Bladder Scanner
Model:M5

User Manual

Version: M5_V1.0.0.1

Suzhou PeakSonic Medical Technology Co.Ltd.

Contents

Chapter I Overview

1.1 Introduction

The M5 bladder scanner manufactured by Suzhou Lischka Medtech Co.,Ltd. provides non-invasive measurement of urinary bladder volume and bladder wall thickness using ultrasonic imaging and measurement principle. The instrument is composed of a host, a probe and a carter. It has the following features:

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

- The instrument is non-invasive and comfortable to use for patients to measure bladder volume. It is accurate, reliable, rapid and simple. Several 2D ultrasound images are obtained within a few seconds after releasing the scan key. By using complex image processing technology, those 2D images are restored to 3D. At the same time it adopts complex algorithm to calculate the bladder volume and display the re-

sults.

- The instrument is non-invasive, reliable, quick and easy to operate for measurement of the bladder wall thickness. 2D B-mode images are displayed after scan. Once the bladder position has been located, press SCAN to freeze the image. Images are processed further to extract relevant information for bladder wall thickness calculation.
- Two orthogonal images, patient information and volume values can be printed for bladder volume. For bladder wall thickness one B-mode image, patient information and bladder wall thickness value are printable.
- Adopt touch screen keyboard for operation.
- Multi-language selection.
- Information management, storage, print and exportation.
- The instrument is composed of probe, host and a carter. It adopts a 10.1 inch LCD with (1280*800) pixels.
- The power supply of the device is alternating current or battery.

1.2 Intended Use

The device projects ultrasound energy through the lower abdomen of the patient to obtain images of the bladder. Those images are then used to calculate bladder volume and bladder wall thickness. The instrument is intended to be used only by qualified medical professionals.

1.3 Carry out Standards

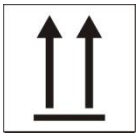
The instrument shall be designed and manufactured strictly according to the international standards IEC/EN 60601-1 <*Medical Electrical Equipment Part 1: General Requirements for Safety*> and IEC/EN 60601-1-2 <*Medical Electrical Equipment General Requirement No. 1-2: Parallel standards, EMC requirements and test methods*> and IEC/EN 60601-2-37 <*Medical Electrical Equipment Part 2-37: Specific Requirements for the Safety of Medical Ultrasonic Diagnostic and Monitoring Equipment*>. The protection type of electric shock hazard is: Type B of Class II.

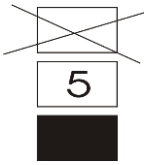
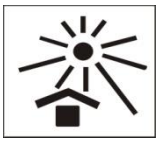
The environment test of the instrument shall meet the requirements of climate environment test Group II and mechanical environment test Group II of GB/T14710-2009 Environmental Requirements and Test Methods for Medical Electrical Equipment.

Industry symbol dictionary:

SN	Serial number		Follow the instructions
	Production date		Type BF applied part
EC REP	EC REP—Authorized Representative in the European Community		Warning or Caution—Consult accompanying documents. Read instructions before connecting or operating.
	Manufacturer	IPX7	Ingress protection (IP) against water
	The waste electrical and electronic equipment shall be recycled according to the regulations	CE 0197	CE—Marked in accordance with the Medical Device Directive (MDD)
FCCID 2AT6UM5-FS	Wireless certification code	℞ ONLY	Prescription use only

Description of packing and transportation marks of the instrument:

	Fragile item, handle carefully
	Limit of temperature
	Upward

	Limit number of stacking layer
	Keep dry
	Avoid heat

1.4 Service Life

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

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

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

1.5 Operating Environmental Requirement

1. Ambient temperature range: +5℃～+40℃

2. Relative humidity range: 30%～75%

3. Atmospheric pressure range: 70KPa～106KPa

1.6 Statement on Electromagnetic Compatibility

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

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

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

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

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

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

1.7 Statement of the Manufacturer

Responsibilities of the manufacturer

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

- The assembly operation, expansion, re-adjustment, improvement and repair are carried out by personnel

approved by Suzhou Lischka Medtech Co., Ltd.;

- Relevant electrical equipment complies with national standards;
- The instrument is used according to operation instruction.

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

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

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

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

1.8 Contraindications

Do not use the Bladder Scanner on the following cases:

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

1.9 Release of the Heat Indexes and Mechanical Indexes

Heat indexes TIS: ＜0.018

TIB: ＜0.018

Mechanical indexes MI: ＜0.80

Chapter II Precautions

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

2.1 Inspection before Operation

- Before operation make sure all cables are connected correctly.
- The instrument is normal.
- Keep the instrument away from the hot or wet objects. Make sure the instrument is in the right place for safe operation.

Warning: Please stop using the device in case of any damage of the device or cable.

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

2.2 Safety Check before Operation

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

2.3 Operating Instructions

Warning: Please do not unplug the device or disconnect the probe during operation to avoid any damage of the device or the probe.

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

2.4 After Operation

1. Switch off the power.
2. Unplug the cable.
3. Clean the instrument and the probe.

2.5 Situations to be Avoided

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

1. Splashing
2. High humidity
3. Poor ventilation
4. Straight sunshine
5. Dust environment
6. Saliferous or sulfurous gas
7. Chemical medicine or gas
8. Strong vibration and collision
9. The company is not liable for any risks arising from the disassembly or modification of the instrument by the user.

2.6 Cautions during Transportation

1. Strictly forbid to dip the probe part which contacts the patients into any liquid.
2. Strictly forbid to heat the probe part which contacts the patients.
3. Strictly forbid to pull or bend the probe cable to avoid any damage.
4. Use the ultrasonic coupling agent which meets the national standards. Prevent use of any other materials such as oil which damages the probe.
5. Keep the probe clean. Wipe off the ultrasonic coupling agent on the probe with neutral detergent or fresh water after use.

2.7 Relocate the Instrument

1. Unplug the cable
2. Prevent falling, vibration or collision

2.8 Malfunction

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

2.9 Regular Inspection and Maintenance of the Instrument

2.10 Do not Disassemble the Instrument or Probe

2.11 Startup

Connect the cable with power adapter and plug into the power supply. If the green light of the power adapter is on it indicates the power adapter is working normally. Insert the DC output plug of the power adapter into the d.c.13.5v jack on the right side of the host and the charging light is on. Yellow light indicates charging is in progress and the green light indicates charging is completed.

Press the power button of the host, and the power indicator on the left side of the host panel, that is, the host power is on, and the working indicator light (green) is on to enter the boot interface.

Press the power button to switch on the instrument. Power indicator (green) on the left side of the host will be on.

Chapter III System Introduction

3.1 Appearance

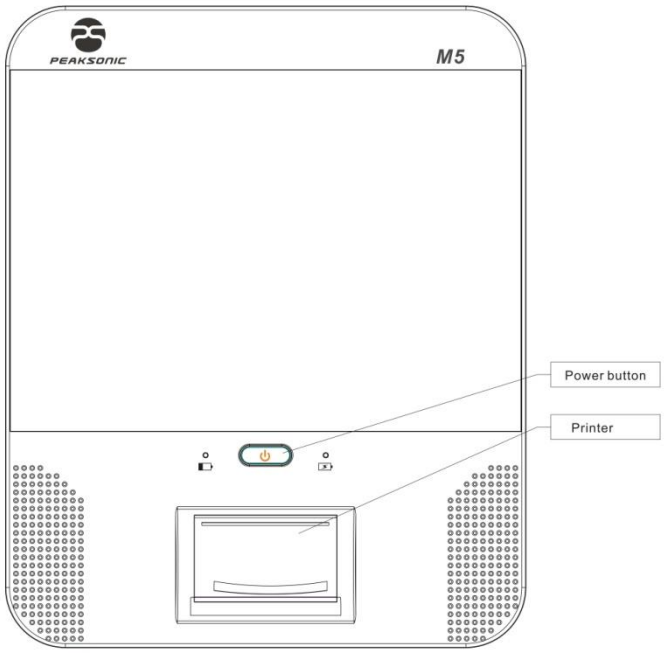


Figure 3-1 M5 Front View

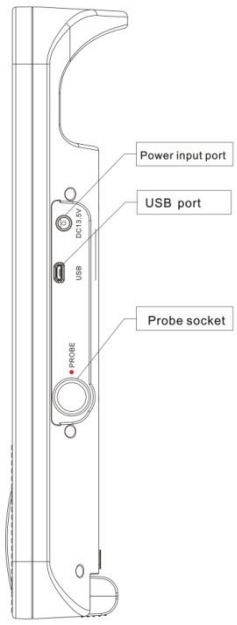


Figure 3-2 M5 Side View

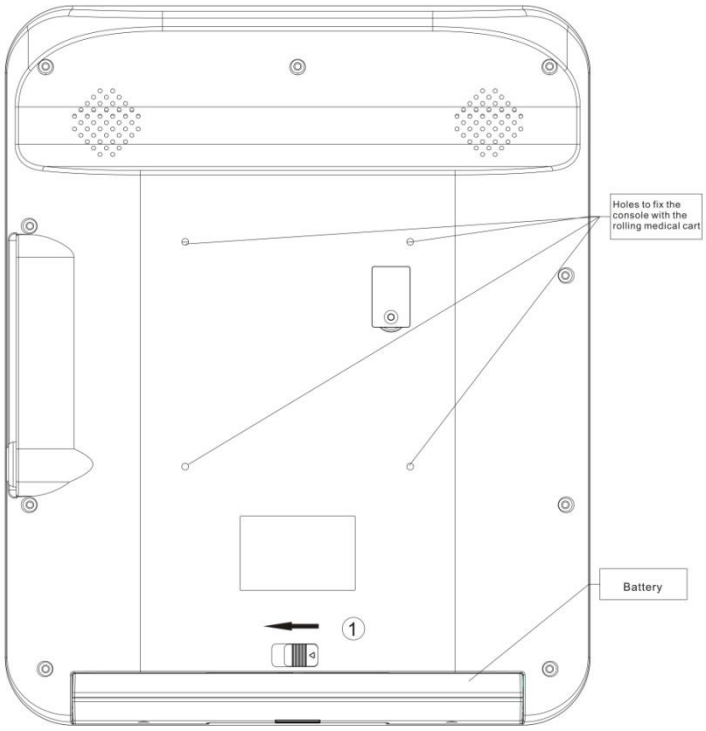


Figure 3-3 M5 Back View

3.2 Technical Specifications

- Probe: P1/2.5MHZ 3D mechanical sector-scanning
- Nominal ultrasonic operating frequency: 2.5MHz±15%
- Volume measurement range: 0ml-999ml
- Volume measurement accuracy: ±7% for volume range from 100 to 999ml, ±7ml for volume<100ml
- Volume display resolution: 1ml
- Scanning time: < 5 seconds
- Bladder wall thickness range: 0mm - 10mm
- Bladder wall thickness measurement accuracy: ±10%
- Battery capacity: 3200mAh
- Operation mode: Touch key
- 2D tissue harmonic imaging
- Bladder 3D scan display: real-time scan images, bladder volume value, bladder shape, bladder

projection, 3D image

- Bladder 2D scan display: real-time scan images, bladder wall thickness value
- Information storage: Images, results and other information of the patient can be stored.
- Information printing: Print the measurement results and pictures
- Information management: Check patient history information, restore original information in the database, store, print, delete and export information
- Information entry: enter patient gender, ID, name, age
- System setting: set gender, operation mode, printing setting, volume alert, automatic shutdown, language, automatic calibration, FPGA software upgrade, date and time, password management, general information
- Multi-language selection
- There are three operation modes: Expert, easy and intelligence mode
- WIFI wireless transmission: upload patient information to the computer
- USB interface: Connect with the computer through this interface
- Probe screen display: volume value, projection, indication arrow in case of intelligence mode
- Size of display screen: 10.1 inch TFT-LCD
- Power: 15VA without battery, 45VA with battery
- Size: 310*260*60MM±0.6mm
- Instrument weight: About 2000g ±50g (including battery)
- Power supply mode: AC or battery

  AC input: AC100-240Vac；Output: DC13.5V±5%

  Battery：DC11.1V；3200mAh
- Battery charging duration: <1 hour & 45 minutes
- Continuous scanning time of battery powered instrument: > 2 hours
- Continuous electrification time of battery powered instrument (screensaver status): > 28 hours
- Continuous electrification time of battery powered instrument (non-screensaver status): > 3 hours & 45 minutes
- The waterproofing grade of the probe front end is IPX7.
- The instrument is composed of a host, a probe and a carter.

3.3 Block Diagram

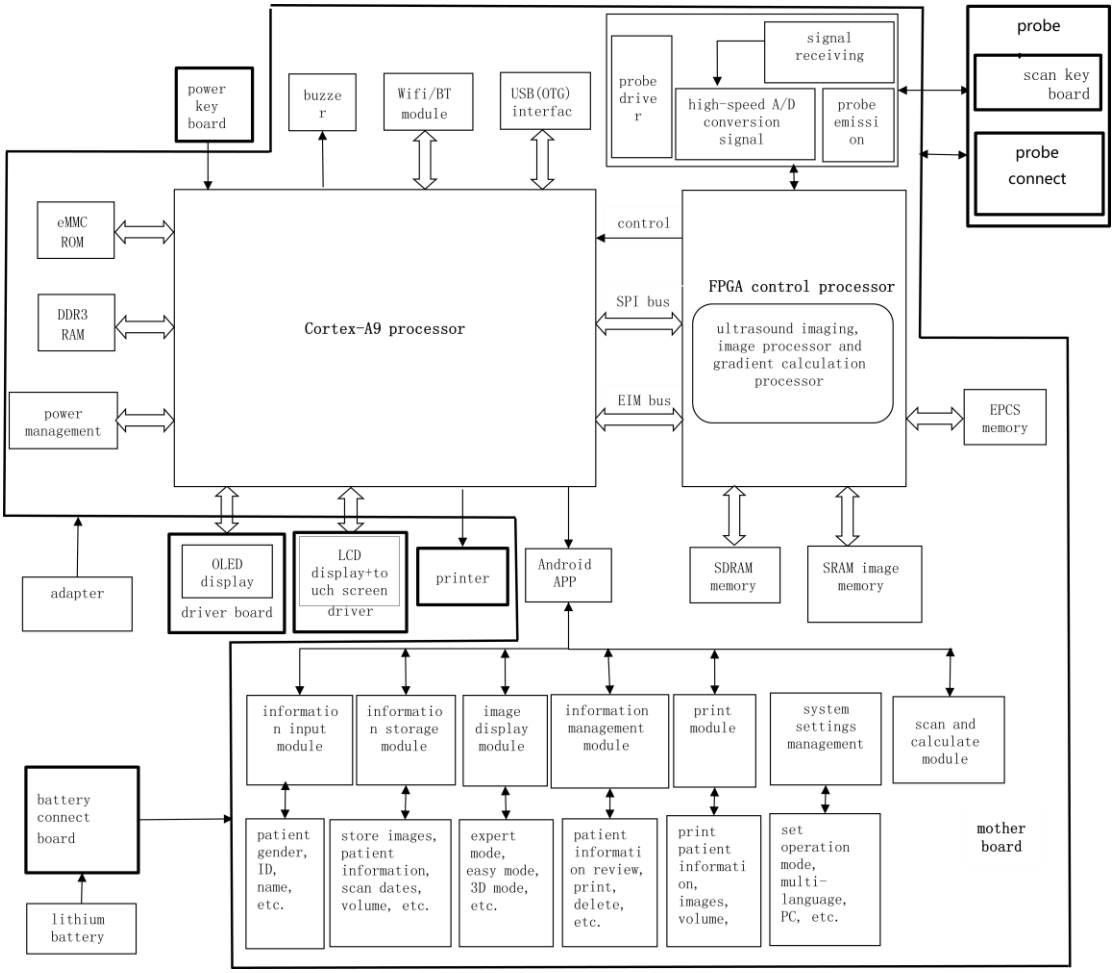


Figure 3-4 M5 Electricity Principle

3.4 Basic Principle

This product is a non-invasive bladder urinary volume measurement device. It non-invasively measures bladder capacity and bladder wall thickness using ultrasonic imaging technology. It adopts Android system, high resolution display screen and capacitive touch screen. By the end of the scanning 12 images are obtained using 3D ultrasonic probe. Bladder urinary volume is measured by plotting the boundary points of bladder and performing point integral operation at the same time. This method rapidly outlines the boarder of the bladder to obtain the boundary data of each section according to the gradient value of the image. At the same time key data of bladder boundary segment points are obtained. For the 12 images obtained through scanning according to the bladder boundary segment points, the curve at the right of the bladder boundary in each image is divided to 5 segments: L1, L2, L3, L4 and L5. According to the division segments of the curve, the integral value of one surface in integral values of L1 is calculated first. The sum of the area values corresponding to all points of L1 is the volume value of L1. And then the positive and negative judgment shall be conducted to the volume value according to key points of L1, L2, L3,

L4 and L5. The volume of the right part of the bladder scanning section is the sum of the volume values corresponding to L1, L2, L3, L4 and L5. The volume of the left part shall be calculated with the same method as that of the right part. The volume value of one scanning section is the sum of the volume values of the right and the left parts. The volume of the whole bladder is the sum of 3-dimensional volume of 12 scanning sections. The instrument adopts a 3D mechanical sector-scanning probe to conduct ultrasonic detection and scanning of the bladder, and then performs complex operation to calculate the bladder volume. The operating principle of the instrument is: Firstly, the instrument sends pulse signal to the 3D probe, and then transmits ultrasonic wave to the human body through the energy converter in the probe. The ultrasonic wave generates reflected or scattered wave in the human body as it passes through tissue planes, and the tissue and organ can be positioned according to its return time. According to its strength, tissue characteristics can be detected. Sending such a set of pulses can only capture one piece of information on a plane of the tissue, i.e., usually a 2D sectional tissue image needs it to be transmitted at least 96 or 128 times (for a 2D ultrasound device), so as to form a section. And then transmitted and received images shall be displayed on the screen successively. With respect to displayed images, gray-scale modulation is conducted to the received sound beam signal intensity, achieving a plane image identical to the actual section. The reflected ultrasonic wave is received by the energy converter to convert the sound energy into electrical energy. This electrical signal is amplified and sent to the digital scanning converter (DSC) for filtering, detection and compression. Due to the difference between the emission scanning imaging mode and the imaging display direction and different imaging speed, in order to achieve the real-time imaging of the 2D section, a digital scanning converter (DSC) must be designed in the instrument to transform the emission scanning mode into the imaging scanning mode, and a series of image digital processing shall be carried out in the digital scanning converter (DSC) to finally form a high-resolution section image displayed on the screen. Secondly, the 3D probe is driven by two motor units to drive the crystal oscillator on the top of the probe to rotate and swing. Of which, the lower stepping motor drives the crystal oscillator to rotate for 180 degrees, and the upper stepping motor drives the crystal oscillator to swing for 120 degrees. When the lower stepping motor reaches the edge position and is fixed, the upper stepping motor swings back and forth for 120 degrees, and an ultrasound image is generated. Then, make the lower stepping motor rotate for 15 degrees and fix, the upper stepping motor swings for 120 degrees to obtain the second image. Next, make the lower stepping motor rotate for 15 degrees, the upper stepping motor scan again and so forth, until the lower stepping motor rotates for 180 degrees and stops. At this time, we have obtained 13 images, with 12 images being processed for calculation to obtain the final bladder volume.

For bladder wall thickness measurement, ultrasonic 3D probe conducts 2D scan. 2D B-mode images are displayed in the screen. Once the bladder position is located, press SCAN button on the probe, image is frozen. Images are then processed to separate relevant information for bladder wall thickness calculation.

3.5 Instrument Components

- Instrument model: M5
- Software: Version M5_V1.0.0.1
- Power adaptor: Model FY1355000, Specifications (input a.c.220V 50/60Hz, 1.2A 120VA, output d.c.13.5V 5A)
- Probe: P1/2.5MHZ, Specification (2.5MHz, 3D mechanical sector scanning, sector angle: 120 degrees)
- User Manual
- Lithium battery: PC063-M5（3ICR19/65） 11.1Vd.c. 3200mAh
- Certificate of Qualification
- Warranty certificate
- Packing list
- Carter

Chapter IV Installation

4.1 Unpacking & Initial Inspection

Open the box and inspect whether there is any transportation damage. Verify according to the "packing list" and ensure you have received all appropriate components. Install according to the requirements and methods specified in “4.2".

4.2 Installation and Disassemble

- Check the power supply of the power adapter. After confirming that it is within the specified power supply range, insert the AC input plug of the power adapter into the power supply socket.
- Connect the host machine with the carter: place the host on the main frame of the carter.

Installation steps: (Figure 4-1)
Step 1. Align the four holes of the back of the host machine with the four holes on the frame of the carter
Step 2. Tighten the four screws with a screwdriver
Step 3. Successfully connect the console with the rolling medical cart

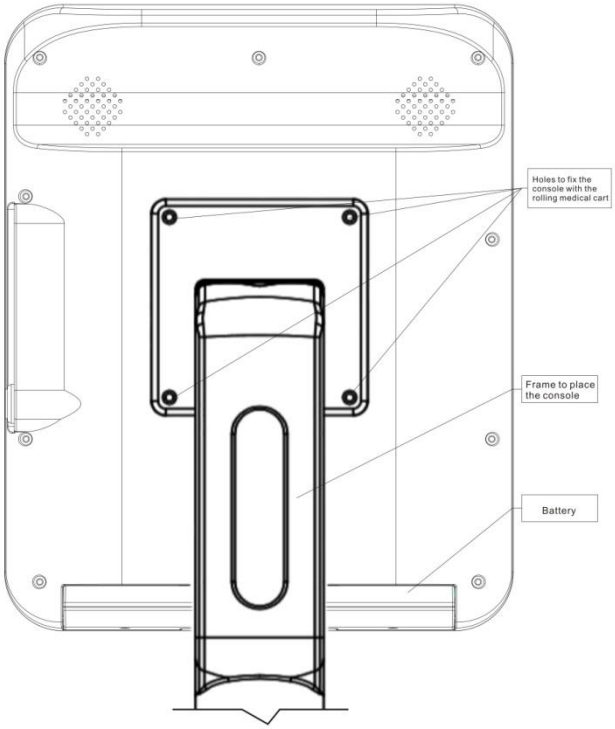


Figure 4-1 M5 connection between cart frame and the console

- Connect the probe with the host machine: align the red dot on probe with the red dot on the side of the host. Plug in the probe (shown as figure 4-2)

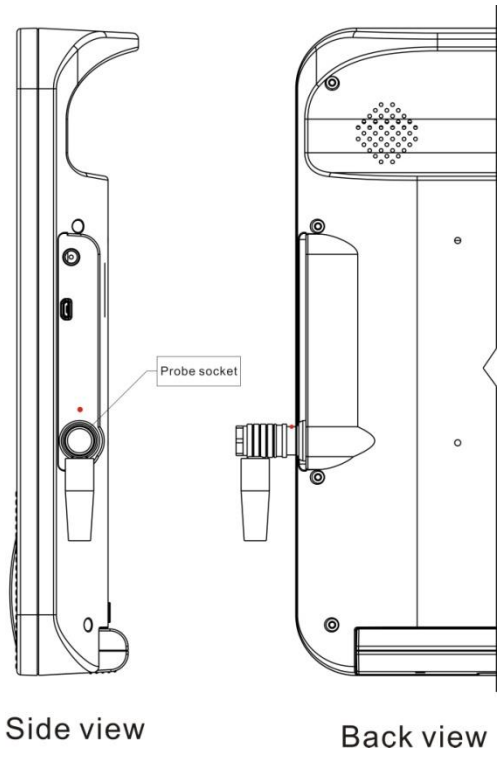


Figure 4-2 M5 Connect the probe with the console

Install and remove the battery: please follow the steps below (as shown in figure 4-3)

Install the battery:

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

Step 2. Push up and insert the battery ② according to the arrow direction.

Remove the battery:

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

Step 2. ③Take out the battery according to the arrow direction.

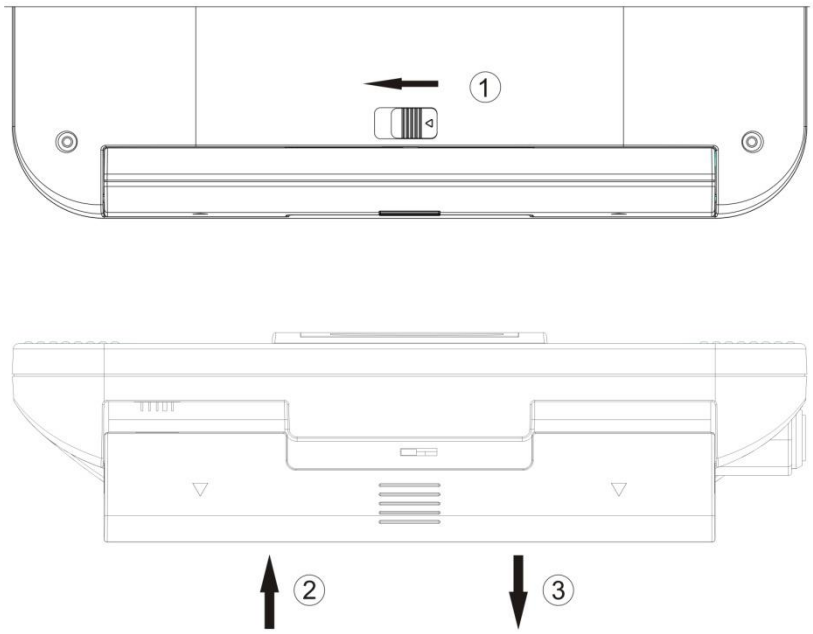


Figure 4-3 M5 Install and Remove the battery

4.3 Power Supply

Power supply mode of the instrument: Battery or AC. The power supply mode can be converted to each other.

4.3.1 Power Supply by AC

- Check whether the power adapter is normal: the power supply voltage is within the specified range; insert the AC input plug of the power adapter into the power supply socket, the output of the power adapter is d.c.13.5v and the green light of the power adapter is on.

- Plug the output plug of the power adapter into the d.c.13.5v power socket on the right side of the host, and the charging indication light on the right side of the host is on, yellow indicates charging, and green indicates charging is completed; if lithium-ion battery is not installed, the indicator light on the right side is off; turn on the host, the power indication light on the left side of the host is on, indicating the instru-

Warning: forbid to use any other power supplies apart from the ones provide by the manufacturer

4.3.2 Power Supply by Battery

- Install the battery in the host machine following “4.2”, press start button and power indication light (green light) on the left side will be one indicating the instrument is powered and on working status.

4.3.3 Charge the Battery

Host battery is charged through the host

- Install the battery in the host
- Plug the output plug of the power adapter into the d.c.13.5V socket on the right side of the host
- Connect the AC input plug of the power adapter to the power supply socket
- When the charging indication light (yellow) on the right side of the host is on regardless the device is on or off, it indicates the battery is being charged. When the charging indicator turns green, it means the battery is full

Chapter V Instrument Interface

5.1 Startup

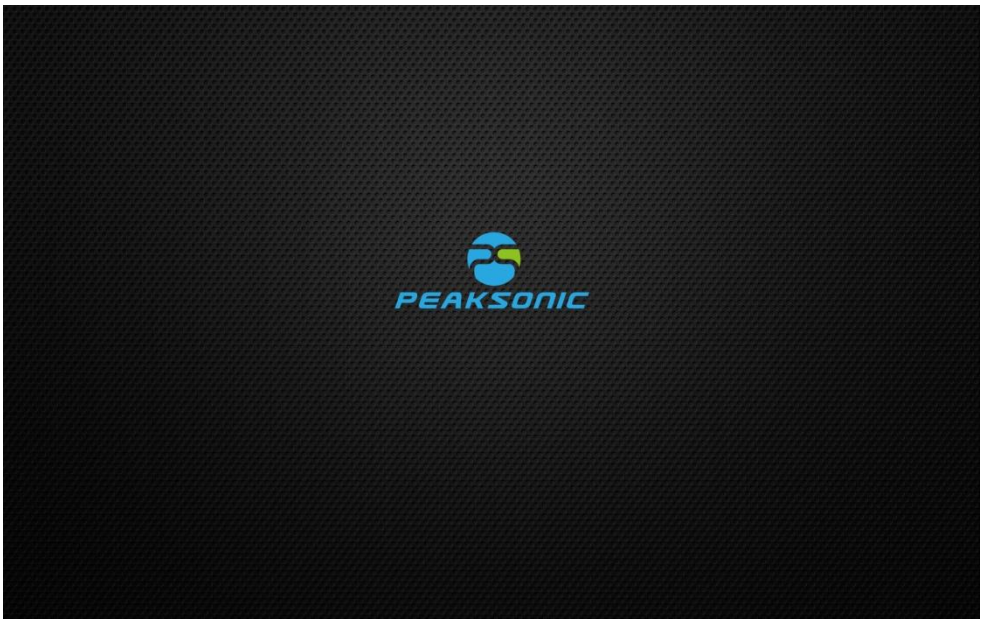


Figure 5-1 M5 Startup Page

5.2 Home Page

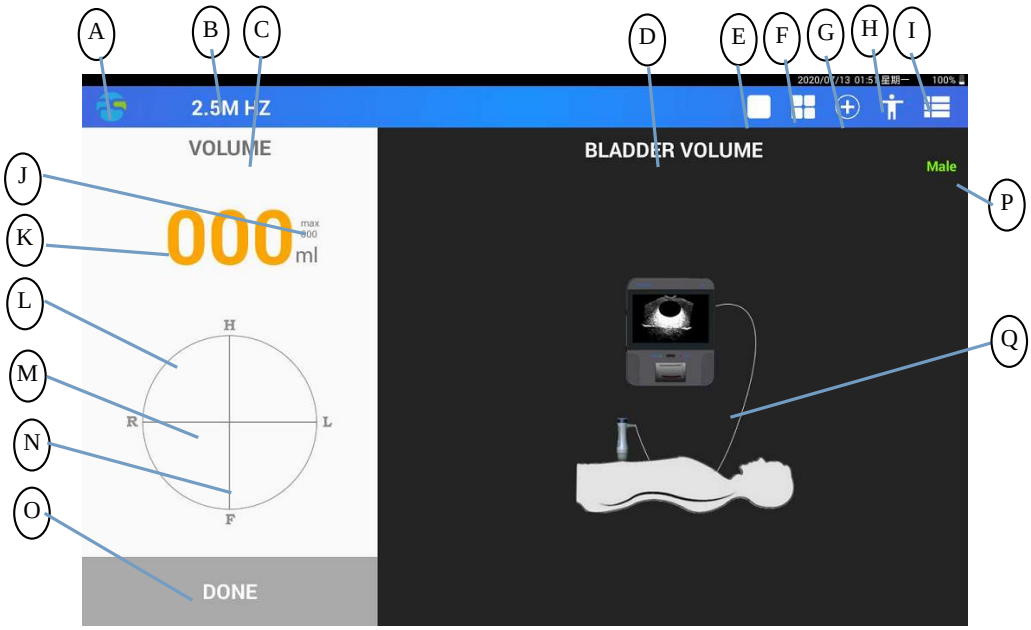


Figure 5-2 M5 Home Page

A: Setting Logo
B: Probe Frequency
C: Parameter
D: Measurement Target
E: Scan Complete Icon
F: Scan Complete Grid View
G: Enter New Patient ID
H: Gender Selection Icon
I: Patient History Information
J: Bladder Capacity
K: Bladder Volume Value
L: Bladder Projection Crosshair
M: Horizontal Line of the Crosshair
N: Vertical line of the Crosshair
O: Scan Completed
P: Gender Display
Q: Device Operation Instruction

5.3 Gender Selection

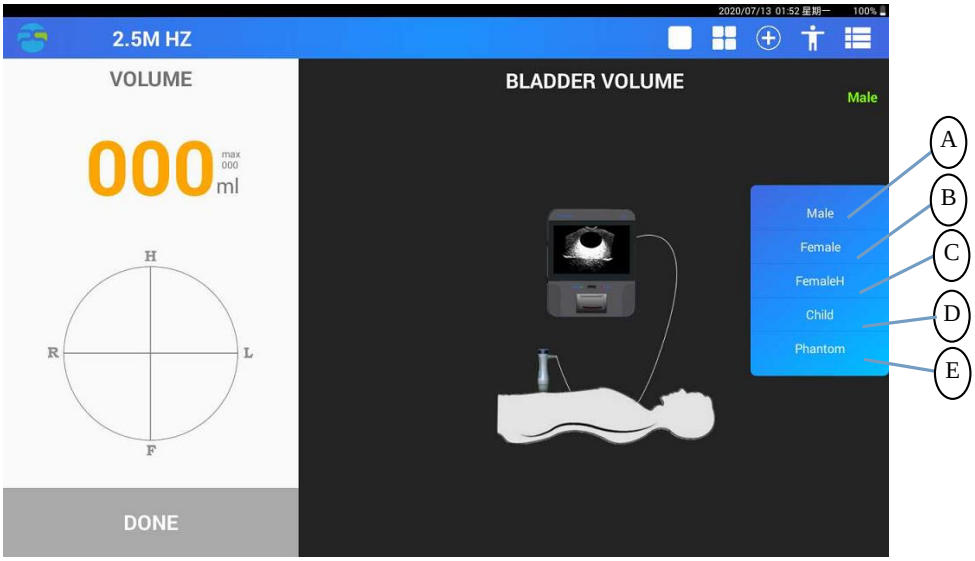


Figure 5-3 M5 Gender Selection Interface

A: Option of Male
B: Option of Female
C: Option of FemaleH
D: Option of Child
E: Option of Phantom

5.4 Pre-scan under Expert Mode

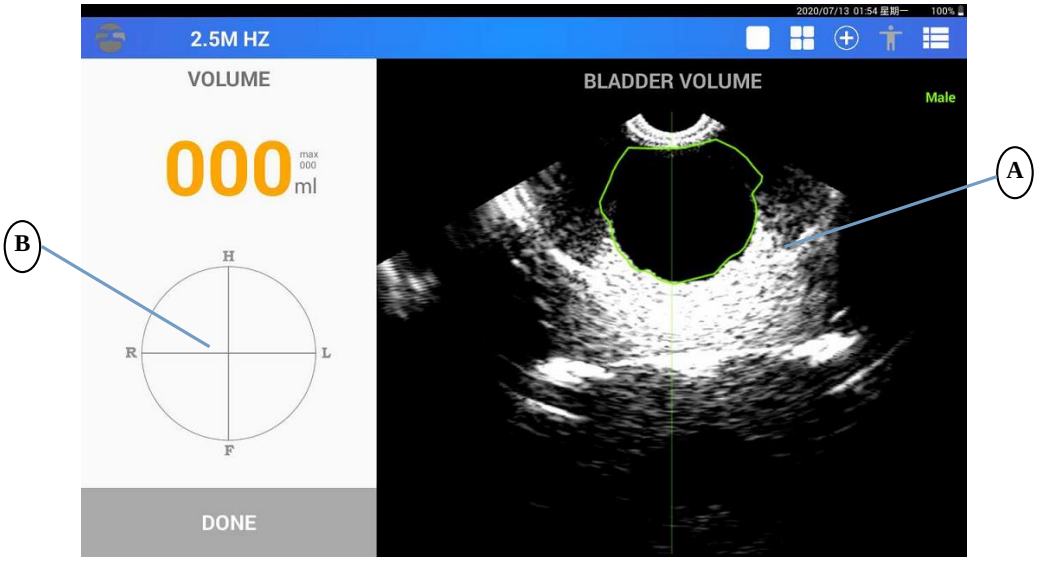


Figure 5-4 M5 Expert Mode Pre-scan Interface

A: Real Time Bladder Display

B: Bladder Projection

5.5 Scan under Expert Mode

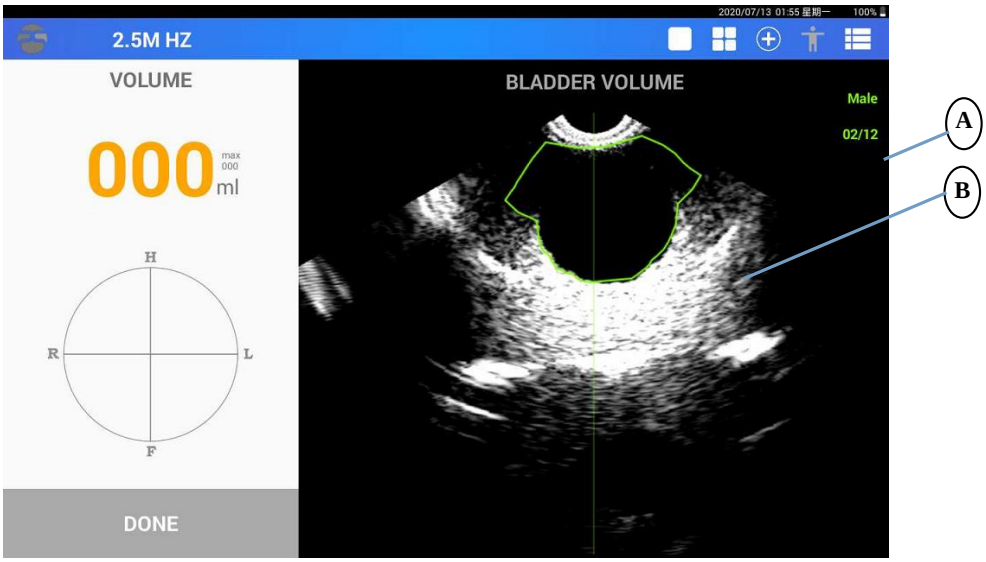


Figure 5-5 M5 Expert Mode Scan Interface

A: Display total number of B-Mode scan images. 12/12 indicates scan and image analysis are completed

and bladder volume has been calculated

B: B-mode scan images are displayed one by one. Upon completion all 12 images are displayed on the screen

5.6 Expert Mode Scan Complete Interface

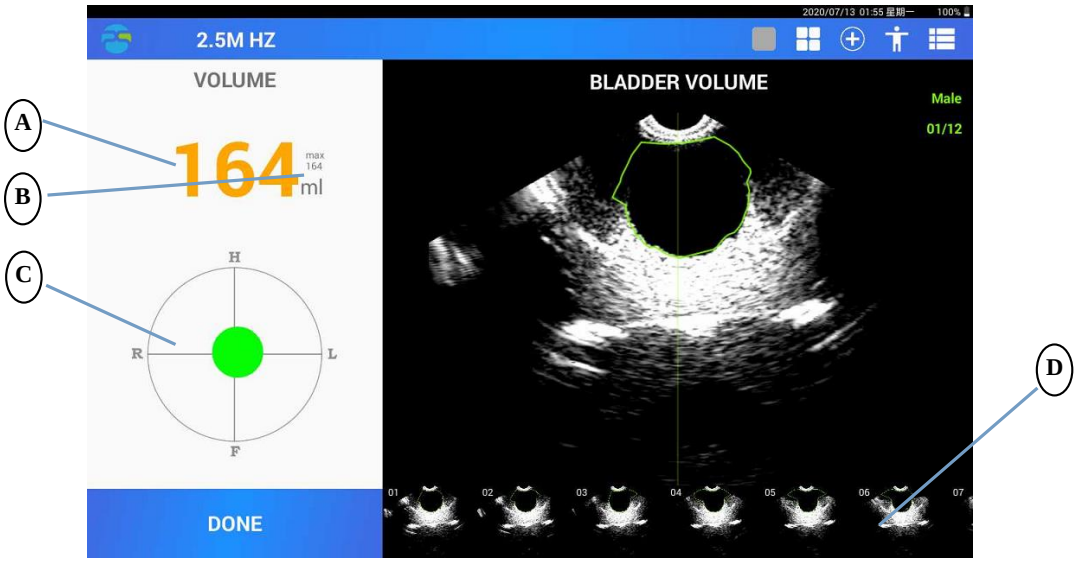


Figure 5-6 M5 Expert Mode Scan Complete Interface - Gallery View

A: Bladder Volume After Scan

B: Bladder Capacity

C: Bladder Projection Image

D: Twelve B-Mode Images Gallery View

5.7 Expert Mode B-Mode Images Display - Grid View

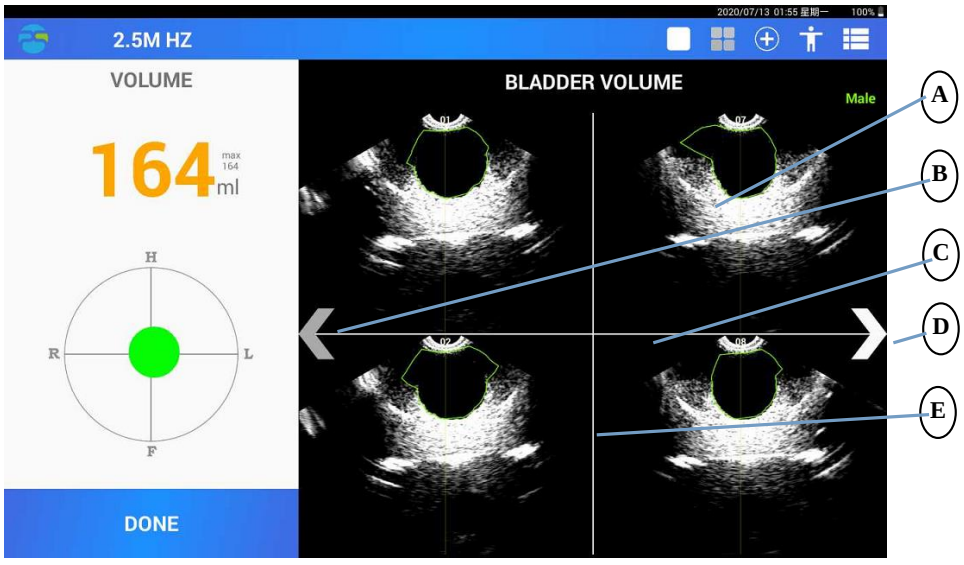


Figure 5-7 M5 Expert Mode B-Mode Images Display - Grid View

A: Four B-Mode Images in Grid View (two orthogonal images at horizontal direction)

B: Previous Page

C: Horizontal Axe of the Grid

D: Next Page

E: Vertical Axe of the Grid

5.8 Pre-scan under Easy Mode

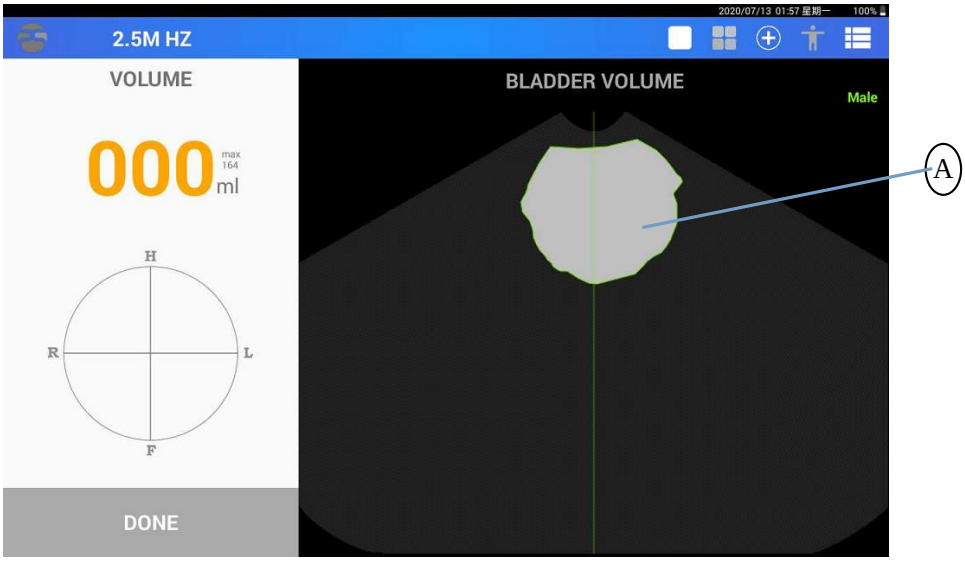


Figure 5-8 M5 Easy Mode Pre-scan Interface

A: Bladder Cross-sectional View

5.9 Scan under Easy Mode

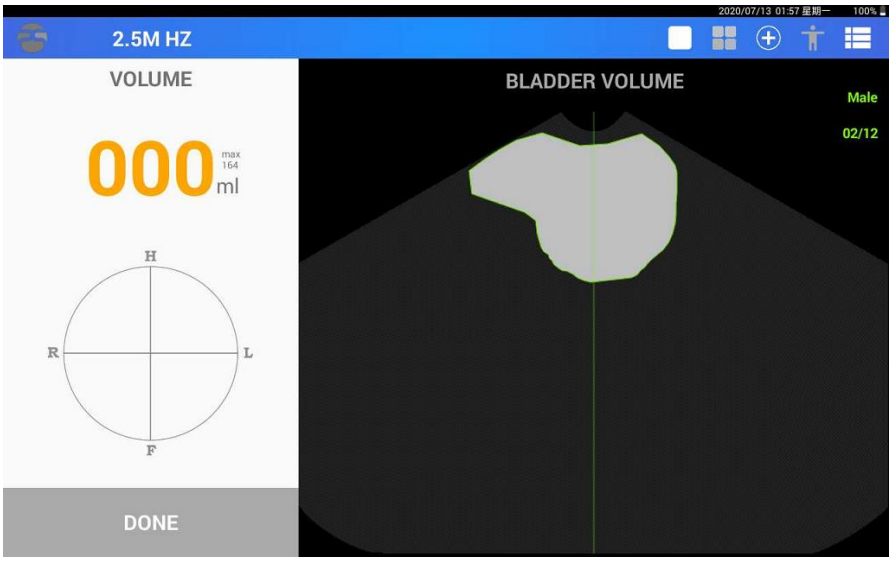


Figure 5-9 M5 Easy Mode Scan Interface

5.10 Easy Mode Scan Complete Interface - Gallery View

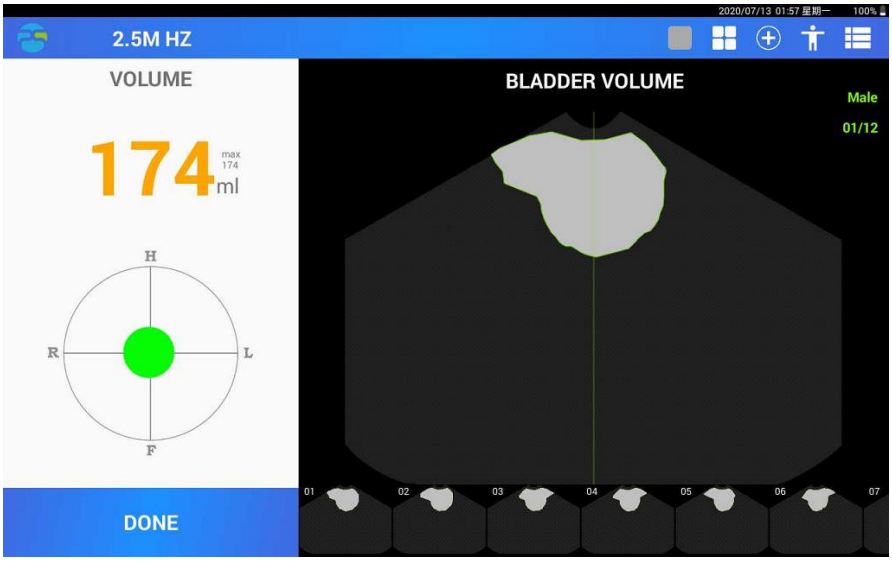


Figure 5-10 M5 Easy Mode Scan Complete - Gallery View

5.11 Easy Mode Scan Complete Interface – Grid View

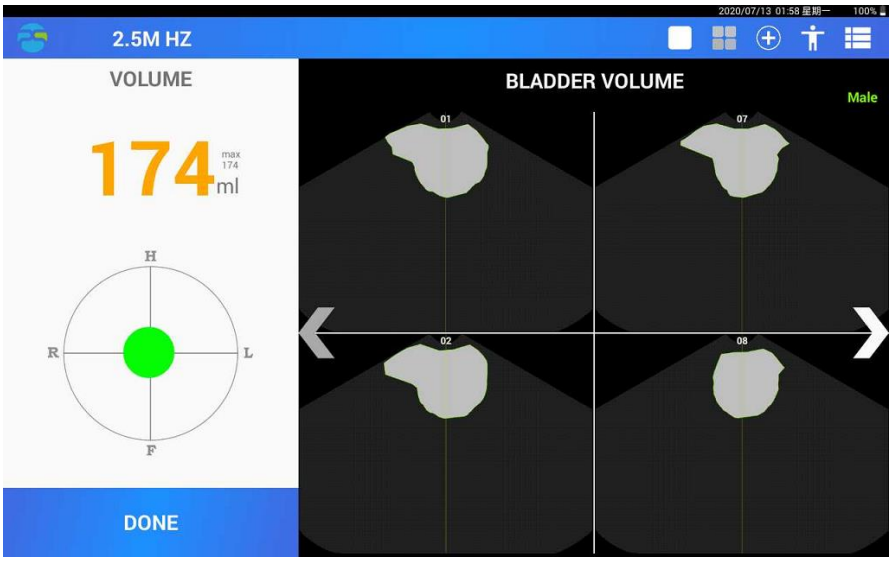


Figure 5-11 M5 Easy Mode Scan Complete Grid View

5.12 Pre-scan under Intelligence Mode

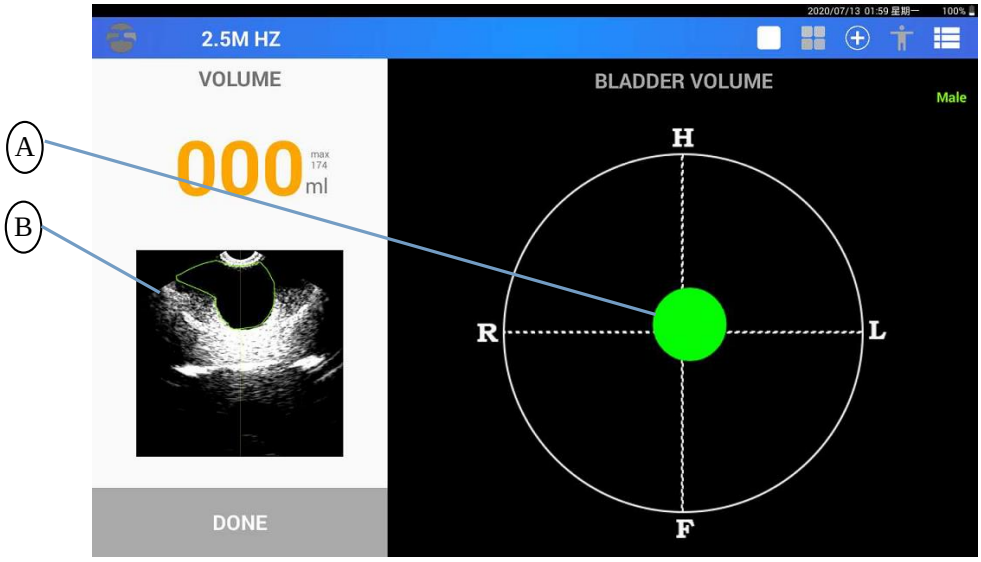


Figure 5-12 M5 Intelligence Mode Pre-scan Interface

A: Bladder Scan Real Time Projection

B: Bladder Scan Real Time 2D B-Mode Image

5.13 Scan under Intelligence Mode

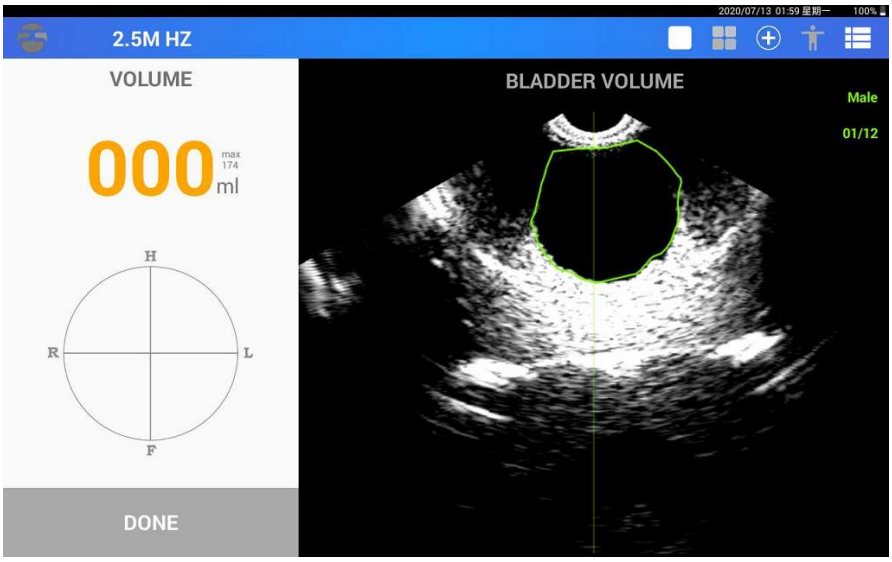


Figure 5-13 M5 Intelligence Mode Scan Interface

5.14 Intelligence Mode Scan Complete Interface - Gallery View

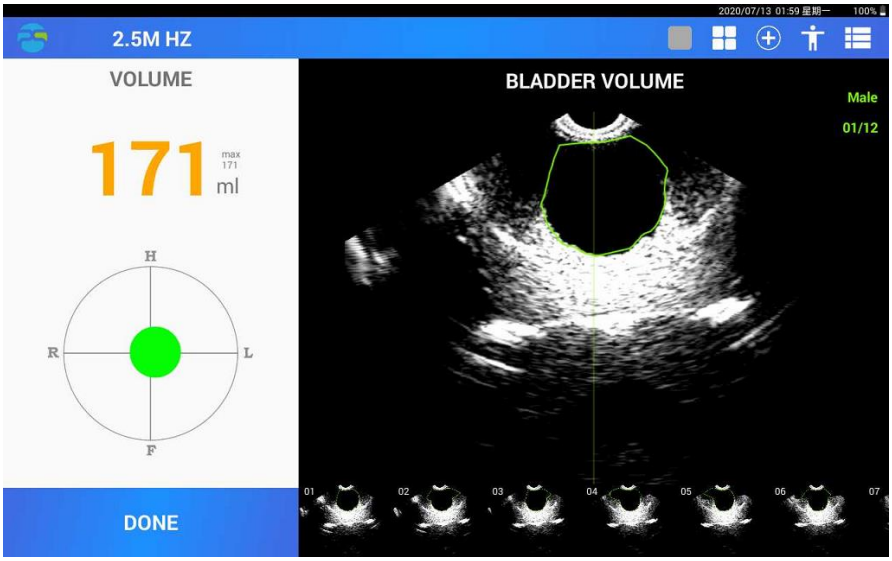


Figure 5-14 M5 Intelligence Mode Scan Complete Interface - Gallery View

5.15 Intelligence Mode Scan Complete Interface - Grid View

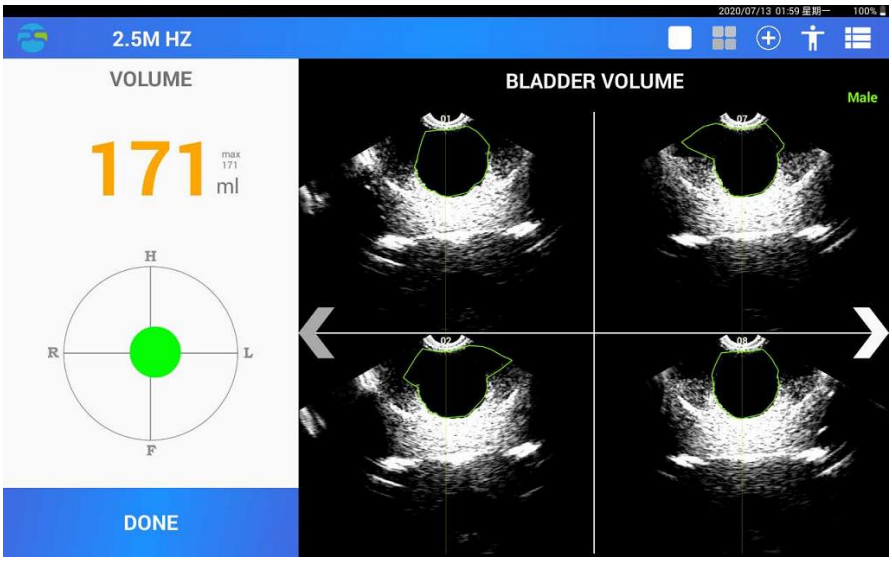


Figure 5-15 M5 Intelligence Mode Scan Complete Interface - Grid View

Remark: Scan Complete Interfaces of Intelligence and Expert Mode are appeared the same

5.16 Expert Mode Bladder 3D Image

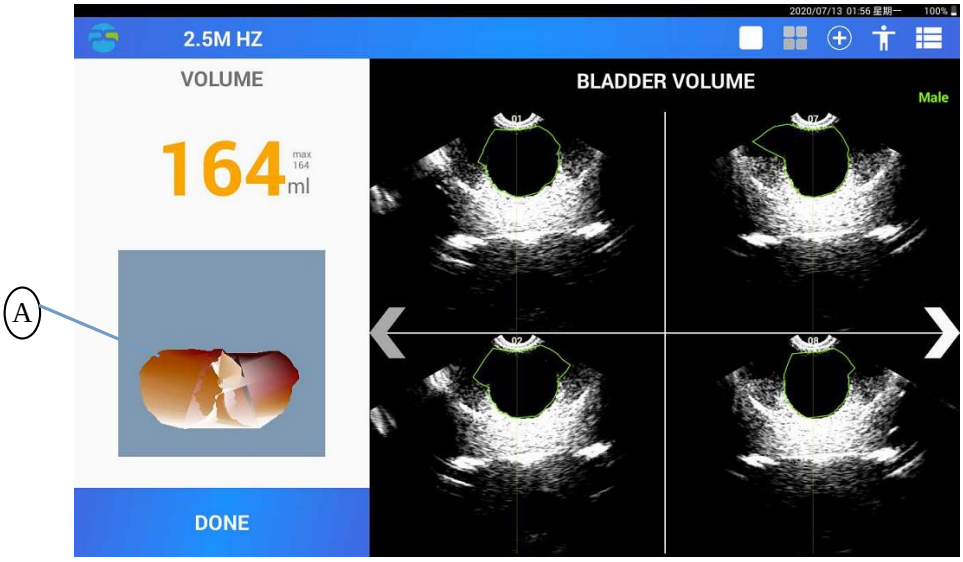


Figure 5-16 M5 Expert Mode Bladder 3D Images

A: Bladder 3D Image

5.17 Easy Mode Bladder 3D Image

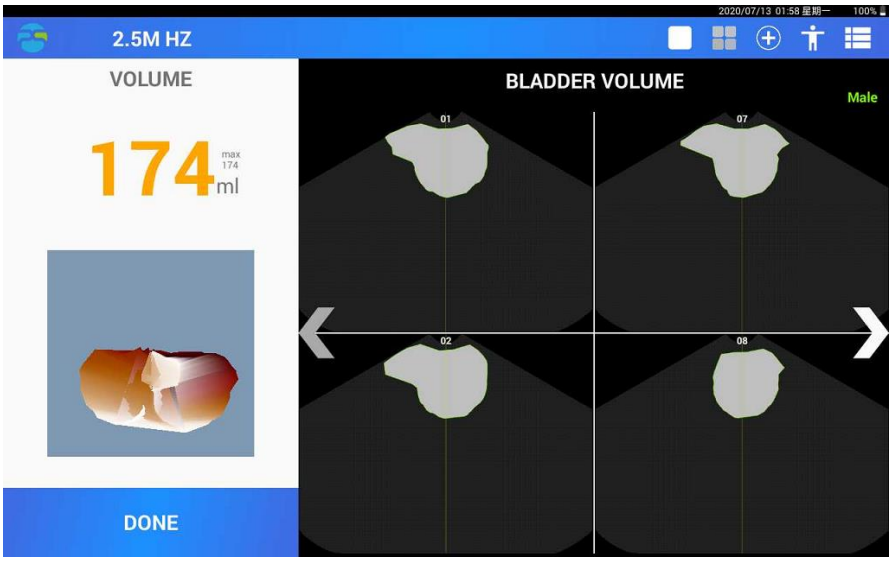


Figure 5-17 M5 Easy Mode Bladder 3D Images

5.18 Intelligence Mode Bladder 3D Image

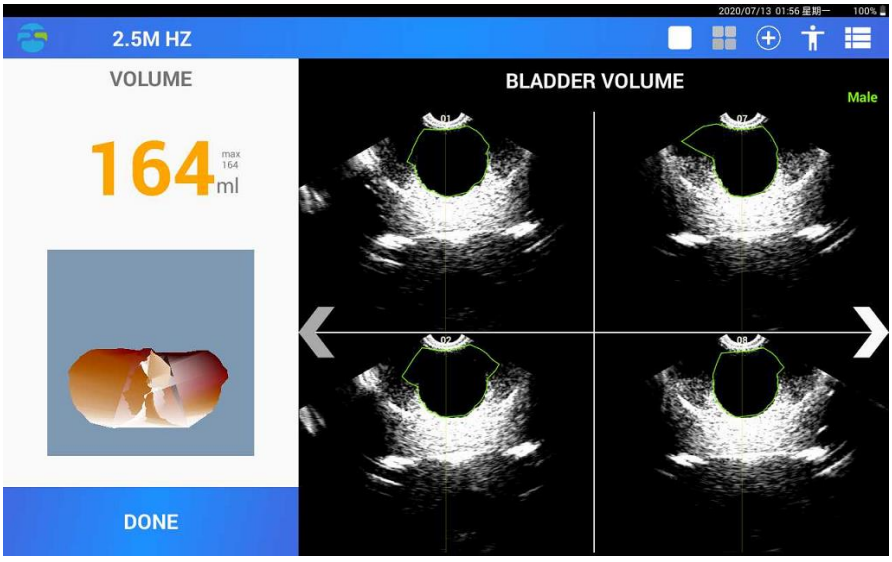


Figure 5-18 M5 Intelligence Mode Bladder 3D Images

Remark: Bladder 3D image interfaces of intelligence and expert modes are appearing the same

5.19 Bladder Wall Thickness Scan Interface

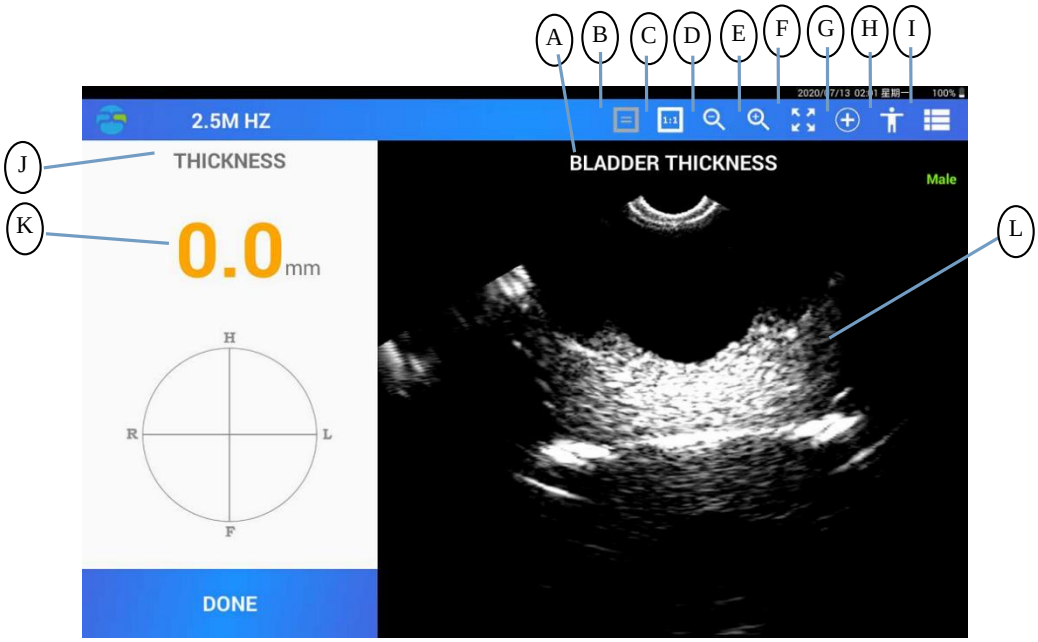


Figure 5-19 M5 Bladder Wall Thickness Scan Interface

A: Measurement Object

B: Bladder Wall Thickness Calculation Icon

C: Bladder Thickness Display

D: Reduce the Image

E: Enlarge the Image

F: Full Screen Image

G: Enter New Patient ID

H: Gender Selection

I: Patient History Information

J: Parameter (Thickness)

K: Bladder Wall Thickness Value

L: Bladder Wall B-Mode Scan Image

5.20 Bladder Wall Thickness Selection and Measurement

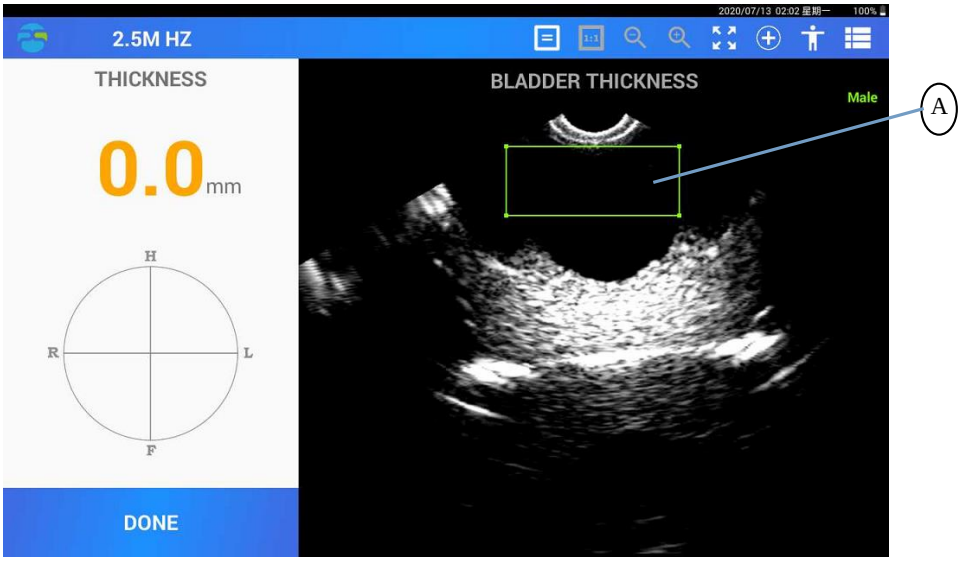


Figure 5-20 M5 Bladder Wall Thickness Measurement Interface

A: Bladder Wall Selection Window

5.21 Patient Information Edition, Storage and Print

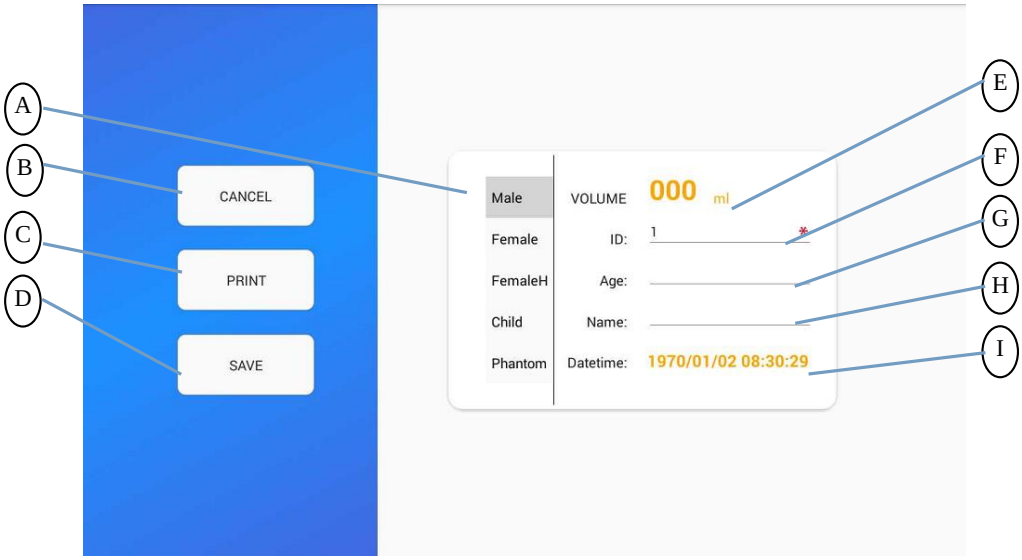


Figure 5-21 M5 Patient Information Edition, Storage and Print

A: Gender

B: Cancel

C: Print

D: Save

E: Measured Bladder Volume Value

F: ID Input

G: Age Input

H: Name Input

I: Measurement Date & Time

5.22 Patient History Information Browse and Login

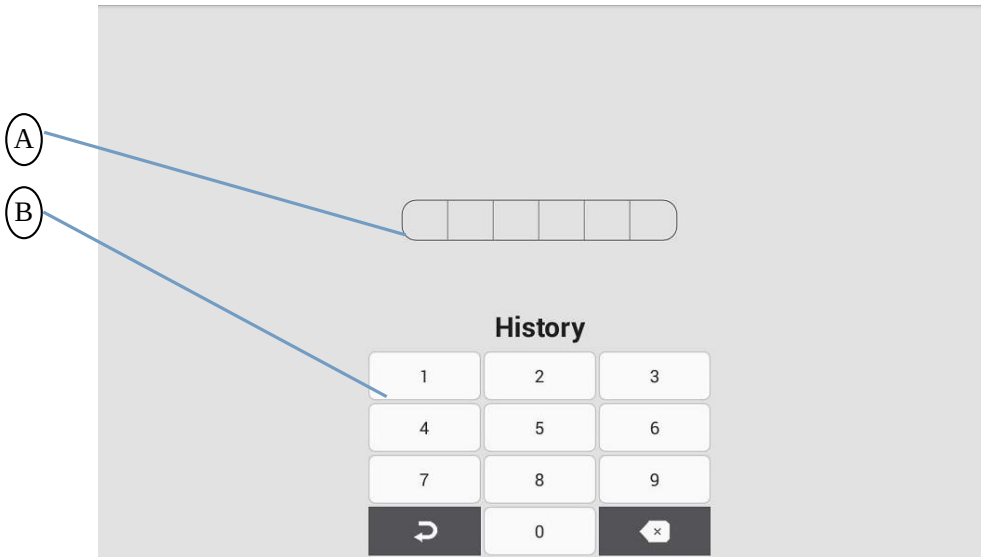


Figure 5-22 M5 Patient History Information Browse and Login

A: Login Password to Enter Database

B: Password Entry Keyboard

5.23 Patient History Information Main Page

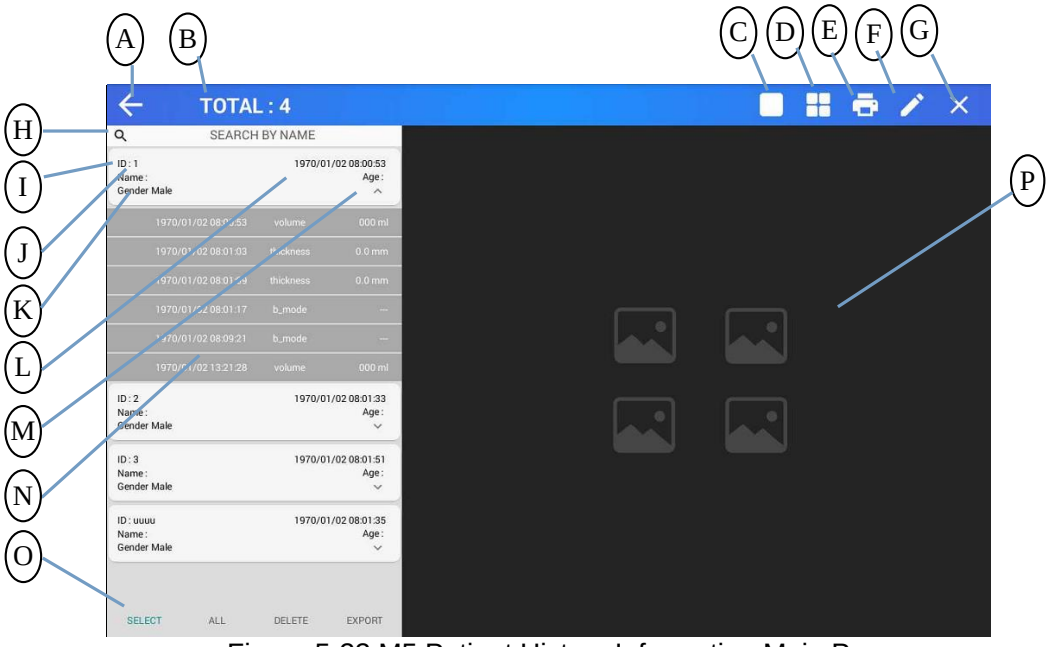


Figure 5-23 M5 Patient History Information Main Page

A: Return to the Home Page

B: Total Number of Patient Information

C: Image Display Gallery View

D: Image Display Grid View

E: Print Patient Information

F: Edit Patient Information

G: Delete Selected Patient Information

H: Search Patient Information

I: Saved Patient ID

J: Saved Name

K: Saved Gender

L: Saving Date & Time

M: Saved Age

N: Patient History Information Incl. Measurement Time, Parameter and Result

O: Delete or Export Information

P: Patient Image Information

.24 Bladder Volume Images - Gallery View

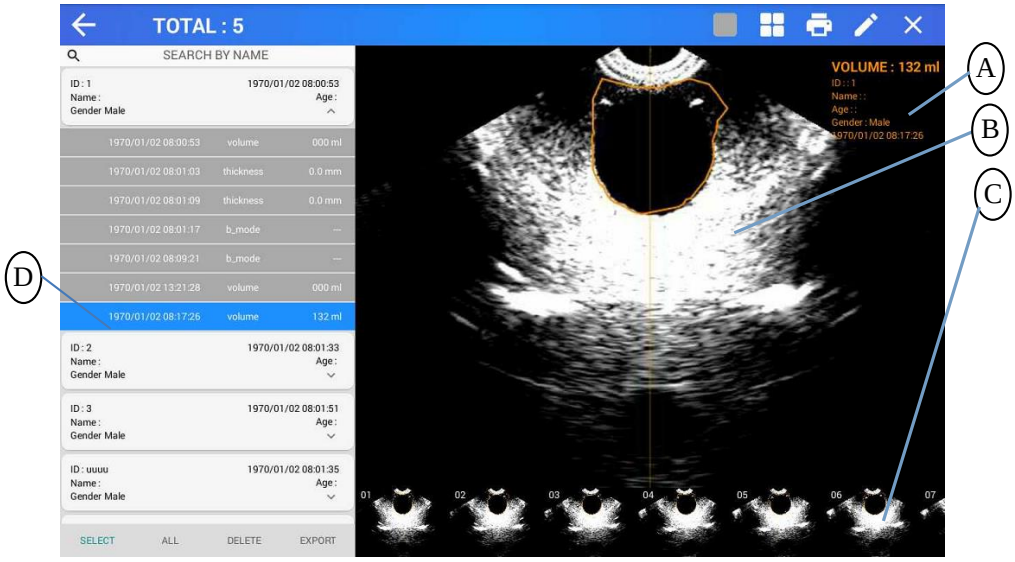


Figure 5-24 M5 Bladder Volume Images - Gallery View

A: Patient Basic Information

B: Enlarged B-Mode Image

C: Twelve B-Mode Images, Projection Images and 3D Images Display

D: Selected Patient Data (when selected the background color turns blue)

5.25 Bladder Volume Images - Grid View

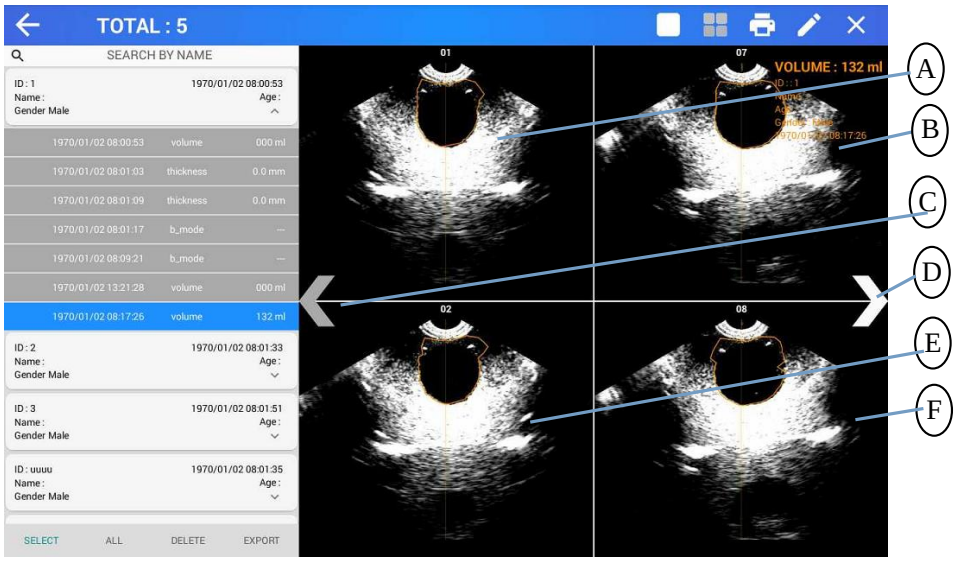


Figure 5-25 M5 Bladder Volume Images - Grid View

A: The First Image (Orthogonal to the second image)

B: The Second Image (Orthogonal to the first image)

C: Select the Current Four Images

D: Select the Next Four Images

E: The Third Image (Orthogonal to the forth image)

F: The Forth Image (Orthogonal to the third image)

5.26 Patient Bladder Wall Thickness Images

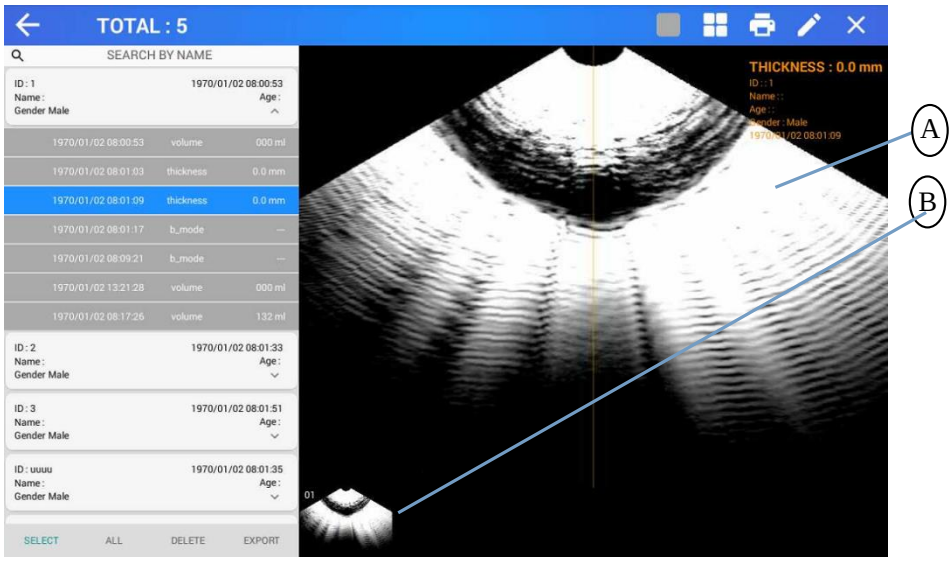


Figure 5-26 M5 Bladder Wall Thickness Images

A: Scan Image of the Bladder Wall Thickness (big in size)

B: Scan Image of the Bladder Wall Thickness (small in size)

5.27 Patient Information Deletion and Exportation

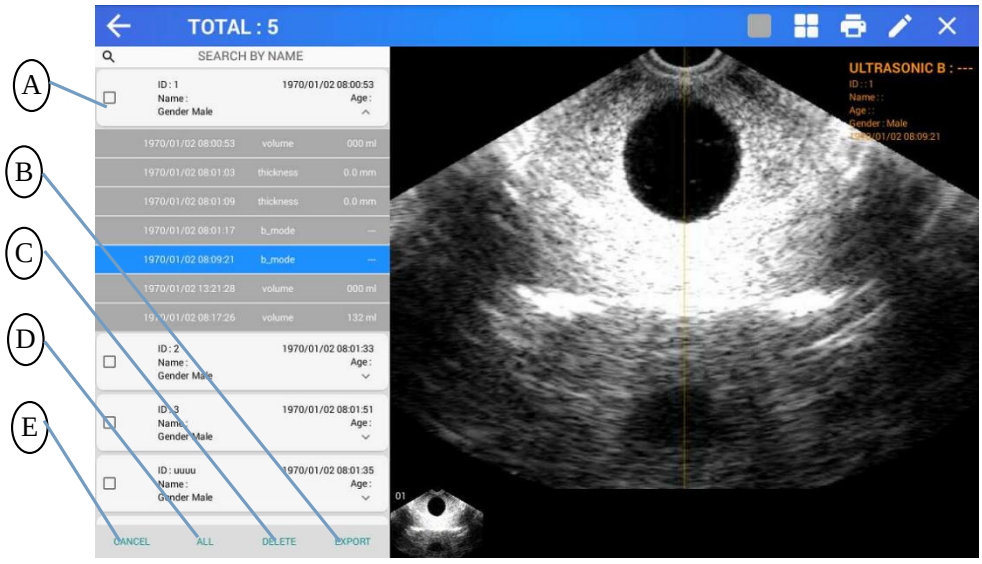


Figure 5-27 M5 Delete or Export Patient Information

A: Ticking Box of Patient Information

B: Export Patient Information

C: Delete Patient Information

D: Select All

E: Cancel the Previous Step(s)

5.28 Patient History Information Upload

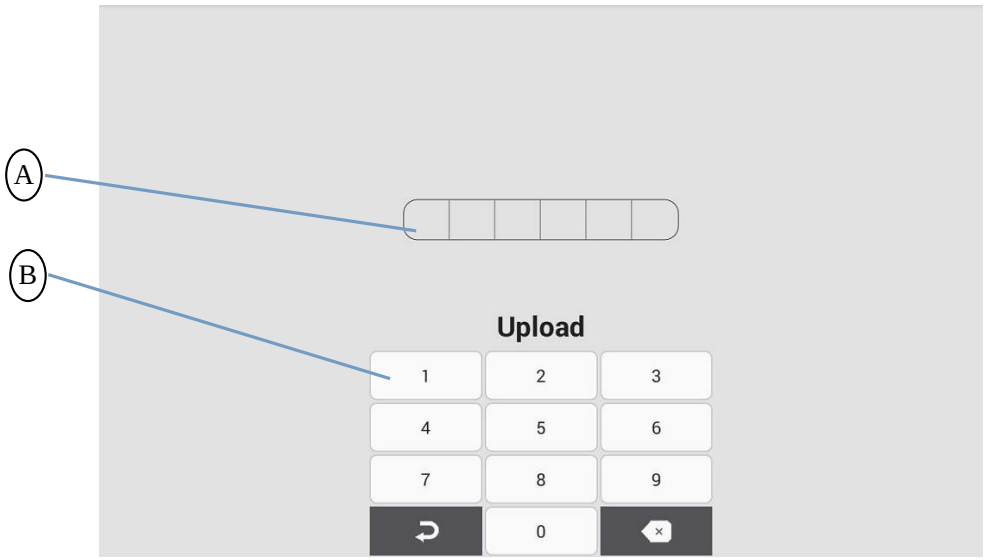


Figure 5-28 M5 Patient History Information Upload

A：Enter Login Password for Data Upload

B：Virtual Keyboard for Data Entry

5.29 Patient History Information Upload Interface

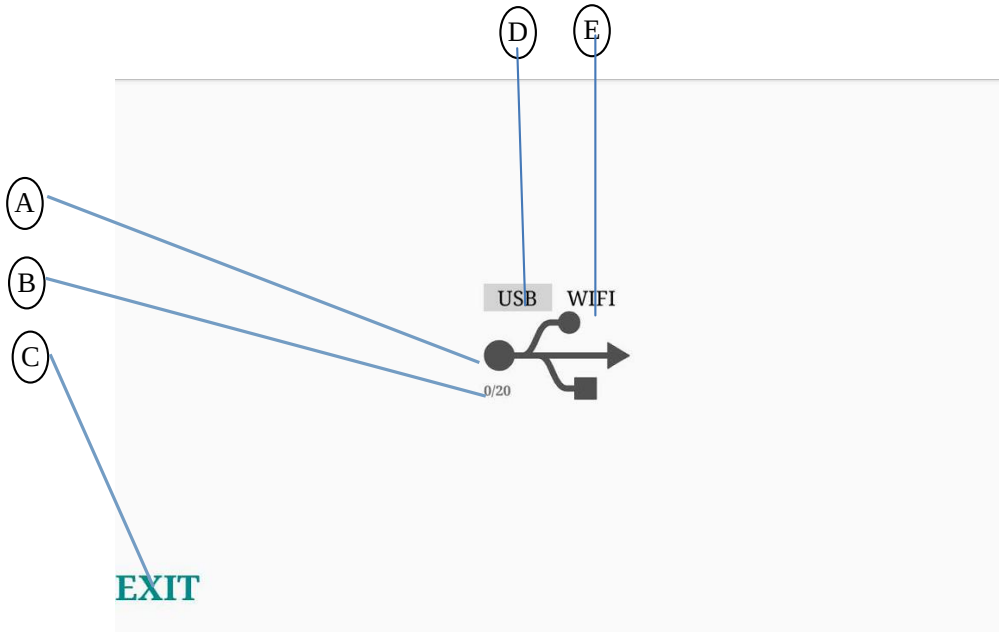


Figure 5-29 M5 Patient History Information Upload Interface

A：Data Connecting Approach B：Upload Progress

C：Return to Information Selection Interface

D：USB Connection

E：WIFI Connection

5.30 Patient History Information Batch Deletion

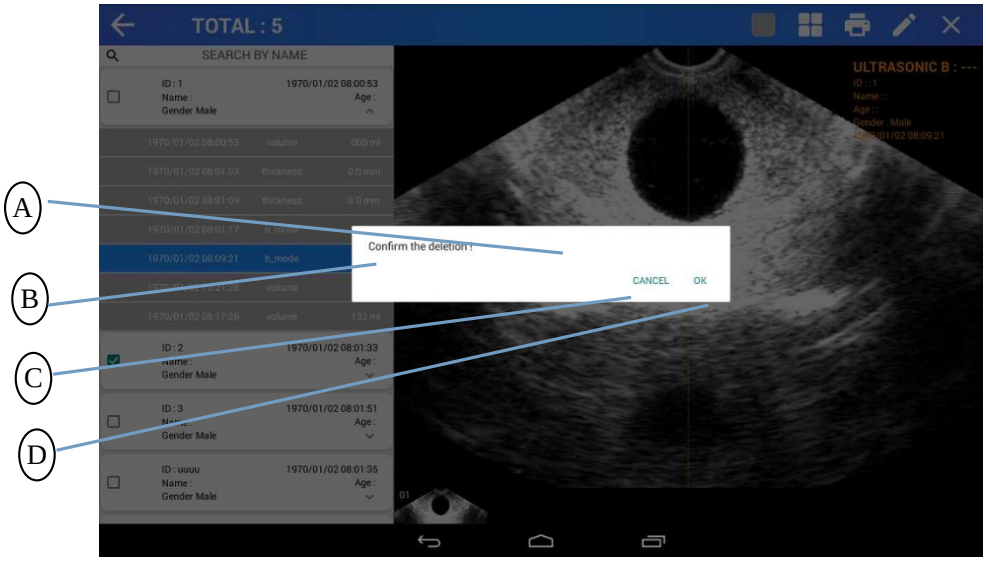


Figure 5-30 M5 Patient History Information Batch Deletion

A：Confirm Deletion Prompt

B：Prompt Message

C：Cancel Deletion

D：Confirm Deletion

5.31 System Setting Interface

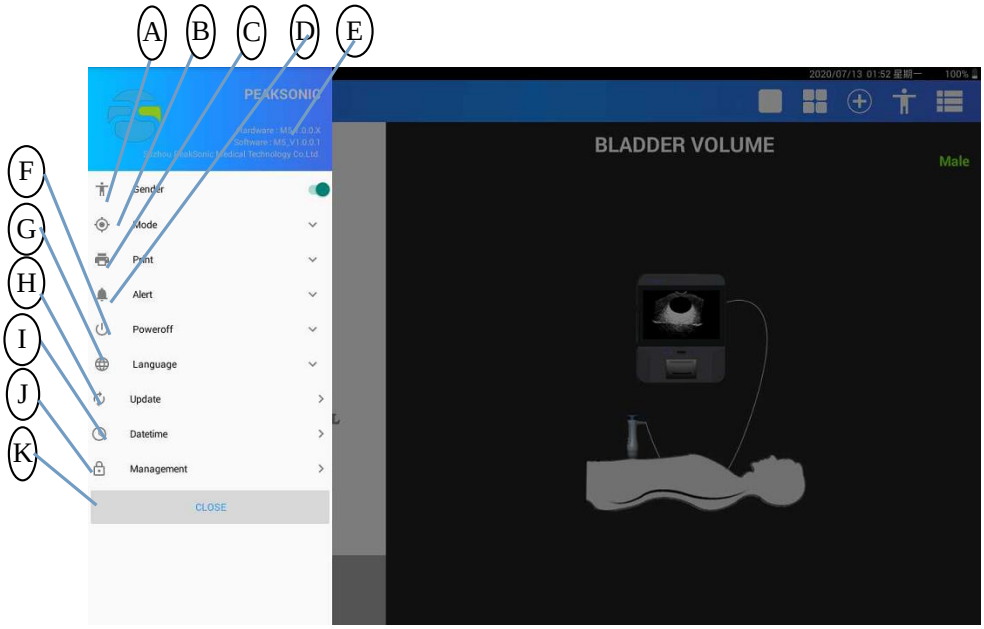


Figure 5-31 M5 System Setting

A: Select Gender

B: Select Operation Mode

C: Select to Print

D: Set up Volume Threshold Alert

E: General Information Display

F: Set up Automatic Shutdown Time

G：Select Language

H：Update Software

I：Set up Date and Time

J: Settings

K: Return to the Home Page

5.32 Operation Mode

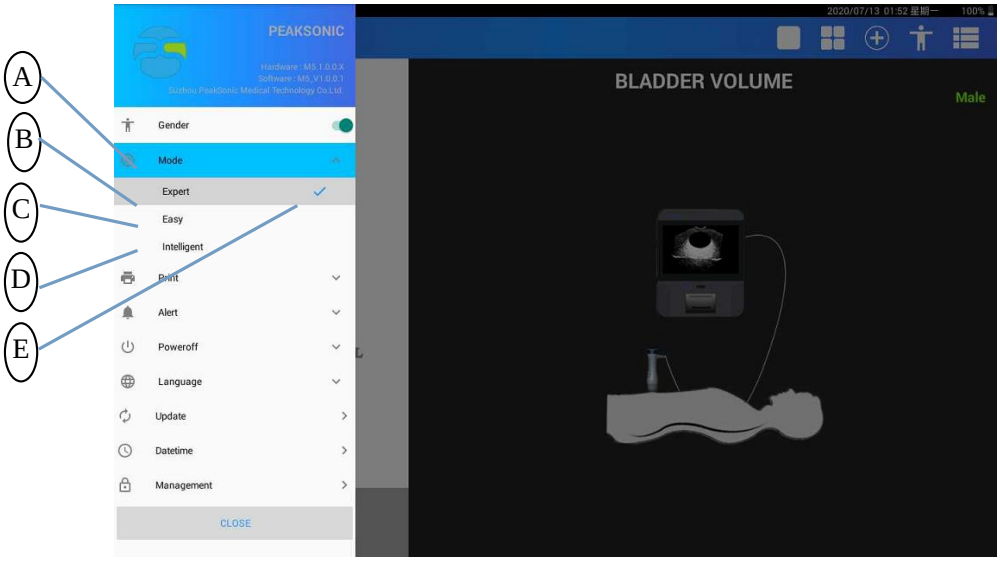


Figure 5-32 M5 Set up Operation Mode

A: Operation Mode Options

B: Option of Expert Mode

C: Option of Easy Mode

D: Option of Intelligence Mode

E: Confirm the Selection

5.33 Printing Options

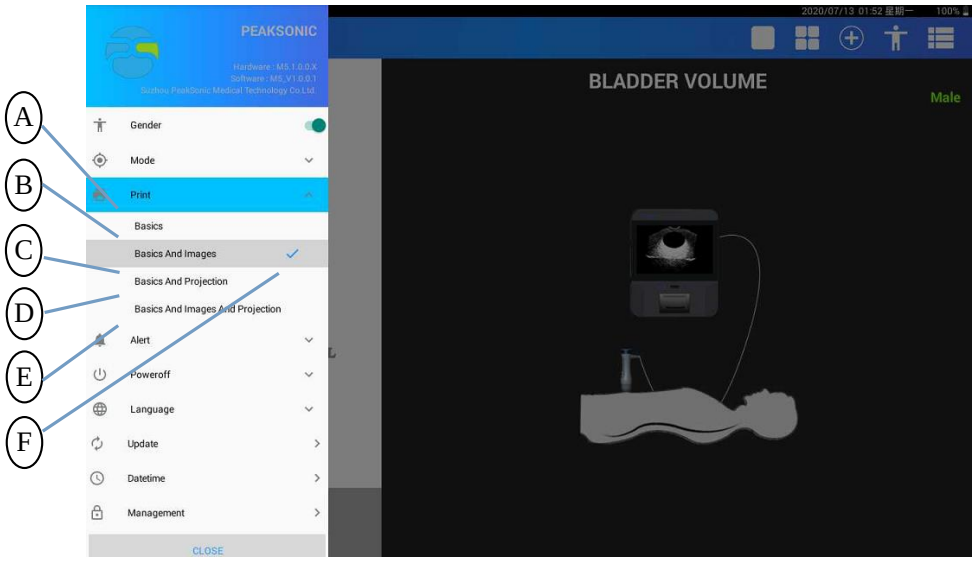


Figure 5-33 M5 Set up Print Interface

A: Select to Print Information

B: Option of Printing Basic Information

C: Option of Printing Basic Information and Two Orthogonal Ultrasound Images

D: Option of Printing Basic Information and Bladder Projection Image

E: Option of Printing Basic Information, Two Orthogonal Ultrasound Images and Bladder Projection Image

F: Tick to Confirm Printing

5.34 Set up Bladder Volume Threshold Alert

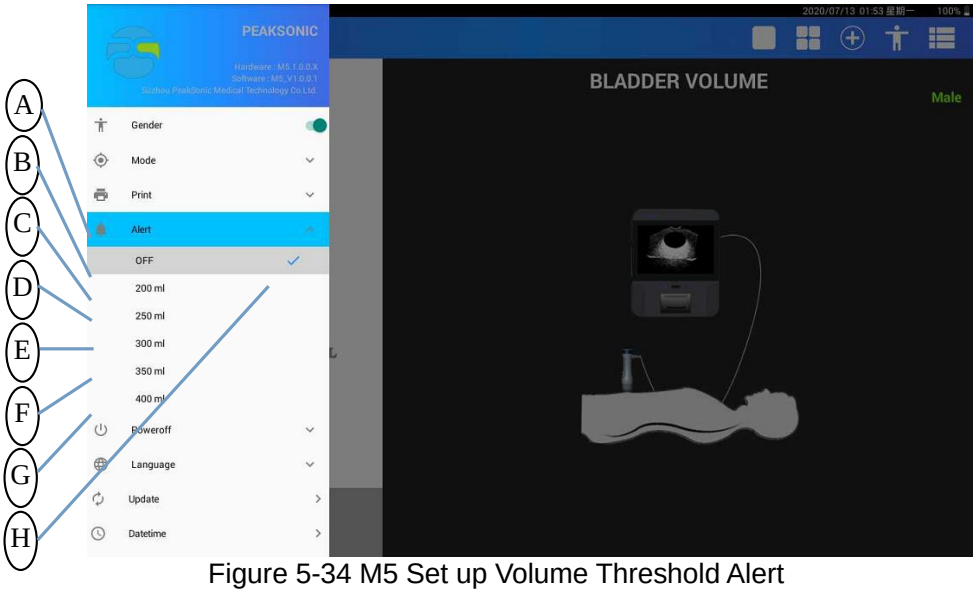


Figure 5-34 M5 Set up Volume Threshold Alert

A: Select to Set up Volume Threshold Alert

B: Turn off the Alert

C: Alert When the Bladder Volume Reaches 200ml

D: Alert When the Bladder Volume Reaches 250ml

E: Alert When the Bladder Volume Reaches 300ml

F: Alert When the Bladder Volume Reaches 350ml

G: Alert When the Bladder Volume Reaches 400ml

H: Confirm to Turn off the Alert

5.35 Set up Automatic Shutdown

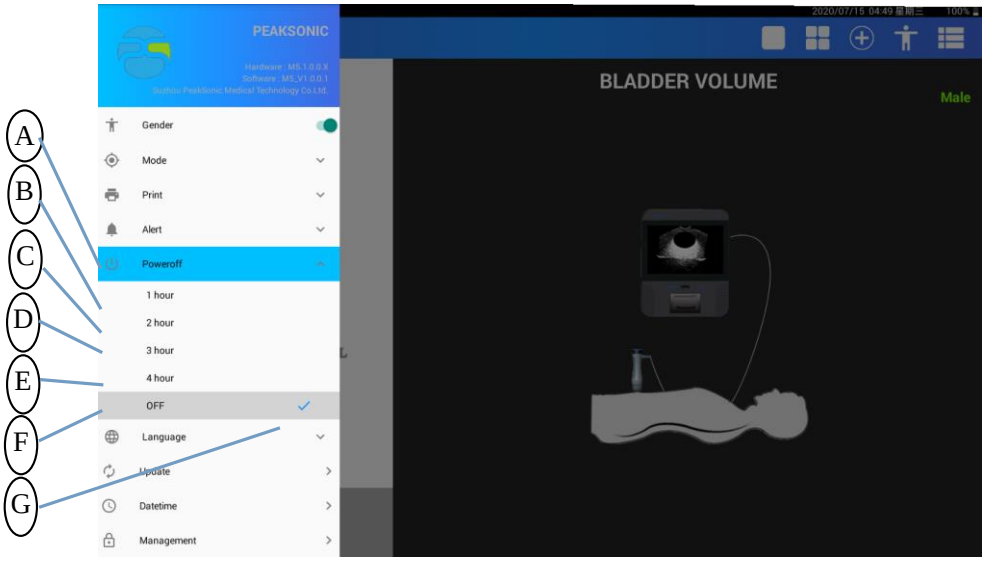


Figure 5-35 M5 Set up Automatic Shutdown

A: Select to Set up Automatic Shutdown

B: Shut down the Device in One Hour

C: Shut down the Device in Two Hours

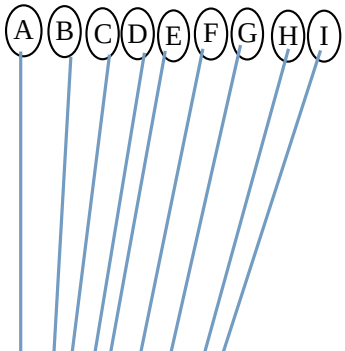
D: Shut down the Device in Three Hours

E: Shut down the Device in Four Hours

F: Turn off Automatic Shutdown

G: Confirm to Turn off Automatic Shutdown

5.36 Set up Language



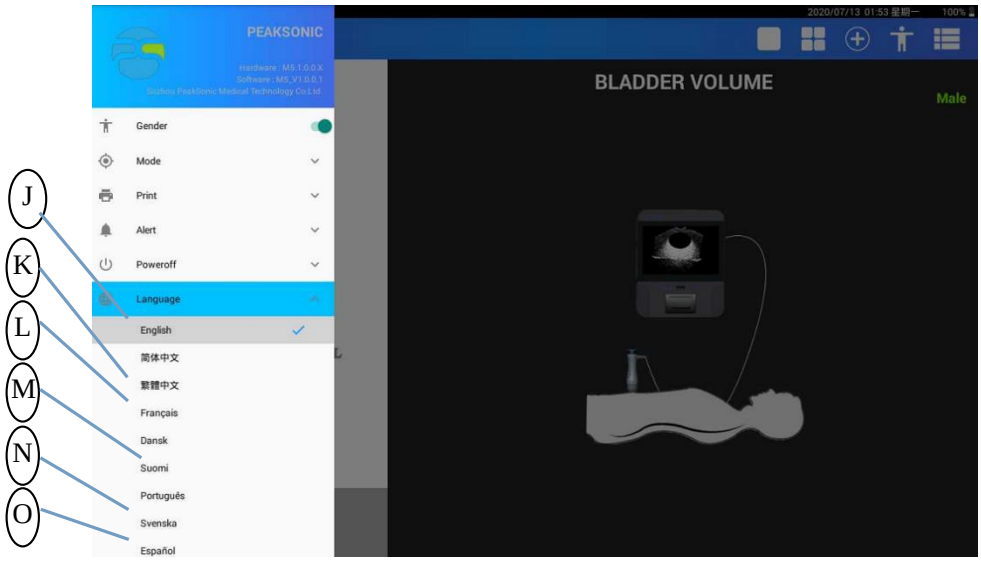


Figure 5-36 M5 Set up Language Interface

A: Select to Set up Language

B: Simplified Chinese

C: (Dansk) Danish

D: (Português) Portuguese

E: (Nederlands) Dutch

F: (Norsk) Norwegian

G: (Deutsch) German

H: Confirm to Select English

I: (Italiano) Italian

J: (English) English

K: Traditional Chinese

L: (Français) French

M: (Suomi) Finnish

N: (Svenska) Swedish

O: (Español) Spanish

Remark: scroll down the screen, options of Dutch, Norwegian, German and Italian will appear

5.37 Software Upgrade and Calibration Progress

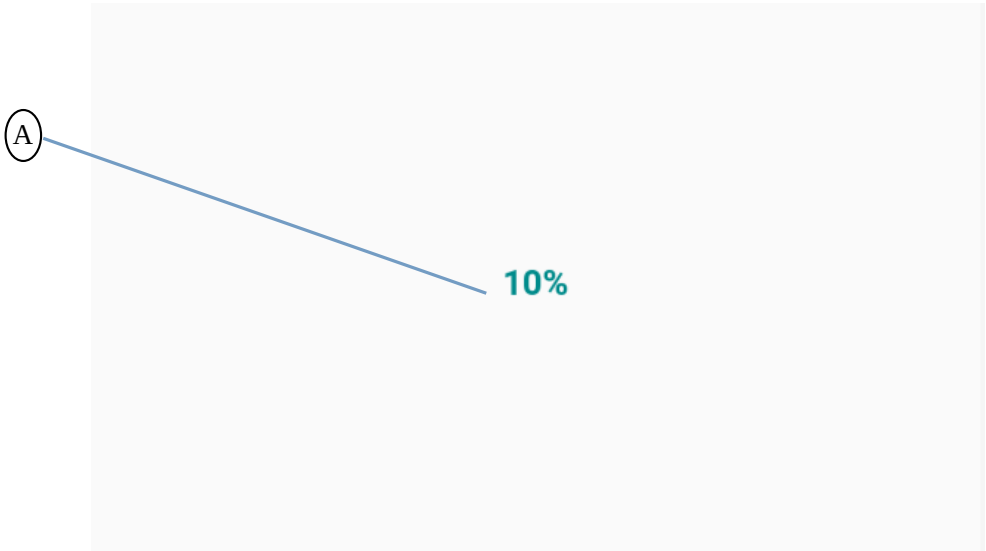


Figure 5-37 M5 Software Upgrade and Calibration Progress

A: Software Upgrade and Calibration Progress in Percentage

5.38 Set up Date and Time

Figure 5-38 M5 Set up Date & Time

A: Select to Set Date and Time

B: Select Time Zone

C: Set Date

D: Scroll Up and Down to Select Date

E: Scroll Up and Down to Select Month

F: Scroll Up and Down to Select Year

G: Select to Set Date and Time Automatically

H: Turn on Automatic Date & Time Set

I: Set Time

J: Scroll Up and Down to Set Hour

K: Scroll Up and Down to Set Minute

L: Scroll Up and Down to Select AM or PM

5.39 Login Management Interface

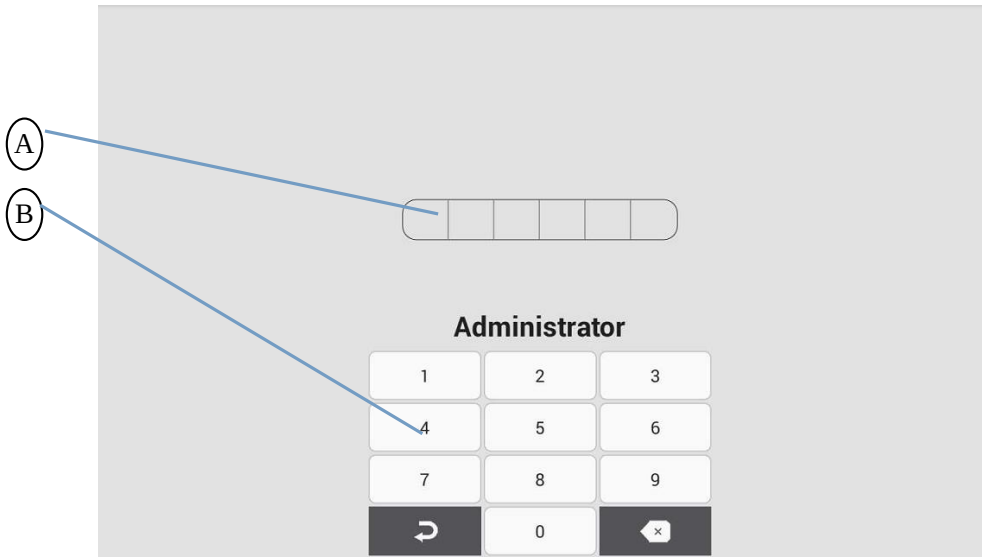


Figure 5-39 M5 Login Management Interface

A: Enter Login Password

B: Virtual Keyboard to Enter Password

5.40 Management Interface

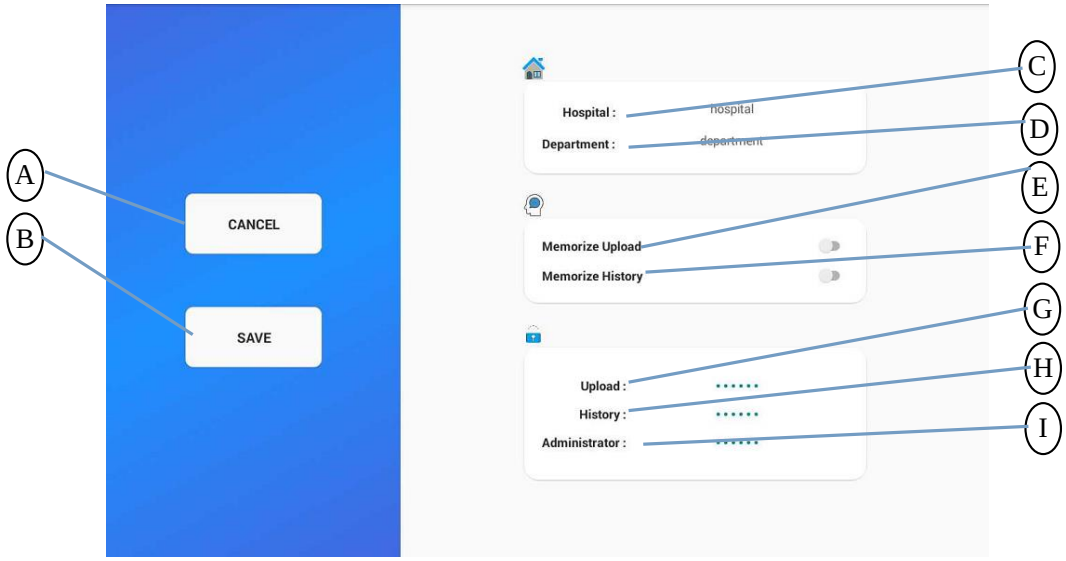


Figure 5-40 M5 Management Interface

A: Return to the Home Page

B: Save the Current Entry e.g. Password, Hospital Name, Department

C: Enter Hospital Name

D: Enter Department Name

E: Save Password for Data Upload

F: Save Password to Save History Information

G: Enter New Password for Data Upload

H: Enter New Password to Browse History Information

I: Enter New Password for Administrator

5.41 Probe Screen Display

Figure 5-41-1 M5 Company Logo

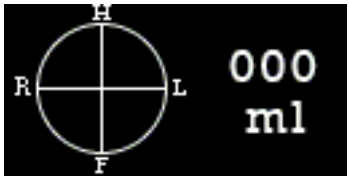


Figure 5-41-2 M5 Scan Complete Interface I

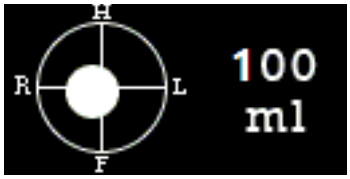


Figure 5-41-3 M5 Scan Complete Interface II

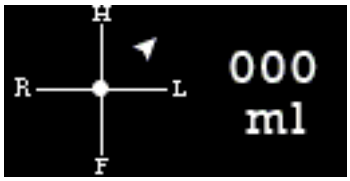


Figure 5-41-4 M5 Intelligence Mode Pre-scan Interface

Chapter VI Operation Procedure

6. 1 Startup and Shutdown

Long press the power button to switch on the device. After about 3 seconds, the company logo PEAKSONIC appears (Figure 5-1), and the main page is displayed in about 30 seconds. When the instrument is turned on, press the power button for a few seconds, the instrument enters the screen saver state and the screen turns black. Press the power button again to release the screen saver, and the instrument will resume its working state.

Long press the power button again to shut down the device. Wait for about 13 seconds till the power supply of the instrument is cut off.

6.2 Operation Function Selection

Select the operation function on the main page (Figure 5-2), and press the "D" position to choose the measurement object between bladder volume and bladder wall thickness.
When the bladder volume measurement function is selected, the volume value xxml and the maximum volume value, 3D images and projection images are displayed on the left side of the screen. Scan completion icon DONE appears at the bottom left of the screen. After scanning, click this key to enter patient information input, editing, storage and printing. The hospital name, department name, date and time, battery power are displayed at the top right end of the screen, followed by setting Icon, probe frequency 2.5M HZ, gallery view icon, grid view icon, add new patient icon, gender selection, patient history information review. On the right side of the screen, gender information appears below the patient history information review icon.

Slide the figure up and down to the left or right side of the bladder projection circle, the screen brightness adjustment icon will appear. Along with the finger movement up and down, the brightness of the screen also changes.

Remark: The icons are active when the color is white. When it turns grey, it means they system is not responding. Only after scan is completed, scan completion icon DONE becomes active.

When the bladder wall thickness measurement is selected, the thickness value xxmm, 3D images and projection images are displayed on the left side of the screen. Scan completion icon 

appears at the bottom left of the screen. After scanning, click this key to enter patient information input, editing, storage and printing. The hospital name, department name, date and time, battery power are displayed at the top right end of the screen, followed by setting Icon  , probe frequency 

, gallery view icon  , grid view icon  , add new patient icon  , gender selection  , patient history information review  . On the right side of the screen, gender information appears below the patient history information review icon. Slide the figure up and down to the left or right side of the bladder projection circle, the screen brightness adjustment icon will appear. Along with the finger movement up and down, the brightness of the screen also changes.

Remark: The icons are active when the color is white. When it turns grey, it means they system is not responding. Only after scan is completed, scan completion icon 

becomes active.

6.3 Gender Selection

Select gender icon  on the main page, gender selection menu appears (Figure 5-3) including options as Male, Female, FemaleH, Child and Phantom. The selected gender appears on the up right corner of the screen after the choice is made. By default gender selection is Male.

6.4 Bladder Volume Measurement Scan

On the main interface (Figure 5-2) press the "D" position to choose the measurement object “Bladder Volume” to enter scan interface.

6.4.1 Bladder Pre-scan

Apply the coupling agent to the surface of the probe which is the main contact area with the patients. Place the probe on the skin of the lower abdomen where bladder is located. Press SCAN button once to start pre-scan. Under expert mode, real-time B-Mode image of the bladder (Figure 5-4) appears in the screen. Cross-sectional image of the bladder (Figure 5-8) appears under easy mode and bladder projection images are displayed under intelligence mode and meanwhile B-mode images appear on the left part of the screen.

Under pre-scan of the expert mode, observe the B-Mode images and move the probe till the biggest image is obtained. While achieving the biggest B-Mode image, make sure the centre of the ultrasonic

image aligns with the green indication line in the middle of the screen.

Under pre-scan of the easy mode, observe the bladder sections and move the probe till the biggest section is obtained. While achieving the biggest sectional view, make sure the centre of the section aligns with the middle point of green indication line.

Under pre-scan of the intelligence mode, observe the position of the bladder projection. If the projection image is off the centre of the crosshair, indication arrows (←↑→↓↖↗↘↙) will appear to guide the moving direction of the probe. Move the probe by following the direction of the arrows till the projection image reaches the centre of the crosshair. When the projection image is green, it means bladder centre has been located. Otherwise it turns to orange.

Under all three operation modes, the brightness of the screen could be adjusted by putting the figure next to the projection image and moving it upside down on the touch screen.

Remark:
During pre-scan some functions are locked including gender selection, patient information edition, storage and print, as well as setting. Icons of those functions turn to grey. After the pre-scan is completed, those functions get unlocked.

When the color of the icons is white, it means those functions are unlocked and can be used. When it turns grey, the functions are locked and cannot be used.

6.4.2 Bladder Scan

After bladder is positioned, keep the probe still and press SCAN button. 3D probe starts to scan.

6.4.2.1 Expert Mode

During scan twelve B-Mode images are displayed on the right side of the screen. Serial number of the images increases from 01 to 12. When it appears as 12/12, it means scan, image analysis and volume calculation is completed.

Under gallery view, bladder volume and 3D bladder projection appears on the left side of the screen. the twelve images are displayed on the bottom right of the screen side by side. Slide left or right to view all twelves images. Tap on any of them, an enlarged image appears.

Under grid view, bladder volume and 3D bladder projection appears on the left side of the screen as same

as the gallery view. In the image display zone on the right side of the screen four images will be displayed which are 01 and 07 above and 02 and 08 below. Every two images are displayed orthogonally. Press > to display the combination of 03 and 09 on top and 04 and 10 on the bottom. Press > again to display the combination of 05 and 11 on top and 06 and 12 on the bottom. Press < to display the orthogonal combination which is opposite to the previous ones.

Gallery view is the view by default. Scan interface of the expert mode as shown in Figure 5-5. Gallery view after scan completion as shown in Figure 5-6 and grid view after scan completion as shown in Figure 5-7.

Remark: if the bladder volume is measured a couple of times for one patient at once, only the highest value will be shown.

6.4.2.2 Easy Mode

During scan twelve bladder sections are displayed on the right side of the screen. Serial number of the images increases from 01 to 12. When it appears as 12/12, it means scan, image analysis and volume calculation is completed.

Under gallery view, bladder volume and 3D bladder projection appears on the left side of the screen. By default the first image is enlarged and shown on the up right part of the screen and above the twelve images displayed on the bottom right side by side. Slide left or right to view all twelves images. Tap on any of them, an enlarged image appears.

Under grid view, bladder volume and 3D bladder projection appears on the left side of the screen as same as the gallery view. In the image display zone on the right side of the screen four images will be displayed which are 01 and 07 above and 02 and 08 below. Every two images are displayed orthogonally. Press > to display the combination of 03 and 09 on top and 04 and 10 on the bottom. Press > again to display the combination of 05 and 11 on top and 06 and 12 on the bottom. Press < to display the orthogonal combination which is opposite to the previous ones.

Gallery view is the view by default. Scan interface of the expert mode as shown in Figure 5-9. Gallery view after scan completion as shown in Figure 5-10 and grid view after scan completion as shown in Figure 5-11.

Remark: if the bladder volume is measured a couple of times for one patient at once, only the highest value will be shown.

6.4.2.3 Intelligence Mode

During scan twelve B-Mode bladder images are displayed on the right side of the screen. Serial number of the images increases from 01 to 12. When it appears as 12/12, it means scan, image analysis and volume calculation is completed.

Under gallery view, bladder volume and 3D bladder projection appears on the left side of the screen. By default the first image is enlarged and shown on the up right part of the screen and above the twelve images displayed on the bottom right side by side. Slide left or right to view all twelves images. Tap on any of them, an enlarged image appears.

Under grid view, bladder volume and 3D bladder projection appears on the left side of the screen as same as the gallery view. In the image display zone on the right side of the screen four images will be displayed which are 01 and 07 above and 02 and 08 below. Every two images are displayed orthogonally. Press **>** to display the combination of 03 and 09 on top and 04 and 10 on the bottom. Press > again to display the combination of 05 and 11 on top and 06 and 12 on the bottom. Press < to display the orthogonal combination which is opposite to the previous ones.

Gallery view is the view by default. Scan interface of the expert mode as shown in Figure 5-13. Gallery view after scan completion as shown in Figure 5-14 and grid view after scan completion as shown in Figure 5-15.

Remark: if the bladder volume is measured a couple of times for one patient at once, only the highest value will be shown.

Under all three operation modes, the brightness of the screen could be adjusted by putting the figure next to the projection image and moving it upside down on the touch screen.

6.5 Check Bladder Volume Ultrasonic Images, Sections, Projections or 3D Images

The system returns to scan complete interface once scan is accomplished. For expert mode, the scan complete interface as shown in Figure 5-6. For easy mode, the scan complete interface as shown in Figure 5-10 or Figure 5-11. For intelligence mode, the interface as shown in Figure 5-14 or Figure 5-15.

Once gallery view is chosen, bladder volume and 3D bladder projection appears on the left side of the screen. By default the first image is enlarged and shown on the up right part of the screen and above the

twelve images displayed on the bottom right side by side. Slide left or right to view all twelves images. Tap on any of them, an enlarged image appears.

Once grid view is chosen, bladder volume and 3D bladder projection appears on the left side of the screen. In the image display zone on the right side of the screen four images will be displayed in grid which are 01 and 07 on the top and 02 and 08 on the bottom. Every two images are displayed orthogonally. Press > to display the combination of 03 and 09 on top and 04 and 10 on the bottom. Press > again to display the combination of 05 and 11 on top and 06 and 12 on the bottom. Press < to display the orthogonal combination which is opposite to the previous ones. Below the bladder volume displayed on the left part of the screen, bladder projection is shown in a crosshair. Tap on the projection to view 3D image (as shown in Figure 5-16, 5-17 and 5-18). Or tap on the 3D image to view projection. Projection image is shown in scan complete interface.

Under expert or easy mode, if the centre of the bladder projection is in line with the centre of the crosshair in the scan complete interface and the color is green, it means the bladder has been correctly targeted. Otherwise the color of the bladder projection turns orange.

6.6 Bladder Wall Thickness Measurement

On the main page (Figure 5-2), tap on function selection to choose BLADDER THICKNESS and enter scan interface (Figure 5-19).

6.6.1 Bladder Wall Thickness Scan

Apply the coupling agent to the tip of the probe which is the main contact area with the patients. Place the probe on the skin of the lower abdomen where bladder is located. Press SCAN button once, bladder 2D image appears and scan starts. The transducer of the probe only swings back and forth in a two-dimensional plane of 120 degrees. Move the probe till position of the bladder wall is located, press SCAN again, 2D ultrasonic image gets frozen which means the scan is completed. This image is used to select the bladder wall and calculate the thickness.

Tap on the white space next to the projection circle, a bar for brightness adjustment appears. Slide up and down to adjust the brightness of the screen.

6.6.2 Bladder Wall Thickness Selection and Measurement

Firstly select the part of the bladder wall for measurement. Before confirm selection, press  to display

1:1 image for further selection. Press  or  to zoom in and out. Keep the figure contact with the screen to move the image up and down, left and right so that the targeted part could be moved to the centre of the display area. The alternative is not to conduct any of the above mentioned movement to have the original image displayed.

Press  to enlarge bladder wall selection window. Keep pressing the window and move up and down or left and right till the selected area is targeted. Or keep the figures on the corner of the window to reduce or enlarge it. After the selection is done, press  to calculate the thickness. Once the calculation is done, the measurement result will appear on the screen as shown in Figure 5-20.

Remark: System would not respond when the color of the icon turns grey. When it becomes white, it's activated. Once the scan is completed, the icon 

will be activated.

6.7 Patient Information Entry, Edit, Storage and Print

Press 

after the scan is completed to enter patient history information database for editing, saving and printing the data (Figure 5-21). In this interface patient bladder volume value, wall thickness value, checking date and time and gender are saved. Gender is changeable while the rest cannot be modified. Enter patient ID, age, name for further saving and printing. Tap

to return to the main interface.

6.7.1 Enter and Edit Patient Information

In the interface as shown in Figure 5-21 patient information could be edited, saved or printed. Enter gender, ID, Age and Name to complete patient profile.

6.7.2 Save Patient Information

Tap 

to save the patient information entered. The save information is encrypted. User could enter the data then save them or save data partially then complete the data entry. Patient information saved includes patient ID, age, gender, save date & time. Additionally bladder volume value, twelve ultrasonic images, 3D images, projection images obtained during bladder volume measurement and bladder wall thickness value, one piece of B-mode image obtained during bladder thickness measurement are also saved in the database.

6.7.3 Print Patient Information

Tap PRINT to print out the information from the database. Before printing, data need to be decrypted. Data entry could happen before or after the printing. Patient ID, age, gender, save time & date, bladder volume value, two orthogonal B-ultrasound images(optional), bladder projection image(optional) can be printed. In case bladder wall thickness is measured, the relevant data could be printed as well which are bladder wall thickness value and one piece of wall thickness B-mode image.

6.8 Browse Historical Information

Press patient information browse icon  on the main page to enter login page. After login successfully users could see an interface which contains total number of patients, search column, patient information list, patient information editing, writing and deleting icons, related images, gallery view, grid view icon and icon to return to the home page.

Select one of the patient information out of the list, tap  to edit the information including ID, age, name, gender. Press SAVE to save the newly added information or changes. Return to the home page after saving. Press PRINT to print out the data. Alternatively press  on the patient history information interface to print. Select one of the patients and tap  for deletion.

6.8.1 Browse and Login Patient History Information

Press  on the main page to view patient history information. Enter password to login patient history information interface. The initial password is 000000 (six zero). Tap  to return to the main page.

6.8.2 Patient History Information Main Interface

Login patient history information interface (Figure 5-23) where users could see total number of patients, patient history information search column  , patient information list, patient information editing, deleting and printing icons, bladder images, gallery view icon, grid view icon and return to the main page icon.

Press patient history information search column, virtual key board pops up. Enter patient name and press , the system will then start searching required information in the database. If the patient has a couple of history information saved in the system, press v below the age to display all the information at chronological order. Tap ∧ to collapse the list. Select one patient out of the list, tap to edit the information. Tap to print the information. And tap to delete the information.

6.8.3 Edit Patient History Information

Press v below the age to display all the information at chronological order. Select one piece by pressing on it using figure. Once it's selected the background color changes from grey to blue. Press to edit, save or print as shown in Figure 5-21.

On the patient history information editing page, enter ID, age, name, select gender, then press SAVE to save the new entry. Press PRINT to print. Once data is saved, system automatically returns to the history information main page. By pressing CANCEL system also automatically returns to the history information main page. On the editing page, bladder volume value, bladder thickness value and editing time are not editable by users.

6.8.4 Delete Patient History Information

There are two way to delete data: Single deletion and batch deletion.

Single deletion: Press v below the age to display all the information at chronological order. Select the single piece which need to be deleted by tapping on it. The background color changes from grey to blue indicating it is selected. Press . Once the deletion is done, system returns to the history information main interface.

Batch deletion: there are four options in the bottom menu SELECT ALL DELETE EXPORT. Tap SELECT to select the information for deletion or exportation. Tap ALL to select all. Tap DELETE to delete in

batches. Tap EXPORT to upload the information to PC. Tap SELECT to enter information deletion and exportation interface (Figure 5-27) on which SELECT becomes CANCEL. ALL DELETE EXPORT turns green ALL DELETE EXPORT indicating they are activated.

Press SELECT, a white tick box ☐ appears in front of each line. Tick the box √ to select the ones need to be deleted. The background color turns to green once it's selected. Press ALL to select all lines. Then tap on DELETE. A prompt "Confirm the deletion？" Pops up. Press OK to delete and CANCEL to cancel and return to the previous interface.

6.8.5 Export Patient History Information

There are four options in the bottom menu SELECT ALL DELETE EXPORT. Tap SELECT to select the information for deletion or exportation. Tap ALL to select all. Tap DELETE to delete in batches. Tap EXPORT to upload the information to PC. Tap SELECT to enter information deletion and exportation interface (Figure 5-27) on which SELECT becomes CANCEL. ALL DELETE EXPORT turns green ALL DELETE EXPORT indicating they are activated.

Press SELECT, a white tick box ☐ appears in front of each line. Tick the box √ to select the ones need to be exported. The background color turns to green once it's selected. Press ALL to select all lines. Tap EXPORT to enter patient history information upload login interface (Figure 5-28). Enter password to login (Figure 5-29). The original password is 000000(six zero). Data connection could be through USB or WIFI. In case of USB, connect the device with PC by USB cable. In case of WIFI, the device is connected with WIFI automatically. Once way of data connection is selected, data start to be exported to PC. The upload progress is displayed in the prompt like x/y. "x" represents the number of cases that have been exported and "y" represents the total number of cases to be exported. After exportation is done, press EXIT to return to the previous page.

6.8.6 Browse Bladder Volume Scan, 3D and Projection Images

Twelve bladder scan images are displayed in the history information display area once a patient is selected. Choose  to have gallery view and choose  to have grid view.

Twelve images in gallery view as shown in Figure 5-24. Slide the images on the bottom left or right to view the twelve scan images, 3D images and projection images. Tap on one of the twelve, the image will be enlarged and appear in the middle of the screen.

Twelve images in grid view as shown in Figure 5-25. In the image display zone on the right side of the screen four images will be displayed in grid which are 01 and 07 on the top and 02 and 08 on the bottom. Press > to display the combination of 03 and 09 on top and 04 and 10 on the bottom. Press > again to display the combination of 05 and 11 on top and 06 and 12 on the bottom. Press > again to display projection and 3D images. Press < to display the previous orthogonal combination. The two images displayed horizontally on the screen are a group of images, and each group is an orthogonal combination.
On the up right corner of the screen, bladder volume, patient ID, name, age, gender and date&time are displayed.

6.8.7 Browse Scan Image of Bladder Thickness

Bladder thickness scan image is as shown in Figure 5-26. Once bladder thickness of a patient is selected in the history information interface, two scan images will appear, a big one and a small one. On the up right corner of the screen, bladder thickness, patient ID, name, age, gender and date&time are displayed.

6.9 Settings

On the main page (Figure 5-2) or scan complete interfaces (Figure 5-6, 5-7, 5-11, 5-14, 5-15), press setting icon  to enter setting interface (Figure 5-31). System setting menu is on the left side of the screen. Setting parameters include gender, mode, print, alert, automatic shutdown, language, calibration, upgrade, management, date&time, and information review. Swipe the menu to the left, the menu will disappear and the system returns to the main page. Or press

to return to the main page.

There are eleven options in setting menu which are explained in details in the following text.

Remark: the option of calibration normally does not show in the menu until user tap  continuously for six times. Calibration can be carried out once this option appears in the menu.

6.9.1 Set Gender

Tap on “Gender” in the system setting menu (Figure 5-31) and activate it by pushing the button to the right and color turns to green.  appears on the up right corner of the screen. Tap on it to see the list which includes male, female, femaleH, child and phantom. Press “gender” again to collapse the list.

6.9.2 Set Operation Mode

Press “Mode” in the menu to choose operation mode (Figure 5-32). There are three operation modes: expert mode, easy mode and intelligence mode. By default the system chooses expert mode.  appears behind the selected operation mode once the choice is made.

Under expert mode, press SCAN button to start bladder pre-scan. B-ultrasound image appears on the screen. Move the probe to search for the biggest bladder image. Press SCAN again when the biggest bladder image is located and the green indication line in the middle of the screen aligns with the centre of the image. During scan twelve B-ultrasound images and their serial number are displayed. The serial number increases from 01/12. Once it reaches 12/12, scan, image analysis and calculation are accomplished. Automatically the first image (01/12) is displayed on the screen and below that the rest are displayed in gallery view. Bladder volume and projection images are also shown on the screen. Tap on the projection to see 3D image or tap on the 3D image to return to the projection view. When the projection image appears green, it means scan is on target. Otherwise the color changes to orange.

Under easy mode, press SCAN to start pre-scan. Move the probe to search for the biggest bladder section. Press SCAN again when the biggest bladder section is located and the green indication line in the middle of the screen aligns with the centre of the image. During scan twelve B-ultrasound images and their serial number are displayed. The serial number increases from 01/12. Once it reaches 12/12, scan, image analysis and calculation are accomplished. Automatically the first image (01/12) is displayed on the screen and below that the rest are displayed in gallery view. Bladder volume and projection images are also shown on the screen. Tap on the projection to see 3D image or tap on the 3D image to return to the projection view. When the projection image appears green, it means scan is on target. Otherwise the color changes to orange.

Under intelligence mode, press SCAN to start pre-scan. During pre-scan bladder projection image appears on the screen. Observe the projection image, if it’s off the target eight indication arrows (←↑→↓↖↗↘↙) appear to guide the movement of the probe. Follow the arrows to move the projection image to the centre of the crosshair. When it turns green, bladder centre is on target. Otherwise it’s off the

target. Twelve B-ultrasound images and their serial numbers are displayed at the same time. The serial number increases from 01/12. Once it reaches 12/12, scan, image analysis and calculation are accomplished. Automatically the first image (01/12) is displayed on the screen and below that the rest are displayed in gallery view. Bladder volume and projection images are also shown on the screen. Tap on the projection to see 3D image or tap on the 3D image to return to the projection view. When the projection image appears green, it means scan is on target. Otherwise the color changes to orange.

When the bladder volume value is smaller than 100ml, it is recommended to use expert mode to measure.

6.9.3 Set up Print

Tap on “Print” from the setting menu to enter print interface (Figure 5-33). In total there are four options including “ Basics”,“ Basics And Images”,“ Basics And Projection”,“ Basics And Images And Projection”. If chose “Basic” printing content includes patient ID, age, gender, bladder volume value, printing date&time. If chose “Basic and Images”, two orthogonal ultrasound images can be printed additionally. In case of “Basic and Projection”, projection images are printed apart from the basic information. In case of “Basic and Image and Projection”, all basic information, two orthogonal ultrasound images and projection images will be printed. “Basics and Images” is the system default setting.  is shown behind the selected option.

6.9.4 Alert

Press “Alert” from the setting menu to enter setting interface (Figure 5-34). The purpose is to give alert when bladder volume reaches the threshold. The options are “200”, “250”, “300”, “350”, “400”ml or “OFF”.  appears after the selected option.

6.9.5 Poweroff

Press “Poweroff” to enter setting interface (Figure 5-35). The purpose is to set up automatic shutdown time. The options are “1 hour”, “ 2 hours”, “ 3 hours”, “4 hours” or “OFF”. “2 hours” is the default setting in the system which means the system automatically shut down after 2 hours.  appears behind the selected option.

6.9.6 Language

Press “Language” to enter setting interface (Figure 5-36). There are 13 languages available to chose including English, simplified Chinese, traditional Chinese, French, Danish, Finnish, Portuguese, Swedish, Spanish, Dutch, Norwegian, German, Italian. By default, English is the system language.  appears behind the selected option.

6.9.7 Calibrate

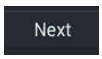
Calibration is not available for normal users. It is managed by the manufacturer or the dedicated service team.

6.9.8 FPGA Software Upgrade

Connect the device with the PC by USB cable. A disk sign appears at PC end once the connection is successful. Copy the system upgrade program into the device. Press “Update” in the setting menu to upgrade the system. Upgrade progress (in %) could be tracked as shown in Figure 5-37. Once it reaches 100%, system upgrade is completed. On the screen it shows “Success” if the upgrade is successful and “Failure” in case of any problem.

6.9.9 Date & Time

Press “Date & Time” to enter setting interface of date and time (Figure 5-37). There are two options “set up date” and “set up time”. Continuously press on it to switch it on and off. When “Automatic Date & Time” is ON, system automatically updates to the local date and time once the device is connected to the internet. If “Automatic Date & Time” is turned off, date and time need to be set up manually.

To set up the date and time manually, press where “China standard time” is shown, a list of world time zone pops up. Choose the local time zone and adjust the date and time accordingly by swiping the list up and down. Once all are set, press 

to save and return to the previous page.

6.9.10 Management

Press “Management” in the setting menu to enter management interface (Figure 5-39). Enter administrator password to login the interface (Figure 5-40). The initial password is 000000 (six zero). On this page login passwords to access patient history information, export patient history information and

modify administrator password are being managed.

Enter new passwords to access patient history information, export patient history information and modify administrator password and press SAVE to save the new entries. Slide the button next to “Memorize history” to the right, it turns to green. Login password to access patient history data is saved and users do not need to enter the password again in the future operation. It is the same for “Memorize upload”. Slide the button to the right to turn it on. Users do not need to reenter the password in the future operation.

On the management interface, enter hospital name and department, press SAVE to save the new entries and press CANCEL to return to the main page.

On the interface (Figure 5-39), enter password “21650” to reset all passwords. All saved passwords return to the initial ones.

6.9.11 General Information

In the setting menu general information of the device could be found including hardware version number M5.V1.0.0.X, software version M5_V1.0.0.1 and company name Suzhou PeakSonic Medical Technology Co.Ltd.

6.10 Screen of the Probe

Once the device is switched on, company logo appears on the screen of the probe (Figure 5-41-1).

Under expert and easy mode, logo keeps showing on the small screen during pre-scan and scan. After scan is completed, users could see bladder volume value and bladder projection on the screen. If the result appears as Figure 5-41-2, it means the bladder position was incorrect. Bladder projection image and volume value cannot be displayed. If the result is shown as Figure 5-41-3, it indicates the scan was successful. Users could see the results including bladder volume and projection image.

Under intelligence mode, during pre-scan the screen looks as Figure 5-41-4. Users could directly see bladder projection image. If the real time projection is off the centre, users would see indication arrows as (←↑→↓↖↗↘↙) which guide the probe to move to the right direction. Follow the arrow till the projection reaches the centre, then press SCAN. Result display interface is as same as that from expert and easy modes.

6.11 Export Data

A software is available in the upper computer for M5. This software is used to export patient data from M5 to the upper computer, display the data, convert the file to PDF and print, manually enter and save hospital name, department and doctor's names, manage login and as well as manage passwords. All patient data are encrypted during the whole process.

6.11.1 Install and Logon Upper Computer Software

Copy "release" folder to the upper computer. Open the folder and find a file called PatientManager_Localization.exe. Press and run the file, prompt pops up as shown in Figure 11-1. Enter initial password 000000 to enter the upper computer interface. If 21650 is entered, all saved passwords are reset to the initial 000000.

Upper Computer Logon Interface as shown in Figure 11-1.

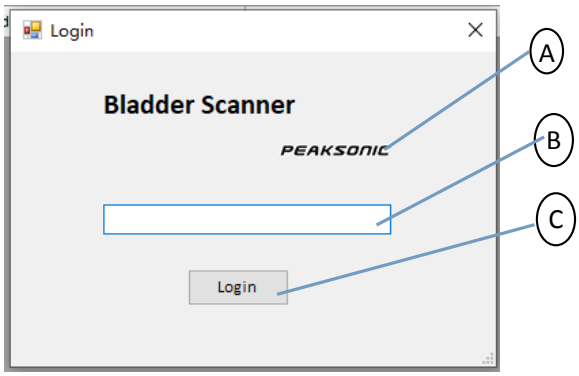


Figure 11-1 M5 Logon Interface of Upper Computer

A: Company Name

B: Password Entry

C: Login

6.11.2 Upper Computer Main Interface

On the main interface there are menu, upper computer information, company logo, patient information and twelve bladder ultrasonic images. The menu includes import data, print, save to PDF and option. Patient information covers patient ID, age, gender, scan time and bladder urine volume. Select one of the patient information, twelve ultrasonic images and one bladder projection image are displayed in a loop.

Upper computer main page as shown in Figure 11-2

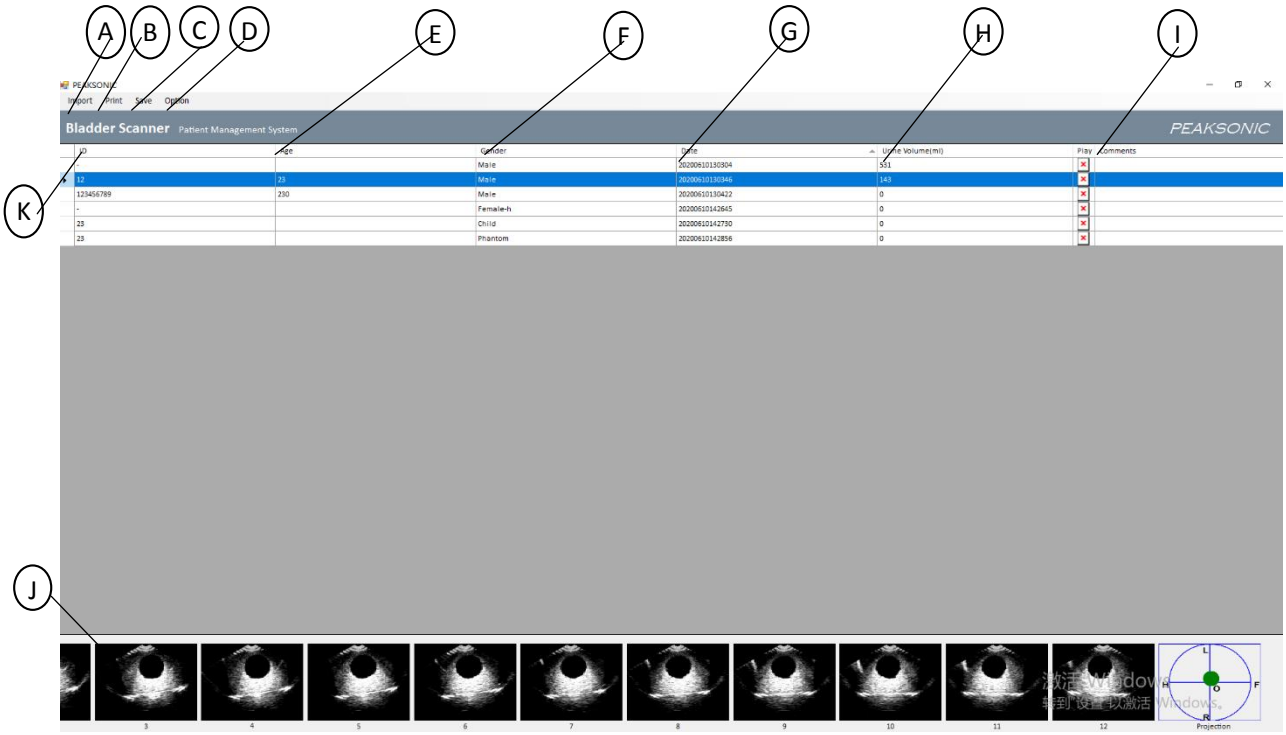


Figure 11-2 M5 Upper Computer Main Page

A: Import Data

B: Print

C: Save to PDF

D: Other Options

E: Patient Age

F: Patient Gender

G: Scan Date

H: Bladder Volume

I: Play Voice Record

J: Bladder Image Display Zone

K:Patient ID

6.11.3 Import Data

Press “Import Data” to pop up a dropdown menu which includes two options “From WIFI” and “From

USB". Chose one of the options and then chose the destination disk to import data from the device to the upper computer.

Upper Computer Import Data Interface as shown in Figure 11-3

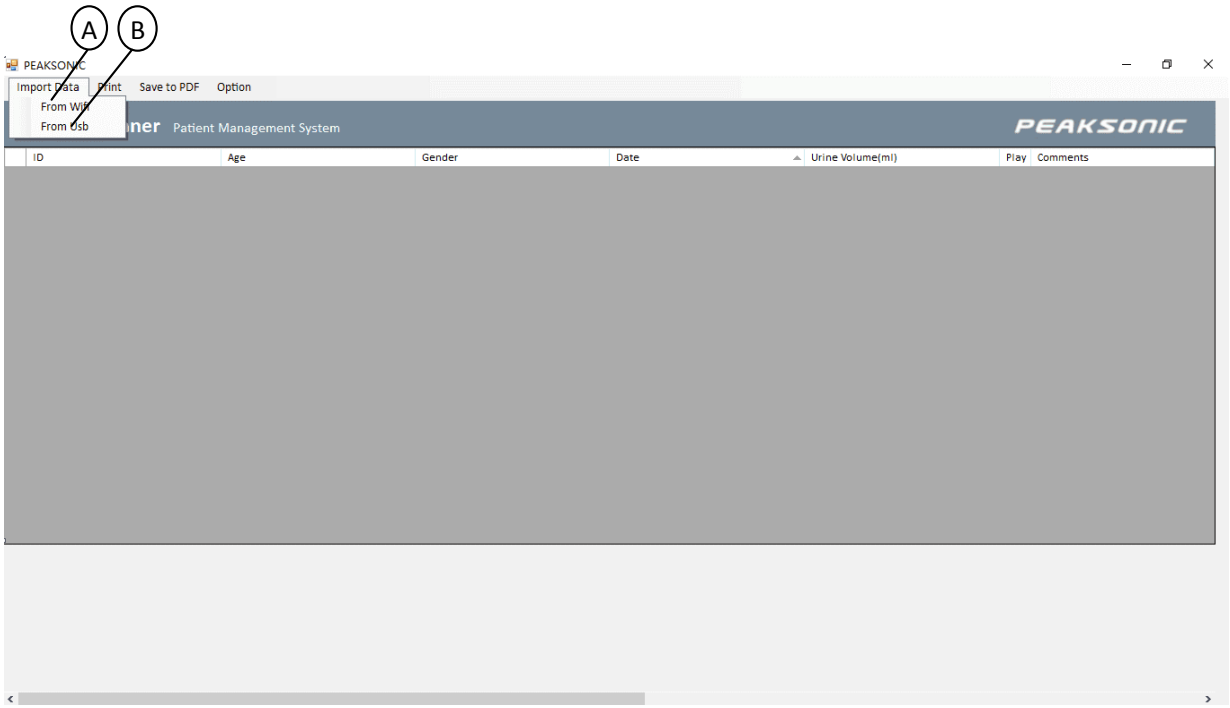


Figure 11-3 M5 Upper Computer Data Import

A: Data transfer through WIFI

B: Data import through USB cable

6.11.4 Options

Press Option to pop up a dropdown menu. Select "Settings" to open the dialogue window. Enter information and press SAVE to return to the previous page. Press CANCEL to erase the entries and return to the previous page.

Upper Computer Option Interface as shown in Figure 11-4:

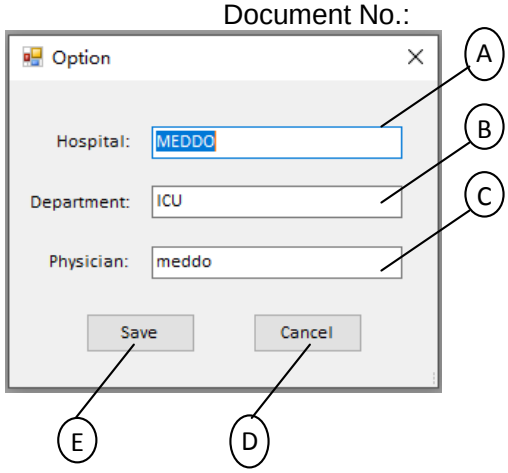


Figure 11-4 M5 Option Interface

A: Hospital Name

B: Department Name

C: Doctor Name

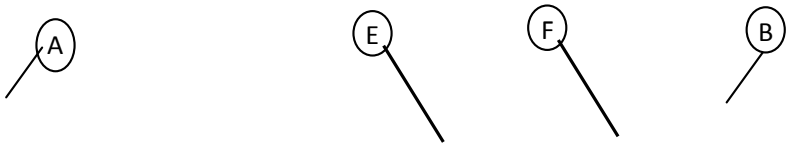
D: Cancel the New Entries

E:Save the New Entries

6.11.5 Upper Computer Printing Interface

Press “Print” and pop up printing interface which includes option button to display six images or twelve images, printing button, hospital name, department name, patient information and bladder ultrasonic images. Press option button to choose six images display, six bladder ultrasonic images are displayed as shown in Figure 11-5. Press PRINT to print the content which does not cover option column to chose six images or twelve images display, printing button and X button. Choose “12 images” to display twelve bladder ultrasonic images and projection (Figure 11-6). Press PRINT to print the content. Information source of hospital name and department name is the option interface and the patient information and bladder ultrasonic images are from upper computer main interface.

Upper computer printing display interface (six images display) as shown in Figure 11-5



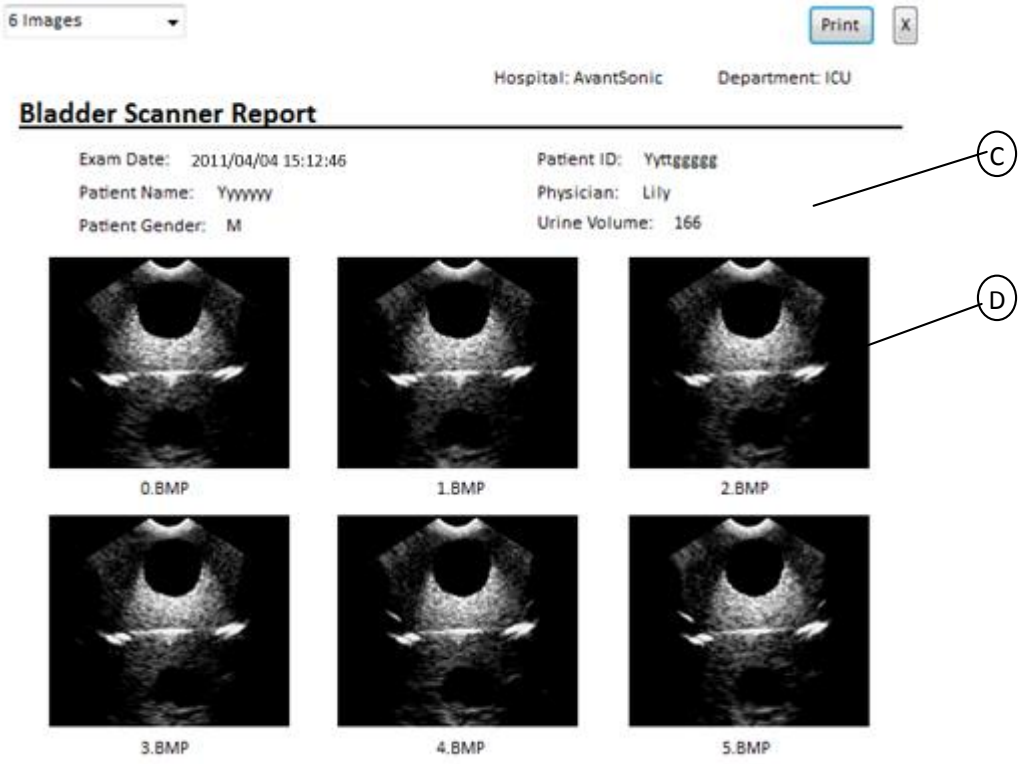


Figure 11-5 M5 Upper Computer Printing Interface (six images)

A: Option Column for Six or Twelve Images Display

B: Printing Button

C: Patient Information

D: Six Bladder Ultrasonic Images

E: Hospital Name

F: Department Name

Upper computer printing interface (twelve images) as shown in Figure 11-6:

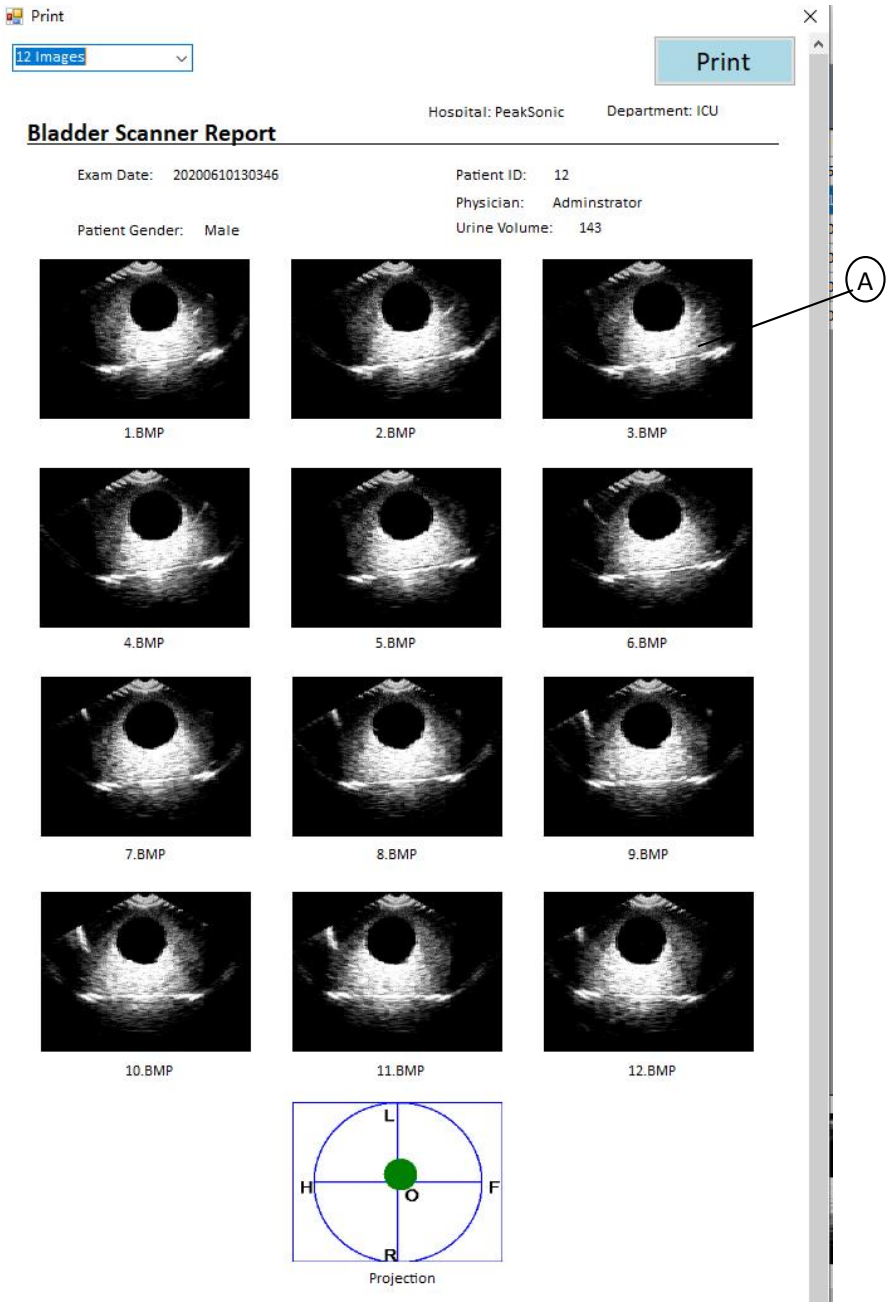


Figure 11-6 M5 Upper Computer Printing Interface (twelve images plus projection)

A: Twelve Bladder Ultrasonic Image plus Projection Image

6.11.6 Save as PDF

Press “Save to PDF” to pop up corresponding window. Options are chose the path to save document, enter document name, select document type which can only be PDF (*.pdf). Save as PDF function makes it convenient to check patient information and bladder images. The content of the PDF file is as same as the one after users press PRINT button.

6.11.7 Change Password of Upper Computer

Press OPTION than PASSWORD to manage password of the computer. Enter six digits old password and then enter twice the new passwords. Tap SAVE to save the new password.

Password management interface of the upper computer as shown in Figure 6-7

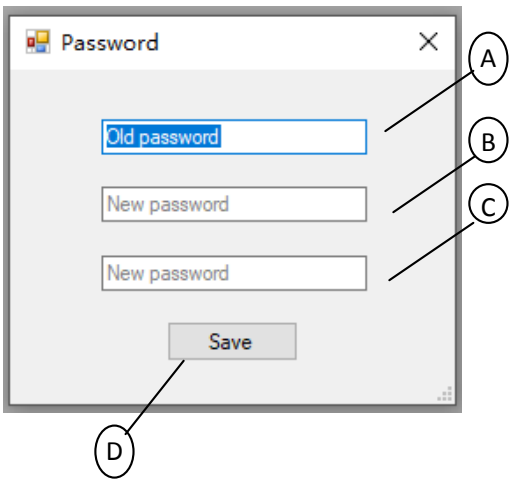


Figure 6-7 M5 Change Password Interface of Upper Computer

A: Enter Old Password

B: Enter New Password

C: Confirm New Password

D: Save New Password

6.12 Battery Capacity

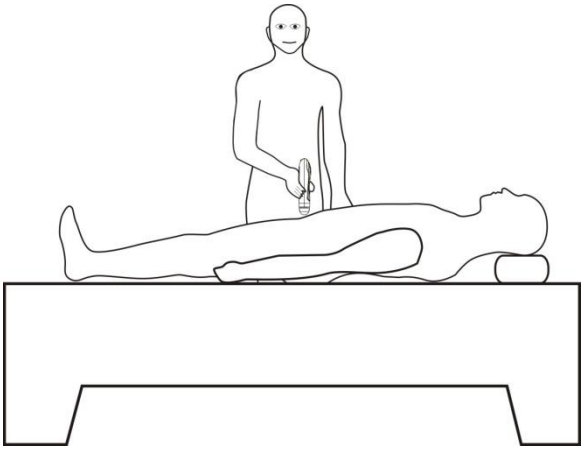
On the up right corner of the screen battery capacity  is displayed in percentage. When it is full it appears as 100%. When it drops to 15% to 30% battery needs to be charged. When it is below 15%, device will soon be shut down.

6.13 Bladder Positioning and Scanning

Correct bladder positioning is the basis of accurate measurement of bladder volume. As shown in the fig-

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

Under expert mode, press SCAN for the first time to activate pre-scan. During pre-scan a green indication line at the centre of the image appears. It is designed to help the user quickly locate the bladder centre. Move the probe to search for the biggest bladder image. Press SCAN again when the biggest bladder B-ultrasound image is located and the green indication line reaches the centre of the image. During scanning, keep the probe still.



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

Under intelligence mode, move the bladder projection to the centre of the crosshairs. If the projection is off the centre, indication arrows (←↑→↓↖↗↘↙) appears to guide the probe movement. Move the probe and the projection image moves along. If the projection appears green, it means the probe has located the bladder centre. Otherwise the color turns to orange. During scanning, keep the probe still.

After scanning is completed under expert, easy and intelligence mode, green projection image appears on the scan completion interface (Figure 5-6, Figure 5-7, Figure 5-10, Figure 5-11, Figure 5-14, Figure 5-15). When the projection image centre is in line with the centre of the crosshairs and the color is green, it means the result is valid. When the color appears orange it indicates error in the result.
For intelligence mode bladder positioning is done before scan starts. Therefore it is positioning before scanning. During bladder positioning, when the color of the projection image is green it means bladder is located in the scanning zone. When the color turns orange, it indicates potential error in the result.

Chapter VII Maintenance

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

7.1 Clean and Maintain the System

7.1.1 Cleaning and Disinfection Steps

(1) Shut down the system.
(2) Use mild, nearly neutral detergent, ethanol (75%) or isopropanol (70%) to clean equipment (including keyboard).
(3) Control the time of cleaning according to the user instruction of the detergent and the interval of cleaning shall meet clinical requirements.
(4) Dry the surface of the system or dry it with clean cloth according to the method described on the detergent user instruction.
(5) Clean fingerprints or other contaminants on the display screen and wipe the display screen with soft and damp cleaning cloth dipped with neutral detergent to ensure that the display screen will not be scratched.

7.1.2 Maintenance

(1) The instrument shall be operated in the environment specified in "1.5".
(2) The instrument shall not be turned on or turned off frequently. After being turned off, it shall be turned on after 5 minutes.
(3) When the instrument is not in use for a long time, it shall be packed well according to the factory packaging standard and stored in accordance with the storage environment requirements specified in "8.2".

7.2 Clean and Maintain the Probe

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

7.2.1 Cleaning and Disinfection Steps

(1) Check the probe, for example: Cracking, liquid leakage, etc. If there is obvious damage, do not continue to use the probe, and immediately contact Suzhou 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 inspection area of the patient. If the coupling agent does not meet the standard, it will damage the probe and irritate the patient's skin.

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

7.3 Use and Maintain the Battery

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

7.4 Dispose Electronic Waste

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

Chapter VIII Transportation and Storage

8.1 Precautions for Handling Instrument

(1) Place the host in the corresponding place of the workbag. The probe and the instrument shall be strictly prevented from falling, vibrating or colliding.
(2) After the workbag is closed, it can be transported.
(3) Tighten the bottle cap of ultrasonic coupling agent to prevent the gel from flowing out and put it in the corresponding place of the workbag.

8.2 Requirements on Transportation and Storage Environment

Ambient temperature range: -40℃～+55℃

Relative humidity range: 10％～80％

Atmospheric pressure range: 50kpa～106kpa

8.3 Transportation

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

8.4 Storage

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

Chapter IX Troubleshooting

9.1 Inspection

- Check whether power supply is normal, whether the cable is connected with the console and has plugged into the power socket.
- Check whether the probe and the console has been correctly connected.

9.2 Troubleshooting

Serial No.	Issue	Troubleshooting
1	After pressing the power button, power indicator is not on and no image displayed on the screen.	1. Inspect whether the battery is installed and charged 2. Inspect power supply 3. Inspect power cable and plug 4. Inspect whether the adapter is normal
2	reticular interference or snow-flake interference on the display screen during scan	1. Inspect the power supply and check whether it is interfered by other devices 2. Check whether electric and magnetic fields in the surrounding space 3. Check whether power plug and socket works properly

9.3 After-sales Service

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

9.4 Device Reparation

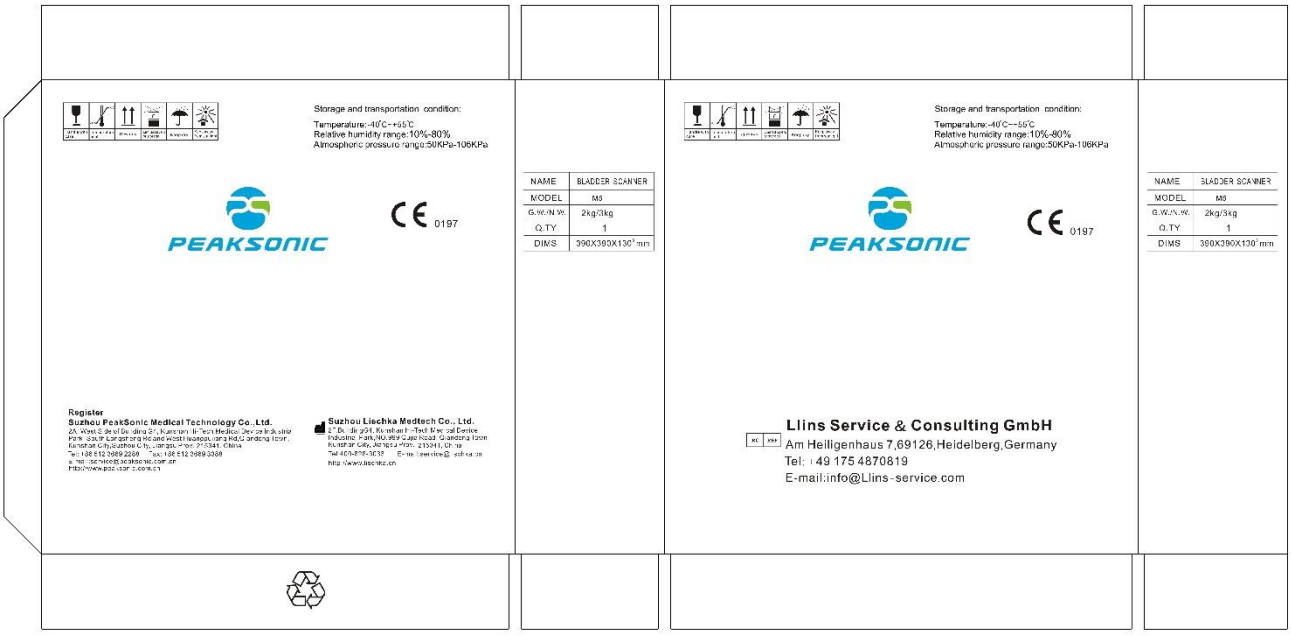
The maintenance of the instrument shall be carried out in the places appointed by the manufacturer. During the maintenance, in case any maintenance documents are needed please contact the manufacturer

Appendix A Labels & Other Identifications

M5 Labels

Name	Bladder Scanner		
Model	M5	SN	BSJ04150001
Safe mode	Type B	Battery	DC11.1V,3200mAH
Input	DC13.5V,5A	CE 0197	Type B Applied Part
Date of Manufacture	2020-04		consult instructione for use
	2026-03		Collect separately from other household waste
FCC ID	2AT6UM5-FS		
Register	Suzhou PeakSonic Medical Technology Co.,Ltd.		
Manufacturer	Suzhou Lischka Medtech Co., Ltd. 2F,BuildingG4, Kunshan Hi-Tech Medical Device Industrial Park, NO.999 Qujia Road, Qiandeng Town,Kunshan City, Jiangsu Prov.		
EC REP	Llins Service & Consulting GmbH Am Heiligenhaus 7,69126,Heidelberg,Germany		

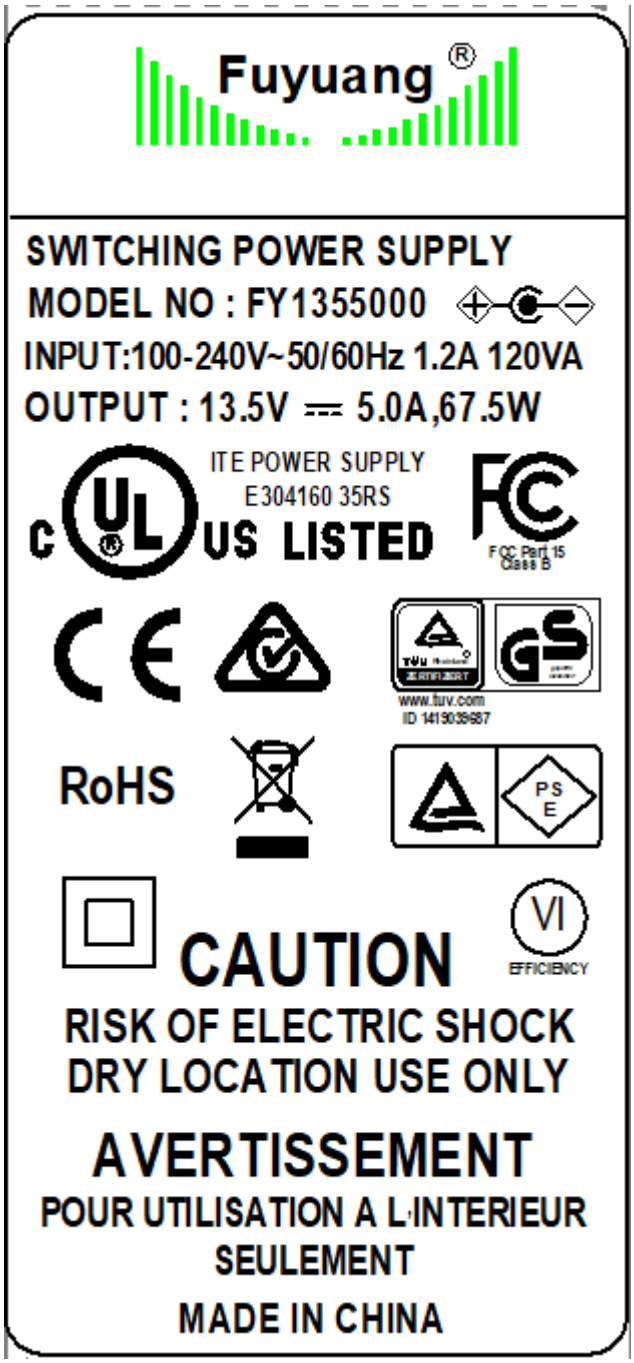
M5 Label on Outer Package



M5 Label on the Rolling Medical Cart

M5 Label on Probe

M5 Label on Adapter



Appendix C Technical Specification for Electro-magnetic Compatibility

Table 201

Guidance and statement of the manufacturer-electromagnetic emission		
M5 portable bladder scanner is intended for use in the electromagnetic environment specified below. The purchaser or user shall ensure that it is used in such an environment.		
Emission test	Conformity	Electromagnetic environment-guideline
RF emission GB 4824	Group 1	M5 portable bladder scanner uses RF energy only for its internal functions. Therefore, its RF emission frequency is very low and it is almost impossible to cause interference to nearby electronic equipment.
RF emission GB 4824	Class B	M5 portable bladder scanner is suitable for use in all facilities, including domestic and residential public low-voltage supply network directly connected to households.
Harmonic emission GB 17625.1	Class A	
Voltage fluctuation/flicker emission GB 17625.2	Compliance	

Table 202

Guidelines and statement of the manufacturer-electromagnetic immunity			
M5 portable bladder scanner is intended for use in the electromagnetic environment specified below. The purchaser or user shall ensure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guideline
Electrostatic discharge GB/T 17626.2	±6KV contact discharge ±8KV air discharge	±6KV contact discharge ±8KV air discharge	The floor shall be wooden, concrete or paved with tiles. If the floor is covered with synthetic material, the relative humidity shall be at least 30%.
Electrical fast transient burst GB/T 17626.4	±2KV for power line ±1KV for input/output line	±2KV for power line ±1KV for input/output line	Quality of network power supply shall be equal to that in typical commercial or hospital environment.

Surge GB/T 17626.5	±BKV wire to wire ±2KV wire to wire	±1KV wire to wire ±2KV wire to wire	Quality of network power supply shall be equal to that in typical commercial or hospital environment.
On power input line Voltage sag, Short interruption and voltage change GB/T 17626.11	<5%UT, continuous for 0.5 week (on UT, >95% of sag) 40% UT, continuous for 5 weeks (on UT, 60% of sag) 70% UT, continuous for 25 weeks (on UT, 30% of sag) <5%UT, continuous for 5s (on UT, >95% of sag)	<5%UT, continuous for 0.5 week (on UT, >95% of sag) 40% UT, continuous for 5 weeks (on UT, 60% of sag) 70% UT, continuous for 25 weeks (on UT, 30% of sag) <5%UT, continuous for 5s (on UT, >95% of sag)	Quality of network power supply shall be equal to that in typical commercial or hospital environment. If the user of M5 portable bladder scanner needs continuous operation during power outage, the M5 portable bladder scanner is recommended to be powered by uninterruptible power supply or battery.
Power frequency magnetic field (50Hz) GB/T 17626.8	3A/m	3A/m	If image distortion occurs, then it is necessary to keep the M5 portable bladder scanner away from the power frequency magnetic field or install magnetic shielding. The power frequency magnetic field in the intended installation site shall be measured to ensure that it is low enough
Note: UT refers to the AC network voltage prior to application of the test voltage.			

Table 204

Guidelines and statement of the manufacturer-electromagnetic immunity			
M5 portable bladder scanner is intended for use in the electromagnetic environment specified below. The purchaser or user shall ensure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guideline

Radio-frequency transmission GB/T 17626.6 Radio-frequency radiation GB/T 17626.3	3V (effective value) 150KHz～80MHz 3V/m 80MHz～2.5GHz	3V (effective value) 3V/m	The portable and mobile radio-frequency communication equipment shall not be closer than the recommended isolation distance to any use part of the M5 portable bladder scanner including cables. And the calculation of that distance shall use a formula corresponding to the frequency of the transmitter. Recommended distance $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80MHz～800MHz $d=2.3\sqrt{P}$ 800MHz～2.5GHz Wherein: P— The maximum output power of the transmitter supplied by transmitter manufacturer, in watt (W); d— Recommended isolation distance, in meter (m). Field strength of fixed radio-frequency transmitter shall be determined by electromagnetic site survey, and it shall be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbols. 

Note 1: At the frequency point of 80 MHz and 800 MHz, the formula of higher frequency band shall be applied.

Note 2: These guidelines may not apply to all situations. Electromagnetic transmission is affected by the absorption and reflection of buildings, objects and human bodies.

* Fixed transmitters, such as: base stations of wireless (cellular/cordless) telephones and ground mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast, their field strength cannot be predicted theoretically and accurately. To assess the electromagnetic environment of fixed radio frequency transmitter, the electromagnetic site survey shall be considered. If it is measured that the field strength of the place where M5 portable bladder scanner locates is higher than the above RF compliance level, observe M5 portable bladder scanner to verify that it can operate normally. If abnormal performance is observed, additional measures may be necessary, such as readjustment of the direction or position of the M5 portable bladder scanner.

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

Table 206

Recommended isolation distance between portable and mobile radio-frequency communication equipment and the M5 portable bladder scanner			
M5 portable bladder scanner is expected to be used in electromagnetic environment where RF radiation disturbance is controlled. According to the maximum output power of communication equipment, the purchaser or user of the M5 portable bladder scanner can prevent electromagnetic interference by maintaining the minimum distance between the portable and mobile radio-frequency communication equipment (transmitter) and the M5 portable bladder scanner.			
Maximum rated output power of the transmitter Output power W	Isolation distances (m) correspond to different frequencies of transmitters		
	150KHz～80MHz d=1.2 $\sqrt{P}$	80MHz～800MHz d=1.2 $\sqrt{P}$	800MHz～2.5GHz d=2.3 $\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For the maximum rated output power of transmitters not listed in the table above, the recommended isolation distance (d) in meter (m) can be determined by the formula corresponding to the frequency of the transmitter, wherein P is the maximum rated output power of the transmitter in watt (W) according to the transmitter manufacturer. Note 1: At the frequency point of 80 MHz and 800 MHz, the formula of higher frequency band shall be applied. Note 2: These guidelines may not apply to all situations. Electromagnetic transmission is affected by the absorption and reflection of buildings, objects and human bodies.			

endix D Ultrasound Intensity and Safety

C.1: Ultrasound in Medicine

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

C.2: Ultrasound Safety and the ALARA Principle

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

FCC Statement

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

-- Reorient or relocate the receiving antenna.

-- Increase the separation between the equipment and receiver.

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

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

§ 15.21 Information to user.

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

§ 15.19 Labelling requirements.

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

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

Register by:
Suzhou PeakSonic Medical Technology Co.Ltd.
2A, West Side of Building G4, Kunshan Hi-
Tech Medical Device Industrial Park, South Longsheng Rd and
West Huangpujiang Rd,Qiandeng Town,Kunshan City,Suzhou City, Jiangsu Prov.

Manufactured by:
SUZHOU LISCHKA MEDTECH CO., LTD.
2F,BuildingG4,Kunshan Hi-Tech Medical Device Industrial Park
NO.999 Qujia Road, Qiandeng Town, Kunshan City
Suzhou Jiangsu, CHINA 215300

After-sales service address: 2A, West Side of Building G4, Kunshan Hi-
Tech Medical Device Industrial Park, South Longsheng Rd and
West Huangpujiang Rd,Qiandeng Town,Kunshan City,Suzhou City, Jiangsu Prov.
Version No.: M5_V1.0.0.1

Tel.: 0512 - 36692288-812

Fax: 0512 - 36693388

Postal code: 215341

Attachment

Engineering Automatic Calibration Instructions:

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

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

If any hospital or any end user regards instrument calibration as fixed operation procedure, the following steps may be used for calibration. Please note American CIRS: 125ML Bladder Phantom 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 but will not affect the measurement accuracy of the bladder volume of real person, therefore, we conduct automatic calibration using American CIRS: 125ML Bladder Phantom to ensure the measurement accuracy of the phantom.

Steps of automatic calibration are as the following:

Step 1. Enter system setting interface (Figure 1). Continuously tap  for six times to activate automatic calibration which is below “Language” in the menu. Automatic calibration is not available for normal users but only for engineering team. Ten minutes after the automatic calibration is activated, it will be automatically shut down.

Step 2. place the probe head into the phantom holder firmly

Step 3. Tap on Calibrate in the menu to initiate automatic calibration. Calibration progress is shown as Figure 2. The progress is displayed in %. When it reaches 100%, calibration is done. Result will also appear. When it’s successful, result appears to be “Success” and when it’s failed, “Failure” is displayed on the screen.

Step 4. Do not remove the probe during the calibration.

Please only conduct automatic calibration when the battery is full.

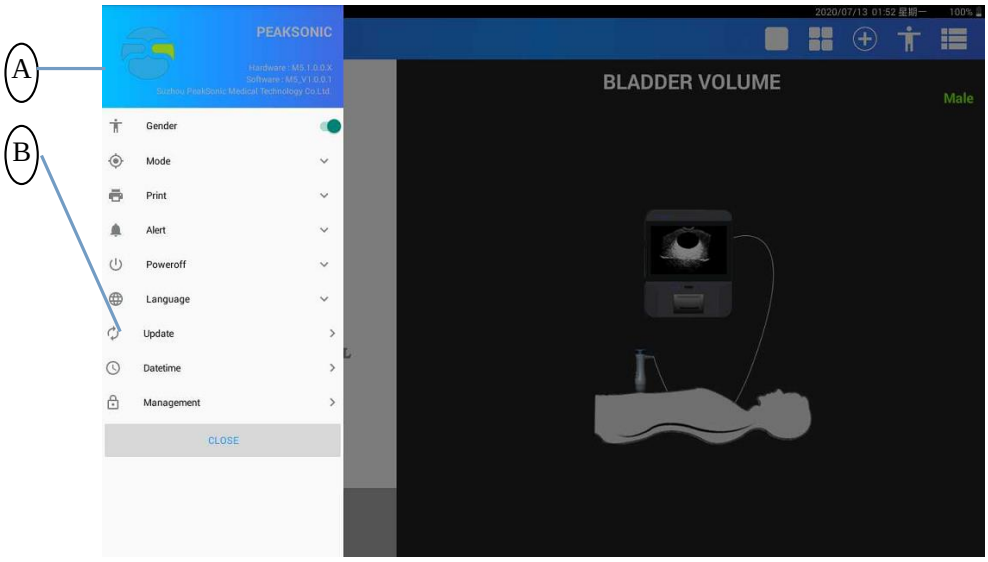


Figure 1 M5 System Setting Interface

A: Setting Icon B: Automatic Calibration

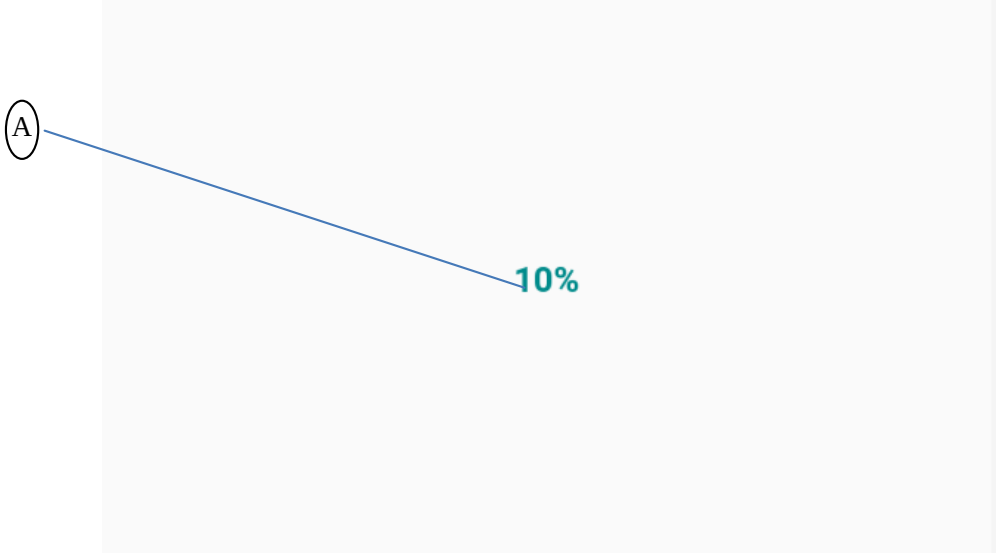


Figure 2 M5 Progress of Automatic Calibration

A: Automatic Calibration Progress in %

FCC Statement

15.19 Labeling requirements.

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

15.21 Information to user.

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

15.105 Information to user.

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

-- Reorient or relocate the receiving antenna.
-- Increase the separation between the equipment and receiver.
-- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
-- Consult the dealer or an experienced radio/TV technician for help.

§ 15.19 Labelling requirements.

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