MD-6000P

Bladder Scanner

USER MANUAL

CE
0123

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FCC Statement

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

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

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

-- Reorient or relocate the receiving antenna.

-- Increase the separation between the equipment and receiver.

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

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

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

Changes or modifications made to this equipment not expressly approved by MEDA may void the FCC authorization to operate this equipment.

FCC ID: 2ARUOMD-6000P

Precautions and Warnings

Precautions

- The device should be operated by trained professionals.
- Please read the User Manual carefully before operation.
- Please use the device according to the requirements of the User Manual; otherwise it will affect the essential performance.
- Please read the User Manual (**§6.2 Maintenance and Attentions of Built-in Battery**) carefully before using the battery.
- Please refer to **Chapter 6** and **Chapter 7** for maintenance details.

Warnings

- Do not make any modification to the device without authorization.
- MEDA Co., Ltd. (hereinafter referred to as “the manufacturer”) will not be responsible for any damage or injury caused by any failure to follow the instructions in the **User Manual**.
- The device is driven by a rechargeable battery; the charger must be disconnected and stop charging when operation.
- If the battery is found hot, odoriferous, discolored, deformed, leaking, or unable to be charged or has other anomalies during using, charging or storage, stop using it and contact your local distributor or the manufacturer for service.
- If the Main Unit is accidentally broken, stop using it and contact your local distributor or the manufacturer for service.
- The device is not used for therapy.
- The charger has obtained the medical electronic device safety qualification. If it is lost or damaged, please contact the manufacturer to purchase a new one; use of charger other than that is provided by the manufacturer may cause increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in abnormal operation and undesirable impact on product safety. The manufacturer shall not be responsible for any consequences arising therefrom.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of MD-6000P. Otherwise, degradation of the performance of MD-6000P could result.
- Use of MD-6000P adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, MD-6000P and the other equipment should be observed to verify that they are operating normally.

- When the battery is charged with AC power, it is prohibited to connect other devices onto the same AC power socket.
- Although the device complies with the requirements of electromagnetic immunity in IEC 60601-1-2, it should be kept away from strong interference sources, such as high-frequency electric knife, magnetic resonance imaging equipment, microwave therapy instruments and other RF treatment equipment.
- According to FDA laws, the device is a prescription device and is to be used by or under the supervision of a licensed physician.
- The manufacturer reserves the rights to modify the device characteristics without previous notice under FDA Laws and MDD (93/42/EEC).
- Without written consent of the manufacturer, no individual or organization is allowed to copy, modify or translate any part of the **User Manual**.
- Do not scratch the surface of the probe cover.
- Keep the original package properly. All detachable accessories should be put into the original package before transportation.
- For any question, please contact your local distributor.

Cautions

- Federal (US) Law restricts this device to sale by or on the order of a physician.

How to prevent cross-infection:

- Between uses on different patients, the probe cover must be cleaned to avoid cross-infection.
- The manufacturer advocates a preventive action and a cleaning procedure in the **Chapter 5 Cleaning and Disinfection**.

Tissue exposure to ultrasound energy:

- The device is designed for use in bladder scanning only.
- The manufacturer is not aware of any reports of adverse effects from using bladder scan, even at FDA pre-enactment levels; no other use is intended or implied.
- For the acoustic output parameters, please refer to Annex B of the **User Manual**.
- No control of ultrasound energy is available to the user other than the duration of exposure, considering the current concern for possible unknown hazards, and despite the extremely low output intensities used in this ultrasound system.
- The manufacturer suggests that patient exposure time during measurement be minimized. In other words, the principle of ALARA (As Low As Reasonably Achievable) should be implemented to perform ultrasound procedure.

Labels and Indicators

SN	Serial Number
	"Type BF" Applied Part
	CAUTION! Important information that operator must read carefully.
	Please Refer to User Manual
	Manufacturer
MEDA®	Logo of Manufacturer
	“ON” or “OFF”
+ −	Charger Interface
CE 0123	CE Conformity Marking
EC REP	Authorized Representative in the European Community
	The battery meets RoHS requirements. Dispose it according to the local law.
	Disposal of the product after its life-cycle should comply with the relevant local environmental protection regulations.

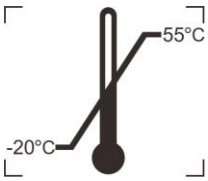
Explanation of Labels and Symbols on the Packing Box

This Way Up

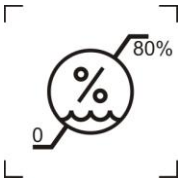
Fragile, Handle with Care

Keep Dry

Stacking Limit by 4



Temperature Limit



Humidity limitation

Chapter 1 Introduction

1.1 General Description

MD-6000P Bladder Scanner (hereinafter referred to as “the device”) is a hand-held device which utilizes ultrasonic distance measuring principle to calculate urine volume in the bladder. It integrates a 2.5MHz B-mode 3D mechanical sector scan probe, a 1.3-inch OLED screen and a Li-ion battery, and comes with a charger.

1.2 Main Features

1. The device utilizes ultrasonic distance measuring principle; it takes mechanical sector scan by 2.5MHz ultrasonic waves and recognizes the reflected waves of the front and back walls of bladder to get the area of bladder section. It makes 12 scans at an interval of 15°, and calculates the urine volume in the bladder with volume integral algorithm.
2. The hand-held design structure offers convenience to users.
3. The device has a pre-scan positioning function, which can locate the real-time position of the bladder through scanning bladder positioning algorithms, and directly guide users to adjust the scanning direction of the device for the convenience of accurate positioning.
4. After measurement, the projection of bladder can be displayed with one-click.
5. Rechargeable battery-driven offers great convenience for use in hospital wards.
6. It can be used together with Tablet PC through Wi-Fi connection, in order to achieve data transmission, case information management, medical report printing and other functions.

1.3 Intended Use

It is intended to measure the urine volume in human bladder.

1.4 Intended Conditions of Use

The device is intended to be used in medical and nursing care institutions.

It should be operated by trained professionals.

The probe cover should be cleaned and disinfected according to the requirements in **Chapter 5** of this User Manual.

1.5 Contraindications

- It is not intended for use on pregnant women.
- It can not be used on wounded skin.

1.6 Software Version

MD60P V1.0

Chapter 2 Specifications

2.1 Working Conditions

- Ambient temperature: 5 ℃~40 ℃
- Relative Humidity: ≤80%
- Atmospheric Pressure: 70-106kPa
- Power Supply:

  —Main Unit (internal power supply): rating voltage: DC7.2V; 2,040mAh rechargeable Li-ion battery.

  —AC/DC Adaptor (Charger): AC 100～240V, 50/60Hz, 0.5A max.

2.2 Specifications

- Nominal Ultrasound Frequency: 2.5 MHz
- Volume Display Resolution: 1ml
- Number of sections in one calculation: 12 sections with an interval of 15 °
- Operation Time: the continuous operation time is not less than 6 hours for normal work when the Main Unit is fully charged.
- Measuring Range: 0 ml - 999 ml
- Measuring Accuracy: ±15% or ±15ml (take the maximum value)

2.3 Safety

1. Basic safety and essential performance: the device meets the requirements of IEC60601-1, IEC60601-2-37 and IEC60601-1-2.
2. See **Annex B** for the acoustic output parameters.

2.4 Storage and Transportation

- Storage Condition

  It must be fully packed and stored in a room at

  Temperature: -20 ℃~55 ℃

  Relative humidity: ≤ 80%

  Atmospheric Pressure: 70-106kPa

  Free of corrosive gas, and well-ventilated

- Transportation Condition

  General transportation is allowed when the device is packed. Avoid severe impact and crash, rain and snow. Transportation temperature: -20 ℃~55 ℃.

⚠***Note: The detachable parts, such as the charger, should be packed into the original package before transportation.***

2.5 Product Classification

1. According to the type of protection against electric shock:

   Internally powered (working); Class II (charging)

2. According to the degree of protection against electric shock: Type-BF Applied Part

3. According to the degree of protection against harmful ingress of water or particulate matter:

   The Main Unit: IPX1

   The Probe Cover: IPX7（See Fig. 3.1a）

4. According to the method of disinfection recommended by the manufacturer:

   See **§5. Cleaning and Disinfection**.

5. According to the degree of safety of application in the presence of flammable anesthetic mixture with oxygen or nitrous oxide: not belong to category AP and APG equipment

6. According to the mode of operation: continuous operation.

2.6 Li-ion Battery

1. Nominal Voltage: DC 7.2 V

2. Nominal Capacity: 2,040 mAh

3. Charging Voltage: 8.4 V ± 0.1 V

4. Charging Time: 2~3 hours (standard charging)

5. End of Discharging Voltage: 6.5 V

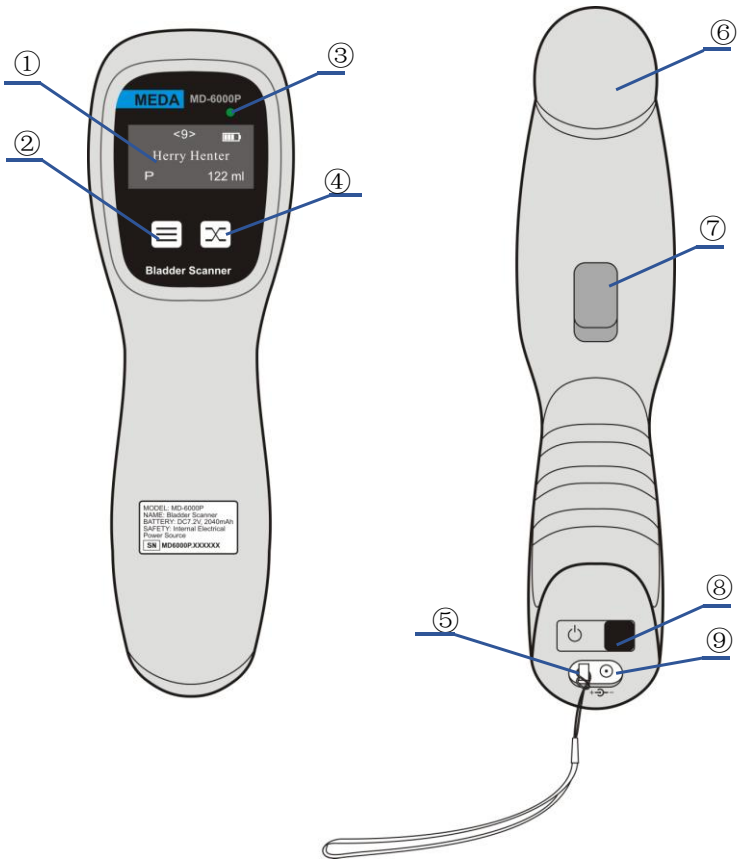
6. Overcharging Protection Voltage: 8.4 V

7. Cycle Life: no less than 300 cycles

Chapter 3 Installation

3.1 Structure

MD-6000P Bladder Scanner is a hand-held device consisting of Main Unit and Charger, which can be used together with Tablet PC.



① OLED Screen

② Menu Key

③ Power Indicator

④ Function Key

⑤ Anti-Drop Lanyard Hole

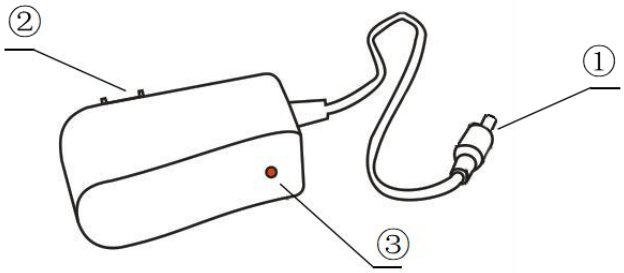
⑥ Probe Cover

⑦ Scan Button

⑧ Power Switch of Main Unit

⑨ Charging Port

(a): Main Unit



① Charger Output Connector

② Power Supply Plug

③ Charging Indicator

(b): Main Unit Charger

Fig. 3.1 External Structure

a) Main Unit

1. OLED Screen

For displaying interface information.

2. Menu Key

The Menu Key is mainly used for screen switching. Please refer to **§4 Operation** for details.

3. Power Indicator

The power indicator lights up when the device is turned on.

The power indicator goes out when the device is turned off.

4. Function Key

The Function Key is mainly used to select sub-functions. Please refer to **§4 Operation** for details.

5. Anti-Drop Lanyard Hole

The Anti-Drop Lanyard can be inserted into the Anti-Drop Lanyard Hole; and the operator may hang the lanyard around the wrist, so that the Main Unit will not drop.

6. Probe Cover

The probe cover is the part through the top of which ultrasound signals are transmitted.

7. Scan Button

Press the **Scan** Button and hold it to access the Pre-scan Positioning Mode;

Release the **Scan** Button under the Pre-scan Positioning to access the 3D Scanning Mode;

Press the **Scan** Button and release it immediately to access the 3D Scanning Mode. See **§4.2.4 Main Unit Scanning** for detailed operation.

8. Power Switch of Main Unit

Power on: Press the button for 1-2 seconds and release it, the Main Unit starts running and the power indicator lights up.

Shutdown: Press the button for 3-4 seconds and release it, the Main Unit turns off and the power indicator goes out.

9. Charging Interface

Charging interface (DC input socket of the charger): used to charge the built-in Li-ion battery.

b) Main Unit Charger

1. Charger Output Connector

For connection to the Main Unit.

2. Power Supply Plug

For connection to the mains power.

⚠***Notes: ① Please connect the device to the mains power only when it is off.***

② The device shall not be positioned where it's difficult to disconnect while charging.

3. Charging Indicator

The charging indicator lights up in red during charging.

The charging indicator lights up in green when the battery is fully charged.

The charging indicator goes out when the charger is disconnected from the mains power.

3.2 Environmental Requirement

The device should be operated in a clean room, preferably one with an air-conditioner, in order to work stably.

Don't place the device near heat sources or cover it for a long time to avoid affecting heat dissipation.

Do not use the device in locations with intense electric or magnetic fields (e.g. RF therapeutic equipment). Avoid excessive shock and direct exposure to sunlight.

3.3 Connection

3.3.1 Charging

As shown in Fig. 3.1(b), connect the DC output of the charger to the charging socket of the device, and connect the other end of the charger to the mains socket. The charging indicator is in red during charging. When the charging indicator turns green, it indicates that the battery is fully charged and the operator shall disconnect the charger from the mains socket.

The Main Unit will stop working while charging and the text of "Charging…" is shown on the charging prompt interface to inform the user that the Main Unit is being charged; a white charging progress bar under the text shows the progress of charging and the length of the charging progress bar represents the battery power, as shown in Fig. 3.2a. Meanwhile, the charging indicator is red.

When the device is fully charged, the length of the charging progress bar is equal to the width of the screen, as shown in Fig. 3.2b. Meanwhile, the charging indicator is green.

Fig. 3.2a Charging Prompt Interface

Fig. 3.2b Fully Charged

3.3.2 Using Together with Tablet PC

The tablet PC can be used as a supporting accessory. It uses an Android operating system with a bladder scan App. It can be used together with the Main Unit.

3.3.2.1 Structure of the Tablet PC

There is no electrical connection between the tablet PC and the Main Unit. Through Wi-Fi connection, data transmission and application management can be realized. The recommended Tablet PC is Lenovo YT3-850F, for specific operation, see **§4.3 Instructions for Jointly-Used Tablet PC**. The structure of the Tablet PC is shown in Fig. 3.3. For other models of Tablet PC, please refer to its user manual for the structure and operation instructions.

① Screen

② Micro USB Port

③ Power Switch of the Tablet PC

Fig. 3.1 Structure of Tablet PC

1. Screen

The display area of the Tablet PC and user interaction area. The screen presents information to users and users can click the screen to enter the information.

2. Micro USB Port

This port can be used for charging and data transmission.

Tablet PC charging: plug the Tablet PC charger plug into the port, it can be charged.

Tablet PC data transmission: insert a flash drive that supports USB On-The-Go (OTG) function for data transmission; you can also insert a data cable to connect the Tablet PC to the computer.

3. Power Switch Button of the Tablet PC

Power on: Press and hold the power switch until the OLED screen is on.

Shutdown: Press and hold the power switch for 3 seconds, then touch the shutdown option on the screen lightly.

Reboot: Long-press the power switch for about 10 seconds.

Close the screen / light up the screen: Click the power switch.

Chapter 4 Operation

4.1 Start-up and Shut-down

4.1.1 Check-up before Start-up

1. Environment

Check whether there is nearby equipment that may emit disturbing radiation.

2. Appearance

Check whether there are cracks on the enclosure of the device and the OLED screen.

3. Check whether the device has leakage, deformation, smell, discoloring and so on.

4. Above check-ups should be done before you start up the device.

4.1.2 Start-up

Press the power switch button on the end of the Main Unit for 1-2 seconds and release, the Main Unit starts working. Right now, the power indicator lights up and the Main Interface is displayed on the screen.

4.1.3 Check-up before use

Please do the following routine check-ups after the device is started and before use.

1. Whether the power indicator lights up;
2. Whether the touch screen works properly;
3. Whether the keys work;
4. Press the **Scan** button and hold it to check whether it initiates a pre-scan. Release the **Scan** button to check whether it takes a 3D-scan. Please refer to **§4.2.4 Scanning** for details.
5. Whether the device gets enough battery power.
6. Check the system setup. Please refer to **§4.2.2 System Setup** for details.
7. Clean up and disinfect the Main Unit according to **§5 Cleaning and Disinfection**.

4.1.4 Shut-down

Press the power switch button on the end of the Main Unit for 3-4 seconds to shut the device down.

If the device has been idle for a preset time, it will be turned off automatically by the energy-saver mode. Please refer to **§4.2.2.4 Automatic Shut-down**.

4.1.5 Shut-down of the Tablet PC

Please refer to **§4.3 Instructions for the Jointly Used Tablet PC** for the shut-down operation of the jointly-used Tablet PC.

4.2 Introduction of the Function Module

4.2.1 Main Interface

Press the power switch button to start up the Main Unit. The screen displays patient information (if it is used together with the Tablet PC), battery power and volume value, and the initial value of the volume is 0 ml, as shown in Fig. 4.1.

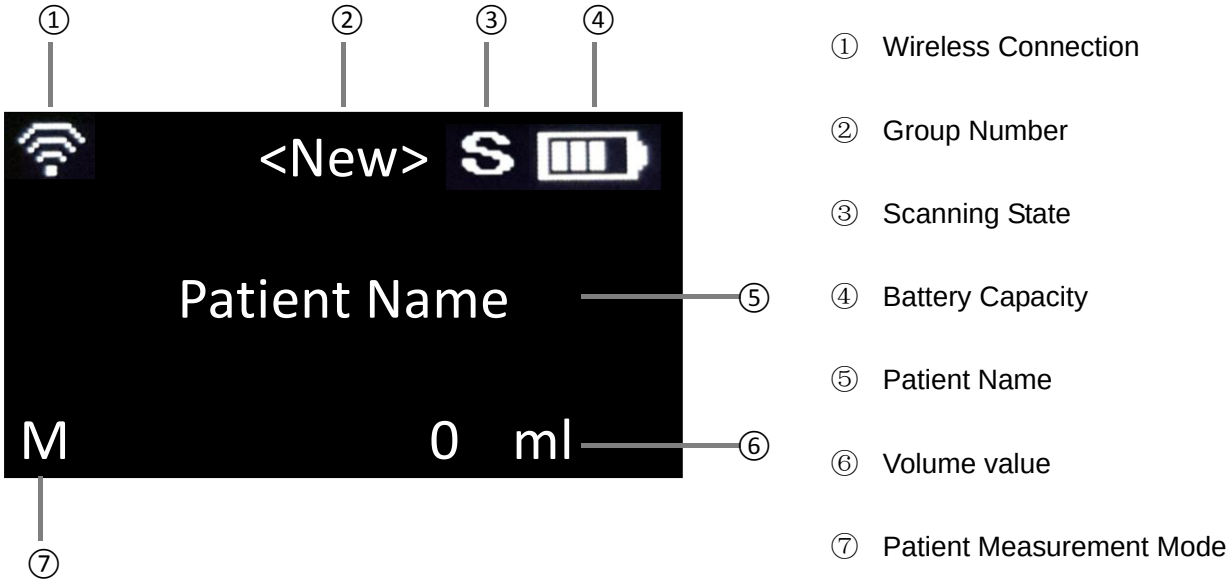


Fig. 4.1 Main Interface

Introduction of Display Area:

① Wireless Connectivity

Wireless connectivity should be used together with the Tablet PC. When the device is connected successfully with the Tablet PC via Wi-Fi connection, the icon of Wi-Fi is displayed in this area, otherwise, the icon will not be displayed, see **§4.3.4 Main Unit Connection**.

② Group Number

The group number of the current measuring case is displayed when it is used together with the Tablet PC.

③ Scanning State

This area displays the scanning state: when the device is scanning, “S” is displayed and there is no display, when the device is not scanning.

④ Battery Power

The remaining battery power is displayed in this area by bars; four bars represent full battery power, as shown in Fig. 4.2a. As the Main Unit consumes the battery power, the indicator bars will become fewer and when the battery power is almost exhausted, there’s no indicator bar, as shown in Fig. 4.2b; please complete the operation as soon as possible and turn off the power. Charge the

battery in time when idle, so as to avoid the excessive consumption of the battery due to continuous usage which will affect its service life.

Fig. 4.2a Full Battery Capacity

Fig. 4.2b Empty Battery Capacity

⚠ ***Note: When the battery power is used up, you can still save the current data. The device will shut down automatically after three buzzes.***

⑤ Patient Name

This area displays the patient name. If the Main Unit is used together with the Tablet PC, the patient name can be configured on the Tablet PC. Please refer to **§4.3.5 Patient Information Input Interface**.

⑥ Volume Value

When a patient's measurement is completed, this area displays the patient's urine volume in the bladder.

⑦ Patient Measurement Mode

This area displays the current patient's measurement mode. The options are M/F/P which corresponds to the three measurement modes of Male/Female/Pediatrics.

4.2.2 System Parameter Setting

Press the **Menu** key under the Main Interface without releasing it, and press the **Scan** button at the same time, the prompt of 'Reading…' is displayed on the screen and you can enter the system parameter setting interface which includes: operator list, measurement mode, Main Unit information, shutdown time, off-screen time, sound control, time display and system information.

Press the **Scan** button to save the settings and return to the main screen.

4.2.2.1 Operator List

Press the **Menu** key continuously under the System Setting interface until you switch to the Operator List interface, as shown in Fig. 4.3. The screen prompts the operator name and number, and the number on the left shows the "selected operator". See **§4.3.14 Operator List** of the Tablet Pc for the configuration for the operator list.

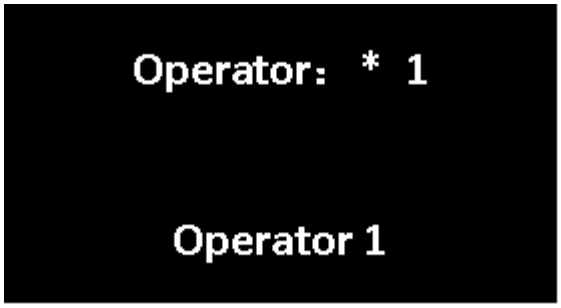


Fig. 4.3 Operator List Interface

Under the Operator List Interface, press the **Function** key and switch through the list to select the operator. If an operator is selected, press the **Scan** button to save automatically and “*” is displayed on the left of the selected operator.

4.2.2.2 Test Mode

Test Mode is used for the measurement on a bladder scanner phantom. Press and hold the **Menu** key under the System Setting interface until you switch to the Test Mode interface, as shown in Fig. 4.4.

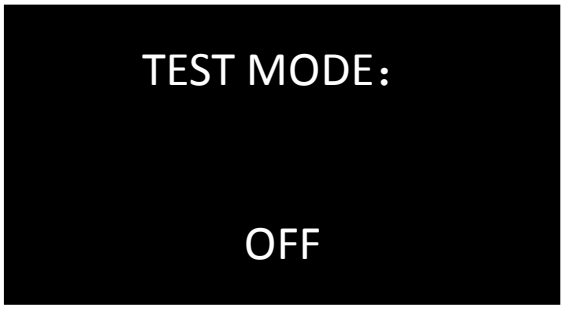


Fig. 4.4 Test Mode Interface

Press the **Function** key to turn the Test Mode on or off, “ON” or “OFF” prompts on the screen. “ON” indicates the Test Mode is on and “OFF” indicates the Test Mode is off. The Test Mode is turned on only when the Main Unit is tested on the bladder scanner phantom; it should be turned off when the Main Unit is used on patient.

⚠ ***Note: The Test Mode is only used for testing on bladder scanner phantom; it is not applied to patients. Don’t turn it on at will.***

4.2.2.3 Serial Number of the Main Unit

Press the **Menu** key continuously under the System Setting interface until you switch to the Main Unit Serial Number interface, as shown in Fig. 4.5. The interface displays the name of the Main Unit, Wi-Fi password and Wi-Fi ON-OFF state.

Fig. 4.5 Interface of Main Unit Serial Number

Press the **Function** key to turn Wi-Fi on or off and “ON” or “OFF” prompts on the screen. “ON” indicates the Wi-Fi connection is on and “OFF” indicates the Wi-Fi connection is off.

4.2.2.4 Automatic Shutdown

Press the **Menu** key continuously under the System Setting interface until you switch to the Automatic Shutdown interface, as shown in Fig. 4.6.

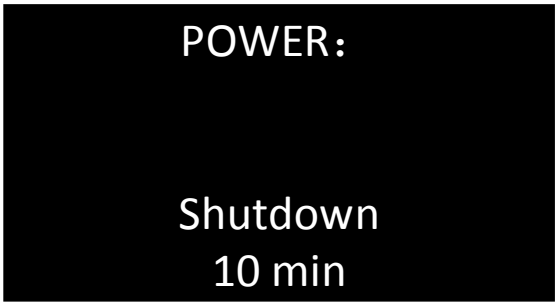


Fig. 4.6 Automatic Shutdown Interface

The Automatic Shutdown Interface displays shutdown time, which is divided into 5 options that are 5 min, 10min, 15min, 20min and Never (deactivating automatic shutdown). Press the **Function** key to switch among each option and press the **Scan** button to save the setting. Note that the selection of “Never” can’t be saved permanently taking into account the risk of battery consumption. When the device is restarted, the shutdown time will resume to the last non-Never time.

After the setting is completed, if there is no operation within the setting time limits, the system automatically shuts down the OLED screen, thereby improving the continuous working time of the device.

4.2.2.5 Automatic Screen Off

Press the **Menu** key continuously under the System Setting interface until you switch to the Automatic Screen-Off interface, as shown in Fig. 4.7.

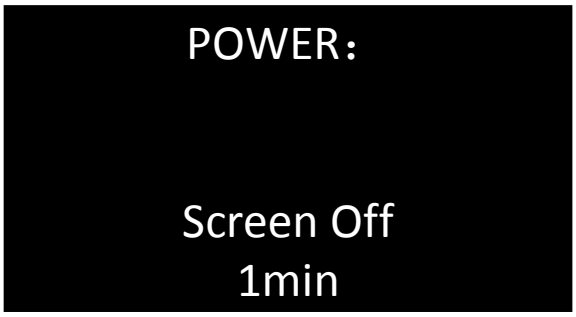


Fig. 4.7 Automatic Screen-Off Interface

Automatic screen off is divided into 5 options that are: 1min, 2min, 3min, 5min and Never (never turn off the screen automatically) (deactivating automatic screen off). Press the **Function** key to switch among these options and press the **Scan** button to save the setting. Note that when “Never” is selected, the screen time of “Never” can’t be saved permanently taking into account the risk of battery consumption. When the device is restarted, the screen off time will resume to the last non-Never time.

After the setting is completed, if there is no operation in the set time period, the system will shut down the screen automatically, thereby improving the battery life of the system.

Press any key of the Main Unit to wake up the screen.

4.2.2.6 Sound Setting

Press the **Menu** key continuously under the System Setting interface until you switch to the Sound Control interface, as shown in Fig. 4.8.

Fig. 4.8 Sound Control Interface

Press the **Function** key to select, “ON” prompted on the screen indicates the sound is turned on and the Main Unit beeps the it scans; and “OFF” prompted on the screen indicates the sound is turned off and the system is in the silent mode.

4.2.2.7 Time Display

Press the **Menu** key continuously under the System Setting interface until you switch to the Time Display interface, where the current time is displayed as shown in Fig. 4.9. The current time is set via the Tablet PC, please refer to **§4.3.18 Main Unit Time Setting** for time setting.

Fig. 4.9 Time Display Interface

4.2.2.8 Version Information

Press the **Menu** key to switch to the Version Information interface and the version information displays the software version as shown in Fig. 4.10.

Fig. 4.10 Version Information Interface

4.2.3 Patient Selection

a) When the group number is “New”, it is the New Patient mode (or press the **Function** key to switch to the New Patient mode). Under this mode, the sex of patient can be selected. Press the **Menu** key of the Main Unit to switch to SEX interface as shown in Fig. 4.11. Then, press the **Function** key to select sex, and press the **Scan** button to save the setting and start scanning.

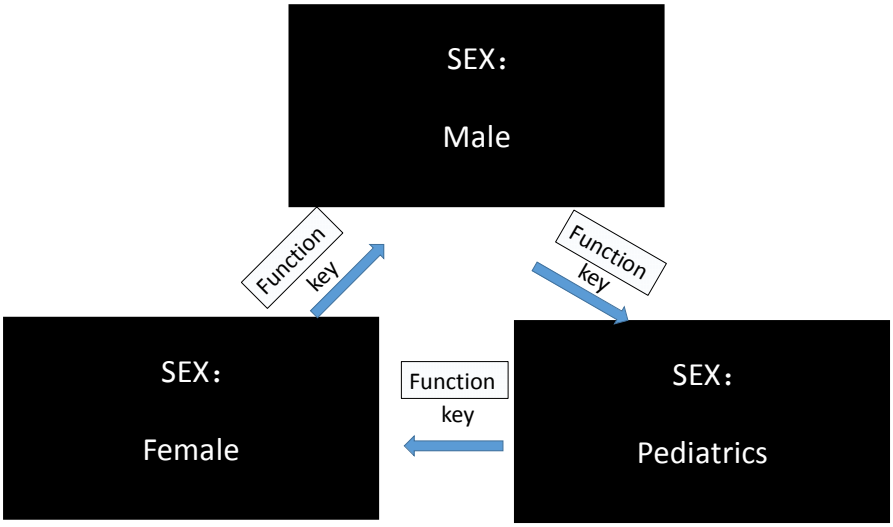


Fig. 4.11 Sex Selection

b) When the group number is not “New”, it is the Pre-set Patient mode, you can press the **Function** key to switch among patients as shown in Fig. 4.12. The pre-set patient list needs to be completed on the Tablet PC together with the Main Unit, please see **§4.4 Pre-set Patient List Mode** for detailed operation

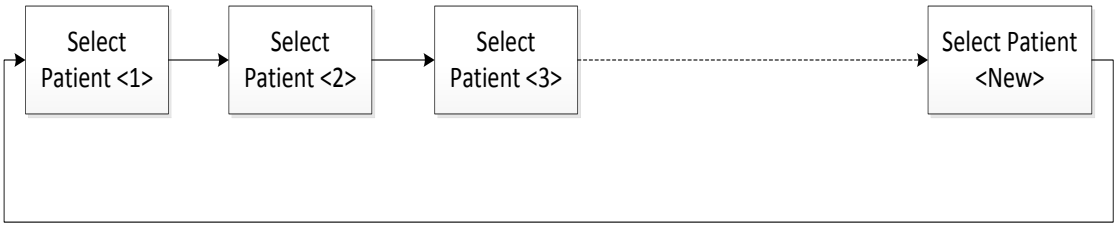


Fig. 4.12 Flow Chart for Switching among Patients

4.2.4 Scanning

4.2.4.1 Bladder Positioning

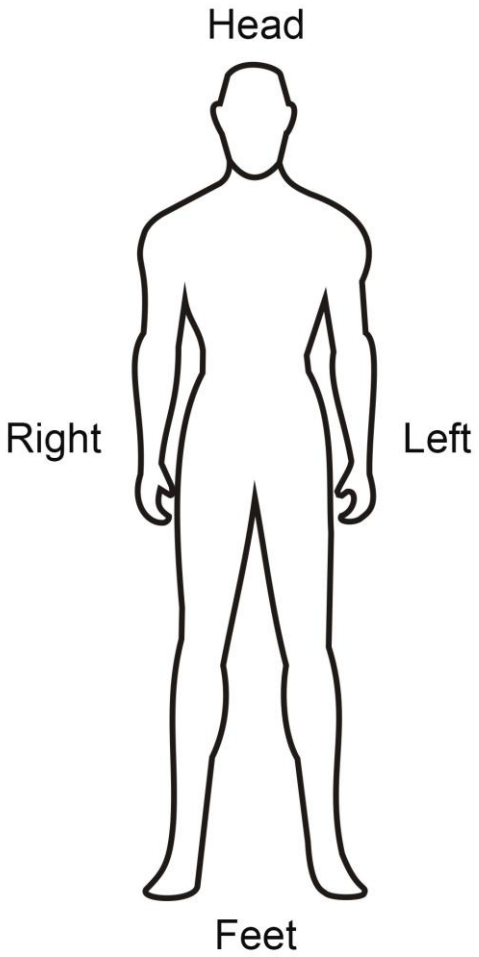
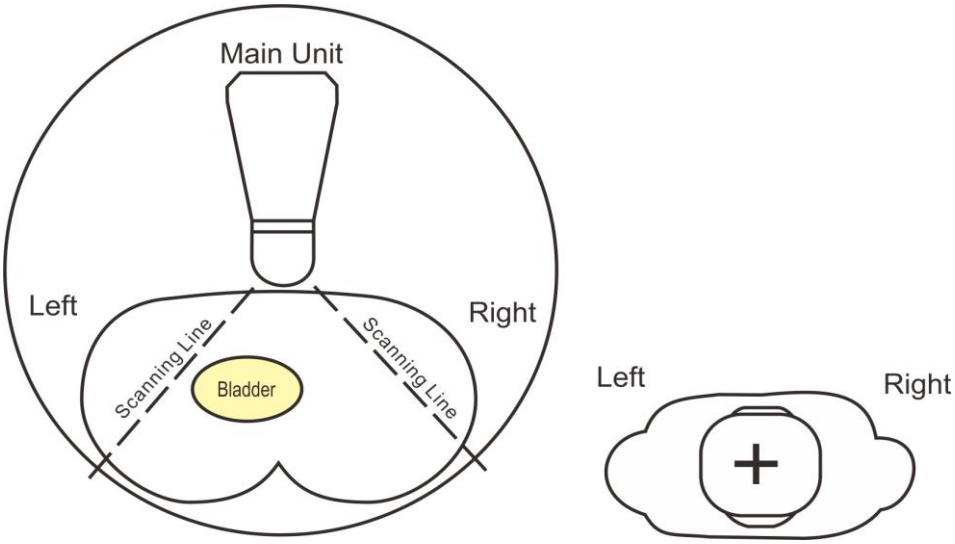
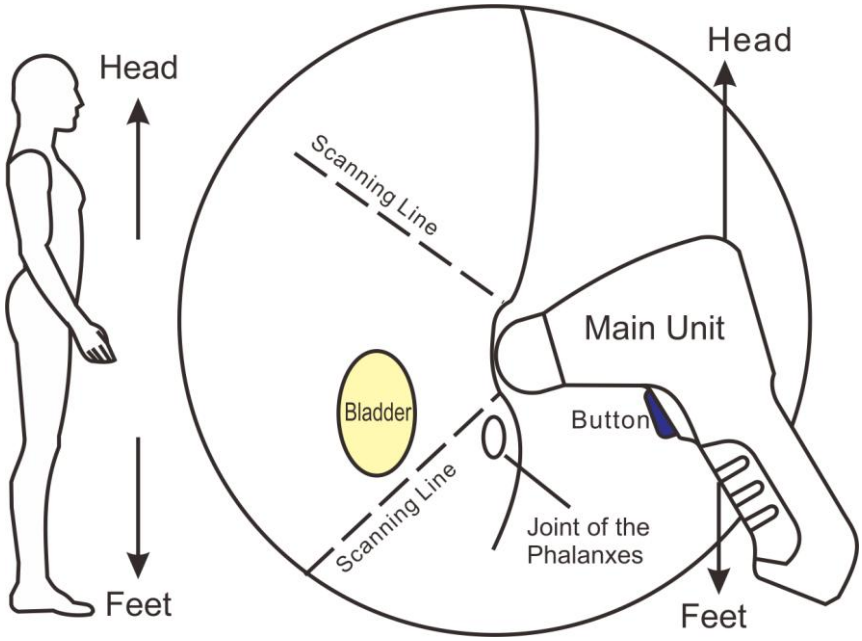


Fig. 4.13 Patient Position

Correct positioning of the bladder is the basis for accurate measurement of bladder volume. As shown in Fig. 4.14, the bladder is located in the lower abdomen of the human body above the joint of phalanxes.



(a) Top View



(b) Side View

Fig. 4.14 Position of the Main Unit

Ultrasonic coupling gel should be applied to the lower abdomen of the patient before measurement and the Main Unit should be placed as shown in Fig. 4.14a and Fig. 4.14b. Note that the top of the Main Unit is directed towards the patient's head and the handle is directed towards the patient's feet.

4.2.4.2 Pre-scan Positioning Mode

The Pre-scan Positioning Mode can help the operator to better position the patient’s bladder for more accurate calculation results. Press the **Scan** button on the Main Unit and hold, the upper left corner of the screen shows the scan icon "S", you can enter the Pre-scan Positioning Mode, as shown in Fig. 4.15 Pre-scan Positioning Mode.

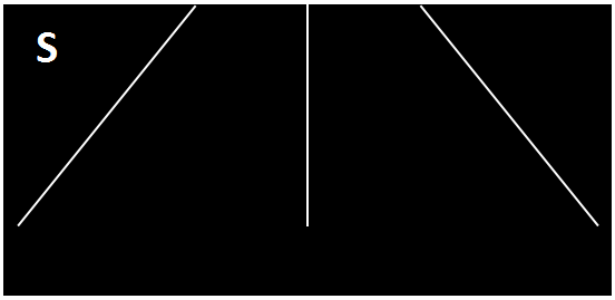


Fig. 4.15 Pre-scan Positioning Mode

The vertical line on the screen is the center line, and the area surrounded by the oblique lines on both sides of the center line represents the scanning area; the circle on the screen represents the bladder, the center of the circle is the center of the bladder, as shown in Fig. 4.16 Bladder Positioning Image.

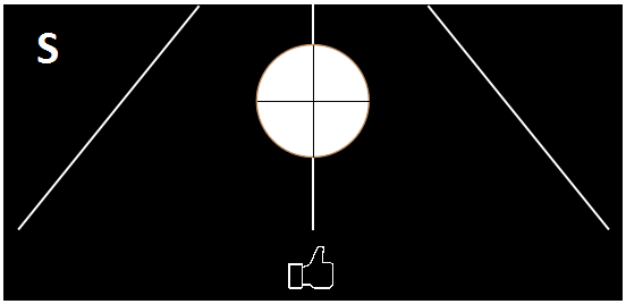


Fig. 4.16 Bladder Positioning Image

Press the **Scan** button and hold, start pre-scanning and observe the screen:

① When the bladder is not found in the scanning area, the circular graph and the indicated area are not displayed as shown in Fig. 4.15. The scanning angle and position should be adjusted at this moment until the bladder is found, that is, the circular graph appears on the screen.

② When the bladder is found in the scanning area, it is displayed as a circular graph. The center of the circle is the center of the bladder and the size of the circular area represents the size of the estimated measured value in real time. The closer the center of the circle is to the center line, the larger the size of the circular area is, and the more accurate the measurement will be.

The area below the screen is the indicated area, when the icon of " " displays, it means the center of the bladder is close to the center line, so the current scanning position is accurate, as shown in Fig. 4.16.

When the scanning position is not accurate, there will be appropriate prompt on the screen with the arrow of left "←" or right "→" that directs you to move the Main Unit to the left or right according to the direction of the arrow, as shown in Fig. 4.17a and Fig. 4.17b.

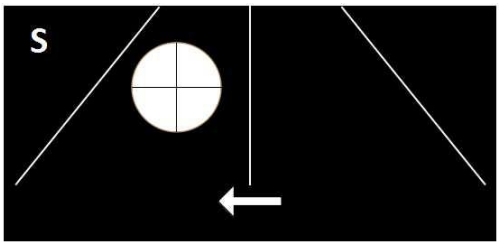


Fig. 4.17a Incorrect position, move the Main Unit to the left.

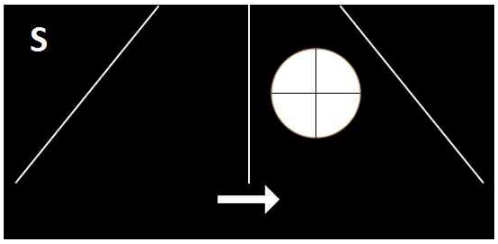


Fig. 4.17b Incorrect position, move the Main Unit to the right.

⚠ ***The continuous pressing of the Scan button shall be within 5 minutes to avoid overheating of the Main Unit.***

4.2.4.3 3D Scanning Mode

The 3D Scanning Mode refers to the process that the Main Unit makes three-dimensional scanning with an interval of 15°, transforming the scanning planes automatically, scanning 12 reference planes continuously, and obtains the volume of urine in the bladder using the volume integral algorithm. If the device in not in the silent mode, there is a long buzz which means the operation of this measurement is completed and the measurement result of the patient's bladder volume is displayed on the screen.

The device provides two different approaches to enter the 3D Scanning Mode according to the different needs of the operator.

Approach 1: Enter the Pre-scan Positioning Mode first for positioning of the bladder, and then enter the 3D Scanning Mode.

1. Place the Main Unit onto the patient's abdomen over the bladder.
2. Press the **Scan** button of the Main Unit and hold, and then the screen displays the positioning image of the bladder slowly, which is the Pre-Scan Positioning Mode.
3. When the bladder is properly located, release the **Scan** button on the Main Unit to enter the 3D Scanning Mode. If the device is not in silent mode, there is a beep sound during the scanning process when two images are scanned and processed.
4. If the device is not in silent mode, it gives a long beep after the measurement, which means this measuring operation is finished. Press the **Menu** key to switch to display the bladder projection.

Approach 2: Press the **Scan** button of the Main Unit and release quickly to enter the 3D Scanning Mode directly.

1. Place the Main Unit onto the patient's abdomen over the bladder.
2. Press the **Scan** button of the Main Unit and release it immediately, it will enter the 3D Scanning Mode directly. If the device is not in silent mode, there is a beep sound during the scanning process when two images are scanned and processed.
3. If the device is not in silent mode, it sends a long beep after the measurement, which means

this measuring operation is finished. Press the **Menu** key to switch to display the bladder projection.

⚠ ***Notes: ① Under 3D Scanning Mode, please hold the Main Unit tightly and steadily till the end of a scan. Otherwise it may result in inaccuracy of the measurement results.***

② When the level of electromagnetic disturbance to which the MD-6000P is subjected exceeds its immunity (see Annex C), if the interference to the B-mode image affects the correct identification of the bladder boundary, it may increase the measurement error of urine volume in the bladder.

4.2.4.4 Bladder Projection Image

To determine whether the measurement position is correct, after scanning, the device switches to the bladder projection interface which can display the bladder projection image, as shown in Fig. 4.18a. If the projection is close to roundness, basically located in the center of the scanning area, and does not exceed the scanning boundary, as shown in Figure 4.18b, then the position of the Main Unit is correct and the measured volume value is valid; otherwise, you should adjust the position of the Main Unit and measure again.

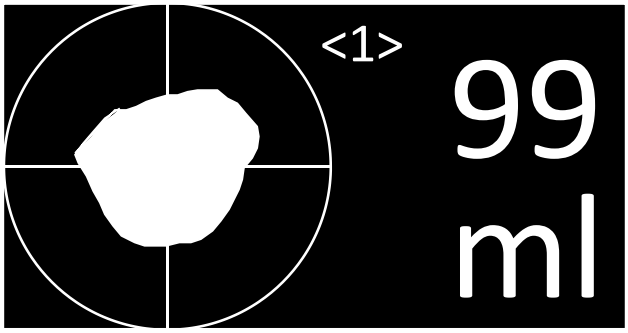
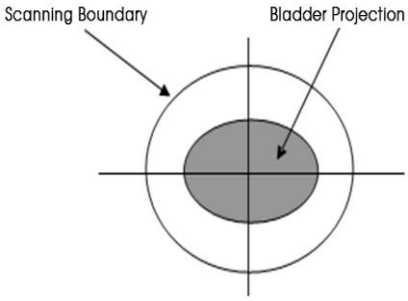


Fig. 4.18a Bladder Projection Image



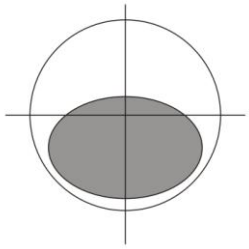


Fig. 4.18b Correct Position **Fig. 4.18c Incorrect Position**

Fig. 4.18b: The bladder projection is basically located in the center of the scanning area, close to roundness, and does not exceed the scanning boundary.

Fig. 4.18c: The bladder projection is beyond the center of the testing area, the measurement result is inaccurate and re-measurement is required.

When the bladder projections are like what is shown in Fig. 4.19a, b, c and d, please adjust the position and angle of the Main Unit and re-measure.

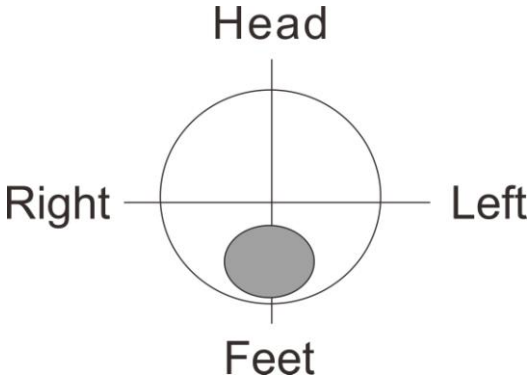


Fig. 4.19a Incorrect Position

Fig. 4.19a: The bladder projection is beyond the center of the testing area. It is under the center of the testing area, the measurement result is inaccurate. Adjust the angle and position of the Main Unit to the lower side of the patent and re-measure it.

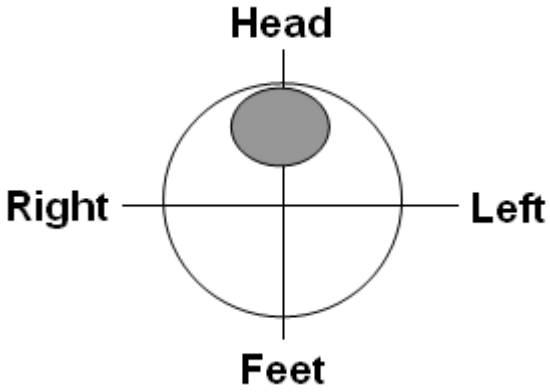


Fig. 4.19b Incorrect Position

Fig. 4.19b: The bladder projection is beyond the center of the testing area. It is above the center of the testing area, the measurement result is inaccurate. Adjust the angle and position of the Main Unit to the upper side of the patent and re-measure it.

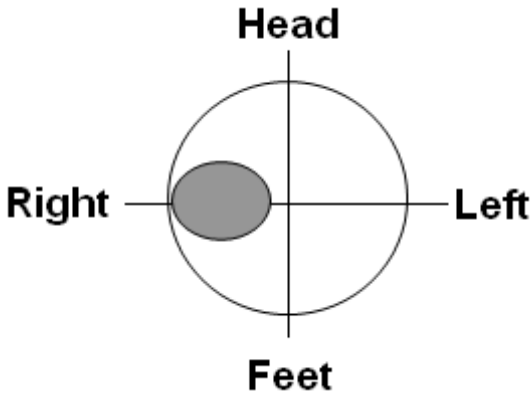


Fig. 4.19c: Incorrect Position

Fig. 4.19c: The bladder projection is beyond the center of the testing area. It is on the left of

the center of the testing area, the measurement result is inaccurate. Adjust the angle and position of the Main Unit to the right side of the patent and re-measure it.

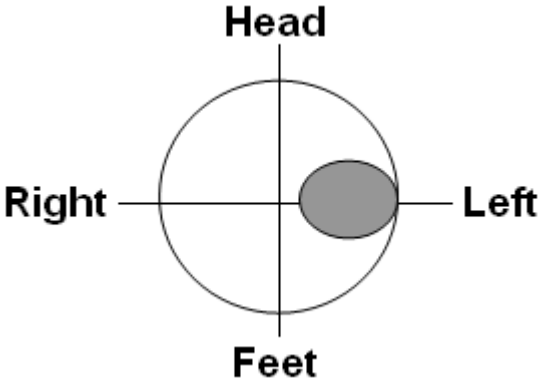


Fig. 4.19d: Incorrect Position

Fig. 4.19d: The bladder projection is beyond the center of the testing area. It is on the right of the center of the testing area, the measurement result is inaccurate. Adjust the angle and position of the Main Unit to the left side of the patent and re-measure it.

⚠ ***Notes: ① The device is neither applicable to the bladder scan of pregnant women nor to the scan on wounded skin.***

② The measurement results for patients with prostatauxe, bladder space occupying diseases and abdominal scars (surgical knife marks or scars, etc.), may go beyond the defined accuracy.

③ No part allowed to be serviced or maintained while in use with the patient.

4.2.5 Recommended Operation Procedure

1. Press the Power Switch to start up the device; the Main Interface will be displayed.

2. If you need to change the system parameters, select or replace the operator, press the **Menu** key and the **Scan** button at the same time to enter the System Parameter Setting Interface.

3. Configure the patient to be tested. If the patient list is already configured on the Tablet PC, press the **Function** key of the Main Unit to switch the patient; if the patient is random and no configuration is required, press the **Function** key to switch to <New> mode, and then press the **Menu** key to select patient sex.

4. Apply coupling gel on the patient's abdomen above the bladder; aim the probe cover of the Main Unit to the patient's abdomen (towards the tailbone) and press the **Scan** button; for skilled operators, it is not necessary to enter Pre-scan Positioning Mode, press the **Scan** button and lift immediately to enter the rapid measurement of 3D Scanning Mode. For a general operator who is not familiar with the bladder position, long-press the **Scan** button to enter Pre-scan Positioning Mode and locate the bladder by real-time bladder positioning, then release the **Scan** button to enter 3D Scanning Mode.

5. Release the **Scan** button to enter the 3D Scanning Mode, the letter "S" flashes on the screen to

prompt scanning and the bladder volume will be displayed.

6. Press the **Menu** key to view the projection image, and select the appropriate position and angle of the Main Unit according to the projection position.

7. Usually, make 3 to 5 measurements for the same patient and select a more accurate measurement result.

4.3 Operation Instructions for the Jointly-Used Tablet PC

4.3.1 Start-up and Shut-down of the Tablet PC

4.3.1.1 Check-up before Start-up

1. Environment

   Check whether there is nearby equipment that may emit disturbing radiation.

   Check whether a dry place is selected.

2. Appearance

   Check whether there are cracks on the enclosure of the device and the OLED screen.

3. Above check-ups should be done before you start up the device.

4.3.1.2 Start-up

Press the power switch button until the LCD lights up.

4.3.1.3 Check-up before use

Please do the following routine check-ups after the device is started up and before use.

1. Whether the screen displays properly;
2. Whether the operations of screen are active;
3. Whether the Tablet PC gets enough battery power.

4.3.1.4 Shut-down of the Tablet PC

Press the power switch for 3 seconds and touch the shut-down item on the screen to shut the device down.

4.3.2 Configuration of the Tablet PC and Software Installation Instructions

4.3.2.1 System Configuration

1. Operating system requirements: Android;
2. Memory requirements: not less than 1GB;
3. Storage requirements: not less than 16GB;
4. Processor frequency: not less than 1GHz;

5. WLAN: 2.4GHz, conforms to 802.11 b/g/n.

4.3.2.2 Software Installation Instructions

Insert the flash drive, which is provided with the device and supports the OTG function, into the Micro USB port of the Tablet PC, open the file manager, select the installation package “Medascan.apk” on the flash drive folder, select "install", start the installation of software, select “continue to install” when there is a prompt of right until the software installation is completed. When the installation is completed, the icon of for "Medascan" application displays on the Tablet PC.

4.3.3 Main Interface

After the Tablet PC is started, click of "Medascan" application icon to start the application procedure. The Main Interface of the Tablet PC software displays on the screen, as shown in Fig. 4.20.

Fig. 4.20 Main Interface of the Tablet PC Software

4.3.3.1 Description of the Display Area

① Patient Information Display

After you input patient information, this area displays the patient information, including Name, Sex and Age. See **§4.3.5 Patient Informaiton Interface** for details.

② Wi-Fi Status

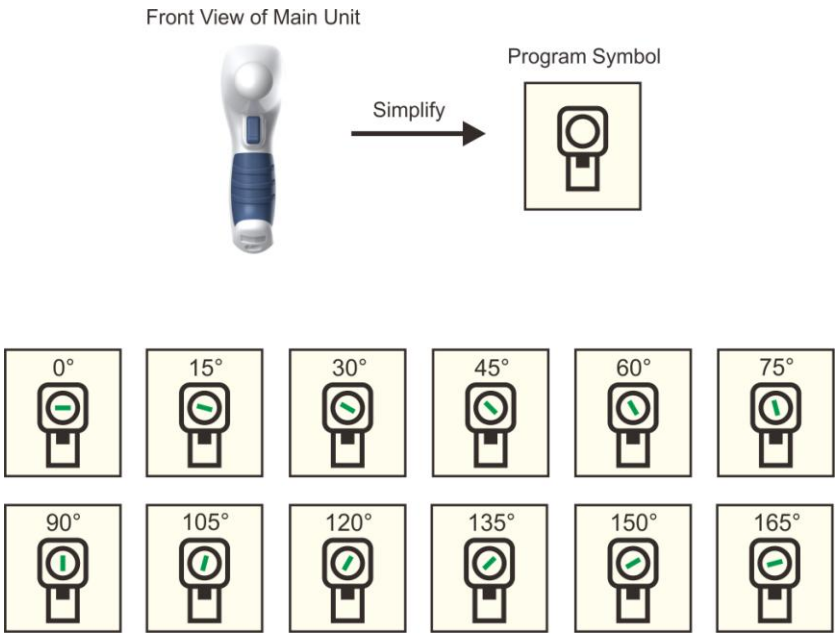
This area displays the status of Wi-Fi, if Wi-Fi is connected successfully, the icon is green, and if not, it is gray and flashes. See **§4.3.4 Main Unit Connection** for details.

③ System Setting

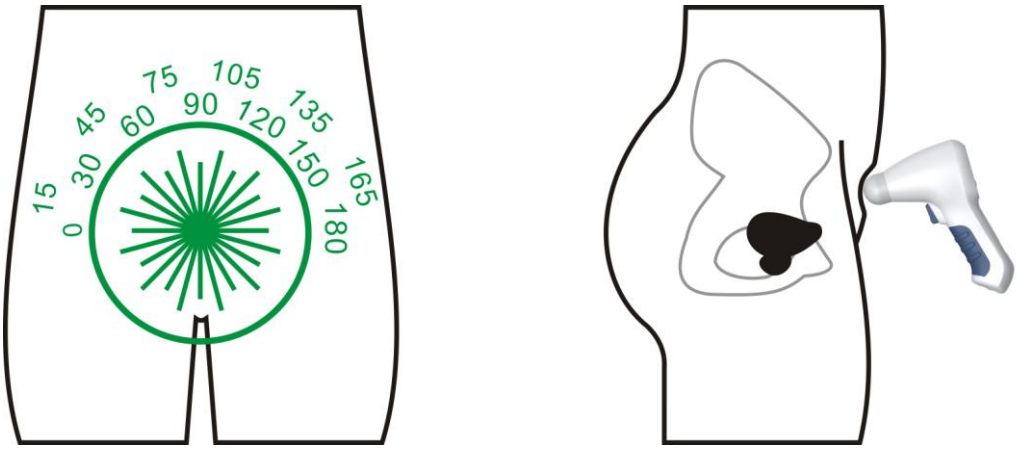
The icon of entering system parameter setting displays in this area. Click it to enter system parameter settings See **§4.2.2 System Parameter Setting** for details.

④ Scanning Section Mark

When a patient's measurement is completed, this area shows the mark of the scanning section of the Main Unit, which corresponds to the ultrasound image one by one, as shown in Fig. 4. 21.



(a) The 12 Scanning Section Marks on the Interface



(b) Scanning Section Marks versus Patients' Positions

Fig. 4.21 Schematic Diagram of Main Unit Scanning Section

⑤ Functional Key Area

This area includes: **NEW**: new patient key; **SAVE**: save patient case; **LOAD**: patient case management; and **REPORT**: case report. Press the key to enter the corresponding sub-function module.

⑥ Ultrasound Image Display

When a patient's measurement is completed, the area displays the ultrasound image of the patient's bladder, the bladder cross-sectional area measurements and the image number. A total of 12 bladder ultrasound images can be displayed and viewed by clicking the **Sliding Page Turning** key.

Click the ultrasound image display area will enter the image magnification interface, which allows the operator to observe the measured images better.

⑦ Sliding Page Turning Area

When a patient's measurement is completed, the 12 bladder ultrasound images will be displayed as thumbnails in the sliding page turning area. Scroll the **Sliding Page Turning** area to view the 12 bladder ultrasound images. The image in the middle of the sliding page turning area displays in the ultrasound image display area.

⑧ Display of Current Measurement

This area displays the latest group of measurement results.

⑨ Display of Five Groups of Measurements

The user may make multiple groups of measurements on the patient and the system will display 5 groups of measurement result which are displayed by order of measurement. The green arrow indicates the current measured value. By clicking on a different measured value, the user may also let other measured value to be displayed in the current position and the green arrow moves accordingly to this measured value.

⑩ Bladder Projection

When a patient's measurement is completed, the area shows the bladder projection which helps the user to locate the position of the bladder. The closer the projection position is to the center of the coordinate, the more accurate the measurement will be. The bladder projection of the Main Unit is consistent with that on the Tablet PC.

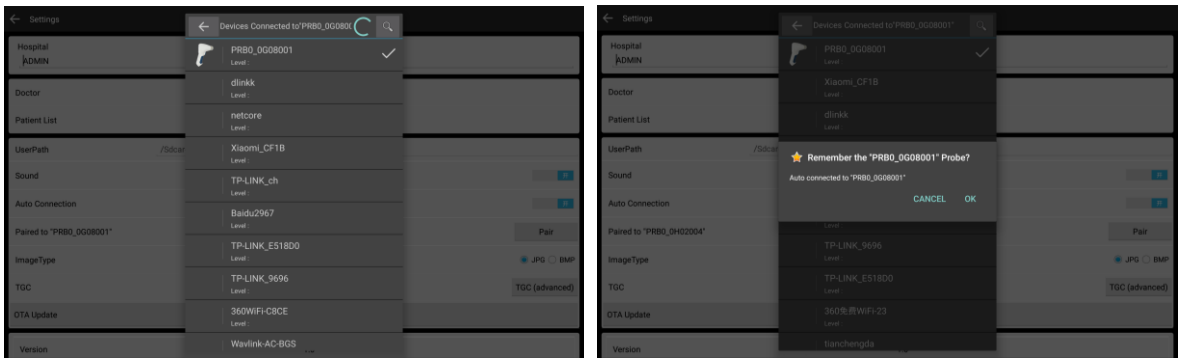
4.3.3.2 Description of Keys on the Main Interface

NEW	New patient key	Click the key to access Patient Information interface and input patient name, ID, age and sex. If the Tablet PC is connected to the Main Unit, the patient information can be sent to the Main Unit. See **§4.3.5 Patient Information Interface.**
SAVE	Save key	Click the key to save patient information and current measurements to the database.
LOAD	Case reading key	Click the key to enter the patient case management interface, where you can load, search, delete and synchronize patient cases. See **§4.3.11 Patient Case Management** for details.

REPORT	Report key	Click the key to integrate images, data and add diagnostic information, and then generate case report. See **§4.3.10 Case Report** for details.
	Wi-Fi key	Press the key to connect it to the paired Main Unit. See **§4.3.4 Main Unit Connection** for details.
	SETUP key	Press the key to set system parameters which include: operator list, patient list, system date and time of the Main Unit, hospital name and system version information. See **§4.3.12 System Parameter Settings** for details.

4.3.4 Main Unit Connection

① Initial connection and pairing: the Tablet PC and the Main Unit should be paired when they are connected for the first time. Click the key to enter the System Parameter Settings interface, and then click the **Pair** key to pair them; select from the Main Unit list and click the Main Unit to be paired, as shown in Fig. 4.22a, and then click ”OK”, they are successfully paired, as shown in Fig. 4.22b. Return to the Main Interface after pairing and there is a prompt of “Connected” on the Main Interface. The **Wi-Fi** key turns green as shown in Fig. 4.24, and it is ready to scan.



(a) List of Main Unit **(b) Remember the Main Unit**

Fig. 4.22 Main Unit List

② Replace the connected device: If it is already paired, click the **UnPair** key to reconnect, the same as the initial connection method.

③ Reconnection with one click: Click the **Wi-Fi** key on the top right corner of the Tablet PC, the Tablet PC connects to the matching Main Unit automatically.

When the connection is successful, the Tablet PC prompts the user with the green icon, as shown in Fig. 4.24, meanwhile, the Wi-Fi icon on the Main Unit shows the connection status as shown in Fig. 4. 23; otherwise the icon on the Tablet PC flashes to indicate it is unconnected, meanwhile, the Wi-Fi icon is not displayed, as shown in Fig. 4. 23b.

Fig. 4. 23a Connected **Fig. 4.23b Unconnected**

Fig. 4.24 Successful Connection

4.3.5 Patient Information Interface

Click the **NEW** key in the Main Interface to enter the Patient Information Interface, as shown in Fig. 4.25. You can input the patient ID, name, age and sex here.

Fig. 4.25 Patient Information Interface

ID	Case ID input box	Click the input box to input patient's ID through the soft numeral keypad popping up from the bottom of the interface.
AGE	Age input box	Click the input box to input patient's age through the soft numeral keypad popping up from the bottom of the interface. (It is a mandatory item, if the age is 12 years old or below, pediatrics mode will be started automatically).
SEX	Sex selection key	Click the round mark directly; when the round mark is solid, it is selected. Sex is switched among "Male", "Female" and "Pediatrics". Select "Pediatrics" to start child mode.
NAME	Name input box	As shown in Fig. 4.26, click the input box, the soft keypad pops up on the screen. Input patient's name with the soft keypad; after that, click the input box again, the soft keypad hides automatically and the patient's name appears in the Name input box at the same time.
OK	Confirmation key	After inputting patient's information, click the **OK** key to save patient's information and return to the Main interface.
Cancel	Cancel key	Click the **Cancel** key to return to the Main Interface without saving any operations this time.

⚠ ***Notes : ① Patient's SEX must be selected correctly since it is associated with the bladder recognition algorithm. The wrong input affects the measurement accuracy directly. When pressing NAME, ID or AGE key, the corresponding information inputted will be cleared.***

② After inputting the information, there is a prompt whether new patient will be created, select OK to clear existing measurement data, and select CANCEL to return.

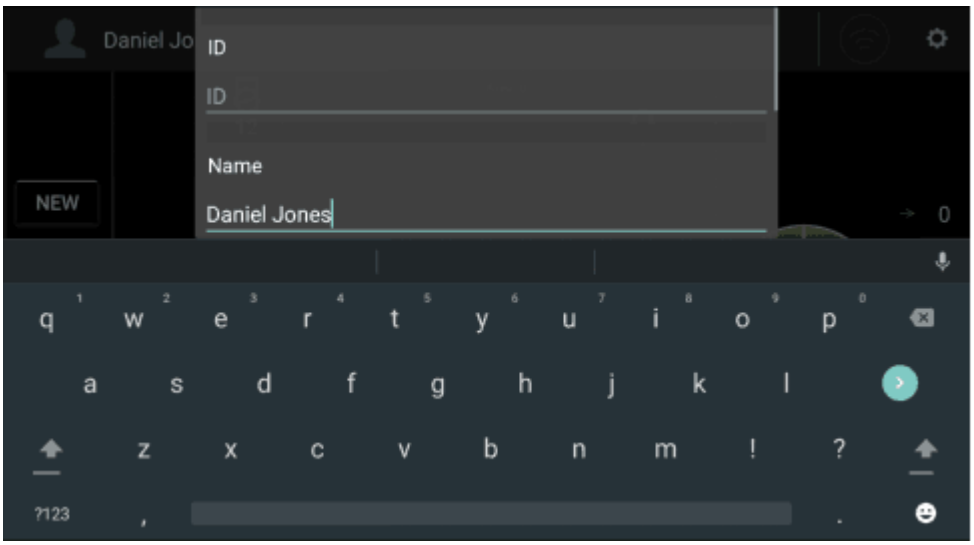


Fig. 4.26 Patient Name Interface

Click the **NEW** key on the Tablet PC to create a new patient, and click the **OK** key will send patient's information to the Main Unit, at the same time the Main Unit switches to the <New> mode. Then, start scanning and the result of scan will be displayed on the Tablet PC; click the **SAVE** key to save it in the Tablet PC.

4.3.6 Pre-scan Positioning Mode

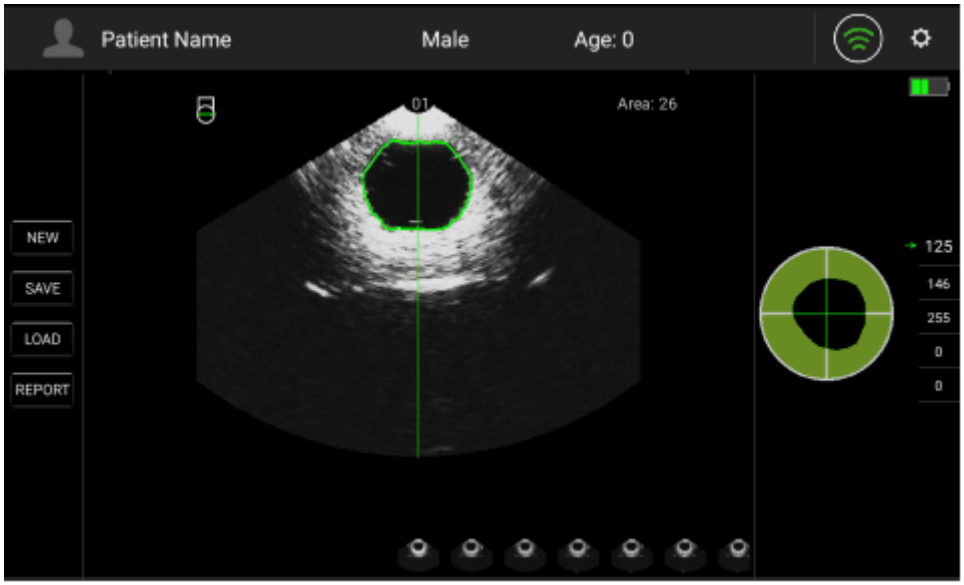


Fig. 4.27 Pre-scan Positioning Mode

The Pre-scan Positioning Mode can help the operator to better position the patient's bladder for more accurate calculation results, as shown in Fig. 4.27. Press the **Scan** button on the Main Unit without releasing it to enter the Pre-scan Positioning Mode. The green line in the image area is the center line. The closer the center of the bladder area to the center line and the larger the size of the bladder area; the more accurate the measurement will be.

4.3.7 3D Scanning Mode

3D Scanning Mode refers to the process that the Main Unit makes a scan and obtains the bladder's cross-sectional areas, and then transforms the scanning planes automatically with an interval of 15°, after continuous scanning on 12 reference planes, calculate the bladder volume with the volume integral algorithm on the basis of the areas of the 12 reference planes, and then exit the scanning mode automatically. Enter the 3D Scanning Mode by raising the **Scan** button on the Main Unit.

⚠ ***Note: Under 3D Scanning Mode, please hold the Main Unit tightly and steadily till the end of a scan. Otherwise it may result in inaccuracy of the measurement results.***

4.3.8 Bladder Projection Image

To determine whether the measurement position is correct, after scanning, the bladder projection image will be displayed on the right of the screen. If the projection is close to roundness, basically located in the center of the scanning area, and does not exceed the scanning boundary, then the position of the Main Unit is correct and the measured volume value is valid; otherwise, you should

adjust the position of the Main Unit and measure again. The bladder projection image is consistent with the bladder projection of the Main Unit, see § **4.2.4.4 Bladder Projection Image** for details.

4.3.9 Save

After measurement on a patient, click the **SAVE** key in the Main Interface to save the case record. At this point, the progress bar popping up on the Main Interface prompts "Please Wait While Saving ...", when the words of the progress bar disappear, the record is successfully saved, meanwhile, the patient's case information is saved to the patient medical record database. The saved record includes the patient information (name, sex, age and ID), 12 bladder ultrasound images, bladder projection, measurement results, measurement time and operator's name.

4.3.10 Case Report

After a patient's scan, click the **REPORT** key in the Main Interface to display the report, as shown in Fig. 4.28. Case reports from top to bottom include hospital name, patient information (name, sex, age and ID), measured volume, bladder projection image, report image, comment, operator signature and current time.

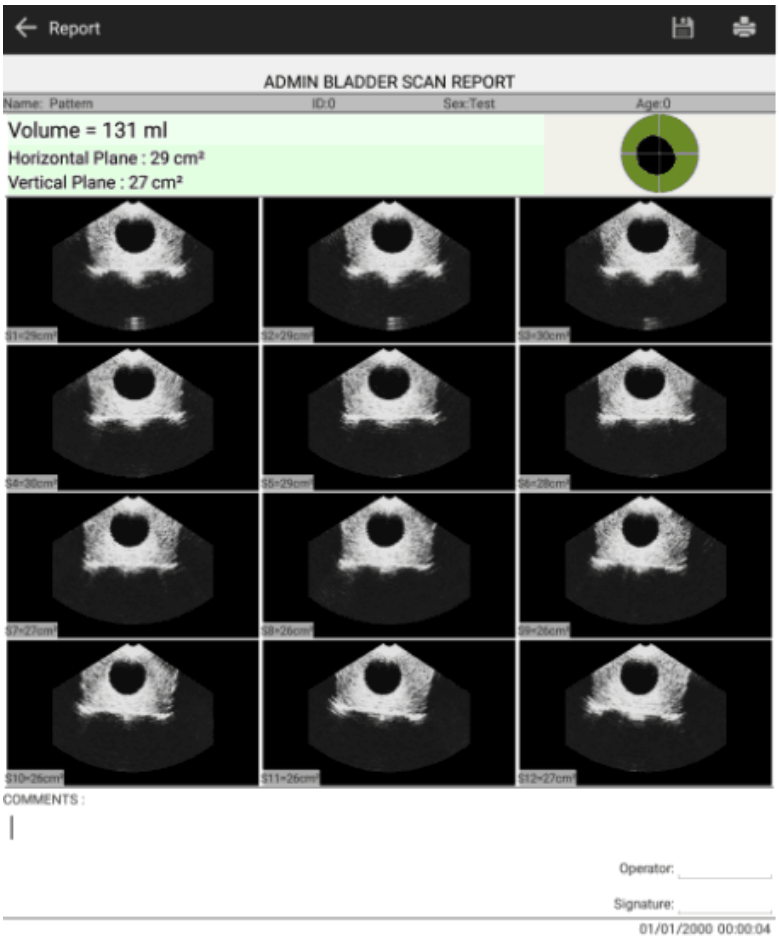


Fig. 4.28 Case Report

⚠ ***Note: The vertical plane and the horizontal plane refer to two scanning planes that are at an angle of 90 degrees to each other.***

Click the printer icon button on the upper right corner to print the report. Report printing supports wireless printer and USB interface printer. Click the save icon button on the upper right corner to save the report.

Note that if there is no printer driver, you need to install the driver. The USB interface printer requires a USB OTG cable to connect the Tablet PC.

4.3.11 Patient Case Management

Click the **LOAD** key in the Main Interface to enter the Patient Case Management interface and load the stored patient medical records, as shown in Fig. 4.29. The Tablet PC can store 10,000 patients' medical records permanently (The available storage space of the Tablet PC is greater than 3GB).

Click the patient's medical record to be loaded, all patient records of this patient are displayed, as shown in Fig. 4.30; then select the record to load it to the Main Interface.

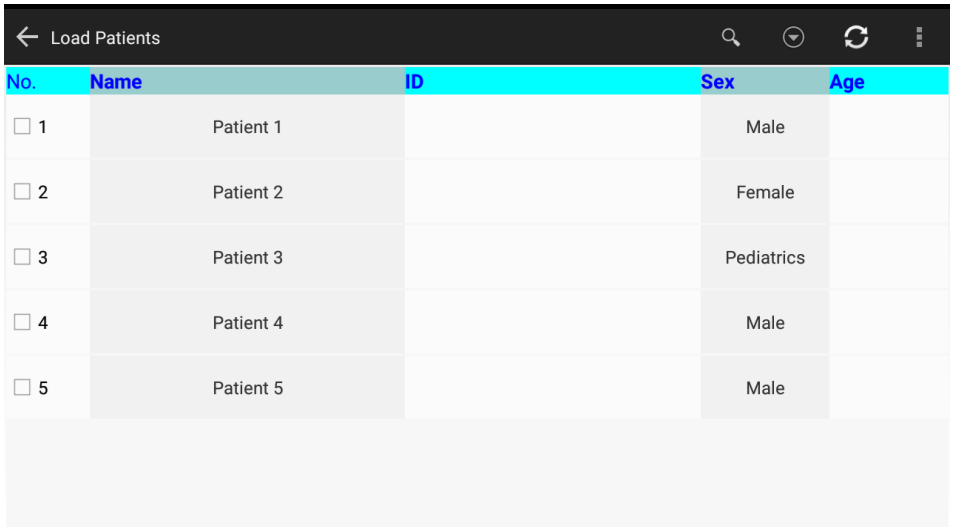


Fig. 4.29 Patient Case Management

Fig. 4.30 Selected Patient Record

	Search key (Search)	Click the key to search for patient medical record according to the patient's name.
	Search key (Conditional search key)	Click the key, the user can select to search according the key words included in Name, ID, Sex, Age, Vol (Volume), Date, Time and Operator.
	SYNC key (Synchronize key)	Click the key to load the patients' medical records (including bladder projection images, patient information and measurement results) to be synchronized in the Main Unit to the Tablet PC, if the Main Unit is connected.
	MENU key	Click the key to display **Delete** key, **Select All** key and **DeSelect All** key. **Delete**: delete key. Select the patient record to be deleted, click this key and confirm deletion to delete this patient's medical record. **Select All**: select all key. Click the key to select all patient medical records in the database. **DeSelect All**: don't select key. Click the key not to select any data.

⚠ ***Note: Please be careful with deletion to prevent misoperation. The medical records can't be restored once they are deleted.***

4.3.12 System Parameter Setting

Click the key in the main interface to enter the System Parameter Setting interface, as shown in Fig.4.31. The system parameter settings include name of medical institution, operator list, patient list, automatic connection switch, pair key, Main Unit time setting, version number and manufacturer's information.

Click to return to the Main Interface will save the current settings automatically.

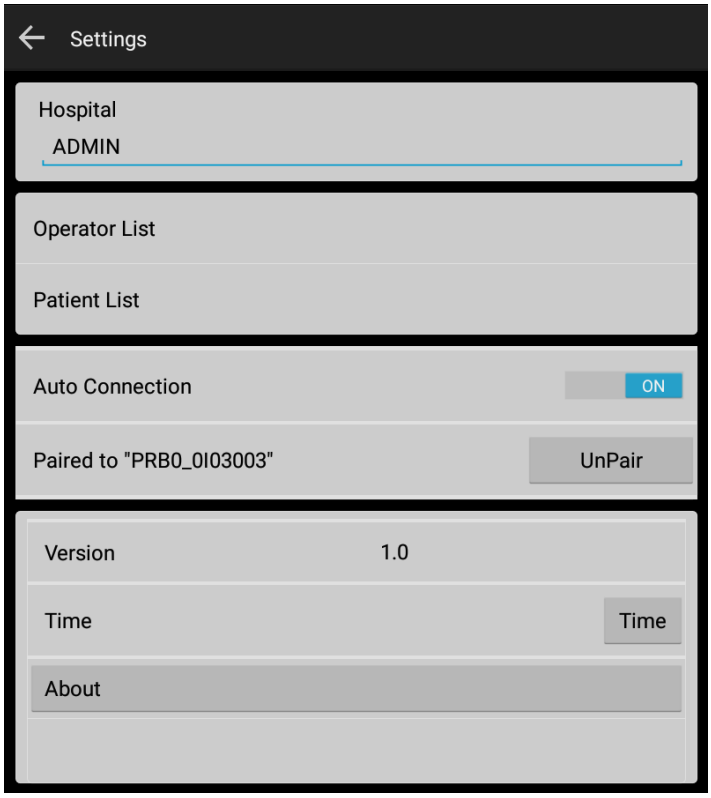


Fig. 4.31 System Parameter Setting

4.3.13 Name of Medical Institution

Click the edit box under “Hospital” to input the name of the medical institution with the soft keypad popped up.

4.3.14 Operator List

Click the item of “Operator” to enter the Operator List Interface, as shown in Fig. 4.32. When you enter the interface, the software automatically reads the operator list stored in the Main Unit to the Tablet PC and displays name with a tick. Users can add, delete and edit the operator list, if necessary, send an operator list to the Main Unit, select the operator to be sent to the Main Unit and tick it, and then click the **UPDATE** key to update it to the Main Unit.

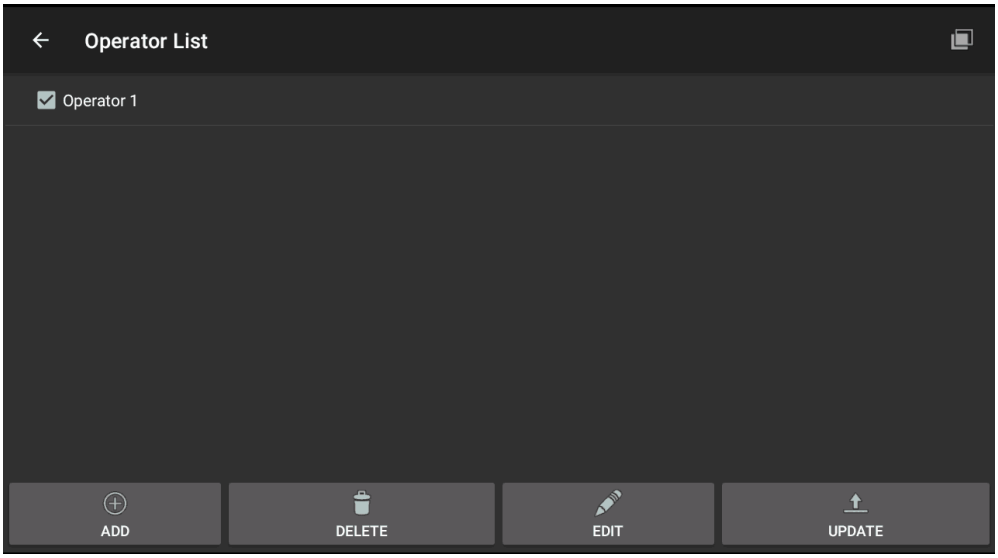


Fig. 4.32 Operator List

ADD	Add key	Click the key to pop up a dialogue box and prompt to enter the operator's name and add a new operator to the Operator list.
DELETE	Delete key	Select the operator to be deleted and click the key to delete the operator in the Operator List.
EDIT	Edit key	Click this key to edit the operator's information.
UPDATE	Update key	Click the key to update the selected and ticked operator to the Main Unit. The operator list is written to the Main Unit only when the synchronous prompt displays that update is successful; if it prompts that update failed, please try again.
	Select All key/ DeSelect All key	Click the key to select or not select the 20 operators in front of the list.

⚠ ***Note: Please be careful with deletion to prevent misoperation. The operator list can't be restored once deleted.***

4.3.15 Patient List

Click the item of Patient List to enter Patient List Interface, as shown in Fig. 4.33.

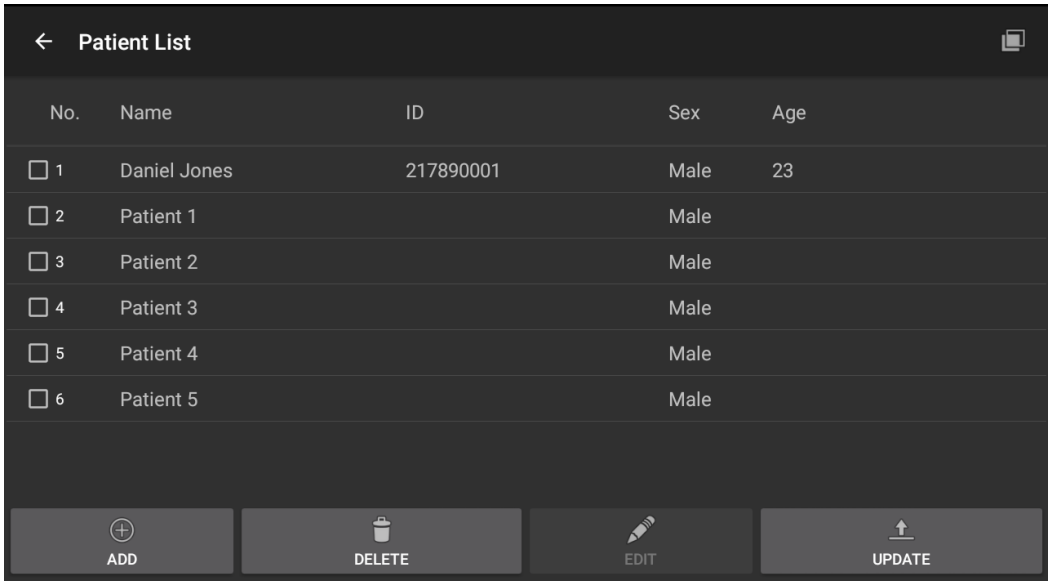


Fig. 4.33 Patient List

ADD	Add key	Click the key to pop up a dialogue box and prompt to enter the patient's ID, name, age and sex, to add a new patient to the patient list.
DELETE	Delete key	Select the patient to be deleted and click the key to delete the patient in the patient list. ⚠ ***Note: Please be careful with deletion to prevent misoperation. The patient list can't be restored once deleted.***
EDIT	Edit key	Click this key to edit patient's information.
UPDATE	Update key	Click the key to update the selected and ticked patient to the Main Unit. The patient list is written to the Main Unit only when update is successful with a prompt of "OK" on the screen; if update failed with a prompt of "ERROR", you need to try again. A maximum of 20 patient's cases can be updated. ⚠***Note: When updating the case list, it will clear the measurement data saved in the Main Unit, and be careful with the operation.***
	Select All key/ DeSelect All key	Click the key to select or not select the 20 patients in front of the list.

4.3.16 Pair Key

Click the key in the Main Interface to enter the settings interface where you can see the Pair key. The display of **UnPair** indicates the Main Unit has been paired and **Pair** indicates not paired.

① Pairing of the Main Unit: Under the state of UnPair, click the **Pair** key to pair, see **§4.3.4 Main Unit Connection** for the pairing process.

② Unpair: Under the state of pair, click the **UnPair** key to release the current paired Main Unit.

4.3.17 Automatic Connection Switch

Click the Auto Connection switch, the switch status is as follows:

When the switch is switched to **ON**, the software automatically connects the paired Main Unit;

When the switch is switched to **OFF**, the software does not automatically connect the paired Main Unit.

4.3.18 Main Unit Time Setting

The time setting is to send the system time of the Tablet PC to the Main Unit to calibrate the time of the Main Unit. After the Main Unit and the Tablet PC are connected, click the **Time** key to complete the calibration.

4.3.19 About

Click the **About** key to enter the system information interface, which include the information of Logo, product model, product name, copyright information, company website and contact information, as shown in Fig. 4.34.

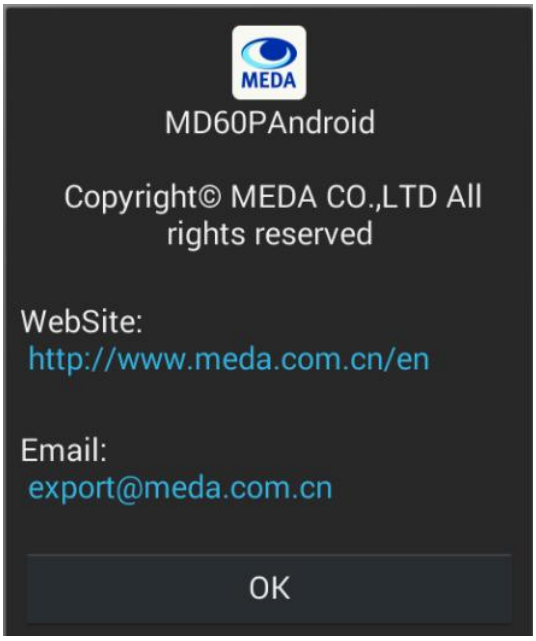


Fig. 4.34 About Interface

4.4 Preset Case List Mode

The mode is suitable for patients with relatively fixed locations, such as nursing homes, fixed bed inpatient departments and other scenes in which the patient information is known. It needs to configure the patient case list in advance for scan.

4.4.1 Patient List Preset

The configuration of Patient List to be tested should be operated in the Tablet PC and uploaded to the Main Unit. Press the Function key of the Main Unit to select the patient to be tested. Press **Scan** button to start measurement (the Main Unit can be used independently during measurement).

⚠***Note: Do not configure the Patient List until the patient's measurement is complete, to avoid clearing the measurement data.***

4.4.2 Medical Record Saving and Loading

Case Saving: After a patient's scan, the Main Unit automatically saves the current case record.

The stored contents include patient information (name, sex, age, ID), operator's name, bladder projection image, measurement results and current system time. The Main Unit can store 20 groups of cases.

Case Loading: Press the **Function** key to switch and select patient, and the Main Unit loads the measurement record of the case automatically.

4.4.3 Medical Record Uploading

After the measurement, connect the Main Unit and the Tablet PC, and click the SYNC key under the Patient Case Management Interface of the Tablet PC to synchronize the measured data.

Chapter 5 Cleaning and Disinfection

5.1 Cleaning of Main Unit

1. Use soft cloth with mild detergent (e.g. diluted Bianex® Special Efficiency Multi-Enzymatic Cleanser) or water to clean the surface of Main Unit. For further disinfection, use soft cloth with prepared disinfectant solution (Sporicidin Sterilizing and Disinfecting Solution) to wipe the surface of the Main Unit.
2. Remove the residual detergent or disinfectant with clean soft cloth dampened in sterile water. Make sure the Main Unit is completely dry before putting it into use again.

⚠ ***Notes: ①Do not use any corrosive cleanser or disinfectant when cleaning the surface of the Main Unit, keep water and any other liquids away from the device.***

②Do not immerse the Main Unit in the disinfectant solution.

③Steam sterilization or ethylene oxide sterilization is prohibited.

5.2 Cleaning of Probe Cover

5.2.1 Protection against Ingress of Liquid

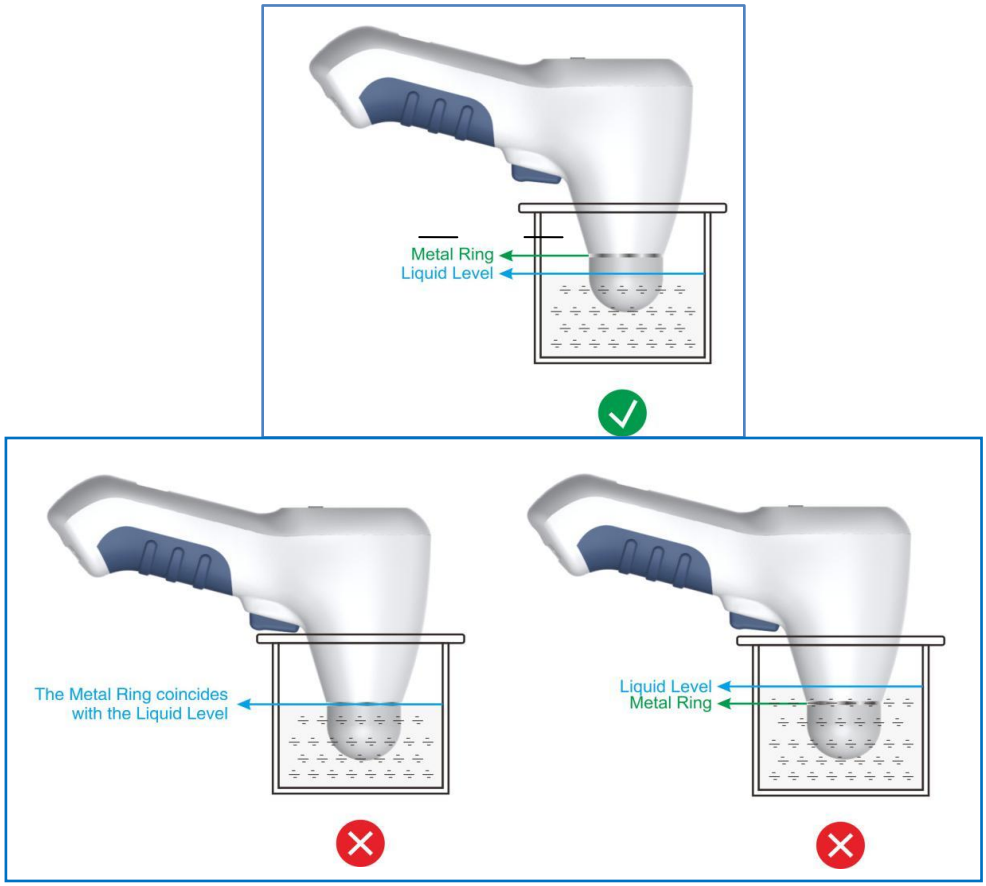


Fig. 5.1: Protection against Ingress of Liquid

See Fig. 5.1, the part under the metal ring is at an IPX7 level; the part above the metal ring is at an IPX1 level.

⚠ ***Note: Do not put the part above the metal ring into liquid.***

5.2.2 Clean-Up

The probe cover should be kept clean. Please use tissue to clean the acoustic gel after each use. Use soft cloth dampened with appropriate hospital cleaning agent (e.g. isopropyl alcohol, medical alcohol) to wipe the probe cover.

For further cleaning, *Bianex® Special Efficiency Multi-Enzymatic Cleanser* is recommended according to the procedures below:

a) Prepare the cleaning solution by adding 1-2ml Bianex® Special Efficiency Multi-Enzymatic Cleanser into 500ml of sterile water. Additional amounts may be required for hard-to-remove matters. The water temperature should be at 20℃-64℃.

b) Immerse the part of probe cover under the metal ring into the container with 500ml cleaning solution for 5 minutes. Clean the probe cover carefully in the cleaning solution with a soft silk brush and shake it to wash; and then take it out and wipe off the cleaning solution with sterile cloth.

c) Rinse the cleaned probe cover by immersing them in 500ml sterile water for 1 minute.

d) Drain the probe cover and wipe it with sterile cloth.

⚠ ***Notes:***

① ***Disposable gloves, eye protection and liquid-proof gowns should be worn when cleaning soiled probe cover.***

② ***For details on Bianex® Special Efficiency Multi-Enzymatic Cleanser, please refer to its supplier's instruction.***

5.3 Disinfection of Probe Cover

Level of disinfection:

Ultrasound probes that are non-critical devices only need to be cleaned and receive intermediate or low-level disinfection between patient uses. (See **§5.2.2 Clean-Up**)

Sporicidin Sterilizing and Disinfecting Solution (k003087) is recommended for disinfection. Please follow its supplier's instruction.

⚠***Note: Disinfection can be carried out in accordance with the disinfection methods identified by local regulations***

Chapter 6 Maintenance and Troubleshooting

6.1 Maintenance and Attentions

1. The device should be operated in a clean, well-ventilated environment without corrosive gases or electromagnetic interference. Do not use or store the device where the humidity and temperature go beyond regulated standards; do not use or store it in place with flammable anesthetic gases mixed with air or with flammable anesthetic gas mixed with oxygen or nitrous oxide.
2. Although anti-interference measures in accordance with IEC 60601-1-2 have been adopted, the device should be placed properly to avoid strong electromagnetic radiation equipment. The device has no special protective measures for the discharging effect of cardiac defibrillators; it is not suitable for use together with high-frequency surgical and/or therapy equipment.
3. Avoid high temperature or direct exposure to sunshine when the device works.
4. Do not use any corrosive cleanser when cleaning the device surface, keep water and any other liquids away from the device. Use soft tissue cloth with neutral detergent or water to clean the device surface.
5. In the humid area or humid season, if the device has been idle for a long period, power on the device for about 1 hour every month to prevent the device from being influenced by humidity.
6. When moving the device, avoid droppage and severe vibration. Pay particular attention to protect the top part of the Main Unit.
7. During transportation, pack all parts, especially the main unit, into the original packages. Therefore, keep the packages properly.
8. Use qualified coupling gel with local approval for marketing. Normal coupling gel for ultrasonic equipment is applicable for the device. Disposal of the waste bottles of coupling gel should follow the local environmental protection regulations
9. The charger equipped with the device complies with the safety requirements of medical electrical equipment, if lost or damaged, please contact your local distributor or the manufacturer to purchase a new one; using other chargers may lead to negative impact on product safety.
10. Disposal of the waste device should follow the relevant provisions of the local environmental protection and may be handled in the same way as electronic information equipment (computer, etc.).
11. Perform repair only after cutting off the power supply and taking out the built-in battery.

6.2 Maintenance and Attentions of Built-in Battery

The Li-ion battery is integrated in the device, do not arbitrarily disassemble it. Be sure to use the device according to the following instructions and attentions. Violation of the use of the device may

cause the battery overheating, overflow, fire and other hazards. The manufacturer shall not be liable for any accidents caused by disobeying these instructions and attentions.

6.2.1 Recommended Use

1. Please use the device under normal indoor environment.
2. The device should be used away from heat sources.
3. The battery can only use the matching charger that comes with the battery (see **§7.2.1 Accessories**). Do not charge the battery for more than 24 hours.
4. Do not disassemble the battery by yourself. Do not put the battery in the damp place to avoid danger.
5. When the battery is not used for a long period, keep it well in a semi-charged state. Keep the battery in a cool and dry place.
6. Disposal of the waste batteries should follow the local environmental protection regulations. Do not put it into fire or water.
7. Do not use a battery with serious crack or deformation. If the battery is broken, stop using and contact your local distributor or the manufacture for maintenance.
8. Charge the battery according to **§3.3.1 Charging**.
9. The rechargeable battery for the device is a Li-ion battery. Please contact the manufacturer to purchase a new one when the battery efficiency is reduced and need to be replaced. (See **§7.2.1 Accessories**).

6.2.2 Hazard Warning

1. Forbid to disassemble the battery

The built-in battery inside the device has a protective mechanism and a protective circuit to avoid danger. Improper disassembly may damage the protective function and may cause the battery to heat, smoke, deform or burn.

2. Forbid to heat and incinerate the battery

Heating and incineration of the battery will cause the isolated element in the battery to dissolve, the loss of protective function or electrolyte combustion and over-heating, which will make the battery heat, smoke, deform or burn.

3. Avoid using the battery near heat sources

Do not use the battery near a fire source and oven or at a temperature of over 80℃. Over-heating will cause the battery to be internally short-circuited and make it heat, smoke, distort or burn.

4. Forbid to put the device into water

Do not put the device into the water; otherwise it will cause the internal protection circuit and its function loss, and abnormal chemical reactions. The battery may be hot, smoking, deformed or burning.

5. Avoid charging near fire or in direct sunlight

Otherwise, it will cause the battery's internal protection circuit and its function to be lost or be subject to abnormal chemical reactions, the battery may be hot, smoking, deformed or burning.

6. Charging the device with a non-dedicated charger may be dangerous

Charging under abnormal condition will cause the battery's internal protection circuit and its function to be lost or subject to abnormal chemical reactions, the battery may be hot, smoking, deformed or burning.

7. Forbid to damage the device

Do not knock and hammer the battery with metal, or damage the battery in any other ways. Otherwise, it will cause the battery to be over-heated, smoking, deformed or burning, or even put it in danger.

8. Forbid to charge the device directly on the power socket or car cigarette lighter

High voltage and high current will damage the battery and reduce its service life, or even cause the battery to be over-heated, smoking, deformed or burning.

9. Do not touch the leaked battery.

10. Stop using the device if it leaks. The leaked electrolyte will cause the skin to be uncomfortable. If it is dropped into eyes, do not rub the eyes, but wash them immediately, and go to the hospital for further treatment.

6.2.3 Warnings

1. If the charging time is much more (more than 24 hours) than the normal charging time, please stop charging. The abnormal charging will cause the battery to heat, smoke, deform or burn.

2. Do not put the device into a microwave oven or any other pressure equipment. If it is instantly heated or leaks (or odors), remove the charger and stop using it. The abnormal battery will cause over-heating, smoking, deformation or burning.

3. The charger has obtained the medical electronic device safety qualification. If it is lost or damaged, please contact the manufacturer to purchase a new one; use of charger other than that is provided by the manufacturer may cause increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in abnormal operation and undesirable impact on product safety. The manufacturer shall not be responsible for any consequences arising therefrom.

4. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of MD-6000P. Otherwise, degradation of the performance of the device could result.

5. Use of the device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, MD-6000P and the other equipment should be observed to verify that they are operating normally.

6. When the level of electromagnetic disturbance to which the MD-6000P is subjected exceeds its immunity (see Annex C), if the interference to the B-mode image affects the correct identification of the bladder boundary, it may increase the measurement error of urine volume in the bladder.

6.2.4 Cautions

1. Notice

Prevent the device from being used directly under the sunlight, so as to avoid heating, deformation and smoking and at least to avoid weakening of its performance and service life.

2. Anti-static

The battery is equipped with a protective circuit to avoid all kinds of accidents. Pay attention to electrostatic protection when touching the charging port. Exceeding the electrostatic environment specified in Annex C may result in failure of the protective circuit, thereby increasing the risk of abnormal work, heating, deformation, smoking, burning of the battery.

3. Charging Temperature Range

The recommended charging temperature range is 0℃-40℃. Charging in the environment beyond this range may lead to the reduction of the battery performance and service life.

4. Read the User Manual carefully before use and as often as necessary.

5. Charging Mode

Please use the charger provided by the manufacturer and the manufacturer's recommended charging method to charge the device under the recommended environmental conditions (**§3.3.1 Charging**).

6. Battery Cycle Life

The battery's cycle life is not less than 300 charging and discharging cycles. The manufacturer will not replace a new device free of charge even in the warranty period due to the improper use rather than quality problem.

6.3 Maintenance and Attentions of the Main Unit

1. Do not use high-temperature sterilization.
2. Handle the Main Unit with care and avoid collision and falling to prevent the Main Unit from being broken and its housing from being damaged.
3. Avoid falling or damage of the Main Unit during use, charging or transportation.
4. If the device drops during transportation or use, please check if it is damaged and whether it still works. If there is any damage on the probe cover of the Main Unit or it doesn’t work, stop using it and contact your local distributor or the manufacturer for repair.
5. Make sure the device is placed in the plastic bag during transportation.

⚠ ***Note: Plastic bags are dangerous, please put them away from infants and children to avoid the risk of suffocation.***

6. The part above the metal ring on the housing of the Main Unit shall not be dipped into water or other liquids. See Fig. 5.1.

6.4 Maintenance of Screen

1. Use glasses cloth, lens paper and other soft tissue to wipe the OLED screen.
2. The OLED screen should be used in a relatively dry environment to prevent moisture from getting into the screen. Prevent any liquids from splashing onto the screen.
3. If the screen does not work, please do not try to open it by yourself.
4. Don’t use any hard objects to touch the screen; otherwise it may cause irreparable damage to the screen.
5. Avoid strong shock or vibration.

6.5 Troubleshooting

1. When the device breaks down, please check the battery capacity first; press on the power switch button to shut down and restart the Main Unit.
2. If the Main Unit and the Tablet PC are unable to be connected, shut down the Main Unit and restart it. Click the Wi-Fi icon on the Tablet PC to re-pair the connection.

If above instructions don’t work, please don’t open the housing without authorization. Contact your local distributor or the manufacturer immediately. Explain the problems in detail for proper and timely support.

When the battery over-discharge failure occurs, the internal slow fuse (5TE 3.15A / 250V) will automatically fuse. The fuse can’t be replaced by the user. Please contact your local distributor or the manufacturer.

When the clock failure occurs, the clock battery inside the device may be exhausted. The clock battery can’t be replaced by the user. Please contact your local distributor or the manufacturer.

If it is required by the qualified maintenance personnel trained by the manufacturer or by the authorized service station, the manufacturer may provide the service manual containing all the necessary information for maintenance.

The device is sophisticated. Only trained and qualified engineers are authorized to repair the device.

The manufacturer will not be responsible for any consequences of safety and effectiveness caused by any kind of unauthorized repair.

6.6 Disposal of Device after its Life-Cycle

Disposal of the device after its life-cycle shall comply with the relevant local environment protection regulations. The same way with the electronic devices (computers, etc) can be taken.

Chapter 7 Service and Support Information

7.1 Warranty

1. The product has a warranty of one year from the purchasing date on the premise of using in accordance with the **User Manual**.
2. If the device does not work properly, please contact your local distributor or the manufacturer immediately.
3. Following services will be charged within the warranty period:
   - Problems caused by man-made damages;
   - Damages caused by unauthorized service;
   - Damages caused by inappropriate operation.
4. We provide continuous maintenance and services after warranty period with certain charges.

7.2 Accessories and Consumables

7.2.1 Accessory

No.	Item	Model No.	Specification
1	Charger	HXY-084V1000A	AC100-240 V 50/60 Hz, 0.5 A max

7.2.2 Optional Accessory

No.	Item	Model No.	Specification
1	Tablet PC	Lenovo YT3-850F	Operating System: Android RAM requirements: ≥1GB ROM requirements: ≥16GB Processor frequency: ≥1GHz WLAN: meet 802.11 b/g/n

⚠ ***Note: If you purchase the Tablet PC by yourself, make sure it should meet the requirements of ICE60950-1.***

7.2.3 Consumable

No.	Item	Model	Specification
1	Acoustic Gel	——	With local approval for marketing.

⚠ ***Notes:*** ***① The Main Unit Charger used with the device must be provided by the manufacturer. Using accessories other than those provided by the manufacturer may cause increased electromagnetic emissions or decreased electromagnetic immunity of the device and result in abnormal operation.***

② The consumable used with the device must be as specified above.

Annex A. Conservation Concept Declaration

A.1 Declaration

The biological effect of ultrasound may be evidenced in future, albeit no evidence on this currently exists. Although MD-6000 itself produces ultrasound of low level, we have to bear the concept of using lowest level of ultrasound that could bring clinic data needed, and use the shortest time as reasonably as possible.

A.2 ALARA

Principle of ALARA (As Low As Reasonably Achievable) should be used in a ultrasound diagnosis. On the premise of diagnostic data, please use lowest level of ultrasound and shortest time, while the energy amount of ultrasound is decided by the output intensity and diagnostic time. And this level and time may vary with different patients.

Not all diagnosis could be achieved through the lowest level and shortest time, which may result in a image of low quality or dismal signal and bring problems to accuracy of diagnosis. But higher level than really needed won't help anything on the diagnosis while it only brings more risk of biological effect.

Operators are responsible for patients' safe and supposed to apply ultrasound level according to the principle of ALARA.

Annex B. Acoustic Output Reporting Table

According to IEC 60601-2-37

System Model: RZ17060020

Transducer Model: MD-6000P

Operating Mode: B

Index Label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			0.148	0.00052		0.00106		0.00106
Index Component Value				0.00052	0.00052	0.00106	0.00052	
Associated acoustic parameters	$p_{r,\alpha}$ at z_{MI}	(Mpa)	0.216					
	P	(mW)		0.068		0.068		0.068
	P_{1x1}	(mW)		0.051		0.051		
	z_s	(cm)			#			
	z_b	(cm)					#	
	z_{MI}	(cm)	3.2					
	$z_{pii,\alpha}$	(cm)	3.2					
	f_{awf}	(MHz)	2.136	2.136		2.136		2.136
Other information	prr	(Hz)	250					
	srr	(Hz)	3.1					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	1.187					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	0.010					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	0.015					
	p_r at z_{pii}	(Mpa)	0.291					
Operating control conditions	Freq	(MHz)	2.5					
	Mode		Pre & 3D scan					
	Others		Default					

(a) Intended use does not include cephalic so TIC is not computed

\# No data reported

According to UD2-2004 and FDA Guide for Track 1

Probe MD-6000P

Operation Mode: B Mode

Working Frequency: 2.5MHz.

Acoustic Output	MI (unitless)	$I_{SPAT.3}$ (mW/cm^2)	$I_{SPPA.3}$ (W/cm^2)
Sample Size	3	3	3
K (P=0.90, gamma=0.9)	4.258	4.258	4.258
Mean (x)	0.225	1.08	2.493
StdDev (Sx)	0.008	0.0436	0.410
Limit (X)	0.259	1.266	4.24

Annex C. Guidance and Manufacturer's Declaration

Guidance and manufacturer's declaration - electromagnetic immunity				
The MD-6000P BLADDER SCANNER is intended for use in the electromagnetic environment specified below. The customer or the user of the MD-6000P BLADDER SCANNER should assure that it is used in such an environment.				
Immunity test	**IEC 60601 test level**		**Compliance level**	**Remarks**
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV (Contact) ±15 kV (Air)		±8 kV (Contact) ±15 kV (Air)	
Radiated Electromagnetic Field IEC 61000-4-3	80～2700(MHz)	10 V/m	10 V/m	
	385 (MHz)	27 V/m	27 V/m	
	450 (MHz)	28 V/m	28 V/m	
	710, 745, 780 (MHz)	9 V/m	9 V/m	
	810. 870, 930 (MHz)	28 V/m	28 V/m	
	1720,1845,1970 (MHz)	28 V/m	28 V/m	
	2450 (MHz)	28 V/m	28 V/m	
	5240, 5500, 5785(MHz)	9 V/m	9 V/m	
Fast Transient (BURST) IEC 61000-4-4	±2kV for AC Power Port		±2kV	
Surge Transient IEC 61000-4-5	±1Kv for AC Power Port			
Conducted Disturbance IEC 61000-4-6	3V / 6V ISM Band / 6V Amateur radio band 0,15 MHz – 80 MHz		3V / 6V ISM Band / 6V Amateur radio band	
Power frequency magnetic field IEC 61000-4-8	30A/m 50/60 Hz		30A/m	
Voltage dips, interruptions and variations on power supply input lines IEC 61000-4-11	0.5 cycle, 100% of V_{NOM} at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 1 cycle, 100% of V_{NOM} at 0° 25/30 cycle, 100% of V_{NOM} at 0° 250/300 cycle(5S), 100% of V_{NOM}		Complies Complies Complies Complies	
Conducted Emissions	150 kHz - 30 MHz		Pass	
Radiated Emissions (Electric Field)	30 MHz - 1000 MHz		Pass	
Harmonic Current Emissions and Voltage Fluctuations and Flicker			Not Applicable	

Annex D. Main Specification of Wireless Wi-Fi

Frequency Range	2,412-2,462 MHz
RF Output Power (EIRP)	13.50 dBm
Modulation	DSSS, OFDM
Mode of Operation (Simplex / Duplex)	Duplex

Annex E. References

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[3] Coombes GM,Millard RJ.The accuracy of portable ultrasound acanning in the measurement of residual urine volume[J].The Journal of Urology,1994,152：2083-2085

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[5] Cardenas, D. D., Kelly, E. Krieger, J. N., Chapman, W. H. (1988). Residual Urine Volume in Patients with Spinal Cord Injury: Measurement with a Portable Ultrasound Instrument. Archives of Physical Medicine and Rehabilitation, 69:514-516

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[7] RiseM, etal. An ultrasonic bladder sensor. Trand. Bio. Eng. 1979; BME26(12); 709