User Manual

Product name: Bladder Scanner

Trademark: AvantSonic

Model: PadScan Z5

Table of Contents

Chapter One Introduction

Statement:

1.1 Brief Introduction

The PadScan Z5 by Avantsonic Technology Co., Ltd. provides non-invasive volume measurement of the bladder by utilizing real-time ultrasound imaging and measuring. The equipment consists of main unit, 3D probe, battery and adapter.
It features:

- Two Operation Modes: Ultrasonic Mode and Easy Mode. During the ultrasonic mode, the real-time 2-dimensional ultrasound image will be displayed on the screen. Doctors can decide if the location and measurement result is right or not according to the cross-section image of the bladder. During the easy mode, 2-dimensional ultrasound image will not be displayed on the screen. The equipment instructs the operator to move the probe to find the right location. (No sonographer is required during the easy mode.)
- Non-invasive, comfortable, correct, reliable, fast and simple operation. When the operator releases the scanning button, multiple 2D plane ultrasound images are acquired in a few seconds. The equipment adopts sophisticated image processing techniques to restore stereo image, adopts sophisticated algorithm to measure bladder volume and displays the measurement result on the screen.
- Printouts with ultrasound images and various parameters
- Touch screen keyboard operation
- Jet molding enclosure with flat structure and adopting 8-inch LCD screen (800x600 pixels)
- Combined power supply with AC adapter and a built-in battery.

1.2 Intended Use

The equipment is used for bladder volume measurement in medical units. It provides the basis for the implementation of clinical catheterization, and makes evaluation of residual volume after patients' voiding and assists the diagnosis of the bladder and renal function diseases. This

equipment also helps the disabled and people who lost the function of automatic micturition to know the time of urination.

1.3 Standards

This equipment is designed and manufactured in strict accordance with:

- IEC60601-1:2005 “Medical electrical equipment Part 1: General requirements for safety”
- IEC 60601-2-2:2007 “Medical electrical equipment -- Part 1-2: Particular requirements for the safety of high frequency surgical equipment”
- IEC60601-2-37 2001 Medical electrical equipment Part 2-37: Ultrasound Diagnosis and Monitor Equipment Safety Specific Requirement
- ISO10993-5 2009 Part 5: Evaluation of Biological Properties of Medical Equipment
- NEMA UD 2 2004: Measurement Standard of Acoustic Output Ultrasound Diagnosis

Equipment Revised Version 3

- ISO 14971 2007 Risk Management
- ISO10993-10 2010 Stimulation and Skin Sensitization Experiment

Symbols

 Type B device

 Attention! Consult accompanying documents

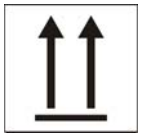
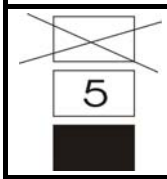
 Switch On (general power)

 Switch Off (general power)

 Signal output

 0482 CE mark and code of certification body

	Handle with care
	Temperature limit

	Upwards
	Limited layers of storage
	Keep dry
	Keep away from sunlight

1.4 Service Life

The service life of the product is six years. Constant use of the equipment after service life will increase the risk of failure and unpredictable risk.

Warning: Users will assume responsibility of the risks associated with the use of the equipment after recommended service life.

Warning: The disposal of the products should comply with the local regulations. Don't scrap the product with household refuse.

1.5 Operational Environment

Temperature: +5℃ to +40℃
Relative humidity: 30% to 75%
Pressure: 70kPa to 106kPa

1.6 Declaration of Electromagnetic Compatibility

PadScan Z5 in operation will not interfere with the wired, wireless or other electrical equipment. It works properly under specified electromagnetic environment.

Warning: Using the PadScan Z5 under strong electromagnetic environment, close to generator, X-ray equipment, dentistry and physiotherapy equipment, broadcasting station or buried cable, etc... will introduce interference signals in the image. This will influence the measurement. Please stop using the equipment at the moment to prevent improper measurement. Use the equipment until the interference of preclusion.

Warning: Sharing power supply with other equipments may produce abnormal image. Eliminate the electromagnetic coupling interference of any equipment by verification.

Warning: Replacing with the substandard spare parts of equipment may cause unpredictable electromagnetic compatibility problems, influencing the location of measurement and causing improper measurement. Only the companies and departments appointed by manufacturer are allowed to replace the spare parts of equipment.

1.7 Declaration of Manufacturer

Users will assume all the risks of modifications for the equipment without the manufacturer's permission.

Warning: It is prohibited to perform any modifications to the equipment without the manufacturer's permission.

Warning: Modifications to the equipment must be tested by appointed department of the nation to ensure the safety of using the equipment.

1.8 Contraindications

Do not use the equipment on patients with sores or wounds to prevent cross-infection.
This equipment is not suitable for the bladder scan of pregnant women and fetus. Do not use the equipment on patients with ascites.
If you scan a patient with a catheter in his/her bladder or with scars in his/her abdomen, measurement accuracy will be affected.

1.9 Heat and Mechanical Indexes

Heat index: PI0.1

Mechanical index: MI＜0.1

Chapter Two Cautions and Warning

To ensure safety, please read the following instructions before using the equipment. The equipment shall only be used by the professionals affirmed or authorized by associated medical institution.

2.1 Equipment Checks

1. Make sure all the cables are properly connected.
2. Make sure the equipment is working properly.
3. Keep the equipment away from sunlight and keep dry.

Warning: If the equipment or cable is damaged, it is prohibited to use the equipment.

2.2 Pre-scan Checks

Check if the probe is properly connected. Make sure no water, chemicals or other material spattered on the equipment. During using the equipment, pay attention to the main parts of it. If there is strange sound or smell, stop using the equipment right away; do not use the equipment until the authorized engineer solves the problem.

2.3 Operation Instructions

Warning: Do not insert nor pull out the probe while the equipment is power on in order not to damage the machine and probe.

1. During using the equipment, please protect the surface of probe and do not clash. Apply the ultrasound gel on the surface of probe to ensure the probe and body is well contacted.
2. Pay attention to the equipment and patient. If the equipment broke down, turn off the power right away and then unplug the power cord.
3. Patients are prohibited to touch the equipment or other electrical equipment.
4. Do not cover the air vent of the equipment.

2.4 Post-scan Checks

1. Turn off the power.
2. Unplug the power cord
3. Clean the equipment and the probe

2.5 Conditions to Avoid

The equipment should avoid the following:

1. Splash
2. High humidity
3. Poor draught
4. Direct sunlight
5. Dust
6. Gas with salt or sulfur
7. Chemical medicines or gas
8. Strong vibration and clash
9. Our company takes no responsibility for any risks caused by disassembling, refitting of the equipment.

2.6 Notice of Using Probe

1. Do not immerse the probe into any liquid.
2. Do not heat the probe.
3. Do not pull or bend the cable of probe in order not to damage it.
4. Use national standard ultrasound gel. Other substance (for example: oil) will damage the probe and the cable of probe.
5. Keep the probe clean. Use neutral detergent or water to clean the ultrasound gel on the probe.

2.7 Handling the Equipment

1. Unplug the power cord
2. Do not drop, vibrate or clash the machine and probe.

2.8 In case of Equipment Failure

If equipment is not working properly, turn off the power and unplug the power cord. Contact qualified maintenance staff.

2.9 Maintenance of Equipment

2.10 Maintain Equipment and Probe Safety

2.11 Starting up

Assemble the power adapter firstly. Then connect its AC input plug with power outlet and insert its DC output plug into the DC 13.5V port on the right side of the main unit. If the left indicator

light on the main unit turns green, it means the DC 13.5V output voltage of the power adapter is working properly.
When you press the power button on the main unit as the right indicator light on the panel turns green, it enters the Power-On interface.

Chapter Three Device Introduction

3.1 Figuration

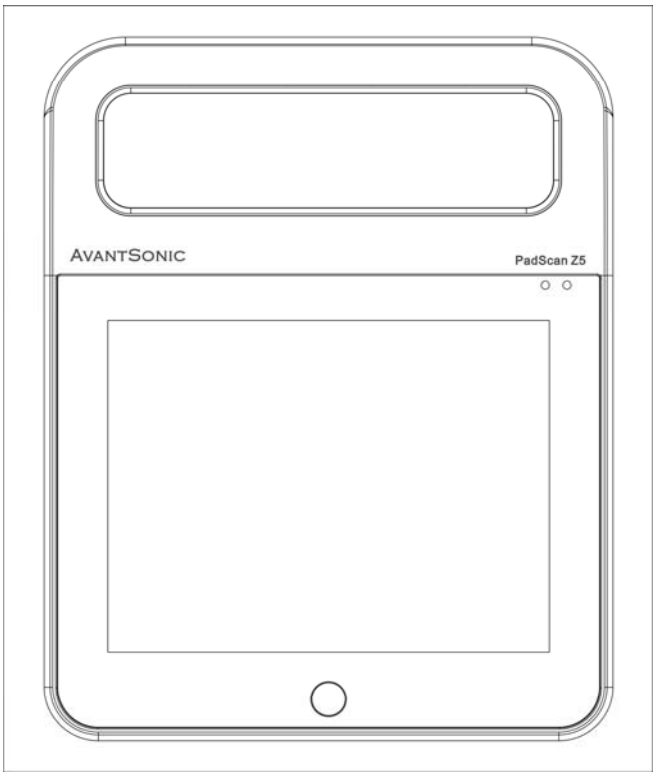


Figure 3-1 PadScan Z5 Front Diagram

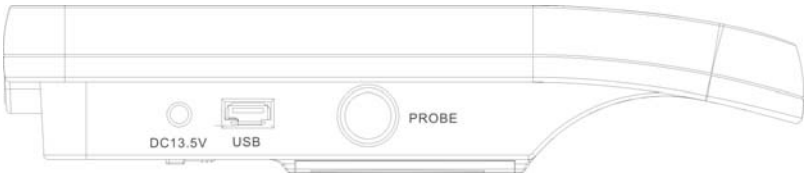


Figure 3-2 PadScan Z5 Diagram of Connection Port Side

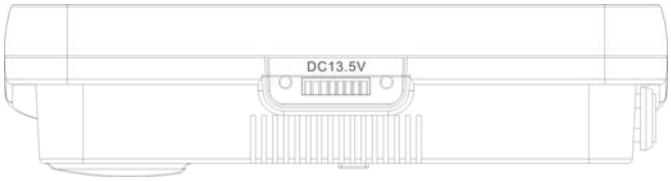


Figure 3-3 PadScan Z5 Bottom Diagram

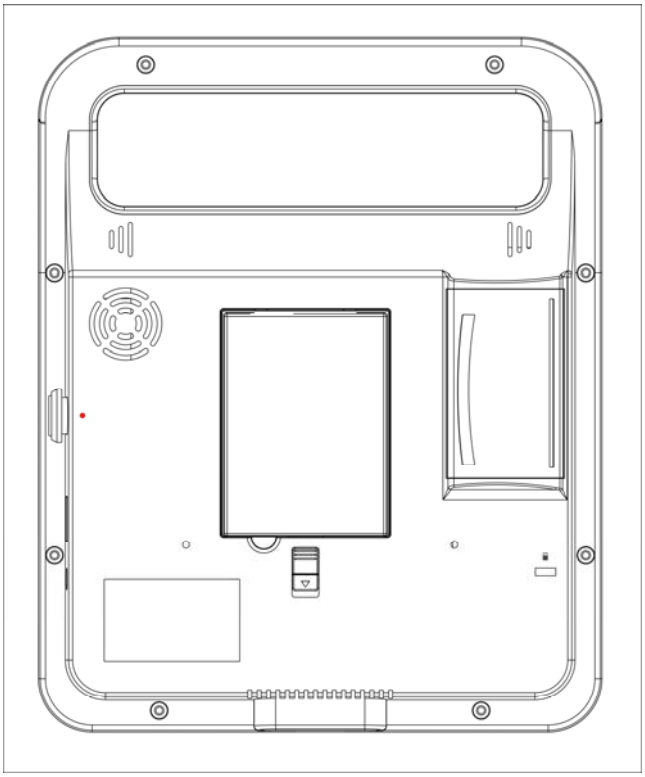


Figure 3-4 PadScan Z5 Back Diagram

3.2 Technical Specification

- Probe: 3D mechanical sector
- Standard ultrasonic frequency of operation: 2.5MHz
- Volume measurement range: 0ml - 999ml
- Volume measurement accuracy: ±10%
- Volume display resolution: 1ml
- Scan time: 5 seconds
- Battery capacity: 2600mA
- Operation methods: touch screen
- Tissue Harmonic Imaging
- Information storage
- Information print
- Multicolored image display selection
- Multicolored screen style selection
- USB port: connecting PC and user information storage

- Bluetooth module: connecting PC by wireless
- Dimension of monitor: 8-inch TFT-LCD
- Consumption: 50W
- Dimension of equipment： 210*260*50 mm
- Weight: about 1500g (including the probe)
- Power at the state of charging: 30-120VA
- Power supplied by AC when battery is full or by the battery: 30-40VA
- Battery charging time: less than 2 hours
- Battery life: more than 4 hours

3.3 Block Diagram

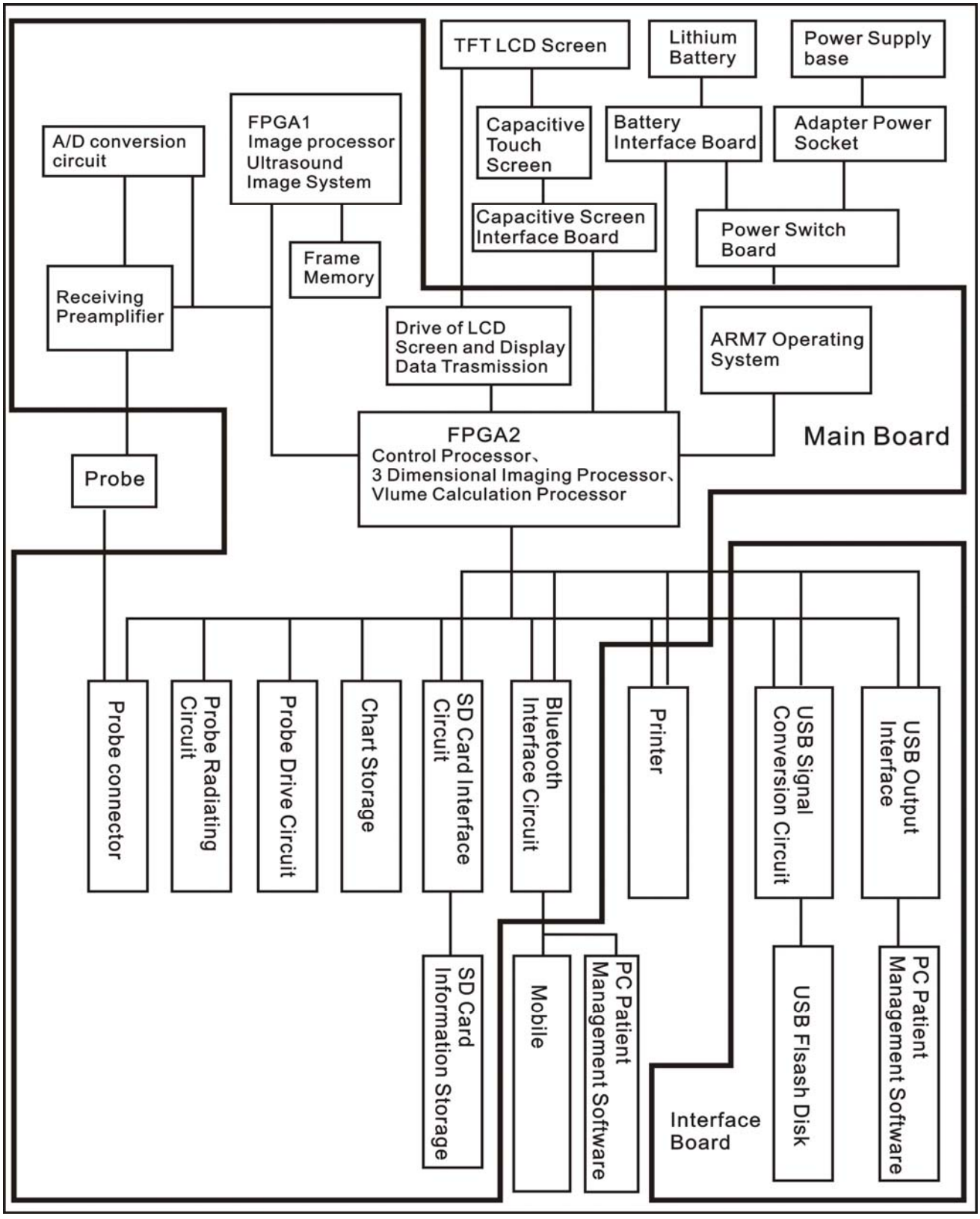


Figure 3-5 PadScan Z5 Principle of Electricity Block Diagram

3.4 Basic Principle

The equipment utilizes 3D mechanical sector probe to scan the bladder, and form into multiple 2D ultrasound images on the basis of detected bladder information. After sophisticated image processing, getting the area of multiple bladder sections, projecting 3D imaging, then it measures the bladder volume by sophisticated algorithm.

Operating principle: 1. Transmits the pulse signal to the 3D probe, emit the ultrasound to the human body by the transducer of probe. When the ultrasound passes the tissue plane of human body, it produces reflected wave and scattered wave and locates the tissues and organs according to the return period. And it detects the feature of tissue according to the acoustic intensity. Transmit such pulses can only acquire one signal of one plane, meaning to produce a sectional 2D image it needs to emit ultrasound at least 96 or 128 times to form one section. Then the emitted and received images will be displayed on the screen. Modulate the grey-scale of signal intensity of acoustic beam and a sectional plane image will be displayed. The electrical signal will be transmitted to digital scan converter for filtering, detecting and compressing after amplification.

The reflected ultrasound converts the acoustic energy into electric energy. Due to the difference of method and display direction of scan imaging and the difference of imaging speed. There is a digital scan converter in the equipment to switch the emission scan into imaging scan in order to realize 2D sectional real-time imaging. A series of imaging processing will be carried out in the digital scan converter then form a sectional image with high definition.

The 3D probe is driven by two electric motors, driving the rotation and swing of crystal at top of the probe. The lower step motor drives 180 degree rotation of the crystal whereas the upper step motor drives 120 degree swing of the crystal. When the lower step motor reaches the edge and become fixed, the upper step motor waggles 120 degree. And we get the first ultrasound image at this moment. Then the lower step motor rotates 15 degree and become fixed. The upper step motor swing 120 degree and we get the second ultrasound image. Then the lower step motor rotate 15 degree and the upper step motor rescan. The lower step motor rotates and upper step motor swings again and again until the lower step motor rotate 180 degree and ends. 13 images are acquired. Then the equipment processes and calculates 12 images of the 13 images, getting the bladder volume.

3.5 Equipment Configuration

- A main unit
- A power adapter：AC100-240V±24V 50/60Hz, 1.2A 120VA 13.5VD.C 5A

  Main unit: DC13.5V±0.5V
- A MP2/2.5MHZ 3D mechanical sector probe
- A bottle of ultrasound gel
- A User Manual
- A Li-ion battery: model: SNLB-325
- A Certificate
- A Warranty Certificate
- A Packing List
- A carrying case

Chapter Four Device Installation

4.1 Unpacking

Please make sure there is no shipping damage once you unpack the device. Check all the parts and components in accordance with the Packing List and install it based on the requirements and methods described in "4.2".

4.2 Installation

- Check the power adapter and insert its AC input plug into a power outlet after making sure adapter's power supply is within the stipulated power range.
- Connect the main unit with the docking station. Align the socket on the bottom of the main unit with the connector of the docking station and then put the main unit onto the docking station.

  The installation is proceeded as below: (as figure 4-1)

  Step 1: put the backrest on the base

  Step 2: tighten the screw

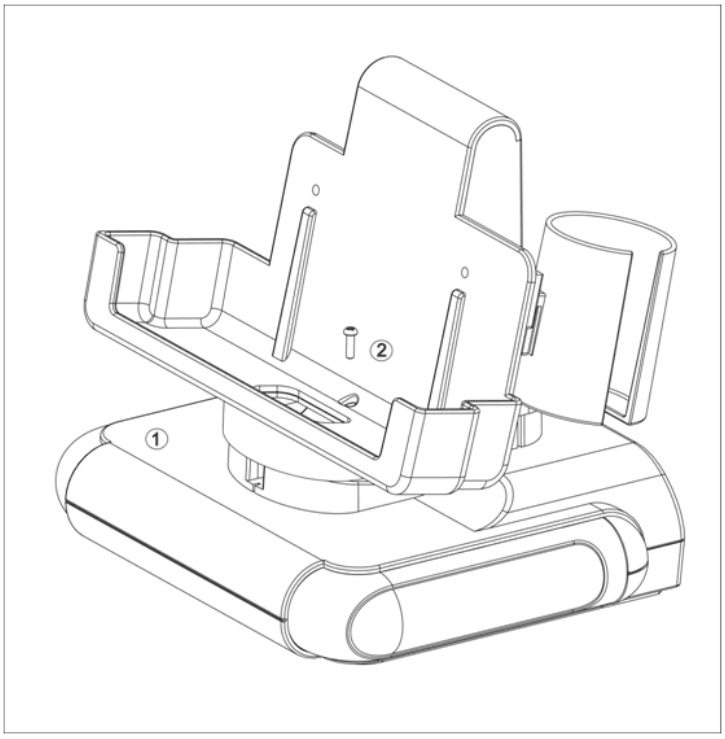


Figure 4-1 PadScan Z5 Docking Station and Main Unit Connection Diagram

Connect the probe to the main unit. Align the red dot on the probe with the red dot on the back of the main unit (Identifier of Probe), and insert the probe into probe socket on right side of the main unit as figure 4-2.

Lock slot: any notebook security lock is applied to this lock slot as figure 4-2.

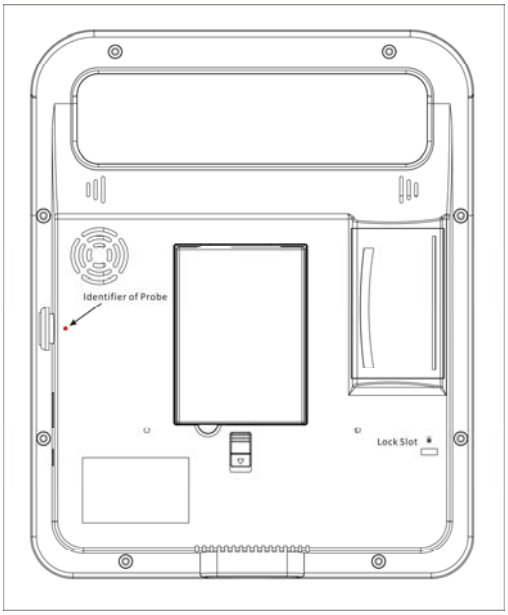


Figure 4-2 PadScan Z5 Probe and Main unit Connection Diagram

- Battery installation and removal

Battery installation:

Insert the alignment plate of the battery into the alignment hole of the battery slot, and move the locking key of the battery following the direction of arrow. Insert the battery into the slot slowly. After that move the locking key to the opposite direction of arrow. Show as figure 4-3:

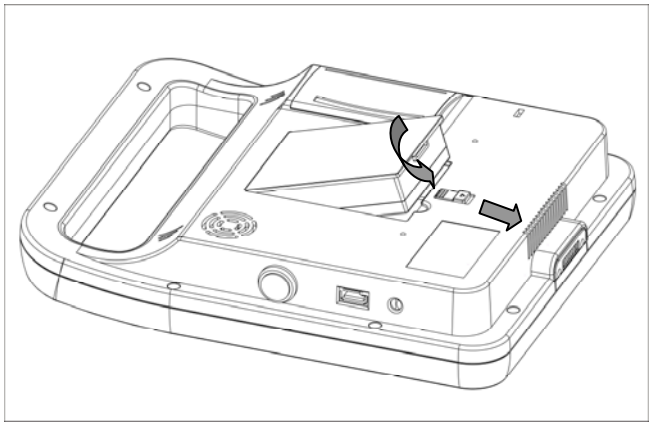


Figure 4-3 PadScan Z5 Battery Installation Diagram

Battery removal：Move the locking key of the battery following the direction of arrow, pull out of the battery at the side seam between the battery and the equipment. Show as figure 4-4.

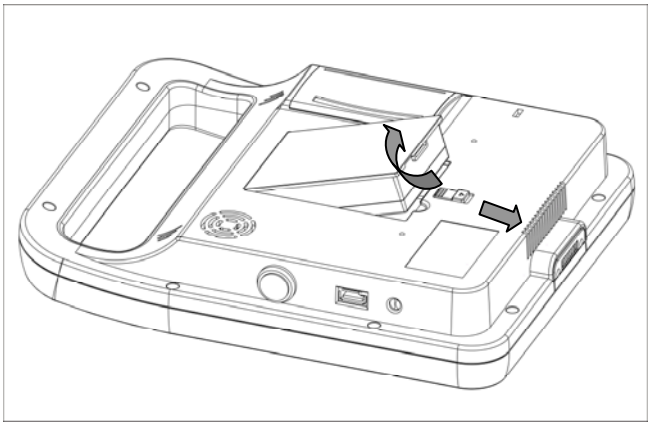


Figure 4-4 PadScan Z5 Battery Removal Diagram

4.3 Power Supply

The device is powered by power adapter and built-in battery, both of which are interchangeable.

4.3.1 Power Supply from Power Adapter

1. Check if the adapter is working properly; verify if the EPS is in the specified range. Insert the AC input plug of the adapter into the socket of the power supply. The output voltage of the adapter is DC 13.5V.

2. Connect the DC output plug of the adapter to the DC 13.5V port on the right side of the main unit. If the left indicator light on the main unit turns green, then the DC 13.5V output voltage of adapter is working properly. Press the power button on the main unit and the right indicator light turns green, entering the working status.

Warning: It is prohibited to use the adapter which is not supplied by manufacturer.

4.3.2 Power Supply from Battery

1. Insert the battery into the main unit as described in "**4.2**". The power indicator light on the left turns green.

2. Press the power button to turn on the machine. The indicator light on the right turns green. The power is on and the machine enters the working status.

4.3.3 Battery Charging

1. Insert the battery into the main unit

2. Connect the DC output plug of power adapter with the DC13.5V socket on the right side of the main unit
3. Connect the AC input plug of power adapter with the power outlet.
4. No matter the device is under the power-on or power-off, the battery is being charged if the left power indicator light on the main unit turns yellow, or fully charged if the light turns green.

Chapter Five Device Interface

5.1 Start-up Interface

Figure 5-1 PadScan Z5 Start-up Interface

A: Company LOGO

5.2 Main Interface

5.2.1Ultrasond Mode

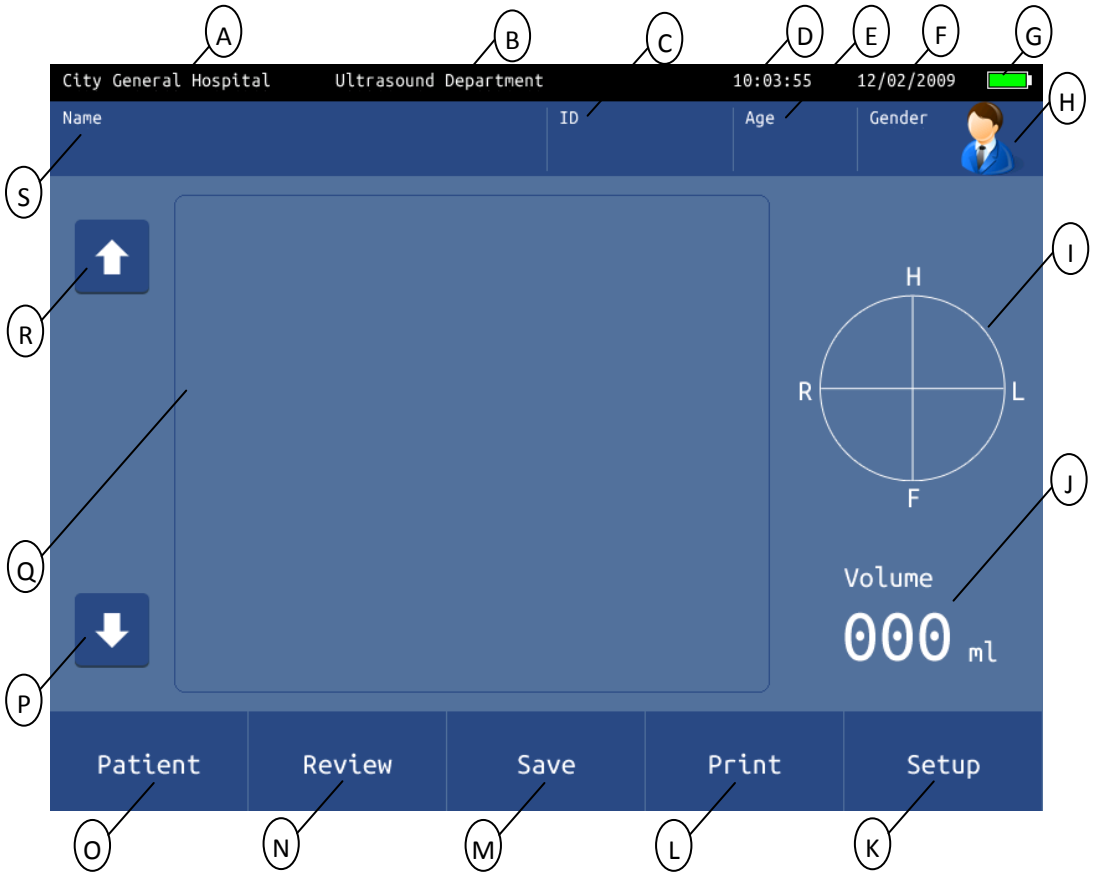


Figure 5-2-1 PadScan Z5 Main Interface in Ultrasound Mode

A: Hospital name

B: Department name

C: Patient ID

D: Time

E: Patient age

F: Date

G: Current battery

H: Gender selection

I: Projection of probe aiming

J: Current bladder volume

K: System setup

L: Patient information print

M: Current patient information storage

N: Patient information review key

O: Patient information input key

P: Turn to the last

Q: Ultrasound image display area

R: Turn to the next

S: Patient name

5.2.2 Easy Mode

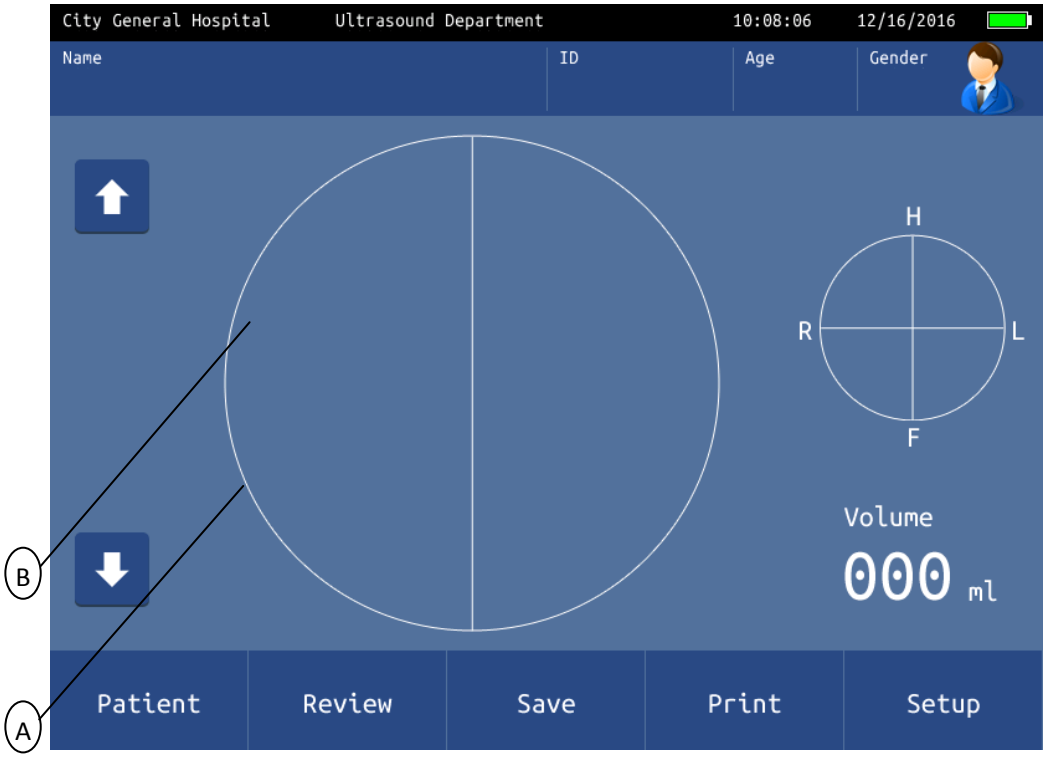


Figure 5-2-2 PadScan Z5 Main Interface in Easy Mode

A. Round frame of easy mode

B. Cross-section of bladder diagram

5.3 Patient Information Interface

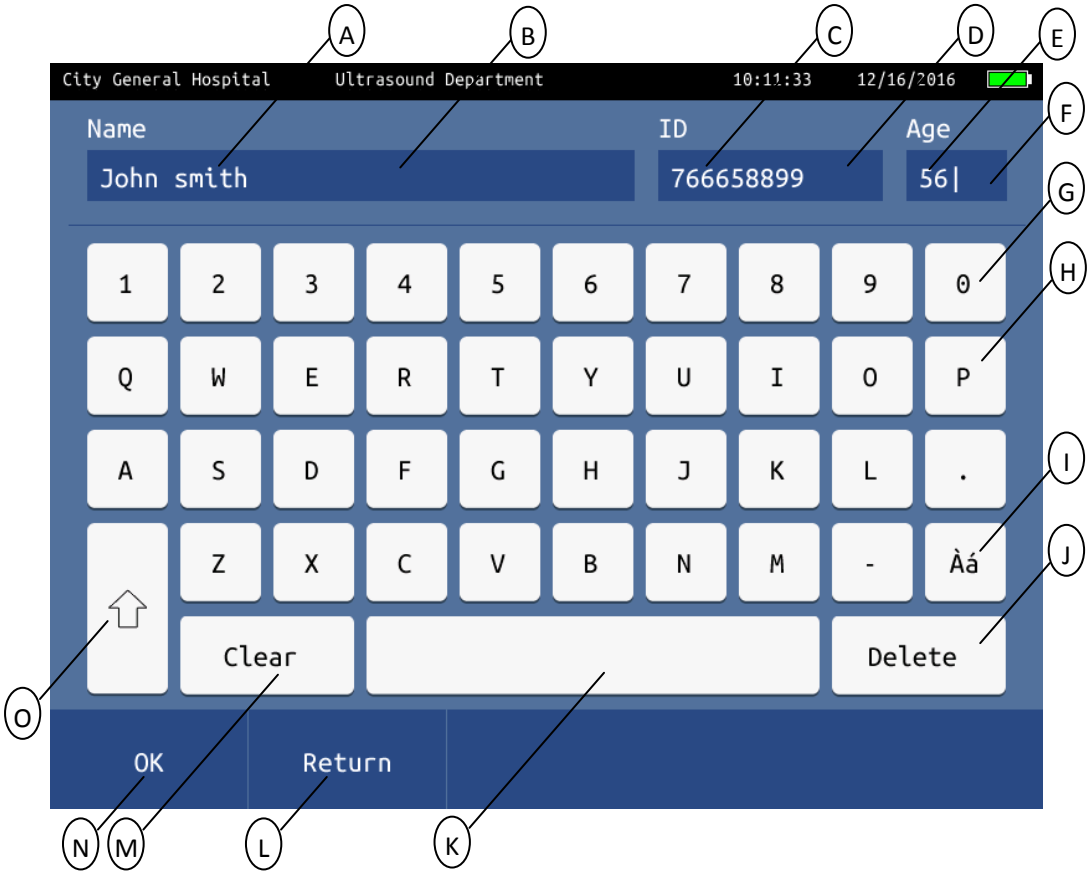


Figure 5-3 PadScanZ5 Patient Information Input Interface

A: Patient name

B: Patient name input box

C: Patient ID

D: Patient ID input box

E: Patient age

F: Patient age input box

G: Number keyboard

H: English keyboard

I: English letter and European letter shift

J: Delete

K: Space

L: Cancel and return

M: Clear

N: Confirm and return

O: Cap lock

5.4 Bladder Scan Interface

5.4.1Ultrasound Scan

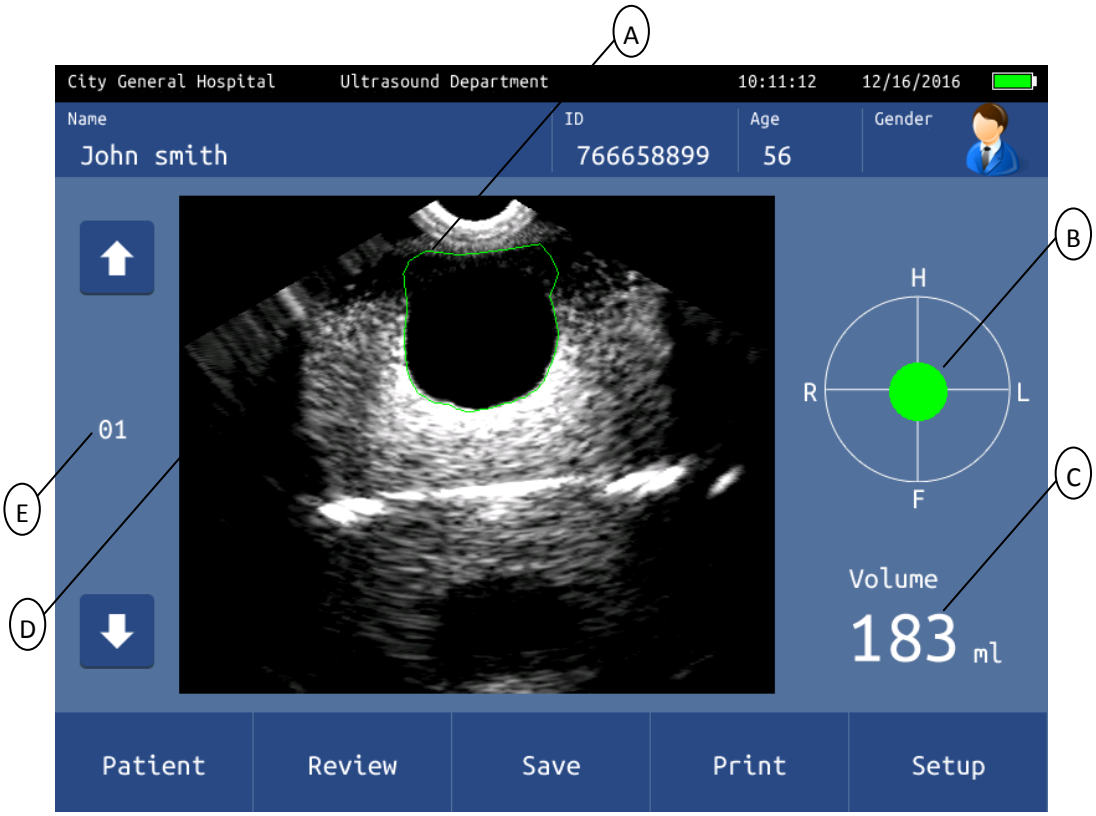


Figure 5-4-1 PadScan Z5 Ultrasound Scan Interface

A: Ultrasound image outline

B: Projection of scanned bladder

C: Current bladder volume

D: Ultrasound image of bladder

E: Serial number of current ultrasound image

5.4.2 Easy Scan

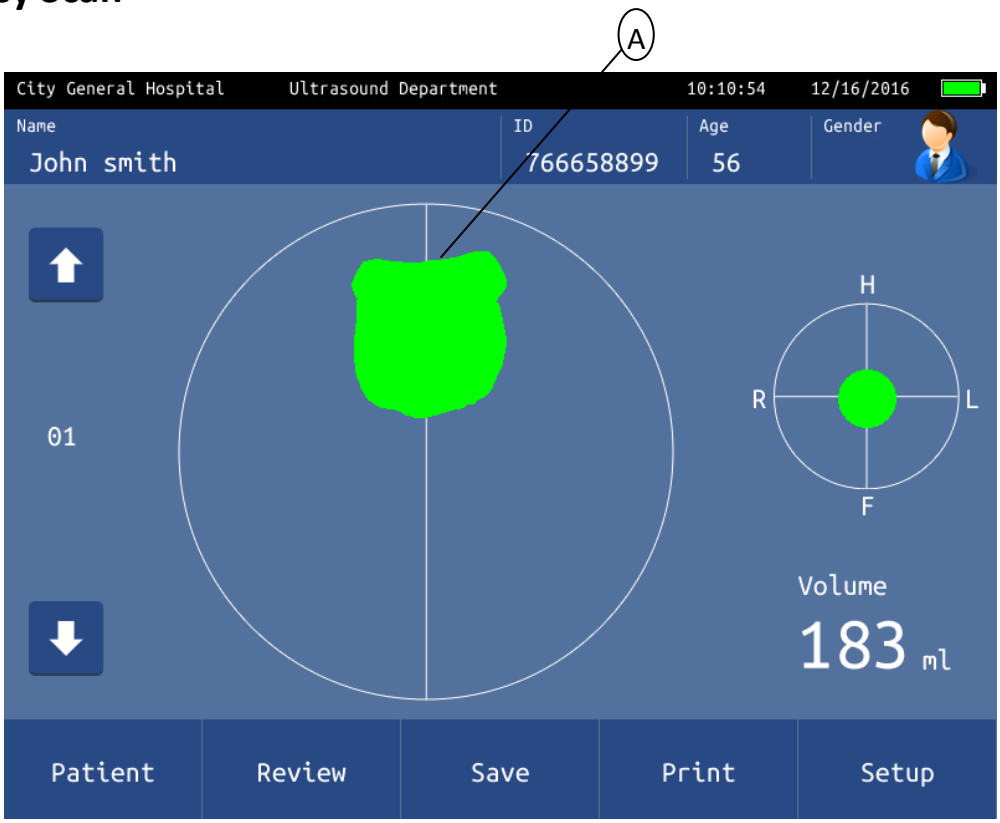


Figure 5-4-2 PadScan Z5 Easy Scan Interface

A: Cross-section of bladder diagram

5.5 Patient Information Review

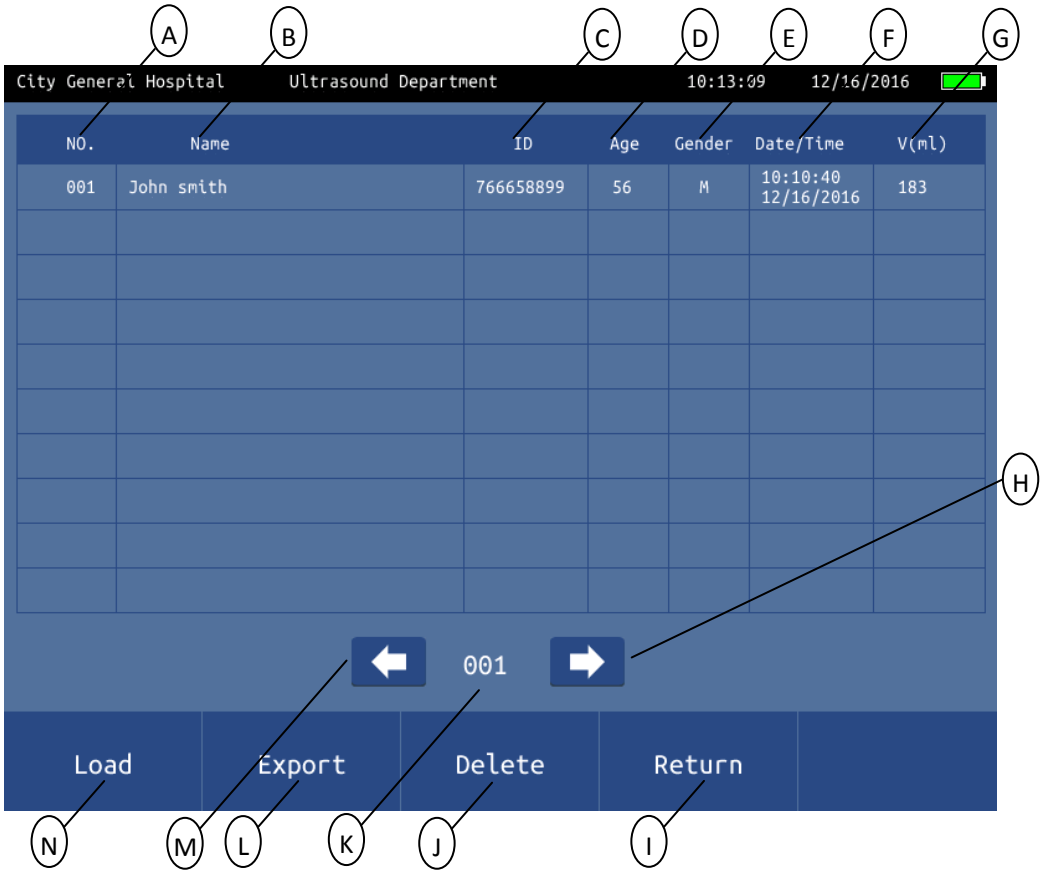


Figure 5-5 PadScan Z5 Patient Information Review Interface

A: Serial number of patient

B: Patient name

C: Patient ID

D: Patient age

E: Patient gender

F: Operation time and date

G: Patient bladder volume

H: Next page

I: Cancel and return

J: Delete

K: Current page

L: Export

M: Previous page

N: Load

5.6 System Setup

Figure 5-6 PadScan Z5 System Setup Interface

A: Z5 Figuration

B: Cancel and return

C: General setup

D: Display mode setup

E: Language setup

F: System information

G: Firmware upgrade

H: Service function

I: Power management

J: Time and date setup

5.7 Time and Date Setup

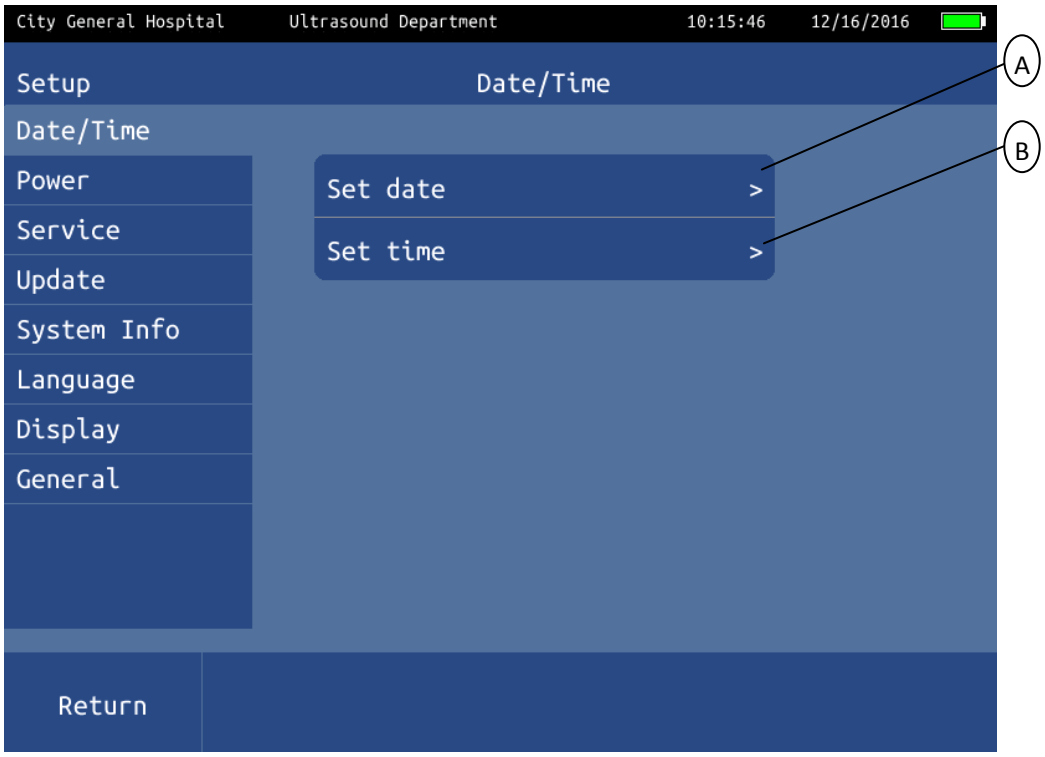


Figure 5-7 PadScan Z5 Time and Date Setup Interface

A: Date setup B: Time setup

5.8 Power Management

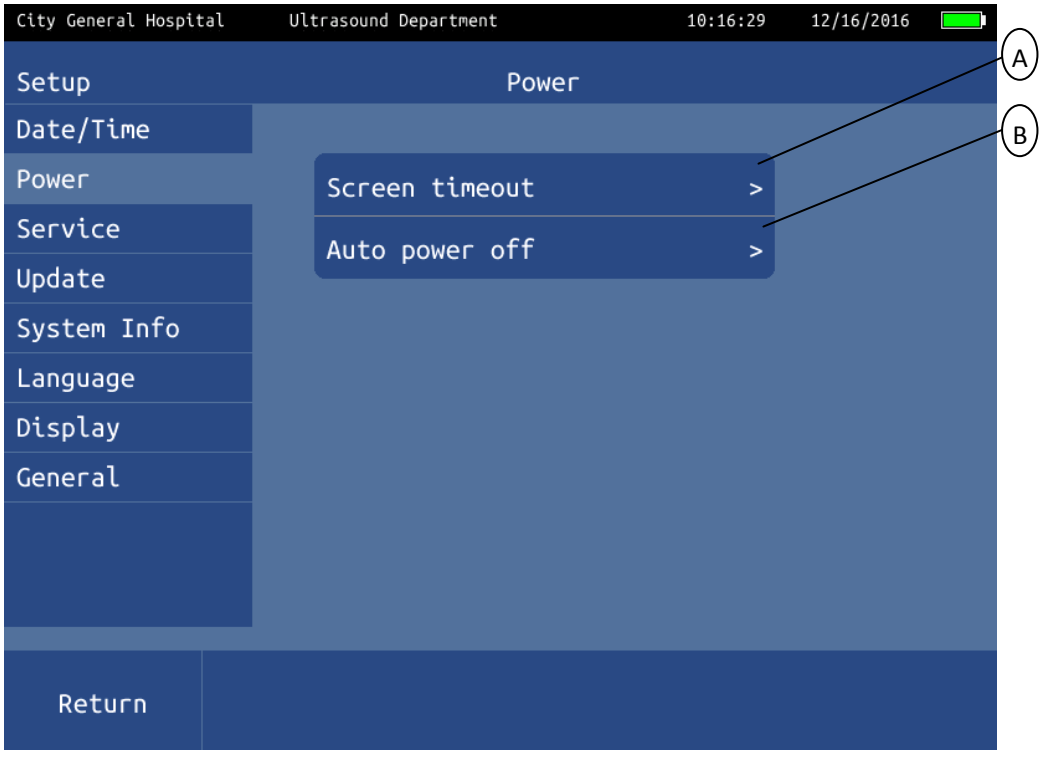


Figure 5-8 PadScan Z5 Power Management Interface

A: Automatic screen timeout setup B: Automatic power off setup

5.9 Service

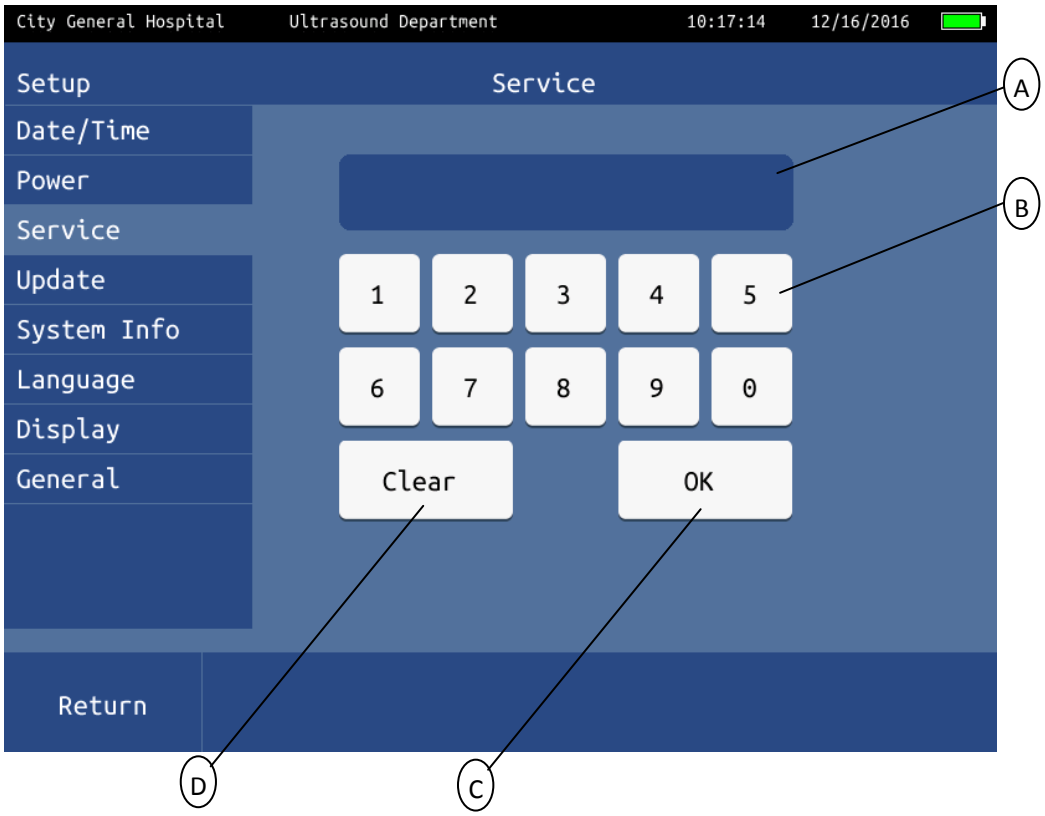


Figure 5-9 PadScan Z5 Service Function Interface

A: Password C: OK

B: Password input keyboard D: Clear the current input

5.9.1 Mode Selection

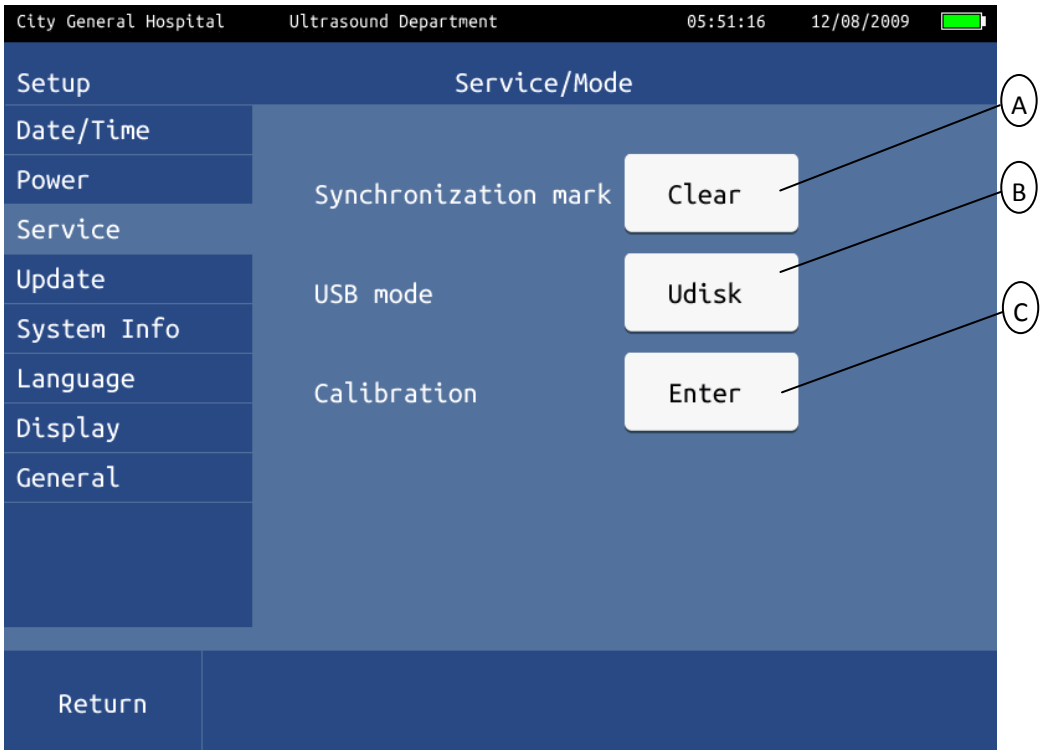


Figure 5-9-1 PadScan Z5 Mode Selection Interface

A: Synchronization mark removal key B: USB/PC mode conversion key

C: Calibration interface access key

5.9.1.1 Calibration

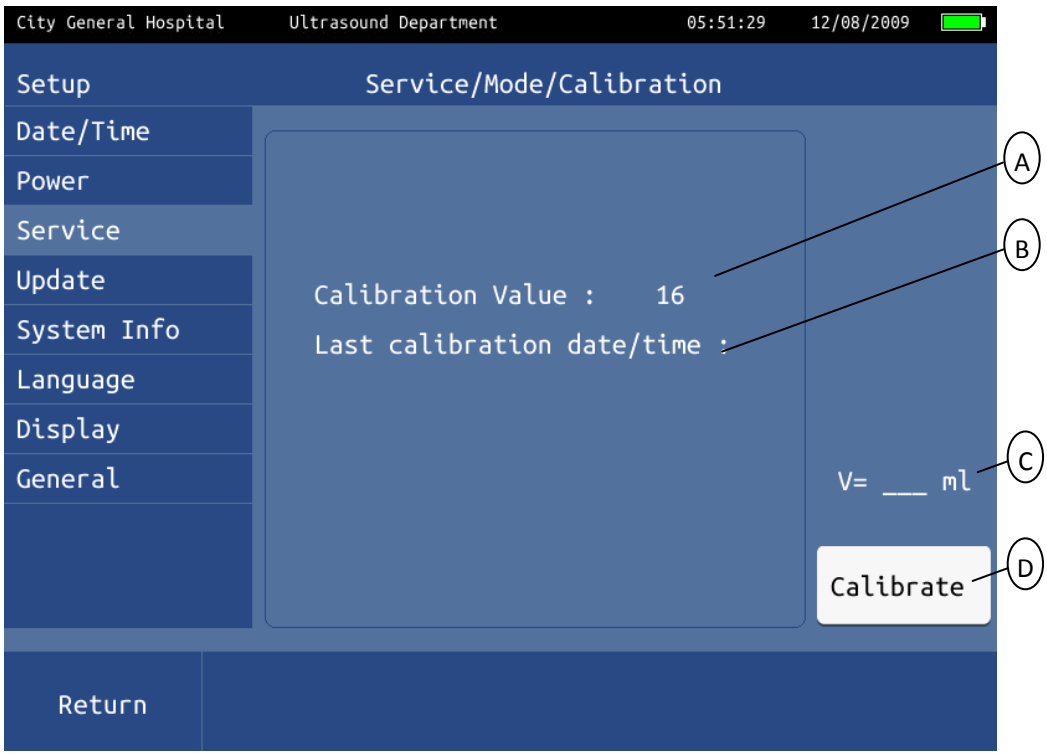


Figure 5-9-1-1 PadScan Z5 Calibration Interface

A: Current calibration value

B: Last calibration date/time

C: Current phantom volume value

D: Calibrate key

5.9.2 Calibration Value Reset

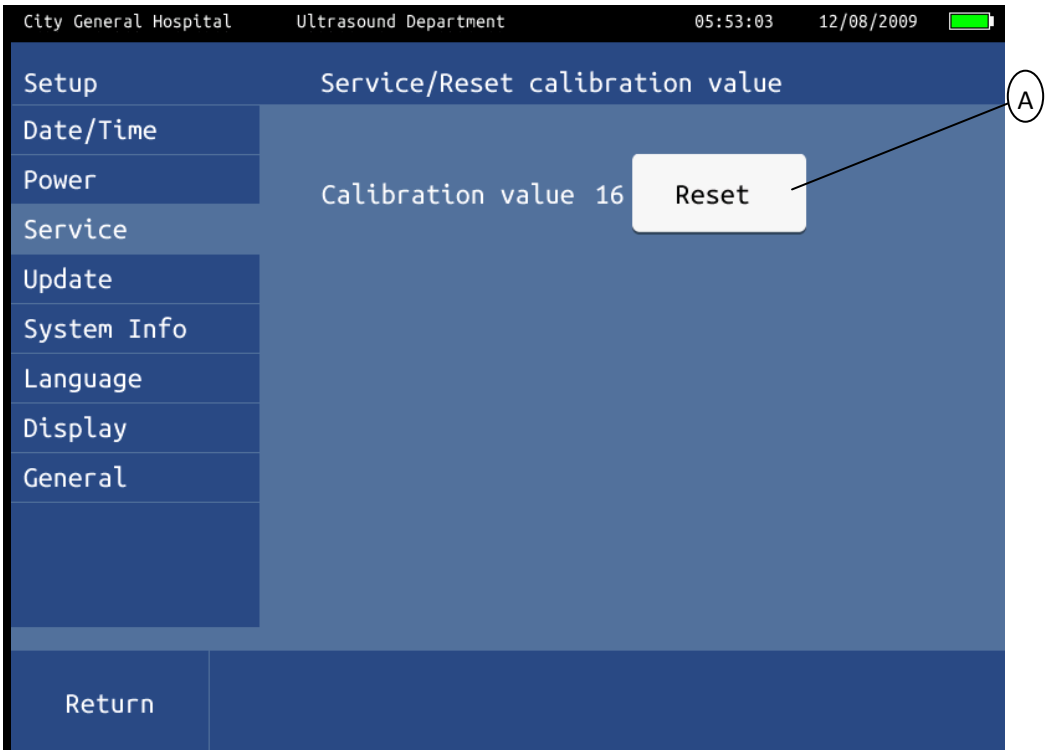


Figure 5-9-2 PadScan Z5 Calibration Value Reset Interface

A: Calibration reset key

5.9.3 System Reset

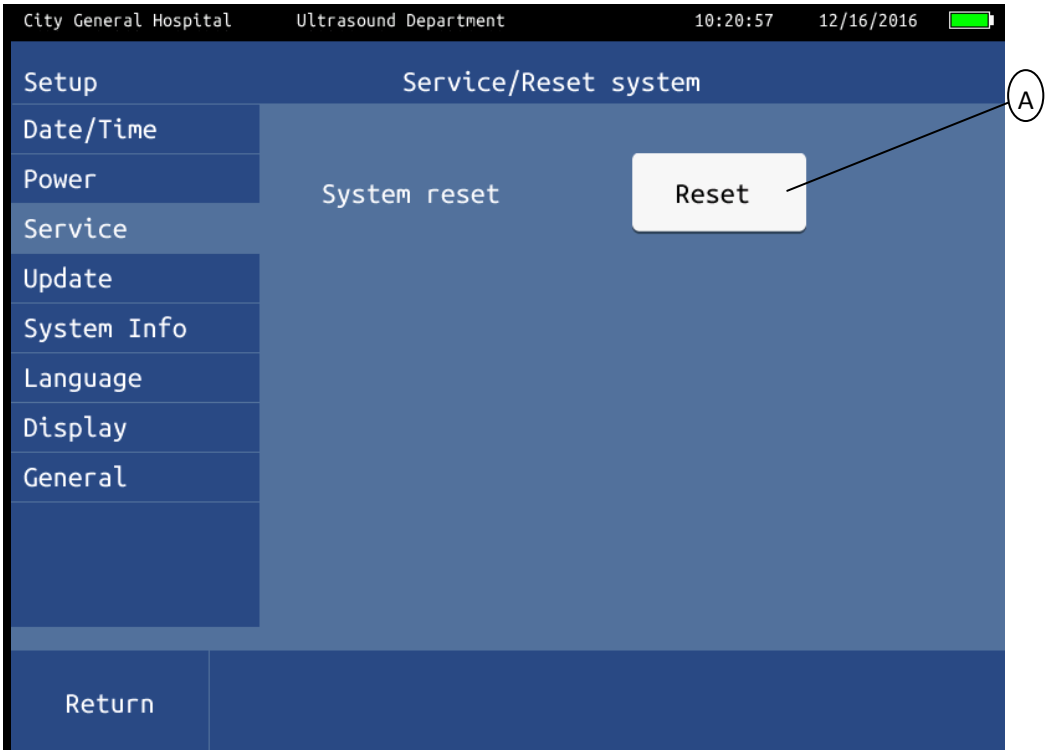


Figure 5-9-3 PadScan Z5 System Reset Interface

A: System reset key

5.10 Firmware Upgrade

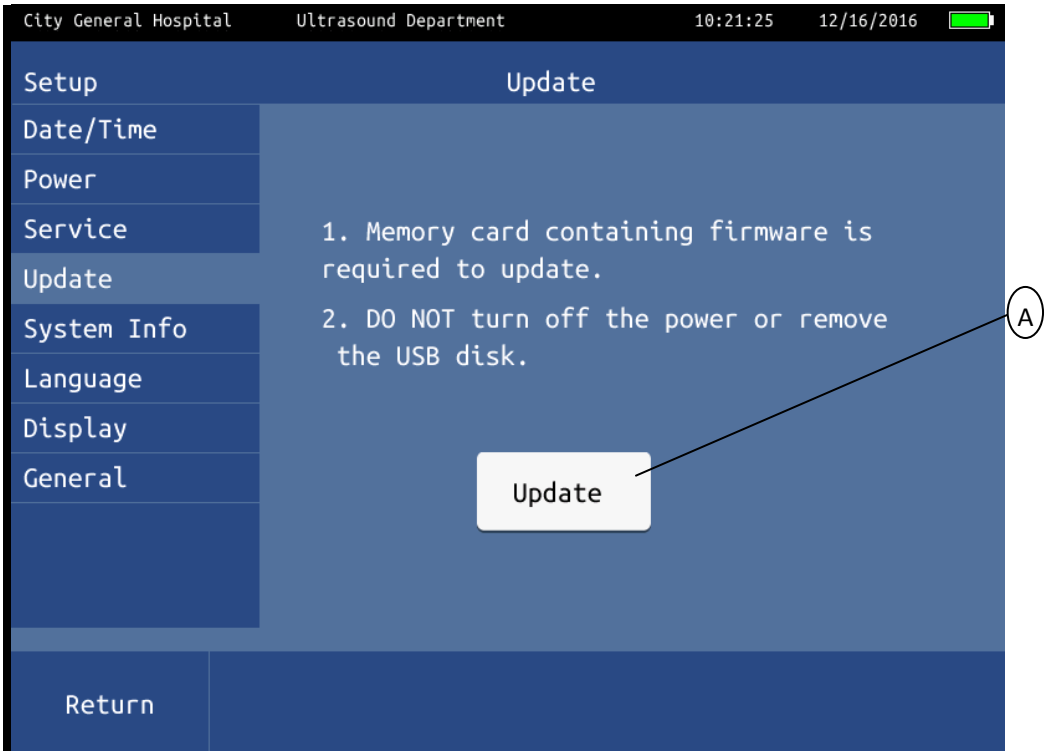


Figure 5-10 PadScan Z5 Firmware Update Interface

A: Update key

5.11 System Information

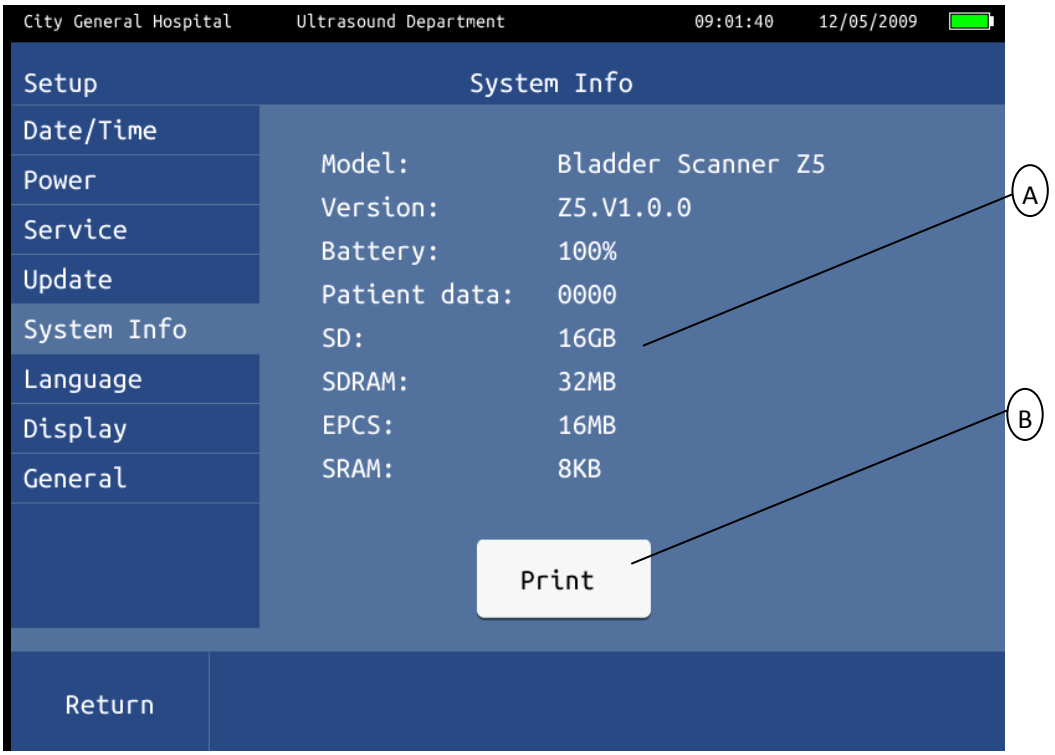


Figure 5-11 PadScan Z5 System Information Interface

A: System information B: System information print

5.12 Language Selection

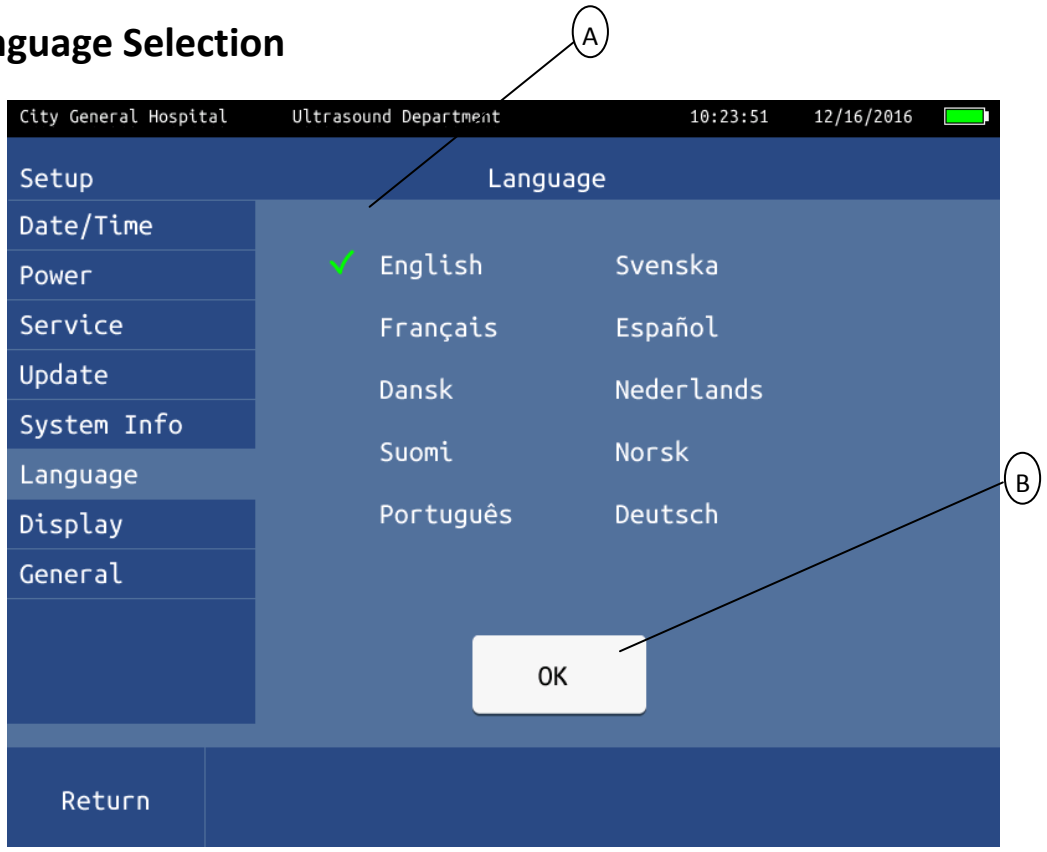


Figure 5-12 PadScan Z5 Language Selection Interface

A: Current language selection marks B: OK

5.13 Display Mode Setup

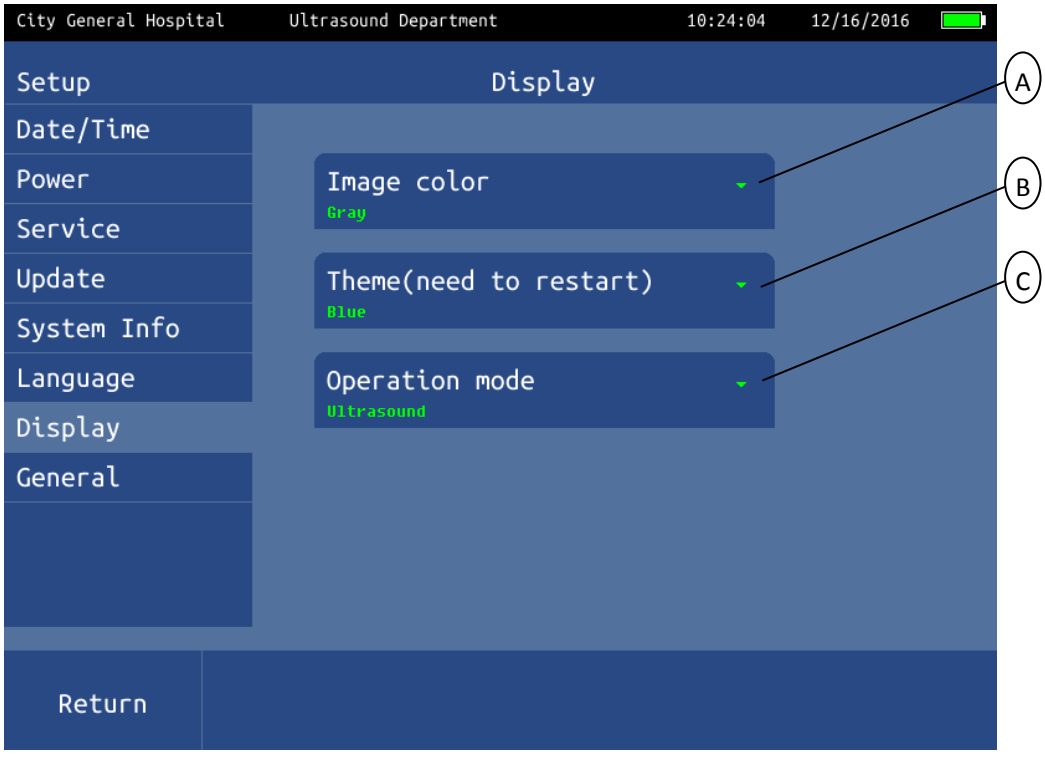


Figure 5-13 PadScan Z5 Display Mode Setup Interface

A: Image color setup

B: Display style setup

C: Operation mode setup

5.13.1 Image Color Setup

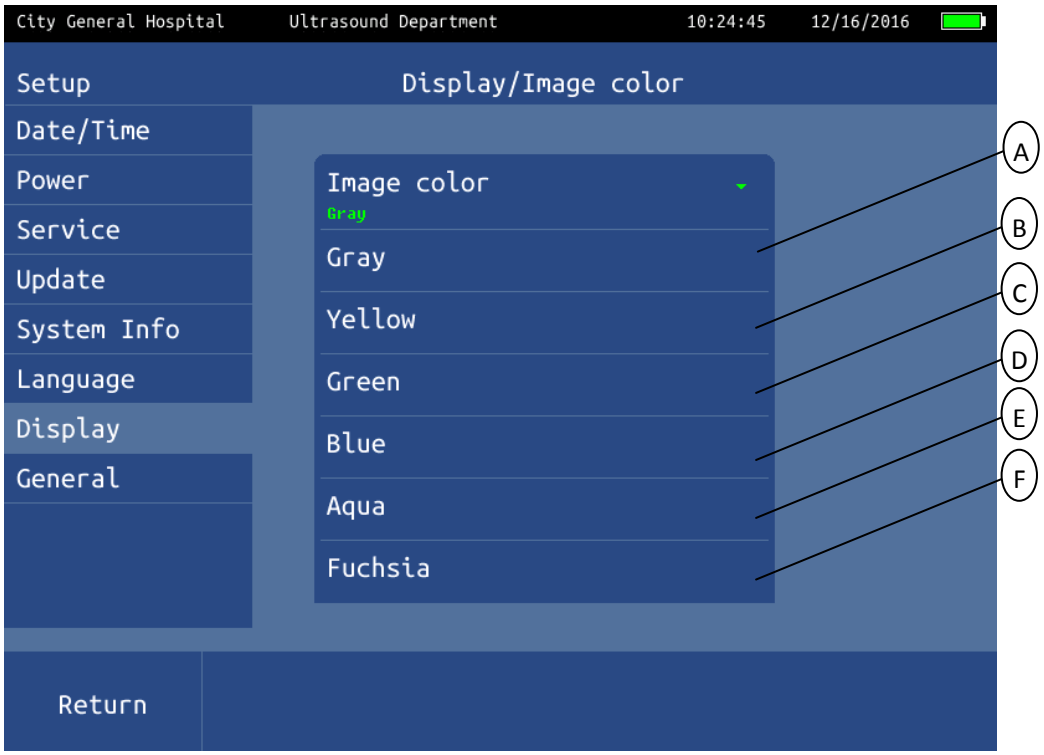


Figure 5-13-1 PadScan Z5 Image Color Setup Interface

A: Gray

B: Yellow

C: Green

D: Blue

E: Aqua

F: Fuchsia

5.13.2 Display Style Setup

Figure 5-13-2 PadScan Z5 Display Style Setup Interface

A: Sets the interface theme to blue B: Sets the interface theme to green

5.13.3 Operation Mode Setup

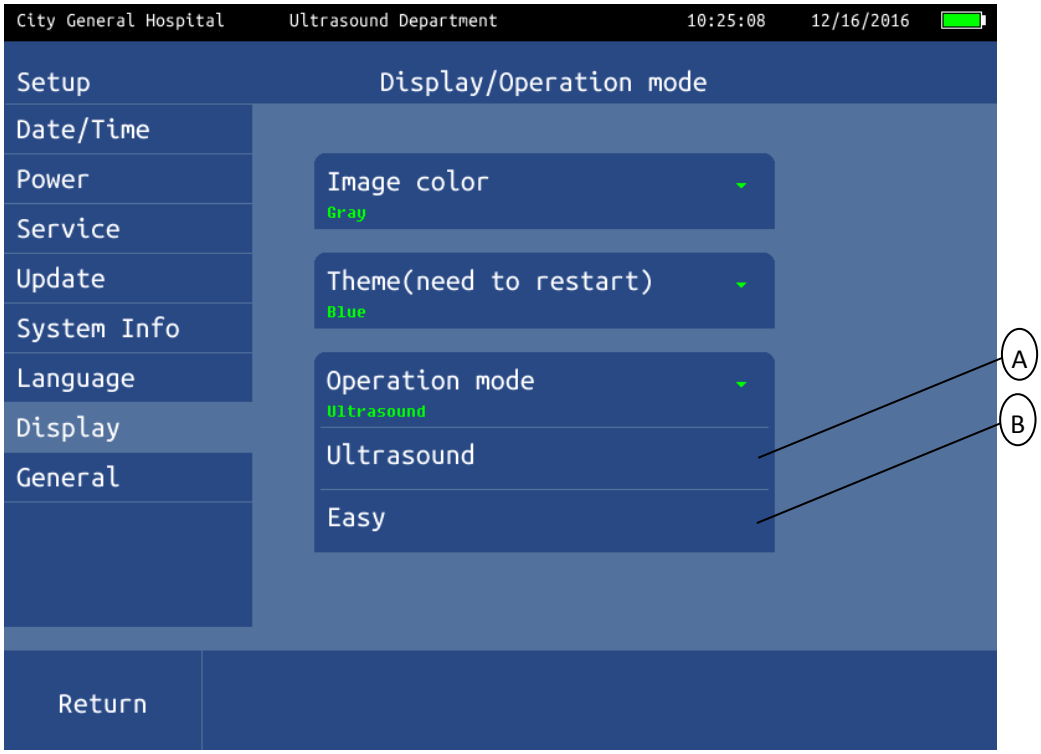


Figure 5-13-3 PadScan Z5 Operation Mode Setup Interface

A: Ultrasound mode B: Easy mode

5.14 General Setup

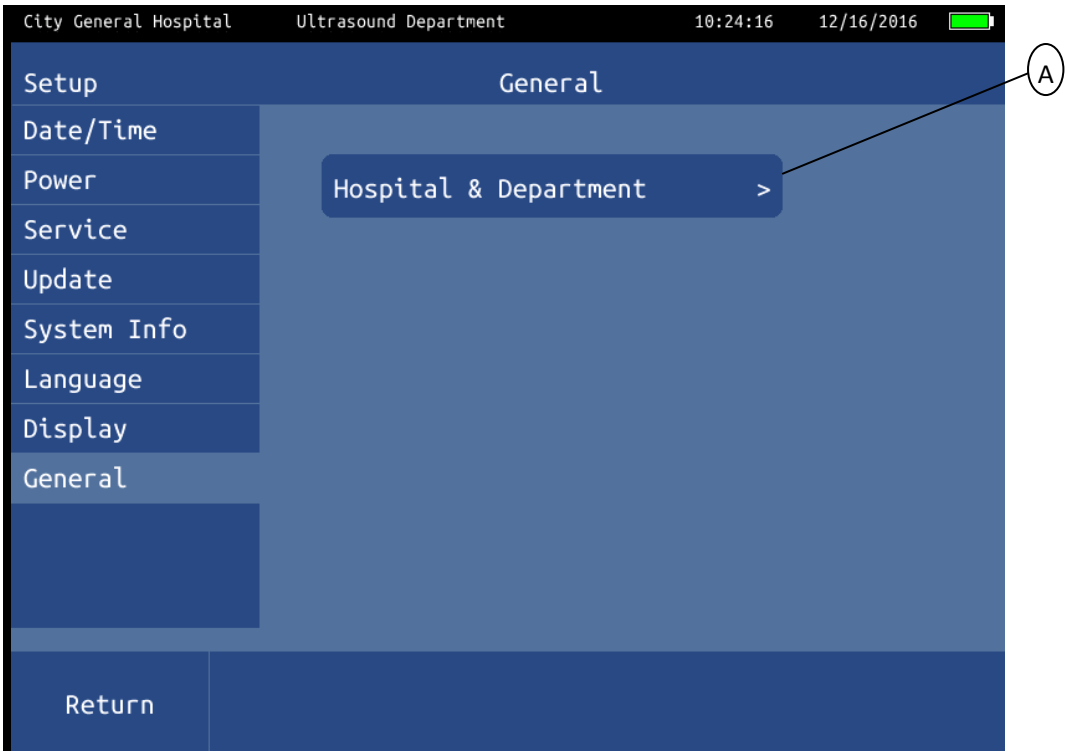


Figure 5-14 PadScan Z5 General Setup Interface

A: Hospital and department names setup

5.14.1 Hospital and Department Names Input

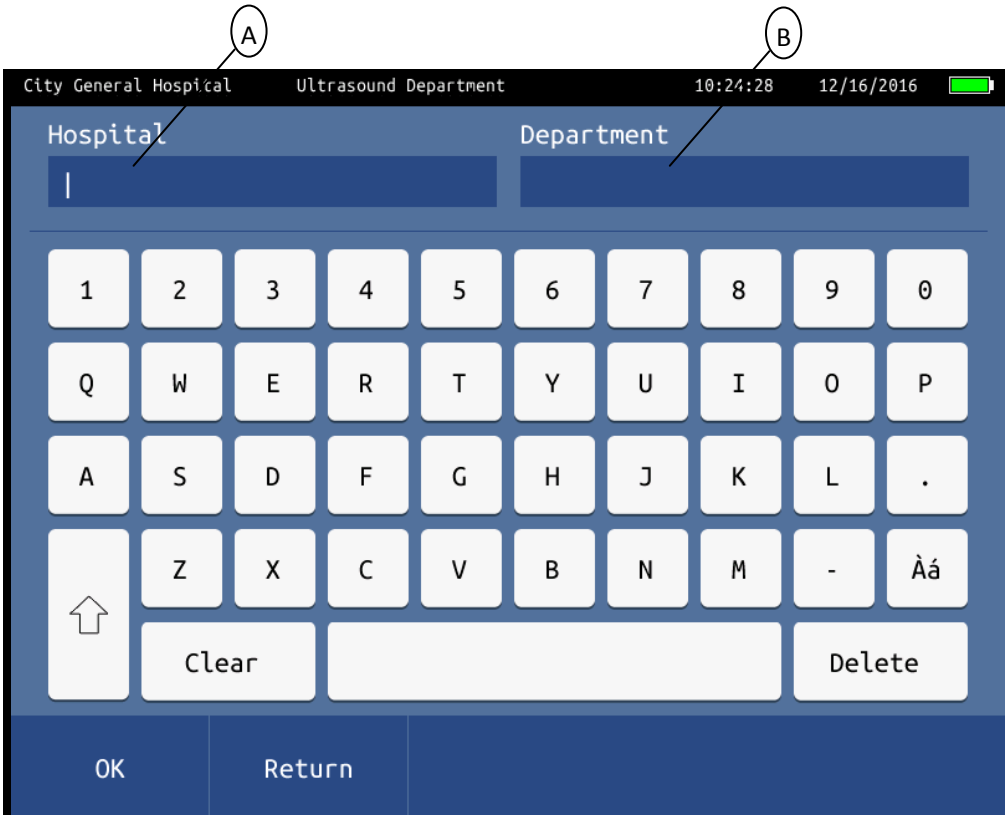


Figure 5-14-1 PadScan Z5 Hospital and Department Names Setup Interface

A: Hospital name B: Department name

Chapter Six Operation Procedure

6.1 Bladder Scanning

6.1.1 Gender Selection

Power on Z5 to check if the system enters into the initialization process. If yes, it means the encryption function works properly. The process of the system initialization includes company LOGO appears, the start-up image appears, self-examination, system status identification, configuration, start-up interface (Figure 5-1). It takes about 6 seconds before automatically enter the main interface (Figure 5-2-1). Click  to switch genders among Male  , Female  , Female with hysterectomy  , Child  and Default option is Male.

6.1.2 Bladder Pre-scan

Place the ultrasound gel on probe and the patient, and put the probe onto the patient's bladder. Press the button on the probe, and patient's bladder ultrasound images (Figure 5-4-1) or bladder section diagram with its serial number (Figure 5-4-2) will display on the screen in the real-time way to enter the pre-scan state.

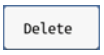
6.1.3 Bladder Scan

After locate the bladder, press the button on the probe again to start 3D probe on scanning. The bladder scanning is in progress while the sector  on the right side of the image increases clockwise. When the sector turns into  , the scanning and image analysis finish when the buzzer sounds and it enter the main interface where bladder urine volume displayed.

6.2 Image Review

After scanning, it will display the bladder urine volume automatically and 12 slices of bladder section (Figure 5-4-1). Operator can review 12 slices of bladder ultrasound images by clicking  or  .  refers that the current images is the first one.

6.3 Patient Information Input

In the main interface (Figure 5-2-1, or figure 5-2-2) click the Patient Name Box, Patient ID Box or Patient Age Box to enter the Patient Information Input interface (Figure5-3) where input the patient Name, ID, Age respectively. 30 digits (Number+ English) can be input at most in “Name Box”, 10 digits (Number+ English) in “ID Box” and 3 digits (Number) in “Age Box”. Click  to switch English into uppercase letters and click it again into lowercase ones. Click  to delete the input information. Click  to delete a character before the cursor. Click  to switch the English into European input method. Click it repeatedly to make the conversion among English and European input methods. Click  to complete the input information and return to the previous interface or  to directly return to the previous interface.

6.4 Print

Click  in the Image Review interface (Figure 5-4-1 or 5-4-2) to start on the printer where Patient Name, ID, Age, Gender, Scanning Time, Bladder Urine Volume, and two current sets of orthogonal B - ultrasound images can be printed out. Among them Name, ID and Age could be input before or after the bladder scanning.

6.5 Patient Data Save

Click  in the Image Review interface (Figure 5-4-1 or 5-4-2) to save current patient information including: Patient Name, ID, Age, Gender, Scanning time , Bladder Urine Volume and 6 Sets of Bladder B - ultrasound Images. Among them, Name, ID and Age could be input before or after bladder scanning.

Note: The current patient information will be saved into the U disk if it is inserted or into Z5 directly if the U disk is not inserted. In the event that patient information is saved in U disk, click  to save the information into Z5 after U disk is removed. All data stored in U disk could be viewed under the SAVE file.

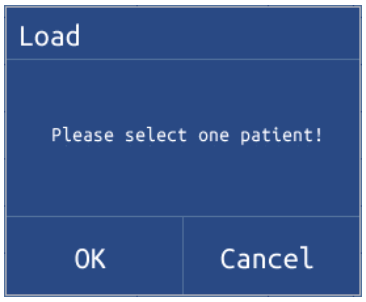
6.6 Patient Information Review

Click Review in the Image Review interface (Figure 5-4-1 or 5-4-2) to enter the Patient Information Review interface (Figure 5-4) where all the saved patient data is listed. Click one data when ✓ on the left side means it's been selected. Click ← or → to review patient information listed in the previous or next page. The maximum storage of Z5 is 1000 cases.

6.6.1 Patient Data Load

Click Load after selecting one patient case to load the current patient data and ultrasound bladder images into the main interface.

Note: if select two or more patient cases and click Load, a dialog of "Please select one patient!" will appear shown as the right figure.

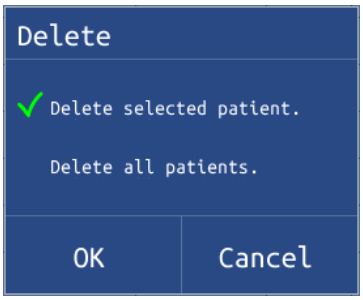


6.6.2 Patient Data Export

Insert the U disk and click Export when the dialog box will appear shown as the right figure. Select "1.Export selected patient." and click OK, to export the selected patient data to the U-disk; Select"2.Export all patients."and click OK to export all the patient data that saved in Z5 to the U disk. The exported data can be reviewed in a folder named after the date. If there is no U disk inserted, it will reminds that "Please insert U disk!"

6.6.3 Patient Data Deletion

Click Delete and the dialog box shown as the right figure will appear. Select "Delete selected patient" and click OK to delete the current selected patient data; or select "Delete all patients" and click OK to delete all the patient data saved in Z5. Deletion is irretrievable so please make sure all the patient data are saved before deleted.

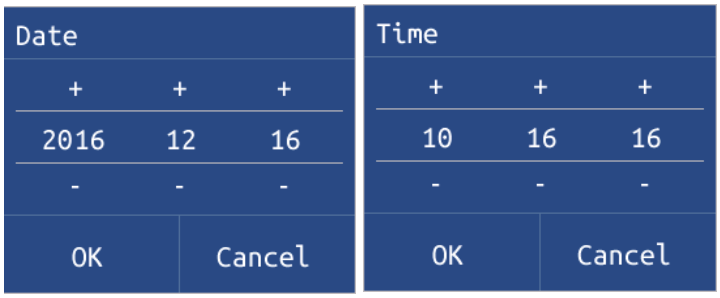


6.7 System Setup

click Setup In the main interface (Figure 5-2-1 or 5-2-2) and enter the System Setup interface (Figure 5-6) where Time and Date, Power management, Service function, Firmware update, System information, Language selection, Display mode and General mode setting are available.

6.7.1 Time and Date Setup

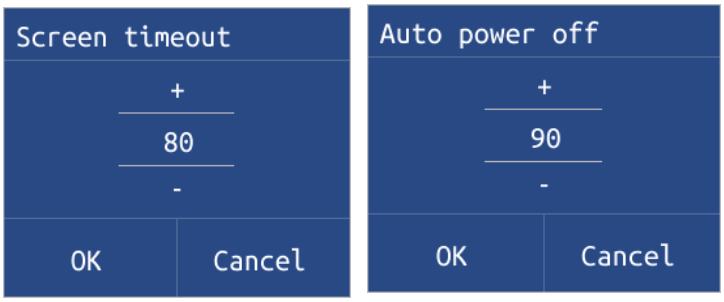
Click “Date/Time” on the left side of the System Setup interface to to enter the Date/Time Setup interface (Figure 5-7) where two options are available：Set date and Set time to set up time and date respectively. Specific steps are as follows: click “Set date” and the dialog box shown as the right figure appears where click + , - to adjust the Year, Month and Day respectively; Click OK to save it and then return to the previous interface or click Cancel to cancel the operation and return to the previous interface.



Click “Set time” and the dialog box shown as above appears where click + , - to adjust Hour, Minute and Second; Click OK to save it and then return to the previous interface or click Cancel to cancel the operation and return to the previous interface.

6.7.2 Power Management

Click “Power” on the left side of the System Setup interface to enter the Power Management interface (Figure 5-8) where two options are available: Screen timeout and Auto power off. Specific steps are as followed: click “Screen timeout” and the dialog box shown as the right figure appears where click + 、 - to adjust the timeout time; Click OK to save it and then return to the previous interface or click Cancel to cancel the current operation and return to the previous interface.



Click “Auto power off” and the dialog box shown as below appears where click + 、 - to adjust the power off time; Click OK to save it and then return to the previous interface or click Cancel to

cancel the current operation and return to the previous interface.

6.7.3 Service

Click "Service " on the left side of the System Setup interface to enter the Service interface (Figure 5-9) where three function interfaces are available : Mode Selection interface, Calibration Value Resetting interface, System Resetting interface. Input the password in this password box and click OK to enter the corresponding function interface for setup.

6.7.3.1 Mode Selection

Input the six-digit password “000000” in the input box of the Service interface，click OK to enter the Mode Selection interface (Figure 5-9-1) where three options available:：Synchronization mark、USB mode and Calibration.

Click Clear behind “Syn mark ” to delete the synchronization mark of patient data. Note： After synchronization of PC and Z5 (all the patient information stored in Z5 have been uploaded to PC), Z5 will mark the patient data that are synchronized. When the patient data increases, only unmarked patient data will be synchronized in PC, instead of all the patient data. If the synchronized patient data has been deleted by accident, clear the synchronization in Z5 to make all patient information synchronized once again.

The Udisk following “USB mode” means to set U-disk mode for USB connection. Enter the Patient Data Review interface and insert the U-disk to save or load patient data to U-disk. Click Udisk to turn it into “PC”，which means the U-disk mode is changed into PC mode for USB connection. Enter the Patient Data Review interface (Figure 5-5), connect with the USB cable, and click the “PC” in the PC Mode Selection interface to upload all the patient data to PC. Repeatedly click this key for mode conversion between U-disk and PC.

Click Enter following the “Calibration” to enter the Device Calibration interface.

6.7.3.1.1 Device Calibration

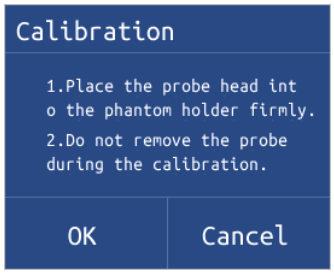
Please be kindly noted, AvantSonic PadScan Z5 has no need to be calibrated for its entire using life due to the patented technologies we have in ultrasound imaging and measurement algorithm. Regarding this, we hereby officially specify:

Within its entire using life, PadScan Bladder Scanner Z5 under the intact condition:

1. **The operators do not need to do the calibration for clinical measuring accuracy before Z5 is used on patients in the first place.**
2. **The operators do not need to do the calibration for clinical measuring accuracy during their daily work.**
3. **The operators do not need to do the calibration for clinical measuring accuracy if Z5 is changed with another probe.**

The Calibration, whether written in our User Manual or set as one of practical functions, is only for the purpose of meeting the requirements of hospital bidding or designated procedure by some end-user customers. If it's required, please follow the next steps where please be kindly noted, Dansk 616 is the only designated phantom model to comply.

Click Enter in the mode selection interface to enter the device calibration interface (Figure 5-9-1-1) where the device is calibrated. The operation steps are as follows: put the probe onto the specific phantom and click Calibrate Dialogue box as the right one appears, showing: 1, place the probe head into the phantom holder firmly, 2 do not remove the probe during the calibration. Click OK to make calibration. After the calibration is completed, it will prompt whether the device calibration is successful or not. If not, adjust the probe and phantom and calibrate the device again until it successes. "_" in the "V=_ml" shows the current phantom value. The device has been calibrated before ex-factory and is not required to be calibrated again.



6.7.3.2 Calibration Value Resetting

Enter the password"410011" in the input box in the Service interface and click OK to enter the interface of calibration value resetting (Figure 5-9-2). Click Reset to reset the calibration value of this device as its default.

6.7.3.3 System Resetting

Enter the password"947010" in the input box in the Service interface and click OK to enter the interface of system resetting (Figure 5-9-3). Click Reset to reset the system, which will come to be the default after you restart Z5 again.

6.7.4 Firmware Upgrade

Click the “Update” in the left side of the interface of the system resetting to enter the interface of the firmware upgrade (Figure 5-10), insert the USB disk with the firmware for upgrading into the main unit and Update to update the device. Do not shut down the device or pull out the USB disk in the process of upgrading. There will be the dialogue box of “no firmware file” if the USB disk isn’t inserted or there is no upgrading firmware in USB disk; If it is upgraded successfully, the dialogue box of “upgrade succeed” will display on the screen and it is advised to restart Z5 to complete the upgrade; If it is failed to upgrade, the dialogue box of “upgrade failed” will display on the screen. Do not shut down the power and upgrade it again until it succeeds.

6.7.5 System Information

Click “System Info” on the left side of the System Setup interface to enter the system information interface (Figure 5-11) which shows the system information about Z5 including device model, the current software version, current battery level, patient ID, SD card storage capacity, SDRAM storage capacity, EPCS capacity and SRAM capacity. Click Print to print out the current system information.

6.7.6 Language

Click the Language in the left side of System Setup interface to enter the language selection interface (Figure 5-12). 10 languages are available in this device, including: English, Danish, Dutch, Finnish, French, German, Norwegian, Portuguese, Spanish and Swedish. English is the default option. Click OK to confirm it.

6.7.7 Display Mode Setup

Click the Display in the left side of System Setting interface to enter the display mode setting interface (Figure 5-13). There are three options in this interface: Image color、Theme(need to restart) and Operation mode.

Click “Image Color” to enter the interface of image color setting (Figure 5-13-1) where “Gray”, ”Yellow”, ”Green”, ”Blue”, ”Aqua” and “Fuchsia” are available. The bladder ultrasound images when scanned and reviewed will be displayed in the color as you chose.

Click the “Theme(need to restart)” to enter the interface of the interface display setting(Figure 5-13-2)

where “Blue” and “Green” are available. The interface theme will be displayed in blue after you choose “Blue” and restart Z5 or in green when you choose “Green”.

Click the “Operation mode” to enter the interface of operation mode setting (Figure 5-13-3) where “Ultrasound” and “Easy” are available. The patient’s bladder B-ultrasound images will be displayed on the screen in a real-time way if you select “Ultrasound” mode for scanning the bladder (Figure 5-4-1)or the patient’s bladder section diagram will be displayed on the screen if you select “Easy” (Figure 5-4-2)

6.7.8 General Setup

Click the “General” in the left side of the System Setup interface to enter the interface of General Setting (Figure 5-14). Then click the “Hospital & Department” to enter the interface of the hospital and department name input (Figure 5-14-1) where 30-digit hospital name is allowed in the input box of the hospital while 20-digit department name is allowed in the input box of department. Click the OK to confirm the input or Return to cancel the input and return to the last interface.

6.8 PC Transmission

PC transmission has two methods: wired and wireless transmission, both of which require to install the USB driver to the PC firstly by opening the software of CH372DRV.EXE under the EXE Catalog/Chip Driver Installation/PC. The driver is automatically installed in 12 seconds. (Notice: it’s installed once for all)

Wired transmission is operated as follows: click the Udisk in Z5 Mode Setup interface (Figure 5-9-1) to turn it into “PC”, and then enter the interface of Patient Information Review (Figure 5-5). Insert one end of USB cable into the PC/USB port and the other end into Z5. Open the PC software of PatientManager.exe where click the PC in the PC Mode Setup interface to log in and then click Sync Data to synchronize the data with the USB cable connected. Since the synchronization is completed, all patient information in Z5 will be uploaded to the PC.

Wireless transmission is operated as follows: click the Review in the Bladder Scan interface (Figure 5-4-1 or Figure 5-4-2) to enter the interface of Patient Information Review (Figure 5-5). Open the PC software of PatientManager.exe where click the Bluetooth in the PC Mode Setup interface to search for accessible Bluetooth device (Notice: Z5 must has the Bluetooth module function firstly) , connect with Z5 successfully,

and then log in to upload all patient information in Z5 to the PC through wireless transmission by clicking Sync Data.

6.8.1 Main Interface

Z5 setup comes firstly: click the 

in Z5 Mode Setup interface (Figure 5-9-1) to turn it into “PC”, which refers to the wired transmission to PC. Wireless transmission is allowed only if Z5 has the Bluetooth module function. Enter the interface of Z5 Patient Information Review. (Figure 5-5)

Then PC setup follows: open the PC software of PatientManager.exe to display the PC Mode Setup interface where PC and Bluetooth are available. In PC connection mode (that is wired transmission to PC), click the PC and connect it with USB cable. Or click the Bluetooth to select the wireless transmission with PC, search for the accessible Bluetooth device (Notice: Z5 must has the Bluetooth module function firstly) and connect with Z5 successfully. Since the connection is completed, it automatically enters the PC main interface (Figure 6-1) which displays: 4 Items, PC information, Company Logo, Patient Information and 12 ultrasound bladder images. 4 items include: Sync Data, Print, Save to PDF and Option. Patient information includes patient ID, name, age, gender; scan time and bladder urinary volume. 12 ultrasound images are shown in image display area by selecting one of patient information. Default display is the first 6 images and the second 6 images are shown by clicking the slider under the image display area

The main interface of the PC as Figure 6-1：

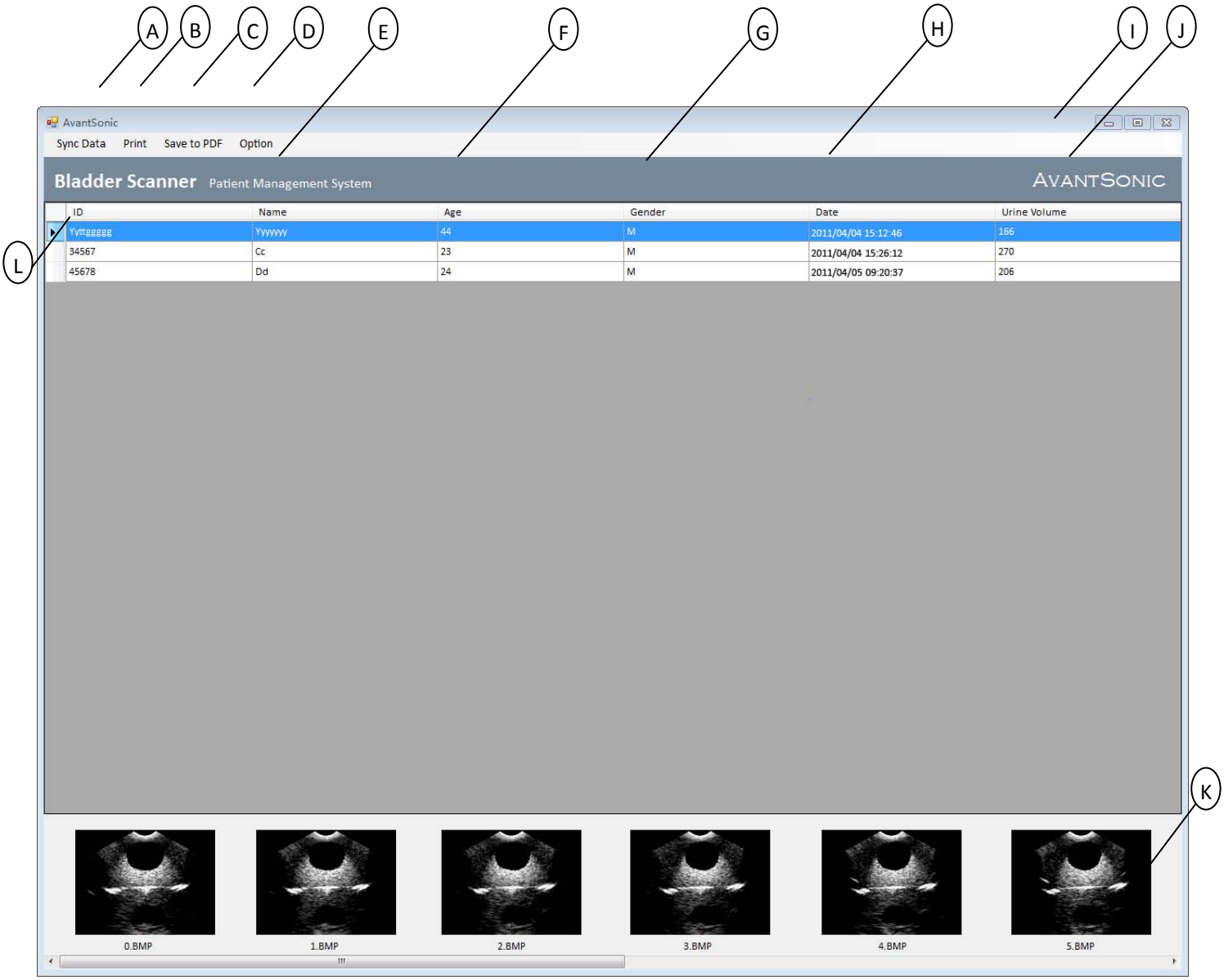


Figure 6-1 Main Interface of the PC of PadScan Z5

A: Sync data

B: Print

C: Save to PDF

D: Option

E: Patient name

F: Patient age

G: Patient gender

H: Date

I: Company LOGO

J: Urine volume

K: Bladder images display

L: Patient ID

6.8.2 Data Synchronization

According to Section “6.8.1 Interface, there are two method to enter the main interface of the PC: select the wire transmission method by clicking PC key and connect with USB cable; select the wireless transmission

method by clicking Bluetooth key, search for the accessible Bluetooth device (Notice: Z5 must has the Bluetooth module function firstly) and connect it with Z5. When it connects successfully, it automatically enters the main interface of the PC.

Click the Sync Data in main interface of the PC and dialogue box of Sync Data appears, showing: Synchronizing... Please wait!, which indicates the unsynchronized patient information in Review interface in Z5 is being synchronized to the PC. When the dialogue box disappears, Synchronize successfully! is shown in the interface, which indicates the synchronization is completed. If there is no unsynchronized patient information in Review interface in Z5, No new data! is shown in the interface; If the connection of Bluetooth and Z5 fails, Open device failed! is shown in the interface.

6.8.3 Option

Click the Option in the main interface of PC, the dialogue box of Option appears (Figure 6-2) and information could be put in and saved by clicking Save key or canceled by clicking Cancel key. All saved information could be reviewed in Patient Manager /option.ini

Option interface in the PC seen as Figure 6-2：

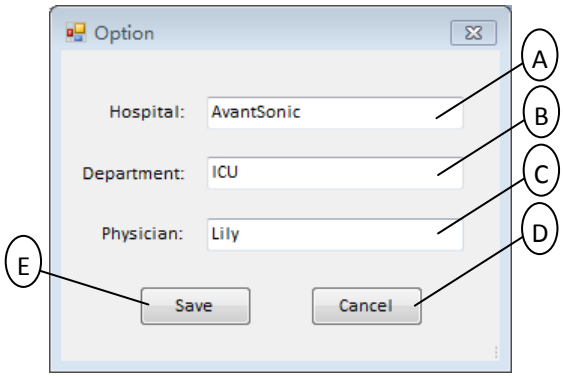


Figure 6-2 Option Interface In the PC of PadScan Z5

A: Hospital name input box

B: Department name input box

C: Physician name input box

D: Cancel key

E: Save key

6.8.4 Print

Click the Print in the main interface of PC, the Print interface appears, which includes：6 or 12 images selection box, print key, hospital name, department name, patient information and bladder ultrasound images. Click 6 or 12 images selection box and select 6 Images, 6 bladder ultrasound images will display in the print interface (Figure 6-3). Click Print key (6 or 12 images selection box, print key and X key will not be

printed); Select 12 Images and 12 bladder ultrasound images will display in the print interface (Figure 6-4),Click Print key(same as above). The names of hospital and department are inputted and saved in Option interface while patient information and bladder ultrasound images are displayed in the main interface of PC The patient information could be reviewed in Patient Manager /Printinfo.ini

The interface of PC (6 images) Figured as Image 6-3:

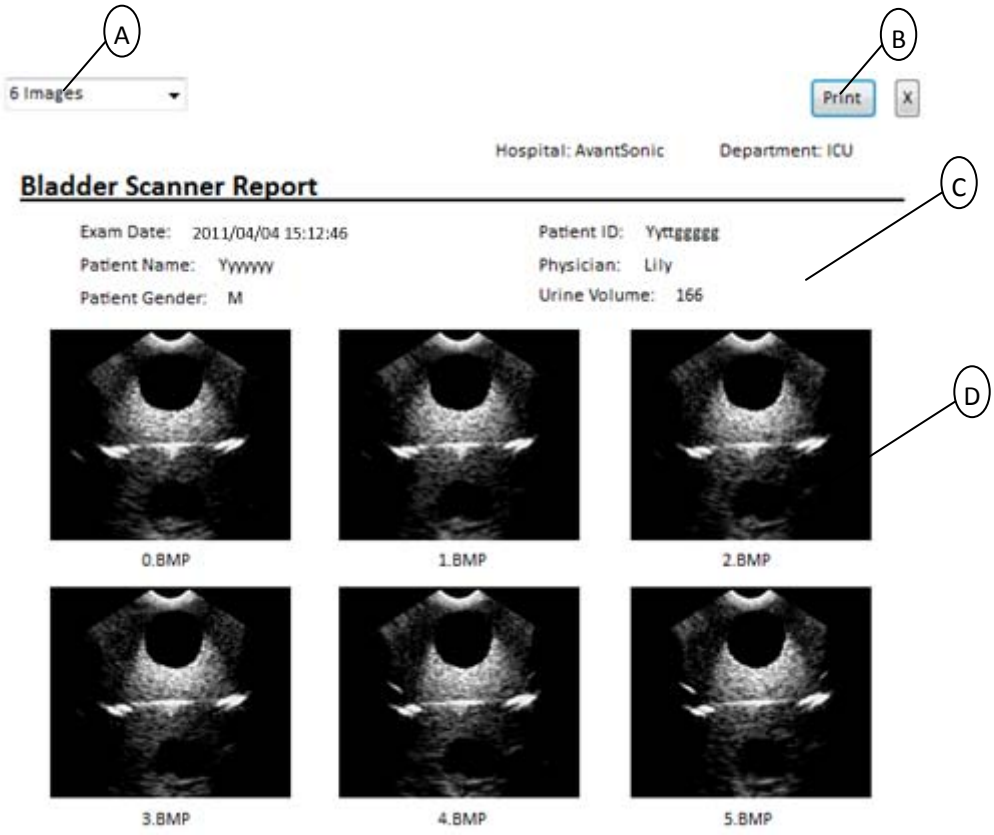


Figure 6-3 Interface of the PC of PadScan Z5 (6 images)

A: Selection box of 6 or 12 images displayed

B: Print button

C: Patient information

D: 6 bladder ultrasound images

The interface of PC (6 images) Figured as Image 6-4:

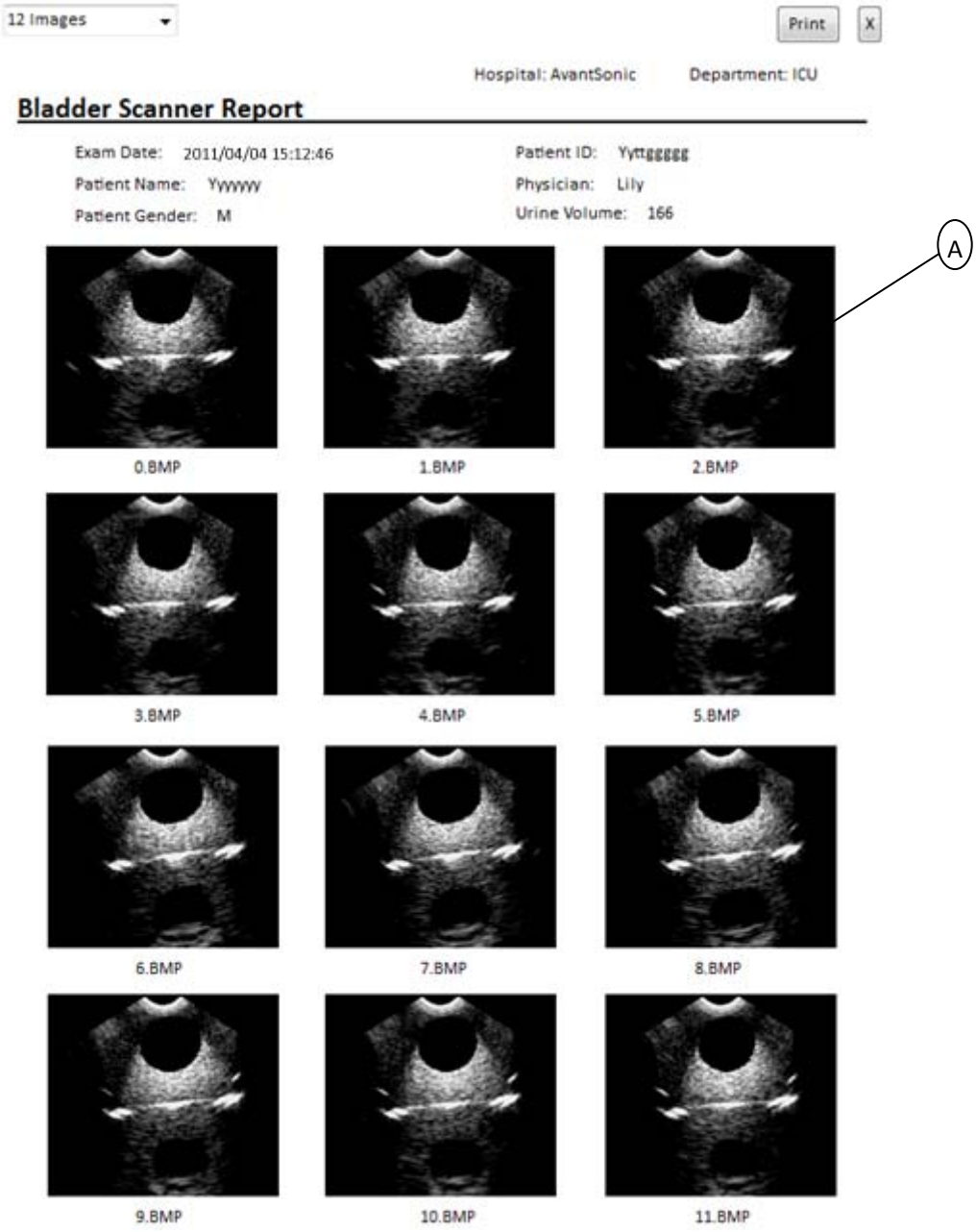


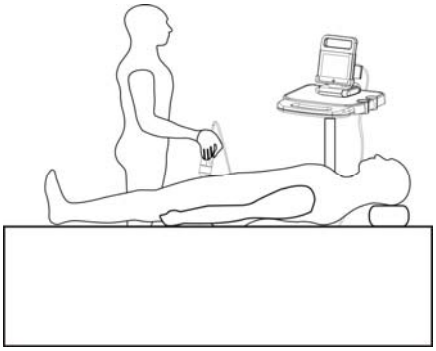
Figure 6-4 Interface of the PC of PadScan Z5 (12 images)

A: 12 bladder ultrasound images

6.8.5 Save to PDF

Click the Save to PDF in the main interface in PC, and the dialogue box of Save to PDF appears, which includes File Save Path, File Name and File Save Type. PDF（*.pdf）is the only type available in File Save Type. It is convenient to store up and review the patient information and images when files are saved as PDF. The information saved as PDF is the same with what printed out (12 images).

6.9 Scan and Bladder Location



Locating the bladder precisely is the basis of accurately measuring the bladder volume. Bladder is beneath the connection of abdomen and pubic bone, shown as the right image. Before scan, place an ample quantity of ultrasound gel on the patient's abdomen, approximately 3cm above the pubic bone, and locate the probe shown as the image. Make sure the probe button face up towards the patient's head.

In order to correctly measure the volume of the bladder, grasp the probe as right image shown.

To make sure user could quickly locate the bladder, there appears a green line in the center of image when pre-scan and scan in expert mode, and user should move the probe to make the bladder image to the center (Green outline indicates the image is centered, while the yellow outline indicates the image deviates from the center) and make sure the bladder section area is the biggest. In easy mode, user should move the center of bladder section to the center of the circle. (Green bladder section indicates the image is centered, while the yellow section indicates the image deviates from the center) and make sure the bladder section area is the biggest.

After scan, green projection will display in the main interface (Figure 5-2-1 or Figure 5-2-2) The scan result counts as long as the center of green projection doesn't deviate from the center of cross-hair circle

Chapter Seven Clean and Maintenance

Components, accessories and probe should be cleaned and maintained regularly to make sure the machine works on well. The mild detergent is recommended for the purpose of cleaning.

7.1 System Cleaning and Maintenance

7.1.1 System Cleaning

- Turn OFF the system power.
- Unplug the power supply from the system.
- Use a mild detergent to clean the device's surface including keyboard.
- Wipe time should follow the instructions of detergent and the wipe intervals should meet the clinical standard.
- If you use a detergent solution to clean the instrument, remove all residual detergent. Let air dry or use a clean soft cloth to wipe dry.
- Use a mild detergent to wipe off the fingerprints or other smears on the screen in case of scratch against the screen.

7.1.2 System Maintenance

- System should be operated under the condition stipulated in "1.5".
- System should not be shut down and opened up too frequently. After shut down, wait five minutes before restarting the system.
- When the device is not used for a long time, pack up the device as ex-work standard and store it in the environment outlined in "8.1".

7.2 Probe Cleaning and Maintenance

Keep the probe clean for its function and long service life.

7.2.1 Cleaning and Disinfect the Probe

- Check the probe and other cables for signs of damage, such as cracking and/or leaking. If any sign of damage appears, stop using the probe and contact Avantsonic Technology Co., Ltd.
- Use a soft cloth dampened with isopropyl alcohol to wipe the Probe.

7.2.2 Probe Maintenance

Prevent the probe surface from being scratched

- Do not crash or drop the probe.
- Use only domestically recognized medical ultrasound gel on the probe and patient. Improper gel would damage the probe and stimulate the skin of patient.
- Always clean the probe after it's used

7.3 Battery Use and Maintenance

- For optimum performance, it is recommended to charge and completely discharge a new battery two to three times before first use.
- Battery could be charged and discharged for hundreds of times. When the service time of battery gets shorter than usual, battery should be changed immediately.
- Always keep battery away from fire.
- Prevent the battery from being short circuit, dampened, disassembled, dropped or crashed.
- The battery should be charged and completely discharged once every two to three months in case of malfunction. Notice: full-power battery will discharge slowly on its own if it's not used for a long time, therefore, charge the battery after long time shelving before use it
- Stop using the battery immediately once the battery becomes deformed or discolored, or gets heat or smell when used, pull it out of the device or battery charger, and dispose it in accordance with the requirement of waste battery.

7.4 Disposal of Electronic Waste

Waste products and battery should be disposed in accordance with the local laws and regulations in environment protection. Or contact our After-sales Service Department.

Chapter Eight Transportation and Storage

8.1 Attention when Transporting the System

（1） Unplug the power cord and put it in the carrying case.

（2） Place the main unit into the corresponding slot of the carrying case carefully. Do not drop, shake or crash the probe or device

（3） The device should be transported after the carry case is closed.

（4） Unplug the probe from the main unit in case of its cord abrading against the ground and carefully place it into the corresponding slot of the carrying case.

（5） Keep the bottle of ultrasound gel closed tightly in case of gel leak and carefully place it into the corresponding slot of the carrying case.

8.2 Transportation and Storage Conditions

Temperature：-40℃～+55℃

Relative humidity：10％～80％

Pressure：50kpa～106kpa

8.3 System Transportation

The labeling of the device packaging fulfills the requirement of GB191”Packaging-Pictorial marking for handing”Simple shockproof materials are equipped with the carrying case, which are suitable for aviation, railway, highway, or steamship transportation. Keep dry, avoid inversion and collision.

8.4 System Storage

- System should be unpacked when storage time exceeds six months. Power it on for four hours, and then re-pack it. Do not place any objects on the package, and do not place it against floors, walls, or roof.
- Keep it in a well-ventilated area away from sunlight or caustic gases.

Chapter Nine Inspecting and Troubleshooting

9.1 Inspecting

● Check if the power supply is functioning properly, and if the power cord of the main unit is connected and plugged into the power adapter.

- Check if the probe and main unit are connected in the correct way.

9.2 Troubleshooting

No.	Symptom	Troubleshooting Method
1	When power button is pressed, the indicator does not turn on and there is no signal on the screen visible.	1. Check the power supply； 2. Check the power cord and its plug； 3. Check if the power adapter is functioning
2	Snow flake-shaped or mesh-shaped interference images appear on the screen.	1. Check if the power supply is interfered by other devices； 2. Check if the environment such as electromagnetic field interferes with the device； 3. Check if the power, probe's plug and the sockets are connected well.

9.3 FCC Statement

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

Any 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.

FCC RF Exposure Information and Statement

The devices has been tested and meet applicable limits for Radio Frequency(RF) exposure. This equipment complies with FCC radiation exposure requirement.The devised can be use in portable exposure condition without RF restriction.Or equivalent meaning.

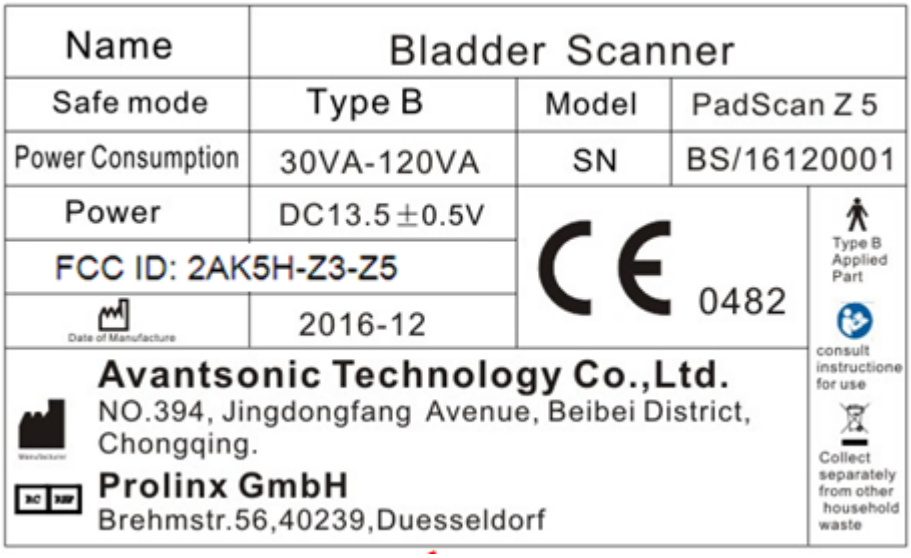
9.4 If problems continue, please contact Avantsonic Technology Co., Ltd.

9.5 Repair

- The device must be repaired by the departments designated by the manufacturer.
- All materials for repair, if needed, will be provided by the manufacturer.

Appendix A Labeling Graphic

Z5 Main Unit Labeling

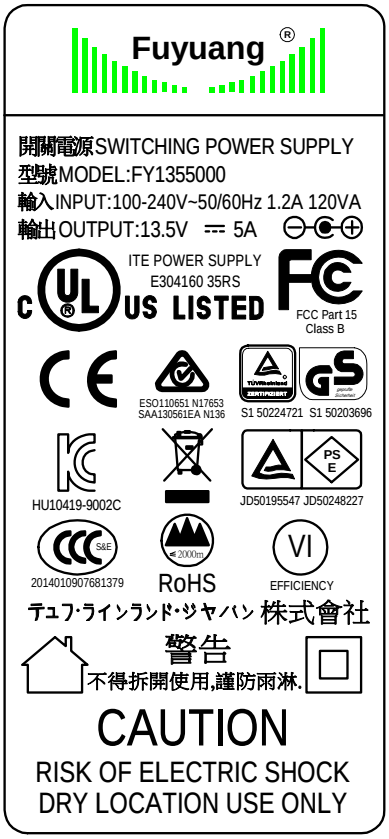


This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions: 1) this device may not cause harmful interference, and 2) this device must accept any interference received, including interference that may cause undesired operation.

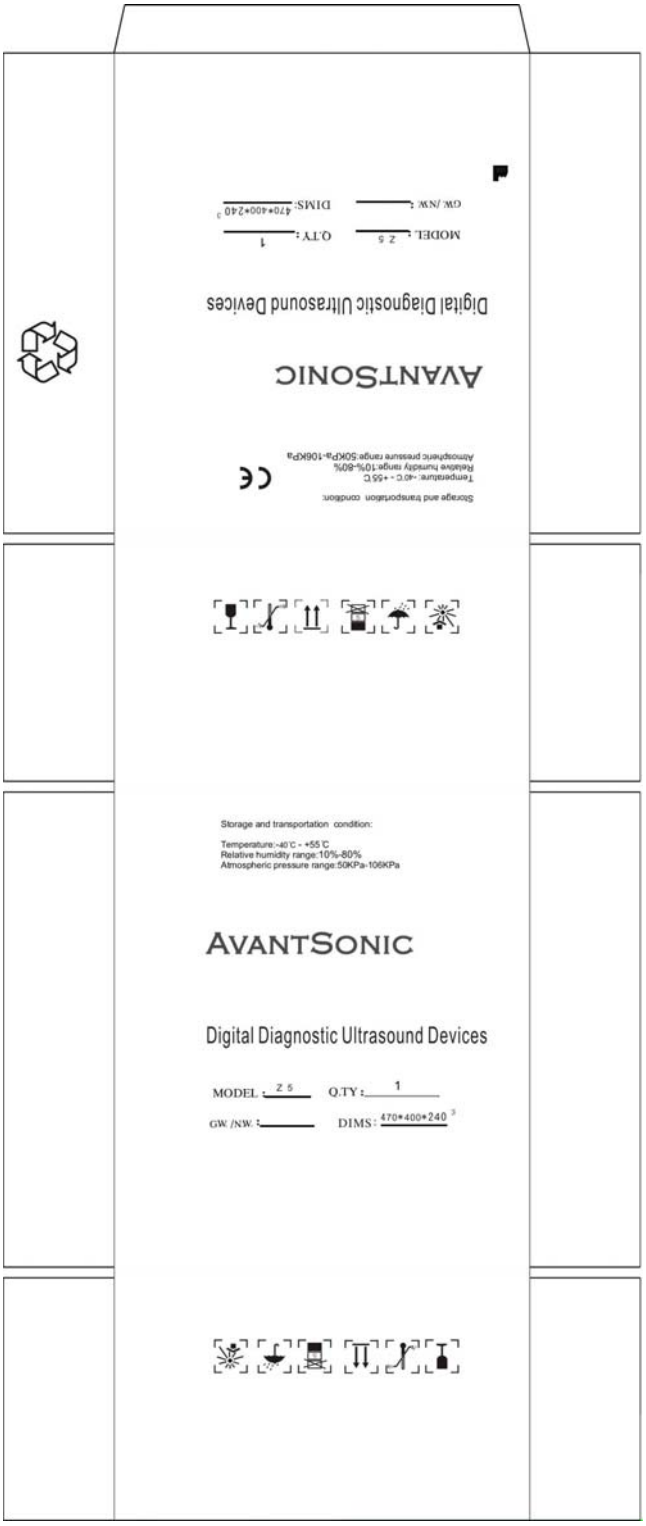
Z5 Probe Labeling

Z5 Base Labeling

Z5 Power Adapter Labeling



Z5 Packaging Box Labeling



Appendix B Acoustic Output Report

Guangzhou Medical Instruments Quality Surveillance and Inspection Center of State Food and Drug Administration

Test Report

IEC 60601-2-37			
Clause	Requirement + Test	Result - Remark	Verdict

Table 201.103 Acoustic output reporting table

B Mode

Index Label			MI	TIS			TIB	TIC
				Scan	Non-Scan		Non-Scan	
					Aaprt <= 1 cm²	Aaprt > 1 cm²		
Maximum Index Value:			0.4816	0.0192				0.0902
Associated Acoustic Parameters	Prα	(MPa)	0.7081					
	P	(mW)		2.011				1.891
	min of [Pa(Z), Ipa α(Z)]	(mW)						
	Za	(cm)						
	Zlpi	(cm)						
	Zb	(cm)						
	Z at max Ipi, α		0.65					
	deq(Zb)	(cm)						
	fawf	(MHz)	2.3872	2.3872				2.3872
	Dim of Aaprt	X (cm)		0.547				0.547
		Y (cm)		0.547				0.547
Other Information	MI	(pi)	0.6738					
	Prr	(Hz)	1250					
	Pr at max Ipi	(MPa)	0.6904					
	deq at max Ipi	(cm)						
	Ipa, out max MI	(W/cm²)	9.0458					
	Focal Length	FLx (cm)						
		FLy (cm)						
Operating Control Conditions	Depth	(cm)	--	--				--
	Focus	(cm)	--	--				--
	Frequency	(MHz)	--	--				--

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