User manual

Product name: Bladder Scanner

Trademark: AvantSonic

Model: PadScan DS3

Table of Contents

Chapter One Introduction

Statement:

Some operations on this document are explained by pictures and these pictures are used only for indicating without any other purpose.

1.1 Brief Introduction

The PadScan DS3 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: Expert Mode and Easy Mode. During the ultrasound 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 7-inch LCD screen (800x480 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

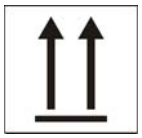
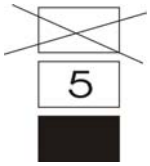
Attention! Consult accompanying documents

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 DS3 in operation will not interfere with the wired, wireless or other electrical equipment. It works properly under specified electromagnetic environment.

Warning: Using the PadScan DS3 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

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 Security Preparations before Operation

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 Instruction

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.

2.6Notice 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

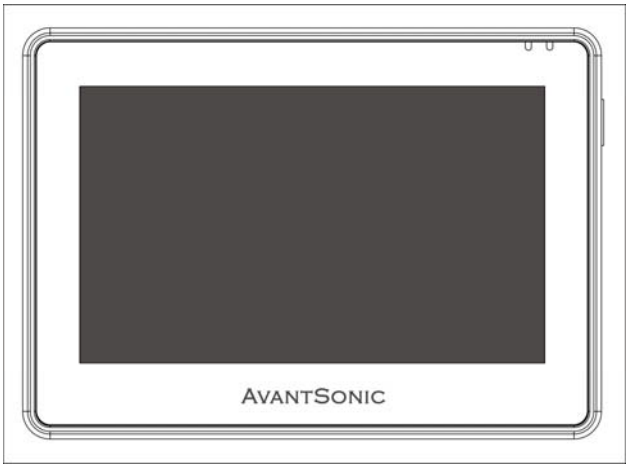


Figure 3-1 PadScan DS3 Front Diagram

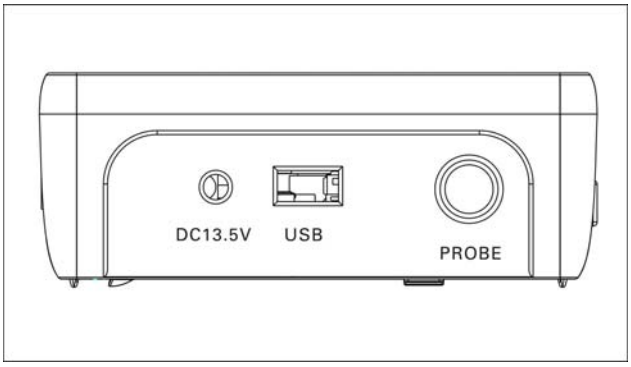


Figure 3-2 PadScan DS3 Diagram of Connection Port Side

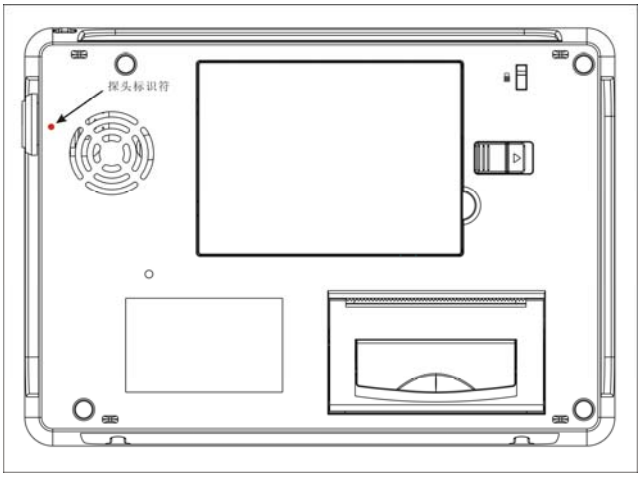


Figure 3-3 PadScan DS3 Back Diagram

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: 7-inch TFT-LCD
- Consumption: 50W
- Dimension of equipment：190*135*52 mm
- Weight: about 1300g (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

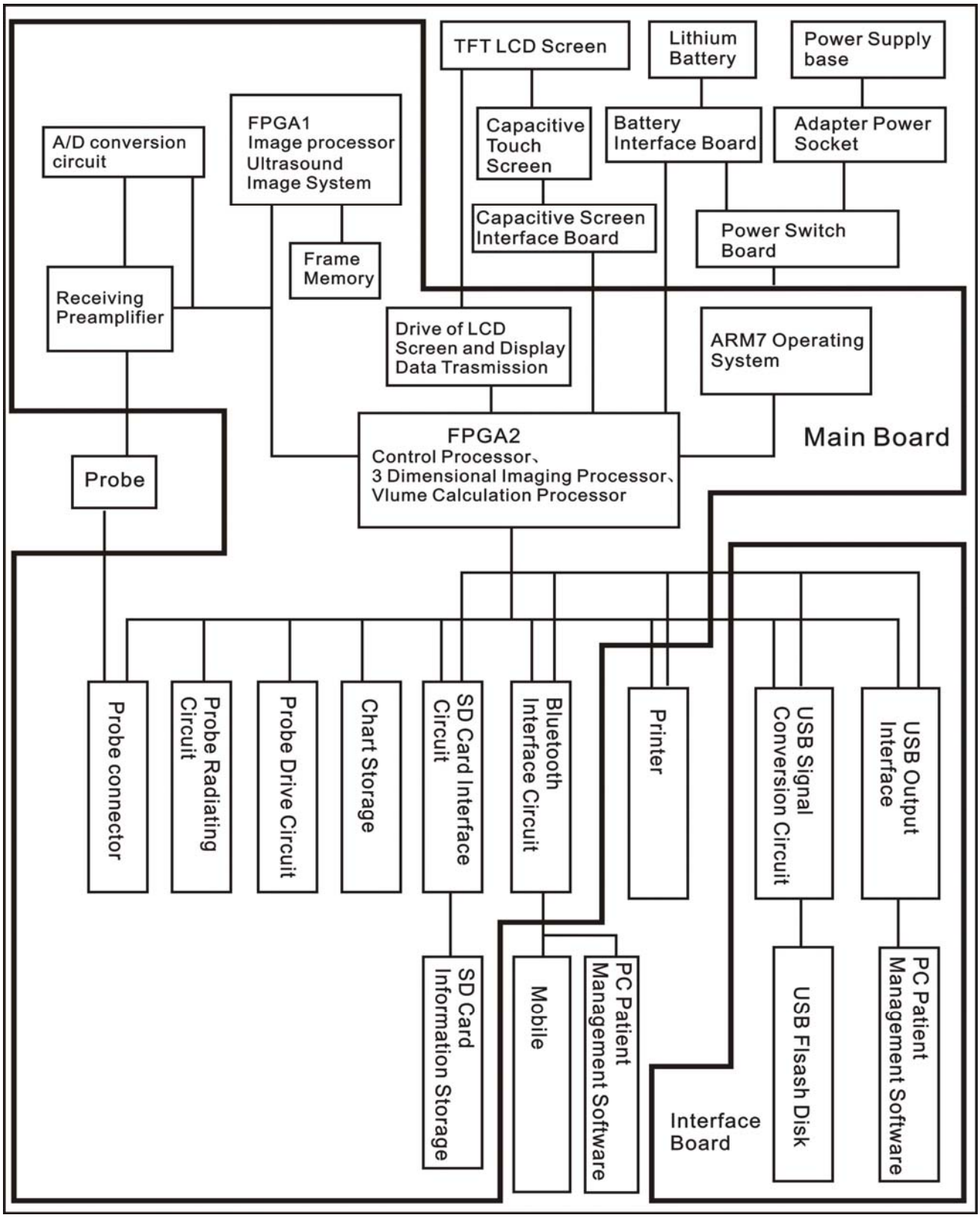


Figure 3-4 PadScan DS3 Principle of Electricity Block Diagram

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 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 4-1.

  Lock slot: any notebook security lock is applied to this lock slot as figure 4-1.

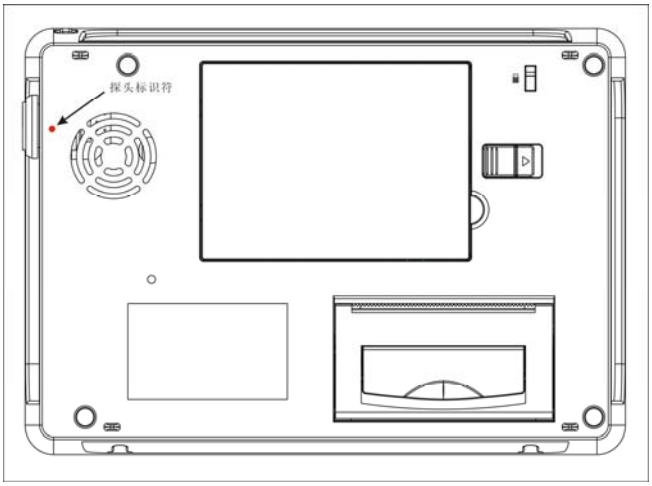


Figure 4-1 PadScan DS3 Probe and Main unit Connection Diagram

- 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 4-2:

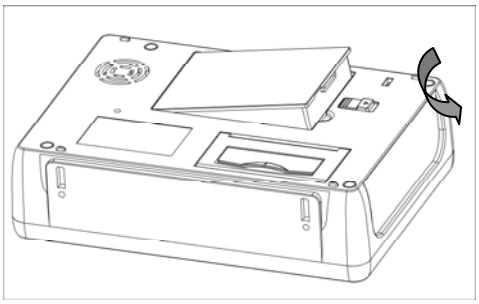


Figure 4-2 PadScan DS3 Battery Installation Diagram

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 4-3.

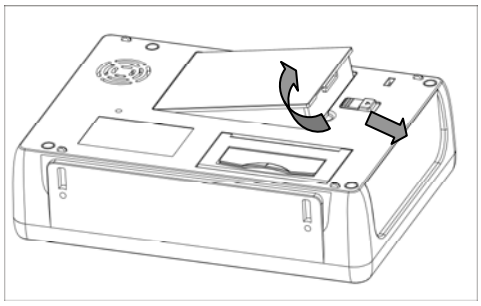


Figure 4-3 PadScan DS3 Removal Installation Diagram

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 DS3 Start-up Interface

A: Company LOGO

5.2 Main Interface

5.2.1 Expert Mode

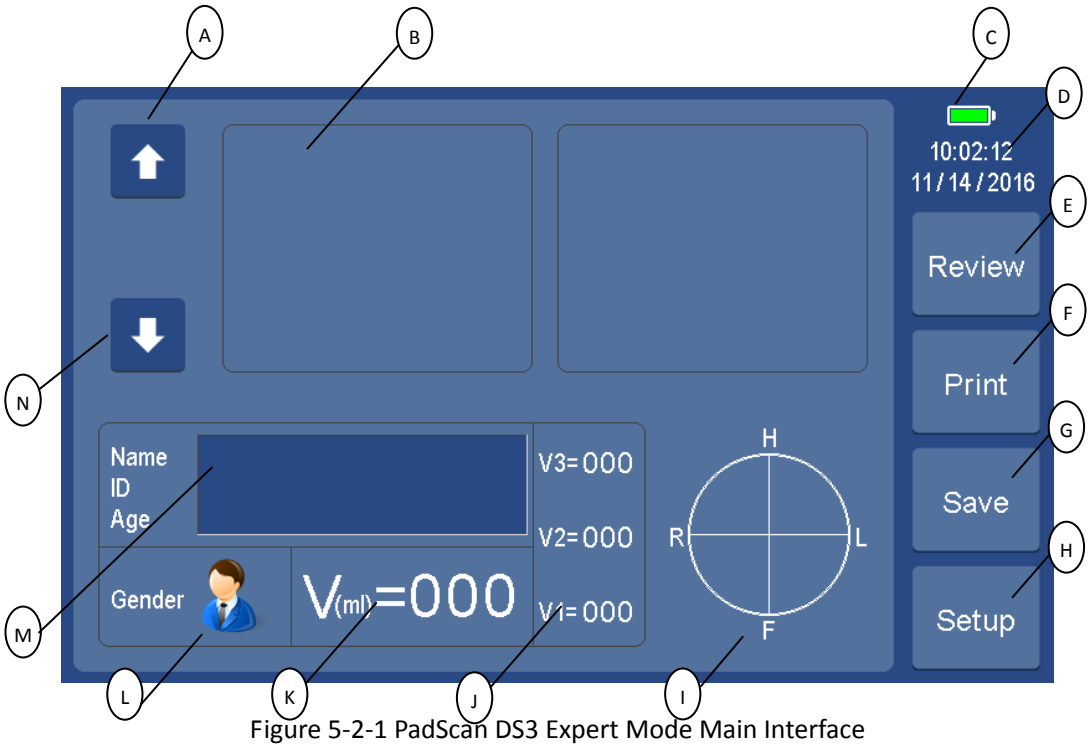


Figure 5-2-1 PadScan DS3 Expert Mode Main Interface

A: Turn to the last

B: Ultrasound image display area

C: Battery status

D: Time and Date

E: View patient information

F: Print Patient information

G: Save current Patient information

H: System Setup

I: Projection of probe aiming

J: Historical bladder volume value

K: Current bladder volume value

L: Gender selection

M: Patient information

N: Turn to the next

5.2.2 Easy Mode

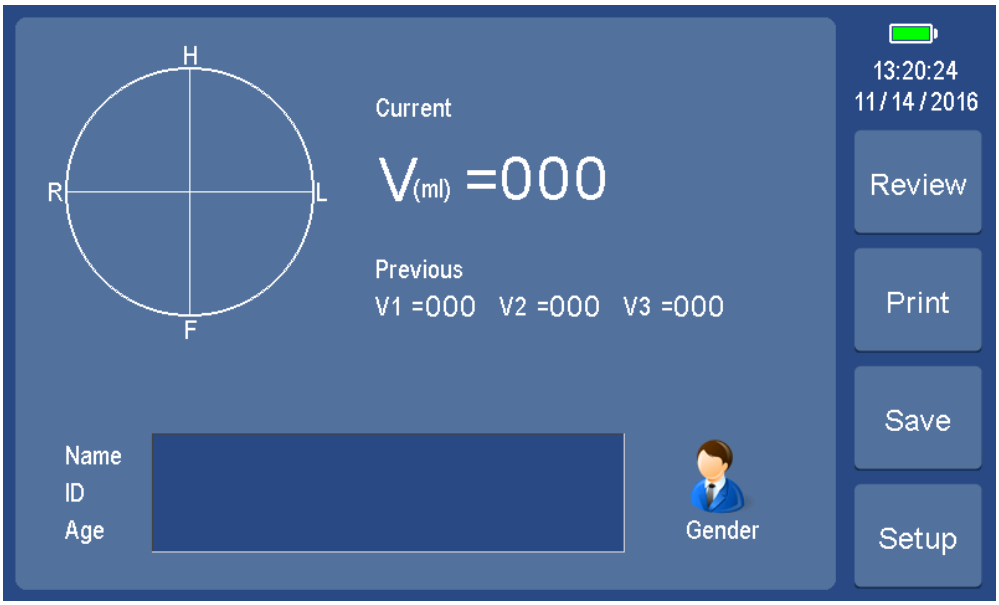


Figure 5-2-2 PadScan DS3 Easy Mode Main Interface

5.3 Patient Information Input Interface

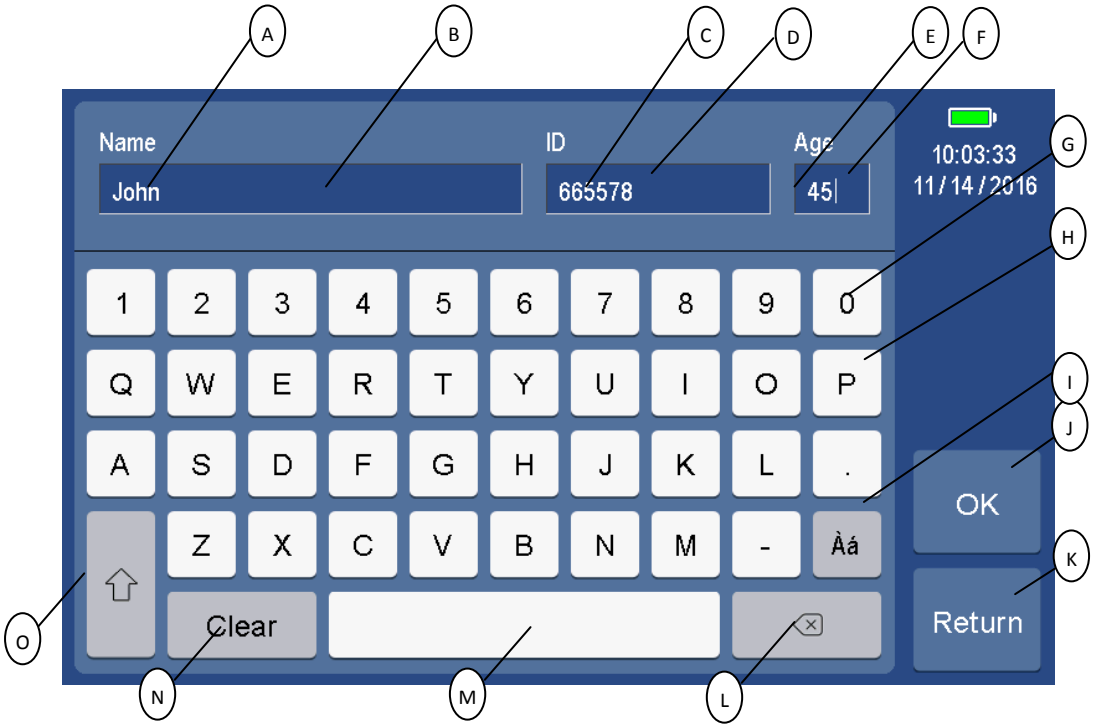


Figure 5-3 PadScan DS3 Patient Information Input Interface

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: Confirm and Return

K: Cancel and Return

L: Delete

M: Space

N: Clear

O: Cap lock

5.4 Bladder Scan Interface

5.4.1 Expert Mode Scan

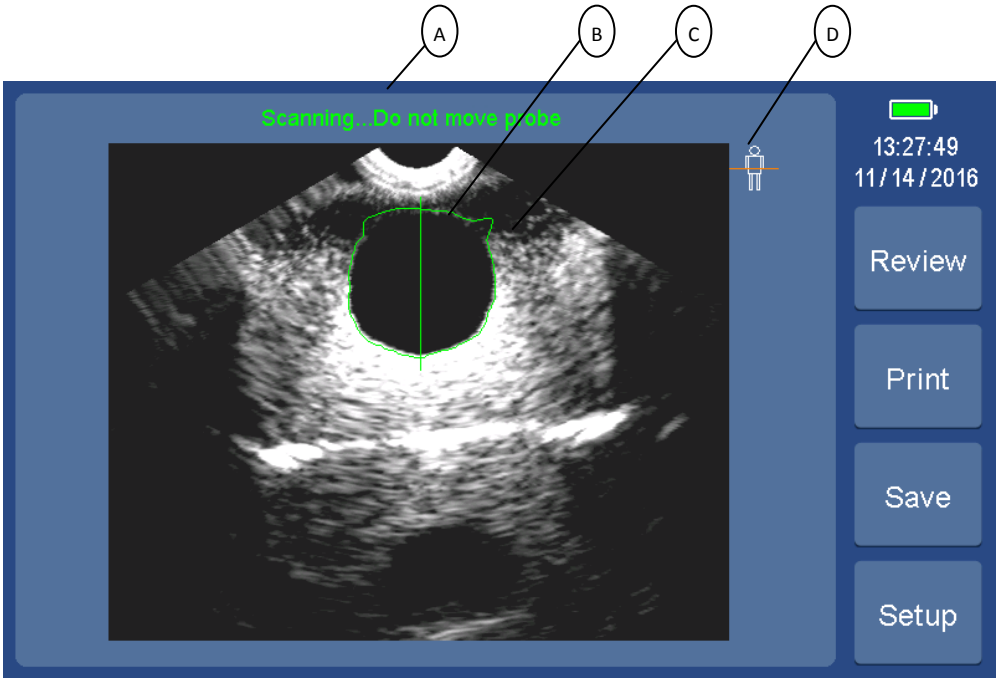


Figure 5-4-1 PadScan DS3 Expert Scan Interface

A: Prompt Information B: Ultrasound image outline

C: Ultrasound image of bladder D: Serial number of current ultrasound images (01 to 12)

5.4.2 Easy Mode Scan

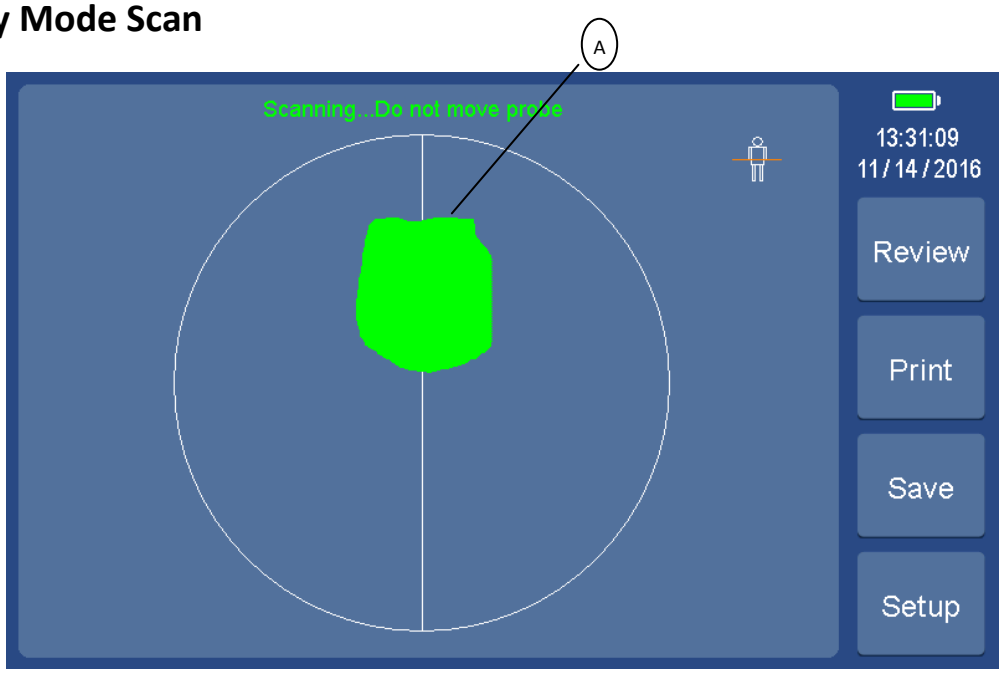


Figure 5-4-2 PadScan DS3 Easy Mode Scan Interface

A: Cross-section of bladder diagram

5.5 Patient Information Review

5.5.1 Expert Scan Image Review Interface

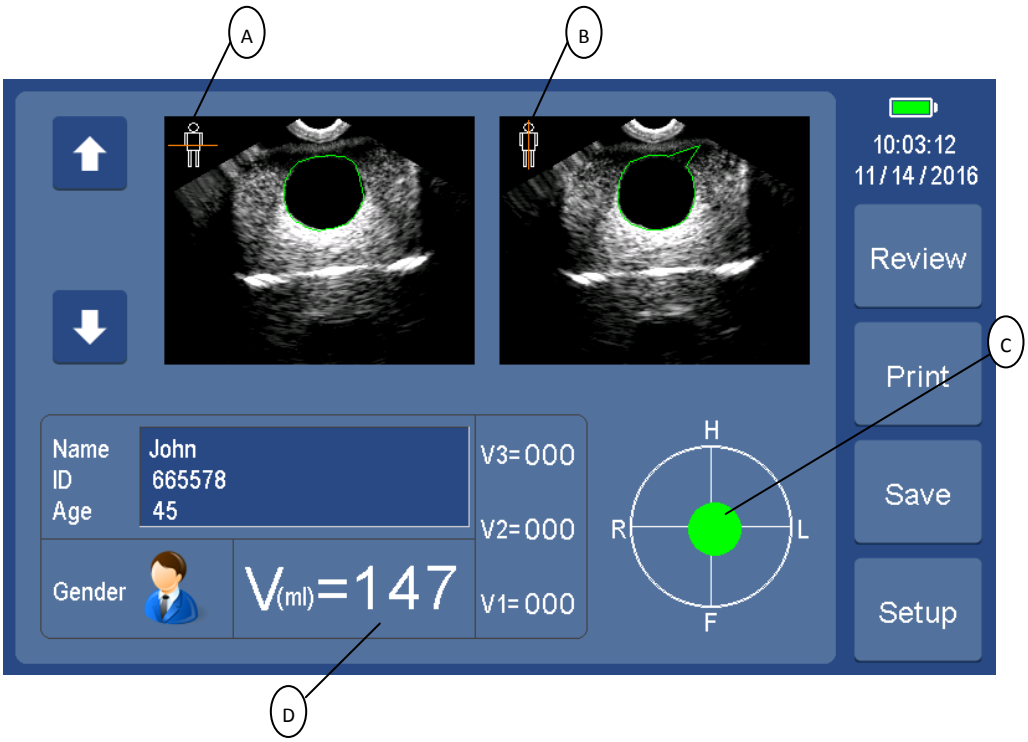


Figure 5-5-1 PadScan DS3 Expert Scan Image Review Interface

A: Serial Number of current ultrasound images (01 to 06) B: Serial Number of Orthogonal

C: Projection of Scanned Bladder D: Current Bladder Volume

5.5.2 Easy Scan Image Review Interface

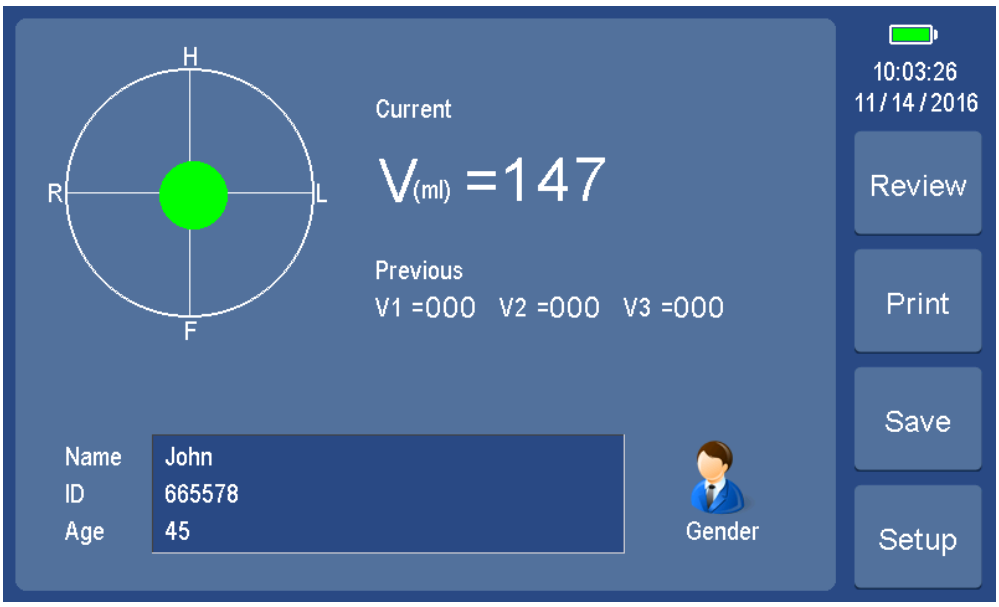


Figure 5-5-2 PadScan DS3 Easy Scan Image Review Interface

5.6 Patient Information Review Interface

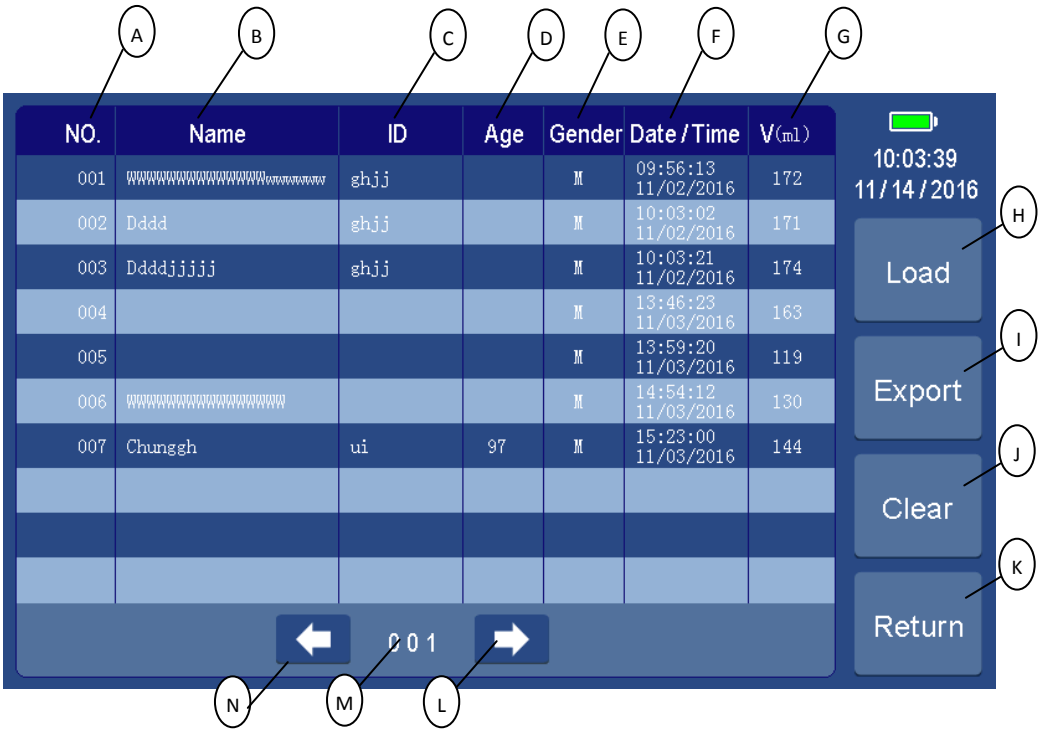


Figure 5-6 PadScan DS3 Patient Information Review Interface

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: Load

I: Export

J: Delete

K: Return

L: Next page

M: Current page

N: Previous page

5.7 System Setup Interface

Figure 5-7 PadScan DS3 System Setup Interface

A: DS3 Figuration

B: Cancel and return

C: Language setup

D: System information

E: Firmware upgrade

F: Service function

G: Power management

H: Time and Date setup

5.8 Time and Date setup

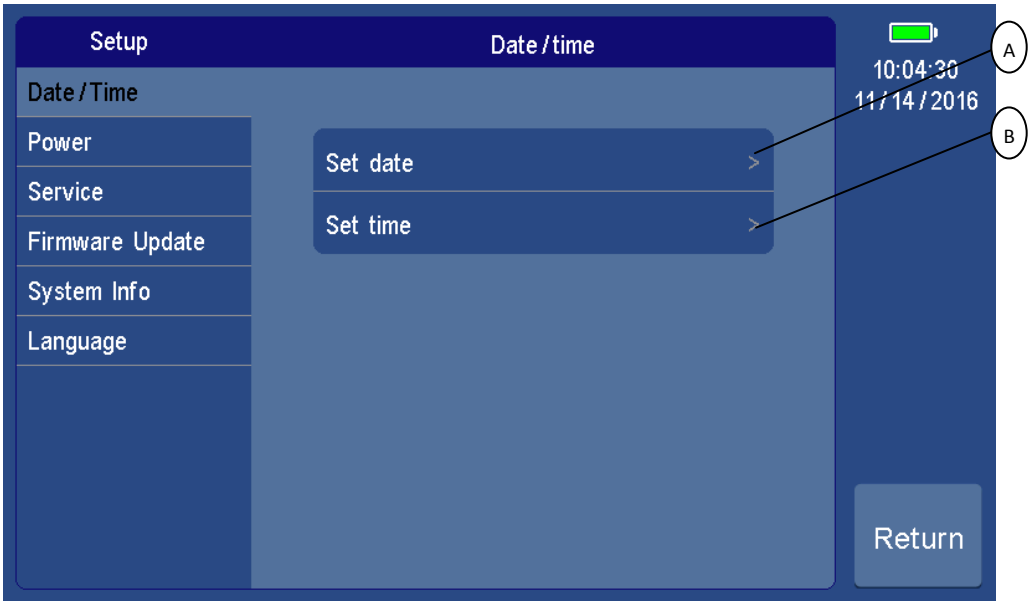


Figure 5-8 PadScan DS3 Time and Date setup Interface

A: Date Setup B: Time Setup

5.9 Power Management

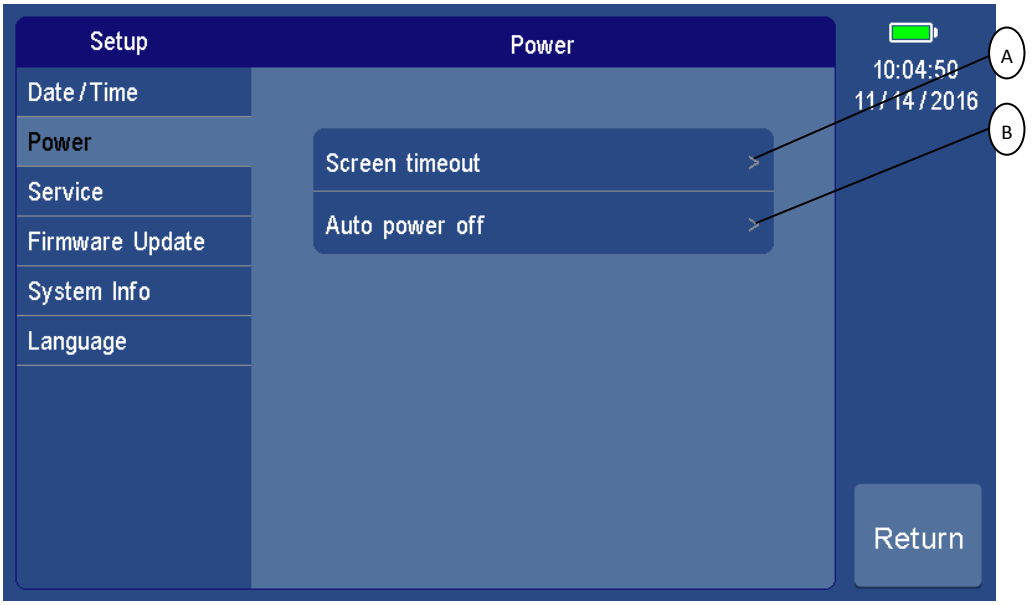


Figure 5-9 PadScan DS3 Power Management Interface

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

5.10 Service

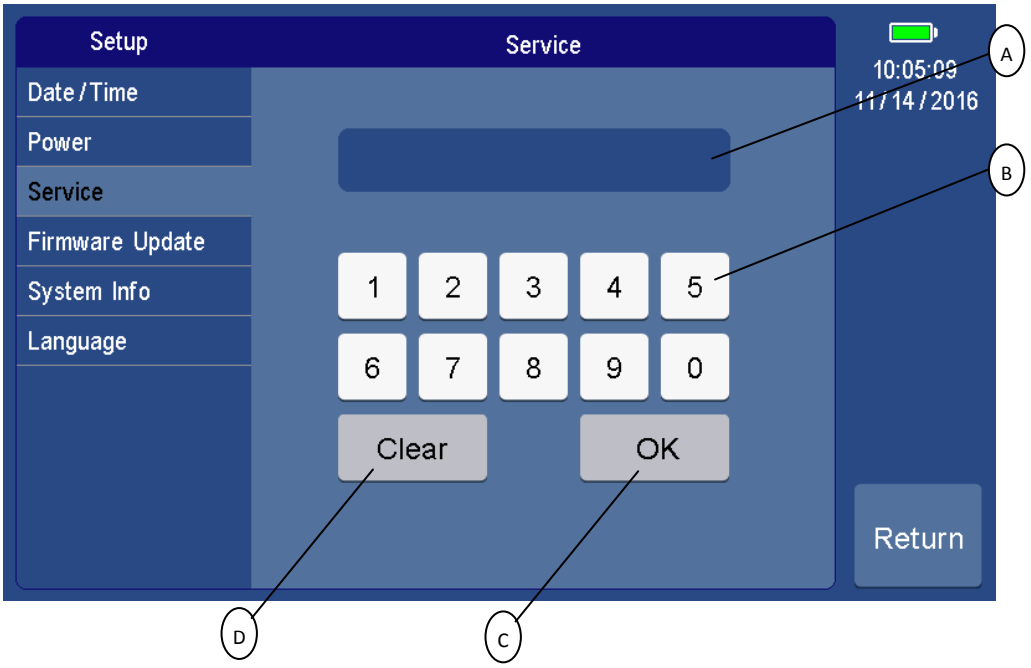


Figure 5-10 PadScan DS3 Service Function Interface

A: Password

B: Password input keyboard

C: OK

D: Clear the current input

5.10.1 Mode Selection

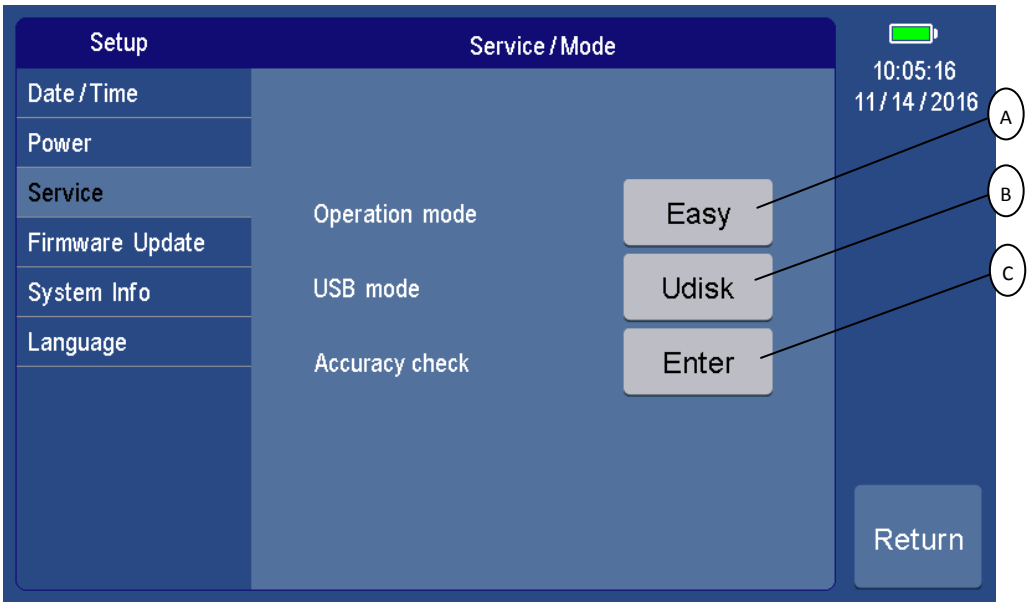


Figure 5-10-1 PadScan DS3 Mode Selection Interface

A： Expert /Easy Mode Conversion Key

B: USB/PC mode conversion key

C: Calibration interface access key

5.10.1.1 Calibration

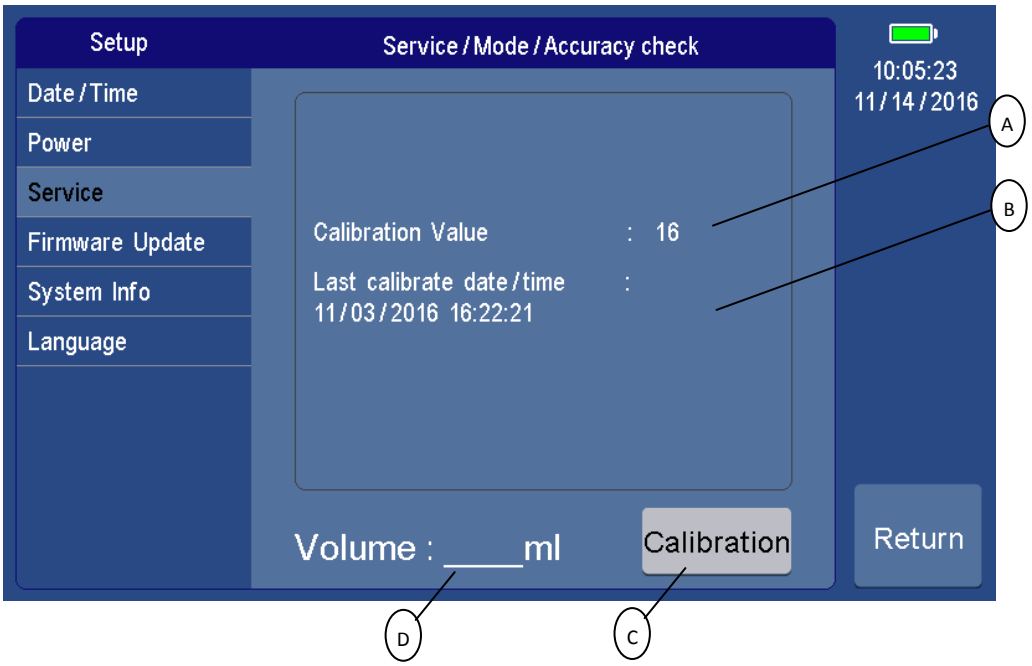


Figure 5-10-1-1 PadScan DS3 Calibration Interface

A: Current calibration value

B: Last calibration date/time

C: Calibrate key

D: Current phantom volume value

5.10.2 Calibration Value Reset

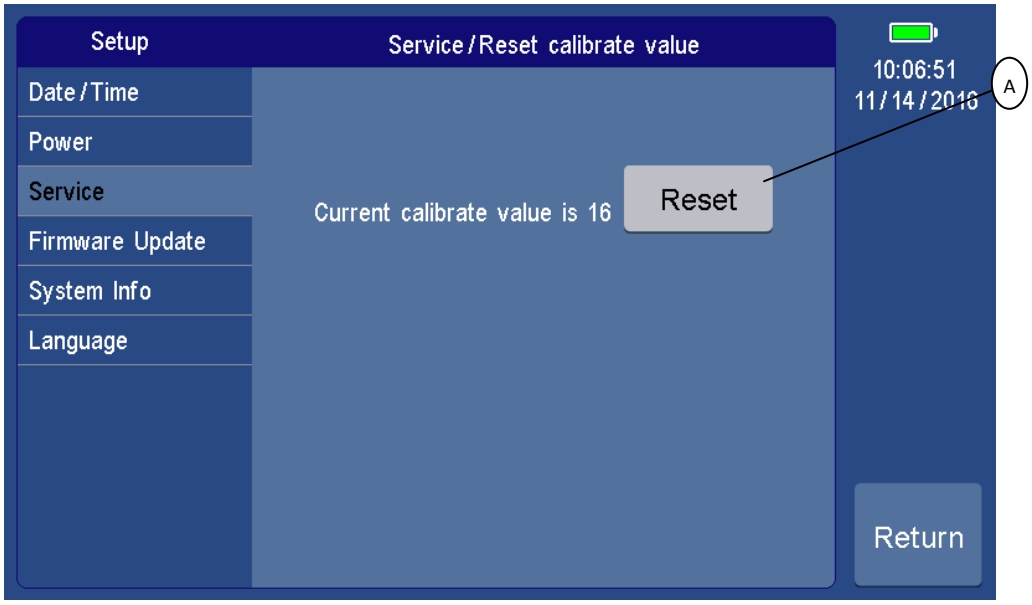


Figure 5-10-2 PadScan DS3 Calibration Value Reset

A: Calibration reset key

5.10.3 System Reset

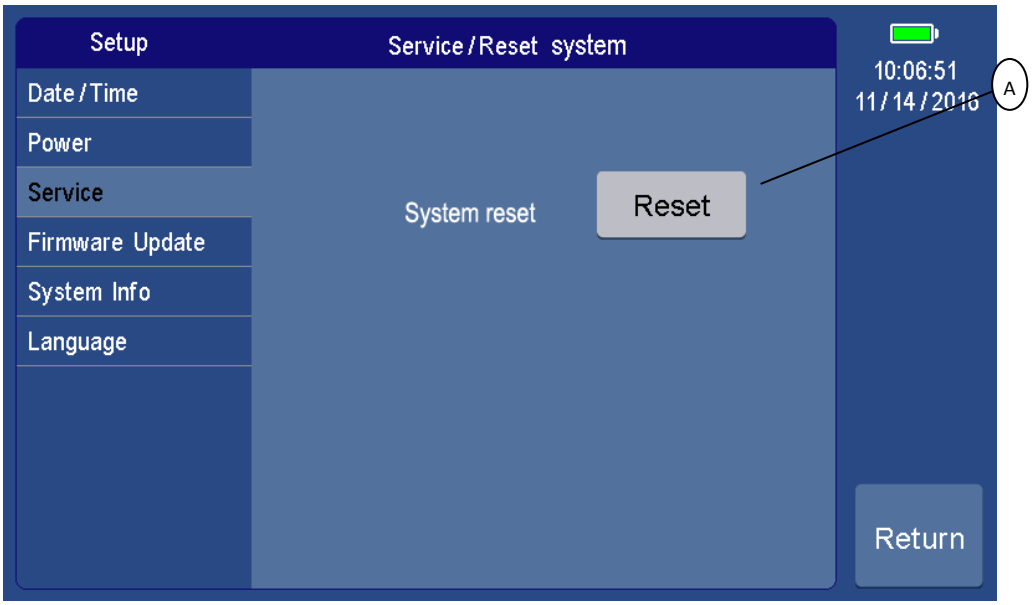


Figure 5-10-3 PadScan DS3 System Reset Interface

A: System Reset Key

5.11 Firmware Update

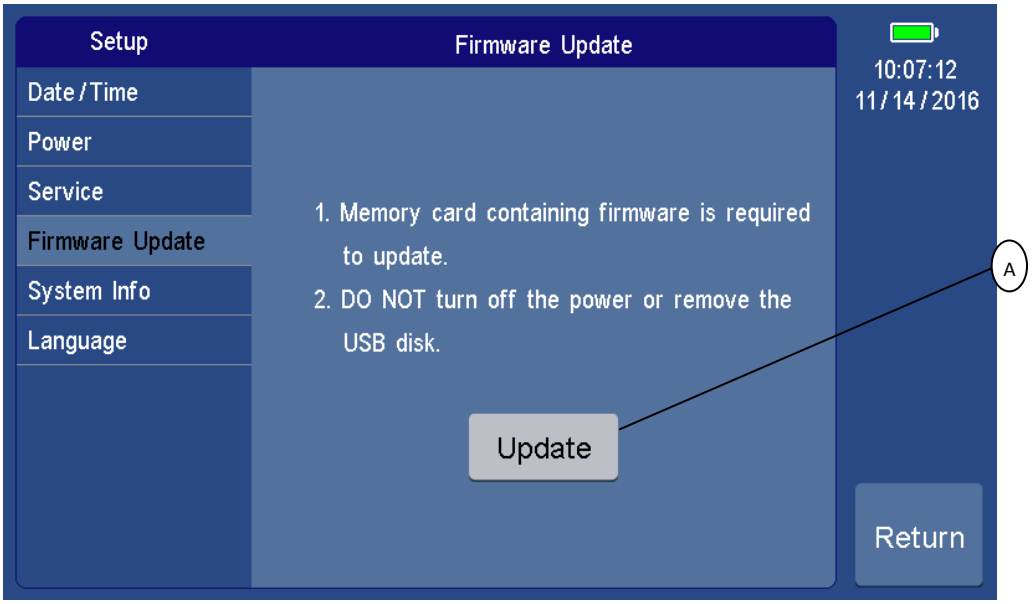


Figure 5-11 PadScan DS3 Firmware Update

A: Update key

5.12 System Information

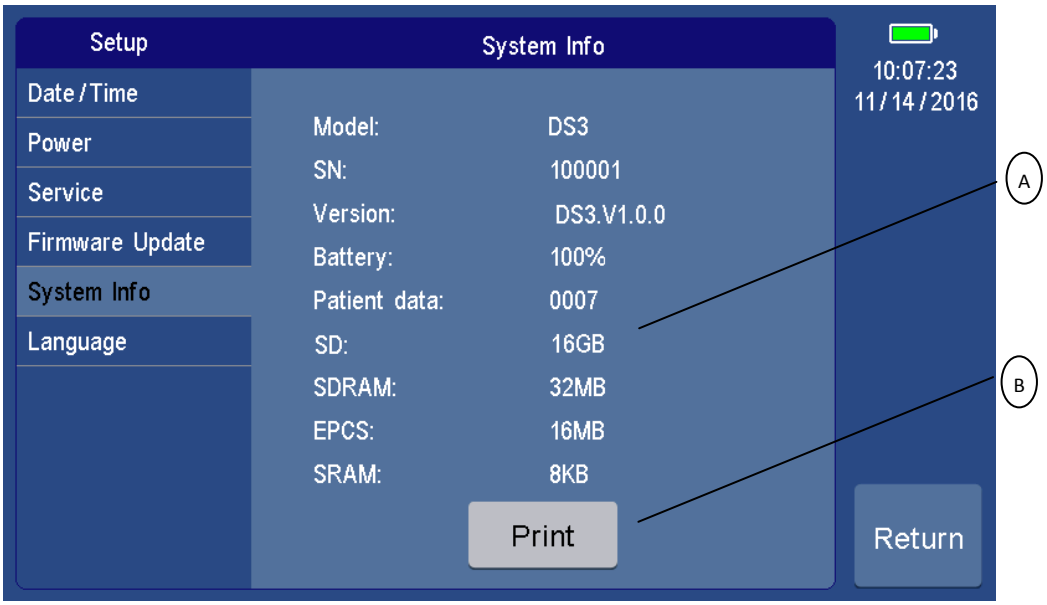


Figure 5-12 PadScan DS3 System Information Interface

A: System Information B: System information print

5.13 Language Selection

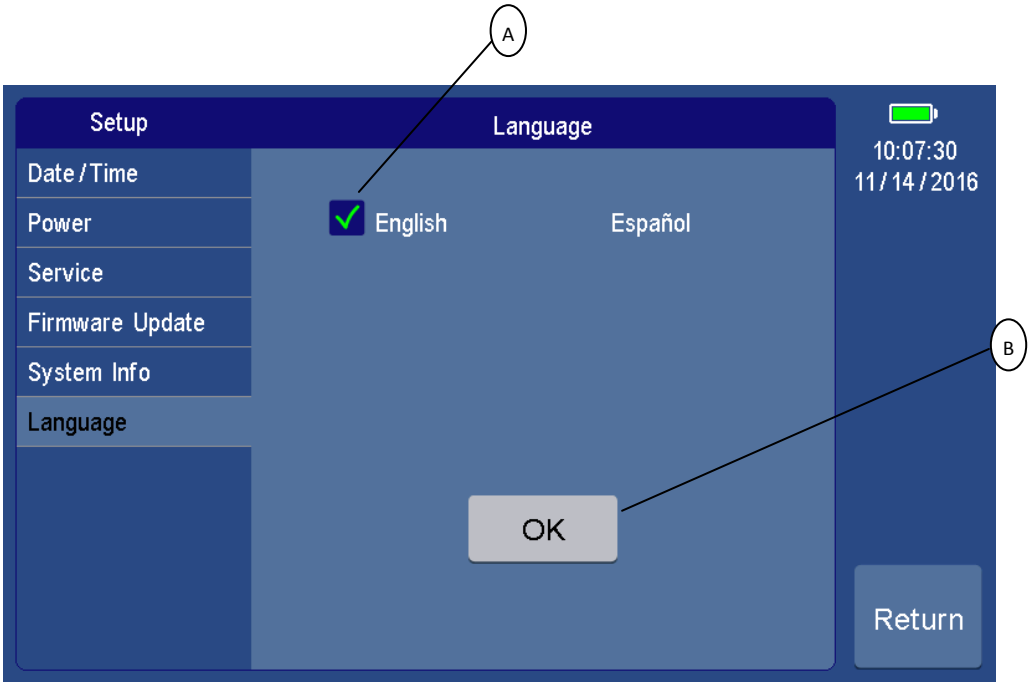


Figure 5-13 PadScan DS3 Language Selection Interface

A: Current language selection marks B: OK

Chapter Six Operation Procedure

6.1 Bladder Scanning

6.1.1 Gender Selection

Power on DS3 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 4 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 or bladder section with its serial number will display on the screen in the real-time way when it reminds that "Locate the bladder" which means it enters 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 when patient's bladder ultrasound images (Figure 5-4-1) or bladder section (Figure 5-4-2) with its serial number (from 01 to 12)。  means 01， The red line on  rotates 15 degrees clockwise， the serial number plus 1). It reminds that "Scanning... Do not move probe" which means the bladder scanning is in progress. When the scanning, image analysis and measurement finish， it automatically enter the Image Review interface.

6.2 Image Review

When the scanning, image analysis and measurement finish, it automatically enter the Image Review interface. The images viewing interface is divided into expert scan images viewing interface

(Figure 5-5-1) and easy scan images viewing interface (Figure 5-5-2).

When enter the Expert scan images viewing interface, 2 orthogonal bladder B-ultrasound images and its serial number, bladder scan projection and current bladder urine volume display. Operator can review 6 sets of orthogonal bladder B-ultrasound images or bladder section diagram by clicking  or  . Among them, the first 6 (from 01-06) orthogonal bladder B-ultrasound images or bladder section diagrams display on the left side of  while the second 6 (from 07-12) orthogonal bladder B-ultrasound images or bladder section diagrams display on the right side of  ; The first 6 and second 6 images are orthogonal, for example：  as the first image and  as the seventh one are orthogonal images.

When enter the easy scan images viewing interface， the bladder scan projection and current bladder urine volume display.

Note: If the bladder is not found during the bladder scanning phase, when jumping into the image viewing interface, the screen will remind: Bladder not found. Please re-scan.

6.3 Patient Information Input

In the main interface (Figure 5-2-1, or figure 5-2-2) click the Patient Information 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. Click  to directly return to the previous interface.

6.4 Print

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

6.5 Patient Date Save

Click Save in the Image Review interface (Figure 5-5-1 or 5-5-2) to save current patient information including: Patient Name, ID, Age, Gender, Scanning time , Bladder Urine Volume and 12 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 DS3 directly if the U disk is not inserted. In the event that patient information is saved in U disk, click Save to save the information into DS3 after U disk is removed. All data stored in U disk could be viewed under the SAVE file.

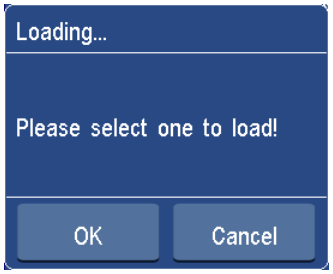
6.6 Patient Information Review

Click Review in the Image Review interface (Figure 5-5-1 or 5-5-2) to enter the Patient Information Review interface (Figure 5-6) 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 DS3 is 1000 cases.

6.6.1 Patient Data Load

Click Load after selecting one patient case to load the current patient data, bladder scan projection and ultrasound bladder images (Expert Mode) into the main interface.

Note: if select two or more patient cases and click Load, a



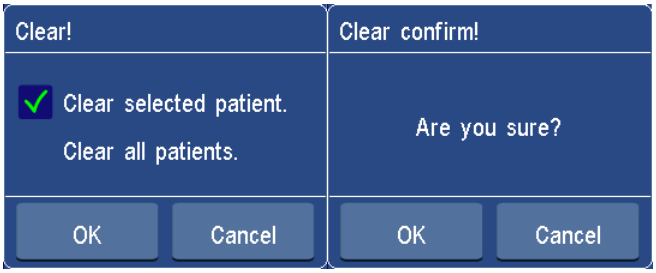
dialog of “Please select one patient!” will appear shown as the right figure.

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 DS3 to the U disk. The Exported data can be reviewed in a folder named after the date. If there is no U disk inserted, the system will not respond.

6.6.3 Patient Data Deletion

Click Delete and the first dialog box pops up. Select “Clear selected patient”, and click OK, the second dialog box pops up, and reminds: Are you sure? Click OK to delete the current selected patient data; Chose “Clear all patients.”， Click OK, the second diaglog box pops up, and reminds : Are you sure? Click OK to delete all the patient data saved in DS3. Deletion is irretrievable so please make sure all the patient data in DS3 are saved before deleted.

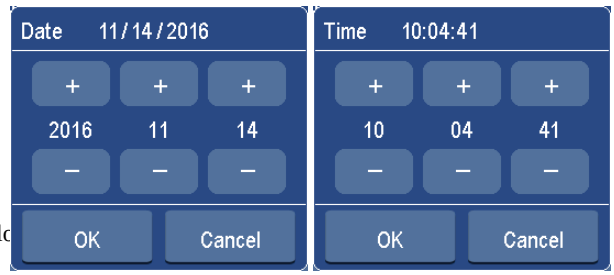


6.7 System Setup

Click Setup In the main interface (Figure 5-2-1 or 5-2-2) and enter the System Setup interface (Figure 5-7) 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

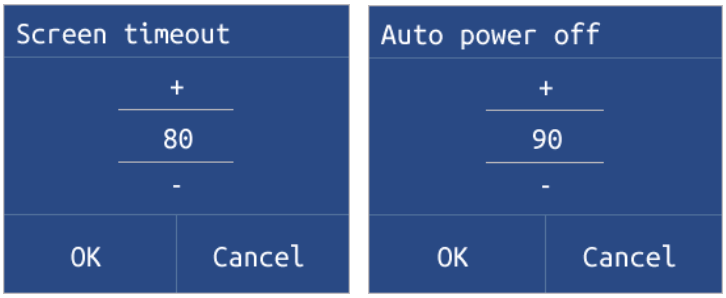
Click “Date/Time” on the left side of the System Setup interface to enter the Date/Time Setup interface (Figure 5-8) where two options are available： Set date, Set time to set up time and date. Specific steps are as follows: click “Set



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 5-9) 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 5-10 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 5-10-1) where three options available:： Operation mode、USB mode and Accuracy check

The Expert following “Operation mode”, means the operation mode is Expert Mode, and will display patient bladder ultrasound images when bladder scanning. Click Easy to turn it to Easy , means the Expert Mode is converted to Easy Mode.

The Udisk following “USB mode” means to set U-disk mode for USB connection. Enter the Patient Data Review interface (Figure 5-6) 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, and then upload all the real time data (patient information and 12 bladder ultrasound images) to PC and save them. Repeatedly click this key for mode conversion between U-disk and PC.

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

6.7.3.1.1 Device Calibration

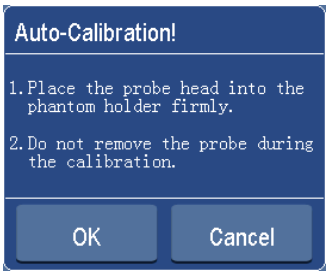
Please be kindly noted, **AvantSonic PadScan** DS3 has no need to be calibrated for its entire using life due to the patented technologies we have in ultrasound imaging and measurement algorithm. Regarding this, we hereby officially specify:

Within its entire using life, **PadScan Bladder Scanner DS3** under the intact condition:

1. The operators do not need to do the calibration for clinical measuring accuracy before DS3 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 DS3 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 5-10-1-1) 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 5-10-2). Click Reset to reset the calibration value of this device as its default（16）.

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 5-10-3). Click Reset to reset the system, which will come to be the default after you restart DS3 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 5-11), 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 middle 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 DS3 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 5-12) which shows the system information about DS3 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 5-13). Two languages are available in this device, including: English and Spanish. English is the default option. Click OK to confirm it.

6.8 Communication Module

There are two functions brought by DS3 communication module: 1. DS3 communication with PC, which refers to that patient information with 12 ultrasound bladder images is uploaded to PC software through wired or wireless transmission to be saved, managed and reviewed. 2. DS3 communication with HL7 system, which means that the real-time data including patient information with 12 ultrasound bladder images scanned and obtained by DS3 is uploaded to HL7 system through wired or wireless transmission to be saved, managed and reviewed.

The wired transmission between DS3 and PC or HL7 system is through USB port connection, while wireless transmission is through Bluetooth module.

6.8.1 DS3 Communication with PC

There are two methods of DS3 communication with PC: wired and wireless transmission, both of which require to install the USB driver to the PC firstly by opening CH372DRV.EXE software 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 

in DS3 Mode Selection interface (Figure 5-10-1) to turn it into 

, and then enter the interface of Patient Information Review (Figure 5-6). Insert one end of USB cable into the PC/USB port and the other end into DS3. Open the PC software of PatientManager.exe where click the PC key in the PC Mode Selection interface to log in and then click Sync Data to synchronize the data while USB cable should be always connected. Since the synchronization is completed, all patient information in DS3 will be uploaded to the PC.

Wireless transmission is operated as follows: click the 

in the Image Review (Figure 5-5-1 or Figure 5-5-2) to enter the interface of Patient Information Review (Figure 5-6). Open the PC software of PatientManager.exe where click the Bluetooth key in the PC Mode Selection interface to search for accessible Bluetooth device (Notice: DS3 must has the Bluetooth module function firstly) , connect with DS3 successfully, and then log in to upload all patient information in DS3 to the PC through wireless transmission by clicking Sync Data.

6.8.2 DS3 communicate with HL7

There are two methods of DS3 communication with HL7: wired and wireless transmission. Specific operations are as followed: 1. Click the patient information box  in the main interface (Figure 5-2-1 or Figure 5-2-2) to enter the patient information input interface where you can input Name, ID and Age by clicking the corresponding input boxes and confirm all entered information before back to the main interface where you can choose the gender by clicking the gender

selection key. 2. Place the probe onto patient's bladder, press once the button of the probe to pre-scan, and press it again to start scanning patient's bladder; 3. In the event that DS3 is set to PC connection with HL7 system through USB port, the real-time data including patient information with 12 ultrasound bladder images scanned will be uploaded to HL7 system when you scan the bladder. In the event that DS3 is successfully connected with HL7 through Bluetooth module (Notice: DS3 default option is Bluetooth connection), the real-time data including patient information with 12 ultrasound bladder images scanned will be uploaded to HL7 system through wireless transmission.

6.9 PC Interface

6.9.1 Main Interface

DS3 setup comes firstly: click the 

in DS3 Mode Setup interface (Figure 5-10-1) to turn it into "PC", which refers to the wired transmission to PC.；Bluetooth connection mode is DS3 default setting, then the wireless transmission to PC can be chosen. Enter the interface of DS3 Patient Information Review (Figure 5-6).

Then PC setup follows: open the PC software (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: DS3 must has the Bluetooth module function firstly) and connect with DS3 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：

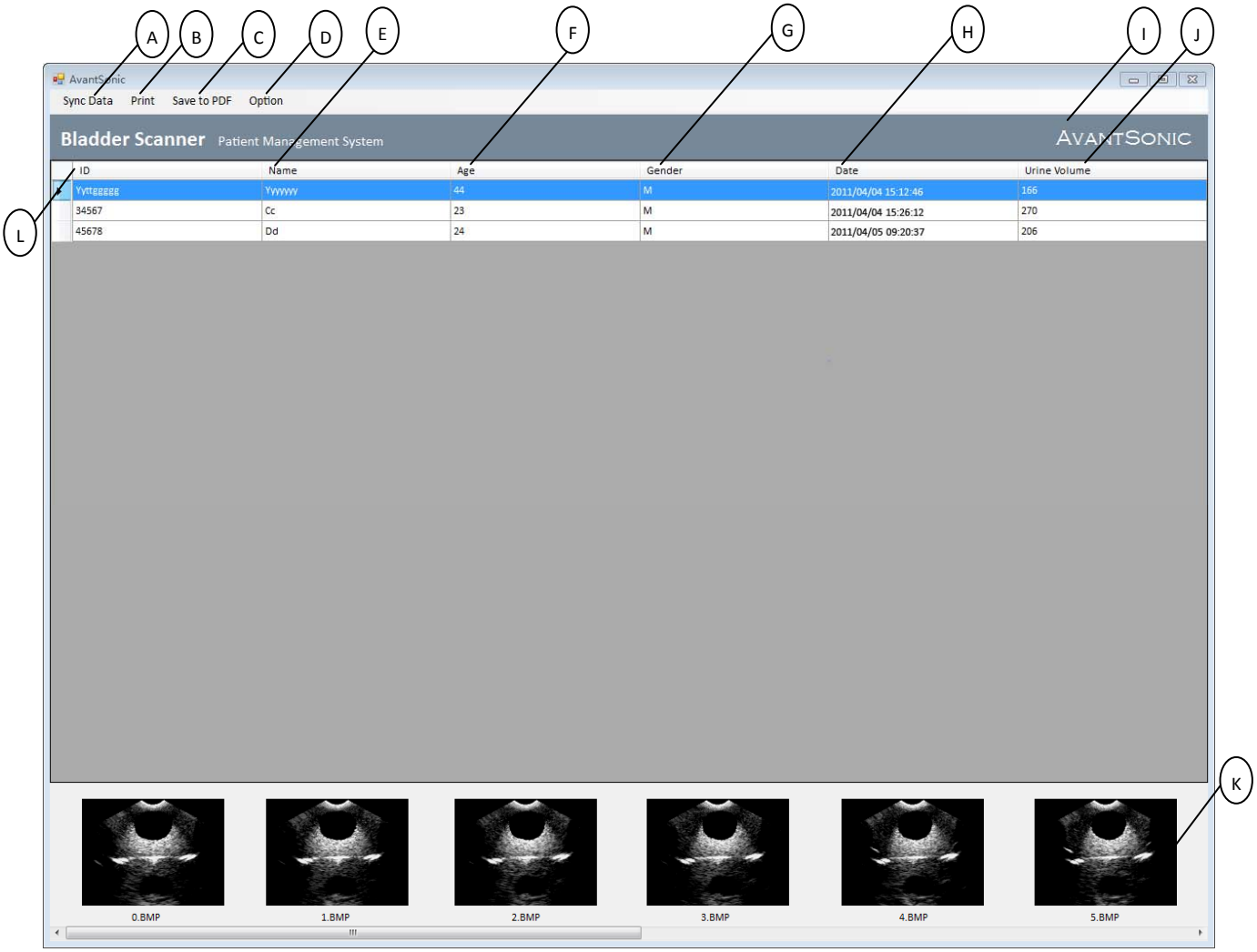


Figure 6-1 PadScan DS3 Main Interface of PC

A: Sync data

B: Print

C: Save to PDF

D: Option

E: Patient name

F: Patient age

G: Patient gender

H: Date and time when scanning

I: Company LOGO

J: Bladder urine volume

K: Bladder images display area

L: Patient ID

6.9.2 Data Synchronization

According to Section “6.9.1 Interface, there are two methods 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: the Bluetooth connection mode is DS3 default setting) and connect it with DS3. 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 DS3 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 DS3, “No new data!” is shown in the interface; If the connection of Bluetooth and DS3 fails, “Open device failed!” is shown in the interface.

6.9.3 Option

Click the Option in the main interface of PC, the dialogue box of Option appears (Figure 6-2) and information could be tapped 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：

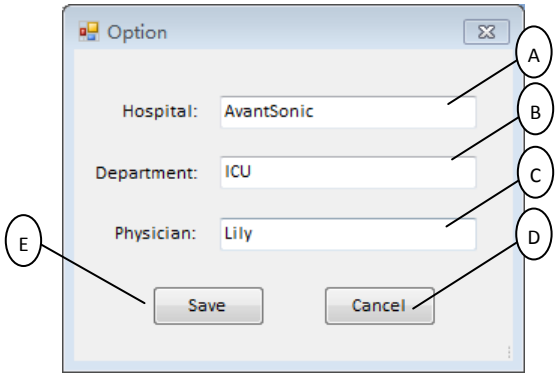


Figure 6-2 Option Interface in the PC of PadScan DS3

A: Hospital name input box

B: Department name input box

C: Physician name input box

D: Cancel key

E: Save key

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

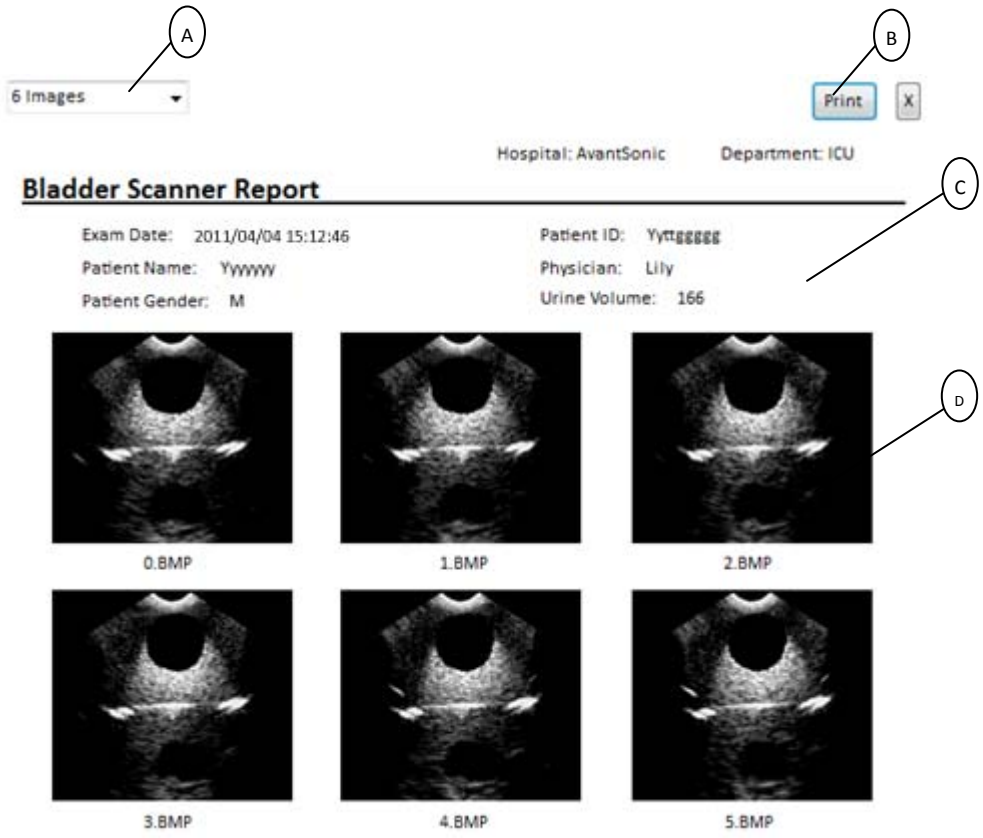


Figure 6-3 Print Interface of the PC of PadScan DS3 (6 images)

A: Selection box of 6 or 12 images displayed

B: Print button

C: Patient information

D: 6 bladder ultrasound images

The Print interface of PC (12 images) Figured as Image 6-4:

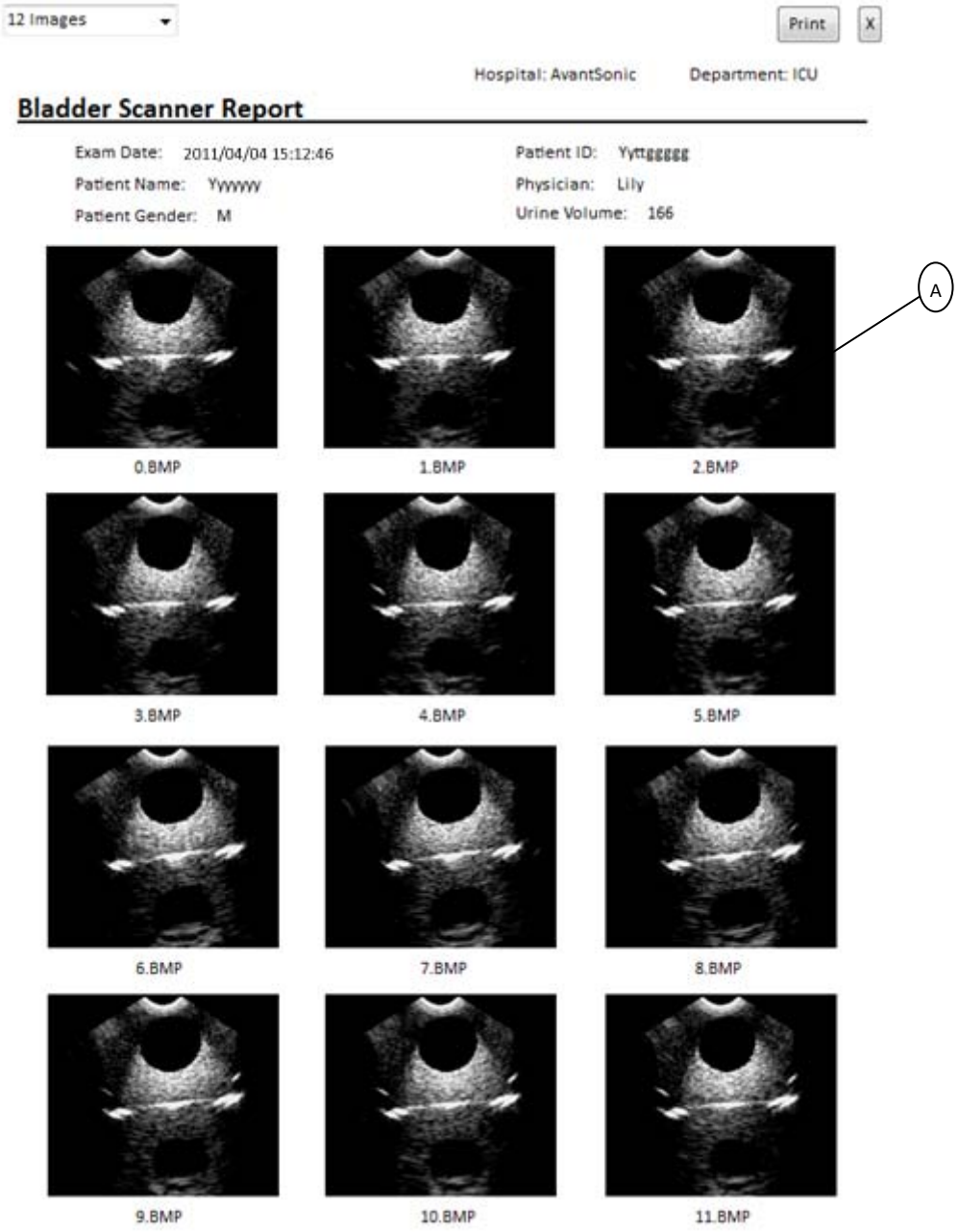


Figure 6-4 Print Interface of PC of PadScan DS3 (12 images)

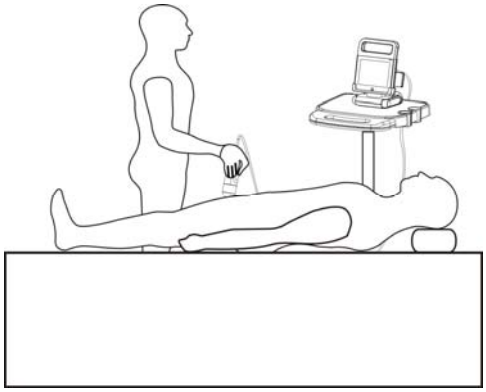
A: 12 Bladder ultrasound images

6.9.5 Save to PDF

Click the Save to PDF in the main interface of the 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)

6.10 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's 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 grey 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 grey section indicates the image deviates from the center) and make sure the bladder section area is the biggest.

After scan, it automatically enters the image review interface where green projection will display (Figure 5-5-1 or Figure 5-5-2). The scan result counts as long as the center of green projection doesn't deviate too much 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

(1) Turn OFF the system power.

(2) Unplug the power supply from the system.

(3) Use a mild detergent to clean the device's surface including keyboard.

(4) Wipe time should follow the instructions of detergent and the wipe intervals should meet the clinical standard.

(5) 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.

(6) 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

(1) System should be operated under the condition stipulated in "1.5".

(2) System should not be shut down and opened up too frequently. After shut down, wait five minutes before restarting the system.

(3) 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

(1) 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.

(2) Use a soft cloth dampened with isopropyl alcohol to wipe the Probe.

7.2.2 Probe Maintenance

Prevent the probe surface from being scratched

(1) Do not crash or drop the probe.

(2) Use only domestically recognized medical ultrasound gel on the probe and patient. Improper gel would damage the probe and stimulate the skin of patient.

(3) Always clean the probe after it's used

7.3Battery Use and Maintenance

(1) For optimum performance, it is recommended to charge and completely discharge a new battery two to three times before first use.

(2) 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.

(3) Always keep battery away from fire.

(4) Prevent the battery from being short circuit, dampened, disassembled, dropped or crashed.

(5) 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

(6) 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.

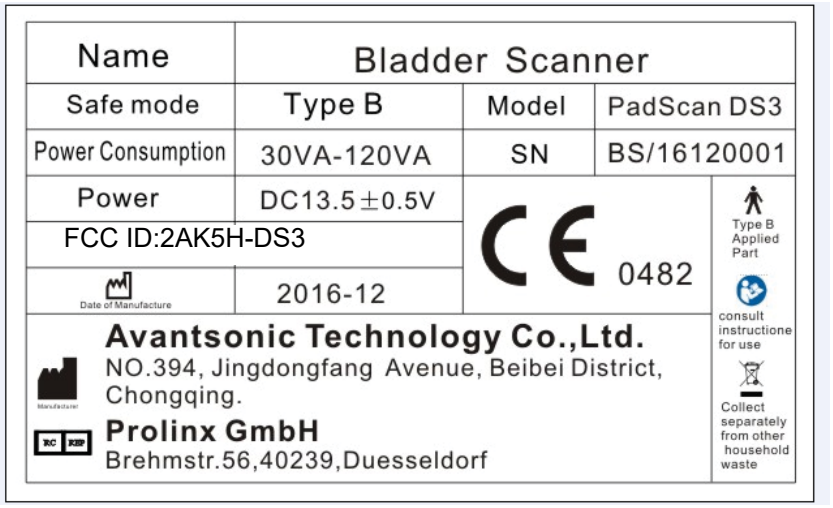
9.4 If problems continue, please contact Avantsonic Technology Co., Ltd.

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.

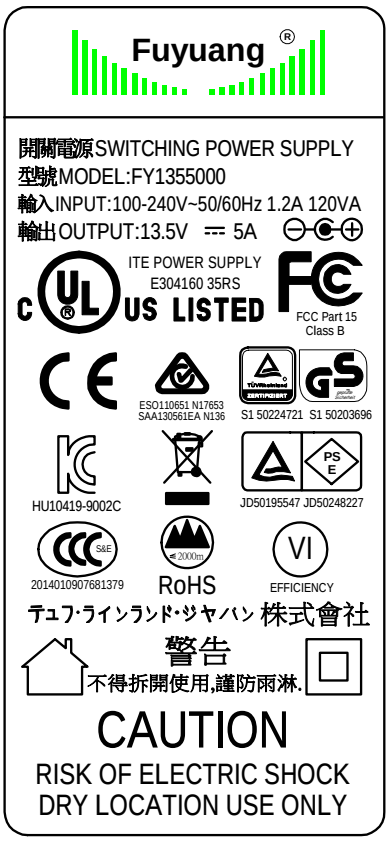
Appendix A Labeling Graphic

DS3 Main Unit Labeling



DS3 Probe Labeling

DS3 Power Adapter Labeling



DS3 Packaging Box Labeling