on the touch screen. When the function is turned on, the window will be automatically switched to the dual windows (one for B image, and the other for Color image). Steer
- Description
   The feature is used to adjust the ROI of color flow of different angles with immobility of the linear probe.

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

   Effects
   This function is used to a direct the second angle of linear problem.
- **Effects** This function is used to adjust the scan angle of linear probes, so as to change the angle between the transmitting beam and flow direction.
- **Impacts** Steer is valid only for linear probes.

Line Density				
Description	<b>h</b> Line density determines the quality and information of the image.			
Operations	Adjust through the [Line Density] item on the touch screen.			
	There are 4 levels of line density provided: H, L, UH, M.			
Effects	The higher the line density, the higher the resolution.			
Impacts	The higher the line density, the lower the frame rate.			
Packet Size				
Description	This function is an indication of the ability to detect flow, which is used to adjust the accuracy of color flow.			
Operations	Rotate the knob under the [Packet Size] item on the touch screen to adjust the value.			
	There are 3 levels of packet size available, 0 represents no packet size control and the bigger the value the higher the sensitivity.			
Effects	The higher the packet size, the more sensitive indication for low-velocity flow.			
Impacts Adjusting the packet size may lead to frame rate changing.				
Flow State				
Description	This function is used for fast image optimization.			
Operations	Adjust through the [Flow State] item on the touch screen.			
	There are 3 levels provided to adjust: L, M, H.			
Persistence				
Description	This function is to adjust the temporal smooth in Color mode to optimize the image.			
Operations	Rotate the knob under the [Persistence] item on the touch screen.			
	The system provides 6 levels of persistence adjustment, 0 represents no persistence and the bigger the value the stronger the effect.			
Smooth				
Description	This feature is used to reject noise and smooth the image.			
Operations	Adjust through the [Smooth] item on the touch screen.			
	The system provides 6 levels of smooth function, the bigger the value the higher the smooth.			

#### Scale

#### Baseline

- **Description** Refers to the area where the velocity is zero in the scale. Adjust according to the actual situation so as to get an optimum flow display.
- **Operations** Use the <Baseline> deflector rod on the upper right part of the control panel to adjust.

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

#### Invert

**Description** To set the display mode of color flow and the color scale will be inverted when the function is turned on.

**Operations** Turn on or off the function through the [Invert] item on the touch screen. Select "Auto Invert" in the "[Setup] (F10) → [System Preset] → [Image]", then the color bar can automatically invert when the color flow is steered to a certain angle to accommodate operator's habit of distinguishing flow direction.

#### **Color Map**

- **Description** This function is a combination of several image parameters, which indicates the display effect of color image.
- **Operations** Rotate the knob under the [Color Map] item on the touch screen to select among the maps.

The system provides 21 different maps to be selected among, where the V group provides 11 ordinary maps and the VV group provides 10 2-D maps.

#### WF (Wall Filter)

Description	It filters out low-velocity signals to provide effective information, and this function is			
	used to adjust the filtered frequency. The real-time value is displayed in the image			
	parameter area in the upper right corner of the screen.			

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

There are 8 levels of wall filter function available, and adjust according to the actual situation.

**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.

**Operations** Rotate the knob under the [Priority] item on the touch screen to select the value. The adjusting range of the priority is 0-100%.

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

#### Velocity tag

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

- **Operation** 1. Touch [Velocity Tag] on the touch screen to enter the velocity marking status, and green mark appears on the color bar.
  - 2. Roll the trackball upwards and downwards to select the marking velocity.
  - 3. Press <Set> to enter the tag range selection status, roll the trackball upwards and downwards to select the range.

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

#### iTouch

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

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

# 5.5 Power Mode Image Optimization

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

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

### 5.5.1 Basic Procedures for Power Mode Imaging

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

### 5.5.2 Power Mode Image Parameters

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

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

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

Parameters consistent with those in Color mode and B mode are not 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.

### 5.5.3 Power Mode Image Optimization

### **Power Gain**

 Description Refers to the overall sensitivity to flow signals, and this function is used to adjust the gain in Power mode. The real-time gain value is displayed in the image parameter area in the upper right corner of the screen.
 Operations Rotate the <Color> knob clockwise to increase the gain, and anticlockwise to decrease. The adjusting range is 0-100.
 Effects Increasing the gain will increase the flow signal presented as well as noise, while the signals may be missing when the gain is adjusted too low.

мар					
Description	This feature indicates the display effect of Power image.				
	The maps in the Power mode image are grouped into two categories: Power maps and Directional Power maps.				
Operations	To select among the maps, turn the knob under [Map] on the touch screen.				
	There are 8 kinds of maps provided: P0-3 belong to Power mode maps, while Dp0-3 belong to Directional Power mode maps.				
	The Power maps provide information of blood flow, which are highly sensitive to the low-velocity flows.				
	The Directional Power maps provide information of flow direction.				

### **Dynamic Range**

N/ ~ ~

- **Description** This function is to adjust the transformation of echo intensity into color signal.
- **Operations** Rotate the knob under the [Dyn Ra.] item on the touch screen to adjust the dynamic range.

The adjusting range is 10-70dB in increments of 5dB.

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

# 5.6 PW/CW Doppler Mode

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

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

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

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

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

PW SVD 82.5 SV 4.0 Angle0°	CW SVD7.2
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 right corner of the screen displays the real-time parameter values as follows:

PW	Parameter	F	G	PRF	WF	SVI	)	SV	Angle
	Meaning	Frequency	Gain	PRF	Wall Filter	SV Pos	ition	SV Size	Angle
CW	Parameter	F	G	PRF	WF		SVD		Angle
	Meaning	Frequency	Gain	PRF	Wall Filte	er	SV P	osition	Angle

During PW/CW mode imaging, menus of image optimizing for B mode and PW/CW mode are displayed on the touch screen at the same time; if there is also Color mode (Power mode) working, menus of certain modes will also be displayed on the touch screen synchronously, and you can switch by clicking the mode tabs.

- When you adjust the depth of the B mode image, related changes will occur in PW/CW mode image as well.
- Most of the parameters are the same for the PW mode and CW mode, so parameters of the both are combined together to be introduced here.

Only phased probes support CW mode.

### 5.6.3 PW/CW Mode Image Optimization

Gain

Description	This function is intended to adjust the gain of spectrum map. The real-time gain value is displayed in the image parameter area in the upper right corner of the screen.
Operations	Rotate the [PW] knob clockwise to increase the gain, and anticlockwise to decrease. The adjusting range is 0-100.
Effects	Increasing the gain will brighten the image and you can see more received signals. However, noise may also be increased.
sv	

Description	To adjust the SV position and size of sampling in PW mode, the real-time value of SV and SVD are displayed in the image parameter area in the upper right corner of the screen.
SV size	Rotate the knob under [SV] on the touch screen to adjust the SV size. Value: 0.5-20mm.
SVD	Roll the trackball to select the SV depth.
Effects	The smaller the SV size, the more accurate the result; and more details are obtained when selected large SV size.

### **CW** focus position

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

#### Image quality

 Description Refers to the operating frequency in PW mode of the probe, the real-time value of which is displayed in the image parameter area in the upper left corner of the screen.
 Operation Rotate the knob under the [Image Quality] on the touch screen to select the different frequency values. The adjusting range of frequency values can be divided into 3 levels, penetration preferred, (Pen), general mode (Gen), resolution preferred (Res). Please select the frequency according to the detection depth and current tissue features.
 Effects The higher the frequency, the worse the axial resolution, and the better the force of penetration.

Scale	
Description	This function is used to adjust the speed range of flow, which is adjusted through PRF in the system.
	The real-time PRF value is displayed in the image parameter area in the upper right corner of the screen.
Operations	Adjust through the <scale> deflector rod on the control panel.</scale>
Effects	To provide a much clearer color flow image.
	Use low PRF to observe low-velocity flows, and use high PRF to observe high- velocity flows.
Impacts	Aliasing may occur if low velocity scale is used and high velocities are encountered.
	Low velocities may not be identified when a high velocity scale is used.
iTouch	

Description	To optimize image parameters as per the current tissue characteristics for a better image effect.
Operations	Press <itouch> on the control panel to turn on the function.</itouch>

### **Auto Calculation**

Description	This function is used to trace the spectrum and calculate parameters of PW/CW mode image, and the results of which are displayed in the result window.
Auto Calculation	Turn on or off the auto calculation function through the [Auto Calc] item on the touch screen.
Auto Calculation Parameter	Select parameters in the dialogue box prompted by clicking [Auto Calc Param] on the touch screen.
Auto Calc	To set the number of heart cycle for auto calculation.
Cycle	Touch [Auto Calc Cycle] on the touch screen to select the cycle number.
Operations	In real-time scanning, the results displayed are derived from the calculation of latest cardiac cycle;
	In the freeze and cine status, the results displayed are calculated from the current selected area.

#### Invert

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

**Operations** Turn on or off the function through the [Invert] item on the touch screen. Select "Auto Invert" in the "[Setup] (F10)  $\rightarrow$  [System Preset]  $\rightarrow$  [Image Preset]", thus the spectrum can automatically invert when the color flow is steered to a certain angle to accommodate operator's habit of distinguishing flow direction.

Speed	
Description	This function is used to set the scanning speed of PW mode imaging.
Operations	Rotate the knob under [Speed] item on the touch screen.
·	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.
Operations	Adjust through the [T/F Res] item on the touch screen.
	There are 5 levels of T/F Res values available.
Wall Filter	
Description	It filters out low-velocity signals to provide effective information, and this function is used to adjust the filtered frequency. The real-time value is displayed in the image parameter area in the upper right corner of the screen.
Operations	Select through the [WF] item on the touch screen.
	There are 7 levels of wall filter function provided.
Impacts	Signals of low-velocity flow may be missing.
Tint Map	
Description	This function provides an imaging process based on color difference rather than gray distinction.
Operations	Rotate the knob under the [Tint Map] item on the touch screen to select the map.
	Press the knob under the [Tint Map] item on the touch screen to turn on/off the function.
Trace	
Trace Area	To set the trace area of the Doppler wave in the spectrum map, applicable for auto calculation.
	Change the trace area through the [Trace Area] item on the touch screen. The available selections are: Above, Below, All.

#### Gray Map

DescriptionThis function applies the gray correction to obtain the optimum images.OperationsTo select among the maps, turn the knob under [Gray Map] on the touch screen.

#### **Display Format**

Description To set the display format of PW mode image with B mode image.
 Operations Touch the different display format ratio buttons on the touch screen to adjust. There are 5 formats to display the images: H2:3, V2:3, V3:2, V3:1, Full.

#### **Duplex/ Triplex**

Description	This function is used to set if B image (B + Color image) and PW image are displayed synchronously.
Operations	Click [Duplex]/ [Triplex] on the touch screen to turn on or off the synchronization.

#### HPRF

Description	HPRF mode is used when detected velocities exceed the processing capabilities of the currently selected PW Doppler scale, or when the selected anatomical site is too deep for the selected PW Doppler scale.
<b>O</b>	

- **Operations** Turn on or off the function through the [HPRF] item on the touch screen.
- Effects HPRF enhances the range of detecting high-velocity flow.

#### Baseline

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

- **Operations** Adjust through the <Baseline> deflector rod on the control panel.
- **Effects** To change the range of flow velocity to optimize the image.

#### Angle

Description This function is used to adjust the angle between Doppler vector and flow to make the velocity more accurate. The real-time adjusting angle value is displayed on the right part of the spectrum map.
 Operations Rotate the <Angle> knob on the control panel to adjust. The adjustable angle range is -80~80°, in increments of 1°.

### **Quick Angle**

Description	To adjust the angle faster, in increments 60°, and the real-time value of which is displayed on the right part of the spectrum map.
Operations	Adjust through the [Quick Angle] item on the touch screen.

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

#### **Dynamic Range**

Description	The dynamic range conveys the information that being transformed from echo intensity to gray scale.
Operations	Adjust through the [Dyn Ra.] item on the touch screen. 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.

#### Audio

Description	This function is used to adjust the output audio in spectrum map.
<b>Operations</b> Rotate the <volume> knob on the left of the touch panel to adjust the</volume>	
	Press <volume> knob to open or shut down the volume.</volume>
	The adjusting range of the audio is 0-100%.
Effects	Utilizing the output audio helps to identify the feature and status of flow.

#### **PW Steer**

Description	This function provides adjustment on angles for sampling line.
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**Operations** Adjust through the <Steer> deflector rod on the control panel.

EffectsThis feature is used to steer the direction of the beam so as to change the angle<br/>between the beam and flow direction with immobility of the linear probe.Values of steer angles vary by probe.

# 5.7 Color M Mode

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

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

### 5.7.1 Enter Color M Mode

- Color Flow M Mode
  - In B + M mode, press <Color> on the control panel.
  - In B + Color, B + Color + PW or B + Color + CW mode, press <M> on the control panel.
- Color Tissue M Mode (TVM)
  - In B + TVI/TVD, or B + TVI + TVD mode, press <M> on the control panel.
  - In Color Flow M mode, press <M> on the control panel.

### 5.7.2 Exit Color M Mode

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

### 5.7.3 Color M Mode Image Parameters

- In Color Flow M mode, parameters that can be adjusted are in accordance with those in B, M and Color modes; please refer to relevant sections of B, Color and M mode for details.
- In Color Tissue M mode, parameters that can be adjusted are in accordance with those in B, M and TVI modes; please refer to relevant sections of B, M and TVI mode for details.
- In Color M mode scanning, the image parameter area in the upper right corner of the screen displays the real-time parameter values 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.

# 5.8 Anatomical M Mode

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

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

Shortcut key setting

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

### 5.8.1 Free Xros M Imaging

### 5.8.1.1 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 touch screen of the B mode tab to enter Free Xros M mode, or press the user-defined key.
- 3. Adjust the M-mark (single or multiple) line to obtain optimized images and necessary information.
- In Dual-split or Quad-split mode, it is the current activated window that enters the Free Xros M mode.

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

### 5.8.1.2 Free Xros M Image Parameters

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

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

- **Description** There are 3 M-mark lines available, each with a symbol of "A", "B" or "C" at the one end as identification and an arrow at the other end as a mark for direction.
- **M-mark Line** Perform the selection through the [Show A], [Show B] or the [Show C] item on the touch screen, and the corresponding image will be displayed on the screen once the related item is selected.
- **Display** Touch [Display Cur.] or [Display All] on the touch screen to select whether to display the image of the current M-mark line or the all.
- Impacts When there is only one M-mark line on the screen, you cannot hide it.

#### Switching between the M-mark Lines

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

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

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

#### Adjustment of the M-mark Line

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

**Operations** • Position Adjustment

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

• Angle Adjustment

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

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

### 5.8.1.3 Exit Free Xros M

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

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

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

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

Only phased probe supports Free Xros CM

### 5.8.2.1 Basic 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 **I**, 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 (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 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:
  - 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.

### **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.

# 5.9 TDI

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

There are 4 types of TDI mode available:

- Tissue Velocity Imaging: This imaging mode is used to detect tissue movement with direction and speed information. Generally the warm color indicates the movement towards the probe, while the cool color indicates the movement away from the probe.
- Tissue Energy Imaging: 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: This imaging mode provides direction and velocity information of the tissue quantificationally.
- Tissue Velocity M Imaging (TVM): This function assists to observe the cardiac motion through a direct angle. TVM mode is also called Color Tissue M mode which has been introduced in Color M mode chapter, please refer to "5.7 Color M Mode" for details.
- Only phased probe can be applied for TDI function.

### 5.9.1 Basic Procedures for TDI Imaging

Enter TDI



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

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

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

### 5.9.2 TDI Image Parameters

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

Parameter	F	G	PRF	WF
Meaning	Frequency	Gain	PRF	Wall Filter

TVD

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

### 5.9.3 TDI Image Optimization

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

### Tissue State

DescriptionThis function is used for fast image optimization.OperationsAdjust through the [Tissue State] item on the touch screen.

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

### 5.9.4 TDI Quantitative Analysis (QA)

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

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

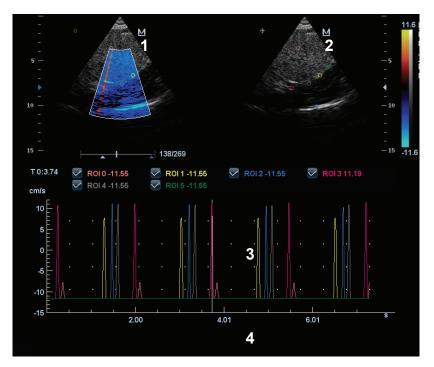
Workflow of TDI QA:

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 if the user has selected an image loop. If the user has selected a saved still image (just one frame), TDI QA function is not available.
- 2. Click [TDI QA] on the TVI touch screen page to activate TDI QA function.
- 3. Mark out the interesting part.
- 4. Save the curved image, export the data and do parameter analysis.
- 5. Exit TDI QA function.
  - Press <Freeze> or <B> key on the control panel.

### 5.9.4.1 TDI QA Screen Description



TDI QA Screen (for reference only)

#### 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 white line that perpendicular to the X axis, can be moved horizontally left to right (right to left) by rolling the trackball.
- Click the check box beside the ROI to set if to hide or to display the QA curve.

4---Displays ECG trace (no ECG trace displayed here).

### 5.9.4.2 Basic Operations of TDI QA

#### Selecting QA 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.

Touch [Cine] page on the touch screen to activate the cine mode menu:

• Setting start time: rotate the knob under [Start Time] and view to the desired image, press the knob to set the current frame to be the first image.

• Setting end time: rotate the knob under [End Time] and view to the desired image, press the knob to set the current frame to be the last image.

#### Setting ROI

This function is used for setting the TDI QA target.

Up to eight ROIs can be saved on the reference image, with the corresponding eight traces plotted simultaneously on the graph. Each ROI display has a different color, and its corresponding trace data is plotted 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. Touch [Standard ROI] on the touch screen.
- 2. Review the image to a desired frame.
- 3. 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).

The average intensity value inside the ellipse is calculated for every image in the image analysis range and plotted in the image display area.

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.

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. Touch [Freehand ROI] on the touch screen, 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. 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 touch screen to clear out all ROIs.

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

Standard Height/Standard Width/Standard Angle

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

#### 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 touch screen to hide or display the analysis curve area.

#### Export/Save Trace Data

1. Click [Export] on the touch screen.

2. Select the drive and enter the file name in the displayed window.

Select [OK] to save the data and return to the QA Analysis screen.

- All displayed ROI traces are saved in the exported file.
- The parameters are included in the trace file if the user has fixed a ROI.
- After the exporting is succeeded, a .BMP format image is displayed in the thumbnail area at the lower part of the screen.
- Only data from the user selected image range is included in the exported trace file.

# 5.10 3D/4D

Tips:

• You can select 4D optional module. 4D module includes 4D and Static 3D functions. You can also select Smart 3D.

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

#### Mode definition

The system supports three 3D imaging modes: Smart 3D, Static 3D and 4D, all of them are targeted for 3D imaging, however, differences exist.

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.

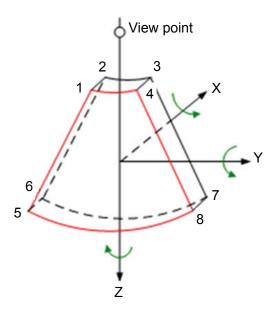
• 4D

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.

## 5.10.1 Overview

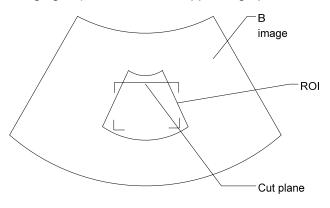
Ultrasound data based on three-dimensional imaging methods can be used to image any structure where a view can't be achieved by standard 2D-mode to improve understanding of complex structures.

- Terms
  - Volume data: the image data set of a 3D object rendered from 2D image sequence.
  - 3D image Volume Rendering (VR): the image displayed to represent the volume data.
  - 4D: Continuous-sweep volume acquisition.
  - View point: a position for viewing volume data/3D image.
  - Section image/MultiPlaner Rendering (MPR): The three sectional planes of the volume acquisition. As shown in the figure below, XY-paralleled plane is C-section, XZ-paralleled plane is B-section, and YZ-paralleled plane is A-section. The probe is moved along the 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 display 3D image in sectional plane.



#### ROI and VOI

After the system enters 3D/4D imaging, a B image with ROI displays on the screen. A line (shown in the following figure) that shows the upper edge position of VOI is inside ROI.



- ROI size and position
   Roll the trackball to change the ROI size and position, press the <Set> key to toggle between setting the size (dotted line) and position (solid line).
- Curved VOI adjustment Roll the trackball to change the curved VOI position, press the <Set> key to switch among the state of changing ROI and curved VOI.

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

It can be adjusted both in acquisition preparation status, and in A, B, C sections of review/ 4D imaging status, while a triangle of control point on the curved VOI is displayed. Depending on the view direction, the orientation and the shape (line or dot) of curved VOI vary:

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

#### About the probes

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

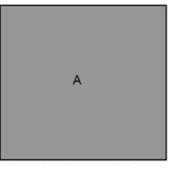
#### Sectional plane

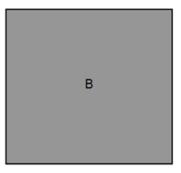
The principle of 3D imaging is to render a 3D image from multiple 2D image information. The following describes the spatial relation of 3 sectional planes (A, B and C) and the 3D image.

The sectional plane can be viewed in the following status:

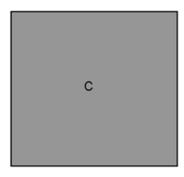
- 3D image viewing status of Smart 3D
- 3D image viewing status of Static 3D
- Real time 4D or frozen 4D

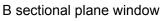
In the quad display format view, the screen displays A, B, C 3 sectional planes and the 3D image.

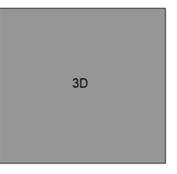




A sectional plane window



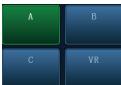




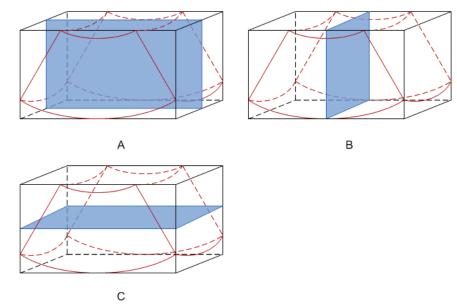
C sectional plane window

3D sectional plane window

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



A, B, C sectional images are corresponding to the following sections of 3D image.



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

• Section C: it is the coronal section in fetal face up posture, as shown in the figure C above. Tips: the upper part of the 3D image in the D window is corresponding to the orientation mark on the probe, if the fetal posture is head down (orientating the mother's feet), and the orientation mark is orientating the mother's head, then the fetus posture is head down in the 3D image, you can make the fetus head up by rotating the 3D image by touching [180°] on the touch screen.

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

#### 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

## 5.10.2 Note before Use

### 5.10.2.1 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 mode is closely related to the fetal condition, angle of a B tangent plane and scanning technique (only for Smart 3D). The following description uses the fetal face imaging as an example, the other parts imaging are as the same.

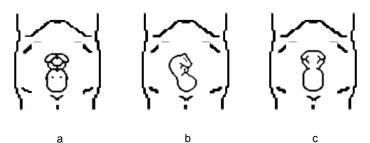
- Fetal Condition
  - (1) Gestational age

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

(2) Fetal body posture

Recommended: cephalic face up (figure a) or face aside (figure b);

NOT recommended: cephalic face down (figure c).



(3) Amniotic fluid(AF) isolation

The region desired is isolated by amniotic fluid adequately.

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

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

The optimum tangent plane to the fetal face 3D/4D imaging is the sagittal section of the face. To ensure high image quality, you'd better scan maximum face area and keep edge continuity.

Image quality in B mode (2D image quality)

Before entering 3D/4D capture, optimize the B mode image to assure:

- High contrast between the desired region and the AF surrounded.
- Clear boundary of the desired region.
- Low noise of the AF area.
- Scanning technique (only for Smart 3D)
  - Stability: body, arm and wrist must move smoothly, otherwise the restructured 3D image distorts.
  - Slowness: move or rotate the probe slowly.
  - Evenness: move or rotate the probe at a steady speed or rate.
- **NOTE:** 1. A region with qualified image in B mode may not be optimal for 3D/4D imaging. E.g. adequate AF isolation for one section 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.

## 5.10.3 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:

3. Press

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



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 touch screen, set parameters like [Angle], [Image Quality] on the touch screen accordingly.
- 5. Press <Update> on the control panel to start the 3D image acquisition.

The system enters into 3D image viewing status when the acquisition is completed; or, you can finish the acquisition ahead by pressing the <Update> or <Freeze>.

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.

do

Press <Update> to return to Static 3D image acquisition preparation; or, press <B> or 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: 10-80°.
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 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.
STIC		Reserved function. Used for fetal heart observation in 4D image.

### 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:

- Pressing <Update> or <Freeze> on the control panel; or,
- 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

Touch [A], [B], [C] or [VR] 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

Touch **Least** on the touch screen to display section images. And the adjustable image parameters are changed into MPR parameters automatically.

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

MPR Only function is available in image acquisition status.

#### Asymmetric

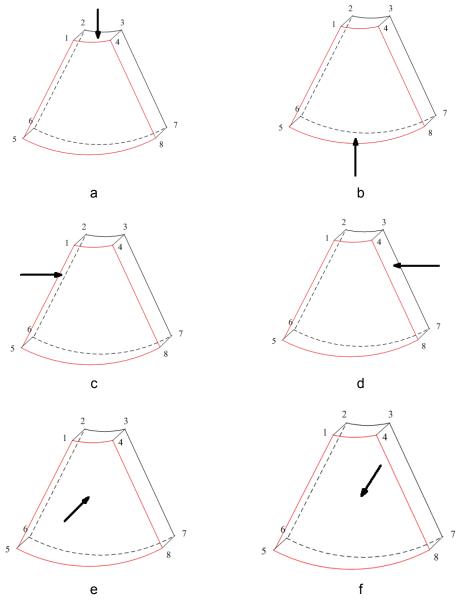
Touch 片

on the touch screen 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.



**View Direction** 

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

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

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

### Adjust VOI

VOI On

VR image displays VOI information.

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

VR image displays ROI information.

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

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

In Accept VOI status, when the 3D image is active or the section image which is perpendicular to the view direction is active, center point of the 3D image displays, and you can adjust the position using the trackball.

#### **Image Rendering Parameters**

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



on the touch screen to select parameter adjustments of VR or

MPR.

- When the [VR] is highlighted in green, parameter adjustment is performed on VR image.
- When the [MPR] is highlighted in green, parameter adjustment is performed on MPR 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%.		
	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.		
Contract	Function: to set the contrast of 3D image.		
Contrast	Range: 0%-100%.		
Tint	Switch on/off tint map, selection: Off, 1-8.		
VR Orientation	To quickly rotate the 3D image.		
VR Onentation	Selection: 0°, 90°, 180°, 270°.		
iClear	Enhances B mode image profile for better boundary details.		
ICIEdi	Range: Off, 1-7.		

#### 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.	
	Мах	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.		
		ion is to inverse the grayscale of the image, so as to enhance r low-echo region, applicable for vessel, cyst and etc.	
	When the function is turned on, the rendering mode parameters change into the corresponding inverse parameters.		

#### 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, touch [Auto Rot.] tab on the touch screen, system enters into auto rotation preparation state.
  - (2) Touch [Left/Right] or [Up/Down] to set the auto rotation direction.
  - (3) Set Start position and End position:

Start position: roll the trackball to view to a certain position, press the trackball function key of "Set Start" according to the trackball hint area.

End position: roll the trackball to view to a certain position, press the trackball function key of "Set End" according to the trackball hint area.

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

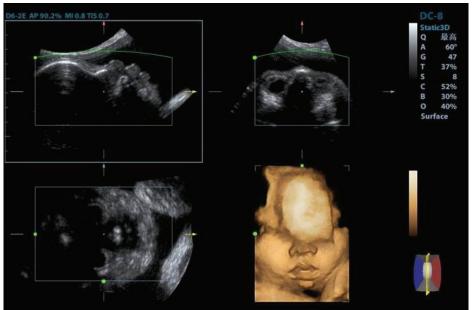


Figure A

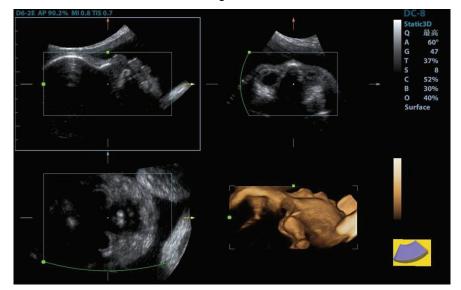


Figure B

#### **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 touching [Edit] tab.

When entered image editing mode, 3D image is automatically displayed on the touch 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] on the touch screen;
- > To undo all cuttings, click [Undo All];

The image cutting parameters are described as follows:

Туре	Parameters	Description
Edit Type	Inside Contour	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.
	Outside Contour	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.
	Inside Rect	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.
	Outside Rect	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.
	Big Rubber	Reserved function.
	Small Rubber	Reserved function.
	Inside Polygon	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.
	Outside Polygon	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 Operations	Undo	To undo the last cut only.
	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.

### 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.

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3. Press 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.
- 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.

Or, press <B> or

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



key to enter B mode.

### 5.10.4.2 4D Acquisition Preparation

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

### 5.10.4.3 4D Real-time Display

In 4D real-time display status, 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.

### 5.10.4.5 3D/4D Fast Switching



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



During 3D imaging viewing mode, press you can obtain the same image of dynamic mode.

to switch to 4D image real-time status quickly, where

## 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.

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 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".

6. Exit Smart 3D.

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

<B> or

to enter B mode.

### 5.10.5.2 Smart 3D Acquisition Preparation

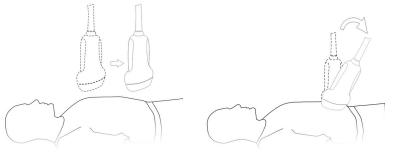
In Smart 3D mode, you may have to set scan method except all other items in Static 3D mode. Other parameters are the same as that of Static 3D, for details; please refer to "5.10.3.2 Static 3D Acquisition Preparation".

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.	
Method	Linear mode: during the sweep, the probe may not be moved parallel, the speed at which you scan should be constant. Rocked mode: in this mode, the probe must be moved to a position where you can clearly see a middle cut of the object you want to scan and render. Tilt the probe to about 30 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. 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.	

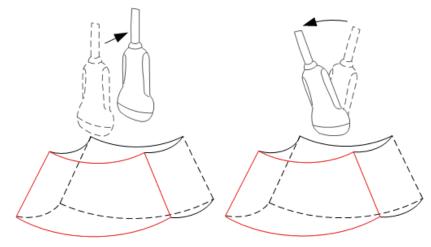
### 5.10.5.3 Smart 3D Image Viewing

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.

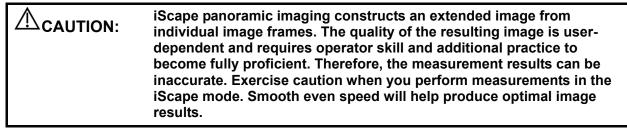
# 5.11 iScape

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 pieces these images together into single, extended B image in real time. Besides, the system supports out-and-back image piecing.

After you obtain the extended image, you can rotate it, move it linearly, magnify it, add comments or body marks, or perform measurements on the extended image.

You can perform the iScape panoramic imaging feature on B (power) real time images using all linear, convex (including 4D probes), and phased probes.



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. Enter iScape:
  - Press <iScape> on the control panel
- 3. Optimize the B mode image:

In the acquisition preparation status, click [B] page tab to go for the B mode image optimization. Do measurement or add comment/body mark to the image if necessary. Tips: in iScape mode, [FOV] is limited to "W".

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 <B> button to return to B mode. If it is in the capture status, press the <Esc> key.

## 5.11.2 Image Acquisition

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

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

To end the image capture:

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

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

Tips:

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

Status	<b>ROI</b> Color	Tips
Speed too low	Blue	Moving speed of the probe is too low.
Appropriate	Green	None.
Speed too high	Red	Moving speed of the probe is too high.

Guidance and precautions for uniform motion:

- Make sure that there is enough coupling gel along the scan path.
- Always move the probe slowly and steadily. .
- Continuous contact is required throughout the length of the extended image. Don't lift the probe from the skin surface.
- Always keep the probe perpendicular to the skin surface. Don't rock, rotate or tilt the probe during the scan.
- The system accommodates a reasonable range of motion velocity. Don't make abrupt changes in speed of motion.
- Deeper scans generally require reduced acquisition speed.

## 5.11.3 iScape Viewing

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

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

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

### 5.11.3.1 Image Parameters Adjusting

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

Image size

Touch [Actual Size] to display the image in its actual size.

Touch [Fit Size] to display the image in an appropriate size according to the current window. Also this is the system default format.

Tint map

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

Ruler

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

### 5.11.3.2 Image Zooming

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

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

### 5.11.3.3 Rotating the Image

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

#### 5.11.3.4 Measurement, Comment, and Body Mark

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

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

### 5.11.3.5 Evaluate Image Quality

Many variables may affect the overall image quality. It is important to evaluate the image content and quality before an image is used for diagnosis or measurements.

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

The following artifacts may produce a sub-optimal image. If the image quality cannot meet the following criteria, you shall delete the image and do image acquisition again.

- The image must be continuous (no part of an image moves suddenly or disappears.)
- No shadow or absent signal along the scan plane.
- Clear profile of anatomy through the entire scan plane without distortion.
- Skin line is continuous.
- The images are captured from the same plane.
- There is no large black area in the image.

## 5.11.4 Cine Review

Click [Review Cine] on the touch screen in panoramic image viewing status to enter cine reviewing mode. In cine reviewing mode, there is a green frame marker indicating the sequence of currently reviewed image in the panoramic image on the left side of screen. In cine review status:

• Roll the trackball to review the captured images frame by frame.

- Click [Auto Play] to start or end auto play.
- In auto play mode, click [Auto Play] on the touch screen; or, press/rotate the corresponding knob to change the play speed. When the speed is 0, the system exits auto play mode.
- Review to a certain image; 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 [iScape] item on the touch screen to exit the cine review mode, and there displays the panoramic image.
- In cine review mode, press <Freeze> on the control panel to return to the acquisition preparation status.

# 5.12 Elastography

## 5.12.1 Basic Procedure for Elastography

1. Perform B scan to locate the region.



- to enter the mode, adjust ROI according to the actual situation.
- 3. Select the probe according to the experiences and actual situation.
- 4. Adjust the image parameters to obtain optimized image and necessary information.
- 5. Adjust ROI on the frozen image if necessary.
- 6. Save the image or review the image if necessary.
- 7. Do measurement or add comment/body mark to the image if necessary.
- 8. Estimate the hardness of lesions according to the results.
- 9. Press <B> to return to B mode.

Only L14-6NE, L14-6WE and L12-3E support elastography imaging.

## 5.12.2 Enter/ Exit

Enter

2. Press

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

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

Exit

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

## 5.12.3 Pressure Hint Curve

The screen displays the pressure curve in real-time:



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

#### **ROI Adjustment**

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

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

Smooth

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

**Operation** To adjust the image smooth, adjust through the [Smooth] item on the touch screen.

Opacity	
Description	To adjust the opacity feature of the Elasto image.
Operation	Rotate the knob under [Opacity] item on the touch screen.
Invert	
Description	To invert the E color bar, thus to invert the color of benign and malignant tissue can be inverted.
Operation	Click [Invert] on the touch screen.
Single E	
Description	To switch between B+E dual window and single E window.
	E represents Elastography image.
Operation	Touch [Single E] on the touch screen, and when the button is highlighted in green, the screen displays the single window E image.
Мар	
Description	To select different maps for observation.
Operation	Rotate the knob under [Map] item on the touch screen to select the map.
	The system provides 6 maps, including 1 grayscale map and 5 color maps.

Tips: In Elasto imaging mode, image magnification is not available.

## 5.12.4 Mass Measurement

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

## 5.12.5 Cine Review

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

**6** Display & Cine Review

# 6.1 Splitting Display

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

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

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

# 6.2 Image Magnification

**NOTE:** Zooming an image changes the frame rate which tends to change thermal indices. The position of the focal zones may also change which may cause the peak intensity to occur at a different location in the acoustic filed. As a result, the MI may change.

## 6.2.1 Spot zoom



To use the function, use the zoom knob on the control panel.

- 1. Press <Zoom> to enter the sample volume definition status.
- 2. Roll the trackball to change the box size and position, press <Set> to toggle between setting the size and position, or rotate the <Zoom> knob to adjust the size. After sample volume is set, press <Zoom> key again to enter spot zoom status.
- Rotate the <Zoom> knob to change the magnification factor. The image magnification factor value will display in real-time in the image parameter area, for example, z1.3 indicates that the magnification factor is 1.3.
- 4. Press <Zoom> again to exit spot zoom.

Tips:

- Spot zoom can only be achieved on real-time image.
- The size and position of sample volume box change along with scanning depth and area.

### 6.2.2 Pan zoom



To use the function, use the zoom knob on the control panel.

- 1. Rotate <Zoom> knob to directly enter the pan zoom status. Image-in-image is displayed.
- Magnification factor adjustment: rotate the [Zoom] knob to change the magnification factor. The image magnification factor value will display in real-time in the image parameter area, for example, Z1.3 indicates that the magnification factor is 1.3.
- 3. Press <Zoom> to exit pan zoom.

## 6.2.3 iZoom (Full-screen Zooming)

Function: to magnify the image in full screen.

Procedures:

2. Press



1. Press to zoom in the image; the zooming area includes image area, parameter area, image banner, thumbnail area and so on.



again to zoom in the image area only.

3. Press *again to exit iZoom*.

# 6.3 Freeze / Unfreeze the Image.

Press <Freeze> key on the control panel to freeze a scanning image. In freezing mode, the probe stops transmitting acoustic power, and all images as well as the parameters are kept still.

Tip: after freezing an image, the system may enter cine review, measure, comment adding, or body mark mode, which is dependent upon preset. (Setting path: [Setup] $\rightarrow$ [System Preset] $\rightarrow$ [Image] $\rightarrow$ "Freeze Config")

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

### 6.3.1 Imaging Mode Switching When Frozen

Imaging mode switching in freeze mode follows the following principles:

- In splitting display B mode, press <Dual>/<Quad> to switch among the windows; press <Single> to exit splitting display mode and enter the image of the currently activated window in full screen.
- In freeze mode, the system supports imaging mode switching between the sub-modes (only for the activated window). For example, if the frozen image is of B+C+PW mode, then the system supports imaging mode switching between B+C+PW, B+C, B+PW and B by pressing <Color> or <PW>.
- The imaging mode and parameters of an unfrozen image is the same as the corresponding one that before frozen; but the display format is the same as the one before unfrozen.

## 6.3.2 Imaging Display Format Switching When Frozen

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

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

If the imaging mode before frozen is 2D (frozen) +PW (real time) or 2D (real time) +PW (frozen), then in freeze mode, you can switch between 2D (frozen) +PW (activated) or 2D (activated) +PW (frozen) by pressing <Update> key on the control panel.

- Dual/quad splitting display mode (Press <Freeze> key in dual/quad splitting display mode)
  - When enters freezing mode, the default activated window is the real time window before frozen. Other image windows display the corresponding cine memories, if a certain cine memory is empty, then no image is displayed.
  - Press [Dual] / [Quad] to switch between dual-splitting and quad-splitting mode.
  - Press <Single> on the control panel to enter the single display format, which displays the currently activated window. In single display format, press <Dual>/<Quad> to return to splitting display mode.
  - Unfrozen: in splitting display status, when you unfreeze the image you can only unfreeze the image in the activated window, other images still keep frozen. In single-window display status, the system displays single image after being unfrozen.

## 6.4 Cine Review

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

The system supports manual review as well as automatic review. The default setup is Manual Cine, but you can switch between Auto Cine and Manual Cine.

In addition, the system supports the images reviewed along with physiological waveforms, if the detection of physiological waveforms is performed.

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

### 6.4.1 Entering/ Exiting Cine Review

- To enter Cine Review:
  - Enter "[Setup]-> [System Preset]-> [Image Preset]-> "Freeze Config", to set "Status after Freeze" to be "Cine". Then the system enters the manual cine review status once press <Freeze> to freeze the image.
  - Open cine files in thumbnail, iStation or Review, the system enters automatic cine review status.
- To exit Cine Review:
  - Press <Freeze> or <B>, the system will return to image scanning and exit cine review.

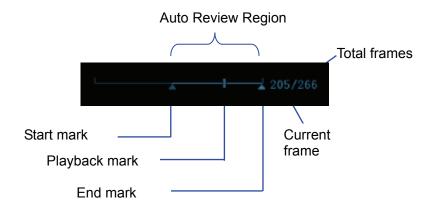
### 6.4.2 Cine Review in 2D Mode (B/B+Color/B+Power/B+TVI/B+TEI)

#### Manual Cine Review:

After entering the cine review of 2D mode, roll the trackball to review the cine images on the screen one by one.

If you roll the trackball to the left, the review sequence is reversed to the image-storing sequence, thus the images are displayed in descending order. Whereas, if you roll the trackball to the right, the review sequence is the same as the image-storing sequence, thus the images are displayed in ascending order. When you review images until the first or the last frame, further rolling the trackball will display the last or first frame.

The cine progress bar at the bottom of the screen (as shown in the figure below):



- Auto Review
  - Reviewing all
    - a) In the manual cine review status, press the knob under the [Auto Play] in the touch screen to activate auto cine review.
    - b) Reviewing speed: In the auto cine review status, rotate the knob under the [Auto Play] in the touch screen to adjust the review speed. When the speed is changed to 0, the system exits the auto cine review.
    - c) In auto play status, press the knob again, or roll the trackball to exit auto play.
  - Setting Region of Auto Review
    - a) Set start frame: rotate the knob under the [Start Frame] in the touch screen, to manually review the images until the frame which you want to set it as start point, press the knob to set it as the start point.
    - b) Set end frame: rotate the knob under the [End Frame] in the touch screen, to manually review the images until the frame which you want to set it as end point, press the knob to set it as the end point.
    - c) Press the knob under the [Auto Play] in the touch screen; the system plays the auto review region automatically.
    - d) Rotate the knob under the [Auto Play] to increase/decrease the auto play speed.
    - e) In the auto cine review, press the knob under the [Auto Play] on the touch screen or rolling the trackball will stop the auto cine review and enter the manual cine review.
    - f) Click [Jump to First]/ [Jump to Last] to review the first or last image.

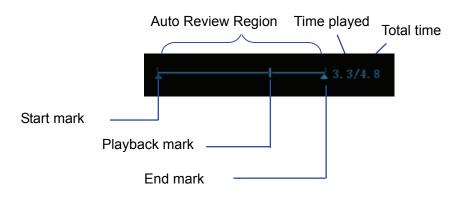
Tips: you can perform cine review on each image window in the dual/ quad splitting mode, and set auto review region for each window.

## 6.4.3 Cine Review in M/ PW/ CW/ TVD Mode

Enter cine review in M/ PW/ CW/ TVD mode, and roll the trackball, the cine images are displayed on the screen one by one.

Roll the trackball 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):



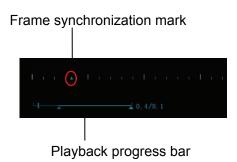
Cine review operations are the same as those of 2D mode.

Tips: There is no audio when the spectrum is reviewed in manual status but audio synchronization can be realized in auto review status with speed of ×1.

## 6.4.4 Linked Cine Review

The linked cine review refers to review of the images captured at the same moment.

- Dual live mode(B+C)
- B+M
- B/B Dual liveDuplex mode
- Triplex mode



The frame mark and the time mark of M/PW image indicates the corresponding 2D image. In the statuses rather than the dual live, you can only review images in the currently active window.

# 6.5 Image Compare

### 6.5.1 Image Compare in Review Mode

- 1. Press <Review> to enter Review screen, press <Ctrl>+<Set> to select files to be compared.
- 2. 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.
- 3. Click [Compare] to enter image compare mode.
- 4. Review the images of different image windows (cine replaying can't be performed for singleframe 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

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

Image compare of different exams for the same patient:

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

### 6.5.2 Frame Compare

- 1. Freeze the image in B/C mode, click [Frame Compare] in "Cine" page on the touch screen to enter frame compare mode.
- 2. Review the images of different image windows (cine replaying can't be performed for singleframe image file), press <Update> or <Dual> key to switch the active image window.
- 3. Save the image if it is necessary.

Measurements, adding comments and body marks are allowed.

4. Click [Frame Compare] again to return to image frozen status; press <Freeze> to enter realtime imaging.

Tips: cine compare can only be performed on single-format 2D images only.

# 6.6 Cine Saving

#### Live capture

Live capture refers to saving the images or cines in image scanning status; after the storage, the system continues image scanning.

Live capture can be divided into 2 kinds: retrospective and prospective.

- Retrospective saving is to save the specified images before the current moment; to save the images stored in the cine memory to the system hard disk.
- Prospective saving is to save the specified images later than the current moment; to save the images to both the cine memory and the system hard disk.

The live capture time can be set.

To perform live capture:

 In scanning mode, press the <Save 1> or <Save 2> 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 2> 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.

## 6.7 Cine Memory

### 6.7.1 Cine Memory Setting

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

Setting path: select "Auto" or "Split" for cine memory in [Preset] $\rightarrow$  [System Preset] $\rightarrow$  "Image ". 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 Split	Single-B/ Color	Dual	Quad
Auto	One memory, with capacity N frames	The memory splits into two, with capacity N/2 frames each	The memory splits into two, 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 two, with capacity N/4 frames each

## 6.8 Preset

### 6.8.1 Setting Cine Length

Open [Setup]  $\rightarrow$  [System Preset] $\rightarrow$  "General", you can perform the following setting:

Non-live storage



- For Time without ECG(s), 1~60s.
- To set the number of ECG loops when saving a cine. Value: 1~16.
- Live capture
  - Type: Retrospective, Prospective.
  - Cine length:

Prospective Cine Lengt	h		
Time(s)	180	(1-480s)	
Beat(heart cycle)	120	(1-390 Cycles)	
Retrospective Cine Len	gth		
Time(s)	6	(1-120s)	
Beat(heart cycle)	120	(1-120 Cycles)	

Tips:

• If the value is out of range, then the system can change it to the most adjacent effective value.

# 7 Physiological Signal

A physiological input panel is available for this system. The physiological module consists of three channels: ECG, PCG and DC IN. DC IN is capable of handling external ECG signals from other ECG signal devices.

The scanned image that is displayed is synchronized with the ECG and PCG traces. So ECG and PCG signals can be applied for time reference in an ultrasonic exam (mainly in cardiology exam).

Without the physiological option, the Physio touch screen is not available.

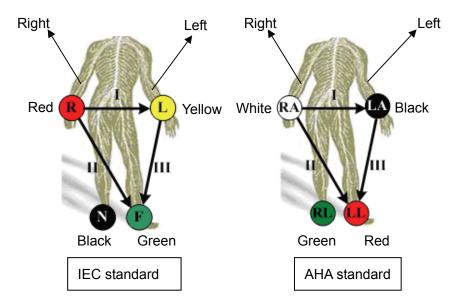
	1. DO NOT use the physiological traces for diagnosis and monitoring.
	2. To avoid electric shock, the following checks shall be performed prior to an operation:
	<ul> <li>The ECG electrode cable and PCG transducer shall not be cracked, frayed or show any signs of damage or strain.</li> <li>The ECG electrode cable and PCG transducer shall be correctly connected.</li> <li>You should use the ECG leads and PCG transducer provided with the physiological module. Otherwise it may result in electric shock.</li> </ul>
	3. 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. DO NOT use PCG with the defibrillator or contact the PCG with patient during defibrillation. This equipment does not have a defibrillator approved applied part.
	9. Frequent trampling or squeezing on the cables may result in cable break-down or fracture.
NOTE: When abo	ormality is detected in physic trace, please check if PCG transducer or

**NOTE:** When abnormality is detected in physio trace, please check if PCG transducer or ECG leads are properly connected with the system.

## 7.1 ECG

### 7.1.1 ECG Operation Basic Procedures

- 1. Connect the device.
  - Turn off the power supply of the system, and connect the ECG cable to the corresponding interface on the physiological module.
  - Turn on the power supply of the system.
     Place the ECG electrodes on the patient's body (as shown in the following figures).



2. Enter physio operation status:

The system provides two methods to enter ECG operation:

Press <Physio> key on the control panel.

- 3. Switch the imaging modes and display formats, adjusting the parameters to get an optimized image.
- 4. Parameter adjusting
  - On the Physio page, you can adjust [Speed] and [ECG Gain].
- 5. Freeze the images and review the images.
- 6. Press <Physio> to exit ECG mode, and remove ECG electrodes from the patient.

## 7.1.2 Parameter Description

The ECG parameters are described as follows:

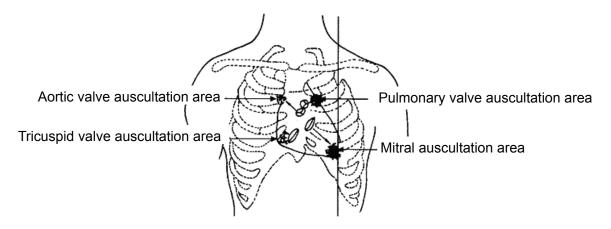
Туре	Parameter	Description
		Function: to control the display of ECG trace in live status.
	ECG	Value: ON/OFF, ON is to display the trace, while OFF is to hide the trace.
		In freeze mode, [ECG] controls the displaying or hiding of ECG trace.
	ECG Source	Select ECG source.
ECG		Function: to set the amplitude of ECG trace.
	ECG Gain	Method: click [Gain] on the touch screen; or, press/rotate the corresponding knob. Each adjustment cycles you to the next setting.
		Value: 0-30, in increments of 1.
	Speed	Function: change the speed of the physio trace.
	opeeu	Value: 1-6.

# 7.2 PCG

NOTE:	1.	PCG transducer shall not be cracked, frayed or show any signs of damage or strain. Before using PCG transducer, make sure to check the transducer. If any abnormity is found, please contact Mindray Customer Service Department or sales representative.
	2.	If no physio trace is displayed after entering the physio mode (PCG trace is displayed as a line), please check if PCG transducer is properly connected with the system.
	3.	Hot-plug is not allowed during PCG application.
	4.	To meet the requirement of signal receiving performance, silica gel is used for the PCG transducer head; don't scrape the head excessively to avoid transducer damage.

### 7.2.1 PCG Operation Basic Procedures

- 1. Connect the PCG transducer.
  - (1) Connect the PCG transducer to the corresponding interface on the physiological panel.
  - (2) Power on the system.
  - (3) Place PCG transducer on the patient's body (as shown in the figure below).
  - Mitral auscultation area: the left 5th intercostal, medial side of subclavian central line;
  - Tricuspid valve auscultation area: bottom of the sternum (to the right);
  - Aortic valve auscultation area: the right edge of sternum, the second intercostal;
  - Pulmonary valve auscultation area: the left edge of sternum, the second intercostal.



2. Enter physio operation status:

Press [Physio] key on the control panel.

When entered PCG mode, if [PCG] is set "ON", then PCG trace can be displayed.

- 3. Switch the imaging modes and display formats, adjusting the parameters to get an optimized image.
- 4. Parameter adjusting:

On the Physio page, you can set [PCG] as "ON" or "OFF", and adjust [PCG Gain], [PCG Smooth] and [Speed].

- 5. Freeze the images and traces, and review them to get desired information.
- 6. Exit PCG mode, and take away the transducer.

## 7.2.2 Parameter Description

The ECG parameters are described as follows:

Туре	Parameter	Description
		Function: to control the display of PCG trace.
	PCG	Value: ON/OFF, ON is to display the trace, while OFF is to hide the trace.
		Tips: in live mode, turn off PCG display will stop PCG signal acquisition.
		In freeze mode, [PCG] controls the displaying or hiding of PCG trace.
PCG		Function: to set the amplitude of PCG trace.
	PCG Gain	Method: click [PCG Gain] on the touch screen.
		Value: 0-30, in increments of 1.
	PCG Smooth	Function: to smooth the PCG trace.
	FCG Shiooth	Value: 1, 2, 3, 4.
	Speed	Function: change the speed of the physio trace.
_	Speed	Value: 1-6.

### 7.2.3 PCG Transducer Cleaning

NOTE:	1.	Before cleaning the PCG transducer, make sure it is disconnected from the ultrasound system.
	2	Don't overevert when clean the PCC transducer with the alcohol, otherwise

2. Don't overexert when clean the PCG transducer with the alcohol, otherwise, damage may result.

Please clean the PCG transducer before and after use. Failure to do so may result in the transducer to becoming sources of infection.

For usage on the general patients Cleaned the transducer with a soft cloth which is dampened with the medical applied alcohol, and then air-dry it or dry it with a clean dry cloth.

For usage on the special patient (patients with skin disease)

Please use a proper protective sheath to seamlessly cover the head of the transducer.

To order a probe sheath, you may 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

# **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].

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.

<ol> <li>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).</li> </ol>
2. If the system is turned off or <end exam=""> is pressed during a measurement, the data not saved will be lost.</end>

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

## 8.1 Basic Operations

To enter/exit measurement

To enter: press <Caliper> on the control panel to enter general measurement; press <Measure> key to enter application measurement.

To exit: press <Caliper> key or <Measure> key again.

Measurement result and help information

The system displays and updates measurement results in the result window.

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	Measures the angle between two intersected planes.
Area	Measures the area and perimeter of a closed region.
Volume	The volume of a target.
Double Dist	Measures the length of two line segments, which are perpendicular to each other.
Parallel Line	Measures the distances between each pair of parallel lines in a sequence.
Trace Length	Measures the length of a curve.
Distance Ratio	The lengths of any two lines 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.
Strain Ratio	Measures strain ratio in the image.
Strain-Hist	Displays strain ratio using the histogram.

### 8.2.2 M General Measurements

M general measurements refer to general measurements on M-mode, CM-mode, AM-mode images. The measurements listed below can be performed:

Measurement Tools	Function
Distance	The vertical distance between two points.
Time	The time interval between any two points.
Slope	Measures the distance and time between two points and calculates the slope.
HR	Measures the time of n (n $\leq$ 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, velocity and PG (pressure gradient) of a point on the Doppler spectrum waveform are measured.
Acceleration	Velocity and time interval between two points are measured to calculate speed difference and acceleration.
D Trace	On the PW mode image, one or several Doppler waveforms are traced to obtain speed and PG, etc.
PS/ED	Velocity and PG between two peaks on the Doppler spectrum to calculate RI (resistance index) and PS/ED (peak systolic/end diastolic).
Volume Flow	Blood flow through some vascular cross section per unit time.

## 8.3 Application Measurement

- Abdomen measurements Used for measurements of abdominal organs (liver, gall bladder, pancreas and kidney, etc.) and large abdominal vessels.
- OB measurements Used for measurements of fetal growth indexes (including EFW) as well as GA and EDD calculations. The fetus can be evaluated through growth graph analysis and fetal biophysical profile.
- Cardiac measurements Used for left ventricle function measurements and measurements of main artery and vein parameters, etc.
- Gynecology measurements Used for the uterus, ovary and follicles, etc.
- Small Part measurements Used for small parts such as thyroid.
- Urology measurements Used for prostate, seminal vesicle, renal, adrenal, micturated and testicle volume.
- Orthopedics measurements Used for hip joint measurement.
- Peripheral vessel measurements Used for carotid, cerebral, upper and lower extremities vessels, etc.

## 8.4 Measurement Accuracy

Table 1 Error of 2D Images

Parameter	Value Range	Error
Distance	Full screen	Within ±3%; or when the measured value is less than 40 mm, the error is less than1.5 mm.
Area (Trace) Full screen		Within $\pm 7\%$ ; or when the measured value is less than 16 cm <sup>2</sup> , the error is less than 1.2 cm <sup>2</sup> .
Area (ellipse, circle)	Full screen	Within $\pm 7\%$ ; or when the measured value is less than 16 cm <sup>2</sup> , the error is less than 1.2 cm <sup>2</sup> .
Angle	Full screen	Within ±3%.
Volume	Full screen	Within $\pm 10$ %; or when the measured value is less than 64 cm <sup>3</sup> , the error is less than 6.4 cm <sup>3</sup> .

Table 2 Time/Motion Measurements

Parameter	Value Range	Error
Distance	Full screen	Within $\pm 3$ %; or when the measured value is less than 40mm, the error is less than 1.5mm.
Time	Timeline Display	Within ±2%.
Heart rate	Timeline Display	Within ±4%.
Velocity (PW	10-200cm/s (for L12- 3E, L14-6NE, L14- 6WE, D6-2E)	
mode)	10-300cm/s (for C5- 2E, C7-3E, P4-2E, D8- 3E, V11-3E)	When angle≤60°, ≤5%.
Velocity (CW mode)	10-300cm/s (for P4- 2E)	When angle≤60°, ≤5%.

**NOTE:** Within the selected field range, the measurement accuracy is ensured within the range mentioned above. The accuracy specifications are performance in the worst conditions, or based on the real test for the system, regardless of acoustic speed error.

9

**Comments and Body Marks** 

## 9.1 Comments

Comments can be added to an ultrasound image to bring attention, notate or communicate information observed during the examination. You can add comments to: zoomed image, cine review image, real-time image, frozen image. You can type the character as comments; insert the pre-defined comments from the comment library; or insert arrow markers. The system supports recording voice comment as well.

**WARNING:** You must ensure that the entered comments are correct. Incorrect comments may cause misdiagnosis!

### 9.1.1 Comment Basic Procedures

To perform a comment:

1. Enter comment status:



• Press any alphanumeric key to enter the comment status; Or,



to enter the arrow-adding status.

Tips:

- 2. Place the cursor to the desired place to set the comment location.
- 3. Add new comment to the image according to actual situation. Here, you can modify, move or delete a completed comment.

Or,

- 4. To exit comment status:
  - In the comment status, press



- In the arrow-adding status, press
- Press <ESC> or other operating mode keys to exit.

### 9.1.2 Touch Screen Display in Comment

The system can be configured with comment text libraries including Abdomen, Cardiology, GYN (Gynecology), OB (Obstetrics), Urology, SMP (Small Part), Vascular, PED (Pediatric), Nerve Blocks and emergency medicine. In comment status, you can enter the comment text using the screen menu or touch screen.

- To set home of comments. Roll the trackball to move the cursor to the desired location for the comment and press <Fn>+<Home> on the control panel.
- Return the cursor to the set home location.
   Press <Home> on the control panel to return the cursor to the set home location.
- Crab/Del Rotate the knob under the [Crab/Del] button on the touch screen, to select the entered comment items; press the knob to delete the selected item.
- Navigate through comment libraries
   To select the comment library, rotate/ press the knob under the [Library] button on the touch screen.
- Add/ modify position comments Click [RT/LT] or [Sag/XS] to directly mark the position.

Move the cursor onto the comment item to be modified, click [RT/LT] or [Sag/XS] to change the already added comment position.

Change Font Size/Arrow Size
 To change font size of comment text, rotate the knob under the [Font Size] button on the touchscreen to select among Small, Medium and Large.

To change arrow size, rotate the knob under the [Arrow Size] button on the touchscreen to select among Small, Medium and Large.

- Comment display/hide Touch [Hide]/[Display] on the touch screen to display or hide the comments.
- Page-turning

If there is more than one page of comment texts for the current exam mode, you can

navigate to the other pages by touching **second second sec** 

- User-defined comments
   You can customize comments if necessary, including adding/deleting comments and adjust comment display on touch screen menu.
- Trace

Touch [Trace] on the touch screen to enter the trace commenting status.

## 9.1.3 Adding Comments

- Typing comment characters
- 1. To set the comment location:

Roll the trackball or press direction-control keys on the keyboard to move the cursor to the desired location for comments.

2. To type the alphanumeric characters:

You can enter the characters through the keyboard or the soft keyboard on the touchpad.

- Type the alphanumeric characters through the qwerty or soft keyboard (The default characters are uppercase).
- In the edit status (the characters are in green color), press <Enter> to move the cursor to the new line, and the location of the cursor is aligned with that of the first line.
- 3. In the edit status, press <Set> or <Enter> on the control panel to confirm the character added, and the color of the character added turns to yellow.
- Adding a Comment Text
- 1. In comment status, select the comment to be added.

You can add comment texts using the following methods:

- Roll the trackball to move the cursor onto the desired comment text on the screen menu and press <Set>, and then the system adds the selected comment text onto the screen. Move the trackball to confirm the adding.
- Touch the desired comment text on the touch screen, the system adds the selected comment text onto the screen where the cursor is anchored; you can edit the comment directly, and roll the trackball to confirm the adding.
- Add combined comment: Rotate the multifunctional knob to view the comments one by one; press the knob again to add the selected item onto the image (comment added in an editable state); rotate the multifunctional knob to search for the next part, and press the knob again to add the second part of the combined comment. Repeat procedures to add other parts of a combined comment. Press <Set> to complete the comment.
- 2. Exit comment edit status

In comment edit status, press <Set> or <Enter> key, or roll the trackball to confirm the added comment text and exit the edit status, the comment changes into yellow.

Adding an arrow

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

To add an arrow:

- (1) Press the <Arrow> key, and an arrow will appear in the default position.
- (2) Adjust the arrow in shape and position:
  - > To posit the arrow to the area of interest: roll the trackball to the desired position.
  - To change the orientation of the arrow: Rotate the <Angle> knob to change the arrow orientation (in increments of 15°).
  - Adjust the arrow size: rotate the knob under the [Arrow Size] button on the touch screen to change the size.
- (3) Press <Set> or <Enter> to anchor the arrow position, and then the arrow turns yellow. Repeat the above steps to add more arrows.
- (4) Press <Arrow> on the control panel to exit the arrow comment status.
- Tracing
  - (1) In comment status, touch [Trace] on the touch screen to activate trace function, and the current image is also displayed on the touch screen.

- (2) Control Panel operation:
  - a) Roll the trackball to a desired position, and press <Set> to confirm the start point.
  - b) Roll the trackball to move the cursor along the edge of the desired region and trace the outline of the region.
    - > Rotate the <Angle> knob anticlockwise, to cancel trace of 1 pixel.
    - > Rotate the <Angle> knob clockwise, to restore trace of 1 pixel.
    - Press <Clear> to delete trace (s).
  - c) Press <Set> to finish a tracing.

Touch screen operation:

- a) Trace around the ROI by touching the touch screen image using your finger.
- b) Remove your finger to finish the tracing.
  - > [Clear]: touch to delete the trace in reverse order one by one.
  - > [Clear All]: touch to delete all traces.
- c) Click [Exit] to exit the tracing.

### 9.1.4 Moving Comments

- 1. Select the comment to be moved.
- 2. Roll the trackball to move the comment to the new position.
- 3. Press the <Set> key to anchor the comment at the new position.

### 9.1.5 Modifying (Editing) Comments

- Modifying (Editing) characters
- 1. In comment status, move the cursor onto the comments to be modified.
  - Press alphabetic keys to enter the character to the cursor position directly.
  - Or, double press <Set> to enter comment editing status, and use the direction-control keys to move the cursor to the desired location to insert/delete characters; you can either type characters by pressing the corresponding keys or select the new comment text from the menu.
- 2. Press <Del> to delete the comment character or text on the right side of the cursor; press <Backspace> to delete the comment character or text on the left side of the cursor.
- 3. Roll the trackball or press <Set> to confirm the modification and to exit the edit status, and the color of the comments turns to yellow.
- Modifying (Editing) Arrows
- 1. Move the cursor on the arrow that needs to be modified. After the cursor turns to 1, 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 <Angle> knob to modify the arrow direction.
- 3. Press <Set> or <Enter> key to complete the operation.

### 9.1.6 Deleting Comments

- Deleting Comment Characters, Texts or Arrows
- 1. Move the cursor to the comment to be deleted.
- 2. Press the <Set> key to select the comment.
- 3. Press the <Del> or <Clear> key to delete the comment.

Deleting a recently-added character, text or arrow

After you add several comments and the cursor is in the "|" or " $\mathscr{A}$ " status, pressing <Clear> can delete the recently-added or recently-edited comment.

Delete All Comments

Long press the <Clear> to delete all the comments.

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

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

### 9.1.7 Comment Setting

- Comment text Setting
- 1. In comment status, touch [Custom] on the touch screen to enter comment user-defined screen.
  - Add new comment texts: posit the cursor in the field box right to [Custom], and enter the text comment through the keyboard, and then click [Add]. Then the directly-entered comment will be added to the current comment text library.
  - Change the comment text position on the touch screen: move the cursor to the text and click to select the text, and then click the desired position, then the text is moved to the position.
  - Delete comment text: move the cursor to select the text to be deleted, click [Delete] to delete the text.
- 2. Click [OK] to save the settings and exit the screen, click [Cancel] to exit the screen without any changes.
- Comment Setting

Enter the "[Preset] $\rightarrow$ [System Preset] $\rightarrow$ [Application]" screen to perform the following setting:

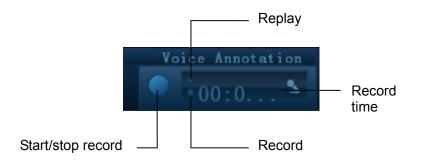
- Besides, you can preset whether to clear the comments when unfreezing the image or change the probe/ exam.
- Set if body mark is erased when the image is unfrozen.
- Set if the voice comment is enabled.

## 9.2 Voice Comment

The system supports adding voice comment to the frozen images.

### 9.2.1 Voice Comment Panel

After the system enters the voice comment status, the voice comment panel will be displayed on the lower left corner of the screen.



### 9.2.2 Adding Voice Comment

- 1. To perform voice comment adding, the function should be enabled through the path: [Preset]→[System Preset]→[Application].
- 2. Connect a microphone used for receiving voice comments to the mic port on the left side of the control panel.
- 3. Acquire the necessary images and press <Freeze> to freeze the image, and the voice comment panel displays on the lower left corner of the screen.
- 4. Press <Cursor> and roll the trackball to move the cursor onto the voice comment panel; click

to start recording, and the 🔲 icon turns red.

5. After the voice recording ends, press the user-defined key for saving the cine.

Note: in voice comment recording status, you can perform measurements, comments adding, body marks adding, print tasks and DICOM tasks.

If you press <Freeze> during the recording course, the already recorded voice comment cannot be saved.

### 9.2.3 Voice Comment Review

Click to open a cine file with voice comment, and during the cine review mode, voice comments are played as well.

## 9.3 Body Mark

The Body Mark (Pictogram) feature is used for indicating the exam position of the patient and transducer position and orientation.

The system supports body marks for Abdomen, Cardiology, GYN, OB, Urology, Small Part and Vascular applications. You can preset the system configured general body marks for each exam mode; also, you can customize the body mark. In addition, the system supports user-defined body marks, and body marks can be imported and exported.

### 9.3.1 Touch Screen Display in Body Mark

The body mark touch screen displays the settings for the current mode:

Library

Rotate the knob under the [Library] button on the touch screen or press the knob to switch the body mark library, the corresponding body marks are shown on the left.

Page-turning

If there is more than one page of the body marks, touch

to turn pages.

User-defined comments

Touch [Custom] to enter the dialogue, you can import body mark graph here.

Save Probe

Under the condition that the probe mark direction and position is determined for the current adding body mark, touch [Save Probe] to save the current direction and position for the probe mark of the current body mark.

### 9.3.2 Adding Body Mark

- 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 multifunctional knob
     Rotate the knob to view the body mark one by one, and press the knob to add the body mark.
  - Adding the body mark using the touch screen.
     Touch the desired body mark on the touch screen directly.
- 3. To adjust the probe position and orientation marker:
  - Roll the trackball to place the probe marker at the correct position.
  - Rotate the <Angle> knob to adjust the orientation.
  - Touch [Save Probe] to save the current direction and position for the probe mark of the current body mark.
- 4. Press <Set> to confirm the position and orientation of the probe marker and exit the body mark mode.

### 9.3.3 Moving Body Mark

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

- 1. Press <Cursor> and roll the trackball to move the cursor onto the body mark. The cursor then changes into , indicating you can move the pictogram to a new position.
- 2. Press <Set> key to select the body mark.
- 3. Roll the trackball to move the Body Mark graphic to the desired position.
- 4. Press <Set> to anchor and confirm the new graphics position.

NOTE: In Dual B Mode, a body mark cannot be moved between the separated image windows.

### 9.3.4 Deleting Body Mark

- 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:** If no object is selected, long pressing the [Clear] key will clear all comments, body marks and general measurements from the screen.

### 9.3.5 Body Mark Setting

Powering off, preset returning, switching the exam/ patient/ mode/ probe will clear the body marks.

# **10** Patient Data Management

An exam record consists of all information and data of one exam.

An exam record consists of the following information:

- Patient basic information and exam data
- Image files
- Report
- **NOTE:** 1. 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 "4.1 Patient Information".

## 10.2 Image File Management

You can store the image files either in the patient database in the system, or to external memory devices. For a saved image, you can perform operations like image reviewing, analyzing and demonstration (iVision).

### 10.2.1 Memory Media

System supported memory media including:

- System hard disk
- USB memory devices: USB flash drive, removable USB hard disk
- DVD+R, DVD+RW, DVD-R, DVD-RW, CD-RW, CD-R

### 10.2.2 Image File Formats

The system supports two types of image file formats: system-relevant and PC-compatible.

- System-relevant formats:
  - Single-frame image file (FRM) Refers to single-frame static image files not to be compressed; you can perform measurements and comments adding on this type of files.
  - Cine file (CIN)

System-defined multi-frame file format; you can perform manual or auto cine review, and perform measurements or add comments for the reviewed images. After you open a stored CIN file, the system automatically enters cine review status.

The system can save FRM files as BMP, JPG, TIFF or DCM files, or save CIN files as AVI, DCM files.

- PC-compatible formats:
  - Screen file (BMP) Single-frame file format, used to save the current screen, non-compressed format;
  - JPG: Single frame export format.
  - TIFF: Single frame export format.
  - Multi-medium file (AVI) Multi-frame export format.
  - DICOM file (DCM)
     DICOM standard files format, single-frame or multi-frame format, used to record patient information and images; you can only open DCM files to view rather than to edit.

### 10.2.3 Image Storage Preset

Set image size

You can set the image size via "[Setup]  $\rightarrow$  [System Preset] $\rightarrow$  [General]":

Image Size [mage Area 🛛 Standard Area

- Set cine saving length (clip length) For details, please refer to "6.8 Preset".
- Set send/ print image after end exam

Open "[Setup] $\rightarrow$ [System Preset] $\rightarrow$ [General]", check "Sending/ printing after End Exam" in Patient Management area. Then every time you press <End Exam>, the system will send images of the exam to the connected default DICOM server.

### 10.2.4 Quickly Saving Images to the System

- To save a single-frame image to the system quickly:
- 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 quickly:
- 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 are displayed in the form of thumbnails on the screen:

- During image scanning, thumbnails of the current exam display at the right of the screen; click or change the display format.
- In the iStation screen, the thumbnails of the current selected patient display at the bottom of the screen. When you move the cursor onto a thumbnail, its name and format will display.
- In the Review screen, the thumbnails refer to the images stored in the same exam. When you move the cursor onto a thumbnail, its name and format will display.
- In the Review screen, open an image to enter the image analyzing status, and all the thumbnails belong to the exam will be displayed on the right.

### 10.2.7 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:

Review						
	Patien.		<b>•</b>			Info
	▼ Image			🔵 Medium	🔵 Large	Report
					iStation	Exit 20-10-2011
					<b>\$</b>	20-10-201

- 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 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 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:

Press the user-defined key for iVision (setting path: [Setup]→[System Preset]→ [Key Config])

- 2. Add the contents to be played and select the demo mode.
- 3. Select an item in the list, and click [Start] to begin the demonstration.
- 4. Click [Exit] or press <ESC> to exit the iVision status.

The iVision screen is shown as follows:

iVision					
Content o	f DEMO				
🔘 Demo	Catalog	🔵 Customize Catalog			Demo Manager
	Number	File Name			
		E:\DC8\Demo			Add File
					Add Catalog
					Delete
					Clear
< >					Export
Demo Mode			Option of DEMO		Start
Interval	l 🛛 🗧 🖕 s		Repetition	🔵 No Repetition	
1					
					Exit

Demonstration item

The demonstration items are the image files in the formats that the system supports. You can add the exam data in patient database or system supported image files and folders to demonstration list. For files and folders in demonstration list, the images in the directory and subdirectory are played one by one, and the system will automatically jump over the files that can't be opened.

Demonstration catalog

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

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

The system supports importing, deleting or clearing the data in demo catalog.

Click [Demo Manager] to operate:

- to import data to demo catalog.
- to delete 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 or the files by the buttons on the right:

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

[Add Catalog]: to add catalog of the files to the list.

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

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

[Export]: to export the selected directory/file to the external storage devices. Click [Export] to pop up the Browse dialogue box, select the path, and click [OK].

Demonstration mode

The system automatically plays all the image files in the list one by one.

The time interval between images played is same and can be changed.

Option of Demo

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

### 10.2.9 Sending Image File

- On the image screen, select a stored image thumbnail, click →(Send To) on the upper left corner of the image, the image can be sent to the external device, DVD recorder, DICOM storage server, DICOM print server, system connected printer and etc.
- In the iStation screen, click ➡ ; or, in Review screen, click [Send To] to send patient data to an external memory device, you can choose if reports are exported with images. See the figure below.
- Press <Control> or <Shift> with <Set> key on the control panel to select more than one exam or image at one time.

See the figure below.

Send To	
Target	
<b>⊡</b> ⊧F:	== F:
<b>E</b> DICOM	
≽ Printer	
	📝 Export Image
Property	🔵 Origin 🛛 🕘 JPG/AVI 🌑 DCM
1%	🔵 BMP/AVI 🌑 TIFF/AVI
Total: 1004 MB	Cine Zoom Mode 640*480 🗸
Free: 995 MB	🕎 Export Report Type 🛛 PDF 🔍
	OK Cancel

- For external memory devices (e.g. USB memory devices or DVD-RW):
  - a) PC format transfer: JPG/ AVI, BMP/ AVI, TIFF/ AVI. Where a single-frame image is exported as JPG, TIFF or BMP, and the cine file exported as AVI.
  - b) DCM format transfer: DCM (including single-frame DCM and multi-frame DCM).
  - c) Cine zoom mode can be changed.
  - d) You can also select if to export report and select the report type.
- For DICOM server, select the DICOM Storage or Print server.
- For a video printer, send images to the video printer connected with the system. For a graph/ text printer, send the images to the default graph/ text printer.

## 10.3 Report Management

Report storage:

The exam reports are stored under the directory of the exam of the patient.

- Importing, exporting and sending a report
  - Import/export report via Backup

In iStation screen, select patient data, click or in the popped up menu to import or export patient information, images and reports from or to an external memory device. See the following figure:

Backup Patient Record		
Destination USB(F:)	V	
Original Format	Cine Zoom Mode	Original 🔽
DICOM Format	<b>Compression Mode</b>	Uncompressed
	<b>Compression Ratio</b>	Lossless
Remove from Local HD	after Backup	
Remove Exams	🔵 Rem	ove Images
Backup		Cancel

You can select the destination and image format, and select whether to remove local data.

#### • Export report via Send To

In iStation or Review screen, click [Send Exam] in the popped up menu to send patient data to an external memory device, you can choose if reports are exported with images. See the figure below.

Send To	
Target	
F:	== F:
<b>DICOM</b>	
Printer	
	📝 Export Image
Property	🔵 Origin 🛛 🔵 JPG/AVI 🌑 DCM
1%	🔵 BMP/AVI 🌑 TIFF/AVI
Total: 1004 MB	Cine Zoom Mode 640*480
Free: 995 MB	
	📝 Export Report Type PDF 🚽
	OK Cancel

To export the report:

- (1) Check "Export Report" on the screen.
- (2) Select report type to be exported.
- (3) Click [OK] to confirm.

You can select paper size for the report print in the path: [Setup]-[Print Preset].

Report printing

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

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

## **10.4 iStation - Patient Data Management**

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

- To Enter iStation
  - Press <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:

	Name	Exam Type	Exam Date/Time	Image	Clip	Exam State	Gender	Age	Backup	
0111101-12580		OB	01/11/2011 12:5			Paused	Female			
0111031-15390		OB	31/10/2011 15:3			Paused	Female			
0111031-11272			31/10/2011 11:2			Paused	Unknown			
0111024-10293			24/10/2011 10:2			Paused	Female			
0111024-09581			24/10/2011 09:5			Paused	Female			
0111017-10215			17/10/2011 10:2			Paused	Female			
0111017-10210			17/10/2011 10:2			Paused	Female			
0111014-16114			14/10/2011 16:1			Paused	Female			
0110910-11395	name	CARD	27/09/2011 16:3			Paused	Female			
0110910-11395	name		27/09/2011 16:2			End	Female			
0110910-11395	name		10/09/2011 11:4			Paused	Female	30Years		
0110909-15375			09/09/2011 15:3			Paused	Female			
0110909-15164			09/09/2011 15:1			Paused	Female			
0110909-14102			09/09/2011 14:1			Paused	Female			
0110909-11571			09/09/2011 11:5			Paused	Female			
0110909-11271			09/09/2011 11:2			Paused	Female			
0110908-15255		ABD	08/09/2011 15:2			Paused	Female			
0110908-14442			08/09/2011 14.4			Paused	Female			

### **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 Image
  Patient Info
  Review Report
  Delete Exam
  Backup Exam
  Restore Exam
  Send Exam
  Export Teaching Files
  Activate Exam
  Resume Exam
- 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 X on the upper left side.

Backup/ Restore

You can back up the selected patient data to the system-supported media in order to view it on PC, or restore the patient data to the system from an external media.

- [Backup Exam]: click to back up the selected patient data to the system-supported media.
  - > Original format: to back up the data in original format.
  - DICOM format: you can change the cine compression mode, and JPEG compression mode.
  - > You can select whether to remove images or the whole exam record from the system.
- [Restore Exam]: click to import the patient data from an external media.
- Send Exam

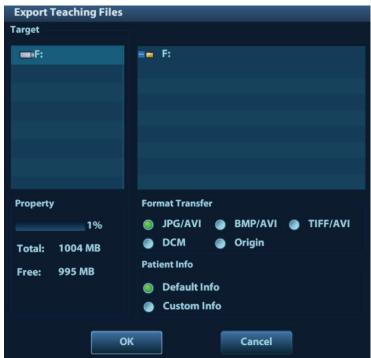
The system supports to send data to external memory devices or print.

 Select the patient record, click [Send Exam] in the menu to send exam data or images of the selected record.

Send To	
Target	
F:	= <b>e</b> F:
<b>DICOM</b>	
≽ Printer	
	🕎 Export Image
Property	🔵 Origin 🛛 🔵 JPG/AVI 🌑 DCM
1%	🔵 BMP/AVI 💿 TIFF/AVI
Total: 1004 MB	Cine Zoom Mode 640*480
Free: 995 MB	🛒 Export Report Type 🛛 🌄
	OK Cancel

- > 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. See "10.2.9 Sending Image File" for details.
- 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. See "10.2.9 Sending Image File" for details.
- 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 Comment 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 [OK] to exit the preset and make the settings effective. Press the [Print] key on the control panel to print.
- Video output settings:

Open [Setup]  $\rightarrow$  [System Preset] $\rightarrow$  [General], then select the image output mode.

Open [Setup]  $\rightarrow$  [System Preset] $\rightarrow$  [General], then select the image storage size.

### 10.5.2 Image Print

Image printing is mainly achieved by video printer, and for DICOM image printing, refer to DICOM chapter.

- 1. Select the desired image in iStation or Review screen.
- 2. Click I icon on the upper left 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 DVD-RW/DVD+RW drive to write data in CD/DVD and to read data from CD/DVD in PC.

The system supports the following media: DVD+RW, DVD+R, CD-RW, CD-R, DVD-R and DVD-RW.

- To write data to a CD/DVD:
  - (1) Put a CD/DVD in the tray.
  - (2) Select the data to be backed up, select [Send Exam] or [Backup Exam] in the popped up menu. Select the target drive in the Send To or Backup Patient Record dialogue box.
  - (3) Click [OK] or [Backup] to begin writing with the symbol displays
  - to pop up the Disc Option dialogue box. (4) After the writing process is completed, click and select [Eject] to eject the CD/DVD.
- 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.
- 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.

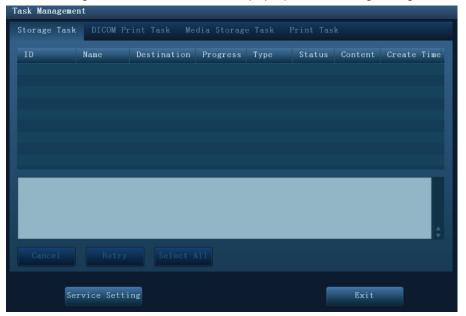
You can check the data writing procedure in patient task manager, for details, please refer to "10.7 Patient Task Management".

**CAUTION:** During the backup process, if a CD/DVD is forcibly taken out or you perform other operations, the backup process will fail or the system may malfunction.

## **10.7 Patient Task Management**

Click





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 used, you can click the icon to check the process.

When there is/are task(s) failed, the task management icon displays as the icon to check the failure reason.

When the task management icon displays as **used**, it means no task is undergoing or failure.

DICOM Service Setting

In the Storage Task and DICOM Print Task page, click [Service Setting] to enter the DICOM service setting screen. For details, please refer to DICOM chapter.

- Troubleshooting
  - If any serious error occurred like network disconnection or operation timeout, the system can try to reconnect the network. The interval time and maximum retries can be set, for details, please refer to DICOM chapter.

## **10.8 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 cannot 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].
- 2. If **Chable 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:

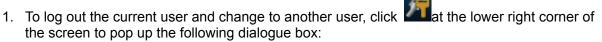
- Before entering the system
- Changing user

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:





- 2. Click [Change User] to pop up the Login dialogue box.
- 3. Enter the user name and password in the field box.
- Lock the system
- 1. Click the *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] $\rightarrow$ [System Preset] $\rightarrow$ [Admin].
- 2. Click [Add] to pop up the following dialogue box.

Adding New User	
User Name	
Password	
Confirm Password	
User Type	Operator 🔽
Note: The password	must consist of 6-1
Caps Lock Off	OK Cancel

- 3. Enter user name.
- 4. Enter the password and the confirmed password.
- 5. Set the user role in the drop-down list: administrator or operator.
- 6. Click [OK] to confirm the setting and exit the dialogue box, then the new user will appear on the User List.

#### Delete a User

Premise: you must log on the system as the system administrator. If not, you will be required to enter administrator name and password before the setting.

- 1. Open the "Admin" page through the path: [Setup] $\rightarrow$ [System Preset] $\rightarrow$ [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] $\rightarrow$ [System Preset] $\rightarrow$ [Admin].
- 2. Select the user name to be modified in User List, click [Change Password] to open the dialogue box (see the figure below).

Change Password	
New Password Confirm New Pas	
Note: The password mu	st consist of 6
Caps Lock Off	OK Cancel

- 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 **2** 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.

The chapter is confined to the preset, connection verification and DICOM services of the DICOMconfigured ultrasound machine, not including SCP configurations like PACS/RIS/HIS.

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 "12.6 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.



I	Name	Description
	AE Title	Application Entity title.
DICOM	Port	DICOM communication port.
Local PDU	PDU	Maximum PDU data package size, ranging from 16384 to 65536; if the value is less than 16384 or greater than 65536, the system automatically sets it to the value 32768.
	Device	Name of the device supporting DICOM services.
	IP Address	IP address of the server.
	Ping	You can ping the other machines after you entered the correct IP address.
Server		Besides, you can select a server in the Device list to ping it.
Setting	Device List	Displays the added device.
	Set DICOM 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.

Storage Print	Worklist MI	PPS StorageCommit	ment Query/Retr	ieve		
Configure the New						
Device		Service Na	me <b>de la company</b>	A	E Title	Port 104
Maximum Retries	s <mark>3</mark>	🗸 Interval T	ime(Sec) 15	T	'imeout(Sec) 1	5
Cine Zoom Mode	Original	Compressio	n Mode <mark>Uncompre</mark>	essed 🔽 C	Compression Ratio	ossless 🗸
Color Mode	Color	🗸 🗸 Allow M	ultiframe Max Fra	umerate <mark>35  3</mark>	BD/4D C	ine 🔽
SR Storage Opti	ion Not Store SF		- Enca	psulated PDF		
Add	Cancel	Update				
Service List						
Device		ervice Name	AE Title	Port	Default	
Delete	Default	Verify Veri	fy Undo!			

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.			
	Cine Zoom Mode	Select the cine zoom mode during image file storage.			
Configure	Compression Mode	Select the compression mode: uncompressed, RLE, JPEG, and JPEG2000.			
New 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.			
	3D/4D	Set the 3D/4D image transfer mode.			
	SR Storage Option	To enable or disenable structured reporting sending.			
	Encapsulated PDF	Select if to encapsulate PDF format report in DICOM standard.			
	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.

Storage Print	Worklist MPPS S	torageCommitment	Query/Retrieve			
Configure the New						
Device				AE T	itle <b>Hereit</b>	Port 104
Maximum Retries	3		c) 15	Timed	out(Sec) 15	
Print Properties —						
Copies	1		RGB		on PORTRAIT 🔽 Pr	iority HIGH
Film Size	8INX10IN		STANDARD\1,1	Medium Type	PAPER 🔽 Tr	im NO 🔽
Min Density	0	Max Density	300	Configuration 3	Info	
Destination	MAGAZINE	Magnification Ty	pe NONE 🔽			\$
Add						
Service List						
Device	Service N	ame AE	Title	Port	Default	
Delete	Default Veri	fy Verify Und				

DICOM print preset items are described as follows:

	Name	Description		
	Device	After you set the server (s) in DICOM Preset screen, the name (s) will appear in the drop-down list, select the name of the print server.		
	Service Name	Default is xxx-Print, user-changeable.		
Configure New	AE Title	Application Entity title, here, it should be consistent with that of the print server.		
Service	Port	DICOM communication port, 104 is default. Here, the port should be consistent with that of the print server port.		
	Maximum Retries	Set the maximum retries.		
	Interval Time (s)	Interval time that the system retries a connection.		
	Timeout	Refers to timeout during association establishment.		
	Copies	Refer to copies of printed files. You can select among 1 through 5, or directly enter the numeral.		
	Settings	The system supports RGB (color printing) and MONOCHROME2 (black and white printing). Please select the type the printer supports.		
Print	Film Orientation	Select between LANDSCAPE and PORTRAIT.		
Properties	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.		

	Name	Description
	Medium Type	Specify print medium: Paper, Clear Film, Blue Film; select Blue Film or Clear Film for black and white printing; select Paper for color printing.
	Trim	Specify whether you want a trim box to be printed around each image on the film: Yes or No.
	Configuration Info	Enter configuration information in the field.
	Min Density	Enter the minimum density of the film.
	Max Density	Enter the maximum density of the film.
	Destination	Specify where the file is exposed: MAGAZINE (stored in the magazine), or, PROCESSOR (exposed in the processor).
		Select how the printer magnifies an image to fit the film.
		Replicate: interpolated pixels belong to duplicate of adjacent pixels);
	Magnification Type	Bilinear: interpolated pixels are generated from bilinear interpolations between adjacent pixels;
		Cubic: interpolated pixels are generated from cubic interpolations between adjacent pixels;
		None: without interpolation.
	Add	Add the DICOM service to the service list
	Cancel	Click to cancel parameter preset.
	Update	Select an item in the service list, change the parameters in the above area, and click [Update] to update the item in the service list.
	Delete	Click to delete the selected service in the service list.
Service 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.

#### 11.1.3.3 DICOM Worklist Preset

- 1. On DICOM Service screen, click [Worklist] page tab to enter the Worklist page.
- 2. Select device, enter the right AE Title, port, etc.
- 3. Click [Add] to add the service to the Service List.

DICOM Worklist service parameters are similar to those described in DICOM Storage Preset, please refer to "11.1.3.1 Storage Service Preset" for details.

#### 11.1.3.4 MPPS Preset

- 1. On DICOM Service screen, click [MPPS] page tab to enter the MPPS page:
- 2. Select device, enter the right AE Title, port, etc.
- 3. Click [Add] to add the service to the Service List.

DICOM MPPS service parameters are similar to those described in DICOM Storage Preset, please refer to "11.1.3.1 Storage Service Preset" for details.

#### 11.1.3.5 Storage Commitment Preset

- 1. On DICOM Service screen, click [Storage Commitment] page tab to enter the Storage Commitment page.
- 2. Select device, enter the right AE Title, port, etc.
- 3. Click [Add] to add the service to the Service List.

Special setting item for DICOM Storage Commitment service is Associated Storage Service, as described in the following; other parameters are similar to those described in DICOM Storage Preset, please refer to "11.1.3.1 Storage Service Preset" for details.

Name	Description
Associated Storage 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.

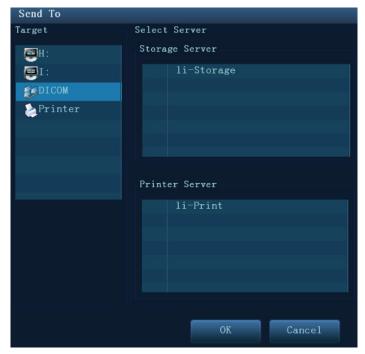
## 11.3 DICOM Services

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 left 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]".
  - 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 Patient Info 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)  $\rightarrow$  [System Preset]  $\rightarrow$  [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)  $\rightarrow$  [DICOM Preset]  $\rightarrow$  [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 Patient Info area.
  - (2) Set a default print server.
    - a) Enter the DICOM Service Preset screen via "[Setup] (F10)  $\rightarrow$  [DICOM Preset]  $\rightarrow$  [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.

Query						
Patient ID			Patient Name	Acce	ession #	
Search Key Requested	Procedure ID	Schedul	ed Station AE Title	Modali	ity Type <mark>US</mark>	<b>•</b>
Exam Date 28/10/2011	1 🔂 To 28/10/201	1 🔂 Wor	kList Server	<b>•</b>	Query	Clear
0 records are listed.						
Patient ID	Patient Name	Accession #	Exam Description	Exam D	Date Ge	DOB
						Exit

- (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 Patient Info 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 multi-frame 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 " $\sqrt{}$ " 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.

Query/Retrieve					
Server and Service		Query			
Source		Patient ID	Patient Name		_
Destination Local Ho	ost	Accession #	Exam Date	DD/MM/YYYY	To DD/MM/YYYY 📆
Bestriation Botal In		Search Key Stud	y ID		Query Clear
Patient(Source)	O records are ]	listed.			
Patient ID	Name	Accession #	Exam Description	Exam Date.	. Gender DOB
Select All Deselect			O records are liste		Cancel
Patient(Destination)					
Patient ID	Name	Accession #	Exam Description	Exam Dat	Co Gender DC
•					•
					Exit

- 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 [Backup] in the popped up menu to open the dialogue box.
- 3. Select destination media and DICOM Format as well as compression mode.
- 4. Set whether to remove the patient data from local hard disk after backup (remove exams or just remove the images).
- 5. Click [Backup] to begin the storage.

If the backup succeeded, there will be a tick marked in the Backup list in iStation screen; otherwise, no tick is marked.

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 " $\sqrt{}$ " in the list below  $\blacksquare$  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.

## **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 [OK] 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 or soft keyboard on the touch screen.
- 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.

Setup		
System Preset	Region General Image Preset Application OB Key Config Admin	
Exam Preset	Hospital Information	
Measure Preset	Name	
iWorks Preset	Address	
Print Preset	Telephone	
Network Preset	Fax Load Logo	
DICOM Preset	Website	
Maintenance	Location Medical Director	
	Associate	
About		
	Language And Time	
	Time Zone (GMT+08:00) Beijing, Chongqing, Hong Kong, Urumqi 🗸	
	Date Format OYYYY/MM/DD O MM/DD/YYYY O DD/MM/YYYY	
	Time Format 💿 12 Hour 🌍 24 Hour	
	System Date 21/10/2011 🛱 System Time 14:07:16 🔶 Time Synch	
		10-201:
	🍇 疗 🗏 🖬 🔢 14:0	07:16

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.
OB	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.

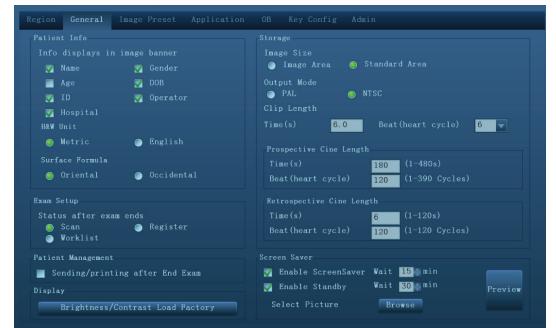
## 12.1.1 Region

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.

Open the Region page via [Setup]-> [System Preset]-> [Region].

## 12.1.2 General

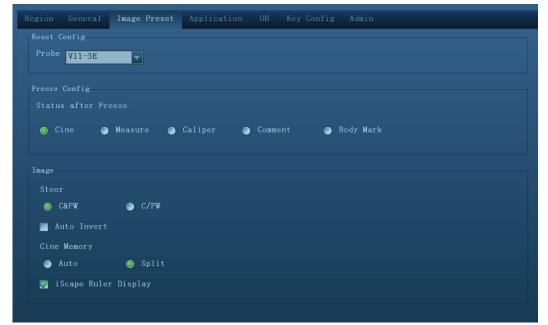
Open the page via [Setup]-> [System Preset]-> [General].



Туре	ltem	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.	
•	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.	
		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 (reserved) status in the drop-down list beside "Wait".	

## 12.1.3 Image Preset

Open the page via [Setup]-> [System Preset]-> [Image].



Туре	ltem	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.		
	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.	
Image	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.	
	Cine Memory	To set the cine memory splitting type.	
	iScape Ruler Display	To set if to display the iScape ruler on iScape imaging mode.	

## 12.1.4 Application

Open the page via [Setup]-> [System Preset]-> [Application]. Through the page, you can set the measure ruler and relevant information. For details, please refer to the Operator's Manual [Advanced Volume]

## 12.1.5 OB Preset

Open the page via "[Setup]-> [System Preset]-> [OB]".Through the page, you can set the gestational age formula, fetal growth formula, fetal weight formula and the relevant information. For details, please refer to the Operator's Manual [Advanced Volume].

## 12.1.6 Key Configuration

Open the page via "[Setup]-> [System Preset]-> [Key Config]".

Key Function F	ootswitch	Output Print Advanced Features Measurement
Key Function Print Savel Save2 F3 F4 F5 F6 F12 P1 P2 ▲	Select Function Dual Probe Save Image to hard dr Save Clip(Retrospectivivision BPD Free Xros CM Dual Probe NULL ExFOV Free Xros M	ExFOV Free Xros M Free Xros CM Dual Probe ColorD iNeedle

Key function setting

You can set the functions for <Print>, <Save1>, <Save2>, F3-F6, F12, P1 and P2.

To assign a function to a key:

- a) Click to select the desired key in the Key Function column at the left side of the page.
- b) Click to select a function in Function area. You can see the available functions selected at the right side.
- c) Click [OK] 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

ltem	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]-> [System Preset]-> [Admin].

For details of access control, please refer to "10.8 Administration.

## 12.2 Exam Preset

Open "[Setup][Exam Preset]" to enter the screen.



You can assign available exam modes for probes.

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

On the right side of the screen, you can view the current exam modes supported by the probe. On the left side, you can view all the available exam modes in the exam library for the probe.

- 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 **C** to delete all items in the Exam Selected area.
- Click [Default] to set a selected exam mode as the default exam mode, and the default exam mode is marked by a "√" on the left upper corner.

## 12.3 Measure Preset

For details about Measure Preset, please refer to the [Advanced Volume].

## 12.4 IWorks Preset

For details, please refer to "Appendix C iWorks".

## **12.5 Print Preset**

The screen is used to set up for printer and image print.

Printer setting

The settings of a printer include print service and print driver.

Print Service In	nage Setting			
Service Name Report Print	Service Type Report Print	Printer	Status Fail to open	Add Service Remove Service Rename Service Add Printer
Property Service Type Printer	Report Print		Service Name Repo	ort Print
Paper Size	Α4		210.0mm * 297.0mm	

- Print Service Setting
  - > Add Service: click to begin print service adding.
  - > Remove Service: click to delete the selected print service.
  - > Rename Service: click to rename the selected print service.
  - > Default print service: click to set the selected print service as the default one.
  - > Property: to preset the property of print services.

For details about adding printer, please refer to "3.6.3 Installing a Graph/Text Printer".

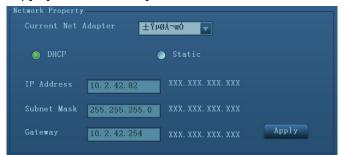
#### Image Settings

You can set brightness, contrast and saturation of image printing, or you can use the default value.

## **12.6 Network Preset**

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.
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.

## 12.7 Maintenance

In the Setup menu, select [Maintenance] enter the screen.

## 12.7.1 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.

Note: trial function does not apply to 01.02.00 version software.

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

#### 12.7.2 Other Settings

Туре	ltem	Description	
	Export Log	Export the operation log.	
Log	Upload Log	Upload the operation log.	
T. I. O	Touch Calibrate	Calibrate the touch screen.	
Touch Screen	Touch Screen Preset	Used for adjusting the touch screen brightness and contrast.	
Remote		You need to contact the service engineer for this function.	
Desktop	Remote Desktop	Please contact Mindray Customer Service Department or sales representative for details.	
	Export	Export preset data to disk.	
Preset Manager	Import	Import the preset data into the system.	
	Load Factory	Local factory default settings.	
Self-Test	/	Perform system self-test and restart the machine.	

#### Remote Desktop

1. Click [Remote Desktop] to open the following dialogue box:

Remote Service			
Password( 1~8 characters )			
🏹 Enable Remote Control			
Run Service	Exit		

2. Set the password, select whether to "Enable remote control", click [Run Service] to run the remote desktop service.

**NOTE:** During remote desktop, the ultrasound system should be connected to network, and be authorized to use the network.

## **12.8 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

## 13.1 Probes

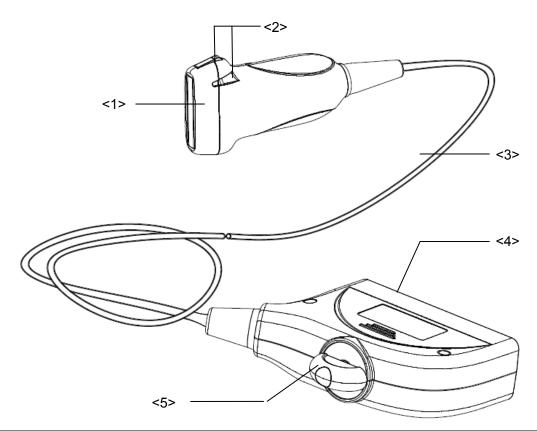
**NOTE:** For details of storage time and condition for disinfected probes and brackets, please refer to Technical standard for Disinfection of Medical and Health Structures.

The system supports the following probes:

C5-2E	D6-2E	
C7-3E	D8-3E	
L12-3E	V11-3E	
L14-6NE	P4-2E	
L14-6WE		

## 13.1.1 Probe Functions by Part

The basic structures and corresponding functions of probes are basically the same; the following will take probe L14-6NE as an example.



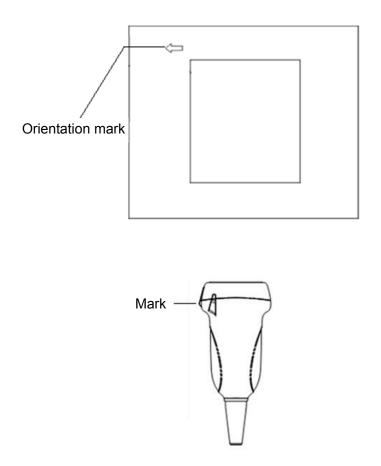
No.	Name	Function
<1>	Probe head	Converts the electrical signal into an ultrasonic signal, focusing the sound beams in a given direction; meanwhile, it receives the reflected ultrasonic signal and converts it into an electrical signal for transmission over the cable. The lens on the surface is the acoustic lens. Apply ultrasound gel on the acoustic lens for correct operation.
<2>	Needle-guided bracket fix tabs and grooves	Provides mounting support of the needle-guided bracket.
<3>	Probe cable	Transmits electrical signals between the probe body and connector.
<4>	Probe connector	Connects the probe and cable to the ultrasonic diagnostic system.
<5>	Lock handle	Locks the connector to the ultrasonic diagnostic system.

Tips:

The probes' structure marked <2> in the figure above may vary with the matched needle-guided brackets.

## 13.1.2 Orientation of the Ultrasound Image and the Probe Head

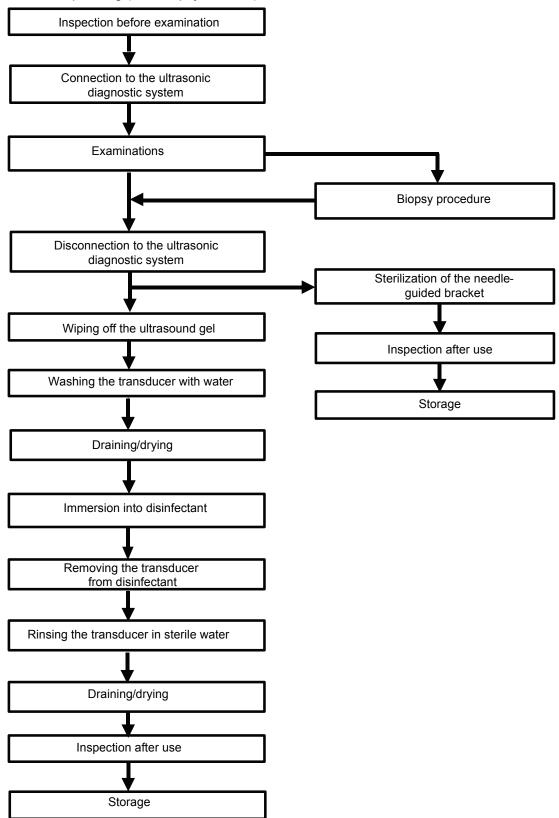
The orientation of the ultrasound image and the probe are shown as below. The "Mark" side of the ultrasound image on the monitor corresponds to the mark side of the probe. Check the orientation before the examination (using a linear probe as an example).



## 13.1.3 Procedures for Operating

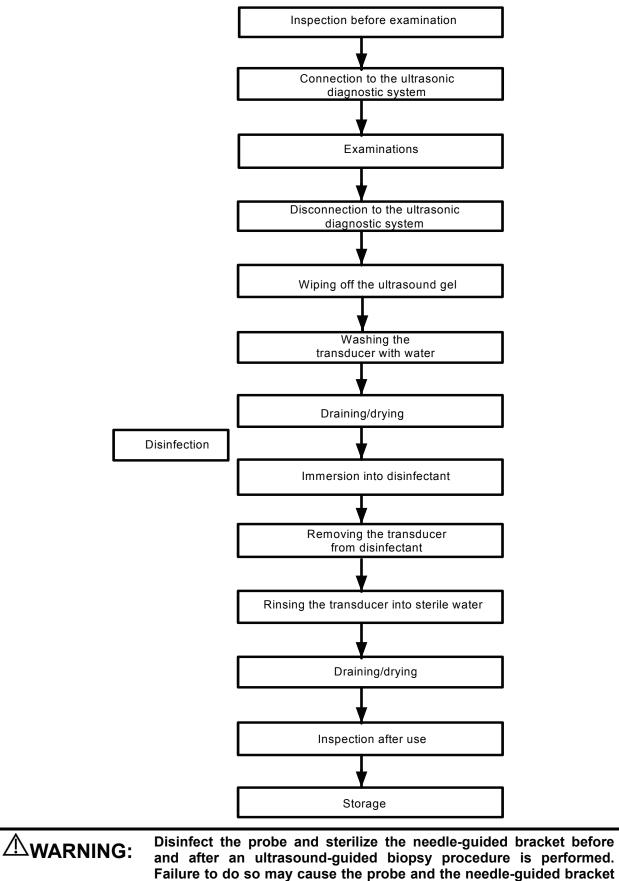
This section describes general procedures for operating the probe. The proper clinical technique to be used for operating the probe should be selected on the basis of specialized training and clinical experience.

Procedures for operating (with biopsy function):



13-4 Probes and Biopsy

Procedures for operating (with no biopsy function):



become a source of infection.

## 13.1.4 Wearing the Probe Sheath

A legally marketed probe sheath must be installed over the probe before performing intra-cavitary and intra-operative examination. Protective barriers may be required to minimize disease transmission. Probe sheaths are available for use with all clinical situations where infection is a concern.

To order probe sheath, contact:

CIVCO Medical Instruments Co.

102 First Street South, Kalona, IA 52247-9589 USA Tel: 1-319-656-4447

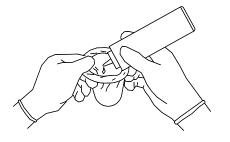
E-mail: info@civco.com

http://www.civco.com

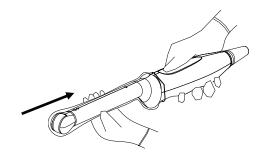
1.	Be sure to cover the probe with a new (unused) probe sheath to prevent infection during examination. If the package of a probe sheath is open or broken, the sterilization of the probe sheath may not be sufficient. DO NOT use such a probe sheath.
2.	The cover contains natural rubber latex and talc that can cause allergic reactions in some individuals.
3.	DO NOT use an expired probe sheath. Before using a probe sheath, verify whether the term of validity has expired.

Method (for reference only):

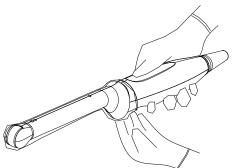
 Place an appropriate amount of gel inside the sheath or on the probe acoustic lens. Poor imaging may result if no gel is used.



2. Insert the probe into the sheath; make sure to use proper sterile technique. Pull cover tightly over probe acoustic lens to remove wrinkles and air bubbles, and taking care to avoid puncturing the sheath.

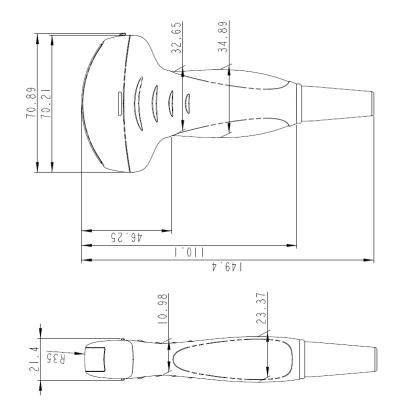


- 3. Secure the sheath with the enclosed elastic bands.
- 4. Inspect the sheath to ensure there is no hole or tear.



Model	Length(mm)	Width(mm)	Height(mm)	Cable Length(mm)
C5-2E	112	64	16.2	2260±50
V11-3E	318	24	9	2260±50
D8-3E	115	60.5	12.2	2260±50
D6-2E	124	71	51.6	2260±50
P4-2E	100	23.4	15.2	2260±50
L14-6WE	100	56.1	10	2260±50
L14-6NE	99	44.2	8.5	2260±50
L12-3E	99	44.2	8.5	2260±50
C7-3E	110	60.5	12.2	2260±50

Refer to the following dimension table of all probes to choose the necessary probe sheath type.



The above is a dimension illustration of the C7-3E probe.

You can select the probe sheath according to the actual application situation.

#### 13.1.5 Probes Cleaning and Disinfection

After completing each examination, clean and disinfect (or sterilize) the probes as required. When biopsy procedures have been performed, be sure to sterilize the needle-guided bracket. Fail to do so may result in the probe and the needle-guided bracket to becoming sources of infection.

# **WARNING:** Never immerse the probe connector into liquid such as water or disinfectant. Immersion may cause electrical shock or malfunction.

	When performing cleaning and disinfection of the probe to prevent infection, wear sterile gloves.	A A A A A A A A A A A A A A A A A A A
2.	After disinfection, rinse the probe thoro remove all chemical residues. Chemical be harmful to the human body.	• •
3.	The efficacy of disinfectants and steriliz guaranteed by MINDRAY. Contact the mon the activity of the products.	

# **NOTE:** 1. After the examination, wipe off the ultrasound gel thoroughly. Otherwise, the ultrasound gel may solidify and degrade the image quality of the probe.

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 follow the instructions in the manual for cleaning.

- 1. Wear sterile gloves to prevent infection.
- 2. Wash the probe with water and remove all foreign matter. Soapy water may be used. A soft urethane sponge can be used to wash the probe. Avoid using a brush, because it may damage the probe.
- 3. Wipe off water on the probe using sterile cloth or gauze after washing it. DO NOT dry the probe by heating.

#### High Level Disinfections

Please follow the instructions in the manual for disinfection.

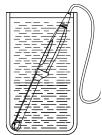
- 1. Wear sterile gloves to prevent infection.
- 2. Clean the probe before disinfecting it. The probe manufacturer recommends the following solutions to disinfect the probe.
- Glutaraldehyde-based disinfectant:

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.

#### Non-glutaraldehyde based disinfectant:

Chemical Name	Trade Name	Procedures
Ortho-Phthalaldehyde (0.55%)	Cidex OPA	Please refer to the instructions provided by the manufacturer of the solution for details.

- 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 probe connector or the cable near it into water or any solution.
- Soak the probe 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 probe with plenty of sterile water (about 2 gallons) for at least 1 minute to remove all chemical residues on it. Or, follow the rinsing method recommended by the disinfectant manufacturer to rinse the probe.
- 4. Wipe off the water on the probe with sterile cloth or gauze after rinsing it. DO NOT dry the probe by heating.



(For reference only)

Disinfection Type	Probe
Low level disinfection	C5-2E, C7-3E, L12-3E, L14-6NE, L14-6WE, P4-2E, D6-2E, D8-3E
High level disinfection	V11-3E
High level disinfection (for biopsy exam)	C5-2E, C7-3E, L12-3E, L14-6NE, L14-6WE, P4-2E, V11-3E

For details about additional infection control procedures or disinfection information, contact Mindray North America Customer Service [Tel: (1-800) 288 2121, (1-201) 995 8000 ].

## 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 stored in a suitable place.

- 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 to 55°C
  - Relative humidity: 30% to 95% (no condensation)
  - Atmospheric pressure: 700 hPa to 1060 hPa

Store and transport the D6-2E probe under the following ambient conditions:

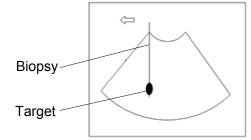
- Ambient temperature: -10°C to 60°C
- Relative humidity: 30% to 95% (no condensation)
- Atmospheric pressure:700 hPa to 1060 hPa
- 3. When the probe is sent to MINDRAY Customer Service Department or sales representative for repair, be sure to disinfect it and keep it in the carrying case to prevent infection.
- 4. Sterilize the carrying case as necessary.

# 13.2 Biopsy Guide

<ol> <li>The person performing biopsy procedures must understand diagnostic ultrasound thoroughly and have been trained adequately, otherwise, side effects may be caused to the patient.</li> </ol>
<ol><li>In situations listed below, the biopsy needle may fail to penetrate the target. The incorrect biopsy may cause various side effects in the patient.</li></ol>
<ul> <li>Use a needle-guided bracket other than that provided.</li> </ul>
<ul> <li>Mount the needle-guided bracket incorrectly.</li> </ul>
<ul> <li>Use a biopsy needle that is unsuitable for the type of biopsy being performed.</li> </ul>
<ul> <li>Use a biopsy needle that is unsuitable for the needle guide.</li> </ul>
3. Before and after a biopsy procedure is performed, confirm that the needle-guided bracket is normal. Manually confirm that the parts of the needle-guided bracket do not slip off or move from their proper positions. If the needle-guided bracket is used when parts are not securely and correctly installed, the patient may be injured. If an abnormality is found on the needle-guided bracket, immediately stop using it and contact MINDRAY Customer Service Department or sales representative.
4. DO NOT use a needle-guided bracket when scanning is performed. The needle may advance in an incorrect direction and possibly injure the patient.
Never perform a biopsy during image scanning.
5. DO NOT freeze an image while performing biopsy procedure.
6. During biopsy procedures, the needle may deviate from the desired course due to the tissue characteristics or the type of needle. In particular, needles of small diameters may deviate to a greater degree.
7. Disinfect the probe and sterilize needle-guided bracket before and after each ultrasound-guided biopsy procedure is performed. Fail to do so may cause the probe and the needle-guided bracket become sources of infection.
8. The needle mark displayed on the ultrasound image does not indicate the actual position of the biopsy needle. Therefore, it should only be used as a reference. Always monitor the relative positions of the biopsy needle during the procedures.
9. Adjust the needle mark before the biopsy procedure is performed.
10. When performing biopsy procedures, use only sterile ultrasound gel that is certified to be safe. And manage the ultrasound gel properly to ensure that it does not become a source of infection.
11. When performing the operation concerning biopsy, wear sterile gloves.
 <ul> <li>12. Image of the biopsy target and the actual position of the biopsy needle:</li> </ul>
Diagnostic ultrasound systems produce tomographic plane images with information of a certain thickness in the thickness

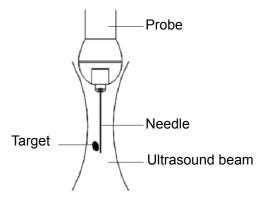
direction of the probe. (That is to say, the information shown in the images consist all the information scanned in the thickness direction of the probe.) So, even though the biopsy needle appears to have penetrated the target object in the image, it may not actually have done so. When the target for biopsy is small, dispersion of the ultrasound beam may lead to image deviate from the actual position. Pay attention to this.

If the target object and the biopsy needle appear in the image as shown in the figures below (For reference only):



The biopsy needle appears to reach the target object in the image

Dispersion of the ultrasound beam



The biopsy needle may not have actually entered the target object even though it appears to have done so on the image. To avoid this problem, note points below:

- Do not rely only on the needle tip on the image. Pay careful attention to that, when the biopsy needle comes into the target object or contacts with it, the object should shift slightly.
- Before you perform the biopsy, please evaluate the size of the object and confirm if the biopsy can be carried out.

## 13.2.1 Needle-guided Brackets

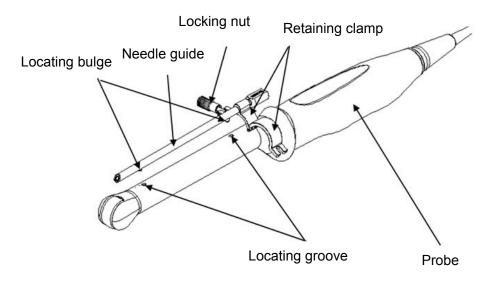
A needle-guided bracket is available for purchase as an optional accessory; it is used in combination with the probe. Some of the probes have matched needle-guided bracket and needles. To order needle-guided brackets, contact MINDRAY Customer Service Department or sales representative.

For biopsy or treatment, ultrasound-guided biopsy procedures can be performed using the probe in combination with a needle-guided bracket (optional accessory) and a biopsy needle (provided by the user).

#### Names of Parts

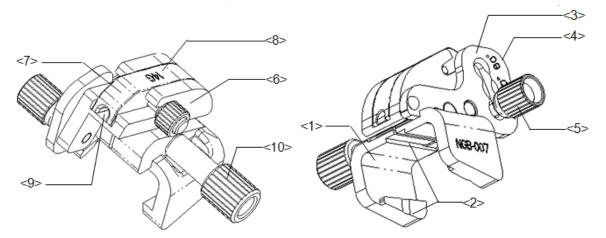
This section describes the parts and corresponding functions of each needle-guided bracket. Here, we take a matched probe as an example.

NGB-004



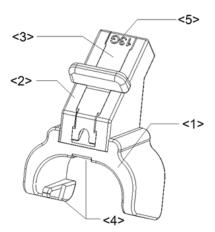
#### ■ NGB-007

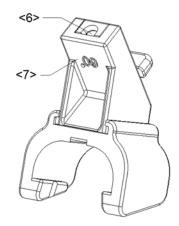
Metal/needle detachable needle-guided bracket:



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 (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.

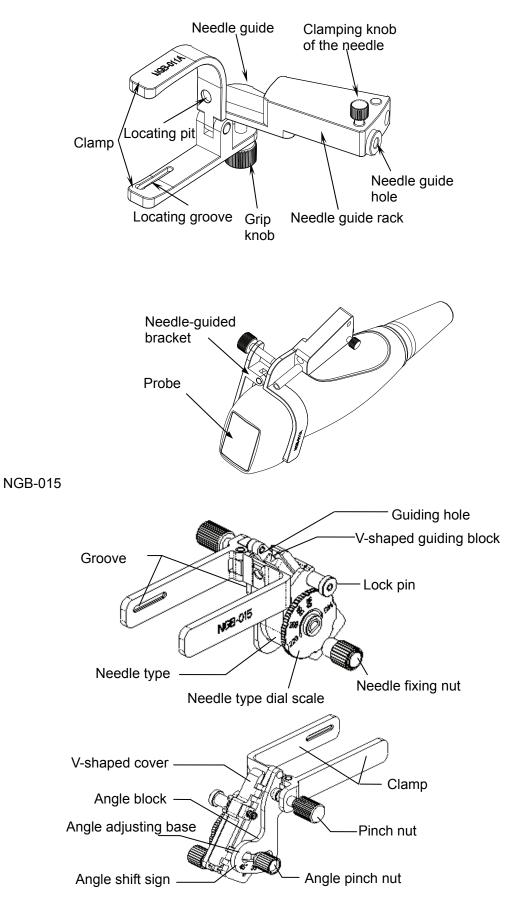
Plastic/needle detachable needle-guided bracket:





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 (60°)	The corresponding biopsy angle is 60°.

NGB-011



NGB-019

Structures of NGB-019 and NGB-015 are similar; refer to descriptions in NGB-015 for details.

#### 13.2.2 Basic Procedures for Biopsy Guiding

- 1. Select the right needle-guided bracket and needle, install them properly. For details, please refer to "13.2.3 Needle-guided Bracket Inspection and Installation".
- 2. Verify the biopsy guide line.
- 3. Press <Biopsy> to enter the biopsy. Before biopsy guiding, you can preset bracket model, biopsy display and guide line dot type. .

Tips:

- If the current probe has no matched bracket; or, the image is frozen and the guide line is hidden before image frozen, then you can't enter Biopsy menu.
- Before entering Biopsy menu, the system will prompt you "Please verify guidelines before biopsy".
- 4. 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.

**ANGER**Fail to match the guidezone displayed to the guide may cause the<br/>needle to track a path outside the zone.It is extremely important that when using the adjustable angle biopsy<br/>guides, the angle displayed on the screen matches the angle set on the<br/>guide, otherwise the needle will not follow the displayed guidezone<br/>which could result in repeated biopsies or patient injury.

#### 13.2.3 Needle-guided Bracket Inspection and Installation

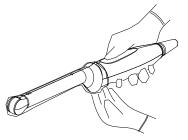
#### 13.2.3.1 Inspection of the Needle-guided Bracket

Be sure to perform inspections before and after use of the needle-guided bracket. If an abnormality is found on the needle-guided bracket, immediately stop using it and contact MINDRAY Customer Service Department or sales representative.

- 1. Sterilize the needle-guided bracket before and after use.
- 2. Confirm that the needle-guided bracket is free of damage, deformation, stripping, malfunction, loose, or missing parts.
- 3. Confirm that the needle-guided bracket is securely mounted in the correct position.

#### 13.2.3.2 Installing the Needle-guided Bracket

- NGB-004
  - (1) Put on the sterile probe sheath.



(2) Open the retaining clamp, align the needle-guided bracket with the probe to locate the locating bulge on the needle guide to the locating grooves on the probe, and then turn the retaining clamp to match it with the probe (See the figure below).



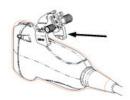
(3) When the retaining clamp is turned to the right position, the locking nut will lock the retaining clamp and the needle-guided bracket is then mounted to the right position.



■ NGB-007

Metal/needle detachable needle-guided bracket:

- (1) Put on the sterile probe sheath.
- (2) Hold the probe by one hand, select the proper needle-guided bracket, and hold it with the other hand. Match the groove and tab with the tab and groove of the probe respectively. Amount the bracket onto the probe.



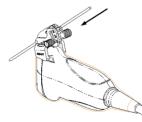


- (3) Screw the pinch nut of the needle-guided bracket to confirm that the needle-guided bracket is properly installed on the probe.
- (4) Select a proper guiding block and push it into the groove above the angle block, and clamp it tightly.





- (5) Screw the nut of the block to secure the block.
- (6) Insert a biopsy needle with the same specification as that of the guiding block into the hole of the guiding block.

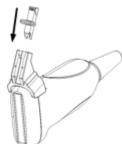


Plastic needle-guided bracket:

- (1) Put on the sterile probe sheath.
- (2) Hold the probe by one hand, select the proper needle-guided bracket, and hold it with the other hand. Align the narrow end tab of the needle-guided bracket with the groove of the probe, then push the needle-guided bracket forward, making the tabs and the grooves of the needle-guided bracket to match with the grooves and tabs of the probe.



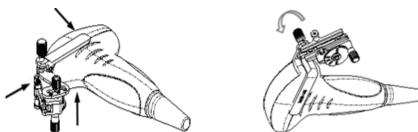
- (3) Check manually to confirm that the needle-guided bracket is securely installed on the probe.
- (4) Select a proper guiding block and push it into the groove above the angle block, and clamp it tightly.



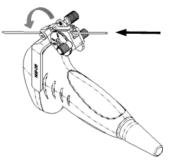
(5) Insert a biopsy needle with the same specification as that of the guiding block into the hole of the guiding block.



- NGB-011
  - (1) Inosculate the locating groove on the clamp with the two raised edges on the probe head and align the locating pit of the clamp to the convex point on the probe head.
  - (2) Turn the grip knob at the tail of the needle-guided bracket tightly.
- NGB-015
  - (1) Put on the probe sheath.
  - (2) Hold the transducer by one hand, select the proper needle-guided bracket, and hold it with the other hand. Match the groove of the bracket with the tab of the transducer. Amount the bracket onto the transducer.



- (3) Screw the pinch nut of the needle-guided bracket to confirm that the needle-guided bracket is properly installed on the transducer.
- (4) Adjust the dial scale to the required needle type shift, and then screw the needle fixing nut to lock the dial scale. (To adjust the dial scale you have to loose the needle fixing nut first.)
- (5) Pull the lock pin and close the V-shaped cover to fix the lock pin in the groove of the needle type adjusting base, so as to install the needle into the guiding hole.



#### NGB-019

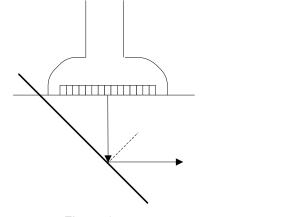
Structures of NGB-019 and NGB-015 are similar; refer to descriptions in NGB-015 for details.

**CAUTION:** Ensure that all guide parts are seated properly prior to performing a biopsy.

### 13.2.4 iNeedle

In the course of biopsy, the metal needle attached to the probe is punctured into the tissue with a certain angle; because of the needle acoustic impedance, the ultrasonic beam cannot penetrate the metal needle, a reflecting boundary is formed. As in figure 1, if the deflection angle is very large, the needle display is not clear.

In the condition of deflected ultrasonic transmission, the beam direction is perpendicular to the needle direction, and the reflection direction will be the same with the needle, as shown in figure 2, when the needle display in the ultrasound image is very clear. The system provides an additional deflection transmission that is approximately perpendicular to the metal needle, as the normal transmission (perpendicular to the transducer surface) is contained as well. And the deflection angel can be chosen by users.



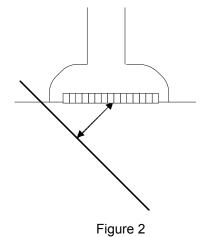


Figure 1

#### To enter/exit iNeedle

To enter iNeedle

Touch [iNeedle] item in B page on the touch screen.

Or, you can assign a user-defined key for entering iNeedle.

- Open iNeedle in Biopsy status
- 1. Perform scanning and locate the target, press <Biopsy> (<F11>) to enter the screen.
- 2. Touch [iNeedle] to enter the status; available adjusting parameters are displayed on the menu.
- To exit iNeedle

Press the user-defined key or touch [iNeedle] to exit the status and enter B mode.

#### **Needle Steer**

**Description** This function adjusts the biopsy needle angle via changing the steer angle of the scan line. The iNeedle affecting region changes correspondingly.

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

#### B/iNeedle

- **Description** This function is used to display B image and iNeedle image synchronously.
- **Operation** To turn on or off the function, touch [B/iNeedle] on the touch screen.

Tips: iZoom (full-screen magnification) is available on iNeedle status.

## 13.2.5 Verifying the Biopsy Guide Line

Adjusting the needle mark is necessary before every biopsy procedure.

- 1. Confirm that the needle-guided bracket has been installed securely in the correct position.
- 2. Prepare a container filled with sterile water.
- 3. Place the head of the probe in the sterile water, and get a biopsy needle into the needle guide.
- 4. When the biopsy needle appears on the image, confirm that the biopsy needle is displayed at almost the same position as the selected needle mark.

# **WARNING:** <sup>1.</sup> Prior to each biopsy procedure, be sure to verify the guide line.

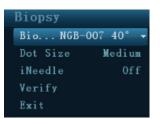
# 2. If the needle is not consistent with the guide line, DO NOT perform the biopsy procedure.

**NOTE:** You can perform guide line verification on a single live B/C image, and all biopsyirrelevant operations are forbidden.

#### **Biopsy Guideline**

You can operate on the touch screen or in the menu.

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

You can also operate on the touch screen. Use menu operation as an example. Click [Verify] in the Biopsy menu to open the Biopsy Verify menu, as shown in the figure below.

Biopsy Veri	fy
Position	-27.5mm
Angle	-37.0°
Save	
Load Factory	
Exit	

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.

### 13.2.6 Removing the Needle-guided Bracket

NGB-004

Hold the probe in the left hand, unscrew the locking nut with the right hand to open the retaining clamp, and then raise the needle-guided bracket to separate the locating bulge from the locating grooves.

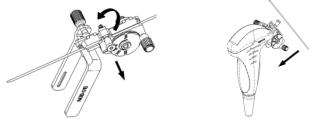
NGB-007

Metal needle-guided bracket:

- (1) Screw the nut of the guiding block and remove the guiding block slightly along the direction of the needle's tail.
- (2) Separate the residual part of the needle-guide bracket and the probe from the needle.
- (3) Screw the pinch nut of the bracket, and remove the needle-guided bracket from the probe. Plastic needle-guided bracket:
- (1) Remove the guiding block slightly along the direction of the needle's tail.
- (2) Separate the residual part of the needle-guide bracket and the probe from the needle.
- (3) Remove the support of needle-guided bracket from the probe.
- NGB-011

Hold the probe and the needle-guided bracket, and then open the grip knob of the needle-guided bracket.

- NGB-015
  - (1) Pull the lock pin and open up the V-shaped cover to expose the needle.



- (2) Separate the bracket and the transducer from the needle.
- (3) Screw the pinch nut to release the needle-guided bracket.



(4) Separate the bracket and the transducer.

NGB-019

Structures of NGB-019 and NGB-015 are similar; refer to descriptions in NGB-015 for details.

# 13.2.7 Clean and Sterilize the Needle-guided Bracket

#### Cleaning

Please follow the instructions in the manual for cleaning.

- 1. Wear sterile gloves to prevent infection.
- 2. Wash the needle-guided bracket with water or soap water to remove all the external matters. Or, clean the needle-guided bracket with urethane sponge.
- 3. Wipe off the water on the needle-guided bracket using sterile cloth or gauze after washing it.

#### Sterilization

- 1. Wear sterile gloves to prevent infection.
- 2. Clean the needle-guided bracket before sterilizing it. MINDRAY recommends the following solution or sterilizing system to sterilize the needle-guided bracket.
- 3. Follow local regulations when selecting and using the disinfectant.
- Glutaraldehyde-based sterilant:

Chemical name	Trade name	Procedures
Glutaraldehyde (2.2-2.7%)	Cidex Activated Glutaraldehyde 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 $^{\circ}$ 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.

#### **13.2.8 Storage and Transportation**

- 1. Don't use the carrying case for storing the needle-guided bracket. If the carrying case is used for storage, it may become a source of infection.
- 2. Between examinations, keep the needle-guided bracket in a sterile environment.
- 3. When the needle-guided bracket is sent to your MINDRAY representative for repair, be sure to disinfect or sterilize it and keep it in the carrying case to prevent infection.
- 4. Sterilize the carrying case as necessary.
- 5. Store or transport the needle-guided bracket under the following ambient conditions:
  - Ambient temperature: -20°C to 55°C
  - Relative humidity: 30% to 85% (no condensation)

#### 13.2.9 Disposal

Be sure to dispose the needle-guided bracket only after sterilizing it.

Contact your MINDRAY representative when disposing of this device.

# 14 DVR Recording

**NOTE:** Strictly observe the procedures described here to perform the recording and replaying operations; otherwise it may result in data loss or system malfunction.

Set the PAL or NTSC in the setup and this shall be consistent with that in the DVR.

Accidental exposure to strong electromagnetic fields or mishandling of the video cassette may result in image and data loss, so check if the recording is successful as soon as possible. Mindray is not responsible for any data loss.

The system provides built-in DVR recording function. You can use the DVR to record and replay videos and audios that can be stored in DVD disc or hard disc.

The recorded video is AVI format; you can save it in the hard disk drive, burn to the DVD or export to the USB disk.

When the built-in DVR is in normal status, the 🔛 displays at the lower right corner of the screen.

# 14.1 DVR Recording

- 1. Perform ultrasound exams, select appropriate views and adjust parameters to prepare for recording.
- 2. Press <F9> to record, and the DVR icon displays as in recording status.

During the recording process, you can perform imaging mode switching, comments adding, body mark adding and measurements.

3. Press <F9> again to stop recording and the DVR icon in the lower right corner turns into data transfer status.

# 14.2 Send Image

- 1. After recording is completed, click the icon, and you can see the file from the dialogue box.
- 2. Click [Send To] to send files to USB disk or DVD optical disk drive, and the icon displays as

# 14.3 DVR Video Replay

You can replay the video and audio record.

Connect the USB disk or optical disk with the file to the PC, open the file directly.

# **15** Acoustic Output

This section of the operator's manual applies to the overall system including the main unit, probes, accessories and peripherals. This section contains important safety information for operators of the device, pertaining to acoustic output and how to control patient exposure through use of the ALARA (as low as reasonably achievable) principle. Also this section contains information regarding the acoustic output testing and the real-time output display.

Read this information carefully before using the system.

# **15.1 Concerns with Bioeffects**

Diagnostic ultrasound is recognized as being safe. In fact, there have been no reports of injuries to patients caused by diagnostic ultrasound.

It cannot be stated categorically that ultrasound is 100% safe. Studies have revealed that ultrasound with extremely high intensity is harmful to body tissues.

Diagnostic ultrasound technology has made a great leap forward during the last several years. This rapid advance has generated concerns about the potential risk of bioeffects when new applications or diagnostic technologies become available.

# 15.2 Prudent Use Statement

Although there are no confirmed biological effects on patients caused by exposures from present diagnostic ultrasound instruments, the possibility exists that such biological effects may be identified in the future. Thus ultrasound should be used in a prudent manner to provide medical benefit to the patient. High exposure levels and long exposure times should be avoided while acquiring necessary clinical information.

# 15.3 ALARA Principle (As Low As Reasonably Achievable)

It is required to practice ALARA when using ultrasound energy. Practicing ALARA ensures that the total energy level is controlled below a low enough level at which bioeffects are not generated while diagnostic information is being accumulated. The total energy is controlled by output intensity and total radiation time. The output intensity necessary for examinations differs depending on the patient and the clinical case.

Not all examinations can be performed with an extremely low level of acoustic energy. Controlling the acoustic level at an extremely low level leads to low-quality images or insufficient Doppler signals, adversely affecting the reliability of the diagnosis. However, increasing the acoustic power more than necessary does not always contribute to an increase in quality of information required for diagnosis, rather increasing the risk of generating bioeffects.

Users must take responsibility for the safety of patients and utilize ultrasound deliberately. Deliberate use of ultrasound means that output power of ultrasound must be selected based on ALARA.

Additional information regarding the concept of ALARA and the possible bioeffects of Ultrasound is available in a document from the AIUM (American Institute of Ultrasound Medicine) title "Medical Ultrasound Safety".

# 15.4 MI/TI Explanation

#### 15.4.1 Basic Knowledge of MI and TI

#### **Mechanical Bioeffect and Thermal Bioeffect**

The relationship of various ultrasound output parameters (frequency, acoustic pressure and intensity, etc.) to bioeffects is not fully understood presently. It is recognized that two fundamental mechanisms may induce bioeffects. One is a thermal bioeffect with tissue absorption of ultrasound, and another one is a mechanical bioeffect based on cavitations. Thermal Index (TI) gives the relative index of temperature increase by thermal bioeffect, and Mechanical Index (MI) gives the relative index of mechanical bioeffect. TI and MI indices reflect instantaneous output conditions, so they DO NOT consider the cumulative effects of the total examination time. TI and MI models contain practical simplifications to complex bioeffects interaction. Then the operator should be aware that the actual worst case temperature rise may be up to several times higher than the displayed TI value.

#### MI (Mechanical Index)

The mechanical bioeffects are the result of compression and decompression of insonated tissues with the formation of micro bubbles that may be referred to as cavitations.

MI is an index that shows the possibility of the cavitations generation based on acoustic pressure, and the value in which the peak-rarefactional acoustic pressure is divided by the square root of the frequency. Therefore MI value becomes smaller when the frequency is higher or the peak- rarefactional acoustic pressure is lower, it becomes difficult to generate the cavitations.

$$MI = \frac{P_{r, \alpha}}{\sqrt{f_{awf}} \times C_{MI}}$$

#### $C_{MI} = 1 (MPa / \sqrt{MHz})$

For the frequency 1 MHz and the peak-rarefactional acoustic pressure 1 MPa, MI becomes 1. It is possible to think MI to be one threshold of the cavitations generation. Especially, it is important to keep MI value to be low when both gases and the soft tissues exist together, for such as lung exposure in cardiac scanning and bowel gas in 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. 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.

Under different operating conditions, once there is a situation that a MI value is greater than 1.0, the start point of displaying MI values is 0.4.

In the same way, once there is a situation that a TI value is greater than 1.0, the TI value will be displayed and the start point is 0.4.

**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.

Display accuracy of MI is  $\leq$ 14.7%, and TI is  $\leq$ 28.5%.

# **15.5 Acoustic Power Setting**

Acoustic power adjustment

Rotate the [A.power] knob to adjust the acoustic power percentage, and its value is displayed on the corresponding item, as well as at the top of the screen. The greater the acoustic power percentage, the greater the current acoustic output. When the image is frozen, the system stops transmitting acoustic power.

Default setting of acoustic power

Selection of diagnostic applications is the most important factor for controlling ultrasound output. The permissible level of intensity of ultrasound differs depending on the region of interest. For fetal examinations, in particular, much care must be exercised.

In this system, imaging setups can be created using the ultrasound output set by you. <u>Once</u> <u>you perform preset settings, default setting values of the system may be changed and</u> <u>invalid. It is the user's responsibility for any change to the default settings.</u>

Adjusting range		
Initial power	3.2% to 100%*	

Definition of 100%: The maximum acoustic power of a probe determined by the increase in probe surface temperature in the selected mode and the acoustic power restrictions specified by the FDA.

Default settings of acoustic power value refer to the best image quality of the probe. The larger the acoustic power value, the better the image quality.

In the DC-8 series products, to obtain optimum images for applications under the requirements of safety and ALARA principle, we set acoustic power default values in factory to be maximum 93.3% in OB1, OB2/3 and Fetal-Cardiac exam modes and maximum 96.6% in other modes for a better image quality. The user can make adjustments according to the imaging effect in practical use.

**NOTE:** This system automatically returns to the settings whenever changes are made to the values (when you turn on the power, switch between probes, press <End Exam>, or select OK or Cancel in the Setup menu). In the factory default settings, the Acoustic Output is limited below settings. Following the ALARA restriction, you are allowed to increase the acoustic power under FDA 510(k) Guidance-Track3 limits and to set it in the image preset screen.

The acoustic output of the system has been measured and calculated in accordance with IEC60601-2-37: 2007, FDA 510(K) GUIDANCE, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment (NEMA UD-2 2004) and the Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment (AIUM and NEMA UD-3 2004).

# **15.6 Acoustic Power Control**

The qualified operator may use the system controls to limit the ultrasound output and to adjust the quality of the images. There are three categories of system controls relative to output. They are,

- Controls that have direct effect on the output
- Controls that indirectly control output
- Controls that are receiver controls
- Direct controls

It is possible to control, if necessary, the acoustic output with the "A.power" item on the touch screen or the corresponding knob at the bottom of touch screen. In this case, the maximum value of the acoustic output never exceeds an MI of 1.9 and an  $I_{SPTA.3}$  of 720 mW/cm<sup>2</sup> in any mode of operation.

Indirect controls

The controls that indirectly affect output are the many imaging parameters. These are operating modes, frequency, focal point positions, overall depth, and PRF.

The operating mode determines whether the ultrasound beam is scanning or non-scanning. Thermal bioeffect is closely connected to M mode, Doppler and Color mode. Acoustic attenuation of tissue is directly related to probe frequency. The focal point is related to active aperture of probe and beam width. For the higher PRF (pulse repetition frequency), the more output pulses occur over a period of time.

Receiver controls

The receiver controls (for example, gain, dynamic range, and image post-processing, etc.) won't affect output. These controls should be used, when possible, to improve the image quality before using controls that directly or indirectly affect output.

# **15.7 Acoustic Output**

#### 15.7.1 Derated Ultrasonic Output Parameters

In order to determine the relevant Ultrasonic Output Parameters, a method is used which allows for the comparison of ultrasound systems which operate at different frequencies and are focused at different depths. This approach, called "derating" or "attenuating", adjusts the acoustic output as measured in a water tank to account for the effect of ultrasound propagation through tissue. By convention, a specific average intensity attenuation value is used, which corresponds to a loss of 0.3 dB/cm/MHz. That is, the intensity of ultrasound will be reduced by 0.3 dB/MHz for every centimeter of travel from the probe. This can be expressed by the following equation:

$$I_{atten} = I_{water} \times 10^{(-0.3/10 \times f_c \times z)}$$

Where  $I_{atten}$  is the attenuated intensity,  $I_{water}$  is the intensity measured in a water tank (at distance z), fc is the center frequency of the ultrasound wave (as measured in water), and z is the distance from the probe. The equation for attenuating pressure values is similar except that the attenuation coefficient is 0.15 dB/cm/MHz, or one-half the intensity coefficient. The intensity coefficient is double the pressure coefficient because intensity is proportional to the square of pressure.

Although the attenuation coefficient chosen, 0.3 dB/cm/MHz, is significantly lower than any specific solid tissue in the body, this value was chosen to account for fetal examinations. In early trimester ultrasound fetal examinations, there may be a significant fluid path between the probe and the

fetus, and the attenuation of fluid is very small. Therefore the attenuation coefficient was lowered to account for this case.

## 15.7.2 Limits of Acoustic Output

In accordance with the FDA Track 3 requirements, the derating (or attenuated) approach was incorporated into the FDA Acoustic Output Limits, as listed below. The maximum acoustic output level from any probe in any operating mode is expected to fall below these limits.

			-	-
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

FDA Maximum Acoustic Output Limits for Track 3 (Attenuated Values)

#### **15.7.3 Differences between Actual and Displayed MI and TI**

In operation, the system will display to the operator the Acoustic Output Parameters Thermal Index, TI, or Mechanical Index, MI (or sometimes both parameters simultaneously). These parameters were developed as general indicators of risk from either thermal or mechanical action of the ultrasound wave. They serve to indicate to the operator whether a particular setting of the system increases or decreases the possibility of Thermal or Mechanical effect. More specifically, they were designed to assist in the implementation of the ALARA principle. As an operator changes a given system control, the potential effect of the change in output will be indicated. However, the Thermal Index is not the same as temperature rise in the body, for several reasons. First of all, in order to provide a single display index to you, a number of simplifying assumptions had to be made. The biggest assumption was the use of the attenuating formula described above, which is much lower than the actual value for most tissues within the body. Scanning through muscle or organ tissue, for example, will produce much higher attenuation than0.3 dB/cm/MHz. There were also significant simplifications made for the thermal properties of tissue. Therefore, scanning through highly perfused tissue, such as the heart or vasculature, will produce significantly less thermal effect than that suggested by the Thermal Index.

Similarly, the Mechanical Index was derived to indicate the relative possibility of mechanical (cavitation) effects. The MI is based on the derated peak-rarefactional pressure and the center frequency of the ultrasound wave. The actual peak-rarefactional pressure is affected by the actual attenuation caused by tissue in the path between the probe and the focal point. Again, all solid tissues within the body have higher attenuation than the proscribed 0.3 dB/cm/MHz value, and therefore, the actual peak-rarefactional pressure will be lower. Further, the actual peak-rarefactional pressure will change depending upon the region of the body being scanned.

For these reasons, the TI and MI displays should only be used to assist the operator in implementing ALARA at the time of the patient examination.

# **15.8 Measurement Uncertainty**

The total estimated measurement uncertainty (where the total uncertainty includes the uncertainties in hydrophone response, measurement, calculation, and positioning) are:

Ispta	32.9%
I <sub>sppa</sub>	32.9%
Center frequency (f <sub>C</sub> )	2%
Total power (W)	32.9 % (5.1% for Scan-mode and Combined-mode)
Rarefactional pressure (pr)	16.4%

# **15.9 References for Acoustic Power and Safety**

- 1. "Bioeffects and Safety of Diagnostic Ultrasound" issued by AIUM in 1993
- 2. "Medical Ultrasound Safety" issued by AIUM in 1994
- 3. "Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, Revision 3" issued by AIUM/NEMA in 2004
- 4. "Standard for real-time display of thermal and mechanical acoustic output indices on diagnostic ultrasound equipment, Revision 2" issued by AIUM/NEMA in 2004
- 5. "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" issued by FDA in 2008
- 6. "Medical electrical equipment Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment" issued by IEC in 2007

# **16** Guidance and Manufacturer's Declaration

The system complies with the EMC standard IEC60601-1-2: 2007.

∕∆w	AR	NING: The use of unapproved accessories may diminish system performance.
NOTE:	1.	Use of accessories, probes, and cables other than those specified may result in increased emission or decreased immunity of system.
	2.	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.
	3.	The system needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.
	4.	Other devices may interfere with this system even though they meet the requirements of <b>CISPR</b> .
	5.	Preventing conducted RF immunity. Due to technological limitations, the conducted RF immunity level are limited to 1Vrms level, conducted RF interference above 1Vrms may cause wrong diagnosis and measurements. We suggest that you position system further from sources of conducted RF noise.
	6.	Operation of system, in the case that the patient physiological signal is lower than the minimum amplitude or value specified in the product specifications, may cause inaccurate results.
	7.	Portable and mobile RF communications equipment can affects system. See tables 1, 2, 3, and 4 below.

#### GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC EMISSIONS

The system is intended for use in the electromagnetic environment specified below. The customer or the user of system should assure that it is used in such an environment.

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIROMENT- GUIDANCE
RF emissions CISPR 11	Group 1	The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The system is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Compliance	network that supplies buildings used for domestic purposes

#### GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC IMMUNITY

The system is intended for use in the electromagnetic environment specified below. The customer or the user of system should assure that it is used in such an environment.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT-GUIDANCE
Electrostatic Discharge(ESD) IEC 61000-4-2	±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	<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	<5% U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 0.5 cycle 40% U <sub>T</sub> (60% dip in U <sub>T</sub> ) for 5 cycle 70% U <sub>T</sub> (30% dip in U <sub>T</sub> ) for 25 cycle <5% U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 5 sec	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.
NOTE: $U_T$ is the A.C. mains voltage prior to application of the test level.			

#### GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC IMMUNITY

The system is intended for use in the electromagnetic environment specified below. The customer or the user of system should assure that it is used in such an environment.

IEC 60601 COMPLIANCE ELECTROMAGNETIC					
IMMUNITY TEST	TEST LEVEL	LEVEL	ENVIRONMENT-GUIDANCE		
Conduced RF IEC 61000-4-6	3 Vrms 150 kHz - 80 MHz	1 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		
			$d = 3.5 x \sqrt{P}$		
			d = 1.2 x $\sqrt{P}$ 80 MHz to 800 MHz		
			d = 2.3 x $\sqrt{P}$ 800 MHz to 2.5GHz		
	3 V/m 80MHz - 2.5GHz	3 V/m	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).		
Radiated RF IEC 61000-4-3			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	<b>Note 1</b> At 80 MHz and 800 MHz, the higher frequency range applies.				
<b>Note 2</b> These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.					
<ul> <li>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.</li> </ul>					
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 system.					
Over the fr	• Over the frequency ranges 150kHz to 80MHz, field strengths should be less than 1V/m.				

#### RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATION DEVICE AND 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.

	Separation Distance According to Frequency of Transmitter			
Rated Maximum Output power of Transmitter (W)	$150 \text{kHz} - 80 \text{MHz}$ $d = \left[\frac{3.5}{1}\right] \sqrt{P}$	(m) 80MHz-800MHz $d = \left[\frac{3.5}{3}\right]\sqrt{P}$	$800 \text{MHz-2.5GHz}$ $d = \left[\frac{7}{3}\right] \sqrt{P}$	
0.01	0.35	0.12	0.23	
0.1	1.11	0.37	0.74	
1	3.50	1.17	2.34	
10	11.07	3.69	7.38	
100	35.00	11.67	23.34	

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.

# **17** System Maintenance

Routine system maintenance shall be carried out by the user. Service maintenance will be provided by Mindray service engineers while the system is under warranty. System maintenance after the warranty has expired is the full responsibility of the owner/operator.

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

1.	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.

NOTE:	1.	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.
	2	Please clean the control nanel periodically otherwise the button may be blocked by

- 2. 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

Please refer to probe chapter 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

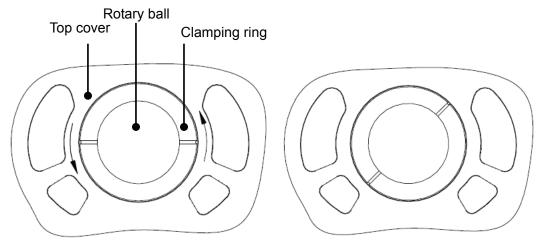
Use a soft cloth, apply a glass cleaner directly to the cloth and wipe down the monitor to remove finger marks, dust and smudges. Then allow the monitor to air-dry.

Cleaning the touch screen

Use a soft cloth to wipe off stains from the touch screen, don't apply detergent.

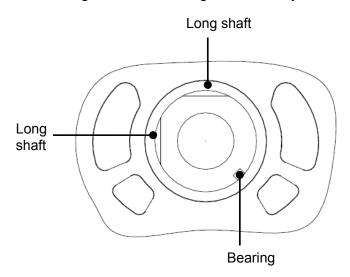
- Cleaning the trackball
- 1. Disassembling the trackball:

Press the bulges on the clamping ring by both hands and turn the ring about 45° counterclockwise until it lifts. Take out the ring and the rotary ball. Be careful not to drop the ball. As shown in figure below.



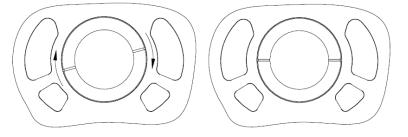
#### 2. Cleaning

Clean the two long shafts, the bearing and the rotary ball with clean soft dry cloth or paper.



Installing the trackball

Put the rotary ball back in the trackball mechanism and put the clamping ring back in (with the bulge direction of 15 ° deviated from the horizontal line), turn the ring clockwise until the bulges are flush with the top cover, and the ring clicks and locks, which means the ring is secured. See figure below.



- Cleaning the main panel, cover and bracket
  - (1) Use dry soft cloth to clean the surface of the system. If the system is dirty, moisten the soft cloth with a mild or neutral detergent and then wipe off any stains.
  - (2) Use dry soft cloth to remove any moisture and allow all hard surfaces to completely air-dry.

## 17.1.2 Checking the Probe

Check the probe connector for crack each time before use. DO NOT use the probe if a crack is inspected. A thorough inspection to the probe including cable and connector is required each time when you clean the probe.

# 17.1.3 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 Maintenance Checks by Service Engineer

The following checks must be performed to ensure and maintain system safety and performance. Please contact Mindray Customer Service Department or sales representative to schedule and carry out these checks.

Check Category	Check Item	
Cleaning	Interior of the system	
Clearing	Peripheral devices	
	Protective conductor resistance	
	Ground leakage current	
Electric safety	Enclosure leakage current	
	Patient leakage current	
	Patient leakage current (110% supply voltage on applied part)	
	Patient auxiliary leakage current	
	Casters	
	Caster mounting sections	
	Monitor mounting mechanism	
Mechanical safety	Main panel	
	Mounting mechanism for the peripheral devices	
	Other mechanical parts	
	External appearance of the probe	
_	External appearance of ECG leads and PCG transducer	
Image recording	Images in each mode	
	Image recording by using the standard probe	

# 17.3 Consumables and Periodic Part Replacement

This system contains some consumables and parts requiring periodic replacement. Before replacing them, please contact Mindray Customer Service Department or sales representative for instructions.

# 17.4 Troubleshooting

# CAUTION:DO NOT spill water or other liquid into the system while you perform<br/>the cleaning. Otherwise, it may result in malfunction or electric<br/>shock.When you want to clean probe connectors and TGC sliders, contact<br/>Mindray Customer Service Department or sales representative.<br/>Cleaning it by yourself may result in malfunction or degradation of<br/>the performance.

To ensure proper system operation and function, it is recommended that a maintenance and inspection plan be established to periodically check the safety of the system. If any system malfunction is experienced, contact Mindray Customer Service Department or sales representative.

If any persistent system malfunction is experienced, e.g. an onscreen error message, blank imaging screen, absent menus, please refer to the table below. If the failure can't be eliminated, please contact Mindray Customer Service Department or sales representative.

Troubleshooting Table

No.	Failure	Cause	Measure
1	After the 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, and then restart the system.</li> <li>Adjust the monitor brightness and contrast back to factory defaults.</li> </ul>
3	The monitor displays the characters and menus but no images.	<ul> <li>The transmission power, overall gain or TGC controls are improperly set.</li> <li>Check if a probe is connected and/or fully connected.</li> <li>The system is in the frozen status.</li> </ul>	<ul> <li>Adjust the transmission power, gain or TGC control.</li> <li>Ensure proper probe connection.</li> <li>Unfreeze the image.</li> </ul>
4	The image quality is degraded	<ul> <li>The exam mode is not correct.</li> <li>The settings of the image post processing are not correct.</li> <li>The image presets are inappropriate.</li> </ul>	<ul> <li>Select an appropriate exam mode.</li> <li>Adjust the settings of the image via post processing or reset the post processing to the default values.</li> <li>Reset the factory default presets.</li> </ul>
5	The button is responseless with the system buzzing	There is too much dirt blocking the button	<ul> <li>Check the control panel for the button being blocked and press it several times to release it.</li> <li>Clean the button.</li> </ul>

# **Appendix A Wireless LAN**

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.
5.	Keep a distance of at least 20cm away from the ultrasound system when wireless LAN function is in use.

# A.1 To Use the W-LAN Function

The system can be configured with built-in wireless net adapter, so as to assist information communication.

- 1. Local TCP/IP setting in preset:
  - a) Press <Setup> to enter the Setup menu.
  - b) Move the cursor onto [Network Preset] to open the screen:

DHCP		Static	
P Address 0	.0.0.0	xxx.xxx.xxx.xx	¢
	.0.0.0	xxx.xxx.xxx.xx	¢
ubnet Mask 0	.0.0.0		
Gateway O	.0.0.0	xxx.xxx.xxx.xx	Apply
-	.0.0.0 ger		Apply Status
Sateway 0 Hess Network Manae Network SSID	.0.0.0 ger Security	XXX.XXX.XXX.XXX Signal Quality 100%	
Gateway O eless Network Manae Network SSID SZHQ-WIFI-6A2	.0.0.0 ger Security	Signal Quality	Status
Gateway O	.0.0.0 ger Security Y	Signal Quality 100%	Status Disconnected

c) Local TCP/ IP preset items are described as follows:

Name	Description	
Current Net Adapter	To select net adapter type, wireless network adapter.	
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 of the system.	
Subnet Mask	Used to set different network segment.	
Gateway	Used to set the gateway IP.	
Apply	To make the settings effective.	

The IP address of the system should not be occupied by other devices in the LAN, or failure may result.

2. Click to select the network in the list in the Wireless Network Manager, and click [Connect] to connect to the network.

When connecting an encrypted network, enter the password in the box on the left first.

3. If the connection is successful, the 🗾 will be displayed on the lower right corner of the screen.

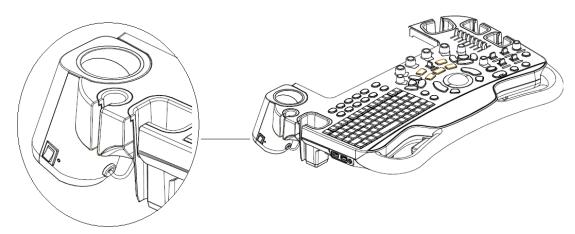
**NOTE:** 1. You can refresh the W-LAN network by switching the current adapter.

2. 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.

# Appendix B Ultrasound Gel Warmer

Ultrasound gel warmer is an option of the system, used for heating the ultrasound gel.

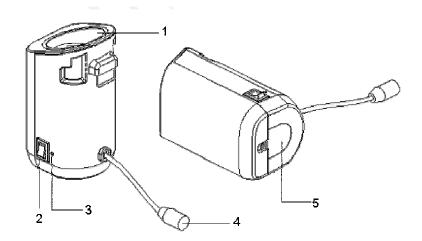
# **B.1** Overview



As shown in the figure above, the warmer is installed at left side of the control panel, the position that is used for placing the ultrasound gel.

To install the warmer, you should remove the ultrasound gel holder first.

# **B.2** Structure



No.	Name	Function
1.	Ultrasound gel box	Used for placing ultrasound gel.
2.	Power button	1
3.	Failure indicator	Displays in red when the temperature is higher than the required value.
4.	Power cable	Connect to the power socket under the control panel.
5.	Bottom cover	1

# **B.3** Specifications

Power supply

Voltage

12V<sup>---</sup>

Power consumption 36W

# **B.4** Function and Requirement

The ultrasound gel warmer can heat the ultrasound gel to about  $36\pm2^\circ\!\mathrm{C}$  at most.

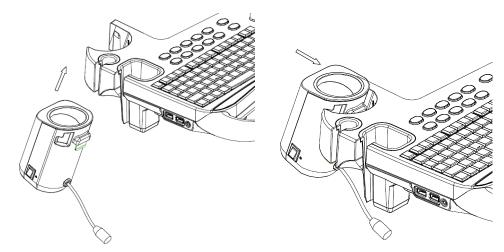
When the gel is put inside the warmer, the time it takes to heat from environmental condition of  $18^{\circ}$ C to 28 °C should be no more than 0.5 hours.

The ultrasound gel warmer can work continuously over 12 hours.

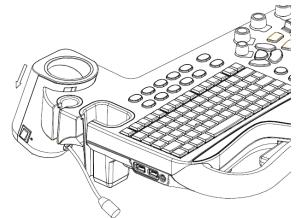
NOTE: 1. When the environment temperature is higher than the requirement temperature of the warmer, the warmer does not function.
 2. The warmer can heat only one bottle of gel at one time.

# **B.5** Install the Warmer

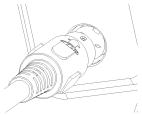
1. As shown in the figure, install the gel warmer as per the arrow direction, to fix the tab of the warmer to the groove in the control panel.



2. Push the warmer as per the arrow direction until it is tightly fixed, and connect the power cable to the power socket under the control panel.



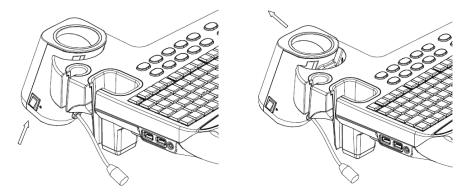
 Insert the power plug of the warmer into the jack in the back side of the control panel. Note: please connect the plug to the jack as per the direction indication, as illustrated in the following figure.



4. Put the gel inside the warmer, and press the power button.

# **B.6** Remove the Warmer

- 1. Pull out the power cable from the control panel jack.
- 2. Push the warmer as per the arrow direction.



3. Remove the warmer as shown in the following figure.

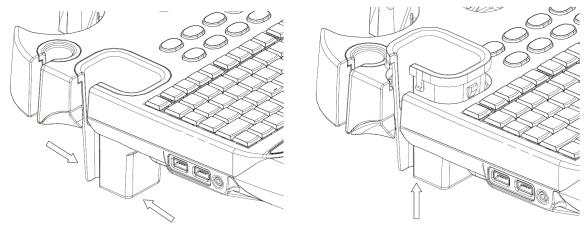


# **B.7** Mount/Remove Probe Holder

To install the gel warmer, you have to remove the probe holder first.

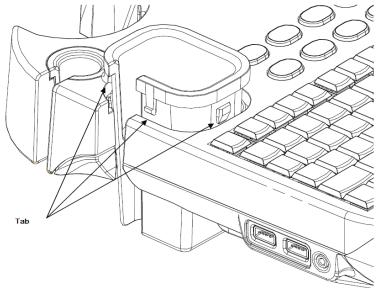
## B.7.1 Remove the Holder

Push towards the arrow direction on the bottom and lift upwards to remove the holder.



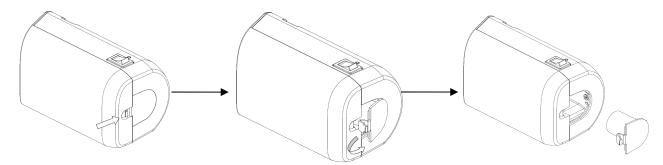
## B.7.2 Mount the Holder

Match the tab with the groove inside the control panel, and push the holder downwards to mount the holder.



# **B.8** Cleaning

1. Press the clasp of the bottom cover to release the cover.



2. Remove the cover and clean the cover.

# Appendix C iWorks

# C.1 Overview

The major objective of ultrasound workflow automation *(iWorks)* is to speed up exam time and reduce the excessive number of user interface manual key strokes that can lead to repetitive motion injuries over time. It automates a clinical work flow in common exam protocols in a logical, "step by step" manner.

A Protocol Event contains series workflow events (annotation comments, body mark and measurements) and image modal commands to assist the user in routine ultrasound examinations.

The system provides different protocol events based on the different application regions.

# C.2 iWorks Basic Procedure

- 1. Enter the patient information.
- 2. Touch [iWorks] on the touch screen to enter the protocol selection screen, and touch the corresponding protocol button to enter the status.
- 3. After the system enters the iWorks screen, the available protocol is displayed on the right part of the screen, perform the scanning and save the images according to the prompts on the upper right part of the screen.

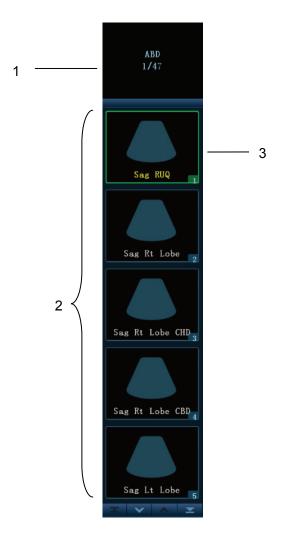
Perform measurements or add comment/body mark to the image if necessary.

- 4. After one view scanning is completed, press the user-defined save key (usually <Save1> or <Save2>) to switch to the next view, or touch [Next] on the touch screen directly.
- 5. Repeat step 3 and step 4 to acquire all necessary images.
- 6. Touch [Exit] on the touch screen to exit iWorks status.

# C.3 Screen Display

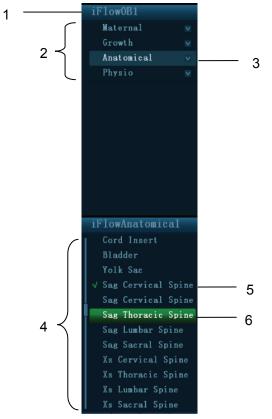
Normal iWorks protocol

For automated protocols of vascular, small parts, cardiac, abdomen and gynecology application regions, the monitor displays the following screen:



Name	Description	
	Displays the protocol name, and the number of views contained;	
1	There may be prompt information here to indicate the following operation,	
·	for instance: after the image is frozen, it displays "Press <update> to enter</update>	
	measurements" if the image needs measurement.	
2	Displays the view steps in the protocol.	
3	3 The current active view, with green solid frame around the image.	

OB iWorks protocol



Name	Description	
1	Displays the protocol name.	
2	Displays the different types of views based on different attributes.	
3	Current view type.	
4	iews contained of the current type.	
5	Already finished view, with a green " $$ " on the left.	
6	The current active view, with green solid frame around the image.	

# C.4 View Operation

In iWorks status, you can perform view selection, repeat, replacement and delete operations by the touch screen.



For some views, the system switches to the relevant imaging modes if necessary.

The comment for the current view has been automatically added to the lower left corner of the image, ready for you to scan the specified anatomy.

#### C.4.1.1 View Selection

Touch [Previous]/[Next] to select the view to be scanned, the current view is around by a green solid frame.

#### C.4.1.2 View Operation

In the current active view, you can perform image scanning, measurements, adding comments and body mark and etc. Operations are the same as those in manual operation; please refer to relevant chapters for details.

#### C.4.1.3 Repeat View

If necessary, touch [Repeat] to insert another template of the current view, then you can perform an extra examination.

#### C.4.1.4 View Replacement

The previous image will be deleted and replaced by the new image.

#### C.4.1.5 Delete View

Touch [Previous]/ [Next] to select the view to be deleted, and touch [Delete] to delete the selected view.

# C.5 Manual Examination

Suspend- Exit out of protocol so user can run system manual. Such case is performed when unusual or atypical workflow is required.

You can run system manually if necessary.

- Start manual examination: touch [Suspend] to pause the current iWorks protocol, and the system enters the manual examination status.
- Return to iWorks: touch [Resume iWorks] to return the system to automated status, and you can continue the previous iWorks scanning.

# C.6 Insert

Insert is specialized protocol event within i Works and i Works OB. It aids in the workflow of documenting and measuring common pathological (disease) states (i.e. Mass, Cyst, Stenosis, Thrombus) that occurs outside a routine, normal examination.

- 1. Touch [Insert] on the touch screen to enter the status.
- 2. Select the necessary protocol, and the system adds the protocol events to the current protocol.
- 3. Perform measurements or add comment/body mark to the image if necessary.

# C.7 iWorks Setting

Enter the iWorks preset screen through the path: "[Preset]→[iWorks Preset]", you can customize the protocols and views here:



# C.7.1 Protocol Management

- Click to select the protocol in the list, the protocol type can be checked on the right.
- Click [Add Protocol] to create a new protocol and it can be customized.
- Click to select a protocol in the list on the left, and click [Copy], then a protocol named "copy of XXX" is created with the copied views, which can be customized.
- Click [Delete] to delete a user-defined protocol.
- Click [Up] or [Down] to move the selected protocol.
- Click [Move to Top]/[Move to Bottom] to move the selected protocol to the top or bottom of the list.

## C.7.2 View Management

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

## C.7.3 Create New Protocol

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

1. In the iWorks preset screen, click [Add Protocol] to create a new protocol, enter the protocol name, type and select the application region.

Or you can select an existed protocol and click [Copy] to customize the protocol based on the previous template.

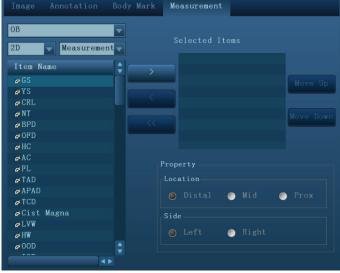
Protocol Name	
iWorks_2	
Protocol Type	
🍥 Sequence Protocol 🛛 💿 Random Protocol	iNCert Protocol
Use This Protocol Under	
ABD	_
GYN	
CARD	-
SMP	-
URO	
VAS	
PED	
Nerve	
EM	

2. Click [Add View] to enter the view name, and perform image settings, as shown in the following figure.

Image Annotation Body Mark	Measurement
View Name	
View	
Mode Combinations	Image Parmeter
🔵 B Mode	Auto Calc
🔵 Dual Mode	🕘 On 🙁 Off
💿 B + Color Mode	iTouch
🔵 B + PW Mode	🔵 On 💿 Off
🔵 B + Color + PW Mode	
🔵 B + CW Mode	
🔵 B + Color + CW Mode	
● B + M Mode	
Position	
🔵 None 🛛 💿 Sag	g 🔵 XS

3. Perform comments, body mark, measurement settings, as shown in the following figure:





4. Use the check box for auto OB measurement and body mark display settings.



5. Click [Save] to complete the setting and exit.

# Appendix D Barcode Reader

The product supports reader for logging data as patient ID: 1-D barcode reader (SYMBOL LS2208). The laser transmitted by the reader is Class 2 laser.

# **WARNING:** Class 2 laser adopts low power, visible LED. DO NOT stare into beam because of unknown hazards of transient radiation provided by class 2 laser.

# **CAUTION:** Ensure the information acquired by barcode reader is consistent with the actual information.

There are 2 operation modes:

Hand-held mode: press the trigger to decode.

Hands-free mode: seat the reader in the stand to enter the mode, the reader decodes automatically. Note: the reader does not support decoding of Multilanguage.

# D.1 1-D Barcode Reader

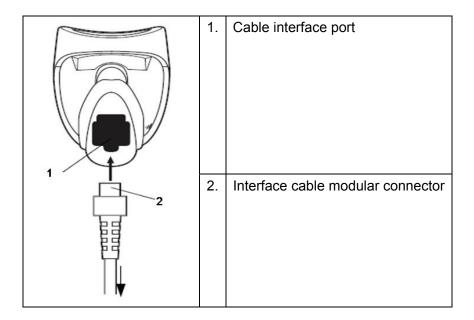
## D.1.1 Overview



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	

# D.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.



# D.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













7



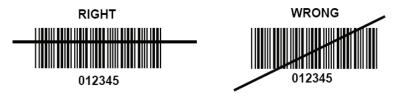


Barcode Reader D-4

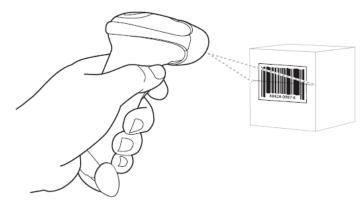
# D.1.4 Scanning in Hand-Held Mode

- 1. Ensure all connections are secure.
- 2. Aim the reader at the barcode. Press the trigger.

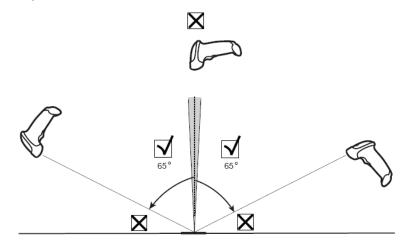
Note: Ensure the scan line crosses every bar and space of the symbol, see the figure below.



3. Upon successful decode, the reader beeps and the LED turns green.

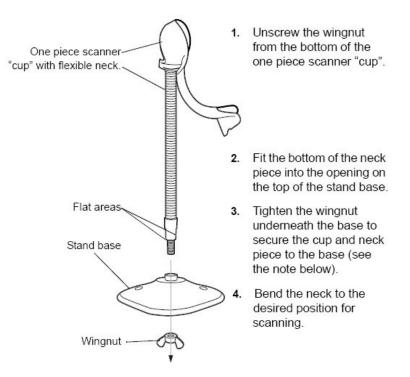


Tips: Do not hold the reader directly over the barcode. Laser light reflecting *directly* back into the reader from the barcode is known as specular reflection. This specular reflection can make decoding difficult. You can tilt the reader up to 55 \_ forward or back and achieve a successful decode



## D.1.5 Scanning in Hands-Free Mode

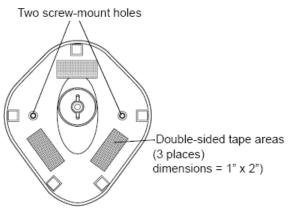
#### D.1.5.1 Assembling the Intellistand



NOTE Before tightening the wingnut under the base, ensure that the flat areas on the flexible neck fit securely in the grooves in the base.

#### D.1.5.2 Mounting the Stand (optional)

You can attach the base of the reader's stand to a flat surface using two screws or double-sided tape (not provided).

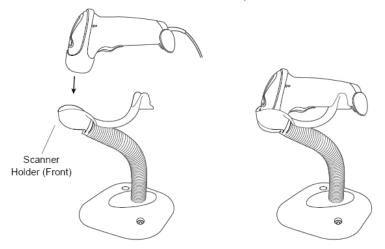


- Screw Mount
- 1. Position the assembled base on a flat surface.
- 2. Screw one #10 wood screw into each screw-mount hole until the base of the stand is secure
- Tape Mount
- 1. Peel the paper liner off one side of each piece of tape and place the sticky surface over each of the three rectangular tape holders.

2. Peel the paper liner off the exposed sides of each piece of tape and press the stand on a flat surface until it is secure.

#### D.1.5.3 Scanning in Hands-Free Mode

When the reader is seated in the stand's "cup", the reader's built-in sensor places the reader in handsfree mode. When you remove the reader from the stand it operates in its normal hand-held mode.



# **D.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

Parameter	Defaults
Set Length(s) for Code 39	2 to 55
Code 39 Check Digit Verification	Disable
Transmit Code 39 Check Digit	Disable
Code 39 Full ASCII Conversion	Disable
Buffer Code 39	Disable
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

# D.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.