

# Full Digital Ultrasonic Diagnostic System



## Operation Guide

Date	Version	Description
2024.3.16	V1.0	Released on March 16th 2024
2024.5.06	V1.1.3	Upgraded the 3D software; Added PW sound storage and play back.
2025.10.31	V1.1.9	Update the 4D software introduction etc.

**The SN series products come in different models, each with distinct functions and parameters. These are not described separately in this user manual!**

## Maintenance

If the device is during warranty period, the manufacturer will provide free maintenance service for you.

If beyond warranty period, the company will provide maintenance service under the condition of charging a reasonable fee, spare parts costs and transportation costs.

But be careful, the company will charge maintenance and spare parts fees if the device has some problems caused by the following reasons:

- 1、 Man-made damage.
- 2、 Improper use.
- 3、 The grid voltage exceeds the scope of the provisions of the product.
- 4、 Irresistible natural disasters.
- 5、 Replacement or use spare parts, which accessories and consumables are without the company approved or maintained by non-defense personnel.
- 6、 Other faults which are not caused by the product itself.

## Important information

Customer shall be solely responsible for the maintenance and management after purchase it.

Only the professional medical staff that has a qualification certificate can use the system.

Quality guarantee does not contain the following content even if the product is still during warranty period.

- 1、 Device purchased from other companies or other unauthorized agents and dealers.
- 2、 Error or man-made damage or loss of system.
- 3、 System and operation conditions do not meet the requirements, such as the fluctuation of power supply or supply is insufficient, incorrect installation etc.
- 4、 Damage or loss caused by irresistible natural disasters or other social factors.
- 5、 Prohibit module disassembly, change the system circuit, electronic device, hardware and software etc.
- 6、 Under any circumstances, problems, loss or damage caused by the non-appointed staff who installs or re-install, change, or repair, the company is not liable for responsibility.
- 7、 This system is designed to provide data relevant to the needs of clinical diagnosis for doctors or hospitals, doctors bear and have responsibilities for the diagnosis process, the company does not assume any responsibility for the diagnosis process.
- 8、 The doctor who operates the device should back up important data. Loss of data stored within the system caused by faulty operation, the company does not assume any responsibility.
- 9、 This manual contains a potential hazard warning about the foreseeable. Stay high alert to those hazards which are not in the manual.
- 10、 When the system administrator has changed, please hand it over to the instructions.

## System Security Introductions

### 1、 Security Overview

To help you operate safely and correctly, the instruction manual includes descriptions of structure, setup, maintenance and operation of the machine. Please read this manual thoroughly before performing and strictly follow the instructions.

Equipment users must comply with the following content:

The equipment is classified as I Class according to electric shock proof type of medical electrical devices, and BF Type according to electric shock proof grade. Please use it correctly according to the contents of this section.

Do not do any modifications to this device. If you have to, please contact us.  
 Do not adjust any fixed parts which are adjustable for it has been completely adjusted.  
 Please cut off the power and contact us if there is any abnormal during using it.  
 The power of this equipment must be grounded well; the ground shall not be removed or dismantled.  
 Do not use high frequency surgical equipment nearby this device for it has no safeguard procedures.  
 Do not assemble the device except authorized personnel.

This equipments should only be used by doctors or special examination technicians who are familiar with the operation of the equipment.

Do not use this device in a flammable environment for it has the potential to explode.

Cut off the power when cleaning the device to avoid water entering it.











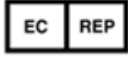


In order to ensure the safety of the examinee, shall not continuously scan imaging on the same part of the client for a long time.









When you adjust the acoustical power output value, it will affect the acoustic output values. MI and TI will also change. (MI said mechanical index, TI said heat index)

You must use gel which complies with relevant standards of qualified.

Inform our company when the equipment needs abandonment.

## 2、 Warning marks

Symbol	Definitions
	BF-type parts
	CF-type parts
	Dangerous voltage
	On/off(used in only one part of the equipment)
 <b>Danger</b>	This symbol indicates urgent danger will happen.If not strictly followed, they could lead to personal death or serious injury or serious property damage.
 <b>Warning</b>	This symbol indicates actions or conditions that should be avoided during operation. If not strictly followed, they could lead to personal death or serious injury or serious property damage such as total loss of equipment or indirect danger such as fire.
 <b>Cautious</b>	This symbol is emphasizing the important notice, providing definitions or explaining to make better use of the product.
 <b>Notice</b>	This symbol indicates actions or conditions that should avoid during operation. If not strictly followed, they could lead to slight or medium personal injury, partly loss of equipment and computer data.
	Notice! Refer to random file
	The name and address of the manufacturer
	The name and address of EU authorised
	Mark of CE
	Equipotential

	manufacturing date
	Series number
	Batch code
	The mark, checking instruction before using
	The mark, using in rooms
	Electronic product environmental protection period (20 years)
	The mark, prohibit dealing with rubbish and used stuff
	Nonionizing radiation

### 3. Biosecurity

This product is the same as all other diagnostic ultrasound products, should reduce time under the premise of obtaining necessary clinical information. Use lower power under the premise of obtaining good image.

### 4. Ultrasonic Security

Maintain the cleanness of the probe. Clean the probe when examining different patients.  
 Keeping freeze state when stop scanning.  
 Please refer to the report about acoustical output.

### 5. Quoted Standard

GB 10152-2009 B mode Ultrasonic Diagnostic Device  
 GB/T 14710-2009 Medical electrical environment requirements and test methods  
 YY 0767-2009 Ultrasound color flow imaging system  
 YY/T 0108-2008 Ultrasonic Diagnostic Device M model test method  
 YY/T 1142-2003 Ultrasonic Diagnostic Device and Monitoring equipment frequency characteristic test method  
 YY 0505-2012 Medical electrical equipment-Part 1-2:General requirements for safety-Collateral standard:Electromagnetic compatibility-Requirements and tests

### 6. Electrical safety classification

IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance  
 IEC60601-1-2 Medical electrical equipment –Part1-2:Particular requirements for the safety of electron accelerators in the range of 1 Mev to 50 Mev  
 IEC60601-2-37 Medical electrical equipment -Part2-37:Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment

### 7. Safety warning information

For patient and operator safety, when using this system please strictly observe the following safety precautions.



#### **Danger:**

Never in the presence of flammable gases, such as anesthetic gases, oxygen, hydrogen, and so on) or flammable liquids (such as ethanol, etc. ) use this system; otherwise there is a risk of explosion.



#### **Warning:**

1、 Using the adapter or multi socket may affect the grounding, the leakage current exceeds the safety

requirements.

- 2、 Before inserting the power plug into the socket, the ground must be good connected. In order to avoid electric shock, unplug the grounding conductor in front, the equipment must be pulled out from the plug socket, so as to avoid electric shock.
- 3、 In the system movement process must guarantee the system ground terminal and the earth connection, connect the grounding cable must be carried out when the device is shutdown, otherwise it could lead to an electric shock.
- 4、 Being sure not ground connection to any gas pipeline or water pipe, otherwise it can cause poor grounding or the detonation danger.
- 5、 Before cleaning the machine , be sure to unplug the power cord ,or it may result in electric shock.
- 6、 This machine does not have any waterproof device, do not use the machine where may enter water . Do not spill any liquid into the machine, otherwise there will be a risk of electric shock. If you accidentally spill liquid on the machine, immediately shut down and unplug the power plug, if necessary, contact the company or authorized customers.
- 7、 Using the probes carefully, if the probe head is scratched, please immediately stop using the probe and contact the company or authorized staff. If using a probe of scratching, there will be a risk of electric shock.
- 8、 It is forbidden that contact live part of this device or other equipment with the patient. If this equipment or other equipment breaks down, the patient can have an electric shock danger.
- 9、 Do not use the probe which is not provided by our company, otherwise it may damage the host or probe and even cause accidents such as fire.
- 10、 Do not knock the probe. A faulty probe may cause electric shock.
- 11、 Do not open the enclosure or panel, otherwise it will cause a short circuit or shock.
- 12、 Do not use the equipment together with high frequency electric knife, high frequency therapeutic equipment or devices such as defibrillators. Otherwise it might shock patients.
- 13、 Precautions during transport: if need to move the unit, hold the handle.
- 14、 All products connected with this ultrasound device must have IEC standards certified.
- 15、 When using intracavitary probe, do not activate the probe outside the patient.



**Notice:**

- 1、 Considerations for clinical examination techniques:
  - This device may only be operated by professionally qualified staff.
  - The operator should not contact the patient and the printer simultaneously.
  - This manual does not describe clinical examination techniques, must correct check on the knowledge of professional training and clinical experience.
- 2、 System exceptions caused by radio waves:
  - If you use this medical electron system nearby the transmit radio equipment, it may interface normal operation. Taking in or using devices that can produce radio waves are forbidden in the room. Such as mobile phone, radio transceiver and etc.
  - If in the vicinity of the system user with the possible radio waves of the device, you must call for the immediate closure of these devices to ensure that the system work normally.
- 3、 Considerations for installation and mobile devices:
  - Please ensure that the machine mounted horizontally.
  - Do not place anything on the monitor for it may drop and cause an injury.
  - Mobile equipment must be confirmed before peripherals have been fixed firmly. Otherwise, damage caused by peripherals may be dumped.
- 4、 Do not exert too much vibration on the device (such as moving equipment), or mechanical parts will be damaged.
- 5、 Always keep the machine dry , avoid the machine quickly moved from a cold place to a warmer place, otherwise there will be condensation or water droplets , causing a short circuit danger.
- 6、 If the circuit protection works, indicating the machine or peripheral equipment failure , please contact the company or authorized service staff, do not do it by yourself.
- 7、 Normal ultrasound check will not have the risk of burns. In order to avoid burning, do not put the probe at the same place of the patient, and reduce the inspection time as far as possible.
- 8、 The equipment and accessories are not sterilized when delivering. Before using the probe and puncture, the user should refer to this manual to do disinfection and sterilization.
- 9、 Do not turn off the power switch directly, or disconnect attachments (such as a printer and so on) the

plug, otherwise it will cause damage to the system.

- 10、 Do not power off the system in the process of printing, saving and transferring data, otherwise it can cause the information loss.
- 11、 In the process of operation, improper power failure may lead to damage or failure of hard disk data.
- 12、 Before using the ultrasonic diagnosis system, please read the ultrasound output part carefully.

**Cautions:**

- 1、 Do not use the system with strong electric or magnetic fields (such as transformers) environment is banned; otherwise it will have adversely affect.
- 2、 Do not near the high frequency device, otherwise it will have adverse affects and even lead to failure.
- 3、 To avoid damaging the system, the following situations are forbidden :
  - 1) Areas exposed to direct sunlight
  - 2) Areas with sharp temperature changes
  - 3) Areas with heavy dust
  - 4) Areas subject to frequent vibration
  - 5) Areas close to heat sources
  - 6) Areas with high humidity
- 4、 You need to wait for at least 5 minutes if you want to restart the machine, otherwise it may lead to failure.
- 5、 Before inserting the probe, the system must be shut down or the image must be frozen through the power switch. Otherwise, it may cause system or probe failure.
- 6、 The probe should be thoroughly cleaned after use.
- 7、 The user can record the registration data (such as a hospital patient information, etc.). To ensure data security, be sure to back-up the information on external storage media, as abnormal operations or failure may cause data loss stored in the system.
- 8、 Avoid applying force on the control panel (the body relies on), or it may damage the machine.
- 9、 Using this system in a narrow and small room may cause an increase in indoor temperature, therefore it is essential to ensure good ventilation.
- 10、 When you need to dispose of this system or any attachments, please contact our company or authorized staff. Our company will not take any responsibility for any damage caused by failure to comply with this provision.
- 11、 With the extension of time, the machine's electrical and mechanical safety performance will be reduced (such as producing leakage currents or mechanical deformation and wear parts), the sensitivity and accuracy of the image may deteriorate. In order to ensure the normal operation of the machine, please inspect the equipment regularly.
- 12、 After the system battery is fully depleted, the system clock may become disrupted. Please contact our company's maintenance engineer to guide you to replace battery.

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## Chapter1 Product Brief Introduction

Note: please read the user's manual chapters and the related contents carefully, which will help you master the machine quickly and operate it safely.

The SN series products come in different models, each with distinct functions and parameters. These are not described separately in this user manual!

### 1.1 Application Range

The device is suitable for clinical ultrasound examination of abdomen, gynecology and obstetrics, small parts, cardiac and peripheral vessel.

### 1.2 Product Formation

This device is composed of host, adapter and transducers.

### 1.3 Contraindication

Not suitable for eye examination.



**Notice:** Not all the descriptions in this manual are suitable for all equipment sales in different areas, please refer to the actual purchase machine which you bought.

## Chapter 2 Product Specifications

### 2.1 Imaging mode

- B,B+B,4B mode
- B+M,M mode
- THI mode
- CFM color flow mode (optional)
- B+CFM mode (optional)
- B+CFM+PW triple mode (optional)
- PDI Power Doppler Mode (optional)
- B+PDI mode (optional)
- PW mode
- CW mode (optional)
- 3D mode (optional)
- 4D mode (optional)

### 2.2 Power source requirement

- 1、 Power supply input voltage: AC 100V-240V ;
- 2、 Frequency:50Hz/60Hz
- 3、 Output Voltage: 19V±1V;
- 4、 Power:50VA;



**Warning:** Please strictly follow the above requirements for power supply, otherwise it may cause damage to the equipment.

### 2.3 Working environment

- 1、 Environment temperature: 5℃~+40℃;
- 2、 Relative Humidity: 25%~80%;
- 3、 barometric pressure: 70kPa~106kPa;
- 4、 An environment free from strong electromagnetic interference and direct sunlight;
- 5、 Do not place anything on the host;
- 6、 Turn off the power and use a dust cover when the device is not used.

### 2.4 Transportation and reserve

- 1、 Temperature: -20℃~+55℃;
- 2、 Relative Humidity: 10%~95%;
- 3、 barometric pressure: 50kPa~106kPa;
- 4、 No corrosive gas, good ventilation.



**Warning:** Do not use under conditions exceeding the specified limits.

### 2.5 Overall dimensions

Overall dimensions: 378mm × 350mm × 56mm

Net weight: almost 4Kg

Package size: 445X185X435mm

Aluminum Box Package size: 445X185X435mm

Gross weight: 6.2Kg

Aluminum Box Gross Weight: 9Kg

### 2.6 Lifespan

The lifespan of the product is 6 years (excluding the battery).

## Chapter 3 System Configuration

This system adopts ultra-thin design and current international advanced ultrasonic imaging technology, based on the high precision of digital beam forming, with clear 2d images, sensitive color doppler information. This system can be equipped with a variety of probes, and is furnished with a simple operational panel as well as a rich selection of application software. The entire system boasts a wide range of applications, capable of meeting the ever-growing demands of clinical diagnosis.

### 3.1 Standard Configuration

The factory standard configuration:

- Host (with adapter)
- Probe (see the product's Packing List)
- Accessories (see the product's Packing List)

### 3.2 Probe parameters

Model	Center frequency	Frequency range	Probe type	Application	Clinical applicability
3.5C8060G-2	3.5MHz	2.0-6.0MHz	Convex probe (R=60)	body surface	ABD/OB/GYN
7.5L8040G-2	7.5MHz	5.0-12.0MHz	Linear Probe (L=40)	body surface	superficial
6.5C8010G-2	6.5MHz	4.5-10.0MHz	Transvaginal probe (R=10)	Transvaginal	OB/GYN
3.5C8020G-2	3.5MHz	2.5-6.0MHz	Micro-convex probe (R=20)	body surface	Cardiac/small organ
6.5C8015G-2	6.5MHz	4.5-10.0MHz	Micro-convex probe (R=15)	body surface	Cardiac/small organ
7.5C8020G-2	7.5MHz	5.0-12.0MHz	Micro-convex probe (R=20)	body surface	Cardiac/small organ
6.5L8064G-2	6.5MHz	5.0-10.0MHz	Linear Probe (L=40)	Rectal	Rectal



**Warning:** Intracavitary convex array cannot be activated outside of the body.

### 3.3 Operating environment

Operating ambient temperature:  $+5^{\circ}\text{C} \sim +40^{\circ}\text{C}$

Relative humidity:  $\leq 80\%$

Atmospheric pressure: 700hPa—1060hPa

Power supply: AC220V $\pm$ 22V, 50Hz $\pm$ 1Hz

Plug seat shall have independent power supply.

Be far away from strong electric field, strong magnetic field equipment and high voltage equipment

### 3.4 Main Functions

**Displayer:** 15.6-inch ultra-thin 1920X1080 high resolution medical display;

**IMT:** Automatic vascular intima measurement;

**Scanning mode:** Convex array, Transvaginal, high-frequency linear array, Micro-convex, Rectal etc;

**Dynamic range:** 80~280dB adjustable;

**Display mode:** B, B/B, M, CFM(Color), CMF/B, PDI(Power), B/PW, THI, CW, 3D, 4D mode etc;

**Application mode:** abdomen, gynecology, obstetrics, superficial organ, urologist, heart and user defined model, total ten models;

**Image mode:** digital beam forming, tissue harmonic imaging;

**Acoustic output:** Mechanical index and thermal index real-time display;

**Acoustic power:** Step is adjustable, real-time display;

**Gray scale:** 256 scales;

**Depth display:**  $\geq 280$ mm;

**Languages:** English, French, Portuguese, German, Indonesian, Russian, Spanish, Arabic, Chinese 9 languages;

**B/D dual-purpose:** linear array: B/PWD; convex array: B/PWD;

**Pseudo color processing:** 16 kinds of pseudo color encoding can optional;

**Gain adjusts:** 8 segments TGC, B/M/D/C is independently adjustable; TGC curve can show and hide automatically;

**Special function(SN50):** ITHI, Denoise, Gray map(Japanese logarithmic curve and self-computed logarithmic curve).

**Image processing:** image optimization and Edge enhancement, Frame average, Line average, Focus Optimization, Noise Restrain, Gamma correction, Contrast, Brightness adjustable

**Self-motion optimize function:** Built-in multiple check type, according to different inspection organs, preset best image check condition, reduce the adjusting operation keys;

**Measurement and calculation:** B mode routine measurement, Distance, circumference, area, volume, angle, ratio, and stenosis rate. M mode routine measurement, Gynecology measurement, Obstetrics measurement, Cardiology measurement, Urology measurement, PW measurements, CW measurements, Other measurement.

**Image storage:** Image storage, video storage, cine loop, disk storage capacity SN50 $\geq 256$ G, SN30 $\geq 128$ G, SN10 $\geq 64$ G;

**Patient data:** Medical record management, report inquiry and printing, image video output (HDD, USB, Optional DVD-RW), built-in ultrasound workstation;

**Reporting system:** automatic report generation system, and can be full screen characters in both Chinese and English editor;

**Output interface:** HDMI, VGA, USB, DICOM interface;

### 3.5 Main Technical Indexes

#### 3.5.1 The performance requirements of gray-scale imaging mode

The color ultrasonic at the gray-scale imaging performance mode should comply with the provisions of the table 3.5.1

Table 3.5.1 At the Gray-scale imaging mode the performance of the probe

performance indexes	probe type and nominal frequency			
	$2.5 \leq f < 6.0$	$2.0 \leq f < 5.0$	$5.0 \leq f < 8.0$	$5.0 \leq f < 12.0$
a) probe type and model	Micro convex 3.5C8020G-2	Convex (3.5C8060G-2)	Cavity (6.5C8010G-2)	Linear array (7.5L8040G-2)
b) nominal frequency (MHz)	3.5	3.5	6.5	7.5
c) Scan depth(mm)	$\geq 140$	$\geq 160$	$\geq 40$	$\geq 50$
d) Lateral resolution (mm)	$\leq 3$ (depth $\leq 80$ ) $\leq 4$ ( $80 < \text{depth} \leq 130$ )	$\leq 3$ (depth $\leq 80$ ) $\leq 4$ ( $80 < \text{depth} \leq 130$ )	$\leq 2$ (depth $\leq 30$ )	$\leq 2$ (depth $\leq 40$ )
e) Axial resolution (mm)	$\leq 2$ (depth $\leq 80$ )	$\leq 2$ (depth $\leq 80$ ) $\leq 3$ ( $80 < \text{depth} \leq 130$ )	$\leq 1$ (depth $\leq 40$ )	$\leq 1$ (depth $\leq 50$ )

f) Blind area (mm)	$\leq 7$	$\leq 5$	$\leq 4$	$\leq 3$
g) Transverse geometry precision (%)	$\leq 20$	$\leq 15$	$\leq 10$	$\leq 10$
h) Longitudinal geometric location accuracy (%)	$\leq 10$	$\leq 10$	$\leq 5$	$\leq 5$
i) Slice thickness (mm)	$\leq 5$	$\leq 5$	$\leq 5$	$\leq 5$
j) Perimeter and areameasured deviation (%)	$\leq \pm 20$	$\leq \pm 20$	$\leq \pm 20$	$\leq \pm 20$
k) M mode time display error (%)	$\leq \pm 10$	$\leq \pm 10$	$\leq \pm 10$	$\leq \pm 10$

### 3.5.2 The performance requirements of color Doppler imaging mode

- The color Doppler imaging mode should comply with the provisions of the table 3.5.2;
- Color blood flow image should be essentially coincident with the gray-scale image of pipe's;
- Blood flow direction should be able to correctly identify, no aliasing phenomenon;

Table 3.5.2 at the color blood flow imaging mode the performance of the probe

Doppler model	Micro convex	Convex array	Cavity	Linear array
Investigation depth at Color blood flow model	$\geq 90\text{mm}$	$\geq 100\text{mm}$	$\geq 40\text{mm}$	$\geq 50\text{mm}$
Investigation depth at Doppler spectrum model	$\geq 90\text{mm}$	$\geq 100\text{mm}$	$\geq 40\text{mm}$	$\geq 50\text{mm}$
Blood flow speed reading error	$\leq \pm 15\%$			

### 3.5.3 The performance requirements of Doppler spectrum mode

- The color ultrasonic at the color Doppler spectrum mode should comply with the provisions of the;
- Blood flow speed reading error should comply with the provisions of the table 3.5.3;
- Pulse wave Doppler mode sampling area cursor position should be accurate;

Table 3.5.3 at the color blood flow imaging mode the performance of the probe

Doppler model	Micro convex	Convex array	Cavity	Linear array
Investigation depth at Color blood flow model	$\geq 90\text{mm}$	$\geq 100\text{mm}$	$\geq 40\text{mm}$	$\geq 50\text{mm}$
Investigation depth at Doppler spectrum model	$\geq 90\text{mm}$	$\geq 100\text{mm}$	$\geq 40\text{mm}$	$\geq 50\text{mm}$
Blood flow speed reading error	$\leq \pm 15\%$			

# Chapter 4 product appearance

## 4.1 Name of the system parts



System appearance figure



SN	Name	Function
1	Monitor	Ultrasound images and each application interface display, etc.
2	Control panel	Text annotations, report writing and ultrasonic applications and other operational control
3	Interface Board	Interfaces such as electric input/output and Video, DICOM
4	Handle	device handle

## 4.2 Control panel





The control panel consists of characters digital key and function keys, the main control and function of ultrasonic equipment are mainly controlled through the implementation of the corresponding function key.

SN	Name	Function
1		To enter or exit the ultrasonic application and prompt to turn it off.
2	<b>Help</b>	Button function introduction
3	<b>Zoom</b>	Press this key to enter the image magnification function,
4	<b>Qsave</b>	Save the current image parameter to Preset.
5	<b>U/D</b>	Change the up or down display direction of the image
6	<b>L/R</b>	Change the direction of the left or right imaging
7	<b>Quad</b>	Under B mode, press <b>【Quad】</b> key,then press <b>【Update】</b> key can into the 4B mode
8	<b>3D/4D</b>	Enter 3D/4D (Reserved)
9	<b>PAN</b>	Enter pan imaging function
10	<b>PDI</b>	Enter PDI mode
11	<b>CW</b>	Enter CW mode (Reserved)
12	<b>THI</b>	Enter THI mode
13	<b>Biopsy</b>	Puncture guide line
14		Press this key to increase the volume of voice
15		Press this key to decrease the volume of voice
16	<b>Cursor</b>	Input cursor on the screen.
17	<b>Preset</b>	Enter the system parameter settings and choose interface
18	<b>Examend</b>	End the current patient's examination
19	<b>Text</b>	Input text on the screen.
20	<b>Clear Text</b>	Clear text info
21	<b>Dual</b>	Under B mode, press <b>【Dual】</b> key,then press <b>【Update】</b> key can into the B+B mode
22	<b>Report</b>	The inspection report module of the current patient; Browse the recent inspection measurement calculation in report
23	<b>Arrow</b>	Click this key can show the arrow mark on the screen. Rotate [Adjust], adjust the direction of the arrow mark.
24	<b>M</b>	Enter B/M mode,then press <b>【Update】</b> key can into the M mode
25	<b>PW</b>	Enter PW mode, then press <b>【Update】</b> key can into the PW mode
26	<b>Color</b>	Enter CFM mode
27	<b>B</b>	B Mode

28	<b>Angle</b>	PW mode Rotate "Adjust" knob can adjust angle of pw sample line.
29	<b>Gain</b>	Rotate knob, adjust the gain of the image. Press the button in the knob to switch between B gain,color gain,PW gain modes.
30	<b>Menu</b>	Press the button in the knob, the parameter menu showed on right side of the screen. Rotate knob to move the light bar to desired item press the knob to determine and then rotate the knob to adjust the selected parmeter.Press "Esc" can hide the menu.
31	<b>Review</b>	Enter the image management application module Browse images and video Export images and video files to external storage device
32	<b>Bodymark</b>	Display and select bodymark
33	<b>Clear</b>	Clear all marks on image.
34	<b>Update</b>	Switch the image at 2B/4B/PW mode
35	<b>Measure</b>	Measurement function
36	<b>Patient</b>	Createa new patient file.
37	<b>Probe</b>	Enter into the probe selection; Select the probe and the application.
38	<b>Print</b>	Print the report.
39	<b>Save Cine</b>	Save playback video or real-time scanning cine.
40	<b>Save Img</b>	Save the current freezed image.
41	<b>Back</b>	Cancel the last move.
42	<b>Set</b>	Confirm the last move
43	 <b>Depth</b>	Press this keytoincreasescanning depth of image.
44	<b>Depth</b> 	Press this keyto redusescanning depth of image.
45	<b>Freeze</b>	To freeze the image
46	<b>Shortcut knob</b>	Rotate"Shortcut knob"can adjust parameter showed on bottom of the screen.Press the botton on "Shortcut knob" can switch in the current option column.
47	<b>Menu knob</b>	Press the botton on "Shortcut knob" can display the option of menu,Rotat the knob switch in the options. Press the botton on "Quick knob" can select.
48	<b>Gain knob</b>	Rotate this knob to adjust gain of imaging gain.
49	<b>Angle knob</b>	Rotate this knob to adjust sampling angle of PW.
50	<b>TGC</b>	8 section slide rod, adjust time gain compensation

**Note: Special attention to** 

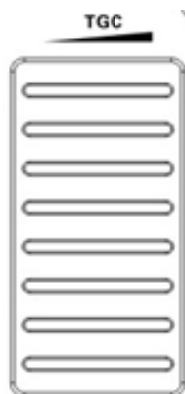
- 1、 Press the button to exit the ultrasonic system,the system needs 40 seconds to save data. Please power off again after the system prompt information.
- 2、 A shutdown without system prompt is regarded as a abnormal shutdown.
- 3、 After pressing ,if the power system don't prompt after a long time, please force a shutdown (if this situation occurs repeatedly, please shut off the power and contact the manufacturer or authorized service personnel) .
- 4、 Please save the records of abnormal shutdowns,as customer service and technical support personnel will need those records when the device malfunctions and needs to be repaired.

 **Warning:**Incorrect shutdown can lead to slow system startup or operation;  
Multiple abnormal shutting down can lead to abnormal failure of ultrasonic equipment damage, or other problems.

**4.3TGC**




Interface board



Slide rod, adjust time gain compensation.

**4.4Interface board**

SN	Name	Function
1	DC IN	DC-19V
2	HDMI	HDMI interface
3	VGA	VGA interface
4	DICOM	Network interface
5		Two usb interface.
6	Audio OUT	Audio out

## Chapter 5 System Installation and Connection

### 5.1 System location

It should be meet below requirement:

- 1、 Use Handle move the machine;
- 2、 Keep minimum 25cm space.



**Warning:** Must keep enough space behind and by side of machine, or it will effect machine heat disperse, then damage the machine

### 5.2 System movement

In order to prevent the accident, please pay attention to the following items:

- 1、 Ensure the system is off.
- 2、 Remove all probes and then move.
- 3、 Remove all other connected devices.
- 4、 Package it well before move, it is better to use factory package.
- 5、 Equipment must not be upside down.

### 5.3 Power connection and ground

#### 5.3.1 Power supply connection

Power supply system must meet the following requirements:

- 1、 Power voltage: AC 100V-240V.
- 2、 mains frequency :50Hz/60Hz.
- 3、 power:50 VA.

#### 5.3.2 Battery power

When the machine starts to work normally with external power, the system is supplied by external power. If there is battery installed in the machine, then the battery is being charged. When the system is working without external power, it could be supplied by chargeable Li-ion battery.

For the specific operation and notes of using the battery, please see chapter 13 Battery.

#### 5.3.3 Equipotential terminal

Equipotential terminal is used to balance between this system and other electrical equipment protective grounding potential. The equipotential terminal of this equipment refers to chapter 4 of the “interface board” icon.



#### **Warning:**

- 1、 When inserting the power plug of the device, the equipotential lead must be connected.
- 2、 To avoid electric shock, the power must be disconnected before removing the bonding wire.
- 3、 When other devices are connected to the system, you must use the equipotential cable to each equipotential connection terminal, which can avoid the possibility of electric shock.
- 4、 You must ground according to local regulation.
- 5、 Connect ground before powering on.
- 6、 Remove ground after powering off.

### 5.4 Connection and removal of probes



**Attention:**

- 1、 Before removing the probe, please ensure that the system is in the frozen state or has been shutdown. Otherwise, it may cause malfunctions.
- 2、 When plugging the probe, it should be placed within the probe protection hook and the probe cable should be suspended on the probe holder to prevent accidental damage.
- 3、 When using the probe, the probe cable should be hung on the probe holder to prevent the probe socket from being deformed or damaged.
- 4、 This system can only use probes provided by the manufacturer. If you try to use other probes, it may cause damage to the equipment and probes, as well as other unpredictable accidents.

**5.4.1 Probe assembly**



**Warning:** Before connecting the probe, it is important to ensure probe matching layer surface, probe cable and the probe socket are in normal state and no cracks or fall off. Using defective probes may lead to electric shock.

- 1、 Push the probe connector into the socket and press it tightly.
- 2、 Rotate the screw clockwise to lock up the probe connector. See the figure below SN10/SN30.

**SN10/SN30**




**SN10Pro/SN30Pro/SN30Plus/SN50**




- 3、 Press the button at the arrow to insert the probe socket as shown- SN10Pro/SN30Pro/SN30Plus

### 5.4.2 Probe Disassembly

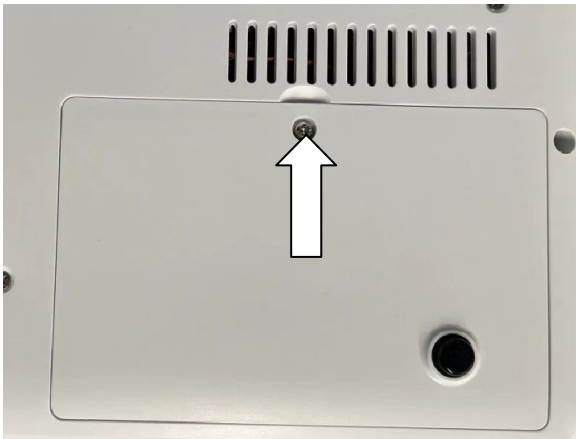
Rotate the screw anticlockwise to unlock the probe connector. Then pull the probe connector out of the socket.

 Before pulling the probe connector, please ensure that the system is in the frozen state or the system has been shut down. Otherwise, it may cause failure.

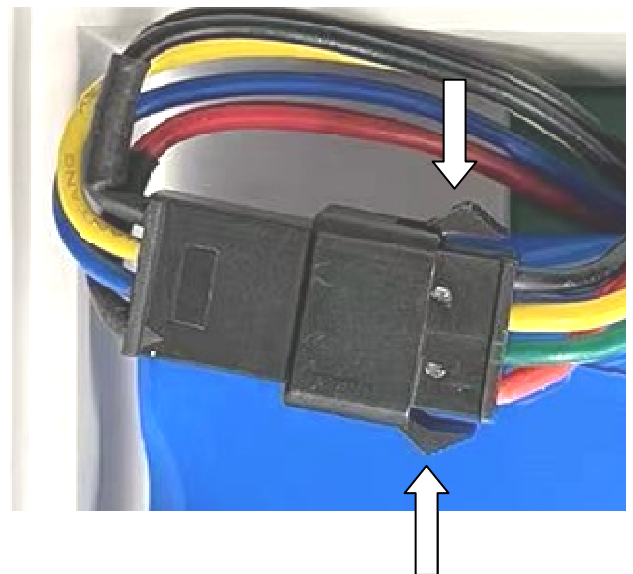
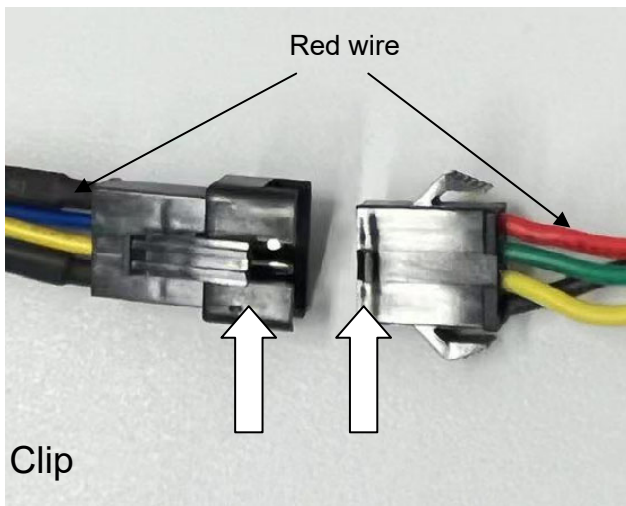
### 5.5 Battery connection(Check "Chapter 13 Battery" for details)

 Before connecting the battery, please ensure that the battery is correctly oriented. Please read Chapter 13 Battery carefully!

Remove the screw as indicated by the arrows in the pictu below



As shown in the following picture,insert the connector in the right direction and connect the battery:



## Chapter 6 Startup and shutdown



### Attention:

- 1、 In order to ensure the safe and effective operation of the system, please keep daily maintenance. When you find the abnormal situation, please shut down immediately and contact the manufacturer or agent. Using defective system will damage the patient and the equipment.


### 6.1 Startup




#### 6.1.1 Check before startup

Before starting, please refer to the following steps or project for inspection and operation.

SN	inspection item
1	Whether the power grid voltage meets the requirement of working conditions
2	Temperature, humidity and atmospheric pressure should meet the requirements of the conditions of use.
3	There should be no condensation in the environment
4	The system and peripheral equipment should not have any phenomena such as deformation, destruction or contamination. If it is found with stain, please clean it according to the instructions in "cleaning systems" section.
5	Monitor and control panel components can not have loose phenomenon or a loose screw
6	Power cable or probe cables shall not be damaged, joint connection parts shall not be loose.
7	Properly clean, disinfect and sterilize the probe according to the maintenance instructions.
8	Do not place sundries on the control panel.
9	Check the socket and all visible interfaces to ensure that there are no abnormal phenomena, such as damage or blockage caused by foreign objects.
10	There should be no obstacles near the movement area or vents
11	A clean and organized working environment and space

#### 6.1.2 Turn on the power

Connect the external adapter, then green light is on, see as below, press  button on control panel, then green light is on, system boots, show image. Press freeze, show B mode.

	This light is on when the external adapter power supplying
	This light is on when the battery in charging
	This light is on when the machine is working; Do not forced power outage when system is shutting down while it is flashing.

Whether the system startup is normal; please refer to the following parameters.

SN	inspection item
1	Do not have any abnormal sound, smell, or overheating phenomenon.
2	System has no error message
3	Cannot exist obvious abnormal sound, discontinuous displays or abnormal dark space exists in the 2d image.
4	Check whether there is an abnormal fever in the probe surface in the process of using the device.
5	The function of the button or knob is normal
6	The system time is in accordance with the current time



**Warning:**

- 1、 Using an unusually hot probe can burn patients.
- 2、 When finding the abnormal situation, shut down it immediately and contact the manufacturer or agent. Using defective system will damage the patient and the equipment.

## 6.2 Failure to start up


If the system is faulty and needs to be shut down and restarted, wait at least five minutes before restarting the system

- 1、 Abnormal screen display.
- 2、 Screen displays an error message, and this information is always displayed.
- 3、 The corresponding operation cannot continue.
- 4、 The working indicator light (green and yellow lights) flash at the same time, which indicates that the machine is overheating.

## 6.3 Power Off

If you do not use the machine for a long time, please shut off the power.

Before powering off, follow the steps below:

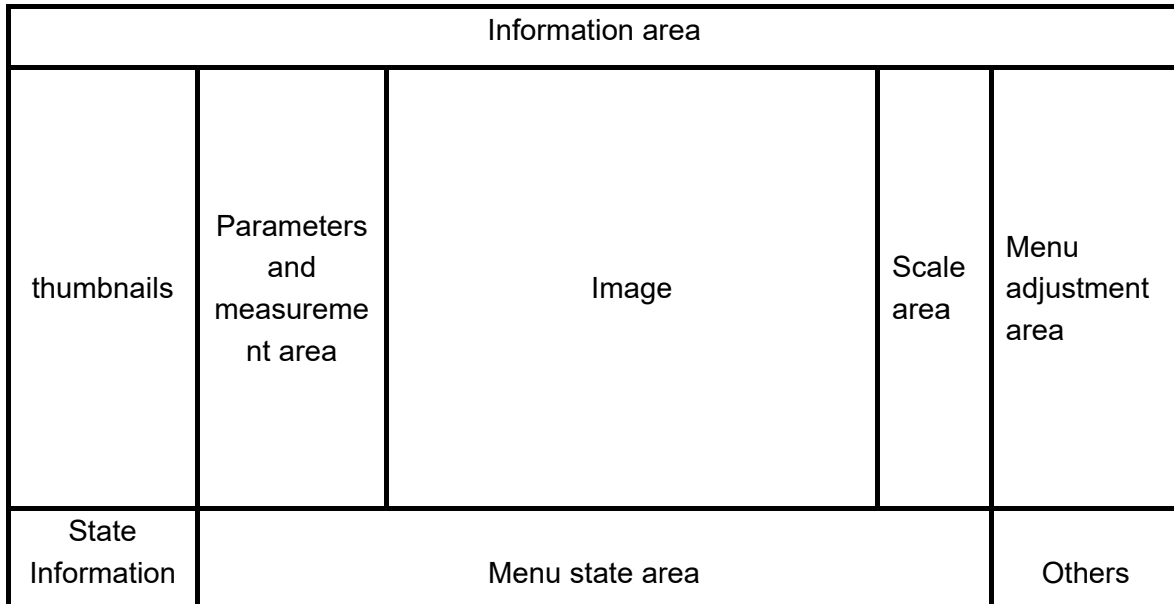
- 1、 Put the probe in the corresponding probe dust cover.
- 2、 Press  button on the control panel, the index lights blinking indicates prompt to turn it off, wait for power and key lights completely off before you unplug the power cable.
- 3、 Close all the peripherals connected to the machine power supply.

# Chapter 7 Main Work Interface

## 7.1 Working Interface

Working interface refers to the display, which shows the ultrasound images, various parameters and corresponding menu operation. There is a slightly difference in menus and parameters between various scan mode.

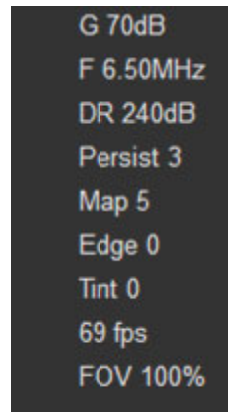
Distribution of Work Interface is as follows.



## 7.2 Information

Display name of the hospital, system date and time, name of the probe, etc in sequence.

- ◆ **Hospital Name**  
Display the name of the hospital. The hospital name can be edited and modified in the “basic parameters” entered by the system by default.
- ◆ **System date and time**  
Display System date and time. The system date and time can be edited and modified in the “basic parameters” entered by the system by default
- ◆ **Name of the probe**  
Show the current probe name, the choice of probe, switch can be selected in the probe selection dialog box.
- ◆ **The current application mode**  
Display the current application mode



## 7.3 Menu adjustment area

- ◆ **Working Parameters display:**  
In real-time scanning work, working parameter display as shown in the figure below (below only for example)

As shown above, the display of 2D and Color, PW, stands for B, CFM and PW mode, which respectively are shown corresponding parameters in this mode . Including the corresponding gain (Gn), the working frequency (Freq), dynamic range (DR), frame average (Persist), average compression curve (Map) and Edge

enhancement (Edge) and pseudo color (Tint), and other parameters.

### ◆ Menu Adjustment

The control menu displays image adjusting and optimizing parameters, which can be adjusted using relevant keys and mouse control. Additionally, this area briefly demonstrates the application of measurement module menu application, body markers, text annotations, and specific display and operation as follows:

SN	Image mode/Menu	Menu Function	Adjustment
1	B,B+B,4B	Image parameter Settings: sound power, pseudo color, black and white and reverse, mirror, compression curve, edge enhancement, brightness, contrast, gamma correction, image enhancement, focus.	Press the button on the <b>【Menu】</b> knob, show menu vertically, rotate the menu knob and press the button on the <b>【Menu】</b> knob to select and adjust the value of the parameter.
2	B+M	Image parameter Settings: sound power, M pseudo color, black and white reverse, images, edge enhancement, gamma correction, contrast and brightness.	
3	CFM,PDI	Image parameter Settings: acoustic power, sample volume, color persist, color balance, color threshold pseudo differential inhibition, pseudo color, black and white reverse, mirror image, edge enhancement, gamma correction, contrast and brightness.	
4	PW,CW	Image parameter Settings: acoustic power, sample volume, the color persists, color balance, color threshold PW,CW frequency, scanning speed, noise suppression, wall filter, PW pseudo color, black and white reverse, mirror image, edge enhancement, brightness, contrast, gamma correction, mute, volume.	
5	Text	Display the current application mode of text annotation.	
6	Body Mark	Display the current application mode of body markers	
7	Measure	Freeze, display the basic measure of the current application mode and application of measurement of present application. Note: the system real-time scanning state, the menu does not display, do not work;	

### 7.4 Scale Display Area

There are always display depth reference, gray scale, CFM speed scale; The TGC curve automatically show and hide according to the set of parameters.

### 7.5 Image Area

Show each mode of image, but also all kinds of text, measurement scale markers in this main display area.

The shape of the ultrasonic image display depends on the width and setting of the selected probe, and also includes image depth indication, focusing indication, etc.

Annotation is meant to help analyze and interpret image information, and it involves manually annotating text/annotating arrows. Image scanning position Graphic information such as human body position state, probe direction, etc.

Under the conventional measurement state and a variety of applications, the annotation information is displayed in the image area in the process of measurement.

## **7.6 Parameter and Measurement Display Area**

### **◆ TI/MI**

Display system current TI (thermal value) and mechanical index MI values. According to the different conditions of real-time scanning, it will show different index value.

### **◆ Measurement Calculation Display**

This area is located below the working parameters, in the bottom left corner of entire image, which are used to display measured values and the corresponding calculation results. The measured values are usually displayed in real-time, and the cursor can be moved during the measurement process to update the measured values in real-time. Once the measurement is completed, the measured values will be fixed, and the corresponding results will be displayed by the relevant application.

## **7.7 Menu State Area**

Display the state of relevant parameters in real-time and frozen condition.

## **7.8 State Information Area**

Prompt system current status, such as in cine mode.

In real time state, display the current image, show cine buffer storage state information; (66-100), 66 shows current image location in a cine buffer, 100 shows total stored image number. The maximum number of frames cine buffer in the system default "system parameter Settings/storage options" to set the maximum number of cine frame buffer.

In frozen state, show total number of frames saved in cine buffer, and the state of current frame information.

## **7.9 Others**

Display the current application mode and volume of system.

## Chapter 8 New Patient

Normally, there is no need to input patient's information. But in order to facilitate the management, research and storage of patient information, we built this system. We also recommend that the user enter patient data when performing the analysis.



### Caution:

- 1、 Before checking the new patient, please press "Patient" to input or update the patient's ID and other information to avoid the mistake in the patient information storage;
- 2、 When the system is set up or the current patient is deleted, if a video or a image needs to be stored , the system automatically enters the patient data entry model, which requests the input of patient information.

### 8.1 Enter/Exit Patient Data input

#### ◆ Enter Patient Data input



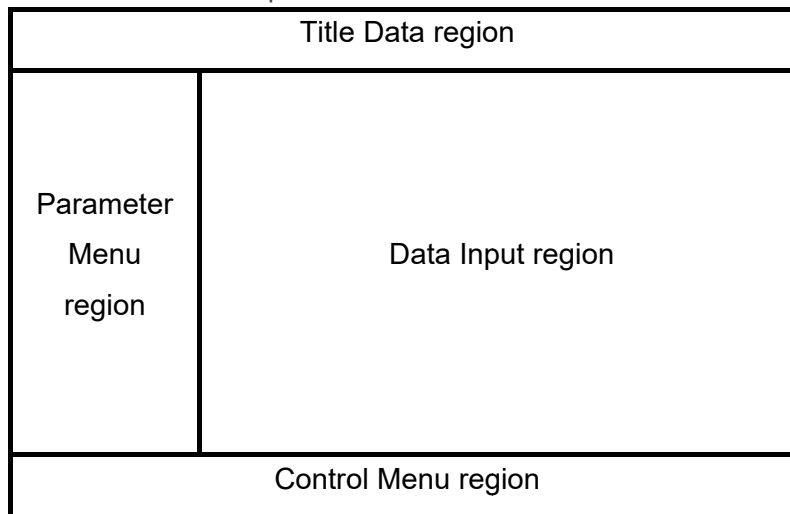
Press "Patient" enter "Patient Data input" interface;

#### ◆ Exit Patient Data input

Under the Patient Data input interface, press " New Patient" or "New Exam", save and exit the patient data input interface; If press "Exit", exit the patient data input interface directly;

### 8.2 The introduction of patient data input interface

Press "Patient" enter "Patient data input" interface.



The layout of each part interface function are as follows:

#### ◆ Title Data region

Display the basic information, such as Hospital name, date and so on;

#### ◆ Parameter Menu region

For anew patient, it includes the following parameters controls to complete different information input operations:

- 1、 New patient: According to need, then input the data for the different exam: GY/OB, Cardiac, urology etc.
- 2、 Properties: Select in Auto ID or Clear All;
- 3、 Action: The function is same with the "Control menu region".

#### ◆ Data Input region

It will display different interfaces depending on the category of new patients and enter different data for different applications. Such as basic information, GY/OB, Cardiac, Urology, other descriptive data, etc.

◆ **Control Menu region**

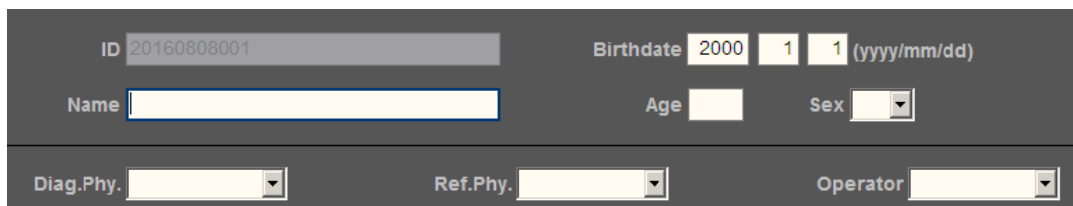
After finishing the input of the patient data, different buttons in control menu region indicate the selection of the next procedure:

- 1、 New patient: Before using the new patient record, save the current edit and input data, exit current mode and return to the image scanning interface .
- 2、 New Exam: Based on the current patient, save the current edit and input data, exit current mode and return to image scanning interface.
- 3、 Save: Save the current edit and input data, don't exit.
- 4、 Exit: Don't save the current edit and input data, exit the interface, back to the images scan interface directly.

### 8.3 Patient information input

#### 8.3.1 Patient basic information

Press [  ] to enter the patient's data into interface as below:



ID	20160808001	Birthdate	2000	1	1	(yyyy/mm/dd)
Name	<input type="text"/>	Age	<input type="text"/>	Sex	<input type="text"/>	
Diag.Phy.	<input type="text"/>	Ref.Phy.	<input type="text"/>	Operator	<input type="text"/>	

The instruction of patient basic information input as below:

◆ **Patient ID (ID)**

If you select "Auto ID", the system will generate the ID one by one. If you don't select "Auto ID", the patient ID should be inputted by the user.

◆ **Patient name (Name)**

Please use the control panel to input the patient's name.

◆ **Birthdate**

Please input the patient birthdate by the sequence of year, month and day. The system will calculate the age by the birthdate. The display sequence and format will adjust automatically according the setting of system preset.

◆ **Age**

The system will automatically calculate and display the age according to the entered birthdate. The user also can fill or change the age.

◆ **Sex**

Click "▼" and select "F", "M" or "O" from the drop-down list.


◆ **Input Diag. Phy. ,Ref. Phy. ,Operator:**

Input Diag.Phy(Diagnostic Doctor),Ref.Phy(Reply Doctor),Operator by the control panel directly.The system will save the input data automatically.



**Caution:** The user can add, modify and delete the stored doctor information in the default system "System parameter Setting/doctor management".

### 8.3.2 Patient detail information input

Press  to open the Patient Data interface as shown in the below figure.

#### 1、 GY/OB data

- ✓ Select GY/OB in parameter menu region, display or close the input interface;
- ✓ GY will need to input the data as following:
  - ☑ LMP
  - ☑ Exp.Ovul.
  - ☑ EDD
  - ☑ GA
  - ☑ Day of Cycle
  - ☑ Gravida
  - ☑ Para
  - ☑ Aborta

#### 2、 Cardiac data

- ✓ Select Cardiac in parameter menu region, display or close the input interface;
- ✓ Cardiac calculation and application need the data as following:
  - ◆ Height,Weight,BSA will be calculated automatically;
  - ◆ Heart Rate;
  - ◆ Systolic, Diastolic

#### 3、 Descriptions Data

- ✓ Select Description in parameter menu region, display or close the input interface;
- ✓ Need to record the patient data carefully, may need the data as following:
  - ◆ Accession #;
  - ◆ Exam Desc.
  - ◆ Indication;
  - ◆ History;
  - ◆ Address;
  - ◆ Phone;
  - ◆ Comments.

## Chapter 9 Application Mode



**Caution:** When the user uses the measurement calculations and comments, after changing the application mode, the measurements, comments and arrows on the main interface will be cleaned, and the measurement data will not be stored.

### 9.1 Application mode

This system has some built-in application modes, you can choose according to your needs as below:

- 1、 Abdomen
- 2、 Kidney
- 3、 Obstetric
- 4、 Gynecology
- 5、 Pelvic vanity
- 6、 Main artery
- 7、 Muscle tissue
- 8、 Small organ
- 9、 Breast
- 10、 Cardiac

#### 9.1.1 The selection of application mode

Press **【Probe】** button, the following interface will pop up, you can select the application mode according to your needs.

After entering into the application mode selection interface, the current application mode will be highlighted automatically.

- ✓ Application mode list: the list displays all of the application modes which are supported by this system, the user can select the application according to need.
- ✓ Set: exit application mode selection interface, the system will work according the parameters of the selected application mode;
- ✓ Exit: exit application mode selection interface.

#### 9.1.2 The setting of application mode

Each application mode is associated with many parameters, the detail setup and modify, please refer to the system default “Application mode”.

### 9.2 Probe exchange

#### 9.2.1 Enter/exit probe exchange

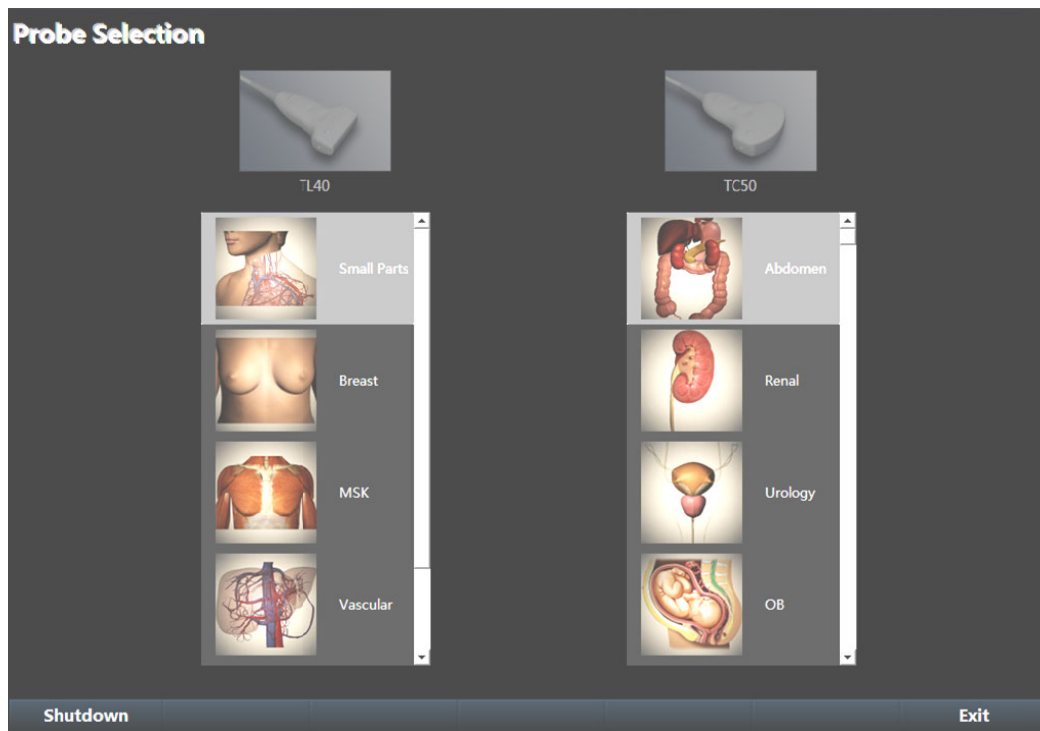
Press **【Probe】** button to enter probe selection interface, you can select the probe which you need and application according to the connected probe and what the patient inspection need.

On the probe exchange interface, press “Exit” on the lower right corner, exit the probe exchange interface, and back to the main work interface.

#### 9.2.2 Probe exchange

##### ◆ Work interface

Press **【Probe】** button to enter into probe selection interface, please check below:



The probe selection interface includes: probe list and application mode list

- ✓ Probe list: List all the probes mode which supported by this system ;
- ✓ Application mode list: List the applied mode of the selected probe can support, the users can select the corresponding mode according to need.
- ✓ This system support switching and selecting between two probes.

◆ **Probe exchange**

Firstly, position the preset application mode, then move the cursor to the top of the probe model, press **【Set】** to finish the probe exchange.

## Chapter 10 Imaging mode





**Warning:** This system imaging is just for the reference of the doctor diagnose, it is not responsibility for the doctor diagnose result. The doctor will be responsible for the diagnose result.

### 10.1 Imaging mode

This system supports the image modes as below:

Mode	Imaging
2D mode	B mode
	B+B mode
	4Bmode
	B+M mode
	THI or ITHI mode
Color mode	CFM
	PDI
	PW
	CW
	Dual synchronous

### 10.2 The work mode exchange

Button	Select and exchange operation
B,B+B,4B	<ul style="list-style-type: none"> <li>·In B mode, press [  Dual ] key , and press [ Update ] key to enter the B+B mode;</li> <li>·In B mode, press [  Quad ] key , and press [ Update ] key to enter the 4B mode;</li> <li>·Rotate [ Gain ] knob to adjust the imaging gain.</li> </ul>
B+M	<ul style="list-style-type: none"> <li>·Press M key to enter B+M mode;</li> <li>·Rotate [ Gain ] knob to adjust the B+M mode imaging gain.</li> </ul>
Color	<ul style="list-style-type: none"> <li>·Press key enter CFM mode;</li> <li>·Rotate [ Gain ] knob to adjust the CFM mode imaging gain.</li> <li>·Press and Rotate [ Gain ] knob again to change B gain</li> </ul>
PDI	<ul style="list-style-type: none"> <li>·Press key enter PDI mode</li> <li>·Rotate [ Gain ] knob to adjust the PDI mode imaging gain.</li> <li>· Press and Rotate [ Gain ] knob again to change B gain</li> </ul>
PW	<ul style="list-style-type: none"> <li>·Press key enter PW mode</li> <li>·Rotate [ Gain ] knob to adjust the PW mode imaging gain.</li> <li>·Press and Rotate [ Gain ] knob again to change B gain</li> </ul>

### 10.3 Imaging parameters adjust

Image parameters adjustment mainly through image menu and control panel to control and realize.

◆ **The main steps of imaging menu adjustment**

- 1、 press **【Menu】** knob, show menu vertically, press **【Menu】** knob to select and rotate the **【Menu】** knob adjust value in the menu
- 2、 press **【Esc】** key, vertical menu will hide.

◆ **The main steps of the control panel operation:**

- 1、 The 6 **【Shortcut knob】** are adjusted according to the parameter values displayed at the bottom of the screen.


### 10.3.1B mode

◆ **B mode image display adjust**

For B mode, it is the adjustment of the 2D image. It can adjust the depth, pseudo color, frequency, focus, invert b/w, mirror, gray map, edge enhancement, gamma correction, brightness, imaging gain and so on.

✓ **Display depth**

Press   **【Depth】** key on the control panel can change the depth of image.

Press  key increase the depth.

Press  key decrease the depth.

For the different probe, the imaging adjustable depth range will be also different.

✓ **Imaging Pseudo Color**

Press **【Menu】** button to select "Pseudo Color" in the main menu display, then rotate **【Menu】** button to select the pseudo color.

This system has over than 10 kinds of built-in pseudo color code. When choosing different pseudo color code, the corresponding pseudo color code will be displayed on the image gray.

Pseudo color code 0 is always B/W gray level. If the user wants to cancel pseudo color, please change the "Pseudo color" to 0, which means back to 256 B/W gray scale.

✓ **ITHI**

Harmonic can be turned on or turn off by rotating the corresponding knob to adjust.

✓ **Working Frequency**

Select one of the 6 **【Shortcut knob】** on the control panel correspond the **【Frequency】** to change the working frequency.

✓ **Focus Point**

Select one of the 6 **【Shortcut knob】** on the control panel correspond the **【Focus】** to change the location of focus point of image.

**Remark:** When the system is working in CFM or PDI mode, the position of focus point will at the central of ROI automatically. At the same time, the user can also adjust it according to need. When CFM ROI moves, the focus point will follow automatically.

✓ **Invert b/w**

Press **【Menu】** key, then press direction key to select and adjust value of "Invert b/w".

The menu contains On and Off.

If the user selects the "pseudo color", its code could be displayed inversely as well. Correspondingly, pseudo color or grayscale images, pseudo color code or black and white grayscale bars will be updated and displayed simultaneously.

✓ **Mirror**

Press **【Menu】** key, then press direction key to select and adjust value of "Mirror" to left/right reverse the imaging.

The menu contains On and Off.

The user can identify the direction of the imaging according the direction mark "●" on the top of the imaging. In the default, the direction mark "●" is in the upper left corner.

#### ◆ **B mode image optimize adjust**

Imaging optimization parameter adjustment will affect the quality of the image. The user can adjust them according to the real need of the patient analysis.

##### ✓ **Gain**

On the control panel, press **【Gain】** and rotate to adjust the 2D imaging gain and doppler imaging gain. The bigger of the value, the higher of the gain. And the brightness will increase.

##### ✓ **TGC**

Compensating attenuation caused by increasing the tissue depth, it need adjust depth again by segmented form. By controlling the eight segments TGC controller on the control panel to adjust, corresponding to the depth of the corresponding segmented images. Pull the TGC controller to right side to increase the gain and brighter image, and pull the TGC controller moves to left side to reduce the gain and darker image.

By adjusting TGC within a certain depth range, the user can make the image optimization.

##### ✓ **Dynamic Range**

Select one of the 6 **【Shortcut knob】** on the control panel correspond the **【Dynamic Range】** to adjust the required dynamic range

Adjusting the dynamic range, viewed from sense, is adjusting the contrast intensity of images; from the working principle, is the fact that the selected grayscale curve condenses and expands the sampling hardware data to correspondingly displayable grey range.

##### ✓ **Frame average**

Select one of the 6 **【Shortcut knob】** on the control panel correspond the **【Frame average】** to change the value of frame average.

The frame average refers to the fact that adjacent B images are weighted average to eliminate the images' noise and save more tissue information for clearer and softer images displayed.

The higher the value is, the more obvious the average effect will be; the lower the value is, the more information of original unprocessed image will be saved.

##### ✓ **Gray map**

Select one of the 6 **【Shortcut knob】** on the control panel correspond the **【Gray map】** to change the gray scale curve.

The system has some built-in gray scale curve, to meet the needs of different inspection item and application.

Using the different gray scale curve, the image quality will be changed a lot.

##### ✓ **Edge enhancement**

Press **【Menu】** key, then press direction key to select and adjust value of "Edge".

##### ✓ **Gamma Correction**

Press **【Menu】** key, then press direction key to select and adjust value of "Gamma Corr".

##### ✓ **Image enhancement**

Press **【Menu】** key, then press direction key to select and adjust value of "IPE".

##### ✓ **Angle**

Press **【Angle】** key then rotate **【Value】** knob to adjust the value.

##### ✓ **Biopsy line**

Press **【Preset】** → Application → Biopsy line → select the biopsy line to be on, then store the data, and select the probe again, the ultrasound imaging interface will display this parameter. Press **【Biopsy】** button to set the biopsy line to be on or off.

When the biopsy line is on, use the **【F】 【G】 【V】 【B】** to move and rotate the biopsy line.

### 10.3.2 M mode

#### ◆ **M mode operation**

Press **【M】** button enter into B+M mode, move the sample line, and adjust it to the suitable position.

#### ◆ **M mode image optimization**

The parameter function and adjustment in M mode is similar with B mode. Please refer to B mode image optimization.

◆ **M mode performance indicator**

M mode performance indicator of each probe, the item display error is not above 10%.

### 10.3.3 CFM Mode

CFM mode is used to observe the color blood flow information, and can be judged the blood flow direction and speed according to the color. Generally, the color up the color baseline means the blood flow which flow to the probe, the color below the color baseline means the blood flow which back to the probe. The closer to the color bar top, the faster the blood flow velocity; The closer to the color baseline, the slower the blood flow speed.

◆ **CFM mode operation**

Press **【CFM】** button enter into CFM mode.

✓ **ROI position**

By default, move the tracking ball, it can adjust the ROI position.

✓ **ROI size**

Press **【Set】** button, a small square will be displayed on the ROI lower right corner, and then move the tracking ball, it can adjust the size of the ROI. Then press **【Set】** again, exit the sample frame size adjustment.

◆ **CFM mode image optimization**

✓ **Color gain**

When enter into CFM mode, press and rotate **【Gain】** button to adjust the color gain.

✓ **Speed scale**

Select one of the 6 **【Shortcut knob】** on the control panel correspond the **【Scale】** to change the CFM speed scale value.

✓ **Samples**

Press **【Menu】** key, then press direction key to select and adjust value of “samples” .

✓ **Color light**

Press **【Menu】** key, then press direction key to select and adjust value of “color light” .

✓ **Color threshold**

Press **【Menu】** key, then press direction key to select and adjust value of “color threshold” .

✓ **Color balance**

Press **【Menu】** key, then press direction key to select and adjust value of “color balance” .

✓ **Pseudo differential restrain**

Press **【Menu】** key, then press direction key to select and adjust value of “Pseudo differential restrain” .

✓ **Steer**

Please note: this adjustment is only applicable to linear probe.

Select one of the 6 **【Shortcut knob】** on the control panel correspond the **【Steer】** to change the scan angle of linear probe.

✓ **Color focus point position**

By default, the color focus point position is in the vertical center position of ROI automatically. If need adjustment, please refer to the B mode focus point adjustment methods.

### 10.3.4 PDI mode

PDI mode is used to explain the speed and density of red blood cell in blood flow in a certain time, identify them in different brightness color, not include the blood flow direction. The imaging parameter adjustment of PDI mode is same as CFM model, please refer to CFM mode.

### 10.3.5 PW mode(CW operation is similar to PW )

PW (Pulse doppler) mode is used to research information of blood flow move according a scan line in a certain area. The horizontal axis of PW spectrum diagram displays the time, and the longitudinal axis displays the doppler shift. Given the angle of voice and blood flow, the speed and the rate of flow of blood flow can be calculated by the doppler shift range, and laminar or turbulent flow information in blood flow also can be judged.

◆ **PW mode operation**

Press **【PW】** button enter into PW mode, and set PW sample volume and blood flow direction correction angle.

✓ **PW baseline**

Select one of the 6 **【Shortcut knob】** on the control panel correspond the **【Base line】** to change the PW baseline position.

✓ **PW sample volume**

Select one of the 6 **【Shortcut knob】** on the control panel correspond the **【Sample volume】** to change the sample volume.

✓ **PW blood flow direction correction**

Press **【Angle】** button then rotate **【Value】** knob on the control panel to change the blood flow direction correction angle.

◆ **PW mode imaging optimization**

✓ **PW gain**

Rotate **【Gain】** on the control panel to adjust the PW gain value.

✓ **Scanning Speed**

Select one of the 6 **【Shortcut knob】** on the control panel correspond the **【Scanning Speed】** to change the suitable value.

✓ **Noise Restrain**

Select one of the 6 **【Shortcut knob】** on the control panel correspond the **【Noise Restrain】** to change the suitable value.

✓ **Filter**

Select one of the 6 **【Shortcut knob】** on the control panel correspond the **【Filter】** to change the suitable value.

✓ **PRF**

Select one of the 6 **【Shortcut knob】** on the control panel correspond the **【Scale】** to change the PRF value.

✓ **Auto Envelope**


With auto enveloping function of static and real-time spectrums

Auto enveloping of static spectrum: Under triplex modes, when the image is frozen, select the switch by 『static envelope』 on the transverse image parameter menu.

Auto enveloping of real-time spectrum: Under triplex modes, select the switch by 『auto envelope』 on the vertical image parameter menu or by directly clicking the 『Auto Calculate』 on touch screen.

✓ **PW or CW volume**

Press  Key to increase PW or CW volume.

Press  Key to decrease PW or CW volume..

✓ **Pseudo color**

PW or CW pseudo color, please refer to B mode.

### 10.3.6 3D Software Operation (Optional)

#### Scan and Run

**Step 1:** Under the main UI of the ultrasound imaging system, press the function key of 3D imaging on the control board, there will be a rectangle for ROI selecting.

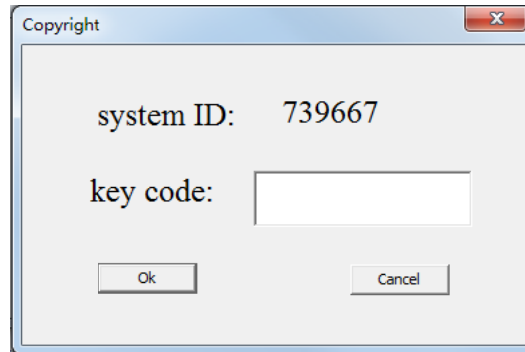
**Step 2:** Set the ROI selecting rectangle at the right place in proper size.

**Step 3:** Press the key of Update, scan of 3D imaging start, the ultrasound probe must be moved in a line in constant speed. When the acquired frame count which is set previously by the system is reached, the 3D imaging module will be run.

**Notice:** During the scanning period, the probe should be moved in a line in constant speed as far as possible. Any rotation or translation will affect the result theoretically. The scan speed has an optimum value, which is the ratio of the side length of the pixel square to the frame rate of the US imaging equipment in use. If scan too fast, the 3D result image seems being compressed in scan direction. On the contrary, it will be looked like being stretched.

**Software register**

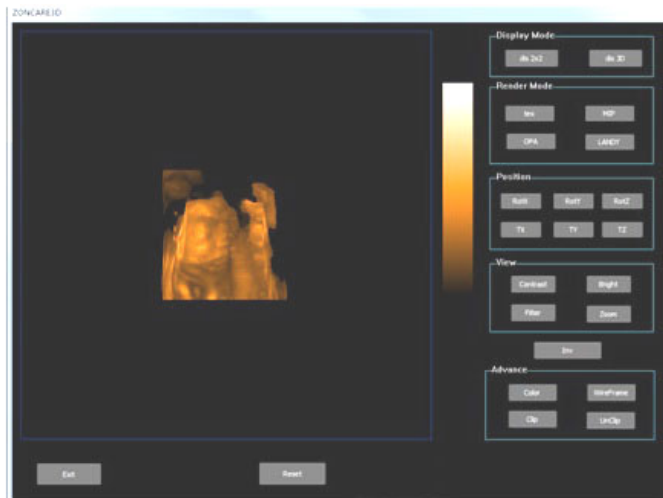
**Step 1:** When the software is the first time running or is not authorized, a dialog for requesting register code will appear. In the dialog, the systemID number is the machine ID, in the example below, the machine ID is 739667.



**Step 2:** Send the machine ID to the after sales service personnel, you will get the register code very soon.

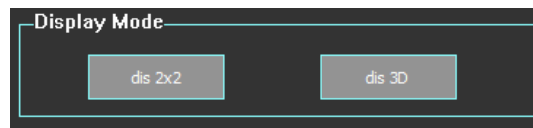
**Step 3:** Enter the register code, press OK button, and complete the registration.

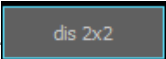
**1. Main UI**

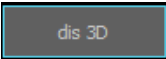


**4. Function of the buttons**

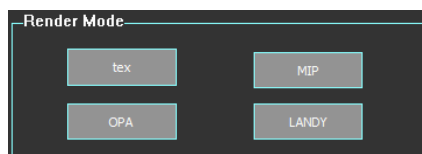
**4.1 Display Mode**

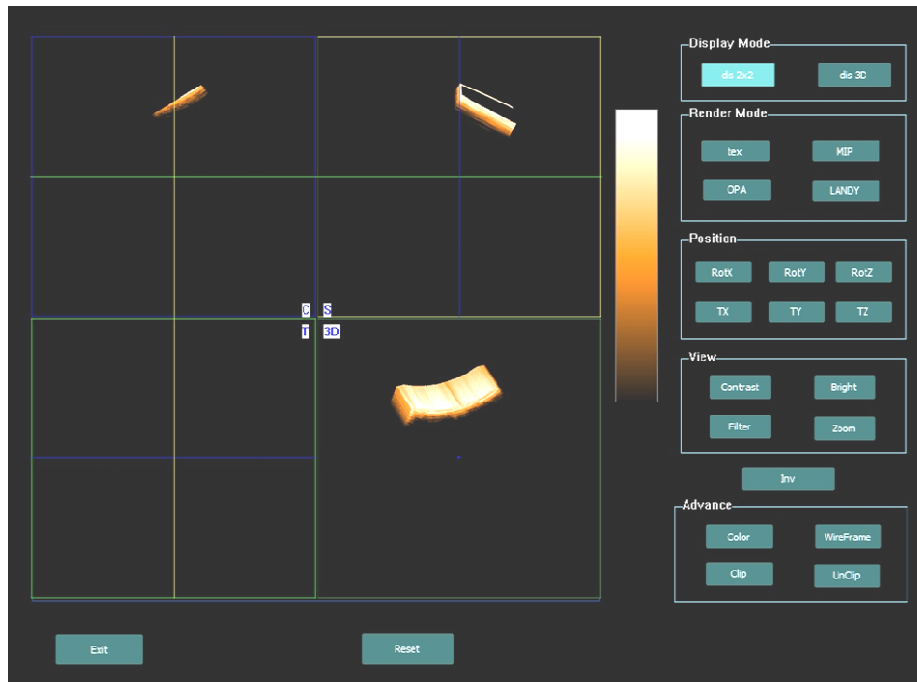


1) dis 2x2:  Display the coronal, sagittal, transverse plane at the current point and 3D image simultaneously in the current field of view. The l (left) ,r (right) ,u (up) ,d (down) , i (in) ,o (out) key can control the current point position. The default point is the center of the 3D image.

2) dis 3D: , only display the rendered 3D image.

**2,Render Mode**





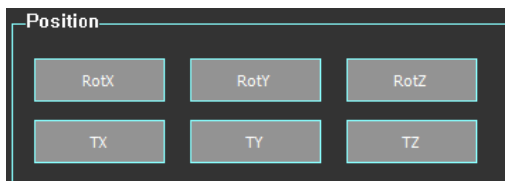
1) tex: tex, display the geometry surface of the 3D field. It is the fastest render mode. It is always used to display the section image.

2) MIP: MIP, the Max Intensity Projection render method, it is used to display the strong intensity target, for example, the contrast-enhanced ultrasound imaging.

3) OPA: OPA, the opacity mixed images render method, like ray casting method. It is used to display the whole object looks like.

4) LANDY: LANDY. It is the special render method of this software, and it can have a more attractive picture.

### 3,Position



1) RotX: RotX, rotate around x axis, the rotation direction is related to the Inv button.

2) RotY: RotY, rotate around y axis, the rotation direction is related to the Inv button.

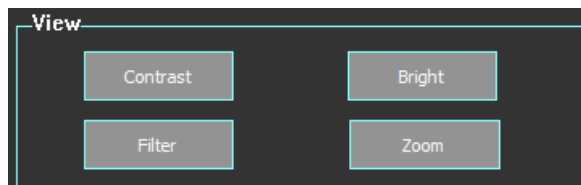
3) RotZ: RotZ, rotate around z axis, the rotation direction is related to the Inv button.

4) Tx: TX, translate along x axis, the translation direction is related to the Inv button.


5) Ty: TY, translate along y axis, the translation direction is related to the Inv button.

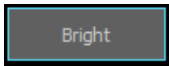
6) Tz: TZ, translate along z axis, the translation direction is related to the Inv button.

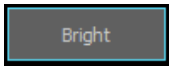
### 4,View

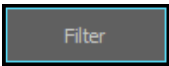


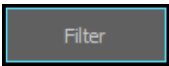


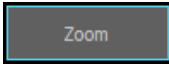
1) Contrast: , adjust the image contrast. Push the button will increase or decrease the contrast, the change direction is related to the Inv button.

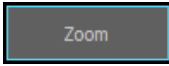


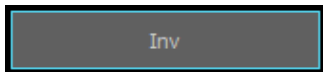
2) Bright: , adjust the image brightness. Push the button will increase or decrease the brightness, the change direction is related to the Inv button.



3) Filter: , adjust the filter threshold. Push the button will increase or decrease the threshold value, the change direction is related to the Inv button.



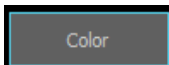
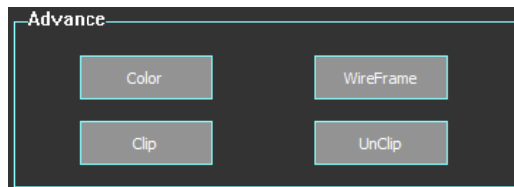
4) Zoom: , adjust the image zoom scale. Push the button will zoom in or zoom out the image, the zoom direction is related to the Inv button.



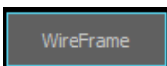
5,Inv:

Push the button every time, the RotX, RotY, RoyZ, Tx, Ty, Tz, Contrast, Bright, Filter, Zoom function adjust direction will be reversed simultaneously.

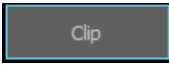
## 6,Advance

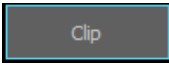


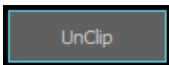
1) Color: , selecting the pseudo color by the custom.

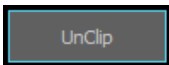


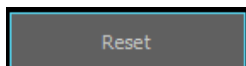
2) WireFrame: , show/hide polyhedron edges reuse function button.



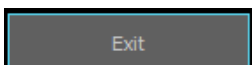
3) Clip: . Simulate the scalpel clip the object surface, press the mouse left button to select two points, one side of the line will be clipped. The two points must be in the polyhedron.



4) UNClip: . Undo the last clip.



7. Reset .Reset to the default field of view.





8. Exit:  Exit the 3D imaging module.

## 9. Keyboard

Press up, down, left, right key can select different process method to improve rendered image result. But it will slow the render procedure down. To cancel the process procedure, press Esc key,

## 10. Mouse control

10.1 When the mouse cursor is out of the polyhedron, the cursor will be changed to . Pressing down the left button(do not release), then moving the mouse, it will rotate the 3D image.

10.2 When the mouse cursor is out of the polyhedron, the cursor will be changed to . Pressing down the left button(do not release), then moving the mouse, it will push/drag the current plane in/out the polyhedron.

10.3 Under the display mode 2x2, the mouse left button double clicked on any of the four image, the image will be displayed in the whole view port. The mouse right button clicked, it will be back to the previously 2x2 display mode.

## 11. Save image

Press the 【Save img】 key to save the image to the current patient, Press the 【Review】 key to review.

### 10.3.7 4D Software Introduction

This 3D/4D software includes functions such as 3D volume probe control, 3D data acquisition, 3D data reconstruction and post-processing.

The 3D/4D system mainly includes 3D probe control module, 3D image reconstruction module and 3D display module.

#### 2. Entering 4D software

- 1) Connect the volume probe;
- 2) Turn on ultrasound system;
- 3) Select 4D volume probe 3D2-5L and obstetrics application to enter B mode;
- 4) Orientate the probe to make the fetal head on the left part of image; adjust imaging parameters to optimize the image; adjust Depth (recommendation:  $\leq 140$ ) and Dynamic Range (recommendation: 160) according to the fetal face and the contrast of amniotic fluid;
- 4) In real-time B mode, press 4D button (Figure 2.1) to enter ROI selection interface (Figure 2.2);



Figure 2.1 4D Button

#### 3. Exit 4D mode

- 1) Press 4D button again.
- 2) Selecting B mode, M mode, CFM mode or PW mode by pressing B, M, CFM or PW button.

#### 4. 4D Operation

##### 4.1 ROI settings

ROI interface appears after the 4D button is pressed (Figure 2.2); use the trackball to move the yellow ROI window, press 【Set】 and roll the trackball to adjust the size of ROI window, and then press 【Set】 again to confirm. Roll the trackball to move ROI window.

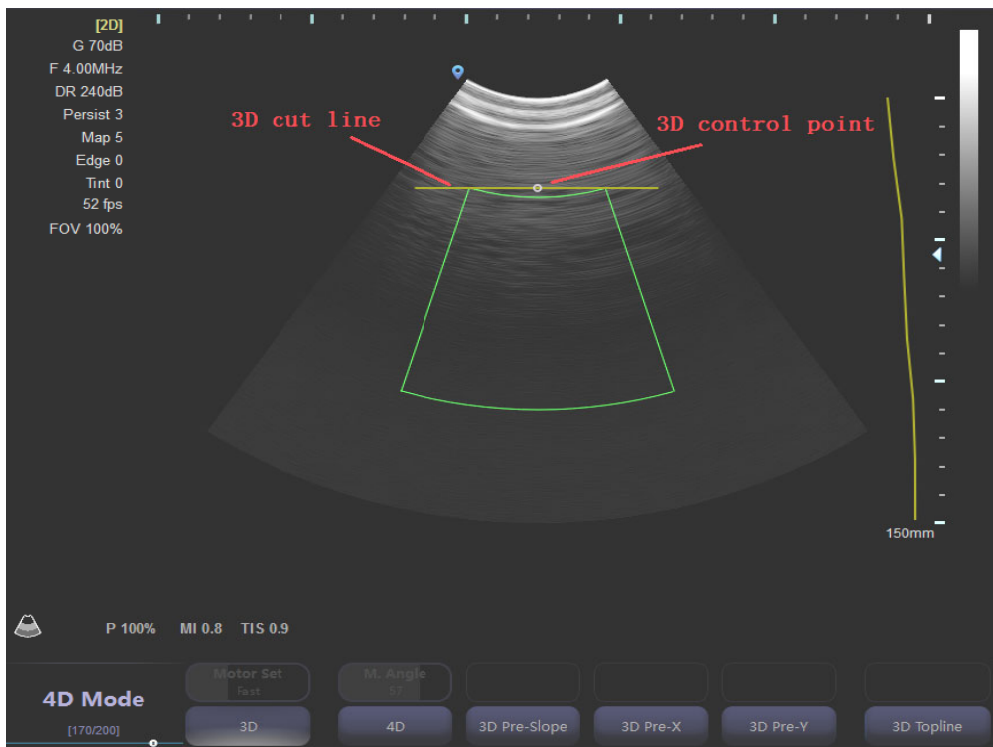


Figure 2.2 ROI Interface

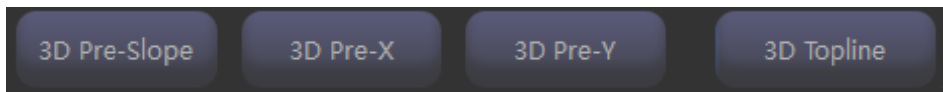
Adjust ROI cut line: Rotate Option Knob 3-6

3D Pre-Slope: Change the slope of 3D cut line.

3D Topline: Move the 3D cut line vertically.

3D Pre-X: Move the 3D control point horizontally.

3D Pre-Y: Move the 3D control point vertically.



(1) Switch 3D/4D: Rotate Option Knob 1 or 2 to switch 3D or 4D mode.



(2) Adjust Motor scan speed and 3D scan angle: Press Option Knob 1 or 2 then rotate.

Motor Set: select a scan speed Fast, Normal or Fine. Default speed is Normal.

M.Angle: select a 3D scan angle. Default angle is 66 degree.



## 4.2 4D Screens

### 4.2.1 On-screen Option List 1

(1) Start 4D Scan: Press **【Update】** button to Start 3D/4D scanning. real-time images of different dimension sand 4D image are shown in Figure 4.2.1

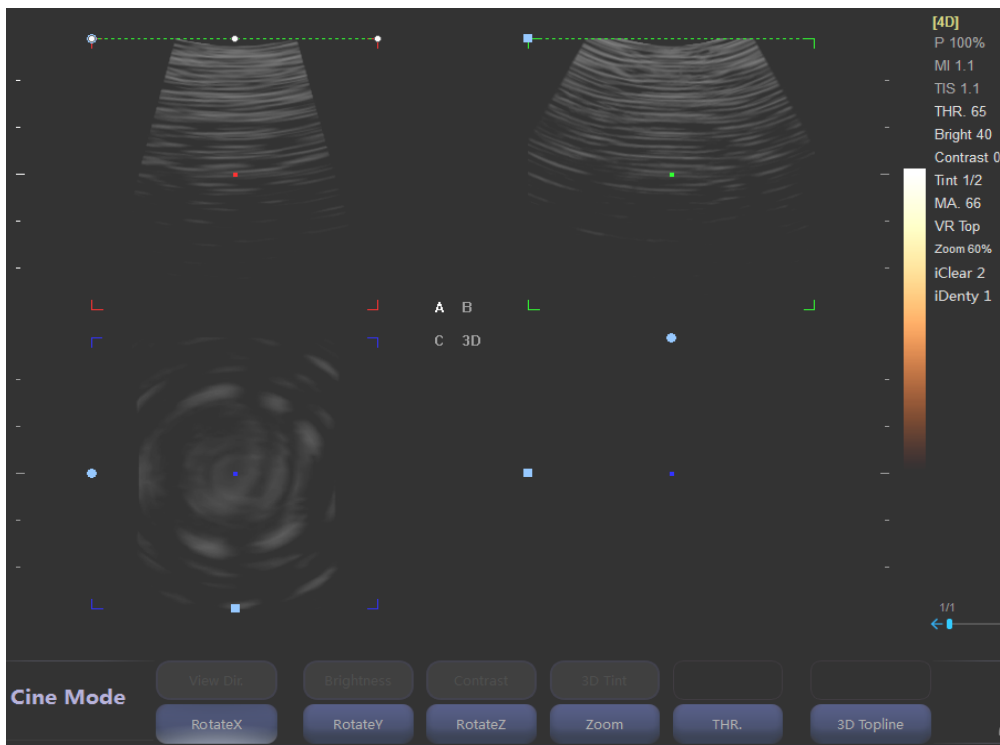


Figure 4.2.1 Real-time 4D Scanning Interface

Press **【Freeze】** button to stop 4D scanning.

(2) Rotate Option Knob 1-6

RotateX: 3D image rotate along the X axis.

RotateY: 3D image rotate along the Y axis.

RotateZ: 3D image rotate along the Z axis.

Zoom: Zoom the 3D image.

THR.: Adjust threshold of 3D image.

3DToplin: Adjust the topline of 3D image.



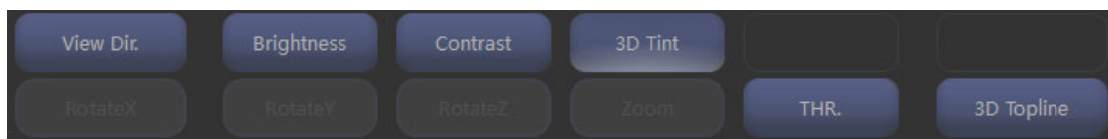
(3) Press Option Knob 1-4 then rotate

View Dir.: Adjust the direction of viewing of 3D image.

Brightness: Adjust the brightness of 3D image.

Contrast: Adjust the contrast of 3D image.

3D Tint: Adjust the tint of 3D image.



#### 4.2.2 On-screen Option List 2

Press knob **【Menu】** and 4D menu are shown in Figure 4.2.2

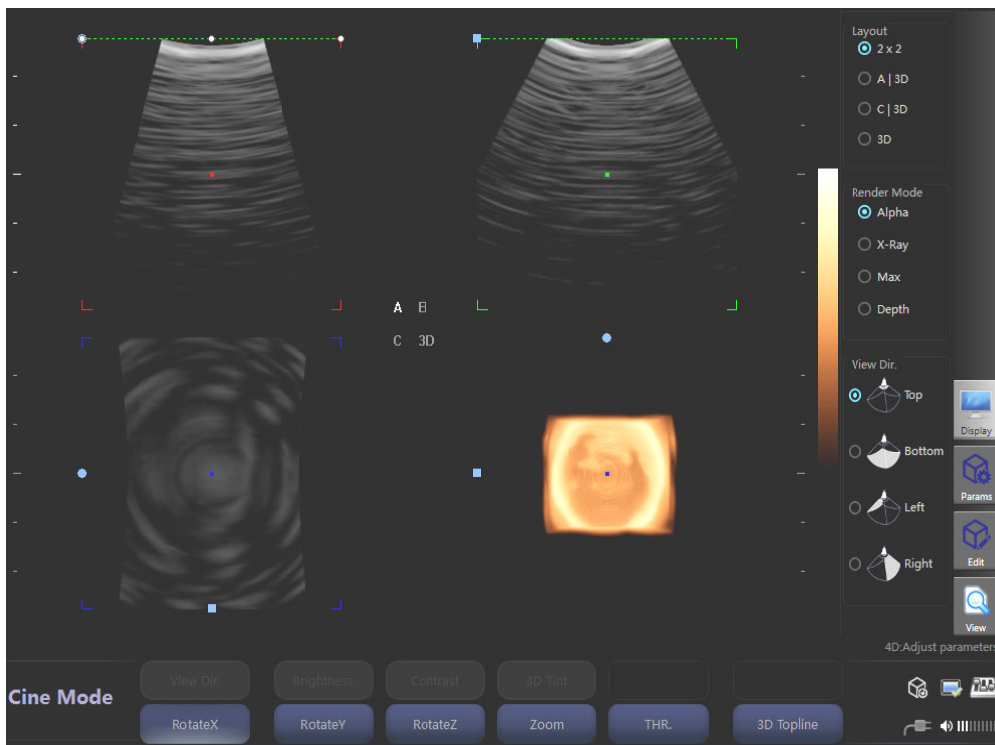
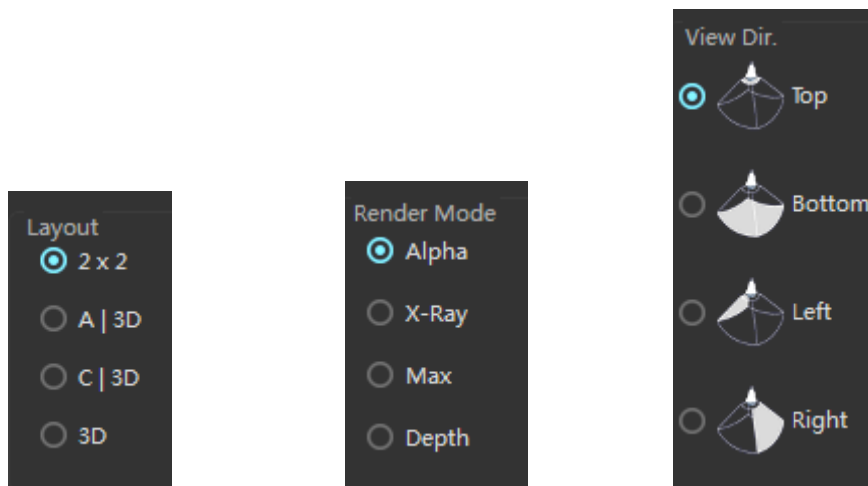


Figure 4.2.2 4D menu Interface

#### 4.2.2.1 Display

(1) Layout: To adjust the layout of the screen (2X2, A|3D,C|3D,3D) by move trackball and pushing **【Set】** button. Quad is the default;

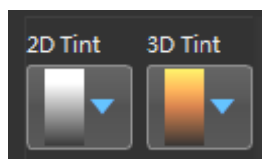


(2) Render Mode: Change the Render mode of the image; there are four render modes, Alpha, X-Ray, Max, Depth.

(3) Direction: Change the direction of the image; there are four directions, Left, Right, Top and Bottom.

#### 4.2.2.2 Params

(1) move trackball and pushing **【Set】** button to select 2D tint and 3D Tint



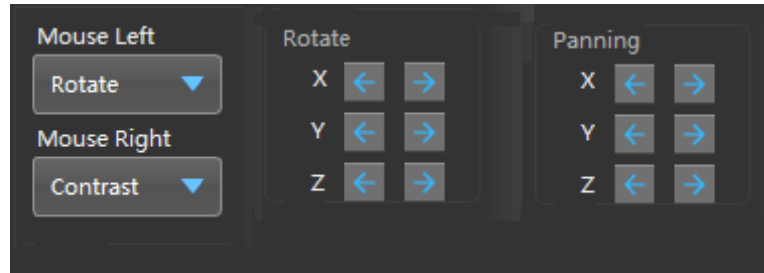
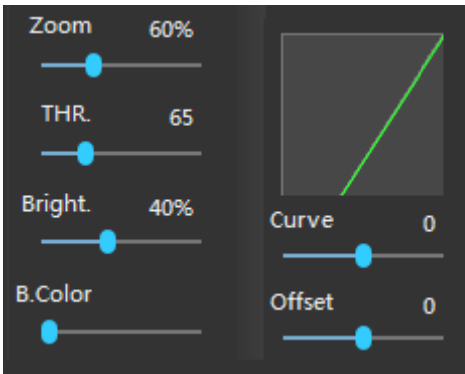
(2) Use the trackball and **【Set】** button to drag the blue point to change the parameter of 3D image.  
Zoom: Zoom in or out 3D image.

THR.:Adjust threshold of 3D image.

Bright.: Adjust the brightness of 3D image.

B.Color: Adjust the background color of 3D image

Curve and Offset: These are compound parameters. Curve and Offset both effect the contrast of 3D image. Change it carefully,inappropriate value will make the quality of 3D image worse.



#### 4.2.2.3 Edit

- (1) Mouse Left and Mouse Right: Redefine **【Set】** button and **【Back】** button.
- (2) Rotate: Rotate 3D image along X/Y/Z axis.
- (3) Panning: Move 3D image along X/Y/Z axis.

### 5. Recommended Operation Skill

To get a better image, it is recommended to scan the patient as shown in Figure 5.1.

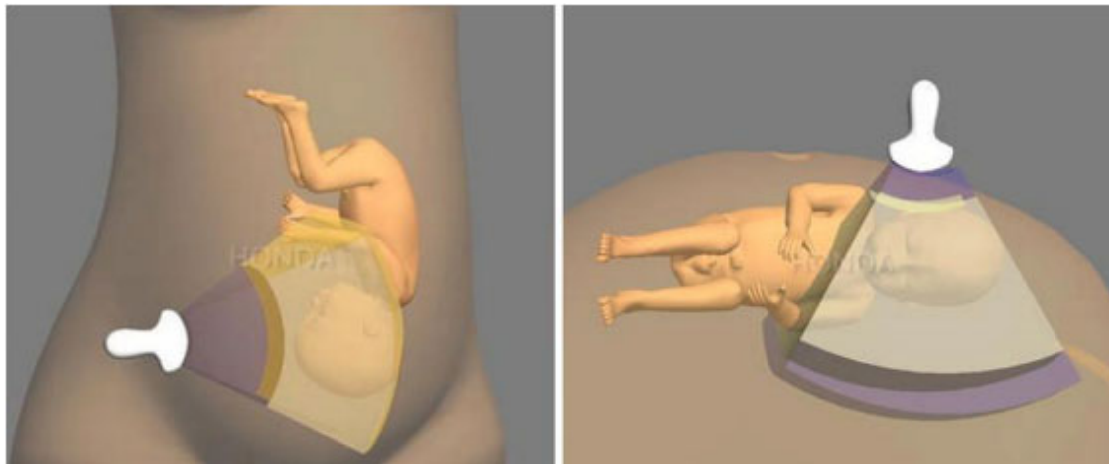


Figure 5.1 Scanning Method

# Chapter 11 Measurement and Calculation



## Notices:

- 1、 During the measurement, in the inspection mode or switch the probe, all the measurements and marks in the image will be cleared.
- 2、 During the measurement, closed system, or "new patient", all unsaved data will be lost.
- 3、 When make the doppler blood flow measurement, please don't let the probe direction and the flow direction in the vertical, otherwise will not be able to get the correct blood information and affect the diagnosis.

## 11.1 Basic Operation

### 11.1.1 entry/exit measurement

Under the image freeze mode , on the control panel, Press **【Measure】** key, the **【Measure】** key light is on, On the right side of the screen "menu adjust area" display the regular menu and application measurement menu, enter to the measurement state, it will display the measurement cross cursor on the image . Press **【Measure】** again, light is off, exit the measurement state.

### 11.1.2 Begin to measurement

#### ◆ The basic measurement except the ellipse

Move the trackball , Press **【Set】** key, put the measuring cursor to the starting point, move the cursor, pull out of measuring line, at the same time, the measured results will show in measurement area . press **【 Set】** key again, Position to the end of the measuring line, the measurement is finished .

#### ◆ The ellipse measurement

Move the trackball, press **【Set】** key, put the measuring cursor to the ellipse first axis measurement starting point, move the cursor, pull out of the ellipse first axis measuring line, at the same time, the measured results will show in measurement area. at this time, if press **【 Back】** key, it can switch the ellipse first axis starting point , find the end point of the ellipse first axis , press **【Set】** key, finish the ellipse first axis measurement .

After select the first axis of ellipse, continue to move the trackball, start selecting elliptic second axis , axis length will be the location of the first axis as the center, automatic display. Select the appropriate elliptic position, press **【Set】** key on the third time. End of the ellipse measurement.

### 11.1.3 Delete measurement

#### ◆ Delete one by one

When the end of the measurement , press **【Back】** key, will delete recent measuring results and measuring reference line in turn.

#### ◆ Delete all

Press **【Clean】** key, Remove all of the measurement result/data, text annotations, and the arrow mark.

### 11.1.4 Measurement result display

Measured results in measurement results area real-time display and update the result.

The measured results show in "parameters and measurement display area" of the lower left corner.

## 11.2 Normal Measurement

### 11.2.1 Normal measurement in B mode

In the B mode, the normal measurement as below:

Measurement Item	Function
Distance	Measure the distance between two points.
Area	Measuring the area of the closed area (ellipse method, the trace method)
Circumference	Measuring the circumference of the closed area(ellipse method, the trace method)
Volume	Measure the volume of a target object (ellipse method, the trace method , BI-plan method)
Ratio	Any length or area between two line segments, and calculate the ratio of length or area .
Angle	Measuring the Angle between the two intersecting plane

### 11.2.2 Normal measurement in M mode

In M mode,the normal measurement as below:

Measurement item	Function
Distance	measure the vertical distance between two points
Heart Rate	On M image, to obtain images of the heartbeat, measure the time interval between 1 ~ 2 heartbeat cycle, calculate the heartbeat per minute
Time	Measure the time interval between any two points
Slope	By measuring the distance between two points and to calculate average speed between two points ( means the slope)

### 11.2.3 Normal measurement in PW mode

In PW mode,the normal measurement as below:

Measurement	Function
Time	Measure the time interval between any two points
Heart Rate	measure the time interval between 1 ~ 2 heartbeat cycle, calculate the heartbeat per minute
Speed	Measure the speed of a point on the doppler spectrum waveform and pressure difference
Acceleration	Measure the speed between two points and the time interval , computing speed difference and acceleration
Resistive Index	In waveform of PW spectrum image of blood flow, measure speed and pressure difference of the two peaks, calculate the resistance index and ratio value
Pulsation index	Arterial blood systolic peak (A or S) and valley value of end-diastolic (B or D), to calculate the S/D or A/B ratio, at the same time can also be calculated pulsation index (PI = A - B/mean value A, B)
Maximum differential pressure	The average pressure difference of maximum velocity wave spectrum

The average differential pressure	The average of the pressure gradient in the all recording area
-----------------------------------	--

#### 11.2.4 Normal measurement in CFM/PDI mode

In CFM/PDI mode, the normal measurement as below:

Measurement item	Function
Distance	Measure the distance between two points.
Circumference	Measuring the circumference of the closed area (ellipse method, the trace method)
Area	Measuring the area of the closed area (ellipse method, the trace method)
Volume	Measure the volume of a target object (ellipse method, the trace method, BI-plan method)
Ratio	Any length or area between two line segments, and calculate the ratio of length or area.
Angle	Measuring the Angle between the two intersecting plane

#### 11.3 Application measurement

##### 11.3.1 Gynecologic application measurement

The gynecologic measuring use for the measuring Uterine, Ovary and advantages of follicle such as gynecologic parameters

Measuring Item	Contents
Uterine measuring	measuring item is : ·Uterine ·Cervix ·The Endometrium
Ovary volume measuring	Measurements include the left ovary volume measurement and right ovary volume measurement
advantage Ovary measuring	Left advantage ovary measuring and right advantage ovary measuring

##### 11.3.2 Obstetric application measurement

Obstetric applications measurements are used to calculate gestational age (GA) and estimated due date (EDD), By measuring the fetal development indicators, including fetal weight, and fetal growth curve, Fetal Physiology score to see if the fetal development is normal.

Measuring Items	Contents
Fetal measuring item	Measure fetal parameter ( such as the GS, CR, BPD, HC )
Fetal calculating item	calculate the gestational age and fetal weight
AFI	measure depth of the amniotic fluid to calculate the AFI

EFW	Through fetal growth parameters to estimate the fetal weight
Fetal Physiology score	Through quite a long period of observation based on the ultrasound images of the fetal, according to the fetal growth parameters which is through testing or measurement, by certain standards of grading speculate the fetal status by certain grading standards, make as a clinical reference index.

### 11.3.3 Superficial organs application measurement

Superficial organs application measurement is mainly used for thyroid parameter measurement and calculation

Measuring Items	Contents
Thyroid Volume	measurement includes left and right side of thyroid volume
Breast	Measurements include the left and right sides of the glandular thickness measurement and upper catheter of the left and right nipple measurement

### 11.3.4 IMT Measurement

In freeze states. Press the left or right button corresponding to IMT item in the bottom menu. There will display a green sampling box. The size of the sampling box can be changed with the mouse and **【Set】** key. When the sampling box is yellow, the sampling box is in the state of adjusting size. After selecting the vascular media by moving the mouse pointer in the sampling box, press **【Back】** key, and the measurement results will be displayed on the right side of the screen automatically.

Measuring item	Content
IMT	IMT is automatic measurement and analysis of vascular intima.

### 11.3.5 Other measurement

Other measurements include parameters such as the hip angle measurement

Measuring item	Content
Hip angle	By drawing the baseline, bones top of line, cartilage top of the line to calculate the hip angle, then can estimate bone dislocation type.

## Chapter 12 System Setup

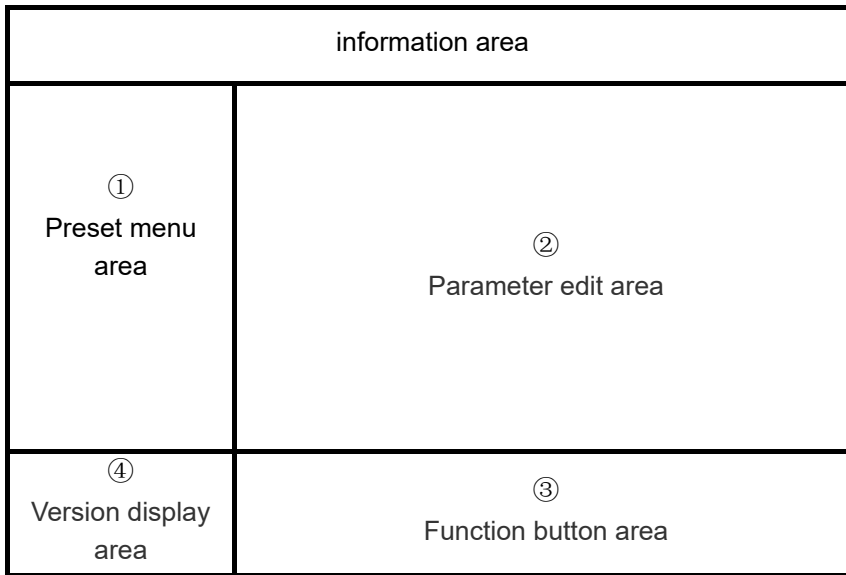
Preset function is used to operating environment of system, status and configuration parameters of each application. Preset parameter is stored in memory of system, parameters are not lost when shutdown and power off. It can ensure when the power is running, automatically load and run preset parameter, which is user desired.



Note: after edit and amend preset parameter, data must be saved, user can see the following. The manufacturer is not liable for the loss of the preset data.

## 12.1 Default working interface

Working interface of edit and print reports as following:



Information area displays information of hospital name, current date, time and so on.

### 1、Preset menu area

Preset menu area shows preset function item of the system parameter, users need to select menu. User can see the following

### 2、Parameter edit area

In default status, if user exit edit interface, parameter edit area will be remained blank. After selecting the corresponding parameter menu, Parameter edit area will display the corresponding edit item. According to the actual situation, user can adjust and modify parameter. User can see the following

### 3、Function button area

In parameter edit area there is no content can be edited, only "Exit" button to display. When parameter editing, button area will display "Set", "Cancel", "Apply". As usual, parameter editing interface corresponding buttons are the same.

- "Set": save the parameters and exit the parameter editing interface;
- "Cancel": do not save, exit editing interface;
- "Apply": Save parameters, do not exit the parameter editing interface.

### 4、Version display area

Version display area displays version number and date of current using software.

## 12.2Entry / Exit Preset

In the ultrasound working interface, press the 【Preset】 to enter the parameter presetting interface.

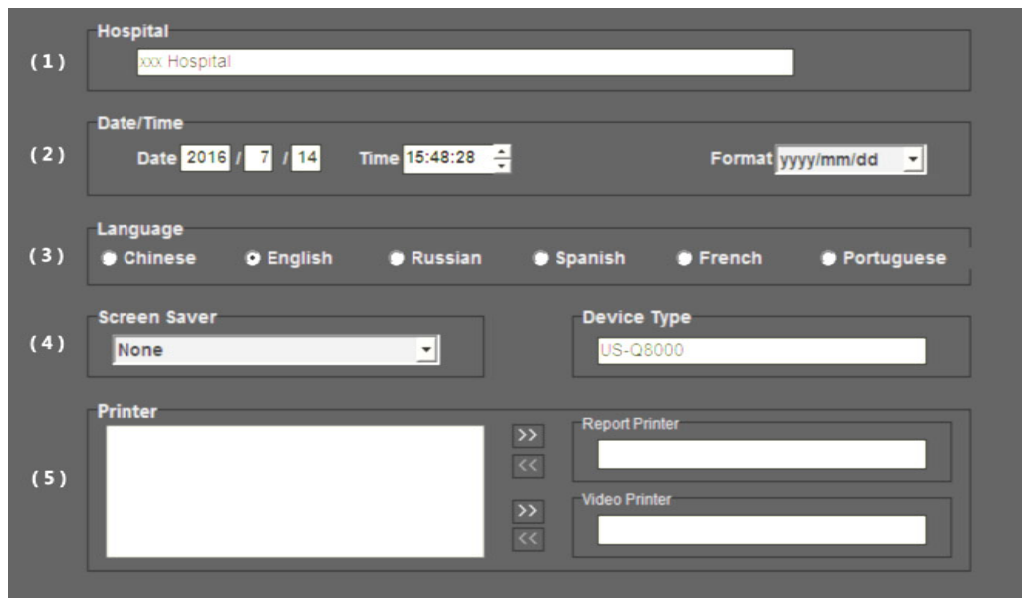
In the presetting parameters interface, move the trackball to the "Exit" and press 【Set】 to exit the parameter presetting interface, and then return to the ultrasound working interface.

## 12.3System parameters preset

System parameters preset including set and modify the parameters of operational status and environment.

### 12.3.1Basic parameters

Select the menu item "General", in parameter edit area will display interface of basic parameters. As follows, button immediately updated.



- 1、 Hospital name: set the hospital name, which is displayed in the information area
- 2、 Date/Time: edit and modify date/time, click the “Format” drop-down box to modify the date format.
- 3、 Language: in the system working interface set language.
- 4、 Screen Saver: Setting the start time of screen saver, “None” indicates enable screen saver.
- 5、 Printer setup: Click”Set Printer”and the printer setup interface pops up

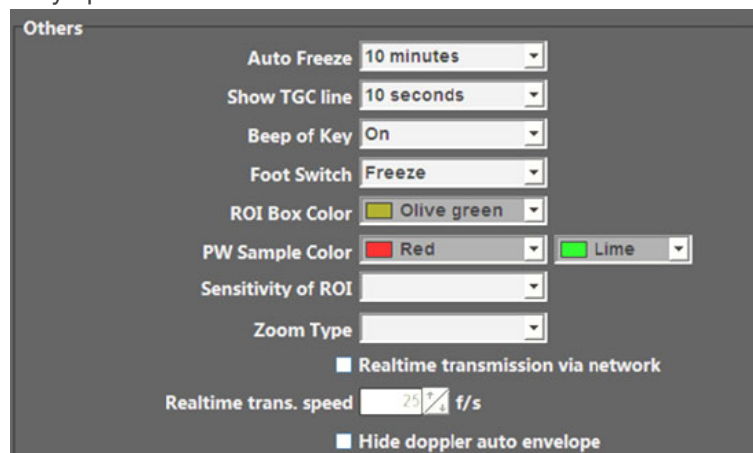
After editing and amending one group of presetting values of parameters, press “set” or “apply” for storing data

Press “cancel” for exiting the edition of parameters

Press “exit” for exiting the parameter presetting, come back to the main picture of ultrasound

### 12.3.2 System Setup – Device presetting

Select the menu "General → Device", in the parameter editing area will display interface of the device. As follows, button immediately updated.



- 1、 Setting parameters related to the system
  - ☑ Auto freeze: Set the time between “off” and “30min”. Click the “Auto Freeze” drop-down box and select the required item.
  - ☑ TCG line display: Set the time between “off” and “60min”. Click the “Show TGC line” drop-down box and select.
  - ☑ Beep of keys: Set the beep of keys as “On” or “Off”. Click the “Beep of Key” drop-down box and select.
  - ☑ Foot switch: Set the function of foot switch. Click the “Foot Switch” drop-down box and select. Options include “Freeze”. “Print”. “Probe Select”. “Image Store”. “Cine Store”.

- Open Network real-time image transmission function.

After editing and amending one group of presetting values of parameters, press “set” or “apply” for storing data

Press “cancel” for exiting the edition of parameters

Press “exit” for exiting the parameter presetting, come back to the main picture of ultrasound

### 12.3.3 System Setup – DICOM presetting

The operator could preset name of the equipment, IP address of DICOM server, DICOM server port and name of DICOM server. Click “DICOM” and the “DICOM” interface pops up, as shown below:

- 1、 Ultrasound Equipment AE Title: Click “AE Title” to enter the title of this ultrasound Equipment
- 2、 Host: set DICOM host server address, port number provided by the server and AE entity title of server.

After editing and amending one group of presetting values of parameters, press “set” or “apply” for storing data

Press “cancel” for exiting the edition of parameters

Press “exit” for exiting the parameter presetting, come back to the main picture of ultrasound

### 12.3.4 System Setup - - Storage

Click [General→ Storage] On this interface, the maximum frame of cinema , image storage format, or data path could be preset. Click “Storage” and the storage interface pops up, It will show the below Figure

- 1、 Cinema –Max Frames: set the max frames, click the “Max Frames” drop-down box and choose the max frames of the cine. Frames is, it will occupy more system resources, and spend longer time to store or output the cine.
- 2、 Storage Keys - Image Format: Set the file format for image storage. Click the “Image Format” drop-down box, select the required item. Choices are “JPG”, “BMP”, which represents “JPG format” and “BMP format” respectively.
- 3、 Data Path: choose the local Disk to store the file

Note: Please do not modify, in order to avoid a new patient or image can not be stored.

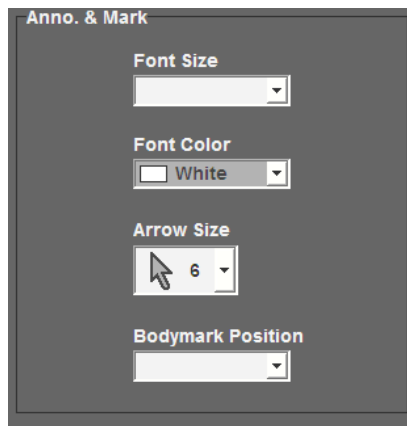
After editing and amending one group of presetting values of parameters, press “set” or “apply” for storing data

Press “cancel” for exiting the edition of parameters

Press “exit” for exiting the parameter presetting, come back to the main picture of ultrasound

### 12.3.5 System Setup –Notes Related

Click “General→ Notes Related”, and then “Notes Related” interface pops up, It will show the below Figure



Preset font size, font color, size arrow and position in this interface.

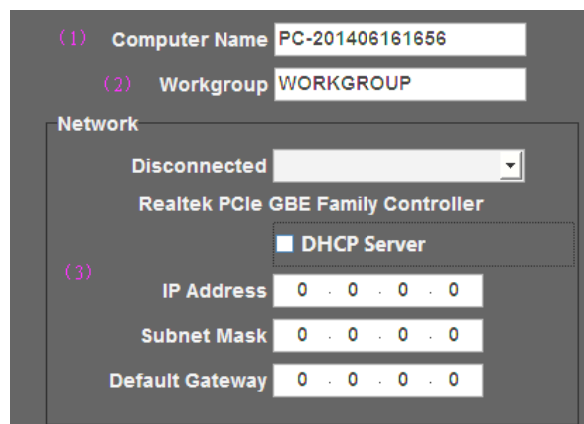
After editing and amending one group of presetting values of parameters, press “set” or “apply” for storing data

Press “cancel” for exiting the edition of parameters

Press “exit” for exiting the parameter presetting, come back to the main picture of ultrasound

### 12.3.6 System Setup – Network presetting

On this screen, the operator could set the computer name, work group and IP Address. Click “Network” and the “Network” screen pops up, as shown in below:



Computer name: Set computer name, click the “Computer Name” edit box and input the new computer name.

Work group: Set work group name, click the “workgroup” edit box and input the new work group name.

Set IP address: Check this item and the operator could manually set IP address. Parameters that should be set are:

- 1IP address: The system supports TCP/IP protocol, and IP address is the unique communication symbol by which the system runs TCP/IP protocol in the network.

- 2Subnet mask code: Together with IP address, subnet mask code divides IP address into two parts, network address and host address.

- 3 Gateway: Gateway is an IP address connecting one network to other networks.

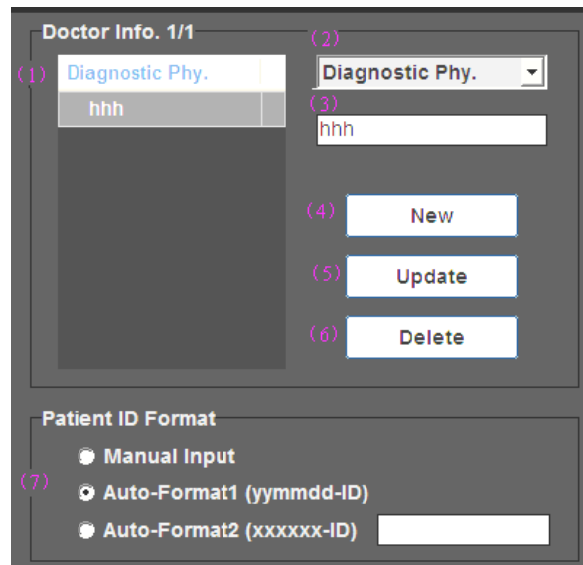
After editing and amending one group of presetting values of parameters, press “set” or “apply” for storing data

Press “cancel” for exiting the edition of parameters

Press “exit” for exiting the parameter presetting, come back to the main picture of ultrasound

### 12.3.7 System Setup –Doctors presetting

Choose the item “Doctors” under the system parameters, preset menu and then the interface of doctor parameter will be showed in the Parameters editing area . The button in the function area will be updated immediately as the below picture:



Doctors:doctor list, show the doctor list which has been entered.

The doctor category table:the three kinds of doctor’s diagnostician , application doctors and operator which related the new patients, when choose the different types, the doctor category box will be updated immediately

The doctor input table:the input box will show the doctor name in the doctor list box, if any new doctor wants to be added or modified, the content of the input box will be added in the doctor list box

New: add content in the input box into the doctor list box, if the content repeats then it will not add.

Update: update the content in the input box to the doctor list box

Delete: delete the doctor name in the doctor input box which will be updated immediately

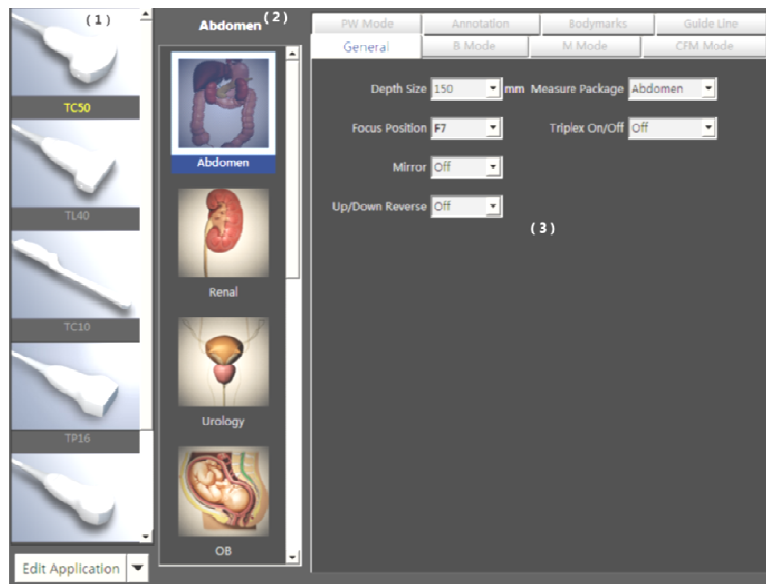
After editing and amending one group of presetting values of parameters, press “set” or “apply” for storing data

Press (cancel) for exiting the edition of parameters

Press (exit) for exiting the parameter presetting, come back to the main picture of ultrasound

### 12.3.8 System Setup –Application presetting

choose application menu, the picture of applying parameters is as follows, the buttons in function button area will be updated display immediately .



The probe list: Display all the probes that the system supports and operating parameters. Choose different list of items, the parameters of a drop-down box on the top of the list will follow the changes;

applying selection form: showing all the applying mode in the system, when select different modes, the parameters in item (3) will be loaded and displayed automatically display all the parameters value of selecting the applying mode

After editing and amending one group of presetting values of parameters, press“set” or “apply” for storing data

Press (cancel) for exiting the edition of parameters

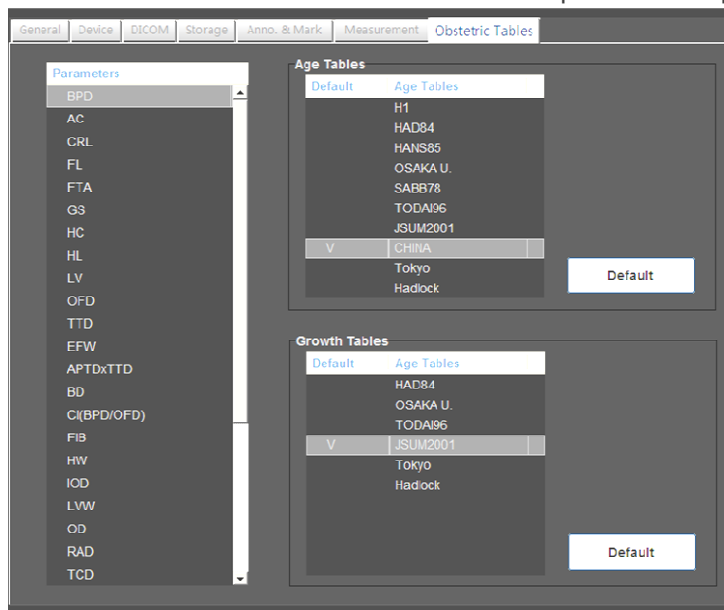
Press (exit) for exiting the parameter presetting, come back to the main picture of ultrasound.



Note: After modify the parameters stored in the application mode, user need to re-select the probe, the data will be displayed.

### 12.3.9 Obstetrics Table

Select the 『General→Obstetric Tables』 on the parameter preset menu, then obstetric tables will appear in parameter edit area, as shown below. And the function buttons will update and display.



The user could select the corresponding obstetric formula as needed.

In obstetric tables, move the trackball and select the intended formula. Click 『Default』 and save the data.

Click 『Exit』 to exit from Parameter Preset and return to the main interface of ultrasound working.

## Chapter 13 Battery



### Warning :

- 1、 Battery free dismounting prohibited  
Inside of battery, it has protection structure and electric circuit which can avoid any risks; improper dismounting will damage protection function and will result over heat, out of shape, smoke or burn.
- 2、 Battery short circuit prohibited  
Do not use metal for connection battery positive and negative plates, do not move or sore battery together with metal. If battery is short circuit, it will have strong power go through it, it will damage battery.
- 3、 heating and burning battery is prohibited  
Heating and burning battery will make thermal barrier of battery be melted and safety function is lost or electrolyte burnt. Over heating will make battery over heat, out of shape, smoke or burn.
- 4、 Please do not use battery in around heating source.  
Please do not use battery in a fire source or brazier area, battery over heat will make inner parts be short circuit and battery will over heat, out of shape, smoke or burn.
- 5、 Moistening battery is prohibited  
Please do not moisten battery, or put battery into water, it will make inner protection circuit function lost or have unusual chemical reaction, battery will over heat, out of shape, smoke or burn.
- 6、 Please do not charge battery in a fire source or direct sunshine area  
It will make inner protection circuit function lost or have unusual chemical reaction, battery will over heat, out of shape, smoke or burn.
- 7、 Destroy battery is prohibited  
Please do not use metal to bash into battery or use other ways to destroy battery, battery will over heat, out of shape, smoke or burn or have risks.
- 8、 Please do not use battery with other types of batteries  
Battery cannot be mixed using with other types of batteries, or else it will make battery be over heated, out of shape, smoke or burned by unusual charging or discharging.
- 9、 Please do not put battery in microwave oven or other pressure vessels  
Heating in a moment or structure destroyed will make battery be over heated, out of shape, smoke or burned.
- 10、 Please do not use unusual battery.If user find battery having smell, out of shape,changing color or angulated, user should put battery out of machine and do not use it again. Using unusual battery, it will make over heated out of shape, smoke or burned.

Battery life depends on the environment and how it is used.

### 13.1 Summary

The system can use lithium battery, it can make the machine be used when it's moving or power cut. When it's under sudden power lost, the system will use battery for charging battery in order to make sure that machine can work continuously.

The battery is under charging status when the system it's connected with external power source.

Normally the battery is discharged fully,the machine is turned off, it should connect with AC power supply, charging for 3 hours.

Notice: Battery can be large current charging when machine is turned off,  
It is better to charging battery at this situation, charging speed will be fast.

Lithium battery can give power supply to the machine when it's not connected with external AC power.

Notice: Please use system requested battery

### 13.2 Notes

- 1、 Before use battery, please read marks on the surface of battery.
- 2、 When use battery at first time, if user find battery is not clean or have smell, please do not use battery.
- 3、 When using the battery, please leave it far away from heat source, high voltage and do not knock battery.
- 4、 Please do not put battery in light exposure area in order to avoid over heat, out of shape, smoulder or battery property degradation.
- 5、 Battery should put in the place that children cannot reach it, children should not take out battery or play with it.
- 6、 Battery can be charged by ultrasound scanner system.
- 7、 When battery power off, if conditions permit, it need to charge battery until battery recover some power in order to avoid battery property degradation.
- 8、 Battery life depends on the environment and how it is used.

### 13.3 Battery installation and removal



**Warning:** The battery was disconnected from the mainframe when leaving the factory because of the relevant regulations of shipping. Prior to the installation or removal of the battery, confirm that the machine is turned off, disconnect the system and the power, it is prohibited that install or remove the battery in the starting state or in case of shutdown but did not cut off the power supply.

- Install the battery
  - 1、 Confirm the system is on the shutdown state, and have been disconnected from the power supply connections.
  - 2、 Open the battery compartment cover behind the machine can be replaced with a new dedicated rechargeable battery. When you reinsert the battery leads, please ensure the battery is connected with the corresponding terminals.
- Remove the battery
  - 1、 Confirm the system is one the shutdown state, and have been disconnected from the power supply connections.
  - 2、 Open the battery cover, disconnect the battery leads, remove battery from the battery bay.

### 13.4 Optimize battery performance

When use the battery in the first time, or don't use the battery more than 3 months (recommended), Customers are advised to take complete discharge/recharge cycle. Suggest storing the battery in a cool location in case of full battery.

A complete discharge/charge process:

- 3、 Discharge the battery completely so that the system shut down automatically.
- 4、 Charge the system to full power.
- 5、 Discharge the system and let shut down automatically.

### 13.5 Check the battery performance Periodically

Battery performance may decrease as time fly. The battery performance inspection must be carried out once a year. Check the battery performance; please refer to the following steps:

- 1、 Stopping all ultrasound examinations.
- 2、 Connect the system to an AC power supply, recharge the battery without interruption until full.
- 3、 Disconnect the AC power; use the battery power to supply the system until the system is shut down.
- 4、 The length of battery life reflects the battery's performance.

If the battery's power supply time is reduced, consider replacing the battery or contact the maintenance personnel.

### 13.6 Battery Life and Recycling

If there is obvious damage or battery power is exhausted, it should be replaced and properly recycle them.

Battery life: 3 years

Battery warranty period:180 days



**Warning : Dispose of used battery, it should comply with the appropriate regulations**

## Chapter 14 System Routine Maintenance

Routine maintenance of the system is completed by the customer and service engineers. After purchasing the product, the user has the full responsibility for the maintenance and operation of the product.

Notice :

- 1、 The other maintenance not include in this user manual ,there must be completed by the professional trained engineer.
- 2、 In order to ensure the performance and security of the system, the user must check the machine regularly.

### 14.1Routine maintenance

The user is responsible for the routine maintenance of the machine.

#### 14.1.1Clean System

Notice:Prior to cleaning the machine, make sure turn off the machine and unplug the power cable.  
Clean the machine under the boot state, it may lead to electric shock.

- 1、 Clear probe

- Probe is the precision electronic devices, even very small shock, it may also cause damage to the probe, it must be very careful, make sure it is not subjected to any shocks, don't hit any hard objects when use it.
- When connecting or disconnecting the probe, you must confirm the host freeze or shut down.
- Pay more attention to not scratch the probe surface head.
- After using the machine, wipe the probe with a soft sponge soaked in water or a soft cloth,do not use any liquid containing alcohol or other organic solvents.
- When install the probe, Please follow the direction to spin the lock bolt, to avoid damaging the connectors
- When use the probe ,avoid bending the twisted probe cable
- Use qualified medical ultrasonic gel; avoid damage caused by poor gel on the probe head.

 **Warning:**

- 1,When make clean and disinfect, the probe cannot connect with the machine.
- 2,When make clean and disinfect, Immersion probe shall not exceed the combination head and handle lines.

■ **Clean**

After use the probe, Use a soft cloth with water to clean the probe surface

If the probe is polluted, firstly clean it with soft cloth attached neutral cleaning fluid, then clean up the cleaning fluid with a soft cloth dipped in water .

 **Warning:**Cannot use alcohol or other organic solvents to clean the probe.

**Notice:**

- 1.Always wear protective glasses and gloves when cleaning, disinfecting or sterilizing any equipment.
- 2.Before cleaning the probe, please remove all protections from the probe set (for example, disposable condom).
- 3.In the process of cleaning the TV probe, be sure to thoroughly clean all surfaces of the TV probe.

**Disinfection or Sterilization**

The probe must be disinfected or sterilized with a liquid chemical disinfectant, such as CIDEX, which should be mixed, stored and used according to the manufacturer's instructions.

The probe head shall be soaked in the disinfectant for not less than 20 minutes, but not more than 1 hour, and the extracted part shall not exceed the combined line of the probe.

After the probe is sterilized, rinse the disinfectant on the probe with water and wipe it with a dry soft cloth.

 **Warning:**

Do not use high-pressure steam treatment probes or contact ethylene oxide. Under no circumstances should the thermal disinfection mode be used. When the temperature exceeds 66 degrees, the probe will be damaged. The probe should not be completely immersed in the liquid, and the extraction portion should not exceed the probe assembly line.

2、 Clean the probe socket

- Wipe the stain on the probe socket with a soft, dry cloth.
- If there are still stains that are difficult to remove, you can clean the dirt with a soft cloth impregnated with a neutral detergent and leave to dry.

3、 Clean the display screen

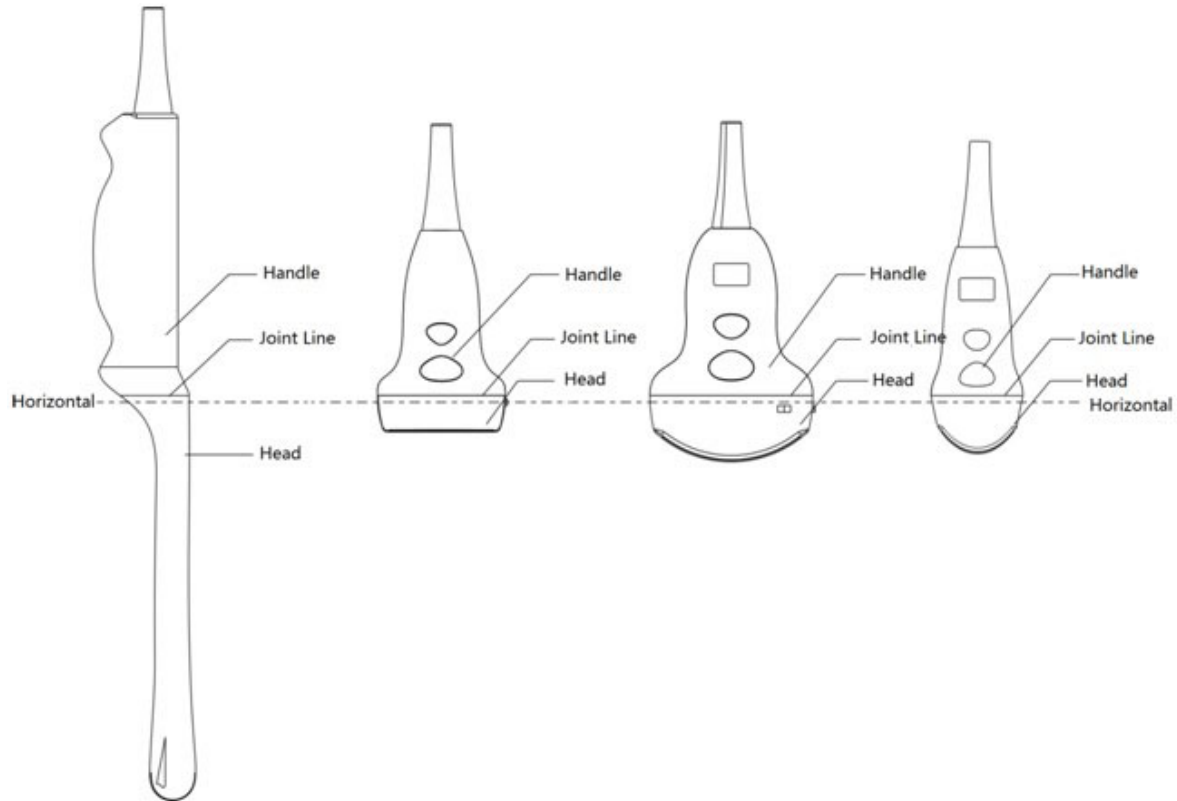
- Wipe the stains on the screen with a soft dry cloth;
- If there are still stains that are difficult to remove, you can clean the dirt with a soft cloth soaked in warm water and leave to dry.

4、 Clean control panels and shell

➤Use a soft dry cloth to clean the surface of the machine. Or wipe the stain with a soft cloth impregnated with neutral detergent semen, and then wipe the machine with a soft cloth or air dry.

### 14.1.2 Cleaning the system

The immersed part of the probe should not exceed the connector line, otherwise it may cause failure. When a fault occurs, contact the manufacturer in time. The depth of the cavity convex array probe, high-frequency linear array probe and convex array probe immersed in the liquid is as follows:



Intracavitary Convex Array

HF Linear Array

Abdomen Convex Array

Micro-convex Array

### 14.1.3 Data Maintenance

Periodically manage data and back up data to external storage media to ensure data security. After data is backed up, delete unnecessary data from the device. Otherwise, system performance may be affected after long-term use.



**Warning:**Data cannot be retrieved after deletion, please operate it carefully!

## 14.2Maintenance

### 14.2.1The maintenance of operator

After the operation is complete, the probe should be cleaned in time. It is recommended that the machine be cleaned every quarter. Maintenance includes the following:

- 1、 Clean the full machine.
- 2、 The machine components (e.g., displays, panels, etc.) is in normal operation or not
- 3、 Allow the immersed in the conductive liquid probe component crack inspection.
- 4、 Check the probe cable and other plug.

### 14.2.2Maintenance and checks by the maintenance personnel

In order to ensure the system's performance and security, the following checks must be carried out. Please contact and consult the producer when making the inspection.

Check Categories	Check Items
Clean	Inner system Peripheral devices
Electrical safety	The grounding impedance The floor drain current The shell leakage current The patient leakage current
Machinery safety	Check the monitor installation part The control panel Peripheral equipment installation Other mechanical components Probe appearance
Image recorder	The image of each mode

### 14.3 Fault checking

In order to ensure the normal operation of the machine, it is recommended that the operator develop maintenance and regular inspection plans, regularly check the safety and performance of the machine, if there is an anomaly, please contact the manufacturer.

If there is no image after the system starts, or a menu is displayed but there is no image, please refer to the following table. If the fault persists, contact the manufacturer.



**Warning:** When cleaning, do not splash water or liquid on the device; otherwise, it may cause device failure or electric shock.

Faults and troubleshooting table:

Item	Fault description	Elimination method
1	switch on the power , the power indicator light is not bright indicator light is not bright.	Check the power supply and cable, ensure they work normal.
2	Power lights, but can't display the images.	switch off the machine, Wait at least 5 minutes after the boot
3	Discontinuous interference stripes appears on the screen, snowflake interference.	1、 Check the power supply, if it is interfered by other equipment. 2、 Environmental inspection, check whether there is space around the machine electromagnetic interference. 3、 Check the power and probe plug , socket contacts whether in good condition.
4	No information in the screen, but there have operation voice ; Image display is not clear	1、 Adjust the TGC, GAIN. 2、 Clean the screen surface ( use the dry, soft cloth to wipe the monitor screen)
5	after switch on ,image properly but fan does not turn	1、 the dust is more inside the fan, can use the brush to remove dust. 2、 the fan may be damaged , replace the fan

### 14.4 Equipment modification instructions

The Company reserves the right to change product design and specifications under the conditions stipulated by law. The Company reserves the right to change the product design and specifications under the conditions stipulated by law.

## Chapter 15 Transport & Storage

The product should be transported facing up to prevent rain and mechanical impact. The number of stacked layers is not less than four. Products should be stored in the limit temperature  $-20^{\circ}\text{C}\sim+55^{\circ}\text{C}$ , relative humidity 10%~95%, atmospheric pressure 50kPa~106kPa, no corrosive gas place.

## Chapter 16 the principle of sound output

This chapter provides the user with information about the acoustic output of the system (including the host, probe, accessories, and peripherals) and how to control the radiation time using the ALARA principle. Please read this chapter carefully before using.

### 16.1 Biological effects

Ultrasound diagnosis is generally considered safe, and to date, there have been no reports of physical harm from ultrasound. But we can't believe that all ultrasounds are absolutely safe. Research has confirmed the harm of high intensity ultrasound to the human body. In recent years, with the development of ultrasonic diagnostic technology, people have paid more and more attention to the potential risks of ultrasonic application and diagnostic technology.

### 16.2 Terms of Use

Although it has not been clearly established whether ultrasound devices can produce biological effects on the human body, it is still possible to prove the existence of biological effects in future applications. We must be careful in the use of ultrasound, in obtaining the necessary clinical data, we must avoid the use of high intensity ultrasound for a long time

### 16.3 Principle of As Low As Reasonably Achievable

When using ultrasound, the ALARA principle should be followed, the use of minimum energy, will not produce biological effects. The energy of ultrasound depends on the output intensity and irradiation time, and different patients and clinical cases require different ultrasound intensity.

Not all tests can be performed with a low-energy ultrasound output. Very low energy ultrasound can only produce low quality images and weak Doppler signals, thus affecting the reliability of diagnosis. But using more sound power than the actual need does not improve the quality of diagnosis. This increases the risk of biological effects.

The user must be responsible for the safety of the patient when using ultrasound, and choose the ultrasonic output power according to the ALARA principle.

For additional information on the ALARA principle and the potential biological effects of ultrasound, users can consult the "Safety in Medical Ultrasound" document published by the American Institute of Ultrasound in Medicine (AIUM).

### 16.4 MI / TI Description

#### 16.4.1 The basics of MI/TI

The relationship between ultrasonic output parameters (such as frequency, sound pressure, sound intensity, etc.) and biological effects is still unclear. However, there are two accepted causes of biological effects. One is the thermal effect, which refers to the absorption of ultrasound by the tissue; The other is mechanical effects including cavitation. The thermal index (TI) is the index caused by the temperature rise, and the mechanical index (MI) is the index of the mechanical effect. TI and MI reflect the instantaneous output. It does not take into account the cumulative effect of time.

a) Mechanical index (MI)

The mechanical effects are caused by the production, increase, vibration and corrosion of tissue microbubbles, i.e. cavitation. MI represents the likelihood of sound pressure, and MI is calculated by dividing the peak negative by the square root of the frequency, so the higher the frequency or the lower the peak negative, the smaller the MI will be. When the frequency is 1MHz and negative 1Mpa, the MI value is 1. We can think of MI as a threshold for cavitation. When gas and soft tissue are present, we need to turn MI down.

b) TI (Thermal Index)

TI is determined by the sum of sound power and power ratio, and can increase the tissue temperature by 1°C. In addition, different tissue structures have different temperatures, so TI is divided into three categories :TIS(soft tissue heat index), TIB(bone heat index), and TIC(cranial heat index).

The World Federation of Ultrasound in Medicine and Biology (WFUMB) states that when radiation for 5 minutes results in a temperature increase of 4 ° C, there may be potential harm to embryos and fetal tissue.

#### 16.4.2MI / TI Display Description

TI and MI will be real-time displayed on the left of screen. In process of inspection operator should monitor these index, the irradiation time and acoustic output remains at the lowest level, and then obtain effective diagnostic information.



Note: If MI or TI is more than 1.0, please carefully follow the ALARA principle.

The accuracy of MI and TI is 0.1.

#### 16.5Control of Acoustic Output

The sound output depends on the operator. Under the premise of effective diagnostic images, the operator should reduce the sound output. There are two ways to control the change of the sound output: direct control and indirect control

a) Direct control

The sound output can be adjusted by directly controlling the sound power. Typical application areas for specific acoustic outputs are shown in Appendix c. In any mode, the sound output must not exceed the maximum loudest output limit (MI limit of 1.9, ISPT.3 limit of 720Mw/cm2).

b) Indirect control

Indirect control of sound output is caused by the control of image-related parameters. These controls include mode of operation, probe and frequency, focus, image depth and pulse repetition rate.

## Chapter 17 Safety Classification

1、 According to the anti-shock type:

According to the medical electrical equipment shock proof type classification belongs to class I.

2、 According to the anti shock degree:

Classified as BF type according to electric shock proof degree of medical electrical devices

3、 According to the protective degree of harmful liquid:

The system host for the IPX0, probe belongs to IPX7

4、 According to the in (with air or oxygen, nitrous oxide) of the presence of mixed inflammable

anesthetic gas use safety degree: Not appropriate in a (with air or oxygen, nitrous oxide) of the presence of inflammable anesthetic gases mixed use of equipment.

5、 According to work mode:

Continues working equipment

6、 According to the installation of the equipment and use way points

Portable equipment

## Chapter18 Electromagnetic compatibility statement



**Warning:** Using incompatible accessories will decrease the performance of this equipment.

### 18.1 Statement of EMC

#### 18.1.1 Basic performance and research on EMC conformance

##### a) Basic performance

The device is suitable for clinical ultrasound examination of abdomen, gynecology and obstetrics, small parts, cardiac and peripheral vessel.

##### b) Research on EMC conformance


EMC is the ability of a product, equipment or system to function properly without causing unsustainable electromagnetic interference to any object in its environment. EMC includes electromagnetic interference (EMI) and electromagnetic sensitivity (EMS). Simply put, EMI refers to a series of test items and indicators set up to prevent a device from interfering with other devices while it is working. EMS refers to a series of test items and indicators set in order to prevent the interference of other equipment when the equipment is working under the electromagnetic interference regulations. At the beginning of the design of all digital color Doppler ultrasonic diagnosis system, electromagnetic interference and electromagnetic interference are fully considered.

The use of the device in electromagnetic fields may cause performance changes or degradation, such as erratic output. If it occurs frequently, it is recommended to check the operating environment of the system to identify possible sources of interference. These disturbances may come from other electrical equipment in the same room or nearby rooms, or from portable and mobile RF communication devices such as cell phones, walkie-talkies, etc., or from radio equipment, television, or microwave transmission equipment. If an all-digital color Doppler ultrasound diagnostic system is subject to electromagnetic interference, it should be moved elsewhere or measures should be taken to prevent electromagnetic interference.

The full digital color Doppler ultrasound diagnostic system (including probe) meets the requirements of the industry standard YY0505-2012.

#### 18.1.2 Precautions for Electrostatic discharge

In low humidity, charge will naturally gather on human body or objects, which makes electrostatic discharge easy to happen. The following precautions help reduce ESD influence such as spraying the anti-static spray on the carpet or linoleum; or using anti-static cushion.

Warning: Don't touch the pin on the connectors marked with ESD sensitivity symbol . While using or connecting, always follow the ESD precautions above.

#### 18.1.3 Protection of ESD electrostatic discharge

##### a) Terms and definitions

- 1、 Static: surplus or deficient static charge on body surface;
- 2、 electrostatic field: electric field formed around the static charge
- 3、 electrostatic discharge: the transfer of electrostatic charge between bodies at different electrostatic potentials by direct contact or induced by electrostatic field. Once the energy of the electrostatic field reaches a certain degree, it will break through the medium and discharge, which is called electrostatic discharge.
- 4、 electrostatic sensitivity: electrostatic discharge voltage the components and parts could withstand.

- 5、 electrostatic sensitive devices: devices sensitive to electrostatic.
- 6、 grounding: electricity is connected to the bodies which supply or absorb abundant charges like the ground and the ship.
- 7、 Neutralization: utilize charges of different polarity to make the electrostatic disappear.
- 8、 anti-static region: a place where is equipped with all kinds of anti-static devices, where electrostatic potentials are restricted, where there are specific regional boundaries, and special marks for electrostatic protection only.

#### **b) Static generation**

- 1、 Friction: In daily life, two bodies of different materials contact and separate, and then static is generated. The most common way of generating the static is friction. The better insulativity of the material is, the easier to generate static though friction. Besides, any two bodies of different materials contacting and separating could generate static.
- 2、 Induction: in terms of the conductive materials, its electrons could freely flow on its surface. If it's put into an electric field, its positive and negative ions will transfer, based on the principle that the same sex repels each other, the opposite sex attracts each other.
- 3、 Conduction: in terms of the conductive materials, its electrons could freely flow on its surface. Contact with the charged body will cause charge transferring.

#### **c) Static's influence on electronic industry**

For integrated circuit components, its capacity of enduring static shock will be weakened, if the circuit is shortened, breakdown voltage is lowered, and circuit area is decreased. Static Electric Field and ESD current will become the deadly killer of those high-density components. At the same time, widespread application of abundant high-insulation materials like plastic products will increase the chance of static generation. In daily life, static will emerge while walking, air flowing and moving. In fact, the circuits with high integration level are sensitive.

- 1、 static influence on electronic components
  - (1) Static absorbs the dust, which changes impedance among circuits and influences the products' function and lifespan.
  - (2) The components can't work as the electric field or current destroys its insulation and conductor. ( completely destroyed)
  - (3) Heat produced by momentary electric field or current would damage the components, and shorten their lifespan while they still could work.
- 2、 characteristics of static damage
  - (1) Concealment
 

Human body can't perceive the static directly unless ESD occurs. Even if it occurs, electric shock will not necessarily be perceived by human body. It's due to the fact that the ESD voltage perceived by human body is 2-3KV.
  - (2) Latency
 

The performance of some electronic components damaged by static will not decline obviously. However, repeatedly-cumulative ESD will cause internal damage to the components, thus forming a hidden peril and increasing the components' sensitivity to the static. There is no way to solve the emerged problems.
  - (3) Randomness
 

Electronic components are threatened by the static through the whole process from a component's generation to the moment before its damage. And those statics are generated randomly. As statics and discharges occur instantaneously, it's difficult to predict and prevent.

#### (4) Complexity

The fine and tiny structure of electronic products makes it time-consuming, troublesome and costly for ESD to damage the board-cutting. Then precise instruments like the scanning electron microscope are used to meet the requirement of complex techniques. Still, it's difficult to distinguish the static damage from the damage caused by other reasons. Then the failure caused by static damage is mistaken as other failures. It's attributed to initial failure and unknown failure before ESD damage is fully realized. Consequently, the true cause is concealed involuntarily.

#### d) Three types of ESD

##### 1、 human body type

It refers to the fact that friction charges generate when the body rubs the clothing in human activities. When the human hand-holds the equipment sensitive to ESD, but doesn't drag and drop the charges to the ground, the friction charges will move to the equipment and give rise to damage.

##### 2、 charged micro-electronic components type

It not only refers to those devices sensitive to ESD, but plastic ones, which generate friction charges in the automatic production. Those friction charges flow swiftly onto high-conductive surface connected firmly to the ground via low-resistance circuits, thus causing damage. Or the metal part of the equipment sensitive to ESD is charged by induction, thus causing damage.

##### 3、 field induction type

Surrounded by high-electricity field, which possibly comes from plastic materials or human clothing, the electron will be converted to cross the oxide layer. If the potential difference exceeds the permittivity of the oxide layer, electric arcs will emerge to destroy the oxide layer, which results in short circuit.

4、 Other types are: robot mode, field enhancing mode, human body metal mode, condenser coupling mode and suspension device mode.

### 18.1.4 Electrostatic protection

#### a) Grounding

Grounding refers to the fact that the static is directly discharged onto the ground with a line connected. This is the most direct and effective measure to prevent static. For conductors, grounding is used generally, such as artificial anti-static wrist strap, and working surface grounding.

Grounding is carried out through the following ways:

- 1、 human body is grounding by wrist strap;
- 2、 human body is grounding by anti-static shoes (or shoelaces) and anti-static floor;
- 3、 grounding by working tables;
- 4、 grounding by test instrument, tool collet, and soldering iron;
- 5、 grounding by anti-static floors, and mats;
- 6、 grounding by anti-static transport trolleys, boxes, and frames
- 7、 grounding by anti-static chairs;

#### b) Electrostatic Shield


Static-sensitive components will be exposed to static areas in storage and transportation. The static influence on electronic components could be weakened by electrostatic shielding. The most common way is to use static shielding bags and anti-static turnover boxes as safeguards. Besides, anti-static garments play a shielding role in human clothing.

#### c) Ion Neutralization

Insulators tend to generate statics, which cannot be eliminated by grounding. The method of ion neutralization (shielding partly) so is usually adopted. That is to say ion fan is used to provide the area of first-grade potential for work.

- 1、 In consequence, in anti-static materials and facilities, products are derived by the three modes above, which could be classified as anti-static meters, anti-static products with the grounding system, shielding package, storage and transportation of anti-static materials, neutralizing static-elimination devices, and other anti-static articles.
- 2、 combined detector of wrist strap, foot band, anti-static shoes;
- 3、 testing foot band;
- 4、 detecting instrument of blower of eliminating the static iron;
- 5、 detector of static field;
- 6、 testing instrument of static shielding bags;
- 7、 measuring instrument of surface resistance;

## 18.2 Warnings and Notes

- 8、 except the parts and cables sold by the device manufacturer as internal components spares, other unauthorized parts and cables might increase emission or reduce noise immunity of Full Digital Colour Doppler Ultrasonic Diagnostic System.
- 9、 the device should not be close to other devices or stacked. If it must be so, please observe and verify it works properly under its practical configuration.
- 10、 preventing electromagnetic interference (conductive anti-interference), due to technical restriction, electrical level of conductive noise immunity is limited to 1Vrms. Higher than the limit will cause interference to the device displaying images, thus influencing the diagnosis and measurement. The device is suggested to stay away from conductive noise source.
- 11、 operating the device under the condition that the patient's physiological signal is below the minimum amplitude value or the minimum value will lead to inaccurate consequences.
- 12、 portable and mobile communication equipment will affect the performance of this device.
- 13、 the device is likely to be interfered by other equipment even if the other equipment meets relevant emission requirements of the national standard.
- 14、 the device should be especially protected according to the EMC, installed and maintained under the condition with EMC information provided below.
- 15、 the product is suggested to stay away from the equipment with the identifier  in case of potential interference, thus affecting its functions.
- 16、 as the PCBA board inside the product is a component sensitive to the static, nonprofessionals or after-sales staff unauthorized should not open it in case of damaging the main board chip.
- 17、 the product should not be contacted with the connector pins with ESD warnings, but only could be contacted with the connectors when the ESD precautions are taken.
- 18、 the device is intended for medical professionals use only. The device might lead to radio interference or disturbing the operation of devices nearby.
- 19、 using the accessories, transducers and cables unauthorized by manufacturer with the device will lead to emission increase or noise immunity reduction of Full Digital Colour Doppler Ultrasonic Diagnostic System.
- 20、 under intensive interference of electromagnetic devices, the performance of this equipment may change, which may lead to unstable output. It's suggested, not to use mobile phones less than 0.5m away from the equipment; not to use radio-frequency interference device with powerful radio launcher such as oxygen arc welding and radio thermal therapy devices, microwave therapy apparatus, short-wave therapy apparatus, X-ray machine, high-frequency electrotome, magnet therapy apparatus or other devices producing electromagnetic wave within 3 m.

## Appendix A Conform to China's Electronic Information Products Pollution Control Measures for the Administration of the Statement

Product name and content of the toxic and harmful substances

(Parts)	Hazardous Substance					
	lead (Pb)	mercury (Hg)	Cadmium (Cd)	hexavalent chromium (Cr6+)	Polybrominated biphenyls (PBB)	Polybrominated diphenyl ethers (PBDE)
Plastic shell	○	○	○	○	○	○
metal rack	○	○	×	×	○	○
silicone keyboard	○	○	○	○	○	○
trackball	×	○	○	○	○	○
wire rod	×	○	○	○	○	○
PCBA	×	○	○	○	○	○
keyboard	○	○	○	○	○	○

○: Indicates that the toxic and harmful substances in the parts of the homogeneous material content are all below the limited requirements in the stipulating standard of SJ/T 11363-2006  
 ×: Indicates that the toxic and harmful substances in the parts of at least one homogeneous material s beyond the limited requirements in the stipulating standard of SJ/T 11363-2006.  
 On the day of sales of the products are sold, it is according to my company in the supply chain of electronic information products may contain these chemicals. Attention: In the product may or may not contain all the components listed.



Attention: When the service life of the equipment has more than deadlines, all of the waste (waste batteries, circuit boards, fragile electronic components, etc.) may cause harm, should be in accordance with local regulations, the disposal of waste, rather than dispose.

### Appendix B technical parameters

1、 Slice thickness

Probe Types	Nominal frequency(MHz)	Slice Thickness(mm)
3.5C8060 convex probe	3.5	≤10
7.5L8040 linear probe	7.5	≤10
6.5C8010 intracavity probe	6.5	≤10

2、 M mode performance indicators: time display error of 10% or less.

3、 Other performance parameters of the system in line with the requirements of GB 10152-10152.

### Appendix C Sound Output Data

Order	Probe Types	Nominal Frequency	Top Temperature	Operation Control Condition
1	3.5C8060	3.5(MHz)	41℃	Specific see "operation control condition of the acoustic output report
2	7.5L8040	7.5(MHz)	38℃	
3	6.5C8010	6.5(MHz)	40℃	

# Sound Output Report

Model: B

Probe: Convex array 3.5C8060

Index Label			MI	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					$A_{aprt} \leq 1 \text{ cm}^2$	$A_{aprt} > 1 \text{ cm}^2$		
Maximum Index Value			1.20	0.83	-	-	-	
Associated Acoustic Parameters	$p_{ra}$	(MPa)	2.15					
	$P$	(mW)		94.5	-		-	
	Min of $P_{\alpha}(z_s)/I_{ta,\alpha}(z_s)$	(mW)				-		
	$z_s$	(cm)				-		
	$z_{bp}$	(cm)				-		
	$z_b$	(cm)				-		
	Z at max $I_{pi,\alpha}$	(cm)	4.48					
	$d_{eq}(z_b)$	(cm)					-	
	$f_{awf}$	(MHz)	2.95	2.95	-	-	-	-
	Dim of $A_{aprt}$	X	(cm)		1.58	-	-	-
Y		(cm)		1.31	-	-	-	-
Other Information	$t_d$	( $\mu\text{sec}$ )	0.475					
	$p_{rr}$	(Hz)	5600					
	$p_r$ at max $I_{pi}$	(MPa)	3.23					
	$d_{eq}$ at max $I_{pi}$	(cm)					-	
	$I_{pa,\alpha}$ at max MI	(W/cm <sup>2</sup> )	322.58					
Operating Control Conditions	Focus		1	1	-	-	-	-
	Focus setting		45mm	45mm	-	-	-	-
	Scanning angle		-	-	-	-	-	-
	Rate of work		50%	50%	-	-	-	-
	Frequency (MHz)		3.5	3.5	-	-	-	-

Note 1: For the mode which does not produce the largest value of TIS, it is not necessary to provide any information of TIS formula.

Note 2: For any transducer assembly which is not intended to be used for transcranial or neonatal head, it is not necessary to provide any information about TIC.

Note 3: If it meets exemptions of 51.2aa) and 51.2dd) for the equipment, it is not necessary to provide any information about MI and TI.

Remark: Mode B and Mode B/B,4B has the same emitter. The sound output of Mode B can be applied for mode B/B,4B.

Model:B+M

Probe: Convex array 3.5C8060

Index Label			MI	TIS			TIB	TIC	
				Scan	Non-scan		Non-scan		
					$A_{aprt} \leq 1 \text{ cm}^2$	$A_{aprt} > 1 \text{ cm}^2$			
Maximum Index Value			1.17	0.83	-	0.12	0.40	-	
Associated Acoustic Parameters	$p_{ra}$	(MPa)	2.10						
	$P$	(mW)		94.4	-		14.4	-	
	Min. of $[P_{\alpha}(z_s), I_{ta,\alpha}(z_s)]$		(mW)				8.75		
	$z_s$	(cm)				2.44			
	$z_{bp}$	(cm)				2.44			
	$z_b$	(cm)					4.38		
	$z$ at max $I_{pi,\alpha}$		(cm)	4.45					
	$d_{eq}(z_b)$		(cm)					0.33	
	$f_{awf}$		(MHz)	2.96	2.95	-	2.96	2.96	-
	$Dim$ of $A_{aprt}$	X	(cm)		1.58	-	1.59	1.59	-
Y		(cm)		1.30	-	1.30	1.30	-	
Other Information	$t_d$		( $\mu$ sec)	0.469					
	$p_{rr}$		(Hz)	201					
	$p_r$ at max. $I_{pi}$		(MPa)	3.10					
	$d_{eq}$ at max. $I_{pi}$		(cm)					0.32	
	$I_{pa,\alpha}$ at max. MI		(W/cm <sup>2</sup> )	327.29					
Operating Control Conditions	Focus		1	1	-	1	1	-	
	Focus setting		45mm	45mm	-	45mm	45mm	-	
	Scanning angle		-	-	-	-	-	-	
	M Speed		H	-	-	H	H	-	
	Rate of work		50%	50%	-	50%	50%	-	
	Frequency (MHz)		3.5	3.5	-	3.5	3.5	-	

Note 1:For the mode which does not produce the largest value of TIS, it is not necessary to provide any information of TIS formula.

Note 2:For any transducer assembly which is not intended to be used for transcranial or neonatal head , it is not necessary to provide any information about TIC.

Note 3:If it meets exemptions of 51.2aa) and 51.2dd) for the equipment, it is not necessary to provide any information about MI and TI.

Model: CFM

Probe: Convex array 3.5C8060

Index Label			MI	TIS			TIB	TI C
				Scan	Non-scan		Non-sc an	
					$A_{aprt} \leq 1 \text{ cm}^2$	$A_{aprt} > 1 \text{ cm}^2$		
Maximum Index Value			1.19	1.38	-	-	-	-
Associat ed Acoustic Paramet ers	$p_{ra}$		(MPa)	2.05				
	$P$		(mW)		68.2	-		-
	Min. of $[P_{\alpha}(z_s), I_{ta,\alpha}(z_s)]$		(mW)			-		
	$z_s$		(cm)			-		
	$z_{bp}$		(cm)			-		
	$z_b$		(cm)				-	
	$z \text{ at max } I_{pi,\alpha}$		(cm)	4.47				
	$d_{eq}(z_b)$		(cm)				-	
	$f_{awf}$		(MHz)	2.96	2.67	-	-	-
	Dim of $A_{aprt}$	X	(cm)		1.59	-	-	-
Y		(cm)		1.30	-	-	-	
Other Information	$t_d$		( $\mu\text{sec}$ )	0.465				
	$p_{rr}$		(Hz)	5555				
	$p_r \text{ at max. } I_{pi}$		(MPa)	3.23				
	$d_{eq} \text{ at max. } I_{pi}$		(cm)				-	
	$I_{pa,\alpha} \text{ at max. MI}$		(W/cm <sup>2</sup> )	784.55				
Operating Control Conditions	Focus			1	1	-	-	-
	Focus setting			45mm	45mm	-	-	-
	Scan angle			-	-	-	-	-
	Speed			-	-	-	-	-
	Rate of work			50%	50%	-	-	-
	Frequency(MHz)			2.5	2.5	-	-	-

Note 1:For the mode which does not produce the largest value of TIS, it is not necessary to provide any information of TIS formula.

Note 2:For any transducer assembly which is not intended to be used for transcranial or neonatal head , it is not necessary to provide any information about TIC.

Note 3:If it meets exemptions of 51.2aa) and 51.2dd) for the equipment, it is not necessary to provide any information about MI and TI.

Model: B+CFM

Probe: Convex array 3.5C8060

Index Label			MI	TIS			TIB	TIC	
				Scan	Non-scan		Non-sc an		
					$A_{aprt} \leq 1 \text{ cm}^2$	$A_{aprt} > 1 \text{ cm}^2$			
Maximum Index Value			1.19	1.38	-	-	-	-	
Associa ted Acusti c Parame ters	$p_{ra}$		(MPa)	2.05					
	$P$		(mW)		2D:94.4 Clr:68.2	-		-	-
	Min. of $[P_{\alpha}(z_s), I_{ta,\alpha}(z_s)]$		(mW)				-		
	$z_s$		(cm)				-		
	$z_{bp}$		(cm)				-		
	$z_b$		(cm)					-	
	$z$ at max $I_{pi,\alpha}$		(cm)	4.47					
	$d_{eq}(z_b)$		(cm)					-	
	$f_{awf}$		(MHz)	2.96	2D:2.96 Clr:2.67	-	-	-	-
	Dim of $A_{aprt}$		X	(cm)		2D:1.59 Clr:1.59	-	-	-
Y			(cm)		1.30	-	-	-	-
Other Informa tion	$t_d$		( $\mu\text{sec}$ )	0.465					
	$p_{rr}$		(Hz)	5555					
	$p_r$ at max. $I_{pi}$		(MPa)	3.23					
	$d_{eq}$ at max. $I_{pi}$		(cm)					-	
	$I_{pa,\alpha}$ at max. $MI$		( $\text{W}/\text{cm}^2$ )	784.55					
Operati ng Control Condi tions	Focus			1	1	-	-	-	-
	Focus setting			45mm	45mm	-	-	-	-
	Scan angle			-	-	-	-	-	-
	Speed			-	-	-	-	-	-
	Rate of work			50%	50%	-	-	-	-
	Frequency(MHz)			2.5	2.5	-	-	-	-

Note 1: For the mode which does not produce the largest value of TIS, it is not necessary to provide any information of TIS formula.

Note 2: For any transducer assembly which is not intended to be used for transcranial or neonatal head, it is not necessary to provide any information about TIC.

Note 3: If it meets exemptions of 51.2aa) and 51.2dd) for the equipment, it is not necessary to provide any information about MI and TI.

Model: PDI

Probe: Convex array 3.5C8060

Index Label			MI	TIS			TIB	TIC	
				Scan	Non-scan		Non-scan		
					$A_{aprt} \leq 1 \text{cm}^2$	$A_{aprt} > 1 \text{cm}^2$			
Maximum Index Value			0.93	0.91	-	-	-	-	
Associated Acoustic Parameters	$p_{ra}$	(MPa)	1.57						
	$P$	(mW)		2D:94.5 Clr:20.4	-		-	-	
	Min. of $[P_{\alpha}(z_s), I_{\alpha,\alpha}(z_s)]$		(mW)				-		
	$z_s$		(cm)				-		
	$z_{bp}$		(cm)				-		
	$z_b$		(cm)					-	
	$z$ at max $I_{pi,\alpha}$		(cm)	4.25					
	$d_{eq}(z_b)$		(cm)					-	
	$f_{awf}$		(MHz)	2.83	2D:2.95 Clr:2.66	-	-	-	-
	Dim of $A_{aprt}$	X	(cm)		2D:1.58 Clr:1.58	-	-	-	-
Y		(cm)		1.30	-	-	-	-	
Other Information	$t_d$		( $\mu\text{sec}$ )	0.465					
	$p_{rr}$		(Hz)	5555					
	$p_r$ at max. $I_{pi}$		(MPa)	2.37					
	$d_{eq}$ at max. $I_{pi}$		(cm)					-	
	$I_{pa,\alpha}$ at max. $MI$		( $\text{W}/\text{cm}^2$ )	160.78					
Operating Conditions	Focus		1	1	-	-	-	-	
	Focus setting		45mm	45mm	-	-	-	-	
	Scan angle		-	-	-	-	-	-	
	Speed		-	-	-	-	-	-	
	Rate of work		50%	50%	-	-	-	-	
	Frequency(MHz)		2.5	2.5	-	-	-	-	

Note 1:For the mode which does not produce the largest value of TIS, it is not necessary to provide any information of TIS formula.

Note 2:For any transducer assembly which is not intended to be used for transcranial or neonatal head , it is not necessary to provide any information about TIC.

Note 3:If it meets exemptions of 51.2aa) and 51.2dd) for the equipment, it is not necessary to provide any information about MI and TI.

Model: B+PDI

Probe: Convex array 3.5C8060

Index Label			MI	TIS			TIB	TIC	
				Scan	Non-scan		Non-scan		
					$A_{aprt} \leq 1 \text{cm}^2$	$A_{aprt} > 1 \text{cm}^2$			
Maximum Index Value			0.93	0.91	-	-	-	-	
Associated Acoustic Parameter s Other Information	$p_{ra}$	(MPa)	1.57						
	$P$	(mW)		2D:94.5 Clr:20.4	-		-	-	
	Min. of $[P_{\alpha}(z_s), I_{ta,\alpha}(z_s)]$		(mW)				-		
	$z_s$	(cm)					-		
	$z_{bp}$	(cm)					-		
	$z_b$	(cm)					-		
	$z$ at max $I_{pi,\alpha}$		(cm)	4.25					
	$d_{eq}(z_b)$		(cm)					-	
	$f_{awf}$		(MHz)	2.83	2D:2.95 Clr:2.66	-	-	-	-
	Dim of $A_{aprt}$	X	(cm)		2D:1.58 Clr:1.58	-	-	-	-
Y		(cm)		1.30	-	-	-	-	
Operating Control Conditions	$t_d$		( $\mu\text{sec}$ )	0.465					
	$p_{rr}$		(Hz)	5555					
	$p_r$ at max. $I_{pi}$		(MPa)	2.37					
	$d_{eq}$ at max. $I_{pi}$		(cm)					-	
	$I_{pa,\alpha}$ at max. $MI$		(W/cm <sup>2</sup> )	160.78					
Focus			1	1	-	-	-	-	
Focus setting			45mm	45mm	-	-	-	-	
Scan angle			-	-	-	-	-	-	
Speed			-	-	-	-	-	-	
Rate of work			50%	50%	-	-	-	-	
Frequency(MHz)			2.5	2.5	-	-	-	-	

Note 1:For the mode which does not produce the largest value of TIS, it is not necessary to provide any information of TIS formula.

Note 2:For any transducer assembly which is not intended to be used for transcranial or neonatal head , it is not necessary to provide any information about TIC.

Note 3:If it meets exemptions of 51.2aa) and 51.2dd) for the equipment, it is not necessary to provide any information about MI and TI.

Model: PW

Probe: Convex array 3.5C8060

Index Label			MI	TIS			TIB	TIC	
				Scan	Non-scan		Non-scan		
					$A_{aprt} \leq 1 \text{ cm}^2$	$A_{aprt} > 1 \text{ cm}^2$			
Maximum Index Value			0.44	1.37	-	-	-	-	
Associated Acoustic Parameters	$p_{ra}$		(MPa)	0.80					
	$P$		(mW)		68.2	-		-	-
	Min. of [ $P_{\alpha}(z_s), I_{ta,\alpha}(z_s)$ ] 值		(mW)				-		
	$z_s$		(cm)				-		
	$z_{bp}$		(cm)				-		
	$z_b$		(cm)					-	
	$z$ at max $I_{pi,\alpha}$		(cm)	5.54					
	$d_{eq}(z_b)$		(cm)					-	
	$f_{awf}$		(MHz)	3.32	2.67	-	-	-	-
$Dim$ of $A_{aprt}$	X	(cm)		1.59		-	-	-	
	Y	(cm)		1.30		-	-	-	
Other Information	$t_d$		( $\mu\text{sec}$ )	2.237					
	$p_{rr}$		(Hz)	4950					
	$p_r$ at max. $I_{pi}$		(MPa)	1.50					
	$d_{eq}$ at max. $I_{pi}$		(cm)					-	
	$I_{pa,\alpha}$ at max. $MI$		( $\text{W}/\text{cm}^2$ )	52.57					
Operating Control Conditions	Focus			1	1	-	-	-	
	Focus setting			45mm	45mm	-	-	-	
	Scan angle			-	-	-	-	-	
	Speed(cm/s)			71	71	-	-	-	
	Rate of work			50%	50%	-	-	-	
	Frequency(MHz)			2.5	2.5	-	-	-	

Note 1:For the mode which does not produce the largest value of TIS, it is not necessary to provide any information of TIS formula.

Note 2:For any transducer assembly which is not intended to be used for transcranial or neonatal head , it is not necessary to provide any information about TIC.

Note 3:If it meets exemptions of 51.2aa) and 51.2dd) for the equipment, it is not necessary to provide any information about MI and TI.

Model:B+CFM+ PW

Probe: Convex array 3.5C8060

Index Label			MI	TIS			TIB	TIC	
				Scan	Non-scan		Non-scan		
					$A_{aprt} \leq 1 \text{ cm}^2$	$A_{aprt} > 1 \text{ cm}^2$			
Maximum Index Value			0.53	0.00	1.67	0.09	0.12	1.12	
Associated Acoustic Parameters	$p_{ra}$	(MPa)	0.83						
	$P$	(mW)		0.10	140.14		140.14	140.14	
	Min. of [ $P_{\alpha}(z_s), I_{ta,\alpha}(z_s)$ ] 值		(mW)				11.71		
	$z_s$	(cm)					3.74		
	$z_{bp}$	(cm)					4.69		
	$z_b$	(cm)	3.74					3.74	
	$z$ at max $I_{pi,\alpha}$		(cm)	5.54					
	$d_{eq}(z_b)$		(cm)					9.27	
	$f_{awf}$		(MHz)	2.50	2.50	2.50	2.50	2.50	2.50
	$Dim$ of $A_{aprt}$	X	(cm)		6.40	6.40	6.40	6.40	6.40
Y		(cm)		1.20	1.20	1.20	1.20	1.200	
Other Information	$t_d$		( $\mu\text{sec}$ )	2.46					
	$p_{rr}$		(Hz)	1500					
	$p_r$ at max. $I_{pi}$		(MPa)	1.15					
	$d_{eq}$ at max. $I_{pi}$		(cm)					3.32	
	$I_{pa,\alpha}$ at max. $MI$		( $\text{W}/\text{cm}^2$ )	0.07					
Operating Control Conditions	Focus		1	-	-	-	-	-	
	Focus setting		45mm	-	-	-	-	-	
	Scan angle		-	-	-	-	-	-	
	Speed(cm/s)		71	-	-	-	-	-	
	Rate of work		50%	-	-	-	-	-	
	Frequency(MHz)		2.5	-	-	-	-	-	

Note 1:For the mode which does not produce the largest value of TIS, it is not necessary to provide any information of TIS formula.

Note 2:For any transducer assembly which is not intended to be used for transcranial or neonatal head , it is not necessary to provide any information about TIC.

Note 3:If it meets exemptions of 51.2aa) and 51.2dd) for the equipment, it is not necessary to provide any information about MI and TI.

Model: B

Probe: Linear array 7.5L8040

Index Label			MI	TIS			TIB	TIC	
				Scan	Non-scan		Non-scan		
					$A_{aprt} \leq 1 \text{cm}^2$	$A_{aprt} > 1 \text{cm}^2$			
Maximum Index Value			1.17	1.00	-	-	-	-	
Associated Acoustic Parameters	$p_{ra}$		(MPa)	2.91					
	$P$		(mW)		34.2	-		-	-
	Min. of $[P_{\alpha}(z_s), I_{ta,\alpha}(z_s)]$		(mW)				-		
	$z_s$		(cm)				-		
	$z_{bp}$		(cm)				-		
	$z_b$		(cm)					-	
	$z$ at max $I_{pi,\alpha}$		(cm)	1.92					
	$d_{eq}(z_b)$		(cm)					-	
	$f_{awf}$		(MHz)	6.17	6.17	-	-	-	-
	$Dim$ of $A_{aprt}$		X	(cm)		0.96	-	-	-
Y			(cm)		0.50	-	-	-	-
Other Information	$t_d$		( $\mu\text{sec}$ )	0.228					
	$p_{rr}$		(Hz)	10000					
	$p_r$ at max. $I_{pi}$		(MPa)	4.39					
	$d_{eq}$ at max. $I_{pi}$		(cm)					-	
	$I_{pa,\alpha}$ at max. $MI$		( $\text{W}/\text{cm}^2$ )	343.29					
Operating Control Conditions	Focus			1	1	-	-	-	-
	Focus setting			20mm	20mm	-	-	-	-
	Scan angle			-	-	-	-	-	-
	Rate of work			50%	50%	-	-	-	-
	Frequency(MHz)			7.5	7.5	-	-	-	-

Note 1:For the mode which does not produce the largest value of TIS, it is not necessary to provide any information of TIS formula.

Note 2:For any transducer assembly which is not intended to be used for transcranial or neonatal head , it is not necessary to provide any information about TIC.

Note 3:If it meets exemptions of 51.2aa) and 51.2dd) for the equipment, it is not necessary to provide any information about MI and TI.

Remark:Mode B and Mode B/B,4B has the same emitter. The sound output of Mode B can be applied for mode B/B,4B.

Model: B+M

Probe: Linear array 7.5L8040

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1 \text{cm}^2$	$A_{aprt} > 1 \text{cm}^2$		
Maximum Index Value			1.14	1.08	0.07	-	0.07	-
Associated Acoustic Parameters	$p_{ra}$	(MPa)	2.87					
	$P$	(mW)		34.5	2.3		2.3	-
	Min. of $[P_{\alpha}(z_s), I_{ta,\alpha}(z_s)]$	(mW)				-		
	$z_s$	(cm)				-		
	$z_{bp}$	(cm)				-		
	$z_b$	(cm)					1.91	
	$z$ at max $I_{pi,\alpha}$	(cm)	1.91					
	$d_{eq}(z_b)$	(cm)					0.26	
	$f_{awf}$	(MHz)	6.25	6.25	6.25	-	6.25	-
	$Dim$ of $A_{aprt}$	X	(cm)		0.97	0.97	-	0.97
Y		(cm)		0.50	0.50	-	0.50	-
Other Information	$t_d$	( $\mu\text{sec}$ )	0.228					
	$p_{rr}$	(Hz)	254					
	$p_r$ at max. $I_{pi}$	(MPa)	4.34					
	$d_{eq}$ at max. $I_{pi}$	(cm)					0.26	
	$I_{pa,\alpha}$ at max. $MI$	( $\text{W}/\text{cm}^2$ )	331.89					
Operating Conditions	Focus		1	1	1	-	1	-
	Focus setting		20mm	20mm	20mm	-	20mm	-
	Scan angle		-	-	-	-	-	-
	M Speed		H	-	H	-	H	-
	Rate of work		50%	50%	50%	-	50%	-
	Frequency(MHz)		7.5	7.5	7.5	-	7.5	-

Note 1:For the mode which does not produce the largest value of TIS, it is not necessary to provide any information of TIS formula.

Note 2:For any transducer assembly which is not intended to be used for transcranial or neonatal head , it is not necessary to provide any information about TIC.

Note 3:If it meets exemptions of 51.2aa) and 51.2dd) for the equipment, it is not necessary to provide any information about MI and TI.

Model: CFM

Probe: Linear array 7.5L8040

Index Label			MI	TIS			TIB	TIC	
				Scan	Non-scan		Non-scan		
					$A_{aprt} \leq 1 \text{ cm}^2$	$A_{aprt} > 1 \text{ cm}^2$			
Maximum Index Value			1.14	1.29	-	-	-	-	
Associated Acoustic Parameters	$p_{ra}$	(MPa)	2.83						
	$P$	(mW)		10.5	-		-	-	
	Min. of $[P_{\alpha}(z_s), I_{ta,\alpha}(z_s)]$		(mW)				-		
	$z_s$	(cm)					-		
	$z_{bp}$	(cm)					-		
	$z_b$	(cm)					-		
	$z$ at max $I_{pi,\alpha}$		(cm)	1.93					
	$d_{eq}(z_b)$		(cm)					-	
	$f_{awf}$		(MHz)	6.20	5.05	-	-	-	-
Dim of $A_{aprt}$	X	(cm)		0.94	-	-	-	-	
	Y	(cm)		0.51	-	-	-	-	
Other Information	$t_d$		( $\mu\text{sec}$ )	0.228					
	$prr$		(Hz)	10000					
	$p_r$ at max. $I_{pi}$		(MPa)	4.23					
	$d_{eq}$ at max. $I_{pi}$		(cm)					-	
	$I_{pa,\alpha}$ at max. $MI$		( $W/\text{cm}^2$ )	331.89					
Operating Control Conditions	Focus		1	1	-	-	-	-	
	Focus setting		20mm	20mm	-	-	-	-	
	Scan angle		-	-	-	-	-	-	
	Speed		-	-	-	-	-	-	
	Rate of work		50%	50%	-	-	-	-	
	Frequency(MHz)		5.0	5.0	-	-	-	-	

Note 1: For the mode which does not produce the largest value of TIS, it is not necessary to provide any information of TIS formula.

Note 2: For any transducer assembly which is not intended to be used for transcranial or neonatal head, it is not necessary to provide any information about TIC.

Note 3: If it meets exemptions of 51.2aa) and 51.2dd) for the equipment, it is not necessary to provide any information about MI and TI.

Model: B+CFM

Probe: Linear array 7.5L8040

Index Label			MI	TIS			TIB	TIC	
				Scan	Non-scan		Non-scan		
					$A_{aprt} \leq 1 \text{cm}^2$	$A_{aprt} > 1 \text{cm}^2$			
Maximum Index Value			1.12	1.27	-	-	-	-	
Associated Acoustic Parameters	$p_{ra}$	(MPa)	2.79						
	$P$	(mW)		2D:34.2 Clr:10.6	-		-	-	
	Min. of $[P_{\alpha}(z_s), I_{ta,\alpha}(z_s)]$		(mW)				-		
	$z_s$	(cm)					-		
	$z_{bp}$	(cm)					-		
	$z_b$	(cm)					-		
	$z$ at max $I_{pi,\alpha}$		(cm)	1.92					
	$d_{eq}(z_b)$		(cm)					-	
	$f_{awf}$		(MHz)	6.21	2D:6.21 Clr:5.03	-	-	-	-
	Dim of $A_{aprt}$	X	(cm)		2D:0.96 Clr:0.96	-	-	-	-
Y		(cm)		0.50	-	-	-	-	
Other Information	$t_d$		( $\mu\text{sec}$ )	0.227					
	$p_{rr}$		(Hz)	10000					
	$p_r$ at max. $I_{pi}$		(MPa)	4.21					
	$d_{eq}$ at max. $I_{pi}$		(cm)					-	
	$I_{pa,\alpha}$ at max. MI		(W/cm <sup>2</sup> )	331.89					
Operating Conditions	Focus		1	1	-	-	-	-	
	Focus setting		20mm	20mm	-	-	-	-	
	Scan angle		-	-	-	-	-	-	
	Speed		-	-	-	-	-	-	
	Rate of work		50%	50%	-	-	-	-	
	Frequency(MHz)		5.0	5.0	-	-	-	-	

Note 1:For the mode which does not produce the largest value of TIS, it is not necessary to provide any information of TIS formula.

Note 2:For any transducer assembly which is not intended to be used for transcranial or neonatal head , it is not necessary to provide any information about TIC.

Note 3:If it meets exemptions of 51.2aa) and 51.2dd) for the equipment, it is not necessary to provide any information about MI and TI.

Model: PW

Probe: Linear array 7.5L8040

Index Label			MI	TIS			TIB	TIC	
				Scan	Non-scan		Non-scan		
					$A_{aprt} \leq 1 \text{ cm}^2$	$A_{aprt} > 1 \text{ cm}^2$			
Maximum Index Value			0.24	1.28	-	-	-	-	
Associated Acoustic Parameters	$p_{ra}$		(MPa)	0.62					
	$P$		(mW)		10.5	-		-	-
	Min. of $[P_{\alpha}(z_s), I_{ta,\alpha}(z_s)]$		(mW)				-		
	$z_s$		(cm)				-		
	$z_{bp}$		(cm)				-		
	$z_b$		(cm)					-	
	$z$ at max $I_{pi,\alpha}$		(cm)	2.03					
	$d_{eq}(z_b)$		(cm)					-	
	$f_{awf}$		(MHz)	6.69	5.05	-	-	-	-
	$Dim$ of $A_{aprt}$	X	(cm)			0.93	-	-	-
Y		(cm)		0.51		-	-	-	-
Other Information	$t_d$		( $\mu\text{sec}$ )	1.119					
	$p_{rr}$		(Hz)	10000					
	$p_r$ at max. $I_{pi}$		(MPa)	1.00					
	$d_{eq}$ at max. $I_{pi}$		(cm)					-	
	$I_{pa,\alpha}$ at max. $MI$		( $\text{W}/\text{cm}^2$ )	17.24					
Operating Conditions	Focus			1	1	-	-	-	-
	Focus setting			20mm	20mm	-	-	-	-
	Scan angle			-	-	-	-	-	-
	Speed(cm/s)			62	62	-	-	-	-
	Rate of work			50%	50%	-	-	-	-
	Frequency(MHz)			5.0	5.0	-	-	-	-
<p>Note 1:For the mode which does not produce the largest value of TIS, it is not necessary to provide any information of TIS formula.</p> <p>Note 2:For any transducer assembly which is not intended to be used for transcranial or neonatal head , it is not necessary to provide any information about TIC.</p> <p>Note 3:If it meets exemptions of 51.2aa) and 51.2dd) for the equipment, it is not necessary to provide any information about MI and TI.</p>									

Model: B+CFM+PW

Probe: Linear array 7.5L8040

Index Label			MI	TIS			TIB	TIC	
				Scan	Non-scan		Non-scan		
					$A_{aprt} \leq 1 \text{ cm}^2$	$A_{aprt} > 1 \text{ cm}^2$			
Maximum Index Value			0.39	0.00	0.92	0.37	0.00	0.39	
Associated Acoustic Parameters	$p_{ra}$		(MPa)	1.02					
	$P$		(mW)		0.02	29.03		29.03	29.03
	Min. of $[P_{\alpha}(z_s), I_{ta,\alpha}(z_s)]$		(mW)				9.61		
	$z_s$		(cm)				2.40		
	$z_{bp}$		(cm)				2.77		
	$z_b$		(cm)	2.40				2.40	
	$z$ at max $I_{pi,\alpha}$		(cm)	2.03					
	$d_{eq}(z_b)$		(cm)					3.76	
	$f_{awf}$		(MHz)	5.00	5.00	5.00	5.00	5.00	5.00
	$Dim$ of $A_{aprt}$		X	(cm)		3.84	3.84	3.84	3.84
Y			(cm)		0.70	0.70	0.70	0.70	0.70
Other Information	$t_d$		( $\mu\text{sec}$ )	1.93					
	$prf$		(Hz)	3000					
	$p_r$ at max. $I_{pi}$		(MPa)	1.77					
	$d_{eq}$ at max. $I_{pi}$		(cm)					0.93	
	$I_{pa,\alpha}$ at max. $MI$		( $\text{W}/\text{cm}^2$ )	0.13					
Operating Control Conditions	Focus			1	1	-	-	-	-
	Focus setting			20mm	20mm	-	-	-	-
	Scan angle			-	-	-	-	-	-
	Speed(cm/s)			62	62	-	-	-	-
	Rate of work			50%	50%	-	-	-	-
	Frequency(MHz)			5.0	5.0	-	-	-	-

Note 1: For the mode which does not produce the largest value of TIS, it is not necessary to provide any information of TIS formula.

Note 2: For any transducer assembly which is not intended to be used for transcranial or neonatal head, it is not necessary to provide any information about TIC.

Note 3: If it meets exemptions of 51.2aa) and 51.2dd) for the equipment, it is not necessary to provide any information about MI and TI.