

RosieScan[®]2





In order to use this device safely and correctly, please read this manual carefully before operating it.

Please register promptly as 10.4 in user's manual after installation.

It is V1.4 for the version number of this user's manual.



Note:

- 1) Please check the power supply of adapter before charging the battery. Stop using once the voltage of the power exceeds the scope printed on the adapter.
- 2) Please check the power cable of charger before charging the battery. Broken or cracked power cable may cause a fire or electric shock which may lead to casualties.

- 3) Please unplug the power cable and take out the battery after charging completed.
Incomplete blackout may result in the occurrence of unusual or unsafe (Such as: thunder strike and static electric fire, etc.)
- 4) Attentions before turning on the device:
 - a. Make sure the probe connect tightly with mainframe;
 - b. Make sure you have good battery, put it into battery case and lock the cover.
- 5) Turn off the power after finishing using.
- 6) Do not be away from the device while it is being used.
- 7) The battery should be taken out from the device if not using for a long time.
- 8) Stop using the device and turn it off in stormy weather; do not use the charger and cut off the power, take out the battery in such weather.
- 9) Please stop charging battery and cut off power, when charging battery or using device, if any irregularities occur as follows:
 - a. Abnormal noise;
 - b. Sudden fume or burnt odor
 - c. Brightness of the display screen is too high.
- 10) If power adapter is damaged, please contact the manufacturer for replacement or purchase the adapter which must be in conformity with the standard IEC 60601-1. Using any non-compliant adapter may be dangerous.
- 11) PBSV5.1 Palm bladder scanner comply the relevant requirements of IEC60601-1-2 standard electromagnetic compatibility.
- 12) The user needs to install and use the device according to electromagnetic compatibility information provided by the accompanying documents.
- 13) Portable and mobile RF communication devices may affect the performance of PBSV5.1 Palm bladder scanner. Please avoid these strong electromagnetic interference such as mobile phones and microwave ovens, etc.
- 14) Guidance and manufacturer's declaration stated in the appendix.
- 15) The equipment carried out risk analysis for network security with reference to IEC/TR 80001-2-2 standard, and took corresponding measures. For details, see 2.3 Network Security. During using the equipment, the user should also follow the 2.3 network security requirements to ensure that the network security capability continues to be met.

Warning:

- 1) Please read the instructions in Appendix C carefully when using the battery.
- 2) The maintenance service must be carried out by professional technicians. Users are not allowed to disassemble the device. Or it may increase the maintenance difficulty and cost, and even cause potential safety hazard.
- 3) Only trained doctors or authorized people by the medical institutions can use the PBS V5.1. The users must fully study the User's manual and understand all the instructions before operating it. It will make the device abnormal or the practice result incorrect if it is not followed by the instructions during the operation. To obtain the latest vision of the User's manual, please contact the distributor in your region.
- 4) The ultrasound is safe in the low acoustic power condition. Its safety has not yet been fully confirmed in case of high acoustic power and long-time ultrasonic irradiation. Please choose the lowest acoustic power and the shortest time to use.
- 5) In general situation, the heat of probe will not bring any uncomfortable feeling on patients. However, if the environment temperature is too high (e.g. in summer), or the probe is continuous used for a long time, the surface temperature of probe acoustic window might increase (when the environment temperature is 40 °C, the highest surface temperature is less than 45 °C), which might make the patients uncomfortable. So per-scan will not be suggested to use for a long time while using the device, especially when the environment temperature is too high, the probe should not be in contact with the patient for more than 1 minute!
- 6) To avoid interference or influence of electromagnetic radiation, do not use this device together with other medical electrical equipment.
- 7) The device is not allowed to use together with high-frequency surgical equipment.
- 8) Please calibrate the date and time before first time using (or not using this device for a long time).
- 9) The system will enter the energy-saving mode without any operation on the device for about 5 minutes if not in the pre-scan mode or touch screen calibration interface. The system will automatically shut down without any operation on the device for 10 minutes.
- 10) Don't pull out the probe while using the device.

- 11) PBSV5.1 Palm bladder scanner should not be close to or stacked with other equipment.
If adjacent or stacked use is necessary, it should be observed to verify normal operation in the configuration.
- 12) Class A equipment is intended for use in an industrial environment. The PBSV5.1 Palm bladder scanner may have potential difficulties in ensuring electromagnetic compatibility in other environments, due to conducted as well as radiated disturbances.
- 13) Do not use your finger or hold the tool to touch the touchable connector contacts (including the USB-B interface, probe interface, etc.) marked with the ESD warning symbol unless you have used the device such as the electrostatic release device for electrostatic protection.

This manual includes user's manual and technical instruction

Thanks for your attention

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Revision History

Version	Date	Description
V1.0	2020.09	First Edition
V1.1	2018.10	Add the illustration for not configuring wireless related hardware
V1.2	2019.06	Add 2.3 Network Security
V1.3	2020.06	To change the background icon into "ready" icon of the schematic diagram for the main interface on Fig 7-3. Revise Appendix D
V1.4	2020.11	Change figure 7-1,figure 7-31,figure 7-46

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Chapter 1 Overview

1.1 Feature

PBSV5.1 Palm bladder scanner is used for measuring bladder volume with its ultrasonic echo. It consists of data processing of main frame and ultrasonic probe. Its display is color TFT-LCD with Pixel 800×600, and its measurement results can be printed out with thermal printer and also can be stored in the built-in flash-disk. The measurement results stored in flash-disk can be sent to the computer through USB interface in the main frame.

The device is strict in accordance with the national standard IEC 60601-1:2005+A1:2012 “Medical electrical equipment Part I: General requirements for basic safety and essential performance” in its design and manufacture. The whole process of design, production and sale are strictly controlled in accordance with the requirements of ISO13485:2016QMS.

The Device on the risk of electrical shock protection type:

Charging device is class II ;

The host is the internal power supply device.

The Device on the risk of electrical shock protection level:

B type applied part

1.2 Structure

PBS V5.1 is clamshell portable, mainly consisting of the host (software version PBS V5.1 V1.01), 3D probe (nominal frequency 2.6 MHz), and power adapter.

1.3 Scope of application

The device is mainly applied to measure the urinary volume in human's bladder.

1.4 Contraindication

The device is not suitable for those who are allergic to ultrasound gel and the people with abdomen skin wound and skin disease.

1.5 Illustration about sign of interface on the device

Sign	Meaning	Sign	Meaning
	18650 battery positive direction.		Class II equipment
	18650 battery negative direction.		Type B application
	Power indicator	IPX4	Level of liquid protection.
	Electrostatic sensitive device		Attention! Check the documents attached with the device
	Direct current (dc)		Alternating current (ac)

1.6 Description of the acoustic output:

1) The device is in accordance with IEC 60601-2-37:2007+A1:2015 “Part 2-37 : Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment”

201.7.9.3.101 Technical data regarding acoustic output levels:

Transducer frequency: 2.6 MHz

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.60	0.014		0.014		N/A
Index component value			0.014	0.014	N/A	0.014	
Acoustic Parameters	$p_{r,0}$ at z_{MI} (MPa)	0.93					
	P (mW)		1.22		1.22		N/A
	P_{TIS} (mW)		1.22		1.22		
	z_0 (cm)			N/A			
	z_b (cm)					N/A	
	z_{MI} (cm)	3.05					
	z_{FUS} (cm)	3.05					
	$f_{s=1}$ (MHz)	2.41	2.41		2.41		N/A
Other Information	p_{rr} (Hz)	409.60					
	s_{rr} (Hz)	5.20					
	n_{pps}	1					
	$I_{p,a}$ at z_{FUS} (W/cm ²)	32.89					
	$I_{sp,a}$ at z_{FUS} or z_{SH} (mW/cm ²)	26.25					
	$I_{sp,a}$ at z_{FUS} or z_{SH} (mW/cm ²)	38.40					
	p_r at z_{FUS} (MPa)	1.21					
Operating control conditions	Focus(mm)	Fixed					
	Depth(mm)	Fixed					
	Frequency(MHz)	2.6					

Fig 1-1 Technical Data Sheet for level of acoustic output

2) Device accords with requirements of IEC 60601-2-37:2007+A1:2015 "Part 2-37 : Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment" 201.12.4.2 a) ,b) . Exempted from showing MI, TI.

$$MI < 1$$

$$TI < 1$$

Chapter 2 Technical Specification

2.1 Main technical specification

2.1.1 Frequency of acoustic work.

The deviation between acoustic working frequency and nominal frequency should be within $\pm 15\%$.

2.1.2 Probe type.

Mechanical sector scanning.

2.1.3 Transducer: 2.6 MHz;

2.1.4 Detect depth: ≥ 140 mm;

2.1.5 Scope of Measurement volume: 0 ml~ 999 ml;

2.1.6 Measurement accuracy: $\pm 15\%$, ± 15 ml (on a Meike tissue-equivalent phantom)

2.1.7 The display unit of volume measurement results: ml

2.1.8 Structure form: clamshell

2.1.9 Power supply voltage adaption range.

Main unit: DC7.4V, Four 3.7v 18650 li-ion batteries meeting the IEC 62133 standard are used for power supply

Power adapter: AC 100V~240V 50Hz/60Hz

2.1.10 Continuous working time : ≥ 2 H (Replaceable battery)

2.2 The main function

2.2.1 Functional requirements

- 1) Storage capacity: 100 cases.
- 2) Display mode: B, 12 B.
- 3) Image processing: gray scale display, 2-color images.
- 4) Case management: storage, browse, export.
- 5) Measurement function: automatic measurement of bladder volume and display results.

- 6) Input interface: one probe interface; one bar code scanning interface; one charging interface.
- 7) Output interface: one USB interface; one wireless interface.

2.2.2 Equipment software function

NO.	Software function item	
1	Software normal switching machine.	
2	Status bar display	Display mode (expert/easy)
3		Printer status
4		Probe connection status.
5		Sound state.
6		Storage of residual space detection and display.
7		Network status display.
8		Battery calibration indication
9	Date display	
10	Operator ID display.	
11	Patient ID input (Barcode scanning entry)	
12	The gender switch	
13	Browse the test record list.	
14	Upload test record	
15	For details of the inspection records.	
16	Print test record	
17	Delete test record	
18	Ultrasonic pre-scan image display.	
19	Ultrasonic pre-scan of bladder position.	
20	Automatic scanning and calculation of results.	
21	Scan and volume calculation progress tips.	
22	Test results display	
23	Bladder relative position target indication.	
24	View the test results image.	
25	Switch between grayscale and 2-color graph.	
26	Bladder contour envelope correction function.	
27	Print current test results and images.	
28	Patient name entry.	
29	Test results saved	
30	System	Operator ID input.
31	Settings	Display mode Settings

32		Scanning bit Settings.
33		Key tone switch Settings.
34		Delete all records
35		Scan mode Settings
36		The probe calibration
37		Volume calibration
38		Time, date setting.
39		Touch screen calibration
40		Equipment information display
41		Equipment calibration function
42	Temperature of overheating prompt.	
43	USB export data to PC.	
44	Wirelessly transmits data to working station	
45	Energy saving mode	
46	Automatic shutdown with no operation for 10 minutes	

2.3 Network Security

2.3.1 Operating Environment

The software of this device is embedded software based on STM32F7 chip system.

2.3.2 Data Interface

1) Transport Protocols: The device provides a USB data interface to transfer data to an external system

2) Data Storage Format: The device's data is stored in a .det file in a non-clear (binary) manner.

2.3.3 Health Data

The health data involved in this device includes: patient name (English letter case, combination of numbers), patient number, gender, stored in a .det file in binary mode. Only the patient's name, patient number, and gender cannot accurately identify a specific individual and are not recognizable.

2.3.4 Network Security Actions

We conducted risk analysis in accordance with the IEC/TR 80001-2-2 standard and adopted the following network security actions.

No.	Network security capability	Equipment Measure	User Operation
-----	-----------------------------	-------------------	----------------

1	Transmission integrity (TXIG)	The device is connected to the computer using a USB interface and uses the standard USB transfer protocol for transmission.	Users cannot insert USB devices such as USB flash drives into the device USB interface.
2	Transmission Confidentiality (TXCF)	Encrypt the patient information that needs to be transmitted and store it in the device as a file.	The item is guaranteed by the equipment.
3	System and application hardening (SAHD)	Fully self-developed embedded systems that only provide the functionality specified in the requirements document. No general hardware and software interface is provided.	The item is guaranteed by the equipment.
4	Third-party component Maintenance plan (RDMP)	Do not use third-party components.	This item is guaranteed by the equipment.
5	Malware detection/protection (MLDP)	Fully self-developed embedded systems that only provide the functionality specified in the requirements document. Third-party software does not work.	This item is guaranteed by the equipment.
6	Safety guidance (SGUD)	Describe the safe operation in the instruction manual.	When the user operates the device, it must follow the instruction of the user manual.
7	Health data storage confidentiality (STCF)	The device does not support mobile medical storage and encrypts patient information.	This item is guaranteed by the equipment.
8	Cyber security product upgrades (CSUP)	Fully self-developed embedded systems only provide the functionality specified in the requirements document, have no third-party network security products.	This item is guaranteed by the equipment.

9	Health data integrity and authenticity (IGAU)	The general hardware and software is not provided, and the device does not provide the function of modifying the stored patient information.	Make sure the input is correct before storing the patient information.
10	Data backup and disaster recovery (DTBK)	The board uses detachable storage media to access the data by reinstalling the storage media on a new device in the event of a device failure or damage.	User cannot disassemble the device by themselves, after the device is damaged, make sure that the memory card is secure.
11	Health data DE-identification (DIDT)	The patient information stored in the device encryption contains only the patient's name (English alphabet) patient number, and gender. It is only used to distinguish the patients when testing.	This item is guaranteed by the equipment.
12	Automatic logoff (ALOF)	Timeout automatically turns off the screen and automatically shuts down.	After auto power off, you need re-enter your password to reboot.
13	Access control	Before the device is used, the user should input the password according to the login operation requirements, and the operation can be performed only after the verification is passed.	Users should ensure that only authorized personnel can master the device password and prevent the operation of non-operating personnel.

Chapter 3 System Principle

3.1 Principle:

Palm bladder scanner is a medical device with high performance combined with modern ultrasound technology and computer technology. The device consists of host and probe. It can speedily complete the detection of bladder area through scan of probe connected with the device, and transmit ultrasound echo signal detected to embedded computer system. The computer system will identify the edge of image and calculate its volume, thus to achieve the measurement of bladder volume. Also the device will display the relative information through LED screen or print out through built-in printer.

3.2 System components

3.2.1 Hardware components

The system consists of three parts, namely the signal processing part, the application interaction part and the power management part, and its composition is shown in Figure 3-1. The signal processing part of ultrasonic signal launch out, the echo signal filtering, amplifying, AD conversion, digital signal processing, etc., in the end by FPGA provides two-dimensional ultrasound images for embedded microcontroller controller for the next operation; The application of interaction part mainly has the embedded microcontroller controller MCU, the monitor, the keyboard, the storage and other peripheral interface or equipment, mainly by the embedded microcontroller controller MCU to complete the ultrasound image processing, boundary recognition, volume estimation, corresponding display by various peripheral equipment; The power management system mainly realizes the voltage of all kinds of standard required by lithium battery charging and power supply through lithium battery.

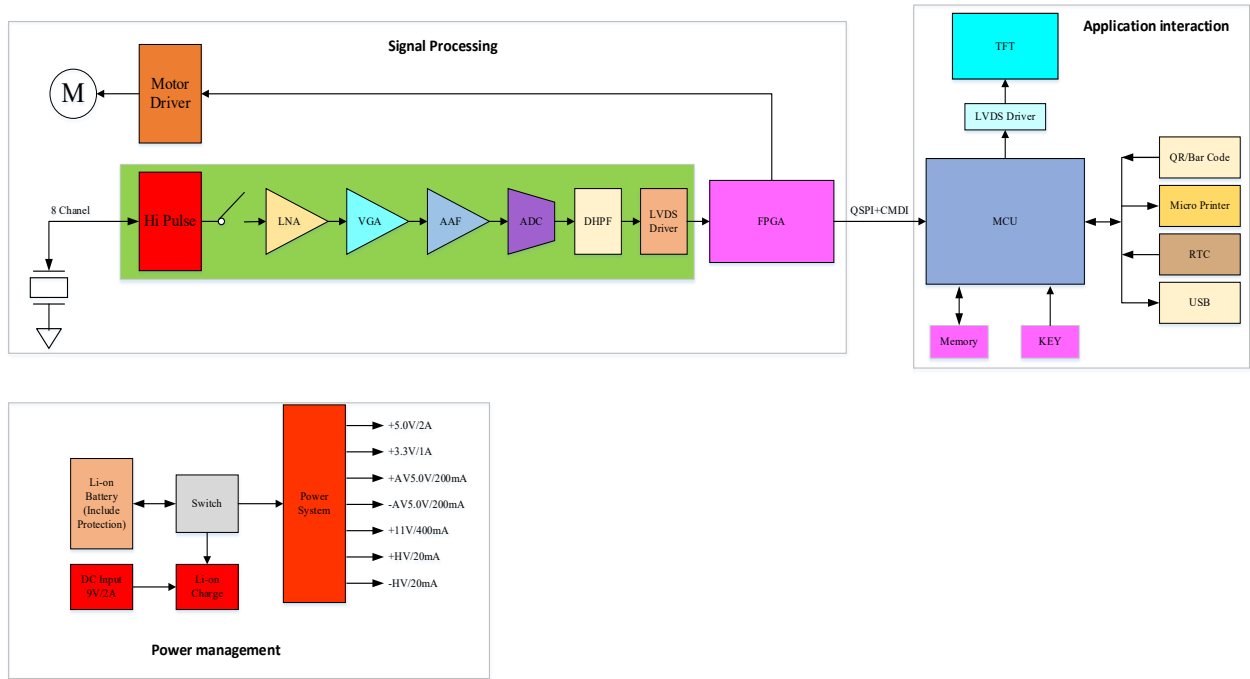


Figure 3-1 Hardware configuration

3.2.2 Embedded software system

Embedded software is based on STM32F7 system to design, using the BOOT guide and task scheduler to perform task allocation patterns, designed a BOOT guidance system, the main task scheduling system ,communication subsystem, interface subsystem, and core algorithm subsystem etc., its composition is shown in figure 3-2.

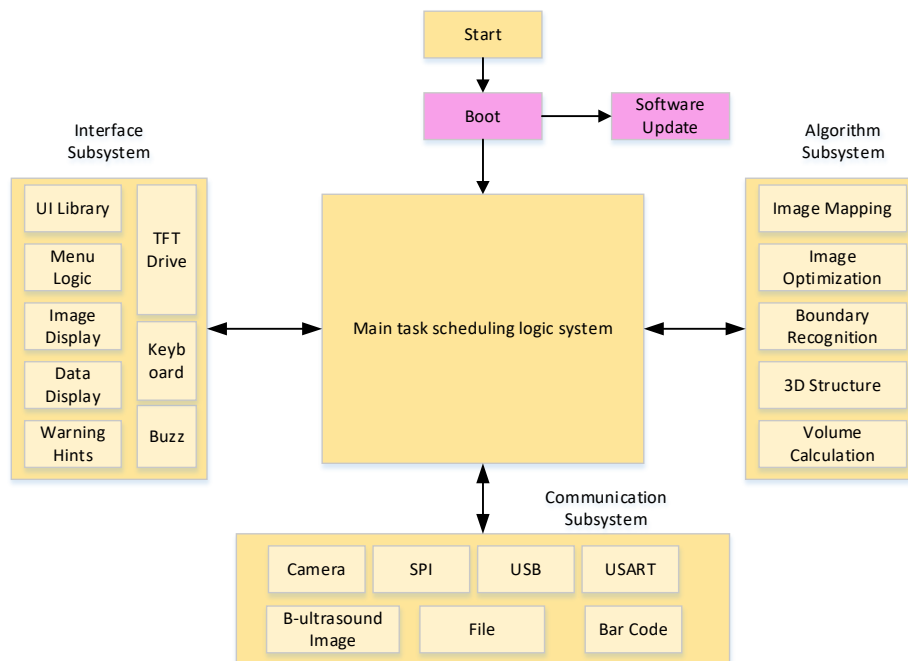


Figure 3-2 Software module block diagram

3.3 Pictures of the device

3.3.1 The picture of the device, see Figure 3-3

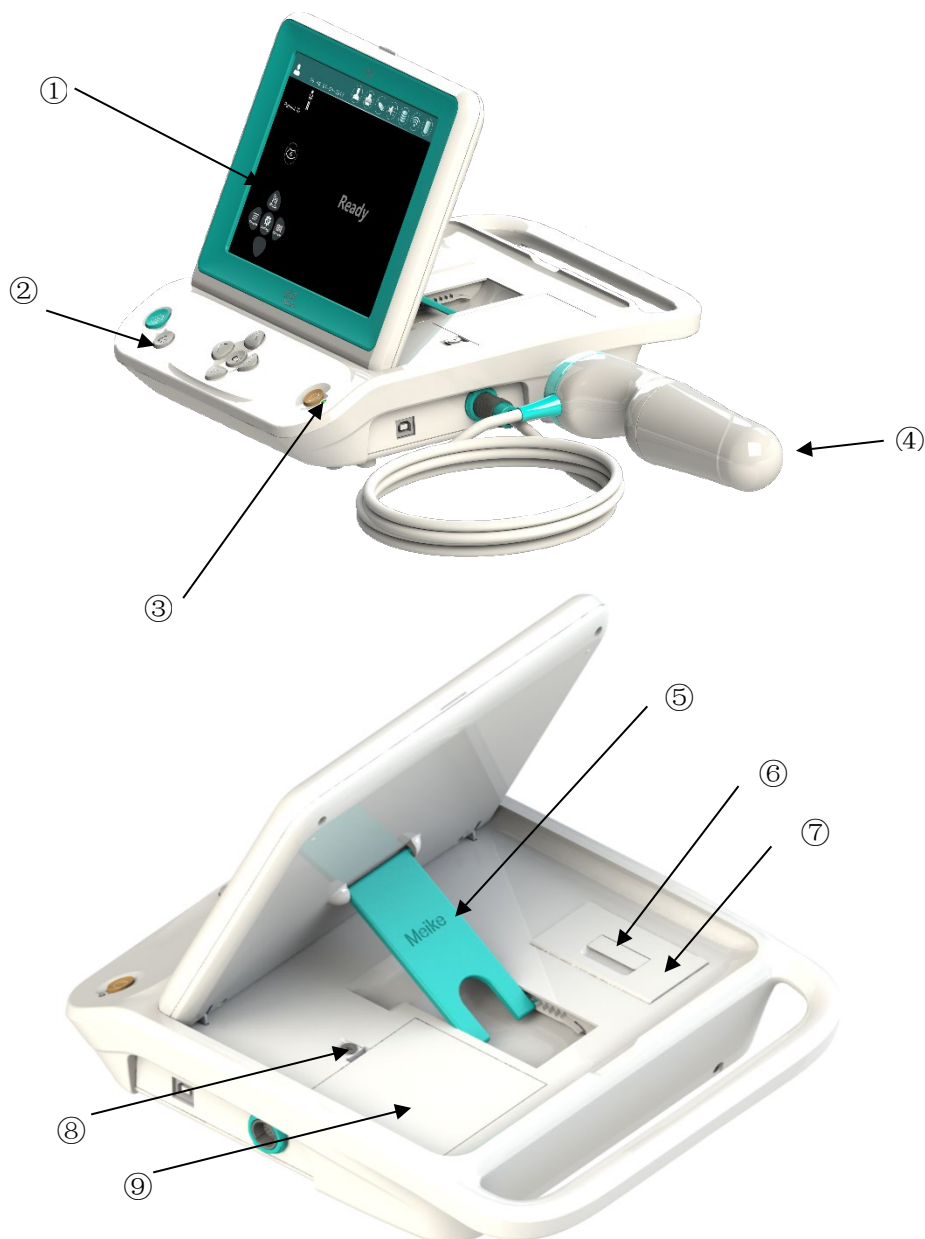


Figure 3-3 Device picture

- | | |
|-------------------|---|
| ① Touch screen | ② Control panel |
| ③ Power indicator | ④ 3D Probe |
| ⑤ Display panel | ⑥ Printer cover buckle |
| ⑦ Printer | ⑧ Battery cover buckle and fastening screw. |
| ⑨ Battery cover | |

3.3.2 Host interface schematic diagram (See Figure 3-4)



Figure 3-4 Host interface schematic diagram

- | | |
|------------------------|------------------------------|
| ① USB interface | ② Probe interface |
| ③ Recharging interface | ④ The bar code scanning port |

3.3.3 3D probe schematic diagram, see Figure 3-5

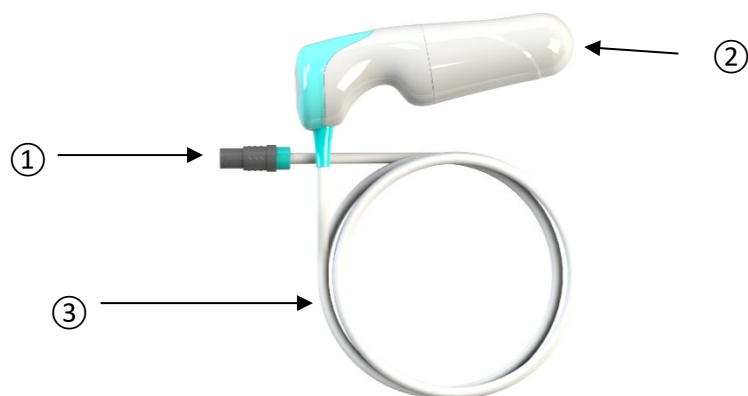


Figure 3-5 3D probe schematic diagram

- | | |
|---------------|-------------------------|
| ① Probe plug | ② Probe acoustic window |
| ③ Probe cable | |

3.4 Circuit Diagram and Components List Description

In case of eligible technicians of user's part have any need to repair device parts permitted and indicated by our company, may apply to our company or any offices for circuit diagram, parts list and other materials connected with the parts

Chapter 4 Control Panel

4.1 Control Panel

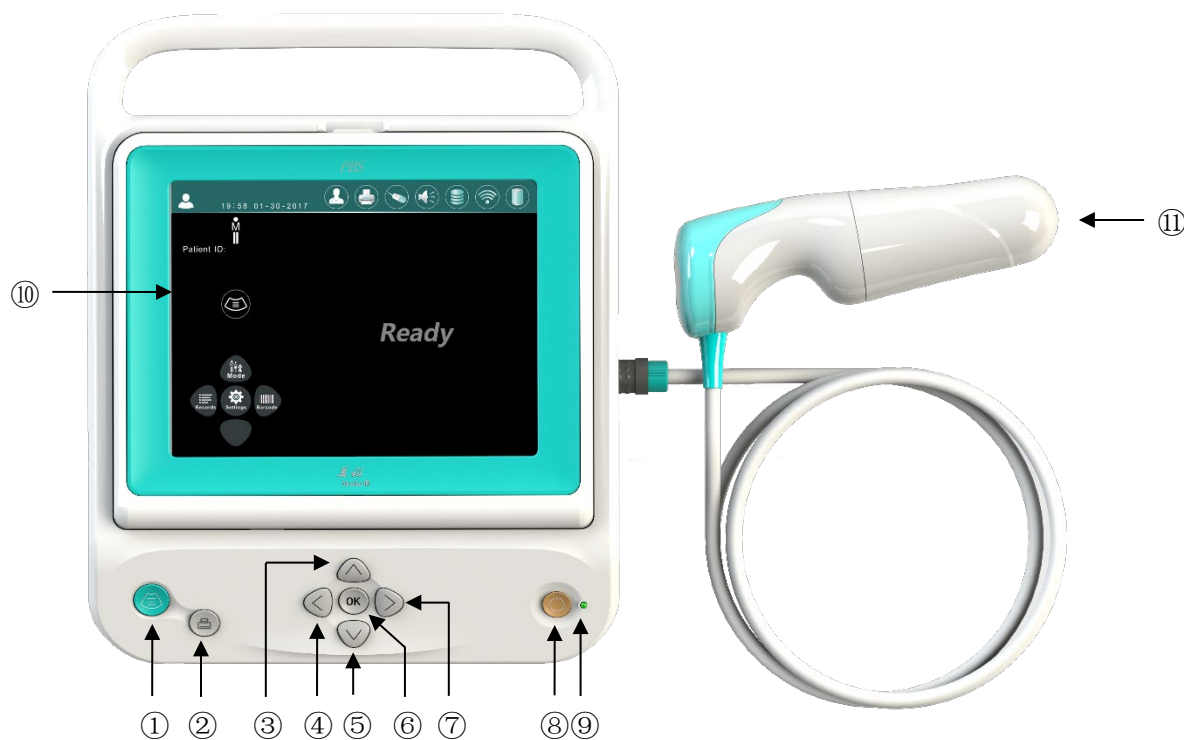


Figure 4-1 Control Panel

- | | |
|----------------|---------------------|
| ① Scan Button | ② Print Button |
| ③ Up Button | ④ Left Button |
| ⑤ Down Button | ⑥ OK Button |
| ⑦ Right Button | ⑧ Power Button |
| ⑨ Power Light | ⑩ LCD(Touch Screen) |
| ⑪ 3D Probe | |

Chapter 5 Environmental Requirement

5.1 Environmental requirement for device use

- 5.1.1 Environment temperature range: $+10^{\circ}\text{C} \sim +40^{\circ}\text{C}$;
- 5.1.2 Relative humidity range: $30\% \sim 75\%$;
- 5.1.3 Atmospheric pressure range: $700 \text{ hPa} \sim 1060 \text{ hPa}$;
- 5.1.4 Power supply of charger: AC 100V~240V 50Hz/60Hz;
- 5.1.5 Away from strong electrical field, strong magnetic field and high-voltage equipment.
- 5.1.6 The operating room should avoid strong light exposure in order to facilitate image observation; the room should be clean and tidy, free of pollution and noiseless.

5.2 Environment requirement for device storage

- 5.2.1 The Range of Environmental Temperature: $-10^{\circ}\text{C} \sim +55^{\circ}\text{C}$;
- 5.2.2 The Range of Relative humidity: $\leq 80\%$
- 5.2.3 The Range of Atmospheric Pressure: $500 \text{ hPa} \sim 1060 \text{ hPa}$

5.3 Environment requirement for transportation

- 5.3.1 The Range of Environmental Temperature: $-10^{\circ}\text{C} \sim +55^{\circ}\text{C}$;
- 5.3.2 The Range of Relative humidity: $\leq 80\%$;
- 5.3.3 The Range of Atmospheric Pressure: $500 \text{ hPa} \sim 1060 \text{ hPa}$

Note:

The battery must be removed out of the device and be packed separately in transportation.

Chapter 6 Device Installation

6.1 Check after opening the carton

6.1.1 Please check the device according to “Packing list”, and confirm if every part have been accorded with the packing list, including in the user's manual, maintenance document and accessories. If any differences from the packing list, please contact your local distributor.

6.1.2 After opening the box, check item by item against the packing list to confirm that the equipment and fittings are aligned and that there is no transportation damage. Thus the device can be installed.

6.2 Device installation

6.2.1 Battery installation



Figure 6-1 Back view of the device without battery

- a. Lift the LCD screen to a certain angle and use the display panel to support it.
- b. Loosen the fastening screws by the tool on the battery cover buckle.
- c. Remove the battery cover
- d. Put four 18650 batteries into the battery tank according to the electrode polarity requirement.
- e. After confirming that the battery is properly loaded, install the battery cover and secure it with the fastening screw.



Figure 6-2 Back view of the device with battery

6.2.2 Taking the battery out

- a. Open the battery cover according to the battery loading process.
- b. Take out the battery in turn.
- c. Install the battery cover according to the way after the battery loading process

Warning:

The battery must be installed in strict accordance with the electrode polarity within the battery tank.

They cannot be used together for the old and new battery!!!

The device must be switched off before taking the battery out!!!

The device must be used the battery provided by our company or 18650 battery with protective plate which meets the requirements of IEC 62133:2012 standard. Some parameters that must be met are shown in table 6-1.

Table 6-1

Parameters	Requirements
Type	18650 battery
Nominal Voltage	3.7 V
Charge Protection Voltage	4.1 V-4.4 V
Short Circuit Protection	Yes
Max. Charge Current	≥ 2 A
Max.Discharge Current	≥ 2 A

6.2.3 Probe Installation

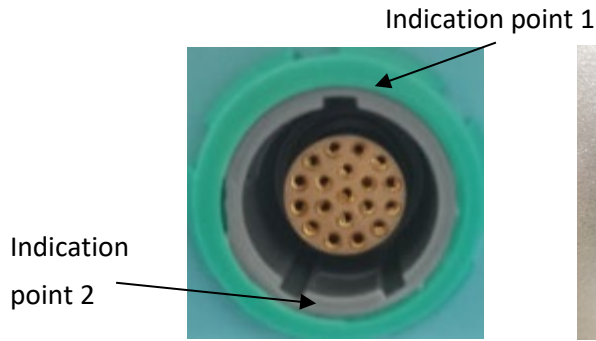


Figure 6-3 Probe socket

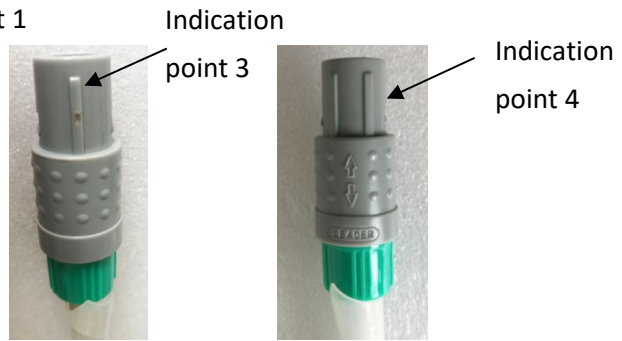


Figure 6-4 Probe plug

- a. Find the indication point 1 and 2 on the probe socket indication point 3 and 4 as shown in Figure 6-3 & 6-4 ;
- b. Align the probe plug indication point 3 with the main probe socket indication point 1, and align the probe plug indication point 4 with the main probe socket indication point 2 and insert it as figure 6-5 shows.



Figure 6-5 Properly connected probe

- c. Make sure the probe plug is properly connected and fully inserted into the probe socket.

Note:

Please pay attention to protect the surface of the probe.

The probe interface is only suitable to the probe designed by ourselves.

Chapter 7 Operation Manual

7.1 Preparation before switching on the device

7.1.1 Check if the battery is properly installed.

7.1.2 Checking if the host and probe are connected properly.

7.1.3 Check if the device is fixed on the trolley steadily according to “Mobile Workstation Installation Instructions” before using PBS.

7.2 Switch on/off the device

7.2.1 The user can press “POWER” button for three seconds to switch on or off the device. The power indicator lights will be green after power on. The interface is displayed as Figure 7-1 after switching on the device.



Figure 7-1 Self-checking interface

Note:

The system will enter its main system interface automatically after displaying the boot interface 3 seconds.

7.3 Login Interface

7.3.1 Login Interface , See Figure 7-2。

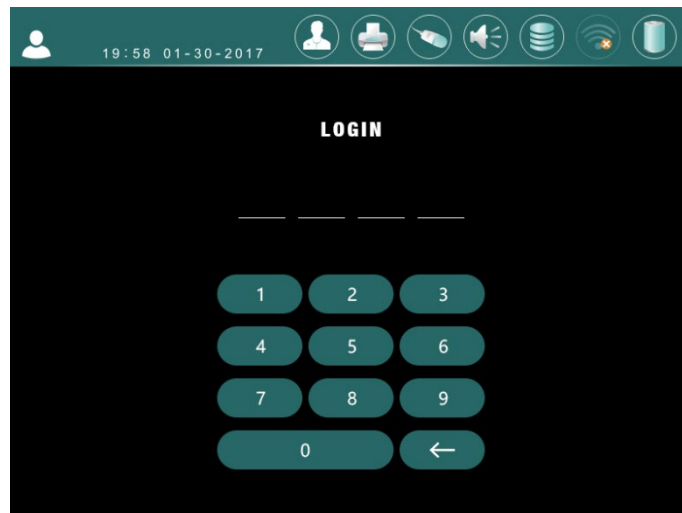


Figure 7-2 Login Interface

7.3.2 Touch the digital icons on the display screen to input the password, and will automatically enter into the system if the password are correct.

Note:

- 1) The password consists of four digits;**
- 2) Please contact the dealer or manufacturer for the password before the first use or after losing the password;**

7.4 Main System Interface

7.4.1 Main system interface is as shown in Figure 7-3.

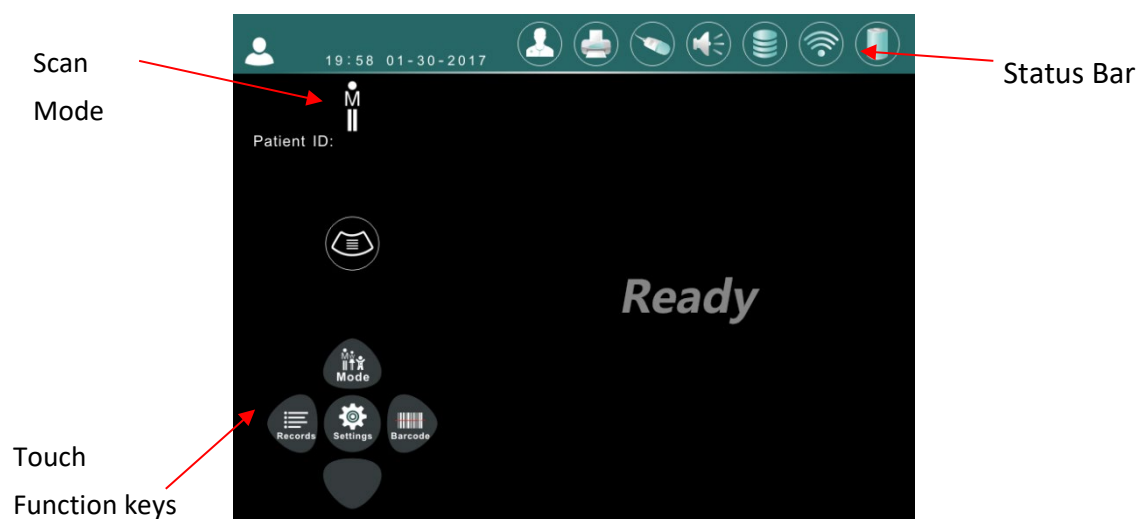


Figure 7-3 Main system interface

7.4.2 Illustration for status bar are as shown in table 7-1

Table 7-1 Illustration for status bar

Icon name	Icon	Description
Operator ID		The operation ID can be input in reset interface.
Operator Type		Expert
		Easy
Printer status		Normal Connection
		Abnormal connection or shortage of printing paper
Probe status		Normal Connection of probe
		Abnormal Connection of probe
sound status		Turn on
		Turn off
Storage		Ample
		Low
		Full
WLAN		Network connected.
		Network not connected.
Battery		Battery capacity is close to 100%
		Battery capacity is close to 70%
		Battery capacity is close to 40%
		Battery capacity is close to 15%

7.4.3 Main System Operation

After entering main system operation interface, both touch function keys and panel buttons can be used to operate.



Figure 7-4 Touch function keys



Figure 7-5 Panel Buttons

- a. Press  button or touch  icon to start barcode scanning; scan the patients' examination application bar code to get the patient ID.
- b. Press  button or touch  icon to enter into the record browse interface.
- c. Press  button or touch  icon to select measurement mode. Icon  for Male, icon  for female, icon  for Pediatric.  mode is only effective to measure volume less than 100 ml;
- d. Press  button or touch  icon to enter the system settings interface.
- e. Press  button or touch  icon to enter Pre-scan interface. If the device is not connected to the probe, it cannot enter the pre-scan interface.

Note:

Each status icon in the status bar changes according to the system settings or system detection.

The function of the touch function icon will vary with the interface.

If the device is in the trial period, the main interface will display "Please calibrate again before: **_**-****" indicating the last date the device can be used.**

When entering the patient ID with the patient's examination application form, please place the barcode on the application form at 5 cm-15 cm at the bar code scanning port.

7.5 Pre-scan interface and Scan interface

7.5.1 The pre-scan interface of expert mode is shown in figure 7-6, and the pre-scan interface in simple mode is shown in figure 7-7.

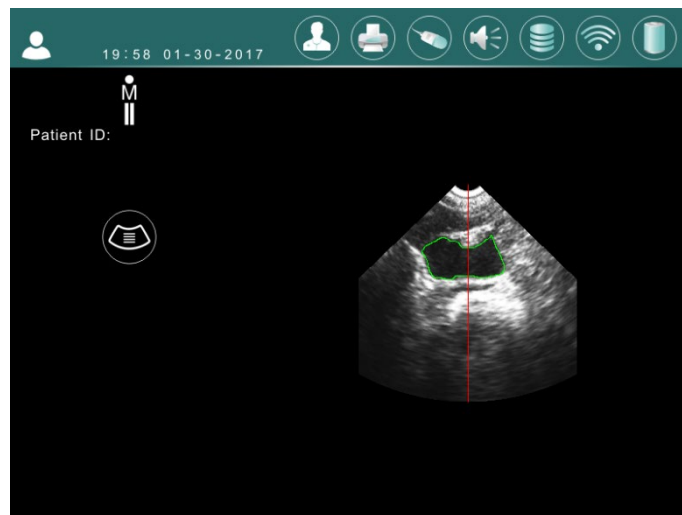


Figure 7-6 The pre-scan interface of expert mode

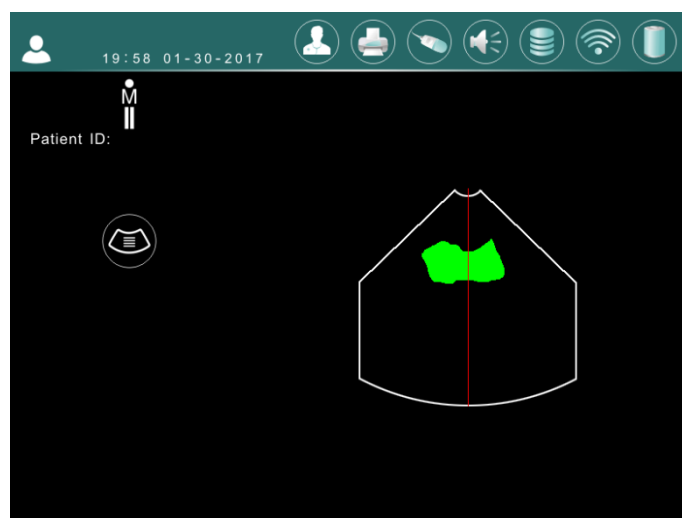


Figure 7-7 The pre-scan interface --simple mode

7.5.2 Pre-scan status of expert mode will show the real-time display of ultrasonic scanning images; In simple mode, only the identified liquid dark area is shown, see figure 7-7 yellow area.

7.5.3 Expert mode will display the bladder contour in real time, and the position state of the bladder will be indicated by the contour color. The scan position is best when the contour is green, otherwise the contour will be orange.

7.5.4 Simple mode will display the identified liquid dark area in real time and fill the color in the liquid dark area to indicate the bladder's position. The scan position is best when the filling color is green, otherwise the filling color will be orange.

7.5.5 The red vertical line of the pre-scan interface is the scanning center line. During each scan, the scan center line should pass through the bladder image liquid dark area and try to be as "symmetrical" as possible. The pre-scan does not respond to other operations except the "scan" key.

7.5.6 Under the pre-scan interface, press the scan button again  or touch  to enter the "scan interface" as shown in figure 7-8.

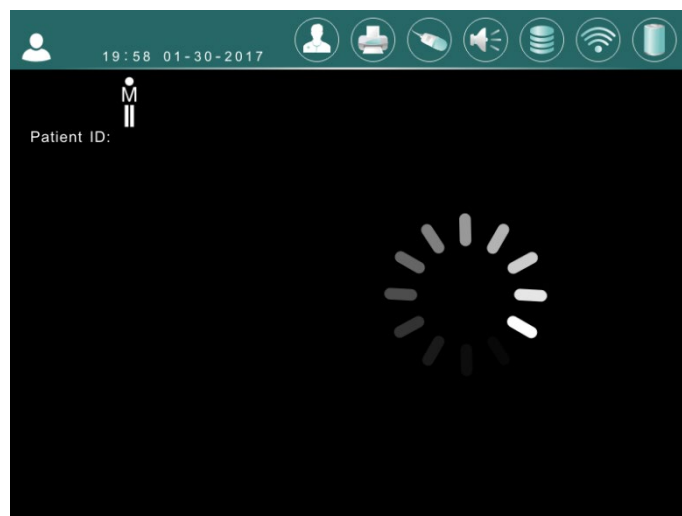


Figure 7-8 Scan interface

7.5.7 During the scanning period, no other operation can be performed. When the "scanning plane" option in the "system setting interface" is set to 12, the scan time is about 5 seconds. When set to 24, the scan time is about 10 seconds.

7.5.8 After the scan is completed, the system automatically enters the "scan result interface".

7.6 Scan result interface.

7.6.1 The interface effect of the scan results is shown in figure 7-9, indicating the current measurement result value and position prompt.

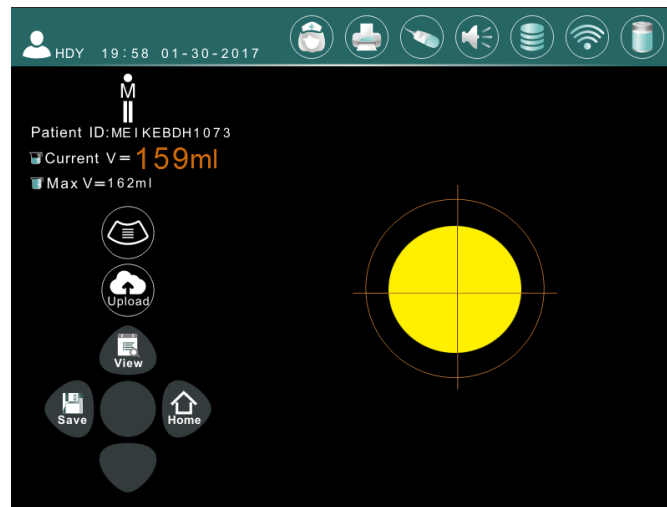


Figure 7-9 The interface effect of the scan results

- Press right button  or touch , back to the "main interface".
- Press left button  or touch , enter "Save edit interface"
- Press up button  or touch , enter "Scan result 2- color interface"
- Press scan button  or touch , enter "Pre-scan interface"
- Press printer button  or touch , upload the testing results wirelessly

Note:

PBSV5.1 with English version is not configured for wireless network export. wireless network export has no effect for the device.

The yellow targeted pattern on the right is the relative position of the center of the bladder identified;

"Maximum" is the maximum volume value of multiple measurements for the same patient. Returning to the main interface or saving successfully is considered to be completed for the patient's test, and the maximum value will be emptied.

The right side of the scan results is the bladder position indication, indicating the relative position of bladder and probe. If the bladder diagram deviates from the outer ring, follow the instructions in section "7.14 Location Prompt " for measurement again.

It is suggested that after the scanning measurement is completed, enter the scan results two-color interface to see if the contour of the bladder and the edge of the liquid dark area in the grayscale image are overlapped. If the deviation is too large, please do manual correction or re-scanning.

7.7 Scanning results two-color interface and grayscale interface.

7.7.1 The interface effect of the scan result of two-color interface is as shown in figure 7-10. The grayscale interface of the scanning results is shown in figure 7-11.

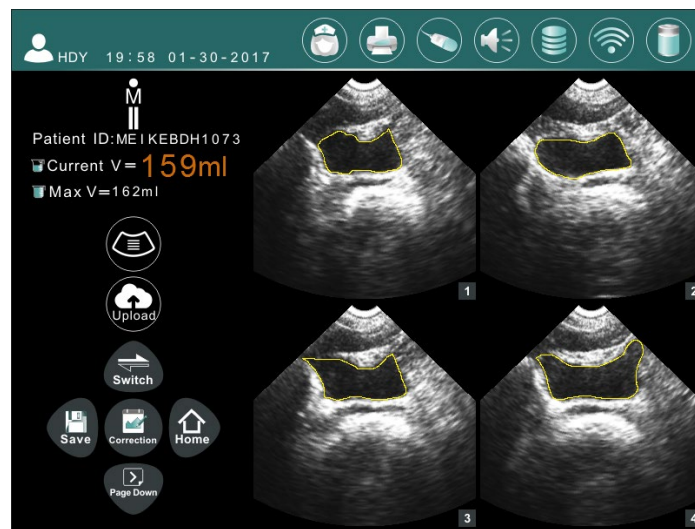


Figure 7-10 two-color interface of the scanning results

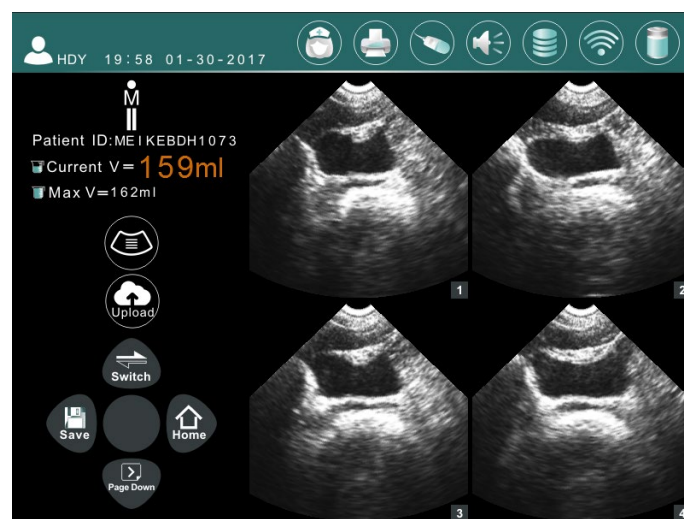


Figure 7-11 the grayscale interface of the scanning results

7.7.2 If the "scanning plane" option in the system setting is set to 12, a total of 12 images will be scanned, which will be displayed in 3 pages and 4 images per page. When the "scanning plane" option in the system settings is set to 24, the scan results are 24 images, which will be displayed in 6 pages and 4 images per page.

a. Press  or touch , back to the "main interface".

b. Press  or touch , Enter the "save edit interface".

c. Press  or touch , switch between grayscale and 2- color graph.

d. Press  or touch , switch the current display images as the last four images of the scan result.

e. Press  or touch , upload the testing results wirelessly.

f. Press  or touch , enter the "pre-scan interface".

g. Press  or touch , enter the "scan result correction interface"

Note:

PBSV5.1 with English version is not configured for wireless network export. wireless network export has no effect for the device.

7.8 Result Correction Interface

7.8.1 Scanning result correction interface is shown in figure 7-12.

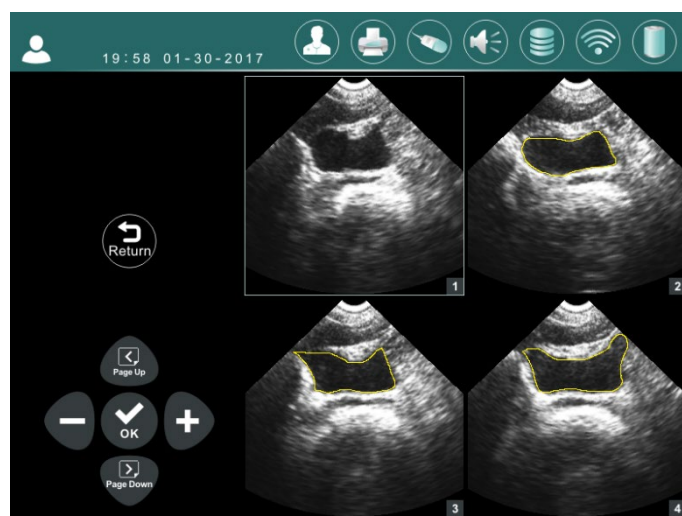


Figure 7-12 Scanning Result Correction Interface

7.8.2 Instruction

- a. Press  button or touch  icon to return two-color images interface.
- b. Touch to select the image which needs to re-locate bladder edge, and re-identify bladder edge at the touched position as the center of bladder dark area. The new envelope of bladder edge can be displayed.
- c. Press  button or touch  icon to increase the envelope of bladder edge.
- d. Press  button or touch  icon to reduce the envelope of bladder edge.
- e. Press  button or touch  icon to switch into the previous 4 images.
- f. Press  button or touch  icon to switch into the next 4 images.
- g. Press  button or touch  icon to save the corrective result and return to “scan result interface”. The new result will be displayed on the result interface after calculating again according to the correction conditions.

7.9 Save & Edit interface

7.9.1 Figure 7-13 is the save/ edit interface

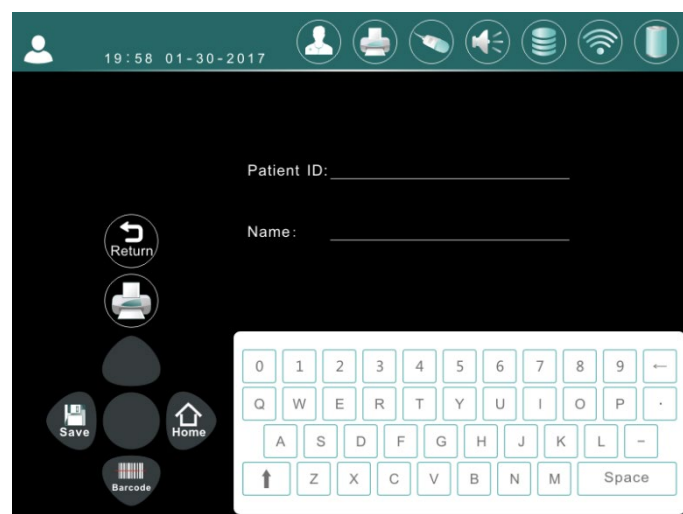


Figure 7-13 Save & Edit Interface

7.9.2 Instruction

- a. Press  button or scan the touch  icon to scan the barcode of the patient examination application form to get the patients' ID.
- b. Input the patients' name from the soft keyboard in the touch screen.
- c. Press  button or touch  icon to save the patients information and measurement result.
- d. Press  button or touch  icon to return the main system interface.
- e. Press  button or touch  icon to print the current patient's information and measurement result.
- f. Press  button or touch  icon to return the scan result interface.

Note:

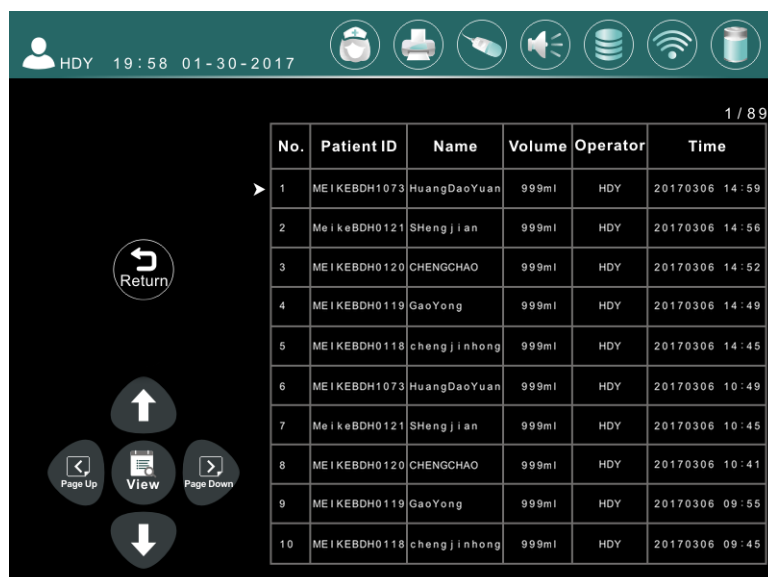
When entering the patient ID with the examination application form, please place the code on the application form at 5 cm-15 cm near the bar code scanning port.

There are up to 22 figures for the name;

It will take about 6 seconds to save the record .Do not press other functional keys during saving the record;

7.10 Browse historical record interface

7.10.1 Figure 7-14 is the historical record interface



The screenshot shows a software interface with a top status bar displaying 'HDY 19:58 01-30-2017' and several icons. Below this is a table of historical records. To the left of the table are navigation buttons: 'Return' (circular arrow), 'Page Up' (left arrow), 'View' (document icon), 'Page Down' (right arrow), and a central 'Up' arrow button. The table has 6 columns: No., Patient ID, Name, Volume, Operator, and Time. It contains 10 rows of data.

No.	Patient ID	Name	Volume	Operator	Time
1	MEIKEBDH1073	HuangDaoYuan	999ml	HDY	20170306 14:59
2	MeikeBDH0121	SHengjian	999ml	HDY	20170306 14:56
3	MEIKEBDH0120	CHENGCHAO	999ml	HDY	20170306 14:52
4	MEIKEBDH0119	GaoYong	999ml	HDY	20170306 14:49
5	MEIKEBDH0118	chengjinhong	999ml	HDY	20170306 14:45
6	MEIKEBDH1073	HuangDaoYuan	999ml	HDY	20170306 10:49
7	MeikeBDH0121	SHengjian	999ml	HDY	20170306 10:45
8	MEIKEBDH0120	CHENGCHAO	999ml	HDY	20170306 10:41
9	MEIKEBDH0119	GaoYong	999ml	HDY	20170306 09:55
10	MEIKEBDH0118	chengjinhong	999ml	HDY	20170306 09:45

Figure 7-14 Browse historical record interface

7.10.2 The historical record browse interface displays all measurement records of the device stored at the list form, and there are 10 cases records per page. To browse the specific information of a record, press up and down button to select the record and then press check button.

7.10.3 Operation Instruction

a. Press  button or touch  icon to move the cursor, and select the last record.

b. Press  button or touch  icon to move the cursor, and select the next record.

c. Press  button or touch  icon to move the cursor, and check the record in the last page

d. Press  button or touch  icon to move the cursor, and check the record in the next page

e. Press  button or touch  icon to enter into "Measurement Record Detail Interface"

- f. Press  button or touch  icon to enter into "Main System Interface".

Note:

It is possible that one of the patient ID and name recorded in the test record is null based on the input condition while saving.

7.11 Check Record Detail Interface

7.11.1 Figure 7-15 is the measurement record detail interface.

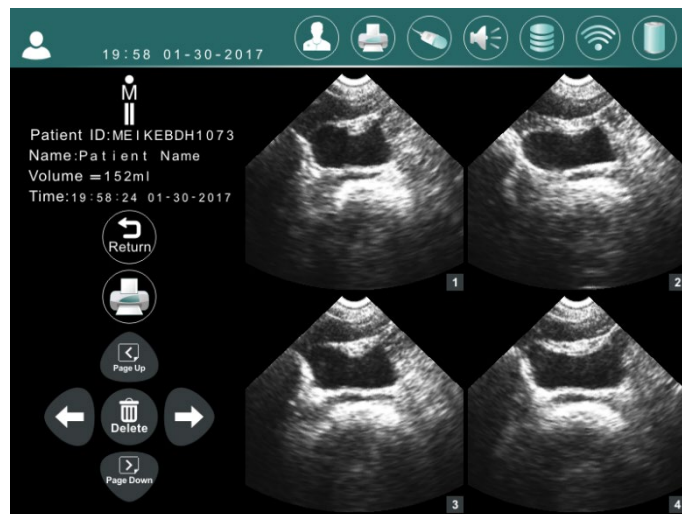


Figure 7-15 Measurement Record Detail Interface

7.11.2 Measurement record detail are including in patient ID, name, measurement result, measurement date, the grayscale of the scan. The current case can be printed or deleted.

7.11.3 Instruction

- a. Press  button or touch  icon to return record browse interface.
- b. Press  button or touch  icon to print measurement record.
- c. Press  button or touch  icon to return to the last record.
- d. Press  button or touch  icon to return to the next record.
- e. Press  button or touch  icon to display the page-up images of this record.

f. Press  button or touch  to display the page-down images of this record.

g. Press  button or touch  to delete this record. Please touch the delete icon for 2 times to delete the measurement record.

7.12 System reset Interface

7.12.1 Figure 7-16 is System reset Interface.



Figure 7-16 System reset Interface

7.12.2 Operator: Set the operator ID and display 3 characters only.

Operation Function Keys as following

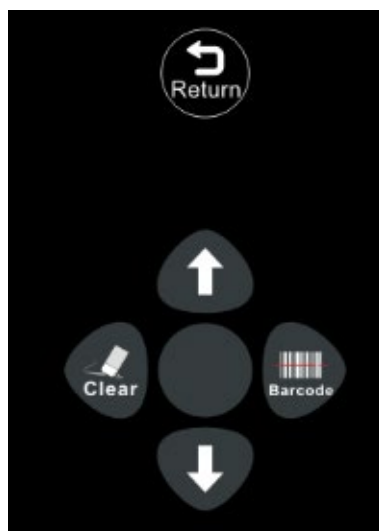


Figure 7-17 Operation Function Keys of Operator Setting

Instruction

a. Press  &  button or touch  &  to move and to select the option of “the operator”.

b. Press  button or touch  to delete the input operator information.

c. Press  button or touch  to start barcode scanning, scan operator code to get the operator ID.

d. Press  button or touch  to save the settings and return back to the main system interface. Or save all settings after other settings are set.

7.12.3 Display mode: Set pre-scan display mode: Expert or easy mode.

Operation Function Keys as following

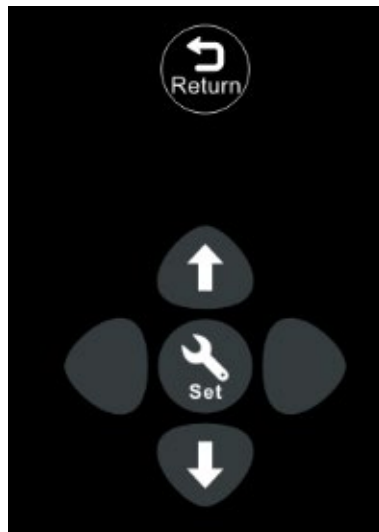


Figure 7-18 Operation Function Keys of Display Mode Setting

Instruction

a. Press  &  button or touch  &  to move to select the display mode.

b. Press  button or touch  to switch easy mode and expert mode.

c. Press  button or touch  to save the settings and return back to the main system interface. Or save all settings after other settings are set.

7.12.4 Scan planes: Set scan planes quantity.

Operation Function Keys as following

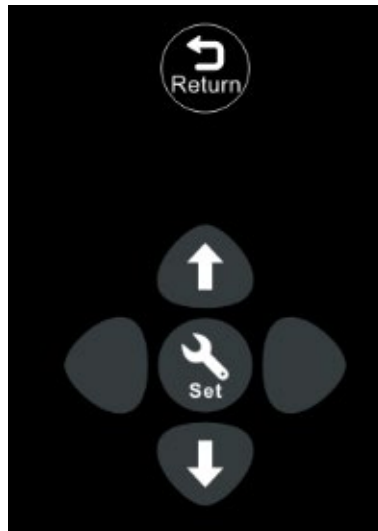


Figure 7-19 Operation Function Keys of Scan Planes Setting

Instruction

a. Press  &  button or touch  &  to move to select the option of “Scan Planes”.

b. Press  or touch  to select 12 planes or 24 planes.

c. Press  button or touch  to save the settings and return back to the main system interface. Or save all settings after other settings are set.

7.12.5 Sound: set the key sound

Operation Function Key as follows,

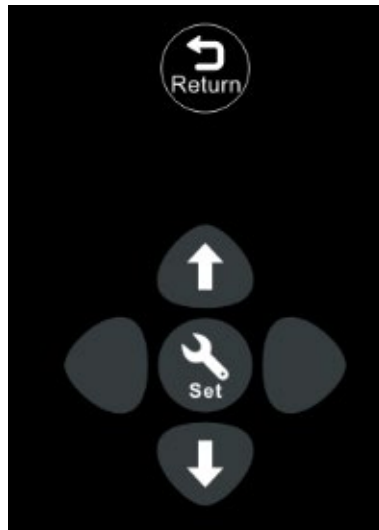


Figure 7-20 Operation Function Keys of Sound Setting

Instruction

a. Press  &  button or touch  &  to move to select the option of sound.

b. Press  button or touch  to set the key sound on/off.

c. Press  button or touch  to save the settings and return back to the main system interface. Or save all settings after all other settings are set.

7.12.6 Format: To delete all measurement records stored in device

Operation Function Keys as following,

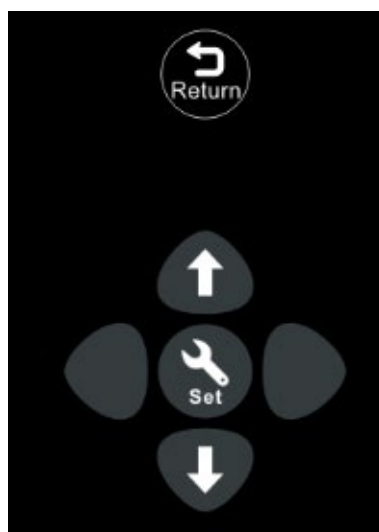


Figure 7-21 Operation Function Keys of Format Setting

Instruction

a. Press  &  button or touch  &  to move to select the option of "memory format".

b. Press  button or touch  icon to enter into memory format sub-menu,
See figure 7-22

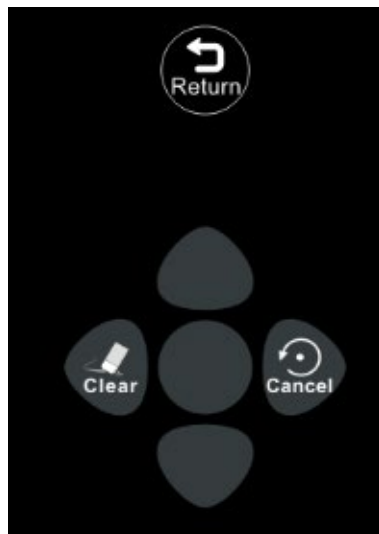


Figure 7-22 Memory Format the sub-menu.

c. Press  button or touch  to select memory format. The formatting progress and status will be displayed in the position of formatting Settings value, and return to the formatting menu after completing.

d. Press  button or touch  to cancel memory Format, and return to memory format setting.

e. Press  button or touch  to save the settings and return back to the main system interface. Or save all settings after other settings are set.

Note:

The formatting option will delete all measurement reports stored in the device. Use it carefully.

7.12.7 Mode: set Human or phantom mode

Operation Function Keys as following

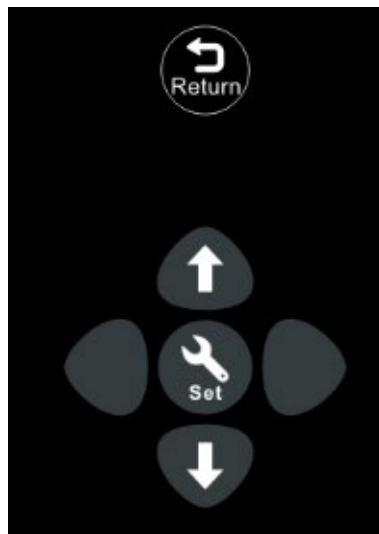


Figure 7-23 Operation Function Keys of Mode Reset

Instruction

a. Press  &  button or touch  &  to move to select the “mode”.

b. Press  button or touch  to switch the scan mode human/phantom.

c. Press  button or touch  to save the settings and return back to the main system interface. Or save all settings after other settings are set.

Note:

If it is phantom mode, some functions of human mode will be forbidden.

7.12.8 Probe Calibration: set the probe adjusting parameter.

Operation Keys as follows

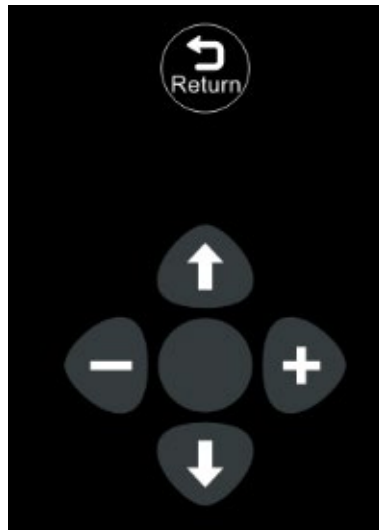


Fig 7-24 Probe Calibration Reset Operation keys

Instruction

- a. Press  button &  button or touch  &  to move and select "Probe Calibration" .
- b. Press  button or touch  to set the value adding 1.
- c. Press  button or touch  to set the value minus 1.
- d. The exact value settings shall follow "Appendix A Probe Calibration Instruction".
- e. Press  button or touch  to save the settings and return back to the main system interface. Or save all settings after other settings are set.

7.12.9 Volume Calibration: Set the volume calibration parameter. The calibration phantom is used as the measurement object. If the measurement value is deviated from the phantom nominal value, the calibration value can be set by adjusting proper parameter.

Operation Keys as follows

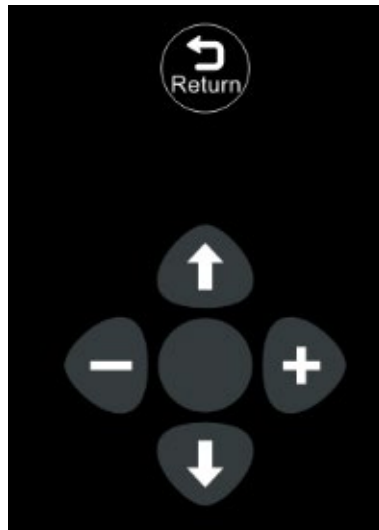


Figure 7-25 Volume Calibration Operation Keys

Instruction

- a. Press  button &  button or touch  &  to move to select “Volume Calibration”
- b. Press  button or touch  to set the value adding 1.
- c. Press  button or touch  to set the value minus 1.
- d. The exact calibration value settings shall follow “Appendix B Volume Calibration Instruction”.
- e. Press  button or touch  to save the settings and return back to the main system interface. Or save all settings after other settings are set.

7.12.10 Time Set: Set real-time date and clock. The format of date is MM-DD-YY. The format of clock is HH:MM:SS.

Operation function keys as shown:

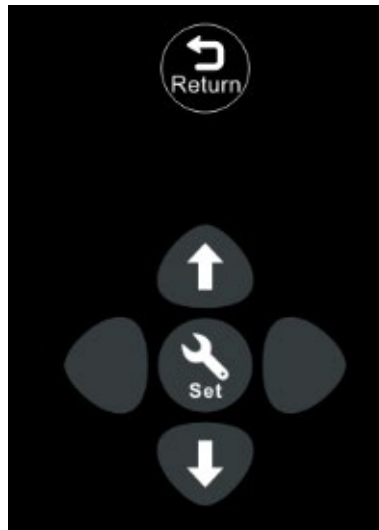


Figure 7-26 Time Setting Function Keys

Instructions:

a. press  button and  or touch  and , move selection items and select the "Time setting" option.

b. press  button or touch , enter the time setting sub-menu, the interface is shown in Figure 7-27:

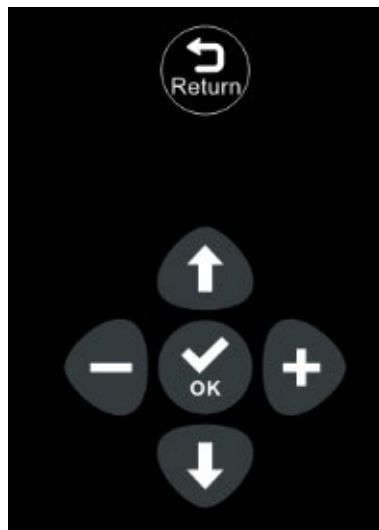


Figure 7-27 Time Setting Sub-menu

c. press  and  button or touch  and , underline moves around month, day, year, hour, minute and second;

- d. Press  and  button or touch  and , adjust the underlined character value;
- e. Press  button or touch , finish time setting, return to time setting menu.
- f. press scan button  or touch , save the setting and return to the main menu. Or wait for other settings and then press this to save all settings.

7.12.11 Touch screen calibration: Calibrate the touch screen.

Operation function keys as shown:

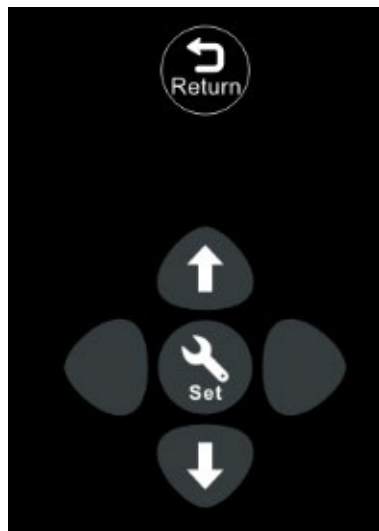


Figure 7-28 Touch Screen Calibration Operation Function Keys

Instructions:

- a. Press  and  button or touch  and , move selection items and select the "Touch screen calibration" option.
- b. Press  button or touch , enter the touch screen calibration interface as shown in Figure 7-29.

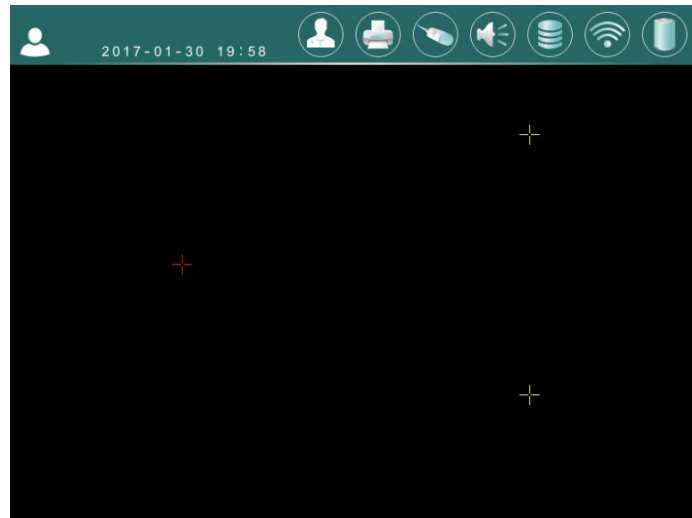


Figure 7-29 Touch Screen Calibration Interface

i. Use touch pen track and click on the center of the red cross cursor (multiple times) to complete touch screen calibration. Exit the touch screen calibration interface after finishing the calibration.

c. Press scan button  or touch , save the setting and return to the main menu. Or wait for other settings and then press this to save all settings.

7.12.12 About: Display device information, including manufacturer information and software version information.

Operation function keys as shown:

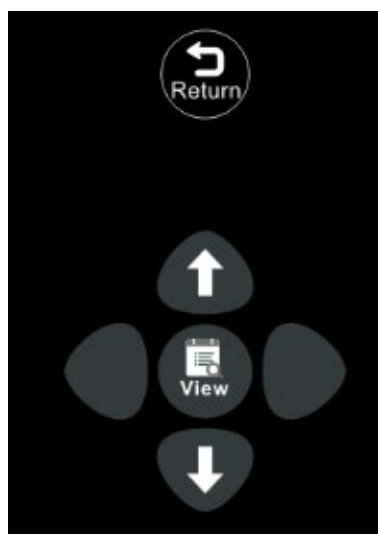


Figure 7-30 Device Information Operation Function Keys

Instructions:

a. Press  and  or touch  and , move selection items and select the "About" option.

b. Press  button or touch  to enter the device information interface as shown in Figure 7-31.



Figure 7-31 Device Information Interface

i. Press scan button  or touch , exit device information interface.

c. Press scan button  or touch , save the setting and return to the main menu. Or wait for other settings and then press this to save all settings.

7.13 Device verification interface

When the trial time expires, the device verification interface will automatically pop up after the device is powered on. As shown in Figure 7-32, the user must perform device re-authorization before it can be used normally.

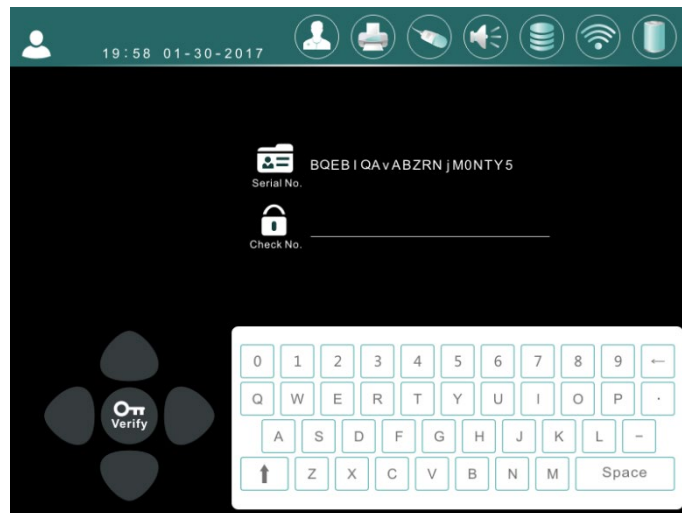


Figure 7-32 Device Calibration Interface

7.13.1 Send the serial number of the device to the distributor to obtain the check number corresponding to the serial number.

7.13.2 Enter the activation code by touching the character keys.

7.13.3 Press  button or touch , verify the product.

7.13.4 It will automatically enter the main interface if the verification succeed; or it will hint that the verification fails. You can only calibrate again or shut down.

7.14 Location prompt

While measuring, the user should put the probe correctly according to the human body's direction marked in the label on the top of the probe. After scanning, if the image of bladder locates in center of the coordinate, the scanned result is effective; if the image of bladder is not in the center of the coordinate such as Figure 7-33 and 7-40, user need to scan again according to the operating instructions.

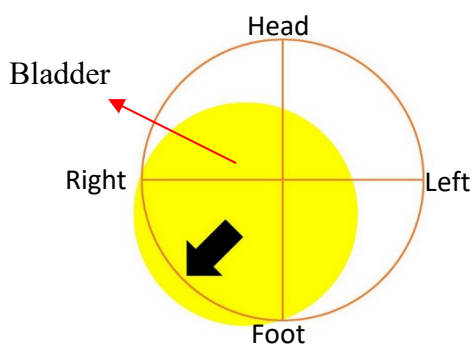


Figure 7-33

Move probe to lower right

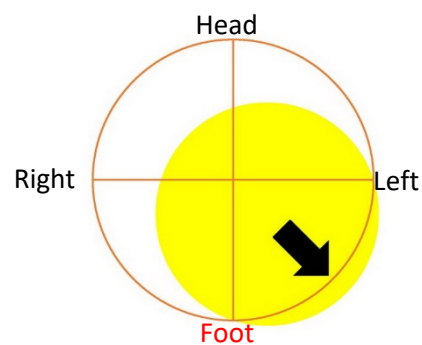


Figure7-34

Move the probe to lower left

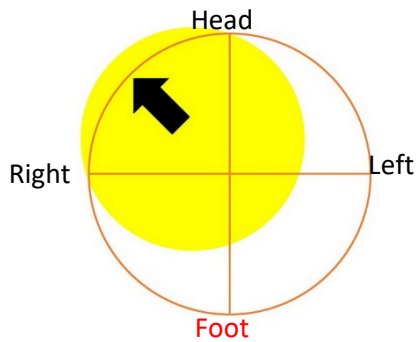


Figure 7-35
Move the probe to up right

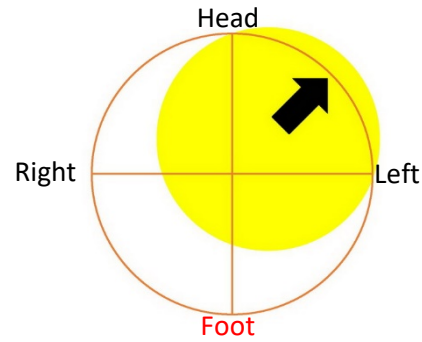


Figure 7-36
Move the probe to up left

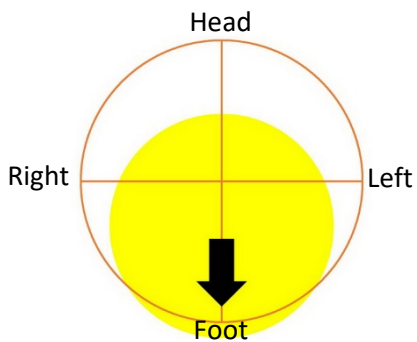


Figure 7-37
Move the probe towards patient's feet.

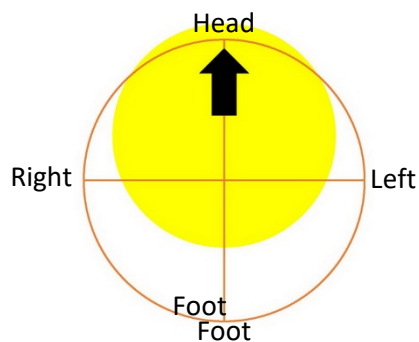


Figure 7-38
Move the probe towards patient's head

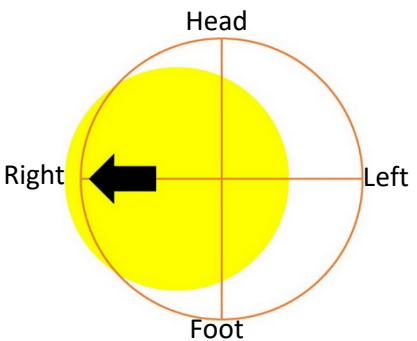


Figure 7-39
Move the probe to right

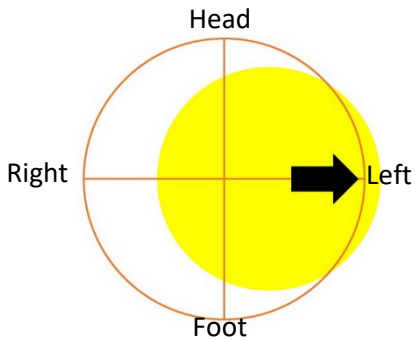


Figure 7-40
Move the probe to left

7.15 Test record printing

7.15.1 The test record can be printed directly by the build-in thermal printer in the interface of saving after scanning, or the saved cases can be printed in the interface of Test Record Details.

7.15.2 The print result is shown in Figure 7-41. The number of images in the print result is 2.

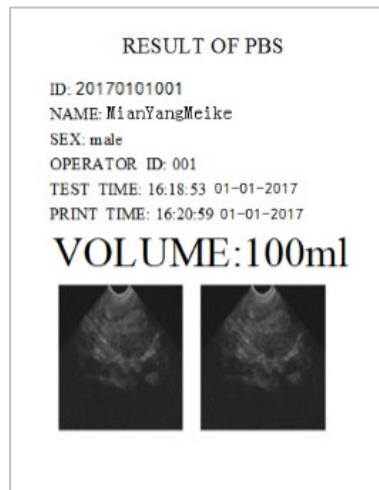


Figure 7-41 Test record print

7.16 Thermal printer

7.16.1 The device has a built-in thermal printer.

7.16.2 Operation for changing the thermal printer paper

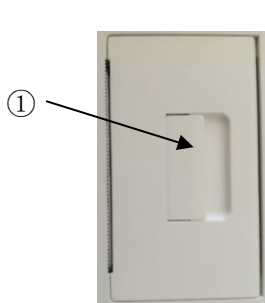


Figure 7-42



Figure 7-43



Figure 7-44



Figure 7-45

- a. As shown in Figure 7-42, open the cover ①.
- b. As shown in Figure 7-43, open the printer cover;
- c. As shown in Figure 7-44, put the paper into paper box, pay attention to the direction of printing paper;
- d. As shown in Figure 7-45, pull out the paper about 5 cm, and close the printer cover.

7.16.3 The specification of the print paper: Φ 20×57 mm (outer diameter*width)

Note:

The printer cannot print results if you put the paper in wrong direction.

7.17 Test Record Export

7.17.1 Each test record is saved in the device memory in the form of a file folder. The folder name is the time when it was saved. It contains an information text file and a collection of bladder grayscale images (12 images). The bladder scanner can export the test records in two ways: USB cable or wireless network .

7.17.2 USB data cable export operation flow

a. In the shutdown state, connect the USB interface of the device and the USB interface of the PC through the USB cable, and press and hold the UP button and the POWER button at the same time to enter into the USB mode interface after confirming that the physical connection is correct. USB mode interface is as shown in Figure 7-46.

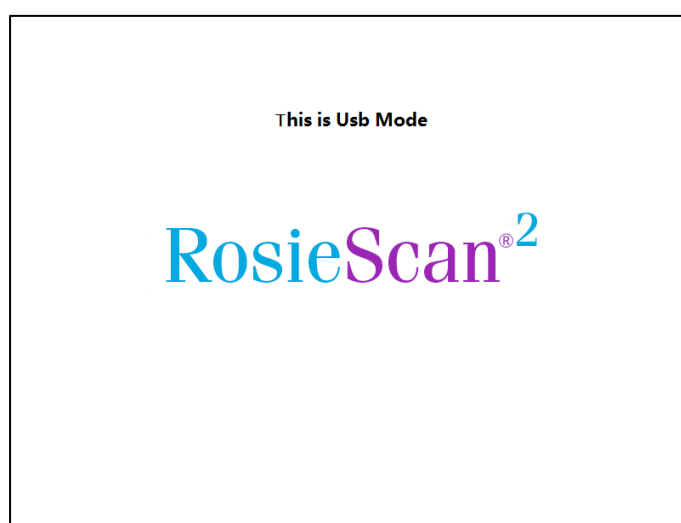


Figure 7-46 USB Mode Interface

b. "This is USB Mode!" is displayed above the USB mode interface. Open the newly discovered removable disk in the PC to copy or cut the detection record file in the internal memory of the device.

c. After the operation is completed, turn off the power of the device and disconnect the USB connection cable.

7.17.3 Wireless network export operation process

a. According to the instruction of workstation system software, the device need to be c onnected correctly.

b. Observe the network status icon on the status bar to ensure that its status is "Netw ork connection is normal".

c. Use the device according to the instructions in "7.6 Scan Result Interface" and "7.7 Scanning Results Two-color Graph Interface", and upload the test records to the server.

Note:

When in USB mode, do not copy unrelated files to the bladder scanner device on the PC.

PBSV5.1 with English version is not configured for wireless network export. wireless network export has no effect for the device.

7.18 Energy Saving Mode

7.18.1 In order to prolong the working time of the device. In the state of being turned on, the device will automatically turn off if there is no operation within 5 minutes and enter the power-saving mode. In power-saving mode, the power indicator is still green.

7.18.2 After the device enters the energy-saving mode, clicking anywhere on the touch screen or pressing any key (except the power switch key) can wake up the device and enter the normal working state.

Note:

No operation refers to not operating the control panel keys and touching the touch screen.

The pre-scan interface and touch-screen calibration interface cannot enter the power-saving mode.

7.19 Over temperature tips

7.19.1 During the operation of the equipment, the core temperature of the equipment will be monitored in real time. When the temperature exceeds a certain limit and the performance of the equipment is affected, a high temperature alarm icon will appear above the date and time display in the status bar. As shown in Figure 7-47.



Figure 7-47 Over Temperature Tips

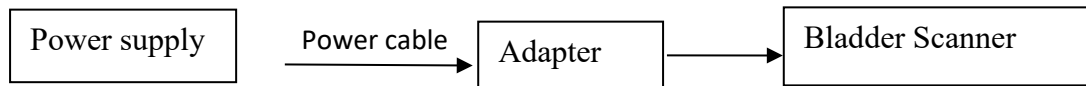
7.19.2 When a high temperature alarm icon appears, stop using the device and turn off the power. Wait for the device temperature to return to normal before turning it on.

7.20 Battery recharging

7.20.1 The 18650 battery can be charged in the following two ways: in-device charging and external charger charging.

7.20.2 In-device charging instructions

Connection method



Instructions:

- a. Follow the instructions in "6.2.1 Battery loading" to properly install the battery in the device.
- b. Plug one end of the power cord into the power adapter and the other end into a power outlet.
- c. Insert the power adapter output into the bladder scanner charging interface to charge the 18650 battery. During battery charging, the power indicator shows yellow;
- d. 4 PCS 18650 batteries (the nominal capacity of a single battery is 3350 mAh) charging time is 5-6 hours
- e. When charging is complete, the power indicator shows blue (recharge is recommended for 2 hours)
- f. After completing the charge, disconnect the power adapter from the power supply and then bladder scanner.

7.20.3 External charger charging instructions

Connection method



Instructions:

- a. Plug one end of the power cord into the charger and the other end into the network power outlet; confirm the charger do work normally and enter into the standby state.
- b. Put 18650 battery into the charger tank.

Warning:

While inserting the battery, it should be placed according to the positive and negative direction as marked on the charger. There will be some danger occurred if reverse the positive and negative poles.

- c. The 18650 battery will be conducted to charge.
- d. When completing the charging, remove the 18650 battery from the charger tank after disconnecting the charger from the network power supply.

Warning:

1) Meike will supply the charger for every device. If the user purchase the out sourcing charger, it must meet the requirements of IEC/EN 60950-1, and Meike will be not responsible for any safety accident.

2) When charging, someone must be on duty! The power adapter, charger, and battery must be kept away from sources of ignition and heat and away from flammable and explosive materials! !

3) The power adapter provided with this device meet the requirements of the IEC 60601-1:2005+A1:2012 standard.

4) In order to ensure the safety of the operator and the patient, the device cannot be started for detection during the charging.

Chapter 8 Clinical Application

8.1 Operation Steps:

8.1.1 Patient should be in supine posture when it is scanned with the device.

8.1.2 The coupling agent will be evenly put on the acoustic window of the probe.

8.1.3 Put the probe placed in the human abdomen at about 2 cm above the pubic bone and the direction of probe must be slightly sloped towards to the head of patient, aiming at the position of bladder.

8.1.4 Pre-scan by press scan key, moving the probe to find the max surface of fluid dark area of bladder, while making it in the central fan-shaped area at the same time.

8.1.5 The Expert Mode and Easy Mode both display the real-time bladder profile and indicate the position of the bladder by the bladder outline color. The outline of bladder is green in its best position, otherwise it is orange.

8.1.6 Scan again by press scan button for measurement. After measurement, suggest to press “check” key to see if both edges of the red line and the dark fluid area in gray scale are overlapped. If the deviation is too large, you can manually modify the scan results according to the method mentioned in Chapter 7. Or re-scan by press scan key.

8.1.7 During scan, the contact position between the probe and the subject easily slides away from the position of the bladder, the operator needs to give appropriate pressure to the abdomen through the probe to ensure that the acoustic window contact fully patient's abdomen through the coupling agent and relatively fixed.

8.1.8 Try to make patient's posture stability during scan, let the patient to breath smoothly, do not speak as well as no abdominal exercise.

8.2 Bladder profile envelope

The outline of the bladder contour and the position of the edge of the liquid dark region in the grayscale image (Figure 8-1 to Figure 8-10).

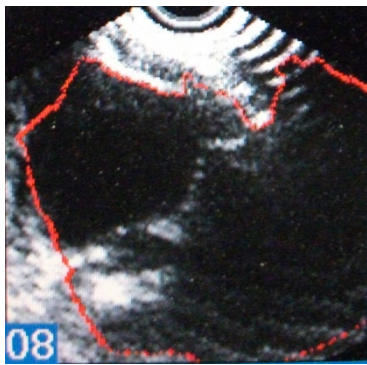


Figure 8-1. Too large red edge line



Figure 8-2 Too large red edge line

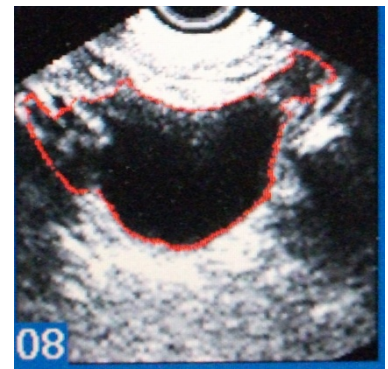


Figure 8-3 Too large red edge line



Figure 8-4 Too small red line

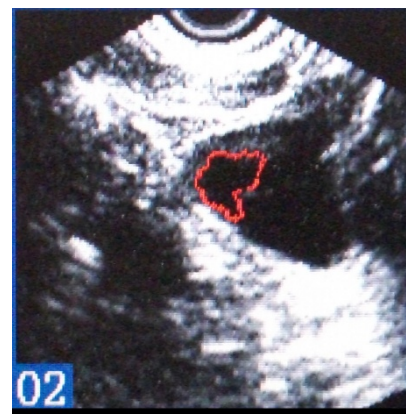


Figure 8-5 Too small red line

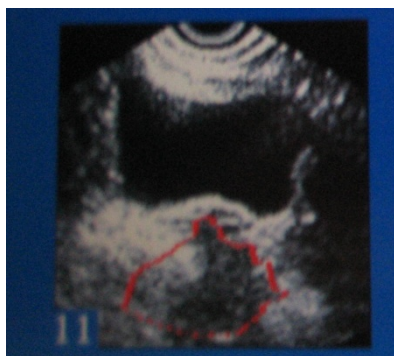


Figure 8-6 red line is not in dark fluid area

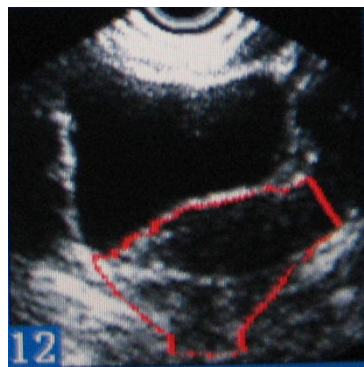


Figure 8-7 Non-fluid area



Figure 8-8 Non-fluid area

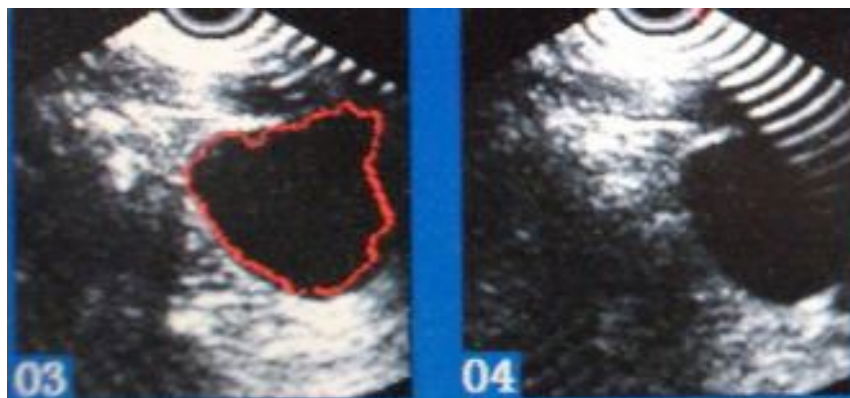


Figure 8-9 Normal red line

Figure 8-10 Non-red line

Note:

If Bladder profile envelope is too big, then its volume will be too big

If Bladder profile envelope is too small, then its volume will be small

If there is no Bladder profile envelope, then the result will be small

If Bladder profile envelope is not in dark fluid area, its scanned result will be ineffective.

Chapter 9 Transportation and Storage

9.1 Transportation

The marks on the device packaging case conform to the requirement of ISO 780:2015 “Packaging-Distribution packaging-Graphical symbols for handling and storage of packages”. With shockproof facility inside of case, be fit for air, railway, highway and steamboat transportation. Any rain, snow, inversion and collision must be avoided during the transportation.

9.2 Storage

When the device storage period exceeds 6 months, it should be took out from case and keep running at least 4 hours. Then packing it as original package and placed properly. Do not put heavy object upon the packaging case. The storage condition should be dry and ventilated, without strong sunlight and corrosion from causticity gas.

Note:

See Chapter 5 for details about transportation and storage condition requirements.

Chapter 10 Maintenance and Service

10.1 Maintenance for probe

10.1.1 As the probe is valuable and damageable part, any collision or falling is forbidden. Especially give attention to the acoustic window of probe, must guard against any damage, even any minim scar also will reduce the effect and its life.

10.1.2 The component of probe is a non-watertight, its degree of protection into liquid is : IPX4;

10.1.3 In order to avoid probe or its protective material be corroded, any conductive liquid to the probe is prohibited.

10.1.4 Please check and stop use the probe for maintenance immediately if there is any crack on the lens material of acoustic window of the probe and its plastic part; or stop use the probe if there is a breakage on the probe cable.

10.1.5 Regarding the medical gel, please select neuter PH, good sonolucency and easy to clean.

10.1.6 After measurement, please scrubbing probe softly and disinfect it before putting it into probe case for storage.

10.1.7 As soon as the probe is connected with the device, do not take the probe off freely, otherwise the plug of probe and socket will be incorrect connection.

10.2 Maintenance for device

10.2.1 Cleaning and disinfection for shell

- a. Clean the probe by a soft cloth with alcohol (or the right medical cleanser).
- b. Please clean the remaining cleanser and dry the probe by a soft cloth if cleaned by the medical cleanser.
- c. If the device need to be disinfected, please wet the soft cloth by medical cleanser like Cidex® or Cidex 7®, or other item like Sporicidin®.
- d. Please wet the soft cloth with aseptis water to clean the cleanser, it's suggested to clean 3 times.
- e. Please clean the device with a clean soft cloth before using it.

10.2.2 Regularly check the visible part of device.

10.3 Service guide

10.3.1 Once the device has problem, firstly check and make sure all of their connection are OK, and enough electricity of battery. If the device still doesn't work after the above work, please contact your local distributor or manufacturer.

10.3.2 the following necessary information must be needed when contacting:

- a. Model of the device and its configuration;
- b. SN of the device and the date of delivery;
- c. Describe the problem as detailed as possible;
- d. Doesn't it have any previous maintenance, if yes, how did you deal with? What's its result after your solution.

10.3.3 Regarding to the device within warranty, free service will be provided by us or our local distributor once the device has problem during normal use.

10.3.4 In general, the device can be used for 6 years (exclude battery). The device must be checked by our authorized technician before continuously using it.

10.3.5 The device must be managed as classified rubbish once it is announced as a waste.

10.4 Register method

10.4.1 Log into www.bladder-scanner.com, fill relevant information to register in the form, including in SN, Hospital Name, contact person, Tel and Address.

10.4.2 Send SN, hospital name, contact person, Tel and address to us by fax or Email, and a representative will register for you;

Fax: +86-816-6355070

Email: meike01@bladder-scanner.com

10.4.3 Call us by 86-816-6355073 (international), and tell us SN, hospital name, contact person, Tel and address. A representative will register for you.

10.5 Production date

See production date on nameplate.

Chapter 11 Simple Problem Elimination

To guarantee the normal use of this device, the solutions for trouble shooting are as below
(For reference only):

- 1) Check that the battery is properly installed and that the battery has a certain charge
- 2) Check the connection between probe and device and lock up.
- 3) When the printer cannot print, check to see if the paper is in place and determine if the placement direction is correct. If you have problem while using the device, please contact our service department.

Appendix A Probe Calibration

A. 1 Fix the probe on a holder and make sure that the probe is placed vertically on the center of acoustic window of phantom (standard phantom 160 ml) See Figure A-1.

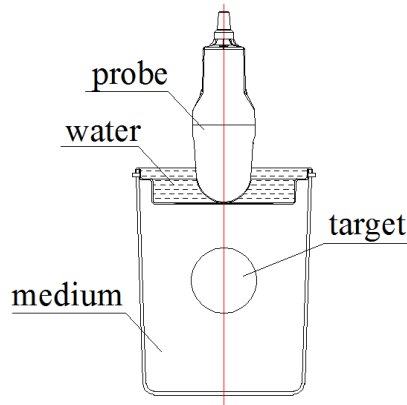


Figure A-1 the place of probe

A. 2 There might have 3 kinds of images on the screen in the pre-scanning. The probe shall be calibrated if the images are as fig. A-2 and fig. A-3.

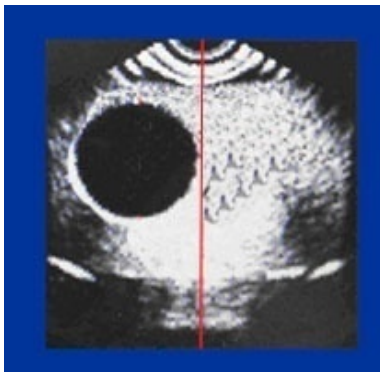


Figure A-2 image center-Left

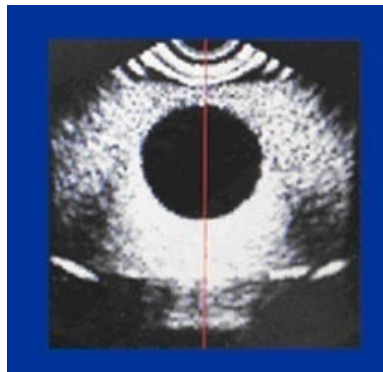


Figure A-3 Correct

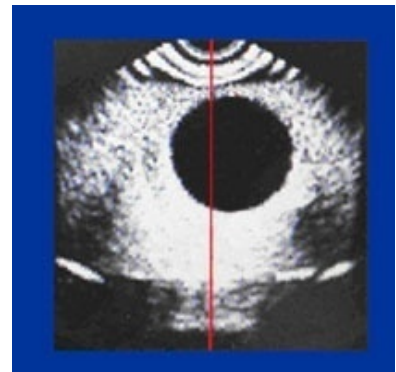


Figure A-4 image center-right

A. 3 Pre-scanning image center-left.

A. 3.1 When the image looks like fig. A-2, the value of probe calibration in the system setting shall be negative. The value is calculated by the degree value of $\angle a$, as fig. A-5 ($\angle a$ equals the center of the image between the red line' degree)

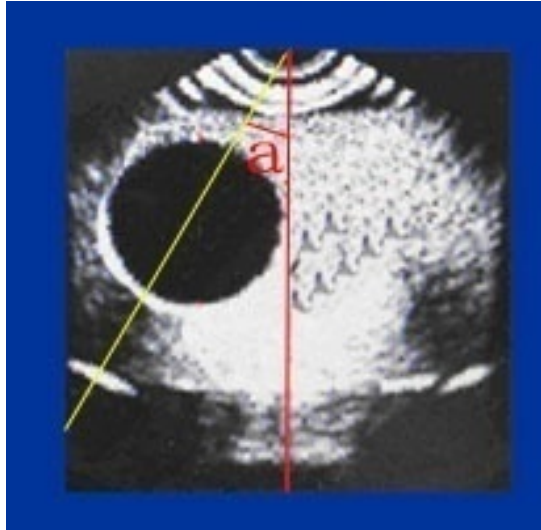


Figure A-5 $\angle a$

Formula: When $0^\circ < \angle a < 15^\circ$, $0 < \text{value of scanning adjust} < 10$
 When $15^\circ < \angle a < 30^\circ$, $10 < \text{value of scanning adjust} < 20$;
 When $30^\circ < \angle a < 45^\circ$, $20 < \text{value of scanning adjust} < 30$;
 When $45^\circ < \angle a < 60^\circ$, $30 < \text{value of scanning adjust} < 40$;

A. 3.2 Back to pre-scan mode to check the red line and image's position, if it's still incorrect, please back to adjust until it is correct (as Fig. A-3) or else, the practice result will with error.

A. 4 Pre-scanning image center-right

A. 4.1 When the image looks like fig. A-4, the value of probe calibration in the system setting shall be positive. The value is calculated by the degree value of $\angle a$, as fig. A-6($\angle a$ equals the center of the image between the red line' degree)

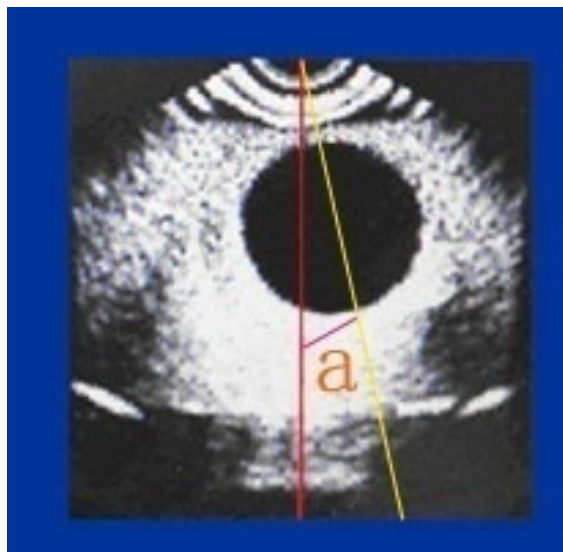


Figure A-6 $\angle a$

Formula: When $0^\circ < \angle a < 15^\circ$, $0 < \text{value of scanning adjust} < 10$

When $15^\circ < \angle a < 30^\circ$, $10 < \text{value of scanning adjust} < 20$;

When $30^\circ < \angle a < 45^\circ$, $20 < \text{value of scanning adjust} < 30$;

When $45^\circ < \angle a < 60^\circ$, $30 < \text{value of scanning adjust} < 40$;

A. 4.2 Back to pre-scan mode to check the red line and image's position, if it still incorrect, please back to adjust until it is correct (as Fig. A-3) or else, the practice result will with error.

Appendix B Volume Calibration

B. 1 Fix the probe on a holder and make sure that the probe is placed vertically on the center of acoustic window of phantom (standard phantom 160 ml) See Figure B-1

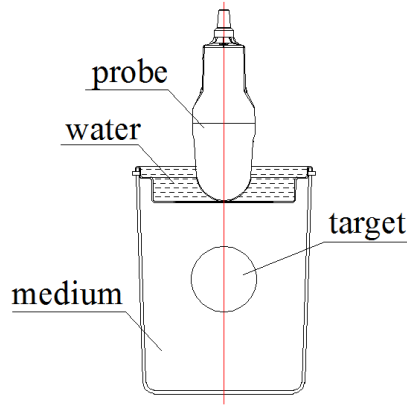


Figure B-1 The place of probe

B.2 Please press “OK” to get into the system setting interface. (As fig. B-2) . Selecting “Phantom” in the “Mode” before return to main system interface.

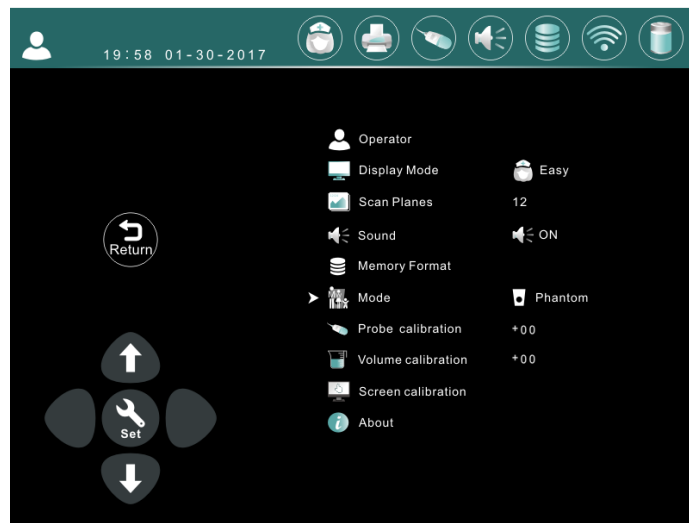


Figure B-2 System setting interface

B. 3. Enter pre-scan state by pressing SCAN key (Figure B-3)

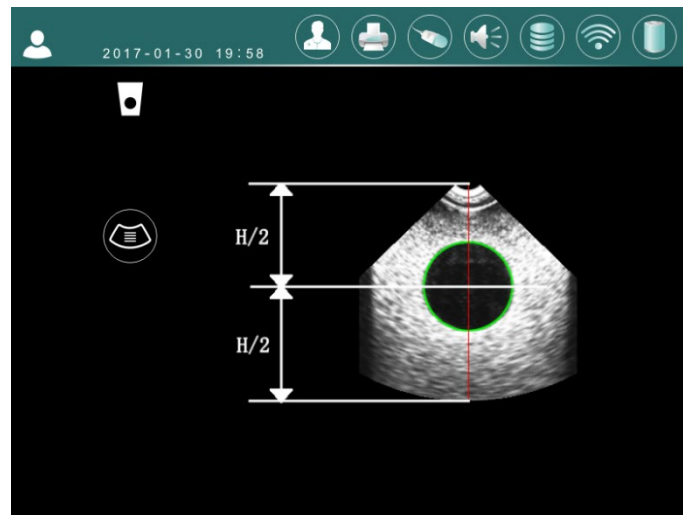


Figure B-3 Pre-scan image

B.4 Find the biggest round dark area(Target) by moving probe, adjust the distance between probe and phantom, let the round dark area (Target) be in the middle of fan-image in pre-scan. The red line shown in Figure B-3 is central line, the object measuring must be across this center line, the edge of round dark area is green.

B.5 Enter Scan interface by pressing SCAN key to get its result. Check result image by pressing UP key, As Figure B-4. Ensure both edges of green line and the round dark area(Target) are overlapped in all scan images.

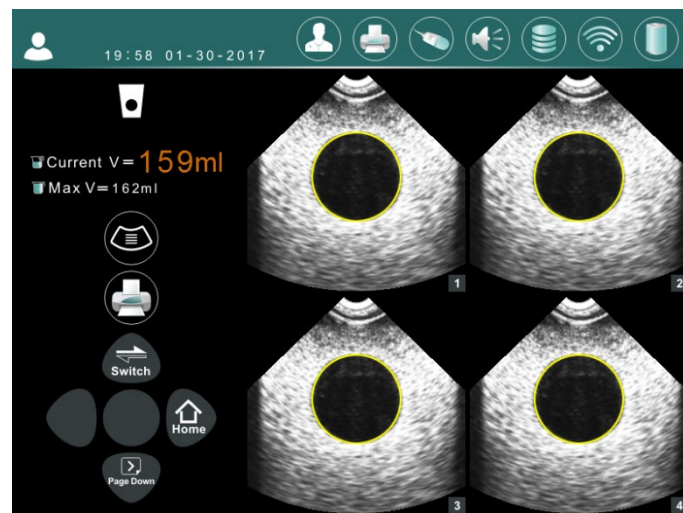


Figure B-4 Clear result image

B.6 Repeat measurement for 5 time , no need calibration to the device if the measurement result are within 160 ± 10 ml.

B. 7 If the measured result is not within 160 ± 10 ml, get the mean value through calculation with 5 time measurement before getting the calibrated with following formula.

160 (phantom volume) – mean value = calibrating value

B.8 Select Calibration in the system reset interface for the volume calibration.

B.9 Phantom Parameter:

Phantom Parameter:

Sound speed of background material: 1540 m/s $\pm$ 10 m/s, 23°C $\pm$ 3°C

Attenuation of background material: 0.7 dB/(cm•MHz) $\pm$ 0.05 dB/(cm•MHz), 23°C $\pm$ 3°C

Protective plate: $\leq$ 0.4 mm

he internal target parameter of the Phantom

Density: 1021 $\pm$ 1 kg/m³

Attenuation at 3 MHz: 0.03 dB $\pm$ 0.02 dB/(cm•MHz)

Sound speed at 23°C: 1547 $\pm$ 1 m/s

Note:

Phantom is 160 ml in the appendix, and other standard phantom can also be used.

Appendix C Precautions for 18650 Battery use

C.1 Prohibition for 18650 Battery

C.1.1 Prohibit to collide the battery with sharp parts.

C.1.2 Keep a clean environment, avoid sharp components exist around battery.

C.1.3 Do not perforate the battery with nail or other edge tools.

C.1.4 Do not transport or keep together with metallic things, such as necklace and barrette.

C.1.5 Do not drop and impact the battery.

C.1.6 Do not knock, throw and trample the battery.

C.1.7 Prohibit any items covered on the battery and charger

C.1.8 Prohibit or mix the battery from different manufacturer as well as mix of old and new one in use of it.

C.1.9 Do not mixed use the battery together with one-off battery capability, or different capability or different mode or different brand battery.

C.1.10 Prohibit the use of non-designated and no safety-certified charger to charge the battery, only the dedicated charger is suitable to the battery. never charge it unattended.

C.1.11 Any electrical short circuit will result in serious damage of the battery, any metal objects are prohibited to use in connection with positive and negative of the battery.

C.1.12 Prohibit use of battery in the following situation.

Stop using the battery right away once the battery are found to hot, the emission of odor, discoloration, deformation or other anomalies

Prohibit use of deformed battery caused by drop, impact and bump.

C.2 Notice for recharging and discharging the battery

C. 2.1 Battery recharging

The recharging current and voltage is not allowed to exceed the following standard, otherwise it might result in damage of mechanical performance and security, also resulting in heat and leakage.

- 1) The charger must be worked with constant current and voltage.
- 2) The current of single battery must be below 1 C during recharging.
- 3) The range of temperature must be 0~ 45℃ during recharging.

4) When using external charger to charge 18650 battery, the voltage of single battery must be less than 4.2 V during charging.

Warning:

Power supply must be cut off once if the battery is found out of the way during recharging, for instance, expand, smoke, break, then before touch or closing to battery in 4 hour later and this battery is forbidden to be used again.

C.2.2 Battery discharging

Discharge current do not exceed the following regulation

The discharge current must be less than 1 C.

The temperature range is -20~60℃ during discharging.

The terminated voltage must be bigger than 2.8 V when battery discharged.

C.3. Storage for Battery

C.3.1 The environment temperature for Long time storage: -5~40℃;

C.3.2 Relative humidity: <80%

C.3.3 The battery needs to be recharged and discharged in every 90 days if you want to store it for a long time. See 7.19 for the way of battery recharging.

Notice

Only remain 50% electricity on it when the battery is stored for one year.

C.4. Battery Transportation

Battery should be transported under the state of 50% electricity.

C.5. Other instruction

C.5.1 Please pay attention to the following prevention for preventing battery from leakage, heat and explosive.

- 1) Prohibit dis-assembly of the battery in any condition
- 2) Prohibit the probe immersed into water, keep it dried.
- 3) Prohibit use or place of battery nearby heat resource, e.g: fire and heater.
- 4) Prohibit heating the battery or throwing it into fire.
- 5) Prohibit doing any soldering on the battery directly.
- 6) Prohibit recharging beside fire or in very hot environment.
- 7) Prohibit battery put in microwave oven or high pressure container

8) Prohibit use or place of the battery in high temp. (e.g: strong sunshine, fire or place with a higher than 60°C inside of car) environment.

C.5.2 you must wash with running water and see the doctor in case the electrolyte leaks out and touch your skin, eyes or other part of body,

C.5.3 Do not use any damaged battery (such as broken battery, breakage of shell, the smell of electrolyte, leakiness, etc.)

C.5.4 Be away from fire or blast if the battery leaks out or smell of electrolyte.

C.5.5 Keep in cool and dry place, keep away from children.

C.5.6 The battery must be away from static field in recharging, use and storage.

C. 5.7 If use the battery beyond the listed environment on the manual, it will cause the fire or shorten the life and worse its performance, even lead to explosion or fire. User will take the full responsibility for the results of missing it.

C. 5.8 Damage of the battery caused by misuse will be user's account.

C. 5.9 Don't casually discard the abandoned battery; don't deal it with the house refuse. Recycle it by the related policy to avoid environment pollution.

Appendix D Guidance and manufacturer's declaration

D.1 Guidance and manufacturer's declaration-Electromagnetic emissions

Guidance and manufacturer's declaration –electromagnetic emissions		
The PBSV5.1 Palm bladder scanner is intended for use in the electromagnetic environment specified below. The customer or the user of the SECP-II should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The PBSV5.1 Palm bladder scanner uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The PBSV5.1 Palm bladder scanner is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	N/A	

D.2 Guidance and manufacturer's declaration-Electromagnetic immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The PBSV5.1 Palm bladder scanner is intended for use in the electromagnetic environment specified below.			
The customer or the user of the PBSV5.1 Palm bladder scanner should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	☐ ±8 kV contact ☐ ±15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5 kV line(s) to line(s) ± 1 kV line(s) to earth	± 0.5 kV line(s) to line(s) ± 1 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 0,5 cycle 40 % <i>UT</i> (60 % dip in <i>UT</i>) for 5 cycles 70 % <i>UT</i> (30 % dip in <i>UT</i>) for 25 cycles <5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 5 s	<5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 0,5 cycle 40 % <i>UT</i> (60 % dip in <i>UT</i>) for 5 cycles 70 % <i>UT</i> (30 % dip in <i>UT</i>) for 25 cycles <5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the PBSV5.1 Palm bladder scanner requires continued operation during power mains interruptions, it is recommended that the PBSV5.1 Palm bladder scanner be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE <i>UT</i> is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The PBSV5.1 Palm bladder scanner is intended for use in the electromagnetic environment specified below. The customer or the user of the PBSV5.1 Palm bladder scanner should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the PBSV5.1 Palm bladder scanner, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz

			where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the PBSV5.1 Palm bladder scanner is used exceeds the applicable RF compliance level above, the PBSV5.1 Palm bladder scanner should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the PBSV5.1 Palm bladder scanner.			
^b Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the PBSV5.1 Palm bladder scanner			
The PBSV5.1 Palm bladder scanner is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PBSV5.1 Palm bladder scanner can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PBSV5.1 Palm bladder scanner as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150kHz to 80MHz $d = 1.2\sqrt{P}$	80MHz to 800MHz $d = 1.2\sqrt{P}$	800MHz to 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 transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80MHz and 800MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Declaration:

All the pictures in this user manual are just for reference.