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## **Foreword**

The Color Ultrasonic Diagnostic Apparatus is a professional ultrasound diagnosis system.

The color Doppler ultrasound diagnostic apparatus is a medical diagnostic product, which is applied to patient, electric shock protection class I, BF type application.

The date of edition of this manual is January 2, 2019, version: V2.0

# Chapter 1 Safety Matters

## 1.1 Warnings:

- ▶ This instrument should be sold and installed by a professional salesperson.
- ▶ This instrument should be operated by or under the guidance of a qualified operator.
- ▶ This instrument can only be used for cardiac measurement functions as specified in the “Instructions”.

## 1.2 Statement:

The manufacturer is only responsible for the safety, reliability and performance of the instrument only if:

- ▶ Assembly operations, expansion, re-tuning, improvement and repair are performed by personnel approved by the manufacturer;
- ▶ The relevant electrical equipment complies with national standards
- ▶ The instrument is used in accordance with the operating instructions.

### Warning:



- Failure to implement a satisfactory maintenance plan of hospital or institution that is responsible for using this instrument may result in abnormal instrument failure and may endanger personal health.

## 1.3 Laser product certificate statement

This ultrasonic device is equipped with read and write disc drive. This part belongs to the laser product. If the user replaces the disc drive, must ensure that it meets the requirements of GB7247 for this type of product.

## 1.4 Important Requirement

- ▶ Before operating the instrument, be sure to read and accurately understand everything in this manual, including host installation, peripheral connections, safety features, function usage and maintenance methods.
- ▶ Special attention to the contents of “Warning”, “Attention” and “Tips” in the manual.
- ▶ Special remind: If the user do not follow the instructions in the “Instructions for Use” or does not follow the instructions of the manufacturer or agent, they will be responsible for any destruction or injury of instrument or personnel.
- ▶ Special remind: Before using, please fill in the “Product Information Sheet” and accurately record the important information such as the host number, display number, probe number, purchase date, etc., and tear it off, keep it together with the product certificate and warranty card.

- ▶ Special remind: When cleaning the ultrasonic host and probe, try not to damage the important symbols such as “device model”, “host number”, “display model and number”, “probe number” and “factory date” on the machine body and probe.
- ▶ Special remind: When the User's Guide is not used frequently, please keep it in a safe place for future reference.
- ▶ Special reminder: The screenshot in the "Instruction Manual" are only schematic diagrams. Specific to the actual instrument.
- ▶ Special remind: Interconnection of multiple devices can lead to the accumulation of leakage current, which may cause the danger of electric shock
- ▶ Special remind: The probe is forbidden to scan the eyes! The reasonable possible range of output power should be used. The time to check human body should not be too long, only to the extent necessary to make a diagnosis. Prolonging the scanning time of probe can damage the health of human body. Ultrasonic probes, which are self-heating and can be realized in the air, should not be used for transvaginal examining; special attention should be paid to reducing the output power and irradiation time of the irradiated sound to the embryo or fetus.
- ▶ Special remind: This instrument cannot be directly applied to the heart. The probe can only be used for cardiac checking through scanning the body surface.
- ▶ Special remind: 6.5MHzC4-9R10 convex array broadband probe, 6.5MHzC5-9R10 convex array broadband probe must be added with oil-free sterile disinfectant rubber sleeve, the rubber sleeve must meet the technical requirements of GB 7544-2009 "natural latex rubber condom" Test method" standard requirements.

## 1.5 Implementation standards

The function and performance of the color Doppler ultrasound diagnostic instrument comply with the national and industry standards GB 10152, YY 0767, YY / T 1279, and the safety standards implement the national standards GB 9706.1, GB 9706.9, and the international standard IEC 60601-1.

EN 60601-1:2006/A1:2013 (IEC 60601-1:2005+A1:2012)	Medical electrical equipment-Part 1: General requirement for basic safety and essential performance
EN 60601-1-2:2015	Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance-Collateral Standard: Electromagnetic disturbances
EN 60601-2-37:2008+A1:2015 (IEC60601-2-37:2007+A1-20)	Medical electrical equipment-Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
EN 60601-1-6:2010+A1:2015 (IEC 60601-1-6:2010)	Medical electrical equipment-Part 1-6: General requirements for basic safety and essential performance-Collateral standard: Usability





## 1.6 Safety classification

- Classified by type of electric shock  
The device belongs to Class I device, which is powered by an external power source.
- Classified by the degree of protection against electric shock  
The equipment application part belongs to BF type.





- Classified by degree of protection against liquid injection  
The host of the device is the ordinary device IPX0, which has no protection against the liquid injection; the degree of anti-injection of the probe is IPX7.
- Classified by operating mode  
The device belongs to continuous operation device.

## 1.7 Equipment Signs

According to the safety classification and markings for medical electrical equipment established by the National Electrotechnical Commission (IEC), the safety classifications and signs used in this instrument are as follows:

	Type of electric shock prevention: Class I ; anti-shock degree: Type BF Special note: no patient contact or operation of the instrument at any time
	“I” and “O” on the power switch indicate “on” and “off” of the power supply
	Attention! Check the related file. Before using this function, be sure to check the explanatory text of the function (such as "User's Guide", etc.) and make sure that the operation of this function is accurately understood.
<b>IPX7</b>	Probe anti-injection level: IPX7
	Protective grounding

The following symbols appear on the product packaging

Signs	Meaning	Description
	up	
	Fragile, handle with care	
	Avoid rain	
	Avoid sun exposure	

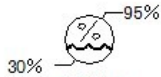


**Prohibit stacking**



**Transportation environment temperature**

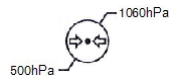
For transportation, the ambient temperature range is  $-20^{\circ}\text{C}$  to  $+40^{\circ}\text{C}$



**Transport humidity**

For transportation, the relative humidity range is 30% to 80%

(no water condensation)



**Transport atmospheric pressure**

For transportation, atmospheric pressure ranges from 500hPa to 1060hPa



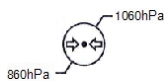
**Storage environment temperature**

For storage, the ambient temperature range is  $-5^{\circ}\text{C}$  to  $+40^{\circ}\text{C}$



**Storage humidity**

For storage, the relative humidity is less than 80%



**Storage atmospheric pressure**

For storage, atmospheric pressure ranges from 860hPa to 1060hPa



**Manufacturer**



**EC-representative**



**Batch No.**



**Serial number**



**Used by**

This symbol shall be accompanied by a date to indicate that the device should not be used after the end of the year, month and day shown.



**Date of manufacture**



The symbol indicates the need for the user to consult the instructions for use.



WEEE

Explanation of symbols used in this "Instruction Manual"

	<p>■ This symbol is used to indicate the user's installation, operation and maintenance information, which is not dangerous, but is important for correct operation.</p>
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## 1.8 Electromagnetic compatibility requirements

Guide and manufacturer's statement - electromagnetic emissions		
color ultrasonic diagnostic apparatus is expected to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in such an electromagnetic environment.		
Emission test	Compliance	Electromagnetic environment - Guide
Radio frequency emission	1 group	color ultrasonic diagnostic apparatus uses RF energy only for its internal function. Therefore, its RF emissions are low and there is little chance of interference with nearby electronic equipment.
Radio frequency emission	A type	color ultrasonic diagnostic apparatus is suitable for use in all facilities that are not directly connected to the home and to the public low voltage power supply network of the home.
Harmonic emission	—	
Voltage fluctuation / flicker emission	—	

(Corresponds to IEC 60601-1-2:2014 and EN 60601-1-2:2015)

Guide and manufacturer's statement - electromagnetic immunity			
color ultrasonic diagnostic apparatus is expected to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - Guide


Electrostatic discharge IEC 61000-4-2:2008	$\pm 8$ kV Contact discharge $\pm 2, 4, 8, 15$ kV Air discharge	$\pm 8$ kV Contact discharge $\pm 2, 4, 8, 15$ kV Air discharge	The ground should be wood, concrete or ceramic. If the floor is covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient burst IEC 61000-4-4:2012	$\pm 2$ kV Power cord	$\pm 2$ kV Power cord	The network power supply should have the quality used in a typical commercial or hospital environment.
Surge IEC 61000-4-5:2005	$\pm 0.5, \pm 1$ kV line to line $\pm 0.5, \pm 1, \pm 2$ kV line to ground	$\pm 0.5, \pm 1$ kV line to line $\pm 0.5, \pm 1, \pm 2$ kV line to ground	The network power supply should have the quality used in a typical commercial or hospital environment.
Voltage dip, interruption and variations IEC 61000-4-11:2004	0% $U_T$ , Lasts for 0.5 cycle (At $0^\circ, 45^\circ, 90^\circ, 135^\circ, 180^\circ, 225^\circ, 270^\circ$ and $315^\circ$ ); 0% $U_T$ , lasts for 1 cycle and 70% $U_T$ , lasts for 25/30 cycles (Single phase: at $0^\circ$ ); 0% $U_T$ lasts for 250/300 cycles	0% $U_T$ , Lasts for 0.5 cycle (At $0^\circ, 45^\circ, 90^\circ, 135^\circ, 180^\circ, 225^\circ, 270^\circ$ and $315^\circ$ ); 0% $U_T$ , lasts for 1 cycle and 70% $U_T$ , lasts for 25/30 cycles (Single phase: at $0^\circ$ ); 0% $U_T$ lasts for 250/300 cycles	The network power supply should have the quality used in a typical commercial or hospital environment. If the user of the ultrasound system needs continuous operation during a power outage, it is recommended that the ultrasound system be powered by an uninterruptible power supply or battery.
Power frequency magnetic field (50Hz/60Hz) IEC	30A/m	30A/m	The power frequency magnetic field should have the characteristics of the power frequency



61000-4-8:2009			magnetic field in a typical place in a typical commercial or hospital environment.
Note: $U_T$ refers to the AC network voltage before the test voltage is applied.			

(Corresponds to IEC 60601-1-2:2014 and EN 60601-1-2:2015)

Guide and manufacturer's statement - electromagnetic immunity			
color ultrasonic diagnostic apparatus is expected to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment:			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - Guide
<p>Conducted Disturbances induced by RF fields</p> <p>IEC 61000-4-6:2013</p> <p>Radio frequency electromagnetic</p>	<p>3V</p> <p>0.15MHz ~ 80 MHz</p>	<p>3V</p> <p>0.15MHz ~ 80 MHz</p>	<p>Portable and mobile RF communications equipment should not be used closer to any part of the ultrasound system, including cables, than the recommended isolation distance. This distance should be calculated by the formula corresponding to the transmitter frequency.</p> <p>Recommended isolation distance</p> $d = 1.2 \sqrt{P}$ <p><math>d = 1.2 \sqrt{P}</math>      80 MHz ~ 800MHz</p> <p><math>d = 3.5 \sqrt{P}</math>      800 MHz ~ 2.5GHz</p> <p>In the formula above:</p> <p>P—based on the transmitter's maximum rated output power, in watts (W);</p> <p>d - is the recommended isolation distance in meters (m).</p> <p>The field strength of a fixed RF transmitter is determined by measuring the electromagnetic field, and each frequency range should be lower than the compliance level.</p>

field  IEC 61000-4-3 :2006+A1 :2007+A2 :2010	3V/m  80 MHz ~ 2.7GHz	3V/m	Interference may occur near devices marked with the following symbols.  
<p>Note 1: At the 80 MHz and 800 MHz frequency points, the formula for the higher frequency band is used.</p> <p>Note 2: These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by the absorption and reflection of buildings, objects and human bodies.</p> <p>a) Fixed transmitters, such as base stations for wireless (peak/cordless) telephones and terrestrial mobile radios, amateur radios, AM and FM radio broadcasts, and television broadcasts, are not theoretically predictable in terms of field strength. In order to assess the electromagnetic environment of a fixed RF transmitter, the survey of the electromagnetic field should be considered. If the measured field strength of the      ultrasonic diagnostic apparatus is higher than the applicable RF compliance level, the      ultrasonic diagnostic apparatus should be observed to verify that it can operate normally. Additional measures may be necessary if abnormal performance is observed, such as reorienting the position or position of the      ultrasound system.</p> <p>b) The field strength should be less than 3V/m over the entire frequency range from 150kHz to 80 MHz.</p>			

(Corresponds to IEC 60601-1-2:2014 and EN 60601-1-2:2015)

Recommended Isolation Distance between portable mobile RF communication equipment with Color Ultrasonic Diagnostic Apparatus			
Depending on the maximum output power of the communication device, the user of the      ultrasound can prevent electromagnetic interference by maintaining a minimum distance between the portable radio communication device (transmitter) with      ultrasound.			
Maximum rated output power of the transmitter W	Isolation distance corresponding to different frequencies of the transmitter/m		
	150kHz~80MHz	80MHz~800MHz	800MHz~2.5GHz
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$

0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For the maximum rated output power of the transmitter not listed in the above table, the recommended isolation distance  $d$  in meters (m) and can be determined by the formula in the corresponding transmitter frequency column, the  $P$  in above table is the transmitter maximum rated output power in watts (W).

Note 1: At the 80 MHz and 800 MHz frequency points, user should choose higher frequency band should be used.

Note 2: These guides may not be suitable for all situations. electromagnetic propagation is affected by the absorption and reflection of buildings, objects and the human body.

(Corresponds to IEC 60601-1-2:2014 and EN 60601-1-2:2015)

Please use the product according to the electromagnetic compatibility information in this manual.

Portable RF communications equipment may affect the normal use of this product. For example mobile phones and walkie-talkie.

Name	Cable length (m)	Model	Manufacturer	Shield or not
power cable	1.7	RVVZ-3P227IEC53(RVV)XD-001	NANCO ELECTRONIC	YES
Video line	1.5	232	ZHUHAI XINHE ELECTRONIC	YES
Adapter	1.0	PH180	ZHUHAI XINHE ELECTRONIC	YES
Probe	1.8	3.5MHZC2-6R65 6.5MHZC4-9R10 7.5MHZL5-12L46 3.0MHZP2-5L19 4.0MHZR40	SHENZHEN ULTRASONIC ELECTRONICS	YES

## 1.9 Safety Precautions

1. This equipment is operated by or under the direction of a qualified operator.
2. The patient should not touch or operate the device at any time.
3. This unit does not have any waterproof device. Do not use the unit where water may enter the unit. Never spill liquid on the machine or allow it to flow into the machine, otherwise there is a risk of electric shock.
4. Please connect the power supply and the ground correctly according to the operation manual , otherwise there is a danger of electric shock. Never connect the ground wire to any gas pipe or water pipe, otherwise there is a risk of poor grounding or explosion.
5. Use the probe carefully. If the contact surface of the probe( the side contact with the human body), stop use the probe immediately and contact the company or its authorized agent. There is a risk of electric shock if using a scratched probe.
6. Do not apply excessive vibration to the unit (such as when delivering equipment), otherwise mechanical parts (such as casters) may be damaged. If the unit needs to move frequently on bumpy ground, please contact the company or its authorized agent.
7. Do not use any probe that is not supplied by our company, otherwise it will cause damage to the unit and the probe. In extreme cases, fires and other accidents may occur.
8. Do not open the case or panel. If the case is opened while the power is on, there is a danger of short circuit or electric shock.
9. Before using the unit, please make sure that all parts are connected correctly and working properly. Any incorrect connection or using abnormal-working unit may cause electric shock.
10. Do not change the built-in parameters of the device. If it is necessary, ask for service with the company or its authorized agent.
11. The device has been adjusted to the best performance before leaving the factory. Except for the operation specified in the instruction manual, the user should not turn on the main unit and adjust any preset control or switch on circuit board.
12. If the equipment malfunctions, please shut down immediately and contact the company or its authorized agent.
13. The input and output interfaces of this device can only be connected to external devices that meet the safety requirements of GB9706.1, GB9706.9 or equivalent international safety standard IEC 60601-1.
14. If need to connect other companies' electronic or mechanical devices, please contact the company or its authorized agent before connecting.
15. Avoid the following operations and expected environment:
  - Ambient temperature is below -5 °C, over 40 °C
  - (Recommended operating temperature: + 5 °C ~ + 40 °C)
  - Atmospheric pressure below 860hPa, over 1060hPa

- the device is exposed to toxic gases
- Relatively high humidity, over 80%
- where the temperature or humidity change sharply
- close to the heat source
- near strong electromagnetic fields (such as transformers)
- near high frequency radiation device ( such as mobile phone)
- the device is exposed to water vapor
- The device is exposed to fog or splashing water
- the device is exposed to dust
- The equipment is exposed to high density LPG
- the device is exposed to salt spray
- The device is exposed to explosive gases or dust
- The device is in a strong impact or vibration environment
- The equipment is placed on the bottom plate with a slope of more than 10 degrees.
- AC power supply voltage is lower than 198V
- a sudden change during the output voltage of the AC supply voltage during operation of the device
- the device is exposed to direct sunlight
- poor ventilation of the equipment

**Warning**

- Do not use the unit in an environment where flammable gases (such as anesthetic gases, oxygen or hydrogen etc) are present. If used in these environments, it may cause an explosion.

**Warning**

- To avoid fatigue of the operator's hands, wrists or arms, please note the following two tips:
- Avoid long-term repetitive operations, take breaks regularly or do other activities;
- Avoid operating in an uncomfortable position that can cause fatigue in the operator's hands, wrists or arms.

**Warning**

- This equipment can not be installed in places with electromagnetic wave sources. Electromagnetic waves may cause the following faults: noise entering the equipment may interfere with the image; electromagnetic waves emitted by other medical equipment may affect the display of the monitor of the equipment, causing the image to be disordered, so it cannot be used at the same time. .
- If used with other equipment, keep the connecting cables at a distance far away from the probe cables, ECG cables, I/O cables, etc. to avoid interference from these devices.
- This instrument cannot be used with defibrillators, pacemakers or high frequency surgical equipment.
- This instrument cannot be applied directly to the heart!
- Equipment such as electric bicycle chargers and oscilloscopes can also cause interfere of this instrument.

**Warning**

- Always keep the unit dry and avoid moving the unit from a cold place to a warm place in short time. Otherwise, condensation or water droplets may occur, which may cause a short circuit.
- Normal ultrasound examinations do not present a risk of burns, even if the probe surface temperature exceeds the patient's temperature due to differences of ambient temperature and inspection mode. To avoid burns, do not leave the probe in the same part of the patient's body for long time. Under the conditions of diagnosis, try to shorten the inspection time.

**Notice**

- When doing thyroid examination, superficial examination and early pregnancy examination, the user should pay attention to controlling the sound power output and scanning time, in order to reduce the effect of sound output power on the organs.

**1.10 Power on / off notes****Prepare before starting up**

1. Power requirements for the running state of the machine: AC220V

Check the power supply voltage in local area. If the voltage is too high, too low or unstable, please configure an AC voltage regulator to ensure that the power supply voltage meets the requirements of the operating environment.

2. Check the electrical connection of the device with accessories or equipment (such as probes) to ensure

accurate and reliable connection of each interface.


3. When connecting this unit to external devices (such as color image recorders, ultrasonic workstations, etc.), it is required that: (1) all external devices must be confirmed according to their respective standards; (2) the electrical and structural properties of all external devices should comply with relevant safety standards. Requirements; (3) When an external device is connected to ultrasound to form a new medical system, it should be ensured that the new system is also in compliance with the relevant safety standards.

4. To avoid the risk of electric shock, the unit must be connected to an external input power outlet with protective earthing.

5. Set the switch of the main unit to “O” Position (off state) and then plug in the power plug.


### **Steps of power on**

1. Check and ensure that the power connection, probe connection and peripheral connections (if any peripherals) are accurate and reliable.

2. Turn on the power switch located on the side of the main unit box, the power indicator lights up, then press this button  on the operation panel, the instrument starts self-test and system initialization. Please do not press the operation panel or slide the trackball at this time, because operation at this time may cause the operation panel to lock up or the system to be confused. If this happens, Please turn it off and wait for 3 minutes before restarting the machine.

3. When the ultrasound completes the self-test and initialization, the system automatically enters the B mode freeze state, unfreeze the image. At this time, the operator can apply the ultrasonic coupling agent to the patient (please use an ultrasonic coupling agent that meets the national standard to make check in B mode, or conversion scan mode, for other methods of inspection.

### **Steps of power off**

1. When the ultrasound is finished used, you must first press the button  to turn off the machine. During this shutdown process, the operating system will record important information and delete the temporary file left during the operation. This process is very important, please be sure to follow.

2. Before leaving the ultrasonic chamber, it is recommended to unplug the power plug. When pulling the power plug, the plug should be held. It is strictly forbidden to pull the cord.

3. Wipe the coupling agent stuck to the probe, cable or other parts of the instrument in time.

4. Place the probe in the probe box of the device.

## **1.11 Safety operation precautions**

### **Host operation precautions**

1. Provide a good environment for use and keep the ultrasound equipment clean.

2. After turning off the power, avoid turning it on immediately, wait at least 5 seconds before turning it on again.

3, pay attention to the protection of the silicone button, the operation should be gentle, to avoid sharp objects scratch the button.

4. Clean the device with the specified cleaning agent (liquid). During the cleaning process, do not spill liquid into the machine, causing circuit failure or even danger.

5. Do not clean the monitor by hydrocarbon-based glass cleaner.

#### **Probe operation precautions**

1. Protect the probe, and it is strictly forbidden to collide, drop or scratch, causing damage to the probe and even causing danger.

2. Use an approved ultrasonic coupling agent.

3. It is strictly forbidden to insert or remove the probe under real-time working conditions.

4. It is strictly forbidden to bend or pull the probe cable and power cord forcibly.

5. Clean and disinfect the probe according to the specified method.

6. Do not touch the probe with paint thinner, ethylene oxide or other organic solvents.

#### **Probe anti-injection degree**

► Probe anti-injection degree: IPX7

Note: The degree of probe anti-immersion liquid meets the requirements of IPX7, namely:

1. 3.5MHz C2-6R65 convex array broadband probe, 7.5MHz L5-12L46 line array wide frequency probe, 3.0MHz P2-5L19 phased array broadband probe, 4.0MHzR40 convex array wide frequency volume probe. The depth of the probe immersed in water shall not exceed 5 mm from the surface of the lens;

2. The depth of 6.5MHz C4-9R10 convex array broadband probe and 6.5MHz C5-9R10 convex array broadband probe immersed in water should not exceed 10cm from the lens surface.

### **1.12 Biological effect**

During the ultrasound examination, ultrasound enters the body and interacts with the examined physiological structural zone and surrounding tissue. A small portion of the transmitted ultrasound is reflected back to the probe for image acquisition and the rest is consumed in the tissue. A sufficiently high interaction between ultrasound energy and tissue can produce biological effects, which may be mechanical or thermal effects. Although the biological effect is due to the application of diagnostic ultrasound, this biological effect is generally not required in the diagnosis, and it may be dangerous under certain conditions.。

So far, although there is no report that diagnostic ultrasound has caused significant biological effects in humans, it is generally believed that the frequency, intensity, and irradiation time of diagnostic ultrasound do not cause harmful biological effects, and people continue to conduct research on biological effects.

Clinicians should judge the pros and cons of ultrasound.



In March 1993, the American Society of Ultrasound Medicine published a formal statement on the safety of clinical application of ultrasound: "Diagnostic ultrasound has been applied since the late 1950s, and its advantages and effectiveness as a medical diagnostic tool have been proven, including in pregnant humans. Application. The American Academy of Ultrasound in Medicine hereby submits a clinical safety statement for ultrasound applications: there is no known report of biological effects caused by the patient's or instrument operators due to the conventional intensity of current diagnostic ultrasound instruments. The possibility of biological effects may be determined in the future, but current data suggest that the use of diagnostic ultrasound with caution is far more beneficial to patients than hazard, if the hazard exists."

The American Society of Ultrasound Medicine (AIUM) has issued the following statement on obstetric ultrasound: "AIUM promotes responsible ultrasound diagnostic applications. AIUM strongly opposes non-medical ultrasound applications for psychological, social or recreational purposes. 2D or three-dimensional (3D) ultrasound to observe only the fetus, to obtain images of the fetus, or to determine the sex of the fetus in the absence of medical evidence is inappropriate, contrary to medical professional ethics. Although currently it is still not confirmed whether it will cause biological effects on patients when exposing to ultrasound diagnosis, but this biological effect is likely to be determined in the future. Therefore, ultrasound should be applied with caution to provide medical benefits to patients."

### **Thermal effect**

Like other forms of energy, ultrasound energy is attenuated and converted into energy as it passes through the tissue. If this energy is generated a lot, it will heat up the tissue and may cause harm. The main factors affecting the thermal effect are mainly the organizational characteristics or control parameters.

The physical properties of the tissue such as acoustic impedance, attenuation, absorption and permeability determine the generation and transmission of heat.

The time average intensity of the ultrasonic energy is determined by the ultrasound parameters. These parameters include: output frequency, pulse amplitude, pulse duration, pulse period, beam shape, and beam motion. These parameters are controlled by the operator's choice of device options such as probe type, operating mode, focus depth, sample volume position, and output settings. It can also have a significant impact if operator change the direction of motion and dwell time of the probe. These parameters give the operator the ability to minimize thermal effects.

### **Mechanical effect**

Similar to the thermal effect, the interaction between ultrasonic energy and tissue can produce mechanical effects. The most important of these is the cavitation effect caused by the ultrasonic pressure on the tiny bubbles inside the tissue. In laboratory small animal experiments, cavitation effects cause cell-level mechanical damage such as minute rupture and bleeding. The main factors affecting mechanical effects are organizational characteristics or control parameters:

The physical properties of the tissue, such as the presence and size of tiny bubbles, and the sensitivity of the tissue to cavitation effects all influence the generation and action of cavitation effects.

Ultrasonic field parameters (eg, ultrasonic output frequency, pulse peak amplitude, and possible pulse duration) are the main factors affecting cavitation effects. These factors can be controlled by the operator through appropriate equipment control options.

**Operator intervention**

Try to optimize the gain and other image enhancement functions before increasing the sound power output or before changing other device control parameters that will significantly affect the sound power output.

Develop and practice techniques for determining anatomy and quickly optimizing image quality, and freeze the image as soon as the required diagnostic information is obtained. It takes time to cause tissue warming, so reducing the exposure time can greatly reduce the possibility of injury.

Avoid possible tissue damage if possible by changing the probe position, angle of incidence or probe type.

The penetration depth of the high frequency probe is small. Line array probes have lower energy intensity.

Avoid focusing on tissues with little bone or blood penetration. Do not let the ultrasound beam pass through the eye, focus on the eye or near the eye.

**ALARA principle**

We have a simple principle of using ultrasonic energy, called "ALARA" (as low as reasonably achievable, ALARA), which is the principle that ultrasonic irradiation should be "as low as reasonably possible". Following this principle means that we keep the overall ultrasound exposure as reasonably low as possible, while at the same time obtaining the most appropriate diagnostic information.

The amount of control that does not significantly affect the image quality should be set to minimize the sound power output, and the setting that can change the image quality but also increase the amount of control of the sound power output should be as small as possible while obtaining the diagnostic level image.



- The sound output limit of this device is lower than the US FDA's limit when it is turned on.
- This device maintains an acoustic output below the appropriate limit for various applications, as shown below. Because the size difference is significant, it is required to select the correct application and not to quit the application, so as to ensure that the correct application restrictions are used in the corresponding application environment.
- The sound output limits of the diagnostic system are as follows:  
 $I_{spta.3} < 720 \text{ mW/cm}^2$ ;  
 $MI < 1.9$ ;  
 $TI < 6.0$

**1.13 Waste treatment**

The waste generated during the packaging and use of this product, such as cleaning paper and empty bottles after using up the coupling agent, should be disposed of in accordance with the regulations of the local

environmental protection department.

## Chapter 2 System Overview

### 2.1 Product Introduction

- ▶ Color Ultrasonic Diagnostic Apparatus consists of a host (including software) and a probe. The structure type is a cart type, including a cart type single screen and a cart type double screen.
- ▶ Probe includes: 3.5MHzC2-6R65 convex array broadband probe, 6.5MHz C4-9R10 convex array broadband probe, 7.5MHz L5-12L46 line array broadband probe, 3.0MHz P2-5L19 phased array broadband probe, 4.0MHzR40 convex array broadband volume probe, 6.5 MHzC5-9R10 convex array broadband probe.
- ▶ The main unit includes: ultrasonic transmitting/receiving circuit, signal processing and image display.
- ▶ Highly integrated digital color Doppler technology
- ▶ Strong combined modular software design
- ▶ Full digital large-capacity image storage and file archiving management
- ▶ Software related information
- ▶ Software Name: Dawei color Doppler ultrasound diagnostic application software
- ▶ The full version number of this software: V1.0.0.1010, release version: V1.0

Operating environment:

Hardware configuration	Processor	performance is higher than or equivalent to PM1.8G CPU
	Internal memory	at least 2G memory
	External memory	at least 32G hard disk
	External interface	at least one RS232 serial port
	Peripheral devices	CD drive, mouse, keyboard, printer
Software Environment	System Software	32 Microsoft Windows® XP
	Support Software	.NET Framework 4.0
	Security software	Windows Firewall
Network condition	network architecture	no requirement

	Network type	no requirement, single or networked PC
	Bandwidth requirements	no requirement

### ► Cybersecurity information

#### ❖ Data transmission

Network condition: Wired network

Network port: RJ-45 Port, 10/100/1000M self-adaption

Storage format: system data format, i.e. BMP, DICOM, JPEG, DEFAULT

Data type: PII data (clinical application)

Transmission protocol: TCP/IP

Transmission direction: uni-directional both between the device and server/PACS and between the device and printer

#### ❖ Remote control: NA

#### ❖ User identification: User name, password

User type: Users

User Authentication: user can get access to product normally after logging in correct user name and password.

#### ❖ Network condition

Network type: Wired network

Network port: RJ-45

Network architecture: none

DIMDI code: DIMDI Code: DE/0000047791

#### ❖ Security software: none.

## 2.2 Clinical application

The blood flow of abdominal organs, heart, superficial tissues and organs is imaged by convex, transvaginal and transrectal probes. It does not include the unconventional application and contact with circulating blood. The clinical scope, imaging mode and function of all probes are as follows:

a) System: Color Ultrasonic Diagnostic Apparatus

Probe: 3.5MHzC2-6R65 convex array broadband probe

Intended use: ultrasound diagnostic imaging or human blood flow analysis

Clinical application	work mode, function														
Specific application	B	2B	4B	B/M	M	PWD	CPWD	CFM	B/C	B/C/D	B/D	Tri-sync / Bi-sync selection	Speed, energy, variance	zone	beam sampling line
fetus	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Abdomen	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Pediatrics	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√

b) System: Color Ultrasonic Diagnostic Apparatus

Probe: 6.5MHz C4-9R10 convex array broadband probe

Intended use: ultrasound diagnostic imaging or human blood flow analysis

Clinical application	work mode, function														
Specific application	B	2B	4B	B/M	M	PWD	CPWD	CFM	B/C	B/C/D	B/D	Tri-sync / Bi-sync selection	Speed, energy, variance	zone	beam sampling line
Transrectal	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Transvaginal	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√

c) System: Color Doppler Ultrasound Diagnostic System

Probe: 6.5MHz C5-9R10 convex array broadband probe

Intended use: ultrasound diagnostic imaging or human blood flow analysis

Clinical application	work mode, function														
Specific application	B	2B	4B	B/M	M	PWD	CPWD	CFM	B/C	B/C/D	B/D	Tri-sync / Bi-sync selection	Speed, energy, variance	zone	beam sampling line
Transvaginal	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√

## d) System: Color Doppler Ultrasound Diagnostic System

Probe: 7.5MHz L5-12L46 linear array wide frequency probe

Intended use: ultrasound diagnostic imaging or human blood flow analysis

Clinical application	work mode, function															
Specific application	B	2 B	4B	B/ M	M	PW D	CP WD	CF M	B/C	B/C/ D	B/D	Wide view imaging	Tri-sync / Bi-sync selection	Speed, energy, variance	zone	beam sampling line
pediatrics	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Small organs (breast, thyroid, testicles)	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Musculoskeletal (on the epidermis )	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Peripheral blood vessel	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√

## e) System: Color Ultrasonic Diagnostic Apparatus

Probe: 3.0MHz P2-5L19 phased array wide frequency probe

Intended use: ultrasound diagnostic imaging or human blood flow analysis

Clinical application	work mode, function															
Specific application	B	2B	4B	B/M	M	PWD	CPWD	CFM	B/C	B/C/D	B/D	CW	Tri-sync / Bi-sync selection	Speed, energy, variance	zone	beam sampling line
Adult cardiac	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Pediatric cardiac	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√

f) System: Color Ultrasonic Diagnostic Apparatus

Probe: 4.0MHzR40 convex array wide frequency volume probe

Intended use: ultrasound diagnostic imaging or human blood flow analysis

Clinical applicat ion	work mode, function																
Specific applicati on	B	2B	4B	B/ M	M	PW D	CP WD	CF M	B/C	B/C/D	B/D	3D imagi ng	Real- time 3D imagi ng	Tri-sync / Bi-sync selectio n	Spee d, energ y, varia nce	zone	beam sampli ng line
fetal	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√



abdomen	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
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- When the user is doing superficial small organ examination and early pregnancy examination, attention should be paid to control the ultrasonic power and scanning time to reduce the action time of the acoustic output power on the organ.

## 2.3 Contraindications

- This equipment is not suitable for the examination of gas-containing organs such as lungs.
- It is recommended not to explore wounded or acutely inflammatory sites to avoid cross infection.
- The vaginal and rectal probes are disabled in the following patients: vaginal inflammation, such as trichomonas vaginitis, fungal vaginitis, sexually transmitted diseases, etc .; unmarried; vaginal deformities; menstrual periods; postmenopausal vaginal atrophy; vaginal ultrasound examination difficulties; vaginal bleeding ; Patients with placenta previa and so on.
- Puncture is disabled in the following patients:  
Hypertension, coronary heart disease, patients with coagulopathy and bleeding tendency.

## 2.4 System description

### Shape

- ▶ Host size: 600 × 917 × 1450mm
- ▶ Host weight: 126Kg
- ▶ Display: 21.5-inch LCD monitor, 13.3-inch touch screen

### Power requirements

- ▶ Power requirements: AC220V ± 22V, frequency 50Hz ± 1Hz
- ▶ Input power: 350VA.

### scanning method

- ▶ Electronic linear array, electronic convex array

### Digital beamforming

- ▶ Fully digital
- ▶ Real-time global dynamic focus
- ▶ Variable Aperture
- ▶ Focus distance adjustable

**Imaging mode**

Including: B, 2B, 4B, B / M, M, PWD (up and down or left and right), CPWD (up and down or left and right), CFM, B / C split screen, B / C / D, B / D, CW, Wide View Imaging, 3D imaging, real-time 3D imaging, tri-sync / bi-sync selection, speed, energy (direction), variance, local magnification, beam sampling line, etc.

Among them: PWD (up and down or left and right), CPWD (up and down or left and right), CW, wide-field imaging, 3D imaging, real-time 3D images are optional functions



The color blood flow mode is convenient for observing the information of color blood flow and judging the flow direction and speed of blood flow by color. Generally, the color above the baseline of the color bar indicates the flow to the probe, and the color below indicates the blood flow away from the probe. The brighter the color, the faster the blood flow, and the darker the color, the slower the blood flow.

**Gain adjustment**

- ▶ 8-segment TGC adjustable
- ▶ Total gain adjustment
- ▶ PW gain adjustment
- ▶ CFM gain adjustment
- ▶ B / M, M gain adjustment

**Black and white image function adjustment**

- ▶ Sound power adjustment
- ▶ Second harmonic adjustment
- ▶ Transmission frequency adjustment
- ▶ Focus number adjustment
- ▶ Scan density adjustment
- ▶ Scan range adjustment
- ▶ Dynamic range adjustment
- ▶ Image optimization adjustment
- ▶ Smooth processing adjustment
- ▶ Edge Enhancement Adjustment
- ▶ Frame-dependent B adjustment
- ▶ Grayscale curve adjustment
- ▶ Smart optimization

- ▶ Flip up and down
- ▶ Left and right black and white flip
- ▶ Doppler stereo output volume adjustable

#### **Color image function adjustment**

- ▶ Sound power adjustment
- ▶ Threshold adjustment
- ▶ Transmission frequency C adjustment
- ▶ Wall filter adjustment
- ▶ Display mode adjustment
- ▶ Deflection angle adjustment
- ▶ Frame-dependent C adjustment
- ▶ Sampling block size adjustment
- ▶ Pulse repetition frequency adjustment
- ▶ Blood line density adjustment
- ▶ Baseline adjustment
- ▶ Spatial filter adjustment
- ▶ Sampling frame adjustment

#### **Doppler function adjustment**

- ▶ Sound power adjustment
- ▶ Volume adjustment
- ▶ Transmission frequency adjustment
- ▶ D linear speed adjustment
- ▶ Deflection angle adjustment
- ▶ Baseline adjustment
- ▶ Doppler angle adjustment
- ▶ Sampling volume adjustment
- ▶ Blood flow adjustment

#### **3D imaging / real-time 3D imaging adjustment**

- ▶ 4 side / 2 side / single side image adjustable
- ▶ Image rotation adjustable

- ▶ ZOOM zoom
- ▶ Grayscale curve adjustable
- ▶ Color adjustment
- ▶ Smooth adjustment

#### **Basic measurement calculation functions**

▶ B mode basic measurement: line segment, angle, perimeter and area (ellipse method, track method), volume, histogram, cross-section

- ▶ M mode basic measurement: time, distance, heart rate, valve speed

#### **Doppler measurement calculation function**

- ▶ Time, heart rate, speed, acceleration, general measurement, Doppler measurement, Doppler trace

#### **Obstetric measurement calculation function**

▶ Can measure fetal sac (GS), head-rump length (CRL), double parietal diameter (BPD), head circumference (HC), abdominal circumference (AC), femur length (FL), humerus length (HL), abdominal transverse diameter (TAD), spine length (LV), occipital frontal diameter (OFD), cerebellar diameter (EREb), fibula length (FIB), radius length (RADIUS), Magna pool (CM), orbital distance (IOD), Orbital distance (OOD), amniotic fluid index (AFI), fetal heart rate (HR), length, area, and estimated cervical transparent layer length (NT).

- ▶ Selection of obstetric database version
- ▶ Edition of obstetric database version
- ▶ Calculate gestational age and estimate the due date
- ▶ Obstetric Measurement Calculation Report
- ▶ Estimated Fetal Weight
- ▶ Estimating gestational weeks and expected birth functions from LMP and BBT

#### **Gynecological measurement calculation function**

- ▶ Uterus, left ovary, right ovary, left follicle, right follicle measurement calculation
- ▶ Gynecological measurement calculation report

#### **Urology measurement and calculation function**

▶ Measurement and calculation of left kidney, right kidney, bladder, and bladder (Residual urine vol) after urination

- ▶ Urology measurement calculation report
- ▶ Calculate residual urine volume

#### **Peripheral vascular measurement calculation function**

- ▶ Measurement and calculation of area stenosis rate and tube diameter stenosis rate

- ▶ Peripheral vascular measurement calculation report

#### **Small organ measurement calculation function**

- ▶ Thyroid, breast, and mass measurement calculations
- ▶ Small organ measurement calculation report

#### **Cardiac measurement calculation function**

- ▶ Provide left ventricle, aorta, mitral valve, ventricle (right / left ventricle) measurements

#### **3D imaging / real-time 3D imaging measurement calculation function**

- ▶ Distance, trace, area, perimeter, angle, volume, ellipse measurement

#### **Human body sign**

- ▶ Body mark  $\geq 100$  for each organ

#### **Annotation and display**

- ▶ Real-time clock display
- ▶ Image area annotation

#### **Movie playback function**

- ▶ Auto playback
- ▶ Store picture dynamic playback
- ▶ Playback frame selection
- ▶ 3D playback
- ▶ Cancel, resume, pause, playback control

#### **Storage function**

- ▶ Image storage capacity:  $\geq 120\text{G}$
- ▶ Image format: BMP, JPEG, PNG, DICOM

#### **Report editing print function**

- ▶ Report editing functions
- ▶ Report printing

#### **Grayscale**

- ▶ 256 gray levels

#### **Interface language**

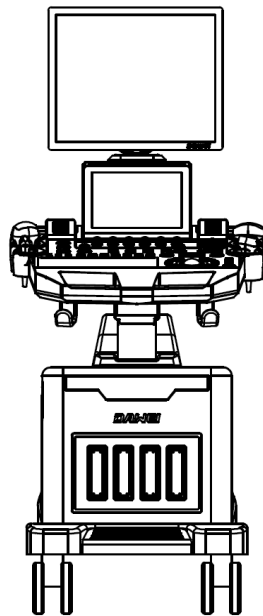
- ▶ 10 types languages

#### **In / Out interface**

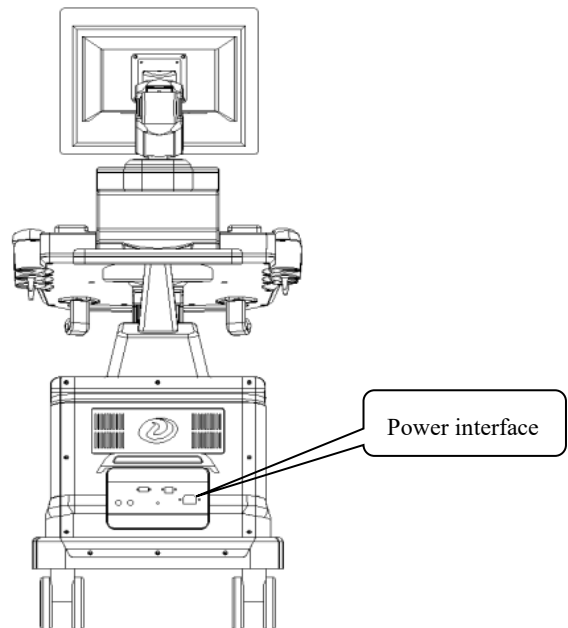
- ▶ USB interface
- ▶ Network Interface
- ▶ HDMI interface

## 2.5 Host appearance

The appearance of the device host is as follows:

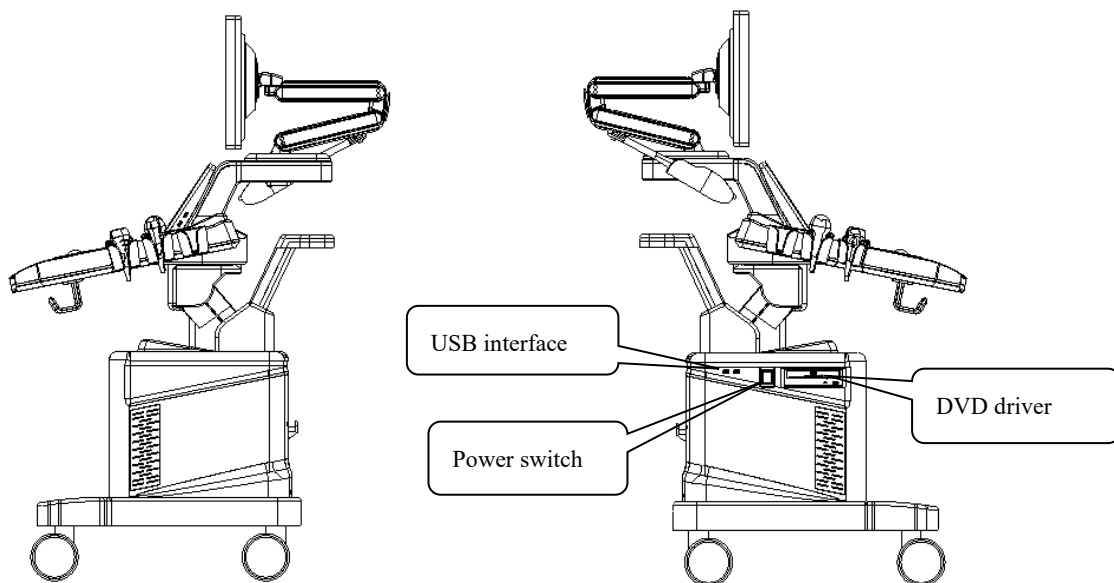


Front view



Back view

HD display



Side(right) view

Side(left) view

## Chapter 3 Probe Introduction

### 3.1 Probe configuration

The host can configure the probe types as follows:

Probe model	3.5MHzC2-6R65	6.5MHzC4-9R10	7.5MHzL5-12L46	3.0MHzP2-5L19	6.5MHzC5-9R10	4.0MHzR40
Probe type	Convex array wide frequency probe	Convex array wide frequency probe	Linear array wide frequency probe	Phased array wide frequency probe	Convex array wide frequency probe	Convex array wide frequency volume probe
Frequency range MHz	2.0~5.5	5.0~9.0	6.0~12.0	2.0~5.0	5.0~9.0	2.0~5.5
Nominal frequency MHz	3.5	6.5	7.5	3.0	6.5	4.0

### 3.2 Grayscale imaging performance index

3.5MHzC2-6R65 Convex Array Broadband Probe Parameters					
Probe frequency	2.0MHz (frequency)	3.0MHz (frequency conversion)	3.5 MHz (standard)	4.0MHz (frequency conversion)	5.5 MHz (frequency conversion)
Probe type	3.5MHzC2-6 R65				
Acoustic operating frequency	The deviation between the working frequency of the sound of the probe and the nominal frequency of the machine should be within $\pm 15\%$ .				
Detection depth mm	$\geq 160$	$\geq 160$	$\geq 160$	$\geq 100$	$\geq 100$
Lateral resolution mm	$\leq 3$ (depth $\leq 80$ ) $\leq 4$ ( $80 < \text{depth} \leq 130$ )	$\leq 3$ (depth $\leq 80$ ) $\leq 4$ ( $80 < \text{depth} \leq 130$ )	$\leq 3$ (depth $\leq 80$ ) $\leq 4$ ( $80 < \text{depth} \leq 130$ )	$\leq 2$ (depth $\leq 60$ )	$\leq 2$ (depth $\leq 60$ )
Axial resolution mm	$\leq 2$ (depth $\leq 80$ ) $\leq 3$ ( $80 < \text{depth} \leq 130$ )	$\leq 2$ (depth $\leq 80$ ) $\leq 3$ ( $80 < \text{depth} \leq 130$ )	$\leq 2$ (depth $\leq 80$ ) $\leq 3$ ( $80 < \text{depth} \leq 130$ )	$\leq 1$ (depth $\leq 80$ )	$\leq 1$ (depth $\leq 80$ )



Blind area mm	≤5	≤5	≤5	≤4	≤4
Slice thickness mm	≤9	≤9	≤9	≤9	≤9
Transverse geometric position accuracy%	≤15	≤15	≤15	≤15	≤15
Longitudinal geometric position	≤10	≤10	≤10	≤10	≤10
Perimeter and area measurement	±20	±20	±20	±20	±20
M mode time display deviation %	±11	±11	±11	±11	±11
M mode distance display deviation%	±11	±11	±11	±11	±11
6.5MHzC4-9R10 Convex array broadband probe parameters					
Probe frequency	5.0 MHz（frequency	6.5 MHz（standard）		9.0MHz（frequency	
Probe type	6.5MHzC4-9 R10				
Acoustic operating frequency	The deviation between the working frequency of the sound of the probe and the nominal frequency of the machine should be within ± 15%.				
Detection depth mm	≥80		≥40		≥40
Lateral resolution mm	≤2（depth≤40）		≤2（depth≤30）		≤1（depth≤30）
Axial resolution mm	≤1（depth≤40）		≤1（depth≤40）		≤0.5（depth≤30）
Blind area mm	≤5		≤4		≤3
Slice thickness mm	≤5		≤5		≤5
Transverse	≤20		≤10		≤5
Longitudinal	≤10		≤5		≤5
Perimeter and area	±20		±20		±20
M mode time display deviation %	±11		±11		±11
M mode distance	±11		±11		±11
7.5MHzL5-12L46 Linear array broadband probe parameters					
Probe frequency	6.0 MHz（frequency conversion）	7.5 MHz（standard）		12.0 MHz（frequency conversion）	
Probe type	7.5MHzL5-12 L46				

Acoustic operating frequency	The deviation between the working frequency of the sound of the probe and the nominal frequency of the machine should be within $\pm 15\%$ .		
Detection depth mm	$\geq 50$	$\geq 50$	$\geq 30$
Lateral resolution	$\leq 2$ (depth $\leq 40$ )	$\leq 2$ (depth $\leq 40$ )	$\leq 1$ (depth $\leq 30$ )
Axial resolution	$\leq 1$ (depth $\leq 50$ )	$\leq 1$ (depth $\leq 50$ )	$\leq 0.5$ (depth $\leq 30$ )
Blind area mm	$\leq 3$	$\leq 3$	$\leq 2$
Slice thickness mm	$\leq 5$	$\leq 5$	$\leq 5$
Transverse	$\leq 10$	$\leq 10$	$\leq 5$
Longitudinal	$\leq 5$	$\leq 5$	$\leq 5$
Perimeter and area	$\pm 20$	$\pm 20$	$\pm 20$
M mode time	$\pm 11$	$\pm 11$	$\pm 11$
M mode distance	$\pm 11$	$\pm 11$	$\pm 11$
3.0MHzP2-5L19 Phased array broadband probe parameters			
Probe frequency	2.0 MHz (frequency conversion)	3.0 MHz (standard)	5.0 MHz (frequency conversion)
Probe type	3.0MHzP2-5 L19		
Acoustic operating frequency	The deviation between the working frequency of the sound of the probe and the nominal frequency of the machine should be within $\pm 15\%$ .		
Detection depth mm	$\geq 140$	$\geq 140$	$\geq 80$
Lateral resolution mm	$\leq 3$ (depth $\leq 80$ ) $\leq 4$ ( $80 < \text{depth} < 130$ )	$\leq 3$ (depth $\leq 80$ ) $\leq 4$ ( $80 < \text{depth} < 130$ )	$\leq 2$ (depth $\leq 40$ )
Axial resolution	$\leq 2$ (depth $\leq 80$ )	$\leq 2$ (depth $\leq 80$ )	$\leq 1$ (depth $\leq 40$ )
Blind area mm	$\leq 7$	$\leq 7$	$\leq 5$
Slice thickness mm	$\leq 9$	$\leq 9$	$\leq 9$
Transverse geometric position	$\leq 20$	$\leq 20$	$\leq 20$
Longitudinal geometric position accuracy %	$\leq 10$	$\leq 10$	$\leq 10$
Perimeter and area measurement deviation %	$\pm 20$	$\pm 20$	$\pm 20$
M mode time display deviation %	$\pm 11$	$\pm 11$	$\pm 11$
M mode distance display deviation%	$\pm 11$	$\pm 11$	$\pm 11$

6.5MHzC5-9R10 Convex array broadband probe parameters			
Probe frequency	5.0 MHz (frequency conversion)	6.5 MHz (Standard)	9.0MHz (frequency conversion)
Probe type	6.5MHzC5-9 R10		
Acoustic operating frequency	The deviation between the working frequency of the sound of the probe and the nominal frequency of the machine should be within $\pm 15\%$ .		
Detection depth mm	$\geq 80$	$\geq 40$	$\geq 40$
Lateral resolution	$\leq 2$ (depth $\leq 40$ )	$\leq 2$ (depth $\leq 30$ )	$\leq 1$ (depth $\leq 30$ )
Axial resolution	$\leq 1$ (depth $\leq 40$ )	$\leq 1$ (depth $\leq 40$ )	$\leq 0.5$ (depth $\leq 30$ )
Blind area mm	$\leq 5$	$\leq 4$	$\leq 3$
Slice thickness mm	$\leq 5$	$\leq 5$	$\leq 5$
Transverse geometric position	$\leq 20$	$\leq 10$	$\leq 5$
Longitudinal geometric position accuracy %	$\leq 10$	$\leq 5$	$\leq 5$
Perimeter and area	$\pm 20$	$\pm 20$	$\pm 20$
M mode time display deviation %	$\pm 11$	$\pm 11$	$\pm 11$
M mode distance	$\pm 11$	$\pm 11$	$\pm 11$
4.0MHzR40 Convex array broadband volume probe parameters			
Probe frequency	2.0 MHz (frequency conversion)	4.0 MHz (Standard)	5.5MHz (frequency conversion)
Probe type	4.0MHz R40		
Acoustic operating frequency	The deviation between the working frequency of the sound of the probe and the nominal frequency of the machine should be within $\pm 15\%$ .		
Detection depth mm	$\geq 160$	$\geq 100$	$\geq 100$
Lateral resolution mm	$\leq 3$ (depth $\leq 80$ ) $\leq 4$ ( $80 < \text{depth} \leq 130$ )	$\leq 2$ (depth $\leq 60$ )	$\leq 2$ (depth $\leq 60$ )
Axial resolution mm	$\leq 2$ (depth $\leq 80$ ) $\leq 3$ ( $80 < \text{depth} \leq 130$ )	$\leq 1$ (depth $\leq 80$ )	$\leq 1$ (depth $\leq 80$ )
Blind area mm	$\leq 5$	$\leq 4$	$\leq 4$
Slice thickness mm	$\leq 9$	$\leq 9$	$\leq 9$

Transverse	≤15	≤15	≤15
Longitudinal	≤10	≤10	≤10
Perimeter and area	±20	±20	±20
M mode time	±11	±11	±11
M mode distance	±11	±11	±11

### 3.3 Color flow imaging mode performance

► In color flow imaging mode, the depth of each probe at corresponding Doppler operating frequency should meet the requirements in the table below.

Color flow imaging mode performance

No.	Performance	Unit	Performance requirements					
			3.5MHzC2-6R65 Convex array broadband probe		6.5MHzC4-9R10 Convex array broadband probe		7.5MHzL5-12L46 Linear array broadband probe	
1	Doppler frequency	MHz	2.0	3.0	5.0	5.5	6.0	6.5
2	Probe Scanning depth	mm	≥100	≥80	≥40	≥30	≥40	≥30
3	Maximum displayed scanning depth of blood flow	mm	300	300	160	160	110	110
No.	Performance	Unit	Performance requirements					
			3.0MHzP2-5L19 Phased array broadband probe		6.5MHzC5-9R10 Convex array broadband probe		4.0MHzR40 Convex array broadband volume probe	
4	Doppler frequency	MHz	2.0	3.0	5.0	5.5	3.0	3.5
5	Probe Scanning depth	mm	≥100	≥80	≥40	≥30	≥80	≥60

6	Maximum displayed scanning depth of blood flow	mm	300	300	160	160	300	300
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► In color flow imaging mode, the depth of each probe at corresponding Doppler operating frequency should meet the requirements in the table above.

- The color blood flow image should basically coincide with the corresponding grayscale image
- The direction of blood flow should be correctly identified without aliasing.
- 

### 3.4 Spectral Doppler mode performance

► In Spectral Doppler mode, the depth of each probe at corresponding Doppler operating frequency should meet the requirements in the table below.

Spectral Doppler mode performance

No.	Performance	Unit	Performance requirements					
			3.5MHzC2-6R65 Convex array broadband probe		6.5MHzC4-9R10 Convex array broadband probe		7.5MHzL5-12L46 Linear array broadband probe	
1	Doppler frequency	MHz	2.0	3.0	5.0	5.5	6.0	6.5
2	Probe Scanning depth	mm	≥100	≥80	≥40	≥30	≥40	≥30
3	Maximum displayed scanning depth of blood flow	mm	300	300	160	160	110	110
No.	Performance	Unit	Performance requirements					
			3.0MHzP2-5L19 Phased array broadband probe		6.5MHzC5-9R10 Convex array broadband probe		4.0MHzR40 Convex array broadband volume probe	
4	Doppler frequency	MHz	2.0	3.0	5.0	5.5	3.0	3.5
5	Probe Scanning depth	mm	≥100	≥80	≥40	≥30	≥80	≥60

6	Maximum displayed scanning depth of blood flow	mm	300	300	160	160	300	300
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► In Spectral Doppler mode, the depth of each probe at corresponding Doppler operating frequency should meet the requirements in the table above.

### 3.5 Color blood flow velocity measurement display

► In spectral Doppler mode, the minimum resolvable blood flow velocity displayed by the color flow velocity measurement should meet the requirements in the table below.

Color blood flow velocity measurement display

No.	Performance	Unit	Performance requirements					
			3.5MHzC2-6R65 Convex array broadband probe		6.5MHzC4-9R10 Convex array broadband probe		7.5MHzL5-12L46 Linear array broadband probe	
1	Doppler frequency	MHz	2.0	3.0	5.0	5.5	6.0	6.5
2	Minimum resolvable blood flow velocity	cm/s	0.2	0.2	0.2	0.2	0.2	0.2
3	Maximum display blood flow velocity	cm/s	1150	800	570	470	480	470
No.	Performance	Unit	Performance requirements					

			3.0MHzP2-5L19 Phased array broadband probe		6.5MHzC5-9R10 Convex array broadband probe		4.0MHzR40 Convex array broadband volume probe	
4	Doppler frequency	MHz	2.0	3.0	5.0	5.5	3.0	3.5
5	Minimum resolvable blood flow velocity	cm/s	0.2	0.2	0.2	0.2	0.2	0.2
6	Maximum display blood flow velocity	cm/s	1000	740	570	470	480	470

► In spectral Doppler mode, the maximum blood flow velocity displayed by the color flow velocity measurement should meet the requirements in the above table.

- The error of blood flow velocity of color ultrasound should not exceed 20%.
- The sampling position of the sampling area in pulse wave Doppler mode should be accurate.

### 3.6 3D Imaging mode performance

For 4.0 MHzR40 convex array wide-band volume probe in 3D/real-time 3D imaging mode: detecting depth, blind zone, lateral resolution of scanning direction, lateral resolution of pitch direction, axial resolution, spatial geometric position accuracy of scanning direction, space of pitch direction Geometric position accuracy, axial spatial geometric position accuracy, and volume measurement error should meet the requirements of the following table.

Probe model	4.0MHzR40		
Probe frequency	2.0 MHz ( frequency conversion )	4.0 MHz ( standard )	5.5MHz ( frequency conversion )
Probing depth mm	≥160	≥100	≥100
Blind area mm	≤5	≤4	≤4
Scanning direction	≤3 ( depth≤80 ) ≤4 ( 80<depth≤130 )	≤2 ( depth≤60 )	≤2 ( depth≤60 )
Lateral resolution mm	≤3 ( depth≤80 ) ≤4 ( 80<depth≤130 )	≤2 ( depth≤60 )	≤2 ( depth≤60 )

Pitch direction	$\leq 2$ (depth $\leq 80$ ) $\leq 3$ (80<depth $\leq 130$ )	$\leq 1$ (depth $\leq 80$ )	$\leq 1$ (depth $\leq 80$ )
Scanning direction space geometric position accuracy%	$\leq 15$	$\leq 15$	$\leq 15$
Pitch direction space geometric position accuracy%	$\leq 15$	$\leq 15$	$\leq 15$
Axial spatial geometric position accuracy%	$\leq 10$	$\leq 10$	$\leq 10$
Volume measurement error %	$\pm 30$	$\pm 30$	$\pm 30$

## Chapter 4 Instrument Installation

### 4.1 Installation conditions

#### Environmental requirements

The equipment should be used in a dark room environment with no strong electromagnetic field interference, no strong electric interference in the power grid line, good ventilation, relatively stable room temperature, clean, clean, non-toxic, non-corrosive, and no flammable gas.

The equipment should be operated, stored and transported under the following parameters.



	Working	Transportation and storage
Environment temperature range	+5°C~+40°C	-40°C~+55°C
Relative humidity range	30%~80%	< 90%
Atmospheric pressure range	860hPa~1060hPa	860hPa~1060hPa
power supply	AC220V±22V, Frequency 50Hz±1Hz	——



- When the device enters the room after being transported, it may be affected by the outdoor environment, and it may be very cold or hot. This temperature difference may cause water vapor condensation inside the device. Therefore, it is necessary to adapt the environment before powering on. If the outdoor temperature is below 10 ° C or above 40 ° C, the device needs to be placed in the use environment for more than half an hour, and the placing time will increase by one hour for temperature difference of each 2.5 ° C.



- The working environment of the equipment should be far away from generators, X-ray machines, ultrasonic atomizers, lithotripters, radio stations, television stations, computers, and transmission cables to avoid interference with the image.
- The equipment works best in an air-conditioned environment.

### **Power requirements**

Use an independent network power supply socket, and keep it away from strong electric field, strong magnetic field equipment and high voltage equipment.

For domestic users, the ultrasound studio should have an alternating current (AC) 220V "hospital-grade" or "hospital-dedicated" power supply, the power socket should have a current capacity of 10A or more, and it must have terminals or grounding devices connected to protective ground.

Recommended working voltage: AC 220V22V 50Hz1Hz



- To avoid the risk of fire, the equipment must be powered separately.
- Use the power cord provided with the power supply, and do not replace it at will.
- Make sure the network power supply is reliably grounded. Do not use a two-core power adapter board.

### **Preparation for installation**

Before installing, please check:

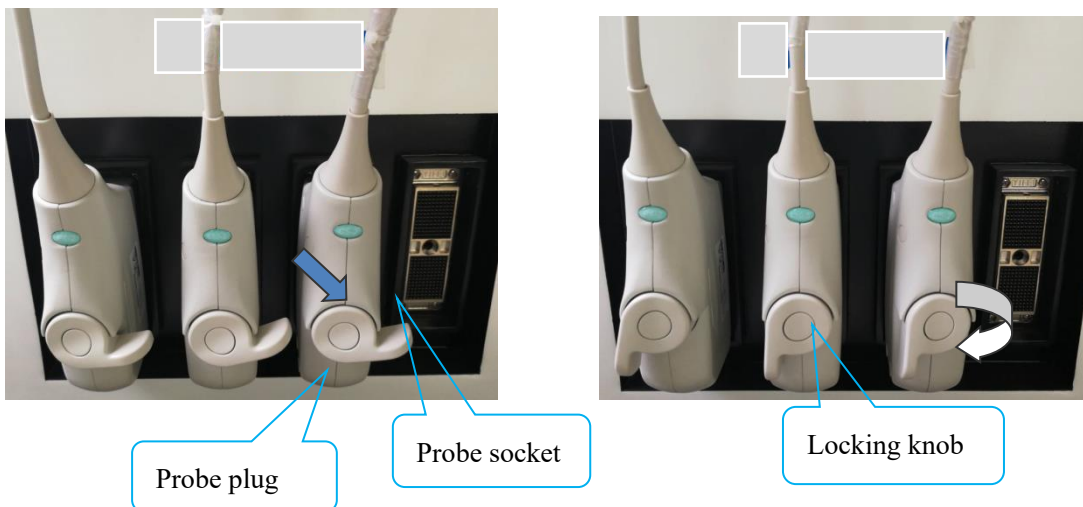
- Make sure that the environment in which the device is used meets the requirements, such as temperature, humidity, cleanliness, and whether there is a strong source of interference. Especially check whether the standby power supply and plug and socket meet the requirements.
- Open the packing box and check the listed items according to the packing list, which should be consistent with the actual situation, and the appearance should not be damaged.

## **4.2 Installation instructions**

### **4.2.1 Probe installation**

1. Carefully open the probe cable. Do not allow the probe to hang freely.
2. Make sure that the lock knob of the probe knob is loose (the lock lever is in the horizontal direction).
3. Align the probe plug with the probe interface and push it carefully.
4. After confirming that the plug of the probe and the socket of the host are closely fitted, turn the knob locking lever 90 ° clockwise to lock the plug securely.
5. Hang the probe cable naturally and hang it through the probe cable bracket, so as not to drag the cable to the ground.

As shown below.



- ① Insert the probe plug into the probe socket      ② Rotate the probe knob clockwise 90 °



- Use only probes produced by our company, otherwise diagnostic operations will not be possible.
- The device must be frozen or turned off before connecting or removing the probe.
- The number of probe sockets of this device is four sockets. It is recommended that the rightmost socket be connected to a volume probe.

### **4.2.2 Protective Earth Connection**

Take out the grounding wire (cross-sectional area 15mm<sup>2</sup>, yellow-green) from the packing box, fix one end of the soldering pad to the protective ground terminal under the rear panel of the host, and connect the other end to the ground wire of the ultrasonic studio (The access point must be a safe, effective, and reliable land).

#### 4.2.3 Power connection

Prepare the power supply socket board according to the power supply requirements of the instrument (AC220V, 50Hz), check the power supply of the instrument, and confirm that it is within the specified power supply range.

Check to make sure that the "green" power switch on the side of the main unit should be in the "OFF" position. Take out the supplied power cord, insert the power cord output plug face down into the power input hole on the back of the host, and then insert the AC220V power cord input plug into the power outlet board.



- Do not place liquid on the main unit. If the liquid is scattered, it will touch the live parts of the machine, increasing the possibility of electric shock.
- To avoid the danger of electric shock, the ultrasound must only be connected to an external input power socket with a protective ground.
- **After using the device, please cut off the power in time and unplug the power plug!**

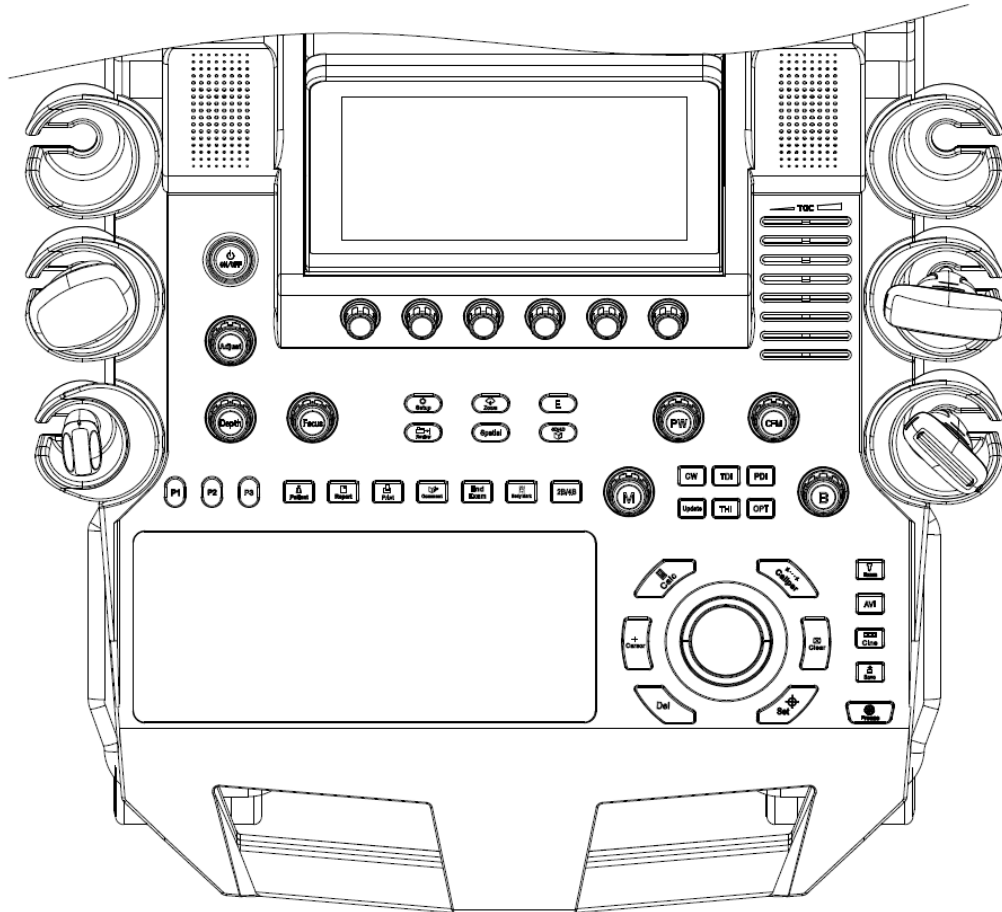
#### 4.2.4 Installation of external video equipment

The video output HDMI interface of the host can be connected to the video output equipment recommended by our company. Please install it according to the instructions of its use. When connecting to the host, you only need to connect its video plug to the corresponding video output socket on the back of the host.

## Chapter 5 Operation Panel




### 5.1 Panel layout



















The panel layout is as follows:














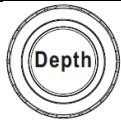









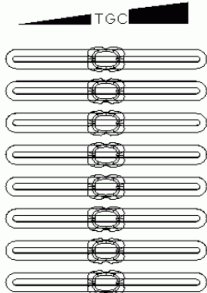
Operation panel diagram

### 5.2 Function key description

Key	Function description
	Equipment system switch
	Movie save button: save movie
	Image save button: save image

 Exam	Probe selection button: Enter/exit probe and inspection selection interface, equivalent to pressing the “probe button” on the touch screen
 Cine	Movie playback button: movie playback selection
 Report	Report generation key: diagnostic report generation
 Print	Print button: for real-time image printing, report printing (external printer required)
 3D/4D	3D/4D button: Activate 3D/Real 3D mode (if equipped)
 End Exam	End detection key: End last detection, create a new ID in order
 2B/4B	2B/4B button: Switch to double display mode or four display modes
 TDI	Tissue Doppler: Activate tissue Doppler mode
 PDI	Energy Doppler Key: Activate Energy Doppler Mode
 CW	Continuous Doppler button: Activate continuous Doppler mode (connected phased array probe)
 OPT	One-click optimization key: One-click optimization of current scan mode parameters
 Zoom	Image enlargement button: enlarge image
 E	Elastography button: Enter/Exit elastography mode
 Review	Case library selection button: enter/exit the medical record library
 + Cursor	Arrow keys: arrows indicate the call button
 Setup	Set button: enter / exit settings interface
 P1	Customized function key: Usually placed in a convenient location, it is easy for users to define according to their own habits. The actual corresponding function can be customized in the setting interface menu.
 P2	Customized function key: Usually placed in a convenient location, it is easy for users to define according to their own habits. The actual corresponding function can be customized in the setting interface menu.

	Customized function key: Usually placed in a convenient location, it is easy for users to define according to their own habits. The actual corresponding function can be customized in the setting interface menu.
	New Case Key: Enter/Exit New Case Interface
	Body key: enter/exit body map mode
	Comment button: full screen comment activation
	Organize harmonic keys: When scanning in B mode, switch 2D, inverting harmonics and filtered harmonics. Different types of harmonics are suitable for different probes
	Space composite imaging key: closed/on space composite imaging
	Exit key: equivalent to the right mouse button during operation
	Clear key: clear measurement data and comment information on the screen
	Multi-function button: It should be laid out in a convenient operation position. Multi-view display mode switching active view when switching modes
	Professional measurement button: specialist / obstetric measurement callout
	Distance measurement: distance measurement
	Confirmation key, equivalent to the left mouse button
	Freeze/thaw button: Press this button continuously to cycle into the freeze/thaw state
	Depth adjustment knob: Rotate to adjust the current depth
	Focus adjustment knob: Rotate to adjust the current focus position

	Function adjustment keys: different functions in different function modes
	B knob: Rotate to adjust the gain value, press to enter B mode
	M knob: Press to enter B/M mode, press again to enter M mode
	Color mode: press to enter color Doppler mode, rotate to adjust the color gain value
	Spectrum mode: press to enter the pulse Doppler mode, rotate to adjust the spectral gain value
	Trackball: equivalent to mouse sliding movement
	<p>TGC adjustment slider:</p> <p>The TGC real-time state is divided into 8 segments to control the image region signal compensation, sliding from left to right, the gain is increased; otherwise, the gain is reduced.</p>

#### Quick operation knob (below the keypad):



Quickly adjust the function displayed by the corresponding button below the touch screen. Different functions in different imaging modes

## **Chapter 6 Starting the System**

### **6.1 Start**

Step 1. Turn on the main power switch on the left side of the host;

Step 2. Press the "ON / OFF" key on the top left of the keyboard, the device enters the normal startup state. The normal startup time is about 1 minute.

Note: Please make sure the display is powered on when you turn on the machine; please do n't insert U disk before turning on.

### **6.2 Shutdown**

Step 1. Press the "ON / OFF" key at the top left of the keyboard;

Step 2. Wait for the display to show nothing;



Step 3. Turn off the main power switch on the left side of the host.

Note: When shutting down, please shut down strictly in this order to avoid equipment damage due to instantaneous power loss.

### 6.3 Main screen and touch screen display introduction

Figure 6-1 Main screen display interface

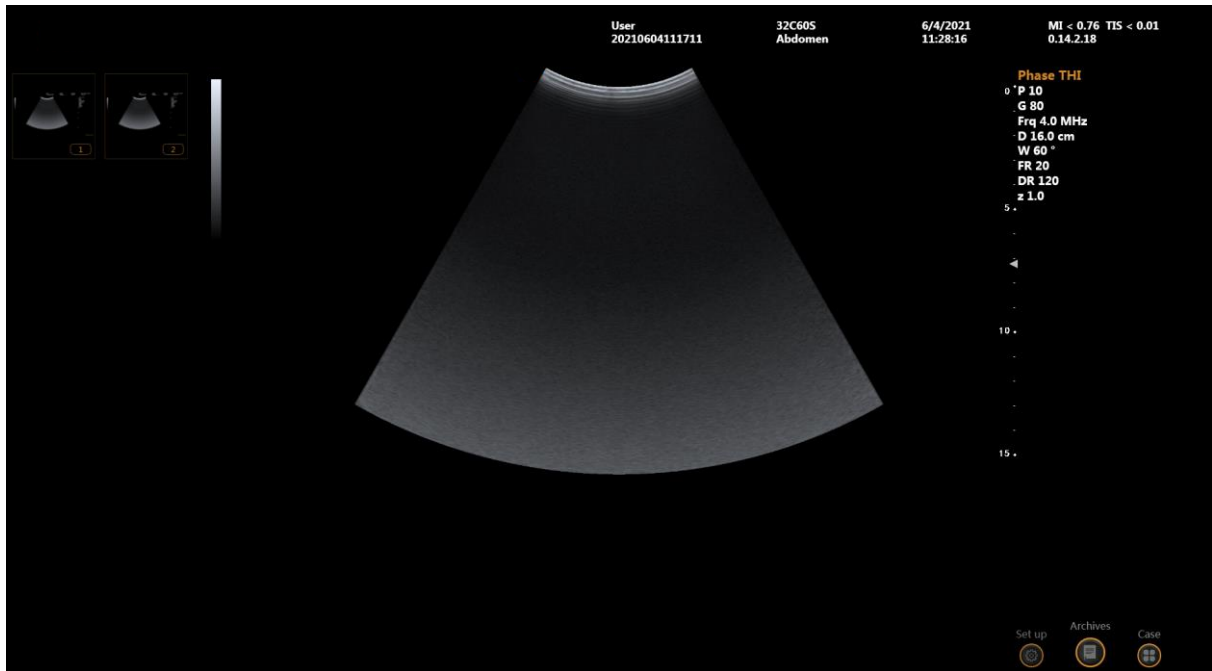


Figure 6-2 Touch screen display interface



No	Meaning	Description
1	LOGO	You can load the LOGO of the hospital or manufacturer in the settings interface.
2	hospital name	Make settings in the system settings;
3	Patient information	In Patient Information, click New Patient, the system automatically assigns an ID, and enters the patient's name and age.
4	Probe and inspection part	Press the [Exam] key or the touch screen probe model, select application probes and clinical applications;
5	Safety rate	Mechanical index and heat index, please ensure that the MI and TIS values are always less than 1;
6	Date, time	Display the current inspection time and display the current inspection date;
7	Software version	Display the currently used software version number;
8	Parameter display area	The parameter display area is always displayed regardless of whether the system is frozen or unfrozen.
9	focus	The system adjusts the focus depth by default. For more information, please refer to the relevant chapters of this manual;
10	Depth ruler	Display the scale value of the current image scan depth
11	System status bar	System status information, as well as shortcuts for frequently used

		functions;
12	Thumbnail	After the user saves the image, the thumbnail will be displayed in this area, or it can be displayed at the bottom of the screen, depending on the style selected by the user;
13	Movie playback	After freezing the image, it will enter the movie playback;
14	Image area	Display each mode image;
15	Grayscale strip	Display B mode grayscale chromatography and CFM mode chromatography
16	Probe switching area	After clicking the probe identifier, it will enter the scan part list corresponding to the current probe. After clicking the name of the part to be scanned, the user can enter the scan;
17	Pattern identification	Display the current scan mode;
18	Application menu switching area	Switch menus for scanning, reporting, and setting application features;
19	Quick parameter adjustment menu	Adjust the corresponding operating parameters on the control panel to adjust the corresponding parameter values;
20	toolbar	Click the corresponding function button to realize the function marked on the button;
21	Menu Bar	Display different image optimization functions and their levels in different modes
22	soft keyboard	Click to enter the software version function

## 6.4 Introduction to specific operations

### 6.4.1 Interface Settings

**Description** User can customize system settings after system is turned on

**Operation**

1. Press the touch screen [Settings] and continue to press [System Settings] to pop up the setting interface as shown in the figure below;
2. Click [System], Imaging, DICOM, Peripheral, Theme, License, About, etc. to enter the relevant settings interface. After completing the settings, click Save to complete. For the basic

settings of the system, click Cancel to not set, and exit the setting interface.

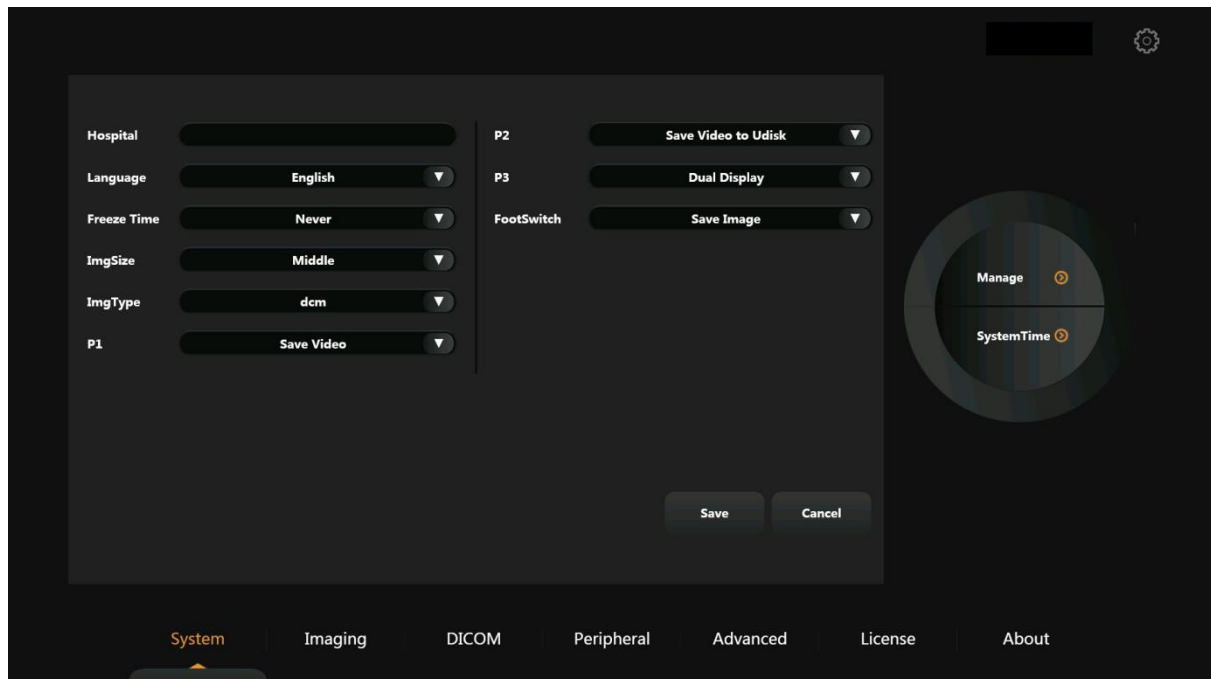


Figure 6-3 Setting interface

#### 6.4.2 System Settings

**Description** Set the system default hospital name, system language, image display, probe mark, freeze protection time

**Operation** 1. Click the setting interface System to enter the system setting interface. The first interface after entering is also the system setting interface.

2. Refer to Table 1.2. After the setting is completed, click “Save”. If you click “Cancel”, the current operation will be canceled and the system default value will be restored.

System settings	
hospital name	Enter the name of the hospital;
Language	Choose the language type and currently support both Chinese and English;
Image display	The user selects the default image size of the system, which is available in three sizes: small, medium and large.
Freeze	This function is mainly to detect that the machine automatically freezes when the user has not

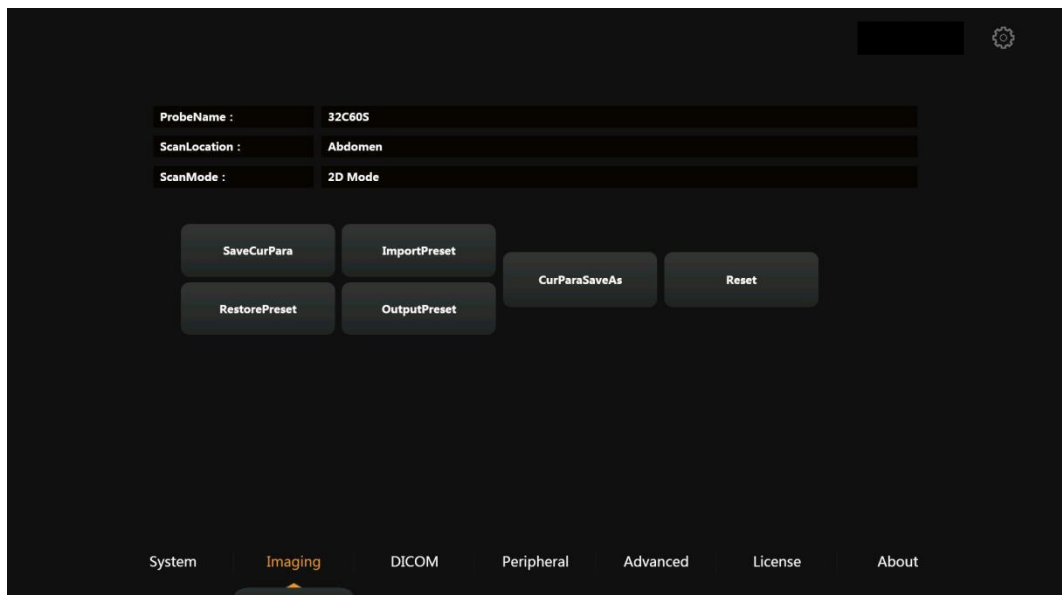
protection	used the machine for a long time;
Picture type	Save the settings function of the image format;

### 6.4.3 Imaging settings

**Description** The imaging setup is a pre-set of the imaging parameters for the selected probe and the inspection part. For example, the user can re-adjust the parameters such as gain during the carotid artery examination of the array probe, and can be saved in the imaging setting interface. After saving, the user-adjusted gain and other parameters are used in the subsequent carotid examination.

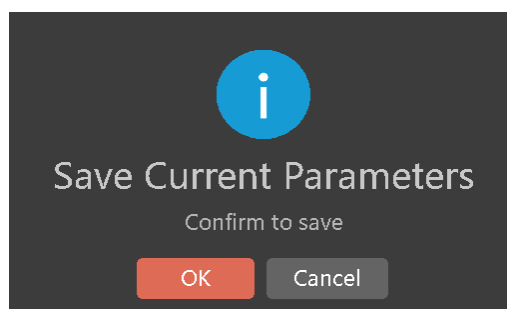
**Save the preset value**

1. Select the probe and inspection part to enter the image scan, and the user can adjust the parameters to get the best image.
2. To save the adjusted parameters, click on the setting interface Imaging to switch to the imaging settings;

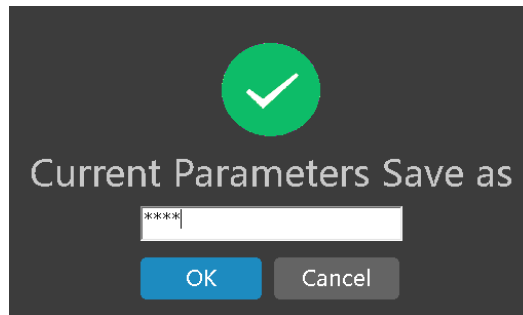


Imaging setting interface

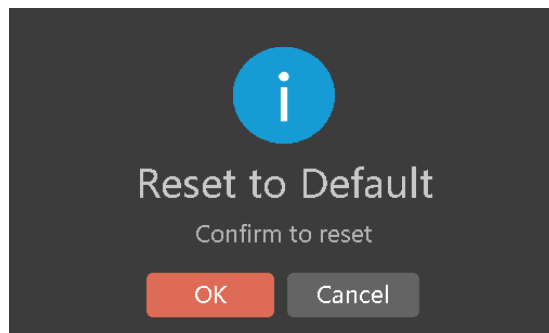
3. The system automatically reads the scan mode, probe model and scan position of the current inspection site. Click [Save Current Parameter], the following dialog box will pop up, click [OK] to save the current parameter as the default parameter; click [Cancel] will not save



**Save preset** Click “Save as parameter”, the following dialog box will pop up; after the user enters the preset name, click “OK” to save the current scan parameters as a set of presets; click “Cancel” will not save;



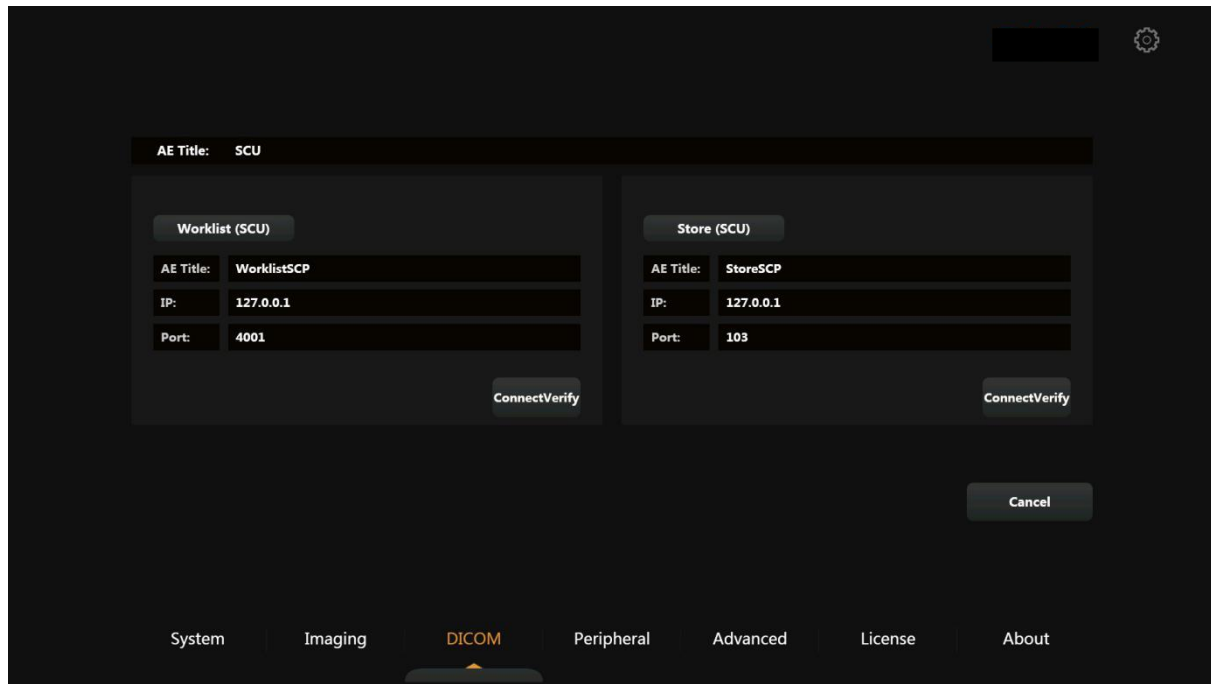
**Restore factory defaults** Click [Restore Factory Settings], the following dialog box will pop up and click [OK] to restore the system default scan parameters of the system; click "Cancel" will not be restored



#### 6.4.4 DICOM Setting

**description** The DICOM setting mainly completes the settings of SCU, Store (SCP), Worklist (SCP), related AE, IP, Port, etc. After the setting is completed, you can click [Connection Verification] to verify whether the SCU and SCP are connected.

**operating** Click 『DICOM』 to enter the DICOM setting interface, set the relevant parameters of SCU and SCP respectively, and click Connect Verification to perform connectivity verification; after the connection is successful, click Save to complete the setup, and click Cancel to cancel the setup.



DICOM Setting Interface

### 6.4.5 Peripheral settings

**description** Set up peripherals connected to the ultrasound system

- Network settings**
1. Click Current IP to use the current IP settings of the system and automatically fill in the network related parameters.
  2. Click [Automatically Obtain IP] to automatically obtain IP settings from the gateway device and automatically fill in network related parameters.
  3. Click Set IP to apply network parameters to the system network settings.

Setup N...

IP: 192 . 168 . 0 . 104

SubNetMa... 255 . 255 . 255 . 0

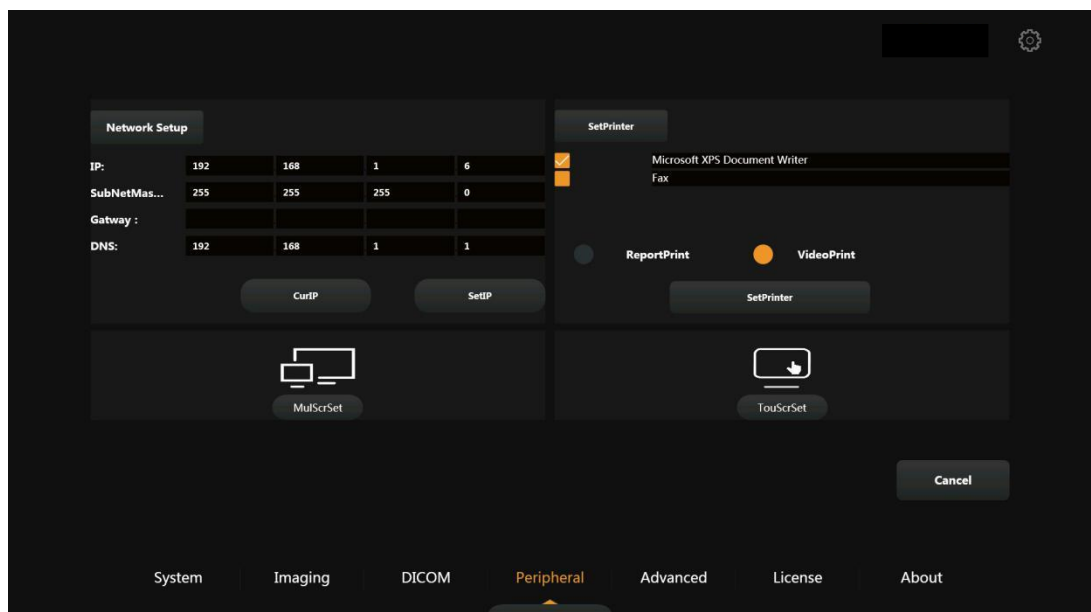
Gateway : 192 . 168 . 0 . 1

DNS: 192 . 168 . 1 . 1

CurIP SetIP AutoIP

### Printer settings

1. List all printers installed in the system, including virtual printers
2. Select a printer in the list
3. Click Set Printer to set the selected printer as the ultrasound system default printer.

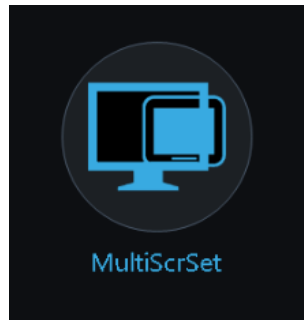


### Multi-screen settings

Adding external monitors, video workstations, etc., may cause the display position, resolution, and main screen settings of the main screen and touch screen to return to the system default state, and need to be reset.

1. Click the Multi-Screen Settings button to bring up the settings interface. The ultrasound software will detect the configuration change of the display when it starts up, and it will automatically pop up the setting interface.





2. The setup screen will appear on each connected screen, and the operation on any one screen will have the same effect. The model number and number of the display are displayed at the top of each screen to distinguish each display.



3. Automatic setting: the setting interface will count down after popping up, and will automatically set after the countdown ends.

4. Manual setting: Select the screen type below the screen thumbnail to specify it as “Home Screen”, “Touch” or “External”, then click “Apply Screen Settings” to complete the setting.

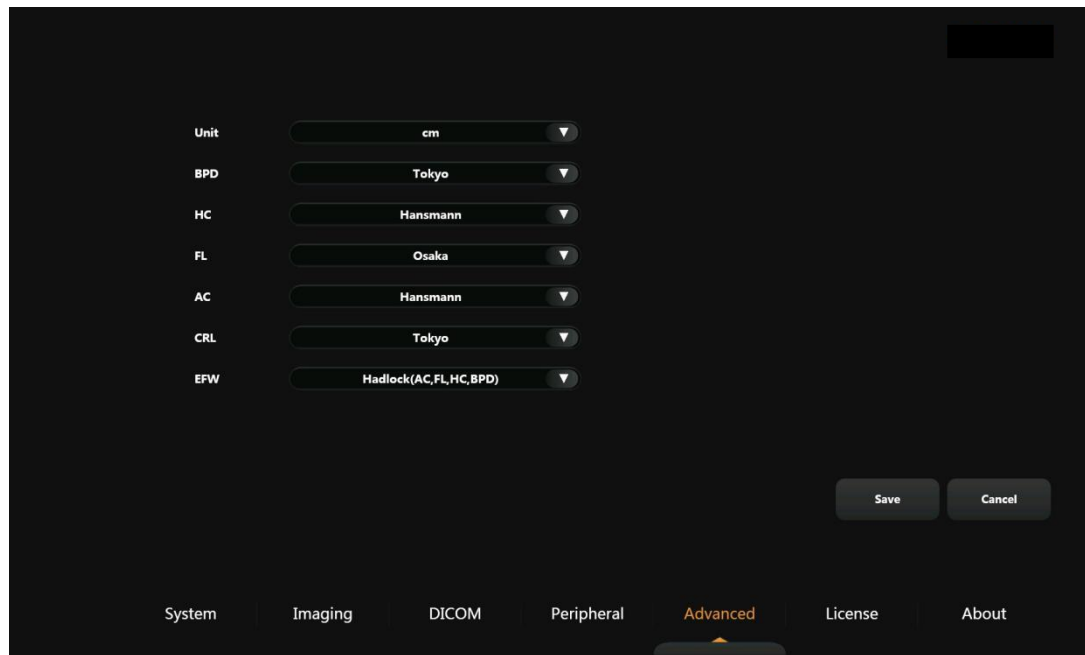
5. After the multi-screen setting is completed, the corresponding screen of the touch screen may be invalid. You can click the calibrate touch screen to reset the corresponding relationship of the touch screen.

6. Click “Restart Effective”, the ultrasound system will be restarted, and the settings of multi-screen and touch screen will take effect after restart.

#### 6.4.6 Advanced settings

**Description** The advanced settings mainly complete the setting of parameter types in the system

**Operation** 1. Click [Save] to complete the setting; click [Cancel] to abandon and exit

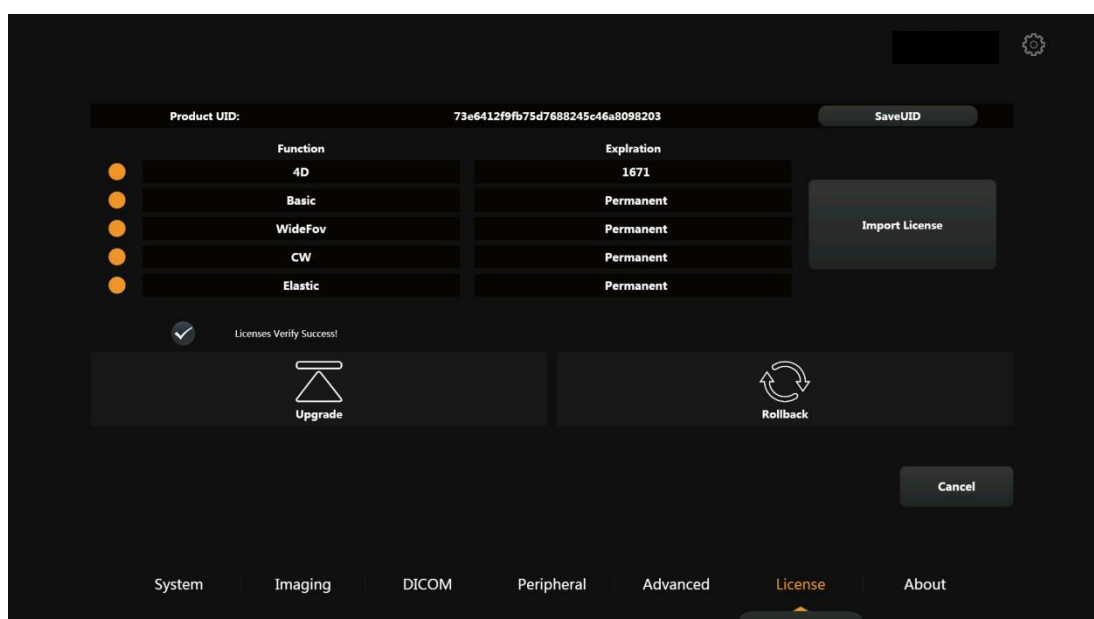


### 6.4.7 License Management

**Description** Import ultrasound function license files and upgrade ultrasound software

**Import license** If you need to add a new function or change the time limit of an existing function, and a valid license file has been obtained, then import a valid license file in the License management interface

1. click 『Import License』



2. Select the license file to be imported in the pop-up file selection dialog box, such as

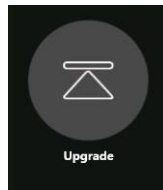
lic\_aabbcc\_Ba\_El\_CW\_.lic

3. If the license is valid, the authorized functions will be added to the ultrasound system

### **Update System**

Software upgrades inherit the licenses already in the system. The new version of the software is provided as an installation package. Insert the CD or U disk into the system

1. Click the Upgrade button



2. In the pop-up dialog box, select the installation package executable file, such as

us-setup-1.2.3.4-aabbcc.exe

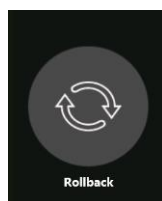
3. The installation package will run. Follow the installation instructions to complete the upgrade installation.

4. The upgrade software will take effect automatically the next time you start the ultrasound system

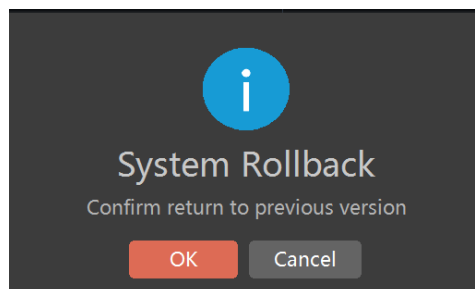
### **Fallback version**

After upgrading the installation software, the RollBack button appears on the license management interface. If you are not used to the new version, you can roll back to the previous version

1. Click the [RollBack] button



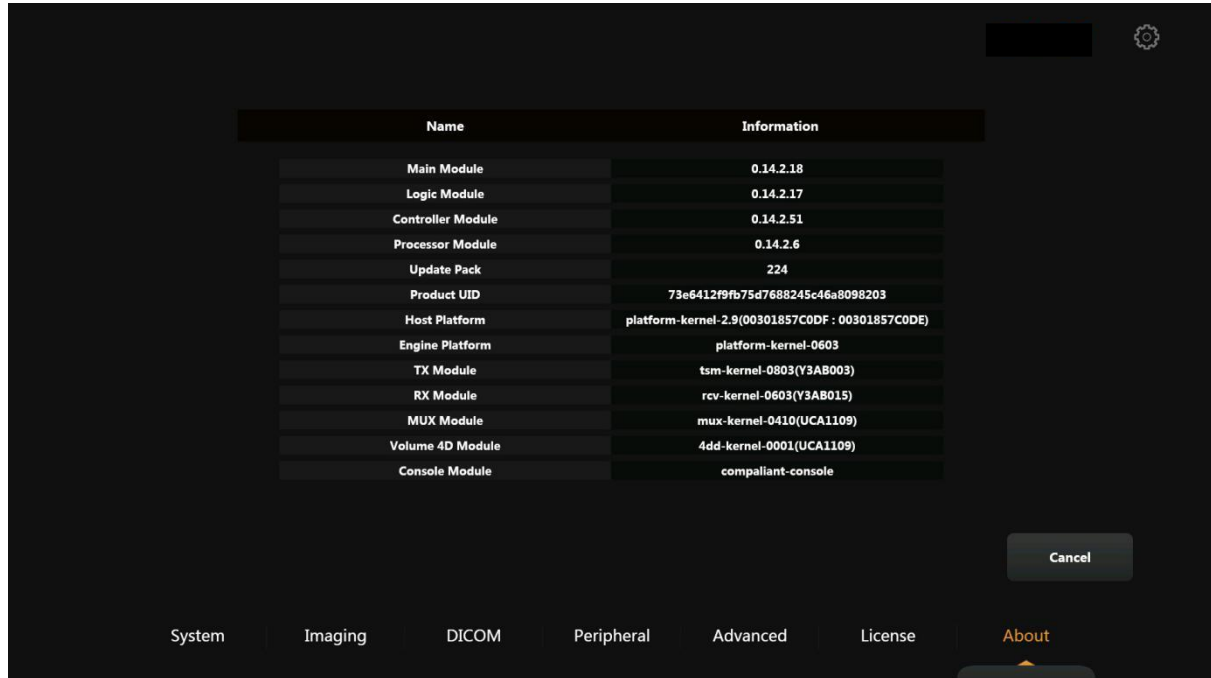
2. Confirmation dialog pops up



3. Click the [Confirm] button to roll back to the previous version and restart to take effect

### 6.4.8 About Information

Click [About] in the setting interface to pop up the system information interface. The system information mainly shows the software and hardware module information of the ultrasound system, so as to facilitate related work such as after-sales



About Interface

## Chapter 7 Settings Before Inspection

### 7.1 New patient registration

- Description** Before the exam, enter new patient information. Users can enter basic patient information through the Patient Information interface
- Operation**
1. Press the [Report] key on the touch screen and continue to press [Patient Information] to bring up the new patient registration interface;
  2. Enter basic patient information (such as patient name, gender, date of birth, etc.)
  3. Click to select the inspection categories such as General, Obstetrics, or Heart, and enter the corresponding information;
  4. After entering the new patient information, click OK to store the new patient information, exit the new patient interface, and return to the imaging mode. If you click [Cancel], the saving of the new patient information is cancelled.
  5. Users can also click “Quick Registration” to register new patients without any input information.

BasicInfo

Name : User ID : 20210604111711

Age : 0 Gender : Male

Obs. Car. **Abd.** Gyn. Org. Ped. Ner.

Height : 0 (cm) Weight : 0 (kg)

BSA : 0 m

Comments

Library New Patient Worklist Reset

DoctorInfo :

Apply... Diagnostic... Operator...

Confirm Cancel

#### 7-1 Patient Info Interface



© Body surface area under Heart and gestational age and due date under Obstetrics do not require user input. The system will automatically calculate its value based on related

information.



© Always be clear about the correct identification of all patient data and verify the accuracy of such data when entering patient names or ID numbers. Ensure that the patient identification provided in all recorded data and printouts is correct. Incorrect identification can lead to incorrect diagnosis.

© Please ensure the confidentiality of patient data.

## 7.2 Patient Information Database

**Description** Users can find the saved patient data through the "Information Database" interface, browse reports, view pictures,

New examinations can be created from the patient information found;

**Operation**

1. Click [Information Database] on the [Patient Information] interface to enter the patient information database interface;
2. After entering the patient name or the examination period, click [Find]. After the patient information is displayed, it will be displayed in a list. The user can see some information, such as name, gender, and examination site.
3. Click [Browse Information] to view all the information registered by the patient;
4. Click [View Report] to view the examination report of the patient;
5. Click New Exam to create a new exam based on the patient's information;
6. After clicking [Delete], the corresponding list item will turn red, and then click [Apply], and the patient information corresponding to the list item will be deleted from the list;
7. Click the [Cancel] button to exit the database interface;

## 7.3 WorkList

**Description** Users can find the patient information that has been reserved through the Worklist interface, and create new patient information based on the patient information that is found;

**Operation**

1. On the Patient Information interface, click the Worklist button to enter the patient information database interface.
2. The user enters the patient's name or patient ID and clicks the [Query] button to check. After finding the reserved patient, it will be displayed in a list.

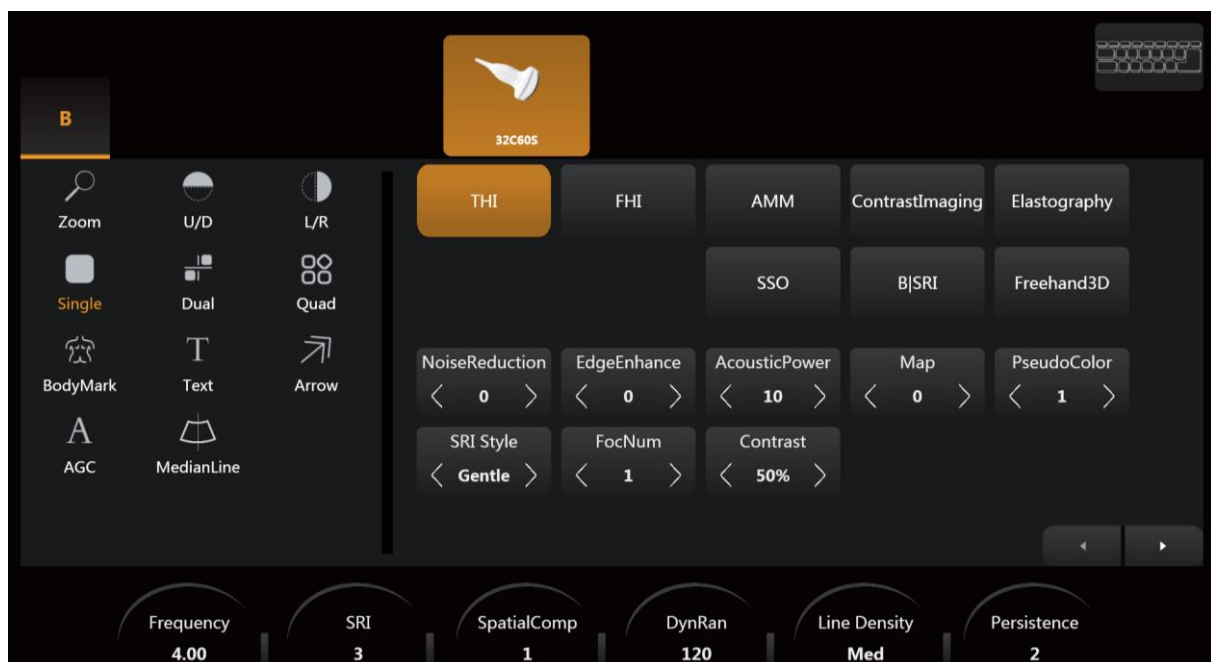
3. After finding the information, click [Confirm] to create a new patient based on the information in this list;
4. Click [Cancel] to exit the Worklist interface

## 7.4 Select probe and inspection site

**Description** The user can press the Exam key on the control panel to enter the probe and location switching interface on the main interface, or enter the probe and location switching interface on the touch screen by pressing the probe logo on the touch screen;

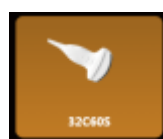
**Operation**

1. Press the [Exam] key on the control panel or press the probe logo on the touch screen to enter the switching interface;
2. Click the corresponding part name button, and the system will immediately switch between the probe and the scanning part;

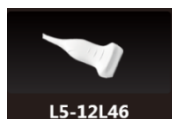


7-2 Probe and part switching interface on touch screen

**Note:** The probe in use will have a green triangle mark on the probe switching interface, as shown in the figure:



**Note:** The background color of the unselected probe is white, as shown in the figure:



## Chapter 8 Imaging Modes and Operations

### 8.1 Imaging mode switching

Mode Switch	Operation Method	Remarks
B mode	1. The system starts in B mode by default; 2. In other modes, press [B] to enter B mode;	B mode is commonly called as 2D mode.
FHI mode	1. When real-time scanning under B mode, press the touch screen [Harmonic Fusion] to activate FHI mode; 2. Press the touch screen [Harmonic Fusion] again to exit FHI mode;	Harmonic fusion imaging only supports convex array probe
THI mode	During B-mode real-time scanning, press the touch screen [Harmonic Imaging] to cycle through the normal B-mode (fundamental), inverse harmonic (THI Phase), and filtered harmonic (THI Filter)	THI image
Trapezoidal	1. Linear array probe, in B mode, rotate the [Adjust] key to enter the	trapezoidal



imaging mode	trapezoidal imaging mode; 2. Press the [Adjust] key again to exit the trapezoidal imaging mode;	imaging is only available for line array probes.
Extend imaging mode	1. Convex, micro convex or cavity probe in B mode, rotate the [Adjust] key to adjust the fan angle to the full angle of the probe and enter the extended imaging mode. 2. Rotate the [Adjust] key to adjust the fan angle to the full angle of the probe and exit the extended imaging mode.	Extended imaging is only suitable for curved fan forming probes.
M mode	1. In B mode, press the [M] key to enter the B+M mixed mode; 2. In the B+M mixed mode, press the [Zoom] key to enter the full screen M display;	
Anatomical M mode	1. In the B mode or B+M mixed mode, press the touch screen anatomical M imaging to enter the anatomy M mode; 2. Press the touch screen [Exit] to exit the anatomy M mode, return to B mode or M mode.	In the anatomy M mode, the system supports three sampling lines at the same time.
CFM mode	1. In B mode, press the [CFM] key to enter the C mode; 2. Press the [CFM] key again to exit the C mode;	the C mode is the color flow mode.
Power Doppler mode	In C mode, press the touch screen [Energy Doppler] or press the [PDI] key to enter the PDI mode;	PDI mode for short
Directional power Doppler mode	In C mode,, press the touch screen directional power doppler to enter the DPDI mode;	DPDI mode for short
Color blood flow dual real-time mode	1. Press the touch screen toolbar [double real-time] once, real-time double-display C / B; 2. Press the touch screen [double real-time] twice, real-time double-display C / PDI; 3. Press the touch screen [double real-time] three times, real-time double-display C / DPDI; 4. Press the touch screen [double real-time] again to return to C mode;	
TDI(Tissue Doppler) imaging mode	1. In C mode, press the touch screen [Tissue Doppler] or press the [TDI] key to activate the TDI mode; 2. Press the touch screen [Tissue Doppler] again or press the [TDI]	TDI mode only supports phased array probes

	key to exit the TDI mode.	
SR(strain rate) imaging mode	<ol style="list-style-type: none"> <li>1. Under B mode, press the touch screen Strain Rate Imaging to activate the SR mode;</li> <li>2. Press the touch screen Strain Rate Imaging again to exit SR mode;</li> </ol>	SR mode only supports phased array probes
CW mode	Phased array probe, press [CW] to start continuous Doppler spectrum scanning;	only phased array probes are supported.
D (PW) mode	<ol style="list-style-type: none"> <li>1. In B or C mode, press the [PW] key to enter the PW mode, move the sampling volume to the position of interest, and then press the [PW] key again to start the PW Doppler spectrum scan;</li> <li>2. During the scanning process, moving the trackball will reactivate BC, pause D, and stop moving to resume Doppler spectrum scanning. Press the [Update] key repeatedly to switch the D / BCD / CD real-time image;</li> </ol>	D mode is commonly be named as PW mode.
Wide view mode	<ol style="list-style-type: none"> <li>1. Press the touch screen [Wide View Imaging] to enter the wide-view imaging preset state;</li> <li>2. Press the touch screen [Exit] to exit the wide-angle imaging operation;</li> </ol>	Wide-field imaging of this machine is only suitable for linear array probes and convex array probes.
Elastography mode	<ol style="list-style-type: none"> <li>1. Press the touch screen Elastography Imaging to enter the Elastography imaging mode;</li> <li>2. Press the touch screen [Exit] to exit the Elastography imaging mode</li> </ol>	E mode for short. Not applicable for phased array probes
Free hand 3D image mode	<ol style="list-style-type: none"> <li>1. Press the touch screen [Free hand 3D] to enter the free arm 3D image mode;</li> <li>2. Press the touch screen [Exit] to exit the free hand 3D imaging mode.</li> </ol>	Free hand 3D is not suitable for phased array probes.
4D mode	<ol style="list-style-type: none"> <li>1. Press the touch screen [4D/3D] to enter the 4D/3D imaging mode;</li> <li>2. Press the touch screen [3D Imaging] or 4D Imaging to enter the corresponding mode.</li> <li>3. Touch screen [Exit] to exit 4D/3D imaging;</li> </ol>	4D/3D imaging only for volume probe

Dual, Quad mode	<ol style="list-style-type: none"> <li>1. In B or C mode, press the touch screen <b>[[Dual]]</b> to enter the dual image;</li> <li>2. Press [Quad] to enter four real-time images;</li> <li>3. Press the [Update] key to switch the live image between the views;</li> </ol>	
Sub-mode parameter switching	In the composite mode, to change any mode parameter, press B, C, PW, M on the touch screen to switch the sub-mode parameters.	
Real-time image	<ol style="list-style-type: none"> <li>1. When dual/quad display, press [Update] to switch the live image;</li> <li>2. In PW mode, press [Update] repeatedly to switch images in real time between D/BCD/CD;</li> </ol>	
Contrast imaging mode	<ol style="list-style-type: none"> <li>1. Press the touch screen <b>[[Contrast]]</b> to enter the contrast imaging mode;</li> <li>2. Press the touch screen <b>[[Exit]]</b> to exit the contrast imaging mode</li> </ol>	Contrast imaging only supports four types of probes: convex array, volume, transvaginal and micro-convex.

## 8.2 B Mode

### 8.2.1 B mode overview

**Use** B mode, also known as 2D mode, is the system's default mode. It is used to display two-dimensional images and to measure soft tissue anatomy.



8-1 B mode image display



8-2 B mode menu

### 8.2.2 Typical B mode inspection scheme

**Operation** 1. Press [Report] on the touch screen and continue to press [Patient Information] to open the new patient registration interface and enter patient information.

2. Press the [Exam] key or the probe button on the touch screen to select the probe and clinical application type;
3. Set reasonable parameters, cooperate with doctors and patients, perform scanning, and get the best image;
4. Press the [Freeze] key to freeze the image.
5. Make measurements and calculate data as needed;
6. Collect all the data to complete the inspection;

### 8.2.3 B mode display format

#### Image Invert

<b>Description</b>	Invert the image horizontally or vertically.
<b>Values</b>	image is rotated 180 degrees to the left/right; the image is rotated 180 degrees up/down.
<b>Affected parameters</b>	Probe direction.
<b>Operation</b>	<ol style="list-style-type: none"> <li>1. Press the touch screen [Up and Down invert ], the image is inverted vertically.</li> <li>2. Press the touch screen [ Left and Right Development], the image is inverted horizontally.</li> </ol>



© When viewing the inverted image, pay attention to the direction of the probe to avoid confusion in the scanning direction or the image left/right or up/down.

#### Enlarge image

<b>Description</b>	The entire scanned image is enlarged.
<b>Values</b>	The image can be enlarged by 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0 times.
<b>Operation</b>	Overall Enlargement Adjust the [Zoom] key to zoom in or out the entire image in sequence by 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0 times.



- ◎ Real-time image, frozen image and movie playback image can be enlarged, and you can measure, annotate, or add body image on the enlarged image.。

## Scanning area

<b>Description</b>	In addition to linear array probes, other probes can make the ROI window larger or smaller by adjusting the sector angle
<b>Values</b>	Except for linear array probes, the sector angle is displayed in the parameter display area in "degree (°)" units.
<b>Affected parameters</b>	Frame rate: The smaller the sector angle, the higher the frame rate
<b>Operation</b>	<ol style="list-style-type: none"> <li>1. Linear array probe, in real-time state of B mode, press [Adjust] key to turn trapezoidal imaging on or off;</li> <li>2. Linear array probe, when the B mode is in real time, turn the [Adjust] key to adjust the angle of the B mode image;</li> <li>3. For other probes, in B mode, turn the [Adjust] key to adjust the angle of the sector in the B mode image.</li> </ol>



- ◎ Increase the sector angle to see a wider field of view.
- ◎ Decrease the sector angle and the frame rate becomes faster. It is commonly used when examining moving organs, such as cardiac examinations.

## Scan depth

<b>Description</b>	Depth adjustment can change the depth range of B-mode imaging. Increasing the imaging depth results in an image of deeper tissue; reducing the imaging depth facilitates superficial tissue imaging. When using low depth inspection, the image area of interest should be covered as much as possible. It is recommended to maintain a high frame rate.
<b>Operation</b>	<ol style="list-style-type: none"> <li>1. To display a deeper tissue structure, turn the [Depth] key clockwise to increase the depth.</li> <li>2. To display the shallow tissue structure, turn the [Depth] key counterclockwise to decrease</li> </ol>

the depth.



- ⊙ As the depth value increases, the field of view of the scanned image is widened in the vertical direction, and the field of view in the horizontal direction is narrowed.
- ⊙ When the image is frozen, the depth is not adjustable.

## 8.2.4 Optimizing B-mode images

### Frequency

<b>Description</b>	The system provides multiple frequencies for each probe. Adjust the frequency for better image resolution and tissue penetration.
<b>Values</b>	The lower the frequency, the better the penetrating power, but the worse the image resolution; the higher the frequency, the worse the penetrating power, but the better the image resolution. Especially when imaging superficial organs, it is often used a reasonable depth High frequency to improve image resolution. The frequency is displayed in “MHz” in the parameter display area.
<b>Affected parameters</b>	MI, TIS value.
<b>Operation</b>	When scanning in B mode in real time, adjust the value of the touch screen [Frequency] menu.

### Frame correlation

<b>Description</b>	Frame correlation, also called afterglow, is a time filter that averages frame images together, that is, to synthesize an image with more pixels, which will provide a smoother and softer image. Adjusting frame correlation will reduce system noise (electronic noise)
<b>Values</b>	The larger the value, the stronger the frame correlation. “0” means the function is turned off
<b>Operation</b>	When scanning in B mode in real time, rotate the Frame Correlation key on the touch screen to adjust the frame correlation level.



© If the frame correlation is too high, the motion organization will be blurred, especially the fast-moving organization / structure.

### Noise suppression

<b>Description</b>	Noise suppression is mainly used to remove the blur caused by the composite technology and SRI on the B-mode image, so that the B-mode display is clearer.
<b>Values</b>	A larger value indicates stronger noise suppression, and "0" indicates that the function is turned off. A proper noise suppression level will make the image clear.
<b>Affected parameters</b>	Image Resolution.
<b>Operation</b>	When scanning in B mode in real time, adjust the Noise Suppression key on the touch screen to adjust the noise suppression level.

### Edge enhancement

<b>Description</b>	Edge enhancement can enhance tissue structure, such as tissue edges / boundaries.
<b>Values</b>	A larger value indicates stronger enhancement, and "0" indicates that the function is turned off
<b>Operation</b>	When scanning in B mode in real time, rotate the Edge Enhancement key on the touch screen to adjust the edge enhancement level.



© Edge enhancement is only available in real-time mode, not in freeze or movie mode.

© If the edge enhancement level is too high, the image grain will become larger. Please use it with caution.



## Speckle Suppression (SRI)

<b>Description</b>	Speckle noise is caused by the coherent superposition of the signals returned by the tissue. SRI is an image post-processing function that can suppress speckle noise and improve contrast resolution without blurring structural details.
<b>Values</b>	A larger value indicates stronger suppression, and "0" means the function is turned off
<b>Operation</b>	During real-time scanning in B mode, adjust the [Speckle Suppression] level of the touch screen menu.



© Appropriate SRI level can make the image clearer, but the level is too high, which will cause the image to be blurred, especially for fast-moving organizations.

## Spatial composition (SC)

<b>Description</b>	Spatial synthesis improves the image resolution by acquiring ultrasound images from multiple different angles to form a single frame image. Spatial compositing also helps organize the visual display of boundaries / edges.
<b>Values</b>	A larger value indicates that more angles are used for synthesis or larger angles. "0" means the function is disabled. The higher level of spatial synthesis is only suitable for small organ inspection of linear array probes.
<b>Operation</b>	When scanning in B mode in real-time, press [Spatial Composition] on the touch screen to adjust the spatial composition level.



© If the level of spatial composition is too high, the image will be blurred, especially the fast-moving organization / structure. In this case, it is recommended to reduce or close the spatial composition.

© The space composite shows the frame image after the ultrasound images of different angles are combined. Therefore, the size of the composite image is smaller than the unprocessed image.

© Current software version, phased array probes do not support spatial synthesis.

## Dynamic Range

**Description** This feature can also be called image compression, because we usually need to compress a large range of ultrasound signals to match the limited dynamic range provided by the display. Increased dynamic range (compression) produces more signals (even noise) and brightens the image display. The dynamic range (compression) is reduced, and weak signals appear darker.

**Values** The larger the value, the larger the dynamic range. The dynamic range (compression) is displayed in the parameter display area.

**Affected parameters** B-mode gain (image brightness)

**Description** During B-mode real-time scanning, operate the touch screen [Dynamic Range] to adjust the dynamic range.



⊙ A small dynamic range (compression) value can suppress the weak signal (make the blood flow and the inside of the cyst fluid tissue cleaner) but may make the image particles larger and not dense enough.

⊙ If the dynamic range is too high, more noise may appear.

## Harmonic Fusion (FHI)

**Description** Harmonic fusion (FHI) will make the midfield image clearer and more detailed, while maintaining the near-field and far-field image quality. Harmonic Fusion (FHI) mode is only available for convex array probes.

**Description**

1. Convex array probe, in real-time scanning in B mode, press [Harmonic Fusion] on the touch screen to activate FHI mode;
2. Press [Harmonic Fusion] on the touch screen again to return to B mode.

## 2B/4B display

**Description** 2B or 4B mode images.

**Description**

1. In real-time scanning in B mode, press [Dual] on the touch screen to activate 2B display image;
2. Press [Quad] on the touch screen to activate the 4B display image;

3. Press the [Update] key repeatedly to switch views;
4. Press the [B] key to exit the 2B / 4B image display.

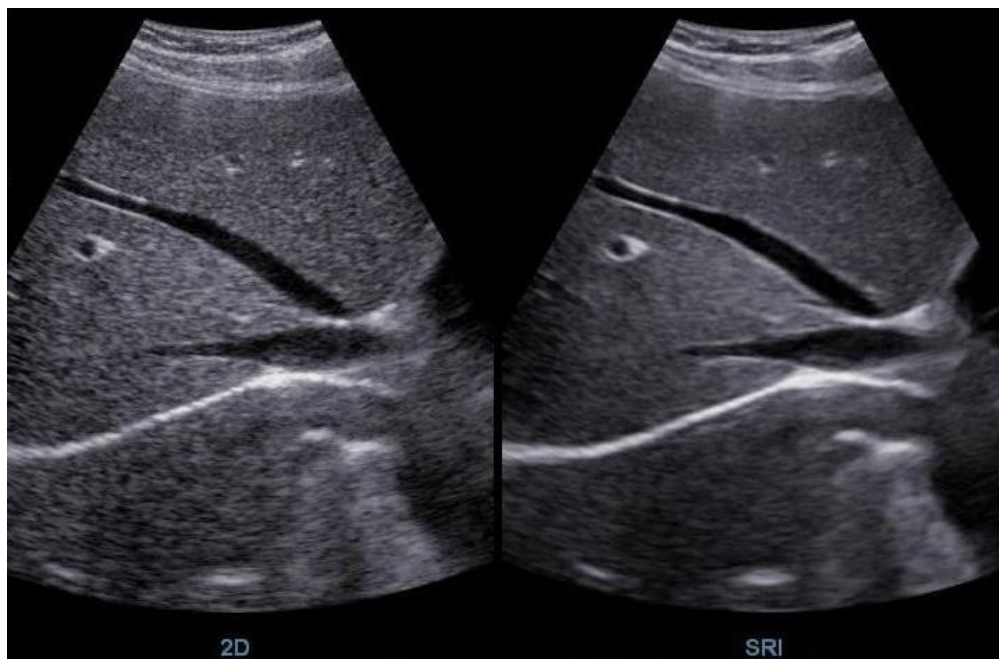
## B/SRI

**Description** Real-time dual image display, showing B-mode image and SRI image at the same time

- Description**
1. During real-time scanning in B mode, press [B | SRI] on the touch screen to display B / SRI images in real time;
  2. Press B | SRI again to return to B mode.



© If the SRI level is too high, the image will be blurred, especially the fast moving tissue / structure.



## Pseudo-color

**Description** Pseudo-color is a traditional method of colorizing B-mode images to make them more visual.

**Value** The value indicates a pseudo color number, and the pseudo color number "0" represents the default grayscale display.

**Operation** When scanning in B mode in real time, press False Color on the touch screen to select false color.

## Sound power

<b>Description</b>	Adjusting the sound power can bring more output energy to the ultrasound signal. The larger the output energy, the brighter the image; the smaller the output energy, the darker the image.
<b>Value</b>	The larger the value, the greater the sound power. The sound power is displayed in the parameter display area.
<b>Affected parameters</b>	MI, TIS value, image brightness. After adjusting the output energy, you need to adjust the gain. Generally, if you increase the output energy, you need to decrease the gain; if you decrease the output energy, you need to increase the gain.
<b>Operation</b>	When scanning in B mode in real time, press [Sound Power] on the touch screen to adjust the sound power.



⊙ When using more sound power, make sure that you are within a safe range. Please keep in mind that both the safety index MI (mechanical index) and TIS (soft tissue thermal index) should be less than 1.

⊙ Before adjusting the sound power, please optimize the B mode gain first, and then decide whether to increase the sound power.

## Linear density

<b>Description</b>	Line density refers to the scanning line density, which is actually the number of scanning lines during beam forming. The higher the line density, the higher the lateral resolution, and the longer the scan time, resulting in a lower frame rate.
<b>Value</b>	Low Medium High. The system default middle line density. Low means low linear density and high means high linear density. The number of lines corresponding to the different line density levels of different probes at different inspection sites
<b>Affected parameters</b>	Frame rate. As the line density increases, the frame rate decreases.
<b>Operation</b>	When scanning in B mode in real time, press the touch screen [Line Density] to adjust the line density level.

## Harmonic imaging (THI)

**Description** THI (Tissue Harmonic Imaging) improves the image resolution by transmitting two ultrasound waves to obtain an image, especially the midfield resolution.

**Value** During real-time scanning in B mode, you can switch between B mode, Phase THI and Filter THI by pressing [Harmonic Imaging] on the touch screen.



© THI will increase the mid-field image resolution, but will make the near-field and far-field images not good enough.

© Considering the compromise of the frame rate and image performance requirements of the application site, convex array probes and line array probes only support inverse harmonics, and phased array probes only support filtered THI.

## B mode gain

**Description** The B-mode gain increases or decreases the amount of echo information displayed in the image. If enough echo information is produced, it has the effect of brightening and darkening the image.

**Value** The larger the value, the greater the gain. The B-mode gain is displayed in the parameter display area.

**Affected parameters** Gain and TGC affect each other.

**Operation** Rotate the [B] key to adjust the overall gain in B mode.



© For better image brightness, always optimize the B-mode gain before deciding whether to increase the sound power.

© If the image is still not clear after the gain is changed, try to apply some ultrasound gel again.

## Freeze image

**Description** The image freeze function stops the live image to view a still image.

**Operation**

1. When scanning in B mode in real time, press the [Freeze] key to freeze the image;
2. Press the [Freeze] key again to enter the real-time image scanning state.



© Using the freeze button, a group of images will be saved to the movie playback storage space for review and measurement.

**Focus**

<b>Description</b>	The user can change the number of focal points, depth and spacing. Increasing the number of focal points or changing the focal position can make the scanning beam in a specific area closer.
<b>Affected parameters</b>	Frame rate. The greater the number of focus points, the lower the frame rate.
<b>Operation</b>	<p>1. Focus depth adjustment During real-time scanning in B mode, rotate the [Focus] key to change the depth of focus.</p> <p>2. Increasing or decreasing the number of focus points In real-time scanning in B mode, press the [Focus] key. The focus indicator arrow changes color. Rotate the [Focus] key to increase / decrease the number of focus points one by one.</p> <p>3. Adjustment of focus distance In real-time state of B mode, in the case of multiple focus, press the [Focus] key, the focus indicator arrow changes color, and rotate the [Focus] key to increase / reduce the focus distance one by one.</p> <p>⊙ Changing the number of focal points will affect the frame rate. The larger the number of focus areas, the lower the frame rate.</p> <p>⊙ The best focus when scanning is in the focus position. The user can move the focus position to track the center of the anatomical structure of interest.</p>

**TGC**

<b>Description</b>	TGC amplifies the return signal and corrects tissue attenuation. The TGC slider is proportional to the corresponding image depth. When adjusting TGC, the main interface automatically pops up the TGC curve.
<b>Value</b>	8 TGC sliders. The image depth is evenly divided into 8 segments from top to bottom, and each segment corresponds to a TGC slider from top (near field in the image area) to bottom (far field in the image area). Each TGC slider defines a range of gains
<b>Affected parameters</b>	Gain and TGC affect each other.
<b>Operation</b>	Slide the [TGC] slider left or right to adjust the gain of the corresponding depth on the image.

**8.2.5 Method for obtaining high-quality B mode image**

**General practice**

1. Please select the appropriate default parameter settings when scanning, you can add the presets you created as the default values;
2. Whenever the ROI window should be in the center of the image;
3. Use high frequency to increase image resolution and decrease scan depth to increase frame rate;
4. As long as the image area covers the ROI window, reducing the scanning angle can obtain a large frame rate;
5. In linear array probe B mode, press the [Adjust] key to turn on trapezoidal imaging to obtain a larger scanning area;
6. Turn on the synthetic aperture function without worrying about the frame rate;
7. It is recommended to use the SRI function with low-level spatial composition at the same time, so that turning off frame correlation or using low-level frame correlation can avoid image blur, especially in fast-moving tissue / structure inspection.

**Gain adjustment**

1. The following methods can be used to adjust the gain (or brightness):
2. Sound power (transmit power-analog signal)
3. B gain (analog gain)
4. Brightness / contrast (digital linear graph)
5. Dynamic range (digital compression)
6. TGC slider (depth depends on digital gain)



© It is recommended not to change the sound power frequently. If it changes, please ensure that it is within the MI and TIS security range.

© Please avoid trying to increase the brightness of the image by increasing the dynamic range, increasing the TGC gain, or adjusting the brightness / contrast when using too low B gain. This is because when the gain of the B mode is too low and the input signal energy is low, the digital gain function mentioned above will bring noise.

© The dynamic range controls the dynamic display range. When the dynamic range is high, the image graininess will be reduced, but it may bring noise in the non-echo area; when the dynamic range is low, the image will be sharpened, and the weak signal area will be displayed darker. Generally speaking, abdominal scanning requires a larger dynamic range, and cardiac scanning requires a smaller dynamic range. This system provides two types of dynamic range compression: Sharp (image sharpening) and Dense (image softening), while maintaining dynamic range unchanged. Dense is used for routine examinations, and Sharp is better for examination of diseased tissues. Press the [Update] key to switch between Sharp or

Dense.

◎ Adjust the brightness / contrast to improve the image quality. Brightness adjustment can increase or decrease the overall brightness of the image. This system realizes the adaptive adjustment of the brightness and contrast functions, that is, each input image will be converted by this function.

◎ The TGC slider should be in the center position, because the simulated TGC gain has been achieved through the B gain compensation organization depth attenuation. Therefore, the TGC slider can be used to fine-tune or enhance the image. For example, bow-shaped TGC curves are required for cardiac imaging (ie, low TGC gain in the near and far fields, and high TGC gain in the mid field).

### Image Resolution

1. Proper use of the following features can improve image resolution:

2. Space Synthesis (SC)
3. Speckle noise suppression (SRI)
4. Frame correlation
5. Edge Enhancement
6. Noise suppression



◎ SC provides a natural and effective way to improve image resolution. The disadvantage is that the composition of image frames is not on the same anatomical plane when inspecting fast-moving organs, which will cause a delay (smear) of the image. So SC is mostly used to check organs that move less (this may require a sufficiently high frame rate)

◎ Unlike SRI, SRI is an image post-processing function. It is recommended to use an appropriate SRI level to reduce speckle noise in the image without making the tissue image too smooth.

◎ We recommend using a lower level SRI to reduce speckle in the image. Too high a SRI level will cause the image to be too smooth and look blurry.

◎ Frame correlation is a time filter that averages images one frame at a time. Frame correlation reduces system (or electronic) noise and improves resolution without changing the frame rate. When examining fast-moving organs, applying low-level frame correlation can avoid image blur.

◎ Using SC and SRI at the same time, the image resolution becomes better, and using low frame correlation will avoid image blur.

◎ The edge enhancement function will sharpen the tissue boundary / edge display. This function does not change the resolution of the image, but can make the image display more



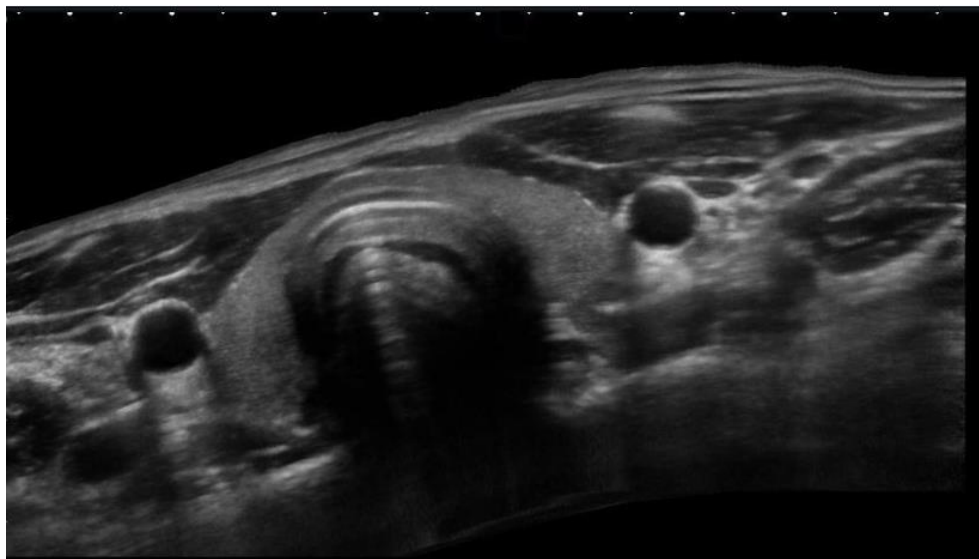
intuitively. Setting the edge enhancement level too high can blur the image.

© The noise suppression function is used to reduce the residual noise formed by the hardware and image post-processing functions in the system. Increasing the noise suppression level will make the image cleaner, but too high a level may reduce the signal energy and blur the image

### 8.2.6 Panoramic Imaging

**Description** Panoramic imaging, also known as ultra-wide-field imaging. Compared with ordinary ultrasound imaging, wide-field imaging provides a new perspective for clinical diagnosis, and has very important clinical diagnostic significance for observing large lesions and the relationship between the lesions and surrounding tissues.

The meaning of panoramic imaging is to obtain a series of two-dimensional slice images through the movement of the probe, and then use the computer reconstruction method to stitch the two-dimensional images into a continuous slice image, as shown in the figure below.



Panoramic Imaging show the intact thyroid and its adjacent tissue

**Operation**

1. Press [Wide View Imaging] on the touch screen to enter the wide view imaging preparation state;
2. Adjust the parameters to obtain the best image;
3. Press [Start Wide View] on the touch screen to start wide-range imaging, move the probe uniformly to generate a WFOV image, and press the [Freeze] key to complete;
4. Press [View Full Frame] on the touch screen to get a wide-screen image in full screen

display;

5. Press [Redo] on the touch screen to restart wide-range imaging;

6. Press [Exit] on the touch screen to exit the wide-field imaging and return to the B mode;

© To obtain high-quality wide-field imaging, the probe can only scan at a uniform speed in one direction. It is recommended that the operator practice a few more times, especially when using wide-field imaging for measurement.



© In the current software version, wide-field imaging is only applicable to linear array probes.

### 8.2.7 Puncture guidance

**description** The puncture guidance function is also called the biopsy sampling function. Before using the puncture guide function, the puncture guide and the guide wire of the puncture guide must be calibrated. The calibration can be performed in the puncture phantom or a bucket of water. Please do not use it before calibration.

**Operation**

1. Press [Guiding Guide] on the touch screen to activate the biopsy sampling function;
2. Adjust the number of lines on the touch screen to change the number of puncture guide lines;
3. Adjust the "Fine Adjustment Distance" of the touch screen to fine-tune the distance of the guide line;
4. Adjust the "Fine Angle" of the touch screen to fine-tune the angle of the guide line;
5. Adjust the [Adjust Angle] of the touch screen to greatly change the angle of the guide line. This key is mainly used for calibration;
6. Press [Exit] on the touch screen to exit the biopsy sampling function and return to B mode.

© Under the current software version, puncture guidance is applicable to linear array probes, convex array probes and intracavity probes.



© The transvaginal probe has only one angle.

© Do not use the puncture guidance function in the following cases:

- ☐ Frozen state;
- ☐ When the scanning angle is changed;
- ☐ in trapezoidal imaging mode;

Without calibration.

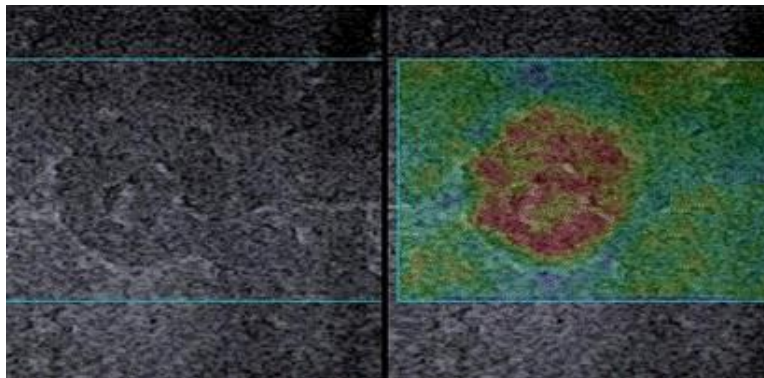
## 8.3 Freehand mode

### 8.3.1 1 Overview of the free hand elastography mode

**Applications** Freehand elastography can help doctors distinguish between soft / hard lesions and surrounding tissues. Because this imaging mode based on external force compression provides relative tissue stiffness calculated from the strain value, a large enough ROI window is needed to cover the potentially diseased tissue and its surrounding tissue.

The value that the body organs deform under external force (such as the pressure of the probe moving vertically) is called the strain value. The strain value can be quantified by the echo signals generated before and after the external force is applied. Since the deformation depends on the tissue elasticity coefficient, the degree of deformation or the strain value can be converted into an elastic image or a strain image displayed in grayscale or pseudo color (as shown below), and the corresponding function menu is shown in the following figure.

In the figure below, the center area of the left image shows a normal hard tissue elastic phantom image, and the right image shows a strain image with color coding superimposed on the normal B-mode image. The bar in the lower left corner shows red for hard tissue and green for normal background.



**Quality indicator**

There are two "quality indicators" at the bottom of the freehand elastography area. The "quality index" on the left (as shown below) shows the trajectory of the probe in real time. Normally, a sine curve means that the doctor is performing a stable bottom-up probe movement. To get good elastography, try to keep a sinusoidal curve.



Probe up and down motion amplitude

The “Quality Indicator” on the right (as shown below) shows a moving arrow to indicate the pressure or force applied by the sonographer to move the probe during the exam. It is recommended that this pressure or force range be between 1 and 4 for good elastography.



Pressure level indicator

Note:

1. 0-1, white line segment, indicating insufficient pressure;
2. 1-4, green line segment, indicating moderate pressure;
3. 3. 4-5, red line segment, indicating excessive pressure.

### 8.3.2 Typical elastography inspection program

- |                  |   |
|------------------|---|
| <b>Operation</b> | <ol style="list-style-type: none"> <li>1. Press the touch screen [Free hand Elastography] to enter the Free hand Elastography imaging mode;</li> <li>2. Move ROI window position: Use the trackball to move the cursor into the ROI window to move the position of the ROI.</li> <li>3. Adjust the ROI window size: Use the trackball to move the cursor into the ROI window, press the [Set] key once, and the ROI window boundary will change from solid line to dotted line. At this time, move the trackball to adjust the position of the boundary, change the window size, and adjust to the optimal ROI. After pressing the window, press the [Set] key to locate it.</li> <li>4. During the Free hand Elastography imaging process, the user can freeze, save, and measure the image by pressing [Freeze], [Save], [Calc].</li> <li>5. Press the touch screen [E BE] to switch the display format, single E or B E display, single B or B   E display;</li> <li>6. Press the touch screen [Exit] to exit the Free hand Elastography imaging mode and</li> </ol> |
|------------------|---|

return to B mode.



© Free hand Elastography Imaging for Linear Array Probes and Convex Array Probes

### 8.3.3 Optimize the Free hand Elastography imaging mode image

**Description** To obtain high-quality elastography, check the “Quality Indicators” . Make sure to press the probe vertically and with a little force, but if the force is too small, you will not get a reliable strain value. Avoid consistent elastography imaging of moving structures and deeper areas.

#### Frequency

**Value** Same as B mode.

**Operation** Real-time scanning in E mode, adjust the [Frequency] on touch screen to adjust the frequency.

#### Noise removal

**Description** The removal function is used to remove the elastography image of the weak signal region, only display the background image.

**Value** A larger value indicates a stronger noise removal. “0” means to turn off the function.

**Operation** Real-time scanning in E mode, adjust the [Noise Removal] on touch screen to adjust the noise removal level.

#### Frame Correlation

**Description** Frame correlation stabilizes the elastography image by reducing flicker noise to make the image display more continuous.

**Value** A larger value indicates a stronger frame correlation, and a "0" indicates that the function is turned off.

**Operation** Real-time scanning in E mode, adjust the [frame correlation] on touch screen to adjust the frame correlation level

#### Contrast

<b>Description</b>	E contrast adjustment makes the soft and hard tissue display of elastography more distinct.
<b>Value</b>	The larger the value, the stronger the contrast. Increase the contrast to observe the more subtle soft and hard differences, but may cause the hard part image to overflow.
<b>Operation</b>	For real-time scanning in E mode, adjust the touch screen [Contrast] to adjust the contrast value.

## Smooth

<b>Description</b>	Smoothing reduces the noise of elastography and makes the image appear smoother
<b>Value</b>	The higher value, the less elastography noise, but the details may be lost.
<b>Operation</b>	Real-time scanning in E mode, adjust the [Compare] on touch screen to adjust the smooth level.

## Pseudo color

<b>Description</b>	This system provides several pseudo-color maps to make the color coding of soft/hard tissues more intuitive.
<b>Value</b>	Pseudo color number
<b>Operation</b>	Real-time scanning in E mode, Adjust the [Pseudo-color] on touch screen, choose pseudo-color.

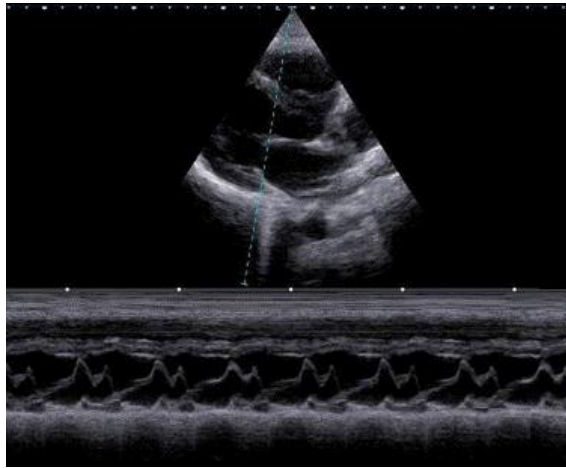


© The imaging function can deal pseudo color style for real-time images, frozen images, and movie playback images, but it can't save AVI format under pseudo-color style

## 8.4 M imaging model

### 8.4.1 M mode overview

<b>Description</b>	The M mode is used to check the tissue movement and display the amplitude change of the sound beam direction selected by the user over time (for example, frame by frame), as shown in the figure below. M mode is often used to scan moving images of the heart. M-mode imaging operations include conventional M-mode and anatomical M-mode imaging. This section describes general M-mode imaging.
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#### 8.4.2 Typical M mode inspection scheme

##### Description

1. Press the [M] key to enter the M mode,
2. Move trackball to move the sampling line to the position of interest and press the [Set] key to locate the sampling line,
3. Adjust the sampling volume by [Sampling Volume] in touch screen,
4. Adjust the scanning speed, frame correlation, edge enhancement, pseudo color, focus and other parameters by user demands,
5. Press the [Freeze] key to freeze the M imaging, then user can measure, calculate, save, report and print,
6. Press the [M] key to exit the M mode.

#### 8.4.3 Method for get high quality M mode images

##### General method

1. Optimize B-mode images, especially need to optimize the organization/structure of the movement, then the tissue movements can be clearly displayed in M-mode imaging;
2. Place the ROI window for motion analysis as closer to the center of the B-mode image as possible (the focus and signal energy is better in this area) for better image quality;
3. If want get high-quality tissue/structure motion M mode imaging, except the excellent B-mode images that also need adjust the M-mode parameters to improved image quality.

#### 8.4.4 Optimize M mode images

##### Overview

In M mode imaging, press touch screen B to switch to B mode. Please refer to the “Optimizing B mode image” section of this manual to adjust the B mode parameters to

optimize the B mode image. Press the touch screen M to return to M mode parameter adjustment.

### M sampling line angle

<b>Description</b>	The M sampling line angle mean the angle between the M line and the image depth direction.
<b>Value</b>	The M sampling line angle is indicate in the M mode parameter display area and in unit of "degrees (°)".
<b>Operation</b>	When the M mode is scan in real time, use trackball movement to adjust the M sample line angle.

### M mode gain

<b>Description</b>	Use the M mode gain to adjust the brightness of the M mode image.
<b>Value</b>	The larger the value, the larger the gain, and the gain is displayed in the M mode parameter display area.
<b>Operation</b>	In the M mode, turn the [M] key to adjust the brightness of the M mode image.

### Scan speed

<b>Description</b>	Adjust to change the scanning speed of the timeline.
<b>Value</b>	Each value represents a different scan time. High scan speeds are better for fast-moving tissues. The scanning speed is displayed in the parameter display area.
<b>Operation</b>	When scanning in M mode, adjust the [Scan Speed] of the touch screen to adjust the scan speed.

### Edge enhancement

<b>Description</b>	Use edge enhancement to make the display of tissue edges or borders clearer and sharper in M-mode imaging.
<b>Value</b>	The larger the value, the stronger the edge enhancement, and "0" indicates that's mean off this function.



<b>Operation</b>	Scan in real time under the M mode, please adjust the touch screen [Edge Enhancement] to adjust the edge enhancement level.
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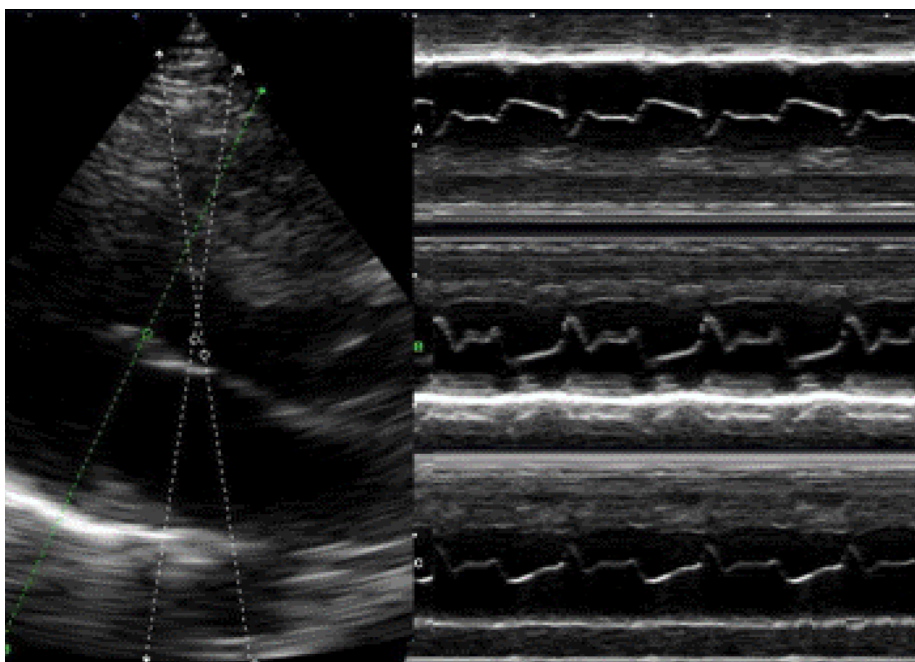
### Sampling volume

<b>Description</b>	Adjust the sampling volume length to better locate the area of interest
<b>Value</b>	Sampling door size in cm (cm)
<b>Operation</b>	During real-time scanning in M mode, adjust the “sampling volume” of the touch screen and adjust the size of the sampling gate.

## 8.5 Anatomical M imaging mode

### 8.5.1 Anatomical M mode overview

<b>Description</b>	<p>The traditional M mode only has one M sampling line, which was limit for the organization movement examination, especially for patients with difficulty in exam. The anatomical M mode compensates for the lack of traditional M-mode examinations for patients with difficult imaging. It provides multiple M-sampling lines that allow you to perform movement analysis with more efficient for M-mode images at different angles and positions.</p>
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### 8.5.2 Anatomical M mode operation

- Operation** When real-time scanning in B mode or M mode , press [anatomy M] in touch screen to activate the anatomical M mode;
1. Rotate the [M] key or [B] to adjust the AMM mode gain.
  2. Adjust the touch screen [Scan speed] to adjust the scanning speed;
  3. Adjust the touch screen [Pseudo-Color] to adjust the pseudo-color;
  4. Press [Display A] or [Display B] or [Display C] on the touch screen to display or hide the corresponding anatomical M line;
  5. Rotate the [Adjust] key to adjust the angle of the sampling line of interest;
  6. Press [Show All] on the touch screen to display all the anatomical lines;
  7. Press [Left or Right] or [Top and Bottom] Display on the touch screen to switch the display mode of the image;
  8. After completing the inspection, press the touch screen [Exit] to exit the anatomical M mode imaging;



© Anatomical M imaging mode parameter adjustment is only available for real-time scanning.

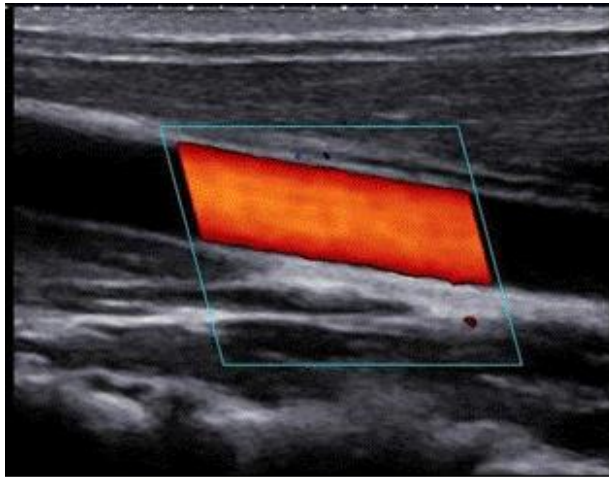
### 8.5.3 Optimized anatomical M mode image

- General method** If want to obtain high-quality anatomical M-mode images, must ensure the frame rate of the B-mode image is as large as possible to reduce the time interval between the M-sampling lines, so it may be need turn off the spatial synthesis, synthetic aperture etc functions. Press touch screen B to switch to B mode. Please refer to present manual of optimize the edge image parameters in the optimize the B mode image section

## 8.6 Color blood flow imaging mode

### 8.6.1 CFM Mode overview

- Description** C mode is a color-coded imaging mode that adds blood flow velocity to a B-mode image. Qualitative information of red and blue color coding related to the relative speed and direction of fluid motion is added to the C-mode image, as shown below



C mode Image

### 8.6.2 Typical C mode inspection program

- Operation**
1. Obtain a higher-quality B-mode image, and place the area of interest in the center of the B-mode image;
  2. Press the [C] key to activate the C mode. The image area displays a default ROI window. The C mode source depth is located at the center of the ROI window.
  3. Move ROI window: Move the trackball to move the ROI window position
  4. Adjust the size of the ROI window: Use the trackball to move the cursor into the ROI window and press the [Set] key once. The boundary line of the ROI window changes from a solid line to a dotted line. At this time, moving the trackball can adjust the position of the boundary line, change the window size, and adjust to the best ROI window, then press the keyboard [Set] key to locate.
  4. Linear array probe, operate the [Adjust] key to adjust the ROI window direction;
  5. Optimize color blood flow parameters, such as wall filtering, color gain, number of sampling packets, smoothing, etc., to obtain high-quality C-mode images;
  6. Press the [Freeze] key to freeze the image and perform measurement operations on the image during movie playback;
  7. To exit the color blood flow mode, press the [B] or [C] key.

### 8.6.3 Optimize C mode image

- Overview**
- To obtain high-quality C-mode images, especially the blood flow section on the scanning plane, like carotid imaging, ensure that the angle between the ultrasound beam and the direction of the blood flow is as small as possible, so that to get the most reliable and

sensitive color blood flow .

## Smoothing

<b>Description</b>	Smoothing is an image post-processing function. Smoothly reduces color noise and makes color blood flow more continuous, but too high smoothing level will reduce color resolution.
<b>Value</b>	A larger value indicates stronger smoothing. "0" means the function is off.
<b>Affected parameter</b>	Color resolution.
<b>Operation</b>	When scanning in C mode in real time, press [Smoothing] on the touch screen to adjust the smoothing level.

## B Suppression

<b>Description</b>	B suppression refers to a tilt threshold. When the corresponding B value of the detected color error area is greater than the threshold value, it is displayed that the indicated area is tissue rather than blood flow. B-suppression prevents bright tissue boundaries (such as blood vessel walls) from being detected as blood flow. However, a low B suppression level may delete real blood flow information, especially in relatively dark imaging areas.
<b>Value</b>	Values indicate that the lower the threshold, the stronger the tissue suppression. "0" indicates that tissue detection is maximized.
<b>Operation</b>	During real-time scanning in C mode, press [B Suppression] on the touch screen to adjust the B suppression level.

## Frequency

<b>Description</b>	The system C mode supports multiple frequencies. The lower the frequency, the more energy, the better the penetration and sensitivity. High frequency and high blood flow resolution. The C-mode frequency is always smaller than the B-mode frequency, because C-mode flow detection is usually easier than resolution.
<b>Operation</b>	During real-time scanning in C mode, adjust the frequency by pressing [Frequency] on the touch screen.

**Speed pass**

<b>Description</b>	Speed Pass refers to a speed threshold. The higher the speed passing level, the lower the threshold value, which means that if the speed of a pixel region is greater than the threshold value, the pixel is detected as blood flow. Use low-level speeds by preventing fast-moving tissue from being detected as blood flow, but too low a level removes true low-speed blood flow.
<b>Value</b>	A larger value indicates a lower threshold load through the blood flow velocity. "0" indicates that the flow velocity suppression is maximized.
<b>Operation</b>	When scanning in C mode in real time, press the touch screen [Speed Pass] to adjust the speed pass level.

**Sound power**

<b>Description</b>	If necessary, increasing the sound power brings more energy signals, which can improve the color sensitivity. Please ensure that MI and TIS are always less than 1.
<b>Value</b>	The larger the value, the greater the sound power
<b>Operation</b>	When scanning in C mode, press [Sound Power] on the touch screen to adjust the sound power.

**Color Map**

<b>Description</b>	The system provides a variety of color maps to make the images better displayed in different clinical applications.
<b>Value</b>	The value indicates the color map number.
<b>Operation</b>	For real-time scanning in C mode, adjust the touch screen [Chromatography] and select the color of interest.

**Parameter display**

<b>Description</b>	Switch color blood flow display parameters. The current software version has two parameters, flow rate and variance. Speed is the display parameter used by the system default check. Variance can show the level of blood flow disturbances and can help detect eddies and even turbulence.
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**Value** Speed, variance.

**Operation** For real-time scanning in C mode, press [Display Parameters] on the touch screen and select the display speed or variance.

### Frame rate

**Description** Adjusting the frame rate can turn off parallel scanning and increase the color resolution, but it will reduce the frame rate. In color blood flow imaging mode, a higher frame rate is usually required, so the system enables parallel scanning by default.

**Operation** When scanning in C mode in real time, press [Frame Rate] on the touch screen to adjust the frame rate.

### Dual real-time

**Description** Real-time dual display allows two modes to be activated simultaneously.

**Value** C/B、C/P、C/DP

**Operation**

1. Press the touch screen [Dual Real Time] once to display C / B in real time.
2. Press the touch screen [Dual Real Time] twice to display C / P (Power) in real time.
3. Press the touch screen [Dual Real Time] three times to display C / DP (Directional Power) in real time.
4. Press the touch screen [Dual Real Time] again to return to C mode.

### C mode gain

**Description** C-mode gain increases or decreases the overall Doppler signal. Too much gain will cause color noise, and insufficient gain will reduce color blood flow information.

**Value** The higher the value, the higher the gain. The gain is displayed in the C mode parameter display area.

**Operation** Turn the [C] key to adjust the C mode gain.

### PRF

<b>Description</b>	Pulse repetition frequency (PRF) is the inverse of the pulse repetition period (the time interval between two pulses). Detection of high-speed blood flow requires a large PRF, otherwise it will cause color confusion. To detect low-speed blood flow, a small PRF is required to keep low-frequency signals from being filtered out, so that low-speed blood flow can be detected.
<b>Affected parameter</b>	Speed scale, ROI window size, frame rate, wall filtering, MI value, TIS value. When you adjust the speed scale, the system clears the playback memory.
<b>Operation</b>	When scanning in C mode in real time, adjust the touch screen [Speed] and adjust the PRF value.



© The adjustment range of PRF is limited by the scanning depth. For example, a deep color ROI does not support high PRF.


### Wall filter

<b>Description</b>	Filter low-speed signals from tissue movement. Excessive wall filtering will remove true low-speed blood flow information.
<b>Value</b>	The higher the value, the stronger the low-speed signal filtering. The wall filter is displayed in the parameter display area.
<b>Operation</b>	During real-time scanning in C mode, adjust the wall filter [Wall Filter] and adjust the wall filter level.

### Frame correlation

<b>Description</b>	Frame correlation, also called afterglow, is a time filter that averages images frame by frame. Frame correlation reduces color noise and makes the blood flow display continuous, but too high levels will bring false colors. Its adjustment is the same as that of B mode, please refer to Optimize B Mode Image.
<b>Value</b>	A larger value indicates a stronger frame correlation. "0" means the function is disabled.
<b>Operation</b>	During real-time scanning in C mode, adjust the touch screen [Frame Correlation] to adjust the frame correlation level.

### Sampling packets

<b>Description</b>	The number of sampling packets controls how much of a single color bloodstream scan harness. These scan harnesses are processed to calculate blood flow velocity and other parameters.
<b>Value</b>	Sampling packet value. Using a large number of sample packets will show better blood flow sensitivity, but the frame rate will decrease.
<b>Affected parameter</b>	Frame rate. The number of sampling packets becomes larger and the frame rate decreases.
<b>Operation</b>	During real-time scanning in C mode, adjust the number of sampling packets on the touch screen and select the sampling packet value.
	⊙ In cardiac examination, using a small number of sampling packets such as 6 or 8 can maintain a high frame rate. When inspecting other parts, as long as the frame rate is appropriate (at least 10 frames), a larger number of sampling packets can be used.

#### Blood flow priority

<b>Description</b>	Blood flow priority sets the blood flow threshold for tissue / blood detection. Large blood flow priority will make it easier to detect blood flow in small tissue vessels, but at the same time increase blood flow noise during tissue movement.
<b>Value</b>	The larger the value, the more sensitive the blood flow detection, but it may introduce more blood flow noise.
<b>Operation</b>	During real-time scanning in C mode, adjust the touch screen [Blood Flow Priority] to adjust the blood flow priority level.

#### 8.6.4 Method for obtaining high quality C mode image

<b>Maintain high frame rate</b>	<ol style="list-style-type: none"> <li>1. Reduce the scanning angle of the B-mode image so that the color ROI of interest is covered on the blood stream;</li> <li>2. Use an appropriately-sized color ROI; generally, a wide ROI (ie, horizontal size) significantly reduces the frame rate than a longer ROI (ie, depth direction).</li> <li>3. Parallel mode is turned on by default in C mode. If you turn off parallel scanning manually, the frame rate will decrease. If you can always keep the frame rate greater than 10Hz, you can also get a reasonable color blood flow.</li> </ol>
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<b>Appropriate PRF</b>	Increasing the PRF can remove the color aliasing, but the PRF too high will lose low-speed blood flow. Therefore, a suitable PRF value is needed for blood flow testing. Generally, a low PRF is used to obtain color blood flow, and if necessary, the PRF is increased to remove the color aliasing phenomenon.
<b>Blood flow sensitivity</b>	<ol style="list-style-type: none"><li>1. To improve blood flow sensitivity, first optimize the front-end related parameters (also called pre-processing parameters); sound power, color gain, frequency, PRF, frame rate, and number of sampled packets.</li><li>2. Ensure sufficient acoustic power to ensure blood flow signals. If the PRF is low, the sound power can be increased to increase blood flow sensitivity. However, make sure that MI and TIS are within the safe range. At the same time, make sure that the probe cannot overheat during scanning.</li><li>3. Color gain can be increased as long as there is no noise in the color blood flow.</li><li>4. In general, the lower the frequency, the higher the energy, and the better the color image, especially at deeper depths. However, you must not use low frequencies for color resolution.</li><li>5. Based on the above, adjust the appropriate PRF and overall size, and maintain a high frame rate.</li></ol>
<b>Blood flow consistency</b>	<ol style="list-style-type: none"><li>1. Color blood flow post-processing function can improve the continuity, compactness and consistency of C-mode imaging display. Image post-processing parameters like wall filtering, axial sampling, smoothing, frame correlation, and blood flow priority can be used for color optimization. Generally, the image pre-processing parameters (blood flow sensitivity parameters) are optimized first to obtain sufficient blood flow signals, and then the image post-processing parameters are optimized to further improve color blood flow imaging.</li><li>2. Use small wall filtering to display low-speed blood flow on the screen, and improve wall filtering to remove color noise and color aliasing caused by tissue movement.</li><li>3. Use large axial sampling to make blood flow consistent, but this will reduce blood flow resolution.</li><li>4. Adjust the smoothness to reduce the color noise to make the color blood flow display dense, and avoid the excessive smoothness that causes the blood flow display to overflow.</li><li>5. Adjust the frame correlation (ie frame averaging) to reduce the color noise and make the color blood flow display continuous.</li><li>6. High priority of blood flow will enhance the detection ability of blood flow in a relatively slow tissue movement environment. However, too high a priority for blood flow can produce a false color flow.</li></ol>

## 8.7 Power Doppler Imaging and Directional Power Doppler Imaging Mode

### 8.7.1 Power Doppler Imaging Mode

- Usage** Power Doppler imaging (PDI) is used to show the strength (or energy) of a blood flow signal, not the blood flow rate. Because Doppler frequency shift information is not used, PDI is less prone to confusion and does not depend on the scanning angle;
- Operation**
1. During real-time scanning in C mode, press [Energy Doppler] on the touch screen to activate PDI mode;
  2. Refer to C mode for ROI adjustment and optimize image parameters;
  3. Use higher frame correlation than C mode to enhance blood flow sensitivity;
  4. Press the touch screen [Dual Real-time] to switch to P / B, P / C, P / DP display format in sequence;
  5. Adjust the touch screen [Speed], adjust PRF; adjust the touch screen [Smooth] to adjust the smoothing level; adjust the touch screen [Frame Correlation] to adjust the frame correlation level; adjust the touch screen [Frequency] to adjust the frequency; adjust the touch screen [Chromatography] to adjust the chromatography level; adjust the touch screen [Line Density] Adjust the line density;
  6. Press [Energy Doppler] on the touch screen again to exit the PDI mode.

### 8.7.2 Directional Power imaging mode

- Usage** Direction Power Doppler Image mode (DPDI) shows the direction of blood flow in PDI imaging, away from or toward the probe. DPDI imaging has all the advantages of PDI imaging, as well as orientation information that is not available in PDI imaging.
- Operation**
1. During real-time scanning in C mode, press [Direction Energy Doppler] on the touch screen to activate DPDI mode;
  2. Refer to C mode for ROI adjustment and optimize image parameters;
  3. Use higher frame correlation than C mode to enhance blood flow sensitivity;
  4. Press [Dual Real Time] to switch to P / B, P / C, P / DP display format in sequence;
  5. Adjust the touch screen [Speed], adjust PRF; adjust the touch screen [Smooth] to adjust the smoothing level; adjust the touch screen [Frame Correlation] to adjust the frame correlation level; adjust the touch screen [Frequency] to adjust the frequency; adjust the touch screen [Chromatography] to adjust the chromatography level; adjust the touch

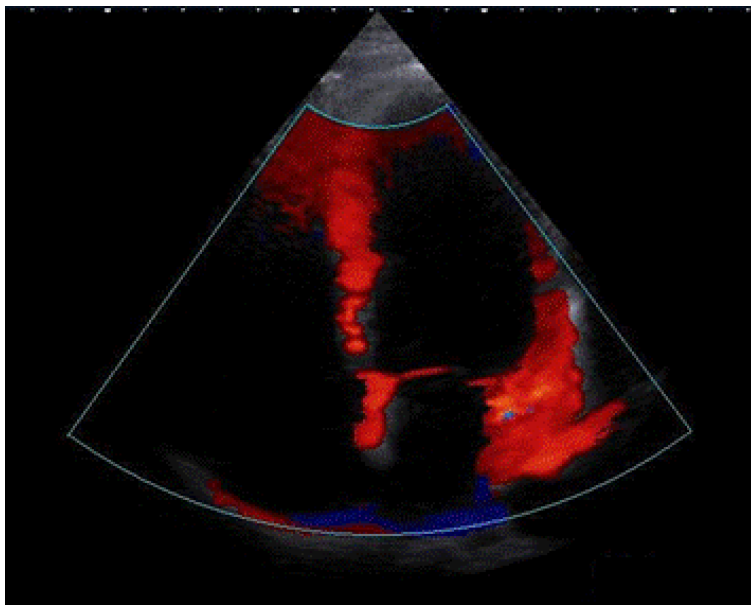
screen [Line Density] to adjust the line density;

6. Press [Direction Energy Doppler] again to exit the DPDI mode.

## 8.8 Tissue Doppler Imaging Mode

### 8.8.1 TDI mode overview

**Description** Tissue Doppler imaging mode is abbreviated as TDI mode. The principle of motion Doppler is used to estimate the tissue movement, such as the speed of myocardial movement. TDI mode can obtain motion information and generate color-coded images of tissue motion speed, as shown below



### 8.8.2 TDII mode operation

**Operation**

1. Phased array probe or convex array probe, get a higher quality B-mode image, place the area of interest in the center of the B-mode image;
2. Press [C] to activate the C mode, and press the touch screen [Organize Doppler] to activate the TDI mode. The default ROI window is displayed in the image area;
3. Move ROI window: Move trackball to move ROI window position
4. Adjust the size of the ROI window: Use the trackball to move the cursor into the ROI window and press the [Set] key once. The boundary line of the ROI window changes from a solid line to a dotted line. At this time, moving the trackball can adjust the position of the boundary line, change the window size, and adjust After the best ROI window, press the [Set] key to locate.

5. Rotate the [C] key to adjust the TDI mode gain;
6. Adjust the touch screen [Speed] and PRF; adjust the touch screen [Frame Correlation] to adjust the frame correlation level; adjust the touch screen [Frequency] to adjust the frequency;
7. Adjust the touch screen [Tissue Priority] to adjust the organization priority level. The Tissue priority function provides different levels of thresholds to enhance Tissue movement.
8. Press [Exit] on the touch screen to exit TDI mode.



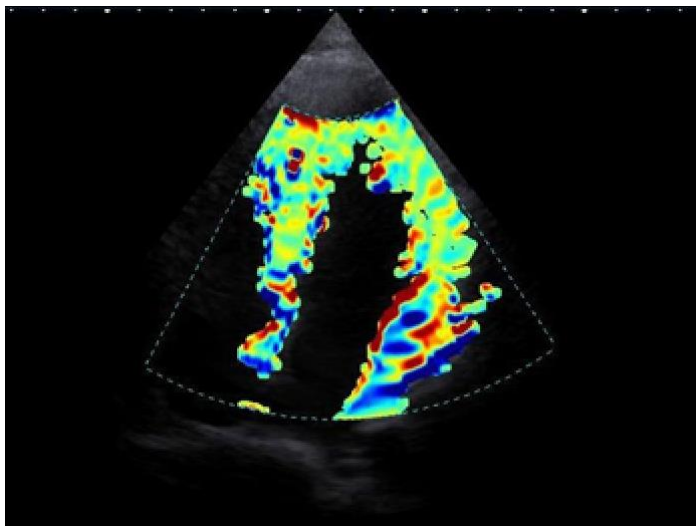
⊙ C mode deals with blood flow signals, and TDI gets information about tissue movement.

⊙ TDI without wall filter function, other function menus are the same as C mode

### 8.8.3 Strain rate imaging mode

#### Description

Strain rate imaging mode, referred to as SR mode, is an extension of TDI. Strain rate is the spatial gradient of velocity data calculated by TDI. Strain rate imaging shows tissue deformation in the beam direction. As shown in the figure below, the strain rate color coding is superimposed on the B-mode imaging.



### 8.8.4 SR mode operation

#### Operation

1. Phased array probe or convex array probe, get a higher quality B-mode image, place the area of interest in the center of the B-mode image;
2. Press Tissue Doppler on the touch screen to activate the TDI mode, and then press

Strain Rate Imaging on the touch screen to activate the SR mode. The default ROI window is displayed in the image area;

3. Move ROI window: Move the trackball to move the ROI window position;
4. Adjust the size of the ROI window: Use the trackball to move the cursor into the ROI window and press the [Set] key once. The boundary line of the ROI window changes from a solid line to a dotted line. At this time, moving the trackball can adjust the position of the boundary line, change the window size, and adjust. After the best ROI window, press the [Set] key to locate.
5. Turn the [C] key to adjust the SR mode gain;
6. Adjust the touch screen [Speed] and adjust PRF; adjust the touch screen [Frame Correlation] to adjust the frame correlation level; adjust the touch screen [Frequency] to adjust the frequency; adjust the touch screen [Organization Priority] to adjust the organization priority level;
7. Press [Exit] on the touch screen to exit the SR mode.

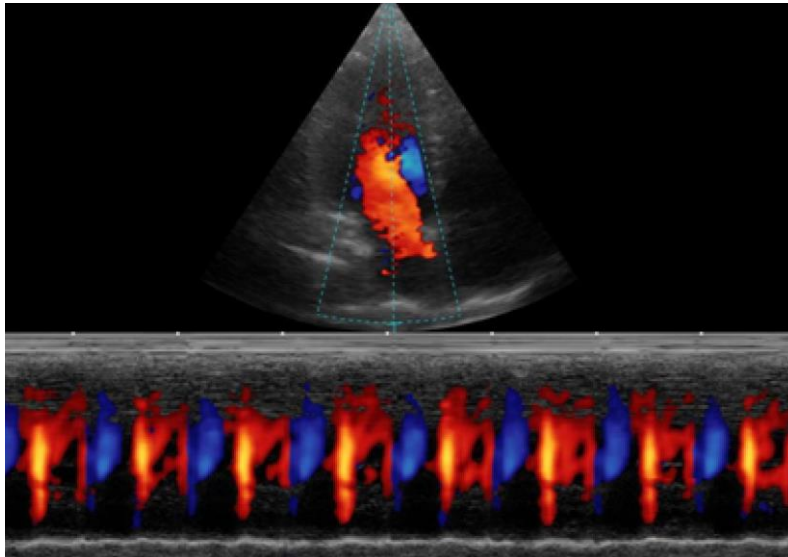


© The user can adjust the dynamic display range using the strain color scale. If the maximum value of the color ruler is set too low, slight distortion will also be displayed and cause the image color information to be oversaturated. To eliminate this oversaturation, you can set a higher maximum value of the color ruler. The strain rate appears to show tissue deformation in the direction of the beam. In general, the apical view provides the best viewing window because the beam is almost parallel to the longitudinal myocardium.

## 8.9 M Color Blood Flow mode

### 8.9.1 MC mode description

**Description** M color blood flow mode is referred to as MC mode, which is used for cardiac examination applications. Color blood flow uses velocity and variance color maps to color superimpose on M-mode images. The color blood flow covers the B-mode image and the M-mode timeline, as shown below.



M color blood flow mode image

### 8.9.2 Typical MC mode check scheme

#### Operation

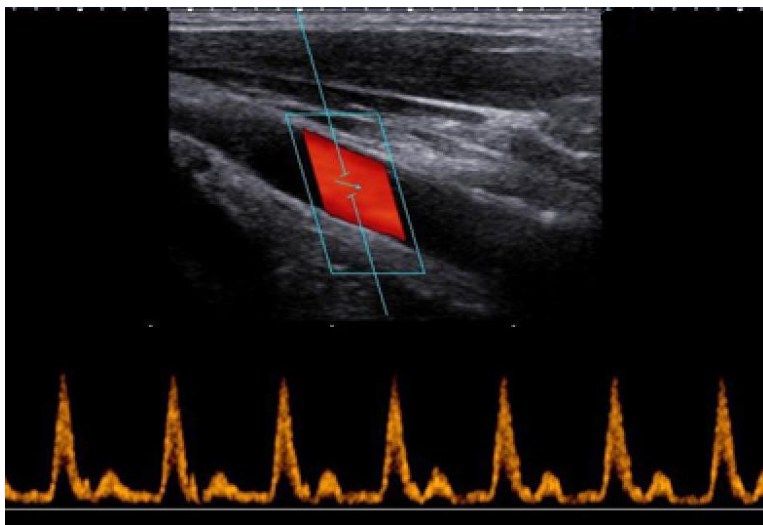
1. In C mode, a higher quality C mode image is obtained, and the area of interest is placed at the center of the C mode image;
2. Move ROI window: Move the trackball to move the ROI window position
3. Adjust the size of the ROI window: Use the trackball to move the cursor into the ROI window and press the [Set] key once. The boundary line of the ROI window changes from a solid line to a dotted line. At this time, moving the trackball can adjust the position of the boundary line, change the window size, and adjust to the best. After the ROI window, press the [Set] key to locate.
4. Press the [M] key to activate the MC mode, and an M sampling line is displayed in the image area;
5. Move the trackball to move the sampling line to the position of interest and collect the MC image;
6. Rotate the [C] key to adjust the MC mode gain;
7. With reference to C mode, press the touch screen image parameters to adjust the frequency, number of sampling packets, speed pass, and sound power;
8. Adjust the touch screen [Speed], adjust PRF; adjust the touch screen [Smooth] to adjust the smoothing level; adjust the touch screen [Frame Correlation] to adjust the frame correlation level; adjust the touch screen [Frequency] to adjust the frequency; adjust the touch screen [Chromatography] to adjust the chromatography level;

9. Press the [Freeze] key to freeze the image and press the [Save] key to save the image;
10. To exit the MC mode, press the [B] or [M] key.

## 8.10 Spectral Doppler imaging mode

### 8.10.1 D mode overview

**Description** D mode is also called PW mode. PW Doppler allows you to selectively check blood flow data from a small area( namely the sample volume) PW Doppler displays blood flow information through a constantly moving spectrum, which graphically describes the functional relationship between blood flow velocity and time.



D mode image

### 8.10.2 PW mode imaging operation

- Operation**
1. Get a higher quality B or C mode image;
  2. Press the [D] key, a PW sampling line and sampling volume appear;
  3. Use the trackball to move the position of the PW sampling line, adjust the length of the sampling volume through the touch screen menu [Sampling Volume], and [Blood Flow Angle] adjust the blood flow angle in the sampling volume;
  4. Move the sampling volume line to the position of interest and press [Update] to start Doppler spectrum scanning;
  5. In BD composite mode, press [Update] to switch between static B / real-time D and real-time BD image display;
  6. In BCD composite mode, press [Update] to switch between static B / real-time CD,

real-time BCD and static BC / real-time D image display;

7. When only the real-time PW spectrum is displayed, move the trackball to automatically activate the real-time B / C image, which is convenient to find the exact sampling volume position, stop moving the trackball, and start the real-time D spectrum display again;

8. Press the [D] or [B] key to exit D mode.

### 8.10.3 PW mode display format

#### Full screen spectrum

<b>Description</b>	The PW spectrum is displayed in full screen.
<b>Operation</b>	Under D mode real-time scan, press the touch screen Full Screen Spectrum, the PW spectrum will be displayed in full screen;

#### Right/down display

<b>Description</b>	Switch the display mode.
<b>Value</b>	Left/Right display, Up/Down display
<b>Operation</b>	<ol style="list-style-type: none"><li>1. Under D mode real-time scan, press the touch screen [Right/Down] to switch the display format to left/right display;</li><li>2. Press the touch screen [Right/Down] again to return to the default up/down display format.</li></ol>

#### Automatic baseline

<b>Description</b>	The baseline is automatically adjusted from the baseline. The automatic baseline function can be used whether the D-mode image is frozen or not.
<b>Operation</b>	In D mode, press [Auto Baseline] on the touch screen to automatically adjust the spectrum baseline.

#### Baseline reversal

<b>Description</b>	Flip the positive and negative of the speed scale while flipping the up or down display of the spectrum waveform.
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<b>Operation</b>	Under D mode real time scan, press the touch screen [Baseline Reversal] and the baseline is reversed.
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#### 8.10.4 Optimize PW mode image

##### Dynamic range (compression)

<b>Description</b>	Adjust the dynamic range of the PW spectrum on the display. A high dynamic range will show a weak signal spectrum, but will bring more background noise; a lower dynamic range will provide a clearer spectral image, but will lose the weak signal spectrum.
<b>Value</b>	The larger the value, the greater the dynamic range
<b>Affected parameter</b>	Spectrum brightness, spectrum width.
<b>Operation</b>	Under D mode real-time scan, press the touch screen [Dynamic range] to adjust the dynamic range (compression) size.

##### Sampling volume

<b>Description</b>	The sampling volume is adjusted to cover the region for Doppler spectral examination. Large sampling volumes increase signal-to-noise ratio but reduce blood flow resolution.
<b>Value</b>	Sampling gate length (mm).
<b>Affected parameter</b>	PRF value.
<b>Operation</b>	Under D mode real-time scan, adjust the touch screen [Sampling Volume] to adjust the sampling volume length.

##### Frequency

<b>Description</b>	Under D mode, system offers a variety of frequencies. The lower the frequency, the more energy is added, increasing the maximum detectable blood flow velocity.
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<b>Value</b>	Frequency (MHz). Frequency displays on parameter area under D mode.
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<b>Affected parameter</b>	MI, TIS.
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<b>Operation</b>	Under D mode real-time scan, press the touch screen [Frequency] to adjust the frequency.
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## Smooth

<b>Description</b>	Smooth is an image post-processing function used to reduce noise and continuously display Doppler spectral images.
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<b>Value</b>	The larger the value, the stronger the smooth.
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<b>Operation</b>	Under D mode real-time scan, press the touch screen [Smooth] to adjust the smooth level.
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## Sound power

<b>Description</b>	Adjusting sound power brings more energy to the signal
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<b>Value</b>	The larger the value, the greater the sound power. The sound power is displayed in the D mode parameter display area.
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<b>Operation</b>	When scanning in D mode in real-time, press [Sound Power] on the touch screen to adjust the sound power.
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## volume

<b>Description</b>	Adjust the PW spectrum sound level.
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<b>Operation</b>	During real-time scanning in D mode, press [Volume] on the touch screen to adjust the sound volume of D mode spectrum.
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## Pseudocolor

<b>Description</b>	Pseudo-color is to enable users to quickly pseudo-colorize spectral images, better display image sensitivity, and enhance visualization.
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<b>Value</b>	Fake color number.
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<b>Operation</b>	For real-time scanning in D mode, press False Color on the touch screen to select false color.
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#### Audio filter

<b>Description</b>	The audio filter function is used to filter low-frequency sounds.
<b>Value</b>	The higher the level, the more low-frequency sounds are removed. "0" means the function is disabled.
<b>Operation</b>	During real-time scanning in D mode, adjust the audio filter level by pressing [Audio Filter] on the touch screen.

#### D Mode Gain

<b>Description</b>	The D-mode gain adjusts the energy of the Doppler signal. Appropriate gain makes the spectrum image display clearer, but too high gain will bring more background noise.
<b>Value</b>	The larger the value, the greater the gain. The gain is displayed in the D mode parameter display area.
<b>Operation</b>	When scanning in D mode in real time, turn the [D] key to adjust the gain in D mode.

#### PRF

<b>Description</b>	PRF is the reciprocal of the time in which two sound beams are continuously emitted in Doppler mode. High PRF is used to display the full-spectrum waveform of high-speed blood flow without aliasing. For low-velocity blood flow, choose a low PRF to ensure that the spectrum display covers the entire velocity range.
<b>Affected parameters</b>	Speed scale, scanning speed. If the PRF value is too small, the scanning speed will be too small.
<b>Operation</b>	When scanning in D mode in real time, press the touch screen [PRF] to adjust the PRF value.

#### Scan speed

<b>Description</b>	The scan speed controls the speed of the scan timeline. The higher the scanning speed, the shorter the time to grasp the heart cycle, but the detailed information may not be displayed
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on the spectrum waveform.

**Value** The larger the value, the faster the timeline image is refreshed.

**Operation** When scanning in D mode in real time, press [Scan Speed] to adjust the scan speed.

### Wall filtering

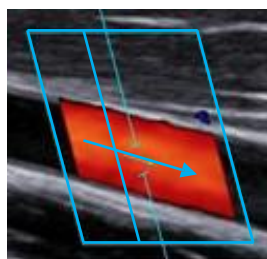
**Description** Wall filtering filters out low-speed signals, such as signals from tissue movement. Excessive wall filtering may filter out true low-speed blood flow signals.

**Value** The larger the value, the more low-speed signals are filtered out. The wall filter is displayed in the D mode parameter display area.

**Operation** During real-time scanning in D mode, press [Wall Filter] on the touch screen to adjust the wall filter level.

### Blood flow angle

**Description** To obtain a reliable flow rate, adjust the PW blood flow angle to be consistent with the direction of blood flow in the vessel (as shown below)要



**Value** Angle value in degrees (°)

**Operation** During real-time scanning in D mode, press the touch screen [Blood Flow Angle] to adjust the blood flow angle.

### Baseline position

**Description** When the spectrum is displayed, adjust the baseline upward or downward to avoid aliasing images disguised as part of the spectrum displayed at the other end of the spectrum display area.

<b>Operation</b>	During real-time scanning in D mode, press the touch screen [Baseline] to adjust the position of the baseline (zero speed).
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#### 8.10.5 Method for obtaining high-quality PW Doppler spectrum image

<b>General Method</b>	<ol style="list-style-type: none"> <li>1. Before entering the mixed mode imaging, determine the position of the sampling volume on the B or C mode image.</li> <li>2. To obtain a reliable flow measurement, make sure that the angle between the PW sampling line and the direction of blood flow is less than 60 °.</li> <li>3. The sampling volume is long and the signal-to-noise ratio is high, but the speed resolution will be reduced. Therefore, the appropriate sampling volume length should be selected according to clinical application.</li> </ol>
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### 8.11 Continuous Doppler imaging mode

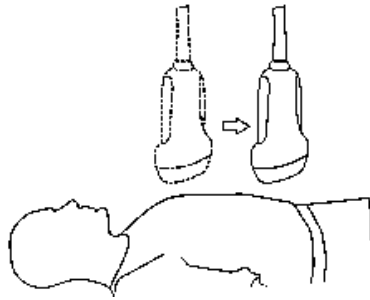
<b>Description</b>	The continuous Doppler imaging mode is referred to as the CW mode, and the Doppler spectrum display is obtained by continuously transmitting and receiving ultrasonic signals. Compared with PW Doppler, CW achieves a high sampling rate in a fixed sampling gate range. CW Doppler is suitable for high-speed blood flow detection applications (such as cardiac examination), but it will cause a certain range of blur.
<b>Operation</b>	<ol style="list-style-type: none"> <li>1. Phased array probe, press [CW] key to enter CW imaging mode;</li> <li>2. Move the trackball left and right to adjust the angle of the sampling line, move the trackball up and down to adjust the area of interest, and press the [Set] key to start continuous Doppler spectral scanning;</li> <li>3. Press the [Update] key to switch between B-mode real-time image and CW-mode real-time image;</li> <li>4. Refer to D-mode image optimization and adjust the image optimization parameters by touching the screen;</li> <li>5. Press the [B] key or the [CW] key to exit the CW imaging mode.</li> </ol>

### 8.12 Freehand 3D imaging

#### 8.12.1 Freehand 3D imaging Overview

<b>Description</b>	Freehand 3D imaging mode provides a method for generating 3D images when using standard line array, convex array, and cavity probe inspection. The process of freehand 3D imaging is to obtain a series of frame images (refer to the following figure, moving the
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probe in parallel at a uniform speed) and apply volume rendering technology to reconstruct the volume data and display the 3D rendered image. The quality of the 3D rendered image is closely related to the method of probe movement. Therefore, make sure that the probe is perpendicular to the body surface and keep moving at a constant speed during scanning. Based on this, freehand 3D images are for reference only and are not recommended for clinical diagnosis and measurement.



Flat scan icon

### 8.12.2 Freehand 3D imaging operation

#### Description

1. Select the probe:

Press the [Exam] key or select the probe and its inspection part on the touch screen to obtain a high-quality B-mode image;

2. Activate freehand 3D imaging:

Press the touch screen **[[Freehand 3D]]** to activate the freehand 3D imaging mode;

3. Adjust the ROI window:

Use the trackball and the [Set] key to adjust the ROI size and position to ensure that the ROI is large enough to cover the area of interest. For example, to obtain an image of a fetal face during an obstetric examination, the ROI should include amniotic fluid;

4. Start 3D data acquisition:

Press [Start Acquisition] on the touch screen to start 3D data acquisition, enter the 3D data acquisition mode, and move the probe in parallel at a uniform speed to obtain a series of images used to generate 3D volume data;

#### 5. Stop 3D data acquisition:

Press [End Collection] on the touch screen to stop 3D data acquisition, and open the free-hand 3D operation interface, which displays the rendered 3D image;

#### 6. Adjust the 3D view angle:

You can change the viewing angle of the 3D image by rotating the 3D image along the X, Y, or Z axis by operating the Rotate X, Rotate Y, or Rotate Z touch-screen menus;

7. Save 3D image: To save the screen, the image is frozen, press the [Save] key to save the 3D image, and view the saved image in the browse window.

#### 8. Exit Freehand 3D Imaging:

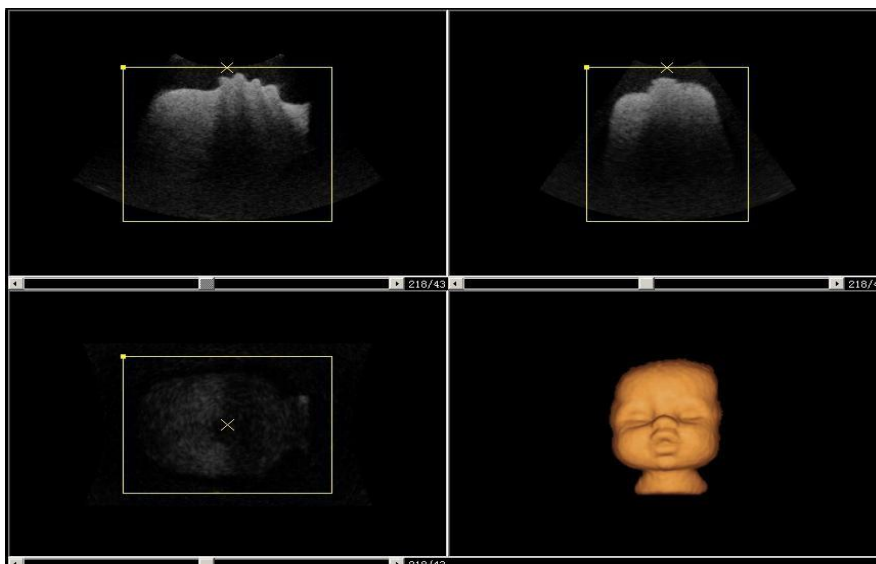
Press the touch screen [Exit] to exit the freehand 3D imaging mode

## 8.13 Volume 3D / 4D imaging mode

### 8.13.1 3D/4D Image Overview

#### Overview

4D imaging, also known as real-time 3D imaging, provides an interactive means of viewing dynamic 3D imaging. This function is only available on machines with a 4D imaging module. Unlike the unarmed 3D imaging mode, which requires the probe to move at a constant speed, the volume probe needs to be fixed at one position during 4D imaging inspection and cannot be moved. The mechanical components inside the probe can perform stable continuous scanning of different positions by swinging to obtain a series of continuous Stable frame image, so the quality of the 3D rendered image is higher than that of freehand 3D imaging. The 3D imaging of the volume probe is a roll of 4D imaging. Because real-time is not considered, the imaging parameters are more optimized and the imaging quality is higher.



### 8.13.2 3D/4D Imaging operation

#### Description

1. Select the volume probe:

Press the [Exam] key to open the probe selection interface and select the 4D volume probe (or select the 4D volume probe and the inspection site on the touch screen) to obtain a high-quality B-mode image;

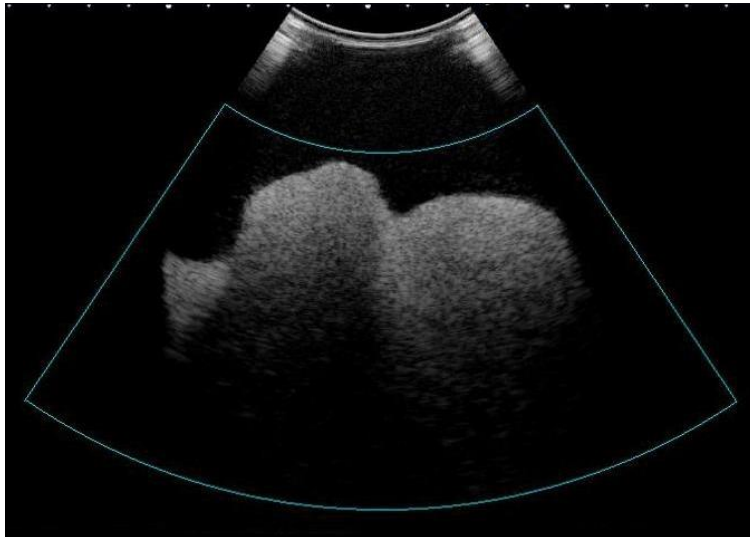
2. Activate the 4D imaging function:

Press the touch screen **〔4D / 3D〕** to activate the 3D / 4D imaging mode;

3. Adjust the ROI window:

Use the trackball and the [Set] key to adjust the size and position of the ROI, as shown in the figure below, to ensure that the ROI is large enough to cover the area of interest, for example, to obtain an image of a fetal face during an obstetric examination. ROI should include amniotic fluid;





4. Optimize image parameters:

- a) Press [Frame Correlation] on the touch screen to adjust the frame correlation level;
- b) Press Noise Suppression on the touch screen to adjust the noise suppression level;

5. Adjust the swing angle:

Press the [Swing Angle] key on the touch screen to adjust the swing angle;

6. Select the imaging quality level:

Press the [Imaging Quality] key on the touch screen to adjust the imaging quality level.  
The higher the level, the better the 3D / 4D image quality, but the frame rate decreases.

7. Start data collection:

- a) Press the touch screen **[[4D]]** to start the 4D data acquisition and open the 4D imaging interface. The 4D imaging menu is shown in the figure below. At this time, the probe is fixed in a position until the 4D rendering is displayed;
- b) Press the touch screen **[[3D]]** to enter the 3D imaging mode of the volume probe. After scanning a volume of 3D image, it will enter the 3D imaging display interface;

8. Adjust the view angle:

Press [Scroll Rotate X], [Rotate Y] or [Rotate Z] on the touch screen to rotate the 3D / 4D image along the X, Y or Z axis to adjust the 3D / 4D image viewing angle; click [Z axis

rotate 90 °] on the touch screen 3D / 4D image will be flipped at 90 °;

9. Optimization parameters:

a) Press [Threshold] on the touch screen, adjust the threshold, and delete the area image whose amplitude is smaller than the threshold; the threshold is adjusted to generate a good appearance of the three-dimensional surface image. Use this feature to remove noise or low-level echoes.

b) Press [Transparency] on the touch screen, adjust the transparency threshold, and delete the area image whose amplitude gradient is less than the threshold; transparency will affect the threshold effect. Low transparency can define distinct surface edges, and high transparency defined surfaces are more diffusive.

c) Press [Smooth] on the touch screen to adjust the smoothing level. Smoothing removes noise and smoothes uneven surfaces, but too high a level loses detail.

d) Press [Shadow Flip] on the touch screen to invert the brightness of the image.

10. Image display:

When 3D / 4D imaging, click [Single Window], [Double Window] or [Four Windows] to change the view to single view, dual view or quad view display respectively;

11. Rendering mode:

For 3D / 4D imaging, click Rendering Type to select the imaging mode of interest: Surface, Maximum, Minimum, Perspective

12. Save the image:

When scanning in 4D mode, press the [Freeze] key to freeze the image; or in 3D mode, the imaging is in a frozen state. Press the [Save] key to save the 3D / 4D image

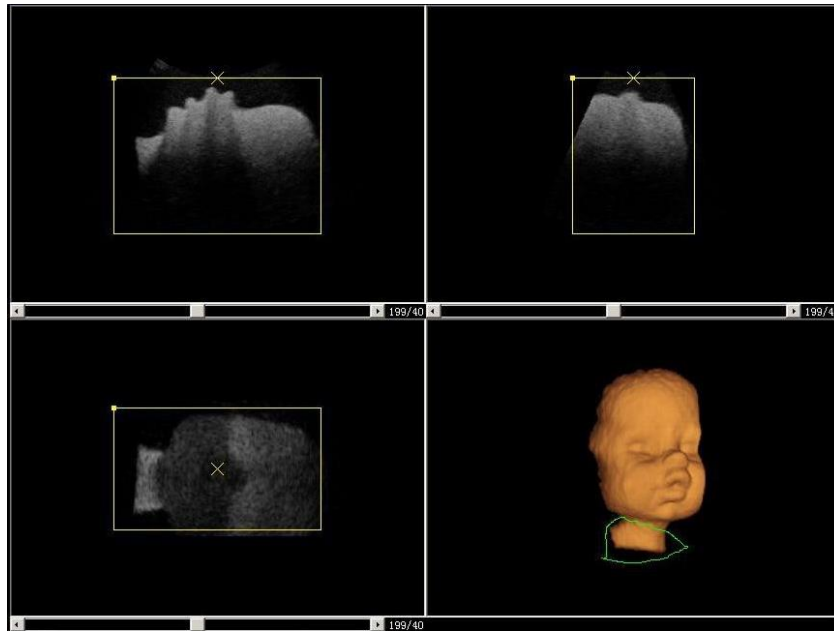
13. Stop 4D data acquisition: Press the [Freeze] key to stop 4D data acquisition;

14. Exit 3D / 4D imaging mode: Press [Exit] on the touch screen to exit the 4D imaging function.

### 8.13.3 Editing 3D / 4D images

**Operation** Edit 3D / 4D images for better images.

1. When the 4D mode image is frozen, or the 3D mode imaging is completed, press the touch screen [Magic Scissor] to use the trackball to select a closed area in the 4D view, and then press the [Set] key again to delete the image of the selected area, as shown below;

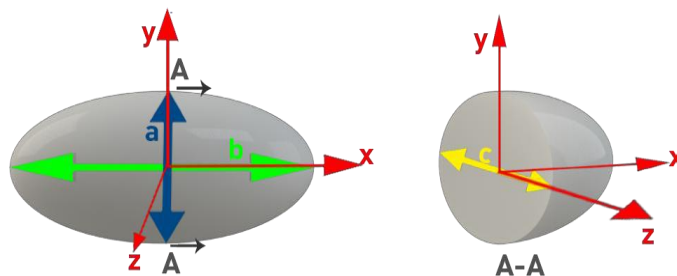


2. When using the trackball to select a closed area in the 4D view, press the [Del] key to reselect the area;
3. Adjust the view angle by pressing [Rotate X], [Rotate Y] or [Rotate Z] on the touch screen, and delete unnecessary parts according to the above steps to obtain a high-quality 3D image. Press the [Save] key to save the image. ;

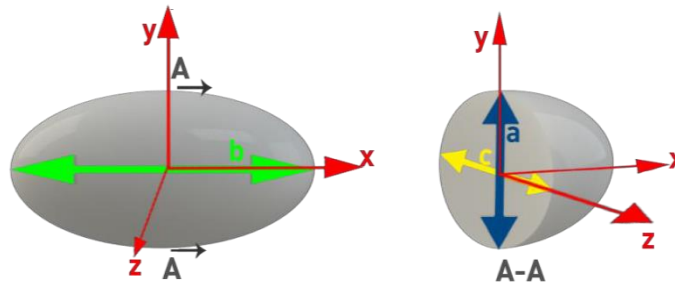
#### 8.13.4 Measure 3D / 4D images

##### Measurement methods

The system provides a fast volume measurement tool. This volume measurement function is based on the ellipsoid formula, which assumes that the object to be measured is an ellipsoid. To calculate the ellipsoid volume, you need to obtain its width and height on its front view cut plane, and then obtain its thickness in the side view. Or get the width in the front view cut plane, and then get the height and thickness in the side view. As shown below.



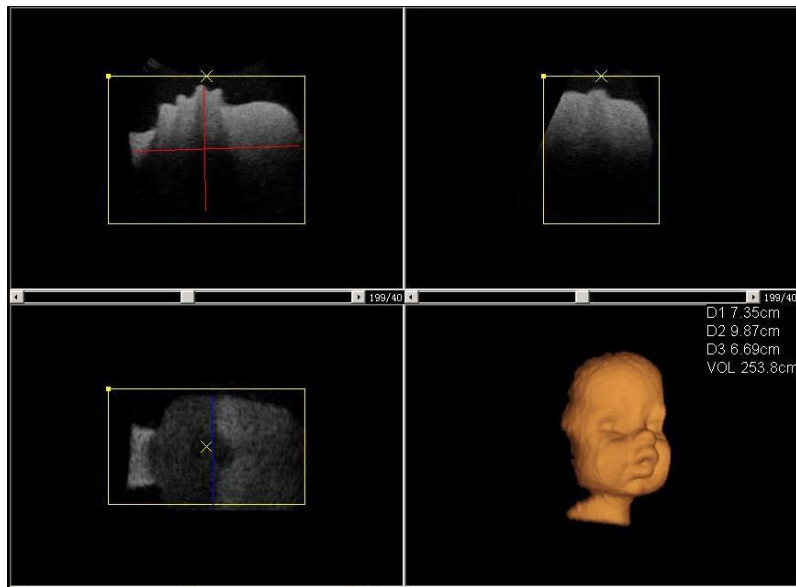
Front view gets width and height, side view gets thickness



Obtain width in front view, get height and thickness in side view

### Operation

1. When the 4D image is frozen, press [Measure] on the touch screen to activate the measurement function;
2. In the forward view, use the trackball and the [Set] key to measure the height and width, and measure the thickness in the side view, as shown below



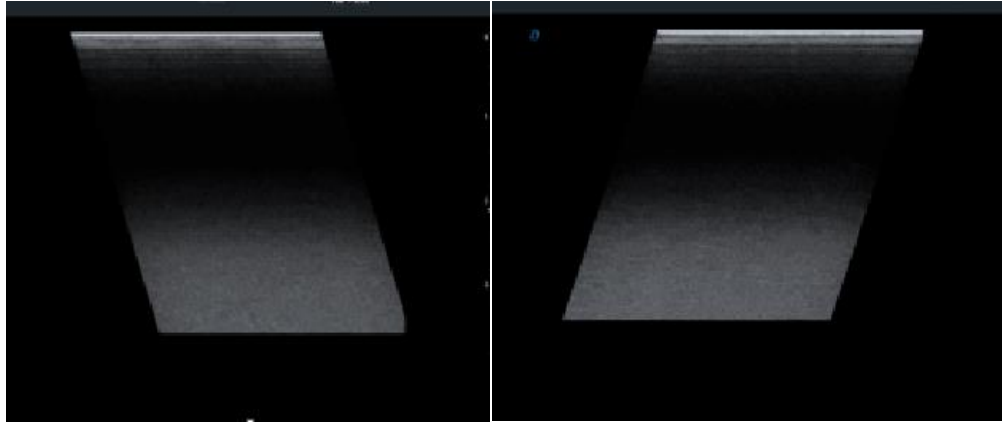
3. After the three length measurements are completed, the volume results are displayed in the upper right of the 4D view.

## 8.14 Deflection imaging mode

### 8.14.1 Overview of Deflection Imaging Modes

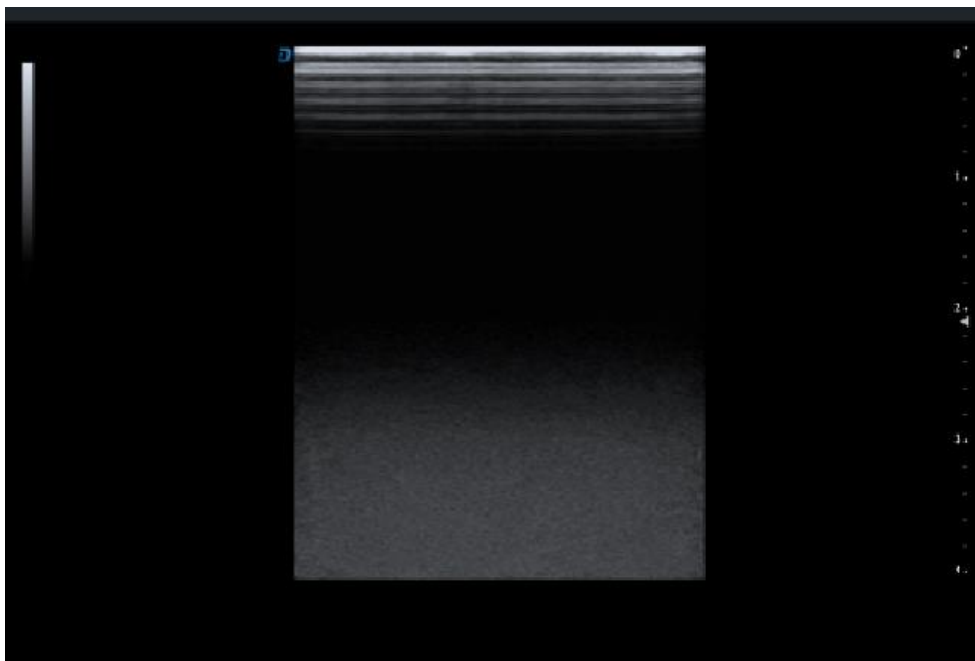
#### Overview

Deflection imaging refers to transforming the line data of a linear array probe into parallelogram images through coordinate transformation and interpolation, which is an extended imaging. The original rectangular style image is converted into a parallelogram,

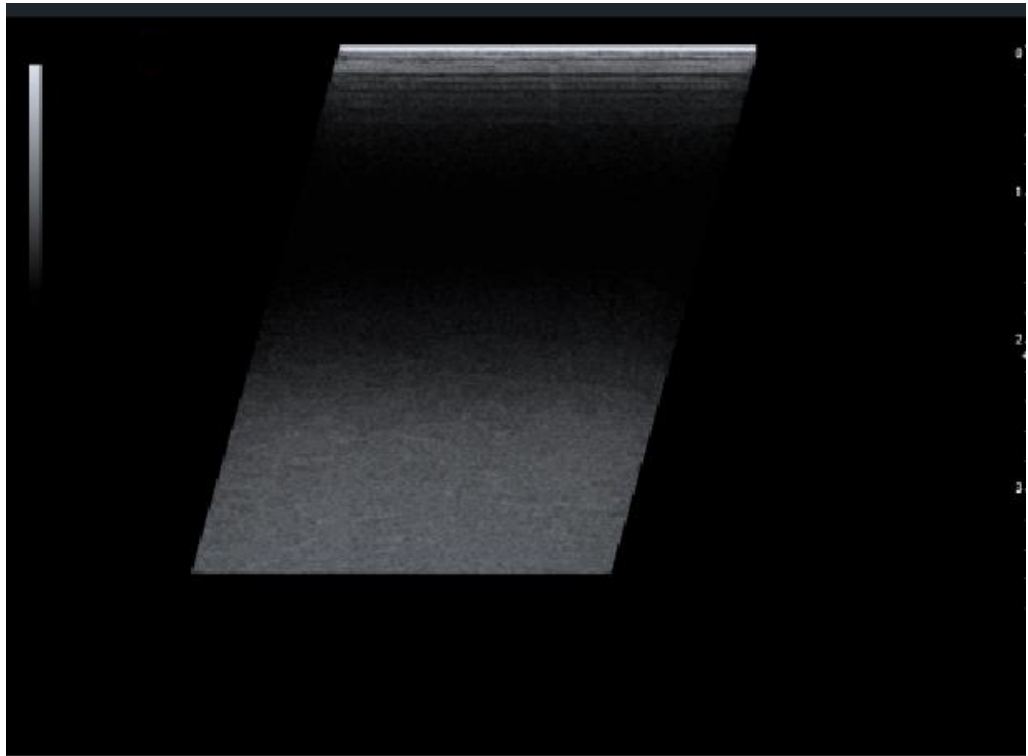


#### 8.14.2 Deflection imaging mode operation

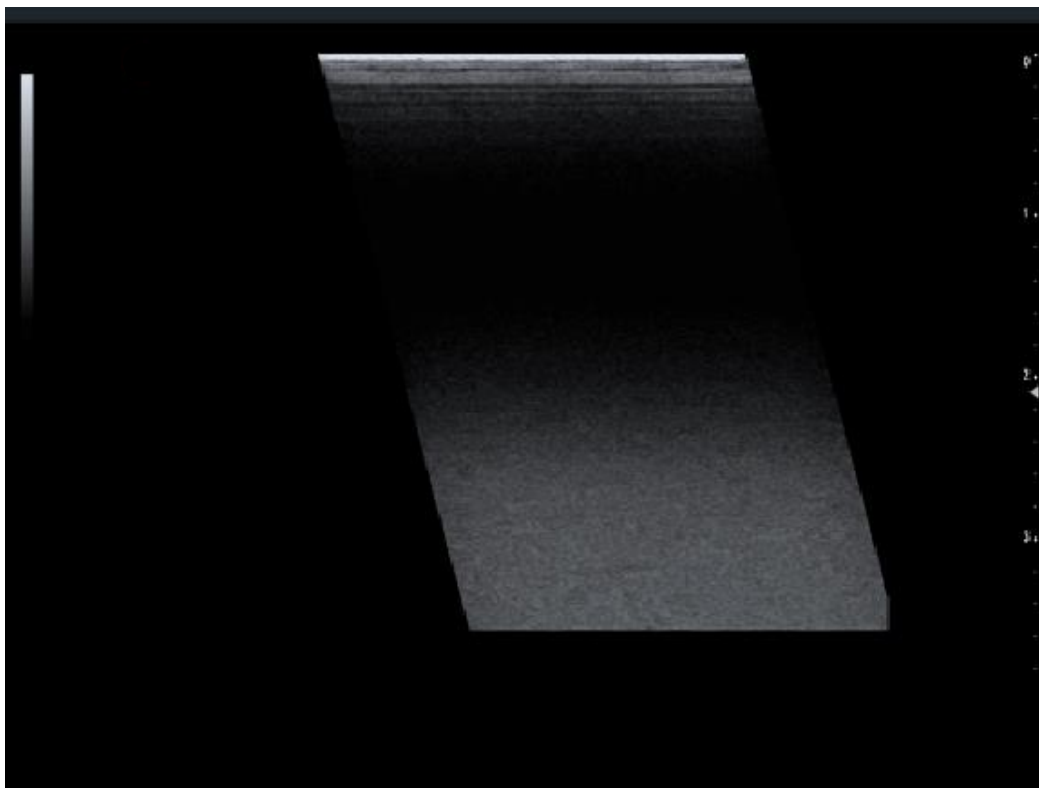
**Operation** 1. Select the line array probe--L5-12L46 and enter the operation interface



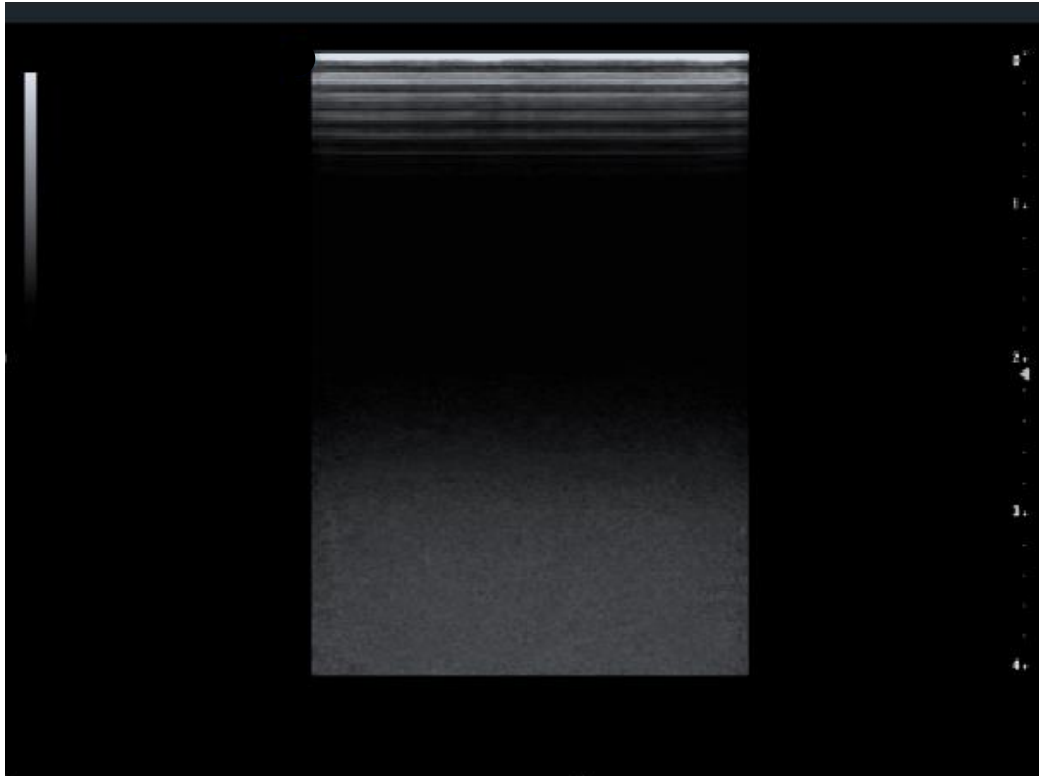
2. Turn the Adjust knob left and right to enter the parallel four sides to form the image mode



**Note:** The above picture shows the Adjust knob turned counterclockwise to the left, and the picture shows the Adjust knob turned clockwise



3. Turn the Adjust knob to make the sector vertical, and then you can exit the parallel four sides to form an image, as shown in the figure below:



## 8.15 Trapezoidal Imaging Mode

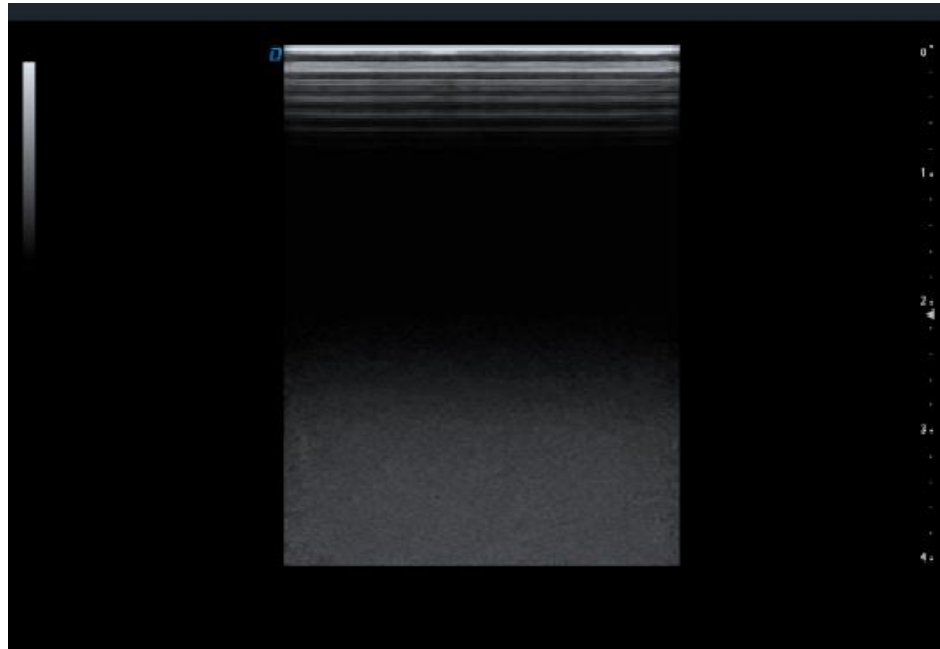
### 8.15.1 Overview of Trapezoidal Imaging Mode

**Overview** Trapezoidal imaging refers to converting the line data of a linear array probe into a trapezoidal image through coordinate transformation and interpolation. The original rectangular style image is transformed into a trapezoid, and the left and right sides are expanded to have a wider field of view.

### 8.15.2 Trapezoidal mode operation

**Operation** 1. Select the line array probe--L5-12L46 and enter the operation interface





2. Press the Adjust knob on the operation panel to enter the trapezoidal imaging mode.



3. Press the Adjust knob again to exit the trapezoidal imaging mode

## 8.16 Contrast Imaging Mode

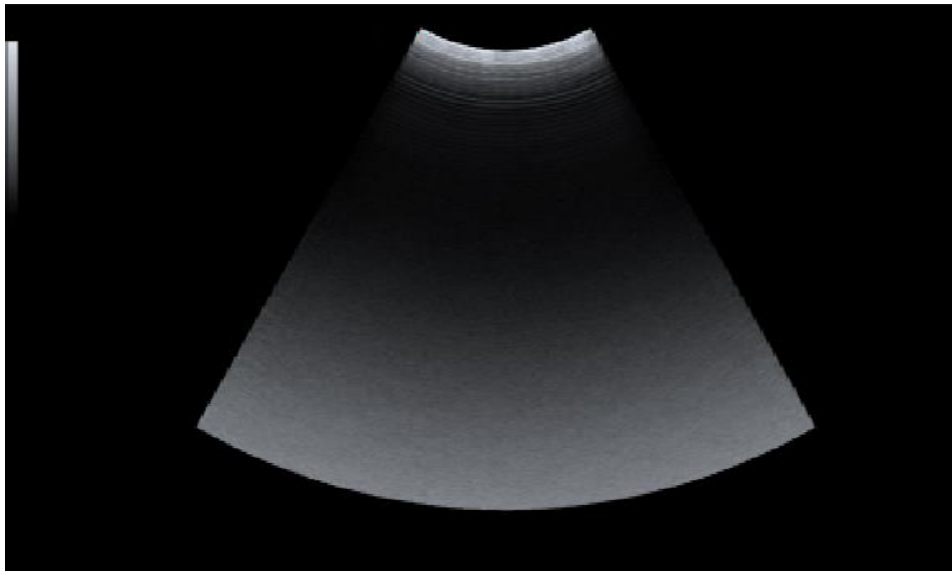
### 8.16.1 Overview of Contrast Imaging Modes



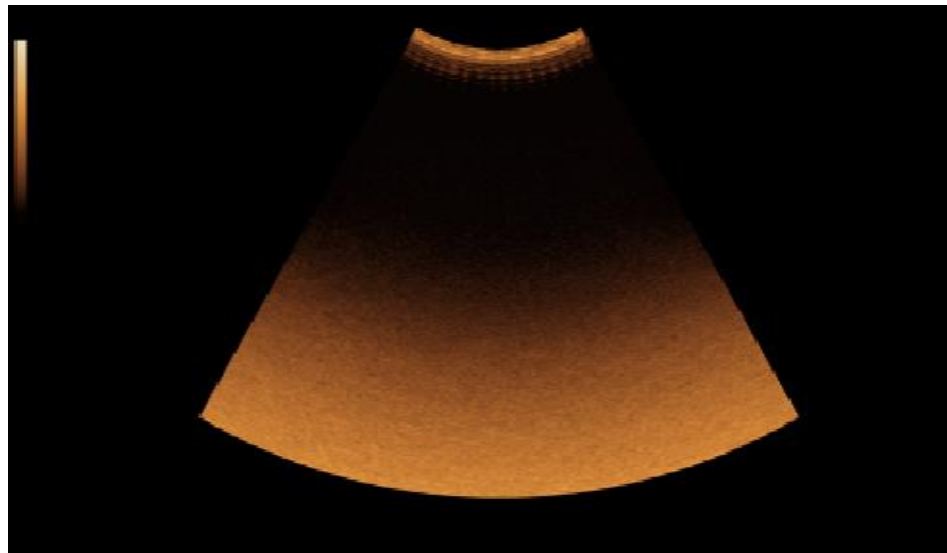
**Overview** Contrast imaging is the use of foreign substances that have significantly different echo characteristics from the human soft tissue, or that have significant differences in acoustic impedance (specific acoustic impedance) into the body cavity, duct, or blood vessel to enhance damage to organs or lesions. Organizational display.

### 8.16.2 Contrast imaging mode operation

**Operation** 1. Select the probe to enter the ultrasound interface



2. Activate contrast imaging mode, click on the contrast imaging on the touch screen



3. Click on the touch screen to exit to close the imaging mode

### 8.16.3 Method for obtaining high-quality contrast imaging image

**General  
practice**

Please select the appropriate default parameter settings when scanning, you can add the presets you created as the default values;

1. Using high frequency can increase the image resolution, and reducing the scanning depth can increase the frame rate;
2. As long as the image area covers the ROI window, reducing the scanning angle can obtain a large frame rate;
3. Turn on the synthetic aperture function without worrying about the frame rate;
4. It is recommended to use the SRI function with low-level spatial composition at the same time. In this way, turning off frame correlation or using low-level frame correlation can avoid image blur, especially in fast-moving tissue / structure inspection.

**Gain  
adjustment**

The following methods can be used to adjust the gain (or brightness):

1. Sound power (transmit power-analog signal)
2. B gain (analog gain)
3. Brightness / contrast (digital linear graph)
4. Dynamic range (digital compression)
5. TGC slider (depth depends on digital gain)



© It is recommended not to change the sound power frequently. If it changes, please ensure that it is within the MI and TIS security range.

© Please avoid trying to increase the brightness of the image by increasing the dynamic range, increasing the TGC gain or adjusting the brightness / contrast when using too low B gain. This is because when the gain of the B mode is too low and the input signal energy is low, the digital gain function mentioned above will bring noise.

© The dynamic range controls the dynamic display range. When the dynamic range is high, the image graininess will be reduced, but it may bring noise in the non-echo area. When the dynamic range is low, the image will be sharpened and the weak signal area will be displayed darker. Generally speaking, abdominal scanning requires a larger dynamic range, and cardiac scanning requires a smaller dynamic range. This system provides two types of dynamic range compression: Sharp (image sharpening) and Dense (image softening), while maintaining the dynamic range unchanged. Dense is used for routine examinations, and Sharp is better for examination of diseased tissues. Press the [Update] key to switch between Sharp or Dense.

© Adjust the brightness / contrast to improve the image quality. Brightness adjustment can increase or decrease the overall brightness of the image. This system realizes the adaptive adjustment of the brightness and contrast functions, that is, each input image will be

converted by this function.

© The TGC slider should be in the center position, because the simulated TGC gain has been achieved through the B gain compensation organization depth attenuation. Therefore, the TGC slider can be used to fine-tune or enhance the image. For example, bow-shaped TGC curves are required for cardiac imaging (ie, low TGC gain in the near and far fields, and high TGC gain in the mid field).

## **Image Resolution**

Proper use of the following features can improve image resolution:

1. Space Synthesis (SC)
2. Speckle noise suppression (SRI)
3. Frame correlation
4. Noise suppression



© SC provides a natural and effective way to improve image resolution. The disadvantage is that the composition of image frames is not on the same anatomical plane when inspecting fast-moving organs, which will cause a delay (smear) of the image. So SC is mostly used to check organs that move less (this may require a sufficiently high frame rate)

© Unlike SRI, SRI is an image post-processing function. It is recommended to use an appropriate SRI level to reduce speckle noise in the image without making the tissue image too smooth.

© We recommend using a lower level SRI to reduce speckle in the image. Too high a SRI level will cause the image to be too smooth and look blurry.

© Frame correlation is a time filter that averages images one frame at a time. Frame correlation reduces system (or electronic) noise and improves resolution without changing the frame rate. When examining fast-moving organs, applying low-level frame correlation can avoid image blur.

© Using SC and SRI at the same time, the image resolution becomes better, and using low frame correlation will avoid image blur.

© The noise suppression function is used to reduce the residual noise formed by the hardware and image post-processing functions in the system. Increasing the noise suppression level makes the image cleaner, but too high a level may reduce the signal energy and blur the image.

## Chapter 9 Conventional Measurements and Calculations

### 9.1 Quick measurement

**Description** Quick measurement is the most commonly used series of basic measurements in each mode provided by the system. The user can enter the quick measurement function by pressing the [Caliper] key on the control surface;

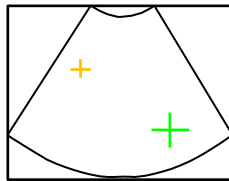
#### 9.1.1 Quick measurement in B mode

##### Distance

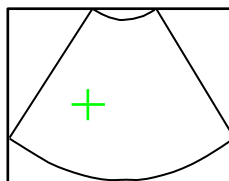
**Description** Measure the distance between two points on the B-mode image.

**Operation**

1. In B mode, find the image to be measured by scanning, press the [Caliper] key to activate the quick measurement menu, and a green “+” cursor is displayed in the image area;
2. Move the green “+” cursor to the starting point of the B-mode image measurement, and press the [Set] key to locate it;
3. Continue to move the green “+” cursor to the end point of the B-mode image measurement. The measurement result will be updated in real time as the cursor moves. Press the [Set] key to locate the end point of the measurement.



4. Press the [Del] key to cancel the last measurement. Press the [Clear] key to clear all measurement information.



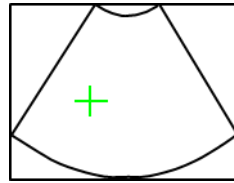
5. Perform the next distance measurement and repeat steps 2 and 3 above.

## Area

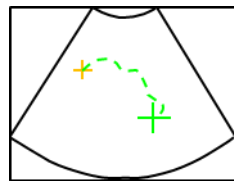
**Description** The area of a closed area on the B-mode image is measured by tracing.

**Operation**

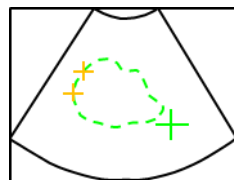
1. In B mode, scan to obtain the image to be measured, press [Caliper] key to activate the quick measurement menu, and the image area displays a green "+" cursorB
2. The user selects the area measurement by moving the trackball. When the cursor is on the area measurement menu, click the [Set] key to enter the area measurement;



3. Move the green "+" cursor to the measurement starting point and press the [Set] key to locate it;



4. Use the trackball to trace the boundary of the prediction area, and move the green "+" cursor to the end of the measurement. The measurement results will be updated in real time as the cursor moves. Press the [Set] key to locate, the area and perimeter results are displayed on the right side;



5. Press the [Del] key to cancel the last measurement. Press the [Clear] key to clear all measurement information.
6. Perform the next area measurement and repeat steps 3 and 4 above.

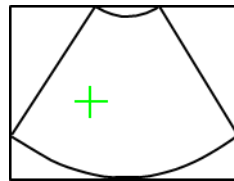
## Ellipse

### Description

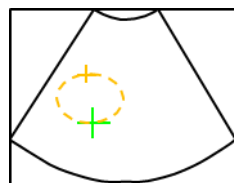
The ellipse method measures area and perimeter.

### Operation

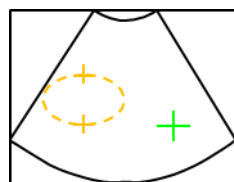
1. In B mode, scan to get the image to be measured, press the [Caliper] key to activate the quick measurement menu, and the image area displays a green "+" cursor;
2. The user selects the ellipse measurement by moving the trackball. When the cursor is on the ellipse measurement menu, click the [Set] key to enter the ellipse measurement item;
3. Move the green "+" cursor to the starting point of the B-mode image measurement, and press the [Set] key to locate it;



4. Continue to move the green "+" cursor to the end point of the B-mode image measurement. Press [Set] to locate the system. The system will automatically generate an ellipse. Use the trackball to control the size of the ellipse and update it in real time as the cursor moves



5. Press the [Set] key to complete the measurement. The area and perimeter measurement results are displayed on the right side of the screen;

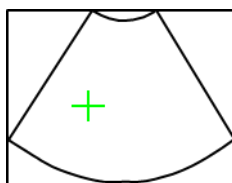


6. Press the [Del] key to cancel the last measurement. Press the [Clear] key to clear all measurement information.
7. Perform the next ellipse measurement and repeat steps 3 ~ 5 above.

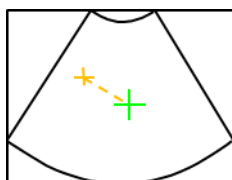
## Angle

### Operation

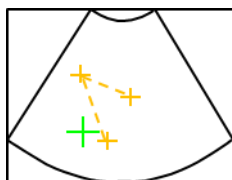
1. When the B-mode image is frozen, press the [Caliper] key to open the general measurement menu;
2. Click the angle measurement menu to activate the angle measurement, and the image area displays a green "+" cursor;



3. Move the green "+" cursor to the measurement starting point, and press the [Set] key to locate, the yellow dotted line is displayed;

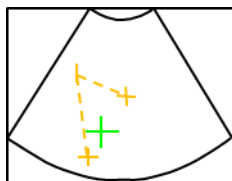


4. Continue to move the green "+" cursor to the end point of the first measurement line, and press the [Set] key to locate it;



5. Continue to move the green "+" cursor to the end of the second measurement line, and press [Set] to locate. The measurement is finished and the angle measurement result is

displayed on the right side of the screen

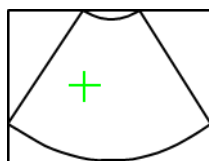


6. Press the [Del] key to cancel the last measurement. Press the [Clear] key to clear all measurement information.
7. Perform the next angle measurement and repeat steps 3 ~ 6 above.

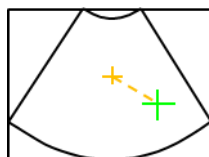
### Distance ratio

**Description** Used to measure the ratio between two distances on a B-mode image.

- Operation**
1. When the B-mode image is frozen, press the [Caliper] key to open the general measurement menu;
  2. Click on the distance ratio measurement item and the green “+” cursor will be displayed in the image area;

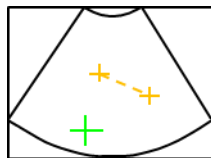


3. Move the green “+” cursor to the start point of the B-mode image measurement, and press [Set] to locate it. A yellow dotted line will be displayed;

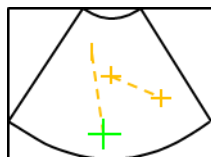


4. Continue to move the green “+” cursor to the end point of the first measurement line, and press the [Set] key to locate it;

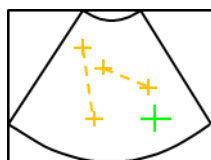




5. Move the green "+" cursor to the starting point of the second measurement line, and press the [Set] key to locate;



6. Continue to move the green "+" cursor to the end point of the second dashed line of measurement, and press [Set] to locate it. The current measurement is over, and the two distances and ratios are displayed in the result window.



7. Press the [Del] key to cancel the last measurement. Press the [Clear] key to clear all measurement information.
8. Perform the next distance ratio measurement and repeat steps 3 to 6 above.

## Area ratio

### Description

Measure the area ratio between a small area and a large area.

### Operation

1. When the B-mode image is frozen, press the [Caliper] key to open the general measurement menu;
2. Click the area ratio measurement item on the menu, and the image area will display a green "+" cursor;点

3. Locate the first area: ① Move the green "+" cursor to the measurement starting point of the area and press [Set] to locate it; ② Use the trackball to trace the boundary of the predicted area and continue to move the green "+" cursor to the area Measurement end point, press [Set] key to locate;
4. Locate the second area: ① Move the green "+" cursor to the measurement start point of the second area and press [Set] to locate it; ② Continue moving the green "+" cursor to the measurement end point of the area and press [Set] Key positioning, the measurement is finished, the system automatically generates an ellipse, and the area / perimeter and area ratio are displayed on the right side of the screen;
5. Press the [Del] key to cancel the last measurement. Press the [Clear] key twice to clear all measurement information.
6. Perform the next area ratio measurement and repeat steps 3 to 4 above

## Volume

### Description

The volume is calculated by Measurement three distances.

### Operation

1. When the B-mode image is frozen, press the [Caliper] key to open the general measurement menu;
2. Click the volume measurement on the menu, and the green "+" cursor will be displayed in the image area;
3. Measure three radial lines, move the green "+" cursor to the start and end points of each radial line, and press the [Set] key to locate;
4. Press the [Set] key to locate the end point of the third radial line. At the end of this measurement, the volume calculation result is displayed on the right side of the screen immediately;
5. Press the [Del] key to cancel the last measurement. Press the [Clear] key to clear all

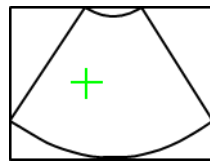
measurement information.

6. Perform the next volume measurement and repeat steps 3 to 4 above.

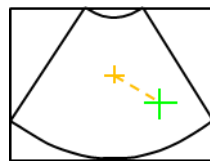
## Cross

**Description** The cross-line method measures area and perimeter.

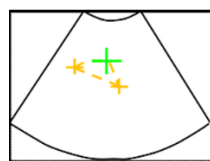
- Operation**
1. When the B-mode image is frozen, press the [Caliper] key to open the general measurement menu;
  2. Click the cross-line measurement item on the measurement menu, and the image area displays a green "+" cursor;
  3. Move the green "+" cursor to the start point of the B-mode image measurement, and press the [Set] key to locate, the yellow dotted line will be displayed;



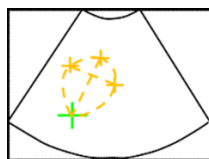
4. Continue to move the green "+" cursor to the location of interest, and press the [Set] key to locate it;



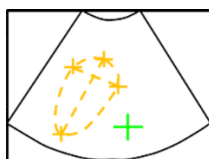
5. Move the green "+" cursor to the starting point of the second measurement line, and press the [Set] key to locate the cross line;



6. Continue to move the green “+” cursor to the end of the measurement and press the [Set] key to locate it. This measurement ends.



7. The distance, area and perimeter of the two segments are displayed on the right side of the screen;



8. Press the [Del] key to cancel the last measurement. Press the [Clear] key to clear all measurement information.
9. Perform the next crosshair measurement and repeat steps 3 ~ 6 above.

## Volume(Ellipse)

### Description

Volume is measured from an elliptical area selected on the image. Obviously this volume value is obtained by rotating the ellipse 360 degrees.

### Operation

1. When the B-mode image is frozen, press the [Caliper] key to open the general measurement menu;
2. Click the volume (ellipse) measurement item on the menu, and the image area will display a green "+" cursor;
3. Move the green “+” cursor to the measurement starting point and press the [Set] key to locate it;
4. Continue to move the green "+" cursor to the end of the measurement, and press [Set] to locate it. The system will automatically generate an ellipse. Use the trackball to control the

size of the ellipse and update it as the cursor moves

5. During measurement, press the [Set] key multiple times to activate the start and end points of the measurement in sequence, and move the trackball to control the rotation, position, and size of the ellipse;

6. Press the [Set] key to complete the measurement and fix the measurement end point. The area, perimeter and volume measurement results are displayed on the right side of the screen;

7. Press the [Del] key to cancel the last measurement. Press the [Clear] key to clear all measurement information.

## Joint Angle

### Description

Measure the angle between the two joints based on a baseline and two crossing line segments. Joint angle measurements always take an included angle that is less than or equal to 90 °.

### Operation

1. When the B-mode or C-mode image is frozen, press the [Caliper] key to open the general measurement menu;

2. Click the joint angle measurement item on the menu, a yellow straight line will appear in the image area with a point on the straight line;

3. Use the trackball to move the straight line to the starting point of the measurement, turn the [Adjust] key to adjust the straight line angle, determine the baseline position and press the [Set] key to locate and display the yellow dotted line;

4. At this time, a second line appears on the screen. Follow step 3 to determine the position of the second line. Press [Set] to locate the angle  $\alpha$  value in the result window on the right side of the screen.

5. Determine the position of the third straight line according to step 3. When the third line is

determined, the angle  $\beta$  value is also displayed in the result window on the right side of the screen;

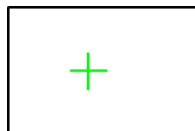
6. Press the [Del] key to cancel the last measurement. Press the [Clear] key to clear all measurement information.

### 9.1.2 Quick measurement in M mode

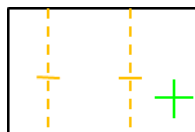
#### HR

**Description** The HR measurement is a measurement of the time interval between 2 heartbeat cycles on the M image and calculates the number of heartbeats per minute.

- Operation**
1. When scanning in M mode or freezing in real time, press the [Caliper] key to open the shortcut measurement menu, and a green “+” cursor is displayed in the image area
  2. Move the green crosshair to the starting point of M mode image measurement, and press the [Set] key to locate;



3. Continue to move the crosshair to the end point of the M-mode image measurement and press the [Set] key to locate. At the end of this measurement, the measured value of the heart rate value is displayed in the result window

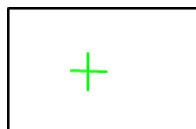


4. Press the [Del] key to cancel the last measurement. Press the [Clear] key to clear all measurement information.
5. Perform the next heart rate measurement and repeat steps 2 and 3 above.

#### Time

**Operation**

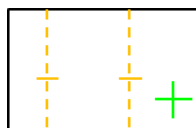
1. When scanning in M mode or the image is frozen, press the [Caliper] key to open the shortcut measurement menu image area and display a "+" cursor;]
2. Select the time measurement item by sliding the trackball, and press [Set] to enter the time measurement item. The M image area displays a crosshair;



3. Move the crosshair to the starting point of M mode image measurement, and press [Set] key to locate;



4. Continue to move the crosshair to the end point of M mode image measurement, press [Set] key to locate, the current measurement ends, and the current time measurement will be displayed on the right side of the screen;



5. Press the [Del] key to cancel the last measurement. Press the [Clear] key to clear all measurement information.
6. Perform the next time measurement and repeat steps 3 ~ 4 above.

**Slope****Description**

Slope measurement calculates the average degree between two points by Measurement the distance and time between two points on the M image.

- Operation**
1. When scanning in M mode or the image is frozen, press the [Caliper] key to open the general measurement menu;
  2. Click the slope measurement on the measurement menu, the M image area displays a crosshair;
  3. Move the crosshair to the starting point of M mode image measurement and press [Set] key to locate;
  4. Continue to move the crosshairs to the end point of the M-mode image measurement and press the [Set] key to locate the measurement. The current distance, time and slope will be displayed on the right side of the screen;
  5. Press the [Del] key to cancel the last measurement. Press the [Clear] key to clear all measurement information.
  6. Perform the next slope measurement and repeat steps 3 to 4 above.

### Distance (M) measurement

**Description** The distance (M) measurement measures the distance between two points on the M-mode image.

- Operation**
1. When the M mode image is frozen, press the [Caliper] key to open the general measurement menu;
  2. Click the distance (M) measurement menu, and the “+” cursor will be displayed in the M image area;
  3. Move the “+” cursor to the starting point of M mode image measurement, and press [Set] to locate;
  4. Continue to move the “+” cursor to the end of the M mode image measurement, and press



[Set] to locate. The current measurement will end and the current distance will be displayed on the right side of the screen;

5. Press the [Del] key to cancel the last measurement. Press the [Clear] key to clear all measurement information.

6. Perform the next distance (M) measurement and press the [Set] key, then repeat the above steps 3 ~ 4.

### 9.1.3 Quick measurement in C mode

**Description** In C mode, press the [Caliper] key to activate the quick measurement menu.

The quick measurement items in C mode are the same as those in B mode. Please refer to B mode for measurement operation.

### 9.1.4 D mode routine measurement

**Description** In C mode, press the [Caliper] key to activate the quick measurement menu.

The quick measurement items in C mode are the same as those in B mode. Please refer to B mode for measurement operation.

### Automatic spectrum envelope

**Description** The system automatically envelopes the spectrum and calculates the relevant parameters.

**Description** 1. When the image in D mode is frozen, press the [Caliper] key to open the shortcut measurement menu, and a green crosshair cursor will be displayed in the image area;

2. Find the beginning of the spectrum cycle and press the [Set] key;

3. Move the trackball to the end of the spectrum cycle again, and press the [Set] key again, the measurement result will be displayed on the screen;

4. Press the [Del] key to cancel the last measurement. Press the [Clear] key to clear all measurement information.

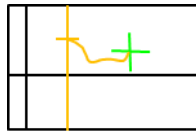
### Manual envelope measurement

**Description** The manual envelope of Doppler spectrum is obtained by drawing one or several Doppler waveforms on the D-mode image to obtain clinical indicators of speed and pressure step index.

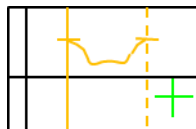
- Description**
1. When the D mode image is frozen, press the [Caliper] key to open the general measurement menu;
  2. Click on the manual envelope measurement item in the menu, the green cross line will be displayed in the D image area;



3. Move the green cross to the starting point of the trace and press the [Set] key to locate it;



4. Move the green "cross-line envelope Doppler waveform along the spectrum boundary. Roll the trackball to the left to delete the envelope. In this way, move the trackball to the end of a cardiac cycle. Press the [Set] key to locate the measurement end point. The end of each measurement, the measurement results are automatically displayed on the right side of the screen;



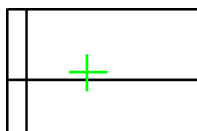
5. Press the [Del] key to cancel the last measurement, and press the [Clear] key to clear all measurement information;

6. Perform the next manual envelope measurement and repeat steps 3 to 4 above.

### Resistance index measurement

**Description** Measure the speed and pressure difference of two peak points on the blood flow waveform in the multi-spectrum of D mode, and calculate the ratio of the resistance index.

- Operating**
1. When the D mode image is frozen, press the [Caliper] key to open the general measurement menu;
  2. Click on the resistance index measurement item on the menu, the green cross line is displayed in the D image area;



3. Move the green cross line to the starting point of the measurement and press the [Set] key to locate the second cross line;



4. Continue to move the green cross to the end of the measurement, and press [Set] to locate it. This measurement ends. The Doppler flow velocity and resistance index at the start and end points are displayed in the result window.



5. Press the [Del] key to cancel the last measurement, and press the [Clear] key to clear all measurement information;

6. Perform the next resistance index measurement and repeat steps 3 to 4 above.

### Pulsation index measurement

#### Operating

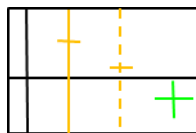
1. When the D mode image is frozen, press the [Caliper] key to open the general measurement menu;
2. Click the pulsatility index measurement item in the menu, and the D image area displays a green cross line;



3. Move the green cross to the starting point of the measurement and press the [Set] key to locate the Doppler flow velocity measurement at the first peak point;



4. Continue to move the green cross line to the end of the measurement, and press [Set] to locate the measurement. The Doppler flow velocity and pulsation index at the start and end points are displayed in the result window



5. Press the [Del] key to cancel the last measurement, and press the [Clear] key to clear all measurement information;
6. Perform the next beat index measurement and repeat steps 3 to 4 above.

### S/D measurement

**Operating**

1. When the D mode image is frozen, press the [Caliper] key to open the general measurement menu;
2. Click the S / D measurement item in the menu, and the D image area displays a green cross line;
3. Move the green cross to the starting point of this measurement and press the [Set] key to locate;
4. Continue to move the green "+" cursor to the end of the measurement and press the [Set] key to locate it. This measurement ends and the measurement result is automatically displayed on the right side of the screen;
5. Press the [Del] key to cancel the last measurement, and press the [Clear] key to clear all measurement information;

Perform the next S / D (manual) measurement and repeat steps 3 to 4 above.

## Chapter 10 Software Package Measurement and Calculation

### 10.1 Package Measurement and Calculation Overview



© To achieve the special measurement in the software package, you must enter the corresponding part.



© Software package measurement can measure frozen images, movie playback images, and browser window images, but it cannot measure saved image format images and AVI format images.

© If the image is thawed during the measurement, the basic measurement results will be lost.

© The measurement results will be saved to the patient's reporting system only after pressing the [Save] key.

### 10.2 Obstetric measurement



© Before obstetric measurement, please first select the application probe and clinical application type. After the setting is completed, register the new patient and create a new patient;

© Please make sure that the current system check date is correct, otherwise the calculated gestational age and expected delivery date are wrong.

© Obstetric measurement and calculation should ensure that the dignity and privacy of patients are not violated.

#### Measurement items

Obstetric (OB) measurement can evaluate fetal development and its indicators. By Measurement each parameter of the fetus, the system automatically calculates the gestational age, the expected date of birth, the fetal weight, and evaluates the fetal development status.

#### Enter information before checking

Before obstetric examination, in addition to registering the basic information of the patient, you also need to enter the patient's last menstruation, number of miscarriages, number of births, number of pregnancy, and number of births in the obstetrics page of the new patient interface for clinical diagnosis reference;

#### 10.2.1 B-mode measurement

The following measurement items are calculated in the obstetric examination mode. Some measurements can only be used in specific inspection calculations.

**Measurement example: Double top diameter**

To measure the double top diameter, you need to measure a distance:

1. Select the "double top diameter" measurement item, a cross cursor will be displayed;
2. Move the trackball to select a starting point for the double top diameter, and press the [Set] key;
3. Move the trackball to select the end point on the other side of the double top diameter, and press the [Set] key. The measurement result will be displayed in the screen area;

The following table lists these special measurements

Type	Item	Method
measurement	BPD	2D distance
	FL	
	AFI(2) D1	
	AFI(2) D2	
	AFI(4) D1	
	AFI(4) D2	
	AFI(4) D3	
	AFI(4) D4	
	GSLen	
	GSLen1	
	GSLen2	
	GSLen3	
	CRL	
	OFD	

	Ulna	
	NT	
	Fibula	
	Humerus	
	N.B.L	
	Radius	
	Tibia	
	HC	2D area
	AC	
Research kit	AFI	
Calculated item	AFI(2)	$AFI = D1 + D2$
	AFI(4)	$AFI = D1 + D2 + D3 + D4$
Research kit	EFW	Hodlock1, Hodlock2, Hodlock3, Hodlock4, Merz1, Merz2

The following table lists the methods for Measurement the fetal weight.

Type	Item	Method
Research kit	EFW (Hodlock1)	AC, FL
	EFW (Hodlock2)	AC, FL,BPD
	EFW (Hodlock3)	AC, FL, HC
	EFW (Hodlock4)	AC, FL, HC,BPD
	EFW (Merz1)	AC, BPD
	EFW (Merz2)	AC



The following table lists the calculation formulas used for the measurement items.

Formula name	Formula description	Unit
Hadlock1	$EFW = 10^{(1.304 + (0.05281 \times AC) + (0.1938 \times FL) - (0.004 \times AC \times FL))}$ $SD = 0.154 \times EFW$	g
Hadlock2	$EFW = 10^{(1.335 - (0.0034 \times AC \times FL) + (0.0316 \times BPD) + (0.0457 \times AC) + (0.1623 \times FL))}$ $SD = 0.146 \times EFW$	g
Hadlock3	$EFW = 10^{(1.326 - (0.00326 \times AC \times FL) + (0.0107 \times HC) + (0.0438 \times AC) + (0.158 \times FL))}$ $SD = 0.148 \times EFW$	g
Hadlock4	$EFW = 10^{(1.3596 - (0.00386 \times AC \times FL) + (0.0064 \times HC) + (0.00061 \times BPD \times AC) + (0.0424 \times AC) + (0.174 \times FL))}$ $SD = 0.146 \times EFW$	g
Merz1	$EFW = -3200.40479 + (157.07186 \times AC) + (15.90391 \times (BPD^2))$	g
Merz2	$EFW = 0.1 \times (AC^3)$	g

### 10.2.2 M-mode measurement

The following measurement items are calculated in the obstetric examination mode. Some measurements can only be used in specific inspection calculations. These special measurements are listed below.

Type	Item	Method
Measurement	fetal heart rate (2)	M heart rate

### 10.2.3 D-mode measurement

The following measurement items are calculated in the obstetric examination mode. Some measurements can only be used in specific inspection calculations. These special measurements are listed below.

Type	Item	Method
Measurement	fetal heart rate (2)	D heart rate

### 10.3 Gynecological measurement



© Before gynecological measurement, please first select the application probe and clinical application type. After the setting is completed, register a new patient and create a new patient

© Gynecological measurements and calculations should ensure that the dignity and privacy of patients are not violated.

#### 10.3.1 B-mode measurement

The following measurement items are calculated in the gynecological examination mode. Some measurements can only be used in specific inspection calculations.

#### Measurement examples: uterine long diameter, wide diameter and thick diameter

Each item is a standard distance measurement, usually the long and thick diameters are measured on the sagittal plane, and the wide diameter is measured on the horizontal plane:

1. Scan the appropriate plane of the patient's part;
2. Select the study package "Uterus", then select "Uterine Long Diameter", "Uterine Wide Diameter", and "Uterine Thick Diameter". The system displays an activated cross ruler
3. Measure a standard distance measurement;
4. To measure the second and third distance measurements, repeat 2 ~ 3. After finishing three distance measurements, the system will display the value of uterine volume in the result window;

The following table lists these special measurements

Type	Item	Method
------	------	--------

Measurement	UT L	2D Distance
	UT W	
	UT T	
	Cervix L	
	Cervix T	
	Cervix W	
	Uterus Body	
	Cervix	
	Lt.Ovary L	
	Lt.Ovary W	
	Lt.Ovary T	
	Rt.Ovary L	
	Rt.Ovary W	
	Rt.Ovary T	
	Lt.DOF L	
	Lt.DOF W	
	Rt.DOF L	
	Rt.DOF W	
	UTB HR	
	UTB VR	
	APBU R	
	Endo L	

## 10.4 Urinary measurement



© Before urinary measurement, please select the application probe and clinical application type. After the setting is completed, register a new patient and create a new patient

© Urinary measurement and calculation should ensure that the dignity and privacy of patients are not violated.

#### 10.4.1 B-mode measurement

The following measurement items are listed in the measurement package in urological examination mode. Some measurement items are only available with specific calculation options.

#### Measurement examples: kidney long diameter, wide diameter, thick diameter

Each of these measurements is a standard distance measurement. Usually, length and height are measured in the longitudinal section. Measure width in cross section:

1. Select "Kidney long diameter, Kidney wide diameter, Kidney thick diameter", a cross cursor will be displayed on the screen;

2. Select the correct section, and measure kidney length, kidney width, and kidney thickness respectively.

3. After the last distance measurement, the results of the kidney volume will be displayed on the screen

The following table lists these special measurements

Type	Item	Method
Measurement	Prostate L	2D Distance
	Prostate W	
	Prostate T	
	RU L	
	RU W	
	RU T	
	Lt. Kid. L	
	Lt. Kid. T	
	Lt. Kid. W	

	Lt. Renal CT	
	Rt. Kid. L	
	Rt. Kid. T	
	Rt. Kid. W	
	Rt. Renal CT	
	Lt. AG L	
	Lt. AG T	
	Lt. AG W	
	Rt. AG L	
	Rt. AG T	
	Rt. AG W	
	Lt. Testi. L	
	Lt. Testi. W	
	Lt. Testi. T	
	Rt. Testi. L	
	Rt. Testi. W	
	Rt. Testi. T	
	Lt. Sperm. L	
	Lt. Sperm. W	
	Lt. Sperm. T	
	Rt. Sperm. L	
	Rt. Sperm. W	
	Rt. Sperm. T	

## 10.5 Vascular measurement



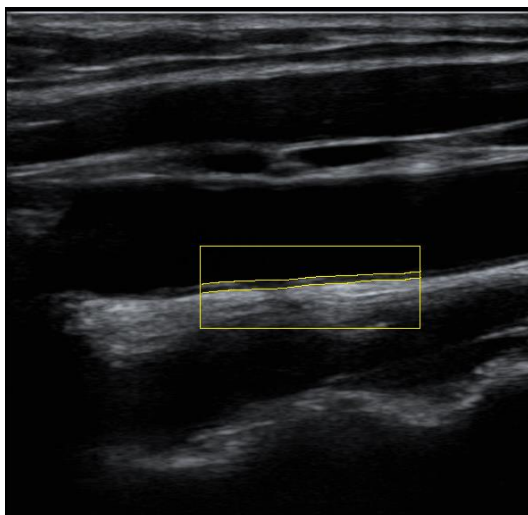
© Before vascular measurement, please first select the application probe and clinical application type. After the setting is completed, register a new patient and create a new patient.

### 10.5.1 B-mode measurement

The following measurement items are listed in the measurement package in vascular examination mode. Some measurement items are only available on specific calculation tabs. The vascular measurement menu includes measurement items such as diameter stenosis ratio, area stenosis ratio, carotid intimal thickness (rear wall), and carotid intimal thickness (anterior wall).

#### Measurement example: Carotid intimal thickness (rear wall)

1. Click on the carotid intimal thickness (back wall) measurement item on the menu, a yellow ROI sampling box will pop up
2. Move the trackball to control the position of ROI sampling to the posterior wall of the carotid artery to be measured (ROI must contain the intima to be measured)
3. Press the [Set] key, and the measurement result will be displayed on the screen.



The following table lists these special measurements

Type	Item	Method
Measurement	Stenosis diameter	2D distance measurement
	Normal diameter	

	Narrow area	2D area measurement
	Normal area	
Calculation	Percent stenosis (diameter)	Percent stenosis (diameter) = $(\text{Normal diameter} - \text{narrow diameter}) / \text{normal diameter}$
	Percent stenosis (area)	Percent stenosis (area) = $(\text{Normal area} - \text{narrow area}) / \text{normal area}$
Measurement	Carotid intimal thickness (rear wall)	Automatic calculation
	Carotid intimal thickness (anterior wall)	Automatic calculation

## 10.6 Cardiac measurement and calculation



© Before cardiac measurement, please first select the application probe (select phased array probe) and clinical application type (select heart). After the setting is completed, register a new patient and create a new patient.

Press the [Calc] key to activate the application measurement and calculation. The following are the menu options for the Heart B mode software package, Heart M mode software package, and Heart D mode



software package.

Heart B Mode Package

Heart M Mode Package

Heart D Mode Package

### 10.6.1 B-mode measurement

The following measurement items are listed in the measurement package in cardiac examination mode. Some measurement items are only available with specific calculation options.

#### Measurement example: main pulmonary artery diameter

Each of these measurements is a standard distance measurement:

1. Select "Inner Diameter of the Primary Pulmonary Artery", a green cross cursor will appear on the screen;
2. Standard distance measurement
3. The measurement result is displayed in the result window of the screen

The following table lists these special measurements



Type	Item	Method
Measurement	LVLd	2D Distance
	LVLs	
	LVIDd	
	LVIDs	
	LVPWd	
	IVSTd	
Measurement	LVALd	Area
	LVALs	
	LVAMd sax MV	
	LVAMs sax MV	
	LVAPd sax PM	
	LVAPs sax PM	
Research	SP Ellipse	
	BP Ellipse	
	Bullet	
	Simpson	
	Simpson SP	
	Simpson BP	

### 10.6.2 M-mode measurement

The following measurement items are listed in the measurement package in cardiac examination mode, and some measurement items are only available in specific calculation tabs.

Type	Item	Method
------	------	--------

Measurement	IVSTd	M Distance
	LVIDd	
	LVPWd	
	IVSTs	
	LVIDs	
	LVPWs	
Measurement	CE	M Distance
	CA	
	AOD	
	ACS	
	LAD	
	ACV	M Slope
	EFSLP	
	CycleT	
	AT	
	DT	
	MV C-O dur	

### 10.6.3 D-mode measurement

Some measurement items are only available in specific calculation tabs in D mode.

Type	Item	Method
Measurement	MR-VTI	D Mode Trace
	LVOT VTI	
	TV VTI	
	PV VTI	

	AV VTI	
	D-Wave-VTI	
	S-Wave-VTI	
Measurement	AV	D Mode Velocity
	Velocity	
	MV-E	
	MV-A	
	AOR-Vmax	
	AOR-Ved	
	LVOT-Vel	
	TV Velocity	
	TR Velocity	
	PV Velocity	
	S2-Wave-V	
	S1-Wave-V	
	PVA-Wave-V	
	D-Wave-V	
Measurement	MV-Dct	Acceleration
	PW-Dct	
	BF-AcT	
	BF-DcT	
Measurement	PHT	Time
	MV-IRT	
	E-Wave-Vel	
	A-Wave-Vel	

	AR-Time	
	BF CycleT	
	LVET	

### 10.6.4 Single plane ellipse

There are a series of measurements in B mode and M mode for calculating left ventricular cardiac function, and a series of left ventricular cardiac function values are calculated according to the corresponding measurements of the left ventricle at two different phases of end systole and end diastole.

#### Left ventricular function table

Type	Item	Method
SV	Stroke volume	$SV(\text{ml}) = EDV(\text{ml}) - ESV(\text{ml})$
CO	Cardiac output	$CO(\text{l/min}) = SV(\text{ml}) \times HR(\text{bpm}) / 1000$
EF	Ejection fraction	$EF(\text{No unit}) = SV(\text{ml}) / EDV(\text{ml})$
SI	Stroke Volume Index	$SI(\text{No unit}) = SV(\text{ml}) / \text{Body surface area}(\text{m}^2)$
CI	Cardiac output index	$CI(\text{No unit}) = CO(\text{l/min}) / \text{Body surface area}(\text{m}^2)$
FS	Shorten the score	$FS(\text{No unit}) = (LVIDd(\text{cm}) - LVIDs(\text{cm})) / LVIDd(\text{cm})$
MVCF	Average peripheral shortening rate	$MVCF = (LVIDd(\text{cm}) - LVIDs(\text{cm})) / (LVIDd(\text{cm}) \times ET(\text{s}))$

#### Research item

Type	Item	Method
LVLd	Left ventricular long axis	2D distance measurement
LVAd	Apical left ventricular long axis area	2D area measurement
LVLs	Left ventricular long axis	2D distance measurement
LVAAs	Systolic left ventricular long axis area	2D area measurement

HR	Heart rate	M mode heart rate measurement or direct input
----	------------	---

## Research result

Type	Item	Method
EDV (Single Plane Ellipse)	End-diastolic left ventricular volume	$EDV = 8/3\pi \times LVA_d (\text{cm}^2)^2 / LVL_d (\text{cm})$
ESV (single plane ellipse)	Left ventricular volume	$EDV = 8/3\pi \times LVA_s (\text{cm}^2)^2 / LVL_s (\text{cm})$
SV (Single Plane Ellipse)	Volume per blog	Calculated according to the "Left Ventricular Function Table"
CO (single plane ellipse)	Cardiac output	
EF (single plane ellipse)	Ejection fraction	
SI (Single Plane Ellipse)	Volume index	
CI (single plane ellipse)	Cardiac output index	

## Steps

1. Select [Single Plane Ellipse] in the measurement menu
2. At the end of the diastolic apical long-axis section, measure the following parameters:  
LVLd, LVA<sub>d</sub>  
The EDV value can be obtained.
3. At the end of the systole, the apical long axis section was measured with the following parameters:  
LVLs, LVA<sub>s</sub>  
ESV value can be obtained;  
System calculates SV and EF;  
If height and weight are entered, the system automatically calculates SI
4. If HR is measured or entered

The system automatically calculates CO and calculates CI based on the entered height and weight

### 10.6.5 Biplane ellipse

#### Invention project

Type	Description	Method
LVIDd	Left ventricular short axis diameter	2D distance
LVIDs	Left ventricular short axis diameter	
LVAd sax MV	End-diastolic mitral valve left ventricular short-axis area	2D area
LVAAs sax MV	Left ventricular short-axis area of mitral level at the end of systole	
LVAd	Apical left ventricular long axis area	
LVAAs	Systolic left ventricular long axis area	
HR	Heart rate	M mode heart rate measurement or direct input

#### Research result

Type	Description	Method
EDV (biplane ellipse)	End-diastolic left ventricular volume	Formula 1
ESV (biplane ellipse)	Left ventricular volume	Formula 2
SV (biplane ellipse)	Stroke volume	See left ventricular function table
CO (biplane ellipse)	Cardiac output	
EF (biplane ellipse)	Ejection fraction	
SI (biplane ellipse)	Stroke Volume Index	
CI (biplane ellipse)	Left ventricular displacement index	

Formula 1:

$$\text{EDV (ml)} = 8/3\pi \times \text{LVAd (cm}^2\text{)} \times \text{LVAd s ax MV (cm}^2\text{)} / \text{LVIDd (cm)}$$

Formula 2:

$$\text{EDV (ml)} = 8/3\pi \times \text{LVAs (cm}^2\text{)} \times \text{LVAs s ax MV (cm}^2\text{)} / \text{LVIDs (cm)}$$

### Steps

1. Select [Dual Plane Ellipse] in the measurement menu.

2. In the left ventricular short-axis section, measure the following parameters:

End of Diastole: LVIDd

End of contraction: LVIDs

3. On the horizontal short axis section of the mitral valve, measure the following parameters:

End of Diastole: LVAd sax MV

End of contraction: LVAs sax MV

4. In the apical long axis section, measure the following parameters:

LVAd and calculate EDV

LVAs and calculate ESV

After Measurement LVAs apical, the system calculates SV and EF;

If height and weight are entered, the system automatically calculates SI;

5. If HR is measured or entered. The system automatically calculates CO and calculates CI based on the entered height and weight.

### 10.6.6 Bullet volume

### Invention project

Type	Description	Method
LVLd apical	Left ventricular long axis	2D distance
LVLs apical	Left ventricular long axis	
LVAd sax MV	End-diastolic mitral valve left ventricular short-axis area	2D area
LVAAs sax MV	Left ventricular short-axis area of mitral level at the end of systole	
HR	Heart rate	HR measurement in M mode or direct input

### Research result

Type	Description	Formula
EDV(Bullet)	End-diastolic left ventricular volume	$EDV(ml) = 5/6 \times LVLd(cm) \times LVAd \text{ sax MV}(cm^2)$
ESV(Bullet)	Left ventricular volume	$ESV(ml) = 5/6 \times LVLs (cm) \times LVAAs \text{ sax MV}(cm^2)$
SV(Bullet)	Stroke volume	See left ventricular function table
CO(Bullet)	Cardiac output	
EF(Bullet)	Ejection fraction	
SI(Bullet)	SV Index	
CI(Bullet)	CO Index	

### Steps

1. Select [Bullet Volume] in the measurement menu.
2. On the long-axis section of the left ventricular apex, measure the following parameters:

End of Diastole: LVLd



End of contraction: LVLs

3. In the horizontal short-axis section of the left ventricular mitral valve, the following parameters were measured:

End of Diastole: LVAd sax MV and calculate EDV

End of contraction: LVAs sax MV, and calculate ESV

System calculates SV and EF;

4. If height and weight are entered, the system automatically calculates SI;

5. If HR is measured or directly input, the system automatically calculates CO and calculates CI based on the entered height and weight.

#### 10.6.7 The Simpson Method

##### Invention project

Type	Description	Measurement methods
LVLd	Left ventricular long axis	2D distance
LVLs	Left ventricular long axis	
LVAd sax MV	End-diastolic mitral valve left ventricular short-axis area	2D area
LVAs sax MV	Left ventricular short-axis area of mitral level at the end of systole	
LVAd sax PM	Left ventricular short axis area at the end of diastolic papillary muscle level	
LVAs sax PM	Left ventricular short axis area at the end of systolic papillary muscle level	
HR	Heart rate	M mode measurement or direct input

**Research result**

Type	Description	Formula
EDV(Simpson)	End-diastolic left ventricular volume	Formula 1
ESV(Simpson)	Left ventricular volume	Formula 2
SV(Simpson)	Stroke volume	See left ventricular function table
CO(Simpson)	Cardiac output	
EF(Simpson)	Ejection fraction	
SI(Simpson)	SV Index	
CI(Simpson)	CO Index	

Formula 1 :

$$\begin{aligned}
 \text{EDV}[\text{mL}] = & \frac{\text{LVLd}[\text{cm}]}{9} \\
 & \times \left( 4 \times \text{LVAd sax MV} [\text{cm}^2] + \text{LVAd sax PM}[\text{cm}^2] \right. \\
 & \left. + \sqrt{\text{LVAd sax MV}[\text{cm}^2] \times \text{LVAd sax PM}[\text{cm}^2]} \right)
 \end{aligned}$$

Formula 2 :

$$\begin{aligned}
 \text{ESV}[\text{mL}] = & \frac{\text{LVLs}[\text{cm}]}{9} \\
 & \times \left( 4 \times \text{LVAs sax MV} [\text{cm}^2] + \text{LVAs sax PM}[\text{cm}^2] \right. \\
 & \left. + \sqrt{\text{LVAs sax MV}[\text{cm}^2] \times \text{LVAs sax PM}[\text{cm}^2]} \right)
 \end{aligned}$$

**Steps**

1. Select Simpson in the measurement menu.
2. On the long-axis section of the left ventricular apex, measure the following parameters:

End of Diastole: LVLd

End of contraction: LVLs

3. In the horizontal short-axis section of the left ventricular mitral valve, the following parameters were measured:

End of Diastole: LVAd sax MV

End of contraction: LVAs sax MV

4. In the horizontal short-axis section of the left ventricular papillary muscle, measure the following parameters:

End of Diastole: LVAd sax PM and calculate EDV

End of contraction: LVAs sax PM and calculate ESV

System calculates SV and EF;

5. If height and weight are entered, the system automatically calculates SI;

6. If HR was measured or entered. The system automatically calculates CO (Simpson), and calculates CI (Simpson) based on the entered height and weight.

#### 10.6.8 Simpson Single Plane



© Only measure apical two-chamber view or apical four-chamber view

#### Steps

1. Select [Simpson Single Plane] in the measurement menu or touch screen.

2. Measure the endocardium:

Measure end-diastolic left ventricular endocardium and set the long axis position to get EDV;

Measure the left ventricular endocardium at the end of systole and set the long axis position to get ESV;

System calculates SV and EF;

3. If height and weight are entered, the system automatically calculates SI, EDV Index and ESV Index;
4. If Measurement the latter enter HR. The system automatically calculates CO, and calculates CI based on the entered height and weight

### 10.6.9 Left ventricular myocardial mass

The left ventricular myocardial mass (LV Mass) is calculated by measurement, and the left ventricular myocardial mass index (LV Mass-I) is calculated:

$$\text{LV MASS-I (No unit)} = \text{LV Mass (g)} / \text{body surface area (m}^2\text{)}$$

### Invention project

Type	Description	Methods
IVSd	End-diastolic ventricular septal thickness	Same as 2D / M conventional "distance" measurement
LVIDd	Left ventricular short axis diameter	
LVPWd	Posterior left ventricular wall thickness	

### Research Result

Type	Description	Formula
LV Mass (Cube)	Left ventricular myocardial mass	$\text{LV Mass (g)} = 1.04 \times ((\text{LVPWd(cm)} + \text{IVSd(cm)} + \text{LVIDd(cm}^3\text{)}) - \text{LVIDd(cm}^3\text{)}) - 13.6$
LV MASS-I (Cube)	Left ventricular myocardial mass index	$\text{LV MASS-I (No unit)} = \text{LV Mass(g)} / \text{Body surface area(m}^2\text{)}$

### Steps

1. Select [Left Ventricular Myocardium] in the measurement menu or touch screen.
2. At the end of left ventricular diastole, measure the following parameters:  
 IVSd  
 LVIDd

**LVPWd**

The system calculates LV Mass (Cube).

3. If height and weight have been entered, the system calculates LV MASS-I (Cube).

**10.6.10 Left ventricular myocardial performance index**

The ventricular myocardial performance index LV TEI reflects the overall function of ventricular systole and diastole.

**Invention project**

Type	Description	Operation
MV C-O dur	Time interval between mitral valve closing and opening	Same as M / Doppler conventional "time" measurement
LVET	Left ventricular ejection time	

**Research Result**

In addition to the measurement results in the "Research Project" above, the following research results can also be obtained:

Type	Description	Formula
LV TEI	Left ventricular myocardial performance index	$LV\ TEI(Nounit) = (MV\ C - O\ dur(s) - LVET(s)) / LVET(s)$

**10.7 Small organ**

Small organ measurement package mainly includes thyroid measurement package and testis measurement package;

**10.7.1 B-mode measurement**

The following measurement items are listed in the measurement package in small organ examination mode, some measurement items are only available on specific calculation tabs

Type	Description	Method
Measurement	Left thyroid long diameter	2D distance
	Left thyroid wide diameter	
	Left thyroid thickness	
	Right thyroid long diameter	
	Right thyroid wide diameter	
	Right thyroid thickness	
	Left testicle length	
	Left testicle width	
	Left testicular thickness	
	Right testicle length	
	Right testicle width	
	Right testicular thickness	

## Chapter 11 Image Storage and Reporting

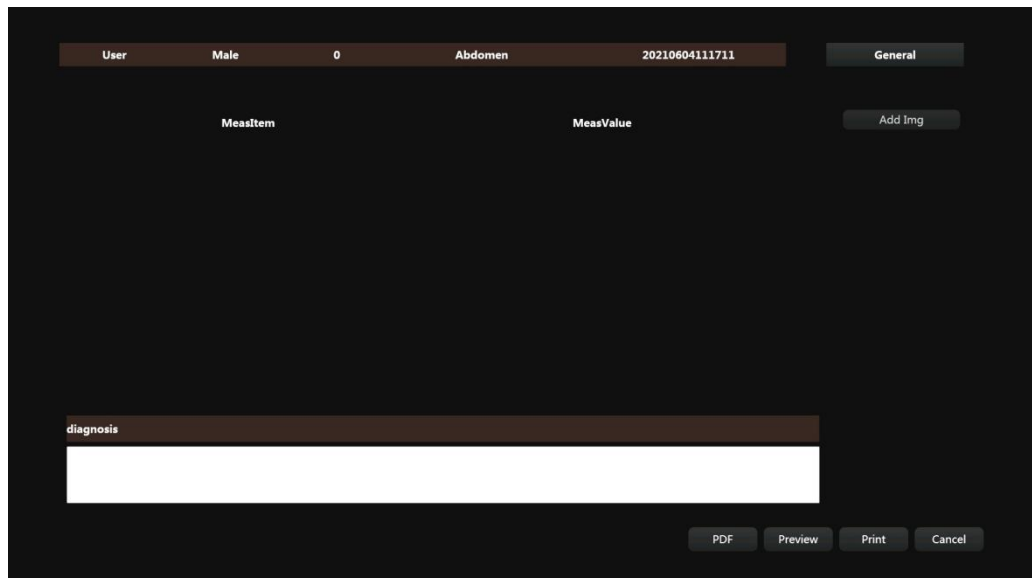
### 11.1 Image Storage

**Real-time image storage** In the real-time scanning state, 2D images are stored in the movie playback memory in chronological order and frame by frame. If the movie playback memory is full of images, the first stored image is moved out of the memory while the latest frame of images is being stored, so the movie playback memory always retains the most recent series of images. After the images are frozen, these images can be called up and displayed frame by frame, or they can be automatically played back in a loop.

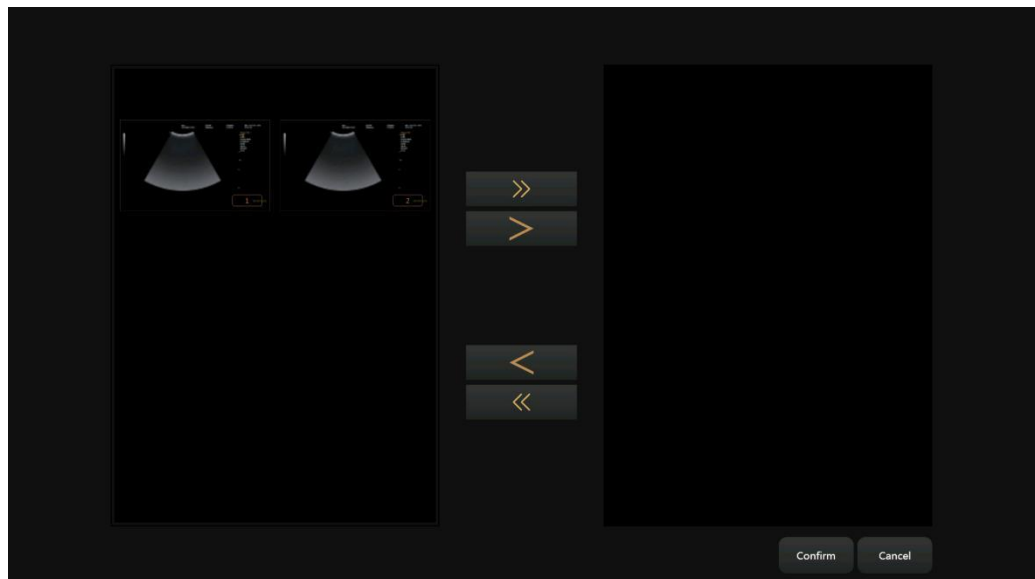
- Store real-time single frame image
- During real-time image scanning, to save the image of interest:
1. Press the [Freeze] key to freeze the image;
  2. Press the [Save] key, the icon shown in the figure below appears in the lower right corner of the screen, and the current image is stored digitally under the current patient and displayed in the corresponding image storage area on the screen.
- Store AVI format image
1. In the real-time scanning state, press the [AVI] key, the icon shown below will appear in the lower left corner of the screen, and real-time storage will start;
  2. To end real-time storage, press the [AVI] key again. The stored movie image is stored under the current patient in AVI format and displayed in the image storage area at the bottom of the screen.

## 11.2 Generate report

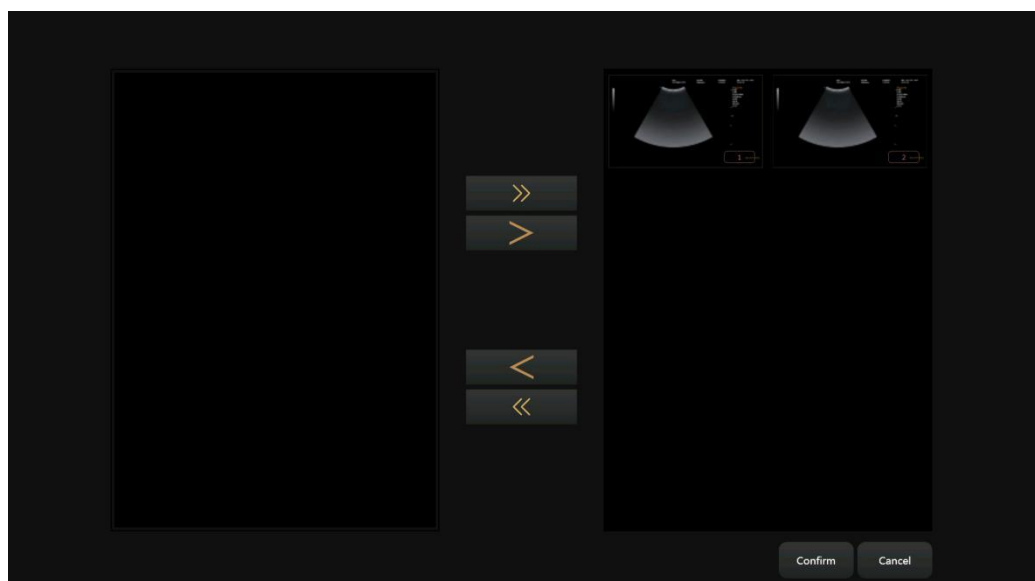
- Operation**
1. After the measurement is completed, press the [Report] key or the touch screen [Report] to open the current patient report interface, as shown in the figure below:



Click the "+" key on the interface to add pictures. The interface as follow:



After selecting the image, click ">" to move the selected image to the right, which means that the image is selected to enter the report. ">>" is to move the images on the left to the right; as shown below



Click the [OK] button to enter the following interface, you can see that the measurement results corresponding to this image are also displayed on the interface;

After entering the remark information in the remarks column, the user can click Preview or Print. The preview interface is as follows:



The screenshot displays a software interface for an ultrasound report. The title 'Ultrasound report' is centered at the top. Below it, a form contains patient data: 'Check parts: Abdomen', 'Name: User', 'Gender: Male', 'Age: 0', 'PatientID: 20230604111711', 'Department: ...', 'Bed No: ...', 'Hospital number: ...', and 'Instrument: ...'. Two ultrasound images are shown side-by-side. Below the images, there are fields for 'Ultrasound see:' and 'diagnosis:'. At the bottom of the form, there are fields for 'Apply physician:', 'Diagnostic physician:', and 'check the time: 6/4/2021'. A small disclaimer at the bottom of the form reads: 'The results of this test only reflect the condition of the subject at that time, for print.' Below the form, there are four buttons: 'Last', 'Next', 'Print', and 'Cancel'.

If there are multiple pages, users can click «Previous Page» or «Next Page» to browse respectively; if a printer is connected, click «Print» to print;

## Chapter 12 Care and Maintenance

### 12.1 Warranty commitment

The Color Ultrasonic Diagnostic Apparatus mainframe warranty period is 2 years, and the probe warranty period is 2 years. The warranty period starts from the date of purchase. During the warranty period, users can repair and replace damaged parts free of charge. The failures specified in this warranty refer to the failures of the equipment when operated under the conditions specified in the instruction manual.

It does not include the following:

- ▶ Loss or damage caused by external factors, such as lightning strike, earthquake, theft, accident, fall, improper use, etc.
- ▶ Damage caused by unauthorized or unauthorized attempted modification, replacement of parts or assembly.
- ▶ Damage caused by other equipment or unauthorized connection of other equipment, and unauthorized use of critical connection cables such as power cords or power sockets with filters not provided by our company.
- ▶ Surface damage.

### 12.2 Precautions

#### 12.2.1 Probe considerations



**Degree of Anti-Liquid**

**IPX7**

- ▶ Degree of protection against liquid ingress of the probe: IPX7

**Note: The degree of probe anti-immersion liquid meets the requirements of IPX7, namely:**

1. 3.5MHzR65 convex array wideband probe, 3.0MHzL19 phased array wideband probe, 4.0MHzR40 convex array wideband volume probe and 7.5MHzL46 linear array wideband probe, the depth of immersion in water should not exceed 5mm from the lens surface
2. The depth of the 6.5MHzR10 convex array broadband probe immersed in water should not exceed 10cm from the lens surface.

▪ When using a 6.5MHz R10 convex array wideband probe, it is strictly forbidden to insert the probe directly into the human body. The probe is required to be used in a sterile oil-free disinfecting rubber sleeve. The rubber sleeve must conform to GB 7544-2009 "Technical Requirements and Requirements Test method "standard requirements. Add an appropriate amount of ultrasonic coupling agent (also known as "sound guiding glue") in the sterile oil-free disinfection rubber sleeve, so that the coupling between the surface of the probe's acoustic lens and the sterile oil-free disinfection rubber sleeve is filled with the coupling agent. All air, but not too much couplant. During operation, pinch the sterile oil-free disinfection rubber sleeve with your fingers, and then gently send the probe into the human body for diagnosis.

- Protect the probe well and do not bump or drop it.
- Use an approved ultrasonic couplant.
- Do not plug or unplug the probe in real-time operation.
- Never bend or pull the probe cable, power cord, etc. forcibly.
- Clean and disinfect the probe in the prescribed way.
- Do not allow paint thinner, ethylene oxide, or other organic solvents to come into contact with the probe.

### 12.2.2 Host Precautions

- Provide a good use environment and keep equipment clean.
- Wait at least 5 seconds after turning off the machine before turning it on again.
- Pay attention to the protection of the operation panel film. The operation should be gentle to avoid scratching or breaking the operation panel film with sharp objects.
- Try to use a soft cloth dipped in water to clean the device. If it is still dirty, use a wet soft cloth and detergent to clean it. Never spill liquid into the machine.
- Do not use hydrocarbon-based glass cleaners to clean the monitor.

## 12.3 Maintenance

1. In use, when cleaning the equipment, try not to damage important marks such as "B-type", "host number", "monitor model and number", "probe number", "date of manufacture" and so on.

When this "Instruction Manual" is used infrequently, please keep it in a safe place.

2. Regular inspection of the equipment is required. The specific methods are as follows:

### Daily inspection checklist

- After each use, wipe the couplant on the probe thoroughly with a soft cloth dampened with water.
- Check the probes and cables for damage and aging. If so, they must be discontinued.
- Clean the used probe.



- If the probe or cable is found to be damaged, stop using it immediately, otherwise there is a danger of electric shock.

### Weekly checklist

- Check the probe for damage.
- Check the system power cord for cracks or damage.
- Disinfect used probes.

- Power off the device, unplug it for cleaning.



- If the equipment is not used for a long time, the system should be checked for power-on every three months.
- If the device is not used for a long time, the motherboard battery must be taken out by our company's professionals, and the user must not disassemble it.

### **Security check**

At least every 24 months, the following security checks are carried out by qualified personnel:

- Inspect mechanical and functional damage to the equipment and its accessories.
- Check that safety-related labels are easily identifiable.
- Check the fuse to verify compliance with the rated current and open circuit characteristics.
- Test protection impedance to ground, not exceeding  $0.1\Omega$ .
- Test to ground leakage current: Normal state, no more than  $500\mu\text{A}$

Single fault condition, no more than  $1000\mu\text{A}$

- Test case leakage current: Normal state, no more than  $100\mu\text{A}$
- Single fault condition, no more than  $500\mu\text{A}$
- Test patient leakage current: normal condition, no more than  $100\mu\text{A}$
- Single fault condition, no more than  $500\mu\text{A}$

▪ Test patient leakage current (application part plus power supply voltage test for single fault state): not more than  $5\text{mA}$

If any of the above safety inspections do not meet the requirements, the instrument should be discontinued immediately and contact the manufacturer or an authorized maintenance department for repair.

## **12.4 Cleaning and disinfecting the probe**

- Gently and thoroughly wipe the probe with a 75% medical alcohol cotton ball on a regular basis.
- Do not sterilize the probe with gas or heat.

## **12.5 Confirmation and elimination of simple faults**

Phenomenon		Cause	Elimination
No image is displayed	Power light is off	▪The power cord may come off the socket	▪ Reconnect the power cord

after turning on the power	Power light is on	<ul style="list-style-type: none"> <li>▪ The brightness and contrast of the monitor may not be adjusted properly</li> <li>▪ Possible adjustment of ultrasonic gain potentiometer</li> </ul>	<ul style="list-style-type: none"> <li>▪ Adjust monitor brightness and contrast</li> <li>▪ Adjust the ultrasonic gain potentiometer to the appropriate position</li> </ul>
After entering the ultrasound software, the probe cannot be identified after thawing (three probe interfaces prompt No Probe)		<ul style="list-style-type: none"> <li>▪ Software exception</li> </ul>	<ul style="list-style-type: none"> <li>▪ Select Exit Program on the menu to exit to the Windows desktop. Double-click the ultrasound software shortcut on the desktop to re-enter the ultrasound system.</li> <li>▪ If the above method does not work, restart the system</li> </ul>
The probe does not produce an image or the image is unclear on the patient		<ul style="list-style-type: none"> <li>▪ The device may be frozen</li> <li>▪ Probably incorrect gain control knob, monitor brightness and contrast adjustment</li> </ul>	<ul style="list-style-type: none"> <li>▪ Check and unfreeze images</li> <li>▪ Proper adjustment of image gain, power, etc. ; proper adjustment of monitor brightness and contrast</li> </ul>
Image has black vertical bars		There may be dirt on the probe	Clean the probe surface
Noisy or moiré noise on the image		<ul style="list-style-type: none"> <li>▪ May be close to other devices and magnetic fields (such as compatible computers, etc.)</li> <li>▪ Using with other equipment (such as ultrasound workstation, etc.)</li> <li>▪ Power grid interference</li> <li>▪ The probe is placed in the probe box</li> </ul>	<ul style="list-style-type: none"> <li>▪ Adjust working environment, keep away from other equipment and magnetic field</li> <li>▪ If possible, change the environment and get a good power supply. If it cannot be replaced on a good power grid, please contact our company to purchase a special filter power cord</li> <li>▪ Buy our company's equipment special power socket</li> <li>▪ The position of the probe box is close to the side of the host. It is normal for the live image to have a slight interference pattern.</li> </ul> <p>Ask users to freeze images when they are not using the device</p>
Occasionally freezes during startup or operation		<ul style="list-style-type: none"> <li>▪ The temperature is too cold or too hot</li> <li>▪ Illegal operation</li> </ul>	Press Ctrl + X to exit the ultrasound system, turn off the machine and wait 5 seconds before turning it on again.

Occasionally an image interface error or corresponding grayscale error	<ul style="list-style-type: none"> <li>▪ Improper background or grayscale window operation</li> </ul>	Press Ctrl + X to exit the ultrasound system, turn off the machine and wait 5 seconds before turning it on again.
After booting, the machine cannot start normally	<ul style="list-style-type: none"> <li>▪ System software is damaged</li> </ul>	Restore the system with the "Maintenance CD"



- If the equipment fails and cannot be eliminated by the methods described above, please contact the manufacturer or an authorized service department and inform them of the relevant information, that is, the description of the failure, equipment number, probe number, date of purchase, etc.

## 12.6 Usage of maintenance - U disk



- Starting the operation of "maintaining-U disk" and performing the "recovery of the ultrasound system" on the system will result in the loss of the original case data in the system, so users are requested to try to read out useful information before starting the "recovery of the ultrasound system" function.
- When the ultrasound system is completely damaged, it is often impossible to operate the hard disk, so it is best to pay attention to backing up useful data to other memory media (such as removable hard disks).

When the ultrasound system cannot be turned on normally, it can be started with the random "maintenance U disk" to repair the system software failure caused by abnormal operation or abnormal startup / shutdown.

## Appendix A Safety Precautions

### ● Patient safety

The following items can seriously affect the safety of patients undergoing ultrasound examinations:

The patient's name must be entered accurately to ensure that all recorded data and the hard copy provide the correct medical record number, otherwise it will lead to misdiagnosis.

### ● Diagnostic information

Malfunctions or incorrect settings of the equipment can cause image measurement errors or undetectable pathological details. In order to optimize the advantages of the equipment and avoid possible error operation, the equipment user should be familiar with the operation of the equipment after training, and increase the operator's confidence through the equipment quality assurance program.

### ● Clinical diagnosis

The display data of the measurement function is only used as a tool, and the user should carefully study and accumulate the measurement data and clinical actual data of the device to improve the more accurate clinical diagnosis.

### ● Mechanical injury

Use of a damaged probe or incorrect use of an intracavity probe can cause injury or increase the risk of infection. The user should carefully operate the probe and protect the appearance of the probe.

### ● Selection of equipment with system configuration

The equipment configured with the system must be the model provided by the manufacturer of the ultrasound instrument. It is required that each configuration device and additional ground wire must be grounded.

### ● Infection control

It is the responsibility of the user of the device to clean it to prevent transmission between the patient and the staff. In order to avoid cross-infection, relevant hospital departments should have a prevention system.

## Appendix B Acoustic Output Announcement

- **Danger of sound power output**

Although it has not been proven that ultrasound power levels have a negative effect on the human body, unnecessary radiation to the human body should be avoided. Incorrect scan settings, probe positioning, and tissue type selection can cause injury. Reasonable selection of the focus position can change the pulse frequency and change the focal area of the emission, so that the received radiation reaches the minimum limit. (It is recommended to use the middle focus mode). When no patient diagnosis is performed, the ultrasound should be frozen to reduce acoustic radiation.

According to the requirements of GB 9706.9 / IEC 60601-2-37 "Medical Electrical Equipment-Part 2-37: Special Requirements for the Safety of Ultrasound Diagnostic and Monitoring Equipment", the acoustic output level information of this ultrasound is published as follows:



## Technical data of sound output level

Probe Type			3.5MHzC2-6R65      B+M					
Index name			MI	TIS			TIB	TIC
				Scanni ng	Non-scanning		Non- scannin g	
					$A_{aprt} \leq 1\text{cm}^2$	$A_{aprt} \geq 1\text{cm}^2$		
Max.Index			0.69	0.27	0.08	——	0.08	——
Relate d acousti c parame ters	$p_{ra}(MPa)$		1.23	/	/	/	/	/
	P(mW)		/	18.1	5.2	/	5.2	——
	$P_a(z_s)$ and $I_{ta\bullet a}(z_s)$ Min.		/	/	/	——	/	/
	$z_s$ (mm)		/	/	/	——	/	/
	$z_{hp}$ (mm)		/	/	/	——	/	/
	$z_b$ (mm)		/	/	/	/	56.7	/
	Z (mm) at the maximum $I_{pi\bullet a}$		56.7	/	/	/	/	/
	$d_{eq}$ (cm)		/	/	/	/	0.27	/
	$f_{awf}$ (MHz)		3.16	3.16	3.16	——	3.16	——
	$A_{aprt}$ ( mm ) Diameter	X	/	41.2	2.38	——	2.38	——
Y		/	2.92	2.92	——	2.92	——	
Other Info	$t_d$ (μs)		1.034	/	/	/	/	/
	$p_{rr}$ (kHz)		2.34	/	/	/	/	/
	$p_r$ at the maximum $I_{pi}$ (MPa)		1.74	/	/	/	/	/
	$d_{eq}$ (cm) at the maximum $I_{pi}$		/	/	/	/	0.27	/
	$I_{pa\bullet a}$ at the		72.71	/	/	/	/	/

	maximum MI ( $\text{mW}/\text{cm}^2$ )						
Operating control conditions	Control 1	—	—	—	—	—	—
	Control 2	—	—	—	—	—	—
	Control 3	—	—	—	—	—	—

Probe Type		3.5MHzC2-6R65 PWD					
Index name		MI	TIS			TIB	TIC
			Scanni ng	Non-scanning		Non-sca nning	
				$A_{aprt} \leq 1\text{cm}^2$	$A_{aprt} \geq 1\text{cm}^2$		
Max.Index		0.61	——	0.67	——	0.67	——
Related acousti c paramete rs	$p_{ra}(MPa)$	1.05	/	/	/	/	/
	P(mW)	/	——	47.4	/	47.4	——
	$P_a(z_s)$ and $I_{ta\bullet a}(z_s)$ min.	/	/	/	——	/	/
	$z_s$ (mm)	/	/	/	——	/	/
	$z_{hp}$ (mm)	/	/	/	——	/	/
	$z_b$ (mm)	/	/	/	/	57.2	/
	at the maximum $I_{pi\bullet a}$ z (mm)	57.2	/	/	/	/	/

	$d_{eq}$ (cm)		/	/	/	/	0.22	/
	$f_{awf}$ (MHz)		2.96	—	2.96	—	2.96	—
	$A_{aprt}$ diameter (mm)	X	/	—	2.12	—	2.12	—
		Y	/	—	2.09	—	2.09	—
Other Info	$t_d$ (μs)		4.20	/	/	/	/	/
	$p_{rr}$ (kHz)		4.36	/	/	/	/	/
	$p_r$ at the maximum $I_{pi}$ (MPa)		1.47	/	/	/	/	/
	$d_{eq}$ at the maximum $I_{pi}$ (cm)		/	/	/	/	0.22	/
	$I_{pa\alpha}$ at the maximum MI (mW/cm <sup>2</sup> )		127.41	/	/	/	/	/
Operat ing control conditi ons	Control 1		—	—	—	—	—	—
	Control 2		—	—	—	—	—	—
	Control 3		—	—	—	—	—	—

Probe Type	3.5MHzC2-6R65 CF
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Index name		MI	TIS			TIB	TIC	
			Scanni ng	Non-scanning		Non-sca nning		
				$A_{aprt} \leq 1\text{cm}^2$	$A_{aprt} \geq 1\text{cm}^2$			
Max.Index		0.78	0.66	——	——	——	——	
Relate d acousti c parame ters	$p_{ra}(MPa)$	1.33	/	/	/	/	/	
	P(mW)	/	47.9	——	/	——	——	
	$P_a(z_s)$ and $I_{ta\bullet a}(z_s)$ min	/	/	/	——	/	/	
	$z_s$ (mm)	/	/	/	——	/	/	
	$z_{hp}$ (mm)	/	/	/	——	/	/	
	$z_b$ (mm)	/	/	/	/	——	/	
	at the maximum $I_{pi\bullet a} z$ (mm)	61.1	/	/	/	/	/	
	$d_{eq}$ (cm)	/	/	/	/	——	/	
	$f_{awf}$ (MHz)	2.91	2.91	——	——	——	——	
	$A_{aprt}$ diameter (mm)	X	/	24.31	——	——	——	——
		Y	/	3.15	——	——	——	——
Other Info	$t_d$ (μs)	1.84	/	/	/	/	/	
	$p_{rr}$ (kHz)	2.59	/	/	/	/	/	
	$p_r$ at the maximum $I_{pi}$ (MPa)	1.81	/	/	/	/	/	
	$d_{eq}$ at the maximum $I_{pi}$ (cm)	/	/	/	/	——	/	
	$I_{pa\bullet a}$ at the maximum MI (mW/cm <sup>2</sup> )	11.72	/	/	/	/	/	
Operat ing control	Control 1	——	——	——	——	——	——	
	Control 2	——	——	——	——	——	——	

conditions	Control 3	—	—	—	—	—	—
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Probe Type			6.5MHzC4-9R10 B+M					
Index name			MI	TIS			TIB	TIC
				Scanning	Non-scanning		Non-scanning	
					$A_{aprt} \leq 1\text{cm}^2$	$A_{aprt} \geq 1\text{cm}^2$		
Max.Index			0.98	0.24	0.14	——	0.14	——
Related acoustic parameters	$p_{ra}(MPa)$		1.96	/	/	/	/	/
	P(mW)		/	8.7	5.2	/	5.2	——
	$P_a(z_s)$ and $I_{ta \bullet a}(z_s)$ min		/	/	/	——	/	/
	$z_s$ (mm)		/	/	/	——	/	/
	$z_{hp}$ (mm)		/	/	/	——	/	/
	$z_b$ (mm)		/	/	/	/	41.2	/
	at the maximum $I_{pi \bullet a} z$ (mm)		41.2	/	/	/	/	/
	$d_{eq}$ (cm)		/	/	/	/	0.23	/
	$f_{awf}$ (MHz)		5.72	5.72	5.72	——	5.72	——
	$A_{aprt}$	X	/	11.21	2.21	——	2.21	——

	diameter (mm)	Y	/	2.39	2.39	—	2.39	—
Other Info	$t_d$ (μs)		0.53	/	/	/	/	/
	$p_{rr}$ (kHz)		2.31	/	/	/	/	/
	$p_r$ at the maximum $I_{pi}$ (MPa)		2.92	/	/	/	/	/
	$d_{eq}$ at the maximum $I_{pi}$ (cm)		/	/	/	/	0.23	/
	$I_{pa\alpha}$ at the maximum MI (mW/cm <sup>2</sup> )		39.2	/	/	/	/	/
Operat ing control conditi ons	Control 1		—	—	—	—	—	—
	Control 2		—	—	—	—	—	—
	Control 3		—	—	—	—	—	—

Probe Type	6.5MHzC4-9R10      PWD					
Index name	MI	TIS			TIB	TIC
		Scanning g	Non-scanning		0.74	
			$A_{aprt} \leq 1\text{cm}^2$	$A_{aprt} \geq 1\text{cm}^2$		
Max.Index	1.68	——	1.05	——	1.05	——

Related acoustic parameters	$p_{ra}(MPa)$	3.36	/	/	/	/	/
	P(mW)	/	—	37.2	/	37.2	—
	$P_a(z_s)$ and $I_{ta^*a}(z_s)$ min	/	/	/	—	/	/
	$z_s$ (mm)	/	/	/	—	/	/
	$z_{hp}$ (mm)	/	/	/	—	/	/
	$z_b$ (mm)	/	/	/	/	37.21	/
	at the maximum $I_{pi^*a}$ $z$ (mm)	37.21	/	/	/	/	/
	$d_{eq}$ (cm)	/	/	/	/	0.21	/
	$f_{awf}$ (MHz)	5.92	—	5.92	—	5.92	—
	$A_{aprt}$ diameter (mm)	X /	—	1.92	—	1.92	—
		Y /	—	1.96	—	1.96	—
Other Info	$t_d$ (μs)	1.62	/	/	/	/	/
	$p_{rr}$ (kHz)	7.51	/	/	/	/	/
	$p_r$ at the maximum $I_{pi}$ (MPa)	4.72	/	/	/	/	/
	$d_{eq}$ at the maximum $I_{pi}$ (cm)	/	/	/	/	0.21	/
	$I_{pa^*a}$ at the maximum MI ( $mW/cm^2$ )	192.71	/	/	/	/	/
Operating control conditions	Control 1	—	—	—	—	—	—
	Control 2	—	—	—	—	—	—
	Control 3	—	—	—	—	—	—

Probe Type			6.5MHzC4-9R10      CF					
Index name			MI	TIS			TIB	TIC
				Scanning	Non-scanning		Non-scanning	
					$A_{aprt} \leq 1\text{cm}^2$	$A_{aprt} \geq 1\text{cm}^2$		
Max.Index			1.44	1.10	——	——	——	——
Related acoustic parameters	$p_{ra}(MPa)$		2.97	/	/	/	/	/
	P(mW)		/	38.9	——	/	——	——
	$P_a(z_s)$ and $I_{ta\bullet a}(z_s)$ min		/	/	/	——	/	/
	$z_s$ (mm)		/	/	/	——	/	/
	$z_{hp}$ (mm)		/	/	/	——	/	/
	$z_b$ (mm)		/	/	/	/	——	/
	at the maximum $I_{pi\bullet a}$ z (mm)		36.72	/	/	/	/	/
	$d_{eq}$ (cm)		/	/	/	/	——	/
	$f_{awf}$ (MHz)		5.94	5.94	——	——	——	——
	$A_{aprt}$ diameter (mm)	X	/	14.21	——	——	——	——
		Y	/	2.30	——	——	——	——
Other Info	$t_d$ (μs)		1.46	/	/	/	/	/
	$p_{rr}$ (kHz)		2.49	/	/	/	/	/



	$p_r$ at the maximum $I_{pi}$ (MPa)	3.98	/	/	/	/	/
	$d_{eq}$ at the maximum $I_{pi}$ (cm)	/	/	/	/	—	/
	$I_{pa \cdot a}$ at the maximum MI ( $\text{mW}/\text{cm}^2$ )	117.2	/	/	/	/	/
Operating control conditions	Control 1	—	—	—	—	—	—
	Control 2	—	—	—	—	—	—
	Control 3	—	—	—	—	—	—

Probe Type		6.5MHzC5-9R10    B+M					
Index name		MI	TIS			TIB	TIC
			Scanning	Non-scanning		Non-scanning	
				$A_{aprt} \leq 1\text{cm}^2$	$A_{aprt} \geq 1\text{cm}^2$		
Max.Index		0.76	0.23	0.15	——	0.15	——
Related acoustic parameters	$p_{ra}(MPa)$	1.52	/	/	/	/	/
	P(mW)	/	8.7	5.6	/	5.6	——
	$P_a(z_s)$ and $I_{ta \bullet a}(z_s)$ min	/	/	/	——	/	/

	$\mathcal{Z}_s$ (mm)		/	/	/	——	/	/
	$z_{hp}$ (mm)		/	/	/	——	/	/
	$z_b$ (mm)		/	/	/	/	40.32	/
	at the maximum $I_{pi^*a}$ z (mm)		40.32	/	/	/	/	/
	$d_{eq}$ (cm)		/	/	/	/	0.31	/
	$f_{awf}$ (MHz)		5.66	5.66	5.66	——	5.66	——
	$A_{aprt}$ diameter (mm)	X	/	7.68	2.83	——	2.83	——
Y		/	2.95	2.95	——	2.95	——	
Other Info	$t_d$ (μs)		10.6	/	/	/	/	/
	$p_{rr}$ (kHz)		2.30	/	/	/	/	/
	$p_r$ at the maximum $I_{pi}$ (MPa)		2.29	/	/	/	/	/
	$d_{eq}$ at the maximum $I_{pi}$ (cm)		/	/	/	/	0.31	/
	$I_{pa^*a}$ at the maximum MI (mW/ $cm^2$ )		64.79	/	/	/	/	/
Operat ing control conditi ons	Control 1		——	——	——	——	——	——
	Control 2		——	——	——	——	——	——
	Control 3		——	——	——	——	——	——

Probe Type			6.5MHzC5-9R10 PWD					
Index name			MI	TIS		TIB	TIC	
				Scanning	Non-scanning			Non-scanning
					$A_{aprt} \leq 1\text{cm}^2$	$A_{aprt} \geq 1\text{cm}^2$		
Max.Index			1.39	——	1.12	——	1.12	——
Related acoustic parameters	$p_{ra}(MPa)$		2.78	/	/	/	/	/
	P(mW)		/	——	40.2	/	40.5	——
	$P_a(z_s)$ and $I_{ta \cdot a}(z_s)$ min		/	/	/	——	/	/
	$z_s$ (mm)		/	/	/	——	/	/
	$z_{hp}$ (mm)		/	/	/	——	/	/
	$z_b$ (mm)		/	/	/	/	37.21	/
	at the maximum $I_{pi \cdot a}$ z (mm)		37.21	/	/	/	/	/
	$d_{eq}$ (cm)		/	/	/	/	0.24	/
	$f_{awf}$ (MHz)		5.86	——	5.86	——	5.86	——
	$A_{aprt}$ diameter (mm)	X	/	——	2.13	——	2.13	——
Y		/	——	2.13	——	2.13	——	
Other Info	$t_d$ (μs)		1.69	/	/	/	/	/
	$p_{rr}$ (kHz)		9.66	/	/	/	/	/
	$p_r$ at the maximum $I_{pi}$ (MPa)		4.03	/	/	/	/	/
	$d_{eq}$ at the maximum $I_{pi}$		/	/	/	/	0.24	/

	(cm)						
	$I_{pa\bullet a}$ at the maximum MI (mW/cm <sup>2</sup> )	96.72	/	/	/	/	/
Operating control conditions	Control 1	—	—	—	—	—	—
	Control 2	—	—	—	—	—	—
	Control 3	—	—	—	—	—	—

Probe Type		6.5MHzC5-9R10      CF					
Index name		MI	TIS			TIB	TIC
			Scannin g	Non-scanning		Non-sca nning	
				$A_{aprt} \leq 1\text{cm}^2$	$A_{aprt} \geq 1\text{cm}^2$		
Max.Index		1.43	0.81	——	——	——	——
Relate d acousti c parame ters	$p_{ra}(MPa)$	2.85	/	/	/	/	/
	P(mW)	/	29.6	——	/	——	——
	$P_a \ (z_s)$ and $I_{Ia\bullet a} \ (z_s)$ min	/	/	/	——	/	/
	$Z_s \ (\text{mm})$	/	/	/	——	/	/
	$z_{hp} \ (\text{mm})$	/	/	/	——	/	/
	$z_b \ (\text{mm})$	/	/	/	/	——	/

	at the maximum $I_{pi\alpha}$ z (mm)	39.67	/	/	/	/	/
	$d_{eq}$ (cm)	/	/	/	/	—	/
	$f_{awf}$ (MHz)	5.77	5.77	—	—	—	—
	$A_{aprt}$ diameter (mm)	X	/	4.76	—	—	—
		Y	/	2.98	—	—	—
Other Info	$t_d$ (μs)	1.03	/	/	/	/	/
	$p_{rr}$ (kHz)	4.94	/	/	/	/	/
	$p_r$ at the maximum $I_{pi}$ (MPa)	3.96	/	/	/	/	/
	$d_{eq}$ at the maximum $I_{pi}$ (cm)	/	/	/	/	—	/
	$I_{pa\alpha}$ at the maximum MI (mW/cm <sup>2</sup> )	119.21	/	/	/	/	/
Operating control conditions	Control 1	—	—	—	—	—	—
	Control 2	—	—	—	—	—	—
	Control 3	—	—	—	—	—	—

Probe Type	7.5MHz L46 B+M
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Index name		MI	TIS			TIB	TIC	
			Scannin g	Non-scanning		Non-sca nning		
				$A_{aprt} \leq 1\text{cm}^2$	$A_{aprt} \geq 1\text{cm}^2$			
Max.Index		0.96	0.18	0.13	——	0.13	——	
Relate d acousti c parame ters	$p_{ra}(MPa)$	1.92	/	/	/	/	/	
	P(mW)	/	5.3	3.8	/	3.8	——	
	$P_a(z_s)$ and $I_{ta \cdot a}(z_s)$ min	/	/	/	——	/	/	
	$z_s$ (mm)	/	/	/	——	/	/	
	$z_{hp}$ (mm)	/	/	/	——	/	/	
	$z_b$ (mm)	/	/	/	/	32.51	/	
	at the maximum $I_{pi \cdot a}$ z (mm)	32.51	/	/	/	/	/	
	$d_{eq}$ (cm)	/	/	/	/	0.31	/	
	$f_{awf}$ (MHz)	7.21	7.21	7.21	——	7.21	——	
	$A_{aprt}$ diameter (mm)	X	/	21.71	2.72	——	2.72	——
		Y	/	2.92	2.92	——	2.92	——
Other Info	$t_d$ (μs)	0.43	/	/	/	/	/	
	$p_{rr}$ (kHz)	2.41	/	/	/	/	/	
	$p_r$ at the maximum $I_{pi}$ (MPa)	2.92	/	/	/	/	/	
	$d_{eq}$ at the maximum $I_{pi}$ (cm)	/	/	/	/	0.31	/	
	$I_{pa \cdot a}$ at the maximum MI (mW/ $cm^2$ )	74.81	/	/	/	/	/	
Operat	Control 1	——	——	——	——	——	——	

ing control conditi ons	Control 2	—	—	—	—	—	—
	Control 3	—	—	—	—	—	—

Probe Type		7.5MHz L46 PWD					
Index name		MI	TIS			TIB	TIC
			Scannin g	Non-scanning		Non-sca nning	
				$A_{aprt} \leq 1\text{cm}^2$	$A_{aprt} \geq 1\text{cm}^2$		
Max.Index		0.87	——	1.06	——	1.06	——
Relate d acousti c parame ters	$p_{ra}(MPa)$	1.73	/	/	/	/	/
	P(mW)	/	——	30.2	/	30.2	——
	$P_a(z_s)$ and $I_{ta^*a}(z_s)$ min	/	/	/	——	/	/
	$z_s$ (mm)	/	/	/	——	/	/
	$z_{hp}$ (mm)	/	/	/	——	/	/
	$z_b$ (mm)	/	/	/	/	31.61	/
	at the maximum $I_{pi^*a}$ z (mm)	31.61	/	/	/	/	/
	$d_{eq}$ (cm)	/	/	/	/	0.26	/
	$f_{awf}$ (MHz)	7.40	——	7.40	——	7.40	——

	$A_{aprt}$ diameter (mm)	X	/	—	2.31	—	2.31	—
		Y	/	—	2.61	—	2.61	—
Other Info	$t_d$ (μs)	0.91	/	/	/	/	/	/
	$p_{rr}$ (kHz)	10.61	/	/	/	/	/	/
	$p_r$ at the maximum $I_{pi}$ (MPa)	2.69	/	/	/	/	/	/
	$d_{eq}$ at the maximum $I_{pi}$ (cm)	/	/	/	/	0.26	/	/
	$I_{pa\alpha}$ at the maximum MI (mW/cm <sup>2</sup> )	117.2	/	/	/	/	/	/
Operat ing control conditi ons	Control 1	—	—	—	—	—	—	—
	Control 2	—	—	—	—	—	—	—
	Control 3	—	—	—	—	—	—	—

Probe Type	7.5MHz L46 CF					
Index name	MI	TIS			TIB	TIC
		Scanning	Non-scanning		Non-scanning	
			$A_{aprt} \leq 1\text{cm}^2$	$A_{aprt} \geq 1\text{cm}^2$		
Max.Index	0.82	1.04	——	——	——	——



Related acoustic parameters	$p_{ra}(MPa)$	1.63	/	/	/	/	/
	P(mW)	/	29.4	—	/	—	—
	$P_a(z_s)$ and $I_{ta^*a}(z_s)$ min	/	/	/	—	/	/
	$z_s$ (mm)	/	/	/	—	/	/
	$z_{hp}$ (mm)	/	/	/	—	/	/
	$z_b$ (mm)	/	/	/	/	—	/
	at the maximum $I_{pi^*a}$ $z$ (mm)	29.61	/	/	/	/	/
	$d_{eq}$ (cm)	/	/	/	/	—	/
	$f_{awf}$ (MHz)	7.40	7.40	—	—	—	—
	$A_{aprt}$ diameter (mm)	X /	8.81	—	—	—	—
		Y /	3.61	—	—	—	—
Other Info	$t_d$ (μs)	0.75	/	/	/	/	/
	$p_{rr}$ (kHz)	5.14	/	/	/	/	/
	$p_r$ at the maximum $I_{pi}$ (MPa)	2.38	/	/	/	/	/
	$d_{eq}$ at the maximum $I_{pi}$ (cm)	/	/	/	/	—	/
	$I_{pa^*a}$ at the maximum MI (mW/cm <sup>2</sup> )	135.64	/	/	/	/	/
Operating control conditions	Control 1	—	—	—	—	—	—
	Control 2	—	—	—	—	—	—
	Control 3	—	—	—	—	—	—

Probe Type		3.0MHz L19 B+M					
Index name		MI	TIS			TIB	TIC
			Scanning	Non-scanning		Non-scanning	
				$A_{aprt} \leq 1\text{cm}^2$	$A_{aprt} \geq 1\text{cm}^2$		
Max.Index		0.71	0.41	0.26	——	0.26	——
Related acoustic parameters	$p_{ra}(MPa)$	1.23	/	/	/	/	/
	P(mW)	/	29.2	18.1	/	18.1	——
	$P_a(z_s)$ and $I_{ta\bullet a}(z_s)$ min	/	/	/	——	/	/
	$z_s$ (mm)	/	/	/	——	/	/
	$z_{hp}$ (mm)	/	/	/	——	/	/
	$z_b$ (mm)	/	/	/	/	68.12	/
	at the maximum $I_{pi\bullet a}$ z (mm)	68.12	/	/	/	/	/
	$d_{eq}$ (cm)	/	/	/	/	0.35	/
	$f_{awf}$ (MHz)	2.98	2.98	2.98	——	2.98	——
	$A_{aprt}$ diameter (mm)	X	/	7.23	3.41	——	3.41
Y		/	3.16	3.16	——	316	——

Other Info	$t_d$ ( $\mu\text{s}$ )	1.86	/	/	/	/	/
	$p_{rr}$ (kHz)	2.45	/	/	/	/	/
	$p_r$ at the maximum $I_{pi}$ (MPa)	1.87	/	/	/	/	/
	$d_{eq}$ at the maximum $I_{pi}$ (cm)	/	/	/	/	0.35	/
	$I_{pa}$ at the maximum MI ( $\text{mW}/\text{cm}^2$ )	46.21	/	/	/	/	/
Operating control conditions	Control 1	—	—	—	—	—	—
	Control 2	—	—	—	—	—	—
	Control 3	—	—	—	—	—	—

Probe Type		3.0MHz L19 PWD					
Index name		MI	TIS			TIB	TIC
			Scanning	Non-scanning		Non-scanning	
				$A_{aprt} \leq 1\text{cm}^2$	$A_{aprt} \geq 1\text{cm}^2$		
Max.Index		1.16	——	0.92	——	0.92	——
Related acoustic parameters	$p_{ra}(MPa)$	1.98	/	/	/	/	/
	P(mW)	/	——	66.7	/	66.7	——
	$P_a(z_s)$ and	/	/	/	——	/	/

ters	$I_{ta^*a} (z_s) \text{ min}$						
	$z_s \text{ (mm)}$		/	/	/	—	/
	$z_{hp} \text{ (mm)}$		/	/	/	—	/
	$z_b \text{ (mm)}$		/	/	/	/	63.8
	at the maximum $I_{pi^*a}$ $z \text{ (mm)}$		63.8	/	/	/	/
	$d_{eq} \text{ (cm)}$		/	/	/	/	0.31
	$f_{awf} \text{ (MHz)}$		2.89	—	2.89	—	2.89
	$A_{aprt}$ diameter (mm)	X	/	—	2.92	—	2.92
		Y	/	—	2.72	—	2.72
Other Info	$t_d \text{ (}\mu\text{s)}$		2.17		/	/	/
	$p_{rr} \text{ (kHz)}$		9.17	/	/	/	/
	$p_r$ at the maximum $I_{pi}$ (MPa)		2.96	/	/	/	/
	$d_{eq}$ at the maximum $I_{pi}$ (cm)		/	/	/	/	0.31
	$I_{pa^*a}$ at the maximum MI (mW/cm <sup>2</sup> )		137.61	/	/	/	/
Operat ing control conditi ons	Control 1		—	—	—	—	—
	Control 2		—	—	—	—	—
	Control 3		—	—	—	—	—

Probe Type		3.0MHz L19 CF					
Index name		MI	TIS			TIB	TIC
			Scanning	Non-scanning		Non-scanning	
				$A_{aprt} \leq 1\text{cm}^2$	$A_{aprt} \geq 1\text{cm}^2$		
Max.Index		0.99	0.91	——	——	——	——
Related acoustic parameters	$p_{ra}(MPa)$	1.72	/	/	/	/	/
	P(mW)	/	66.2	——	/	——	——
	$P_a(z_s)$ and $I_{ta \cdot a}(z_s)$ min	/	/	/	——	/	/
	$z_s$ (mm)	/	/	/	——	/	/
	$z_{hp}$ (mm)	/	/	/	——	/	/
	$z_b$ (mm)	/	/	/	/	——	/
	at the maximum $I_{pi \cdot a}$ z (mm)	73.2	/	/	/	/	/
	$d_{eq}$ (cm)	/	/	/	/	——	/
	$f_{awf}$ (MHz)	2.89	2.89	——	——	——	——
	$A_{aprt}$ diameter (mm)	X / Y /	3.18 3.92	—— ——	—— ——	—— ——	—— ——
Other Info	$t_d$ (μs)	1.88		/	/	/	/
	$p_{rr}$ (kHz)	4.37	/	/	/	/	/
	$p_r$ at the maximum $I_{pi}$ (MPa)	2.89	/	/	/	/	/
	$d_{eq}$ at the	/	/	/	/	——	/

	maximum $I_{pi}$ (cm)						
	$I_{pa}$ at the maximum MI (mW/cm <sup>2</sup> )	132.4	/	/	/	/	/
Operating control conditi ons	Control 1	—	—	—	—	—	—
	Control 2	—	—	—	—	—	—
	Control 3	—	—	—	—	—	—

Probe Type		4.0MHz R40 B+M					
Index name		MI	TIS			TIB	TIC
			Scanning	Non-scanning		Non-scanning	
				$A_{aprt} \leq 1\text{cm}^2$	$A_{aprt} \geq 1\text{cm}^2$		
Max.Index		0.87	0.62	0.11	——	0.11	——
Related acoustic parameters	$p_{ra}(MPa)$	1.73	/	/	/	/	/
	P(mW)	/	33.6	5.9	/	5.9	——
	$P_a(z_s)$ and $I_{ta}(z_s)$ min	/	/	/	——	/	/
	$z_s$ (mm)	/	/	/	——	/	/
	$z_{hp}$ (mm)	/	/	/	——	/	/
	$z_b$ (mm)	/	/	/	/	59.21	/

	at the maximum $I_{pi\bullet a}$ z (mm)	59.21	/	/	/	/	/
	$d_{eq}$ (cm)	/	/	/	/	0.39	/
	$f_{awf}$ (MHz)	3.88	3.88	3.88	—	3.88	—
	$A_{aprt}$ diameter (mm)	X	/	14.72	3.63	—	3.63
		Y	/	3.69	3.69	—	3.69
Other Info	$t_d$ (μs)	0.82		/	/	/	/
	$p_{rr}$ (kHz)	3.61	/	/	/	/	/
	$p_r$ at the maximum $I_{pi}$ (MPa)	2.41	/	/	/	/	/
	$d_{eq}$ at the maximum $I_{pi}$ (cm)	/	/	/	/	0.39	/
	$I_{pa\bullet a}$ at the maximum MI (mW/cm <sup>2</sup> )	72.36	/	/	/	/	/
Operating control conditions	Control 1	—	—	—	—	—	—
	Control 2	—	—	—	—	—	—
	Control 3	—	—	—	—	—	—

Probe Type			4.0MHz R40 PWD					
Index name			MI	TIS			TIB	TIC
				Scanning	Non-scanning		Non-scanning	
					$A_{aprt} \leq 1\text{cm}^2$	$A_{aprt} \geq 1\text{cm}^2$		
Max.Index			0.80	——	0.46	——	0.46	——
Related acoustic parameters	$p_{ra}(MPa)$		1.26	/	/	/	/	/
	P(mW)		/	——	39.8	/	39.8	——
	$P_a(z_s)$ and $I_{ta\cdot a}(z_s)$ min		/	/	/	——	/	/
	$z_s$ (mm)		/	/	/	——	/	/
	$z_{hp}$ (mm)		/	/	/	——	/	/
	$z_b$ (mm)		/	/	/	/	59.63	/
	at the maximum $I_{pi\cdot a}$ z (mm)		59.63	/	/	/	/	/
	$d_{eq}$ (cm)		/	/	/	/	0.29	/
	$f_{awf}$ (MHz)		2.45	——	2.45	——	2.45	——
	$A_{aprt}$ diameter (mm)	X	/	——	2.76	——	2.76	——
Y		/	——	2.43	——	2.43	——	
Other Info	$t_d$ (μs)		2.08		/	/	/	/
	$p_{rr}$ (kHz)		9.21	/	/	/	/	/
	$p_r$ at the maximum $I_{pi}$ (MPa)		1.72	/	/	/	/	/
	$d_{eq}$ at the maximum $I_{pi}$ (cm)		/	/	/	/	0.29	/
	$I_{pa\cdot a}$ at the maximum MI (mW/ $cm^2$ )		112.3	/	/	/	/	/



Operating control conditions	Control 1	—	—	—	—	—	—
	Control 2	—	—	—	—	—	—
	Control 3	—	—	—	—	—	—

Probe Type		4.0MHz R40    CF					
Index name		MI	TIS			TIB	TIC
			Scanning	Non-scanning		Non-scanning	
				$A_{aprt} \leq 1\text{cm}^2$	$A_{aprt} \geq 1\text{cm}^2$		
Max.Index		0.55	0.43	——	——	——	——
Related acoustic parameters	$p_{ra}(MPa)$	0.87	/	/	/	/	/
	P(mW)	/	36.8	——	/	——	——
	$P_a(z_s)$ and $I_{ta\bullet a}(z_s)$ min	/	/	/	——	/	/
	$z_s$ (mm)	/	/	/	——	/	/
	$z_{hp}$ (mm)	/	/	/	——	/	/
	$z_b$ (mm)	/	/	/	/	——	/
	at the maximum $I_{pi\bullet a}$ z (mm)	63.81	/	/	/	/	/
	$d_{eq}$ (cm)	/	/	/	/	——	/
	$f_{awf}$ (MHz)	2.46	2.46	——	——	——	——
$A_{aprt}$	X	/	4.71	——	——	——	——

	diameter (mm)	Y	/	3.63	—	—	—	—
Other Info	$t_d$ (μs)	2.29		/	/	/	/	
	$p_{rr}$ (kHz)	5.03	/	/	/	/	/	
	$p_r$ at the maximum $I_{pi}$ (MPa)	1.36	/	/	/	/	/	
	$d_{eq}$ at the maximum $I_{pi}$ (cm)	/	/	/	/	—	/	
	$I_{pa\alpha}$ at the maximum MI (mW/cm <sup>2</sup> )	88.35	/	/	/	/	/	
Operat ing control conditi ons	Control 1	—	—	—	—	—	—	
	Control 2	—	—	—	—	—	—	
	Control 3	—	—	—	—	—	—	

## Appendix C Packing List

	No.	Name	Specification	Unit	Number
Com mon confi gurati	1	Main machine		piece	1
	2	Display	LED	piece	1
	3	Convex Array	3.5MHzC2-6R65	piece	1

on		Broadband Probe			
	4	power cable	250V 10A	piece	1
	5	Explanation book		piece	1
	6	Warranty Card		piece	1
	7	Qualified certificate		piece	1
	8	Three cards		piece	3
	9	Support		piece	1
	10	Six corners		piece	1
Other confi gurati ons	1	Probe	6.5MHzC4-9R10 convex array wideband probe	piece	1
	2	Probe	7.5MHzL5-12L46 line array wideband probe	piece	1
	3	Probe	3.0MHzP2-5L19 Phased Array Broadband Probe	piece	1
	4	Probe	4.0MHzR40 convex array wideband volume probe	piece	1
	5	Probe	6.5MHzC5-9R10 convex array wideband probe	piece	1