Bladder Scanner M2-W

User Manual

Version:1.0

Product Standard：

Production License No.：

Registration Certificate No.：

Suzhou Lischka Medtech Co., Ltd.

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Chapter One Introduction

Statement:

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1.1 Brief Introduction

The M2-W manufactured by Suzhou Lischka Medtech Co., Ltd. provides non-invasive bladdervolume measurement utilizing real-time ultrasonic imaging and measurement. The equipment consists of the main unit, 3D probe, battery and power adapter.

Performance:

- TwoOperation Modes: Expert Mode and Easy Mode. Under the expert mode, the real-time 2-dimensional ultrasound image will be displayed on the screen. Doctors can decide if the location and measurement results are acceptable or not according to the cross-section image of the bladder. Under the easy mode, a 2-dimensional ultrasound image will not be displayed on the screen. The equipment instructs the operator to move the probe to find the right location. (No sonographer is required under the easy mode).
- Non-invasive, comfortable, correct, reliable, fast and simple operation. When the operator releases the button on the probe, multiple 2D plane ultrasound images are acquired in a few seconds. The equipment adopts sophisticatedimage processing techniques to restore the stereo image, and adopts a sophisticated algorithm to measure bladder volume and displays the measurement results on the screen.

- Printouts with ultrasound images and various parameters
- Touch screen keyboard operation
- SD card storage
- Voice recording function
- Multi-language selection
- Injection molded shell, the main unit and the probe are all-in-one, 2.4-inch LCD screen(240x320pixels)
- Power supply with built-in battery.

1.2 Intended Use & Indication for use

Intended use:

The Bladder Scanner(model: M2-W) 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 M2-W Bladder Scanner is intended to be used only by qualified medical professionals.

Indications for use:

The Bladder Scanner(model: M2-W) is B-mode pulsed-echo ultrasound device. It intended as a handheld battery-operated device. The M2-W 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 M2-W Bladder Scanner is intended to be used only by qualified medical professionals.

1.3 Standards

This equipment is designed and manufactured in strict accordance with: National Standard

GB9706.1—2007 “Medical electrical equipment Part 1: General requirements for safety” and

GB9706.9-2008 “Medical electrical equipment: Ultrasonic Diagnosis and Monitor Equipment Safety

Specific Requirement”. The type of defense and protection against electric shock is Class II Type B.

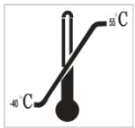
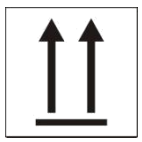
 Environment test on the equipment conforms to the requirements of climate environment test group II and mechanical environment test group II from GB/T 14710-2009 “Medical electrical

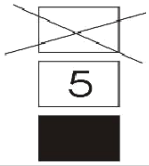
equipment environment requirement and test method”

Instructions on the labelidentification on the Equipment

SN	Serial number of the product		Follow instructions for use
	Date of the product		B applied part
EC REP	The authorized EU-representative		Caution.
	Information of manufacture	IPX7	Protected against the effects pf temporary immersion in water
	Waste Electrical and Electronic Equipment Directive	CE 0197	CE Mark
FCCID	Wireless Authentication Code		

Instructions on the packaging and shipping identification on the Equipment

	Handle with care
	Temperature limit
	Upwards

	Limited layers of storage
	Keep dry
	Keep away from sunlight

1.4 Service Life

The service life of the product is six years. Constant use of the equipment after the service life will increase the risk of failure and unpredictable hazards.

Warning: Users will assume responsibility of the risks associated with the use of the equipment after recommended service life.

Warning: The disposal of the products should comply with local regulations. Don't dispose of the product with household refuse.

1.5 Operational Environment

Temperature: +5℃ to +40℃

Relative humidity: 30% to 75%

Pressure: 70kPa to 106kPa

1.6 Declaration of Electromagnetic Compatibility

The M2-W in operation will not interfere with wired, wireless or other electrical equipment. It works properly under specified electromagnetic environments.

Warning: When the battery is charged in the instrument, the power supply of the instrument is disconnected, so the battery can not be used when charging.

Warning: Using the M2-W under strong electromagnetic environment, close to a generator, X-ray equipment, dentistry and physiotherapy equipment, broadcasting station or buried cable, etc., may introduce interference signals in the image. This will influence the measurement. Please stop using the equipment at the moment to prevent improper measurement. Wait for electromagnetic interference exclusion before use.

Warning: Sharing a power supply with other equipment may produce abnormal images. Eliminate the electromagnetic couplinginterference of any equipment by verification.

Warning: Replacing with the substandard spare parts may cause unpredictable electromagnetic compatibility problems, influencing the location of measurement and causing improper measurement. Only the companies and departments appointed by the manufacturer are allowed to replace the spare parts

1.7 Declaration of the Manufacturer

Users will assume all the risks of modifications for the equipment without the manufacturer's permission.

Warning: It is prohibited to perform any modifications to the equipment without the manufacturer's permission.

Warning: Modifications to the equipment must be tested by an appointed department of the nation to ensure the safety of using the equipment.

1.8 Contraindications

Do not use the equipment on patients' sores or wounds to avoid cross-infection.

This equipment is not suitable for the bladder scan of pregnant women and fetus. The knife scratch or scars on patients' abdomens will decrease the measurement accuracy. Do not use the equipment on patients with ascites. If you scan a patient with a catheter in his/her bladder, measurement accuracy will be affected.

1.9 Heat and Mechanical Indexes

Heat index: TIS:
TIB:

Mechanical index: MI:

Chapter Two Cautions and Warning

To ensure safety, please read the following instructions before using the equipment. Theequipment may only be used by the professionals authorized by the associated medical institution.

2.1 Equipment Checks

1. The instrument is normal.
2. Do not place the instrument near hot or damp items to ensure that the operation is safe.

Warning: Please install the battery for the use of the random distribution of the company. If users use other types of batteries without authorization, it may cause safety hazards to users or instruments.

2.2 Pre-scan Checks

Check if the probe is properly connected. Make sure no water, chemicals or other material have spattered on the equipment. During use of the equipment, pay attention to the main parts. If there is strange sound or smell, stop using the equipment immediately. Do not use the equipment until an authorized engineer solves the problem.

2.3 Operation Instructions

- During use of the equipment, please protect the surface of the probe and do not clash.

Apply the ultrasound gel on the surface of the probe and the patient to make sure the probe and the body is better contacted.

- Pay attention to the equipment and patient. If the equipment brakes down, turn off the power right away and then unplug the power cord.
- Patients are prohibited to touch the equipment or other electrical equipment.
- Do not seal off the air vent of the equipment.

2.4Post-scan Checks

1. Turn off the power.
2. Unplug the power cord
3. Clean the equipment and the probe

2.5 Conditions to Avoid

The equipment should avoid the following:

1. Splashing of water.
2. High humidity.
3. Poor ventilation
4. Direct sunlight.
5. Dust.
6. Gas with salt or sulfur.
7. Chemical medicines or gas.
8. Strong vibrations.
9. Our company takes no responsibility for any risks caused by disassembling of refitting of the equipment.
10. It is strictly forbidden to immerse the probe into any liquid.
11. The probe part of the heating instrument is strictly prohibited.
12. Using ultrasonic coupling agent that meets the requirements of national standards, other substances will damage the probe.

2.6 Handling the Equipment

1. Unplug the power cord.
2. Do not drop, vibrate or clash the machine and probe.

2.7 In case of Equipment Failure

If equipment is not working properly, turn off the power and unplug the power cord. Contact qualified maintenance staff.

2.8 Regular Examination and Maintenance of Equipment

2.9 Do not disassemble the Equipment and Probe randomly

2.10 Power on

Press the power button of the instrument (about 2 seconds) to enter the boot interface.

2.11 Power off

After finishing the operation for the device, long press the power key (approximately 2 seconds) to turn off the device.

Chapter Three Device Introduction

3.1 Figuration

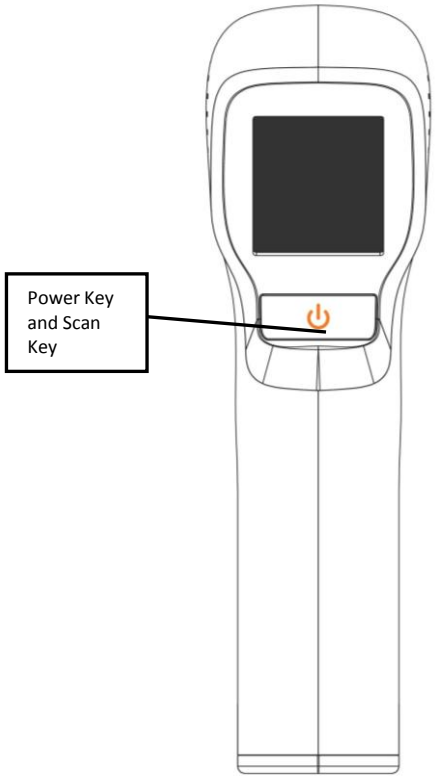


Figure 3-1 M2-W Front Diagram

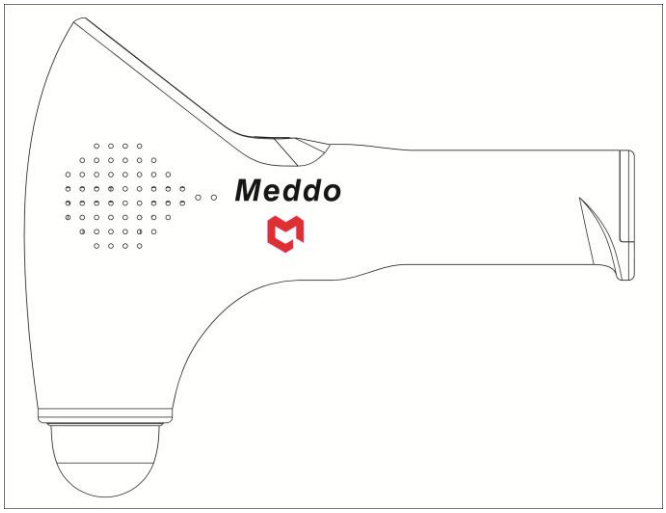


Figure 3-2 M2-W Side sketch Diagram

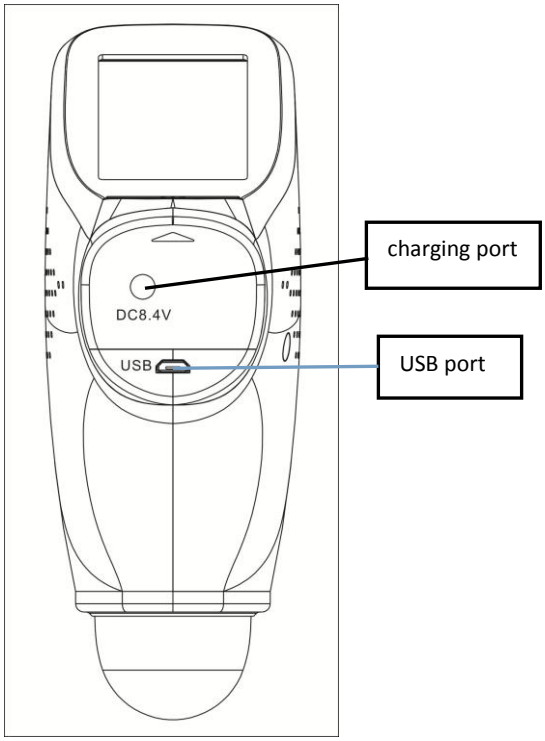


Figure 3-3 M2-W Foresight Diagram

3.2 Technical Specifications

● Probe: 3D mechanical sector

- Standard ultrasonic frequency of operation: 3.5MHz±15%
- Volume measurement range: 0ml - 999ml
- Volume measurement accuracy: ±7%,±7ml
- Volume display resolution: 1ml
- Scan time: ＜5 seconds
- Battery capacity: 2600mA
- Operation methods: touch keyboard
- Tissue Harmonic Imaging
- Information storage: information such as images and results of patients can be stored
- Information printing: printing results and pictures by Bluetooth control
- Wifi wireless transmission: uploading patient information to a computer or cell phone
- USB port: connect with the computer through this interface; it can store a large amount of user information
- Voice entry function
- Multilingual choice
- Two kinds of instrument models: expert model and simple mode
- Display size: 2.4 inches TFT-LCD
- Power: 13VA
- Instrument size: host size: 208 * 169 * 62mm + 0.6mm; size with base: 260 * 173 * 120mm + 0.6mm
- Weight: about 500 G + 50g (containing batteries)
- Power supply mode: battery power supply: DC7.4V + 0.5V
- Continuous scanning time of battery powered instrument: > 2 hours and 30 minutes.
- Battery life: more than 5 hours The waterproof level of the front end of the probe is IPX7

- The instrument is composed of the integration of the host probe

3.3 Block Diagram

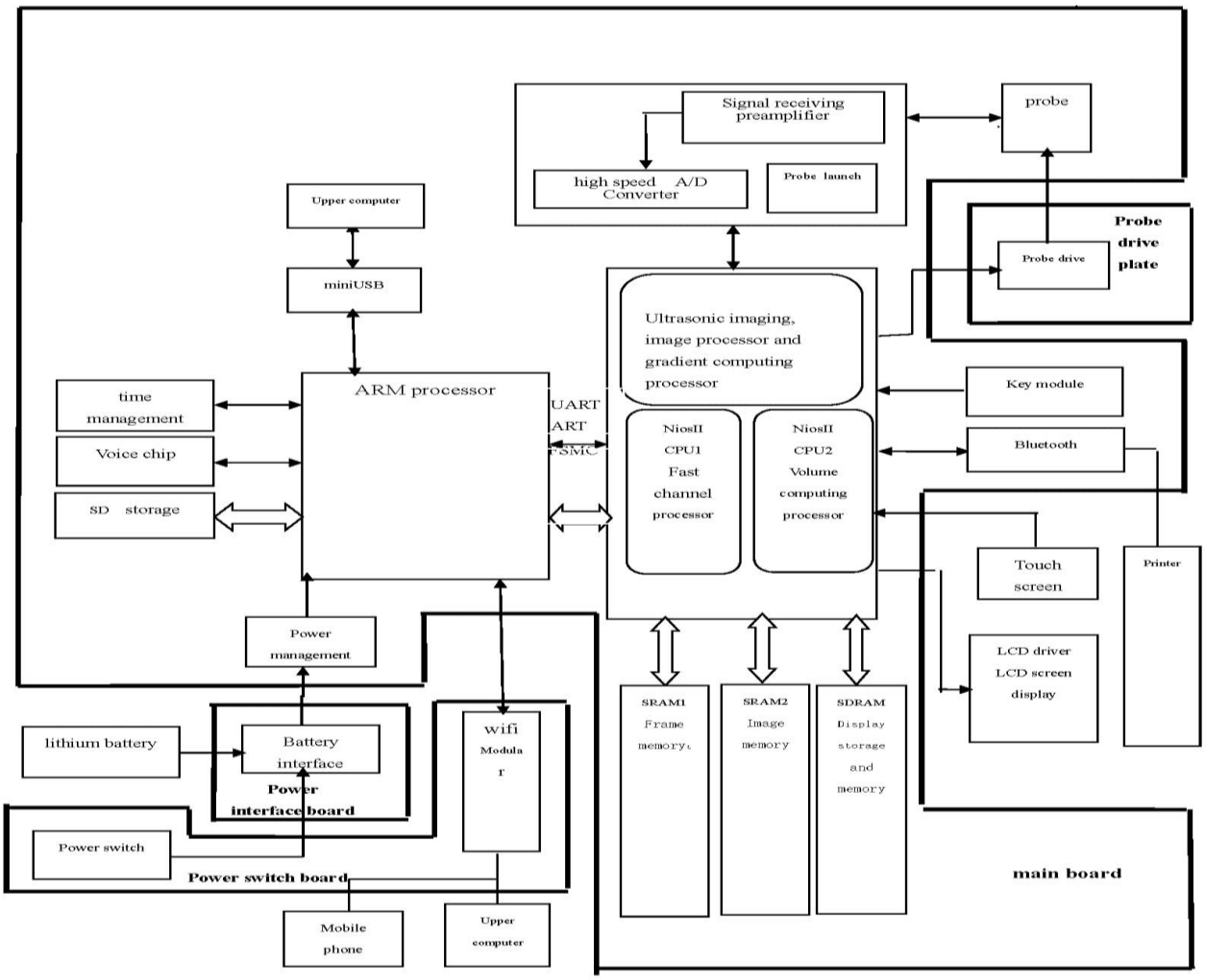


Figure 3-5 M2-W Electric principle block diagram

3.4 Basic Principles

This product is a noninvasive bladder urine volume measuring instrument. Because ultrasonic diagnosis is a noninvasive and noninvasive method, the device first uses the ultrasonic imaging principle and technology to obtain 12 images by using 3D ultrasonic probe, using one side to draw the bladder boundary point and the one edge point integral operation technique to carry out the bladder. Capacity measurement. This method is the key data to get the boundary data of each cross section of the bladder at the same time according to the image gradient. The curve of the right side of each bladder boundary is divided into L1, L2, L3, L4 and L5 segments, according to the key point of the bladder boundary segment.

The dividing section of a curve, first calculating the integral value of an integral value of the L1 section curve, adding the value of the corresponding area value of all points in the L1 section to the volume value corresponding to the L1 segment, and then judging the volume value according to the key points of each segment L1, L2, L3, L4 and L5, and accumulating the volume values corresponding to the L1, L2, L3, L4, and the segments. The volume of the right side of the bladder is the right volume of the cross section of the bladder, and the left volume value of the image is calculated with the right side. The volume value of the right and left sides is a volume value of the scanning cross section. The volume of the whole bladder is calculated by the calculation of the volume of the 12 scanning cross sections. The realization of this method makes the accuracy and miscalculation of the calculation change fundamentally to the maximum extent, which brings great convenience to clinical diagnosis.

The instrument uses 3D mechanical fan scanning probe to detect ultrasound of the bladder, and then calculates the volume of the bladder by complex operation. The working principle of the instrument is: first, the instrument sends the pulse signal to the 3D probe, and the ultrasonic wave is transmitted to the human body through the transducer in the probe. The ultrasonic wave produces reflected or scattered waves in the human body through the tissue interface. According to the time it returns, the tissue can be located. According to its strength, the characteristics of the tissue can be detected. Such a group of pulses can only obtain one of the information on a plane of the tissue, that is, a two-dimensional tissue map. Like at least 96 or 128 times (for a two-dimensional ultrasonic device), a tangent surface is formed. Then the image that is transmitted and received in turn is displayed on the display screen. The display image is the intensity of the received sound beam signal to be grayscale modulation, and a plane image that is the same as the actual tangent surface is obtained. The reflected ultrasonic wave is received by the transducer to convert the sound energy into electrical energy, which is filtered, detected and compressed through a amplified back to digital scanning converter (DSC). In order to realize real-time imaging of two-dimensional tangent, a digital scan converter (DSC) must be designed to realize the imaging scan mode of transmitting and scanning, and in the digital scanning converter (DSC), in order to realize the real-time imaging of the two-dimensional tangent, the scanning imaging mode is different from the imaging display direction. A series of image digital processing is carried out, and finally a high-definition cross-sectional image is displayed on the display screen. Secondly, the 3D probe is driven by the crystal oscillator at the top of the probe driven by the two electric units. In which the stepper motor drives the crystal oscillator to rotate 180 degrees, and the stepper motor drives the crystal oscillator to swing back and forth for 120 degrees. When the stepper motor reaches the edge position, the stepper motor is fixed and the stepper motor is held back and forth for 120 degrees. Swing, at this time we get an ultrasonic image, then let the step motor rotate 15 degrees, fixed, the step motor then swinging 120 degrees, get second images, then the next step motor rotates 15 degrees, the stepper motor is re scanned, and then again, until the next step motor rotates 180 degrees. We stopped. At this time, we obtained 13 images, took 12 of them, processed and calculated them, and finally calculated the volume of the bladder.

3.5 Device constituent

- Instrument model: M2-W
- The integration of the host and the probe（3D machanical sector probe：3.5MHz）
- Software: version M2-W.V1.0.0
- Charger model: HXY-084V1500A-UL, input: AC100-240Vac adjustment range: AC80-264V 50/60Hz 0.5A, output: no-load output voltage range: 8.35-8.65V, full load output voltage range: 7.8-8.6V, 12.6W
- Base model: BASE1
- An user manual
- Lithium battery type: UR18650ZY-2600mAh (SNLB-435) specification: DC7.4V + 0.5V 2600mAh
- Certificate
- Warranty certificate
- A packing list
- Tool bag

Chapter Four Device Installation

4.1 Unpacking

Please make sure there is no shipping damage once you unpack the device. Check all the parts and components in accordance with the Packing List and install it based on the requirements and methods described in "4.2".

4.2 Installation

4.2.1 Battery installation and removal.

Battery installation：

- Slide the cover plate of the battery ①according to the reverse direction of arrow.
- ②Insert the battery into the battery slot according to the direction of arrow.
- Push the cover plate of battery ①according to the direction of arrow.

Shown as figure 4-1

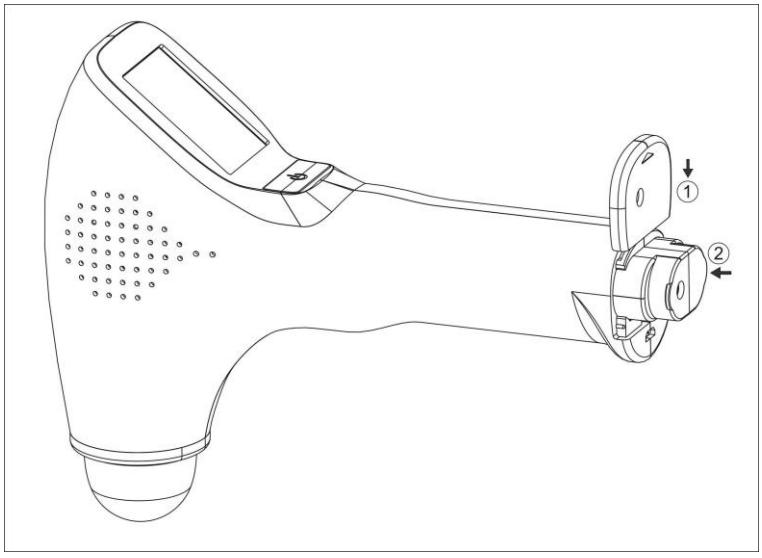


Figure 4-1 M2-W battery installation diagram

Battery removal：

- Slide the cover plate of battery ① according to the direction of arrow.
- ②Take out the battery from the battery slot according to the direction of arrow

Shown as figure 4-2

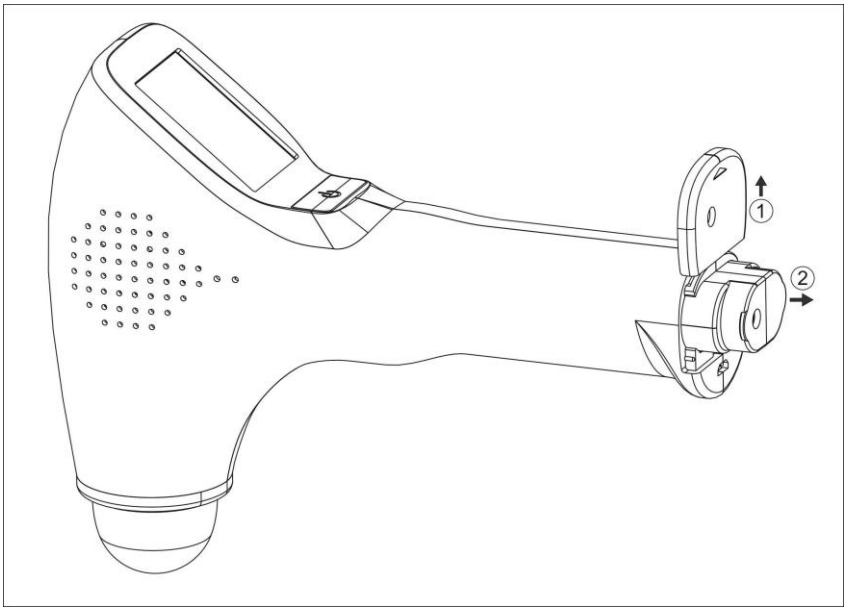


Figure 4-2 M2-W battery removal diagram

4.2.2 Base Placement Diagram

Shown as figure 4-3

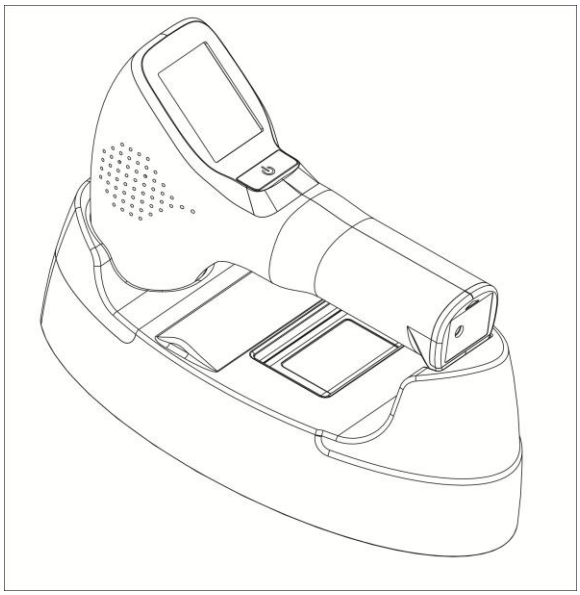


Figure 4-3 M2-W Base placement diagram

4.2.3 Bluetooth printer installation and disassembly

Bluetooth printer installation:

- First, adjust the position of the printer's power charging hole and the preset hole of the base, then put the printer ③ into the bottom shell frame.
- Press the print button ①, slide the arrow back and cover the printer's fixed cover ②.

Disassembly of the Bluetooth printer:

- press key ①
- Press the printer's fixed cover ② to slide out in the direction of arrow.
- And then remove the Bluetooth printer from the front press ③

Shown as figure 4-4

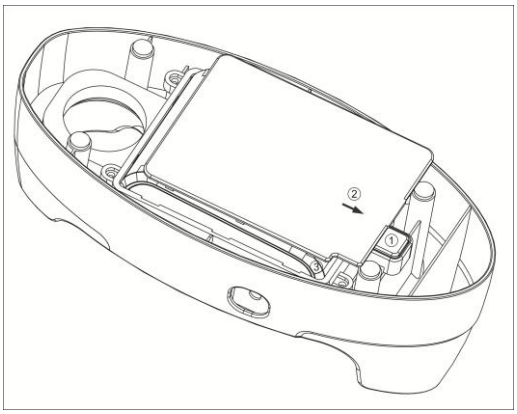


Figure 4-3 M2-W schematic diagram for the installation and disassembly of the printer

4.3 Power supply

The power supply: battery.

4.3.1 Battery power supply

1. The battery is installed on the main engine according to the "4.2" method.
2. Press the power button of the instrument host, and the instrument enters the working state.

4.3.2 Battery charging

The mainframe battery charge is charged through the charger：

1.The battery is removed from the main engine and connected to the charger output plug, and the charger outlet plug can also be inserted into the DC 8.4V hole socket on the main machine.

2. Connect the AC input plug of the charger to the power supply outlet.

3. The power indicator (red) on the charger is lit, charging the battery at that time. When the charging indicator turns green, it means that the battery is full.

The battery charge of the printer is charged by the charger：

1. Plug the charger outlet into the DC 8.4V hole socket on the base.

2. Connect the AC input plug of the charger to the power supply outlet.

3. The power indicator (red) on the charger is lit, charging the battery at that time. When the charging indicator turns green, it means that the battery is full.

Chapter Five Device Interface

5.1 Start-up Interface

Figure 5-1 M2-W Start-up Interface

A: Company logo and company name

5.2 Expert Mode

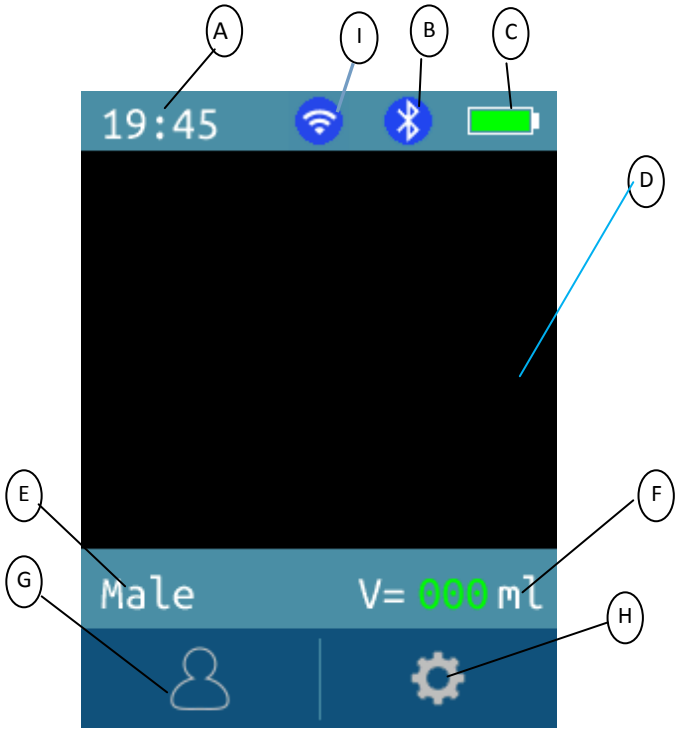


Figure 5-2 M2-W Expert mode interface

A: Time display

B: Bluetooth identification

C: battery electric power display

D: Image display area

E: Gender switching key

F: Current volume of bladder

G: Patient information input key

H: System settings key

I: WiFi identification

5.3 Easy Mode

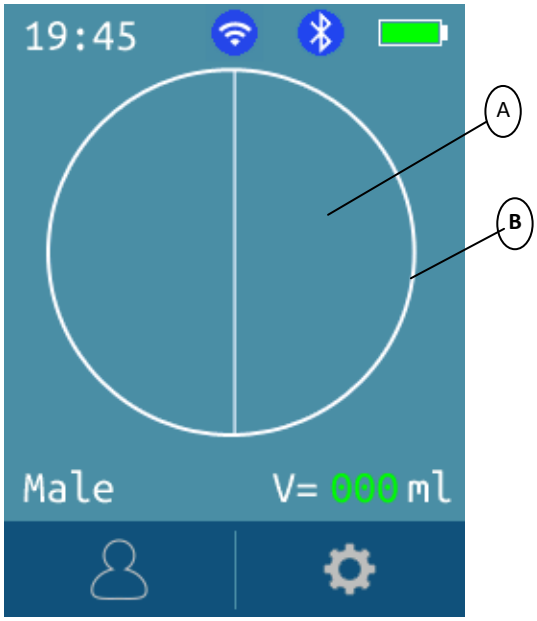


Figure 5-3 M2-W Easy mode interface

A: Schematic diagram of bladder cross section

B:Simple round frame

5. 4 Expert mode scanning interface

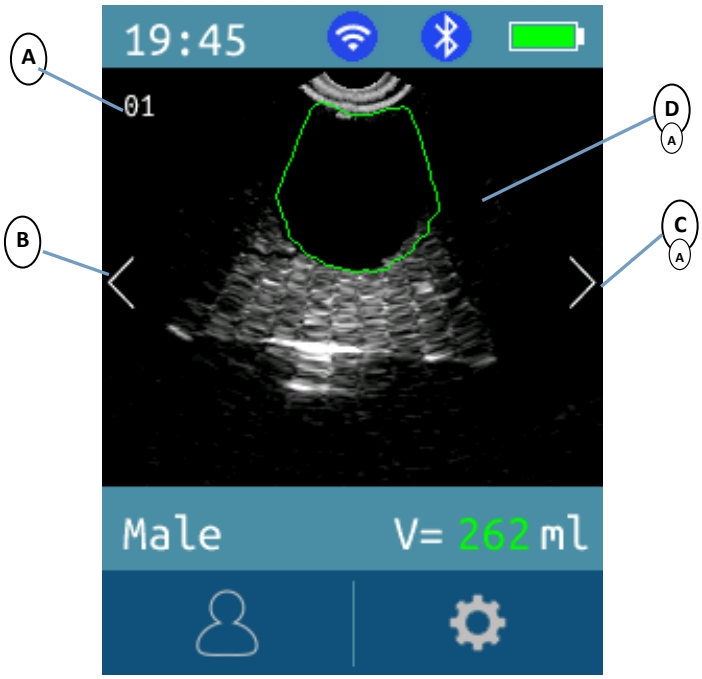


Figure 5-4 M2-W Expert mode scanning interface

A: From 01 to 12, scanning and image analysis and computation are finished, showing bladder volume.

B: View the projection key

C: View 12 image information keys

D: Bladder image area

5.5 Simple mode scanning interface

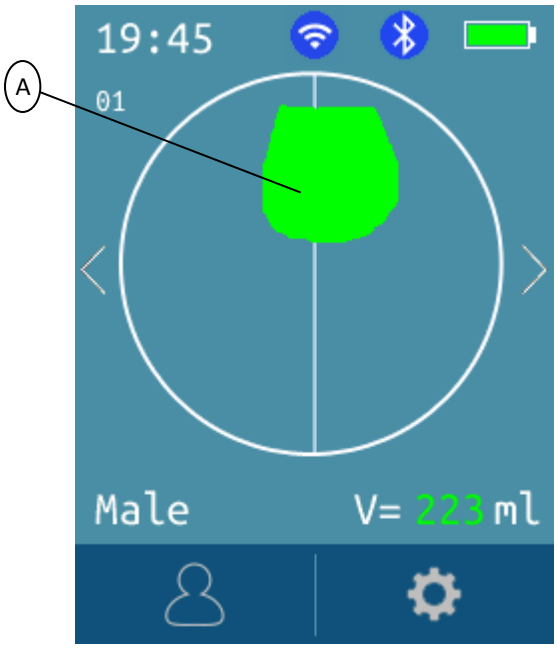


Figure 5-5 M2-W Simple mode scanning interface

A: Bladder sectional area

5.6 Bladder projection interface

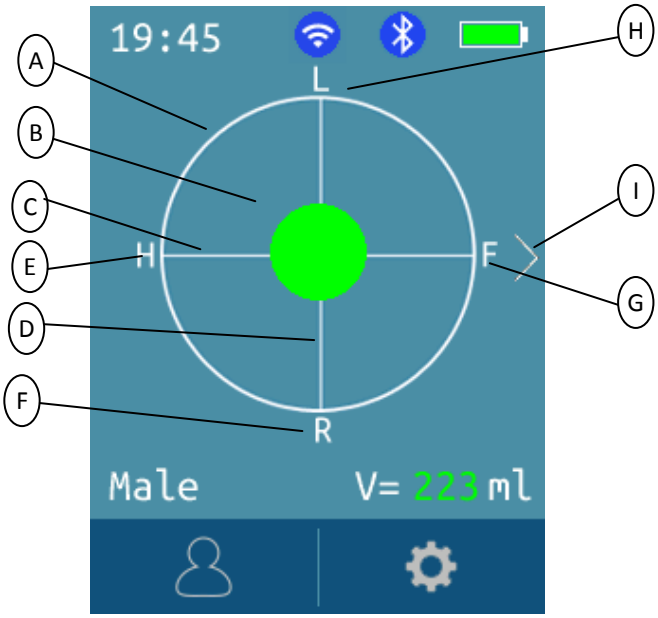


Figure 5-6 M2-W Bladder projection interface

A: Projection circle

B: Projection display area

C: Transverse line

D: Longitudinal line

E: Upper display area

F: Right display area

G: Lower side display area

H: Left display area

I： Return to the expert mode scan interface or simple mode scan interface key

5.7 **Patient input interface**

Figure 5-7 M2-W Patient input interface

A: ID code input box

B: Age input box

C: Voice input key

D: Digital input keyboard

E: Clear the current input key

F: Patient information storage key

G: Patient information print key

H: Cancel and return key

5.8 Patient information storage and print interface

Figure 5-8 M2-W Patient information storage interface

A: Store information prompt window background

B: Storage prompt character

C: Storage completion progress prompt

D: Storage key

E: Print key

5.9 System setting 1 interface

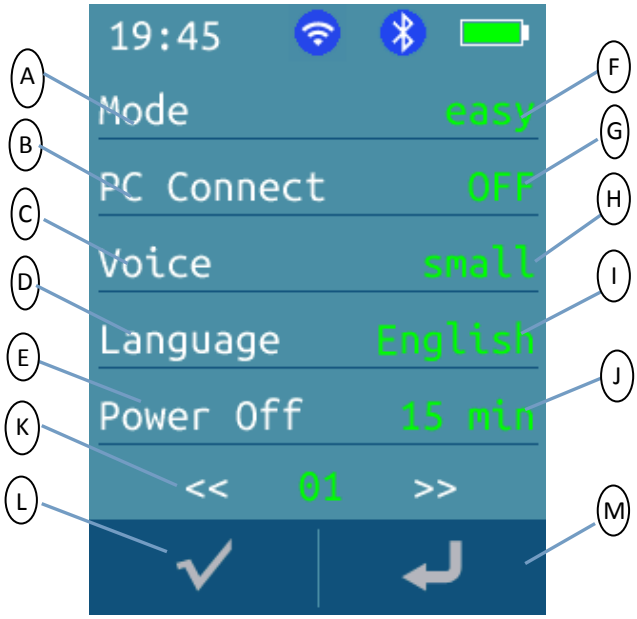


Figure 5-9 M2-W System setting 1 interface

A: Schema selection setting
B: PC connection settings
C: Volume setting
D: Interface language settings
E: Automatic shutdown time setting
F: Simple mode
G: Close up the upper computer mode
H: Voice volume is small
I: The language of the interface is English
G: Automatic shutdown time 15 minutes
K: Setting the page number selection bar
L: Confirmation key
M: Cancel and return the key

5.9.1 PC connection dialogue interface

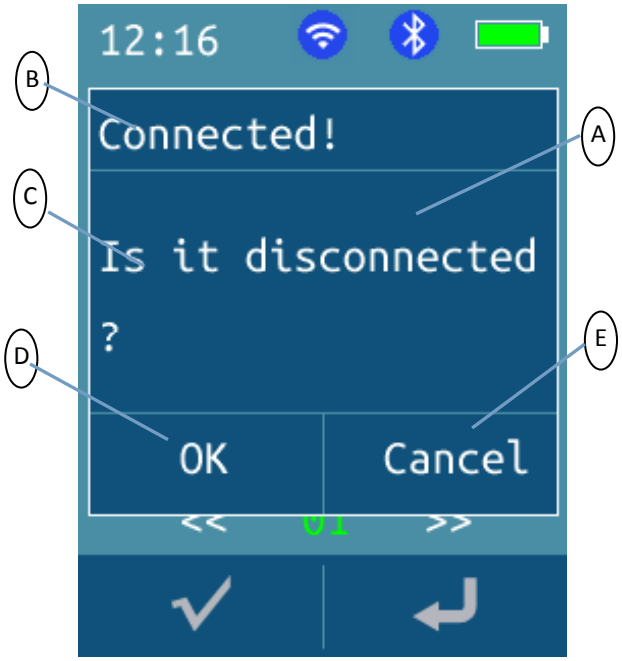


Figure 5-9-1 M2-W PC connection dialogue interface

A: PC connection dialog prompt window background

B: PC connection dialog window name

C: PC connection dialog box

D: Connection confirmation key

E: Disconnect the connection and return the key

5.10 System setting 2 interface

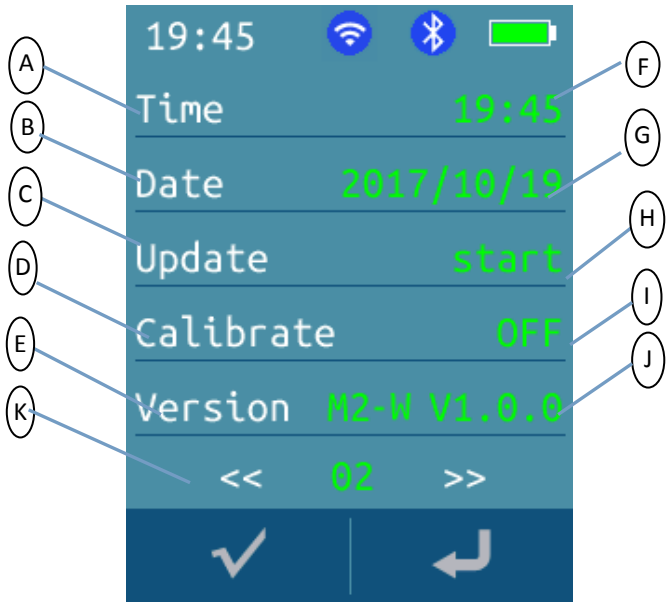


Figure 5-10 M2-W System setting 2 interface

A: Time setting

B: Date setting

C: Firmware update

D: Calibration

E: Version number

F: Current time

G: Current date

H: Start the upgrade key

I: 不显示主界面的校准值

J: Current version number of the instrument

K: Setting the page number selection bar

5.10.1 **Time setting interface**

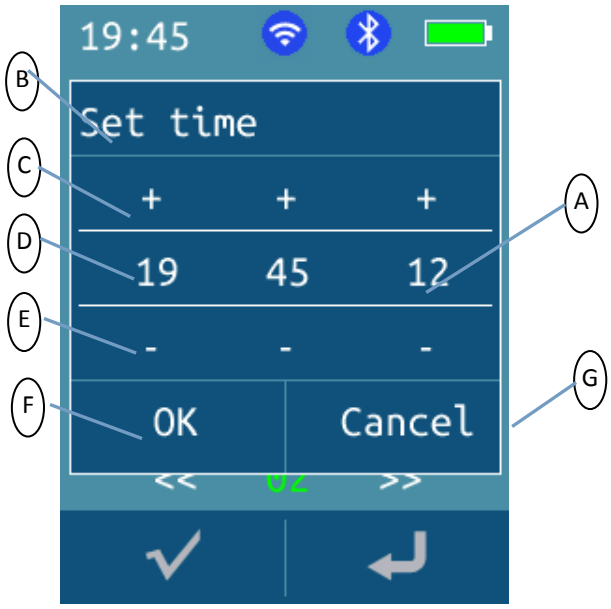


Figure 5-10-1 M2-W Time setting interface

A: Setting the prompt window background for time

B: Time setting window name

C: Time increase bar

D: Time display bar

E: Time reduction column

F: Setting the confirmation key

G: Escape key

5.10.2 Date setting interface

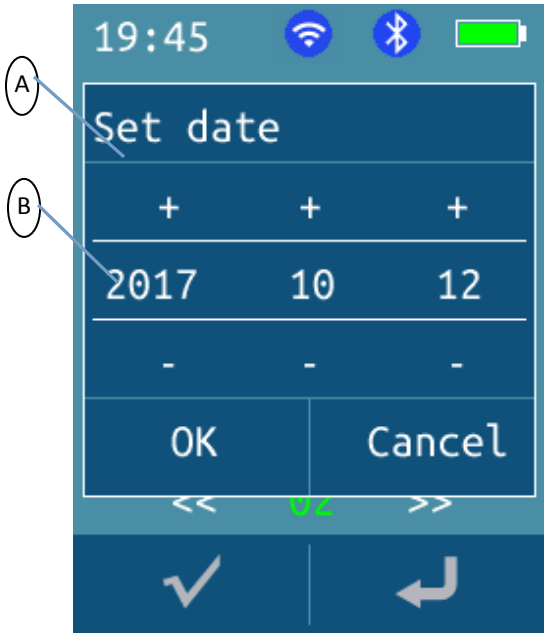


Figure 5-10-2 M2-W Date setting interface

A: Date setting prompt window name

B: Date display bar

5.10.3 Software upgrade interface

Figure 5-10-3 M2-W Software upgrade interface

A: Software upgrade prompt window background

B: Software upgrade window name plus update progress display

C: Software upgrade prompt

5.10.3.1 Software upgrade successful interface

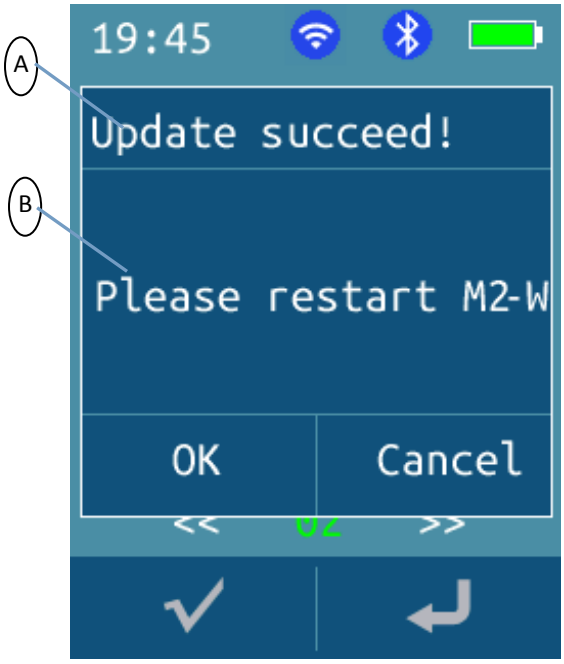


Figure 5-10-3-1 M2-W Software upgrade successful interface

A: Software upgrade successful window name B: Software upgrade prompt

5.10.3.2 Software upgrade failure interface

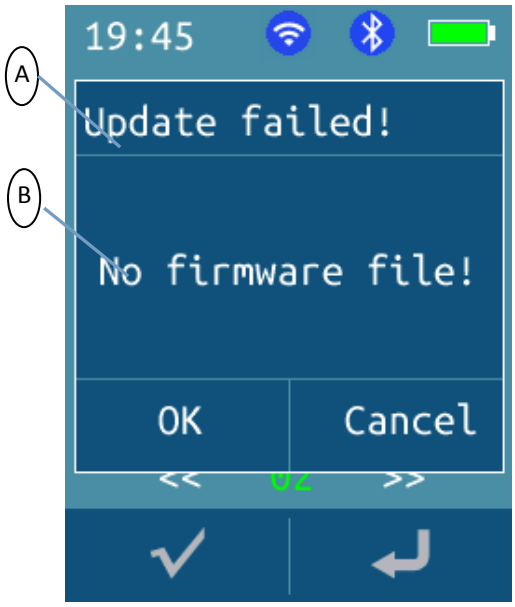


Figure 5-10-3-2 M2-W Software upgrade failure interface

A: Software upgrade failed window name B: Software upgrade failure prompt

5.10.4 Instrument calibration interface

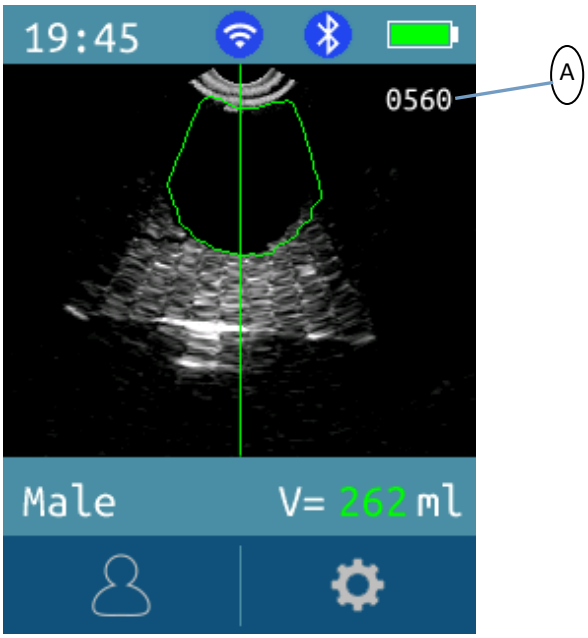


Figure 5-10-4 M2-W Instrument calibration interface

A: Calibration value

Chapter Six Operation Procedure

6.1 The opening and closing of the instrument

In shutdown state, a long time pressing the scan button can start the machine. In the boot state, press the scan key to turn off the machine.

6.2 Bladder scanning

6.2.1 Gender Selection

When the instrument is turned on, it will enter the boot interface (Figure 5-1). The boot interface will stay for about 4 seconds and automatically jump into the main interface (Figure 5-2). The sex of the defaults was male (Male). Click Male region to switch gender: male (Male), ordinary female (Female), womb free (FemaleH), child (Child).

6.2.2 Bladder Pre-scan

Apply the coupling agent on the probe surface and the patient's contact area and place the instrument probe in the bladder part of the patient. By pressing the scan key, the bladder screen will display the B-ultrasound image of the patient's bladder (Figure 5-4) or the cut surface of the bladder (Figure 5-5) on the screen.

6.2.3 Bladder Scan

After determining the location of the bladder, then press the scan button on the instrument, and the three-dimensional probe enters the scanning stage, indicating that the bladder scan is underway. The ordinal number (Figure 5-4) on the upper left part of the image is increased from 01, and when it changes to 12, it indicates the end of scanning and image analysis and computation. The volume of bladder volume was shown.

6.3 View the scanned images and projections

After the bladder scan is completed, the operator can click the “〈” or“〉” button on the interface to see 12 bladder ultrasound images respectively. “01 "means that the current image is first. At the first interface, click "<" to view the projection interface (Figure 5-6).

Please make the projection of the bladder close to the center of the cross as far as possible, and ensure that all the projection areas are connected to the cross, so as to ensure that the bladder is in the scanning area.

6.4 Patient information input

Click on the patient information icon  at the main interface (Figure 5-2 or figure 5-3) and enter the patient information input interface (Figure 5-7). Click the number (ID) and age (Age) input box to input the corresponding information at this time. ID can input 10 digit Age and enter 3 digit digits. Record the recording according to the recording Icon  and play the recording just now.

6.5 Patient information preservation and printing

After input of the patient information in 6.4, click Save icon  and start the patient information storage (Figure 5-8). The contents are: patient number, age, sex, volume value, storage date and time, voice information, and 12 ultrasonic images.

After entering the patient's information in 6.4, click on the print Icon  and begin to print the patient information. The contents of the patient are: patient number, age, sex, volume value, printing date and time, and 2 ultrasonic images. Note: only after the connection between Bluetooth printer and host can print. After connecting, the Bluetooth logo  will be displayed above the interface.

6.6 System setup

Click the set icon  on the main interface to enter the first page of the system setup interface (Figure 5-9). Click on “〈〈” or “〉〉” to look at the first page (Figure 5-9) and the second page (figure 5-10). The system setup interface has 10 options. The functions are as follows:

6.6.1 Schema selection setting

Click on the Mode bar to switch operation mode: Expert mode or simple mode. The default is an expert mode.

6.6 .2 Connection computer settings

Click on the PC Connect column, open the computer connection, pop up the connection dialog box (Figure 5-9-1), at this time you need to use the provided USB line to connect the M2-W host and the computer end. At this time, there will be a disk at the computer end, which stores the patient information. Click "OK" or "Cancel" to disconnect and return.

6.6.3 Voice size setting

Click the Voice bar to change the voice size: small (small), moderate (medium), maximum (large). The default is small.

6.6.4 Interface language settings

Click the Language column to switch the current language and support 11 languages: English, French, Danish, Finnish, Portuguese, Swedish, Spanish, Dutch, Norwegian, German, Italian. The default is English.

6.6.5 Automatic shutdown setting

Click on the Power Off bar to switch the automatic shutdown time. There are 5 files, 5 minutes, 10 minutes, 15 minutes, 20 minutes, and no automatic shutdown (OFF). The default is to turn off automatically after 5 minutes.

6.6.6 Time setting

Click the Time bar, jump out of the time set interface (Figure 5-10-1), click "+" to increase, "-" to reduce, after setting up click "OK", save time and back to the setting interface.

6.6.7 Date setting

Click the Date column, jump out of the date set interface (Figure 5-10-2), click "+" to increase, "-" to reduce, after setting up click "OK", save the date and back to the setting interface.

6.6.8 Upgrade settings

Click the Update column and jump out of the software upgrade interface (Figure 5-10-3). At this time, if there is an upgrade file in the memory, the system starts to upgrade automatically. After the upgrade is completed, the upgrade dialog box (Figure 5-10-3-1) is popped up (Figure 5-10-3-1), and the instrument needs to be restarted at this time. If there is no upgrade file in the memory, the upgrade failure dialog box is popped up (Figure 5-10-3-2).

Note: instrument upgrade must be carried out in full capacity.

6.6.9 Calibration setting

Click the Calibrate bar to switch the calibration status: turn on (ON) or close (OFF). If the state is opened, it will return to the main interface (Figure 5-10-4), and the current image calibration value will appear in the upper right corner of the image when pre scanning. If it is closed, it will not appear.

6.6.10 Version number display

The last column shows the software version number (Version).

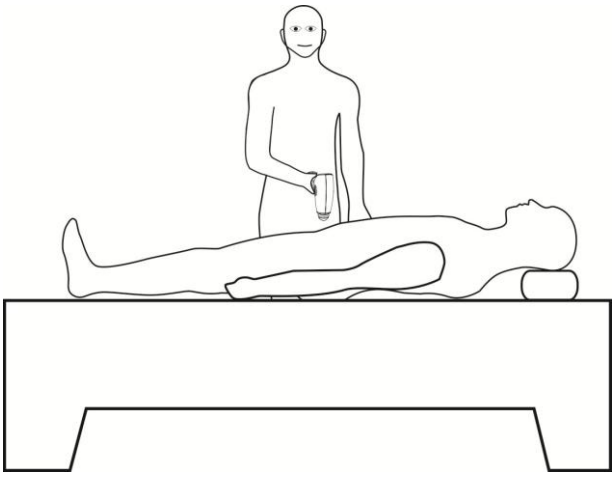
6.7 WiFi wireless uploading information

After the computer can search the WiFi signal of the host, the patient's information of the host can be uploaded to the computer or cell phone through WiFi wireless.

6.8 Scan and Bladder Location

Correct location of bladder position is the basis for accurate measurement of bladder volume. As shown in the right picture, the bladder is located in the lower abdomen and below the pubic symphysis. Before the test, the ultrasonic coupling agent should be applied at three centimeters above the pub of the examiner, and the instrument is placed according to the position shown in the diagram, and the Logo of the instrument should be pointed to the head of the subject.

In order to facilitate the user to locate the bladder position quickly, in the expert mode, the image center has a green indicator in pre scanning and scanning. The user only needs to move the probe to make the image middle, and make the largest section of the bladder. In simple mode, when scanning and scanning, users only need to shift the center of the bladder cross section to the center of the circle, and make the bladder cross section the largest.



After the scan is completed, there will be a green projection display on the main interface (Fig. 5-6). When the green center and the center of the circle deviate from each other, it indicates that the scan results are effective.

Chapter Seven Clean and Maintenance

Components, accessories and probe should be cleaned and maintained regularly to make sure the machine operates well. A mild detergent is recommended for the purpose of cleaning.

7.1 System Cleaning and Maintenance

7.1.1 System Cleaning

- Turn OFF the system power.
- Using mild neutral detergent, ethanol (75%) or isopropanol (70%) cleaning equipment (including keyboard).
- Wipe time should follow the detergent instructions and the wipe intervals should reach the clinical standards.
- If you use a detergent solution to clean the instrument, remove all residual detergent. Let it air dry or use a clean soft cloth to wipe dry.
- Use a mild detergent to wipe off the fingerprints or other smears on the screen in case of scratches against the screen.

7.1.2 System Maintenance

- The system should be operated under the condition stipulated in “1.5”.
- The system should not be shut down and started too frequently. After shut down, wait for five minutes before restarting the system.
- If the device is not used for a long time, pack up the device according to the ex-work standard and store it in the environment outlined in “8.2”.

7.2 Probe Cleaning and Maintenance

Keep the probe clean to ensure its function and long service life.

7.2.1 Cleaning and Disinfecting the Probe

1.Check the probe and other cables for signs of damage, such as cracking and/or leaking. If any signs of damage appear, stop using the probe and contact Suzhou Lischka Medtech Co., Ltd.

2. Wipe the probe with a neutral detergent.

7.2.2 Probe Maintenance

Prevent the probe surface from being scratched

1. Do not crash or drop the probe.
2. Only use domestically recognized medical ultrasound gel on the probe and patient. Improper gel may damage the probe and irritate the patient's skin.
3. Always clean the probe after it is used.

7.3 Battery Use and Maintenance

1. For optimum performance, it is recommended to charge and completely discharge a new battery two to three times before its first use.
2. The battery can be charged and discharged for hundreds of times. When the service time of the battery gets shorter than usual, the battery should be changed immediately.
3. Always keep the battery away from fire.
4. Prevent the battery from being short circuited, dampened, disassembled, dropped or crashed.
5. The battery should be charged and completely discharged once every two to three months in case of malfunction. Notice: a full-power battery will discharge slowly on its own if it's not used for a long time, therefore, charge the battery after long time shelving before using it.
6. Stop using the battery immediately once the battery becomes deformed or discolored, or gets hot or emits a smell when used. Pull it out of the device or battery charger, and dispose of it in accordance with the waste battery requirements.
7. There is a fuse in the battery charger of the random battery, but it can not be replaced. If it is found that the battery charging can not work properly, please contact our after-sales service to handle it in time.

7.4 Disposal of Electronic Waste

Waste products and the battery should be disposed of in accordance with the local laws and regulations of environmental protection. Or contact our After-sales Service Department for assistance.

Chapter Eight Transportation and Storage

8.1 Attention when Transporting the System

- Put the mainframe in the corresponding area of the work bag, strictly prohibit falling, vibration and collision of probes or instruments.
- After covering the cover of the work bag, it can be carried.
- Tighten the bottle cap of the ultrasonic coupling agent so as not to drain the colloid and put it in the working bag.

8.2 Transportation and Storage Conditions

Temperature：-40℃～+55℃

Relative humidity：10％～80％

Pressure：50kpa～106kpa

8.3 System Transportation

The labeling of the device packaging fulfills the GB191”Packaging-Pictorialmarkingforhanding” requirements. Simple shockproof materials are equipped with the carrying case, which are suitable for aviation, railway, highway, or steamship transportation. Keep dry, avoid inversion and collision.

8.4 System Storage

- The system should be unpacked when the storage time exceeds six months. Power it on for four hours, and then re-pack it according to the instructions on the box. Do not place any objects on the package, and do not place it tightly against floors, walls, or on the roofs.
- Keep it in a well-ventilated area away from sunlight or caustic gases.

Chapter Nine Inspecting and Troubleshooting

9.1 Inspecting

Check whether the power supply (battery) is installed.

9.2 Troubleshooting

No.	Symptom	Troubleshooting Method
1	When the power button is pressed, the indicator does not turn on and there is no signal on the screen visible.	1.Check whether the battery is installed. 2. Check whether the battery has electricity.
2	Snow flake-shaped or mesh-shaped interference images appear on the screen.	1. Check whether the battery is normal. 2. Check if the environment such as electromagnetic fields interferes with the device.
3	The display has an image display, and the key can not be operated.	Pull out the battery, then insert the battery and turn on the machine.

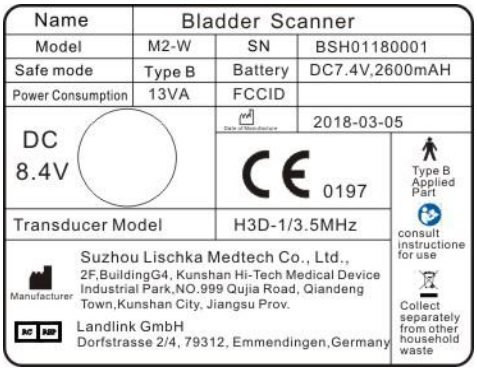
2.2 If problems continue, please contact Suzhou Lischka Medtech Co., Ltd.

2.3 Repair

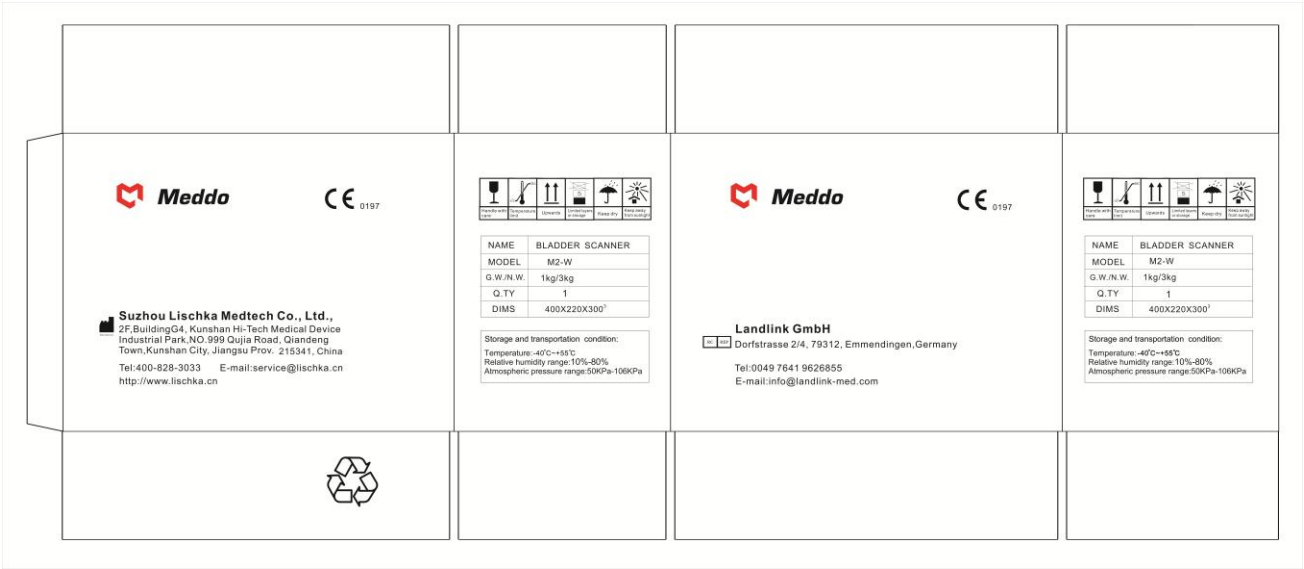
- The device must be repaired by the departments designated by the manufacturer.
- All materials for repair, if needed, will be provided by the manufacturer.

Appendix A Labeling Graphics

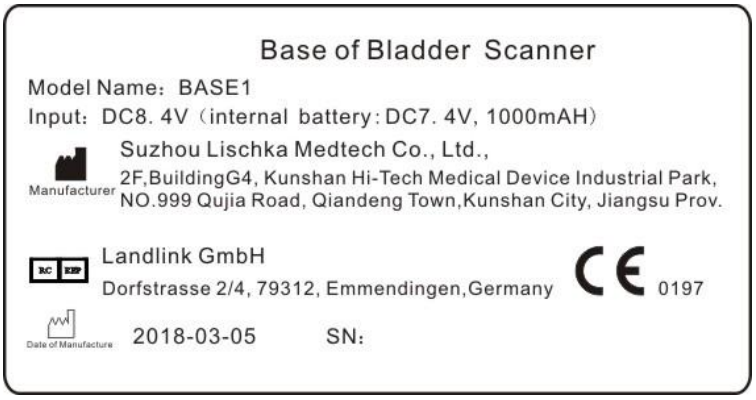
M2-W Main Unit Labeling



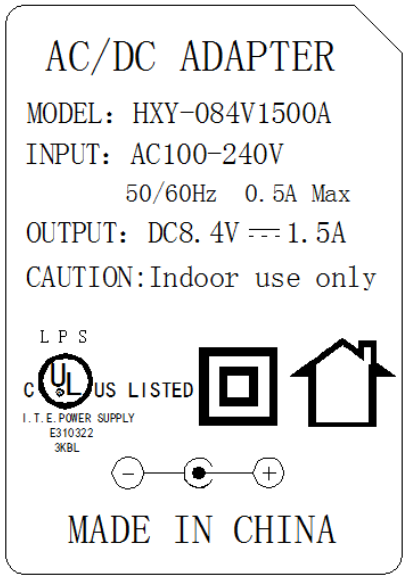
M2-W Packaging Box Labeling

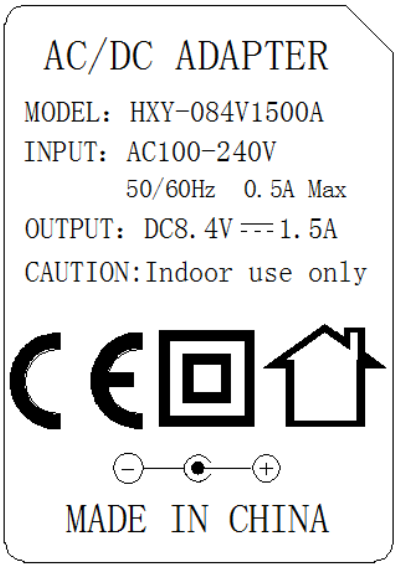


M2-W Base Labeling



M2-W Chargers Labeling





Appendix B Acoustic Output Report

Suzhou Lischka Medtech Co., Ltd.

Registered Address: 2F,BuildingG4, Kunshan Hi-Tech Medical Device Industrial Park, NO.999 Qujia Road, Qiandeng Town,Kunshan City, Jiangsu Prov., CN

Manufacturing Address: 2F,BuildingG4, Kunshan Hi-Tech Medical Device Industrial Park, NO.999 Qujia Road, Qiandeng Town,Kunshan City, Jiangsu Prov., CN

After-sale Service Address: 2F,BuildingG4, Kunshan Hi-Tech Medical Device Industrial Park, NO.999 Qujia Road, Qiandeng Town,Kunshan City, Jiangsu Prov., CN

Tel : 0512—36692288-812

Fax : 0512—36693388

Postal Code : 215341

Version: M2-W.V1.0.0

Created Date:

FCC Statement

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

-Reorient or relocate the receiving antenna.

-Increase the separation between the equipment and receiver.

-Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

-Consult the dealer or an experienced radio/TV technician for help.

FCC RF Exposure Information and Statement

When carrying the product or using it while worn on your body, either use an approved accessory such as a holster or otherwise maintain a distance of 5 mm from the body to ensure compliance with RF exposure requirements. Use of other accessories may not ensure compliance with FCC RF exposure guidelines.