Bladder Volume Tester
Operation Manual

Introduction

Thank you for purchasing MSLPU43 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.

The use^s manual issue date: September 19, 2016, Version: V1.01

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

Intellectual Property Information

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Statement

Medsinglong has the final explanation right of this use^s manual.

Medsinglong was considered responsible for the safety, reliability and performance in case of meeting all the following requirements:

1. Assembly, expansion, readjustment, improve and repair are all performed by professionals recognized by Medsinglong ;
2. All replacement parts and accessories, consumables involved repairs are Medsinglong company (original) or approved by Medsinglong ;
3. Related electrical equipment complies with national standards and the requirements of the use^s manual;
4. Operate the product in accordance with the use^s manual.

Warranty and repair service

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

The qualified service personnel who get Medsinglong written authorization can repair the instrument out of warranty by themselves. But this should be agreed by Medsinglong Global Group 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.

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:

   Damage or loss caused by error or rough using.

   Damage or loss caused by force majeure (such as fires, earthquakes, floods, or lightning etc.).

   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.

   Damage or loss caused by not used the system in the initial buy region.

   Damage or loss caused by the system purchased not by Medsinglong 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, Medsinglong shall not be liable for the problems, damages or losses due to re-installation, alteration

or repair the system by non-Medsinglong designated personnel.

6. This product is intended to provide clinical diagnostic data for the doctor.
   The doctor shall be responsible for the diagnostic process. Medsinglong 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 operators error or abnormal condition causing the data stored in the internal system is lost, Medsinglong is not responsible.
9. This use^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. Medsinglong shall not be liable for the damages and losses arising out of neglecting to follow the operation instructions herein described.
10. This use^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 use^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 Medsinglong Global Group Co., Ltd
13. Professional engineer mentioned in the use^s manual is the person who has been trained and authorized by Medsinglong Global Group Co., 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 use^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
火	Type B applied part	rtf	Up
–	Direct current	厂-n 半-	Keep dry
(1)	Power switch	r	Fragile
来	Power supply indication	⌈r	Stacking limit by number
	Adapter connection indication	aiti	Temperature limits (Storage and transport)
1	Battery charge indicator	r	Humidity limitation (Storage and transport)
o	Follow instructions for use		Atmospheric pressure limitation (Storage and transport)
X	Marking for the separate collection of electrical and electronic equipment		

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) Introduction

MSLPU43 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.

MSLPU43 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 MSLPU43 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").

MSLPU43 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:

10.2.1 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.

10.2.2 Electromagnetic disturbance does not make the instrument generate the display of incorrect numerical values associated with the diagnosis to be performed.

10.2.3 Electromagnetic disturbance does not make the instrument generate the production of unintended or excessive ultrasound output.

10.2.4 Electromagnetic disturbance does not make the instrument generate the production of unintended or excessive transducer assembly surface.

(2) Intended Use

MSLPU43 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

6.2 Technical data

1. Monitor: 3.5" LCD
2. Adapter rating: 100-240V~，1.2-0.6A, 50-60Hz (model: BJE01-40-001M)
3. Output of adapter: DC12.8V 3.0A
4. Main device rating: DC12V 3.0A
5. Main Unit Size: approx. 90 * 98 * 25 (L * M * H，mm)
6. Weight of main unit: approx. 750g (including battery and probe)

6.2 Primary functions

7.3.1 System date and time setting function.

7.3.2 Probe protection function.

7.3.3 Energy saving.

7.3.4 Alarm volume prompt function.

7.3.5 Image contrast adjustment function.

7.3.6 Patient type selection function.

7.3.7 Urine volume measurement function.

7.3.8 Store images in the U disk.

7.3.9 Display date and time，battery electricity.

7.3.10 Switch Standard-Lite function.

7.3.11 Switch Chinese-English function.

6.2 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

1. Structure composition of the instrument

MSLPU43 bladder volume tester is composed of main unit, probe, etc.

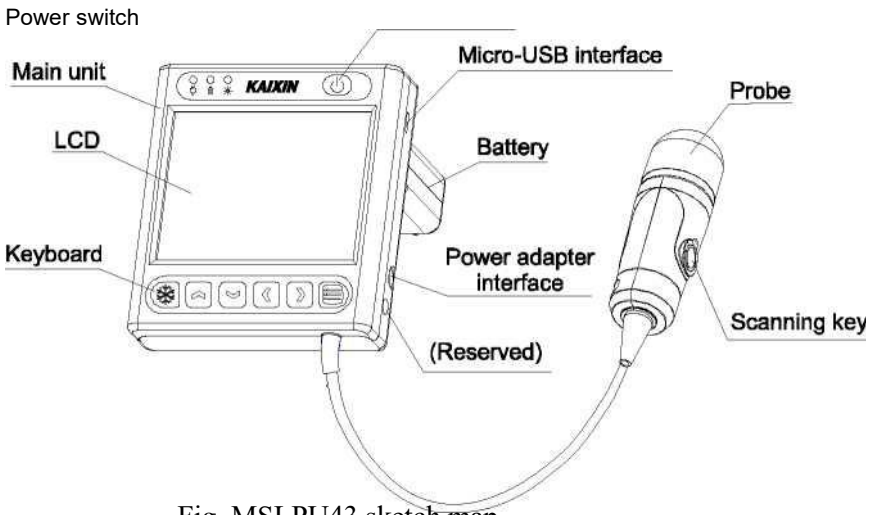


Fig. MSLPU43 sketch map

2. Components name

3. Parts of the probe

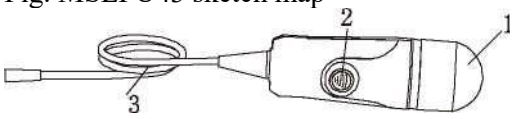


Fig. Parts name of 2.5MHz probe

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

3.4 Function keys description

SN.	Key symbol	Key name	Key function
1	(6)	Power switch	Turn on or turn off the power of main unit
2		Freeze key	Press the key to freeze/unfreeze the image
3	___	Menu key	In frozen status, press the key to enter system preset interface
4	OO	Direction key	1. In real-time mode, press the up direction ke^Dto select the desired patient type; 2. In real-time mode, press the down direction ke^3to adjust the contrast of the image; 3. In image frozen status, insert U disk, press the down direction ke^3to store image. 4. In image frozen status, press the left/right direction keys ® Oto switch displaying six groups of orthogonal images; 5. In the system preset interface, press the left/right direction keys® Oto select the system preset item, and then press up/down direction keys to adjust the parameter of the item.

Chapter Four System Configuration

4.1 Typical configuration

1. Main unit	1 unit	2.5MHz 3D probe	1 pc
3. Power adapter	1 pc	1. Internal battery	1 pc
5. Portable bag	1 pc	6. OTG U disk	1 pc

4.2 Optional parts

1. Verification cup 7.2.1 Plastic seal box

Chapter Five Operation Condition

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.

2. Operation Environment

Ambient temperature: 10DC-40DC Relative humidity: 30%-75% (without condensation) Atmospheric pressure: 800hPa-1060hPa Altitude: < 2000 m

Overvoltage: Overvoltage Category II Pollution degree: 2

3. Storage and Transport

Ambient temperature: -20C-55C
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:

Splash weather 2. Moist 3. Rain 4. Thunderstorm
10.2.5 **No ventilation 6. Dust 7. Close to heat source 8. Direct sunlight**
9. Dramatic temperature change 10. Chemical medicines 11. Poisonous gas
7.3.12 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.

△W: arning:

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.

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.

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.

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.

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.

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 Medsinglong 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 and battery as described in this section are replaced by operator. But these parts must be provided by Medsinglong or his authorized supplier.**

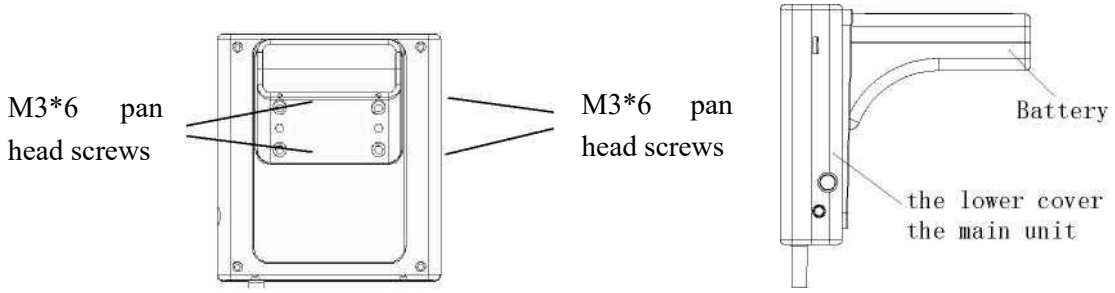
System placement

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.

Install/Remove the battery

According to the schematic diagram, fix the battery on the lower cover of the main unit with four M3*6 pan head screws. When removing the battery, use a screwdriver to unscrew the four M3*6 pan head screws, remove the battery.



Battery installation and removal schematic

arning: Do not short-circuit the battery terminals.

Connection to power

6.1 Connect to the power adapter

Insert the output plug of adapter into DC power input port, which is on the right side of main unit.

6.2 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:

5.1 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.

5.2 AC/DC adapter is as a part of the equipment, please only use the AC/DC adapter provided by Medsinglong Company.

5.3 To avoid damaging power adapter or harming people by unexpected fallen, make sure the power adapter is placed on the leveled desk.

5.4 The operator must not touch signal input/output and patient simultaneously.

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.

Main unit check before and after operation

1. **Inspection before start-up**

Check the following items before starting the machine:

The temperature, humidity and atmospheric pressure shall meet the requirements of operation condition.

No condensation occurs.

No distortion, damage or contamination on system and peripheral. Clean the parts as specified in relevant sections, if the contaminant is present.

Check the keyboard, LCD screen and enclosure to ensure they are in good working condition and free of abnormity (such as cracks and loosened screws).

No damage on cables (e.g. power cable, etc.), and not loose the connection.

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.

See to it that probe has been cleaned, disinfected; else dispose it as specified in relevant sections.

Check all the ports of the machine for possible damage or blockage.

Clean the field and environment.

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; 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 (e.g. no excessive noise or flicker).
5. Check the keyboard to ensure normal operation condition.
6. 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.

6.6 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 Functional Operation

(1) **Startup and Shutdown**

In shutdown status, hold down CS) key at the top of the screen, machine starts up, power indicator # lights.

In startup status, hold down (S) key, machine shuts down, power indicator 来 goes out.

(2) **Work main interface**

1. Real-time work interface

or

Turn on the machine; the system will enter frozen status, press the scanning key@*on the probe ^ press the keyCDon the keyboard to unfreeze the image, the system enters real-time work interface.

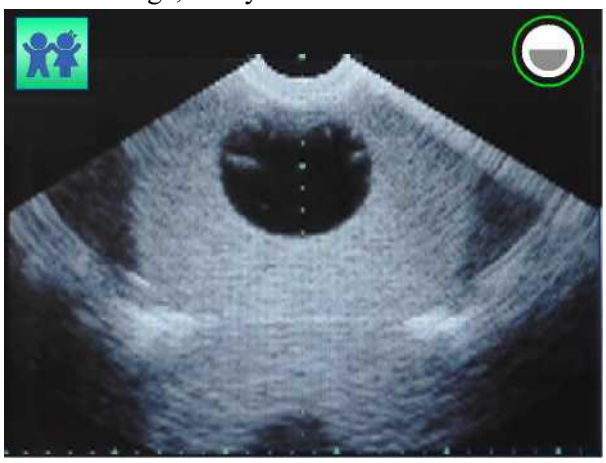


Fig. Real-time work interface

In real-time status, the work interface displays a large B-mode image, patient type icon and image contrast icon.

In real-time status, press the up direction ke^^Jto select the desired patient type: standard modeU obesity mod^^and child mode 轉.The patient type icon is shown in the upper left corner of the image.

In real-time status, press the down direction key 二 to adjust the contrast of the image: Hig^^l, Mediu^^-4and Lo^^l. The contrast icon is shown in the upper right corner of the image.

2. Frozen work interface

In real-time status, press the scanning key®^on the probe or press the keyCDon the keyboard to freeze the image, the system enters frozen work interface, a schematic diagram is shown below:

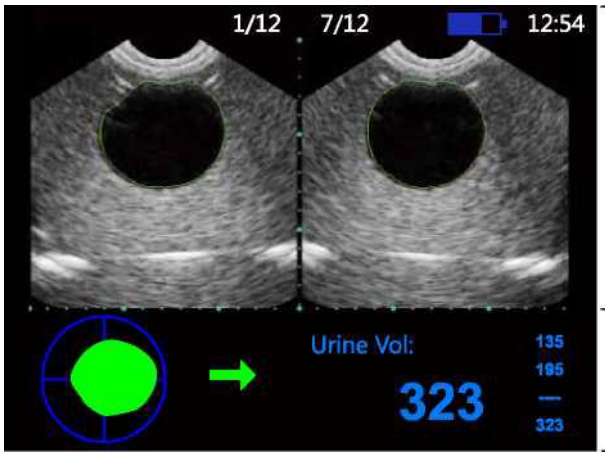


Fig. Frozen work interface

The work interface displays the B-mode images of bladder section and measured result. The work interface mainly is divided into image display area and measured result display area.

consisting of two orthogonal images; you can switch the images by pressing the keys^C (3on the keyboard. The six groups of orthogonal images are generated by the scanning planes automatically

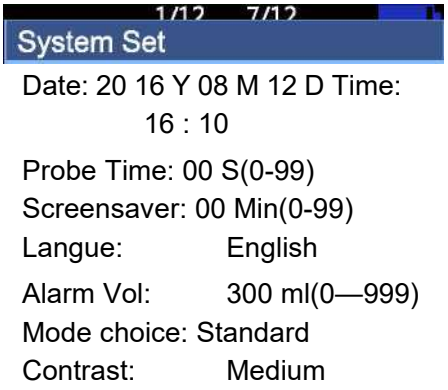
The image display area displays the system time, the remaining battery electricity and 12 sectional images of the bladder. Among them, the system time can be modified in the "System Set". Sectional images of bladder have a total of 12 frames, which are divided into six groups, each group

changed by 15° intervals, the number of frames corresponding to an image is shown above each image.

In the measured result display area, displays the bladder projection scanned by the probe 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 four sets of measured results; it is convenient for doctors to compare. The current measured result is always shown at the bottom.

7.3 System set

In frozen status can be set as follows:



1. Date setting

1. PressB^key to enter "System Set" menu;
2. PressElorElkey to move the cursor to "Date" item, and then pressL^Jor date; key to adjust the
3. PressB^key to confirm the date setting and quit system setting interface.

2. Time setting

10.1 PressB^key to enter "System Set" menu;

10.2 PressElorElkey to move the cursor to "Time" item, and then press or time; key to adjust the

10.3 PressBkeyto confirm the time setting and quit system setting interface.

3. Probe protect time setting

PressB^key to enter "System Set" menu;

PressElorElkey to move the cursor to "Probe Time" item, and then press the probe protect time;

Probe protect time is "0-99" seconds, "0" stands for turn off the probe protection; or key to adjust

PressBkeyto confirm this setting and quit system setting interface.

Note: For example, the probe time is set to 10 seconds; in real-time status, after the system reaches 10 seconds, the probe will automatically start scanning bladder function. If set to 0, the probe does not automatically start scanning.

4. Screensaver setting

1. PressB^key to enter "System Set" menu;

2. PressE)orl3key to move the cursor to "Screensavef ' item, and then pressE- or^3key to adjust the screensaver time;

3. Screensaver time is "0-99" minutes, "0" stands for turn off the screensaver;

4. PressBkeyto confirm this setting and quit system setting interface.

Note: Go beyond the system setting screensaver time without pressing any key, the machine will automatically enter a black screen status. Press any key, the system will return to normal operation status.

5. Chinese-English setting

(1) PressB)key to enter "System Set" menu;

(2) PressElorElkey to move the cursor to "Langue" item, and then pressE> or key to choose Chinese or English;

(3) PressBkeyto confirm this setting and quit system setting interface.

6. Alarm volume setting

10.1.1 PressB)key to enter "System Set" menu;

2. PressE)orl3key to move the cursor to "Alarm Vol" item, and then press the or key to adjust value; Values are adjusted in steps per 5ml;

6.3 The range of alarm volume is "0-999" milliliter (ml), the default value is 300ml;

6.4 PressBkeyto confirm this setting and quit system setting interface.

Note: When the measured bladder volume exceeds the set alarm volume, the machine will issue continuous "Didi" alarm tone; if not exceeds the set volume value, the alarm tone will not appear.

7. Mode setting

PressB^key to enter "System Set" menu;

PressElorElkey to move the cursor to "Mode choice" item, and then press △or the key to select Standard or Lite;

PressBkeyto confirm this setting and quit system setting interface.

Note: For more information on the Standard and Lite, see section 8.2 Operation processes.

8. Contrast setting

1. PressB)key to enter "System Set" menu;
2. PressElorElkey to move the cursor to "Contrast" item, and then pressE> or key to select the contrast of the image;
3. The contrast of the image is divided into Hig^^, Mediu^^^ and Lo^^^, the default is Medium;
4. PressOkey to confirm this setting and quit system setting interface.

7.4 Image storage and viewing

(1) **Image storage**

1. Insert OTG U disk into the Micro-USB interface at the right side of main unit, the upper left corner of the screen appears "U Disk" prompt;

2. After complete the scanning, press^lkey to freeze the image;

3. Press the down direction ke^3, the system issues a "tick" tone, that the current screen contents stored in the "IMG" folder of the U disk;

4. Press^Jkey to return to the real-time status.

Note 1: The "IMG" folder includes "images folder".

Note 2: The "images folder" is automatically named by the machine current date; the image is automatically named by the machine current time.

Such as:

U:\IMG\20160812\104835.bmp

It represents that at 10:48:35 on August 12,2016, save a "104835.bmp" image on the storage path U:\IMG\20160812.

(2) **Image viewing**

Insert OTG U disk to computer to view the stored images.

Chapter Eight Bladder volume measurement

should adjust the position of probe and re-measurement.

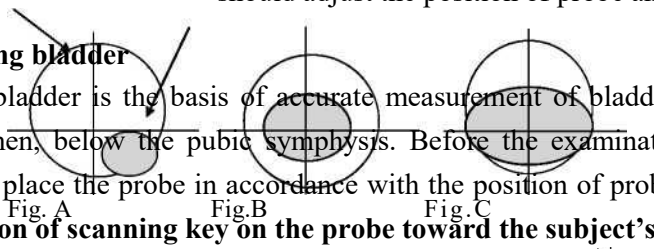


Fig. A Fig.B Fig.C

8.1 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.**

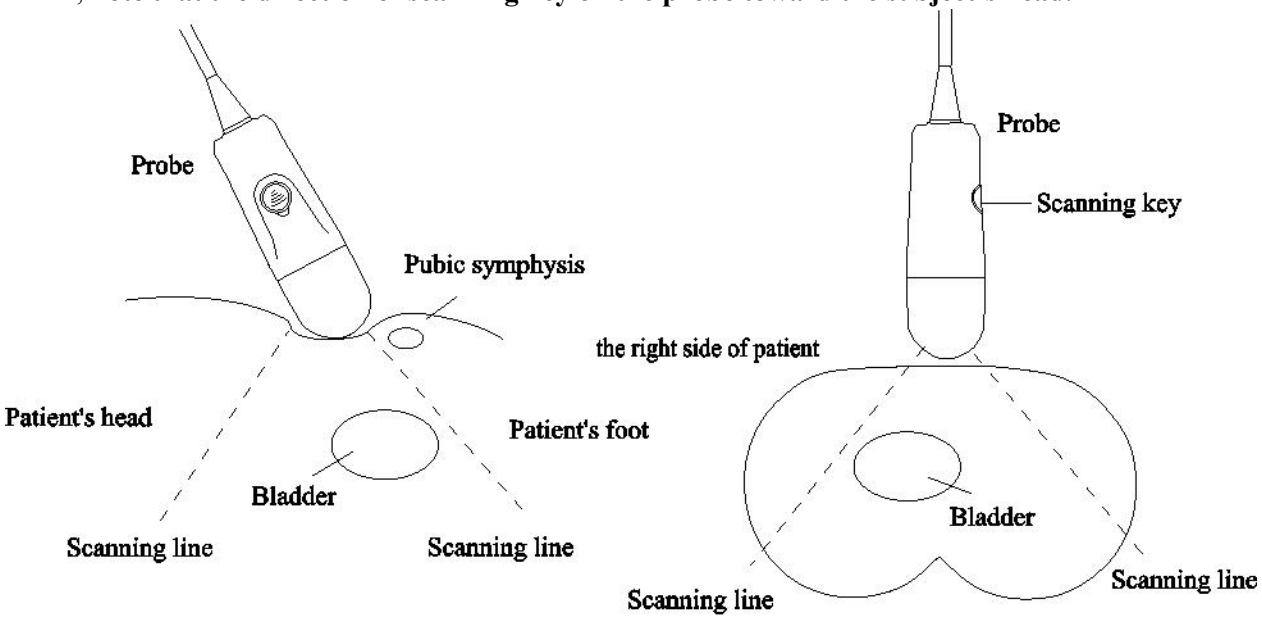


Fig. Probe position

To determine the correct measurement position, the bottom of the image displays the bladder proj ection. If the proj ection 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

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.

Operation processes

Hold down the power key@), machine starts up, the power indicator ✳ lights;

Press the scanning key®^on the probe or press the keyCDon the keyboard to scanning the image;

Press the up direction key to select the desired patient type: standard mod^］，obesity mod^'land child modeM;

Description: Child mode is generally applicable to children for 6-12 years old. Excessive weight and height of children can choose the standard mode.

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);

Press the down direction ke^3to adjust the contrast of the image: High©，MediumC3and LowO;

Place the probe towards the direction of tailbone. When measuring，the probe should be maintained perpendicular to the front wall of the bladder (slightly inclined to the direction of the tailbone)，and should remain stable to prevent displacement. After accurate positioning the bladder，press the scanning key®*on the probe or press the keyCDon the keyboard to freeze the image，when you see the blue progress line at the far right of the screen is drawn from the bottom to the top，the scan is completed.

1. If the machine is set to Standard: the image display area will generate 12 frames sectional images of bladder and automatically draw the border of boarder; the measured result display area shows the bladder projection and the bladder volume. You can view the six groups of images by pressing the keys^C (3on the keyboard.
2. If the machine is set to Lite: the system will generate projection of top view of the bladder; the measured result display area shows the bladder volume and the alarm volume.

Confirm the scanning results.

1. If the measured result shows "----"，it indicates no detectable result，you need to re-measure.
2. If appears orange arrow next to 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;
3. If appears green arrow next to 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;
4. If no arrow appears next to the projection，it indicates the measurement result is correct.

△Attention: To ensure the accurate measurement, please make sure:

here 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;

he stability of machine when scanning, avoid shaking cause the measurement error;

hen measuring, the probe should be remained stable to prevent displacement; the position offset of probe or the angel of inclination is too large, resulting in larger measurement errors.

here is no catheter in the patient's bladder, the presence of catheter may affect the accurate measurement of bladder volume.

Chapter Nine Principle of Sound Power

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.

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.

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.

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.

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.

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.

9.7 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 Ten 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.

(1) **Inspection and verification by users**

1. **Probe general inspection**

8.2 The probe should be checked before use for any visible damage;

8.3 Always check the cable for frayed or broken wires which may interfere with the proper functioning of the probe.

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 °C 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), in real-time^status press the up

direction ke^^Jto select the standard mode_ and then press the scanning key on the probe or

press the keyCJon the keyboard to measure, three times repeated measurements. If the measurement result is within the range of 140ml ± 15%, then prove that the machine performance is normal.

(2) **Maintenance by users**

10.2.1 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 liquid into the system when cleaning or maintaining; otherwise it will cause malfunction or electric shock.

△Attention:

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

△Attention:

7.3.1 **In the process of cleaning and disinfection, avoid probe overheat (exceeding 60 °C) as it may be deformed or damaged under excessive heat.**

7.3.2 **In the operation of disinfection, please refer to medical institutions disinfection technical specifications.**

- **Clean the probe**

10.1.1 Must wear sterilized gloves to prevent possible infection.

10.1.2 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.

10.1.3 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.

- **High-level disinfection**

Please follow the disinfection method provided in this use^s manual for disinfection.

a. Before disinfection, wear sterilized gloves to prevent possible infection;

b. 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.

1. **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 the cable close to probe connector.**
2. **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).**
3. **Please follow local laws and regulations to choice the disinfectants.**

c. 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.

d. 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.

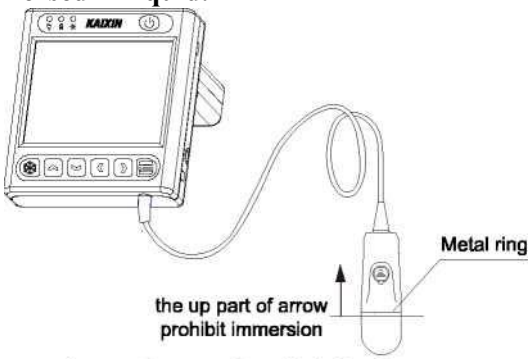


Fig. Probe regular disinfection

Attention：

2. **It is a normal phenomenon that color of the acoustic lens may change and color of the probe label may fade away.**
3. **The regular disinfection times should be minimized as it may lead to degrade of the probe safety and performance.**

4. **Check probe after cleaning and disinfection**

8.1 Check the probe enclosure and its cable to ensure they are free of abnormity (such as scuffing, cracks or drop-off);

8.2 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.

5. **Clean the probe cable**

1. Clean the probe cable with soft, dry cloth.

2. In case of die-hard blots, clean with soft cloth dipped in moderate detergent and then air-dry it.

6. **Clean the LCD screen**

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.

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

7. **Clean the control panel and shell**

Clean the instrument surface with soft, dry cloth or with soft cloth dipped in moderate water cleaning media to remove the blots, and then dry the instrument with soft, dry cloth or with air.

(3) **Use and maintenance for the rechargeable battery**

1. Only use the battery pack (model HYLB-1997) provided by Medsinglong Company; the battery pack can only be charged in the main unit. Service personnel or operator can replace the battery pack.
2. Plug the output port of adapter into the DC power input interface of main unit to charge. The charge indicator is red and blinking state when charging; the charge indicator is green and no blinking when fully charged.
3. The charging time is about 4-5 hours, over-charging or discharging will shorten the battery life; the full charged battery can be used about 5 hours.

△Attention: A battery indicator " " 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.

4. 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.
5. The excess high or low temperature will affect the charging and discharging performance, and short the battery life and capacity.

△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 do not intend to use the equipment within such a period of time, please remove the battery.

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

△Attention:

(1) **Do not throw the battery into water or be wet, which will lead to the battery leakage, explosion or fire;**
(2) **Do not use or store the battery near the heat source, such as fire or heater, which will lead to the battery leakage, explosion or fire;**
(3) **Do not connect the anode and cathode reversely, which will lead to the battery leakage, explosion or fire;**
(4) **Do not heat up or throw the battery into fire, which will lead to the leakage, explosion or fire;**
(5) **Do not connect the anode and cathode with any metal or conductor; do not transport or store the battery together with necklaces, hairpins or other metal objects, which will lead to the leakage, explosion or fire;**
(6) **Do not hammerblow, throw or mechanically shake the battery, which will lead to the leakage, explosion or fire;**
(7) **Do not insert the battery with nail or other spiculate objects; do not hammerblow or trample the battery, which will lead to the leakage, explosion or fire;**
(8) **Do not weld the battery terminal directly, which will lead to the leakage, explosion or fire;**
(9) **Do not disassemble the battery in any way, which will lead to the leakage, explosion or fire;**
(10) **Do not charge the battery near the heat source or extra-hot environment, which will lead to the leakage, explosion or fire;**
(11) **Do not put the battery into the microwave oven or pressure vessel, which will lead to the leakage, explosion or fire;**
(12) **Do not mixed use the battery together with one-off battery (such as dry battery), or different capability or different model or different brand battery, which will lead to the leakage, explosion or fire;**
(13) **Do not use the abnormal battery with particular smell or abnormal heat or distortion or turn colors or abnormal phenomena, which will lead to the leakage, explosion or fire;**
(14) **Do stop the charge and pull out the battery from the charger at once if any abnormal phenomenon happens to the battery, such as particular smell or abnormal heat or distortion or turn colors. Otherwise, each of above will lead to the leakage, explosion or fire;**
(15) **Remove the battery from the near fire if the battery leaks or emits an odor, otherwise electrolyte leakage may cause a fire or explosion;**
(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.**

(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 Medsinglong approval.**
2. **Before replacing the fuse, please contact Medsinglong and replace it under the guidance of Medsinglong .**
3. **Before replacing the fuse, you must disconnect the mains supply from the mains supply.**
4. **Fuse Type: T3.15AH250VAC.**

(5) **Replacement of power supply cord**

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

(6) **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 Medsinglong 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 Medsinglong 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.

(7) **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 Medsinglong 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.

4. Inspect the equipment and accessories for mechanical and functional damage.

5. Inspect the essential performance, including the ultrasound energy output and surface temperature.
6. Inspect the safety relevant labels for legibility.
7. Inspect the fuse to verify compliance with rated current and breaking characteristics.
8. Verify that the device functions properly as described in the instructions for use.
9. Test the protection earth resistance according to IEC 60601-1: Limit: 0.1Q.
10. Test the earth leakage current according to IEC 60601-1: Limit: Normal Condition 500^A, Single Fault Condition: 1000pA.
11. Test the touch current according to IEC 60601-1: Limit: Normal Condition 100^A, Single Fault Condition: 500pA.
12. Test the patient leakage current according to IEC 60601-1: Limit: for a.c.: 100^A for d.c.: 10^A
13. 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.: 500^A for d.c.: 50^A.

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.

(8) **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 Eleven Storage and Transportation

a) 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.

b) 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.

c) 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 Twelve 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 Thirteen Safety Classification

7.1 Classified according to electric shock protection type:
Class I, internally powered equipment

7.2 Classified according to electric shock protection degree:
Type B applied part

7.3 Classified according to the degree of protection against ingress of liquid:
Main unit belong to IPX0 equipment

7.4 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

7.5 Classified according to mode of operation:
Continuous operation equipment

7.6 Classified according to the protection of radio services:
Group I Class A equipment

Chapter Fourteen 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 sys tem 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、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%UT (>95%dip in UT) for 0.5 cycle 40%UT (60 % dip in UT) for 5 cycles 70%UT (30 % dip in UT) for 25 cycles <5%UT (>95%dip in UT) for 5 sec	<5%UT (>95%dip in UT) for 0.5 cycle 40%UT (60 % dip in UT) for 5 cycles 70%UT (30 % dip in UT) for 25 cycles <5%UT (>95%dip in UT) 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: UT 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	3 Vrms 150 kHz to 80 MHz	[1V]rms	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/V1]VP d=[3.5/E1] VP 80MHz to 800MHz d=[7/E1h/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: ((([]))
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	1V/m	

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.

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.

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

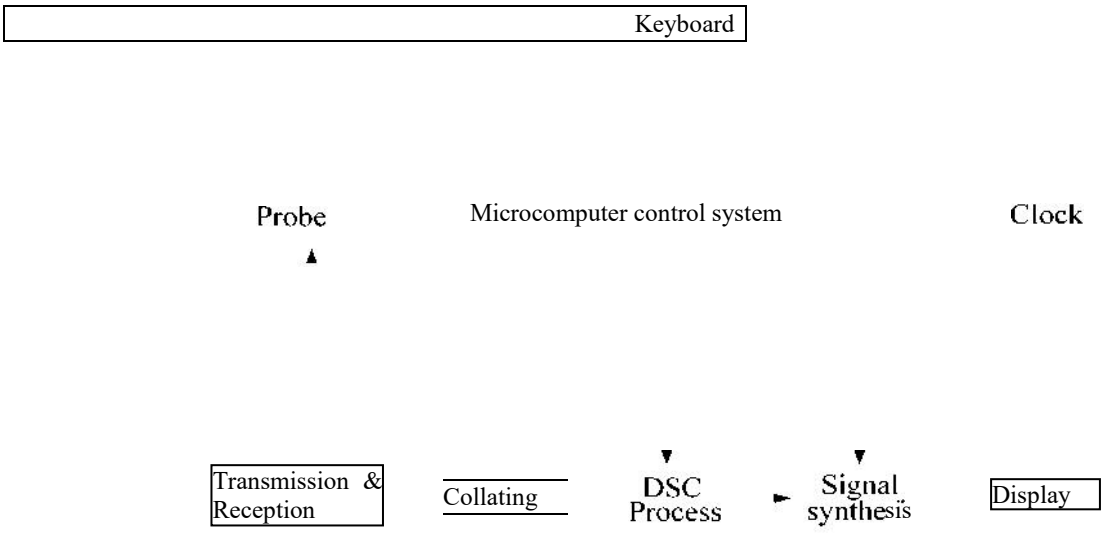
This equipment is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) 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/V1] *4P*	**80 MHz to 800 MHz** d=[3.5/E1] VP	**800 MHz to 2.5 GHz** d=[7/E1] *4P*
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 Medsinglong 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	
						^aprt<1cm²	^aprt>1cm²		
Maximum Index Value				0.37	0.017	-	-	-	-
Associated Acoustic Parameters	Pra		(MPa)	0.61					
	P		(mW)		1.3	-		-	-
	Min. of [Pa(0, ^ta, a(^s)]		(mW)				-		
	Zs		(cm)				-		
	zbp		(cm)				-		
	Zb		(cm)					-	
	z at max. /p^ a		(cm)	5.4					
	$d_{eq}(z_b)$		(cm)					-	
	f_{awf}		(MHz)	2.78	2.78	-	-	-	-
	Dim of ^aprt	X	(cm)		0.82	-	-	-	-
		Y	(cm)		1.02	-	-	-	-
Other Information	td		(^sec)	0.724					
	prr		(Hz)	760					
	Pr at max. /pi		(MPa)	1.03					
	deq at max. /pi		(cm)					-	
	$I_{pi,a}$ at max. *MI*		(Jcm²)	9.06					
	Focal Length	*FLx*	(cm)	-	-	-	-	-	-
		FLy	(cm)	-	-	-	-	-	-
Operating Control Conditions	Frequency (MHz)			2.5	2.5	-	-	-	-
	Default setting			/	/	-	-	-	-

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