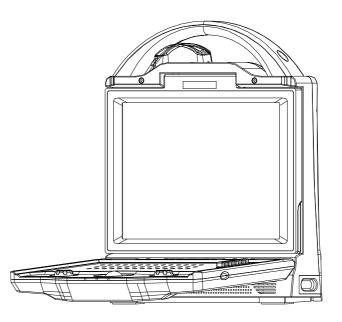




Full Digital Ultrasonic Diagnostic Instruments (Vet)

# **User's Manual**





#### Introduction

Thank you for purchasing KX5600 full digital ultrasonic diagnostic instruments.

Users shall carefully read through this manual and fully understand the text before operating the equipment.

Please keep this manual after reading so that you can access at any time when needed.

The user's manual issue date: June 15, 2014, Version: V1.00

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

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- 2. All replacement parts and accessories, consumables involved repairs are Kaixin company (original) or approved by Kaixin;
- 3. Related electrical equipment complies with national standards and the requirements of the user's manual;
- 4. Operate the product in accordance with the user's manual.

#### Warranty and repair service

Purchased the product warranty, sees the company's service policies.

# **Manufacturer's Information**

Xuzhou Kaixin Electronic Instrument Co., Ltd. Kaixin Mansion, C-01, Economic Development Zone, Xuzhou, Jiangsu, China. Post Code: 221004 Tel: +86-516-87732932 87733758 Fax: +86-516-87732932 87792848 Website: http://www.kxele.com E-mail: gm01@kxele.com

### **Important Statement**

- 1. User shall be fully responsible for the maintenance and management of this product after purchasing this product.
- 2. Even in the warranty period, warranty does not include the following:
  - a) Damage or loss caused by error or rough using.
  - b) Damage or loss caused by force majeure (such as fires, earthquakes, floods, or lightning etc.).
  - c) Damage or loss caused by not meeting the conditions of use specified by the system, such as inadequate power supply, incorrect installation or environmental conditions do not meeting the requirements.
  - d) Damage or loss caused by not used the system in the initial buy region.
  - e) Damage or loss caused by the system purchased not by Kaixin or its authorized dealer or agents.
- 3. Medical personnel qualified with professional qualifications only to use this system.
- 4. Do not modify the software or hardware of the equipment without authorization of the manufacturer.
- 5. In any case, Kaixin shall not be liable for the problems, damages or losses due to re-installation, alteration or repair the system by non-Kaixin designated personnel.
- This product is intended to provide clinical diagnostic data for the doctor. The doctor shall be responsible for the diagnostic process. Kaixin shall not be liable for any problems arising out of the process.
- 7. Be sure to back up important data to external storage media, such as notebooks.
- 8. Due to operator's error or abnormal condition causing the data stored in the internal system is lost, Kaixin is not responsible.
- 9. 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.
- 10. This user's manual shall be furnished with the machine so that managerial and operating 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.
- 11. Deal with the exhausted product according to the local statute.
- 12. The maintenance and servicing of product shall be performed by the trained engineer or by Kaixin Electronic Instrument Company Ltd.

# **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.		
Awarning	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.		

# 2. Safety Symbols

Symbols	Meaning	Symbols	Meaning
<b>†</b>	Type B applied part		Up
Ċ	Power switch		Keep dry
☆	Power supply indication		Fragile
Ą	Adapter connection indication	ſ M ∎ ⊥	Stacking limit by number
Ē	Battery charge indicator	30%	Humidity limitation
A	Dangerous voltage	TOKPa	Atmospheric pressure limitation
	Follow instructions for use		Temperature limits
X	Marking for the separate collection of electrical and electronic equipment		

# 3. Labels

Label	Description
MIXED USE WITH FLAMMABLE GAS WILL LEAD TO DANGEROUS EXPLOSION. NOTICE BEFORE USING THE PROBE CAREFULLY USE THE PROBE, BECAUSE IT IS EXTREMELY SENSITIVE TO SHAKE.	<ul> <li>Danger:</li> <li>1. It may have explosion hazard if used with flammable gas.</li> <li>2. Operate the probe with care. Read the probe information in</li> </ul>
PLEASE DO REFER TO THE USER'S GUIDE TO USE AND CLEAN THE PROBE STRICTLY.	the relevant manual for proper probe use.

▲ ATTENTION NO OBJECT AND NO OUTSIDE FORCE CAN BE PUT ON THE DEVICE. CLOSE THE KEYBOARD WHEN MOVE IT.	Attention:Do not place object on the machine.Do not apply external force on themachine. Close the keyboard beforemoving the machine.
ATTENTION ANY NICK OR PRESS TOWARDS THE LCD WILL LEAD TO THE DAMAGE OF THE LCD.	Attention: It is prohibited to scratch or squeeze the LCD.
WARNING The device should be used only with external AC/DC adapter provided by manufacturer,Use of other AC/DC adapter may cause damaged to the device or cause fire and electric shock hazards.	Warning: The device should be used only with external AC/DC adapter provided by manufacturer. Use of other AC/DC adapter may cause damaged to the device or cause fire and electric shock hazards.



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.

# Contents

Chapter One	Technical Specifications	1
Chapter Two	System Outline	2
2.1 System	structure components	2
2.2 Compon	ients name	2
2.3 Parts of	the probe	2
	nel instruction	
	n keys instruction	
	System Configuration	
-	Operation Condition	
	System Installation and Check	
	placement	
	racket installation	
	nic probe installation	
	Remove the battery	
	foot switch	
	tion to video recorder	
	ion to power	
	nic probe check before and after operation	
	nit check before and after operation	
	reset	
	Preset	
1	preset	
<i>v</i> 1	al	
	la preset	
	ettng	
	e	
	Functional Operation	
	Functional Operation	
1		
	rd light basic information	
	election	
	election	
	node	
	de	
	node	
	de	
	uality adjustment and image control	
	e brightness adjustment	
	adjustment	
	gain adjustment	
	nic range adjustment	
	ency adjustment (Frequency conversion)	
	e correlation adjustment	
_	enhancement adjustment	
	ression curve adjustment	
	post-process adjustment	
7.6.10 Imag	ge optimization	16
7.6.11 Dept	h range selection	16

<b>U</b>	b/down reverse	
7.6.13 Image le	ft/right reverse	16
7.6.14 Angle/W	fidth change	16
7.6.15 Color se	lection	16
7.6.16 Image fr	eeze/unfreeze	16
_	uide	
7.8 Lithotripsy	positioning line	17
	· · · · · · · · · · · · · · · · · · ·	
	orage	
	and Measurement	
	L	
	unction	
	mage management	
	image management	
	agement interface	
	e folder and file	
	int and Transfer files	
	print	
	.t	
	MP files	
	General Measurement	
	measurement	
	ence/area measurement	
	easurement	
	surement	
10.5 Histogram	measurementasurement	24
	surement	
	tio measurement	
-	B Obstetric Measurement	
	ent and Calculation items	
11.2 Obstetric-l		27
	canine, equine, feline, goat, llama, ovine, and swine	
	ent of Swine's lean percentage	
1	M General Measurement	
	surement	
-	surement	
	measurement	
	surement	
Chapter Thirteen	System Maintenance	
	ce by users	
	cleaning and disinfection	
1	ne fuse	
	naintenance for the rechargeable battery	
	ooting	
	afety checks	
	ock diagram	
Chapter Fourteen	Storage and Transportation	
Chapter Fifteen	Safety Classification	37

# **Chapter One** Technical Specifications

#### **1.1 Technical Parameter**

- 1. Gray scale: 256
- 2. Monitor: 10.4" LCD
- 3. Adapter rating: 100-240V~, 1.2-0.6A, 50-60Hz
- 4. Output of Adapter: DC12.8V 3.0A
- 5. Main device rating: DC12V 3.0A
- 6. Main Unit Size: approx. 256 \* 150 \* 326 (L \* M \* H, mm)
- 7. Weight of main unit: approx. 4.5 kg (excluding accessories)

#### **1.2 Primary Functions**

- 1. Mode conversion function;
- 2. M speed conversion function;
- 3. Depth range selection function;
- 4. Probe switching function;
- 5. Compression curve function;
- 6. Frequency conversion function;
- 7. Frame correlation function;
- 8. Edge enhancement function;
- 9. Image post-process function;
- 10. Image optimization function;
- 11. Image freeze/unfreeze;
- 12. Many segments adjustable TGC, adjustment of total gain and dynamic range;
- 13. Image storage function;
- 14. Image management function;
- 15. Image up/down and left/right reversal;
- 16. Angle/width change function;
- 17. Auto time display, case information and image annotation;
- 18. Body marks function;
- 19. B general measurement of distance, depth, circumference/area, volume, angle, histogram, profile, stenosis ratio;
- 20. OB software package includes 25 obstetric tables about 8 kinds of animals and it can automatically calculate GA and EDC;
- 21. M general measurement of depth, slope, heart rate and time;
- 22. System preset function;
- 23. Transfer image to Network Printer by one-key;
- 24. Network print function;
- 25. LCD brightness adjustment function;
- 26. PAL-NTSC conversion;
- 27. Puncture guide function;
- 28. Lithotripsy positioning line function;
- 29. Cine playback function;
- 30. Energy-saving function;
- 31. Chinese-English switch function;
- 32. Have various reports.

# Chapter Two System Outline

# 2.1 System structure components

KX5600 full digital ultrasonic diagnostic instruments (Vet) are composed of main unit, probe etc.

#### 2.2 Components name

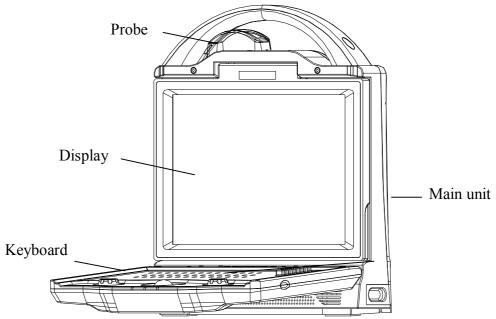
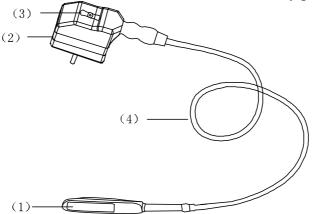


Fig. KX5600 Main unit sketch map

# 2.3 Parts of the probe (Take 6.5MHz animal transrectal linear array probe for example)



Name	Function		
(1) Acoustic lens To convert electric signal to ultrasonic signal based on principle of converse piezoelectric effect. The ultrasonic signal, after entering thuman body, is reflected as echo wave and converted to electric signal. The acoustic lens is on the probe surface. Supply ultrasonic coupling gel to the acoustic lens surface when performing ultrasonic diagnosis.			
(2) Probe connector	To connect the probe to ultrasonic diagnostic system		
(3) Lock/loosen knob	To lock/loosen the connection of probe to ultrasonic diagnostic system		
(4) Cable	To connect the probe to the probe connector		

Fig. Nan	ne of 6.5MH	z animal	transrectal	linear	array	probe	parts

# 2.4 Rear panel instruction

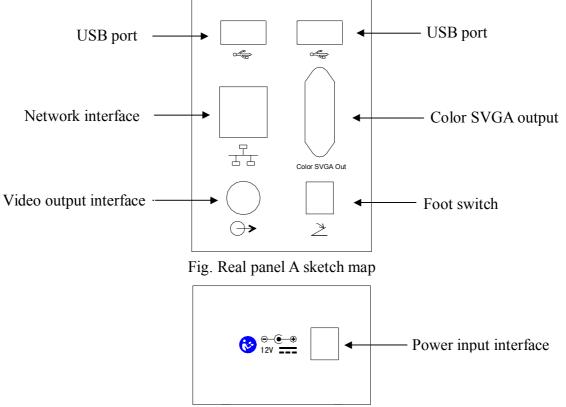


Fig. Real panel B sketch map

# 2.5 Function keys instruction

2.5 F	unction keys in		
SN	Key symbol	Key name	Key function
1	Esc	Exit	Exit dialog, menu or measurement;
2	( Setup)	Preset	Enter/exit system preset interface;
3	F1 F2	User-defined keys (reserved)	
4	Guide	Puncture guide	Display or switch the puncture guide line;
5	Power	Acoustic power (to be upgraded)	In real-time scanning mode, press the key to adjust the acoustic power parameters of system;
6	IP	Image post-process	Press key to adjust the image post-process;
8	€ Save	Store	In frozen status, the current display image or report is saved to C disk or U disk;
9	E IME	Change language	Switching Russian and English;
10	iStation	One-key transfer image	Press the key to transfer images to the software MetworkPrinter.exe, the specific use of Network Printer sees its instructions for use;
11	<b>₩ ₩</b>	LCD setting	Adjust the brightness of LCD;
12	Back	Backspace	Delete the character before the cursor while the cursor move left;

13	ration	New patient	•Access to new patient module; •Input the information and data for new patient;
14	Arrow	Arrow	<ul> <li>In annotation status, press the key to enter the function of arrow mark;</li> <li>Now, through rotate [Gain] or [Function] knob to adjust the direction of arrow mark.</li> </ul>
15	CAPS	Case conversion	Switch the input between capital letters and small letters;
16	Shift	Shift	Shift key with the standard keyboard;
17	Enter	Enter	Accept the input data;
18	Space	Space	Input space character;
19	Clear	Clear	Press the key to clear annotations, arrow marks, body mark, measurement markers and measured results on the image;
20	Omit	Numbers, letters, symbols	<ul> <li>Main characters: characters on the keyboard, next-row letters/numbers/symbols of the multiplex keys;</li> <li>Superscript characters: up-row letters and symbols of the multiplex keys.</li> </ul>
21		Direction keys	<ul> <li>Adjust the start-end positon and angle of punction guide lines;</li> <li>Direction keys can be used to change the position of cursor.</li> </ul>
22		B mode	Press key to enter B mode;
23		B/B mode	Press key to enter B/B mode;
24		4B mode	Press key to enter 4B mode;
25		M mode	Press the key to enter B/M mode; press again to enter M mode;
26	Probe	Switch probe	Switch the probe model;
27	ABC Comment	Text input	In frozen status, enter/exit text input status;
28	Body mark	Body marks	Press the key to enter body mark module;
29		Print	Press the key to print the image or report;
30	Freq	Frequency	Press the key to adjust the conversion frequency;
31	đ	Frame average	In real time mode, press the key to adjust the frame average;
32	¢ isave	Store	In frozen status, the current display image or report is saved to C disk or U disk;
35	िन्म् Review	Image management	·In frozen status, enter the image management module; ·Review the saved patient images;
36	Cine <sup>1</sup>	Cine playback	In frozen status, press the key to enter the cine playback status;
37	Megane Inmini	Measurement and calculation	•Press the key to enter/exit the measurement menu; •In the measurement, press key to exchange starting point and end point;

38	OB	Obstetric	Press the key to enter/exit obstetric measurement menu;
39	( Set	Set	<ul><li>Press key to perform the confirm function;</li><li>Press the key to increase the values of parameters;</li></ul>
40	Back	Back	Press the key to decrease the values of parameters;
41		Freeze	Press the key to freeze or unfreeze the image;
42	[TGC]	TGC	Through the segments to adjust the gain at different depths;
43	Gain	Gain	Rotate 【Gain】 knob to adjust the image's gain;
44	Function	Depth range selection	In real time status, press key to select depth range; In real time status, press number key 0-9, can fast select the corresponding depth range.
45	0	Power switch	Open/close the main unit;
46		Keyboard light	Open/close the keyboard light.

#### **Chapter Three System Configuration**

#### **3.1** Typical configuration

- 1. Main unit
- 3. Power adapter

# **3.2 Optional parts**

- 1. 3.5 MHz convex array probe
- 3. 4.0 MHz convex array transrectal probe
- 5. 7.5 MHz high frequency linear array probe

1 unit

1 PC

- 7. Foot switch
- 9. Charger

2. 6.5MHz animal transrectal linear array probe 1 PC

- 2. 3.5 MHz linear array loin probe
- 4. 6.5 MHz micro-convex probe
- 6. Video recorder
- 8. Internal battery

#### **Chapter Four Operation Condition**

# 4.1 Power supply

Adapter rating: 100-240V~, 1.2-0.6A, 50-60Hz Adapter model: BJE01-40-001M Output of Adapter: DC12.8V 3.0A Main device rating: DC12V 3.0A

# **4.2 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 Pollution degree: 2

# 4.3 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. Moist		
3. Rain	4. Thunderstorm weather		
5. No ventilation	6.Close to heat source		
7. Direct sunlight	8. Dramatic temperature change		
9. Poisonous gas	10. Corrosive gas		
11. Strong shock	12. Strong electromagnetic field (e.g. MRI)		
13. Radiation (e.g. X-ray, CT)	14. Defibrillators or short wave therapy equipment		

# **Chapter Five** 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.

# **AWarning**:

- 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 with this ultrasonic system.
- 2. All plugs of instruments of this system shall be connected into the power socket with protective 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 has some unknown defects, it may cause danger of electric shock.
- 5. If the integrity of the external protective conductor in the installation or its arrangement is in doubt, equipment shall be operated from its internal electrical power source.

# **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. Turn off power and pull out of the plug from socket after each ultrasonic diagnostic operation.
- 3. 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 and change it for new one.
- 4. It is forbidden to load and unload the probe or move the instrument in galvanic to avoid danger of safety.
- 5. Pull out of the plug from socket after operation in thunderstorm weather to avoid the instrument being damaged by lightening.
- 6. If the temperature changes greatly in short time will cause vapor recovery inside of instrument, the case may damage the instrument.
- 7. The instrument is turned off completely only by disconnecting the power supply from the wall socket.

A Warning: The power adapter, probes, foot switch, battery as described in this section may be replaced by operator. To replace according to the method of this section, does not result in an unacceptable risk.

# 5.1 System placement

Please carefully read through and fully understand the safety cautions before moving and placing the system.

- 1. Unpack the instrument case and check the goods for its completeness according to the packing list.
- 2. Place the instrument on a stable and leveled position.
- 3. Leave adequate space of 20 centimeters as minimum from rear, left and right side of the instrument.

Attention: Adequate space from rear, left and right side of the machine shall be reserved, or the machine may malfunction under excessive heat inside the enclosure.

#### 5.2 Probe bracket installation

The probe bracket should be mounted behind the main unit.

5.3 Ultrasonic probe installation

# **Warning**:

- 1. The Kaixin ultrasonic probe shall be connected to the dedicated Kaixin ultrasonic system only. Select proper probe 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 may cause patient subjected to electric shock.
- 4. Unauthorized disassembly of the probe shall be prohibited as it may cause electric shock.

# **Attention**:

- 1. Turn off the ultrasonic system before disconnecting the ultrasonic probe. Disconnecting the probe with system power on may damage the system or probe.
- 2. Before disconnecting the ultrasonic probe, place the probe on the probe bracket 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.

#### **5.3.1 Ultrasonic 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.

- 1. Open the probe locking knob with the cable to right; insert the probe connector into the probe socket on the right-hand of the main unit until the metal spring plates is evenly contacted. Tightly press the connector.
- 2. Rotate the probe locking knob 90 degree clockwise and lock it.
- 3. Check if the probe connector is locked. After turning off the system, plug the probe connector in the probe socket then rotate the locking knob clockwise to lock it.

# 5.3.2 Ultrasonic probe disconnection

Shutdown the system; rotate the locking knob 90 degree counterclockwise, pull out the probe connector vertically.

# **5.4 Install/Remove the battery**

# 1. Install the battery

Shutdown the system; remove the battery cover on the right side of main unit. According to the direction of battery indication to install the battery and then install the battery cover.

# 2. Remove the battery

Shutdown the system; remove the battery cover on the right side of main unit, push forward the battery putter at the bottom of main unit and the battery is launched, remove the battery.

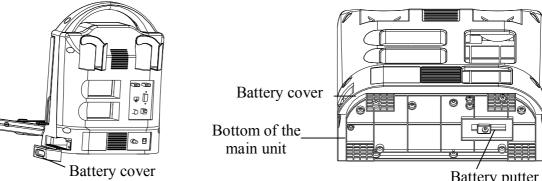


Fig. Install, Remove the battery

# Battery putter

# **5.5 Install foot switch**

Shutdown the system; insert the plug of foot-switch into the " $\geq$ " socket at the back of the main unit.

# Attention: The waterproof grade of foot switch is IPX1.

# 5.6 Connection to video recorder

- 1. Shutdown the system; connect the equipotential terminal ( $\stackrel{\downarrow}{\bigtriangledown}$ ) of the video recorder to the earthing;
- 2. Connect one end of the video cable to the video recorder and the other end to the video output interface on the rear panel of the main unit;
- 3. Insert one end of power plug (jack) of the video recorder to its power input socket, the other end to the power supply socket.

# 5.7 Connection to power

# **1.** Connect to the power adapter

Insert the output plug of adapter into DC power input port, which is on the right 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. The instrument uses three-core power supply. It connects with the protective earth line when power plug inserts into its socket.

# **Warning**:

- 1. Adapter has no switch. The isolation of the system with the MAINS used to unplug the adapter as the intended isolation means.
- 2. The equipment should be used only with adapter provided by Kaixin Company.
- 3. To avoid damaging power adapter or harming people by unexpected fallen, make sure the power adapter is placed on the leveled desk.
- 4. The operator must not touch signal input/ signal output and patient simultaneously.

# 5.8 Ultrasonic 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, cleaned or disinfected.

# 5.9 Main unit check before and after operation

# 5.9.1 Inspection before start-up

Check the following items before starting the machine:

- 1. The temperature, humidity and atmospheric pressure shall meet the requirement of operation conditions.
- 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. Check the control panel, LCD screen and enclosure to ensure they are in good working condition and free of abnormity (such as cracks and loosened screws).
- 5. No damage on cable (such as power cable), and hard up on its connection.
- 6. Check probe and its cable to ensure they are free of abnormity (such as scuffing, drop-off or contamination). If the contaminant is present, clean the contaminated objects as specified in relevant sections.
- 7. See to it that there are no foreign objects on the control panel (Remove the object if any).
- 8. No barriers around the intake of equipment.
- 9. See to it that whether probe has been cleaned, disinfected; else dispose it as specified in relevant sections.
- 10. Check all the ports of the machine for possible damage or blockage.
- 11. Clean the field and environment.

# 5.9.2 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; startup picture is shown on the screen, and then the machine will automatically enter 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 too high local temperature will not appear.

# 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.

#### 5.10 System reset

In case of abnormal screen display or not work for system operation, try to restart the system by turning on/off the power.

# Chapter Six Preset

#### 6.1 System preset

 $\operatorname{Press}^{(\overset{\circ}{\operatorname{Setup}})}$  key on the keyboard, "System Preset" menu will be displayed on the screen.

System Preset	
Normal	
Formula	
Network	
Password	
About	

Fig. System preset menu

#### 6.1.1 Normal

Move the cursor to the "Normal", press [Set] key, the cursor is in the input box of hospital name.

#### • Hospital Name setting

Press "Number/Character" keys to enter hospital name; if need to revise, press Device direction keys or

operate trackball and press Set key, move the cursor to the back of revised position, press key to delete the previous character and retype.

#### • Key Sound setting

Move the cursor to the "Key Sound" selection box, press  $\llbracket$  Set  $\rrbracket$  key, " $\checkmark$ " will be shown in the selection box, key sound is open.

#### • Character Brightness setting

Move the cursor to the "Char Bright" drop-down box, press  $\llbracket$  Set  $\rrbracket$  key to select the desired brightness.

#### • Waiting Time setting

1. Move the cursor to the "Waiting Time" input box, press [Set] key to confirm the cursor position;

2. Input the screensaver time, number (0-100), screensaver time in minute.

Note: Go beyond the system setting energy-saving time without pressing any key, the system will automatically enter the energy saving status. Press any key, system will return to normal operation status.

#### • Time, Date and the Format of date

- 1. Move the cursor to the "Time Set" input box and press Set key to confirm the cursor position then input "hour, minute, second";
- 2. Move the cursor to the "Date Set" input box and press [Set] key to confirm the cursor position then input "year, month, day";
- 3. Move the cursor to drop-down box of the "Date Format" and choose the right format.

#### • Language setting

Move the cursor to the dot of "Chinese" or "English", press [Set] key to confirm.

• Video Format selection

Move the cursor to the dot of "PAL" or "NTSC", press [Set] key to confirm.

#### • CPU Temperature

Move the cursor to the "CPU Temp" drop-down box, press [Set] key to to select the desired CPU shutdown temperature of main unit.

After presetting the system parameters "Hospital", "Key Sound", "Char Bright", "Waiting Time",

"Time set", "Date Set", "Date Format", "Language", "Video Format" and "CPU Temperture", move the cursor to  $\lceil OK \rfloor$  then press  $\llbracket Set \rrbracket$  key, the system will preserve the data of preset and exit the dialog box; If choose  $\lceil Cancel \rfloor$ , press  $\llbracket Set \rrbracket$  key, the system will give up the data of preset and exit the dialog box. You also can press  $\llbracket Set \rrbracket$  to give up and exit the preset.

# 6.1.2 Formula preset

Move the cursor to the "Formula", press [Set] key to show the "Formula" dialog box.

Move the cursor to the setting position of gestational week for the bovine, canine, equine, feline, goat, llama, ovine and swine, press "Default"; then choose goat species or obstetric table for canine, move the cursor to  $\lceil OK \rfloor$  after finishing the preset and press  $\llbracket Set \rrbracket$  key, the system will preserve those data of preset and exit the dialog box; If you choose  $\lceil Cancel \rfloor$  and press  $\llbracket Set \rrbracket$  key, the system will give up those data of preset and exit the dialog box. You also can press  $\llbracket Esc \rfloor$  key to give up and exit the preset.

# Warning: After software upgraded, start the machine and must first click "Default" in the "Formula" to restore the default values; otherwise obstetric table may occur calculation error.

# 6.1.3 Net Setting

1. Move the cursor to the [Net Setting], press [Set] key to show the "Net Setting" dialog box, the setting is as shown below:

- Use the following IP address Set the IP address of full digital ultrasonic diagnostic instrument: IP address: IP address of KX5600 instrument;
- LAN Server Set Set LAN server's network properties: IP address: IP address of LAN server (that is IP address of PC installing print program); TCP Port: the default is 8866.
- 2. Finish the settings of LAN server and properly connected to the LAN;
- 3. Run the **WetworkPrinter**. exe on the PC;
- 4. Press [OK] in the Net Setting interface, press [Set] key, the screen pops up warning information "Shut down and power on in 1 min", after the instrument reboots, the lower right corner of the screen will appear icon **D**, it indicates that the network connection is successful; If the network is not connected successfully, please check the IP address and TCP port, as well as the network cable is properly connected.
- 5. Choose [Cancel] press [Set] key or directly press key to exit the net preset.

Net Setting	
Use the following IP	address:
IP address:	92 - 168 - 000 - 251
LAN Server Set:	
IP address:	192 - 168 - 000 - 181
TCP Port:	8866
OK	Cancel

#### 6.1.4 Password preset

Move the cursor to the "Password", press [Set] key to display the "Password" dialog box.

#### • Password setting

- 1. Move the cursor to the "Demo Date" column, press [Set] key to confirm the cursor position, enter the trial "Day" number;
- 2. Move the cursor to the "Enter Password" column, press Set key to confirm the cursor position, enter the password;
- 3. Again move the cursor to the "Confirm Password" column, press [Set] key to confirm the cursor position, re-enter the password;
- 4. Move the cursor to select [PassWord Set] in the dialog box, press [Set] key to pop up "Password successfully set!" prompt box;

5. Move the cursor to select  $\lceil OK \rfloor$ , press  $\llbracket Set \rrbracket$  key to exit the password preset interface. **Explanation:** 

- 1. Trial days setting range: 1 to 999 days.
- 2. Password setting range: Password is composed of numbers and its length is up to 6-bit.
- 3. When the trial days are up to the setting date, the system will automatically freeze and stop working, the freeze icon will flash.
- Cancel the password setting
- 1. Enter the system preset interface;
- 2. Move the cursor to the "Password", press [Set] key. Display the "Password" dialog box;
- 3. In the "Enter Password" box, enter the password has been set;
- 4. Move the cursor to the [Password Remove], press [Set] key, the system pops up prompt box "Password is canceled";
- 5. Move the cursor to the  $\lceil OK \rfloor$ , press  $\llbracket Set \rrbracket$  key to exit the password preset interface.

# Warning: Business personnel or service personnel setting the password, be sure to remember the set password, make notes! If you forget password, consult Kaixin Company.

#### **Functional Operation** Chapter Seven

## 7.1 Startup and Shutdown

Press the button () on the bottom of screen, turn on the machine. If you want to turn off the machine, please press the button  $\bigcirc$  again, then pull out mains plug from the supply mains.

# 7.2 Keyboard light

Press the button (a) on the bottom of screen, open the keyboard light. If you want to close the light, press the button again.

# 7.3 Patient basic information

- 1. Press key, "Patient Data Input" dialog box will be showed;
- 2. Move the cursor to "Name", "Age" and "ID", press [Set] key, input the data individually;
- 3. Choose the sex;
- 4. Move the cursor to [OK] of the dialog box after inputting, press [Set] key to confirm saving and exit:
- 5. Press [Cancel] of the dialog box it will give up inputting information and exiting the dialog box.

# 7.4 Probe selection

Press key to realize the interchange of probe. The probe model is shown in the upper right of the image area.

# 7.5 Mode selection

# 7.5.1 B mode

B mode is a basic operation mode. On starting the machine or press  $(\bigcirc_{\mathbb{B}})$  key, a single-framed image in B mode is displayed. Press freeze key to freeze or unfreeze the current image. In real-time mode, press  $\bigcirc$  or  $\bigcirc$  wey to exit B mode.

# 7.5.2 B/B mode

- 1. Press key to enter B/B mode;
- 2. Switch the B/B image. In real-time mode, press key to switch the display for left image or right image. The switched image is activated and the other image is frozen;
- 3. Press freeze key to freeze or unfreeze the current image;
- 4. In real-time mode,  $\operatorname{press}^{(\square)}$  or  $\operatorname{he}^{(\square)}$  key to exit B/B mode.

# 7.5.3 4B mode

Press (4) key to enter 4B mode and display the first real-time image, press (4) key again to display the second real-time image while the first image is frozen. There are all together 4 images to be displayed in sequence by pressing the 4B mode key, one image being activated and the other three images frozen. Press this key repeatedly to switch images between "frozen" and "real-time".

In real-time mode, press  $\bigcirc$  or  $\bigcirc$  bor  $\bigcirc$  key to exit 4B mode.

# 7.5.4 B/M mode

- 1. Press key to enter B/M mode;
- 2. In real-time mode, press () keys to move sample line;
- 3. Press freeze key to freeze or unfreeze the current image;
- 4. In real-time B/M mode, press  $\bigcirc$  or  $\bigcirc$  or  $\bigcirc$  bor  $\bigcirc$  bor  $\bigcirc$  key to exit B/M mode.

# 7.5.5 M mode

1. Press key to enter B/M mode, press key again to enter M mode;

- 2. Press freeze key to freeze or unfreeze the current image;
- 3. In real-time M mode, press  $\bigcirc$  or  $\bigcirc$  or  $\bigcirc$  where to exit M mode.

#### 7.6 Image quality adjustment and image control

#### 7.6.1 Image brightness adjustment

Proper brightness of the LCD is essential for a quality image. The brightness adjustment should be done in relation to the ambient brightness. Therefore the actual brightness shall be adjusted according to the specific environmental condition.

Method of operation:

1. Press keys *\**, the "LCD Settings" adjustment box appear on the screen;

- 2. Press direction keys ( to change the brightness of LCD;
- 3. Finish the settings, press  $\underbrace{\overrightarrow{Esc}}$  key to exit the "LCD Settings" adjustment box.
- Tip: In general, the brightness adjustment is performed according to the gray scale. It should be adjusted in such that the background appears dark while all the gray scale strips can be seen.

#### 7.6.2 TGC adjustment

In real-time mode, move TGC adjustment key to realize the image control.

#### 7.6.3 Total gain adjustment

Clockwise rotate [Gain] knob on the panel to increase the total gain value, and counterclockwise to decrease the value. Adjust the total gain knob can control the total gain of the image until the image quality is satisfied. The total gain value is shown on "GN" position on the right of the image area.

# Note: If the total gain is adjusted to the biggest but still can't be satisfied, you can adjust TGC to compensate when connect to the high frequency probe.

#### 7.6.4 Dynamic range adjustment

- 1. In real- time mode, move the cursor to the submenu [Dynamic] of [B Mode Menu];
- 2. Press [Set] or [Back] key to realize the change of dynamic range. The dynamic range value is shown on "Dyn" position on the right of the image area.

# 7.6.5 Frequency adjustment (Frequency conversion)

In real-time mode, press  $(F_{Free})$  key to change the frequency. The frequency value is displayed on the "Freq" position on the right of the image area.

#### 7.6.6 Frame correlation adjustment

# A. Shortcut key adjust the frame correlation

In real-time mode, press key to realize four levels of the frame correlation. The frame correlation is displayed in the [Frame Avg] of the left menu.

#### **B.** Adjust the frame correlation by the menu

- 1. In real-time mode, move the cursor to the submenu [Frame Avg] of [B Mode Menu];
- 2. Press [Set] or [Back] key to realize four levels of the frame correlation. Four kinds of frame correlation are 0, 1, 2, 3 and displayed in the [Frame Avg] of left menu.

#### 7.6.7 Edge enhancement adjustment

- 1. In real-time mode, move the cursor to the submenu [Edge] of [B Mode Menu];
- 2. Press Set or Back key to realize image sharpening. A sharpened picture can better highlight the organ outline for convenient observation. Four kinds of edge enhancement are 0, 1, 2, 3 and displayed in the Edge of left menu.

#### 7.6. 8 Compression curve adjustment

1. In real-time or frozen mode, move the cursor to the submenu [Comp Curve] of [B] Mode

Menu];

- 2. Press [Set] or Back key to realize compression curve processing. The compression curve falls into eight levels, which are 0-7 and displayed in the Comp Curve of the left menu.
- Note: If use 3.5 MHz probe, it is recommended to choose 5 or 6; if use 5.0 MHz probe, recommend choose 3 or 4; if use 6.5 MHz probe, recommend choose 1 or 2; if use 7.5 MHz probe, recommend choose 0 or 1.

# 7.6.9 Image post-process adjustment

- 1. In real-time or frozen mode, move the cursor to the submenu [IP] of [B Mode Menu];
- 2. Press [Set] or [Back] key to realize image post-process. Image post-process falls into four levels, which are 0-3 and displayed in the [IP] of the left menu. NO.2 is recommended when normal use.

# 7.6.10 Image optimization

- 1. In real-time mode, move the cursor to the submenu [[iImage]] of [B Mode Menu];
- 2. Press Set or Back key to realize 10 kinds of image optimization processing. Image optimization falls into 0-9 and displayed in the [iImage] of the left menu. The default value is 4.

# 7.6.11 Depth range selection

In real-time mode, rotate [Function] knob on the panel to get images in different depth, B, B/B, 4B mode has 10 kinds of depth range; B/M, M mode has 6 kinds of depth range. Users also can fast select depth range with 0-9 number keys.

#### 7.6.12 Image up/down reverse

- 1. In real-time or frozen mode, move the cursor to the submenu [V Rev] of [B Mode Menu];
- 2. Press [Set] or [Back] key to realize image vertical reversal.

# 7.6.13 Image left/right reverse

- 1. In real-time mode, move the cursor to the submenu [H Rev] of [B Mode Menu];
- 2. Press [Set] or [Back] key to realize image horizontal reversal that change the probe scanning direction.

# 7.6.14 Angle/Width change

- 1. In real-time mode, move the cursor to the submenu [Angle Change] of [B Mode Menu] in B mode;
- 2. Press [Set] or [Back] key to convert the scanning angle/width. Angle/width change falls into 0, 1, 2, 3 and displayed in the [Angle Change] of the left menu. (Convex array for scanning angle and linear array for scanning width)

# 7.6.15 Color selection

- 1. In real-time or frozen mode, move the cursor to the submenu [B Color] of [B Mode Menu].
- 2. Press [Set] or [Back] key to achieve the conversion of eight kinds of colors (including one kind of black and white).

# 7.6.16 Image freeze/unfreeze

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

#### 7.7 Puncture guide

In real-time B mode and in the status of **(**B Mode Menu **)**, press key, two puncture guide lines will be showed on the screen, press direction keys  $\textcircled{}{}^{\textcircled{}}$  to change the angle of the first puncture guide line, press direction keys  $\textcircled{}^{\textcircled{}}$  to change the start position of the first puncture guide line.

Press Guide key to switch puncture guide line, press direction keys F to change the angle of the second puncture guide line, press direction keys F to change the start position of the second puncture guide line. Press Esc key to exit the puncture guide status.

#### 7.8 Lithotripsy positioning line

- 1. In real-time mode, move the cursor to the submenu [ESWL Line] of [B Mode Menu];
- 2. Press [Set] key, ESWL line will be shown in the image area and the measurement depth of ESWL "X: 0.0mm" is real-time shown at the lower left corner at the same time, operate trackball or up/down direction keys to positioning ESWL depth;
- 3. Press  $\vec{Esc}$  key exit the ESWL line status.

#### 7.9 Body mark

This system contains 27 body marks. The parts of body marks are divided into 7 categories, as follows:

1. General 2. Bovine 3. Canine 4. Equine 5. Feline 6.Cardiac 7. Swine Operation steps:

- 1. In froze status, press key to enter [Body Mark] dialog;
- 2. Move the cursor to the page of the body part you need, press [Set] key, the body mark on this page will be showed in the dialog;
- 3. Move the cursor to the body mark you need, press [Set] key, the body mark will be selected and showed at the lower right corner of the screen;
- 4. Operate the trackball to move the position of the probe mark, rotate <sup>Gain</sup> Or Function knob to change the direction of probe mark, press Finter or Esc key to confirm;
- 5. Press key to clear the body mark and probe mark.

#### 7.10 One-key storage

Freeze the current image; press key, the prompt "Been stored" appears at the left corner of the screen, the content displayed on the current screen will be stored to the folder in the C disk or U disk. Folder name and file name will be automatically generated by the system based on the current date and time.

Such as:

Folder name: "05\_06\_14", File name: "16\_32\_56.bmp"

It represents that the diagnostic images at 16:32:56 on May 6<sup>th</sup> 2014.

# Explanation: The functions for same and same key are the same.

# Attention:

- 1. When you plug in U disk, the default storage path is U disk; if you do not plug in U disk, the default storage path is C disk.
- 2. Operating U disk should allow sufficient storage time to prevent the files from missing.
- 3. U disk storage should be concerned about the free space to prevent the invalid storage.

#### 7.11 Play back and Measurement

• Play back

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

Freeze image, press key to enter the manual playback status, press direction keys or move the trackball to choose the image needed playback. Press key again to return to

automatic playback status. Press  $\underbrace{Esc}$  key to exit playback status. Press  $\underbrace{}$  key unfreeze and exit playback status.

• Playback measurement

In manual playback status and choose measured image, press key to exit playback status and perform measurement. The detail measurement method refers to corresponding chapters.

Press key again to return to manual playback status.

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

#### 7.12 Annotation

- 1. In frozen status, press (comment key, the cursor will be showed on the screen;
- 2. Move the cursor to the needed position, press [Set] key;
- 3. Press character keys to input the annotation, press [Set] key to confirm. It can annotate many times by moving the cursor;

Press key to switch between capital letters and small letters. When capital, the "Caps" mark is shown in the lower right corner of the screen.

Press<sup>Shift</sup>key to switch between upper function and lower function of a key. When annotating the special characters, the "Shift" mark is shown in the lower right corner of the screen.

Press key to enter a space during the text input.

- 4. If need to be modified during annotation, press direction keys (D) to move the cursor to the character behind you want to modify, press key to delete and input again;
- 5. If need to input arrow, press key, move the cursor to the desired position to add arrow, rotate <sup>Gain</sup> or <sup>Depth</sup>knob to change the direction of the arrow, press key, the selected arrow is to be added to the cursor position;
- 6. Press key to exit annotation after finish inputting;
- 7. Press  $(c_{ear})$  key to clear the annotation;
- 8. Press key to unfreeze and clear the screen.

# 7.13 M image function

# 7.13.1 M work mode selection

- 1. In real-time mode, move the cursor to the [M Work Mode] of the [M Mode Menu] of M mode;
- 2. Press [Set] or [Back] key to choose M work mode.

# Explanation: Work mode 0 is scanning way; work mode 1 is rolling way.

# 7.13.2 M speed selection

- 1. In real-time mode, move the cursor to the [M Speed] of the [M Mode Menu];
- 2. Press [Set] or [Back] key to change the M speed. The scanning speed of M mode will be displayed in the [M Speed] of left menu.

#### Explanation: M speed is fixed at 4 in B|M mode.

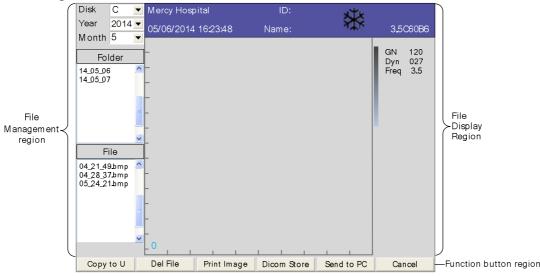
#### 7.13.3 Dynamic range, edge enhancement, compression curve and post-process

They are the same as B image function.

#### **Chapter Eight Image management**

The system stores and manages the frozen images or reports in BMP format.

The image management interface is divided into file management region, file display region and function button region. The work interface is as follows:



#### 8.1 Enter/exit image management

- 1. Freeze the current interface, press key to enter image management interface.
- 2. Choose the [Cancel] button on the image management interface to exit; You also can directly press key to exit image management interface.

# 8.2 Image management interface

- 1. File management region is to save the stored image or report to the appropriate path, which is located on the left side of the screen.
  - Disk: select the desired file path, C disk or U disk;
  - Year, month: respectively according to the year and month, to view the desired folder or file;
  - Folder: the position that save the folders;
  - File: the file position on the folder.
- 2. Files display region displays the current selected image or report, which is located on the center of screen.
- 3. Function buttons region provides respective functions for the folder and file.

#### 8.3 Manage the folder and file

For the folder, function buttons region provides the following buttons, to complete their respective functions:

- Delete Folder: delete folders in the C disk or U disk;
- Cancel: to exit the image management interface.

For the file, function buttons region provides the following buttons, to complete their respective functions:

- Copy to U: files in the C disk are copied to U disk;
- Delete File: delete files in the C disk or U disk;
- Print Image: print the selected image or report, the details refer to "Chapter Ten Print and Transfer files":
- Dicom Store: the images or reports in the C disk or U disk are send to DICOM server;
- Send to PC: the images or reports in the C disk or U disk are send to Network Printer of PC;
- Cancel: to exit the image management interface.

# Description: for selection of folder or file, you can operate the trackball to select (press

[Set] key to confirm), or (when the cursor has within the folder or file area, press [Set] key to confirm) operate (\*) (\*) keys to select.

# Chapter Nine Print and Transfer files

#### 9.1 Print

The system supports network print and USB print.

#### 9.1.1 Network print

Before using the network print, you must install the PC application software "Network Printer" and successfully set the network.

### • Install Network Printer

- 1. PC connected to local or network printer;
- 2. Copy the Network Printer files to PC;
- 3. Double click NetworkPrinter. exe icon to run this software, icon appears at the bottom right of the taskbar in the PC;
- 4. Set the port: click the system setting icon 🖗, set the port number, the default value is 8866. Generally it does not need to re-set.

# • Network Print

- 1. This instrument and the PC connected to the same local area network;
- 2. Set the network properties of this instrument:
  - IP address: IP address of KX5600 instrument;
- 3. Set the IP address of printer connected to this instrument (LAN Server Set):

IP address: IP address of PC installing printer;

TCP Port: the default is 8866.

- 4. For details, see the [Net Setting] in the **(**System Preset**)**. After completion of network settings, you can print by network.
- 5. Freeze the current interface, press key on the keyboard, the prompt "Print success" appears at the left corner of the screen, the content images or a variety of diagnosis reports displayed on the current screen will be printed out.

# **AWarning**:

- 1. It is forbidden to unplug the printer data cable in the case of without shutting down the system's power switch and printer's power switch; or it may cause the system or printer damage or electrical shock.
- 2. It is forbidden to unplug the printer's power plug in the case of without shutting down the printer's power switch; or it may cause the printer damage or electrical shock.

# **Attention**:

- 1. Some network anomalies cause a timeout for a long time, especially unplug the network cable in the phase of connecting and printing, need to wait several minutes to tens of minutes, so recommend the user not to do network anomalies operation.
- 2. During the network printing, do not close the RetworkFrinter. exe software.
- **3.** Make sure the printer connected to the system normally, the printer has papers and the printer's work status is normal.

#### 9.1.2 USB Print

- 1. Insert U disk into the USB port at the back of main unit;
- 2. When U disk connected to this instrument, the status bar at the bottom right of the screen will pop upaUSB icon;
- 3. Save the images or reports within the system to U disk, unplug the U disk after completed saving;
- 4. Connect U disk to PC, you can print out the images or reports by the default printer in the PC.

#### 9.2 Transfer BMP files

After successfully set the network, the images or reports can be transferred to PC application software "Network Printer".

Operation: After successfully set the network, freeze the image, press key on the keyboard to transfer the image. When the lower-left corner of the screen shows "Transfer success", it indicated the image or report has been transferred to Network Printer. If prompts "Transfer fail", see the [Net Setting] in the [System Preset], reset the network,

Description: the specific use of Network Printer sees its instructions for use.

# Chapter Ten B General Measurement

Attention: The accuracy of software measurement: distance measurement  $\leq 0.1$  mm; area measurement  $\leq 0.1$  mm<sup>2</sup>; volume measurement  $\leq 0.1$  mm<sup>3</sup>; heart rate measurement  $\leq 1$  bpm; time measurement  $\leq 1$  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.

In B, B/B, 4B mode, press [Measure] key to enter [B Meas] menu. B general measurement menu is shown as follows:

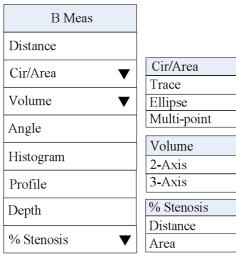


Fig. B general measurement menu

#### **10.1 Distance measurement**

Function: measure the distance between two dots.

Operation steps:

- 1. Choose the valuable image in B, B/B or 4B mode;
- 2. Press [Measure] key, the cursor will show "+";
- 3. Operate the trackball or the direction keys to move the "+" mark to the desired position, press [Set] key, make the "+" position as the starting point to be measured;
- 4. Operate the trackball or the direction keys to move the "+" mark to the end point of the measurement, at the same time a lighted dotted line appears between two measurement marks as the locus of the measurement, the measured value will be automatically shown at the right hand of the screen;
- 5. Press [Measure] key to exchange the starting point and the end point;
- 6. Press [Set] key to finish the first time measurement;
- 7. Repeat the steps from 3 to 6 to complete multi-group data measurement;
- 8. Press [Measure] key to exit the measurement.

#### 10.2 Circumference/area measurement

#### Three kinds of operation methods

#### A. Trace measurement

Function: Measure the circumference/area of a confined area with the trace method.

- 1. Choose a valuable image in B, B/B or 4B mode;
- 2. Press [Measure] key, the cursor will show "+", move the cursor to the [Trace] of [Cir/Area] submenu of [B Meas], press [Set] key;
- 3. Operate the trackball or the direction keys to move the "+" mark to the desired position, press

[Set] key, make the "+" position as the starting point to be measured;

- 4. Operate the trackball or the direction keys to move the "+" mark to the end point of the measurement, at the same time it appears a trace between two measurement marks along the direction of operation. The measured circumference value is automatically displayed at the built-in mark "C1: ----mm" on the right part of the screen. Press [Set] key to display the measured value of the area formed by measurement line enclosure;
- 5. Repeat the steps 3~4 to complete multi-group data measurement;
- 6. Press [Measure] key to exit the measurement.

#### **B.** Ellipse measurement

Function: Measure the circumference/area of a confined area with the ellipse approximations.

- 1. Choose a valuable image in B, B/B or 4B mode;
- 2. Press [Measure ] key, the cursor will show "+", move the cursor to the [Ellipse ] of [Cir/Area] submenu of [B Meas], press [Set] key;
- 3. Operate the trackball or the direction keys to move the "+" mark to the desired position, press [Set] key, make the "+" position as the starting point to be measured;
- 4. Operate the trackball or the direction keys to move the "+" mark to end point of the measurement, at the same time it appears elliptic curve, then rotate [Gain] or [Function] knob to change the minor axis of the ellipse to make it satisfy the area need to be measured, press [Measure] key to exchange the starting point and the end point, press [Set] key, the measured values of circumference and area are automatically displayed on the right part of the screen;
- 5. Repeat the steps 3~4 to complete multi-group data measurement;
- 6. Press [Measure] key to exit the measurement.

#### C. Multi-point measurement

Function: Measure the circumference/area of a confined area with the multi-point method.

- 1. Choose a valuable image in B, B/B or 4B mode;
- 2. Press [Measure ] key, the cursor will show "+", move the cursor to the [Multi-point ] of [Cir/Area] submenu of [B Meas], press [Set] key;
- 3. Operate the trackball or the direction keys to move the "+" mark to the desired position, press [Set] key to mark the first point, continue to operate the trackball or the direction keys, move the "+" mark to next desired position, press [Set] key to mark the second point; By analogy, to mark all desired points;

#### Note: The number of points must be within 8 to 32.

- 4. When completed the marking of desired points, press key, it appears trace on the screen (trace is automatically drawn along the order of marking point until close the beginning point and end point), the measured values of circumference and area are automatically displayed on the right part of the screen; If continuously marks the thirty-two point, it directly appears trace on the screen and the measured values of circumference and area are automatically displayed on the right part of the screen;
- 5. Repeat the steps 3~4 to complete multi-group data measurement;
- 6. Press [Measure] key to exit the measurement.

#### **10.3 Volume measurement**

#### A. 2-axis method

Function: Measure the volume of the subject. 2-Axis method only needs to measure the vertical section of the subject.

Formula of 2-axis method:  $(\pi/6) * A * B^2$ 

Where, A is the major axis of the ellipse; B is the minor axis of the ellipse.

- 1. Choose a valuable image in B, B/B or 4B mode;
- 2. Press [Measure] key, the cursor will show "+", move the cursor to the [2-Axis] of [Volume] submenu of [B Meas], press [Set] key;
- 3. Operate the trackball or the direction keys to move the "+" mark to the desired position, press [Set] key, make the "+" position as the starting point to be measured;
- 4. Operate the trackball or the direction keys to move the "+" mark to end point of the measurement, at the same time it appears elliptical curve then rotate [Gain] or [Function] knob to change the minor axis of the ellipse to make it satisfy the area need to be measured, press [Measure] key to exchange the starting point and the end point, press [Set] key, the measured values of area and volume are automatically displayed on the right part of the screen;
- 5. Repeat the steps 3~4 to complete multi-group data measurement;
- 6. Press [Measure] key to exit the measurement.

#### **B. 3-axis method**

- 1. Choose a valuable image in B, B/B or 4B mode;
- 2. Press [Measure] key, the cursor will show "+", move the cursor to the [3-Axis] of [Volume] submenu of [B Meas], press [Set] key;
- 3. Operate the trackball or the direction keys to move the "+" mark to the desired position, press [Set] key, make the "+" position as the starting point to be measured;
- 4. Operate the trackball or the direction keys to move the "+" mark to end point of the measurement, at the same time it appears elliptical curve then rotate [Gain ] or [Function ] knob to change the minor axis of the ellipse to make it satisfy the area need to be measured, press [Measure ] key to exchange the starting point and the end point, press [Set ] key, the measured value of area is automatically displayed on the right part of the screen; Move the cursor to the starting point to be measured, press [Set ] key, operate the trackball or the direction keys to move the "+" mark to end point of the measurement, the measured values of distance and volume are automatically displayed on the right part of the screen, press [Set ] key to finish this measurement;
- 5. Repeat the steps 3~4 to complete multi-group data measurement;
- 6. Press [Measure] key to exit the measurement.

#### **10.4 Angle measurement**

Function: measure the included angle of the two straight lines. (0°  $-180^{\circ}$  ) Operation steps:

- 1. Choose a valuable image in B, B/B or 4B mode;
- 2. Press [Measure] key, the cursor will show "+", move the cursor to the submenu [Angle] of [B Meas], press [Set] key;
- 3. At first draw line along one hand of the measurement angle referring to the "Distance" measurement;
- 4. Then draw line again along the other hand of the measurement angle referring to the "Distance" measurement. At last the included angle of two lines and their length will show on the right of the shown area;
- 5. Press [Measure] key to exit the measurement.

#### 10.5 Histogram measurement

- 1. Freeze a valuable image in B, B/B or 4B mode;
- 2. Press [Measure] key, the cursor will show "+", move the cursor to the submenu [Histogram]

#### of **[**B Meas**]**, press **[**Set**]** key;

- 3. Operate the trackball or the direction keys to move the "+" mark to the desired position, press [Set] key, make the "+" position as the starting point to be measured;
- 4. Operate the trackball or the direction keys to move the "+" mark to end point of the measurement, at the same time it appears rectangle region, operate the trackball or the direction keys to change the size of the rectangle to make it satisfy the area need to be measured; press [Set] key, the peak of histogram is automatically displayed at the right part of the screen, at the same time the histogram is displayed in the lower left of the screen;
- 5. Press [Measure] key to exit the measurement.

#### **10.6 Profile measurement**

- 1. Freeze a valuable image in B, B/B or 4B mode;
- 2. Press [Measure] key, the cursor will show "+", move the cursor to the submenu [Profile] of [B Meas] then press [Set] key;
- 3. Operate the trackball or the direction keys to move the "+" mark to the desired position, press [Set] key, make the "+" position as the starting point to be measured;
- 4. Operate the trackball or the direction keys to move the "+" mark to end point of the measurement, at the same time a dashed line appears between two measurement marks, press [Measure] key to exchange the starting point and end point; press [Set] key, the measured values are automatically displayed at the right part of the screen, at the same time profile is displayed in the image area;
- 5. Repeat the steps 3~4 can measure for several times;
- 6. Press [Measure] key to exit the measurement.

#### **10.7 Depth measurement**

Operation steps:

- 1. Choose the valuable image in B mode;
- 2. Press [Measure] key, the cursor will show "+", move the cursor to the submenu [Depth] of [B Meas], press [Set] key;
- 3. Operate the trackball or the up/down direction keys to move the "+" mark to the end point of the measurement, the "D1: ----mm" position of the right hand of the screen will show the depth value;
- 4. Press Set key to complete the first measurement;
- 5. Repeat the steps 3, 4 to complete four groups depth measurement;

6. Press [Measure] key to exit the measurement.

#### Note: Left/right direction keys cannot work in the depth measurement.

#### 10.8 Stenosis ratio measurement

Function: measure and calculate the stenosis degree of the blood vessel. There are two kinds of stenosis ratio, one is distance stenosis ratio the other is area stenosis ratio. Both are calculated according to the distance and area.

Stenosis ratio formulas:

Distance stenosis ratio: %D = [(D1-D2)/D1] \* 100%

Area stenosis ratio: %A = [(A1-A2)/A1] \* 100%

Where, D1 is the distance at the non-stenosis position; A1 is the area at the non-stenosis position either. D2 and A2 are separately the distance and area at the stenosis position.

#### 10.8.1 Distance stenosis ratio measurement

1. Choose a valuable image in B, B/B or 4B mode;

2. Press [Measure] key, the cursor will show "+", move the cursor to the submenu [Distance]

- of [[% Stenosis]] of [[B Meas]], press [[Set]] key;
- 3. Measure the distance D1 at the non-stenosis position, the method is the same as "Distance" measurement;
- 4. Measure the distance D2 at the stenosis position, the method is the same as "Distance" measurement. After finishing the measurement, the calculated value DSR will be showed on the right of the shown area;
- 5. Repeat the steps 3~4 to measure distance stenosis ratio for next time;
- 6. Press [Measure] key to exit the measurement.

#### 10.8.2 Area stenosis ratio measurement

- 1. Choose a valuable image in B, B/B or 4B mode;
- 2. Press [Measure] key, the cursor will show "+", move the cursor to the submenu [Area] of [% Stenosis] of [B Meas] then press [Set] key;
- 3. Measure the area A1 at the non-stenosis position, the method is the same as "Cir/area" of the "Ellipse";
- 4. Measure the area A2 at the stenosis position and the method is the same as "Cir/area" of the "Ellipse". After finishing the measurement, the calculated value ASR will be showed on the right of the shown area;
- 5. Repeat the steps 3~4 to measure area stenosis ratio for next time;
- 6. Press [Measure] key to exit the measurement.

# Chapter Eleven B Obstetric Measurement

Obstetric calculation is usually done in B image mode.

In B, B/B, 4B or B/M mode, press [OB] key to open "B-OB Meas" menu. B obstetric measurement menu is shown as below:

B-OB Meas	
Bovine	
Canine	
Equine	
Feline	
Goat	
Llama	
Ovine	
Swine	

Fig. B obstetric measurement menu

# **11.1 Measurement and Calculation items**

Gestational weeks and estimated date of childbirth of the bovine, canine, equine, feline, goat, llama, ovine and swine

#### 11.2 Obstetric-Bovine

Operation steps:

- 1. Move the cursor to [Bovine] of BOB Meas] menu, press Set! key to enter "Bovine" menu.
- 2. Measurement of BD, BPD, CRL, CWM, CWW, TD, UD Measurement method:
  - (1) Move the cursor to the item which be measured, press [Set] key then move the cursor to the image area and the cursor shows "+";
  - (2) The detailed operation refers to the "Distance" measurement of "B general measurement";
  - (3) The corresponding measurement result, Gestational Age (GA) and Estimated Delivery of Confinement (EDC) will be showed on right side of the display area;
  - (4) Repeat steps (1) $\sim$ (3) to measure next time;
  - (5) Press [OB] key to exit the measurement.
- 3. Obstetric report
  - (1) Move the cursor to the [Report] menu, press [Set] key to enter.

(2) Store report: Press key to store the report shown in the current screen.

(3) Print report: Press key to print the obstetric report. The printing operation method refers to "Chapter Nine Print and Transfer files".

#### 11.3 Obstetric-canine, equine, feline, goat, llama, ovine and swine

The measurement methods refer to "OB-Bovine" measurement.

# 11.4 Measurement of Swine's lean percentage

#### % Lean calculation formula uses NSIF formula.

- 1. Move the cursor to [Swine] of B-OB Meas] menu, press Set key to enter "Swine" menu;
- 2. Move the cursor to [[%Lean]], press [[Set]] key, "Weight Input" dialog box will be showed on the screen, input weight (range 1~300kg), move the cursor to [ OK ] of the dialog box after inputting and press [[Set]] key to confirm saving and exit;
- 3. Measure fat thickness and loin, method is the same as the "Distance" measurement of "B general measurement";
- 4. The result of %Lean will be showed on the right of the shown area;
- 5. Repeat the step 3 to measure next time;
- 6. Press **[OB]** key to exit the measurement.

# Chapter Twelve M General Measurement

In B/M, M mode, press [Measure] key to enter [M Meas] menu. M general measurement menu is shown as follows:

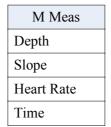


Fig. M general measurement menu

# 12.1 Depth measurement

Function: Measure the distance between the vertical two points in M image. Measurement method:

- 1. Move the cursor to the [Depth ] item of [M Meas], press [Set] key to enter measurement status;
- 2. Operate the trackball or the direction keys to move the cursor to the starting point, press [Set] key to confirm the starting point of the measurement;
- 3. Operate the trackball or the direction keys to move the cursor to the end point, now the cursor only can move vertically and the measured value will be showed on the right of the display area in real time; press [Measure] key to exchange the starting point and the end point of the cursor;
- 4. Press **[**Set**]** key to finish the measurement;
- 5. Repeat steps 2~4 to measure next time;
- 6. Press [Measure] key to exit the measurement.

# **12.2 Slope measurement**

Function: Measure the (speed) slope between two points and at the same time measure the depth and time between the two points.

Measurement method:

- 1. Move the cursor to the Slope litem of M Meas , press Set key to enter measurement status;
- 2. Operate the trackball or the direction keys to move the cursor to the starting point and press [Set] key to confirm the starting point of the measurement;
- 3. Operate the trackball or the direction keys to move the cursor to the end point, the measured value will be showed on the right of the display area in real time; press [Measure] key to exchange the starting point and the end point of the cursor;
- 4. Press **[**Set] key to finish the measurement;
- 5. Repeat steps 2~4 to measure next time;
- 6. Press [Measure] key to exit the measurement.

# 12.3 Heart rate measurement

Function: calculate the number of bit per minute in the heartbeats image.

- Measurement method:
- 1. Move the cursor to the [[Heart Rate]] item of [[M Meas]], press [[Set]] key to enter measurement status;
- 2. Operate the trackball or the direction keys to move the cursor to the starting point and press [Set] key to confirm the starting point of the measurement;
- 3. Operate the trackball or the direction keys to move the cursor to the end point, now the cursor only can move horizontally and the measured value will be showed on the right of the display area in real time; press [Measure] key to exchange the starting point and the end point of the cursor;

- 4. Press **[**Set] key to finish the measurement;
- 5. Repeat steps 2~4 to measure next time;
- 6. Press [Measure] key to exit the measurement.

#### **12.4** Time measurement

Function: Measure the time interval between two points in M image.

Measurement method:

- 1. Move the cursor to the [Time] item of [M Meas], press [Set] key to enter measurement status;
- 2. Operate the trackball or the direction keys to move the cursor to the starting point and press [Set] key to confirm the starting point of the measurement;
- 3. Operate the trackball or the direction keys to move the cursor to the end point, now the cursor only can move horizontally and the measured value will be showed on the right of the display area in real time; press [Measure] key to exchange the starting point and the end point of the cursor;
- 4. Press [Set] key to finish the measurement;
- 5. Repeat steps 2~4 to measure next time;
- 6. Press [Measure] key to exit the measurement.

## Chapter Thirteen System Maintenance

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

13.1 Maintenance by users

13.1.1 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.

## **AWarning**:

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



- 1. To prevent possible infection, it is advisable to wear sterilized gloves when cleaning, disinfecting the ultrasonic probe.
- 2. Clean the probe with sterile water to remove the residual chemicals after disinfection, because the residual chemicals may be harmful for humans.
- **3.** Kaixin Company will not make any guarantee for the efficacy of disinfector. Please contact the appropriate manufacturer for details.

## **Attention**:

- 1. In the process of cleaning and disinfection, avoid probe overheat (exceeding 60°C) as it may be damaged or deformed under excessive heat.
- 2. In the operation of disinfection, please refer to medical institutions disinfection technical specifications.

#### 1. Clean the probe

- (1) Must wear sterilized gloves to prevent possible infection.
- (2) Rinse the probe with water or soapy water to remove all contaminants, or use a soft urethane sponge to wipe the probe. Do not use brushes as it may damage the probe.
- (3) After finishing the rinsing, use a sterilized cloth or gauze to wipe the water on the surface of probe. Do not dry the probe by heating it.

#### 2. High-level disinfection

Please follow the disinfection method provided in this user's manual for disinfection.

- (1) Before disinfection, wear sterilized gloves to prevent possible infection;
- (2) You must clean the probe before disinfection. Recommend the solution to disinfect in the following table.

Glutaraldehyde-based disinfectant:

[	Chemical Name	Reagent Name	Step
	Glutaraldehyde (2.4%)	Cidex Glutaraldehyde disinfectant	Please refer to the instructions of the solution for details.

Non-glutaraldehyde-based disinfectant:

Chemical Name	Reagent Name	Step	
Phthalaldehyde solution (0.55%)	Cidex OPA	Please refer to the instructions of the solution for details.	

- Please follow the instructions about disinfectant concentration and disinfection method, as well as the precautions about disinfectants provided by disinfectant provider. But do not rinse or soak the probe connector or close to connector cable.
- The soaking time of probe in the disinfectant is limited to the minimum time recommended by disinfectant manufacturer (e.g., Cidex OPA manufacturer recommended minimum 12 minutes).
- Please follow local laws and regulations to choice the disinfectants.
- (3) After disinfection, rinse the probe with a large number of sterile water (about 2 gallons) for at least one minute to remove the residual chemicals. You may follow the recommended method by the disinfectant manufacturer to rinse.
- (4) After finishing the rinsing, use a sterilized cloth or gauze to wipe the water on the surface of probe. Do not dry the probe by heating it.

Attention: The waterproof grade of intra-cavity probe is IPX7, immersion depth from probe's acoustic head to the sheath of probe handle; the waterproof grade for other probes is IPX4.

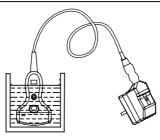


Fig. Immersion disinfection of probe (except intra-cavity probe)

Fig. Immersion disinfection of intra-cavity probe (sketch map)

## **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. The regular disinfection times should be minimized as it may lead to degrade of the probe safety and performance.

### 3. Check probe after cleaning and disinfection

- (1) Check the probe enclosure and its cable to ensure they are free of abnormity (such as scuffing, cracks or drop-off);
- (2) The sound window of probe is thin; ensure that there are no any abnormity on the sound

window, such as scuffing, cracks, peeling, and bulge.

#### 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 liquid crystal display

Use a soft cloth dipped in glass cleaner to clean the LCD screen, and then air-dried.

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

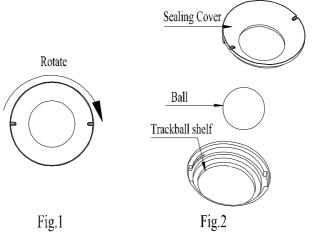
Attention: Prohibit using sharp objects to touch the LCD screen, and prohibit pressing or squeezing against the LCD screen.

#### 6. Clean the trackball

Attention: Trackball should be cleaned regularly, or because of dust, stains, etc. resulting in the non-flexible use of trackball.

• Dismantle trackball

Respectively hold down the both sides of sealing cover with middle fingers of left hand and right hand or hold down the two grooves of the cover with two small screwdriver, and then forced rotate it clockwise, remove the cover and take out the trackball. As follows:



- Clean the trackball
  - ① Clean the trackball shelf lightly with dry, soft flax or anti-static LCD clean cloth generally.
  - ② In case of die-hard blots, clean with soft cloth dipped in moderate detergent and then air-dry it.
- Clean the trackball shelf

Clean the trackball shelf lightly with dry, soft flax or anti-static LCD clean cloth.

• Install trackball

Place the sealing cover into the trackball shelf, respectively hold down the both sides of sealing cover with middle fingers of left hand and right hand or hold down the two grooves of the cover with two small screwdriver, and then forced rotate it counterclockwise to lock the cover (When locking, the two grooves of the sealing cover are in the horizontal line).

#### 7. Clean the control panel, shell and probe bracket

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.

#### 8. Clean the video recorder and foot switch

- (1) Use the soft dry cloth to wipe the video recorder and foot switch.
- (2) If it is difficult to wipe away the blemish, clean with soft cloth dipped in moderate detergent and then air-dry it.

#### 13.2 Replace the fuse

Replace the fuse is to replace the power adapter.

Attention: The fuse is inside the power adapter. Fuse shall be replaced by professional engineer.

#### 13.3 Use and maintenance for the rechargeable battery

#### • The battery use for main unit

- 1. Only use charger and battery pack (model HYLB-1614) provided by KaiXin Company.
- 2. The output port of adapter plugs into the input port of "charger" to charge (see the charge sketch map for main unit battery). The charge indicator is green and blinking state when charging; the charge indicator is green and no blinking when fully charged.
- 3. The charging time is about 3 hours, over-charging or discharging will shorten the battery life; the full charged battery can be used about 3.5 hours.

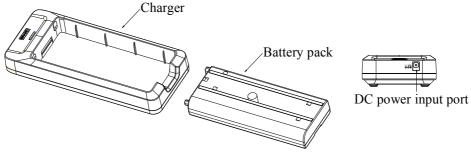


Fig. the charge sketch map for main unit battery

Attention: Main unit will power off automatically 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.

#### • The maintenance for the rechargeable battery pack

- 1. 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.
- 2. The excess high or low temperature will affect the charging and discharging performance, and short the battery life and capacity.

#### **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.

Attention: Battery charger shall meet the requirements of the 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: 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.

#### **13.4 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 abnormity 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	1. Check power supply.
display is present when starting	2. Check power cable and connector.
the machine.	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> <li>Check power supply (spark interference present).</li> <li>Check environment (source of interference around the machine, such as electric motor, ultrasonic atomizer, automobile, computer or other interference).</li> <li>Check power plug/socket of the instrument or probe connectors. They shall be properly contacted.</li> </ol>
Image display is not clear.	<ol> <li>Adjust the total gain, TGC.</li> <li>Adjust the brightness.</li> </ol>
Control panel malfunction	Turn off the machine and restart it.

#### **13.5 Periodic Safety Checks**

To ensure the system performance and safety, it must be checked after using 1 year. When check the instrument, please consult the International Trade Dept of Kaixin or its dealers, as they need to have professional technology engineers.

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.

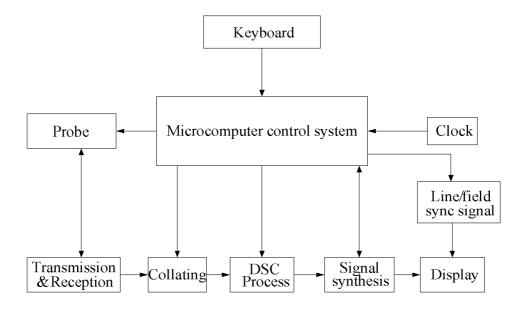
- Inspect the equipment and accessories for mechanical and functional damage.
- Inspect the safety relevant labels for legibility.
- Inspect the fuse to verify compliance with rated current and breaking characteristics.
- Verify that the device functions properly as described in the instructions for use.
- Test the protection earth resistance according to IEC 60601-1: Limit:  $0.1\Omega$ .
- Test the earth leakage current according to IEC 60601-1: Limit: NC 500µA, 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 (B), for d.c.: 10µA (B).
- 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 (B), for d.c.: 50µA (B).

The leakage current should 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.

#### 13.6 System Block Diagram



## **Chapter Fourteen** 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.
- Environment requirement: Ambient temperature: -20°C − 55°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 Fifteen 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 Sixteen Guidance and Manufacturer's Declaration

This product complies with EMC test standard EN60601-1-2

Warning: The use of inappropriate accessory will reduce the performance of the product.

## **Attention**:

- 1. The use of the accessory, transducer or cable other than those specified may result in increased emissions or decreased immunity of the system.
- 2. The system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the system should be observed to verify normal operation in the configuration in which it will be used.
- 3. The system needs to be specifically for EMC protection, and need to be installed and maintenance in the environment meeting the following provided EMC information.
- 4. The system may be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements.
- 5. Prevent electromagnetic interference (Conducted Immunity). Due to technical limitations, conducted immunity level is limited to 1 Vrms, conducted immunity level higher than 1 Vrms may cause the image display of the system interference and affecting the diagnosis and measurement. We recommend the system away from the conduction noise source.
- 6. Operation of the system below minimum amplitude or value of patient physiological signal may cause inaccurate results.
- 7. Portable and mobile communications equipment can affect the performance of the system. See the following tables 1, 2, 3, 4.

This equipment is intended Customer or user shall assur	he electromagnetic environment specified below. I in such an environment.		
Emission test	Compliance	Electromagnetic environment-guidance	
RF emissions CISPR 11	Group 1	This equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.	
RF emissions CISPR 11	Class A	This equipment is suitable for use in all establishments other than domestic and those	
Harmonic emissions IEC61000-3-2	Class A	directly connected to the public low-voltage power supply network that supplies building used domestic purposes.	
Voltage fluctuations/flicker Emissions IEC61000-3-3	Complies		

#### Table 1 - Guidance and manufacturer's declaration—electromagnetic emission

Γ

This equipment is in Customer or user shall	nvironment specified below. ent.		
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC61000-4-2	± 6 KV contact ± 8 KV air	± 6 KV contact ± 8 KV air	Floors shall 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 IEC61000-4-4	± 2 KV for power supply lines	± 1 KV for power supply lines	Mains power quality shall be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	$\pm 1 \text{ KV}$ differential mode $\pm 2 \text{ KV}$ common mode	$ \begin{array}{l} \pm 1 \text{ KV differential} \\ \text{mode} \\ \pm 2 \text{ KV common} \\ \text{mode} \end{array} $	Mains power quality shall be that of a typical commercial or hospital environment.
Power frequency magnetic field(50Hz) IEC61000-4-8	3A/m	3A/m	Mains power quality should be that of a typical commercial or hospital environment.

## Table 2 - Guidance and manufacturer's declaration—electromagnetic immunity

Table 3 - Gui	dance and manufact	urer's declaration-	—electromagnetic immunity		
This equipment is intended for use in the electromagnetic environment specified below. Customer or user shall assure that it is used in such an environment.					
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment-guidance		
Voltage dips short interruptions and voltage variations on power supply input lines IEC61000-4-11			Mains power quality shall be that of a typical commercial or hospital environment. If the equipment requires continued operation during power mains interruptions, it is recommended that this equipment be powered from an uninterruptible power supply.		
Conducted RF IEC61000-4-6 Radiated RF IEC61000-4-3	$ \begin{array}{c cccc} for 25 cycles & for 25 cycles \\ <5\% U_{T} & <5\% U_{T} \\ (>95\% dip in U_{T}) & (>95\% dip in U_{T}) \end{array} $				
<ul> <li>Note 1: U<sub>T</sub> is the a.c. mains voltage prior to application of the test level.</li> <li>Note 2: At 80MHz and 800MHz, the higher frequency range applies.</li> <li>Note 3: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures objects and people.</li> </ul>					
<ul> <li>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 transmitter, an electromagnetic site survey should be considered. If the measured field strength in the location in which this equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment.</li> </ul>					

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

necessary, such as reorienting or relocating the equipment.

# Table 4 - Recommended separation distance between portable and mobile RF communications equipment and this equipment

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

Rated maximum output power of transmitter (W)	$150 \text{KHz to 80MHz} \\ d=3.5 \sqrt{P}$	80MHz to 800MHz d=1.75√P	800MHz to 2.5GHz d=2.33 $\sqrt{P}$
0.01	0.35	0.12	0.23
0.1	1.11	0.37	0.74
1	3.50	1.17	2.33
10	11.07	3.69	7.38
100	35.00	11.67	23.33

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 watt (W) according to the transmitter manufacturer.

Note1: At 80MHz and 800MHz, the separation distance for the higher frequency range applies. Note2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures objects and people.

#### Statement:

When performing common mode conducted RF disturbance test (IEC61000-4-6), trivial radiation stripes may appear on the screen when 1V disturbing voltage is added. That disturbance does not affect the diagnosis.

## KAIXIN ELECTRONIC XUZHOU KAIXIN ELECTRONIC INSTRUMENT CO., LTD.



Kaixin Mansion, C-01. Economic Development Zone, Xuzhou, Jiangsu, China

Post Code: 221004 Tel: +86-516-87732932/87733758 Fax: +86-516-87732932/87792848

Website: <u>http://www.kxele.com</u> E-mail: gm01@kxele.com

Information contained in this manual is subject to change without further notice.