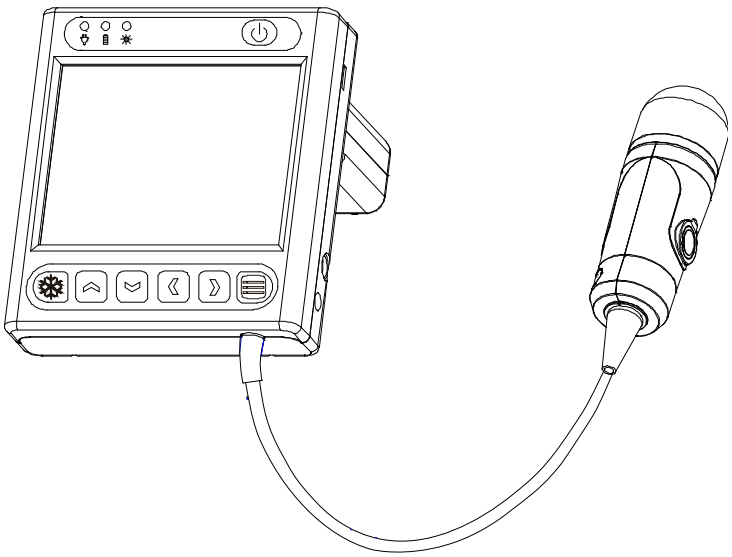
KAIXIN

BVT02 Bladder Scanner

User's Manual



Xuzhou Kaixin Electronic Instrument Co., Ltd.

Introduction

Thank you for purchasing BVT02 Bladder Scanner.

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

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

The user's manual issue date: September 1, 2023, Version: V1.12

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

Intellectual Property Information

Statement

Kaixin has the final explanation right of this user's manual.

Kaixin 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 Kaixin;
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

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

⚠**Caution: U.S.A. Federal law restricts this device to sale by or on the order of a physician.**

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 Co., Ltd.
13. Professional engineer mentioned in the user's manual is the person who has been trained and authorized by Kaixin Electronic Instrument Co., Ltd.

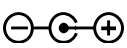
Safety Cautions

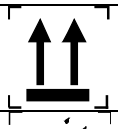
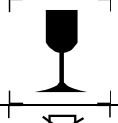
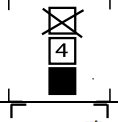
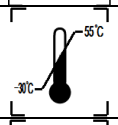
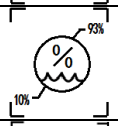
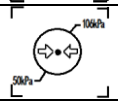
1. Warning Symbols and Definitions

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 user's manual. These symbols convey specific meanings as detailed in the table below:

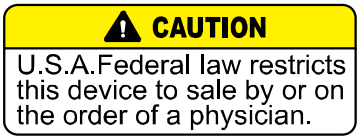
Symbols & Words	Connotation
⚠**Danger**	Indicates an imminent danger that may result in personal death or serious injury if not avoided.
⚠**Warning**	Indicates a potential danger that may result in personal injury if not avoided.
⚠**Attention**	Indicates a potential danger or unexpected use condition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

2. Symbols Directory

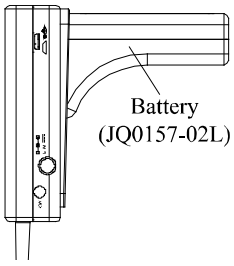
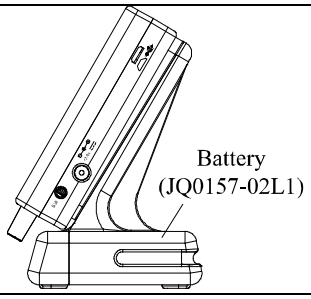
Symbols	Description
	Type B applied part
	Follow instructions for use
	Indicates the need for the user to consult the instructions for use for important cautionary information.
	Power switch
	Power supply indication
	Adapter connection indication
	Battery charge indicator
	Polarity of direct current power connector
	Direct current
	Manufacturer
	Date of manufacture
	Use-by date
	Serial number
	Micro-USB interface
SW	Foot switch (Reserved)
	Probe scanning key
IPX7	Degrees of protection for enclosure: Protected against the effects of temporary immersion in water
CE 0123	CE-Marked in accordance with the Medical Device Directive

	Up
	Keep dry
	Fragile
	Stacking limit by number
	Temperature limits (Storage and transportation)
	Humidity limitation (Storage and transportation)
	Atmospheric pressure limitation (Storage and transportation)
	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.

3. Labels

	Caution: U.S.A. Federal law restricts this device to sale by or on the order of a physician.
	Download method of ultrasound workstation software. **Remove this label before using.**

Battery differences

Battery model	JQ0157-02L	JQ0157-02L1
Battery sketch map		
Note: The machine can be configured with two types of batteries (model: JQ0157-02L or JQ0157-02L1). This user's manual takes the JQ0157-02L battery as an example to introduce the product.		

Contents

Chapter One Overview

1.1 Introduction

The BVT02 Bladder Scanner is composed of main unit, probe, power adapter, 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.

The BVT02 Bladder Scanner 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 BVT02 Bladder Scanner is 6 years.

The BVT02 measurement accuracy must meet the following indicators: Urine volume display resolution is 1mL. When urine volume is within 20mL～99mL, the measurement error is ±15mL; urine volume is within 100mL～999mL, the measurement error is ±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 temperature.

1.2 Intended Use

The BVT02 Bladder Scanner projects ultrasound energy through the lower abdomen of the patient to obtain images of the bladder which is used to calculate bladder volume noninvasively. The BVT02 Bladder Scanner is intended to be used only by qualified medical professionals.

Contraindications: The equipment is not suitable for fetal use or pregnant patients, patients with ascites, patients with open or damaged skin, wounds in the suprapubic region.

⚠**Warning: This equipment cannot be used at home.**

⚠**Warning: This equipment cannot 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.**

1.3 Prescription Statement

⚠**Attention: Federal Law restricts this device to sale by or on the order of a physician.**

Chapter Two Technical Specifications

2.1 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: DC12.8V 3.0A
5. Main unit size: approx. 90 ×140 ×85 (Length ×Width ×Height, mm)
6. Weight of main unit: approx. 750g (including battery and probe)

2.2 Primary functions

1. System date and time setting function;
2. Probe protective time can be set;
3. Screen saver time can be set;
4. Urine volume tip function;
5. Image contrast adjustment function;
6. Select the patient type;
7. Urine volume measurement function;
8. Store images in the U disk;
9. Transfer images from main unit to PC workstation;
10. Lite mode and expert mode can be set;
11. USB disk can be encrypted to protect patient privacy;
12. Support language selection;
13. Display battery power and low battery reminder function.

2.3 Technical index

1	Probe frequency, MHz	2.5	
2	Urine volume display resolution, mL	1mL	
3	Urine volume measurement range, mL	20mL～999mL	
4	Urine volume measurement accuracy, mL	20mL～99mL	measurement error: ±15mL
		100mL～999mL	measurement error: ±15%

Chapter Three System Outline

3.1 Structure composition of the instrument

The BVT02 Bladder Scanner is composed of main unit, probe, power adapter, etc.

3.2 Components name

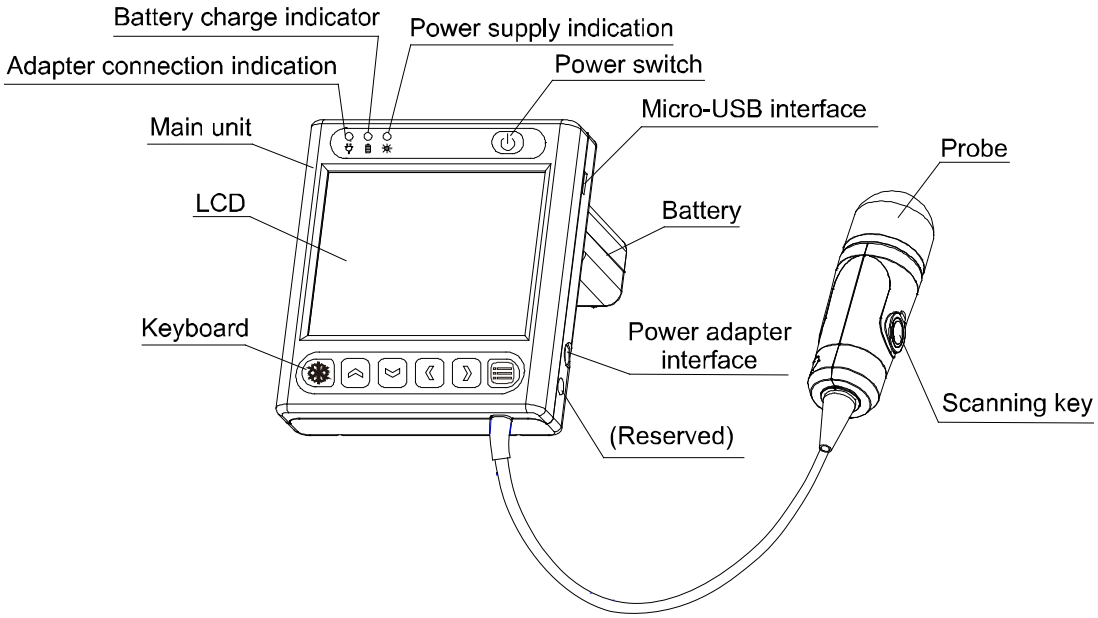


Fig. BVT02 sketch map

3.3 Parts of the probe

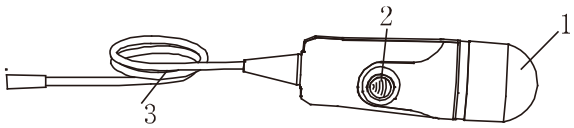
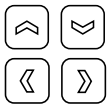


Fig. Parts name of 2.5MHz probe

SN.	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	Two-dimensional scan or three-dimensional scan.
3	Cable	To connect the probe to the main unit.

3.4 Function keys description

SN.	Key symbol	Key name	Key function
1	⏻	Power switch	Turn on or turn off the power of main unit.
2	❄	Scanning key	In the power-on state, press this key to start two-dimensional scan, press this key again to start the three-dimensional scan.
3	☰	Menu key	In the power-on or the three-dimensional scan ending state, press this key to enter system setting menu.

4		Direction key	● In the two-dimensional scan state, press the up direction key to select the desired patient type; ● In the two-dimensional scan state, press the down direction key to adjust the contrast of the image; ● In the state of three-dimensional scan ending, insert U disk, press the down direction key to store image. ● In the state of three-dimensional scan ending, press the left/right direction keys to switch displaying six groups of orthogonal images; ● In the system setting menu, press the left/right direction keys to select the system setting 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 (included probe) 1 unit
2. Power adapter 1 pc
3. Battery 1 pc
4. Package box 1 pc
5. Rubber base 1 pc
6. OTG U disk 1 pc
7. PC workstation software (kx_station_2) 1 pc

4.2 Optional parts

Verification cup

Glasses cloth

Bag

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: DC12.8V 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: 5℃-40℃

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

Atmospheric pressure: 700hPa-1060hPa

Altitude: ≤ 3000 m

Overvoltage: Overvoltage Category Ⅱ

Pollution degree: 2

5.3 Storage and Transport

Ambient temperature: -30℃-55℃

Relative humidity: 10%-93% (without condensation)

Atmospheric pressure: 500hPa-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: 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: The mains voltage is varies with different countries or regions.

⚠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 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. **This device is not waterproof, not use this device in place where liquid may into the interior of the device. Never pour any liquid on the device; otherwise there will be danger of electric shock or cause device damage. If accidentally spill liquid on the device, turn off the power immediately and contact your local representative.**
3. **Prohibit the live parts of the device (such as various signal input and output ports, etc.) contact with the patient, if this device has failure, the patient will have danger of electric shock.**
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. **If the integrity of the external protective conductor in the installation or its arrangement is in doubt, equipment shall be operated from its battery power.**

⚠Warning:

1. **When device works abnormally, do stop working, turn off the power and check the reason, then contacts Kaixin 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. **Pull out of the plug from socket after operation in thunderstorm weather to avoid the device being damaged by lightening.**
5. **If the temperature changes greatly in short time will cause vapor recovery inside of device, the case may damage the device.**
6. **The device 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 Kaixin or his authorized supplier.

6.1 System placement

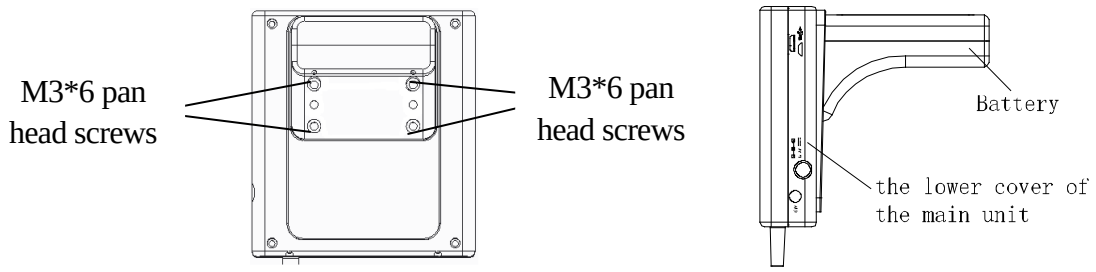
Please carefully read through and fully understand the safety cautions before moving and placing the system.

1. Unpack the instrument case and check the goods for its completeness.
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 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

> ⚠**Warning: Do not short-circuit the battery terminals.**

6.3 Connection to power

1. Connect to the power adapter

Insert the output plug of adapter into DC power input port, which is on the right side 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. Adapter is as a part of the device, please only use the adapter provided by Kaixin. Contact a local distributer or Kaixin for replacements.**
> **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.**

6.4 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.

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

⚠Warning:

1. **Check the probe and connecting cable after diagnostic operation. Use of defective probe may cause electric shock.**
2. **Do not strike or hit the probe; the impact may damage the probe. Using the damaged probe may cause electric shock to the patient.**
3. **Unauthorized disassembly of the probe shall be prohibited as it may cause electric shock.**
4. **For the depth of immersion during disinfection, please refer to "Probe regular disinfection" in Chapter 10.2.1; Failure to disinfect as required can cause internal short circuits and burnout of the board.**

⚠Attention:

1. **Probe is a critical, precision part, do not stress, impact, or fall it. Do not pull or wring wound probe cable.**
2. **Probe is highly sensitive to shake, be used with caution. About probe's use and cleaning, the details see the relevant sections.**
3. **Care should be taken when using the probe normally and it should be handled gently to avoid mechanical damage to the transducer assembly.**
4. **Use a qualified coupling gel to keep the probe dry. If the unqualified coupling gel is used or the probe surface is not cleaned in time, the lens of the probe surface may be corroded and damaged. The surface of the probe may be cleaned with a soft cloth. Do not scrub with hard paper.**
5. **Repeat available machine time should be more than 5 minutes to avoid turn on/off power supply in short time.**

6.5 Main unit check before and after operation

6.5.1 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 keyboard, LCD screen and enclosure to ensure they are in good working condition and free of abnormity (such as cracks and loosened screws).
5. No damage on 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. See to it that probe has been cleaned, disinfected; else dispose it as specified in relevant sections.
8. Check all the ports of the machine for possible damage or blockage.
9. Clean the field and environment.

6.5.2 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 starts work status.
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.

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

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

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

6.6 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

7.1 Startup and Shutdown

In shutdown status, hold down key at the top of the screen, machine starts up, power supply indicator ☼ lights.

In startup status, hold down key, machine shuts down, power supply indicator ☼ goes out.

7.2 Work main interface

7.2.1 Two-dimensional scan interface

After booting, the system defaults to the three-dimensional scan interface, press the scanning key on the probe or press the key on the keyboard to enter two-dimensional scan interface.

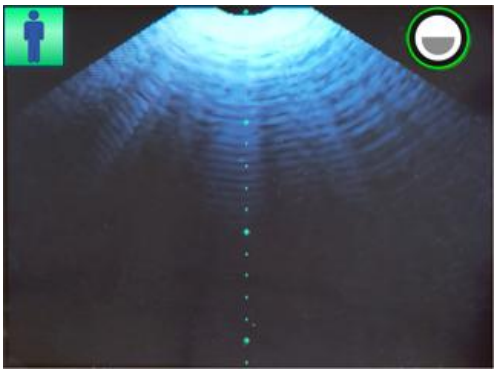


Fig. Two-dimensional scan interface

The two-dimensional scan interface displays a B-mode image, patient type icon and image contrast icon.

In the two-dimensional scan state, press the up direction key to select the desired patient type: male, female, female with hysterectomy, obesity and child. The patient type icon is shown in the upper left corner of the image.

In the two-dimensional scan state, press the down direction key to adjust the contrast of the image: High, Medium and Low. The contrast icon is shown in the upper right corner of the image.

7.2.2 Three-dimensional scan interface

In the two-dimensional scan interface, press the scanning key on the probe or press the key on the keyboard to enter three-dimensional scan interface, a schematic diagram is shown below:

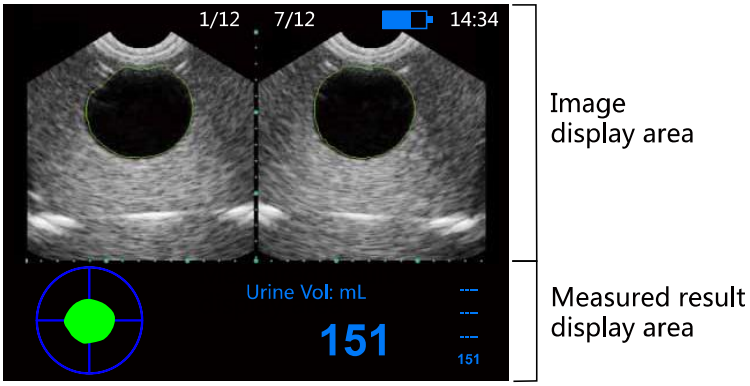


Fig. Three-dimensional scan interface

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

The image display area displays the system time, the battery power, the number of the 12 images and 12 sectional images of the bladder. Among them, the system time can be modified in the "System Set". 12 sectional images of bladder are divided into six groups, each group consisting of two orthogonal images; you can switch the images by pressing the keys《 》on the keyboard. The six groups of orthogonal images are generated by the scanning planes automatically changed by 15° intervals, the number of images corresponding to an image is shown above each image.

The measured result display area displays the scanning direction indication, bladder projection of the bladder contour, urine volume measurement result and the four sets of history records. After completed scanning each time, the projection 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 four sets of history records are convenient for doctors to compare. The current measured result is always shown at the bottom.

7.3 System set

In the power-on or the three-dimensional scan ending state, press menu key to enter system setting menu. The following settings can be made, and the full version and release version of the software can also be viewed in the system setting menu.

7.3.1 Date setting

1. Press key to enter "System Set" menu;
2. Press 《 or 》 key to move the cursor to "Date" item, and then press ^ or v key to adjust the date;
3. Press key to confirm the date setting and quit system setting menu.

7.3.2 Time setting

1. Press key to enter "System Set" menu;
2. Press 《 or 》 key to move the cursor to "Time" item, and then press ^ or v key to adjust the time;
3. Press key to confirm the time setting and quit system setting menu.

7.3.3 Probe protective time setting

1. Press key to enter "System Set" menu;
2. Press 《 or 》 key to move the cursor to "Probe protective" item, and then press ^ or v key to adjust the probe protective time;
3. Probe protective time is "0-99" seconds, "0" stands for turn off the probe protection;
4. Press key to confirm this setting and quit system setting menu.

Note: In the two-dimensional state, when the set probe protective time is reached, the probe automatically stops running.

7.3.4 Screensaver setting

1. Press key to enter "System Set" menu;
2. Press or key to move the cursor to "Screensaver" item, and then press or key to adjust the screensaver time;
3. Screensaver time is "0-99" minutes, "0" stands for turn off the screensaver;
4. Press key to confirm this setting and quit system setting menu.

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.

7.3.5 Language setting

1. Press key to enter "System Set" menu;
2. Press or key to move the cursor to "Language" item, and then press or key to choose language; (Note: In the English version, language switching is not supported.)
3. Press key to confirm this setting and quit system setting menu.

7.3.6 Volume tip setting

1. Press key to enter "System Set" menu;
2. Press or key to move the cursor to "Vol Tip" item, and then press or key to adjust the value; Values are adjusted in steps per 5mL;
3. The range of the prompted volume is "0-999" milliliter (mL), the default value is 300mL;
4. Press key to confirm this setting and quit system setting menu.

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

7.3.7 Display mode setting

1. Press key to enter "System Set" menu;
2. Press or key to move the cursor to "Display mode" item, and then press or key to select the Expert or Lite;
3. Press key to confirm this setting and quit system setting menu.

Note: For more information on the Expert and Lite, see section 8.1 Scanning and Positioning Bladder.

7.3.8 Contrast setting

1. Press key to enter "System Set" menu;
2. Press or key to move the cursor to "Contrast" item, and then press or key to select the contrast of the image;
3. The contrast of the image is divided into High , Medium and Low , the default is Medium;
4. Press key to confirm this setting and quit system setting menu.

7.3.9 Storage path setting

1. Press key to enter "System Set" menu;
2. Press or key to move the cursor to "Storage path" item, and then press or key to select the U-Disk or PC;
3. Press key to confirm this setting and quit system setting menu.

7.3.10 Patient ID setting

1. Press key to enter "System Set" menu;
2. Press or key to move the cursor to "Patient ID" item, and then press or key to select "On";
3. Press key to confirm this setting, quit system setting menu and pop up "Input" dialog box;
4. Press direction key to input patient ID, press or key to select the number of digits, press or key adjust the value.

Note: The default value of the patient ID is 000, and its range is 000-999. The ID is displayed at the top of the image. If the ID is set to "Off", the ID will not be displayed at the top of the image. After power on/off the machine or switch the storage path, the ID is restored to the default value.

7.4 Image storage and viewing

7.4.1 Image storage

⚠Attention:

1. **Before using the OTG U disk to store images, please insert U disk correctly according to the icon and make sure the system recognizes the U disk.**
2. **This system can only use the encrypted U disk with the USB 2.0 interface, otherwise image storage cannot be performed.**
3. **If you want to obtain the U disk encryption folder; please contact International Trade Dept of Kaixin.**

- **U disk encryption**

  Copy the "KX" folder provided by our company to the root directory of the U disk, and the encryption is completed.

- **Identify U disk**

  In the system setting menu, set the Storage path to "U-Disk", the system can identify U disk, the upper left corner of the screen appears "U Disk" prompt; otherwise, it cannot be identified.

  Note: For more information on the Storage path setting, see section 7.3.9.

- **Store image**

  1. According to the icon at the right side of main unit, insert OTG U disk into the Micro-USB interface, the upper left corner of the screen appears "U Disk" prompt;
  2. Press the scanning key on the probe or press the key on the keyboard to enter two-dimensional scan interface; after accurate positioning the bladder, press the scanning key on the probe or press the key on the keyboard to start

three-dimensional scan, when the system issues a "tick" tone, the three-dimensional scan is completed;

3. Press the down direction key, the system issues a "tick" tone, that the current screen contents stored in the "IMG" folder of the U disk;
4. Press the scanning key on the probe or press the key on the keyboard to return to the two-dimensional scan status.

Note 1: The image is stored in the IMG folder of the U disk. If the patient ID has been entered, the image will be saved in the folder named after the ID; if the patient ID has not been entered, the image will be saved in the default ID "000" 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\000\20200812\104835.bmp (the patient ID is not entered)

It represents that when the patient ID is not entered, at 10:48:35 on August 12, 2020, save a "104835.bmp" image on the storage path U:\IMG\000\20200812.

U:\IMG\025\20200812\123709.bmp (the patient ID has been entered)

It represents that when the patient ID has been entered (for example, the ID is 025), at 12:37:09 on August 12, 2020, save a "123709.bmp" image on the storage path U:\IMG\025\20200812.

7.4.2 Image viewing

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

7.5 Image transfer to PC workstation

⚠Attention: Before transferring images to PC workstation, make sure the system recognizes the PC.

- **Identify PC**

  In the system setting menu, set the Storage path to "PC", the system can identify the PC; otherwise, it cannot be identified.

  Note: For more information on the Storage path setting, see section 7.3.9.

- **Transfer images to PC**

1. According to the information provided in the APP download method label pasted on the machine, get "Kaixin ultrasound workstation software", copy to the computer, open the workstation software folder, double-click the icon " kx_station_2" to enter workstation interface;
2. After ensuring that the system can recognize the PC, connect one end of the USB cable to the computer and the other end to the Micro-USB interface of the BVT02 main unit, the upper left corner of the screen appears "PC" prompt;
3. Press the scanning key on the probe or press the key on the keyboard to enter two-dimensional scan interface; after accurate positioning the bladder, press the scanning key on the probe or press the key on the keyboard to start

three-dimensional scan, when the system issues a "tick" tone, the three-dimensional scan is completed;

4. Press the down direction key, the system issues a "tick" tone, that the current screen contents transferred to PC workstation;
5. Press the scanning key on the probe or press the key on the keyboard to return to the two-dimensional scan status.

Note: If unable to transfer image, please restart the workstation software "kx_station_2".

- **Start using PC workstation software (kx_station_2)**

The PC workstation software kx_station_2 is used to view images sent by the BVT02 main unit.

1. Click the left and right arrow keys in the lower right corner of the workstation software to browse the received images;
2. Click the "refresh" button, and the thumbnail images on the right side are displayed in order from the back to the front according to the time of image naming;
3. Click the "path" button to view the storage path of the received image;
4. Click the "" button to close the workstation software.

Note:

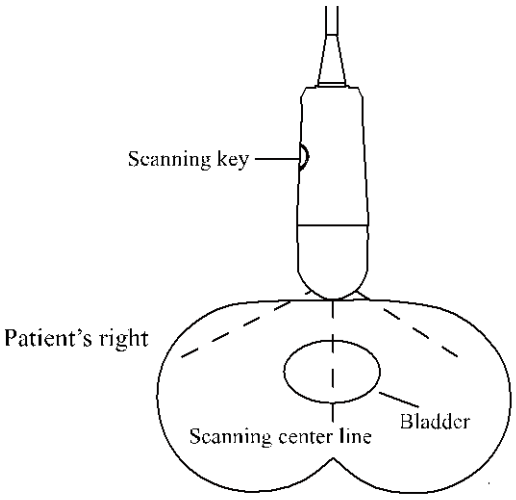
1. Images are named according to the time of main unit.
For example: 20180101102337.png
Indicates the image sent by the BVT02 at 10:23:37, on January 1, 2018.

2. The received png images are stored to the kx_station_2 folder on the D drive of the computer.
The path: open D:\kxStation_2\image folder to view or delete the image.
For example: D:\kxStation_2\image\20180101102337.png

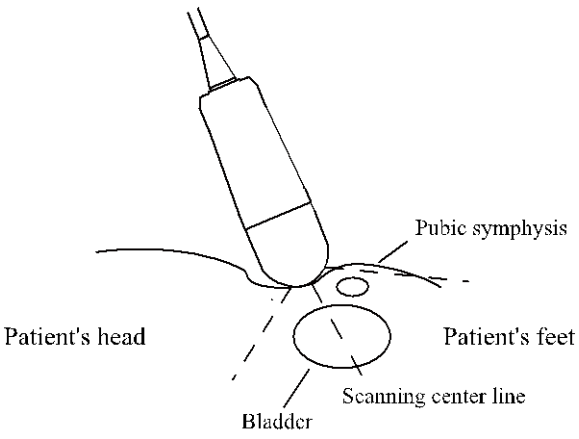
Chapter Eight Bladder volume measurement

8.1 Scanning and positioning bladder

1. Hold down the power key, machine starts up, the power indicator ☼ lights;
2. Press the scanning key on the probe or press the key on the keyboard to enter two-dimensional scan state; Press the up direction key to select the desired patient type: male, female, female with hysterectomy, obesity and child; Press the down direction key to adjust the contrast of the image: High, Medium and Low;
   Description: A child less than 120cm tall and weighing less than 25kg.
3. Position the bladder. Bladder is located in the lower abdomen, below the pubic bone. Before the examination, place an ample amount of ultrasound gel on the patient's abdomen, about 3 cm above the pubic bone, patient is lying in a supine position, place the probe on the ultrasound gel, the scanning key is pointing toward the operator. Press the scanning key, and the motor starts to swing. Slightly adjust the position and direction of the probe according to the actual situation until the bladder section can be completely seen, and make the ultrasonic scanning center line pass through the center of gravity of the bladder cross-sectional area, and then swing up and down to maximize the cross-sectional area. As shown in the figure below:



View from the patient's feet



View from the patient's right side

4. After accurate positioning the bladder, press the scanning key on the probe or press the key on the keyboard to start three-dimensional scan, when you see the blue progress line at the far right of the screen is drawn from the bottom to the top, and the system issues a "tick" tone, the scan is completed.
   (1) If the machine is set to Expert: the image display area will generate 12 sectional images of bladder and automatically draw the border of bladder; 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 on 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 volume tip.

5. 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, it indicates the measurement result 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.

Note: To determine the correct measurement position, the bottom of the image displays the bladder projection. If the projection was nearly round, basically in the center, 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.

The system will automatically identify the border of bladder, the area surrounded by the green border in the image is the bladder, and the bladder volume is calculated according to the border.

⚠**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. **When 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.**
4. **There is no catheter in the patient's bladder, the presence of catheter may affect the accurate measurement of bladder volume.**

Chapter Nine Principle of acoustic Power

9.1 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.

9.2 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.

9.3 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.

9.4 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 acoustic 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.

9.5 The limits of acoustic output

The acoustic output parameters for thermal index and mechanical index are below 1.0.

9.6 Factors impacting acoustic power

The transmission frequency of this system, the transmission voltage of the piezoelectric element, and the area of the piezoelectric element are fixed, so there is no factor affecting the acoustic power.

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.

10.1 Inspection and verification by users

10.1.1 Probe general inspection

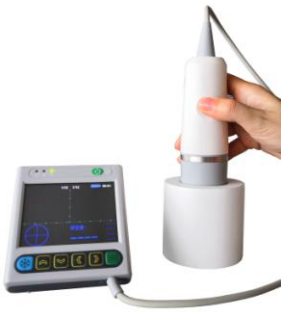
1. The probe should be checked before use for any visible damage;
2. Always check the cable for frayed or broken wires which may interfere with the proper functioning of the probe.

10.1.2 Power-on verification

The system provides a verification cup, used to verify whether the machine can work normally. Before use, wipe the inner wall of the verification cup with a glasses cloth, because the dust on the inner wall will affect the measurement results.

The usage for the verification cup:

At 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 the two-dimensional scan state, press the up direction key to select the male, and then press the scanning key on the probe or press the key on the keyboard to measure, repeat the measurement more than 3 times. If the deviation of each measurement result is stable, it proves that the machine is working normally.



10.2 Maintenance by users

10.2.1 System cleaning and disinfection

⚠Warning: To avoid electric shock, be sure to turn off the power and disconnect the power cord from the outlet before maintenance the system.

⚠Warning: The device is not waterproof. Do not splash any water or liquid 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 probe.**
2. **Clean the probe with sterile water to remove the residual chemicals after disinfection, because the residual chemicals may be harmful for humans.**
3. **Kaixin Company will not make any guarantee for the efficacy of disinfector. Please contact the appropriate manufacturer for details.**

⚠Attention:

1. **In the process of cleaning and disinfection, avoid probe overheat (exceeding 55℃) 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.

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 the cable close to probe connector.**
- **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 IPX7, immersion depth as shown below. The below part of arrow can be immersed in liquid.

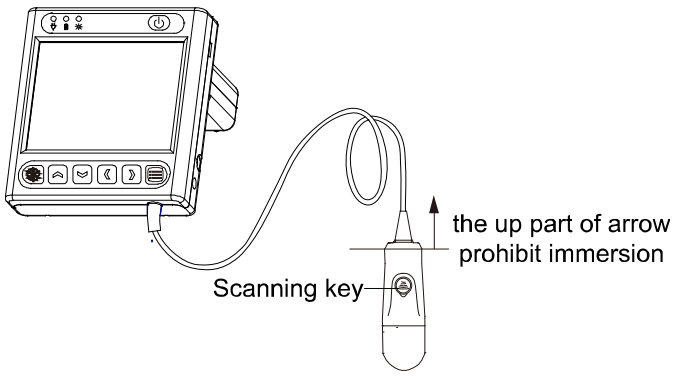


Fig. Probe regular disinfection

⚠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.

4. 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.

5. 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.

6. 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.

10.3 Use and maintenance for the rechargeable battery pack

1. Only use the battery pack (model JQ0157-02L or JQ0157-02L1) provided by Kaixin Company; the battery pack can only be charged in the main unit. Service personnel or operator can replace the battery pack. The battery replacement method sees Chapter 6.2.
2. Plug the output port of adapter into the power input interface of main unit to charge. The charge indicator is orange and blinking state when charging; the charge indicator is orange 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: When the "Low" icon appears in the middle of the screen, the battery power is low and needs to be charged before continuing to use. 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:

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 heat up or throw the battery into fire, which will lead to the leakage, explosion or fire;**
4. **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;**
5. **Do not hammerblow, throw or mechanically shake the battery, which will lead to the leakage, explosion or fire;**
6. **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;**
7. **Do not weld the battery terminal directly, which will lead to the leakage, explosion or fire;**
8. **Do not disassemble the battery in any way, which will lead to the leakage, explosion or fire;**
9. **Do not charge the battery near the heat source or extra-hot environment, which will lead to the leakage, explosion or fire;**
10. **Do not put the battery into the microwave oven or pressure vessel, which will lead to the leakage, explosion or fire;**
11. **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;**
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: 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.

10.4 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.**

10.5 Replacement of power adapter and power supply cord

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

10.6 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 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
When power switch pressed, the power supply indicator does not turn on and no signal on the display screen visible.	1. Check power supply. 2. Check power cable and plug. 3. Check power adapter.
Intermittent stripe, snow, or far-field interference appears on screen.	1. Check power supply.(spark interference present) 2. Check the 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. They shall be properly contacted.

Control panel malfunction	Should shutdown and reboot the system after five minutes.

10.7 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 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.

10.8 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 temperature, should go to a qualified testing organization for IEC 60601-1-2 test.

Chapter Eleven 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: -30℃－55℃; Relative humidity: 10%－93% (without condensation);
   Atmospheric pressure: 500hPa-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 Twelve Standard Compliance

The compliant standards are listed below:

2007/47/EC
EN ISO 14971:2012
IEC 60601-1:2005+CORR.1:2006+ CORR.2:2007+A1:2012
IEC 60601-2-37:2007 +AMD1:2015
NEMA UD 2 Edition 2004, NEMA UD 3 Edition 2004
IEC 60601-1-2:2014
EN ISO 15223-1:2012
ISO 10993-1:2018
ISO 10993-5:2009
ISO 10993-10:2010

Chapter Thirteen Safety Classification

1. Classified according to the type of protection against electric shock:

Class I EQUIPMENT + internally power EQUIPMENT

2. Classified according to the degree of protection against electric shock:

Type B applied part

3. Classified according to the degree of protection against harmful ingress of water:

The main unit belongs to IPX0

Probe belongs to IPX7

4. Classified according to the degree of safety of operation in the presence of a flammable anesthetic mixture with air or oxygen or nitrous oxide:

Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or oxygen or nitrous oxide

5. Classified according to mode of operation:

Continuous operation equipment

6. Classified according to the product structure:

Portable equipment

7. Classified according to whether the device has an applied part that protection against defibrillation discharge effects:

Without defibrillation-proof applied part

8. Classified according to the permanent installation or non-permanent installation:

Non-permanently installed 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. **Strong electromagnetic disturbance may cause interference on the ultrasonic image of this equipment. It is recommended to stop using the device and keep it away from the interference source or the source to be eliminated, then use the equipment.**
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

<table>
<tr><td colspan="3">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.</td></tr>
<tr><th>Emission test</th><th>Compliance</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>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.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class A</td><td rowspan="3">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.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/flicker emissions IEC 61000-3-3</td><td>Complies</td></tr>
</table>

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	±8 kV contact ±15 kV air	±8 kV contact ±15 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 input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	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	0%U_T (>95%dip in U_T) for 0.5 cycle 0%U_T (95%dip in U_T) for 1 cycles 70%U_T (30%dip in U_T) for 25 (50Hz) cycles 0%U_T (>95%dip in U_T) for 250 (50Hz) cycles	0%U_T (>95%dip in U_T) for 0.5 cycle 0%U_T (95%dip in U_T) for 1 cycles 70%U_T (30%dip in U_T) for 25 (50Hz) cycles 0%U_T (>95%dip in U_T) for 250 (50Hz) cycles	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m	30(A/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 2.7 GHz	$3V_{rms}$ 3V/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** $d=\frac{6}{E}\sqrt{P}$ $d=2\sqrt{P}$ 80 MHz to 2.7 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field 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 3V/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.

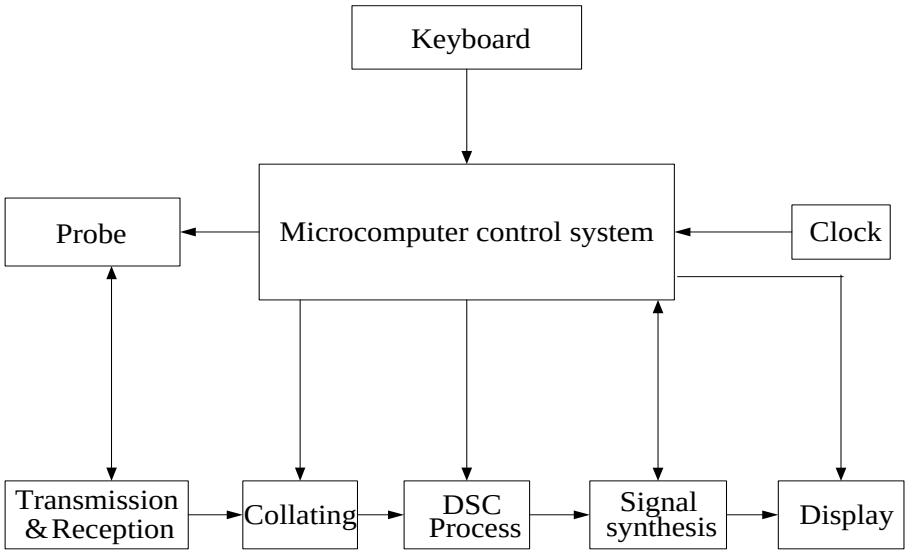
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter**		
	150KHz to 80MHz $\mathbf{d=2\sqrt{P}}$	**80MHz to 800MHz** $\mathbf{d=2\sqrt{P}}$	**800MHz to 2.7GHz** $\mathbf{d=2\sqrt{P}}$
0.01	0.2	0.2	0.2
0.1	0.63	0.63	0.63
1	2	2	2
10	6.3	6.3	6.3
100	20	20	20

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 IEC 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 Scanner

Table 201.103		Transducer Model: 2.5S120M2, Operating Model: B					
Index label		*MI*	*TIS*		*TIB*		*TIC*
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.7537	0.0570		0.0570		N/A
Index component value			0.0570	N/A	N/A	0.0570	
Acoustic Parameters	$p_{r.a}$ at z_{MI} (MPa)	1.2140					
	P (mW)		4.6080		4.6080		N/A
	$P_{1\times1}$ (mW)		4.6080		4.6080		
	z_s (cm)			N/A			
	z_b (cm)					N/A	
	z_{MI} (cm)	3.6250					
	$z_{PII.\alpha}$ (cm)	3.6250					
	f_{awf} (MHz)	2.5960	2.5960		2.5960		N/A
Other Information	*prr* (Hz)	762.94					
	srr (Hz)	762.94					
	n_{pps}	1					
	$I_{pa.\alpha}$ at $z_{PII.\alpha}$ (W/cm^2)	58.7					
	$I_{spta.\alpha}$ at $z_{PII.\alpha}$ or $z_{SII.\alpha}$ (mW/cm^2)	26.67					
	I_{spta} at z_{PII} or z_{SII} (mW/cm^2)	51.1					
	p_r at z_{PII} (MPa)	1.681					
Operating control conditions	Focus (mm)	Fixed					
	Depth (mm)	Fixed					
	Frequency (MHz)	2.5					

Appendix C Acoustic Output Reporting Table for Track1 (Autoscanning Mode)

Table 1

System Model: BVT02 SN:1715161
Transducer Model: 2.5S120M2 SN:1704005
Nominal Frequency: 2.5MHz
Operating Model: B

Acoustic Output			MI	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (W/cm^2)
Global Maximum Value			0.3773	6.7550	14.8300
Associated Acoustic Parameter	$P_{r.3}$ (MPa)		0.6168		
	W_0 (mW)			1.1260	1.1260
	f_c (MHz)		2.6730	2.6730	2.6730
	Z_{sp} (cm)		3.6250		3.6250
	Beam dimensions	X_{-6} (cm)			0.3030
		Y_{-6} (cm)			0.3143
	PD (μsec)		0.5971		0.5971
	PRF (Hz)		762.9400		762.9400
	EDS	Az. (cm)		1.4000	
		Ele. (cm)		0.4000	
Operating Control Conditions	Focus (mm)		Fixed		
	Depth (mm)		Fixed		
	Frequency (MHz)		2.5		

Table 2

System Model: BVT02 SN:1715161
Transducer Model: 2.5S120M2 SN:1704004
Nominal Frequency: 2.5MHz
Operating Model: B

Acoustic Output			MI	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (W/cm^2)
Global Maximum Value			0.5969	15.1300	29.1800
Associated Acoustic Parameter	$P_{r.3}$ (MPa)		0.9567		
	W_0 (mW)			2.1590	2.1590
	f_c (MHz)		2.5680	2.5680	2.5680
	Z_{sp} (cm)		3.6000		3.6000
	Beam dimensions	X_{-6} (cm)			0.3002
		Y_{-6} (cm)			0.3012
	PD (μsec)		0.6794		0.6794
	PRF (Hz)		762.9400		762.9400
	EDS	Az. (cm)		1.4000	
		Ele. (cm)		0.4000	
Operating Control Conditions	Focus (mm)		Fixed		
	Depth (mm)		Fixed		
	Frequency (MHz)		2.5		

Table 3

System Model: BVT02 SN:1715161
Transducer Model: 2.5S120M2 SN:1704006
Nominal Frequency: 2.5MHz
Operating Model: B

Acoustic Output			MI	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (W/cm^2)
Global Maximum Value			0.7537	26.6700	58.7000
Associated Acoustic Parameter	$P_{r.3}$ (MPa)		1.2140		
	W_0 (mW)			4.6080	4.6080
	f_c (MHz)		2.5960	2.5960	2.5960
	Z_{sp} (cm)		3.6250		3.6250
	Beam dimensions	X_{-6} (cm)			0.1827
		Y_{-6} (cm)			0.3881
	PD (μsec)		0.5956		0.5956
	PRF (Hz)		762.9400		762.9400
	EDS	Az. (cm)		1.4000	
		Ele. (cm)		0.4000	
Operating Control Conditions	Focus (mm)		Fixed		
	Depth (mm)		Fixed		
	Frequency (MHz)		2.5		

KAIXIN ELECTRONIC

XUZHOU KAIXIN ELECTRONIC INSTRUMENT CO., LTD.

Kaixin Mansion, C-01, Economic Development Zone,
Xuzhou, Jiangsu, China
Zip Code: 221004

Tel: +86-516-87732932/87733758
Fax: +86-516-87732932/87792848

Website: http://www.kxele.com
E-mail: info@kxele.com

EC REP Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

CE 0123

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