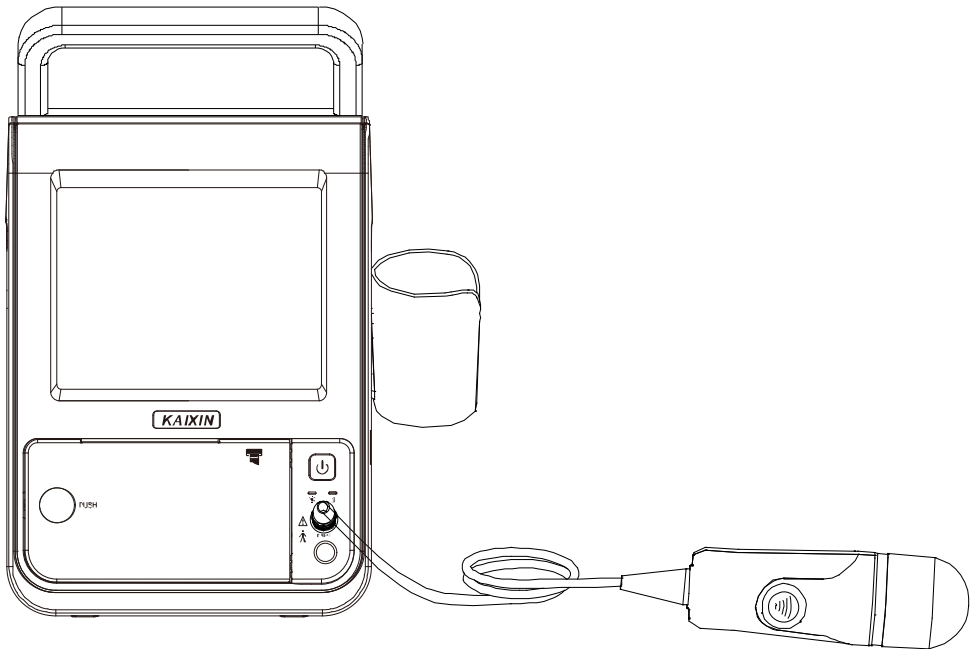
KAIXIN

BVT01 Bladder Volume Tester

User's Manual



Xuzhou Kaixin Electronic Instrument Co., Ltd.

Introduction

Thank you for purchasing BVT01 bladder volume tester.

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.

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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.

The qualified service personnel who get Kaixin written authorization can repair the instrument out of warranty by themselves. But this should be agreed by Xuzhou Kaixin Electronic Instrument Co., Ltd. We will provide circuit diagrams, component part lists or other information to assist service personnel to repair those parts of our equipment that are designated by our company as repairable by service personnel.

Manufacturer's Information

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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 (defined as operator) 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.
6. 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.
13. Professional engineer mentioned in the user's manual is the person who has been trained and authorized by Kaixin Electronic Instrument Company Ltd.

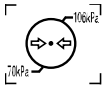
Safety Cautions

1. Warning Symbols and Definitions

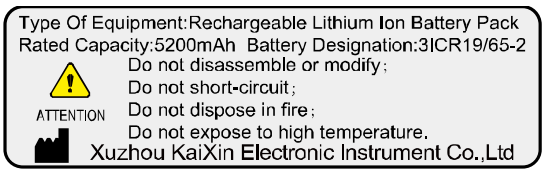
The following warning symbols are used in this manual to indicate safety level and other important items. Please remember these symbols and understand the meaning as you read this user's manual. These symbols convey specific meanings as detailed in the table below:

Symbols & Words	Connotation
⚠Danger	Indicates an imminent danger that may result in personal death or serious injury if not avoided.
⚠Warning	Indicates a potential danger that may result in personal injury if not avoided.
⚠Attention	Indicates a potential danger or unexpected use condition that may result in light injury or property loss or affecting the use if not avoided.

2. Safety Symbols

Symbols	Meaning	Symbols	Meaning
	Type B applied part		Up
	Direct current		Keep dry
	Standby switch		Fragile
	Power supply indication		Stacking limit by number
	Battery charge indicator		Temperature limits (Storage and transport)
	Follow instructions for use		Humidity limitation (Storage and transport)
	Marking for the separate collection of electrical and electronic equipment		Atmospheric pressure limitation (Storage and transport)

3. Labels

Label	Description
	**Attention:** When using the battery should pay attention to precautions.

	**Symbol for the marking of electrical and electronics devices according to Directive 2012/19/EU. 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 Overview

1.1 Introduction

BVT01 bladder volume tester is composed of main unit, probe, etc., which is used to non-invasively measure bladder volume with ultrasound principle. It is used to assess urinary retention and urinary incontinence, and given the timing of implement an objective clinical catheterization to reduce the catheterizing frequency and reduce the risk of urinary tract infections. But also by measuring the amount of residual urine volume after voiding, evaluate the therapeutic effect of certain drugs and treatment for urinary system diseases.

BVT01 bladder volume tester uses 2.5MHz ultrasound to mechanical sector scanning, identify the reflected wave of the front and rear wall of the bladder to obtain the cross-sectional area of the bladder; again through 15° intervals to automatically transform the scanning plane, based on the areas of 12 reference plane to calculate the bladder volume with ellipsoid integration.

To improve the accuracy of the operation and measurement, the screen displays the B-mode image of section bladder and the projection of bladder; it is convenient for doctors to check the location and determine the measurement results.

The expected service life of BVT01 bladder volume tester is 10 years. The applied part is the part between metal ring of probe handle below 5mm and the forefront of the sound head (see Figure 12-1 "Probe regular disinfection").

BVT01 measurement accuracy must meet the following indicators: Urine volume display resolution is 1ml. When urine volume is within 20ml～99ml, the measurement accuracy error is less than or equal to ±15ml; urine volume is within 100ml～999ml, the measurement accuracy error is less than or equal to 15%.

In a typical commercial or hospital environment, the use of instrument depends on the following essential performance:

1. Electromagnetic disturbance does not make the instrument generate artifacts or distortion in an image or error of a displayed numerical value and not alter the diagnosis.
2. Electromagnetic disturbance does not make the instrument generate the display of incorrect numerical values associated with the diagnosis to be performed.
3. Electromagnetic disturbance does not make the instrument generate the production of unintended or excessive ultrasound output.
4. Electromagnetic disturbance does not make the instrument generate the production of unintended or excessive transducer assembly surface.

1.2 Intended Use

BVT01 bladder volume tester is used in medical institutions for clinical measuring urine volume, to provide the basis for the implementation of clinical catheterization and make evaluations for the residual volume after patient voiding.

Contraindications: The equipment is not suitable for pregnant women and infants bladder scan, nor be scanned on the wounded skin.

> ⚠**Warning: This equipment can not be used at home.**

> ⚠**Warning: This equipment can not be used to treat.**

> ⚠**Attention: For patients with hypertrophy of the prostate, space occupying disease or scars, there is a risk of producing a result exceeding the given accuracy range.**

Chapter Two Technical Specifications

2.1 Technical data

1. Monitor: 5.7" LED
2. Adapter rating: 100-240V~, 1.2-0.6A, 50-60Hz
3. Output of adapter: DC12.8V 3.0A
4. Main device rating: DC12V 3.0A
5. Main Unit Size: approx. 200 * 168 * 165 (mm, L * W * H)
6. Weight of main unit: approx. 1.7kg (excluding accessories)

2.2 Primary functions

1. System preset function: hospital name, date format and time.
2. Display basic information: hospital name, patient information (name, ID, age), date and time.
3. Patient information input function.
4. Energy saving.
5. Patient mode selection function.
6. Measurement information store function.
7. Manually marking function.
8. Switch Chinese-English menu.
9. Print function.

2.3 Technical index

Table 1 Essential performance indexes of 2.5MHz 3D probe

S/N	Essential Performance	Performance index	
1	Probe frequency, MHz	2.5	
2	Urine volume calculation reference plane	12 planes, interval 15°	
3	Urine volume display resolution, ml	1ml	
4	Urine volume measurement range, ml	20ml～999ml	
5	Urine volume measurement accuracy, ml	20ml～99ml	error ≤ ±15ml
		100ml～999ml	error ≤ ±15%

Chapter Three System Outline

3.1 Structure composition of the instrument

BVT01 bladder volume tester is composed of main unit, probe, etc.

3.2 Components name

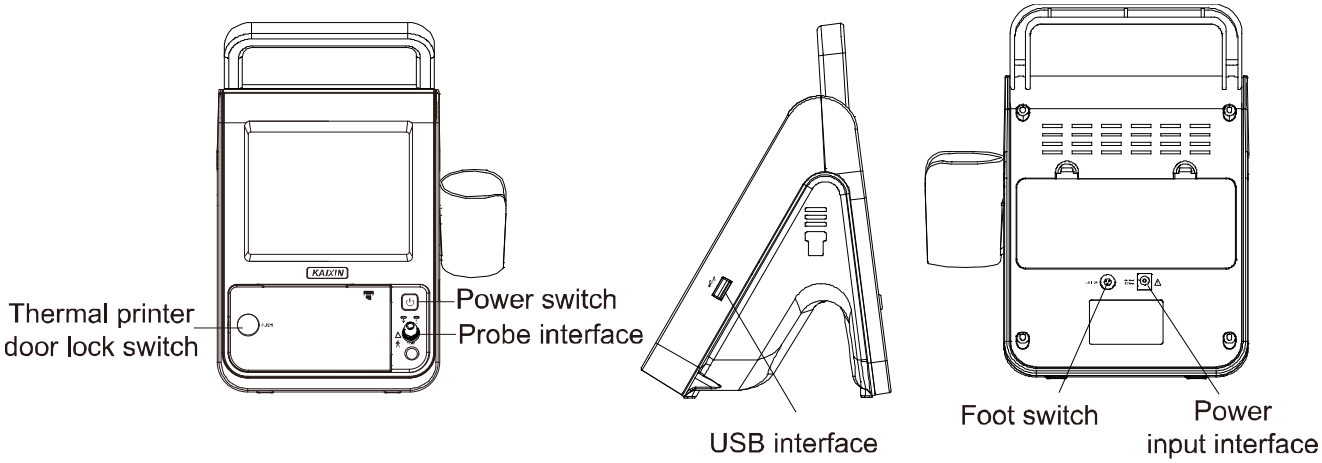


Fig. BVT01 sketch map

3.3 Parts of the probe

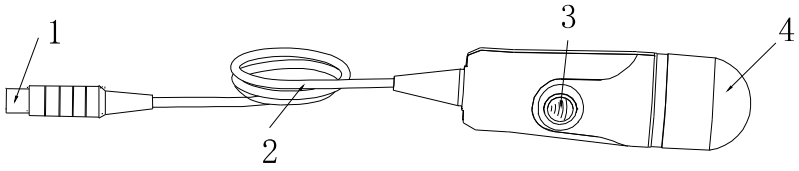


Fig. Parts name of 2.5MHz probe

Name	Function
(1) Probe connector	To connect the probe to ultrasonic diagnostic system.
(2) Cable	To connect the probe to the probe connector.
(3) Scan key	Press this key to start urine volume measurement.
(4) Acoustic lens	Use mechanical methods so that the sound beam transmitted by the transducer can sector scanning for a certain angle.

3.4 Function keys description

SN.	Key symbol	Key name	Key function
1		System preset	Touch the key to enter system setting interface;
2		New patient	·Access to the new patient module; ·Input the information and data for a new patient;
3		Scan	Touch the key to start urine volume measurement;

4		Read data	Touch the key to open data file;
5		Save data	Touch the key to save data file;
6		Print	Print various measurement images/data;
7	 and 	Image selection keys	In main interface, touch the keys to select the desired left or right image;
8	  	Patient mode key	·Repeatedly touch this key to switch the desired patient mode; ·Select the appropriate scan mode, which are divided into child, obesity and standard;
9	 and 	Data files selection keys	Touch the key to select the desired data file;
10		Manual contour key	Touch this key to manually draw the outline of bladder;
11		Undo	Touch the key to revoke the last manual mark operations;
12		Clear	In the manual contour process, touch this key to clear all manual contour operations;
13		Main	Touch the key to return to main interface;
14		Copy to U disk	Touch the key to copy data files to U disk;
15		Exit	Touch the key to exit data file interface and return to main interface;
16	OK	OK	Touch the key to carry out confirm function;
17	Cancel	Cancel	Touch the key to cancel operation;
18	Others	Numeric keys, Letter keys	Numbers or letters to be used for text input.

Chapter Four System Configuration

4.1 Typical configuration

1. Main unit	1 unit	2. 2.5MHz 3D probe	1 pc
3. Power adapter	1 pc	4. Internal battery	1 pc
5. Charger	1 pc	6. Touch pen	2 pcs

4.2 Optional parts

1. Battery 2. Foot switch
3. Verification cup

Chapter Five Operation Condition

5.1 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

⚠Warning: AC/DC adapter is as a part of the equipment, please only use the AC/DC adapter provided by manufacturer.

5.2 Operation Environment

Ambient temperature: 10℃-40℃
Relative humidity: 30%-75% (without condensation)
Atmospheric pressure: 800hPa-1060hPa
Altitude: < 2000 m
Overvoltage: Overvoltage Category Ⅱ
Pollution degree: 2

5.3 Storage and Transport

Ambient temperature: -20℃-55℃
Relative humidity: 30%-93% (without condensation)
Atmospheric pressure: 700hPa-1060hPa

⚠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.

⚠Warning: Avoid using this equipment with high-frequency electric knife, high-frequency therapy equipment or defibrillators and other electronic devices, or may an electric shock occur to the patient.

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

⚠Warning: Using radio transmitting equipment nearby the system may interfere with the normal operation of the system. Prohibited carry or use of devices that can generate radio waves within the room installed this system, such as cell phones, radio transceivers and wireless remote control toys.

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

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

Chapter Six System Installation and Check

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

⚠Warning:

1. **All plugs of instruments of this system shall be connected into the power socket with protectively earth on the wall and the socket must meet the requirement of power rating of instrument. Use of multiple portable socket-outlets may affect protective earth to make leakage currents exceed the safety requirements.**
2. **Please follow the correct electrical connections method to connect the power supply and earth, otherwise there will be danger of electric shock. Do not connect the grounding wire to any gas pipe or water pipe, or it may cause bad grounding and danger of explosion.**
3. **This equipment is not waterproof, not use this equipment in place where liquid may into the interior of the equipment. Never pour any liquid on the equipment; otherwise there will be danger of electric shock or cause equipment damage. If accidentally spill liquid on the equipment, turn off the power immediately and contact your local representative.**
4. **Additional equipment connected to the medical electrical equipment must comply with the respective IEC or ISO standards (e.g. IEC60950 for data processing equipment). Furthermore all configurations shall comply with the requirements for medical electrical systems (see IEC 60601-1-1 or clause 16 of IEC60601-1 3rd, respectively). Anybody connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above mentioned requirements. If in doubt, consult your local representative or the technical service department.**
5. **Prohibit the live parts of the equipment or other devices (such as various signal input and output ports, etc.) contact with the patient, if this equipment or other equipment has failure, the patient will have danger of electric shock.**
6. **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 operation.**
3. **It is forbidden to drag and press the power and probe cables emphatically; regularly inspect whether there is spilt and bareness, if there is the phenomena like this, turn off power supply immediately, stop using it 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.**

⚠Warning: The power adapter, power supply cord, probes, foot switch, battery and charger as described in this section be replaced by operator. But these parts must be provided by KAIXIN or his authorized supplier.

6.1 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 furnished.
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.

6.2 Probe bracket installation

The probe bracket should be mounted on the both sides of the main unit.

6.3 Ultrasonic probe installation

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

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

⚠Warning:

1. Do not use the probe not provided by our company, otherwise the equipment and the probe will cause damage, and may cause fire in extreme cases.
2. Check the ultrasonic probe and connecting cable after diagnostic operation. Use of defective probe may cause electric shock.
3. Do not strike the probe; using the damaged probe may cause electric shock to the patient.
4. Unauthorized disassembly of the probe shall be prohibited as it may cause electric shock.

⚠Attention:

1. Usually the probe should be placed within the probe bracket, not on the desktop or other support to avoid the drop.
2. Probe is a critical, precision part, do not stress, impact, or fall it. Do not pull or wring wound probe cable.
3. Turn off the ultrasonic system before disconnecting the probe. Disconnecting the probe with system power on may damage the system or probe.
4. Before disconnecting the probe, place the probe on the probe bracket in order to prevent the probe may not be damaged by unexpected fall.
5. When the instrument is power on but not in use, please make it in a frozen state, in order to increase of service life of probe.
6. Repeat available machine time should be more than 5 minutes to avoid turn on/off power supply in short time.

6.3.1 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.

⚠Attention: The red mark of connector should be aligned with the red mark on the socket when inserting the probe.

The probe is inserted the "PROBE" socket on the panel.

6.3.2 Ultrasonic probe disconnection

⚠Attention: Disconnecting the probe, do not pull the probe cable to prevent cable damage.

Shutdown the system; hold the red marked part near the probe connector, and pull out the ultrasound probe connector vertically.

6.4 Install foot switch

Shutdown the system; insert the plug of foot-switch into the "FOOT SW" socket on the back of the main unit.

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

6.5 Install/Remove the battery

1. Install the battery

Pull out the ribbon to make it a natural droop, push the battery in the battery storage and tidy up the ribbon, finally cover the "Battery cover".

2. Remove the battery

Hold down the battery-cover buckles above, and remove the battery cover, pull the ribbon and take out the battery.

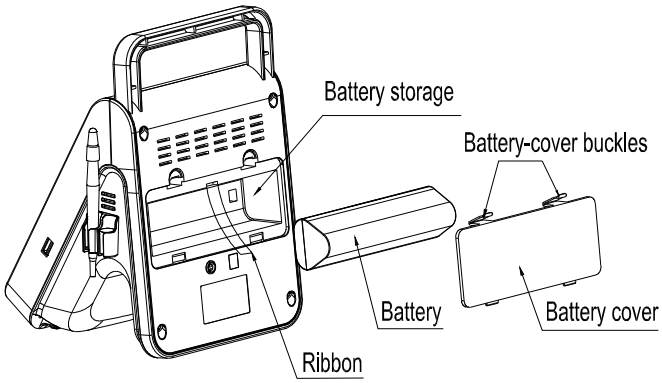


Fig. Install, Remove the battery

6.6 Connection to power

1. Connect to the power adapter

Insert the output plug of adapter into DC power input interface, which is on the back 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 line. It connects with the protective earth line when power plug inserts into the standard power socket.

⚠Warning:

1. **Adapter has no switch. APPLIANCE COUPLER or MAINS PLUG is used as the intended disconnection device from the supply mains. Do not position the EQUIPMENT the place where it is difficult to operate the disconnection device.**
2. **AC/DC adapter is as a part of the equipment, please only use the AC/DC 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/output and patient simultaneously.**

6.7 Use the touch screen

The touch screen provided with the equipment is a highly sensitive device which enables selections to be made and recorded on screen. On-screen selections should only be made by gently using a finger or the provided touch pen. Do not use a pencil, pen, or other sharp object to touch screen.

> ⚠**Attention: Care should be taken when using the equipment so that excessive force is not applied to the touch screen, as it is may become permanently damaged.**

6.8 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, disinfected or cleaned.

6.9 Main unit check before and after operation

6.9.1 Inspection before start-up

Check the following items before starting the machine:

1. The temperature, humidity and atmospheric pressure shall meet the requirements of operation condition.
2. No condensation occurs.
3. No distortion, damage or contamination on system and peripheral. Clean the parts as specified in relevant sections, if the contaminant is present.
4. Check the touch 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 cables (e.g. power cable, etc.), and not loose the connection.
6. Check probe and its connections to ensure they are free of abnormity (such as scuffing, drop-off or contamination). If the contaminant is present, clean, disinfect the contaminated objects as specified in relevant sections.
7. No barriers around the intake of equipment.
8. See to it that probe has been cleaned, disinfected; else dispose it as specified in relevant sections.
9. Examine that the foot switch functions properly is placed in a convenient location, and that the cable is free from becoming entangled.
10. Check all the ports of the machine for possible damage or blockage.
11. Clean the field and environment.

6.9.2 Inspection after start-up

Check the following items after starting the machine:

1. No abnormal voice, strange smell and overheating appear.
2. Check the machine to ensure a normal start-up: The power indication light is on and startup picture is shown on the screen. The machine will be then automatically set in B-mode.
3. Check the acoustic lens for abnormal heat when the probe is in use. This can be done by hand touching the probe to feel the temperature of the lens.
4. Check the image to ensure trouble-free display (e.g. no excessive noise or flicker).
5. Check the instrument to ensure that the phenomenon of local high 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.**

6.10 Reset

In case of abnormal screen display or no-working for system operation, turn off the power and try to restart the system.

Chapter Seven Work Main Interface

7.1 Work main interface

Press the button ⏻ on the front panel, turn on the machine, the touch screen displays the work main interface, as follows:

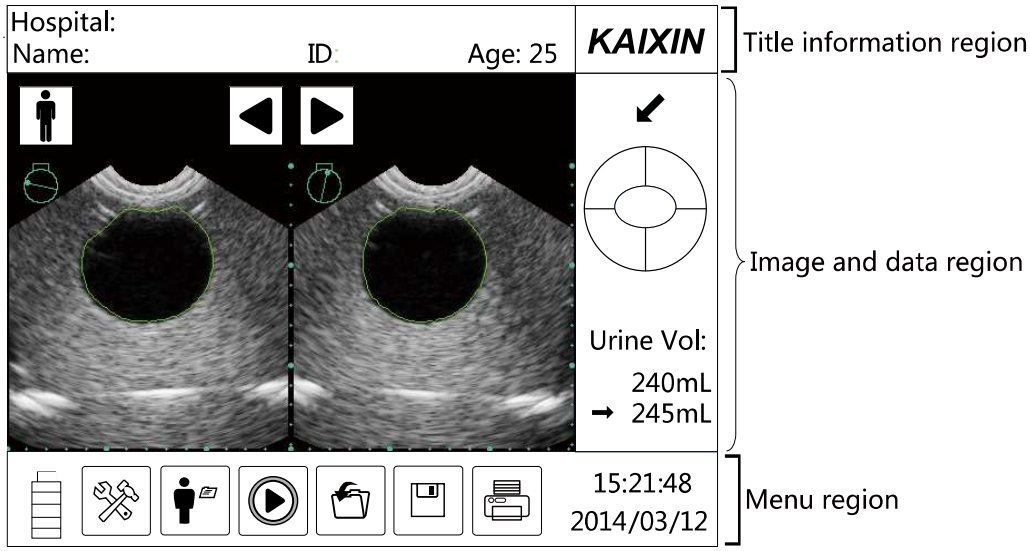


Fig. Work main interface

Work main interface shows the ultrasonic images, various parameters and the corresponding operation menus, etc. Main interface is divided into title information region, image and data region, and menu region.

7.2 Title information region

It displays the hospital name, patient information (name, ID, age), company logo, etc.

1. Hospital name
   Display hospital name. Hospital name can be edited and modified in the "System/Basic Settings".
2. Patient information
   Display the patient's name, ID and age. In the module of "New Patient", input or edit the name, ID and age for the current patient.
3. Company logo
   The company logo is shown on the top right of screen.

7.3 Image and data region

The image and data region is divided into left part and right part.

The upper part of left displays patient mode and image selection keys (◀ / ▶). Patient modes are divided into obesity mode, standard mode and child mode. Touch left or right image to enter manual contour interface, for individual complex images having large error, the doctor may choose manual contour function.

The lower part of left displays B-mode images of bladder section. Sectional images of bladder have a total of 12 frames, which are divided into six groups, each group consisting of two orthogonal images; you can switch the images by touching the keys ◀ and ▶ at the top of images. The six groups of orthogonal images are generated by the scanning planes automatically changed by 15° intervals, the upper left corner of each image displays the scanning position of bladder, respectively are  .

The right part displays the bladder projection generated by completed scanning each time, which can be used to locate the position of bladder. The projection position is closer to the center of the coordinate; the measurement results will be more accurate. The machine can simultaneously display two sets of measurements, it is convenient for doctors to compare, " ➞ " indicates the current measurement result.

7.4 Menu region

Menu region includes six function keys and displays the battery electricity, system date and time, etc.

1. System date and time

   Display the current system date and time. The adjustment of date and time, as well as the format of date can be edited and modified in the "System/Basic Settings".

2. The electric quantity of battery

   Display the remaining electric quantity of battery.

3. Six functional keys

   Six function keys respectively are system preset  , patient information  , scanning  , open data  , save data  and print  .

Chapter Eight System Preset

Touch 『  』 key, the system preset dialog box will be displayed on the screen, as below.

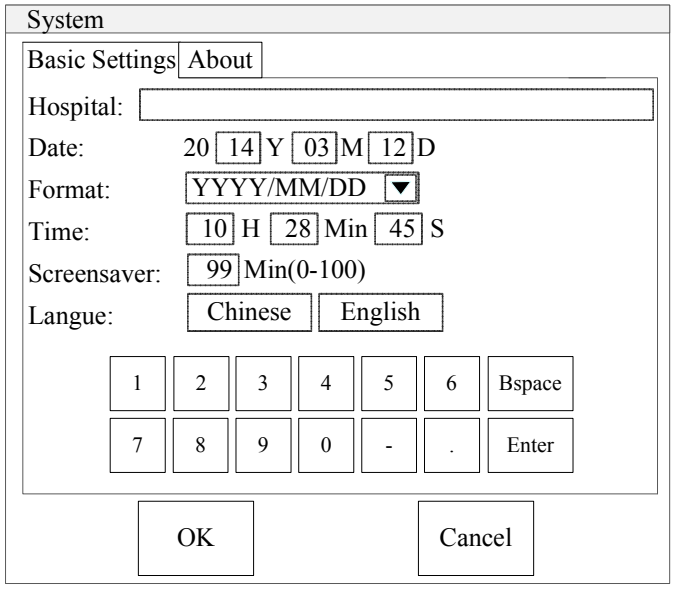


Fig. System preset dialog box

> ⚠**Attention: In the system preset interface, the contents of all input are required, if empty, touch "OK" key does not work. All parameters are entered, touch "OK" key to save the parameters and exit the system preset; otherwise touch "Cancel" key to exit system preset interface without saving the parameters.**

8.1 Basic settings

- **Set hospital name**

1. Touch the "Hospital" input box, and then pop up the "Char Input" keyboard, input the hospital name;

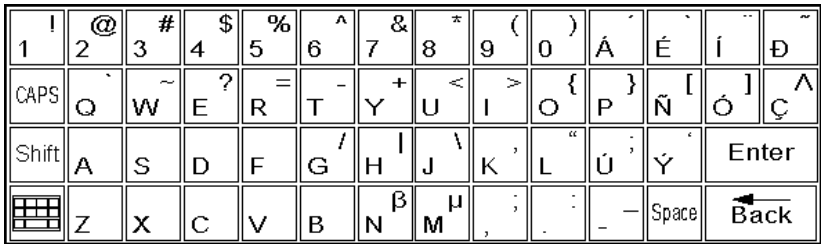


Fig. Character input keyboard

2. If needs input Chinese, touch  key to switch Chinese and English (the key is active in the Chinese version);
3. If needs revise, touch  key to delete the previous character and retype;
4. Touch the「ENTER」key on the upper right side of keyboard when finished.

- **Date, the Format of date and Time**

1. Touch the "Date" input box to confirm the cursor position, enter the "Year, Month, Day" using the following digital keyboard;
2. Touch the "Format" drop-down menu and choose the desired date format;
3. Touch the "Time" input box to confirm the cursor position, enter the "Hour, Minute, Second" using the following digital keyboard;

4. Touch Enter key on the digital keyboard to complete the entry and the cursor automatically jumps to the next input position;
5. If needs revise, touch Bspace key to delete the previous character and retype;

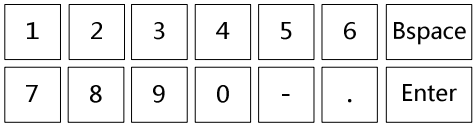


Fig. Digital keyboard

- **Screensaver time**
  1. Touch the "Screensaver" input box to confirm the cursor position;
  2. Enter the screensaver time using the digital keyboard, digitals "0-100", in minute; "0" represents turning off the screensaver time.

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

  Touch the "Chinese" or "English" to switch the langue.

All above parameters have been entered, touch 「OK」 key to save the parameters and exit the system preset; or touch 「Cancel」 key to exit system preset interface without saving the parameters.

Chapter Nine Functional Operation

9.1 Startup and Shutdown

Press the button ⏻ on the front panel, turn on the machine. If you want to turn off the machine, please press the button ⏻ again, then pull out mains plug from the supply mains.

9.2 Input patient information

1. Touch『』key, "Patient Information" dialog box will be showed;
2. Touch "Name" input box, pop up "Char Input" keyboard and input up to 16 characters;
3. Touch "ID" input box; use the below digital keyboard to input up to eight digitals;
4. Touch "Age" input box; use the below digital keyboard to input;
5. Finish inputting, touch「OK」button to save patient information and exit the dialog box;
6. Touch「Cancel」button it will give up inputting information, exit the dialog box.

9.3 Read data

1. Touch『』key, the screen displays "Open Data" dialog box;
2. Touch the drop-down menu▼ in the "Select Driver", and then choose C disk or U disk;
3. Choose the desired file in the "File" area, touch「Open File」, the screen displays the opened file; If want to open the file in the folder, first touch the folder and then touch the file in this folder;
   (1) Touch and keys on the top of image to view six groups of images stored in the data file;
   (2)Touch「」, pop up "Success" dialog box, touch「OK」, the opened data file will be copied to U disk;
   (3) Touch「」or「」key, view the stored data files;
   (4) Touch「」to print out the stored data or pictures;
   (5) Touch「」to exit "Open Data" interface.
4. Touch「Copy to U」, pop up "Success" dialog box, touch「OK」, the selected file will be dumped to "DUMP" folder in the U disk;
5. Touch「Copy All to U」, pop up "Success" dialog box after finish saving, touch「OK」, the files in C disk will all be dumped to "DUMP" folder in the U disk;
6. Select the data file in C disk or U disk, touch「Del File」, pop up warning dialog box, if touch「OK」in the warning dialog box, the file will be deleted, if touch「Cancel」in the warning dialog box, it will give up deleting the file;
7. Select the C disk, touch「Del All File」, pop up warning dialog box, if touch「OK」in the warning dialog box, the files in C disk will all be deleted, if touch「Cancel」in the warning dialog box, it will give up deleting all the file; If want to delete all the files in the U disk, please operate in the computer;
8. Touch「Cancel」key to exit the "Open Data" dialog box.

⚠Attention: When copying the data file to U disk, the system time stops until the data store is complete, the system time will automatically return to normal. Copy all files to U disk may take some time, it is recommended that user do not perform other operations.

9.4 Save data

- **Data saved to main unit**

1. Touch『  』key, the screen displays "Save Data" dialog box;
2. Touch「C:\Save Data」key, pop up "Success" dialog box after finish saving, touch「OK」, the measured data will be saved to C disk;
3. Touch「Cancel」to exit the saving data dialog box.

- **Data saved to U disk**

1. In the boot state, insert U disk to main unit;
2. Touch『  』key, the screen displays "Save Data" dialog box;
3. Touch「U:\Save Data」key, pop up "Success" dialog box after finish saving, touch「OK」, the measured data will be saved to U disk;
4. Touch「Cancel」to exit the saving data dialog box.

- **Screen copied to U disk**

1. In the boot state, insert U disk to main unit;
2. Touch『  』key, the screen displays "Save Data" dialog box;
3. Touch「U:\Save Img」key, pop up "Success" dialog box after finish saving, touch「OK」, the screen content will be saved to U disk;
4. Touch「Cancel」to exit the saving data dialog box.

Explanation:

1. **Touch「U:\Save Img」to save image in bmp format and the bmp file can be opened in the computer.**
2. **Touch「C:\Save Data」or「U:\Save Data」to save DAT file and the DAT file can only be opened on this equipment. Each DAT file includes 6 sets of orthogonal images.**
3. **C disk can store max 100 DAT files.**
4. **When data or picture saved to U disk, if have entered patient ID, data or picture will be saved in the folder (patient ID is the folder name); if not enter patient ID, data or picture will be saved in the "USER" folder, the file name will be automatically generate according to the current date and time, file name is "y*##xzzn.DAT" or "y*##xzzn.BMP".**
5. **File name: one bit "y" represents the check year; one bit "*" represents the check month; two bits "##" represent the check date; one bit "x" represents the check time (hour); two bits "zz" represent the check time (minutes); one bit "n" represents the check time (seconds). Month is expressed by the digital 1 to 9 and the letters ABC in turn; 24hours are expressed by the digital 1 to 9 and the letters A to O in turn.**

   Such as:

   U:\123\4312934A.DAT (has entered ID)

The data file is saved in the "123" (patient ID) folder of U disk, which is saved at 9:34:21 on March 12, 2014.
U:\USER\4A12948B.BMP (not enter ID)

If not enter patient ID, the data file is saved in the "USER" folder of U disk, which is saved at 9:48:22 on October 12, 2014.

⚠Attention:

1. **Turn on the machine and then insert U disk.**
2. **Operating U disk should allow sufficient storage time to prevent the files are missing.**
3. **U disk storage should be concerned about the free space to prevent the invalid storage.**
4. **When saving the data file or images, the system time stops until the store of data or images is complete, the system time will automatically return to normal.**

9.5 Thermal print

Touch 『  』 key to print out the results through the thermal printer.

⚠Attention: If there is no thermal paper, please replace the thermal paper.

Chapter Ten Bladder volume measurement

10.1 Scanning and positioning bladder

The correct positioning of bladder is the basis of accurate measurement of bladder volume. Bladder is located in the lower abdomen, below the pubic symphysis. Before the examination, apply ultrasound coupling gel on the subject, place the probe in accordance with the position of probe shown in the figure below, **note that the direction of scanning key on the probe toward the subject's head.**

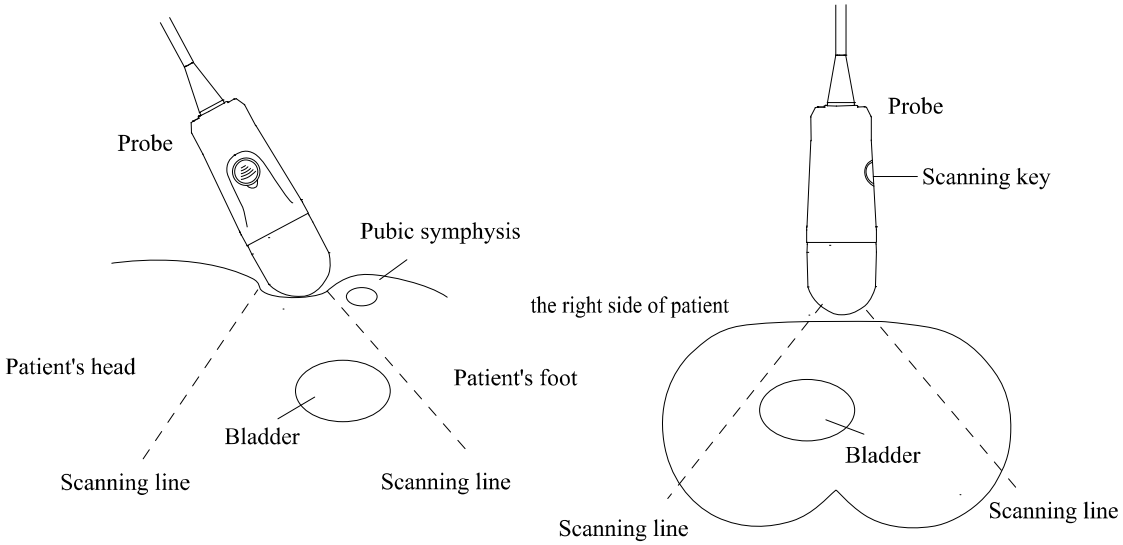


Fig. Probe position

To determine the correct measurement position, the right side of touch screen displays the bladder projection. If the projection was nearly round, basically in the center and not beyond the scanning border (shown in Fig B), it indicates that the position of probe is correct and the volume is valid; otherwise it should adjust the position of probe and re-measurement.

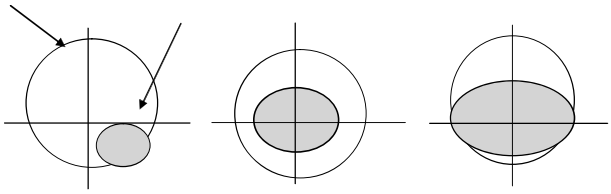


Fig. A Fig. B Fig. C

Fig. Projection position sketch map

Figure A shows: bladder projection obviously deviates from the centerline of the test, which is located in the lower right of the centerline of the probe. The measured data is not accurate, it need to adjust the angle and position of probe, and re-measurement.

Figure B shows: bladder projection basically locates in the center of test area, which was approximately round and does not exceed the scanning boarder. The bladder volume is valid.

Figure C shows: bladder projection is beyond the border, the test data is small, it need to adjust the angle and position of probe, and re-measurement.

The system will automatically identify the border of bladder and calculate the cross-sectional area and volume. The green trace in the image is the border of bladder.

10.2 Operation processes

1. The subject was held in a supine position, so that the abdominal muscles to relax. First find the pubis, and then apply an amount of ultrasound coupling gel on the pubic above 3cm from the center of the abdomen (air bubbles as few as possible);

2. Place the probe towards the direction of tailbone, press the scan key on the probe or touch the key on the touch screen to scanning the image;
3. Touch patient mode key to select the desired mode: standard mode, obesity mode and child mode;
   Description: Child mode is generally applicable to children for 6-12 years old. Excessive weight and height of children can choose the standard mode.
4. After accurate positioning the bladder, press the scan key on the probe or touch the key on the touch screen to freeze the image, the system will generate 12 frames cross-sectional area and automatically draw the border of boarder, also show the bladder volume;
5. Confirm the scanning results.
   (1) If appears orange arrow above the projection, it indicates the measurement result is unacceptable, the probe must be moved according to the arrow direction and re-scan to measure again;
   (2) If appears green arrow above the projection and displays the symbol ">" or "<" in the measurement result, it indicates the measurement result is too small or too large but it is acceptable, you need to slightly adjust the direction of probe and re-scan to measure again;
   (3) If no arrow appears above the projection, it indicates the measurement result is correct.
6. If appear the longer spikes or unclosed gap on the projection of bladder, touch the patient mode key on the screen to optimize the edges of the image, the projection will be automatically optimized and bladder volume will be automatically updated after processing.
7. If the measurement error is large, you can enter manual contour interface to observe the images of large error to carry out manual contour, and then return to the main interface;
8. Touch key to save the patient measurement results;
9. Touch key to print the patient measurement results.

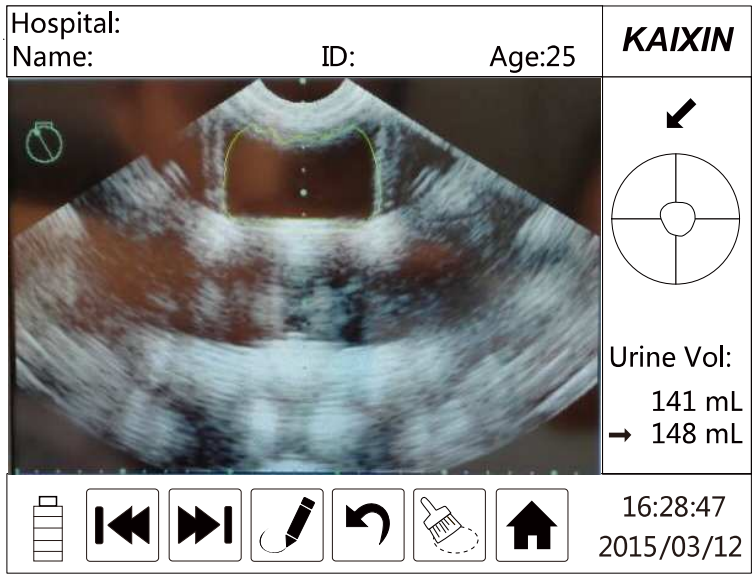
⚠**Attention: To ensure the accurate measurement, please make sure:**
1. **There is no air gap between the probe and the patient's skin when scanning, and use appropriate pressure to keep the contact with the patient's skin;**
2. **The stability of machine when scanning, avoid shaking cause the measurement error;**
3. **There is no catheter in the patient's bladder, the presence of catheter may affect the accurate measurement of bladder volume.**

10.3 Manual contour

Due to the complexity of the patient population, as well as higher demands on accuracy by doctors, the system provides the manual contour function.

For individual complex images having large error, the doctor can choose manual contour.

Directly touch large error image to enter manual contour interface, as follows:



Operation steps:

1. In the main interface, touch keys and to select the image which has a great error;
2. Directly touch left or right image which have large error to enter manual contour interface;
3. Touch key, the icon color will from green to orange, it will begin to manually contour;
4. Draw the points along with the border of bladder, it will automatically connect between points; if the position of point is not correct, you can touch key to cancel each connection step by step, or touch key to erase all connections, re-draw the line;
5. Touch key again, the first point and the last point will be automatically connected to form a closed region, and the bladder volume will be automatically displayed on the right side of the current measurement result;
6. Touch key to return to the main interface.

Note:

(1) Draw lines must be in a clockwise to form a close region, draw lines can not cross.

(2) The point number shall not less than three, but not more than 32.

Chapter Eleven Principle of Sound Power

11.1 Biological effect

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

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

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

11.2 Mechanical effect and thermal effect

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

11.3 Prudent-use statement

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

11.4 ALARA (as low as reasonably achievable) principle

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

Not all diagnosis can be done with extra-low ultrasonic energy output. The extra-low ultrasound power produces poor-quality image or weaker Doppler signal that may reduce the diagnostic reliability. On the other hand, use of sound power larger than diagnostically required makes no more contribution to improvement of the diagnostic information quality and increase the risk of biological effect possibility.

Therefore, user of the diagnostic ultrasound shall be fully aware of the patient's safety and choose a proper output level for a specific purpose based on ALARA principle.

11.5 The limits of acoustic output

When using any probe match in each mode, the acoustic output parameters for thermal index and mechanical index are below 1.0.

11.6 Factors impacting sound power

Because the settings (transmission voltage, transmission frequency, etc.) are fixed in this system, there are no factors impacting sound power.

11.7 Image control impact on sound power output

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

Operation	Influence on sound power output
Freeze	If freeze function makes the power transmission part of system stop operation, the system will not be able to transmit the ultrasound.
Depth change	The different patient mode selects different depth; it will change the acoustic power.
Restart or turn off/on power	Turn off/on the power will set the system in default status and change the sound power output.

Chapter Twelve 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.

Under normal circumstances, a routine consideration of the general inspection for the probe and the functional verification is a good practice and may help to avoid major problems in the future.

12.1 Inspection and verification by users

12.1.1 Probe general inspection

1. The probe should be checked before use for any visible damage;
2. Always check the cable for frayed or broken wires which may interfere with the proper functioning of the probe;
3. When connecting the probe to the instrument, the red mark of connector should be aligned with the red mark on the socket.

12.1.2 Machine functional verification

The system provides a verification cup, used to verify that the performance of machine is normal.

The usage for the verification cup:

At 29 ± 1 ℃ ambient temperature, slowly along the wall of the verification cup to filled with sodium chloride injection (0.9%), stand for a few minutes until no bubbles, handheld probe vertically into the verification cup, keep the probe steady and do not tilt (see figure below), touch patient mode key to select the standard mode, and press the scan key on the probe or touch the key on the touch screen to scanning the image, three times repeated measurements. If the measurement result is within the range of 140ml ± 15%, then prove that the machine performance is normal.

12.2 Maintenance by users

12.2.1 System cleaning and disinfection

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

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

⚠Attention:

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

⚠Attention:

1. In the process of cleaning and disinfection, avoid probe overheat (exceeding 60℃) as it may be deformed or damaged 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 probe is IPX4, immersion depth as shown below. Below 5mm metal ring can be immersed in liquid.

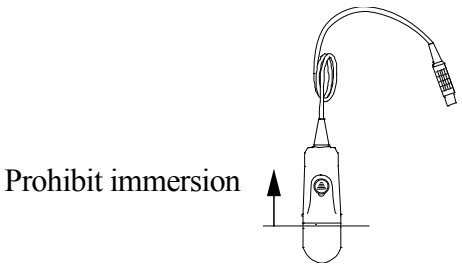


Fig. Probe regular disinfection

⚠Attention:
1. It is a normal phenomenon that color of the acoustic lens may change and color of the probe label may fade away.
2. 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.

12.2.2 Clean the probe socket

1. Clean the probe socket with soft, dry cloth;
2. In case of die-hard blots, clean with soft cloth dipped in moderate detergent and then air-dry it.

12.2.3 Clean the touch screen

Clean the liquid crystal display with dry, soft flax or anti-static LED clean cloth.

⚠Attention: Do not clean the screen with hydrocarbon detergent such as alcohol or OA equipment cleaning media.

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

12.2.4 Clean the foot switch

1. Use the soft dry cloth to wipe the 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.

12.2.5 Clean the 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.

12.2.6 Clean the thermal printer

When appeared unclear handwriting after the thermal printer used for some time, according to the following steps to clean the print-head.

1. Remove the paper from the print-head, raised its head to expose the print-head piece;
2. Clean the dirt on the heating element surface of the print-head piece with a clean cotton swab dipped in a little alcohol. Remember not to use hard objects to clean such as sandpaper, blade or screwdriver; otherwise it would permanently damage the print-head piece.
3. Clean the print-head piece and then air-dried.

12.3 Replace the thermal paper

Built-in printer is the thermal printer, which uses thermal paper. If the thermal paper needs to be replaced, you can purchase in accordance with the company's specified model (57*40mm).

Replacement of thermal paper:

1. Turn off the main unit;
2. Press the "PUSH" button on the front panel to open the cover of thermal printer;
3. Hold down the round button to open the thermal printer's front cover, remove the remaining paper core from the paper washhouse;
4. Put the new thermal paper into the center position, the thermal paper exposing the paper warehouse 3cm, and then close the front cover.

⚠Attention:

1. **When closing the front cover, make sure that the paper exposed a section from the paper exit, allow the roll axis to fully suppress the paper, otherwise it can not be printed.**
2. **When placing thermal paper, make sure that the thermal coating of thermal paper on the top, and then put the thermal paper into the paper washhouse. If the thermal coating is not on the correct surface, the writing will not be printed. If the paper appears deviation, you can re-open the front cover and adjust the paper position.**
3. **Note that when replacing the thermal paper if there is paper, dust on the print-head, if has gently removed it.**

12.4 Replace the fuse

Replace the fuse is to replace the power adapter.

⚠Attention:

1. **The fuse is inside the power adapter. Fuse shall be replaced by qualified service personnel who get Kaixin approval.**
2. **Before replacing the fuse, please contact Kaixin and replace it under the guidance of Kaixin.**
3. **Before replacing the fuse, you must disconnect the mains supply from the mains supply.**
4. **Fuse Type: T3.15AH250VAC.**

12.5 Use and maintenance for the rechargeable battery

1. The battery pack (model RK-HYLB-1676) is charged within main unit or with charger (model RKU10) provided by Kaixin Company. Service personnel or operator can replace the battery pack.
2. Plug the output port of adapter into the input port of charger to charge the battery; the charging time is about 5 hours. Over-charging or discharging will shorten the battery life; the full charged battery usually can be used for 7 hours.
3. Battery is consumable; the battery cycle-life is based on the times of charge and discharge as unit. When the use time reduced significantly compared with normal conditions, the battery should be promptly replaced.
4. The excess high or low temperature will affect the charging and discharging performance, and short the battery life and capacity.

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

⚠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 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;**
13. **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;**
14. **Remove the battery from the near fire if the battery leaks or emits an odor, otherwise electrolyte leakage may cause a fire or explosion;**
15. **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;**
16. **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;**
17. **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 is consumable; the battery cycle-life is based on the times of charge and discharge as unit. When the use time reduced significantly compared with normal conditions, the battery should be promptly replaced.

⚠Attention: A battery indicator "[battery]" will appear on the screen when the electric quantity of battery is too low. Connect the main unit to external power supply and recharge the battery, or turn off the machine to recharge.

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

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

12.6 Replacement of power supply cord

Before replacing the power supply cord, please contact Kaixin Company; replace the power supply cord under the guidance of Kaixin Company. Please use the power supply cord provided by Kaixin Company.

12.7 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 does not illuminate and screen has no display when starting the machine.	1. Check power supply. 2. Check power cable and plug. 3. Check power adapter.
Ultrasonic image is not displayed 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.	1. Check power supply.(spark interference present) 2. Check environment. Interfering source of around the machine, such as electric motor, ultrasonic atomizer, automobile, computer or other interference (Electromagnetic interference present around the machine). 3. Check power plug/socket of the instrument or probe connectors. They shall be properly contacted.
Paper does not advance in printer.	Reload the paper in printer.
Thermal printer has started printing, but no display on paper	Thermal paper may be anti-loaded, reload the paper.
No ultrasonic data are displayed on the screen.	Probe is not properly connected. Turn off the power and reconnect the probe.
Control panel malfunction	Should shutdown and reboot the system after a few seconds.

12.8 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 essential performance, including the ultrasound energy output and probe's surface temperature.
   - Inspect the safety relevant labels for legibility.
   - Inspect the fuse to verify compliance with rated current and breaking characteristics.
   - Verify that the device functions properly as described in the instructions for use.

- Test the protection earth resistance according to IEC 60601-1: Limit: 0.1Ω.
- Test the earth leakage current according to IEC 60601-1: Limit: Normal Condition 500μA, Single Fault Condition: 1000μA.
- Test the touch current according to IEC 60601-1: Limit: Normal Condition 100μA, Single Fault Condition: 500μA.
- Test the patient leakage current according to IEC 60601-1: Limit: for a.c.: 100μA for d.c.: 10μA
- Test the patient leakage current under single fault condition with mains voltage on the applied part according to IEC 60601-1: Limit: for a.c.: 500μA for d.c.: 50μA.

The leakage current should 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.

12.9 Essential Performance Checks

In the cause of using the instrument, due to electromagnetic disturbance making the instrument generate artifacts or distortion in an image or error of a displayed numerical value; or making the instrument generate the display of incorrect numerical values associated with the diagnosis to be performed; or making the instrument generate the production of unintended or excessive ultrasound output; or making the instrument generate the production of unintended or excessive transducer assembly surface, should go to a qualified testing organization for IEC 60601-1-2 test.

Chapter Thirteen Storage and Transportation

1. If the instrument is stored over 3 months, take out the instrument from the packing case, connect it to power supply for 4 hours, and then disconnect the power and place it in the case again following the direction indicated by arrows on the package. Store the case in the warehouse. Do not pile the case. The instrument case should have adequate space from ground, walls and ceiling of the warehouse.
2. Environment requirement
   Ambient temperature: -20℃－55℃; 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 Fourteen Standard Compliance

The compliant standards are listed below:

2007/47/EC
EN ISO 14971:2012
EN 60601-1:2006+A1:2013+A2:2014
EN 60601-2-37:2008 +A1:2011
IEC 60601-1-2:2007
EN ISO 15223-1:2012
EN 1041/A1:2013
EN ISO 10993-1:2009
EN ISO 10993-5:2009
EN ISO 10993-10:2013

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 IEC 60601-1-2

⚠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.**

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

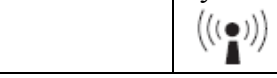
The equipment is intended for use in the electromagnetic environment specified below. The customer or the user shall assure that they are used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	This equipment uses RF energy only for their internal function. Therefore, their 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 may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **Warning:** This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the equipment or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

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

The equipment is intended for use in the electromagnetic environment specified below. The customer or the user should assure that they are used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for signal lines	± 2 kV for power supply lines ± 1 kV for signal lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	＜5%U_T (＞95%dip in U_T) for 0.5 cycle 40%U_T (60%dip in U_T) for 5 cycles 70%U_T (30%dip in U_T) for 25 cycles ＜5%U_T (＞95%dip in U_T) for 5 sec	＜5%U_T (＞95%dip in U_T) for 0.5 cycle 40%U_T (60%dip in U_T) for 5 cycles 70%U_T (30%dip in U_T) for 25 cycles ＜5%U_T (＞95%dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Mains power quality should be that of a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Table 3 - Guidance and manufacturer's declaration—electromagnetic immunity

The equipment is intended for use in the electromagnetic environment specified below. The customer or the user should assure that they are used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V_{rms} 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	$1V_{rms}$ 1V/m	Portable and mobile RF communications equipment should be used no closer to any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=[3.5/V_1]\sqrt{P}$ $d=[3.5/E_1]\sqrt{P}$ 80MHz to 800MHz $d=[7/E_1]\sqrt{P}$ 800MHz to 2.5GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strength from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80MHz and 800MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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.

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

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.

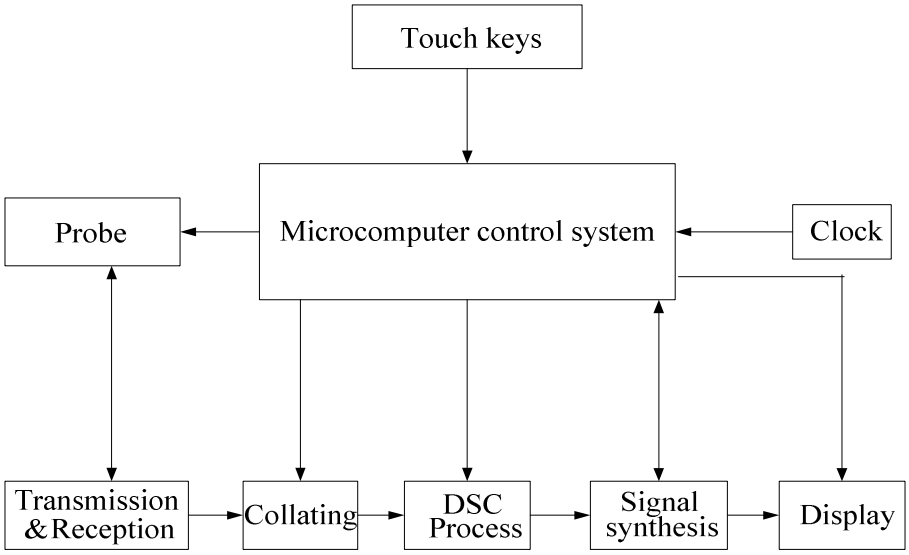
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter**		
	150 kHz to 80 MHz $d=[3.5/V_1]\sqrt{P}$	**80 MHz to 800 MHz** $d=[3.5/E_1]\sqrt{P}$	**800 MHz to 2.5 GHz** $d=[7/E_1]\sqrt{P}$
0.01	0.35	0.35	0.7
0.1	1.1	1.1	2.21
1	3.5	3.5	7
10	11	11	22.13
100	35	35	70

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.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Appendix A: System Block Diagram



Appendix B: Acoustic Output Data Disclosure

Pursuant to the provisions of EN 60601-2-37 "Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment", acoustic output data disclosure as follows:
In the acoustic output measurement data, the MI uncertainty is 12%, TI uncertainty is 23%.

Manufacturer: Xuzhou Kaixin Electronic Instrument Co.,Ltd.
Product Name: Bladder Volume Tester

Test Mode: B-Mode **Probe Type: 2.5S120M1** **Probe No.: 1503008**

Index Label				*MI*	*TIS*			*TIB*	*TIC*
					Scan	Non-scan		Non-scan	
						$A_{aprt} \leq 1cm^2$	$A_{aprt} > 1cm^2$		
Maximum Index Value				0.37	0.017	-	-	-	-
Associated Acoustic Parameters	p_{ra}		(MPa)	0.61					
	P		(mW)		1.3	-		-	-
	Min. of $[P_\alpha(z_s), I_{ta,\alpha}(z_s)]$		(mW)				-		
	z_s		(cm)				-		
	z_{bp}		(cm)				-		
	z_b		(cm)					-	
	z at max. $I_{pi,\alpha}$		(cm)	5.4					
	$d_{eq}(z_b)$		(cm)					-	
	f_{awf}		(MHz)	2.78	2.78	-	-	-	-
	Dim of A_{aprt}	X	(cm)		0.82	-	-	-	-
		Y	(cm)		1.02	-	-	-	-
Other Information	t_d		(μsec)	0.724					
	prr		(Hz)	760					
	p_r at max. I_{pi}		(MPa)	1.03					
	d_{eq} at max. I_{pi}		(cm)					-	
	$I_{pi,\alpha}$ at max. MI		($\mu J/cm^2$)	9.06					
	Focal Length	FLx	(cm)	-	-	-	-	-	-
		FLy	(cm)	-	-	-	-	-	-
Operating Control Conditions	Frequency (MHz)			2.5	2.5	-	-	-	-
	Default setting			✓	✓	-	-	-	-

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