DP-9900 Digital Ultrasonic Diagnostic Imaging System

Operator's Manual

[Basic Volume]

Contents

For this Operator's Manual, the issue date is 2014-02.

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- the electrical installation of the relevant room complies with the applicable national and local requirements; and
- the product is used in accordance with the instructions for use.

⚠ Note ⚠

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

⚠ Warning ⚠

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

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- **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

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Important Information

1. The responsibility for maintenance and management of the product after delivery resides with the customer who has purchased the product.
2. The warranty does not cover the following items, even during the warranty period:
   (1) Damage or loss due to misuse or abuse.
   (2) Damage or loss caused by Acts of God such as fires, earthquakes, floods, lightning, etc.
   (3) Damage or loss caused by failure to meet the specified conditions for this system, such as inadequate power supply, improper installation, or unacceptable environmental conditions.
   (4) Damage or loss due to use outside the territory in which the system was originally sold.
   (5) Damage or loss involving 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 product.
5. In no event shall Mindray be liable for problems, damage, or loss caused by relocation, modification, or repair performed by personnel other than those designated by Mindray.
6. The purpose of this system is to provide physicians with data for clinical diagnosis.
   The responsibility for diagnostic procedures lies with the physicians involved. Mindray shall not be liable for the results of diagnostic procedures.
7. Important data must be backed up on external recording media such as clinical records, notebooks etc.
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. Be alert at all times to dangers other than those indicated. Mindray shall not be liable for damage or loss that results from negligence or from ignoring the precautions and operating instructions contained in this operator’s manual.
10. On the occasion of change of the administrator or manager for this system, be sure to hand over this operator’s manual.

⚠CAUTION: **U.S.A. Federal Law restricts this device to be sale by or on the order of a physician.**

⚠CAUTION: **The DP-9900 Ultrasound system is not intended for ophthalmic use. Its use in this clinical specialty is contraindicated.**

Before placing the transducer, use ultrasonic gel such as EcoGel 200 as a coupling media between the patient skin and the transducer face. Place gel on the probe to ensure good penetration of ultrasound into the body. Lack of coupling media will reflect into reduced image clarity.

⚠CAUTION: A sterile transducer sheath is recommended during endocavity procedures. Do not use or apply the endocavity transducer to the patient without a sterile, surgically clean sheath.

Introduction

This operator's manual describes the functions and applications of the system. To ensure safe and correct operation of the system, carefully read and understand the manual before operating the system.

The functions described in operator's manuals of this system, are not provided for all models sold in all regions. What functions are available depends on specific system you purchased.

All figures in this manual are only for reference. What some figures show may be different from the system you purchased.

1. Operator's manuals

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

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

◆ Operator's manual of the main unit

Describes detailed system information on preparation, operating procedures, maintenance checks, and functions.

2. Interfaces in This Operator's Manual

Depending on the software version and configuration of each system, interfaces or menus may appear different from those shown in this manual.

NOTE: The following manuals are available besides the Basic Volume:

- Advanced Volume
- Acoustic power data

Safety Precautions

1. Meaning of Signal Words

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

Signal word	Meaning
⚠DANGER	**Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.**
⚠WARNING	**Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.**
⚠CAUTION	**Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.**
NOTE	Indicates a potentially hazardous situation which, if not avoided, may result in property damage.

2. Meaning of Safety Symbols

Symbol	Description
	Type-BF applied part All ultrasound transducers which can be connected to this system are Type-BF applied parts.
	"Attention" indicates the points requiring attention. Be sure to read the operator's manual concerning these points before using the equipment.

3. Safety Precautions

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

⚠DANGER: Do not use flammable gasses such as anesthetic gas, oxygen or hydrogen, or flammable liquids such as ethanol, near this system and probes, because there is danger of explosion.

⚠WARNING:

1. **Do connect the plug of this equipment to the wall receptacle meeting the ratings indicated on the rating nameplate.**

   The video printer must be connected to the designated AC outlet. （Please refer to chapter 4）

   Using adapter or multi-functional receptacle may affect the system's grounding performance and thus cause leakage current exceeding safety requirement.

2. **Be sure to connect the potential-equalization lead wire before inserting the equipment power plug into the receptacle and be sure to remove the equipment power plug from the receptacle before disconnecting the wire, in order to avoid electrical shock.**

3. **Connect the earth conductor only before turning ON the system. Disconnect the grounding cable only after turning OFF the system. Otherwise, electric shock may result.**

4. **For the connection of power and grounding, follow the appropriate procedures described in this installation manual. Otherwise, there is risk of electric shock. Do not connect the grounding cable to a gas pipe or water pipe, otherwise functional grounding may not be effective or there may be risk of a gas explosion.**

5. **Do not connect this system to outlets with the same circuit breakers and fuses that control current to devices such as life-support systems. If this system malfunctions and generates an overcurrent, or when there is an instantaneous current at power ON, the circuit breakers and fuses of the building's supply circuit may be tripped.**

6. **No waterproof device is applied to this equipment. Do not use this equipment in any place with the possibility of water ingress. There is risk of electric shock if any water is sprayed on or into the equipment. If you carelessly spray any water onto/into the equipment contact the Mindray sales office, customer service department or representative.**
7. **Use the transducer carefully. In case that the human body contacts the scratched transducer surface, immediately stop using the transducer and contact the Mindray sales office, customer service department or representative. There is risk of electric shock if using the scratched transducer.**
8. **After the sterilization or disinfection of accessories, chemicals must be washed out thoroughly from the accessories. Remaining residual chemicals will not only result in damage to the accessories but also be harmful to human bodies.**
9. **Be careful not to let the patient contact the ultrasound equipment. If the ultrasound equipment is defective, there is risk of electric shock.**
10. **Do not subject the equipment to excessive shock such as when moving the equipment, otherwise mechanical parts such as the casters may be damaged. If the equipment is moved over a bumpy floor frequently, contact the Mindray sales office, customer service department or representative.**
11. **Do not use the transducers other than those specified in this manual. If a transducer other than those specified in this manual is connected, the equipment and the transducer may be damaged, causing an accident such as a fire in the worst case.**
12. **Do not subject the transducers to knocks. Use of defective transducers may cause an electric shock.**
13. **Do not open the shell or front panel. If open the shell when the machine is powered on, there may be a short circuit or electric shock.**
14. **Do not use the equipment at the same time use equipment such as an electric scalpel, high-frequency therapy equipment or a defibrillator, etc. In addition, do not allow ultrasonic transducers to come into contact with the patient. The patient may be burned or injured by an electric shock.**
15. **Precautions during transportation: When moving the equipment, hold the handle. If the user holds other sections, the equipment may be subject to unnatural force and may be damaged. Do not move the equipment in the left/right direction. If the equipment is moved in the left/right direction, the equipment may fall.**
16. **Prolonged and repeated use of keyboards can result in hand or arm nerve disorders in some individuals. Observe the local institution work safety/health regulations on keyboard use.**

17. **Accessory equipments connected to the analogue and digital interfaces must be complied with the relevant IEC standards. Furthermore all configurations should comply with the standard IEC60601-1-1. Everybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of IEC60601-1-1. If in doubt, consult Mindray customer service department or your local distributor.**

⚠CAUTION:

1. **Precautions concerning clinical examination techniques**

   (1) **This system must be used only by medical personnel fully trained in clinical examination techniques.**

   (2) **This operator's manual does not describe clinical examination techniques. Selection of the proper clinical examination technique must be based on specialized training and clinical experience.**

2. **Malfunctions due to radio waves**

   (1) **Use of radio wave-emitting devices in the proximity of this kind of medical electronic system may interfere with its operation. Do not bring or use devices which generate radio waves, such as cellular telephones, transceivers, and radio controlled toys, in the room where the system is installed.**

   (2) **If a user brings a device which generates radio waves near the system, they must be instructed to immediately turn OFF the device. This is necessary to ensure the proper operation of the system。**

3. **Precautions concerning installation and movement of the system**

   (1) **Be sure to install the system on a level floor and lock the casters. Otherwise, the system may move, and injure the patient.**

   (2) **Do not push the system from the sides. If the system is pushed from the side, it may fall down and cause injury.**

(3) When the system is moved over a sloped surface, it must be moved slowly by two persons. Otherwise, the system may slide unexpectedly and cause a serious injury.

(4) Do not sit on the system.
The system may move, causing you to lose your balance and fall.

(5) Do not place any objects on top of the monitor. They may fall, causing injury.

(6) Confirm that the peripheral units are secured before you move the system. Otherwise, the peripheral units may fall and cause injury.

(7) When the system is moved over a step, be careful not to allow the system to fall. When holding the system at the bottom to help move it over a step, take special care to prevent hand injuries.

4. Be sure to supply power to video printer from the outlet provided on this equipment. For electrical safety, do not connect to an external outlet.
In addition, be sure to use the cable supplied with the system to connect a printer. If a different cable is used, there is a risk of electric shock.

5. Always keep the machine dry. Avoid transporting this machine quickly from the cold place to the warm place, otherwise condensation or water drops may be formed, which will cause short circuit.

6. If the circuit breaker is tripped or the fuse is blown, it indicates that the machine or the peripheral devices have problems. In these cases, the user cannot repair by him but contact the Mindray sales office, customer service department or representative.

7. There is no risk of high-temperature burns during routine ultrasound examinations. To prevent high-temperature burns, do not apply the transducer to the same spot on the patient for a long time. Apply the transducer only for as long as required time for diagnosis.

8. Before cleaning the system, be sure to disconnect the power cable from the outlet. If the system is defective, there is a risk of electric shock.

9. Before examining a new patient, press 『Patient』 to delete the patient information and data recorded in the memory for the previous patient. Otherwise, the new data may be confused with the data of the previous patient.

10. When the system is turned OFF or 『Patient』 is pressed, all the measured data are lost. (If obstetric measurement data have been saved, they are in obstetric history report.)

11. When a CIN or FRM file is opened, the current patient information as well as the measurement data and image file of the patient will be cleared. Then the system will set the patient that is related to the CIN or FRM file as the current patient.

12. After you open a CIN or FRM file, unfreezing the image will clear up all comments, general measurements, BodyMarks and patient information.

13. Press 『Clear』 key, all comments, BodyMarks, measurements scale and general measurement data on the screen will be cleared up.

14. Do not pull out plugs of the system and its accessories without turning OFF the power. Otherwise it may result in equipment damage or even electric shock.

15. Do not turn OFF the power supply of the system during printing, saving, or invoking. Otherwise it may result in abnormality of these processes or damage the hard disk.

16. Please use the USB storage device compliant with the relevant local regulations. The format of the USB storage device file system should be FAT or FAT32, and the instruction is SCSI.

17. Some USB portable hard disks must be connected to the external power（the external power must be compliant with the relevant local regulations）, otherwise they can not be distinguished.

18. Use ultrasound gel complying with local regulations.

NOTE:

1. Do not use the machine in the vicinity of strong electromagnetic field (such as the transformer), which may affect the performance of the monitor.
2. Do not use the machine in the vicinity of high-frequency radiation source (such as the cellular phone), which may affect the performance of the machine or even lead to failure.
3. To avoid damaging the machine, do not use the machine in following environment:

   (1) Locations exposed to direct sunlight;

   (2) Locations subject to sudden changes in 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 OFF for more than 5 seconds. If the system is turned ON immediately after being turned OFF, it may result in malfunction of the system.
5. Turn OFF the system or stop transmission (freeze) before connecting or disconnecting a transducer. If a transducer is connected or disconnected with an image displayed, it may result in malfunction of the system and/or the transducer.
6. After using the transducer, remove the gel on it. Otherwise, water in the gel may enter the acoustic lens, thus adversely affecting the performance and safety of the transducer.
7. To ensure the safety of the data, be sure to back up the data stored in the system on external storage media. Since the data stored in the system may be lost due to improper operation or an accident.
8. Do not subject the control panel to excessive force, such as by leaning on it. Otherwise, the equipment may be damaged.
9. If this equipment is used in a small room, the room temperature may rise. Proper ventilation must be provided.
10. The fuse inside the machine can be replaced only by the Mindray service engineer or the technician specified by Mindray.

11. When disposing of this system or any part of the system, contact Mindray sales office, customer service department or representative. Do not dispose of this system without consulting Mindray sales office, customer service department or representative first. Mindray does not assume any responsibility for damage resulting from disposal of this system without consulting Mindray。
12. Deterioration of electrical and mechanical safety characteristics (such as generation of a leakage current or deformation/abrasion of mechanical parts) and of image sensitivity and resolution may occur over a period of time. Check and maintenance the system periodically. To ensure system performance, signing a maintenance and service contract to avoid accidents and misdiagnose is recommended.
13. The output power outlets on the main unit are used for providing power to recommended external optional devices. Do not connect other devices to the outlets otherwise the output power may be exceeded and the equipment may malfunction. The output of the auxiliary power supply is 100-240V～ 50/60Hz 1.5-0.8A.
14. Do not connect equipments other than specified in this manual to the system.
15. Be sure to use the system under the circumstances specified in this manual.

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

⚠WARNING:

1. **This ultrasonic probe is only for use with the specified ultrasonic diagnostic system. Please refer to "3.3** Optional Transducers**" to select the proper probe.**
2. **Confirm that the probe and cable are normal before and after each 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 to avoid the possibility of electric shock.**
5. **Never immerse the probe connector into liquids such as water or disinfectant because the connector is not waterproof. Immersion may cause electric shock or malfunction.**
6. **Ultrasonic probe is only for use with the specified ultrasonic diagnostic system. Please refer the ultrasonic diagnostic system operation manual to select the proper probe.**
7. **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 ultrasound gel. Please use the ultrasound gel compliant with the relevant local regulations.**
3. **In normal diagnostic ultrasound mode, there is no danger of a normal-temperature burn; however, keeping the probe on the same region of the patient for a long time may cause such a burn.**
4. **Do not use the carrying case for storing the probe. If the carrying case is used for storage, it may become a source of infection.**
5. **The probe and accessories supplied with it are not delivered disinfected or sterilized. Sterilization (or high-level disinfect) before use is required.**
6. **It is required to practice ALARA when operating ultrasound system. Minimize the acoustic power without compromising the quality of images.**
7. **Disposable components are packaged sterile and are single-use only. Do not use if integrity of packaging violated or if expiration date has passed. Please use the disposable components compliant with the relevant local regulations.**
8. **Please use the disinfection or sterilization solution that recommended in this operator's manual, otherwise Mindray will not be liable for damage caused by other solutions. If you have any questions, please contact Mindray Customer Service Department or sales representative.**
9. **Do not use pre-lubricated condoms as a sheath. Lubricant may not be compatible with the transducer material and damage may result.**
10. **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.

NOTE:

1. Read the following precautions to prevent the probe from malfunction.
   - Before connecting or disconnecting the probe, freeze or turn off the ultrasound diagnostic system.
   - Clean and disinfect the probe before and after each examination.
   - After the examination, wipe off the ultrasound gel thoroughly. Otherwise, the ultrasound gel may solidify and the image quality would be degraded.
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
   - excessive vibration
   - heat generators
   - Use the probes under the following ambient conditions:

- ambient temperature: 0°C to 40°C
- relative humidity: 30% to 90% (no condensation)
- atmospheric pressure: 700 hPa to 1060 hPa

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

4. Latex Alert

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

Therefore, when choosing the transducer cover, we recommend that the user contact CIVCO directly for obtaining transducer cover, pricing information, samples and local distribution information. For CIVCO information, please contact the following:

CIVCO Medical Instruments

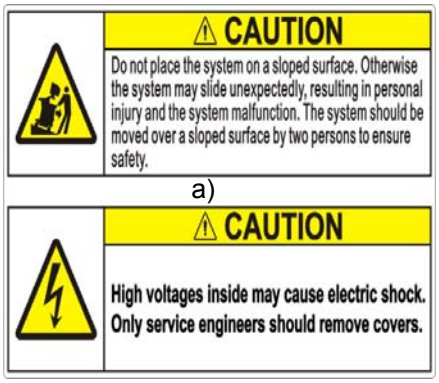
Tel: 1-800-445-6741

WWW.civco.com

5. WARNING Labels

Various WARNING labels are attached to this system in order to call the user's attention to potential hazards.

The symbol ⚠ on the WARNING labels attached to the system indicates safety precautions. The name, appearance and the indication of each WARNING label are as follows. Read them carefully and understand them.

No.	Label	Meaning
<1>		Do not sit on the system.
<2>	 a) b)	(a) Cautions of explosion risk if used with flammable anesthetics. (b) Transducer use precautions: The transducer is highly sensitive to shock; always handle carefully; refer to the operation manual for handling and cleaning instructions.
<3>	 a) b)	a) CAUTION: Do not place the system on a sloped surface. Otherwise the system may slide, resulting in personal injury or the system malfunction. Two persons are required to move the system over a sloped surface. b) CAUTION: High voltages inside may cause electric shock. Only service engineers should remove covers.
<4>		Medical equipment with respect to electric shock, fire and mechanical hazards only in accordance with UL60601-1, CAN/CSA-C22.2 NO.601.1-M90, IEC60601-1-1 and IEC60601-2-37.

1 Intended Use

The DP-9900 digital ultrasonic diagnostic imaging system is applicable for adults, pregnant women, pediatric patients and neonates, and is intended for use in abdominal, cardiac, small parts (breast, testes, thyroid, etc.), peripheral vascular, fetal, transrectal, transvaginal, pediatric, neonatal cephalic, musculoskeletal (general and superficial) exams.

Use of the DP-9900 system is contraindicated for ophthalmic applications.

2 Specifications

2.1 Conditions

(1) Power

Line voltage: 100-240V~

Line frequency: 50/60Hz

Power consumption: 4.0-1.7A

Fuse: 250VAC T 6.3A

(2) Operating environmental conditions

Ambient temperature: 0°C-40°C (32F-104F)

Relative humidity: 25%-90% (no condensation)

Atmospheric pressure: 550 hPa-1060 hPa

(3) Storage and transportation conditions

Ambient temperature: -40°C-60°C (-40F-140F) (with CRT); -20°C~60°C (-4F-140F) (with LCD)

Relative humidity: 10%-95% (no condensation)

Atmospheric pressure: 500 hPa-1060 hPa

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

NOTE: The line voltage differs depending on different countries and regions.

2.2 External Dimensions and Weight

(a) External dimensions: 508mm×702mm×1288mm (W×D×H)

(b) Weight (not including optional units): Approx. 60 kg

3 System Configuration

3.1 Basic Configuration

(1) Main unit

(2) One transducer

(3) Accessories (refer to the package list)

3.2 Optional Units

Unit	Model
Footswitch	971-SWNOM
DICOM software	DICOM3.0
LCD	/

3.3 Optional Transducers

Model	Frequency (MHz)	Intended use	Applicable region
35C50HA	2.5/3.5/5.0 H4.6(harmonic) H6.0(harmonic)	Abdomen, pediatrics, gynecology and obstetrics	Body surface
35C20HA	2.0/2.5/3.5/5.0	Cardiac, abdomen, pediatrics, gynecology and obstetrics	Body surface
65EC10HA	5.0/6.5/7.5/8.5	Gynecology and obstetrics, urology	Transvaginal, Transrectal
65C15HA	5.0/6.5/7.5/8.5	Neonatal head and abdomen, pediatrics	Body surface

Model	Frequency (MHz)	Intended use	Applicable region
75L38HA	6.0/7.5/8.5/10.0	Small parts (breast, thyroid, testes, etc.), Neonatal cephalic, Peripheral vascular, Musculoskeletal (conventional and superficial)	Body surface
75L38HB	6.0/7.5/8.5/10.0	Small parts (breast, thyroid, testes, etc.), Neonatal cephalic, Peripheral vascular, Musculoskeletal (conventional and superficial)	Body surface
75L60HB	6.0/7.5/8.5/10.0	Small parts (breast, thyroid, testes, etc.), Neonatal cephalic, Peripheral vascular, Musculoskeletal (conventional and superficial)	Body surface

3.4 Peripheral Devices

Device	Model
Video printer	SONY UP-895MD SONY UP-897MD MITSUBISHI P93W
Graph/text printer	HP DeskJet 5652/5650/3820 (LPT port/USB port) Business Inkjet 1200 (LPT port/USB port) HP LaserJet2420d (LPT port/USB port) HP DeskJet6548 (USB port) HP Photosmart D5368 (USB port)

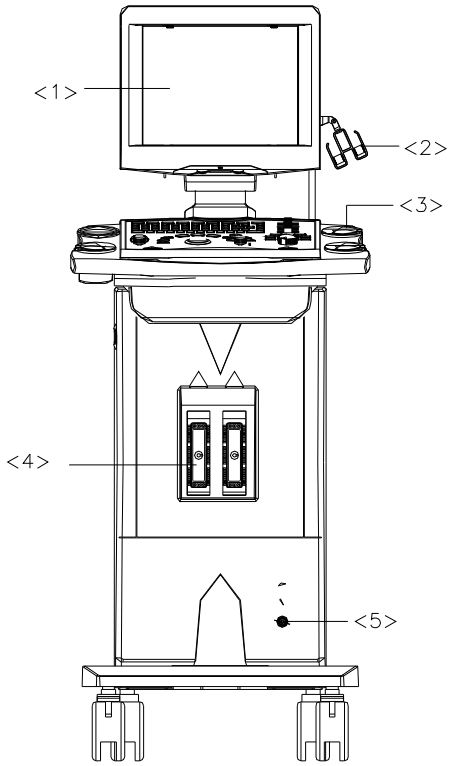
⚠WARNING: **This system complies with IEC60601-1-2: 2007, and its RF emission meets the requirements of CISPR11 Class B. In a domestic environment, the customer or the user should guarantee to connect the system with Class B peripheral devices; otherwise RF interference may result and the customer or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

NOTE: For any question about choice and use of the printers, contact Mindray customer service department.

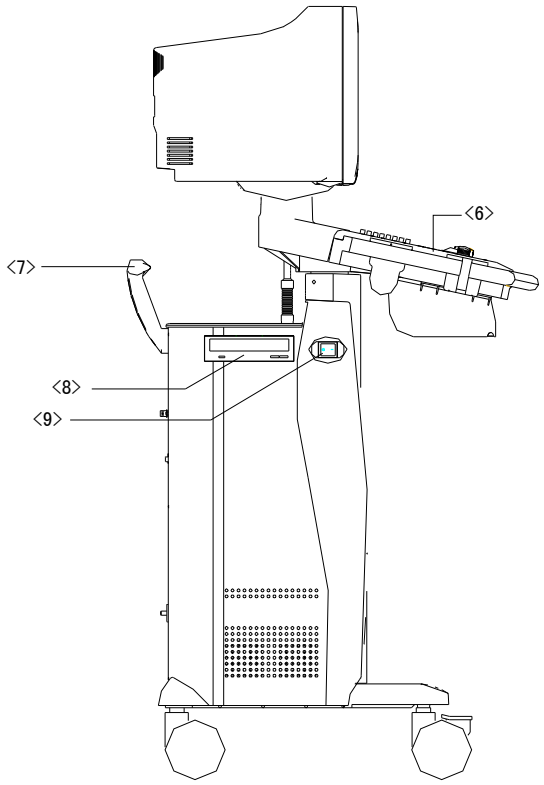
4 System Overview

This chapter introduces the structure of the system, taking the system with CRT as example.

4.1 Parts



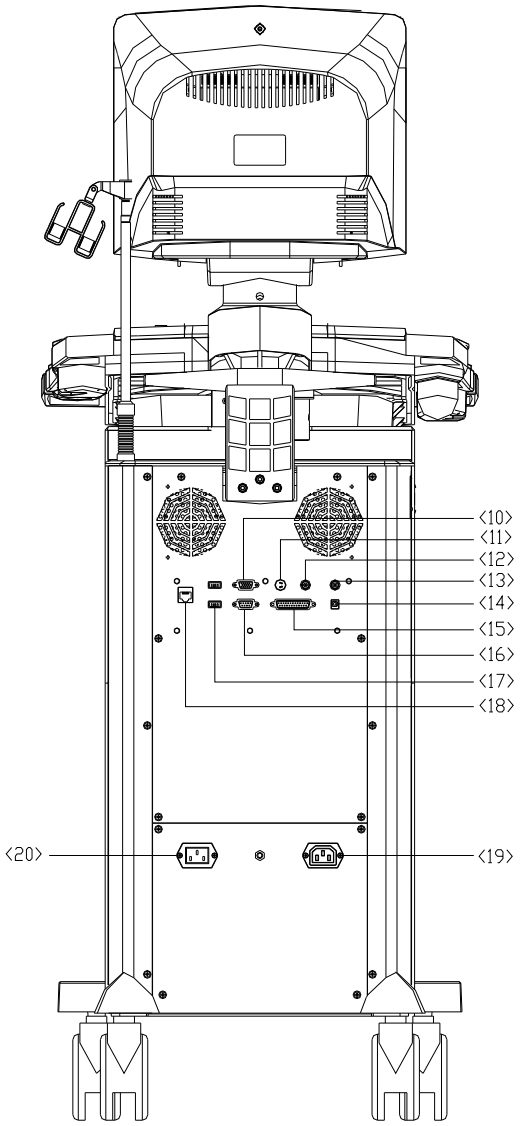
Front view



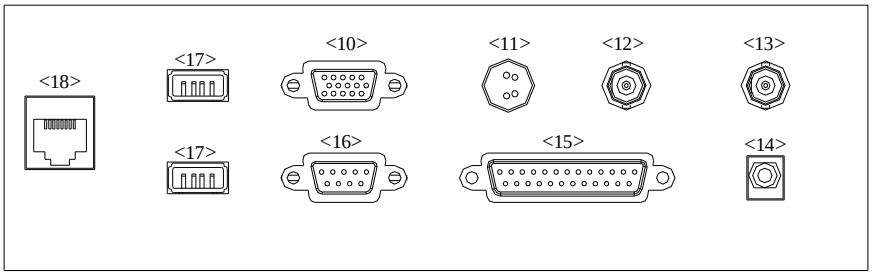
Left side view

No.	Part	Introduction
<1>	Monitor	Display images and parameters, etc. 14″ monitor
<2>	Transducer cable hanger	Hook for the transducer cable
<3>	Transducer holder	Place the transducer provisionally
<4>	Transducer socket	Connect or disconnect the transducer with the main unit
<5>	Footswitch socket	Connect or disconnect footswitch
<6>	Control panel	User interface
<7>	Handle	Move the system
<8>	DVD-RW	Backup the data in hard disk or USB storage device into a CD, or read out the files from a CD (The imaging system supports CD-RW record only).
<9>	Power switch	Power on / off

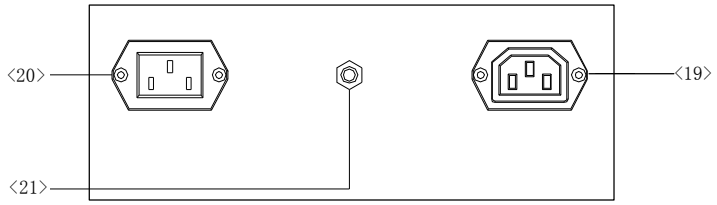
4.2 Rear Panel



Rear view



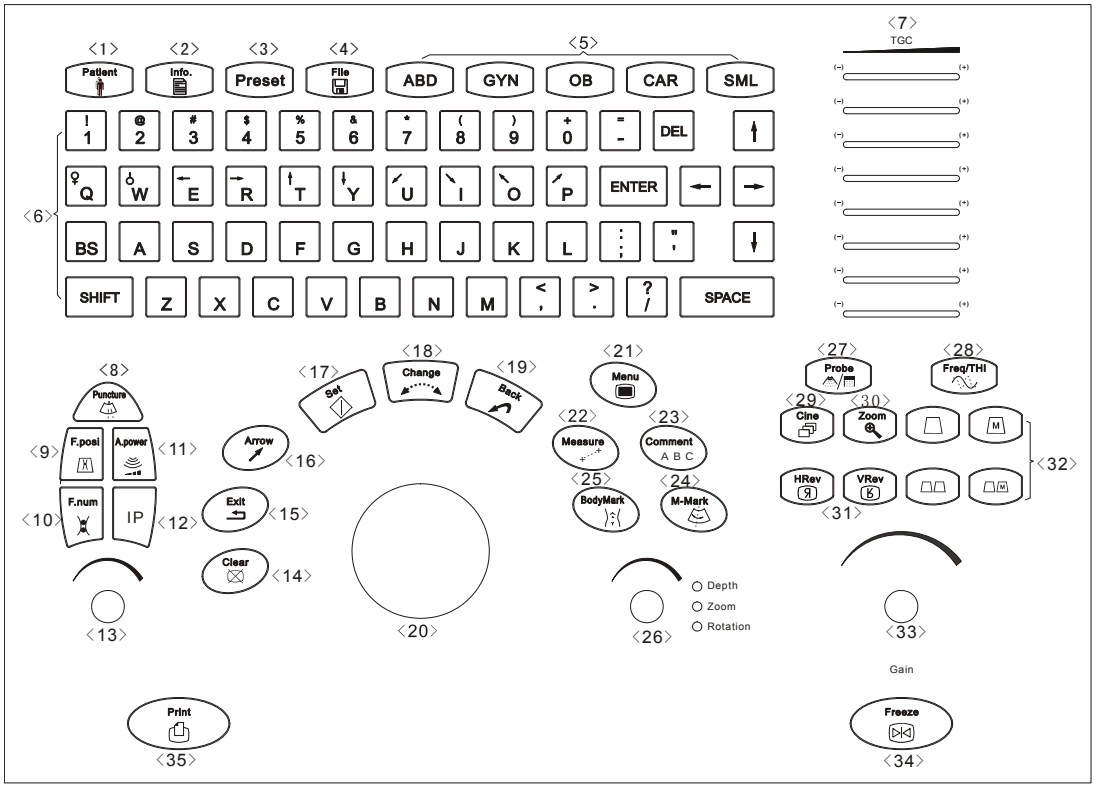
I/O panel



Power panel

No.	Name	Introduction
<10>	VGA port	VGA input and output
<11>	S-Video port	Video input and output
<12>	Video output	Connects a video printer
<13>	Video output	Connects a video printer
<14>	Remote	Connects the remote cable for the video printer
<15>	Graph/text printer port	Connects the parallel port of the Graph/text printer
<16>	RS232 port	Reserved
<17>	USB port	Connects the USB storage device or graph/text printer, etc.
<18>	Ethernet port	Connects network
<19>	AC out	Connects the power cable of video printer
<20>	AC input	Connects power cable for the system
<21>	Equipotential terminal	Equipotential connecting

4.3 Control Panel



No.	Key	Function
<1>	Patient	Delete the data for the previous patient, including the ID and measured values, and begin with a new patient.
<2>	Info	The patient information screen appears.
<3>	Preset	Invoke the registered initial settings (presets).
<4>	File	Quickly save image files.
<5>	ABD/GYN/OB/CAR/SML	Select the exam mode
<6>	Character Key	Used to enter characters and symbols When the backlight indicator of SHIFT key is on, the symbols on the upper row of the keys can be entered.
<7>	TGC	Adjust the ultrasound echo reception sensitivity according to the depth.
<8>	Puncture	Enter/exit the biopsy status

No.	Key	Function
<9>	F.Posi	Adjust the focus position.
<10>	F.Num	Adjust the focus number.
<11>	A.power	Adjust the acoustic power
<12>	IP	Select the combination of image processing parameters, to adjust the image display effect.
<13>	Parameter adjust knob	Adjust some value of Puncture, F.Posi, F.Num, A.Power and IP with combination of corresponding key.
<14>	Clear	Clear all comments, bodymarks, measurement scales and general measurement results on the screen
<15>	Exit	Exit the current work mode
<16>	Arrow	Enter the arrow comment mode and add arrows.
<17>	Set	Determine the cursor position for measurement, and confirm the selected items, and adjust the value or items in menus etc.
<18>	Change	Switch between the fixed end and active end in the measurement.
<19>	Back	Delete the arrow comment or return to the previous operation, and adjust the value or items in menus etc.
<20>	Trackball	Move the cursor or mark during image movement or measurement.
<21>	Menu	Open or close the menu on the screen.
<22>	Measure	Enter/exit the measurement mode
<23>	Comment	Enter/exit the comment mode
<24>	M-Mark	Enter/exit the M-Mark mode
<25>	BodyMark	Enter/exit the BodyMark mode.
<26>	Depth/Zoom/Rotation	Adjust the viewing depth for display, the zoom mode, and the arrow rotation of the ultrasound images.
<27>	Probe	Switch transducers
<28>	Freq/THI	Adjust the transducer frequency and switch to the harmonic frequency of 35C50HA.
<29>	Cine	Enter the manual playback mode.

No.	Key	Function
<30>	Zoom	Enter the mode of amplifying the image
<31>	HRev / VRev	Reverse the image horizontally or vertically
<32>	B/M/M+B/B+B	Select the image mode
<33>	Gain	Adjust the sensitivity of black/white images.
<34>	Freeze	Freeze or unfreeze the image. If an image is frozen, the output of acoustic power is stopped. In the Freeze status, the user can perform file-saving operations via the Freeze menu.
<35>	Print	Activate the printing function for the video printer connected.

4.4 Symbols

This system uses the following symbols. For safety symbols, refer to page Ⅶ.

Symbol	Description
	Refer to the Operator's manual when you see this symbol on the machine to avoid the safety accident.
	Dangerous voltage
	AC (Alternating current)
	Equipotentiality
	Protective earth
	Main switch OFF (The AC power is turned OFF.)
	Main switch ON (The AC power is turned ON.)
	Footswitch
	USB port
	Ethernet port
 A	Transducer socket A

Symbol	Description
	Transducer socket B
	Graph/text printer port
	Serial port
	Video remote
	Video output
	Serial number
	Date of manufacture

5 Preparation for Examination

5.1 Moving and Placing the System

Please read and understand the safety precautions before moving and placing the system.

1 Unlock the four casters.

2 Move the system using the handle.

3 When the system is in the desired position, lock the four casters.

4 Leave at least 20cm clearance at the back and left side of the machine.

⚠**CAUTION:**	**Ensure enough clearance at the back and left side of the machine, otherwise failure may happen because of the increasing temperature inside the machine.**

5.2 Connect/Disconnect the Transducer

⚠**CAUTION:**	**1. Connect/disconnect the transducer only after the system power is turned off or the image is frozen, otherwise failure may happen.** **2. When connecting/disconnecting the transducer, place the transducer on the corresponding transducer holder and hook the transducer cable on the cable hanger to avoid accidental falling of the transducer, which may damage the transducer.**

NOTE:	Only use the transducer provided by Mindray. The application of any transducer other than that provided by Mindray may damage the equipment and transducer.

5.2.1 Connecting the Transducer

⚠WARNING: Prior to the connection of the transducer, you should ensure that the transducer, the cable and the connector are all in good condition (no rift or fall-off). Electric shock may happen if you use a defective transducer.

1 Release the lock on the transducer connector. Hold the cable upward and plug the transducer connector into the connector socket.

2 Contact transducer connector with metal leaf, and press it tightly.

3 Turn the lock clockwise for 900. See figure 1 below.

4 Check if the transducer socket is locked securely.

5.2.2 Disconnecting the transducer

Turn the lock on the connector counter-clockwise for 900, plug out the connector vertically. See figure 2 below.

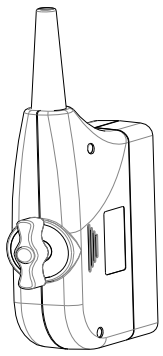


Figure 1 Connecting the transducer

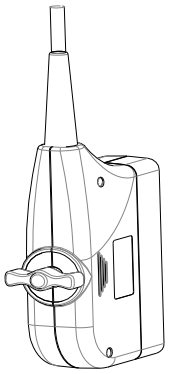


Figure 2 Disconnecting the transducer

5.3 Connecting the Power Cable and Protective Earth

5.3.1 Power connection

The power system for this machine must satisfy the following specifications:

- 100~240V～
- 50/60 Hz
- Output power of the supply system 4.0-1.7A

5.3.2 Grounding terminal

The power cable of the machine is three-wire cable. The grounding terminal should be connected to the grounding protection phase of the power system. Ensure the normal function of the grounding protection phase of the power system.

Connect the power plug to an outlet for medical equipment. By doing so, the protective earth line is connected.

⚠WARNING: **Do not connect the three-wire power cable of the machine to a two-wire plug without grounding protection phase, otherwise electric shock may happen.**

5.3.3 Equipotential terminal

 is the equipotential terminal, used to balance the grounding protection potential between this equipment and other electric device.

⚠WARNING:

1. **Be sure to connect the potential-equalization lead wire before inserting the equipment power plug into the receptacle. Also, be sure to remove the equipment power plug from the receptacle before disconnecting the wire to avoid electrical shock.**
2. **When there is other device connected to the equipment, the user should use the equipotential cable to connect their each equipotential terminal, otherwise electric shock may happen.**
3. **Connect the earth conductor only before turning ON the system. Disconnect the grounding cable only after turning OFF the system. Otherwise, electric shock may result.**
4. **Do not connect this system to outlets with the same circuit breakers and fuses that control the current to devices such as life-support systems. If this system malfunctions and generates an overcurrent, or when there is an instantaneous current at power ON, the circuit breakers and fuses of the building's supply circuit may be tripped.**

5.4 Connecting Printers

Please refer to chapter 4 for each port of the system.

Please refer to the operator's manual of the printer manufacturer concerning detailed operation procedure of the printer.

5.4.1 Connecting the video printer

1. Turn off the ultrasonic diagnostic imaging system and the video printer.
2. Connect the "VIDEO IN" port of the video printer and the "Video output" port of the ultrasonic diagnostic imaging system by the data cable of the printer.
3. Connect the "REMOTE" port of the video printer and the "REMOTE" port of the ultrasonic diagnostic imaging system by the remote cable of the printer.
4. Connect the "AC IN" port of the video printer and the "AC OUT" port of the ultrasonic diagnostic imaging system by the power cable of the printer.
5. After turning on the printer and the system, the printer can work normally.

5.4.2 Connecting the graph/text printer

1. Turn off the ultrasonic diagnostic imaging system and the graph/text printer.
2. Connect the parallel port of the printer and the graph/text printer port of the ultrasonic diagnostic imaging system by the parallel data cable of the printer; if using the USB port to connect the printer, connect the USB port of the printer and the USB port of the ultrasonic diagnostic imaging system by the USB data cable of the printer.
3. Connect the power cable of the printer to the power supply net.
4. After turning on the printer and the system, the printer can work normally.
5. If the printers cannot be connected, set the printer type in the general preset dialog box. For detailed operations, please refer to section 1.3 of the operator's manual (Advanced Volume).

5.5 Adjusting Image Size on Screen

1. Press down both "Contrast+" and "Brightness-" buttons simultaneously for at least 3 seconds, the image size adjusting menu appears.
2. Enter the menu and select item by pressing "Contrast+" button.

Press “Brightness+” and “Brightness-” to zoom in or zoom out the image (4-level adjustable).

3. Press “Contrast -” to exit the menu when getting a proper image size.

6 Power ON/OFF

6.1 Power On

6.1.1 Check the items below before turning ON the power

1 Check all the power supplies and the connecting cables for any abnormity such as scratch or crack.

2 Check the control panel, display and the shell of the equipment for any abnormity such as slit.

3 Check the transducer and the connecting parts for any abnormity such as scratch or fall-off.

4 Check the outlet of the auxiliary power supply of this equipment and all I/O ports to ensure that there is no abnormity such as damage or occlusion by foreign objects.

6.1.2 Turning on the power

1 Turn on the power of the equipment (The power switch is on the upper part of the left side panel). The start-up screen is displayed. After 15 seconds or so, the menu and the image are displayed. Check if the equipment is started up normally.

2 Check the transducer surface in use for abnormal heat.

⚠WARNING： Using the transducer giving abnormal heat may burn the patient.

NOTE: When starting the system power or switching transducers, you will hear the sound of cracks, which is normal.

3 Check the following items:

(1) Check the image for any abnormity such as abnormal noise or flash.

(2) Check the control panel and ensure that the keys and rotary knob can function

normally.

⚠**WARNING：**	**If any abnormity is detected, it indicates that the equipment is defective. In this case, shut down the machine immediately and contact the Mindray sales office, customer service department or representative.**

6.2 Power OFF

After using the system, you must turn off the power. Before turning off the power, follow these steps:

1 Place the transducer on the transducer holder and hook the transducer cable on the cable hanger.

2 As per the requirements in the manual, turning off all the power supplies for the peripheral devices connected to this equipment.

6.3 Power OFF/ON in the System Failure

When any of the following abnormalities occurs in the system, the system may be able to recover from the abnormality by power OFF/ON.

- An error message is displayed and does not disappear.
- The screen display is abnormal.
- The system operations are disabled.

7 Checks

⚠WARNING: **Daily maintenance and checks are required to ensure the safe and effective performance of the system. Do the following checks prior to each start-up. Once any abnormity is detected, shut down the system immediately and contact the Mindray sales office, service department or representative. Using the system with abnormal function may harm the patient and damage the equipment.**

7.1 Checks before Power on

Before turning ON the power, perform the following checks.

No.	Check item	Check mark
1	The temperature, humidity, and atmospheric pressure should meet the conditions for operation.	☐
2	There should be no condensation.	☐
3	There should be no deformation, damage, or stains to the system and peripheral units. * If any stains are present, perform the cleaning according to the section "Cleaning the system" of this manual.	☐
4	There should no backlash or loose screws in the casters, monitor, and panel, etc.	☐
5	Caster locks should function correctly.	☐
6	There should be no damage to the cables and no looseness in the connectors.	☐

No.	Check item	Check mark
7	There should be no damage or stains to the transducer and transducer cables. * If any stains are present, perform cleaning, disinfection, or sterilization according to the operator's manual provided with the transducer.	☐
8	No sundries are placed on the control panel.	☐
9	There should be no obstacles near the movable sections and air filter of the system.	☐
10	Cleaning the transducer. (Please refer to the operator's manual provided with the transducer.)	☐
11	Cleaning the field and environment.	☐

7.2 Checks after Power ON

After starting the system, perform the following checks.

No.	Check item	Check mark
1	There should be no abnormal sound, unusual smells, or overheating.	☐
2	No error message is displayed in use.	☐
3	There should be no obviously abnormal noise, discontinuous display, or dark areas for B-mode images in use.	☐
4	The acoustic lens surface of the transducer should not be unusually hot. (Perform the check by hand.)	☐
5	Keys and knobs on the panel should function normally.	☐

⚠WARNING:

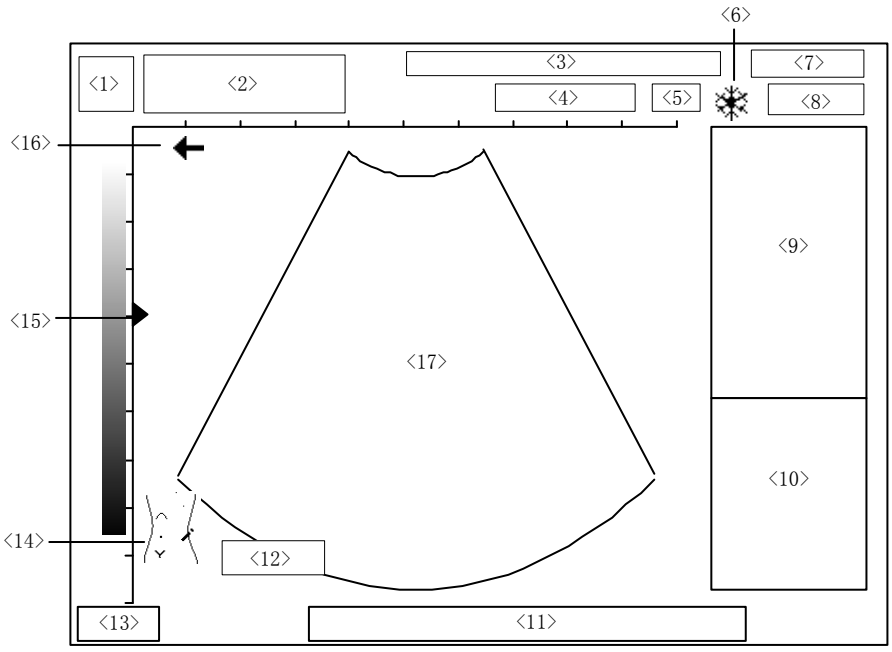
1. **To avoid the possibility of infection, do not use the transducer without being cleaned and disinfected.**
2. **The remaining chemical reagent and gases may not only damage the transducer but also harm the patient.**
3. **If using the system in a dusty environment, failure may occur because of overheat caused by the poor ventilation.**

8 Basic Interface and Menu

8.1 Interface

After you turn on the system power in normal condition, the system will enter the corresponding interface according to the initial settings.

The following figure gives explanation of interface by using B mode image in abdomen exam mode as an example.

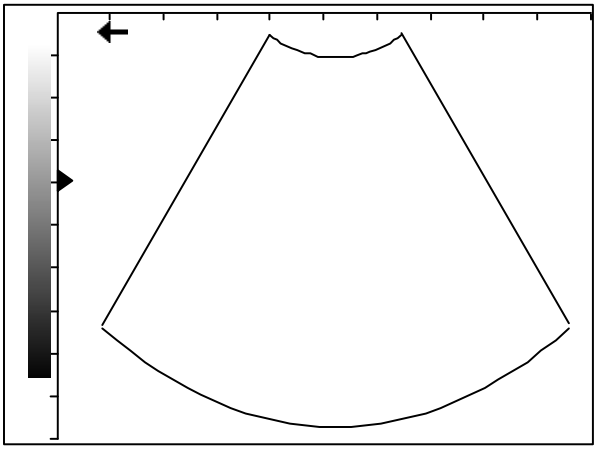


No.	Introduction
<1>	Manufacturer’s logo
<2>	Display area for preset hospital name, patient name and ID
<3>	Current image parameters, such as BG, MG, AP, IP and FR. Refer to the chapter “Image Control and Adjustment” for more information.

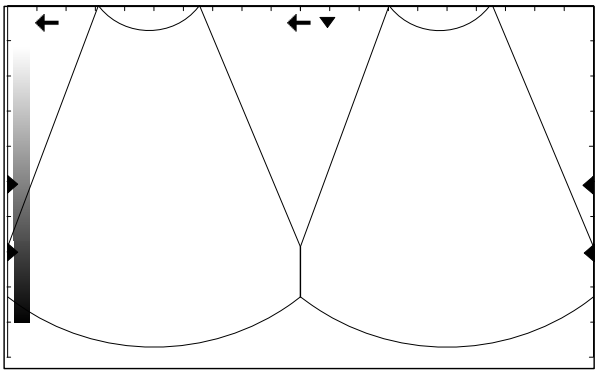
No.	Introduction
<4>	Display of transducer model
<5>	Display of the transducer's current frequency
<6>	FREEZE icon (when an image is frozen, this icon appears)
<7>	System current date (For a frozen image, the displayed date is the date when the image is frozen.)
<8>	System current time (For a frozen image, the displayed time is the time when the image is frozen.)
<9>	Menu display area
<10>	Display area for measurement or calculation result
<11>	Prompt information
<12>	Display of current image depth
<13>	Display of current exam mode
<14>	Bodymark icon
<15>	Focus icon
<16>	The first scanning line from the left is corresponded to the initial scanning position of the transducer
<17>	Image area

8.2 Image Mode

- **B mode**

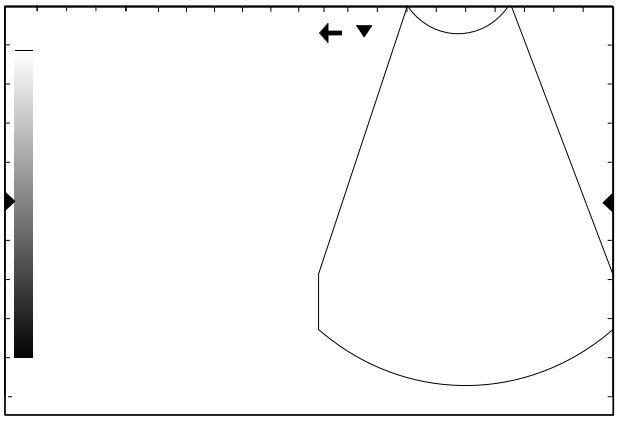


◆ **B+B mode**



◆ **M mode**

◆ **M+B mode**



8.3 Menu and Menu Types

The menus are displayed on the right side of the screen. There are the following types of menus.

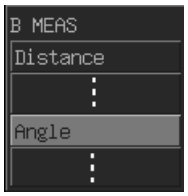
Menu Type	Function
Command	Execute an action, such as starting a measurement, popping up a dialog box, etc.
Number	Adjust a numerical parameter, such as [Dyn Rng]
Switch	Toggle a switch-type parameter, such as [Display]
Character	Adjust a character parameter, such as [TSI]
Sub-menu	Open a sub-menu, such as [Cir/Area]

8.3.1 Command menu items

Command menu items are used to order the system to execute an action, such as popping up a dialog box or starting a measurement, etc.

Use the [Angle] item in the menu of B MEAS as an example to explain the operating method of command menu items:

Roll the trackball to highlight the [Angle] item. Press the 『Set』 key to start the Angle Measurement. See the figure below:



8.3.2 Number menu items

Number menu items are used to adjust the value of the specified parameter in the menu. The name of the parameter being adjusted is displayed in the left side of the menu item while the value is in its right.

Use the [Dyn Rng] item in the B MODE MENU as an example to explain the operating method of the number menu items:

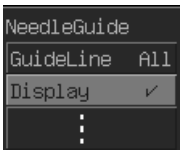
Roll the trackball to highlight the [Dyn Rng] item. Press the 『Set』 key to increase the value and the 『Back』 key to reduce the value. See the figure below:

8.3.3 Switch menu items

Switch menu items are used to adjust the states of parameters: On and Off. The name of the parameters being adjusted is displayed in the left side of the item and the symbols like "√" or "×" in its right, indicating On or Off respectively.

Use the [Display] item as an example to explain the operating method of the switch menu items:

Roll the trackball to anchor the cursor to the [Display] item, which is then highlighted. Press the 『Set』 or the 『Back』 key to toggle between On and Off. See the figure below:



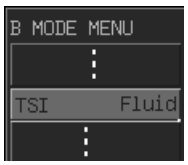
8.3.4 Character menu items

Among the character menu items, the name of the parameter being adjusted is displayed in the left side of the item and the value in its right. What is different from the number menu items is that the value is displayed in characters.

Use the [TSI] item in the B MODE MENU as an example to explain the operating method of character menu items:

Roll the trackball to highlight the [TSI] item in the B MODE MENU. Press the 『Set』 or the 『Back』 key to toggle among the setup values of the character menu items.

See the figure below:



8.3.5 Submenu Items

The submenu item is used to open a sub-menu. The name of the sub-menu is displayed in the left side of the item and an angle sign "▶" in its right indicates that there is a sub-menu for this item.

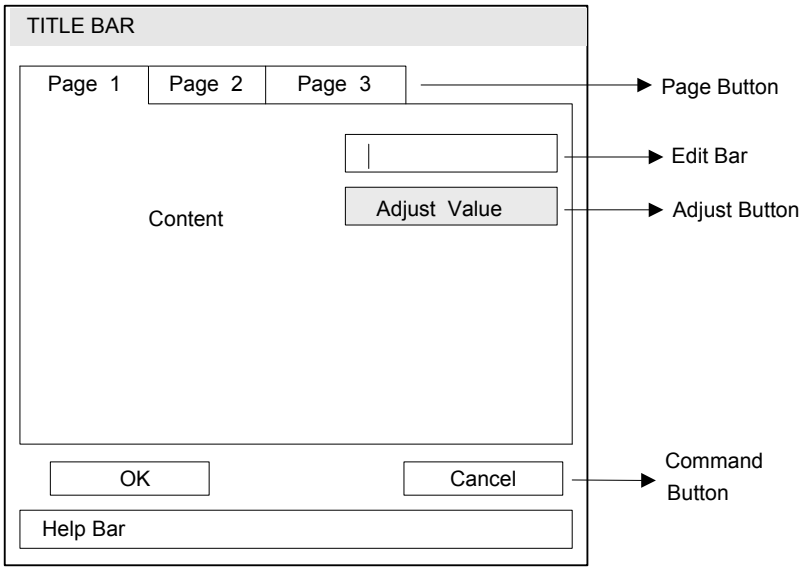
Use the [Cir/Area] item in the B MODE MENU as an example to explain the operating method of an item for a sub-menu:

Roll the trackball to highlight the [Cir/Area] item, at the same time a sub-menu appears. Anchor the cursor to the item in the sub-menu to execute the corresponding operation.

See the figure below:

8.4 Dialog Box

The schematic for the dialog box is shown in figure below. A dialog box consists of the following parts.



Composition	Description
Title Bar	The title bar is used to give a general description for the dialog box. Besides, the user can use it to drag the dialog box.
Page	Some dialog boxes have too much data to be put in the dialog box. In this case, the system will divide these data into different pages based on their content. Some other dialog boxes have only one page and no page buttons.
Content	The content is the object to be operated. Different dialog boxes have different contents, such as Edit Bar, Adjust Button and Command Button, etc.

Composition	Description
[OK] and [Cancel]	After the operation for the dialog box completes, press [OK] or [Cancel] button to save or cancel the operation in this box and close the dialog box.
Help Bar	Users can obtain some Prompt Information about the operation.

- Operating buttons or bars in the dialog box

  The operation of Adjust Buttons is the same as that of the menus. See the instructions of menus for detailed operation method.

  For a Command Button, move the cursor to it and press the 『Set』 key, the system will then perform related operation.

  For an Edit Bar, move the cursor into it and press the 『Set』 key, then you can enter characters or numbers in it.

- Switching pages

  If you want to switch the page from the current to another, move the cursor to the page button you want, and press the 『Set』key.

- Moving the dialog box

  If you want to move the current dialog box, complete the following steps.

  1. Move the cursor to the Title Bar, and as the cursor changes into ✣, press the 『Set』 key,
  2. Move the trackball and locate the rectangular frame that moves with the cursor to the appropriate site.
  3. If you want to move the dialog box to the site, press the 『Set』key; if you want to cancel the moving, press the 『Back』key and the dialog box will not be moved.

9 Starting Examination

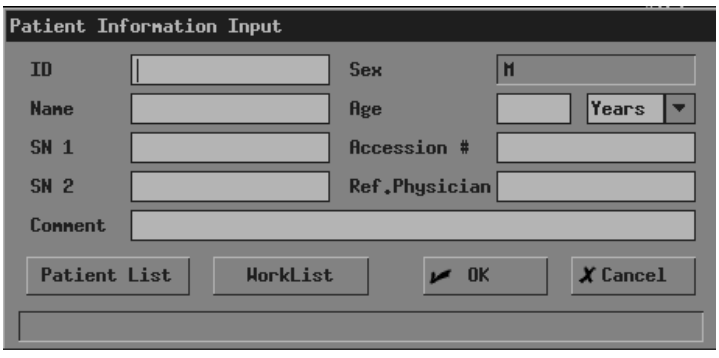
9.1 Selecting Exam Mode

After the power is on, the system automatically enters the preset exam mode.

Press [ABD], [GYN], [OB], [CAR] or [SML] to enter corresponding exam mode.

9.2 Entering Patient Information

To enter the patient information, press the [Info.] key or move the cursor to the name or ID on the screen and press the『Set』key. At this time, the『Info.』indicator lights up and the Patient Information Input box pops up as shown in following figure.



(1) Press the 『Set』 or 『Back』 key to change “M” and “F” in [Sex] option.

(2) Other items are entered by users.

ID: English letters, numbers 0-9 and “-” can be entered, up to 12 English characters. ID value can’t be empty or repeated.

Name: Chinese characters are supported but wildcard characters “?” and “*” are not

allowed.

Age: numbers 0-9 are allowed; the range is between 0 and 150.

Accession #: refers to exam number for DICOM.

SN 1/SN 2: .refers to number for outpatient and number for hospitalization.

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

Comment: exam-specific explanation or remarks.

(3) After the patient ID is entered, if it is present, the system will automatically invoke the basic information of this patient stored previously.

(4) After entering the patient information, press the [OK] button to save the patient information in the system and the dialog box exits, and at this time the name and ID of the patient are displayed at top of the screen.

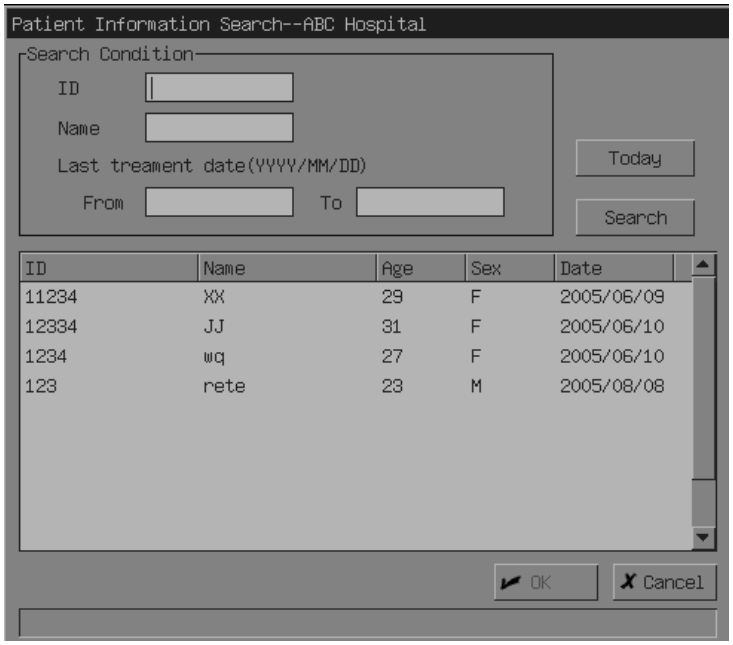
(5) To cancel the entry of the patient information, press the [Cancel] button or 『Exit』 key on the control panel, and the dialog box exits. Thus this entry is invalid.

Note: Be sure to enter proper ID. Otherwise, wrong patient data may be produced.

9.3 Searching/Changing Patient Data

If patient information has been stored in the system, you can view, browse and edit it.

1. In the [Patient Information Input] box, press the [Patient List] button. The screen displays the dialog box shown as follows.



2. In the [Search Condition] bar, enter one or multiple items of the patient ID, name and the last treatment date; press the『Search』button, and the patient data that meet these conditions will be displayed in the list. Press the [Today] button to search intraday patients.

3. Searching a patient in sequence: respectively click ID/Name/Age/Sex/Date button and the patient data will be arranged respectively according to ID/ Name/Age/Sex/Date in order to easily search the patient.

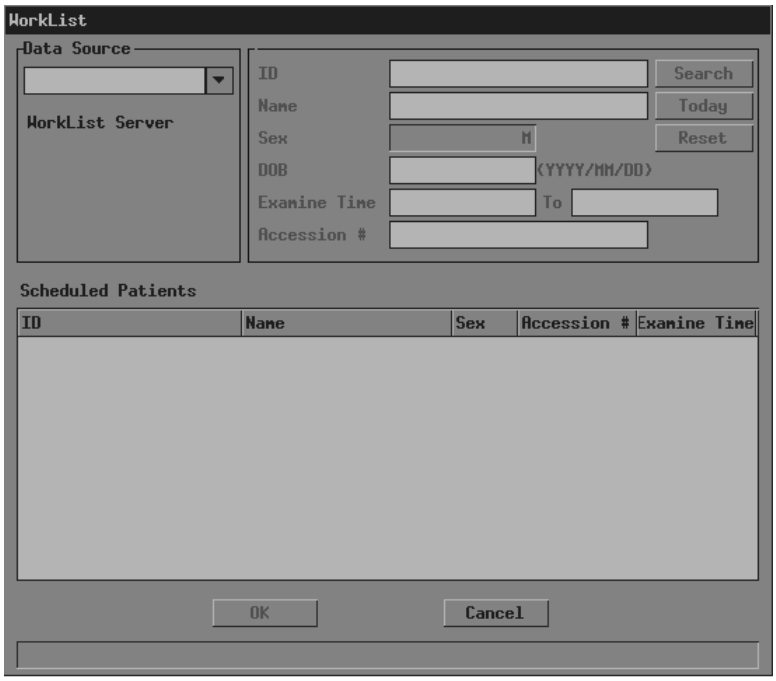
4. After the patient is selected, press the [OK] button or double-click it and enter the [Patient Information Input] dialog box. Now you can edit the patient information (but can not change patient's ID), and after you complete the edit, press the [OK] button to save the patient information in the system. Now the screen displays the new patient information at top of it.

5. If changing the current patient information, you can directly click the information of the patient at the upper part of the screen, and a dialog box of [Patient Information Input] will pop up. After you edit the information, press the『OK』button to save them.

6. Press the『Cancel』button or the『Exit』key, you can cancel the change of the patient information.

9.4 Worklist

After installing the DICOM package and setting the Worklist server, the user can import the patient information in the Worklist to the ultrasound system. See the screen below.



1. Data Source: selects the worklist server.

2. Setting patient conditions: ID, Name, Sex, DOB, Exam Date or Accession #.

3. Click the “Search” button, and the system starts the corresponding patient information as per the set conditions. Click the “Today” button to search the patients examined today.

4. To change the set conditions, click the “Reset” button to reset the setting.

5. Select a patient in the scheduled patient list, and click [OK] to import the patient information to the ultrasound system.

10 Presets

10.1 Introduction

Preset function is used to set the system operating environment, status and the configuration parameters for each exam mode. The preset values are saved in the memory inside the system, which will not be lost if power-off occurs, thus ensuring that the system automatically operates in the desired status each time the system is started. This chapter gives introduction about how to configure the system using the preset menu in the preset mode. Please refer to the [Advanced Volume] of operator's manual for the detailed operation.

10.2 Entering/Exiting Preset Mode

10.2.1 Entering preset mode

Press the 『Preset』 key on the control panel, and the preset indicator lights up. The PRESET menu appears on the right part of the screen. See the figure below. The system enters the preset mode.

Move the cursor to an item of the PRESET menu and press the 『Set』 key to enter the corresponding dialog box to preset parameters.

10.2.2 Exiting preset mode

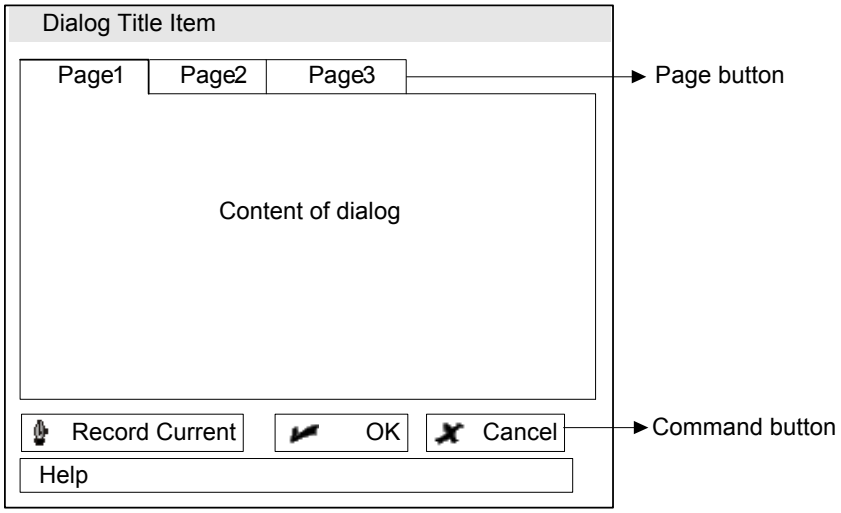
In the preset mode, press the 『Preset』 or 『Exit』 key, or move the cursor to the [Return] item of the menu and press the 『Set』 key to close the PRESET menu. The preset indicator turns off. Then the system exits the preset mode and begins running according to the modified parameters.

NOTE: After defining the parameters, press the『Preset』 key again, or press the『Exit』 key, or move the cursor to the [Return] item of the menu and press the 『Set』 key to exit and to apply the new settings.

10.3 Displaying/Modifying Preset Information

10.3.1 Modifying preset information

To set up all the preset parameters and curves, the user should select the item in the PRESET menu to call up the preset dialog box. The general outline of the preset dialog box is shown in the figure.



Follow these steps:

(1) Select the corresponding item and press the 『Set』 key to enter the corresponding preset dialog box.

(2) Move the cursor to select the button of the desired page to open the corresponding preset page

(3) Use the 『Set』 or the 『Back』 key to adjust the parameter. At this time, the help information is displayed in the bottom of the box.

(4) After setting the information in the current page, select the button of another page to set other parameters. After all the parameters have been set up, press the 『Set』 key on the [OK] button to make these settings effective and to be saved in the system, and at this time the dialog box closes.

(5) To cancel the modifications, just press the 『Set』 key on the [Cancel] button. In such a manner, the dialog box closes.

(6) Press the 『Preset』 or 『Exit』 key, or move the cursor to the [Return] item of the preset menu and press the 『Set』 key, to close the PRESET menu. The preset indicator turns off. The system exits the Preset mode and begins to reset according to the modified preset parameters.

10.3.2 Special function button

➢ [Record Current]

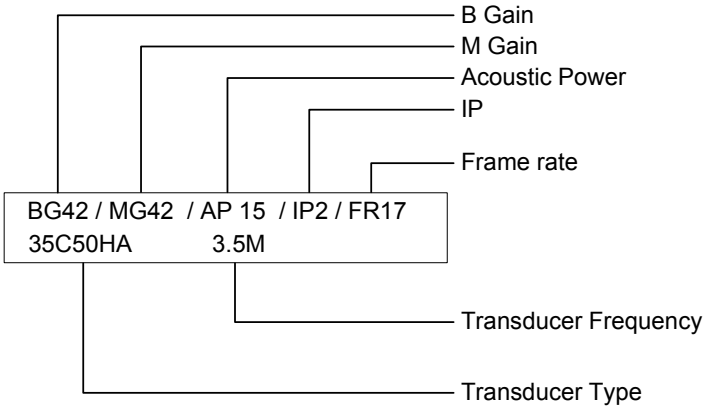
Besides setting the parameters in the current page one by one, you can also use the “record the current value” method to preset parameters. Press the 『Set』 key on the [Record Current] to set each parameter as the value used by the system before entering the preset mode. Namely, set up the current operating parameters of the system as the preset parameters.

Note:	The [Record Current] button is only valid on the current preset page.

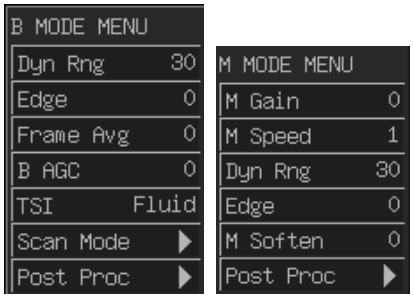
11 Image Control and Adjustment

11.1 Adjusting Image Parameters

The keys on the control panel and items in the menus are provided to adjust images. For numeric parameters to be adjusted by keys on the control panel, most of their values are displayed in the Parameter Area on the top of the screen. See the figure below.



For numeric parameters to be adjusted through menu item, their values are displayed to the right of the menu items.



11.1.1 B/M gain

B/M gain adjustment is to adjust the gain of the whole receiving system and the signal sensitivity of B/M images. The adjusting range is between 0dB and 100dB. B-mode and M-mode gains are displayed in the Parameter Area on the top of the screen.

Turning the『Gain』knob on the control panel can adjust B-mode and M-mode gains simultaneously. You can also adjust M-mode gain independently by using the [M Gain] item in M MODE MENU. See the figure below.

You cannot adjust the gain when an image is frozen.

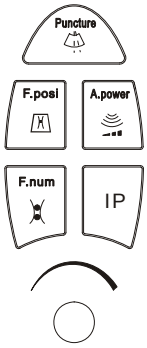
11.1.2 Acoustic power

Acoustic power refers to the power consumption of the ultrasonic wave emitted from the transducer. You must select the proper acoustic power in use according to the real situation and the rules of applying acoustic power.

Press the『A.power』key, and its indicator will light up. Turn the parameter adjust knob to adjust the acoustic power. At the same time, the acoustic power value is displayed in the Parameter Area on the top of the screen. To reduce the acoustic power, turn the knob counterclockwise; to increase the acoustic power, turn the knob clockwise.

The adjustment range of acoustic power is between 0 and 15, where 0 represents the minimum and 15 represents the maximum.

You cannot adjust acoustic power when an image is frozen.



11.1.3 Transducer frequency

Press the 『Freq/THI』key to adjust the transducer and switch to the harmonic frequency.

11.1.4 TGC

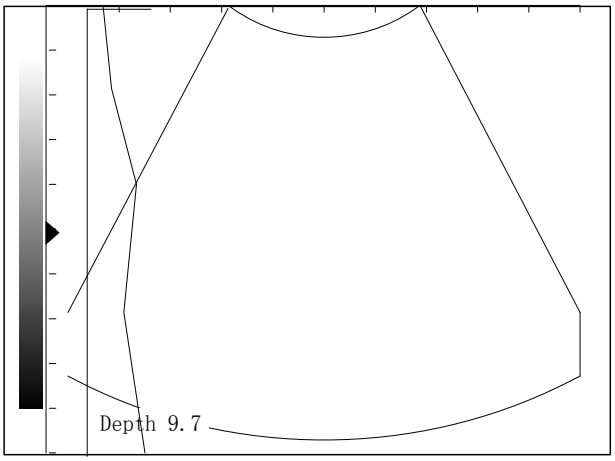
TGC refers to depth segmental gain compensation curve. You can use eight TGC sliders on the control panel to adjust the different segments of the current depth. Move the TGC slider on the control panel to adjust the TGC of the corresponding scanning depth.

When you adjust TGC, the TGC curve appears automatically on the left part of the screen, which will change as the slider moves. See the figure below.

When you stop adjusting the TGC, 1.5 seconds later, the TGC curve will disappear automatically.

The TGC adjustment is invalid when the image is frozen and becomes effective after the

image is unfrozen.

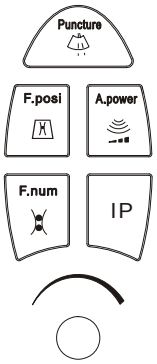


11.1.5 Number of focuses

B-mode images can have 1～4 emitting focuses. However, the number of focuses is also limited by the scanning depth. M-mode images have only one focus; namely, the number of focuses of M-mode image cannot be changed.

Press the『F.num』 key, and its indicator will light on. Turn the knob to change the number of focuses.

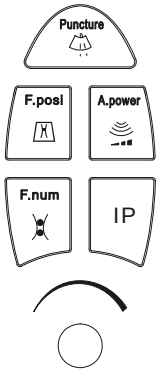
The number of focuses cannot be changed when ane image is frozen.



11.1.6 Focus position

Press the『F.posi』key, and its indicator will light on. Turn the adjustment knob to change the focus position. When you adjust the focusing position, focuses will move together but only in the display range of the current image.

The focus position cannot be adjusted when an image is frozen.



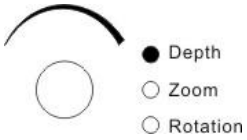
11.1.7 Depth

Confirm that the『Depth』 indicator lights up, and then turn the function knob (shown in the figure below) to change the imaging depth.

The depth range of low frequency transducer is 4.31 – 24.8cm.

The depth range of high frequency transducer is 2.16 – 11.9cm.

The depth cannot be adjusted when an image is frozen.



11.1.8 Dynamic range

Dynamic range is provided to adjust the contrast resolution of B-mode or M-mode images, and to compress or enlarge gray display range. Dynamic range is between 30dB and 100dB in increments of 5dB.

The dynamic range of either B-mode image or M-mode image can be adjusted through the [Dyn Rng] menu item in their respective menus. The current value of dynamic range of B or M-mode image is displayed in the menu item.

Dynamic range cannot be adjusted when an image is frozen.

11.1.9 Edge enhancement

Edge enhancement is provided to highlight the image contour so that you can identify the tissue structure more clearly. The range of edge enhancement is between 0 and 4. The value of 0 represents no edge enhancement while 4 the maximum.

The edge enhancement of B-mode image can be adjusted through the [Edge] menu item. The current value of edge enhancement is also displayed in the menu item.

Edge enhancement cannot be adjusted when an image is frozen.

11.1.10 Frame average

Frame average means to add up the adjacent B-mode images and calculate the average value in order to remove the noise on the image and make the image's details clearer. Its range is between 0 and 7. The value of 0 represents no frame average has been adopted while 7 means to add up 8 continuous images and calculate the average.

Frame average is valid only on B-mode image. You can adjust it through the [Frame Avg] item in B MODE MENU.

Frame average cannot be adjusted when an image is frozen.

11.1.11 M soften

M Soften means to add up the scanning lines of M-mode image and calculate the average value in order to remove the noise on the image and make the image's details clearer. Its range is between 0 and 15. The value of 0 represents no M Soften has been done while 15 means to add up 16 continuous scanning lines and calculate the average.

M Soften is valid only on M-mode image. You can adjust it through the [M Soften] item in the M MODE MENU.

M Soften cannot be adjusted when an image is frozen.

11.1.12 B AGC

AGC refers to the automatic gain control, and its adjustment range is 4 steps, from 0 to 3.

AGC is only valid on the B image, and can be adjusted through the [B AGC] item of the [B MODE MENU]. The current AGC value is also displayed on the menu item.

When an image is frozen, AGC cannot be adjusted.

11.1.13 Tissue specific imaging (TSI)

In the B MODE MENU, you can adjust the TSI parameters such as General, Muscle, Fatty and Fluid.

11.1.14 M speed

M Speed is provided to adjust the refresh speed of M-mode images.

Its range is between 1 and 4. The value of 1 indicates the slowest scanning speed while 4 the fastest.

M Speed function is valid only on M-mode image. You can adjust it through the [M Speed] item in the M MODE MENU. The current value of M Speed is also displayed in the menu item.

M Speed cannot be adjusted when an image is frozen.

11.1.15 Scan mode

- **Scan Angle**

This function is provided to change the scan angle and only valid on B-mode images. The scan angle is related to the frame rate. The smaller the scan angle, the higher the frame rate will be. Its range is between 0 and 3. The value of 0 indicates the minimum scang angle while 3 the maximum.

You can adjust the scanning angle through the [Angle] in [Scan Mode] of the B MODE MENU. The current value of scan angle is displayed in the sub-item.

The scan angle cannot be adjusted when an image is frozen.

- **Scan line density**

Scan line density is provided to adjust the density of scanning lines on the B-mode image; therefore this function is valid only on the B-mode image. Density of scanning lines has two types: high density and high frame rate. The former is used for better image quality and the latter for higher frame rate.

You can adjust the scan line density by selecting [Hi Density] or [Hi Frm Rate] in [Scan Mode] of B MODE MENU.

Line density cannot be adjusted when an image is frozen.

11.1.16 Post processing

Post processing is used to apply the gray correction to the image in order to obtain the image with optimum vision.

You can select anyone from the eight kinds of preset post processing effects in the Post Proc menu. And you can adjust gray transform curve, gray rejection curve andγ correction, respectively.

Post processing operation is valid on the real-time B-mode image, frozen B-mode image and CINE loop B-mode image.

Post processing is independent for B-mode image and M-mode image. You can adjust them independently through the [Post Proc] item in their respective menus.

- **Gray Map**

The system presets eight kinds of Gray Map, namely Map1, Map2, Map3, Map4, Map5, Map6,

Map7, Map8. Each gray map is a combination of gray transform curve, gray rejection curve and γ correction.

Gray Map1 is obtained by compressing the brightness of areas in low lightness and high lightness based on linear change. The contrast of the image increases gradually from Map1 to Map8.

You can select a Gray Map through [Gray Map] in [Post Proc] of B MODE MENU. The current value of Gray Map is displayed in this submenu item as well.

- **Gray Transform Curve**

（1）Select the [Curve] item in the [Post Process] submenu, and the “Gray Trans Curve” dialog box pops up. See the figure below;

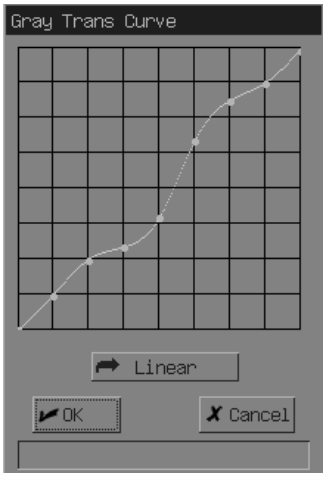
（2）Move the cursor onto a “•” dot, and the cursor will turn into a “✣”. Press the『Set』 key and roll the trackball to move “•” dot so as to adjust gray transform curve. You can see the image changing during adjustment;

（3）Press the 『Set』key again to fix the “•” dot to the new position; the cursor will return to a “↖”. Repeat the above steps to adjust the next dot;

（4）After the step 2 is completed, you can either press the『Back』key to cancel the adjustment to the dot. The “•” will return to its original position;

（5）If you press the『Set』key on the [Linear] button, the gray transform curve will change into a straight line with 45°slope;

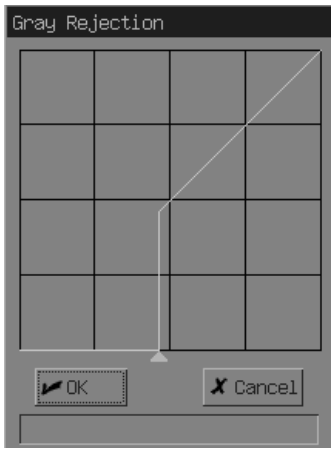
（6）Press the『Set』key on [OK], the system will save the modification and exit the dialog box; press the『Set』 key on [Cancel], the system will restore original curve and exit the dialog box.



➢ **Gray Rejection Curve**

Adjustment of gray rejection curve is to suppress the image signal below a certain gray scale.

(1) Select the [Rejection] item in [Post Proc] submenu, and the “Gray Rejection” dialog box pops up. See the figure below;



(2) Move the cursor onto the “▲” dot, the cursor will turn into a “✣”. Press the『Set』 key and roll the trackball to move the dot so as to adjust the gray rejection curve. You can see the image changing during adjustment;

(3) After adjustment, press the『Set』key again, the cursor will return to a “↖”;

(4) After the step 2 is completed, you can either press the『Back』key to cancel the modification. The “▲” will return to its original position;

(5) Press the『Set』 key on [OK], the system will save the modification and exit the dialog box; press the『Set』on [Cancel], the system will restore original curve and exit the dialog box.

➢ **γ Correction**

γ Correction is provided to modify the nonlinear distortion of the image.

γ correction has four grades, 0, 1, 2 and 3 corresponding to γ correction coefficients 1.0, 1.1, 1.2 and 1.3, respectively.

You can adjust γ value through [γ] in [Post Proc] of B MODE MENU. γ correction is displayed in the submenu item.

11.1.17 IP

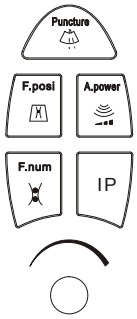
IP refers to a combination of a group of image processing parameters including dynamic range, edge enhancement, frame average and B AGC. IP represents a kind of image processing effect.

IP can be set between 1 and 8, representing 8 kinds of IP. The smaller the IP value is, the

bigger the image contrast will be. The larger the IP value is, the softer the image will be.

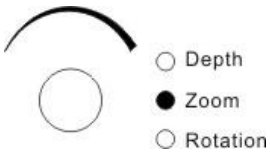
IP value is valid only on the B-mode image. IP value cannot be changed when an image is frozen.

You can change IP value by using the『IP』key and the parameter knob. Press the 『IP』key, and its indicator will light on; then turn the parameter knob to change IP value.



11.2 Zoom

The『Zoom』key and the functional knob are used together to amplify an image. The amplifying multiple is between 100％ and 400％ (this proportion is used for the area).



Method for zooming out/in an image:

(1) Press the『Zoom』key, and the indicator lights up. A viewfinder frame appears in the middle of the image window. In the B/B-mode, only the real-time image reacts to the ZOOM function. When the『Zoom』indicator of the functional knob lights up, it indicates the knob is in ZOOM adjustment status;

(2) Roll the trackball in order to use the viewfinder frame to position the amplification center;

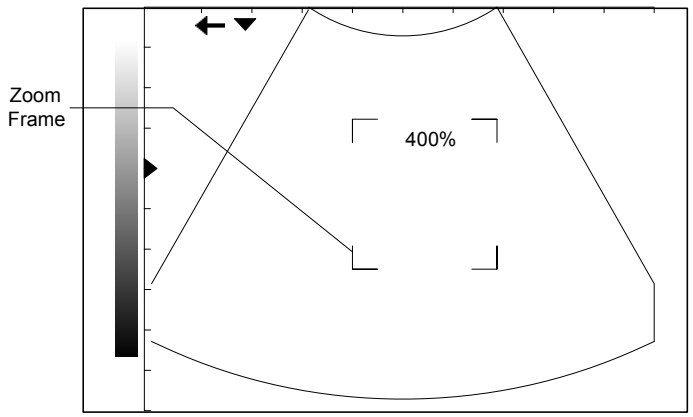
(3) Turn the functional knob to change the multiple; the size of viewfinder frame changes accordingly. Turn the knob clockwise, and the viewfinder frame reduces and ZOOM multiple increases; turn the knob counterclockwise, the viewfinder frame enlarges and ZOOM multiple decreases;

(4) Preset the『Set』key, the viewfinder frame will disappear and the screen will display the amplified image;

(5) Roll the trackball, and the amplified image will move inside the image window;

(6) Turn the functional knob to change the ZOOM multiple of the image;

(7) Press the『Set』key again to fix the center of the image. The cursor appears;



(8) At this time, turn the functional knob, and you can also change the ZOOM multiple of the image.

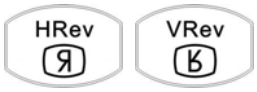
(9) Press the『Zoom』or『Exit』key again to exit ZOOM mode. The system restores to display the image with normal proportion. The『Zoom』indicator of the functional knob turns off and instead the『Depth』indicator lights up.

The real-time image, frozen image and CINE loop image can all be amplified. Additionally, measurements, comments or body marks can be executed or added on the amplified image.

11.3 Image Reversal

B-mode images can be reversed upside down and left or right. Press the『VRev』key to reverse the image upside down or the『HRev』key to reverse the image left or right.

The status symbols in the upper left corner of the image window have the following meanings: The "←" means that the first scanning line on the left is the start scanning point of the transducer; "→" means that the first scanning line on the right is the start scanning point of the transducer.



11.4 Images Merge

Images can be merged in B/B mode if they meet all of the following conditions and can be measured cross the two windows (the scale can be used cross the two windows):

(1) The preset switch of ImgMerge is on.

(2) Linear array transducer.

(3) There are images both in B/B windows.

(4) The images parameters are same: depth, Up/Down reverse, rotary status, non-zooming mode

(5) All images of the transducer are displayed in the windows.

12 Cine

12.1 Introduction

⚠**CAUTION:**	**When performing examination of a new patient, press 「Patient」 to delete the recorded data of the previous patient in the image memory. Otherwise, the new data may be confused with the data of the previous patient.**

When an image is frozen, the images immediately before the frozen image can be played back and edited. This function is called Cine. Cine images are cleared by turning OFF the power or unfreezing the frozen image.

In the live image status, B images or M images can be stored in the Cine memory according to the time sequence and in the unit of frame or line. The B/B or M/B images in the left and right windows can be stored respectively. If the Cine memory is fully stored with images and a new frame or line of image is to be stored, the earliest image in the memory will be removed. Therefore the Cine memory always reserves the recent images. After the images are frozen, they can be invoked and displayed in the form of frame one by one（in manual review）.B Cine images can be reviewed automatically and cyclically.

In the high-density scanning mode, the memory can store up to 128 frames of B image; whereas in the low-density scanning mode, the memory can store up to 256 frames of B image. In the B/B mode, the memory is divided into two equal parts. The maximum storing capacity is 2048 lines in the M mode. The final image is always the latest one and the first image is always the earliest one.

12.2 Cine Review in B Mode

12.2.1 Manual review

The manual review is the default Cine review of the system.

In the B mode or the B/B mode, after you press the 『Freeze』key to freeze the image, the 『Cine』key lights up and the system automatically enters the manual review status.

Roll the trackball, and then the stored Cine images will be displayed on the screen in turn. Roll the trackball to the right, and the B images will be displayed in ascending sequence according to the frame numbers, i.e. the images are displayed in the same sequence as which they are stored. Roll the trackball to the left, and the B images will be displayed in descending sequence.

The indicating bar at the bottom of the screen shows the orientation of the Cine review. The B image numbers respectively represent the current frame number and the total frame number. Take the B mode as an example, and see the following figure. The arrow shows the orientation of the Cine review.

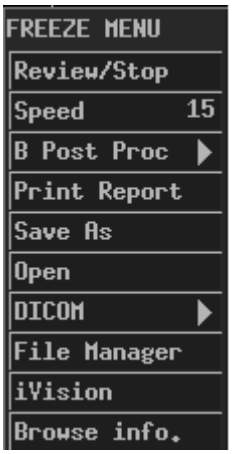
In the B/B mode, press the 『B/B』key, and you can switch the current Cine images between the left and right windows.

In the manual review status, press the『Cine』key, and then the『Cine』key turns off and the manual review status exits.

12.2.2 Auto review

In the B mode or the B/B mode, press the 『Freeze』key to freeze the image, and then the system automatically enters the manual review status.

After the『Cine』key lights up, you should confirm whether the B freezing menu is displayed on the screen. If not, press the『Menu』key. The B freezing menu is shown in the following figure.



Press the 『Cine』key to exit the manual review status, and you can perform operation for the FREEZE MENU and click the [Review/Stop] item of the B freezing menu, and the system will automatically review the stored images in the ascending sequence.

Click the [Review/Stop] item again, and the review will automatically stop.

Before or during the auto review, you can change the speed of the Cine review by the [Speed] item of the B freezing menu. The current speed is displayed at the right side of this menu item.

Press the [B post proc] submenu to adjust B image post-process parameters.

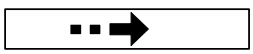
In the B/B mode, press the 『B/B』key, and you can also switch the live reviewed images between the left and right windows.

12.3 Cine Review in M Mode

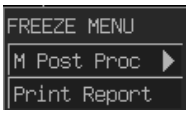
In the M mode, press the 『Freeze』key to freeze the image, and then the『Cine』key lights up, and the system automatically enters the manual review status.

Roll the trackball, and the stored Cine images will be displayed on the screen in turn. Roll the trackball to the right, and the indicating bar of Cine review moves to the left and the image moves to the right, and the early-stored M image will be displayed. Whereas, roll the trackball to the left, and the indicating bar of Cine review moves to the right and the image moves to the left.

The Cine review indicator shows the current Cine image storage time and the total Cine image storage time.

5.4/10.6 

In the manual review status, press the 『Cine』key, and the 『Cine』key turns off, and the manual review status exits. At this time you can perform operation for the FREEZE MENU.



In the M/B（B live）mode, press the 『Freeze』key to freeze the image, and the M Cine review status is entered. Press the 『M/B』key, the status is switched to the B Cine review.

In the M/B（B not live）mode, press the 『Freeze』key to freeze the image, and the M Cine review status is entered. Press the 『M/B』key, the status can't be switched to the B Cine review.

12.4 Others

The magnified images can also be stored in the CINE review memory, which can be reviewed after the images are frozen. The method of reviewing the magnified images is the same as that of reviewing ordinary CINE images.

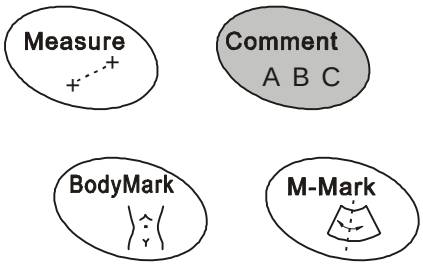
You can magnify the images in the CINE review memory, modify them, perform measurements, and add comments and Body Marks on them.

13 Adding/Deleting Comments

Three methods of comment entry are available; characters can be entered from the keyboard, comment library characters or the arrow.

⚠WARNING: **Please ensure the correct comments are entered. Incorrect comments may cause misdiagnosis!**

13.1 Entering/Exiting Comment Status



To enter the comment status, there are two methods shown as follows:

1. Press the 『Comment』 key to enter the comment status. The 『Comment』 indicator lights up. In the image window, the cursor changes into a "|".
2. Pressing the 『Arrow』 key can enter the comment status, and add arrows as well.

To exit the comment status:

In the comment status, press the 『Comment』 key again or other operating mode keys to exit the comment status. The 『Comment』 indicator turns off.

13.2 Adding Comments from Keyboard

1. Press the『Comment』key to enter comment status. The cursor changes into a "|".
2. Confirm the position in which the comment is to be added. Roll the trackball or use 『→』、『←』、『↑』、『↓』keys to move the cursor to the position where comment is required.

3. Enter the characters by keyboard.

   ✧ By pressing the keys on the keyboard to directly enter the normal characters.

   ✧ If you want to enter the upper characters of the keys, press the 『SHIFT』key first and the key indicator lights up. Then you can enter the characters by pressing the keys.

4. Line feed: Under the comment edit status (background of character entering bar is white), press the『Enter』key, the cursor will go to the next line, and the initial position after the line feed is the longitudinal position of comment in the previous line.

5. Press the『Set』key to confirm.

13.3 Adding Comments from Comment Library

1. In the comment status, move the cursor to the position where the comment is to be added in the image. Then press the 『Change』key, the dialog box of Comment Library appears on the screen.

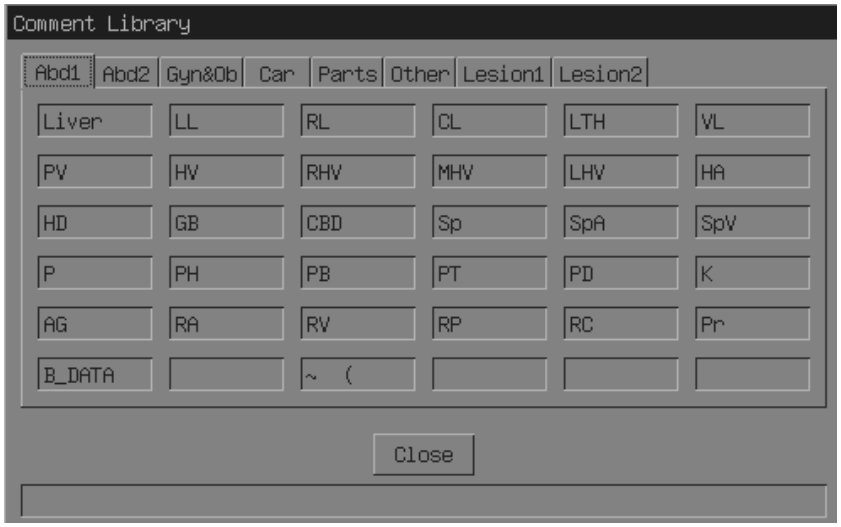
2. Move the cursor to the desired item, if there isn't any item desired in the current page, move the cursor to other page button and press the key to look for the item. Press the 『Set』key to close the dialog box. The system automatically adds the selected term to the specified position.

3. At this time, the background of comment bar is white, indicating it is the edit status; the user can still edit the comment added.

4. Press the『Set』key to confirm and the comment edit status exits.

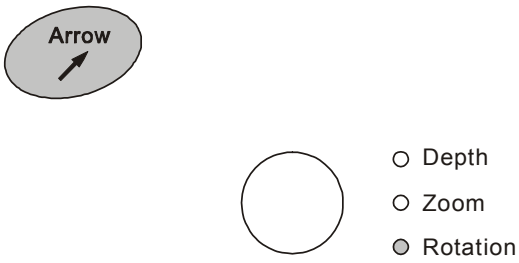
5. When the Comment Library is open but no item is to be entered, position cursor on the [Cancel] item in the dialog box and press『Set』key to close the dialog box.

The dialogue of comment library is shown in the figure below:



13.4 Adding Arrows

The arrow is used to mark the position on the image where the comment is required or the position to be stressed.



1. In the comment status or other statuses, press the 『Arrow』 key, the 『Arrow』indicator lights up and there is an arrow which is around a frame, indicating it is the selection status, in which orientation can be adjusted and the arrow can be deleted. At this time, the “Rotation” indicator of multifunction knob also lights up.
2. Roll the trackball to move the arrow to the position where you want to add an arrow.
3. Turn the multifunction knob to change the orientation of the arrow.
4. Press the『Set』key to add the arrow.
5. Repeat the steps above to add an arrow.
6. Continuously press the『Arrow』key to add multiple arrows.
7. Press the 『Arrow』key to exit the comment status.

13.5 Moving Comments

1. In the comment status, move the cursor on an existing comment item, that is, a text

comment or an arrow.

2. After the cursor changes into"✣", press the 『Set』 key. As the background of character bar changes into gray, it is selected.

3. Roll the trackball to move the frame which is the same size as the comment bar to the target position on the screen.

4. If you want to locate the frame at the target position, press the『Set』key and the selected comment is moved there; if you want to cancel the moving, press the 『Back』key.

13.6 Modifying Comments

1. Move the cursor on the comment to be modified.

2. Press the 『Set』 key twice, and the cursor will appear in the editing box. The background of comment bar changes to white.

3. Using the『→』and 『←』 keys on the keyboard, move the cursor to where you want to insert characters, then type or select the new comment from comment library and insert characters;

   Move the cursor to the left side of characters to be deleted, and press the 『DEL』 key to delete the characters or comments. Or, move the cursor to the right side of characters to be deleted, and press the『BS』key to delete the characters or comments.

4. Press the『Set』key to exit the comment edit status.

The method described above is unavailable for arrow comments.

13.7 Deleting Comments

13.7.1 Deleting characters

In the Comment status, roll the trackball or use 『→』and 『←』 keys to anchor the cursor, then press the 『DEL』 key or 『BS』 key to delete the character at the right side or left side of the cursor.

13.7.2 Deleting arrows

In the status of arrow selected (there is a frame), press 『DEL』, [Back] or [BS] key to delete it.

13.7.3 Deleting all comments and arrows

In the comment status, i.e. the cursor is in the status of "|" but no comment item is activated (highlighted), pressing 『DEL』, 『BS』 or 『Clear』key can delete all the comment characters,

comments and arrows.

NOTE:	Pressing the『Clear』key will clear all comments, body marks, measurement scales and general measurement data on the screen.

13.8 Comment Library

Users can select the appropriate comment from the comment library by referring to the list.

Abdomen：

Symbol on screen	Full description
Liver	Liver
LL	left lobe of liver
RL	right lobe of liver
CL	caudal lobe of liver
LTH	Ligament teres hepatis
VL	Venous Ligament
PV	Portal Vein
HV	Hepatic Vein
RHV	Right Hepatic Vein
MHV	Medium Hepatic Vein
LHV	Left Hepatic Vein
HA	Hepatic Artery
HD	Hepatic bile duct
GB	Gallbladder
CBD	Common Bile Duct
Sp	Spleen
SpA	Splenic Artery
SpV	Splenic Vein
P	Pancreas
PH	Pancreatic Head
PB	Pancreatic Body
PT	Pancreatic Tail
PD	Pancreatic Duct
K	Kidney
AG	Adrenal Gland
RA	Renal Artery

Symbol on screen	Full description
RV	Renal Vein
RP	Renal Pelvis
RC	Renal Calices
Pr	Pyramid
RCo	Renal Column
Ur	Ureter
Bl	Bladder
Pro	Prostate
SV	Seminal Vesicle
Sto	Stomach
Ca	Cardia
E	Esophagus
Bo	Bowel
Du	Duodenum
Co	Colon
Ap	Appendix
SMA	Superior Mesentery Artery
SMV	Superior Mesentery Vein
Ao	Abdominal Artery
IVC	Inferior Vena Cava

Gynecology & Obstetrics：

Symbol on screen	Full description
Ut	Uterus
Ov	Ovary
Cx	Cervix
V	Vagina
En	Endometrium
IUD	Internal uterus Device
GS	Gestational Sac
Embryo	Embryo
YS	Yolk Sac
Am	Amnion

Symbol on screen	Full description
Pl	Placenta
UC	Umbilical Cord
AF	Amniotic Fluid
F	Fetus
FH	Fetal Head
F_Sp	Fetal Spine
F_Sto	Fetal Stomach
FK	Fetal Kidney
F_Lb	Fetal limbs

Cardiac：

Symbol on screen	Full description
LV	Left Ventricle
RV	Right Ventricle
LA	Left Atrium
RA	Right Atrium
AAO	Ascending Aorta
PA	Pulmonary Aorta
MV	Mitral Valve
TV	Tricuspid Valve
AV	Aortic Valve
PV	Pulmonary Valve
IVS	Interventricular Septum
IAS	Interatrial Septum
LVPW	Left Ventricular Posterior Wall
CT	Tendinous Cords
PM	Papillary Muscle
CS	Coronary Sinus
CA	Coronary Artery
RVOT	Right Ventricular Outflow Tract
RVAW	Right Ventricular Anterior Wall

Small Parts：

Symbol on screen	Full description
Thy	Thyroid
MG	Mammary Gland
Eye	Eye
Ts	Testicle
Ep	Epididymis
LyN	Lymph Node
CCA	Common Carotid Artery
IJV	Internal Jugular Vein
ICA	Internal Carotid Artery
ECA	External Carotid Artery
VA	Vertebral Artery
IIA	Internal Iliac Artery
IIV	Internal Iliac Vein
EIA	External Iliac Artery
EIV	External Iliac Vein
FA	Femoral Artery
FV	Femoral Vein
GSV	Great Saphenous Vein

Others：

Symbol on screen	Full description
L	left
R	right
U	up
D	down
♂	male
♀	female
Anterior	anterior
Posterior	posterior

Lesion：

Symbol on screen	Full description
M	Mass
T	Tumor

Symbol on screen	Full description
Sc	Scar
St	Stone
Cy	Cyst
Abs	Abscess
Hma	Hematoma
Eff	Effusion
Asc	Ascites
Nec	Necrosis
Sed	Sediment
Meta	Metastasis
Cal	Calcification
Hcc	Hepatocarcinoma
Ang	Angioma
Polyp	Polyp
As	Ascaris
FB	Foreign Body
Tb	Tuberculosis
Fe	Fecalith
Th	Thrombus
Plaque	Plaque
Myo	Myoma
HM	Hydatidiform Mole
Any	Anencephaly
Hyd	Hydrocephalus
SB	Spina Bifida
VSD	Ventricular Septal Defect
ASD	Atrial Septal Defect
PDA	Patent Arterial Duct
MS	Mitral Stenosis
MR	Mitral Regurgitation
MVP	Mitral valve prolapse
MVV	Mitral Valve Vegetation
LAM	Left Arterial Myxoma

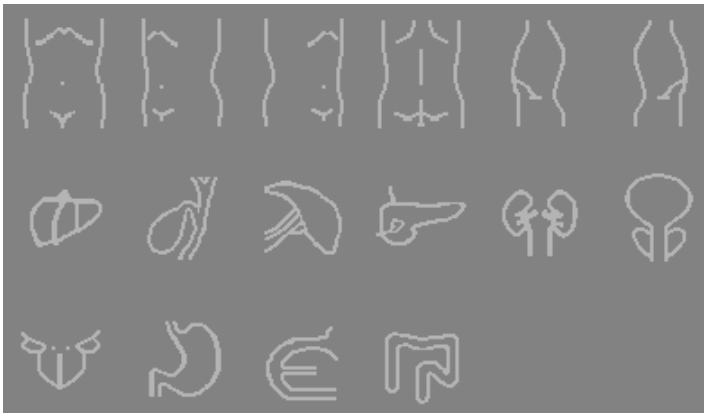
Symbol on screen	Full description
PE	Hydropericardium
AAn	Aortic Aneurysm
Asa	Aortic sinusal aneurysm
AS	Aortic Stenosis
PS	Pulmonic Stenosis

14 Body Mark

14.1 Introduction

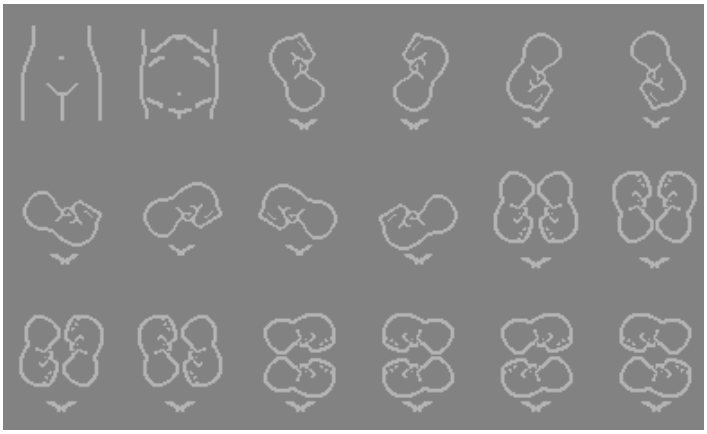
Body Marks are used to point out the body part being examined and the detecting direction of the transducer. In fact the Body Marks act as comments on an image.

In the system, five categories are available: abdomen, gynecology, obstetrics, cardiology, and small parts. Each category has some different Body Marks. See the following figures.



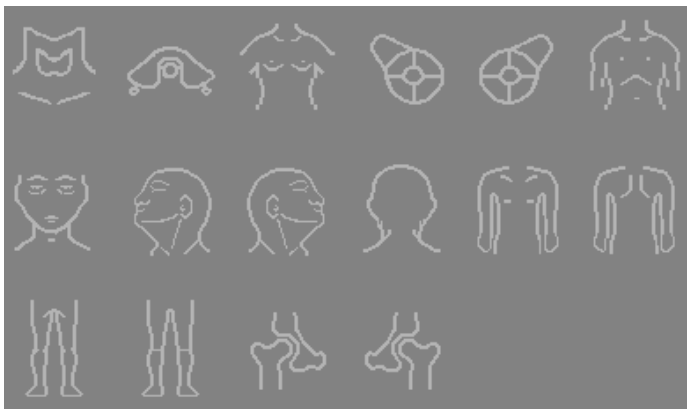
Abdominal Body Marks

Gynecology Body Marks



Obstetric Body Marks

Cardiac Body Marks



Small Parts Body Marks

14.2 Adding Body Mark

1 Press the 『BodyMark』 key. The [Body Mark] dialog box pops up and the BodyMark indicator lights up.

2 If there is no desired Body Mark in the current page, move the cursor to the desired page button and press the『Set』key to open another page and look for the desired Body Mark.

3 If you want to exit the [Body Mark] dialog box, press the 『BodyMark』 key, or move the cursor to the [Close] button and press the 『Set』 key. Then the BodyMark indicator turns

off.

Otherwise, go to the next step.

4 Move the cursor to a Body Mark, which then is framed. Press the 『Set』 key to close the [Body Mark] dialog box and add the selected Body Mark at the bottom left corner of the image window.

5 If you do not want to adjust the transducer position and orientation on the Body Mark, press the『Set』key to complete the Body Mark adding. Then the BodyMark indicator turns off.

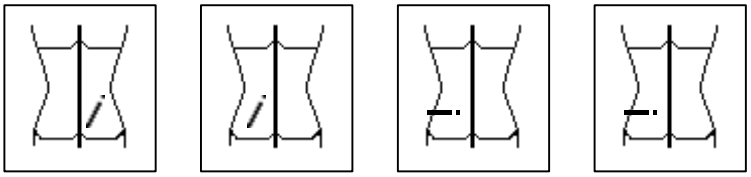
If you want to clear the displayed Body Mark, press the 『Clear』 key. Then the BodyMark indicator turns off.

Otherwise, go to the next step.

6 To adjust the position of the transducer in the Body Mark, roll the trackball.

7 To adjust the orientation of the transducer, turn the multifunction knob.

8 Press the 『Set』 key to complete adding Body Mark. Then BodyMark indicator turns off.



NOTE: In the B/B mode, Body Marks can be added on the two images respectively.

14.3 Moving Body Mark

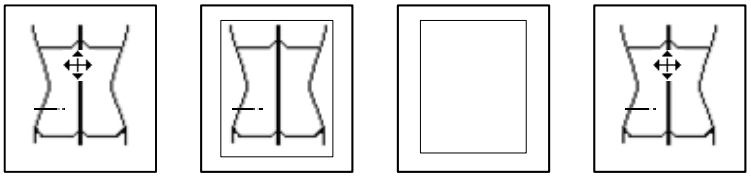
The Body Mark can be moved to other position of image area.

1 Move the cursor onto the Body Mark. The cursor changes into a "✣".

2 Press the 『Set』 key and the Body Mark is framed.

3 Roll the trackball to move the frame to the target position, where the Body Mark is to be moved.

4 Press the 『Set』 key and the Body Mark is moved to the new position.



14.4 Clearing Body Mark

The ways to clear the Body Mark is described as follows:

1 Press the 『BodyMark』 key for consecutive two times.

2 Press the 『Clear』 key.

NOTE:	In B/B mode, pressing the 『Clear』 key will clear all general measurements in the image window as well as comments and Body Marks in two windows.

15 Measurement

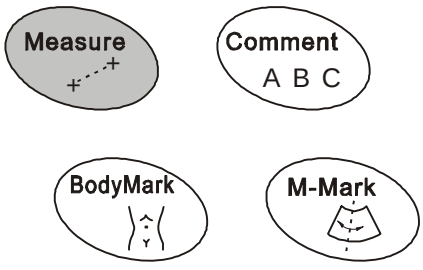
⚠WARNING: **Be sure to measure the correct objects and image during measurement, otherwise it may cause misdiagnosis.**

⚠CAUTION:
1. **The measurement scales and general measurement data will be cleared, when an image is unfrozen or an exam mode is changed during measurement. (If it is an application measurement, the data is kept in report.)**
2. **When the system is turned OFF or the 『Patient』 key is pressed, all the measured data will be lost. (If obstetric measurement data have been saved, they are in obstetric history report.)**

15.1 Basic Operation

15.1.1 Entering measurement status

Press the 『Measure』 key to enter Measurement status. The 『Measure』 indicator is on. The menu on the right side of the screen is switched to the Measurements and Calculations menu.



15.1.2 Measurement menu

The measurement menu is displayed on the right part of the screen. If the menu is not displayed, press the 『Menu』 key.

There are 8 menus for B mode measurements and calculations.

- B MEAS menu: used for general measurements and calculations of abdomen, gynecology, and small parts exam mode.
- B-OB MEAS menu: used for measurements and calculations of GA, fetal weight, EDD, etc. when the system is in obstetric exam mode.
- B-OB TWIN MEAS menu: used for measurements and calculations of GA, fetal weight, EDD, etc. when the system is in obstetric twin exam mode.
- B-CAR MEAS: used for left ventricular function calculations, etc. in cardiac exam mode.
- B-GYN MEAS menu: used for uterine and ovary measurements & calculations in gynecology exam mode.
- B-SML MEAS menu: used for thyroid measurements in small part exam mode.
- B-URO MEAS menu: used for residual volume, PV and PPSA measurements and calculations in urology exam mode.
- B-ORTH MEAS menu: used for HIP measurements in orthopedics exam.

There are 2 menus for M mode measurements and calculations.

- M MEAS: used for the general measurements on the M mode image, such as distance, heart rate, time, and slope.
- M-CAR MEAS menu: Used for the general measurements in M cardiac exam mode, such as LV, Mitral, Aorta, LVMW and so on.

To toggle among menus:

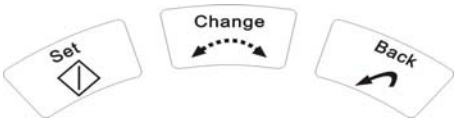
- Press mode keys.
- Select menu items in [Others] submenu.

15.1.3 Measured Result and Help Information

The system displays and updates measured and calculated results in the Result Area located below the menu.

The prompt information for each step in the process of measurement and calculation is displayed in the Help Bar located at the bottom of the screen.

15.1.4 Keys Used in Measurement



The keys used during measurement are shown in the figure, which are to be used in conjunction with the trackball.

『Set』:

Used to start or end the measurement, or to anchor the starting and end points of line measuring scale. The function of the key is to be described detailed in following practice.

『Back』:

This key has two functions: to return to the previous step during measurement; to delete the previous measurement. The 『Back』 key has different functions, which are to be discussed below.

『Change』:

Used for switching the fixed end and the active end in measurements.

15.1.5 Classification of Measurements and Calculations

All examination items in the menu are divided into two major categories: measurement and calculation.

- Measurement is only active in the current image mode. Switching the image mode will clear all the measurements and the displayed results in the current image window.
- Calculation consists of some measurements, which are organized based on a certain steps. According to each measured result, the system determines the calculated results using specific formula. Calculations can be made in different image windows. As long as the current measuring step of the calculation can be done in the new image window, the current step of the calculation can be performed.

Do not move the cursor out of the image window until the measurement is completed.

Measurements can be performed on magnified images, CINE review images, real-time images, or frozen images.

15.2 B-mode Measurements

The measurements listed below can be performed in B mode.

Measurement item	Description
Distance	The distance between two points is measured.
Area/circumference	The area/circumference can be measured by the following methods. (1) Ellipse (2) Trace
Volume	Measure the volume of the target object.

Measurement item	Description
Ratio	Measure and calculate the ratio between two measured distance values.
% Stenosis	Measure and calculate the stenosis of the blood vessels.
Angle	The angle between two lines is measured in addition to the distance between two points.
Histogram measurement	The distribution of the grey scale of the B-mode echoes within the traced area is measured.
Profile	Measure the gray distribution of the ultrasound signals on a profile in the vertical or horizontal direction.
OB measurement	Evaluates fetal growth.
CAR measurement	Measure and calculate LV function, RV, PA, etc.
GYN Measurement	Measure parameters of uterine, endometrium, ovary and FO-D in gynecology exam.
SML measurement	Measure volume of the left and right thyroid.
URO measurement	Measure RUV, the volume of prostate and PPSA.
ORTH measurement	Measure HIP.

15.3 M-mode Measurements

The measurements listed below can be performed in M mode.

Measurement item	Description
Distance	The distance between two points in the M mode is measured.
Time	The elapsed time between two points is measured.
Slope	The slope between two points is measured.
Heart rate	Calculate the number of heart beats per minute on the cardiac image.
CAR measurement	Measure and calculate LV function, mitral, aortic, etc.

16 File System

16.1 Overview

The file system stores the frozen image data and preset data into the storage media and manages the files as well.

The image files formats supported by the system:

- BMP
- JPG
- CIN
- FRM
- AVI
- DCM

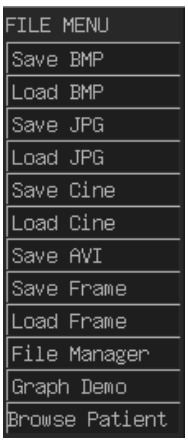
NOTE: JPEG CODEC may result in the distortion of image.

Storage medium:

Using USB storage device or hard disk to write and read the image files (BMP, JPG, Frame, CIN, DCM, AVI), patient information, OB exam reports and preset data files; Make/delete/rename directories in USB storage device or hard disk; Delete/rename/copy/paste files in USB storage device or hard disk.

Using DVD-RW to backup files in the USB storage device or hard disk to a CD; Read files in a CD; Copy files in a CD and paste them to the USB storage device or hard disk; Erase files in a CD.

Enter/Exit the File status: Press the 『File』 key to enter the File status. The 『File』 indicator lights up and the FILE MENU appears on the screen.



Press the 『File』 key again or press the 『Exit』 key, then the 『File』 indicator turns off and the system exits the File status.

And we explain the detailed operation, for example of BMP files.

16.2 Quickly Saving Files

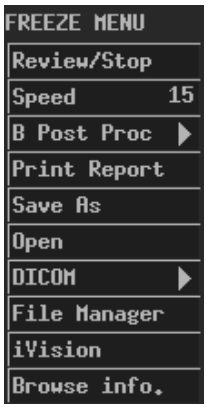
Press the『File』key, and the system will save the current image in the specific directory in the default file type.

To set the default file type: Open the “General Preset” dialog box and change the file format in the Snapshot Type.

To save the file in the specific path: If the patient information is available, the specific path is D:\PatientData\patient’s ID\; if no patient information is available, the specific path is D:\TempImage\.

16.3 Entering File Management

Press『Freeze』 to freeze the image, and the system automatically enters the manual cine review status, and the Freeze menu appears on the screen. Press『Cine』to exit the cine review status, move the cursor onto the Freeze menu, and select the menu items to perform operations of file management.

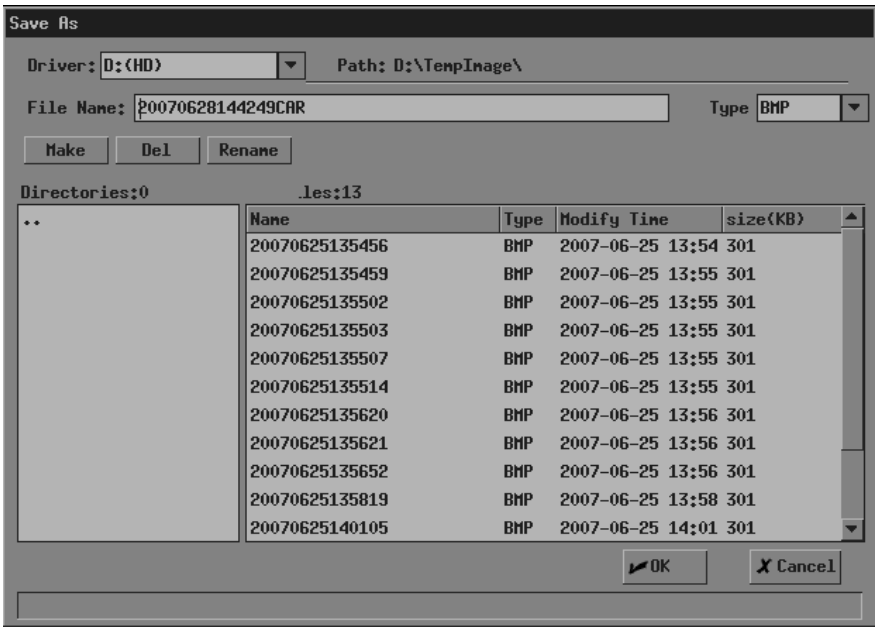


B Freeze menu

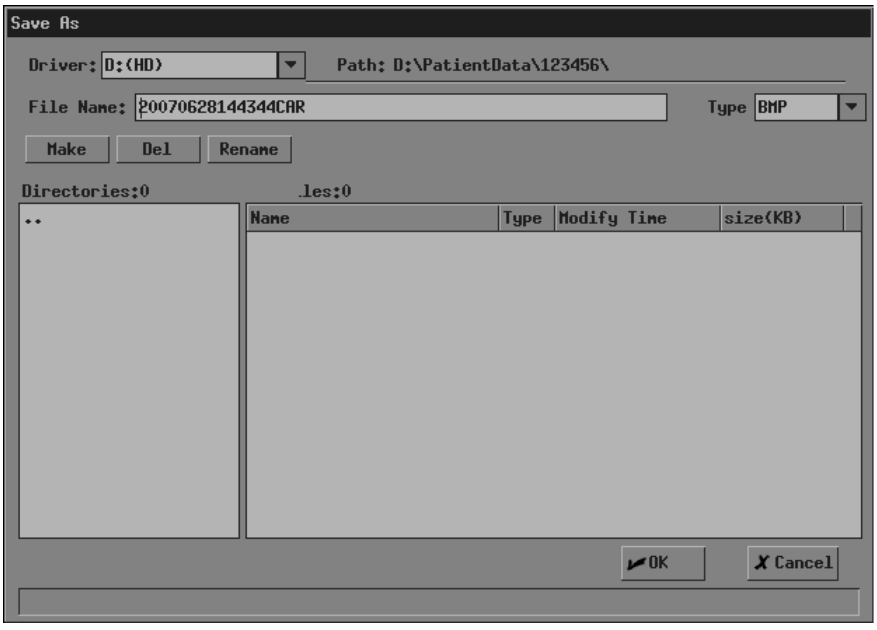
M Freeze menu

16.4 Generally Saving Files

1. Move the cursor onto [Save As] of the Freeze menu, press the 『Set』key, and the “Save As” dialog box appears on the screen, as shown in the figure below.



The default path for file saving when no patient information is available



The default path for file saving when patient information is available

2. The dialog box displays the default path and default file name of the file to be stored: If no patient information, the default path is D:\TempImage\; If the patient information has been entered, the default path is D:\PatientData\Patient ID\. the default file name is: file storing time＋current exam mode+ .file type.

The file type can be selected through the file type pull-down list.

Users can modify the file path and file name. The operation method is described as followed:

Select the drive:

Select the drive in a pull-down list. Move the cursor to the "▼" sign to the right of the drive. Press 『Set』 key, a list appears. The list shows to us the disk drives applicable to the system. C,D,E represent hard disks, F is DVD-RW drive, H and all following disk symbols are USB storage device.

Move the cursor to select the drive to be opened and then press『Set』key to close the list. Then the selected drive becomes the current drive.

Change the disk path:

Move the cursor to the directory item in the directory list. Double click the 『Set』 key to enter the directory. To return to the upper directory, just move the cursor to the [··] item and double press the 『Set』 key for consecutive two times.

Enter the file name:

Anchor the cursor into the FILE bar and press the 『Set』 key. Enter the file name. The file type can be changed.

To replace the existed file, just move the cursor to the corresponding file in the file list and press the 『Set』 key.

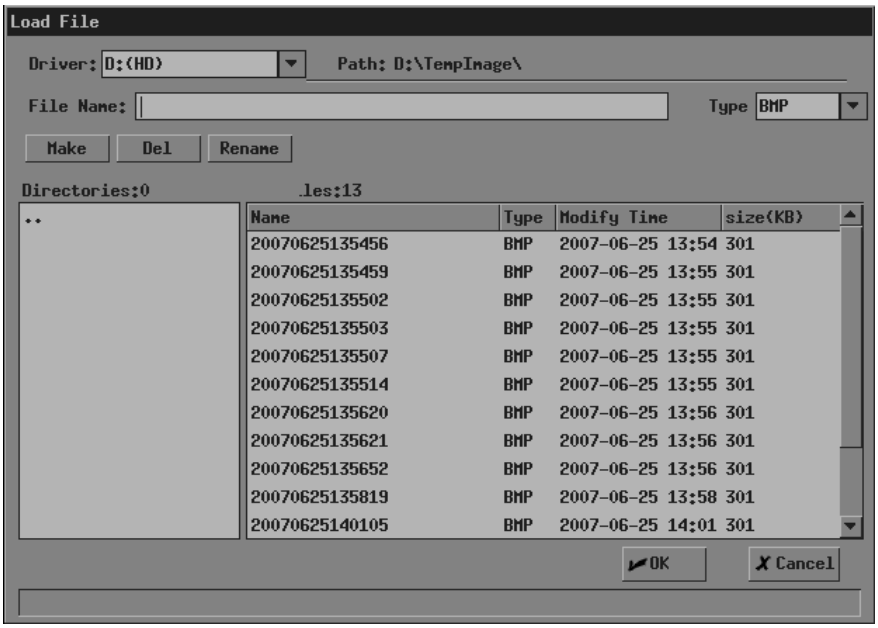
3. Click the [OK] button to close the dialog box. The system will automatically store the information displayed on the current screen into the specified file.
4. Click the [Cancel] button to cancel the operation and close the dialog box.

16.5 Loading Files

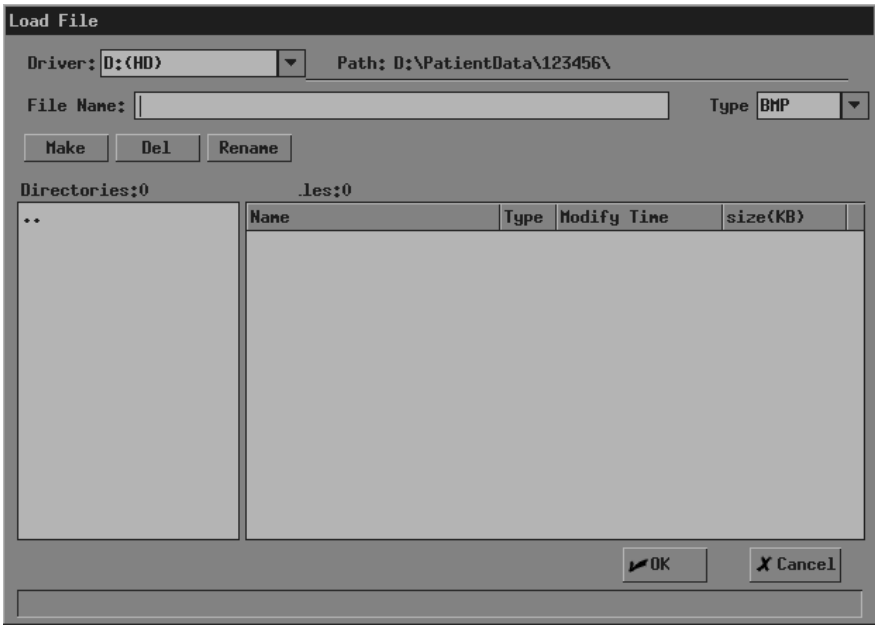
Use this function to view the image files in the disk and display the image on the screen.

The procedures are similar to those for generally saving files.

1 Move the cursor onto the [Open] item of the Freeze menu and press the 『Set』 key. The dialog box of Load File appears on the screen.



the dialog box of loading files while no patient information is available



the dialog box of loading files while patient information is available

2 Although the dialog box displays the default path, the user can search the required file as per the actual path where the file is saved (Refer to “Select the drive” and “Change the disk path”).

3 Select the file type in the Type pull-down list, and all the files of this type will be displayed below.

4 Move the cursor to the file to be opened in the list and press the 『Set』 key. The selected file is then highlighted.

5 Press the 『Set』 key on the [OK] button or just press the 『Set』 key on the selected file to close the dialog box. The system will read out the images stored the file and display them on the screen.

6 Press the 『Set』 key on the [Exit] button located on the bottom right corner of the screen of the open BMP file to close the BMP file. The system is still in the File status.

In B/B mode: the two windows images can be stored as a cine file, keep two B images when opening the file.

In M/B mode: the two windows images can be stored as a cine file, keep B images and M image when opening the file.

The cine file that is stored from merged images keeps merging status when opening the file.

16.6 AVI File

AVI files can record a seriate screen images, the storing method is the same as that for saving other files.

□ Cine images can be saved as AVI files.

□ Cine images from CIN, FRM files can be saved as AVI files.

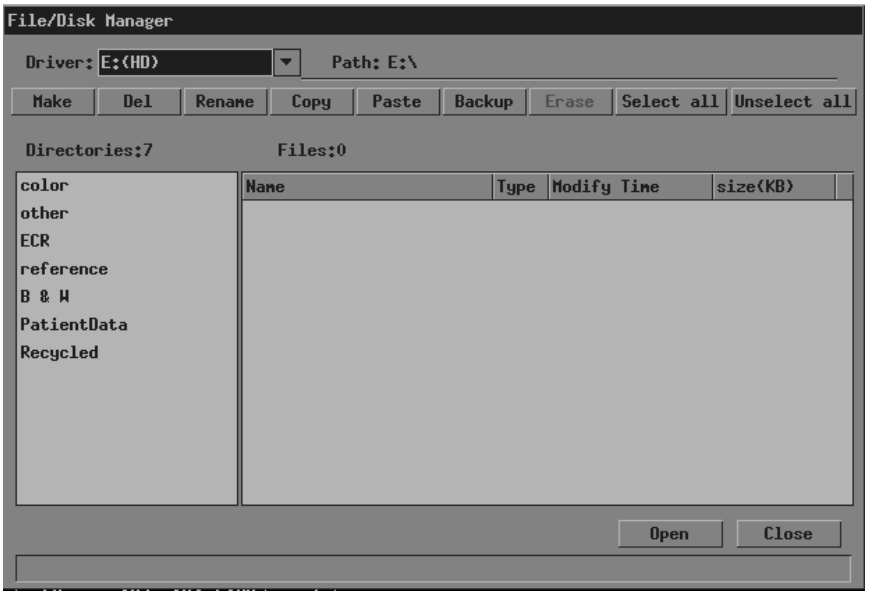
□ The Ultrasonic Diagnostic Imaging System doesn't support loading AVI files.

□ The AVI files can be played in the Windows system.

16.7 Disk Management

Function: manage the directories and files stored onto the disk.

Move the cursor to the [File Manager] item of the Freeze Menu and press the 『Set』 key. The "File/Disk Manager" dialog box appears on the screen.



16.7.1 Directory management

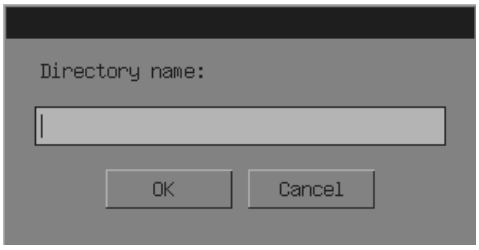
Directory management includes making, renaming and deleting a directory, and is only valid for USB devices and hard disks.

To create a directory:

1 First select the drive in which a directory is to be created in the pull-down list of drive. Then select the position at which the directory is to be created.

2 Move the cursor to the [Make] item in the dialog box and press the 『Set』 key. The “Info input” dialog box pops up.

3 Enter the directory name into the dialog box. And press the 『Set』 key on the [OK] button to close the dialog box and the new created directory is added into the directory table. Or press the 『Set』 key on the [Cancel] button to cancel all operations.



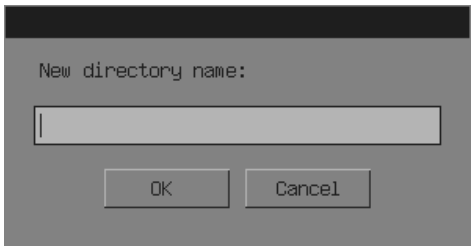
To rename a directory:

1 First select the drive in which a directory is to be created in the pull-down list of drive.

2 Then select the position at which the directory is to be created.

3 Press the 『Set』 key on the [Rename] button. The “Info input” dialog box pops up.

4 Enter the new directory name in the dialog box. Press the 『Set』 key on the [OK] button to close the dialog box and the previous name in the directory table is updated to the new name. Or press the 『Set』 key on the [Cancel] button to cancel all operations.



To select multiple directories:

Move the cursor onto a directory, and press the 『Set』key to select this directory and it is highlighted.

To select multiple directories, press the『Shift』key and move the cursor onto the directory and press the 『Set』key, the directory is selected; repeating this operation can select multiple

directories, and all the selected directories are highlighted. To deselect a directory, move the cursor onto the selected directory and press the 『Set』key, and the directory is deselected.

The user can also click the “Select All” and “Unselect All” to select or deselect all the directories.

To copy and paste a directory:

1. Select a directory, move the cursor onto the 「Copy」 button and press the『Set』key.
2. Open the directory for copying the directory, move the cursor onto the [Paste]button, and press the『Set』key to perform the copying and pasting operation. Finally, the directory will appear at the specified path.
3. If the directory name has existed, the system will prompt “This directory has existed, are you sure to overwrite it?”. The user can select “OK” or “Cancel” to determine if the previous directory is overwritten.

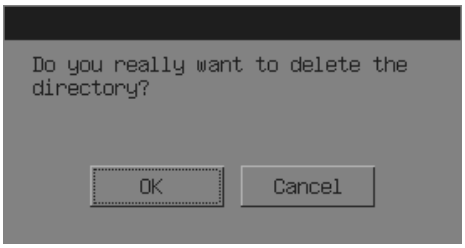
To delete a directory:

1 First select the drive containing the directory to be deleted in the drive table.

2 Then select the directory to be deleted in the directory table.

3 Press the 『Set』 key on the [Del] button. The dialog box pops up.

4 Press the 『Set』 key on the [OK] button to close the dialog box. Then the selected directory name in the directory table is deleted. Or press the 『Set』 key on the [Cancel] button to cancel all operations.



16.7.2 File management

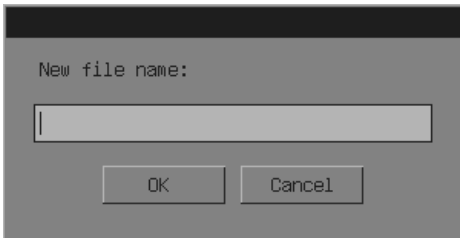
File management includes renaming, deleting, copying and pasting a file as well as deleting all the files under the current directory, and is only valid for files in USB devices and hard disks.

To rename a file:

Select the drive and the directory under which the file to be renamed exists.

Select the file to be renamed in the file table. Press the 『Set』 on the [Rename] button, the “Info input” dialog box pops up.

Enter the new file name into the dialog box and press the 『Set』 key on the [OK] button for confirmation or on the [Cancel] button to cancel all operations.



To sequence files:

In the File/Disk Manager screen, the user can click “Name”, “Type” or “Modify Time” in the file list box to sequence the files.

To select multiple files:

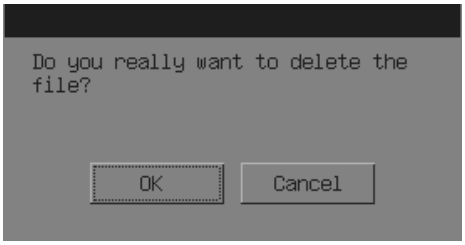
The operations for selecting multiple files are the same as those for selecting multiple directories.

To delete a file:

1 Select the drive and the directory under which the file to be deleted exists.

2 Select the file to be deleted in the file table and press the 『Set』 key on the [Del] button. The dialog box pops up.

3 Press the 『Set』 key on the [OK] button for confirmation or on the [Cancel] button to cancel all operations.



To copy and paste a file:

1 Select the file to be copied. Move the cursor to the [Copy] button and press the 『Set』 key.

2 Enter the directory under which the file is to be pasted. Move the cursor on the [Paste] button and press the 『Set』 key to start the pasting operation. After the pasting process being completed, the pasted file is displayed under the directory.

3 If there is a file of the same name with the file to be pasted under the directory. The system will pop up the dialog box to give the prompt like “The file existed, replace it or not?” Select [OK] or [Cancel] button to determine whether to replace the original file or not.

16.7.3 CD files backup and erasing

To backup files to a CD:

The data in the hard disks or USB storage device can be backed up in the CD by DVD-RW.

1 Insert an empty CD into the DVD-RW driver.

2 Select the file to be backed up in the hard disks or USB storage device, and move the cursor onto the [Backup] button and click the 『Set』 key to confirm it.

3 The “Please wait” message appears on the screen, and the DVD-RW driver begins to back up the data.

4 After the data backup is completed, the CD pops up automatically.

5 Take out the CD and push the CD seat back to the driver.

To erase CD files:

If a DVD-RW disk, it can be erased and rewritten.

1 Insert the DVD-RW disk into the DVD-RW driver.

2 Open G disk driver.

3 Press the [Erase] button, and the DVD-RW disk is erased.

To open CD files:

Select the file in a CD, press the [Open] button and click the 『Set』 key, the system will read out the file and display it on the screen.

To copy CD files:

Copy files in a CD and paste them to the other media, such as USB storage devices or hard disks.

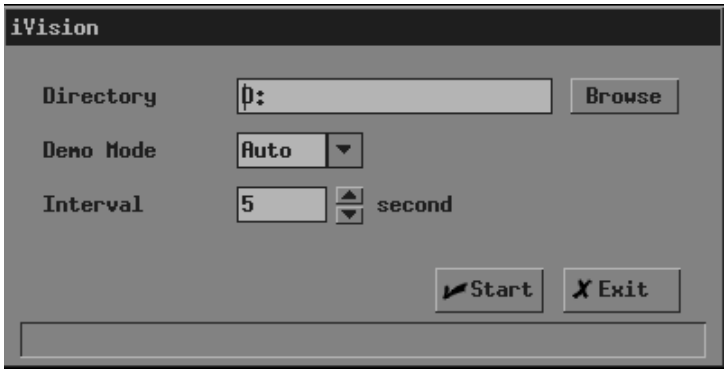
Select the files in a CD, press the [Copy] button and click the 『Set』 key, then select the intended directory of the USB device or the hard disk and press the [Paste] button.

16.8 iVision

iVision displays clinic images one by one in the image files (except AVI file).

⚠CAUTION: If you exit iVision during the process of CIN or FRM demonstration, the current patient information may be cleared.

1 Click the [iVision] item in the Freeze menu, and the iVision dialog box pops up.



2 Press the [Browse] button to select the path for the demo file.

3 Set interval time for the auto demo, which ranges from 0 to 500 seconds.

4 Demo mode: you can select auto or manual demo.

□ Auto demo: the system automatically plays current image files one by one according to the set interval.

* Play the image files cyclically according to the file storage sequence.

* Each image file is played in the same interval.

* If the files are Cine files, the system automatically plays the Cine review.

□ Manual Demo: the image files are played manually.

* The image files are displayed forwards or backwards by『→』and『←』keys, and they cannot be displayed cyclically. The『→』key: the image files are displayed according to the storage sequence; the『←』key: the image files are displayed according to the reversed storage sequence.

* If the files are Cine files, they are manually reviewed by the trackball.

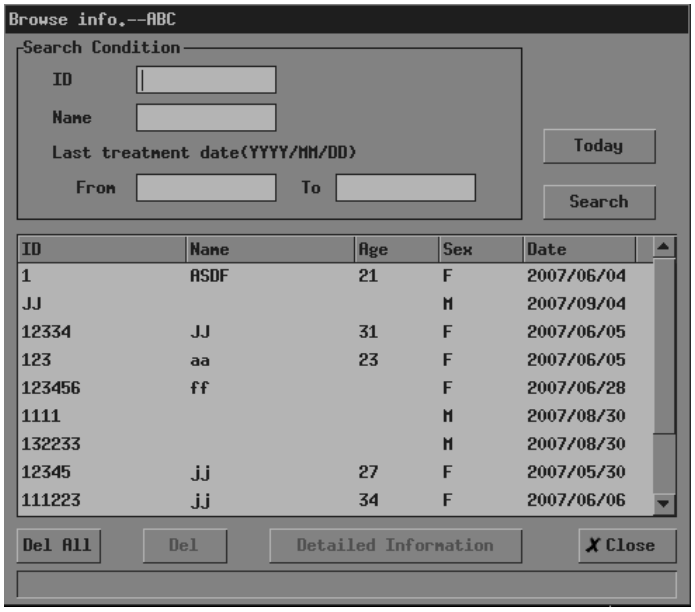
5 To start the graph demo, press the [Start] button; to exit the Graph Demo dialog box, press the [Exit] button.

During the demo, you can press the『Exit』key to exit it.

16.9 Browsing Patient Information

Users can browse patient information that stored in D:\PatientData\patientID\ directory in the “Browse info” dialog box.

1 Click the [Browse info.] item in the Freeze menu .The dialog box below appears on the screen.

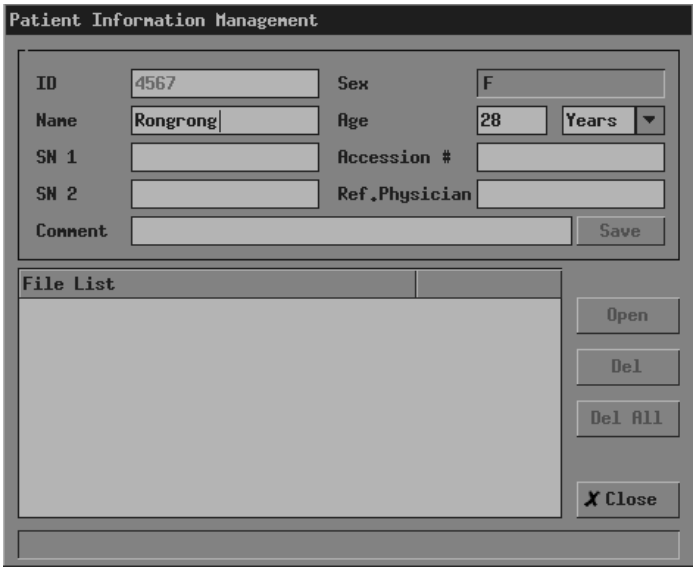


2 In the “Search Condition” bar, enter one or multiple items of the patient ID, name and the latest treatment date; press the『Search』button, and the patient data meeting the condition will display in the list. Press the [Today] button to search in today’s patients.

To search a patient in sequence: respectively click ID/Name/Age/Sex/Date button and the patient data will be arranged respectively according to ID/ Name/Age/Sex/Date in order to easily search the data.

3 After you select a patient, press the “Del” button and all data of the patient are deleted; press the “Del All” button, and the data of all patients are deleted.

4 After you select a patient, press the [Detailed Information] button and the dialog box of patient information management appears on the screen. See the figure below. In this dialog box, you can see all the data of this patient.



5 In the figure above, you can edit the items of patient information, such as sex, Accession

#, SN 1, SN 2, name, age and clinic diagnosis, except ID. After you finish the edit, press the [Save] button and you can save the new information and overwrite the previous data.

6 In the file list displays all the clinic files for that patient that stored in D:\PatientData\Patient ID\ directory. You can open, delete or delete all the files using the button on the right

7 Press the [Close] button, and you can close the “Patient Information Management” dialog box.

16.10 DICOM File

You can save, open or send DCM files or DCM images.

16.10.1 Opening DCM file

This function is used for reading or viewing the DCM files in the disk.

Refer to “Loading Files” for specific operations.

16.10.2 Saving DCM file

You can only save the DCM file on a frozen image.

Refer to “Generally Saving Files” for specific operations.

16.10.3 Sending DCM file

You can send the DCM files in the disk to the current storage server.

1 Click the [Send DCM File] item of the DICOM submenu in the Freeze menu. The dialog box for sending the files appears on the screen.

2 Refer to the section “Loading Files” for the subsequent steps.

3 The prompt “Sending data…” appears at bottom of the screen, and after the files are sent, the prompt that the files have been successfully sent will appear on the screen.

16.10.4 Sending DCM image

You can send the image on the current screen to the current storage server.

1 Click the [Send DCM Image] item of the [DICOM]’s submenu to send the DCM image.

2 The prompt “Sending data…” appears at bottom of the screen, and after the files are sent, the prompt that the files have been successfully sent will appear on the screen.

16.10.5 Print DCM File

You can send the DCM file of the [DICOM]’s submenu in the disk to the current print server to print.

1. Click the [Print DCM File] of the [DICOM]’s submenu to open the file selection

dialogue box.

2. Select the DCM file, and click [OK] to send the file to print.
3. The prompt “Sending data…” appears at bottom of the screen, and after the files are print, the prompt that the files have been successfully print will appear on the screen.

16.10.6 Print DCM Folder

You can send all the DCM files in the folder to the current print server to print.

1. Click the [Print DCM Folder] of the [DICOM]’s submenu to open the folder selection dialogue box.
2. Select the DCM file, and click [OK] to send the files to print.
3. The prompt “Sending data…” appears at bottom of the screen, and after the files are print, the prompt that the files have been successfully print will appear on the screen.

16.10.7 Print DCM Image

You can send the current screen image to the print server to print.

1. Click the [Print DCM Image] of the [DICOM]’s submenu to open the file selection dialogue box.
2. The prompt “Sending data…” appears at bottom of the screen, and after the images are print, the prompt that the files have been successfully print will appear on the screen.

Note:	**If communication fails when the ultrasound system is connected to the DICOM printing device via direct RJ45, try to use a switcher or hub to connect the system and the device to ensure a successful communication.**

16.11 Detaching USB Storage Device Safely

1 When a USB storage device is connected to the ultrasound system through a USB port, the icon “  ” will appear at the bottom right corner of the screen.

2 If it needs to remove the USB storage device, move the cursor onto “  ”, press the 『Set』 key and a dialogue box below pops up.

3 Select the USB storage device to be detached, press [OK] to detach it safely.

⚠WARNING:

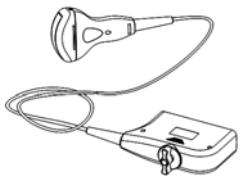
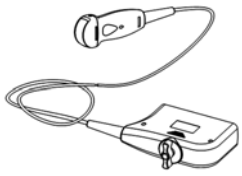
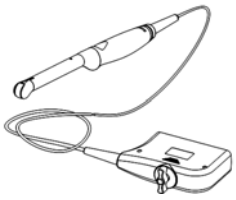
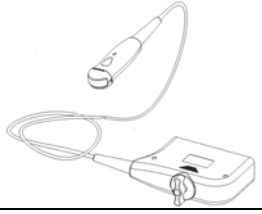
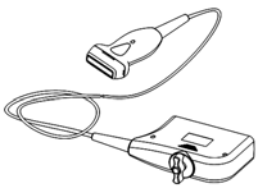
Do not detach the USB storage device directly from the ultrasound system without performing the prescribed procedures. Otherwise, it may damage the USB storage device and the ultrasound system.

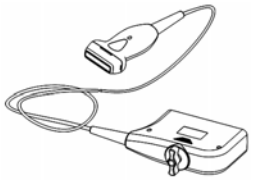
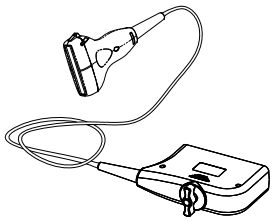
17 Transducers and Biopsy

17.1 Transducers

Note: For details of storage time and condition for disinfected probes or sterilized probes and brackets, please refer to Technical standard for Disinfection of Medical and Health Structures

The system supports the following transducers:

No.	Transducer Model	Illustration
1.	35C50HA	
2.	35C20HA	
3.	65EC10HA	
4.	65C15HA	
5.	75L38HA	

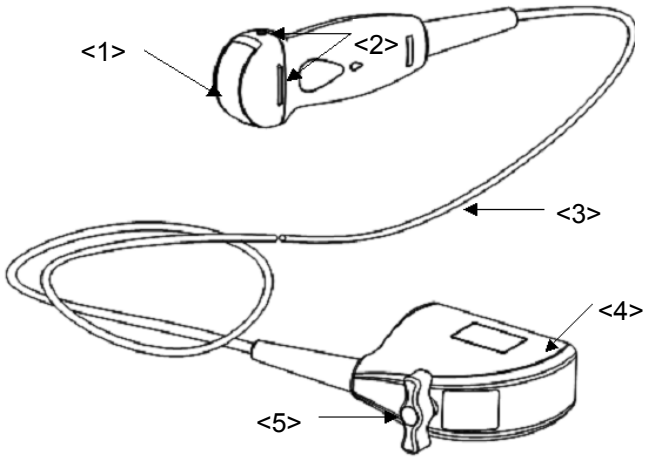
No.	Transducer Model	Illustration
6.	75L38HB	
7.	75L60HB	

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

Transducer Model	Needle-guided Bracket Model	Biopsy Angle/Depth	Type	Applicable Biopsy Needle
35C20HA	NGB-003	11º, 23º	Metal/needle un-detachable	14G, 16G, 18G, 20G, 22G
			Metal/needle detachable	13G, 15G, 16G, 18G, 20G
35C50HA	NGB-001	25º, 35º, 45º	Metal/needle un-detachable	13G, 15G, 16G, 18G, 20G
			Metal/needle detachable	14G, 16G, 18G, 20G, 22G
65C15HA	NGB-005	12.7º, 24.2º	Metal/needle un-detachable	20G, 18G, 16G, 15G, 13G
65EC10HA	NGB-004	/	Metal/needle un-detachable	16G, 17G, 18G
75L38HA/ 75L38HB	NGB-002	40º, 50º, 60º	Metal/needle un-detachable	13G, 15G, 16G, 18G, 20G
75L60HB	NGB-012	40º, 50º, 60º	Metal/needle detachable	14G, 16G, 18G, 20G, 22G
			Plastic/needle detachable	13G, 15G, 16G, 18G, 20G

17.1.1 Name and Function of Each Part of the Transducer

The basic structures and corresponding functions of transducers are basically the same; the following will take transducer 35C20EA as an example.



No.	Name	Function
<1>	Transducer head	It converts the electrical signal into ultrasound signal, making the sound beams focus in the given direction; meanwhile, it will receive the ultrasound signal and then convert the received signal into electrical signal. The lens on the surface is the acoustic lens. Apply ultrasound gel on the acoustic lens.
<2>	Needle-guided bracket fix tabs and grooves	Used to mount the needle-guided bracket.
<3>	Transducer cable	Used to transmit electrical signals between the transducer body and connector.
<4>	Transducer connector	Used to connect the transducer to the ultrasonic diagnostic system.
<5>	Lock handle	Used to lock the connector to the ultrasonic diagnostic system.

Tips:

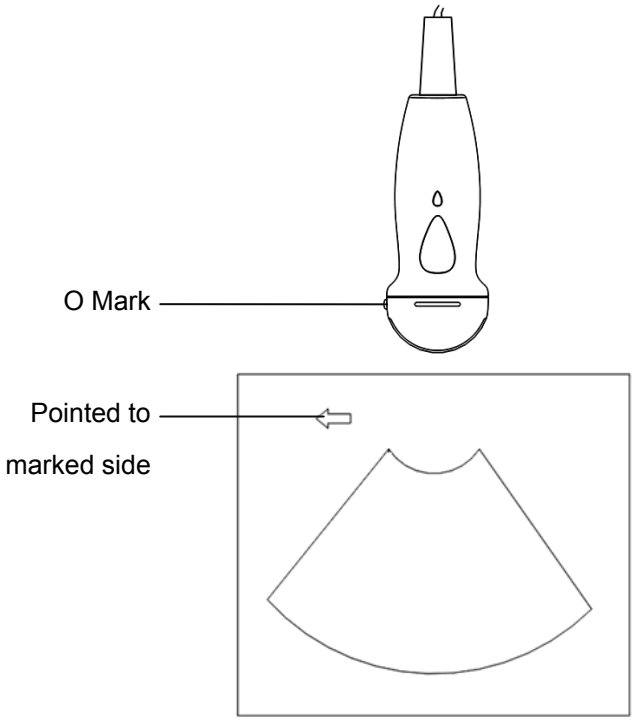
The transducers' structure marked <2> in the figure above may vary with the matched needle-guided brackets.

17.1.2 Orientation of the Ultrasound Image and the Transducer Head

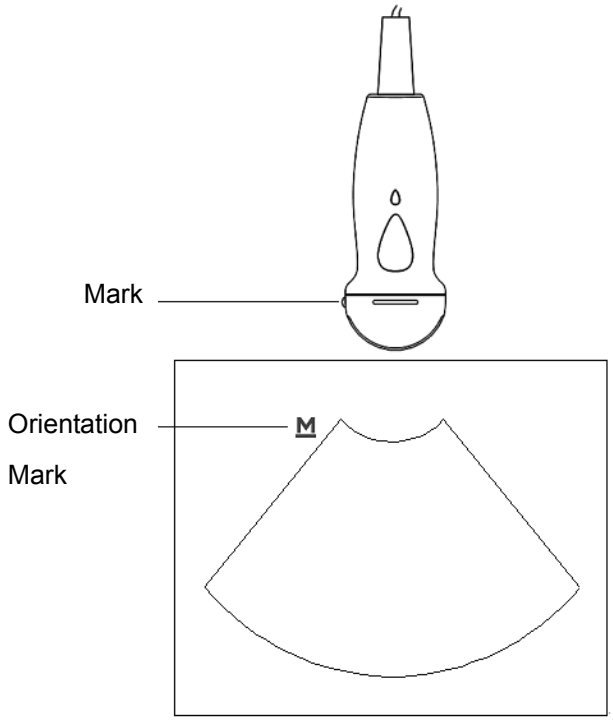
The orientation of the ultrasound image and the transducer are shown as below. The “Mark” side of the ultrasound image on the monitor corresponds to the mark side of the transducer. Check the orientation before the examination.

- Method 1

  The arrow on the ultrasound image is corresponding to the O mark on the transducer (taking convex transducer as an example).



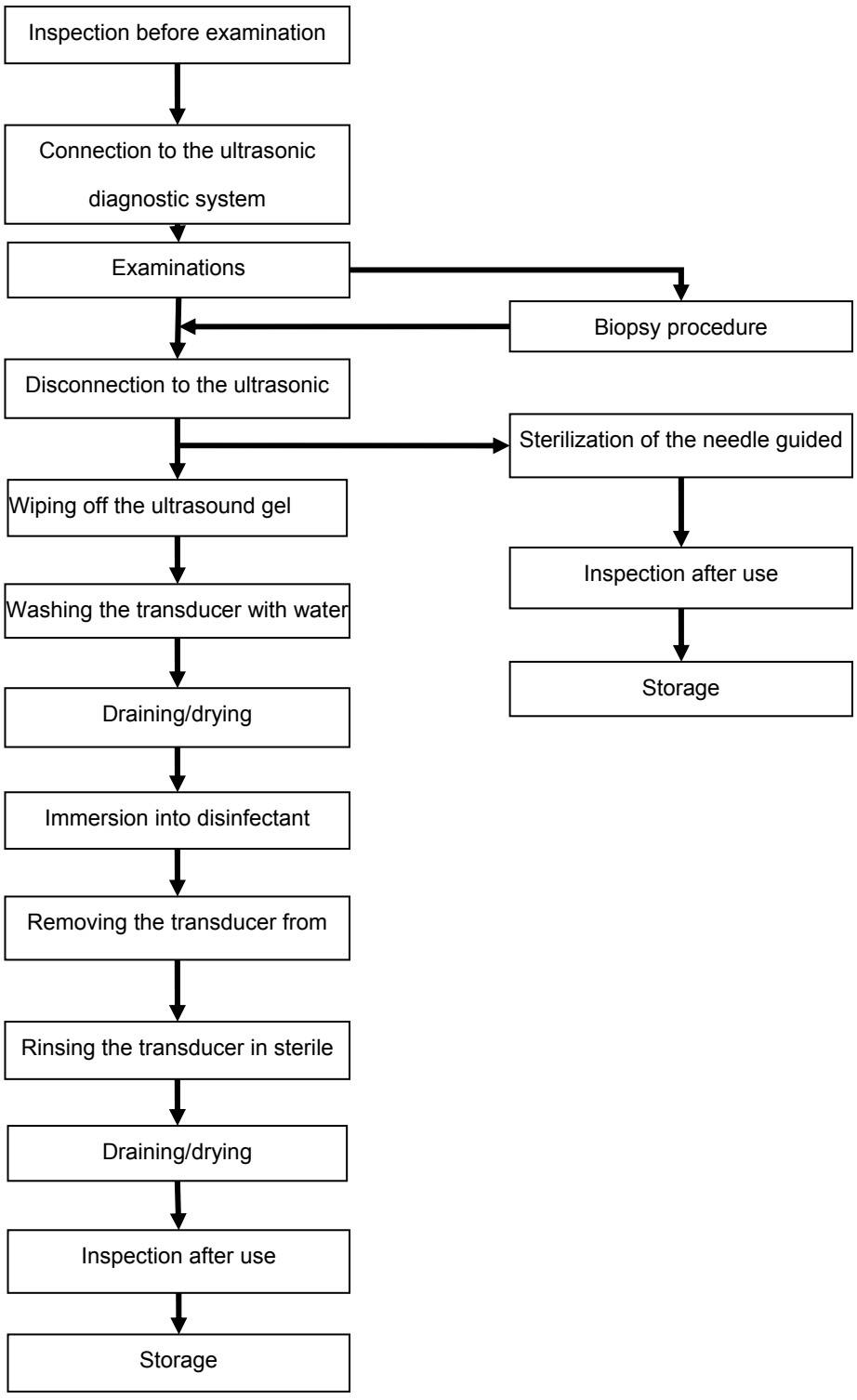
- Method 2



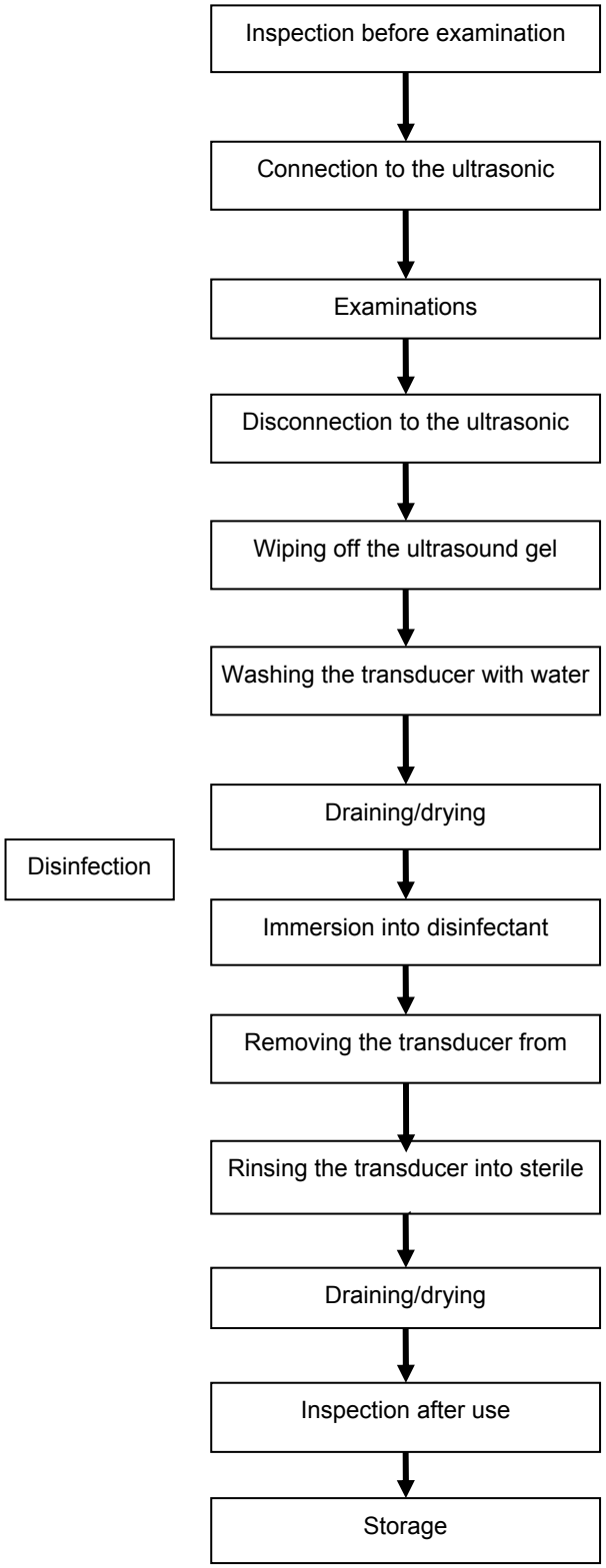
17.1.3 Procedures for Operating

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

Procedures for operating (with biopsy function):



Procedures for operating (with no biopsy function):



⚠WARNING:	**Disinfect the transducer and sterilize the needle-guided bracket before and after an ultrasound-guided biopsy procedure is performed. Failure to do so may cause the transducer and the needle-guided bracket become source of infection.**

17.1.4 Wearing the Transducer Sheath

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

To order transducer sheath, contact:

CIVCO Medical Instruments Co.

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

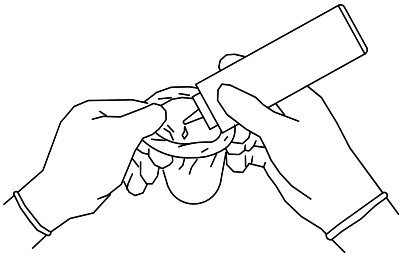
E-mail: info@civco.com

http://www.civco.com

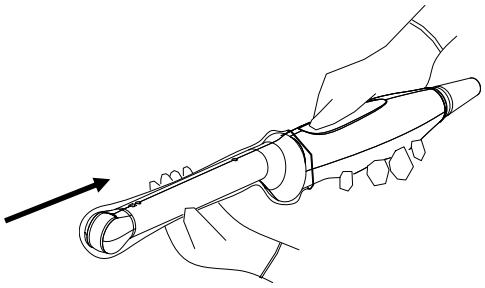
⚠CAUTION:	**1. Be sure to cover the transducer with a new (unused) transducer sheath to prevent infection during examination. If the package of a transducer sheath is open or broken, the sterilization of the transducer sheath may not be sufficient. DO NOT use such a transducer sheath.** **2. The cover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

Method (for reference only):

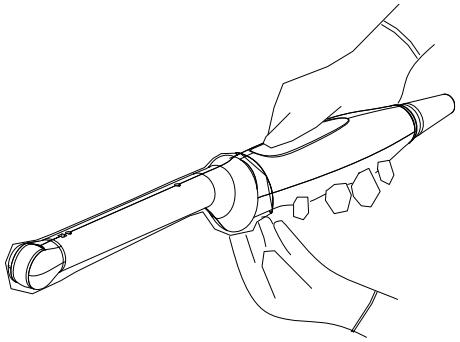
1. Place an appropriate amount of gel inside the sheath or on transducer face. Poor imaging may result if no gel is used.



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



3. Secure the sheath with enclosed elastic bands.
4. Inspect the sheath to ensure there are no holes or tears.



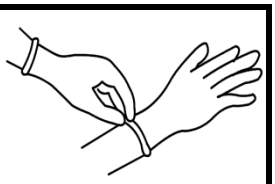
17.1.5 Transducers Cleaning and Disinfection

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

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

⚠CAUTION:

1. **When performing cleaning and disinfection of the probe to prevent infection, wear sterile gloves.**



2. **After disinfection, rinse the probe thoroughly with sterile water to remove all chemical residues. Chemical residues on the probe may be harmful to the human body.**
3. **No cleaning and disinfecting may result in the probe becoming a source of infection.**

NOTE:

1. After the examination, wipe off the ultrasound gel thoroughly. Otherwise, the ultrasound gel may solidify and degrade the image quality of the transducer.
2. DO NOT make the probe to become overheated (more than 55°C) during cleaning and disinfections. High temperature may cause the probe to become deformed or damaged.

Cleaning

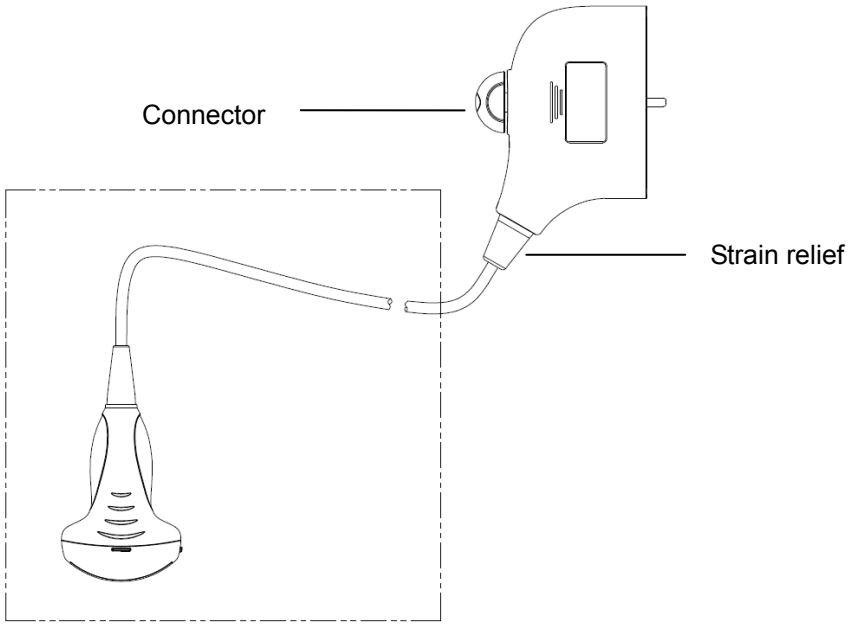
Please refer to the instructions in the manual and follow your hospital policy and procedures for cleaning.

1. Disconnect the probe from the system.
2. Wear sterile gloves to prevent infection.
3. Wash the transducer with clean water or soapy water to remove all the foreign matters, or, wipe the transducer with a soft ethyl carbamate sponge. Avoid using a brush, because it may damage the transducer.
4. Dry the transducer using a sterile cloth or gauze after rinsing. Do not dry the transducer by heating it.

Disinfecting with Sprays

⚠CAUTION:	Use protective eyewear when disinfecting using sprays.

1. Wear sterile gloves to prevent infection.
2. After you have finished cleaning, spray the transducer with a disinfectant. Follow the disinfectant manufacturer's recommended contact time and mode.
3. Remove any residue with a water-moistened soft cloth on the transducer.
4. Wipe off water on the transducer using sterile cloth or gauze after washing.

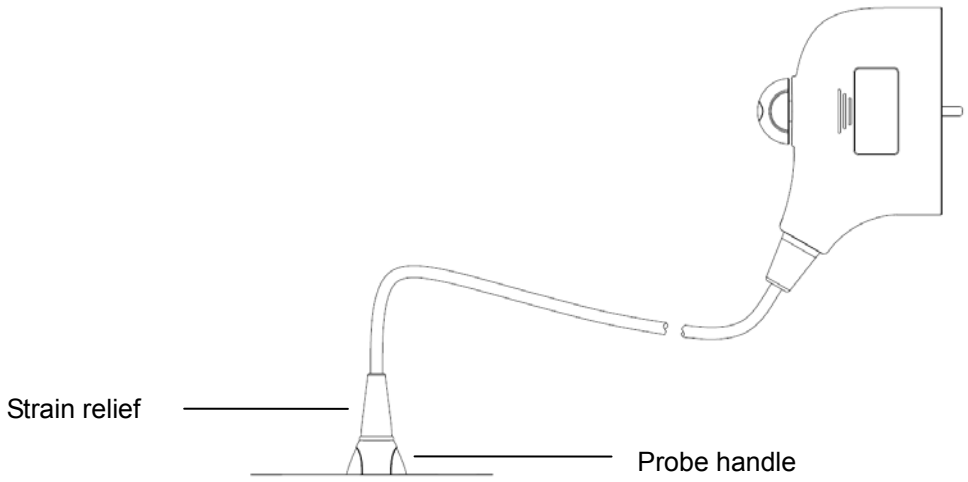


NOTE:	Observe the graph here carefully to perform disinfection. Do not spray the strain relief on the connector end or the connector.

Disinfecting by Immersion

1. Wear sterile gloves to prevent infection.

2. Clean the transducer before disinfecting it.MINDRAY recommends the following solutions to disinfect the transducer.
   - Refer to the instructions provided by the chemical manufacturer concerning concentration of the disinfectant solution, method of disinfection and dilution and cautions during use.Do not soak the transducer connector or the cable near it into water or any solution.
   - Soak the transducer into the disinfectant solution for the shortest time the manufacturer recommends (for example, the shortest time recommended by the manufacturer for soaking Cidex OPA is 12 minutes).
   - Follow local regulations when selecting and using the disinfectant.
3. Rinse the transducer with plenty of sterile water (about 2 gallons) for at least 1 minute to remove all chemical residues on it.Or, follow the rinsing method recommended by the disinfectant manufacturer to rinse the transducer.
4. Wipe off the water on the transducer with sterile cloth or gauze after rinsing it.Do not dry the transducer by heating.



NOTE: 1. Observe the graph here carefully to immerse the transducer. Only soak parts of the transducer below the strain relief.

Compatible Disinfectants

Manufacturer	Trade Name	Procedures	Type
Pharmaceutical Innovations, Inc.	T-Spray II	Please refer to the instructions provided by the manufacturer of the solution for details.	Spray
Parker Laboratories Inc.	PROTEX™ DISINFECTANT SPRAY	Please refer to the instructions provided by the manufacturer of the solution for details.	Spray

Manufacturer	Trade Name	Procedures	Type
Metrex	MetriZyme	Please refer to the instructions provided by the manufacturer of the solution for details.	Solution
ASP	Cidex Activated Dialdehyde Solution	Please refer to the instructions provided by the manufacturer of the solution for details.	Solution
ASP	Cidex OPA	Please refer to the instructions provided by the manufacturer of the solution for details.	Solution
Nanosonics Limited	TrophonSonex-HL (Used with Trophon EPR Ultrasound Probe Disinfector)	Please refer to the instructions provided by the manufacturer of the solution for details.	Solution

17.1.6 Storage and Transportation

When all examinations for the day have been completed, confirm that the transducer is in good condition. After disinfecting the transducer, confirm that the transducer is in good condition and store it in a suitable place so that the next examination can be conducted smoothly.

1. To prevent the transducer from being damaged, DO NOT store it in locations where it may be exposed to:
   - Direct sunlight or X-rays
   - Sudden changes in temperature
   - Dust
   - Excessive vibration
   - Heat generators
2. Store and transport the transducer 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
3. When the transducer is sent to MINDRAY Customer Service Department or sales representative for repair, be sure to disinfect it and keep it in the carrying case to prevent infection.
4. Sterilize the carrying case as necessary.

17.2 Biopsy Guide

⚠WARNING:

1. The person performing biopsy procedures must understand diagnostic ultrasound thoroughly and have been trained adequately, otherwise, side effects may be caused to the

patient.

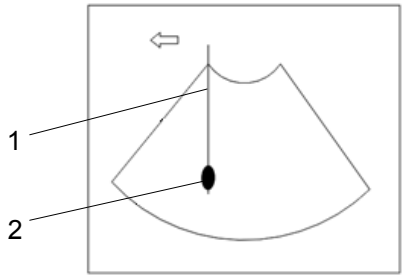
2. **In situations listed below, the biopsy needle may fail to penetrate the target. The incorrect biopsy may cause various side effects in the patient.**
   - **Use a needle-guided bracket other than that provided.**
   - **Mount the needle-guided bracket incorrectly.**
   - **Use a biopsy needle that is unsuitable for the type of biopsy being performed.**
   - **Use a biopsy needle that is unsuitable for the needle guide (or guiding block).**
3. **Before and after a biopsy procedure is performed, confirm that the needle-guided bracket is normal. Manually confirm that the parts of the needle-guided bracket do not slip off or move from their proper positions. If the needle-guided bracket is used when parts are not securely and correctly installed, the patient may be injured. If an abnormality is found on the needle-guided bracket, immediately stop using it and contact MINDRAY Customer Service Department or sales representative.**
4. **DO NOT use a needle-guided bracket when scanning is performed. The needle may advance in an incorrect direction and possibly injure the patient.**

   Never perform a biopsy during image scanning.
5. **DO NOT freeze an image while performing biopsy procedure.**
6. **During biopsy procedures, the needle may deviate from the desired course due to the tissue characteristics or the type of needle. In particular, needles of small diameters may deviate to a greater degree.**
7. **Clean and disinfect the transducer, clean and sterilize the the needle-guided bracket before and after each ultrasound-guided biopsy procedure is performed. Fail to do so may cause the transducer and the needle-guided bracket become sources of infection.**
8. **The needle mark displayed on the ultrasound image does not indicate the actual position of the biopsy needle. Therefore, it should only be used as a reference. Always monitor the relative positions of the biopsy needle during the procedures.**
9. **Adjust the needle mark before the biopsy procedure is performed.**
10. **When performing biopsy procedures, use only sterile ultrasound gel that is certified to be safe. And manage the ultrasound gel properly to ensure that it does not become a source of infection.**
11. **When performing the operation concerning biopsy, wear sterile gloves.**
12. **Image of the biopsy target and the actual position of the biopsy needle:**

    Diagnostic ultrasound systems produce tomographic plane images with information of a certain thickness in the thickness direction of the transducer. (That is to say, the information shown in the images consist all the

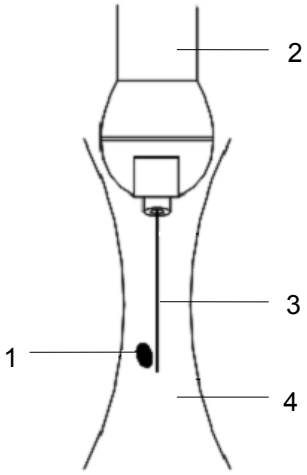
information scanned in the thickness direction of the transducer.) So, even though the biopsy needle appears to have penetrated the target object in the image, it may not actually have done so. When the target for biopsy is small, dispersion of the ultrasound beam may lead to image deviate from the actual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

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



1. Biopsy 2. Target

The biopsy needle appears to reach the target object in the image



1. Target 2. Transducer 3. Needle 4. Ultrasound beam

Dispersion of the ultrasound beam

The biopsy needle may not have actually entered the target object even though it appears to have done so on the image. To avoid this problem, note points below:

- **Do not rely only on the needle tip on the image. Pay careful attention to that, when the biopsy needle comes into the target object or contacts with it, the object should shift slightly.**
- **Before you perform the biopsy, please evaluate the size of the object and confirm if the biopsy can be carried out.**

17.2.1 Needle-guided Brackets

A needle-guided bracket is available for purchase as an optional accessory; it is used in combination with the transducer. Some of the transducers have matched needle-guided

bracket and needles. To order needle-guided brackets, contact MINDRAY Customer Service Department or sales representative.

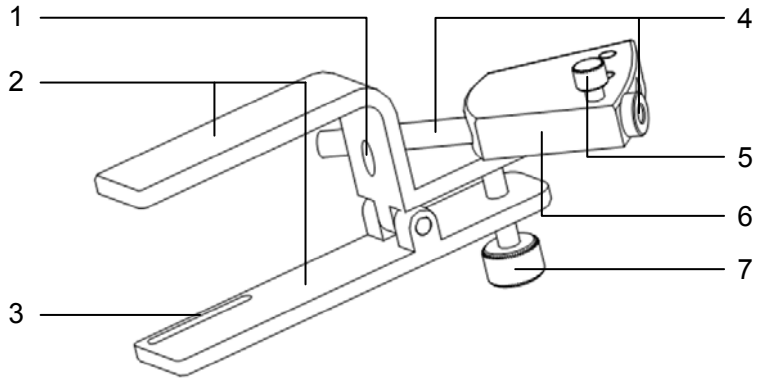
For biopsy or treatment, ultrasound-guided biopsy procedures can be performed using the transducer in combination with a needle-guided bracket (optional accessory) and a biopsy needle (provided by the user).

17.2.2 Names of Parts

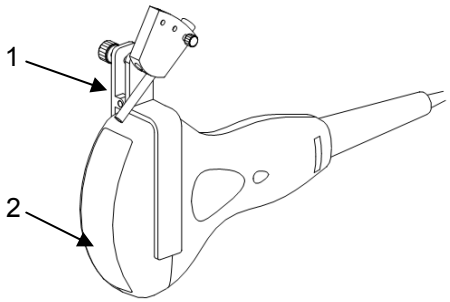
This section describes the parts and corresponding functions of each needle-guided bracket. Here, we take a matched transducer as an example.

- NGB-001, NGB-002, NGB-003, and NGB-005 (Metal/needle un-detachable)

  The structure of metal/needle un-detachable needle-guided bracket NGB-001, NGB-002, NGB-003 and NGB-005 are similar to each other. The following figure shows the structure with NGB-001 as an example.

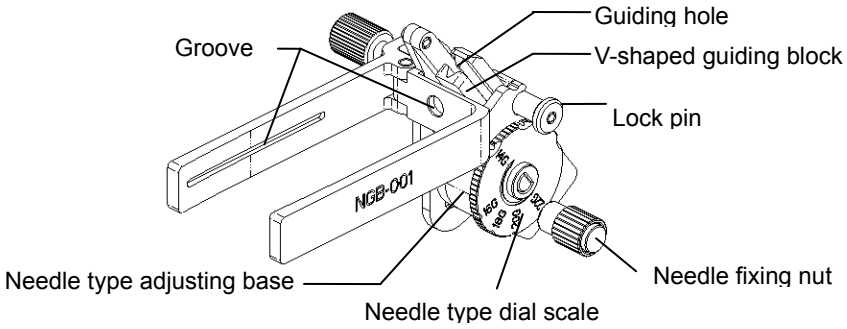


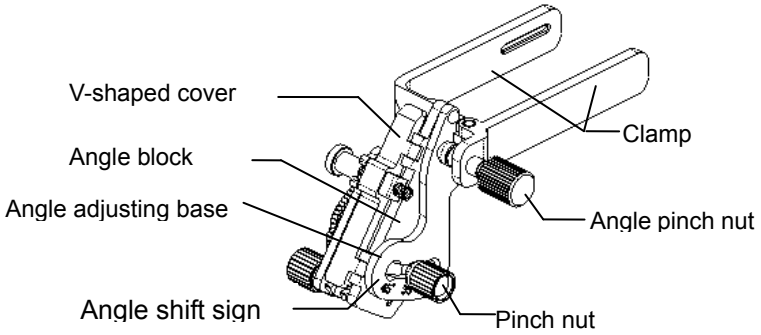
1. Locating pit 2. Clamp 3. Locating groove 4. Needle guide and the hole
5. Clamping knob of the needle guide 6. Needle guide rack 7. Grip knob



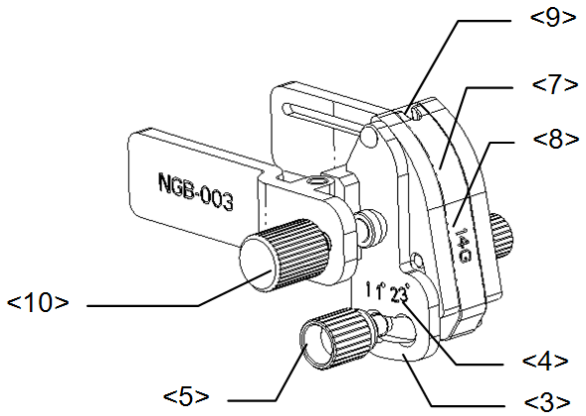
1. Needle-guided bracket 2. Transducer

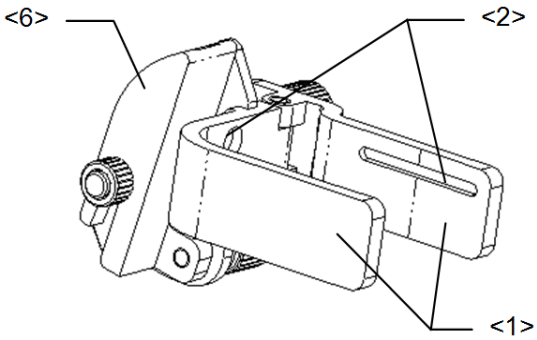
■ NGB-001 (Metal/needle detachable)





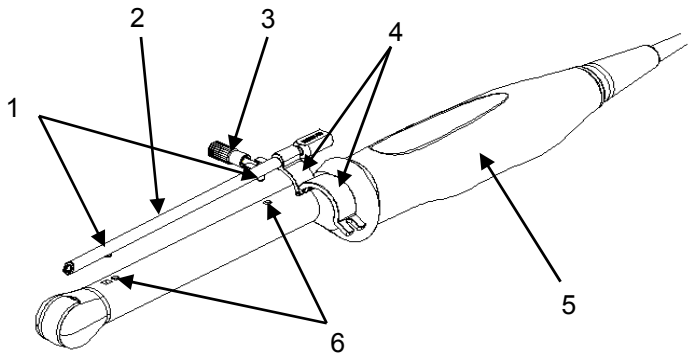
■ NGB-003 (Metal/needle detachable)





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 2 types of angles available to be adjusted
<4>	Angle shift sign(11°, 23°)	Matched with the biopsy angle(11°, 23°)
<5>	Angle pinch nut	Used for fixing the angle lock at a chosen angle
<6>	Angle block	Used for determining the angle of the biopsy; different specifications of blocks can be used
<7>	Guiding block	Used for installing biopsy needle; there are five specifications of guiding blocks for different biopsy needles
<8>	Specification of guiding block(14G)	Matched with the corresponding biopsy needle(14G)
<9>	Needle guide hole	Used for installing the biopsy needle
<10>	Pinch nut of needle-guided bracket	Used for locking the needle-guided bracket and the transducer

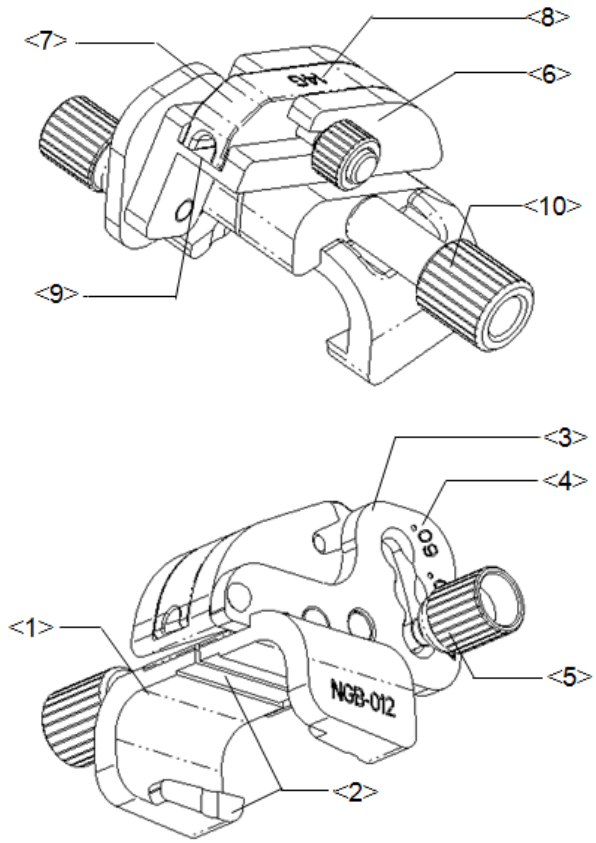
■ NGB-004 (Metal/needle un-detachable)



1. Locating bulge 2. Needle guide 3. Locking nut
4. Retaining clamp 5. Transducer 6. Locating groove

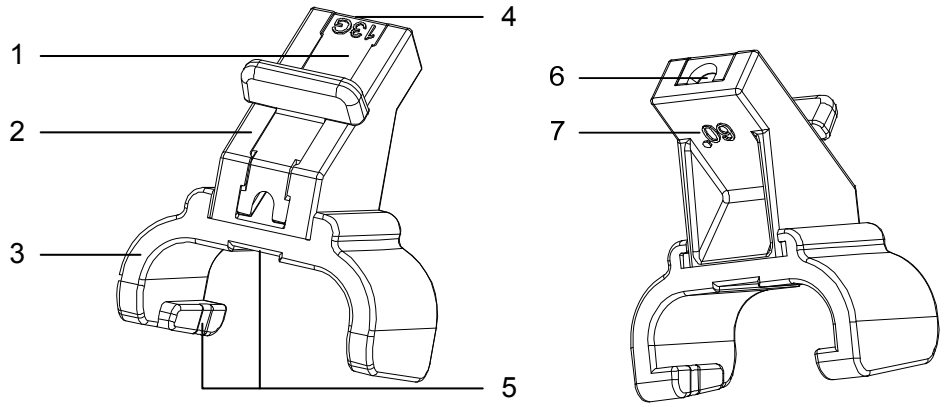
■ NGB-012

Metal/needle detachable needle-guided bracket:



No.	Name	Description
1	Support of needle-guided bracket	Used for installing the needle-guided bracket on the transducer
2	Groove and tab of needle-guided bracket	Respectively matched with the tab and groove of the transducer
3	Angle adjusting base	There are 3 types of angles available to be adjusted
4	Angle shift sign(40°,50°,60°)	Matched with the biopsy angle (40°,50°,60°)
5	Angle pinch nut	Used for fixing the angle lock at a certain angle
6	Angle block	Used for determining the angle of the biopsy; different specifications of blocks can be used
7	Guiding block	Used for installing biopsy needle; there are five specifications of guiding blocks for different biopsy needles
8	Specification of guiding block (14G)	Matched with the corresponding biopsy needle (14G)
9	Needle guide hole	Used for installing the biopsy needle
10	Pinch nut of needle-guided bracket	Used for locking the needle-guided bracket and the transducer

Plastic/needle detachable needle-guided bracket:



No.	Name	Description
1	Guiding block	Used for installing biopsy needle; there are five specifications of guiding blocks for different biopsy needles
2	Angle block	Used for determining the angle of the biopsy; there are three specifications of blocks of angle
3	Support of needle-guided bracket	Used for installing the needle-guided bracket on the transducer
4	Specification of guiding block (13G)	Matched with the corresponding biopsy needle (13G)
5	Groove and tab of the needle-guided bracket	Respectively matched with the tab and groove of the transducer
6	Needle guide hole	Used for installing the biopsy needle
7	Specification of angle block (60°)	Corresponding to the size of the biopsy angle (60°)

17.2.3 Needle-guided Bracket Inspection and Installation

Inspection of the Needle-guided Bracket

Be sure to perform inspections before and after use of the needle-guided bracket. If an abnormality is found on the needle-guided bracket, immediately stop using it and contact MINDRAY Customer Service Department or sales representative.

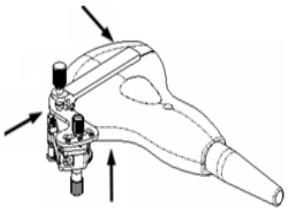
1. Sterilize the needle-guided bracket before and after use.
2. Confirm that the needle-guided bracket is free of damage, deformation, stripping, malfunction, loose, or missing parts.
3. Confirm that the needle-guided bracket is securely mounted in the correct position.

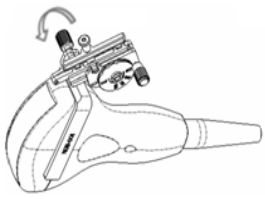
Installing the Needle-guided Bracket

- NGB-001 metal/needle detachable needle-guided bracket

  (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.

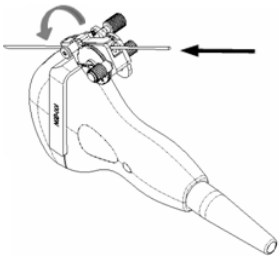




  (3) Screw the pinch nut of the needle-guided bracket to confirm that the needle-guided bracket is properly installed on the transducer.

  (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.)

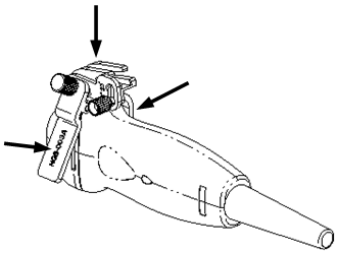
  (5) Pull the lock pin and close the V-shaped cover to fix the lock pin in the groove of the needle type adjusting base, so as to install the needle into the guiding hole.

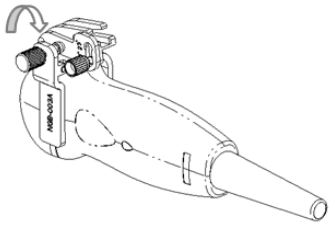


- NGB-003 metal/needle detachable needle-guided bracket

  (1) Put on the transducer cover.

  (2) Select a proper needle-guided bracket, and match the groove with the tab of the transducer respectively. Mount the bracket onto the transducer.



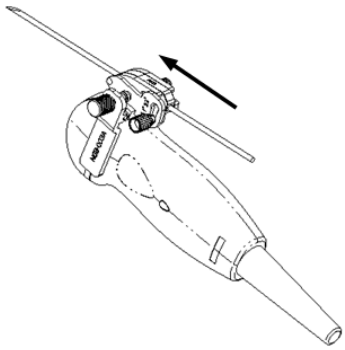


  (3) Screw the pinch nut of the needle-guided bracket to confirm that the needle-guided bracket is properly installed on the transducer.

  (4) Select a proper guiding block and push it into the groove above the angle block.

(5) Screw the nut of the block to secure the block.

(6) Insert a biopsy needle with the same specification as that of the guiding block into the hole of the guiding block.



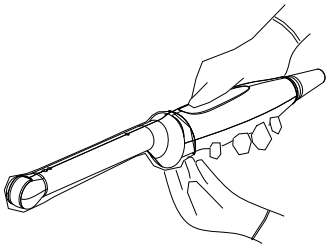
- NGB-001, NGB-002, NGB-003 and NGB-005 metal/needle un-detachable needle-guided bracket (taking NGB-001 as example)

  (1) Inosculate the locating groove on the clamp with the two raised edges on the transducer head and aligning the locating pit of the clamp to the convex point on the transducer head.

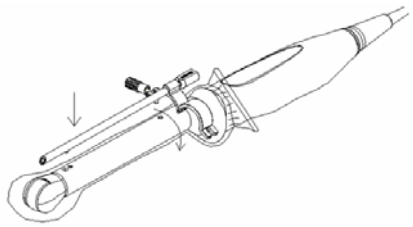
  (2) Turn the grip knob at the tail of the needle-guided bracket tightly.

- NGB-004 metal/needle un-detachable needle-guided bracket

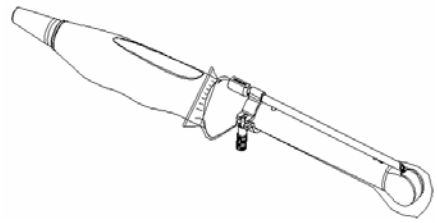
  (1) Put on the sterile transducer sheath.



(2) Open the retaining clamp, align the needle-guided bracket with the transducer to locate the locating bulge on the needle guide to the locating grooves on the transducer, and then turn the retaining clamp to match it with the transducer (See the figure below).



(3) When the retaining clamp is turned to the right position, the locking nut will lock the retaining clamp and the needle-guided bracket is then mounted to the right position.

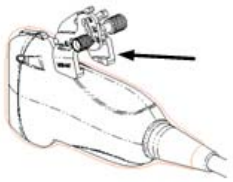


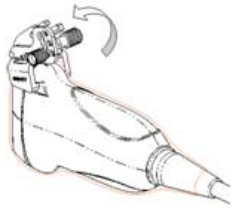
■ NGB-012

Metal/needle detachable needle-guided bracket:

(1) Put on the sterile transducer sheath.

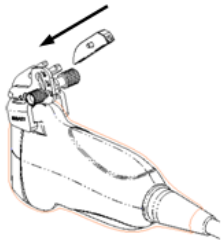
(2) Hold the transducer by one hand, select the proper needle-guided bracket, and hold it with the other hand. Match the groove and tab with the tab and groove of the transducer respectively. Amount the bracket onto the transducer.

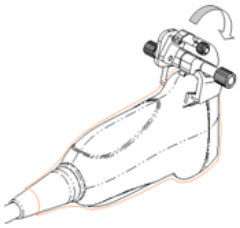




(3) Screw the pinch nut of the needle-guided bracket to confirm that the needle-guided bracket is properly installed on the transducer.

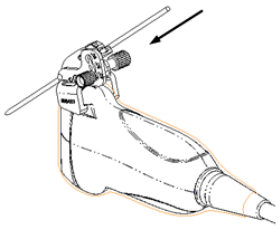
(4) Select a proper guiding block and push it into the groove above the angle block, and clamp it tightly.





(5) Screw the nut of the block to secure the block.

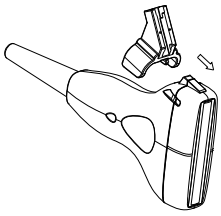
(6) Insert a biopsy needle with the same specification as that of the guiding block into the hole of the guiding block.



Plastic/needle detachable needle-guided bracket:

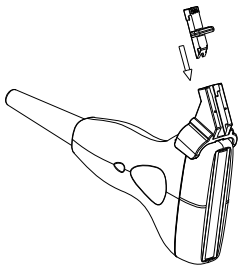
(1) Put on the sterile transducer sheath.

(2) Hold the transducer by one hand, select the proper needle-guided bracket, and hold it with the other hand. Align the narrow end tab of the needle-guided bracket with the groove of the transducer, then push the needle-guided bracket forward, making the tabs and the grooves of the needle-guided bracket to match with the grooves and tabs of the transducer.

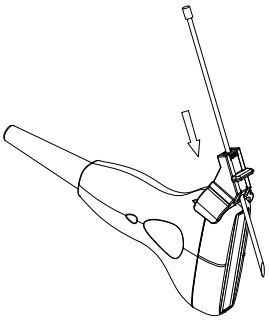


(3) Check manually to confirm that the needle-guided bracket is securely installed on the transducer.

(4) Select a proper guiding block and push it into the groove above the angle block, and clamp it tightly.



(5) Insert a biopsy needle with the same specification as that of the guiding block into the hole of the guiding block.

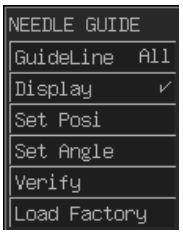


⚠CAUTION:	**Ensure that all guide parts are seated properly prior to performing a biopsy.**

17.2.4 Entering/Exiting Needle Guide Mode

When the B-mode image is in real-time status, press the 『Puncture』 key to enter the needle guide mode.

If the transducer has no biopsy kits, “This transducer has no biopsy kit!” will be displayed on the screen, which expresses the transducer couldn’t use to biopsy. Otherwise the indicator of the 『Puncture』 key lights up, “Please calibrate biopsy guide line before each biopsy check.” will be displayed on the screen. After this dialog box is closed, the biopsy guide line is displayed in the Image area and the [NEEDLE GUIDE] menu is displayed on the upper right side of the screen. See the figure below.



⚠WARNING: Do not freeze image during biopsy.

Press the 『Puncture』 key again when the system is in needle guide mode to exit it. The indicator turns off and the [NEEDLE GUIDE] menu closes at the same time but the biopsy guide line in the image area will still display.

17.2.5 Selecting Guide Line

Every needle-guide bracket has most three guide lines. You can let the system display different guide lines by using the [Guide Line]] item of the [NEEDLE GUIDE] menu.

Click the [Guide Line] item, different guide line will be displayed circularly. The value of the current angle and position will also be displayed on the menu item. The “All” option means to display all guide lines.

Scale of the needle guide lines: corresponds to the current depth.

If the depth range is from 2.3cm to 8cm, interval of two dots is 0.5cm.

If the depth range is from 8cm to 24cm, interval of two dots is 1cm.

17.2.6 Hiding/Displaying Needle Guide Line

You can use the [Display] item of the [NEEDLE GUIDE] menu to let the system hide or display the guide line.

Click the [Display] item, the guide line will be displayed or hidden alternatively.

17.2.7 Adjusting Needle Guide Line

⚠WARNING:

1. **Prior to each puncture, adjust the needle guide line.**
2. **If the positions of the needle and needle guide line are not consistent, do not execute biopsy operation.**

NOTE: If B mode image is not real-time, the biopsy guide line cannot be adjusted.

Adjusting method:

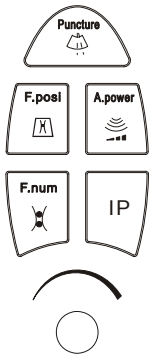
- Move the needle guide line horizontally:

  Use the [Set Posi] item in the puncture menu to move the needle guide line horizontally.

  When the cursor is on the [Set Posi] item, press 『Set』key to increase the position value or 『Back』key to decrease it. The value of the current position is also displayed in this menu item.

- Adjust needle guide line angle:

  Use the [Set Angle] item in the puncture menu to adjust needle guide line angle. The operating procedures are the same as [Set Posi]. When the [Puncture』 indicator is on, turn the 『Parameter Adjustment』knob to trim the angle of the biopsy guide line. The knob can be adjusted guide line separately.



← Parameter adjustment knob

- Save verified values

  After adjusting the position and angle of the needle guide line, click on the [Verify] item, the system will then save the data of the current biopsy guide line. When starting up the system next time, the displayed position of the biopsy guide line will consequently be the position after adjusting.

- Restore factory value of the biopsy guide line

  Click the [Load Factory] item, the position and angle of the needle guide line will return to the factory setup value.

17.2.8 Others

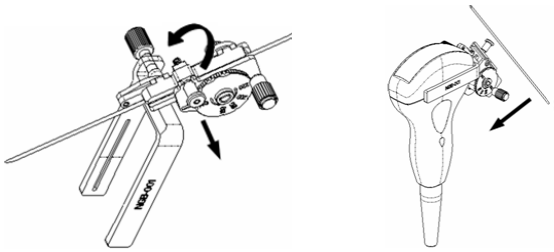
In needle guide mode, press 『Puncture』key or others function keys to exit adjusting needle guide status, the 『Puncture』key light off, but the biopsy guide line in the Image area will still display. At this time user can't adjust it but can adjust the image parameters, perform measurement, add comments and body marks.

17.2.9 Removing the Needle-guided Bracket

- NGB-001

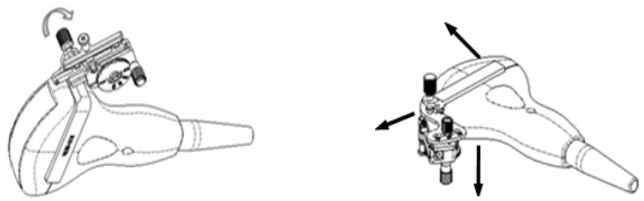
  Metal/needle detachable needle-guided bracket:

  (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.

Metal/needle un-detachable needle-guided bracket:

While holding the transducer and the needle-guided bracket, open the grip knob of the needle-guided bracket.

- NGB-002 metal/needle un-detachable needle-guided bracket:

  While holding the transducer and the needle-guided bracket, open the Grip knob of the needle-guided bracket.

- NGB-003

  Metal/needle detachable needle-guided bracket:

  (1) Screw the nut of the guiding block and remove the guiding block slightly along the direction of the needle's tail.

(2) Separate the residual part of the needle-guide bracket and the transducer from the needle.

(3) Screw the pinch nut of the bracket, and remove the needle-guided bracket from the transducer.

Metal/needle un-detachable needle-guided bracket:

While holding the transducer and the needle-guided bracket, open the Grip knob of the needle-guided bracket.

- NGB-004 metal/needle un-detachable needle-guided bracket:

  Hold the transducer in the left hand, unscrew the locking nut with the right hand to open the retaining clamp, and then raise the needle-guided bracket to separate the locating bulge from the locating grooves.

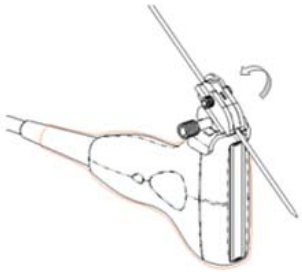
- NGB-005 metal/needle un-detachable needle-guided bracket

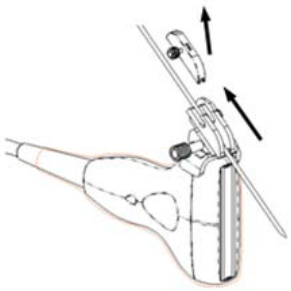
  Hold the transducer and the needle-guided bracket, open the grip knob of the needle-guided bracket.

- NGB-012

  Metal/needle detachable needle-guided bracket:

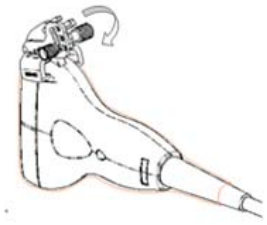
  (1) Screw the nut of the guiding block and remove the guiding block slightly along the direction of the needle's tail.

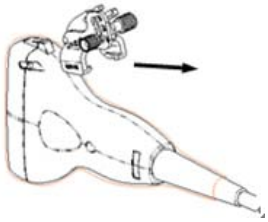




  (2) Separate the residual part of the needle-guide bracket and the transducer from the needle.

  (3) Screw the pinch nut of the bracket, and remove the needle-guided bracket from the transducer.





  Plastic/needle detachable needle-guided bracket:

  (1) Remove the guiding block slightly along the direction of the needle's tail.

  (2) Separate the residual part of the needle-guide bracket and the transducer from the needle.

  (3) Remove the support of needle-guided bracket from the transducer.

17.2.10 Clean and Sterilize the Needle-guided Bracket

Cleaning

Please follow the instructions in the manual for cleaning.

1. Wear sterile gloves to prevent infection.
2. Wash the needle-guided bracket with water or soap water to remove all the external matters. Or, clean the needle-guided bracket with urethane sponge.
3. Wipe off the water on the needle-guided bracket using sterile cloth or gauze after washing it.

Sterilization

1. Wear sterile gloves to prevent infection.
2. Clean the needle-guided bracket before sterilizing it. MINDRAY recommends the following solution or sterilizing system to sterilize the needle-guided bracket.
3. Follow local regulations when selecting and using the sterilant.

■ Glutaraldehyde-based sterilant:

Chemical name	Trade name	Procedures
Glutaraldehyde (2.4%)	Cidex Activated Dialdehyde Solution	Please refer to the instructions provided by the manufacturer of the solution for details. Soak the transducer into the activated solution for 10 hours (20-25℃)

Before safety and performance is affected, plastic bracket NGB-012 can be sterilized by Cidex Activated Glutaraldehyde Solution for at least 233 times (10 hours for one time).

- Refer to the instructions provided by the chemical manufacturer concerning concentration of the solution, and method of disinfections and dilution. Note that the glutaraldehyde sterilant solution needs an activating solution.
- Rinse the needle-guided bracket thoroughly with sterile water to remove all chemical residues on it.
- Wipe off the water on the needle-guided bracket with sterile cloth or gauze after rinsing it.

■ STERRAD 100S low-temperature hydrogen peroxide gas plasma sterilization system

Chemical name	Trade name	Procedures
Hydrogen peroxide gas plasma	Hydrogen peroxide vapor	Please refer to the instructions provided by the producer of the solution for details.

- Refer to the instruction of STERRAD 100S sterilizing system provided by the manufacturer for operation instructions and cautions.
- The STERRAD 100S low-temperature hydrogen peroxide gas plasma sterilization system is available for metal needle-guided brackets.

■ High-pressure steam sterilization (only applicable for metal guided-bracket)

Autoclaving (moist heat) 121° C for 20 minutes.

NOTE: 1. Repeated sterilization may degrade the safety and performance of the needle-guided bracket.

2. The high-pressure steam/ immersion sterilization do not affect the bracket duration life, and the duration life is affected by the daily application of the bracket. Please check the appearance of the bracket before using.

17.2.11 Storage and Transportation

1. Don't use the carrying case for storing the needle-guided bracket. If the carrying case is used for storage, it may become a source of infection.
2. Between examinations, keep the needle-guided bracket in a sterile environment.
3. When the needle-guided bracket is sent to your MINDRAY representative for repair, be sure to disinfect or sterilize it and keep it in the carrying case to prevent infection.
4. Sterilize the carrying case as necessary.
5. Store or transport the needle-guided bracket under the following ambient conditions:
   - Ambient temperature: -20°C to 55°C
   - Relative humidity: 30% to 85% (no condensation)

17.2.12 Disposal

Be sure to dispose the needle-guided bracket only after sterilizing it.

Contact your MINDRAY representative when disposing of this device.

18 Acoustic Power Principle

18.1 Concerns with Bioeffects

Diagnostic ultrasound is recognized as being safe. In fact, there have been no reports of injuries to patients caused by diagnostic ultrasound. 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. Although the possibility exists that such biological effects may be identified in the future, current data indicate that benefits of using ultrasound for diagnosis overweighs the risk of using it in patients, if any of such exits.

18.2 Prudent Use of Ultrasound Energy

Although there are no confirmed biological effects on patients caused by exposures from present diagnostic ultrasound instruments, the possibility exists that such biological effects may be identified in the future. Thus ultrasound should be used in a prudent manner to provide medical benefit to the patient. High exposure levels and long exposure times should be avoided while acquiring necessary clinical information.

18.3 ALARA (As Low As Reasonably Achievable) principle

A patient examination with ultrasound should be performed with acoustic output levels and exposure time As Low As Reasonable Achievable (ALARA) to obtain acceptable diagnostic results. It is then recommended that exposure times and transmitted acoustic power do not exceed those which are necessary to collect the desired diagnostic information. Prudent use of this system occurs when patient exposure is limited to the lowest output for the shortest amount of time necessary to achieve acceptable diagnostics.

Practicing ALARA ensures that the total energy level is controlled below a low enough level at which bioeffects are not generated while diagnostic information is being accumulated. The total energy is controlled by output intensity and total radiation time. The output intensity

necessary for examinations differs depending on the patient and the clinical case.

Not all examinations can be performed with an extremely low level of acoustic energy. Controlling the acoustic level at an extremely low level leads to low-quality images or insufficient Doppler signals, adversely affecting the reliability of the diagnosis. However, increasing the acoustic power more than necessary does not always contribute to an increase in quality of information required for diagnosis, rather increasing the risk of generating bioeffects.

Users must take responsibility for the safety of patients and utilize ultrasound deliberately. Deliberate use of ultrasound means that output power of ultrasound must be selected based on ALARA.

NOTE: The acoustic output of the DP-9900 system does not exceed the FDA pre-amendment values. This system conforms to Track 1.

18.4 Parameters Affecting Acoustic Power

Acoustic Power is affected by transmission conditions such as focus, drive frequency, acoustic power setting which determined the voltage applied to piezoelectric elements, frame rate which is affected by the selected depth setting and scan conditions. Each transducer model delivers a specific acoustic power value. These values and other acoustic parameters are referred to the manual of acoustic power with the system.

Acoustic Output Values

The acoustic intensity generated by an ultrasonic probe is usually described by the following terms:

Ispta: The derated spatial-peak temporal-average intensity which is the highest intensity within the field, averaged over the entire scan frame period, in milliwatts per square centimeter.

MI: The derated mechanical index which is the peak rarefactional pressure at the point of maximum pulse intensity integral divided by the square root of the ultrasonic center frequency.

In order to calculate the in-situ intensity values which are meaningful for bioeffects considerations, intensity measurements made in water tanks must be derated to reflect the expected intensity encountered at the tissue site.

The derated intensities (in situ) are calculated by multiplying the intensities measured in water by the derating factor. This factor is found using the center frequency measured (fc, MHz) from the acoustic signal, and the distance from the transducer under test to the hydrophone (Zsp, cm) and is given by e-0.069*fc*Zsp (e-0.0345*fc*Zsp for pressure values). This function attempts to compensate for the attenuation of ultrasound as it passes through tissue to the focal location. The attenuation is a function of both the focal depth (there is more attenuation at deeper depth) and the emitted ultrasound frequency (there is more attenuation at higher

frequencies). The derating factor is based upon the assumed 0.3dB/cm/MHz attenuation the average tissue attenuation- taking into consideration the effects of ultrasound passage through fluids. Thus the attenuation is lower that 0.5dB/cm/MHz typically used for soft tissue, but higher than the lossless case of ultrasound propagation through water. The in-water intensity levels may be found for any reported derated intensity by multiplying by the factor e0.069*fc*Zsp(e0.0345*fc*Zsp for pressure values). Both the center frequency fc and the depth to the derated focal points Zsp are presented in the tables.

18.5 Acoustic Power Setting

Press the [A.power] key at the left end of the control panel, the [A.power] lamp lights on. Turn the [Parameter Adjustment] knob to adjust the acoustic power, whose value is displayed in the Parameter area on the top part of the screen. To decrease acoustic power, turn the knob counterclockwise; to increase acoustic power, turn the knob clockwise.

Acoustic power can be set in the range from 1 to 8, where 1 corresponds to minimum acoustic power and 8 corresponds to maximum acoustic power.

When the image is frozen, the acoustic power cannot be adjusted.

18.6 Imaging Functions that Change Acoustic Output Power

Changes of imaging mode and adjustments to controls also affect the acoustic output power.

Specific information is provided in the following table.

Operation	**Effect on the acoustic output power**
Transducer change	The maximum acoustic output power of each transducer is optimized to produce the best image quality within FDA guidelines. Thus, the acoustic output power will change as the operator changes the active transducer.
Imaging Mode change	Since B and M modes use difference default imaging parameters, changing the mode will change the acoustic output power of the system. No changes occur when switching from B to B/B, since the basic imaging parameters remain the same. In most cases, the acoustic output power for M-mode is larger than in B-mode; however, it depends in the specific presets for B and M-mode.
Field of view(sector Angle or scan Width)	Change the sector angle or scan width may result in change to the frame rate, and thus change the acoustic output power.
Image depth change	Changing the image depth changes the repetition of pulses along

	the line of sight, and thus changes the acoustic output power.
Number of Focal Zones	Since the number of focal zones influences the frame rate and the actual position of the focal zones, changing the number of focal zones changes the acoustic output power.
Focus location	The transmit focus location change will cause the acoustic output power change, even though the transmitting electrical energy level and the aperture remains the same. In most cases, the acoustic output power will increase if the focal point is moved closer to the transducer.
Freeze	Active the freeze function stops the electrical energy transmits part of the system, thus disabling the system from generating ultrasound waves.
Transmit power	The transmit power level change will change the electrical output of the system to the transducer, and thus change the acoustic output power.
Frequency change	Changing the operating frequency changes the focal characteristics of the acoustic waves, thus changes the acoustic output power.
Line density	Changing the number of acoustic lines generated (line density) affects the acoustic output power.
Preset	Since the system and user presets contain all of the above imaging parameters, changing the preset will change the acoustic output power.
Reset or Power Off/On	Resetting or powering the system on or off causes the system to return to the default status, thus changing the acoustic output power.

NOTE: The surface heating of the probe is limited to 43℃. The DP-9900 Digital Ultrasonic Diagnostic Imaging System is equipped with a thermal switch to limit the power output in case of excessive consumption or device malfunction. Sensing elements are placed at the front end pulser circuitry to detect any current draw and voltage drops beyond the normal operating limits which may cause overheating

18.7 Track 1-Summary Table

Table of Global Maximum Derated Ispta and Mechanical Index Values

Transducer Model	M Mode		B Mode/BB Mode		B/M Mode	
	Ispta.3 (mW/cm2)	MI	Ispta.3 (mW/cm2)	MI	Ispta.3 (mW/cm2)	MI
35C20HA1	3.41E+01	5.28E-01	1.05E+01	5.40E-01	3.82E+00	5.40E-01
35C50HA	8.98E+01	5.95E-01	6.21E+01	5.87E-01	9.99E+00	5.95E-01
65C15HA	8.33E+01	9.79E-01	3.97E+01	8.76E-01	6.39E+00	9.79E-01
65EC10HA	6.48E+01	7.94E-01	9.84E+00	8.65E-01	4.97E+00	8.65E-01
75L38HA	9.30E+01	7.09E-01	7.95E+00	7.28E-01	7.19E+00	7.28E-01
75L38HB	8.61E+01	8.03E-01	7.60E+00	7.63E-01	6.63E+00	8.03E-01
75L60HB	9.18E+01	7.03E-01	6.89E+00	7.04E-01	7.05E+00	7.04E-01

1 Values apply indistinctly to all clinical applications described in the tables below.

CLINICAL APPLICATIONS/OPERATING MODES

Transducer: 35C20HA

Application/Mode	A	B	M	PWD	CWD	CD	Combined B/M, B/B	Other
Ophthalmic								
Fetal Imaging & Other*		x	x				x	
Cardiac, Adult & Pediatric		x	x				x	
Peripheral Vessel								

Transducer: 35C50HA

Application/Mode	A	B	M	PWD	CWD	CD	Combined B/M, B/B	Other
Ophthalmic								
Fetal Imaging & Other*		x	x				x	
Cardiac, Adult & Pediatric								
Peripheral Vessel								

Transducer: 65C15HA

Application/Mode	A	B	M	PWD	CWD	CD	Combined B/M, B/B	Other
Ophthalmic								
Fetal Imaging & Other*		x	x				x	
Cardiac, Adult & Pediatric		x	x				x	
Peripheral Vessel								

Transducer: 65EC10HA

Application/Mode	A	B	M	PWD	CWD	CD	Combined B/M, B/B	Other
Ophthalmic								
Fetal Imaging & Other*		x	x				x	
Cardiac, Adult & Pediatric								
Peripheral Vessel								

Transducer: 75L38HA

Application/Mode	A	B	M	PWD	CWD	CD	Combined B/M, B/B	Other
Ophthalmic								
Fetal Imaging & Other*		x	x				x	
Cardiac, Adult & Pediatric								
Peripheral Vessel		x	x				x	

Transducer: 75L38HB

Application/Mode	A	B	M	PWD	CWD	CD	Combined B/M, B/B	Other
Ophthalmic								
Fetal Imaging & Other*		x	x				x	
Cardiac, Adult & Pediatric								
Peripheral Vessel		x	x				x	

Transducer: 75L60HB

Application/Mode	A	B	M	PWD	CWD	CD	Combined B/M, B/B	Other
Ophthalmic								
Fetal Imaging & Other*		x	x				x	
Cardiac, Adult & Pediatric								
Peripheral Vessel		x	x				x	

*Abdominal, Intraoperative, Pediatric, Small Organ (breasts, thyroid, testes), Neonatal Cephalic, Adult Cephalic, Musculo-Skeletal (conventional and superficial).

* Tissue Harmonic Imaging does not use contrast agents.

18.8 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) “Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers” issued by FDA in 1997

19 Maintenance

The maintenance of the system is completed by customers and service engineers. When the system is delivered to the customer, the customer should assume all the responsibilities in operation and maintenance.

⚠WARNING: Only engineers trained and authorized by Mindray can do maintenance not introduced in this manual. Contact Mindray customer service department or your local distributor for details.

19.1 Maintenance by Customers

The following maintenance is to be performed by users.

19.1.1 Cleaning system

⚠WARNING: Before cleaning the system, be sure to turn off the power and disconnect the power cable from the outlet. Cleaning the machine when the power is "on" may result in electric shock.

⚠CAUTION:

1. **Be sure not to allow water or liquid to enter the system during cleaning to avoid malfunctions or electric shock.**
2. **To clean the connector, TGC controls and other connectors for the peripheral devices, contact Mindray customer service department or your local distributor. The cleaning by the user may cause failure or degrade the performance of the system.**

1. Cleaning the transducer

   Please refer to the operator's manual of corresponding transducer to do cleaning, disinfection and sterilization.

2. Cleaning the connector of transducer

   （a） Use soft dry cloth to erasure besmirch on the connector.

   （b） If necessary, clean the connector using soft cloth dipped with mild cleanser, then air–dry it.

3. Cleaning the monitor

   Erase the monitor using soft cloth dipped with glass detergent, and then air-dry it.

NOTE:	Do not use hydrocarbon glass cleanser or cleanser for OA equipments to clean the monitor. The substance may cause deterioration in the monitor.

4. Cleaning the control panel, shell and holder

   Use dry soft cloth to clean the surface of the machine.

   If necessary, use soft cloth dipped with mild cleanser to clean the surface of the machine, then dry it with dry soft cloth or air-dry it.

19.1.2 Backup

To prevent any deterioration or loss of data stored in the system hard disk, backup the hard disk periodically.

19.2 Maintenance by Service Personnel

The following maintenance is to assure the performance and safety of the system. Only professional service personnel can perform them. Contact Mindray customer service department or your local distributor when needed.

Category	Maintenance items	Interval
Cleaning	Interior of the system Peripheral units	1 year
Electric safety	Protective conductor resistance Ground line leakage current Enclosure leakage current Patient leakage current I Patient leakage current III	1 year

Category	Maintenance items	Interval
Mechanical safety	Check of the casters Check of the caster mounting sections Check of the monitor mounting mechanism Operating panel Mounting mechanism for the peripheral devices Other mechanical parts External appearance of the transducer	1 year
Image recording	Images in each mode Image recording using the standard transducer	1 year

19.3 Consumables and Replacing Parts

This system contains some parts requiring periodic replacement and some consumable parts. The consumable parts include casters, fuses, etc.

Only professional personnel trained and authorized by Mindray can replace these parts. Contact Mindray customer service department or your local distributor if needed.

19.4 Troubleshooting

To ensure the normal operation of the machine, it is recommended to establish the maintenance plan to periodically check the safety of the machine. If you find anything abnormal, contact Mindray customer service department or your local distributor.

If some abnormal phenomena such as that after the start-up, there is no image, or there is menu but no image, please troubleshoot first by referring to the table below. If the failure remains, please contact Mindray customer service department or your local distributor.

No.	Failure	Cause	Measure
1	The power switch is turned on, but the power indicator does not light on.	Abnormal power system or incorrect connection of the power cable.	Check the power system and the power cable to ensure they are in normal status.

No.	Failure	Cause	Measure
2	The power light is on but no image is displayed.	1. The time span between shutdown and restart-up is too short. 2. The contrast or the brightness of the display is in abnormal status.	1. After shutdown, wait for 1 minute and then restart-up the machine. 2. Adjust the contrast or the brightness knob of the monitor.
3	The monitor shows the character and menu but no scan image.	1. The emitting power, gain or TGC control is in abnormal condition. 2. No is connected or the connection is not corrected. 3. The machine is in Freeze mode.	1. Adjust the emitting power, gain or the TGC control. 2. Ensure correct connection. 3. Unfrozen the image.
4	The image quality is abnormal.	1. The exam mode is not right. 2. The setup of the image post process is not right.	1. Select the appropriate exam mode. 2. Adjust the setup of the image post process or set the post process to the default value.

20 Accuracy of Measurement

Accuracy of Measurements and Range of Operating Conditions

The accuracy of the biometric measurements has been obtained using tissue mimicking phantoms for which the speed of sound is 1540m/s. Estimated accuracies for biological tissues have been obtained assuming the average value of the speed of sound in tissue = 1540m/s and an uncertainty of 3%. Accuracy of dimension and time motion measurements is listed below for the specified transducers and imaging modes. The listed accuracies apply indistinctly to all transducer models.

TRANSDUCERS

35C50HA
35C20HA
65EC10HA
65C15HA
75L38HA
75L38HB
75L60HB

Dimension Measurements for B and B/M modes

Parameter	Range	Measured Error in Phantom	Estimated Error in Biological Tissue
Distance/Depth	2.0 up to237.0mm	< 3%	< 5%
Area (ellipse, circle)	5 mm2 up to 326cm2	< 6%	< 11%
Trace Area	5 mm2 up to 493cm2	< 7%	< 11%
Angle	0～180 degrees	< 2.5%	< 10%
% Stenosis	0.1 to 1.0	< 6%	< 10%
Volume	12.5 mm3 up to 3250cm3	< 10%	< 20%

Time Motion Measurements for M and B/M modes

Parameter	Range	Measured Error in Phantom	Estimated Error in Biological Tissue
Depth	2.0 up to247.0mm	< 3%	< 5%
Time	4.08ms to 8.09s	< 1%	< 1%
Heart Rate	14 ～ 3000bmp	< 3%	< 4%
Velocity	0mm/s to 12.9m/s	< 4%	< 4%

Description and Justification of Test Methodology for Determining Accuracy

The accuracy of measurements performed by the DP-9900 system is ascertained by a worst case analysis of image display geometry and is confirmed by scans and actual measurements of phantom objects for which the dimensional parameters (i.e., distance, area, volume, etc.) are known.

Test Methodology

Depth of Penetration: The maximum sensitivity or depth of penetration is determined by measuring the depth in the tissue mimicking phantom at which the usable echo information disappears.

Distance Accuracy: Distance accuracy is assessed by comparing the measured distance between the selected targets in the phantom with the known distance. The test distances are determined by the selected probe and depth of penetration. Distance accuracy is measured for the vertical and horizontal axis.

Area Accuracy: Area accuracy is assessed by measuring areas of known phantom circular objects and comparing these values with the calculated ones, using phantom manufacturer information such as object radius or diameter. To obtain area accuracy for elliptical objects, an

ellipse is drawn in which the semi axes correspond to fixed targets. The measured area is compared to the calculated ellipse area obtained using the known distance between the targets.

Perimeter Accuracy: a circular object is drawn in which a selected pin-target serves as the circle center. A second pin target is then used to determine the circle radius. The measured perimeter is then compared to the calculated perimeter obtained using the selected pin-target spatial positions.

Time Motion: Time motion measurements are upper limited by the assessed distance accuracy for 2 dimensional measurements. Distance accuracy assessment methodology applies in a similar way to Time Motion measurements. Uncertainty in time measurements was determined to be less than 80 ms or 1/(slowest Frame Rate).

Volume A 3 dimensional object is imaged and 2-axes and 3 axes volume calculation system functions are used. The measured volume is compared to the actual object volume provided by the 3 dimensional phantom manufacturers.

Statistics Several measurements are obtained for each measurement function as to reduce human cursor positioning errors. In each case, a data sheet is filled out for the specific accuracy measurement. Standard statistical methods are then used to calculate average measured value, standard deviation and percentage error.

NOTE: Measurements in any area of the selected viewing range can meet the required precisions. Precisions given above are for the worst possible working situation of the equipment or obtained from the actual tests to the equipment.

21 Safety Classification

(1) According to the type of protection against electric shock:

CLASS I EQUIPMENT

(2) According to the degree of protection against electric shock:

EQUIPMENT WITH TYPE-BF APPLIED PARTS

(3) According to the degree of protection against harmful ingress of water:

- IPX0 (for the main unit)
- Footswitch: 971-SWNOM belongs to IP68.

(4) 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

(5) According to the mode of operation:

CONTINUOUS OPERATION

(6) According to the Degree of Mobility

MOBILE EQUIPMENT

22 Guidance and Manufacturer's Declaration

This product complies with the EMC standard EN 60601-1-2:2007.

⚠CAUTION: The use of unapproved accessories may diminish the performance of the system.

Note:

1. The system should not be used adjacent to or stacked with other equipment. If the adjacent or tacked use is necessary, the system should be observed to verify normal operation in the configuration in which it will be used.
2. The system needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.
3. Preventing conducted RF immunity. Due to technological limitations, the conducted RF immunity level are limited to 1Vrms level, conducted RF interference above 1Vrms may cause wrong diagnosis and measurements. We suggested that you position the system further from sources of conducted RF noise.
4. Portable and mobile RF communications equipment can affects DP-8800Plus.

Guidance and manufacturer's declaration - electromagnetic emissions		
The EQUIPMENT is intended for use in the electromagnetic environment specified below. The customer or the user of the EQUIPMENT should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The EQUIPMENT uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The EQUIPMENT is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The EQUIPMENT is intended for use in the electromagnetic environment specified below. The customer or the user of the EQUIPMENT 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 differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines 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 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the EQUIPMENT requires continued operation during power mains interruptions, it is recommended for the EQUIPMENT to be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The EQUIPMENT is intended for use in the electromagnetic environment specified below. The customer or the user of the EQUIPMENT should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the EQUIPMENT, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	1 Vrms	$d = 3.5\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 Vrms	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the EQUIPMENT is used exceeds the applicable RF compliance level above, the EQUIPMENT should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the EQUIPMENT.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT

The EQUIPMENT is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the EQUIPMENT can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the EQUIPMENT as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 3.5\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.35	0.12	0.23
0.1	1.11	0.38	0.73
1	3.50	1.2	2.3
10	11.07	3.8	7.3
100	35.00	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated 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.

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.

23 Year of Manufacture

The year of manufacture is shown on the label attached on the rear of the system.

Appendix A Electrical Safety Inspection

The following electrical safety tests are recommended as part of a comprehensive preventive maintenance program. They are a proven means of detecting abnormalities that, if undetected, could prove dangerous to either the patient or the operator. Additional tests may be required according to local regulations.

All tests can be performed using commercially available safety analyzer test equipment. These procedures assume the use of a 601PROXL International Safety Analyzer or equivalent safety analyzer. Other popular testers complying with IEC 60601-1 used in Europe such as Fluke, Metron, or Gerb may require modifications to the procedure. Follow the instructions of the analyzer manufacturer.

The electrical safety inspection should be periodically performed every two years. The safety analyzer also proves to be an excellent troubleshooting tool to detect abnormalities of line voltage and grounding, as well as total current loads.

A.1 Power Cord Plug

A.1.1 The Power Plug

Test Item		Acceptance Criteria
The power plug	The power plug pins	No broken or bent pin. No discolored pins.
	The plug body	No physical damage to the plug body.
	The strain relief	No physical damage to the strain relief. No plug warmth for device in use.
	The power plug	No loose connections.
The power cord		No physical damage to the cord. No deterioration to the cord.
		For devices with detachable power cords, inspect the connection at the device.
		For devices with non-detachable power cords, inspect the strain relief at the device.

A.2 Device Enclosure and Accessories

A.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.).

A.2.2 Contextual Inspection

Test Item	Acceptance Criteria
The enclosure and accessories	No unusual noises (e.g., a rattle 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.

A.3 Device Labeling

Check the labels provided by the manufacturer or the healthcare facility are present and legible.

- Main unit label
- Integrated warning labels

A.4 Protective Earth Resistance

a. Plug the probes of the analyzer into the device's protective earth terminal and protective earth terminal of the AC power cord.

b. Test the earth resistance with a current of 25 A.

c. Verify the resistance is less than limits.

■ **LIMITS**

ALL COUNTRIES R = 0.2 Ω Maximum

A.5 Earth Leakage Test

Run an Earth Leakage test on the device being tested before performing any other leakage tests.

The following outlet conditions apply when performing the Earth Leakage test.

- normal polarity(Normal Condition);
- reverse polarity(Normal Condition);
- normal polarity with open neutral(Single Fault Condition);
- reverse polarity with open neutral(Single Fault Condition).

■ LIMITS

For UL60601-1,

- 300 μA in Normal Condition.
- 1000 μA in Single Fault Condition.

For IEC60601-1,

- 500 μA in Normal Condition.
- 1000 μA in Single Fault Condition.

A.6 Enclosure Leakage Test

The following outlet conditions apply when performing the Enclosure Leakage test.

- normal polarity(Normal Condition);
- reverse polarity(Normal Condition);
- normal polarity with open neutral(Single Fault Condition);
- reverse polarity with open neutral(Single Fault Condition);
- normal polarity with open earth(Single Fault Condition);
- reverse polarity with open earth(Single Fault Condition).

■ LIMITS

For UL60601-1,

- 100μA in Normal Condition.
- 300 μA in Single Fault Condition.

For IEC60601-1:

- 100μA in Normal Condition.
- 500 μA in Single Fault Condition.

A.7 Patient Leakage Current

Patient leakage currents are measured between a selected applied part and mains earth. All measurements have a true RMS only.

The following outlet conditions apply when performing the Patient Leakage Current test.

- normal polarity(Normal Condition);
- reverse polarity(Normal Condition),
- normal polarity with open neutral(Single Fault Condition);
- reverse polarity with open neutral(Single Fault Condition).
- normal polarity with open earth(Single Fault Condition);
- reverse polarity with open earth(Single Fault Condition).

■ LIMITS

For BF  applied parts,

- 100μA in Normal Condition.
- 500μA in Single Fault Condition.

A.8 Mains on Applied Part Leakage

The Mains on Applied Part test applies a test voltage, which is 110% of the mains voltage, through a limiting resistance, to selected applied part terminals. Current measurements are then taken between the selected applied part and earth. Measurements are taken with the test voltage (110% of mains) to applied parts in the normal and reverse polarity conditions.

The following outlet conditions apply when performing the Mains on Applied Part test.

- Normal Polarity;
- Reversed Polarity.

■ LIMITS

- For BF  applied parts: 5000 μA.

A.9 Patient Auxiliary Current

Patient Auxiliary currents are measured between any selected Applied Part connector and the remaining Applied Part connectors. All measurements may have a true RMS only response.

The following outlet conditions apply when performing the Patient Auxiliary Current test.

- normal polarity(Normal Condition);
- reverse polarity(Normal Condition);
- normal polarity with open neutral(Single Fault Condition);
- reverse polarity with open neutral(Single Fault Condition);
- normal polarity with open earth(Single Fault Condition);
- reverse polarity with open earth(Single Fault Condition).

■ LIMITS

For BF  applied parts,

- 100μA in Normal Condition.
- 500μA in Single Fault Condition.

Note:	Make sure the safety analyzer is authorized comply with requirement of IEC61010-1. Follow the instructions of the analyzer manufacturer.

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