PEAKSONIC

Document No.:

Bladder Scanner
Model:M4

User Manual

Version: M4-V2.0

Suzhou PeakSonic Medical Technology Co.Ltd.

Contents

Chapter I Overview

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1.1 Introduction

The M4 bladder scanner registered by Suzhou PeakSonic Medical Technology Co.Ltd. and manufactured by Suzhou Lischka Medtech Co.,Ltd. provides non-invasive measurement of urinary bladder volume using ultrasonic imaging and measurement principle. This instrument is composed of a handheld wireless scanning device and a mobile phone. It has the following characteristics:

- This instrument has three operation modes: The expert mode, the easy mode and the intelligence mode. Under the expert mode, the real-time 2D B-ultrasound image can be displayed. The operator can determine whether the position and the result of the measurement are correct based on the bladder section image displayed. Under the easy mode, there is no real-time 2D scanning image, and the operator is guided by the instrument to move the probe to find the correct position for measurement (the operator doesn't need to have expertise in ultrasonic diagnosis). Under the intelligence mode, in the pre-scanning stage, it only displays the real-time projection position map of the scanning surface of the bladder. The position of the bladder shall be found before scanning (the operator does not need to have medical background, and moves the probe according to the real-time projection position). Position before scanning

- During measurement, the instrument is non-invasive and comfortable to patients. It is accurate, reliable, rapid and simple in operation. When the user releases the scan key, within several seconds, it can get several 2D ultrasound images. It adopts complex image processing technology to restore them to 3D images, and adopts complex algorithm to calculate the bladder volume and display the results.
- Two orthogonal images, patient information and volume value can be printed.
- Adopt touch screen keyboard on mobile phone for operation.
- Multi-language selection.
- Theme colour options (blue, black).
- Volume preset alert.
- Bluetooth wireless print report.
- Information management, storage and printing.
- The instrument is composed of a handheld wireless scanning device with an injection moulding case and a mobile phone.
- Adopt built-in battery for power supply.

1.2 Intended Use

The 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 non-invasively. The bladder scanner is intended to be used only by qualified medical professionals.

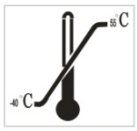
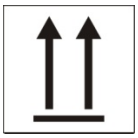
1.3 Carry out Standards

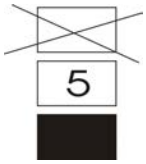
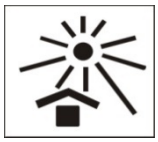
The instrument shall be designed and manufactured strictly according to national standards IEC/EN 60601-1 *Medical Electrical Equipment Part 1: General Requirements for Safety*, IEC/EN 60601-1-2 *Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard Electromagnetic compatibility - Requirements and tests* and IEC/EN 60601-2-37 *Medical electrical equipment - Part 2-37: Particular requirements for the safety of ultrasonic medical 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 *The environmental requirements and test methods for medical electrical equipment*.

Description of instrument nameplate and identification:

SN	Product serial No.		Follow the instructions
	Production date of the product		Type B equipment
EC REP	Authorized representative information of the European Union		Notice! Look up random files
	Manufacturer information	IPX7	Waterproofing grade
	The waste electrical and electronic equipment shall be recycled according to the regulations	CE 0197	CE identifier and code of the certification body
FCC ID 2AT6UM4-HD	Wireless certification code	Rx ONLY	Prescription use only

	Handle with care
	Limit of temperature
	Upward

	Limit number of stacking layer
	Keep dry
	Avoid heat

Description of packing and transportation identification of the instrument:

1.4 Service Life

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

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

Note: Scrapping disposal of the product shall be in compliance with local regulations. Don't scrap with household garbage.

1.5 Operating Environment Requirement

a) Ambient temperature range: +5℃ ~ +40℃

b) Relative humidity range: 30% ~ 75%

c) Atmospheric pressure range: 70KPa ~ 106KPa

1.6 Statement on Electromagnetic Compatibility

The use of M4 equipment will not affect the normal performance of wired and wireless information transmission and other electronic equipment, and it can work normally under the specified electromagnetic environment.

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

Warning: If the user replaces with non-conforming equipment parts voluntarily, there may be unforeseen electromagnetic compatibility problems which interfere with the measurement position resulting in mismeasurement. 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 the 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, therefore, the instrument cannot be used during battery charging.

1.7 Statement of the Manufacturer

Responsibility of the manufacturer

Suzhou PeakSonic Medical Technology 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 PeakSonic Medical Technology Co.Ltd.;
- Relevant electrical equipment complies with national standards;
- The instrument is used according to operation guidance;

In case of the following circumstances, Suzhou PeakSonic Medical Technology Co.Ltd. is not responsible for the safety, reliability and operation of the product;

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

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

Warning: If the equipment is modified, corresponding inspection 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 following cases:

a) Fetal use or pregnant patients.

b) Patients with ascites.

c) Patients with open or damaged skin.

d) Wounds in the suprapubic region.

1.9 Heat Index and Mechanical Index

Heat Index TIS： < 0.018

TIB： < 0.018

Mechanical Index MI: < 0.68

Chapter II Precautions

In order to ensure safety, during the operation of the equipment, the following contents must be read first. This instrument is only allowed to be operated by a person confirmed or authorised by relevant medical institution.

2.1 Inspection before Operation

- The instrument is normal.
- Do not keep the instrument close to hot or wet articles. Keep the instrument in place to ensure safe operation.

Warning: Please install and use the battery that is provided with the instrument by the company to carry out the work. If the user arbitrarily uses the battery of other specifications and models, it may cause safety hazards to the user or the instrument.

2.2 Safety Check before Operation

Check whether the instrument is in good condition. Make sure that no water, chemicals or other substances have been spilled on the instrument. If there is any strange noise or smell during the operation, the instrument shall be stopped immediately, until the authorized engineer resolves the problems.

2.3 Operating Instructions

- During operation, the surface of the probe shall be well protected to prevent collision, and the surface of the probe shall be applied with coupling agent to enable better contact between the human body and the probe.
- Closely monitor the operation of the instrument and the patient. If the instrument fails, turn off the power immediately.
- The patient is prohibited from touching the instrument or other electric appliances.
- The vent of the instrument shall not be closed.

2.4 After Operation

- Switch off the power.
- Clean the instrument and the probe.
- Place the instrument on the base.

2.5 Situations to be Avoided

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

(1) Water splashing.

(2) Too 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 voluntarily.

(10) Strictly forbid to dip the instrument probe which contacts with the patient into any liquid.

(11) Strictly forbid to heat the instrument probe which contacts with the patient.

(12) Use the ultrasonic coupling agent which meets the national standard requirements. Other materials (such as: oil) will damage the probe.

(13) The instrument probe which contacts with the patient shall be kept clean. After each use, wipe off the ultrasonic coupling agent on the probe with neutral detergent or fresh water.

2.6 Cautions during Transportation

(1) Turn off the power supply.

(2) Drop, vibration and collision of the instrument are strictly prohibited.

2.7 Operations in case of Malfunction

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

2.8 Regular Inspection and Maintenance

2.9 Do not Disassemble the Instrument

2.10 Startup

Long press (about 2 seconds) the power button of the scanning device to start it, click the App icon  of the mobile phone to enter the startup interface.

2.11 Shutdown

After the operation of the device is completed, long press (about 2 seconds) the power button of the scanning device again to turn off the scanning device. The power supply of the scanning device of the instrument is turned off. Press the exit button of the mobile phone to exit the App.

Chapter III System Introduction

3.1 Appearance

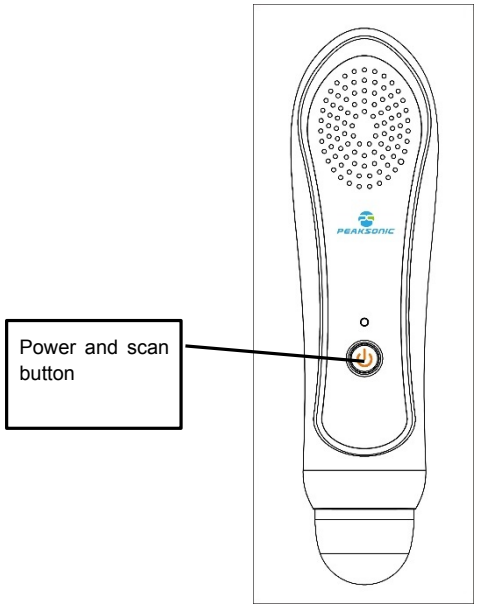


Figure 3-1 Front View of M4 scanning device

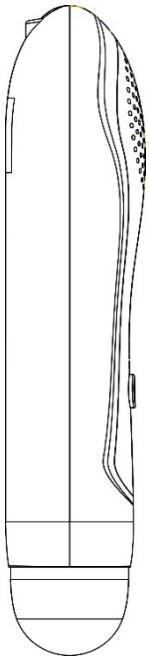


Figure 3-2 Side View of M4 scanning device

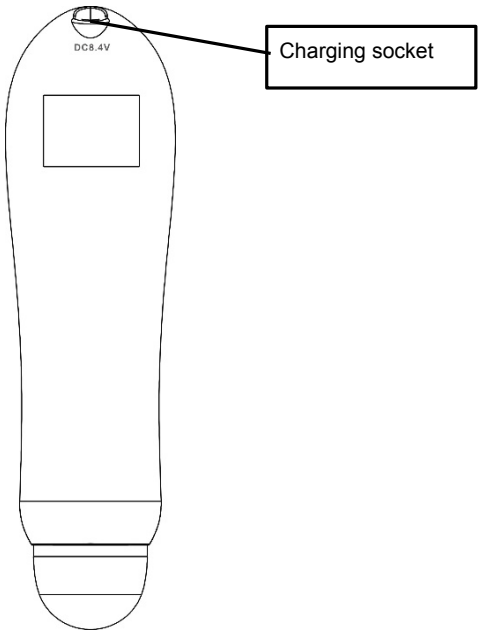


Figure 3-3 Back View of M4 scanning device

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 of±7%, ±7ml.
- Volume display resolution: 1ml.
- Scanning time: < 5 seconds
- Battery capacity: 2400mAh.
- Operation mode: Touch keys on the mobile phone.
- Have 2D tissue harmonic imaging image.
- 3D scanning display: Real-time scanned image, volume value, outline information, projection information, 3D graphics.
- Information storage: Images, results and other information of the patient can be stored.
- Information printing: Print the measurement results and pictures through bluetooth printer.
- Information management: Call out patient information for review (playback of original database information), storage, printing, deletion and other operations.
- Information input: Enter the gender, number, name and age of the patient.
- Wireless two-way transmission: The patient information is uploaded to the mobile phone for display, storage and printing. At the same time, a mutual transmission command is needed between the scanning device and the mobile phone.

- System setting: Including (calibration, mode, volume alert, Automatic Shutdown, interface language, print, theme color, password management, System information view, software update).
- Multi-language selection.
- The instrument has three operation modes: Expert mode, easy mode and intelligence mode.
- Display screen: Display on the mobile phone.
- Power: 13VA.
- Instrument size Host size: 215*56*45mm±0.6mm；Boundary dimension with the base: 260*120*223mm±0.6mm.
- Instrument weight: About 500g ±50g (including battery).
- Power supply mode: Battery powered: DC7.4V±0.5V.
- Continuous scanning time of battery powered instrument: > 2 hours and 20 minutes.
- Continuous electrification time of battery powered instrument: > 4 hours and 20 minutes.
- The waterproofing grade of the front end of the probe is IPX7.
- The instrument is composed of a handheld wireless scanning device and a mobile phone.

3.3 Block Diagram

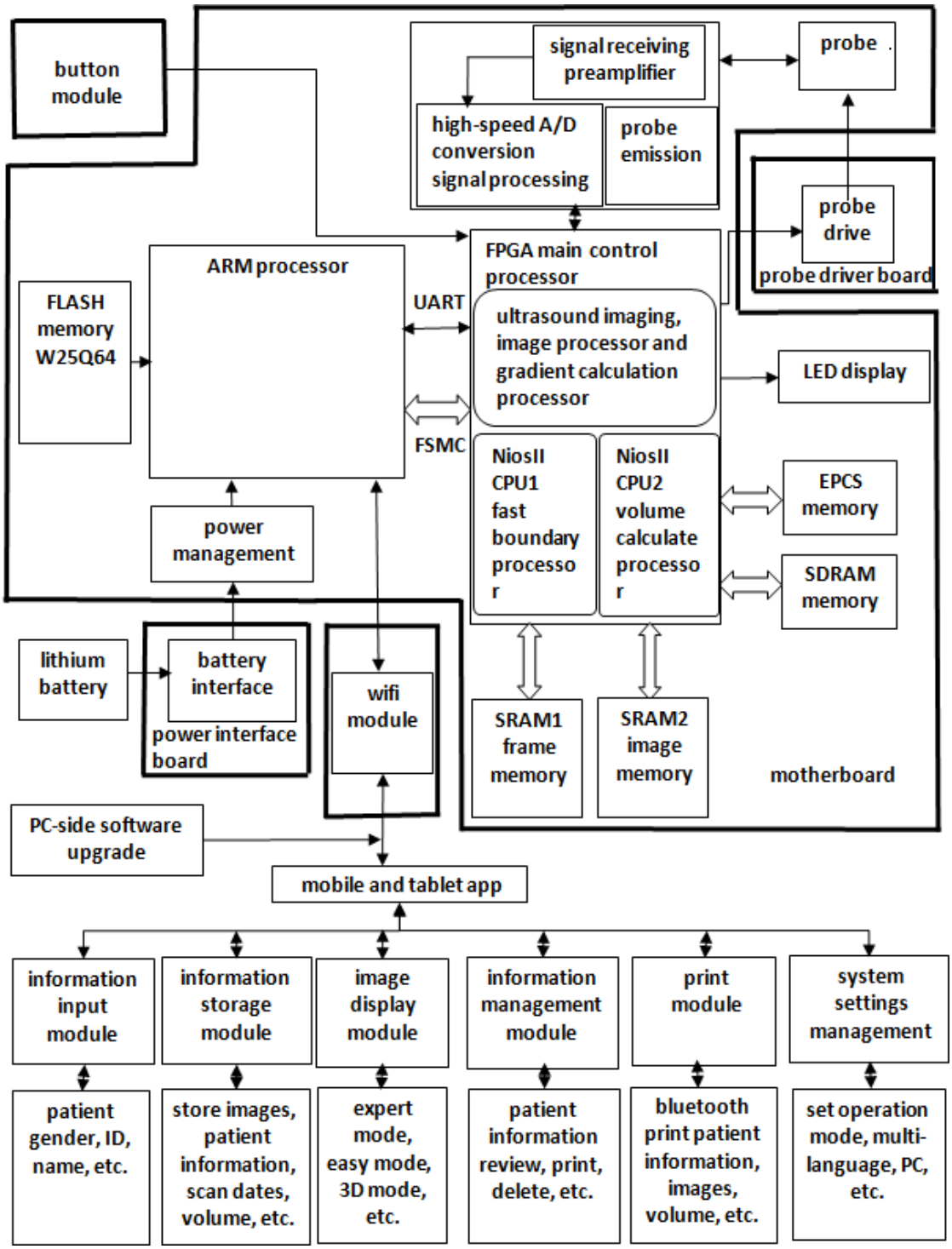


Figure 3-4 Block diagram of electrical principle of M4

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 first 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 bladder 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 divided segments of the curve, calculate the integral value of one section 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 as follow: Firstly, the instrument sends pulse signal to the 3D probe, and 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 one 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 will 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 2D section, a digital scanning converter (DSC) must be designed in the instrument to convert 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 and for calculation to obtain the final bladder volume.

3.5 Instrument Components

- Instrument model: M4
- The instrument is composed of a handheld wireless scanning device and a mobile phone (including 3D mechanical sector-scanning probe: 2.5MHZ)
- Software name: bladder volume analyzer software calculation and analysis system (M4) Version V1.2
- 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 BASE2
- User manual
- Lithium battery: model NCA653864SA-2400 mAh (PC015-2S1P) 7.4Vd.c. 2400mAh
- Certificate of quality
- Warranty certificate
- Packing list

Chapter IV Installation

4.1 Unpacking & Initial Inspection

After the instrument is unpacked, first confirm that there is no transportation damage of the instrument, then inspect according to the "packing list" and install according to the requirements and methods specified in "**4.2**".

4.2 Installation

4.2.1 Place scanning device on docking station

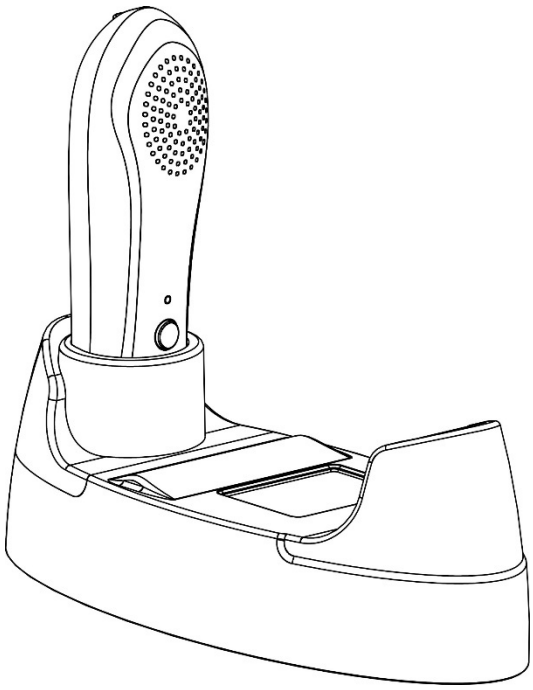


Figure 4-1 M4 scanning device on docking station

4.2.2 Install and remove bluetooth printer

Install 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 fixation cover ② according to the reverse arrow direction to cover it.

Remove bluetooth printer:

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

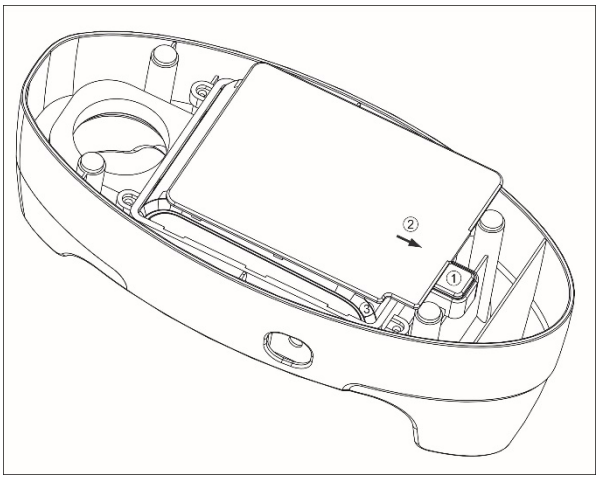


Figure 4-2 Install or remove printer

4.3 Power Supply

Power supply mode of the scanning device: battery powered.

4.3.1 Battery powered

Press the power button of the scanning device of the instrument, and the scanning device enters the working state.

4.3.2 Charge battery

Host battery is charged through the charger:

- Plug the charger output plug into the DC 8.4V round hole socket on the scanning device.
- Plug the AC input plug of the charger into the power socket.
- The power indicator light (red) on the charger is on. At this time, the battery is charged. When the charging indication light turns green, the battery is fully charged.

Printer battery is charged through the charger:

- Plug the charger output plug into the DC 8.4V round hole socket on the base.
- Plug the AC input plug of the charger into the power socket.

- The power indicator light (red) on the charger is on. At this time, the battery is charged. When the charging indicator light turns green, the battery is fully charged.

Chapter V Interfaces

5.1 Main Interface

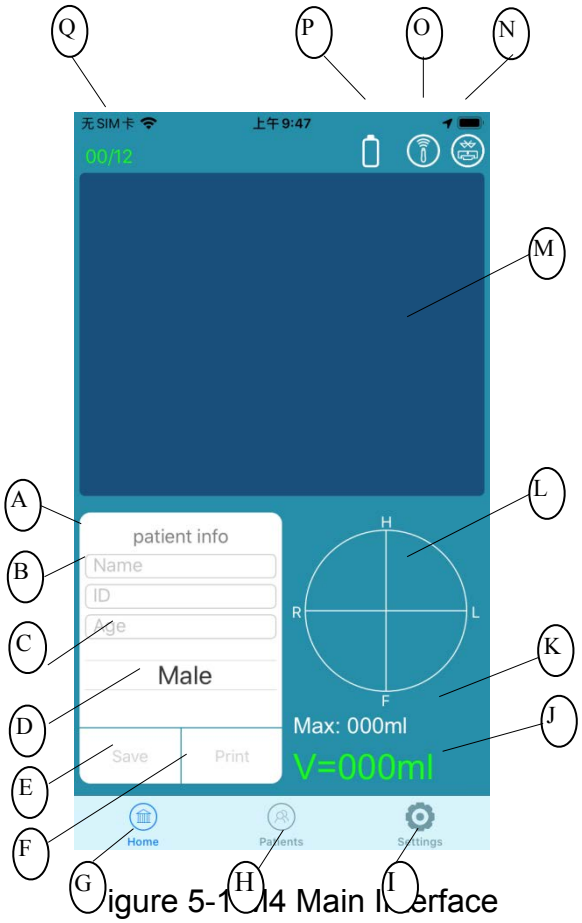


Figure 5-1 M4 Main Interface

A: Patient name

B: Patient ID

C: Patient age

D: Patient gender

E: Save patient data

F: Print patient data

G: Home page

H: Browse patient data

I: System setting

J: Bladder volume

K: Max. Bladder volume

L: Projection crosshair

M: Scanning image

N: Bluetooth

O: Probe connection

P: Probe battery level

Q: Number of scanning image

5.2 Expert Mode

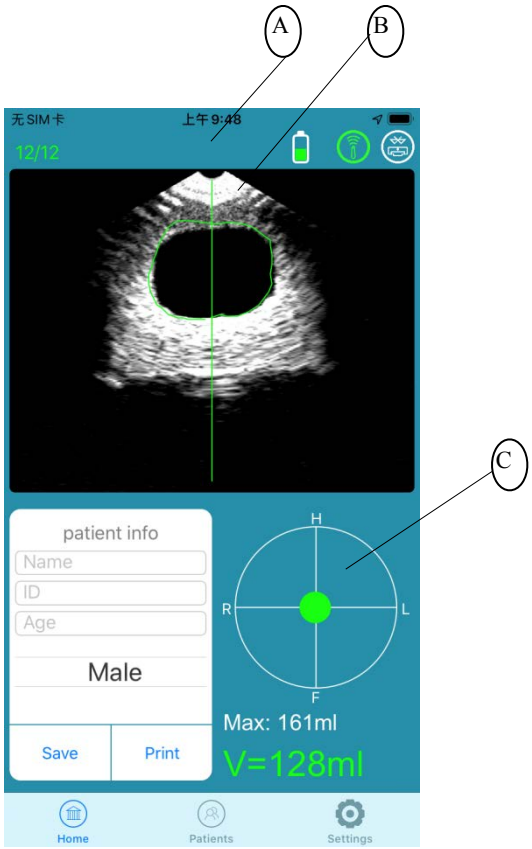


Figure 5-2 M4 Expert mode

A: Indication line

B: Outlined image boundary

C: Bladder projection image

5.3 Easy Mode

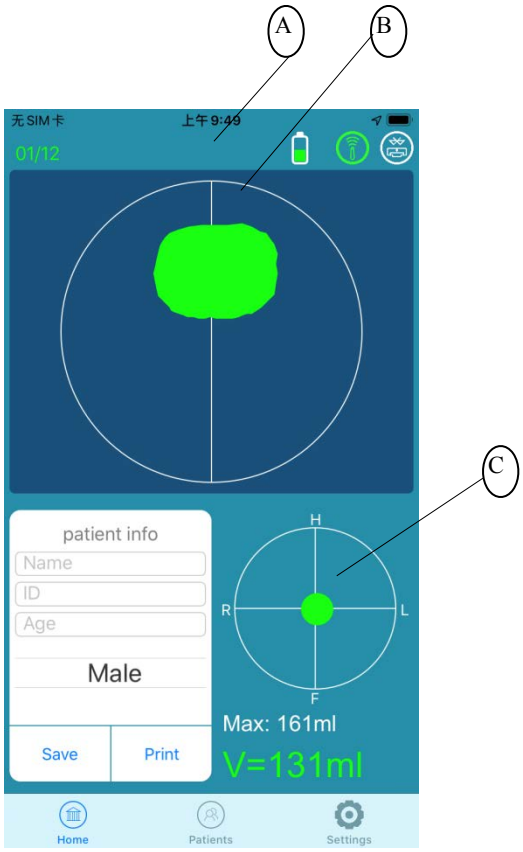


Figure 5-3 M4 Easy mode

A: Auxiliary circle

B: Bladder cross-sectional view

C: Bladder projection image

5.4 Intelligence Mode

5.4.1 Intelligence Mode - Pre-scan

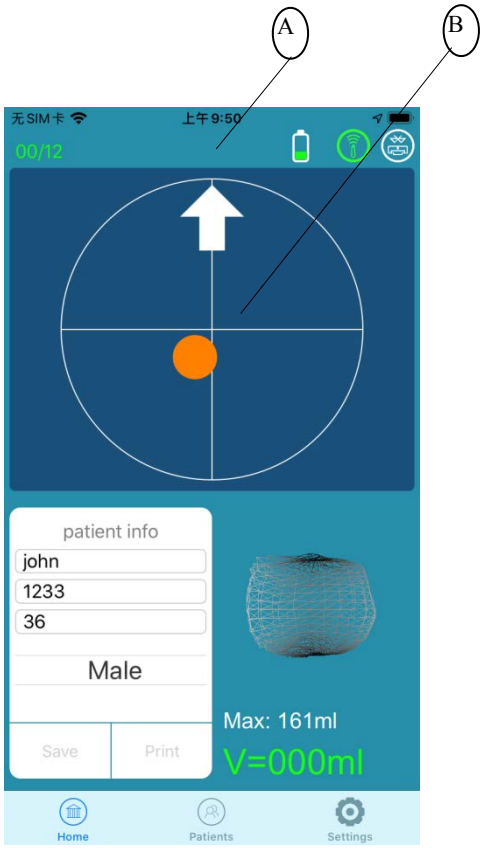


Figure 5-4-1 M4 Intelligence mode pre-scan

A：Direction arrow

B：Bladder position

5.4.2 Intelligence Mode - Scan

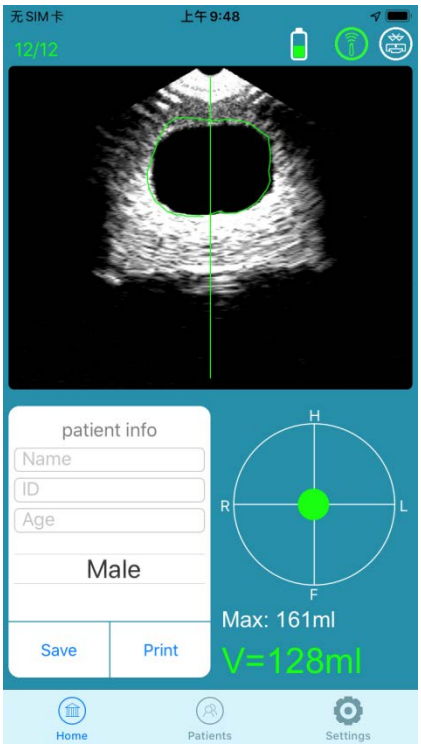


Figure 5-4-2 M4 Intelligence mode - scan

5.5 Browse Patient History Information

5.5.1 Browse patient history information login interface

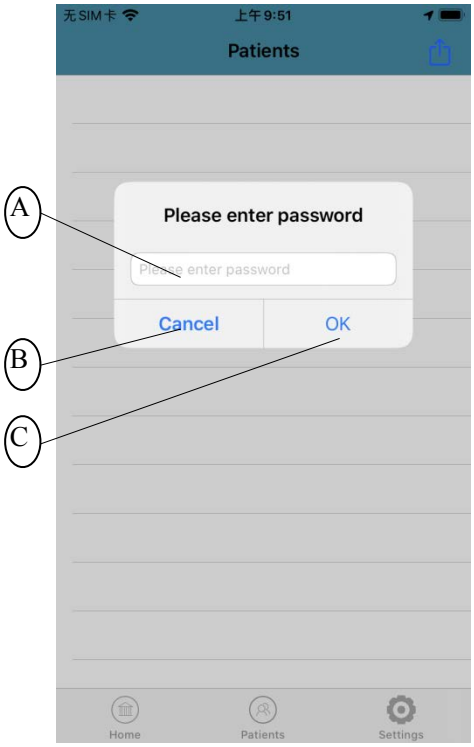


Figure 5-5-1 M4 Browse patient information login interface

A：Enter login password

B：Cancel login and return to the previous page

C：Confirm to login

5.5.2 Patient history information main interface

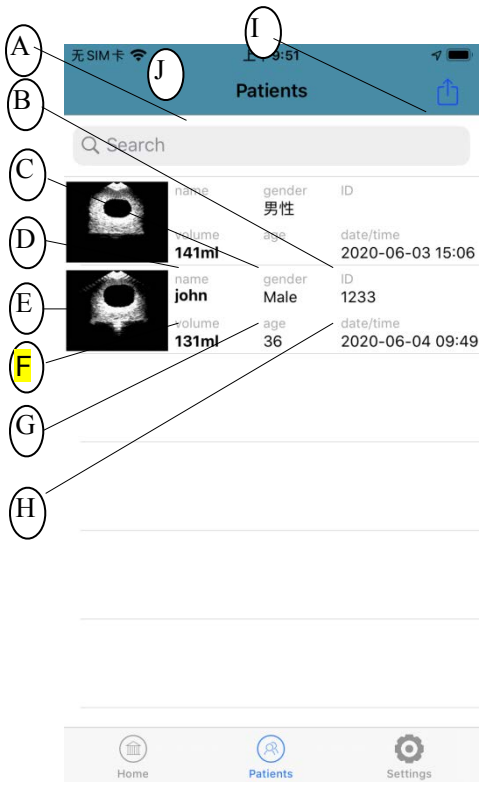


Figure 5-5-2 M4 Patient history information main interface

A: Search patient information

B: Saved patient ID

C: Saved patient gender

D: Saved patient name

E: Saved bladder images

F: Saved patient bladder volume

G: Saved patient age

H: Saved measurement date/time

I: Export patient data

5.5.3 Manage patient history information

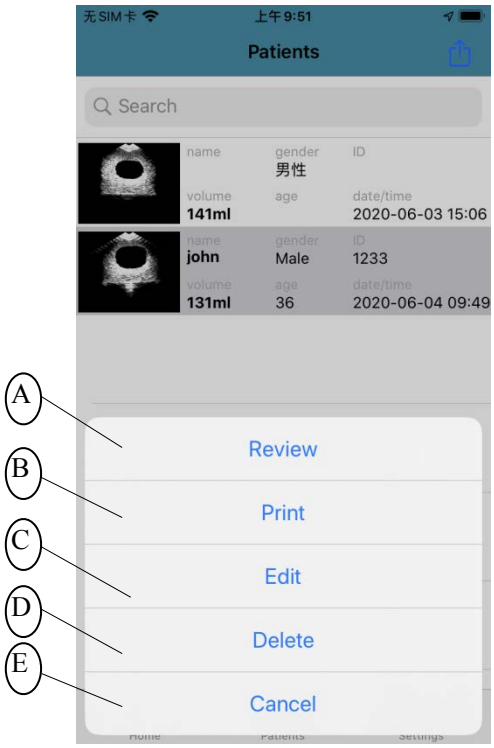


Figure 5-5-3 M4 Patient history information management interface

A: Review patient data

B: Print patient data

C: Edit patient data

D: Delete patient data

E: Cancel

5.5.4 Review patient history information

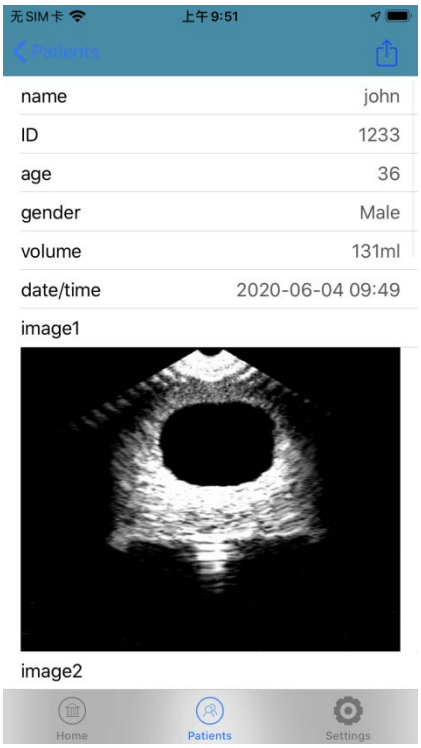


Figure 5-5-4 M4 Review patient history information

5.5.5 Edit patient history information

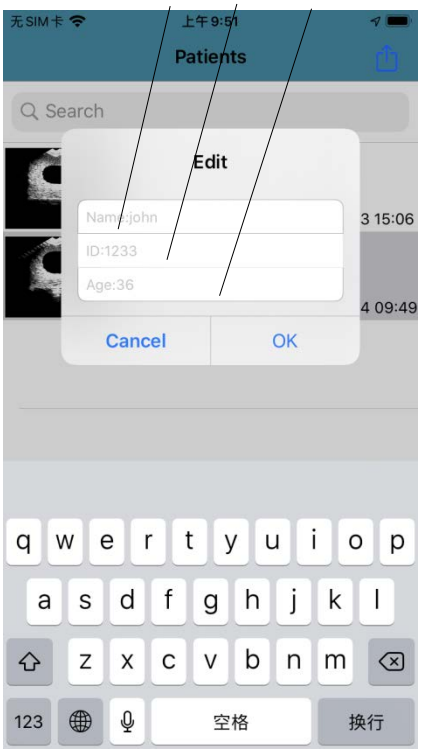


Figure 5-5-4 M4 Patient history information editing page

A: Edit patient name

B: Edit patient ID

C: Edit patient age

5.6 System Setting

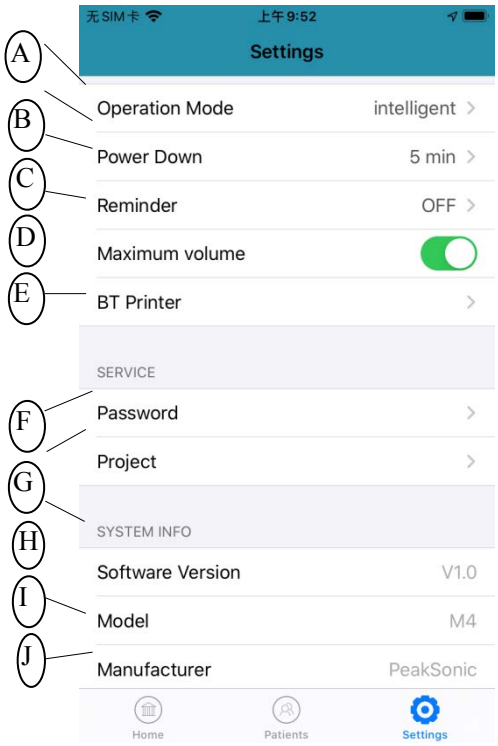


Figure 5-6 M4 System Setting

A: Operation modes options

B: Automatic shutdown

C: Bladder volume reminder

D: Maximum volume display

E: Bluetooth printer setting

F: Password management

G: Project setting

H: Software version number

I: Model type

J: Name of manufacturer

5.6.1 Operation mode

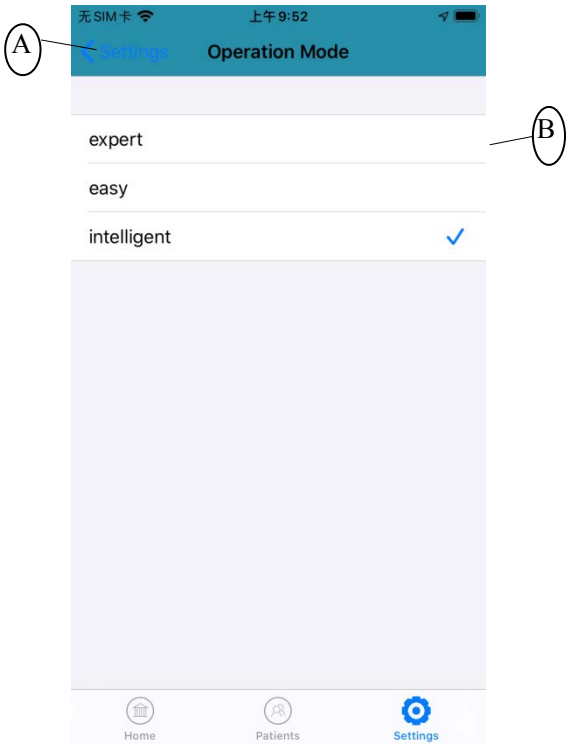


Figure 5-6-1 M4 Operation mode

A: Return to the previous setting page

B: Tick to confirm the choice

5.6.2 Automatic shutdown

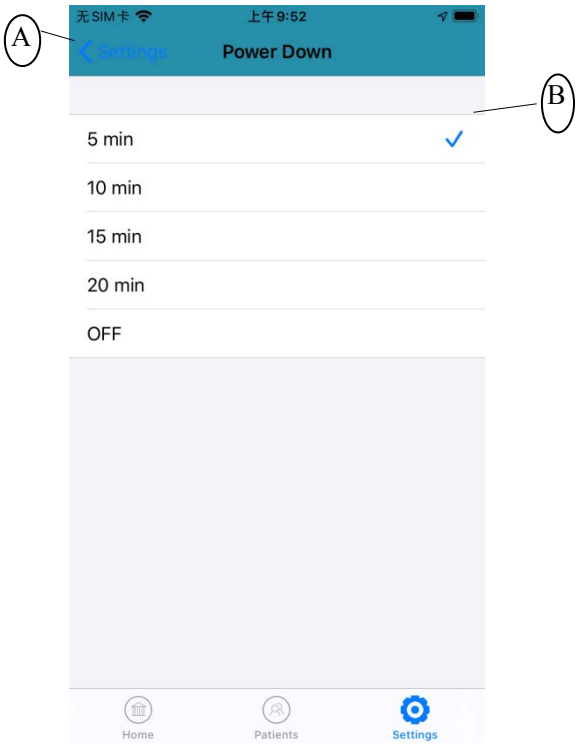


Figure 5-6-2 M4 Automatic shutdown

A: Return to the previous setting page

B: Confirm the choice

5.6.3 Volume alert

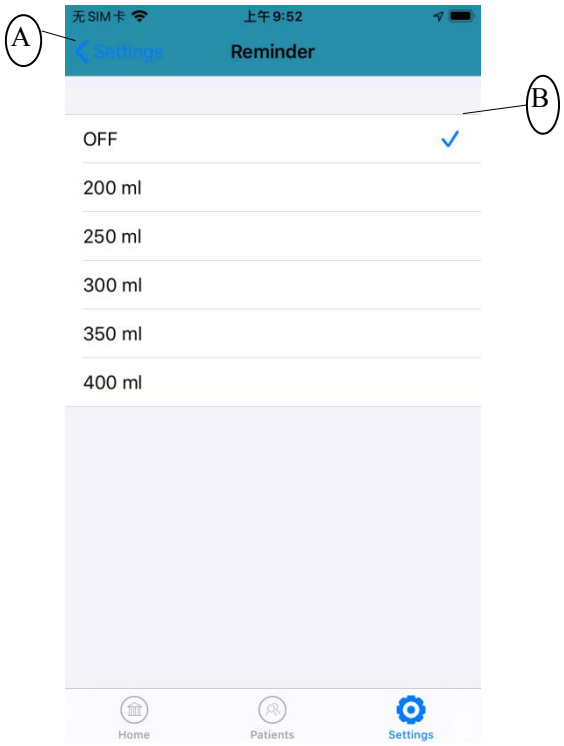


Figure 5-6-3 M4 Set up volume threshold reminder

A: Return to the previous setting page

B: Confirm the choice

5.6.4 Bluetooth printer

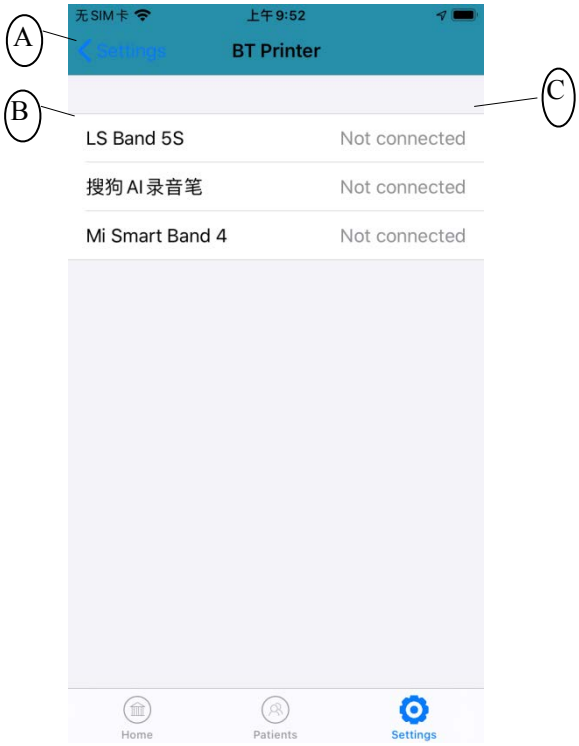


Figure 5-6-4 M4 Bluetooth printer options

A: Return to the previous setting page

B: Name of searched bluetooth devices

C: Connection status

5.6.5 Login as administrator

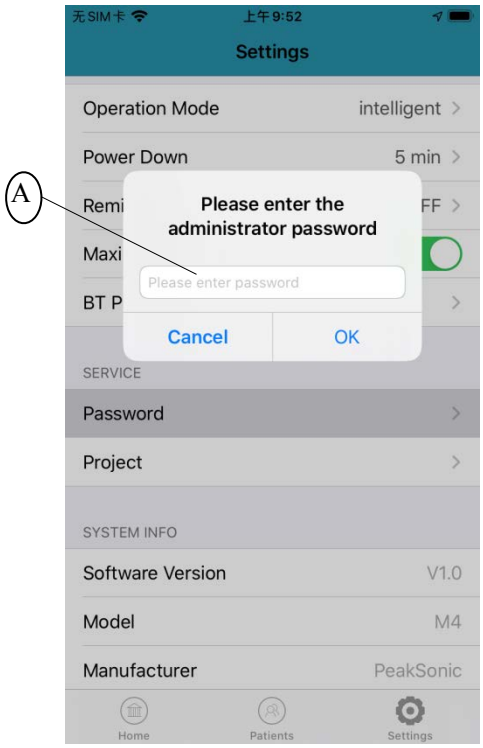


Figure 5-6-5 M4 Administrator login interface

A: Enter administrator password

5.6.6 Manage password

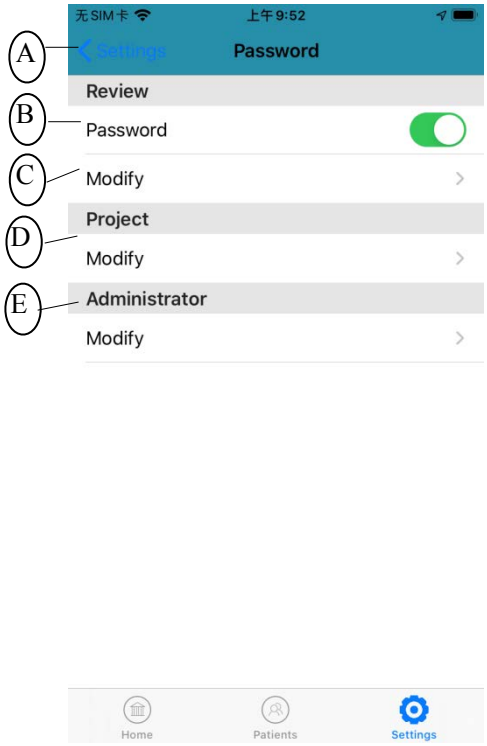


Figure 5-6-6 M4 Password management interface

A: Return to the previous setting interface

B: Password required before checking patient information

C: Modify password for patient database access

D: Modify password to edit project

E: Modify login password as administrator

5.7 System Language

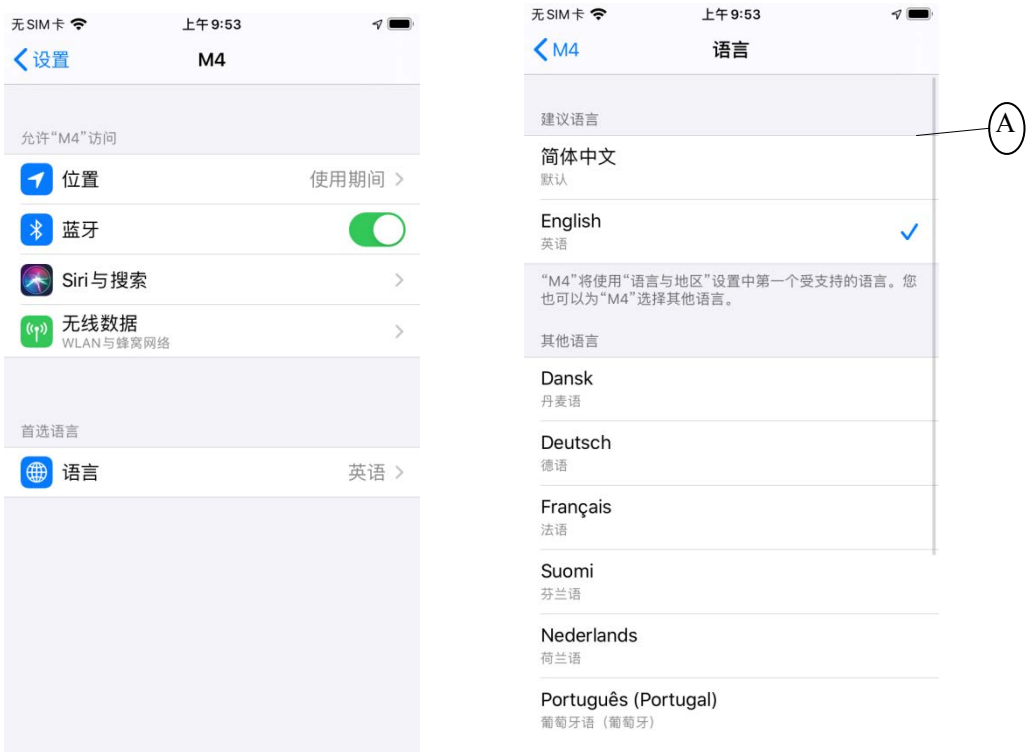


Figure 5-7 M4 System language setting

A: Confirm choice of language

Chapter VI Operation of Device

6.1 Turn on/off the Device

Long press the power button to turn on the probe. Tap icon  from the tablet to enter the main page. Long press the power button again to turn the probe off. Tap “Home” of the tablet to exit the program.

6.2 Wireless Connection with iPhone

Select Wi-Fi named Peak_M4_XXXXXXXX from the iPhone to connect the probe with the phone. The last eight digits of the Wi-Fi name are composed of English letters and Arabic numerals. They are generated automatically by the system. Open the app. Once the probe connection sign appears as  in the screen, it means the connection is successful.  shows the battery level of the device.

6.3 Bladder Scan

6.3.1 Select gender

Users can select gender in the main interface. Scroll up and down to select among Male, Female, FemaleH, Child and Phantom.

6.3.2 Bladder pre-scan

Apply the coupling agent to the skin of the lower abdomen where the probe head touches to check. Press Scan button to start pre-scan, the bladder real time B-mode ultrasonic images (as shown in Figure 5-2) or bladder cross-sectional view (as shown in Figure 5-3) or real time bladder projection image will appear in the screen. Pre-scan starts.

Select “Expert mode”. During pre-scan users can see B-mode ultrasonic images of the

bladder. Move the probe till the biggest bladder cross-sectional zone is located. Align the centre of the section with the centre of the auxiliary circle in the screen during the process.

Select “Easy mode”. During pre-scan users can view bladder section. Move the probe till the biggest bladder section appears. Align the centre of the section with the centre of the auxiliary circle in the screen during the process.

Select “Intelligence mode”. During pre-scan observe the bladder projection image. Move the probe till the projection image reaches the centre of the crosshairs. When the projection is green, it means bladder is on target. When it’s off the target projection image turns orange. During pre-scan direction arrow appears to guide the user move the probe to reach the right place.

Remark:

1. Only when the phone and the probe are connected users can see bladder images during pre-scan and scan. When the icon  at the up left corner of the screen turns green it means connection is successful. When it appears white, connection between the phone and the probe is yet to be done.
2. During pre-scan, selection options such as gender, save, print, patient information review and setting are all locked. After scan is completed they get unlocked in the system.

6.3.3 Bladder scan

After bladder position is located, press Scan button again to start bladder scanning. Keep the probe still during scanning.

6.3.3.1 Bladder scan under expert mode

Under expert mode, once the counting of image increases from 01 to 12 at the up left corner of the screen, it means scanning, image analysis and calculation are completed. 12 big B-mode ultrasonic images will be visible in the middle of the screen. On the right part of the screen bladder 3D projection and bladder volume will be displayed.

Remark: If bladder scan is executed a couple of times for one patient, only the maximum value will be displayed by the end of the scan.

6.3.3.2 Bladder scan under easy mode

Under easy mode, once the counting of image increases from 01 to 12 at the up left corner of the screen, it means scanning, image analysis and calculation are completed. 12 big bladder cross-sectional images will be visible in the middle of the screen. On the right part of the screen bladder 3D projection and bladder volume will be displayed.
Remark: If bladder scan is executed a couple of times for one patient, only the maximum value will be displayed by the end of the scan.

6.3.3.3 Bladder scan under intelligence mode

Under intelligence mode, once the counting of image increases from 01 to 12 at the up left corner of the screen, it means scanning, image analysis and calculation are completed. 12 big bladder ultrasonic images will be visible in the middle of the screen. On the right part of the screen bladder 3D projection and bladder volume will be displayed.
Remark: If bladder scan is executed a couple of times for one patient, only the maximum value will be displayed by the end of the scan.

6.4 View Bladder Ultrasonic Images, Projections or 3D Images

After scan is completed, 12 bladder images can be viewed at the bottom of the screen. Swipe the images left or right to see all images. At the right part of the screen a bladder projection image is displayed in a crosshair. Swipe the projection to the right, a 3D image will appear.
Under Expert or Easy mode, align the centre of the projection with the crosshair. Ensure all projection zone is attached to the crosshair which indicates bladder is within the scan range. If the projection appears green it means bladder is on target. When it’s off the target, the projection turns orange.

6.5 Enter Patient Data

Patient data including name, ID, age can be entered in the main interface in corresponding columns (Figure 5-1, 5-2, 5-3 or 5-4-2)

6.6 Save Patient Data

After patient data is entered, press Save to save the information. Additional information can be saved later. Patient profile includes name, ID, age, gender, saved date/time, bladder volume and B-mode ultrasonic images.

6.7 Connect to Bluetooth Printer

There are two steps to connect to the bluetooth printer:

1. Press bluetooth printing icon  on the main interface. A list of bluetooth devices pop up as shown in Figure 5-6-4.
2. Tap the printer name out of the list to connect. After connection is established, the bluetooth printing icon turns to green as shown  .

6.8 Print Patient Information

After patient data entry is completed, press Print to print out the information. Additional information can be saved and printed later. Patient profile including name, ID, age, gender, saved date/time, bladder volume and two orthogonal ultrasonic images can be all printed out.

Remark: printing function is only available when printer and tablet are connected.

6.9 Browse Patient History Information

Tap patient information icon  to enter information browse login interface (Figure 5-5-1). Log in as shown in Figure 5-5-2. Tap on patient name to illustrate 12 bladder images on the right side of the screen.

6.9.1 Print patient history information

Tap on one of the patient names and swipe left. Three options appears which are Print, Edit and Delete (Figure 5-5-3). If the printer has been connected, tap Print to print out patient information and images. In case connection is not established, prompt “Printer is not

connected” pops up.

6.9.2 Edit patient history information

Tap one of the patient names, three options appear which are Review, Print, Edit, Delete and Cancel (Figure 5-5-3). Select Edit to enter new data such as gender, ID or age.

6.9.3 Delete patient history information

Tap one of the patient names, three options appear which are Review, Print, Edit, Delete and Cancel (Figure 5-5-3). Select Delete. A prompt pops up to confirm with the user about deletion. Alternatively choose one patient out of the patient list and swipe left, press Delete.

6.9.4 Upload patient data

Get connected with the upper computer through Wi-Fi signal called “Peaksonic_UCxx”. Press icon  . A prompt pops up confirming whether all patient data need to be uploaded. Press Confirm to start exporting data.

6.10 Settings

Press setting icon  to enter system setting interface (Figure 5-5). Setting includes mode, power down, alert, maximum bladder volume display, bluetooth printing, password management, project management, software version, model and manufacturer information.

6.10.1 Operation mode

Tap Mode in the setting menu to enter mode selection interface (Figure 5-6-1). Operation modes to be selected are expert, easy and intelligence mode. By default it is expert mode.

The option with  is the selected mode.

Under Expert mode, observe the B-mode bladder image during pre-scan. Move the probe till image is centred and the biggest bladder section is reached. During scan 12 B-mode images are displayed (Figure 5-2). After scan bladder volume and projection image are shown in the screen. Swipe the projection image to the left, bladder 3D image will appear. Swipe it right, projection image comes back. When projection appears green it means bladder is on target while orange projection indicates bladder is off target.

Under Easy mode, observe the bladder section during pre-scan. Move the probe till centre of the section aligns with centre of the auxiliary circle and the biggest bladder section is reached. During scan 12 real time bladder sections are displayed (Figure 5-3). After scan bladder volume and projection image are shown in the screen. Swipe the projection image to the left, bladder 3D image will appear. Swipe it right, projection image comes back. When projection appears green it means bladder is on target while orange projection indicates bladder is off target.

Under intelligence mode, observe the bladder projection image during pre-scan. Move the probe till the projection image centre aligns with the centre of the auxiliary circle. If the bladder is off centre, direction arrow will appear to guide the user. Move the probe by following the arrow till the arrow disappears which means bladder has been positioned correctly and scan can start. Bladder B-mode images are displayed in a roll at the upper part of the screen. During scan image counting starts. When the image number turns to 12 it indicates scanning, image analysis and calculation are completed. After scan bladder volume and projection image are shown in the screen. Swipe the projection image to the left, bladder 3D image will appear. Swipe it right, projection image comes back. When projection appears green it means bladder is on target while orange projection indicates bladder is off target.

When bladder volume is lower than 100ml, use Expert mode to measure the volume.

6.10.2 Power down

Power Down button is for users to sett up automatic shutdown time of the device in order to save the battery power. The options include 5 mins, 10 mins, 15 mins, 20 mins and OFF. When OFF is selected, the device will not be automatically shut down.

6.10.3 Alert

Alert is to set up a reminder when the bladder volume reaches certain level, the device gives a warning by making “beep”. Alert options are 200ml, 250ml, 300ml, 350ml, 400ml and OFF. Select OFF to switch off the alert.

6.10.4 Maximum volume

Maximum bladder volume displays the biggest measurement result of one patient after bladder scan a few times. Swipe the button left or right to turn this function off and on.

6.10.5 BT printer

Press BT printer (bluetooth printer) to enter interface as shown in Figure 5-6-4. Look for printer named “MSP-100” to connect. Connection status appears on the right side of the screen.

6.10.6 Administrator password

Tap Password and enter administrator password to enter password management interface. By default the password is 00000 (five zeros).
Users can set up password to view patient data. Swipe the button to the right and the colour turns green which means password will be requested before viewing patient data. If keep the button grey no password will be requested. Data is open for all users to access. Password is also requested to access Project. By default it is 00000 (five zeros). Modify the password by pressing Modify. Project function is irrelevant to normal users. Administrator password can also be modified by pressing Modify button. By default it is 00000 (five zeros).

6.10.7 Software version

This field displays software version number.

6.10.8 Model

This field displays model of the device.

6.10.9 Manufacturer

This field displays name of the manufacturer.

6.11 Language

Language can be selected according to the needs of users. There are twelve languages available in the system including English, Simplified Chinese, French (Français), Denish (Dansk), Finnish (Suomi), Portuguese (Português), Swedish (Svenska), Spanish (Español), Dutch (Nederlands), Nordish (Norsk), German (Deutsch), Italian (Italiano). Select the desired language and it will be applied to the system.

6.12 Software Update

Enter “bladder scanner” or “peaksonic” and search for the corresponding app in App Store. Press UPDATE if needed. Update can only be done when the phone or tablet is connected to the internet.

6.13 Upper Computer Transmission & Functions

Upper computer software is developed based on Windows system as auxiliary software for data transfer of M3, M4 and M5. The software is used to transfer encrypt data including patient information, bladder images and measurement result through USB cable or hotspot. Data can be displayed through exporting in PDF format or printing. Hospital name, department names or doctor names can be manually entered, saved and displayed. It enables login and password management. The program of the wireless scanning devices can be upgraded once they get connected with the software. All measurement data stored in the mobile devices can be transferred to the upper computer using this software. During the process, data are encrypted.
Remark: M3, M4 and M5 are the model names of bladder scanners developed by PeakSonic. Data transfer by USB cable is only applicable for Android tablet and smartphone and M5. The system supports automatic data transfer from multiple devices to the upper computer at the same time. Data transfer by self-created wireless hotspot is applicable for Android tablet/smartphone, Apple tablet/smartphone and M5. The system support data transfer from multiple devices to the upper computer at the same time.

6.13.1 Run upper computer software

Copy the "release" folder of the software into the upper computer. Open the folder and look for the file named PatientManagerSystem.exe. Click the file to run the software. Login interface will then pop up as shown in Figure 6-1. In PWD enter the original login password (default password is “abcd1234") to enter the upper computer main interface. When entering password "superadmin", the login password will be restored to the original one “abcd1234” and all the patient data previous saved in the software will be removed.

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

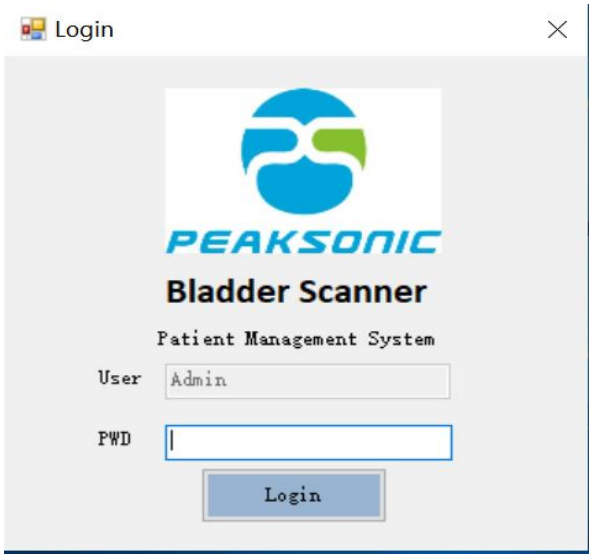


Figure 6-1 M4 Upper computer login interface

6.13.2 Upper Computer Main Interface

On the main interface users could see four menu items, upper computer information, Logo, patient information and twelve bladder ultrasound images. Menu items include File, Edit, Tool and Help. The patient information includes patient ID, age, gender, scanning time and bladder urine volume value. Select one patient to display twelve ultrasound images and a projection image. Scroll the screen left or right to view all the ultrasonic images.

The main interface of upper computer as shown in Figure 6-2 and Figure 6-3:

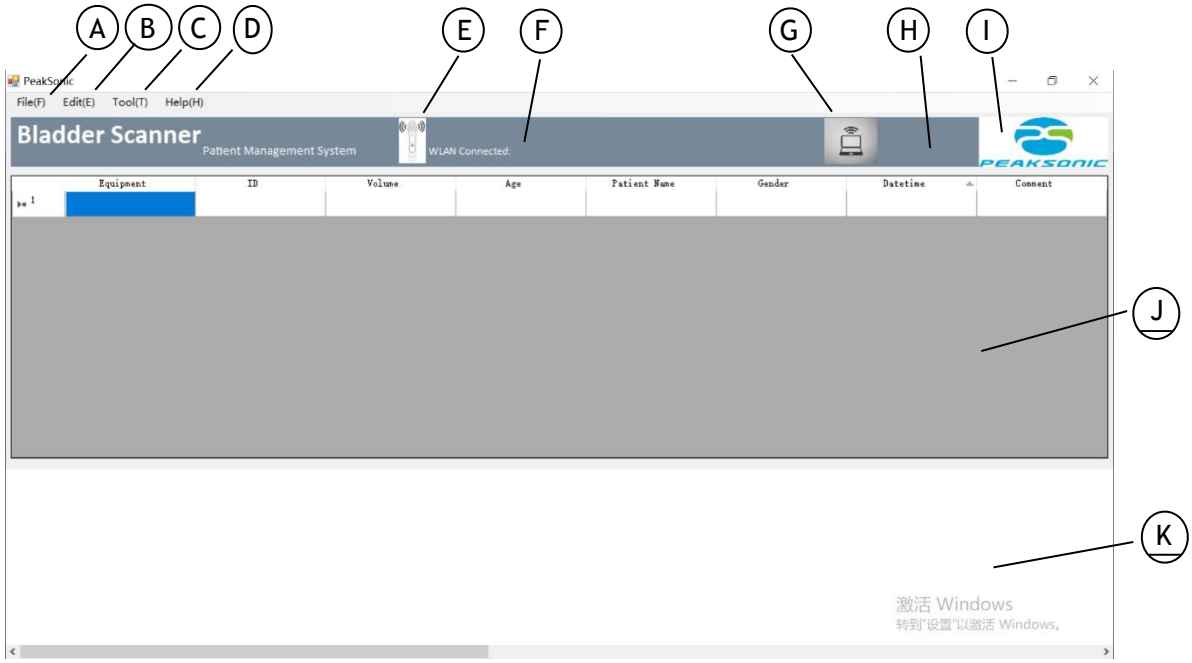


Figure 6-2 Main interface of M4 Upper computer

A: File management

B: Edit

C: Tool

D: Help

E: Wi-Fi icon of wireless scanning device

F: Name of the connected WLAN (for wireless scanning device software upgrade)

G: Hotspot sign from upper computer

H: Name of the hotspot from upper computer (only visible after the probe gets connected with the PC)

I: Logo of the company

J: Patient data list

K: Ultrasonic image and projection display area

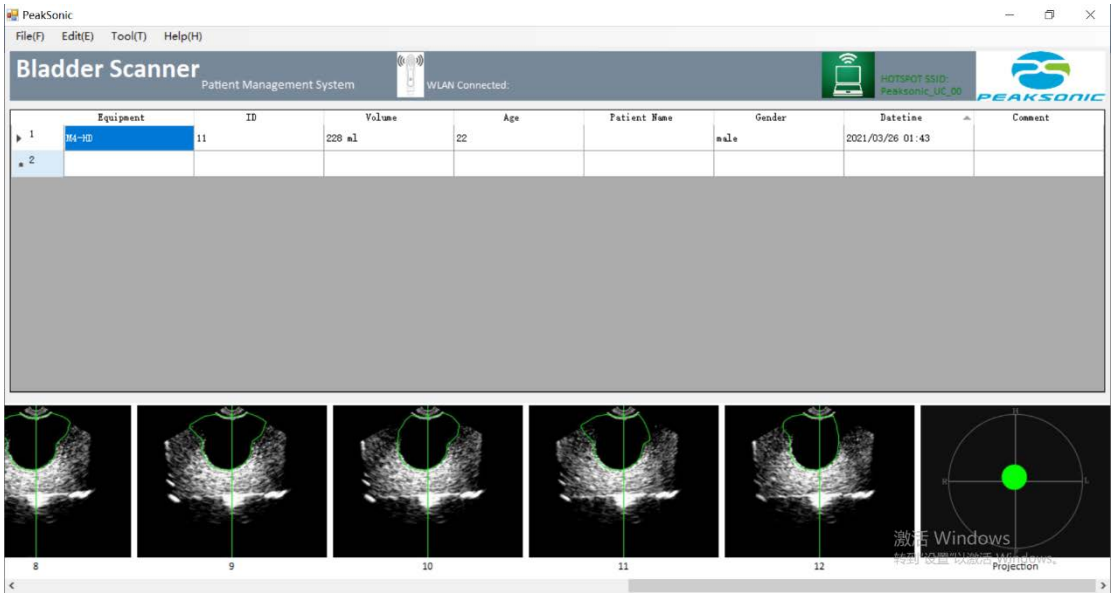


Figure 6-3 Upper computer main interface - bladder ultrasonic images and projection display

Remark: only one bladder ultrasound image is displayed for M3 or M3 HD. No projection images are displayed.

6.13.3 Manage file

The sub-menu of File includes six options which are Open, Open Dir, Save, Save as, Print and Exit as shown in Figure 6-4. Use “Open” to export single data. Click “Open”, select one patient information (.json or .data file) and export into upper computer. By using “Open Dir” all data can be exported to the supper computer at once. Use “Save” to save the data in default folder in PID.pdf format. Tap “Save as” to save the data under the name or folder user selects. Press Print to print the selected patient information.

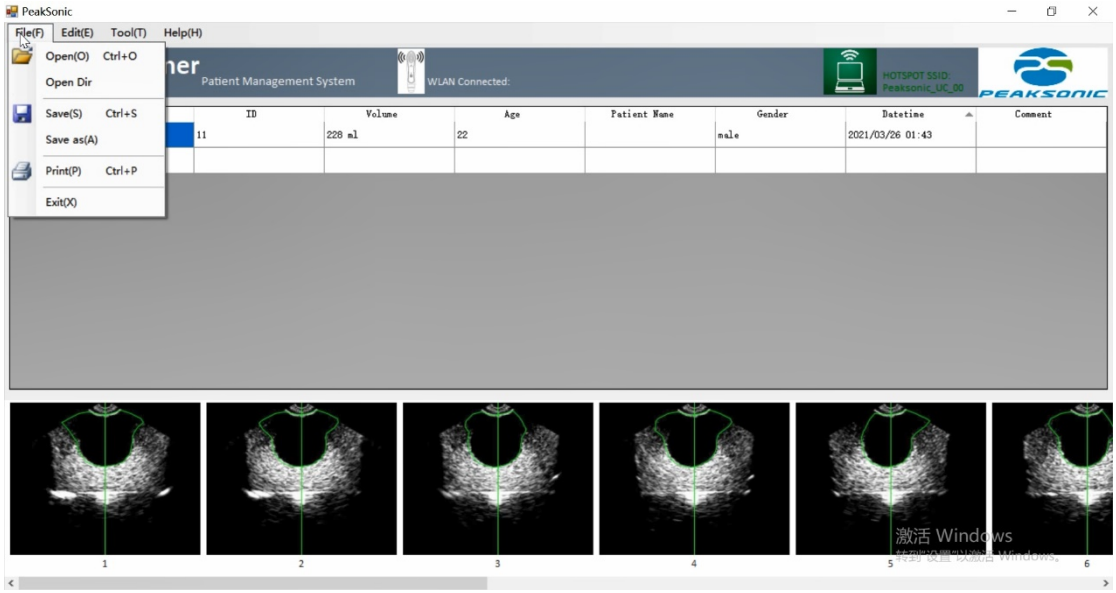


Figure 6-4 File management submenu

6.13.4 Edit

The three options from the sub-menu of Edit includes Undo, Delete and Delete all as shown in Figure 6-5. By pressing Undo user could restore the last piece of deleted information. Press Delete to remove the selected information. Use Delete all to remove all patient data from the upper computer. Password is required before executing Delete all. Delete all is not restorable. Make sure you really want to delete all information before using it.

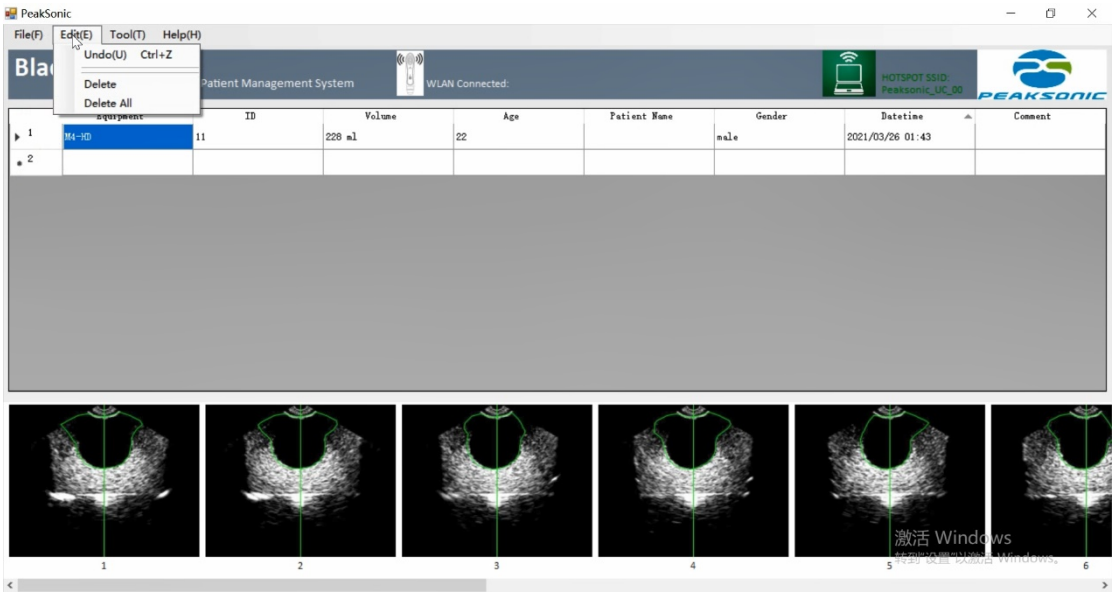


Figure 6-5 Edit submenu

6.13.5 Import data

There is no specified menu item for data import from the scanner to the upper computer. The import is automatically done in the system background.

Data import can be conducted through establishing hotspot for M3,M4 and M5. Switch on hotspot in tablets or phone according to 6.11.6. A data transfer prompt will appear after the connection has been established. After the transfer is successfully completed a dialogue window will show to remind user synchronisation has been conducted successfully. System support data transfer from maximum eight devices to the upper computer simultaneously.

USB cable is another way of data transfer. This approach supports tablets or smartphones with Android system. M5 is supported as well. Switch on USB file transfer mode (MTP mode). Once Android mobile devices are connected with the upper computer all data saved in the mobile devices will be automatically transferred to upper computer. When data transfer is completed, a success prompt will pop up.

When wireless data transfer or automatic USB transfer are interrupted, user can manually import data. Copy the data from Android tablet, smart phone or M5 into the upper computer using USB cable. Press “Open dir” according to 6.11.3. Data will be loaded. Manual data import is not applicable for ISO system.

Steps of automatic USB data transfer:

1. Connect the mobile devices with the upper computer through USB cable
2. Set USB interface as “file transfer” (MTP mode) in Android mobile devices or M5.
3. Run PatientManagerSystem.exe. Data will be automatically imported from the mobile devices to the upper computer. A prompt appears when data import is successfully conducted.

Steps of manual USB data transfer:

1. Connect the mobile devices with the upper computer through USB cable
2. Set USB interface as “file transfer” (MTP mode) in Android mobile devices or M5.
3. Click “This Computer” and search for corresponding disks of Android mobile devices.

Open the disk and look for folder named “cn.com.peaksonic”. Copy this folder into the upper computer.

4. Click “Open dir” referring to 6.11.3 to manually import the data.

6.13.6 Tool

The sub-menu of Tool includes Option, WLAN, Hotspot and Update as shown in Figure 6-6.

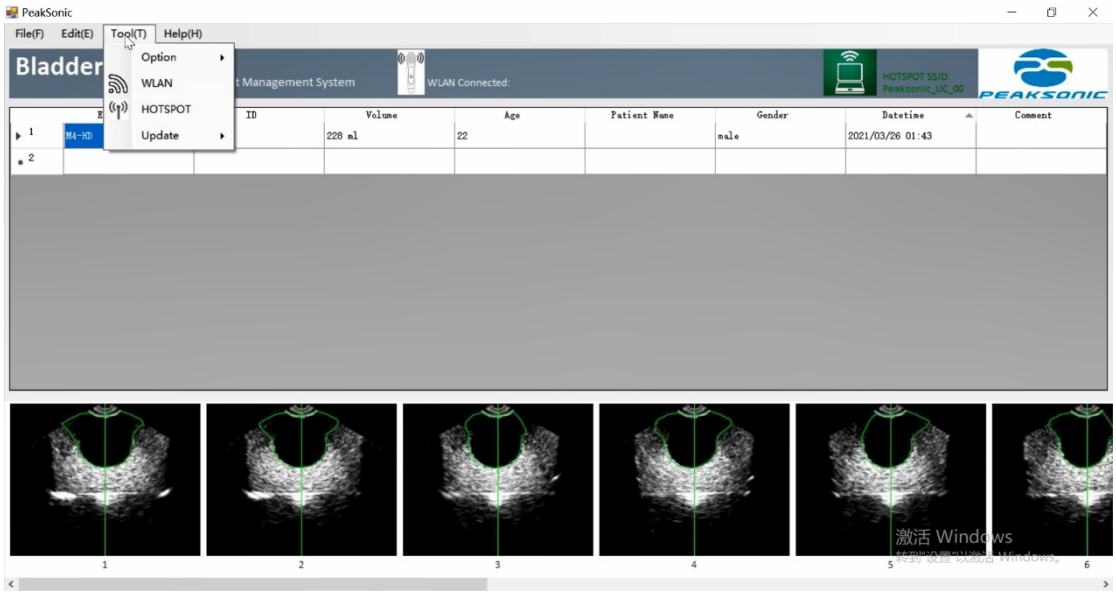


Figure 6-6 Tool submenu

Choose Option -> System Info to pop up dialogue window as shown in Figure 6-7. Enter corresponding information and press Save to save the entered information or Cancel to cancel what has been entered and return to the previous page.

Upper computer option interface as shown in Figure 6-7：

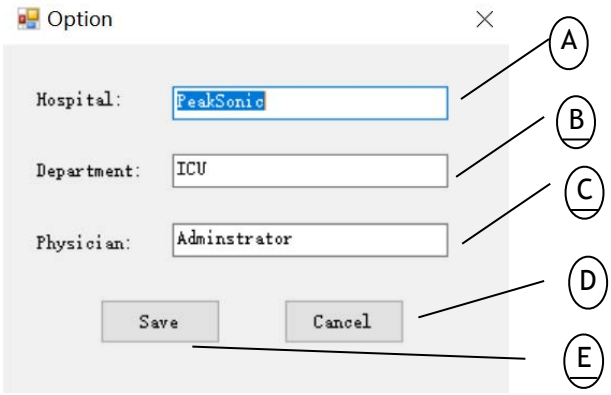


Figure 6-7 Upper computer option interface

A: Hospital name

B: Department

C: Doctor ID

D: Cancel and return

E: Save

Press Option -> Password to enter password modification page. Enter 8-digits old password once and new passwords twice, then press APPLY. A valid password shall contain no less than eight digits which have to be a combination of letters and Arabic numerals. Password modification interface as shown in Figure 6-8:

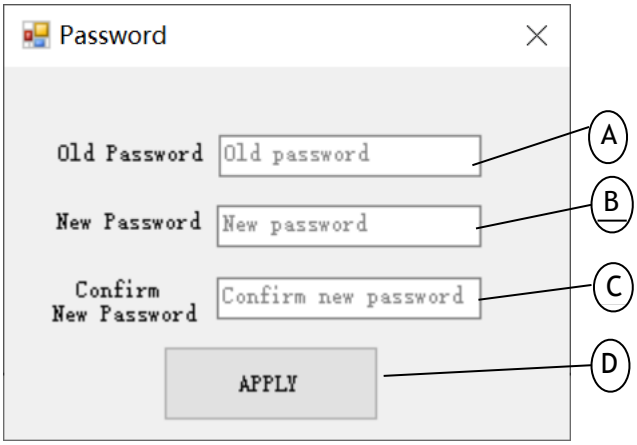


Figure 6-8 Upper computer password modification

A: Enter old password

B: Enter new password

C: Confirm new password

D: Save new password

Press Tool -> WLAN to pop up WLAN option list as shown in Figure 6-9. Press the selected WLAN and enter password as shown in Figure 6-10. Tap OK to get connected. (Remark: for PeakSonic M series it is not needed to enter password to get connected to WLAN. Press Cancel to skip this step.) Name of the connected WLAN will appear behind “Current Connected” and the colour of WLAN icon turns blue. The purpose of this WLAN connection is for internal program upgrade instead of data transfer only. It is not available with M5.

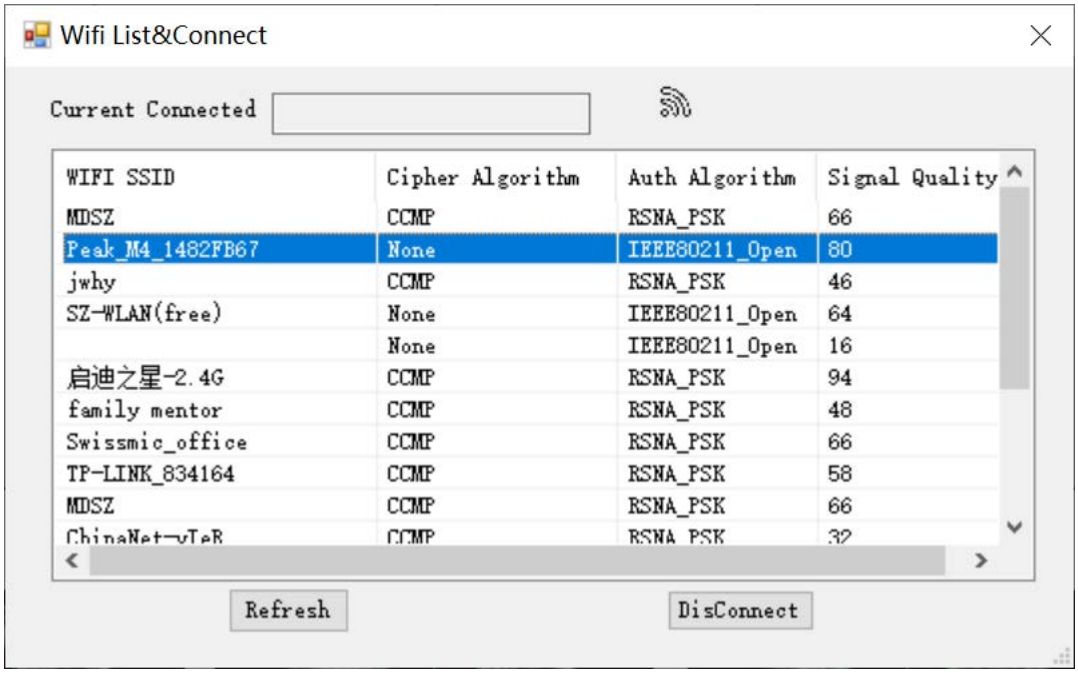


Figure 6-9 WLAN list

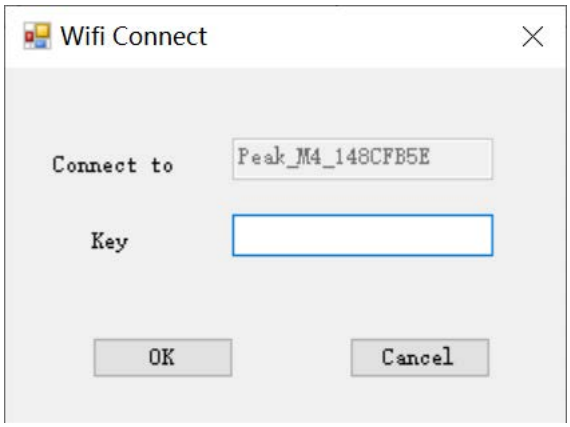


Figure 6-10 Wi-Fi connection prompt

Press Tool -> HOTSPOT to pop up wireless hotspot setting interface as shown in Figure 6-11. Tap Start Hotspot to set it up. After this step the Hotspot icon on the main page turns green and Wi-Fi named Peaksonic_UC_xx can be found. Tap Stop Hotspot to turn it off.

Remark: the name of the hotspot in PeakSonic upper computer has the format as Peaksonic_UC_xx. XX stands for the serial number of the hotspot. It is assigned automatically by the system from 00 to 99. The password to connect to the hotspot is 12345678. It is only available for software version more advanced than Windows 7 with wireless internet card embedded.

After setting up hotspot, data transfer could be conducted accordingly. Double clicking hotspot icon on the main page to turn on/off the hotspot.

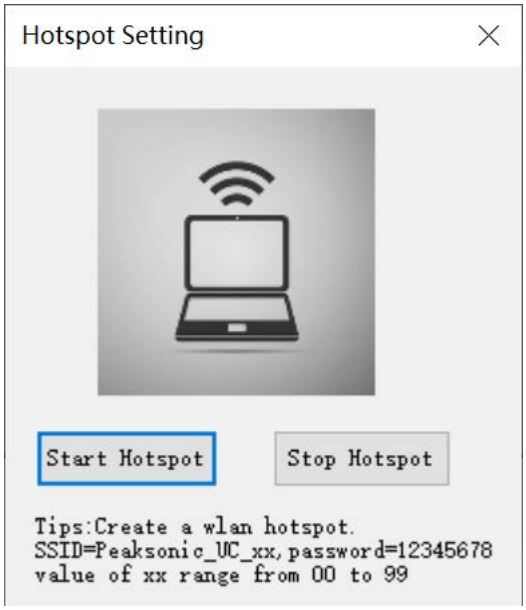


Figure 6-11 Hotspot setup interface

Press Tool -> Update to pop up hardware options as shown in Figure 6-12. Choose the selected hardware and its corresponding data file as shown in Figure 6-13 to enter update data transfer prompt. Meanwhile the power light of the wireless probe will be flashing. Once the upgrade is completed the light will be on. Reboot the wireless probe to refresh the system. Before update, make sure the upper computer is connected to the wireless probe through WLAN.

Figure 6-12 Update submenu

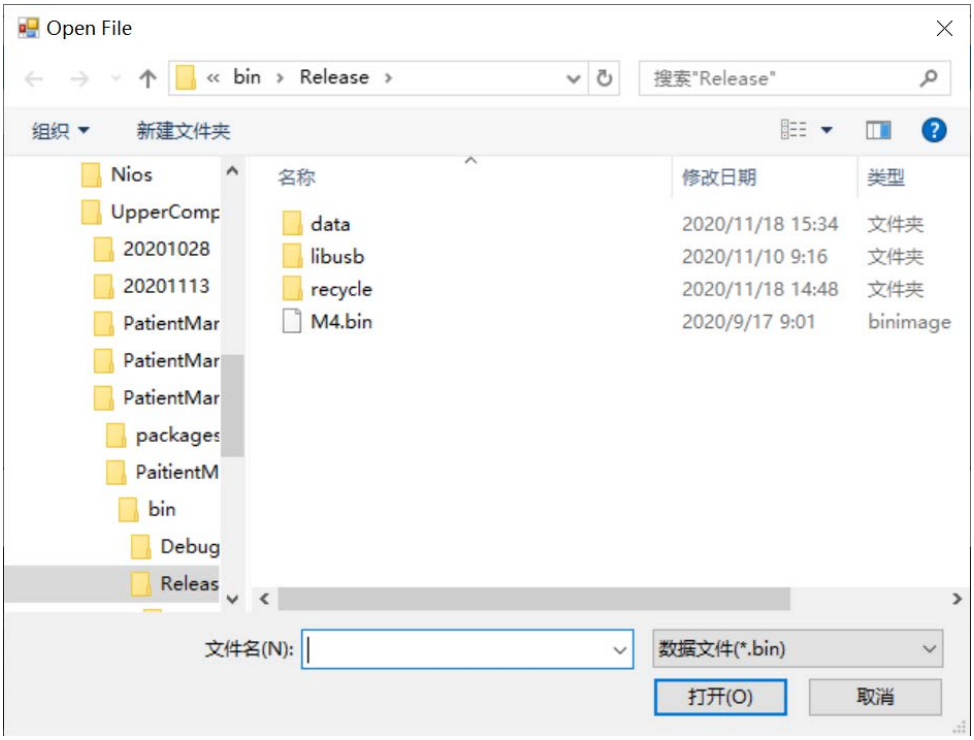


Figure 6-13 Update - choose data file dialogue window

6.13.7 Right click the mouse

Select the target patient information and right click the mouse to pop up menu which contains Save, Print and Delete (Figure 6-14) to execute the corresponding functions. Save and Print are as same as the functions from File. Delete is as same as the one from Edit on the top menu.

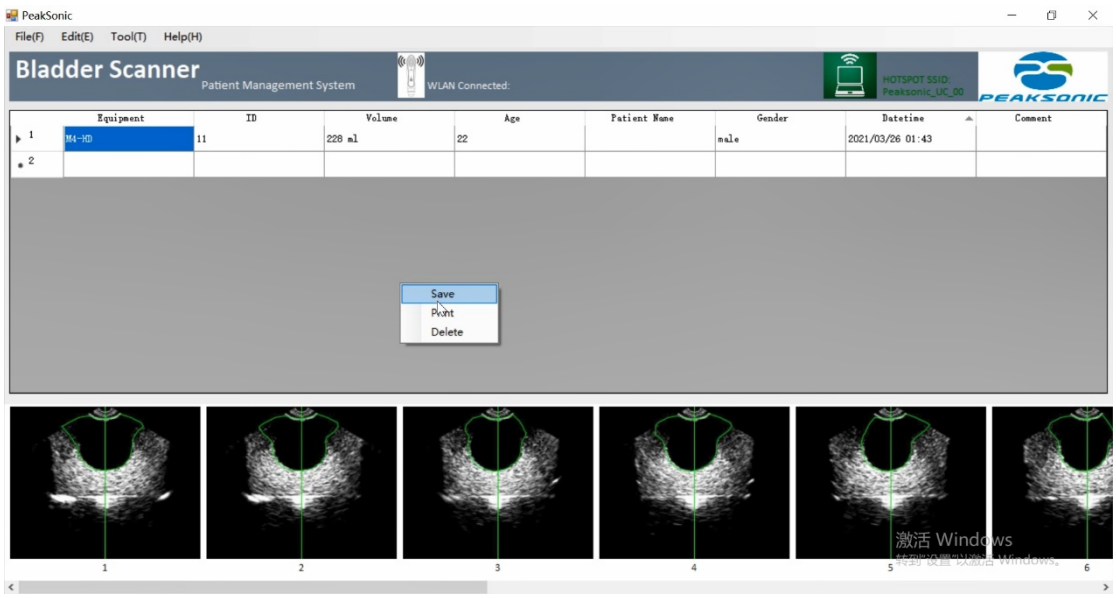


Figure 6-14 Submenu after right clicking the mouse

6.13.8 Print report

Choose the target patient information and right click the mouse and press Print to pop up printing interface. Alternatively press File -> Print for the same result. Printing interface includes drop-down button to display 6 or 12 images, print button, name of the hospital, department, patient information, bladder ultrasonic images and bladder projection. Tap the drop-down button and choose 6 Images to display 6 bladder ultrasonic images (Figure 6-15) and bladder projection. Press Print to print them out. Tap the drop-down button and choose 12 Images to display 12 bladder ultrasonic images (Figure 6-16) and bladder projection. Press Print to print them out. Hospital and department names come from the data saved using Tool - Option - System Info. Patient information and ultrasonic images are from the upper computer main interface.

Upper computer printing interface (6 images) as shown in Figure 6-15:

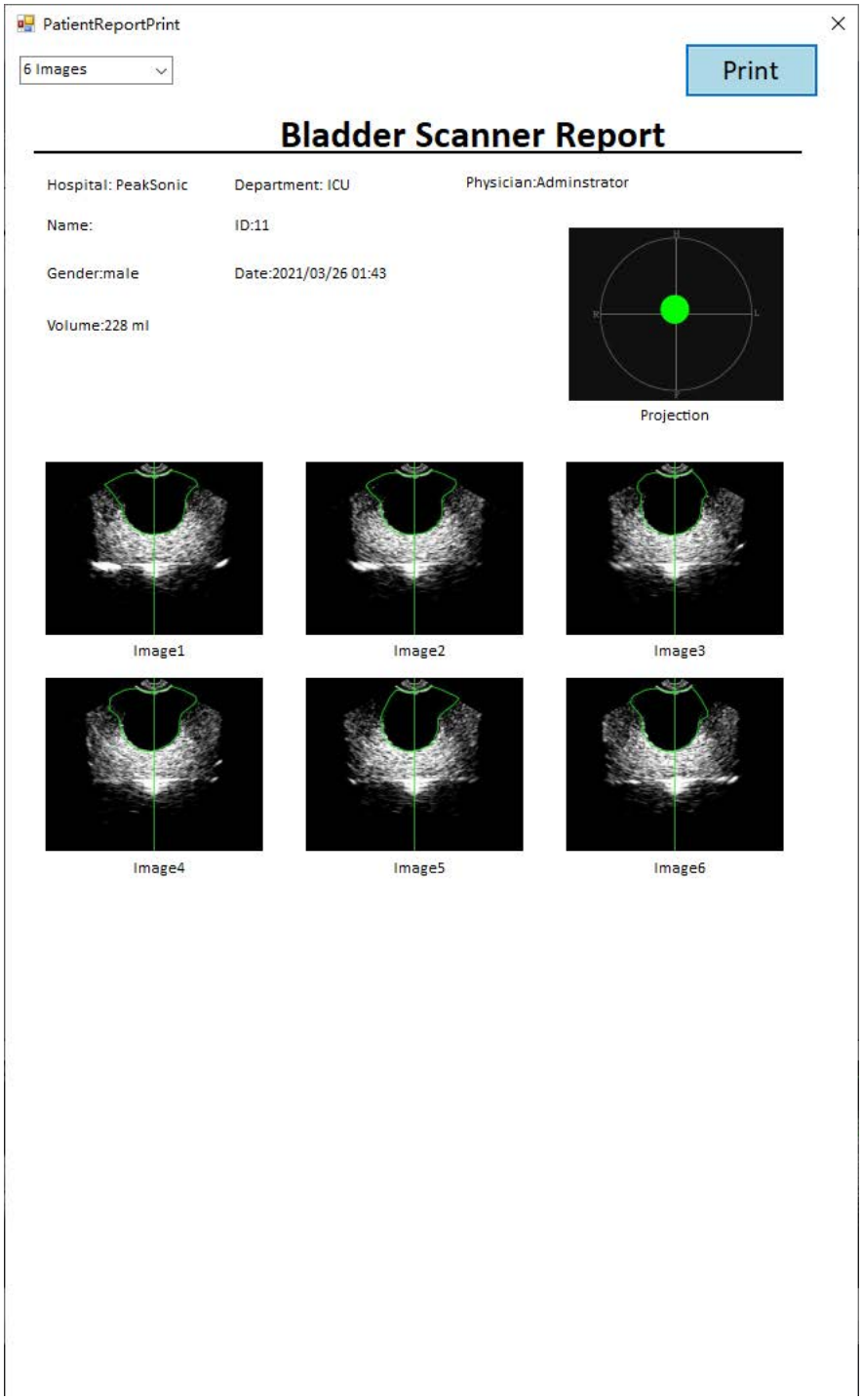


Figure 6-15 Upper computer printing interface (6 images)

Upper computer printing interface (12 images) as shown in Figure 6-16:

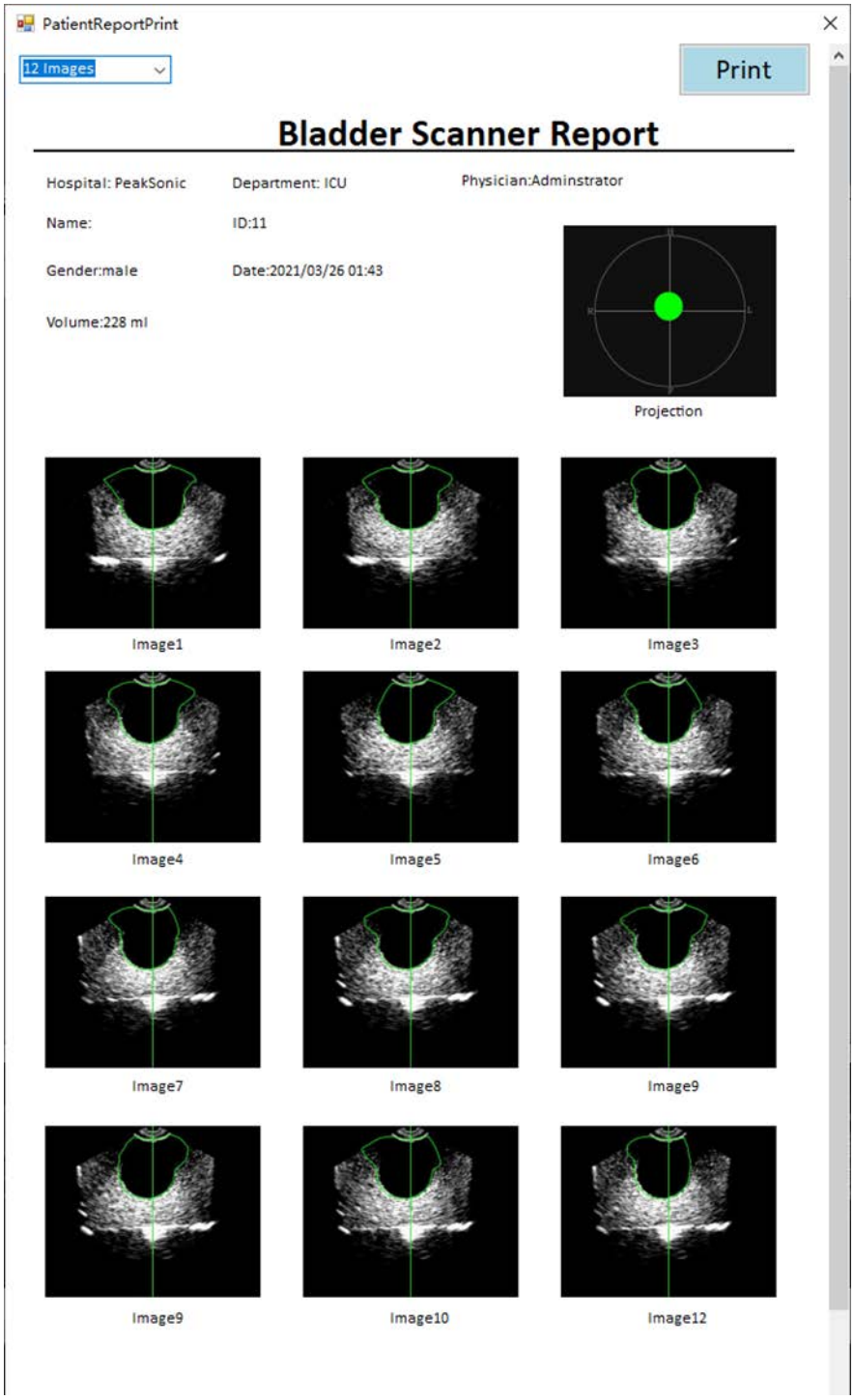


Figure 6-16 Upper computer printing interface (12 images)

Remark: For M3 or M3 HD only one bladder ultrasound image is displayed. No projection images are visible.

6.13.9 Data filter

Start data filter: Double click anywhere on the data sheet as shown in Figure 6-17 to pop up a prompt as shown in Figure 6-18. Choose the category using drop-down menu and enter the information which need to be filtered (Figure 6-19). Press List to filter out the

needed data.

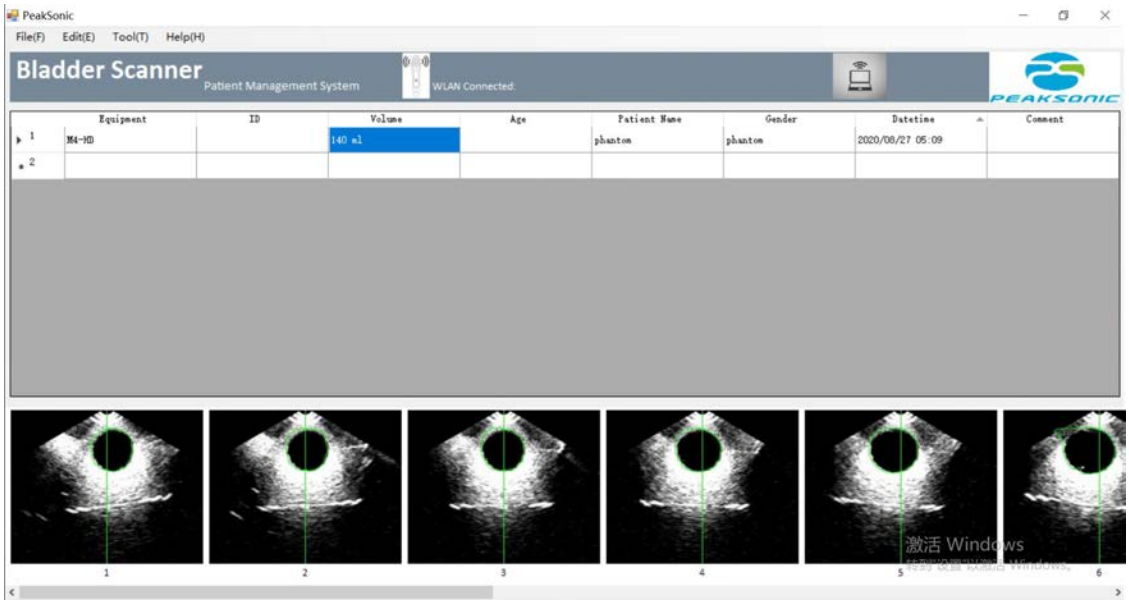


Figure 6-17 double clicking the data sheet

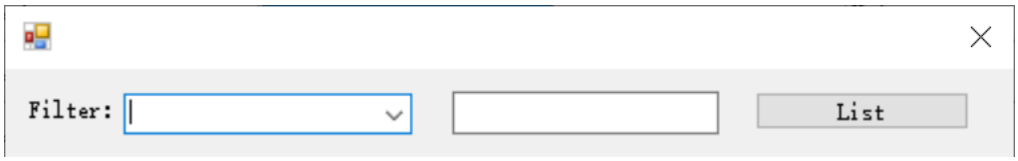


Figure 6-18 Filter interface

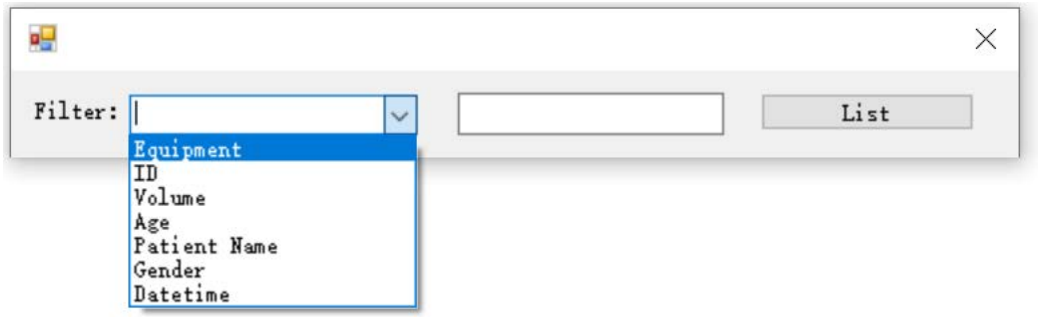
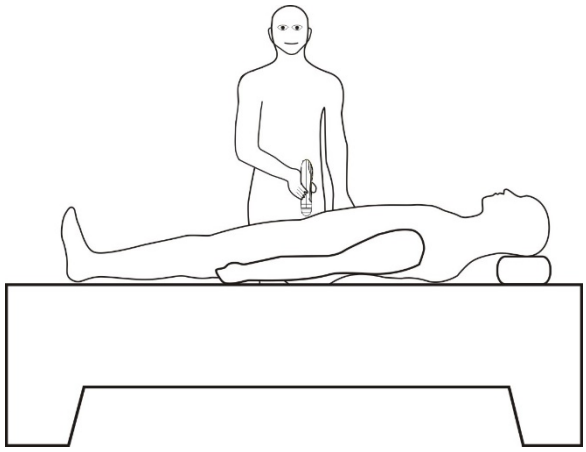


Figure 6-19 Filter drop-down menu

Remove the filtered information: double clicking anywhere on the data sheet to pop up a window as shown in Figure 6-19. Do NOT choose any item in the drop-down menu and clear the content in the box next to it. Press List. Filter is removed and all data will be displayed.

6.14 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 detection, the ultrasonic coupling agent shall be applied to the place 3cm above the pubis of the patient, the instrument shall be placed at the position shown in the figure, and the key of the scanning device of the instrument shall be oriented towards the head of the patient.



Under the expert mode, in order to facilitate the user to quickly locate the bladder, there is a green indicator line in the image center during pre-scanning and scanning. The user only needs to move the probe to center the image and maximize the section area of the bladder B-ultrasound image during pre-scanning. During scanning, just keep the probe still. During pre-scanning and scanning under the easy mode, there is a green indicator line in the center of the circle in the image display area. During pre-scanning, the user only needs to move the center of the bladder section to the center line of the circle and maximize the bladder section area. During scanning, just keep the probe still. Under the intelligence mode, during pre-scanning, the user needs to move the real-time bladder scanning projection to the center of the circle. When the projection is displayed in green, it means that the bladder is in the scanning area; otherwise, it is in orange. During scanning, just keep the probe still.

After scanning under the expert mode, the easy mode and the intelligence mode, there will be a green projection on the main interface. When the center of the green circle and the center of the cross circle do not deviate much, and the projection is green, it indicates that the scanning result is effective. If the projection is orange, the measurement result may have error.

The intelligence mode is to conduct real-time bladder projection positioning before scanning, positioning first and scanning later. The operation mode of positioning first and scanning later is realized. In the process of projection positioning, when the projection is green, it means that the bladder is in the scanning area. If the projection is orange, the measurement result may have error.

Chapter VII Maintenance

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

7.1 Cleaning and Maintenance of the System

7.1.1 Cleaning and disinfection steps

(1) Turn off the system.
(2) Use mild, nearly neutral detergent, ethanol (75%) or isopropanol (70%) to clean equipment (including keyboard).
(3) Control the time of wiping according to the instructions for use of detergent and the interval of wiping shall meet clinical requirements.
(4) Dry the surface of the system or dry it with cleaning cloth according to the method described on the detergent label.
(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 Cleaning and Maintenance of the Probe

Keep the probe clean to ensure that it can operate properly and to extend its 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 PeakSonic Medical Technology 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 examination part 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 window surface of the probe shall be cleaned after being used every time.

7.3 Battery Use and Maintenance

(1) A new battery shall be charged and discharged for twice or 3 times to achieve the best effect.
(2) The battery can be charged and discharged for hundreds of times. When the use time of the battery is obviously shortened, the battery shall be replaced in time.
(3) The use, storage and charging of the battery must be away from fire.
(4) Operations damaging the battery, such as short circuit, dampness, disassembly, falling and impact shall be prevented.
(5) 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.
(6) 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 on scrapped battery.
(7) 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 Disposal of 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 Internet Security

8.1 Data Interface

Connect the scanning device and mobile app through Wi-Fi interface:

The scanning device uses 802.11b/g/n protocol to build wireless LAN. The mobile app connects to the scanning device through the WLAN, and uses TCP / IP protocol for data transmission and communication.

Android app and upper computer:

1. With USB 2.0 interface, data transfer is through USB cable using USB protocol.
2. With Wi-Fi interface, upper computer with wireless network card creates 802.11b/g/n protocol to build up WLAN hotspot. Mobile app connects with the upper computer through WLAN and uses TCP / IP protocol for data transmission and communication.

8.2 Data Storage Format

After compression, the ultrasound images and patient information data are stored in the SQLite database meddo-m3.db/meddo-m4.db of the mobile app. The patient information is stored in the database “patient” table and the bladder images are stored in the “bladder_info” table.

8.3 User Types and Permissions

1. User type: There are two user types. Users without password and users with password. User without password can perform measurements and save information but can neither access history information stored, nor transmit patient information externally. User with password can use all functions of the device and transfer data externally.
2. User access permission: user without password can only perform measurements, view current measurement results and save data. User with password has permission to access all functions of the device.

Chapter IX Transportation and Storage

9.1 Precautions for Handling Instrument

(1) Place the instrument in corresponding place of the packaging box, strictly prevent falling, vibration and collision of the probe or the instrument.
(2) After the packaging box is covered, it can be transported.
Tighten the bottle cap of ultrasonic coupling agent to prevent the gel from flowing out and put it in corresponding place of the packaging box.

9.2 Requirements for Transportation and Storage Environment

Ambient temperature range: -40℃～+55℃

Relative humidity range: 10%～80%

Atmospheric pressure range: 50kpa～106kpa

9.3 Transportation

The marks on the packaging boxes of the instrument shall meet the requirements of GB/T191-2008 *Packaging — Pictorial marking for handling of goods*. The packaging boxes of the instrument are equipped with simple shake proof facilities, suitable for air, railway, road and ship transportation. Avoid rain and snow splashing, inversion and collision.

9.4 Storage

- When the storage period of the instrument is more than 6 months, the

instrument shall be taken out of the packaging box, charged for 4 hours, and then be put into the box according to the direction shown on the package and placed in the warehouse. Do not stack the instrument up, or place it against the floor, walls and roof.

- The interior shall be well ventilated and avoid intense sunlight and corrosive gas erosion.

Chapter X Trouble Shooting

10.1 Inspection

Inspect whether the power supply (battery) is installed.

10.2 Trouble Shooting

Serial No.	Fault phenomenon	Elimination method
1	Press the power button of the scanning device, but the indicator light is not on.	Inspect whether the battery is charged.
2	The key of the scanning device cannot be operated.	Charge the scanning device with the charger and turn it on.
3	The image on the mobile phone has mesh interference and snowflake interference.	1. Inspect whether the instrument battery is normal; 2. Environment inspection for interference of electric field and magnetic field in the surrounding space of the instrument.
4	The mobile phone cannot connect with the scanning device.	Turn off the scanning device and restart it.
5	There are white strips on the printed B-ultrasound image of the patient.	The printer is low in power and needs to be charged.

10.3 After Sales Support

If the fault cannot be eliminated, please contact Suzhou PeakSonic Medical Technology Co.Ltd. at support@peaksonic.com.cn

10.4 Maintenance instructions

The maintenance of the instrument shall be carried out in the unit and department designated by the manufacturer. During maintenance, the maintenance documents of the instrument are needed. And it is necessary to contact the manufacturer.

Appendix A Labels & Other Identification

M4 Labels

Name	Bladder Scanner		
Model	M4	SN	BSI03180001
Safe mode	Type B	Battery	DC7.4V,2400mAH
Input	DC8.4V,1.5A	CE 0197	
FCC ID	2AT6UM4-HD		
Date of Manufacture	2019-03-18	2025-02	
Transducer Model		H3D-1/2.5MHz	

Register Suzhou PeakSonic Medical Technology Co.,Ltd.

Manufacturer: Suzhou Lischka Medtech Co., Ltd.
2F,BuildingG4, Kunshan Hi-Tech Medical Device Industrial Park,NO.999 Qujia Road, Qiandeng Town,Kunshan City, Jiangsu Prov.

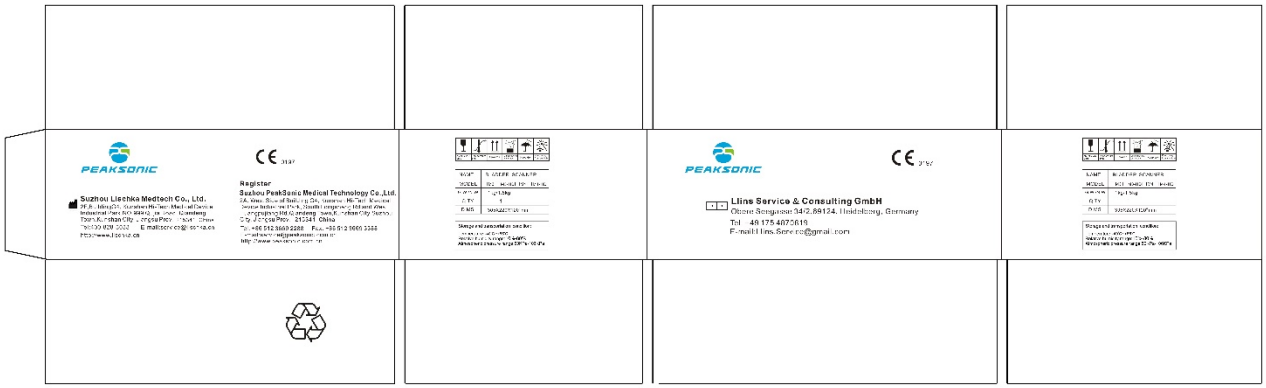
EC REP: Llins Service & Consulting GmbH
Obere Seegasse 34/2,69124, Heidelberg, Germany

Type B Applied Part

consult instructione for use

Collect separately from other household waste

M4 Labels on Outer Package



M4 Labels on Docking Station

Base of Bladder Scanner

Model Name: BASE2

Input: DC8. 4V (internal battery: DC7. 4V, 1000mAH)

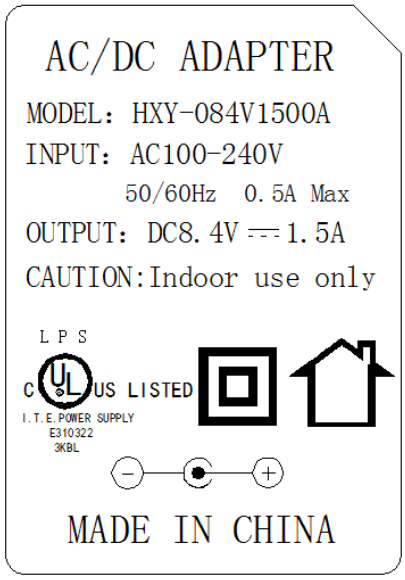
Register Suzhou PeakSonic Medical Technology Co.,Ltd.

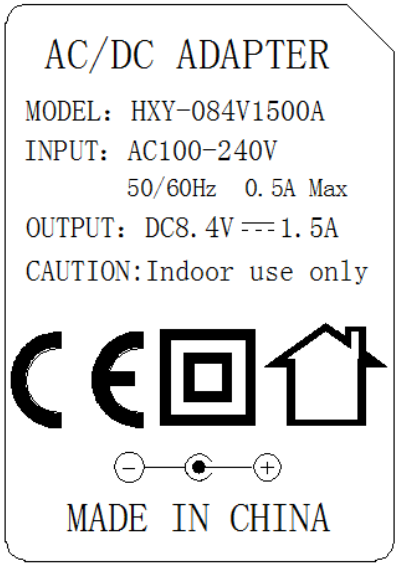
Manufacturer: Suzhou Lischka Medtech Co., Ltd.
2F,BuildingG4, Kunshan Hi-Tech Medical Device Industrial Park,
NO.999 Qujia Road, Qiandeng Town,Kunshan City, Jiangsu Prov.

EC REP: Llins Service & Consulting GmbH
Obere Seegasse 34/2,69124, Heidelberg, Germany
CE 0197

Date of Manufacture 2019-03-18 SN BSI03180001 2025-02

M4 Labels on Charger





Appendix B Ultrasound Output Report

Delta Technology Service (Shenzhen) Co., Ltd.

Acoustic Output Reporting Table for Track 1 (Autoscanning Mode)

System Model: M4-HD SN:BSH12180005
Transducer Model: H3D-1/2.5MHz SN:201810M DR0002
Nominal Frequency:2.5MHz
Operating Mode: B Mode

Acoustic Output			MI	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (W/cm^2)
Global Maximum Value			0.68	17.23	34.90
Associated Acoustic Parameter	$P_{r.3}$ (MPa)		1.00		
	W_0 (mW)			1.76	1.76
	f_c (MHz)		2.16	2.16	2.16
	Z_{sp} (cm)		2.88		2.88
	Beam dimensions	X_{-6} (cm)			0.28
		Y_{-6} (cm)			0.29
	PD (usec)		0.65		0.65
	PRF (Hz)		793.82		793.82
	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 Track 1 (Autoscanning Mode)

System Model: M4-HD SN:BSH12180005
Transducer Model: H3D-1/2.5MHz SN:201810M DR0004
Nominal Frequency:2.5MHz
Operating Mode: B Mode

Acoustic Output			MI	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (W/cm^2)
Global Maximum Value			0.53	10.88	21.88
Associated Acoustic Parameter	$P_{r.3}$ (MPa)		0.78		
	W_0 (mW)			1.73	1.73
	f_c (MHz)		2.13	2.13	2.13
	Z_{sp} (cm)		3.40		3.40
	Beam dimensions	X-6 (cm)			0.34
		Y-6 (cm)			0.33
	PD (usec)		0.63		0.63
	PRF (Hz)		793.82		793.82
	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 Track 1 (Autoscanning Mode)

System Model: M4-HD SN:BSH12180005
Transducer Model: H3D-1/2.5MHz SN:201810M DR0001
Nominal Frequency:2.5MHz
Operating Mode: B Mode

Acoustic Output			MI	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (W/cm^2)
Global Maximum Value			0.50	11.67	21.99
Associated Acoustic Parameter	$P_{r.3}$	(MPa)	0.78		
	W_0	(mW)		1.77	1.77
	f_c	(MHz)	2.42	2.42	2.42
	Z_{sp}	(cm)	3.38		3.38
	Beam dimensions	X_{-6} (cm)			0.32
		Y_{-6} (cm)			0.33
	PD	(usec)	0.66		0.66
	PRF	(Hz)	793.82		793.82
	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

Guideline and statement of the manufacturer-electromagnetic emission		
M4 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	Compliance	Electromagnetic environment-guideline
RF emission GB 4824	1 group	M4 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	M4 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

Guideline and statement of the manufacturer-electromagnetic immunity			
M4 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	IEC60601 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	±1KV line-to-line ±2KV line-to-ground	±1KV line-to-line ±2KV line-to-ground	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 M4 bladder scanner needs continuous operation during power outage, M4 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 M4 bladder scanner away from the power frequency magnetic field source 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 the application of test voltage.			

Table 204

Guideline and statement of the manufacturer-electromagnetic immunity			
M4 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	IEC60601 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 M4 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 Wherein: P— 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 field 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 points 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) telephone and ground mobile radio, 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 field survey shall be considered. If it is measured that the field strength of the place where M4 bladder scanner locates is higher than the above RF compliance level, observe M4 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 M4 bladder scanner.

*In the frequency range of 150kHz to 80MHz, field strength shall be less than 3V/m.

Table 206

Recommended isolation distance between portable and mobile radio-frequency communication equipment and M4 bladder scanner			
M4 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 M4 bladder scanner can prevent electromagnetic interference by maintaining the minimum distance between the portable and mobile radio-frequency communication equipment (transmitter) and M4 bladder scanner.			
Maximum rated output power of the transmitter Output power W	Isolation distances (m) corresponding to different frequencies of the transmitter		
	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 the transmitter 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) provided by the transmitter manufacturer. Note 1: At the frequency points 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).

FCC Statement

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.

§ 15.21 Information to user.

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

§ 15.19 Labelling requirements.

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.

During operation, the separation distance between user and the antenna shall be at least 20cm.

Register by:
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Version No.: M4-V2.0

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Attachment

Automatic calibration:

PeakSonic M-series bladder scanner has patented technology in the fields of ultrasound imaging, measurement algorithm and probe. Therefore, the M-series bladder scanner has clinical advantage that it functions without calibration for life. In this regard, we formally state that as long as the bladder scanner and the probe are intact in their life-long clinical application,

1. Users do not need to calibrate the bladder scanner before using it to measure bladder volume for the first time
2. Users do not need to calibrate the bladder scanner during daily operation

If the hospital or any end-user regards the instrument calibration as a fixed operation procedure, they can refer to the following steps for calibration. However, please note that model616ver.2014 bladder scanner calibration phantom caresono is the only applicable calibration phantom model. Since the purchased phantom provided by the supplier is made separately, the consistency cannot be guaranteed. The material of different phantom is slightly different, which will affect the measurement accuracy of the phantom (it will not affect the measurement accuracy of human bladder capacity). Therefore, we carry out automatic calibration for the model616ver.2014 bladder scanner calibration phantom caresono to ensure the result accuracy.

Automatic calibration steps:

Step 1. Go to setting ->project, type password (default password 000000) to enter project interface. Tap automatic calibration to enter the related interface.

Step 2. Press “start” to start the automatic calibration

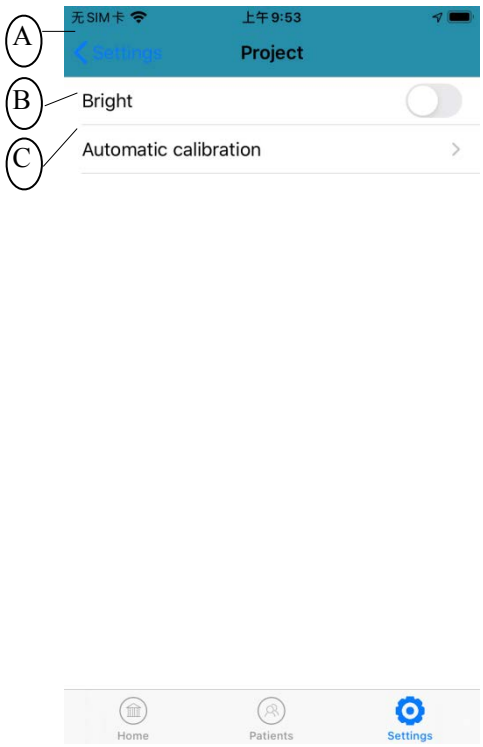
Step 3. During calibration progress bar appears. Wait till it comes to the end.

Step 4. Calibration result appears after it’s finished. Users are informed whether it has succeeded or not.

Tap “project” to return to the previous page.

Remark: automatic calibration can only be conducted when the battery is full.

Project management interface



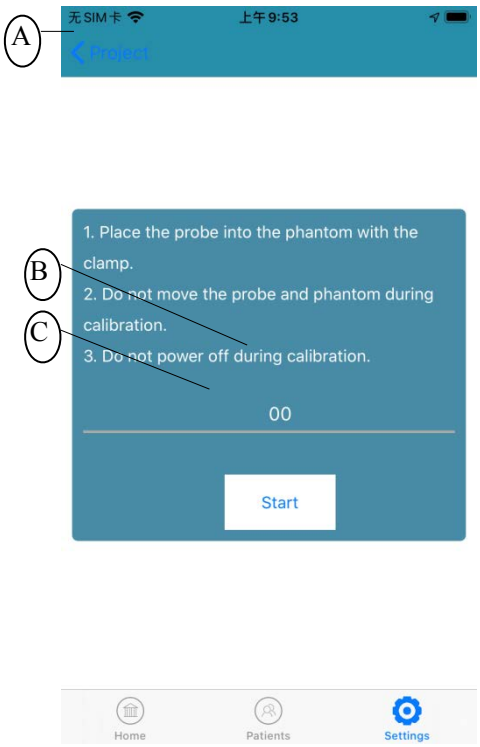
M4 Project management interface

A：Return to setting

B：Option to show brightness

C：Start automatic calibration

Automatic calibration interface



M4 Automatic calibration interface

A: Return to project

B: Calibration progress

C: Start calibration