DC-90/DC-88/DC-90S/DC-90Q/DC-95/DC-95S/DC-88S/DC-80A/DC-80A Exp/DC-80A Pro/DC-8X/DC -8Q/DC-81/DC-82

**Diagnostic Ultrasound System** 

# **Operator's Manual**

[Basic Volume]

# **Contents**

C	onten	nts	i
	Intell	ectual Property Statement	I
		ponsibility on the Manufacturer Party	
		anty	
	E	xemptions	II
	С	ustomer Service Department	III
	Impo	rtant Information	IV
	Abou	ıt This Manual	IV
	Nota	tion Conventions	IV
	Oper	rator's Manuals	V
	Hard	copy Manuals	V
		vare Interfaces in this Manual	
	Conv	ventions	VI
	Prod	uct Difference	VI
1	Sat	fety Precautions	1-1
	1.1	Safety Classifications	1-1
	1.2	Meanings of Signal Words	
	1.3	Meaning of Safety Symbols	
	1.4	Safety Precautions	
	1.5	Latex Alert	
	1.6	Warning Labels	1-10
2	Sv	stem Overview	2-1
	2.1	Intended Use	
	2.2	Contraindication	
	2.3	Product and Model Code	
	2.4	Product Specifications	
	2.5	System Configuration	
	2.6	Introduction of Each Unit	
	2.7	I/O Panel	2-8
	2.8	Power Supply Panel	2-9
	2.9	Physio Panel	
	2.10	Control Panel	2-11
	2.11	Symbols	2-15
3	Sy	stem Preparation	3-1
	3.1	Move/Position the System	
	3.2	Connecting the Power Cord & Protective Grounding	
	3.3	Monitor Adjustment	
	3.4	Control Panel Position Adjustment	
	3.5	Connecting a Probe	
	3.6	Connecting Peripheral Devices	
	3.7	Installing a Printer	
	3.8	Basic Screen & Operation	
4	Exa	am Preparation	4-1
	4.1	Patient Information	
	4.2	Select Exam Mode and Probe	
	4.3	Select the Imaging Mode	

	4.4	Activate & Continue an Exam	4-9
	4.5	Pause & End an Exam	4-10
5	lma	age Optimization	5-1
	5.1	Imaging Mode	5-1
	5.2	B Mode Image Optimization	5-3
	5.3	M Mode Image Optimization	5-10
	5.4	Color Mode Image Optimization	5-12
	5.5	Power Mode Image Optimization	5-18
	5.6	PW/CW Doppler Mode	5-20
	5.7	Color M Mode	5-26
	5.8	Anatomical M Mode	5-27
	5.9	TDI	5-30
	5.10	3D/4D	5-35
	5.11	Contrast Imaging	5-76
	5.12	iScape View (Real-time Panoramic Imaging)	5-82
	5.13	Elastography	5-86
	5.14	Stress Echo	5-94
	5.15	Tissue Tracking Quantitative Analysis (QA)	5-103
	5.16	Fusion Imaging	5-108
	5.17	RIMT (Real-time Intima-Media Thickness)	5-133
	5.18	Smart Pelvic Floor	5-134
6	Dis	play & Cine Review	6-1
	6.1	Splitting Display	6-1
	6.2	Image Magnification	
	6.3	Freeze/Unfreeze the Image	
	6.4	Cine Review	
	6.5	Image Compare	
	6.6	Cine Saving	
	6.7	Setting Cine Length	
7	Phy	ysiological Signal	7-1
-	7.1	ECG	
	7.2	Respiratory Wave	
_			
8	Me	asurement	
	8.1	Basic Operations	8-1
	8.2	General Measurements	
	8.3	Application Measurements	
	8.4	Measurement Accuracy	8-4
9	Co	mments and Body Marks	9-1
	9.1	Comments	9-1
	9.2	Body Mark	9-5
10	Pat	ient Data Management	10-1
		Patient Information Management	
	10.2	Image File Management	
	_	Report Management	
		iStation - Patient Data Management	
	10.5	iStorage	
		Print	
		Back Up Files using the DVD Drive	

		Patient Task Management	
		Administration	
	10.10	V-Access	10-25
11	DIC	OM/HL7	11-1
	11.1	DICOM Preset	11-2
	11.2	Verify Connectivity	11-10
	11.3	DICOM Services	11-11
	11.4	DICOM Media Storage	11-15
	11.5	Structured Report	
	11.6	Showcase Recording	11-17
	11.7	DICOM Task Management	11-17
12	Set	up	12-1
		System Preset	
		Exam Mode Preset	
		Measurement Preset	
		Comment Preset	
	12.5	iWorks Preset	
	12.6	Stress Echo Preset	
		DICOM/HL7 Preset	
		Print Preset	
	12.9	Network Preset	
	12.10	Maintenance	
		Security	
		System Information	
13		bes and Biopsy	
		Probes	
		Biopsy Guide	
		Middle Line	
14		Recording	
		DVR Recording	
		Send Image	
	14.3	DVR Video Replay	14-2
15	Acc	oustic Output	15-1
	15.1	Concerns with Bioeffects	15-1
	15.2	Prudent Use Statement	15-1
	15.3	ALARA Principle (As Low As Reasonably Achievable)	15-1
	15.4	MI/TI Explanation	
	15.5	Acoustic Power Setting	15-3
	15.6	Acoustic Power Control	15-4
	15.7	Acoustic Output	15-4
	15.8	Measurement Uncertainty	15-5
	15.9	References for Acoustic Power and Safety	15-6
16	EM	C Guidance and Manufacturer's Declaration	16-1
17	Svs	tem Maintenance	17-1
	-	Daily Maintenance	
		Troubleshooting	
Αp	pend	-	

Appendix B	Barcode Reader	B-1
Appendix C	iWorks (Auto Workflow Protocol)	C-1
Appendix D	Wireless LAN	D-1
Appendix E	Battery	E-1
Appendix F	Ultrasound Gel Warmer	F-1
Appendix G	Electrical Safety Inspection	G-1
Appendix H	Indications For Use	H-1
1. 1		

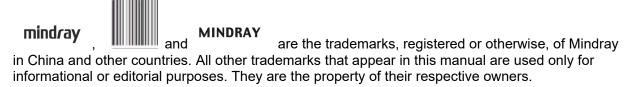
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# Responsibility on the Manufacturer Party

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.



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.

### **Customer Service Department**

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# **Important Information**

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

### **About This Manual**

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

### **Notation Conventions**

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

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

**∆**CAUTION:

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

U.S.A. Federal Law restricts this device to sale by or on the order of a physician.

# **Operator's Manuals**

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

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

# **Hardcopy Manuals**

- Operator's Manual [Basic Volume]
  - Describes the basic functions and operations of the system, safety precautions, exam modes, imaging modes, preset, maintenance and acoustic output, etc.
- Operator's Manual [Advanced Volume]
- Operator's Manual [Acoustic Power Data and Surface Temperature Data]
   Contains data tables of acoustic output for transducers.
- Operation Note

Contains a quick guide for basic system operations.

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

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

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

### Software Interfaces in this Manual

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

# **Conventions**

In this manual, the following conventions are used to describe the buttons on the control panel, items in the menus, buttons in the dialog boxes and some basic operations:

- <Buttons>: angular brackets indicate buttons, knobs and other controls on the control panel or on the keyboard.
- [Items in menu or buttons in dialog box]: square brackets indicate items in menus, on the soft menu or buttons in dialog boxes.
- Click [Items or Buttons]: move the cursor to the item or button and press <Set> or use the soft key corresponding to the soft menu.
- [Items in menu] → [Items in submenu]: select a submenu item following the path.

# **Product Difference**

Product Model	B-Histogram	B-Profile	Color Vel	Double dist	Trace Len(Spline)	Parallel
DC-90	√	√	V	√	V	√
DC-90S	√	√	<b>√</b>	√	V	х
DC-90Q	х	√	х	√	V	<b>√</b>
DC-95	√	х	V	√	V	√
DC-95S	√	х	<b>√</b>	√	V	х
DC-88	√	√	х	х	V	√
DC-88S	√	√	х	х	V	х
DC-80A	√	√	V	√	х	√
DC-80A Exp	√	√	х	√	х	<b>√</b>
DC-80A Pro	√	х	V	√	х	√
DC-8X	х	√	<b>√</b>	√	х	<b>√</b>
DC-8Q	V	х	х	√	х	<b>√</b>
DC-81	х	х	<b>√</b>	√	х	<b>√</b>
DC-82	х	<b>√</b>	х	√	х	√

# **1** Safety Precautions

# 1.1 Safety Classifications

- According to the type of protection against electric shock:
   Externally powered CLASS I EQUIPMENT + internally powered equipment
- According to the degree of protection against electric shock:

Type-BF applied part

According to the degree of protection against harmful ingress of water:

The main unit is rated IPX0

The probes are rated IPX7

The foot switch is rated IPX8

- According to the disinfection and sterilization method(s) recommended by manufacturer: Equipment with disinfection and sterilization method(s) recommended by manufacturer.
- According to the degree of safety of application in the presence of a FLAMMABLE ANESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE
   EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE
- According to the mode of operation:

**CONTINUOUS OPERATION** 

■ Does the equipment has any defibrillation-proof applied parts:

Non-defibrillation-proof applied part

■ Permanently installed equipment or non-permanently installed equipment:

Non-permanently installed equipment

# 1.2 Meanings of Signal Words

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

Signal word	Meaning
<b>△</b> DANGER	Indicates an imminently hazardous situation that, if not avoided, will result in death or serious injury.
<b>∆</b> WARNING	Indicates a potentially hazardous situation that, if not avoided, could result in death or serious injury.
<b>△</b> CAUTION	Indicates a potentially hazardous situation that, if not avoided, may result in minor or moderate injury.
NOTE	Indicates a potentially hazardous situation that, if not avoided, may result in property damage.
Description	Important information that helps you use the system more effectively.

# 1.3 Meaning of Safety Symbols

Symbol	Description		
	Type-BF applied part		
∱	The ultrasound probes connected to this system are type-BF applied parts.		
	The ECG leads within this system are type-BF applied parts.		
$\triangle$	Caution.		
<u>^</u>	General warning sign.		
	Patient injury or tissue damage from ultrasonic radiation. The ALARA principle must be practiced when operating the ultrasound system.		

# 1.4 Safety Precautions

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

**⚠DANGER**:

Do not operate this system and probes in an atmosphere containing flammable gases or liquids such as anesthetic gases, hydrogen and ethanol, because there is danger of explosion.

# **≜**WARNING:

- Connect the power plug of this system to wall receptacles that meet the ratings indicated on the nameplate. If adapters or multifunctional receptacles are used, it may cause the leakage current to exceed the safety requirements.
- 2. Within 1.5 meters of the patient, connect peripherals to an auxiliary power outlet which is capable of isolation protection, or power peripherals by an auxiliary output cable or isolation transformer which complies with IEC 60601-1 in Chapter 16 or a power input of the same safety level.
- 3. DO NOT use different-phase power supplies to power peripherals, such as air conditioning power supply.
- 4. When using peripherals which are not powered by the ultrasound system's auxiliary output, or peripherals other than those permitted by Mindray, ensure the overall leakage current of peripherals and the ultrasound system meets the requirement of the local medical device electrical regulations (e.g., the touch leakage current should be no more than 500uA as per IEC 60601-1 in Chapter 16), and the responsibility is held by the user.
- 5. Connect the grounding conductor before turning the system ON. Disconnect the grounding cable after turning the system OFF. Failure to do so may result in electric shock.
- 6. For connecting power and grounding, follow the appropriate procedures described in this operator's manual. Failure to do so may result in the risk of electric shock. Do not connect the grounding cable to a gas pipe or water pipe. This may lead to improper grounding or a gas explosion.
- Before cleaning the system, disconnect the power cord from the outlet. Failure to do so may result in system failure and electric shock.
- 8. This system is not waterproof. Do not use this system in any location where water leakage may occur. If any water is sprayed on or into the system, this may lead to electric shock. If water is accidentally sprayed on or into the system, contact the Mindray Customer Service Department or a sales representative.
- 9. DO NOT use a probe that has a damaged or scratched surface, or exposed wiring of any kind. Immediately stop using the probe and contact the Mindray Customer Service Department or a sales representative. There is a risk of electric shock if using a damaged or scratched probe.

- 10. Do not allow the patient to come into contact with live parts of the ultrasound system or other devices, e.g., signal I/O ports. This may lead to electric shock.
- 11. Do not use an aftermarket probe other than those specified by Mindray. Such probes may damage the system causing a profound failure, with fire being the worst-case scenario.
- 12. Do not subject the probes to knocks or drops. Use of a defective probe may lead to electric shock.
- 13. Do not open the covers or the front panel of the system. Short circuit or electric shock may occur when the system hardware is exposed and powered on.
- 14. Do not use this system when any digital device, such as a high-frequency electrotome, high-frequency therapy device or defibrillator, is already applied. This would result in a risk of electric shock to the patient.
- 15. Only use the ECG leads provided with the physiology module. Failure to do so may result in electric shock.
- 16. When moving the system, hold the handle. Failure to do so may result in damage by abnormal force. Do not push the system from the left/right side. This may cause it to topple over.
- 17. The system's auxiliary power output is used to supply power for the recommended peripheral devices. Do not connect other devices to the outlet. The rated output power limitation may be exceeded and this may lead to failure.
- 18. Additional equipment (analog or digital) connected to the ultrasound system must comply with the relevant IEC standards (e.g., IEC 60950 information technology equipment safety standard and IEC 60601-1 medical equipment standard). Furthermore, all configurations must comply with the standard IEC 60601-1. It is the responsibility of the person who connects the additional equipment to the signal input or output ports and configures a medical system to verify that the system complies with the requirements of IEC 60601-1 in Chapter 16. If you have any questions regarding these requirements, consult your sales representative.
- 19. Prolonged and repeated use of keyboards may result in hand or arm nerve disorders for some individuals. Observe local safety or health regulations concerning the use of keyboards.
- 20. When using intra-cavity probes, do not activate the probe outside the patient's body.
- 21. DO NOT touch the Signal I/O ports if in contact with the patient. This may lead to electric shock.
- 22. To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- 23. Connecting electrical equipment to MSO effectively leads to creating an ME SYSTEM, and can result in a reduced level of safety.

- 24. Use detachable power supply cord as mains power breaking device. DO NOT set equipment in place where difficult for disconnection of detachable power supply cord!
- 25. Do not modify this equipment without authorization of the manufacturer.
- 26. Always read and follow carefully the manufacturer instructions on the contrast agent label.
- 27. When using a probe, pay attention to the status of the ultrasound image. Do not use the probe to perform image acquisition when the image is frozen.

### **ACAUTION:**

Precautions concerning clinical examination techniques:
 This system must only be used by qualified medical professionals.
 This operator's manual does not describe clinical examination

techniques. The clinician should select the proper examination techniques based on specialized training and clinical experience.

2. Malfunctions due to radio waves:

If a device emitting radio waves is used in the proximity of this system, it may interfere with operations. Do not use or take any devices transmitting RF signals (such as cellular phones, transceivers and radio-controlled products) into the room where the system is located.

If a person brings a device that generates radio waves near the system, ask him/her to immediately turn the device OFF.

3. Precautions concerning moving the system:

Install the system on a flat surface with the casters locked. Accidental moving may result in damage.

Do not move the system laterally. This may result in damage in case of toppling.

If on a slope, the system should be moved slowly by two people. Unexpected sliding may result in damage.

Do not sit on the system. This may result in the individual falling if the system moves.

Objects placed on the monitor may fall and result in injury to individuals.

Fasten and fully secure any peripheral devices before moving the system. Loose peripheral devices may fall and result in injury to individuals.

When moving the system on steps, ensure the system does not topple.

4. If the circuit protector is tripped, it indicates that the system or a peripheral device was improperly shut down and the system is unstable. You cannot repair the system under this circumstance and must call the Mindray Customer Service Department or a sales representative.

- 5. There is no risk of high-temperature burns during normal ultrasound examinations. It is possible for the surface temperature of the probe to exceed the patient's body temperature due to factors involving environmental temperature and exam type. Do not apply the probe to the same region on the patient for a prolonged period of time. Apply the probe only for the period of time required for the purpose of diagnosis.
- 6. Do not use the system to examine a fetus for a prolonged period of time.
- 7. The system and its accessories are not disinfected or sterilized prior to delivery. The operator is responsible for cleaning and disinfecting probes and sterilizing biopsy brackets according to the manuals prior to use. All items must be thoroughly processed to completely remove harmful residual chemicals, which are not only harmful to the human body, but also damage the accessory.
- 8. It is necessary to press <End Exam> to end the current scan that is in progress and clear the current Patient Information field. Failure to do so may result in new patient data being combined with the previous patient's data.
- 9. Do not connect or disconnect the system's power cord or its accessories (e.g., a printer or a recorder) without turning the system power OFF first. This may damage the system and its accessories or cause electric shock.
- 10. If the system is improperly powered off during operation, it may result in damage to the data on the system hard drive or system failure.
- 11. Do not use a USB memory device (e.g., a USB flash drive, or a removable hard disk) which contains unsafe data. This may result in system damage.
- 12. It is recommended to only use the video devices specified in this manual.
- 13. Do not use gel, disinfectant, probes, probe sheath or needle-guided brackets that are not compatible with the system.
- 14. The applied contrast agents should be compliant with the relevant local regulations.
- 15. Read the Acoustic Output Principle in the operation manual carefully before operating this system in clinical examinations.
- 16. The cover contains natural rubber that can cause allergic reactions in some individuals.
- 17. Use ultrasound gel which complies with the relevant local regulations.
- 18. Normal operation may be affected by an unstable mains power supply. It is recommended that the product be powered from an uninterruptible power supply.
- 19. DO NOT expose the system to excessive vibration through transportation. Mechanical damage may result.

20. Always keep the system dry. Avoid transporting this system quickly from a cold place to a warm place; otherwise condensation or water droplets may form allowing a short circuit and possible electric shock.

#### NOTE:

- 1. DO NOT use the system in the vicinity of strong electromagnetic fields (such as transformers), which may affect the performance of the system.
- 2. Do not use the system in the vicinity of high-frequency radiation sources (e.g., cellular phones), which may affect the performance of the system or even lead to failure.
- 3. When using or positioning the system, keep the system level to avoid instability.
- 4. To avoid damaging the system, do not use it in the following environments:
  - Locations exposed to direct sunlight
  - Locations subject to sudden changes in environmental temperature
  - Dusty locations
  - Locations subject to vibration
  - Locations near heat generators
  - Locations with high humidity.
- 5. Turn the system ON only after the power has been turned OFF for a period of time. If the system is turned ON immediately after being turned OFF, the system may not reboot properly and could malfunction.
- 6. Press the <Freeze> key to freeze an image or turn off the system power before connecting or disconnecting a probe. Failure to do so can lead to the system and/or probe being damaged.
- 7. Remove the ultrasound gel from the face of the probe when the examination is complete. Water in the gel may enter the acoustic lens and adversely affect the performance and safety of the probe.
- 8. You should back up the system properly to a secure external storage media, including system configuration, settings and patient data. Data stored to the system's hard drive may be lost due to system failure, improper operation or accident.
- 9. Do not apply external force to the control panel. This can lead to the system being damaged.
- 10. If the system is used in a small room, the room temperature may rise. Provide proper ventilation and free air exchange.
- 11. To dispose of the system or any part thereof, contact the Mindray Customer Service Department or a sales representative. Mindray is not responsible for any system content or accessories that have been discarded improperly.
- 12. Electrical and mechanical performance may be degraded due to long usage (such as current leakage or distortion and abrasion). Image sensitivity and precision may also deteriorate. To ensure optimal system operation, it is recommended to maintain the system under a Mindray service agreement.
- 13. The replaceable fuse is inside the chassis. Refer replacement operations to Mindray service engineers or engineers authorized by Mindray only.
- 14. Do not turn OFF the system power supply during printing, file storage or invoking of other system operations. An interrupted process may not be completed, and can become lost or corrupted.

- 15. The iScape feature constructs a single extended image from a series of individual image frames. The quality of the final image is user-dependent and requires skill to efficiently apply the feature and technique. Exercise caution when measurements are performed from an iScape image.
- 16. Ensure that the current exam date and time are the same as the system date and time.
- 17. Use detachable cables as mains power breaking device.

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

# $\triangle$ WARNING:

- 1. The probe is only for use with the specified ultrasound diagnostic system. See "2.5.2 Probes and Needle-guided Brackets Available" to select the proper probe.
- 2. The ultrasonic probe must only be used by qualified professionals.
- Confirm that the transducer and probe cable appear normal before and after each examination. A defective probe may cause electric shock to the patient.
- 4. Do not subject the probe to shock. A defective probe may cause electric shock to the patient.
- Do not disassemble the probe to avoid the possibility of electric shock.
- 6. Never immerse the probe connector in liquids, such as water or disinfectant, as the connector is not waterproof. Immersion may cause electric shock or malfunction.
- 7. A probe sheath must be installed over the probe before performing intra-cavity or intra-operative examinations.

# **△ CAUTION**:

- When using the probe, wearing sterile gloves can help to prevent infection.
- 2. Be sure to use sterile ultrasound gel. Use ultrasound gel which complies with the relevant local regulations. and manage the ultrasound gel properly to ensure that it does not become a source of infection.
- 3. In normal diagnostic ultrasound mode, there is no danger of a normal-temperature burn. However, keeping the probe on the same region of the patient for a prolonged period of time may cause such a burn.
- 4. Do not use the carrying case to store the probe. If the carrying case is used for storage, it may become a source of infection.
- 5. The ALARA principle must be practiced when operating the ultrasound system. Minimize the acoustic power without compromising the quality of images.
- The probe and the accessories supplied with it are not delivered disinfected or sterilized. Sterilization (or high-level disinfecting) is required before use.

- 7. Disposable components should be packaged sterile and for singleuse only. Do not use if the integrity of the packaging has been violated or if the expiration date has passed. Use disposable components which comply with the relevant local regulations.
- 8. Use disinfection or sterilization solutions recommended in this operator's manual. Mindray will not be liable for damage caused by other solutions. If you have any questions, please contact the Mindray Customer Service Department or a sales representative.
- 9. Do not use pre-lubricated condoms as a sheath. Lubricant may not be compatible with the probe material and may result in damage.
- 10. Contact with improper gel or cleaner may result in damage to the probe:
  - DO NOT soak or saturate probes in a strong polar solution such as ethanol, chloride of lime, ammonium chloride, acetone or formaldehyde.
  - DO NOT bring the probe into contact with solutions or ultrasound gels containing oily mediums such as mineral oil or lanoline.

**NOTE:** Read the following precautions to prevent probe malfunction:

- Before connecting or disconnecting the probe, freeze or turn off the diagnostic ultrasound system.
- Clean and disinfect the probe before and after each examination.
- After an examination, wipe the ultrasound gel off thoroughly. Failure to do so may result in the ultrasound gel solidifying and the image quality being degraded.

Repeated disinfection will eventually damage the probe. Check the probe's performance periodically.

### 1.5 Latex Alert

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

**CIVCO Medical Instruments** 

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



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

# 1.6 Warning Labels

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

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

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

No.	Warning Labels	Meaning
1.	a d	a. Do not place the system on a sloped surface. Otherwise the system may slide, resulting in personal injury or the system malfunction. Two persons are required to move the system over a sloped surface.
		b. Do not sit on the system.
	b (3) c	c. DO NOT push the system. when the casters are locked. d. Caution! please carefully read this manual before
		use system.
2.		Beware of excessive stress exerted to the system.
3.		Mind your hands.
4.	No lifting	Please do not lift the hanger or try to push the ultrasound system by using it.

# 2 System Overview

### 2.1 Intended Use

The DC-80A /DC-80A Exp/DC-80A Pro/DC-8X/DC-8Q/DC-81/DC-82/DC-88/DC-90/DC-95/DC-88S/DC-90S/DC-95S/DC-90Q Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, Intra-operative (abdominal, thoracic, and vascular), pediatric, small organ (breast, thyroid, testes), neonatal and adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal(conventional, superficial), adult and pediatric cardiac, Trans-esoph. (Cardiac), peripheral vessel and urology exams.

This device is a general purpose diagnostic ultrasound system intended for use by qualified and trained healthcare professionals for ultrasound imaging, measurement, display and analysis of the human body and fluid, which is intended to be used in a hospital or medical clinic.

Modes of operation include: B, M, PWD, CWD, Color Doppler, Amplitude Doppler, Tissue Harmonic Imaging, Smart 3D, 4D, iScape, TDI, Color M, Biopsy Guidance, Elastography, Contrast imaging (Contrast agent for Liver), Contrast imaging (Contrast agent for LVO), STE, STQ, Ultrasound Fusion Imaging, GYN/Pelvic and Combined mode:B+M, PW+B, Color+B, Power+B, PW+Color+B, Power+PW+B.

#### NOTE:

The system is not intended for central cardiovascular or central nervous system use.

### 2.2 Contraindication

The diagnostic ultrasound system is not intended for ophthalmic use.

### 2.3 Product and Model Code



# 2.4 Product Specifications

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

### 2.4.1 Power supply

Voltage $100-240 \text{V} \sim$ Frequency50/60 Hz

Power consumption 630VA

Fuse T5AH 250Vac

T10AH 250Vac

Battery DC 14.8V

6600mAh

#### Auxiliary output power

Voltage 100-240V $\sim$  Frequency 50/60Hz

**Power consumption** 240VA (maximum auxiliary output power of the outlet)

#### 2.4.2 Environmental Conditions

Operating conditions Storage and transportation conditions

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

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

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

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

### 2.4.3 Dimensions and Weight

21.5 inch monitor (folded): 825±5mm (Length) × 510±5mm (main unit)/533±5mm (display) (Width) × 1090±5mm (Height)

23.8 inch monitor (folded): 825±5mm (Length) × 510±5mm (main unit)/575±5mm (display) (Width) × 1090±5mm (Height)

Weight (including built-in batteries): <85KG.

# 2.5 System Configuration

# 2.5.1 Standard Configuration

- Main unit
- System software
- Accessories
  - Ultrasound gel
  - Control panel overlay
  - Operator's manual
  - Intra-cavity probe bracket
  - Basic accessories (holders, dust-proof cover and cables etc.)

### 2.5.2 Probes and Needle-guided Brackets Available

For details about the probes and needle-guided brackets, please refer to "13 Probes and Biopsy".

### 2.5.3 Options

No.	Item	Remarks
1.	ECG	1
2.	DC-IN cable	ECG module should be configured.
3.	Three-cable lead	ECG module should be configured.
4.	Built-in Battery	1
5.	CW module	1
6.	4D module	1
7.	Ultrasound Gel Warmer	1
8.	Built-in Wireless Adapter	1
9.	iClear <sup>+</sup> Dongle	These two options should be configured at
10.	iClear <sup>+</sup>	the same time.
11.	iScape View	1
12.	Smart 3D	1
13.	Free Xros M	1
14.	Free Xros CM	1
15.	Tissue Doppler Imaging	Cardiology Package should be configured.
16.	TDI QA	Tissue Doppler Imaging should be configured.
17.	Smart Volume	4D module should be configured.
18.	Strain Elastography	1
19.	STE	1
20.	STE(DE, FR, NA)	1
21.	STQ	1

22. STQ(DE, FR, NA)	No.	Item		Remarks
24. iWorks / Cardiology Package should be configured. 26. SCV* 4D module should be configured. 27. STIC 4D module should be configured. 28. Color 3D 4D module should be configured. 29. Niche 4D module should be configured. 30. iLive 4D module or Smart 3D should be configured. 31. iNeedle / David or Smart 3D should be configured. 32. iPage* 4D module should be configured. 33. Contrast Imaging / David or Smart 3D should be configured. 34. Contrast Imaging / David or Smart 3D should be configured. 35. LVO Cardiology Package should be configured. 36. Smart Planes CNS Obstetrics Package and 4D module should be configured. 37. Smart Planes FH Obstetrics Package and 4D module should be configured. 38. Smart Face Obstetrics Package and 4D module should be configured. 39. Fusion imaging module (including trolley) Contains 1 magnetic navigation controller, 1 magnetic generator and 2 fusion imaging sensors. Fusion imaging should be configured. 40. Fusion imaging module (including trolley) Fusion imaging should be configured. 41. Trolley for magnetic generator / Contains 1 magnetic navigation controller, 1 magnetic generator, 2 fusion imaging sensors and 1 trolley for magnetic generator. Fusion imaging sensors and 1 trolley for magnetic generator. Fusion imaging sensors and 1 trolley for magnetic generator. Fusion imaging sensors and 1 trolley for magnetic generator. Fusion imaging sensors and 1 trolley for magnetic generator. Fusion imaging sensors and 1 trolley for magnetic generator. Fusion imaging sensors and 1 trolley for magnetic generator. Fusion imaging sensors and 1 trolley for magnetic generator. Fusion imaging sensors and 1 trolley for magnetic generator. Fusion imaging sensors and 1 trolley for magnetic generator. Fusion imaging sensors and 1 trolley for magnetic generator. Fusion imaging sensors and 1 trolley for magnetic generator. Fusion imaging sensors and 1 trolley for magnetic generator. Fusion imaging sensors and 1 trolley for magnetic generator. Fusion imaging sensors and 1 trolley for magnetic generato	22.	STQ(DE, FR, NA)		1
25. Stress Echo Cardiology Package should be configured. 26. SCV* 4D module should be configured. 27. STIC 4D module should be configured. 28. Color 3D 4D module should be configured. 29. Niche 4D module should be configured. 30. iLive 4D module should be configured. 31. iNeedle // 4D module should be configured. 32. iPage* 4D module should be configured. 33. Contrast Imaging // 4D module should be configured. 34. Contrast Imaging // 4D module should be configured. 35. LVO Cardiology Package should be configured. 36. Smart Planes CNS Obstetrics Package and 4D module should be configured. 37. Smart Planes FH Obstetrics Package and 4D module should be configured. 38. Smart Face Obstetrics Package and 4D module should be configured. 39. Fusion imaging module (including trolley) 40. Fusion imaging module (including trolley) 41. Trolley for magnetic generator // 42. Motion sensor support Fusion RESP should be configured. 43. Au 44. Navigation support Fusion Imaging module should be configured. 45. Navigation support Fusion Imaging module should be configured. 46. Fusion Imaging module should be configured. 47. Ultrasound Fusion Imaging Fusion Imaging module should be configured. 48. Fusion RESP Fusion Imaging and motion sensor support should be configured.	23.	Tissue Tracking QA		Cardiology Package should be configured.
26. SCV¹ 4D module should be configured.  27. STIC 4D module should be configured.  28. Color 3D 4D module should be configured.  29. Niche 4D module should be configured.  30. ILive 4D module or Smart 3D should be configured.  31. iNeedle /  32. iPage¹ 4D module should be configured.  33. Contrast Imaging /  34. Contrast Imaging QA Contrast Imaging should be configured.  35. LVO Cardiology Package should be configured.  36. Smart Planes CNS Obstetrics Package and 4D module should be configured.  37. Smart Planes FH Obstetrics Package and 4D module should be configured.  38. Smart Face Obstetrics Package and 4D module should be configured.  40. Fusion imaging module  40. Fusion imaging module (including trolley)  40. Fusion imaging module (including trolley)  41. Trolley for magnetic generator /  42. Motion sensor support Fusion RESP should be configured.  43. Navigation support Fusion Imaging module should be configured.  44. Navigation support Fusion Imaging module should be configured.  45. Pusion Imaging Fusion Imaging Fusion Imaging Fusion Imaging module should be configured.  46. Fusion RESP Fusion Imaging module should be configured.	24.	iWorks		1
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28. Color 3D 4D module should be configured.  29. Niche 4D module should be configured.  30. iLive 4D module or Smart 3D should be configured.  31. iNeedle /  32. iPage 4 4D module should be configured.  33. Contrast Imaging /  34. Contrast Imaging QA Contrast Imaging should be configured.  35. LVO Cardiology Package should be configured.  36. Smart Planes CNS Obstetrics Package and 4D module should be configured.  37. Smart Planes FH Obstetrics Package and 4D module should be configured.  38. Smart Face Obstetrics Package and 4D module should be configured.  39. Fusion imaging module  40. Fusion imaging module (including trolley)  40. Fusion imaging module (including trolley)  41. Trolley for magnetic generator /  42. Motion sensor support Fusion RESP should be configured.  43. Navigation support Fusion RESP should be configured.  44. Navigation support Fusion Imaging module should be configured.  45. Pusion Imaging  48. Fusion RESP Fusion Imaging module sensor support should be configured.	26.	SCV <sup>+</sup>		4D module should be configured.
29. Niche  4D module should be configured.  30. iLive  31. iNeedle  32. iPage*  4D module or Smart 3D should be configured.  33. Contrast Imaging  34. Contrast Imaging QA  35. LVO  Cardiology Package should be configured.  36. Smart Planes CNS  37. Smart Planes FH  38. Smart Face  Obstetrics Package and 4D module should be configured.  38. Smart Face  Obstetrics Package and 4D module should be configured.  Obstetrics Package and 4D module should be configured.  Contains 1 magnetic navigation controller, 1 magnetic generator and 2 fusion imaging sensors. Fusion imaging should be configured.  Contains 1 magnetic navigation controller, 1 magnetic generator and 2 fusion imaging sensors. Fusion imaging sensors and 1 trolley for magnetic generator, 2 fusion imaging sensors and 1 trolley for magnetic generator. Pusion imaging sensors and 1 trolley for magnetic generator. Pusion imaging should be configured.  40. Trolley for magnetic generator  41. Trolley for magnetic generator  42. Motion sensor support  43. Navigation support  44. Navigation support  45. Navigation support  46. Navigation lmaging  Fusion imaging module should be configured.  47. Ultrasound Fusion Imaging  Fusion imaging and motion sensor support should be configured.	27.	STIC		4D module should be configured.
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31. iNeedle  32. iPage*  4D module should be configured.  33. Contrast Imaging /  34. Contrast Imaging QA  35. LVO  Cardiology Package should be configured.  36. Smart Planes CNS  Obstetrics Package and 4D module should be configured.  37. Smart Planes FH  Obstetrics Package and 4D module should be configured.  38. Smart Face  Obstetrics Package and 4D module should be configured.  Obstetrics Package and 4D module should be configured.  Contains 1 magnetic navigation controller, 1 magnetic pacentar and 2 fusion imaging sensors. Fusion imaging should be configured.  Contains 1 magnetic navigation controller, 1 magnetic generator and 2 fusion imaging sensors and 1 trolley for magnetic generator, 2 fusion imaging sensors and 1 trolley for magnetic generator. Fusion imaging should be configured.  40. Fusion imaging module (including trolley)  Fusion RESP should be configured.  Navigation support  NB-011  NB-022  NB-028  NB-035  Fusion Imaging module should be configured.  Fusion Imaging module should be configured.  Fusion Imaging module should be configured.  Fusion Imaging and motion sensor support should be configured.	29.	Niche		4D module should be configured.
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35. LVO  36. Smart Planes CNS  37. Smart Planes FH  38. Smart Face  39. Fusion imaging module  40. Fusion imaging module (including trolley)  41. Trolley for magnetic generator  42. Motion sensor support  43. Navigation support  44. Navigation support  45. Where is a support should be configured.  Cardiology Package and 4D module should be configured.  Obstetrics Package and 4D module should be configured.  Contains 1 magnetic navigation controller, 1 magnetic generator and 2 fusion imaging sensors. Fusion imaging should be configured.  Contains 1 magnetic navigation controller, 1 magnetic generator, 2 fusion imaging sensors and 1 trolley for magnetic generator. Fusion imaging sensors and 1 trolley for magnetic generator. Fusion imaging sensors and 1 trolley for magnetic generator. Fusion RESP should be configured.  41. Trolley for magnetic generator  42. Motion sensor support  NB-011  NB-022  NB-028  NB-035  For details, please refer to "5.16.2 Magnetic Navigator"  Fusion Imaging module should be configured.  48. Fusion RESP  Fusion Imaging and motion sensor support should be configured.	33.	Contrast Imaging		1
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42.   Motion sensor support   Fusion RESP should be configured.     43.     NB-011     NB-022   For details, please refer to "5.16.2   Magnetic Navigator"     46.   NB-035   Fusion imaging module should be configured.     48.   Fusion RESP   Fusion Imaging and motion sensor support should be configured.	40.	Fusion imaging module (including trolley)		1 magnetic generator, 2 fusion imaging sensors and 1 trolley for magnetic generator. Fusion imaging should be
A3.   NB-011   NB-022   For details, please refer to "5.16.2   Magnetic Navigator"	41.	Trolley for magnetic g	jenerator	1
44. 45.Navigation supportNB-022 NB-028For details, please refer to "5.16.2 Magnetic Navigator"46.NB-03547.Ultrasound Fusion ImagingFusion imaging module should be configured.48.Fusion RESPFusion Imaging and motion sensor support should be configured.	42.	Motion sensor suppor	rt	Fusion RESP should be configured.
Navigation support   NB-028   Magnetic Navigator"   NB-035	43.		NB-011	
45. NB-028 Magnetic Navigator  46. Ultrasound Fusion Imaging Fusion imaging module should be configured.  48. Fusion RESP Fusion Imaging and motion sensor support should be configured.	44.	Navigation support	NB-022	For details, please refer to "5.16.2
47. Ultrasound Fusion Imaging  Fusion imaging module should be configured.  Fusion RESP  Fusion Imaging and motion sensor support should be configured.	45.	Navigation Support	NB-028	Magnetic Navigator"
48. Fusion RESP Configured.  48. Fusion RESP Support should be configured.	46.		NB-035	
support should be configured.	47.	Ultrasound Fusion Im	aging	
49. Glazing Flow /	48.	Fusion RESP		
	49.	Glazing Flow		/

No.	Item	Remarks
50.	DVR Module	1
51.	McAfee	1
52.	DICOM Basic	1
53.	DICOM Worklist	DICOM Basic should be configured.
54.	DICOM Query/Retrieve	DICOM Basic should be configured.
55.	DICOM MPPS	DICOM Basic should be configured.
56.	DICOM Abdomen SR	DICOM Basic should be configured.
57.	DICOM OB/GYN SR	DICOM Basic should be configured.
58.	DICOM Cardiac SR	DICOM Basic should be configured.
59.	DICOM Vascular SR	DICOM Basic should be configured.
60.	DICOM Breast SR	DICOM Basic should be configured.
61.	Abdomen/General Package	1
62.	Obstetrics Package	1
63.	Smart OB	Obstetrics Package should be configured.
64.	Gynecology Package	1
65.	Cardiology Package	1
66.	Small Parts Package	1
67.	Urology Package	1
68.	Vascular Package	1
69.	Pediatrics Package	1
70.	Nerve Package	1
71.	Emergency&Critical Package	1
72.	IMT	Vascular Package should be configured.
73.	RIMT	Vascular Package should be configured.
74.	Smart NT	Obstetrics Package should be configured.
75.	IVF	Gynecology Package should be configured.
76.	Smart FLC	Gynecology Package and 4D module should be configured.
77.	AutoEF	Cardiology Package should be configured.
78.	Smart Pelvic	Gynecology Package should be configured.
79.	V-Mapping	Vascular Package should be configured.
80.	Built-in DVD recorder	1

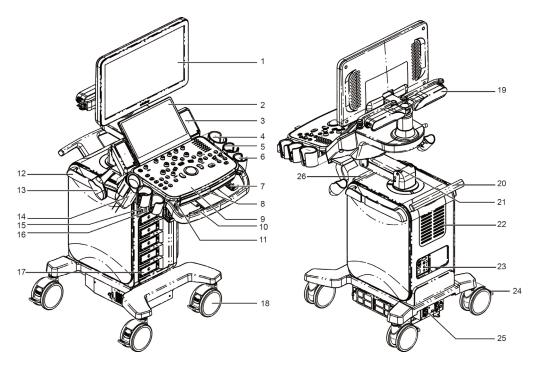
# 2.5.4 Peripherals Supported

Item	Model
Black/white digital video printer	MITSUBISHI P95DW-N
Black/white analog video	MITSUBISHI P93W-Z
printer	SONY UP-X898MD
Color digital video printer	SONY UP-D25MD
Graph/text printer	HP OFFICEJET PRO 8100 (the printer driver requires manually installed)
	USB port: FS-81-SP-2 (1-pedal)
Foot switch	USB port: 971-SWNOM (2-pedal)
	USB port: 971-SWNOM (3-pedal)
Bar code reader	LS2208
Dai Coue readei	DS4308

- Parts that can be used within patient environment:
  - Main unit.
  - Probes.
  - Footswitch.
  - Printers

	NOTE:	If the ultrasound system cannot recognize the SONY UP-X898MD printer
		automatically, you may need to change the settings on the printer: push <push< th=""></push<>
		ENTER> to enter the main menu and select [DIGITAL]->[DRIVER], and select [897].
L		

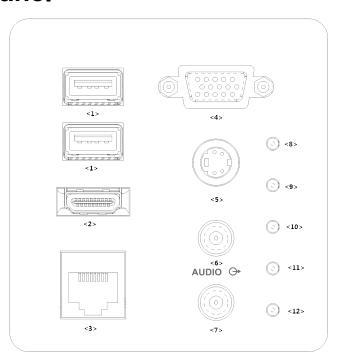
# 2.6 Introduction of Each Unit



No.	Name	Function
1.	Monitor	Displays the images and parameters during scanning.
2.	Touch screen panel	Operator-system interface or control.
3.	Speaker	Sound output.
4.	Ultrasound gel holder	Used for placing the ultrasound gel.
5.	Probe holder	Used for placing the general probe (not including pencil probe or intra-cavity probe).
6.	Pencil probe holder	Used for placing the pencil probe.
7.	Probe cable hook	Used for fixing the probe cable.
8.	Keyboard	Used for typing characters or entering some functions.
9.	Main control panel	Operator-system interface or control.
10.	Control panel adjusting lever	Used for lifting or swiveling the control panel.
11.	USB_MIC port	USB/MIC port
12.	Hanger	/
13.	Intracavitary probe holder	Used for fixing the intracavitary probe.
14.	Ultrasound gel holder/gel warmer	Used for placing the ultrasound gel or installing the gel warmer.
15.	Physio panel	Used for connecting the ECG leads and external ECG device.
16.	Compartment	Used for positioning the B/W video printer.
17.	Probe port	Sockets connecting transducers and the main unit.

No.	Name	Function
18.	Caster	Used for securing or moving the system.
19.	Monitor supporting arm	Supports the monitor, for adjusting the height and position of the monitor.
20.	Rear handle	Used for pushing and moving the system.
21.	Supporting arm locking lever	Used for locking/unlocking the supporting arm
22.	Cooling vent	1
23.	I/O Panel	Interface panel used for inputting and outputting signals.
24.	Caster brake	Used for locking/unlocking the caster
25.	Power supply panel	Electrical port panel.
26.	DVD-RW	DVD-RW drive.

# 2.7 I/O Panel



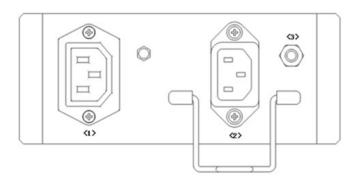
No.	Symbol	Function
<1>	•4	USB ports.
<2>	HDMI	High definition multimedia interface.
<3>	<del></del>	Network port.
<4>	VGA I□I⊕	VGA signal output.
<5>	S-Video	Used for separate video output.
<6>	$\rightarrow$	Audio signal output port, left channel.
<7>		Audio signal output port, right channel.

No.	Symbol	Function
<8>	1	12V power indicator
<9>	1	5V power indicator
<10>	1	3.3V power indicator
<11>	1	PC_LVDS indicator
<12>	1	PHV protection indicator

NOTE: 1. The S-VIDEO port performs better with analog video printing.

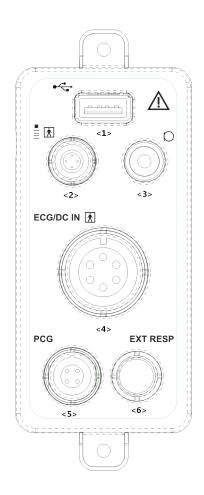
2. When connecting an external video device (HDMI/VGA), make sure the display resolution setting is 1280x1024, otherwise the image quality may be degraded.

# 2.8 Power Supply Panel



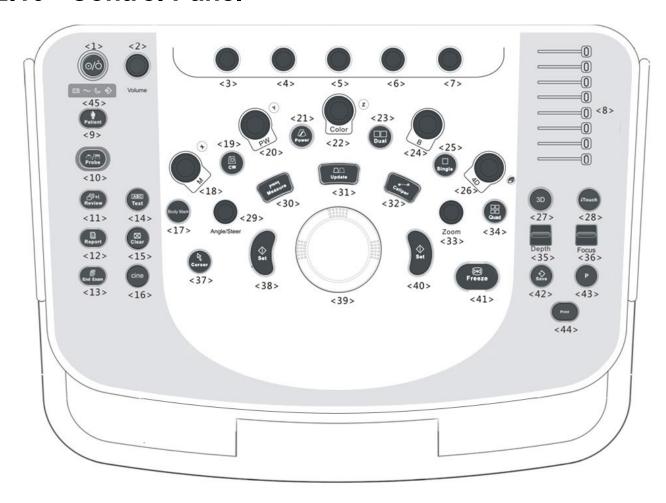
No.	Name	Function
<1>	Power outlet	Supplies power to optional peripheral devices.
<2>	Power inlet	AC power inlet.
<3>	Equipotential terminal	Used for equipotential bonding which balances the protective earth potentials between the system and other electrical equipment.

# 2.9 Physio Panel



No.	Name	Function
<1>	USB port	Connects USB device.
<2>	Pencil probe port	Used for connecting a pencil probe.
<3>	MIC port	Used for connecting a microphone.
<4>	ECG lead signal input port/external ECG signal input port	Connects to ECG leads to directly obtain the patient's ECG signals.
<b>\4</b> 2		Connects the signal output port of an external ECG monitoring device.
<5>	PCG signal input port	Reserved.
<6>	Reserved port	Reserved.

# 2.10 Control Panel



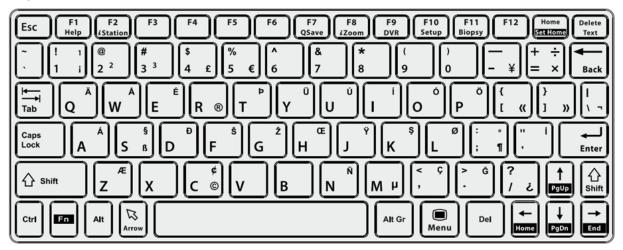
No.	English Name	Description
<1>	1	Power button  Press the button to turn on the system, the system enters the work status and the indicator becomes green.
<2>	Volume	Adjust the volume.
<3>	1	
<4>	1	
<5>	1	Adjust the corresponding functions on the touch screen.
<6>	1	
<7>	1	
<8>	TGC	Slide to adjust the depth gain.
<9>	Patient	Enter/exit Patient Info screen.
<10>	Probe	Switch probe and exam mode.
<11>	Review	Review the stored images.
<12>	Report	Open/close the exam report.
<13>	End Exam	End the current exam.

No.	English Name	Description
<14>	Text	Enter/exit the textual comment status.
<15>	Clear	Clear the comments or measurement caliper.
<16>	Cine	Press to enter the Cine Review status from non-cine status when there is a multi-frame cine file playing.
<17>	Body Mark	Enter/exit Body Mark.
<18>	М	Press to enter M mode, and rotate to adjust M mode gain. While in 3D/4D mode, rotate the knob to make the 3D image to rotate around X-axis.
<19>	CW	Enter CW mode.
<20>	PW	Press to enter PW mode, and rotate to adjust PW or CW gain. While in 3D/4D mode, rotate the knob to make the 3D image rotate around Y-axis.
<21>	Power	Enter Power mode.
<22>	Color	Press to enter Color mode, and rotate to adjust Color or Power gain. While in 3D/4D mode, rotate the knob to make the 3D image rotate around Z-axis.
<23>	Dual	Enter Dual mode in Non-Dual mode.
~23/	Duai	Switch between the two display windows in the Dual mode.
<24>	В	Press to enter B mode, and rotate to adjust B mode gain.
<25>	Single	Enter single window in multiple window mode.
<26>	4D	Press to enter 4D function and rotate to make the 3D image rotate.
<27>	3D	Enter the 3D imaging function: Smart 3D or Static 3D.
<28>	iTouch	Optimize the image.
<29>	Angle/Steer	Adjust the angle. Adjust the steering of the probe.
<30>	Measure	Enter/exit the application measurement mode.
<31>	Update	Switching key: Press to change the currently active window.  Start/stop image acquisition in iScape or 3D/4D mode.
<32>	Caliper	Enter/exit the general measurement mode.
<33>	Zoom	Rotate to enter the pan-zoom mode, and press to enter the spot-zoom mode.
<34>	Quad	Enter Quad mode in Non-Quad mode.  Switch between the four display windows in the Quad mode.
<35>	Depth	Adjust the depth in real-time imaging.
<36>	Focus	Change the focus position.
<37>	Cursor	Show/hide the cursor.
<38>	Set	Confirm an operation. The function is same with the left-button of the mouse.
<39>	1	Move the trackball to change the cursor position.

No.	English Name	Description
<40>	Set	Confirm an operation. The function is same with the left-button of the mouse.
<41>	Freeze	Freeze/defreeze the image.
<42>	Save	Save the image; user-defined key.
<43>	Р	User-defined keys, functions of which can be defined in preset.
<44>	Print	Print: user-defined key.
-45		Battery status indicator.  Charging status: It illuminates in green when batteries are charged fully.  Discharging status: It illuminates in green when the power of the batteries is sufficient; It illuminates in orange for low battery capacity.
<45>	~	AC indicator The indicator is on at AC supply.
	6	Standby indicator. Standby: blinking in orange.
	<b>♦</b>	Hard disk status indicator. The indicator blinks in green when hard disk is running.

NOTE: "/" means the key are undefined or have no silk print. For the undefined keys, you can customize them.

# Keyboard



#### ■ Common functional keys

No.	Key	Function
1.	Enter	Confirm the entered data, or move the cursor to the top of the next row of the text or input field.
2.	Esc	Cancel the operation or exit.

No.	Key	Function
3.	Tab	Jump to the next operable item.
4.	Space key	Insert a space.
5.	Caps Lock	Switch between upper/lowercase.
6.	Home	Activate the Home function: return to start position of the comment.
7.	Set Home	Activate the Home function, move the cursor to the target position, then press <set home=""> to set the start position of the comment</set>
8.	Delete Text	Delete all comments on the screen.
9.	Direction-control keys	Move the cursor one letter each time, or, select the surrounding objects in the selectable area.
10.	Del	Delete the character after the cursor
11.	Back Space	Delete the character before the cursor

#### ■ Functions of the F1 to F12 keys

No.	Key	Function
1	F1 Help	Open or close the accompanying help documents.
		Select the keyword, view the directory, jump to the corresponding page and turn the pages after open the document.
2	F2 iStation	Enter or exit the Patient Info system.
3	F3~F6	User-defined keys, the functions of which can be preset.
4	F7 QSave	Save the current image parameters quickly.
5	F8 iZoom	Enter/exit full-screen zoom status.
6	F9 DVR	Reserved, enter/exit DVR mode.
7	F10 Setup	Enter/exit Setup.
8	F11 Biopsy	Display/hide the guide line.
9	F12	User-defined keys, the functions of which can be preset.

#### ■ Functions of key combinations

The system supports multi-language input using key combinations. Key combinations include [Shift], [Alt Gr], [Ctrl], [Fn] and some alphabet keys. For details about switching the system to multi-language, see "12.1.1 Region" for details.

#### Shift> key

<Shift> + key: enter the top left letter on the key.

For the alphabet keys (<A>~<Z>), press <Shift> + key to enter the current letter in a different case.

#### • [Alt Gr] key

Combined with other letter keys, [Alt Gr] can be used for entering other languages.

Press [Alt Gr] and a letter key simultaneously. The letter in the top-right corner of the key is entered.

#### [Ctrl] key combined keys

On the iStation or Review screen, use <Ctrl> and <Set> to select more than one patient or more than one image.

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

No.	Fn+	Name	Function	
1.	$\rightarrow$	End	Move the cursor to the end of the row, or the rightmost side of an editable unit.	
2.	<b>←</b>	Home	lome	
3.	<b>↑</b>	Pg Up	Turn pages upward.	
4.	$\downarrow$	Pg Dw	Turn pages downward.	
5.	Home	Set Home	Activate the Set Home function: set the start point of a comment.	

# 2.11 Symbols

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

Symbol	Description			
<b>*</b>	Type-BF applied part			
$\triangle$	Caution			
$\sim$	AC (Alternating current)			
	Protective earth (ground)			
$\overline{\Diamond}$	Equipotentiality			
⊙/Ô ≥ 	Power button			
2	Foot switch			
<u> </u>	Transducer sockets			
	Pencil probe port			
	Network port			
	USB port			
VGA I□I⊖→	Used for VGA output.			
S-VIDEO →	Reserved, used for separate video output			
AUDIO →	Used for stereo audio output.			
HDMI	High definition multimedia interface.			
D	Microphone input jack			
2	When the lever located at the bottom of the monitor supporting arm			
1	points to 🔳, you can move the monitor to the right and left.			
$\bigcap$	When the lever located at the bottom of the monitor supporting arm			
<u> </u>	points to , the supporting arm is fixed in the middle position.			

Symbol	Description
SN	Product serial number
M	Manufacture date
Rx Only	Caution: Federal Law restricts this device to sale by or on the order of a physician.
MR	MR Unsafe – the system is not intended to be used within magnetic resonance (MR) environment.
ETL CLASSIFIED  C  C  C  C  C  C  C  C  C  C  C  C  C	CONFORMS TO AAMI STD ES 60601-1, IEC STD 60601-1-6, 60601-2-37 CERTIFIED TO CSA STD C22.2 NO. 60601-1, NO. 60601-1-6, NO. 60601-2-37
Intertek 3179617	

# **3** System Preparation

# **<b>MARNING**:

- Do not connect the system's three-wire cable with a two-wire plug without protective grounding. This may lead to electric shock.
- 2. Connect the power plug of this system to wall receptacles that meet the ratings indicated on the nameplate. If adapters or multifunctional receptacles are used, it may cause the leakage current to exceed the safety requirements.
- 3. Within 1.5 meters of the patient, connect peripherals to an auxiliary power outlet which is capable of isolation protection, or power peripherals by an auxiliary output cable or isolation transformer which complies with IEC 60601-1 in Chapter 16 or a power input of the same safety level.
- 4. DO NOT use different-phase power supplies to power peripherals.
- 5. When using peripherals which are not powered by the ultrasound system's auxiliary output, or peripherals other than those permitted by Mindray, ensure the overall leakage current of peripherals and the ultrasound system meets the requirement of the local medical device electrical regulations (e.g., the enclosure leakage current should be no more than 500uA as per IEC 60601-1 in Chapter 16), and the responsibility is held by the user.

# 3.1 Move/Position the System

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

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

# $\triangle$ CAUTION:

- Maintain a generous, free air flowing space around the back and both sides of the system. Not doing so may result in failure due to the increased rise in the system's operating temperature.
- 2. Pay extra attention when moving the system on a sloping surface. Do not move it on a surface with a slope of more than 10° to avoid the system toppling.

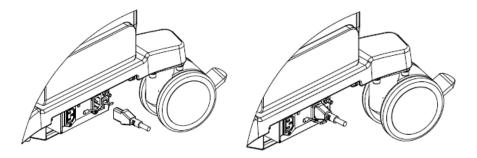
# 3.2 Connecting the Power Cord & Protective Grounding

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

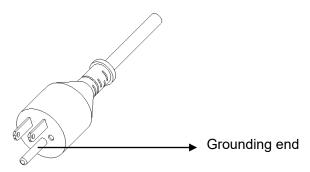
**NOTE:** When the system is powered by the batteries, imaging modes including static 3D, STE, STQ, STIC and 4D continuous capturing, self-test, and DVR recording are not supported.

# 3.2.1 Connecting Power

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



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



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

# 3.2.2 Powered by Battery

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

# 3.2.3 Equipotential terminal

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

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

# 3.2.4 Power the System ON

CAUTION:

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

■ Check before Powering ON

Check before the system is powered on:

No.	Check Item				
	The temperature, relative humidity and atmospheric pressure meet the requirements of				
	the operating condit	ions. See "0			
	Auxiliary output power				
	Voltage	100-240V~			
1	Frequency	50/60Hz			
	Power consumption	240VA (maximum auxiliary output power of the outlet)			
	Environmental Conditions" for details.				
2	There is no condensation.				

No.	Check Item	
	There is no distortion, damage or dirt on the system and peripheral devices.	
3	If any dirt is found, cleaning shall be performed as illustrated in section "17 System Maintenance."	
4	There are no loose screws on the monitor or control panel.	
5	There is no cable damage (e.g., power cord). Maintain secure connections to the system	
	at all times.	
6	The probes and probe cables are free from damage or stains.	
Ü	See chapter "13 Probes and Biopsy" for details of probe cleaning and disinfection.	
7	No miscellaneous odds and ends are attached or affixed to the control panel.	
	Ensure that all connections are free from damage and remain clear of foreign object	
8	blockages.	
	There are no obstacles around the system and its air vent.	
9	Probe cleaning and disinfection.	
10	The entire scanning environment and field must be clean.	
11	The locking mechanism of the casters works normally.	

Before turning the system on, check if the system is plugged in. Press the power button (to the left of the control panel) to power the system on.

Check the system after it is powered on Check after the system is powered on:

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

# WARNING: If you use a probe giving off excessive heat, it may burn the patient. If you find anything not functioning properly, this may indicate that the system is defective. In this case, shut down the system immediately and contact Mindray Customer Service Department or sales representative.

# 3.2.5 Power the System OFF

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

■ To power the system off normally

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

- Shut down: to power the system off normally.
- Standby: to enter standby status.
- Cancel: to cancel the operation.

NOTE:

- 1. DO NOT rush direct shutdown of the system. It may damage the data.
- After the system is upgraded, use "Shut Down" to power the system off to make the upgraded data effective.

# 3.2.6 Standby

When the batteries are charged to full capacity, the system's standby time is no less than 24 hours.

■ To enter standby:

Open [Setup]  $\rightarrow$  [System]  $\rightarrow$  "General" to set the time for screensaver and standby. If the system is not carrying out an operation, the screensaver appears after the screensaver delay period. If there is still no operation, the system enters standby after the standby delay period.



Press the power button and select "Standby", the system enters standby mode.

To exit standby:

Press the power button.

Under the standby status:

Press the power button to exit standby status and then power off the system.

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

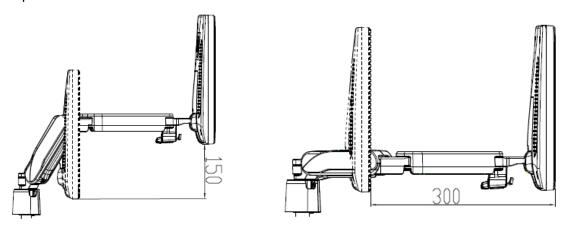
# 3.3 Monitor Adjustment

# 3.3.1 Monitor Position Adjustment

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

■ Height and displacement adjustment

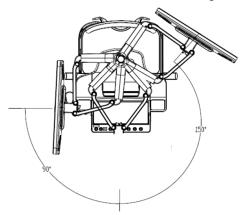
Move the monitor support arm up or down to adjust the height, back and forth to adjust the displacement



**NOTE:** Take care not to trap your hands when adjusting the monitor up and down.

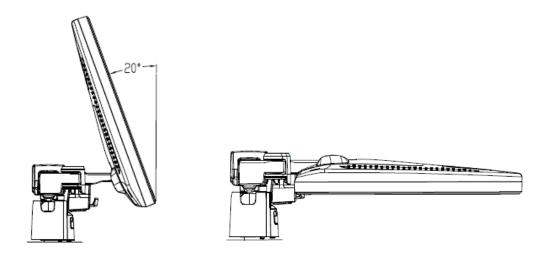
■ Rotate the monitor

The monitor can be rotated 90° to the left and 150° to the right along with the supporting arm.



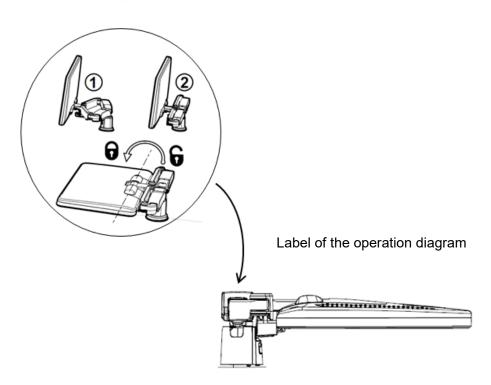
■ Tilt the monitor

When positioned vertically, the monitor can be tilted 20° backward and can be tilted forward to a horizontal position. When transporting or moving the system, keep the monitor in the horizontal position, as shown below:



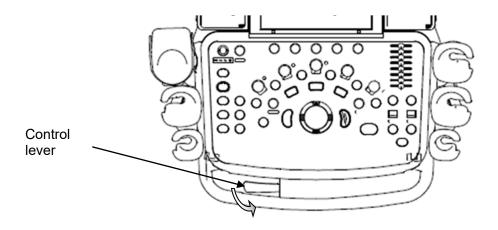
#### ■ Lock the monitor

If the ultrasound system is required to be moved within a short distance (for example: move to other department), turn the monitor to the horizontal level, push it to the locking structure, and then the monitor can be locked. For more details, please refer to the operation diagram that is attached to the supporting arm.



# 3.4 Control Panel Position Adjustment

Press the control lever downwards for about 30° to rotate the control panel ±90°. Press the lever downwards for about 60° to move the control panel upwards or downwards.



# 3.5 Connecting a Probe

# CAUTION:

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

NOTE:

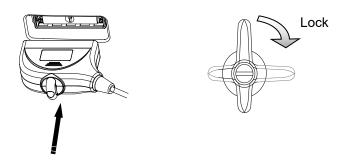
If a probe port is not used for a long period of time, use the dustproof cover to protect the probe port from dust. Failure to do so may result in bad contact.

# 3.5.1 Connecting a Probe

 $\triangle$ WARNING:

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

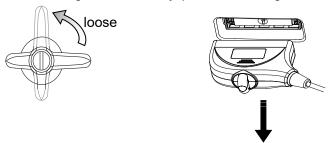
- 1. Keep the cable end of the transducer to the right side of the system, insert the connector into the system port, then press in fully. (Shown in the left figure)
- 2. Turn the lock handle 90° clockwise to lock it securely. (Shown in the right figure)
- 3. Position the probe properly to avoid it being treaded on or becoming wrapped around other devices. DO NOT allow the probe head to hang free.



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

# 3.5.2 Disconnecting a probe

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



# 3.6 Connecting Peripheral Devices

# 3.6.1 Connecting USB Devices

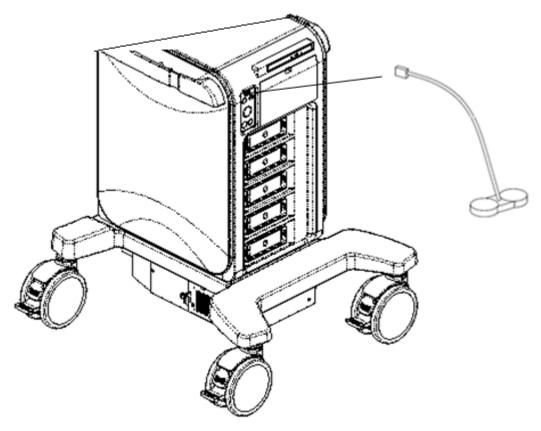
**WARNING:** DO NOT directly remove a USB memory device, as the USB device and/or the system may become damaged.

- When connecting a USB memory device to the ultrasound system via a USB port, a sound is heard if it is connected successfully and the symbol appears in the bottom-right corner of the screen.
- To remove the USB device: click to open the [Remove USB Device] screen. Select the device to be removed and click [OK]. A sound is heard when removing the USB memory device.

# 3.6.2 Connecting a Foot Switch

The system supports USB port-type foot switches.

Connection
 Directly insert the USB port of the foot switch into the system's applicable USB port.



■ Function setting

The function of the foot switch can be preset. For details, see "12.1.6 Key Configuration."

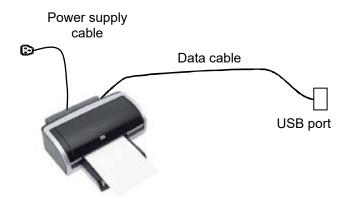
# 3.7 Installing a Printer

# 3.7.1 Installing a Graph/Text Printer

Connecting a local printer

Note: Unless otherwise specified, printers listed in "2.5.4 Peripherals Supported" Chapter have drivers installed already.

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



- 1. Connect the data cable to the USB port on the ultrasound system.
- 2. Power the system and the printer on.
- 3. Install the printer driver. For details, please contact the Mindray service engineer.

#### ■ Print

Both report and image can be printed on a graph / text printer.

To set the default report printer and its attribute:

In "[Setup]→[Print]" screen, select the "Report Print" column in the service list. You can select printer from the driver list next to "Printer" in the lower screen and set the items in the "Property" box. Click [Save] after you have finished setting.

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

# 3.7.2 Installing a Video Printer

The system support video printers, consist of the B/W digital printers and color digital printers. Note: Unless otherwise specified, printers listed in "2.5.4 Peripherals Supported" Chapter have drivers installed already.

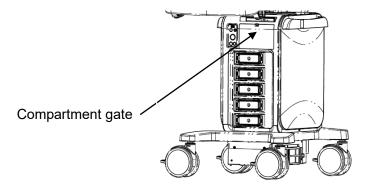
- Local printer installation
- 1. Position the printer in the proper place.
- 2. Plug the printer power cord into an appropriate outlet.
- 3. Use a USB cable to connect between the system's USB port and the printer's USB port.
- 4. Load a paper roll, and turn on the system and printer.
- 5. Install the printer driver. For details, please contact the Mindray service engineer.
- 6. Add a print service:
  - (1) Open the "[Setup] → [Print]" screen.
  - (2) Click [Add Service] to enter the page.



- (3) Select the service type and enter the service name manually.
- (4) Click [OK] to return to the page.
- (5) Select the target printer from the drop-down list in the "Property" box and set other printing properties.
- (6) Click [Save] to complete.

#### 3.7.3 Position the Printer

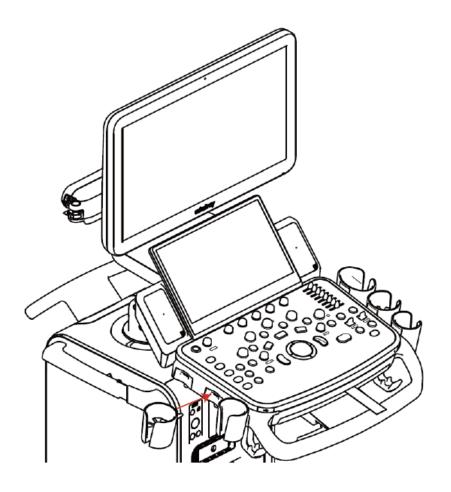
As shown in the following figure, you can open the video printer compartment gate and then place the black/white digital video printer in the video printer compartment.



# 3.7.4 Installing/ uninstalling Probe/Gel Holder

#### Installing

As shown in the figure below, align the buckle of the holder to the slot at the side of the control panel and then insert the buckle into the slot until the buckle clicks and locks.



# ■ Uninstalling

Press the clip in the direction of the arrow to get out the holder.



# 3.8 Basic Screen & Operation

# 3.8.1 Screen Display

The screen displays ultrasound images, parameters, menus and measurement results windows.

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

		Hosp	ital Nan	ne	I Patient Name I		Exam mode	Probe Model	
	Date		Time	Operator	ID	HR	Age /DOB	Gender/ GA	
			Pr	obe param	eter area				
Menu	Gray scale / Color Bar			lma	ge Area			Image parameter area	Thumbnail Area
	,			Е	ECG Curve				
	Cine Review								
Trackball hint area	Soft menu parameter window key a gestu			User- defined key and gesture hint area					
_	Help Information System Status Icon								

#### ■ Patient/Exam information

The Information area consists of the hospital name, patient name, the exam mode, the probe model, the exam time, operator, patient ID, DOB, GA or age etc. To preset which kind of patient information is displayed, enter the path: [Setup]→[System]→[General]. For more details, please refer to "12.1.2 General" chapter.

- Hospital name
   Display the hospital name. Hospital name can be set via "[Setup] → [System] → [Region]".
- Patient Information

Displays patient name, ID, gender, GA and age(DOB) etc. Enter the patient information through the "Patient Info" screen. Or, import the saved patient data from DICOM/HL7 Worklist server. See "4.1 Patient Information" chapter for details.

Exam Mode

Displays the currently used exam type, e.g. Abdomen.

Probe Model

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

Probe parameter area

Displays the acoustic power. Including the acoustic power, MI (Mechanical Index) and TI (Thermal Index). For how to set, see "MI/TI Display."

Exam time

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

Operator

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

Menu area

Includes the image menu, measurement menu, comment menu, body mark menu, and so on.

■ Image area

The image area displays the ultrasound images, ECG waveforms, probe mark (or activating window mark "M"), coordinate axis (including depth, time, velocity/frequency) and focal position (located on the depth axis in the form of . Annotations, body marks, measurement calipers, color bar/grayscale bar are also displayed here.

■ Image parameter area

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

■ Clip board/Thumbnails

Displays the thumbnail images stored under the current patient.

- ECG
  - ECG icon

Displays the ECG icon, which consists of a heart icon and heart rate, e.g.,



ECG curve

**ECG** Display

Tip: The amplitude and position of ECG waveform can be changed.

■ Help information area

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

Tip: In terms of help information, "TB" refers to "Trackball".

Grayscale/color bar

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

■ Soft Menu area

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

System status icon

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

■ User-defined key and gesture function display region

This area displays the function defined for those user-defined keys and gestures. For details about user-defined key, see "12.1.6 Key Configuration".

■ Trackball hint area

This area displays current function of trackball.

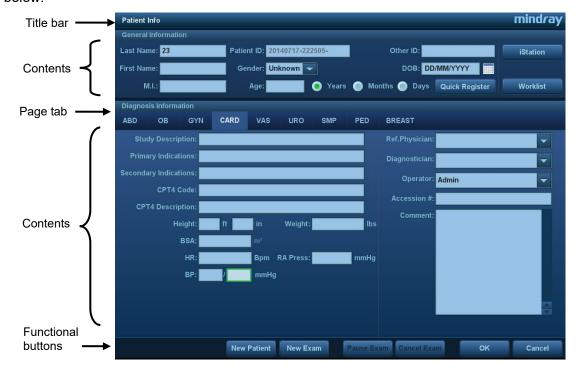
Other Operations

The positions of areas illustrated here are not fixed. They can be moved within a certain area on the monitor using the trackball.

- Results window
- Comments area
- Body marks area

# 3.8.2 Basic Operations of the Dialog Box

A dialog box screen consists of a title, page tabs, contents and buttons, as shown in the figure below:



Composition	Description	
Title Bar	The title bar is used to give a description of the content and function of the screen.	
Page Tab	For some screens, the contents are distributed across several pages. Use the <set> key to open/close the available pages.</set>	
Contents	<ul> <li>■ Radio box: click to select the item.</li> <li>■ Check box: click to check or uncheck the item.</li> <li>■ Entry box: enter characters manually using the keyboard.</li> <li>■ Drop-down list box: click ▼ to show the list and select an item.</li> </ul>	

Composition	Description
Functional buttons	When a screen's operation is complete, click the [OK] or [Cancel] button to save or cancel the operation, and close the screen.

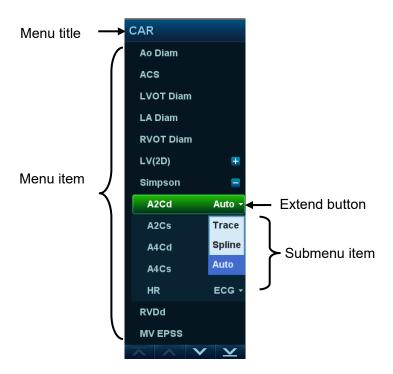
- To reposition a dialog box which is not a full-screen dialogue box:
- 1. Roll the trackball to move the cursor over the title bar of the dialog box. The cursor becomes a 

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

# 3.8.3 Menu Operation

Use the trackball to use the menu.

Menus of different modes display in real time in the top-left corner of the screen.

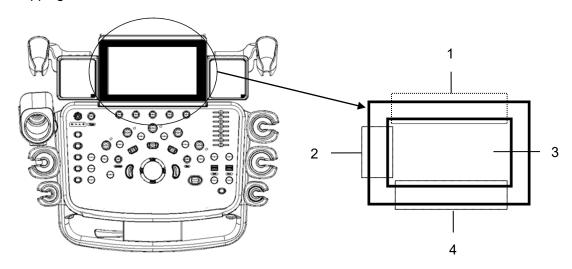


For details of measurement menu operations, see the [Advanced Volume].

- Operate the menu using the trackball and left/right <Set> key.
- 1. Press <Cursor> to show the cursor.
- 2. Roll the trackball to position the cursor on the item to be adjusted.
  - For a commanding item or command optional item: press <Set> to activate the item.
  - For a parameter item or ON/OFF item: press <Set> to activate the item (the item turns green when active), then press <Set> to switch between the available values.
  - For a parameter optional item: press <Set> to extend the available parameters and position the cursor on the list. Roll the trackball to position the cursor on the item to be adjusted, then press <Set> to set the value.

# 3.8.4 Touch Screen Operation

#### ■ Mapping mode



Operating region	Operations			
1	Swipe from this area to bottom to enter the mapping mode.			
2	Under mapping mode, swipe from this area to right to display the mapping menu.			
3	Under mapping mode, this area displays mapping menu, soft menu and tool bar, where you can adjust image parameters, perform measurement, image sending and review. See "5.1.2 Image Adjustment" for details. Under mapping/non-mapping mode, you can do fast operation using two-finger gesture according to the gesture hints on the bottom-right of the screen.			
4	Under mapping mode, swipe from this area to the top to exit mapping mode.			

#### Enter mapping mode

Swipe the touch screen from top (region 1) to bottom to enter the mapping mode. The system maps the image of the monitor onto the touch screen. See the figure below. Tips: if a dialogue box is displayed on the screen, mapping mode is not available.



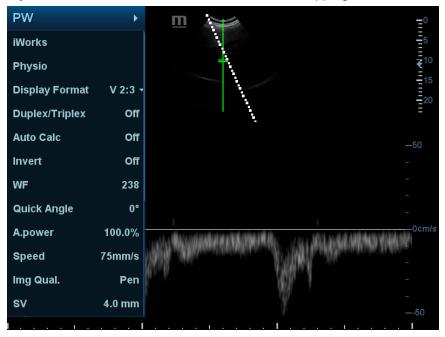
#### Menu Operations

Swipe the touch screen from left (region 2) to right to show the mapping menu. See the figure below.

For detailed operations, see Chapter "5.1.2 Image Adjustment".

Touch or flip the menu to the left/right to adjust the image parameters; touch the measurement menu to select measurement tools and start measurement.

Click any blank area on the touch screen to hide the mapping menu.



See "5.1.2 Image Adjustment" for menu operation.

Soft Menu Operations

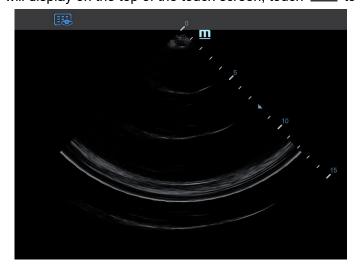
Under mapping mode, rotate the knobs beneath the touch screen to show the soft menu. Rotate the knob to complete the adjustment.

Two-finger gesture

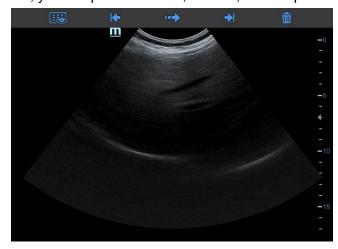
For details about two-finger gesture function setting, see "12.1.6 Key Configuration" chapter.

Swipe the touch screen (region 3) with two fingers by the hint in user-defined key function display region on the bottom-right of the screen. (See "3.8.1 Screen Display" chapter for details)

- Operations on Tool Bar
  - Under mapping mode, touch the real-time image on the touch screen (region 3), a toolbar will display on the top of the touch screen, touch to enter review status.



• Under mapping mode, open the saved image on the main screen, and touch the saved image on the touch screen (region 3), a toolbar will display on the top of the touch screen, you can perform review, send to, delete operations.



Icon	Description	
	Enter review status, see "10.2.10.1 Review an Image" for details.	
<b>+</b>	View last image.	
••	Send image file, see "10.2.12 Sending Image Files" for details.	
<b>→</b> I	View next image.	
葷	Delete the current image.	

- Exit mapping mode
   Swipe the touch screen from bottom to top to exit the mapping mode.
- Non-mapping mode of touch screen
  The layout of the touch screen varies with the applications or modes. Swipe the touch screen to go to another interface. Learn the interface display and operations by referring to related chapters.

# 3.8.5 Soft Keyboard

Under report, setup, comment adding and iStation screen, the soft keyboard icon is displayed on the touch screen. Touch the icon to enter the soft keyboard typing screen. Or, under patient info screen, you can see the soft keyboard typing screen on the touch screen directly.



# 4 Exam Preparation

A patient exam can be started as per the following situations:

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

General procedure for an exam:

Enter the patient information  $\rightarrow$  select an exam mode and probe  $\rightarrow$  Choose an imaging mode  $\rightarrow$  Start the exam.

■ The system supports image scanning and measurement without patient information.

## 4.1 Patient Information

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



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

- To enter the Patient Info screen
  - Press <Patient>.
- To exit the Patient Info screen
  - Click [OK] on the Patient Info screen, press <Patient> on the control panel.
  - Click [Cancel] on the Patient Info screen and touch [Cancel] on the touch screen. Or press <Esc> on the control panel to exit the screen without saving any of the entered patient data.
  - Press <B> or <Freeze> to return to the current exam mode and save the entered information.
- Click [Quick Register] on the screen to quickly save the patient information and return to the main screen.

#### 4.1.1 New Patient Information

The Patient Info screen is shown as follows:



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

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

#### 1. General information

Patient ID

The Patient ID is generated automatically by the system after starting a new patient, and can be modified manually. "\", "\*" or "?" is not permitted.

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

Name

Enter the patient's name using the keyboard.

Gender

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

DOB (date of birth):

You can either enter the patient's date of birth manually,

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

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

**NOTE:** When you enter dates manually, enter them in same the format as that of the system.

#### 2. Exam Type

#### ■ Exam application type

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

#### General information:

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

**Primary indications:** To enter the primary indications (reason for performing the exam.)

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

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

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

**Remarks:** Exam-specific explanation or remarks.

#### ■ Exam-specific information:

Exam Type	Information	Description			
	Height	/			
	Weight	1			
ABD (Abdomen)	BSA (body surface area)	After the height and weight are entered, the system will automatically calculate the BSA based on the formula which is set via "[Setup] $\rightarrow$ [System] $\rightarrow$ [General]."			
(Abdomen)	ВМІ	After the height and weight are input, the system will automatically calculate the Body Mass Index.			
	Fasting	1			
	ALT	Alanine transaminase.			
	Height	1			
	Weight	1			
		Calculate the gestation age (GA) and estimated delivery date (EDD) based on the last menstrual period (LMP), date of conception (DOC), in vitro fertilization (IVF), basic body temperature (BBT) and previous exam date (PRV). Select LMP, DOC, IVF, PRV, BBT, or EDD from the drop-down list, or calculate the GA and LMP according to the EDD and entered date.			
OB (Obstetrics)	Calculation index	<ul> <li>LMP: after you enter the LMP, the system will calculate the GA and EDD.</li> <li>DOC: after you enter the DOC, the system will calculate the GA and EDD.</li> <li>IVF: after you enter IVF, the system will calculate the GA and EDD.</li> <li>PRV: enter the date and GA of the last exam, the system will calculate a new GA and EDD.</li> <li>BBT: enter the BBT, the system will calculate the GA and EDD.</li> <li>EDD: after you enter the EDD, the system will calculate and display the GA and LMP.</li> </ul>			
	Gravida	Times of pregnancy.			

Exam Type	Information	Description
	Ectopic	Times of abnormal pregnancy, e.g., extrauterine pregnancy
	Gestations	Number of embryos (1, 2, 3, 4)
	Para	Times of delivery.
	Abort	Times of abortion.
GYN (Gynecology)	Height	1
	Weight	1
	LMP	Last menstrual period.
	Gravida	Times of pregnancy.
	Para	Times of delivery.
	Ectopic	Times of abnormal pregnancy, e.g., extrauterine pregnancy.
	Abort	Times of abortion.
	IVF Info	Female hormone basic level and drugs inducing the ovulation.
	Height	/
	Weight	/
CARD (Cardiology)	BSA (body surface area)	After the height and weight are entered, the system will automatically calculate the BSA based on the formula which is set via "[Setup] → [System] → [General]."
,	ВР	Blood pressure.
	HR	/
	RA Press.	Right Atrium Pressure.
	Height	1
	Weight	1
VAS (Vascular)	BP(L) (blood pressure)	Input left blood pressure.
	BP(R) (blood pressure)	Input right blood pressure.
	Height	1
URO	Weight	1
(Urology)	Serum PSA	1
	PPSA Coefficient:	1
SMP (Small Parts)	Height	1
	Weight	1
PED (Pediatrics)	Height	1
	Weight	1
Breast	Height	/
	Weight	1

#### 3. Operating Information

Accession #: refers to the exam number used in DICOM.

Diagnostician: person responsible for the exam.

Operator: person responsible for image collection and scanning.

Ref. Physician: person who requires the operator to carry out the ultrasound.

Tip: If the name has been entered before, it is memorized by the system and can be selected from the drop-down list.

#### 4. Functional keys

- [Pause Exam]: pauses the current exam due to particular circumstances or system power off.
- [Cancel Exam]: cancels the current exam.

**NOTE:** A canceled exam cannot be restored.

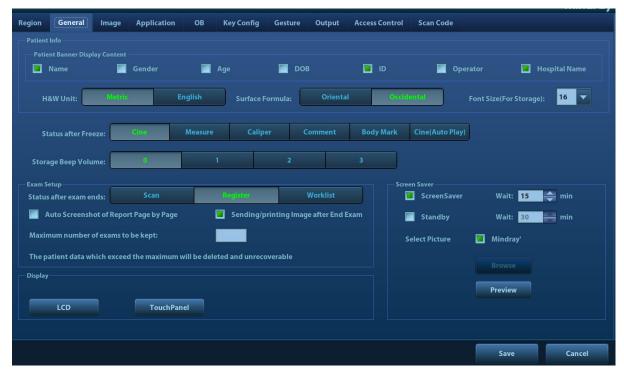
- [New Patient]: clears the current patient information in the patient information screen so new patient information can be entered.
- [New Exam]: clears the current exam information so a new exam can be created for the current patient.
- [OK]: saves the patient data entered and exits the screen.
- [Cancel]: cancels the patient data entered and exits the screen.

#### 4.1.2 Retrieve Patient Information

#### 4.1.2.1 iStation

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

- 1. To enter the iStation screen (the screen is shown below):
  - Press <iStation> on the keyboard, or
  - Click [iStation] in the Patient Info screen, or
  - Click [iStation] in the Review screen.



- 2. Select the data source
  - Select the data source from the "Data Source" drop-down list.
- 3. Enter the search condition:
  - Item: including Name, ID, DOB and Exam Date. Then enter a keyword in accordance with the Item selected.
  - Select "Find in results." The system will search on the keyword in the existing searched results.
- 4. Select the desired patient information in the list, and the system brings up the following menu:



Button	Function	Description
	Review an Image	Click to enter the review screen.
	Patient Information	Click to enter the patient info screen.
	Review Report	Click to enter diagnostic report screen.
	Delete Exam	Click to delete the selected record.
	Backup Exam	Click to back up the selected patient record to supported media.

Button	Function	Description
6	Restore Exam	Click to import the patient data from an external media.
	Send Exams	Click to send the selected patient data to an external device, MedTouch/MedSight devices, DICOM storage server or printer.
	Activate Exams	Click to continue an exam that has been completed within 24 hours.
	Resume Exams	Click to continue an exam that has been paused within 24 hours.

#### Other buttons:

- [New Exam]: click to enter the Patient Info screen. The corresponding patient information is also imported to the new exam simultaneously. After editing the patient information in the Patient Info screen, select [OK] to start a new exam.
- [Select All Exams]: click to select all records.
- [Exit]: click to exit iStation.

#### 4.1.2.2 Worklist

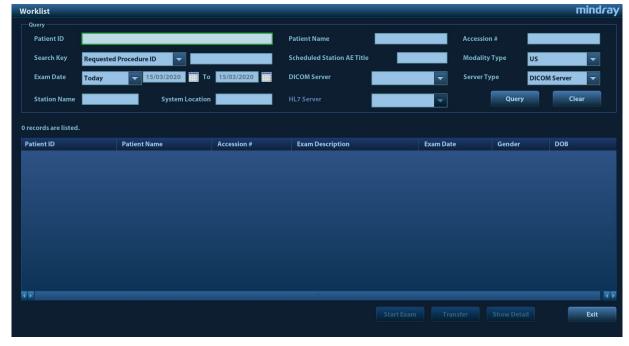
Worklist is an option. To use Worklist function, you have to configure DICOM Basic and DICOM Worklist options.

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

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

#### Basic operation:

- (1) Press the <Patient> key to open the Patient Info screen.
- (2) Click [Worklist] to enter the Worklist page.



- (3) Select the data source: after select the service type, select the worklist server from the corresponding server (DICOM and HL7 server).
- (4) Enter the search condition:

- a) Input the searching condition:
  - Select "DICOM server". You can search via patient ID, accession #, key words, AE title, worklist server or exam date.
  - Select HL7 server. Search via patient ID, patient name.
- b) Click [Query]. The scheduled patients, which meet the criteria, are displayed in the lower part of the screen.
- After the first query, you can perform the second query based on the preview results. The scheduled patients in the list will update in real time.
- Enter patient ID, patient name, accession # and exam date, the system affords the result in real-time.
- Or select the keyword type, enter the keywords and then click [Query] to search.
- To reset the criteria, click [Clear] button.
- (5) Select the desired patient record in the displayed patient list:
  - a) Select the desired patient and click [Start Exam]. The patient information is imported into the system and then an exam is started.
  - b) Click [Transfer] and the patient information is imported into the [Patient Info] screen. After editing the patient information in the Patient Info screen, select [OK] to start a new exam.
  - c) Click [Show Detail] to see details of patient data.
- (6) Click [Exit] to exit the Worklist.

# 4.2 Select Exam Mode and Probe

 $\triangle$ CAUTION:

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

- Selecting exam mode
- 1. Connect suitable probes to the system and press <Probe> on the control panel. The touch screen displays the following dialog box:



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

# 4.2.1 Dual-probe Switch

A user-defined key for dual-probe switch can be defined in preset, by which you can fast switch the probe under B/ Color/ Power mode.

This function applies only to probes with the same exam modes.

- 1. Scan to obtain the image by current probe.
- 2. Press the user-defined key. The available probes appear on the screen.
- 3. Choose the probes to be compared. The system enters dual-probe mode. The image from previous probe is frozen.
- 4. Scan and obtain the required image from the current probe.
- 5. Press the user-defined key to switch the images of two probes.

The path for setting the keys: <F10 Setup>→[System]→[Key Settings].

- 1. Select the key to be defined from [Key] tab on the left side. Or, select a key from [Footswitch] tab.
- 2. Select [Image Mode]→[Dual-Probe].
- 3. Click [OK] to confirm the setting or exit. The setting comes into effect then.

# 4.3 Select the Imaging Mode

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

# 4.4 Activate & Continue an Exam

#### 4.4.1 Activate an Exam

On the iStation screen, select an exam record which was completed within 24 hours and click [Activate Exam] from the menu which appears. Or click [Active Exam] on the iStation or Review screen to activate the exam.

Tip:

- The system can automatically load the patient information and exam data to continue the exam.
- If you want to continue an exam with data in an external memory database, first allow the system to load the patient data to the system's patient database.
- For an activated exam, you can modify the patient ID if this patient has only one exam recorded in the system.

#### 4.4.2 Continue an Exam

On the iStation screen, select an exam record which was paused within 24 hours, and click [Resume Exam] from the menu which appears to continue the exam.

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

For an activated exam, you can modify the patient ID if this patient has only one exam recorded in the system.

# 4.5 Pause & End an Exam

## 4.5.1 Pause an Exam

- Sometimes it is necessary to stop an uncompleted exam due to particular circumstances. When the exam is paused, the system can begin other exams.
- 1. Press <Patient> to enter the Patient Info screen.
- 2. Click [Pause Exam].
  - If the system is powered off during scanning, the exam status turns to "paused" after the system restarts.

When an exam is paused, the system will:

- 1. Save the exam-related images, reports and measurement data, and modify the status as "Paused."
- 2. Save the exam information, including imaging mode, exam mode, image parameters, operation mode, and so on.

#### 4.5.2 End an Exam

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

To end an exam, do one of the following:

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

# 5 Image Optimization

# **≜**WARNING:

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

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

# 5.1 Imaging Mode

# 5.1.1 Switching Between Imaging Modes

Switch between imaging modes according to the actual situation. See "2.10 Control Panel" for details.

# 5.1.2 Image Adjustment

- Adjust using the image menu: For details about menu adjustment, see chapter "3.8.3 Menu Operation."
- Adjust using the touch screen (non-mapping mode)



- 1. Mode display area (or main functional tabs): displays the current modes. Touch the tab to enter the mode.
- 2. Other application mode access: displays the available related application modes. Touch to enter the modes.
- 3. Parameter adjusting area: displays the parameters in the current imaging mode or function.

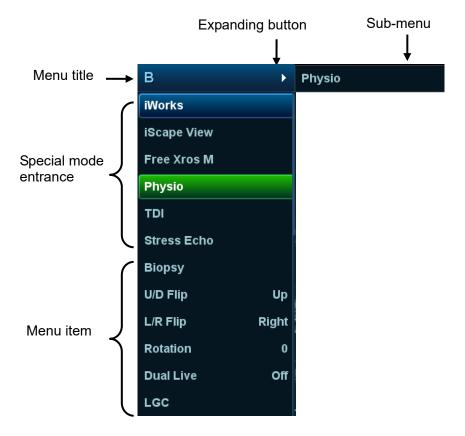
- 4. Probes that can be switched to: select an appropriate probe for quick switch.
- 5. Recently used exam modes: select an appropriate exam mode for quick switch.
  - Parameter magnitude setting: touch or to increase/decrease the value.
  - ON/OFF setting: some of the parameters can only be set to ON or OFF. ON activates the function, and when the function is activated the key is highlighted in green.
  - Page selection: if there is more than 1 page for the current mode, touch to turn the pages.



- Functional item: touch to go to the corresponding function.
- 6. Knob-adjusting area: displays the knob-controlled parameters.

There are five knobs at the bottom of the touch screen. Their functions vary depending on the current menu. Press or rotate the knobs to adjust the corresponding parameters.

- Adjust using the touch screen (mapping mode)
- 1. Enter the mapping mode to see the following mapping menu. See "3.8.4 Touch Screen Operation" for details.



- 2. Touch the item on the touch screen to operate:
- a) Menu title: displays current imaging mode. Touch the expanding button to show all available imaging modes under the current status, Touch to enter the modes.
- b) Current available special mode entrance: displays the available imaging modes related, touch to enter the modes. For example: iWorks, Physio.
- c) Parameter adjusting area: displays the parameters in the current imaging mode or function.
  - Value adjustment: touch the parameter to adjust the value. To increase the value by flipping from left to right and decrease the value by flipping from right to left.

- ON/OFF setting: some of the parameters only can be set at ON or OFF, ON is to activate the function, and when the function is activated, the menu item is highlighted in green.
- Functional item: touch to go to the corresponding function.
- Scroll bar item: when a scroll bar displays on the right of the menu, touch the item and swipe it
  up or down to show all menu items.
- Control Panel

Adjust using the trackball, control panel key, deflector rod, knob or slider.

## 5.1.3 Quickly Saving Image Settings

Press <F7> to access the image data saving dialog box.



- Save the image parameter adjustment:
  - Click [Save] to save the current image values for the current exam mode of the particular probe.
- Create new exam data (using the current image parameter settings):
  - Enter the name in the box after "Save As" to assign a name for a user-defined exam mode, and click [Create] to save the current image parameters, measurements, comments and body mark settings to the exam mode.
- Restore the factory settings:
  - The settings of the current exam mode and the probe can be restored to factory data by clicking [Restore].
- Check image parameter level and other settings:
  - Click [Show Parameter] to check levels of different image parameters.
  - Select "Advanced" tab to set TIC/TIB/TIS parameter.
  - Select "Advanced" and set "Sampling Line Displaying" to "On", then PW/M/TVM mode can be entered by pressing the imaging mode key only one time.
  - Select "Advanced" tab, set "Monitor CCT" to adjust color temperature, set "Monitor Gamma" to adjust brightness.

This function is not available under dual-probe frozen mode.

# 5.2 B Mode Image Optimization

B mode is the basic imaging mode that displays real-time images of anatomical tissues and organs.

## 5.2.1 Basic Procedures for B Mode Imaging

- 1. Enter the patient information. Select an appropriate probe and exam mode.
- 2. Press <B> on the control panel to enter B mode.
- 3. Adjust the parameters to optimize the image.
- 4. Perform other operations (e.g., measurement and calculation) if necessary.
- Press <B> on the control panel to return to B mode at any time.

## 5.2.2 B Mode Parameters

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

Parameter	F	D	G	FR	DR	iClear	iBeam	iTouch	Zoom	Echo Boost
Meaning	Frequency	Depth	Gain	Frame Rate	Dynamic Range	Dis	play whe	n the fund	ction is tu	rned on.

## 5.2.3 B Mode Image Optimization

#### **Image Quality**

#### **Description**

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

Rotate the knob under [Img Qual.] on the touch screen to select the different fundamental/harmonic frequency values.

Press the knob to switch between fundamental frequency and harmonic frequency.

The adjusting range of the fundamental frequency values can be divided into 4 levels: penetration preferred (HPen), general mode (HGen), resolution preferred (HRes), and the mode between penetration preferred and general mode (HPen-Gen).

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

#### **Impacts**

The system provides an imaging mode using harmonics of echoes to optimize the image. Harmonic imaging enhances near-field resolution and reduces low-frequency and large amplitude noise, so as to improve small parts imaging.

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

#### Gain

**Description** To adjust the gain of the whole receiving information in B mode. The real-time gain

value is displayed in the image parameter area in the top-right corner of the screen.

**Operations** Rotate the <B> knob clockwise to increase the gain, and counter-clockwise to

decrease it.

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

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

However, noise may also be increased.

Depth

**Description** This function is used to adjust the sampling depth, the real-time value of which is

displayed in the image parameter area in the top-right corner of the screen.

**Operations** Use the <Depth> deflector rod in the bottom-right part of the control panel to adjust the

depth.

The adjustable depth values vary depending on the probe types.

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

tissue in shallower locations.

**TGC** 

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

image.

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

the image.

**Operations** To increase the gain compensation in an area of interest, move the TGC slider to the

right.

To decrease the gain compensation in the corresponding area of interest, move the

TGC slider to the left.

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

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

**Acoustic Power** 

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

of which is displayed in the upper part of the screen.

**Operations** Adjust the acoustic power through the [A.Power] item on the touch screen. The

adjusting range is 3.2-100%.

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

the image and the force of penetration.

Impacts You should perform exams according to actual situations and follow the ALARA

Principle.

**Focus** 

**Description** Refers to adjusting the focus of the ultrasonic beams, using the "\" symbols which are

displayed to the right of the image.

**Operations** Adjust the focus number using the [Focus Number] item on the touch screen or by the

mapping-menu on the touch screen.

Use the <Focus> deflector rod in the bottom-right part of the control panel to adjust the

focus position.

In B mode, the available focus number can be switched between 1-4.

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

**Impacts** The greater the number of focal zones, the slower the frame rate.

### **Imaging Adjustment**

#### **Description**

More information can be obtained without moving the probe or changing the sampling position.

# FOV (Field of View)

- 1. To change the scan range, touch [FOV] on the touch screen to enter the FOV range and FOV position adjustment status.
- 2. Press <Set> to switch between FOV range and FOV position.
- 3. Rotate the trackball to adjust the FOV position or the FOV range.

When the scan range is adjusted to its widest, the FOV position cannot be changed.

Or you can adjust the focus by the mapping-menu on the touch screen.

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

The frame rate decreases when using a larger FOV.

**B** Steer

Use the <Angle/Steer> deflector rod on the control panel to adjust the steer angle.

ExFOV (Extended FOV)

Touch [ExFOV] or the mapping-menu item on the touch screen to turn the function on/off.

For linear probes, the ExFOV function displays as trapezoid imaging.

For convex probes, the ExFOV function displays as extending the scanning angle.

**Impacts** 

The FOV position/range is available only for convex and phase probes.

The ExFOV function is available only for linear and convex probes.

The B Steer function is available only for linear probes.

#### **Line Density**

**Description** 

The function determines the quality and information of the image.

**Operations** 

Adjust the line density using the [Line Density] item or the mapping-menu item on the

touch screen.

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

Effects

The higher the line density, the higher the resolution.

**Impacts** 

The higher the line density, the lower the frame rate.

#### **Dynamic Range**

Description

This function is used to adjust the B image resolution to compress or expand the gray display range. The real-time value displays in the image parameter area in the top-right corner of the screen.

**Operations** 

Adjust the dynamic range through the [Dyn Ra.] item or mapping-menu on the touch

screen.

Rotate the knob clockwise to increase the value. Rotate the knob counterclockwise to

decrease the value.

The adjusting range is 30-240dB.

**Impacts** 

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

contrast with more noise.

**iClear** 

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

boundary for optimization.

**Operations** Adjust using the [iClear] item or mapping-menu on the touch screen.

The system provides 7 levels of iClear adjustment: off represents no iClear effect, and

the bigger the value, the stronger the effect.

iClear+

**Description** iClear<sup>+</sup> is the advanced version of iClear. It can better enhance image quality, reject

noise, provide better contrast resolution, and identify positive lesion.

**Operations** The operation is the same as that of the iClear item. After configuring the iClear<sup>+</sup> and

iClear<sup>+</sup> Dongle options, the original iClear item becomes iClear<sup>+</sup> in the touch screen.

**Persistence** 

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

optimize the image and remove noise.

**Operations** Rotate the knob under the [Persistence] item or the mapping-menu item on the touch

screen to adjust the value.

The system provides 0-7 levels of frame average adjustment: the bigger the value the

stronger the effect.

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

**Impacts** Increasing Persistence may lead to missing signals.

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

**Description** The function provides better observation for image display.

**Rotation** Rotate the image using the [Rotation] item or the mapping-menu item on the touch

screen.

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

When the image is rotated by 90° or 270°, the depth scale is displayed in the top part

of the screen.

Invert (U/D Flip and L/R

To invert the image horizontally or vertically.

Flip and L/R Flip)

Touch [U/D Flip] or [L/R Flip] on the touch screen or the mapping-menu to invert the

image

**Effects** You can identify the image orientation using the "M" mark on the screen. By default,

the M mark is located in the top-left corner of the imaging area.

iBeam (Spatial Compound Imaging)

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

achieve image optimization.

**Operations** Adjust using the [iBeam] item or the mapping-menu item on the touch screen.

The system provides different levels of iBeam adjustment in single B mode. Off

represents no iBeam.

Effects Images can be optimized with less spot noise and higher resolution, so that more

details for the structure are revealed.

**Impacts** iBeam is not valid for phased probes.

**Image Merge** 

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

type, depth, invert status, rotation status and magnification factor, the system will

merge the two images so as to extend the field of vision.

**Operations** Turn the function on or off using the [Auto Merge] item or the mapping-menu item on

the touch screen.

**Impacts** The function is valid only for linear probes.

**Gray Map** 

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

**Operations** Select from among the maps by rotating the knob under the [Gray Map] item or the

mapping-menu item on the touch screen. The system provides 8 different gray effect

maps.

**Tint Map** 

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

distinction.

**Operations** Rotate the knob under the [Tint Map] item or the mapping-menu item on the touch

screen to select the map. The system provides 8 different color effect maps.

**TSI (Tissue Specific Imaging)** 

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

to tissue characteristics.

**Operations** Select from among the TSI modes using the [TSI] item or the mapping-menu item on

the touch screen.

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

and fat.

iTouch (Auto Image Optimization)

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

image effect.

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

The iTouch symbol will be displayed in the image parameter area of the screen once

<iTouch> is pressed.

Select different levels of iTouch effect using [iTouch] on the touch screen or the

mapping-menu.

Long press the <iTouch> key to exit the function.

#### H Scale

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

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

**Operations** 

Touch [H Scale] or the mapping-menu item on the touch screen to display or hide the scale.

#### **Dual Live**

**Description** Display different image effects of one probe for better observation.

Operation

Touch [Dual Live] item or the mapping-menu item on the touch screen to turn the function on/off. Dual-split windows of the images are displayed on the main screen.

Two pages of adjustable parameters are displayed in the touch screen. Shared parameters and left window parameters are displayed in the B(L) page, while right window parameters are displayed in the B(R) page.

In the image parameter area in the top-right corner of the main screen, parameters of both windows are displayed.

**Impacts** 

Image magnification is available in dual live mode.

#### **LGC**

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

Operation

Touch [LGC] or the mapping-menu item on the touch screen to access the adjusting dialog box.

The 8 rods displayed on the touch screen indicate the corresponding image areas on the main screen.

Touch the to adjust the gain, move downwards to decrease the gain, or move upwards to increase the gain.

The system also provides several preset parameters for imaging.

#### **Echo Boost**

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

boundary can be seen.

**Operation** Touch [Echo Boost] on the touch screen or the mapping-menu item to turn the function

on (when the function is turned on, the [Echo Boost] button is highlighted in green and

the system indicates "Echo Boost" in the image parameter area).

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

**Dehaze** 

**Description** This function can restrain noise, so as to enhance the contrast resolution of the image.

**Operations** Rotate the knob under the [Dehaze] item or the mapping-menu item on the touch

screen to adjust the value.

The adjusting range is 0-30 in increments of 1.

Ref. Line

**Description** A reference line and a help line meeting the probe icon side 45° display on the 2D

image under GYN and Pelvic Floor exam mode. This helps to locate midsagittal plane

of pelvic floor precisely and define the reference line for measurement.

**Operation** Tap [Ref. Line] in the B tab on the touch screen:

Roll the trackball to move the reference line;

Rotate the <Angle> to rotate the reference line around the intersection point.

NOTE: Ref. Lline can be adjusted by pressing <Set> in frozen state.

**Impacts** Use intra-cavity probe to activate the function in GYN or Pelvic Floor exam mode.

# **5.3** M Mode Image Optimization

## 5.3.1 Basic Procedures for M Mode Imaging

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

If "Sampling Line Displaying" is selected, then the screen will display the sampling line all the time and pressing <M> one will lead to entering M mode directly. See "5.1.3 Quickly Saving Image Settings" chapter for details.

## 5.3.2 M Mode Image Parameters

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

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

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

## 5.3.3 M Mode Image Optimization

Gain

**Description** To adjust the gain of M mode image. The real-time gain value is displayed in the image

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

**Operations** Rotate the <M> knob clockwise to increase the gain, and counter-clockwise to

decrease it.

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

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

However, noise may also be increased.

**Display Format** 

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

**Operations** Touch the different display format ratio buttons on the touch screen to adjust.

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

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

analysis through comparison.

**Speed** 

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

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

screen.

**Operations** Rotate the knob under the [Speed] item or the mapping-menu item on the touch screen

to adjust.

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

**Effects** Changing speed makes it easier to identify disorders in cardiac cycles.

**Tint Map** 

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

distinction.

**Operations** Rotate the knob under the [Tint Map] item or the mapping-menu item on the touch

screen to select the map. The system provides 8 different color effect maps.

Press the knob under the [Tint Map] item on the touch screen to turn the function

on/off.

**Gray Map** 

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

**Operations** To select from among the maps, turn the knob under [Gray Map] item or the mapping-

menu item on the touch screen. The system provides 8 different gray effect maps.

### Edge Enhance

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

boundary for optimization.

**Operations** Adjust using the [Edge Enhance] item or the mapping-menu item on the touch screen.

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

stronger the effect.

**Impacts** Larger edge enhance may lead to increased noise.

### **Dynamic Range**

**Description** This function is used to adjust the M image resolution to compress or expand the gray

display range.

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

top-right corner of the screen.

**Operations** Rotate the knob under the [Dyn Ra.] item or the mapping-menu item on the touch

screen

The adjusting range is 30-240dB.

**Effects** The more the dynamic range, the more specified the information.

M Soften

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

image details clearer.

**Operations** Adjust using the [M Soften] item or the mapping-menu item on the touch screen.

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

the effect.

**Time Mark** 

**Description** To show the time mark in M mode image.

**Operation** Turn on or off the function through [Time Mark] item in the menu in the upper left corner

of the screen.

**Effects** When time mark is displayed on the M mode image, it's much easier to identify the

cardiac cycles and detect more details.

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

# 5.4 Color Mode Image Optimization

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

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

## 5.4.1 Basic Procedures for Color Mode Imaging

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

## 5.4.2 Color Mode Image Parameters

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

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

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

## 5.4.3 Color Mode Image Optimization

#### **Color Gain**

**Description** Refers to the overall sensitivity to flow signals. This function is used to adjust the gain

in Color mode. The real-time gain value is displayed in the image parameter area in

the top-right corner of the screen.

**Operations** Rotate the <Color> knob clockwise to increase the gain, and counter-clockwise to

decrease it.

The adjusting range is 0-100 in increments of 2.

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

be missing when the gain is adjusted too low.

### **ROI Adjustment**

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

**Operations** When the ROI box is a dotted line, roll the trackball to change the size.

When the ROI box is a solid line, roll the trackball to change the position.

Press <Set> to switch between the solid line and the dotted line.

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

color sensitivity.

### **Image Quality**

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

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

**Operations** Rotate the knob under [Img Qual.] on the touch screen or the mapping-menu item to

select the different frequency values.

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

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

Frequency values vary according to probe types. Select the frequency according to the

needs of the detection depth and the current tissue characteristics.

**B/C Align** 

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

**Operations** Turn the function on or off using the [B/C Align] item or the mapping-menu item on the

touch screen.

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

**Dual Live** 

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

**Operations** Turn the function on or off using the [Dual Live] item or the mapping-menu item on the

touch screen.

When the function is turned on, the window will automatically switch to dual windows

(one for the B image, and the other for the Color image).

Steer

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

immobility of the linear probe.

**Operations** Adjust using the <Angle/Steer> deflector rod on the control panel.

**Effects** This function is used to adjust the scan angle of linear probes, so as to change the

angle between the transmitting beam and flow direction.

**Impacts** Steer is only valid for linear probes.

**Line Density** 

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

**Operations** Adjust using the [Line Density] item or the mapping-menu item on the touch screen.

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

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

**Impacts** The higher the line density, the lower the frame rate.

**Packet Size** 

**Description** This function is an indication of the ability to detect flow, which is used to adjust the

accuracy of color flow.

**Operations** Rotate the knob under the [Packet Size] item or the mapping-menu item on the touch

screen to adjust the value.

There are 3 levels of packet size available: 0 represents no packet size control and the

bigger the value the higher the sensitivity.

**Effects** The higher the packet size, the more sensitive the indication for low-velocity flow.

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

Flow State

**Description** This function is used for fast image optimization.

**Operations** Adjust using the [Flow State] item or the mapping-menu item on the touch screen.

3 levels are provided: L, M, H.

**Persistence** 

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

**Operations** Adjust through the [Persistence] item or the mapping-menu item on the touch screen.

The system provides 6 levels of persistence adjustment: 0 represents no persistence,

and the bigger the value the stronger the effect.

**Smooth** 

**Description** This feature is used to reject noise and smooth the image.

**Operations** Adjust using the [Smooth] item or the mapping-menu item on the touch screen.

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

effect.

Scale

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

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

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

**Operations** Rotate the knob under [Scale] on the touch screen or the mapping-menu item on the

touch screen.

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

according to the actual situation.

**Effects** Provides a much clearer color flow image.

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

flows.

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

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

**Baseline** 

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

actual situation so as to get an optimum flow display.

**Operations** Rotate the knob under [Baseline] on the touch screen or the mapping-menu item on

the touch screen.

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

means increase the signals below the baseline.

Invert

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

function is turned on.

**Operations** Turn the function on or off using the [Invert] item or the mapping-menu item on the

touch screen.

Select "Auto Invert" in "[Setup] (F10)  $\rightarrow$  [System]  $\rightarrow$  [Image]", so the color bar can automatically invert when the color flow is steered to a certain angle to accommodate

the operator's desire to distinguish the flow direction.

Auto invert function is available only for linear probes.

**Color Map** 

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

display effect of the color image.

**Operations** Rotate the knob under the [Color Map] item or the mapping-menu item on the touch

screen to select from among the maps.

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

maps and the VV group provides 10 2D maps.

### WF (Wall Filter)

**Description** It filters out low-velocity signals to provide effective information, and this function is

used to adjust the filtered frequency. The real-time value is displayed in the image

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

**Operations** Select using the [WF] item or the mapping-menu item on the touch screen.

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

actual situation.

**Impacts** Flow signals may be missing.

#### **Smart Track**

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

image effect. The angle and the position of the ROI are adjusted after the function is

enabled. The area is tracked without being affected by the dynamic moves.

**Operation** Tap [Smart Track] on the touch screen under Color/Power mode. The angle and the position of the ROI are adjusted automatically. The vessels lay in the middle of the ROI.

### **Priority**

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

signal or color signal.

**Operations** Rotate the knob under the [Priority] item or the mapping-menu item on the touch

screen to select the value.

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

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

grayscale signals are first to be displayed.

#### Velocity tag

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

Operation 1. Touch [Velocity Tag] or the map

1. Touch [Velocity Tag] or the mapping-menu item on the touch screen to enter the velocity marking status. A green mark appears on the color bar.

- 2. Roll the trackball upwards and downwards to select the marking velocity.
- 3. Press <Set> to enter the tag range selection status, and roll the trackball upwards and downwards to select the range.

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

#### iTouch (Auto Image Optimization)

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

image effect.

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

### **HR Flow (High Resolution Flow)**

**Description** This function enhances the micro vessel imaging effect, and can be used to analyze

the tissue blood supply condition.

**Operations** Touch [HR Flow] or the mapping-menu item on the touch screen to turn on HR Flow

status (the [HR Flow] button is highlighted in green when the status is turned on.)

The parameters in HR Flow mode are independent from those in Color mode.

**B** Display

**Description** To turn on or off the B image display as Color imaging remains active.

**Operation** Turn on or off the function through the [B Display] item in the menu in the upper left

corner of the screen.

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

**Glazing Flow** 

**Description** This function applies glazing effect to the vessel flow, so as to make it more

stereoscopic.

**Operation** Adjust through the [Glazing Flow] item on the touch screen.

There are 3 levels provided to adjust: Low, Mid, and High.

**Impacts** The color codes of the vessel velocity and power will change after the Glazing Flow

function is enabled. During diagnosis, users should exam the ROI without using the

Glazing Flow function. Otherwise, misdiagnosis may occur.

# 5.5 Power Mode Image Optimization

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

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

## 5.5.1 Basic Procedures for Power Mode Imaging

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

## 5.5.2 Power Mode Image Parameters

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

Parameter	F	G	PRF	WF
-----------	---	---	-----	----

Meaning	Frequency	Power Gain	Pulse Repetition Frequency (PRF)	Power Wall Filter

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

Parameters consistent with those in Color mode and B mode are not to be introduced. See the relevant Color mode and B mode sections, while special items of the Power mode are introduced in the following.

## 5.5.3 Power Mode Image Optimization

#### **Power Gain**

**Description** Refers to the overall sensitivity to flow signals. This function is used to adjust the gain

in Power mode.

The real-time gain value is displayed in the image parameter area in the top-right

corner of the screen.

**Operations** Rotate the <Color> knob clockwise to increase the gain, and counter-clockwise to

decrease it.

The adjusting range is 0-100 in increments of 2.

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

be missing when the gain is adjusted too low.

**Color Map** 

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

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

and Directional Power maps.

**Operations** To select from among the maps, turn the knob under [Color Map] on the touch screen

or adjust through the mapping-menu item.

There are 8 kinds of maps provided: P0-3 belong to Power mode maps, while dP0-3

belong to Directional Power mode maps.

The Power maps provide information about blood flow, which are highly sensitive to

the low-velocity flows.

The Directional Power maps provide information about flow direction.

### **Dynamic Range**

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

**Operations** Adjust through the [Dyn Ra.] item or the mapping-menu item on the touch screen to

adjust the dynamic range.

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

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

enhancing the range of signals to display.

# 5.6 PW/CW Doppler Mode

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

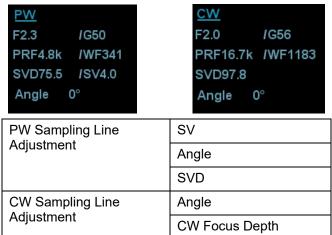
PW mode provides a function for examining flow at one specific site for its velocity, direction and features. CW mode proves to be much more sensitive to high-velocity flow display. Thus, a combination of both modes will contribute to a much more accurate analysis.

CW imaging is an option.

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

## 5.6.1 Basic Procedures for PW/CW Mode Exam

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



- 3. Set the position of the sample line by moving the trackball left and right. Set the SVD by moving the trackball up and down. Adjust the angle and SV size according to the actual situation.
- 4. Press <PW>/<CW> or <Update> again to enter PW/CW mode and perform the examination. You can also adjust the SV size, angle and depth in real-time scanning.
- 5. Adjust the image parameters during PW/CW mode scanning to obtain optimized images.
- 6. Perform other operations (e.g., measurement and calculation) if necessary.

If "sampling line displaying" is selected, then the screen will display the sampling line all the time and pressing <M> one will lead to entering M mode directly. For details, see "5.1.3 Quickly Saving Image Settings" chapter.

# 5.6.2 PW/CW Mode Image Parameters

In PW/CW mode scanning, the image parameter area in the top-right corner of the screen displays the real-time parameter values as follows:

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

Meaning Frequency Gain PRF Wall Filter SV Position	Angle
--	-------

- During PW/CW mode imaging, the image optimizing menus for B mode and PW/CW mode are displayed on the touch screen at the same time. If Color mode (Power mode) is also working, menus for certain modes will be displayed on the touch screen synchronously, and you can switch between them by clicking the mode tabs.
- When you adjust the depth of the B mode image, related changes will occur in the PW/CW mode image as well.
- Most of the parameters are the same for the PW mode and CW modes, so parameters of both are combined together to be introduced here.

Only phased and pencil probes support CW mode.

## 5.6.3 PW/CW Mode Image Optimization

#### Gain

**Description** This function is intended to adjust the gain of the spectrum map. The real-time gain

value is displayed in the image parameter area in the top-right corner of the screen.

**Operations** Rotate the [PW] knob clockwise to increase the gain, and counter-clockwise to

decrease it.

The adjusting range is 0-100 in increments of 2.

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

However, noise may also be increased.

SV

**Description** To adjust the SV position and size of sampling in PW mode, the real-time value of SV

and SVD are displayed in the image parameter area in the top-right corner of the

screen.

**SV size** Rotate the knob under [SV] or the mapping-menu item on the touch screen to adjust

the SV size.

Value: 0.5-20 mm.

**SVD** Roll the trackball to select the SV depth.

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

selecting a large SV size.

### **CW Focus Position**

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

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

**Operation** Roll the trackball to select the focus depth.

### **Image Quality**

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

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

#### Operation

Rotate the knob under [Img Qual.] item or the mapping-menu item on the touch screen to select the different frequency values.

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

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

#### Scale

#### Description

This function is used to adjust the speed range of the flow, which is adjusted using the PRF in the system.

The real-time PRF value is displayed in the image parameter area in the top-right corner of the screen.

#### **Operations**

Rotate the knob under the [Scale] item on the touch screen or through the mappingmenu item.

#### **Effects**

Provides a much clearer color flow image.

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

flows.

#### **Impacts**

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

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

#### iTouch

#### Description

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

image effect.

#### **Operations**

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

#### **Auto-Calculation**

#### **Description**

This function is used to trace the spectrum and calculate the PW/CW mode image parameters. The results are displayed in the results window.

- 1. Touch [Auto Calc] on the touch screen or the mapping-menu to turn the auto calculation function on or off.
- 2. After the auto calculation function is turned on, touch "Auto Calculation" tab.

### Auto Calculation Parameter

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

### Auto Calculation Cycle

To set the heart cycle number for auto-calculation.

Touch [Auto Calc Cycle] on the touch screen to select the cycle number, the adjusting range is 1-5.

#### **Trace Area**

To set the trace area of the Doppler wave in the spectrum map, applicable for auto calculation, V Max and V Mean display.

To change the trace area, adjust through [Trace Area] item or the mapping-menu item on the touch screen.

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

### **Trace**

To set the smooth level when tracing.

Smooth To change the trace area, adjust through [Trace Smooth] item or the mapping-menu

item on the touch screen.

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

smooth processing.

Trace Sensitivity

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

To change the trace area, adjust through [Trace Sensitivity] item or the mapping-menu

item on the touch screen.

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

sensitivity.

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

latest cardiac cycle.

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

selected area.

Invert

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

**Operations** Turn the function on or off using the [Invert] item or the mapping-menu item on the

touch screen.

Select "Auto Invert" in the "[Setup] (F10)  $\rightarrow$  [System]  $\rightarrow$  [Image]", so the spectrum can automatically invert when the color flow is steered to a certain angle to accommodate

the operator's desire to distinguish the flow direction.

**Speed** 

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

**Operations** Adjust using the [Speed] item or the mapping-menu item on the touch screen.

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

**Effects** Changing the speed makes it easier to identify the cardiac cycles and to detect more

details.

T/F Res.

**Description** This function is used to create a balance between time resolution and spatial

resolution.

**Operations** Adjust using the [T/F Res] item or the mapping-menu item on the touch screen.

There are 4 levels of T/F Res. values available.

**Wall Filter** 

**Description** It filters out low-velocity signals to provide effective information, and this function is

used to adjust the filtered frequency. The real-time value is displayed in the image

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

**Operations** Select using the [WF] item or the mapping-menu item on the touch screen.

**Impacts** Signals of low-velocity flow may be missing.

**Tint Map** 

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

distinction.

**Operations** Adjust through the [Tint Map] item or the mapping-menu item on the touch screen to

select the map. There are 8 color effect maps available.

**Gray Map** 

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

**Operations** To select from among the maps, adjust through the [Gray Map] item on the touch

screen. There are 10 gray effect maps available.

**Display Format** 

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

**Operations** Touch the different display format ratio buttons on the touch screen to adjust.

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

**Duplex/Triplex** 

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

displayed synchronously.

**Operations** Touch [Duplex/Triplex] on the touch screen or on the mapping-menu to turn the

synchronization on or off.

**Smart Track** 

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

image effect.

Operation Tap [Smart Track] on the touch screen under Color/Power+PW mode. The angle and

the position of the PW sampling line, SV size, SV position and SV angle are adjusted

automatically. The vessels lay in the middle of the ROI.

**HPRF** 

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

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

for the selected PW Doppler scale.

**Operations** Turn the function on or off using the [HPRF] item or the mapping-menu item on the

touch screen.

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

**Baseline** 

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

**Operations** Rotate the knob under [Baseline] or use the mapping-menu to adjust.

**Effects** Changes the flow-velocity range to optimize the image.

**Angle** 

**Description** This function is used to adjust the angle between Doppler vector and flow to make the

velocity more accurate.

The real-time adjusting angle value is displayed on the right part of the spectrum map.

**Operations** Rotate the <Angle/Steer> knob on the control panel to adjust it.

Or rotate the knob under [Angle] to adjust it.

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

**Quick Angle** 

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

right part of the spectrum map.

**Operations** Adjust using the [Quick Angle] item or the mapping-menu item on the touch screen.

Or press the knob under [Angle] to adjust it.

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

**Dynamic Range** 

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

intensity to grayscale.

**Operations** Adjust using the [Dyn. Ra.] item or the mapping-menu item on the touch screen.

The adjusting range is 24-72dB.

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

contrast with more noise.

**Audio** 

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

**Operations** Rotate the <Volume> knob on the left of the touch panel to adjust the volume.

Press the <Volume> knob to open or shut down the volume.

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

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

**PW Steer** 

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

**Operations** Press the <Angle/Steer> knob on the control panel to switch to "Steer adjustment".

Rotate the knob to adjust.

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

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

The values of steer angles vary according to the probe.

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

**Time Mark** 

**Description** To show the time mark in M mode image.

Operation Turn on or off the function through [Time Mark] item in the menu in the upper left corner

of the screen.

Effects When time mark is displayed on the PW mode image, it's much easier to identify the

cardiac cycles and detect more details.

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

## 5.7 Color M Mode

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

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

CM mode is not available for linear probes.

## 5.7.1 Enter Color M Mode

- Color Flow M Mode
  - In B + M mode, press <Color> on the control panel to enter the sampling line adjustment status, and press <M> again.
  - In B + Color, B + Color + PW or B + Color + CW mode, press <M> twice on the control panel.
- Color Tissue M Mode (TVM)
  - In B + TVI/TVD, or B + TVI + TVD mode, press <M> twice on the control panel.
  - In Color Flow M mode, press <TDI> on the control panel, press user-defined key for TDI on the control panel (Assign a key as user-defined TDI: the setting path is "[Setup]→ [System] →[Key Config]", see "12.1.6 Key Configuration" chapter for details) or touch [TDI] on the touch screen to enter the sampling line adjustment status, and press <M> again.

## 5.7.2 Exit Color M Mode

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

## 5.7.3 Color M Mode Image Parameters

- In Color Flow M mode, the parameters that can be adjusted are the same as those in B, M and Color modes. See the relevant B, Color and M mode sections for details.
- In Color Tissue M mode, the parameters that can be adjusted are the same as those in B, M and TVI modes. See the relevant B, M and TVI mode sections for details.
- In Color M mode scanning, the image parameter area in the top-right corner of the screen displays the real-time parameter values.
- ROI Adjustment

The ROI determines the size and position of the color flow or color tissue displayed in the Color M mode image.

- Press <Set> to switch the status among ROI position adjustment, ROI size adjustment, the position of the sampling line adjustment and the sampling gate adjustment.
- Set the ROI position by moving the trackball.
- Or, set the ROI size by moving the trackball.
- Or, set the position of the sampling line by moving the trackball. Press <Update>, then press
   <set> repeatedly and moving the trackball to adjust the position and size of the sampling gate.
- Press <Update> on the control panel to switch between the real-time mode and freeze mode.

## 5.8 Anatomical M Mode



Anatomical M Mode and Color Anatomical M mode images are provided for reference only, not for confirming diagnoses. Compare the image with those of other machines, or make diagnoses using non-ultrasound methods.

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

Shortcut key setting

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

Free Xros M imaging and Free Xros CM imaging are options.

## 5.8.1 Free Xros M Imaging (Anatomical M-Mode)

## 5.8.1.1 Basic Procedures for Free Xros M Imaging

- 1. In real-time 2D mode or M mode, adjust the probe and image to obtain the desired plane. Or select the desired 2D cine files.
- 2. Click [Free Xros M] on the touch screen of the B mode tab to enter Free Xros M mode, or press the user-defined key.
- 3. Adjust the M-mark (single or multiple) line to obtain optimized images and necessary information.

■ In Dual-split or Quad-split mode, it is the currently activated window that enters the Free Xros M mode.

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

## 5.8.1.2 Free Xros M Image Parameters

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

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

**Description** There are 3 M-mark lines available, each with "A", "B" or "C" at the one end as

identification and an arrow at the other end to mark the direction.

M-mark Line Selection

Perform the selection using the [Show A], [Show B] or [Show C] item on the touch screen or the mapping-menu, and the corresponding image will be displayed on the

screen once the related item is selected.

Display current

Touch [Display Cur.] or [Display All] on the touch screen or the mapping-menu to select

whether to display the image of the current M-mark line or all.

**Impacts** When there is only one M-mark line on the screen, it cannot be hidden.

### Switching between the M-mark Lines

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

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

cursor.

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

### Adjusting the M-mark Line

**Description** 

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

**Operations** 

Position Adjustment

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

Angle Adjustment

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

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

### 5.8.1.3 Exit Free Xros M

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

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

**CAUTION**:

Free Xros CM images are provided for reference only, not for confirming diagnoses. Compare the image with those of other machines, or make diagnoses using non-ultrasound methods.

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

Only the phased probe supports Free Xros CM.

#### 5.8.2.1 Basic Procedures for Free Xros CM

- 1. In 2D real-time imaging mode, adjust the probe and image to get the desired image, then fix the probe.
- 2. Press [TDI] or the user-defined key to enter TDI imaging and acquire the necessary images.
- 3. Press the user-defined key for Free Xros CM or touch [Free Xros CM] on the touch screen to enter Free Xros CM mode.
- 4. Roll the trackball to define the start point of the sample line on the 2D image. The cursor displays as ■, and can only be moved within the 2D image.
- 5. Press <Set> to fix the start point. The digital number "1" is marked beside the point.
- 6. Define the next point using the trackball and <Set> key (touch [Undo] to cancel the current point and activate the preview point). The system updates the time-motion curve in real time. The sample line is displayed in green, and each point is marked with a number in sequence.
- 7. Repeat Step 6 to finish the sample line.
- 8. Double-click the <Set> key to end editing. The sample line is displayed in white.
- 9. Adjust the image parameters to optimize the image, obtain the relevant tissue image for data analysis, then save the image if necessary.
- 10. Press the user-defined key again or <B > to exit Free Xros CM mode.

### **Sample Line Modification**

- To enter curve (sample line) modification status:
   For a completed sample line, set [Edit] to "On" and the sample line is editable.
- 2. Anchor the cursor to a certain point, press the <Set> key to activate the point, then roll the trackball to drag the point for a desired sample line.
- 3. Double-click the <Set> key to end editing. The sample line is displayed in white.

#### **Delete a Sample Line**

Touch [Delete] to delete the selected line. You can re-create a new sample line.

Tip:

The free Xros M mode and Free Xros CM mode parameters are independent of each other, but their functions are the same. Free Xros CM parameters are not to be introduced. See the relevant M mode and Free Xros M mode sections.

## 5.9 TDI

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

4 types of TDI mode are available:

- Tissue Velocity Imaging (TVI): this imaging mode is used to detect tissue movement with direction and speed information. In general, the warm color indicates movement toward the probe, while the cool color indicates movement away from the probe.
- Tissue Energy Imaging (TEI): this imaging mode reflects the status of cardiac movement by displaying the intensity of tissue. The brighter the color the less the intensity.
- Tissue Velocity Doppler Imaging (TVD): this imaging mode provides quantifiable direction and velocity information about the tissue.
- Tissue Velocity M Imaging (TVM): this function assists in observing the cardiac motion through a direct angle. TVM mode is also called Color Tissue M mode which has been introduced in the Color M mode chapter. See "5.7 Color M Mode" for details.

TDI imaging and TDI QA are options. Cardiology Package should be configured first.

## 5.9.1 Basic Procedures for TDI Imaging

- Press user-defined key for TDI on the control panel in real-time scanning to enter the modes (Assign a key as user-defined TDI: the setting path is "[Setup]→ [System] →[Key Config]", see "12.1.6 Key Configuration" chapter for details), or touch [TDI] on the touch screen directly:
  - ➤ In B or B+Color mode: to enter TVI Mode, TVI mode parameters will be displayed on the touch screen.
  - ➤ In Power mode: to enter TEI Mode, TEI mode parameters will be displayed on the touch screen.
  - ➤ In PW mode: after pressing the [TDI], press <PW> or <Update> to enter TVD Mode, TVD mode parameters will be displayed on the touch screen.
  - ➤ In M mode: after pressing the [TDI], press <M> or <Update> to enter TVM Mode, TVM mode parameters will be displayed on the touch screen.
- Switching between the TDI sub-modes
  - In TDI mode, press <Color>, <Power>, <M> or <PW> to switch between the modes.
- Exit TDI
  - Press the user-defined key to exit TDI mode and enter general imaging modes.
  - Or, press <B> on the control panel to return to B mode.

## **5.9.2** TDI Image Parameters

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

Parameter	F	G	PRF	WF
Meaning	Frequency	Gain	PRF	Wall Filter

TVD

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

## 5.9.3 TDI Image Optimization

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

#### **Tissue State**

**Description** This function is used for fast image optimization.

**Operations** Adjust using the [Tissue State] item or mapping-menu item on the touch screen.

3 levels are provided: L, M, H.

## 5.9.4 TDI Quantitative Analysis (QA)

CAUTION:

TDI Quantitative Analysis results are provided for reference only, not for confirming diagnoses. Compare the results with those of other machines, or make diagnoses using non-ultrasound methods.

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

The system provides 3 kinds of curves for quantitative analysis:

- Speed Time curve;
- Strain Time curve;
- Strain Rate Time curve.

Strain:	Deformation and displacement of the tissue within the specified time.
Strain rate:	Speed of the deformation, as myocardial variability will result in velocity gradient. Strain rate is commonly used to evaluate how fast the tissue is deforming.

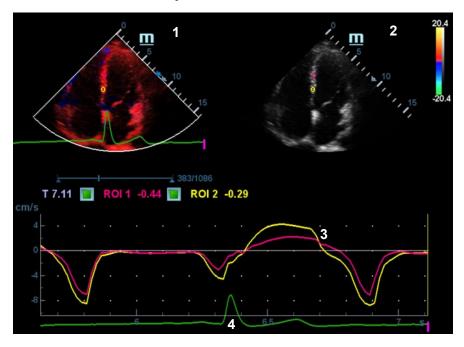
### TDI QA Workflow:

 Perform image scanning on cardiac muscle, freeze the image and select a range of images for analysis, or select a desired cine loop from the stored images.

Tip:

- Images from the current scan session (already in freeze mode) or from a saved image loop can be used for TDI QA.
- TDI QA is only available if the user has selected an image loop. If the user has selected a saved still image (just one frame), the TDI QA function is not available.
- 2. Touch [TDI QA] on the TVI touch screen page to activate the TDI QA function, or press the userdefined key for TDI QA directly.
- 3. Mark out the part of interest.
- 4. Select the quantitative analysis curve: touch [Speed] / [Strain Rate] / [Strain] to select.
- 5. Save the curved image, export the data and perform parameter analysis.
- 6. Touch [Exit] to exit the TDI QA function.

## 5.9.4.1 TDI QA Screen Description



TDI QA Screen (using the Speed – Time curve as an example)

#### 1 - TVI Cineloop window

Sample area: indicates the sampling position of the analysis curve. The sample area is color-coded, 8 (maximum) sample areas can be indicated.

### 2 - B Cineloop window

Tip:

- The images in the TVI cineloop window and B cineloop window are the frozen image of the same moment. Roll the trackball to review the images in the two cineloop windows.
- Sample areas are linked in the TVI cineloop window and B cineloop window.
- 3 Displays the analysis curve
  - The Y-axis represents the speed (unit: cm/s). [In the Strain Rate Time curve, the Y-axis represents the strain (%). In the Strain Time curve, the Y-axis represents the strain rate (1/s).]
  - The X-axis represents the time (unit: s).
  - Frame marker: a white line perpendicular to the X-axis which can be moved horizontally left to right (and right to left) by rolling the trackball.
  - Click the checkbox beside the ROI to set whether to hide or display the QA curve.
  - You can get the current X/Y-axis value by moving the cursor onto one point on the curve. If you
    press <Set> now, the frame marker will move to that spot.
- 4 Displays the ECG trace (no ECG trace displayed here).

### 5.9.4.2 Basic TDI QA Procedures

#### Setting the ROI

This function is used for setting the TDI QA target.

Up to eight ROIs can be saved on the reference image, with the corresponding eight traces plotted simultaneously on the graph. Each ROI display has a different color, and its corresponding trace data is plotted with the same color.

There are two different methods for determining the shapes of the sample area: Standard ROI and Freehand ROI.

### ROI types:

- Standard ROI: if selected, the ROI is drawn automatically with its shape determined by "Standard Height/Width/Angle".
- Ellipse ROI: if selected, the ROI is drawn by the trackball.

#### Standard ROI

- 1. Touch [Standard ROI] on the touch screen.
- 2. Browse the image to a desired frame.
- 3. When the trackball positions the cursor over the reference image(s), an elliptical ROI is automatically generated and displays on the reference image(s).
- 4. When scanning with an elliptical ROI, press <Set> to fix the ROI position and freeze its corresponding trace on the plot.

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

The last generated or selected ellipse is considered to be the active ROI, and its trace plot automatically updates as the user repositions it on the reference image.

A new active ROI is generated whose position is manipulated by the trackball and whose analysis curve traces will be plotted as before, while the previous ROI and trace remain fixed at the points they were saved at.

Press <Clear> to delete last ROI.

### ■ Ellipse ROI

- 1. Touch [Ellipse ROI] on the touch screen. When the cursor appears in the image review area (TVI image review window or 2D image review window), it displays as a color-coded ellipse.
- 2. Browse the image to a desired frame.
- 3. Use the trackball to position the caliper on the reference image at the start point. Press <Set> to fix the start point.
- 4. Trace the outline of the desired ROI by moving the cursor with the trackball.
- 5. Press the <Set> key, and roll the trackball to create the ROI. When a suitable ROI has been drawn, confirm the ROI by double-clicking the <Set> key. Press the <Clear> key to cancel the drawing.

#### Delete an ROI

Press the <Clear> key to clear the last ROI. Touch [Delete All] on the touch screen to clear all ROIs.

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

Press <Clear> to delete the last added ellipse ROI.

#### Standard Height/Standard Width/Standard Angle

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

#### Strain Distance

Sampling distance for calculating deformation. Use the knob under [Strain Dist.] on the touch screen to select the corresponding value for the Strain – Time curve or Strain Rate – Time curve.

#### **ROI tracking**

Touch [ROI Tracking] to be On to start tracking.

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

Tip:

- Elliptical ROIs can be positioned in any way that keeps their center within the image boundaries. If part of the ROI is outside the image boundary, only data from within the image boundary is used for calculating the mean intensity value.
- When the user repositions an ROI, the old trace data is erased from the plot and the trace data for the new position re-plotted.

#### X Scale

Rotate the knob under [X Scale] on the touch screen to choose a different value. The X scale display will be changed. This function can be used to track detailed tissue information.

#### **Smooth**

Use this function to smooth the curve. The system provides 7 levels of smooth effect.

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

- 1. Click [Export] on the touch screen.
- 2. Select the drive and enter the file name in the displayed window.

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

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

## 5.10 3D/4D

3D/4D imaging is largely environment-dependent, so the images obtained are provided for reference only, not for confirming diagnoses.

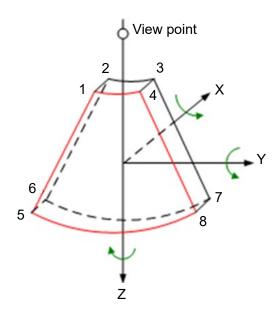
## 5.10.1 Overview

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

#### ■ Terms

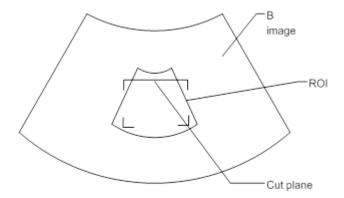
NOTE:

- 3D image Volume Rendering (VR): the image displayed to represent the volume data.
- 4D: continuous-sweep volume acquisition.
- View point: a position for viewing volume data/3D image.
- MultiPlaner Rendering (MPR): the three sectional planes of the volume acquisition. As shown
  in the figure below, the XY-paralleled plane is the C-section, the XZ-paralleled plane is the Bsection, and the YZ-paralleled plane is the A-section. The probe is moved along the X-axis.
- ROI (Region of Interest): a volume box used to determine the height and width of scanning volume.
- VOI (Volume of Interest): a volume box used to display the 3D image (VR) by adjusting the region of interest in MPR.



#### ROI and VOI

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



### ROI size and position

Roll the trackball to change the ROI size and position. Press the <Set> key to toggle between setting the size (dotted line) and position (solid line).

#### Curved VOI adjustment

Roll the trackball to change the curved VOI position. Press the <Set> key to switch between the changing ROI and curved VOI states.

This function changes the curved shape of the nearest VOI section and facilitates observation of the volume data of interest.

When a triangle of control point is displayed on the curved VOI, it can be adjusted both in acquisition preparation status, and in the A, B and C sections of review/4D imaging status.

The orientation and shape (line or dot) of curved VOI vary depending on the view direction:

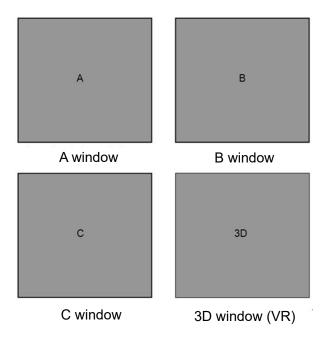
View	Curved VOI
U/D	At the upper part of curved VOI
D/U	At the lower part of curved VOI
L/R	At the left part of curved VOI
R/L	At the right part of curved VOI
F/B	Displays as a dot
B/F	Displays as a dot

#### About the probes

A 2D imaging probe can be applied for Smart 3D imaging. However, to realize Static 3D imaging, 4D imaging, STIC, iPage<sup>+</sup>, SCV<sup>+</sup>, Color 3D, Smart Volume, Smart FLC, Smart Planes CNS, Smart Face, Smart Planes FH or Niche, a volume probe should be selected.

#### ■ MPR

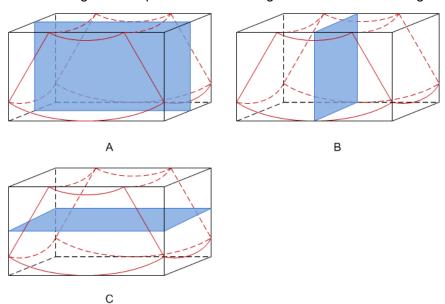
The principle of 3D imaging is to render a 3D image from multiple 2D image information. The following describes the spatial relationship of 3 MPRs (A, B and C) and the 3D image (VR). In the quad display format view, the screen displays 3 MPRs (A, B and C) and the 3D image.



On the touch screen, the current window's icon is highlighted, as shown below. Window A is the currently activated window.



A, B and C sectional images correspond to the following sections of the 3D image.



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

Tip: the upper part of the 3D image in the 3D window corresponds to the orientation mark on the probe. If the fetal posture is head down (toward the mother's feet), and the orientation mark is toward the mother's head, then the fetus posture is head down in the 3D image. The 3D image can be rotated by touching [180°] on the touch screen to show the fetus head-up.

 $\triangle$ CAUTION:

Ultrasound images are provided for reference only, not for confirming diagnoses. Use caution to avoid misdiagnosis.

#### ■ Free View (Free View Imaging)

With this function, the probe scanning direction can be controlled just by changing the probe scanning angle. The image of interest can be easily found without any actual probe position and direction change. This not only reduces the operations, but most importantly, it decreases patient discomfort resulting from moving the probe.

When the intra-cavity 4D probe is activated, the parameter [Free View] can be adjusted on the B image touch screen for adjusting the probe angle.

Range: -45°~+45°, in increments of 5°.

### Wire cage

When viewing a 3D/4D image on the display monitor, it is sometimes difficult to recognize the orientation. To help, the system displays a three-dimensional drawing to illustrate the orientation. The blue plane shows the image acquisition where started, while the red plane shows the image acquisition where ended. A yellow plane in the wire cage shows the position of the MPR. See the image below:



Wire Cage

## 5.10.2 Note Before Use

## 5.10.2.1 3D/4D Image Quality Conditions

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

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

#### ■ Fetal Condition

(1) Gestational age

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

(2) Fetal body posture

Recommended: cephalic face up (Figure a) or face to the side (Figure b);

NOT recommended: cephalic face down (Figure c).







(3) Amniotic fluid (AF) isolation

The desired region is adequately isolated by amniotic fluid.

The region to be imaged is not obscured by limbs or umbilical cord.

- (4) The fetus keeps still. If there is fetal movement, it is necessary to rescan.
- Angle of a B tangent plane

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

■ Image quality in B mode (2D image quality)

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

- High contrast between the desired region and the surrounding AF.
- Clear boundary of the desired region.
- Low noise of the AF area.
- Scanning technique (only for Smart 3D)
  - Stability: the body, arm and wrist must move smoothly, otherwise the restructured 3D image distorts.
  - Slowness: move or rotate the probe slowly.
  - Evenness: move or rotate the probe at a steady speed or rate.

#### NOTE:

- 1. A region with a qualified image in B mode may not be optimal for 3D/4D imaging. E.g., adequate AF isolation for one MPR does not mean the whole desired region is isolated by AF.
- 2. Practice is needed for a high success rate of qualified 3D/4D imaging.
- 3. Even with good fetal condition, acquiring a suitable 3D/4D image may require more than one scanning.

## 5.10.3 Static 3D

Static 3D provides single frame image acquisition of 3D images. During scanning, the probe performs the scanning automatically.

## 5.10.3.1 Basic Procedures for Static 3D Imaging

To perform Static 3D imaging:

- 1. Select the appropriate probe and exam mode. Make sure there is sufficient gel on the probe for scanning.
- 2. Obtain a 2D image.

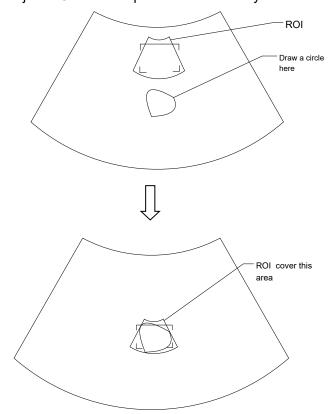
Make sure there is:

- High contrast between the desired region and the surrounding AF (amniotic fluid).
- Clear boundary of the desired region.
- Low noise of the AF area.
- 3. Press to enter Static 3D acquisition preparation mode, and define the ROI as well as the curved VOI.

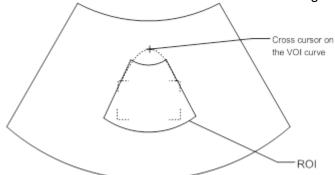
To adjust the ROI:

- Under acquisition preparation status: roll the trackball to change the ROI size, ROI position and curved VOI, press the <Set> key to toggle between setting the ROI position, ROI size and curved VOI.
- Tap [Flip VOI] to flip VOI. Tap [Reset VOI] to reset the angle of VOI to the original status.
- Enter touch screen mapping mode, see "3.8.4 Touch Screen Operation" for details.

Draw a circle around the interested region, then the system will position the ROI to cover the region. You can adjust ROI size and position if necessary.



Touch the cross cursor on the VOI curve and move the cursor with finger to adjust VOI curve.



For setting the ROI, be sure to:

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

**NOTE:** When defining an ROI, try to eliminate useless data so as to reduce the volume data and shorten the time for image storing, processing and rendering.

- 4. Select a render mode on the touch screen and set parameters such as [Angle] and [Image Quality] on the touch screen accordingly.
- 5. Press <Update> on the control panel to start the 3D image acquisition. The system enters 3D image viewing status when the acquisition is completed. In image viewing status, you can perform VOI setting, image editing and other operations. For details, see "5.10.3.3 Static 3D Image Viewing."
- 6. Exit Static 3D.

# 5.10.3.2 Static 3D Acquisition Preparation

Description of parameters:

Туре	Parameter	Description			
	Analo	Function: to set the range for imaging.			
	Angle	Range: 10-80°.			
Parameter adjusting	Quality	Function: to adjust the image quality by changing the line density. Image quality can affect the imaging speed: the better the image quality, the longer the time.			
		Range: Low2, Low1, Mid, High1, High2			
	Mix	Set the Mix ratio of main render to sub render.			
		Function: set Surface as the 3D image rendering mode.			
	Surface	This is useful for surface imaging, such as fetus face, hand or foot.			
		Tip: you may have to adjust the threshold to obtain a clear body boundary.			
	Max	Function: set Max as the 3D image rendering mode. Displays the maximum echo intensity in the observation direction.			
		This is useful for viewing bony structures.			
Render Mode	Min	Function: set Min as the 3D image rendering mode. Displays the minimum echo intensity in the observation direction.			
		This is useful for viewing vessels and hollow structures.			
	X-Ray	Function: set X-ray as the 3D image rendering mode. Displays the average value of all gray values in the ROI.			
		X Ray: used for imaging tissues with different internal structures or tissues with tumors.			
	iLive	Function: add the light rendering effect based on the general rendering effect.			
	icive	iLive cannot be selected as sub render mode. When it is set as main render mode, the sub render mode is disabled.			
STIC		sed on the movements of the fetus, rebuilt and show the anatomical structure nin a physical movement by using the interconnection between the time and the ce.			

## 5.10.3.3 Static 3D Image Viewing

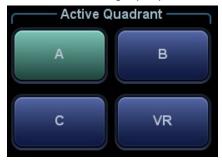
## **Enter/Exit Image Viewing**

- To enter image viewing:

  The system enters image viewing when image acquisition is complete.
- Exit
  To return to 3D/4D image acquisition preparation status, press <Update> or <Freeze>.

#### **Activate MPR**

Touch [A], [B], [C] or [VR] to activate MPR or 3D image (VR).

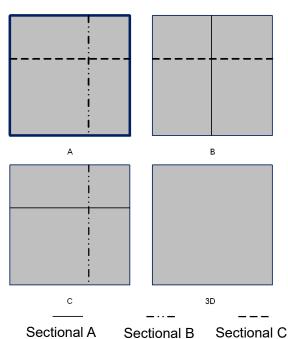


## **MPR Viewing**

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

- Window A is blue, and the lines (representing MPR A) displayed in the other two windows are also blue.
- Window B is yellow, and the lines (representing MPR B) displayed in the other two windows are also yellow.
- Window C is orange, and the lines (representing MPR C) displayed in the other two windows are also orange.

The positions of the other two MPRs are indicated in the selected plane. You can roll the trackball to change the position.



#### **MPR Only**

Touch on the touch screen to display MPR only. The adjustable image parameters are changed to MPR parameters automatically.

Only A, B and C MPR are displayed, and VR is not displayed.

The MPR Only function is available in image acquisition status.

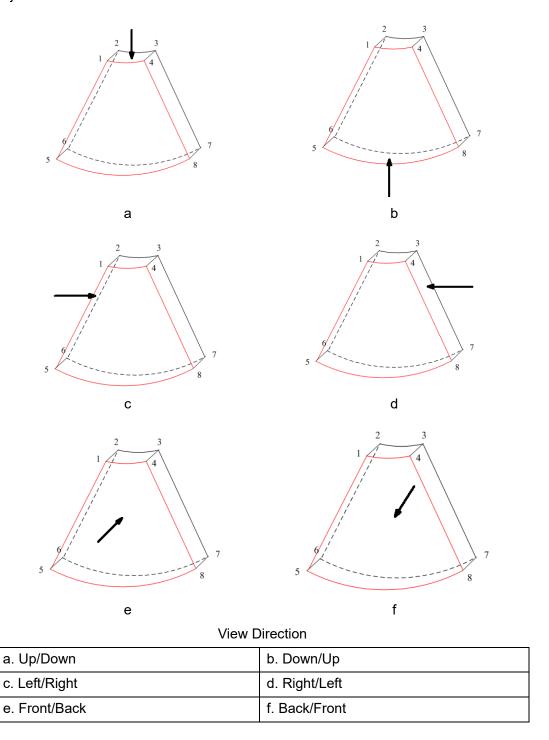
## **Asymmetric**

Touch on the touch screen to display MPR along with VR. A larger VR image along with 3 small MPR images will be displayed.

#### **View Direction**

The Region of Interest (ROI), also referred to as the Render Box in rendering, contains the section of the volume you want to render. Therefore, objects that are not inside the box are not included in the render process and are cut out (this is important in surface mode to allow a free line of sight). This may or may not be the entire VOI.

You can adjust the view direction of the ROI.



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

Touch [Flip] on the touch screen to view in the opposite direction to the current direction, as shown in Figures b, d and e.

## **Adjust VOI**

#### VOI On

The VR image displays VOI information.

- 1. In image viewing status, touch [VOI] to turn it to "On."
- 2. Select the desired window by touching [A], [B] or [C] or [VR].
- 3. Roll the trackball to adjust the VOI position, size and curved VOI, and press <Set> to switch between the adjusting status. Or rotate the <4D> knob on the control panel to adjust the relative position of MPRs so as to slice through the VR.
- VOI Off

The VR image displays ROI information.

Touch [VOI] to turn it to "Off." The ROI image is displayed on the screen. Roll the trackball to observe the MPR.

- Accept VOI
- 1. This function is usually used for MPR observation and to determine the relative position of the MPR to the VR.
- 2. Touch [Accept VOI] on the touch screen.
- 3. Select the desired MPR by touching [A], [B] or [C] or [VR].
- 4. Roll the trackball to view the current active MPR. The other two MPRs change correspondingly. Or rotate the <4D> knob to adjust the relative position of MPRs so as to slice through the VR.

In Accept VOI status, when the VR is active or the MPR which is perpendicular to the view direction is active, the center point of the VR displays. Adjust the position using the trackball.

#### **Image Rendering Parameters**

In image viewing status, render the image by adjusting the relevant parameters.

Render setting parameters description:



on the touch screen to select VR or MPR parameter adjustments.

- When [VR] is highlighted in green, parameter adjustment is performed on the VR image.
- When [MPR] is highlighted in green, parameter adjustment is performed on the MPR.

Adjustable parameters are as follows:

Parameter	Description
Threshold	Function: to set the threshold for 3D image rendering. 3D image is rendered on the signal above thresholds by eliminating noise via the Threshold parameter. Lower threshold can eliminate lower range noises and echo, which will contribute to a clearer and smoother image.
	Range: 0% to 100%.
	Available only in Surface rendering mode.

Parameter	Description				
	Function: to adjust the transparency value for 3D image rendering. It implies the transparency of the light. The higher the value is, the tougher the surface becomes.				
Opacity	Range: 0% to 100%.				
	The lower the number is, the more transparent the gray scale information will be.				
	Available only in Surface rendering mode.				
	Function: to set the smoothness of 3D image.				
Smooth	Range: 0 to 10. 0 refers to no smooth effect; 1-10 provides 10 effects in incremental order.				
	Tip: insufficient smoothness can result in a fuzzy image; however, too much smoothness will lead to image distortion.				
	Function: to set the brightness of image.				
Brightness	Range: 0%-100%, in increments of 2%.0% represents the minimum brightness, while 100% represents the maximum.				
	NOTE: the adjustment for 3D (VR) and MPR.				
	Function: set the contrast scale of the image (contrast).				
Contrast	As long as the contrast becomes larger, the bright spot and dark spot on the image change as well.				
	Range: 0%-100%, in increments of 2%.				
	NOTE: the adjustment for 3D (VR) and MPR				
Tint	Function: enable/disable tint map. The color of image change according the tint value.				
	Selection: OFF, 1-8.				
Gray Map	Function: enable/disable gray map. The color of image change according the gray scale value.				
	Adjusting level: tap [MPR]. Rotate [Gray Map] knob. The adjusting range: 1-8.				
VD Orientation	To quickly rotate the VR.				
VR Orientation	Selection: 0°, 90°, 180°, 270°.				
3D iClear	Function: The 3D adaptive filtering is used to enhance the spatial continuity of tissue structure, and restrain speckle noise to increase image contrast, so as to optimize volume image data.  Selection: OFF, 1-7.				
	Select VR imgae. Adjust 3D iClear to optimize VR image.				
	Select MPR imgae. Adjust 3D iClear to optimize MPR image.				
	Optimize the signal of the face area to reduce the noise of the AF area and				
Face+	improve the signal-noise ratio of the face area, make the face more fullness to easily obtain the image of fetal face.				
	Range: 1-3.				
VR Refine	Function: Optimize the signal-noise ratio and the contrast of VR image.  Selection: OFF, 1-7.				
	Function: Poduce the poice and keep the boundary of the image mare clearly				
MagiClean	Function: Reduce the noise and keep the boundary of the image more clearly.				

Parameter	Description			
Depth VR	Function: Superimpose the tint map basic on the VR image to improve the stereoscopic sensation and the contrast of the image.  Selection: Off, Black, Cyna, Blue, Rose			
	Function: Improve the transparency in iLive rendering mode to observe the			
	tissue, such as cyst.			
Hyaline	Adjust method: Click [Hyaline] under iLive render mode, the merging ratio of two render modes between Hyaline and iLive is 100%; or, select [Hyaline] and adjust hyaline range.			
	Effect: Adjust the merging ratio of two render modes between Hyaline and iLive			
	Function: adjust the rendering thickness of the plane.			
Thickness	Adjusting level: tap [MPR]. Rotate [Thickness] knob. The adjusting range: 0-30mm.			

## ■ Reset Curve

Parameter	Description		
Reset Ori. To reset the volume rotation, shifting and zooming to its original status.			
Reset Curve	To reset the curve to its original status.		
Reset All	To reset the volume to its original orientation and original parameters.		

## ■ Render Mode

Parameter		Description			
		Function: set Surface as the VR rendering mode.			
	Surface	This is useful for surface imaging, such as fetus face, hand or foot.			
		Tip: you may have to adjust the threshold to obtain a clear body boundary.			
	Max	Function: set Max as the VR rendering mode. Displays the maximum echo intensity in the observation direction.			
		This is useful for viewing bony structures.			
Gray/Inversion	Min	Function: set Min as the VR rendering mode. Displays the minimum echo intensity in the observation direction.			
Gray/iiivoroioii		This is useful for viewing vessels and hollow structures.			
	X-Ray	Function: set X-Ray as the VR rendering mode. Displays the average value of all gray values in the ROI.			
		X Ray: used for imaging tissues with different internal structures or tissues with tumors.			
	iLive	iLive brings you a better imaging experience by adding lighting rendering effect to the traditional way, allowing human tissue texture to be revealed more clearly.			
		iLive cannot be selected as sub render mode. When it is set as main render mode, the sub render mode is disabled.			

Parameter		Description
The above five modes.		rendering methods can be applied to both gray and inversion
		n means to invert the grayscale of the image, so as to enhance low-echo regions, applicable for vessels, cysts, etc.
		tion is turned on, the rendering mode parameters change to the inverse parameters.

### Rotate an Image

The system supports the following rotation modes:

- Axial rotation
- Auto rotation
- Axial rotation

Axial rotation rotates the currently activated image around the X-, Y- or Z-axis.

- Procedures
  - a) Select the current image.
  - b) Rotate the corresponding knobs to make the image rotate:
  - ➤ To rotate along the X-axis: rotate the <M> button on the control panel clockwise and the image rotates right along the X-axis. Rotate the button counter-clockwise and the image rotates to the left.
  - ➤ To rotate along the Y-axis: rotate the <PW> button on the control panel clockwise and the image rotates right along the Y-axis. Rotate the button counter-clockwise and the image rotates to the left.
  - ➤ To rotate along the Z-axis: rotate the <Color> button on the control panel clockwise and the image rotates right along the Z-axis. Rotate the button counter-clockwise and the image rotates to the left.
- Or, enter the touch screen mapping mode and hide the tool bar. Rotate the image by touching the image window and move slowly.
  - To rotate along the X-axis: swipe from top to bottom and the image rotates right along the X-axis. Swipe from bottom to top and the image rotates to the left.
  - To rotate along the Y-axis: swipe from left to right and the image rotates right along the Y-axis. Swipe right to left and the image rotates to the left.

#### Auto rotation

- (1) In 3D viewing mode, touch the [Auto Rot.] in the [Tools] tab on the touch screen. The system enters the auto rotation preparation state.
- (2) Touch [Left/Right] or [Up/Down] to set the auto rotation direction.
- (3) Set the Start position and End position:

Start position: roll the trackball to view at a certain position. Press the trackball "Set Start" function key according to the trackball hint area.

End position: roll the trackball to view at a certain position. Press the trackball "Set End" function key according to the trackball hint area.

(4) Set the rotation mode: touch for single direction rotation, and touch bidirectional rotation.

- (5) Touch [Speed] to set the rotation speed.
- (6) Touch to activate rotation.
- (7) Touch [Step] to set the rotate step.

NOTE:

You can view the back of the VR by rotating it 180°. The back view image may not be as vivid as the front. (Here we call the initial view of the VR the "front"). It is recommended to re-capture rather than rotate the VR if a certain desired region is obscured in the VR.

#### Inversion

Function: vessel shape is correct with the capture target. The vessel wall is smooth and clear.

#### **Surface Enhancement**

- Description: This function is to make the edge structure of the image and surface details clearer, so as to enhance the overall contrast.
- Operation: Touch [Surf. ENH] to adjust the enhancement level.
- Effect: The higher the level is, the clearer the edge structure of the image is.

When the level is higher than 0 and [Move Light] is highlighter, image close to the light source is clearer, and image away from the light source is darker.

### Move the light

- This function is to adjust the position of the light source as VR is considered. The image becomes clearer as keeping closer to the light.
- Adjustment: roll the trackball and change the light position to make fine adjustments after tapping [Move Light].

## **Image Zooming**

To adjust the zoom factor of VR. The sectional images will be zoomed in/out accordingly.

Operation

Set the VR window as the current window.

- Rotate the <Zoom> knob to increase or decrease the magnification factor.
- Under touch screen mapping mode, zoom the image by pinching the two fingers on the touch screen.

#### Sync

This function switches the view direction perpendicular to the current active plane, so as to get a better view of VR.

In the following image, the current active plane is MPR A. After performing Sync on Figure A, you can see the same fetal face profile in VR.



Figure A



Figure B

## **Comments and Body Marks**

■ Function:

Add comments and body marks to the MPR and VR.

Operation:

The operation is the same as adding comments and body marks in B image mode.

### Image Editing

#### Function

Image editing is a more elaborate function than VOI adjusting for optimizing the 3D image by clipping (removing) the obscured part of the region of interest.

Tip:

- In image editing status, no image parameters can be changed. A cutting cursor is displayed or an eraser cursor , and the system enters "Accept VOI" status.
- The editing function is available only on VR.

#### Procedures

- 1. Enter image editing status by touching the [Edit] tab.
- 2. Select an edit/erase tool:
  - Polygon
    - a) Press <Set> to position the start point, roll the trackball to set a region, and press <Set> to trace the region.
    - b) When the start point and end point coincide, the region is selected, or press <Set> twice to finish tracing.
    - c) Move the cursor to the region you want to cut and press <Set> again to cut.

#### Contour

- a) Press <Set> to position the start point, and roll the trackball to trace the region.
- b) When the start point and end point coincide, the region is selected, or press <Set> twice to finish tracing.
- c) Move the cursor to the region you want to cut and press <Set> again to cut.

#### Rectangle

- a) Press <Set> to fix the rectangle's position, roll the trackball to change the size, and press <Set> again to finish drawing the rectangle
- b) Move the cursor to the region you want to cut and press <Set> again to cut.

#### Line

- a) Press <Set> to position the start point and the system will display a reference line. Roll the trackball to set the line orientation and press <Set> to start drawing. Press <Set> when ends are required. Press <Set> twice to finish drawing.
- b) Move the cursor to the region you want to cut and press <Set> again to cut.

#### Soft/ hard eraser

Press <Set> to position the start point and roll the trackball to select the region. Press <Set> when ends are required. You can repeat the step to erase all parts blocking the interesting region.

- rotate the knob under [Eraser Diam.] to adjust eraser diameter.
- To undo the last cutting, touch [Undo] on the touch screen.
- To undo all cuttings, touch [Undo All].

The image cutting parameters are described as follows:

Туре	Parameters	Description				
	Contour	Allows you to trace the portion of the image you want to cut.				
Edit Type	Rect.	Displays a box which can be used to define the portion of the image you want to cut.				
,. ,.	Soft eraser	Applies to softer or smoother boundary within a small range of the image.				
	Hard eraser	Applies to a distinct boundary of within a wider range of the image.				

Туре	Parameters	Description			
	Polygon	Allows you to trace a polygon on the image you want to cut.			
	Line Use a multi-point line to trace the boundary quickly.				
	Eraser Diam.	As the eraser erases the image by means of sphere, you can adjust the size so as to adjust the erased area and depth.  The eraser sphere center has a more distinct effect of clearing compared to other parts.			
Edit Depth	Depth	Reserved.			
Other	Undo	To undo the last cut only.			
Operations	Undo All	To undo all cuts since you entered image edit mode.			

Section image (MPR) measurement.

2D related measurements can be performed on MPR. For details, see [Advanced Volume]. Measurement is not available in acquisition preparation status.

## 5.10.3.4 Image Saving and Reviewing in Static 3D

- Image saving
  - In 3D viewing mode, press the single image Save key (Save Image to hard drive) to save the current image to the patient information management system in the set format and image size.
  - Save Cine: in 3D viewing mode, press the user-defined Save key (Save Cine (Retrospective) to hard drive) to save a CIN-format clip to the hard drive.
- Image review

Open an image file to enter the image review mode. In this mode, you can perform the same operations as in VR viewing mode.

## 5.10.3.5 Color Static 3D (Color 3D)

The system also supports the color Static 3D flow image function. For details, see "5.10.10 Color 3D."

## 5.10.4 4D

4D provides continuous, high-volume acquisition of 3D images. During scanning, the probe performs the scanning automatically.

4D image acquisition operations are similar to those of Static 3D. The only difference is that in static 3D mode, only a single frame 3D image is captured, while in 4D mode, continuous, high-volume acquisition of 3D images is provided.

4D imaging is an option.

## 5.10.4.1 Basic Procedures for 4D Imaging

- 1. Select the appropriate 4D-compatible probe and exam mode. Make sure there is sufficient gel on the probe for scanning.
- 2. Obtain a 2D image as described in the Static 3D imaging procedure.
- 3. Press to enter 4D imaging preparation status. Define the ROI as well as the curved VOI. For details, see "5.10.3.1 Basic Procedures for Static 3D Imaging."
- 4. Select a render mode, and set parameters.
- 5. Press <Update> on the control panel to enter the 4D image real-time display status.

- 6. Press <Freeze> on the control panel to freeze the image. Perform image cutting, rotation, annotation and image saving if necessary. For detailed operations, see "5.10.3.3 Static 3D Image Viewing."
- 7. Exit 4D.

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



or, press <B> or the

kev to enter B mode.

## 5.10.4.2 4D Acquisition Preparation

The parameters are the same as those for Static 3D. For details, see "5.10.3.2 Static 3D Acquisition Preparation."

## 5.10.4.3 4D Real-time Display

In 4D real-time display status, operations are similar to those in Static 3D. For details, see the corresponding section in Static 3D.

## 5.10.4.4 4D Image Saving

- In 3D viewing mode, press the single image Save key (Save Image to hard drive) to save the current image to the patient information management system in the set format and image size.
- Save Cine: in 3D viewing mode, press the user-defined Save key (Save Cine (Retrospective) to hard drive) to save a CIN-format clip to the hard drive.

Tip: After freezing a 4D image, press <Cine> to switch between cine auto-play mode and manual mode.

## 5.10.4.5 3D/4D Fast Switching

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

In 3D imaging viewing mode, press to quickly switch to 4D image real-time imaging status, where you can obtain the same image in dynamic mode.

## 5.10.5 Smart 3D

The operator manually moves the probe to change its position/angle when performing the scan. After scanning, the system carries out image rendering automatically, then displays a frame of the 3D image. Smart 3D is an option.

## 5.10.5.1 Basic Procedures for Smart 3D Imaging

NOTE:

In Smart 3D image scanning, if the probe orientation mark is oriented to the operator's finger, perform the scan from right to left in linear scan, or rotate the probe from left to right in rocked scanning. Otherwise, the VR direction will be wrong.

To perform Smart 3D imaging:

- 1. Select the appropriate probe (non-4D probe) and exam mode. Make sure there is sufficient gel on the probe for scanning.
- 2. Obtain a 2D image. Optimize the image as described in the Static imaging procedure.

- 3. Press to enter the Smart 3D imaging preparation status, and define the ROI as well as the curved VOI.
- 4. Select a render mode.
- 5. Select an acquisition method, and set the corresponding parameters on the touch screen.

Rocked mode: set [Angle] parameter.

Linear mode: set [Distance] parameter.

6. Press < Update > on the control panel to start the 3D image acquisition.

The system enters the 3D image viewing status when the acquisition is complete. Or, end the acquisition by pressing <Freeze> or <Update> on the control panel.

In image viewing status, operations such as VOI setting and image editing can be performed. For details, see "5.10.3.3 Static 3D Image Viewing."

7. Exit Smart 3D.

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



to enter B mode.

## 5.10.5.2 Smart 3D Acquisition Preparation

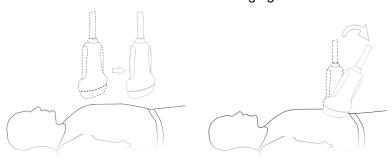
In Smart 3D mode, you need to set the scan method in addition to the other items in Static 3D mode. The other parameters are the same as those for Static 3D. For details, see "5.10.3.2 Static 3D Acquisition Preparation."

■ Method

Capture images using Linear scan or Rocked scan.

Linear scanning

Move the probe across the surface. See the following figure.



Rocked scanning

Rotate the probe once from the left to the right side (or from the right to the left) to include the entire desired region. See the figure.

## ■ Description of parameters:

Parameter	Description					
	Function: select the image acquisition method.					
	Selection: Rocked, Linear.					
	Linear mode: during the sweep, the probe must be kept parallel. The scanning speed should be constant.					
Method	Rocked mode: in this mode, the probe must be moved to a position where you can clearly see a middle cut of the object you want to scan and render. Tilt the probe to about 30 degrees until the object you want to scan disappears. Start the acquisition and tilt the probe over a distance of around 60 degrees until the object disappears again. During the sweep, the probe may not be moved parallel, just tilted.					
	Tip: the speed is related to scanning distance or angle.					
Distance	Function: to set the distance the probe covered from one end to the other end during a linear sweep.					
	Range: 10-200 mm, in increments of 10 mm.					
Angle	Function: to set the angle the probe covered during a fan sweep.					
Aligie	Range: 10-80°, in increments of 1°.					
Acquiring Time	Function: to set the acquiring time of the Smart 3D acquisition.					

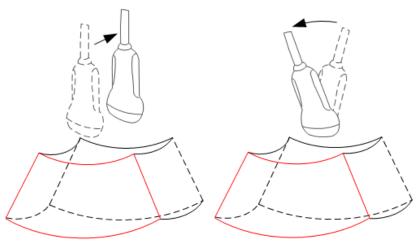
## 5.10.5.3 Smart 3D Image Viewing

In VR viewing, the system supports the following functions:

- Render setting.
- B-mode parameter adjustment.
- Setting the display format.
- Viewing MPR.
- Image zooming.
- Rotation.
- Image editing.
- VR parameter adjustment.
- Scanning plane and probe movement

Move the probe across the body surface.

The arrow in the figure below indicates the movement of the probe (you can move the probe in the opposite direction to the arrow.).



## 5.10.5.4 Image Saving and Reviewing in Smart 3D

- Image saving
  - In 3D viewing mode, press the single image Save key (Save Image to hard drive) to save the current image to the patient information management system in the set format and image size.
  - Save Cine: in 3D viewing mode, press the user-defined Save key (Save Cine (Retrospective) to hard drive) to save a CIN-format clip to the hard drive.
- Image review

Open an image file to enter the image review mode. In this mode, you can perform the same operations as in VR viewing mode.

#### 5.10.5.5 Color Smart 3D

The system also supports the color Smart 3D flow image function. For details, see "5.10.10 Color 3D."

# 5.10.6 STIC (Spatio-Temporal Image Correlation)

The STIC function provides sectional images of high spatial resolution as well as good time resolution, which is mainly used in fetal heart observation and cardiac hemodynamic exams.

STIC is an option, and it is not available in Smart 3D mode.

Acquired images are post-processed to calculate a Volume Cine sequence representing one complete heart cycle.

In order to achieve a good result, try to adjust the size of the volume box and the sweep angle to be as small as possible. The longer the acquisition time, the better the spatial resolution will be.

The user must ensure minimal movement of the participating persons (e.g., mother and fetus), and that the probe is held absolutely still throughout the acquisition period.

Movement will lead to acquisition failure. If the user (trained operator) clearly recognizes a disturbance during the acquisition period, the acquisition must be canceled.

One or more of the following items in the data set indicate a disturbance during acquisition:

- Sudden discontinuities in the reference image B
  - These are due to movement of the mother, the fetus or fetal arrhythmia during acquisition.
- Sudden discontinuities in the color display
  - Movement of the mother, the fetus or fetal arrhythmia affects the color flow in the same way it affects the gray image.
- Fetal heart rate far too low or far too high
  - After acquisition the estimated fetal heart rate is displayed. If the value does not correspond to the estimations based on other diagnostic methods, the acquisition failed and must be repeated.
- Asynchronous movement in different parts of the image.
  - E.g., the left part of the image is contracting while the right part is expanding.
- Color "moves" through the image in a certain direction.
  - This item is caused by a failure in detecting the heart rate due to a low acquisition frame rate. Use a higher acquisition frame rate for better results.



- 1. In all of the above cases the data set must be discarded and the acquisition must be repeated.
- 2. STIC fetal cardio acquisition cannot be performed if there is severe fetal arrhythmia.

riangleWARNING:

Diagnoses made only by assessing this 3D/4D acquisition are not permitted. Every diagnostic finding must also be evaluated in 2D.

NOTE:

2. Press

The user must ensure that none of the participating persons (mother, fetus, and user) move during the acquisition. Movement will lead to acquisition failure. If the user recognizes a movement during the scan, the acquisition must be canceled.

#### 5.10.6.1 Basic Procedures for STIC

1. Obtain a feasible 2D image (fetus heart).

To observe a small structure, zoom in on the part of interest (Spot zooming is usually applied for good image quality).





to enter 3D/4D acquisition preparation mode.

- 3. Touch [STIC] to enter STIC acquisition preparation mode.
- Set the acquisition and display the related parameters.
  - Select the parameter package.
  - Set the acquisition time and angle according to the target size and the motion conditions. For fetuses aged 20-30 weeks, the acquisition time range is: 10~12.5 secs, and the angle range is: 10-20°.
    - If the gestation age is more than 20-30 weeks, the acquisition time should be about 15 secs, and the angle should be about 30°.
  - Adjust the size and position of the sample box so the interested region is contained within the sample box.

However, the box should be small enough to contain only the heart, not the whole thorax.

### NOTE:

In order to achieve a good result, try to adjust the volume box and the sweep angle to be as small as possible. The longer the acquisition time, the better the spatial resolution will be.

- 5. Place the sample box over the region of interest.
- 6. Press < Update > to begin image acquisition.
  - Keep the probe still. Volume acquisition proceeds automatically and the acquired images are displayed.
  - To avoid external interference to the image, ensure that there is minimal movement of the mother.
  - In case of movement of the mother or the fetus, or the probe position changes, cancel the current acquisition and begin a new acquisition.

After the calculation, the estimated heart rate is shown on the screen.

Judge whether the estimated heart rate displayed is reasonable. If the result is not reasonable, touch [Reject All] to perform the acquisition again. Touch [Accept HR] to accept the result and go to image review, or touch [Reject HR] to reject the HR but save the volume data.

Operations in review mode are the same as those in 4D cine review mode. See the details in the 4D chapter.

Tip: After STIC acquisition, press <Cine> to switch between cine auto play mode and manual mode.

## 5.10.6.2 Operation Controls

Controls consistent with those in 3D/4D mode are not to be introduced here. Only STIC mode special controls will be introduced here.

Acquisition Time

The time required for a complete acquisition.

Range: 7.5~17.5 secs.

■ Angle

The range from acquisition beginning to acquisition end.

Range: 10~85°.

## 5.10.6.3 Color STIC 3D

The system also supports the color STIC 3D flow image function. For details, see "5.10.10 Color 3D."

# 5.10.7 3D Layout

The function compiles the 3 MPRs together according to their relative positions, to provide a much clearer interior anatomical structure.

This function is provided by the [Niche] option, and does not support Smart 3D image data.

#### **Niche**

- 1. Touch the [3D Layout] tab in the [Tools] tab on the touch screen, then the [Niche] button is highlighted.
- 2. Touch [A]/[B]/[C]/[Niche] on the touch screen to select the reference plane as Plane A, Plane B, Plane C or Niche.
- 3. Set the view direction for niche display mode using the touch screen: from the front of the reference image or from the back.
- 4. Roll the trackball to view sectional images as necessary. Rotate <M>, <PW>, <Color> to perform axial rotation or rotate the <4D> knob to adjust the nearest VOI section (cut plane) position. Click [Reset Ori.] to reset the rotation, the center point position, and the position of the MPR.

#### 3Slice

- 1. Touch the [3D Layout] tab on the touch screen, then touch [3Slice].
- 2. Touch [A]/[B]/[C]/[3Slice] on the touch screen to select the reference plane.
- 3. Roll the trackball to view sectional images as necessary. Rotate <M>, <PW>, <Color> to perform axial rotation or rotate the <4D> knob to adjust the nearest VOI section (cut plane) position. Click [Reset Ori.] to reset the rotation, the center point position, and the position of the MPR.

# 5.10.8 iPage+

iPage<sup>+</sup> is iPage+SCV function. iPage (Multi-Slice Imaging) is a "Visualization" mode for displaying sectional images. The data is presented as slices through the data set, which are parallel to each other. When SCV (Slice Contras View) function is turned on, the system expands the parallel section images into a slice region with a specified thickness, and draws this region with 3D rendering effect to enhance the image.

NOTE: iPage<sup>+</sup> imaging is an option, and it is not available in Smart 3D mode.

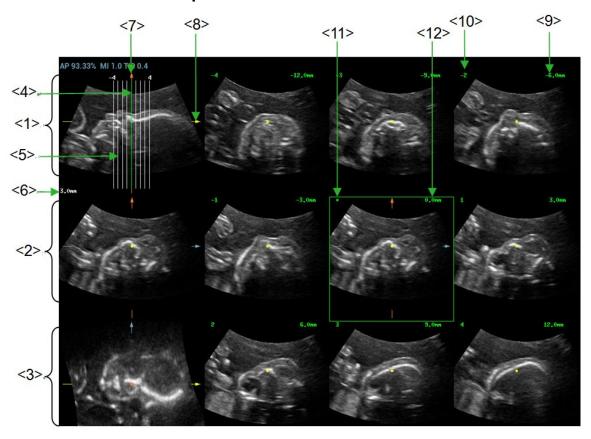
## **5.10.8.1 Operating Procedures**

- iPage operation
- 1. Acquire necessary 3D/4D data.
  - Single-frame VR:

- > STIC/4D mode: freeze the system, and then roll the trackball to select the image.
- Static 3D: a frame of image is acquired after the acquisition is finished automatically.
- Multi-frame 3D images: acquire multiple 3D images in 4D imaging mode.
- 2. Perform operations like rotation, VOI adjusting to the image to find the interested region.
- 3. Tap [iPage<sup>+</sup>] on touch screen.
- 4. Check A/B/C sectional planes, and select the reference image.
- 5. Confirm if the slices displayed are the target planes, if not, re-select the reference image again.
- Observe the interested structure through multiple slices.
   Select the proper image layout and space according to the size of the target structure.
   To observe the details or the tiny part of the interested region, do image zooming please.
- 7. Rotate the 3D image to observe the slices of other orientations. Repeat step 6 if necessary.
  - If the target orientation and region can't be observed even after image rotation, tap [Reset Ori.] to reset the 3D image.
- 8. Do operations like comment to the interested region.
- 9. Save images as necessary.
- iPage+SCV operation

Adjust the parameter [Thickness] in iPage<sup>+</sup> screen when SCV imaging is needed.

## 5.10.8.2 Basic Screen & Operation



<1>	A plane (the current	<2>	B plane	<3>	C plane
	reference image)				

<4>	Central slice line (Current active slice)	<5>	Slice line	<6>	Space between two slice lines
<7>	Y-axis	<8>	X-axis	<9>	Slice position (to the central slice)
<10>	Slice order number	<11>	Central slice mark	<12>	Active slice be highlighted in green

### ■ Layout

The system supports several types of displaying layout: 2\*2, 3\*3, 4\*4 and 5\*5, touch the corresponding icon on the touch screen to select, and the selection [Slice Number] changes accordingly.

## ■ Reference image

Tap [A], [B], or [C] to select the reference image.

#### ■ Slice and slice line

- Central slice: the central slice line corresponding plane are the central slice, which is marked with a green "\*" at the upper left corner of the image.
- Tap to place the slice lines vertically, and touch to place the slice lines horizontally.
- Active slice: the green slice line corresponding plane is the active slice, which is marked with a
  green box. The default active slice is the central slice.
- Slice order number: indicating the order of the slices, the order of central slice is "0", the slices before the central slice are marked with negative integral numbers, and the slices after the central slice are marked with positive integral numbers.
- Slice position (to the central slice): displayed at the upper left corner of each image, indicating the position of each image (such as -6mm, -3mm, 3mm, 6mm).
- Coordinate axis: indicated on the A, B, C three reference images, match together with the central slice line, and will move accordingly with the central slice line.

#### Slice shifting

Roll the trackball to shift the crossing point of central axis up/down, left/right, and the slice lines will shift accordingly with the crossing point.

Rotate the knob under [Range Pos] on the touch screen to fine-tune slice lines horizontally.

#### Slice position

Rotate the knob under [Slice position] to move the active slice line (green) either forward or backward within the range, then the corresponding slice will be highlighted in green.

#### Spacing

The value is displayed at the upper right side of the slice, unit: mm. Adjust it through rotating the knob under [Spacing].

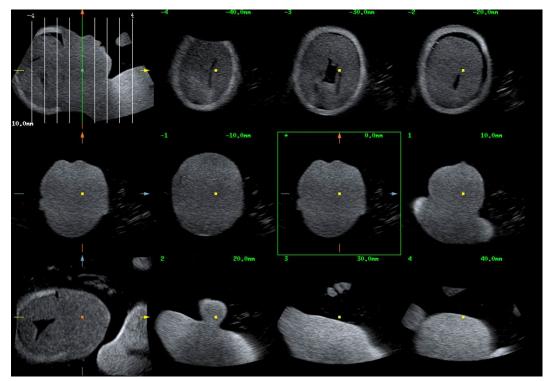
#### ■ Slices number

Change slices number as necessary using the knob under [Slices Number] on the touch screen.

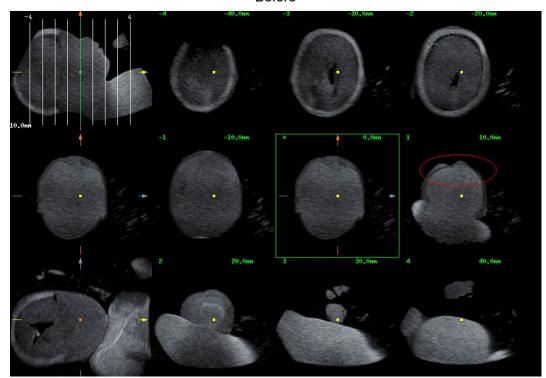
#### Thickness

Rotate the knob under [Thickness] to adjust the SCV thickness. When the thickness value is larger than zero, the SCV function is on. (NOTE: thickness cannot be larger than Spacing)

Figures below are the effect before and after the SCV function is turned on. You can see the body structure within the range of the thickness is added to the image after the SCV function is on.



Before



After

## ■ Image rotation

Rotate <M>, <PW>, <C> to perform axial rotation or rotate <4D> knob to adjust the nearest VOI section (cut plane) position.

For details, refer to descriptions in Static 3D.

■ Image zooming

Same as Static 3D image zooming.

■ Hide/show reference image

The system displays 3 standard sectional images (A plane, B plane, C plane) on the left side

indicating the position of the slice lines; tap to hide the 3 reference images, and then slices are displayed on the whole image area.

Quick switch to single display

Select a certain slice, double click <Set> to see the slice full screen, and double click <Set> again to return to the original display format.

Reset Ori.

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

Comment & Body Mark

Operations are the same as those in the other modes.

Measurement

Measurement can be done on any slice when it is in the single format display.

## 5.10.9 SCV+

SCV<sup>+</sup> is SCV (Slice Contrast View) +CMPR (Curved MPR).

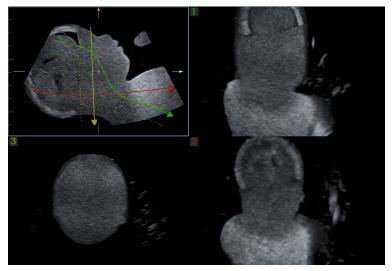
SCV imaging can reduce speckle noise and improve contrast resolution as well as enhance signal-noise ratio, which helps in discovering diffuse pathology in organs.

The curved MPR function allows straightening of a curved surface/anatomy. In clinical application, this is usually used for imaging fetal spine, as illustrated below.

NOTE: SCV<sup>+</sup> imaging is an option, and it is not available in Smart 3D mode.

## 5.10.9.1 Basic Procedures

- SCV operation
- 1. Acquire necessary 3D/4D data.
- 2. Tap [SCV<sup>+</sup>] tab on the touch screen to enter SCV imaging, and the system displays three section images in A, B and C window.
- 3. Rotate the knob under [Thickness] on the touch screen to adjust imaging thickness.
- 4. Save images as necessary.
- SCV+CMPR operation
- 1. Enter SCV+.
- 2. Tap [A Plane], [B Plane] or [C Plane] on touch screen to select current window.
- Tap [CMPR] on touch screen to turn on the CMPR function. Window A on main screen displays the current window and three other windows are blank. Select reference section, perform rotation and shifting operations to adjust image.
- 4. Tap [1], [2], or [3] button in Active Quadrant on touch screen.
- 5. Select trace options: tap [Line], [Trace] or [Spline] on the touch screen.
- 6. Draw on the reference image. You can draw three curves at most and the CMPR imaging for the curve are displayed in the selected [1], [2] or [3] window respectively as shown in figure below.



- 7. Perform rotation and shifting operation to reference line.
- 8. Save images as necessary.

## 5.10.9.2 Operation Controls

#### SCV

Current Quadrant

Tap [A], [B] and [C] to select current active section image.

Reset

Click [All] in Reset field to reset parameters, orientation and zooming status.

### **CMPR**

- Trace Options
- Line
- 1. Tap [Line] on the touch screen.
- 2. Rotate the trackball to place the cursor and press right <Set> key to fix the starting point, rotate the trackball to extend the line and press right <Set> key again to finish drawing; or you can press left <Set> key to reset starting point.
- 3. After line is finished, press left <Set> key to change line position.

Tap [Reset Curve] to cancel current drawing.

- Trace
- 1. Tap [Trace] on the touch screen.
- Rotate the trackball to place the cursor and press right <Set> key to fix the starting point, move the
  cursor along the target to trace the outline, and press right <Set> again to finish tracing. During
  tracing, press left <Set> to cancel a series of tracing, or you can roll the trackball backwards to
  delete latest tracing.
- 3. After tracing, press left <Set> key to change tracing outline position.

Tap [Reset Curve] to cancel current drawing.

- Spline
- 1. Tap [Spline] on the touch screen.
- 2. Rotate the trackball to place the cursor and press right <Set> key to fix the starting point, move the cursor along the area of interest and press right <Set> to anchor several reference points; or press left <Set> to cancel a series of lines.
- 3. Press <Set> twice to set the end point of the spline.
- 4. After tracing, press left <Set> key to change tracing outline position.

Tap [Reset Curve] to cancel current drawing.

## **Other Operations**

■ Single image zoom

Press <3D> to view single SCV image.

Zoom in

Same as these in 3D/4D mode.

Rotation

Rotate <M>, <PW>, <C> to perform X/Y/Z rotation or rotate <4D> knob to adjust the nearest VOI section (cut plane) position.

Comment and Body Mark

Same as these in other modes.

Section image (MPR) measurement.

2D related measurement can be performed on MPR. For details, please refer to [Advanced Volume].

## 5.10.10 Color 3D

Color 3D imaging provides more visualized flow information, especially in heart and kidney applications, which is useful when observing cardiovascular diseases.

Color 3D is an option.

#### 5.10.10.1 Basic Procedures for Color 3D

- 1. Enter color 3D image acquisition preparation status:
  - (1) Obtain a feasible Power/Color image with the volume probe.
  - (2) Press to enter 3D/4D image acquisition preparation status.
- 2. Set the acquisition, display the related parameters, and select the acquisition mode. See "5.10.3.1 Basic Procedures for Static 3D Imaging" for details.
- 3. Press < Update > to begin image acquisition.
- 4. After the acquisition is complete, the system enters image view status. Here you can perform operations such as image edit and storage.
- 5. Save the image as required.

The Color 3D feature is available in Smart 3D, Static 3D and STIC modes.

## 5.10.10.2 Operation Controls

Parameter	Description
Display	Function: you can choose to display only color images or grayscale images, or to mix them.
	Range: VR, MPR, B, C, B&C.
Priority	Function: to determine the color information displayed on grayscale images.  Range: 1-100.
Threshold	Function: to eliminate color noise and motion items.
	Range: 0%-100%.
	Affects MPR as well as VR.

Parameter	Description
Opacity	Function: to set the transparency value for VR rendering.
	Range: 0%-100%.
Smooth	Function: to smooth the Color image and erase items by time averaging.
	Range: 0-10.
	Affects MPR as well as VR.
Mix	Function: to adjust the mix percentage of grayscale information and color information. When the display format is 2D&C, you can adjust this parameter.
	Range: 0-100%.
Image Zooming	Same as in 3D/4D mode.
Comments & Body Marks	The operations are the same as those in the other modes.
MPR Measurement	2D related measurements can be performed on MPR. For details, see [Advanced Volume].
	Tip: You cannot perform measurement in acquisition preparation status.

## 5.10.11 Smart Volume

The system provides a fast volume calculation method, using computer technology to define and enclose a boundary of the target within the ROI area (the computer technology allows the ultrasound system to fit an ellipsoid that can be most approximate to the target) and then calculating this volume. It can be used to measure the volume of the mass, gestational sac, bladder or gall bladder. Smart Volume is an option, and is not available for Smart 3D image.

**CAUTION:** The Smart Volume result is provided for reference only, not for confirming diagnoses.

#### 5.10.11.1 Basic Procedure for Smart Volume

- 1. Acquire the necessary 3D/4D data.
- 2. Touch the [Smart-V] tab on the touch screen to enter Smart Volume. The system is in "Edit VOI" status (the [Edit VOI] button is highlighted in green).
- 3. Set the VOI position and size, and touch [Calc] (after touching the button, the button is highlighted in green to indicate the status).
- 4. The system starts to calculate.
- 5. Auto-calculation is completed:
  - There are green solid curves enclosing the target region in each MPR image (A, B, C) window.
  - The 3D image (VR) displays the image of the target region in red.
  - The parameter area in the top right screen displays the calculation result.

**NOTE:** To ensure the accuracy of the result, ensure that the VOI position and size setting has entirely enclosed the target and is approximate to the target before using the Smart Volume function.

## 5.10.11.2 Results Display



After calculating, the following result will be displayed in the top-right part of the screen.

Where L, W and H represent 3 diameter lengths of the fitting ellipsoid.

V represents the calculated volume value.

## 5.10.11.3 Operation Controls

### **Edit the VOI (Volume of Interest)**

Adjusting the VOI box size and position selects the volume data needed for calculation.

- (1) Touch [Edit VOI] on the touch screen to turn it on (green highlighted status).
- (2) Select the desired MPR image by touching [A], [B] or [C].
- (3) Roll the trackball to adjust the VOI position and size, and press <Set> to switch between the adjusting statuses. Or, rotate the <4D> knob on the control panel to adjust the section image position.

## **Accept VOI**

After touching [Calc] to be on, the system starts calculation.

#### **Reset Curve**

Parameter	Description
Reset Ori.	To reset the volume rotation, shifting and zooming to its original status.
Reset Curve	
Reset All	1

## Zoom

Same as for 3D/4D image zooming.

## **Comments and Body Marks**

The operations are the same as those in the other modes.

#### MPR measurement.

2D related measurements can be performed on MPRs. For details, see [Advanced Volume].

## 5.10.12 iLive

iLive brings you a better imaging experience by adding a light rendering effect to the traditional method. It supports the point lighting mode, parallel lighting mode as well as the torch lighting mode, allowing human tissue texture to be revealed more clearly.

iLive is an option, and is available under Smart 3D, Static 3D and 4D modes. To use the iLive function, you must configure the Smart 3D module or the 4D module.

#### To Activate iLive

- 1. Enter 3D/4D image viewing status, or double-click the saved 3D/4D cine file in the iStation or Review screen.
- 2. Tap [iLive] on the touch screen to turn the function on, and adjust the parameters.

#### Imaging using iLive

1. Select the imaging mode:

Use the ordinary probe and press to enter Smart 3D.



- 2. Select the render mode to be iLive by touching the touch screen, and set the related parameters (quality and angle, etc.).
- 3. Press < Update > to begin acquisition.
- 4. The system finishes acquisition and enters the image viewing screen.
  In image review status, you can perform operations such as VOI setting, image editing, comment adding, body mark adding, etc.
- 5. Or press <B> or to exit the mode.

## 5.10.12.1 Operation Controls

Adjustable parameters for iLive are on the touch screen.



#### Shading

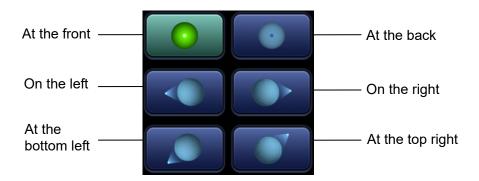
Adjusts the effect of shadowing and scattering. When the selected level is 0, the rendered image will be bright and sharp, and the shadow border will be clear while the area of the shadow will be relatively

small. As the level increases, the rendered image will become warmer but the details remain the same. Also, the shadow border will be smoother while the shadow area will be large

## Light source adjustment

This function adjusts the position of the light source toward the VR image.

Select the direction by touching the buttons under the "Light Position" box.



You can also make fine adjustments by tapping [Move Light] and rolling the trackball to adjust. Grad View

After this function is activated, VR details will be revealed and enhanced.

Other operation controls and adjusting methods are similar to those in 3D/4D mode.

## **Lighting Mode**

#### **Basic Procedures**

- 1. Tap " on the [iLive] to enter the iLive settings interface.
- 2. Tap the desired lighting mode.
  - a) If necessary, tap " on the lighting mode to adjust parameters for the selected lighting mode.
  - b) After parameter settings, tap [Exit XXX] to exit the lighting mode settings.
  - c) Tap [Refresh] to refresh the thumbnails on the iLive settings interface.
- 3. Tap [Return] to apply the selected lighting mode.

## Operation Controls for Lighting Mode Settings

Parameter	Description
VL Saturation	Adjust the saturation for light 1/2/3.
VL Hue	Adjust the color for light 1/2/3.
VL Distance	Adjust the distance for light 1/2/3 when the light source is set to torch or point.
	The larger the distance, the more the illuminated part on the surrounding area of the image; vice versa.
VL Angle	Adjust the angle for light 1/2/3 when the light source is set to torch.
	The larger the angle, the larger the scope of light beam, and the larger the illuminated area; vice versa.

Parameter	Description
Reset Classic/ IntPoint/ ExtPoint/ Parallel/ Torch/ 3-Light/ User 1/ User 2	Reset the lighting mode to the original status.
Copy to	Copy the lighting mode to customized lighting mode "User 1" or "User 2"

## **Other Operations**

Zoom

Same as in 3D/4D mode.

Rotation

Roll the trackball to view sectional images as necessary. Rotate <M>, <PW>, <C> to perform axial rotation or rotate the <4D> knob to adjust the nearest VOI section (cut plane) position.

Comments and Body Marks

Same as in other modes.

# 5.10.13 Smart FLC (Smart Follicles Calculation)

**ACAUTION:** Smart FLC result is provided for reference only, not for confirming a diagnosis.

NOTE: Smart FLC is an optional function, and it is not available in Smart 3D mode.

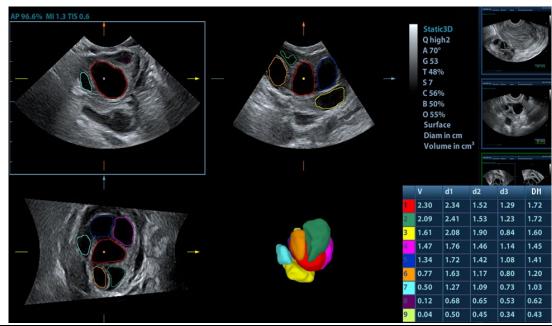
### 5.10.13.1 Basic Procedures for Smart FLC

- 1. Acquire necessary 3D/4D data and freeze.
- 2. Tap [Smart FLC] tab on the touch screen to enter Smart FLC, and the system is in the "Edit ROI" status ([Edit ROI] button is highlighted in green);
- 3. Set the position and size of the ROI box.
- 4. Tap [Calc] on the touch screen.
- 5. Auto calculation is finished:
  - Section image (A, B, C) is enclosed with colored lines and the color corresponds to the follicle in VR window.
  - 3D image (VR);
  - Results on the right of the screen are displayed in a table.

V: Volume

d1, d2, d3: diameters of the follicle

MD: Follicle Diam



**NOTE:** To ensure the correctness of the results, please select an image with clear follicle boundary when entering smart FLC.

## 5.10.13.2 Operation Controls

#### **Edit ROI**

Same as the operation in ROI editing in Smart-V.

## **Edit/ Undo**

Tap [Edit] on touch screen to turn on the editing function. It supports dividing, merging, adding and deleting of the follicle.

Tap [Undo], [Redo] or [Undo All] on touch screen to undo, redo or cancel previous editing.

#### Zoom

Same as those in 3D/4D mode.

#### **Annotation and Body Mark**

Same as those in other modes.

#### Measurement

2D related measurement can be performed on MPR. For details, please refer to [Advanced Volume].

### Save the image

The Smart FLC supports saving single-frame image only, does not support saving multi-frame cine file.

## 5.10.14 Smart Planes CNS

The doctor finds fetus's sagittal view by judgments on image features, and then makes an observation. The fetus's s sagittal view is hard to be detected or cannot be detected sometimes because of the fetus's move inside.

Taking the key anatomical tissues and organs's features from 3D data of fetus's intracranial, Smart Planes CNS is a mode-wise technology, which detects the middle of the fetus's sagittal view, transverse plane of thalami, transverse plane of lateral ventricles and transverse plane of cerebellum. It helps the

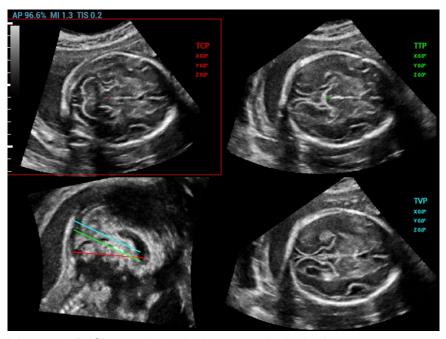
doctors find the sagittal view rapidly and is easy for doctors accessing the anatomical structure on sagittal view. (such as corpus callosum, cerebellar vermis, etc).

## NOTE:

Smart Planes CNS is an option, which does not support Smart 3D mode.

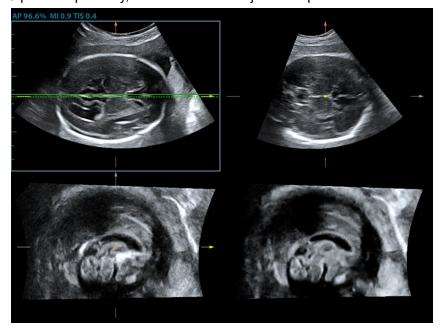
## 5.10.14.1 Basic Procedures for Smart Planes CNS

- 1. Acquire necessary 3D data.
- 2. Tap [S-Planes CNS]. There are four views detected by the system, which includes TCP, TTP, MSP and TVP.



- 3. Adjust the brightness, 3D iClear and the thickness to obtain the image.
- 4. Tap [MSP]. There are A/B/C images appearing on the screen. The sagittal plane of the fetus appears on window C.

Rotate A, B or C plane respectively, or rotate <4D> to adjust each plane.



**NOTE:** To ensure the correctness of the result, please make sure the cerebral midline on the anatomical plane is displayed clearly and ROI enclose the whole cranial region.

- 5. Tap [Accept] to accept the edit to the MSP. The system recalculates the TCP, TTP and TVP according to MSP's position. The position and the angle for TCP, TTP and TVP appear on MSP plane.
- 6. Tap [TCP]/[TTP]/[TVP] to select the plane, and rotate <M>, <PW> or <C> knob to rotate the image plane along with X/Y/Z axis. The angle value appears on the right of the image.
- 7. Rotate the reference line on the MSP plane. See Chapter 5.10.14.2 Other Operations for details.
- 8. Tap [Auto Measure]. Tap [Edit] to edit the measurements. See Chapter 5.10.14.2 Other Operations for details.
- 9. Click [Auto Comment], the system adds the orientation and the organ comments to the desired area according to the active ultrasound image. See Chapter 5.10.14.2 Other Operations for details.
- 10. Tap [Accept Result] to save the measurements to the report.
- 11. Add the comment and body mark on the plane. Perform the measurement, and save the single frame/multi-frame image.

## 5.10.14.2 Other Operations

## Parameter adjusting

Brightness

**Description** Adjusting the brightness of the images.

**Operation** Rotate [Brightness] to adjust the parameter.

The adjusting range is: 0-100% in increment of 2%.

Thickness

**Operation** Rotate [Thickness] to adjust the parameter.

The adjusting range is: 0-30 in increment of 1.

**Impacts** The bigger the value is, the more the thickness information appears.

3D iClear

**Operation** Tap [3D iClear] to adjust the parameter.

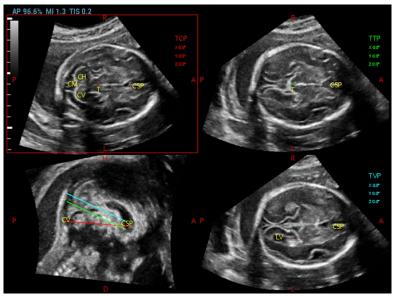
The adjusting range is: 1-7 in increment of 1.

**Impacts** The bigger the value of iClear is, the less the noise becomes.

#### **Auto Comment**

The system adds the orientation and the organ comments to the desired area according to the active ultrasound image.

- 1. Acquire 3D data. Tap [S-Planes CNS] to enter the automatic detection of the mode.
- Click [Auto Comment]. The comments appear on the image automatically.Each of them is:
  - The orientation comments describe the location of the plane, referring to A (anterior), P (posterior), L (Left), R (right), U (up), D (down).
  - Organ comments describe the position of the organ, referring to CSP (cavum septum pellucidum), T (thalamus), CH (cerebellar hemisphere), CV (cerebellar vermis), CM (cisterna magna), LV (lateral ventricles).



- 3. Rotate [Font Size] knob to adjust the font size of the comment.
- 4. See "9.1 Comments" for adding, moving or deleting the comments.
- 5. Save the image.
- 6. Click [Auto Comment] again to clean them.

#### **Axis Rotation**

- 1. Acquire 3D data. Tap [S-Planes CNS] to enter the automatic detection of the mode.
- 2. Tap [TCP]/[TTP]/[TVP] to select the plane, and rotate <M>, <PW> or <C> knob to rotate the image plane along with X/Y/Z axis. The angle value appears on the right of the image.

NOTE: it supports the rotation to the saved image.

#### Reference line rotating

- 1. Acquire 3D data. Tap [S-Planes CNS] to enter the automatic detection of the mode.
- 2. Press <Cursor> to show the cursor. Move the cursor over the red line of the MSP plane. Press left <Set> to select the red reference line after the cursor becomes hand-shaped. Then, the red reference line becomes dotted line.
- 3. Move the trackball left or downwards. The reference line rotates anticlockwise along the center. TCP image rotates clockwise along the Y-axis, and the value of Y-axis becomes bigger.
- 4. Move the trackball right or downwards. The reference line rotates clockwise along the center. TCP image rotates anticlockwise along the Y-axis, and the value of Y-axis becomes smaller.
- 5. The operations to green reference line and blue reference line are the same.TTP rotates along Y-axis when green reference line rotating. TVP rotates along Y-axis when blue reference line rotating.

## **MSP** editing

- 1. Acquire 3D data. Tap [S-Planes CNS] to enter the automatic detection of the mode.
- 2. Tap [MSP]. There are A, B and C views appearing on the screen, in which C plane refers to MSP, and A and B planes refer to MPR plane.
- 3. Rotate A, B or C plane respectively, or rotate <4D> to adjust each plane.
- 4. Tap [Accept] to accept the edit to the MSP. The system recalculates the TCP, TTP and TVP according to MSP's position. The position and the angle for TCP, TTP and TVP appear on MSP plane.
- 5. Click [Cancel] to cancel the editing result.

#### **Automatic Measurement**

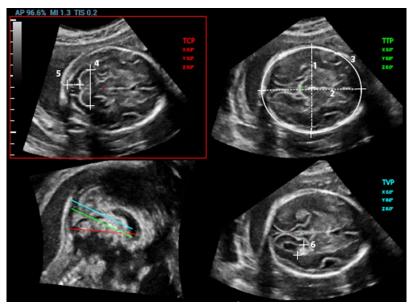
There are 6 measurements:

TCP supports the measurements on TCD, cerebral fossa pool;

TTP supports the measurements on BPD, OFD, HC;

TVP plane supports the measurement on LVW.

- 1. Acquire 3D data. Tap [S-Planes CNS] to enter the automatic detection of the mode.
- Tap [Auto Measure] to show the caliper and the measurement number. The measurement results appear on the right of the screen.



**NOTE** The automatic measurement results appear only for these having the same characteristics on the planes.

- 3. Tap [Edit] to edit the measurements. The measurements on the right of the screen update in real time.
  - a) Tap [Edit] to modify the measurements. The caliper becomes green.
     Or, press <Set> to activate the caliper (becoming green).
  - b) Move the trackball and press <Update> to modify the length and the position of the caliper.
  - c) Press <Set> to confirm the caliper. The caliper becomes white. [Edit] is off.

#### NOTE:

Once the automatic measurements are completed, the operations to axial rotation, reference line rotation, parameter adjustment, MSP editing, zooming/panning, dual/quad-split display will remove the measurement results.

## Reset

All planes

Acquire 3D data. Tap [S-Planes CNS] to enter the automatic detection of the mode. Reset the following operations:

- ➤ Tap [All Planes] to reset the planes. The position and the angle to TCP, TTP, TVP, MSP and reference line return to the initial condition.
- ➤ Tap [All Planes] to reset the planes. The position to TCP, TTP, TVP, MSP and reference line returns to the last MSP condition. The angle to CP, TTP, TVP, MSP and reference line returns to 0°.
- Current plane

Acquire 3D data. Tap [S-Planes CNS] to enter the automatic detection of the mode. Reset the following operations:

- ➤ Tap [Current Plane] to reset the plane. The position of the current plane returns to the initial condition. The angle of the current plane returns to 0°.
- ➤ Tap [Current Plane] to reset the current plane. The position and the angle to the current plane returns to the last MSP condition.

## Other related Operations

- Zooming/panning adjustment
   Same as these in 3D/4D mode.
- Measurement, comments, and body mark Same as these in other modes.
- Hiding the reference
   Tap to hide or show the reference line.
- Hiding the measurement
   Tap to hide or show the measurement.
- Switching between the single and quad-split display
   Press and between the single and quad-split display.

## **5.10.15 Smart Face**

**NOTE:** Smart Face is only used for obtaining fetal face features, not for confirming a diagnosis.

This feature allows the system to recognize fetal face and remove the shading obstacle data automatically, then display the face in a recommended viewing angle.

Note:

Tips: 4D module and OB package should be installed first.

Smart Face is an option.

#### **Basic Procedures**

- 1. Acquire Static 3D image or frozen 4D single-frame image of fetal face.
- 2. Tap [SmartFace] to enter the function and the system adjust fetal face angle (fetal head facing up) automatically and remove the shading obstacle data.

#### Parameter adjusting

Parameters under Smart Face are similar to those under Static 3D mode.

FaceContact

Description The higher the value, the more adjacent the VR image is to the fetal face, and

the more obstacles cleared.

The lower the value, the further the VR image is to the fetal face, and the less obstacles cleared.

obstacies dicarea.

Operation Rotate [FaceContact] to adjust the parameter.

The adjusting range is: -15-15 in increment of 1.

VR Orientation

Description Rotate the image quickly.

Operation Adjust in VR Orientation: 0°, 90°, 180°, 270°.

## 5.10.16 Smart Planes FH (Smart Planes on Fetal Heart)

By using this fetal heart automatic recognition feature, you can observe anatomical structures of fetal heart quickly.

Tips: 4D and OB package should be installed first.

Smart Planes FH is an option and not available under STIC or Smart 3D mode.

#### **Basic Procedures**

- 1. Acquire necessary 3D/4D data of fetal heart and save the file. Open the saved cine file.
- 2. Tap [S-Planes FH] and [Navigate] to enter the screen. The system detects a rta and displays A/B/C plane automatically. A refers to four-chamber view, B refers to a rtic horizontal section and C refers to a rtic vertical section.
- 3. Change the A plane slightly for a better observation by rotating X/Y/Z-axis or shifting operation.
- 4. Select the crossing in the four-chamber view.
  - Refer to the four-chamber view on the left as an example. The red "+" symbol represents the crossing point. Press <Cursor> to acquire the cursor and move the cursor onto the crossing in A plane and press <Set>. The system then displays four-chamber view, left ventricular outflow tract view, right ventricular outflow tract view, 3VT, and Ductal Arch view and stomach bubble view.
- 5. Adjust the view if necessary, you can perform shifting, axis rotation or quick adjustment.
- 6. Adjust image parameters such as brightness, contrast and slice.
- 7. Save the file.

### Axis rotation and shifting

Rotate <M>/<PW>/<C> knob to rotate the view along X/Y/Z-axis.



Rotate the

knob to scroll the view.

### Quick adjustment.

After corresponding views are displayed, select the view and tap [Quick Adjust] to adjust the view. If four-chamber view, Ductal Arch view or stomach bubble view is selected, tap [Quick Adjust] to scroll the view along Z-axis.

If current view is left ventricular outflow tract view (LVOT), tap [Quick Adjust] to move the view along Y-axis.

If current view is L3VT view or right ventricular outflow tract view (RVOT), tap [Quick Adjust] to move the view along X-axis.

#### Reset

[Reset All]: tap to undo all operations on A/B/C plane and go back to status in step 4.

[Reset Ori]: tap to undo all orientation adjustments on A/B/C plane and go back to status in step 4.

[Reset All/Current View]: tap to restore operations on all views or current view and go back to status in step 4.

#### Parameter adjusting

Parameters under Smart Plane FH are similar to those under Static 3D mode. For details, refer to "5.10.3.3 Static 3D Image Viewing".

# 5.11 Contrast Imaging

2D contrast imaging is used in conjunction with ultrasound contrast agents to enhance imaging of blood flow and microcirculation. Injected contrast agents re-emit incident acoustic energy at a harmonic frequency much more efficient than the surrounding tissue. Blood containing the contrast agent stands out brightly against a dark background of normal tissue.

Contrast imaging is an option.



- 1. Set MI index by instructions in the contrast agent accompanied manual.
- 2. Read contrast agent accompanied manual carefully before using contrast function.

### NOTE:

Make sure to finish parameter setting before injecting the agent into the patient to avoid affecting image consistency. This is because the acting time of the agent is limited.

The applied contrast agency should be compliant with the relevant local regulations.

## 5.11.1 Basic Procedures for Contrast Imaging

To perform a successful contrast imaging, you should start with an optimized 2D image and have the target region in mind. To perform a contrast imaging:

- 1. Select an appropriate probe, and perform 2D imaging to obtain the target image, and then fix the probe.
- 2. Tap [Contrast] on the touch screen or press user-defined key for contrast imaging (Assign a key as user-defined contrast imaging: the setting path is "[Setup] → [System] → [Key Config]", see "12.1.6 Key Configuration" chapter for details) to enter the contrast imaging mode.
- 3. Adjust the acoustic power experientially to obtain a good image.
  - Touch [Dual Live] to be "On" to activate the dual live function. Observe the tissue image to find the target view.
- 4. Inject the contrast agent, and set [Timer 1] at "ON" to start the contrast timing. When the timer begins to work, the time will be displayed on the screen.
- 5. Observe the image, use the touch screen button of [Pro Capture] and [Retro Capture] or the user-defined key (usually "Save1" and "Save2") to save the images. Press <Freeze> to end the live capture.
  - Perform several live captures if there are more than one interested sections.
- 6. At the end of a contrast imaging, set [Timer 1] as "OFF" to exit the timing function. Perform procedures 3-5 if necessary.
  - For every single contrast imaging procedure, use [Timer 2] for timing.
  - If necessary, activate destruction function by touching [Destruct] as "ON" to destruct the microbubbles left by the last contrast imaging; or to observe the reinfusion effect in a continuous agent injecting process.
- 7. Exit contrast imaging.
  - Tap [Contrast] on the touch screen or press user-defined key to exit the contrast imaging mode; or, press <B> button to return to B mode.

## **5.11.2 Contrast Image Parameters**

## 5.11.2.1 Parameter Area Display

When entering contrast imaging mode, the screen displays the contrast image, and if [Dual Live] item on the touch screen is "ON", both the contrast image (marked with "D") and tissue image (marked with "D") are displayed (the two window position can be changed). Parameter area displays as follows:

Туре	Parameter	Description
	FCH	Contrast frequency.
	D	Depth.
	G	Gain.
Contrast	FR	Frame rate.
	DR	Dynamic Range.
	iTouch	iTouch status
	iClear	iClear level
	G	Gain
Tiecue	DR	Dynamic Range.
Tissue	iTouch	iTouch status
	iClear	iClear level
Zoom	Z	Magnification factor
Timing (If timer is "ON")  Real time: 00:00:08  Freeze: 00:00:09		In real time mode, the time displayed is the elapsed time. In freeze mode, the timer stops working, the elapsed time is displayed.

### 5.11.2.2 Image Optimization

To adjust contrast image as well as tissue image, touch the corresponding tab on the touch screen first. Parameters in Contrast mode are similar to those in B mode; please refer to B chapter for details, special Contrast imaging parameters are introduced in the following.

#### 5.11.2.3 Timer

The two timers are used to record total time of contrast imaging and single time of one contrast exam. After the image is frozen, Timer 1 is still timing, and after unfreezing the image, the corresponding time can be seen.

Timer 2 stops timing when one contrast exam is frozen, and after unfreezing the image, the Timer 2 is off.

**NOTE:** The starting time displayed may be inconsistent with the actual one due to system error or some other man-made mistakes; please check the agent-injecting time.

Set [Timer 1] as "ON" to start the timing at the moment you inject the contrast agent. Here, the screen displays the times at the lower right corner.

- The time begins at 0.
- In live mode, there displays the elapsed time. For example, 00:00:08, it means the elapsed time is 8s
- Freeze the image during the timing, the timer stops working, and there displays the elapsed time. For example, 00:00:09, it means the elapsed time between begin timing and freeze the image is 9s.
- Set [Timer 1] or [Timer 2] as "OFF", the timer discontinues its work.

#### 5.11.2.4 Micro-bubble Destruction

Function: destruct the micro-bubbles left by the last contrast imaging; or to observe the reinfusion effect in a continuous agent injecting process.

- Entering: touch [Destruct] on the touch screen to enable the micro-bubble destruction function.
- Parameters: set the parameters through the touch screen/menu.
  - DestructAP: adjust the destruct acoustic power by the touch screen/menu item.
  - DestructTime: adjust the destruct time by the touch screen/menu item.

Caution: Use the contrast imaging according to the residual level of the micro-bubbles, using contrast imaging continuously may result in human harm.

### 5.11.2.5 **Dual Live**

In live mode or freeze mode, set touch screen item [DualLive] as "ON" to enable dual live function. Both the contrast image (marked with "I") and tissue image (marked with "I") are displayed (the position can be changed). Meanwhile, you can switch to [Contrast] or [Tissue] page to adjust the corresponding parameters.

Tips:

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

Click [CEUSPos] on the touch screen to adjust the position of the contrast image. The image displays at the left side of the screen.

#### 5.11.2.6 Mix Map

This function is to mix the contrast image with the tissue image, so that interested contrast regions can be located.

Touch [Mix] to select different mixing mode, and select different maps by knobs under [Gray Map]/[Tint Map]/[Mix Map] on the touch screen.

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

Select the map through the [Mix Map] item.

#### 5.11.2.7 iTouch

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

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

The symbol of iTouch will be displayed in the image parameter area in the upper right corner of the screen once press <iTouch>.

Select different levels of iTouch effect through [iTouch] on the touch screen.

■ Long press the <iTouch> key to exit the function.

### 5.11.2.8 Image Saving

Live capture

In live mode, you can save the interested images by touching [Pro Capture] and [Retro Capture].

Cine saving

In live mode, press the <Freeze> key on the control panel to enter cine review status.

## 5.11.3 Left Ventricular Opacification

Basic Procedures for LVO:

- 1. Acquire ECG signal;
- 2. Press or tap an appropriate probe for quick switch in the touch screen to open Probe/Exam Mode selecting dialogue box;
- 3. Select an appropriate probe and LVO exam mode;
- 4. Workflow of LVO is similar to abdomen contrast imaging.

## 5.11.4 Measurement, Comment and Body Mark

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

### 5.11.5 Micro Flow Enhancement

MFE superimposes and processes multiple frames of contrast image during the cycle; it indicates tiny vessel structures in detail by recording and imaging microbubbles.

#### MFE switch

During real-time scanning, touch [MFE] on the touch screen to start MFE imaging (MFE key is highlighted in green).

Tips: MFE imaging is available only for real-time imaging or cine file of auto review mode. If a MFE cine is reviewed manually, MFE effect cannot be displayed.

#### **MFE Period**

Rotate the knob under [MFE Period] on the touch screen to select different imaging period suitable for current flow. Where, MAX is the maximum superimposing effect.

NOTE: In MFE status, patient should lie down and hold breath, and transducer should be kept still.

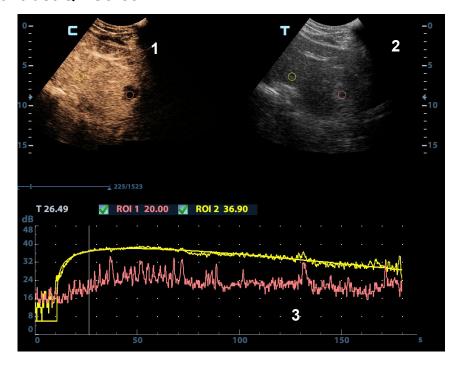
## 5.11.6 Contrast Imaging QA

Contrast Imaging QA images are provided for reference only, not for confirming a diagnosis.

Contrast Imaging QA adopts time-intensity analysis to obtain perfusion quantification information of velocity flow. This is usually performed on both suspected tissue and normal tissue to get specific information of the suspected tissue.

- 1. Perform image scanning, freeze the image and select a range of images for analysis; or select a desired cine loop from the stored images.
  - Images from the current scan session (already in freeze mode) or from a saved image loop can be used.
- Clicking the "Tissue" or "Contrast". Touch [Contrast QA] on the touch screen page to activate the function.
- 3. Mark out the interested part (ROI).
  - If necessary, perform curve fitting on the time-intensity curve.
- 4. Analyze the parameters of the curve, or perform B measurement.
- 5. Save the curved image, export the data and do parameter analysis.
- 6. Click [Exit] on the touch screen to exit the contrast imaging QA.

### 5.11.6.1 Contrast QA Screen



(For reference only)

#### 1---Contrast cineloop window

Sample area: indicates sampling position of the analysis curve. The sample area is color-coded, 8 (maximum) sample areas can be indicated.

#### 2---B Cineloop window

Sample areas are linked in the contrast cineloop window and B cineloop window.

### 3---Time-intensity curve

- Y axis represents the intensity (unit: dB), while X axis represents the time (unit: s).
- Frame marker: a white line that is perpendicular to the X axis, can be moved horizontally left to right (right to left) by rolling the trackball.
- Click the check box beside the ROI to set if to hide or to display the QA curve.

### 5.11.6.2 Basic Operations of Contrast QA

### **QA Analysis Image Range**

The system set the starting time and ending time of the cine to be first frame and last frame of QA analysis range.

### **Setting ROI**

This function is used for setting the target.

Up to eight ROIs can be saved on the reference image, with the corresponding eight traces plotted simultaneously on the graph. Each ROI display has a different color, and its corresponding trace data is plotted using that same color.

There are two different methods for determining the shapes of the sample area: Standard ROI and Freehand ROI.

#### Trace ROI

- 1. Touch [Trace ROI] on the touch screen.
- 2. Review the image to a desired frame.
- 3. Rotate the trackball to position the image display cursor over the reference image(s).
- 4. Press the <Set> key to fix the starting point.
- 5. Press the <Set> key, and roll the trackball to depict the ROI. When a suitable ROI has been drawn, confirm the ROI by double clicking <Set> key, press <Clear> key to cancel the last point.

The system automatically links the start point to the end point by drawing a straight line between them.

#### ■ Ellipse ROI

- 1. Touch [Ellipse ROI] on the touch screen, when the cursor is evolved in the image review area, it displays as a color-coded ellipse.
- 2. Review the image to a desired frame.
- 3. Use the trackball to position the caliper on the reference image at the start point. Press <Set> to fix the start point.
- 4. Trace the outline of the desired ROI by moving the cursor with the trackball.
- 5. Press the <Set> key to fix the end point, and roll the trackball to depict the ROI. When a suitable ROI has been drawn, confirm the ROI by double pressing <Set> key, press <Clear> key to cancel the last point.
- Delete ROI

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

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

### **Motion Tracking**

Click [Motion Tracking] (the button is highlighted) on the touch screen to turn on the function.

This function provides a motion compensated ROI as precise time-intensity information can be acquired using active tracking. It can enhance the calculation accuracy as reducing the impact of probe or patient respiratory movement.

Tips: Elliptical ROIs can be positioned in any manner that keeps their center within the image boundaries. In the case that part of the ROI is outside the image boundary, only data from within the image boundary is used for calculating the mean intensity value.

#### X Scale

Rotate the knob under [X Scale] on the touch screen to choose different value, so that the X scale display manner will be changed. This function can be used to track detailed tissue information.

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

- 1. Touch [Export] on the touch screen.
- 2. Select the drive and enter the file name in the displayed window.

- 3. Select [OK] to save the data and return to the QA Analysis screen.
  - All displayed ROI traces are saved in the exported file.
  - The parameters are included in the trace file if the user has fixed a ROI.
  - After the exporting is succeeded, a .BMP format image is displayed in the thumbnail area at the lower part of the screen.
  - Only data from the user selected image range is included in the exported trace file.

### **Curve Fitting**

The system can calculate characteristic parameters according to curve fitting formula and data, display fit curve for time-intensity curve, and perform data analysis on time-intensity curve for data table.

- Touch [Fit Curve] on the touch screen to turn on the function, where color of the fitted curve is consistent with color of the current ROI curve.
- Touch [Raw Curve] to hide/display raw curve, when the button is highlighted in green, raw curve is displayed.
- Touch [Table Display] to check parameters.

Parameters calculated include the following:

- GOF (Goodness of Fit): to calculate the fit degree of the curve; range: 0-1, where 1 means the fit curve fits the raw curve perfectly.
- BI (Base Intensity): basic intensity of no contrast agent perfusion status.
- AT (Arrival Time): time point where contrast intensity appears, generally, the actual time value is 110% higher than the base intensity.
- TTP (Time To Peak): time when the contrast intensity reaches peak value.
- PI (Peak Intensity): contrast peak intensity.
- AS (Ascending Slope): ascending slope of contrast, the slope between the start point of lesion perfusion to the peak.
- DT/2: time when the intensity is half the value of the peak intensity.
- DS (Descending Slope): descending slope of the curve.
- AUC (Area Under Curve): to calculate the area under the time-intensity curves during contrast.

**NOTE:** If the contrast signal inside the selected ROI does not meet the requirements of gamma fitting condition, that is the bulleting injection, curve fitting may not be available.

#### **Set Fit Range**

You can set range for the fit curve. After the range is set, the system displays fit curve within the range only. Roll the trackball to the time-intensity curve to move the frame marker position.

- Set starting point of the fit curve: roll the trackball to select the starting time and click [Set Fit Start] on the soft menu.
- Set end of the fit curve: roll the trackball to select the end time and click [Set Fit End] on the soft menu.

# 5.12 iScape View (Real-time Panoramic Imaging)

The iScape panoramic imaging feature extends your field of view by piecing together multiple B images into a single, extended B image. Use this feature, for example, to view a complete hand or thyroid.

When scanning, move the probe linearly and acquire a series of B images. The system pieces these images together into a single, extended B image in real time. The system also supports out-and-back image piecing.

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

The system provides a color iScape function, so you can get more information from extended images. iScape imaging is an option.



- iScape panoramic imaging constructs an extended image from individual image frames. The quality of the resulting image is user-dependent and requires operator skill and additional practice to become fully proficient. Therefore, the measurement results can be inaccurate. Exercise caution when you perform measurements in iScape mode. A smooth and even speed will help produce optimal image results.
- 2. Color iScape images are provided for reference only, not for confirming diagnoses.

Tip:

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

## **5.12.1** Basic Procedures for iScape Imaging

To perform iScape imaging:

- 1. Connect an appropriate iScape-compatible probe. Make sure there is enough coupling gel along the scan path.
- 2. Set the user-defined key for iScape via the path: [Setup] → [System] → [Key Config]. Press the user-defined key for iScape or touch [iScape View] on the touch screen directly:
- 3. Optimize the B mode (Power mode) image:
  - In the acquisition preparation status, touch the [B] ([Power]) page tab to select B mode (color) image optimization. Perform measurement or add comments/body marks to the image if necessary. Tip: in iScape mode, [FOV] is limited to "W."
- 4. Image acquisition:

Click the [iScape] page tab to enter the iScape acquisition preparation status. Click [Start Capture] or press <Update> on the control panel to begin the acquisition. For details, see "5.12.2 Image Acquisition."

The system enters image viewing status when the acquisition is completed. You can perform operations such as parameter adjusting. For details, see "5.12.3 iScape Viewing."

- 5. Exit iScape:
  - Press <Freeze> or <Update>, or touch [Recapture] on the touch screen to enter image acquisition status.
  - Press the <B> button to return to B mode.

## 5.12.2 Image Acquisition

To create an iScape image, start with an optimized 2D (color) image. The 2D image serves as the midline for the resulting iScape image.

- 1. Press the <Update> key or touch [Start Capture] on the touch screen to start the iScape image capture.
- 2. Scan slowly to obtain a single extended field of view image. You can also erase and retrace if the image is not satisfactory.
- 3. End image capture:

To end the image capture:

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

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

Tip:

- During image acquisition, none of the parameters are adjustable, and functions such as measurement, comments and body marks are not available.
- ROI: a green box on the image indicating the boundary between the merged images and the unfinished images.
- Tip on the probe speed: During image slicing, the system gives feedback on the probe's moving speed in the form of colors and words. The meanings are as follows:

Status	ROI Color	Tip
Speed too low	Blue	Moving speed of the probe is too low.
Appropriate	Green	None.
Speed too high	Red	Moving speed of the probe is too high.

Guidance and precautions for even movement:

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

## 5.12.3 iScape Viewing

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

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

- Setting image parameters. For details, see "5.12.3.1 Adjusting Image Parameters."
- Image zooming. For details, see "5.12.3.2 Image Zooming."
- Image rotation. For details, see "5.12.3.3 Rotating the Image."
- Measurement, comments and body marks. For details, see "5.12.3.4 Measurement, Comments and Body Marks."

## **5.12.3.1 Adjusting Image Parameters**

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

Image size

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

Touch [Fit Size] to display the image in a size that fits the current window. This is the system's default format.

Tint map

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

■ Ruler

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

Color Display (in Power iScape)

Touch [Color Disp.] on the touch screen to display or hide the color image.

Color Map (in Power iScape)
 Rotate the knob under [Color Map] on the touch screen to select the map, as in Power mode.

### 5.12.3.2 Image Zooming

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

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

### 5.12.3.3 Rotating the Image

For the convenience of image viewing, you can rotate the image by rotating the knob under [Rotation] on the touch screen in increments of 5°.

### 5.12.3.4 Measurement, Comments and Body Marks

In iScape image viewing status, you can perform measurement, comments and body marks. The operations are the same as in B mode.

NOTE:

- 1. The measurement accuracy for spliced images may be degraded exercise caution when measurements are performed on an iScape image.
- 2. If there is a trace during the retracing, do not perform measurement across the trace.

## 5.12.3.5 Evaluate Image Quality

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

NOTE:

iScape panoramic imaging is intended for use by well-trained ultrasound operators or physicians. The operator must recognize image items that will produce a sub-optimal or unreliable image.

The following items may produce a sub-optimal image. If the image quality does not meet the following criteria, you must delete the image and repeat image acquisition.

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

### 5.12.4 Cine Review

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

- Roll the trackball to review the captured images frame by frame.
- Click [Auto Play] to start or end auto play.

- In auto play mode, press/rotate the corresponding knob to change the play speed. When the speed is off, the system exits auto play mode.
- Review to a certain image. Press the knob under [Set Begin] to set the start point. Review to another image. Press the knob under [Set End] to set the end point. In auto play mode, the review region is confined to the set start point and end point.
- Click [Return] on the touch screen to exit cine review mode. The panoramic image displays.
- In cine review mode, press <Freeze> on the control panel to return to the acquisition preparation status.

# 5.13 Elastography

CAUTION: Elastography images are provided for reference only, not for confirming diagnoses.

## 5.13.1 Strain Elastography

It is produced based on the slight manual-pressure or human respiration in 2D real-time mode. The tissue hardness of the mass can be determined by the image color and brightness. Besides, the relative tissue hardness is displayed in quantitative manners.

Strain Elastography imaging is an option.

### 5.13.1.1 Basic Procedure for Elastography

- 1. Perform a B scan to locate the region.
- 2. Touch [Elasto]→[StrainE] on the touch screen or press the user-defined key for Elastography or StrainE on the control panel to enter the mode (Set the user-defined key for Elastography or StrainE via the path: [Setup] → [System] → [Key Config]). Adjust the ROI according to the actual situation.
  - Select the probe according to the experience and actual situation.
  - Adjust the image parameters to obtain the optimized image and necessary information.
  - Adjust the ROI on the frozen image if necessary.
  - Save the image or review the image if necessary.
  - Perform measurement or add comments/body marks to the image if necessary.
- 3. Estimate the hardness of lesions according to the results.
- 4. Press <B> to return to B mode.

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

#### 5.13.1.2 Enter/Exit

■ Enter

Select [Elasto]→[StrainE] on the touch screen to enter the mode.

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

■ Exit

Press <B> on the control panel or touch [StrainE] on the touch screen to exit the mode.

### 5.13.1.3 Strain E Curve

The screen displays the pressure curve in real time:



The X-axis represents time and the Y-axis represents pressure.

### **ROI Adjustment**

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

**Operation** When the ROI box is solid line, roll the trackball to change its position.

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

Smooth

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

**Operation** To adjust the image smoothness. Adjust using the [Smooth] item or the mapping-menu

item on the touch screen.

The system provides 5 levels of smooth function: the bigger the value the stronger the

effect.

**Opacity** 

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

**Operation** Rotate the knob under the [Opacity] item or adjust through the mapping-menu item on

the touch screen.

The system provides 5 levels of opacity function: the bigger the value the stronger the

effect.

Invert

**Description** To invert the E color bar and therefore invert the colors of benign and malignant tissue.

**Operation** Touch [Invert] or the mapping-menu item on the touch screen.

Map

**Description** To select different maps for observation.

**Operation** Rotate the knob under the [Map] item on the touch screen or adjust through the

mapping-menu item to select the map.

The system provides 6 maps, including 1 grayscale map and 5 color maps.

**Map Position** 

**Description** This feature is used to adjust the up/down position of the map.

**Operations** Tap [Map Position] on the touch screen to adjust the parameter.

Effects When the E Average function is enabled or disabled, the elasto curve is displayed

based on different statistical amounts.

### **Display Format**

**Description** Adjust the display format of ultrasound image and the Elasto image.

**Operation** Tap [H 1:1], [V 1:1], [Full] on the touch screen to adjust.

The system provides 3 types of display format:

H 1:1: right and left display (the real-time ultrasound image appears on the left, and the

elasto image appears on the right);

V 1:1: up down display (the elasto image appears above, and the real-time ultrasound

image appears below).

Full: the elasto image only displayed.

Impacts Adjust according to the actual situation and obtain a desired analysis through

comparison.

#### Strain Scale

**Description** Adjust the strain scale of the strain bar in different situations.

**Operations** Rotate the knob under the [Strain Scale] item on the touch screen to adjust the

parameter.

**Effects** The system provides 5 levels of strain scale function: under the same pressure, the

bigger the value, the lower the strain bar.

### 5.13.1.4 Mass Measurement

Press <Measure> to enter measurement status.

You can measure shell thick, strain ratio, strain-hist, etc.

For details, see [Advanced Volume].

#### 5.13.1.5 Cine Review

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

## 5.13.2 STE Imaging (Sound Touch Elastography)

Keep the probe still to produce the elastography image in real-time STE mode. The tissue hardness of the mass can be determined by the image color and brightness. Besides, the relative tissue hardness is displayed in quantitative manners. STE imaging provides you real elasto modulus for quantification analysis.

STE imaging is an option.

### 5.13.2.1 Basic Procedures for STE Imaging

- 1. Select a proper probe. Perform 2D scan to locate the region.
- Tap [Elasto]→[STE] on the touch screen. Or press the user-defined key (set the user-defined key via [Preset]→[System]→[Key Config]) to enter the STE mode.
- 3. Adjust the ROI based on the lesion size, and press <Set> to adjust the ROI size and the position. To compare the hardness between the lesion and the normal tissue, the ROI should include the lesion and the normal tissue.
- 4. Keep the probe still to imaging, and adjust the parameter to obtain premium image.
- 5. Freeze the image, and replay the image if necessary.

- 6. Perform the measurement or add comment/body mark to the image if necessary.
- 7. Save the single-frame and multi-frame image.
- 8. Acquire high-quality image if necessary (for details, refer to "5.13.2.2 STE Mode Image Optimization").
- 9. Press <B> on the control panel to exit the shear wave elastography mode, and return to B mode.

### **5.13.2.2 STE Mode Image Optimization**

### **Image Quality**

**Description** Used to select the transmitting frequency of the current probe, the real-time value of

which is displayed in the image parameter area in the upper right side of the screen.

**Operation** Rotate the knob under [E Quality] on the touch screen to select the different THI

frequency value.

The adjusting range of basic frequency values can be divided into penetration preferred (Pen), general mode (Gen), resolution preferred (Res). Please select the frequency

according to the detection depth and current tissue features.

**Impacts** Used to optimize the resolution and the penetrability of the image.

**Elas Metric** 

**Description** Used to adjust the elastography metric.

**Operation** Rotate the knob under [Elas Metric] to adjust the value on the touch screen.

The metric includes Young's modulus E (unit: kPa), shear modulus G (unit: kPa), and

shear wave velocity Cs (unit: m/s).

The current elastic modulus or the shear wave velocity (including the unit) appears on

the top of the color bar.

**Scale** 

**Description** Used to change the maximum scale to make the map related to the color at the top of

the bar. Optimize the elasto modulus, or mirror the elasto wave velocity to the map.

**Operation** Rotate the knob under [Scale] on the touch screen. The value on the top of the Map

changes as the Scale changes.

The adjusting range: 0 to 29 in increment of 1.

**Impacts** Parts which exceed maximum elasto modulus or shear wave velocity will be mapped

onto the color on top of the color bar at top-left part of the image. Thus if the color in the ROI is mainly the color on top of the color bar, you need to increase the metric range.

Opacity

**Description** Used to adjust the opacity feature of the Elasto image.

**Operation** Tap [Opacity] on the touch screen. The adjusting range: 0 to 5 in increment of 1.

Map

**Description** Used to adjust the color map to achieve the switch between the gray map and the color

тар.

**Operation** Tap [Map] on the touch screen to select the map. E1 is a gray map; E2 and E3 are color

maps.

**ROI Adjustment** 

**Description** This feature is used to adjust the ROI position and scale of the lesion detected in STE

imaging.

**Operation** Rotate the knob under the [Fixed ROI] item on the touch screen to adjust the fixed size

of the ROI, or press the <Set> key and roll the trackball to adjust the ROI position and

scale. The ROI includes lesions and surrounding normal tissues.

The Depth value of the ROI center is displayed at the bottom right corner of the screen.

**Display Format** 

**Description** Used to adjust the display format of ultrasound image and the Elasto image, and return

to the previous state.

**Operation** Tap each soft key on the touch screen to complete the adjustment.

The system provides 3 types of display format:

H 1:1; V 1:1; Full.

**Impacts** More accurate result is obtained based on the actual situation.

**HQElasto** 

**Description** Turn on high-quality scanning mode to optimize penetration.

**Operation** Tap [HQElasto] to enable the function and the button will be highlighted.

**Impacts** When the feature is activated, the system turns into single-frame scanning mode.

Pressing < Update > acquires one frame image of B and Elasto.

**RLB Map** 

**Description** Used to help the user judge the region where it is suitable for elasto measurements

based on the distinctive colors in elasto image in quality map.

The RLB Index shows the signal reliability of the STE inside the ROI, and it helps the

user judge the effectiveness of the current elasto measurement.

**Operation** Tap [RLB Map] to enable the function (the soft key is highlighted). The quality map

appears on the left side of the image.

With both real-time ultrasound image and elasto image displaying, the real-time

ultrasound image is replaced with the quality image.

With only elasto image displaying, the elasto image is replaced with the quality image.

The higher the RLB Index is, the more reliability the signal becomes; vice versa.

There are three colors showing the RLB Index: Red (low reliability), Yellow (medium

reliability) and White (high reliability).

The color in High area is suitable for the imaging of shear wave elastography. **Impacts** 

> The color in Low area is not suitable for the imaging of shear wave elastography (liquid, gas. bone, etc). It can be used as a tool to detect the tissue or the lesion.

**RLB View** 

This feature supports the less qualified region or the region that fails to receive shear Description

waves of the gas or liquid to be displayed in hollow.

Operation Tap [RLB View] on the touch screen to enable the function and the button will be

highlighted.

After the RLB View function is enabled, the less qualified region is displayed in hollow. The hollow region can be seen in B images. The hollow region corresponds to the

purple region in the reliability image.

### M-STB Index/Sensibility

**Description** The STE imaging can easily be affected by respiration, pulse of the main artery, or

> transducer movement, which may cause uncertainty and unreliability. The M-STB Index helps users judge whether the current elasto image is captured in stable state. Based on the judgment, capturing method, capturing part, and patient cooperation can

be adjusted accordingly.

Operation Tap [M-STB Index] on the touch screen to enable the function and the button will be highlighted. Then the M-STB Index is displayed at the upper side of the image.

> Grading definition of the M-STB Index: 1 star indicates that the motion interference is extremely strong, and it is not recommended to use the elasto image; 2 stars indicates that the motion interference is relatively strong, and it is not recommended to use the elasto image; 3 stars indicates that the motion interference is general, and it is not recommended to use the elasto image; 4 stars indicates that the motion interference is not strong, and the image can be used; 5 stars indicates that the motion interference is

few or slight, and it is recommended to use the elasto image.

Tap [M-STB Sensi.] on the touch screen to set the grading threshold of the M-STB

Index.

The stronger the sensibility of the motion stability is, the higher the judgment accuracy

of the motion interference becomes.

**Effects** Users can determine the interference degree of the currently-captured elasto image

according to the M-STB Index.

**iNatural** 

**Description** This feature is used to optimize the review effect of multi-frame images to improve the

stability between frames and provide a more continuous and smooth review effect of

the multi-frame image.

Operation Tap [iNatural] to enable the function and the button will be highlighted.

**Effects** In auto cine review mode, the effect is more continuous and smooth.

**Smooth** 

Description This feature is used to reject the noise and smooth the image. **Operations** Tap [Smooth] on the touch screen to adjust the parameter.

**Effects** The bigger the level is, the higher the smooth effect achieves.

**Persistence** 

**Description** This feature is used to superimpose and average adjacent elasto images, so as to

optimize the image.

**Operations** Tap [Persistence] on the touch screen to adjust the parameter.

The bigger the value is, the higher the frame optimization effect achieves.

Effects The persistence function can remove image noise and optimize image effect to gain a

more detailed image.

**FS Mode** 

**Description** This feature is used to improve the frame rate (FR).

**Operations** Tap [FS Mode] on the touch screen to enable the function and the button will be

highlighted.

Invert

**Description** Invert the map to satisfy the different doctors to define the benign lesion or malignant

esion.

**Operation** Tap [Invert] to enable the function (the soft key is highlighted).

iLayering

**Description** To increase the layer display in elasto images.

**Operation** Tap [iLayering] to enable the function.

**Filtering** 

**Description** To filter the noise of the elasto image.

**Operation** Rotate the knob under [Filter] on the touchpad.

The higher the level is, the smaller the noise of the elasto image becomes, and the

clearer the edge of the field target appears.

**Impacts** The system restarts scanning B image and E image after the filtering is completed.

**Map Position** 

**Description** This feature is used to adjust the up/down position of the map.

**Operations** Tap [Map Position] on the touch screen to adjust the parameter.

Lesion

**Description** It is used to distinguish elastography data of the different lesion region.

**Operations** Tap [Lesion] on the touch screen to adjust.

E Avg

**Description** Used to optimize the measurement result via equalizing the elasto metric of the current

frames and the previous frames.

**Operation** Rotate [E Avg] knob to adjust the value.

The adjusting range is: 2-10.

Off represents the E Avg is disabled. The larger the scale is, the more the frames of the

elasto metric are equalized.

**Impacts** Decrease the image noise.

E bar

**Description** This feature supports the elasto curve to be displayed based on different statistical

amounts.

**Operations** Tap [E bar] on the touch screen to adjust the parameter.

Save All

**Description** Used to send all current elasto curve data to the relevant exam report.

**Operation** Tap [Save All] on the touch screen to send the data.

### **5.13.2.3 Measuring**

Press <Caliper> to enter general measurements. You can perform the measurements of Elastography, Elas. Ratio, Directional Ratio, Elas. Hist and etc.

Press <Measure> to enter application measurement. You can perform measurements on Isthmus and Mass, etc.

Refer to Operator's Manual (Advanced Volume) for details.

#### **5.13.2.4 Cine Review**

Press <Freeze> to freeze the image and enter cine review state.

Or, click the cine to enter the cine review state.

## 5.13.3 STQ Imaging (Sound Touch Quantification)

The STQ imaging is an option.

### 5.13.3.1 Basic Procedures for the STQ Imaging

- 1. Select a proper probe. Perform 2D scan to locate the lesion.
- 2. Tap [Elasto]→[STQ] on the touch screen, Or press the user-defined key (set the user-defined key via [Preset]→[System]→[Key Config]) to enter the STQ imaging mode.
- 3. Adjust the ROI based on the lesion size and the position.

4. Press <Update> to generate the acquisition. Place the probe still with stable force (not pressing, sweeping or moving the probe) to acquire the image. Adjust the B image parameters to obtain a premium image.

The stress curve shows at the bottom of the screen after entering the real-time acquisition.

The following indices display besides end of the curve in real-time:

- Elasto modulus inside the ROI of the current frame;
- The mean value, maximum value, minimum value, SD value of shear velocity;
- Depth value of the active elasto modulus.
- 5. Freeze the image, and replay the image if necessary.
- 6. Save the single-frame and multi-frame image.
- 7. Reacquire the image if necessary.
- 8. Press <B> on the control panel or tap [STQ] on the touch screen to exit the elastography imaging mode, and return to B mode.

### 5.13.3.2 STQ Mode Image Optimization

#### Scale

**Description** Used to optimize the display effect of the elasto average metric inside ROI via

changing the Y-axis size.

**Operation** Rotate [Scale] knob to adjust the value.

The adjusting range is: 0-9 in increment of 1.

**Impacts** If elasto metric average value inside ROI of a certain frame image exceeds the

maximum scale on the elasto curve, elasto metric will display in the maximum scale

value.

Other parameters of the STQ imaging are the same to those of the STE imaging. For details, please refer to "5.13.2.2 STE Mode Image Optimization".

## 5.14 Stress Echo

Stress Echo is an option.

CAUTION:

Stress echo data are provided for reference only, not for confirming diagnoses.

### 5.14.1 Overview

The Stress Echo feature allows you to capture and review cardiac loops for multiple-phase (multiple-stage) Stress Echo protocols.

Stress Echo data consists of Stress Echo loops, wall motion scores, and all other information pertaining to the Stress Echo portion of a patient examination.

A loop is a clip that displays the motion of an entire heart cycle, or from the beginning systole to the end systole, as indicated by the R-wave of the ECG trace and determined by the QT – Time Table.

The loops in a given protocol are acquired by stages (phases), according to stage configuration (continuous (prospective) or retrospective (non-continuous)).

 Loops in non-continuous stages are limited to a specified loop-per-view maximum (such as four). View labels can only be selected in the configured order. Acquisition is retrospective when you press the <Save> key on the control panel, the system saves the previously acquired images. Loops in continuous stages are limited by time rather than a maximum number of loops - the system stops acquisition after two minutes. Acquisition is prospective - when you select the stage label and then press the <Save> key on the control panel, the system starts saving newly acquired images. In some protocols, the system will jump to Select Mode after retrospective saving.

When images are saved, the system places a green checkmark to the right of the view or continuous stage and then shifts the red mark to the next view or next stage.

## 5.14.2 Stress Echo Acquisition Procedure

To acquire Stress Echo loops, you must enable the ECG function.

- Use the proper probe and cardiac-related exam mode, press the user-defined key for Stress Echo
  (Set the user-defined key for Stress Echo via the path: [Setup] → [System] → [Key Config].) or touch
  [Stress Echo] on the touch screen on the top left of the screen to enter stress echo imaging.
- 2. The system displays the "Select Protocol" window with the protocol selections. Select the desired protocol and then click [OK].

The system displays the real-time imaging screen.

If the Stress Echo manual ROI option is selected in the Maintenance dialog box ([Setup]->[Stress Echo]->[Maintenance]), the system also displays a region of interest (ROI). If Acquire Mode is set as Full-screen in Maintenance, then no ROI box is displayed. For details, see "5.14.5 Maintenance and Protocol."



- 3. According to the help information in the bottom of the screen, if an ROI is displayed, adjust the ROI size and position. Press <Update> key on the control panel to confirm the ROI.
  - Tip: When you confirm the ROI size by pressing <Update>, you cannot adjust the ROI size during acquisition. You can only adjust the ROI position using the trackball.
- 4. Press the <Save> key on the control panel to start acquisition.
  - The system displays the Protocol window on the left of the screen, listing the phases for the selected protocol along with the first phase views (phases are stages). The system selects the first view for acquisition by default, indicating the selected view by placing a red mark to the right of the view name.
- 5. Proceed through each view in each stage according to the following instructions:
  - Non-continuous stages:
    - To save acquired images for the selected view, press the <Save> key on the control panel. The
      system goes to the next view for acquisition by default, saved views are marked with a green
      "√."

• Rotate the knob under [Stages XXX] or [Views XXX] to select the stage and view for image acquisition (or reacquisition). Press the <Save> key to start acquisition.

Tip: Views can be re-acquired until you click [End Acquisition].

- If the protocol contains continuous stages (for alternative workflows), then proceed through each continuous stage according to the following instructions:
  - To begin saving acquired images for the selected stage, press the <Save> key on the control panel.

The system displays a percentage marker below the selected stage indicating the progress of the continuous capture.

- To stop saving acquired images for the selected stage, rotate the knob under [Pause] on the touch screen or press <Freeze> directly. The percentage stops increasing.
- Select [Continue] or press the <Freeze> key again to continue.
- To end the current acquisition, press <Save> on the control panel.
- To select another continuous stage, rotate the knob under [Stage XXX] on the touch screen.
- Suspending is not allowed under continuous exam.

When acquisition is complete for each stage, the system advances to the next stage. If the stage is non-continuous, the system displays the stage views. When image acquisition is completed for all views and continuous stages, the system switch to Select Mode.

- 6. To start or restart the timer, click [Stage Timer]/[Exam Timer] on the soft menu to turn it on.
  - The Stage time is displayed to the right side of each stage in the protocol list, while the Exam time is displayed in the left side of the screen.
  - Each saved image will be marked with two times T1 and T2. T1 refers to the total time of the whole acquisition, while T2 indicates the time the acquisition lasted for a certain stage.
- 7. To review loops before ending acquisition, select [Review/WMS] on the menu. You can redisplay the real-time imaging screen to continue acquisition by selecting [Acquire].
- 8. To end the acquisition and review the acquired images, click [End Acquisition].

**NOTE:** When the acquisition is ended, no stress echo image acquisition can be performed for the same exam.

## 5.14.3 Selecting Preferred Stress Echo Loops (Select Mode)

The selected clips are used for analysis in the review mode and wall motion scoring mode. Select Mode is used to select the best loops of the examination.

When the acquisition is ended, select mode is enabled automatically.

In Select Mode, you can select the representative loop ("preferred" loop) for each view.

To select "preferred" loops:

- 1. Use the <Update> key according to tips in the trackball hint area or select [Select] on the menu to enter the Select Mode, or the system enters the Select Mode directly after the acquisition is finished.
- 2. Select the loop. Use the buttons displayed during Select Mode to designate another loop or another view for display.
  - Use [Stage: XX] or [View: XX] on the soft menu to select the target stage/view.
  - Single-click a clip to select the clip for current stage/view and zoom in the clip to the full-screen.
  - Double-click a clip. The clip will be magnified.
  - Touch , do or on the touch screen to display another loop in the current view.
  - Click buttons on the left side of the screen to view the cine files by frame.



3. Select the stage and view to display all loops for the view and then continue designating the "preferred" loop for each displayed view until all views are completed.

### **Description of select mode controls:**



### Touch screen controls:

Selection	Description
Stages: XX	Rotate the corresponding knob under the button to select a stage.
Views: XX	Rotate the corresponding knob under the button to select a view.
Acquire/	To switch the mode status.
Select/ Review/WMS	
1. Clip /2. Clip /3. Clip /4. Clip	For selecting views in the selected stage.
Next <b>N</b>	Next four Clips.
Previous <a>I</a>	Previous four Clips.
First	Go to "first" Clips.
Last 📘	Go to "last" Clips.
Play	Click to play/stop cine play.

Selection	Description
Prev frame	See previous frame of the cine file.
Next frame	See next frame of the cine file.
First frame	See first frame of the cine file.
Last frame	See last frame of the cine file.
<b>&gt;</b> + / <b>&gt;</b> -	Decreases or increases playback speed.
Text "On"/"Off"	Function that turns the screen graphic text "On" or "Off." The function is the same as the Labels on/off icon at the top of the screen.
	Information includes: name of level, name of view, heart rate, time stamp acquisition, timers, frame slider, loop ID, clip control. For the cine without distributed view, the name of level and name of view are displayed in "".
Apply edit all	Clip edit applied to all clips taken.
Clip Length	Specify the clip segments: systole, diastole, full cycle or user-defined.
Bookmark	For continuous acquisition, when the bookmark is set to "On", only the selected loops for the current view can be displayed.
Delete Unselected	Delete clips that are not selected. If selected, the system will delete all clips that are not selected after the exam is ended.
Suspend exam	Pauses the stress echo exam but does not end the stress echo exam.
	When a stress echo exam is suspended, the user can perform image acquisition of all other imaging modes, or perform operations such as measurement.
End SE exam	End the stress echo exam.

## 5.14.4 Review/WMS Mode

Review/WMS mode is used by cardiologists to evaluate clips for cardiac wall motion abnormalities. Different views from different stages are selected for comparison across a wide variety of combinations. The most common workflow is to compare "same views" but at "different stages" of the exam (e.g., PSLA view, Rest stage compared to PSLA view, Post-exercise stage).

### 5.14.4.1 Enter review mode

Select [Review/WMS] on the menu on the left side of the screen.

- 1. Select [Shuffle Mode] on the touch screen.
- 2. Select the label of the phase or view (for example, Rest or Long Axis) on the right part of the screen.



The system displays all loops that represent the selected phase or view.

- To display phases for the selected view(s)
- 1. To include a phase or view for display, select the leftmost, gray box to the left of each required phase and/or view.

The system inserts a checkmark into each selected gray box.

2. To exclude a phase or view from display, select the blue box to the left of each required phase and/or view.

The system inserts a red X into each selected box, like



3. Select [Display Selected] on the touch screen.

The system displays the selected phases for each selected view side by side.

■ To display all views for a specific phase:

Select the phase label (for example, Rest).

To display all phases for a specific view:

Select the view label (for example, PLAX).

The system displays all phases for the selected view.

- To display a loop in full-screen format:
- 1. Double-click the loop to display in full-screen format.
- 2. Double-click the loop again to display the loop in its initial size, select the loop again. Description of review/WMS mode keys (keys with the same function as in select mode are not described below):

Key	Description
	Perform side-by-side comparison of the same views at different stages (PLAX, PSAX, A4C, A2C at "Rest" compared to PLAX, PSAX, A4C, A2C "Post-Exercise"). Clips are synchronized.
	Selection: On, Off
Shuffle	Under [Shuffle Mode] "Off" status, when you select one stage, all view loops are displayed on the screen; when you select one view, all loops of the same view in different stages will be displayed on the screen.  Set [Shuffle Mode] to "Off", the system will select loops of first two views of the first two stages to display automatically. If you choose [Shuffle Forward], then loops of the next two views of the first stages will be displayed. If you click [Shuffle Back],
	loops of the first two views in the 3 <sup>rd</sup> and 4 <sup>th</sup> stage will be displayed. In the meantime, if you choose one stage, loops of all views under this stage will be displayed on the screen (4 at most), and choosing one view will lead to loops of this view in different stages be displayed (4 at most).
Display Selected	Displays loops of all the stages and views selected.

### 5.14.4.2 Wall Motion Scoring

The WMS-Report lists user-assigned wall motion scores and associated data.

The Wall Motion Score (WMS) measurement is an application prepared for assisting in stress echo semi-quantitative evaluations of abnormalities with left ventricular wall motion or changes in wall thickness. The left ventricle is divided into segments for scoring to evaluate the degree of abnormality from the sum of the scores in each segment using the motion of the walls of the entire left ventricle.

You can assign wall motion scores to specific portions within each view (representative loop). You can also assign a normal wall motion score (WMS) to the currently selected view or to all displayed views.

Two methods of chamber segment division, ASE 16 and ASE 17, are supported. In addition, each segment has 3 kinds of scoring method: 4, 5 and 7 points. Select through the [Scoring] control on the touch screen.

To assign a wall motion score (WMS):

1. Select a colored number in the bottom-right area of the screen.

The meanings and colors used in segments are listed in the table below.

Score	Meaning	Color
1	Normal	Green
2	Hypokinesis	Yellow
2.5	Severe Hypokinesis	Khaki
3	Akinesis	Blue
4	Dyskinesis	Red
5	Aneurysm	Purple

- 2. Roll the trackball to select the value and then click the target segments, then the segment is assigned with a value.
- 3. Repeat step 2 to perform value assign for all segments.
  - To assign a normal wall motion score (WMS) to all currently displayed loops: Select [Set All Normal] on the touch screen.
  - To assign a normal wall motion score (WMS) to the currently selected loop: Select [Set Current Normal] on the touch screen.

## 5.14.5 Maintenance and Protocol

### 5.14.5.1 Maintenance

Select "<F10 Setup>->[Stress Echo]->[Maintenance]" to enter the screen.



Item	Function Description	
Acquire mode	Set the type of ROI: manual ROI or full-screen.	
Overlay	Select the items to be labeled on each loop.	
WMS score type	Set the chamber segment division method.	
QT-Time table	To customize the length of systolic duration acquired for a specific heart rate If "Trigger" is selected as "R-R Systolic" in Protocol Editor, it will store the cli duration. You can add and remove entries in this table. You can also load the factory defaults.	
Heart rate	Enter the heart rate.	
Syst. duration	Enter the systolic duration.	
Load factory	To reset the QT time table.	

### **QT-Time Table Operation:**

■ To add an entry:

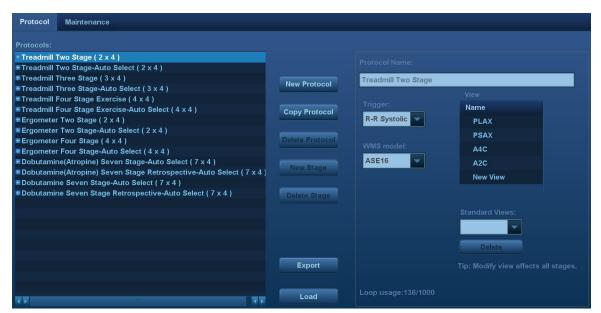
Enter a heart rate and the referring systolic duration and then click [Update].

■ To delete an entry:

Select the required heart rate and systolic duration pair from the QT – Time Table and then click [Delete].

### 5.14.5.2 Protocol Edit

You can create, edit and delete Stress Echo protocols using the Protocol Editor dialog box. Access the Protocol Editor dialog box by clicking [Protocol] in [Setup]->[Stress Echo]->[Protocol], or clicking [Edit] on the Select Protocol screen as shown in the figure below:



Item	Function Description	
Protocol name	Enter the protocol name.	
Trigger	Set the trigger type.	
WMS model	Set the chamber segment division method.	
Loop usage	Displays the acquired loop number as well as the total usable loop number.	

Item	Function Description	
View	Set the views for each stage.	
Standard view	Set the standard view.	
Load	Import a protocol.	
Export	Export a protocol.	
New protocol	Create a new protocol.	
Copy protocol	Create a new protocol with an existing one.	
Load	Load an existing protocol.	
Save	Save the changes to the protocol.	
Delete protocol	Delete the protocol.	
New stage	Create a stage for the current protocol.	
Quit	Remove the Protocol Editor dialog box.	

### **Creating a Stress Echo Protocol**

To create a stress echo protocol:

- 1. Click the [New Protocol] button to the right of the Protocol Editor dialog box.
- 2. Enter the protocol name in the Protocol Name box at the top.
- 3. For each view (all views display for each phase):
  - (a) Select "New View" in the View list.
  - (b) Select a standard view from the Standard View list. Or you can customize the view name.
- 4. For each phase in the protocol:
  - (a) Select "new" in the Stage list.
  - (b)Enter a phase name.
  - (c) Select "Auto Select", the system jumps to Select Mode after retrospective acquisition.
  - (d) Select the required option from the Clip Capture drop-down list.
  - (e)Select the number of loops to acquire (per view in the selected phase) in the Loops list (for non-continuous stages).
  - (f) Select the type: exercise or drug.
- 5. Click [Save] to save changes and quit.

#### **Editing or Deleting a Stress Echo Protocol**

To delete a protocol:

Select the protocol or one of its component phases or views and then click [Delete].

- To Edit a Stress Echo Protocol:
- 1. Click an available protocol on the Select Protocol screen.
- 2. Click [Edit] to enter the Protocol Editor screen.
- 3. Edit the protocol as described in the create protocol.

## 5.14.6 Saving Stress Echo Data

Stress Echo data consists of Stress Echo loops, wall motion scores, and all other information pertaining to the Stress Echo portion of a patient examination.

When the exam is ended, the system will save all images within the exam.

## 5.14.7 Exiting the Stress Echo Feature

To exit the Stress Echo feature:

Press the <End Exam> key on the control panel or click [End SE exam] on the screen.

## 5.14.8 Measurement and Report

Suspend the stress echo exam by selecting [Suspend Exam] on the soft menu. Press the measurement related keys or buttons to enter cardiology measurement. For details, see the [Advanced Volume].

Reports contain the entered indication, if any, and also any entered comments that are specific to the report. You can include or exclude data from specific phase(s). You can preview and print the report for the currently selected mode. You can also enable colored report printing in Maintenance.

■ Entering Indications or Comments for the Reports

You can enter an indication for display in Stress Echo reports.

To enter an indication:

- 1. Press <Report> on the control panel to open the report.
- 2. Use the keyboard to enter text in the Indication dialog box and then click [OK].

# 5.15 Tissue Tracking Quantitative Analysis (QA)

Apart from the TDI imaging function, the system also provides a tissue tracking QA function for myocardial movement evaluation.

Using the tissue tracking QA function, the ultrasound system will scan each pixel position by frame within the cardiac cycle, then use the region matching method and auto-correlation searching method to trace each spot and calculate the movement, so as to determine myocardial motion in a more quantitative way.

CAUTION:

Tissue Tracking Quantitative Analysis images are provided for reference only, not for confirming diagnoses.

Tissue tracking feature is an option.

## 5.15.1 Basic Procedures for Tissue Tracking QA

- 1. Select a saved B mode cardiac cine file (a cin. format file which contains more than 1 cardiac cycle (with 2 R waves) and ECG signal).
- 2. Touch [TT QA] on the touch screen to activate the function:
  - a) You can determine the image of interest by previewing the image
  - b) To find the image of interest, roll the trackball or rotate the knob under [Cycle] on the touch screen to select.

Select the corresponding section name on the touch screen and press <Cursor> to show the cursor. Use the cursor to set the reference point (for details, see chapter "5.15.4 Myocardial Boundary Tracing"):

- Long axis section: use the "3-point" method or "Manual" method to set
- Short axis section: enter multiple points (at least 6 points) using the cursor manually to set.
- 3. After reference points are set, the system will display the boundary of the endocardium and epicardium. Adjust the thickness if necessary.

If the traced result is poor, touch [Reload] on the touch screen to re-trace the reference points, or make fine adjustments to the points using the cursor.

If the cycles are not adequate to provide the information, switch to another cycle to trace.

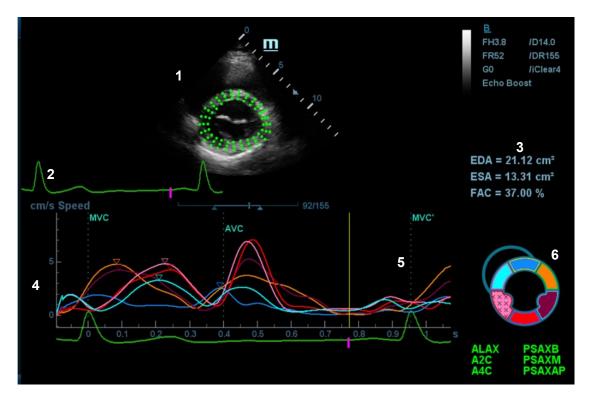
- 4. Touch [Start Tracking] on the touch screen to start the tracking function. Adjust the parameters if necessary.
  - Touch [Edit] on the touch screen to display the free cursor. Roll the trackball and press <Set> to reselect the trace reference points. Move the cursor to the exact boundary position and press <Set> again to set the right place.
- 5. Touch [Accept & Compute] on the touch screen to calculate and display the curve. Adjust the parameters if necessary.
- 6. Touch on the touch screen to turn to the other page. Touch [Bull's Eye] to see the result.
- 7. Press <Save> to save the result if necessary.
- 8. Repeat Steps 3-8 to track another section if necessary.

#### NOTE:

The screen displays the result of the current section, and Bull's Eye displays the average of all tracked sections.

- 9. Touch [Data Export] on the touch screen to export analyzed data.
- 10. Touch [Exit] on the touch screen.

## 5.15.2 Tissue Tracking QA Screen Description



- 1 Displays the image used to generate the trace curve
- 2 Displays the ECG trace
- 3 Displays the measurement and calculation results:

**EDV:** maximum value of the end diastolic volume during the trace.

**EDA:** maximum value of the end diastolic area (Left Ventricular) during the trace.

**ESV:** maximum value of the end systolic volume (Left Ventricular) during the trace.

**ESA:** maximum value of the end systolic area (Left Ventricular) during the trace.

**FAC:** Fractional Area Change = (EDA - ESA)/EDA.

This parameter is available in the short axis section.

**EF:** Ejection fraction.

This parameter is available in the long axis section.

**HR:** Heart rate.

**GS** Global strain.

**GS\_rate** Global strain rate.

The system also displays the TPSD value on the Bull's Eye graph:

Time to Peak Standard Deviation (TPSD):

$$TPSD = \sqrt{\frac{\displaystyle\sum_{1}^{N} \left(TP_{i} - \overline{TP}\right)^{2}}{N}}$$

Where the standardized value of time to peak data:  ${TP_i \mid i \in [1,N]}$  (N is the number of time to peak data) Average standardized value of time to peak data:  $\overline{TP}$ 

4 - Display curve: Velocity/Displacement/Strain/Strain Rate. Each curve on the image is matched with a certain segment in the cardiac segmentation model (6), identified by different colors.

Volocity ourse	The X-axis represents time (s);
Velocity curve	The Y-axis represents velocity (cm/s).
Displacement curve	The X-axis represents time (s);
	The Y-axis represents displacement (mm).
Strain curve	The X-axis represents time (s);
	The Y-axis represents deformation of the tissue (%).
Strain-rate curve	The X-axis represents time (s);
Strain-rate curve	The Y-axis represents strain by time (s <sup>-1</sup> ).

- 5 Displays the corresponding time of AVO (aortic valve open)/AVC (aortic valve close)/MVO (mitral valve open)/MVC (mitral valve close).
- 6 Displays the cardiac segmentation model. Each segment name is illustrated beneath the model.
- In the figure, 

  marks the peak position of the curve.
- Click on a segment in the cardiac segmentation model. The segment turns gray and its corresponding curve no longer displays.
- You can get the current X/Y-axis value by moving the cursor onto one point on the curve. If you press <Set> now, the frame marker will move to that spot.
- If the segment is filled with "XXX", it means that this segment is not well tracked.

## 5.15.3 Select Image and Cardiac Cycle

You can select images with a better image quality to get a better analysis result.

- Switch cine files
- 1. Press <Review> on the control panel to enter review status
- 2. Double-click the target file
- 3. The system closes the currently displayed file and switches to the newly selected file.

- Switch cardiac cycles within the cine file
- 1. After a cine file with more than one cycle is opened, the system displays a thumbnail of each cardiac cycle on the thumbnail area.
- 2. Press <Cursor> to acquire the cursor. Roll the trackball to position the cursor over the desired image.
- Double-click the file, the system will switch to the selected cycle.
   Or rotate the knob under the [Cycle] item on the touch screen to select directly.

## 5.15.4 Myocardial Boundary Tracing

- The system provides two kinds of tracing methods for two kinds of sections:
  - Long axis section (A4C, A2C, ALAX): the 3-point method and manual tracing method are both available.
    - > 3-point method

As shown in the following figure, after pressing <Set> to place 3 points clockwise on the image, the system generates the trace automatically.





#### Manual trace method

Press <Set> and roll the trackball along the boundary to add the trace points gradually. After the trace is finished, press <Set> twice to finish tracing.

At least 6 points should be determined by you before the system generates an automatic trace.

- Short axis section (PSAX B, PSAX M, PSAX AP): only manual tracing is available.
- Retracing

If the current trace is not satisfactory, touch [Reload] on the touch screen to clear the trace and start another tracing.

During the trace, press <Clear> to clear already-traced items.

Make fine adjustments to the trace

You can make fine adjustments to the trace:

- 1. In tracing curve adjusting status, the cursor becomes ...
- 2. Move the cursor to the editable point (inner dotted line of the curve) and press <Set>.
- 3. Roll the trackball to drag the curve to the desired position. Press <Set> again to set the point in the new position.
- 4. Repeat steps 2-3 to complete all points that need adjustment.

In tracking status, touch [Edit] on the touch screen to enter the status.

## **5.15.5 Tissue Tracking Operations**

#### Switch the operation controls

[Start Tracking]: touch to start tracking.

- [Accept & Compute]: touch to start calculation and display the curve.
- [Exit]: touch to exit tissue tracking.
- [Parameter]: rotate to select the curve type.
- [Bull's Eye]: touch to turn on/off bull's eye and the peak data table.

### **View Selection**

Before tracing, touch the corresponding button to select the view.

- [A4C]: apical four-chamber view.
- [A2C]: apical two-chamber view.
- [ALAX]: apical long axis view.
- [PSAX B]: short axis base view.
- [PSAX M]: short axis mid view.
- [PSAX AP]: short axis apex view.

#### **Parameter Adjustment**

- [Thickness]: adjusts the tracing thickness, i.e., the distance between the endocardium wall and the tracking points on the epicardium.
- [Tracking Points]: adjusts the number of points within the segment.
- [Cycle]: rotates clockwise to select the next cycle, and vice versa.
- [Smooth]: adjusts the smooth effect of the curve.
- [Display Effect]: turns on/off the arrow vector graphical display of the myocardial movement.
- [Velocity Scale]: adjust the scale length of the velocity.
- [Display Style]: display the endometrial, the epicardium, the myocardial or all.
- [Tracking Cycles]: Select the cycles to be tracked.
- [Average Cycles]: Obtain the average parameter curves of the tissue.
- [Cycle Select]: Select among different cycles.

#### Image display

According to the status of the current section, touch the appropriate button on the touch screen to check the corresponding time.

- [AVO]: displays the aortic valve open time.
- [AVC]: displays the aortic valve close time.
- [MVO]: displays the mitral valve open time.
- [MVC]: displays the mitral valve close time.

## 5.15.6 Bull's Eye

After tracking, the system displays a Bull's Eye graph for judging the reverse movement or scope of myocardium.

1. Touch [Bull's Eye] on the touch screen to turn the function on:

You can acquire:

- Time to peak value and peak value of the 17 segments;
- Display measurement result EDV/ESV/EF/TPSD.
- 2. Rotate the knob under [Parameter] on the touch screen to see a bull's eye graph for different parameters.



<sup>&</sup>quot;-" will display in the table to indicate those segments that are not well tracked.

## 5.15.7 Measurement/Comment

In tissue tracking QA mode, only the Time measurement is available. For details, see the Operator's Manual [Advanced Volume].

Comments and Body Mark operations are the same as in other modes.

## 5.15.8 Data Export

The system provides a data exporting function, so that you can export calculation results for analysis (for instance, SPSS analysis).

Touch [Data Export] on the touch screen to export analyzed data for each segment.

# 5.16 Fusion Imaging

### 5.16.1 Overview

Ultrasound Fusion Imaging completes the matching of multiply modalities and overlapping for ultrasound images and 3-dimensional data, such as pre-operative computed tomography (CT)/magnetic resonance imaging (MRI) 3-dimensional data, etc. With the benefits of high spatial resolution, wide field of view and free-interference of the air, it offers adequate diagnostic information to the doctor.

Spatial Positioning: Import CT/MR volume data to the Ultrasound System. CT/MR volume data will be set as a CT/MR 3-dimensional cubic image. After the doctor registers the ultrasound real-time image with a certain plane of CT/MR image, the Ultrasound System receives the probe position information

from "positioning (probe) sensor". The Ultrasound System shows the CT/MR image aligned with the ultrasound image in account of the magnetic spatial navigation function.

Lesion Viewing and Marking: to show the lesions marked on the ultrasonic planes, the ultrasound image and CT/MR image are displayed simultaneously via the spatial positioning device based on the old lesion marks on CT/MR image. The lesion marks on CT/MR image appear on the ultrasound image in real time. It helps the doctor spot the old lesion mark and perform the surgical plan to the tumor ablation.

Clinical applications: the lesions not-easily-detected in the ultrasonic exams; the panorama of the large lesion not-fully-displayed in therapeutic ultrasound; surgical operations to tumor ablation; biopsy and ablation to the liver neoplasms (enabled in the biopsy to renal tumor, lung neoplasms and prostate).

**Note** 

1. Fusion imaging is an optional function. Configure "Fusion (software optional)", "Fusion RESP (software optional)", "Fusion Imaging Kit (hardware optional)", Motion Sensor Support (hardware optional) first before conduct the Fusion Imaging exam. See also Chapter "2.5.3 Options" for details.

# **△ WARNING**

The Fusion Imaging is contraindicated to the person wearing the internal pacemaker, cochlear implant or nerve stimulator. People wearing the implant or intracorporeal devices should keep one-meter away when the magnetic generator starts working.

## 5.16.2 Magnetic Navigator

Note:

Place the set of the magnetic navigator away from the electromagnetic interference sources, such as power filter, signal indication, magnetically activated metal materials, cell phone in the use of the devices.

Connect the magnetic navigator when the magnetic navigation controller is OFF.

Exit Fusion imaging before reconnecting/disconnecting sensor from the magnetic navigation controller. Turn off the magnetic navigation controller before connecting/disconnecting connecting generator.

Plug the auxiliary output power supply cable, data cable, magnetic generator and sensor to the magnetic navigator respectively following the arrow's guide.



The description of the magnetic navigator is given in details. See the table below.

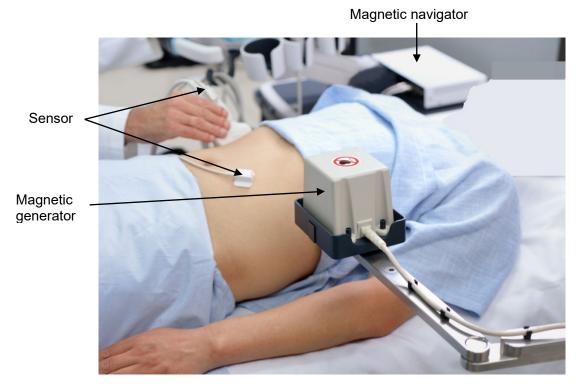
No.	Device Name	Port	Description
<1>	Auxiliary output power supply cable	Power supply port	Plug the auxiliary output power supply cable to the port of the magnetic navigator, and connect the power supply.  Note: please use the auxiliary output power supply cable equipped with the Ultrasound System.
<2>	<2> USB data cable USB port m		Plug one end of the USB data cable to the USB port of the magnetic navigator, and another end to the USB port of the Ultrasound System.

No.	Device Name	Port	Description
<3>	Magnetic generator	Transmitter port	Plug the magnetic generator to the Transmitter port. Place it around the patient's shoulder or two sides of the patient's abdomen. The magnetic generator should be frontal-faced with the lesion. The frontal face of the magnetic generator keeps 15-60 cm from the target within the scope 30 cm up/down.  Front  NOTE: keep the magnetic generator away from the metal devices or electromagnetic interference.
<4>~<9 >	Sensor (2), Positioning (probe) navigation support Motion (abdomen) sensor support	Positioning (probe) sensor port Motion (abdomen) sensor port	1. Plug two sensors to positioning (probe) sensor port    Positioning

No.	Device Name	Port	Description
			Fastened here
			3. Positioning (probe) sensor: fix the positioning (probe) sensor which is already plugged in positioning (probe) sensor port to the cavity of the positioning (probe) navigation support following guide.
			Positioning (probe) navigation support  Face downward  Positioning (probe) sensor
			Note: if failed to plug the positioning (probe) sensor following guide, it may lead to non-correlation of
			<ul><li>spatial positioning.</li><li>4. Positioning (probe) sensor sterile sheath: wear the probe sterile sheath after probe sensor and bracket are installed.</li></ul>
			<ul> <li>5. Motion (abdomen) sensor: fix the motion (abdomen) sensor which is already plugged in motion (abdomen) sensor port to the cavity of the motion (abdomen)</li> </ul>
			sensor support following guide.
			Face downward
			<ol> <li>Motion (abdomen) sensor sterile sheath: wear the sterile sheath after abdomen sensor and bracket are installed.</li> </ol>
			7. Motion (abdomen) sensor support: stick the sensor

No.	Device Name	Port	Description
			support against the top left of the patient's abdomen with the medical plasters (below left costal arch, right above the navel, the area where the skin moves apparently with the respiration).
<10>	Magnetic navigator	1	Place the magnetic navigator behind the Ultrasound System. Power on the navigator to enable the positioning function.

Magnetic devices positioning:

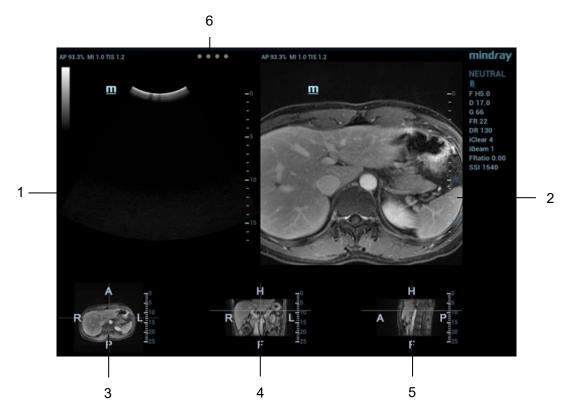


The navigation support equipped with the probe shows below:

Probe Type	Navigation Support
SP5-1E	NB-011
C5-1E/SC6-1E	NB-022
SC5-1E	NB-028
L14-5WE	NB-035

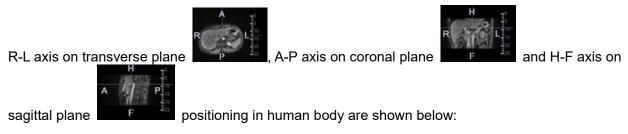
# 5.16.3 Screen Description

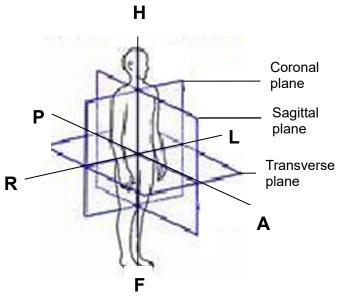
You should connect the magnetic devices, and then enter Fusion Imaging. The Fusion Imaging screen appears. See Chapter "5.16.2 Magnetic Navigator" for details.



3, 4 and 5 windows show the three anatomical planes of CT/MR 3-dimensional image (there are transverse plane, coronal plane and sagittal plane respectively). The position for each plane is shown below:

Each of them is:





Five windows descriptions are given below:

No.	Image	Description	
1	Ultrasound Display	When Fusion Ratio is among -1 to 0, the Ultrasound System registers CT/MR image to ultrasound image. The fusion display appears then. See also Chapter "5.16.9 Parameter Setting" for fusion parameter adjustment.	
2	Fusion Display	When Fusion Ratio is among 0 to 1, the Ultrasound System registers ultrasound image to CT/MR image. The fusion display appears then. See also Chapter "5.16.9 Parameter Setting" for fusion parameter adjustment.	
3	Transverse plane	R, L, A, and P imply the right, left, anterior and posterior of the patient.	
4	Coronal plane	R, L, H, and F imply the right, left, head and foot of the patient.	
5	Sagittal plane	H, F, A, and P imply the head, foot, anterior and posterior of the patient.	
	Indicator	Four indicators (1st indicator is on positioning (probe) sensor and 2nd indicator is on motion (abdomen) sensor. 3st indicator is on Needle Navigation Guiding sensor. 4 indicator are reserved functions.)	
		Check the indicator becomes green in use.	
		Different indicator color:	
		Blinks green: excellent.	
6		Blinks yellow: mediocre.	
		Blinks red: poor.	
		<ul> <li>Stays grey: no signal activated. (Magnetic navigation is not enabled.)</li> </ul>	
		Note: if the signal of the sensor becomes poor, check the connections of the magnetic devices. Reset the distance/orientation among the magnetic generator, sensors and the patient. Exclude the interference from the metal devices (ward beds made of metal materials) or the electromagnetic.	

### 5.16.4 Basic Procedures

- 1. Select a proper probe and correct exam. Enter real-time B/Color/Power/Contrast mode (non-cardiac Contrast Imaging mode).
- 2. Get magnetic devices prepared. Connect the magnetic devices (see also Chapter "5.16.2 Magnetic Navigator"). Power on the magnetic navigator.
- 3. Activating the magnetic positioning:
  - a) Press user-defined key to enter Fusion Imaging mode (see also Chapter "5.16.2 Magnetic Navigator" for key preset operations). Tap [Tracking System] on the touch screen. The magnetic navigation positioning is activated when the soft key becomes highlighted (it is usually activated by default).
  - b) Checking indicator
    - The Fusion Imaging works when the indicator becomes green.
    - See also Chapter "5.16.2 Magnetic Navigator" (table) for indicator descriptions.
- 4. Acquire/import CT/MR volume data. See also Chapter "5.16.5 Acquiring/Importing CT/MR Volume Data".

Note: the Ultrasound System sets CT/MR volume data to 3-dimensional image automatically after importing CT/MR volume data. One of anatomical planes (2-dimensional image) from CT/MR appears on the screen.

- 5. The brightness and the grey level of CT/MR image can be completed via Window Width and Window Level. Set Window W and Window L. See also Chapter "5.16.9 Parameter Setting".
- 6. Obtain an optimum plane as the registration plane from CT/MR image (registered with the ultrasound plane).

It is suggested that the plane concentrated with blood vessels, organs, tissue margins, lesions is optimum for registering.

Toggle <Steer> left to change CT/MR plane (transverse plane/coronal plane/sagittal plane). The pan (using the trackball), the shift or the rotation (along Z-axis) can be completed on CT/MR plane until an optimum plane for registering appears.

See also Chapter "5.16.10 Rotating/Scrolling CT/MR Image" for CT/MR image operations.

7. Obtain an ultrasound plane consistent with CT/MR plane (taking as the registration plane) from human body in ultrasonic scan.

Note: it is usually easier to obtain an optimum plane when the probe sweeps.

The registration is only approved when the image is frozen after pressing <Freeze>.

- 8. Data registering (first time registering):
  - a) Tap [Register] to activate the registration. Toggle <Steer> right.
  - b) To register the ultrasound image with the CT/MR image, perform the following procedures to set CT/MR image.
    - The icons for different plane operations appear after pressing <Set> for multiply times.

**Note:** After tapping [Register] each time, toggle [Steer] right to activate the steer. It is convenient for panning or scrolling CT/MR image.

lcon	Operation
Scroll Set Begin Set End Pan	Move the trackball to pan CT/MR image.
Cine Set End Set End	Move the trackball to scroll CT/MR image. See also Chapter "5.16.10 Rotating/Scrolling CT/MR Image" for scrolling operations.
Pan Cine Set Begin	Move the trackball to view the ultrasound cine.

- Toggle <Steer> left to change the active plane of CT/MR image (sagittal plane, transverse plane, coronal plane). Varied planes can be panned, scrolled or rotated through the axis.
- Rotate CT/MR image axially. See also Chapter "5.16.10 Rotating/Scrolling CT/MR Image" for operations.
- Rotate [Fusion Ratio] to adjust the display ratio that the ultrasound image registers with the CT/MR image. The ultrasound image and CT/MR image are displayed well. See also Chapter "5.16.9 Parameter Setting" for operations.

- Rotate <Zoom> on the control panel to zoom in or zoom out CT/MR image;
- Rotate the knobs beneath [Offset X] and [Offset Y]. Pan the CT/MR image. See also Chapter "5.16.9 Parameter Setting" for operations.
- c) Tap [Confirm Registration] to complete registering. The ultrasound image and CT/MR image appear synchronously after the registration accomplishment.

Note:

Do not move the magnetic generator and the patient for any circumstances after the registration accomplished. Otherwise, the registration display for CT/MR image and the ultrasound image is affected.

9. Checking registration effect:

After completing 8<sup>th</sup> step (first registration), move the probe and adjust the probe scan angle and position. View the synchronous effect of varied planes (coronal plane, sagittal plane, transverse plane) from the ultrasound image and CT/MR image.

Synchronous display effect: The Ultrasound System represents the ultrasound image and CT/MR image synchronously after the ultrasound image and CT/MR image are registered first time with the magnetic spatial positioning and in the aid of positioning (probe) sensor receiving the spatial message from the probe.

10. Fine tuning (second time registering):

If the ultrasound image and VT/MR image are not registered precisely after first-time registering, perform the fine tuning operations below:

- a) Tap [Fine Tuning] on the touch screen. Press <Freeze> to freeze the image.
- Unfreeze the ultrasound image (tapping [Freeze US] to dim the soft key);
   For CT/MR image is frozen, whereas the ultrasound image is not, take CT/MR image as the comparison reference (keeping CT/MR image still); tune the probe scan orientation and position to obtain the ultrasonic plane which is identical with that on the CT/MR image (the ultrasonic plane moved).
- Or, unfreeze the CT/MR image (tapping [Freeze MPR] to dim the soft key);
   For the ultrasound image is frozen, whereas the CT/MR image is not, take the ultrasound image as the comparison reference (keeping ultrasonic plane still); tune the probe scan orientation and position to obtain the CT/MR plane which is identical with that on the ultrasound image (the CT/MR plane moved).
- b) Tap [Freeze US] and [Freeze MPR] to highlight the soft keys, tap [Confirm Registration] to complete the fine tuning.

Note:

- Use the plane concentrated with the patient's lesions to perform the fine tuning.
- The adjusting levels of the CT/MR plane and the ultrasound plane become finer after entering the fine-tuning. The ultrasound image and CT/MR image can precisely be registered after several times of fine tuning.
- Freeze the ultrasound image and CT/MR image simultaneously after the fine tuning. Tap [Register]→[Confirm Registration] to make the fine tuning worked.
- 11. Respiration compensation (it is suggested that the respiration compensation should be operated according to your demands).

The respiration compensation can possibly enhance the fusion accuracy of the ultrasound image and CT/MR image, and reduce the aspiration motion effects to the image. See also Chapter "5.16.7 Respiratory Compensation".

- 12. Conduct the ultrasonic exam and operation after the registration is completed.
- 13. Freeze the ultrasound image to save the single frame image or multi-frame cine.

### Marks (setting the mark based on your need)

Mark the lesion position on CT/MR image. See also Chapter "5.16.6 Marks".

Note: mark the tumor on CT/MR image after CT/MR data is imported. Generally, it is available to mark the tumor before/during/after the registration.

### Ultrasound Contrast Fusion (conducting the Contrast Fusion based on your need)

Inject the contrast gel after the registration is completed. Enter Ultrasound Contrast Fusion imaging mode. See also Chapter "5.16.8 Contrast Fusion Imaging".

### Data registration of same patient/body part in different phases

When different phases of CT/MR data from the same patient/body part exist and one CT/MR data has been registered already, system will register the data by previous information if other phases data are imported.

### 5.16.5 Acquiring/Importing CT/MR Volume Data

#### Note

- Only support DICOM CT/MR volume data.
- The following CT/MR volume data not accepted:

Slices less than 4;

Discontinuous or corrupted data;

Slice space not equal or larger than 5 mm;

Data from varied alignment (tissue, plane);

- The liver enveloped in CT/MR volume data.
- The registration effect will be better if the CT/MR volume data already bears the data of Contrast Imaging with the ultrasound image.

### **Acquiring CT/MR Volume Data**

Two methods to obtain CT/MR volume data:

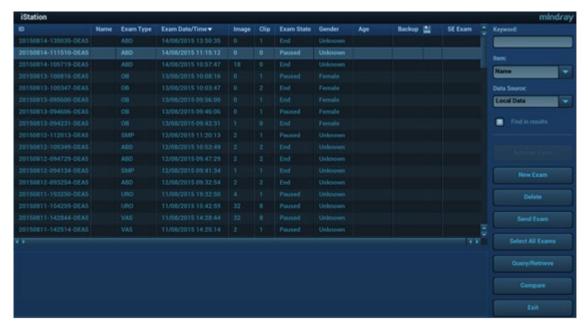
Method 1: acquiring CT/MR volume data from network server.

### Note:

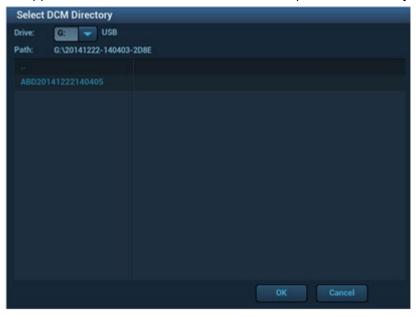
- It is only applied to the Ultrasound System that is configured with DICOM software package (see also Chapter "2.5.3 Options" for DICOM options).
- The storage path should be short and clear for network server obtaining. Space or Chinese character is not allowed.
- 1. Configure DICOM service. See also Chapter "11.1.2 DICOM Local Preset".
- 2. Configure Query/Retrieve service. See also Chapter "11.1.3.6 Query/Retrieve Preset".
- 3. Load CT/MR volume data to iStation. See also Chapter "11.1.3.6 Query/Retrieve Preset".

### Method 2: acquiring CT/MR volume data from external storage medium.

- 1. Save CT/MR volume to USB disk, portable hard disk, optical disk, etc.
- Press <F2 iSation> to enter the iStation page. Select from the drop-down list of the data source, such as USB.



Select the CT/MR volume data disk from the drive drop-list (or portable hard disk, optical disk).
 Click [OK]. The icon appears after the CT/MR volume data is acquired successfully.



### Note:

- a) The icon at the right lower corner of the screen shows the progress of the task. Click the icon to see the progress.
- b) The icon appears after all tasks are completed, which implies that the patient data are loaded to the ultrasound system successfully.

**Note:** The dialog box does not appear for:

- If any file (Ultrasound patient data) is named with "DC80" in the external storage medium. Please rename the file, and conduct step 2. The dialog box given above appears then.
- If DICOMDIR CT/MR volume data or backup file of the Ultrasound patient data is in the root directory of USB disk (portable hard disk, optical disk), the Ultrasound System does not pop up the path. However, CT/MR volume data or patient data is loaded to **iStation** data base.

4. Press <Esc> to return to **iStation** page. Press <**F2 iStation**> again to enter the **iStation** page. You can see the CT/MR volume data which is loaded successfully.

### Importing CT/MR Volume Data

Acquire CT/MR volume data to **iStation**. Then, import the data to Fusion exam with the procedures below.

 Press user-defined Fusion key (see also Chapter "12.1.6 Key Configuration") to enter Fusion Imaging mode. Tap [CT/MR Database]. The page appears as shown below. Select the CT/MR volume data, and click [OK].



 Check "US-Patient Information" and "CT/MR Patient Information". The information should be from same one patient (the name, the gender and DOB also should be from same one patient). Click [Accept] to load CT/MR volume data.



CT/MR volume data is loaded to Fusion Imaging exam. The page is given below:

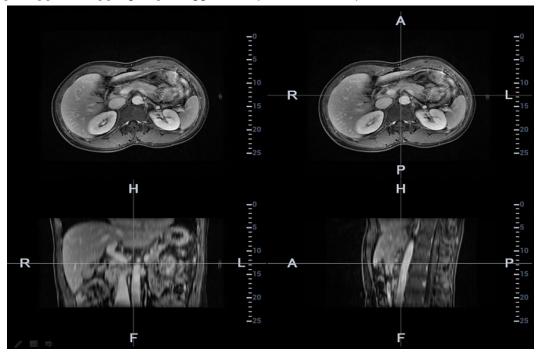


### 5.16.6 Marks

Mark tumor position, lesion position on CT/MR image. Be sure of the lesion appearing on US and CT/MR image at the same time after the registration is completed.

**Note:** Mark the tumor or lesion on CT/MR image after CT/MR data is imported. Generally, it is available to mark the tumor or lesion before/during/after the registration.

1. Tap [Mark on CT/MR] to enter the page. Select [Add Marks]→[Display Marks] to activate the mark. Tap [Axial]/[Coronal]/[Sagittal] to toggle the top-left reference plane.



2. Press <Cursor> to show the cursor. Mark on the axial plane (top-right)/coronal plane (bottom-left)/sagittal plane (bottom-right). The procedures to make marks are given below:

Select "Ball" or "Slice Trace" in the "Marker Type" drop-down list.

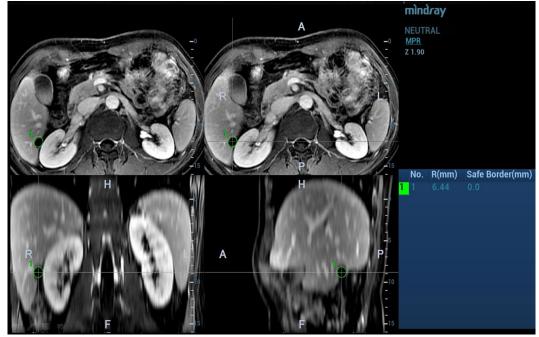
Ball: Press <Set> to locate the center at the core of the lesion. Roll the trackball to adjust the radius. Envelop the tumor or the lesion with the circle. Double press <Set> to complete adding the mark.

Manual tracing: roll the trackball to manually envelop the lesion. Rotate the multifunctional

knob to scroll the CT/MR image and continue to mark the lesions. After lesions of all the desired CT/MR planes are marked, tap [Accept Slice Trace] to add marks. Tips: At least two CT/MR planes should be marked when performing manual tracing.

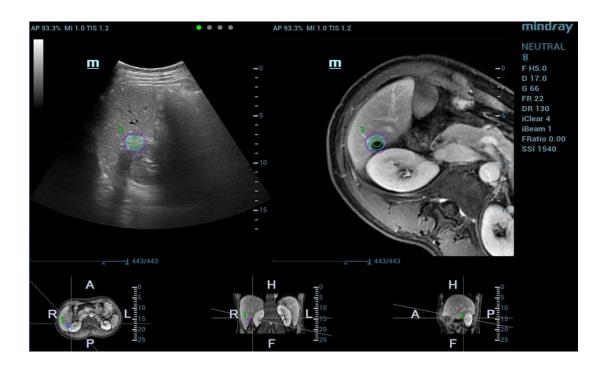
**Note:** The Ultrasound System adds 3-dimensional sphere mark to CT/MR volume data. Set the target mark based on your sphere center and sphere radius.

- Rotate [Ablative Margin] to add the ablative margin for this mark. See also "Ablative Margin" description below.
- Mark the tumor (a maximum of 20 tumors can be marked). The color of the mark can be green, blue, or red in turn. These colors appear in circle. The sphere diameter and ablative margin appear in the result pane.



3. Click [Esc] to exit. Enter Fusion Imaging page. Move the probe to view the mark situation in varied planes.

The mark in the following figure is enveloped with three circles. There are real-time tumor, mark tumor (completed in step 3), and ablative margin from inside to outside.



**Note:** It is not allowed to conduct other operations, such as, freezing, measuring, adding body mark, at the exception of adding the mark on the plane.

### ■ Saving/Loading the Mark

1. Saving the mark.

Enter tumor mark page. Mark varied tumors on CT/MR image. Tap [Save Marks] to type the mark name. Click [OK].

Save the tumor mark of the patient. It is convenient to load the tumor mark when conducting the tumor ablation for the patient.



**Note:** "Mark Group Name" is not permitted to have same name in all exams (including the exam ended) of one patient.

### 2. Loading the mark.

Tap [Load Marks]. All mark groups of previous exams of this patient are displayed. See the figure below. Select the mark group. Click [Import]. The marks are loaded to the CT/MR plane (in general, the marks saved in one week are loaded).



### Ablative Margin

**Description** The tumor infiltrates the neighboring organs, which leads to the tumor boundary unclear.

The ablation scope is larger than practical tumor boundary's. The enlargement scope is

called ablative margin.

The ablative margin is about setting a safe boundary on the lesion which is already marked. It also implies another boundary mark outside the lesion mark on image.

The ablative margin reminds of the narrowest boundary for surgical ablation. It takes significant effect on ablating the tumor.

**Operation** Rotate [Ablative Margin] to adjust the value. The increment is 1. The adjusting range is

0~10 mm.

### ■ Moving the mark

Select one tumor mark from the result pane (the cross appearing in the circle). Move the cursor inside the circle. The cursor becomes arrow-shaped. Press <Set> to select the mark. Move the mark to the desired position. Press <Set> to relocate the mark.

### Removing the mark

Select one mark from the result pane (the cross appearing in the circle). Tap [Delete Cur.] to remove the tumor mark.

Tap [Delete All] to remove all tumor marks.

Note: the button <Clear> is disabled when tumor mark is activated.

### Displaying/Hiding the mark

Tap [Display Marks] to activate it. All tumor marks appear on CT/MR image.

Tap [Display Marks] to dim it. All tumor marks hide on CT/MR image.

### Adding the comment

It is available to add the comment before adding tumor mark or after tumor mark is added. See also Chapter "9 Comments and Body Marks".

# 5.16.7 Respiratory Compensation

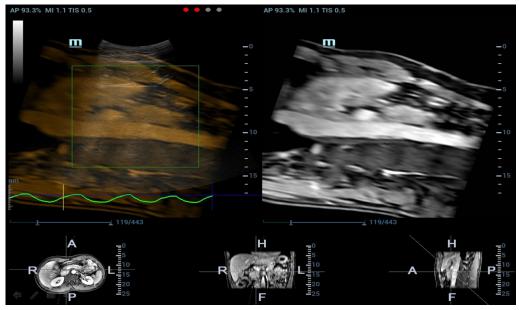
### Note

- Fusion RESP Component (Fusion Respiration Component) is an option.
- Configure Fusion RESP Component (optional software), one fusion imaging sensor, one
  motion sensor support (optional hardware) before enabling Fusion RESP Component.
  See also Chapter "2.5.3 Options". Stick respiration sensor to the patient's abdomen before
  entering Fusion Imaging mode.

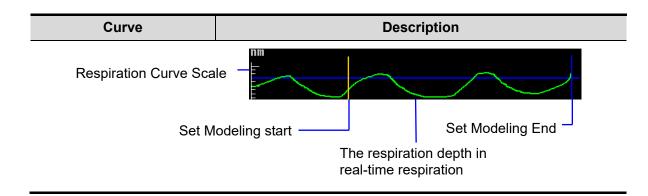
Respiration Compensation sets a motion model for the movement regularities of the liver, and compensates the CT image in real time. The fusion dynamic accuracy is enhanced apparently.

- Enter Fusion Imaging mode. Tap [Display Resp Curve] to activate it (it becoming highlighted by default).
   The respiratory curve appears on the image.
- 2. Keep the patient breathing regularly. Tap [Capture US&Resp] to capture the cine until the respiration curve becomes stable. Keep the probe still when capturing the cine. The progress bar appears on the screen. The ultrasound cine plays automatically after the capturing is finished.

Note: the Ultrasound System selects one premium phase of respiration curve automatically after the capturing is finished. It is prepared for the motion modeling. You can set the start frame and end frame to select one phase of the respiration curve.



Respiration Curve Description:

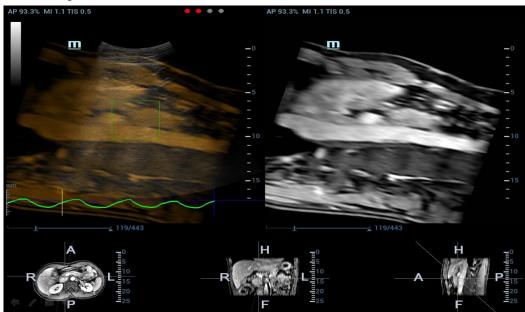


Curve	Description
nm E	Respiration Curve Scale (respiration depth).
	Set Modeling start (start point of motion modeling of the respiration curve).
	Set Modeling End (end point of motion modeling of the respiration curve).
	The blue curve is the respiration depth at last registration.
	The green curve is the respiration depth in real-time respiration.

Tap [Set Modeling ROI] to highlight it (it is activated by default). Move the trackball to set ROI position and size.

Set ROI position and size. Envelope the liver with the ROI.

Press <Set> again to adjust ROI position and size, and to set the start frame and end frame of the motion modeling.

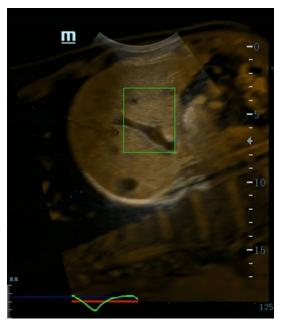


4. Tap [Motion Modeling]. If modelling succeeds, the system will play the cineloop automatically, and ROI moves along with the motion of the respiration curve.

Note: RMQF scale is 0~1. 0 represents the poor motion modeling; 1 represents the premium motion modeling.

Conduct step 4~5 repeatedly based on your demands. Set motion modeling repeatedly until a premium one appears.

5. Tap [Motion Compen] to activate it. Move the probe. The Ultrasound System shows the CT image which is processed by respiration compensation (Fusion Imaging with the respiration compensation).



6. Save multi-frame cine.

### **Respiration Range**

**Description** The aspiration curve appears due to the active respiration depth. The respiration curve

beyond the scale becomes the straight line.

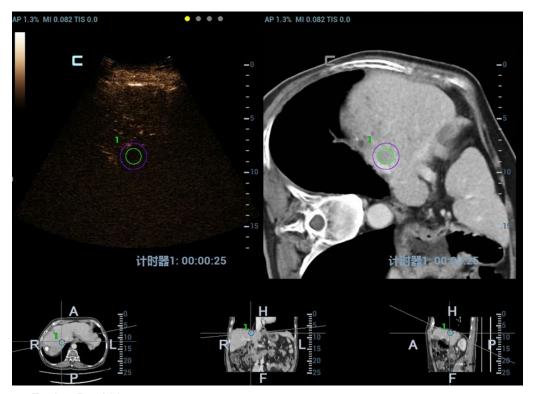
**Operation** Rotate the knob beneath [Resp Range].

Respiration curve scale and the unit appear on the right-axis.

# 5.16.8 Contrast Fusion Imaging

Contrast Fusion Imaging increases the possibility of diagnosing the difficult lesions in the pre-operation; improves the accuracy to ablating the lesion in the intra-operation; estimates the therapeutic effect of the target in the post-operation.

Tap [Contrast] to enter Contrast Fusion Imaging after the Fusion Imaging is registered.
 Set fusion ratio. Adjust the display ratio of two split windows that the contrast image registers with CT/MR image. (See also Chapter 5.16.9 Parameter Setting).



### 2. Contrast Fusion Dual Live:

Select [Contrast]→[Dual Live] to adjust the fusion ratio. Adjust the display ratio that tissue image registers with CT/MR image (see Window 1 and window 2). Adjust the display ratio that contrast image registers with CT/MR image (see window 3 and window 4).



Inject the contrast agent. Enable the timer, and save the dynamic image. See also Chapter "5.11 Contrast Imaging".

# 5.16.9 Parameter Setting

The parameters of the Fusion Imaging are described below:

### Nav System

### Operation

Tap [Tracking System] to enable or disable the function.

CT/MR image and the ultrasound image build up the coordinate relation. The sensor indicator becomes green (navigation signal state indicator).

### **Fusion Ratio**

### **Description**

Adjust the display ratio that the ultrasound image registers with the CT/MR image.

### Operation

Rotate the knob beneath [Fusion Ratio] to set the ratio.

The adjusting range is  $-1 \sim 1$  in increments of 0.1.

• 0~1 represents that the ultrasound image registers with the CT/MR image; the change of the fusion ratio appears on the right window side.

The larger the value is, the better the display effect becomes for the ultrasound image registering with the CT/MR image; and vice versa. 0 only relates to CT/MR image on the right window side and 1 only relates to ultrasound image on the right window side.

• -1~0 represents that the CT/MR image registers with the ultrasound image; the change of the fusion ratio appears on the left window side.

The larger the value is, the poorer the display effect becomes for the CT/MR image registering with the ultrasound image; vice versa. -1 only relates to CT/MR image on the left window side and 0 only relates to ultrasound image on the left window side.

### **Image Magnification**

### **Description**

The lesion or tumor ultrasound and CT/MR image becomes clearer and easier to register via <Zoom> key.

### Operation

Rotate <Zoom> to zoom in or zoom out the image.

The parameter "Z" on the right side of the image refers to the magnification value. The adjusting scale is: 0.8-10.

### **Toggling CT/MR Anatomical Plane**

### Description

The Ultrasound System sets CT/MR volume data to 3-dimensional image automatically after importing Ct/MR volume data. There are transverse plane, coronal plane, sagittal plane displaying from left to right at the bottom of the screen.

It is available to toggle and register among three planes.

### Operation

Toggle [Steer] left. Toggle the CT/MR anatomical planes (among the sagittal plane, transverse plane, coronal plane).

### **Cycling CT/MR Image Axially**

Description

Rotate X/Y/Z to rotate CT/MR 3D image. Obtain the desired CT/MR plane to register.

Operation

Rotate <M>, <PW>, or <C> knob to cycle CT/MR image through X-axis, Y-axis or z-axis in increment of  $2^{\circ}$ . The rotation range is  $0^{\circ} \sim 360^{\circ}$  in increment of  $2^{\circ}$ .

See also Chapter 5.16.10 Rotating/Scrolling CT/MR Image.

### Offset X/Offset Y CT/MR Image

**Description** It is available to offset CT/MR image through X-axis and Y-axis and obtain a proper

position to register.

**Operation** Rotate [Offset X]/[Offset Y] to offset the CT/MR image.

### Scrolling CT/MR Image

**Description** It is available to scroll one certain plane (sagittal/transverse/coronal) of CT/MR 3D

image on the Ultrasound System and obtain a desired CT/MR plane to register.

Operation

Rotate the multifunctional knob to scroll CT/MR plane.

See also Chapter 5.16.10 Rotating/Scrolling CT/MR Image for scrolling operations.

### Window Width (Window W)/Window Level (Window L)

**Description** It is available to set CT/MR image contrast via the window width.

It is available to set CT/MR image grey scale via the window level.

Window Width Rotate [Window W] to set the value in increment of 1.

**Effect** The larger the window width is, the poorer the image contrast becomes.

The smaller the window width is, the better the image contrast becomes.

Window Level Rotate [Window L] to set the value in increment of 1.

Effect The darker image on CT/MR image may be missed if the window level becomes larger.

The image with brighter grey scale may appear then.

The darker scale on CT/MR image may appear on the screen if the window level

becomes smaller.

Window W/Window

Tap [Fast Adjust Window W/L]. Move the trackball to set the window width and window

level

Move the trackball left; the window width becomes smaller, and the window level

becomes larger; the image contrast becomes more visible.

Move the trackball right; the window width becomes larger, and the window level

becomes smaller; the image contrast becomes poorer.

### Reset Width (Reset W)/Reset Level (Reset L)

**Description** It initializes the window width and window level of the CT/MR image.

**Operation** Tap [Reset W/L] to initialize the width/level of the CT/MR image.

### Reset CT/MR

**Description** It initializes CT/MR image when CT/MR image is cycled axially, panned, scrolled or

zoomed, etc, after CT/MR volume data is imported to Ultrasound System.

**Operation** Tap [Reset CT/MR] to initialize the CT/MR image.

**Tint Map** 

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

distinction for CT image.

**Operations** Rotate the knob under the [Tint Map] item on the touch screen to select the map. The

system provides 8 different color effect maps.

Press the knob under the [Tint Map] item on the touch screen to turn on/off the

function.

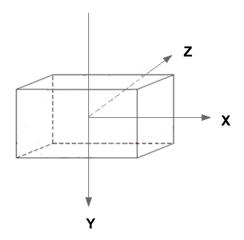
### 5.16.10 Rotating/Scrolling CT/MR Image

The Ultrasound System sets the Ct/MR volume data to 3-dimensional image after the CT/MR image is imported to iStation. Each of any CT/MR anatomical planes (2-dimensional) appears on the screen via rotating or scrolling the CT/MR image.

### **Rotating CT/MR Cubic Image**

Rotate the knob <M>, the knob <PW>, the knob <C> to cycle the CT/MR cubic image through X-axis, Y-axis and Z-axis. The 2-dimensional CT/MR anatomical plane cycles simultaneously.

The relations of X-axis, Y-axis and Z-axis are given below:



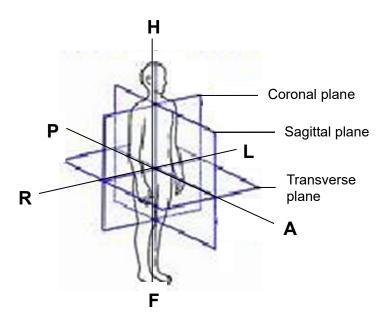
Rotate the knob <M> clockwise to cycle CT/MR image clockwise through X-axis; Rotate the knob <PW> clockwise to cycle CT/MR image clockwise through Y-axis;

Rotate the knob <C> clockwise to cycle CT/MR image clockwise through Z-axis;

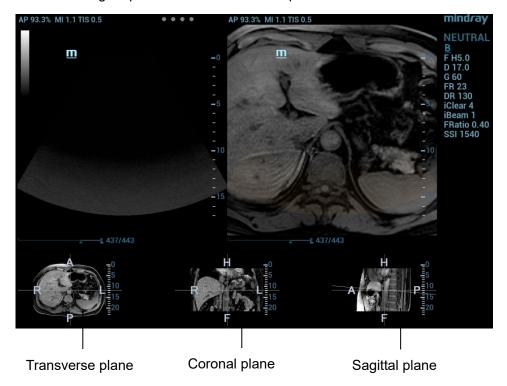
### Scrolling CT/MR Image

The description of "scrolling the transverse plane" is given below:

Rotate the multi-functional knob clockwise. The transverse plane moves towards the patient's head. The R~L axis and A~P axis on the transverse plane move towards the patient's head.



R~L axis, A~P axis correspond with the axe of coronal plane and sagittal plane. R~L axis of coronal plane and A~P axis of sagittal plane move towards the cephalosome.



# **5.16.11 Measuring**

It is available to conduct the general measurements on the image that the ultrasound image registers with the CT/MR image. See also Chapter "8.2 General Measurements".

Note: it is unavailable to conduct the application measurement on Fusion Imaging mode.

# 5.16.12 Comment and Body Mark

It is available to conduct the comment and the body mark on the image that the ultrasound image registers with the CT/MR image. See also Chapter "9 Comments and Body Marks".

# 5.17 RIMT (Real-time Intima-Media Thickness)

RIMT early detects and prevents coronary heart disease, artery vessel from being pathological, and estimates the therapeutic effects. RIMT detects the changes of the vascular intima in real time, and monitors and calculates the thickness of the carotid intima automatically.

Note RIMT is an option.

It is merely available to enter RIMT imaging mode in B single window and dual window when adopting linear probe for carotid exam.

Do not press the probe after entering RIMT imaging mode when scanning the image in real time.

- 1. Select the probe first. Perform B mode in carotid exam mode. Detect the patient's carotid in B mode. Keep the acoustic beam vertical with the anterior and the posterior of the vascular and make the anterior and the posterior of the intima visible at the carotid stenosis to obtain a premium image.
- 2. Tap [RIMT] to activate the function. Rotate [Side] to select left or right carotid.
- 3. Roll the trackball to locate ROI over the target area. The dotted line of the ROI is in the middle of the blood vessel. Press <Set> to confirm the position and size of the ROI.

**Note** RIMT inside ROI is highlighted in red, yellow and green. There is no gap between the filling area and the vascular wall.

The green color indicates the normal acceptable value.

The red color or yellow color indicates the abnormal unacceptable value.



- 4. Tap [Start Calc] to measure RIMT of left carotid and right carotid. Six RIMT values (each RIMT value represents maximum IMT value within one cardiac cycle), RIMT average value (arithmetic mean value of the 6 RIMT values), SD (standard deviation of the 6 RIMT values) and ROI width are displayed in the result window.
- 5. Tap [Accept Result] or press <Set>. The image is frozen. You may save single frame image and results of the result window.
  - Tap [Cancel Result] to recalculate RIMT. Repeat steps 4~5 to reset the RIMT.
- 6. Press <Report> to view the report. Only last acceptable data, including RIMT on left and right carotid, is in the data sheet. You can perform:
  - Deleting data: select RIMT data from the data sheet. Tap [Delete Rows] to remove the RIMT data of the left and the right carotid.
  - Viewing graphic: tap [IMT Trend] to view the RIMT graphic. The data on the graphic is same
    with these in data list. The RIMT average value, SD and ROI length of the exams are
    displayed at the bottom of the graphic (including the current exam).
  - Previewing the report: tap [Print Preview] to show IMT. The RIMT average value, SD and ROI length of the exams are displayed.

See Advanced Volume for setting, printing, saving or loading the report.

7. Tap again [RIMT] to exit.

### 5.18 Smart Pelvic Floor

### **Description**

- 1. Smart Pelvic Floor is an option.
- 2. This feature is available only under GYN or pelvic floor exam mode.
- Two Dimensional Image
- Perform scanning under GYN or pelvic floor exam mode. Press <Freeze> and tap [Smart Pelvic] tab.
- 2. Roll the trackball to select the target frame in the frozen cine file and tap [Rest] to set rest frame.
- 3. Tap [Measure] and press <Set> to anchor measurement calipers of location S/P/U/E/R/V by the indications on the screen. The system then calculates corresponding parameters.
  - S- Symphysis Pubis bottom, P- Central axis of Symphysis pubis, U- Uretha-Bladder joint, E- Uretha proximal, R- Bladder posterior wall near uretha, V- Bladder posterior wall bottom, SP- Pubic symphysis.
  - Following results are obtained: BSD (Bladder Neck Symphyseal Distance), PVA (Pubovesical Angle), PUA (Pubourethral Angle), RVA (Retrovesical Angle), BND(Bladder Neck Descent), UTA (Urethral Tilt Angle), URA (Urethral Rotation Angle).
- 4. Set Valsalva frame as described in step 2-3 and finish measurements.
- 5. Tap [Jump to Rest] / [Jump to Valsalva] to review the corresponding measurement results.

Tap [Rest] / [Valsalva] again to delete marks of rest frame and Valsalva and corresponding measurement results.

Tap [Meas Parameters] to select measurement tool and perform step 3 to measure. Result window displays only selected measurement results.

Tap [Ref Coord C1] / [Ref Coord C2] / [Ref Coord C3] for different measurement methods when necessary.

Tap [Edit] to edit the calipers, and corresponding measurement results changes.

Tap [Hide], and tick measurement tools to be displayed, and the result window will hide results of unchecked measurement tools.

Add comments and body marks if necessary. For details, refer to chapter "9 Comments and Body Marks".

- 6. Save the cine file. See "6.6 Cine Saving" for details.
- 3D/4D image data
- 1. Select probe and GYN/ pelvic floor exam mode.
- 2. Acquire 4D image and then press <Freeze> to tap [Smart Pelvic] tab. Or, acquire static 3D image, and then tap [Smart Pelvic] tab.
- 3. Tap [VR] to perform measurement on VR image.
- 4. Tap [Input] and enter U and Bottom in the VR image. The system starts calculation. U refers to urethral center and Bottom is anterior margin of puborectalis muscle. Different values in Rest/Maximum Valsalva/Contraction status are calculated: Levator Hiatus anteroposterior/lateral Diameter, Levator Hiatus circumference/area, Levator Urethra Gap.
- 5. Tap [Edit], U and Bottom points are distributed on VR image automatically. Roll the trackball to drag the points or modify measurements. Tap [Edit] again to exit.
- 6. Tap [Smooth] to smooth the boundary of levator ani muscle.
- 7. Tap [Rest]/[Valsalva]/[Contraction] to mark current image status.

Tap [Hide] to hide measurement results if necessary. Tap [Undo] to undo last operation. Tap [Undo All] to undo all operations. Press <Clear> to delete measurement results.

For other parameter adjustments, refer to chapter "5.10 3D/4D" for details.

# **Display & Cine Review**

#### **Splitting Display** 6.1

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

Dual-split: press the



key on the control panel to enter dual-split mode.

Under Dual-split mode, press <Freeze> to freeze the image and then use between the two images.



Press <B> on the control panel to exit.

Modes support dual-split display: B mode, Color mode, Power mode, PW mode, CW mode, M mode and Color M mode.

Quad-split: press the



key on the control panel to enter the quad-split mode.



to switch

Under Quad-split mode, press <Freeze> to freeze the image and then use between the four images.

Press <B> on the control panel to exit.

Modes support quad-split display: B mode, Color mode and Power mode.

For the detailed display format, see the imaging mode chapters.

### 6.2 **Image Magnification**

NOTE:

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

#### 6.2.1 Spot zoom



To use the function, use the **Zoom** knob on the control panel.

- 1. Press <Zoom> to enter the sample volume definition status.
- 2. Roll the trackball to change the box size and position. Press <Set> to toggle between setting the size and position, or rotate the <Zoom> knob to adjust the size. After the sample volume is set, press the <Zoom> key again to enter spot zoom status.
- 3. Rotate the <Zoom> knob or to change the magnification factor. Or enter the touch screen mapping mode, and zoom the image by pinching two fingers on the touch screen. The image magnification factor value will display in real time in the image parameter area. For example, **Z1.3** indicates that the magnification factor is 1.3.
- 4. Press <Zoom> again to exit spot zoom.

Tip: The size and position of the sample volume box change along with the scanning depth and area.

#### 6.2.2 Pan zoom



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

- 1. Rotate the <Zoom> knob to directly enter the pan zoom status. Or enter the touch screen mapping mode, and zoom the image by pinching the two fingers on the touch screen. Image-inimage is displayed.
- 2. Magnification factor adjustment: rotate the [Zoom] knob or pinch two fingers under mapping mode to change the magnification factor. The image magnification factor value will display in real time in the image parameter area. For example, 21.3 indicates that the magnification factor is 1.3.
- 3. Shifting the image: roll the trackball or touch and translate the image.
- 4. Press <Zoom> to exit pan zoom.

#### iZoom (Full Screen View) 6.2.3

Function: to magnify the image in full screen.

Procedures:

- 1. Press Zoom on the control panel to zoom in on the image. The zoom area includes the image area, parameter area, image banner, thumbnail area and so on.
- 2. Press the key again to zoom in on the image area only.
- 3. Press the key again to exit iZoom.

F8

#### 6.3 Freeze/Unfreeze the Image.

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

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

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

#### **Imaging Mode Switching When Frozen** 6.3.1

Imaging mode switching in freeze mode follows these principles:

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

### 6.3.2 Imaging Display Format Switching When Frozen

Image display format switching in freeze mode follows these principles:

- 2D+PW (press <Freeze> in 2D+PW imaging mode)
  - If the imaging mode before freezing is 2D (frozen) + PW (real time) or 2D (real time) + PW (frozen), then in freeze mode, you can switch between 2D (frozen) + PW (activated) or 2D (activated) + PW (frozen) by pressing the <Update> key on the control panel.
- Dual/quad splitting display mode (press the <Freeze> key in dual/quad splitting display mode)
  - When entering freeze mode, the default activated window is the real-time window before
    freezing. Other image windows display the corresponding cine memories. If a certain cine
    memory is empty, then no image is displayed.
  - Press <Dual>/<Quad> to switch between dual-splitting and guad-splitting modes.
  - Press <Single> on the control panel to enter the single display format, which displays the currently activated window. In single display format, press <Dual>/<Quad> to return to splitting display mode.
  - Unfrozen: in splitting display status, when you unfreeze the image you can only unfreeze the image in the activated window, other images remain frozen. In single-window display status, the system displays the single image after being unfrozen.

# 6.4 Cine Review

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

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

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



Cine Review images can be inadvertently combined in-between separate patient scans. The Cine Review memory must be cleared at the end of the current patient exam and before starting the next new patient exam by pressing the <End Exam> key on the control panel.

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

# 6.4.1 Entering/Exiting Cine Review

- To enter Cine Review:
  - Enter "[Setup] → [System] → [Image] → "Freeze Config." to set "Status after Freeze" to
    "Cine." The system enters manual cine review status once <Freeze> is pressed to freeze
    the image.
  - Open cine files in thumbnail, iStation or Review, the system enters automatic cine review status.
  - Under touch screen mapping mode, touch leftwards/rightwards to review the cine file.

    / or swipe the screen
- To exit Cine Review:

Press <Freeze> or <B> and the system will return to image scanning and exit cine review.

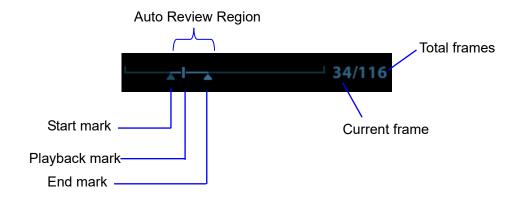
# 6.4.2 Cine Review in 2D Mode (B/B+Color/B+Power/B+TVI/B+TEI)

### Manual Cine Review:

After entering cine review in 2D mode, roll the trackball to review the cine images on the screen one by one. Or under touch screen mapping mode, touch the touch screen and swipe left and right to review the images.

If you roll the trackball to the left or swipe leftwards (under mapping mode), the review sequence is reversed to the image-storing sequence, and the images are displayed in descending order. If you roll the trackball to the right or swipe rightwards, the review sequence is the same as the image-storing sequence, and the images are displayed in ascending order. When you review images to the first or last frame, rolling the trackball further will display the last or first frame.

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



### Auto Review

- Reviewing all
  - a) In manual cine review status, press the knob under [Auto Play] (not selecting "Stop") on the touch screen to activate auto cine review.
  - b) Reviewing speed: in auto cine review status, press the knob under [Auto Play] on the touch screen to adjust the review speed or use the mapping menu. When the speed is changed to 0, the system exits auto cine review.
  - c) In auto play status, set [Auto Play] to "Stop" or roll the trackball to exit auto play.
- Setting the Auto Review Region

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

- a) Set the start frame: rotate the knob under [Start Frame] in the touch screen to manually review the images for the frame you want to set as the start point; or manually review the cine file by trackball and touch [Set Begin] on the touch screen to set current frame to be the start point.
- b) Set the end frame: rotate the knob under [End Frame] in the touch screen to manually review the images for the frame you want to set as the end point; or manually review the cine file by trackball and touch [Set End] on the touch screen to set current frame to be end.
- c) Press the knob under [Auto Play] on the touch screen or use the mapping menu. The system plays the auto review region automatically.
- d) Rotate the knob under [Auto Play] to increase/decrease the auto play speed or use the mapping menu.

- e) In auto cine review, pressing the knob under [Auto Play] on the touch screen or rolling the trackball will stop the auto cine review and enter the manual cine review.
- f) Click [Jump to First]/[Jump to Last] to review the first or last image.

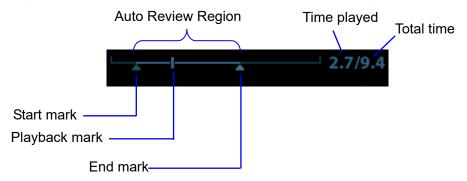
Tip: you can perform cine review on each image window in the dual/quad splitting mode, and set the auto review region for each window.

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

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

Roll the trackball to the left. Or under touch screen mapping mode, swipe the touch screen leftwards. The review progress slider moves to the left, the images move to the right and the earlier stored images are displayed. Or, roll the trackball to the right (swipe rightwards). The review progress slider moves to the right, the images move to the left and the recently stored images are displayed. When you review images to the first or last frame, rolling the trackball further will display the last or first frame.

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



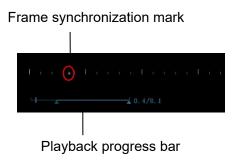
Cine review operations are the same as those in 2D mode.

Tips: when replaying the spectrum cine files, the audio is synchronous with image file when the auto play speed is set 1.

### 6.4.4 Linked Cine Review

Linked cine review reviews images captured at the same moment.

- Dual live mode (B/Color/Power/TVI/TEI)
- B+M
- B/B Dual liveDuplex mode (B+PW/CW/TVD)
- Triplex mode, TVM or CM mode



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

# 6.5 Image Compare

### 6.5.1 Image Compare under Review Mode

You can perform image compare through the path:

- Thumbnail area in the main screen;
- iStation screen (press <iStation> to enter);
- Review screen (press <Review> to enter).
- 1. In the above condition, press <Cursor> to show the cursor and click the target image file.
- 2. 3 buttons will appear to the right of the image, click to select the image for comparison marked by  $|\star|$ .

If the wrong image has been chosen, click to cancel the selection of this image.

Tip: for B/B+COLOR/B+TVI/B+POWER/B+TEI mode image, you can select at most 4 images; for PW/M/CW/TVD/Elasto single mode image, you can select at most 2 images.

- 3. Repeat the above steps to add other image files for comparison.
- 4. Click [Image Compare] (click in thumbnail status) to enter image compare mode.
- 5. Review images from different image windows. Press the <Dual> or <Quad> key to switch the active image window.

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

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

Image compare of different exams for the same patient:

- a) Select different exams in the iStation screen, then select [Review Image] in the menu which appears to enter the Review screen.
- b) In the Review screen, click [Exam History] to select the exam. Click to select the image to be compared in different exams, and click [Compare].

You can select if cine files are synchronously replayed by the soft menu control: select [PlayMode: XX] to [SyncPlay] to play all files synchronously or [ASyncPlay] to play asynchronously.

# 6.5.2 Frame Compare

- 1. Freeze the image in B/C mode. Touch [Frame Compare] on the touch screen to enter frame compare mode.
- 2. Review the images of different image windows (cine replaying cannot be performed for single-frame image files). Press the <Update> or <Dual> key to switch the active image window.
- 3. Save the image if necessary.

Measurements and adding comments and body marks are allowed.

4. Touch [Frame Compare] again to return to image frozen status. Press <Freeze> to enter real-time imaging.

Tip: Cine compare can only be performed on single-format 2D images.

# 6.5.3 iCompare

1. Set the user-defined key through the path: [Setup]→ [System]→ [Key Config]. Select a key in the Key Function field on the left side and select "iCompare" in the Advanced Feature page of Function field on the right side.

- 2. In live mode or freeze mode, press the user-defined key for iCompare.
- 3. Select a single-frame image, multi-frame image, or screenshot in the iStation screen (press <iStation> to enter), Review screen (press <Review> to enter), or thumbnail area in the main screen.
- 4. Press the <Dual> key to switch between the left and right windows. Roll the trackball to review the cine image on the screen one by one.

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

When the left window is a screenshot, you cannot switch windows.

5. Save the image if it is necessary.

Measurements, adding comments and body marks are allowed.

6. Press <B>, <Single>, or the user-defined key to exit iCompare.

Tips: iCompare can only be performed on B, Color, Power, PW, CW, or M mode for FRM/CIN/PNG/DCM files.

# 6.6 Cine Saving

### ■ Live capture

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

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

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

The live capture time can be set.

• In imaging mode, tap [Pro Capture] / [Retro Capture] ont the touch screen or press the user-defined key for "Save Cine (Prospective)/(Retrospective)" on the control panel.

Tip:

- Press the save key again or <Freeze> to stop saving.
- When saving is complete, a thumbnail displays in the Thumbnail area.
- Frozen image storage

In frozen mode, tap [Pro Capture] / [Retro Capture] ont the touch screen or press the user-defined key for "Save Cine (Prospective)/(Retrospective)" on the control panel.

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

The live capture time can be set.

# 6.7 Setting Cine Length

### ■ Live capture:

Prospective Cine Length

Prospective cine duration: set the time that the user taps [Pro Capture] as the start time. The system proceeds saving the cine.

Procedures:

With the ECG disabled: tap [Cine] tab, and rotate [Time (Pro)] knob to adjust it.

With the ECG enabled: tap [Cine] tab. Tap [Loop Type (Pro)] to choose the type of the saving time and the cardiac cycles. Rotate [Time (Pro)] or [Cycle (Pro)] to adjust it.

Retrospective Cine Length:

Retrospective cine duration: set the time that user taps [Retro Capture] when playing the first frame of the image. It also refers to saving the cine or cycles retrospectively.

### Procedures:

With the ECG disabled: tap [Cine] tab, and rotate [Time (Retro)] knob to adjust it.

With the ECG enabled: tap [Cine] tab. Tap [Loop Type (Retro)] to choose the type of the saving time and the cardiac cycles. Rotate [Time (Retro)] or [Cycle (Retro)] to adjust it.

### ■ Freeze storage setting:

Press <Freeze> to freeze the image. The system takes the time of pressing the retrospective/prospective key as the first frame of the image. The system proceeds saving the cine.

TIP: after being frozen, the cine length of the prospective keeps the same with the real-time prospective.

NOTE: the system ends up saving if the cine length goes beyond the maximum value.

# 7 Physiological Signal

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

The scanned image displayed is synchronized with the ECG traces. So ECG signals can be used as a time reference in an ultrasound exam (mainly in cardiology exams).

The ECG function is an option.

# **≜**WARNING:

DO NOT use the physiological traces for diagnosis and monitoring.

To avoid electric shock, the following checks must be performed prior to an operation:

The ECG electrode cable must not be cracked, frayed or show any signs of damage or strain.

The ECG electrode cable must be correctly connected.

You must use the ECG leads provided with the physiological module. Failure to do so may result in electric shock.

The ECG electrode cable must be connected to the system first. Only after the cable is connected to the system can the patient be connected to the ECG electrodes. Failure to follow these instructions can subject the patient to electric shock.

DO NOT place the ECG electrodes directly in contact with the patient's heart. This can stop the patient's heartbeat.

DO NOT apply the ECG electrodes if the voltage exceeds 15 volts. This could result in an electric shock.

Before using the high-frequency electric surgical unit, high-frequency therapeutic equipment or defibrillator, be sure to remove the ECG electrode from the patient in order to prevent electric shock.

Conductive parts of electrodes and associated connectors for ECG must not come into contact with other conductive parts including earth/grounding.

Frequent trampling on or squeezing of the cables may result in cable failure or fracture.

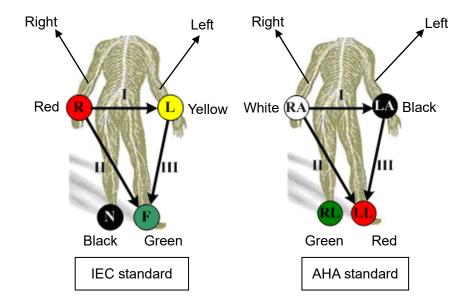
If an abnormality is detected in physio trace, check that the ECG leads are properly connected to the system.

### 7.1 ECG

### 7.1.1 ECG Operation Basic Procedures

- 1. Connect the device.
  - Turn off the system power supply, and connect the ECG cable to the ECG port on the physio panel of the machine.
  - Turn on the system power supply.

Place the ECG electrodes on the patient's body (as shown in the following figures).



- 2. Touch [Physio] on the touch screen to enter physio operation status.
- 3. Switch the imaging modes and display formats. Adjust the parameters to obtain an optimized image.
- 4. Parameter adjustment:
  - On ECG touch screen page, touch [ECG] to be On (highlighted in green).
  - Adjust the [Speed], [ECG Gain], [Position] and [Invert].
- 5. Trigger:
  - Select the trigger mode, or switch on [Real & Trig], set the trigger time.
- 6. Freeze the image(s) and review the image(s).
- 7. Touch [Physio] to exit ECG mode, and remove the ECG electrodes from the patient.

  If an external ECG is used as input for the ECG signal, touch [ECG source] to be "External".

# 7.1.2 ECG Triggering

### 7.1.2.1 **Overview**

ECG triggering means that image scanning is activated at some time points of ECG signals, thus obtaining B images at these time points. In most cases, the triggered images are 2D-mode images.

For single/dual trigger, when ECG triggering occurs, a mark appears on the ECG waveform, indicating the time points when the B images are captured (corresponding to the delay time from R curve started).

Tips:

- The trigger mark is displayed in both freeze mode and live mode.
- The marks in Dual trigger are different in color.
- Trigger function is unavailable if the ECG trace is disappeared. Only the live 2D image can be triggered.
- No delay time or time interval shall less than the time required to scan a single image.
- If the delay time is longer than a heart cycle, then the heart cycle between the delay time
  is omitted, that is to say no trigger is occurred when R waveform is detected in the
  duration.

### 7.1.2.2 Triggering Mode

There are three triggering modes available: Single, Dual and Timer.

- Single Trigger: when an R waveform is detected, the image will be triggered after delay time T1. The value of T1 can be changed in triggering status.
- Dual Trigger: when an R waveform is detected, the image will be triggered respectively
  after delay time T1 and T2. The value of T1 and T2 can be changed in triggering status.
- Timer Trigger: an image will be triggered after a certain interval. The time interval can be changed in triggering status.

The image trigger operation is described as follows (Take single trigger as an example):

- 1. Select exam mode.
- 2. Touch [Trig Mode] on the touch screen to enable the trigger.
- 3. Select [Single].
- 4. Set the delay time on the soft menu according to actual situation.

### 7.1.2.3 Real & Trigger

Click [Real & Trigger] on the soft menu to enable or disable the real trigger function.

After the [Real & Trigger] is turned on, two images are displayed respectively in two windows, one is triggered by ECG, and the other is non-triggered real time image.

# 7.2 Respiratory Wave

# 7.2.1 Respiratory Wave Operation Basic Procedures

- 1. Connect the ECG lead and position the ECG electrodes. For details of ECG lead connection, see "7.1.1 ECG Operation Basic Procedures".
- 2. Press <F12 Physio> on the control panel to enter Physio screen.
- 3. Switch the imaging modes and display formats, adjusting the parameters to get an optimized image.
- 4. Parameter adjusting
  - In Physio menu, click [RESP] on the touch screen. Adjust [Speed], [RESP Gain], [Position] and [Invert].
- 5. Exit Respiratory display mode, and remove ECG electrodes from the patient.
- 6. Press <F12 Physio> to exit physio mode.

# 7.2.2 Parameter Description

The physio parameters are described as follows:

Parameter	Description	
ECG Source	Select ECG source.	
	Function: to set the amplitude of the trace.	
Gain	Method: click [Gain] on the soft menu, or press/rotate the corresponding knob. Each adjustment takes you to the next setting.	
	Value: 0-30, in increments of 1.	
	Function: to set the vertical position of the traces on the image display.	
Position	Method: select [Position] on the touch screen. Each adjustment cycles you to the next setting.	
	Value: 0%-100%, in increments of 5%.	
Speed	Function: change the speed of the physio trace.	
	Value: 20-145mm/s.	
T1 Function: to set the delay time T1 in Single trigger or Dual trigger.		
T2	Function: to set the delay time T2.	
12	Method: select a proper value in the drop-down list.	
Interval	Function: to set the time interval for Timer.	
IIIIGI VAI	Method: select a proper value.	
Invert To invert the display.		

# **8** Measurement

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

# $\triangle$ WARNING:

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

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

# CAUTION:

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

If the system is turned off or <End Exam> is pressed during a measurement, unsaved data will be lost.

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

# 8.1 Basic Operations

■ To enter/exit measurement

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

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

Measurement results and help information

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

The help information concerning measurement and calculation is displayed in the Help Information area at the bottom of the screen.

# 8.2 General Measurements

## 8.2.1 2D General Measurements

2D general measurements are general measurements on images in B, Color, Power or iScape imaging modes. The measurements listed below can be performed:

Measurement Tools	Function
Distance	Measures the distance between two points of interest.
Depth	Measures the distance between the probe surface and the probing point along the ultrasound beam.
Angle	Measures the angle between two intersecting planes.
Area	Measures the area and perimeter of a closed region.
Volume	Measures the volume of a target.
Double Dist.	Measures the length of two line segments which are perpendicular to each other.
Parallel	Measures the distances between each pair of parallel lines in a sequence.
Trace Length	Measures the length of a curve.
Distance Ratio	Measures the lengths of any two lines and calculates the ratio.
Area Ratio	Measures the areas of any two regions and calculates the ratio.
B histogram	Measures the grayscale distribution of ultrasonic echo signals in a closed region.
B profile	Measures the grayscale distribution of ultrasonic echo signals across a line.
Color Velocity	Measures the color flow-velocity (only in Color mode).
Volume Flow	Measures the blood flow through a vascular cross section per unit time.
Strain Ratio	Measures the strain ratio in the image.
Elasto ratio	Measure the elastography ratio
Strain-Hist	Displays the strain ratio using the histogram.
Elasto-Hist	Display the elasto value of the ROI in a histogram
IMT	Measure intima-media thickness

# 8.2.2 M General Measurements

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

Measurement Tools	Function		
Distance	Measures the vertical distance between two points.		
Time	Measures the time interval between any two points.		
Slope	Measures the distance and time between two points and calculates the slope.		

Measurement Tools	Function		
HR	Measures the time of n (n≤8) cardiac cycles and calculates the heart rate in M mode images.		
Velocity	Calculates the average velocity by measuring the distance and time between two points.		

# 8.2.3 Doppler General Measurements

Doppler general measurements are general measurements on PW/CW-mode images. The measurements listed below can be performed:

Measurement Tools	Function		
Time	Measures the time interval between any two points.		
HR	N intervals (n≤8) are measured to calculate a PW mode derived HR value in Beats Per Minute (BPM).		
Velocity	On Doppler mode images, velocity and PG (pressure gradient) of a point on the Doppler spectrum waveform are measured.		
Acceleration	The velocity and time interval between two points are measured to calculate the speed difference and acceleration.		
D Trace	On PW mode images, one or several Doppler waveforms are traced to obtain the speed and PG, etc.		
PS/ED	Velocity and PG between two peaks on the Doppler spectrum are measured to calculate the RI (resistance index) and PS/ED (peak systolic/end diastolic).		
Volume Flow	Measures the blood flow through a vascular cross section per unit time.		
Ratio (Vel.)	Measures the D velocity and calculates the ratio value for blood analysis.		
Ratio (VTI)	Measures the VTI values from the spectrum and then calculates the ratio value.		

# 8.3 Application Measurements

- Abdomen measurements used for measuring abdominal organs (liver, gall bladder, pancreas and kidney, etc.) and large abdominal vessels.
- OB measurements used for measuring fetal growth indices (including EFW) as well as GA and EDD calculations. The fetus can be evaluated through growth graph analysis and the fetal biophysical profile.
- Cardiac measurements used for left ventricle function measurements and measuring main artery and vein parameters, etc.
- Gynecology measurements used for the uterus, ovary and follicles, etc.
- Small Part measurements used for small parts such as the thyroid.
- Urology measurements used for the prostate, seminal vesicle, renal, adrenal, micturated and testicular volume.
- Pediatrics measurements used for hip joint measurement.
- Vascular measurements used for carotid, cerebral, upper and lower extremities vessels, etc.
- EM measurements used for EM-related full functional measurements.
- Nerve measurements used for nerve measurements.

# 8.4 Measurement Accuracy

Table 1 2D Image Measurements

Parameter		Range	Error	
	Distance	Full Screen	Within ±3%	
Tr	ace Area	Full Screen	Within ±7%	
	Circ	Full Screen	Within ±10%	
Angle		Full Screen	Within ±3%	
Volume		Full Screen	Within ±10 %	
Distance (iScape)  Linear probes, macro convex probes, and phased array probes		Full Screen	Within ±5 %	
	Micro-convex probe	Full Screen	Within ±10 %	

Table 2 Basic Time Motion Measurements

Parameter	Range	Error	
Distance	Full Screen	Within ±3 %	
Time	Timeline Display	Within ±2%	
Heart Rate	Timeline Display	Within ±4%	
Velocity (PW mode)  10-200cm/s  10-300cm/s (for transcranial application)		When angle≤60°, ≤±5%.	

Parameter	Range	Error	
Velocity (CW mode)	10-200cm/s 10-300cm/s (for transcranial application)	When angle≤60°, ≤±5%. (not including pencil probe)	

Table 3 3D/4D image measurements

Parameter	Range	Error
Distance	Section A/B/C	Single window display: Within ±5% (not including Smart 3D mode)
Trace Area	Section A/B/C	Single window display: Within ±7% (not including Smart 3D mode)
Circ	Section A/B/C	Single window display: Within ±10% (not including Smart 3D mode)
Angle	Section A/B/C	Single window display: Within ±5% (not including Smart 3D mode)
Volume	Section A/B/C	Within ±20 % (not including Smart 3D mode)

Table 4 Contrast image measurements

Probe	Maximum Depth (cm)
C5-1E	≥8.5
SP5-1E	≥12
SC6-1E	≥8
SC5-1E	≥7
C6-2GE	≥10
C7-3E	≥7

Table 5 Strain Elastography image measurements

Probe	L12-3E, L14-5WE, L20-5E, L9-3E, L13-3WE, L14-6WE, V11-3HE, DE11-3E, V11-3E, V11-3BE	
Maximum Depth	≥30mm	
Spatial Resolution	≤10.5mm	
Accuracy of Geometric for the Lateral	Within ±20%	
Repetition Rate	Within 0.2	
Strain Deviation	Within ±70%	

Table 6 STE image measurements

Probe	SC6-1E, L12-3E, L14- 5WE, L9-3E, C5-1E, SC5- 1E, L13-3WE		
Maximum Depth	≥30mm		
Velocity Deviation	Within ±70%		
Repetition Rate	Within 20%		
Spatial Resolution	≤10mm		
Accuracy of Geometric for the Lateral	Within ±70%		

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

# 9 Comments and Body Marks

## 9.1 Comments

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

riangleWARNING:

Ensure that the entered comments are correct. Incorrect

comments may lead to misdiagnosis!

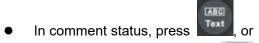
## 9.1.1 Comments Basic Procedures

To enter a comment:

1. Enter comment status:



- Press any alphanumeric key or the space bar to enter comment status, or,
- Press to enter arrow-adding status.
- 2. Position the cursor over the desired location for the comment,
- 3. Add a new comment to the image in accordance with the actual situation. You can modify, move or delete a completed comment.
- 4. To exit comment status:



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

## 9.1.2 Touch Screen Display in Comments

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

• To set the comment home location.

Roll the trackball to move the cursor to the desired comment location and touch [Set Home] on the touch screen.

Return the cursor to the set home location.

Press <Home> on the control panel or touch [Home] on the touch screen to return the cursor to the set home location.

Grab/Del.

Rotate the knob under the [Grab/Del.] button on the touch screen to select the entered comment items. Press the knob to delete the selected item.

Navigate through the comment libraries

To select the comment library, rotate/press the knob under the [Library] button on the touch screen.

Edit comments

Tap [Edit] to enter

Change active text color/fix text color: select a desired color block to change the active text color or fix text color. The default active text color is green and fix text color is yellow.

You can also tap the button on the touch screen to select more colors.

Change Arrow style: Select arrow style.







on the touch screen to select

Change Arrow Size: Drag the slider or tap the -/+ button on the touch screen to select arrow size.

Change text size: Drag the slider or tap the A-/A+ button on the touch screen to select text size. Add/modify comment positions

Comment display/hide

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

Page-turning

If there is more than one page of comment text for the current exam mode, you can navigate to other pages by swiping the touch screen leftwards/rightwards.

User-defined comments

You can customize comments if necessary, including adding/deleting comments and adjusting the comment display on the touch screen menu.

Trace

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

Tracing by trackball

Move the trackball to the desired starting point and press <Set>.

Roll the trackball to trace the curve: roll the trackball to the right to draw the curve and to the left to cancel the curve.

Press <Set> to confirm the end; or the trace curve will close automatically if the cursor is near the starting point.

> Trace on touch screen

Touch the touch screen to set the starting point and trace the curve, touch the touch screen again to set the end.

Quickly select a comment in a group

Configure groups to List 1, List 2, and List 3. For details about group configuration, please refer to "12.4 Comment Preset". Select a comment in a group by pressing or rotating the Knob under the [List 1], [List 2], or [List 3] button on the touch screen. The selected comment is displayed in the main screen synchronously.

## 9.1.3 Adding Comments

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

Roll the trackball or press the direction keys on the keyboard to move the cursor to the desired comment location.

2. To type alphanumeric characters:

You can enter characters using the keyboard.

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

You can add comment texts using the following methods:

- Roll the trackball to move the cursor over the desired comment text on the screen menu and press <Set>. The system adds the selected comment text to the screen. Move the trackball to confirm.
- Touch the desired comment text on the touch screen. The system adds the selected comment text to the screen where the cursor is positioned. Edit the comment directly and roll the trackball to confirm.
- 2. Exit comment edit status

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

#### Adding an arrow

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

To add an arrow:

- (1) Press the <Arrow> key and an arrow will appear in the default position.
- (2) Adjust the shape and position of the arrow:
  - ➤ To position the arrow on the area of interest: roll the trackball to the desired position.
  - ➤ To change the orientation of the arrow: rotate the <Angle> knob to change the arrow's orientation (in increments of 15°).
  - ➤ Adjust the arrow size: rotate the knob under the [Arrow Size] button on the touch screen to change the size.
- (3) Press <Set> or <Enter> to anchor the arrow's position. The arrow turns yellow. Repeat the above steps to add more arrows.
- (4) Press <Arrow> on the control panel to exit arrow comment status.

## ■ Tracing

- (1) In comment status, touch [Trace] on the touch screen to activate the trace function. The current image is also displayed on the touch screen.
- (2) Control Panel operation:
  - a) Roll the trackball to the desired position and press <Set> to confirm the start point.
  - b) Roll the trackball to move the cursor along the edge of the desired region and trace the outline of the region.
  - ➤ Rotate the <Angle> knob counter-clockwise to cancel 1 pixel of trace.
  - ➤ Rotate the <Angle> knob clockwise to restore 1 pixel of trace.
  - ➤ Short press <Clear> to clear last trace. Long press <Clear> to delete all tracing.
  - c) Press <Set> to finish tracing.

### Touch screen operation:

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

## 9.1.4 Moving Comments

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

## 9.1.5 Modifying (Editing) Comments

- Modifying (Editing) characters
- 1. In comment status, move the cursor over the comments to be modified.
  - Press the alphabetic keys to enter the character at the cursor position.
  - Or, double press <Set> to enter comment editing status and use the direction keys to
    move the cursor to the desired location to insert/delete characters. Either type characters
    by pressing the corresponding keys or select the new comment text from the menu.
- 2. Press <Del.> to delete the comment character or text on the right side of the cursor. Press <Backspace> to delete the comment character or text on the left side of the cursor.
- 3. Roll the trackball or press <Set> to confirm the modification and exit the edit status. The comment turns to yellow.
  - If there are already comments on the screen, press the space bar to enter editing status.
- Modifying (Editing) Arrows
- 1. Move the cursor over the arrow that needs to be modified. After the cursor turns to the <Set> key. The current arrow turns green, and there is a green frame around the arrow indicating that the arrow can be edited. Move the cursor to change the arrow's position.
- 2. Rotate the <Angle> knob to modify the arrow's direction.
- 3. Press the <Set> or <Enter> key to complete the operation.

#### 9.1.6 **Deleting Comments**

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

Or, rotate the knob under [Grab/Del] on the touch screen to select the comment, then press the knob to delete the comment.

Deleting a recently-added character, text or arrow

In comment status, press <Clear> to delete the latest added/modified comment unit.

In comment status, enter letters by pressing the alphanumeric key on the keyboard and use blank key to divide the letters. Press user-defined key for "Delete Word" to delete latest added/modified comment unit (<F10> -> [System] -> [Key Config]).

Delete letters one by one

In comment editing status, press <Back> to delete letters before cursor "|".

In comment editing status, press <Del.> to delete letters after cursor "|".

In comment status, enter letters by pressing the alphanumeric key on the keyboard. Press user-defined key for "Delete Word" to delete letters before cursor "|" (<F10> -> [System] -> [Key Config]).

■ Delete All Comments

NOTE:

Press < Delete Text> key or long press < Clear> key to delete all the comments.

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

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

#### 9.1.7 Comment Setting

See "12.4 Comment Preset" for comment preset.

Comment Setting

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

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

#### 9.2 **Body Mark**

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

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

The system supports body marks for Abdomen, Cardiology, GYN, OB, Urology, Small Part and Vascular applications. In addition, the system supports to import user-defined body marks.

#### 9.2.1 Touch Screen Display in Body Mark

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

■ Library

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

■ Page-turning

If there is more than one page of body marks, rotate the knob under [Page] to turn the pages.

■ User-defined body mark

Touch [Custom] to enter the dialog. You can import body mark graphs here.

You can import a user-defined body mark in BMP/PNG format of 120\*120 (unit: pixel) in size.

■ Save Probe

If the probe mark direction and position is determined for the current body mark being added, touch [Save Probe] to save the current probe mark direction and position for the body mark.

## 9.2.2 Adding Body Marks

- 1. Enter Body Mark status. Use the knob under [Library] to select the body mark category.
- 2. Adding Body Marks:
  - Adding body marks using the trackball and <Set> key.
     Move the cursor over the desired body mark to highlight your choice. Press <Set> to add the body mark.
  - Adding body marks using the touch screen.
     Touch the desired body mark on the touch screen directly.
- 3. To adjust the probe position and orientation marker:
  - Roll the trackball to position the probe marker.
  - Rotate the <Angle/Steer> knob to adjust the orientation.
  - Touch [Save Probe] to save the current probe mark direction and position for the body
    mark
- 4. Press <Set> to confirm the position and orientation of the probe marker and exit body mark mode.

## 9.2.3 Moving Body Marks

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

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

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

# 9.2.4 Deleting Body Marks

- 1. Use the trackball to position the cursor over the body mark graphic and press <Set> to select.
- 2. Press <Clear> to delete the selected body mark.

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

# 9.2.5 Body Mark Setting

Returning to the preset or changing the exam/patient/mode/probe will clear the body marks.

# 10 Patient Data Management

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

An exam record consists of the following information:

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

## NOTE: 1.

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

# 10.1 Patient Information Management

## 10.1.1 Enter Patient Information

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

# 10.2 Image File Management

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

# 10.2.1 Memory Media

The system supports memory media including:

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

# 10.2.2 Image File Formats

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

- System-relevant formats:
  - Single-frame image file (FRM)
     Refers to single-frame static image files which cannot be compressed. You can add measurements and comments on this type of file.
  - Cine file (CIN)

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

The system can save FRM files as BMP, JPG, TIFF, PNG or DCM files, or save CIN files as AVI or DCM files by Send To function in iStation screen. For details, please refer to "10.2.12 Sending Image Files" chapter.

- PC-compatible formats:
  - Screen file (BMP)
     Single-frame file format, used to save the current screen, non-compressed format.
  - JPG: single frame export format.
  - TIFF: single frame export format.
  - Multi-medium file (AVI)
     Multi-frame export format.
  - DICOM file (DCM)

DICOM standard file format, single-frame or multi-frame format, used to record patient information and images, you can only open DCM files to view rather than to edit.

# 10.2.3 Image Storage Preset

Set image size

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



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

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

# 10.2.4 Quickly Saving Images to the System

- To save a single-frame image to the system quickly:
  - Operating procedure:
    - a) Set the user-defined key via the path: [Setup] → [System] → [Key Config]. Select a key in the Key Function field on the left side, and select "Save Image" in the Output page of the Function field on the right side.
    - b) Press the user-defined key to save the image.
  - Format:
    - a) On the image screen, the image is saved with the default filename in the default file directory in FRM format.
    - b) When a dialog box is displayed on the current screen, interface for the current dialogue box is saved in BMP format.

Single-frame image is saved to the system by default name. The image thumbnail will appear in the thumbnail area on the right side of the screen. When you move the cursor over the thumbnail, its filename and suffix will be displayed.

- To save a cineloop image to the system quickly:
- Set the user-defined key via the path: [Setup] → [System] → [Key Config]. Select a key in the Key Function field on the left side, and select "Save Cine (Retrospective)" or "Save Cine (Prospective)" in the Output page of the Function field on the right side.
- 2. Press the user-defined key to save the cine file in the default file directory in CIN format.

The image thumbnail will appear in the thumbnail area on the bottom of the screen. When you move the cursor over the thumbnail, its filename and suffix will be displayed.

You can set the clip saving length in the path: [Setup]  $\rightarrow$  [System]  $\rightarrow$  [General].

## 10.2.5 Quickly Saving Full Screen Images to the System

- Operating procedure:
- Set the user-defined key via the path: [Setup] → [System] → [Key Config]. Select a key in the
  Key Function field on the left side, and select "Save Screen" in the Output page of the Function
  field on the right side.
- 2. Press the user-defined key to save the image in BMP format.

The image thumbnail will appear in the thumbnail area on the bottom side of the screen. When you move the cursor over the thumbnail, its filename and suffix will be displayed.

## 10.2.6 Quickly Saving Images to USB Flash Drive

Use the user-defined key to quickly save the single-frame to USB flash drive.

The image file is stored in the directory: patient name + ID\exam type + exam time\image ID.

- 1. Set the user-defined key via the path: [Setup]  $\rightarrow$  [System]  $\rightarrow$  [Key Config].
  - Select a key in the Key Function field on the left side, and select "Send Image to USB disk" in the Output page of the Function field on the right side. Click [Save] to exit setup.
- 2. Press the user-defined key to save the image to the USB flash drive.

## 10.2.7 Quickly Exporting Cine File to USB Flash Drive

Use the user-defined key to quickly save the cine file to USB flash Drive directly (without saving to the hard disk).

The file is stored in the directory: X (USB flash drive name): patient name+ ID\exam type + exam time \ image ID.

- Set the user-defined key through the path: [Setup]→ [System]→ "Key Config". Select a key in the Key Function page on the left side and select "Send Cine to USB disk" in the Output page of Function field on the right side. Click [Save] to exit preset page.
- 2. Scan and freeze the image
- 3. Press the user-defined key to save the cine to the USB flash drive.

# 10.2.8 Auxiliary Output Function

For the following three functions, the system provides auxiliary output function setting: "Save Image", "Save Cine (Retrospective)" and "Save Cine (Prospective)". When the corresponding user-defined key is pressed, the ultrasound system can perform multiple operations one by one as per the preset.

- Save Image
  - Send Image to DICOM Storage
  - Send Image to USB disk
  - Send Image to iStorage
- Save Cine (Retrospective)/(Prospective):
  - Send Cine to DICOM Storage
  - Send Cine to USB disk
  - Send Cine to iStorage

Setting method (take "Save Image" as an example, add the auxiliary functions "Send Image to DICOM Storage" and "Send Image to USB disk"):

- Set the user-defined key through the path: [Setup]→ [System]→ [Key Config]. Select a key in the Key Function field on the left side and select "Save Image" in the Output page of Function field on the right side.
- 2. Click [Add] in the middle part of the screen, then there will be "Function2: NULL" under the key function in the Key Function Field on the left side, and at the same time, "Output" column on the right side will show the available auxiliary functions for current key. Select "Send Image to DICOM Storage" in the "Output" column on the right side. Then the Function2 on the left side turns into "Send Image to DICOM Storage".
- 3. Click [Add] again, then there will be "Function3: NULL" under the key function in the Key Function Field on the left side. Select "Send Image to USB disk" in the "Output" column on the right side. Then the Function 3 on the left side turns into "Send Image to USB disk".
- 4. Click [Save] to confirm.
- 5. Scan and freeze the image
- 6. Press the user-defined key, then the system will perform three steps: 1. Save the image to the local hard disk; 2. Send image to DICOM Storage server; 3. Send the image to USB disk.

Tips: repeat step 3 will continue adding auxiliary functions, you can add 6 functions at most.

## 10.2.9 Thumbnails

Stored images are displayed in the form of thumbnails on the screen:

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

# 10.2.10 Image Review and Analysis

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

## 10.2.10.1 Review an Image

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

The cine file is played automatically in image review screen.

- To enter image review:
  - During image scanning, saved image thumbnails display in the bottom of the screen.
     Move the cursor over a thumbnail and press <Set> twice to open the image. If the stored image is a cine file, double-click the thumbnail to enter the auto cine review.
  - Press <Review> to enter the Review screen. Images of the current exam and the current patient are displayed.
  - Select a patient's exam in the iStation screen and press <Review> or double-click the exam to enter the Review screen to review the images of the patient.
  - Under touch screen mapping mode, touch screen;
  - If a saved image has been open from the main screen, under touch screen mapping mode, touch and icon on the toolbar or swipe the touch screen to review the image.

The Review screen is shown as follows:



### To exit Review:

- Click [Exit] on the Review screen
- Press <ESC> or press <Review> again.

Functions in the Review screen:

• Exam History:

You can select more than one exams of one patient in iStation screen to check the patient exam history.

Info

Click to enter the Patient Info screen, you can review or edit the currently-selected patient's information.

Report

Click to review or edit the currently-selected patient's report.

Image operations

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

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

[Send To]: click to send the selected image to another location, DICOM server, MedTouch/MedSight devices, DVD recorder, printer, etc. Or select the image and click the

icon at the top right of the image.

[Delete]: click to delete the selected image.

[Image Compare]: image compare function. For details, see "6.5 Image Compare" chapter.

Thumbnail Size

To change the thumbnail size.

- Other operations:
  - ➤ [New Exam]: click to create a new exam for the selected patient and open the Patient Info screen.
  - ➤ [Activate Exam]: activate the currently-selected exam (already ended) and enter the image scanning screen.
  - [iStation]: click to enter the iStation screen.
  - [Exit]: click to exit Review status and return to the main screen.

## 10.2.10.2 Image Analysis

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

- To enter image analysis:
  - In image scanning or freeze status, double-click a thumbnail stored in this exam to enter the image analysis status, or
  - In image review status, double-click the selected thumbnail to open the image.
- To exit image analysis:
  - Press <Freeze> to exit and enter real-time scanning status.
  - Click [Return] to exit image analysis and enter review status.

In image analysis status, the selected image is displayed on the screen and the thumbnails of the same exam are displayed on the thumbnail area. Turn pages and change the image display format using the buttons below the thumbnail.

Other operations

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

## 10.2.11 iVision

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

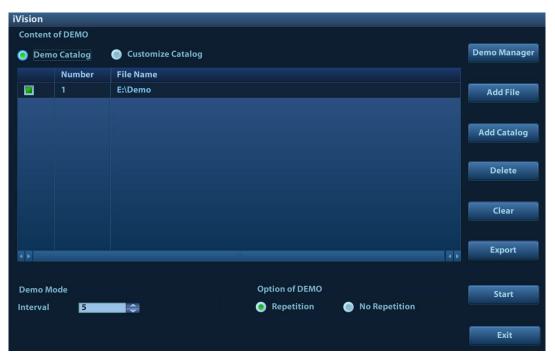
To perform image demonstration:

1. Enter the iVision screen:

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

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

The iVision screen is shown as follows:



#### Demonstration item

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

## Demonstration catalog

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

 Demo Catalog: the demo catalog is a folder on the hard disk where the factory DEMO is stored. The system plays the images in this folder when performing demonstrations.

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

Click [Demo Manager] to operate:

[>]: to import data into the demo catalog.

[<]: to delete selected data.

[<<]: to delete all data.

• Customize Catalog: the catalog of the displayed images is saved here. The system plays the images in the catalog when performing demonstrations.

Operate the catalog or the files using the buttons on the right:

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

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

[Delete]: to delete selected files or catalogs from the file list.

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

[Export]: to export selected directories/files to external storage devices. Click [Export] to bring up the Browse dialog box, select the path and click [OK].

## ■ Demonstration mode

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

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

## Demo options

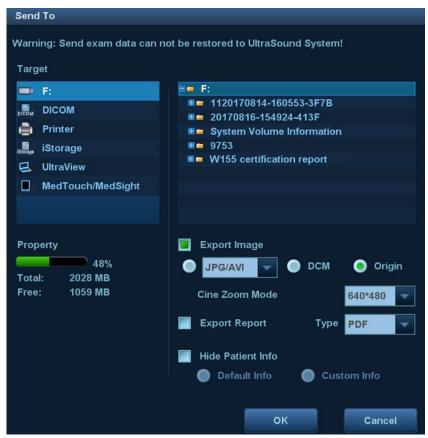
You can choose whether to repeat the demonstration or exit after a demonstration is complete.

## 10.2.12 Sending Image Files

**NOTE:** Data saved this way can only be reviewed on the PC and cannot be restored to the ultrasound system. See "10.4.3 Patient Data View & Management" chapter for details about data backup.

- On the image screen, select a stored image thumbnail and click (Send To) in the top-right corner of the image. Or you can touch icon on the touch screen under touch screen mapping mode (see "3.8.4 Touch Screen Operation" for details). The image can be sent to the external device, DVD recorder, MedTouch/MedSight devices, DICOM storage server, DICOM print server, system connected printer, etc.
- In the iStation screen, click →, or, in the Review screen, click [Send To] to send patient data to an external memory device. See the figure below.

See the figure below.



- For external memory devices (e.g., USB memory devices or DVD-RW) or iStorage:
   a) PC format transfer: JPG/AVI, BMP/AVI, TIFF/AVI, JPG/MP4, BMP/MP4, TIFF/MP4.
   Where a single-frame image is exported as JPG, TIFF or BMP, and the cine file is exported as AVI (windows), MP4(Mac OS).
  - b) DCM format transfer: DCM (including single-frame DCM and multi-frame DCM).
  - c) Cine zoom mode, compression mode, compression ratio, and Doppler audio can be changed.
  - d) You can also select whether to export reports and select the report type.
  - e) To select to hide patient information.
- For DICOM servers, select the DICOM Storage or Print server.
- For video printers, send images to the video printer connected to the system. For graph/text printers, send images to the default graph/text printer.
- For UltraView, send images to UltraView connected to the system.

- Used for UltraView required environment setting, should be used combined with off-line software. For details, please refer to UltraView operator's manual.
- Send the image to MedTouch/MedSight as necessary.

NOTE: The file sent to MedTouch/MedSigh is transferred into PNG format, and the cine file is transferred into AVI or MP4 format.

If the transferred AVI file cannot be played normally on PC, please try to transfer the multi-frame cine file in MP4 format or use a VLC media player.

You can select whether to hide patient info: if "Default Info" is selected, the patient name is hide after backup; if "Custom Info" is selected, the system prompts a message requiring you to input the customed patient name, which will be displayed after backup.

# 10.3 Report Management

You can create user-defined report templates using the UltraAssist tool and then import them into the ultrasound system to carry out specific measurements.

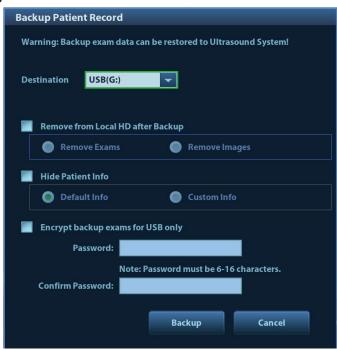
For details about this feature, see the UltraAssist manual.

Report storage:

Exam reports are stored under the patient exam directory.

- Importing, exporting and sending reports
  - Import/export reports via Backup

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



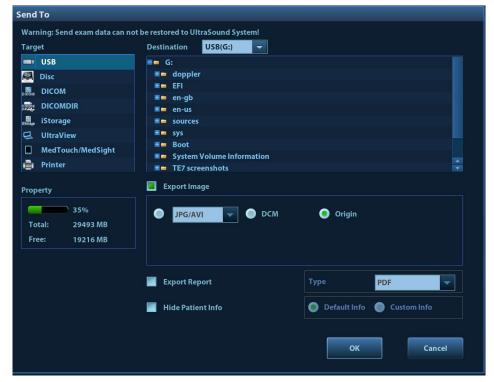
- 1) Select the destination.
- Select whether to remove from local HD after Backup: if "Remove Exams" is selected, the
  patient information and images are removed; if "Remove Images" is selected, only the
  patient images are removed.

- 3) Select whether to hide patient info: if "Default Info" is selected, the patient name is hide after backup; if "Custom Info" is selected, the system prompts a message requiring you to input the customed patient name, which will be displayed after backup.
- 4) Select whether to encrypt backup exams for USB only: input the password and confirm password in the field box, and then click [Backup]. A "Patient.7z" compressed package is backed up to the USB device, and you need to input the password to open the package.

Notes: 1. If the password is forgotten, you cannot open the backup package.

- 2. The password cannot be multi-language or Chinese characters.
- Export reports via Send To

In the iStation or Review screen, click [Send Exam] in the menu which appears to send patient data to an external memory device or iStorage. You can choose whether reports are exported with images. See the figure below.



To export reports:

- (1) Check "Export Report" on the screen.
- (2) Select the report type to be exported.
- (3)Select whether to hide patient info: if "Default Info" is selected, the patient name is hide after backup; if "Custom Info" is selected, the system prompts a message requiring you to input the customed patient name, which will be displayed after backup.
- (4) Click [OK] to confirm.

You can select the paper size for the report print in the path:  $[Setup] \rightarrow [Print]$ .

Report printing

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

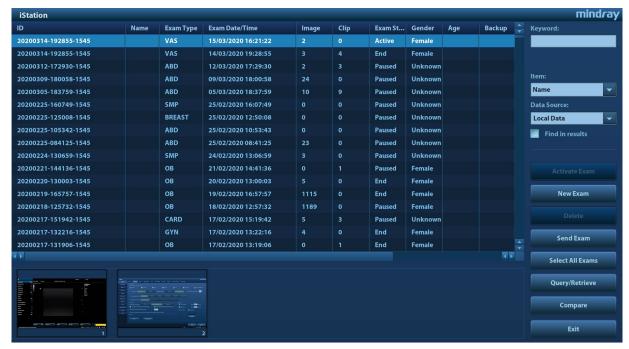
For details on report-related operations, see [Advanced Volume].

# 10.4 iStation - Patient Data Management

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

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

The iStation screen is shown as follows:



# 10.4.1 Viewing Patient Information

Data Source

Select the patient data's data source; the system patient database is the default.

■ Patient list

Display patient information, exam mode, number of images and cines, exam state, whether backed up or not.

New Exam

After you select a patient data or exam in the iStation screen, click the [New Exam] to enter the Patient Info screen where you can select the exam mode and click [OK] to begin a new exam.

■ Select All/Deselect All

Click [Select All] to select all the patient data listed. The button changes to [Deselect All]. Cancel all the selections by clicking [Deselect All].

# 10.4.2 Searching a Patient

1. Select the data source:

Click [Data Source] to select the patient data's data source; the system patient database is the default.

- 2. Set search conditions by Name, ID, DOB, Exam Date in the "Item" drop-down list.
- 3. Enter the keyword according to the "Item" selected.

4. When you select a patient in the patient list, images of this patient will be displayed at the bottom of the screen.

## 10.4.3 Patient Data View & Management

Select the desired patient information in the list. The following menu appears:



■ Review an Image

Select a patient exam, click [Review Image] to enter the Review screen.

■ Patient Information

Select a patient exam, click [Patient Info] to check the patient information for this exam.

■ Review Report

After selecting a patient exam, click [Review Report] to view the report of this exam for this patient.

- Delete Exam
  - Select an exam record, click [Delete Exam] to delete the record. You cannot delete patient data which is being printed, exported or sent, or delete the current exam.
  - To delete an image, select the image first and then click on the top right side. Or touch on the toolbar on the touch screen in touch screen mapping status. See "3.8.4 Touch Screen Operation" for details
- Backup/Restore

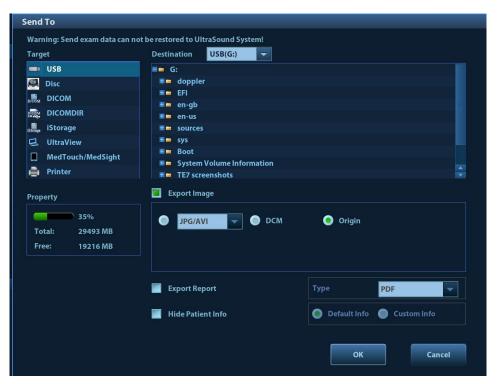
You can back up the selected patient data to the system-supported media in order to view it on the ultrasound system, or restore patient data to the system from an external media.

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

## ■ Send Exams

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

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



## 2. Select target:

- DICOM: send data or images to the storage server or send images to DICOM printer.
- DICOMDIR: back up data in DICOMDIR format; change the cine zoom mode, compression mode, and compression ratio.
- USB storage device or DVD-RW/DVD+RW drive: send exam to USB storage device or DVD-RW/DVD+RW drive.
  - Report format can be selected.
  - ➤ Format transfer is available when sending images to USB device or disk. See "10.2.12 Sending Image Files" for details.
- Print: send image to the connected printer to print.
   Press <Ctrl> or <Shift> with the <Set> key on the control panel to select more than one exam at a time.
- MedTouch/MedSight: send the exam to MedTouch/MedSight devices for review.

#### ■ New Exam

After you select a patient data or exam in the iStation screen, click the [New Exam] to enter the Patient Info screen where you can select the exam mode and click [OK] to begin a new exam.

## ■ Select All/Deselect All

Click [Select All] to select all the patient data listed. The button changes to [Deselect All]. Cancel all the selections by clicking [Deselect All].

#### Activate an Exam

After selecting an exam which has been performed within 24 hours, click [Activate Exam] to activate the exam and load the basic patient information and measurement data to continue the exam.

If you want to select patient data in an external memory database to start a new exam or recover the exam, first allow the system to load the patient data to the system's patient database.

### ■ Continue an Exam

Select an exam that has been paused within 24 hours, click [Continue Exam] to activate the exam and load the basic patient information and measurement data to continue the exam.

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

## ■ Recycle bin

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

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

- (1) Select items to be recovered in the list. Select operations:
- Click [Restore Items] to restore the item to iStation.
- Click [Delete] to delete the item permanently. The item can never be restored again.
- Click [Restore All Items] to restore all the items to iStation.
- Click [Empty Recycle Bin] to empty the recycle bin. All the items can never be restored again.
- (2) Click [Exit] to exit the Recycle Bin screen.

**NOTE:** If there are more than 200 records in recycle bin, the system will ask you to clear the bin or not. Mindray recommends you clear the recycle bin regularly.

# 10.5 iStorage

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

Open "[Setup] → [Network]→[iStorage]" to set the iStorage settings (see "12.9.1 iStorage Preset" chapter for details).

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

To use iStorage function, you need UltraAssist software in 2.0 version (with V1.0 network protocol); consult Mindray service engineer for details.

# **10.6** Print

## 10.6.1 Print Setting

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

- Print Service Setting
- 1. Open [Setup] → [Print] and select an existing printer service from the list.
- 2. Select the printer type in the Property box.
- 3. Set printing properties.
- 4. Click [Save] to confirm the setting and exit the preset page.
- User-defined shortcut key for printing

To use the <Print> key on the system's control panel, you may need to:

- 1. Press the <F10 Setup> key to show the Setup menu. Click the [System] item to open the [System] screen, and click the [Key Config] tab.
- 2. Click to select "Print" on the left. Click to select the desired print key on the right.
- 3. Click [Save] to exit the preset and make the settings effective. Press the <Print> key on the control panel to print.
- Output settings:

Open [Setup]  $\rightarrow$  [System]  $\rightarrow$  [Output], then select the video output mode: PAL or NTSC.

Open [Setup]  $\rightarrow$  [System]  $\rightarrow$  [Output], then select the digital output mode: Full screen or stand area.

## 10.6.2 Image Printing

Image printing is mainly achieved by video printer. For DICOM image printing, see the DICOM chapter.

- Modify a print service:
  - (1) Select an existing printer service from the list.
  - (2) Select the printer model, then set the properties in the Property box.
  - (3) Click [Save] to complete.
- Image print
- 1. Select the desired image in the iStation or Review screen.
- 2. Click the icon on the top right side of the image, and select the printer in the dialog box which appears.
- 3. Click [OK] to start printing.

See the accompanying printer manuals for more details.

## 10.6.3 Report Printing

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

- 1. Press <Report> to enter the report dialog box.
- 2. Select [Print] on the touch screen to print the report.

See the accompanying printer manuals for more details.

# 10.7 Back Up Files using the DVD Drive

The system supports writing data to CD/DVD using the DVD-RW/DVD+RW drive and reading data from CD/DVD on the PC.

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

- To write data to a CD/DVD:
  - (1) Put a CD/DVD in the tray.
  - (2) Select the data to be backed up. Select [Send Exam] or [Back up Exam] in the menu which appears. Select the target drive in the Send To or Back Up Patient Record dialog box.
  - (3) Click [OK] or [Back up] to begin writing when the symbol displays.
  - (4) After the writing process is complete, click to bring up the Disc Option dialog box, and select [Eject] to eject the CD/DVD.

Tip:

- Writing data using "Send To" supports the PC format transfer function, while CD/DVD writing using "Back Up" supports only system-relevant formats.
- The symbol indicates that the input CD/DVD is damaged or contains data in an incorrect format.

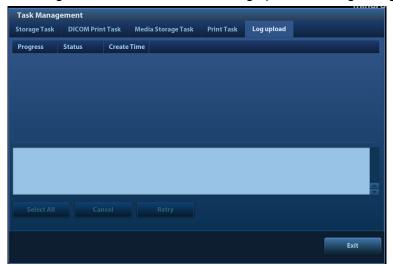
You can check the data writing procedure in the patient task manager. For details, see "10.8 Patient Task Management."

CAUTION:

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

# 10.8 Patient Task Management

Click in the bottom-right corner of the screen to bring up the following dialog box:



The system supports following types of task management:

- Storage Task: displays the DICOM storage task.
- DICOM Print Task: displays the DICOM print task.
- Media Storage Task:
  - DICOM media storage task (including disc and USB devices): in iStation screen, select the target exam and click [Send Exam], then click DICOMDIR in the menu which appears.
  - Back up task (system-relevant format): select the exam to be backed up in iStation and click [Back Up Exam].
  - Send to external devices (including disc and USB devices): select exam data or images in the iStation or Review screen. Click [Send Exam] or for the image.
  - iStorage task: in iStation screen, select the target exam and click [Send Exam], then click iStorage in the menu which appears.
  - MedTouch/MedSight storage task:
    - In iStation screen, send exam to MedTouch/MedTouch devices.
    - On review screen, iStation screen, thumbnail area, send the image(s) to MedTouch/MedSight devices.

- Log upload: displays log uploading tasks.
- Print Task: displays image or report printing tasks.

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

You can perform the following operations:

- Click [Delete] to delete the task.
- Click [Retry] to retry the failed task.
- Click [Select All] to select all the tasks.
- Task Status

When there are tasks underway, the task management icon displays as . Click the icon to check the process.

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

When the task management icon displays as **[**], it means no task is underway or has failed.

■ DICOM Service Setting

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

Troubleshooting

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

## 10.9 Administration

## 10.9.1 Access Control

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

Administrator

The system administrator can access all function modules, and view all patient data, such as patient information, images and reports, etc. Only one administrator is configured by default. The administrator can add or delete operators.

### Operator

The operator can only access the function modules with assigned privileges (for details about privilege assignment, please refer to "10.9.4 Local Privilege Management" and "10.9.5 LDAP Privilege Management"). The operator can only view exam information saved in the system and operated by him or herself, such as patient information, images and reports, etc. The operator cannot view exam data operated by others.

## 10.9.2 Enabling Access Control

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

Access control only can be set by the system administrator.

Setting access control:

- 1. Open the "Access Control" page using the path: [Setup] → [System] → [Access Control].
- 2. If Enable User Account Control is selected, you must be authorized before accessing the data, and you can configure password policy and LDAP, and change password. If unselected, you

can access all the data without authorization, and you cannot configure password policy and LDAP, and change password.

3. If \_\_\_\_\_\_ is selected, the administrator can edit privileges for emergency users. If unselected, the administrator cannot edit privileges for emergency users.

## 10.9.3 System Login

If access control has been set by the system administrator, you can access data in the system only after logging onto the system.

You must log in again after system restart or dormancy.

Logging onto the system:

1. The following dialog box appears:



- 2. Select the login type (Local or LDAP), and user name in the drop-down list.
- 3. Enter the password and click [Login].

To change users:

1. To log out the current user and change to another user, click in the bottom-right corner of the screen to bring up the following dialog box:



- 2. Click [Change User] to bring up the Login dialog box.
- 3. Select the login type, and user name in the drop-down list.
- 4. Enter the password and click [Login]

Lock the system

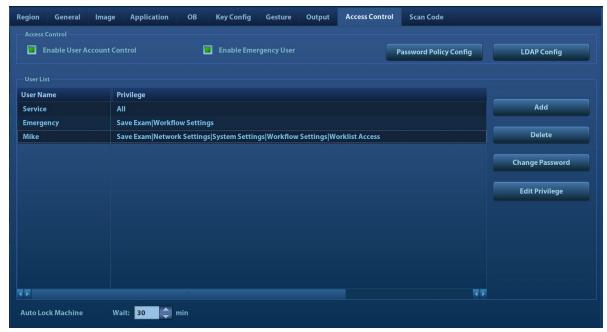
- 1. Click the in the bottom-right corner of the screen to bring up the dialog box.
- 2. Select [Lock Machine] and the system is locked. You must log on before using the system.

## 10.9.4 Local Privilege Management

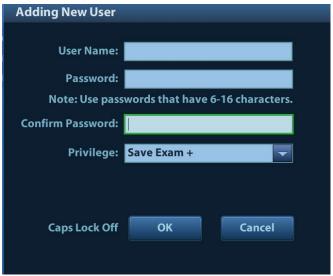
The system administrator can add and delete users, and assign privileges, while the operator cannot. The privileges can be assigned through the local system or LDAP server.

## Adding a User/ assigning privilege

Turn on the access control function and log in to the system as Administrator before you add the user.



- 1. Open the "Access Control" page using the path: [Setup]  $\rightarrow$  [System]  $\rightarrow$  [Access Control].
- 2. Click [Add] to bring up the dialog box.



- 3. Enter the user name and password, confirm password, and select or deselect the check box from the privilege list. Users can only access the function module with assigned privilege.
- 4. Click [OK] to confirm the setting and exit the dialog box. The new user and the privilege will appear in the User List.

#### Deleting a User

Turn on the access control function and log in to the system as Administrator before you delete the user.

- 1. Open the "Access Control" page using the path: [Setup]  $\rightarrow$  [System]  $\rightarrow$  [Access Control].
- 2. Select the user to be deleted in the User List. Click [Delete] to delete the selected user.

## **Editing privilege**

Turn on the access control function and log in to the system as Administrator before you edit privileges.

- 1. Open the "Access Control" page using the path: [Setup]  $\rightarrow$  [System]  $\rightarrow$  [Access Control].
- 2. Select a user, click [Edit Privilege] to enter the "Edit user privilege" dialog box, and select or deselect the check box from the privilege list.



3. Click [OK] to confirm the editing and exit the dialog box. The edited privileges will appear in the User List.

## **Modifying Passwords**

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

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

"Access Control" page (administrators can modify the password)

- 1. Open the "Access Control" page using the path: [Setup]  $\rightarrow$  [System]  $\rightarrow$  [Access Control"].
- 2. Select the user name to be modified in User List. Click [Change Password] to open the dialog box.



- 3. Enter both the previous and new passwords, and confirm the new password in the dialog box.
- 4. Click [OK] to exit.

Session Manage page (general operators and administrators can modify the password).

When the user has logged onto the system, is visible in the bottom-right corner of the screen.

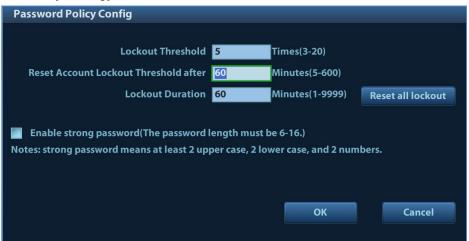
- 1. Click in the bottom-right corner to bring up the Session Manage dialog box where you can see the current user's information.
- 2. If you want to modify the current password, click [Change Password] to bring up the Change Password dialog box.
- 3. Enter both the previous and new passwords, and confirm the new password in the dialog box.
- 4. Click [OK] to exit.



## Configuring password policy

Turn on the access control function and log in to the system as Administrator before you configure the password policy.

Open the "Access Control" page using the path: [Setup] → [System] → [Access Control]. Click [Password Policy Config]:



Parameter	Description	Remark
Lockout Threshold	Set the maximum time that a user can input the wrong password. If you exceed the maximum times, your account will be locked.	For example, assume that the "Lockout Threshold" is set to 5, the "Reset Account Lockout Threshold after" is set to 60, and the "Lockout Duration" is set to 60. That is, a
Reset Account Lockout Threshold after	Set the duration allowed for a user to continuously input the wrong password.	

Parameter	Description	Remark
Lockout Duration	Set the duration after an account is locked.	user inputs the wrong password for 5 times within 60 minutes, the account is locked, and the user can log in to the system only after 60 minutes. Other users with unlocked accounts can still log in to the system normally.
Reset all lockout	Reset all locked accounts.	1
Enable strong password	<ul> <li>If the strong password is enabled and you log in to the system with the account that is added before the strong password is enabled, the system prompts a warning message to inform you whether your password conforms to the password policy.</li> <li>Warning</li> <li>Login succeeded.</li> <li>However, your password doesn't compty with password policy.</li> <li>To reset passwords, please go to Access Control preset to change the password.</li> <li>If the strong password is enabled and you add a new user account, the system prompt an error message to inform you that the password is too weak:</li> <li>Error</li> <li>Password is too weak!</li> <li>Password is too weak!</li> <li>Please modify the password according to the error message.</li> </ul>	

## Setting automatic machine locking time

Turn on the access control function and log in to the system as Administrator before you set the automatic maching locking time. Deselect [ScreenSaver] or [Standby] via [Setup]-> [System]-> [General].

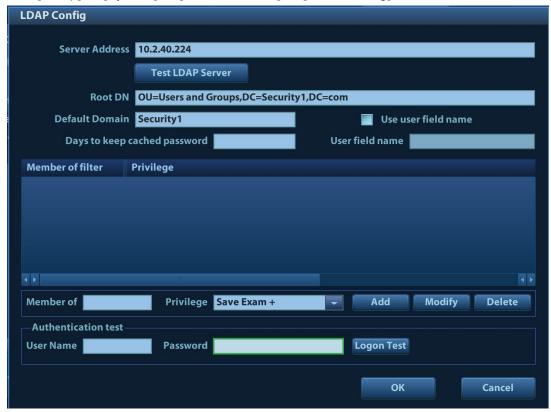
1. Open the "Access Control" page using the path: [Setup]  $\rightarrow$  [System]  $\rightarrow$  [Access Control].

- 2. Set the automatic machine locking time in the drop-down list beside "Auto Lock Machine".
- 3. Click [Save] to exit.
- 4. The system automatically locks the machine after exceeding the set time. In this case, you can unlock the current account or change users.

# 10.9.5 LDAP Privilege Management

Turn on the access control function and log in to the system as Administrator before you edit privileges for the LDAP (Lightweight Directory Access Protocol) users.

1. Enter [Setup]  $\rightarrow$  [System]  $\rightarrow$  [Access Control]  $\rightarrow$  [LDAP Config].



- 2. Enter the server address in the field box after accessing the network.
- 3. Click [Test LDAP server] to test whether the LDAP server is accessible. If the LDAP is accessible, the system prompts the following message "Server test succeeded."

Parameter	Description
Root DN	It is automatically displayed after the server is successfully tested.
Default Domain	The default domain is the DC name in the Root DN. For example, if DC=security1, then input "security1" in the field box of the "Default Domain"

Parameter	Description
	Set days to keep the cached passwords in the local system
	Users can log in to the server even without accessing the network within the setting days.
Days to keep cached password	<ul> <li>Empty: the passwords are kept in the local system permanently.</li> </ul>
	0: no passwords are kept in the local system.
	<ul> <li>&gt;1: for example, if it is set to 5, the passwords are kept in the local system for 5 days.</li> </ul>

#### Adding a user

- 1. Enter [Setup] → [System] → [Access Control] → [LDAP Config].
- 2. Enter the member name, and select or deselect privileges from the drop-down list of "Privilege".
- 3. Click [Add], and the new members and privileges will appear in the Member of filter list.

#### Deleting a user

- 1. Enter [Setup]  $\rightarrow$  [System]  $\rightarrow$  [Access Control]  $\rightarrow$  [LDAP Config].
- 2. Select a member to be deleted, and click [Delete].

#### Modifying the member name or privileges

- 1. Enter [Setup]  $\rightarrow$  [System]  $\rightarrow$  [Access Control]  $\rightarrow$  [LDAP Config].
- 2. Select a member to be modified, modify the member name, and select or deselect privileges from the drop-down list of "Privilege".
- 3. Click [Modify], and the modified member name and privileges will appear in the Member of filter list.

#### Logon test

- 1. Enter [Setup]  $\rightarrow$  [System]  $\rightarrow$  [Access Control]  $\rightarrow$  [LDAP Config].
- 2. Enter the User name and password in the field boxes of the Authentication test area.
- 3. Click [Logon Test] to test whether the user is authenticated. After successful authentication, the system prompt the following message:



#### User field name

- 1. Enter [Setup]  $\rightarrow$  [System]  $\rightarrow$  [Access Control]  $\rightarrow$  [LDAP Config].
- 2. Select [Use user field name] to customize the user field name. After that, the members and privileges cannot be edited.
- 3. Enter the user field name in the field box of the "User field name" (the user field names are configured in the LDAP server. For details, please refer to the LDAP server manual).

#### 10.9.6 User Field Name

The user field name corresponding to privileges are as follows:

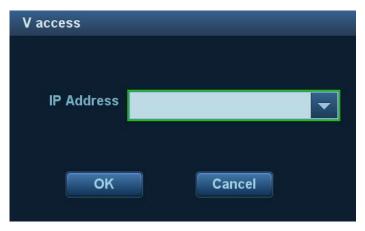
Privilege	User field name
iStation Access	1
Save Exam	2
Export Exam	4
Network Settings	8
Maintenance Menus	16
System Settings	32
Workflow Settings	64
Worklist Access	128

Note: the privilege items can be combined randomly. For example, if user A is assigned with all the above 8 privileges, the user field name for user A is 1+2+4+8+16+32+64+128=255.

# 10.10 V-Access

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

- Set the user-defined key via the path: [Setup] → [System] → [Key Config]. Select a key in the Key Function field on the left side, and select "V Access" in the Other page of the Function field on the right side.
- 2. Press the user-defined key to use the function.
- 3. The system brings up a dialog box for entering the IP address of the remote server.



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

# 11 DICOM/HL7

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

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

The DICOM package is optional. For details, see "2.5.3 Options".

This system supports the following DICOM functions:

- Verify Connectivity
- DICOM Storage
- DICOM Print
- DICOM Worklist
- MPPS (Modality Performed Procedure Step)
- Storage Commitment
- Query/Retrieve
- Structured Report
- DICOM Medium Storage (DICOMDIR Review)
- DICOM Task Management

DICOM Preset and Applications workflows are briefly described as follows:

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

#### ■ Terms

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

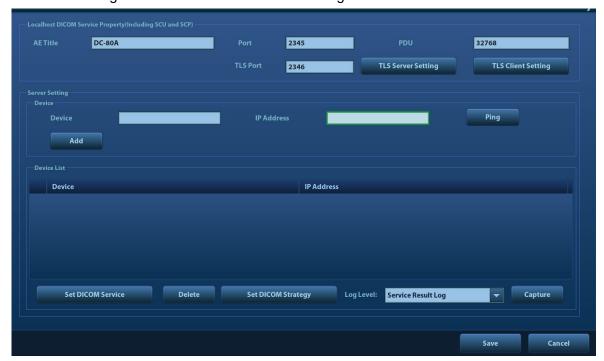
# 11.1 DICOM Preset

## **11.1.1 IP Preset**

See "Appendix D Wireless LAN" for details.

## 11.1.2 DICOM Local Preset

- 1. Enter the DICOM local preset screen using the path: [Setup]  $\rightarrow$  [DICOM/HL7].
- 2. Enter AE Title, Port and PDU according to the actual situation, then click [Save] to exit the screen. Setting items are introduced in the following.



Name		Description
AE Title		Application Entity title.
	Port	DICOM communication port.
PDU	Maximum PDU data package size, ranging from 16384 to 65536. If the value is less than 16384 or greater than 65536, the system automatically sets it to the value 32768.	
DICOM	TLS Port	Set the TLS port.
Local	TLS Server Setting	Import the encryption key/certificate.
	TLS Client Setting	After importing TLS certificates, and selecting Verify Certificate check box, the system verifies the effectiveness of the TLS function in the DICOM storage, print, and worklist services.  Import trusted certificates, or delete certificates.
Server	Device	Name of the device supporting DICOM services.
Setting	IP Address	IP address of the server.

ı	Name	Description
	Ping	You can ping other machines after entering the correct IP address.
	i ilig	You can also select a server in the Device list to ping it.
	Device List	Displays the added device.
	Set DICOM Service	Provides server settings of DICOM service. For details, see the following chapters.
	Add	Click to add servers to the Device List.
	Delete	Click to delete selected servers from the device list.
	Set DICOM Strategy	Click to enter the Configure The Strategy screen.
	Log Level	For angineer use only
Capture	For engineer use only.	

#### ■ Set DICOM Strategy

#### TIP:

- The DICOM strategy must be configured by qualified personnel with good knowledge of DICOM standards.
- The qualified personnel must ensure the validity of the DICOM strategy.

#### Perform the following procedure:

- 1. Click [Set DICOM Strategy].
- 2. Edit the DICOM strategy:
  - Add: Enter strategy name and description, and click [Add] to add a new strategy. Then the
    added strategy will be displayed in the Strategy List.
  - Delete: Select a strategy from the Strategy List, and click [Delete].
  - Update: Select a strategy from the Strategy List, enter strategy name or description again, and click [Update].

#### 3. Configure the item:

Select a strategy name from the Strategy List, and assign strategy items to the selected strategy.

- Add: Set the function from the drop-list box, enter the parament 1 and parament 2, and click [Add]. Then the added strategy item will be displayed in the Strategy Items List.
- Delete: Select a strategy item from the Strategy Items List, and click [Delete].
- Update: Select a strategy from the Strategy Items List, select the function or enter the parament 1/2 again, and click [Update].

#### Import/Export strategy:

 Import: Click [Import], browse the desired strategy file and operate according to the screen prompts.

The imported file type for DICOM strategy must be .xml.

 Export: Select a strategy from the Strategy List, click [Export], select the export path, and type the file name.

E drive is default, and the file type is .xml.

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

#### Tip:

The AE Title should be the same as the SCU AE Title preset in the server (PACS/RIS/HIS). For example, if the AE Title of the server preset in the storage server is Storage, and the AE Title of the accepted SCU is preset as Machine, then in the figure above, the AE Title of Local should be Machine, and the AE Title of the storage server should be Storage.

#### 11.1.3 Service Preset

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

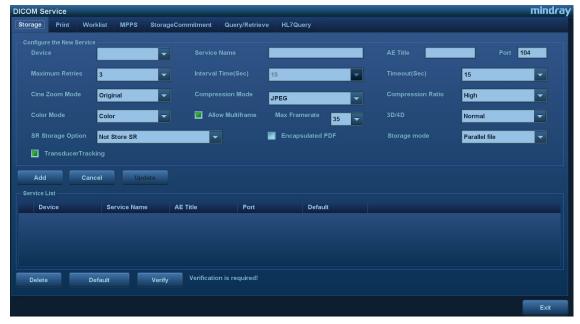
When the system is configured with the DICOM basic function module, and installed with DICOM Worklist, MPPS, DICOM structured reports and DICOM query/retrieve modules, the corresponding preset can be found in the DICOM Service screen.

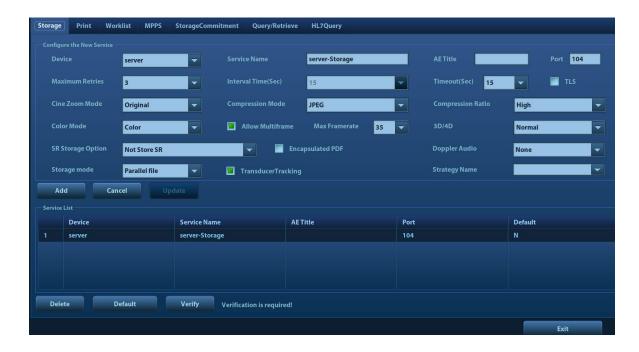
To open the DICOM Service screen:

- 1. Press the <F10 Setup> key to show the Setup menu.
- 2. Select [DICOM/HL7] and click [Set DICOM Service] to open the DICOM Service preset screen.

#### 11.1.3.1 Storage Service Preset

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





DICOM storage preset items are described as follows:

Name		Description
	Device	After setting the servers in the DICOM Preset screen, the names will appear in the drop-down list. Select the name of the storage server.
	Service Name	The default is xxx-Storage, user-changeable.
	AE Title	Application Entity title. It should be consistent with that of the storage server.
	Port	DICOM communication port, 104 is the default. The port should be consistent with that of the storage server port.
Configure New	Maximum Retries	Set the maximum retries (0-9). The default value is 3. If the DICOM task sending to the server fails, the retry times should be 3.
Service	Interval Time(Sec)	Interval time for the system to retry a connection.
	Timeout(Sec)	Refers to the amount of time after which the system will stop trying to establish a connection to the service.
	TLS	Transport Layer Security. Select whether to encrypt the data during network transportation.
	Cine Zoom Mode	Select the cine zoom mode during image file storage.
	Compression Mode	Select the compression mode: uncompressed, RLE (the image not compressed), JPEG and JPEG2000.
	Compression Ratio	Select the JPEG compression ratio: lossless, low, medium and high.

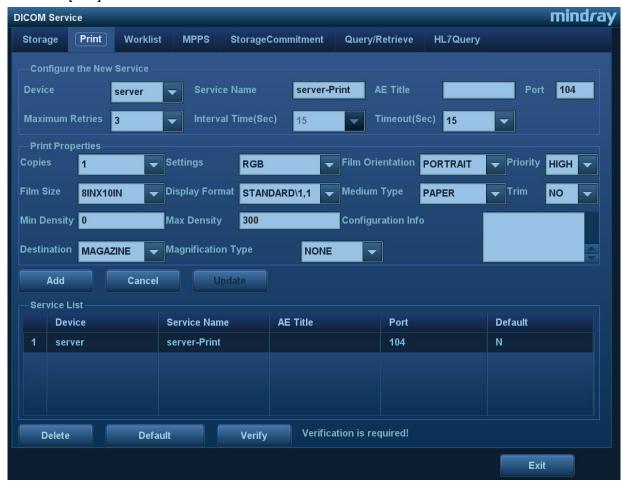
Name		Description
	Color Mode	Select the color mode.
		If you choose the mixed or the grey, RLE/JPEG is unavailable.
		The image uses 24 bit when sending the image from the ultrasound device to the server; it depends on the image when choosing the mixed. The image use 8 bit if the image is captured in color mode or the image has the tint. All images use 8 bit when choosing the grey.
	Allow Multiframe	If SCP supports this function, select it.
	Max Frame Rate	Set the frame range for transferring cine files to DCM multi-frame files. It is editable to the user.
		Set the 3D/4D image transfer mode.
		Set the transfer mode for the 3D/4D cine sending.
	3D/4D	<ul> <li>Normal: use the way that 2D image adopts to send;</li> </ul>
	557.5	<ul> <li>Volume: use Enhanced US Volume Storage IOD to send;</li> </ul>
		Raw Date: used to obtain 3D/4D image for 4D Viewer.
	SR Storage Option	To enable or prevent structured report sending.
	Encapsulated PDF	Select whether to encapsulate PDF format reports in DICOM standard.
		It becomes available if SCP supports the function.
	Doppler Audio	Set to save the audio of PW mode.
	Transducer Tracking	If this is ticked, files of images that are saved in DCM format through DICOM or DICOMDIR contain transducer serial number information.
	Storage mode	Set the storage mode for image and cine file:
		Parallel file: save the current file, and is ready for the storage of the next file.
		Parallel frame: send the current frame, and is ready for sending the next frame.
	Strategy Name	Set the DICOM strategy.
	Add	Add the DICOM service to the service list.
	Cancel	Click to cancel parameter setting.
	Update	Select an item in the service list, change the parameters in the above area, and click [Update] to update the item in the service list.
	Delete	Click to delete the selected service from the service list.
Service List	Default	Select an item in the service list. Click [Default] and you will see "Y" in the Default column.
	Verify	Click to verify that the two DICOM application entities are properly connected.

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

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

#### 11.1.3.2 Print Service Preset

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



DICOM print preset items are described as follows:

	Name	Description
	Device	After setting the servers in the DICOM Preset screen, the names will appear in the drop-down list. Select the name of the print server.
Configure New	Service Name	The default is xxx-Print, user-changeable.
Service	AE Title	Application Entity title. It should be consistent with that of the print server.
	Port	DICOM communication port, 104 is the default. The port should be consistent with that of the print server port.

Name		Description
	Maximum Retries	Set the maximum retries (0-9). The default value is 3. If the DICOM task sending to the server fails, the retry times should be 3.
	Interval Time(Sec)	Interval time for the system to retry a connection.
	Timeout(Sec)	Refers to timeout during association establishment.
	TLS	Transport Layer Security. Select whether to encrypt the data during network transportation.
	Copies	See copies of printed files. You can select from 1 to 5, or directly enter the number.
	Settings	The system supports RGB (color printing) and MONOCHROME2 (black and white printing). Please select the type the printer supports.
	Film Orientation	Select from between LANDSCAPE and PORTRAIT.
	Priority	Specify printing task priority from HIGH, MED and LOW.
	Film Size	Select film size from the selections listed in the drop-down list.
	Display Format	Specify the quantity of printed files, e.g., STANDARD\2, 3 indicates 6 images are printed for each page.
	Medium Type	Specify print medium: Paper, Clear Film, Blue Film. Select Blue Film or Clear Film for black and white printing; select Paper for color printing.
	Trim	Specify whether you want a trim box to be printed around each image on the film: Yes or No.
	Configuration Info	Enter configuration information in the field.
Print	Min Density	Enter the minimum density of the film.
Properties	Max Density	Enter the maximum density of the film.
	Destination	Specify where the file is exposed: MAGAZINE (stored in the magazine) or PROCESSOR (exposed in the processor).
		Select how the printer magnifies an image to fit the film.
		Replicate: interpolated pixels belong to duplicates of adjacent pixels)
	Magnification Type	Bilinear: interpolated pixels are generated from bilinear interpolations between adjacent pixels
		Cubic: interpolated pixels are generated from cubic interpolations between adjacent pixels
		None: without interpolation.
	TLS	Transport Layer Security. Select whether to encrypt the data during network transportation.
	Add	Add the DICOM service to the service list
	Cancel	Click to cancel parameter preset.
	Update	Select an item in the service list, change the parameters in the above area, and click [Update] to update the item in the service list.
Service	Delete	Click to delete the selected service from the service list.

Name		Description
List	Default	Select an item in the service list. Click [Default] and you will see "Y" in the Default column.
	Verify	Click to verify that the two DICOM application entities are properly connected.

#### 11.1.3.3 DICOM Worklist Preset

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

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

#### **11.1.3.4 MPPS Preset**

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

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

#### 11.1.3.5 Storage Commitment Preset

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

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

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

#### 11.1.3.6 Query/Retrieve Preset

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

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

#### 11.1.3.7 HL7Query Preset

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

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

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

Two special setting items for the HL7Query service are the Listen Port and Listen Mode, as described in the following. "Verify" function is not available under HL7Query preset. Other parameters are similar to those described in DICOM Storage Preset. See "11.1.3.1 Storage Service Preset" for details.

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

#### 11.1.3.8 Other Settings

You can configure different type of DICOM services in different scenarios. See "12.1.9 Admin" chapter for details.

# 11.2 Verify Connectivity

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

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

If verification failed, possible causes may be:

- The ultrasound machine cannot communicate normally with the server. Check that the cable is properly connected, or,
  - Check that the IP of the server is configured in the same segment as that of the ultrasound machine, or,
  - Check that the network adapter, router, exchanger and HUB are working normally.
- The server does not support the verification. If the connection is normal, it can be concluded that the server does not support the verification.
- The server supports the verification, but this function is not activated. Please check that the verification function is activated.

Tip:

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

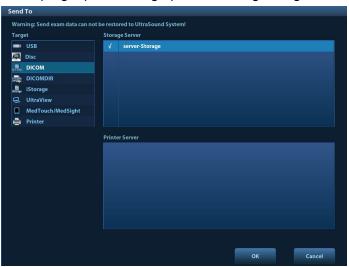
# 11.3 DICOM Services

If all the DICOM presets on the DICOM Service Preset screen are completed, you are ready for the Storage, Print, Worklist (HL7 Query), MPPS, Storage Commitment and Query/Retrieve applications.

## 11.3.1 DICOM Storage

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

- Send images on iStation/Review/main screens
  - (1) Select images
  - Press <iStation> on the control panel to open the iStation screen. Click to select a patient
    or an exam record in the list. Thumbnails are displayed in the thumbnail area in the lower
    part of the screen, then click to select a thumbnail or several thumbnails. Or
  - Press <Review> on the control panel to enter the Review screen. Click to select a thumbnail or several thumbnails. Or
  - On the main screen, select a thumbnail or several thumbnails.
  - (2) Click in the top-right part to bring up the following dialog box.



- (3) Click to select "DICOM" in the Target box on the left side, then select the DICOM storage server in the Storage Server box on the right side.
- (4) Click [OK] to start sending.
- To send images using a shortcut key

You can save single-frame images or multi-frame images to a DICOM server while saving to hard drive using a shortcut key. The procedure is as follows:

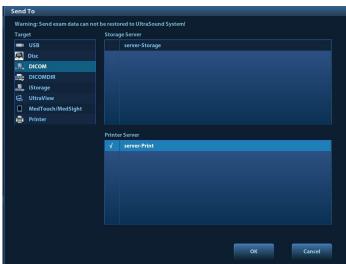
- (1) Define the key. For details, see "10.2.8 Auxiliary Output Function".
- (2) Set a default storage server:
  - a) Enter the DICOM Service Preset screen via "[Setup] $\rightarrow$  [DICOM Preset]  $\rightarrow$  [Set DICOM Service]."
  - b) Select a storage server in the Service List and click [Default]. You will see "Y" marked in the Default column.
  - c) Click [Exit] to exit the page and return to the Setup menu, then click [Save] on the Setup menu to make the preset take effect.
- (3) Press the key to send to DICOM storage.

- To send images to storage after an exam ends
  - (1) Open "[Setup]→ [System] → [General]" and then check
     Sending/printing after End Exam in the Patient Info area.
  - (2) Set a default storage server.
    - a) Enter the DICOM Service Preset screen via "[Setup] $\rightarrow$  [DICOM Preset]  $\rightarrow$  [Set DICOM Service]."
    - b) Select a storage server in the Service List and click [Default]. You will see "Y" in the Default column.
    - c) Click [Exit] to exit the page and return to the Setup menu, then click [Save] on the Setup menu to make the preset take effect.
  - (3) After finishing the presets, perform image scanning. Each time <End Exam> is pressed on the control panel, the system will send the image to the default DICOM storage server for storage.

#### 11.3.2 DICOM Print

DICOM Print is used to send images to the DICOM print server for printing.

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



- 3. Click [OK] to begin printing.
- To send images using a shortcut key

You can send single-frame images to a DICOM print server while saving to hard drive using a shortcut key.

- 1. Define the short key. For details, see "10.2.8 Auxiliary Output Function".
- 2. Set a default printer server.
  - a) Enter the DICOM Service Preset screen via "[Setup]  $\rightarrow$  [DICOM Preset]  $\rightarrow$  [DICOM Service]."
  - b) Click [Print] to open the Print page.
  - c) Select a Print server in the Service List and click [Default]. You will see "Y" marked in the Default column.
  - d) Click [Exit] to exit the page and return to the Setup menu, then click [Save] on the Setup menu to make the preset take effect.

- 3. Press Key1 (defined as the shortcut key for Save Image to Hard Disk and Send to DICOM Printer). The system captures the current screen and sends it to the print server.
- To print images for storage after an exam ends
  - (1) Open "[Setup]→ [System] → [General]" and then check
    Sending/printing after End Exam in the Patient Info area.
  - (2) Set a default print server.
    - a) Enter the DICOM Service Preset screen via "[Setup]→ [DICOM Preset] → [DICOM Service]."
    - b) Click [Print] to open the Print page.
    - c) Select a Print server in the Service List and click [Default]. You will see "Y" marked in the Default column.
    - d) Click [Exit] to exit the page and return to the Setup menu, then click [Save] on the Setup menu to make the preset take effect.
  - (3) After finishing the presets, perform image scanning. Each time <End Exam> is pressed on the control panel, the system will send the image to the default DICOM print server for printing.

#### 11.3.3 DICOM Worklist

For details, see "4.1.2.2 Worklist".

#### 11.3.4 MPPS

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

The status information is described as follows:

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

## 11.3.5 Storage Commitment

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

Before using storage commitment, set the associated storage service.

- Storage commitment after sending images on the iStation screen.
- 1. Open the iStation screen.
- 2. Select an exam (a suspended exam or an inactive exam) (images are stored in the exam record). Click the [Send Exam] button in the menu which appears to open the Send To dialog box.
- 3. Click to select "DICOM" in the Target box on the left side, then select the DICOM storage server in the Storage Server box on the right side.
- 4. Click [OK] to start sending. The system will send all the images stored in the exam record to the storage server. Meanwhile, it will send storage commitment to the storage commitment server.

- To send storage commitment after an exam ends
- Open [Setup] → [System] → [General], then check in the Patient Info area.
- 2. Set the default storage server and storage commitment server.
  - a) Enter the DICOM Service Preset screen via "[Setup] → [DICOM Preset] → [Set DICOM Service]."
  - b) Set a default server in the Storage page and set an associated storage service in Storage Commitment page.
  - c) Click [Exit] to exit the page and return to the Setup menu, then click [Save] on the Setup menu to make the preset take effect.
- 3. After finishing the presets, perform image scanning. Each time <End Exam> is pressed on the control panel, the system will send the image to the default DICOM storage server for storage and send storage commitment to the storage commitment server.

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

Tip:

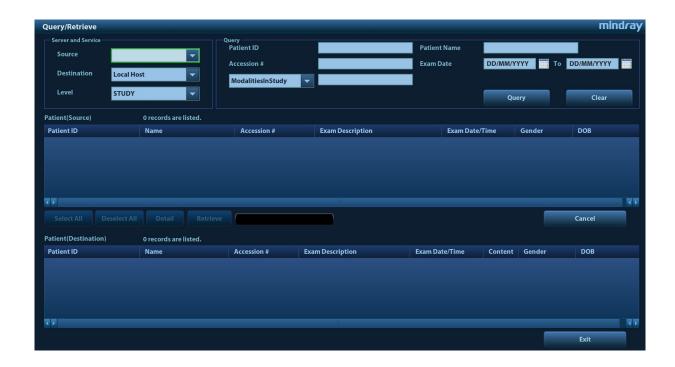
Storage commitment is confined to the whole exam. Not each image sending can be indicated.

NOTE: Multi-frame storage is not allowed if "Allow Multiframe" is not selected ([Setup] → [DICOM/HL7] → [Set DICOM Service] → "Storage"). For example, even if there is a multi-frame file in the exam to be sent, only single-frame image storage will be performed. After the storage is complete, there is no "√" marked in the list below in the iStation screen.

## 11.3.6 Query/Retrieve

The query/retrieve function is used to query and retrieve patient exam records in a designated server. After setting the DICOM query/retrieve server, you can perform the query/retrieve function in the iStation screen.

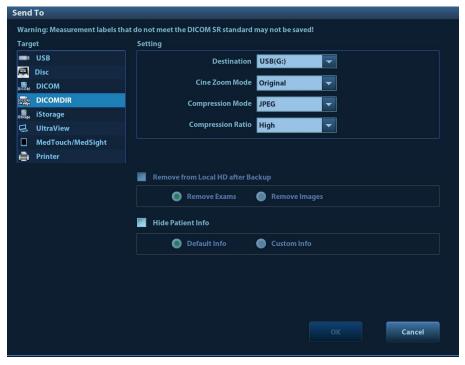
- 1. Open the iStation screen: press <iStation> on the control panel.
- 2. Click [Query/Retrieve] to open the screen.



- Select the server in "Server and Service" area (source, destination, and level).
   Select Level from the drop-down list:
  - Study: search by exams;
  - Series: search by file types, such as US or SR.
- 2. Enter the query information, such as Patient ID, Patient Name, Accession #, Exam Date, or other patient properties from the drop-down list.
  - Click [Clear] to empty the entered query information.
- 3. Click [Query], the system performs the query and lists out the results into the patient (source) list.
  - You can perform further query basing on the results by entering new query information.
- 4. Select one or more patient records according to the actual situation.
  - Click [Select All] to select all the patient records in the list.
  - Click [Deselect All] to deselect all the patient records in the list.
- 5. Click [Retrieve] to retrieve the patient records in the DICOM query/retrieve server into the local machine.
- 6. Click [Exit], you can see the retrieved patient records are listed in the iStation screen.

# 11.4 DICOM Media Storage

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



#### **Media Storage**

- 1. Select patient records in the iStation screen.
- 2. Click [Send Exam] in the menu which appears to open the dialog box.
- 3. Select the destination to "DICOMDIR", cize zoom mode, compression mode, and compressiom ratio. You can select to delete the exam or the image after the backup, and select to hide patient information.
- 4. Click [OK] to begin the storage.

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

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

#### **Data Restore**

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

- 1. Connect the external media containing DCM files to the system.
- 2. In iStation, review the data stored on the external media.
- 3. Select the data to be restored in iStation.
- 4. Click on the iStation screen.

**NOTE:** Only system-accessible media can be selected.

# 11.5 Structured Report

DICOM OB/GYN Structured reports, Cardiac Structured reports, Vascular Structured reports, Breast Structured reports, and Abdomen Structured reports are supported by this system. They can be sent together with the exam only.

- Send images and structured reports for storage in the iStation screen
  - (1) Select "Attach SR when store images" or "Only Store SR" on the DICOM Storage preset page. For details, see "11.1.3.1 Storage Service Preset."
  - (2) Create new patient information or load scheduled patient information.
  - (3) Perform measurements.
  - (4) Save the images.
  - (5) End the exam.
  - (6) Open the iStation screen, select the patient exam, and click the corresponding [Send Exam] button in the menu which appears in order to open the Send To dialog box.
  - (7) Click to select "DICOM" in the Target box on the left side, then select the DICOM storage server in the Storage Server box on the right side.
  - (8) Click [OK]. Check for the result in the DICOM Task Management dialog box. After successful storage of both the image and structured report, you will see the storage commitment mark "√" in the list below in the iStation screen.

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

Back up structured report

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

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

# 11.6 Showcase Recording

Showcase software can be employed for DICOM image file viewing.

When files and structured reports are saved in DCM format through DICOMDIR and sent to storage devices, the showcase can be sent to the storage devices together. Connect the storage device, and the user can view files in DCM format through showcase.

NOTE: To view the DCM files successfully, it is suggested to install NET Framework (Visual Studio.Net) of a version later than 2.0, if your computer was installed with TortoiseSVN.

# 11.7 DICOM Task Management

DICOM Task Management is used for viewing task progress or managing tasks after sending images for storage, printing or media storage. For details, see "10.8 Patient Task Management."

# 12 Setup

The Setup function is designed to set the configuration parameters of operating the system and maintaining user workflow setup data. The setup data of the user and system are stored to the hard drive, and should be backed up to CD/DVD or USB memory device.

**△ CAUTION**:

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

■ To enter Setup:

Press the <F10 Setup> key on the keyboard to enter the setup menu.

■ To exit Setup:

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

Select [Cancel] in the Setup menu or press <ESC> to close the Setup menu.

When you change the system language and click [OK] in the Setup menu, the system automatically shuts down to make the modification effective.

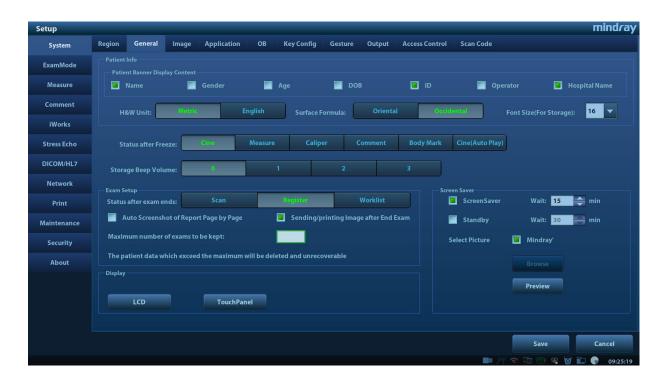
Basic operations

The commonly-used setting types are:

- Text box: position the cursor over the corresponding field box. Enter the desired value using the keyboard or soft keyboard on the soft menu.
- Radio button: click the button to select an item.
- Check box: click the checkbox to select one or more options.
- Drop-down list: click the arrow beside the list to select an item.

# 12.1 System Preset

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



Page	Description
Region	To set the hospital name, language, time zone, time format and system date/time.
General	To set patient information, exam setup, system dormancy, display and so on.
Image	To set general parameters in imaging modes.
Application	To set the measure ruler, measure setting, follicle method, comment setting and so on.
ОВ	To set the relevant information about fetal gestational age, fetal growth formula and fetal weight.
Key Config	To assign functions to footswitch and the user-defined keys.
Gesture	Preset the gesture on the touch screen.
Output	Set the output format, the range and the resolution for the image.
Access Control	To set the user account control relevant information.
Scan Code	To set the code parameters for barcode reader.

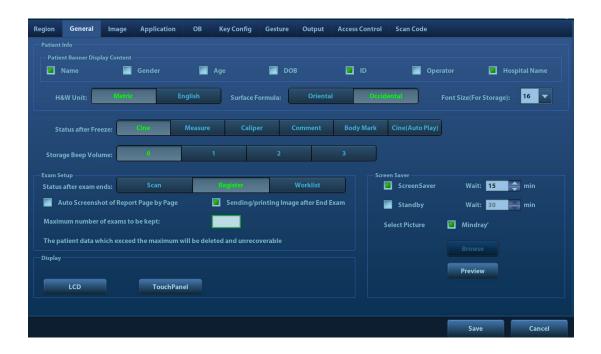
# 12.1.1 Region

Open the Region page via [Setup]  $\rightarrow$  [System]  $\rightarrow$  [Region].

Item	Description
Hospital Information	To set the hospital-relevant information such as name, address, telephone, and so on.
Language	To select a language (input) for the system.
Load Logo	Import image for logo loading.  NOTE: For a better display effect, please try to use an image with 400*400 pixels.
Time Zone	To select the time zone.
Time Format	To select the time format.
Date Format	To set the date format.
System Date	To set the date for the system.
System Time	Move the cursor over the corresponding field and enter the time manually using the keyboard, or, move the cursor over the time segment and press <set>, then increase or decrease the required value by clicking the icons on the right side.</set>
Time Sync	To assign a time server and make the time of the ultrasound machine consistent with the server.

## **12.1.2** General

Open the page via [Setup]  $\rightarrow$  [System]  $\rightarrow$  [General].

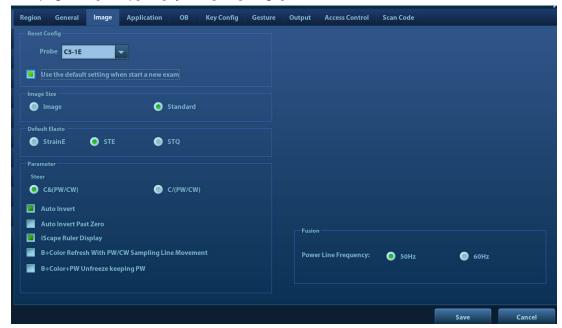


Туре	Item	Description
	Patient Banner Display Content	To select if to display the available patient information items on the screen.
Patient Info	H&W Unit	To set the unit for patient height and weight.
	Surface Formula	To set the surface formula.
	Font Size (For Storage)	To set the font size of the patient information
Freeze Setting	Status after freeze	To set the system state after the image is frozen.
Storage Volume	Storage Beep Volume	Set the key volume for saving single / multi-frame image.
	Status after exam ends	To set the system status when an exam ends.
Exam Setup	Auto Screenshot of Report Page by Page	After selected, perform measure application and save single frame image, then end the patient exam, the system will save the report image in iStation.
	Maximum number of exams to be kept	To set the maximum number of exams to be kept in iStation.
	Sending/printing after End Exam	Select if to automatically archive the exam data to DICOM server for storage/print.
Display	LCD	To set the brightness and the contrast of the main screen, or restore to the default.
Display	TouchPanel	After selection, the system restores the touch screen settings back to factory.

Туре	Item	Description
Screen Saver Screen		Select the different saver methods to the system.
		After enabling the screen saver, check "Mindray" to select the image from the system. Or click [Browse] to select the image on your own. Click [Preview] to preview the screen saver image.
	Screen Saver	To set the waiting time before the system enters dormancy status in the drop-down list beside "Wait".
		The system enters screen saver automatically if the system waiting time exceeds the screen saver already set.
		The system enters screen saver automatically if the system waiting time exceeds the screen saver already set and standby time.

# 12.1.3 Image Preset

Open the page via [Setup]  $\rightarrow$  [System]  $\rightarrow$  [Image].



Туре	Item	Description
		To set the default probe model for the system from the drop-down list.
Reset Config	Probe	The default parameters are applied to the new probe if checking <i>Use the default setting when start a new exam.</i>
Image size	1	Set the standard for saving the image or using the digital/graph printer.
Default Elasto	1	To set the default elasto imaging mode for the system.

Type	Item	Description
	Steer	To set the steer mode in B+ Color +PW/CW imaging mode.  C&(PW/CW): select to adjust the sample volume in color mode and sample line in PW or CW mode together.  C/(PW/CW): select to adjust the sample volume in color mode and sample line in PW or CW mode individually.
Image	Auto Invert	The spectrum can automatically invert when the color flow is steered to a certain angle, thus accommodating operator's habit of distinguishing flow direction.
	Auto Invert Past Zero	Set smart invert mode of Color Map.
	B+Color Refresh with PW/CW Sampling Line Movement	To set whether to turn on the function that when moving PW/CW sampling line, B+Color image is activated under B+Color+PW/CW mode.
	B+Color+PW UnFreeze keeping PW	To set whether to retain PW images when unfreezn under B+Color+PW mode.
	iScape Ruler Display	To set if to display the iScape ruler on iScape imaging mode.
Fusion imaging	Power Line Frequency	Select the power frequency.

# 12.1.4 Application

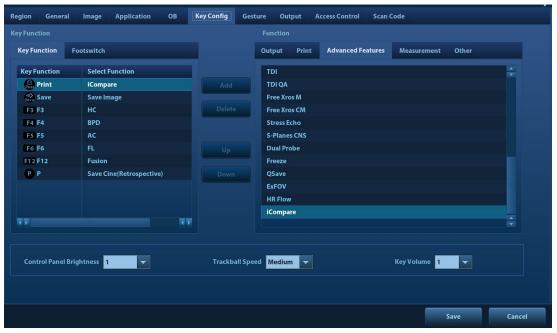
Open the page via [Setup]  $\rightarrow$  [System]  $\rightarrow$  [Application]. On this page, you can set the measurement ruler and relevant information. For details, see the Operator's Manual [Advanced Volume]

### 12.1.5 **OB Preset**

Open the page via "[Setup]  $\rightarrow$  [System]  $\rightarrow$  [OB]." On this page, you can set the gestational age formula, fetal growth formula, fetal weight formula and relevant information. For details, see the Operator's Manual [Advanced Volume].

# 12.1.6 Key Configuration

Open the page via "[Setup]  $\rightarrow$  [System]  $\rightarrow$  [Key Config]."



#### Key function setting

You can set the functions for <Save>, <Print>, user-defined keys (including F3, F4, F5, F6, F12 and P) and two-finger gesture. See "3.8.4 Touch Screen Operation" for details about two-finger gesture operation.

To assign a function to a key:

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

#### Foot switch function setting

You can assign a function to the left/middle/right key of the foot switch. The method is similar to setting key functions. See the steps above.

#### Other Settings

Item	Description
Key Volume	To set the key volume at 3 levels, 0 means no sound.
Control Panel Brightness	To set the brightness for the control panel.
Trackball Speed	To set the speed of the trackball when moving the trackball.

#### 12.1.7 **Gesture**

The gesture setting is the same with the settings of other keys. See Chapter "12.1.6 Key Configuration" for details.

# 12.1.8 Output



Туре	Item	NOTE
		Set the image quality of unloaded AVI. The system unloads according to the settings.
AVI encode	Image quality	The higher the image quality is, the clearer the unloaded image is. The unloading speed become slower with the larger space.
	Operating System	Set the unloading format of the AVI. The system unloads according to the settings.
	Compatibility	If checking "Mac OS", saving CIN files to USB flash drive as "MP4 Video".
Analog output mode	Select the format to output/separate the video format: NTSC or PAL.	
Digital Output Size	Output Size	Select the HDMI output area.
Retrospective Cine Length/ Prospective Cine Length	To Set the maximum times and beat (heart cycle) of retrospective or prospective cine.	

## 12.1.9 Admin

Open the page via "[Setup]  $\rightarrow$  [System]  $\rightarrow$  [Admin]." For details, please refer to "10.9 Administration"

## 12.1.10 Scan Code Preset

See "Appendix B Barcode Reader" chapter for details.

# 12.1.11 Biopsy

Open the Biopsy page via "[Setup]  $\rightarrow$  [System Preset]  $\rightarrow$  [Biopsy]".



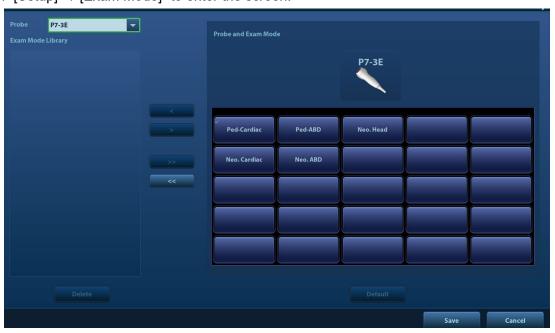
Parameter setting

Guide Line Dot Type: Small, Medium, Large.

Grid Size: 2x2, 4x4, 6x6. Grid Type: Circle, +, X, Dot.

## 12.2 Exam Mode Preset

Open "[Setup]  $\rightarrow$  [Exam Mode]" to enter the screen.



You can assign available exam modes for probes.

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

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

On the right side of the screen, you can view the current exam modes assigned to the probe.

- Select the exam from the Exam Library on the left and click [>] to add it to the Exam Mode Selected.
- Click [<<] to delete all exam modes in the Exam Selected area.</li>
- To delete an exam supported by the current probe, first select the exam and then click [<]
  to delete it.</li>

- Click [Delete] to delete a user-defined exam in the Exam Mode Library area.
- Click [Default] to set a selected exam mode as the default exam mode. The default exam mode is marked by a " $\sqrt{}$ " in the top-left corner.

# 12.3 Measurement Preset

For details about Measurement Preset, see the [Advanced Volume].

## 12.4 Comment Preset

Comment Configure

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



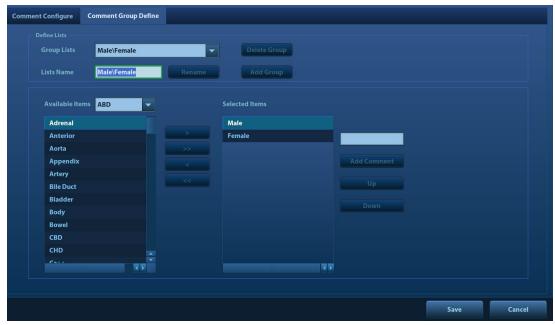
- 1. Add comments: directly enter user-defined comment texts, or select available items (select comment texts for the comment library or select comment in groups).
  - Directly enter user-defined comment texts: posit the cursor in the field box above [Add Comment], enter the text comment through the keyboard, and then click [Add Comment].
     Then the directly-entered comment will be added to the Available Items and Selected Items.
  - Select available items: First select a comment library and "Comment" from the drop-down lists beside "Available Items", and then all items will be displayed below "Available Items".
     Or Select "Group" from the drop-down list beside "Available Items", all groups will be displayed below "Available Items".
    - ➤ Click [>] to add the item in Available Items on the left into Selected Items on the right.
    - Click [>>] to add all items in Available Items on the left into Selected Items on the right.
- 2. Change position of the selected items: select an item on the right side box and click [Up], [Down], [Left] or [Right] button to change the position of the item.
- 3. Withdraw or delete a user-defined comment:
  - Withdraw an item (from the library or user-defined) in the Selected Items list:
    - > Click [<] to withdraw selected Items to the Available Items list.
    - ➤ Click [<<] to withdraw all items in Selected Items.

• Delete a user-defined item in the Available Items box: You can only delete the user-defined items rather than the items in the system library. After a user-defined item is deleted, it will not be available.

Select a user-defined item in the Available Items box, and click [<].

- 4. List Config: select a desired group from the drop-down list.
- 5. After you customize comments, click [Save] to confirm and exit the screen.
- Comment Group Define

You can add user-defined comment group for current exam mode. The groups in the library are provided by the system or user-defined ones.



- 1. Add groups: posit the cursor in the field box near [Lists Name], enter the group name through the keyboard, and then click [Add Group]. Then the entered group will be added to the Group Lists.
- 2. Rename groups: select a user-defined group, enter the group name through the keyboard, and then click [Rename]. Then the new group name will be displayed in the group lists.
- 3. Delete groups: select a user-defined group, click [Delete Group]. After a user-defined group is deleted, it will not be available.
- 4. Add comments to groups: the operation is the same to that of the "Comment Configure" tab.
- 5. Change position of the selected items: the operation is the same to that of the "Comment Configure" tab.
- 6. After you customize groups, click [Save] to confirm and exit the screen.

Note: You can rename, add comment to, delete comment from, or change position of the selected items in the user-defined groups, while system standard groups cannot be modified

# 12.5 iWorks Preset

For details, see "Appendix C iWorks."

# 12.6 Stress Echo Preset

For details, see "5.14.5 Maintenance and Protocol".

# 12.7 DICOM/HL7 Preset

For details, see "11.1 DICOM Preset."

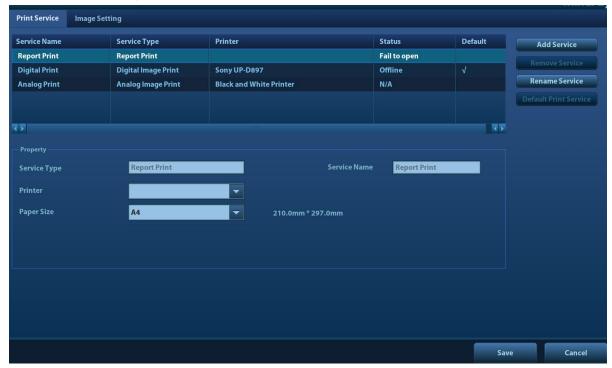
# 12.8 Print Preset

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

Click [Print] in the preset menu to enter.

Printer setting

The printer settings include print service and print driver.



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

For details about adding printers, see "3.7 Installing a Printer."

#### Image Settings

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

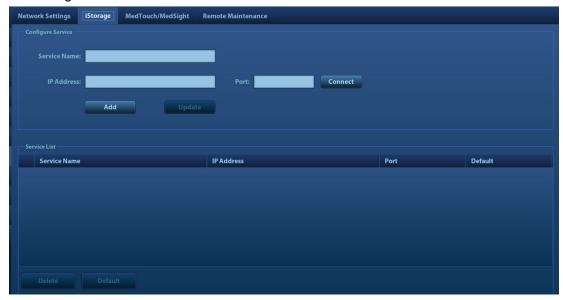
# 12.9 Network Preset

Parameters for transferring are set here. For details of local IP setting, see "Appendix D Wireless LAN".

# 12.9.1 iStorage Preset

You can send exam data or images to the iStorage server and perform analysis using UltraAssist. For details about this feature, see the UltraAssist manual.

The iStorage screen is as follows:

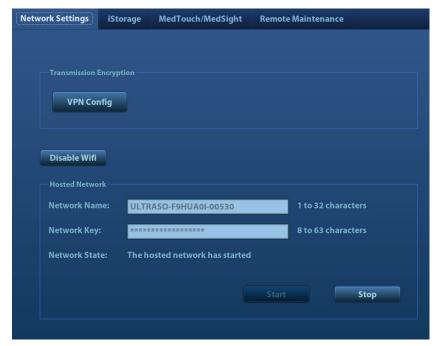


Name	Description	
Service Name	The name of the iStorage service.	
IP Address	IP address of the iStorage service device.	
Port	Port for transmitting.	
Connect	Click to verify connection.	
Add	Click to add the Network service to the service list.	
Update	To save the changed parameters.	
Delete	Click to delete the selected service from the service list.	

- Add an iStorage service
- 1. Set the iStorage server properties as described above.
- 2. Click [Add] to add the service to the Service list.
- Modify a network service
- 1. Select the service to be updated in the service list.
- 2. You can see properties in the Configure Service area.
- 3. Modify the parameters and click [Update] to update the setting.

# 12.9.2 Network Settings

The Network Settings screen is as follows:



#### ■ Transmission Encryption

After accessing the network, click [VPN Config] to enter the "VPN Config" interface.



Parameter	Description
	No driver: click [SetupDriver] to enter the "TAP-Windows 9.21.2 Setup" interface, and do as instructed.
	Ready: the VPN is ready for use.
Status	Advance: VPN Advance Configuration
	Connected: VPN is successfully connected.
	Disconnected: VPN is disconnected.
	Error: error connection.
Server IP	
Group	
User Name	
Password	

Parameter	Description		
Hide characters	The password is displayed as *.		
Connect/ Disconnect	Connect or disconnect VPN.		
	Enters the "VPN Advance Config" interface.		
	VPN Advance Config		
Advance	If click config and no response, please click reset  Reset  Config		
	Reset: if the system does not respond after you click [Config], click [Reset].		
	Config: enters the "OpenConnect-GUI VPN client" interface. For details about the settings, please refer to the TAP manual.		
	Note: after exiting the "VPN Advance Config" interface, you need to reboot the system; otherwise, you cannot connect VPN normally.		
Close	Close the "VPN Config" interface.		

#### Turn on hosted network function:

You can set the system as a hotspot. When other devices (with available wireless network function) are connected to the system, DICOM, iStorage and network print function can be implemented this way.

- 1. Select [Network Settings] page in Network Preset screen.
- 2. Confirm the Wi-Fi is enabled: you see [Disable Wifi] in the screen.
- 3. Enter the name and password for this hotspot in the Hosted Network box.
- 4. Click [Start] to enable the function.
- 5. Use other devices to search and connect to this network.

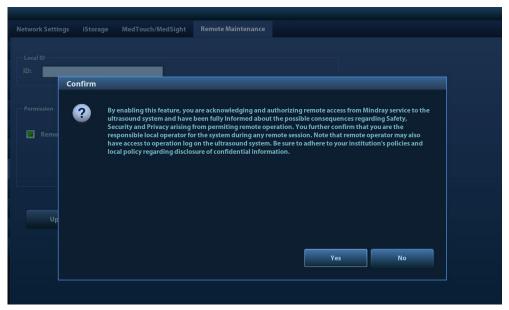
## 12.9.3 MedTouch/MedSight Preset

You can set environment for MedTouch/MedSight here and then use the MedTouch/MedSight function by mobile phone or tablet computers. See MedTouch/MedSight manual for details.

## 12.9.4 Remote Maintenance

1. Press <F10> to enter the Setup interface, choose [Network]→[Remote Maintenance], and select [Remote Maintenance Permission].

Risk Explanation	After the remote maintenance permission is enabled, it indicates that the ultrasound equipment permits remote access from the remote controller to upgrade the equipment, transmit files, or check and download logs.
	Once enabled, the remote maintenance permission is enabled by default after restarting the ultrasound equipment.



2. Select [Upload logs to remote server] to upload logs to the remote server, Mindray service engineers can acquire and handle those log.

Check the process in "task management" page, please refer to 10.8 Patient Task Management.

## 12.10 Maintenance

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

The [Maintenance] function is designed for you to import or export user data, restore factory setting and export log. You may also execute self-test and option installation/trial through the maintenance menu.

If you require other maintenance functions, please contact Mindray Customer Service Department or sales representative.

## 12.10.1 Option

The system enters the Option page after entering the Maintenance screen. In the Option list, the system lists all the system-supported options and their installation status (not installed or installed).

- Install and uninstall
  - Click [Install] to begin installing a disabled option.
  - Click [Uninstall] to begin uninstalling a previously-installed option.

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

## 12.10.2 Exporting Setup Data

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

You can select 3 types of preset data to export from the system:

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

#### Procedures:

- 1. Select the target module.
- 2. Click [Export] to open the [Export All Data] screen.
- 3. Select the path to save the data.
- 4. Select the exported file and type as PDP and click [OK].

## 12.10.3 Importing Setup Data

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

#### Procedures:

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

## 12.10.4 Probe Check

This function enables users to check if a transducer element is in malfunction, so as to evaluate the transducer performance.

- Click [Probe Check] to open the Probe Check screen. The system automatically performs
  probe check to the element of the currently activated probe. If a transducer element is in
  malfunction, it is displayed as a red spot. If a transducer element functions well, it is displayed
  as a green spot.
- You can export the result image to the external device.



Notes: Each time a transducer is connected to the main system or activated, the users are recommended to implement probe check of transducer performance.

Before probe check, make sure the probe is clean and not being used for scan.

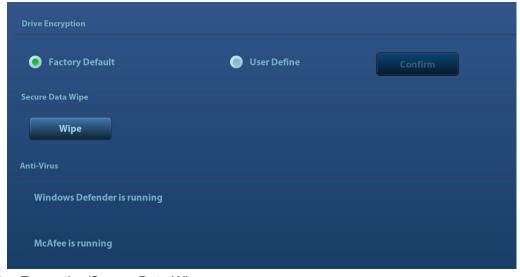
## 12.10.5 Other Settings

Item		Description	
	Export Log	Export the log.	
	Self Test	Perform system self-test and restart the machine.	
	Recover	Recover the ultrasound system (including Operating System and Doppler).	
	Enter Windows	For this function, you need a one-time password, please contact the service engineer or your agent.	
Setup	Prepay Installment	Entrance of prepay of payment function.	
	Start/Stop WinProxy	Cursor debug interface.	
	Fast Startup	To speed up the startup process.  Note: After installing McAfee, please disable the Fast Startup function to avoid McAfee failure.	

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

## 12.11 Security

Click [Security] on the Setup menu to enter the security-setting screen.



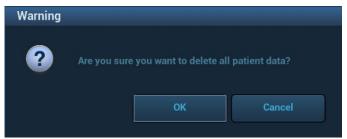
1. Drive Encryption/Secure Data Wipe

Encrypt the patient data stored in the hard disk. The system provides two encryption methods: Factory Default and User Define.

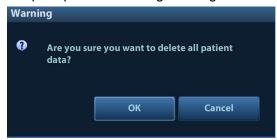
- Factory Default: the system is in factory state by default.
- User Define: add a user-defined password.
- Select [User Define]. If the patient data are already stored in the hard disk, the system prompts the following message: (if no patient data are stored in the hard disk, perform steps 5 to 6 directly)



2) Click [OK] to return to the Security screen, click [Wipe], and the system prompts the following message:



3) Click [OK], and the system prompts the following message:



- 4) Click [Yes] to wipe the patient data.
- 5) Select [User Define] and click [Confirm].
- 6) Input the password and click [Confirm] to finish the password setting.

Notes If you want switch to Factory Default, perform steps 1 to 6 again. The password is the same as that of the User Define.

#### 2. Anti-Virus

The system provides two pieces of anti-virus software: Windows Defender and McAfee. They can effectively prevent the ultrasound system from being attacked by virus, spyware, or other malware.

- Windows Defender is already installed on the system.
- The McAfee software is an option. If the McAfee software is installed, the system displays "McAfee is running". If you want to buy McAfee, contact Mindray representatives.

Notes:

- 1. McAfee cannot be uninstalled after successful installation.
- 2. After the option is installed, the system will be restarted. And after restart, the system installs McAfee automatically, which needs about one hour.

## 12.12 System Information

Click [About] on the Setup menu to enter the system information screen.

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

# 13 Probes and Biopsy

## 13.1 Probes

The system supports the following probes:

C11-3E	P7-3E	
L12-3E	SP5-1E	
L9-3E	DE11-3E	
SC6-1E	V11-3HE	
L20-5E	SD8-1E	

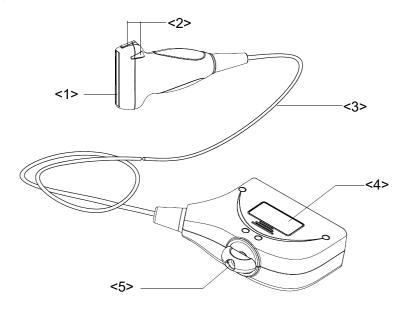
L14-5WE		SC5-1NE	
C5-1E		SC5-1E	
C6-2GE		C7-3E	
L14-6WE		L16-4HE	
/	/	L13-3WE	
P10-4E		6LB7E	

CB10-4E	V11-3E	
V11-3BE	DE10-3WE	
D7-2E	P7-3TE	
CW5s	CW2s	

For details about the TEE probe, please refer to the TEE Ultrasonic Transducer manual.

## 13.1.1 Probe Functions by Part

The basic structures and corresponding functions of probes are basically the same. Take the following probe as an example.



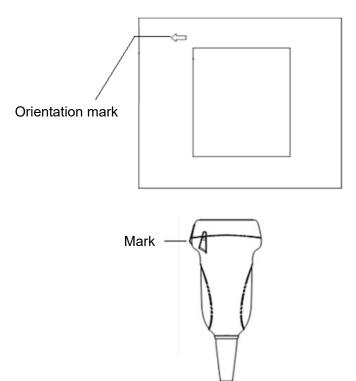
No.	Name	Function
<1>	Probe head	Converts the electrical signal to an ultrasonic signal, focusing the sound beams in a given direction while it receives the reflected ultrasonic signal and converts it to an electrical signal for transmission over the cable. The lens on the surface is the acoustic lens.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

Tip:

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

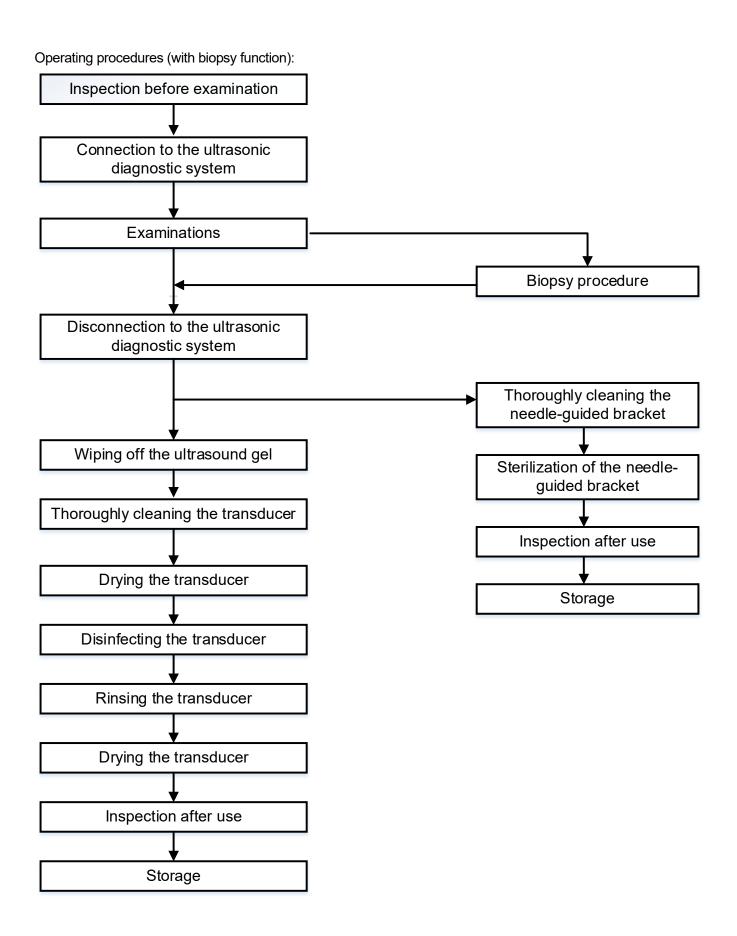
## 13.1.2 Orientation of the Ultrasound Image and the Probe Head

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

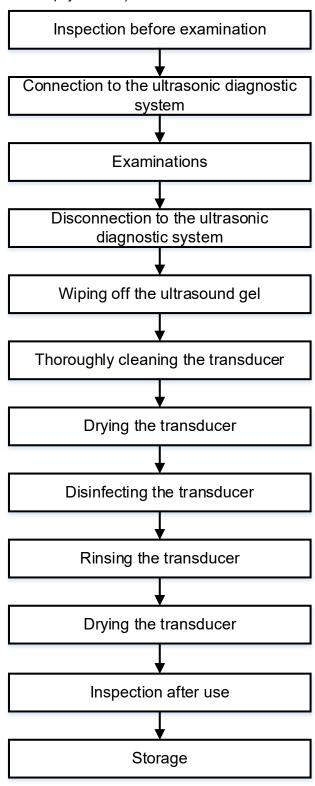


## 13.1.3 Operating Procedures

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



Operating procedures (with no biopsy function):



 $\triangle$ WARNING:

Thoroughly clean the probe and needle-guided bracket, then disinfect the probe and sterilize the needle-guided bracket before and after each ultrasound-guided biopsy procedure is performed. Failure to do so may cause the probe and the needle-guided bracket to become sources of infection.

## 13.1.4 Wearing the Probe Sheath

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

To order probe sheaths, contact:

CIVCO Medical Instruments Co.

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

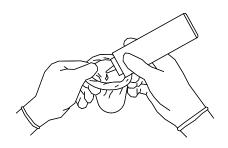
E-mail: info@civco.com http://www.civco.com

## CAUTION:

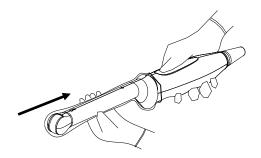
- 1. Be sure to cover the probe with a new (unused) probe sheath to prevent infection during examination. If the probe sheath packaging is open or broken, the probe sheath may not be sufficiently sterilized. DO NOT use the probe sheath in such circumstances.
- 2. The cover contains natural rubber latex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

Method (for reference only):

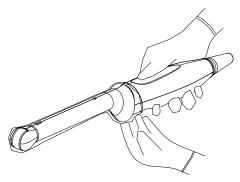
1. Place an appropriate amount of gel inside the sheath or on the probe acoustic lens. Poor imaging may result if no gel is used.



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



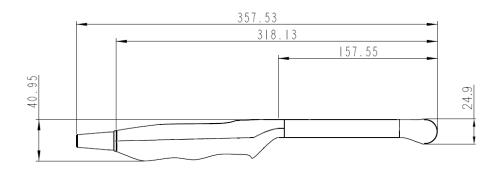
3. Secure the sheath with the enclosed elastic bands.

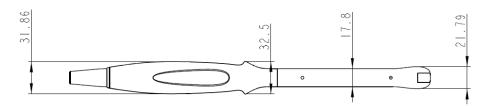


4. Inspect the sheath to ensure there are no holes or tears.

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

Model	Length(mm)	Width(mm)	Height(mm)	Cable Length(mm)
C11-3E	94	33	25	1950±50
L12-3E	102	61	24	1950±50
P7-3E	102	38	30	1850±50
SP5-1E	102	38	30	2200±50
L9-3E	101	58	23	1950±50
V11-3HE	320	38	33	1950±50
SC6-1E	109.5	76.7	28	1950±50
SD8-1E	120	77.6	53	1950±50
L14-5WE	98	66.4	25.5	2100±50
L20-5E	98	43	24.1	1950±50
DE11-3E	323.6	37	46.7	1950±50
SC5-1NE	109.5	76.7	28	1950±50
C5-1E	109.5	76.7	28	1950±50
SC5-1E	110	81	28	1950±50
C6-2GE	115	39.4	21	2730±50
C7-3E	110	71	23	1950±50
L14-6WE	102	70	25	1950±50
L16-4HE	77.8	34.6	11.5	2964(0/+50)
L13-3WE	102.1	65.4	25.5	1950±50
P10-4E	83	29	20	1950±50
6LB7E	339.9	39	39.2	1950±50
CB10-4E	324	39	35	1950±50
V11-3E	317	41	33	1950±50
V11-3BE	319	64	32	1950±50
DE10-3WE	294.1	43.4	52.4	2400±50
D7-2E	117.4	68.4	45	1950±50
P7-3TE	1402	59	60	1432 (1232 after repair)
CW5s	123	11	11	1850±50
CW2s	120	80	18	2100±50





The above is a dimension illustration of the V11-3Ws probe.

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

## 13.1.5 Probes Cleaning, Disinfection and Sterilization

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

**MWARNING**:

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

**∆**CAUTION:

- No cleaning and disinfecting may result in the probe becoming a source of infection.
- 2 Please follow the disinfectant manufacturer's manual for performing cleaning and disinfection, including preparing sterile water and cleaning and disinfection time.

NOTE:

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

#### Cleaning and Disinfection/sterilization Overview

Cleaning and disinfection refer to two distinct processes. According to the Centers for Disease Control and Prevention (CDC) "Guideline for Disinfection and Sterilization in Healthcare Facilities" (2008):

"Cleaning is the removal of visible soil (e.g. organic and inorganic material) from objects and surfaces and normally is accomplished manually or mechanically using water with detergents or

enzymatic products. Thorough cleaning is essential before high-level disinfection and sterilization because inorganic and organic material that remains on the surfaces of instruments interfere with the effectiveness of these processes."

"Disinfection describes a process that eliminates many or all pathogenic microorganisms, except bacterial spores."

**Low-Level Disinfection**—Destruction of most bacteria, some viruses, and some fungi. Low-level disinfection will not necessarily inactivate *Mycobacterium tuberculosis* or bacterial spores.

**High-Level Disinfection (HLD)**—Destruction/removal of all microorganisms except bacterial spores.

"Sterilization describes a process that destroys or eliminates all forms of microbial life and is carried out in healthcare facilities by physical or chemical methods."

#### Selecting a Microbicidal Method

Transducers can be divided into three categories based on their intended use. Some transducers may fall into more than one category (e.g. transducers use for biopsy procedures). When selecting a disinfectant, determine the required level of disinfection based on intended use and possibility of cross-contamination.

**Contacts intact skin:** Transducers that only come into contact with clean, intact skin are considered noncritical devices and require cleaning after every use. Cleaning may be followed by a low-level disinfectant spray or wipe.

**Contacts mucous membranesand non-intact skin**: This category includes all endocavity transducers - intravaginal, transrectal, and transesophageal (TEE) and transducers use for biopsy procedures. These semi-critical transducers must be cleaned with an appropriate cleaner after use followed by high-level disinfection.

**Contacts otherwise sterile tissue or body-space**: These transducers are considered critical and include all intraoperative transducers. These transducers must be cleaned with an appropriate cleaner after each use, followed by a sterilization process.

#### Cleaning

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

- 1. Wear a pair of gloves to prevent infection.
- 2. Disconnect the ultrasound probe from the ultrasound system. If the sheath is used, take off the sheath and discard it.
- 3. Wipe away the ultrasound gel or other dirt on the surface of the probe by using a piece of disposable lint-free soft cloth or tissue.
- 4. Prepare a cleaning solvent (enzymatic or neutral pH detergent, e.g., liquinox, MetriZyme) by using distilled or softened water in accordance with the operator's manual provided by the manufacturer.
- 5. Immerse the ultrasound probe fully in the cleaning solvent for at least 1 minute or a period specified by the manufacturer.
- 6. Wipe and wash the probe surface gently by using a piece of lint-free soft cloth or soft sponge until no dirt is visible. When necessary, wash the locating groove of the needle-guided bracket and other items by using disposable cotton swabs. Avoid using a brush to wash the lens

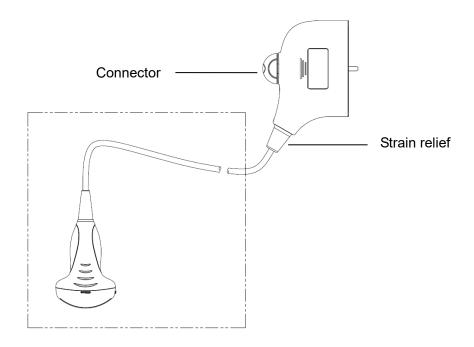
- because it may damage the probe.
- 7. Rinse the probe thoroughly by using a large amount of distilled or softened water (about 2 gallons) at room temperature for about 30s to remove the residual dirt and cleaning solvent. Repeat the operation twice.
- 8. Dry the probe by wiping with a piece of disposable lint-free soft cloth or tissue. Do not dry the probe by heating.
- 9. Inspect the probe. If visible dirt still exists, repeat the preceding steps to wash the probe until it is all clean.
- 10. Check whether the probe has defects such as peeling, rifts, bumps, cracks, or liquid spill. If such defects exist, the probe has reached the end of its service life. In this case, stop using it and contact the Mindray service department.

#### Low-level disinfection of a non-critical probe

CAUTION:

Use protective eyewear when disinfecting using sprays.

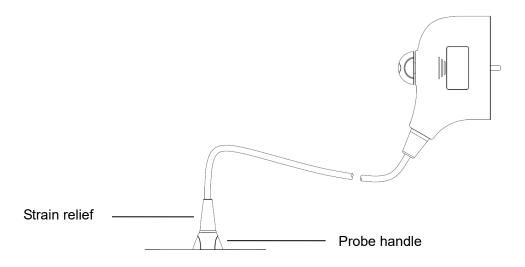
- 1. Wear a pair of gloves to prevent infection.
- 2. Clean the probe thoroughly in accordance with the cleaning procedure before disinfection.
- 3. Disinfect the probe by using an appropriate low-level disinfectant. If you use a wet wipe for disinfection, refer to the wiping method specified by the supplier and the wiping duration specified in the operator's manual provided by the manufacturer.
- 4. If you use a disinfectant spray, spray the disinfectant on a piece of disposable lint-free soft cloth and wipe the probe. For details about the wiping duration, see the operator's manual provided by the manufacturer.
- 5. Wipe away the residual disinfectant on the probe by using a piece of lint-free soft cloth soaked with distilled water. Wipe three times. Or rinse the probe thoroughly by using a large amount of distilled or softened water (about 2 gallons) at room temperature.
- 6. Dry the probe by wiping with a piece of disposable lint-free soft cloth. Do not dry the probe by heating.
- 7. Check whether the probe has defects such as peeling, rifts, bumps, cracks, or liquid spill. If such defects exist, the probe has reached the end of its service life. In this case, stop using it and contact the Mindray service department.
- 8. Store the probe in a cool, clean and dry environment. And repeat the cleaning and disinfection process before the next use.



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

#### High-level disinfection of a semi-critical probe

- 1. Wear a pair of gloves to prevent infection.
- 2. Clean the probe thoroughly in accordance with the cleaning procedure before disinfection.
- 3. Disinfect the probe by using an appropriate high-level disinfectant. For how to use a high-level disinfectant, see the operator's manual provided by the manufacturer. Prepare a disinfectant by using distilled or softened water when necessary.
- 4. Immerse the probe head partially in the disinfectant and shake the probe appropriately to remove any bubbles on the probe surface. For details about the probe immersion duration, see the operator's manual provided by the manufacturer.
- 5. Rinse the probe thoroughly by using a large amount of distilled or softened water (about 2 gallons) at room temperature for about 30s to remove the residual disinfectant. Repeat the operation twice.
- 6. Dry the probe by wiping with a piece of disposable lint-free soft cloth. Do not dry the probe by heating.
- 7. Check whether the probe has defects such as peeling, rifts, bumps, cracks, or liquid spill. If such defects exist, the probe has reached the end of its service life. In this case, stop using it and contact the Mindray service department.
- 8. Store the probe in a cool, clean and dry environment. And repeat the cleaning and disinfection process before the next use.

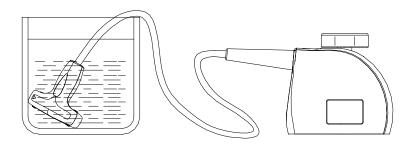


**NOTE:** 1. Observe the graph here carefully to immerse the transducer. Only soak parts of the transducer below the strain relief.

#### Sterilization of a critical probe

For intra-operative transducers, they have to be thoroughly cleaned and sterilized after completing each examination.

- 1. Wear a pair of gloves to prevent infection.
- 2. Clean the probe thoroughly in accordance with the cleaning procedure before sterilization.
- 3. Sterilize the probe by using an appropriate sterilant. MINDRAY recommended the following solution to sterilize the probe. For how to use the sterilant, see the operator's manual provided by the manufacturer. Prepare a sterililant by using sterile water when necessary.
  - Refer to the instructions provided by the chemical manufacturer concerning concentration of the sterilization solution, method of sterilization and dilution and cautions during use.
  - Do not soak the transducer connector or the cable near it into water or any solution.
  - Follow local regulations when selecting and using the sterilization solution.
- 4. Immerse the probe head partially in the sterilant and shake the probe appropriately to remove any bubbles on the probe surface. For details about the probe immersion duration, see the operator's manual provided by the manufacturer.
- 5. Rinse the probe thoroughly by using a large amount of sterile distilled water (about 2 gallons) at room temperature for about 30s to remove the residual disinfectant. Repeat the operation twice. Or, follow the rinsing method recommended by the manufacturer of the sterilant to rinse the probe.
- 6. Dry the probe by wiping with a piece of sterile disposable lint-free soft cloth. Do not dry the probe by heating.
- 7. Check whether the probe has defects such as peeling, rifts, bumps, cracks, or liquid spill. If such defects exist, the probe has reached the end of its service life. In this case, stop using it and contact the Mindray service department.
- 8. Store the probe in a cool, clean and dry environment. And repeat the cleaning and sterilizing process before the next use.



Immerse the intra-operative transducer in the solution (for reference)

**∆** CAUTION:

Repeated sterilization will eventually damage the transducer, please check the transducer's performance periodically.

## **Compatible Cleaner, Disinfectants and Sterilants**

For the cleaner, disinfectants and sterilants information, please refer to Mindray Transducer Disinfectant Recommendation.

## 13.1.6 Environment

## **Working condition**

Use the probes in the following ambient conditions:

Probe	Ambient temperature	Relative humidity	Atmospheric pressure
6LB7E	0℃-40℃	30%~85%RH (no condensation)	700hPa ~ 1060hPa
CB10-4E	0℃-40℃	30%~85%RH (no condensation)	700hPa∼1060hPa
D7-2E	10℃-40℃	25%~90%RH (no condensation)	700hPa∼1060hPa
L12-3E	0℃-40℃	30%~85%RH (no condensation)	700hPa∼1060hPa
C7-3E	0℃~40℃	30%~85%RH (no condensation)	700hPa∼1060hPa
L14-6WE	0°C∼40°C	30%~85%RH (no condensation)	700hPa∼1060hPa
P10-4E	0°C∼40°C	30%~85%RH (no condensation)	700hPa∼1060hPa
C11-3E	0℃~40℃	30%~85%RH (no condensation)	700hPa∼1060hPa
V11-3E	0°C∼40°C	30%~85%RH (no condensation)	700hPa∼1060hPa
V11-3BE	0°C∼40°C	30%∼85%RH (no condensation)	700hPa∼1060hPa
C5-1E	0°C∼40°C	30%~85%RH (no condensation)	700hPa∼1060hPa
SP5-1E	0°C∼40°C	20%~85%RH (no condensation)	700hPa∼1060hPa
DE11-3E	18℃~30℃	20%~85%RH (no condensation)	700hPa∼1060hPa
C6-2GE	0°C∼40°C	20%~85%RH (no condensation)	700hPa∼1060hPa
SC6-1E	0℃~40℃	20%∼85%RH (no condensation)	700hPa∼1060hPa

Probe	Ambient temperature	Relative humidity	Atmospheric pressure
V11-3HE	0℃~40℃	20%~85%RH (no condensation)	700hPa∼1060hPa
L9-3E	0℃~40℃	20%~85%RH (no condensation)	700hPa∼1060hPa
SD8-1E	18℃~30℃	20%~85%RH (no condensation)	700hPa∼1060hPa
L14-5WE	0℃~40℃	20%~85%RH (no condensation)	700hPa ~ 1060hPa
P7-3E	10℃~40℃	30%~85%RH (no condensation)	700hPa∼1060hPa
DE10-3WE	18℃~30℃	10%~90%RH (no condensation)	700hPa∼1060hPa
P7-3TE	0℃~40℃	10%~85%RH (no condensation)	700hPa∼1060hPa
L20-5E	0℃~35℃	15%~80%RH (no condensation)	700hPa ~ 1060hPa
L16-4HE	10℃~40℃	30%~85%RH (no condensation)	700hPa∼1060hPa
SC5-1E	0℃~40℃	30%~85%RH (no condensation)	700hPa∼1060hPa
CW2s	0℃~40℃	30%~85%RH (no condensation)	700hPa∼1060hPa
CW5s	0℃~40℃	30%~85%RH (no condensation)	700hPa∼1060hPa
SC5-1NE	0℃~40℃	20%~85%RH (no condensation)	700hPa∼1060hPa
L13-3WE	0℃~40℃	20%∼85%RH (no condensation)	700hPa∼1060hPa

## Storage and transportation Condition

Store and transport the probes in the following ambient conditions:

Probe	Ambient temperature	Relative humidity	Atmospheric pressure
6LB7E	-20℃~55℃	30%~95%RH (no condensation)	700 hPa ~ 1060 hPa
CB10-4E	-20℃~55℃	30%~95%RH (no condensation)	700 hPa ~ 1060 hPa
D7-2E	-10℃~60℃	30%~95%RH (no condensation)	700 hPa ~ 1060 hPa
L12-3E	-20℃~55℃	30%~95%RH (no condensation)	700 hPa ~ 1060 hPa
C7-3E	-20℃~55℃	30%~95%RH (no condensation)	700 hPa ~ 1060 hPa
L14-6WE	-20℃~55℃	30%~95%RH (no condensation)	700 hPa ~ 1060 hPa
P10-4E	-20℃~55℃	30%~95%RH (no condensation)	700 hPa ~ 1060 hPa
C11-3E	-20℃~55℃	30%~95%RH (no condensation)	700 hPa ~ 1060 hPa
V11-3E	-20℃~55℃	30%~95%RH (no condensation)	700 hPa ~ 1060 hPa
V11-3BE	-20℃~55℃	30%~95%RH (no condensation)	700 hPa ~ 1060 hPa
C5-1E	-20℃~55℃	30%~95%RH (no condensation)	700 hPa ~ 1060 hPa
SP5-1E	-20℃~55℃	20%~95%RH (no condensation)	700 hPa ~ 1060 hPa

Probe	Ambient temperature	Relative humidity	Atmospheric pressure
DE11-3E	-10℃~50℃	30%~95%RH (no condensation)	700 hPa ~ 1060 hPa
C6-2GE	-20℃~55℃	20%~95%RH (no condensation)	700 hPa ~ 1060 hPa
SC6-1E	-20℃~55℃	20%~95%RH (no condensation)	700 hPa ~ 1060 hPa
V11-3HE	-20℃~55℃	20%~95%RH (no condensation)	700 hPa ~ 1060 hPa
L9-3E	-20℃~55℃	20%~95%RH (no condensation)	700 hPa ~ 1060 hPa
SD8-1E	-10℃~50℃	20%~95%RH (no condensation)	700 hPa ~ 1060 hPa
L14-5WE	-20℃~55℃	20%~95%RH (no condensation)	700 hPa ~ 1060 hPa
P7-3E	-20℃~55℃	30%~95%RH (no condensation)	700 hPa ~ 1060 hPa
DE10-3WE	-10℃~50℃	10%~90%RH (no condensation)	700 hPa ~ 1060 hPa
P7-3TE	-10℃~45℃	30%~90%RH (no condensation)	700 hPa ~ 1060 hPa
L20-5E	-20℃~60℃	15%~90%RH (no condensation)	700 hPa ~ 1060 hPa
L16-4HE	0℃~60℃	30%~95%RH (no condensation)	700 hPa ~ 1060 hPa
SC5-1E	-10℃~60℃	20%~95%RH (no condensation)	700 hPa ~ 1060 hPa
CW2s	-20℃~55℃	30%~95%RH (no condensation)	700 hPa ~ 1060 hPa
CW5s	-20℃~55℃	30%~95%RH (no condensation)	700 hPa ~ 1060 hPa
SC5-1NE	-20℃~55℃	20%~95%RH (no condensation)	700 hPa ~ 1060 hPa
L13-3WE	-20℃~55℃	20%~95%RH (no condensation)	700 hPa ~ 1060 hPa

When all examinations for the session have been completed, confirm that the probe is in good condition. After disinfecting the probe, confirm that the probe is in good condition and stored in a suitable place.

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

## 13.1.7 Sensor (Fusion Imaging) Support Cleaning and Disinfection

Before performing the fusion imaging exam, clean and disinfect (or sterilize) the fusion sensor support as required.



 When performing cleaning and disinfection of the sensor support to prevent infection, wear sterile gloves.



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

The efficacy of disinfectants and sterilizing solutions is not guaranteed by MINDRAY. Contact the manufacturers for information on the activity of the products.

#### Cleaning

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

#### **Disinfecting with Sprays or Wipes**



Use protective eyewear when disinfecting using sprays.

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

#### **Disinfecting by Immersion**

- 1. Wear sterile gloves to prevent infection.
- 2. Clean the sensor support before disinfecting it. MINDRAY recommends the following solutions to disinfect the sensor support (fusion).
  - Refer to the instructions provided by the chemical manufacturer concerning concentration
    of the disinfectant solution, method of disinfection and dilution and cautions during use.
  - Soak the sensor support 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 sensor support 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 sensor support.
- 4. Wipe off the water on the sensor support with sterile cloth or gauze after rinsing it.

#### **Compatible Disinfectants**

Manufacturer	Trade Name	Procedures	Туре
Metrex	MetriZyme	Please refer to the instructions provided by the manufacturer of the solution for details.	Solution
ASP	Cidex Activated Glutaraldehyde Solution	Please refer to the instructions provided by the manufacturer of the solution for details.	Solution
ASP	Cidex OPA	Please refer to the instructions provided by the manufacturer of the solution for details.	Solution
Ecolab Inc.	Ster-Bac	Please refer to the instructions provided by the manufacturer of the solution for details.	Solution
Advanced Ultrasound Solutions Inc.	SONO Ultrasound Wipes	Please refer to the instructions provided by the manufacturer of the solution for details.	Wipe
Professional Disposables International,Inc.	Sani-Cloth	Please refer to the instructions provided by the manufacturer of the solution for details.	Wipe

## 13.1.8 Storage and Transportation for Sensor Support (Fusion)

When all examinations for the day have been completed, confirm that the sensor support is in good condition. After disinfecting the probe, confirm that the sensor support is in good condition and stored in a suitable place.

- 1. To prevent the sensor support from being damaged, DO NOT store it in locations where it may be exposed to:
  - Direct sunlight
  - Sudden changes in temperature
  - Dust
  - Excessive vibration
  - Heat generators
- 2. Store and sensor support under following ambient conditions:
  - Ambient temperature: -20°C ~ 55°C
  - Relative humidity: 20% ~95% (no condensation)
  - Atmospheric pressure: 700 hPa ~1060 hPa

## 13.1.9 Sensors (Fusion Imaging) Cleaning and Disinfection

**△**CAUTION:

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



- 2. After disinfection, rinse the sensor thoroughly with sterile water to remove all chemical residues. Chemical residues may be harmful to the human body.
- 3 No cleaning and disinfecting may result in the sensor becoming a source of infection.
- 4 The efficacy of disinfectants and sterilizing solutions is not guaranteed by MINDRAY. Contact the manufacturers for information on the activity of the products.

### **Disinfecting with Sprays or Wipes**

**△ CAUTION**:

Use protective eyewear when disinfecting using sprays.

- 1. Wear sterile gloves to prevent infection.
- 2. Spray or wipe the sensor (fusion) with a disinfectant. Follow the disinfectant manufacturer's recommended contact time and mode.
- 3. Remove any residue with a water-moistened soft cloth on the sensor.
- 4. Wipe off water on the sensor using sterile cloth or gauze after washing.

#### **Compatible Disinfectants**

Manufacturer	Disinfectants Name	Disinfect times	Procedures	Туре
Advanced Ultrasound Solutions Inc.	SONO Ultrasound Wipes	5200 times, 3 min/time	Please refer to the instructions provided by the manufacturer of the solution for details.	Wipe
Professional Disposables International,Inc.	Sani-Cloth	5200 times, 4min/time	Please refer to the instructions provided by the manufacturer of the solution for details.	Wipe

## 13.1.10 Disposal of the Sensor Support

Be sure to dispose of the sensor support only after sterilizing it.

Contact your MINDRAY representative when disposing of this device.

## 13.2 Biopsy Guide

## **⚠WARNING**:

The person performing biopsy procedures must understand diagnostic ultrasound thoroughly and have been adequately trained, otherwise the patient may suffer consequences.

In the situations listed below, the biopsy needle may fail to penetrate the target. Incorrect biopsy may cause various consequences for the patient.

- Using a needle-guided bracket other than that provided.
- Mounting the needle-guided bracket incorrectly.
- Using a biopsy needle that is unsuitable for the type of biopsy being performed.
- Using a biopsy needle that is unsuitable for the needle guide.

Before and after a biopsy procedure is performed, confirm that the needle-guided bracket is normal. Manually confirm that the parts of the needle-guided bracket do not slip or move from their proper positions. If the needle-guided bracket is used when parts are not securely and correctly installed, the patient may be injured. If an abnormality is found on the needle-guided bracket, immediately stop using it and contact the MINDRAY Customer Service Department or a sales representative.

DO NOT use a needle-guided bracket while scanning is performed. The needle may advance in an incorrect direction and possibly injure the patient.

Never perform a biopsy during image scanning.

DO NOT freeze an image while performing a biopsy procedure.

During biopsy procedures, the needle may deviate from the desired course due to tissue characteristics or the type of needle. In particular, needles with small diameters may deviate to a greater degree.

Disinfect the probe and sterilize the needle-guided bracket before and after each ultrasound-guided biopsy procedure is performed. Failure to do so may cause the probe and the needle-guided bracket to become sources of infection.

The needle mark displayed on the ultrasound image does not indicate the actual position of the biopsy needle. Therefore, it should only be used as a reference. Always monitor the relative positions of the biopsy needle during procedures.

Adjust the needle mark before the biopsy procedure is performed.

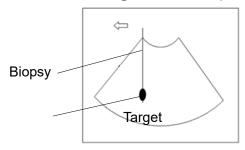
When performing biopsy procedures, only use sterile ultrasound gel that is certified as safe and manage the ultrasound gel properly to ensure that it does not become a source of infection.

When performing an operation involving biopsy, wear sterile gloves.

Image of the biopsy target and the actual position of the biopsy needle:

Diagnostic ultrasound systems produce tomographic plane images with information about particular thicknesses in the thickness direction of the probe. (That is to say, the information shown in the images consists of all the information scanned in the thickness direction of the probe.) Therefore, even though the biopsy needle appears to have penetrated the target object in the image, it may not actually have done so. When the biopsy target is small, dispersion of the ultrasound beam may lead to the image deviating from the actual position. Be aware of this.

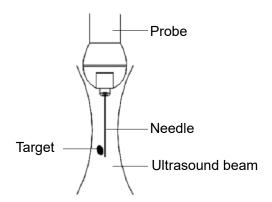
The target object and biopsy needle appear in the image as shown in the figures below (for reference only):



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

•

## Dispersion of the ultrasound beam



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

 Do not rely only on the needle tip in the image. Pay careful attention to the fact that when the biopsy needle enters the target object or comes into contact with it, the object should shift slightly.

Before performing the biopsy, evaluate the size of the object and confirm whether the biopsy can be carried out.

## 13.2.1 Needle-Guided Brackets

■ Some of the probes have corresponding needle-guided brackets for biopsy. The available probes and the corresponding needle-guided brackets are listed as follows:

Probe model	Needle-guided Bracket Model	Biopsy angle/depth (±1°)	Applicable Biopsy Needle
V11-3E/V11- 3BE/CB10-4E	NGB-004 metal/needle un- detachable	0.8°	16G, 17G, 18G
L12-3E/L14- 6WE	NGB-007 plastic/needle detachable metal/needle detachable	40°, 50°, 60°	Metal: 14G, 16G, 18G, 20G, 22G Plastic: 13G, 15G, 16G, 18G, 20G
6LB7E	NGB-009 metal/needle detachable	0°	13G, 15G, 16G, 18G, 20G
SP5-1E	NGB-011 metal/needle un- detachable	11°, 23°	13G, 15G, 16G, 18G, 20G
C11-3E	NGB-018 Metal/needle detachable	15°, 25°, 35°	14G, 16G, 18G, 20G, 22G
C7-3E	NGB-019 metal/needle detachable	20°, 30°, 40°	14G, 16G, 18G, 20G, 22G
DE10-3WE	NGB-021 metal/needle un- detachable	2°	16G, 17G, 18G
SC6-1E/SC5- 1NE/C5-1E	NGB-022 metal/needle detachable	25°, 35°, 45°	14G, 16G, 18G, 20G, 22G
C6-2GE	NGB-024 metal/needle detachable	7°, 25°, 35°	14G, 16G, 18G, 20G, 22G
V11-3HE	NGB-025 metal/needle un- detachable	1.6°	16G, 17G, 18G
DE11-3E	NGB-027 metal/needle un- detachable	1.7°	16G, 17G, 18G
SC5-1E	NGB-031 metal/needle detachable	25°, 35°, 45°	14G, 16G, 18G, 20G, 22G

Probe model	Needle-guided Bracket Model	Biopsy angle/depth (±1°)	Applicable Biopsy Needle
L9-3E	NGB-034 metal/needle detachable	40°, 50°, 60°	14G, 16G, 18G, 20G, 22G
L14-5WE	NGB-035 metal/needle detachable	47°, 53°, 59°, 65°	14G, 16G, 18G, 20G, 22G
SD8-1E	NGB-039 metal/needle detachable	21°, 26°, 33°	14G, 16G, 18G, 20G, 22G
L13-3WE	NGB-054 metal/needle detachable	15mm (65°), 23.7mm (55°), 35mm (45°)	11G ~ 23G

#### ■ CIVCO Bracket

Probe model	Needle-guided Bracket Model
L12-3E	CIVCO 658-001
V11-3E\V11-3BE\V11- 3HE\CB10-4E	CIVCO 610-543
	CIVCO 610-1274

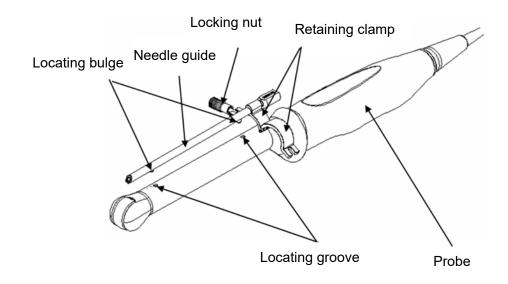
Needle-guided brackets are available for purchase as optional accessories and are used in combination with the probe. Some probes have corresponding needle-guided brackets and needles. To order needle-guided brackets, contact the MINDRAY Customer Service Department or a sales representative.

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

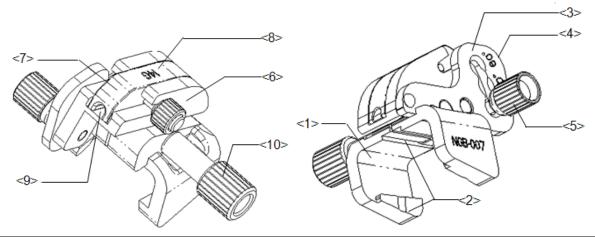
#### **Names of Parts**

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

## ■ NGB-004



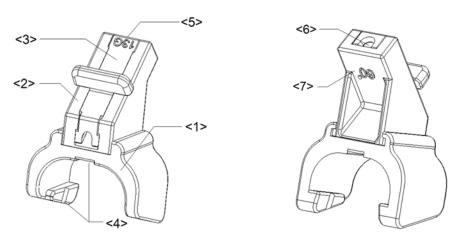
## ■ NGB-007 Metal/needle detachable needle-guided bracket:



No.	Name	Description	
<1>	Support for needle- guided bracket	Used for installing the needle-guided bracket on the probe.	
<2>	Tab and groove for the needle-guided bracket	Corresponding to the tab and groove of the probe.	
<3>	Angle-adjusting base	There are 3 types of angles available for adjustment.	
<4>	Angle shift sign (40°, 50°, 60°)	Corresponding to the biopsy angle (40°, 50° and 60°).	
<5>	Angle pinch nut Used for fixing the angle lock at a chosen angle.		
<6>	Angle block	Used for determining the angle of the biopsy. Different specifications of blocks can be used.	
<7>	Guiding block	Used for installing biopsy needles. There are five guiding block specification for different biopsy needles.	

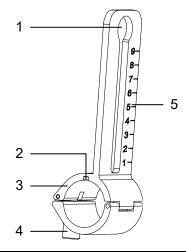
No.	Name	Description
<8>	Guiding block specification (14G)	Matched with the corresponding biopsy needle (14G).
<9>	Needle guide hole	Used for installing the biopsy needle.
<10>	Needle-guided bracket pinch nut	Used for locking the needle-guided bracket and the probe.

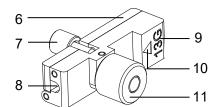
## Plastic/needle detachable needle-guided bracket:



No.	Name	Description	
<1>	Support for needle- guided bracket	Used for installing the needle-guided bracket on the probe.	
<2>	Angle block  Used for determining the angle of the biopsy. There are t angle block specifications.		
<3>	Guiding block	Used for installing biopsy needles. There are five guiding block specification for different biopsy needles.	
<4>	Tab and groove for the needle-guided bracket	Corresponding to the tab and groove of the probe.	
<5>	Guiding block specification (13G)	Matched with the corresponding biopsy needle (13G).	
<6>	Biopsy needle guiding hole	Used for installing the biopsy needle.	
<7>	Angle block specification (60°)	The corresponding biopsy angle is 60°.	

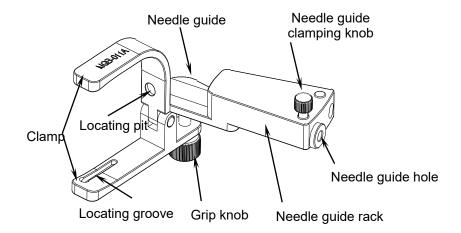
## ■ NGB-009

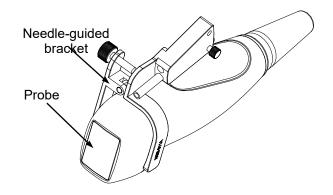




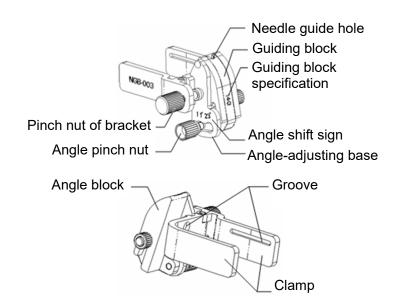
No.	Name	Description
<1>	Support of needle-guided bracket	Used for installing the needle-guided bracket on the transducer.
<2>	Knob of fixing needle-guided bracket	Used for fixing the needle-guided bracket on the transducer.
<3>	Groove	Match with the tab on the transducer.
<4>	Hole for installing guiding block	Used for installing the knob of fixing needle-guided bracket.
<5>	Needle distance scales	Indicate distance between needle and the transducer head surface.
<6>	Guiding block	Used for installing biopsy needle; there are five specifications of guiding blocks for different needles.
<7>	Knob of fixing the needle	Used for fixing the needle.
<8>	Guiding hole of the needle	Used for installing the biopsy needle.
<9>	Specification of guiding block	Matched with the corresponding biopsy needle.
<10>	Mark of indicating scales	Indicating needle distance scales.
<11>	Knob of fixing the guiding block	Used for fixing the guiding block.

#### ■ NGB-011

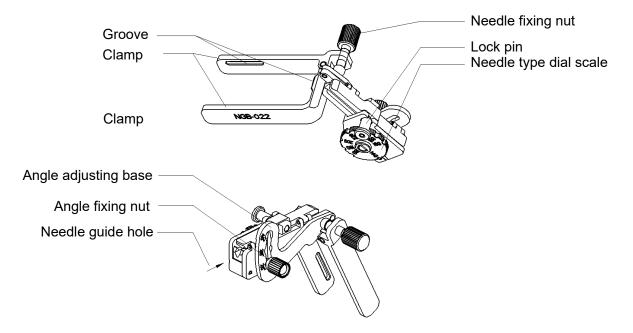




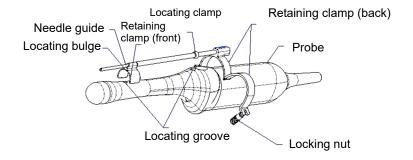
#### ■ NGB-018



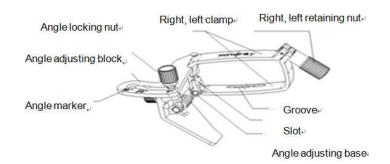
#### ■ NGB-019/NGB-022

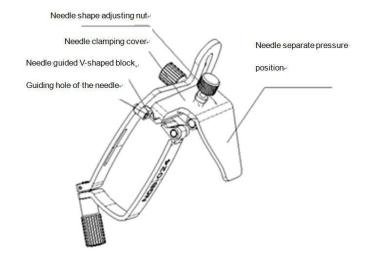


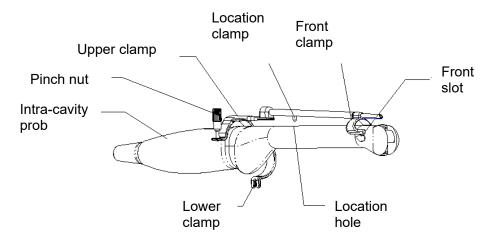
#### ■ NGB-021



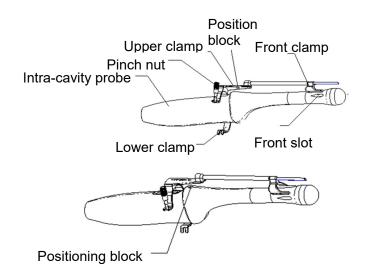
#### ■ NGB-024

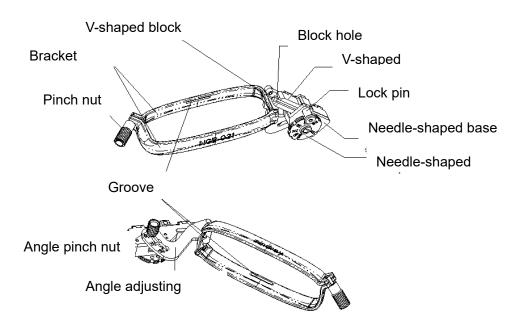


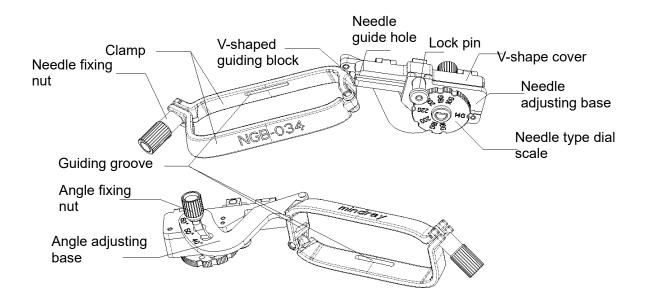


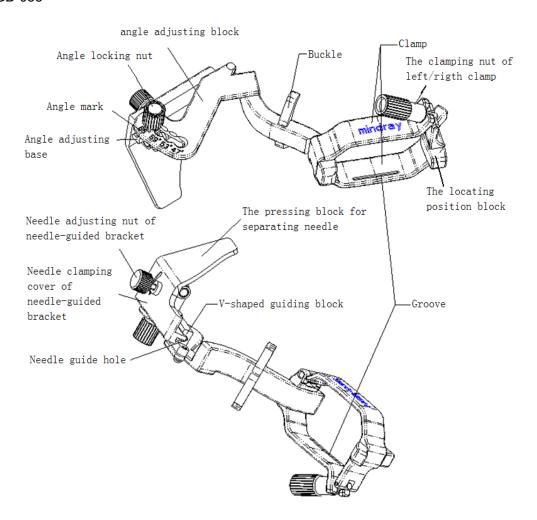


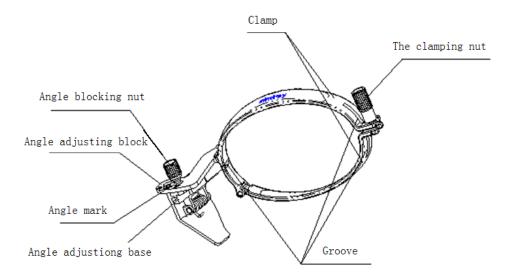
## ■ NGB-027

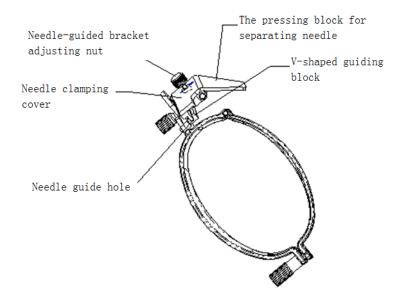




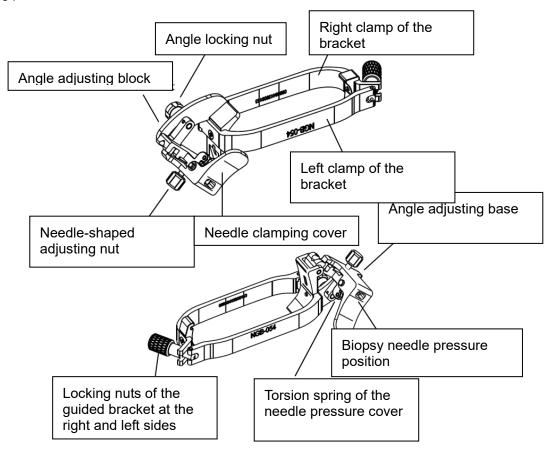








#### NGB-054



Note: the above needle-guided brackets whose name starts with NGB are reusable. The CIVCO brackets are disposable.

# 13.2.2 Basic Procedures for Biopsy Guiding

- 1. Select the correct needle-guided bracket and needle and install them properly. For details, see "13.2.3 Needle-Guided Bracket Inspection and Installation."
- 2. Verify the biopsy guide line.
- 3. Press <F11 Biopsy> on the keyboard or touch [Biopsy] on the touch screen to enter the biopsy. Tip:
  - If the current probe has no corresponding bracket, or the image is frozen and the guide line was hidden before the image was frozen, then you cannot enter the Biopsy menu.
  - Before entering the Biopsy menu, the system will display the prompt "Please calibrate guidelines before biopsy!."
- 4. Use touch screen controls to select the bracket and guide line according to the actual situation.
- 5. In the Biopsy menu, touch [Verify] to enter the Verify menu to verify the guide line. After verification, click [Save] to save the parameter setting. Then click [Exit] to return to the Biopsy status.

Tip:

- If you changed the probe or needle-guided bracket during the biopsy, verify the guide line again.
- When exiting the Verify menu without saving, the system will display the prompt "Are you sure to save data changes?" Click [Yes] to save the setting and return to the Biopsy status.
- 6. Scan to locate the target. Center the target in the electronic guidezone path.
- 7. Direct the needle into the area of interest for specimen.
- 8. After extracting the biopsy sample is complete, gently remove the probe from the body. To exit Biopsy: press <F11 Biopsy>.
- 9. Disassemble the items and properly dispose of these items as required.



Failure to match the guidezone displayed to the guide may cause the needle to track a path outside the zone.

It is extremely important that when using the adjustable angle biopsy guides, the angle displayed on the screen matches the angle set on the guide, otherwise the needle will not follow the displayed guidezone and this could result in repeated biopsies or patient injury.

# 13.2.3 Needle-Guided Bracket Inspection and Installation

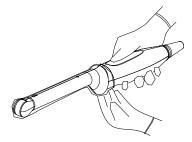
# 13.2.3.1 Inspection of the Needle-Guided Bracket

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

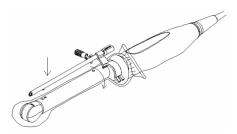
- 1. Sterilize the needle-guided bracket before and after use.
- 2. Confirm that the needle-guided bracket is free from damage, deformation, stripping, malfunction, loose or missing parts.
- 3. Confirm that the needle-guided bracket is securely mounted in the correct position.

# 13.2.3.2 Installing the Needle-Guided Bracket

- NGB-004
  - (1) Put on the sterile probe sheath.



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



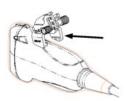
(3) When the retaining clamp is turned to the right position, the locking nut will lock the retaining clamp and the needle-guided bracket is then mounted to the right position.



#### ■ NGB-007

Metal/needle detachable needle-guided bracket:

- (1) Put the sterile probe sheath on.
- (2) Hold the probe in one hand, select the correct needle-guided bracket and hold it with the other hand. Match the groove and tab with the tab and groove of the probe respectively. Mount the bracket onto the probe.





- (3) Screw the pinch nut of the needle-guided bracket to ensure that the needle-guided bracket is properly installed on the probe.
- (4) Select a suitable guiding block and push it into the groove above the angle block, then clamp it tightly.





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

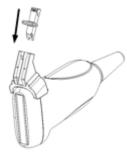


Plastic needle-guided bracket:

- (1) Put the sterile probe sheath on.
- (2) Hold the probe in one hand, select the correct needle-guided bracket and hold it with the other hand. Align the tab at the narrow end of the needle-guided bracket with the groove of the probe, then push the needle-guided bracket forward, so the tabs and grooves of the needle-guided bracket align with the grooves and tabs of the probe.



- (3) Check manually to confirm that the needle-guided bracket is securely installed on the probe.
- (4) Select a suitable guiding block and push it into the groove above the angle block, then clamp it tightly.

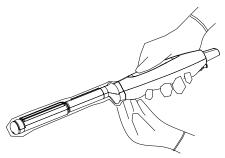


(5) Insert a biopsy needle with the same specification as that of the guiding block into the guiding block hole.

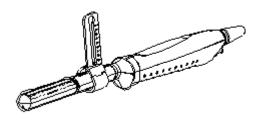


## NGB-009

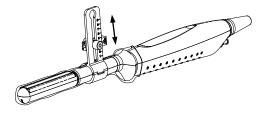
(1) Put on the transducer cover.



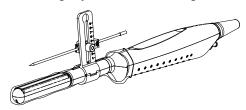
(2) Cover the support of needle-guided bracket on the transducer, making the groove of the needle-guided bracket to match with the tab of the transducer. Set the needle-guided bracket at the desired position, turn tightly the knob of fixing needle-guided bracket to fix the needle-guided bracket.



(3) Select a proper guiding block and thread the knob of fixing the guiding block through the hole of installing guiding block, move the guiding block to the desired position, then turn tightly the knob of fixing the guiding block to fix the guiding block on the support of needle-guided bracket.



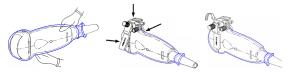
(4) Insert a biopsy needle with the same specification as that of the guiding block into the hole of the guiding block and turn tightly the knob of fixing the needle.



- (1) Connect the locating groove on the clamp with the two raised edges on the probe head and align the locating pit of the clamp with the convex point on the probe head.
- (2) Turn the grip knob at the tail of the needle-guided bracket tightly.

#### ■ NGB-018

- (1) Put the sterile probe sheath on.
- (2) Select a suitable needle-guided bracket and match the groove to the tab of the transducer. Mount the bracket onto the transducer. The needle-guided brackets may be different from each other, but the methods are the same.



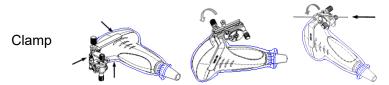
- (3) Screw the pinch nut of the needle-guided bracket to ensure that the needle-guided bracket is properly installed on the transducer.
- (4) Select a suitable guiding block and push it into the groove above the angle block.



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

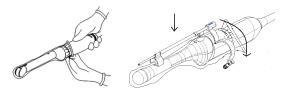
## ■ NGB-019/NGB-022

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

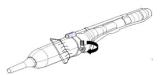


- (3) Screw the pinch nut of the needle-guided bracket to confirm that the needle-guided bracket is properly installed on the transducer.
- (4) Adjust the dial scale to the required needle type shift, and then screw the needle fixing nut to lock the dial scale. (To adjust the dial scale you have to loose the needle fixing nut first.)
- (5) Pull the lock pin and close the V-shaped cover to fix the lock pin in the groove of the needle type adjusting base, so as to install the needle into the guiding hole.

- (1) Put on the sterile transducer sheath.
- (2) Loose the retaining clamp, align the needle-guided bracket with the transducer to locate the locating clamp on the needle guide to the locating grooves on the transducer, and then press the retaining clamp (front) to match the locating clamp and the locating bulge on the front retaining clamp to the corresponding groove.



(3) Screw the retaining clamp to match with the transducer structure. When the 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-024

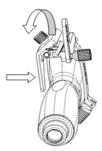
- (1) Put on the sterile transducer sheath.
- (2) Select a proper needle-guided bracket, and match the groove with the tab of the transducer. Mount the bracket onto the transducer.



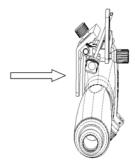
(3) Rotate the clamping nuts of the guided bracket on right and left side to fix the bracket and the transducer. Rotate the needle-type adjusting nut to the ultimate position as shown in the figure.



(4) Hold the transducer. Press the biopsy needle to separate needle guided V-shaped block from pressure position of the needle.



(5) Put the needle into the needle guided-bracket, and the needle leans to V-shaped block.



(6) Hold the transducer, and release the pressure position of the needle. Adjust the needletype adjusting nut manually (following the direction of the arrow). The needle moves smoothly at the vertical direction due to its gravity.

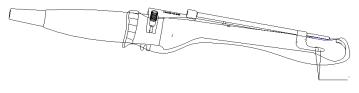


#### ■ NGB-025

1. Put on the sterile probe sheath.

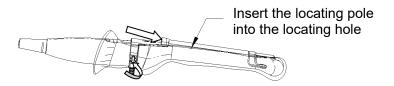


2. Open the clamp. Insert the front clamp to the front groove.



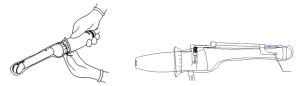
Align front clamp with front groove

3. Push the bispy forward (arrow's direction) until the locating pole inserting into the location hole. Turn the lower clamp againsy the intra-cavity probe. Tighten the nut to lock the biopsy (arrow's direction).



#### ■ NGB-027

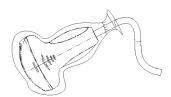
1. Put on the sterile transducer sheath.



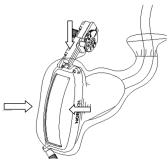
- 2. Open the clamp. Insert the front clamp to the front groove.
- 3. Push the biopsy forward (arrow's direction) until the locating pole inserting into the location hole. Turn the lower clamp against the intra-cavity probe. Tighten the nut to lock the biopsy (arrow's direction).



(1) Put on the sterile probe sheath.



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



(3) Tighten the pinch nut of the needle-guided bracket (following the arrow's direction) to confirm that the needle-guided bracket is properly installed on the probe.



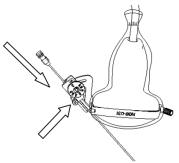
(4) Adjust the dial scale to the required needle type shift.



(5) Adjust the needle angle to the proper shift as required (loosen the nut first, and then tighten the nut based on the shift you need).



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



## ■ NGB-034

1. Put on the sterile probe sheath.



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



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



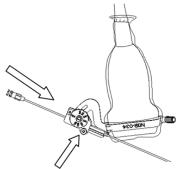
4. Adjust the dial scale to the required needle type shift.



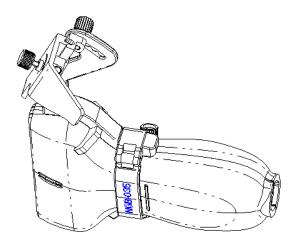
5. Adjust the needle angle to the proper shift as required (loosen the nut first, and then tighten the nut based on the shift you need).



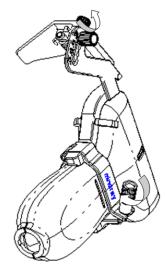
6. Pull the lock pin and close the V-shaped cover to fix the lock pin in the groove of the needle type adjusting base, so as to install the needle into the guiding hole.



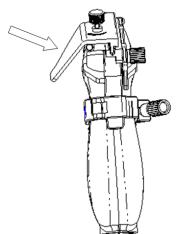
- (1) Put the sterile sheath on the probe.
- (2) Select a proper needle-guided bracket, and match the locating groove with the tab of the transducer. Mount the bracket onto the transducer.



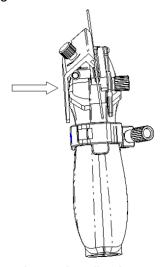
(3) Tighten the pinch nut of the needle-guided bracket to confirm that the needle-guided bracket is properly installed on the probe. Loosen the angle adjusting nut.



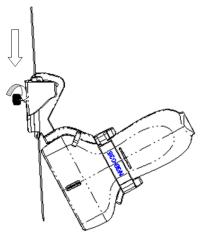
(4) Hold the probe and press the pressing block to separate V-shaped guiding block from the pressing block.



(5) Insert the needle into V-shaped guided block.



(6) Release the pressing block, adjust the angle adjusting nut to confirm that the needle can freely slide in a vertical direction.

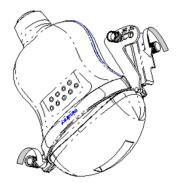


#### ■ NGB-039

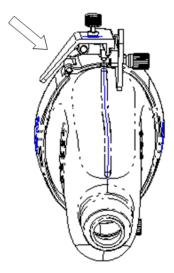
- (1) Put the sterile sheath on the probe.
- (2) Select a proper needle-guided bracket, and match the locating groove with the tab of the transducer. Mount the bracket onto the transducer.



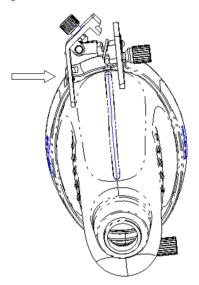
(3) Tighten the pinch nut of the needle-guided bracket to confirm that the needle-guided bracket is properly installed on the probe. Loosen the angle adjusting nut.



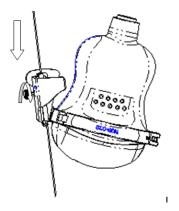
(4) Hold the probe and press the pressing block to separate V-shaped guiding block from the pressing block.



(5) Insert the needle into V-shaped guided block.

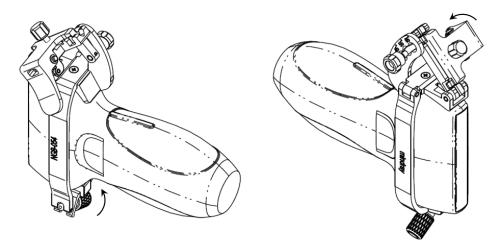


(6) Release the pressing block, adjust the angle adjusting nut to confirm that the needle can freely slide in a vertical direction.

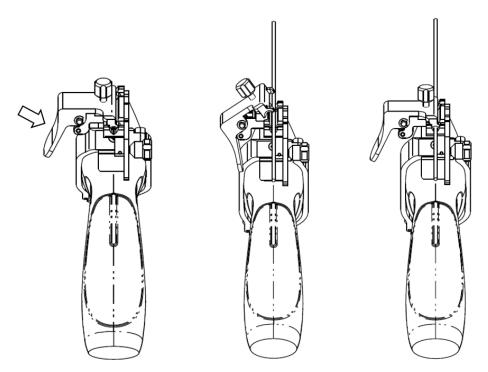


## NGB-054

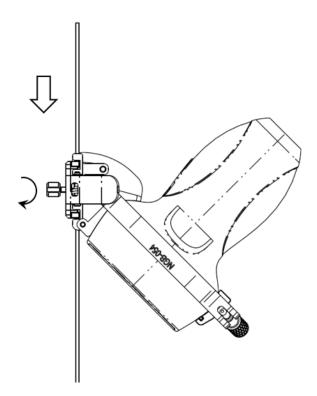
- (1) Put on the sterile transducer sheath.
- (2) Hold the transducer in one hand, select the correct needle-guided bracket and hold it with the other hand. Match the inside of the bracket with the outside of the transducer respectively. Mount the bracket onto the transducer. Rotate the locking nuts of the guided bracket at the right and left sides to fix the bracket and the transducer. Rotate the needle-shaped adjusting nut to the ultimate position as shown in the figure.



(3) Hold the transducer. Press the biopsy needle pressure position to separate it from the V-shaped guiding block. Put the needle into the V-shaped guiding block of the needle guided-bracket.



(4) Hold the transducer, and release the pressure position of the needle. Adjust the needle-shaped adjusting nut manually (following the direction of the arrow). The needle moves smoothly at the vertical direction due to its gravity.



## **Select the Needle**

Select the proper needle according to the specification above, and adjust the needle shift to the same specification of the selected needle.

**CAUTION**:

Ensure that all guide parts are properly fixed prior to performing a

biopsy.

# 13.2.4 Biopsy Menu/Guideline Verification

Adjusting the needle mark is necessary before each biopsy procedure.

- 1. Confirm that the needle-guided bracket has been installed securely in the correct position.
- 2. Prepare a container filled with sterile water.
- 3. Place the head of the probe in the sterile water and place a biopsy needle in the needle guide.
- 4. When the biopsy needle appears on the image, confirm that the biopsy needle is displayed at almost the same position as the selected needle mark.

 $\triangle$ WARNING:

Prior to each biopsy procedure, be sure to verify the guide line.

If the needle is not consistent with the guide line, DO NOT perform the biopsy procedure.

NOTE:

You can perform guide line verification on a single live B/C image, and all biopsy-irrelevant operations are forbidden.

## **Biopsy Guideline**

Press <F11 Biopsy> to enter Biopsy or touch [Biopsy] on the touch screen.

You can also operate on the menu. Use touch screen operations as an example.

■ Select the biopsy bracket angle/guide line

If the needle-guided bracket supports more than one biopsy angle or guide line, select the angle/guideline by touching the [Biopsy Kit: NGB-XXX-XX] on the touch screen (last two letters are angle or the guide line).

■ Select the guide line dot size

Touch [Dot Size] to select the dot size from Small, Medium and Big.

Tip:

- The guide line is a dotted line which consists of three kinds of dots. The distance between two dots is depth-dependent. Move the cursor over the big dot and a numeral, representing the biopsy depth, is displayed.
- The biopsy guidezone adjusts along with image adjustments, such as image inversion/rotations, zoom and depth changes.
- When the imaging depth and area are changed, the guide line is adjusted.
- Select guide grid size (only applicable for the 6LB7E probe)
   Touch [Grid Size] to select the the grid size among 2x2, 4x4 and 6x6.
- Select guide grid type (only applicable for the 6LB7E probe)
   Touch [Grid Type] to select the grid type among Circle, +, X and Dot.
- Exit
  - Touch [Biopsy Kit XXX] to be OFF or press <F11 Biopsy>.

Tips: in real-time status, press <F11 Biopsy> to exit biopsy status; in frozen status, press <F11 Biopsy> to hide/show the guide line if biopsy function is enabled.

#### Verification

Touch [Verify] to open the Biopsy Verify menu.

Adjust the guide line position

Rotate the knob under [Position] on the touch screen to change the position of the guide line.

Adjust the angle

Rotate the knob under [Angle] on the touch screen to change the guide line angle.

Biopsy guide grid

Note: touch the [C-L] item on the touch screen or press the user defined key/footswitch assigned with the "2 in 1 Probe Switch" function to switch the linear and convex plane.

For probe 6LB7E-C, the biopsy needle appears as a spot on the image.

On the image, find and select the guide grid point corresponding to the biopsy needle insertion point of the template grid, and then adjust the parameters of the menu on the screen to make sure that the biopsy needle is displayed at almost the same position as the selected guide grid point.

For probe 6LB7E-L, select one grid point in the D column of the template grid to insert the needle, and the biopsy needle appears as a line on the image.

On the image, find and select the guide grid line corresponding to the biopsy needle insertion line of the template grid, and then adjust the parameters of the menu on the screen to make sure that the biopsy needle is displayed at almost the same position as the selected guide grid line.

- > Rotate the knob under [Position] on the touch screen to move the grid in the horizontal direction.
- Rotate the knob under [Depth] on the touch screen to move the grid in the vertical direction.
- Save the verified settings

After the position and angle of the guide line are adjusted, touch [Save] and the system saves the current guide line settings. If biopsy is entered again, the displayed Position and Angle are the verified value.

Restore the factory default settings

Touch [Load Factory] and the position and angle of the guide line are restored to the factory default settings.

■ Exit biopsy verify status

Touch [Exit] and the system exits the guide line verification status.

**NOTE:** For biopsies performed with a biplanar probe, verification is performed on the first guide line. The other guide lines move together with the first one in parallel.

# 13.2.5 Removing the Needle-Guided Bracket

■ NGB-004

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

#### ■ NGB-007

Metal needle-guided bracket:

- (1) Loosen the guiding block's nut and slightly move the guiding block in the direction of the needle's tail.
- (2) Separate the residual part of the needle-guide bracket and the probe from the needle.
- (3) Loosen the bracket's pinch nut and remove the needle-guided bracket from the probe.

Plastic needle-guided bracket:

- (1) Slightly move the guiding block in the direction of the needle's tail.
- (2) Separate the residual part of the needle-guide bracket and the probe from the needle.
- (3) Remove the needle-guided bracket support from the probe.

#### NGB-009

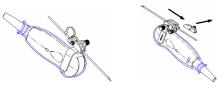
- (1) Turn on the knob of fixing the needle and separate the needle from the needle-guided bracket.
- (2) Turn on the knob of fixing guiding block and remove the guiding block from the hole of installing guiding block.
- (3) Turn on the knob of fixing needle-guided bracket and remove the needle-guided bracket.

#### ■ NGB-011

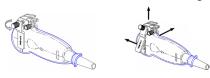
Hold the probe and the needle-guided bracket, then open the grip knob of the needle-guided bracket.

#### ■ NGB-018

(1) Loosen the guiding block's nut and slightly move the guiding block in the direction of the needle's tail.



- (2) Separate the residual part of the needle-guide bracket and the transducer from the needle.
- (3) Loosen the bracket's pinch nut and remove the needle-guided bracket from the transducer.

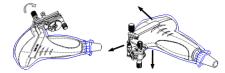


#### ■ NGB-019/NGB-022

(1) Pull the lock pin and open up the V-shaped cover to expose the needle.



- Clamp
- (2) Separate the bracket and the transducer from the needle.
- (3) Screw the pinch nut to release the needle-guided bracket.



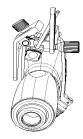
(4) Separate the bracket and the transducer.

#### ■ NGB-021

Hold the transducer in the left hand, unscrew the locking nut with the right hand to loose the retaining clamp. Raise the needle-guided bracket to separate the locating clamp/ bulge from the locating grooves.

(1) Hold the transducer. Press the biopsy needle to separate the needle from pressure position of the needle.



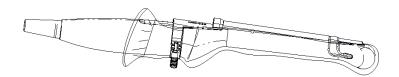


- (2) Separate the bracket and the transducer from the needle.
- (3) Rotate the clamping nuts of the needle guided-bracket on right and left side (following the direction of the arrow). The needle guided-bracket is separate from the transducer. Hold the transducer and take out the bracket.



#### ■ NGB-025

Hold the prober in the left hand; unscrew the locking nut with the right hand to loose the clamp (arrow's direction). Lift the biopsy up (towards arrow's direction). The locating pole, front clamp, the locating hole and the front clamp become loose.



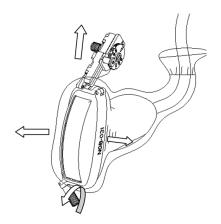
#### ■ NGB-027

Hold the prober in the left hand; unscrew the locking nut with the right hand to loose the clamp (arrow's direction). Lift the biopsy up (towards arrow's direction). The locating pole, front clamp, the locating hole and the front clamp become loose.



## ■ NGB-031

Unscrew the pinch nut to separate the needle-guided bracket from the probe. Release the needle-guided bracket from the probe.



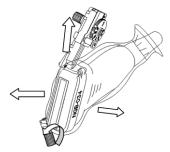
- Separate needle from bracket during surgery (NGB-034)
  - 1. Pull the lock pin out until the V-shaped cover can be turned and opened up.



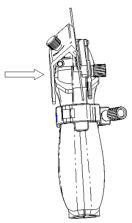
2. Turn over the V-shaped cover to expose the needle. Remove the probe and bracket.



Separate
 Screw the pinch nut to release the needle-guided bracket.



(1) Hold the probe and press the pressing block to separate V-shaped guiding block from the pressing block.

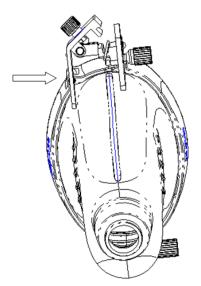


- (2) Remove the needle.
- (3) Rotate the clamping nut to separate the bracket from the probe.

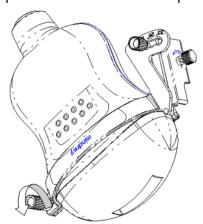


## ■ NGB-039

(1) Hold the probe and press the pressing block to separate V-shaped guiding block from the pressing block.

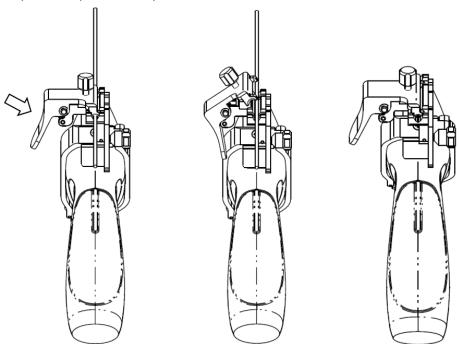


- (2) Remove the needle.
- (3) Rotate the clamping nut to separate the bracket from the probe.

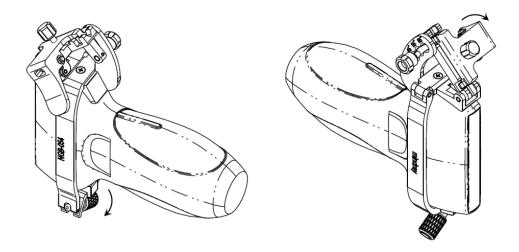


## NGB-054

(1) Hold the transducer. Press the biopsy needle pressure position to separate the biopsy needle from the pressure position. Separate the bracket and the transducer from the needle.



(2) Rotate the locking nuts of the needle guided-bracket at the right and left sides (following the direction of the arrow). The needle guided-bracket is separate from the transducer. Hold the transducer and take out the bracket.

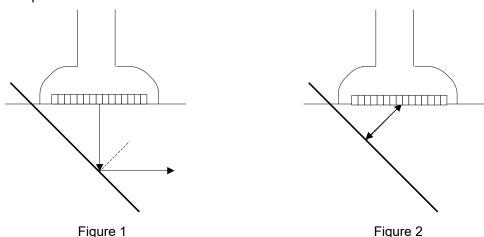


# 13.2.6 iNeedle (Needle Visualization Enhancement)

During a biopsy, the metal needle attached to the probe pierces the tissue at a certain angle. Due to the needle's acoustic impedance, the ultrasonic beam cannot penetrate the metal needle and a reflecting boundary is formed. As in Figure 1, if the deflection angle is very large, the needle display is not clear.

In deflected ultrasound transmission, the beam direction is perpendicular to the needle direction and the reflection direction is the same as the needle, as shown in Figure 2, meaning the needle display in the ultrasound image is very clear. The system provides additional deflection transmission that is approximately perpendicular to the metal needle when the normal transmission (perpendicular to the transducer surface) is being processed. The deflection angle can be chosen by the user.

iNeedle is an option.



## To enter/exit iNeedle

■ To enter iNeedle

Touch the [iNeedle] item on the B page on the touch screen.

Or, assign a user-defined key for entering iNeedle.

- Open iNeedle in Biopsy status
- 1. Perform scanning and locate the target, press <F11 Biopsy> to enter the screen.
- 2. Touch [iNeedle] to enter the status. Available adjusting parameters are displayed in the menu.

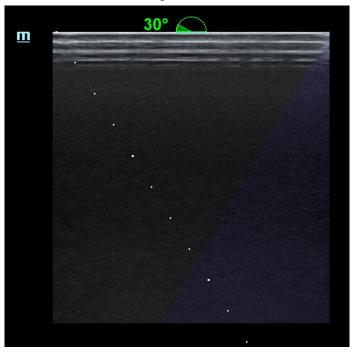
#### ■ To exit iNeedle

Press the user-defined key or touch [iNeedle] to exit the status and enter B mode.

■ Premium angle display

The premium angle appears on the screen after entering iNeedle.

The appropriate angle is 30° as shown in the figure below.



#### **Needle Direction**

**Description** This function adjusts the biopsy needle direction according to actual direction of

needle insertion. The iNeedle region changes correspondingly.

**Operation** Rotate the knob under the [Needle Dir.] item on the touch screen to select the

direction, which can be left or right.

#### B/iNeedle

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

**Operation** To turn the function on or off, touch [B/iNeedle] on the touch screen.

Tip: iZoom (full-screen magnification) is available in iNeedle status.

## Verify

To verify the biopsy guide line, see "13.2.4 Biopsy Menu/" chapter for details.

# 13.2.7 Clean and Sterilize the Needle-Guided Bracket

Only the CIVCO brackets are disposable. Needle-guided brackets whose name starts with NGB are reusable, and need thorough cleaning and sterilization before and after each biopsy.

#### Cleaning

Follow the cleaning instructions in the manual.

- 1. Wear a pair of gloves to prevent infection.
- 2. After use, immerse the needle-guided bracket in distilled water immediately to prevent dirt from

- drying. Wipe the entire surface of the needle-guided bracket by using a piece of disposable lint-free soft cloth to remove coarse dirt.
- 3. Prepare a cleaning solvent (enzymatic or neutral pH detergent, e.g., liquinox, MetriZyme) by using distilled or softened water in accordance with the operator's manual provided by the manufacturer.
- 4. Detach all the detachable parts of the needle-guided bracket and immerse the detached parts fully in the cleaning solvent for at least 1 minute or a period specified by the manufacturer. Please refer to "13.2.5 Removing the Needle-Guided Bracket".
- 5. Immerse the needle-guided bracket and all its parts fully in the cleaning solvent. Wipe and wash the surface and connecting parts of the needle-guided bracket gently by using a soft brush until no dirt is visible. Place the needle-guided bracket inside an ultrasonic cleaner and perform ultrasonic cleaning for 3–5 minutes.
- 6. Rinse the needle-guided bracket thoroughly by using a large amount of distilled or softened water (about 2 gallons) at room temperature for about 30s to remove the residual dirt and cleaning solvent. Repeat the operation twice.
- 7. Wipe away the water on the needle-guided bracket by using a piece of disposable lint-free soft cloth.
- 8. Inspect the needle-guided bracket. If visible dirt still exists, repeat the preceding steps to wash the bracket until it is all clean.
- 9. Check whether the needle-guided bracket has defects such as deformation and rusting. If such defects exist, the bracket has reached the end of its service life. In this case, stop using it and contact the Mindray service department.

#### Sterilization with a sterilant

- 1. Wear a pair of gloves to prevent infection.
- 2. Clean thoroughly in accordance with the cleaning procedure before sterilization.
- 3. Sterilize the needle-guided bracket by using an appropriate sterilant. MINDRAY recommended the following solution to sterilize the needle-guided bracket. For how to use a sterilant, see the operator's manual provided by the manufacturer. Prepare a sterilant by using sterile distilled water when necessary.
- 4. Immerse the needle-guided bracket fully in the sterilant and shake the bracket appropriately to remove any bubbles on the surface. Use a syringe to draw an appropriate amount of sterilant and inject the sterilant into the hole to remove the bubbles inside the hole. For details about the immersion duration, see the operator's manual provided by the manufacturer.
- 5. After sterilization, wash the needle-guided bracket thoroughly by using a large amount of sterile distilled water (about 2 gallons) at room temperature for about 30s to remove the residual sterilant. Repeat the operation twice.
- 6. Dry the needle-guided bracket by using a piece of sterile disposable lint-free soft cloth.
- 7. Check whether the needle-guided bracket has defects such as deformation and rusting. If such defects exist, the bracket has reached the end of its service life. In this case, stop using it and contact the Mindray service department.
- 8. Store the needle-guided bracket in a cool, clean and dry environment. And repeat the cleaning and sterilizing process before the next use.
- Glutaraldehyde-based sterilant:

Trade name	Chemical name	Procedures
Cidex Activated Dialdehyde Solution (applicable for FDA region only)	Glutaraldehyde (2.4%)	Refer to the instructions provided by the solution manufacturer for details.

■ Hydrogen Peroxide and Peroxyacetic Acid based sterilant:

Trade name	Chemical name	Procedures
MINNCARE LIQUID DISINFECTANT (applicable for Canada region only)	22% Hydrogen Peroxide 4.5% Peroxyacetic Acid	Refer to the instructions provided by the solution manufacturer for details.

- High-pressure steam sterilization (High-pressure steam sterilization is preferred for the metal guided brackets)
- 1. Wear a pair of gloves to prevent infection.
- 2. Clean the needle-guided bracket thoroughly in accordance with the cleaning procedure before sterilization.
- 3. Package the needle-guided bracket in accordance with the sterilization requirements of surgical instruments using the sterilization wrap or pouch cleared by FDA.
- 4. Place the packaged needle-guided bracket inside a high-temperature steam sterilizer and perform sterilization. The sterilization parameters are 121°C and 30 minutes for a gravity displacement steam sterilizer.
- 5. Take out the sterilization package after sterilization and dry it in an oven at 60°C for 20–30 minutes
- 6. Keep the sterilization package together with other sterilized surgical instruments in a sterile item storage area.
- 7. Check whether the needle-guided bracket has defects such as deformation and rusting before use. If such defects exist, the bracket has reached the end of its service life. In this case, stop using it and contact the Mindray service department.

#### **NOTE:** 1.

- 1. Repeated sterilization with liquid sterilant may degrade the safety and performance of the plastic needle-guided bracket. Please check the needle-guided bracket's performance periodically.
- 2. Needle guided brackets are required to verified before each biopsy. If the verification fails, it indicates that the needle-guided brackets are out of service life. For details about needle guided bracket verification, please refer to "13.2.4 Biopsy Menu/Guideline Verification".

# 13.2.8 Storage and Transportation

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

# 13.2.9 Disposal

Be sure to sterilize the needle-guided bracket before disposing of it.

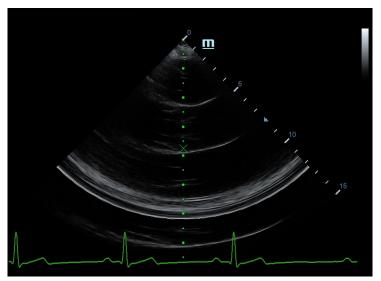
Contact your MINDRAY representative when disposing of this device.

# 13.3 Middle Line

Middle Line helps to locate and observe the focus point of lithotripsy wave during lithotripsy treatment. By means of providing information for the lithotripsy machine as well as a tool for watching the procedure of lithotripsy in real-time, you can adjust the intension and frequency of the lithotripsy wave through lithotripsy machine.

**NOTE:** This function in the ultrasound system is for lesion (stone) location and observation only. For details, please refer to lithotripsy machine accompanying manuals.

■ To enter the mode: touch [Middle Line] in the biopsy tab or preset a shortcut key for middle line function (for details, see "12.1.6 Key Configuration"). Press the user-defined key to turn on the function.



- The middle line is a vertical dotted line located in the middle of the screen, the position and direction of which cannot be changed.
- There is a mark icon of "x" located on the middle line which can be moved up and down along the line by rolling the track ball.
- To use the Middle Line function of the ultrasound system:
  - a) Use the trackball to change the mark position and by adjusting lithotripsy machine tools or patient posture to locate the stone center at the mark.
  - b) Read the depth of the mark by observing the depth caliper on the right of the image.
  - c) After the stone is located, refer to lithotripsy machine manuals to perform the lithotripsy.
- The depth of the mark is displayed in the image parameter area of the screen.

# 14 DVR Recording

#### NOTE:

Strictly observe the procedures described here to perform the recording and replaying operations; otherwise it may result in data loss or system malfunction.

Accidental exposure to strong electromagnetic fields may result in image and data loss, so check if the recording is successful as soon as possible. Mindray is not responsible for any data loss.

The system provides built-in DVR recording function. You can use the DVR to record and replay videos and audios that can be stored in DVD disc or hard disc.

The recorded video is AVI format; you can save it in the hard disk drive, burn to the DVD or export to the USB disk.

When the built-in DVR is in normal status, the displays at the lower right corner of the screen.

# **DVR Recording**

After recording, the system will save the recording file automatically, you can select to save in Hard disk, U disk or optical disk.

- 1. Perform ultrasound exams, select appropriate views and adjust parameters to prepare for recording.
- 2. Click to open the dialogue box and select desired recording type: Hard disk/USB/CDROM;
- 3. Click [Close] to enter recording status;
- 4. Press <F9> to record, and the DVR icon displays as in recording status. During the recording process, you can perform imaging mode switching, comments adding, body mark adding and measurements.
- 5. Press <F9> again to stop recording, the DVR icon in the lower right corner turns into data transfer status
  - If USB/CDROM is selected, the system sends the recorded file to the target storage media (USB disk or DVD optical disk drive) in the meantime.
  - If Hard disk is selected, the system saves the file to the path: D:\dvr.

In the patient task management screen, click [Media Storage Task] tab to check transferring status.

# Send Image

The system also supports exporting recorded images that are saved in the local disk.

- 1. Click to open the dialogue box, and click [Local Video Manage] to enter the managing dialogue box;
- 2. Select the destination and the target file, click [Send] to send the file to the selected path.

During sending progress, the icon displays as



# 14.3 DVR Video Replay

You can replay the video and audio record.

■ Replay on PC

Connect the USB disk or optical disk with the file to the PC, open the file directly.

- Replay on the ultrasound system
- 1. Click to open the dialogue box;
- 2. Click [Play] to open the dialogue box;
- 3. Select the path and type for the file and then click [OK] to replay the file, or double-click the file name directly.

# 15 Acoustic Output

This section of the operator's manual applies to the overall system, including the main unit, probes, accessories and peripherals. This section contains important safety information for device operators pertaining to acoustic output and how to control patient exposure through use of the ALARA (as low as reasonably achievable) principle. This section also contains information regarding acoustic output testing and real-time output display.

Read this information carefully before using the system.

# 15.1 Concerns with Bioeffects

Diagnostic ultrasound is recognized as being safe. There have been no reports of injuries to patients caused by diagnostic ultrasound.

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

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

# 15.2 Prudent Use Statement

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

# 15.3 ALARA Principle (As Low As Reasonably Achievable)

The ALARA principle must be practiced when using ultrasound energy. Practicing ALARA ensures that the total energy level is controlled below a low enough level at which bioeffects are not generated while diagnostic information is being accumulated. The total energy is controlled by output intensity and total radiation time. The output intensity necessary for examinations differs depending on the patient and the clinical case.

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

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

Additional information regarding the concept of ALARA and the possible bioeffects of ultrasound is available in a document from the AIUM (American Institute of Ultrasound Medicine) entitled "Medical Ultrasound Safety."

# 15.4 MI/TI Explanation

# 15.4.1 Basic Knowledge of MI and TI

#### Mechanical Bioeffect and Thermal Bioeffect

The relationship of various ultrasound output parameters (frequency, acoustic pressure and intensity, etc.) to bioeffects is not fully understood at present. It is recognized that two fundamental mechanisms may induce bioeffects. One is a thermal bioeffect involving tissue absorption of ultrasound, and another is a mechanical bioeffect based on cavitations. Thermal Index (TI) gives the relative index of temperature increase by thermal bioeffect, and Mechanical Index (MI) gives the relative index of mechanical bioeffect. TI and MI indices reflect instantaneous output conditions. They DO NOT consider the cumulative effects of the total examination time. TI and MI models contain practical simplifications for complex bioeffect interactions. The operator must be aware that the actual worst case temperature rise may be up to several times higher than the displayed TI value.

#### ■ MI (Mechanical Index)

The mechanical bioeffects are the result of compression and decompression of insonated tissues with the formation of micro bubbles that can be referred to as cavitations.

MI is an index that shows the possibility of cavitation generation based on acoustic pressure, and the value at which the peak rarefactional acoustic pressure is divided by the square root of the frequency. Therefore, the MI value becomes smaller when the frequency is higher or the peak rarefactional acoustic pressure is lower, and it becomes more difficult to generate the cavitations.

$$MI = \frac{P_{r, \alpha}}{\sqrt{f_{awf}} \times C_{MI}}$$

$$C_{MI} = 1 \text{ (MPa } / \sqrt{\text{MHz}} \text{ )}$$

For the frequency 1 MHz and the peak rarefactional acoustic pressure 1 MPa, MI becomes 1. It is possible to consider MI as one threshold of cavitation generation. It is particularly important to keep the MI value low when both gases and soft tissues exist together, such as with lung exposure in cardiac scanning and bowel gas in abdominal scanning.

#### ■ TI (Thermal Index)

The TI is determined by the ratio of the total acoustic power to the acoustic power required to raise the tissue temperature by 1°C. In addition, because the raise in temperature can be greatly different according to tissue structures, TI is divided into three kinds: TIS (Soft-tissue Thermal Index), TIB (Bone Thermal Index) and TIC (Cranial-bone Thermal Index).

TIS: Thermal index related to soft tissues, such as abdominal and cardiac applications.

TIB: Thermal index for applications such as fetal (second and third trimester) or neonatal cephalic (through the fontanel) applications, in which the ultrasound beam passes through soft tissue and the focal region is in the immediate vicinity of bone.

TIC: Thermal index for applications such as pediatric and adult cranial applications, in which the ultrasound beam passes through bone near the beam entrance into the body.

Although the output power is automatically controlled for the selected applications, high TI values should be kept to a minimum or avoided in obstetric applications. WFUMB (World Federation for Ultrasound in Medicine and Biology) guidelines state that temperature increases of 4°C for 5 minutes or more should be considered as potentially hazardous to embryonic and fetal tissue.

The smaller the MI/TI values, the lower the bioeffects.

## 15.4.2 MI/TI Display

TI and MI values are displayed in the top part of the screen in real time. The operator should monitor these index values during examinations and ensure that exposure time and output values are maintained at the minimum amounts required for effective diagnosis.

**NOTE:** If a value of MI or TI exceeds 1.0, the ALARA principle must be practiced.

The display precision is 0.1.

Display accuracy of MI is  $\leq$ 14.7%, and TI is  $\leq$ 28.5%.

# 15.5 Acoustic Power Setting

#### ■ Acoustic power adjustment

Click the [A.power] on the soft menu to adjust the acoustic power percentage. Its value is displayed on the corresponding item, as well as at the top of the screen. The greater the acoustic power percentage, the greater the current acoustic output. When the image is frozen, the system stops transmitting acoustic power.

#### ■ Default acoustic power setting

Selection of diagnostic applications is the most important factor in controlling ultrasound output. The permissible level of intensity of ultrasound differs depending on the region of interest. For fetal examinations, in particular, much care must be exercised.

Within this system, imaging setups can be created using the ultrasound output set by you.

Once you set the preset settings, the system's default setting values may be changed and invalid. The user is responsible for any change to the default settings.

### Adjusting range

Initial power: 3.2% to 100%\*

Definition of 100%: the maximum acoustic power of a probe determined by the increase in probe surface temperature in the selected mode and the acoustic power restrictions specified by the FDA.

Default settings of the acoustic power value refer to the best image quality for the probe. The larger the acoustic power value, the better the image quality.

In the DC-80A series product, to obtain optimum images for applications under the requirements of safety and ALARA principle, we set acoustic power default values in factory to be maximum 96.6% in all exam modes for a better image quality. The user can make adjustments according to the imaging effect in practical use.

#### NOTE:

This system automatically returns to the settings whenever changes are made to the values (when you turn on the power, switch between probes, press <End Exam>, or select OK or Cancel in the Setup menu). In the factory default settings, the Acoustic Output is limited to below 100%. Following the ALARA restriction, you are allowed to increase the acoustic power under FDA 510(k) Guidance-Track 3 limits and to set it in the image preset screen.

The system's acoustic output has been measured and calculated in accordance with IEC60601-2-37: 2015, FDA 510(K) GUIDANCE, IEC 62359: 2017, Ultrasonics-Field characterization-Test methods for the deter mination of thermal and mechanical indices related to medical diagnostic ultrasonic fields.

# 15.6 Acoustic Power Control

A qualified operator may use the system controls to limit the ultrasound output and to adjust the quality of the images. There are three categories of system controls relating to output. They are:

- Controls that have direct effect on the output
- Controls that indirectly control the output
- Controls that are receiver controls
- Direct controls

It is possible to control, if necessary, the acoustic output with the "A.power" item on the soft menu or the corresponding knob at the bottom of the soft menu. In this case, the maximum value of the acoustic output never exceeds an MI of 1.9 and an I<sub>SPTA.3</sub> of 720 mW/cm<sup>2</sup> in any mode of operation.

#### ■ Indirect controls

The controls that indirectly affect output are the many imaging parameters. These are operating modes, frequency, focal point positions, overall depth and PRF.

The operating mode determines whether the ultrasound beam is scanning or non-scanning. Thermal bioeffect is closely connected to M mode, Doppler and Color mode. Acoustic attenuation of tissue is directly related to probe frequency. The focal point is related to the active aperture of the probe and beam width. For higher PRF (pulse repetition frequency), the more output pulses occur over a period of time.

#### ■ Receiver controls

The receiver controls (for example, gain, dynamic range and image post-processing, etc.) do not affect output. These controls should be used, when possible, to improve the image quality before using controls that directly or indirectly affect output.

# 15.7 Acoustic Output

# 15.7.1 Derated Ultrasonic Output Parameters

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

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

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

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

## 15.7.2 Limits of Acoustic Output

In accordance with the FDA Track 3 requirements, the derating (or attenuated) approach was incorporated into the FDA Acoustic Output Limits, as listed below. The maximum acoustic output level from any probe in any operating mode is expected to fall below these limits.

#### FDA Maximum Acoustic Output Limits for Track 3 (Attenuated Values)

Application	I <sub>spta.3</sub> (mW/cm <sup>2</sup> )	I <sub>sppa.3</sub> (W/cm <sup>2</sup> )		MI
Regions (except eyes)	≤ 720	≤ 190	or	≤ 1.9

# 15.7.3 Differences between Actual and Displayed MI and TI

In operation, the system will display the Acoustic Output Parameters Thermal Index (TI) or Mechanical Index (MI) (or sometimes both parameters simultaneously) to the operator. These parameters were developed as general indicators of risk from either thermal or mechanical action of the ultrasound wave. They serve to indicate to the operator whether a particular system setting increases or decreases the possibility of Thermal or Mechanical effect. More specifically, they were designed to assist in the implementation of the ALARA principle. As an operator changes a given system control, the potential effect of the change in output is indicated. However, the Thermal Index is not the same as the raise in temperature in the body, for several reasons. First of all, in order to provide a single display index, a number of simplifying assumptions had to be made. The biggest assumption was the use of the attenuating formula described above, which is much lower than the actual value for most tissues within the body. Scanning through muscle or organ tissue, for example, will produce much higher attenuation than 0.3 dB/cm/MHz. Significant simplifications were also made for the thermal properties of tissue. Therefore, scanning through highly-perfused tissue, such as the heart or vasculature, will produce significantly less thermal effect than that suggested by the Thermal Index.

Similarly, the Mechanical Index was derived to indicate the relative possibility of mechanical (cavitation) effects. The MI is based on the derated peak rarefactional pressure and the center frequency of the ultrasound wave. The actual peak rarefactional pressure is affected by the actual attenuation caused by tissue in the path between the probe and the focal point. Again, all solid tissues within the body have higher attenuation than the prescribed 0.3 dB/cm/MHz value, and therefore, the actual peak rarefactional pressure will be lower. Further, the actual peak rarefactional pressure will change depending on the region of the body being scanned.

For these reasons, the TI and MI displays should only be used to assist the operator in implementing ALARA at the time of the patient examination.

# 15.8 Measurement Uncertainty

The total estimated measurement uncertainty (where the total uncertainty includes uncertainties in hydrophone response, measurement, calculation and positioning) are:

Acoustic Quantities	Total Uncertainties (Standard)				
Power	26.48% for non-scan modes; 6.03% for scan modes.				
Frequency	0.22%				
Pressure	13.01%				
lta	26.48% for non-scan modes; 26.95% for scan modes.				
lpa	26.5%				
Mechanical Index	13.01%				
	Non-scan Modes	Scan-Modes			

Total Uncertainty for TIS	26.48%	6.03%
Total Uncertainty for TIB	26.48% or 18.72%	6.03%
Total Uncertainty for TIC	26.48%	6.03%

# 15.9 References for Acoustic Power and Safety

- 1. "Bioeffects and Safety of Diagnostic Ultrasound" issued by AIUM in 1993
- 2. "Medical Ultrasound Safety" issued by AIUM in 1994
- 3. Marketing Clearance of Diagnostic Ultrasound Systems and Transducers, June 27, 2019. Center for Devices and Radiological Health.
- 4. Medical electrical equipment-Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment issued by IEC in 2015
- 5. IEC 62359, Ultrasonics-Field characterization-Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields, 2017.

# **16** EMC Guidance and Manufacturer's Declaration

DC-90 series complies with the EMC standard IEC60601-1-2:2014+A1:2020.

Intended Environments: HOME HEALTHCARE ENVIRONMENT (except for near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging).

### **WARNING:**

- 1. The use of unapproved accessories may diminish system performance.
- 2. Use of components, accessories, probes, and cables other than those specified may result in increased emission or decreased immunity of system.
- 3. Operation of system, in the case that the patient physiological signal is lower than the minimum amplitude or value specified in the product specifications, results may not be obtained (results can be obtained when the HR is in the range of 30-250 bmp or when the QRS wave amplitude is between 0.5-5 mV.)
- 4. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- 5. Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- 6. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of DC-90 series, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- 7. Keep a distance of at least 20 cm away from the monitor when WiFi function is in use
- 8. DC-90 series needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.
- 9. Other devices may interfere with this equipment even though they meet the requirements of CISPR.
- 10. Preventing conducted RF immunity. Due to technological limitations, the conducted RF immunity level are limited to 3Vrms level, conducted RF interference above 3Vrms may cause wrong diagnosis and measurements. We suggest that you position system further from sources of conducted RF noise.

- 11. Portable and mobile RF communications equipment could affect system. See below tables.
- 12. DC-90 Series should be away from RFID, MRI, diathermy, and electrocautery testing, wireless power transfer, 5G cellular and security equipment (such as electromagnetic anti-theft system and metal detector). If the devices are near and are interfered by the concealed and undiscovered RF transmitter (for example, scanning mode changes or image disturbances affecting diagnosis), the user should immediately take mitigation measures, such as redirecting, repositioning or shielding the RF transmitter.
- 13. This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
- 14. This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
  - Reorient or relocate the receiving antenna.
  - Increase the separation between the equipment and receiver.
  - Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
  - Consult the dealer or an experienced radio/TV technician for help. Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

The device has been evaluated to meet general RF exposure requirement.

The device can be used in portable exposure condition without restriction.

If DC-90 series is operated within the electromagnetic environment listed in TABLE EMC-1, EMC-2, EMC-3, EMC-4, EMC-5, EMC-6 DC-90 series will remain safe and will provide the following basic performances:

- Imaging;
- Doppler acoustic spectral displaying;
- Taking measurements;
- Patient information;
- Date/time information.

### GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC EMISSIONS

DC-90 series is intended for use in the electromagnetic environment specified below. The customer or the user of system should assure that it is used in such an environment.

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIROMENT – GUIDANCE		
RF Emissions CISPR 11	Group 1	DC-90 series 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	DC-90 series is suitable for use in all establishments		
Harmonic Emissions IEC 61000-3-2	O1 1	including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic		
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Compliance	purposes.		

## GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC IMMUNITY

DC-90 series 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 ENVIROMENT – GUIDANCE
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact; ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact; ±2 kV, ±4 kV, ±8 kV, ±15 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	$\pm 0.5 \text{ kV}, \pm 1 \text{ kV line(s)}$ to line(s); $\pm 0.5 \text{ kV}, \pm 1 \text{ kV}, \pm 2 \text{ kV}$ line(s) to earth	$\pm 0.5 \text{ kV}, \pm 1 \text{ kV line(s)}$ to line(s); $\pm 0.5 \text{ kV}, \pm 1 \text{ kV}, \pm 2 \text{ kV}$ line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, Short interruptions and voltage variation on power supply input voltage IEC 61000-4-11	0 % U <sub>T</sub> ; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U <sub>T</sub> 1 cycle 70% U <sub>T</sub> for 25/30 cycle at 0° 0 % U <sub>T</sub> ; 250/300 cycle	0 % U <sub>T</sub> 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U <sub>T</sub> 1 cycle 70% U <sub>T</sub> for 25/30 cycle at 0° 0 % U <sub>T</sub> ; 250/300 cycle	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	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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

#### GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC IMMUNITY DC-90 series 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. ELECTROMAGNETIC ENVIROMENT - · IEC 60601 **IMMUNITY** COMPLIANCE TEST LEVEL **GUIDANCE TEST** LEVEL 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. 3 Vrms 3 Vrms Recommended separation distance: 0.15 MHz - 800.15 MHz - 80Conduced RF $d = 1.2 \text{ x} \sqrt{P}$ MHz MHz IEC 61000-4-6 6 Vrms in 6 Vrms in $d = 2 \times \sqrt{P}$ ISM<sup>a</sup> and ISM<sup>a</sup> and amateur radio amateur radio bandsa bandsa between 0,15 between 0,15 MHz and 80 MHz and 80 MHz MHz Radiated RF 10 V/m 10 V/m $d = 1.2 \text{ x} \sqrt{P}$ 80 MHz ~ 800 MHz 80MHz -IEC 61000-4-3 80MHz - $_{d\,=\,2.3~x}\sqrt{P}~_{800~MHz}~\sim~2.7GHz$ 2.7GHz 2.7GHz Where, P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site

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.

survey<sup>b</sup>, should be less than the compliance

Interference may occur in the vicinity of equipment marked with the following

level in each frequency range<sup>c</sup>.

symbol:  $(((\bullet)))$ 

<sup>a</sup>The ISM<sup>a</sup> (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

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

<sup>c</sup> Over the frequency ranges 150 kHz to 80 MHz, field strengths should be less than 3V/m.

#### **TABLE EMC-4**

GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC IMMUNITY
DC-90 series 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 ENVIROMENT – GUIDANCE
	8 A/m 30 kHz	8 A/m 30 kHz	
	CW	CW	
	65 A/m	65 A/m	
Proximity magnetic	-	134,2 kHz	
fields	Pulse modulation	Pulse modulation	/
IEC 61000-4-39	2,1 kHz	2,1 kHz	
	7,5 A/m	7,5 A/m	
	13,56 MHz	13,56 MHz	
	Pulse modulation	Pulse modulation	
	50 kHz	50 kHz	

TABLE EMC-5 Test specifications and minimum distances

#### Recommended separation distances between portable and mobile RF communications equipment and system

DC-90 series is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and DC-90 series as recommended below, according to the maximum output power of the communications equipment. Portable and mobile radio communications equipment (e.g. two-way radio, cellular/ cordless telephones and similar equipment) should be used no closer to any part of this system, including cables, than determined according to the following method:

Test frequency (MHz)	Band(MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380 - 390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430 -470	GMRS 460 FRS 460	FM ±5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704 - 787	LTE Band 13,17	Pulse modulation 217 Hz	0.2	0.3	9
810 870		GSM 800/900, tetra 800,	Pulse modulation			
930	800 - 960	iDEN 820, CDMA 850,	18 Hz	2	0.3	28
1720		LTE Band 5 GSM 1800,				
1970	1700 -1990	CDMA 1900, GSM 1900, DECT,	Pulse modulation 217 Hz	2	0.3	28
		LTE Band 1, 3,4,25,UMTS				
2450	2400 -2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240 5500 5785	5100 -5800	WLAN, 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9

# RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATION DEVICE AND THE SYSTEM

DC-90 series 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	Separa	Separation Distance According to Frequency of Transmitter					
Maximum	150kHz -80MHz	150kHz -80MHz	80MHz-800MHz	800MHz-2.7GHz			
Output power	Out ISM and	in ISM and amateur					
of	amateur radio	radio bands					
Transmitter	bands		_				
(W)	$d=1.2\sqrt{P}$	d=2 √P	$d=1.2\sqrt{P}$	$d=2.3\sqrt{P}$			
0.01	0.12	0.2	0.12	0.23			
0.1	0.38	0.64	0.38	0.73			
1	1.2	2	1.2	2.3			
10	3.8	6.4	3.8	7.3			
100	12	20	12	23			

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

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

Note 1: At 80 MHz and 800 MHz, the 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.

#### **TABLE EMC-7**

No.	Name	Cable length (m)	Shield or not	Remarks
1	Power input	2.5m	Not shielded	/
2	SIP/SOP	<3.0m	Shielding	/
3	ECG Cable	2.9m	Shielding	/
4	ECG Lead	1.0m	Shielding	/
5	Probe Cable	<3.0m	Shielding	/
6	Footswitch Cable	2.9m	Shielding	/

# Radio Regulatory Compliance

RF parameter

Til parameter			
Features	2.4GHz	5GHz	
	2412MHz~2483.5MHz	5.15~5.25GHz	
Enaguanay Daga		5.25~5.35GHz	
Frequency Rage		5.47~5.725GHz	
		5.725~5.850GHz	
Modulation	DSSS and OFDM	OFDM	
Output Power	≤20dBm		

NOTE: Keep a distance of at least 20cm away from the monitor when Wi-Fi function is in use.

# 17 System Maintenance

Routine system maintenance shall be carried out by the user. System maintenance after the warranty has expired is the full responsibility of the owner/operator.

The responsibility for maintenance and management of the product after delivery resides with the customer who has purchased the product.

If you have any questions, please contact the Mindray Customer Service Department or a sales representative.

# **△WARNING**:

- 1. Only an authorized Mindray service engineer can perform maintenance which is not specified in this operator's manual.
- 2. For the sake of system performance and safety, perform periodical checks of the system.

# 17.1 Daily Maintenance

You are responsible for daily maintenance.

# 17.1.1 Cleaning the System

# **≜WARNING**:

- 1. Before cleaning the system, be sure to turn off the power and disconnect the power cord from the outlet. Cleaning the system while the power is "On" may result in electric shock.
- DO NOT directly spray solution onto the monitor, system control
  panel or hard surfaces that are under pressure or pumped.
  Ingress fluid leakage into the monitor or system can damage the
  monitor or system, causing possible electric shock or system
  failure.

CAUTION:

Do not spill water or other liquids into the system while cleaning. This may result in malfunction or electric shock.

#### NOTE:

- DO NOT use hydrocarbon glass cleaner or cleaner for OA (Office Automation)
  equipment to clean the monitor. These substances may cause deterioration of the
  monitor.
- Clean the control panel periodically, otherwise the button may become blocked with dirt and the system will buzz while the button has no effect.

- Cleaning the probe cover and connector:
  - Tools: mild soapy water, soft dry cloth, soft brush
  - Method:
    - a) Wipe away dust attached to the surface of the probe head, connector and cable.
    - b) Use a soft brush to gently brush away dust from inside the probe connector.
    - c) Remaining stains or dust attached to the surface of the cable or connector should be wiped away using a cloth with a little soapy water and then air dried.

Refer to chapter "13.1.5 Probes Cleaning, Disinfection and Sterilization" for cleaning and disinfection for the probes.

**NOTE:** Do not use a wet cloth to clean the probe connector.

- Cleaning the probe cable
  - a) Use a soft dry cloth to wipe away stains from the probe cable.
  - b) If the stains are difficult to remove, use a soft cloth dipped in a mild detergent and then let the cable air dry.
- Cleaning holders
  - Tools: soft dry cloth, soapy water, soft brush
  - Method:

The surface of the power button should be cleaned with a soft dry cloth. Remaining stains should be wiped away using a cloth with clean or soapy water (NOTE: the cloth should not be made too wet, as this may cause electric shock) and the surface left to air dry.

- a) Use a soft dry cloth to wipe away dust attached to the inside, outside and gaps in the probe holder or gel holder. Use a soft brush to brush away dust or stains from the small intra-cavity probe holder or its gap.
- b) Remaining stains on the inside and outside of the holder should be wiped away using a cloth with a little soapy water and then air dried.
- c) Gel warmer: remove the gel warmer after pulling out the power supply cable. Use a soft dry cloth to wipe away dust attached to the inside and outside, then brush away dust in the gel warmer or brush stains with a little soapy water and then air dry.
- Cleaning the monitor and the touch screen
  - Tool: soft dry cloth, clean or soapy water
  - Method:

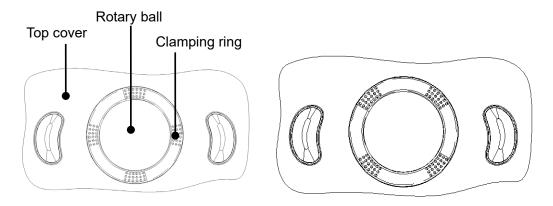
The surfaces of the monitor and touch screen should be cleaned with a soft dry cloth. Remaining stains should be wiped away using a cloth with a little clean or soapy water and then air dried.

#### Cleaning the trackball

- Tools: paper, dry cloth, mild soapy water
- Method:

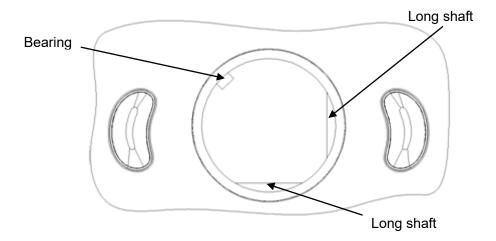
#### 1. Disassembling the trackball:

Press the bulges on the clamping ring using both hands and turn the ring about 35° clockwise until it lifts. Take out the ring and the rotary ball. Be careful not to drop the ball. See the figure below.



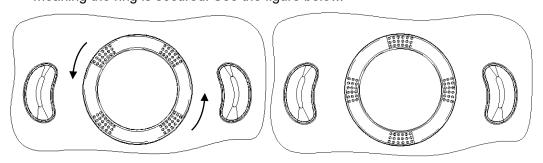
### 2. Cleaning

Clean the two long shafts, the bearing and the rotary ball with a clean soft dry cloth or paper.



#### 3. Installing the trackball

Put the rotary ball back in the trackball mechanism and put the clamping ring back in. Turn the ring counterclockwise until the bulges are flush with the top cover and the ring clicks and locks, meaning the ring is secured. See the figure below.



- Cleaning the main panel
  - Tools: soft dry cloth, soapy water
  - Method:

Use a soft dry cloth to clean the surface of the control panel (including the keystrokes, encoders and sliders). If the control panel is dirty, moisten the soft cloth with a little mild soapy water and wipe away any stains. Use another soft dry cloth to remove any moisture and allow all hard surfaces to completely air dry. If the control panel is difficult to clean, disassemble the encoder caps first and then clean it with mild soapy water.

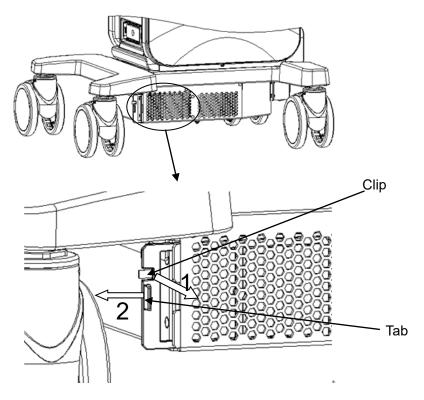
**NOTE:** The keyboard on the control panel should be cleaned periodically, otherwise the keys may become blocked with dirt and when the buzzer rings the keys will not work.

- Cleaning the cover
  - Tools: soft dry cloth, soapy water
  - Method:

Use a soft dry cloth to clean the system's cover. If the system is dirty, moisten the soft cloth with mild soapy water, wipe away any stains, then air dry.

- Clean the dust-proof cover
  - Tools: soft brush
  - Method:
    - a) Disassemble the dustproof cover before cleaning.

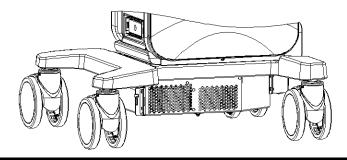
System's dustproof cover: use one hand to pull the dust proof clip in the direction of arrow 1 and use the other hand to pull the dust proof cover in the direction of arrow 2 at the same time.



Probe port dustproof cover: Pull it out.

- b) Clean with a soft brush and then wipe away the dust.
- c) Assemble the dustproof covers.

Insert the dustproof clasp into the slot on the main unit, push the dustproof clasp inward until it is fixed in the slot.



**∆**CAUTION:

Please clean all the system's dustproof covers periodically (once per month). Failure to do so may result in system damage. Cleaning times can be increased when the system is used in the open air or somewhere more dusty.

**NOTE:** Use a soft brush to brush away dust attached to all visible sockets or interfaces (such as probe sockets, sockets or interfaces in the IO panel and power supply panel). Do not use a cloth and water.

#### Cleaning the peripherals

Carry out cleaning maintenance according to your actual peripheral configuration. Items which are not configured can be skipped.

Content	Description	
Color and B/W video printer	Wipe away dust or stains on the printer cover with a soft dry cloth, then clean the inside of the printer. Carry out cleaning maintenance according to the operation manual if necessary.	
Graph/text printer	Wipe away dust or stains on the printer cover with a soft dry cloth, then clean the inside of the printer. Carry out cleaning maintenance according to the operation manual if necessary.	
Foot switch	Use a soft dry cloth with a little mild soapy water to wipe away dust or stains attached to the foot switch pedals or cable.	
Barcode reader	Use a soft dry cloth to wipe away dust from the glass panel of the reader, then wipe away dust or stains from the cable and bracket. See Appendix B Barcode Reader for details.	

# 17.1.2 Checking the Probe

- Visually check to confirm that there are no cracks or expansion of the probe head.
- Visually check to confirm that there is no deterioration or erosion of the probe cable.
- Visually check to confirm that none of the connector pins are bent, destroyed or falling off.

## 17.1.3 Checking the Power Cable and Plug

- Visually check to confirm that there are no wrinkles, cracks or deterioration.
- Manually check to confirm that there is no looseness or rupture. The connection of the plug is reliable.

# 17.1.4 Checking Appearance

Check if there are any cracks in the covers:

- Ultrasound system covers
- Probe appearance
- External appearance of the ECG lead

# 17.1.5 System Hard Drive Backup

To prevent deterioration or loss of data stored in the system hard drive (including patient info data, preset data, etc.), create a backup copy of the hard drive at regular intervals.

# 17.2 Troubleshooting

If any persistent system malfunction is experienced, e.g., an onscreen error message, blank imaging screen, absent menus, see the table below. If the failure cannot be resolved, contact the Mindray Customer Service Department or a sales representative.

#### Troubleshooting Table

No.	Failure	Cause	Measure
	After the AC power	Abnormal power system or	Check that the system is plugged in.
1	input is connected, the power indicator does not light up.	incorrect connection of the power cord.	Check that the plug has not become loose or dislodged from the back of the system.
2	The power indicator of the monitor is lit up, but the image is blank.	The interval between turning off and restarting the system is too short.	Turn off the system and wait at least 1 minute, then restart the system.
		The monitor brightness or contrast may be improperly set.	Adjust the monitor brightness and contrast.
3	The monitor displays the characters and menus but no images.	The frequency (image quality parameter), overall gain or TGC controls are improperly set.	Adjust the frequency, gain or TGC control.
		Check that a probe is connected and/or fully connected.	Ensure proper probe connection.
		The system is in freeze status.	Unfreeze the image.
	The image quality is degraded	The exam mode is incorrect.	Select an appropriate exam mode.
4		The image post-processing settings are incorrect.	Adjust the image post-processing settings or reset post-processing to the default values.
		The image presets are inappropriate.	Reset the factory default presets.
5	The button does not respond and the system is buzzing	oond and the hutton	Check the control panel for the blocked button and press it several times to release it.
	System is buzzing		Clean the button.

# Appendix A iScanHelper

By providing the referential information, such as, the ultrasonic image, the anatomic graphic, scanning pictures/other scanning tips or diagnosis comments, the system helps the doctors to operate the scanning by iScanHelper. Furthermore, it is a good platform for the self-learning and training of ultrasound scanning technique for doctors. The system also plays a role in the assistant software system in fulfilling training and education.

Tips: iScanHelper feature is available under abdominal, urological, obstetrics, gynecology and small parts exam modes.

NOTE:

THIS "iScanHelper" IS FOR REFERENCE OR TUTORIAL PURPOSES ONLY, AND THE MANUFACTURER WILL NOT BE LIABLE FOR DAMAGES AND/OR OTHER UNDESIRABLE CONSEQUENCE IN ANY KIND THAT MAY OCCUR TO THE PATIENT OR THE USERS BY USING THE SOFTWARE.

## A.1 Enter/ Exit

■ Enter

Press the user-defined key for entering iScanHelper (setting path: [Setup] (F10)  $\rightarrow$  [System]  $\rightarrow$  [Key Config]).

■ Exit

Press the user-defined key again to exit iScanHelper.

# A.2 Use iScanHelper for Reference

- 1. Perform ordinary scanning procedure.
- 2. Press the user-defined key for entering iScanHelper to enter iScanHelper status.
- 3. Rotate the trackball to move the cursor onto the target view name in the view selecting box and then press <Set>.
- 4. Perform scanning according to information displayed on the help information area. You can zoom in a single window in the help information area to see the window more clearly. For details, please refer to "A.4.3 Single/quad-window Display".
- 5. Press the user-defined key for entering iScanHelper again to exit.

# A.3 Use iScanHelper for Learning or Training

- 1. Switch to the exam modes that support iScanHelper.
- 2. Press the user-defined key for entering iScanHelper to enter iScanHelper status.
- 3. Learn and practise views by system defaulted sequence according to the information displayed on help information area; or select unfamiliar views to practise.
  - You can zoom in a single window in the help information area to see the information. For details, please refer to "A.4.3 Single/quad-window Display".
- 4. Press the user-defined key for entering iScanHelper again to exit iScanHelper.

# A.4 Basic Screen and Operation

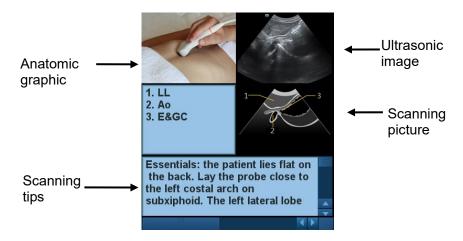


# A.4.1 View Selecting Area

Rotate the trackball to move the cursor onto the target view and press <Set>, related information will be displayed on the help information area.

## A.4.2 Help Information Area

Help information area displays on the lower right corner of the screen, providing ultrasonic image, anatomic graphic, scanning picture and scanning tips.



- Ultrasonic image
   It is used to compare with images scanned by the operator.
- Anatomic graphic Related anatomical tissue information are provided here.
- Scanning picture
   Ordinary scanning tips can be observed here, including posture, probe mark, probe swing/sweep techniques.

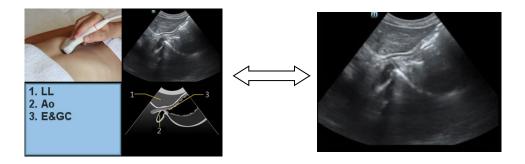
Scanning tips

You can read tissue related anatomical information and adjacent tissue information here.

# A.4.3 Single/quad-window Display

You can zoom in the anatomic graphic, ultrasonic image as well as scanning picture to view those information more conveniently.

Press <Cursor> to obtain the cursor. Move the cursor on the anatomic graphic, the ultrasonic image or scanning tips. Double-click <Set> to go to the single window of each of them. Double-click single window again to return to quad-window display.



# A.5 Measurement, Comments, and Body Mark

Switching probe or exam, measurement, comments and the body mark are unavailable under iScanHelper status.

# **Appendix B Barcode Reader**

The product supports two kinds of readers for logging data as patient ID: 1-D barcode reader (SYMBOL LS2208) and 2-D barcode reader (ZEBRA DS4308). The laser transmitted by the two readers is Class 2 laser. ZEBRA DS4308 is classified as "EXEMPT RISK GROUP" according to IEC 62471: 2006 and EN 62471: 2008.

 $\triangle$ WARNING:

Class 2 laser adopts low power, visible LED. DO NOT stare into beam because of unknown hazards of transient radiation provided by class 2 laser.

DO NOT stare into beam emitted by ZEBRA DS4308 for more than 10s.

 $\triangle$ CAUTION:

Ensure the information acquired by barcode reader is consistent with the actual information.

There are 2 operation modes:

Hand-held mode: press the trigger to decode.

Hands-free mode: seat the reader in the stand to enter the mode, the reader decodes automatically.

Note: the reader does not support decoding of Multilanguage.

# **B.1** 1-D Barcode Reader

## **B.1.1** Overview

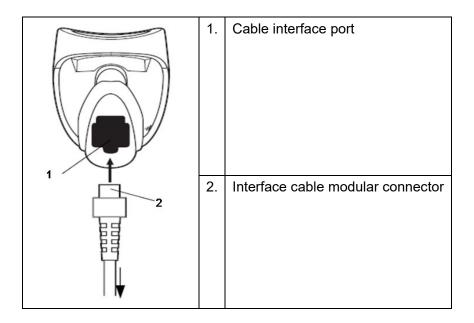


1.	LED	Green: A barcode was successfully decoded.
		Red: A data transmission error or reader malfunction occurred.

2.	Scan window	Scan the barcode.
3.	Trigger	Press to decode

# B.1.2 Setting Up the Reader (Take LS2208 as an example)

- 1. Plug the interface cable modular connector into the cable interface port on the bottom of the reader handle, and ensure the connector is properly secured.
- 2. Connect the other end of the interface cable to the host.



# **B.1.3** Setting

The reader has factory settings; please refer to A.4 for details.

The reader supports some user-defined functions as introduced below.

For more details, please contact the SYMBOL reader agents or Mindray Customer Service Department.

#### Volume setting:

Scan the following barcode to set the volume parameter.



Low Volume



Medium Volume



**High Volume** 

■ code 93 and codebar scanning:

To enable or disable Code 93, scan the appropriate barcode below.



Enable Code 93

To enable Codebar, scan the appropriate barcode below.



**Enable Codabar** 

■ code 39 full ASCII scanning:

Code 39 Full ASCII is a variant of Code 39 which pairs characters to encode the full ASCII character set. To enable or disable Code 39 Full ASCII, scan the appropriate barcode below.



Enable Code 39 Full ASCII



Disable Code 39 Full ASCII

■ I 2 of 5 symbols setting:



I 2 of 5 - One Discrete Length

Select this option to decode only I 2 of 5 symbols containing a selected length. Select the length using the numeric barcodes below. For example, to decode only I 2 of 5 symbols with 8 characters, scan I 2 of 5 - One Discrete Length, then scan 0 followed by 8.



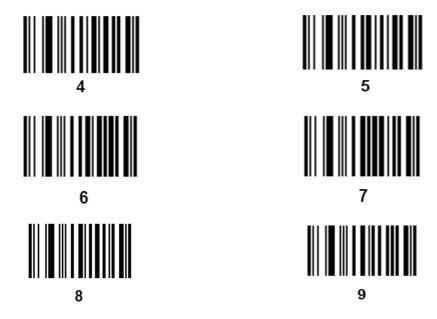
0





1

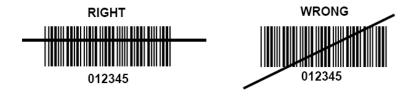




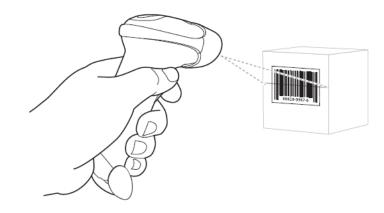
# **B.1.4** Scanning in Hand-Held Mode

- 1. Ensure all connections are secure.
- 2. Aim the reader at the barcode. Press the trigger.

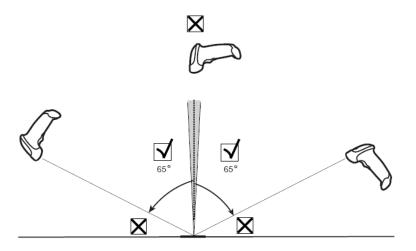
Note: Ensure the scan line crosses every bar and space of the symbol, see the figure below.



3. Upon successful decode, the reader beeps and the LED turns green.

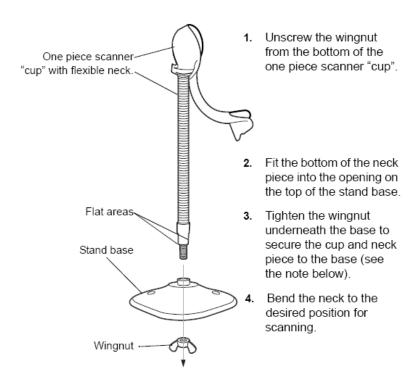


Tips: Do not hold the reader directly over the barcode. Laser light reflecting *directly* back into the reader from the barcode is known as specular reflection. This specular reflection can make decoding difficult. You can tilt the reader up to  $55 \square \square$  forward or back and achieve a successful decode



# **B.1.5** Scanning in Hands-Free Mode

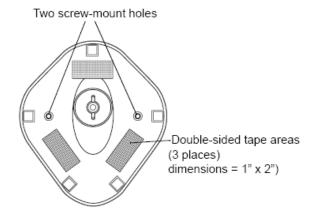
## B.1.5.1 Assembling the Intellistand



NOTE Before tightening the wingnut under the base, ensure that the flat areas on the flexible neck fit securely in the grooves in the base.

### **B.1.5.2** Mounting the Stand (optional)

You can attach the base of the reader's stand to a flat surface using two screws or double-sided tape (not provided).

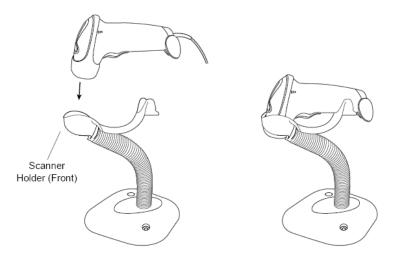


#### ■ Screw Mount

- 1. Position the assembled base on a flat surface.
- 2. Screw one #10 wood screw into each screw-mount hole until the base of the stand is secure
- Tape Mount
- 1. Peel the paper liner off one side of each piece of tape and place the sticky surface over each of the three rectangular tape holders.
- 2. Peel the paper liner off the exposed sides of each piece of tape and press the stand on a flat surface until it is secure.

### **B.1.5.3** Scanning in Hands-Free Mode

When the reader is seated in the stand's "cup", the reader's built-in sensor places the reader in hands-free mode. When you remove the reader from the stand it operates in its normal hand-held mode.

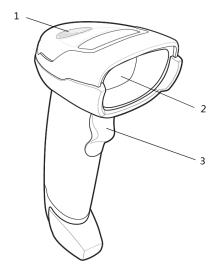


# B.2 2D Barcode Reader (Take DS4308 as an example)

The 2-D barcode reader supports hand-deld operation mode.

Hand-held mode: press the trigger to decode.

# **B.2.1** Overview

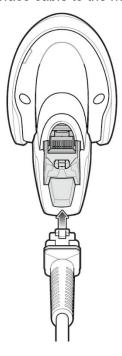


1.	LED	Green: A barcode was successfully decoded.
		Red: A data transmission error or reader malfunction occurred.
2.	Scan window	Scan the barcode.
3.	Trigger	Press to decode

# **B.2.2** Setting Up the Digital Imager Reader

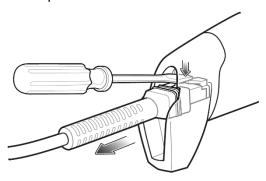
## **B.2.2.1** Installing the Interface Cable

- 1. Plug the interface cable modular connector into the cable interface port on the bottom of the reader handle and ensure the connector is properly secure.
- 2. Connect the other end of the interface cable to the host.



## **B.2.2.2** Removing the Interface Cable

1. Using the tip of a screwdriver or some other tools with a sharp head, depress the cable's modular connector clip.



2. Carefully slide out the cable.

# **B.2.3 Setting**

The reader has factory settings; please refer to A.4 for details.

The reader supports some user-defined functions as introduced below.

For more details, please contact the SYMBOL reader agents or Mindray Customer Service Department.

Volume setting:

Scan the following barcode to set the volume parameter.



Low Volume (2)



Medium Volume (1)



\*High Volume (0)

code 93 and codabar setting

To enable Code 93, scan the appropriate barcode below.



\*Enable Code 93

To enable Codabar, scan the appropriate barcode below.



\*Enable Codabar (1)

code 39 full ASCII setting

Code 39 Full ASCII is a variant of Code 39 which pairs characters to encode the full ASCII character set. To enable or disable Code 39 Full ASCII, scan the appropriate barcode below.



Enable Code 39 Full ASCII (1)



\*Disable Code 39 Full ASCII

I 2 of 5 symbols setting



I 2 of 5 - One Discrete Length

Select this option to decode only I 2 of 5 symbols containing a selected length. Select the length using the numeric barcodes below. For example, to decode only I 2 of 5 symbols with 8 characters, scan I 2 of 5 - One Discrete Length, then scan 0 followed by 8.





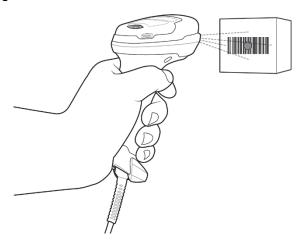




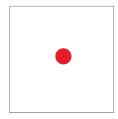


## **B.2.4** Scanning in Hand-Held Mode

- 1. Ensure all connections are secure (see the appropriate host chapter.)
- 2. Aim the digital imager reader at the barcode.

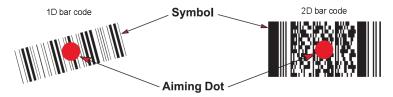


3. When the digital imager reader senses movement, in its default **Auto Aim** trigger mode, it projects a red LED dot which allows positioning the barcode within the field of view.



If necessary, the digital imager reader turns on its red LEDs to illuminate the target barcode.

4. Center the symbol. Be sure the entire symbol is within the rectangular area formed by the illumination LEDs.

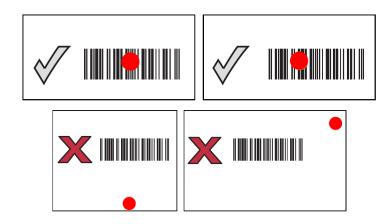


5. Hold the trigger until the digital imager reader beeps, indicating the barcode is successfully decoded.

NOTE: Steps 2 - 4 may be required to repeat on poor quality or difficult barcodes.

The aiming pattern is smaller when the digital imager reader is closer to the symbol and larger when it is farther from the symbol. Scan symbols with smaller bars or elements (mil size) closer to the digital imager reader, and those with larger bars or elements (mil size) farther from the digital imager reader.

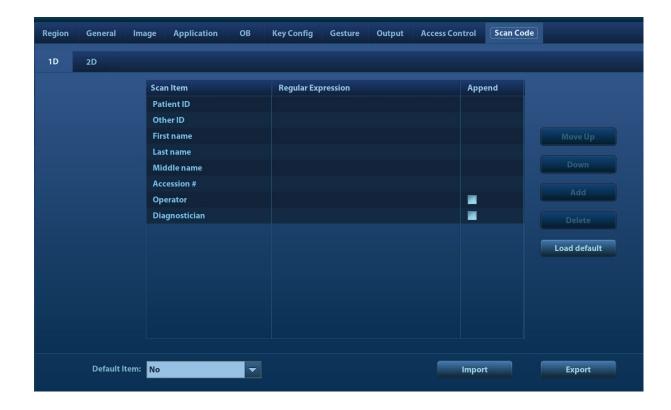
The digital imager reader can also read a barcode presented within the aiming dot not centered. The top examples in show acceptable aiming options, while the bottom examples cannot be decoded.



# **B.3** Setting in Ultrasound System

Press <Setup> to enter the Setup menu and select [Scan Code] to see the following screen.

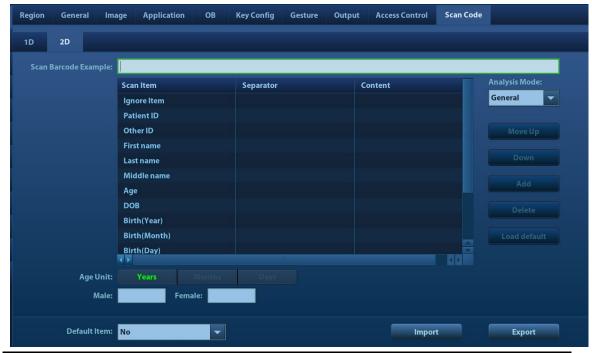
■ 1-dimension barcode reader (1D):



Parameter	Description
	After scanning 1D bar code, the regular expression is matched in the priority order: "Patient ID -> Other ID -> First name -> Last name -> Middle name -> Accession# -> Operator -> Diagnostician". If the regular expression is matched successfully, the data of 1D bar code will be displayed in this item in Patient page automatically.
Scan Item	Example: The data of the bar code is 123 after scanning 1D bar code. The regular expression is matched in the priority order: "Patient ID -> Other ID -> First name -> Last name -> Middle name -> Accession# -> Operator -> Diagnostician". If the regular expression of "Other ID" is matched successfully, "123" will be displayed in "Other ID" item in Patient page automatically.
Regular Expression	Set the regular expression according to the bar code format.
	The information of operator or diagnostician can be appended after selecting the check box.
Append Options	For example, after scanning a 1D barcode of an operator or diagnostician, the obtained data is A, and A will be displayed in "Operator" or "Diagnostician" item in Patient page automatically.
	After scanning a 1D barcode of an operator or diagnostician for a second time, the obtained data is B, and A will be appended by B in "Operator" or "Diagnostician" item in Patient page automatically.
Default Item	If the default item is set to "No", and both the 2D and 1D barcodes fail to be matched, the obtained data of the barcode is input as a string of characters. After selecting a default item from the drop down list of "Default Item", the obtained data of the scanned barcode will be displayed in the corresponding selected default item.
	For example, if the default item is set to "Patient ID", and both the 2D and 1D barcodes fail to be matched, the obtained data is displayed in the "Patient ID" item in Patient page automatically.
Move up/Down	Move up or Move down a selected item.
Add/Delete	Add or delete a selected item. (Only the default item can be added or deleted.)
Load default	Restore the parameter value to the default value.
Import/Export	Import and export configuration files to preset the barcode. For details, please contact the Mindray service engineer.

## 2-dimension barcode reader (2D):

Select "General" from "Analysis Mode" drop-down list: The scan codes consist of Patient ID, Other ID, Patient Name, Birth, etc..



Parameter	Description	
Scan Barcode Example	Input a barcode example, barcode example is separated by separators (the separator is used to set the start and end position of each item), and the barcode data is displayed in the following items in turn.	
	<ul> <li>Input a barcode example, and you can change the information of Patient ID, Other ID, First Name, Last Name, Middle Name, Birth(Day), Birth(Month), Birth(Year), Age, Gender and etc. in the "Content" list.</li> <li>Note: Ignore item is used to add one line below the selected item to</li> </ul>	
	hide unimportant patient information	
Parameters	<ul> <li>Set the start and end position of each item via separators. After inputting a barcode example, you can select item separators from the drop-down list of the Separator. (Only separators that are input in the field box of the Scan Barcode Example can be displayed in the drop- down list of the Separator.)</li> </ul>	
	Note: You can customize the age unit of Birth(Day), Birth(Month), Birth(Year) in the Content column. If the DOB provided by the patient contains only digit, the system displayed an auto-generated age.	
Age Unit	Select an age unit from the drop-down list of the "Age Unit": Year, Month, or Day.	
Male/Female	Input the customized gender symbol besides the Male and Female field box, such as Male (M) or Female (F).	

Select "Advanced" from "Analysis Mode" drop-down list: user enters scan barcode example and regular expression and click [Match], the system will match scan barcode example with regular expression automatically, and if which is matched successfully, the scan item will display the barcode by separators.

# **B.4** Parameter Defaults

Refer to the following table for parameter defaults of LS2208 and DS4308.

Parameter	Defaults
1-D Symbologies	
UPC/EAN	
UPC-A	Enable
UPC-E	Enable
UPC-E1	Disable
EAN-8/JAN 8	Enable
EAN-13/JAN 13	Enable
Bookland EAN	Disable
Decode UPC/EAN/JAN Supplementals (2and 5 digits)	Ignore
UPC/EAN/JAN Supplemental Redundancy	10
Transmit UPC-A Check Digit	Enable
Transmit UPC-E Check Digit	Enable
Transmit UPC-E1 Check Digit	Enable
UPC-A Preamble	System Character
UPC-E Preamble	System Character
UPC-E1 Preamble	System Character
Convert UPC-E to A	Disable
Convert UPC-E1 to A	Disable
EAN-8/JAN-8 Extend	Disable
UCC Coupon Extended Code	Disable
Code 128	Diganic
Code 128	Fnoble
UCC/EAN-128	Enable Enable
ISBT 128	Enable
Code 39	le u
Code 39	Enable
Trioptic Code 39	Disable
Convert Code 39 to Code 32 (Italian Pharmacy Code)	Disable
Code 32 Prefix	Disable
Set Length(s) for Code 39	2 to 55
Code 39 Check Digit Verification	Disable
Transmit Code 39 Check Digit	Disable
Code 39 Full ASCII Conversion	Disable
Buffer Code 39	Disable
Code 93	
Code 93	Enable
Set Length(s) for Code 93	4 to 55
Interleaved 2 of 5 (ITF)	
Interleaved 2 of 5 (ITF) Enable	Enable
Set Lengths for I 2 of 5	14
I 2 of 5 Check Digit Verification	Disable
Transmit I 2 of 5 Check Digit	Disable
Convert I 2 of 5 to EAN 13	Disable
Codabar (NW - 7)	
Codabar	Enable
Set Lengths for Codabar	5 to 55
CLSI Editing	Disable
NOTIS Editing	Disable
2.D Symbologies	
2-D Symbologies PDF417	Enable
MicroPDF417	Disable
Code 128 Emulation	
	Disable
Data Matrix	Enable
Maxicode	Enable

Parameter	Defaults
QR Code	Enable

### **B.5** Maintenance

Cleaning the exit window is the only maintenance required. A dirty window can affect scanning accuracy.

- Do not allow any abrasive material to touch the window.
- Remove any dirt particles with a damp cloth.
- Wipe the window using a tissue moistened with ammonia/water.
- Do not spray water or other cleaning liquids directly into the window.

# Appendix C iWorks (Auto Workflow Protocol)

### C.1 Overview

The main objective of ultrasound workflow automation (iWorks) is to speed up exam times and reduce the excessive number of user interface manual key strokes that can lead to repetitive strain injuries over time. It automates a clinical workflow in common exam protocols in a logical "step by step" manner. It also prevents missing important parts of examinations as well as decreasing exam times.

A Protocol Event contains series workflow events (annotation comments, body marks and measurements) and image modal commands to assist the user in routine ultrasound examinations.

The system provides different protocol events based on the different application regions. iWorks is an option.

### C.2 Normal iWorks Basic Procedure

- 1. Enter the patient information.
- 2. Touch [iWorks] on the touch screen or press the user-defined key for iWorks to enter the protocol selection screen, and touch the corresponding protocol button to enter the status.
- 3. After the system enters the iWorks screen, the available protocol is displayed on the bottom of the screen. Perform the scanning and saving according to the screen prompt.
  - Perform measurements or add comments/body marks to the image according to the screen prompt.
- 4. After a view scanning is complete, press the user-defined save key (usually <Save1> or <Save2>) to switch to the next view according to the screen prompt.
- 5. Repeat step 3 and step 4 to acquire all the necessary images.
  - If a pathology is discovered, touch [Insert] to select a protocol outside of the normal routine to start scanning.
  - Touch [Repeat] to add a copy of the selected view to work on if necessary.
  - Touch [Next] or [Prev] to skip to a particular view you are interested in.
  - Touch [Replace] to delete images and operations for the selected view and restart operations on that view.
  - Touch [Delete] to delete the currently activated view.
  - Touch [Suspend] to start a manual scan when an unusual or atypical workflow is required, and touch [Resume iWorks] to restart the iWorks procedure.
- 6. After all views are finished, the system will prompt you to exit iWorks. Touch [Yes] to exit.

### C.3 iWorks OB Procedure

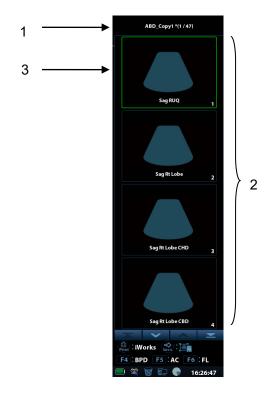
iWorks OB is a variation on the "iWorks" feature. iWorks is based on protocol events occurring in a linear "step by step" succession. iWorks OB accommodates protocol events that occur in a "random" or non-linear manner.

- 1. Enter the patient information.
- 2. Touch [iWorks] on the touch screen to enter the protocol selection screen, and touch the corresponding protocol button to enter the status.
- 3. After the system enters the iWorks screen, four categories of available views are displayed on the left part of the screen.
- 4. Navigate the menu and press the knob to select a view (after pressing the knob, the view will be highlighted).
- 5. Scan and save according to the screen prompt.
- 6. Perform measurements or add comments/body marks to the image according to the screen prompt.
- 7. Repeat step 4 and step 5 to acquire all the necessary images.
  - If a pathology is discovered, touch [Insert] to select a protocol outside of the normal routine to start scanning.
  - Touch [Repeat] to add a copy of the selected view to work on if necessary.
  - Touch [Next] or [Previous] to skip to a particular view you are interested in.
  - Touch [Replace] to delete images and operations for the selected view and restart operations on that view.
  - Touch [Delete] to delete the currently activated view.
  - Touch [Suspend] to start a manual scan when an unusual or atypical workflow is required, and touch [Resume iWorks] to restart the iWorks procedure.
- 8. After all views are finished, the system will prompt you to exit iWorks. Touch [Yes] to exit.

### C.4 Screen Display

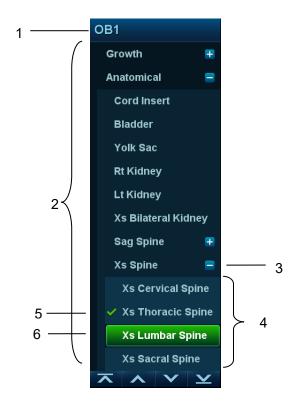
#### ■ Normal iWorks

For automated protocols of vascular, small parts, cardiac, abdomen and gynecology application regions, the monitor displays the following screen:



Name	Description	
Displays the protocol name and the number of views contained.		
'	There may be prompt information here to indicate the following operation.	
2	Displays the view steps in the protocol.	
3	The current active view, with a solid green frame around the image.	

■ iWorks OB



Name	Description
1	Displays the protocol name.
2	Displays the different types of views based on different attributes.
3	Current view type.
4	Contained views of the current type.
5	Completed view, with a green " $$ " on the left.
6	The current active view, with a solid green frame around the image.

#### **C.5 View Operation**

In iWorks status, you can perform view selection, repeat, replacement and delete operations using the touch screen.

For some views, the system switches to the relevant imaging modes if necessary.

The comment for the current view has been automatically added to the bottom-left corner of the image, ready for you to scan the specified anatomy.

#### C.5.1 View Selection

Touch [Prev]/[Next] to select the view to be scanned. The current view is surrounded by a solid green frame.

#### C.5.2 **View Operation**

In the current active view, you can perform image scanning, measurements, and adding comments and body marks, etc. Operations are the same as those for manual operation. See the relevant chapters for details.

#### C.5.3Repeat View

If necessary, touch [Repeat] to insert another template of the current view. You can then perform an extra examination.

#### C.5.4 **View Replacement**

The previous image will be deleted and replaced by the new image.

#### C.5.5 **Delete View**

Touch [Prev]/[Next] to select the view to be deleted. Touch [Delete] to delete the selected view.

### C.6 Manual Examination

Suspend - Exit the protocol so the user can run the system manually. This is used when an unusual or atypical workflow is required.

You can run the system manually if necessary.

- Start manual examination: touch [Suspend] to pause the current iWorks protocol. The system enters manual examination status.
- Return to iWorks: touch [Resume iWorks] to return to automated status. You can continue the previous iWorks scan.

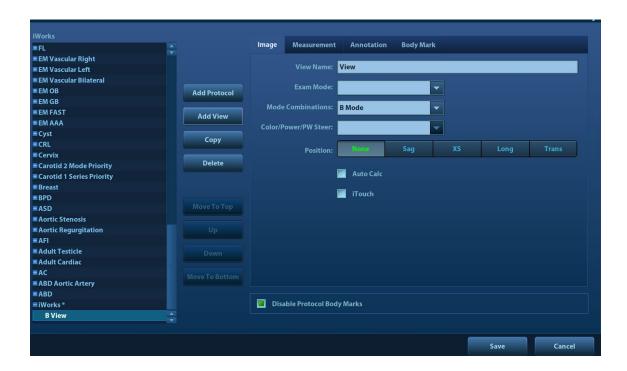
### C.7 Insert

Insert is a specialized protocol event within iWorks and iWorks OB. It assists with the workflow for documenting and measuring common pathological (disease) states (i.e. Mass, Cyst, Stenosis, Thrombus) that occurs outside a routine, normal examination.

- 1. Touch [Insert] on the touch screen to enter the status.
- 2. Select the necessary protocol and the system adds the protocol events to the current protocol.
- 3. Perform measurements or add comments/body marks to the image if necessary.

### C.8 iWorks Setting

Enter the iWorks preset screen using the path: "[Setup]  $\rightarrow$  [iWorks]." Here you can customize the protocols and views:



### C.8.1 Protocol Management

- Click to select the protocol in the list. The protocol type can be checked on the right. Check to select applied exam modes in the "Apply to" column.
- Click [Add Protocol] to create a new protocol. It can be customized.
- Click to select a protocol in the list on the left and click [Copy]. A protocol named "XXX\_Copy1" (Copy1, Copy2, Copy3 etc.) is created with the copied views, which can be customized.
- Click [Delete] to delete a user-defined protocol.
- Click [Up] or [Down] to move the selected protocol.
- Click [Move to Top]/[Move to Bottom] to move the selected protocol to the top or bottom of the list.

### C.8.2 View Management

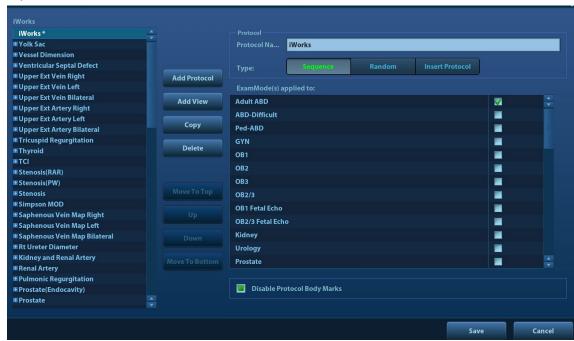
- Click to select the views in the list. The image, annotation, body mark and measurement settings can be checked on the right.
- Click to select a user-defined protocol in the list. Click [Add View] to add a view template to the protocol.

#### C.8.3 Create New Protocol

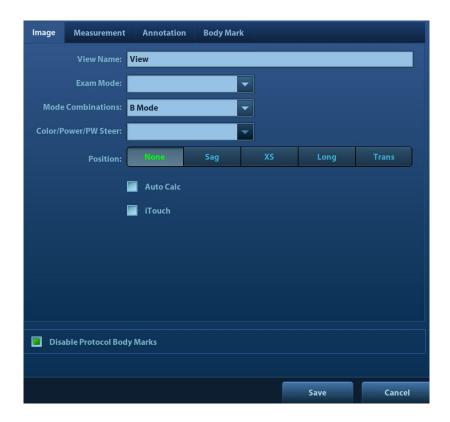
You can create user-defined protocols and customize the automated procedure.

1. In the iWorks preset screen, click [Add Protocol] to create a new protocol. Enter the protocol name, type and select the application region.

Or, select an existing protocol and click [Copy] to customize the protocol based on the previous template.

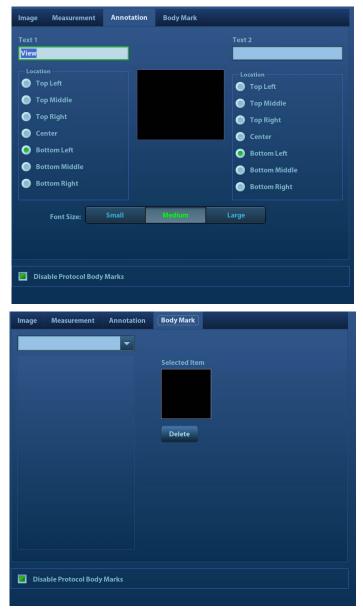


2. Click [Add View] to enter the view name and perform image settings as shown in the following figure.



3. Add comments, body marks and perform measurement settings, as shown in the following figure:





In the image setting, if "Measurement on next section" is selected, the system will save two section images after finishing the section operation. One of the two sections will include the measurement result.

4. Select the checkbox for body mark display settings.



5. Click [Save] to complete the setting and exit.

# Appendix D Wireless LAN

The system provides wireless net adapter configuration, so as to assist information query and unlimited network service.

### **⚠** WARNING

Use the wireless LAN function prudently in OR/ICU/CCU as it may interfere with other devices.

When the wireless LAN function is turned on, the ultrasound system may suffer interference from other equipment, even if that other equipment complies with CISPR EMISSION requirements.

Keep at least 20 cm away from the ultrasound system when the wireless LAN function is in use.

**NOTE:** For a better wireless LAN transmission effect, please take the following settings:

- SSID>80% with stable WLAN network;
- Wireless router and the server are in the same network segment;
- Router setting:
  - Wireless standard 802.11n
  - ➤ Maximum transmission speed ≥300M
  - Use AP (access point) setting;
  - Number of the devices connected to the same router ≤5.
- Target server setting:
  - Network is stable and not under overloading state (e.g. high CPU/memory usage, fast HDD speed, limited HDD space);
  - Level other than the highest level of firewall is adopted;
  - Operating system is Win8 or higher versions and it supports a Gigabit Ethernet.

#### ■ Use the Wireless feature

- 1. Press <Cursor> to show the cursor, click in the bottom bar to open the wireless network manager.
- 2. Roll the trackball and press <Set> to select the target network, click [Connect] to connect to the network.

When connecting an encrypted network, enter the password in the box first. You can select to hide password characters or not.

3. The system tries to connect and the wireless manager icon turns into or after successful connection.



#### ■ IP Config

Note:

When the system background is processing network task (DICOM sending for example), please do not enter network setting to change the IP, otherwise the background task may fail. You can check if there are tasks undergoing in the task manager.

IP config is used for setting local network parameters, which is also applied to DICOM connection.

1. In Wireless network manager screen, click [IP Config] to open the page:



- If "DHCP" is selected, the IP address will be automatically obtained from the DNS server.
  - ➤ Click [Refresh] to check current IP address.
- If "Static" is selected (using a static IP address), enter the IP address.
  - > IP address of the system should be in the same network segment with the server.
  - > Subnet Mask: set different network segment.
  - Gateway: set the gateway IP.
  - ➤ Host Name: Ultrasound device name. it is automatically displayed.
- 2. Click [Apply] to save current setting. Click [Close] to exit.

**Note:** If the IP address displays as 0.0.0.0, this means that the network is abnormal. The reason for the failure may be disconnection or the system cannot obtain the IP address.

# **Appendix E Battery**

### $\Delta$ WARNING:

The battery is inside the machine. Only Mindray technical professionals or engineers authorized by Mindray following training can perform battery installation and uninstallation.

If you need to change the battery or buy a new one, contact your sales representative.

The lithium-ion battery has a service life of five years. Replace your battery when it reaches the end of its service life.

### E.1 Overview

Battery is an option.

When the system is working, the battery charges when its capacity is not full. The indicator turns green when the capacity is full.

• Under power off or standby status, charging time of the battery from capacity 0 to 100% takes less than 4 hours.

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

### **E.2** Battery Status Indicator

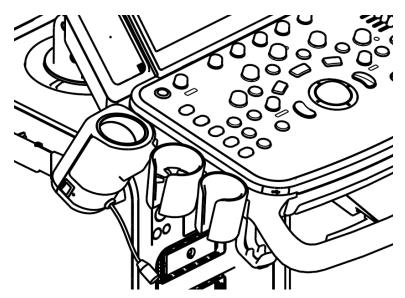
The battery status indicator is located in the bottom-right corner of the screen, indicating the battery capacity.

- Indicates the battery capacity is nearly empty.
- Indicates the battery capacity is full.

# **Appendix F Ultrasound Gel Warmer**

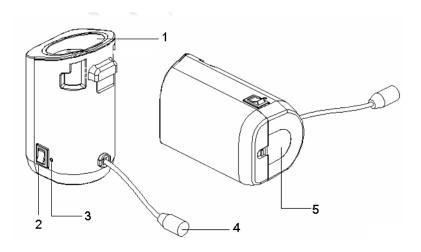
Ultrasound gel warmer is a system option used for heating the ultrasound gel.

### F.1 Overview



As shown in the figure above, the warmer is installed on the left side of the control panel, where the ultrasound gel is positioned.

### F.2 Structure



No.	Name	Function
1.	Ultrasound gel box	Used for positioning the ultrasound gel.
2.	Warming control switch	Set the gel warmer to the temperature of 37°C/40°C, or turn off.
3.	Status indicator	Working normally: green.
J.	Status II fulcator	Failure: blink in orange.
4.	Power cable	Connects to the power socket under the control panel.

No.	Name	Function
5.	Bottom cover	

# F.3 Specifications

#### Power supply

Voltage	12 V <sup></sup>
Power consumption	12 W

#### ■ Environmental conditions

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

# F.4 Function and Requirement

The ultrasound gel warmer can heat the ultrasound gel to about 40±1°C at the most.

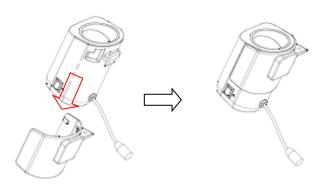
When the gel is placed inside the warmer, the time it takes to heat from an ambient temperature of 18°C to 28°C should be no more than 0.5 hours.

The ultrasound gel warmer can work continuously over 12 hours.

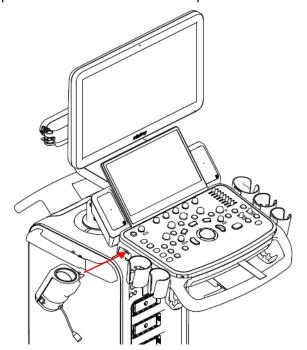
NOTE:	1.	When the ambient temperature is higher than the required temperature of the warmer, the warmer does not function.
	2.	The warmer can only heat one bottle of gel at a time.

### F.5 Install the Warmer

1. As shown in the figure below, install the gel warmer into the gel holder on the control panel.



2. Align the buckle of the holder to the slot at the side of the control panel and then insert the buckle into the slot, push the warmer in the direction of the arrow until the buckle clicks and locks. Connect the power cable to the power socket under the control panel.

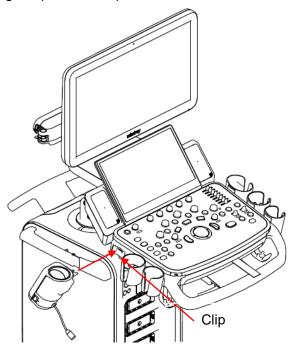


- 3. Insert the warmer's power plug into the jack on the back of the control panel.
- 4. Put the gel inside the warmer, and press the warming control switch, the gel warmer starts to work. There are three levels on the switch:
  - II: sets the warmer to 40°C
  - I: Sets the warmer to 37 ℃.
  - O: turn the warmer off.

**NOTE:** If the status indicator is off or blinks in orange after connecting the power cord, it means the gel warmer is not working normally, please turn it off and contract the service engineer.

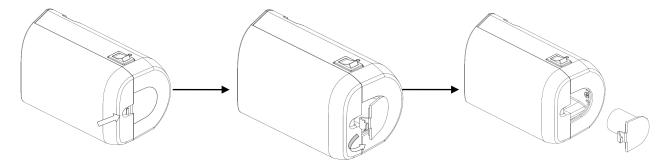
### F.6 Remove the Warmer

- 1. Pull out the power cable from the control panel jack.
- 2. As shown in the above figure, press the clip in the direction of the arrow to remove the warmer.



## F.7 Cleaning

1. Press the clasp on the bottom cover to release the cover.



2. Remove and clean the cover.

# Appendix G Electrical Safety Inspection

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

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

An electrical safety inspection should be periodically performed every two years. The safety analyzer is also an excellent troubleshooting tool for detecting abnormalities in line voltage and grounding, as well as total current loads.

#### **Power Cord Plug G**<sub>-</sub>1

#### The Power Plug G.1.1

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

### **G.2** Device Enclosure and Accessories

### **G.2.1 Visual Inspection**

Test Item	Acceptance Criteria					
	No physical damage to the enclosure and accessories.					
The enclosure and accessories	No physical damage to meters, switches, connectors, etc.					
The enclosure and accessories	No residue of fluid spillage (e.g., water, coffee, chemicals, etc.).					
	No loose or missing parts (e.g., knobs, dials, terminals, etc.).					

### **G.2.2 Contextual Inspection**

Test Item	Acceptance Criteria				
	No unusual noises (e.g., rattles inside the case).				
The enclosure and accessories	No unusual smells (e.g., burning or smoky smells, particularly from ventilation holes).				
	No taped notes that may suggest device deficiencies or operator concerns.				

### **G.3** Device Labeling

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

- Main unit label
- Integrated warning labels

### **G.4** Protective Earth Resistance

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

ALL COUNTRIES R =  $0.2 \Omega$  Maximum

### G.5 Earth Leakage Test

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

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

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

#### ■ LIMITS

#### For UL60601-1:

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

#### For IEC60601-1:

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

### **G.6** Enclosure Leakage Test

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

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

#### ■ LIMITS

#### For UL60601-1:

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

#### For IEC60601-1:

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

### **G.7** Patient Leakage Current

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

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

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

#### **■** LIMITS

For BF applied parts:

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

### G.8 Mains on Applied Part Leakage

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

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

- Normal Polarity;
- Reversed Polarity.
- LIMITS
  - For BF applied parts: 5000 μA.

### **G.9** Patient Auxiliary Current

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

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

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

For BF applied parts,

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

**NOTE:** Make sure the safety analyzer is authorized and complies with the requirements of IEC61010-1. Follow the analyzer manufacturer's instructions.

# **Appendix H Indications For Use**

N=new indication; P=previously cleared by FDA; E=added under Appendix E
Additional comments: Combined modesB+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.
*Intraoperative includes abdominal, thoracic, and vascular
**Small organ-breast, thyroid, testes.
***Other use includes Urology.
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.
Note 2: Smart3D
Note 3:4D(Real-time 3D)
Note 4: iScape
Note 5: TDI
Note 6: Color M
Note 7: Biopsy Guidance
Note 8: Strain Elastography
Note 9: Contrast imaging (Contrast agent for Liver)
Note 10: Contrast imaging(contrast agent for LVO)
Note 11: STE
Note 12: STQ
Note 13: Ultrasound Fusion Imaging
Note 14: GYN/Pelvic

Note: The system and intraoperative probe are not intended for central cardiovascular or central nervous system use.

System:	DC-90/DC-95/D 81/DC-82/DC-8						80A /DC-80/	A Exp/DC-80	OA Pro/DC-8X/DC-8Q/DC-		
Transducer:	N/A										
Intended Use:	Diagnostic ultra	soun	d ima	ging or fl	uid flow	analysis of	the human b	ody as follow	s:		
Clinical Application	n n	Mode of Operation									
General (Track 1 Only)	Specific (Track 1 & 3)	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)		
Ophthalmic	Ophthalmic										
Fetal Imaging &	Fetal	Р	Р	Р		Р	Р	Р	Note 1, 2,3, 4, 6, 7,13		
Other	Abdominal	Р	Р	Р	Р	Р	Р	Р	Note 1, 2,3, 4,6,7,9,11,12,13,14		
	Intra-operative (Specify*)	N	N	N		N	N	N	Note1,2,4		
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric	Р	Р	Р	Р	Р	Р	Р	Note 1, 2, 4,6,7,13		
	Small Organ (Specify**)	Р	Р	Р		Р	Р	Р	Note 1,2, 4,7,8,11,12,13		
	Neonatal Cephalic	Р	Р	Р	Р	Р	Р	Р	Note 1, 2, 4,6,7,13		
	Adult Cephalic	Р	Р	Р	Р	Р	Р	Р	Note 1,2,4,6,7,13		
	Trans-rectal	Р	Р	Р		Р	Р	Р	Note 1, 2,3, 4, 6, 7, 8		
	Trans-vaginal	Р	Р	Р		Р	Р	Р	Note 1, 2,3, 4, 6, 7, 8,14		
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo- skeletal (Conventional)	Р	Р	Р		Р	Р	Р	Note 1, 2, 4,6,7,8,11,12,13		
	Musculo- skeletal (Superficial)	Р	Р	Р		Р	Р	Р	Note 1, 2, 4,7,8,11,12,13		
	Intravascular										
Cardiac	Cardiac Adult	Р	Р	Р	Р	Р	Р	Р	Note 1, 2,4,5,6,7,10,13		
	Cardiac Pediatric	Р	Р	Р	Р	Р	Р	Р	Note 1, 2, 4,5,6,7,13		
	Intravascular (Cardiac)										
	Trans-esoph. (Cardiac)	N	N	N	N	N	N	N	Note 1, 5,6		
	Intra-cardiac										
Peripheral vessel	Peripheral vessel	Р	Р	Р	N	Р	Р	Р	Note 1, 2, 4,6,7,13		
	Other (Specify***)	Р	Р	Р		Р	Р	Р	Note 1, 2,3, 4, 6, 7,8		

Transducer:	C11-3E											
Intended Use:	Diagnostic ultras	sound	d imag	ging or fl	uid flow	analysis of	f the human b	oody as follow	vs:			
Clinical Applicat	tion	Mode of Operation										
General (Track 1 Only)	Specific (Track 1 & 3)	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)			
Ophthalmic	Ophthalmic											
Fetal Imaging	Fetal											
& Other	Abdominal	Р	Р	Р		Р	Р	Р	Note 1, 2, 4,6,7			
	Intra-operative (Specify*)											
	Intra-operative (Neuro)											
	Laparoscopic											
	Pediatric	Р	Р	Р		Р	Р	Р	Note 1, 2, 4,6,7			
	Small Organ (Specify**)											
	Neonatal Cephalic	Р	Р	Р		Р	Р	Р	Note 1, 2, 4,6,7			
	Adult Cephalic											
	Trans-rectal											
	Trans-vaginal											
	Trans-urethral											
	Trans-esoph. (non-Card.)											
	Musculo- skeletal (Conventional)											
	Musculo- skeletal (Superficial)											
	Intravascular											
Cardiac	Cardiac Adult											
	Cardiac Pediatric	Р	Р	Р		Р	Р	Р	Note 1, 2, 4,6,7			
	Intravascular (Cardiac)											
	Trans-esoph. (Cardiac)											
	Intra-cardiac											
Peripheral vessel	Peripheral vessel	Р	Р	Р		Р	Р	Р	Note 1, 2, 4,6,7			
	Other (Specify***)											

Transducer:	L12-3E											
Intended Use:	Diagnostic ultra	sound	d imag	ging or fl	uid flow	analysis of	f the human b	oody as follow	vs:			
Clinical Application		Mode of Operation										
General (Track 1 Only)	Specific (Track 1 & 3)	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)			
Ophthalmic	Ophthalmic											
Fetal Imaging	Fetal											
& Other	Abdominal	Р	Р	Р		Р	Р	Р	Note 1, 2, 4,7			
	Intra-operative (Specify*)											
	Intra-operative (Neuro)											
	Laparoscopic											
	Pediatric	Р	Р	Р		Р	Р	Р	Note 1, 2, 4,7			
	Small Organ (Specify**)	Р	Р	Р		Р	Р	Р	Note 1,2, 4,7,8,11,12			
	Neonatal Cephalic											
	Adult Cephalic											
	Trans-rectal											
	Trans-vaginal											
	Trans-urethral											
	Trans-esoph. (non-Card.)											
	Musculo- skeletal (Conventional)	Р	Р	Р		Р	Р	Р	Note 1, 2, 4,7,11,12			
	Musculo- skeletal (Superficial)	Р	Р	Р		Р	Р	Р	Note 1, 2, 4,7,11,12			
	Intravascular											
Cardiac	Cardiac Adult											
	Cardiac Pediatric											
	Intravascular (Cardiac)											
	Trans-esoph. (Cardiac)											
	Intra-cardiac											
Peripheral vessel	Peripheral vessel	Р	Р	Р		Р	Р	Р	Note 1, 2, 4,7			
	Other (Specify***)											

Transducer:	P7-3E								
Intended Use:	Diagnostic ultras	sound	l imaç	ging or fl	uid flow	analysis of	f the human b	oody as follov	vs:
Clinical Applicat	tion	Mod	de of (	Operatio	n				
General (Track 1 Only)	Specific (Track 1 & 3)	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging	Fetal								
& Other	Abdominal	Р	Р	Р	Р	Р	Р	Р	Note 1,2,4,6
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	Р	Р	Р	Р	Р	Р	Р	Note 1,2,4,6
	Small Organ (Specify**)								
	Neonatal Cephalic	Р	Р	Р	Р	Р	Р	Р	Note 1,2,4,6
	Adult Cephalic	Р	Р	Р	Р	Р	Р	Р	Note 1,2,4,6
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo- skeletal (Conventional)								
	Musculo- skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult	Р	Р	Р	Р	Р	Р	Р	Note 1, 2,4,5,6
	Cardiac Pediatric	Р	Р	Р	Р	Р	Р	Р	Note 1, 2,4,5,6
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)								

Transducer:	L9-3E										
Intended Use:	Diagnostic ultrasou	nd im	nagin	g or fluic	l flow an	alysis of th	e human boo	dy as follows:			
Clinical Applicat	Мо	Mode of Operation									
General (Track 1 Only)	Specific (Track 1 & 3)	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (Specify)		
Ophthalmic	Ophthalmic										
Fetal Imaging	Fetal	N	N	N		N	N	N	Note 1,2, 4,7		
& Other	Abdominal	Р	Р	Р		Р	Р	Р	Note 1,2, 4,7		
	Intra-operative (Specify*)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric	Р	Р	Р		Р	Р	Р	Note 1,2, 4,7		
	Small Organ (Specify**)	Р	Р	Р		Р	Р	Р	Note 1,2, 4,7,8,11,12		
	Neonatal Cephalic										
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skeletal (Conventional)	Р	Р	Р		Р	Р	Р	Note 1,2, 4,7,11,12		
	Musculo-skeletal (Superficial)	Р	Р	Р		Р	Р	Р	Note 1,2, 4,7,11,12		
	Intravascular										
Cardiac	Cardiac Adult										
	Cardiac Pediatric										
	Intravascular (Cardiac)										
	Trans-esoph. (Cardiac)										
	Intra-cardiac										
Peripheral	Peripheral vessel	Р	Р	Р		Р	Р	Р	Note 1,2, 4,7		
vessel	Other (Specify***)										

Transducer:	DE11-3E											
Intended Use:	Diagnostic ultrasour	nd im	agin	g or fluid	flow an	alysis of th	e human bod	ly as follows:				
Clinical Application			Mode of Operation									
General (Track 1 Only)	Specific (Track 1 & 3)	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (Specify)			
Ophthalmic	Ophthalmic											
Fetal Imaging	Fetal	Р	Р	Р		Р	Р	Р	Note 1, 3, 4, 6, 7			
& Other	Abdominal											
	Intra-operative (Specify*)											
	Intra-operative (Neuro)											
	Laparoscopic											
	Pediatric											
	Small Organ (Specify**)											
	Neonatal Cephalic											
	Adult Cephalic											
	Trans-rectal	Р	Р	Р		Р	Р	Р	Note 1, 3, 4, 6, 7, 8			
	Trans-vaginal	Р	Р	Р		Р	Р	Р	Note 1, 3, 4, 6, 7, 8, <b>14</b>			
	Trans-urethral											
	Trans-esoph. (non-Card.)											
	Musculo-skeletal (Conventional)											
	Musculo-skeletal (Superficial)											
	Intravascular											
Cardiac	Cardiac Adult											
	Cardiac Pediatric											
	Intravascular (Cardiac)											
	Trans-esoph. (Cardiac)											
	Intra-cardiac											
Peripheral	Peripheral vessel											
vessel	Other (Specify***)											

Transducer:	V11-3HE											
Intended Use:	Diagnostic ultrasour	nd in	nagin	g or fluid	l flow an	alysis of th	e human boo	dy as follows:				
Clinical Application		Мо	Mode of Operation									
General (Track 1 Only)	Specific (Track 1 & 3)	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (Specify)			
Ophthalmic	Ophthalmic											
Fetal Imaging	Fetal	Р	Р	Р		Р	Р	Р	Note 1, 2, 4, 6, 7			
& Other	Abdominal											
	Intra-operative (Specify*)											
	Intra-operative (Neuro)											
	Laparoscopic											
	Pediatric											
	Small Organ (Specify**)											
	Neonatal Cephalic											
	Adult Cephalic											
	Trans-rectal	Р	Р	Р		Р	Р	Р	Note 1, 2, 4, 6, 7, 8			
	Trans-vaginal	Р	Р	Р		Р	Р	Р	Note 1, 2, 4, 6, 7, 8, 14			
	Trans-urethral											
	Trans-esoph. (non-Card.)											
	Musculo-skeletal (Conventional)											
	Musculo-skeletal (Superficial)											
	Intravascular											
Cardiac	Cardiac Adult											
	Cardiac Pediatric											
	Intravascular (Cardiac)											
	Trans-esoph. (Cardiac)											
	Intra-cardiac											
Peripheral	Peripheral vessel											
vessel	Other (Specify***)	Р	Р	Р		Р	Р	Р	Note 1, 2, 4, 6, 7, 8			

Transducer:	SP5-1E											
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:											
Clinical Application			Mode of Operation									
General (Track 1 Only)	Specific (Track 1 & 3)	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)			
Ophthalmic	Ophthalmic											
Fetal Imaging & Other	Fetal											
	Abdominal	Р	Р	Р	Р	Р	Р	Р	Note 1, 2,4, 6,7,13			
	Intra-operative (Specify*)											
	Intra-operative (Neuro)											
	Laparoscopic											
	Pediatric	Р	Р	Р	Р	Р	Р	Р	Note 1, 2,4, 6,7,13			
	Small Organ (Specify**)											
	Neonatal Cephalic											
	Adult Cephalic	Р	Р	Р	Р	Р	Р	Р	Note 1, 2,4, 6,7,13			
	Trans-rectal											
	Trans-vaginal											
	Trans-urethral											
	Trans-esoph. (non-Card.)											
	Musculo- skeletal (Conventional)											
	Musculo- skeletal (Superficial)											
	Intravascular											
Cardiac	Cardiac Adult	Р	Р	Р	Р	Р	Р	Р	Note 1, 2,4,5,6,7,10,13			
	Cardiac Pediatric	Р	Р	Р	Р	Р	Р	Р	Note 1, 2,4,5,6,7,13			
	Intravascular (Cardiac)											
	Trans-esoph. (Cardiac)											
	Intra-cardiac											
Peripheral vessel	Peripheral vessel											
	Other (Specify***)											

Transducer:	SC6-1E										
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:										
Clinical Application		Mode of Operation									
General (Track 1 Only)	Specific (Track 1 & 3)	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (Specify)		
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal	Р	Р	Р		Р	Р	Р	Note 1, 2, 4, 6,7,13		
	Abdominal	Р	Р	Р		Р	Р	Р	Note 1, 2, 4,6,7,9,11,12,13, <b>14</b>		
	Intra-operative (Specify*)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric										
	Small Organ (Specify**)										
	Neonatal Cephalic										
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skeletal (Conventional)	Р	Р	Р		Р	Р	Р	Note 1, 2, 4,6,7,13		
	Musculo-skeletal (Superficial)										
	Intravascular										
Cardiac	Cardiac Adult										
	Cardiac Pediatric										
	Intravascular (Cardiac)										
	Trans-esoph. (Cardiac)										
	Intra-cardiac										
Peripheral vessel	Peripheral vessel	Р	Р	Р		Р	Р	Р	Note 1, 2, 4,6,7,13		
	Other (Specify***)										

Transducer:	SD8-1E								
Intended Use:	Diagnostic ultrasour	nd im	agin	g or fluid	flow an	alysis of th	e human bod	ly as follows:	
Clinical Applicat	ion	Мо	de of	Operati	on				
General (Track 1 Only)	Specific (Track 1 & 3)	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging	Fetal	Р	Р	Р		Р	Р	Р	Note 1, 3, 4, 6,7
& Other	Abdominal	Р	Р	Р		Р	Р	Р	Note 1, 3, 4,6,7, <b>14</b>
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral	Peripheral vessel								
vessel	Other (Specify***)								

Transducer:	L14-5WE								
Intended Use:	Diagnostic ultra	sound	d ima	ging or fl	uid flow	analysis o	f the human l	oody as follow	VS:
Clinical Applicat	ion	Mod	de of	Operatio	n				
General (Track 1 Only)	Specific (Track 1 & 3)	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging	Fetal								
& Other	Abdominal	Р	Р	Р		Р	Р	Р	Note 1,2, 4,7,13
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	Р	Р	Р		Р	Р	Р	Note 1,2, 4,7,13
	Small Organ (Specify**)	Р	Р	Р		Р	Р	Р	Note 1,2, 4,7,8,11,12,13
	Neonatal Cephalic	Р	Р	Р		Р	Р	Р	Note 1,2, 4,7,13
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo- skeletal (Conventional)	Р	Р	Р		Р	Р	Р	Note 1,2, 4,7,11,12,13
	Musculo- skeletal (Superficial)	Р	Р	Р		Р	Р	Р	Note 1,2, 4,7,11,12,13
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	Р	Р	Р		Р	Р	Р	Note 1,2, 4,7,13
	Other (Specify***)								

Transducer:	L20-5E								
Intended Use:	Diagnostic ultras	sound	limaç	ging or fl	uid flow	analysis of	the human b	oody as follov	vs:
Clinical Applicat	tion	Mod	de of (	Operatio	n				
General (Track 1 Only)	Specific (Track 1 & 3)	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging	Fetal								
& Other	Abdominal								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)	Р	Р	Р		Р	Р	Р	Note 1, 2, 4
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo- skeletal (Conventional)	Р	Р	Р		Р	Р	Р	Note 1, 2, 4, 8
	Musculo- skeletal (Superficial)	Р	Р	Р		Р	Р	Р	Note 1, 2, 4, 8
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	Р	Р	Р		Р	Р	Р	Note 1, 2, 4
	Other (Specify***)								

Transducer:	SC5-1NE								
Intended Use:	Diagnostic ultrasou	nd im	nagin	g or fluid	l flow an	alysis of th	e human boo	dy as follows:	
Clinical Applicat	ion	Мо	de of	Operati	on				
General (Track 1 Only)	Specific (Track 1 & 3)	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging	Fetal	Р	Р	Р		Р	Р	Р	Note 1, 2, 4, 6,7
& Other	Abdominal	Р	Р	Р		Р	Р	Р	Note 1, 2, 4,6,7
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	Р	Р	Р		Р	Р	Р	Note 1, 2, 4,6,7
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral	Peripheral vessel	Р	Р	Р		Р	Р	Р	Note 1, 2, 4,6,7
vessel	Other (Specify***)								

Transducer:	C5-1E								
Intended Use:	Diagnostic Ultrasound	imag	ging c	or fluid flo	ow analy	sis of the l	numan body	as follows:	
Clinical Applica	tion	Мо	de of	Operati	on				
General (Track 1 Only)	Specific (Track 1 & 3)	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging	Fetal	N	N	N		N	N	N	Note 1, 2, 4,6,7,13
& Other	Abdominal	N	N	N		N	N	N	Note 1,2,4,6,7,9,11,12,13,14
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	Ν	N		N	N	N	Note 1, 2, 4,6,7,13
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non- Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	Note 1, 2, 4,6,7,13
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral	Peripheral vessel	N	N	N		N	N	N	Note 1, 2, 4,6,7,13
vessel	Other (Specify***)								

Transducer:	SC5-1E								
Intended Use:	Diagnostic Ultrasound	imagi	ing o	r fluid flo	w analy	sis of the h	uman body a	s follows:	
Clinical Applicat	tion	Мо	de of	Operati	ion				
General (Track 1 Only)	Specific (Track 1 & 3)	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging	Fetal	N	N	N		N	N	N	Note 1, 2, 4,6,7,13
& Other	Abdominal	N	N	N		N	N	N	Note 1,2,4,6,7,9,11,12,13,14
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	Note 1, 2, 4,6,7,13
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	Note 1, 2, 4,6,7,13
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral	Peripheral vessel	N	N	N		N	N	N	Note 1, 2, 4,6,7,13
vessel	Other (Specify***)								

Transducer:	C6-2GE								
Intended Use:	Diagnostic Ultrasound i	magir	ng or	fluid flow	/ analysi	s of the hu	man body as	follows:	
Clinical Applicat	tion	Мо	de of	Operation	on				
General (Track 1 Only)	Specific (Track 1 & 3)	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging	Fetal	N	N	N		N	N	N	Note1,2,4,6,7
& Other	Abdominal	N	N	N		N	N	N	Note1,2,4,6,7, <b>9,14</b>
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	Note1,2,4,6,7
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non- Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral	Peripheral vessel								
vessel	Other (Specify***)								

Transducer:	C7-3E								
Intended Use:	Diagnostic Ultrasound ima	ging	or flui	d flow a	nalysis c	of the huma	an body as fo	llows:	
Clinical Applica	tion	Мо	de of	Operatio	n				
General (Track 1 Only)	Specific (Track 1 & 3)	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging	Fetal	N	N	N		N	N	N	Note 1, 2, 4,6,7
& Other	Abdominal	N	N	N		N	N	N	Note 1, 2, 4,6,7,9,14
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	Note 1, 2, 4,6,7
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non- Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral	Peripheral vessel	N	N	N		N	N	N	Note 1, 2, 4,6,7
vessel	Other (Specify***)								

Transducer:	L14-6WE								
Intended Use:	Diagnostic Ultrasound ima	ging	or flui	d flow ar	nalysis o	f the huma	n body as fo	llows:	
Clinical Applicat	tion	Мо	de of	Operatio	n				
General (Track 1 Only)	Specific (Track 1 & 3)	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging	Fetal								
& Other	Abdominal	N	N	N		N	N	N	Note 1,2, 4,7
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	Note 1,2, 4,7
	Small Organ (Specify**)	N	N	N		N	N	N	Note 1,2, 4,7,8
	Neonatal Cephalic	N	N	N		N	N	N	Note 1,2, 4,7
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non- Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	Note 1,2, 4,7
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	Note 1,2, 4,7
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral	Peripheral vessel	N	N	N		N	N	N	Note 1,2, 4,7
vessel	Other (Specify***)								

Transducer:	L16-4HE								
Intended Use:	Diagnostic Ultrasound ima	ging	or flui	d flow a	nalysis c	of the huma	n body as fo	llows:	
Clinical Applicat	tion	Мо	de of	Operatio	n				
General (Track 1 Only)	Specific (Track 1 & 3)	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging	Fetal								
& Other	Abdominal	N	N	N		N	N	N	Note1,2,4
	Intra-operative (Specify*)	N	N	N		N	N	N	Note1,2,4
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	Note1,2,4
	Small Organ (Specify**)	N	N	N		N	N	N	Note1,2,4
	Neonatal Cephalic	N	N	N		N	N	N	Note1,2,4
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non- Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	Note1,2,4
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	Note1,2,4
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral	Peripheral vessel	N	N	N		N	N	N	Note1,2,4
vessel	Other (Specify***)		1						

Transducer:	L13-3WE								
Intended Use:	Diagnostic Ultrasound ima	ging	or flui	id flow a	nalysis o	of the huma	an body as fo	llows:	
Clinical Applicat	tion	Мо	de of	Operation	n				
General (Track 1 Only)	Specific (Track 1 & 3)	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging	Fetal								
& Other	Abdominal	N	N	N		N	N	N	Note 1,2, 4,7
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	Note 1,2, 4,7
	Small Organ (Specify**)	N	N	N		N	N	N	Note 1,2, 4,7,8,11,12
	Neonatal Cephalic	N	N	N		N	N	N	Note 1,2, 4,7
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non- Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	Note 1,2, 4,7,11,12
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	Note 1,2, 4,7,11,12
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral	Peripheral vessel	N	N	N		N	N	N	Note 1,2, 4,7
vessel	Other (Specify***)								

Transducer:	P10-4E								
Intended Use:	Diagnostic Ultrasound ima	ging	or flui	d flow aı	nalysis o	f the huma	n body as fo	llows:	
Clinical Applicat	tion	Мо	de of	Operatio	n				
General (Track 1 Only)	Specific (Track 1 & 3)	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging	Fetal								
& Other	Abdominal	N	N	N	N	N	N	N	Note 1, 2,4,6
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N	N	N	N	N	Note 1, 2,4,6
	Small Organ (Specify**)								
	Neonatal Cephalic	N	N	N	N	N	N	N	Note 1, 2,4,6
	Adult Cephalic	N	N	N	N	N	N	N	Note 1, 2,4,6
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non- Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult	N	N	N	N	N	N	N	Note 1, 2,4,5,6
	Cardiac Pediatric	N	N	N	N	N	N	N	Note 1, 2,4,5,6
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral	Peripheral vessel								
vessel	Other (Specify***)								

Transducer:	6LB7E													
Intended Use:	Diagnostic Ultrasound	imag	ing or	fluid flo	v analys	is of the hu	ıman body a	s follows:						
Clinical Applicat	tion	Mod	Mode of Operation											
General (Track 1 Only)	Specific (Track 1 & 3)													
Ophthalmic	Ophthalmic													
Fetal Imaging	Fetal													
& Other	Abdominal													
	Intra-operative (Specify*)													
	Intra-operative (Neuro)													
	Laparoscopic													
	Pediatric													
	Small Organ (Specify**)													
	Neonatal Cephalic													
	Adult Cephalic													
	Trans-rectal	N	N	N		N	N	N	Note 1,2,4,6,7					
	Trans-vaginal													
	Trans-urethral													
	Trans-esoph. (non- Card.)													
	Musculo-skeletal (Conventional)													
	Musculo-skeletal (Superficial)													
	Intravascular													
Cardiac	Cardiac Adult													
	Cardiac Pediatric													
	Intravascular (Cardiac)													
	Trans-esoph. (Cardiac)													
	Intra-cardiac													
Peripheral	Peripheral vessel													
vessel	Other (Specify***)	N	N	N		N	N	N	Note 1,2,4,6,7					

Transducer:	CB10-4E												
Intended Use:	Diagnostic Ultrasound ima	ging	or flui	d flow ar	nalysis o	f the huma	in body as fol	llows:					
Clinical Application		Mode of Operation											
General (Track 1 Only)	Specific (Track 1 & 3)	B M PWD CWD Color Amplitude Combined (specify) Other (specify)											
Ophthalmic	Ophthalmic												
Fetal Imaging	Fetal												
& Other	Abdominal												
	Intra-operative (Specify*)												
	Intra-operative (Neuro)												
	Laparoscopic												
	Pediatric												
	Small Organ (Specify**)												
	Neonatal Cephalic												
	Adult Cephalic												
	Trans-rectal	N	N	N		N	N	N	Note 1, 2, 4,6,7				
	Trans-vaginal												
	Trans-urethral												
	Trans-esoph. (non- Card.)												
	Musculo-skeletal (Conventional)												
	Musculo-skeletal (Superficial)												
	Intravascular												
Cardiac	Cardiac Adult												
	Cardiac Pediatric												
	Intravascular (Cardiac)												
	Trans-esoph. (Cardiac)												
	Intra-cardiac												
Peripheral	Peripheral vessel												
vessel	Other (Specify***)	N	N	N		N	N	N	Note 1, 2, 4,6,7				

Transducer:	V11-3E											
Intended Use:	Diagnostic Ultrasound ima	ging	or flui	d flow aı	nalysis d	of the huma	an body as fo	llows:				
Clinical Application		Mode of Operation										
General (Track 1 Only)	Specific (Track 1 & 3)	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)			
Ophthalmic	Ophthalmic											
Fetal Imaging	Fetal	N	N	N		N	N	N	Note 1, 2, 4,6,7			
& Other	Abdominal											
	Intra-operative (Specify*)											
	Intra-operative (Neuro)											
	Laparoscopic											
	Pediatric											
	Small Organ (Specify**)											
	Neonatal Cephalic											
	Adult Cephalic											
	Trans-rectal	N	N	N		N	N	N	Note 1, 2, 4,6,7,8			
	Trans-vaginal	N	N	N		N	N	N	Note 1, 2, 4,6,7,8,14			
	Trans-urethral											
	Trans-esoph. (non- Card.)											
	Musculo-skeletal (Conventional)											
	Musculo-skeletal (Superficial)											
	Intravascular											
Cardiac	Cardiac Adult											
	Cardiac Pediatric											
	Intravascular (Cardiac)											
	Trans-esoph. (Cardiac)											
	Intra-cardiac											
Peripheral	Peripheral vessel											
vessel	Other (Specify***)	N	N	N		N	N	N	Note 1, 2, 4,6,7			

Transducer:	V11-3BE											
Intended Use:	Diagnostic Ultrasound ima	ging	or flui	d flow a	nalysis c	of the huma	an body as fo	llows:				
Clinical Applicat	Mode of Operation											
General (Track 1 Only)	Specific (Track 1 & 3)	B M PWD CWD Color Amplitude Combined Other (specify Doppler Uspecify)										
Ophthalmic	Ophthalmic											
Fetal Imaging	Fetal	N	N	N		N	N	N	Note 1, 2, 4,6,7			
& Other	Abdominal											
	Intra-operative (Specify*)											
	Intra-operative (Neuro)											
	Laparoscopic											
	Pediatric											
	Small Organ (Specify**)											
	Neonatal Cephalic											
	Adult Cephalic											
	Trans-rectal	N	N	N		N	N	N	Note 1, 2, 4,6,7,8			
	Trans-vaginal	N	N	N		N	N	N	Note 1, 2, 4,6,7,8,14			
	Trans-urethral											
	Trans-esoph. (non- Card.)											
	Musculo-skeletal (Conventional)											
	Musculo-skeletal (Superficial)											
	Intravascular											
Cardiac	Cardiac Adult											
	Cardiac Pediatric											
	Intravascular (Cardiac)											
	Trans-esoph. (Cardiac)											
	Intra-cardiac											
Peripheral	Peripheral vessel											
vessel	Other (Specify***)	N	N	N		N	N	N	Note 1, 2, 4,6,7			

Transducer:	DE10-3WE								
Intended Use:	Diagnostic Ultrasound	imagi	ing or	fluid flo	v analys	is of the hu	ıman body a	s follows:	
Clinical Applicat	tion	Mod	de of (	Operatio	n				
General (Track 1 Only)	Specific (Track 1 & 3)	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	Note 1, 3, 4, 6,7
	Abdominal								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	N	N	N		N	N	N	Note 1, 3, 4, 6,7
	Trans-vaginal	N	N	N		N	N	N	Note 1, 3, 4, 6,7,14
	Trans-urethral								
	Trans-esoph. (non- Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral	Peripheral vessel								
vessel	Other (Specify***)	N	N	N		N	N	N	Note 1, 3, 4, 6,7

Transducer:	D7-2E												
Intended Use:	Diagnostic Ultrasound ima	ging	or flui	d flow aı	nalysis o	f the huma	n body as fo	llows:					
Clinical Application		Mode of Operation											
General (Track 1 Only)	Specific (Track 1 & 3)	B M PWD CWD Color Amplitude Combined Other (specify Doppler Uspecify)											
Ophthalmic	Ophthalmic												
Fetal Imaging	Fetal	N	N	N		N	N	N	Note 1, 3, 4, 6				
& Other	Abdominal	N	N	N		N	N	N	Note 1, 3, 4, 6,14				
	Intra-operative (Specify*)												
	Intra-operative (Neuro)												
	Laparoscopic												
	Pediatric												
	Small Organ (Specify**)												
	Neonatal Cephalic												
	Adult Cephalic												
	Trans-rectal												
	Trans-vaginal												
	Trans-urethral												
	Trans-esoph. (non- Card.)												
	Musculo-skeletal (Conventional)												
	Musculo-skeletal (Superficial)												
	Intravascular												
Cardiac	Cardiac Adult												
	Cardiac Pediatric												
	Intravascular (Cardiac)												
	Trans-esoph. (Cardiac)												
	Intra-cardiac												
Peripheral	Peripheral vessel												
vessel	Other (Specify***)												

Transducer:	P7-3TE											
Intended Use:	Diagnostic Ultrasound ima	ging	or flui	d flow ar	nalysis o	f the huma	n body as fo	llows:				
Clinical Application		Mode of Operation										
General (Track 1 Only)	Specific (Track 1 & 3)	B M PWD CWD Color Amplitude Combined Other (specify Doppler Uspecify)										
Ophthalmic	Ophthalmic											
Fetal Imaging	Fetal											
& Other	Abdominal											
	Intra-operative (Specify*)											
	Intra-operative (Neuro)											
	Laparoscopic											
	Pediatric											
	Small Organ (Specify**)											
	Neonatal Cephalic											
	Adult Cephalic											
	Trans-rectal											
	Trans-vaginal											
	Trans-urethral											
	Trans-esoph. (non- Card.)											
	Musculo-skeletal (Conventional)											
	Musculo-skeletal (Superficial)											
	Intravascular											
Cardiac	Cardiac Adult											
	Cardiac Pediatric											
	Intravascular (Cardiac)											
	Trans-esoph. (Cardiac)	N	N	N	N	N	N	N	Note 1, 5,6			
	Intra-cardiac											
Peripheral	Peripheral vessel											
vessel	Other (Specify***)											

Transducer:	CW5s											
Intended Use:	Diagnostic Ultrasound ima	ging	or flui	d flow ar	nalysis o	f the huma	n body as fol	llows:				
Clinical Application		Mode of Operation										
General (Track 1 Only)	Specific (Track 1 & 3)	B M PWD CWD Color Amplitude Combined (specify)  Other (specify)										
Ophthalmic	Ophthalmic											
Fetal Imaging	Fetal											
& Other	Abdominal											
	Intra-operative (Specify*)											
	Intra-operative (Neuro)											
	Laparoscopic											
	Pediatric											
	Small Organ (Specify**)											
	Neonatal Cephalic											
	Adult Cephalic											
	Trans-rectal											
	Trans-vaginal											
	Trans-urethral											
	Trans-esoph. (non- Card.)											
	Musculo-skeletal (Conventional)											
	Musculo-skeletal (Superficial)											
	Intravascular											
Cardiac	Cardiac Adult											
	Cardiac Pediatric											
	Intravascular (Cardiac)											
	Trans-esoph. (Cardiac)											
	Intra-cardiac											
Peripheral	Peripheral vessel				N							
vessel	Other (Specify***)											

Transducer:	CW2s											
Intended Use:	Diagnostic Ultrasound ima	ging	or flui	d flow ar	nalysis o	f the huma	n body as fo	llows:				
Clinical Application		Mode of Operation										
General (Track 1 Only)	Specific (Track 1 & 3)	B M PWD CWD Color Amplitude Combined Other (specific Doppler Doppler (specify)										
Ophthalmic	Ophthalmic											
Fetal Imaging	Fetal											
& Other	Abdominal											
	Intra-operative (Specify*)											
	Intra-operative (Neuro)											
	Laparoscopic											
	Pediatric				N							
	Small Organ (Specify**)											
	Neonatal Cephalic											
	Adult Cephalic				N							
	Trans-rectal											
	Trans-vaginal											
	Trans-urethral											
	Trans-esoph. (non- Card.)											
	Musculo-skeletal (Conventional)											
	Musculo-skeletal (Superficial)											
	Intravascular											
Cardiac	Cardiac Adult				N							
	Cardiac Pediatric				N							
	Intravascular (Cardiac)											
	Trans-esoph. (Cardiac)											
	Intra-cardiac											
Peripheral	Peripheral vessel											
vessel	Other (Specify***)											

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