

DP-10/DP-10T/DP-11/DP-15/DP-18
Digital Ultrasonic Diagnostic Imaging System

Operator's Manual

[Basic Volume]

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For this Operator's Manual, the issue date is 2012-09.


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Contents of this manual are subject to change without prior notice.

All information contained in this manual is believed to be correct. Mindray shall not be liable for errors contained herein or for incidental or consequential damages in connection with the furnishing, performance, or use of this manual.

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

- all installation operations, expansions, changes, modifications and repairs of this product are conducted by Mindray authorized personnel;
- the electrical installation of the relevant room complies with the applicable national and local requirements; and
- the product is used in accordance with the instructions for use.

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.

Warranty

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

Exemptions

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

This warranty shall not extend to:

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

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Important Information

1. 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.

Preface

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

Structure of Operator's Manual

This manual mainly describes the structure, functions, installation, operation, maintenance of the system.




This manual has two volumes.

Basic volume – describes the structure, functions, operations and maintenance of the system.

Advanced volume – describes the preset and measurements in detail.






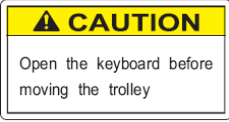










Symbols in Operator's Manual
















The following table explains the safety symbols that may be used in this manual.

Symbol	Signification
 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.

Labels and Symbols on System

The following table explains the labels and symbols attached on the system.

Label or Symbol	Signification
	General warning, caution, risk of danger.
	Before using the system, be sure to carefully read the relevant content of this operator's manual.
	(a) General warning, caution, risk of danger. (b) Urges Caution related to handling of the transducers. For handling of the transducers, refer to the transducers' manuals.
	Cautions that the system must not be removed covers because the high voltage may cause electric shock.
 (a) (b)	This labels are available when the system works with the mobile trolley. (a) DO NOT sit on the system. (b) DO NOT push the trolley when the casters are locked.
	This label is available when the system works with the mobile trolley. Open the keyboard before moving the trolley.
	Type-BF applied part
	General warning, caution, risk of danger.
	Patient/user infection due to contaminated equipment. Be careful when performing the cleaning, disinfection and sterilization.
	Patient injury or tissue damage from ultrasound radiation. It is required to practice ALARA when operating ultrasound system.
	Dangerous voltage
	Power button
	Serial number
	Date of manufacture
	Manufacturer
	AC (alternating current)

Label or Symbol	Signification
	Ethernet port
	Video output
	Equipotential terminal
	Remote control port
VGA 	VGA out
	USB port
 A	Transducer socket A
 B	Transducer socket B
	Reserved
	Reserved
	Brightness of the display
	Contrast of the display
	Authorized representative in the European Community.
	The device is fully in conformance with the Council Directive Concerning Medical Devices 93/42/EEC. The number adjacent to the CE marking (0123) is the number of the EU-notified body.
	<p>The following definition of the WEEE label applies to EU member states only: The use of this symbol indicates that this product should not be treated as household waste. By ensuring that this product is disposed of correctly, you will help prevent bringing potential negative consequences to the environment and human health. For more detailed information with regard to returning and recycling this product, please consult the distributor from whom you purchased the product.</p> <p>* For system products, this label may be attached to the main unit only.</p>

Conventions

This manual uses the following way to mark keys on the control panel and words displayed on the screen.

Keys on the control panel are marked with < >. For example, <Back> represents the “Back” key on the control panel.

Words displayed on the screen are marked with []. For example, [B MEAS] represents the name of the “B MEAS” menu.

Figures

Depending on the model, software version, preset, options and so on, the figures in this manual may appear different from what you see from your system.

The figures in this manual are only for reference or explanation.

Safety Precautions

Be sure to observe the following safety precautions.



DANGER:

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



WARNING:

- 1. Only medical personnel fully trained in clinical examination techniques can use the system.**
- 2. Connect the power plug of the system to the wall receptacle properly grounded and meeting the ratings indicated on the rating nameplate.**
- 3. When the system is connected with other equipments, be sure to connect their equipotential terminals before inserting any of their power plugs into a receptacle, and also, be sure to remove the power plugs from receptacles before disconnecting the equipotential terminals.**
- 4. Use peripherals and optional parts provided with the system or recommended. Use cables provided with the system. Use other peripherals or cables may degrade system performance or even cause electric shock.**

**WARNING:**

5. Do not connect the system to receptacles that control current to devices such as life-support systems and are equipped with the same circuit breakers and fuses as those of the system. If the 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 the system. Do not use the system in any place with the possibility of water ingress. There is risk of electric shock if any water is sprayed on or into the system.
7. Use the system only in the environment specified in this manual.
8. Use transducers specified in this manual. Using transducers not specified in this manual may damage the system and transducer or even cause an accident such as a fire.
9. Use the transducer carefully. In case that the human body contacts the scratched transducer surface, immediately stop using the transducer and contact our company's Customer Service Department or your local distributor. Using scratched transducer may cause electric shock.
10. If finding any abnormality in the system or transducer during the scan, stop scanning immediately and turn off the system.
11. The system and accessories are neither disinfected nor sterilized before they are sold. Disinfect or sterilize transducers and needle-guided brackets as the transducers' manuals describe before using them.
12. After disinfecting or sterilizing accessories, thoroughly clear chemicals from the accessories. Residual chemicals may damage the accessories and cause injury.
13. Do not let the patient contact the system or other equipments. If the system or other equipments are defective, electric shock may occur.
14. Do not subject transducers to knocks. Using defective transducers may cause electric shock.
15. Do not open the shell or panel. Opening the shell or panel when the system is connected to the receptacle may cause short circuit or electric shock.
16. Do not use the system at the same time when using equipment such as an electro-surgical unit, high-frequency therapy equipment or a defibrillator, etc.

**WARNING:**

17. Before moving the system, power it off, close the control panel and then remove all connections (including connections to transducers). Then hold the system's handle to move the system to a proper location carefully.
18. Before cleaning the system, power it off and remove the power plug from the receptacle to avoid electric shock.
19. To avoid system damage or electric shock, do not remove the power plug from the receptacle before turning off the system.
20. To avoid equipment damage or electric shock, do not remove the power plug from the receptacle before turning off the peripheral.
21. To avoid system or printer damage or electric shock, do not connect/disconnect printer's data cable before turning off the system and printer.
22. Accessory equipments connected to the system's analogue and digital interfaces must be complied with the relevant IEC standards (e.g., IEC 60950 Information Technology Equipment standard and IEC 60601-1 Medical Electrical Equipment standard). 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 our company's Customer Service Department or your local distributor.
23. Use ultrasound gel complying with local regulations.
24. This system is not intended for ophthalmic use.

**CAUTION:**

1. This manual does not describe clinical examination techniques. Selection of proper clinical examination technique must be based on specialized training and clinical experience.
2. 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.
3. Ensure the system date and time are consistent with current date and time. If they are not consistent, misdiagnosis may occur.

4. **Always keep the system dry. Do not move the system quickly from a cold place to a warm one. Condensation or water drops formed may cause short circuit.**
5. **If the circuit breaker is tripped or the fuse is blown, it indicates that the system or peripherals have problems. In these cases, do not repair by yourself but contact our company's Customer Service Department or your local distributor.**
6. **Do not place any object on the system.**
7. **Ensure other equipments are secured before moving the system. Otherwise, the equipments may fall and cause injury.**
8. **Ensure proper measurement targets and images and measurements are performed in valid image area. Incorrect measurement results may cause misdiagnosis.**
9. **Prolonged or repeated use of the keys and trackball on the control panel may result in hand or arm nerve disorders. Observe the local safety/health regulations.**

NOTE:

1. Do not use the system in the vicinity of strong electromagnetic field (such as the transformer), which may affect the performance of the monitor.
2. Using devices transmitting RF signals in the vicinity of the system may affect the system's performance. Do not use or take any devices intentionally transmitting RF signals such as cellular phones, transceivers and radio controlled products in the room placing the system.
3. Transport, store and use the system under the circumstance specified in this manual. Additionally, store and use the system in a clean location where there is no direct sunlight, no sudden changes in temperature, no condensation, few dust, no vibration, and far from heat generators.
4. After turning off the system, wait at least 10 seconds before turning it on again. Otherwise, failure may occur.
5. Before connecting/disconnecting the transducer, turn off the system or stop emitting (freeze the image). Otherwise, the system or transducer may malfunction.
6. After using the transducer, remove the gel on it and place it properly. Otherwise, water in the gel may enter the acoustic lens to adversely affect the performance and safety of the transducer.
7. If the system is used in a small room, the room temperature may rise. Proper ventilation must be provided.
8. The system must keep good elimination of heat. Do not cover radiation holes on the system.

9. Only engineers of our company or authorized by our company can replace the fuses.
10. Only perform operations described in this manual.
11. Do not modify system parameters. If it is necessary to change system parameters, contact our company's Customer Service Department or your local distributor.
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 precision may occur over a period of time. Check and maintain the system periodically. To ensure system performance, it is recommended to sign a maintenance and service contract to avoid accidents and misdiagnosis.
13. To dispose of the system or any part, contact our company's Customer Service Department or your local distributor first. Our company does not assume any responsibility for damage resulting from disposal of the system without consulting our company.
14. When using this system with portable package, be careful not to block the ventilation slots.
15. Do not use a USB memory device (e.g., a USB flash drive, removable hard disk) which has unsafe data. Otherwise system damage may result.

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 "A.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 specified ambient conditions.

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

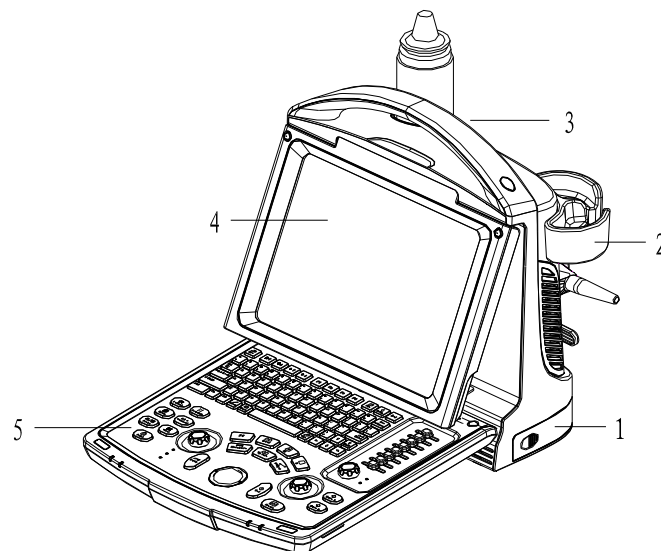
1

System Basics

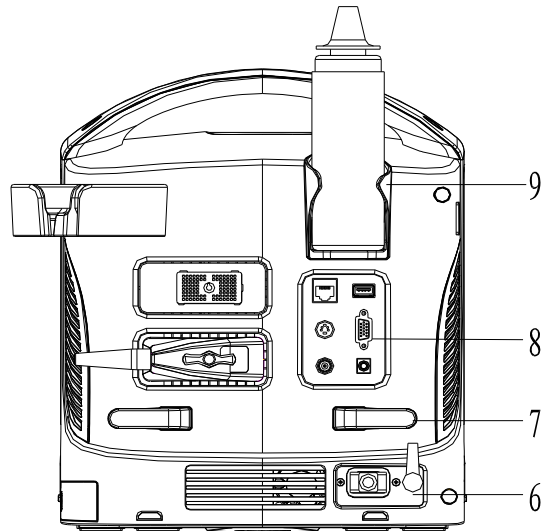
The system is intended for diagnosis of human liver, gallbladder, spleen, kidney, pancreas, bladder, ureter, uterus, uterine appendages, small parts and pregnant women in hospitals and clinics.

This chapter introduces the system structure, control panel, basic elements of software interface and general operations of the elements.

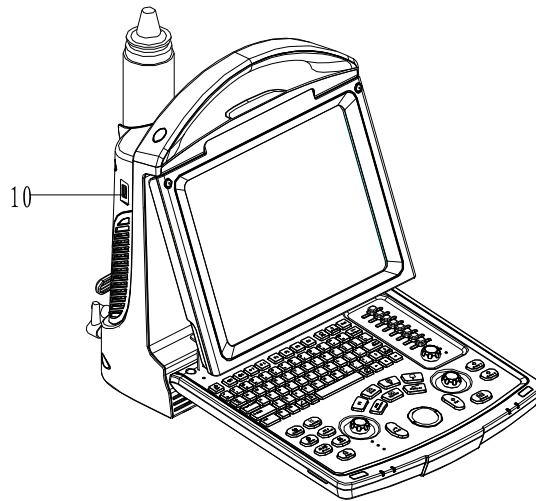
1.1 Structure



No.	Part	Description
1	Battery cover	/
2	Probe holder	Used to place probes temporarily
3	Handle	Used to lift the machine
4	LED monitor	Used to displays the image and parameters
5	Control Panel	Operate the system



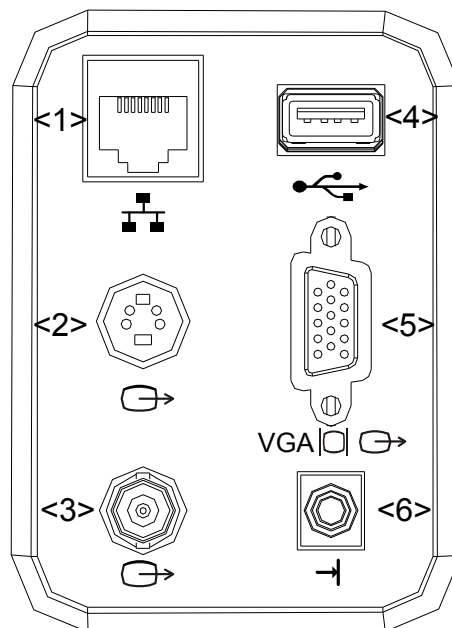
No.	Part	Description
6	Power supply panel	Panel of electrical interfaces
7	Winding rack	Used to wind the power cable.
8	I/O Panel	Refer to 1.2 I/O Panel
9	Gel holder	Used to place the ultrasound gel temporarily.



No.	Part	Description
10	USB port	Used to connect USB devices

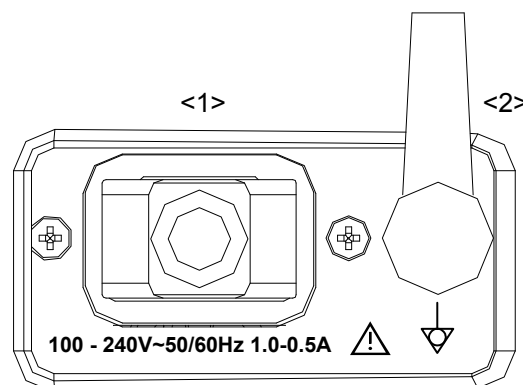
1.2 I/O Panel

The I/O panel locates at the back of the system.



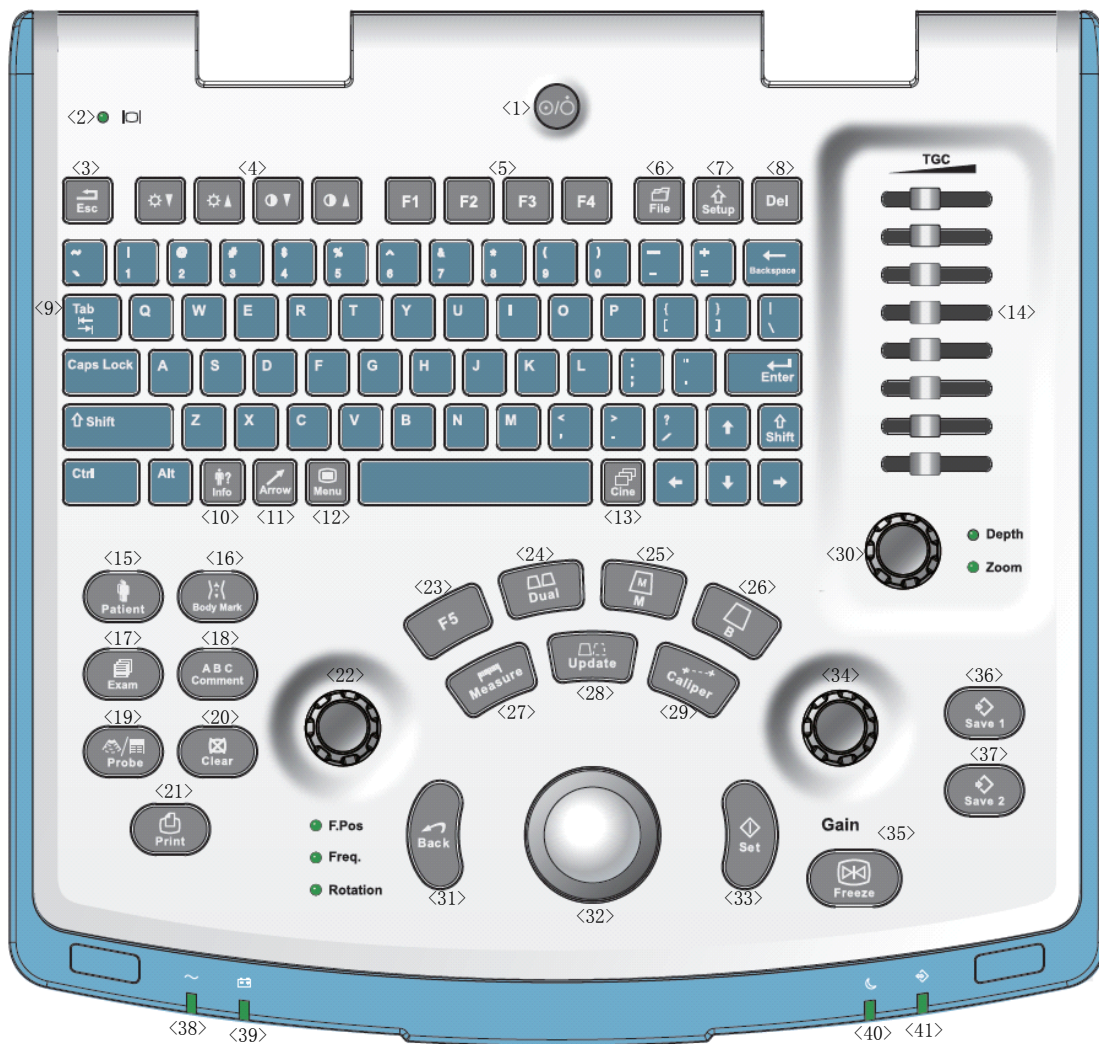
No.	Name	Function
1	Network port	To connect the network cable
2	S-Video output	Separate video output, connecting video printer or monitor
3	Video output (coaxial-cable)	Video output, connecting video printer or monitor
4	USB ports	Used to connect USB devices.
5	VGA output	VGA signal output
6	Video printing control	Connects the remote cable of the video printer.

1.3 Power Supply Panel



No.	Name	Function
1.	Power inlet	AC power inlet
2.	Equipotential terminal	Used for equipotential connection, that balances the protective earth potentials between the system and other electrical equipment.

1.4 Control Panel



No.	Name	Description	Function
1.	/	Power button	Power button Press to turn on/off the system
2.	/	Monitor status indicator	Green: working in normal status; Orange: no signal.
3.	Esc	Exit	Press to exit the current status to the previous status.

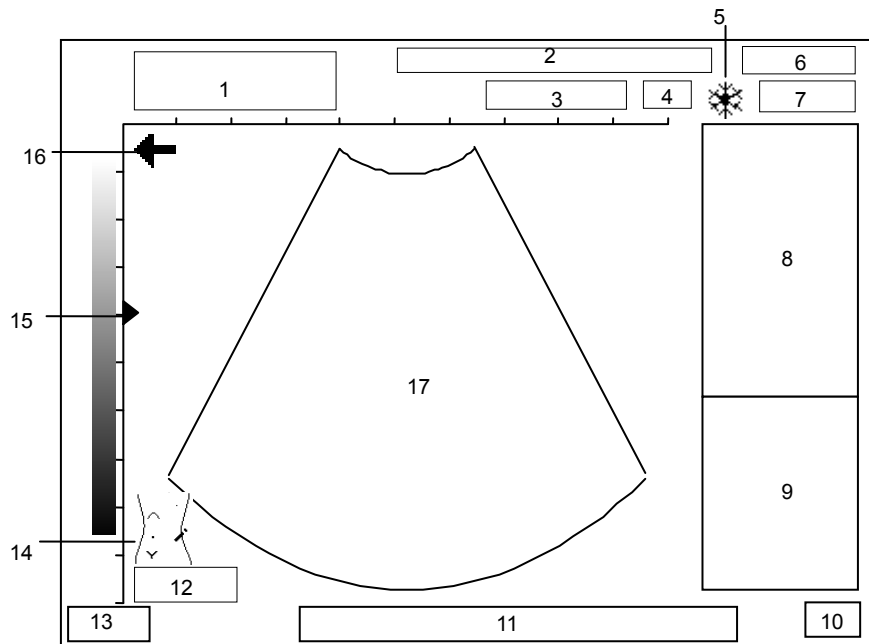
No.	Name	Description	Function
4.	/	Direction key	To adjust monitor brightness or contrast when pressing with <Fn> key.
5.	F1~F4	User-defined key	You can assign a function to the key.
6.	File	File	To enter/exit file system (iStation)
7.	Setup	Setting	To open/close the Setup menu.
8.	Del	/	Press to delete the comment, etc.
9.	/	Alphanumeric keys	Same as on PC
10.	Info	Patient Info	To open/ exit patient information screen.
11.	Arrow	Arrow	Press to enter or exit the arrow comment status.
12.	Menu	Main menu	Press to display or hide a mode-specific parameter menu.
13.	Cine	Cine Review	Press to enter/ exit the Cine Review status.
14.	TGC	/	TGC slider, to adjust the depth gain.
15.	Patient	End Exam	To end the current exam.
16.	Body Mark	Body Mark	To enter/ exit the Body Mark status.
17.	Exam	/	To select and start an exam.
18.	Comment	Comments	Press to enter/ exit the character comment status.
19.	Probe	Transducer switch	Press to switch Probe and Exam Type
20.	Clear	/	Press to clear the comments or measurement calipers on the screen.
21.	Print	/	Press to print: user-defined key.
22.	F.Pos Freq Rotation	Focus Position Frequency Rotation	Press: switch between F.Pos and Freq Rotate: adjust rotation angle
23.	F5	User-defined key	You can assign a function to the key.
24.	Dual	Dual-split screen	To enter Dual mode in Non-Dual mode; Switch between windows in Dual mode
25.	M	/	Press to enter the M mode.
26.	B	/	Press to enter the B mode
27.	Measure	/	Press to enter/Exit Measurement
28.	Update	/	Measurement status: press to switch between the fixed and active end of the caliper; Multi-imaging mode: press to change the currently active window.

No.	Name	Description	Function
29.	Caliper	/	Press to enter/exit Measurement
30.	Depth Zoom	/	Press: to switch between Depth and Zoom; Rotate: to adjust corresponding parameter
31.	Back	/	Press to decrease parameter value or undo last step during measurement
32.	/	Trackball	Roll the trackball to change the cursor position.
33.	Set	/	Used in selection.
34.	Gain	/	To adjust B or M gain
35.	Freeze	/	Press to freeze or unfreeze the image.
36.	Save 1	/	Press to save, user-defined key
37.	Save 2	/	Press to save, user-defined key
38.	/	Indicator 1	AC indicator AC supply: light green; Battery supply: light off.
39.	/	Indicator 2	Battery indicator The light is off since no battery is configured with the system
40.	/	Indicator 3	Reserved
41.	/	Indicator 4	Reserved

1.5 Interface Elements and Operations

1.5.1 Interface

The following figure takes the interface of abdomen exam in the B mode as the example to introduce the software interface.

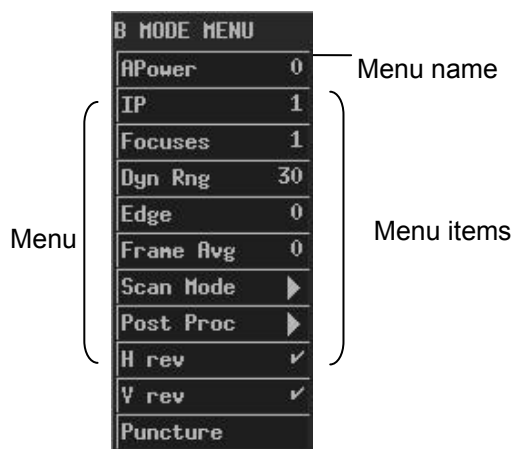


No.	Introduction
1	Hospital name, patient name and ID
2	Some of the current image parameters, including BG (B gain), MG (M gain), AP (acoustic power), IP (image process), FR (frame rate)
3	Transducer model
4	Current frequency of the transducer
5	Frozen symbol (when the image is frozen, the symbol appears)
6	Current date of the system (the date displayed on a frozen image is the date when the image is frozen)
7	Current time of the system (the time displayed on a frozen image is the time when the image is frozen)
8	Menu
9	Results of measurements and/or calculations
10	Input method
11	Help information of operation
12	Current image depth
13	Current exam mode
14	Body mark
15	Focus symbol

No.	Introduction
16	<p>The direction where the arrow indicates shows the initial scan position of the transducer (“←” means the first scan line from the left is the initial scan position of the transducer; “→” means the first scan line from the right is the initial scan position of the transducer).</p> <p>When scanning, ensure the transducer orientation corresponds to the arrow. See the operation manual of transducer for detail.</p>
17	Ultrasonic image

1.5.2 Menu

The following figure is an example of menu.

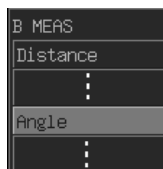


The menu items can be classified to the following types.

- Command menu items
- Number menu items
- Switch menu items
- Character menu items
- Submenu menu items

1.5.2.1 Command Menu Items

A command menu item makes the system to execute an action, such as popping up a dialog box or starting to measure.



To operate a command menu item, turn the trackball to move the cursor onto the menu item and then press <Set>.

1.5.2.2 Number Menu Items

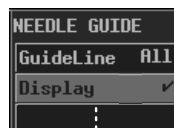
A number menu item adjusts the value of a parameter. The parameter name is on the left of the menu item and the value is on the right.



To operate a number menu item, turn the trackball to move the cursor onto the menu item and then press <Set> or <Back> once or more until the value you want appears (to increase the value, press <Set>; to decrease the value, press <Back>).

1.5.2.3 Switch Menu Items

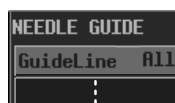
A switch menu item switches between the “on” and “off” status of a parameter. The parameter name is on the left of the menu item and the symbol of “√” or “x” is on the right (“√” represents “on” and “x” represents “off”).



To operate a switch menu item, turn the trackball to move the cursor onto the menu item and then press <Set> or <Back>.

1.5.2.4 Character Menu Items

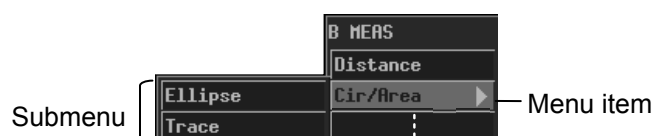
A character menu item adjusts the value of parameter. The parameter value is described in characters. The parameter name is on the left of the menu item and the value described in characters is on the right.



To operate a character menu item, turn the trackball to move the cursor onto the menu item and then press <Set> or <Back> once or more until the value you want appears.

1.5.2.5 Submenu Menu Items

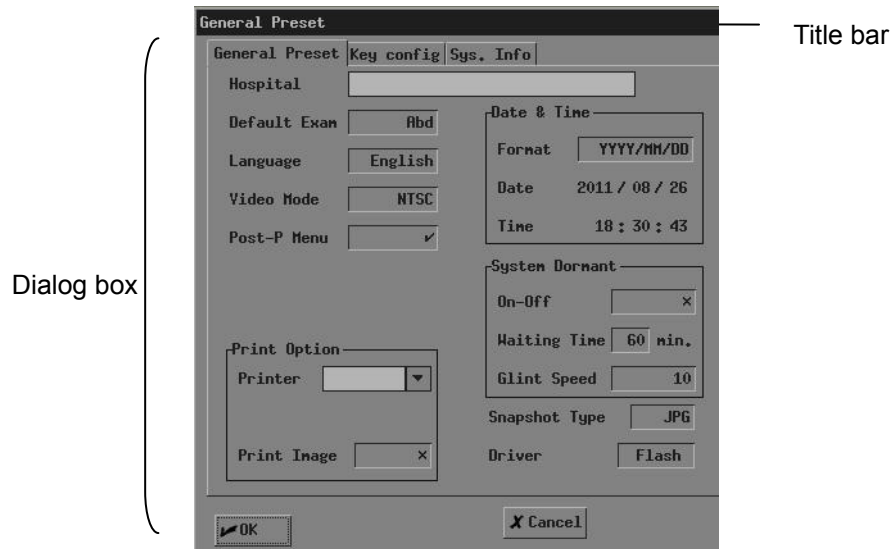
A submenu menu item opens a submenu.



To operate a submenu menu item, turn the trackball to move the cursor onto the menu item and its submenu pops up. Then, turn the trackball to move the cursor onto one item of the submenu and press <Set>.

1.5.3 Dialog Box

The following figure is an example of dialog box.



To move a dialog box,

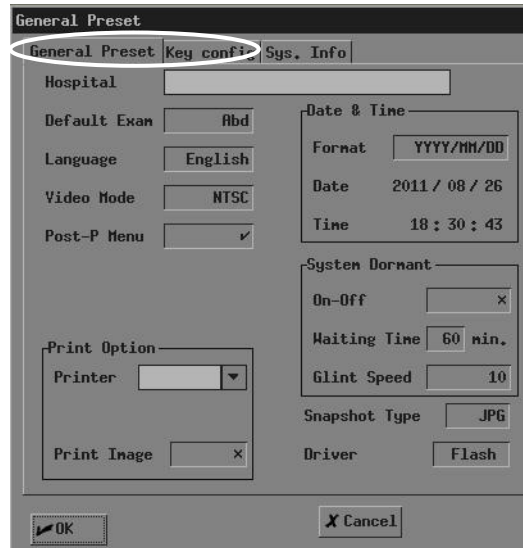
- 1 Turn the trackball to move the cursor onto the title bar. The cursor is displayed as a "⤴". Press <Set>.
- 2 Turn the trackball. A rectangle whose size is the same as that of the dialog box is moving with the trackball. Place the rectangle where you want the dialog box is moved to.
- 3 If you want to move the dialog box here, press <Set>; if you do not want to move the dialog box, press <Back>.

A dialog box may have the elements as follows.

- Page label

A page label marks a page when the contents of a dialog box are displayed in several pages.

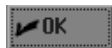
Page labels



To enter a page, turn the trackball to move the cursor onto the corresponding page label and then press <Set>.

- Button

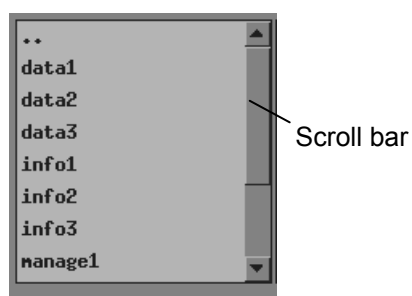
A button is used for some operation.





To click a button, turn the trackball to move the cursor onto the button and then press <Set>.

- Scroll bar

When not all of contents can be displayed in the current area, the scroll bar appears. Different contents can be displayed as the scroll bar is moving.




To drag the scroll bar, turn the trackball to move the cursor onto  or  and then press <Set> once or more until the content you want appears.

- Pull-down list

A pull-down list is used to select an option.



Pull-down list

To select an option from a pull-down list, turn the trackball to move the cursor onto the pull-down list or  and then press <Set> to pop up the options. Then turn the trackball to move the cursor onto the option you want and then press <Set>.

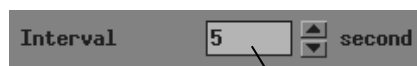
■ Edit box

You can enter characters into an edit box. There are two kinds of edit boxes.





Edit box

Turn the trackball to move the cursor onto the edit box shown above and the cursor is displayed as a "|". Then press <Set> and the cursor appears on the leftmost part of the edit box. After that, you can enter characters into the edit box.



Edit box

To enter characters into the edit box shown above, turn the trackball to move the cursor onto  or  and then press <Set> once or more until the value you want appears.

■ Combo box

A combo box is the combination of an edit box and a pull-down list. You can enter characters into it, as you do to an edit box; you can also select an option from it, as you do to a pull-down list.



Combo box

■ Selection box

A selection box is used to select an option.



Selection box

To select an option, turn the trackball to move the cursor onto the selection box and then press <Set> or <Back> once or more until the option you want appears.

■ List

A list displays multiple contents in a line.

Name	Type	Modify Time
26173846	BMP	2006-07-26 17:39
27090407	CIN	2007-07-27 09:04

To select an item in a list, turn the trackball to move the cursor onto the item you want and then press <Set>.

2 System Connection

This chapter introduces how to connect the power supply, equipotential terminal, transducers and peripherals to the system.

NOTE:	Before connecting the system, put the system in a proper place and ensure at least 20cm of clearance at the back and sides of the system. The transportation, storage and operating environments of the system must meet requirements listed in the appendix. Besides, store and use the system in a clean location where there is no direct sunlight, no sudden changes in temperature, no condensation, few dust, no vibration, and far from heat generators.
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2.1 Connecting Power Supply

Connect the power plug of the system to an outlet meeting the following requirements:

Voltage: 100-240V~

Frequency: 50/60Hz

Input current: 1.0-0.5A



WARNING:

1. Do not connect the system to outlets with the same circuit breakers and fuses that control current to devices such as life-support systems. If the 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.
2. 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.
3. Use the power input cord as the power breaking facility of the system.

2.2 Connecting Equipotential Terminal

When the system is connected with other equipments such as printers, be sure to connect the equipotential terminal of the system and those of other equipments with lead wire.

⚠ WARNING: When the system is connected with other equipments, be sure to connect their equipotential terminals before inserting any of their power plugs into a receptacle, and also, be sure to remove the power plugs from receptacles before disconnecting the equipotential terminals.

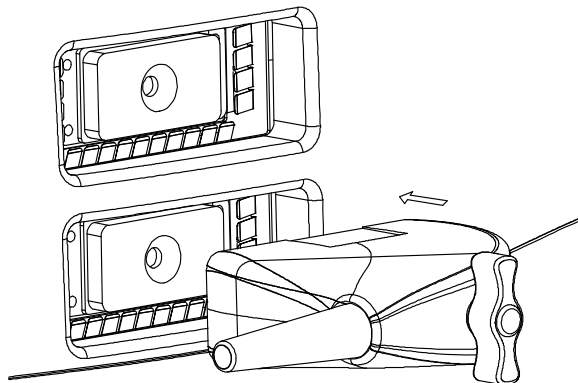
2.3 Connecting Transducer

⚠ WARNING: Use only transducers specified in this manual. Otherwise, the system and transducer may be damaged or an accident such as a fire may occur.

Ensure the transducer and its connector and cable are intact before connecting it to the system. Using defective transducers may cause electric shock.

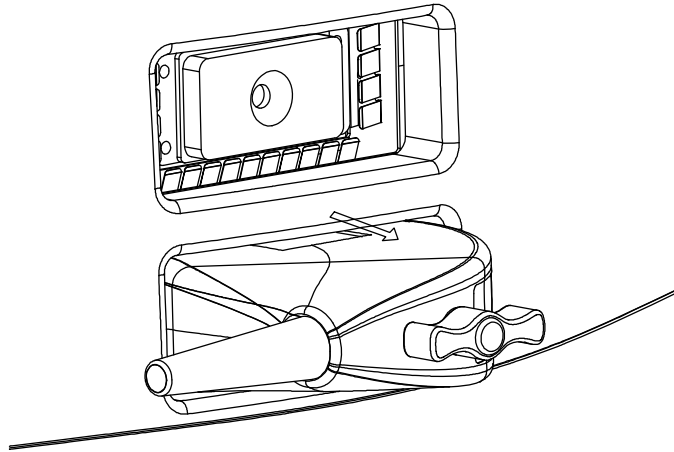
NOTE: Before connecting or disconnecting a transducer, be sure to turn off the system or stop emitting (freeze the image). Otherwise, the system or transducer may be damaged.

To connect a transducer



- 1 Turn off the system or freeze the image.
- 2 Put the lock handle to the position shown in the figure below.
- 3 Plug the transducer connector into the transducer socket on the system.
- 4 Turn the lock handle 90° clockwise.

To disconnect a transducer



- 1 Turn off the system or freeze the image.
- 2 Turn the lock handle 90° counterclockwise.
- 3 Remove the transducer connector from the transducer socket on the system.


2.4 Connecting a Footswitch

Plug the connector of the footswitch to the socket with the bulge of the footswitch connector aligning with the groove of the socket.

2.5 Connecting Peripherals

Only the system supporting the USB port can connect the USB storage device and graph/text printer.


To connect a USB storage device

- 1 Plug the USB connector of a storage device into the USB port on the rear of the system.
- 2 As the USB storage device is connected to the system, “” appears on the lower right corner of the screen.

To disconnect a USB storage device

- 1 Move the cursor onto “” and press <Set>. The following dialog box pops up.



- 2 Click [OK].
- 3 After “” disappears, remove the USB connector from the USB port.

NOTE:	If you remove the USB connector from the USB port directly without performing the steps above, the USB storage device and the system may be damaged.
--------------	--

To connect a video printer

- 1 Turn off the system and the printer.
- 2 Use the data cable of printer to connect the "VIDEO IN" port on the printer and the video output port on the system.
- 3 Use the power cord of printer to connect the power input port on the printer and the receptacle.

To connect a graph/text printer

- 1 Turn off the system and the printer.
- 2 Use the USB data cable of printer to connect the USB ports on the printer and on the system.
- 3 Use the power cord of printer to connect the power input port on the printer and the receptacle.

3


Startup/Shutdown

This chapter introduces procedures of startup and shutdown of the system.

3.1 Startup

- 1 Before the startup, complete the following checks:
 - The ambient temperature, humidity and atmospheric pressure meet requirements listed in the appendix.
 - The system is placed in a clean location where there is no direct sunlight, no sudden changes in temperature, no condensation, few dust, no vibration, and far from heat generators. Ensure at least 20cm of clearance at the back and sides of the system.
 - The system and peripherals have no deformation, damage or dirt. If necessary, clean the system (see the “System Maintenance” chapter for details).
 - There are no obstacles in the area where the system can be moved and near the radiator holes of the system.
 - All power cables and connection cables are intact.
 - The transducer(s) has(have) been cleaned and disinfected (see transducers’ manuals for details).
 - The transducer(s), connector(s) and cable(s) are intact.
 - The transducer(s) is(are) connected to the system.
 - Peripherals to be used are connected to the system.
 - All connections are secure.
- 2 Ensure the power plug of the system is connected to an outlet meeting requirements.
 - For peripherals to be used, ensure their power plugs are connected to receptacles meeting requirements.
- 3 Turn on the system. For peripherals to be used, turn them on.

- 4 After the startup, check the system as follows.

 **WARNING:** If you find any abnormality, turn off the system and refer to “13.3 Troubleshooting” to see if the section lists any solution for the problem. If not, contact our company’s Customer Service Department or your local distributor.

Check whether the startup is normal.

Check whether the system has any abnormal noise or smell or is overheated.

Check by hand whether the surface of transducer is overheated.


 **WARNING:** Using overheated transducers may burn patients.

Check whether the keys and trackball on the control panel can work properly.

Check whether the image is normal.

Check whether any error information appears.

Check whether the system date and time are the same as current ones and whether they are displayed correctly. If not, modify the system date and time (see the “Preset” chapter in the Advanced Volume for details).

 **CAUTION:** If the system date and time are not the same as current ones, misdiagnosis may occur.

3.2 Shutdown

- 1 Put the transducer(s) on the transducer holder.
- 2 Turn off peripherals connected to the system.
- 3 Turn off the system.
- 4 If the system is not to be used for a period of time, remove power plugs of the system and peripherals from receptacles.
- 5 Clean and disinfect the transducer(s) (see the transducers’ manuals for details) and keep the transducer(s).

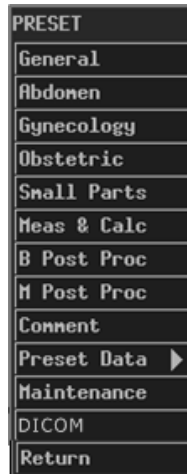
NOTE: The system can be turned on again at least 10 seconds after it is turned off.

4 Preset

This chapter briefly describes how to preset the system. Refer to the Advanced Volume for details.

The preset function is used to set the operating status, configuration parameters of each exam mode, post process and others. The system runs automatically with the preset parameters after each startup. Before examining patients, ensure proper parameters have been preset.

- 1 Press <Setup> and then the [PRESET] menu pops up.



- 2 Preset parameters.
- 3 After all preset is completed, press <Esc> or select [Return] in the [PRESET] menu to close the [PRESET] menu. The system runs with the modified preset data.

Note that the modified preset data takes effect only after the preset status exits using the above method.

5

Beginning Exam

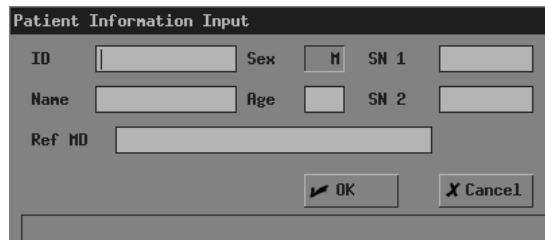
This chapter describes the general procedure before scanning a patient.

CAUTION: Before examining a patient, press <Patient> to update the patient information. Otherwise, the patient information does not correspond to the patient data and misdiagnosis may occur.

5.1 Inputting Patient Information

CAUTION: Although you can scan a patient without inputting the patient information, it is recommended to input patient information before scanning the patient to avoid misdiagnosis. The system identifies a patient via the ID. Input correct IDs to avoid misdiagnosis.

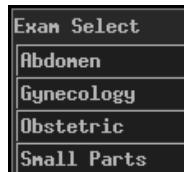
- 1 Press <Patient>, or move the cursor onto the “Name” or “ID” on the screen and then press <Set>. The [Patient Information Input] dialog box pops up.



- 2 Input patient information in the [Patient Information Input] dialog box.
In the dialog box,
ID: It must be input. You can enter letters, numbers (0-9) and “-“ and cannot exceed 12 characters.
Name: You can enter 12 characters at most. “?” and “*” are forbidden.
Age: The range is 0-150.
SN1/SN2: You can enter 8 characters at most in each edit box.
Ref MD: Enter the diagnostic conclusion independent of ultrasonic exam. You can enter 32 characters at most.
- 3 If you want to save the input information, click [OK]; if you want to save nothing, click [Cancel] or press <Patient> or press <Esc>.

5.2 Selecting Exam Mode

If the system is not in the exam mode you want, press <EXAM> to enter the [Exam Select] menu and then select the exam mode.



The system supports the following exam modes:

- Abdomen
- Gynecology
- Obstetric
- Small parts

5.3 Selecting Transducer

For the system connecting two transducers, if the current transducer is not the one you want, press <Probe> to switch to the other transducer.

5.4 Selecting Image Mode

If the current image mode is not the one you want, press , <M>, <B/B> or <M/B> to select the image mode.

The system supports the following image modes:

- B
- M
- B/B
- M/B

5.5 Adjusting M-mark Position

As entering the M/B mode, you can turn the trackball leftward or rightward to adjust the position of M-mark.

To adjust the position of M-mark again, follow the steps below.

- 1 Enter the [M MODE MENU] menu (if no menu is displayed, press <Menu>).
- 2 In the [M MODE MENU] menu, select [M-Mark].
- 3 Turn the trackball leftward or rightward to adjust the position of M-mark.

6

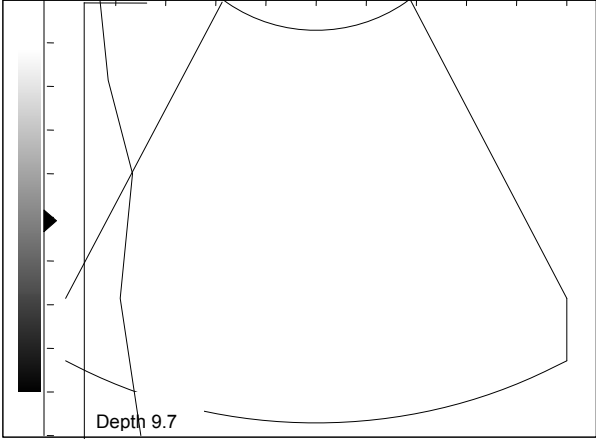
Image Control and Adjustment

This chapter describes how to control and adjust the image.

6.1 Adjusting Image Parameters

To obtain a better image, it is recommended to rotate the brightness knob and contrast knob to make the marks on them in the top position.

Parameter	Description
B/M gain	<p>Adjusting the B/M gain is to adjust the gain of receiving system and the signal sensitivity of B and M images.</p> <p>The B gain (BG) and M gain (MG) are displayed on the upper part of the screen.</p> <p>You can only adjust the parameter on real-time images.</p> <ul style="list-style-type: none">■ To adjust the parameter, turn the gain knob. The B gain and M gain are adjusted simultaneously. The range is 0dB-98dB. <p>It is recommended to adjust the B/M gain to 48dB. When B/M gain is 48dB, you can obtain a better image.</p>
Acoustic power	<p>The acoustic power is the emitting power of the transducer. You should select proper acoustic power according to the actual condition and the principle of acoustic power.</p> <p>You can only adjust the parameter on real-time images.</p> <ul style="list-style-type: none">■ To adjust the parameter, enter the [B MODE MENU] menu and then set [Power] in the menu. The range is 0-7 (0 represents the minimal acoustic power and 7 represents the maximal).
Transducer frequency	<p>You can only adjust the parameter on real-time images.</p> <ul style="list-style-type: none">■ Focus position (F.Pos.), frequency (Freq.) and Rotation share the same <Multifunctional Knob> (left). Press the knob to switch among the items and rotate the knob to adjust the item when the corresponding indicator is lit up. <p>Press the <Multifunctional Knob (L)> until the indicator corresponding to "Freq." is lit up, and then rotate the knob to adjust the frequency.</p>

Parameter	Description
TGC	<p>TGC (time gain control) means using the gain compensation curve separated to several segments by depth to optimize the image. Four groups of TGC keys adjusts the current image by segments.</p> <p>The TGC curve appears on the left of screen when it is being adjusted and changes as a TGC key is pressed, which is shown in the figure below. After the adjustment stops, the TGC curve will disappear automatically.</p> <p>You can only adjust the parameter on real-time images.</p>  <ul style="list-style-type: none"> ■ To adjust the parameter with the TGC sliders on the control panel.
Number of focuses	<p>The B image has 1-4 focuses. The number of focuses also lies on the depth. The M image has only one focus.</p> <p>You can only adjust the parameter on real-time B images.</p> <ul style="list-style-type: none"> ■ To adjust the parameter, enter the [B MODE MENU] menu and then set [Focuses] in the menu.
Focus position	<p>When the focus position is adjusted, one or more focuses moves on the current image simultaneously.</p> <p>You can only adjust the parameter on real-time images.</p> <ul style="list-style-type: none"> ■ To adjust the parameter, press <F.position>.
Depth	<p>You can only adjust the parameter on real-time images.</p> <ul style="list-style-type: none"> ■ Use <Zoom/Depth> knob to adjust the parameter.
Dynamic range	<p>The dynamic range adjusts the contrast resolution of B or M images and compress or expand their display range of gray scale.</p> <p>You can only adjust the parameter on real-time images.</p> <ul style="list-style-type: none"> ■ To adjust the parameter of B image, enter the [B MODE MENU] menu and then set [Dyn Rng] in the menu; to adjust the parameter of M image, enter the [M MODE MENU] menu and then set [Dyn Rng] in the menu. The range is 30dB-90dB and the increment is 4dB.

Parameter	Description
Edge enhancement	<p>The edge enhancement increases image profile to distinguish image boundary.</p> <p>You can only adjust the parameter on real-time images.</p> <ul style="list-style-type: none"> ■ To adjust the parameter of B image, enter the [B MODE MENU] menu and then set [Edge] in the menu; to adjust the parameter of M image, enter the [M MODE MENU] menu and then set [Edge] in the menu. The range is 0-4 (0 represents no edge enhancement and 4 represents the maximal edge enhancement).
Frame average	<p>The frame average superimposes and averages adjacent B images to remove image noise and make image details clearer.</p> <p>You can only adjust the parameter on real-time B images.</p> <ul style="list-style-type: none"> ■ To adjust the parameter, enter the [B MODE MENU] menu and then set [Frame Avg] in the menu. The range is 0-7 (0 represents no frame average, and n (n=1-7) represents superimposing and averaging the adjacent (n+1) frames).
Scan mode	<p>The scan mode adjusts the density of scan lines of B images.</p> <p>You can only adjust the parameter on real-time B images.</p> <ul style="list-style-type: none"> ■ To adjust the parameter, enter the [B MODE MENU] menu and then switch between [Hi Frm Rate] and [Hi Density] in [Scan Mode] (Images of high density have better quality and those of high frame rate have higher frame rate).
M speed	<p>The M speed adjusts the refresh speed of M images.</p> <p>You can only adjust the parameter on real-time M images.</p> <ul style="list-style-type: none"> ■ To adjust the parameter, enter the [M MODE MENU] menu and then set [M Speed] in the menu. The range is 1-4 (1 represents the slowest scan speed and 4 represents the fastest).
M soften	<p>The M soften superimposes and averages scan lines of M images to remove image noise and make image details clearer.</p> <p>You can only adjust the parameter on real-time M images.</p> <ul style="list-style-type: none"> ■ To adjust the parameter, enter the [M MODE MENU] menu and then set [M Soften] in the menu. The range is 0-3 (0 represents no M soften and n (n=1-3) represents superimposing and averaging the successive (n+1) scan lines).
Post process	<p>The post process applies the gray correction to images to obtain images with optimum map.</p> <p>You can select a map from the eight maps, or adjust gray transform curve, gray rejection curve and γ correction.</p> <p>You can adjust the post process effect on real-time, frozen and cine images, on opened FRM, CIN files, and on their zoomed images.</p> <ul style="list-style-type: none"> ■ To adjust the parameter, see the following contents below this table for details. If [Post-P Menu] in the [General Preset] dialog box is set to "off" (see the "Preset" chapter in the Advance Volume for details), the gray transform, gray rejection and γ correction cannot be performed.

Parameter	Description
IP	<p>IP is an image process effect, which is a group of image process parameters including the dynamic range, edge enhancement and frame average.</p> <p>You can preset IP in the [PRESET] menu (see the “Preset” chapter in the Advance Volume for details).</p> <p>You can only adjust the parameter on real-time images.</p>
H rev	<p>In B, B/B or M/B mode, the real-time image, frozen image, cine review image, FRM file, CIN file and zoomed image can be reverted horizontally.</p> <ul style="list-style-type: none"> ■ Press [Menu] and select [H rev] to revert the image.
V rev	<p>In B, B/B or M/B mode, the real-time image, frozen image, cine review image, FRM file, CIN file and zoomed image can be reverted vertically.</p> <ul style="list-style-type: none"> ■ Press [Menu] and select [H rev] to revert the image.

Note that if [Post-P Menu] in the [General Preset] dialog box is set to “off” (see the “Preset” chapter in the Advance Volume for details), the corresponding “post process” items in the [B MODE MENU], [M MODE MENU] and [FREEZE MENU] are not displayed and the gray transform, gray rejection and γ correction cannot be performed.

Gray map

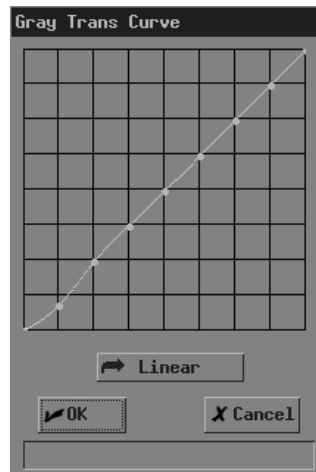
There are eight gray maps, from Map1 to Map8. Each map is a post process effect, which is a group of gray transform curve, gray rejection curve and γ correction. Gray maps can be preset in the [B Post Process Preset] dialog box (see the “Preset” chapter in the Advance Volume for details).

- To adjust the gray map,
 - 1 For real-time B images, enter the [B MODE MENU] menu.
For real-time M images, enter the [M MODE MENU] menu.
For frozen or cine images, or opened FRM/CIN files, enter the [FREEZE MENU] menu.
 - 2 Set [Gray Map] in [Post Proc] or [B Post Proc] or [M Post Proc] (if [Post-P Menu] in the [General Preset] dialog box is set to “on”).
Or, set [Gray Map] (if [Post-P Menu] in the [General Preset] dialog box is set to “off”).

Gray transform

- To adjust the gray transform curve,

- 1 For real-time B images, enter the [B MODE MENU] menu.
For real-time M images, enter the [M MODE MENU] menu.
For frozen or cine images, or opened FRM/CIN files, enter the [FREEZE MENU] menu.
- 2 Select [Curve] in [Post Proc] or [B Post Proc] or [M Post Proc]. The [Gray Trans Curve] dialog box pops up.



During the adjustment, if necessary, you can click [Linear] in the dialog box to set the curve to a 45° straight line.

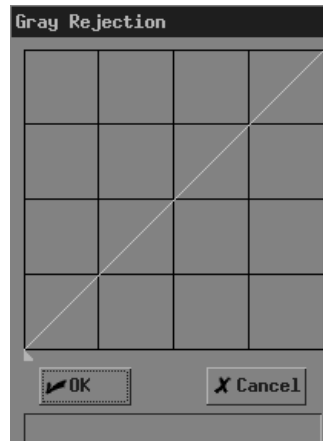
- 3 Move the cursor to the node “•” you want on the gray scale curve and the cursor changes to “⤴” . Press <Set>.
- 4 Move the trackball and “•” moves with it. Move “•” to the position you want.
- 5 If you want to place “•” in the current position, press <Set>; if you want to cancel the operation to “•” and restore it to its original position, click <Back>.
- 6 If you want to move another node, return to the step 3.
- 7 If you want to save the setting, click [OK]; if you want to abandon the setting and restore the curve to the shape before adjustment, click [Cancel] or press <Esc>.

Gray rejection

The gray rejection rejects image signals lower than some gray scale.

- To adjust the gray rejection curve,
 - 1 For real-time B images, enter the [B MODE MENU] menu.
For real-time M images, enter the [M MODE MENU] menu.
For frozen or cine images, or opened FRM/CIN files, enter the [FREEZE MENU] menu.

- 2 Select [Rejection] in [Post Proc] or [B Post Proc] or [M Post Proc]. The [Gray Rejection] dialog box pops up.



- 3 Move the cursor to “▲” and the cursor changes to “↕”. Press <Set>.
- 4 Move the trackball and “▲” moves with it. Move “▲” to the position you want.
- 5 If you want to place “▲” in the current position, press <Set>; if you want to cancel the operations to “▲” and restore it to its original position, press <Back>.
- 6 If you want to save the setting, click [OK]; if you want to abandon the setting and restore the curve to the shape before adjustment, click [Cancel] or press <Esc>.

γ correction

The γ correction corrects non-linear distortion of images.

The γ correction parameter can be 0, 1, 2 or 3, respectively representing the γ coefficient is 1, 1.1, 1.2 or 1.3.

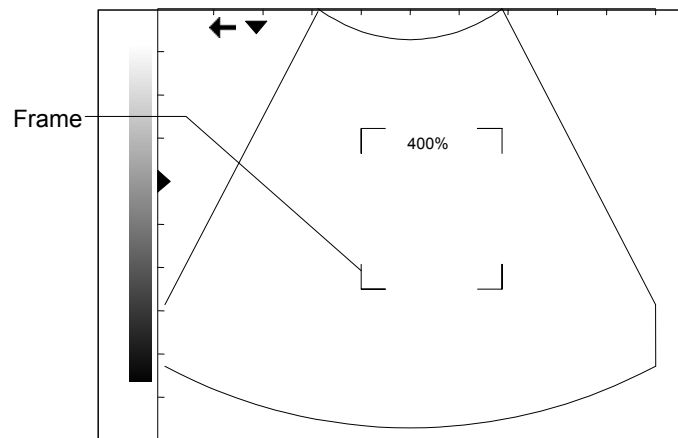
- To adjust the γ correction parameter,
 - 1 For real-time B images, enter the [B MODE MENU] menu.
For real-time M images, enter the [M MODE MENU] menu.
For frozen or cine images, or opened FRM/CIN files, enter the [FREEZE MENU] menu.
 - 2 Set [γ] in [Post Proc] or [B Post Proc] or [M Post Proc].

6.2 Image Zoom

B images (including real-time, frozen and cine images, and opened FRM/CIN files) can be zoomed. The percentage of area zoom is 100%-400%.

- 1 In the B, B/B or M/B mode, press <Zoom/Depth> knob to light the Zoom indicator, and a frame appears on the center of image.

Note that in the B/B mode, only the active window can be zoomed.



- 2 Move the trackball to move the frame to select the zoom center.
- 3 Rotate <Zoom/Depth> to change the size of frame. The zoom percentage changes with it.
- 4 Press <Set> and the frame disappears. The zoomed image is displayed.
- 5 You can move the trackball to move the zoomed image.
- 6 Rotate <Zoom/Depth> to change the zoom percentage of image.
- 7 Press <Set> to fix the center of zoomed image. The cursor appears.
- 8 Rotate <Zoom/Depth> to change the zoom percentage of image.
- 9 Press <Zoom/Depth> or <Esc>. The indicator lights off, the zoom status exits and normal image is displayed.

6.3 Image Reverse

B images (including real-time, frozen, cine images, opened FRM files and zoomed images) can be reversed horizontally or vertically.

In the B, B/B or M/B mode, press [Menu] to display the image menu, and select [V.Rev] or <H.Rev> to reverse the image vertically or horizontally.

7

Cine

This chapter introduces the cine and its operation method.



CAUTION:

Before examining a patient, press <Patient> to update the patient information and clear the cine memory. Otherwise, the patient information does not correspond to the patient data and misdiagnosis may occur.

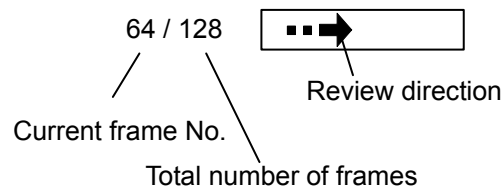
The system supports only the cine of B images.

Real-time images (including zoomed images) are automatically stored into the cine memory by the system. They are stored frame by frame and in the sequence of time. After the image is frozen, images prior to the frozen one can be reviewed. This function is called cine.

The cine must be performed in frozen status. Turning off the system, unfreezing the image or pressing <Patient> will clear the cine memory.

7.1 Cine Indicator

In the cine, the cine indicator shown in the figure below is displayed on the bottom of screen. In it, the numbers are the current frame No. and the total number of frames in the cine memory, and the arrow indicates the review direction.



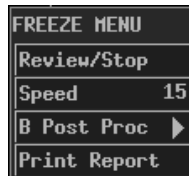
7.2 Manual Cine and Auto Cine

The cine includes the manual cine and auto cine. The manual cine is the default.

General procedure of cine

- 1 In the B, B/B or M/B mode, press <Freeze> to enter the manual cine. The [FREEZE MENU] menu is displayed (if no menu is displayed, press <Menu>).

Note that in the B/B mode, only the window that is active when <Freeze> is pressed has the cine.



- 2 If you want to perform the auto cine, press <Cine> or <Esc> to exit the manual cine.
Note:
 - (1) You can operate the [FREEZE MENU] menu only after exiting the manual cine.
 - (2) To enter the manual cine again, press <Cine>. Pressing <Cine> can switch between entering and exiting the manual cine.
- 3 Perform the manual cine or auto cine. See the following contents for details.
- 4 You can perform post process, measurements, comments and body mark on a cine image.
- 5 After all the operation is completed, press <Freeze> to unfreeze the image.

■ Procedure of manual cine

- 1 Enter the manual cine.
- 2 Turn the trackball leftward or rightward and the images are displayed one by one (turning the trackball leftward can display the images in the ascending sequence of frame No.; turning the trackball rightward can display the images in the descending sequence of frame No.).


■ Procedure of auto cine


- 1 Exit the manual cine.
- 2 If you want to set speed for the auto cine, set [Speed] in the [FREEZE MENU] menu.
- 3 Click [Review/Stop] in the [FREEZE MENU] menu to begin the auto cine.
During the auto cine, you can modify [Speed] in the [FREEZE MENU] menu.
- 4 Click [Review/Stop] in the [FREEZE MENU] menu to stop the auto cine.

8

Measurements

This chapter briefly introduces measurements on B and M images. Refer to the Advanced Volume for details.

 **WARNING:** Ensure proper measurement targets and images and measurements are performed in valid image area. Incorrect measurement results may cause misdiagnosis.

 **CAUTION:** For a measurement in frozen status, unfreezing the image will clear measurement calipers and general measurement data. During a measurement, switching to another measurement menu from [Others] or to another exam mode will clear measurement calipers and general measurement data. Shutting down the system or pressing <Patient> will delete all images not saved and all patient data and measurement data on the screen.

8.1 Measurement Menu

For B images, measurement menus are:

[B MEAS]: general measurements on B images.

[B-OB MEAS]: calculates GA and EDD and evaluates fetal growth on B images.

[B-OB TWIN MEAS]: calculates GA and EDD and evaluates fetal growth for twins on B images.

[B-GYN MEAS]: measures parameters for such as uterine, endometrium, ovary and follicle on B images.

[B-ORTH MEAS]: measures HIP on B images.

For M images, measurement menu is:

[M MEAS]: general measurements on M images.

8.2 General Procedure of Measurements

Measurements can be performed on real-time, frozen, cine images, on opened FRM/CIN files, and on their zoomed images.

- 1 Press <Measure> to enter the measurement status. The corresponding measurement menu will be displayed (if no menu is displayed, press <Menu>).
- 2 Select items to perform measurements and calculations.
- 3 To switch to another measurement menu, you can
Press <EXAM> to select the exam mode you want; for the system connecting two transducers, select the proper transducer; then press <Measure>.
Or, select the measurement you want in [Others] of the current measurement menu.
- 4 After all measurements are completed, you can exit the measurement status by
Pressing <Measure> or <Esc>.
Or, directly pressing another key such as <Comment>, <BodyMark> or <File>.

9

Comment

This chapter introduces how to add, modify and delete comments.



WARNING:

Be sure to add correct comments. Otherwise, misdiagnosis may occur.

9.1 Entering Comment Status

Press <Comment> to enter the comment status. The cursor is displayed as a "|".

9.2 Adding Comments

You can add comments on real-time, frozen and cine images, on opened FRM/CIN files, and on their zoomed images.

You can add comments in any image mode.

Comments can be input from the keyboard and the comment library, and arrows can also be added in.

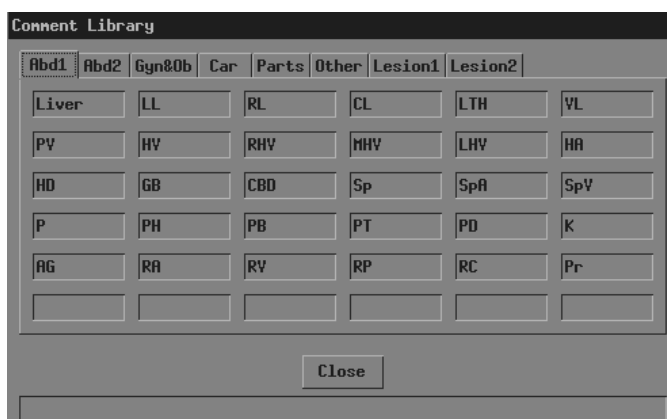
To add a comment from the keyboard

- 1 Enter the comment status.
- 2 Turn the trackball or press <→>, <←>, <↑> or <↓> to move the cursor where you want the comment to be located.
- 3 Input a comment from the keyboard.
- 4 If you want to adopt the comment, press <Set>;
If you want to adopt the comment and put the cursor to the next line, press <ENTER>.

To add a comment from the comment library

- 1 Enter the comment status.
- 2 Turn the trackball or press <→>, <←>, <↑> or <↓> to move the cursor where you want the comment to be located.

- 3 Press <Update>. The [Comment Library] dialog box pops up and the page corresponding to the current exam mode is displayed.



- 4 If none of the comments in the [Comment Library] dialog box is what you need, click [Close] or press <Update> or press <Esc> to close the [Comment Library] dialog box. The operation is over.

If none of the comments in the current page is what you need, enter other pages to find it. Then go to the next step.

- 5 Move the cursor onto the comment you want and then press <Set>. The comment appears on the screen.

You can edit the comment (add characters, delete characters, etc.) or return to the step 3 to add another comment from the library.

- 6 If you want to adopt the comment, press <Set>;
If you want to adopt the comment and put the cursor to the next line, press <ENTER>.


To add an arrow

Arrows can be added to an image to mark what should be emphasized.


- 1 Enter the comment status.
- 2 Turn the trackball or press <→>, <←>, <↑> or <↓> to move the cursor where you want the comment to be located.
- 3 Press <Set> to add an arrow. The arrow has a frame, which means the arrow can be moved, its orientation can be adjusted and so on.
- 4 If you want to move the arrow, turn the trackball.
If you want to adjust the orientation of arrow, press <→>, <←>, <↑> or <↓> (pressing <→> or <↓> can rotate the arrow clockwise; pressing <←> or <↑> can rotate the arrow counterclockwise).
- 5 If you want to adopt the arrow, press <Set>;
If you want to cancel the arrow, press <Back>.

9.3 Moving Comments

To move a comment (excluding arrow)


- 1 Enter the comment status.
- 2 Move the cursor onto the comment to be moved. The cursor changes to “”.
- 3 Press <Set>. The selected comment has a gray background.
- 4 Turn the trackball and a frame whose size is the same as that of the comment moves with it. Move the frame where you want to locate the comment.
- 5 If you want to locate the comment to the new position, press <Set>;
If you do not want to move the comment, press <Back>.

To move an arrow


- 1 Enter the comment status.
- 2 Move the cursor onto the arrow to be moved. The cursor changes to “”.
- 3 Press <Set>. The selected arrow has a frame.
- 4 Turn the trackball to move the arrow where you want.
- 5 Press <Set>.

9.4 Editing Comments

To edit a comment (excluding arrow)

- 1 Enter the comment status.
- 2 Move the cursor onto the comment to be edited. The cursor changes to “”.
- 3 Press <Set>. The selected comment has a gray background.
- 4 Press <Set> again. The comment has a white background and can be edited.
- 5 Press <→> or <←> to move the cursor where you want. Then input new comment from the keyboard or comment library, or delete the characters on the right of the cursor.
- 6 If you want to adopt the new comment, press <Set>;
If you want to adopt the new comment and put the cursor to the next line, press <ENTER>.

To change the orientation of an arrow

- 1 Enter the comment status.
- 2 Move the cursor onto the arrow to be modified. The cursor changes to “”.
- 3 Press <Set>. The selected arrow has a frame.
- 4 Press <→>, <←>, <↑> or <↓> to adjust the orientation of arrow (pressing <→> or <↓> can rotate the arrow clockwise; pressing <←> or <↑> can rotate the arrow counterclockwise).
- 5 Press <Set>.

9.5 Deleting Comments

9.5.1 Deleting All Comments

First method to delete all comment (including arrows)

Press <Clear> to clear all comments (including arrows), body mark, measurement calipers and general measurement data on the screen.

Second method to delete all comments (including arrows)


- 1 Enter the comment status.
- 2 If no comments (including arrows) are being edited or selected, press to clear all comments (including arrows) on the screen.

9.5.2 Deleting One Comment


To delete the latest comment (including arrow)

- 1 Enter the comment status.
- 2 If no comments (including arrows) are being edited or selected, press <Back> to delete the latest comment (including arrow).

To delete the select comment (excluding arrow)

- 1 Enter the comment status.
- 2 Move the cursor onto the comment to be deleted. The cursor changes to “”.
- 3 Press <Set>. The selected comment has a gray background.
- 4 If you want to delete the selected comment, press ;
If you do not want to delete the selected comment, press <Back>.

To delete the selected arrow

- 1 Enter the comment status.
- 2 Move the cursor onto the arrow to be deleted. The cursor changes to “”.
- 3 Press <Set>. The selected arrow has a frame.
- 4 If you want to delete the selected arrow, press or <Back>;
If you do not want to delete the selected arrow, press <Set>.

9.6 Exiting Comment Status


After all operations of comment are completed, you can exit the comment status by

Pressing <Comment> or <Esc>.

Or, directly pressing another key such as <Measure>, <BodyMark> or <File>.

10 Body Mark

This chapter introduces how to add, move and clear the body mark.

 **WARNING:** Be sure to add correct body mark. Otherwise, misdiagnosis may occur.

The body mark indicates the body position on which the scan is performed and the transducer orientation to interpret the image.

10.1 Adding/changing Body Mark

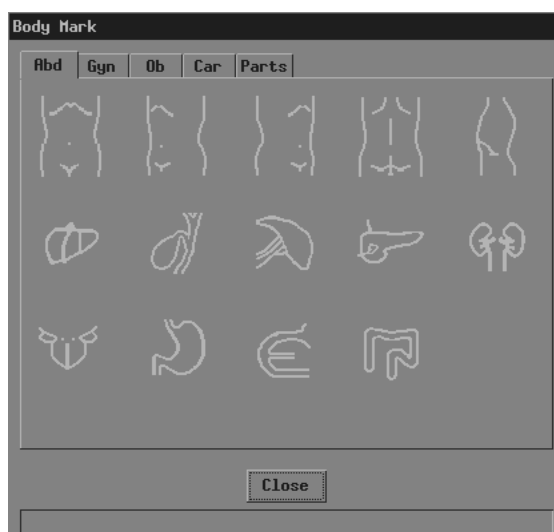
You can add body marks on real-time, frozen and cine images, on opened FRM/CIN files, and on their zoomed images.

You can add a body mark in any image mode.

In the M/B mode, the body mark is added only on the B image. In the B/B mode, while the body mark can be added on both windows respectively, it can be added only on the active window at a time.


To add a body mark on the current image or change the current body mark on the image to another

- 1 Press <BodyMark>. The [Body Mark] dialog box pops up and the page corresponding to the current exam mode is displayed.



- 2 If you do not want to add any body mark, click [Close] or press <BodyMark> or press <Esc> to close the dialog box. No body mark appears on the image. The operation is over.
If the body mark you want is not in the current page, enter other pages to find it and then go to the next step.
- 3 Move the cursor onto the body mark you want. The body mark protrudes.
- 4 Press <Set> to close the [Body Mark] dialog box. The body mark appears on the lower left corner of screen.
- 5 If you want to change the orientation of transducer symbol, press <→>, <←>, <↑> or <↓> (pressing <→> or <↓> can rotate the transducer symbol clockwise; pressing <←> or <↑> can rotate the transducer symbol counterclockwise).
- 6 If you want to change the location of transducer symbol, turn the trackball to move the transducer symbol to the place you want.
- 7 Press <Set> or <BodyMark> or <Esc>.

10.2 Moving Body Mark

- 1 Ensure it is not in the comment status, measurement status or manual cine.
- 2 Move the cursor onto the body mark on the screen. The cursor changes to “”.
- 3 Press <Set> and a frame appears around the body mark.
- 4 Turn the trackball and the frame moves with it. Move the frame where you want the body mark to be located.
- 5 If you want to move the body mark to the new position, press <Set>;
If you do not want to move the body mark, press <Back>.

10.3 Clearing Body Mark

First method to clear the body mark

Press <Clear> to clear all of the body mark(s), comments (including arrows), measurement calipers and general measurement data.

Note that in the B/B mode, both body marks are cleared.

Second method to clear the body mark

Press <BodyMark> twice successively to clear the body mark.

Note that in the B/B mode, only the body mark in the active window is cleared.

11 File System

This chapter introduces the file system and its operation.

The file system saves image data to files in a storage device after the image is frozen and manages the files.

The system supports the following file formats.

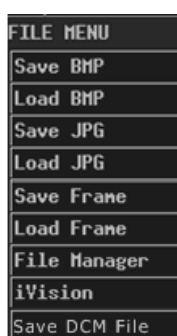
- Screen file (BMP)
- Screen file (JPG)
- Cine file (CIN)
- Frame file (FRM)
- DICOM file (DCM) (only the system configuring DICOM supports this format)

The screen file is the copy of current screen information and saves all information on the screen. It can be browsed on a PC.

The JPEG compression method may cause distortion of images.

11.1 Entering File System

Press <File> and the [FILE MENU] menu is displayed (if no menu is displayed, press <Menu>).

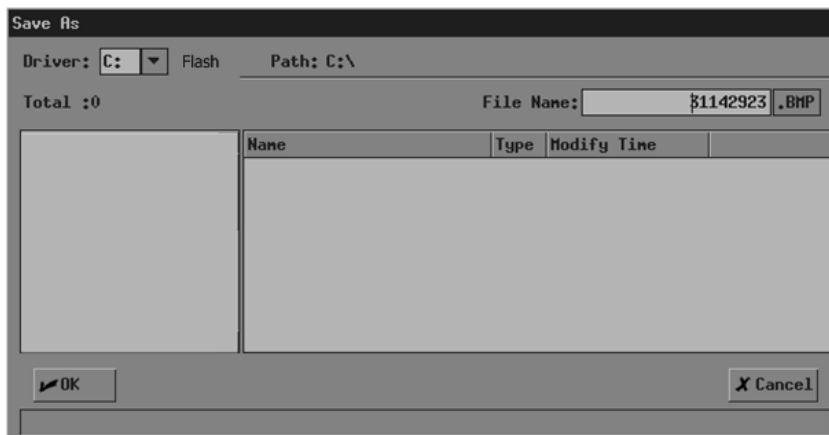


11.2 Saving Files

You can save image files to a storage device.

The following procedure describes the saving of a BMP file. The saving of files with other formats is similar to it and not described in this manual (note that the saving of DCM files is only available in the system configuring DICOM).

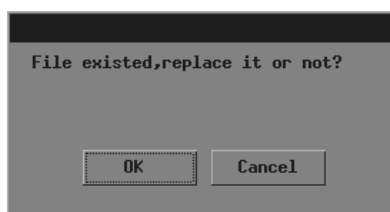
- 1 Freeze the image. If necessary, review images until the image to be saved is displayed on the screen.
- 2 Press <File> and the [FILE MENU] menu is displayed (if no menu is displayed, press <Menu>).
- 3 In the [FILE MENU] menu, click [Save BMP]. The [Save As] dialog box pops up.



In the dialog box, the default directory to save the file and the default file name are displayed.

- 4 If you want to change the directory to save the file, perform the following steps.
 - (1) Select the driver in [Driver:]. The Flash memory in the system is the driver C, and the remaining driver(s) belong(s) to the USB storage device if a USB storage device is connected.
 - (2) If the USB storage device is selected in the previous step, move the cursor onto the item you want in the directory list and then press <Set> twice successively to enter the directory. If you want to return to the parent directory, move the cursor onto [..] and then press <Set> twice successively.
 - 5 If you want to modify the file name, input the new file name in [File Name:]. The file type (BMP) cannot be modified.
- If you want to replace an existing file, move the cursor onto the file in the file list and then press <Set>.
- 6 If you want to save the current screen information, click [OK]; if you want to save nothing, click [Cancel] or press <Esc>.

If you have selected to replace an existing file, the following dialog box pops up.



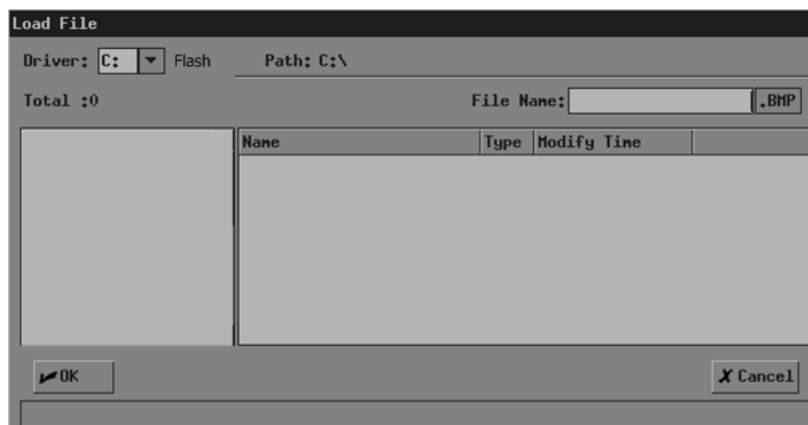
If you want to replace the existing file with the current image, click [OK]; if you do not want to replace the existing file, click [Cancel] and the current image is not saved.

11.3 Opening Files

You can open and browse the image files in a storage device.

The following procedure describes the opening of a BMP file. The saving of files with other formats is similar to it and not described in this manual (note that the opening of DCM files is only available in the system configuring DICOM).

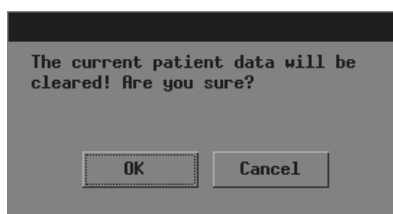
- 1 Enter the [FILE MENU] menu.
- 2 In the [FILE MENU] menu, click [Load BMP]. The [Load File] dialog box pops up.



In the dialog box, the default directory is displayed.

- 3 If the file you want to open is not in the current directory, perform the following steps to select the directory.
 - (1) Select the driver in [Driver:]. The Flash memory in the system is the driver C, and the remaining driver(s) belong(s) to the USB storage device if a USB storage device is connected.
 - (2) If the USB storage device is selected in the previous step, move the cursor onto the item you want in the directory list and then press <Set> twice successively to enter the directory. If you want to return to the parent directory, move the cursor onto [..] and then press <Set> twice successively.
- 4 Load the file you want to the screen and close the [Load File] dialog box by
 - Moving the cursor onto the file you want in the file list and then pressing <Set> twice successively.
 - Or, moving the cursor onto the file you want in the file list, pressing <Set>, and then clicking [OK].

Note that the system prompts if the current patient information is to be deleted before a FRM/CIN file is opened, shown in the dialog box below.



If you want to delete the current patient information and open the selected FRM/CIN file, click [OK]; if you do not want to delete the current patient information, click [Cancel] and no image file is opened.

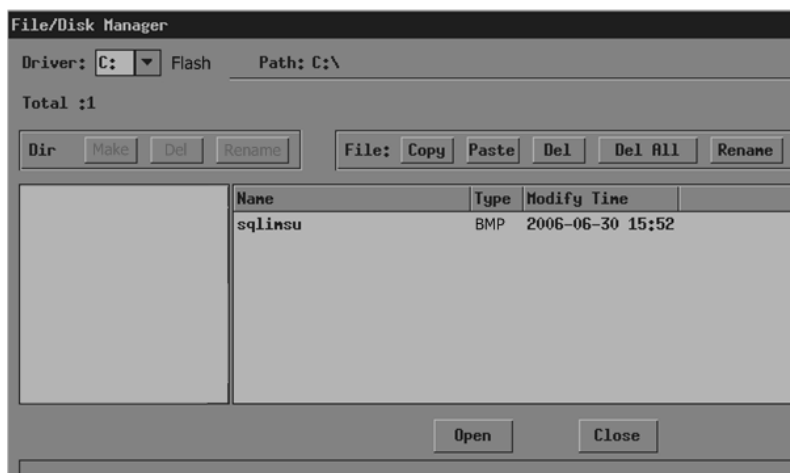
- 5 You can click [Exit] on the lower right corner of screen or press <Esc> to close the loaded file (this only applies to BMP, JPG and DCM files).

Note that during the steps above, you can click [Cancel] in the [Load File] dialog box or press <Esc> to close the dialog box and open none of files.

11.4 File/Directory Management

You can manage directories and files in the Flash memory and USB storage device.

- 1 Enter the [FILE MENU] menu.
- 2 In the [FILE MENU] menu, click [File Manager]. The [File/Disk Manager] dialog box pops up.



In the dialog box, the default directory is displayed.

- 3 You can manage files and directories in the [File/Disk Manager] dialog box. See “11.4.1 File Management” for details.
- 4 You can follow the steps below to open files in the [File/Disk Manager] dialog box.
 - (1) Follow the step 3 in “11.3 Opening Files” to operate.
 - (2) Select the file to be opened in the file list.
 - (3) Click [Open].
- 5 After all operations are completed, click [Close] or press <Esc> to close the [File/Disk Manager] dialog box.

11.4.1 Directory Management

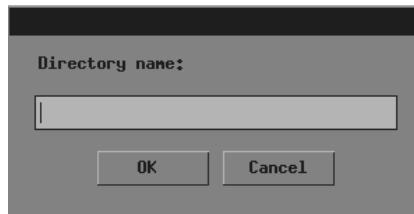
You can create, rename and delete directories only in the USB storage device.

Note that the Flash memory has no directories.

To create a directory

- 1 If the directory to be created is not in the current directory, perform the following steps in the [File/Disk Manager] dialog box.
 - (1) Select the driver (except the driver C) in [Driver:].

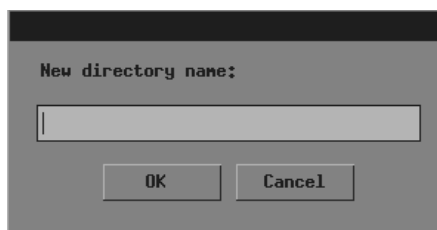
- (2) Move the cursor onto the item you want in the directory list and then press <Set> twice successively to enter the directory. If you want to return to the parent directory, move the cursor onto [..] and then press <Set> twice successively.
- 2 Click [Make] and the following dialog box pops up.



- 3 Input the directory name in the dialog box.
- 4 If you want to create the directory, click [OK]; if you do not want to create any directory, click [Cancel] or press <Exit>.

To rename a directory

- 1 If the directory to be renamed is not in the current directory, perform the following steps in the [File/Disk Manager] dialog box.
 - (1) Select the driver (except the driver C) in [Driver:].
 - (2) Move the cursor onto the item you want in the directory list and then press <Set> twice successively to enter the directory. If you want to return to the parent directory, move the cursor onto [..] and then press <Set> twice successively.
- 2 Select the directory to be renamed in the directory list.
- 3 Click [Rename] in the left part of dialog box and the following dialog box pops up.

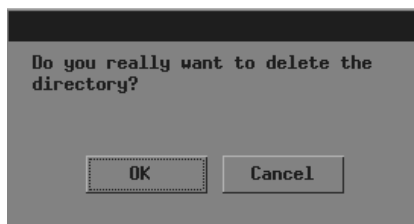


- 4 Input the new directory name in the dialog box.
- 5 If you want to rename the directory with the new name, click [OK]; if you do not want to modify the directory name, click [Cancel] or press <Exit>.

To delete a directory

- 1 If the directory to be deleted is not in the current directory, perform the following steps in the [File/Disk Manager] dialog box.
 - (1) Select the driver (except the driver C) in [Driver:].
 - (2) Move the cursor onto the item you want in the directory list and then press <Set> twice successively to enter the directory. If you want to return to the parent directory, move the cursor onto [..] and then press <Set> twice successively.

- 2 Select the directory to be deleted in the directory list.
- 3 Click [Del] in the left part of dialog box and the following dialog box pops up.



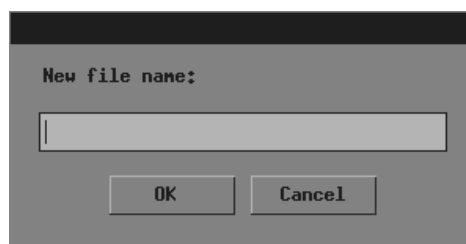
- 4 If you want to delete the selected directory, click [OK]; if you want to delete nothing, click [Cancel] or press <Exit>.

11.4.2 File Management

You can copy, rename and delete a file in the Flash memory.

To rename a file

- 1 If the file to be renamed is not in the current directory, perform the following steps in the [File/Disk Manager] dialog box.
 - (1) Select the driver in [Driver:]. The Flash memory in the system is the driver C, and the remaining driver(s) belong(s) to the USB storage device if a USB storage device is connected.
 - (2) If the USB storage device is selected in the previous step, move the cursor onto the item you want in the directory list and then press <Set> twice successively to enter the directory. If you want to return to the parent directory, move the cursor onto [..] and then press <Set> twice successively.
- 2 Select the file to be renamed in the file list.
- 3 Click [Rename] in the right part of dialog box and the following dialog box pops up.

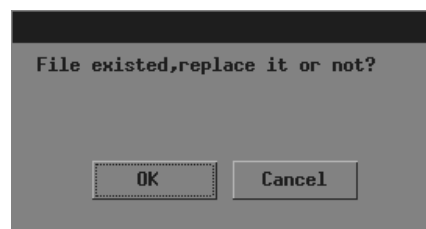


- 4 Input new file name in the dialog box.
- 5 If you want to rename the file with the new name, click [OK]; if you do not want to modify the file name, click [Cancel] or press <Exit>.

To copy a file

- 1 If the file to be copied is not in the current directory, perform the following steps in the [File/Disk Manager] dialog box.

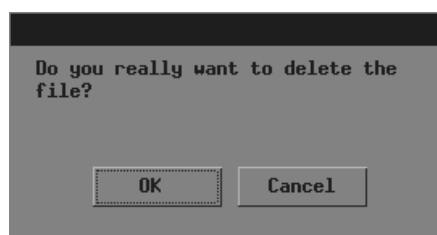
- (1) Select the driver in [Driver:]. The Flash memory in the system is the driver C, and the remaining driver(s) belong(s) to the USB storage device if a USB storage device is connected.
 - (2) If the USB storage device is selected in the previous step, move the cursor onto the item you want in the directory list and then press <Set> twice successively to enter the directory. If you want to return to the parent directory, move the cursor onto [..] and then press <Set> twice successively.
- 2 Select the file to be copied in the file list.
 - 3 Click [Copy].
 - 4 If the destination directory to which the selected file is copied is not the current one, follow the substeps in the step 1 to select it.
 - 5 Click [Paste] and one of the following conditions will occur:
 - (1) The selected file is copied to the current directory.
 - (2) If a file whose name is the same as the selected one exists in the current directory, the following dialog box pops up.



If you want to replace the file in the current directory with the selected one, click [OK]; if you do not want to replace the file in the current directory, click [Cancel] and the selected file is not copied.

To delete a file

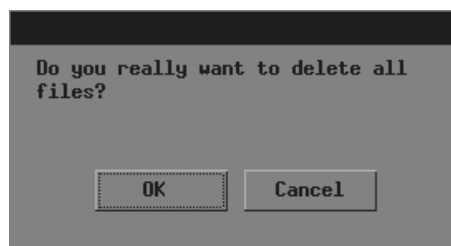
- 1 If the file to be deleted is not in the current directory, perform the following steps in the [File/Disk Manager] dialog box.
 - (1) Select the driver in [Driver:]. The Flash memory in the system is the driver C, and the remaining driver(s) belong(s) to the USB storage device if a USB storage device is connected.
 - (2) If the USB storage device is selected in the previous step, move the cursor onto the item you want in the directory list and then press <Set> twice successively to enter the directory. If you want to return to the parent directory, move the cursor onto [..] and then press <Set> twice successively.
- 2 Select the file to be deleted in the file list.
- 3 Click [Del] in the right part of dialog box and the following dialog box pops up.



- 4 If you want to delete the selected file, click [OK]; if you want to delete nothing, click [Cancel] or press <Exit>.

To delete all files in a directory

- 1 If the files to be deleted are not in the current directory, perform the following steps in the [File/Disk Manager] dialog box.
 - (1) Select the driver in [Driver:]. The Flash memory in the system is the driver C, and the remaining driver(s) belong(s) to the USB storage device if a USB storage device is connected.
 - (2) If the USB storage device is selected in the previous step, move the cursor onto the item you want in the directory list and then press <Set> twice successively to enter the directory. If you want to return to the parent directory, move the cursor onto [..] and then press <Set> twice successively.
- 2 Click [Del All] and the following dialog box pops up.

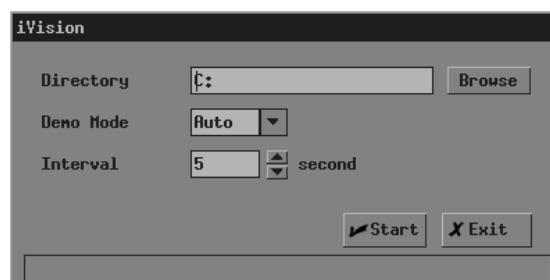


- 3 If you want to delete all files in the current directory, click [OK]; if you want to delete nothing, click [Cancel] or press <Exit>.

11.5 iVision

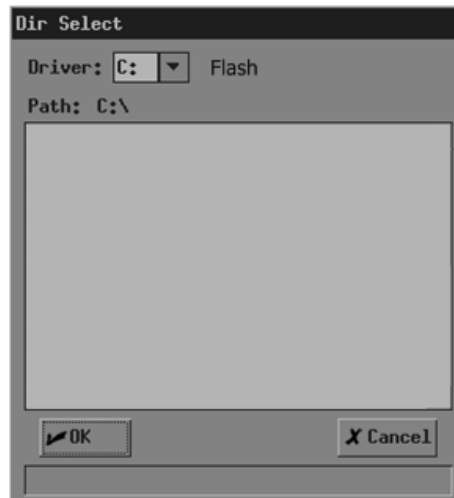
iVision is the function of image demonstration, which plays image files image by image.

- 1 Enter the [FILE MENU] menu.
- 2 In the [FILE MENU] menu, select [iVision]. The [iVision] dialog box pops up.



In the dialog box, the default directory is displayed.

- 3 If demo files are not in the current directory, click [Browse]. The [Dir Select] dialog box pops up.



- (1) Select the driver in [Driver:]. The Flash memory in the system is the driver C, and the remaining driver(s) belong(s) to the USB storage device if a USB storage device is connected.
 - (2) If the USB storage device is selected in the previous step, move the cursor onto the item you want in the directory list and then press <Set> twice successively to enter the directory. If you want to return to the parent directory, move the cursor onto [..] and then press <Set> twice successively.
 - (3) If you want to enter the selected directory, click [OK]; if you do not want to enter the selected directory, click [Cancel] or press <Exit>.
- 4 Select "Auto" or "Manual" in [Demo Mode].

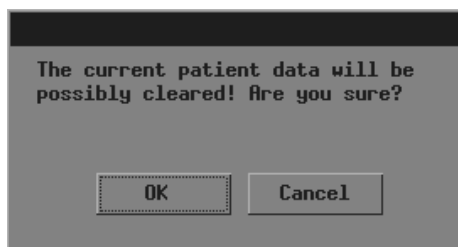
"Auto" means the system automatically plays image files with the set time interval.

 1. The image files are circularly played in the sequence of file storage;
 2. Time intervals of files are the same;
 3. If the files are CIN files, auto cine is performed.

"Manual" means the image files are played manually.

 4. Press <→> or <←> to play image files.
 5. If the files are CIN files, manual cine is performed. Turn the trackball to review.
- 5 If "Auto" is selected, set time interval in [Interval] (the range is 0-500 seconds).

- If you want to start the demo, click [Start] and the demo starts or if the files to be played include CIN or FRM files, the following dialog box pops up; if you do not want to start the demo, click [Exit] or press <Exit>.



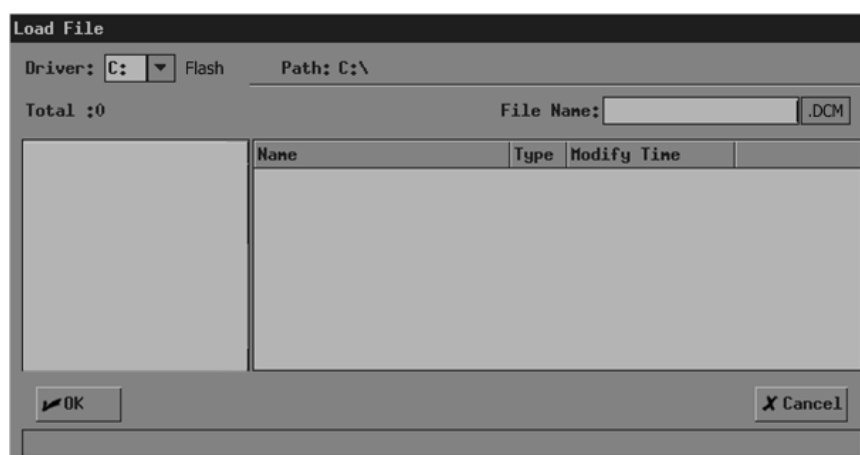
If you want to start the demo, click [OK] in the dialog box and the system deletes the current patient information and starts the demo; if you do not want to delete the current patient information, click [Cancel] and the system neither deletes the current patient information nor starts the demo.

- During the demo, you can press <Exit> to end the demo.

11.6 Sending DCM Files

Only the system configuring DICOM can send DCM files in the Flash memory or USB storage device to the current server.

- Enter the [FILE MENU] menu.
- In the [FILE MENU] menu, click [Send DCM File]. The [Load File] dialog box pops up.



- Follow the steps 3 and 4 in “11.3 Opening Files” to operate.
- “Transmitting...” is displayed at the lower part of screen. After the file is sent, the system will prompt the successful transmitting.

11.7 Sending DCM Images

Only the system configuring DICOM can send the current image to the current server.

- Freeze the image. If necessary, review images until the image to be sent is displayed on the screen.
- Press <File> and the [FILE MENU] menu is displayed (if no menu is displayed, press <Menu>).

- 3 In the [FILE MENU] menu, click [Send DCM Image]. The system starts to send the current image to the server.
- 4 “Transmitting...” is displayed at the lower part of screen. After the image is sent, the system will prompt the successful transmitting.

11.8 Exiting File System


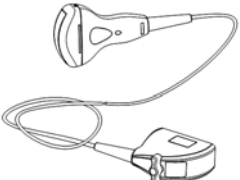

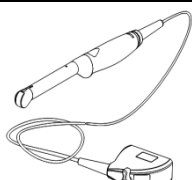
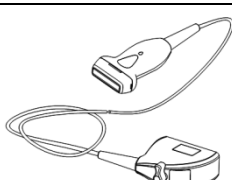
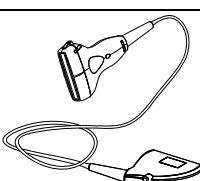
After all operations to the file system are completed, press <File> or <Esc> to exit the file system.

12 Transducers and Biopsy

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

12.1 Transducers

The system supports the following transducers:

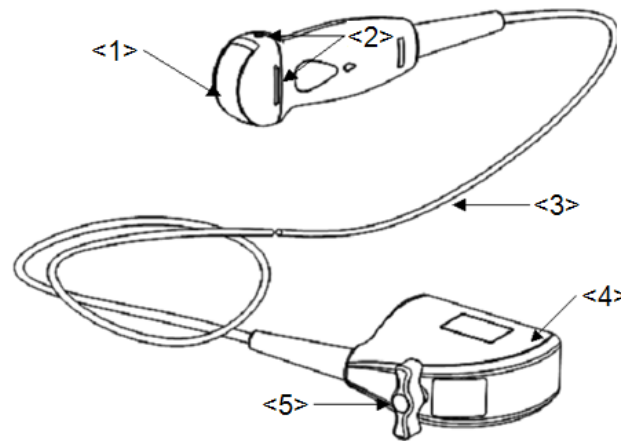
No.	Probe	Type	Illustration
1	35C20EA	Convex	
2	35C50EB	Convex	
3	65C15EA	Convex	
4	65EC10EB	Convex	
5	75L38EB	Linear	
6	75L60EA	Linear	

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
35C20EA	NGB-003	11°, 23°	Metal/needle un-detachable	14G, 16G, 18G, 20G, 22G
			Metal/needle detachable	13G, 15G, 16G, 18G, 20G
35C50EB	NGB-001	25°, 35°, 45°	Metal/needle un-detachable	13G, 15G, 16G, 18G, 20G
			Metal/needle detachable	14G, 16G, 18G, 20G, 22G
65C15EA	NGB-005	12.7°, 24.2°	Metal/needle un-detachable	20G, 18G, 16G, 15G, 13G
65EC10EB	NGB-004	/	Metal/needle un-detachable	16G, 18G
75L38EB	NGB-002	40°, 50°, 60°	Metal/needle un-detachable	13G, 15G, 16G, 18G, 20G
75L60EA	NGB-012	40°, 50°, 60°	Metal/needle detachable	14G, 16G, 18G, 20G, 22G
			Plastic/needle detachable	13G, 15G, 16G, 18G, 20G

12.1.1 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.

12.1.2 Orientation of the Ultrasound Image and the Transducer

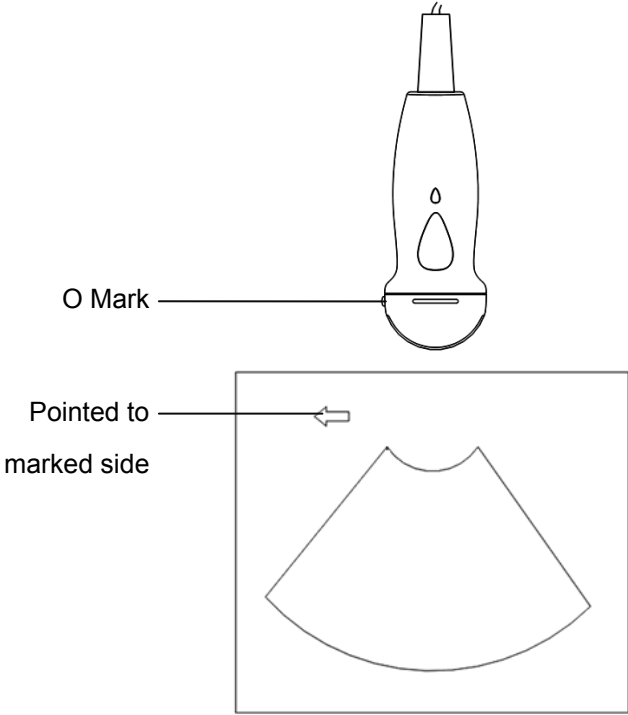
Head

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.

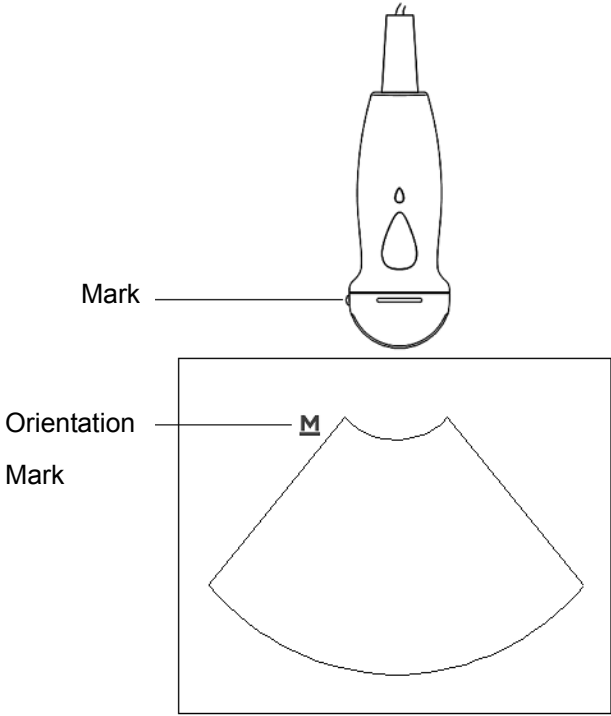
Check the orientation before the examination.

■ Method 1

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



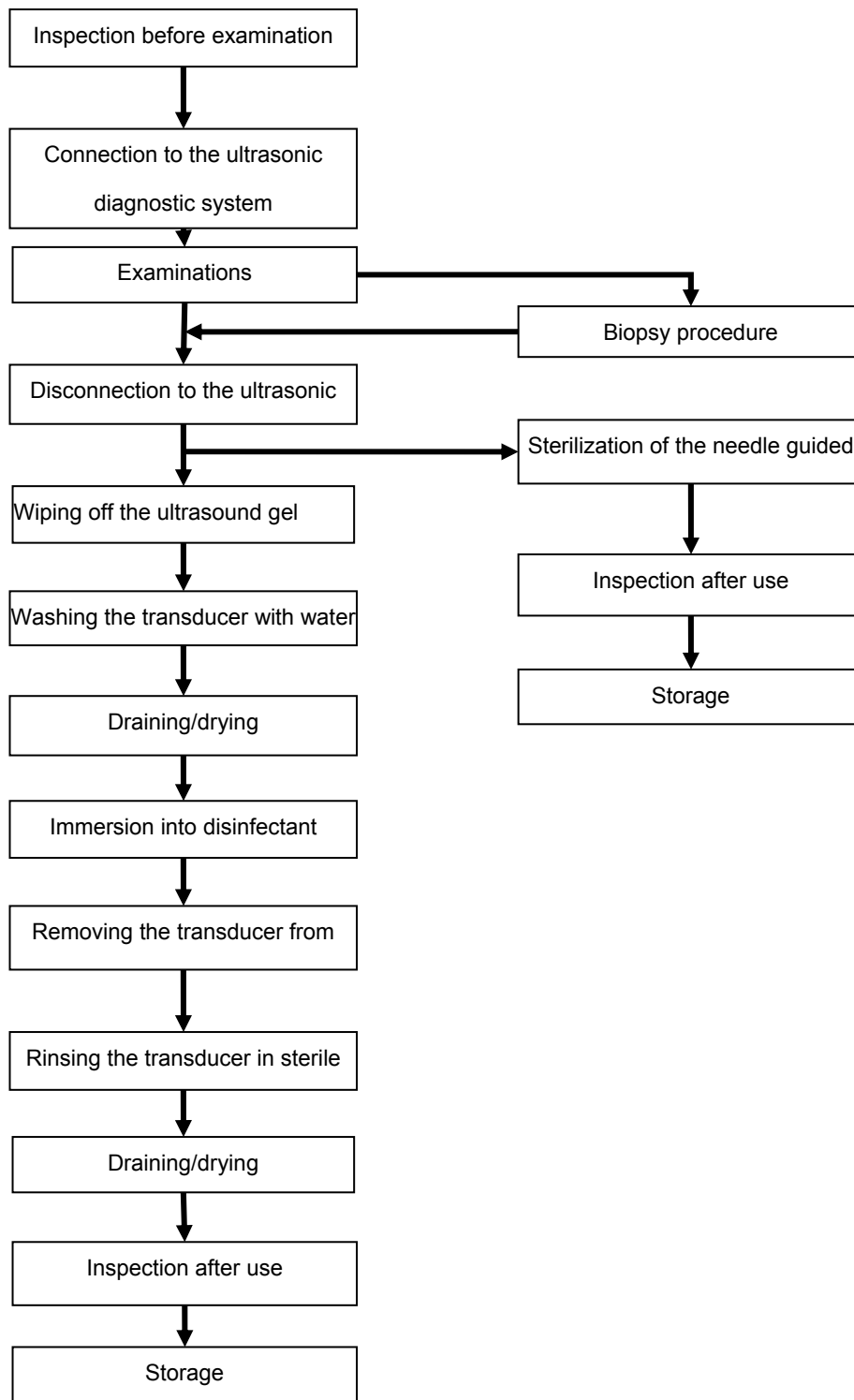
■ Method 2



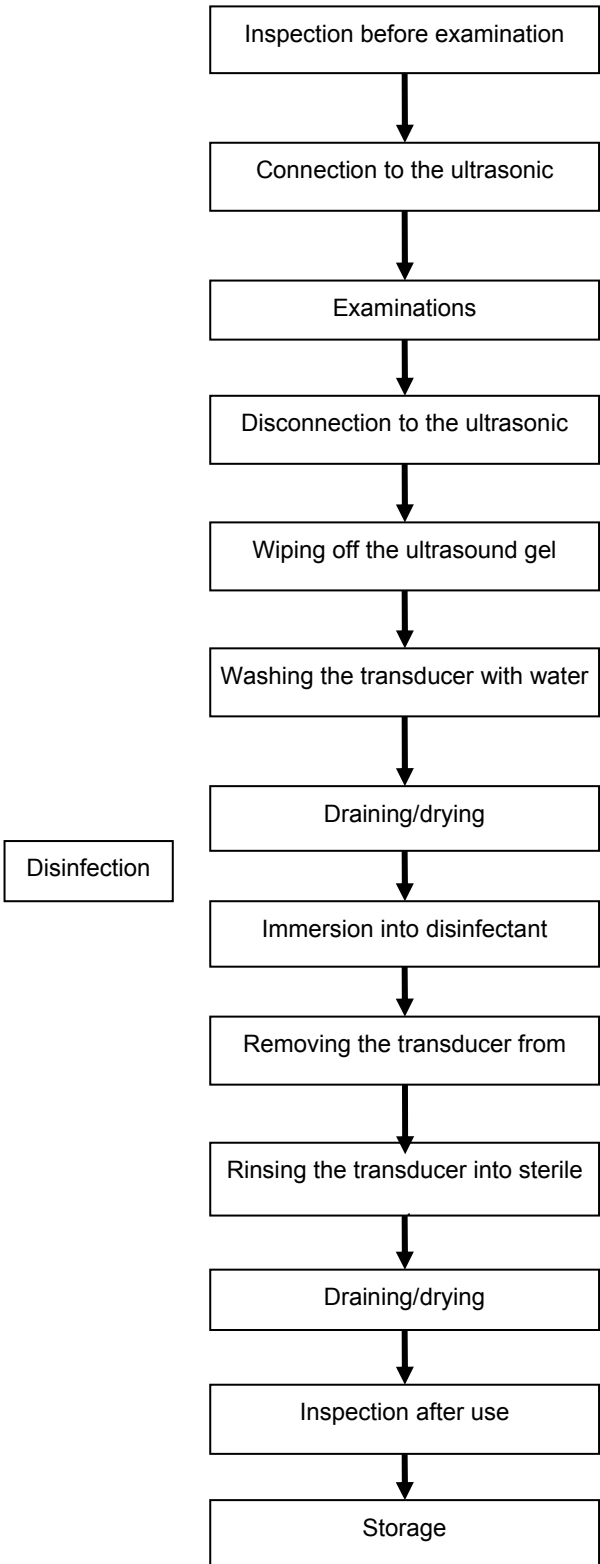
12.1.3 Procedures for Operating

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.

12.1.4 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

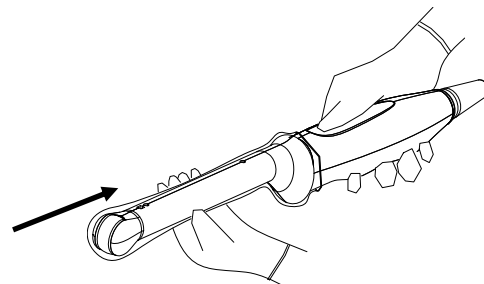
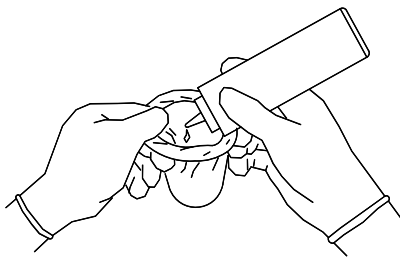
<http://www.civco.com>

**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.**

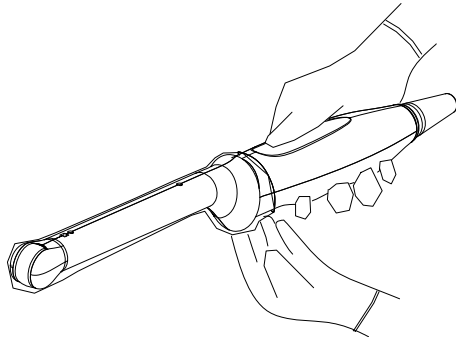
Method (for reference only):

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.




12.1.5 Transducers Cleaning and Disinfection

Once you turn off the ultrasonic diagnostic system after completing each examination, then clean and disinfect the transducers as required. When biopsy procedures have been performed, be sure to sterilize the needle-guided bracket. Fail to do so may result in the transducer and the needle-guided bracket to becoming sources of infection. Please follow the instructions in the manual for cleaning.

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

⚠ CAUTION:

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



2. After disinfection, rinse the transducer thoroughly with sterile water to remove all chemical residues. Chemical residues on the transducer may be harmful to the human body.
3. The efficacy of disinfectants and sterilizing solutions is not guaranteed by MINDRAY. Contact the manufacturers for information on the activity of the products.

NOTE:

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

Cleaning

Please follow the instructions in the manual for cleaning.

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

High Level Disinfections

Please follow the instructions in the manual for disinfection.

1. Wear sterile gloves to prevent infection.
2. Clean the transducer before disinfecting it. The transducer manufacturer recommends the following solutions to disinfect the transducer.

Glutaraldehyde-based disinfectant:

Chemical Name	Trade Name	Procedures
Glutaraldehyde (2.4%)	Cidex Activated Dialdehyde Solution	Please refer to the instructions provided by the manufacturer of the solution for details.

Non-glutaraldehyde based disinfectant:

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

N-Dodecylpropane-1, 3-diamine based disinfectant:

Chemical Name	Manufacturer	Trade Name	Procedures
N-Dodecylpropane-1, 3-diamine	Antiseptica	Triacid-N	Please refer to the instructions provided by the manufacturer of the solution for details.

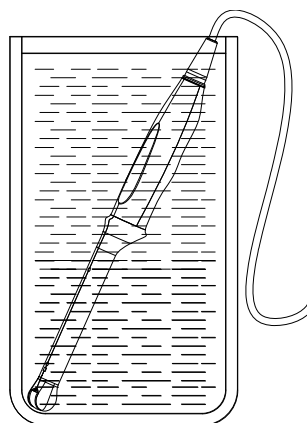
Quaternary Ammoniums based disinfectant:

Chemical Name	Manufacturer	Trade Name	Procedures
Quaternary Ammoniums	Ecolab Inc.	Ster-Bac	Please refer to the instructions provided by the manufacturer of the solution for details.

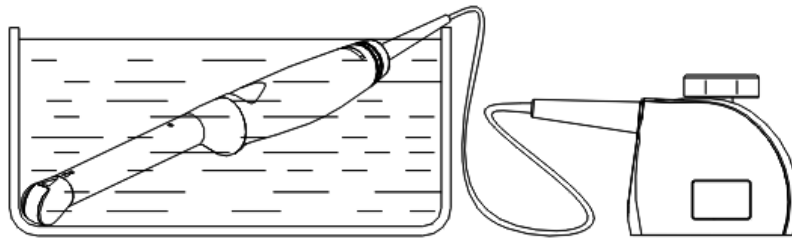
Hydrogen Peroxide and Peroxyacetic Acid -based disinfectant:

Trade Name	Chemical Name	Procedures
Minnicare® Cold Sterilant	22% Hydrogen Peroxide 4.5% Peroxyacetic Acid	Please refer to the instructions provided by the manufacturer of the solution for details.

- Refer to the instructions provided by the chemical manufacturer concerning concentration of the disinfectant solution, method of disinfection and dilution and cautions during use.
 - DO NOT soak the 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.



(For general transducer)



(For intra-cavitary transducer)

NOTE: Repeated disinfection may degrade the performance and safety of the transducer.

12.1.6 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 specified ambient conditions.
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.

12.2 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.

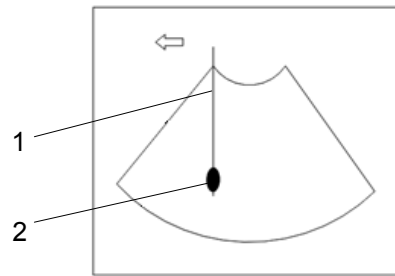
Never perform a biopsy during image scanning.

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.

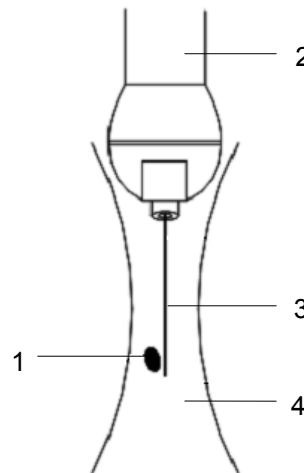
If the target object and the biopsy needle appear in the

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.

12.2.1 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).

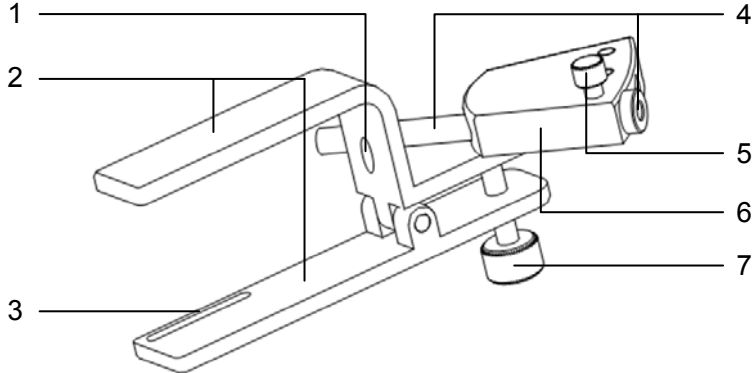
12.2.2 Names of Parts

This section describes the parts and corresponding functions of each needle-guided bracket.

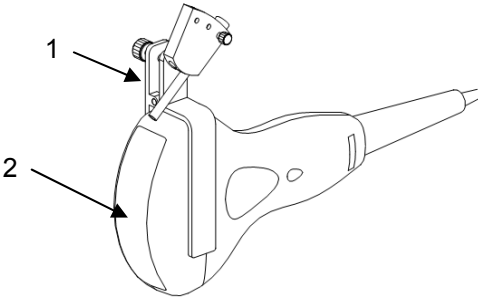
Here, we take a matched transducer as an example.

- 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.

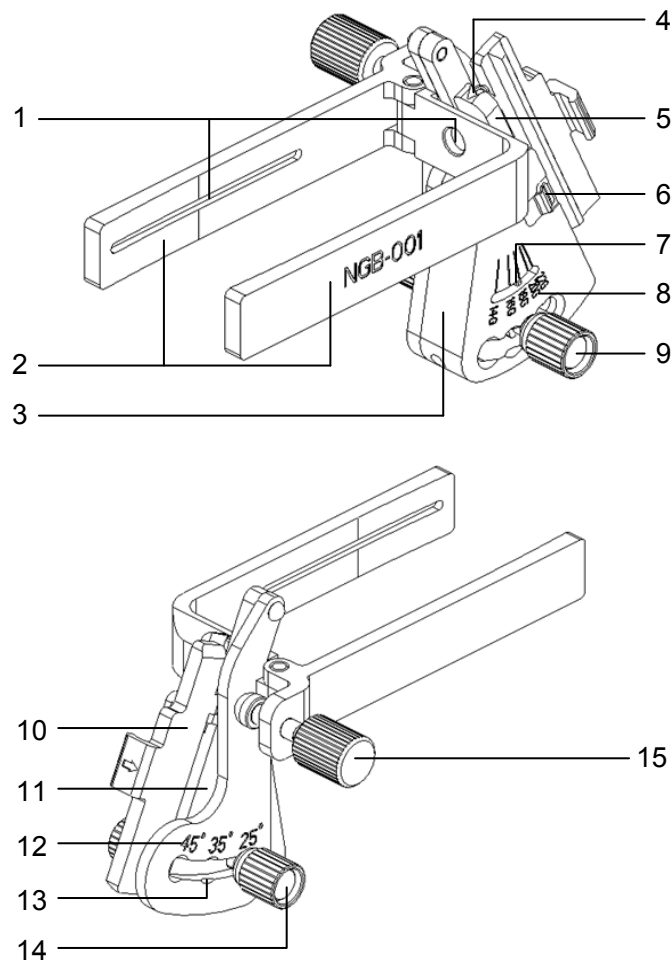


- 1. Locating pit 2. Clamp 3. Locating groove 4. Needle guide and the hole
- 5. Clamping knob of the needle guide 6. Needle guide rack 7. Grip knob



- 1. Needle-guided bracket 2. Transducer

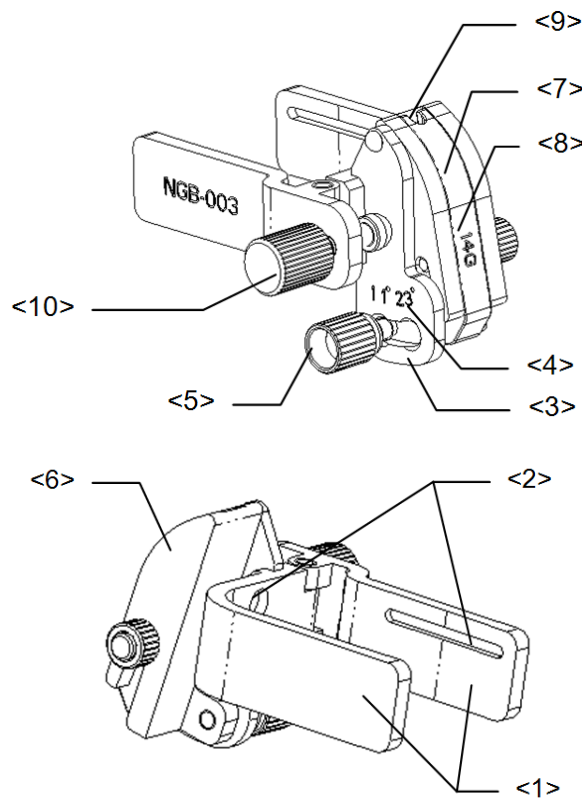
■ NGB-001 (Metal/needle detachable)



No.	Name	Description
1	Groove of the needle-guided bracket	Matches with the tab of the transducer
2	Clamp of needle-guided bracket	Used for installing the needle-guided bracket on the transducer
3	Adjusting base of needle type	The size of the guiding hole: 5 types of needles can be adjusted
4	Guiding hole of biopsy needle	Holds the biopsy needle. It is determined by the V-shaped guiding block and the V-shaped cover
5	V-shaped guiding block	Determines the size of the guiding hole, the position of which is controlled by the adjusting nut of needle type
6	Buckle	Buckles the V-shaped cover
7	Indication pole of shift	Indicates the shift
8	Shift sign of needle type	Matches with the corresponding biopsy needle (14G, 16G, 18G, 20G, 22G)
9	Adjusting nut of needle type	Adjusts and fastens the V-shaped guiding block to a desired shift

No.	Name	Description
10	V-shaped cover	Determines the guiding hole together with the V-shaped guiding block. It can be opened and closed.
11	Angle block	Determines the angle of the biopsy; different specifications of blocks can be used
12	Angle shift sign (25° , 35° , 45°)	Matches with the biopsy angle (25° , 35° , 45°)
13	Angle adjusting base	There are 3 types of angles available to be adjusted
14	Angle pinch nut	Used for fixing the angle lock at a chosen angle
15	Pinch nut of needle-guided bracket	Used for locking the needle-guided bracket and the transducer

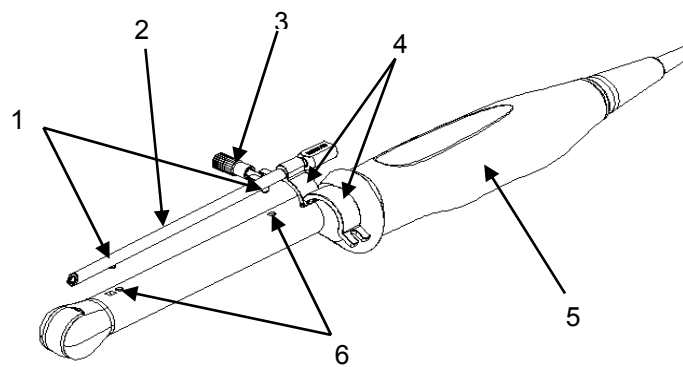
■ NGB-003 (Metal/needle detachable)



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

No.	Name	Description
<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

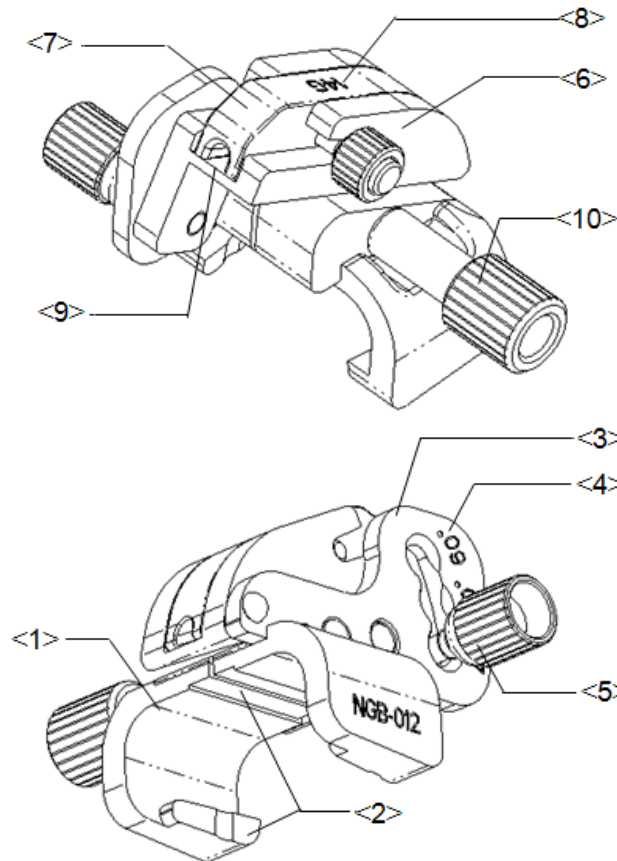
■ NGB-004 (Metal/needle un-detachable)



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

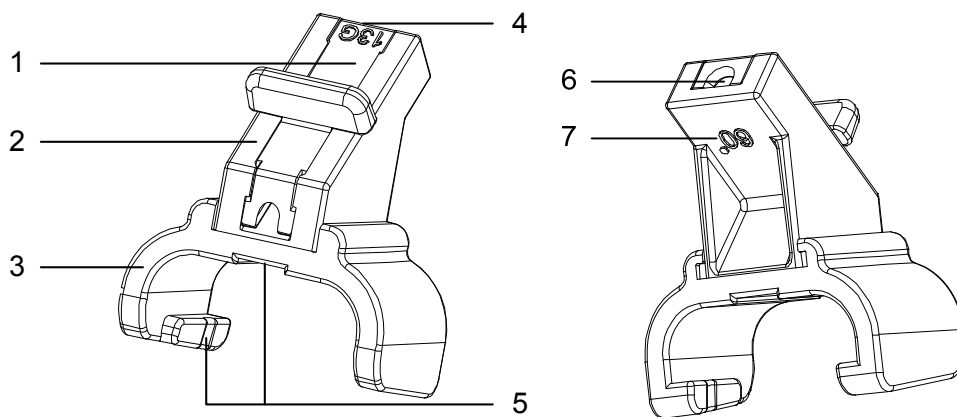
■ NGB-012

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°)

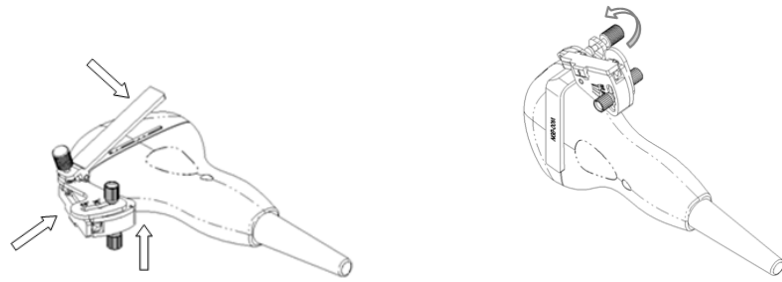
12.2.3 Inspection of the Needle-guided Bracket

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.

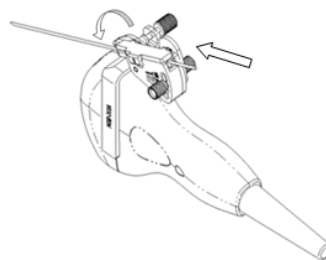
1. Sterilize the needle-guided bracket before and after use.
2. Confirm that the needle-guided bracket is free of damage, deformation, stripping, malfunction, loose, or missing parts.
3. Confirm that the needle-guided bracket is securely mounted in the correct position.

12.2.4 Installing the Needle-guided Bracket

- NGB-001 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. 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) Adjust the adjusting nut of needle type to a desired shift and screw the nut to fix the guiding block.
- 5) Close the V-shaped cover and insert the needle to the guiding hole.



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

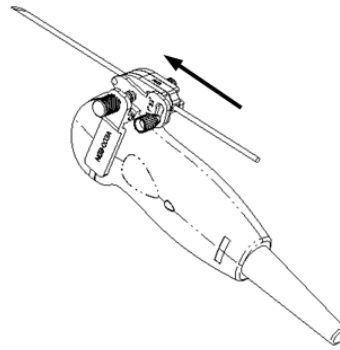
- 1) Put on the transducer cover.
- 2) Select a proper needle-guided bracket, and match the groove with the tab of the transducer respectively. Mount the bracket onto the transducer.



- 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.

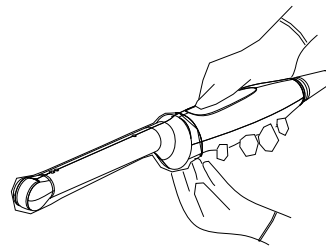


- NGB-001, NGB-002, NGB-003 and NGB-005 metal/needle un-detachable needle-guided bracket (taking NGB-001 as example)

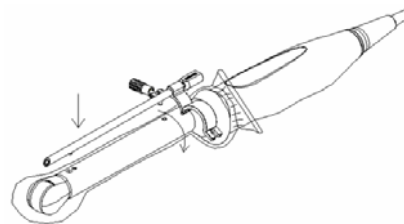
- 1) Inosculate the locating groove on the clamp with the two raised edges on the transducer head and aligning the locating pit of the clamp to the convex point on the transducer head.
- 2) Turn the grip knob at the tail of the needle-guided bracket tightly.

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

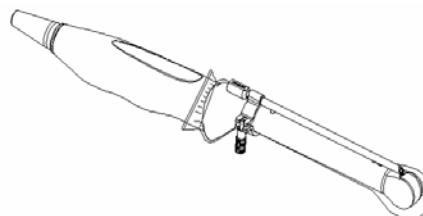
- 1) Put on the sterile transducer sheath.



- 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.

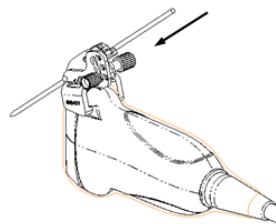
- 2) Hold the transducer by one hand, select the proper needle-guided bracket, and hold it with the other hand. Match the groove and tab with the tab and groove of the transducer respectively. Amount the bracket onto the transducer.



- 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.

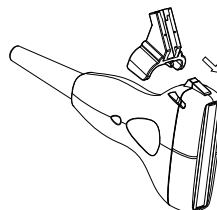


- 5) Screw the nut of the block to secure the block.
- 6) Insert a biopsy needle with the same specification as that of the guiding block into the hole of the guiding block.

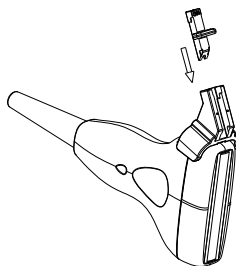


Plastic/needle detachable needle-guided bracket:

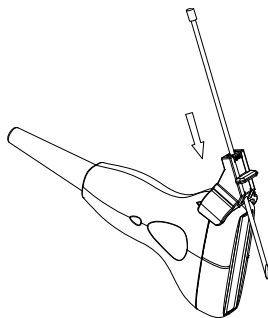
- 1) Put on the sterile transducer sheath.
- 2) Hold the transducer by one hand, select the proper needle-guided bracket, and hold it with the other hand. Align the narrow end tab of the needle-guided bracket with the groove of the transducer, then push the needle-guided bracket forward, making the tabs 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.



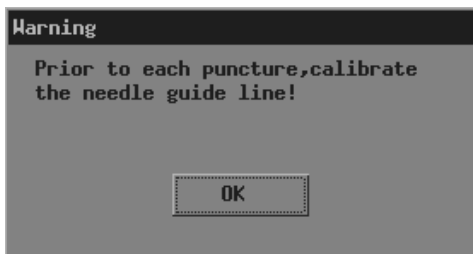
5) Insert a biopsy needle with the same specification as that of the guiding block into the hole of the guiding block.



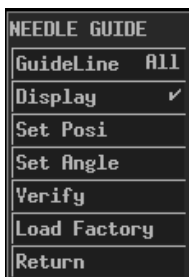
CAUTION: Ensure that all guide parts are seated properly prior to performing a biopsy.

12.2.5 Entering Status of Guide Line Adjustment

- 1 When the B image is real-time, select [Puncture] in the [B MODE MENU] menu. The following dialog box pops up.



- 2 Click [OK] in the dialog box. The [NEEDLE GUIDE] menu and guide lines appear.



Each needle-guided bracket has three guide lines at most.

When the image depth is between 2.16cm and 8cm, interval of two adjacent dots is 0.5cm;

When the image depth is between 8cm and 24.8cm, interval of two adjacent dots is 1cm.

12.2.6 Selecting Guide Line

- 1 Enter the status of guide line adjustment.
- 2 In the [NEEDLE GUIDE] menu, select the guide line you want in [GuideLine]. In it, "All" represents all guide lines.

12.2.7 Adjusting Guide Line

NOTE: Guide lines can only be adjusted on real-time B images.
--

To move a guide line horizontally

- 1 Enter the status of needle guide adjustment.
- 2 In the [NEEDLE GUIDE] menu, select a guide line in [GuideLine].
- 3 Adjust [Set Posi] in the [NEEDLE GUIDE] menu to move the selected guide line horizontally.

To adjust the angle of a guide line

- 1 Enter the status of needle guide adjustment.
- 2 In the [NEEDLE GUIDE] menu, select a guide line in [GuideLine].
- 3 Adjust [Set Angle] in the [NEEDLE GUIDE] menu to change the angle of selected guide line.

To restore factory settings of all guide lines

- 1 Enter the status of needle guide adjustment.
- 2 Click [Load Factory] in the [NEEDLE GUIDE] menu to restore positions and angles of all guide lines to factory settings.

To save settings of all guide lines

- 1 Enter the status of needle guide adjustment.
- 2 Adjust positions and angles of guide lines if necessary.
- 3 Click [Verify] in the [NEEDLE GUIDE] menu and the system saves current data of positions and angles of all guide lines.

After <Patient> is pressed or the system starts up again, the positions and angles of all guide lines use the saved data.

12.2.8 Displaying/hiding Guide Line

- 1 Enter the status of needle guide adjustment.
- 2 Set [Display] in the [NEEDLE GUIDE] menu to display or hide the guide line(s).
In it, "√" represents displaying the guide line(s) and "x" represents hiding the guide line(s).

12.2.9 Exiting Status of Guide Line Adjustment

You can exit the status of guide line adjustment by:

Clicking [Return] in the [NEEDLE GUIDE] menu or pressing <Esc>.

Or, directly pressing another key such as <Measure>, <Comment>, <BodyMark> or <File>.

After the status of guide line adjustment exits, the guide line(s) is displayed until <Patient> is pressed but cannot be adjusted.

12.2.10 Removing the Needle-guided Bracket

■ NGB-001

Metal/needle detachable needle-guided bracket:

- 1) Open the V-shaped cover to release the biopsy needle.



- 2) Remove the transducer and the needle-guided bracket from the biopsy needle.



- 3) Screw the pinch nut of the bracket to release the needle-guided bracket.

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.

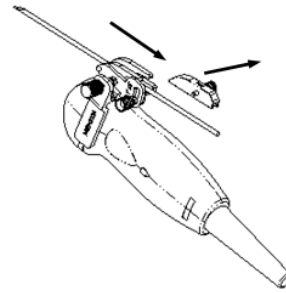
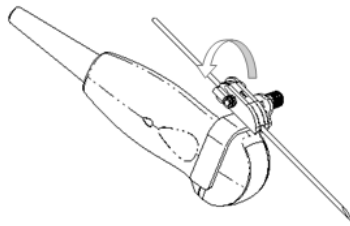
■ NGB-002 metal/needle un-detachable needle-guided bracket:

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

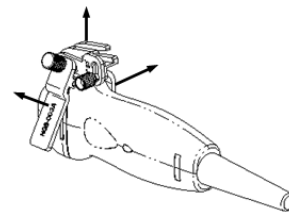
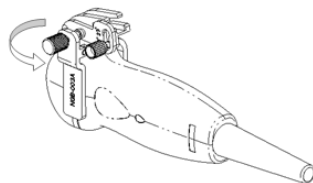
■ NGB-003

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.

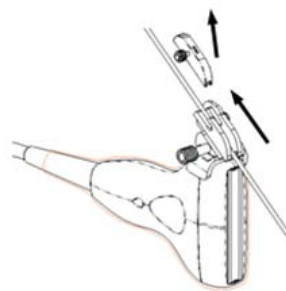
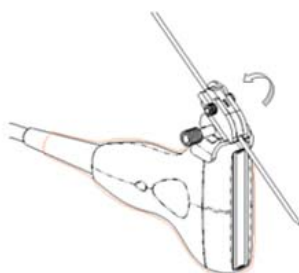
■ **NGB-005 metal/needle un-detachable needle-guided bracket**

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

■ **NGB-012**

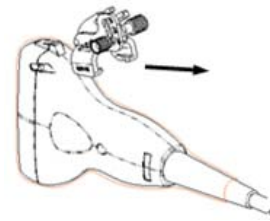
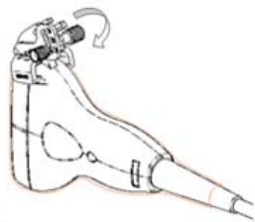
Metal/needle detachable needle-guided bracket:

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.

12.2.11 Clean and Sterilize the Needle-guided Bracket

Cleaning

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

Please follow the instructions in the manual for cleaning.

Sterilization

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

■ Glutaraldehyde-based sterilant:

Chemical name	Trade name	Procedures
Glutaraldehyde (2.2-2.7%)	Cidex Activated Glutaraldehyde Solution	Please refer to the instructions provided by the manufacturer of the solution for details. Soak the transducer into the activated solution for 10 hours (20-25°C)

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).

■ Hydrogen Peroxide and Peroxyacetic Acid -based sterilant:

Trade Name	Chemical Name	Procedures
Minnicare® Cold Sterilant	22% Hydrogen Peroxide 4.5% Peroxyacetic Acid	Dilute the sterilant with sterilized purified water (1:20). Immersed time: 11 hours. Temperature: 20°C-25°C. Please refer to the instructions provided by the manufacturer of the solution for details.

Before safety and performance is affected, plastic bracket NGB-012 can be sterilized by Minncare COLD STERILANT for at least 245 times (11 hours for one time).

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

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

Chemical name	Trade name	Procedures
Hydrogen 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 dual life, and the dual life is affected by the daily application of the bracket. Please check the appearance of the bracket before using.
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12.2.12 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)


12.2.13 Disposal

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

Contact your MINDRAY representative when disposing of this device.

13 System Maintenance

This chapter introduces the system maintenance and simple troubleshooting.


 **WARNING:** The system maintenance is completed by the user and the service engineer. After the system is delivered to the user, the user assumes all the responsibilities in maintenance and operation.
For problems not described in this chapter or unable to be solved, contact our company's Customer Service Department or your local distributor.


NOTE: It is recommended to establish maintenance and periodic check plans. If finding any abnormality, contact our company's Customer Service Department or your local distributor.

13.1 Maintenance Performed by Users

The following maintenance is performed by users.

13.1.1 Cleaning

 **WARNING:** Before cleaning, turn off the system and disconnect its power plug from the outlet. Otherwise, electric shock may occur.
Do not leak any liquid into the system. Otherwise, the system may fail or electric shock may occur.

 **CAUTION:** Refer to the instruction of detergent for details on how to use the detergent.

NOTE: Do not clean parts such as connectors by yourself. If you want to clean them, contact our company's Customer Service Department or your local distributor.

13.1.2 Backup

To prevent data saved in the flash memory of the system from being damaged or lost, backup the data in it periodically.

You can copy the files in the flash memory to a USB storage device and then save the files in

proper external storage media. See “To copy a file” in “11.4 File/Directory Management” for details.

Note that only the system supporting the USB port can backup data.

- To clean the transducer

Refer to the transducer’s manual to clean and disinfect the transducer.

- To clean the screen

Use soft cloth dipped with glass detergent to clean the screen and then air dry it.

NOTE: Do not use hydrocarbon detergent or detergent used on OA equipments to clean the screen.

- To clean the transducer holder, control panel and shell

Use soft dry cloth to clean the surface of system. If necessary, use soft cloth dipped with neutral detergent to clean it and then air dry it.

13.2 Maintenance Performed by Service Engineers

The following maintenance is to assure the performance and safety of the system. Only professional service engineers can perform them. Contact our company’s Customer Service Department or your local distributor to perform the maintenance.

Category	Maintenance Item
Cleaning	Interior of the system Peripherals
Electric safety	Earthing impedance Earth leakage current Enclosure leakage current Patient leakage current Patient leakage current (Mains voltage on the applied part)
Mechanical safety	Control panel Mounting mechanism of peripherals Other mechanical parts Transducer appearance
Image	Images in each mode Images obtained from standard transducers

13.3 Troubleshooting

The following troubleshooting can be performed by users.

If any failure listed in the table below occurs, follow the measure in the table to troubleshoot it.

If you cannot restore the system from the failure after performing the measure, contact our company's Customer Service Department or your local distributor.

Failure	Measure
The system does not work after it is powered on.	After turning off the system, perform the following checks: <ol style="list-style-type: none"> 1. Check if the power cable is connected to the outlet. 2. Check if the power supply is normal. Turn on the system again.
The system works but the screen does not display.	<ol style="list-style-type: none"> 1. Turn the brightness knob and contrast knob to adjust the brightness and contrast of screen. 2. If the screen still displays nothing, turn off the system and then turn it on again (after turning off the system, wait at least 10 seconds before turning it on again).
The screen displays characters but no images.	<ol style="list-style-type: none"> 1. Check if the transducer is connected to the system properly. 2. If the image is frozen, unfreeze it. 3. Turn the gain knob or press TGC keys. 4. If the screen still displays no images, turn off the system and then turn it on again (after turning off the system, wait at least 10 seconds before turning it on again).
The image is abnormal.	<ol style="list-style-type: none"> 1. Select a proper exam mode. 2. Adjust the image.
The screen displays abnormally.	Turn off the system and then turn it on again (after turning off the system, wait at least 10 seconds before turning it on again).
An error message displays on the screen and always displays.	Turn off the system and then turn it on again (after turning off the system, wait at least 10 seconds before turning it on again).
An operation cannot be performed.	Turn off the system and then turn it on again (after turning off the system, wait at least 10 seconds before turning it on again).

14 Acoustic Power Principle

14.1 Concerns with Bioeffects

Diagnostic ultrasound is recognized as being safe. In fact, there have been no reports of injuries to patients caused by diagnostic ultrasound.

It cannot be stated categorically that ultrasound is 100% safe. Studies have revealed that ultrasound with extremely high intensity is harmful to body tissues.

Diagnostic ultrasound technology has made a great leap forward during the last several years. This rapid advance has generated concerns about the potential risk of bioeffects when new applications or diagnostic technologies become available.

14.2 Prudent Use Statement

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

14.3 ALARA

It is required to practice ALARA (As Low As Reasonably Achievable) when using ultrasound energy. Practicing ALARA ensures that the total energy level is controlled below a low enough level at which bioeffects are not generated while diagnostic information is being accumulated. The total energy is controlled by output intensity and total radiation time. The output intensity necessary for examinations differs depending on the patient and the clinical case.

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

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

It was verified that the MI and TI values didn't exceed 1.0 in each exam mode.

14.4 Derated Ultrasonic Output Parameters

In order to determine the relevant Ultrasonic Output Parameters, a method is used which allows for the comparison of ultrasound systems which operate at different frequencies and are focused at different depths. This approach, called "derating" or "attenuating", adjusts the acoustic output as measured in a water tank to account for the effect of ultrasound propagation through tissue. By convention, a specific average intensity attenuation value is used, which corresponds to a loss of 0.3 dB/cm/MHz. That is, the intensity of ultrasound will be reduced by 0.3 dB/MHz for every centimeter of travel from the transducer. This can be expressed by the following equation:

$$I_{atten} = I_{water} \times 10^{(-0.3/10 \times f_c \times z)}$$

Where I_{atten} is the attenuated intensity, I_{water} is the intensity measured in a water tank (at distance z), f_c is the center frequency of the ultrasound wave (as measured in water), and z is the distance from the transducer. The equation for attenuating pressure values is similar except that the attenuation coefficient is 0.15 dB/cm/MHz, or one-half the intensity coefficient. The intensity coefficient is double the pressure coefficient because intensity is proportional to the square of pressure.

Although the attenuation coefficient chosen, 0.3 dB/cm/MHz, is significantly lower than any specific solid tissue in the body, this value was chosen to account for fetal examinations. In early trimester ultrasound fetal examinations, there may be a significant fluid path between the transducer and the fetus, and the attenuation of fluid is very small. Therefore the attenuation coefficient was lowered to account for this case.

It was verified that the MI and TI values didn't exceed 1.0 in each exam mode.

14.5 Measurement Uncertainty

Total Uncertainty for Mechanical Index	16.4 %		
	Non-scan Mode	Scan-Mode	Combined-Mode
Total Uncertainty for TIS	32.9%	5.1%	32.9% or 5.1% ($A_{aprt} > 1$)
			33.4% ($A_{aprt} \leq 1$)
Total Uncertainty for TIB	32.9%	5.1%	32.9% or 5.1%
Total Uncertainty for TIC	32.9%	5.1%	33.4%

14.6 Parameters Affecting Acoustic Power

Acoustic Power is affected by transmission conditions (focus, drive frequency, voltage applied to piezoelectric elements, etc.), scan conditions, settings, etc.

14.7 Imaging Functions Changing 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 acoustic output power will change as the operator changes the active transducer.
Imaging Mode change	Since B and M modes use different 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.
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 PRF, and thus changes the acoustic output power.
Number of focuses	Since the number of focuses influences the frame rate and the actual position of the focuses, changing the number of focuses 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 focus is moved closer to the transducer.
Freeze	Active the freeze function stops the electrical energy transmit part of the system, thus disabling the system from generating ultrasound wave.
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.

Operation	Effect on the acoustic output power
Reset or Power Off/On	Resetting or turning on/off the system causes the system to return to the default status thus may change the acoustic output power.

14.8 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

Appendix A System Configuration

A.1 Basic Configuration

Main unit

Accessories

- a) Operator's manual
- b) Gel
- c) Power cord of the main unit
- d) Probe holder
- e) Gel holder
- f) Remote cable of printer

A.2 Options

- DICOM software: DICOM3.0
- Mobile trolley: UMT-110
- Portable package
- Foot switch: 971-SWNOM
- Keyboard dust-proof cover
- Dual-transducer socket
- Needle-guided bracket
- Dust-proof cover

A.3 Optional Transducers

Model	Intended Use	Applied Region
35C50EB	Gynecology, Obstetrics, Pediatric, Abdominal	Body surface
65EC10EB	Gynecology, Obstetrics, Urology,	Transvaginal, Transrectal
75L38EB	Small organ, Pediatric, Cephalic, Vascular, Musculo-skeletal	Body surface
65C15EA	Pediatric, Cephalic, Abdominal	Body surface
75L60EA	Small organ, Pediatric, Cephalic, Vascular, Musculo-skeletal	Body surface
35C20EA	Gynecology, Obstetrics, Abdominal, Pediatric, Cardiac	Body surface

A.4 Peripherals

- USB storage device
- Footswitch
- Video printer
- Graph/text printer

The system supports the USB storage devices using FAT16 or FAT 32 file format and SCSI instructions.

The system supports the following video printers:

- SONY UP-895MD
- SONY UP-897MD
- MITSUBISHI P93W

The system supports the following graph/text printers (local print):

- HP DeskJet 5652/5650/3820/1280 (USB port)
- Business Inkjet 1200 (USB port)
- HP LaserJet2420d (USB port)
- HP DeskJet6548 (USB port)

Appendix B Specifications

B.1 Image Mode

The system supports the following image modes:

- B
- M
- B/B
- M/B

B.2 Power Supply

Voltage: 100-240V~

Frequency: 50/60 Hz

Input current: 1.0-0.5A

Fuse: 250V~ T3.15AH

B.3 Environment Conditions

B.3.1 Operating Environment

Ambient temperature: 0°C-40°C

Relative humidity: 30%-85% (no condensation)

Atmospheric pressure: 700hPa-1060hPa

B.3.2 Storage and Transportation Environment

Ambient temperature: -20°C-55°C

Relative humidity: 30%-95% (no condensation)

Atmospheric pressure: 700hPa-1060hPa

B.4 Size and Weight

Size (excluding handle and transducer holder): 290mm×354mm×161mm

(Wide×Height×Depth)

Weight (without accessories): <6 kg

Appendix C Measurement Accuracy

Within the selected field range, the measurement accuracy is ensured within the range mentioned above. The accuracy specifications are performance in the worst conditions, or based on the real test for the system.

■ Depth and time

Item	Error range
Depth	Range: full screen $\leq \pm 4\%$
M-mode image time	Range: full time-axis display $\leq \pm 0.3\%$

■ Accuracy of Measurement

Item	Error range
Distance/Depth	Range: full screen $\leq \pm 4\%$, or < 2 mm if measured value is less than 40 mm
Area (Trace)	Range: full screen $\leq \pm 8\%$, or < 130 mm ² if measured value is less than 1600 mm ²
Area (Ellipse)	Range: full screen $\leq \pm 8\%$, or < 130 mm ² if measured value is less than 1600 mm ²
Angle	Range: full screen $\leq \pm 3\%$
Circumference	$\leq \pm 20\%$

■ Time/Motion Measurements


Item	Error range
Distance	Range: full screen $\leq \pm 4\%$, or < 2 mm if measured value is less than 40 mm
Time	Range: full time-axis display $\leq \pm 1\%$
Heart Rate	Range: full time-axis display $\leq \pm 5\%$
Slope	Range: full time-axis display $\leq \pm 5\%$

■ Volume Measurements

Item	Error range
Volume	Range: full screen $\leq \pm 12\%$, or < 8000 mm ³ if measured value is less than 64000 mm ³

Appendix D Guidance and Manufacturer's Declaration

The system complies with the EMC standard IEC60601-1-2: 2007.

 **WARNING:** The use of unapproved accessories may diminish system performance.

NOTE: Use of accessories, transducers, and cables other than those specified may result in increased emission or decreased immunity of system.

The system should not be used adjacent to or stacked with other equipment. If adjacent or tacked use is necessary, system should be observed to verify normal operation in the configuration in which it will be used.

The system needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.

Preventing conducted RF immunity. Due to technological limitations, the conducted RF immunity level are limited to 1Vrms level, conducted RF interference above 1Vrms may cause wrong diagnosis and measurements. We suggest that you position system further from sources of conducted RF noise.

Operation of system, in the case that the patient physiological signal is lower than the minimum amplitude or value specified in the product specifications, may cause inaccurate results.

Portable and mobile RF communications equipment can affects system. See tables 1, 2, 3, and 4 below.

TABLE 1

GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC EMISSIONS		
The system is intended for use in the electromagnetic environment specified below. The customer or the user of system should assure that it is used in such an environment.		
EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIROMENT— GUIDANCE
RF emissions CISPR 11	Group1	The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	system 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 IEC61000-3-2	Class A	
Voltage Fluctuations/Flicker Emissions IEC61000-3-3	Compliance	

TABLE 2

GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC IMMUNITY

The system is intended for use in the electromagnetic environment specified below. The customer or the user of system should assure that it is used in such an environment.


IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT-GUIDANCE
Electrostatic Discharge(ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast Transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, Short interruptions and voltage variation on power supply input 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 cycle 70% U_T (30% dip in U_T) for 25 cycle <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycle 70% U_T (30% dip in U_T) for 25 cycle <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If you require continued operation during power mains interruptions, it is recommended that our product be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 HZ) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the A.C. mains voltage prior to application of the test level.

TABLE 3

GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC IMMUNITY

The system is intended for use in the electromagnetic environment specified below. The customer or the user of system should assure that it is used in such an environment.

IMMUNITY TEST	IEC 60601-1-2 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT-GUIDANCE
Conducted RF IEC 1000-4-6	3 Vrms 150kHz to 80MHz	1 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 3.5 \times \sqrt{P}$ $d = 1.2 \times \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \times \sqrt{P}$ 800 MHz to 2.5GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).b
Radiated RF IEC 1000-4-3	3 V/m 80MHz to 2.5 GHz	3V/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.

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

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

TABLE 4

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATION AND system

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

Rated Maximum Output power of Transmitter W	Separation Distance According to Frequency of Transmitter m		
	150kHz -80MHz $d = 3.5\sqrt{P}$	80MHz -800MHz $d = 1.2\sqrt{P}$	800MHz -2.5GHz $d = 2.3\sqrt{P}$
0.01	0.35	0.12	0.23
0.1	1.11	0.37	0.74
1	3.50	1.17	2.34
10	11.07	3.69	7.38
100	35.00	11.67	23.34

For transmitters at a maximum output power not listed above, the recommended separation distanced in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

If system image distortion occurs, it may be necessary to position system further from sources of conducted RF noise or to install external power source filter to minimize RF noise to an acceptable level.

Note 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Appendix E Maximum Surface Temperature of Transducers

According to the requirements of the section 42.3 in the standard IEC 60601-2-37: 2007, the transducer surface temperature has been tested in two kinds of conditions: the transducer suspended in still air or transducer contacting human-tissue mimicking material. The calculation of the expanded uncertainty is based on the ISO Guide to the Expression of uncertainty in measurement. Three transducer samples have been tested and the confidence coefficient is at 95%, the value of $t_{.975}$ is 4.30.

* The measurement data were obtained under the test conditions employed at Mindray.

Transducer model	Maximum surface temperature (°C) ^{*1} Contacting TMM	Maximum surface temperature (°C) ^{*1} Suspending in air
35C50EB	38.87±0.40	34.97±0.31
65EC10EB	31.50±0.37	31.40±0.37
75L38EB	38.57±0.47	34.20±0.57
65C15EA	38.03±0.47	31.93±0.40
75L60EA	39.23±0.40	35.40±0.37
35C20EA	36.67 ±0.40	30.90±0.37

*1: Values following the "±" mark indicate the expanded uncertainty with a confidence level of 95%, $t_{.975} = 4.30$.

Appendix F Acoustic Output Reporting Table(61157-2007)

F.1 35C20EA

Mode Parameter	B	M	B+M
System settings Standard used: IEC 61157 Ed2	Display depth10.8cm focus 8cm AP100%	Display depth10.8cm focus 8cm AP100%	Display depth10.8cm focus 8cm AP100%
p_r (MPa)	0.75±0.12	0.75±0.12	0.75±0.12
I_{spta} (mW/cm ²)	0.38±0.12	9.81±3.24	10.19±3.37
I_{ob} (mW/cm ²)	0.53±0.18	0.16±0.05	0.88±0.29
Power output (mW)	8.43±0.48	2.54±0.14	13.93±0.74
Output beam dimensions ^a (∅) (mm)	44.95	44.95	44.95
Z_p (mm)	5.07±0.25	5.07±0.25	5.07±0.25
w_{12} () (mm)	12.80±0.13	5.57±0.13	12.80±0.13
w_{12} (⊥) (mm)	1.24±0.13	7.00±0.13	1.24±0.13
f_{awf} (MHz)	3.29±0.08	3.29±0.08	3.29±0.08
prf (KHz)	-	1,000.00±1.00	1,000.00±1.00
srr (Hz)	45.00±1.00	-	16.00±1.00
Z_{tt} (mm)	1.51	1.51	1.51
Z_{ts} (mm)	contact	contact	contact
Acoustic output freeze	Yes	Yes	Yes
Inclusive modes	-	-	-
a: D_{eq} , equivalent aperture diameter, in IEC60601-2-37			

F.2 65C15EA

Mode Parameter	B	M	B+M
System settings Standard used: IEC 61157 Ed2	Display depth4.31cm focus 2.5cm AP100%	Display depth4.31cm focus 2.5cm AP100%	Display depth4.31cm focus 2.5cm AP100%
p_r (MPa)	2.27±0.37	2.27±0.37	2.27±0.37
I_{spta} (mW/cm ²)	2.31±0.76	56.18±18.53	58.47±19.29
I_{ob} (mW/cm ²)	13.89±4.57	2.41±0.79	13.40±4.42
Power output (mW)	8.53±0.46	1.48±0.08	8.23±0.47
Output beam dimensions ^a (∅) (mm)	8.84	8.84	8.84
Z_p (mm)	1.66±0.25	1.66±0.25	1.66±0.25
w_{12} () (mm)	1.02±0.13	3.69±0.13	1.02±0.13
w_{12} (⊥) (mm)	0.60±0.13	2.80±0.13	0.60±0.13
f_{awf} (MHz)	6.40±0.16	6.40±0.16	6.40±0.16
prf (KHz)	-	1,000.00±1.00	1,000.00±1.00
srr (Hz)	45.00±1.00	-	16.00±1.00
Z_{tt} (mm)	1.15	1.15	1.15
Z_{ts} (mm)	contact	contact	contact
Acoustic output freeze	Yes	Yes	Yes
Inclusive modes	-	-	-
a: D_{eq} ,equivalent aperture diameter,in IEC60601-2-37			

F.3 75L60EA

Mode Parameter	B	M	B+M
System settings Standard used: IEC 61157 Ed2	Display depth2.16cm focus 2cm AP100%	Display depth2.16cm focus 2cm AP100%	Display depth2.16cm focus 2cm AP100%
p_r (MPa)	2.21±0.36	2.21±0.36	2.21±0.36
I_{spta} (mW/cm ²)	7.56±2.49	87.07±28.71	94.63±31.20
I_{ob} (mW/cm ²)	3.95±1.30	1.93±0.64	6.22±2.05
Power output (mW)	7.77±0.42	3.79±0.20	12.23±0.64
Output beam dimensions ^a (∅) (mm)	15.82	15.82	15.82
Z_p (mm)	1.44±0.25	1.44±0.25	1.44±0.25
w_{12} () (mm)	3.93±0.13	3.64±0.13	3.93±0.13
w_{12} (⊥) (mm)	0.50±0.13	2.85±0.13	0.50±0.13
f_{awf} (MHz)	6.29±0.16	6.29±0.16	6.29±0.16
prf (KHz)	-	1,000.00±1.00	1,000.00±1.00
srr (Hz)	45.00±1.00	-	16.00±1.00
Z_{tt} (mm)	1.15	1.15	1.15
Z_{ts} (mm)	contact	contact	contact
Acoustic output freeze	Yes	Yes	Yes
Inclusive modes	-	-	-
a: Deq ,equivalent aperture diameter,in IEC60601-2-37			

F.4 35C50EB

Mode Parameter	B	M	B+M
System settings Standard used: IEC 61157 Ed2	Display depth8.62cm focus 7cm AP100%	Display depth8.62cm focus 7cm AP100%	Display depth8.62cm focus 7cm AP100%
p_r (MPa)	1.23±0.20	1.23±0.20	1.23±0.20
I_{spta} (mW/cm ²)	2.10±0.69	47.54±15.72	49.60±16.40
I_{ob} (mW/cm ²)	1.73±0.57	1.61±0.53	1.63±0.54
Power output (mW)	5.37±0.31	4.97±0.26	5.05±0.30
Output beam dimensions ^a (∅) (mm)	19.85	19.85	19.85
Z_p (mm)	5.51±0.25	5.51±0.25	5.51±0.25
w_{12} () (mm)	2.50±0.13	4.50±0.13	2.50±0.13
w_{12} (⊥) (mm)	1.24±0.13	6.15±0.13	1.24±0.13
f_{awf} (MHz)	3.52±0.09	3.52±0.09	3.52±0.09
prf (KHz)	-	1,000.00±1.00	1,000.00±1.00
srr (Hz)	45.00±1.00	-	16.00±1.00
Z_{tt} (mm)	1.19	1.19	1.19
Z_{ts} (mm)	contact	contact	contact
Acoustic output freeze	Yes	Yes	Yes
Inclusive modes	-	-	-
a: D_{eq} , equivalent aperture diameter, in IEC60601-2-37			

F.5 65EC10EB

Mode Parameter	B	M	B+M
System settings Standard used: IEC 61157 Ed2	Display depth2.16cm focus 2cm AP100%	Display depth2.16cm focus 2cm AP100%	Display depth2.16cm focus 2cm AP100%
p_r (MPa)	2.18±0.36	2.18±0.36	2.18±0.36
I_{spta} (mW/cm ²)	2.43±0.80	57.21±18.87	59.61±19.66
I_{ob} (mW/cm ²)	2.76±0.91	0.40±0.13	3.93±1.30
Power output (mW)	9.07±0.49	1.33±0.07	12.93±0.71
Output beam dimensions ^a (∅) (mm)	20.46	20.46	20.46
Z_p (mm)	1.44±0.25	1.44±0.25	1.44±0.25
w_{12} () (mm)	2.65±0.13	3.64±0.13	2.65±0.13
w_{12} (⊥) (mm)	1.24±0.13	2.48±0.13	1.24±0.13
f_{awf} (MHz)	6.59±0.17	6.59±0.17	6.59±0.17
prf (KHz)	-	1,000.00±1.00	1,000.00±1.00
srr (Hz)	45.00±1.00	-	16.00±1.00
Z_{tt} (mm)	1.19	1.19	1.19
Z_{ts} (mm)	contact	contact	contact
Acoustic output freeze	Yes	Yes	Yes
Inclusive modes	-	-	-
a: D_{eq} ,equivalent aperture diameter,in IEC60601-2-37			

F.6 75L38EB

Mode Parameter	B	M	B+M
System settings Standard used: IEC 61157 Ed2	Display depth6.47cm focus 3cm AP100%	Display depth6.47cm focus 3cm AP100%	Display depth6.47cm focus 3cm AP100%
p_r (MPa)	2.55±0.42	2.55±0.42	2.55±0.42
I_{spta} (mW/cm ²)	9.00±2.97	84.88±27.99	93.88±30.96
I_{ob} (mW/cm ²)	11.89±3.92	1.81±0.60	16.67±5.49
Power output (mW)	9.13±0.53	1.39±0.07	12.80±0.70
Output beam dimensions ^a (∅) (mm)	9.89	9.89	9.89
Z_p (mm)	1.42±0.25	1.42±0.25	1.42±0.25
w_{12} () (mm)	1.54±0.13	2.75±0.13	1.54±0.13
w_{12} (⊥) (mm)	0.50±0.13	2.87±0.13	0.50±0.13
f_{awf} (MHz)	6.68±0.17	6.68±0.17	6.68±0.17
prf (KHz)	-	1,000.00±1.00	1,000.00±1.00
srr (Hz)	45.00±1.00	-	16.00±1.00
Z_{tt} (mm)	1.05	1.05	1.05
Z_{ts} (mm)	contact	contact	contact
Acoustic output freeze	Yes	Yes	Yes
Inclusive modes	-	-	-
a: D_{eq} ,equivalent aperture diameter,in IEC60601-2-37			

Appendix G Safety Classification

No.	Standard of Classification	Type of Product
1	According to the type of protection against electric shock	CLASS I EQUIPMENT or EQUIPMENT WITH INTERNAL POWER SUPPLY
2	According to the degree of protection against electric shock	EQUIPMENT WITH TYPE-BF APPLIED PARTS
3	Degree of protection against harmful ingress of water	Enclosure: IPX0, transducers: IPX7, foot switch: IPX8.
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	PORTABLE EQUIPMENT MOBILE EQUIPMENT (when mounted onto the mobile trolley)

Appendix H Input of Characters

This appendix describes how to input characters from the keyboard.

To input characters

Press keys on the keyboard to input characters.

Pressing <Caps Lock> can switch between the uppercase and lowercase. For example, if the current letters are lowercase, press <Caps Lock> and then press letter keys. You can see the input letters become uppercase.

Other rules

To input a character shown in the upper part of a key, keep pressing <SHIFT> and press the key. For example, to input “♀” in the upper part of the “Q” key, keep pressing <SHIFT> and then press <Q>.

To input a blank, press <SPACE>.

During the input, to insert a character among the characters already input, press <→> or <←> to move the cursor where the character is to be inserted, and then input the character.

During the input, to delete a character already input, press <→> or <←> to move the cursor to the right of the character to be deleted, and then press .

Appendix I 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.

I.1 Power Cord Plug

I.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.

I.1.2 Device Enclosure and Accessories

I.2 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.).

I.2.1 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.

I.3 Device Labeling

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

- Main unit label
- Integrated warning labels

I.4 Protective Earth Resistance

- Plug the probes of the analyzer into the device's protective earth terminal and protective earth terminal of the AC power cord.
- Test the earth resistance with a current of 25 A.
- Verify the resistance is less than limits.

■ LIMITS

ALL COUNTRIES R = 0.2 Ω Maximum

I.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 μ A in Normal Condition.
- 1000 μ A in Single Fault Condition.

For IEC60601-1,

- 500 μ A in Normal Condition.
- 1000 μ A in Single Fault Condition.

I.6 Enclosure Leakage Test

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

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

■ LIMITS

For UL60601-1,

- 100 μ A in Normal Condition.
- 300 μ A in Single Fault Condition.

For IEC60601-1:

- 100 μ A in Normal Condition.
- 500 μ A in Single Fault Condition.

I.7 Patient Leakage Current

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

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

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

■ LIMITS

For BF  applied parts,

- 100 μ A in Normal Condition.
- 500 μ A in Single Fault Condition.

I.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 μ A.


I.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,

- 100 μ A in Normal Condition.
- 500 μ A 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.

