TE7 Diagnostic Ultrasound System

Operator's Manual

[Basic Volume]

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

Customer Service Department

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

Mindray Building, Keji 12th Road South, High-tech industrial park, Nanshan, Shenzhen 518057,P.R.China Address:

Website: www.mindray.com

E-mail Address: service@mindray.com

Tel: +86 755 81888998

Fax: +86 755 26582680

EC-Representative: Shanghai International Holding Corp. GmbH(Europe)

Address: Eiffestraße 80, Hamburg 20537, Germany

Tel: 0049-40-2513175

Fax: 0049-40-255726

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:
 - (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.
- The purpose of this system is to provide physicians with data for clinical diagnosis. The physician is responsible for the results of diagnostic procedures. Mindray shall not be liable for the results of diagnostic procedures.
- 7. Important data must be backed up on external memory media.
- 8. Mindray shall not be liable for loss of data stored in the memory of this system caused by operator error or accidents.
- 9. This manual contains warnings regarding foreseeable potential dangers, but you shall also be continuously alert to dangers other than those indicated. Mindray shall not be liable for damage or loss resulting from negligence or ignorance of the precautions and operating instructions described in this operator's manual.
- 10. If a new manager takes over this system, be sure to hand over this operator's manual to the new manager.

About This Manual

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

Notation Conventions

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

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

 \triangle CAUTION:

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

Operator's Manuals

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

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

Hardcopy Manuals

■ Operator's Manual [Basic Volume]

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

- Operator's Manual [Advanced Volume]
- Operator's Manual [Acoustic Power Data and Surface Temperature Data]
 Contains data tables of acoustic output for transducers.
- Operation Note

Contains a quick guide for basic system operations.

NOTE:

Manuals on CD are the manuals translated into languages other than English, according to the English manuals.

If you find that the contents of the manuals on CD are NOT consistent with the system or the English manuals, refer ONLY to the corresponding English manuals.

The accompanying manuals may vary depending on the specific system you purchased. Please refer to the packing list.

Software Interfaces in this Manual

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

Conventions

In this manual, the following conventions are used to describe the buttons on the display (main screen), items in the menus, buttons in the dialog boxes and some basic operations:

- [Items in menu or on the screen or buttons in dialog box]: square brackets indicate items in menus or on the screen, or buttons in dialog boxes.
- Tap [Items or Buttons]: tap the corresponding item on the screen.
- [Items in menu] -> [Items in submenu]: select a submenu item following the path.

1 Safety Precautions

1.1 Safety Classifications

- 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 is rated IPX0
 - The probes are rated IPX7
 - The foot switch (can be applied in the operating room) is rated IPX8.
 - The power adapter is rated IPX1.
- According to the disinfection and sterilization method(s) recommended by manufacturer:
 - Equipment with disinfection and sterilization method(s) recommended by manufacturer.
- According to the degree of safety of application in the presence of a FLAMMABLE ANESTHETIC MIXTURE WITH AIR OR WITH OXYGEN OR NITROUS OXIDE
 - EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANESTHETIC MIXTURE WITH AIR OR WITH OXYGEN OR NITROUS OXIDE
- According to the mode of operation:
 - Continuous operation
- According to the installation and use:
 - Portable equipment
 - Mobile equipment (when the system is installed on the trolley)
- Does the equipment has any defibrillation-proof applied parts:
 - Non-defibrillation-proof applied part
- Permanently installed equipment or non-permanently installed equipment:
 - Non-permanently installed equipment

1.2 Meanings of Signal Words

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

Signal word	Meaning	
\triangle DANGER	⚠DANGER Indicates an imminently hazardous situation that, if not avoided, will result in death or serious injury.	
≜ WARNING	Indicates a potentially hazardous situation that, if not avoided, could result in death or serious injury.	
A CAUTION	CAUTION Indicates a potentially hazardous situation that, if not avoided, may result in minor or moderate injury.	
NOTE	Indicates a potentially hazardous situation that, if not avoided, may result in property damage.	
Tips	Important information that helps you 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 within this system is type-BF applied part.
\triangle	General warning sign.
&	Patient/user infection due to contaminated equipment. Be careful when performing cleaning, disinfection and sterilization.
	Patient injury or tissue damage from ultrasonic radiation. The ALARA principle must be practiced when operating the ultrasound system.

1.4 Safety Precautions

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

 Δ DANGER:

DO NOT use flammable gasses, such as anesthetic gas or hydrogen, or flammable liquids such as ethanol, near this system, because there is danger of explosion.

⚠WARNING:

 Do connect the adapter power plug of this system and power plugs of the peripherals to well-grounded wall receptacles that meet the ratings indicated on the rating nameplate. Using a multifunctional receptacle may affect the system protective grounding performance, and cause the leakage current to exceed safety requirements.

Use the cable provided with this system to connect the printer. Other cables may result in electric shock.

You must use the power adapter provided with the system; otherwise electric shock may result.

You can only use the power supply method provided by Mindray, other power supply modes (e.g. using a UPS) may result in electric shock.

- 2. Connect the protective grounding conductor before turning ON the system. Disconnect the grounding cable after turning OFF the system. Otherwise, electric shock may result.
- 3. 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 protective grounding may result or a gas explosion may occur.
- 4. Before cleaning the system, disconnect the power cord from the outlet. Failure to do so may result in system failure and electric shock.
- 5. This system is not water-proof designed. DO NOT use this system in any place where water or any liquid leakage may occur. If any water is sprayed on or into the system, electric shock or device malfunction may result. If water is accidentally sprayed on or into the system, power off the system immediately and contact Mindray Customer Service Department or sales representative.
- 6. 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 a damaged or scratched probe is used.
- 7. 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.

- 8. 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.
- 9. Do not subject the probes to knocks or drops. Use of a defective probe may cause an electric shock.
- 10. 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.
- 11. DO NOT use this system simultaneously with equipment such as an electrosurgical unit, high-frequency therapy equipment, or a defibrillator, etc. This would result in a risk of electric shock to the patient.
- 12. When moving the system, you should first fold the LCD display, disconnect the system from other devices (including probes) and disconnect the system from the power supply.
- 13. Accessory equipment connected to the analog and digital interfaces 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 chapter 16 ME System. 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 chapter 16 ME System. If you have any questions regarding these requirements, consult your sales representative.
- 14. Prolonged and repeated use of display controls may result in hand or arm nerve disorders for some individuals. Observe the local safety or health regulations concerning the use.
- 15. DO NOT contact both the patient and the ultrasound system or the live parts of the ultrasound system (e.g. signal I/O ports). Electric shock may occur.
- 16. When using intra-cavity transducers, do not activate the transducer outside the patient's body.
- 17. If you have any doubts of the installation or routing of external protective cables, use the internal power supply of the system.
- 18. DO NOT put the ultrasound system in any soft materials (e.g. soft cloth or cotton, etc.) in case that the air vent becomes blocked.
- 19. Always read and follow carefully the manufacturer instructions on the contrast agent label.
- 20. Only use the ECG leads provided with the ECG module; otherwise electric shock may result.

△ CAUTION:

1. Precautions concerning clinical examination techniques:

This system must be used only by qualified medical professionals.

This operator's manual does not describe clinical examination techniques. The clinician should select the proper examination techniques based on specialized training and clinical experience.

- 2. Malfunctions due to radio waves:
 - If a device emitting radio waves 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) into the room where the system is located.
 - 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:
 - When you place the system on the trolley and move them together, you must secure all objects on the trolley to prevent them from falling. Otherwise you should separate the system from the trolley and move them individually.
 When you have to move the system with the trolley
 - When you have to move the system with the trolley upward or downward the stairs, you must separate them first and then move them individually.
 - Object placed on the display may fall and injure an individual when moving.
 - Confirm that there is no peripheral device connected to the system before moving the system. Otherwise, peripheral device may fall and cause injury.
- 4. DO NOT expose the system to excessive vibration through transportation. Mechanical damage may result.
- 5. Do not connect this system to outlets with the same circuit breakers and fuses that control the current of devices such as life-support systems. If this system malfunctions and generates over current, or when there is an instantaneous current at power ON, the circuit breakers and fuses of the building's supply circuit may be tripped.
- 6. Always keep the system dry. Avoid transporting this system quickly from a cold place to a warm place; otherwise condensation or water droplets may form allowing a short circuit and possible electric shock.
- 7. If the circuit protector is tripped, it indicates that the system or a peripheral device was improperly shut down and that the system is unstable. You cannot repair the system under this circumstance and must call the Mindray Customer Service Department or sales representative.

- 8. 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 mode combinations. Apply the probe only for a period of time required for the purpose of diagnosis.
- 9. 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.
- 10. It is necessary to tap [End] in the bottom-left corner of the operating panel to end the current scan that is in progress and clear the current Patient Information field. Failure to do so may result in new patient data being combined with data of the previous patient.
- 11. DO NOT connect or disconnect the system's power cord or its accessories (e.g., a printer or a recorder) without turning OFF the power first. This may damage the system and its accessories or cause electric shock.
- 12. If the system is powered off improperly during operation, it may result in data damage of the system's hard disk or system failure.
- 13. Do not use the system to examine a fetus for a long period of time.
- 14. 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.
- 15. It is recommended to only use the video devices specified in this manual.
- 16. Do not use gel, disinfectant, probes, probe sheath or needle-guided brackets that are not compatible with the system.
- 17. Read the Acoustic Output Principle in the operation manual carefully before operate this system on clinical examination.
- 18. Please use the ultrasound gel compliant with the relevant local regulations.

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, which may affect the performance of the system or even lead to failure.

- 3. To avoid damaging the system, DO NOT use it in following environment:
 - (1) Locations exposed to direct sunlight.
 - (2) Locations subject to sudden changes in environmental temperature.
 - (3) Dusty locations.
 - (4) Locations subject to vibration.
 - (5) Locations near heat generators.
 - (6) Locations with high humidity.
- 4. 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.
- 5. When using or placing the system, keep the system horizontal to avoid imbalance.
- 6. Remove ultrasound gel from the face of a probe when the examination is complete. Water in the gel may enter the acoustic lens and adversely affect the performance and safety of the probe.
- You should properly back up the system to a secure external storage media, including system configuration, settings and patient data. Data stored to the system's hard drive may be lost due to system failure, improper operation or accident.
- 8. Do not apply external force to the touch screen; otherwise, the system may be damaged.
- 9. If the system is used in a small room, the room temperature may rise. Please provide proper ventilation and free air exchange.
- 10. 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.
- 11. Electrical and mechanical performance may be degraded due to long period of 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.
- 12. Ensure that the current exam date and time are the same as the system date and time.
- 13. 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.
- 14. Use detachable power supply cord as mains power breaking device. DO NOT set equipment in a place where it is difficult to disconnect the detachable power supply cord!

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

⚠WARNING: 1.

- The ultrasonic probe is only for use with the specified ultrasonic
 diagnostic system. Please refer to the 2.4.2 Probes and Needleguided Brackets Available to select the proper probe.
- Confirm that the probe and cable are normal before and aftereach examination. A defective probe may cause electric shock to the patient.
- 3. Do not subject the probe to shock. A defective probe may cause electric shock to the patient.
- 4. Do not disassemble the probe as this may cause electric shock or malfunction.
- Never immerse the probe connector into liquids such as water or 5. disinfectant because the connector is not waterproof. Immersion may cause electric shock or malfunction.
- A probe sheath must be installed over the probe before performing intra-cavity or intra-operative examination.

△CAUTION:

- 1. When using the probe, wear sterile gloves to prevent infection.
- 2. Be sure to use sterile ultrasound gel. Please use the ultrasound gel compliant with the relevant local regulations. And manage the ultrasound gel properly to ensure that it does not become a source of infection.
- In normal diagnostic ultrasound mode, there is no danger of a normal-temperature burn; however, keeping the probe on the same region of the patient for a long time may cause such a burn.
- 4. Do not use the carrying case for storing the probe. If the carrying case is used for storage, it may become a source of infection.
- It is required to practice ALARA when operating ultrasound system. Minimize the acoustic power without compromising the quality of images.
- The probe and the accessories supplied with it are not delivered disinfected or sterilized. Sterilization (or high-level disinfection) is required before use.
 - Disposable components (for example the probe sheath, the sterile gloves) are packaged sterile and are single-use only. Do
- 7. not use if the integrity of the packaging has been violated or if the expiration date has passed. Use disposable components which comply with the relevant local regulations.
 - Please use the disinfection or sterilization solution that recommended in this operator's manual; otherwise Mindray will
- 8. not be liable for damage caused by other solutions. If you have any questions, please contact Mindray Customer Service Department or sales representative.
- 9. The probe sheath contains natural rubber that can cause allergic reactions in some individuals.

Do not use pre-lubricated condoms as a sheath. Lubricant may not be compatible with the transducer material and damage may result.

Transducer damage may be caused by inappropriate gel, detergent or cleanser:

Do not soak or saturate transducers with solutions containing alcohol, bleach, ammonium chloride compounds, acetone or formaldehyde.

Avoid contact with solutions or coupling gels containing mineral oil or lanolin.

The contrast agent used must comply with the relevant local regulations.

NOTE: 1. Read the following precautions to prevent the probe from malfunction:

- Clean and disinfect the probe before and after each examination.
- After the examination, wipe off the ultrasound gel thoroughly. Otherwise, the ultrasound gel may solidify and the image quality would be degraded.
- 2. Ambient conditions:

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

- Direct sunlight or X-rays
- Sudden changes in temperature
- Dust

you purchased the system.

- Excessive vibration
- Heat generators

Use the probes under the following ambient conditions:

- ambient temperature: 0°C ~ 40°C
- relative humidity: 30% \sim 85% (no condensation)
- ullet atmospheric pressure:700 hPa \sim 1060 hPa.

Use the probe L16-4Hs under the following working conditions:

- ambient temperature: 10°C ~ 40°C
- relative humidity: 30% \sim 85% (no condensation)
- ullet atmospheric pressure: 700 hPa \sim 1060 hPa.
- 3. Repeated disinfection will eventually damage the probe, please check the probe's performance periodically.

NOTE: The following definition of the WEEE label applies to EU member states only: The use of this symbol indicates that this system should not be treated as household waste. By ensuring that this system is disposed of correctly, you will help prevent bringing potential negative consequences to the environment and human health. For more detailed information with regard to returning and recycling this system, please consult the distributor from whom



For system products, this label may be attached to the main unit only.

1.5 Latex Alert

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

CIVCO Medical Instruments

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



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

1.6 Warning Labels

Warning labels are attached to this system to call your attention to potential hazards. The symbol on warning labels indicates safety precautions.

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

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

No.	Warning Labels	Meaning
1.		There is explosion risk if the system is used in proximity to flammable anesthetics.
2.	The following labels are available when the system works with the trolley.	 (a) Do not position the system with the trolley on a sloped surface. This may lead the system to slide, resulting in personal injury or system malfunction. Two people are required to move the system over a sloped surface. b DO NOT sit on the trolley. c When the casters are locked, DO NOT push the trolley.

2 System Overview

2.1 Intended Use

TE7 Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, intra-operative (abdominal, thoracic, and vascular), pediatric, small organ (breast, thyroid, testes), neonatal and adult cephalic, trans-esoph. (Cardiac), trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), urology, peripheral vessel, adult and pediatric cardiac exams.

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

2.2 Contraindication

This ultrasound system should not be used in ophthalmic procedures or any procedure that causes the acoustic beam to pass through the eye.

2.3 Product Specifications

2.3.1 Imaging Mode

B Mode B
M Mode M
C Mode Color

Power(DirPower)

D Mode PW/CW

Special imaging Left Ventricular Opacification (LVO)

2.3.2 Power supply

Voltage 100-240V∼;

19Vdc (DCU direct input)

Frequency 50/60Hz

Power input 2.0A (Power adapter)

3.5A (Trolley)

Fuse T5AL, 250Vac (Power adapter)

Battery 14.8Vdc

2.3.3 Environmental Conditions

Operating conditions Storage and transportation conditions

Ambient temperature 0°C~40°C -20°C~55°C

Relative humidity 30%~85% (no condensation) 20%~95% (no condensation)

Atmospheric pressure 700hPa~1060hPa 700hPa~1060hPa

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

2.3.4 Dimensions and Weight

Dimensions: 97 (Depth) imes 295 (Width) imes 380 (Height) mm

Weight (including batteries, three-probe socket configuration and one probe): <8.2Kg.

2.4 System Configuration

2.4.1 Standard Configuration

- Main unit (select configuration between one-probe socket and three-probe socket)
- Built-in batteries
- Built-in SSD card
- System software
- Wireless adapter (built-in)
- Accessories
 - Operator's manual and operation note
 - Ultrasound gel (made by Eco-Med Pharmaceuticals, model: Eco Gel 200, K955246)
 - Cables

Applied part: probes.

2.4.2 Probes and Needle-guided Brackets Available

Probe model	Probe Type	Intended Use	Region Applied
C5-2s	Convex	Gynecology, Obstetrics, Vascular, Pediatric	Body surface
C11-3s	Convex	Abdominal, Cephalic, Vascular, Small organ, Musculo-skeletal, Pediatric	Body surface
L12-4s	Linear	Small organ, Vascular, Musculo-skeletal,	Body surface
L7-3s	Linear	Abdominal, Pediatric	Body surface
L14-6s	Linear	Small organ, Vascular, Musculo-skeletal, Pediatric	Body surface
L14-6Ns	Linear	Breast, Musculo-skeletal, Nerve, Small organ (Superficial), Vascular (Superficial), Pediatric hip	Body surface
P4-2s	Phased	Cardiac, Abdominal, Cephalic, Pediatric	Body surface
V11-3Ws	Convex	Gynecology, Obstetrics, Urology	Transvaginal
7LT4s	Linear	Intraoperative (Abdominal, Cardiac, Vascular), Small organ, Vascular, Musculo-skeletal, Abdominal, Pediatric	Body surface
P7-3Ts	Phased	Cardiac	Transesophageal
L16-4Hs	Linear	Musculo-skeletal, Nerve, Small organ, Vascular, pediatric hip, neonatal cephalic	Body surface

Some of the probes have corresponding 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
V11-3Ws	NGB-004 metal/needle non-detachable	/	16G, 17G, 18G
L12-4s/ L7-3s/ L14-6Ns	NGB-007 plastic/needle detachable metal/needle detachable	40°, 50°, 60°	Metal: 14G, 16G, 18G, 20G, 22G Plastic: 13G, 15G, 16G, 18G, 20G
7LT4s	NGB-010 (metal/needle detachable)	30°, 40°, 50°	13G, 15G, 16G, 18G, 20G
P4-2s	NGB-011 metal/needle non-detachable	11°, 23°	13G, 15G, 16G, 18G, 20G
C5-2s	NGB-015 Metal/needle detachable	25°, 35°, 45°	14G, 16G, 18G, 20G, 22G
L14-6s	NGB-016 Metal/needle detachable	30°, 40°, 50°	14G, 16G, 18G, 20G, 22G
C11-3s	NGB-018 metal/needle detachable	15°, 25°, 35°	14G, 16G, 18G, 20G, 22G

2.4.3 Options

	Item	Remarks
Footswitch		Types: 2-pedal/3-pedal
Trolley See chapter "Appendix D Trolley and Accessories" for details.		
Wall mount/Table stand		
Power adapter		Table stand or wall mounting bracket should be configured.
Travelling case		/
Pack		/
External DVD recorder		1
ECG module		1
ECG cables		ECG function should be configured.
DC-IN cable		ECG function should be configured.
Barcode reader		/
CW module		/
LVO		/
iNeedle		/
Abdomen/General Package		/
Obstetrical Package		/
Gynecology Package		/
Cardiac Package		/
Small Parts Package		/
Urological P	ackage	/
Vascular Pa	ckage	/
Nerve Pack	age	/
Emergency	& Critical Package	/
	DICOM Basic (including verify (SCU and SCP), task management, DICOM Storage, DICOM Print, DICOM Storage Commitment, DICOM Media Storage (including DICOM DIR))	/
	DICOM Worklist	
DICOM	DICOM MPPS	
	DICOM OB/GYN SR	1
	DICOM Vascular SR	DICOM Basic should be configured.
	DICOM Cardiac SR	1
	DICOM Query/Retrieve	1
	DICOM Breast SR	1
	Trolley Wall mount/ Power adap Travelling ca Pack External DV ECG module ECG cables DC-IN cable Barcode rea CW module LVO iNeedle Abdomen/G Obstetrical I Gynecology Cardiac Pac Small Parts Urological F Vascular Pac Nerve Pack Emergency	Footswitch Trolley See chapter "Appendix D Trolley and Wall mount/Table stand Power adapter Travelling case Pack External DVD recorder ECG module ECG cables DC-IN cable Barcode reader CW module LVO iNeedle Abdomen/General Package Obstetrical Package Gynecology Package Cardiac Package Small Parts Package Urological Package Vascular Package Nerve Package Emergency & Critical Package DICOM Basic (including verify (SCU and SCP), task management, DICOM Storage, DICOM Print, DICOM Storage (including DICOM DIR)) DICOM Worklist DICOM Worklist DICOM OB/GYN SR DICOM OB/GYN SR DICOM Cardiac SR DICOM Cardiac SR DICOM Query/Retrieve

2.4.4 Peripherals Supported

No.	Item	Model
1.	Digital graph/text printer	HP Officejet 7000 wide format
2.		MITSUBISHI P95DW-N
	Black / white video printer(digital)	SONY UP-D897
		SONY UP-D898MD
		SONY UP-X898MD
3.	Digital color video Printer	SONY UP-D25MD
		Cannon SELPHY CP800
4.	Barcode reader	SYMBOL DS6707-SR
	Darcode reader	SYMBOL LS2208-SR
5.	External DVD R/W drive	ASUS DVD

- Parts that can be used within patient environment:
 - Main unit;
 - Probes:
 - Footswitch;
 - Printers: MITSUBISHI P95DW-N, SONY UP-D897, Cannon SELPHY CP800, SONY UP-D25MD, SONY UP-D898MD, and SONY UP-X898MD.

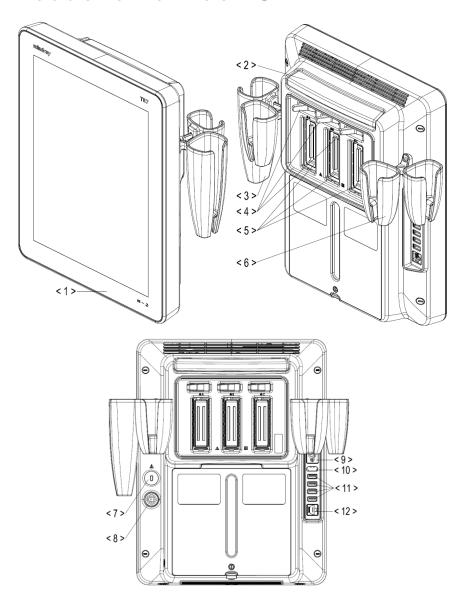
NOTE:

- If the ultrasound system can not recognize the SONY UP-X898MD and SONY UP-D898MD printers automatically, you may need to change the settings on the printer: push <PUSH ENTER> to enter the main menu and select [DIGITAL]->[DRIVER], and select [897].
- 2. USB cable length of the printers should be within 5-6 ft, otherwise the lifting of the trolley will be affected if the USB cable is too short or even the ultrasound system and the printer can not be connected; or it's not easily to arrange the cable tidily if the USB cable is too long.

riangleWARNING:

This system complies with IEC60601-1-2:2007, and its RF emissions meet the requirements of CISPR11 Class B. In a domestic environment, the customer or user should ensure the system is connected to Class B peripheral devices, otherwise RF interference may occur, and the customer or user must take adequate measures accordingly.

2.5 Introduction of Each Unit



No.	Name	Function
<1>	Touch screen and display	Operator-system interface or control; displays the image and parameters during the scan. - Battery status indicator. - Charging status: It illuminates in orange when batteries are charging; It illuminates in green when batteries are charged fully. - Discharging status: It illuminates in green color when the power of the batteries is sufficient; It blinks in orange color for low battery power. - AC indicator The indicator is green at AC supply. The indicator is off when batteries are supplied without AC supply. - Standby indicator. Standby: blinking in orange. Other status: light off.
<2>	Telescoping handle	Used for moving the system occasionally.
<3>	Intra-cavity probe holder	Used for placing the probe.
<4>	Probe locking switch	Locks or unlocks the probe connecting with the main unit.
<5>	Probe port	Connects a probe to the main unit.
<6>	Probe holder	Used for placing the probe.
<7>	Kensington lock	Locks the main unit to the trolley in case of loss.
<8>	Power inlet	Connects with the power adapter.
<9>	Serial port for connecting ECG	Connects with the ECG module
<10>	HDMI	Used for extending the monitor.
<11>	USB ports	Connects USB devices.
<12>	Network port	Connects to network.

NOTE: Mindray recommends using Category 2-certified HDMI output cables (marked as "High Speed") according to HDMI 1.3 standard for a good output effect. Otherwise, abnormal display effect may result. You can use a HDMI-to-DVI adapter for outputting to a display with DVI input.

When connecting TE7 with an external display or recording devices via HDMI, choose a right output setting resolution ([Setup] ->[System] ->[Peripheral] -> [Display]), and please make sure the scan rate of 60Hz progressive is supported by the external device, otherwise malfunction may result.

2.6 Symbols

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

Symbol	Description
\triangle	Caution!
ҡ	Type-BF applied part
\otimes	No user serviceable parts (power adapter)
₩	Battery installation position
SN	Product serial number
	Manufacture date
<u>-</u>	Battery status indicator
~	AC (Alternating current)
D	Standby status indicator
Ī	Probe connector unlocking symbol
1	Probe connector locking symbol
→	Extending port
HDMI	HDMI port
•<-	USB port
 _	Network port
<u> </u>	Probe socket
19V 7.9A MAX	Power consumption
△ 4kg/8.8lbs	Maximum load for printer bracket on the trolley
AC 100-240V 50/60Hz 240VA	Trolley input
AC 100-240V 50/60Hz 407VA	Trolley output
△ 3.1kg/6.8lbs	Maximum load for storage bin on the trolley
EC REP	Authorized representative in the European Community

Symbol	Description
	This product is provided with a CE marking in accordance with the regulations stated in Council Directive 93 / 42 / EEC concerning Medical Devices. The number adjacent to the CE marking (0123) is the number of the EU-notified body certified for meeting the requirements of the Directive.
((0 ₁₂₃	The radio device used in this product is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC (Radio Equipment and Telecommunications Terminal Equipment Directive). The product is in compliance with ETSI EN 300 328 and ETSI EN 301 489.
	NOTE : The product complies with the Council Directive 2011/65/EU.

3 System Preparation

3.1 Move/Position the System

Read and understand the safety precautions before positioning the system to ensure the safety of both the operator and the devices.

- 1. Switch off the power, and pull out the power plug.
- 2. Disconnect all cables from off-board peripheral devices.
- 3. Place the system in a desired location.
- 4. Leave at least 20cm at the back and both sides of the system.

CAUTION:

Maintain a generous, free air flowing space around the back and both sides of the system. Not doing so may result in failure due to the increased rise in the system's operating temperature.

3.2 Power ON/OFF

3.2.1 Power the System ON

 \triangle CAUTION:

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

Check before Powering ON
 Check before the system is powered on:

No.	Check Item	
1	The temperature, relative humidity and atmospheric pressure meet the requirements of	
	the operating conditions. See "2.3.3 Environmental Conditions" for details.	
2	There is no condensation.	
	There is no distortion, damage or dirt on the system and peripheral devices.	
3	If any dirt is found, cleaning should be performed as illustrated in section "16 System	
	Maintenance."	
4	There are no loose screws on the display or the trolley.	
5	There is no cable damage (e.g., power cord).	
Ü	Maintain secure connections to the system at all times.	
6	The probes and probe cables are free from damage or stains.	
O	See chapter "13 Probes and Biopsy" for details of probe cleaning and disinfection.	
7	No miscellaneous odds and ends are attached or affixed to the display.	
-	Ensure that all connections are free from damage and remain clear of foreign object	
8	blockages.	
	There are no obstacles around the system and its air vent.	
9	Probe cleaning and disinfection.	
10	The entire scanning environment and field must be clean.	
11	The locking mechanism of the casters (if there is a trolley) works normally.	

Check the system after it is powered on
 Press the power button at the right side of the ultrasound system to power the system on.
 Check after the system is powered on:

No.	Check Item						
1	There are no unusual sounds or smells indicating possible overheating.						
2	There are no persistently displayed system error messages.						
3	There is no evident excessive noise, or discontinuous, absent or black items in the B mode image.						
4	Check whether there is abnormal heat on the surface of the probe during an ultrasound procedure. If you use a probe which is giving off excessive heat, it may burn the patient.						
5	The display (main screen) can respond functionally.						
6	The date and time are displayed correctly.						

⚠WARNING:

If you use a probe giving off excessive heat, it may burn the patient.

If you find anything not functioning properly, this may indicate that the system is defective. In this case, shut down the system immediately and contact Mindray Customer Service Department or sales representative.

NOTE:

When you start the system or switch between transducers, you may hear clicking sounds – this is expected behavior.

3.2.2 Power the System OFF

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

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

- 1. Disconnect the power adapter.
- 2. Disconnect the mains power.
- 3. Turn off powers of all peripherals connected to the system.
- To power the system off normally
- 1. Press the power button at the right side of the ultrasound system to see the option:
 - Shut down: to power the system off normally.
 - Standby: to enter standby status.
 - Cancel: to cancel the operation.
- 2. Select [Shut Down] to power the system off.
- To shut down the system directly if it cannot be done normally:

Press and hold the power button for a long time and the system will power off without displaying the "Shutdown Confirm" screen. However, shutting down the system this way may destroy the data.

NOTE: DO NOT rush direct shutdown of the system. It may damage the data.

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

3.2.3 Standby

- To enter standby:
 - Select [Setup] -> [System] -> [General] to set the time for screensaver and standby. If the
 system is not carrying out an operation, the screensaver appears after the screensaver
 delay period. If there is still no operation, the system enters standby after the standby
 delay period.



- Press the power button and select [Standby].
- To exit standby:

Touch the screen lightly or press the power button.

Under the standby status:Exit standby status and power off the system after 5s.

NOTE: Power off the system if the system will not be used for a long period of time (including storage/ transportation condition), and do not leave the system in standby status, otherwise the batteries will run out of power and be permanently damaged.

If the system will not be used for a long period of time, you should disconnect the power adapter, disconnect the mains power, and turn off the power to all peripherals connected to the system.

3.3 Connecting the Power Cord

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

3.3.1 Connecting Power

- 1. Connect the connector of the power adapter to the adapter port in the system.
- 2. Use a three-wire cable to connect the adapter with the external power supply.
- 3. The external power supply must meet the requirements in chapter "2.3.2 Power supply".

If you have any question about the power adapter, please contact your sales representative.

NOTE: You must use the specified power adapter.

Do not use this power adapter in conditions other than those specified.

3.3.2 Powered by Batteries

- When connecting to the external power supply, the system is powered by the external power. The lithium ion batteries inside it are in the charging status.
- If disconnected from the external power supply, the system is powered by the lithium ion batteries. Refer to "Appendix B Battery" for the detailed operations and precautions.

3.4 Connecting a Probe

CAUTION:

Tap [Freeze] to freeze an image or turn off the system power before connecting or disconnecting a probe. Failure to do so may result in system or probe failure.

When connecting or disconnecting a probe, place it in the proper position to prevent the probe from falling off or becoming damaged.

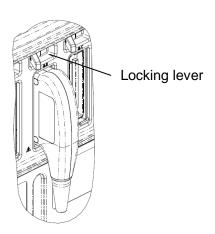
Only use probes provided by Mindray. Aftermarket probes may result in damage or cause a fire.

3.4.1 Connecting a Probe

 \triangle WARNING:

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

- 1. Keep the cable end of the transducer to the right side of the system; insert the connector into the system port, then press in fully
- 2. Toggle the locking lever to the left position.
- 3. Position the probe properly to avoid it being treaded on or becoming wrapped around other devices. DO NOT allow the probe head to hang free.

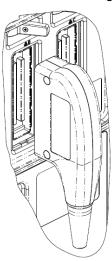


NOTE:

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.

3.4.2 Disconnecting a probe

- 1. Turn the locking lever to the right position to unlock the connector.
- 2. Pull the probe connector straight out as shown in the figure below.



3.5 Connecting the Footswitch

 \triangle WARNING:

DO NOT connect more than one wireless footswitch receiver to the ultrasound system at the same time; otherwise, malfunction may result.

The system supports USB port-type footswitches and wireless type footswitches.

The function of the foot switch can be preset. See chapter "12.1.6 Footswitch" for details.

3.6 Connecting USB Devices

≜WARNING:

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

- When connecting a USB memory device to the ultrasound system via a USB port, a sound is
 - heard if it is connected successfully and the symbol appears in the top-right corner of the screen.
- To remove the USB device: tap to open the [Remove USB Device] screen. Select the device to be removed and tap [OK]. A sound is heard when removing the USB memory device.
- The system supports option of external DVD R/W drive. The DVD R/W drive is connected to the ultrasound system via USB port.

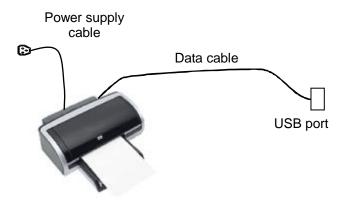
NOTE: If the USB flash drive cannot be recognized by the system, please try disconnecting and then connecting again several times, or try another USB flash drive. If the problem still exists, please contact Mindray service engineer.

3.7 Installing a Graph/Text Printer

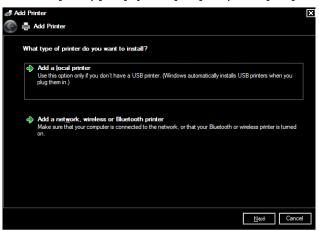
Connecting a local printer

NOTE: Printers listed in "2.4.4 Peripherals Supported" chapter have drivers installed already.

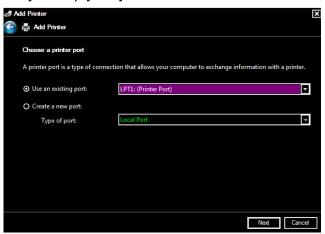
As shown in the figure below, a graph / text printer has a power cord and data cable. The power cord should be directly plugged into a well-grounded outlet.



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

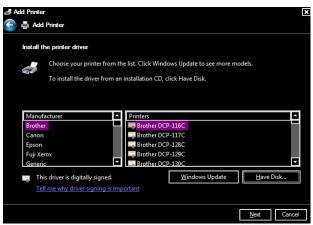


5. Select [Add a local printer] and tap [Next] to enter the screen used for browsing driver.



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

6. Tap [Have Disk] to find the driver path (the installation type should be WIN7 64), and then tap [Next] to install the driver.



- 7. Complete the operation according to the tips on the screen. Tap [Finish] to end the installation.
 - Add network printer
- 1. As the system is connected into a LAN, open [Setup] -> [System] -> [Peripheral] screen.
- 2. Tap [Add Printer], select [Add a network, wireless or Bluetooth printer].
- 3. The system starts to search all available printers within the network. Select the target printer and tap [Next], the system tries to connect to this printer.
- 4. When the connection is successful, the system prompts the dialogue box, tap [Next] according to the screen tips and then tap [Finish]. The printer is installed successfully.

Tips: the system has combined many types/brands of printer drivers, if targeted printer driver is not included in the system, you may need to install the driver for the network printer. Please use the optical disk or USB flash drive with the driver to install according to the system prompts.

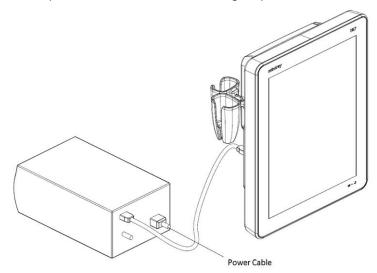
NOTE: When you install the printer's driver, you must specify the specific path for installation. A vague path may result in longer searching times.

The network printer functions depending on the configured network environment in the hospital, please consult the network configuration manager in case of failure.

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

3.8 Installing a Video Printer

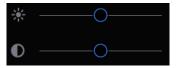
The system support video printers, consist of the B/W digital printers and color digital printers.



- 1. Position the printer in the proper place.
- 2. Plug the printer power cord into an appropriate outlet.
- 3. Use a USB cable to connect between the system's USB port and the printer's USB port.
- 4. Load a paper roll, and turn on the system and printer.
- 5. See section "3.7 Installing a Graph/Text Printer" for the driver installation procedure (printer drivers listed in chapter "2.4.4 Peripherals Supported" are installed already).

3.9 Brightness and Contrast Adjustment

1. Tap in the top-right corner of the screen to open the system tool bar.



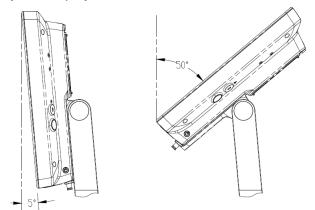
2. Drag the slider to change the brightness/contrast on the brightness control or contrast control.

NOTE: Avoid operating in direct sunlight or the touch screen could be obscured.

3.10 Display Position Adjustment

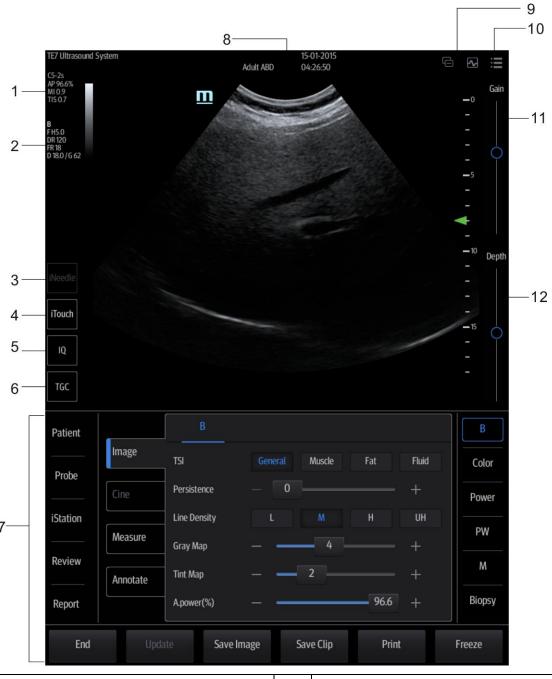
Gently hold the bottom edge of the display when adjusting its position.

When positioned vertically, the display can be tilted for 50° backward and 20° forward.



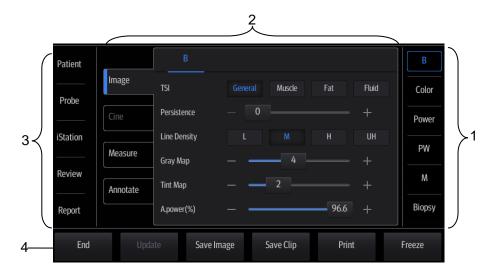
3.11 Basic Screen & Operation

3.11.1 Screen Display



1.	Probe model, acoustic output value and MITI index	2.	Parameter area
3.	iNeedle	4.	iTouch
5.	Frequency adjustment	6.	TGC control
7.	Operating panel	8.	Patient Information area
9.	System status icon	10.	System tool bar
11.	Gain control	12.	Depth control

3.11.2 Operating panel



Operating panel located under the image area; consists of imaging mode buttons, menu area and exam related buttons.

1. Imaging mode area

Tap imaging buttons to start imaging.

- 2. Menu area
 - Imaging parameter menu: swipe the menu downwards/upwards to see parameter controls;
 - Cine review menu (under frozen or cine review status);
 - Measurement menu;
 - Annotation and body mark menu.
- 3. Exam operating area

Tap each button to enter the screen.

- Patient information:
- Exam mode and probe switching;
- iStation;
- Image review;
- Report review.
- 4. Other buttons

You can perform operations using those buttons, including end exam, switching modes, save an image/cine, print single frame image or freeze/unfreeze image, etc.

4 Exam Preparation

A patient exam can be started under the following situations:

- New patient information: to start a new patient exam, patient information must first be entered.
- New exam: to start a new exam for patient who is already registered, the recorded information can be obtained through either iStation or Worklist. See chapter "4.1.2 Retrieve Patient Information" for details.
- Activate exam: to select an exam that has been completed within 24 hours, continue the exam with imported patient information and exam data.

General procedure for an exam:

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

Tips: The system supports image scanning and measurement without patient information.

4.1 Patient Information

To start a new patient exam, it is best to enter 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.

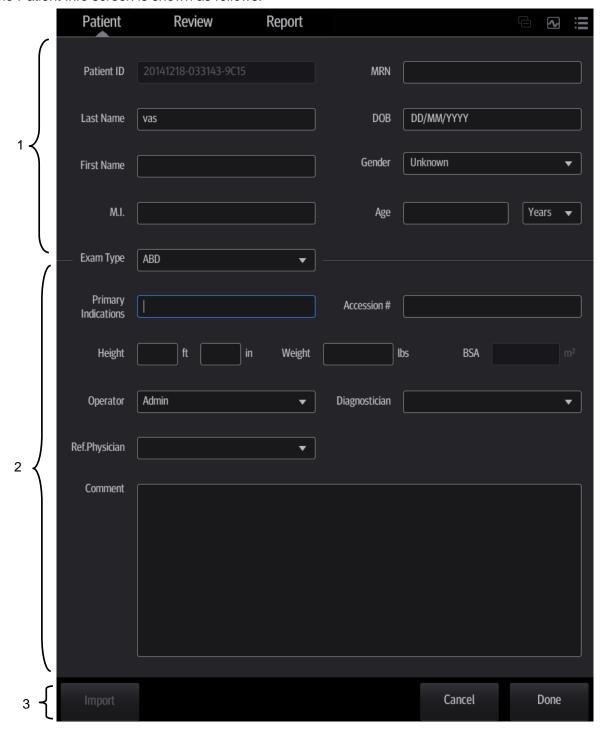


Before examining a new patient, tap [End] in the bottom-left corner of the operating panel to end the exam of the previous patient. Update the patient ID and information to avoid mixing data between patients.

- To enter the Patient Info screen
 - Tap [Patient] on the left side of the operating panel.
- To exit the Patient Info screen
 - Tap [Done] on the Patient Info screen.
 - Tap [Cancel] on the Patient Info screen to exit the screen without saving any of the entered patient data.

4.1.1 New Patient Information

The Patient Info screen is shown as follows:



Tap to select the desired field. The field box is highlighted and a flashing cursor appears. Information can be entered or selected from the options.

Information includes:

1. General information

Patient ID

The Patient ID is generated automatically by the system after starting a new patient, and can be modified manually.

The ID can also be obtained using the bar code reader.

Tip: you can change patient ID when there is no other exams of the current patient in the system (including the recycle bin) and the exam is the current active exam.

- Name
- Gender
- DOB (date of birth):
- Age

Auto-generated age: once the DOB is obtained, the system displays an auto-generated age in the field box. The unit can be "Years", "Months" or "Days." If the age is less than one year, the system will automatically calculate the age in months or days.

You can also enter the age manually.

2. Exam information

Exam application type

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

Select the exam type drop-down list to enter exam-specific information.

■ General information:

Primary indications:To enter the primary indications (reason for performing the exam.)Accession #To enter the exam number used in DICOM.MRN:To enter the secondary indications.Diagnostician:Person responsible for the exam.Operator:Person responsible for image collection and scanning.Ref. Physician:Person who requires the operator to carry out the ultrasound.Comment:To enter the exam-specific explanation or remarks.

■ Exam-specific information:

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

Exam Type	Information	Description		
	Calculation	Calculate the gestation age (GA) and estimated delivery date (EDD) based on the last menstrual period (LMP), date of conception (DOC), in vitro fertilization (IVF), basic body temperature (BBT) and previous exam date (PRV). Select LMP, DOC, IVF, PRV, BBT, or EDD from the drop-down list, or calculate the GA and LMP according to the EDD and entered date. • LMP: after you enter the LMP, the system will calculate the GA and EDD. • DOC: after you enter the DOC, the system will calculate		
OB (Obstetrics)	index	 the GA and EDD. IVF: after you enter IVF, the system will calculate the GA and EDD. PRV: enter the date and GA of the last exam, the system 		
		 will calculate a new GA and EDD. BBT: enter the BBT, the system will calculate the GA and EDD. 		
		 EDD: after you enter the EDD, the system will calculate and display the GA and LMP. 		
	Gravida	Times of pregnancy.		
	Ectopic	Times of abnormal pregnancy, e.g., extrauterine pregnancy		
	Para	Times of delivery.		
	Aborta	Times of abortion.		
	LMP	Last menstrual period.		
0.01	Gravida	Times of pregnancy.		
GYN (Gynecology)	Para	Times of delivery.		
() (),	Ectopic	Times of abnormal pregnancy, e.g., extrauterine pregnancy.		
	Aborta	Times of abortion.		
CARD	BSA (body surface area)	After the height and weight are entered, the system will automatically calculate the BSA based on the formula which is set via [Setup] -> [System] -> [General].		
CARD (Cardiology)	BP	Blood pressure.		
	HR	/		
	RA Press.	Right Atrium Pressure.		
VAS	BP(L) (blood pressure)	Input left blood pressure.		
(Vascular)	BP(R) (blood pressure)	Input right blood pressure.		
URO	Serum PSA	/		
(Urology)	PPSA coefficient:	/		
SMP (Small Parts) None /		/		
Breast	None	/		

3. Functional controls:

- [Import]: imports patient data from iStation or DICOM Worklist. See chapter "4.1.2 Retrieve Patient Information" for details.
- [Done]: saves the patient data entered and exits the screen.
- [Cancel]: cancels the patient data entered and exits the screen.

4.1.2 Retrieve Patient Information

You can import patient information from iStation or DICOM Worklist for anonymous patients.

4.1.2.1 Retrieve from iStation

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

- 1. In Patient screen, select [Import] -> [iStation] in the bottom-left corner to enter the screen.
- 2. Select an exam: you can either swipe the screen downwards to search or using the keyword filter.
- 3. The system enters the Patient screen, and the selected exam information is imported already.
- 4. Change the patient information if necessary and then tap [Done] to start exam.

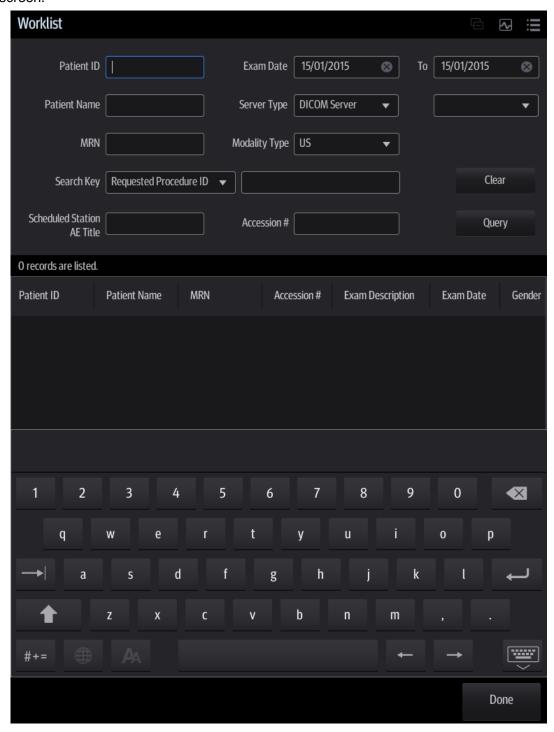
4.1.2.2 Retrieve from Worklist

Worklist is an option. To use Worklist function, you have to configure DICOM Basic and DICOM Worklist options.

When the DICOM basic package is configured and the Worklist server has been set, tap [Worklist] in the Patient Info screen to query or import the patient data. (For details about the Worklist server setting, see chapter "11.1.3.3 DICOM Worklist Preset" chapter.)

Worklist can retrieve patient data of two kinds of protocols: DICOM and HL7.

1. In Patient screen, select [Import] -> [Worklist] in the bottom-left corner to enter the import screen.



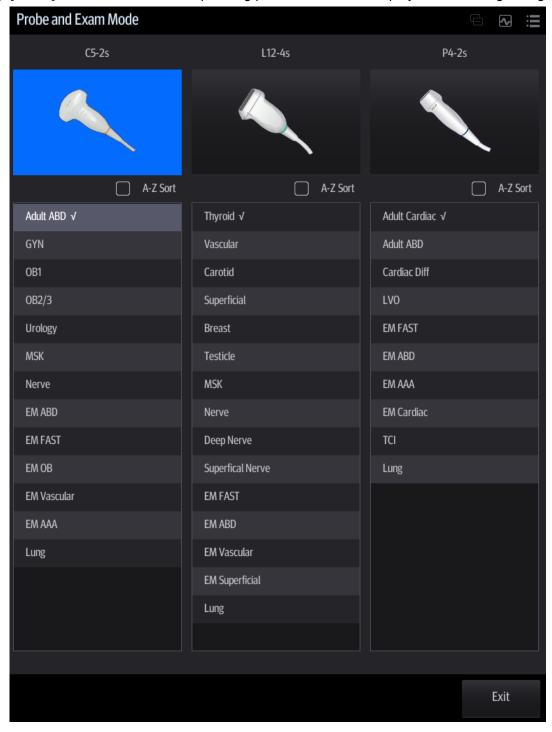
- 2. Select the data source: select the server type (DICOM or HL7), choose a Worklist server in the "Worklist Server" drop-down list, and all the patient exam records are listed.
- 3. Enter the search condition:
 - Set query criteria from Patient ID, Patient Name, MRN, Scheduled Station AE Title, Worklist Server, Modality Type or Exam Date. Or select the search key, enter the keywords, then tap [Query] to search.
 - To reset the criteria, tap [Clear].
- 4. Select the desired patient record in the displayed patient list.
- 5. Select the desired patient and tap [Done]. The patient information is imported into the system and then an exam is started.

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 general measurement data will be lost, but application measurement data will be stored in the reports.

- Selecting exam mode
- 1. Tap [Probe] on the left side of the operating panel. The screen displays the following dialog box:



2. Tap to select the probe model and exam mode. The system exits the dialog box and enters the selected exam mode and probe.

- Tap [Exit] to cancel the selection and exit the screen.
- Tap and hold any exam mode until it floats, and then drag to change the exam mode list sequence.
- Tap [A-Z Sort] to sort exam modes by alphabetical order for each probe.

4.3 Select the Imaging Mode

Enter the imaging mode by tapping imaging buttons at the right part of the operating panel. Swipe the area to see the hidden imaging modes.

For detailed operations in each imaging mode, see chapter "5 Image Optimization."

4.4 End an Exam

Be sure to avoid mixing data between patients.

Before examining a new patient, tap [End] in the bottom-left corner of the operating panel to end the exam of the previous patient.

4.5 Activate an Exam

On the iStation screen, select an exam record which was completed within 24 hours and select [Options] -> [Activate Exam].

Tips:

- The system can automatically load the patient information and exam data to continue the exam.
- For an activated exam, you can modify the patient ID if there are no other recorded exams of this patient (including the recycle bin) in the system.

⚠WARNING:

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

Tissue Harmonic Imaging does not use contrast agents.

5.1 Imaging Mode

5.1.1 Switching Between Imaging Modes

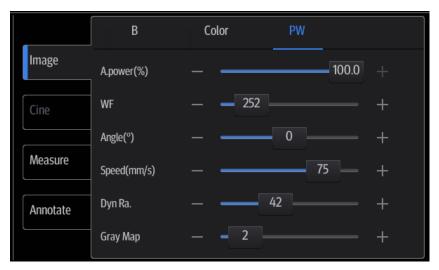


On the operating panel, tap imaging mode buttons on the right to switch the mode.

Current imaging mode is indicated by highlighting the button in blue. For instance, the above status shows that the system is under B+Color+PW mode (triplex is turned on).

5.1.2 Image Adjustment

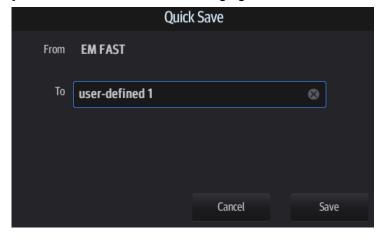
- 1. Tap [Image] on the operating panel to open the image parameter control menu under different imaging modes.
- 2. Swipe the menu downwards/upwards to check and change parameter controls.



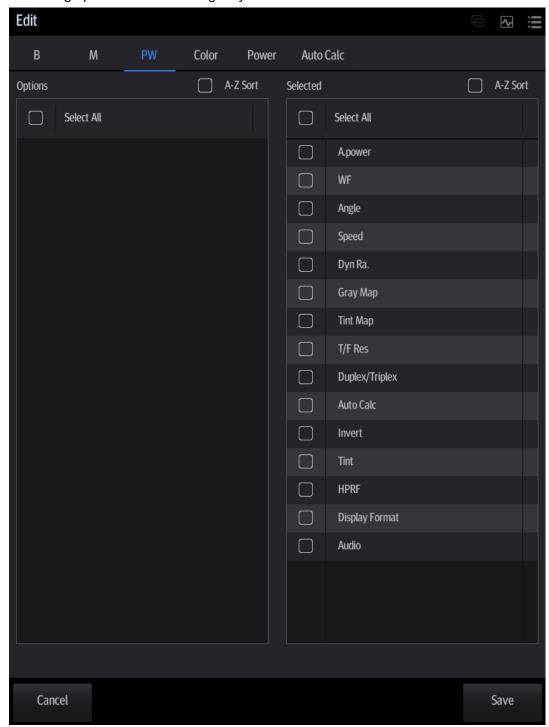
See the following imaging chapters for details.

5.1.3 Quickly Saving Image Settings

- Create a new exam mode using current image settings (user-defined exam mode):
- 1. Tap [Quick Save] in the image menu to bring out the Quick Save dialogue box.
- 2. Enter the name in the box after "To" to assign a name for a user-defined exam mode.
- 3. Tap [Save] to save the current image parameters for the user-defined exam mode. Tip: the [Quick Save] control is available under all imaging modes.



Check image parameter and change layout:



- 1. Tap [Edit] to enter the screen for checking the current image menu display for the current exam mode of the particular probe.
- 2. Tap and hold any parameter until it floats, then you can:
 - Drag upwards/downwards to change its position on the image menu;
 - Drag leftwards/rightwards to change its display on the image menu: drag it to the left "Options" list to delete its display or drag it to the right "Selected" list to display the parameter.
- 3. Tap [Save] to save the settings or tap [Cancel] to cancel changes you made.

Tip: the [Quick Save] and [Edit] controls are available under all imaging modes.

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. Tap [B] on the right side of the operating panel to enter B mode.
- 3. Tap [Image] to open the image menu. Adjust the parameters to optimize the image.
- 4. Perform other operations (e.g., measurement and calculation) if necessary.

Tip: tap [B] to return to B mode at any time (except LVO mode).

5.2.2 B Mode Parameters

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

Parameter	F	D	G	FR	DR
Meaning	Frequency	Depth	Gain	Frame Rate	Dynamic Range

5.2.3 B Mode Image Optimization

Frequency (Image Quality)

Description

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

Select the different frequency values through

at the left part of the image

The adjusting range of the harmonic 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).

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

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.

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 top-left corner of the screen.

Operations Drag the [Gain] control on the right part of the image area to adjust the gain.

Effects Increasing the gain will brighten the image and you will 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 top-left corner of the screen.

Operations Drag the [Depth] control on the right part of the image area to adjust the depth.

The adjustable depth values vary depending on the probe types.

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

tissue in shallower locations.

TGC

Description

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

Tap in the bottom-left corner of the image area to open the TGC adjusting dialogue box.

There are 6-segment TGC sliders corresponding to the areas of the image.

Operations

To increase the gain compensation in an area of interest, drag the TGC control to the right.

To decrease the gain compensation in the corresponding area of interest, drag the control to the left.

Double-click any area on the dialogue box, all 6 TGC controls will return to middle

About 1.5 seconds after the adjustment is complete, the TGC curve disappears.

Effects Adjust the signal gain for a particular image area to achieve a balanced image.

Acoustic Power

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

value of which is displayed in the top-left part of the screen.

Operations Adjust through [A.Power(%)] on the menu.

The adjusting range is 3.2-100.0.

Tap [-] or [+] to change the value slightly or drag the control directly.

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 situations and follow the ALARA

Principle.

Focus

Description Refers to adjusting the focus of the ultrasonic beams, using the symbols

which are displayed to the right of the image.

Operations Adjust the focus number through [Focus Number] on the menu.

Tap [-] or [+] to change the value slightly or drag the control directly.

Drag on the right part of the image area to change the focus position.

In B mode, the available focus number can be switched between 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.

Image Adjustment

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

sampling position.

FOV (Field of View)

Adjust through [FOV Size (%)] on the menu.

Tap [-] or [+] to change the value slightly or drag the control directly.

You can get a much larger field of view when selecting a larger FOV.

The frame rate decreases when using a larger FOV.

B Steer Steer the probe by tapping buttons on the bottom of the image area.



ExFOV (Extended FOV)

Adjust through [ExFOV] on the menu. Off represents no ExFOV effect. 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 range is available only for convex and phased probes.

The ExFOV function is available only for convex and phased probes. When ExFOV function is turned on, [FOV Size (%)] cannot be changed.

The B Steer function is available only for linear probes.

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

Description The function provides better observation for image display.

Rotation Rotate the image using the [Rotation] control.

Images can be rotated by 0°, 90°, 180° and 270°.

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

Invert the image using the [L/R Flip]/[U/D Flip] control: tap [Up]/ [Down]/ [Left]/ [Right] to invert the image at different directions

Flip) [Right] to invert the image at different directions.

Effects You can identify the image orientation using the "m" mark on the screen. By

default, the "m" mark is located in the top-left corner of the image.

iBeam (Spatial Compound Imaging)

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

to achieve image optimization.

Operations Adjust through [iBeam] on the menu.

The system provides different levels of iBeam effect. 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 The adjustable iBeam levels vary depending on the probe types.

iBeam is valid for linear and convex probes, and it is not available when the

ExFOV function is turned on.

Gray Map

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

Operations Select maps by using [Gray Map] control.

The system provides 8 different gray effect maps.

Tint Map

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

gray distinction.

Operations Select maps or turn on/off the function by using [Tint Map] control.

The system provides 8 different color effect maps.

iTouch (Auto Image Optimization)

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

image effect.

Operations

Tap

on the left part of the image area to start iTouch.

Long press I

Adjust iTouch gain value through [iTouch] control on the image menu.

H Scale

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

iTouch

to exit.

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

Operations Select [H Scale] control to display or hide the scale.

Line Density

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

Operations Adjust through [Line Density] on the menu.

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. The real-time value displays in the image parameter area in

the top-left corner of the screen.

Operations Adjust through [Dyn Ra.] on the menu.

Tap [-] or [+] to change the value slightly or drag the control directly.

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

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 [iClear] on the menu.

Tap [-] or [+] to change the level slightly or drag the control directly.

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 increased noise.

Persistence

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

optimize the image and remove noise.

Operations Adjust through [Persistence] on the menu.

Tap [-] or [+] to change the level slightly or drag the control directly.

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 clearer.

Impacts Increasing Persistence may lead to missing signals.

TSI (Tissue Specific Imaging)

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

according to tissue characteristics.

Operations Select different TSI modes using the [TSI] control.

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

fluid and fat.

Echo Boost

Description This function can improve contrast and decrease noise, so that a much clearer

boundary can be seen.

Operation Set [Echo Boost] to be "On" to turn the function on.

Impacts This function is only available using the phased probe in cardiac exam mode (probe

P7-3Ts does not support this function)

Patient Temperature

Description If the current active probe is P7-3Ts, the parameter will display under the B mode

menu. You can enter the patient temperature by this function.

Operation Enter the temperature by tapping [Patient Temperature].

≜WARNING:

If the patient temperature is above 37° C (98.6° F) and the [Patient Temperature] setting is below the actual reading, the system could overestimate the temperature of TEE transducer's distal tip. This could trigger the Auto-Cool feature. If the patient temperature reaches or is near 37° C (98.6° F) and the [Patient Temperature] setting is above the actual reading, the system could underestimate the temperature of the TEE transducer's distal tip. The patient is exposed to excessive temperatures.

Middle Line

Description "Middle Line" helps to locate the focus point of shock wave during the treatment.

By watching the treatment procedure in real-time and adjusting the intension and frequency of the shock wave, the harm to the patients can be reduced to the least.

Operations Click [Middle Line] on the image menu to hide or display the line.

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 position the area of interest in the center of the B mode image.
- 2. Tap [M] on the right side of the operating panel to enter M sampling line status, and drag the sampling line to the desired position.
- 3. Tap [M] again or tap [Update] (at the bottom-left part of the operating panel) to enter M mode. You can then observe the tissue motion along with the 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 top-left corner of the screen displays the real-time parameter values as follows:

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

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

Operations Drag the [Gain] control on the right part of the image area to adjust the gain.

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

However, noise may also be increased.

Display Format

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

Operations Select different layout through [Display Format].

There are 4 formats available for image display: V2:3, V3:2, V3:1, Full.

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

analysis through comparison.

Speed

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

time speed value is displayed in the image parameter area in the top-left corner of

the screen.

Operations Adjust through [Speed (mm/s)] on the menu.

There are 6 levels of scan speed available.

Effects Changing speed 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 Select maps or turn on/off the function by using [Tint Map] control.

The system provides 8 different color effect maps.

Gray Map

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

Operations Select maps by using [Gray Map] control.

The system provides 8 different gray effect maps.

Edge Enhance

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

boundary for optimization.

Operations Adjust through [Edge Enhance] on the menu.

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

stronger the effect. 0 represents no edge enhance effect.

Impacts Larger edge enhance may lead to increased noise.

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

top-left corner of the screen.

Operations Adjust through [Dyn Ra.] on the menu.

Tap [-] or [+] to change the value slightly or drag the control directly.

The adjusting range is 30-180, in increments of 5.

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

image details clearer.

Operations Adjust through [M Soften] on the menu.

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

stronger the effect.

5.4 Color Mode Image Optimization

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

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

5.4.1 Basic Procedures for Color Mode Imaging

- 1. Select a high-quality image during B mode scanning, and adjust to position the area of interest in the center of the B mode image.
- 2. Tap [Color] on the right side of the operating panel to enter Color mode.
- 3. Change the position and size of the Region of Interest (ROI).
- 4. Adjust the image parameters during scanning to obtain optimized images.
- 5. 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 top-left corner of the screen displays the real-time parameter values as follows:

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

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

5.4.3 Color Mode Image Optimization

Color Gain

Description Refers to the overall sensitivity to flow signals. 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 top-left corner of the screen.

Operations Drag the [Gain] control on the right part of the image area to adjust the gain.

Effects Increasing the gain will increase the flow signal presented and noise. The signals

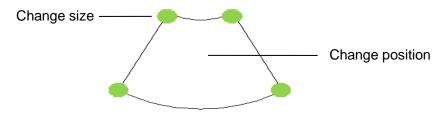
may be missing when the gain is adjusted too low.

ROI Adjustment

Description This function adjusts the width and position of the ROI in Color mode.

Operations Tap the corner (green dot) of the ROI and drag to change the size.

Tap inside the ROI box and drag to change the position.



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

color sensitivity.

Frequency (Image Quality)

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

of which is displayed in the image parameter area in the top-left corner of the

screen.

Operations

Select the different frequency values through at the left part of the image

area.

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

preferred (1 en), general mode (Gen), and resolution preferred (ites).

Frequency values vary according to probe types. Select the frequency according to the needs of the detection depth and the current tissue characteristics.

B/C Align

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

ROI.

Operations Turn the function on or off using the [B/C Align] control.

Impacts The frame rate increases when the function is turned on.

Steer

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

immobility of the linear probe.

Operations Steer the probe by tapping buttons on the bottom of the image area.



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 only valid for linear probes.

Line Density

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

Operations Adjust through [Line Density] on the menu.

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.

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 Select different effects through [Packet Size].

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 the indication for low-velocity flow.

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

Flow State

Description This function is used for fast image optimization.

Operations Select different effects through [Flow State].

3 levels are provided: L, M, H.

Persistence

Description This function adjusts the temporal smoothing in Color mode to optimize the image.

Operations Select different effects through [Persistence].

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 [Smooth] on the menu.

The system provides 6 levels of smooth function: the bigger the value the stronger

the effect.

Scale

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

using the PRF in the system. The real-time PRF value is displayed in the image

parameter area in the top-left corner of the screen.

Operations Use [Scale] to adjust PRF values.

Tap [-] or [+] to change the value slightly or drag the control directly.

The adjusting range varies according to the frequency, probe and depth. Adjust

according to the actual situation.

Effects Provides a much clearer color flow image.

Use a low PRF to observe low-velocity flows, and a high PRF to observe high-

velocity flows.

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

encountered.

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

Baseline

Description Refers to the area where the velocity is zero in the scale. Adjust according to the

actual situation so as to get an optimum flow display.

Operations Adjust through [Baseline] on the menu.

A positive value means increase the signals above the baseline, and a negative

value means increase the signals below the baseline.

Invert

Description To set the display mode of the color flow. The color scale will be inverted when the

function is turned on.

Operations Turn the function on or off using the [Invert] control.

Select "Auto Invert" in [Setup] -> [System] -> [Image], so the color bar can automatically invert when the color flow is steered to a certain angle to accommodate the operator's desire to distinguish the flow direction.

Impacts Auto invert function is available only for linear probes.

Color Map

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

display effect of the color image.

Operations Select maps by using [Color Map] control.

The system provides 21 different maps for selection. The V group provides 11

ordinary maps and the VV group provides 10 2D 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 top-left corner of the screen.

Operations Adjust through [WF] on the menu.

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

actual situation.

Impacts Flow signals may be missing.

Priority

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

grayscale signal or color signal.

Operations Adjust through [Priority (%)] on the menu.

Tap [-] or [+] to change the level slightly or drag the control directly.

The adjusting range of the priority is 0-100% in increments of 1%.

The higher the value, color signals are first to be displayed. The lower the value,

grayscale signals are first to be displayed.

iTouch (Auto Image Optimization)

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

image effect.

Operations

Tap on the left part of the image area to get iTouch optimization.

For probe L12-4s under EM Vas, Vascular or Carotid exam mode, using iTouch

can also achieve ROI optimization and auto-tracking.

Smart tracking (ROI auto position/steer in Color/PW mode)

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

image effect. When Smart Tracking is turned on, the system optimizes ROI angle and position automatically to achieve an active tracking by reducing the impact of

patient respiratory movement.

Operation Turn on/off the function by [Smart Tracking] on the menu.

Under B+Color+PW mode, this feature also optimizes PW sampling line angle, SV

size and position.

Impacts Smart tracking is available only for L12-4s probe under EM Vas, VAS and Carotid

exam mode.

5.5 Power Mode Image Optimization

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

DirPower (Directional Power mode) provides additional information of the flow direction toward 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 position the area of interest in the center of the image.
- 2. Tap [Power] on the right side of the operating panel to enter Power mode.
- 3. Change the size and position of the ROI (the same as in Color mode).
- 4. Adjust the image parameters during B + Power mode scanning to obtain optimized images.
- 5. 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 top-left corner of the screen displays the real-time parameter values as follows:

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

■ In Power mode, the acoustic power is synchronous with that of B mode. Adjustment of the depth to the B mode image will lead to corresponding changes in Power mode image.

Parameters consistent with those in Color mode and B mode are not described. See the relevant Color mode and B mode sections, 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. 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 top-left

corner of the screen.

Operations Drag the [Gain] control on the right part of the image area to adjust the gain.

Effects Increasing the gain will increase the flow signal presented and noise. The signals

may be missing when the gain is adjusted too low.

Power Map

Description This feature indicates the display effect of the Power image.

Maps in the Power mode image are grouped into two categories: Power maps and

Directional Power maps.

Operations Select maps by using [Color Map] control.

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 about blood flow, which are highly sensitive

to the low-velocity flows.

The Directional Power maps provide information about flow direction.

Dynamic Range

Description This function adjusts the transformation of echo intensity into color signal.

Operations Adjust dynamic range through [Dyn Ra.].

Tap [-] or [+] to change the value slightly or drag the control directly.

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

Effects Increasing the dynamic range leads to higher sensitivity to low-power signals, thus

enhancing 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 spectrum display. The horizontal axis represents time, while the vertical axis represents Doppler frequency shift.

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

CW imaging is an option.

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 position the area of interest in the center of the image.
- 2. Tap [PW]/[CW] on the right side of the operating panel to enter PW/CW sampling line adjustment status.

The sampling status will be displayed in the image parameter area in the top-left corner of the screen as follows:

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

- 3. Set the position of the sample line by dragging the sampling line; drag the SV gate to place the SV on the target.
- 4. Adjust the angle and SV size according to the actual situation: drag the PW angle line to change the angle, pinch on the image area to adjust SV size.
- 5. Tap [PW]/[CW] again or tap [Update] (at the bottom-left part of the operating panel) to enter PW/CW mode and perform the examination. You can also adjust the SV size, angle and depth in real-time scanning.
- 6. Adjust the image parameters during PW/CW mode scanning to obtain optimized images.
- 7. Perform other operations (e.g., measurement and calculation) if necessary.

Tap [Update] to switch between B (B+Color) and PW image.

5.6.2 PW/CW Mode Image Parameters

In PW/CW mode scanning, the image parameter area in the top-left 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	r	SV P	osition	Angle

- When you adjust the depth of the B mode image, related changes will occur in the PW/CW mode image as well.
- Most of the parameters are the same for the PW mode and CW modes, so parameters of 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 the spectrum map. The real-time

gain value is displayed in the image parameter area in the top-left corner of the

screen.

Operations Drag the [Gain] control on the right part of the image area to adjust the gain.

Effects Increasing the gain will brighten the image and you will 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 top-left corner of

the screen.

SV size Adjust SV size by finger gesture. Use two fingers to adjust the SV size by pinching

movement on the image area.

The adjusting range is 0.5-20 mm.

SVD Tap and drag the SV gate to change depth.

Effects The smaller the SV size, the more accurate the result. More details are obtained

when selecting a large SV size.

CW Focus Position

Operation

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

image parameter area in the top-left corner of the screen.

Operation Tap and drag the SV to select the focus depth.

Frequency (Image Quality)

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

which is displayed in the image parameter area in the top-left corner of the screen.

Calact the adifferent francisco according the

Select the different frequency values through at the left part of the image

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

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

Select the frequency according to the detection depth and current tissue features.

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

the force of penetration.

Scale

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

the PRF in the system.

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

corner of the screen.

Operations Use buttons on the right part of the image area to adjust PRF values.

Scale

Effects Provides a much clearer color flow image.

Use a low PRF to observe low-velocity flows, and a high PRF to observe high-

velocity flows.

Impacts Aliasing may occur if a 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

Tap on the left part of the image area to get iTouch optimization.

For L12-4s probe under EM Vas, VAS and carotid exam modes, you can use

iTouch to optimize PW sampling line automatically.

Auto-Calculation

Description This function is used to trace the spectrum and calculate the PW/CW mode image

parameters. The results are displayed in the results window.

Tap [Auto Calc] to turn the auto calculation function on or off.

After auto calculation function is turned on, select "Auto Calc" tab to enter the auto

calculation menu.

Auto Calculation Parameter Select parameters in the dialog box prompted by tapping [Auto Calc Param.] on

the Auto Calc menu.

Auto
Calculation
Cycle

To set the heart cycle number for auto-calculation.

Adjust through [Auto Calc Cycle] on the menu.

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

calculation, V Max and V Mean display.

Adjust through [Trace Area] on the menu.

The available selections of trace area are: Above, Below, All.

Trace To set the smooth level when tracing.

Smooth Adjust through [Trace Smooth] on the menu.

There are 4 levels of smooth effect provided, the bigger the value, the higher the

smooth processing.

Trace This function is used to set the sensitivity of tracing in the spectrum.

Sensitivity Adjust through [Trace Sensitivity] on the menu.

There are 5 levels of sensitivity adjustment, the bigger the value the higher the

sensitivity.

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

latest cardiac cycle.

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

selected area.

Invert

Description This function is used to set how the spectrum is displayed.

Operations Turn the function on or off using the [Invert] control.

Select "Auto Invert" in the [Setup] -> [System] -> [Image], so the spectrum can

automatically invert when the color flow is steered to a certain angle to accommodate the operator's desire to distinguish the flow direction.

Speed

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

Operations Adjust through [Speed (mm/s)] on the menu.

There are 6 levels of scan speed available.

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 create a balance between time resolution and spatial

resolution.

Operations Adjust through [T/F Res.] on the menu.

There are 4 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 top-left corner of the screen.

Operations Adjust through [WF] on the menu.

7 levels of wall filter function are 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 Select maps or turn on/off the function by using [Tint Map] control.

There are 8 color effect maps available.

Gray Map

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

Operations Select maps by using [Gray Map] control.

There are 10 gray effect maps available.

Display Format

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

Operations Select different layout through [Display Format].

There are 4 formats for displaying the images: V2:3, V3:2, V3:1, Full.

Duplex/Triplex

Description This function is used to set whether a B image (B + Color image) and PW image

are displayed synchronously.

Operations Select [Duplex]/[Triplex] to turn the synchronization on or off.

HPRF

Description HPRF mode is used when detected velocities exceed the processing capabilities

of the currently selected PW Doppler scale, or when the selected anatomical site is

too deep for the selected PW Doppler scale.

Operations Turn the function on or off using the [HPRF] control.

Effects HPRF enhances the range for detecting high-velocity flow.

Baseline

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

Operations Tap and drag the green baseline on the spectrum to change the position.

Effects Changes the flow-velocity range 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 left part of the spectrum

map.

Operations Adjust through [Angle] on the menu.

Tap [-] or [+] to change the value slightly or drag the control directly.

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

Quick Angle

Description To adjust the angle faster, in increments of 60°. The real-time value is displayed on

the left part of the spectrum map.

Operations Tap the three buttons above [Quick Angle] on the bottom of the image area.

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

Dynamic Range

Description The dynamic range conveys the information which is being transformed from echo

intensity to grayscale.

Operations Adjust dynamic range through [Dyn Ra.].

Tap [-] or [+] to change the value slightly or drag the control directly.

The adjusting range is 24-72.

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

contrast with more noise.

PW Volume

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

Operations Adjust through [Volume] on the menu.

Tap [-] or [+] to change the value slightly or drag the control directly.

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

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

PW Steer

Description This function is used to adjust the angles for the sampling line.

Operations Steer the probe by tapping buttons on the bottom of the image area.

20° Steering

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

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

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

5.7 Left Ventricular Opacification (LVO)

Left ventricular opacification is used in conjunction with ultrasound contrast agents to enhance the imaging of blood flow and microcirculation. Injected contrast agents re-emit incident acoustic energy at a harmonic frequency which is much more efficient than the surrounding tissue. Blood containing the contrast agent stands out brightly against a dark background of normal tissue.

Only P4-2s supports LVO.

LVO feature is an option.

⚠CAUTION:

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

Read contrast agent accompanied manual carefully before using contrast function.

NOTE:

Be sure to finish setting the parameters before injecting the agent into the patient to avoid affecting the image consistency. This is because the agent's acting time is limited.

The contrast agent used must comply with the relevant local regulations.

5.7.1 Basic Procedures for LVO

To perform successful contrast imaging, start with an optimized B image and have the target region in mind. To perform LVO imaging:

- 1. Select the P4-2s probe and LVO exam mode; tap [Image] to open the image menu.
- 2. Fix the probe.
- 3. Adjust the acoustic power experientially to obtain a good image.
 - Tap [Dual Live] to turn it to "On" and activate the dual live function. Observe the tissue image to find the target view.
- 4. Inject the contrast agent, and set [Timer 1] to "ON" to start the contrast timing. When the timer begins to work, the time will be displayed on the screen.
- 5. Observe the image. Use the [Pro Capture] and [Retro Capture] on the menu to save the images. Tap those controls again or tap [Freeze] to end the live capture.
 - Perform several live captures if there are more than one sections of interest.
- 6. At the end of contrast imaging, set [Timer 1] to "OFF" to exit the timing function. Perform procedures 3-5 if necessary.
 - For every single contrast imaging procedure, use [Timer 2] for timing.
 - If necessary, activate the destruction function by selecting [Destruct] to "ON" and destruct the micro-bubbles left by the last contrast imaging, or to observe the reinfusion effect in a continuous agent injecting process.

5.7.2 LVO Parameters

Parameter Area Display

When entering LVO imaging mode, the screen displays the contrast image. If the [Dual Live] is "ON", both the contrast image (marked with "a") and tissue image (marked with "a") are displayed (the two window positions can be changed). Parameter area displays as follows:

Туре	Parameter	Meaning	
	FC H	Contrast frequency	
	D	Depth	
Contrast	G	Gain	
	FR	Frame rate	
	DR	Dynamic Range	
Tissue	G	Gain	
HSSUE	DR	Dynamic Range	

Image Optimization

The parameters in Contrast mode are similar to those in B mode. See B mode imaging parameters for details. Special LVO imaging parameters are introduced below.

Timer

The two timers are used to record the total time of the contrast imaging and the single time of one contrast exam.

After the image is frozen, Timer 1 is still running, and after unfreezing, the corresponding time can be seen.

Timer 2 stops timing when a LVO exam is frozen, and after unfreezing, Timer 2 is off.

NOTE: The starting time displayed may be inconsistent with the actual one due to system error or some other human error. Check the agent-injecting time.

Set [Timer 1(2)] to "ON" to start timing from the moment you inject the contrast agent. The screen displays the times in the bottom-right corner.

- The time begins at 0.
- In live mode, the elapsed time is displayed. For example, 00:00:08 means the elapsed time is 8 seconds
- If the image is frozen during timing, the timer stops working and the elapsed time is displayed.
- Set [Timer 1] or [Timer 2] to "OFF" and the timer stops running.

Micro-bubble Destruction

Function: to destroy the micro-bubbles left by the previous contrast imaging, or observe the reinfusion effect in a continuous agent injecting process.

- Entering: tap [Destruct] to enable the micro-bubble destruction function.
- Parameters: set the parameters using the menu controls.
 - [DestructAP(dB)]: adjust the destruct acoustic power.
 - [Des.Time(ms)]: adjust the destruct time.

Dual Live

In live mode or freeze mode, set the item [Dual Live] to "ON" to enable the dual live function. Both the contrast image (marked with "I") and the tissue image (marked with "I") are displayed (the position can be changed).

Tips:

- In dual live mode, the screen displays the contrast image and tissue image
- In freeze mode, only one cine review progress bar displays as the contrast image and tissue image are reviewed synchronously.
- Image position

Use [CEUSPos: XX] to adjust the position of the contrast image.

When it is selected as "Left", the image displays at the left part of the image area on the screen.

Mix Map

This function combines the contrast image with the tissue image, so that the contrast regions of interest can be located.

Select options besides [Mix] to select different mixing modes: Contrast, C&T, and Tissue.

- When the dual live function is on, you can see the mixed effect on the contrast image.
- When the dual live function is off, you can see the mixed effect on the full-screen image.

iTouch

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

- Tap to turn the function on (the icon turns blue).
- Long press to exit the function.

Image Saving

Live capture

In live mode, you can save the images of interest by tapping [Pro Capture] and [Retro Capture].

Cine saving

In freeze mode, tap [Save Clip] at the bottom of the operating panel.

5.7.3 Measurement, Comments and Body Marks

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

Display & Cine Review

Splitting Display 6.1

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

- 1. Select [Dual] to be "on" from B image menu to enter dual-split mode.
- 2. Tap each window to switch the active window (marked with "m" icon.)
- 3. Tap [B] or select [Dual] to be "Off" to exit to single window.

6.2 Image Magnification

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

Use two fingers to pinch on the image area to zoom in/out the image.

Tips: for the following mode, you need to tap [Image] -> [B] to highlight B menu first.

- B+Color
- B+M

NOTE:

- B+PW/CW
- B+Color+PW/CW
- B+Power+PW/CW

iZoom (Full Screen View) 6.3

This feature magnifies the image area in full screen for a better observation.

To enter iZoom:

Swipe the screen from the top to the bottom.

■ To exit iZoom:

Swipe the screen from the bottom to the top.

6.4 Freeze/Unfreeze the Image.

Tap [Freeze] in the bottom-right corner of the operating panel to freeze a scanning image. In freeze mode, the probe stops transmitting acoustic power, and all images and parameters are frozen.

Tip: After freezing an image, the system may enter cine review, measure, comment adding, body mark mode or current mode, depending on what has been preset. (Setting path: [Setup] -> [System] -> [Image] -> "Freeze Config")

Tap [Unfreeze] in freeze mode to unfreeze the image, and the system continues image scanning.

6.4.1 Imaging Mode Switching When Frozen

Imaging mode switching in freeze mode follows these principles:

- In splitting display B mode, tap each image window to switch between the windows.
- 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 in B+Color+PW mode, the system supports imaging mode switching between B+Color+PW, B+Color, B+PW and B by tapping [Color] or [PW].

6.5 Cine Review

After tapping [Freeze], the system allows you to review and edit the images prior to the image being frozen. This function is called cine review. 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.

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



Cine Review images can be inadvertently combined in-between separate patient scans. The Cine Review memory must be cleared at the end of the current patient exam and before starting the next new patient exam by tapping [End] in the bottom-left corner of the operating panel.

Cine files stored in the system's hard drive should contain patient information, to avoid the selection of an incorrect image file and potential misdiagnosis.

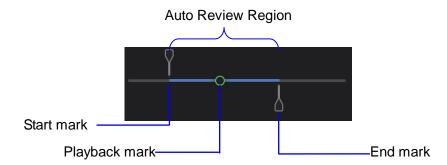
6.5.1 Entering/Exiting Cine Review

- To enter Cine Review:
 - Enter [Setup] -> [System] -> [Image] -> "Freeze Config" screen to set "Status after Freeze" to "Cine." The system enters manual cine review status once [Freeze] is tapped.
 - Open cine files in Review screen. The system enters automatic cine review status.
- To exit Cine Review:

Tap [Freeze] or [B] and the system will return to image scanning and exit cine review.

6.5.2 Cine Review

Under cine review status, cine review control bar will be displayed on the cine menu.



For B/B+Color/B+Power mode, bottom-left corner will indicate current frame and total frames.



For B/B+M/B+PW/B+CW mode, bottom-left corner will indicate time played and total time.



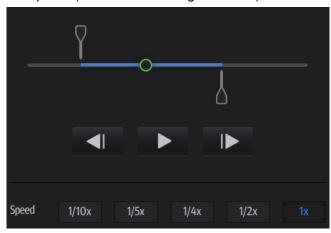
Manual Cine Review:

After entering cine review in 2D mode, drag playback mark to review the cine images on the screen one by one.

Drag the playback mark to the left to display the earlier stored images; drag the playback mark to the right to display the recently stored images.

Or, swipe the image area to the right to display the earlier stored images; swipe the image area to the left to display the recently stored images.

The cine progress control panel (as shown in the figure below):



Auto Review

- Reviewing all
 - a) In manual cine review status, tap to activate auto cine review.
 - b) Review speed: in auto cine review status, tap to select different speeds: 1/10x, 1/5x, 1/4x, 1/2x, 1x.
 - c) In auto play status, tap to stop auto play.
- Setting the Auto Review Region

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

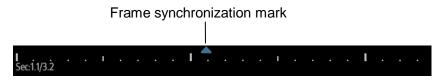
- a) Set first frame: drag to the frame as start point.
- b) Set end frame: drag to the frame as end point.
- c) Tap ____ to start play and select the speed.
- d) Tap to end auto play.

Tip: When the cine file is saved, only images within the auto review region are saved.

6.5.3 Linked Cine Review

Linked cine review reviews images captured at the same moment.

- B+M
- Duplex mode (B+PW/CW)
- Triplex mode



The frame mark on the time mark of the M/PW/CW image indicates the corresponding 2D image.

6.6 Cine Saving

Live capture

Live capture refers to saving the images or cines in image scanning status. After storing, the system continues with image scanning.

Live capture can be divided into two types: retrospective and prospective.

- Retrospective saving saves specified images which were captured before the current moment. Images stored in the cine memory are saved to the system's hard drive.
- Prospective saving saves specified images which are captured later than the current moment. Images are saved to both the cine memory and the system's hard drive.

The live capture time can be set.

To perform live capture:

- Tap [Pro Capture] or [Retro Capture] in LVO real-time mode.
- Tap [Save Clip] to pro/retro capture the images (setting path: [Setup] -> [System] -> [General]->"Live Capture"->[Save Clip])
- Frozen image storage

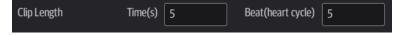
In frozen mode, tap [Save Cine].

6.7 Preset

6.7.1 Setting Cine Length

Select [Setup] -> [System] -> [General] to perform the following settings:

■ Cine saving storage (for [Save Clip] at the bottom of the operating panel)



- Live capture
 - Type: Retrospective, Prospective. (for [Retro Capture] and [Pro Capture] in LVO mode)
 - Cine length:



Tip: If the value is out of range, the system can change it to the acceptable effective value.

7 Measurement

You can perform measurements on zoomed images, cine reviewing images, real-time images or frozen images. For measurement details, see the [Advanced Volume].

MARNING:

Be sure to measure areas of interest from the most optimal image plane to avoid misdiagnosis arising from inaccurate measurement values.

To obtain accurate Doppler flow measurement values, make sure the transmitting beam is not perpendicular to the flow as this may lead to false readings and potential misdiagnosis.

Acaution:

If an image is unfrozen or the mode is changed during a measurement, the calipers and measurement data will be cleared from the screen. Measurement data will be stored in the report.

If the system is turned off or [End] is tapped during a measurement, unsaved data will be lost.

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 diagnoses.

7.1 Basic Operations

- To enter/exit measurement
 - Tap [Measure] -> [Basic] on the operating panel to enter basic measurement.
 - Tap [Measure] -> [Advanced] on the operating panel to enter advanced measurement.
- To exit: tap [Basic] or [Advanced] again.
- Measurement results window

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

7.2 General Measurements

There are measurements for B/B + Color/B + Power mode, M mode and Doppler (PW/CW) mode.

Measurement Tools	Function
Distance	Measures the distance between two points of interest.
Depth	Measures the distance between the probe surface and the probing point along the ultrasound beam.
Angle	Measures the angle between two intersecting planes.
Ellipse	Fix a closed ellipse region by two axes perpendicular to each other and calculate the area of the closed region.
Trace	Fix a closed region by trace manually and calculate the area of the closed region.
Volume	Measures the volume of a target.
Distance Ratio	Measures the lengths of any two lines and calculates the ratio.
Area Ratio	Measures the areas of any two regions and calculates the ratio.
Time	Measures the time interval between any two points.
Slope	Measures the distance and time between two points and calculates the slope.
HR	Measures the time of n (n≤8) cardiac cycles and calculates the heart rate in M mode images.
Velocity	Calculates the average velocity by measuring the distance and time between two points.
D Trace	On PW mode images, one or several Doppler waveforms are traced to obtain the speed and PG, etc.
D Trace (Car)	On PW mode images in cardiology, one or several Doppler waveforms are traced to obtain the speed and PG, etc.
PS/ED	Velocity and PG between two peaks on the spectrum are measured to calculate the RI (resistance index) and PS/ED (peak systolic/end diastolic).

7.3 Advanced Measurements

The categories of the advanced measurements are as follows:

- Abdomen measurements used for measuring abdominal organs (liver, gall bladder and kidney, etc.) and large abdominal vessels.
- OB measurements used for measuring fetal growth indices (including EFW) as well as GA and EDD calculations. The fetus can be evaluated through the fetal biophysical profile.
- Cardiac measurements used for left ventricle function measurements and measuring 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 the thyroid, breast, MSK, superficial.
- Urology measurements used for the prostate, renal, micturated and testicular volume.
- Vascular measurements used for carotid, cerebral, upper and lower extremities vessels, etc.
- EM measurements used for EM-related full functional measurements.
- Nerve measurements used for nerve measurements.

7.4 Measurement Accuracy

Table 1 Basic Dimension Measurements

Parameter	Range	Error
Distance	Full Screen	Within ±4%
Area (ellipse, circle)	Full Screen	Within ±7%
Trace Area	Full Screen	Within ±7%
Circ	Full Screen	Within ±10%
Angle	Full Screen	Within ±3%
Volume	Full Screen	Within ±12 %

Table 2 Basic Time Motion Measurements

Parameter	Range	Error	
Distance	Full Screen	Within ±4 %	
Time	Timeline Display	Within ±2%	
Heart Rate	Timeline Display	Within ±5%	
Velocity (PW mode)	10-200cm/s (for C11-3s, V11- 3Ws, L14-6Ns, L12-4s, C5-2s, 7LT4s, L14-6s, L7-3s, L16-4Hs) 10-300cm/s (for P4-2s, P7-3Ts)	When angle≤60°, ≤5%.	
Velocity (CW mode)	10-300cm/s (for P4-2s, P7-3Ts)	When angle≤60°, ≤5%. (not including pencil probe)	

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

Physiological Signal

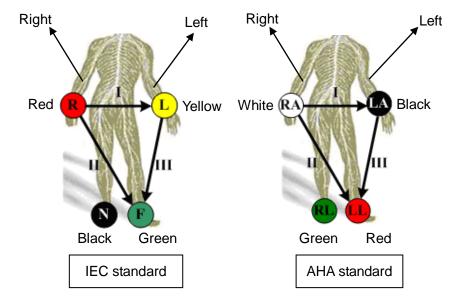
ECG function in the ultrasonic exam (mainly in cardiac exams) is used to display the physiological signal waves for observing the ultrasonic image synchronously and to locate the ultrasonic image by time according to the time phase signal provided by this function. The ECG function is an option.

- Do not use the physiological traces for diagnosis and monitoring.
- WARNING: 2. To avoid electric shock, the following checks shall be performed prior to an operation:
 - a) The ECG electrode cable shall not be cracked, frayed or show any signs of damage or strain.
 - b) The ECG electrode cable shall be correctly connected.
 - c) You should use the ECG leads and PCG transducer provided with the physiological module. Otherwise it may result in electric shock.
 - 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. Otherwise, it may cause electric shock to the patient.
 - 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.
 - Do not apply the ECG electrodes if the voltage exceeds 15 volts. This could produce an electric shock.
 - 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.
 - Conductive parts of electrodes and associated connectors for ECG should not contact other conductive parts including earth / grounding.
 - Frequent trampling or squeezing on the cables may result in cable break-down or fracture.
 - If an abnormality is detected in physio trace, check that the ECG leads are properly connected to the system.

8.1 ECG

8.1.1 ECG Operation Basic Procedures

1. Connect the ECG module to the serial port on the rear cover of the main unit. Place the ECG electrodes on the patient's body.



- 2. Press the <Physio> on the right of the screen to enter physio operation status.
- 3. Switch the imaging modes and display formats. Adjust the parameters to obtain an optimized image.
- 4. Parameter adjusting
 - In image menu, tap [ECG] in the menu to turn ON/OFF the ECG wave display. Adjust the [Speed], [ECG Gain], [Position] and [Invert]
- 5. Trigger:
 - Touch Trig Mode to open the triggering function and sect the trigger time.
- 6. Freeze the image and review the image and waves.
- 7. Exit ECG mode, and remove ECG electrodes from the patient.
- 8. Tap [Physio] to exit the ECG mode.

8.1.2 ECG Triggering

8.1.2.1 Overview

ECG triggering means that image scanning is activated at some time points of ECG signals, thus obtaining B images at these time points. Tin most cases, 5he triggered image are 2D-mode image. When ECG triggering occurs, a mark appears on the ECG waveform, indicating the time points when the B images are captured (corresponding to the delay time from R curve started). NOTE:

- The trigger mark is displayed in both freeze mode and live mode.
- Trigger function is unavailable if the ECG trace is disappeared. Trigger function is unavailable if the ECG trace is disappeared. Only the live 2D image can be triggered.

- No delay time or time interval shall less than the time required to scan a single image.
- If the delay time is longer than a heart cycle, then the heart cycle between the delay time
 is omitted, that is to say no trigger is occurred when R waveform is detected in the
 duration.

8.1.2.2 Triggering Mode

This system supports single trigger.

 Single Trigger: When an R waveform is detected, an image will be triggered after delay time T1. The value of T1 can be changed in triggering status.

The operational steps are as follows:

- 1. Select exam mode.
- 2. Tap [Trig Mode] to turn on the trigger function.
- 3. Set the delay time T1.

8.1.3 ECG Review

8.1.3.1 Review Principle

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

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

8.1.3.2 Linked Review of ECG Signal, M/D Images and 2D Images

If the real (triggered) physio signal, M/D images and 2D image are frozen at the same time, then they will be reviewed synchronously in the linked status.

8.2 Parameters description

The physio parameters are described as follows:

Parameter	Description
ECG Source	Select ECG source. Lead/External
Gain	Function: to set the amplitude of the trace.
Jaiii	Value: 0-30, in increments of 1.
Position(%)	Function: to set the vertical position of the both traces on the image display.
1 03111011(70)	Value: 0-100%, in increments of 5%.
0 1	Function: adjust the speed of the physio trace.
Speed	Range: 20-145 mm/s
Trig Mode	Turn on/off the triggering function.
Invert	Invert the ECG signal wave for observation.
T1	Function: to set the delay time T1 in Single trigger.

9 Annotations and Body Marks

9.1 Annotations

Annotations can be added to an ultrasound image to bring attention, notate or communicate information observed during the examination. You can add annotations to: zoomed images, cine review images, real-time images, frozen images. You can type annotations as characters, insert pre-defined annotations from the annotations library or insert arrow markers.

≜WARNING:

Ensure that the entered annotations (body marks) are correct. Incorrect annotations may lead to misdiagnosis!

9.1.1 Annotations Basic Procedures

To enter an annotation:

- 1. Tap [Annotate] on the operating panel to enter annotation status as well as entering the annotation sub-menu.
- 2. Tap to put the cursor over the desired location on the image area for the annotation.
- 3. Add a new annotation to the image in accordance with the actual situation. You can modify, move or delete a completed annotation.
 - Arrow: tap [Arrow] to put an arrow on the image.
 - Type annotation: tap [Keyboard] to enter the text-typing status.
 - Select an annotation text directly from the menu.
- 4. Tap [Annotate] again to exit annotation status.

9.1.2 Annotation Menu

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



[Edit Comments]: Tap to enter comment preset page, you can add custom comments and change comment layout. See chapter "12.2.3 Comment Preset" for details.

9.1.3 Adding Annotations

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

Tap to position the cursor on the desired location within the image area.



2. Tap Keyboard to open the soft keyboard:

- Type alphanumeric characters using the soft keyboard (characters are uppercase by default).
- In edit status (the characters are green in color), tap new line. The cursor is aligned with the first line.
- 3. In edit status, tap regions other than the annotation on the image area to confirm the added character. The color of the added character turns to yellow.
- Adding an annotation text

In annotation status:

- 1. Tap to select the desired annotation text on the annotation menu.
- 2. The system adds the selected annotation text to the screen (in current status, the annotation is in green, which means you can continue editing the annotation).

Add/change position indication: select [RT]/[LT]/[XS]/[Sag]/[Mid]/[Dist]/[Pro] to indicate anatomical location.

- 3. Tap regions other than the typed in annotation on the image area to confirm the added character. The annotation changes to yellow.
- Adding an arrow

You can add an arrow to a location you want to highlight.



- 1. Tap Arrow and an arrow will appear in the cursor position.
- 2. Adjust the shape and position of the arrow:

To position the arrow on the area of interest and change the orientation: tap and rotate the arrow icon to change the arrow position; tap and rotate the dotted line under arrow icon to change the arrow orientation.

3. Tap regions other than the added arrow on the image area to confirm the arrow position. The arrow turns yellow. Repeat the above steps to add more arrows.

9.1.4 Moving Annotations

- 1. Under annotation status (annotation menu is highlighted in blue), tap to select the annotation to be moved.
- 2. Tap the desired position to move the annotation to current position.
- 3. Tap regions other than the moved annotation on the image area to confirm the position.

9.1.5 Modifying (Editing) Annotations

■ Modifying (Editing) characters

- In annotation status, tap to select the annotations to be modified.
 Tap to select the added annotation, the annotation turns into green in editing status.
- 2. Tap Keyboard to show the soft keyboard and use the direction keys to move the cursor to the desired location to insert/delete characters. Either type characters by tapping the corresponding keys or select the new annotation text from the menu directly.
- 3. Tap to delete the annotation character or text on the left side of the cursor.
- 4. Tap regions other than the edited comment on the image area to confirm the modification and exit the edit status. The annotation turns to yellow.
- Modifying (Editing) Arrows
- 1. Tap to select the arrow that needs to be modified, the arrow then turns green. Change the arrow's position or change the orientation as described in "Adding an Arrow" in "9.1.3 Adding Annotations" chapter.
- 2. Tap regions other than the modified arrow on the image area to confirm the change.

9.1.6 Deleting Annotations

- Deleting annotation characters, texts or arrows
- 1. Tap to select the annotation to be deleted, a [Delete] button displays on the bottom of the image area.
- 2. Tap [Delete] to delete the annotation.
- Delete all annotations

Tap [Clear Comment] on the annotation menu to delete all the annotations.

NOTE: After powering off, the system will clear all annotations on the image.

9.2 Body Mark

The Body Mark (Pictogram) feature is used to indicate the patient's position during the exam as well as the transducer position and orientation.

The system supports body marks for Abdomen, Cardiology, GYN, OB, Urology, Small Part and Vascular applications.

9.2.1 Adding Body Marks

- 1. Select [Annotate] -> [Body Markers] on the operating panel to enter Body Mark status as well as open the body marker menu.
- 2. Tap to select the desired body mark to bring out the Position Probe Marker dialogue box.
- 3. To adjust the probe position and orientation marker:
 - Tap and rotate the bold solid green line to position the probe marker.
 - Tap and rotate the dotted line to adjust the probe marker orientation.
- 4. Tap [Set] to confirm the position and orientation of the probe marker and add the mark.

9.2.2 Moving Body Marks

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

- 1. Tap to select the body mark. The body mark is covered by a green frame, indicating you can move it to a new position.
- 2. Tap the desired position to place the body mark.

NOTE: In Dual-split mode, a body mark cannot be moved between the separate image windows.

9.2.3 Deleting Body Marks

Tap [Clear Markers] to delete the added body mark.

9.3 Settings

- See chapter "12.2.3 Comment Preset" for custom comment adding and layout setting.
- General Setting

Enter the [Setup] -> [System] -> [General] screen to perform the following setting:



- You can preset whether to clear the annotations when unfreezing the image or changing the probe/exam.
- Set whether body marks are erased when the image is unfrozen.

Exit [Setup] page or changing the exam/patient/mode/probe will clear the body marks.

10 Patient Data Management

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

An exam record consists of the following information:

- Patient basic information and exam data
- Image files
- Report

NOTE: 1.

- 1. DO NOT use the internal hard drive for long-term image storage. Daily backup is recommended. External storage media is recommended for archiving images.
- 2. The system's patient database space is limited. Back up or clear patient data regularly.
- 3. Mindray is not responsible for lost data if you DO NOT follow the recommended backup procedures.

10.1 Patient Information Management

General patient information and exam information are entered using the Patient Info screen. For details, see "4.1 Patient Information."

10.2 Image File Management

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

10.2.1 Memory Media

The system supports 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 which cannot be compressed. You can add measurements and comments on this type of file.

You can tap [Save Image] at the bottom of the operating panel to save a single-frame image file.

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.

You can tap [Save Clip] at the bottom of the operating panel to save a multi-frame image file.

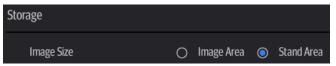
The system can save FRM files as BMP, JPG, TIFF or DCM files, or save CIN files as AVI or DCM files by Send To function in iStation/Review screen. For details, please refer to "10.2.7 Sending Image Files" chapter.

- 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.
 - PNG: single frame storage format.
 - Multi-medium file (AVI)
 Multi-frame export format.
 - DICOM file (DCM)
 DICOM standard file 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 storage size via [Setup] -> [System] -> [General]:



- Set cine saving length (clip length)
 For details, see "6.7 Preset."
- Set send/print image after ending the exam

Select [Setup] -> [System] -> [General], check "Sending/printing after Ending Exam" in the Patient Management area. Then every time you tap [End], the system will send images of the exam to the connected default DICOM server.

Image/clip storage settings

Select [Setup] -> [System]->General], check options in the Image/Clip Storage area. Then every time you save an image/clip, the system will send images of the exam to the connected default printer/DICOM Storage server/DICOM Print server/iStorage server.

10.2.4 Quickly Saving Full Screen Images to the System

Tap in the top-right corner of the screen and select to save single frame image (full screen).

The image is saved in BMP format, you can check the image in Review screen.

10.2.5 Image Review and Analysis

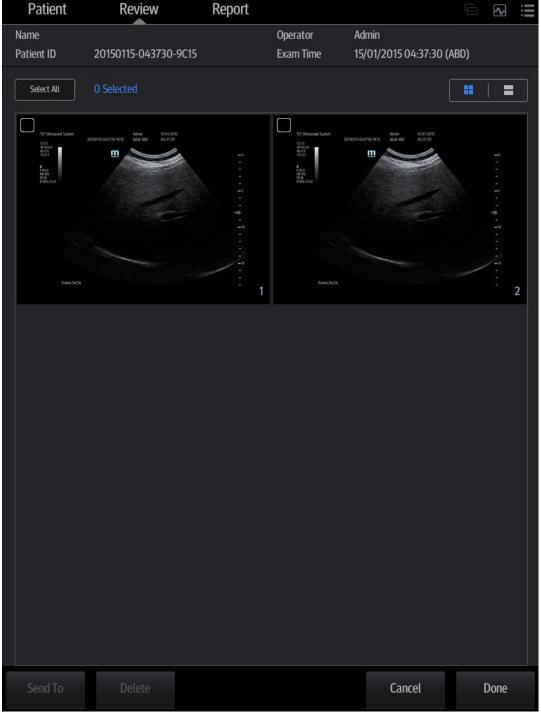
You can review and analyze stored images (only refer to images stored in the system default path).

10.2.5.1 Review an Image

You can review all images stored in an exam, and send, delete or analyze the stored images.

Tap [Review] on the left side of the operating panel to enter Review screen or double-click the exam in iStation screen. Images of the current exam and the current patient are displayed.

The Review screen is shown as follows:



Controls on the Review screen:

Report

Select [Report] tab to review or edit the currently-selected patient's report.

Patient

Select [Patient] tab to review or edit the currently-selected patient information.

Image operations

[Select All]: tap to select all images in the thumbnail window.

[Deselect All]: after selecting [Select All], the button changes to [Deselect All]. Cancel all selections by selecting [Deselect All].

[Send To]: tap to send the selected image to another location, DICOM server, printer, etc.

[Delete]: tap to delete the selected image.



: Tap to change the layout.

■ Tap [Done] to exit Review:

10.2.5.2 Image Analysis

In image analysis status, you can view, zoom, perform image parameter adjustment and measurements, add comments and perform cine (multi-frame) review for a stored image. The operation steps are the same as those for real-time scanning. See the relevant sections for details.

To enter image analysis:

In image review status, double-click the selected thumbnail to open the image.

- Tap [Return] to exit image analysis:
- Other operations

You can perform cine review operations in image analysis status. For details, see "6 Display & Cine Review."

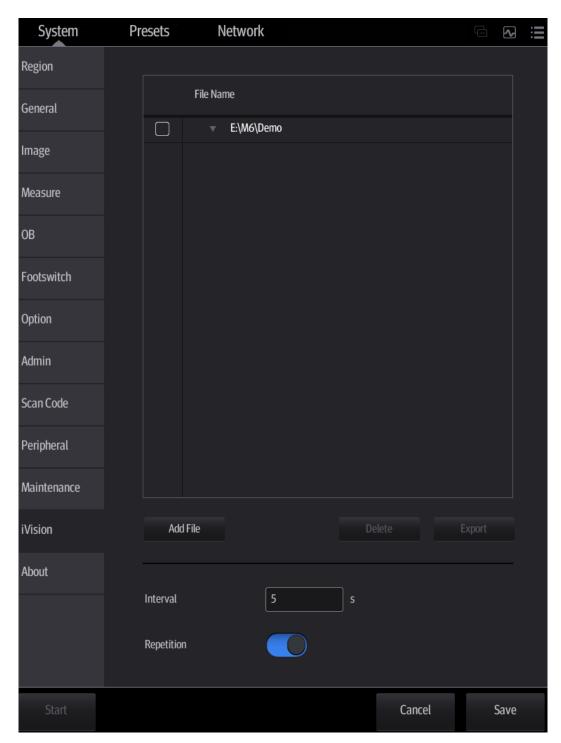
10.2.6 iVision

The iVision function is used to demonstrate the stored images. Image files are played one by one according to file names (including system-relevant and PC-compatible format images).

To perform image demonstration:

- 1. Select [Setup] -> [General] -> [iVision] to enter the iVision setting screen.
- 2. Add the contents to be played and select demo mode.
- 3. Select an item in the list and tap [Start] (in the bottom-left corner of the screen) to begin the demonstration.
- 4. Tap [Exit] to exit iVision status.

The iVision setting screen is shown as follows:



Demonstration item

Demonstration items are image files in formats supported by the system. You can add exam data from the patient database or system-supported image files and folders to the demonstration list. For files and folders in the demonstration list, the images in the directory and subdirectory are played one by one, and the system will automatically skip files that cannot be opened.

- [Add File]: to add files to the file list.
- [Delete]: to delete selected files or catalogs from the file list.
- [Export]: to export selected directories/files to external storage devices.

■ Interval

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

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

Repetition

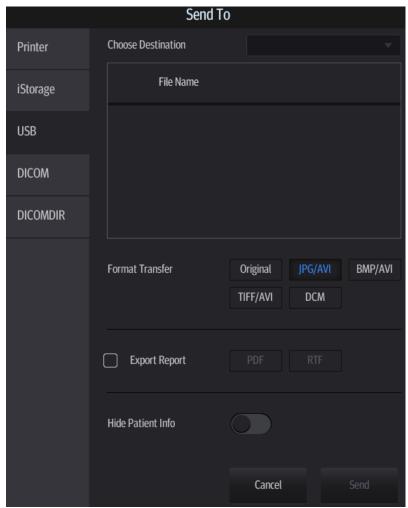
You can choose whether to repeat the demonstration or exit after a demonstration is complete.

10.2.7 Sending Image Files

NOTE: Data saved this way can only be reviewed on the PC and cannot be restored to the ultrasound system. See chapter "10.4.2 Patient Data View & Management" for details about data backup.

■ In the iStation screen, select an exam and then tap [Send To], or, in the Review screen, tap [Send To] to send patient images to an external memory device, DICOM Storage server, DICOM Print server or local connected printer. You can choose whether reports are exported with images. See the figure below.

See the figure below.



- For external memory devices (e.g., USB memory devices) or iStorage:
 - ➤ 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 is exported as AVI.
 - ➤ DCM format transfer: DCM (including single-frame DCM and multi-frame DCM). You can also select whether to export reports and select the report type.
 - You can select if to hide patient information.

 For DICOM servers, select the DICOM Storage or Print server.
- For DICOM media storage (DICOMDIR), you can select cine file compression mode.

• For video printers, send images to the video printer connected to the system. For graph/text printers, send images to the default graph/text printer.

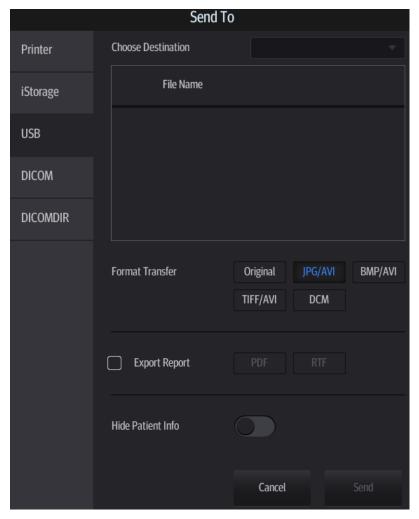
10.3 Report Management

- Report storage:
 - Exam reports are stored under the patient exam directory.
- Importing, exporting and sending reports
 - Export/import reports via Backup (in ultrasound system format)
 In the iStation screen, select patient data, then select [Options] -> [Back Up]/ [Restore] to import patient information, images and reports to or from an external memory device. See the following figure:



You can select the destination, and select whether to remove local patient exam data.

Export reports via Send To (in PC format)
 In the iStation or Review screen, use [Send To] to send patient data/image to an external memory device (e.g., USB memory devices) or iStorage. You can choose whether reports are exported with images. See the figure below.



- Export reports in Report screen
 - a) Tap [Report] on the left side of the operating panel.
 - b) Select [Preview] to enter report preview screen.
 - c) Tap [Export] to open the exporting dialogue box and select the path to export.
- Report printing

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

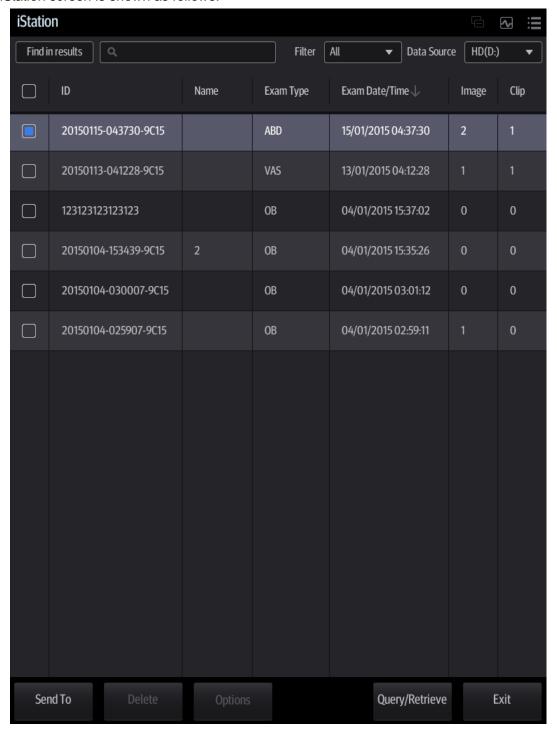
For details on report-related operations, see [Advanced Volume].

10.4 iStation - Patient Data Management

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

■ Tap [iStation] on the left side of the operating panel to Enter iStation.

The iStation screen is shown as follows:



10.4.1 Searching a Patient

1. Select the data source:

Select the data source from the "Data Source" drop-down list in the top-right corner of the screen.

- 2. Enter the search condition:
 - Filter: including Name, ID, DOB and Exam Date. Then enter a keyword in accordance with the Item selected.
 - Tap [Find in results] to make it highlighted, then the system can search on the keyword in the existing searched results.
- 3. The system searches and displays the results in the patient list.
- 4. Swipe the screen from left to right to check other information of the patient.

10.4.2 Patient Data View & Management

Double-click the patient exam to enter review screen, you can check patient information data, report and images then.

Tap to select the desired patient exam in the list, you can:

■ Backup/Restore

You can back up the selected patient data to the system-supported media in order to view it on the ultrasound system, or restore patient data to the system from an external media. For exams ended/paused within 24 hours, you can select to activate/continue the exam. For details, see "4 Exam Preparation" chapter.

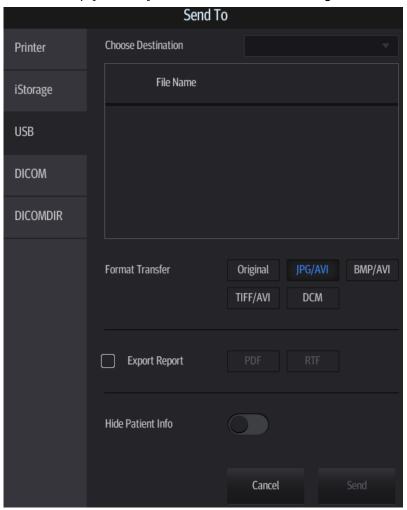
- [Options] -> [Back Up]: back up the selected patient data to the system-supported media.
- [Options] -> [Restore]: import patient data from an external media.
- Activate an Exam

After selecting an exam which has been performed within 24 hours, tap [Options] -> [Activate Exam] to activate the exam and load the patient information to continue the exam.

Send Exam

The system supports sending data to external memory devices, print or iStorage. You can use this function to export the exam data to external devices (in PC data or DICOMDIR data format) and then import to PC or restore to the ultrasound system to review the data (DICOMDIR).

1. Select the patient record, tap [Send To] to send exam data and images of the selected record.



2. Select target:

- DICOM: send data or images to the storage server or send images to DICOM printer.
- DICOMDIR: back up data in DICOMDIR format; change the cine Compression mode and JPEG Compression mode.
- USB storage device: send exam to USB storage device.
 - > Report format can be selected.
 - ➤ Format transfer is available when sending images to USB device. See "10.2.7 Sending Image Files" for details.
- Print: send image to the connected printer to print.

Delete Exam

Select an exam record, tap [Delete] to delete the record. You cannot delete patient data which is being printed, exported or sent, or delete the current exam.

■ Query/Retrieve

DICOM Query/Retrieve function, see chapter "11.3.6 Query/Retrieve" for details.

10.5 Recycle bin

The recycle bin is used to store deleted patient data, exam data and images.

To recover deleted patient data, tap in the top-right corner of the screen and select to enter the Patient Recycle Bin screen.

- 1. Select items in the list. Select operations:
 - Tap [Restore Items] to restore the item to iStation.
 - Tap [Delete] to delete the item permanently. The item can never be restored again.
- 2. Tap [Done] to exit the screen.

10.6 iStorage

iStorage is used to save image files and measurement reports to the remote PC server.

Select [Setup] -> [Network] -> [Network Preset] to set the iStorage settings (see chapter "12.3.2 iStorage Preset" for details).

- Enter the iStation screen. Select one (or more than one) patient data or image in the local data source.
- 2. Tap [Send To].
- 3. Select [iStorage] in the Send To dialog box on the left and select the PC server on the right.
- 4. Select PC transfer format to send the report.
- 5. Tap [Send] to start sending.

10.7 Print

10.7.1 Print Setting

For printer connection and driver installation, please refer to "3.7 Installing a Graph/Text Printer" chapter.

- Print Service Setting
- 1. Select [Setup] -> [System] -> [Peripheral] and select an existing printer service from the list on the upper part of the screen.
- 2. Select the printer type in the Property box.
- 3. Set printing properties.
- 4. Tap [Save] to confirm the setting and exit the preset page.

See chapter "12.1.9 Peripheral Preset" for details about printer selection and print service setting.

- Modify a print service:
- 1. Select [Setup] -> [System] -> [Peripheral Preset] and select an existing printer service from the list on the upper part of the screen.
- 2. Select the printer model, then set the properties in the Property box.
- 3. Tap [Save] to complete.
- Digital image print range setting: [Setup] -> [System] -> [General] -> Storage -> Image Size.

10.7.2 Image Printing

Image printing is mainly achieved by video printer. See chapter "11 DICOM/HL7" for details about DICOM printing.

- Print current screen image
 - In the main screen, use [Freeze] to freeze the image and tap [Print] to print the current screen image.
- Image print via send to function
- 1. Select the desired image in the iStation or Review screen.
- 2. Tap [Send To] and select the printer in the dialog box which appears.
- 3. Tap [Send] to start printing.

See the accompanying printer manuals for more details.

10.7.3 Report Printing

Both reports and images can be printed on a graph/text printer.

- 1. Tap [Report] on the left side of the operating panel to enter the report dialog box.
- 2. Tap [Preview] to enter report preview screen.
- 3. Select [Print] to print the report.

See the accompanying printer manuals for more details.

10.8 Back Up Files using the DVD Drive

The system supports writing data to CD/DVD using the external DVD-RW/DVD+RW drive.

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 external DVD R/W drive.
- 2. Select the data to be backed up and then select [Option] -> [Back up] in the iStation screen. Select the target drive in the Back Up Patient Record dialog box.
- 3. Tap [Back up] to begin writing.

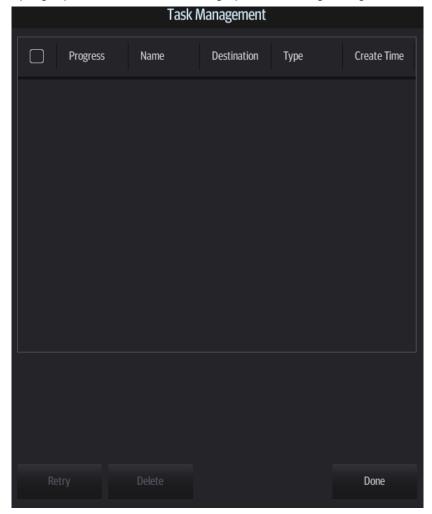
You can check the data writing procedure in the patient task manager. For details, see "10.9 Patient Task Management."



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

10.9 Patient Task Management

Tap in the top-right part of the screen to bring up the following dialog box:



In the Task Management dialog box, the patient name, destination, progress, type and task created time are displayed.

You can perform the following operations:

- Tap [Delete] to delete the task.
- Tap [Retry] to retry the failed task.
- Media storage task:
 - Storage Task: displays the DICOM storage task.
 - DICOM media storage task (USB devices): in iStation screen, select the target exam and tap [Send To], then select DICOMDIR in the menu which appears.
 - Back up task (system-relevant format): select the exam to be backed up in iStation and tap [Options] -> [Back Up].
 - Send to external devices (USB devices): select exam data or images in the iStation or Review screen. Tap [Send To] for the image.
 - iStorage task: in iStation screen, select the target exam and tap [Send To], then select iStorage in the menu which appears.

- DICOM print task: displays DICOM print tasks.
- Task Status

When there are tasks underway, the task management icon displays as



When tasks have failed, the task management icon displays as . Click the icon to check the reason for the failure.

When the task management icon displays as _____, it means no task is underway.



Troubleshooting

If a serious error occurs, such as network disconnection or operation timeout, the system can try to reconnect the network. The interval time and maximum retries can be set as desired. For details, see chapter "11 DICOM/HL7".

10.10 Administration

10.10.1 Access Setting

The system supports two types of users: system administrator and operator.

Administrator

The system administrator can view all patient data, such as patient information, images and reports, etc.

Operator

The operator can only view exam information saved in the system and operated by him or herself, such as patient information, images and reports, etc. The operator cannot view exam data operated by others.

10.10.2 Setting Access Control

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

Access control only can be set by the system administrator.

Setting access control:

- 1. Select [Setup] -> [System] -> [Admin] to enter access control setting screen.
- 2. If "Enable User Account Control" is selected, you must be authorized before accessing the data. If unselected, you can access all the data without authorization.

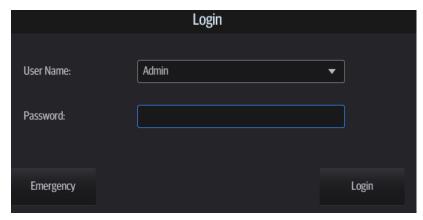
10.10.3 System Login

If "Enable User Account Control" has been set by the system administrator, you can access data in the system only after logging onto the system.

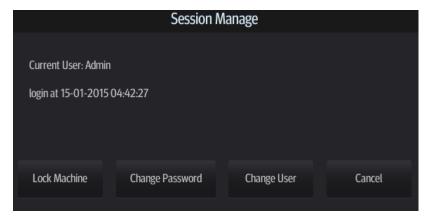
You must log in again after system restart or dormancy.

Logging onto the system:

Select the user type and enter the password and tap [Log in].



- To change users:
- 1. Tap in the top-right corner of the screen and select to bring up the following dialog box:



- 2. Tap [Change User] to bring up the Login dialog box.
- 3. Enter the user name and password in the field box.
- Lock system
- 1. Tap from the system tool bar in the top-right corner of the screen to bring up the dialog
- 2. Select [Lock Machine] and the system is locked. You must log on before using the system.

10.10.4 Add/Delete Users

The system administrator can add and delete users, while the operator cannot.

When adding a user, type in the password for the user.

Before you perform adding/deleting users, please turn on the "Enable User Account Control" feature first and then enter the screen in "Admin" account: [Setup] -> [System] -> [Admin].

10.10.5 Modify Passwords

The system administrator can modify all user passwords. The administrator password is empty by factory default. You can set this password.

An operator can only modify his/her own password. There are two ways to modify passwords: on the "Admin" page or in the "Session Manage" dialog box.

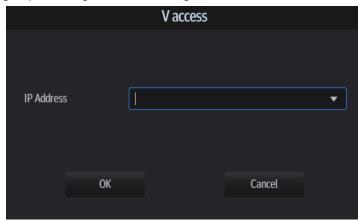
- "Admin" page (administrators can modify the password)
- 1. Open the "Admin" page using the path: [Setup] -> [System] -> [Admin].

- 2. Select the user name to be modified in User List. Tap [Change Password] to change the password.
- Session Manage page (general operators and administrators can modify the password).
- 1. Tap from the system tool bar in the top-right corner of the screen to bring up the dialog box.
- 2. Tap [Change Password] to change the password.

10.11 V-Access

The ultrasound system can be used to log on to a remote server to check or modify patient data on the server.

- 1. Tap from the system tool bar in the top-right corner of the screen to enter the function.
- 2. The system brings up a dialog box for entering the IP address of the remote server.



- 3. Enter the IP address and tap [OK].
- 4. Log on with the server account and password.
- 5. Check the data transferred and carry out operations as necessary.

10.12 Q-Path

NOTE:

When logging on the Q-path service, the ultrasound system is connected to the external network and it may be infected by virus. Please do not access the unrelated website or perform any unrelated operations.

If abnormal data or link is discovered after logging on the Q-path service, please stop operation and contact the Q-path service provider.

10.12.1 Overview

You can use the ultrasound system to check data on browser directly. After you have ordered storage service of a network website service, you can check data using the website, authorized account and password (provided by the service vendor).

Q-path is a network server provided by Telexy Healthcare Inc. for digital image storage. For details, please contact Q-Path service provider.

10.12.2 Q-Path Basic Procedure

1. Set related setting in the path: [Setup] -> [Network] -> [Q-Path].

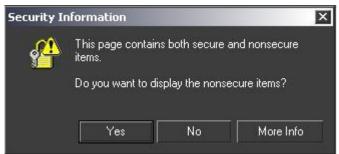
- a) Select "Enable Q-Path" in the path;
- b) Enter the website, account and password of the target service.



- 2. Tap [Save] to exit Setup screen.
- 3. Tap in the top-right corner of the screen and select Tips:

If network connection is not normal, the system will prompt "Loading Q-path application, please wait...."

The following prompt may display every time you enter Q-Path after powering on the machine. If you see this information, select "Yes" to enter the website service.



4. Tap X to exit the function.

NOTE: If you use Q-Path function to connect to websites other than Q-Path applications (website setting is described above), the system will prompt the following information: Only Q-Path application is allowed to be loaded!

11 DICOM/HL7

NOTE: Before using DICOM, read the DICOM CONFORMANCE STATEMENT electronic file provided with the device.

The chapter is restricted to the preset, connection verification and DICOM services of the DICOM-configured ultrasound machine, and does not include SCP configurations such as PACS/RIS/HIS.

The DICOM package is optional. For details, see "2.4.3 Options".

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

DICOM Preset and Applications workflows are briefly described as follows:

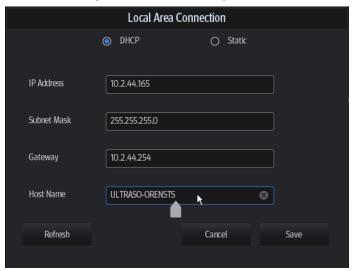
- 1. DICOM preset (network property, DICOM local preset, server and service preset).
- 2. Verify connectivity (tap [Verify] in corresponding screen).
- 3. Services application.
- 4. DICOM task management.
- Terms

Abbreviations	Description		
DICOM	Digital Imaging and Communications in Medicine		
AE	Application Entity		
MPPS	Modality Performed Procedure Step		
PDU	Protocol Data Unit		
SCU	Service Class User (DICOM client)		
SCP	Service Class Provider (DICOM server)		
SOP	Service-Object Pair		

11.1 DICOM Preset

11.1.1 IP Preset

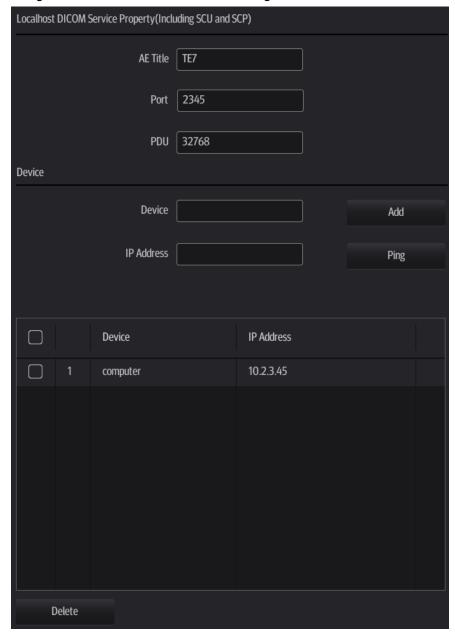
If wireless network connection is used, see chapter "Appendix A Wireless LAN" for details. If wired network connection is used, please follow the steps below to do the configuration.



- 1. Tap in the top-right part of the screen to open the local connection dialogue box.
- 2. Select DHCP/ Static for the network.
- 3. Tap [Save] to exit the dialogue box after finishing the setting.

11.1.2 DICOM Local Preset

- 1. Enter the DICOM local preset screen using the path: [Setup] -> [Network].
- 2. Enter AE Title, Port and PDU according to the actual situation, then tap [Save] to exit the screen. Setting items are introduced in the following.



Name		Description		
DICOM Local	AE Title	Application Entity title.		
	Port	DICOM communication port.		
	PDU	Maximum PDU data package size, ranging from 16384 to 65536. If the value is less than 16384 or greater than 65536, the system automatically sets it to the value 32768.		
Server Setting	Device	Name of the device supporting DICOM services.		
	IP Address	IP address of the server.		
	Ping	You can ping other machines after entering the correct IP address. You can also select a server in the device list below to ping it.		
	Add	Select to add servers to the device list.		
	Delete	Select to delete selected servers from the device list.		

Server setting procedure:

- 1. Enter the server device name and IP address. Tap [Ping] to check the connection.
- 2. Tap [Add] to add the server to the device list. Its name and address are displayed in the list.

Tip:

The AE Title should be the same as 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 the storage server should be Storage.

11.1.3 Service Preset

The DICOM Service screen is used to set Storage, Print, Worklist, MPPS, Storage Commitment and Query/Retrieve attributes.

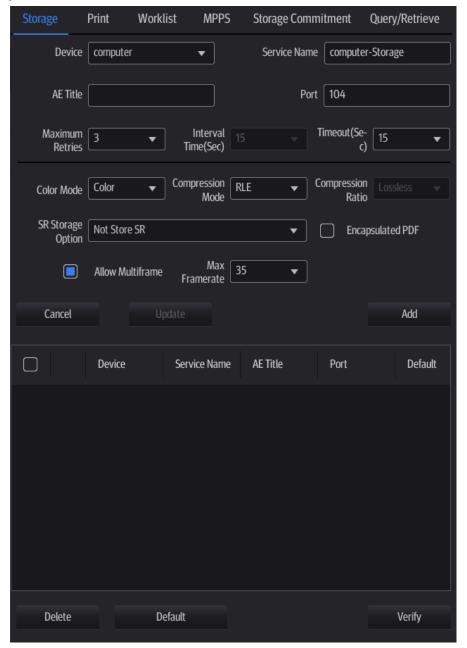
When the system is configured with the DICOM basic function module, and installed with DICOM Worklist, MPPS, DICOM structured reports and DICOM query/retrieve modules, the corresponding preset can be found in the DICOM Service screen.

To open the DICOM Service screen:

Select [DICOM/HL7] in the [Setup] -> [Network] menu and select corresponding tabs to enter the screen.

11.1.3.1 Storage Service Preset

- 1. On the DICOM/HL7 screen, select the [Storage] page tab to enter the Storage page.
- 2. Select a device and enter the correct AE Title, port, etc.
- 3. Tap [Add] to add the service to the Service List.



DICOM storage preset items are described as follows:

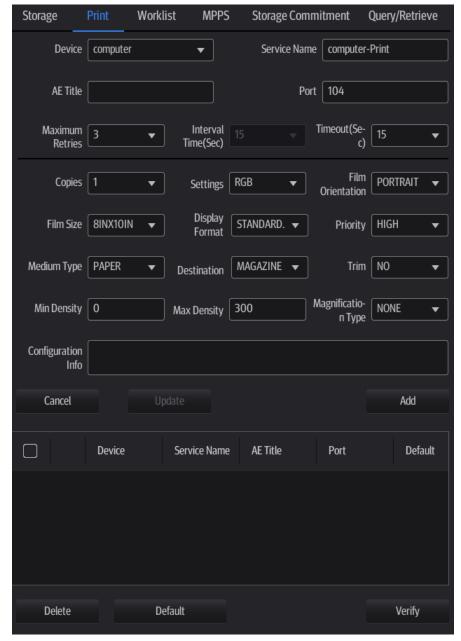
Name		Description		
	Device	After setting the servers in the DICOM local screen, the names will appear in the drop-down list. Select the name of the storage server.		
	Service Name	The default is xxx-Storage, user-changeable.		
	AE Title	Application Entity title. It should be consistent with that of the storage server.		
	Port	DICOM communication port, 104 is the default. The port should be consistent with that of the storage server port.		
	Maximum Retries	Set the maximum retries.		
	Interval Time(Sec)	Reserved.		
	Timeout (Sec)	Refers to the amount of time after which the system will stop trying to establish a connection to the service.		
	Color Mode	Select the color mode.		
Configure New Service	Compression Mode	Select the Compression mode: uncompressed, RLE, JPEG and JPEG2000.		
	Compression Ratio	Select the JPEG Compression ratio: lossless, low, medium and high.		
	Allow Multiframe	If SCP supports this function, select it.		
	Max Frame Rate	Set the frame range for transferring cine files to DCM multi-frame files.		
	SR Storage Option	Select structured report sending options.		
	Encapsulated PDF	Select whether to encapsulate PDF format reports in DICOM standard.		
	Add	Add the DICOM service to the service list.		
	Cancel	Select to cancel parameter setting.		
	Update	Select an item in the service list, change the parameters in the above area, and tap [Update] to update the item in the service list.		
Service List	Delete	Select to delete the selected service from the service list.		
	Default	Select an item in the service list. Tap [Default] and you will see "Y" in the Default column.		
	Verify	Select to verify that the two DICOM application entities are properly connected.		

Tip: RLE, JPEG and JPEG2000 are not supported by all SCPs. Refer to the SCP's DICOM CONFORMANCE STATEMENT electronic file to check whether SCP supports it or not. Do not select these Compression modes if the storage server does not support them.

- Images of PW/M mode (B image is not frozen) and images other than PW/M mode: if "Max Frame rate" is not "Full" and the actual frame rate is larger than the set value, the system will save the image files in a frame rate of the set value, and transfer in a frame rate of B mode.
- Images of PW/M mode (B image is frozen), the system will save/transfer the images files in frame rate of 6.

11.1.3.2 Print Service Preset

- 1. On the DICOM/HL7 screen, select the [Print] page tab to enter the Print page.
- 2. Select a device and enter the correct AE Title, port, etc.
- 3. Tap [Add] to add the service to the Service List.



DICOM print preset items are described as follows:

Name		Description		
	Device	After setting the servers in the DICOM local screen, the names will appear in the drop-down list. Select the name of the print server.		
	Service Name	The default is xxx-Print, user-changeable.		
Configure New Service	AE Title	Application Entity title. It should be consistent with that of the print server.		
	Port	DICOM communication port, 104 is the default. The port should be consistent with that of the print server port.		
	Maximum Retries	Set the maximum retries.		
	Interval Time(Sec)	Reserved.		
	Timeout(Sec)	Refers to timeout during association establishment.		
	Copies	See copies of printed files. You can select from 1 to 5, or directly enter the number.		
	Settings	The system supports RGB (color printing) and MONOCHROME2 (black and white printing). Please select the type the printer supports.		
	Film Orientation	Select from between LANDSCAPE and PORTRAIT.		
	Priority	Specify printing task priority from HIGH, MED and LOW.		
	Film Size	Select film size from the selections listed in the drop-down list.		
	Display Format	Specify the quantity of printed files, e.g., STANDARD\3, 2 indicates 6 images are printed for each page.		
	Medium Type	Specify print medium: Paper, Clear Film, Blue Film. Select Blue Film or Clear Film for black and white printing; select Paper for color printing.		
Print	Trim	Specify whether you want a trim box to be printed around each image on the film: Yes or No.		
Properties	Configuration Info	Enter configuration information in the field.		
	Min. Density	Enter the minimum density of the film.		
	Max. Density	Enter the maximum density of the film.		
	Destination	Specify where the file is exposed: MAGAZINE (stored in the magazine) or PROCESSOR (exposed in the processor).		
		Select how the printer magnifies an image to fit the film.		
	Magnification Type	Replicate: interpolated pixels belong to duplicates of adjacent pixels)		
		Bilinear: interpolated pixels are generated from bilinear interpolations between adjacent pixels		
		Cubic: interpolated pixels are generated from cubic interpolations between adjacent pixels		
		None: without interpolation.		
	Add	Add the DICOM service to the service list		
	Cancel	Select to cancel parameter preset.		

Name		Description		
	Update	Select an item in the service list, change the parameters in the above area, and tap [Update] to update the item in the service list.		
Service List	Delete	Select to delete the selected service from the service list.		
	Default	Select an item in the service list. Tap [Default] and you will see "Y" in the Default column.		
	Verify	Select to verify that the two DICOM application entities are properly connected.		

11.1.3.3 DICOM Worklist Preset

- 1. On the DICOM/HL7 screen, select the [Worklist] page tab to enter the Worklist page.
- 2. Select a device and enter the correct AE Title, port, etc.
- 3. Tap [Add] to add the service to the Service List.

The DICOM Worklist service parameters are similar to those described in DICOM Storage Preset. See "11.1.3.1 Storage Service Preset" for details.

11.1.3.4 MPPS Preset

- 1. On the DICOM/HL7 screen, select the [MPPS] page tab to enter the MPPS page.
- 2. Select a device and enter the correct AE Title, port, etc.
- 3. Tap [Add] to add the service to the Service List.

The DICOM MPPS service parameters are similar to those described in DICOM Storage Preset. See "11.1.3.1 Storage Service Preset" for details.

11.1.3.5 Storage Commitment Preset

- 1. On the DICOM/HL7 screen, select the [Storage Commitment] page tab to enter the Storage Commitment page.
- 2. Select a device and enter the correct AE Title, port, etc.
- 3. Tap [Add] to add the service to the Service List.

A special setting item for the DICOM Storage Commitment service is the Associated Storage Service, as described in the following. Other parameters are similar to those described in DICOM Storage Preset. See "11.1.3.1 Storage Service Preset" for details.

Name	Description	
Associated Storage Service	The associated storage server should be preset before storage commitment. Storage commitment can only be created after the exam is sent out.	

11.1.3.6 Query/Retrieve Preset

- 1. On the DICOM/HL7 screen, select the [Query/Retrieve] page tab to enter the Query/Retrieve page.
- 2. Select a device and enter the correct AE Title, port, etc.
- 3. Tap [Add] to add the service to the Service List.
- 4. Tap [Exit] to confirm the preset and exit the page.

The DICOM Query/Retrieve service parameters are similar to those described in DICOM Storage Preset. See "11.1.3.1 Storage Service Preset" for details.

11.1.3.7 HL7Query Preset

HL7 protocol, enacted by Health Level Seven organization in 1987, is a 7th layer (application layer) based on the OSI model (Open System Interconnection) released by ISO (International Standard Organization).HL7 is used to rule and manage communications between HIS/RIS system and devices, as well as reduce the intercommunication cost.

The following HL7 protocol versions are supported in the ultrasound system: V2.3, V2.4, V2.5 and V2.6.

- 1. On the DICOM/HL7 screen, select the [HL7Query] page tab to enter the HL7Query preset page.
- 2. Select a device and enter the correct AE Title, port, etc.
- 3. Tap [Add] to add the service to the Service List.

Two special setting items for the HL7Query service are the Listen Port and Listen Mode, as described in the following. Other parameters are similar to those described in DICOM Storage Preset. See "11.1.3.1 Storage Service Preset" for details.

"Verify" function is not available under HL7Query preset.

Name	Description
Listen Mode	This function enables the ultrasound system to use the listen port for data receiving.
Listen Port	Port for ultrasound system to receive data after the listen mode function is activated. Here, the port should be consistent with that of the Worklist server port. For details of listen port setting, refer to settings in the server.

11.2 Verify Connectivity

To verify connectivity (not essential), tap [Verify] on the Storage, Print, Worklist, MPPS, Storage Commitment and Query/Retrieve pages respectively.

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

If verification failed, possible causes may be:

- The ultrasound machine cannot communicate normally with the server. Check that the cable is properly connected, or,
 - Check that the IP of the server is configured in the same segment as that of the ultrasound machine, or,
 - Check that the network adapter, router, exchanger and HUB are working normally.
- 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 that the verification function is activated.

Tip:

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

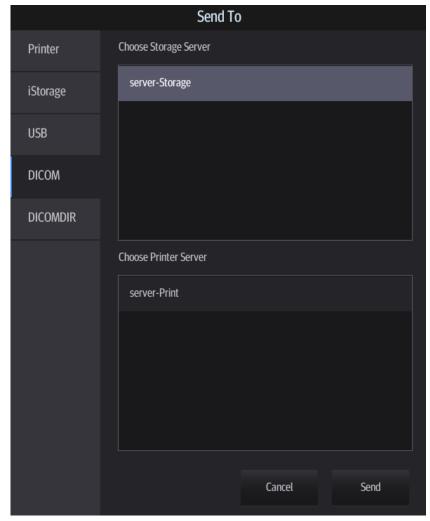
11.3 DICOM Services

If all the DICOM presets on the DICOM Service Preset screen are completed, you are ready for the Storage, Print, Worklist, MPPS, Storage Commitment and Query/Retrieve applications.

11.3.1 DICOM Storage

DICOM Storage is used to send images to the DICOM storage server for storage.

- Send images on iStation/Review
- 1. Select images
 - Tap [iStation] on the left side of the operating panel to open the iStation screen. Tap to select an exam record in the list. Or
 - Tap [Review] on the left side of the operating panel to enter the Review screen. Tap to select a thumbnail or several thumbnails.
- 2. Tap [Send To] to bring up the following dialog box.



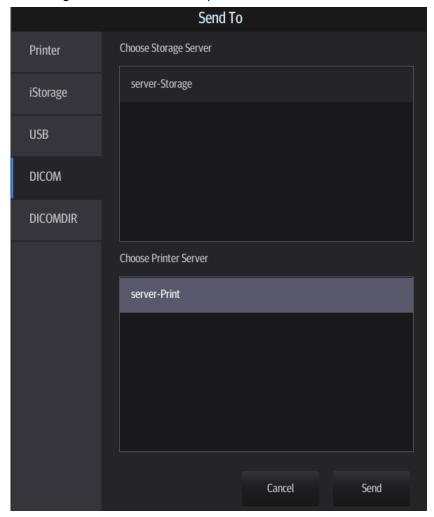
- 3. Tap to select "DICOM" in the Target box on the left side, then select the DICOM storage server in the Choose Storage Server box on the right side.
- 4. Tap [Send] to start sending.
- To send images to storage after an exam ends
- 1. Select [Setup] -> [System] -> [General] and then check [Sending/Printing after End Exam] in the Patient Info area.

- 2. Set a default storage server:
 - a) Enter the DICOM Service Preset screen via [Setup] -> [Network] → [DICOM/HL7].
 - b) Select a storage server in the Service List and tap [Default]. You will see "Y" in the Default column.
 - c) Tap [Exit] to exit the page and return to the Setup menu, then tap [Save] on the Setup menu to make the preset take effect.
- 3. After finishing the presets, perform image scanning. Each time [End] is tapped, 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 images to the DICOM print server for printing.

- Print images on iStation/Review
- 1. Select images. Operations are the same as for DICOM storage.
- 2. In the Send To dialog box, select a DICOM print server.



- 3. Tap [Send] to begin printing.
- To send image to DICOM print after an exam ends
- 1. Select [Setup] -> [System] -> [General] and then check [Sending/Printing after End Exam] in the Patient Management area.
- 2. Set a default print server.
 - a) Enter the DICOM Service Preset screen via [Setup] -> [Network] -> [DICOM/HL7].

- b) Set default DICOM printer. For details, see chapter "11.1.3.2 Print Service Preset".
- 3. After finishing the setting, perform image scanning. Each time [End] is tapped, the system will send the image to the default DICOM print server for printing.
- To print images after saving image
- 1. Select [Setup] -> [System] -> [General] and then check "While Storing Image to Hard Disk, Send to DICOM Printer.
- 2. Set a default print server.
 - a) Enter the DICOM Service Preset screen via [Setup] -> [Network] -> [DICOM/HL7].
 - b) Set default DICOM printer. For details, see chapter "11.1.3.2 Print Service Preset".
- 3. After finishing the setting, perform image scanning. Each time you use [Save Image] to save image, the system will send the image to the default DICOM print server for printing.

11.3.3 DICOM Worklist

For details, see "4.1.2.2 Retrieve from Worklist".

11.3.4 MPPS

MPPS is used to send exam state information to the configured server. This facilitates the other systems in obtaining the exam progress in time.

The status information is described as follows:

- When you begin an exam or send images during an exam, the system sends "Active" status information to the MPPS server.
- When the exam is complete, the system sends "End" status information to the MPPS server.
- When a paused exam is continued, the system sends "Active" status information to the MPPS server.
- When an exam is canceled, the system sends "Canceled" status information to MPPS server.

11.3.5 Storage Commitment

Storage commitment is used to confirm whether the images or structured reports are successfully stored on the DICOM storage server.

Before using storage commitment, set the associated storage service.

- Storage commitment after sending images on the iStation screen.
- 1. Open the iStation screen.
- 2. Select an exam (a suspended exam or an inactive exam) (images are stored in the exam record). Tap [Send To] to open the Send To dialog box.
- 3. Tap to select "DICOM" in the Target box on the left side, then select the DICOM storage server in the Choose Storage Server box on the right side.
- 4. Tap [Send] to start sending. The system will send all the images stored in the exam record to the storage server. Meanwhile, it will send storage commitment to the storage commitment server.
- To send storage commitment after an exam ends
- 1. Select [Setup] -> [System] -> [General], then check [Sending/Printing after End Exam] in the Patient Management area.
- 2. Set the default storage server and storage commitment server.
 - a) Enter the DICOM Service Preset screen via [Setup] -> [Network] -> [DICOM/HL7].

- a) Set a default server in the Storage page and set the associated storage service in Storage Commitment page.
- b) Tap [Save] on the Setup menu to make the preset take effect.
- After finishing the presets, perform image scanning. Each time [End] is tapped, the system will
 send the image to the default DICOM storage server for storage and send storage
 commitment to the storage commitment server.

If images are successfully sent to the storage server, the storage commitment server will return information about the successful image storage. In the iStation screen, you will see a tick " $\sqrt{}$ " marked in the list below "Storage Commitment".

Tip:

Storage commitment is confined to the whole exam. Single image sending cannot be indicated.

NOTE:

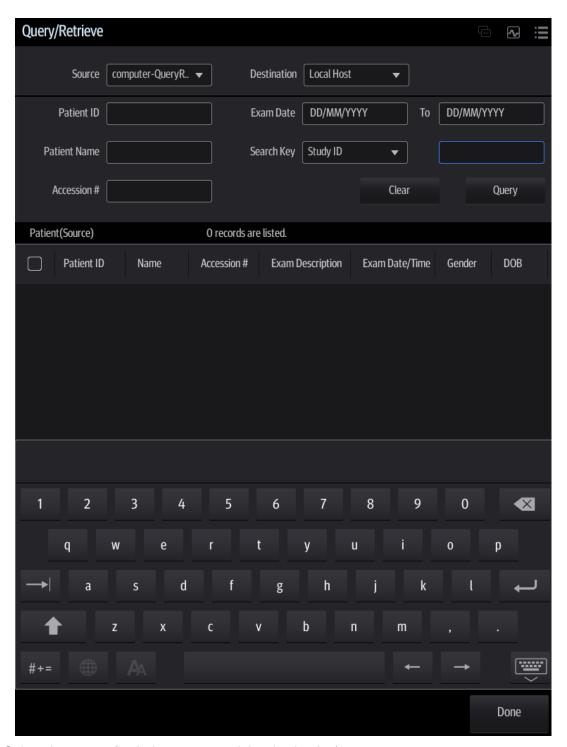
Multi-frame storage is not allowed if "Allow Multiframe" is not selected ([Setup] -> [Network] -> [DICOM/HL7] -> "Storage"). For example, even if there is a multi-frame file in the exam to be sent, only single-frame image storage will be performed.

11.3.6 Query/Retrieve

The query/retrieve function is used to query and retrieve patient exam records in a designated server.

After setting the DICOM query/retrieve server, you can perform the query/retrieve function in the iStation screen.

- 1. Open the iStation screen: Tap [iStation] on the left side of the operating panel.
- 2. Tap [Query/Retrieve] to open the screen.



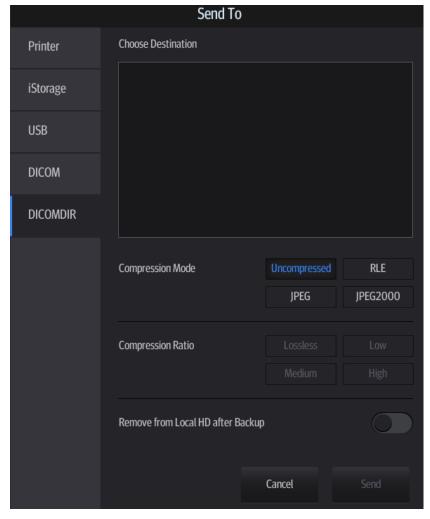
- 3. Select the server (both the source and the destination).
- 4. Enter the query information, such as Patient ID, Patient Name, Accession #, Exam Date or keywords.
 - Tap [Clear] to empty the entered query information.
- 5. Tap [Query]. The system performs the query and lists the results in the patient (source) list. You can perform further queries based on the results by entering new query information.
- 6. Select patient records according to the actual situation.
- 7. Tap [Retrieve] to retrieve the patient records in the DICOM query/retrieve server to the local machine.
- 8. Tap [Done]. The retrieved patient records are listed in the iStation screen.

11.4 DICOM Media Storage

Patient data in the ultrasound system can be saved on external media in DCM format, while DCM files can be accessed in the ultrasound system.

Media Storage

- 1. Select patient records in the iStation screen.
- 2. Tap [Send To] to open the following dialogue box.



- 3. Select the destination to "DICOMDIR" and DICOM Format as well as Compression mode.
- 4. Set whether to remove the patient data from the local hard disk after backup (remove exams or just remove the images).
- 5. Tap [Send] to begin the storage.

If the backup is successful, a tick will appear in the Backup list in the iStation screen. If not, there will be no tick.

There must be no DICOMDIR/DCMIMG/IHE_PDI files on the external storage media of the same name as the one being backed up. Otherwise, the backup cannot proceed. Ensure there is enough storage space, or the backup may fail due to shortage of space.

Data Restore

After the DICOM format data are saved to external media, restore the data to the ultrasound system.

- 1. Connect the external media containing DCM files to the system.
- 2. In iStation, review the data stored on the external media.

- 3. Select the data to be restored in iStation.
- 4. Select [Options] -> [Restore] on the iStation screen.

NOTE: Only system-accessible media can be selected.

11.5 Structured Report

DICOM OB/GYN Structured reports, Cardiac Structured reports, Vascular Structured reports and Breast Structured reports are supported by this system.

- Send images and structured reports for storage in the iStation screen
- 1. Select "Attach SR When Storing Images" or "Only Store SR" on the DICOM Storage preset page. For details, see "11.1.3.1 Storage Service Preset."
- 2. Create new patient information or load scheduled patient information.
- 3. Perform measurements.
- 4. Save the images.
- 5. End the exam.
- 6. Open the iStation screen, select the patient exam, and tap [Send To] to open the Send To dialog box.
- 7. Select "DICOM" in the Target box on the left side, then select the DICOM storage server in the Storage Server box on the right side.
- 8. Tap [Send]. Check for the result in the DICOM Task Management dialog box.

 The structured report can be sent automatically. For details, see "11.3.1 DICOM Storage."
- Back up structured report

When recording or storing exams that have structured reports to external media (DICOMDIR), the structured reports can be backed up together.

NOTE: Only the PACS system from the Medstreaming company (http://www.medstreaming.com/default.aspx) supports sending self-defined measurements by DICOM SR.

11.6 DICOM Task Management

DICOM Task Management is used for viewing task progress or managing tasks after sending images for storage, printing or media storage. For details, see "10.9 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 on the hard drive, and should be backed up to CD/DVD or USB memory device.



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

- To enter Setup: Tap in the top-right corner of the screen and select to enter the setup menu.
- To exit Setup:

Select [Save] in the Setup menu. The parameter settings are saved.

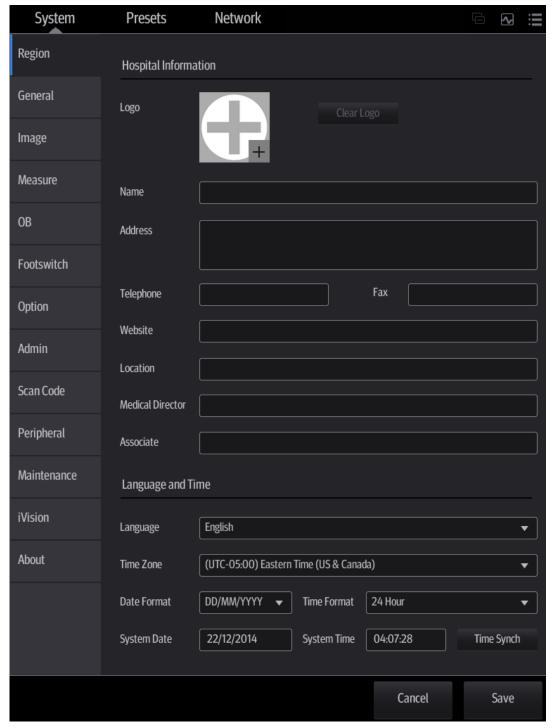
Select [Cancel] in the Setup menu to close the Setup menu.

If you change the system language and tap [Save] in the Setup menu, the system automatically shuts down to make the modification effective.

Tip: configuration parameters may not be all fit on one screen view, swipe downwards to see more options.

12.1 System Preset

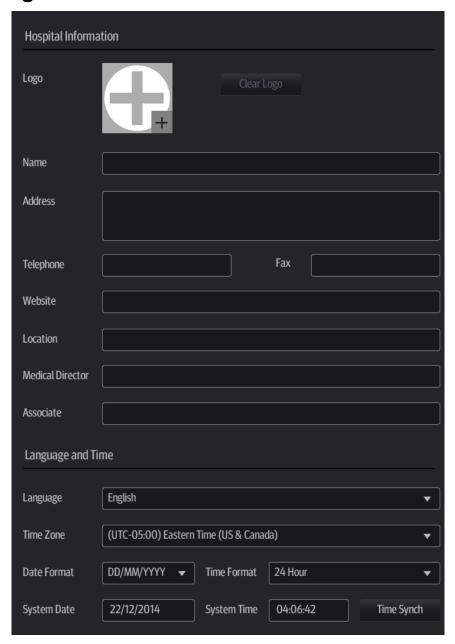
The system automatically enters the [System] screen after you enter Setup.



The following gives a brief introduction of each page, see the following chapters for details.

Page	Description
Region	To set the hospital name, language, time zone, time format and system date/time.
General	To set patient information, exam, patient management, storage related parameters, system dormancy, annotation and body mark and so on.
Image	To set general parameters in imaging modes.
Measure	To set the measurement ruler, measurement setting, follicle method and so on.
ОВ	To set the relevant information regarding the fetal gestational age and fetal weight.
Footswitch	To assign functions to the footswitch.
	To check installed options and you can also install/trial options that are not installed yet.
Option	You can trial each option for 3 months at most. Each option can only be trialed once.
	If you have any questions, please contact the service engineer or your agent.
Admin	To set the user account control relevant information.
Scan Code	To set the code parameters for barcode reader.
Peripheral	To set printer and display parameters.
Maintenance	To import or export user data, restore factory setting and export log.
iVision	To set iVision related parameters and perform demonstration.
About	You can check system versions and information here.

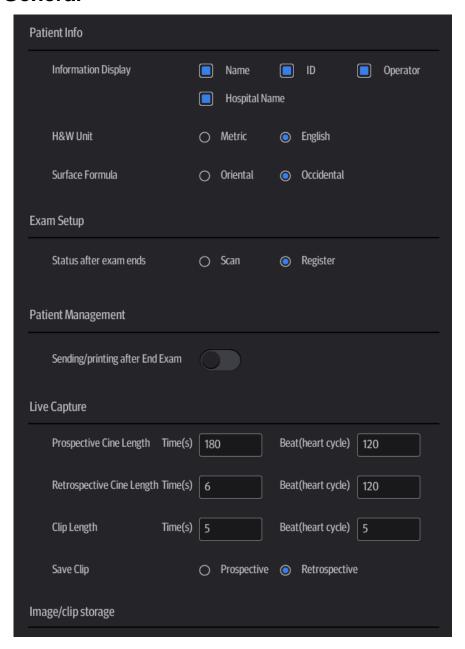
12.1.1 Region



Controls are as follows:

Item	Description	
Hospital Information	To set the hospital-relevant information such as name, address, telephone, and so on.	
Language	To select a language display for the system. Available languages are Chinese, English, German, Italian, Portuguese, Russian, Spanish, Polish, Czech, Turkish, Norwegian, Serbian.	
	Import image for logo loading.	
Load Logo	NOTE: For a better display effect, please try to use an image with 400*400 pixels.	
Time Zone	To select the time zone.	
Time Format	To select the time format.	
Date Format	To set the date format.	
System Date	To set the date for the system.	
Time Sync	To assign a time server and make the time of the ultrasound machine consistent with the server.	

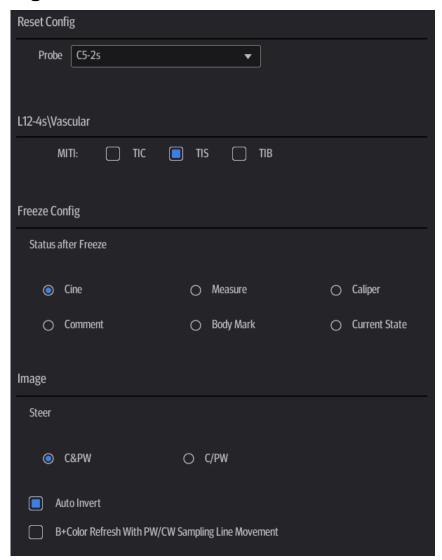
12.1.2 General



Controls are as follows: (swipe downwards to check all settings)

Туре	Item	Description
	Info displays in an image banner	To select whether to display the available patient information items on the top of the screen.
Patient Info	H&W Unit	To set the unit for calculating patient height and weight.
	Surface Formula	To set the surface formula.
Exam Setup	Status after exam ends	To set the system status when an exam ends.
Patient Management	Sending/printing after End Exam	Select whether to automatically archive the exam data to the DICOM server for storage/print.
	Prospective Cine Length	To set the cine length for prospective live capture.
Live Capture	Retrospective Cine Length	To set the cine length for retrospective live capture.
	Clip Length	To set the cine length and heart cycle.
	Save Clip	To set the mode for [Save Clip] button on the operating panel: Prospective or Retrospective.
Image/clip	While Storing Image to Hard Disk	To set if an image is sent to local default printer/DICOM Storage/DICOM Printer/iStorage/USB flash drive when the image is saved.
Storage	While Storing Image to Hard Disk	To set if cine is sent to DICOM Storage/iStorage/USB flash drive when the cine is saved.
Storage	Image Size	To set the image size when saving an image or print an image: Image Area or Stand Area.
		To select a system dormancy type.
Screen Saver	Screen Saver	After the screen saver function is enabled, tap [Browse] to select the figure used for the screen saver and tap [Preview] to see the effect.
		To set the delay before the system enters dormancy/standby status in the drop-down list beside "Wait."
Comments and Body Markers	Body mark/Comments	To set if body marker is cleared when the system is unfrozen.
	Clear	To set if body markers/comments are cleared during unfreeze or changing probe/exam.

12.1.3 Image Preset



Controls are as follows:

Туре	Item	Description
Reset Config.	Probe	To set the default probe model for the system.
Probe/Exam mode	MITI	To set MI TI indexes displayed for current probe/exam mode.
Freeze Config	Status after Freeze	To set the system status after the image is frozen.
Image	Steer	To set the steer mode in B + Color + PW imaging mode. C&PW: select to adjust the sample volume in color mode and sample line in PW mode together. C/PW: select to adjust the sample volume in color mode and sample line in PW mode separately.
	Auto Invert	The spectrum can automatically invert when the color flow is steered to a certain angle, thus accommodating the operator's wish to distinguish the flow direction.
	B+Color Refresh with PW/CW Sampling Line Movement	To set whether to turn on the function that when moving PW/CW sampling line, B image is activated under B+Color+PW/CW mode.

12.1.4 Measure

See the Operator's Manual [Advanced Volume] for details.

12.1.5 OB

See the Operator's Manual [Advanced Volume] for details.

12.1.6 Footswitch



You can assign a function to the left/middle/right key of the foot switch here.

12.1.7 Admin

See chapter "10.10 Administration" for details.

12.1.8 Scan Code Preset

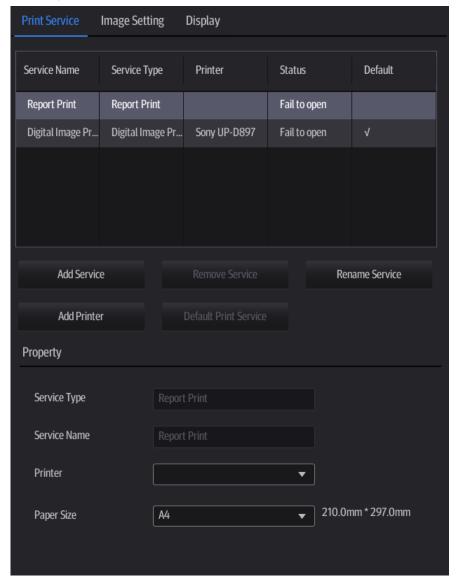
See chapter "C.3 Setting in Ultrasound System" for details.

12.1.9 Peripheral Preset

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

Printer setting

The printer settings include print service and printer driver.



- Print Service Setting
 - ➤ Add Service: tap to begin adding print services.
 - > Remove Service: tap to delete the selected print service.
 - > Rename Service: tap to rename the selected print service.
 - > Default print service: tap to set the selected print service as the default one.
 - ➤ Property: set print service properties for the selected print service from the list above. For details about adding printers (install drivers), see "3.7 Installing a Graph/Text Printer."

Image Settings

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

Display

Tap [Display] to enter the page, you can set output resolution and range for the connected external display.

12.1.10 Maintenance

The [Maintenance] function is designed for you to import or export user data, restore factory setting and export log. You may also execute self-test and option installation/trial through the maintenance menu. If you require other maintenance functions, please contact Mindray Customer Service Department or sales representative.

■ Exporting Setup Data

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

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

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

Procedures:

- 1. Select the target module.
- 2. Tap [Export] to open the [Export Data] screen.
- 3. Select the path to save the data.
- 4. Select the exported file and type as PDP and tap [OK].
- Importing Setup Data

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

Procedures:

- 1. Tap [Import] to open the Load Data screen.
- 2. Select the imported file.
- 3. Tap [OK], a progress bar will appear and the setup data is imported to the specified path.
- 4. To restore the factory setup data, tap [Load Factory] on the right side of the screen.

You can use [Load Factory] at the bottom of the screen to restore all factory setup data of the system.

Other Settings

Туре	Item	Description
Load Factory		Local factory default settings.
	Extract Preset Data	/
	Export Log	Export the log.
	Self-Test	Perform system self-test and restart the machine.
Setup	Enter Windows	For password, please contact your service engineer.
	Pairing Wireless Footswitch	After the wireless footswitch receiver is connected, you need to pair the footswitch before using.
	Recover	To recover the system.

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

12.1.11 iVision

See chapter "10.2.6 iVision" for details.

12.1.12 System Information

This screen displays the system software version and versions of other devices. You cannot edit the information, only view them. The information varies depending on the system configurations and version.

12.2 Exam Related Preset

Select [Setup] -> [Presets] to enter the screen. You can assign exam modes for each probe or set measurement, body mark and annotation settings for current exam mode.

12.2.1 Exam Mode Preset



You can assign available exam modes for probes.

- 1. Select the probe model in the drop-down list beside Probe column.
- 2. Check current configured exam modes:

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

On the right side, you can view the current exam modes assigned to the probe. (Tapping [Probe] on the left side of the operating panel to see the list.)

3. Tap and hold any exam mode until it floats, then you can:

- Drag the exam mode from "Library" column to "Selected" column to make the exam mode available for the probe.
- Drag the exam mode from "Selected" column to "Library" column to make the exam mode unavailable for the probe.
- 4. Change default exam mode or delete user-defined exam mode if necessary:
 - Tap [Delete] to delete a user-defined exam in the Exam Mode Library area. See "5.1.3 Quickly Saving Image Settings" for details about creating a user-defined exam mode.
 - Tap [Default] to set a selected exam mode as the default exam mode. The default exam mode is marked by a " $\sqrt{}$ ".
- 5. Tap [Save] to save the settings or tap [Cancel] to cancel changes you made.

12.2.2 Measurement Preset

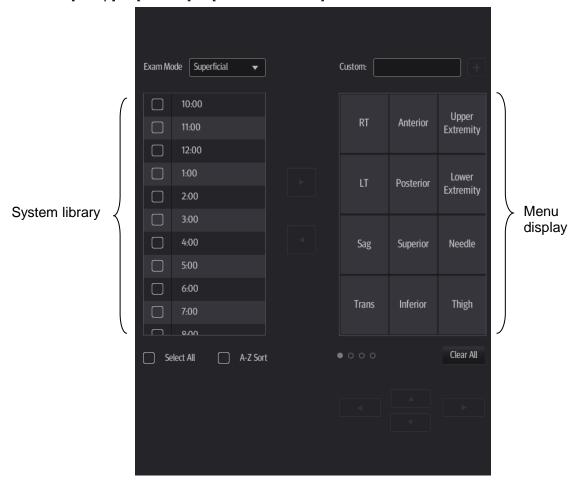
See the Operator's Manual [Advanced Volume] for details.

12.2.3 Comment Preset

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

In Body Mark preset page, you can change the body mark menu for current exam mode. Body Mark preset is similar to Comment preset, here Comment preset is introduced as an example.

1. Select [Setup] -> [Presets] -> [Comment Preset] to enter the screen.



2. Add comments: directly enter user-defined comment texts, or select comment texts for the annotation menu for current exam mode.

- Directly enter user-defined comment texts: tap in the field box besides "Custom", enter the text comment through the soft keyboard, and then tap . Then the directly-entered comment will be added to the menu. Swipe downwards to see more comments.
- Select available items:
 - a) First select a comment library in the drop-down list beside "Exam Mode", all available items will be displayed on the left.
 - b) Tap to add the item from system library on the left into annotation menu on the right.
- 3. Change position of the selected items:
 - Tap an item on the right side box to make it highlighted in blue, and tap the desired position to move the item to the position;
 - Or you can use directional buttons below to make the change.



- 4. Withdraw a comment or delete a user-defined comment:
 - Withdraw an item in the annotation menu:

Select an item in annotation menu on the right, and tap to withdraw it

Delete a user-defined item in the annotation menu:

Select a user-defined item in the annotation menu on the right, and tap

You can only delete the user-defined items rather than the items in the system library.

After a user-defined item is deleted, it will not be available.

5. After you customize comments, tap [Save] to confirm and exit the screen.

12.3 Network Preset

Select [Setup] -> [Network] to enter the screen. You can configure network related settings here, including DICOM setting, iStorage setting and Q-Path setting.

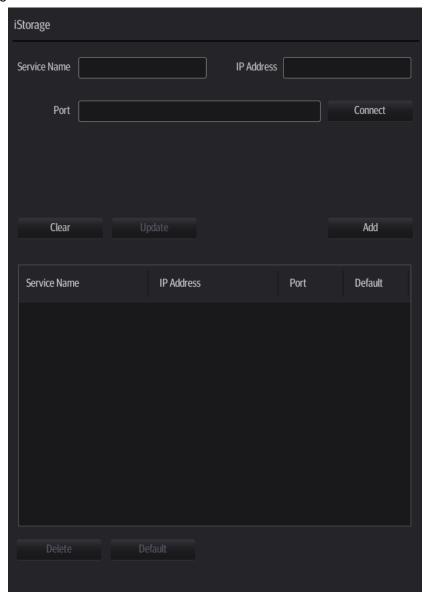
For details of local IP setting, see "11.1.1 IP Preset".

12.3.1 DICOM Local and DICOM/HLP Preset

See "11.1 DICOM Preset" for details.

12.3.2 iStorage Preset

■ The iStorage screen is as follows:



Name	Description
Service Name	The name of the iStorage service.
IP Address	IP address of the iStorage service device.
Port	Port for transmitting.
Connect	Tap to verify connection.
Clear	Clear the information that is being typed in. (service not added yet)
Add	Tap to add the Network service to the service list.
Update	To save the changed parameters.
Delete	Tap to delete the selected service from the service list.
Default	To set the server as the default one.

- Add an iStorage service
- 1. Set the iStorage server properties as described above.
- 2. Tap [Add] to add the service to the service list.
- Modify a network service
- 1. Select the service to be updated in the service list.
- 2. Modify the parameters in the upper part of the screen and tap [Update] to update the setting.

12.3.3 Q-Path

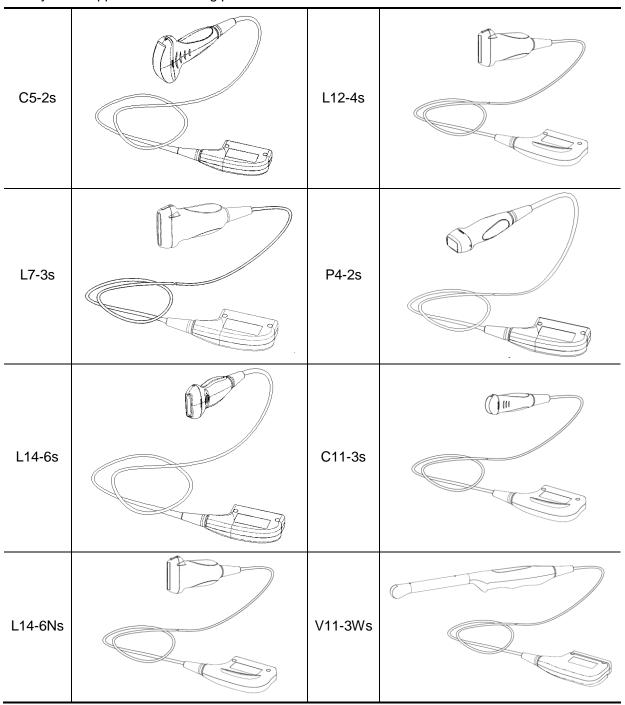
See chapter "10.12 Q-Path" for details.

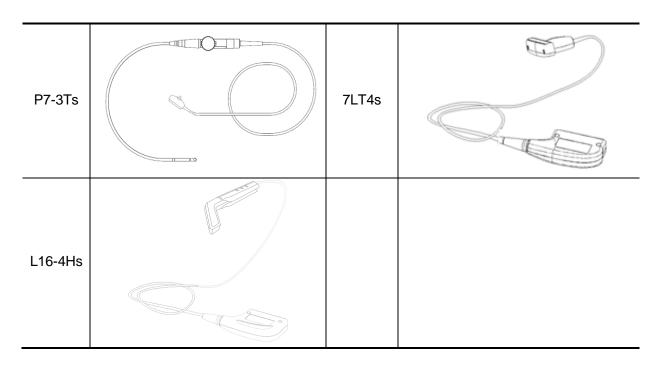
13 Probes and Biopsy

13.1 Probes

NOTE: For details of storage times and conditions for disinfected probes and brackets, refer to the Technical standard for Disinfection of Medical and Health Structures.

The system supports the following probes:

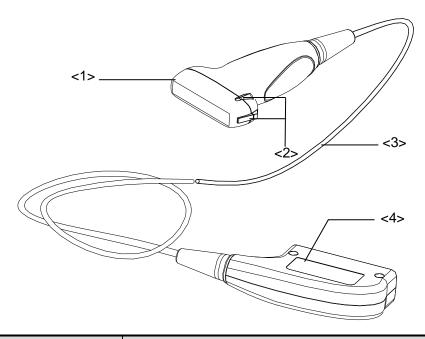




For details of probe P7-3Ts, see P7-3Ts Ultrasonic Transducer Operator's Manual.

13.1.1 Probe Functions by Part

The basic structures and corresponding functions of probes are basically the same. The following takes probe L14-6Ns as an example.



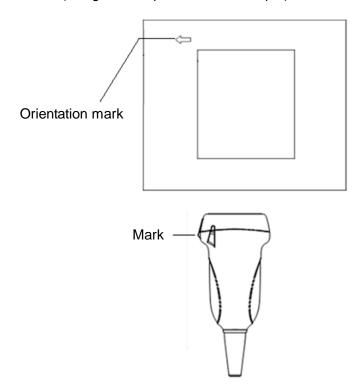
No.	Name	Function
<1>	Probe head	Converts the electrical signal to an ultrasonic signal, focusing the sound beams in a given direction while it receives the reflected ultrasonic signal and converts it to an electrical signal for transmission over the cable. The lens on the surface is the acoustic lens. Apply ultrasound gel to the acoustic lens for correct operation.
<2>	Needle-guided bracket fixing tabs and grooves	Provides mounting support for 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 ultrasound diagnostic system.

Tip:

The probes' structure, marked <2> in the figure above, may vary depending on the corresponding needle-guided brackets.

13.1.2 Orientation of the Ultrasound Image and the Probe Head

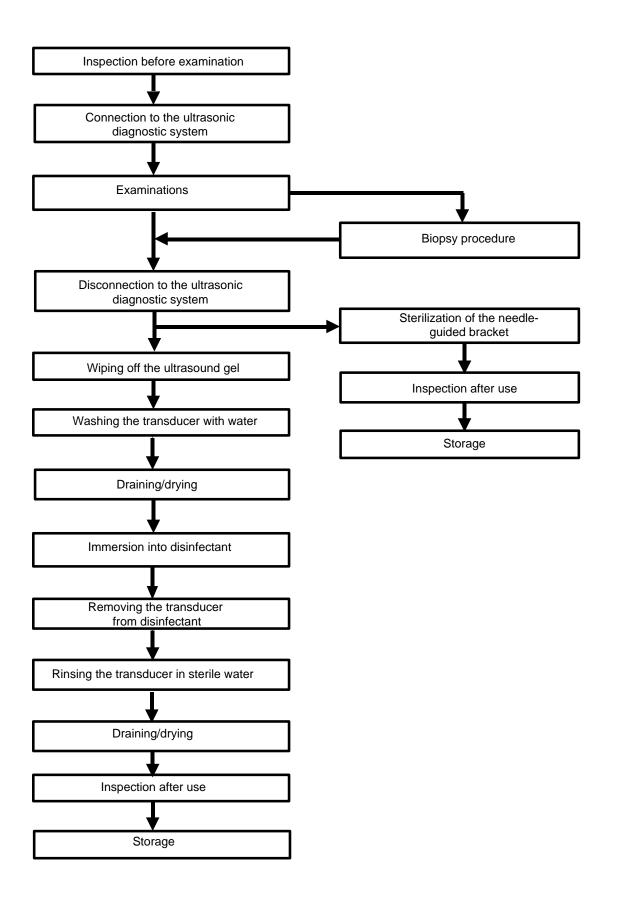
The orientation of the ultrasound image and the probe are shown below. The "Mark" side of the ultrasound image on the display corresponds to the mark side of the probe. Check the orientation prior to the examination (using a linear probe as an example).



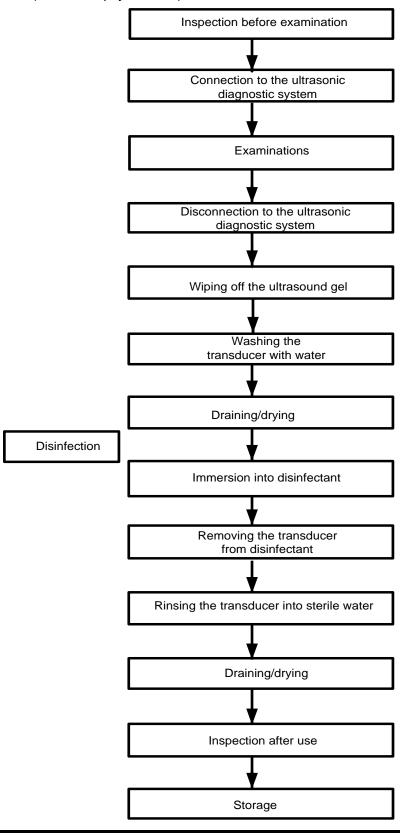
13.1.3 Operating Procedures

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

Operating procedures (with biopsy function):



Operating procedures (with no biopsy function):



△WARNING:

Disinfect the probe and sterilize the needle-guided bracket before and after an ultrasound-guided biopsy procedure is performed. Failure to do so may cause the probe and the needle-guided bracket to become sources of infection.

13.1.4 Wearing the Probe Sheath

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

To order probe sheaths, 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



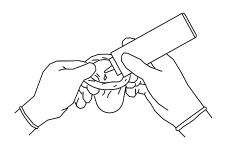
Be sure to cover the probe with a new (unused) probe sheath to prevent infection during examination. If the probe sheath packaging is open or broken, the probe sheath may not be sufficiently sterilized. DO NOT use the probe sheath in such circumstances.

The cover contains natural rubber latex and talc that can cause allergic reactions in some individuals.

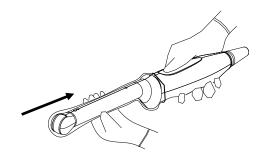
DO NOT use an expired probe sheath. Before using, verify that the probe sheath is within the expiration date.

Method (for reference only):

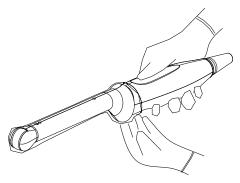
1. Place an appropriate amount of gel inside the sheath or on the probe acoustic lens. Poor imaging may result if no gel is used.



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



3. Secure the sheath with the enclosed elastic bands.



4. Inspect the sheath to ensure there are no holes or tears.

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. Failure to do so may result in the probe and the needle-guided bracket becoming sources of infection. Please follow the instructions in the manual for cleaning.

⚠WARNING:

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

CAUTION:

When performing cleaning and disinfection of the probe to prevent infection, wear sterile gloves.

After disinfection, rinse the probe thoroughly with sterile water to remove all chemical residues. Chemical residues on the probe may be harmful to the human body.

No cleaning and disinfecting may result in the probe becoming a source of infection.

NOTE:

After the examination, wipe off the ultrasound gel thoroughly. Otherwise, the ultrasound gel may solidify and degrade the image quality of the transducer.

DO NOT make the probe overheated (more than 55°C) during cleaning and disinfections. High temperature may cause the probe to become deformed or damaged.

Cleaning

Please refer to the instructions in the manual and follow your hospital policy and procedures for cleaning.

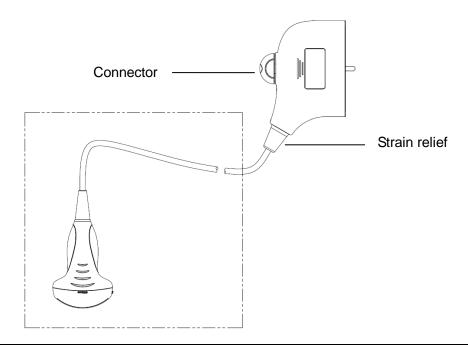
- 1. Disconnect the probe from the system.
- 2. Wear sterile gloves to prevent infection.
- 3. Wash the transducer with clean water or soapy water to remove all the foreign matters, or, wipe the transducer with a soft ethyl carbamate sponge. Avoid using a brush, because it may damage the transducer.
- 4. Dry the transducer using a sterile cloth or gauze after rinsing. Do not dry the transducer by heating it.

Disinfecting with Sprays or Wipes

CAUTION:

Use protective eyewear when disinfecting using sprays.

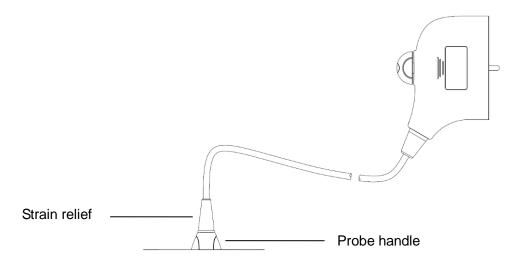
- 1. Wear sterile gloves to prevent infection.
- 2. After you have finished cleaning, wipe or spray the transducer with a disinfectant. Follow the disinfectant manufacturer's recommended contact time and mode.
- 3. Remove any residue with a water-moistened soft cloth on the transducer.
- 4. Wipe off water on the transducer using sterile cloth or gauze after washing.



NOTE: Observe the figure above carefully to perform disinfection. Do not spray the strain relief on the connector end or the connector.

Disinfecting by Immersion

- 1. Wear sterile gloves to prevent infection.
- 2. Clean the transducer before disinfecting it. MINDRAY recommends the following solutions to disinfect the transducer.
 - Refer to the instructions provided by the chemical manufacturer concerning concentration
 of the disinfectant solution, method of disinfection and dilution and cautions during use.
 Do not soak the transducer connector or the cable near it into water or any solution.
 - Soak the transducer into the disinfectant solution for the shortest time the manufacturer recommends (for example, the shortest time recommended by the manufacturer for soaking Cidex OPA is 12 minutes).
 - Follow local regulations when selecting and using the disinfectant.
- 3. Rinse the transducer with plenty of sterile water (about 2 gallons) for at least 1 minute to remove all chemical residues on it. Or, follow the rinsing method recommended by the disinfectant manufacturer to rinse the transducer.
- 4. Wipe off the water on the transducer with sterile cloth or gauze after rinsing it. Do not dry the transducer by heating.



NOTE: Observe the figure above carefully to immerse the transducer. Only soak parts of the transducer below the strain relief.

Compatible Disinfectants

Manufacturer	Trade Name	Procedures	Туре
Pharmaceutical Innovations, Inc.	T-Spray II		Spray*
Parker Laboratories Inc.	PROTEX [™] DISINFECTANT SPRAY		Spray*
Metrex	MetriZyme		Solution*
ASP	Cidex Activated Dialdehyde Solution		Solution
ASP	Cidex OPA	Please refer to the instructions	Solution
Nanosonics Limited	Trophon Sonex-HL (Used with Trophon EPR Ultrasound Probe Disinfector)	provided by the manufacturer of the solution for details.	Solution*
Parker Laboratories Inc.	TRANSEPTIC		Spray*
Parker Laboratories Inc.	PROTEX [™] DISINFECTANT WIPES		Wipe*
Tristel Solutions Limited	Tristel Solo		Spray*

^{■ *} denotes if the disinfectant is not applicable for following probes: P7-3Ts.

See P7-3Ts accompanied manual for P7-3Ts disinfection.

Sterilization

For intra-operative probes (7LT4s), they have to be sterilized after completing each examination.

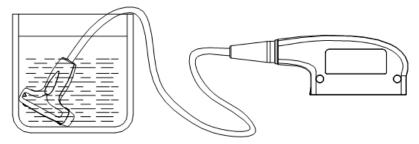
- 1. Wear sterile gloves to prevent infection.
- 2. Clean the probe before sterilizing it. MINDRAY recommends the following solutions to sterilize the probe.

Glutaraldehyde-based sterilization solution

Trade Name	Chemical Name	Procedures
Cidex Activated Dialdehyde	2.4% Glutaraldehyde	Soak the transducer into the activated solution for 10 hours (20-25℃)
Solution		Please refer to the instructions provided by the manufacturer of the solution for details.

Before safety and performance is affected, probe 7LT4s can be sterilized by Cidex Activated Glutaraldehyde Solution for at least 217 times (10 hours for one time).

- Refer to the instructions provided by the chemical manufacturer concerning concentration
 of the sterilization solution, method of sterilization and dilution and cautions during use.
- Do not soak the probe connector or the cable near it into water or any solution.
- Follow local regulations when selecting and using the sterilization solution.
- 3. Rinse the probe with plenty of sterile water (about 2 gallons) for at least 1 minute to remove all chemical residues on it. Or, follow the rinsing method recommended by the sterilization solution manufacturer to rinse the probe.
- 4. Wipe off the water on the probe with sterile cloth or gauze after rinsing it. Do not dry the probe by heating.



Immerse the probe in the solution (take 7LT4s as an illustration)

NOTE: Repeated disinfection may degrade the performance and safety of the probe.

13.1.6 Storage and Transportation

When all examinations for the session have been completed, confirm that the probe is in good condition. After disinfecting the probe, confirm that the probe is still in good condition and stored in a suitable place.

- 1. To prevent the probe from being damaged, DO NOT store it 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 (L12-4s, L14-6Ns, V11-3Ws and C11-3s) under the following ambient conditions:
 - Ambient temperature: -20°C to 55°C
 - Relative humidity: 20% to 95% (no condensation)
 - Atmospheric pressure: 700 hPa to 1060 hPa

Store and transport the probe (C5-2s, L7-3s, L14-6s, P4-2s and 7LT4s) 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 P7-3Ts probe under the following ambient conditions:

- Ambient temperature: -10°C to 45°C
- Relative humidity: 30% to 90% (no condensation)
- Atmospheric pressure: 700 hPa to 1060 hPa

Store and transport the L16-4Hs probe under the following ambient conditions:

- Ambient temperature: 0°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 the MINDRAY Customer Service Department or a 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

\triangle WARNING:

The person performing biopsy procedures must understand diagnostic ultrasound thoroughly and have been adequately trained, otherwise the patient may suffer consequences.

In the situations listed below, the biopsy needle may fail to penetrate the target. Incorrect biopsy may cause various consequences for the patient.

- Using a needle-guided bracket other than that provided.
- Mounting the needle-guided bracket incorrectly.
- Using a biopsy needle that is unsuitable for the type of biopsy being performed.
- Using a biopsy needle that is unsuitable for the needle guide.

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 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 the MINDRAY Customer Service Department or a sales representative.

DO NOT use a needle-guided bracket while scanning is performed. The needle may advance in an incorrect direction and possibly injure the patient.

Never perform a biopsy during image scanning.

DO NOT freeze an image while performing a biopsy procedure.

During biopsy procedures, the needle may deviate from the desired course due to tissue characteristics or the type of needle. In particular, needles with small diameters may deviate to a greater degree.

Disinfect the probe and sterilize the needle-guided bracket before and after each ultrasound-guided biopsy procedure is performed. Failure to do so may cause the probe and the needle-guided bracket to become sources of infection.

The needle mark displayed on the ultrasound image does not indicate the actual position of the biopsy needle. Therefore, it should only be used as a reference. Always monitor the relative positions of the biopsy needle during procedures.

Adjust the needle mark before the biopsy procedure is performed.

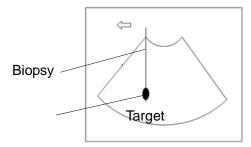
When performing biopsy procedures, only use sterile ultrasound gel that is certified as safe and manage the ultrasound gel properly to ensure that it does not become a source of infection.

When performing an operation involving biopsy, wear sterile gloves.

Image of the biopsy target and the actual position of the biopsy needle:

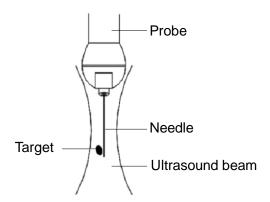
Diagnostic ultrasound systems produce tomographic plane images with information about particular thicknesses in the thickness direction of the probe. (That is to say, the information shown in the images consists of all the information scanned in the thickness direction of the probe.) Therefore, even though the biopsy needle appears to have penetrated the target object in the image, it may not actually have done so. When the biopsy target is small, dispersion of the ultrasound beam may lead to the image deviating from the actual position. Be aware of this.

The target object and 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 in the image. To avoid this, note the points below:

 Do not rely only on the needle tip in the image. Pay careful attention to the fact that when the biopsy needle enters the target object or comes into contact with it, the object should shift slightly.

Before performing the biopsy, evaluate the size of the object and confirm whether the biopsy can be carried out.

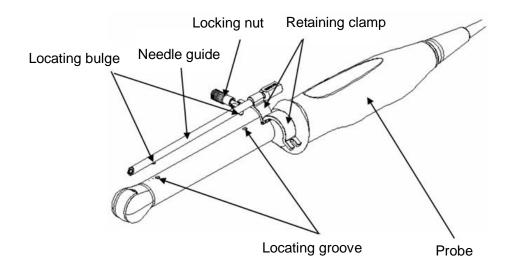
13.2.1 Needle-Guided Brackets

Needle-guided brackets are available for purchase as optional accessories and are used in combination with the probe. Some probes have corresponding needle-guided brackets and needles. To order needle-guided brackets, contact the MINDRAY Customer Service Department or a sales representative.

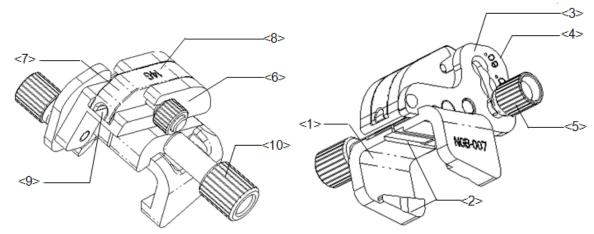
For biopsy or treatment, ultrasound-guided biopsy procedures can be performed using the probe together with a needle-guided bracket (optional accessory) and a biopsy needle (provided by the user).

Names of Parts

This section describes the parts and corresponding functions of each needle-guided bracket. Here, we take a corresponding probe as an example.

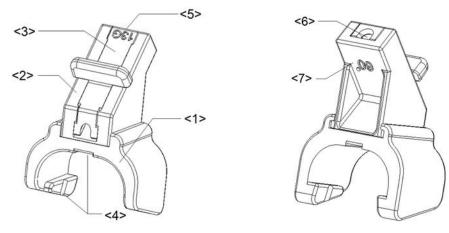


NGB-007 Metal/needle detachable needle-guided bracket:

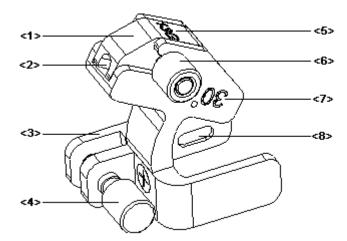


No.	Name	Description
<1>	Support for needle- guided bracket	Used for installing the needle-guided bracket on the probe.
<2>	Tab and groove for the needle-guided bracket	Corresponding to the tab and groove of the probe.
<3>	Angle-adjusting base	There are 3 types of angles available for adjustment.
<4>	Angle shift sign (40°, 50°, 60°)	Corresponding to 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 needles. There are five guiding block specification for different biopsy needles.
<8>	Guiding block specification (14G)	Matched with the corresponding biopsy needle (14G).
<9>	Needle guide hole	Used for installing the biopsy needle.
<10>	Needle-guided bracket pinch nut	Used for locking the needle-guided bracket and the probe.

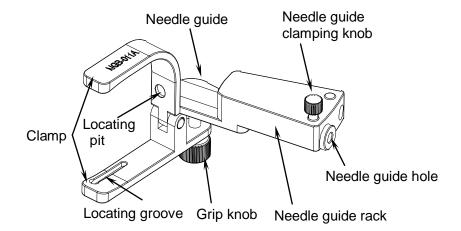
Plastic/needle detachable needle-guided bracket:

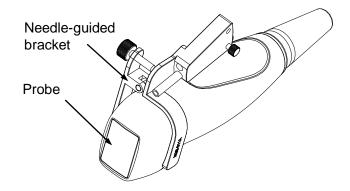


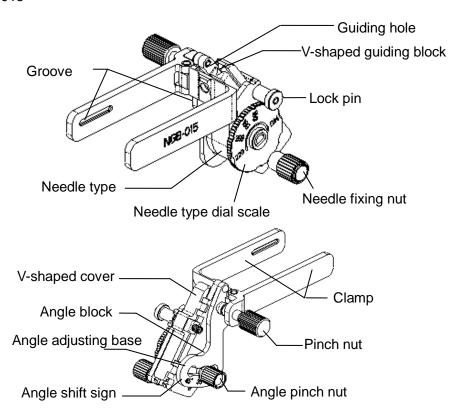
No.	Name	Description
<1>	Support for needle- guided bracket	Used for installing the needle-guided bracket on the probe.
<2>	Angle block	Used for determining the angle of the biopsy. There are three angle block specifications.
<3>	Guiding block	Used for installing biopsy needles. There are five guiding block specification for different biopsy needles.
<4>	Tab and groove for the needle-guided bracket	Corresponding to the tab and groove of the probe.
<5>	Guiding block specification (13G)	Matched with the corresponding biopsy needle (13G).
<6>	Biopsy needle guiding hole	Used for installing the biopsy needle.
<7>	Angle block specification (60°)	The corresponding biopsy angle is 60°.

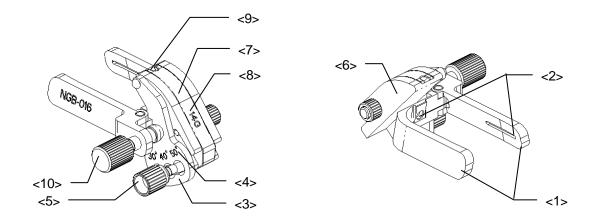


No.	Name	Description
<1>	Guiding block	Used for installing biopsy needle; there are five specifications of guiding blocks for different biopsy needles.
<2>	Guiding hole of the biopsy needle	Used for installing the biopsy needle.
<3>	Support of needle- guided bracket	Used for installing the needle-guided bracket on the probe.
<4>	Knob of fixing needle- guided bracket	Used for fixing the needle-guided bracket on the probe.
<5>	Specification of guiding block (13G)	Matched with the corresponding biopsy needle (13G).
<6>	Knob of fixing the guiding block	Used for fixing the guiding block.
<7>	Needle guide angle	The needle guide angle of this needle-guided bracket.
<8>	Grooves of the needle-guided bracket	Matched with the tabs of the probe.



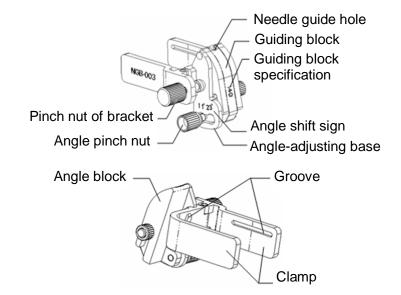






No.	Name	Description
<1>	Clamp of needle-guided bracket	Used for installing the needle-guided bracket on the transducer.
<2>	Groove of the needle- guided bracket	Matches with the tab of the transducer.
<3>	Angle adjusting base	There are 3 types of angles available to be adjusted.
<4>	Angle shift sign (30°, 40°, 50°)	Matches with the biopsy angle (30°, 40°, 50°).
<5>	Angle pinch nut	Used for fixing the angle lock at a chosen angle.
<6>	Angle block	Determines the angle of the biopsy; different specifications of blocks can be used.
<7>	Guiding block	Used for installing the needles of different specifications, 5 types of needles are available.
<8>	Specification of guiding block (14G)	Matched with the corresponding biopsy needle (14G).
<9>	Guiding hole of biopsy needle	Used for installing the needles.
<10>	Pinch nut of needle- guided bracket	Used for locking the needle-guided bracket and the transducer.

■ NGB-018



13.2.2 Basic Procedures for Biopsy Guiding

- 1. Select the correct needle-guided bracket and needle and install them properly. For details, see "13.2.3 Needle-Guided Bracket Inspection and Installation."
- 2. Verify the biopsy guide line. See chapter "13.2.6 Verifying the Biopsy Guide Line" for details.
- 3. Tap [Biopsy] to enter the biopsy.

Tips:

- If the current probe has no corresponding bracket, or the image is frozen and the guide line was hidden before the image was frozen, then you cannot enter the Biopsy menu.
- Before entering the Biopsy menu, the system will display the prompt "Please verify guidelines before biopsy."
- 4. Select the bracket and guide line according to the actual situation.
- 5. In the Biopsy menu, tap [Alignment] to enter the Verify menu to verify the guide line. After verification, tap [Save] to save the parameter setting. Then tap [Exit] to return to the Biopsy menu.

Tips:

- If you changed the probe or needle-guided bracket during the biopsy, verify the guide line again.
- When exiting the Verify menu without saving, the system will display the prompt "Data have changed. Do you want to save the changes?" Tap [Yes] to save the setting and return to the 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 extracting the biopsy sample, gently remove the probe from the body. To exit the Biopsy menu: tap [Biopsy].
- 9. Disassemble the items and properly dispose of these items as required.

\triangle DANGER:

Failure to match the guidezone displayed to the guide may cause the needle to track a path outside the zone.

It is extremely important that when using the adjustable angle biopsy guides, the angle displayed on the screen matches the angle set on the guide, otherwise the needle will not follow the displayed guidezone and this 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 using the needle-guided bracket. If an abnormality is found on the needle-guided bracket, immediately stop using it and contact the MINDRAY Customer Service Department or a sales representative.

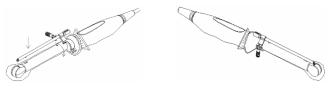
- 1. Sterilize the needle-guided bracket before and after use.
- 2. Confirm that the needle-guided bracket is free from damage, deformation, stripping, malfunction, loose or missing parts.
- 3. Confirm that the needle-guided bracket is securely mounted in the correct position.

13.2.3.2 Installing the Needle-Guided Bracket

- NGB-004
- 1. Put the sterile probe sheath on.



2. Open the retaining clamp, align the needle-guided bracket with the probe to align the locating bulge on the needle guide with the locating grooves on the probe, then turn the retaining clamp to align it with the probe (see the figure below).



3. When the retaining clamp is turned to the correct position, the locking nut will lock the retaining clamp and the needle-guided bracket is then mounted in the correct position.

■ NGB-007

Metal/needle detachable needle-guided bracket:

- 1. Put the sterile probe sheath on.
- 2. Hold the probe in one hand, select the correct needle-guided bracket and hold it with the other hand. Match the groove and tab with the tab and groove of the probe respectively. Mount the bracket onto the probe.





- 3. Screw the pinch nut of the needle-guided bracket to ensure that the needle-guided bracket is properly installed on the probe.
- 4. Select a suitable guiding block and push it into the groove above the angle block, then clamp it tightly.





- 5. Screw the block's nut to secure the block.
- 6. Insert a biopsy needle with the same specification as that of the guiding block into the guiding block hole.



Plastic needle-guided bracket:

- 1. Put the sterile probe sheath on.
- 2. Hold the probe in one hand, select the correct needle-guided bracket and hold it with the other hand. Align the tab at the narrow end of the needle-guided bracket with the groove of the probe, then push the needle-guided bracket forward, so the tabs and grooves of the needle-guided bracket align 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 suitable guiding block and push it into the groove above the angle block, then clamp it tightly.





5. Insert a biopsy needle with the same specification as that of the guiding block into the guiding block hole.

■ NGB-010

- 1. Put on the probe cover.
- 2. Hold the probe by one hand, select proper needle-guided bracket, and hold it with the other hand, and align the grooves of the needle-guided bracket with the tabs of the probe, then push the needle-guided bracket forward, making the grooves of the needle-guided bracket to match with the tabs of the probe. Set the needle-guided bracket at the desired position, turn tightly the knob of fixing needle-guided bracket to fix the needle-guided bracket.



- 3. Check manually to confirm the needle-guided bracket is securely installed on the probe.
- 4. Select a proper guiding block and push it into the groove above the support of needle-guided bracket, then turn tightly the knob of fixing the guiding block to fix the guiding block on the support of needle-guided bracket.



- 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. Connect the locating groove on the clamp with the two raised edges on the probe head and align the locating pit of the clamp with the convex point on the probe head.
- 2. Turn the grip knob at the tail of the needle-guided bracket tightly.
- NGB-015
- 1. Put on the sterile transducer 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-016
- 1. Put on the transducer sheath.

2. Select a proper needle-guided bracket, and match the groove with the tab of the transducer. Mount the bracket onto the transducer.





- 3. Screw the pinch nut of the needle-guided bracket to confirm that the needle-guided bracket is properly installed on the transducer.
- 4. Select the appropriate guiding block, and fit it into the groove on the angle block.





- 5. Screw the nut on the guiding block to secure the guiding block with the needle-guided bracket.
- 6. Insert the needle of the same specification with that of the guiding block into the guiding hole.



- NGB-018
- 1. Put the sterile probe sheath on.
- 2. Select a suitable needle-guided bracket and match the groove to the tab of the transducer. Mount the bracket onto the transducer. The needle-guided brackets may be different from each other, but the methods are the same.



- 3. Screw the pinch nut of the needle-guided bracket to ensure that the needle-guided bracket is properly installed on the transducer.
- 4. Select a suitable guiding block and push it into the groove above the angle block.



- 5. Screw the block's nut to secure the block.
- 6. Insert a biopsy needle with the same specification as that of the guiding block into the guiding block hole.

 \triangle CAUTION:

Ensure that all guide parts are properly fixed prior to performing a biopsy.

13.2.4 Biopsy Menu

Tap [Biopsy] from the right side of the operating panel (you may need to swipe downwards to see the button) to enter Biopsy and tap [Image] to open the biopsy menu.



- Select the biopsy bracket angle/guide line

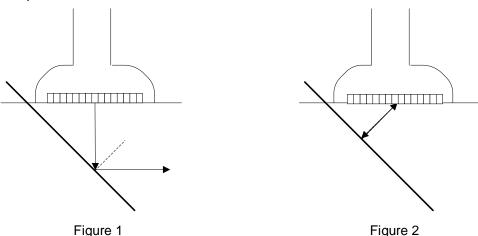
 If the needle-guided bracket supports more than one biopsy angle, select the angle/guideline by tapping the drop-down list [NGB-XXX-XX] (last two letters are angle or the guide line).
- Select the guide line dot size
 Use [Dot Size] to select the dot size from Small, Medium and Big.

13.2.5 iNeedle (Needle Visualization Enhancement)

During a biopsy, the metal needle attached to the probe pierces the tissue at a certain angle. Due to the needle's acoustic impedance, the ultrasonic beam cannot penetrate the metal needle and a reflecting boundary is formed. As in Figure 1, if the deflection angle is very large, the needle display is not clear.

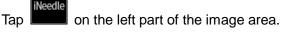
In deflected ultrasound transmission, the beam direction is perpendicular to the needle direction and the reflection direction is the same as the needle, as shown in Figure 2, meaning the needle display in the ultrasound image is very clear. The system provides additional deflection transmission that is approximately perpendicular to the metal needle when the normal transmission (perpendicular to the transducer surface) is being processed. The deflection angle can be chosen by the user.

iNeedle is an option.



To enter/exit iNeedle

To enter iNeedle



■ To exit iNeedle

Tap [iNeedle] again or tap [B] to enter B mode.

Best angle indication



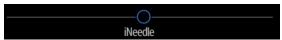
In iNeedle mode, recommended needle angle is given on the top of the screen. As shown in the above figure, the current recommended angle is 50° to the horizontal plane.

Needle Steer

Description This function adjusts the biopsy needle angle by changing the steer angle of the

scan line. The iNeedle region changes correspondingly.

Operation Use the control bar under the image to change the angle:



Click the bar to change by 10 increment;

Or, drag the control directly to make slight changes.

B/iNeedle

Description This function is used to display the B image and iNeedle image synchronously.

Operation Tap [Image] to open the menu and use [B/iNeedle] control to turn on/off the

function.

Verify

To verify the biopsy guide line, see chapter "13.2.6 Verifying the Biopsy Guide Line" for details.

13.2.6 Verifying the Biopsy Guide Line

 \triangle WARNING:

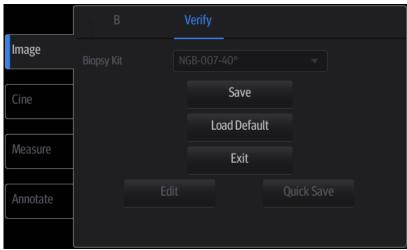
Prior to each biopsy procedure, be sure to verify the guide line.

If the needle is not consistent with the guide line, DO NOT perform the biopsy procedure.

NOTE: You can perform guide line verification on a single live B/C image, and all biopsy-irrelevant operations are forbidden.

Adjusting the needle mark is necessary before each biopsy procedure.

- 1. Confirm that the needle-guided bracket has been installed securely in the correct position.
- 2. Prepare a container filled with sterile water.
- 3. Place the head of the probe in the sterile water and place a biopsy needle in the needle guide.
- 4. When the biopsy needle appears on the image, select [Biopsy] -> [Alignment] to align the guide line with the biopsy needle.



Tap [Alignment] in the Biopsy menu to enter the Biopsy Verify menu.

Adjust the guide line position

Tap and drag the top dot on the line to change the position of the guide line.

Adjust the angle

Tap and drag the bottom dot on the line to change the guide line angle.

Save the verified settings

After the position and angle of the guide line are adjusted, tap [Save] and the system saves the current guide line settings. If biopsy is entered again, the displayed Position and Angle are the verified value.

Restore the factory default settings

Tap [Load Default] and the position and angle of the guide line are restored to the factory default settings.

Exit biopsy verify status

Tap [Exit] and the system exits the guide line verification status.

13.2.7 Removing the Needle-Guided Bracket

■ NGB-004

Hold the probe in your left hand. Unscrew the locking nut with your right hand to open the retaining clamp, then raise the needle-guided bracket to separate the locating bulge from the locating grooves.

■ NGB-007

- Metal needle-guided bracket:
 - a) Loosen the guiding block's nut and slightly move the guiding block in the direction of the needle's tail.
 - b) Separate the residual part of the needle-guide bracket and the probe from the needle.
 - c) Loosen the bracket's pinch nut and remove the needle-guided bracket from the probe.
- Plastic needle-guided bracket:
 - a) Slightly move the guiding block in the direction of the needle's tail.
 - b) Separate the residual part of the needle-guide bracket and the probe from the needle.
 - c) Remove the needle-guided bracket support from the probe.

■ NGB-010

- 1. Remove the guiding block slightly along the direction of the needle's tail, and separate the residual part of the needle-guide bracket and the probe from the needle.
- 2. Remove the support of needle-guided bracket from the probe.
- NGB-011

Hold the probe and the needle-guided bracket, 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-016
- 1. Unscrew the nut on the guiding block to release the biopsy needle.





- 2. Remove the guiding block in the direction of the needle tail, and then remove the needle.
- 3. Screw the pinch nut of the bracket to release the needle-guided bracket.





4. Separate the transducer and the needle-guided bracket.

■ NGB-018

1. Loosen the guiding block's nut and slightly move the guiding block in the direction of the needle's tail.





- 2. Separate the residual part of the needle-guide bracket and the transducer from the needle.
- 3. Loosen the bracket's pinch nut and remove the needle-guided bracket from the transducer.





13.2.8 Clean and Sterilize the Needle-Guided Bracket

Cleaning

Follow the cleaning instructions in the manual.

- 1. Wear sterile gloves to prevent infection.
- 2. Wash the needle-guided bracket with water or soapy water to remove all external material. Or, clean the needle-guided bracket with a urethane sponge.
- 3. After washing, dry the needle-guided bracket using sterile cloth or gauze.

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 for sterilizing the needle-guided bracket.
- 3. Follow local regulations when selecting and using disinfectant.
- Glutaraldehyde-based sterilant:

Chemical name	Trade name	Procedures
Glutaraldehyde (2.2-2.7%)	Cidex Activated Glutaraldehyde Solution	Refer to the instructions provided by the solution manufacturer for details.

The plastic bracket NGB-007 can be sterilized using Cidex Activated Glutaraldehyde Solution at least 233 times (10 hours per time) before its safety and performance is affected.

■ Hydrogen Peroxide and Peroxyacetic Acid based sterilant:

Trade Name	Chemical Name	Procedures
Minncare [®] Cold Sterilant	22% Hydrogen Peroxide 4.5% Peroxyacetic Acid	Refer to the instructions provided by the solution manufacturer for details.

The plastic bracket NGB-007 can be sterilized using Minncare COLD STERILANT at least 245 times (11 hours per time) before its safety and performance is affected.

- Refer to the instructions provided by the chemical manufacturer concerning concentration
 of the solution, and disinfection and dilution methods. Note that glutaraldehyde
 disinfectant solution requires an activating solution.
- Rinse the needle-guided bracket thoroughly with sterile water to remove all chemical residues from it.
- After rinsing, dry the needle-guided bracket with sterile cloth or gauze.
- STERRAD 100S low-temperature hydrogen peroxide gas plasma sterilization system

Chemical name	Trade name	Procedures
Hydrogen peroxide gas plasma	Hydrogen peroxide vapor	Refer to the instructions provided by the solution producer for details.

- Refer to the STERRAD 100S sterilizing system's instructions 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 brackets)
Autoclaving (moist heat) 121°C for 20 minutes.

NOTE: Repeated sterilization may degrade the safety and performance of the needle-guided bracket.

High-pressure steam/immersion sterilization does not affect a bracket's life duration. The life duration is affected by the bracket's daily application. Please check the appearance of the bracket before use.

13.2.9 Storage and Transportation

- 1. Do not use the carrying case for storing the needle-guided bracket. If the carrying case is used for storage, it may become a source of infection.
- 2. Between examinations, keep the needle-guided bracket in a sterile environment.
- 3. If the needle-guided bracket is sent to your MINDRAY representative for repair, be sure to disinfect or sterilize it and keep it in the carrying case to prevent infection.
- 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)

13.2.10 Disposal

Be sure to sterilize the needle-guided bracket before disposing of it.

Contact your MINDRAY representative when disposing of this device.

14 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 device operators pertaining to acoustic output and how to control patient exposure through use of the ALARA (as low as reasonably achievable) principle. This section also contains information regarding acoustic output testing and real-time output display.

Read this information carefully before using the system.

14.1 Concerns with Bioeffects

Diagnostic ultrasound is recognized as being safe. There have been no reports of injuries to patients caused by diagnostic ultrasound.

However, 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.

14.2 Prudent Use Statement

Although there are no confirmed biological effects on patients caused by exposure 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 the necessary clinical information.

14.3 ALARA Principle (As Low As Reasonably Achievable)

The ALARA principle must be practiced 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 the quality of the 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 the output power of ultrasound must be selected based on the ALARA principle.

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) entitled "Medical Ultrasound Safety."

14.4 MI/TI Explanation

14.4.1 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 at present. It is recognized that two fundamental mechanisms may induce bioeffects. One is a thermal bioeffect involving tissue absorption of ultrasound, and another 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. They DO NOT consider the cumulative effects of the total examination time. TI and MI models contain practical simplifications for complex bioeffect interactions. The operator must 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 can be referred to as cavitations.

MI is an index that shows the possibility of cavitation generation based on acoustic pressure, and the value at which the peak rarefactional acoustic pressure is divided by the square root of the frequency. Therefore, the MI value becomes smaller when the frequency is higher or the peak rarefactional acoustic pressure is lower, and it becomes more difficult to generate the cavitations.

$$MI = \frac{P_{r, \alpha}}{\sqrt{f_{amf}} \times C_{MI}}$$

$$C_{MI} = 1 \text{ (MPa } / \sqrt{\text{MHz}} \text{)}$$

For the frequency 1 MHz and the peak rarefactional acoustic pressure 1 MPa, MI becomes 1. It is possible to consider MI as one threshold of cavitation generation. It is particularly important to keep the MI value low when both gases and soft tissues exist together, such as with lung exposure in cardiac scanning and bowel gas in abdominal scanning.

■ TI (Thermal Index)

The TI is determined by the ratio of the total acoustic power to the acoustic power required to raise the tissue temperature by 1°C. In addition, because the raise in temperature can be greatly different according to tissue structures, TI is divided into 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) applications, in which the ultrasound beam passes through soft tissue and the 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 increases of 4°C for 5 minutes or more should be considered as potentially hazardous to embryonic and fetal tissue.

The smaller the MI/TI values, the lower the bioeffects.

14.4.2 MI/TI Display

TI and MI values are displayed in the top part of the screen in real time by preset (see chapter "12.1 System Preset" for details.) The operator should monitor these index values during examinations and ensure that exposure time and output values are maintained at the minimum amounts required for effective diagnosis.

NOTE: If a value of MI or TI exceeds 1.0, the ALARA principle must be practiced.

The display precision is 0.1.

Display accuracy of MI is \leq 14.7%, and TI is \leq 28.5%.

14.5 Acoustic Power Setting

Acoustic power adjustment

Use the [A.power(%)] on the image menu to adjust the acoustic power percentage. Its value is displayed on the corresponding item, as well as on 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 acoustic power setting

Selection of diagnostic applications is the most important factor in 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.

Within this system, imaging setups can be created using the ultrasound output set by you.

Once you set the preset settings, the system's default setting values may be changed and invalid. The user is responsible for any change to the default settings.

Adjusting range

Initial power: 3.2% to 100%*

Definition of 100%: the maximum acoustic power of a probe determined by the increase in probe surface temperature in the selected mode and the acoustic power restrictions specified by the FDA.

Default settings of the acoustic power value refer to the best image quality for the probe. The larger the acoustic power value, the better the image quality.

NOTE:

This system automatically returns to the settings whenever changes are made to the values (when you turn on the power, switch between probes, tap [End] in the bottom-left corner of the operating panel, or select [Save] or [Cancel] in the preset menu). In the factory default settings, the Acoustic Output is limited to below 100%. Following the ALARA restriction, you are allowed to increase the acoustic power under FDA 510(k) Guidance-Track 3 limits and to set it in the image preset screen.

The system's acoustic output 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).

14.6 Acoustic Power Control

A 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 relating to output. They are:

- Controls that have direct effect on the output
- Controls that indirectly control the 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 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/cm² in any mode of operation.

■ Indirect controls

The controls that indirectly affect output are the many imaging parameters. These are operating modes, frequency, focal point positions, overall depth and PRF.

The operating mode determines whether the ultrasound beam is scanning or non-scanning. Thermal bioeffect is closely connected to M mode, Doppler and Color mode. Acoustic attenuation of tissue is directly related to probe frequency. The focal point is related to the active aperture of the probe and beam width. For higher PRF (pulse repetition frequency), the more output pulses occur over a period of time.

Receiver controls

The receiver controls (for example, gain, dynamic range and image post-processing, etc.) do not affect output. These controls should be used, when possible, to improve the image quality before using controls that directly or indirectly affect output.

14.7 Acoustic Output

14.7.1 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 ultrasound intensity 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.

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.

14.7.2 Limits of Acoustic Output

In accordance with the FDA Track 3 requirements, the derating (or attenuated) approach was incorporated into the FDA Acoustic Output Limits, as listed below. The maximum acoustic output level from any probe in any operating mode is expected to fall below these limits.

FDA Maximum Acoustic Output Limits for Track 3 (Attenuated Values)

Application	I _{spta.3} (mW/cm ²)	I _{sppa.3} (W/cm ²)		MI
Regions (except eyes)	≤ 720	≤ 190	or	≤ 1.9

14.7.3 Differences between Actual and Displayed MI and TI

In operation, the system will display the Acoustic Output Parameters Thermal Index (TI) or Mechanical Index (MI) (or sometimes both parameters simultaneously) to the operator. 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 system setting 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 is indicated. However, the Thermal Index is not the same as the raise in temperature in the body, for several reasons. First of all, in order to provide a single display index, a number of simplifying assumptions had to be made. The biggest assumption was the use of the attenuating formula described above, which is much lower than the actual value for most tissues within the body. Scanning through muscle or organ tissue, for example, will produce much higher attenuation than 0.3 dB/cm/MHz. Significant simplifications were also made for the thermal properties of tissue. Therefore, scanning through highly-perfused tissue, such as the heart or vasculature, will produce significantly less thermal effect than that suggested by the Thermal Index.

Similarly, the Mechanical Index was derived to indicate the relative possibility of mechanical (cavitation) effects. The MI is based on the derated peak rarefactional pressure and the center frequency of the ultrasound wave. The actual peak rarefactional pressure is affected by the actual attenuation caused by tissue in the path between the probe and the focal point. Again, all solid tissues within the body have higher attenuation than the prescribed 0.3 dB/cm/MHz value, and therefore, the actual peak rarefactional pressure will be lower. Further, the actual peak rarefactional pressure will change depending on 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.

14.8 Measurement Uncertainty

The total estimated measurement uncertainty (where the total uncertainty includes uncertainties in hydrophone response, measurement, calculation and positioning) are:

Ispta	28.5%
I _{sppa}	28.5%
Center frequency (f _C)	2%
Total power (W)	28.5 % (5.1% for Scan-mode and Combined-mode)
Rarefactional pressure (pr)	14.7%

14.9 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

15 Guidance and Manufacturer's Declaration

The system complies with the EMC standard IEC 60601-1-2: 2007.

Δ WARNING:

- 1. The use of unapproved accessories may diminish system performance.
- 2. Use of components, accessories, probes, and cables other than those specified may result in increased emission or decreased immunity of system.
- The system or its components should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the system or its components should be observed to verify normal operation in the configuration in which it will be used.
- 4. Operation of system, in the case that the patient physiological signal is lower than the minimum amplitude or value specified in the product specifications, results may not be obtained (results can be obtained when the HR is in the range of 30-250 bmp or when the QRS wave amplitude is between 0.5-5 mV.)

NOTE: 1

- 1 The system needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.
- 2 Other devices may interfere with this system even though they meet the requirements of CISPR.
- 3 Preventing conducted RF immunity. Due to technological limitations, the conducted RF immunity level are limited to 3Vrms level, conducted RF interference above 3Vrms may cause wrong diagnosis and measurements. We suggest that you position system further from sources of conducted RF noise.
- 4 Portable and mobile RF communications equipment can affects system. See tables 1, 2, 3, and 4 below.

If the system is operated within the electromagnetic environment listed in Table 2 and Table 3, the system will remain safe and will provide the following basic performances:

- Imaging;
- Doppler acoustic spectral displaying:
- Taking measurements;
- Patient information:
- Date/time information.

TABLE 1

GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC EMISSIONS

The system is intended for use in the electromagnetic environment specified below. The customer or the user of system should assure that it is used in such an environment.

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIROMENT— GUIDANCE
RF emissions CISPR 11	Group 1	The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and the possibility to cause interference in nearby electronic equipment is minimal.
RF emissions CISPR 11	Class B	The system is suitable for use in all
Harmonic Emissions IEC 61000-3-2	Class A	establishments including domestic establishments and those directly connected to the public low-voltage
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Compliance	power supply network that supplies buildings used for domestic purposes

TABLE 2

GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC IMMUNITY

The system is intended for use in the electromagnetic environment specified below. The customer or the user of system should assure that it is used in such an environment.

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_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 $	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.

TABLE 3

GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC IMMUNITY

The system is intended for use in the electromagnetic environment specified below. The customer or the user of system should assure that it is used in such an environment.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT-GUIDANCE
Conduced RF IEC 61000-4-6	3 Vrms 150 kHz - 80 MHz	3 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 $d=3.5\ x\ \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80MHz - 2.5GHz	3 V/m	$d = 1.2 \times \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \times \sqrt{P}$ 800 MHz to 2.5GHz Where, P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:
			following symbol:

Note 1 At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular /cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which system is used exceeds the applicable RF compliance level above, system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the system.

TABLE 4

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATION DEVICE AND THE SYSTEM

The system is intended for use in an electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and system as recommended below, according to the maximum output power of the communication equipment.

Rated Maximum Output power of	Separation Distance According to Frequency of Transmitter (m)			
Transmitter	150kHz -80MHz	80MHz-800MHz	800MHz-2.5GHz	
(W)	d=1.2√P	d=1.2√P	d=2.3√P	
0.01	0.12	0.12	0.23	
0.1	0.38	0.38	0.73	
1	1.2	1.2	2.3	
10	3.8	3.8	7.3	
100	12	12	23	

For transmitters at a maximum output power not listed above, the recommended separation distanced in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

If system image distortion occurs, it may be necessary to position system further from sources of conducted RF noise or to install external power source filter to minimize RF noise to an acceptable level.

Note 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Cable sample

No.	Name	Cable length (m)	Shield or not	Remarks
1	AC inlet cable for the main	2.5	Not shielded	/
	unit			
2	AC inlet cable for the trolley	2.5	Not shielded	/
3	Foot-switch control cable	2.8	Not shielded	/
4	Probe cable	2.2	Shielding	/
5	ECG Lead	1.4	Not shielded	/

16 System Maintenance

Routine system maintenance shall be carried out by the user. System maintenance after the warranty has expired is the full responsibility of the owner/operator.

The responsibility for maintenance and management of the product after delivery resides with the customer who has purchased the product.

If you have any questions, please contact the Mindray Customer Service Department or a sales representative.

≜WARNING:

Only an authorized Mindray service engineer can perform maintenance which is not specified in this operator's manual.

For the sake of system performance and safety, perform periodical checks of the system.

16.1 Daily Maintenance

You are responsible for daily maintenance.

16.1.1 Cleaning the System

⚠WARNING:

Before cleaning the system, be sure to turn off the power and disconnect the power cord from the outlet. Cleaning the system while the power is "On" may result in electric shock.

DO NOT directly spray solution onto the display, system display or hard surfaces that are under pressure or pumped. Ingress fluid leakage into the display or system can damage the display or system, causing possible electric shock or system failure.

△ CAUTION:

Do not spill water or other liquids into the system while cleaning. This may result in malfunction or electric shock.

NOTE:

DO NOT use hydrocarbon glass cleaner or cleaner for OA (Office Automation) equipment to clean the display. These substances may cause deterioration of the display.

Cleaning the probe

Tools: mild soapy water, soft dry cloth, soft brush

- 1. Wipe away dust attached to the surface of the probe head, connector and cable.
- 2. Use a soft brush to gently brush away dust from inside the probe connector.

3. Remaining stains or dust attached to the surface of the cable or connector should be wiped away using a cloth with a little soapy water and then air dried.

NOTE: Do not use a wet cloth to clean the probe connector.

- Cleaning the probe cable
- 1. Use a soft dry cloth to wipe away stains from the probe cable.
- 2. If the stains are difficult to remove, use a soft cloth dipped in a mild detergent and then let the cable air dry.
- Cleaning holders

Tools: soft dry cloth, soapy water, soft brush

The surface of the power button should be cleaned with a soft dry cloth. Remaining stains should be wiped away using a cloth with clean or soapy water (NOTE: the cloth should not be made too wet, as this may cause electric shock) and the surface left to air dry.

- 1. Use a soft dry cloth to wipe away dust attached to the inside, outside and gaps in the probe holder or gel holder. Use a soft brush to brush away dust or stains from the small intra-cavity probe holder or its gap.
- 2. Remaining stains on the inside and outside of the holder should be wiped away using a cloth with a little soapy water and then air dried.
- Cleaning the display

Tools: soft dry cloth, alcohol or neutral detergent.

Clean the system in power off status; or in power on status, tap in the top-right corner of the screen and select to lock the system for 10 seconds.

Clean the display surface with a soft dry cloth. Remaining stains should be wiped away using a cloth with a little neutral detergent or alcohol and then leave to air dry.

NOTE: Do not use chemical solvents, acid or alkaline solution to clean the display.

Cleaning the cover

Tools: soft dry cloth, soapy water

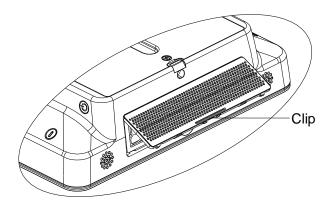
Use a soft dry cloth to clean the system's cover. If the system is dirty, moisten the soft cloth with mild soapy water, wipe away any stains, then air dry.

∆CAUTION:

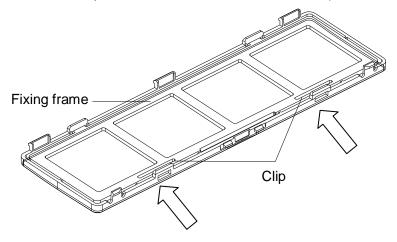
Please clean all the system's dustproof covers periodically (once per month). Failure to do so may result in system damage. Cleaning times can be increased when the system is used in the open air or somewhere more dusty.

NOTE: Use a soft brush to brush away dust attached to all visible sockets or interfaces (such as probe sockets, sockets or interfaces in the IO panel and power supply panel). Do not use a cloth and water.

- Dust-proof cover cleaning
- 1. Press the clip of the dust-proof cover and unfold it outwards (shown in the figure below).



2. To remove the fixing frame of the dust-proof cover and the cover itself, press two clips on the fixing frame of the dust-proof cover towards arrow's direction (shown in the figure below).



3. Clean the dust-proof mesh with water or soft brush.



Please clean all dust-proof covers of the system periodically (1 time per month); otherwise, system damage may result. Cleaning times can be increased when the system is used in the open air or somewhere dust is more.

Compatible Disinfections used to clean the main unit

The disinfections supported to use when cleaning the main system are listed in table below:

Manufacturer	Trade Name	Туре
DR.SCHUMACH ER.GMBH	Cleanisept WIPES	Wipe
Advanced Ultrasound Solutions, Inc.	SONO Ultrasound Wipes	Wipe

NOTE:	Disinfectants above are used to clean the housing and the display of the
	main unit only, not for the probe disinfection.

Cleaning the peripherals

Carry out cleaning maintenance according to your actual peripheral configuration. Items which are not configured can be skipped.

Content	Description
Color and B/W video printer	Wipe away dust or stains on the printer cover with a soft dry cloth, then clean the inside of the printer. Carry out cleaning maintenance according to the operation manual if necessary.
Graph/text printer	Wipe away dust or stains on the printer cover with a soft dry cloth, then clean the inside of the printer. Carry out cleaning maintenance according to the operation manual if necessary.
Foot switch	Use a soft dry cloth with a little mild soapy water to wipe away dust or stains attached to the foot switch pedals or cable.
Barcode reader	Use a soft dry cloth to wipe away dust from the glass panel of the reader, then wipe away dust or stains from the cable and bracket. See Appendix C Barcode Reader for details.

16.1.2 Checking the Probe

- Visually check to confirm that there are no cracks or expansion of the probe head.
- Visually check to confirm that there is no deterioration or erosion of the probe cable.
- Visually check to confirm that none of the connector pins are bent, destroyed or falling off.

16.1.3 Checking the Power Cable and Plug

- Visually check to confirm that there are no wrinkles, cracks or deterioration, and no cracks or expansion on the surface of the adapter.
- Manually check to confirm that there is no looseness or rupture. The connection of the plug is reliable.

16.1.4 Checking Appearance

Check if there are any cracks in the covers:

- Ultrasound system covers
- Probe appearance.
- External appearance of the ECG lead.

16.1.5 System Hard Drive Backup

To prevent deterioration or loss of data stored in the system hard drive (including patient info data, preset data, etc.), create a backup copy of the hard drive at regular intervals.

16.2 Troubleshooting

If any persistent system malfunction is experienced, e.g., an onscreen error message, blank imaging screen, absent menus, see the table below. If the failure cannot be resolved, contact the Mindray Customer Service Department or a sales representative.

Troubleshooting Table

No.	Failure	Cause	Measure
	The system cannot be powered on.	Abnormal power system or incorrect connection of the power cord.	Check that the system is plugged in.
			Check that the plug has not become loose or dislodged from the back of the system.
2	The display has no output.	The interval between turning off and restarting the system is too short – wait at least 20 seconds.	Turn off the system and wait at least 1 minute, then restart the system.
		The display brightness or contrast may be improperly set.	Adjust the display brightness and contrast.
The touch screen displays the characters and menus but no images.	The acoustic power, gain or TGC controls are improperly set.	Adjust the [A.Power] control, gain or TGC control.	
	Check that a probe is connected and/or fully connected.	Check probe connection.	
		The system is in frozen status.	Unfreeze the image.
	The image quality is degraded	The exam mode is incorrect.	Select an appropriate exam mode.
		The image parameter settings are incorrect.	Adjust the image parameters.

Appendix A Wireless LAN

The system provides wireless net adapter configuration, so as to assist information query and unlimited network service.

\triangle WARNING:

It is prohibited to use the wireless LAN function in an airplane, as this may violate the relevant provisions in the aviation regulations.

Use the wireless LAN function prudently in emergency ambulances (or other vehicles) as other devices or communication signals may be interfered with.

Use the wireless LAN function prudently in OR/ICU/CCU as it may interfere with other devices.

When the wireless LAN function is turned on, the ultrasound system may suffer interference from other equipment, even if that other equipment complies with CISPR EMISSION requirements.

Keep at least 20 cm away from the ultrasound system when the wireless LAN function is in use.

NOTE: For a better wireless LAN transmission effect, please take the following settings:

- SSID>80% with stable WLAN network;
- Wireless router and the server are in the same network segment;
- Router setting:
 - Wireless standard 802.11n
 - ➤ Maximum transmission speed ≥300M
 - Use AP (access point) setting;
 - ▶ Number of the devices connected to the same router \leq 5.
- Target server setting:
 - ➤ Network is stable and not under overloading state (e.g. high CPU/memory usage, fast HDD speed, limited HDD space);
 - Level other than the highest level of firewall is adopted;
 - ➤ Operating system is Win8 or higher versions and supports a Gigabit Ethernet.

Disconnection may be caused if the devices connected excess the router capacity (please refer to settings of the router, generally it should be \leq 5.)

DO NOT connect devices other than specified into the LAN.

Medical devices within the same LAN may interfere with each other, the operator should be cautious. (Do not connect devices that may cause strong interference. For example, life-supporting devices should not be connected in the same LAN.)

Other non-medical devices in the same frequency band may cause interference, please be cautious.

Wi-Fi function is not affected when the system is imposed with radiation interference complied with IEC60601-1-2:2007 standard.

A.1 Use the Wireless feature

1. Tap in the top-right part of the screen to open the wireless network manager.



- Tap to select the target network, tap [Connect] to connect to the network.When connecting an encrypted network, enter the password in the box first. You can select to hide password characters or not.
- 3. The system tries to connect to the selected network. The icon turns into after successful connection.

■ IP Configuration

When the system background is processing network task (DICOM sending for example), please do not enter network setting to change the IP, otherwise the background task may fail. You can check if there are tasks undergoing in the task manager.

IP configuration is used for setting local network parameters, which is also applied to DICOM connection.

1. In Wireless network manager screen, tap [IP Config] to open the page:



- If "DHCP" is selected, the IP address will be automatically obtained from the DNS server.
 - Tap [Refresh] to check current IP address.
- If "Static" is selected (using a static IP address), enter the IP address.
 - > IP address of the system should be in the same network segment with the server.
 - > Subnet Mask: set different network segment.
 - > Gateway: set the gateway IP.
 - ➤ Host Name: displays the machine name of the system, if changed, the system should be restarted.
- 2. Tap [Save] to save current setting or tap [Cancel] to exit.

NOTE: If the IP address displays as 0.0.0.0, this means that the network is abnormal. The reason for the failure may be disconnection or the system cannot obtain the IP address.

A.2 Specifications

■ Wireless specification and technology:

Item	Specifications
Standards	IEEE 802.11 b/g/n
Modulation mode	802.11b: DSSS 802.11g/n: OFDM
Operating frequency	2.412-2.472 GHz, 2.484 GHz
Channel spacing	5 MHz
Output power	≤17dbm
Wireless network mode	Infrastructure, ad-hoc

■ Wireless Quality of Service:

Item	Specifications
	802.11b: up to 11 Mbps @ 2.4 GHz
Data rate	802.11g: up to 54 Mbps @ 2.4 GHz
	802.11n: up to 300 Mbps @ 2.4 GHz and 5 GHz
Data security	WPA2-PSK encryption
Application-layer reliability	Application failure will be notified to the user immediately.
System capacity	No more than one device can be allowed to link to the ultrasound system.
System anti-interference	Can be coexistent with other Wi-Fi devices.
Network interruption alarm	Network interruption is notified by disconnection icon and failure in transmission is notified by the dialog box.
EMC test process	Wi-Fi function is not affected when the system is imposed with radiation interference complied with IEC60601-1-2:2007 standard.

A.3 Troubleshooting

Failure	Measure
Unable to connect the network.	Verify that network is available.
	2. The SSID and password of the device should be consistent with those of the wireless AP.
	3. Check for IP address conflict. If yes, set the IP address correctly.
	4. Check if Mindray recommended wireless AP is used. If not, verify the AP effective transmission rate meets the throughput requirements of the connected devices.
The ultrasonic device is frequently off line or disconnects from the network.	Check if Mindray recommended wireless AP is used. If not, verify the AP effective transmission rate meets the throughput requirements of the connected devices.
The transmission delay is too long.	2. Verify that no unauthorized devices are connected to the wireless AP.

Appendix B Battery

॔WARNING:

The battery is inside the machine; only technical professionals from Mindray or engineers authorized by Mindray after training can perform battery installation and uninstallation.

If you need to change the battery or buy a new one, please contact your sales representative.

B₋1 Overview

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

- Under power off or standby status, charging time of the battery from capacity 0 to 100% takes less than 3 hours.
- The system lasts more than 22 hours in standby mode with full battery.

NOTE: Power off the system if it will not be used for a long period of time (including storage/transportation condition). Do not leave the system in standby status, otherwise the batteries will be discharged and permanently damaged.

B.2 Battery specification

14.8V Voltage

Capacity 5800mAh (single battery)

Battery Status Indicator B₋3

The battery status indicator is located in the top-right corner of the screen, indicating the battery status.

- : indicates charging status.
- : indicates discharging status.

Appendix C Barcode Reader

The product supports two kinds of readers for logging data as patient ID: 1-D barcode reader (SYMBOL LS2208) and 2-D barcode reader (SYMBOL DS6707). The laser transmitted by the two readers is Class 2 laser.

 \triangle WARNING:

A Class 2 laser uses a low-power, visible LED. DO NOT stare into the beam due to unknown hazards of transient radiation from Class 2 lasers.

∆ CAUTION:

Ensure the information acquired by the barcode reader is consistent with

the actual information.

There are 2 operation modes:

Hand-held mode: press the trigger to decode.

Hands-free mode: position the reader in the stand to enter the mode. The reader decodes automatically.

NOTE: The reader does not support Multilanguage decoding.

C.1 1D Barcode Reader

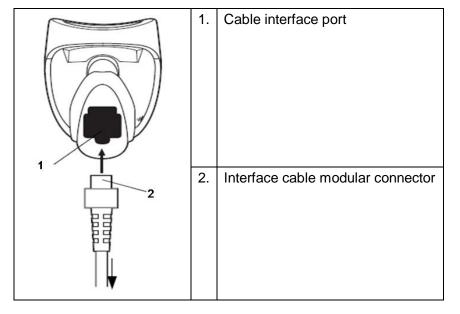
C.1.1 Overview



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	Tap to decode	

C.1.2 Setting Up the Reader (taking 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.



C.1.3 Setting

The reader has factory settings. See A.4 for details.

The reader supports some user-defined functions as described below.

For more details, contact the SYMBOL reader agent or the 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.



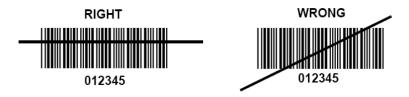




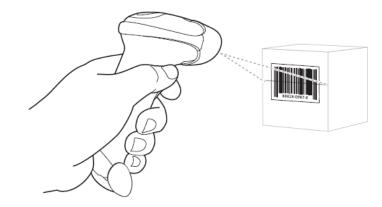
C.1.4 Scanning in Hand-Held Mode

- 1. Ensure all connections are secure.
- 2. Aim the reader at the barcode. Press the trigger.

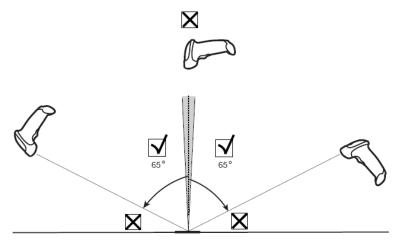
NOTE: Ensure the scan line crosses every bar and space of the symbol, see the figure below.



3. If decoding is successful, the reader beeps and the LED turns green.

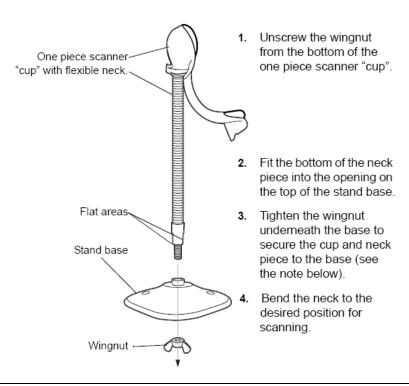


Tip: Do not hold the reader directly over the barcode. Laser light reflecting *directly* back into the reader from the barcode is known as specular reflection. Specular reflection can make decoding difficult. You can tilt the reader up to 55° forward or backward and achieve a successful decoding



C.1.5 Scanning in Hands-Free Mode

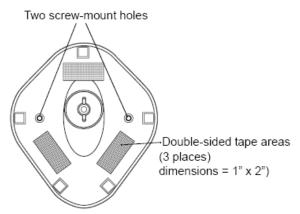
Assembling the Intellistand



NOTE: Before tightening the wingnut under the base, ensure that the flat areas on the flexible neck fit securely in the grooves in the base.

Mounting the Stand (optional)

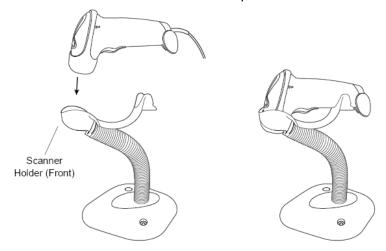
You can attach the base of the reader's stand to a flat surface using two screws or double-sided tape (not provided).



- Screw Mount
- 1. Position the assembled base on a flat surface.
- 2. Screw one #10 wood screw into each screw-mount hole until the base of the stand is secure
- Tape Mount
- 1. Peel the paper liner off one side of each piece of tape and place the sticky surface over each of the three rectangular tape holders.
- 2. Peel the paper liner off the exposed sides of each piece of tape and press the stand on a flat surface until it is secure.

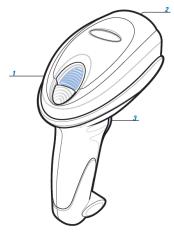
Scanning in Hands-Free Mode

When the reader is seated in the stand's "cup", the reader's built-in sensor puts the reader into hands-free mode. When the reader is removed from the stand it operates in its normal hand-held mode.



C.2 2-D Barcode Reader (Take DS6707 as an example)

C.2.1 Overview

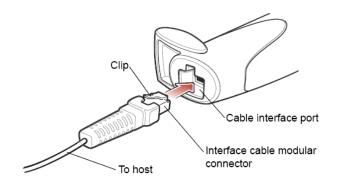


1.	LED	Green: A barcode was successfully decoded.	
		Red: A data transmission error or reader malfunction occurred.	
2.	Scan window	Scan the barcode.	
3.	Trigger	Tap to decode	

C.2.2 Setting Up the Digital Imager Reader

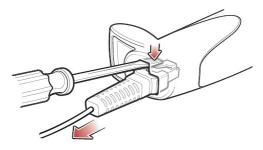
C.2.2.1 Installing the Interface Cable

- 1. Plug the interface cable modular connector into the cable interface port on the bottom of the reader handle and ensure the connector is properly secure.
- 2. Connect the other end of the interface cable to the host



C.2.2.2 Removing the Interface Cable

1. Using the tip of a screwdriver or some other tools with a sharp head, detouch the cable's modular connector clip.



2. Carefully slide out the cable.

C.2.3 Setting

The reader has factory settings; please refer to A.4 for details.

The reader supports some user-defined functions as introduced below.

For more details, please contact the SYMBOL reader agents or Mindray Customer Service Department.

■ Volume setting:

Scan the following barcode to set the volume parameter.



Low Volume (02h)



Medium Volume (01h)



High Volume (00h)

code 93 and codebar setting
 To enable Code 93, scan the appropriate barcode below.



Enable Code 93 (01h)

To enable Codebar, scan the appropriate barcode below.



Enable Codabar (01h)

■ code 39 full ASCII setting

Code 39 Full ASCII is a variant of Code 39 which pairs characters to encode the full ASCII character set. To enable or disable Code 39 Full ASCII, scan the appropriate barcode below.



Enable Code 39 Full ASCII (01h)



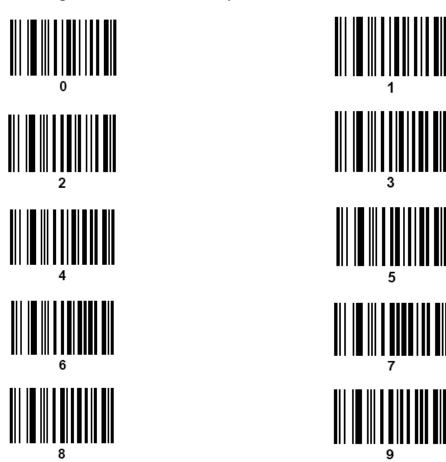
Disable Code 39 Full ASCII (00h)

I 2 of 5 symbols setting



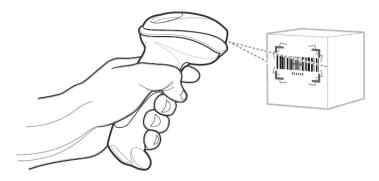
I 2 of 5 - One Discrete Length

Select this option to decode only I 2 of 5 symbols containing a selected length. Select the length using the numeric barcodes below. For example, to decode only I 2 of 5 symbols with 8 characters, scan I 2 of 5 - One Discrete Length, then scan 0 followed by 8.

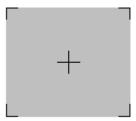


C.2.4 Scanning in Hand-Held Mode

- 1. Ensure all connections are secure (see the appropriate host chapter.)
- 2. Aim the digital imager reader at the barcode.

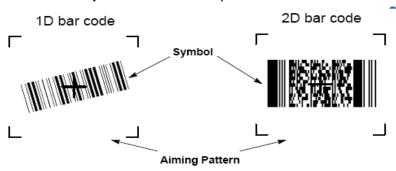


3. When the digital imager reader senses movement, in its default **Auto Aim** trigger mode, it projects a red laser aiming pattern which allows positioning the barcode or object within the field of view.



If necessary, the digital imager reader turns on its red LEDs to illuminate the target barcode.

4. Center the symbol in any orientation within the aiming pattern. Be sure the entire symbol is within the rectangular area formed by the brackets in the pattern.



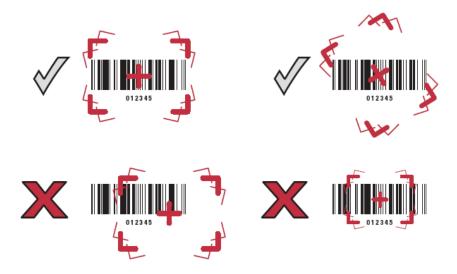
5. Hold the trigger until the digital imager reader beeps, indicating the barcode is successfully decoded.

NOTE: Steps 2 - 4 may be required to repeat on poor quality or difficult barcodes.

Tips: Hold the digital imager reader between two and nine inches (depending on symbol density) from the symbol, centering the aiming pattern cross hairs on the symbol.

The aiming pattern is smaller when the digital imager reader is closer to the symbol and larger when it is farther from the symbol. Scan symbols with smaller bars or elements (mil size) closer to the digital imager reader, and those with larger bars or elements (mil size) farther from the digital imager reader.

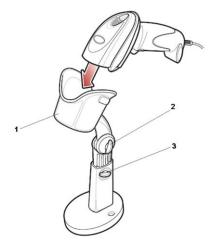
The digital imager reader can also read a barcode presented within the aiming pattern but not centered. The top examples below show acceptable aiming options, while the bottom examples cannot be decoded.



C.2.5 Scanning in Hands-Free Mode

The optional Intellistand adds greater flexibility to scanning operation. When the digital imager reader is seated in the stand's "cup," the digital imager reader's built-in sensor places the digital imager reader in hands-free mode. When the digital imager reader is removed from the stand it operates in its normal hand-held mode.

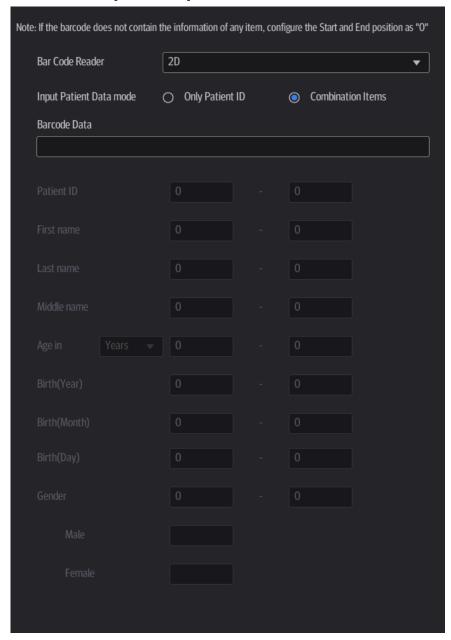
Use the Intellistand's adjustment knobs to adjust the height and angle of the digital imager reader.



1.	Reader holder (cup)
2.	Angle adjustment knob
3.	Height adjustment knob

C.3 Setting in Ultrasound System

Enter the Setup menu and select [Scan Code] to see the screen.



Setting items are described as follows:

Parameter	Description		
Bar Code Reader	Select type: 1D or 2D.		
	Select the mode for inputting patient data.		
Only Patient ID: only patient ID is acquired from barcode reader. If this f is selected, patient ID can be acquired via barcode reading in Patient, W or QR screen.			
	Combination Item: patient ID, patient name and other information can be acquired from barcode.(available only in 2-D reader)		
Barcode Data	When 2-D reader is adopted, you should first scan a sample barcode here and then set the parts definition for the information.		
Patient ID	Set the start and end position of each item.		
Patient Name	NOTE:		
Age	1. Length of birth month and data are of 2 letters.		
Birth	2. If one item of information is not included in the barcode, set the start and end		
Gender	position of the item to be 0 respectively.		

C.4 Parameter Defaults

Refer to the following table for parameter defaults of LS2208 and DS6707.

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 Transmit UPC-E1 Check Digit	Enable
UPC-A Preamble	
	System Character
UPC-E Preamble	System Character
UPC-E1 Preamble	System Character
Convert UPC-E to A	Disable
Convert UPC-E1 to A	Disable
EAN-8/JAN-8 Extend	Disable
UCC Coupon Extended Code	Disable
Code 128	
Code 128	Enable
UCC/EAN-128	Enable
ISBT 128	Enable
Code 39	
Code 39	Enable
Trioptic Code 39	Disable
Convert Code 39 to Code 32 (Italian Pharmacy Code)	Disable
Code 32 Prefix	Disable
Set Length(s) for Code 39	2 to 55
Code 39 Check Digit Verification	Disable
Transmit Code 39 Check Digit	Disable
Code 39 Full ASCII Conversion	Disable
Buffer Code 39	Disable
Code 93	
Code 93	Enable
Set Length(s) for Code 93	4 to 55
Interleaved 2 of 5 (ITF)	. 10 00
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)	Disable
	Enchic
Codabar Set Lengths for Codabar	Enable 5 to 55
Set Lengths for Codabar	5 to 55
CLSI Editing	Disable
NOTIS Editing	Disable
2-D Symbologies	
PDF417	Enable
MicroPDF417	Disable
Code 128 Emulation	Disable
Data Matrix	Enable
Maxicode	Enable
QR Code	Enable

C.5 Maintenance

Cleaning the exit window is the only maintenance required. A dirty window can affect scanning accuracy.

- Do not allow any abrasive material to touch the window.
- Remove any dirt particles with a damp cloth.
- Wipe the window using a tissue moistened with ammonia/water.
- Do not spray water or other cleaning liquids directly into the window.

Appendix D Trolley and Accessories

≜WARNING:

DO NOT connect the trolley to the outlets with the same circuit breakers and fuses that control the current to devices such as life-support systems. If the trolley or the system malfunctions and generates over-current, or when there is an instantaneous current at power ON, the circuit breakers and fuses of the building's supply circuit may be tripped.

 \triangle CAUTION:

When moving the trolley with mounted system, please take care of the connector of the power adapter in case of damage.

Maximum output power of the outlet in the trolley is 240VA.

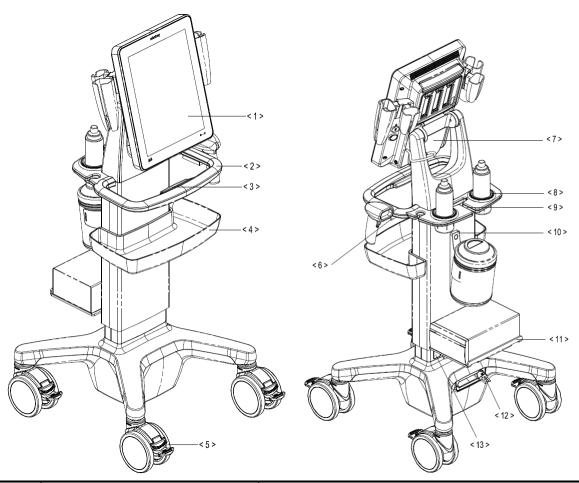
NOTE: Use a power cable no less than 1.5m and no longer than 1.8 m for the printer on the trolley.

D.1 Trolley

D.1.1 Trolley Accessories

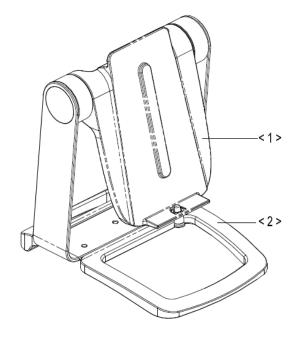
- Gel holder
- Storage bin
- Black/white video printer tray
- Towelette holster

D.1.2 Introduction of Each Unit



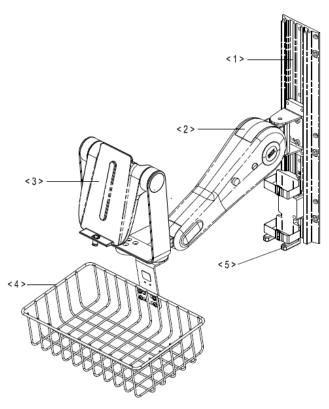
No.	Name	Function	
<1>	Main unit of ultrasound system	/	
<2>	Trolley handle	Used for ascending/descending the trolley or moving the trolley.	
<3>	Height lever	Press to adjust the height of the stand.	
<4>	Storage bin	Used for keeping the cases, towelette, etc.	
<5>	Caster	Used for securing or moving the system.	
<6>	Reader support	Used for placing the barcode reader.	
<7>	Main unit support	Used for fixing the ultrasound system.	
<8>	Gel holder	Used for placing the gel.	
<9>	Cable management slot	Used for organizing the probe cables and peripheral cables.	
<10>	Towelette holster	Used for placing the towelette container.	
<11>	Printer bracket	Used for placing the printer.	
		AC power supply cable.	
<12>	Retractable cable	CAUTION: DO NOT insert fingers into the gap next to the plug in case of injury.	
<13>	Power outlet	Supplies the power for peripheral devices.	

D.2 Table Stand



No.	Name	Function	
<1>	Main unit support	Used for fixing the ultrasound system.	
<2>	Base	Used for fixing the main unit support.	

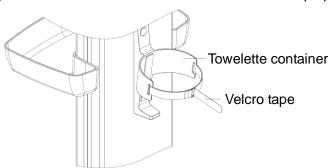
D.3 Wall Mount



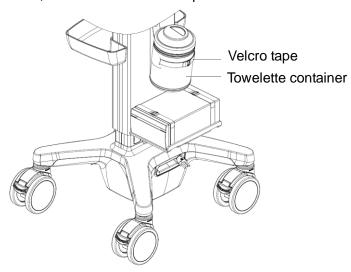
No.	Name	Function
<1>	Guide way of wall mount	Used for fixing the wall mount.
<2>	Support arm of wall mount	Used for adjusting the angle of wall mount.
<3>	Main unit support	Used for fixing the ultrasound system.
<4>	Storage tray	Used for holding tissue, etc.
<5>	Adapter holder	Used for fixing the external adapter.

D.4 Install Towelette Container

1. Thread the velcro tape through the holes of the towelette holster. Fasten the tape properly.



2. Put the container into the holster, and fasten the velcro tape of the towelette container.



Appendix E Electrical Safety Inspection

The following electrical safety tests are recommended as part of a comprehensive preventive maintenance program. They are a proven means of detecting abnormalities that, if undetected, could prove dangerous to either the patient or the operator. Additional tests may be required according to local regulations.

All tests can be performed using commercially-available safety analyzer test equipment. These procedures assume the use of a 601PROXL International Safety Analyzer or equivalent safety analyzer. Other popular testers which comply with IEC 60601-1 and are used in Europe, such as Fluke, Metron or Gerb, may require modifications to the procedure. Follow the analyzer manufacturer's instructions.

An electrical safety inspection should be periodically performed every two years. The safety analyzer is also an excellent troubleshooting tool for detecting abnormalities in line voltage and grounding, as well as total current loads.

E.1 Power Cord Plug

E.1.1 The Power Plug

Test Item		Acceptance Criteria	
	The power plug pins	No broken or bent pins. No discolored pins.	
	The plug body	No physical damage to the plug body.	
The power plug	The strain relief	No physical damage to the strain relief. No plug warmth when device is in use.	
	The power plug	No loose connections.	
The power cord		No physical damage to the cord. No deterioration to the cord.	
		For devices with detachable power cords, inspect the connection with the device.	
		For devices with non-detachable power cords, inspect the strain relief at the device.	

E.2 Device Enclosure and Accessories

E.2.1 Visual Inspection

Test Item	Acceptance Criteria
The enclosure and accessories	No physical damage to the enclosure and accessories.
	No physical damage to meters, switches, connectors, etc.
	No residue of fluid spillage (e.g., water, coffee, chemicals, etc.).
	No loose or missing parts (e.g., knobs, dials, terminals, etc.).

E.2.2 Contextual Inspection

Test Item	Acceptance Criteria
The enclosure and accessories	No unusual noises (e.g., rattles inside the case).
	No unusual smells (e.g., burning or smoky smells, particularly from ventilation holes).
	No taped notes that may suggest device deficiencies or operator concerns.

E.3 Device Labeling

Check that the labels provided by the manufacturer or the healthcare facility are present and legible.

- Main unit label
- Integrated warning labels

E.4 Protective Earth Resistance

- 1. Plug the analyzer probes into the device's protective earth terminal and the protective earth terminal of the AC power cord.
- 2. Test the earth resistance with a current of 25 A.
- 3. Verify the resistance is less than the limits.
- LIMITS

ALL COUNTRIES R = 0.2Ω Maximum

E.5 Earth Leakage Test

Run an Earth Leakage test on the device being tested before performing any other leakage tests.

The following outlet conditions apply when performing the Earth Leakage test.

- normal polarity (Normal Condition);
- reverse polarity (Normal Condition);
- normal polarity with open neutral (Single Fault Condition);
- reverse polarity with open neutral (Single Fault Condition).

■ LIMITS

For UL60601-1:

- 300 uA in Normal Condition.
- 1000 µA in Single Fault Condition.

For IEC60601-1:

- 500 µA in Normal Condition.
- 1000 μA in Single Fault Condition.

E.6 Enclosure Leakage Test

The following outlet conditions apply when performing the Enclosure Leakage test.

- normal polarity (Normal Condition);
- reverse polarity (Normal Condition);
- normal polarity with open neutral (Single Fault Condition);
- reverse polarity with open neutral (Single Fault Condition):
- normal polarity with open earth (Single Fault Condition);
- reverse polarity with open earth (Single Fault Condition).

■ LIMITS

For UL60601-1:

- 100 µA in Normal Condition.
- 300 μA in Single Fault Condition.

For IEC60601-1:

- 100 µA in Normal Condition.
- 500 μA in Single Fault Condition.

E.7 Patient Leakage Current

Patient leakage currents are measured between a selected applied part and mains earth. All measurements have a true RMS only.

The following outlet conditions apply when performing the Patient Leakage Current test.

- normal polarity (Normal Condition);
- reverse polarity (Normal Condition);
- normal polarity with open neutral (Single Fault Condition);
- reverse polarity with open neutral (Single Fault Condition).
- normal polarity with open earth (Single Fault Condition);
- reverse polarity with open earth (Single Fault Condition).

■ LIMITS

For BF applied parts:

- 100 µA in Normal Condition.
- 500 μA in Single Fault Condition.

E.8 Mains on Applied Part Leakage

The Mains on Applied Part test applies a test voltage, which is 110% of the mains voltage using a limiting resistance, to selected applied part terminals. Current measurements are then taken between the selected applied part and earth. Measurements are taken with the test voltage (110% of mains) on applied parts in the normal and reverse polarity conditions.

The following outlet conditions apply when performing the Mains on Applied Part test.

- Normal Polarity;
- Reversed Polarity.
- LIMITS
 - For BF 🖈 applied parts: 5000 μA.

E.9 Patient Auxiliary Current

Patient Auxiliary currents are measured between any selected Applied Part connector and the remaining Applied Part connectors. All measurements may have a true RMS response.

The following outlet conditions apply when performing the Patient Auxiliary Current test.

- normal polarity (Normal Condition);
- reverse polarity (Normal Condition);
- normal polarity with open neutral (Single Fault Condition);
- reverse polarity with open neutral (Single Fault Condition);
- normal polarity with open earth (Single Fault Condition);
- reverse polarity with open earth (Single Fault Condition).
- LIMITS

For BF applied parts,

- 100 μA in Normal Condition.
- 500 μA in Single Fault Condition.

NOTE: Make sure the safety analyzer is authorized and complies with the requirements of IEC60601-1. Follow the analyzer manufacturer's instructions.

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