

KAIXIN[®]

KX5200

**Full Digital Ultrasonic Diagnostic
Instruments**

User's Manual



Information for Users

Users shall carefully read through this manual and fully understand the text before operating the equipment. This manual shall be placed easy of access for future reference; otherwise it may cause instrument damage or person injury.

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1. This user's manual contains warnings for predictable dangers. Users shall also exercise care at any time to be aware of the dangers unforeseen in this manual. Kaixin shall not be liable for the damages and losses arising out of neglecting to follow the operation instructions herein described.
2. This user's manual shall be furnished with the machine so that operating and managerial personnel can refer to it any time as necessary. Once the managerial personnel of the system changes, it shall hand over this user's manual.
3. Medical personnel qualified with professional qualifications only to use this system.
4. This product is intended to provide clinical diagnostic data for the doctor. The doctor in charge of the diagnosis shall be responsible for the diagnostic process. Kaixin shall not be liable for any problems arising out of the process.
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 - (1) Unauthorized components are assembly, stretching, readjustment;
 - (2) Users fail to properly operate the equipment in accordance with the requirements specified in this user's manual.
9. The maintenance and servicing of product shall be performed by the trained engineer or by Kaixin Electronic Instrument Company Ltd.

Product Information

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Version: V1.02

Limited warranty

Repair Service

1. Kaixin offers Type B-ultrasound lifetime warranty and charge free repair service from the day of purchasing the equipment: eighteen months for main unit and typical configured probe, six months for other components.
2. The company will not assume free warranty for the following situation:
 - 1) Malfunction or damage arising from failing to comply with the instructions of the User's Manual;
 - 2) Malfunction or damage caused by falling during moving after purchased;
 - 3) Warranty is expired;
 - 4) Malfunction or damage due to human factors;
 - 5) Damage or malfunction caused by disassembling and assembling, alteration and repair without the consent of the company;
 - 6) Damage caused by force majeure (like abnormal power supply, fire, flood, lightning strike, earthquake etc.);
 - 7) Damage or malfunction caused by use of unqualified ultrasonic coupling gel;
 - 8) Damage or malfunction caused by use of probe not provided by our company;
3. The company will offer repair service for instrument out of warranty, but additional fees of materials and repair service will be charged.
4. The customer can repair the instrument out of warranty by themselves, and if necessary, the company can provide circuit diagram and components under customers' request.

Warning: Only manufacturer is permitted to repair the device. So if the device is in abnormal condition, do not use it and send it to manufacturer.

Return of Goods

Follow the procedure below if you need to return the purchased equipment:

To obtain the right to return the goods, contact local dealer of Kaixin Company, indicating serial number of main unit, this number is located on the nameplate of main unit. Please mark the product model, the serial number of main unit and reason to return the product.

Manufacturer's Information



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Instructions concerned

For the changes of appearance, this manual is subject to change without further notice!












Safety Cautions


1. Warning Symbols and Definitions

The following warning symbols are used in this manual to indicate safety level and other important items. Please remember these symbols and understand the meaning as you read this user's manual. These symbols convey specific meanings as detailed in the table below:

Symbols & Words	Connotation
 Danger	Indicates an imminent danger that may result in personal death or serious injury if not avoided.
 Warning	Indicates a potential danger that may result in personal injury if not avoided.
 Attention	Indicates a potential danger or unexpected use condition that may result in light injury or property loss or affecting the use if not avoided.
	Indicates that make sure refer to relevant contents in this manual.

2. Safety Symbols

Symbols	Meaning	Symbols	Meaning
	Type B applied part		Keep dry
	Power supply indication		Fragile
	DC Power		Stacking limit by number
	Follow instructions for use		Temperature limits
	Up		Humidity limitation
			Atmospheric pressure limitation

	Symbol for the marking of electrical and electronics devices according to Directive 2002/96/EC. The device, accessories and the packaging have to be disposed of waste correctly at the end of the usage. Please follow Local Ordinances or Regulations for disposal.
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Chapter One Overview

1.1 Introduction

KX5200 full digital ultrasonic diagnostic instruments are portable equipment, which are composed of main unit, probe and display. In principle, it includes microcomputer control parts, transmitting parts, receiving parts, DSC processing parts, probe connection parts, display parts, power part, indicator, etc. KX5200 full digital ultrasonic diagnostic instruments apply microcomputer control, which adopt multi-point auto-focus, continuous dynamic variable aperture, logarithmic compression, TGC control, dynamic filtering, edge enhancement, frame correlation, continuously adjustable dynamic range, linear interpolation, digital beam composite, digital scan converter (DSC), pre-process, post-process techniques, to make image clear, stable, high sensitivity and strong resolution.

Applied part of KX5200 full digital ultrasonic diagnostic instruments is probe; its biocompatibility has been proven effectively.

1.2 Intended Use

KX5200 full digital ultrasonic diagnostic instruments are applicable to ultrasonic diagnose abdominal viscera (include trans-vagina, gynecologic, obstetric) and small parts.

⚠Attention: Although ultrasonic diagnostic does not hurt human body, do consider the scanning stop time and frequency for pregnant woman and fetus on the basis of ALARA principle.

⚠Attention: The method below should be followed when the intra-cavity probe is used for gynecology and obstetrics.

1. Explain the importance and necessity to the subject to get the understanding and coordination.
2. Get the bladder calculus, no need to fill the bladder.
3. Smear the coupling gel on the top of the probe then put condom on it, and then put the coupling gel on it again. Then place the probe to different position of the uterine cervix and fornix along pelvis axis slowly.
4. Use of the rotation, tilt, pumping the basic approaches of pelvic structure sagittal, coronal, traverse and other cross-sectional profile scanning.
5. Pay attention to the scanning depth so that the organ of near-filed or the far-filed get into the accumulation area for observing. If the position of organ is higher, the operator can press lower abdomen gently (such as bilannual gynecological examination) by left hand to make it next to probe and get the best showing.

Chapter Two Technical Specifications

2.1 Technical Data

1. Gray scale: 256
2. Monitor: 5.7" LCD
3. Adapter ratings: 100-240V~, 50-60Hz, 70VA (model: MW125RA1203F01)
4. Output of adapter: DC12V 3.0A
5. Main device rating: DC12V 3.0A
6. Main Unit Size: approx. 155×180×80mm³ (L×W×H)
7. Weight of main unit: approx. 1.1kg (excluding accessories)

Warning: the device should be combined with provided AC/DC adapter as an ME SYSTEM. Other adapters are prohibited

2.2 Primary Functions

1. Mode conversion function.
2. Magnification conversion function.
3. Frequency conversion function.
4. Frame correlation function.
5. Image post-process function.
6. Edge enhancement function.
7. Image freeze/unfreeze.
8. Depth range selection function.
9. Depth heighten/pan function.
10. Color display function.
11. Local zooming.
12. Angle/width change.
13. Adjustment and display of near field, far field, total gain and dynamic range.
14. Single-point, multi-point focusing.
15. Image storage.
16. Vertical, horizontal reverse and B/W conversion.
17. Case information, image annotation and auto time display.
18. Body marks.
19. Measurement of distance, depth, circumference, area, volume, slope, heart rate and cycle.
20. OB software package including 15 obstetric tables, automatic calculation of EDC and EFW.
21. Puncture guide.
22. Cine loop.
23. PAL-NTSC Conversion.
24. Energy saving.
25. Chinese-English Switch.
26. Obstetric report.

Chapter Three System Outline and Structure

3.1 Structure composition of the instrument

KX5200 full digital ultrasonic diagnostic instruments are composed of main unit, probe and display, etc.

3.2 Components name

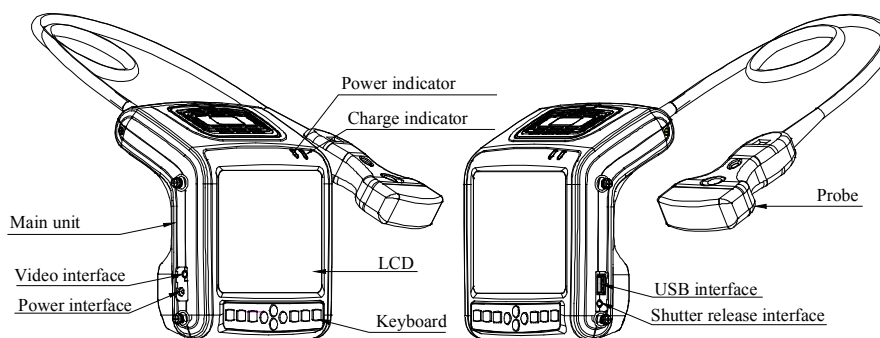


Fig. KX5200 main unit sketch map

3.3 Parts of the probe (Take 3.5MHz convex array probe for example)

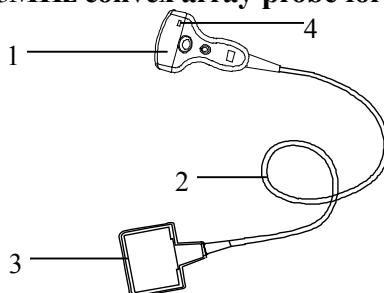


Fig. Parts name of 3.5MHz convex array probe

Name	Function
(1) Acoustic lens	To convert electric signal to ultrasonic signal based on principle of converse piezoelectric effect. The ultrasonic signal, after entering the human body, is reflected as echo wave and converted to electric signal again. The acoustic lens is on the probe surface. Supply ultrasonic coupling gel to the acoustic lens surface when performing ultrasonic diagnosis.
(2) Cable	To connect the probe to the probe connector.
(3) Probe connector	To connect the probe to ultrasonic diagnostic system.
(4) Fix puncture anchor point	Fix the puncture bracket.

Warning: USB port max. loading current: 0.3A.

3.4 Function keys description

SN.	Function keys	Real-time mode function	Freeze mode function
1		Mode Selection	Text Input
2		Enter Confirm menu	
3		Main-menu / Cine loop	
4		Freeze/Unfreeze	
5		Direction Keys	
6		Quit	
7		Power switch	

Chapter Four System Configuration

4.1 Typical configuration

1. Main unit	1 unit	2. 3.5MHz convex array probe	1 PC
3. Power adapter	1 PC	4. Internal battery	2 PCS
5. Charger	1 PC	6. Support bracket	1 PC
7. Arm-band	1 PC	8. Straps	2 PCS
9. Leather bag	1 PC	10. Shutter release	1 PC

4.2 Optional parts

1. 5.0MHz micro convex array probe	2. 6.5MHz intra-cavity probe
3. 7.5 MHz high frequency linear array probe	4. Video recorder P93W-S
5. Mouse	6. Probe holder
	7. Plastic seal box

Chapter Five Operation Condition

5.1 Power supply

Adapter ratings: 100-240V~, 50/60Hz, 70VA

Adapter model: MW125RA1203F01

Output of adapter: DC12V 3.0A

Main device rating: DC12V 3.0A

5.2 Operation Environment

Ambient temperature: 10°C-40°C;

Relative humidity: 30%-75% (without condensation);

Atmospheric pressure: 700hPa-1060hPa;

Altitude: < 2000 m;

Overvoltage: Overvoltage Category II .

5.3 Storage and Transport

Ambient temperature: -20°C-55°C;

Relative humidity: 30%-93% (without condensation);

Atmospheric pressure: 700hPa-1060hPa.

⚠Attention: The mains voltage is varies with different countries or regions.

⚠Warning: Avoid using this equipment with high frequency operational equipment, or danger may occur.

⚠Danger: Do not use this equipment where flammable gas (such as anesthetic gas, oxygen or hydrogen) or flammable liquid (such as alcohol) are present. Failure to do so may result in explosion.

⚠Attention: System should be avoided using in following environments:

- | | |
|--------------------------------|---|
| 1. Splash | 2. No ventilation |
| 3. Direct sunlight | 4. Dramatic temperature change |
| 5. Strong shock | 6. Close to heat source |
| 7. Chemical medicines | 8. Dust |
| 9. Poisonous gas | 10. Corrosive gas |
| 11. Rain | 12. Moist |
| 13. Thunderstorm weather | 14. Strong electromagnetic field (e.g. MRI) |
| 15. Radiation (e.g. X-ray, CT) | 16. Defibrillators or short wave therapy equipmen |

Chapter Six System Installation and Check

⚠Warning: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

⚠Warning:

1. If breakers and fuse of the mains power socket are identical to those of this system, and they are used to control the current for equipment like life support system, the system shall not be connected to such power supply socket as it may cause breaker or fuse to trip and cut off the power supply to the entire premise in case of malfunction or over current or transient current generated at power-on with this ultrasonic system.
2. All plugs of instruments of this system shall be connected into the power socket with protectively earth on the wall and the socket must meet the requirement of power rating of instrument. Multiple portable socket-outlets can not be used for the system.
3. Equipment that connects the signal input part or signal output part must only connect the accessories authorized in this manual, and connect the equipment that complies with the respective IEC standards(IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). If in doubt, consult the technical service department or your local representative.
4. When this system is installed or used around patient, try to avoid the patient touching the system. If system is with some unknown defects, it may cause danger of electric shock.

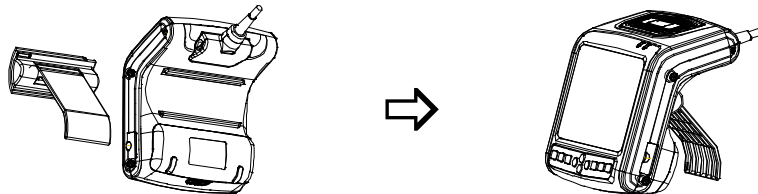
⚠Warning:

1. When instrument works abnormally, do stop working, turn off the power and check the reason, then contacts the KAIXIN Company about it.
2. Operator in contact with the input/output interfaces can not touch patients at the same time.
3. Turn off power and pull out of the plug from socket after each ultrasonic diagnostic operation.
4. It is forbidden to drag and press the power and probe cables emphatically; regularly inspect whether there is pull-apart and bareness, if there is the phenomena like this, turn off power supply immediately, stop using it and change it for new one.
5. It is forbidden to load and unload the probe or move the instrument in galvanic to avoid danger of safety.
6. Pull out of the plug from socket after operation in thunderstorm weather to avoid the instrument being damaged by lightening.
7. If the temperature changes greatly in short time will cause vapor recovery inside of instrument, the case may damage the instrument.
8. The instrument is switched completely only by disconnecting the power supply from the wall socket.

6.1 System installation

Please carefully read through and fully understand the use-method before installing the system. Check the goods for its completeness according to the packing list furnished. This system provides following several usages, for the user to select:

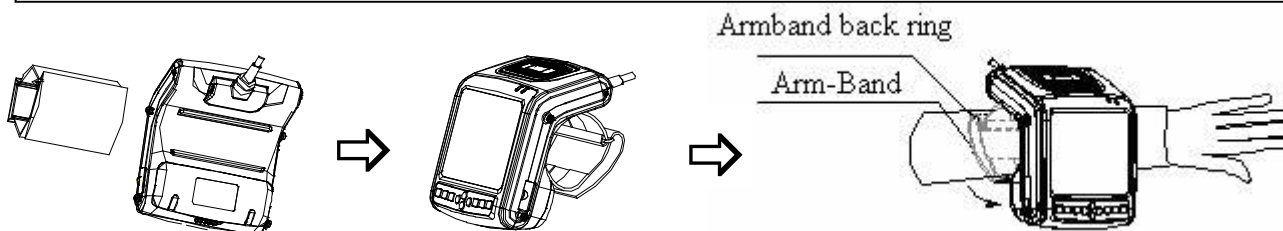
1. Place the instrument on a desktop to use



As shown in fig, insert the support bracket from the back of the instrument, place the instrument on a desktop; adjust the angle of the support bracket to adjust the screen visual angle.

2. Instrument fixed in the arm to use

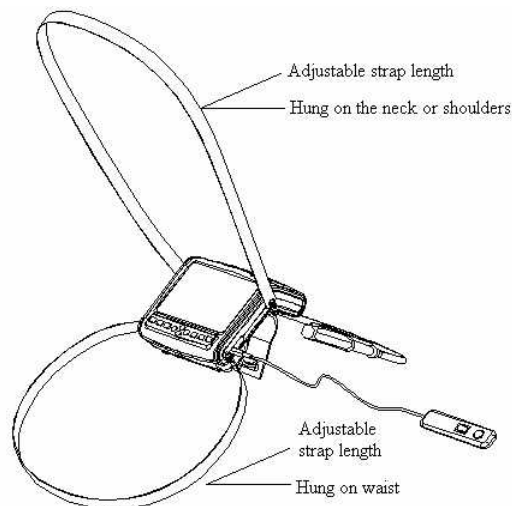
⚠ Attention: when using the arm-band, if allergy, please consult a doctor immediately and increase protective measures (e.g. Wear gloves before use).



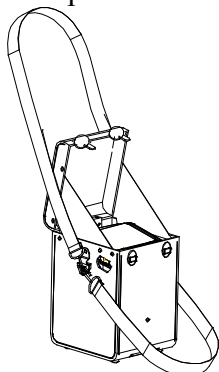
- a. Lock the arm-band as figures from the back of the instrument;
- b. Extend your arm into the arm-band according to arrow direction, or disconnect the arm-band to put on your arm, the long end through the back ring.
- c. Strain the arm-band and stick it firmly on the Velcro.

3. Instrument hanging on the chest to use

- a. Take out the attached straps; install the straps on the rings of main unit as fig shown;
- b. Adjust the strap length, the front strap hung on the neck, the back strap fixed on the waist, two straps can also adjust to similar length to meet the requirements of the screen visual angle, while hanging around the neck to use.



4. Instrument places on the leather lag and hangs on the chest to use



Installation:

- a. Take out the instrument and accessory, install the probe;
- b. The probe passes through the oval hole of the leather bag, and put the instrument into the leather lag;
- c. Install the straps on the rings of leather bag as fig shown;
- d. Adjust the strap length, the one hung on the neck, the other one fixed on the waist, you can also use a strap around your neck or diagonal used in your shoulder.

The benefits of using this method:

- a. Self-built darkroom for the strong-light environments.
- b. The protection of leather bag can avoid collisions and pollution in the use process..

6.2 Probe installation

⚠ Danger: Use together with flammable anaesthetic, it may result in explosion.

⚠ Attention: Probe is highly sensitive to shake, be used with caution. About probe's use and cleaning, the details see the relevant sections.

⚠ Warning:

1. The Kaixin ultrasonic probe shall be connected to the dedicated Kaixin ultrasonic system only. Select proper probe model according to the relevant instructions of ultrasonic diagnostic system.
2. Check the ultrasonic probe and connecting cable after diagnostic operation. Use of defective probe may cause electric shock.
3. Do not knock or bump the probe, or it may be damaged and cause electric shock.
4. Unauthorized disassembly of the probe shall be prohibited as it may cause electric shock hazard.

⚠ Attention:

1. Turn off the ultrasonic system before disconnecting the probe. Disconnecting the probe with system power on may damage the system or probe.
2. Before disconnecting the probe, place the cable and probe on a stable and leveled position so that the probe may not be damaged or injury person by unexpected fall.
3. Freeze the instrument when instrument is start-up without operation to increase of service life of probe.
4. Repeat available machine time should be more than 5 minutes to avoid turn on/off power supply in short time.

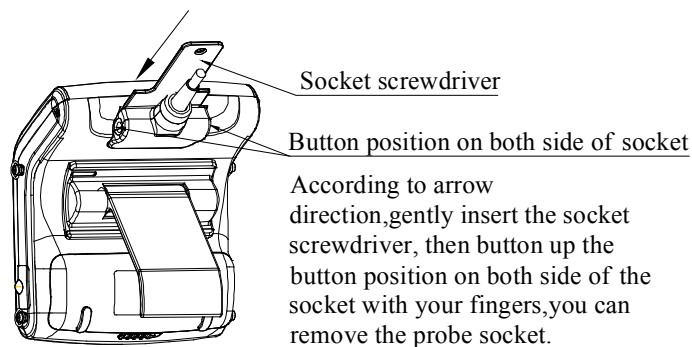
6.2.1 Probe connection

⚠ Warning: Before connecting or using the probe, make sure that the probe, connecting cable and connector are in normal condition (free of cracks or drop). Use of defective probe may cause electric shock.

Insert the probe connector into the probe socket at the back of the main unit.

6.2.2 Probe disconnection

Turn off the system, and use probe screwdriver to remove the probe with figure's method and instructions.



6.3 Install/dismantle the battery

1. Install battery

Put the battery into battery storage of main unit; cover the "Upper cover of battery storage" into corresponding position, and then toggle the push button in the opposite direction, lock the "Upper cover of battery storage".

2. Dismantle battery

According to the direction of the arrow, toggle "Push button of battery storage", removed "Upper cover of battery storage" as shown in figure, take out the battery.

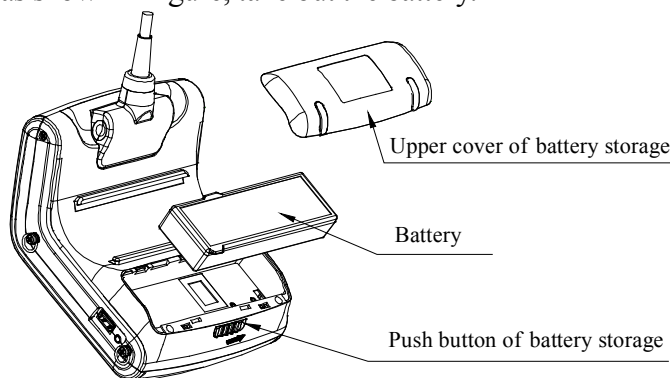
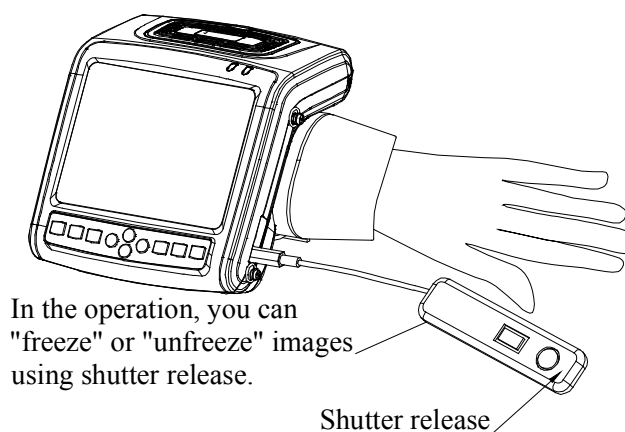


Fig. Install, dismantle the battery

6.4 Shutter release installation

Install shutter release to shutter release interface (Freeze interface) as shown in the figure.



6.5 Video recorder installation

1. Turn off the system, connect the equipotential terminal (▽) of the video recorder to the earthing;
2. Connect one end of the video connection line to the video recorder and the other end to the video output interface on the left of main unit;
3. Insert one end of power plug (jack) of the video recorder to the power input socket of the video recorder, the other end to the power supply socket.

6.6 Connect to the mouse

Connect the mouse to USB interface on the right side of the main unit.

6.7 Connect to power

1. Connect to the power adapter

Insert the output plug of adapter into DC power input interface, which is on the left of main unit.

2. Connect to the main power supply

Insert the power plug (jack) furnished with the machine into power input socket of the power adapter, the other end to the mains socket-outlet.

⚠Warning:

1. Appliance coupler is intended to be used as disconnecting device. please keep appliance coupler easily reached by the operator and use appliance coupler as disconnecting device.
2. The device should be used only with power adapter provided by Kaixin Company.
3. To avoid damaging power adapter or harming people by unexpected fallen, make sure power adapter is placed on the leveled desk.

⚠Warning: the operator must not touch SIP/SOP and patient simultaneously.

6.8 Probe check before and after operation

Before and after ultrasonic diagnosis to check if there are any exceptionally on the surface of the probe or cable jacket, such as peeling, cracks, bulge, or if the acoustic lens is reliable, disinfected or cleaned.

6.9 Main unit check before and after operation

6.9.1 Inspection before start-up

Check the following items before starting the machine:

1. The temperature, humidity and atmospheric pressure shall meet the requirements of operation condition.
2. No condensation occurs.
3. No distortion, damage or contamination on system and peripheral. Clean the parts as specified in relevant sections, if the contaminant is present.
4. Examine the control panel, LCD screen and enclosure to ensure they are in good working condition and free of abnormality (such as cracks and loosened screws).
5. No damage on power cable, and hard up on its connection.
6. Check probe and its connections to ensure they are free of abnormality (such as scuffing, drop-off or contamination). If the contaminant is present, clean, disinfect the contaminated objects as specified in relevant sections.
7. No barriers around the intake of equipment.
8. See to it that probe has been cleaned, disinfected; else dispose it as specified in relevant sections.
9. Check all the ports of the machine for possible damage or blockage.
10. Clean the field and environment.

6.9.2 Inspection after start-up

Check the following items after starting the machine:

1. No abnormal voice, strange smell and overheating appear.
2. Check the machine to ensure a normal start-up: The power indication light is on and startup picture is shown on the screen. The machine will be then automatically set in B mode.
3. Check the acoustic lens for abnormal heat when the probe is in use. This can be done by hand touching the probe to feel the temperature of the lens.
4. Check the image to ensure trouble-free display (no excessive noise or flicker).
5. Check the control panel to ensure normal operation condition.
6. Check the instrument to ensure that the phenomenon of local high temperature will not appear.

⚠Warning: Only use the coupling gel that in accordance with MDD regulations.

⚠Attention: If the overheat acoustic lens is placed on the patient's skin, heat injury may occur.



⚠Attention: Thoroughly clean the coupling gel on the probe surface each time after ultrasonic operation, or the coupling gel may become hardened on the acoustic lens of the probe, deteriorating quality of image.



6.10 System reset

In case of abnormal screen display or no-working for system operation, try to restart the system by turning on/off the main unit power.

Chapter Seven Functional Operation











7.1 Startup and Shutdown

In shutdown status, press  key, machine starts up, power indicator  lights.











In startup status, press  key, machine shuts down, power indicator  goes out. Please note that when shut down the machine, the time of pressing key is a rather long than normal pressing key.

7.2 System Functions Setting











7.2.1 Time Setting

1. Press  key to enter main-menu and press direction keys   to move cursor to “Preset”;
2. Press direction keys   to enter setting interface;
3. Press direction keys   to select “Minutes, Hours, Day, Month and Year”;
4. When setting minutes, hours, day, month and year, press direction key  to increase value or press direction key  to decrease value;
5. Press  key to confirm the time setting and quit setting interface.











7.2.2 TV Mode Setting

1. Press  key to enter main-menu and press direction keys   to move cursor to “Preset”;
2. Press direction keys   to enter setting interface;
3. Press direction keys   to move symbol “<” to point to “TV mode”;
4. Press direction keys   to realize TV mode conversion between PAL and NTSC;
5. Press  key to quit setting interface.









7.2.3 Energy Saving Setting

1. Press  key to enter main-menu and press direction keys   to move cursor to “Preset”;
2. Press direction keys   to enter setting interface;
3. Press direction keys   to move symbol “<” to point to “Sleep”;
4. Press direction keys   to select energy saving time among 1~99 minutes or select “Off”;
5. Press  key to quit setting interface.

7.2.4 Characters Brightness Setting

1. Press  key to enter main-menu and press direction keys   to move cursor to “Preset”;
2. Press direction keys   to enter setting interface;
3. Press direction keys   to move symbol “<” to point to “Font Bright”;
4. Press direction keys   to select characters brightness among 160, 192, 224 and 255;
5. Press  key to quit setting interface.


7.2.5 Hospital Name Setting







1. Press  key to enter main-menu and press direction keys   to move cursor to “Preset”;
2. Press direction keys   to enter setting interface;
3. Press direction keys   to move symbol “<” to point to “Hospital”;
4. Press  key, the cursor is located above “NAME”; at the same time characters input menu will be shown at the bottom of the screen:

Caps 0 1 2 3 4 5 6 7 8 9 a b c d e f g h











Shift i j k l m n o p q r s t u v w x y z

Press direction keys or operate mouse to move cursor to point to Caps, and then press 











click left mouse to achieve capital and small letter conversion; If the cursor point to Shift, press  key or click left mouse again to achieve the conversion between the letter and punctuation;

5. Press direction keys to choose “numbers” or “characters” and press  key to confirm; Or operate mouse to click “numbers” or “characters” to input;
6. If need modify the content, press  key to quit the character input menu, press direction keys   to delete input content; press  key again to retype;
7. Press  key to save this setting and quit setting interface.

7.2.6 Key Sound Setting








1. Press  key to enter main-menu and press direction keys   to move cursor to “Preset”;
2. Press direction keys   to enter setting interface;
3. Press direction keys   to move symbol “<” to point to “Key Sound”;
4. Press direction keys   to select between “On” and “Off”;
5. Press  key to quit setting interface.

7.2.7 Compression Curve Setting











1. Press  key to enter main-menu and press direction keys   to move cursor to “Preset”;
2. Press direction keys   to enter setting interface;
3. Press direction keys   to move symbol “<” to point to “Compression Curve”;
4. Press direction keys   to select compression curve among “00” –“07”;
5. Press  key to quit setting interface.

Note: If use 3.5MHz probe, it is recommended to choose 05 or 06; if use 5.0MHz probe, recommend choose 03 or 04; if use 7.5MHz probe, recommend choose 00 or 01; if use 6.5MHz probe, recommend choose 01 or 02.

7.2.8 Chinese-English Setting

1. Press  key to enter main-menu and press direction keys   to move cursor to “Preset”;
2. Press direction keys   to enter setting interface;
3. Press  key to switch between Chinese and English;
4. Press  key to quit setting interface.


7.3 System Formula Setting

1. Press  key to enter main-menu and press keys   to move cursor to “Preset”;
2. Press direction keys   to enter setting interface;
3. Press direction keys   to move symbol “<” to point to “Formula Set”;
4. Press direction keys   to select the desired formula;
5. Press  key to confirm this setting and quit setting interface.

Formula preset table

Preset items	Options	Preset items	Options	Preset items	Options	
BPD	ASUM China Hadlock Hansmann Jeanty Kurtz Merz Osaka Paris Rempen Shinozuka Tokyo	GS	China Hansmann Hellman Rempen Tokyo	AC	ASUM Hadlock Hansmann Jeanty Merz Shinozuka	
	CRL		FL		China Hadlock Hansmann Jeanty Merz Osaka Paris Shinozuka Tokyo	FT
HL		Jeanty Merz Osaka		EFW	Campell German Hadlock1 Hadlock2 Hadlock3 Hadlock4 Hansmann Merz1 Merz2 Osaka Shepard Tokyo	
TAD		Eriksen Hansmann Paris				
HC		Hadlock Hansmann Jeanty Merz				








7.4 Mode selection

In real-time mode, press  key repeatedly to realize mode switching of B, B/B, 4B, B/M and M.








7.4.1 B Mode

B mode is a basic operation mode after startup and a single-framed B mode image is displayed.








7.4.2 B/B Mode

1. In real-time mode, press  key to enter B/B mode.
2. B/B image switch. Press  key to enter main-menu and press direction keys   to move the cursor to "B/B Mode" and then press direction keys   to switch image display. Or right click mouse to switch image display, the selected image is activated and the other one is frozen.
3. In real-time mode, press  key to exit B/B mode.

7.4.3 4B Mode

1. In real-time mode, press  key to enter 4B mode.
2. 4B image switch. Press  key to enter main-menu and press direction keys   to move the cursor to "4B Mode", then press direction keys   to switch display among four images; or right click mouse to switch display among four images, the selected image is activated and the other three are frozen.
3. In real-time mode, press  key to exit 4B mode.













7.4.4 B/M Mode

1. In real-time mode, press  key to enter B/M mode.
2. Change of scan mode. Press  key to enter main-menu and press direction keys   to move cursor to "M Mode" and then press direction keys   to change the M ultra-scan mode. Or click mouse to realize the change of scan mode.
3. Move sample line. Press  key to quit the current using status for direction keys. Press d

keys to move sample line.








4. In real-time mode, press  key to exit B/M mode.



7.4.5 M Mode

1. In real-time mode, press  key to enter M mode.
2. Change of M-scan mode: Press  key to enter main-menu and press direction keys   to move cursor to "M Mode" and then press direction keys   to change the M ultra-scan mode. Or right click mouse to realize the change of scan mode.
3. Change of M speed: Press  key to enter main-menu and press direction keys   to move cursor to "M Speed" and then press direction keys   to select the eight kinds of scan speed. Or left click mouse to switch M speeds.
4. In real-time mode, press  key to exit M mode.






7.5 Image Quality Adjustment

7.5.1 Brightness and Contrast Adjustment






In the startup default status, press freeze key to unfreeze, press  key to quit the current using status, the adjustment bars of brightness and contrast will be displayed on the screen by pressing direction keys  , adjust them according to actual need. Press direction key  to increase brightness and contrast, direction key  to decrease them; press direction keys   to select brightness or contrast adjustment.

Note: If direction keys   cannot be adjusted when adjust brightness in normal operation mode, must be exit current operating condition of direction keys.






7.5.2 Total Gain Adjustment

In real-time mode, press  key to enter main-menu and press direction keys   to move cursor to "Gain: " in the display area. Press direction key  to increase image total gain and direction key  to reduce total gain so as to control the total gain of the entire image.






7.5.3 Near Field Gain Adjustment

In real-time mode, press  key to enter main-menu and press direction keys   to move cursor to "Near: " in the display area. Press direction key  to increase near field gain and direction key  to reduce near field gain so as to control the gain in near field region.






7.5.4 Far Field Gain Adjustment

In real-time mode, press  key to enter main-menu and press direction keys   to move cursor to "Far: " in the display area. Press direction key  to increase far field gain and direction key  to reduce far field gain so as to control the gain in far field region.




7.5.5 Dynamic Range Adjustment




In real-time mode, press  key to enter main-menu and press direction keys   to move cursor to "Dyn: " in the display area. Press direction key  to increase the value of dynamic range and direction key  to decrease the value of dynamic range so as to control the dynamic range of the entire image.

7.5.6 Frequency Adjustment (Frequency conversion)

In real-time mode, press  key to enter main-menu and press direction keys   to move cursor to "Freq." in the display area. Press direction keys   to realize frequency conversion.






7.5.7 Focus Adjustment and Control

In real-time mode and in B, B/B or 4B mode, press  key to enter main-menu and move cursor to "F. Num" and then press direction keys   to choose from the four focus modes of stage 1(Full dynamic focus), 2, 3 and 4.

In real-time mode and in B, B/B, 4B, B/M or M mode, press  key to quit menu mode direction keys   again to move the focus up and down.

Note: In B/M or M mode, only allowed choosing single focus mode.






7.5.8 Frame Correlation Adjustment

In real-time mode, press  key to enter main-menu and press direction keys   to move cursor to “Avg” in the display area. Press direction keys   to realize four levels of frame correlation.

7.5.9 Image Post-process Adjustment




In real-time mode, press  key to enter main-menu and press direction keys   to move cursor to “IP” in the display area and then press direction keys   to obtain corrected image. System default is 2.

7.5.10 Edge Enhancement Adjustment







In real-time mode, press  key to enter main-menu and press direction keys   to move cursor to “Edge” in the display area and then press direction keys   to gain four levels of sharpened images. System default is 0.

7.6 Image Control








7.6.1 Magnification Selection

In real-time mode, press  key to enter main-menu and move cursor to “Zoom” and then press direction keys   to choose eight kinds of magnification.







7.6.2 Depth Range Selection and Depth Enhancement

In real-time mode, press  key to enter main-menu and press direction keys   to move cursor to “Depth” in the display area and then press direction keys   to select depth, press  key to quit depth range selection.

Note: There is no depth selection function when main unit matching probe which its nominal frequency greater than or equal to 6.5MHz.






In real-time mode, press  key to enter main-menu and press direction keys   to move cursor to “Upgrade” in the display area and then press direction keys  , “” appears on the screen. Press direction keys or operate mouse to move image up/down or left/right so as to observe the images of different depth and width. Press  key to quit depth heighten/pan status.

7.6.3 Local Zoom and Local Additive Color






In real time mode, press  key to enter main-menu and press direction keys   to move cursor to “Local Zoom” in the display area and then press direction keys  , a box appears. Press direction keys or operate mouse to move the box to the position to be enlarged, the selected image be enlarged; Press  key to quit local zoom status.

In the color display, the selected image which by above mentioned operation will be enlarged and added color.






7.6.4 Image Left/right Reverse

In real-time mode and in B, B/B, 4B or B/M mode, press  key to enter main-menu and press direction keys   to move cursor to “H Rev” and then press direction keys   to realize image horizontal reverse. Or left click mouse also to realize image horizontal reverse. The image horizontal reverse is the change of probe scanning direction. The probe scanning direction is indicated by the arrow on the upper left area of the image.






7.6.5 Image Up/down Reverse

In real-time mode, press  key to enter main-menu and press direction keys   to move cursor to “V Rev” and then press direction keys   to realize image vertical reverse.






7.6.6 Image Negative

In real-time mode, press  key to enter main-menu and press direction keys   to move cursor to “Image POS” and then press direction keys   to realize negative function.



7.6.7 Color Selection

In real-time mode, press  key to enter main-menu and press direction keys   to move cursor to “Color” in the display area and then press direction keys   to realize color conversion of eight colors (including one kind of black and white).






















7.6.8 Scan Range (Angle/Width Change)








In real-time B mode, press  key to enter main-menu and press direction keys   to move cursor to “Angle” and then press direction keys   to choose angle/width.(convex array for scanning angle and linear array for scanning width).

7.6.9 Image Freeze/Unfreeze

In real-time mode, press  key or middle mouse key to freeze the image; in frozen status, press  key or middle mouse key to unfreeze the image.









7.7 Puncture guide and lithotripsy positioning line

Puncture guide line: In real-time B mode, press  key to enter main-menu and press direction keys   to move cursor to “Puncture:” and then press direction keys   to choose line 1, press  key to confirm, two puncture guide lines appear on the screen, press direction keys   to change the angle of the first puncture guide line, press direction keys   to change the start position of the first puncture guide line. Press  key again to enter main-menu and press direction keys   to move cursor to “Puncture” and then press direction keys   to choose line 2, press  key to confirm, press direction keys   to change the angle of the second puncture guide line, press direction keys   to change the start position of the second puncture guide line. Press  key to quit the puncture guide status.

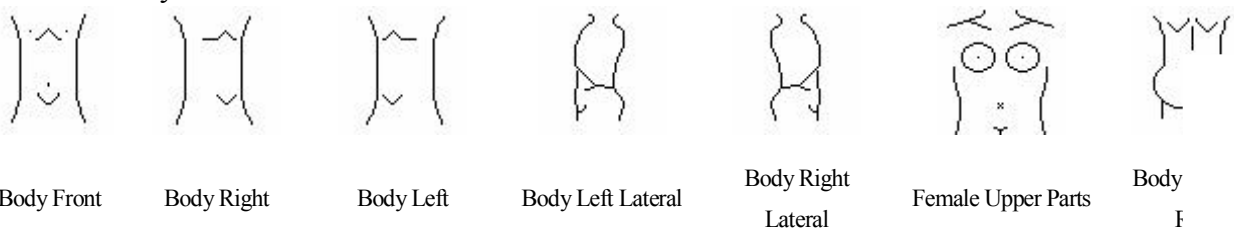
Lithotripsy positioning line: In real-time B mode, press  key to enter main-menu and press direction keys   to move cursor to “Puncture” and then press direction keys   to choose line 3, press  key to confirm, lithotripsy positioning line appears on the screen; At the same time, the measurement depth of lithotripsy positioning line “+: 0.0mm” is shown at the top right corner, operate the up/down keys to positioning the depth. Press  key to quit.


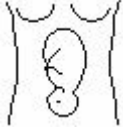
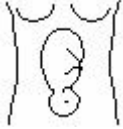


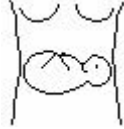
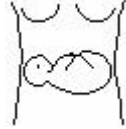

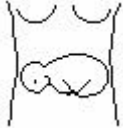








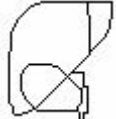
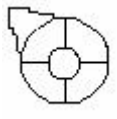
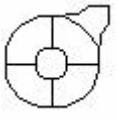

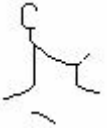
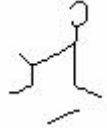



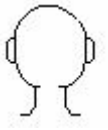

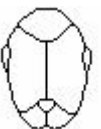
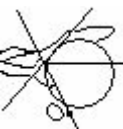
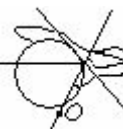


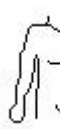
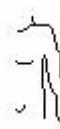











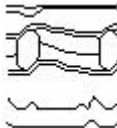



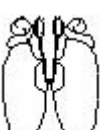





7.8 Body Mark and Probe Mark

This product contains 64 body marks that are divided into two pages when display, 32 marks for each page. The operation steps are as follows:

1. In frozen status, press  key to enter main-menu and press direction keys   to move cursor to “Body Mark”, press  key, body marks will be showed in the image area, press direction keys to change pages;
2. Press direction keys to move to the position of desired body mark, press  key to confirm the selected body mark;
3. Press direction keys or operate mouse to change the probe mark position; press  key to change probe mark direction;
4. Press  key to quit body mark and probe mark status;
5. Press  key to quit froze and body mark status.

The 64 body marks are listed below:









						
Mother Front	Left Front	Right Front	Left Butt Front	Right Butt Front	Left Shoulder Rear	Right Shoulder Rear
						
Left Shoulder Front	Right Shoulder Front	Uterine Appendages	Uterus Rear	Uterus Level	Uterus Front	Uterine Body Transection
						
Uterine Neck Transection	Uterine Base Transection	Uterine Transection	Liver	Breast 1	Breast 2	Neck Front
						
Neck Right Lateral	Neck Left Lateral	Head Right Lateral	Head Left Lateral	Head Front	Head Rear	Head Top
						
Skull Fontanelle Transection	Eyeball 1	Eyeball 2	Lower Limb Front	Lower Limb Rear	Right Arm	Left Arm
						
Fetus Heart 1	Fetus Heart 2	Bilocular Heart	Quad Heart	Apical Four Chamber	Apical Five Chamber	Left Ventricle Major Axis Cross Section
						
Aortic Arch Major Axis 1	Aortic Arch Major Axis 2	Aorta Minor Axis	Bicuspid valve M-type curve	Aortic valve M-type curve	Large Intestine	Stomach
						
Thoracic Cavity	Testes	Knee Joint 1	Knee Joint 2	Foot 1	Foot 2	Hand 1
						H







7.9 Image storage and recall

7.9.1 Save image


●Storage to main unit

1. Freeze the image;
2. Press  key, a “Save” prompt appears on lower right corner of the screen;
3. Press direction keys   to select the image code need to be saved in the “LOCAL”, such as choose “003”;
4. Press  key to appear “Wait” prompt. After the prompt disappear, the current image is saved in the frame for coded “003”. The saved image code is preceded with asterisk “*”;
5. Press  key to quit saving status and press  key to return to real-time status.

●Storage to U disk







1. Plug U disk;
2. Freeze the image;
3. Press  key, a “Save” prompt appears on lower right corner of the screen;
4. Press direction keys   to select the image code need to be saved in the U disk, such as choose “004”;
5. Press  key to appear “Wait” prompt. After the prompt disappear, the current image is stored in the folder for patient number (ID) as folder name in the U disk, and file name is arranged by the selected saving code that is “4”. If user did not enter the number (ID), the folder name defaults to “USER”;
6. Press  key to quit saving status and press  key to return to real-time mode.

Explanation:







1. Each number (ID) corresponds to a folder, the largest storage for each folder is 100 images.
2. Press  key, can select “LOCAL” or “U Disk”.
3. If you want to use number (ID) for the folder name, must first input number (ID) and then store image. Folder name is made up of underline, letters or numbers, without spaces.

7.9.2 Open image



●Open image in the main unit

1. Freeze the image;
2. Continuously press  key twice, a “Read” prompt appears on lower right corner of the screen;
3. Press direction keys   to select the image code need to be read out in the “LOCAL”, such as choose “003*”;
4. Press  key to appear “Wait” prompt. After the prompt disappear, the image stored in frame “003*” is read out;
5. Press  key to quit reading status and press  key to return to real-time status.

●Open image in the U disk

1. Plug U disk;
2. Freeze the image;
3. Continuously press  key twice, a “Read” prompt appears on lower right corner of the screen;
4. Press direction keys   to select the image code need to be read out in the U disk, such as choose “004*”;
5. Press  key to appear “Wait” prompt. After the prompt disappear, the image stored in frame is read out;
6. Press  key to quit reading status and press  key to return to real-time status.







Explanation:

1. When reading images, it must choose the image code with “*”.
2. If you want to read out the images within the folder identified by number (ID) under the U disk, must input ID first before reading, then do as the above steps; if did not enter the number (ID), it would default to read out the images in the “USER” folder under the U disk.
3. If has read out the images in the U disk, also would like to re-read the local image, must press  key to exit this reading status, then press  key to choose “LOCAL”, and vice versa.







7.10 Single dump and mass dump

7.10.1 Single dump

● From main unit to U disk

1. Read out the image in the main unit, “Img” with highlight status is displayed on lower right corner of the screen;
2. Press  key, a “Dump” prompt appears on lower right corner of the screen;
3. Press direction keys   to select the image saving code in the U disk, such as choose “005”;
4. Press  key, “Dump” prompt disappears, until the “Dump” re-appears, the current image can be dumped in the frame for coded “005”. The dumped image code is preceded with asterisk “*”;
5. Press  key to quit dumping status and press  key to return to real-time status.

● From U disk to main unit






1. Enter the number (ID), after completed it, exit the enter status;
2. Read out the image in the U disk, “Img” with highlight status is displayed on lower right corner of the screen;
3. Press  key, a “Dump” prompt appears on lower right corner of the screen;
4. Press direction keys   to select the image saving code in the “LOCAL”, such as choose “006”;
5. Press  key, “Dump” prompt disappears, until the “Dump” re-appears, the current image can be dumped in the frame for coded “006”. The dumped image code is preceded with asterisk “*”;
6. Press  key to quit dumping status and press  key to return to real-time status.

Note: If not enter number (ID), it will select the image within the system default “USER” folder.






The operation steps are 2-6.

7.10.2 Mass dump


● From main unit to U disk

1. Freeze the image, continuously press cine loop key  until enter “PAUSE” status;
2. Press  key, “LOCAL -> U Disk Mass Dump?” prompt display at the bottom of the screen;
3. Press  key, “Dumping” prompt appears, images are mass dumped under the “DUMP” folder in the U disk, and the number behind “PAUSE” character is the number of files name of mass dumping. After finishing mass dumping, return to “PAUSE” status;
4. Press  key to quit mass dumping status and press  key to return to real-time status.







● From U disk to main unit

1. Plug U disk;
2. Freeze the image, continuously press cine loop key  until enter “PAUSE” status;
3. Press  key twice, “U Disk -> LOCAL Mass Dump?” prompt display at the bottom of the screen;
4. Press  key, “Dumping” prompt appears, the number behind “PAUSE” character is the number of files name of mass dumping. After finishing mass dumping, return to “PAUSE” status;
5. Press  key to quit mass dumping status and press  key to return to real-time status.

Explanation:

1. Mass dump, which is dump images from main unit to “DUMP” folder in the U disk; can also dump the images under the “DUMP” folder in the U disk to main unit.
2. If U disk does not have “DUMP” folder, or “DUMP” folder does not have images, or the images within the “DUMP” folder are not named by digital 1-100, press  key, although the screen prompt “Dumping”, the image number is not appeared on the right corner of the screen.






7.11 Delete the image

1. Freeze the image, press  key to enter reading or saving image status;
2. Press  key to switch “LOCAL” and “U disk”, identified the location “LOCAL” or “U disk” for file need to be deleted;
3. Press direction key   to select the image code to be deleted, such as “002*”;
4. Press  key, the image will be deleted, “*” will automatically disappear;
5. Repeat the 2-3 steps, delete other images;
6. Press  key to return to real-time mode.

Explanation:






If you want to delete the images within the folder identified by number (ID) under the U disk, must input ID first before deleting, then do as the above steps; if did not enter the number (ID), it would default to delete the images in the “USER” folder under the U disk.


7.12 Image review


1. Freeze the image, press  key to enter reading or saving image status;
2. Press  key to enter the function of “LOCAL” image review, images will be automatically played by the fixed time interval;
3. Press direction keys   to select the previous or the next image to review;
4. Press  key to return to frozen status.

7.13 Cine loop

In real-time mode, the system is always saving the scanned image. The playback images are for a period time images before freeze.

Freeze the image, continuously press  key three times to enter the automatic playback status; Press  key to enter pause status when playing back; Press direction keys   or operate mouse to view images frame by frame in pause status; Continuously press  key three times again to return to automatic playback status. In the process of saving and playback, relevant data of image frames saved and played are shown on the lower right corner of the screen.



Press  key to return to frozen status.

Press  key unfreeze and quit playback status.

Note: If the images appear abnormal, that is without enough storage time and the images have not been stored full.



7.14 Text Input












Operation steps:

1. Freeze image;
2. Press  key, the cursor is located behind name;
3. Press  key again or right click mouse, at the same time characters input menu will be show bottom of the screen:

Caps 0 1 2 3 4 5 6 7 8 9 a b c d e f g h

Shift i j k l m n o p q r s t u v w x y z












Press direction keys or operate mouse to move cursor to point to Caps, and then press  key or left click mouse to achieve capital and small letter conversion; If the cursor point to Shift, press  key or left click mouse again to achieve the conversion between the letter and punctuation;

4. Press direction keys to choose “numbers” or “characters” and press  key to confirm; Or operate mouse to click “numbers” or “characters” to input;
5. After inputting name, press  key and then press direction key  to move cursor to “ID” and press  key again to input according to Step 4, the number (ID) only be made up of numbers, letters or underlines;
6. After inputting ID, press  key and press direction keys to move cursor to image area and press  key again to input according to Step 4;
7. If need modify the content, continuously press  key twice to quit annotation status, press direction keys   to select “Clear”, at last press  key to clear all noted marks and retype;
8. Press  key to quit.
















Warning: after use the device, please pull out the power plug from the outlet.



Chapter Eight General Measurement

8.1 Distance Measurement

1. In B, B/B or B/M mode, choose desired image and freeze it, the cursor is located in the “Measure” position of display area;
2. Press  key, the measurement methods are showed in the lower left of the screen, press direction keys   to choose “Distance”, press  key again, the cursor will show “+”;
3. Press direction keys or operate mouse to move the “+” mark to desired position, press  key or click left mouse to set the “+” mark position as the starting point of the measurement;
4. Press direction keys or operate mouse to move the “+” mark to the end point of the measurement. A lighted dotted line appears between the start and the end as the dashed locus of the measurement. The measured value is automatically displayed at the built-in mark “+: ----mm” on the right side of the screen;
5. Press  key or click left mouse repeatedly to exchange the starting point and end point of the measurement;
6. Press  key or click right mouse to finish the first measurement;
7. Repeat the steps 3~6 to complete the multi-group data measurement;
8. Continuously press  key twice to quit the measurement status;
9. Press direction keys   to choose “Clear” or synchronously click the left and right key of mouse to clear all marks and data;
10. Press  key or click the middle mouse to unfreeze, clear all marks and data and quit the measurement status.

8.2 Depth Measurement












1. In B, B|B, B|M or M mode, choose desired image and freeze it, the cursor is located in the “Measure” position of display area;
2. Press  key, the measurement methods are showed in the lower left of the screen, press direction keys   to choose “Distance”, press  key again, the cursor will show “+”;
3. Press  key, a dotted line of depth measurement appears in the middle of screen, press direction keys   or operate the mouse to move the dotted line to desired position, press direction keys   or operate the mouse to move the “+” mark to the end point of the measurement, the measured value of depth is automatically displayed at the built-in mark “+: ----mm” on the right side of the screen;
4. Press  key or click right mouse to complete the multi-group depth measurement;
5. Press  key to return to the status of distance measurement;
6. Continuously press  key twice to quit the measurement status;
7. Press direction keys   to choose “Clear” or synchronously click the left and right key of mouse to clear all marks and data;
8. Press  key or click the middle mouse to unfreeze, clear all marks and data and quit the measurement status.

Note: Direction keys   cannot work in the depth measurement when connecting convex array probe.
















8.3 Circumference/Area/Volume Measurement

● Circumference/area measurement with trace method

1. In B, B/B mode, choose desired image and freeze it, the cursor is located in the “Measure”₁ of display area;

2. Press  key, the measurement methods are showed in the lower left of the screen, press direction keys   to choose "Trace", press  key again, the cursor will show "+";
3. Press direction keys or operate mouse to move the "+" mark to desired position, press  key or click left mouse to set the "+" mark position as the start of the measurement; or click right mouse to set the "+" mark position as the starting point of the measurement;
4. Press direction keys or operate mouse to move the "+" mark to the end point of the measurement. At the same time, a locus appears in the direction of operation between the two measurement marks. The measured circumference value is displayed automatically at the built-in mark "C: 00000mm" on the right part of the screen. Press  key or click right mouse to display at the built-in mark "A: 00000mm²" the value of the measured area formed by measurement line enclosure;
5. Press  key, the measurement methods are showed in the lower left of the screen, continue to choose "Trace" to measure;
6. Repeat steps 3, 4 to complete the multi-group data measurement;
7. Continuously press  key twice to quit the measurement status;
8. Press direction keys   to choose "Clear" or synchronously click the left and right key of mouse to clear all marks and data;
9. Press  key or click the middle mouse to unfreeze, clear all marks and data and quit the measurement status.

● Circumference/area/volume measurement with ellipse method

1. In B, B/B mode, choose desired image and freeze it, the cursor is located in the "Measure" position of display area;
2. Press  key, the measurement methods are showed in the lower left of the screen, press direction keys   to choose "Ellipse", press  key again, the cursor will show "+";
3. Press direction keys or operate mouse to move the "+" mark to desired position, press  key or click left mouse to set the "+" mark position as the starting point of the measurement;
4. Press direction keys or operate mouse to move the "+" mark to the end point of the measurement, at the same time the elliptic curve appears; or click middle mouse to appear elliptic curve;
5. Press  key, the "←◁▷+" mark appears on the screen. Hold down  or  key to change the minor axis of the ellipse so as to satisfy the test area. The measured values are displayed at the built-in characters "C: 00000mm, A: 00000mm², V: 00000 cm³" on the right part of the screen automatically;
6. Press  key again to quit the minor axis status; Press  key or repeatedly click left mouse to exchange the starting point and end point;
7. Press  key or click right mouse to finish the first measurement;
8. Repeat the steps from 3 to 7 to complete the multi-group data measurement;
9. Continuously press  key twice to quit the measurement status;
10. Press direction keys   to choose "Clear" or synchronously click the left and right key of mouse to clear all marks and data;
11. Press  key or click the middle mouse to unfreeze, clear all marks and data and quit the measurement status.

8.4 Slope/Heart rate/Cycle Measurement

The method to measure slope/heart rate/cycle is identical with distance measurement.

Note: In B/M mode, if both starting point and end point of the measurement mark fall into B-mode area, the value of the "+: "refers to distance; if starting point and end point

measurement mark fall into the M-mode area, the value of the “+” refers to depth; if the starting point and end point are in separate areas, the “+” will display “----” sign or invalid value.

+: denotes depth measured in mm (millimeter)

EF: denotes slope coefficient measured in mm/s (millimeter per second)

HR: denotes heart rate measured in times/minute (times per minute)

T: denotes cycle measured in ms (millisecond)

⚠ Attention: The accuracy of software measurement: distance measurement $\leq 1\text{mm}$; area measurement $\leq 1\text{mm}^2$; volume measurement $\leq 1\text{cm}^3$; heart rate measurement $\leq 1\text{bmp}$; time measurement $\leq 1\text{ms}$. Due to differences in images obtained by each user in different times, the actual object for the accuracy of the measurement may be greater than the above-mentioned values.

Chapter Nine Obstetric Measurement

9.1 Measurement and Calculation items

BPD (Biparietal Diameter), CRL (Crown Rump Length), GS (Gestational Sac), FL (Femur Length), HL (Humerus Length), LV (Lumbar Vertebrae), TTD (Thorax Transverse Diameter), APTD (Antero-posterior Thorax Diameter), HC (Head Circumference), AC (Abdominal Circumference), FT (Foot Length), TAD (Abdominal Transverse Diameter), THD (Thorax Height Diameter), TCD (Transverse Cerebellum Diameter), OFD (Occipitofrontal Diameter), EFW (Estimated Fetus Weight), EDC (Estimated Date of Confinement), GA (Gestational Age).

9.2 Fetus growth parameters measurement

The following parameters are common evaluation specification of fetus growth. When you measure one of the parameters the system will calculate the GA automatically.

⚠ Attention:







1. The measured value of GA is the diagnostic GA.
2. The formulae of every measurement item have been embedded in main unit.
3. Make sure that the measurement is in the effective image area or else it can't calculate right or lead to wrong calculation.

9.2.1 Measurement of GA and EDC

9.2.1.1 Measurement of BPD, CRL, GS, FL, HL, LV, TTD, APTD, FT, TAD, THD, TCD, OFD

Follow the steps below:


















1. In B, B/B mode, freeze the desired image, press direction keys \uparrow \downarrow to choose “OB” in the display area;
2. Press Enter key to display the obstetric parameters on the lower part of the screen;
3. Press direction keys \leftarrow \rightarrow to select corresponding measurement parameters items: BPD, CRL, GS, FL, HL, LV, TTD, APTD, FT, TAD, THD, TCD, OFD, press Enter key to confirm, the cursor will show “.”;
4. Press direction keys or operate mouse to move the “+” mark to desired position, press Enter click left mouse to set the “+” mark position as the starting point of the measurement;
5. Press direction keys or operate mouse to move the “+” mark to the end point of the measurement GA and EDC value to be displayed in real time in the right area of the screen;

6. Press  key or repeatedly click left mouse to exchange the starting point and end point;
7. Press  key or click right mouse to finish the first measurement;
8. Repeat the steps from 3 to 7 to complete the multi-group data measurement;
9. Press  key to quit the measurement status;
10. Press direction keys   to choose "Clear" or synchronously click the left and right key of mouse to clear all marks and data;
11. Press  key or click the middle mouse to unfreeze, clear all marks and data and quit the measurement status.

9.2.1.2 Measurement of HC and AC

Measure HC and AC using ellipse method







Follow the steps below:

1. In B, B/B mode, freeze the desired image, press direction keys   to choose "OB" in the display area;
2. Press  key to display the obstetric parameters on the lower part of the screen;
3. Press direction keys   to select measurement parameters in HC, AC, then press  key to confirm, the cursor will show "+";
4. Press direction keys or operate mouse to move the "+" mark to desired position; press  key or click right mouse to set the "+" mark position as the starting point of the measurement;
5. Press direction keys or operate mouse to change the major axis of the ellipse; Press  key the "←▷+>" mark appears on the screen, hold down  or  key to change the minor axis of the ellipse so as to satisfy the test, circumference, area, volume, G.A and EDC value will be displayed in real time in the right area of the screen;
6. Press  key again to quit the minor axis status; Press  key or repeatedly click left mouse to exchange the starting point and end point;
7. Press  key or click right mouse to finish the first measurement;
8. Repeat the steps from 3 to 7 to complete the multi-group data measurement;
9. Press  key to quit the obstetric measurement status;
10. Press direction keys   to choose "Clear" or synchronously click the left and right key of mouse to clear all marks and data;
11. Press  key or click the middle mouse to unfreeze, clear all marks and data and quit the measurement status.

9.2.2 Fetus weight measurement

Fetus weight measurement can be done in B, B/B mode. Multi-parameter measurement and storage are required as different formulas are applied to the measurement. These parameter groups for fetus weight measurement include BPD, FTA, FL or BPD, APTD, TTD, FL. Ellipse method shall be used for area and circumference measurement for the fetus weight measurement.

The calculation methods for fetus weight measurement are as follows:

1. In B, B/B mode, freeze the desired image, press direction keys   to choose "OB" in the display area;
2. Press  key to display the obstetric parameters on the lower part of the screen;
3. Press direction keys   to select the "EFW" parameter, press  key to confirm, the cursor will show "+"; For example, set the calculation formula of fetus weight to "Osaka", the right area screen will appear:

EFW ---- g




1) ----mm


2) ----mm²

3) ----mm

At the same time together with relevant parameters “1. BPD, 2.FTA, 3. FL” required for the calculation will be displayed at the bottom of the screen.







In accordance with the order of shown parameters at the bottom of the screen, measure the parameters respectively:

- a. Measure BPD with distance measurement method. The measured value of BPD is saved and displayed at “1) ---- mm” position in the EFW zone of the right display area.
- b. ① Press  key to exit BPD measurement status;
 ② Obtain the desired image and freeze it again;
 ③ Measure FTA with ellipse method of measuring HC, AC. The measured value of FTA is saved and displayed at “2) ---- mm²” position in the EFW zone of the right display area.
- c. ① Press  key to exit FTA measurement status;
 ② Obtain the desired image and freeze it again;
 ③ Measure FL with distance measurement method. The measured value of FL is saved and displayed at “3) ---- mm” position in the EFW zone of the right display area.
4. When values are available for all the selected parameters, the EFW value is automatically displayed in “EFW ---- g” position;
5. Press  key to quit the measurement status.

 **Attention:** The formulas of fetus weight measurement are all based on estimation. Due to differences in development of individual fetuses and quality of images obtained in different times, the estimated fetus weight may deviate. Therefore, besides using more accurate parameters, it is advisable to measure the fetus weight in various formulae and average the values.

Note: Select other formulas measuring fetus weight. The method and steps are identical with those above.

9.3 Obstetric report

In frozen status, press  key to enter main-menu and press direction keys   to move the cursor to the position “Report”. Press direction keys   to display obstetric report. Press  key to exit obstetric report status.

Note:

1. For measurements done with the given obstetric table, the distance, gestational week and estimated date of confinement are automatically stored in the corresponding places of the obstetric report.
2. When performing fetus weight measurement, the system will store the last measurement value only and display the value at the EFW position of the obstetric report.

9.4 Measurement items

1. Items measurable in B mode: distance, depth, circumference, area, volume, gestational age (GA), estimated date of confinement (EDC) and fetus weight.
2. Items measurable in B/B mode: distance, depth, circumference, area, volume, gestational age (GA), estimated date of confinement (EDC) and fetus weight.
3. Items measurable in B/M mode: distance or depth, slope, heart rate and cycle.
4. Items measurable in M mode: depth, slope, heart rate and cycle.
5. If the display becomes “----”, it indicates an invalid measurement value.

Chapter Ten Principle of Sound Power

10.1 Biological effect

It is generally recognized that ultrasonic diagnosis is safe for human's health. So far, there has been no report on bodily harm done by ultrasound.

Nevertheless it is also believed that not all types of ultrasound are absolutely safe. Relevant researches have already indicated that high-intensity ultrasound is harmful for human body.

With the development of ultrasonic diagnosis technology in recent years, people are more aware of the potential risk in biological effect caused by use of ultrasound and application of ultrasonic diagnostic technology.

10.2 Mechanical effect and thermal effect

Research indicates that two different ultrasonic properties influence human body: one is when ultrasonic sub-pressure exceed some limited number, air pocket forms mechanical effect; Another is when tissues absorb ultrasonic, appearance of heat energy of ultrasonic may cause thermal effect. Two parameters which are mechanical index MI and heat index TI can explain two types of effects influencing level, the smaller value of MI/TI is, the less bio effect produce.

10.3 Prudent-use statement

Whereas it is not proved that ultrasonic diagnostic instrument may result in biological effect in human body, there is possibility that such biological effect is proved to be true in the future. Therefore we shall exercise prudence in applying the diagnostic ultrasound to clinical practice. We shall obtain clinical information necessary for the diagnosis with reasonable ultrasound and avoid using high-intensity ultrasound for long period of time.

10.4 LARA (as low as reasonably achievable) principle

Application of ultrasound shall be based on the ALARA principle that requires a minimized, biological effect-free energy output to obtain necessary diagnostic information. The ultrasonic energy intensity is related to output power and exposure time. Different patients and cases require different ultrasonic intensity.

Not all diagnosis can be done with extra-low ultrasonic energy output. The extra-low ultrasound power produces poor-quality image or weaker Doppler signal that may reduce the diagnostic reliability. On the other hand, use of sound power larger than diagnostically required makes no more contribution to improvement of the diagnostic information quality and increase the risk of biological effect possibility. Therefore, user of the diagnostic ultrasound shall be fully aware of the patient's safety and choose a proper output level for a specific purpose based on ALARA principle.

10.5 Factors impacting sound power

There are various factors that may have impact on sound power output. These factors include generation condition (focus, transmission frequency, transmission voltage for piezoelectric element), scanning condition and control settings.

10.6 Image control impact on sound power output

Change of image control settings may have influence on sound power output. See table below:

Operation	Consequential impact on sound power output
Change probe	The maximum sound power for each probe has been optimized to FDA standard in order to obtain the best image quality. Therefore the sound power varies with the probe change.
Change image mode	Different parameters are used for B mode and M mode. Therefore change mode may lead to the change of sound power. If the mode is switched from B/B, or to 4B, the sound power will not change as the basic parameters remain same. In most cases, sound power output in M mode is larger than that in B

Number of focus	The number of focus influences frame frequency and focus location, thereby changes the sound power output.
Focus location	Change of transmission focus location leads to change of transmission level and aperture, thereby the change of sound power output.
Freeze	Freeze function initiation disables the system elements transmitting electric energy; therefore the system is not able to transmit the ultrasound.
Transmission power	Change of transmission power will cause the change of system electric output to the probe, hence the change of sound power output.
Change frequency	Change of frequency will lead to the change of wave focus characteristic, thereby the change of sound power output.
Restart or turn off/on	Restart or turn off/on the power will set the system in default mode and change the sound power output.

Chapter Eleven System Maintenance

The system maintenance should be performed by the user and service engineer. Users shall be in full charge of maintenance, repair and operation of the system after purchasing the product.

11.1 Maintenance by users

11.1.1 System cleaning and disinfection

⚠ Warning: Turn off the instrument and pull out the power supply wire before cleaning every instrument of the system. It may cause electric shock if clean the system under power is on.

⚠ Warning: There is no any waterproof device in the system. Do not splash any water or liquor into the system when cleaning or maintaining; otherwise it will cause malfunction or electric shock.

⚠ Attention:

1. Probe without cleaning, disinfection may become the source of contamination, so cleaning or disinfection to the probe is very necessary after every ultrasonic diagnosis.
2. To prevent possible infection, it is advisable to wear sterilized gloves when cleaning, disinfecting the ultrasonic probe.
3. In the process of cleaning and disinfection, avoid probe overheat (exceeding 60°C) as it may be deformed or damaged under excessive heat.
4. To prevent the infection or the cross infection, the intra-cavity probe surface should be covered with a condom every time before examination.
5. Do not use the probe packing box to store the probe as the box may become the source of contamination.
6. The waterproof grade of intra-cavity probe is IPX7, immersion depth from probe's acoustic head to the sheath of probe handle; others are IPX4.

1. Clean the probe

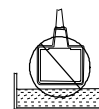
- (1) Wear sterilized gloves to prevent possible infection.
- (2) Clean the probe with sterile water to remove all contaminants. Do not use brush as

damage the probe.

- (3) Dry the probe with sterilized cloth or gauze after cleaning. Do not dry the probe by heating it.
2. Routinely disinfect the probe
 - (1) Wear sterilized gloves to prevent possible infection in the process of routine disinfection.
 - (2) Clean the probe firstly before routine disinfection, and then wipe the probe twice with 75% alcohol.
 - (3) Clean the probe with sterile water to remove residual chemicals.
 - (4) Clean the water off the probe surface with sterilized cloth or gauze. Never dry the probe by heating it.

⚠Warning:

Do not place the ultrasonic probe connector into water or disinfection, as it may cause electric shock.



3. Regularly disinfect the probe

- (1) Wear sterilized gloves to prevent possible infection in the process of regular disinfection.
- (2) Clean the probe firstly before regular disinfection. 2% glutaraldehyde disinfectant is recommended for the probe. Immerse the sound head part of the probe (See regular disinfection sketch map) in liquid for more than 10 hours for disinfection.

⚠Attention:

1. Please carefully read the instructions provided by disinfectant provider about the disinfection liquid concentration and disinfection method as well as the description of the dilution method.
2. Glutaraldehyde liquid should use the activator.

- (3) Clean the probe with sterile water to thoroughly remove residual chemicals.
- (4) Clean the water off the probe surface with sterilized cloth. Never dry the probe by heating it.

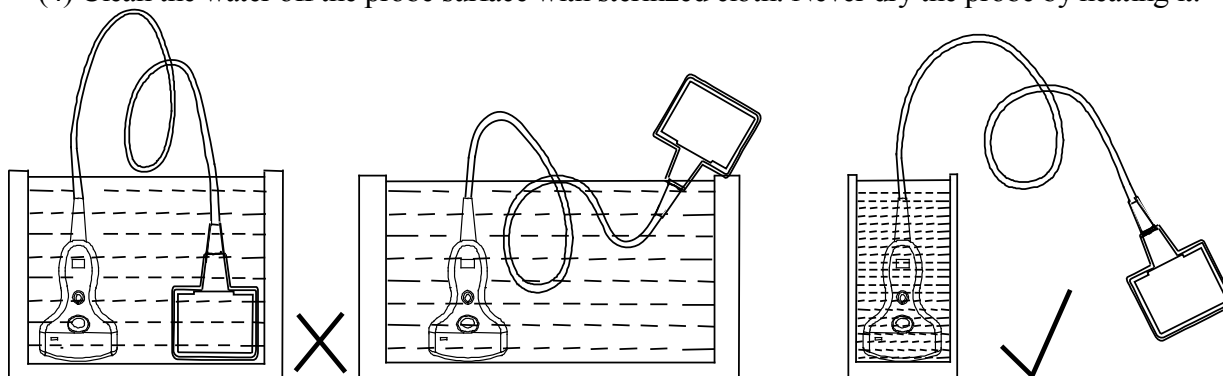


Fig. Wrong 3.5MHz probe regular disinfection Fig. Correct 3.5MHz probe regular disinfection

⚠Attention:

1. It is a normal phenomenon that color of the acoustic lens may change and color of the probe label may fade away.
2. To prevent the infection or the cross infection, such cleaning, disinfection for puncture bracket and probe is very necessary before and after every puncture operation.
3. The regular disinfection times should be minimized as it may lead to degrade of the probe safety and performance.

4. Clean the probe cable and its connector

- (1) Clean the probe cable and its connector with soft, dry cloth.

- (2) In case of die-hard blots, clean with soft cloth dipped in moderate detergent and then air-dry it.
5. Clean the LCD screen
Clean the liquid crystal display with dry, soft flax or anti-static LCD clean cloth.

⚠Attention: Do not clean the screen with hydrocarbon detergent for example alcohol etc or OA equipment cleaning media. These kinds of liquid may degrade the internal function of the screen.

6. Clean the control panel, shell
Clean the instrument surface with soft, dry cloth or with soft cloth dipped in moderate water cleaning media to remove the blots, and then dry the instrument with soft, dry cloth or with air.
7. Clean the video recorder
(1) Use the soft dry cloth to wipe the video recorder.
(2) If it is difficult to wipe away the blemish, clean with soft cloth dipped in moderate detergent and then air-dry it.

11.1.2 Use and maintenance for the rechargeable battery

1. Only use charger and battery (model CNLB-01) provided by KaiXin Company.
2. The output port of adapter plugs into the input port of charger to charge; the minimum charging time is 3 hours and up to 4 hours. Over-charging or discharging will shorten the battery life; the full charged battery can be used for 2 ~ 3 hours.
3. Battery is consumable; the battery cycle-life is based on the times of charge and discharge as unit. When the use time reduced significantly compared with normal conditions, the battery should be promptly replaced.
4. The excess high or low temperature will affect the charging and discharging performance, and short the battery life and capacity.

⚠Attention: Battery charger shall meet the requirements of IEC60601-1 standard.

⚠Attention: Battery is consumable; the battery cycle-life is based on the times of charge and discharge as unit. When the use time reduced significantly compared with normal conditions, the battery should be promptly replaced.

⚠Attention: A power indicator will appear "X" and glitter continually when the electric quantity is too low. Connect the main unit to external power supply and recharge the battery, or turn off the machine to recharge.

⚠Attention: If long-term use external power or do not intend to use the equipment within such a period of time, please remove the battery, to avoid over-charging or discharging the battery which will curtail battery life, or to reduce other risk.

⚠Attention: Don't throw away the exhausted battery anywhere; especially throw it in the fire. Please deal with it according to local statutes. Use pollution degree II to deal with

⚠Attention:

1. Do not throw the battery into water or be wet, which will lead to the battery leakage, explosion or fire;
2. Do not use or store the battery near the heat source, such as fire or heater, which will lead to the battery leakage, explosion or fire;
3. Do not connect the anode and cathode reversely, which will lead to the battery leakage, explosion or fire;
4. Do not heat up or throw the battery into fire, which will lead to the leakage, explosion or fire;
5. Do not connect the anode and cathode with any metal or conductor; do not transport or store the battery together with necklaces, hairpins or other metal objects, which will lead to the leakage, explosion or fire;
6. Do not hammerblow, throw or mechanically shake the battery, which will lead to the leakage, explosion or fire;
7. Do not insert the battery with nail or other spiculate objects; do not hammerblow or trample the battery, which will lead to the leakage, explosion or fire;
8. Do not weld the battery terminal directly, which will lead to the leakage, explosion or fire;
9. Do not disassemble the battery in any way, which will lead to the leakage, explosion or fire;
10. Do not charge the battery near the heat source or extra-hot environment, which will lead to the leakage, explosion or fire;
11. Do not put the battery into the microwave oven or pressure vessel, which will lead to the leakage, explosion or fire;
12. Do not mixed use the battery together with one-off battery (such as dry battery), or different capability or different model or different brand battery, which will lead to the leakage, explosion or fire;
13. Do not use the abnormal battery with particular smell or abnormal heat or distortion or turn colors or abnormal phenomena, which will lead to the leakage, explosion or fire;
14. Do stop the charge and pull out the battery from the charger at once if any abnormal phenomenon happens to the battery, such as particular smell or abnormal heat or distortion or turn colors. Otherwise, each of above will lead to the leakage, explosion or fire;
15. Do remove the battery from the near fire if any leakage or particular smell happens, which will lead to the leakage, explosion or fire;
16. If any leakage splash into eye, do not wipe the eye, instead of washing it and get help from the doctor as soon as possible. Otherwise, the eye will be injured;
17. Do not use the battery in the extremely hot environment, such as hot sunshine or in the car when it is too hot, because these will catch fire, even worsen its performance and shorten its life;
18. If use the battery beyond the listed environment on the manual, it will worsen its performance or shorten its life, even lead to extreme heat or explosion or fire.

11.2 Troubleshooting

To ensure normal operation, users are recommended to prepare a proper maintenance and regular examination plan to regularly check on product safety performance. If any abnormality occur, timely contact International Trade Dept of Kaixin for support.

If the following problems occur on starting up the machine, try to make corrections following the method in the table. If the problem remains unsolved, contact International Trade Dept of Kaixin for support.

Trouble	Correction
Power light is off and no screen display is present when starting the machine.	<ol style="list-style-type: none"> 1. Check power supply. 2. Check power cable and connector. 3. Check power adapter.
Character and gray scale are displayed, but no ultrasonic image on the screen.	Probe is not properly connected. Turn off the power and reconnect the probe.
Intermittent stripe, snow, or far-field interference appears on screen.	<ol style="list-style-type: none"> 1. Check power supply.(spark interference present) 2. Check environment.(source of interference around the machine, such as electric motor, ultrasonic atomizer, automobile, computer or other interference) 3. Check power plug/socket of the instrument or probe connectors. They shall be properly contacted.
Image display is not clear.	<ol style="list-style-type: none"> 1. Adjust the total gain, near field, far field. 2. Adjust the brightness and contrast level.
Control panel malfunction	Restart the system by turning off the main unit power.

11.3 Periodic Safety Check

1. The following safety checks should be performed at least every 12 months by a qualified person who has adequate training, knowledge, and practical experience to perform these tests.
 - Inspect the equipment and accessories for mechanical and functional damage.
 - Inspect the safety relevant labels for legibility.
 - Inspect the fuse to verify compliance with rated current and breaking characteristics.
 - Verify that the device functions properly as described in the instructions for use.
 - Test the protection earth resistance according to IEC 60601-1: Limit: 0.1Ω.
 - Test the earth leakage current according to IEC 60601-1: Limit: NC300μA, 300uA(for UL) SFC: 1000μA.
 - Test the touch current according to IEC 60601-1: Limit: NC 100μA, SFC: 500μA.
 - Test the patient leakage current according to IEC 60601-1: Limit: for a.c.: 100μA, for d.c.: 10μA.
 - Test the patient leakage current under single fault condition with mains voltage on the applied part according to IEC 60601-1: Limit: for a.c.: 500μA, for d.c.: 50μA

The leakage current should be never exceed the limit. The data should be recorded in an equipment log. If the device is not functioning properly or fails any of the above tests, the device has to be repaired.

2. Please clean the plug of power cord at least once a year. Too much dust on plug may cause the fire.

11.4 Please calibrate the device at least once every 12 months.

Chapter Twelve Storage and Transportation

Storage and Transportation

1. If the instrument is stored over 3 months, take out the instrument from the packing case, connect it to power supply for 4 hours, and then disconnect the power and place it in the case again following the direction indicated by arrows on the package. Store the case in the warehouse. Do not pile the case. The instrument case should have adequate space from ground, walls and ceiling of the warehouse.
2. Environment requirement
Ambient temperature: $-20^{\circ}\text{C} - 55^{\circ}\text{C}$; Relative humidity: 30%—93% (without condensation);
Atmospheric pressure: 700hPa-1060hPa. The warehouse should be well ventilated and free of direct sunlight and corrosive gas.
3. Shockproof measures have been taken inside the packing case to allow for transport by air, railway, land and sea. The goods shall not be exposed to poor weather conditions like rain and snow, nor shall the goods be placed upside down, bumped, knocked or over-stacked.

Chapter Thirteen Standard Compliance

The compliant standards are listed below:

93/42/EEC
EN ISO 14971:2009
EN 60601-1:2006
EN 60601-1-1:2001
EN 60601-2-37:2008
IEC 60601-1-2:2007
EN 980:2008
EN 1041:2008
EN ISO 10993-1:2009
EN ISO 10993-5:2009
EN ISO 10993-10:2009

Chapter Fourteen Safety Classification

1. Classified according to electric shock protection type:
Class I, internally powered equipment
2. Classified according to electric shock protection degree:
Type B applied part
3. Classified according to the degree of protection against ingress of liquid:
Main unit belong to IPX0 equipment
4. Classified according to operation safety in condition of existence of flammable anesthetic mixture with air or oxygen or nitrous oxide:
It is neither of category AP equipment nor of category APG equipment
5. Classified according to mode of operation:
Continuous operation equipment
6. Classified according to the protection of radio services:
Group I Class A equipment

Chapter Fifteen Guidance and Manufacturer's Declaration

This product complies with EMC test standard IEC 60601-1-2.

Guidance and manufacturer's declaration — electromagnetic emissions- for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration — electromagnetic emission		
The KX5200 is intended for use in the electromagnetic environment specified below. The customer of the user of the KX5200 should assure that it is used in such and environment.		
Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The KX5200 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class A	The KX5200 is suitable for use in all establishments other than domestic and those directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration — electromagnetic immunity- for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration — electromagnetic immunity			
The KX5200 is intended for use in the electromagnetic environment specified below. The customer or the user of KX5200 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines	± 1 kV for power supply lines	The RESPONSIBLE ORGANIZATION or OPERATOR must take actions (like installing filter on power supply for KX5200) to reduce environmental levels of the ELECTROMAGNETIC DISTURBANCE so that they are less than or equal to the COMPLIANCE LEVEL listed in column 3.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.


Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. The KX5200 can continue the operation during power mains interruptions due to the usage of battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Mains power quality should be that of a typical commercial or hospital environment.
Note U_T is the a.c. mains voltage prior to application of the test level.			

**Guidance and manufacturer's declaration — electromagnetic immunity-
for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING**

Guidance and manufacturer's declaration — electromagnetic immunity

The KX5200 is intended for use in the electromagnetic environment specified below. The customer or the user of KX5200 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 V _{rms} 150 kHz to 80 MHz outside ISM bands	3 V _{rms}	Portable and mobile RF communications equipment should be used no closer to any part of the KX5200, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3V/m	$d = \left[\frac{3.5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed transmitters, as determined by electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b

			<p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the KX5200 is used exceeds the applicable RF compliance level above, the KX5200 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the KX5200.</p>			
<p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM – for EQUIPMENT or SYSTEM that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the KX5200			
<p>The KX5200 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the KX5200 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the KX5200 as recommended below, according to the maximum output power of the communications equipment.</p>			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.73
1	1.2	1.2	2.3
10	3.7	3.7	7.3
100	12	12	23
<p>For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.</p>			
<p>NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p>			
<p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

Appendix A: Acoustic Output Data Disclosure

Pursuant to the provisions of EN 60601-2-37:2008 “Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment”, acoustic output data disclosure as follows:

Manufacturer: Xuzhou Kaixin Electronic Instrument Co., Ltd.

Product Name: Full Digital Ultrasonic Diagnostic Instruments

Test Mode: B-MODE; **Probe Type:** 3.5C60E1

Index label		MI	TIS				TIB	TIC
			Scan	Non-scan		Non-scan		
				$A_{\text{aprt}} \leq 1 \text{cm}^2$	$A_{\text{aprt}} \geq 1 \text{cm}^2$			
Maximum index value		0.64	0.87	-	-	-	-	
Associated acoustic parameters	P_{ra}	(MPa)	1.12					
	P	(mW)		58.6	-		-	
	min of $[Pa(Z_S), I_{\text{ta}, \alpha}(Z_S)]$		(mW)				-	
	Z_S	(cm)					-	
	Z_{bp}	(cm)					-	
	Z_b	(cm)					-	
	Z at max $I_{\text{pi}, \alpha}$	(cm)	3.14					
	d_{eq} (zb)	(cm)					-	
	f_{awf}	(MHz)	3.11	3.11	-	-	-	-
	Dim of A_{aprt}	X	(cm)		1.19	-	-	-
Y		(cm)		1.48	-	-	-	-
Other information	t_d	(μsec)	0.467					
	prr	(Hz)	4132					
	p_r at max I_{pi}	(MPa)	1.58					
	d_{eq} at max I_{pi}	(cm)					-	
	$I_{\text{pa}, \alpha}$ at max MI	(W/cm^2)	74.03					
Operating control conditions	Focus		1	1	-	-	-	-
	Focus setting (mm)		30	30	-	-	-	-
	Frequency (Hz)		3.5	3.5	-	-	-	-

Test Mode: BM-MODE; Probe Type: 3.5C60E1

Index label		MI	TIS			TIB	TIC	
			Scan	Non-scan		Non-scan		
				$A_{\text{aprt}} \leq 1\text{cm}^2$	$A_{\text{aprt}} \geq 1\text{cm}^2$			
Maximum index value		0.64	0.87	-	0.01	0.02	-	
Associated acoustic parameters	P_{ra}	(MPa)	1.12					
	P	(mW)		58.8	-		1.06	-
	min of $[Pa(Z_S), I_{\text{ta}, \alpha}(Z_S)]$		(mW)				0.63	
	Z_S	(cm)				2.26		
	Z_{bp}	(cm)				2.24		
	Z_b	(cm)					3.08	
	Z at max $I_{\text{pi}, \alpha}$		(cm)	3.14				
	$d_{\text{eq}}(z_b)$		(cm)				0.58	
	f_{awf}		(MHz)	3.11	3.11	-	3.11	3.11
Dim of A_{aprt}	X	(cm)		1.19	-	1.19	1.19	-
	Y	(cm)		1.48	-	-	-	-
Other information	t_d		(μsec)	0.467				
	prf		(Hz)	64				
	p_r at max I_{pi}		(MPa)	1.58				
	d_{eq} at max I_{pi}		(cm)				0.58	
	$I_{\text{pa}, \alpha}$ at max MI		(W/cm^2)	74.03				
Operating control conditions	Focus		1	1	-	1	1	-
	Focus setting (mm)		30	30	-	30	30	-
	Frequency (Hz)		3.5	3.5	-	3.5	3.5	-

Test Mode: M-MODE; Probe Type: 3.5C60E1

Index label		MI	TIS			TIB	TIC	
			Scan	Non-scan		Non-scan		
				$A_{\text{aprt}} \leq 1\text{cm}^2$	$A_{\text{aprt}} \geq 1\text{cm}^2$			
Maximum index value		0.64	-	-	0.18	0.26	-	
Associated acoustic parameters	P_{ra}	(MPa)	1.12					
	P	(mW)		-	-		22.4	-
	min of $[Pa(Z_S), I_{\text{ta}, \alpha}(Z_S)]$		(mW)				11.72	
	Z_S	(cm)				2.82		
	Z_{bp}	(cm)				2.24		
	Z_b	(cm)					3.08	
	Z at max $I_{\text{pi}, \alpha}$		(cm)	3.14				
	$d_{\text{eq}}(z_b)$		(cm)				0.95	
	f_{awf}		(MHz)	3.11	-	-	3.11	3.11
Dim of A_{aprt}	X	(cm)		-	-	1.19	1.19	-
	Y	(cm)		-	-	1.48	1.48	-
Other information	t_d		(μsec)	0.467				
	prf		(Hz)	520				
	p_r at max I_{pi}		(MPa)	1.58				
	d_{eq} at max I_{pi}		(cm)				0.94	
	$I_{\text{pa}, \alpha}$ at max MI		(W/cm^2)	74.03				
Operating control conditions	Focus		1	-	-	1	1	
	Focus setting (mm)		30	-	-	30	30	
	Frequency (Hz)		3.5	-	-	3.5	3.5	

Test Mode: B-MODE; Probe Type: 7.5L40E1

Index label		MI	TIS				TIB	TIC
			Scan	Non-scan		Non-scan		
				$A_{\text{aprt}} \leq 1 \text{cm}^2$	$A_{\text{aprt}} \geq 1 \text{cm}^2$			
Maximum index value		0.35	0.85	-	-	-	-	
Associated acoustic parameters	P_{ra}	(MPa)	0.87					
	P	(mW)		24.0	-		-	
	min of $[Pa(Z_S), I_{\text{ta}, \alpha}(Z_S)]$		(mW)			-		
	Z_S	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_b	(cm)				-		
	Z at max $I_{\text{pi}, \alpha}$	(cm)	2.82					
	$d_{\text{eq}}(z_b)$	(cm)				-		
	f_{awf}	(MHz)	7.40	7.40	-	-	-	-
Dim of A_{aprt}	X	(cm)		0.88	-	-	-	
	Y	(cm)		0.80	-	-	-	
Other information	t_d	(μsec)	0.103					
	prr	(Hz)	4149					
	p_r at max I_{pi}	(MPa)	1.57					
	d_{eq} at max I_{pi}	(cm)				-		
	$I_{\text{pa}, \alpha}$ at max MI	(W/cm^2)	38.94					
Operating control conditions	Focus		1	1	-	-	-	
	Focus setting (mm)		30	30	-	-	-	
	Frequency (Hz)		7.5	7.5	-	-	-	

Test Mode: BM-MODE; Probe Type: 7.5L40E1

Index label		MI	TIS				TIB	TIC
			Scan	Non-scan		Non-scan		
				$A_{\text{aprt}} \leq 1 \text{cm}^2$	$A_{\text{aprt}} \geq 1 \text{cm}^2$			
Maximum index value		0.35	0.85	0.011	-	0.013	-	
Associated acoustic parameters	P_{ra}	(MPa)	0.87					
	P	(mW)		24.2	0.37		0.37	
	min of $[Pa(Z_S), I_{\text{ta}, \alpha}(Z_S)]$		(mW)			-		
	Z_S	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_b	(cm)				-		
	Z at max $I_{\text{pi}, \alpha}$	(cm)	2.82				2.82	
	$d_{\text{eq}}(z_b)$	(cm)					0.68	
	f_{awf}	(MHz)	7.40	7.40	7.40	-	7.40	-
Dim of A_{aprt}	X	(cm)		0.88	0.88	-	0.88	
	Y	(cm)		0.80	0.80	-	0.80	
Other information	t_d	(μsec)	0.103					
	prr	(Hz)	64					
	p_r at max I_{pi}	(MPa)	1.57					
	d_{eq} at max I_{pi}	(cm)					0.57	
	$I_{\text{pa}, \alpha}$ at max MI	(W/cm^2)	38.94					
Operating control conditions	Focus		1	1	1	-	1	
	Focus setting (mm)		30	30	30	-	30	
	Frequency (Hz)		7.5	7.5	7.5	-	7.5	

Test Mode: M-MODE; Probe Type: 7.5L40E1

Index label		MI	TIS			TIB	TIC	
			Scan	Non-scan		Non-scan		
				$A_{\text{aprt}} \leq 1\text{cm}^2$	$A_{\text{aprt}} \geq 1\text{cm}^2$			
Maximum index value		0.35	-	0.063	-	0.030	-	
Associated acoustic parameters	P_{ra}	(MPa)	0.87					
	P	(mW)		-	2.2		2.2	
	min of $[Pa(Z_S), I_{\text{ta}, \alpha}(Z_S)]$		(mW)			-		
	Z_S	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_b	(cm)					2.82	
	Z at max $I_{\text{pi}, \alpha}$		(cm)	2.82				
	$d_{\text{eq}}(z_b)$		(cm)					0.51
	f_{awf}		(MHz)	7.40	-	7.40	-	7.40
Dim of A_{aprt}	X	(cm)		-	0.88	-	0.88	
	Y	(cm)		-	0.80	-	0.80	
Other information	t_d		(μsec)	0.103				
	prf		(Hz)	520				
	p_r at max I_{pi}		(MPa)	1.57				
	d_{eq} at max I_{pi}		(cm)					0.48
	$I_{\text{pa}, \alpha}$ at max MI		(W/cm^2)	38.94				
Operating control conditions	Focus		1	-	1	-	1	
	Focus setting (mm)		30	-	30	-	30	
	Frequency (Hz)		7.5	-	7.5	-	7.5	

Test Mode: B-MODE; Probe Type: 5.0C20B1

Index label		MI	TIS			TIB	TIC	
			Scan	Non-scan		Non-scan		
				$A_{\text{aprt}} \leq 1\text{cm}^2$	$A_{\text{aprt}} \geq 1\text{cm}^2$			
Maximum index value		0.75	0.23	-	-	-	-	
Associated acoustic parameters	P_{ra}	(MPa)	1.48					
	P	(mW)		12.4		-	-	
	min of $[Pa(Z_S), I_{\text{ta}, \alpha}(Z_S)]$		(mW)				-	
	Z_S	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_b	(cm)					-	
	Z at max $I_{\text{pi}, \alpha}$		(cm)	2.61				
	$d_{\text{eq}}(z_b)$		(cm)					-
	f_{awf}		(MHz)	3.95	3.95	-	-	-
Dim of A_{aprt}	X	(cm)		0.62	-	-	-	
	Y	(cm)		0.73	-	-	-	
Other information	t_d		(μsec)	0.410				
	prf		(Hz)	4166				
	p_r at max I_{pi}		(MPa)	2.11				
	d_{eq} at max I_{pi}		(cm)					-
	$I_{\text{pa}, \alpha}$ at max MI		(W/cm^2)	119.37				
Operating control conditions	Focus		1	1	-	-	-	
	Focus setting (mm)		20	20	-	-	-	
	Frequency (Hz)		5.0	5.0	-	-	-	

Test Mode: BM-MODE; Probe Type: 5.0C20B1

Index label		MI	TIS			TIB	TIC	
			Scan	Non-scan		Non-scan		
				$A_{\text{aprt}} \leq 1 \text{cm}^2$	$A_{\text{aprt}} \geq 1 \text{cm}^2$			
Maximum index value		0.75	0.24	0.024	-	0.024	-	
Associated acoustic parameters	P_{ra}	(MPa)	1.48					
	P	(mW)		12.6	1.29		1.29	-
	min of $[Pa(Z_S), I_{\text{ta}, \alpha}(Z_S)]$	(mW)				-		
	Z_S	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_b	(cm)					2.48	
	Z at max $I_{\text{pi}, \alpha}$	(cm)	2.61					
	$d_{\text{eq}}(z_b)$	(cm)					0.47	
	f_{awf}	(MHz)	3.95	3.95	3.95	-	3.95	-
Dim of A_{aprt}	X	(cm)		0.62	0.62	-	0.62	-
	Y	(cm)		0.73	0.73	-	0.73	-
Other information	t_d	(μsec)	0.410					
	prr	(Hz)	64					
	p_r at max I_{pi}	(MPa)	2.11					
	d_{eq} at max I_{pi}	(cm)					0.47	
	$I_{\text{pa}, \alpha}$ at max MI	(W/cm^2)	119.37					
Operating control conditions	Focus		1	1	1	-	1	-
	Focus setting (mm)		20	20	20	-	20	-
	Frequency (Hz)		5.0	5.0	5.0	-	5.0	-

Test Mode: M-MODE; Probe Type: 5.0C20B1

Index label		MI	TIS			TIB	TIC	
			Scan	Non-scan		Non-scan		
				$A_{\text{aprt}} \leq 1 \text{cm}^2$	$A_{\text{aprt}} \geq 1 \text{cm}^2$			
Maximum index value		0.75	-	0.19	-	0.74	-	
Associated acoustic parameters	P_{ra}	(MPa)	1.48					
	P	(mW)		-	10.4		10.4	-
	min of $[Pa(Z_S), I_{\text{ta}, \alpha}(Z_S)]$	(mW)				-		
	Z_S	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_b	(cm)					2.48	
	Z at max $I_{\text{pi}, \alpha}$	(cm)	2.61					
	$d_{\text{eq}}(z_b)$	(cm)					0.15	
	f_{awf}	(MHz)	3.95	-	3.95	-	3.95	-
Dim of A_{aprt}	X	(cm)		-	0.62	-	0.62	-
	Y	(cm)		-	0.73	-	0.73	-
Other information	t_d	(μsec)	0.410					
	prr	(Hz)	520					
	p_r at max I_{pi}	(MPa)	2.11					
	d_{eq} at max I_{pi}	(cm)					0.15	
	$I_{\text{pa}, \alpha}$ at max MI	(W/cm^2)	119.37					
Operating control conditions	Focus		1	-	1	-	1	
	Focus setting (mm)		20	-	20	-	20	
	Frequency (Hz)		5.0	-	5.0	-	5.0	

Test Mode: B-MODE; Probe Type: 6.5C11E1

Index label		MI	TIS				TIB	TIC
			Scan	Non-scan		Non-scan		
				$A_{\text{aprt}} \leq 1 \text{cm}^2$	$A_{\text{aprt}} \geq 1 \text{cm}^2$			
Maximum index value		0.43	0.22	-	-	-	-	
Associated acoustic parameters	P_{ra}	(MPa)	0.91					
	P	(mW)		10.6	-		-	
	min of $[Pa(Z_S), I_{\text{ta}, \alpha}(Z_S)]$		(mW)			-		
	Z_S	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_b	(cm)				-		
	Z at max $I_{\text{pi}, \alpha}$	(cm)	1.09					
	$d_{\text{eq}}(z_b)$	(cm)				-		
	f_{awf}	(MHz)	4.48	4.48	-	-	-	-
Dim of A_{aprt}	X	(cm)		0.25	-	-	-	
	Y	(cm)		0.80	-	-	-	
Other information	t_d	(μsec)	0.412					
	prr	(Hz)	4166					
	p_r at max I_{pi}	(MPa)	1.10					
	d_{eq} at max I_{pi}	(cm)				-		
	$I_{\text{pa}, \alpha}$ at max MI	(W/cm^2)	40.54					
Operating control conditions	Focus		1	1	-	-	-	
	Focus setting (mm)		10	10	-	-	-	
	Frequency (Hz)		6.5	6.5	-	-	-	

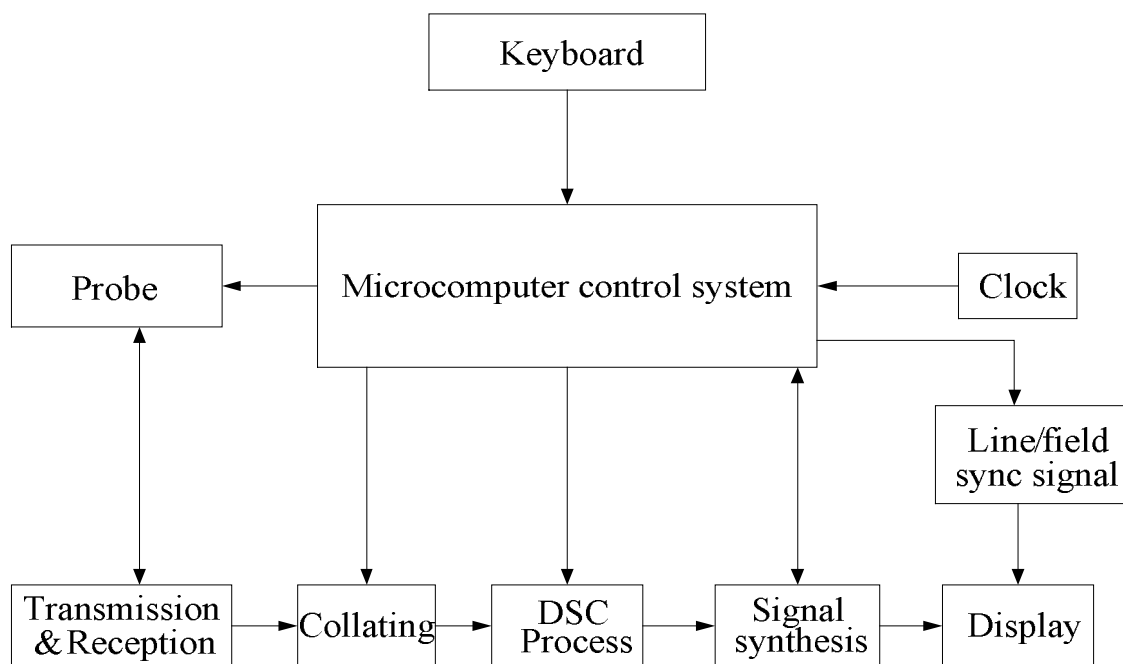
Test Mode: BM-MODE; Probe Type: 6.5C11E1

Index label		MI	TIS				TIB	TIC
			Scan	Non-scan		Non-scan		
				$A_{\text{aprt}} \leq 1 \text{cm}^2$	$A_{\text{aprt}} \geq 1 \text{cm}^2$			
Maximum index value		0.43	0.26	0.028	-	0.021	-	
Associated acoustic parameters	P_{ra}	(MPa)	0.91					
	P	(mW)		12.2	1.32		1.32	
	min of $[Pa(Z_S), I_{\text{ta}, \alpha}(Z_S)]$		(mW)				-	
	Z_S	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_b	(cm)					0.97	
	Z at max $I_{\text{pi}, \alpha}$	(cm)	1.09					
	$d_{\text{eq}}(z_b)$	(cm)					1.03	
	f_{awf}	(MHz)	4.48	4.48	4.48	-	4.48	-
Dim of A_{aprt}	X	(cm)		0.25	0.25	-	0.25	
	Y	(cm)		0.80	0.80	-	0.80	
Other information	t_d	(μsec)	0.412					
	prr	(Hz)	64					
	p_r at max I_{pi}	(MPa)	1.10					
	d_{eq} at max I_{pi}	(cm)					1.02	
	$I_{\text{pa}, \alpha}$ at max MI	(W/cm^2)	40.54					
Operating control conditions	Focus		1	1	1	-	1	
	Focus setting (mm)		10	10	10	-	10	
	Frequency (Hz)		6.5	6.5	6.5	-	6.5	

Test Mode: M-MODE; Probe Type: 6.5C11E1

Index label		MI	TIS			TIB	TIC	
			Scan	Non-scan		Non-scan		
				$A_{aprt} \leq 1 \text{cm}^2$	$A_{aprt} \geq 1 \text{cm}^2$			
Maximum index value		0.43	-	0.034	-	0.086	-	
Associated acoustic parameters	P_{ra}	(MPa)	0.91					
	P	(mW)		-	1.61		1.61	
	min of $[Pa(Z_S), I_{ta, \alpha}(Z_S)]$		(mW)			-		
	Z_S	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_b	(cm)					0.97	
	Z at max $I_{pi, \alpha}$		(cm)	1.09				
	$d_{eq}(z_b)$		(cm)					0.40
	f_{awf}		(MHz)	4.48	-	4.48	-	4.48
Dim of A_{aprt}	X	(cm)		-	0.25	-	0.25	
	Y	(cm)		-	0.80	-	0.89	
Other information	t_d		(μsec)	0.412				
	prf		(Hz)	520				
	p_r at max I_{pi}		(MPa)	1.10				
	d_{eq} at max I_{pi}		(cm)					0.39
	$I_{pa, \alpha}$ at max MI		(W/cm^2)	40.54				
Operating control conditions	Focus		1	-	1	-	1	
	Focus setting (mm)		10	-	10	-	10	
	Frequency (Hz)		6.5	-	6.5	-	6.5	

Appendix B: System Block Diagram



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