Bladder Scanner
Model: M2-W/M2

User Manual

Version: M2-W.V1.0.2/M2.V1.0.2

Suzhou PeakSonic Medical Technology Co.Ltd.

Contents

Chapter I Overview

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1.1 Introduction

The M2-W/M2 bladder scanner manufactured by Suzhou Lischka Medtech Co.,Ltd. provides non-invasive measurement of urinary bladder volume using ultrasonic imaging and measurement principle. The instrument is a handheld structure composed of a host and a probe. It has the following features:

- This instrument has three operation modes: expert mode, easy mode and intelligence mode. In the expert mode, the real-time 2D B-mode ultrasound image is displayed. The operator can determine whether the position and the result of the measurement are correct based on the bladder cross-section image displayed. In the easy mode, there is no real-time 2D scanning image. The operator is guided by the instrument to move the probe to locate the bladder and measure the volume. The operator doesn't need to have expertise in ultrasonic diagnosis. In the intelligence mode, it displays a real-time bladder projection image during pre-scan. The position of the bladder is already located before scan. The operator only need to move the probe till the real-time bladder projection image reaches the centre of the crosshair. Positioning the bladder before scanning is an important feature of the intelligence mode.

- During measurement, the instrument is non-invasive and comfortable to use for patients. It is accurate, reliable, rapid and simple. Several 2D ultrasound images are obtained within a few seconds after releasing the scan key. By using complex image processing technology, those 2D images are restored to 3D. At the

same time it adopts complex algorithm to calculate the bladder volume and display the results.

- Two orthogonal images, patient information and volume values can be printed.
- Adopt touch screen keyboard for operation.
- SD card storage.
- Voice recording function.
- Multi-language selection.
- The instrument is of handheld structure, integrated with injection moulding shell, probe and host. It adopts a 2.4 inch LCD with (240*320) pixels.
- Power supply with built-in battery.

1.2 Intended Use

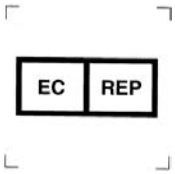
The instrument is suitable for the measurement of bladder volume in primary medical units and nursing homes. It provides the basis for the implementation of clinical catheterisation and evaluates the residual amount of urine after urination. And it helps to make auxiliary diagnosis for the bladder and kidney function diseases. The instrument is also suitable for people with lower body disability and loss of self urination function to master the time of urination.

1.3 Carry out Standards

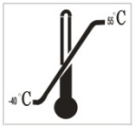
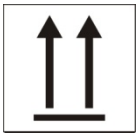
The instrument shall be designed and manufactured strictly according to national standards GB9706.1—2007 *Medical Electrical Equipment Part 1: General Requirements for Safety and* GB9706.9-2008 *Medical Electrical Equipment: Specific Requirements for the Safety of Medical Ultrasonic Diagnostic and Monitoring Equipment*. The protection type of electric shock hazard is: Type B of Class II.

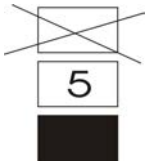
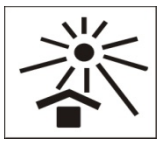
The environment test of the instrument shall meet the requirements of climate environment test Group II and mechanical environment test Group II of GB/T14710-2009 Environmental Requirements and Test Methods for Medical Electrical Equipment.

Industry symbol dictionary:

	Serial number		Follow the instructions
	Production date		Type BF applied part
	EC REP—Authorized Representative in the European Community		Warning or Caution—Consult accompanying documents. Read instructions before connecting or operating.
	Manufacturer	IPX7	Ingress protection (IP) against water
	The waste electrical and electronic equipment shall be recycled according to the regulations	CE 0197	CE—Marked in accordance with the Medical Device Directive (MDD)
FCCID 2APLQ-M2-W	Wireless certification code		Prescription use only

Description of packing and transportation marks of the instrument:

	Fragile item, handle carefully
	Limit of temperature
	Upward

	Limit number of stacking layer
	Keep dry
	Avoid heat

1.4 Service Life

The life cycle of this product is 6 years. Continued use of this product after the life cycle will lead to increased fault rate of the product and unexpected risks.

Warning: All risks arising from the continued use of the product after its life cycle shall be borne by the user.

Note: The scrapping and disposal of the product shall comply with local regulations. Do not scrap them with household waste.

1.5 Operating Environmental Requirement

a) Ambient temperature range: +5°C ~ +40°C

b) Relative humidity range: 30% ~ 75%

c) Atmospheric pressure range: 70KPa ~ 106KPa

1.6 Statement on Electromagnetic Compatibility

The use of M2-W/M2 equipment does not affect the normal wired and wireless information transmission and the performance of other electronic equipment. It can work normally in the specified electromagnetic environment.

Warning: When the instrument is operated in strong electromagnetic environment, such as close to the motor, x-ray equipment, dental and physiotherapy equipment, broadcasting station or underground cable, there will be interference signals on the image affecting the measurement accuracy. At this time, the instrument shall be stopped to prevent mismeasurement and can be reused after the electromagnetic interference is eliminated.

Warning: Sharing power with other equipment may result in abnormal images. The electromagnetic coupling interference caused by any equipment shall be excluded through verification.

Warning: If the user replaces the non-conforming equipment parts voluntarily, there may be unforeseen electromagnetic compatibility problems which interfere with the measurement position resulting in error in measurement. Therefore, replacement of parts must be carried out by the unit and department designated by the manufacturer.

Warning: If the user doesn't use the battery of the model specified by the manufacturer, there may be unforeseen electromagnetic compatibility problems which prevent instrument from working normally. Therefore, the battery of the model specified by the manufacturer must be used.

Warning: When charging the battery when it is in the instrument, the power supply of the instrument shall be disconnected, so the instrument cannot be used during battery charging.

1.7 Statement of the Manufacturer

Responsibilities of the manufacturer

Suzhou Lischka Medtech Co., Ltd. only considers itself responsible for the safety, reliability and performance of the instrument in case of the following circumstances, namely:

- The assembly operation, expansion, re-adjustment, improvement and repair are carried out by personnel approved by Suzhou Lischka Medtech Co., Ltd.;
- Relevant electrical equipment complies with national standards;
- The instrument is used according to operation instruction.

In case of the following situations, Suzhou Lischka Medtech Co., Ltd. is not responsible for the safety, reliability and operation of the products:

- The components are disassembled, stretched and re-debugged;
- The product is not correctly used according to the *User Manuel*.

Warning: Without the permit of the manufacturer, the equipment shall not be modified.

Warning: If the equipment is modified, corresponding detections and tests must be carried out in the department designated by the state to ensure that the equipment can be used continuously and safely.

1.8 Contraindications

Do not use the Bladder Scanner on the following cases:

- Fetal use or pregnant patients.
- Patients with ascites.
- Patients with open or damaged skin.
- Patients with wounds in the suprapubic region.
- Patients with urinary catheter insertion

1.9 Release of the Heat Indexes and Mechanical Indexes

Heat indexes TIS: ＜0.032

TIB: ＜0.032

Mechanical indexes MI: ＜0.54

Chapter II Precautions

In order to ensure safety, please read the following contents before start using the equipment. This instrument is only allowed to be operated by personnel confirmed or authorised by the relevant medical institution.

2.1 Inspection before Operation

(1) The instrument is normal.
(2) Keep the instrument away from the hot or wet objects. Make sure the instrument is in the right place for safe operation.

Warning: Please install and use the battery provided by the manufacturer to carry out the work. In case of using battery of other specifications and models, hazards to the user or the instrument may occur.

2.2 Safety Check before Operation

Check whether the instrument is in good condition. Make sure no water, chemicals or other substances spilled on the instrument. If any abnormal noise or smell occur during the operation, stop using immediately until the authorised engineer resolves the problem(s).

2.3 Operating Instructions

(1) Protect the probe against collision during operation. Apply the coupling agent on the probe to enable better contact with the body.
(2) Closely monitor the running of the instrument and the status of the patient. Turn off the power immediately in case of any breakdown.
(3) Prevent the patients from touching the instrument or any other electronic appliances.
(4) Keep the vent of the instrument open.

2.4 After Operation

(1) Switch off the power.
(2) Clean the instrument and the probe.
(3) Place the instrument back to the docking station.

2.5 Situations to be Avoided

With respect to the instrument, the following situations shall be avoided as far as possible:

(1) Splashing
(2) High humidity
(3) Poor ventilation
(4) Straight sunshine
(5) Dust environment
(6) Saliferous or sulfurous gas
(7) Chemical medicine or gas
(8) Strong vibration and collision
(9) The company is not liable for any risks arising from the disassembly or modification of the instrument by the user.
(10) Strictly forbid to dip the probe part which contacts the patients into any liquid.
(11) Strictly forbid to heat the probe part which contacts the patients.
(12) Use the ultrasonic coupling agent which meets the national standards. Prevent use of any other materials such as oil which damages the probe.
(13) Keep the probe clean. Wipe off the ultrasonic coupling agent on the probe with neutral detergent or fresh water after use.

2.6 Cautions during Transportation

(1) Switch off the power supply.
(2) Prohibit dropping, vibrating and colliding.

2.7 Operation in case of Malfunction

In case of malfunction, turn off the power supply immediately, plug off the battery and contact the qualified maintenance personnel.

2.8 Regular Inspection and Maintenance of the Instrument

2.9 Do not Disassemble the Instrument

2.10 Startup

Long press the power button of the instrument (about 2 seconds) to enter the startup interface.

2.11 Shutdown

Long press the power button (about 2 seconds) to shut down the instrument.

Chapter III System Introduction

3.1 Appearance

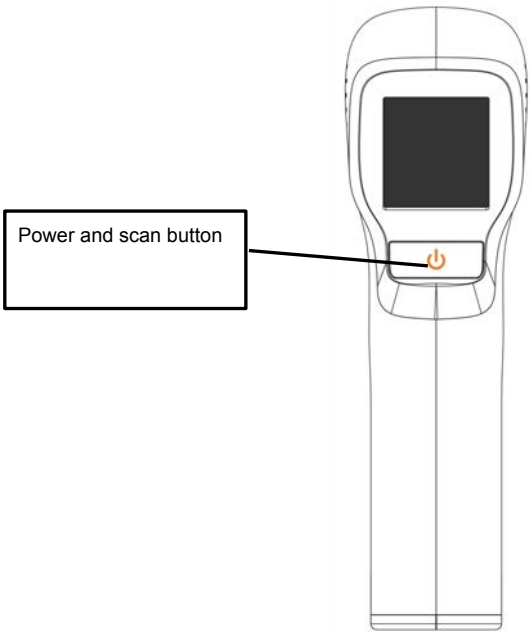


Figure 3-1 Top View of M2-W/M2

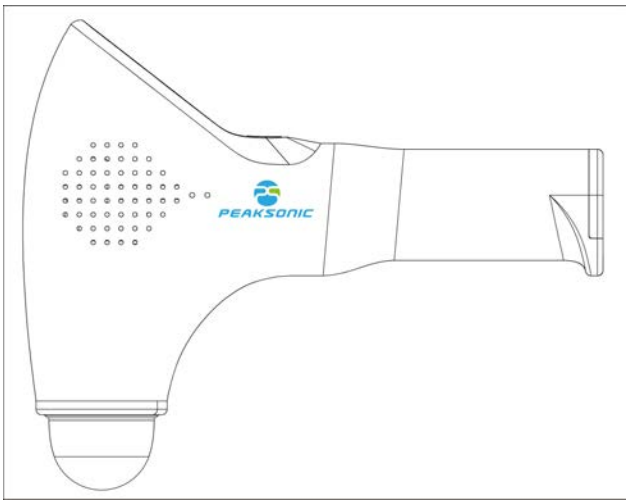


Figure 3-2 Side View of M2-W/M2

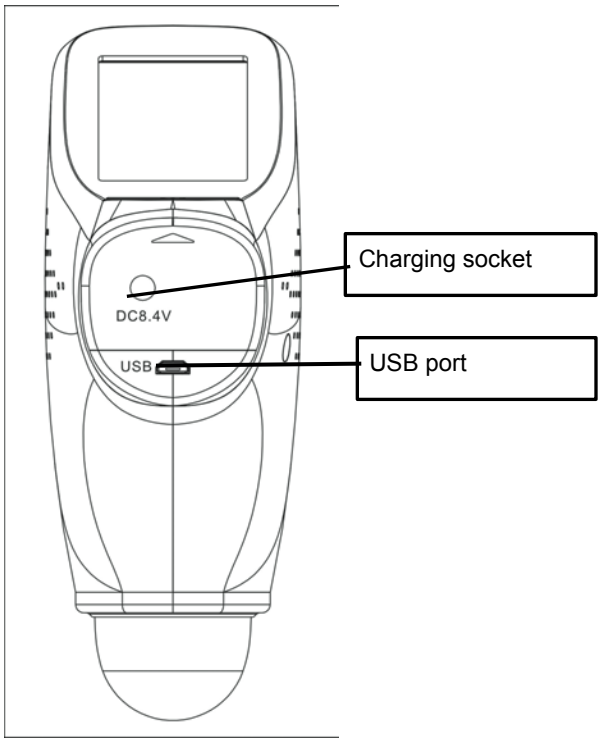


Figure 3-3 Back View of M2-W/M2

3.2 Technical Specifications

- Probe: 3D mechanical sector-scanning
- Nominal ultrasonic operating frequency: 2.5MHz±15%
- Volume measurement range: 0ml-999ml
- Volume measurement accuracy: Error ±7%, ±7ml
- Volume display resolution: 1ml
- Scanning time: < 5 seconds
- Capacity of battery: 2600mAh
- Operation mode: Touch key
- Tissue harmonic imaging
- Information storage: Images, results and other information of the patient can be stored.
- Information printing: Print the measurement results and pictures through Bluetooth control
- WIFI wireless transmission: upload patient information to the computer (Only available with M2-W)
- USB interface: Connect with the computer through this interface; Plenty of user information can be stored.
- Voice recording function
- Multi-language selection

- There are three operation modes: Expert mode, easy mode and intelligence mode
- Size of display screen: 2.4 inch TFT-LCD
- Power: 13VA(M2 Power: 10VA)
- Size: Host size: 208*169*62mm±0.6mm; Boundary dimension with the base: 260*173*120mm±0.6mm
- Instrument weight: About 500g ±50g (including battery)
- Power supply mode: Battery powered: DC7.4V±0.5V mode: Battery
- Continuous scanning time of battery powered instrument: > 2 hours and 30 minutes
- Continuous electrification time of battery powered instrument: > 5 hours
- The waterproofing grade of the front end of the probe is IPX7.
- The instrument is an integrated device consisting of the host and the probe.

3.3 Block Diagram

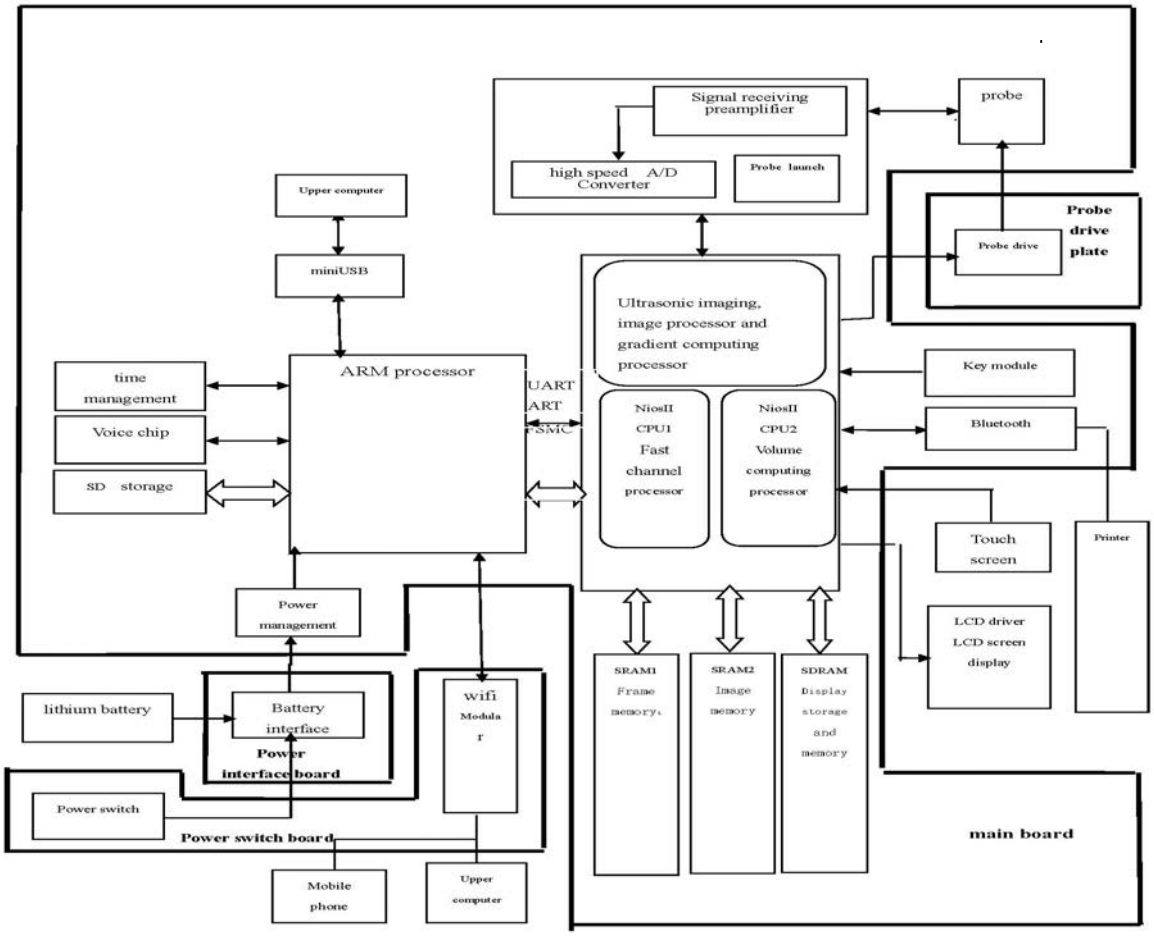


Figure 3-4 Block diagram of electrical principle of M2-W/M2

3.4 Basic Principle

This product is a non-invasive bladder scanner. On account of that ultrasonic diagnosis is a non-invasive examination method, this device firstly uses the principle and technology of ultrasonic imaging and obtains 12 images by using the 3D ultrasonic probe. It measures the bladder volume with the technology of drawing the bladder boundary points and conducting point integral operation at the same time. The method is as follows. According to the gradient value of the image, rapidly outline to obtain the boundary data of each section of the bladder, while obtaining key data of bladder boundary segment points. For the 12 images obtained through scanning according to the bladder boundary segment points, the curve at the right of the bladder boundary in each image is divided to 5 segments: L1, L2, L3, L4 and L5. According to the division segments of the curve, calculate the integral value of one surface in integral values of L1 first. The sum of the area values corresponding to all points of L1 is the volume value of L1. And then the positive and negative judgment shall be conducted to the volume value according to key points of L1, L2, L3, L4 and L5. The volume of the right part of the bladder scanning section is the sum of the volume values corresponding to L1, L2, L3, L4 and L5. The volume of the left part shall be calculated with the same method as that of the right part. The volume value of one scanning section is the sum of the volume values of the right and the left parts. The volume of the whole bladder is the sum of 3-dimensional volume of 12 scanning sections. The instrument adopts a 3D mechanical sector-scanning probe to conduct ultrasonic detection and scanning of the bladder, and then performs complex operation to calculate the bladder volume. The operating principle of the instrument is: Firstly, the instrument sends pulse signal to the 3D probe, and then transmits ultrasonic wave to the human body through the energy converter in the probe. The ultrasonic wave generates reflected or scattered wave in the human body as it passes through tissue planes, and the tissue and organ can be positioned according to its return time. According to its strength, tissue characteristics can be detected. Sending such a set of pulses can only capture one piece of information on a plane of the tissue, i.e., usually a 2D sectional tissue image needs it to be transmitted at least 96 or 128 times (for a 2D ultrasound device), so as to form a section. And then transmitted and received images shall be displayed on the screen successively. With respect to displayed images, gray-scale modulation is conducted to the received sound beam signal intensity, achieving a plane image identical to the actual section. The reflected ultrasonic wave is received by the energy converter to convert the sound energy into electrical energy. This electrical signal is amplified and sent to the digital scanning converter (DSC) for filtering, detection and compression. Due to the difference between the emission scanning imaging mode and the imaging display direction and different imaging speed, in order to achieve the real-time imaging of the 2D section, a digital scanning converter (DSC) must be designed in the instrument to transform the emission scanning mode into the imaging scanning mode, and a series of image digital processing shall be carried out in the digital scanning converter (DSC) to finally form a high-resolution section image displayed on the screen. Secondly, the 3D probe is driven by two motor units to drive the crystal oscillator on the top of the probe to rotate and swing. Of which, the lower stepping motor drives the

crystal oscillator to rotate for 180 degrees, and the upper stepping motor drives the crystal oscillator to swing for 120 degrees. When the lower stepping motor reaches the edge position and is fixed, the upper stepping motor swings back and forth for 120 degrees, and an ultrasound image is generated. Then, make the lower stepping motor rotate for 15 degrees and fix, the upper stepping motor swings for 120 degrees to obtain the second image. Next, make the lower stepping motor rotate for 15 degrees, the upper stepping motor scan again and so forth, until the lower stepping motor rotates for 180 degrees and stops. At this time, we have obtained 13 images, with 12 images being processed for calculation to obtain the final bladder volume.

3.5 Instrument Components

- Instrument model: M2-W/M2
- Integration of the host and the probe (including 3D mechanical sector-scanning probe: 2.5MHZ)
- Software: Version M2-W.V1.0.2/M2.V1.0
- One 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
- Service manual
- Lithium battery: Model UR18650ZY-2600mAh (SNLB-435) Specification: DC7.4V±0.5V 2600mAh
- Certificate of Qualification
- Warranty certificate
- Packing list
- Work package

Chapter IV Installation

4.1 Unpacking & Initial Inspection

Open the box and inspect transportation damage. Verify according to the "packing list" and ensure you have received all appropriate components. Install according to the requirements and methods specified in "4.2" (the installation of the instrument only includes the installation of battery).

4.2 Installation

4.2.1 Insert and Remove the Battery

Insert battery:

Slide the battery door ① according to the reverse arrow direction.

② Insert the battery according to the arrow direction.

Slide the battery door ① according to the arrow direction till it reaches the end.

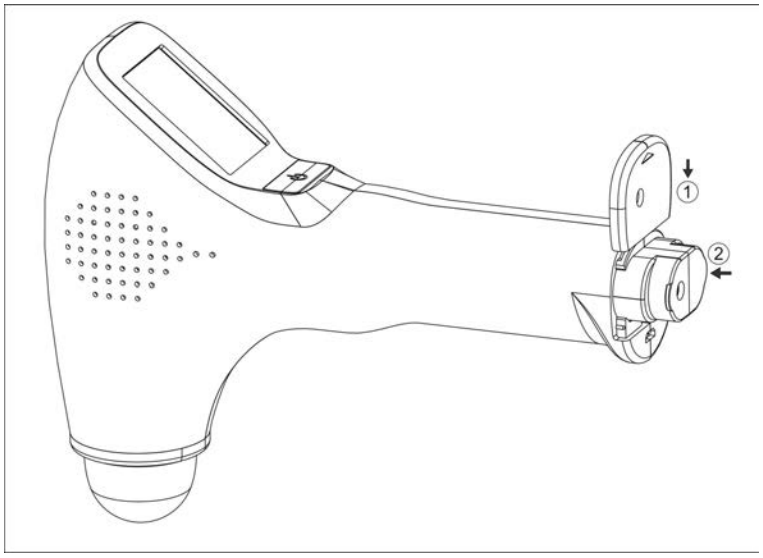


Figure 4-1 M2-W/M2 Install Battery

Remove the battery:

Slide the battery door ① according to the arrow direction.

② Take out the battery according to the arrow direction.

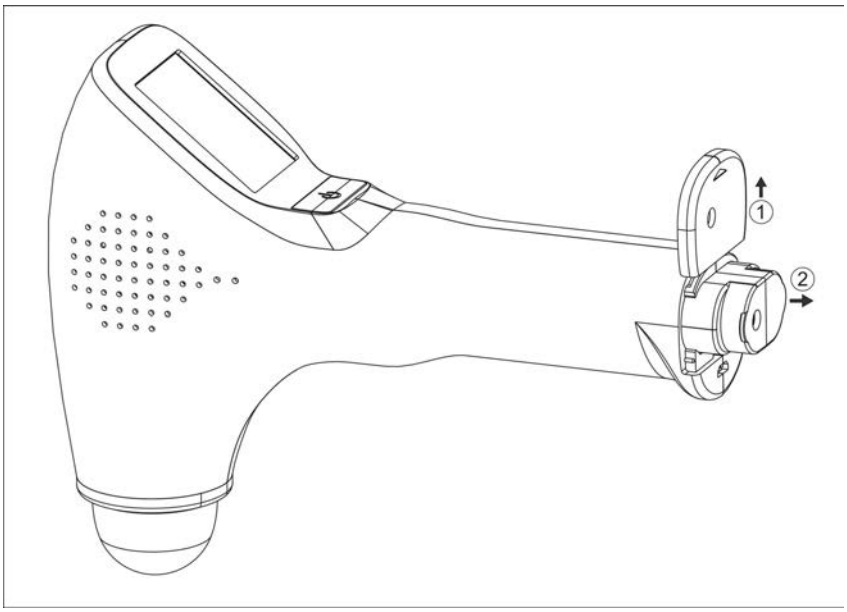


Figure 4-2 M2-W/M2 Disassemble Battery

4.2.2 Place the Instrument on the Docking Station

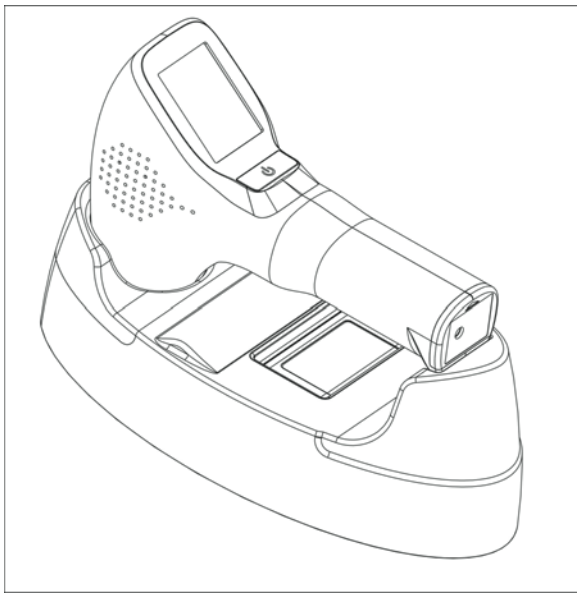


Figure 4-3 M1-W/M1 Place the Instrument on the Docking Station

4.2.3 Attach and Remove the Bluetooth Printer

Attach the Bluetooth Printer:

- First, adjust the power charging port of the printer to be consistent with the direction of the preformed hole on the base, then place the printer ③ into the bottom case frame.
- Press the print key ①, and slide the printer retaining cover ② according to the reverse arrow direction to cover it.

Remove the Bluetooth printer:

- Press the key ①
- Slide the printer retaining cover ② according to the arrow direction to remove it.
- And then press from the front to remove the Bluetooth printer ③

  (As shown in Figure 4-4)

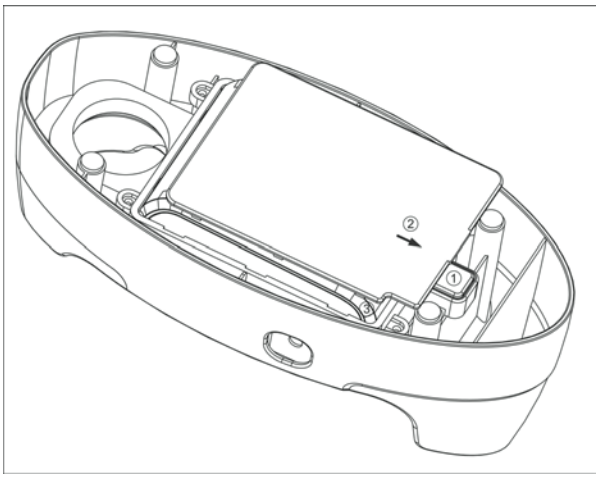


Figure 4-4 M2-W/M2 Printer Attach and Remove

4.3 Power Supply

Power supply mode of the instrument: Battery powered.

4.3.1 Battery Powered

(1) Install the battery on the host according to the method stated in "4.2".
(2) Press the power button on the host to activate the instrument.

4.3.2 Charge the Battery

Host battery is charged through the charger:

(1) Remove the battery from the host and connect it to the batter charger, or plug the charger output plug into the DC 8.4V round hole socket on the host.
(2) Plug the power supply into a standard wall outlet.
(3) If the power indicator light on the charger is red, it means the battery is being charged. When the indicator light turns green, it means the battery is fully charged.

Printer battery is charged through the charger:

(1) Plug the charger output plug into the DC 8.4V round hole socket on the base.
(2) Plug the power supply into a standard wall outlet.
(3) If the power indicator light on the charger is red, it means the battery is being charged. When the indicator light turns green, it means the battery is fully charged.

Chapter V Instrument Interface

5.1 Startup

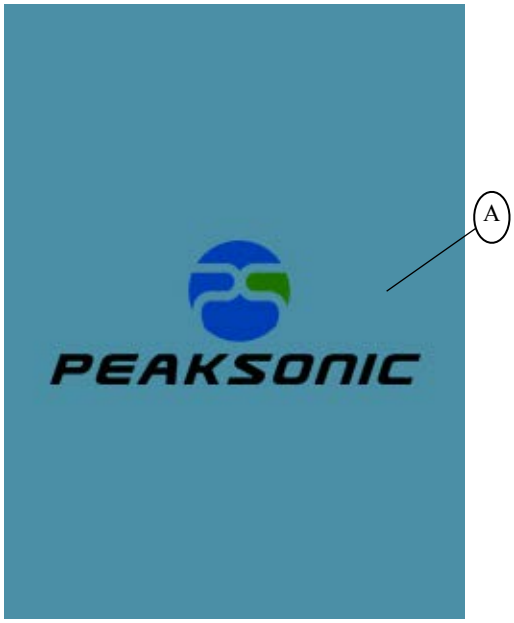


Figure 5-1 M2-W/M2 Startup interface

A: Company Logo and Name

5.2 Expert Mode

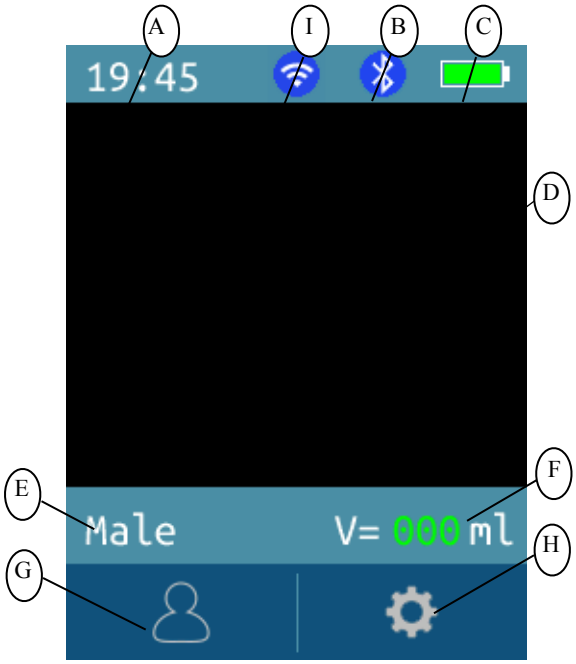


Figure 5-2 M2-W/M2 Expert Mode Interface

A: Time

B: Bluetooth

C: Battery level

D: Bladder ultrasound image display area

E: Gender

F: Current bladder volume

G: Patient information input

H: System setting

I: WIFI(Only available with M2-W)

5.3 Easy Mode

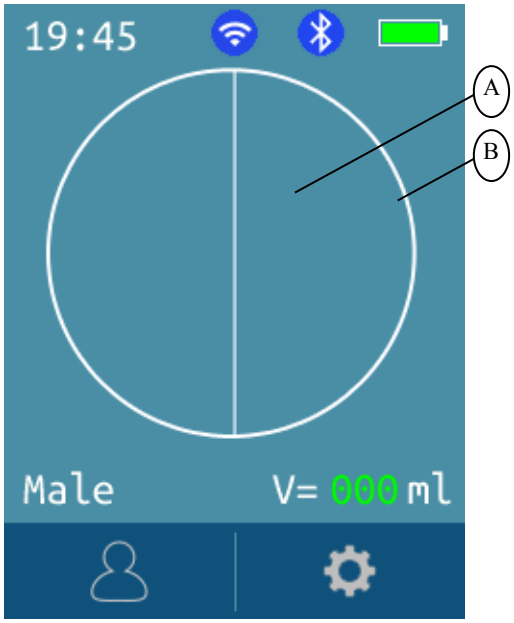


Figure 5-3 M2-W/M2 Easy Mode Interface

A: Bladder cross-section illustration

B: Easy round frame

5.4 Intelligence Mode

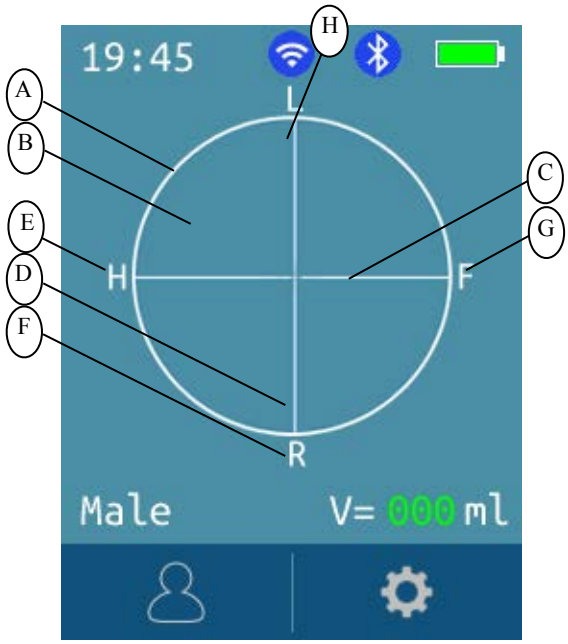


Figure 5-4 M2-W/M2 Intelligence Mode Interface

A: Projection frame

B: Display area of the projection diagram

C: Horizontal line of the crosshairs

D: Vertical line of the crosshairs

E: Head position of the patient

F: Right side of the patient

G: Foot position of the patient

H: Left side of the patient

5.5 Scanning Interface of Expert Mode

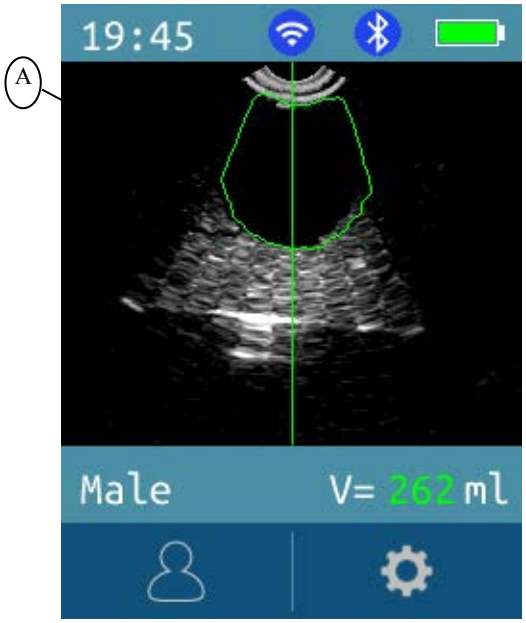


Figure 5-5-1 M2-W/M2 Expert Mode - Pre-scan

A: Bladder ultrasound image display

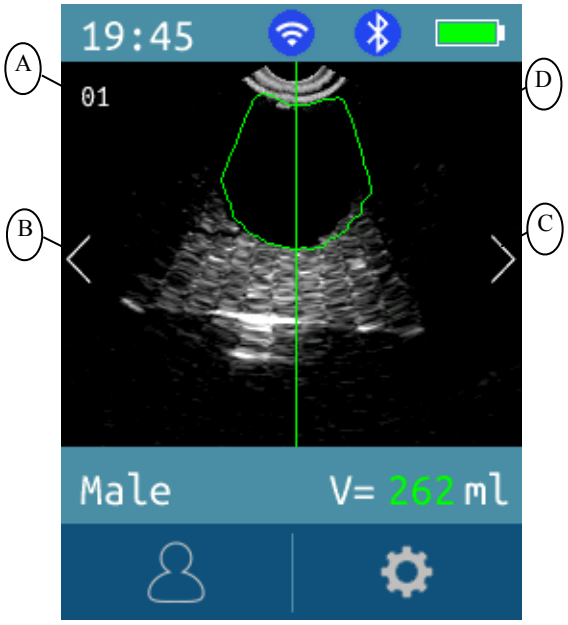


Figure 5-5-2 M2-W/M2 Expert Mode - End of Scanning

A: The value in this area vary from 1 to 12 indicating the number of bladder scanning images. When it reaches 12 which is the max. amount of image, it means scanning is completed and so is the image analysis and bladder volume calculation. Bladder volume will be displayed on the screen.

B: To view 12 scanned bladder images - previous page

C: To view 12 scanned bladder images - next page

D: Bladder ultrasound image display area

5.6 Scanning Interface of Easy Mode

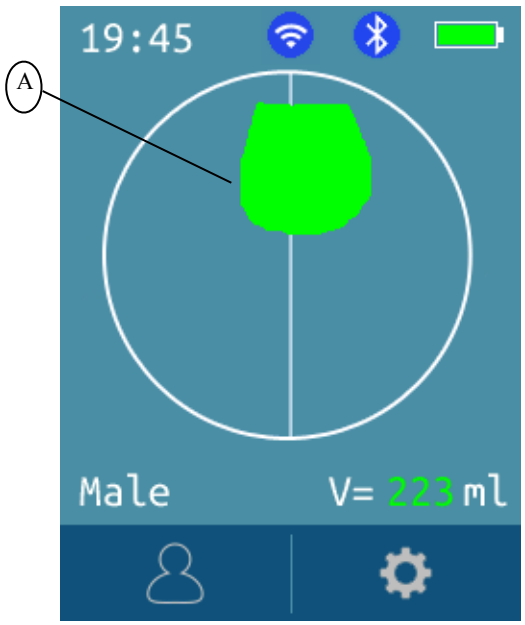


Figure 5-6-1 M2-W/M2 Easy Mode - Pre-scan

A: Bladder cross-sectional view

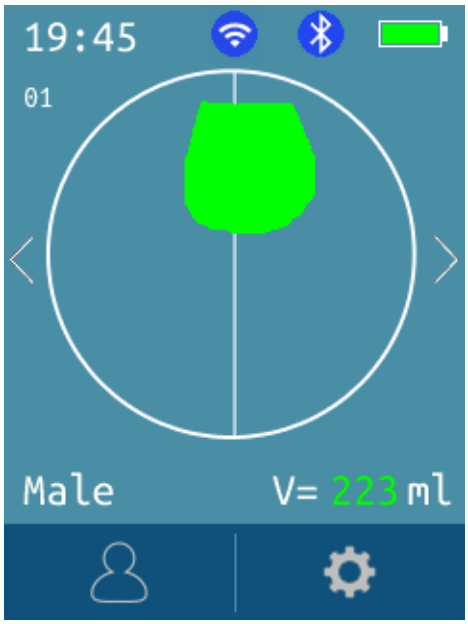


Figure 5-6-2 M2-W/M2 Easy Mode - End of Scanning

Note: The system does not offer the option to flip through images using “<“ and “>” in the Easy Mode.

5.7 Scanning Interface of Intelligence Mode

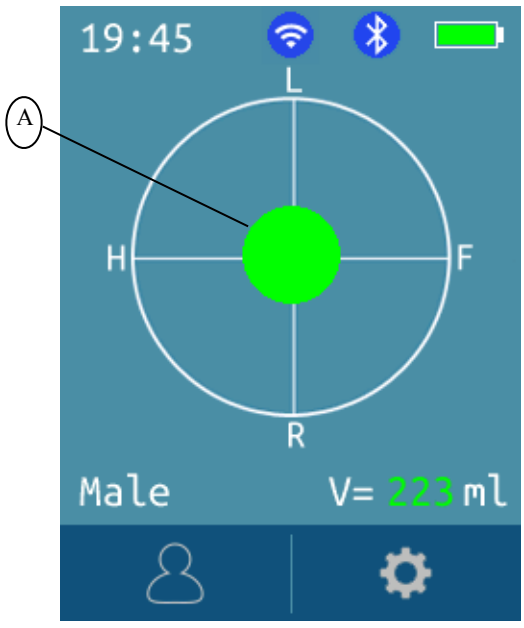


Figure 5-7-1 M2-W/M2 Intelligence Mode - Pre-scan

A: Real-time bladder projection image

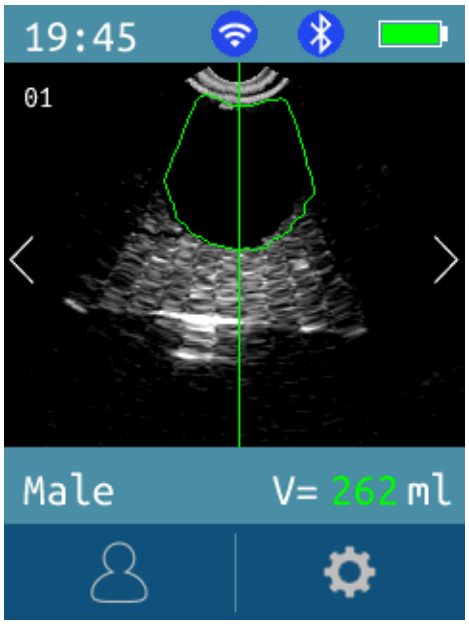


Figure 5-7-2 M2-W/M2 Intelligence Mode - End of Scanning

Note: The End of Scanning interface is as same as that of the expert mode. Press "<" and “>” to flip through the 12 scanned bladder ultrasound images.

5.8 Bladder Projection Interface

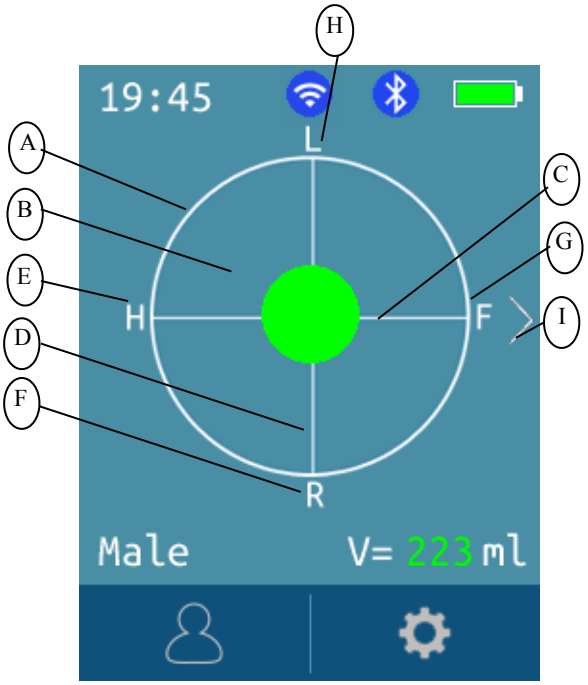


Figure 5-8 M2-W/M2 Bladder Projection Interface

A: Projection frame

B: Display area of the projection diagram

C: Horizontal line of the crosshairs

D: Vertical line of the crosshairs

E: Head position of the patient

F: Right side of the patient

G: Foot position of the patient

H: Left side of the patient

I: Return to the scanning interface

5.9 Input, Save and Print Patient Information

Figure 5-9 M2-W/M2 Patient Information Input Interface

A: Patient ID code input

B: Age

C: Voice input

D: Virtual keyboard

E: Clear current value

F: Save

G: Print

H: Cancel and return

I: Patient history information browse(Only available with M1-W)

5.9.1 Display Patient History Information (Only available with M2-W)

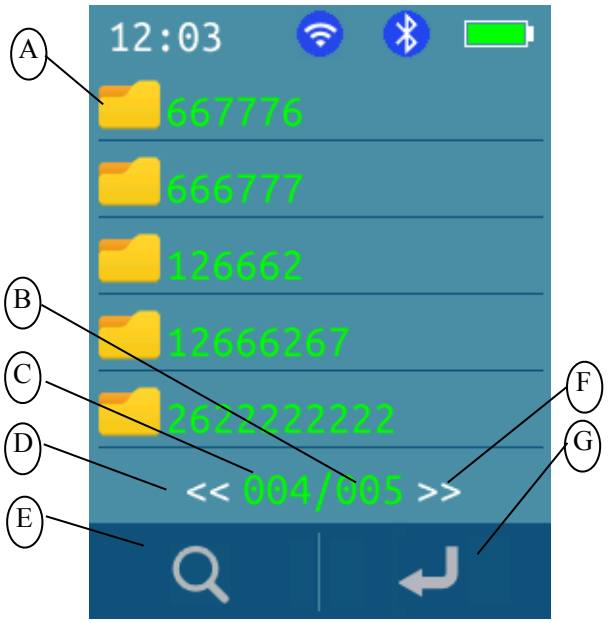


Figure 5-9-1 M2-W Patient History Information Interface

A: Patient history information folder (by ID number)

B: Number of page in total

C: Current page number

D: Previous page

E: Patient history search

F: Next page

G: Cancel and return

5.9.2 Search Patient History Information (Only available with M2-W)

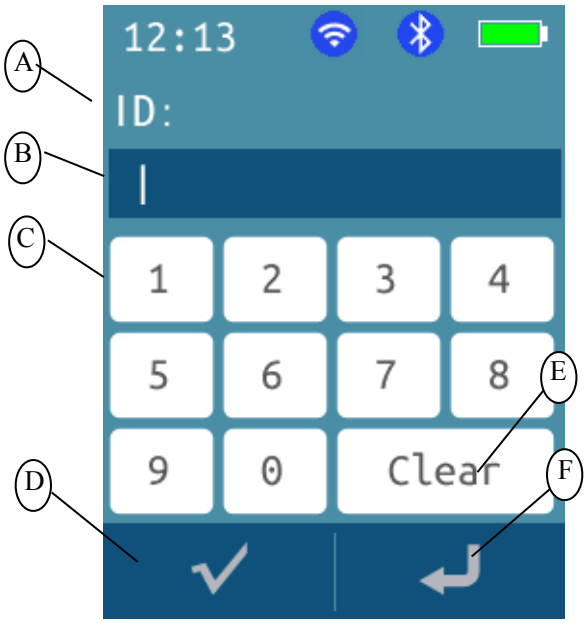


Figure 5-9-2 M2-W Patient History Information Search

A: ID code prompt bar

B: Patient ID code input

C: Virtual keyboard

D: Confirm

E: Clear current input

F: Cancel and return

5.9.3 Browse Patient History Details (Only available with M2-W)

Figure 5-9-3 M2-W Browse Patient History Details

A: Bladder volume prompt

B: Age prompt

C: Gender prompt

D: Voice memo of additional information

E: Measurement time

F: Bladder volume value

G: Patient age

H: Patient gender

I: Voice memo play

J: Time display

K: Current page number

L: Total number of pages

5.10 Store and Print Patient information

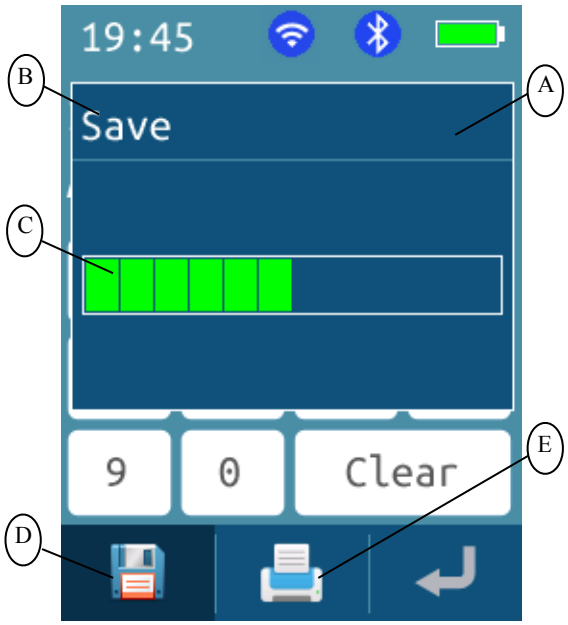


Figure 5-10 M2-W/M2 Store Patient Information

A: Window background

B: Save prompt

C: Save status

D: Save

E: Print

5.11 System Setting Interface I

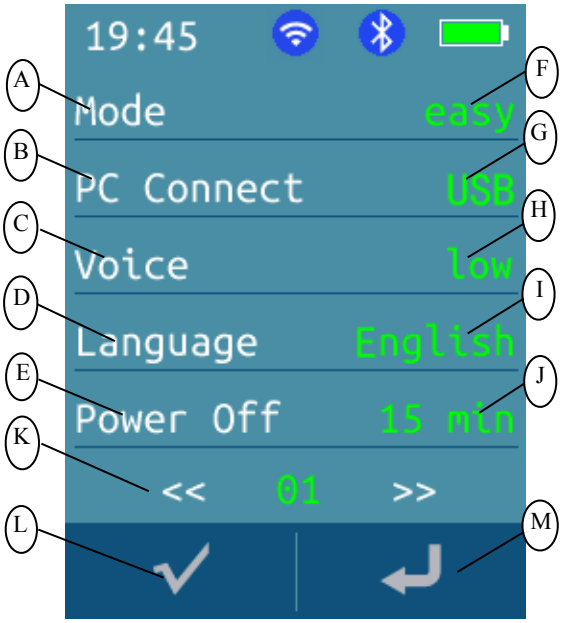


Figure 5-11 M2-W/M2 System Setting Interface I

A: Operation mode

B: PC connection

C: Voice volume

D: Language

E: Automatic shutdown time

F: Selected mode

G: Selected PC connection status

H: Selected voice volume

I: Selected language selection

J: Selected automatic shutdown time value

K: Page selection

L: Confirm

M: Cancel and return

5.11.1 PC Connection Login

Figure 5-11-1 M2-W/M2 PC Connection Login interface

A: PC connection password input prompt

B: PC connection password input

C: Virtual keyboard

D: Clear current input

5.11.2 PC Connection Dialog

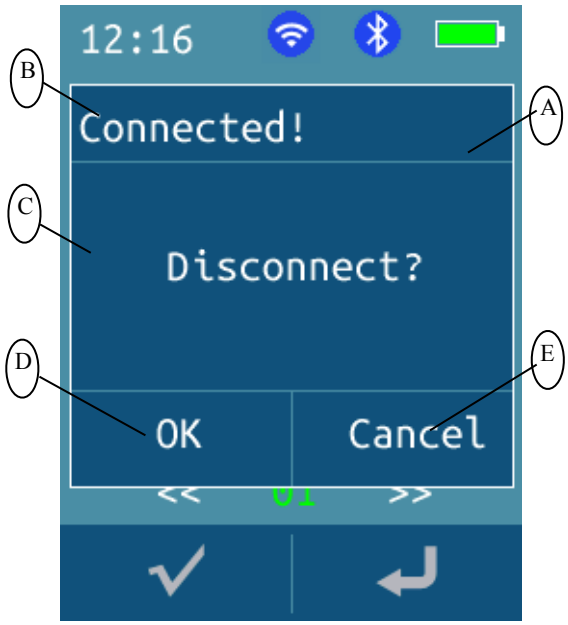


Figure 5-11-2 M2-W/M2 PC Connection Dialog Interface

A: PC connection dialog window background

B: Current status

C: Next step

D: Confirm

E: Disconnect and return

5.12 System Setting Interface II

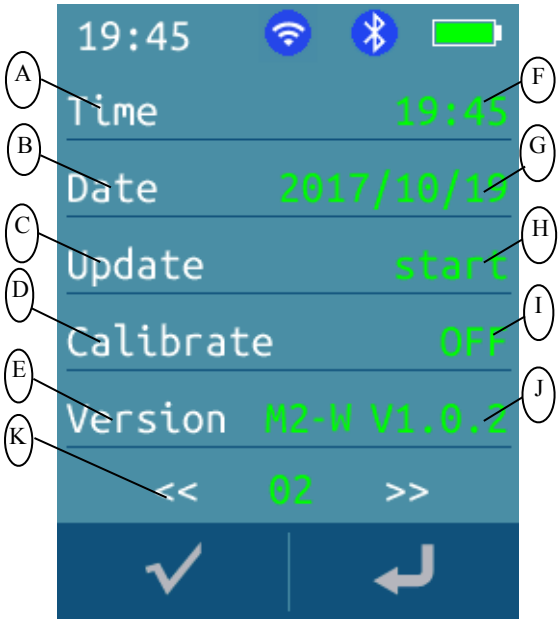


Figure 5-12 M2-W/M2 System Setting Interface II

A: Time setting

B: Date setting

C: Software update

D: Calibration

E: Version number

F: Current time

G: Current date

H: Start update

I: Turn on/off calibration

J: Current version number

K: Page selection

5.12.1 Set up Time

Figure 5-12-1 M2-W/M2 Time Setting Interface

A: Time setting window background

B: Time setting window name

C: Value increase

D: Time display

E: Value decrease

F: Setting confirmation

G: Setting cancellation

5.12.2 Set up Date

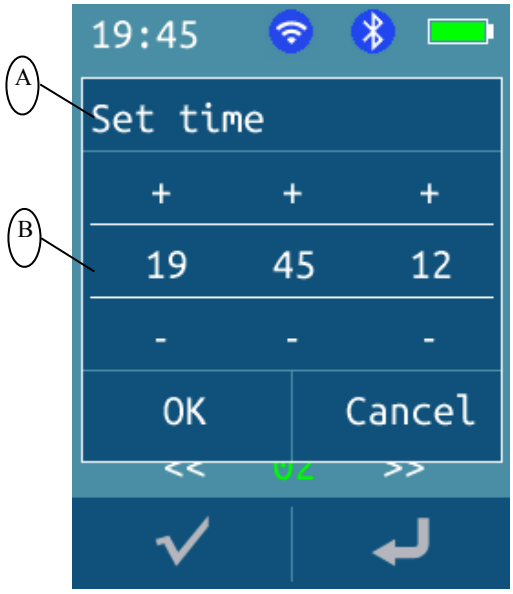


Figure 5-12-2 M2-W/M2 Date Setting interface

A: Date setting prompt B: Date display

5.12.3 Update Software

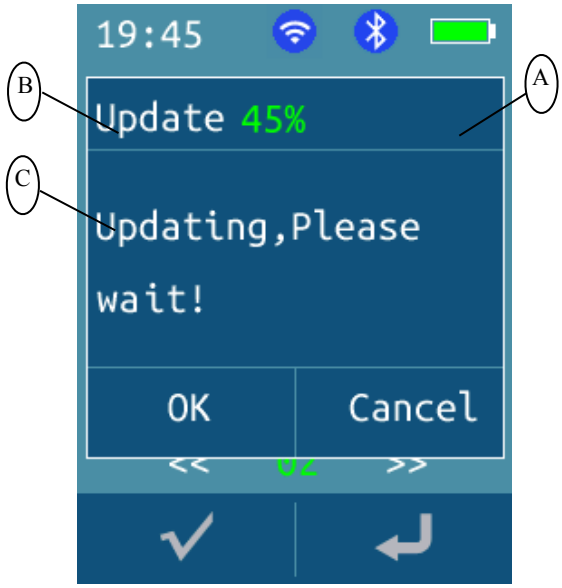


Figure 5-12-3 M2-W/M2 Software Update interface

A: Software update prompt window background C: Update status

B: Update progress in %

5.12.3.1 Software Update Successful

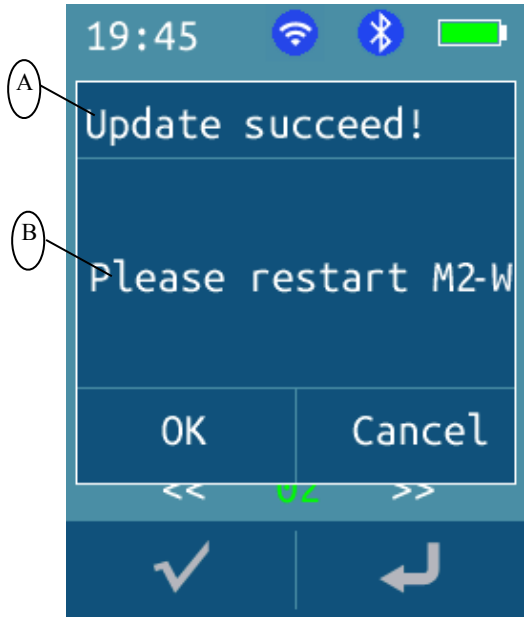


Figure 5-12-3-1 M2-W/M2 Software Update Success Interface

A: Software update status B: Next step

5.12.3.2 Software Update Failed

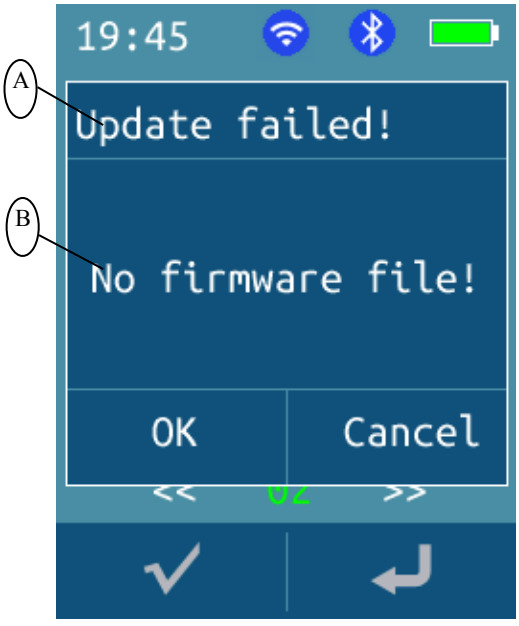


Figure 5-12-3-2 M2-W/M2 Software Update Failure Interface

A: Update status B: Reason of the failure

5.12.4 Calibration

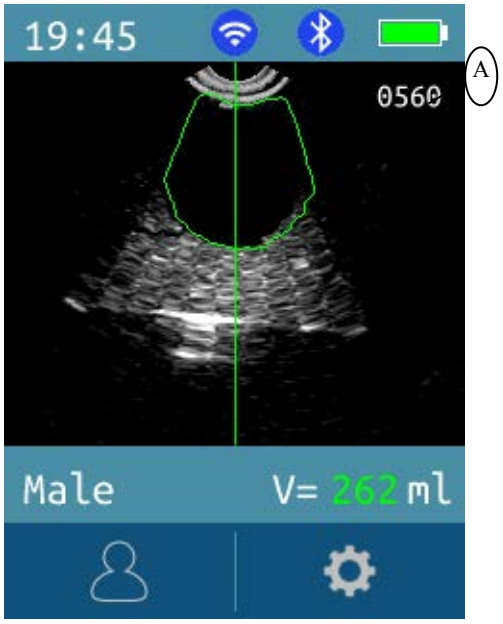


Figure 5-12-4 M2-W/M2 Instrument Calibration Interface

A: Calibration value

Note: The calibration function is not available for users.

5.13 System Setting Interface III

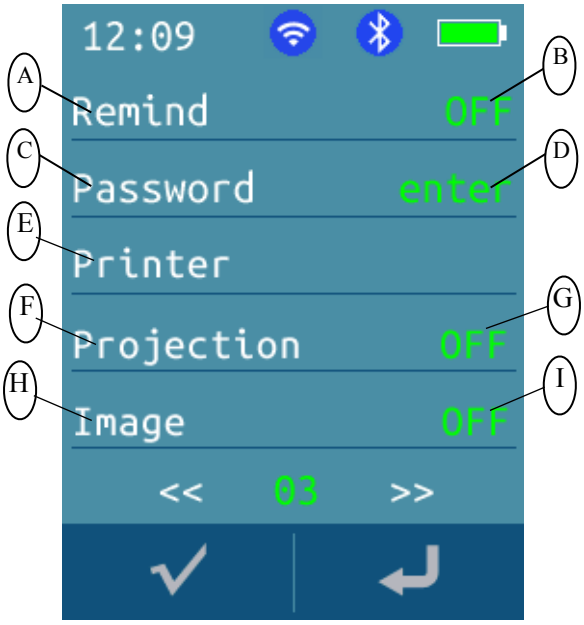


Figure 5-13 M2-W/M2 System Setting Interface III

A: Remind function setting

B: Remind function turned off

C: Password Management

D: Enter the password management login interface

E: Printing

F: Projection

G: Print projection ON/OFF

H: Image

I: Print image ON/OFF

5.13.1 Login Password Management Interface

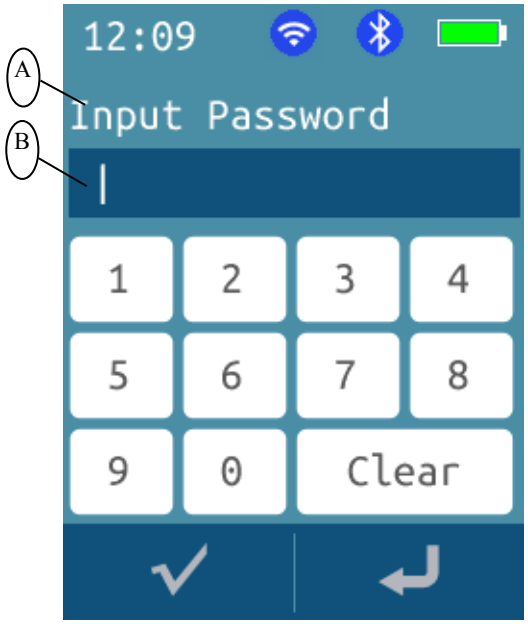


Figure 5-13-1 M2-W/M2 Password Management Login Interface

A: Name of the window

B: Password input field

5.13.2 Manage Password

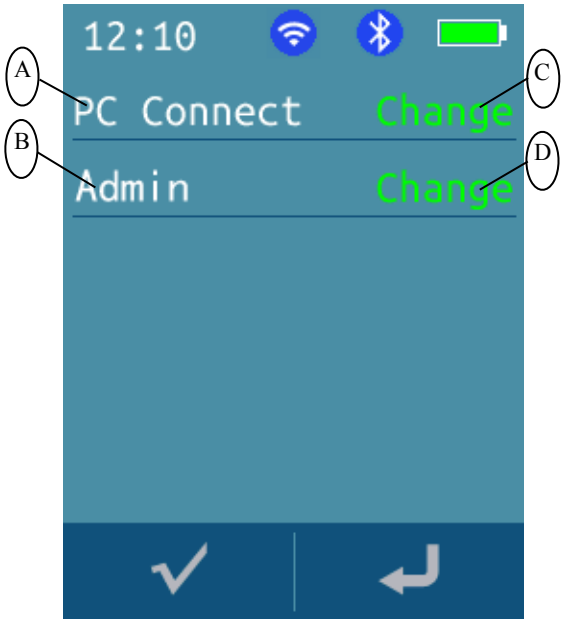


Figure 5-13-2 M2-W/M2 Password Management Interface

A: PC connection prompt

C: Modify PC connection password

B: Admin password prompt

D: Modify admin password

5.13.3 Modify Password

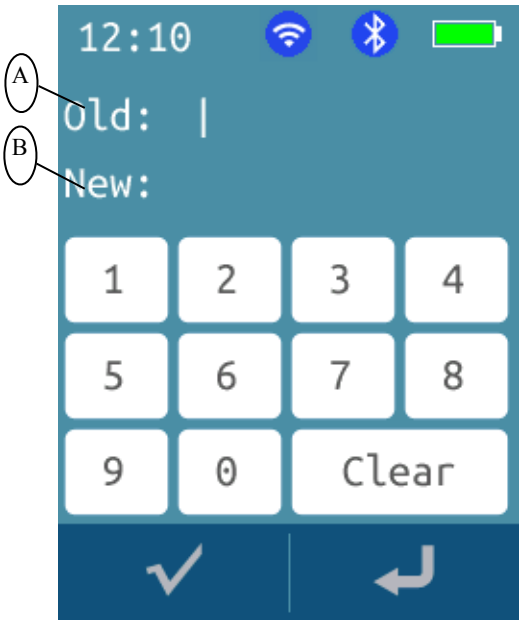


Figure 5-13-3 M2-W/M2 Password Modification Interface

A: Old password input

B: New password input

Chapter VI Operation Procedure

6.1 Instrument Startup and Shutdown

Under the shutdown state, long press the scan key of the instrument to start up. Under the startup state, long press the scan key of the instrument to shut down.

6.2 Bladder Scanning

6.2.1 Gender Selection

After activation startup interface (Figure 5-1) will first appear on the screen. Main display (Figure 5-2) will automatically emerge after about 4 seconds. The patient gender is Male by default. Press **Male** to switch among other options: Male, Female, FemaleH, Child and Phantom.

6.2.2 Bladder Pre-scan

Apply the coupling agent to the contact area between the instrument probe surface and the patient, and place the probe on the patient's bladder. Press **SCAN** button, a real-time bladder B-mode ultrasound image (Figure 5-5-1), a bladder section diagram (Figure 5-6-1) or a real-time bladder position projection diagram (Figure 5-7-1) will be displayed on the screen. This means the machine has entered the pre-scanning status.

6.2.3 Bladder Scan

When the position of the bladder is determined, press **SCAN** button again so that 3D probe enters scanning phase indicating the bladder scanning is in progress. The serial number (Figure 5-5-2, Figure 5-6-2 or Figure 5-7-2) on the top-left corner of the image starts to increase from 01 during scanning. Scanning, image analysis and calculation are completed once this number increases to 12. Upon completion the bladder volume is displayed while the serial number on the top-left corner returns back to 01.

6.3 View the Scanned Images and Projection

After the bladder scanning is complete, the operator can tap "<" or ">" on the interface to view 12 pieces of

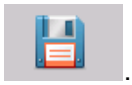
bladder ultrasound images or 12 pieces of bladder cross-section diagrams. "01" means the current image is the first one. In the expert mode and the easy mode, tap "<" on the first image interface to view the projection interface (Figure 5-8). In the intelligence mode, tap ">" to return to the pre-scanning of intelligence mode (Figure 5-7).

When the projection is displayed in green, it means that the bladder is in the scanning area; otherwise, it is in orange.

6.4 Input Patient Information

Tap the patient information icon  on the main display (Figure 5-2, Figure 5-3 or Figure 5-4) to enter the patient information input interface (Figure 5-9). Enter patient ID and age. ID number field can only contain maximum 10 figures and 3 figures maximum for the age input field. Long press the record icon  for recording additional patient information. Release to listen to the voice memo recorded.

6.5 Store and Print Patient Information

Once the patient information entering is complete in 6.4, tap the save icon  . The saved information is encrypted. Contents stored include patient ID, age, gender, bladder volume value, storage date and time, voice information and twelve ultrasound image.

Once the patient information entering is complete in 6.4, tap the print icon  to print the patient information which has been decrypted upfront. Contents printed include patient ID, age, gender, bladder volume value, printing date and time and two ultrasound images (optional) and bladder projection (optional). Note: The printing can be conducted only when the Bluetooth printer is connected with the host. A Bluetooth sign  can be seen on top of the screen after connection.

6.6 Set up System

Tap the setting icon  on the main interface to enter the system setting interface Page 1 (Figure 5-11), and tap “<<” or “>>” to view interface I (Figure 5-11), II (Figure 5-12) and III (Figure 5-13). There are 12 options on the system setting interface including operation mode, PC connection, volume, language,

automatic power-off, time, date, software upgrade, calibration, version number, remind function and password management. The detailed descriptions are as the following:

6.6.1 Operation Mode

Tap **Mode** to switch the operation mode between Expert Mode, Easy Mode and Intelligence Mode. The default mode is Expert Mode.

When selecting **Expert** mode, during pre-scanning, the operator can observe the bladder B-mode ultrasound image of the patient, move the probe to centre the image and maximise the area. During scanning, 12 real-time bladder B-mode ultrasound images (Figure 5-5-2) of the patient will be displayed on the screen.

When selecting **Easy** mode, during pre-scanning, the operator can observe the bladder section of the patient. Move the probe so that the bladder section moves to the centre of the crosshair and the bladder section area is maximised. During scanning, 12 bladder section diagrams (Figure 5-6-2) will be displayed on the screen.

When selecting **Intelligence** mode, the operator can observe the real-time bladder scanning projection position during pre-scanning. Move the probe so that the real-time bladder scanning projection goes to the centre of the crosshair. When the projection is displayed in green, it means that the scanning is on target; otherwise, it turns orange. During scanning, 12 real-time bladder B-mode ultrasound images (Figure 5-7-2) of the patient will be displayed on the screen.

When the bladder volume is less than 100ml, it is recommended to select **Expert** mode for measurement.

6.6.2 PC Connection

Tap **Connect Computer** in the interface I to connect to the PC with three options: "OFF", "USB", "WIFI". The default value of the instrument is "OFF".

Tap **USB** or **WIFI**, press **OK**  , enter the password login interface to connect the computer (Fig. 5-11-1). In the password input field, enter the original password 00000 (5 bits 0) to connect to the PC. After pressing **OK**  , a connection dialog box (Fig. 5-11-2) pops up, prompting " Disconnect?”

If user chooses **USB**, M2-W/M2 host and the PC will be connected through a USB cable. There will be a disc sign appearing on the PC end, which stores the encrypted patient information. The upper computer program needs to decrypt the patient information before user can read the folder "PATIENTS" under the disc sign. Twelve bladder ultrasound images (bmp files), patient information (txt files) and recorded information (wav

files) are stored in the folder. When the connection is complete, tap OK disconnect and Cancel to return.

A 6-digit password “000000” is needed to log in the upper computer program.

6.6.3 Voice Volume

Tap the **Voice** column to switch the voice volume: low, medium and high. It is low by default.

6.6.4 Set up Language

Tap the **Language** column to switch among 11 language options: English, French, Danish, Finnish, Portuguese, Swedish, Spanish, Dutch, Norwegian, German, Italian. Default language is English as shown in Figure 7.

6.6.5 Automatic Shutdown

Tap **Power Off** to switch among the automatic shutdown time options which are 5 minutes, 10 minutes, 15 minutes, 20 minutes, and OFF. The automatic shutdown time is 5 minutes by default.

6.6.6 Set up Time

Tap **Time** in interface II, the time setting interface (Figure 5-12-1) will pop up. Tap "+" to increase and "-" to decrease the value. Tap **OK** to save the new value and return to the setting interface.

6.6.7 Set up Date

Tap **Date** in interface II, and the date setting interface (Figure 5-12-2) will pop up. Tap "+" to increase and "-" to decrease the value. Tap **OK** to save data and return to the setting interface.

6.6.8 Update Software

Tap the **Update**, the software update interface (Figure 5-12-3) will pop up. If the update file is available in the memory, the system will start to update automatically. After the update, the update success dialog box will pop up (Figure 5-12-3-1). The instrument needs to be restarted to activate the new version. If there is no update file in the memory, the update failure dialog box will pop up (Figure 5-12-3-2).

Note: The instrument update must be carried out at full charge.

6.6.9 Calibrate

The calibration setting (Figure 5-12-4) is not available to users and is a dedicated setting for engineering testing.

6.6.10 Version Number

The last column of setting interface II shows the software Version.

6.6.11 Remind Function

Tap **Remind** on the interface III to switch among the bladder volume value options 200ml, 250ml, 300ml, 350ml, 400ml and OFF. It is OFF by default.

6.6.12 Manage Password

Tap **Password** on the interface III to enter the password management login interface (Figure 5-13-1). Enter the original administrator password 00000 in the input field and press **OK**  to enter the password management interface (Figure 5-13-2). PC connection login password and administrator login password can be managed here.

Tap **PC Connect** and **Admin** respectively to enter corresponding password change interface (Figure 5-13-3). Enter the old and new 5-digit password and press **OK**  to confirm.

If entering the password “21650" on the password management login interface (Figure 5-13-1), all passwords will be restored to the original one 000000.

6.6.13 Print Content Selection

Click the "projection" on interface III to enter the selection of print projection image, select ON, print projection image; select OFF, do not print projection image.
Click the "image" on interface III to enter the selection of printing two orthogonal B-ultrasonic images, select ON to print two orthogonal B-ultrasonic images; select OFF if no need to print.
When setting the "projection" OFF and "image" OFF of the interface III, the printed contents include: patient number, age, gender, volume value, printing date and time.
When setting the "projection" OFF and "image" ON of interface III, the printed contents include: patient

number, age, gender, volume value, printing date and time, two orthogonal ultrasound images.
When setting the "projection" ON and "image" OFF, the printed contents include: patient number, age, gender, volume value, printing date and time, bladder projection.
When setting the "projection" ON and "image" ON, the printed contents include: patient number, age, gender, volume value, printing date and time, 2 orthogonal ultrasound images, bladder projection.

6.7 Upload Data through WIFI (Only available with M2-W)

The PC searches for the WIFI signal of the host to connect. The patient information of the host can be wirelessly uploaded to the PC via WIFI upon successful connection.

6.8 Upgrade Software

The upgrade of the software program can be carried out in the following steps:

Step 1: Tap **PC Connect** on the interface I and select **USB**. Enter PC Connect password login interface (Figure 5-11-1) , input original password 00000 and press **OK**  to confirm connection request. The connection dialog box (Figure 5-11-2) and prompt "Is it disconnected?" pops up. At this time, user need to use the USB cable to connect the host and the PC end. If the connection is successful, a disc sign will appear at PC end.

Step 2: Copy the upgrade files of the corresponding machines as follows (FPGA program and ARM program) into the newly added disk sign at PC end. Tap OK or Cancel in （Figure 5-11-2） to disconnect and remove the USB cable.

Model	Upgrade file		Remarks
	FPGA program	ARM program	
M1	M1.bin	ARM1.bin	
M1-W	M1W.bin	ARM1W.bin	
M2	M2.bin	ARM2.bin	
M2-W	M2W.bin	ARM2W.bin	

Step 3: Tap **Upgrade** on interface II and software upgrade interface as shown in Fig. 5-12-3 will appear. The system then starts to upgrade automatically. Upon completion the upgrade success dialog box (Fig. 5-12-3-1) pops up and the instrument will be rebooted. By then the software upgrade is accomplished.

6.9 Search and Browse Patient History Information(Only available with M2-W)

On the patient information input interface (Figure 5-9), tap the patient history information browse icon  to enter the patient history information interface (Figure 5-9-1). This interface contains total pages number, current pages number, previous and next page key, search  , cancel the return key  and patient information folders which are sorted by patient ID number.

Tap **Search**  to enter the patient history information search interface (Figure 5-9-2), input the patient ID number and press **Confirm**  , the corresponding patient information will appear.

Tap one patient information folder to view the patient history details which include bladder volume value, age, gender, voice memo, measurement time, current page number and total page number.

Tap the voice play icon  to play any additional recorded information.

Tap  to display saved images of the patient on the main display. Tap “<” or“> ”key to flip through 12 bladder ultrasound images respectively. Tap the icon to enter the patient information input, save and print page (Figure 5-9). Press the print icon  to print the selected information.

Note: the patient data can be modified before printing. However, the modified part can not be saved into the database and overwrite the historical data.

6.10 Upper Computer Transmission and Function

The Upper computer software is a PC platform control software, which is used together with bladder scanner M2-W/M2. The functions of the upper computer software are as the following: Import encrypted patient data including patient details, bladder ultrasound images and measurement results through accessing USB memory card; Display data, export data after converting to PDF format and print data; Manually input, save

and display the hospital name, department name and doctor name; The system provides login management and password management functions. The whole patient data processing procedure is encrypted.

6.10.1 Install Upper Computer Software and Login

Copy the "release" folder of the software into the upper computer. Click the "release" folder and open it. Find the file named PatientManager_Localization.exe in this folder. Click the file to run the software. Login interface will then pop up (Figure 6-1). Input the original login password (default password 000000) and enter the upper computer main interface. If entering password "21650", the login password will be restored to the original one 000000.

Upper computer login interface is as shown in Figure 6-1:

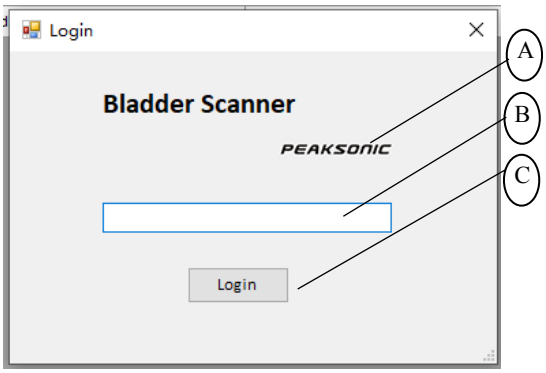


Figure 6-1 M2-W/M2 Upper Computer Login Interface

A: Company name

B: Login password input

C: Login

6.10.2 Main Interface of Upper Computer

There are four menu items on the main interface: Upper computer information, company Logo, patient information and twelve bladder ultrasound images. Menu items include Import Data, Print, Save to PDF and Option. The patient information includes patient ID, age, gender, scanning time and bladder volume value. After you select one patient, twelve ultrasound images and bladder projection image can be seen in the image display area on the bottom part of the screen. The first 6 images are displayed right away. By scrolling the bar below the image display area, the rest 6 will emerge.

The main interface of Upper computer is as shown in Figure 6-2:

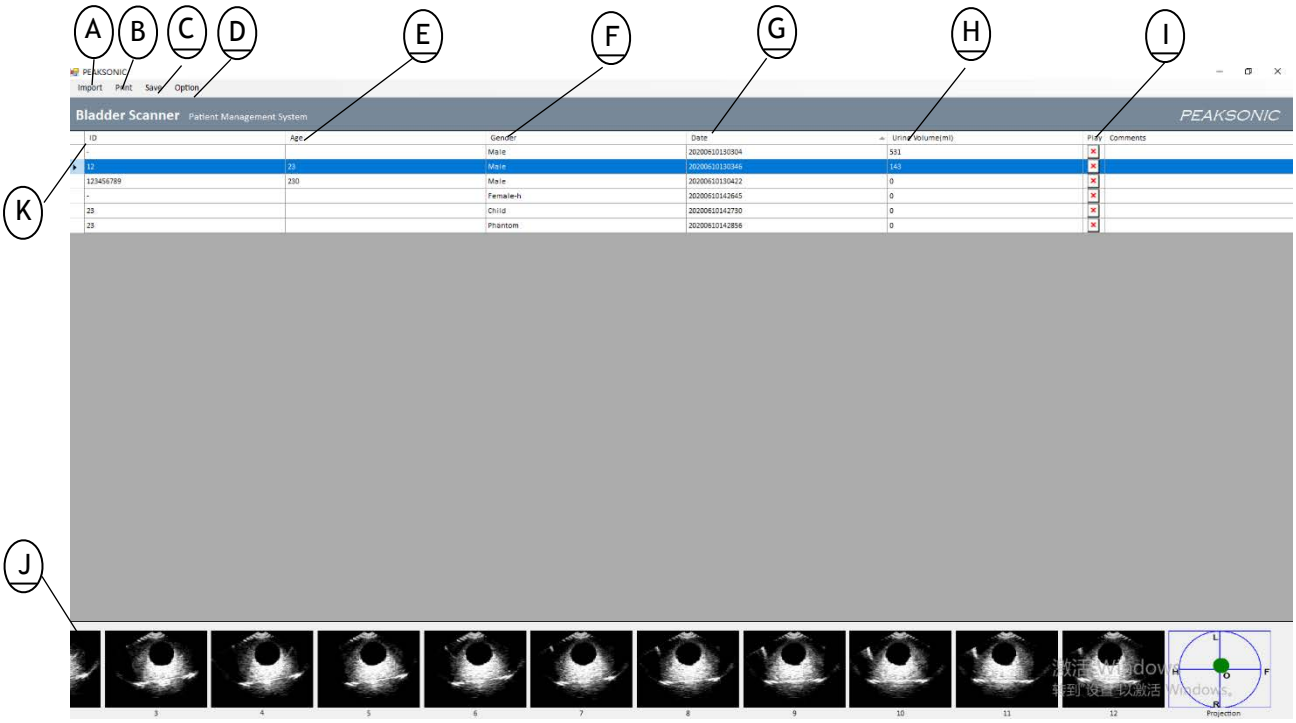


Figure 6-2 M2-W/M2 Upper Computer Main Interface

A: Import Data

B: Print

C: Save to PDF

D: Option

E: Patient age

F: Patient gender

G: Scanning date

H: Bladder urine volume value

I: Voice play

J: Bladder image display area

K: Patient ID number

6.10.3 Import Data

Click **Import Data** on the main interface, the drop-down menu pops up. It includes two options: From WIFI (import data wirelessly) and From USB (import data through USB cable).

If select **From WIFI** (Only available with M2-W), user need to connect to the WiFi named “Peak_M2_XXXXXXXX" first. When the data import is successful, "Synchronize successfully!” appears on the screen.

If select **From USB**, a desktop file directory pops up. Select the default disc character and click the folder named "PATIENTS". Press **Confirm** and the screen appears with the prompt "Synchronising.... Please wait!" . When the prompt window disappears, data import is complete.

Note: Before the upper computer imports data, user must follow the instruction from 6.6.2 PC connection to connect the instrument to the PC.

The data import mode selection interface of the upper computer is as shown in Figure 6-3:

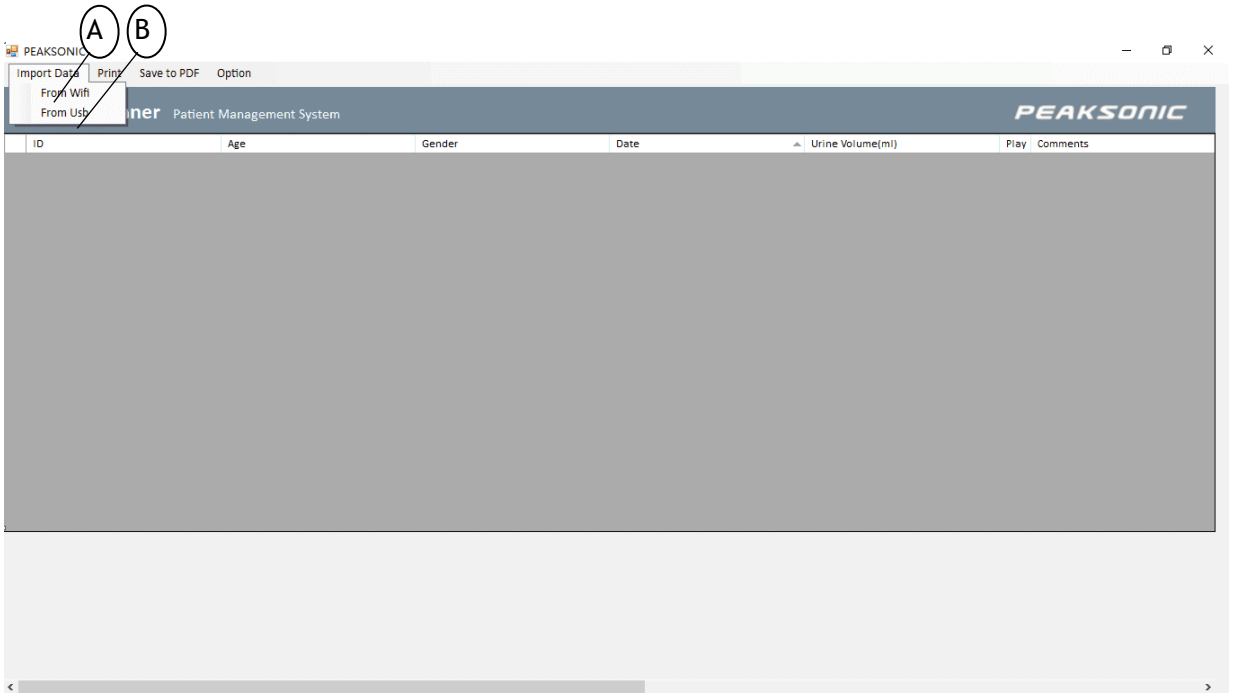


Figure 6-3 M2-W/M2 Upper Computer Data Import Mode Selection Interface

A: Import data through wirelessly B: Import data through USB cable

6.10.4 Upper Computer Option Interface

Click **Option** on the main interface, the drop-down menu pops up. Select **Settings** to open the option interface. Enter corresponding information and click **Save** to save and return. Or click **Cancel** to cancel the input entered and return.

The upper computer option interface is as shown in Figure 6-4:

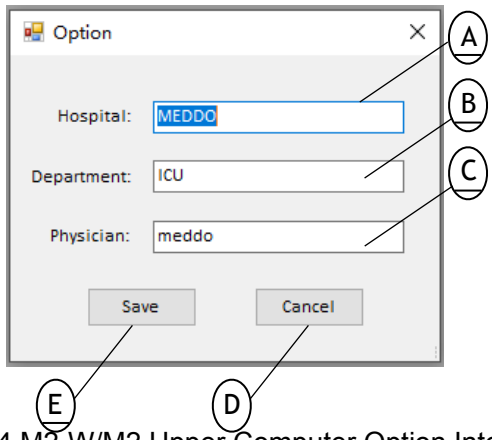


Figure 6-4 M2-W/M2 Upper Computer Option Interface

A: For entering hospital name

B: For entering department name

C: For entering doctor name

D: Cancel the input

E: Save the input

6.10.5 Upper Computer Print Interface

Click **Print** on the main interface, the print interface pops up. The print interface includes a drop-down menu on the top-left corner of the screen to select number of images to be printed (two options: 6 images and 12 images), print key, hospital name, department name, patient information and bladder ultrasound images.

Click the 6 images or 12 images selection box and select "6 Images" to display 6 bladder ultrasound images on the print interface (Figure 6-5), and click **Print** for printing (the printing contents don't include: display 6 images or 12 images selection box, print key and X key). Select "12 Images" to display 12 bladder ultrasound images and one projection image (Figure 6-6), and click the Print key for printing (same as above). The source of hospital name and department name is the information entered and saved in the option interface. The source of patient information and bladder ultrasound images is the information displayed on the main interface of the Upper computer.

The Upper computer print interface (6 images) is as shown in Figure 6-5:

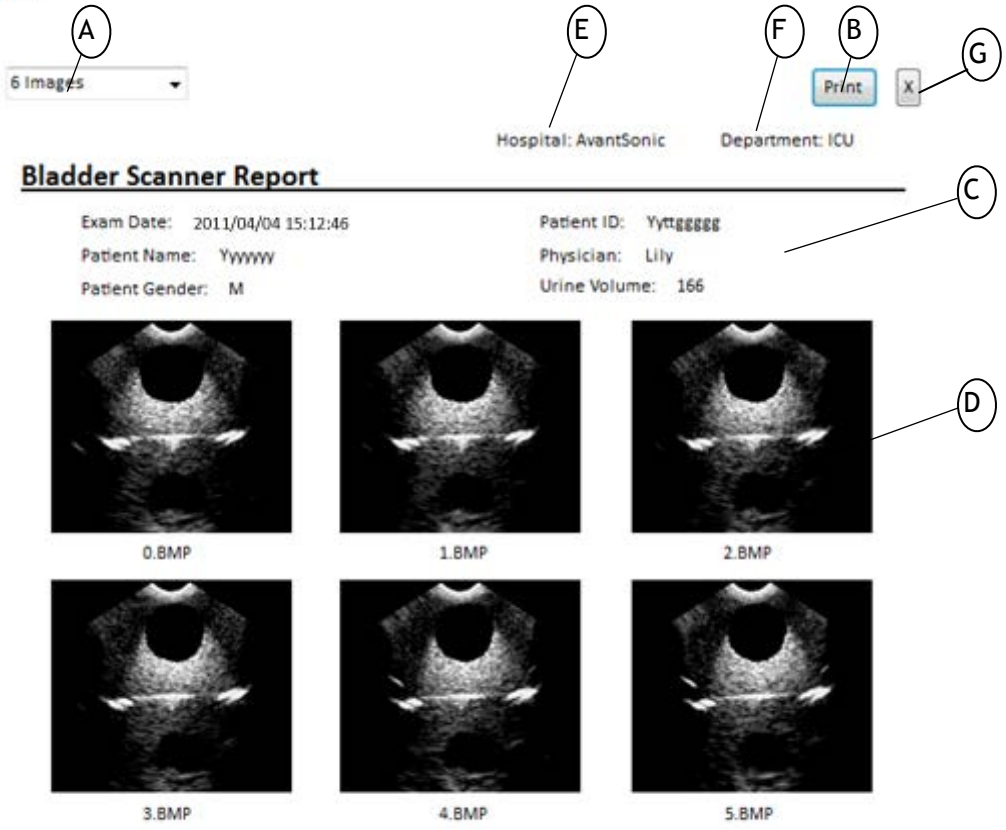


Figure 6-5 M2-W/M2 Upper computer print interface (6 images)

A: Select the number of images to be displayed or printed (two options: 6 images or 12 images)

B: Press to print the page

C: Patient information

D: 6 bladder ultrasound images

E: Hospital name

F: Department name

G: Press X to close the current window

The upper computer print interface (12 images) is as shown in Figure 6-6:

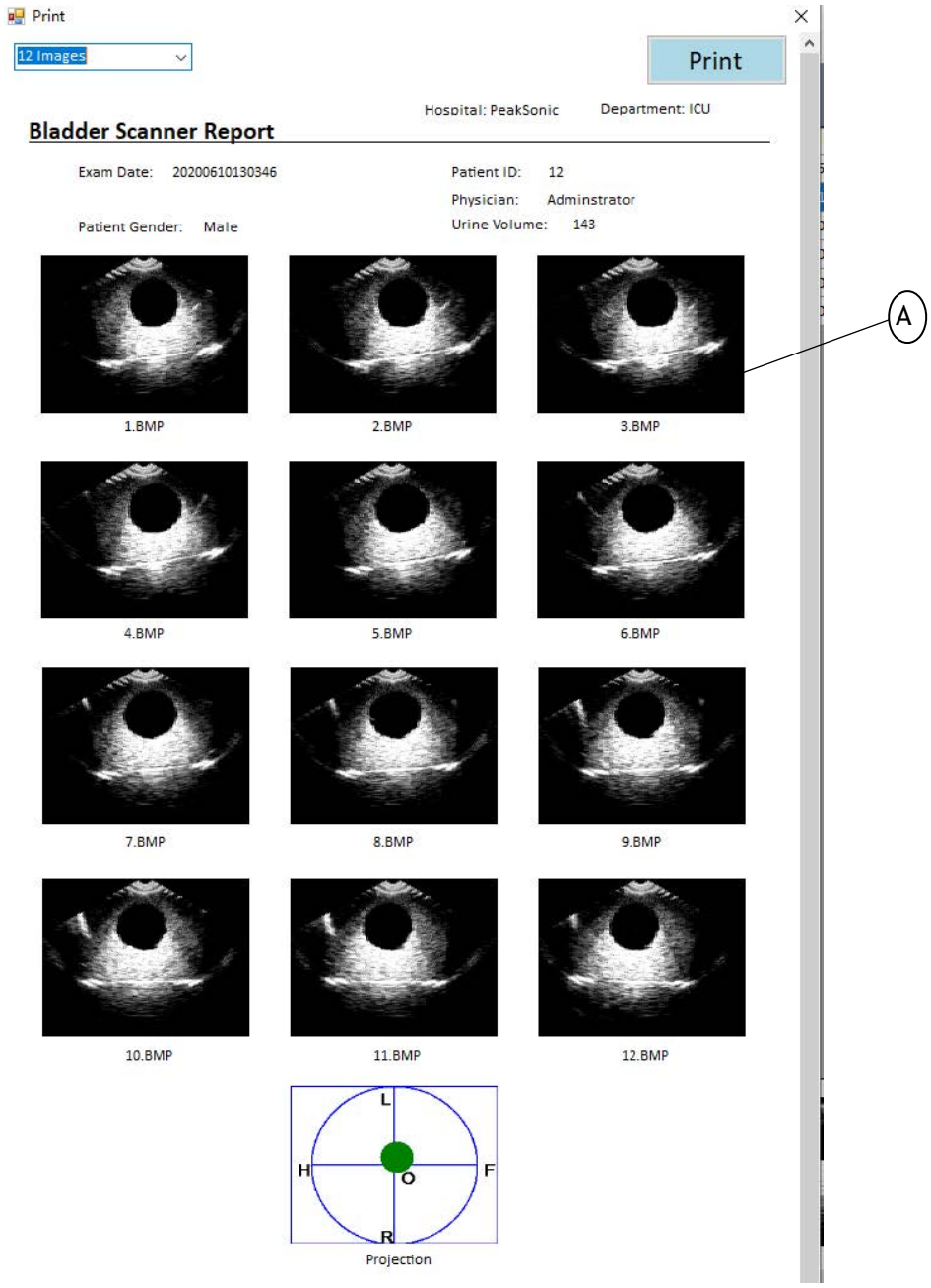


Figure 6-6 M2-W/M2 Upper computer print interface (12 images and one projection)

A: 12 bladder ultrasound images and projection image

6.10.6 Save to PDF

Click **Save to PDF** on the main interface, Save to PDF dialog box pops up. Select the file save path, enter the file name and select the file save type. Type of the file can only be PDF (*.pdf). It is convenient to store and

view a PDF file which contains patient information and bladder images. The information saved as PDF files are as same as the one printed if pressing **Print** (12 ultrasound images).

6.10.7 Upper Computer Password Change

On the main interface of upper computer, click option->password to enter the password change interface. Enter the old 6-digit password once and the new 6-digit password twice. Press **Save** to overwrite the old password by the new one.

The upper computer password change interface is as shown in Figure 6-7:

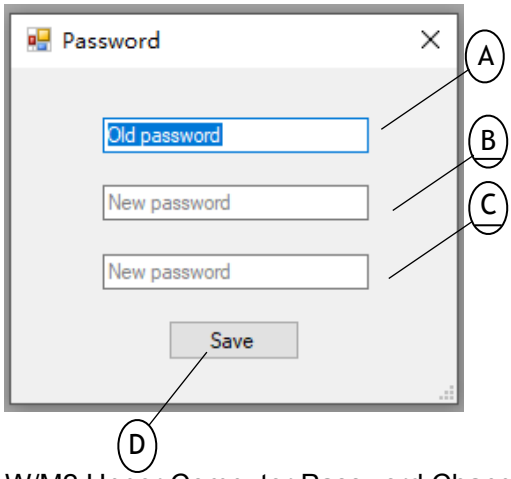


Figure 6-7 M2-W/M2 Upper Computer Password Change Interface

A: Enter old password

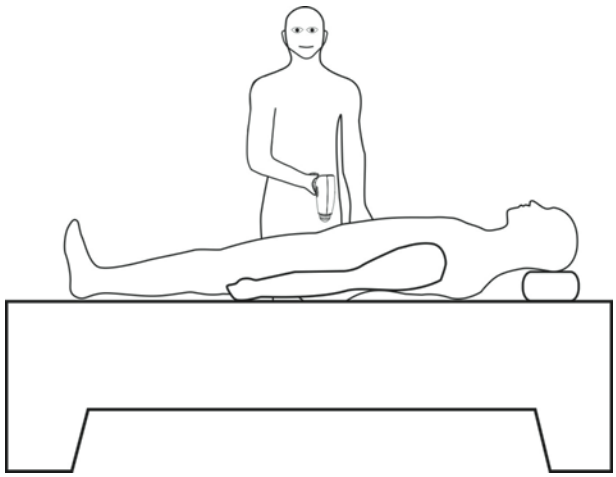
B: Enter new password

C: Confirm new password

D: Save the changes

6.11 Scanning Operation and Bladder Positioning

Correct bladder positioning is the basis of accurate measurement of bladder volume. As shown in the figure on the right, the bladder lies in the hypogastrium of human body and below the symphysis pubis. Before inspection, apply the ultrasonic coupling agent to the skin 3cm above the pubic bone of the patient. Place the instrument at the position shown in the figure and orient the Logo of the instrument towards the head of the patient.



Under expert mode, press SCAN for the first time to activate pre scan. During pre-scan a green indication line at the centre of the

image appears. It is designed to help the user quickly locate the bladder. Move the probe to search for the biggest bladder image. Press SCAN again when the biggest bladder B-ultrasound image is located and the green indication line reaches the centre of the image. During scanning, keep the probe still.

Under easy mode, press SCAN to activate pre scan firstly. During pre scan a green indication line appears to help the user quickly locate the bladder. Move the probe to search for the biggest bladder section. Press SCAN again when the biggest bladder section is located and the green indication line reaches the centre of the section. During scanning, keep the probe still.

Under the intelligence mode, press SCAN to activate pre scan firstly. During pre-scanning, a solid circle appears in the projection frame represents the real-time bladder scanning projection. Move the projection to the centre of the crosshairs. If the projection appears green, it means the probe has located the bladder centre. Adjust the probe slightly till the crosshairs reaches the centre of the solid circle as much as possible, then press SCAN for the second time. If the solid circle appears orange it means it is off the target and the probe position need to be adjusted. During scanning, keep the probe still.

The advantage of the intelligence mode is the bladder centre is located during pre scan. A green projection indicates the machine is on target while an orange one indicates off-target. The method of bladder positioning before scanning greatly increases the accuracy of measurement result. Innovative technology is applied to the intelligence mode which ensures much higher result accuracy and improves the work efficiency of medical staff.

Chapter VII Maintenance

To ensure the normal operation of the instrument, clean the instrument parts, accessories and probe regularly. The material used for cleaning is neutral detergent.

7.1 Clean and Maintain the System

7.1.1 Cleaning and Disinfection Steps

(1) Shut down the system.

(2) Use mild, nearly neutral detergent, ethanol (75%) or isopropanol (70%) to clean equipment (including keyboard).

(3) Control the time of cleaning according to the user instruction of the detergent and the interval of cleaning shall meet clinical requirements.

(4) Dry the surface of the system or dry it with clean cloth according to the method described on the detergent user instruction.

(5) Clean fingerprints or other contaminants on the display screen and wipe the display screen with soft and damp cleaning cloth dipped with neutral detergent to ensure that the display screen will not be scratched.

7.1.2 Maintenance

(1) The instrument shall be operated in the environment specified in "1.5".

(2) The instrument shall not be turned on or turned off frequently. After being turned off, it shall be turned on after 5 minutes.

(3) When the instrument is not in use for a long time, it shall be packed well according to the factory packaging standard and stored in accordance with the storage environment requirements specified in "8.2".

7.2 Clean and Maintain the Probe

Keep the probe clean to ensure proper operation and longer service life.

7.2.1 Cleaning and Disinfection Steps

(1) Check the probe, for example: Cracking, liquid leakage, etc. If there is obvious damage, do not continue to

use the probe, and immediately contact Suzhou Lischka Medtech Co., Ltd.

(2) Wipe the probe with neutral detergent, ethanol (75%) or isopropanol (70%).

7.2.2 Maintenance

For the probe contact surface, carefully protect it from scratch.

(1) Collision and falling are strictly prohibited.

(2) The state-approved medical coupling agent shall be selected as the contact agent between the probe and the inspection area of the patient. If the coupling agent does not meet the standard, it will damage the probe and irritate the patient's skin.

(3) The surface of the probe shall be cleaned after being used every time.

7.3 Use and Maintain the Battery

- A new battery shall be charged and discharged for 2-3 times to achieve the best effect.
- The battery can be charged and discharged for hundreds of times. When the usage time of the battery is obviously shortened, the battery shall be replaced in time.
- The use, storage and charging of the battery must be kept away from fire.
- Battery usage shall be prevented from short circuit, dampness, disassembly, falling and crash.
- The battery shall be charged and discharged every two or three months to prevent battery failure. Note: If the fully-charged battery is not used for a long time, the battery will automatically discharge slowly with time. Therefore, the battery that has not been used for a long time shall be charged first before use.
- If the battery deforms, discolors or is hot or smelly, etc., stop using the battery immediately and remove it from the instrument or charger and dispose it according to the disposal regulations of discarded battery.
- There is a fuse in the attached battery charger, which is non-replaceable. If the attached battery charger cannot work normally, please timely contact our After-sales Service Department for treatment.

7.4 Dispose Electronic Waste

Disposal of waste products and batteries shall be in accordance with local regulations on environmental protection; Or please contact our After-sales Service Department.

Chapter VIII Transportation and Storage

8.1 Precautions for Handling Instrument

(1) Place the host in the corresponding place of the workbag. The probe and the instrument shall be strictly prevented from falling, vibrating or colliding.

(2) After the workbag is closed, it can be transported.

(3) Tighten the bottle cap of ultrasonic coupling agent to prevent the gel from flowing out and put it in the corresponding place of the workbag.

8.2 Requirements on Transportation and Storage Environment

Ambient temperature range: -40°C ~ +55°C

Relative humidity range: 10％ ~ 80％

Atmospheric pressure range: 50kpa ~ 106kpa

8.3 Transportation

The marks on the packaging boxes of this instrument shall meet the requirements of GB/T191-2008 Pictorial Marks for Packaging, Storage and Transportation. The packaging boxes of this instrument are equipped with simple shockproof facilities, suitable for air, rail, road and ship transportation. Avoid rain and snow splashing, inversion and collision.

8.4 Storage

When the storage period of the instrument is more than 6 months, the instrument shall be taken out from the packaging box. After it's charged for 4 hours, put it into the box according to the direction shown on the package and store it in the warehouse. Neither stack the instrument, nor place it against the floor, walls or roof. The interior of the storage space shall be well ventilated. Avoid exposure to the intense sunlight and corrosive gas.

Chapter IX Troubleshooting

9.1 Inspection

Check whether the power supply (battery) is installed.

9.2 Troubleshooting

Serial No.	Issue	Troubleshooting
1	After pressing the power button of the instrument, there is no image on the display screen.	1. Inspect whether the battery is installed properly; 2. Inspect whether the battery is charged.
2	There is reticular interference or snowflake interference on the display screen.	1. Inspect whether the instrument battery is normal; 2. Environment inspection for interference of electric field and magnetic field in the surrounding space.
3	There is image displayed on the display screen, but the keys cannot be operated.	Pull out the battery first, then insert the battery again, and start up.
4	There are white strips on the printed B-ultrasound image of the patient.	The printer is low in power and needs to be charged.

9.3 After-sales Service

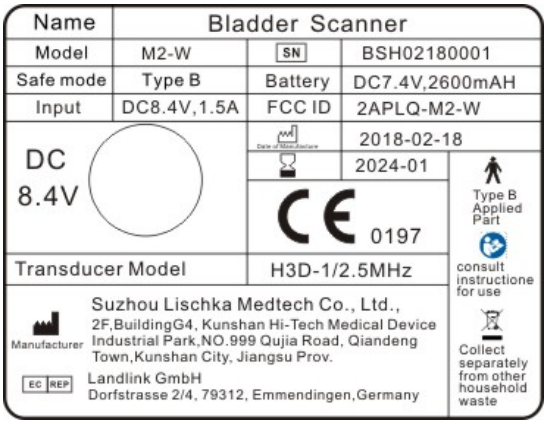
If the issue cannot be solved, please contact us at service@peaksonic.com.cn

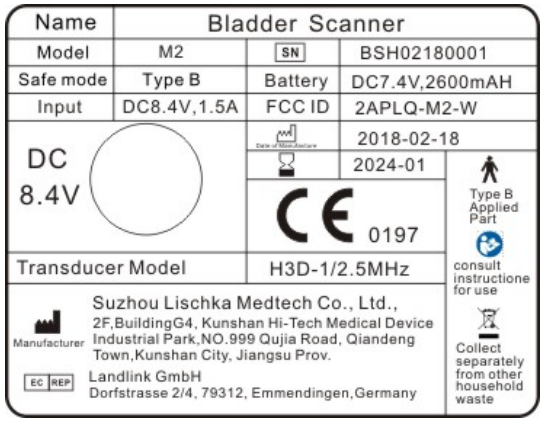
9.4 Maintenance Instructions

The maintenance of the instrument shall be carried out in the places appointed by the manufacturer. During the maintenance, in case any maintenance documents are needed please contact the manufacturer.

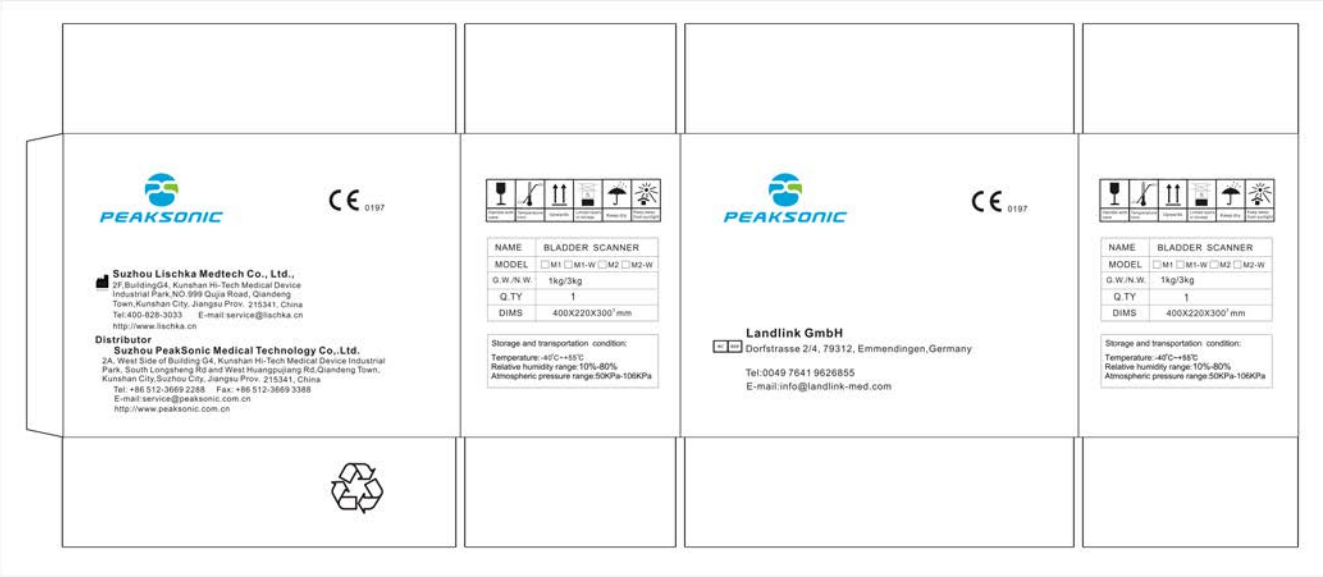
Appendix A Labels & Other Identifications

M2-W/M2 Labels

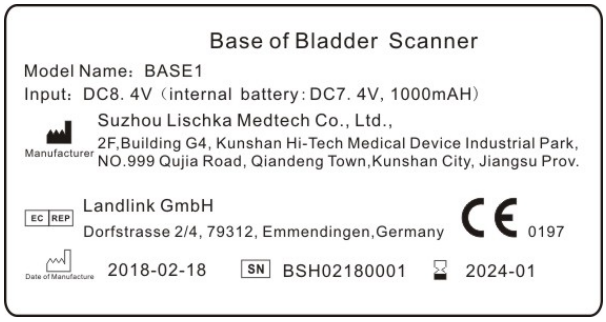




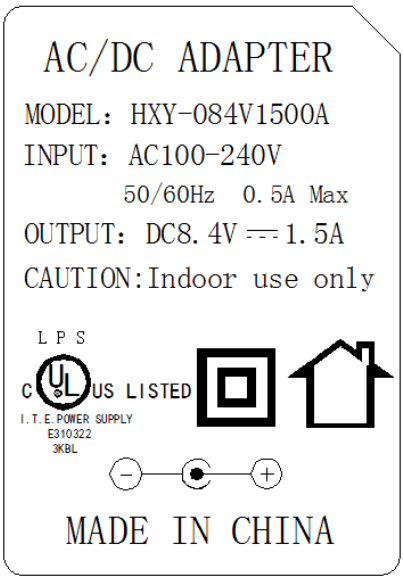
M2-W/M2 Label on Outer Package

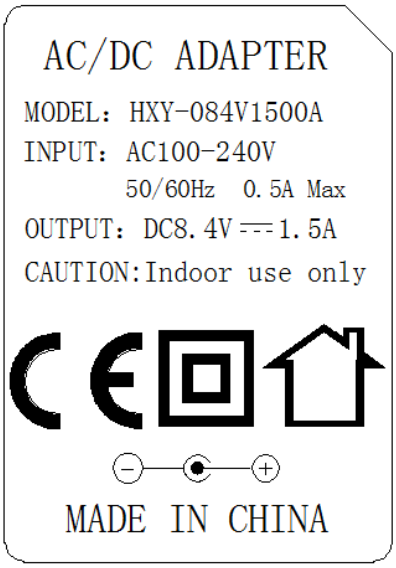


M2-W/M2 Label on the Docking Station



M2-W/M2 Label on the Charger





Appendix B Ultrasound Output Report

Table 201.103		Transducer Model: H3D-1/2.5MHZ Operating Model: B					
Index label		*MI*	*TIS*		*TIB*		*TIC*
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.54	0.032		0.032		N/A
Index component value			0.032	N/A	N/A	0.032	
Acoustic Parameters	$p_{r.\alpha}$ at z_{MI} (MPa)	0.83					
	P (mW)		2.78		2.78		N/A
	P_{1x1} (mW)		2.78		2.78		
	z_s (cm)			N/A			
	z_b (cm)					N/A	
	z_{MI} (cm)	3.33					
	$z_{PII.\alpha}$ (cm)	3.33					
	f_{awf} (MHz)	2.39	2.39		2.39		N/A
Other Information	*prr* (Hz)	1256.30					
	srr (Hz)	1256.30					
	n_{pps}	1					
	$I_{pa.\alpha}$ at $z_{PII.\alpha}$ (W/cm^2)	24.83					
	$I_{spta.\alpha}$ at $z_{PII.\alpha}$ or $z_{SII.\alpha}$(mW/cm^2)	19.11					
	I_{spta} at z_{PII} or z_{SII} (mW/cm^2)	33.75					
	p_r at z_{PII} (MPa)	1.09					
Operating control conditions	Focus(mm)	Fixed					
	Depth(mm)	Fixed					
	Frequency(MHz)	2.5					

Acoustic Output Reporting Table for Tack1(Autoscanning Mode)

System Model: M2-W SN:BSH01180004
Transducer Model: H3D-1/2.5MHz SN:201805 DR0001
Nominal Frequency:2.5MHz
Operating Model: B Mode

Acoustic Output			MI	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (W/cm^2)
Global Maximum Value			0.54	19.11	24.83
Associated Acoustic Parameter	Pr.3	(MPa)	0.83		
	W0	(mW)		2.78	2.78
	fc	(MHz)	2.39	2.39	2.39
	Zsp	(cm)	3.33		3.33
	Beam dimensions	X-6 (cm)			0.32
		Y-6 (cm)			0.32
	PD	(usec)	0.61		0.61
	PRF (Hz)		1256.30		1256.30
	EDS	Az. (cm)		Φ1.48	
		Ele. (cm)		Φ1.48	
Operating Control Conditions	Focus(mm)		Fixed		
	Depth(mm)		Fixed		
	Frequency(MHz)		2.5		

Acoustic Output Reporting Table for Tack1(Autoscanning Mode)

System Model: M2-W SN:BSH01180004
Transducer Model: H3D-1/2.5MHz SN:201805 DR0002
Nominal Frequency:2.5MHz
Operating Model: B Mode

Acoustic Output			MI	$I_{SPTA.3}$ (mW/cm²)	$I_{SPPA.3}$ (W/cm²)
Global Maximum Value			0.57	20.21	26.76
Associated Acoustic Parameter	Pr.3	(MPa)	0.88		
	W0	(mW)		2.98	2.98
	fc	(MHz)	2.39	2.39	2.39
	Zsp	(cm)	3.33		3.33
	Beam dimensions	X-6 (cm)			0.32
		Y-6 (cm)			0.32
	PD	(usec)	0.61		0.61
	PRF (Hz)		1256.30		1256.30
	EDS	Az. (cm)		Φ1.48	
		Ele. (cm)		Φ1.48	
Operating Control Conditions	Focus(mm)		Fixed		
	Depth(mm)		Fixed		
	Frequency(MHz)		2.5		

Acoustic Output Reporting Table for Tack1(Autoscanning Mode)

System Model: M2-W SN:BSH01180004
Transducer Model: H3D-1/2.5MHz SN:201805 DR0003
Nominal Frequency:2.5MHz
Operating Model: B Mode

Acoustic Output			MI	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (W/cm^2)
Global Maximum Value			0.56	19.31	25.40
Associated Acoustic Parameter	Pr.3	(MPa)	0.87		
	W0	(mW)		2.82	2.82
	fc	(MHz)	2.39	2.39	2.39
	Zsp	(cm)	3.33		3.33
	Beam dimensions	X-6 (cm)			0.32
		Y-6 (cm)			0.32
	PD	(usec)	0.61		0.61
	PRF (Hz)		1256.30		1256.30
	EDS	Az. (cm)		Φ1.48	
		Ele. (cm)		Φ1.48	
Operating Control Conditions	Focus(mm)		Fixed		
	Depth(mm)		Fixed		
	Frequency(MHz)		2.5		

Appendix C Technical Specification for

Electromagnetic Compatibility

Table 201

Guidance and statement of the manufacturer-electromagnetic emission		
M2-W/M2 portable bladder scanner is intended for use in the electromagnetic environment specified below. The purchaser or user shall ensure that it is used in such an environment.		
Emission test	Conformity	Electromagnetic environment-guideline
RF emission GB 4824	Group 1	M2-W/M2 portable bladder scanner uses RF energy only for its internal functions. Therefore, its RF emission frequency is very low and it is almost impossible to cause interference to nearby electronic equipment.
RF emission GB 4824	Class B	M2-W/M2 portable bladder scanner is suitable for use in all facilities, including domestic and residential public low-voltage supply network directly connected to households.
Harmonic emission GB 17625.1	Class A	
Voltage fluctuation/flicker emission GB 17625.2	Compliance	

Table 202

Guidelines and statement of the manufacturer-electromagnetic immunity			
M2-W/M2 portable bladder scanner is intended for use in the electromagnetic environment specified below. The purchaser or user shall ensure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guideline
Electrostatic discharge GB/T 17626.2	±6KV contact discharge ±8KV air discharge	±6KV contact discharge ±8KV air discharge	The floor shall be wooden, concrete or paved with tiles. If the floor is covered with synthetic material, the relative humidity shall be at least 30%.
Electrical fast transient burst GB/T 17626.4	±2KV for power line ±1KV for input/output line	±2KV for power line ±1KV for input/output line	Quality of network power supply shall be equal to that in typical commercial or hospital environment.

Surge GB/T 17626.5	±BKV wire to wire ±2KV wire to wire	±KV wire to wire ±2KV wire to wire	Quality of network power supply shall be equal to that in typical commercial or hospital environment.
On power input line Voltage sag, Short interruption and voltage change GB/T 17626.11	<5%UT, continuous for 0.5 week (on UT, >95% of sag) 40% UT, continuous for 5 weeks (on UT, 60% of sag) 70% UT, continuous for 25 weeks (on UT, 30% of sag) <5%UT, continuous for 5s (on UT, >95% of sag)	<5%UT, continuous for 0.5 week (on UT, >95% of sag) 40% UT, continuous for 5 weeks (on UT, 60% of sag) 70% UT, continuous for 25 weeks (on UT, 30% of sag) <5%UT, continuous for 5s (on UT, >95% of sag)	Quality of network power supply shall be equal to that in typical commercial or hospital environment. If the user of M2-W/M2 portable bladder scanner needs continuous operation during power outage, the M2-W/M2 portable bladder scanner is recommended to be powered by uninterruptible power supply or battery.
Power frequency magnetic field (50Hz) GB/T 17626.8	3A/m	3A/m	If image distortion occurs, then it is necessary to keep the M2-W/M2 portable bladder scanner away from the power frequency magnetic field or install magnetic shielding. The power frequency magnetic field in the intended installation site shall be measured to ensure that it is low enough
Note: UT refers to the AC network voltage prior to application of the test voltage.			

Table 204

Guidelines and statement of the manufacturer-electromagnetic immunity			
M2-W/M2 portable bladder scanner is intended for use in the electromagnetic environment specified below. The purchaser or user shall ensure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guideline

Radio-frequency transmission GB/T 17626.6 Radio-frequency radiation GB/T 17626.3	3V (effective value) 150KHz ~ 80MHz 3V/m 80MHz ~ 2.5GHz	3V (effective value) 3V/m	The portable and mobile radio-frequency communication equipment shall not be closer than the recommended isolation distance to any use part of the M2-W/M2 portable bladder scanner including cables. And the calculation of that distance shall use a formula corresponding to the frequency of the transmitter. Recommended distance d=1.2 $\sqrt{P}$ d=1.2 80MHz ~ 800MHz d=2.3 $\sqrt{P}$ 800MHz ~ 2.5GHz $\sqrt{P}$ Wherein: P— The maximum output power of the transmitter supplied by transmitter manufacturer, in watt (W); d— Recommended isolation distance, in meter (m). Field strength of fixed radio-frequency transmitter shall be determined by electromagnetic site survey, and it shall be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbols. 
Note 1: At the frequency point of 80 MHz and 800 MHz, the formula of higher frequency band shall be applied. Note 2: These guidelines may not apply to all situations. Electromagnetic transmission is affected by the absorption and reflection of buildings, objects and human bodies.			
* Fixed transmitters, such as: base stations of wireless (cellular/cordless) telephones and ground mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast, their field strength cannot be predicted theoretically and accurately. To assess the electromagnetic environment of fixed radio frequency transmitter, the electromagnetic site survey shall be considered. If it is measured that the field strength of the place where M2-W/M2 portable bladder scanner locates is higher than the above RF compliance level, observe M2-W/M2 portable bladder scanner to verify that it can operate normally. If abnormal performance is observed, additional measures may be necessary, such as readjustment of the direction or position of the M2-W/M2 portable bladder scanner. * Over the frequency range of 150 kHz to 80 MHz, field strength shall be less than 3 V/m.			

Table 206

Recommended isolation distance between portable and mobile radio-frequency communication equipment and the M2-W/M2 portable bladder scanner			
M2-W/M2 portable bladder scanner is expected to be used in electromagnetic environment where RF radiation disturbance is controlled. According to the maximum output power of communication equipment, the purchaser or user of the M2-W/M2 portable bladder scanner can prevent electromagnetic interference by maintaining the minimum distance between the portable and mobile radio-frequency communication equipment (transmitter) and the M2-W/M2 portable bladder scanner.			
Maximum rated output power of the transmitter Output power W	Isolation distances (m) correspond to different frequencies of transmitters		
	150KHz ~ 80MHz d=1.2 $\sqrt{P}$	80MHz ~ 800MHz d=1.2 $\sqrt{P}$	800MHz ~ 2.5GHz d=2.3 $\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For the maximum rated output power of transmitters not listed in the table above, the recommended isolation distance (d) in meter (m) can be determined by the formula corresponding to the frequency of the transmitter, wherein P is the maximum rated output power of the transmitter in watt (W) according to the transmitter manufacturer. Note 1: At the frequency point of 80 MHz and 800 MHz, the formula of higher frequency band shall be applied. Note 2: These guidelines may not apply to all situations. Electromagnetic transmission is affected by the absorption and reflection of buildings, objects and human bodies.			

Appendix D Ultrasound Intensity and Safety

C.1: Ultrasound in Medicine

The use of diagnostic ultrasound has proved to be a valuable tool in medical practice. Given its known benefits for non-invasive investigations and medical diagnosis， including investigation of the human fetus，the question of clinical safety with regards to ultrasound intensity arises. There is no easy answer to the question of safety surrounding the use of diagnostic ultrasound equipment. Application of the ALARA (As Low As Reasonably Achievable) principle serves as a rule of-thumb that will help you to get reasonable results with the lowest possible ultrasonic output. The American Institute of Ultrasound in Medicine (AIUM) states that given its track record of over 25 years of use and no confirmed biological effects on patients or instrument operators, the benefits of the prudent use of diagnostic ultrasound clearly outweigh any risks.

C.2: Ultrasound Safety and the ALARA Principle

Ultrasound waves dissipate energy in the form of heat and can therefore cause tissue warming. Although this effect is extremely low with Transcranial Doppler, it is important to know how to control and limit patient exposure. Major governing bodies in ultrasound have issued statements to the effect that there are no known adverse effects from the use of diagnostic ultrasound, however, Perform the ultrasound procedure prudently using the principle of ALARA (As Low As Reasonably Achievable).

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Attachment

Engineering Automatic Calibration Instructions:

The M series bladder scanner is patented in the fields of ultrasound imaging, measurement algorithm and probe. Therefore, the M series bladder scanner has the advantage of no calibration required during the service life in clinical application. We officially state that in the lifelong clinical application of the M series bladder scanner and the probe, as long as they are intact, then

1. The operator does not need to calibrate the clinical measurement accuracy of the bladder scanner before first measurement of the patient's bladder volume.
2. The operator does not need to calibrate the clinical measurement accuracy of the bladder scanner during daily application.

If any hospital or any end user regards instrument calibration as fixed operation procedure, the following steps may be used for calibration. Please note that: **Model 616 ver.2014 Bladder Scanner Calibration Phantom for Caresono** is the only applicable calibration phantom model designated. Since the purchased phantoms provided by the supplier are manufactured separately, the consistency cannot be guaranteed. The material formulation of each phantom is slightly different, which will affect the measurement accuracy of the phantom (will not affect the measurement accuracy of the bladder volume), therefore, we conduct Auto Calibrate to **Model 616 ver.2014 Bladder Scanner Calibration Phantom for Caresono** to ensure the measurement accuracy of the phantom.

Engineering Automatic Calibration steps are as follows:

Step I: Enter the password "09370" on the password management login interface (Figure 1), tap OK  , and then tap return  to pop up engineering Automatic Calibration interface (Figure 2).

Step II: Tap 

on the engineering automatic calibration interface to pop up prompt dialog interface (Figure 3), prompting: “Place the probe head into the phantom holder firmly”. Put the probe of the instrument into a specific phantom and tap 

to enter the automatic calibration state and pop up the calibration progress display interface (Figure 4). Reminding message "Calibration Failed!” will appear on the screen if it fails. In case of calibration failure, user could re-determine the position of the probe and the phantom, tap 

for automatic calibration once more. Reminding message "Calibration Successful!” will appear on the screen once it succeeds.

Step III: Enter the password management login interface (Figure 1) again and enter the password “09370”. Tap OK  and then tap return to return to the main interface.

Note: Engineering Automatic Calibration must be carried out at full charge.

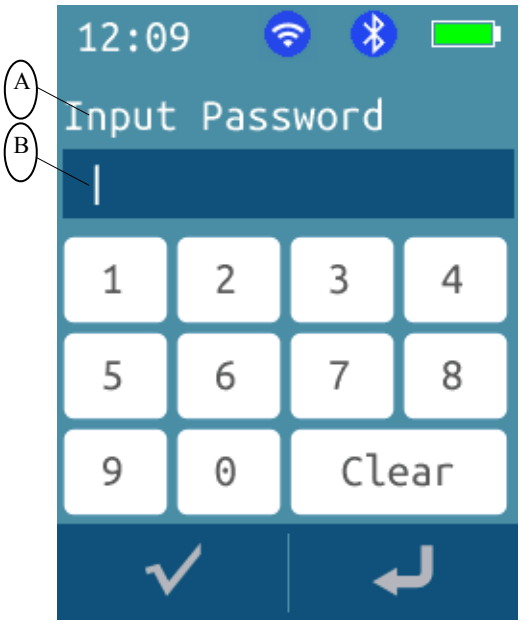

Figure 1 M2-W/M2 Password Management Login Interface

A: Password input prompt B: Password input field

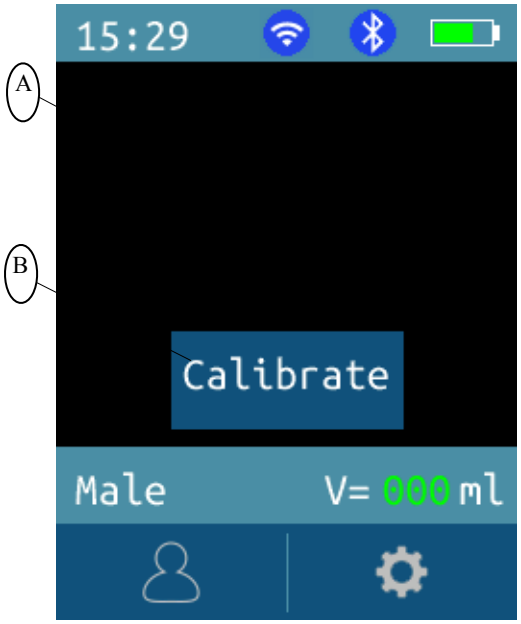

Figure 2 M2-W/M2 Engineering Automatic Calibration Interface

A: Automatic calibration interface B: Calibrate key

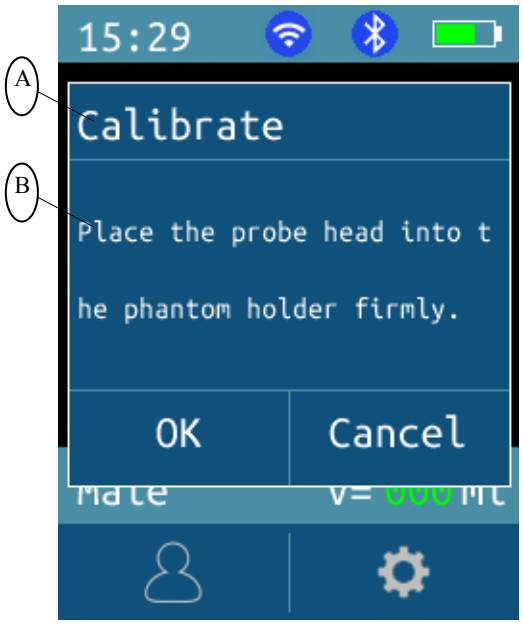

Figure 3 M2-W/M2 prompt dialog interface

A: Calibration prompt bar B: Prompts

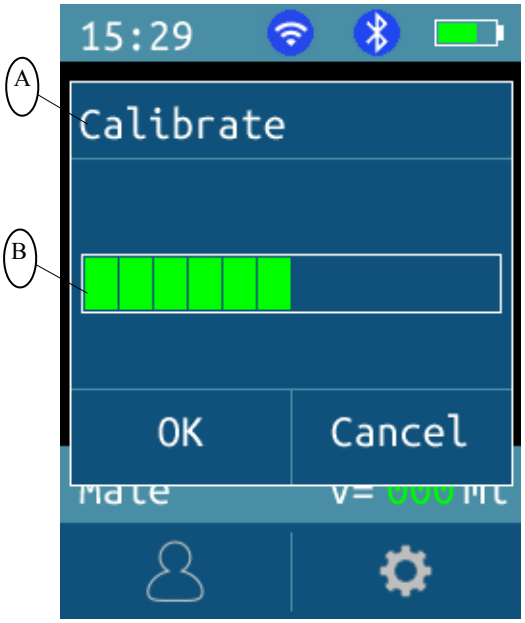

Figure 4 M2-W/M2 Auto Calibrate progress display interface

A: Calibration prompt bar

B: Auto Calibrate progress display

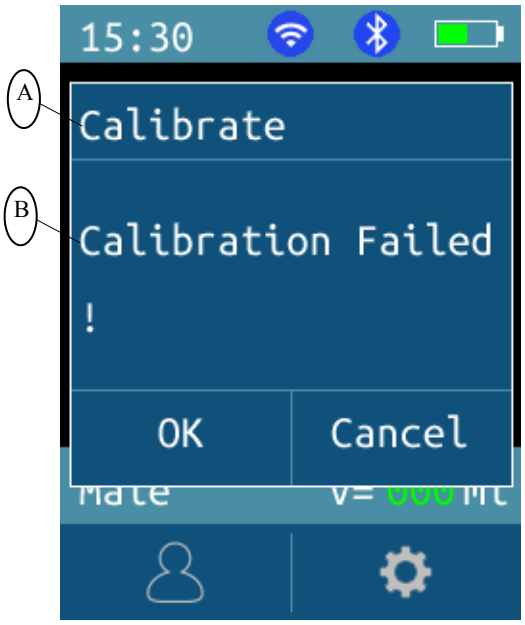

Figure 5 M2-W/M2 Auto Calibrate Failed prompt interface

A: Calibration prompt bar

B: Prompts

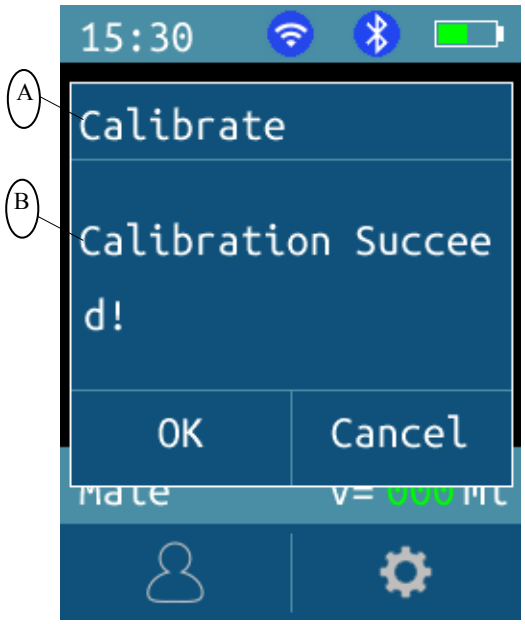

Figure 6 M2-W/M2 Auto Calibrate Successful prompt interface

A: Calibration prompt bar

B: Prompts