Bladder Scanner
Model: M4-HD

User Manual

Version: M4-HD_V1.0.0.1

Product standard: XXX/J XXXX-2018

Production license No.: YSYJXSCX No. XXXXXXX

Registration certificate No.: JSYJX (Z) ZI 2014 No. XXXXX

Suzhou PeakSonic Medical Technology Co.Ltd.

Contents

Chapter I Overview

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1.1 Introduction

The M4-HD bladder scanner manufactured by Suzhou PeakSonic Medical Technology 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 tablet computer. 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 tablet computer for operation.

- Multi-language selection.

- 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 molding case and a tablet computer.

- 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 noninvasively. The Bladder Scanner is intended to be used only by qualified medical professionals.

1.3 Executive 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.
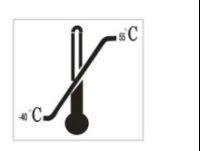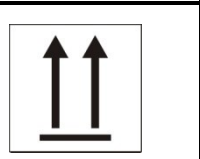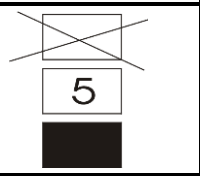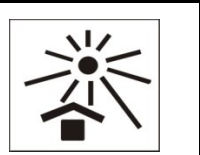
● The environment test of the instrument shall meet the requirements of climate environment test Group II and mechanical environment test Group II of GB/T14710-2009 *The environmental requirements and test methods for medical electrical equipment*.

● 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
FCCID 2AT6UM4-HD	Wireless certification code	**Rx** ONLY	Prescription use only

Description of packing and transportation identification of the instrument:

	Handle with care

	Limit of temperature
	Upward
	Limit number of stacking layer
	Keep dry
	Avoid heat

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-HD equipment will 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 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**

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 Release of heat index and mechanical index

Heat index TIS: <0.042

TIB： ＜0.042

Mechanical index MI: <0.38

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 authorized by relevant medical institution.

2.1 Inspection before operation

(1) The instrument is normal.

(2) 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 preparation 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

(1) 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.

(2) Closely monitor the operation of the instrument and the patient. If the instrument

fails, turn off the power immediately.

(3) The patient is prohibited from touching the instrument or other electric appliances.

(4) The vent of the instrument shall not be closed

2.4 Instructions after operation

(1)   Switch off the power.

(2)   Clean the instrument and the probe.

(3)   Place the instrument on the base.

2.5 Situations shall 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 Relevant matters concerning moving the instrument

(1) Turn off the power supply.

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

2.7 Operations in case of fault

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

2.8 Inspect and maintain the instrument regularly

2.9 Do not disassemble the instrument and probe arbitrarily

2.10 Startup

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

2.11 Poweroff

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 tablet computer to exit the App.

Chapter III System Introduction

3.1 Profile of scanning device
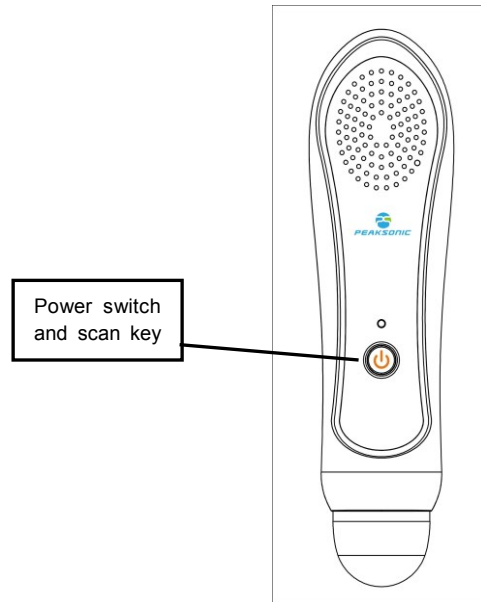
Figure 3-1 Front schematic diagram of M4-HD scanning device

Figure 3-2 Left schematic diagram of M4-HD scanning device

Charging socket
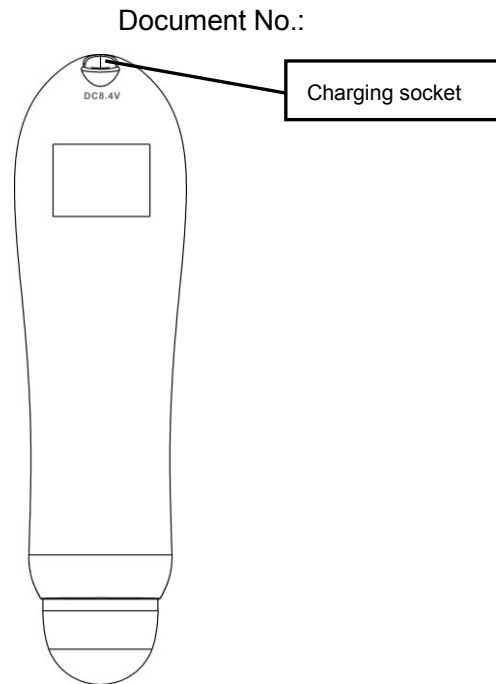
Figure 3-3 Rear schematic diagram of M4-HD scanning device

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 tablet computer

●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 control

●Information management: Call out patient information for viewing (playback of original

database information), storage, printing, deletion and other operations

●Information input: Enter the gender, number, name and age of the patient

●Wifi wireless two-way transmission: The patient information is uploaded to the tablet computer for display, storage and printing. At the same time, a mutual transmission command is needed between the scanning device and the tablet computer.

●System setting: Including (calibration, mode, volume alert, automatic poweroff, interface language, password management, version number view, software update)

●Multi-language selection

●The instrument has three operation modes: Expert mode, easy mode and intelligence mode

●Display screen: Display on the tablet computer

●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 tablet computer.

3.3 Block diagram
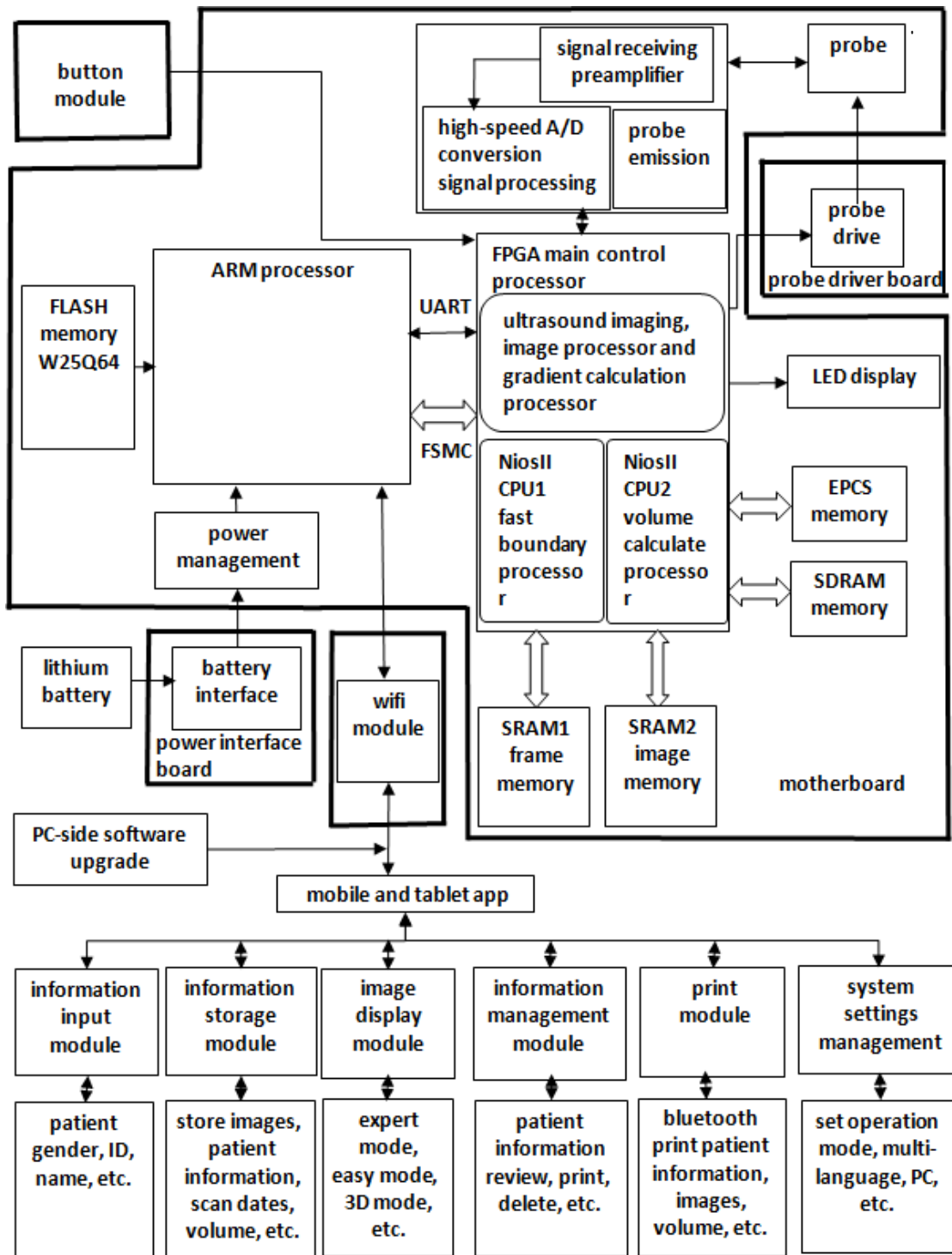
Figure 3-4 Block diagram of electrical principle of M4-HD

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 composition

●Instrument model: M4-HD

●The instrument is composed of a handheld wireless scanning device and a tablet computer (including 3D mechanical sector-scanning probe: 2.5MHZ)

●Software: Version M4-HD_V1.0.0.1

●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

- ●Tablet computer model: Samsung tablet computer A 10.5 SM-T590 10.5" 3GB+32GB WIFI business version

- ●User manual

- ●Lithium battery: model NCA653864SA-2400 mAh (PC015-2S1P) 7.4Vd.c. 2400mAh

- ●Certificate of quality

- ●Warranty certificate

- ●Packing list

- ●Trolley

Instructions: The user can choose the standard tablet computer configured by the company, or configure a tablet computer by itself (the self-configured tablet computer must have CE certificate and FCC certificate)

Chapter IV Instrument Installation

4.1 Unpacking 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

4.2.1Schematic diagram of the base for the scanning device of the instrument
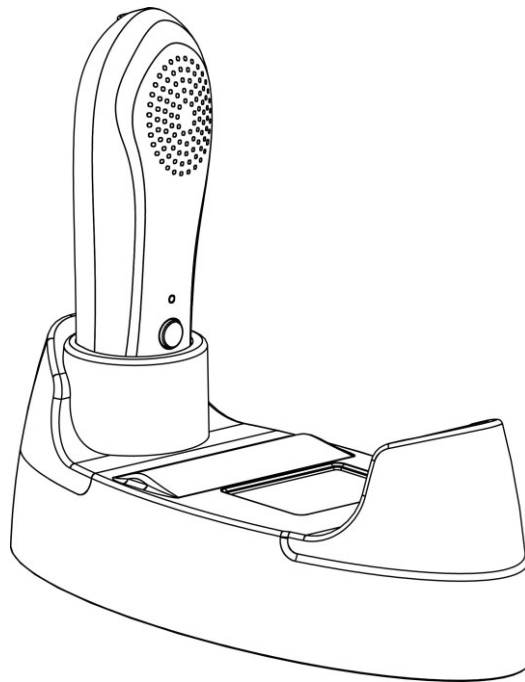
Figure 4-1 Schematic diagram of the base for M4-HD scanning device

4.2.2 Installation and disassembly of Bluetooth printer

Installation of 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.

Disassembly of 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
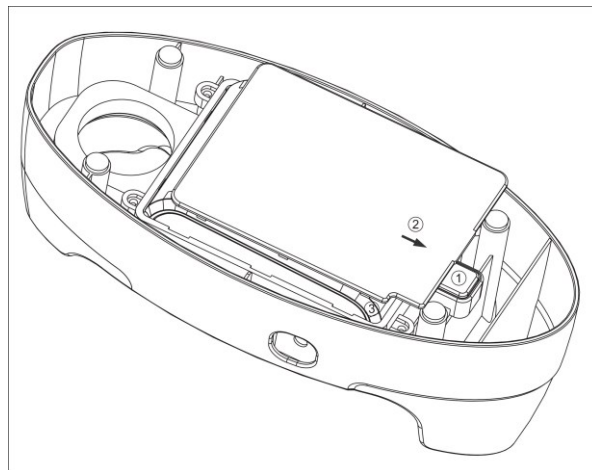
Figure 4-2 Schematic diagram of installation and disassembly of M4-HD printer

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 Battery charging

Host battery is charged through the charger:

(1) Plug the charger output plug into the DC 8.4V round hole socket on the scanning device.

(2) Plug the AC input plug of the charger into the power socket.

(3) 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.

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 AC input plug of the charger into the power socket.

(3) 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 Instrument Interface

5.1 Startup interface
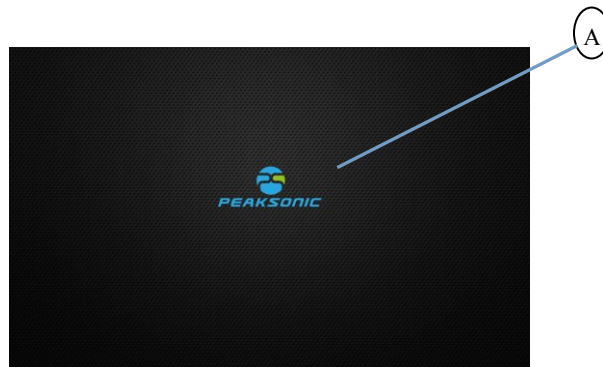
Figure 5-1 M4-HD startup interface

A: Company LOGO and company name

5.2 Main interface of the expert mode
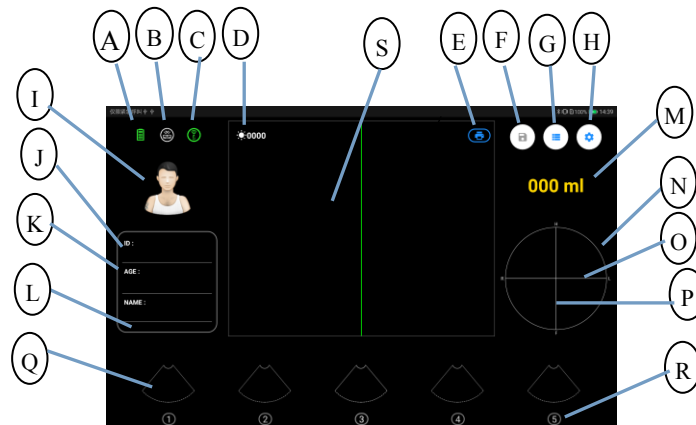
Figure 5-2 Main interface of M4-HD expert mode

A：Battery power display

B: Bluetooth printer connection identification

C: wifi scanning device connection identification

D: Calibration brightness value display

E: Print icon key

F：Save icon key

G: View patient information key

H: System setting key

I: Gender switch icon key

J: ID code input box

K：Age input box

L:Name input box

M: Current bladder volume value

N: Projection positioning round frame

O: Horizontal line of the cross of the display area of the projection positioning diagram

S: Real-time bladder ultrasound image

P:Vertical line of the cross of the display area of the projection positioning diagram

Q：Frame of 12 scanned ultrasonic images

R: Serial No. of 12 scanned ultrasonic images

display area

5.3 Main interface of the easy mode
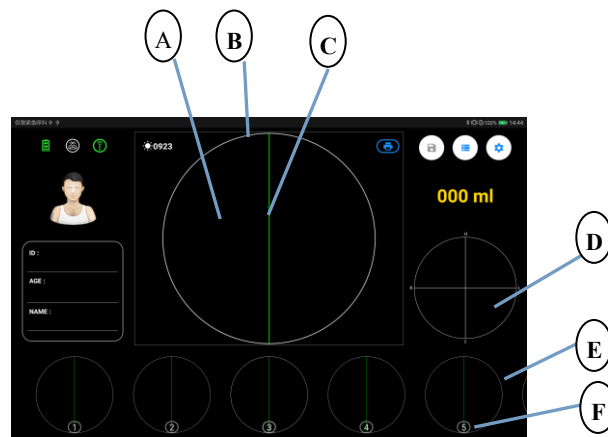
Figure 5-3 Main interface of M4-HD easy mode

A：Display area of the schematic diagram of bladder section

B: Easy round frame

C: Center line of display area of the schematic diagram of bladder section

D: Display area of projection and 3D images

E: Frame of 12 scanned schematic diagrams of bladder section

F: Serial No. of 12 scanned schematic diagrams of bladder section

5.4 Main interface of the intelligence mode
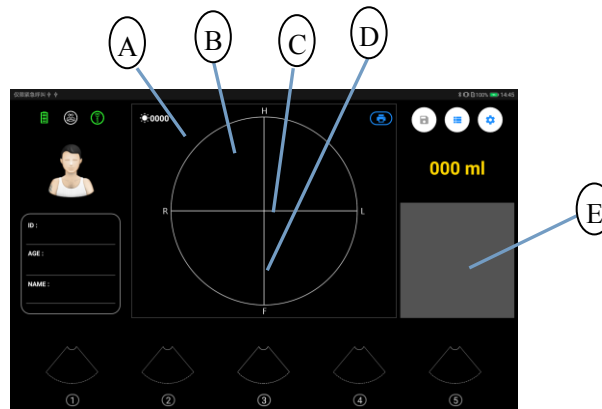
Figure 5-4 Main interface of M4-HD intelligence mode

A: Positioning round frame

B: Display area of the positioning diagram

C: Horizontal line of the cross of the display area of the positioning diagram

D: Vertical line of the cross of the display

area of the positioning diagram

E: Display area of 2D bladder B-ultrasound image

5.5 Scanning under the expert mode

5.5.1 Pre-scanning interface of the expert mode
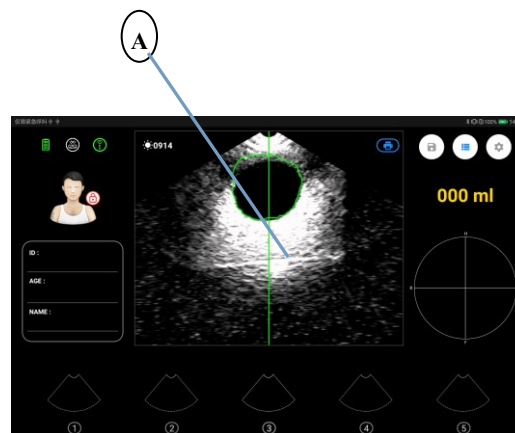
Figure 5-5-1 Pre-scanning interface of M4-HD expert mode

A: Display area of the real-time bladder image

5.5.2 Scanning start interface of the expert mode
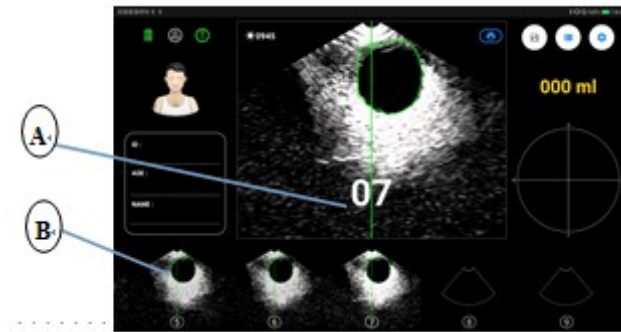
Figure 5-5-2 Scanning start interface of M4-HD expert mode

A: Represent the increase from 01, and when it becomes 12, represent the end of scanning and image analysis and calculation; Display bladder volume value

B: The bladder image will be displayed one by one with the scanning progress, until 12 images are scanned and displayed.

5.5.3 Scanning end interface of the expert mode
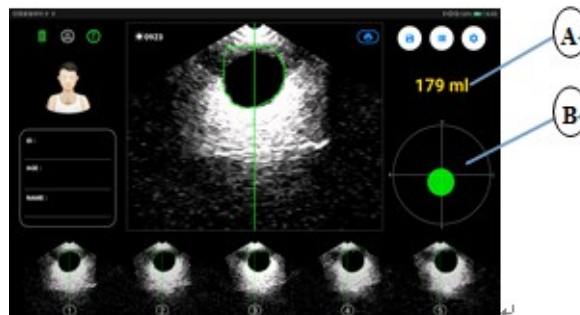
Figure 5-5-3 Scanning end interface of M4-HD expert mode

A: Display the bladder volume after scanning

B: Display the bladder projection after scanning

5.6 Scanning under the easy mode

5.6.1 Pre-scanning interface of the easy mode

Figure 5-6-1 Pre-scanning interface of M4-HD easy mode

A: Bladder scanning section area

5.6.2 Scanning start interface of the easy mode
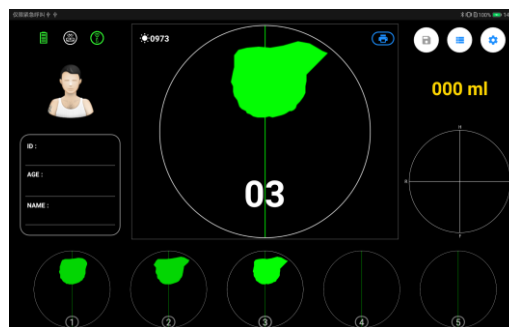
Figure 5-6-2 Scanning start interface of M4-HD easy mode

5.6.3 Scanning end interface of the easy mode
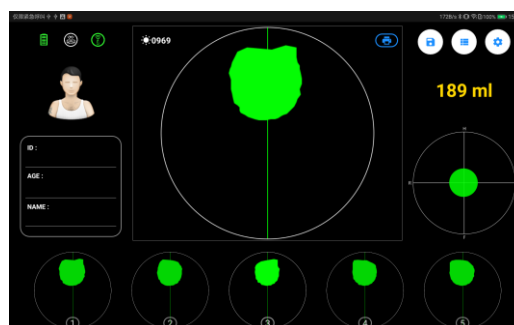
Figure 5-6-3 Scanning end interface of M4-HD easy mode

5.7 Scanning under the intelligence mode

5.7.1 Pre-scanning interface of the intelligence mode
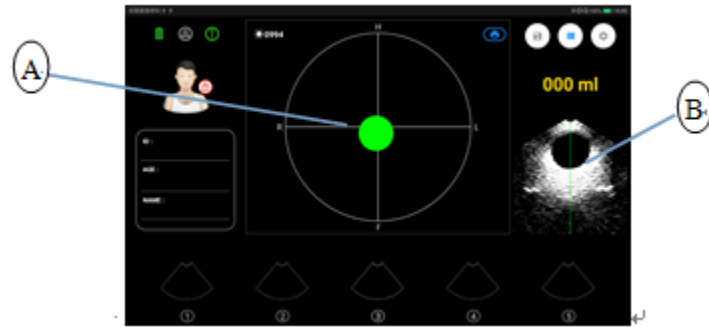
Figure 5-7-1 Pre-scanning interface of M4-HD intelligence mode

A: Real-time projection of bladder scanning

B: 2D B-ultrasound image of bladder

5.7.2 Scanning start interface of the intelligence mode
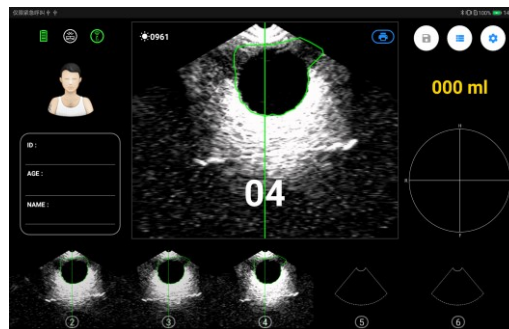
Figure 5-7-2 Scanning start interface of M4-HD intelligence mode

Instructions: The scanning start interface of the intelligence mode is the same with that of the expert mode.

5.7.3 Scanning end interface of the intelligence mode
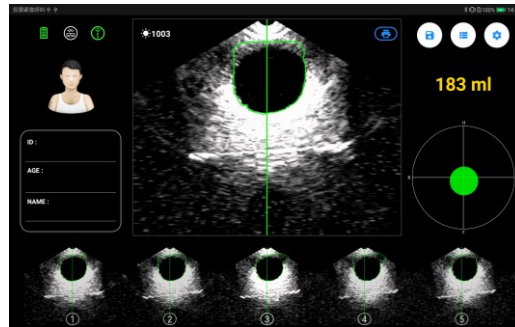
Figure 5-7-3 Scanning end interface of M4-HD intelligence mode

Instructions: The scanning end interface of the intelligence mode is the same with that of the expert mode.

5.8 Bladder projection interface of the expert mode
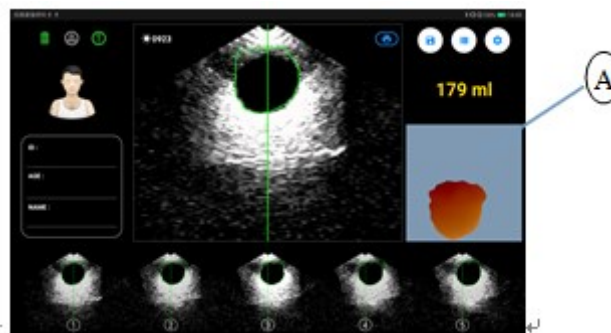
Figure 5-8 Bladder 3D interface of M4-HD expert mode

A: Display of 3D imaging diagram

5.9 Bladder 3D interface of the easy mode

Figure 5-9 Bladder 3D interface of M4-HD easy mode

5.10 Bladder 3D interface of the intelligence mode
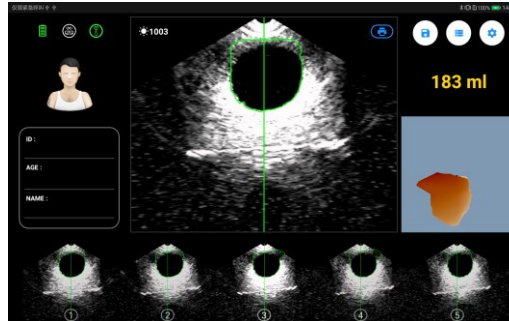
Figure 5-10 Bladder 3D interface of M4-HD intelligence mode

Instructions: The bladder 3D interface of the intelligence mode is the same with that of the expert mode.

5.11 Saved patient information browsing

5.11.1 Patient history information view login interface
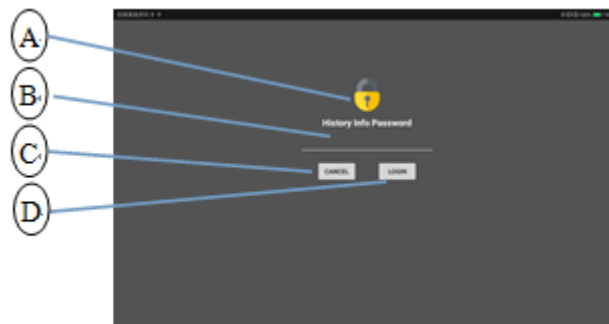
Figure 5-11-1 M4-HD patient history information view login interface

A：Coded lock identification   B：Input field of History Info Password

C：Cancel login and return key   D：Login key

5.11.2 Main interface of patient history information

Figure 5-11-2 Main interface of M4-HD patient history information

A: Total number of saved patient information

B: Saved patient ID code information

C: Saved patient gender information

D: Saved patient age information

E: Saved patient name information

F: Icon key for returning to the main interface

G: Icon key for editing patient information

H: Icon key for deleting the selected patient information

I: Patient information print icon key

J: Enlarged display area of saved patient information image

K: Browsing area of saved patient information, 12 images + 3D model

L：Date and time of saving patient information

M: Saved patient bladder volume value

5.11.3 Editing interface of patient history information
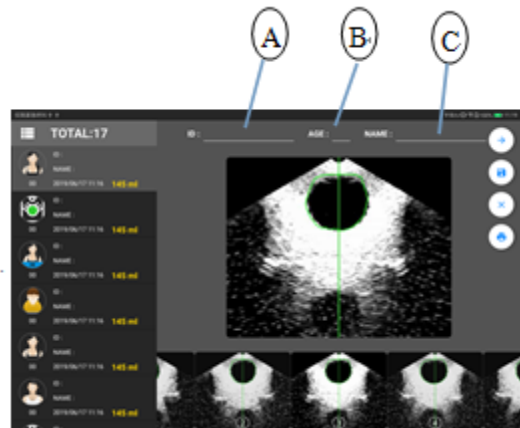
Figure 5-11-3 Editing interface of M4-HD patient history information

A: Edit patient ID code information

B: Edit patient age information

C: Edit patient name information

5.11.4 Interface of patient history information and 3D model
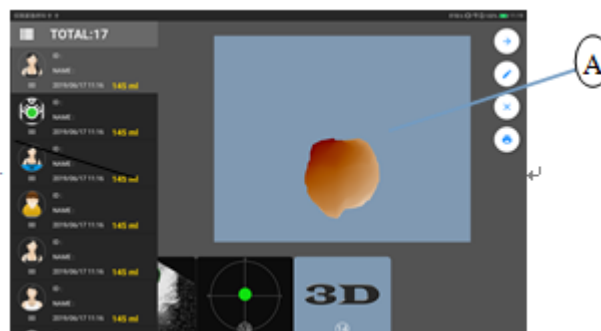
Figure 5-11-4 Interface of M4-HD patient history information and 3D model

A: Enlarged display area of 3D model

5.11.5 Projection interface of patient history information
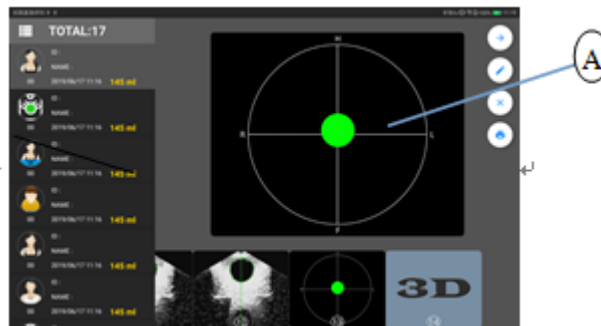
Figure 5-11-5 Projection interface of M4-HD patient history information

A: Enlarged display area of projection

5.11.6 Batch delete and upload selection interface of patient history information
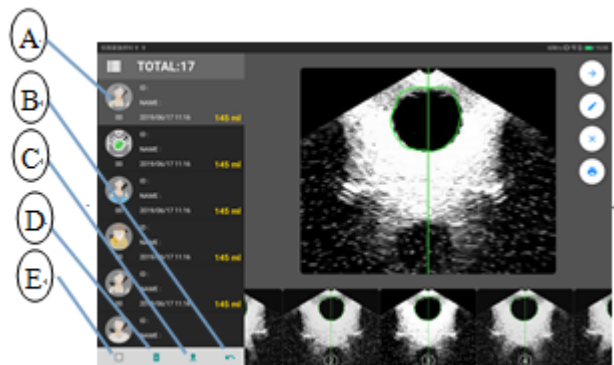
Figure 5-11-6 Batch delete and upload selection interface of M4-HD information

A：The gender box is covered with a translucent white icon

B：Return key

C：Patient information upload key

D：Batch delete patient information key

E: Select all patient information key

5.11.7 Upload login interface of patient history information
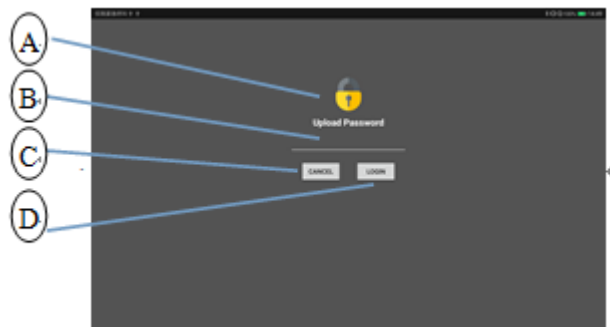
Figure 5-11-7 Upload login interface of M4-HD patient history information

A：Coded lock identification   B：Input field of Upload Password

C：Cancel login and return key   D：Login key

5.11.8 Upload prompt interface of patient history information
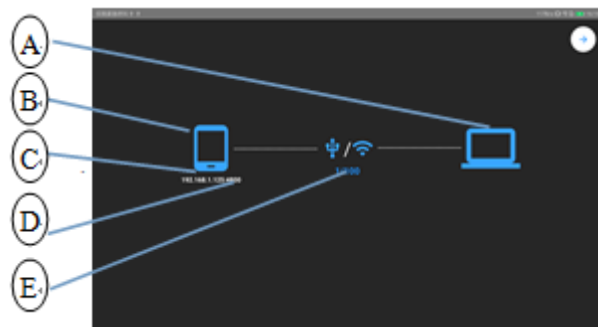
Figure 5-11-8 Upload prompt interface of M4-HD patient history information

A：Host computer identification   D：The last 4 digits of the tablet computer

B：Tablet computer identification   are its port number

C：The first 10 digits of the tablet   E: Upload progress display

computer are its IP address

5.11.9 Single delete confirmation interface of patient history information
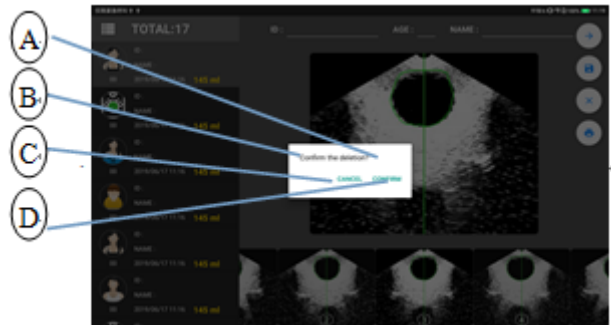
Figure 5-11-9 Single delete confirmation interface of M4-HD patient history information

A：Delete confirmation window

B：Delete confirmation prompt

C：Delete cancellation key

D：Delete confirmation key

5.11.10 Batch delete confirmation interface of patient history information
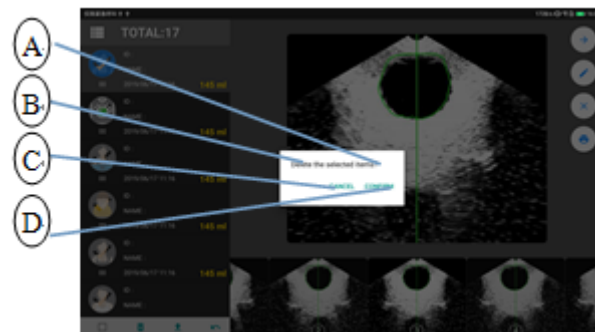
Figure 5-11-10 Batch delete confirmation interface of M4-HD patient history information

A：Delete confirmation window

B：Delete confirmation prompt

C：Delete cancellation key

D：Delete confirmation key

5.12 System setting interface

Figure 5-12 M4-HD system setting interface

A: Mode selection setting

B: Calibration setting

C: Interface language setting

D: Automatic poweroff time setting

E: Volume alert setting

F：Password management

G：System information view

H：Setting interface window prompt

I：View field of setting items

J：Confirmation field of setting items

K:Return to the main interface icon

5.12.1 Operation mode setting interface

Figure 5-12-1 M4-HD operation mode setting interface

A：Select the mode setting item from the setting list

B: Expert mode selection option

C：Easy mode selection option

D: Intelligence mode selection

E: The operation mode is set as the expert mode confirmation item

5.12.2　Calibration setting interface

Figure 5-12-2 M4-HD calibration setting interface

A： Select the calibration item from the setting list

B： Bright Calibrate setting item

C： Auto Calibrate setting item

D: Auto Calibrate setting confirmation light is on in green and off in white.

E: Bright Calibrate setting confirmation light is on in green and off in white

Instructions: The calibration function is not open to users

5.12.3 Interface language setting interface
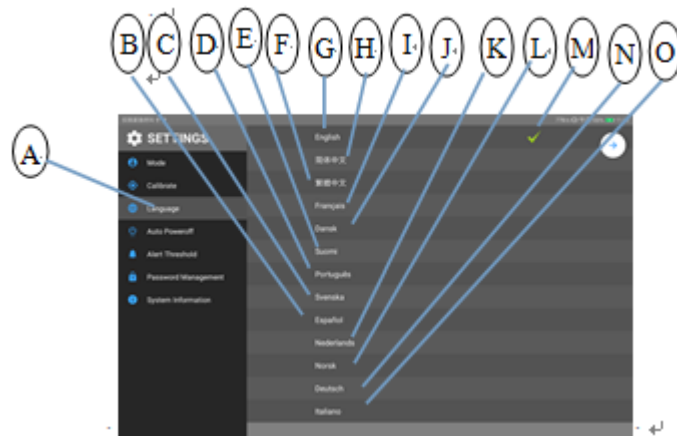
Figure 5-12-3 M4-HD interface language setting interface

A: Select the interface language setting item from the setting list

B: （Español）Spanish

C: （Svenska）Swedish

D: （Português）Portuguese

E: （Suomi）Finnish

F: Traditional Chinese interface language

G: （English）English

H:Simplified Chinese

I: （Français）法语 French

J: （Dansk）Danish

K: （Nederlands）Dutch

L: （Norsk）Norsk

M: Set as English confirmation item

N: （Deutsch）German

O: （Italiano）Italian

5.12.4 Automatic poweroff time setting interface
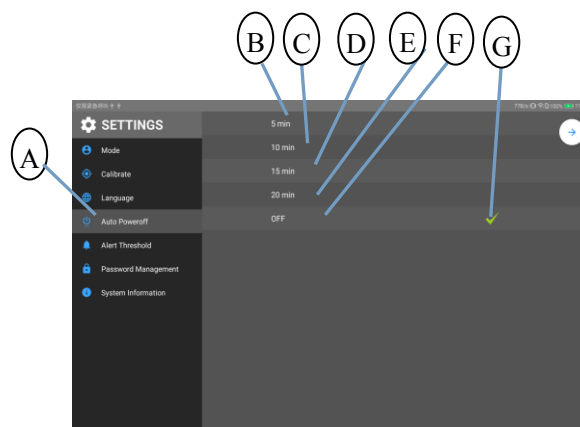
Figure 5-12-4 M4-HD automatic poweroff time setting interface

A ： Select the automatic poweroff setting item from the setting list

B: Select 5min poweroff

C: Select 10min poweroff

D: Select 15min poweroff

E: Select 20min poweroff

F: Turn off automatic poweroff function

G: Automatic poweroff is set as close confirmation item

5.12.5 Volume alert preset setting interface

Figure 5-12-5 M4-HD volume alert preset setting interface

A：Select the volume alert preset setting item from the setting list

B: Volume alert is off

C: Select 200ml

D: Select 250ml

E: Select 300ml

F: Select 350ml

G: Select 400ml

H: Volume alert is preset as close confirmation item

5.12.6 Password management

5.12.6.1 Password management login interface
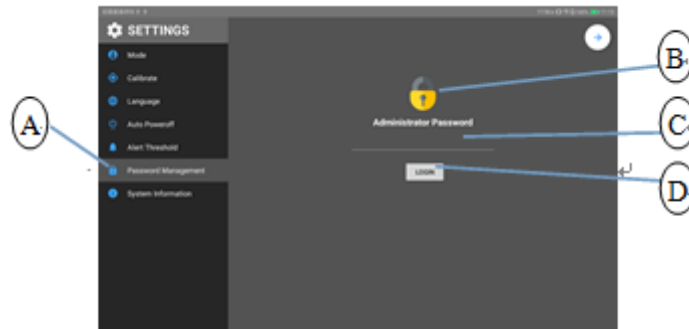
Figure 5-12-6-1 M4-HD password management login interface

A：Select the password management item
from the setting list

B：Coded lock mark

C：Login password management and

password input field

D：Login key

5.12.6.2 Password management interface
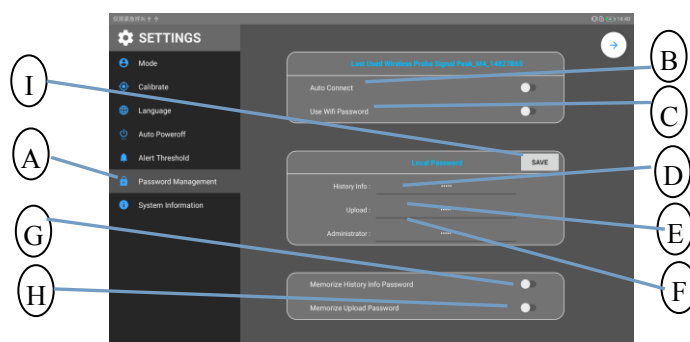
Figure 5-12-6-2 M4-HD password management interface

A：Select the password management
setting item from the setting list

B: wifi Auto/Manual Connect setting

C: Use Wifi Password on/off setting

D:Information view password
management and new password input
field

E:Upload information password

management and new password input field

F:Administrator password management and new password input field

G: Light of Memorize History Info Password

H:Light of Memorize Upload Password

I: Save key (press this key to save the new password)

5.12.6.3 wifi auto connect interface
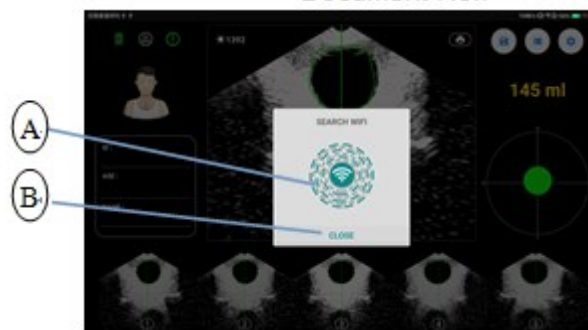
Figure 5-12-6-3 M4-HD wifi auto connect interface

A：wifi auto connect prompt window

B: Auto connect cancel key

5.12.7 System information view interface
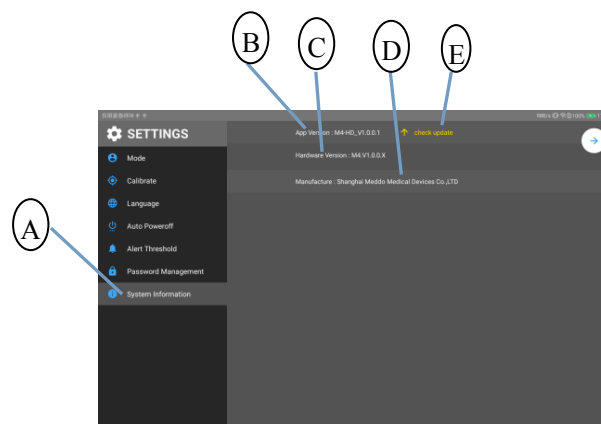
Figure 5-12-7 M4-HD system information view interface

A：Select the system information view item from the setting list

B: Software version No.

C: Hardware version No.

D: Company name

E: Key for entering the software version upgrade interface

5.12.7.1 Software version upgrade interface
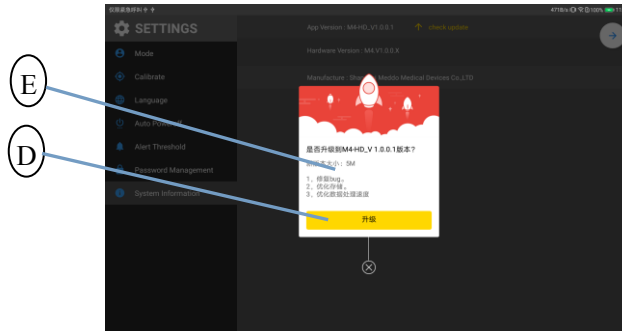
Figure 5-12-7-1 M4-HD software version upgrade interface

A：Software version upgrade window   B：Software version upgrade key

5.13 Printer Bluetooth scanning interface
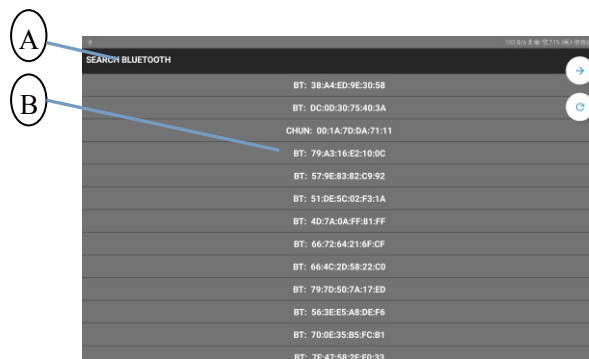
Figure 5-13 M4-HD printer Bluetooth scanning interface

A ： Printer Bluetooth scan prompt   B：Bluetooth model search bar

window

5.14 Bluetooth auto connect interface

Figure 5-14 M4-HD Bluetooth auto connect interface

A：Bluetooth auto connect prompt window

B: Auto connect cancel key

5.15 Battery power identifier
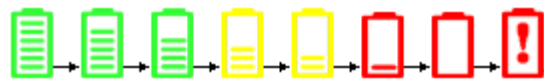
Figure 5-15 M4-HD battery power identifier

Chapter VI Operation Procedures

6.1 Instrument startup and shutdown

Long press the power button of the scanning device to enter the startup state. Click the App icon on the tablet computer to display the startup interface. Stay at the startup interface for about 4 seconds, and then automatically enter the main interface. Long press the power button of the scanning device again to turn off the scanning device. Press the exit button of the tablet computer to exit the App in the tablet computer.

6.2 Wifi connection of tablet computer

There are two wifi connection modes of tablet computer, i.e., Manual Connect and Auto Connect. The first connection is Manual Connect by default when delivery, and no Use Wifi Password is required. First manual connect: Click the wifi connection status white icon at the top of the main interface of the instrument, enter the wifi setting list of the tablet computer, and search for the name of Peak_M4_XXXXXXXX (the last 8 digits are composed of English letters and Arabic numerals and automatically generated by the instrument) to connect the wifi. After successful connection, the wifi connection status icon at the top of the main interface will be displayed as the green icon , indicating that the tablet computer has been connected to the scanning device; If the icon is white, they are not connected.

Note: If the wifi named Peak_M4_XXXXXXXX is not found in the wifi setting list, first turn off the wifi setting list, and then open the wifi setting list to search. Repeat until Peak_M4_XXXXXXXX is found in the wifi setting list.

After the first successful connection, the user can set the status of Auto Connect on (i.e. Auto Connect mode) on the password management interface (Figure 5-12-6-2). After each

startup, the tablet computer and the scanning device will automatically connect. If it is set as Auto Connect off (i.e., the manual connect) on the password management interface, under the manual connect mode, it can be set as Use Wifi Password on (i.e., Use Wifi Password is required for manual connect) on the password management interface. Use Wifi Password shall be entered for connecting the tablet computer and the scanning device after each startup. The original password for wifi connection is: 00000000. If it is set as Use Wifi Password off (i.e., no Use Wifi Password is required for connect) on the password management interface

6.3.1 Gender selection

Click the App icon on the tablet computer to enter the startup interface (Figure 5-1), which will stay for about 4 seconds and then automatically enter the main interface (Figure 5-2). The patient gender is Male ( ) by default. Click area to switch the gender: Male , Female , FemaleH , Child and Phantom .

6.3.2 Bladder pre-scanning

Apply the coupling agent to the contact area between the probe surface of the scanning device of the instrument and the patient, and place the instrument probe on the patient's bladder. Press the scan key, to display the real-time bladder B-ultrasound image (Figure 5-5-1) of the patient or the bladder section diagram (Figure 5-6-1) on the screen of the bladder scanner or display the real-time bladder projection position diagram of the patient while displaying the bladder B-ultrasound image (Figure 5-7-1) of the patient at the bottom right of the display screen, and enter the pre-scanning state.

When selecting the "expert mode", during pre-scanning, the operator can observe the bladder B-ultrasound image of the patient, move the probe to center the image and maximize the area.

When selecting the "easy mode", during pre-scanning, the operator can observe the bladder section of the patient, move the probe to make the center of the bladder section to

the center of the circle, and to maximize the bladder section area.

When selecting the "intelligence mode", during pre-scanning, the operator can observe the real-time bladder scanning projection position of the patient and move the probe to make the real-time bladder scanning projection move 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.

Note:

1. Pre-scanned and scanned images can be viewed on the screen only when the scanning device and tablet computer are wifi connected. The green icon 🛜 will be displayed at the top left of the main interface representing that the tablet computer and the scanning device are connected when the scanning device and tablet computer are wifi connected. If the icon is white, they are not connected.

2. When pre-scanning, the gender selection is locked, the operation cannot be performed, and the save and setting functions cannot be operated (the setting function icon changes from blue to gray). When the pre-scanning is completed, the gender lock function is unlocked, the setting function is restored, and the save function is restored after scanning.

3. The save and setting functions can be operated when the icon is blue and cannot be operated when the icon is grey.

6.3.3 Bladder scanning

After determining the location of the bladder, it is important to keep the probe still, and then press the scan key of the M4-HD scanning device to enter the scanning stage of the three-dimensional probe.

6.3.3.1 Bladder scanning under the expert mode

For the bladder scanning under the intelligence mode, the image display area at the top of the screen displays 12 real-time B-ultrasound images of the patient's bladder successively. The serial number in the lower middle of the image display area increases

from 01. When the serial number is 12, the scanning, image analysis and calculation are completed, and the image display area will automatically jump to the first scanned image. At the same time, the right side of the screen displays the 3D projection of the bladder and the current bladder volume value. The 12 scanned images are displayed at the bottom of the screen. Under the expert mode, the scanning start interface is as shown in Figure 5-5-2 and the scanning end interface is as shown in Figure 5-5-3.

6.3.3.2 Bladder scanning under the easy mode

For the bladder scanning under the easy mode, the image display area at the top of the screen displays 12 bladder section diagrams of the patient successively. The serial number in the lower middle of the image display area increases from 01. When the serial number is 12, the scanning, image analysis and calculation are completed, and the image display area will automatically jump to the first scanned bladder section diagram. At the same time, the right side of the screen displays the 3D projection of the bladder and the current bladder volume value. 12 scanned bladder section diagrams are displayed at the bottom of the screen. Under the easy mode, the scanning start interface is as shown in Figure 5-6-2 and the scanning end interface is as shown in Figure 5-6-3.

6.3.3.3 Bladder scanning under the intelligence mode

For the bladder scanning under the intelligence mode, the image display area at the top of the screen displays 12 real-time B-ultrasound images of the patient's bladder successively. The serial number in the lower middle of the image display area increases from 01. When the serial number is 12, the scanning, image analysis and calculation are completed, and the image display area will automatically jump to the first scanned image. At the same time, the right side of the screen displays the 3D projection of the bladder and the current bladder volume value. The 12 scanned images are displayed at the bottom of the screen. Under the intelligence mode, the scanning start interface is as shown in Figure 5-7-2 and the scanning end interface is as shown in Figure 5-7-3.

Instructions: The bladder scanning under the intelligence mode is the same with the

bladder scanning treatment under the expert mode.

6.4 View ultrasound image of bladder scanning or section diagram, projection and 3D image

After the bladder scanning, it will automatically jump to the main scanning end interface: The main interface after the scanning under the expert mode (Figure 5-5-3); The main interface after the scanning under the easy mode (Figure 5-6-3); The main interface after the scanning under the intelligence mode (Figure 5-7-3); The first scanned image (or the section area) and the current bladder volume image are displayed in the image display area of the main interface. And 12 scanned images +3D images are displayed at the bottom of the screen. The operator can place a finger at the bottom of the screen for displaying 12 scanned images + 3D images, and slide to left and right to view 12 bladder ultrasound images (12 section areas of the scanned bladder) and 3D images respectively. The image scanning projection is displayed in the round frame with a cross in the right middle of the main interface. Click the scanning projection in the round frame to view the 3D images of the bladder (Figures 5-8, 5-9 and 5-10) or click the 3D images of the bladder to view the projection image. The scanning projection interface diagram is shown in the scanning end interface.

When selecting the expert mode or the easy mode, make the projection of the bladder as close to the center of the cross as possible, and ensure that all projection areas are connected to the cross, so as to ensure that the bladder is in the scanning area. When the projection is displayed in green, it means that the bladder is in the scanning area; otherwise, it is in orange.

6.5 Patient information input

On the main interface (Figure 5-2 or Figure 5-3 or Figure 5-4), click the input fields of ID, AGE and NAME to enter corresponding information. Enter the patient ID in the ID input field; Enter the patient age in the AGE input field; Enter the patient name in the Name input field.

6.6 Patient information saving

After entering the patient information in 6.5 (or enter after saving the information), click the save icon on the main interface after the scanning is completed to save patient information. The saved patient information is encrypted. And after saving, a saved prompt message will pop up in the middle of the bottom of the image area. The saved contents are as follows: Patient ID, age, name, gender, storage time and date, bladder urine volume value, 12 B-ultrasound images, 3D images and projection positioning image.

6.7 Printer Bluetooth connection

First printer Bluetooth connection of the instrument: Click the Bluetooth connection status white icon at the top of the main interface of the instrument to enter the printer Bluetooth scanning interface (Figure 5-13), search for the printer Bluetooth device type. After selection, the Bluetooth connection status is green icon , indicating that the tablet computer has connected to the Bluetooth printer and can control to print patient information.

After the first successful search and connection, just press the print key to print the patient information, and the Bluetooth auto connect interface appears (Figure 5-14). After successful connection, the patient information will be printed automatically. Press cancel key on the Bluetooth auto connect interface to cancel Bluetooth auto connect and return to the main interface.

6.8 Patient information printing

After entering the patient information in 6.5 (or enter after saving the information), click the print icon on the main interface after the scanning is completed to print patient information decrypted. And after printing, a print prompt message will pop up in the middle of the bottom of the image area. The printed contents are as follows: Patient ID, age, name, gender, storage time and date, bladder urine volume value and 2 orthogonal B-ultrasound
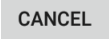
images.

Note: The printing can be conducted only when the Bluetooth printer is connected with the tablet computer. When the Bluetooth printer is connected, the green icon will be displayed at the top of the main interface after scanning, indicating that the tablet computer has been connected to the Bluetooth printer; Otherwise, the icon is white, they are not connected.

6.9 History information browsing

On the main interface (Figure 5-2 or Figure 5-3 or Figure 5-4), pre-scanning interface (Figure 5-5-1 or Figure 5-6-1 or Figure 5-7-1), scanning start interface (Figure 5-5-2 or Figure 5-6-2 or Figure 5-7-2) and the scanning end interface (Figure 5-5-3 or Figure 5-6-3 or Figure 5-7-3), click Patients . Login successfully, and enter the main interface of patient history information. On the main interface of patient history information, there are patient information list, patient information edit key , patient information print key , delete patient information key , patient history picture area, and return to the main interface key . Select certain patient information from the patient information list, click edit key in the main interface of patient history information, enter the editing interface of patient information, respectively click ID, AGE and NAME input fields on the editing interface to input patient information, click save key after inputting to supplement and save information of the patient. After saving, it will automatically return to the main interface of patient history information. On the editing interface of patient information, click print key to print the patient information, or click delete key to delete the patient information.

6.9.1 Patient history information view login

Click Patients to enter the patient history information view login interface (Figure 5-14-1), enter the History Info Password in the login password input filed of the patient history information view login interface: 00000, and click the login key LOGIN to enter the patient history information list interface for browsing information. Press cancel and return key CANCEL to return to the main interface. Note: If entering the correct login password, the coded lock mark is yellow ; if entering the wrong login password, the coded lock mark is red .

6.9.2 Main interface of patient history information

View patient history information. Login successfully, and enter the main interface of patient history information (Figure 5-11-2). On the main interface of patient history information, there are patient information list, patient information edit key , patient information print key , delete patient information key , patient history picture area, and return to the main interface key . Select certain patient information from the patient information list and click the edit key on the main interface of patient history information. Enter the editing interface of patient information. On the main interface of patient history information, select certain patient information from the patient information list to print or delete the patient information.

6.9.3 Editing interface of patient history information

Select certain patient information from the patient information list, click the edit key on the main interface of patient history information, and enter the editing interface of patient history information (Figure 5-11-3). Respectively click ID, AGE and NAME input fields on

the editing interface to input patient information, click save key after inputting to supplement and save information of the patient. After saving, it will automatically return to the main interface of patient history information. On the editing interface of patient history information, select certain patient information from the patient information list to print or delete the patient information.

6.9.4 Delete patient history information

Delete single information: On the main interface or the editing interface of patient history information, touch certain patient information in the patient information list, click delete key to override a prompt box on the main interface or the editing interface of patient history information (i.e., form the delete confirmation interface of single information (Figure 5-11-9) to prompt "Confirm the deletion? ", and press "CONFIRM" to delete the information of the patient. Or press "CANCEL" key to undelete. Click key to return to the main interface or the main interface of patient history information.

Delete batch information: On the main interface or the editing interface of patient history information, long press certain patient information in the patient information list, to enter the delete and upload batch information selection interface (i.e., an operation bar appears at the bottom of the information list on the main interface or the editing interface of patient history information, as shown in Figure 5-11-6). There are four operations in the operation bar of delete and upload batch information selection interface, i.e., select all key , batch delete key , upload key and return key . At the same time, on the delete and upload batch selection information interface, if a translucent white icon covers the gender box of all patients in the information list, it means that it enters the delete and upload batch information selection interface. For deleting the information of the patient, click the gender box of the patient. And several options are allowed. After selection, a translucent blue icon covers the gender box of all patients. Or click the select all key in the operation bar. After select all, a "√" will appear in the

select all key ☐ . At the same time, a translucent blue icon will cover the gender box of all patients. Finally, click the batch delete key 🗑 , a prompt box will appear on the delete and upload batch information selection interface (i.e., form the batch information delete confirmation interface (Figure 5-11-10)) to prompt "Delete the selected items?", and press "CONFIRM" to delete the information of the patient selected. Or press "CANCEL" key to undelete. Click key ⟳ to return to the main interface or the main interface of patient history information.

6.9.5 Upload patient history information

On the main interface or the editing interface of patient history information, long press certain patient information in the patient information list, to enter the delete and upload batch information selection interface (Figure 5-11-6) (i.e., an operation bar appears at the bottom of the information list on the main interface or the editing interface of patient history information). There are four operations in the operation bar ☐ 🗑 ⬆ ↩ of delete and upload batch information selection interface, i.e., select all key ☐ , batch delete key 🗑 , upload key ⬆ and return key ↩ . At the same time, on the delete and upload batch information selection interface, if a translucent white icon covers the gender box of all patients in the information list, it means that it enters the delete and upload batch information selection interface. On the delete and upload batch information selection interface, if it is required to upload the information of the patient, click the gender box of the patient. And several options are allowed. After selection, a translucent blue icon covers the gender box of all patients.

Or click the select all key ☐ in the operation bar. After select all, a "√" will appear in the select all key ☐ . At the same time, a translucent blue icon will cover the gender box of all patients. Finally, click the upload key ⬆ , to pop up the patient history information upload login interface (Figure 5-11-7). Enter the original Upload Password in the login password

input field of the history information upload login interface: 00000, click the login key

LOGIN to enter the upload prompt interface (Figure 5-11-8), prompting that the host computer connects according to the connection IP address (first 10 digits) on the prompt interface and the device port No. (last 4 digits). After successful connection, patient information starts to be uploaded. When uploading, the upload progress display appears in the middle of the upload prompt interface, such as xx/xxx. The first two digits represent the number of patient information transmitted so far, and the last three digits represent the total number of patient information selected for transmission. If the connection between the host computer and the instrument is broken, the instrument keeps the upload prompt interface unchanged, and the host computer reconnects according to the connection IP address on the prompt interface and the device port No. After successful connection, patient information transmission will be continued. After transmission, press the return key ⟳ to return to the main interface of patient history information. Note: If entering the correct password, the coded lock mark is yellow 🔒; if entering the wrong password, the coded lock mark is red 🔒.

6.9.6 Browse scanned images, 3D images and projection positioning images of the bladder

Slide to left and right the patient history image area at the bottom of the main interface or the editing interface of patient history information, to view 12 scanned images of the bladder, 3D images (3D model interface diagram 5-11-4) and projection positioning images (projection interface diagram 5-11-5) one by one. Click one image, to display its enlarged image at the top of the screen.

6.10 Settings

Click settings key ⚙ on the main interface (Figure 5-2 or Figure 5-3 or Figure 5-4) or

the scanning end interface (Figure 5-5-3 or Figure 5-6-3 or Figure 5-7-3), to enter the system setting interface (Figure 5-12). Setting parameters include: Operation mode selection, instrument calibration, interface language, automatic poweroff time, volume alert preset, password management and system information. Click return key 🔁 on the system setting interface to return to the main interface. There are 7 options on the system setting interface, and the functions are as follows:

6.10.1 Mode selection setting

Click the "User Mode" on the system setting interface to enter the operation mode setting interface (Figure 5-12-1). There are three options: Expert mode, easy mode and intelligence mode. It is expert mode by default. After the selection, the "✓" will automatically appear in the setting item confirmation field behind the selected operation mode. Click the return key 🔁, to return to the selected main interface.

When selecting the "expert mode", during pre-scanning, the operator can observe the bladder B-ultrasound image of the patient, move the probe to center the image and maximize the section area of the bladder. During scanning, 12 real-time bladder B-ultrasound images (Figure 5-5-2 and Figure 5-5-3) of the patient will be displayed on the screen. After scanning, the volume value and the scanning projection of the bladder will be displayed on the screen. At this time, click the scanning projection in the round frame to view the 3D image of the bladder. Or click the 3D images of the bladder to view the scanning projection.

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

When selecting the "easy mode", during pre-scanning, the operator can observe the bladder section of the patient, move the probe to make the center of the bladder section to the center line of the circle, and to maximize the bladder section area. During scanning, 12 bladder section diagrams (Figure 5-6-2 and Figure 5-6-3) will be displayed on the screen. After scanning, the volume value and the scanning projection of the bladder will be displayed on the screen. At this time, click the scanning projection in the round frame to

view the 3D image of the bladder. Or click the 3D images of the bladder to view the scanning projection. When the projection is displayed in green, it means that the bladder is in the scanning area; otherwise, it is in orange.

When selecting the "intelligence mode", during pre-scanning, the operator can observe the real-time bladder scanning 3D projection position and move the probe to make the real-time bladder scanning 3D projection move 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. Meanwhile, B-ultrasound image of the bladder is displayed in the projection area of the screen. During scanning, 12 real-time bladder B-ultrasound images (Figure 5-7-2 and Figure 5-7-3) of the patient will be displayed on the screen. After scanning, the volume value and the scanning projection of the bladder will be displayed on the screen. At this time, click the scanning projection in the round frame to view the 3D image of the bladder. Or click the 3D images of the bladder to view the scanning projection.

Note: During screening, the screen display interface of the intelligence mode and that of the expert mode are the same.

6.10.2 Calibration setting

The calibration setting (Figure 5-12-2) is not open to users and is special setting for engineering testing.

6.10.3 Interface language setting

Click the "Language" on the system setting interface to enter interface language setting interface (Figure 5-12-3). The instrument supports the following 13 languages: English, Simplified Chinese, Traditional Chinese, French, Danish, Finnish, Portuguese, Swedish, Spanish, Dutch, Norwegian, Garman and Italian. The default option is English. When the selection is completed, it will automatically return to the system setting interface. After the selection, the "✓" will automatically appear in the setting item confirmation field behind the selected language. Press return key ⟲ to return to the main interface.

6.10.4 Automatic poweroff time setting

Click the "Auto Poweroff" on the system setting interface to enter the automatic poweroff time setting interface (Figure 5-12-4) to switch the automatic poweroff time to "5 min", "10 min", "15 min", "20 min" or "OFF". The default option is "5 min", i.e., the instrument will shut down after 5 minutes automatically. After the selection, the "✓" will automatically appear in the setting item confirmation field behind the selected time. Press return key ⟳ to return to the main interface.

6.10.5 Volume alert preset setting

Click the "Volume Alert Threshold" on the system setting interface to enter the volume alert preset setting interface (Figure 5-12-5), switch the preset bladder volume alert value to "200", "250", " 300", "350", "400" ml or "OFF". The default option is "OFF", i.e., the volume alert is off. After the selection, the "✓" will automatically appear in the setting item confirmation field behind the selected alert preset. Press return key ⟳ to return to the main interface.
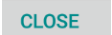
6.10.6 Password management

Click the "Password Management" on the system setting interface to enter the password management login interface (Figure 5-12-6-1), enter the original Administrator Password in the password input field of the password management login interface: 00000, click the login key LOGIN to enter the password management interface (Figure 5-12-6-2), and manage the change of History Info Password, Upload Password, and Administrator Password. On the interface, respectively click the input fields of History Info Password, Upload Password and Administrator Password to enter a new 5-digit password, press save key SAVE after inputting to successfully change corresponding login password. On the

password management interface, the light of Memorize History Info Password is on in green. The system defaults to the login password. Therefore, no login is needed for viewing the patient history information. On the password management interface, the light of Memorize Upload Password is on in green. The system defaults to the login password. Therefore, no login is needed for uploading the patient history information. Note: If entering the correct password management login password, the coded lock mark is yellow 🔓; if entering the wrong login password, the coded lock mark is red 🔒.

In addition, automatic wifi connection can be conducted on the password management interface. For the setting of whether Use wifi Password is required. If Auto Connect is selected on the password management interface, the light of Auto Connect will be on in green. After the instrument is turned on, enter the wifi auto connect interface (Figure 5-12-6-3), to automatically connect the tablet computer and the scanning device. Press cancel key CLOSE on the auto connect interface to cancel automatic wifi connection and return to the main interface. If the Auto Connect on the password management interface is off (i.e., Manual Connect) and the Use Wifi Password is off (i.e., Manual Connect, which doesn't require to enter the password), the connection method is the first manual connection method described in 6.2 tablet computer wifi connection. If the Auto Connect on the password management interface is off and the Use Wifi Password is on (i.e., Manual Connect, which requires to enter the password), i.e., the light of Use Wifi Password is on in green. The specific connection method is as follows: Click the wifi connection status white icon 🛜 at the top of the main interface of the instrument, enter the wifi setting list of the tablet computer, and search for the name of Peak_M4-HD_XXXXXXXX (the last 8 digits are composed of English letters and Arabic numerals and automatically generated by the instrument) to connect the wifi. The original password for wifi connection is: 00000000. After successful connection, the wifi connection status icon at the top of the main interface will be displayed as the green icon 🛜, indicating that the tablet computer has been connected to the scanning device; If the icon is white, they are not connected.

On the password management login interface (Figure 5-12-6-1), if enter the password

"21650", all passwords will be restored to the original password.

6.10.7 System information view

Click the last item "System Info" on the system setting interface to enter the system information view interface (Figure 5-12-7), to show the current App Version: M4-HD_V1.0.0.1. Hardware Version: M4.V1.0.0.X. Company name: Suzhou PeakSonic Medical Technology Co.Ltd. System update prompt box ↑ check update . Click the return key → to return to the main interface of the system.

Note: 1. Click the Version field, the current version No. will not be changed. The clicking operation is invalid to this field. 2. Click the system update prompt box ↑ check update to enter the software version upgrade interface.

6.10.7.1 App upgrade

Click the system update prompt box ↑ check update on the system information view interface, to enter the software version upgrade interface (Figure 5-12-7-1), click the "Upgrade Bar" on this interface to pop up the APP update page, click "Install" on this page for installation of new program. After installation, the program update is successful.

6.11 Host computer transmission and functions

The host computer software provides a PC platform control software, which is used in conjunction with bladder scanner M4-HD. The functions of the host computer software are as follows: Import encrypted patient information data by access to USB memory (including: patient information, bladder ultrasound images and measurement results); Display, export PDF and print the imported information; Manually input, save and display the hospital name, department name and doctor name; The system provides login management and password management functions. Whole-process encryption of patient information.

6.11.1 Login host computer software

Execute the PatientManager.exe to pop up the host computer login interface (Figure 6-1), and enter the original login password (default password 000000). Enter the host computer main interface If entering password "21650", the login password will be restored to the original password 000000.

Host computer login interface is as shown in Figure 6-1:
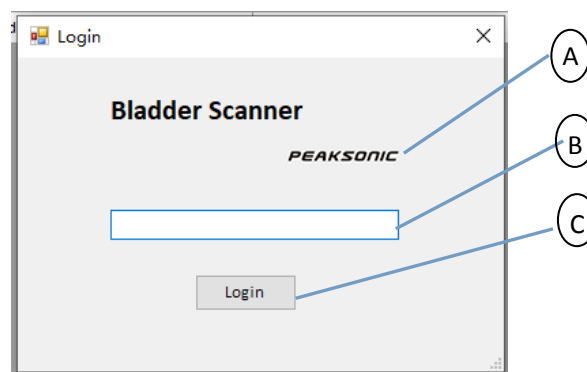
Figure 6-1 M4-HD host computer login interface

A: Company name; B：Input field of login password; C: Login key

6.11.2 Main interface of host computer

There are four menu items, host computer information, company LOGO, patient information and12 bladder ultrasound images on the main interface. Among them, menu items include: Import Data, Print, Save to PDF and Option. The patient information includes: Patient ID, age, gender, scanning time and bladder urine volume value. Select certain patient information and display 12 ultrasonic images of the patient in the image display area (the first 6 images are displayed by default), and display the last 6 ultrasonic images through the scroll bar below the image display area.

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

Figure 6-2 Main interface of M4-HD host computer

A: Import Data; B: Print; C: Save to PDF; D: Option; E: Patient age item; F: Patient gender item; G: Scanning date item; H: Bladder urine volume value item; I: Voice play item; J: Bladder image display area; K: Patient ID item

6.11.3 Import Data

Click the Import Data on the main interface of host computer, to pop up the drop-down menu, including 2 options: From Wifi (wireless import from Wifi) and From Usb (import from Usb cable). Select From Wifi or From Usb, and then select the USB memory directory of the data to complete the import function.

The data import mode selection interface of the host computer is as shown in Figure 6-3:
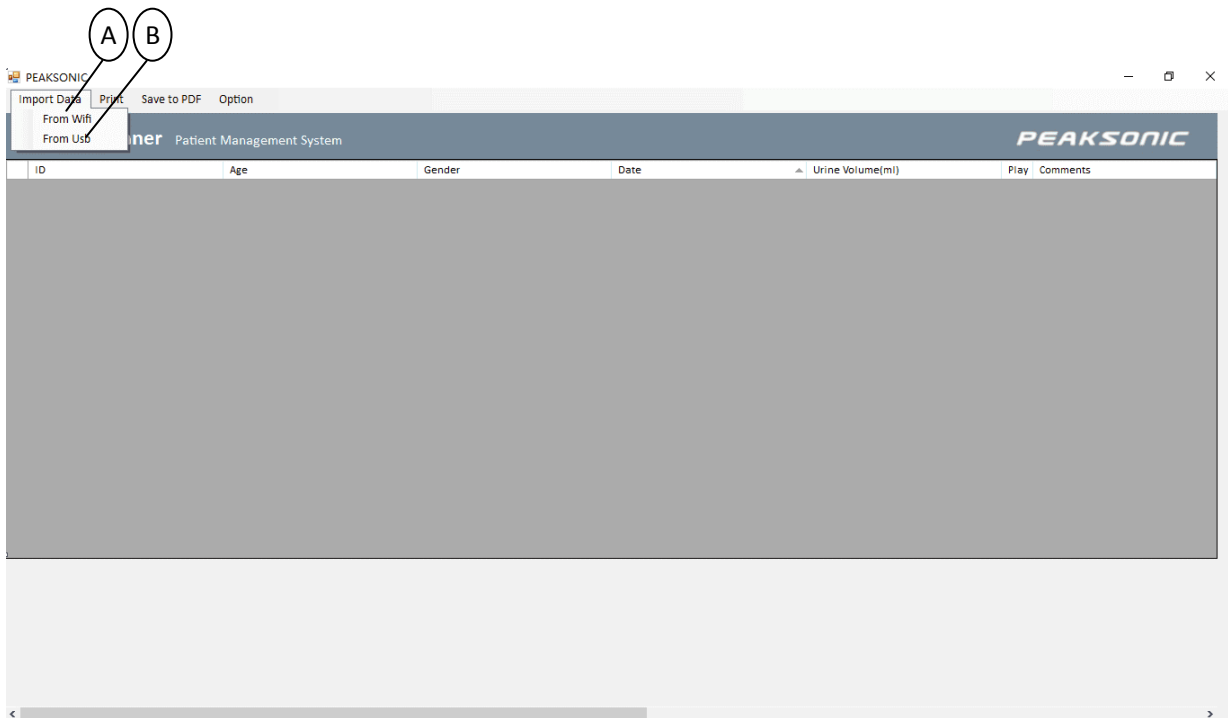
Figure 6-3 Data import mode selection interface of M4-HD host computer

A: Wireless import from Wifi; B: Import from Usb cable

6.11.4 Host computer option interface

Click the Option on the main interface of host computer, to pop up the drop-down menu, select Settings to pop up option interface dialog box and enter corresponding information in the input field, click Save to save and return, or click Cancel to cancel the operation and return.

The host computer option interface is as shown in Figure 6-4:
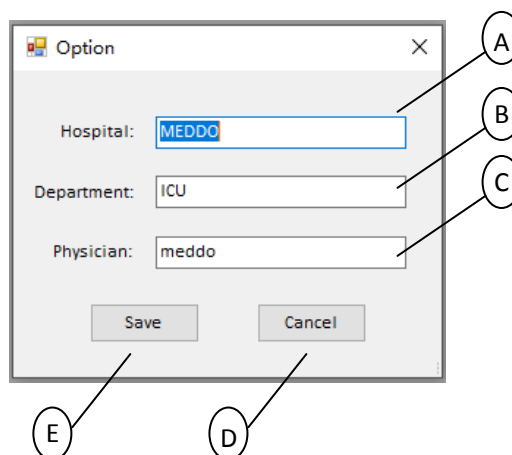
Figure 6-4 M4-HD host computer option interface

A: Input field of hospital name; B: Input field of department name; C: Input field of doctor name; D: Cancel key; E: Save key

6.11.5 Host computer print interface

Click the Print on the main interface of host computer, to pop up the print interface. The print interface includes the following information: Display 6 or 12 image selection box, print key, hospital name, department name, patient information, and bladder ultrasound images. Click the selection box of 6 or 12 Images and select "6 Images" to display 6 bladder ultrasound images on the print interface (Figure 6-5), and click the Print key for printing (the printing contents don't include: Display 6 or 12 image selection box, print key and X key); Select "12 Images" to display 12 bladder ultrasound images (Figure 6-6), and click the Print key for printing (same as above) The source of hospital and department names is the information entered in and saved by the option interface. The source of patient information and bladder ultrasound images is that displayed on the main interface of host computer. 'The host computer print interface (6 images) is as shown in Figure 6-5:

A

6 Images ▾

E   F   B

Print   X

Hospital: AvantSonic   Department: ICU

Bladder Scanner Report

Exam Date: 2011/04/04 15:12:46   Patient ID: Yyttggggg
Patient Name: Yyyyyy   Physician: Lily   C
Patient Gender: M   Urine Volume: 166

D

0.BMP   1.BMP   2.BMP

3.BMP   4.BMP   5.BMP

Figure 6-5 M4-HD host computer print interface (6 images)

A: Display 6 or 12 image selection box; B: Print key; C: Patient information; D: 6 bladder ultrasound images

E: Hospital name; F: Department name

The host computer print interface (12 images) is as shown in Figure 6-6:
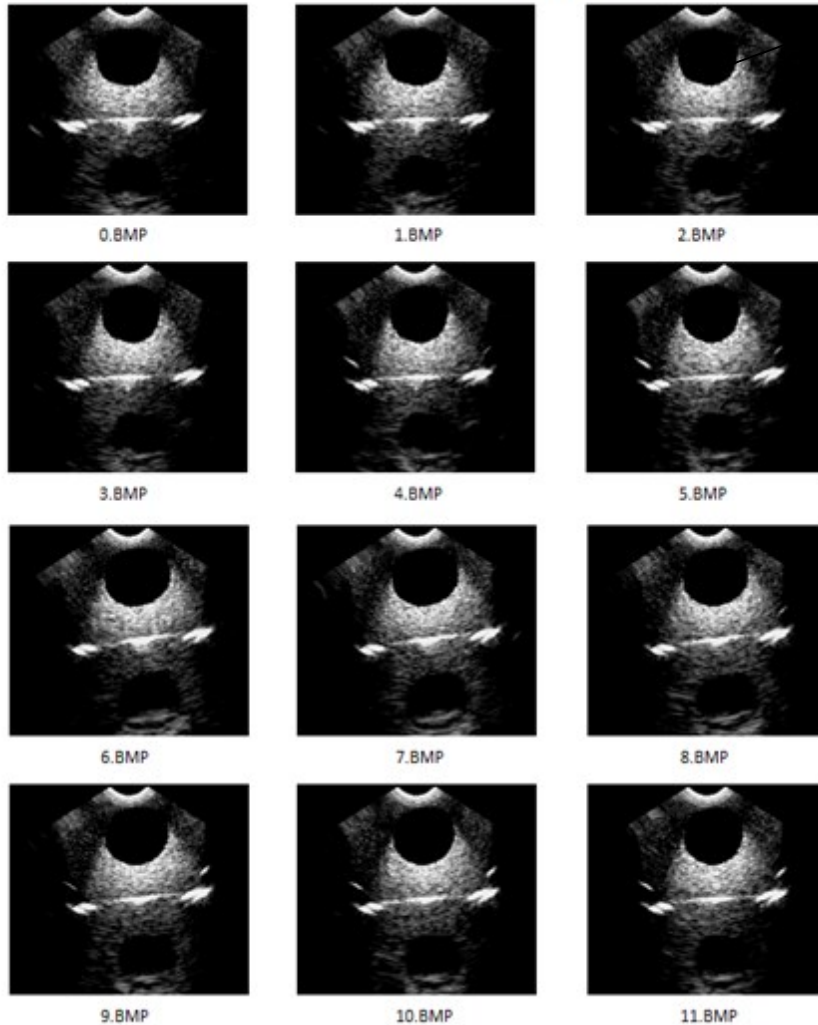
Figure 6-6 M4-HD host computer print interface (12 images)

A: 12 bladder ultrasound images

6.11.6 Save to PDF

Click the Save to PDF on the main interface of host computer, to pop up the Save to PDF dialog box. Operations possible: Select the file save path, enter the file name, and select the file save type. Among them, the file save type can only be PDF (*.pdf). After saving as a PDF file, it is convenient to store and view the patient information and bladder

images at any time. The information of the PDF file is the same as the content printed by clicking the Print (6 or 12 images).

6.11.7 Host computer password change

On the main interface of host computer, click option->password to enter the password change interface to change the password. Enter the old 6-digit password and enter the new 6-digit password twice. Press Save to successfully change the password.

The host computer password change interface is as shown in Figure 6-7:
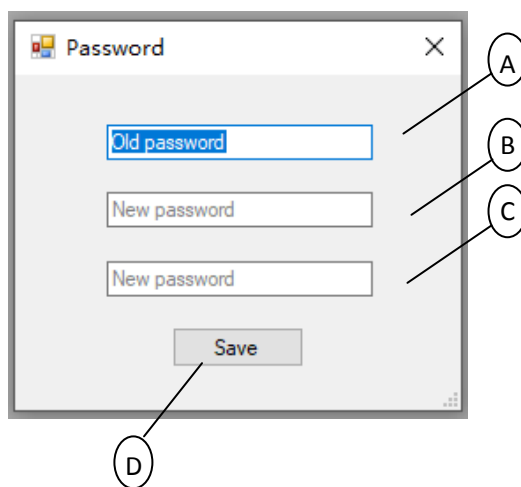
Figure 6-7 M4-HD host computer password change interface

A: Input field of old password; B: Input field of new password; C: New password input

confirmation box; D: Save key

6.12 Battery power identifier

The battery power identifier (Figure 5-15) is displayed at the upper left of the main interface of the instrument. When the battery is fully charged, there are six bars in the battery power identifier. If the battery power is more than 65%, the battery power identifier is displayed in green. If the battery power is between 65% and 30%, the battery power identifier is displayed in yellow. If the battery power is between 30% and 15%, the battery power identifier is displayed in red. At this time, the power indicator of the scanning device turns yellow, indicating that the battery needs to be charged. If the battery power is less than 15%, the battery power identifier is also displayed in red (there is no bar in the

identifier). At this time, the power indicator of the scanning device is also yellow. When the battery is exhausted and the instrument is about to shut down, a "!" will appear in the red battery power identifier. "

6.13 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 (Figure 5-5-3, Figure 5-6-3 and Figure 5-7-3) 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 and Care

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 Transportation and Storage

8.1 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.

8.2 Requirements for transportation and storage environment

Ambient temperature range: -40℃～+55℃

Relative humidity range: 10%～80%

Atmospheric pressure range: 50kpa～106kpa

8.3 Transportation

The marks on the packaging boxes of the instrument shall meet the requirements of GB/T191-200 *Packaging — Pictorial marking for handling of goods*. The packaging boxes of the instrument are equipped with simple shakeproof facilities, suitable for air, railway, 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 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 IX Simple Fault Inspection and Elimination

9.1 Inspection

●Inspect whether the power supply (battery) is installed.

9.2 Simple fault elimination

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 tablet computer 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.
	The tablet computer 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.

9.3 If the fault cannot be eliminated, please contact Suzhou PeakSonic Medical Technology Co.Ltd.

9.4 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 Schematic Diagram of the Complete Machine Identification

Schematic diagram of the nameplate of M4-HD complete machine

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

Suzhou PeakSonic Medical Technology Co.,Ltd.
Manufacturer: 2F, Building G4, Kunshan Hi-Tech Medical Device Industrial Park, No.999 Qujia Road, Qiandeng Town,Kunshan City, Jiangsu Province

EC REP Landlink GmbH
Dorfstrasse 2/4, 79312, Emmendingen,Germany

Collect separately from other household waste

Schematic diagram of the nameplate on M4-HD outer packaging box
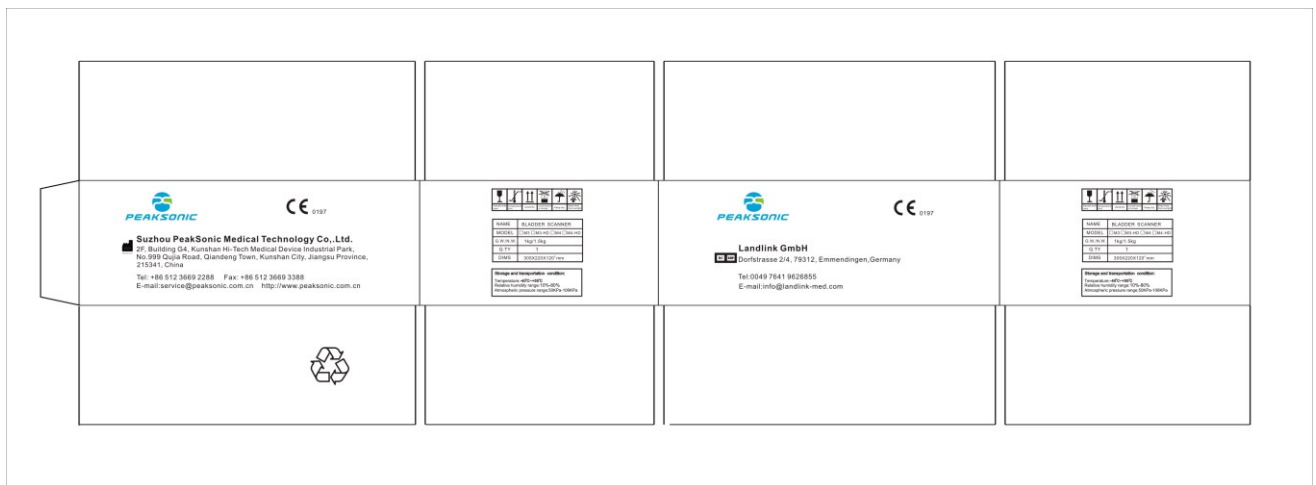
Schematic diagram of the nameplate of M4-HD base

Base of Bladder Scanner
Model Name: BASE2
Input: DC8.4V（internal battery: DC7.4V, 1000mAH）

Manufacturer **Suzhou PeakSonic Medical Technology Co,.Ltd.**
2F, Building G4, Kunshan Hi-Tech Medical Device
Industrial Park, No.999 Qujia Road, Qiandeng Town,
Kunshan City, Jiangsu Province

EC REP Landlink GmbH
Dorfstrasse 2/4, 79312, Emmendingen, Germany CE 0197

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

Schematic diagram of the nameplate of M4-HD charger

AC/DC ADAPTER
MODEL: HXY-084V1500A
INPUT: AC100-240V
50/60Hz 0.5A Max
OUTPUT: DC8.4V --- 1.5A
CAUTION: Indoor use only

L P S
c UL US LISTED
I.T.E. POWER SUPPLY
E310322
3KBL

MADE IN CHINA

AC/DC ADAPTER
MODEL: HXY-084V1500A
INPUT: AC100-240V
50/60Hz 0.5A Max
OUTPUT: DC8.4V --- 1.5A
CAUTION: Indoor use only

CE

MADE IN CHINA
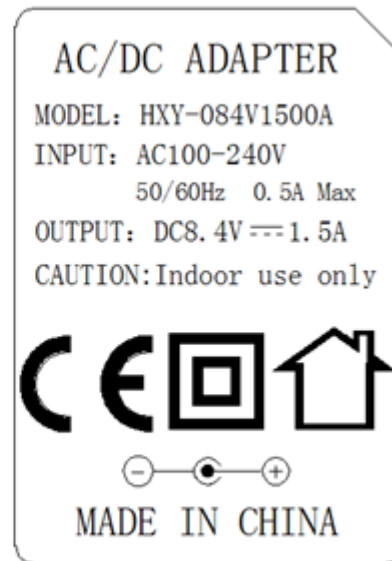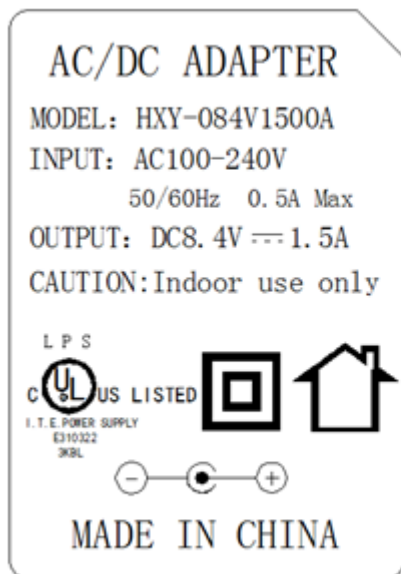
Appendix B Ultrasound Output Report

Delta Technology Service (Shenzhen) Co., Ltd.

Acoustic Output Reporting Table for Tackl(Autoscanning Mode)

System Model: M2 SN:BSH01180005
Transducer Model: H3D-1/3.5MHz SN:201803 DR0002
Nominal Frequency:3.5MHz
Operating Model: B

Acoustic Output			MI	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (W/cm^2)
Global Maximum Value			0.38	11.96	19.81
Associated Acoustic Parameter	$P_{r.3}$	(MPa)	0.66		
	W_0	(mW)		2.43	2.43
	f_c	(MHz)	3.06	3.06	3.06
	Z_{sp}	(cm)	4.60		4.60
	Beam dimensions	X_{-6} (cm)			0.30
		Y_{-6} (cm)			0.28
	PD	(usec)	0.49		0.49
	PRF (Hz)		1256.30		1256.30
	EDS	Az. (cm)		$\Phi 1.48$	
		Ele. (cm)		$\Phi 1.48$	
Operating Control Conditions	Focus(mm)		Fixed		
	Depth(mm)		Fixed		
	Frequency(MHz)		3.5		

Delta Technology Service (Shenzhen) Co., Ltd.

Acoustic Output Reporting Table for Tack1(Autoscanning Mode)

System Model: M2   SN:BSH01180005
Transducer Model: H3D-1/3.5MHz   SN:201803 DR0003
Nominal Frequency:3.5MHz
Operating Model: B

Acoustic Output			MI	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (W/cm^2)
Global Maximum Value			0.36	11.31	18.38
Associated Acoustic Parameter	$P_{r.3}$	(MPa)	0.64		
	W_0	(mW)		2.27	2.27
	f_c	(MHz)	3.18	3.18	3.18
	Z_{sp}	(cm)	4.35		4.35
	Beam dimensions	X_{-6} (cm)			0.28
		Y_{-6} (cm)			0.30
	PD	(usec)	0.48		0.48
	PRF (Hz)		1256.30		1256.30
	EDS	Az. (cm)		$\Phi 1.48$	
		Ele. (cm)		$\Phi 1.48$	
Operating Control Conditions	Focus(mm)		Fixed		
	Depth(mm)		Fixed		
	Frequency(MHz)		3.5		

PEAKSONIC

DTECH   Delta Technology Service (Shenzhen) Co., Ltd.

Acoustic Output Reporting Table for Tack1(Autoscanning Mode)
System Model: M2   SN:BSH01180005
Transducer Model: H3D-1/3.5MHz   SN:201803 DR0010
Nominal Frequency:3.5MHz
Operating Model: B

Acoustic Output			MI	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (W/cm^2)
Global Maximum Value			0.37	11.43	18.80
Associated Acoustic Parameter	$P_{r.3}$	(MPa)	0.65		
	W_0	(mW)		2.30	2.30
	f_c	(MHz)	3.07	3.07	3.07
	Z_{sp}	(cm)	4.33		4.33
	Beam dimensions	X_{-6} (cm)			0.30
		Y_{-6} (cm)			0.29
	PD	(usec)	0.49		0.49
	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)		3.5		

Appendix C Technical Specification for Electromagnetic Compatibility

Table 201

Guideline and statement of the manufacturer-electromagnetic emission		
M4-HD 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-HD 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-HD 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-HD 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	<5%UT, continuous for 0.5 week	<5%U_T, continuous for 0.5 week	Quality of network power supply shall be equal to that in

interruption and voltage change GB/T 17626.11	(on U_T, >95% of sag) 40% U_T, continuous for 5 weeks (on U_T, 60% of sag) 70% U_T, continuous for 25 weeks (on U_T, 30% of sag) <5%U_T, continuous for 5s (on U_T, >95% of sag)	(on U_T, >95% of sag) 40% U_T, continuous for 5 weeks (on U_T, 60% of sag) 70% UT, continuous for 25 weeks (on U_T, 30% of sag) <5%UT, continuous for 5s (on U_T, >95% of sag)	typical commercial or hospital environment. If the user of M4-HD bladder scanner needs continuous operation during power outage, M4-HD 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-HD 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: U_T refers to the AC network voltage prior to the application of test voltage.			

Table 204

Guideline and statement of the manufacturer-electromagnetic immunity			
M4-HD 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-HD bladder scanner including cables. And the calculation of that distance shall use a formula corresponding to the frequency of the transmitter. Recommended distance $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80MHz～800MHz $d=2.3\sqrt{P}$ 800MHz～2.5GHz Wherein: Maximum output power of the

			transmitter supplied by transmitter manufacturer, in watt (W); 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-HD bladder scanner locates is higher than the above RF compliance level, observe M4-HD 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-HD 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-HD bladder scanner		
M4-HD 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-HD bladder scanner can prevent electromagnetic interference by maintaining the minimum distance between the portable and mobile radio-frequency communication equipment (transmitter) and M4-HD bladder scanner.		

Maximum rated output power of the transmitter 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.

FCC Part15.19

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.

FCC Part15.21

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

FCC Part15.105

For a Class B digital device or peripheral, the instructions furnished to the user shall include the following or similar statement, placed in a prominent location in the text of the manual:

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

—Reorient or relocate the receiving antenna.

—Increase the separation between the equipment and receiver.

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

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

Attached page to the Specification

Instructions for Auto Calibrate:

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 clinical application of no calibration required during the service life. For this, we officially state that: In the lifelong clinical application of the M series bladder scanner and the probe, as long as they are intact:

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 the 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.

The steps of Auto Calibrate are as follows:

Step I: Enter the last item "System Info" on the system information view interface (Figure 1), and click the hardware version number (Hardware Version: M4-HD.1.0.0.X) of the display instrument for 5 times continuously. Activate, and the Auto Calibrate switch light is on in green. The calibration confirmation interface appears (Figure 2).

Step II: Operate according to the prompts on the calibration confirmation interface: 1. Connect the wireless probe first. 2. Place the probe head into the phantom holder firmly. 3. Do not remove the probe during the calibration. After the operation, press the Start key

START in the calibration confirmation interface prompt box to start Auto Calibrate. Auto Calibrate progress interface pops up at the same time. Press cancel key CLOSE on the Auto Calibrate confirmation interface. Return to the Auto Calibrate interface.

Step III: Auto Calibrate progress interface (Figure 3). The Auto Calibrate progress prompt is displayed on the interface, and the calibration result interface appears after the Auto Calibrate is completed. Press cancel key CLOSE on the Auto Calibrate progress interface. Return to the Auto Calibrate interface.

Step IV: The calibration result interface (Figure 4) appears after the Auto Calibrate is completed. Tick √ in the prompt box for success and tick × in the prompt box for failure.

Press cancel key CLOSE on the Auto Calibrate result interface. Return to the Auto Calibrate interface.

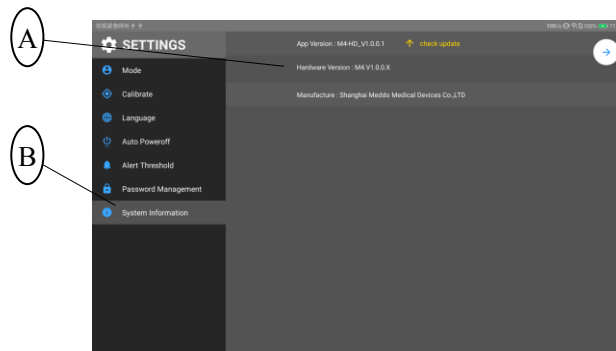Note: The Auto Calibrate must be carried out at full charge.

Figure 1 M4-HD system information view interface

A: System information view item window prompt

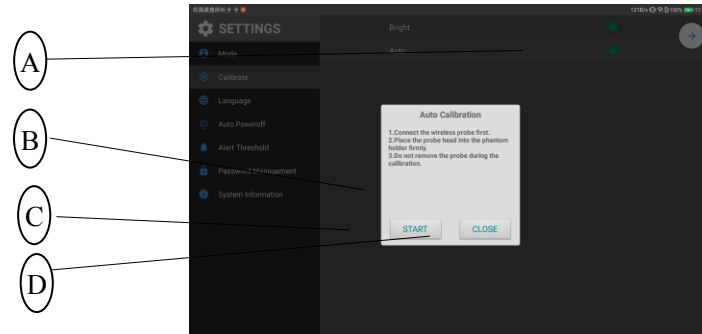B: Select the system information view item from the setting list

Figure 2 M4-HD Auto Calibrate confirmation interface

A: Activate Auto Calibrate, with the Auto Calibrate switch light green.

B: Calibration confirmation interface prompt box

C: Auto Calibrate start key
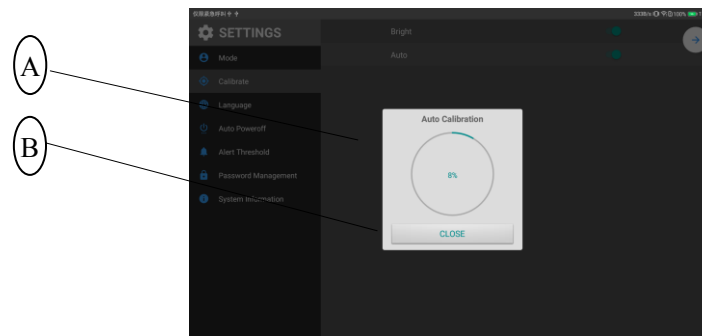
D: Auto Calibrate cancel key

Figure 3 M4-HD Auto Calibrate progress interface

A: Auto Calibrate progress prompt box
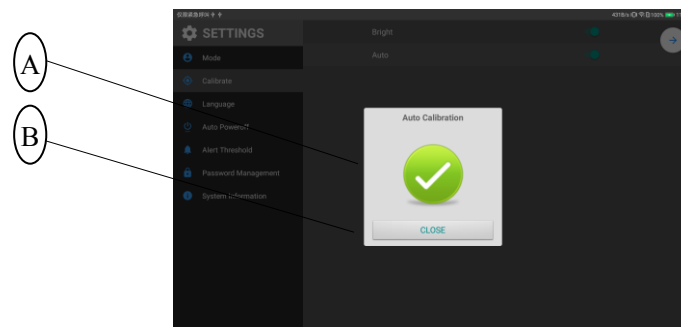
B: Auto Calibrate cancel key

Figure 4 M4-HD Auto Calibrate result interface

A: Auto Calibrate result prompt bar

B: Auto Calibrate cancel key