PadScan HD 3

Bladder Scanner

User’s Manual

Caresono

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Contents

Chapter One Summary

Statement:

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1.1 Introduction

The PadScan HD3 by Caresono Technology Co., Ltd. provides real-time ultrasound imaging and measuring, and also provides non-invasive volume measurement of the bladder. The device consists of main unit, 3D probe, battery and adapter.

It features:

- One operating mode: expert mode. In the expert mode, real-time 2-dimensional ultrasound image will be displayed. Doctors can determine whether the location and the measurement result are right or not according to the cross-section image of the bladder.
- Non-invasive, comfortable, accurate, reliable, fast and simple operation. When the operator releases the scanning button, multiple 2D plane ultrasonic images are acquired in several seconds. Three dimensional image will be formed by using sophisticated image processing techniques and bladder volume will be calculated by using sophisticated algorithms.
- Printouts of ultrasound images with multi-parameters.
- Adopting touch screen pad operation
- Injection molded shell, tablet, 7-inch LCD screen(800x480pixels)
- Combined power supply with AC adapter and a built-in battery.

1.2 Intended use

The device is used in medical departments for bladder volume measurement, which provides the basis for the implementation of clinical catheterization, and makes evaluation of residual volume after patients' voiding and diagnoses the diseases of the bladder and renal function. This device also helps the people with paraplegia and urinary dysfunction to get the time of urination right.

1.3 Standards

This device is designed and manufactured in strict accordance with IEC60601-1:2005 " Medical electrical equipment part 1: General requirements for safety" and IEC60601-2-37:2007 "medical electrical equipment: Particular safety requirements for medical ultrasound diagnostic, monitoring and nursing equipment ". Type of protection against risk of electric shock is: Type B, Class II

The environmental test of this device meet the requirement of GB/T 14710-2009<environment requirement and

test methods for medical electrical equipment>, climate environment test group II and mechanical environment test group II.

- Safety Symbols：

Type B Device

Attention! Consult accompanying documents

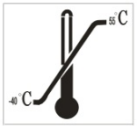
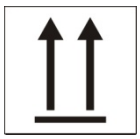
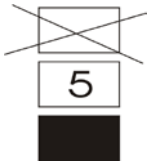
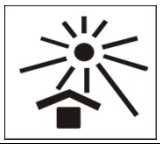
Switch ON the general power

Switch OFF the general power

Signal output

CE 0482 CE mark and code of certification body

Package and transportation symbols：

	Handle with care
	Temperature limit
	Upwards
	Limited layers of storage
	Keep dry
	Keep away from sunlight

1.4 Service life

Product life service: Six years. Continuing using the device after service life will increase the risk of failure and unpredictable risks.

Warning: Users will assume responsibility of the risks associated with the use of the device after recommended.

Warning: The disposal of the products should comply with the local regulations.

1.5 Operating conditions

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

1.6 Declaration of electromagnetic compatibility

The operation of PadScan HD 3 will not interfere with other wired, wireless equipment and/or other electrical equipment. And it works properly under specified electromagnetic environment.

Warning: Use of the PadScan HD 3 under strong electromagnetic environments, close to generator, X-ray device, dental and physical therapy equipment, broadcasting station, or buried cables, etc... may appear signal interference in the image. Stop using the PadScan HD 3 until removal of the electromagnetic interference.

Warning: Sharing power supply may cause signal interference in the image. Eliminate the interference of electromagnetic coupling by means of test and verification.

Warning: Users replacing the equipment without prior permission from CARESONO may cause unintended electromagnetic compatibility problems. Only CARESONO-trained technicians can service the system.

1.7 Manufacturer declarations

The users will assume all the risks of changes or modifications of the device without the manufacturer’s permission.

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

Warning： Modifications must be inspected and tested by approved departments.

1.8 Contraindications

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

1.9 Promulgation of heat index and mechanical index

Heat index: PI＜0.1

Mechanical index: MI＜0.1

Chapter Two Cautions and Warnings

To ensure safety, please read the following contents before the operation. The device shall be operated only by the professional appointed or authorized by relevant medical institutions.

2.1 Pre-scan checks

(1) Make sure that all the cables are properly connected.
(2) Make sure the device is properly functioning.
(5) Keep the device away from sunlight and keep dry.

> **Warning:** Do not use if any part of the device or if cables display any signs of damage.

2.2 Safety preparation before operation

Make sure the probe is properly connected; make sure no water, chemicals or other material are on the device. During operation, pay attention to the main parts of the device. If there is strange sound or smell, stop using the device until the authorized engineer solves the problem.

2.3 Operation instructions

> **Warning:** Do not plug or unplug the probe into the system while the power is ON. Connecting the probe while the power is ON may cause damage to the probe and main unit.

1. Do not drop the probe. Always use ultrasound gel with the probe to ensure proper contact.
2. Pay attention to the main parts of the device. If strange noises or smells are emitted from the device, stop the operation at once, power OFF and unplug all cables.
3. Patients must not touch other electrical equipment during examination.
4. Do not cover the air vent of the device.

2.4 Notice after operation

1. Turn off the power supply.
2. Pull out the power plug from the power sockets.
3. Clean the device and the probe.

2.5 Conditions to avoid

This device should avoid the following:

(1) Spraying water
(2) High humidity
(3) Poor draught
(4) Direct sunlight
(5) Dust environment
(6) Gas with salt or sulfur
(7) Chemical medicines or gas
(8) Strong vibration and crash
(9) Our company takes no responsibility for the risk of disassembling, refitting without our permission.

2.6 Cautions when using the probe

(1) Do not immerse the probe in water or any other liquids.
(2) Keep probe away from heat sources.
(3) To avoid damaging the cable or transducer connector, handle them with care. Do not bend or pull probe cable.
(4) It is recommended to use standard ultrasound gel only. Other substances may damage the probe and the probe cable.
(5) Keep the probe clean. Use standard detergent or clean water to clean the ultrasound gel off the probe.

2.7 Cautions when handling the device

(1) Always pull out of the power plug
(2) Do not drop, shake, or hit the probe and the device.

2.8 In case of device failure

If it is suspected that the device is not operating properly, turn OFF the power and unplug the power. Contact CARESONO technical support for help.

2.9 Regular check and maintenance of the device

2.10 Do not disassemble the device and the probe at random

2.11 Power on

Plug the AC input plug of the adapter into a power outlet. Insert the DC output plug of the adapter into the DC14V port on the side of the device. The DC output indicator light turns green to signal it is working properly.

Afterwards, turn on the machine, the indicator light on the left of Power On button will turn green, and then it will come into the operating interface.

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Chapter Three System Introduction

3.1 Figuration

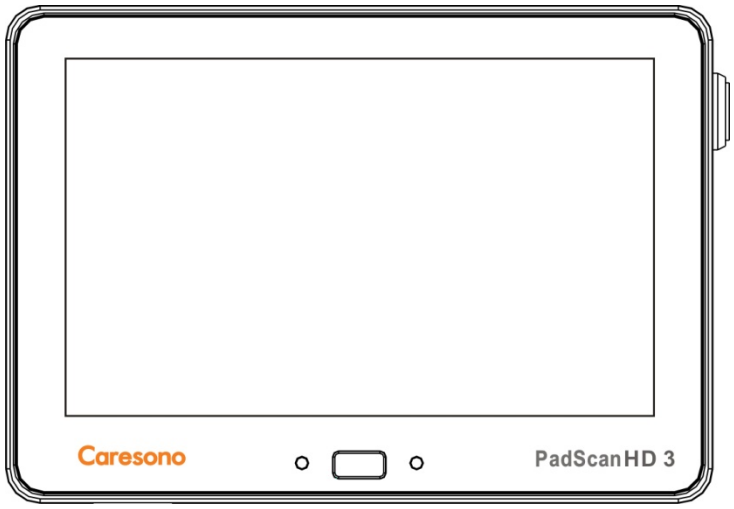


Figure 3-1 PadScan HD3 front

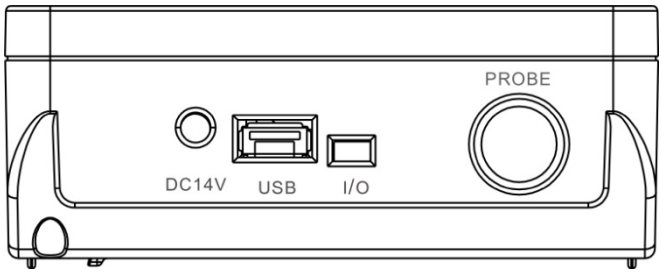


Figure 3-2 PadScan HD3 side connection ports

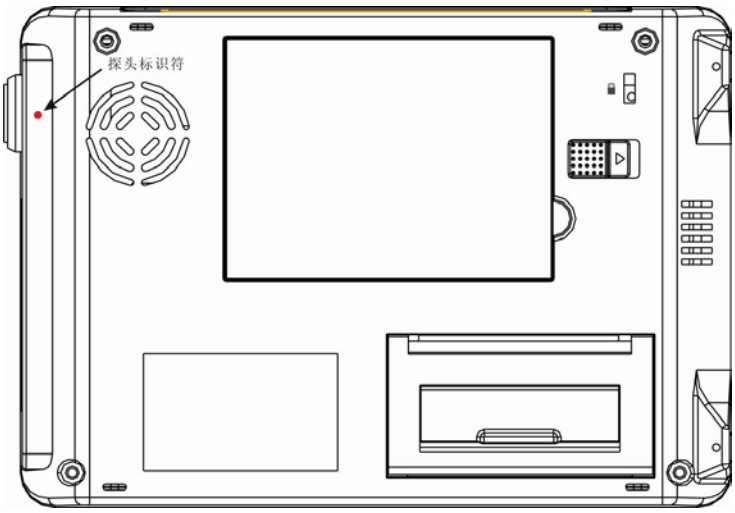


Figure 3-3 PadScan HD3 back

3.2 Specification

- Probe：3D mechanical sector probe
- Standard ultrasonic frequency of operation: 2.5MHz
- Volume measure range： 0ml-999ml
- Volume measure accuracy：±15%
- Volume display resolution：1ml
- Scan time：＜5 seconds
- Battery capacity：2600mAh
- Operation methods：touch screen
- Tissue Harmonic Imaging
- Patient data storage
- Information print
- 3D display：Dynamic figure of the bladder
- Socket of USB disk: Save the patient data through USB disk
- USB port：Connect with the computer
- Monitor size：7 inch TFT-LCD
- Power：50W
- Dimensions：185x130x50mm
- Weight：approximately 1200g（including the probe）
- Power at the state of charging：40-120VA
- AC power supply, batteries full charged or supply by the batteries：30-40VA
- Battery charge time：2 hours
- Battery life：3 hours continuous scanning

3.3 Block diagram

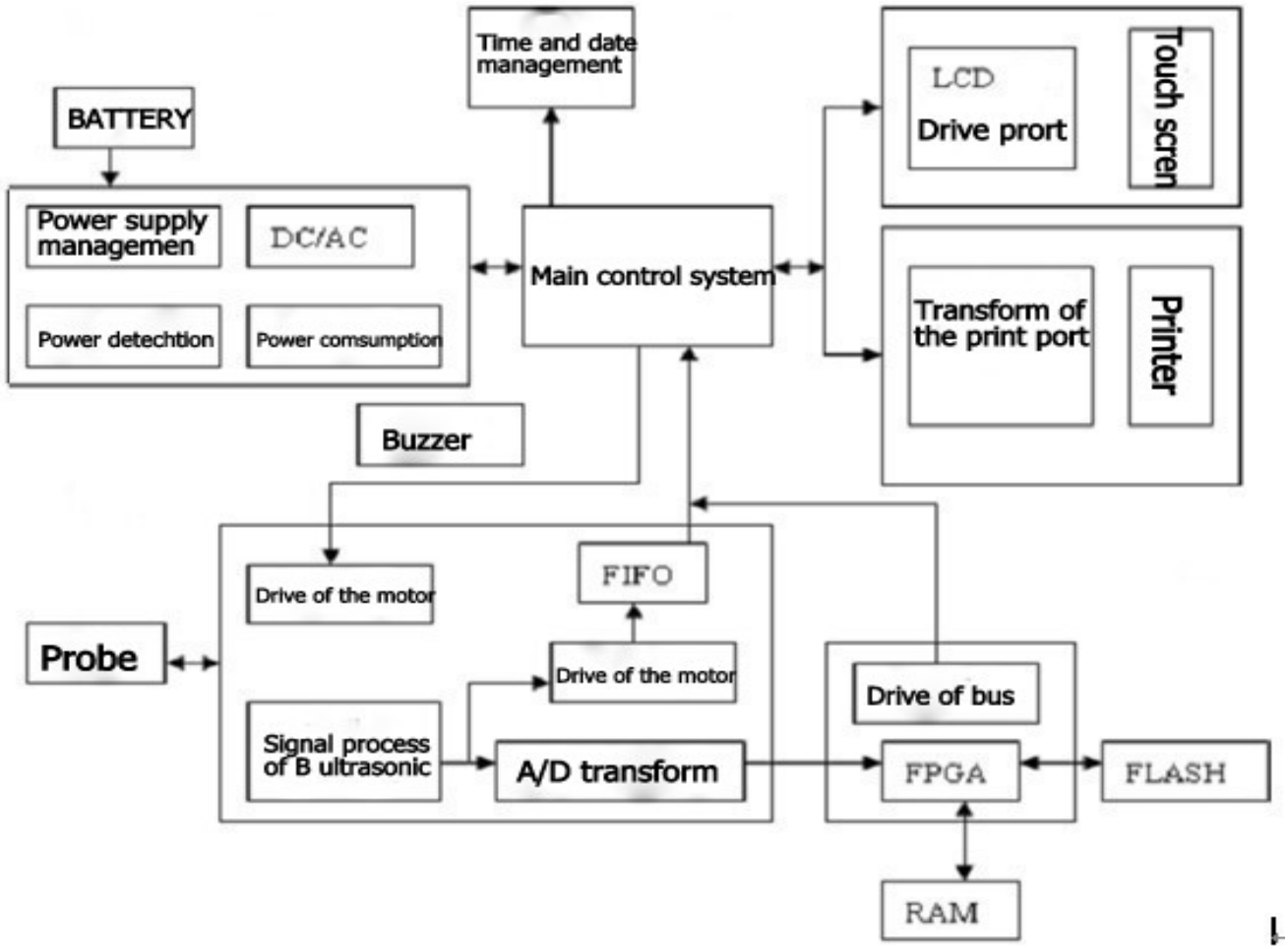


Figure 3-4 PadScan HD3 electricity principle diagram

3.4 Basic Principle

The device utilizes a 3D Mechanical sector scanning probe to provide ultrasonic scans of the bladder, and translates the scanned information of the bladder into 2D ultrasonic images. It captures multiple cross-sectional areas of the bladder through an enhanced image processing technique and produces 3D images, which calculates the volume of the bladder.

Operating principle: 1. Transmits the pulse signal to the 3D probe. Launch the ultrasonic wave to the human body via the transducer of the probe (such pulses can only acquire one signal of one plane, meaning to produce a 2D image section it needs to send ultrasonic waves at least 96 or 128 times to form one section.) The ultrasonic wave transmits, or scatters, a wave through the body, and sends the received reflected signal to the DSC via the transducer, and proceeds with a serials of signal processing methods: logarithms compression, detection, dynamic filter, edge enhancement, frame relevance, line relevance, etc., to form one high-definition section image to display on the screen.

2. Two generator systems drive the crystal oscillator located on the top of the 3D probe in a rotate and pendulum motion. The bottom motor drive of the crystal oscillator performs a rotation motion of 1800, the top motor drive of

the crystal oscillator performs an oscillating motion of 1200. When the bottom motor reaches the edge and remains fixed; the top motor performs 1200 oscillating motion to acquire an ultrasonic image. The bottom motor rotates 150, is fixed, and the top motor rotates 1200, acquiring the second image. The process is performed repeatedly until the bottom motor rotates 1800, stops, acquires 13 images, takes 12 of them, processes and calculates by the inner core of FPGA to figure out the volume of the bladder.

3.5 Device constituent

- A main unit
- A power adapter：AC100-240V±24V　50/60Hz,　Main unit：DC14V±0.5V
- A N2/2.5MHZ 3D mechanical sector scanning probe
- A Li-ion battery: model: UR18650ZY-2600mAh (SNLB-159)
- An user manual
- A packing list
- A carrying case

Chapter Four Installation

4.1 Unpacking inspection

After unpacking, first affirm that there is no shipping damage, then check the device according to "Packing List" and install it according to the requirements and methods described in "4.2".

4.2 Installation and disassembly

- Check the adapter to see if it works well, make sure it is in the specified range and then plug the AC input plug of the adapter into a power outlet.
- Connect the main unit to the docking station. Align the socket on the bottom of the main unit with the docking station and place it into the docking station. See the following diagram as figure 4-1:

  Step 1: insert here

  Step 2: screw in tightly

  Step 3: tighten the screws as shown

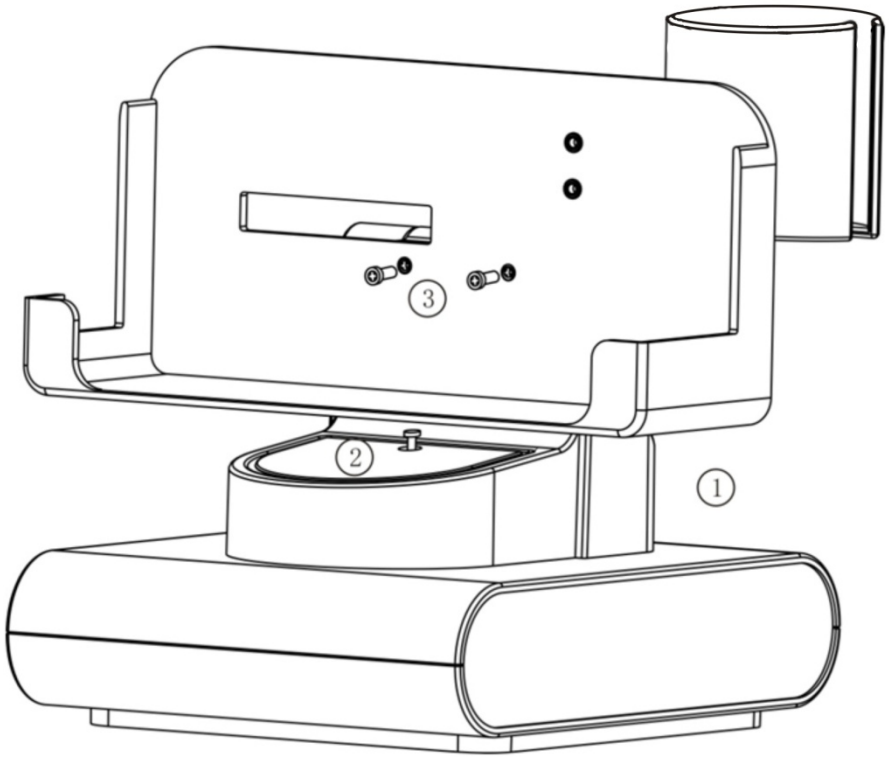


Figure 4-1 PadScan HD3 docking station and main unit connection diagram

● 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, and insert the probe into the main unit as figure 4-2.

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

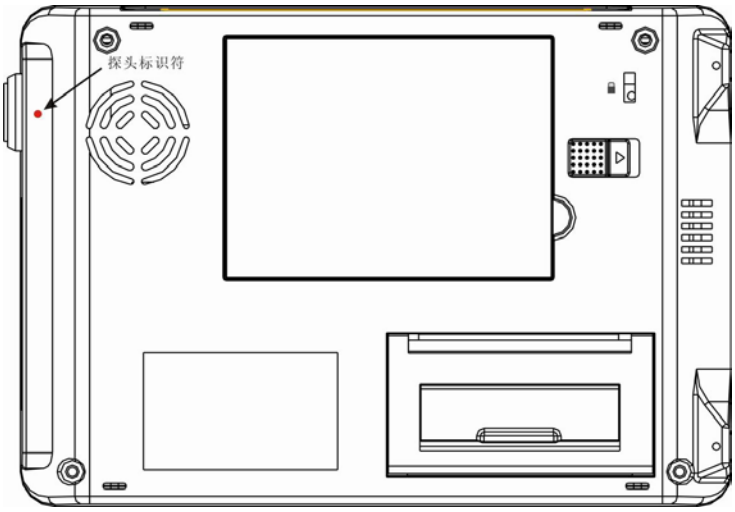


Figure 4-2 PadScan HD3 probe and main unit connection diagram

● Battery installation and removal

Battery installation: Insert the locating plate of the battery into the locating hole of the battery slot, and move the locking key of the battery to top. Insert the battery into the slot slowly, and then move the locking key to the end of the device. Show as figure 4-3:

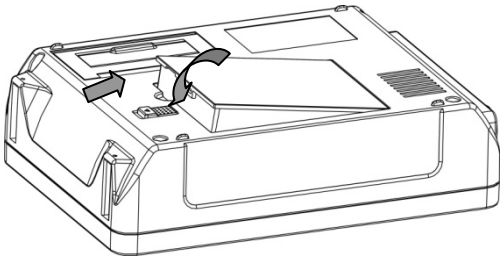


Figure 4-3 PadScan HD3 battery installation diagram

Battery removal：Move the locking key of the battery to the top of the device, pull out of the battery box at the side seam between the battery and the device. Show as figure 4-4.

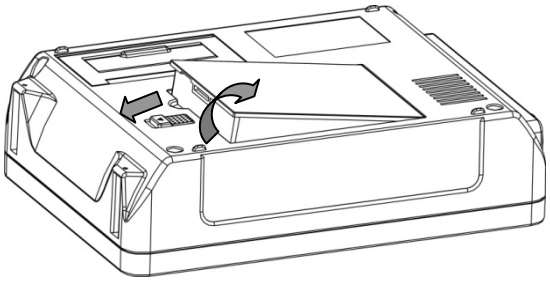


Figure 4-4 PadScan HD3 battery removal diagram

4.3 Power supply

The power is supplied by two interchangeable methods: adapter and built-in battery.

4.3.1 Adapter power supply

1. Check the adapter to see if it works well, check the EPS to see if it is in the specified range. Insert the AC input plug of the adapter into the base of the power supply. The output voltage of the adapter is DC 14V.
2. Insert the output plug of the adapter into the DC14V socket on the right side of the device. the power light indicator on the right turns green to signal it is functioning. Press the power button to turn on the main unit. The light indicator on the left turns green to signal it is functioning.

> **Warning:** Use only CARESONO supplied power adapters. Ensure a tight connection between the power cord and the connectors.

4.3.2 Battery power supply

1. Install the battery into the main unit as described in "**4.2**". The power light indicator on the right turns green.
2. Press the power button to turn on the main unit. The light indicator on the left turns green to signal it is functioning.

4.3.3 Battery power charging

1. Install the battery into the main unit
2. Insert the output plug of adapter into DC14V socket on the right of the main unit
3. Insert the AC plug of the adaptor into the power supply socket
4. When the main unit is on or off, the power light indicator on the right turns yellow to signal it is charging. When the light turns green, it means the battery is fully charged.

Chapter Five Operating Interface

5.1 Main interface

5.1.1 Expert Mode

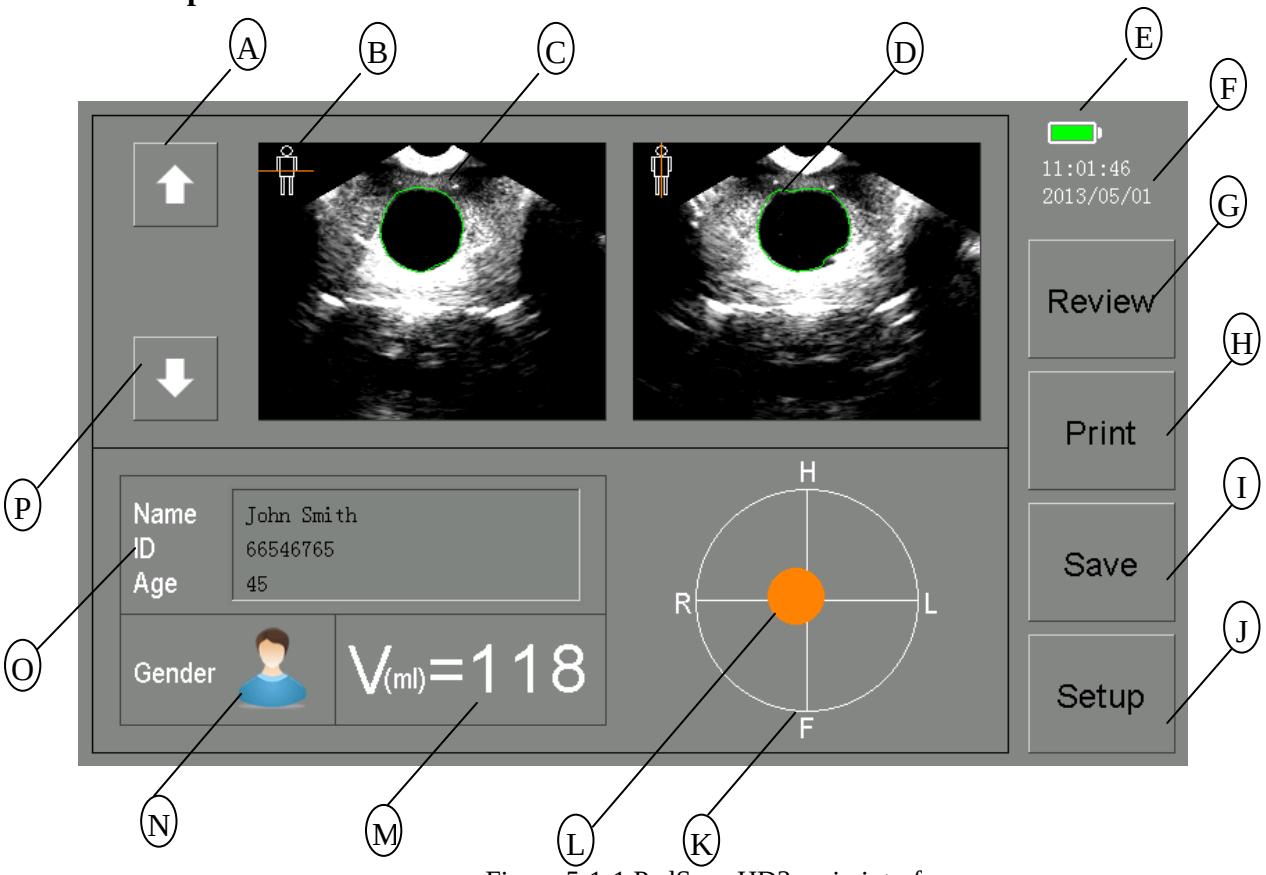


Figure 5-1-1 PadScan HD3 main interface

A：Tap to review the previous image
B：Current scanning position
C：Bladder ultrasound image
D：Ultrasound image outlining
E：Battery status indicator
F：Date and time
G：Tap to review patient data
H：Tap to print current scan
I：Tap to save current scan
J：Tap to enter setup menu
K：Projection crosshair
L：Bladder projection
M：Current volume value
N：Tap to choose gender
O：Patient information
P：Tap to review next image

5.1.2 Easy Mode

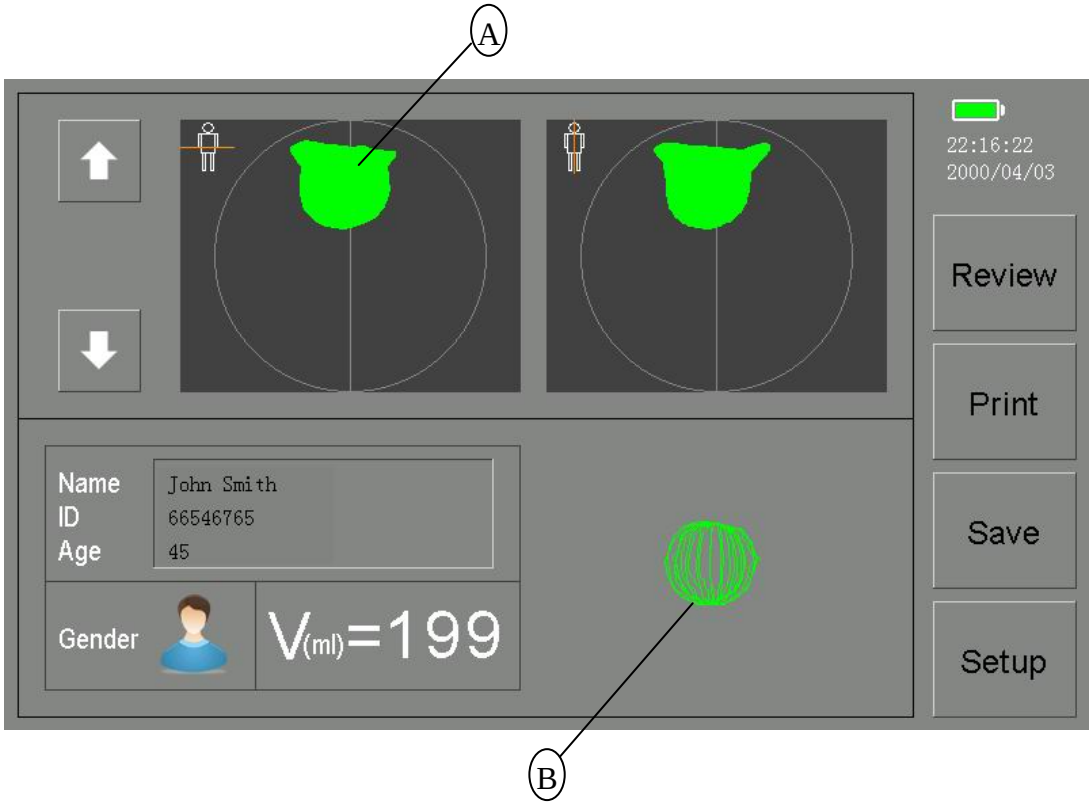


Figure 5-1-2 PadScan HD3 main interface

A. Section sketch of the bladder

B. 3D display of the bladder

5.2 Bladder scanning interface

5.2.1 Expert Mode

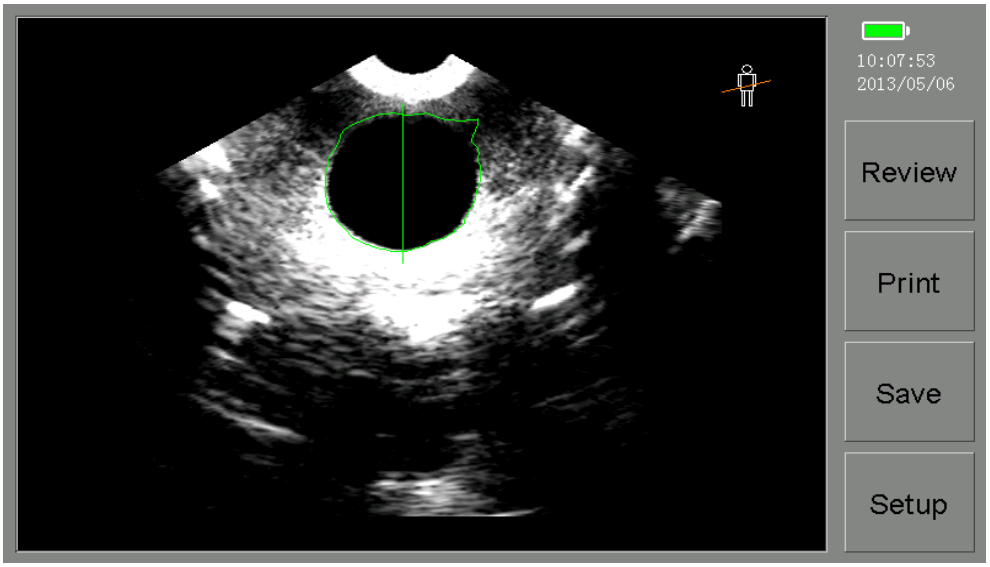


Figure 5-2-1 PadScan HD3 Expert Mode bladder scanning interface

5.2.2 Easy Mode

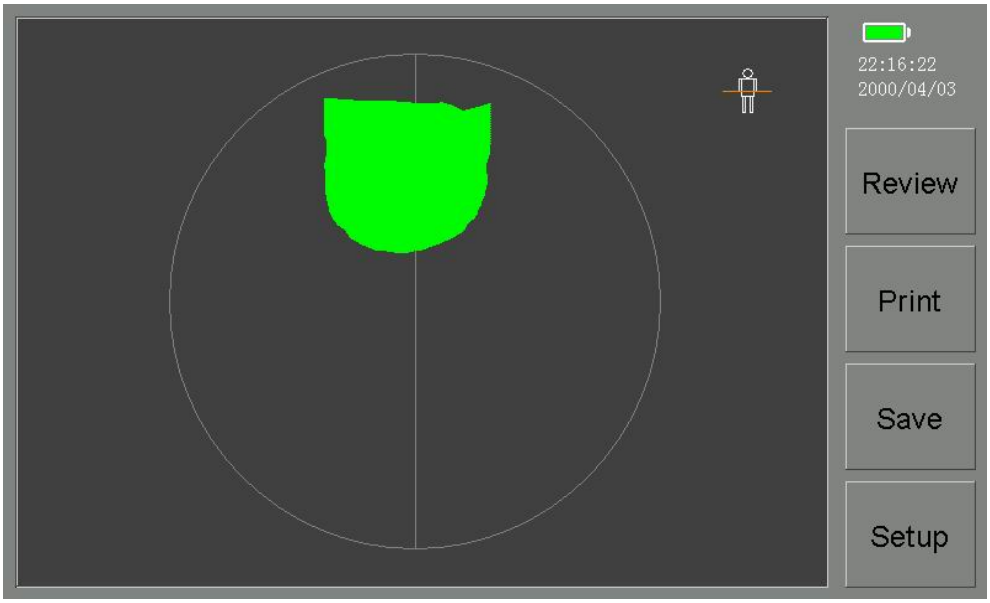


Figure 5-2-2 PadScan HD3 Easy Mode bladder scanning interface

5.3 Patient information input interface

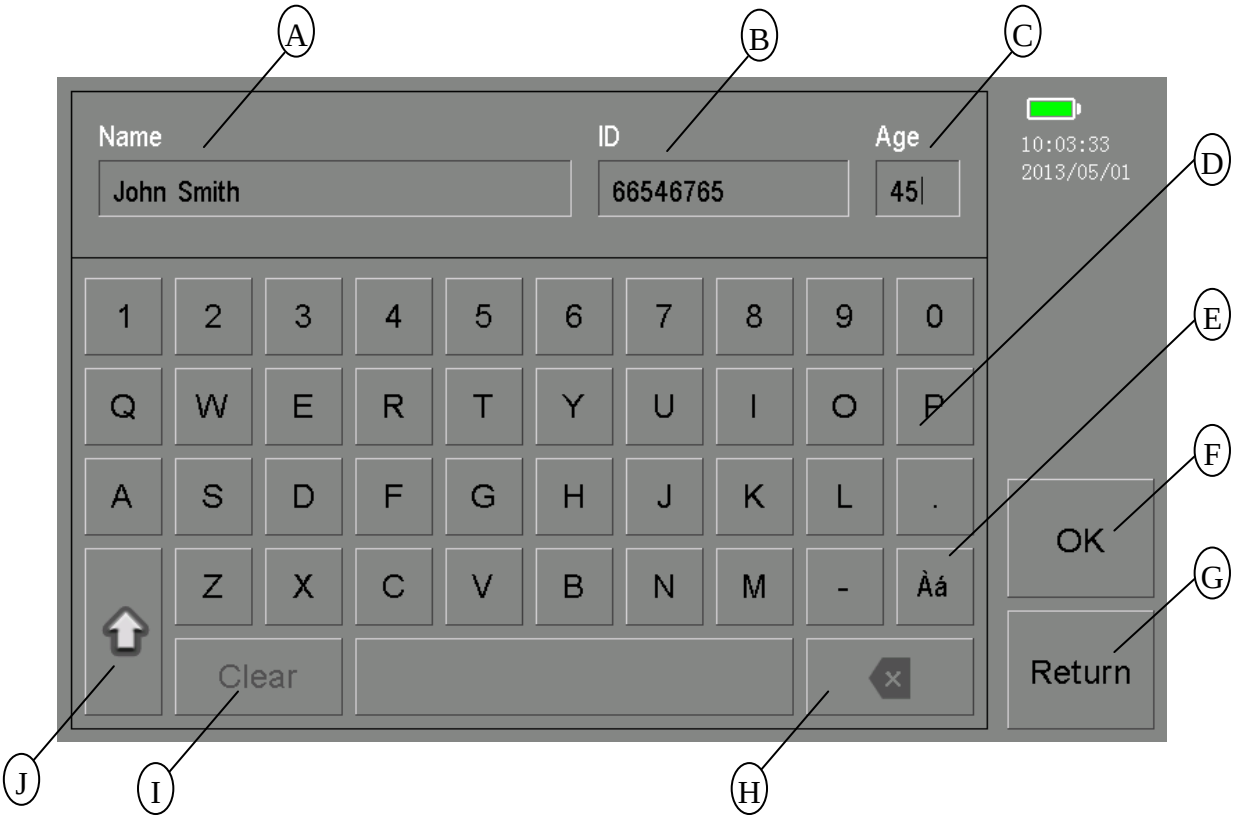


Figure 5-3 PadScan HD3 patient information input interface

A：Patient name
B：Patient ID
C：Patient age
D：English keyboard
E：Switch to multilingual keyboard
F：Confirm and return
G：Cancel and return
H：Backspace
I：Clear current input
J：Caps lock

5.4 Patient information review interface

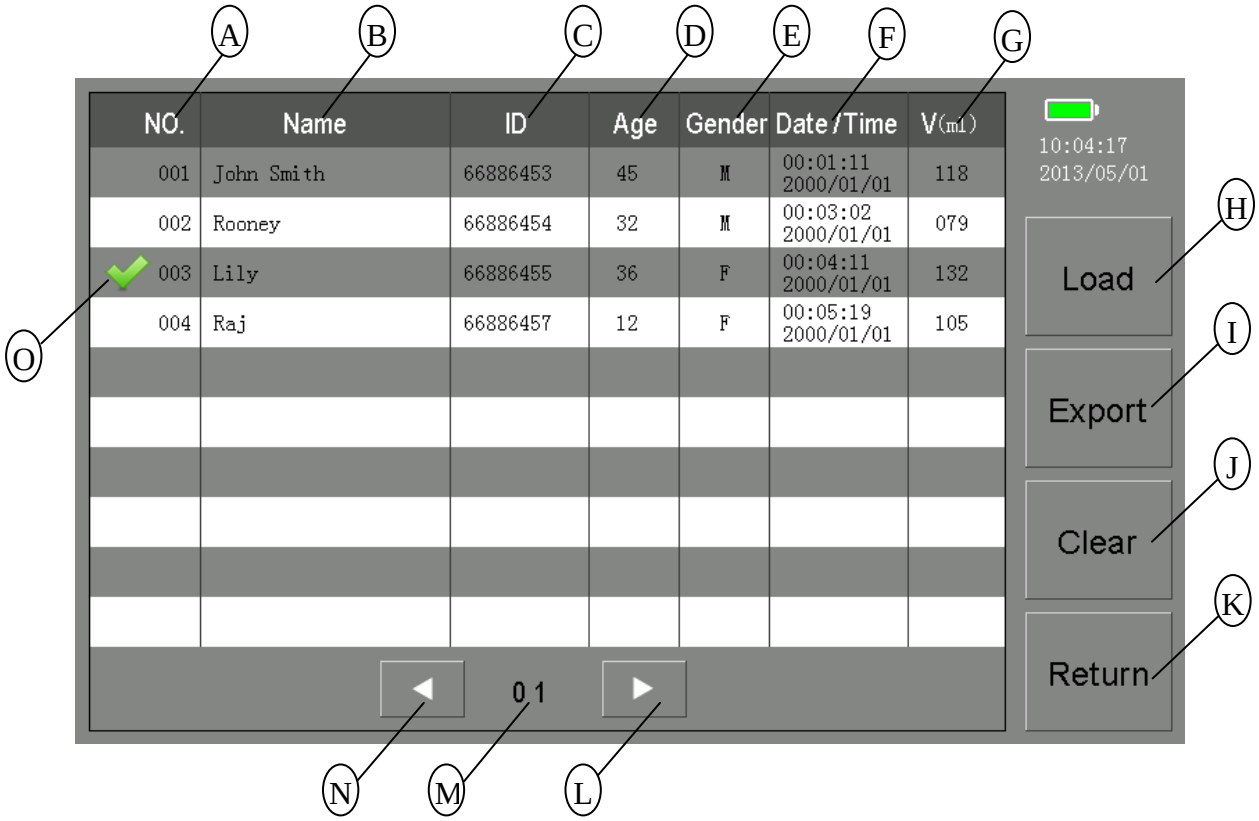


Figure 5-4 PadScan HD3 patient information review interface

A：Sequence number
B：Patient name
C：Patient ID
D：Patient age
E：Patient gender
F：Time and date
G：Urine volume
H：Load selected patient case
I：Export all patient data to USB disk
J：Clear synchronization mark/Clear all patient data
K：Tap to quit the patient management interface
L：Next page
M：Current page
N：Previous page
O：Selected patient

5.5 System setup interface

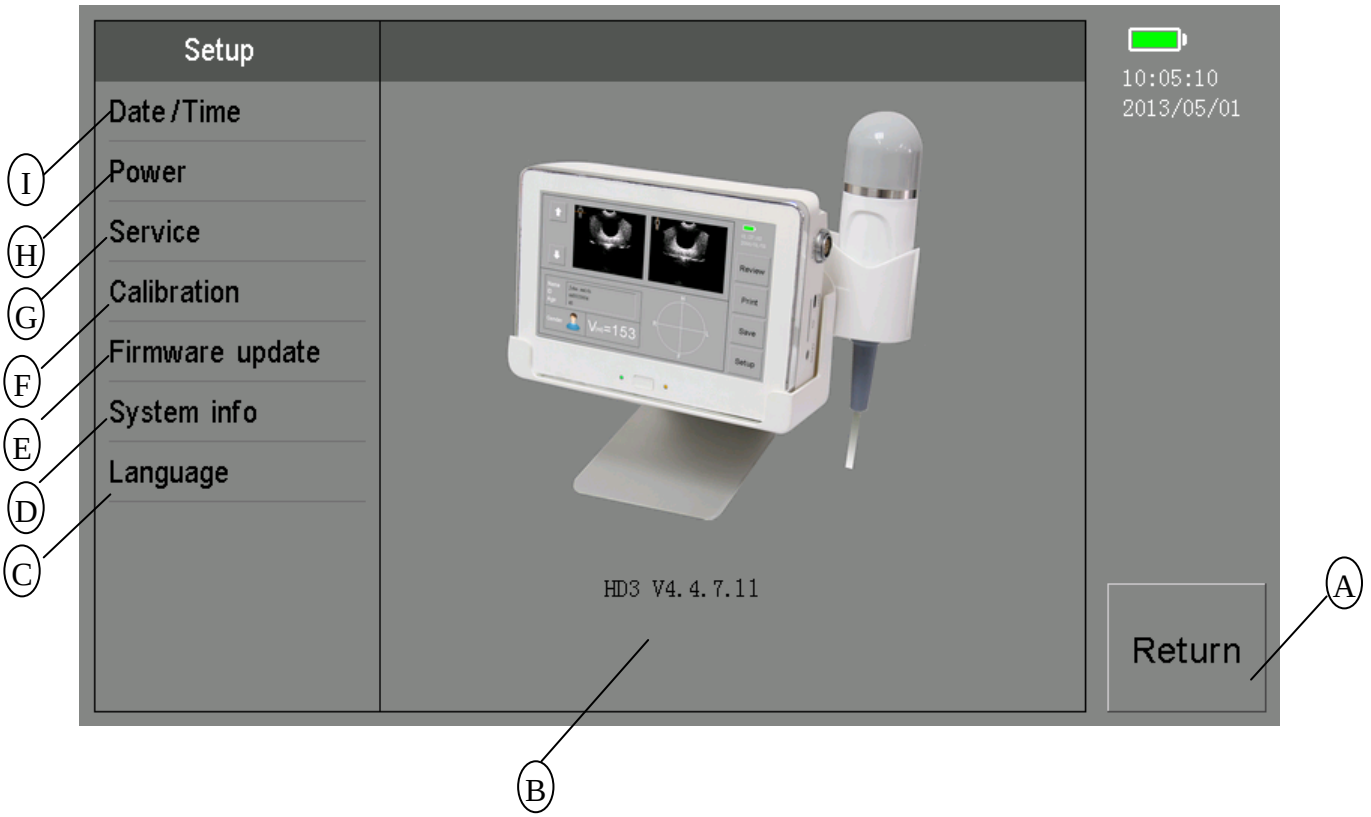


Figure 5-5 PadScan HD3 system setup interface

A：Tap to quit system setup interface
B：Version number
C：Tap to setup interface language
D：System information
E：Firmware update
F：Device calibration
G：Service
H：Power management
I：Time and date

5.6 Time and date setup interface

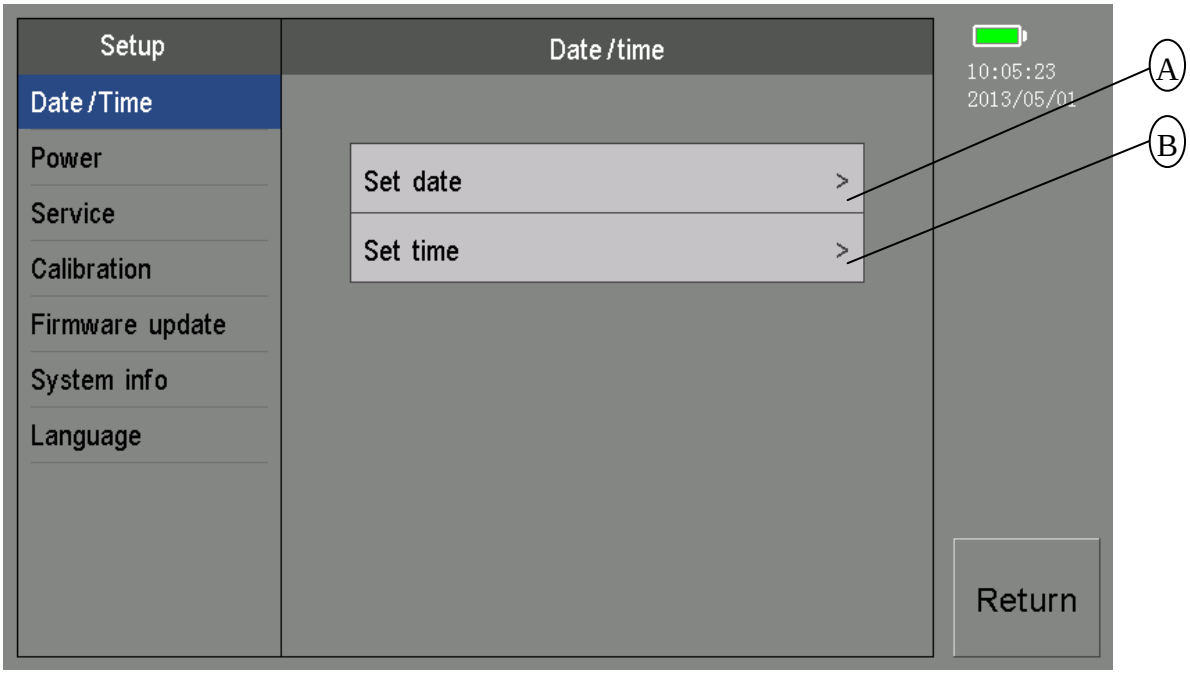


Figure 5-6 PadScan HD3 time and date setup interface

A：Set date

B：Set time

5.7 Power management interface

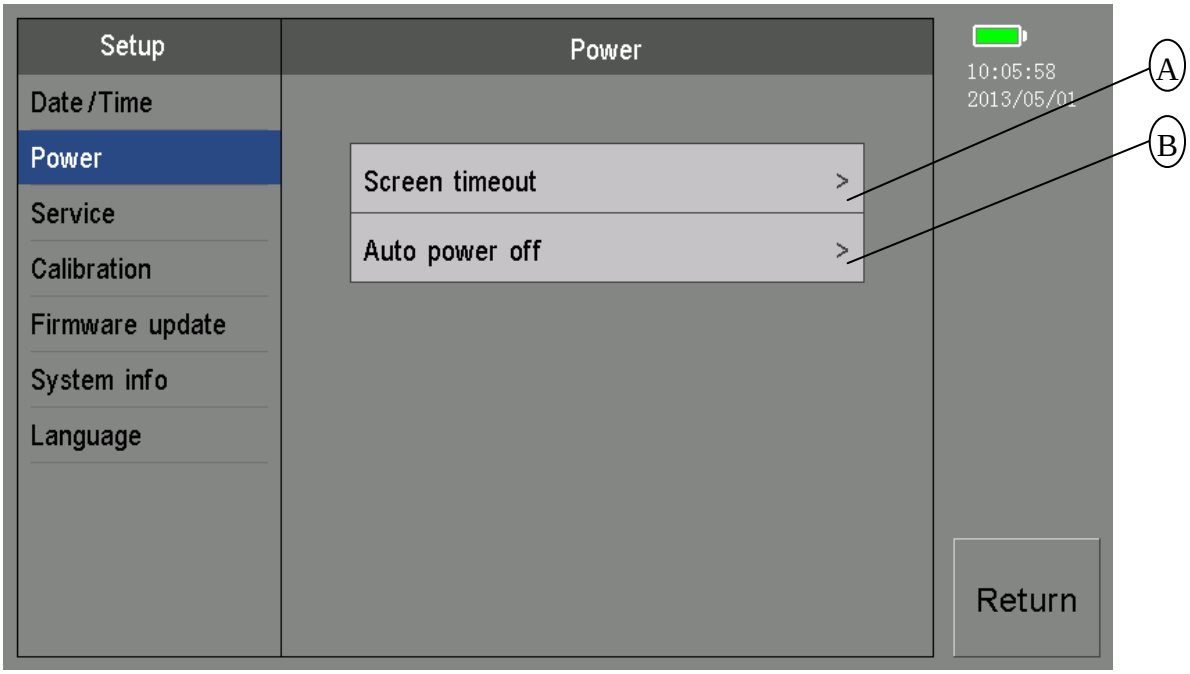


Figure 5-7 PadScan HD3 power management interface

A：Screen timeout setup

B：Auto power off setup

5.8 Service interface

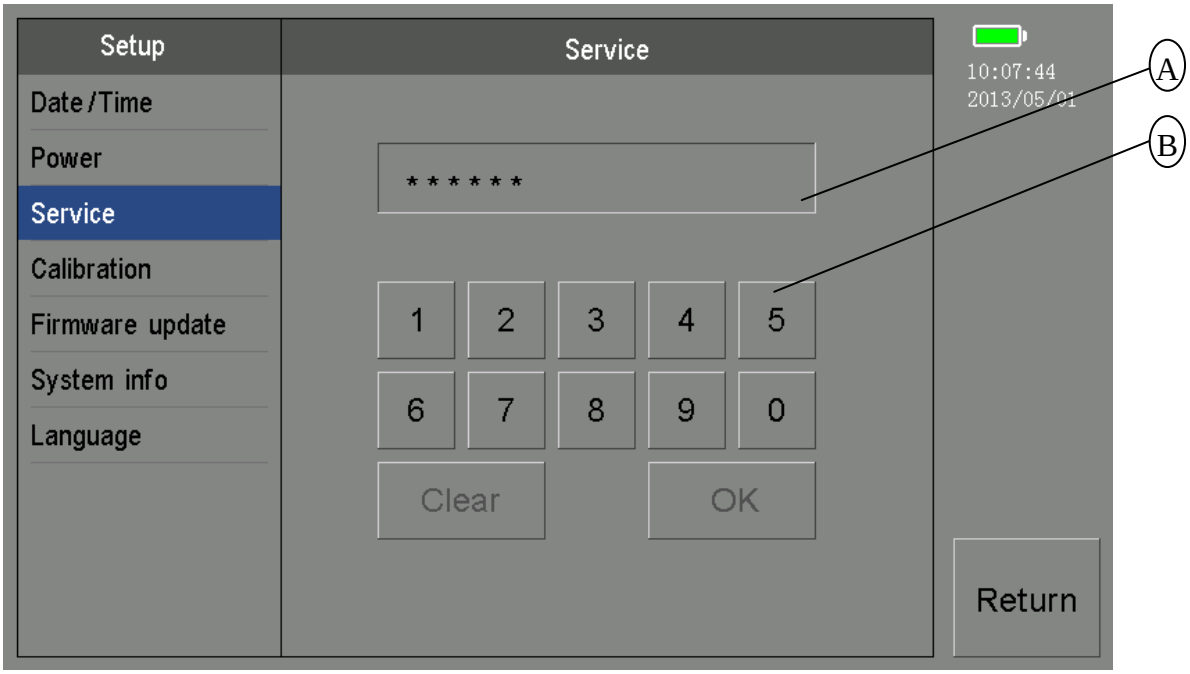


Figure 5-8 PadScan HD3 service interface

A：Password input

B：Password input keyboard

5.9 Device calibration interface

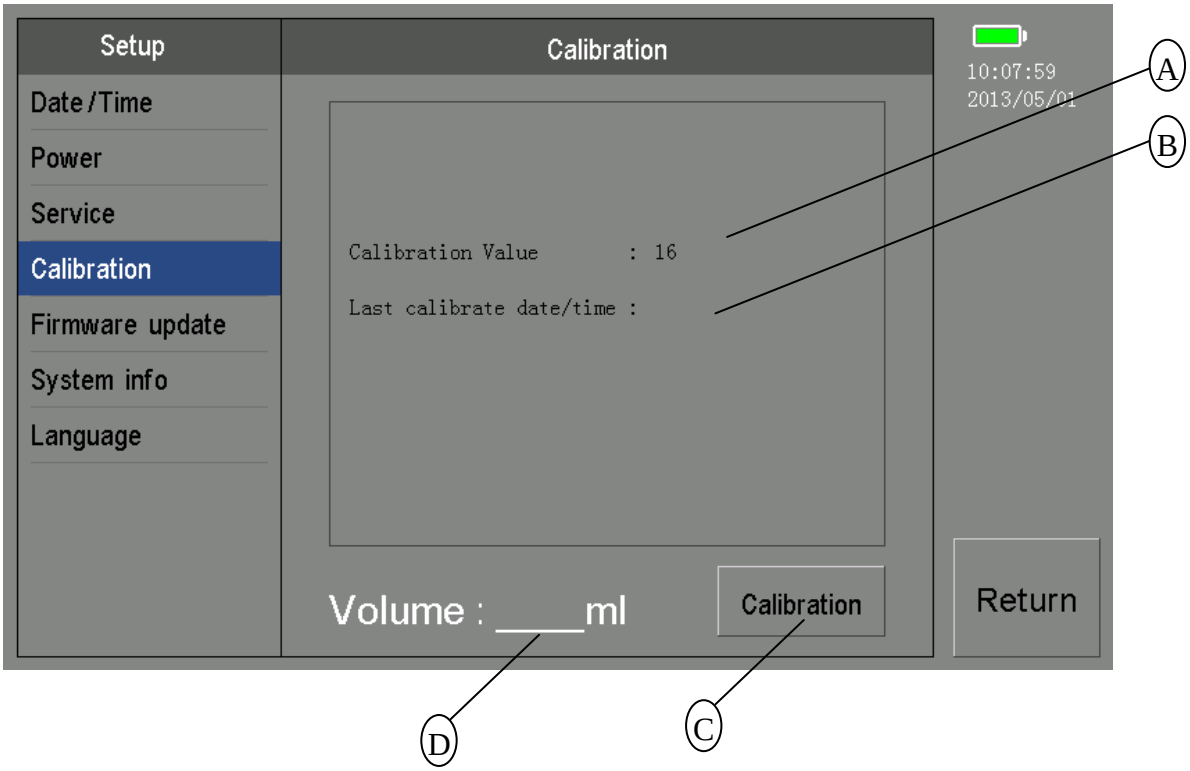


Figure 5-9 PadScan HD3 device calibration interface

A：Current calibration value

B：Last calibration date/time

C：Calibration key

D：Current phantom volume value

5.10 Firmware update interface

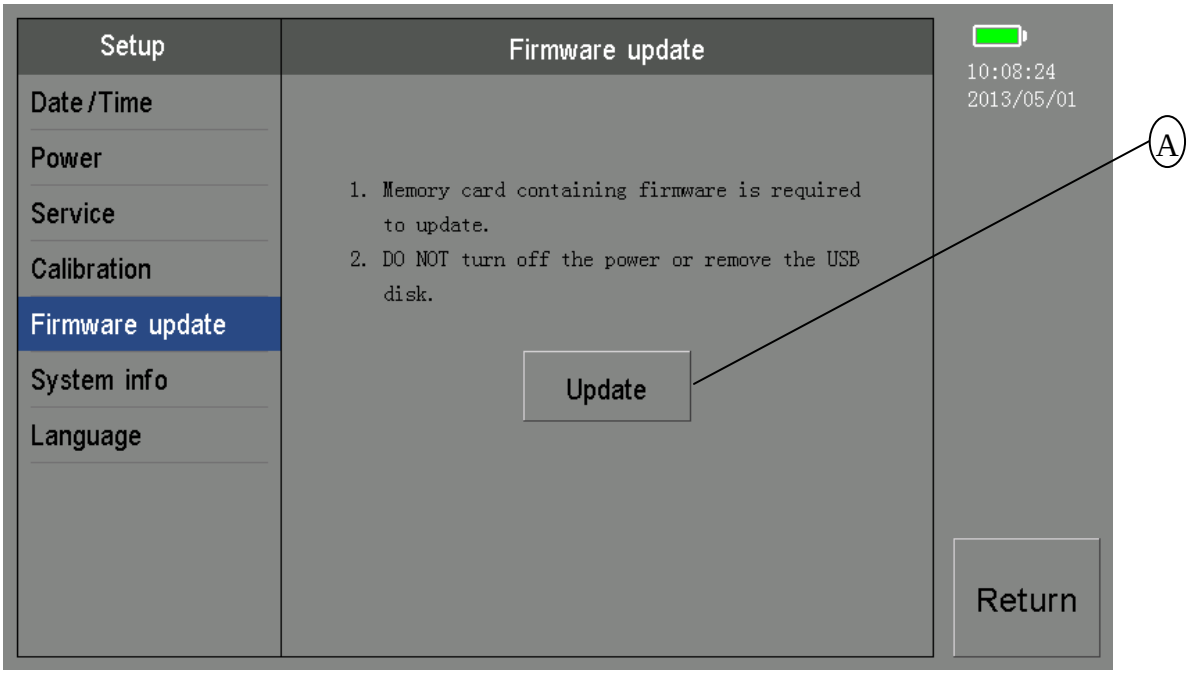


Figure 5-10 PadScan HD3 firmware update interface

A：Tap to update firmware

5.11 System information interface

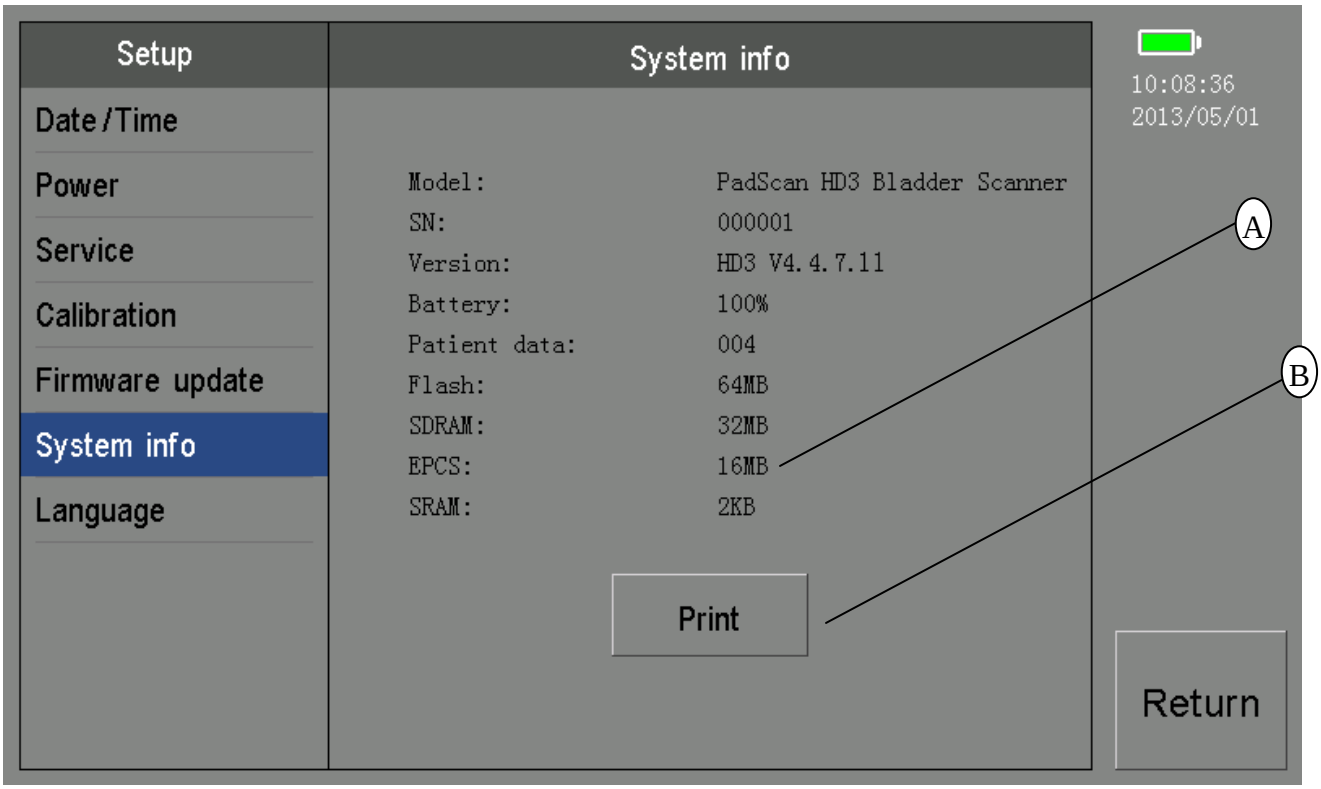


Figure 5-11 PadScan HD3 system information interface

A：System information

B：System information printout

5.12 Language selection interface

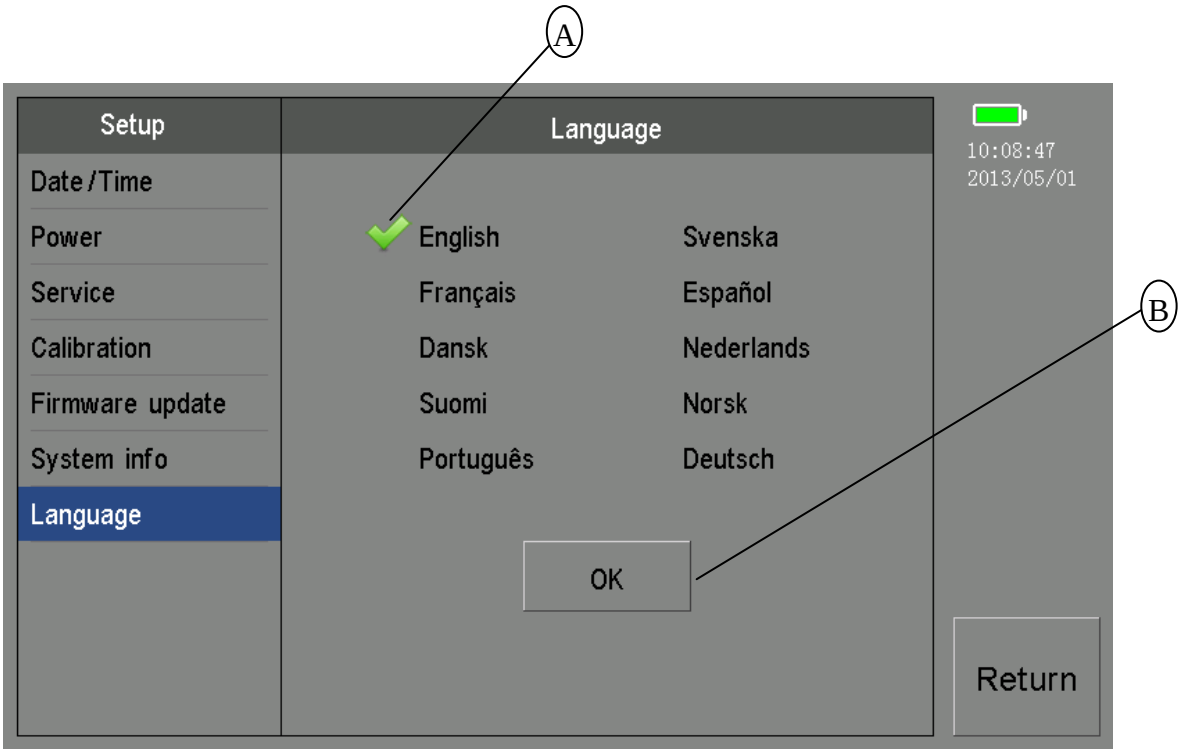


Figure 5-12 PadScan HD3 language selection interface

A：Current interface language selected marker

B：Confirm key

Chapter Six Operation

6.1 Bladder scanning

6.1.1 Gender

Power on and enter the main interface shown as figure 5-1-1. Tap  to change gender. The default gender is male. (male  , common female  , hysterectomized female  , child ).

6.1.2 Pre-scan

Coat the hypogastrium of the patient and the probe with ultrasound gel before the scan. Place the probe on the patient's bladder. Press the button on the probe to start Pre-scan, now B ultrasonic real time image of the bladder (figure 5-2-1) or section sketch of bladder(figure 5-2-2) will be displayed on the screen.

6.1.3 Scanning

After locating the bladder, press the button on the probe again to start scanning. The upper right image  displays the scanning position. Afte scanning, the beep sound will be heard. Return to the main interface and the bladder volume value will be dsipalyed on the main interface.

6.2 View the scanned images

Tap the  and  to view six groups of sectional iamges of the bladder.  indicates the current scanning position.

6.3 Input patient information

Tap 

on the main interface to enter patient information input interface (figure 5-3). Tap "Name、ID、Age" to input corresponding information. Tap 

to swithc English keyboard and multi-language keyboard. Note: for Name, 20 letters can be added. For ID, 10 letters can be added. For Age, 3 digits can be added.

6.4 Print patient information

Tap Print on the main interface to print current patient information(name, ID, age, gender and volume value) and current two ultrasound images. Name, ID and age can be inputted before scanning or after scanning.

6.5 Save patient information

Tap Save on the main sceen to save current patient information(name, ID, age, gender and volume value) and six groups of sectional ultrasoud iamges. Name, ID and age can be inputted before scanning or after scanning. Note: if the operator inserts the U disk when saving, data will be saved to the U disk first. After removing the U disk, data can be saved into HD3 once more. If no U disk is inserted, data will be directly saved into the HD3.

6.6 View patient information

Tap Review on the main interface to enter patient information interface (figure 5-4). All saved patient informaiton is listed on this interface. Tap ◀ and ▶ to view all the patient information. 100 patients' information can be saved.

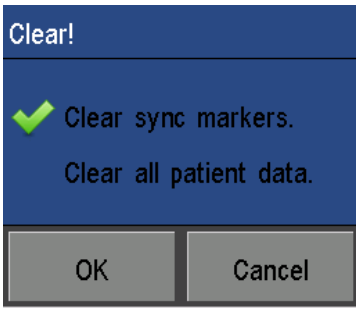
6.6.1 Export patient information to the main interface

After selecting the patient information, tap Load and current patient informaitonand iamge will be exported to the main interface.

6.6.2 Export patient information to the U disk

Insert the U disk, select patient information and tap Export, the dialog on the right will appear on the screen. Select 1 to export the selected patient information, while select 2 to export all the patient information. Tap OK to export. If no U disk is inserted, the system will prompt that no U disk can be found.

6.6.3 Clear sync markers/Clear all patient data



Tap Clear and the dialog on the right will appear. If the operator selects the first one, sync markers will be cleared. After the upper computer synchronizes with HD3, HD 3 will mark the sychronized patient data. When the patient information saved on HD 3 has increased, the upper compute will only synchronize patient information that has not been marked. When the synchronized patient information is cleared by mistake, all the patient information will be synchronized again as long as the markers are cleared on HD 3.

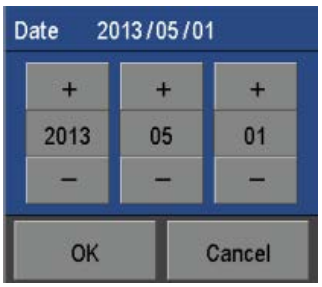
If the operator selects the second one, all the patient information will be cleared. Please make sure the patient data are saved on HD 3 before clearing. This operation cannot be restored.

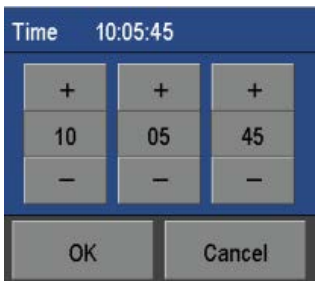
6.7 System setup

Tap Setup on the main interface to enter system setup interface（figure 5-5）. Time and date, power management, service function, device calibration, firmware update, system information print and interface language can be set on this interface.

6.7.1 Time/Date

Tap “Date/Time” on the system setup interface to enter time and date setup interface (figure 5-6）. Tap “Set Date” and the dialog box on the right will appear. Tap “+”, “ -” to change the date. Tap “OK” to save and return.

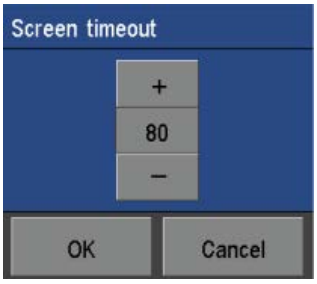


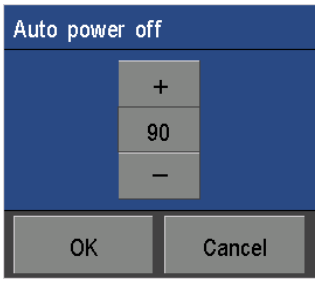


Tap “Set Time” and right dialog will appear. Tap “+”, “-” to change the time. Tap “OK” to save and return.

6.7.2 Power management

Tap “Power” on the system setup interface to enter power management interface Figure 5-7）. Tap “Screen timeout”





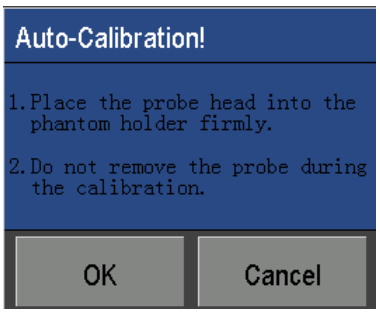
and dialog box on the right will appear. Tap “+”, “-” to adjust effective time of screen timeout. Tap “OK”to save and return.

Tap “Auto power off” and right dialog will appear. Tap “+” , “-” to change the time of auto power off. Tap “OK” to save and return.

6.7.3 Service function

Tap “Service” on the main interface to enter service function interface（figure 5-8）, and input password “136919” to enter calibration setup interface. Tap “Reset” to reset the calibration value to default value 16. Input “123456” for entering interface of option mode, click “expert” or “easy”for switching mode.

6.7.4 Device calibration



Tap “Calibration” on the system setup interface to enter device calibration interface (figure 5-9). Place the probe into given phantom, tap scan and the current volume value will be displayed. Tap Calibration, the dialog box on the right will appear. Place the probe into given phantom. Do not move the probe during calibration. Tap OK to do calibration. System will prompt if the calibration is successful or not when it is done. The device has been calibrated when manufacturing. There is no need for the users to do calibration.

6.7.5 Firmware update

Tap “Firmware Update” on the system setup interface to enter firmware update interface (figure 5-10). Insert the U-disk that has update firmware into the main unit. Then tap update.

6.7.6 System information

Tap “System info” on the system setup interface to enter system information interface (figure 5-11). System information of HD3 will display on this interface. Tap Print to print current system information.

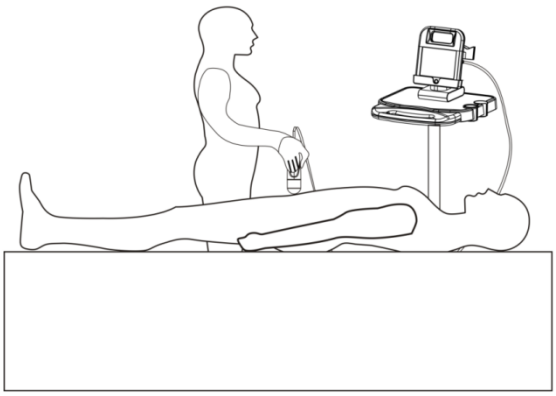
6.7.7 Interface language

Tap “Language” on the system setup interface to enter language selection interface (figure 5-12). The device supports 10 languages. They are English, French, Danish, Finnish, Portuguese, Swedish, Spanish, Dutch, Norwegian and German. Select the language and tap OK.

6.8 Connect to PC

First install upper computer USB driver. Methods of installation: run CH372DRV.EXE under upper computer\chip driver installation\EXE directory. Wait for 12 seconds and the driver will be installed automatically. Then insert the big head of USB transfer line into the USB of computer, and the other head into HD 3. Power on HD3 and enter patient information management interface. Run PatientManager.exe and tap Tool\Sync Data to sync upload. Do not unplug the USB line during synchronization**.** After synchronization, all the patient data on HD3 flash will upload onto upper computer.

6.9 Prepare patient and position probe

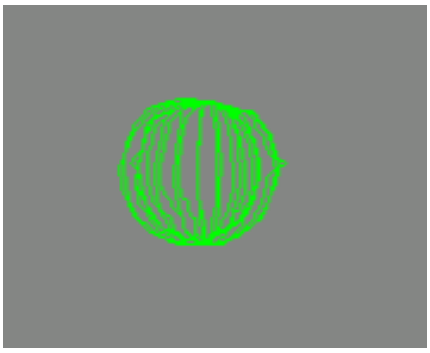


Locating the position of the bladder is the most important step of obtaining correct volume measurements. As illustrated in the figure on the right, the bladder is located in the hypogastrium, below the navel. Apply ultrasound gel on the lower abdomen of the patient before the scanning. Place the probe as illustrated in the figure; tilt the probe slightly toward the patient’s coccyx (tailbone) so the scan clears the pubic bone. The probe button should always face up toward the patient’s head.

In order to correctly measure the volume of the bladder, grasp the probe as shown in the figure on the right.
A guideline visible on screen helps center the bladder during pre-scan and scan.
The operator moves the probe to ensure the image of the bladder is centered on the screen.
It is to get the biggest and centered cross-section area of the bladder.
If it is centered, the guideline will be in green.
Otherwise, the guideline will be in orange.
After scanning, there will be orange projection displayed on the screen (figure 5.1).
If the orange center doesn’t deviate from the crosshair too much, which means the scanning is effective.

6.10 3D dynamic display of bladder

After scanning, the projection will be displayed on the main screen first. The user can refer to the projection to decide if the scanning is effective. After few seconds, green 3D image of the bladder will display as shown in the right figure. Referring to 3D image, the user can view dimensional shape of the bladder. If the rotating 3D image shows the bladder is off-center, which means the probe isn’t placed in the center of the bladder during scanning.



Chapter Seven Cleaning and Maintenance

To ensure that the device functions normally, please perform regular cleaning and maintenance of parts, accessories and probes with neutral detergent.

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 soft, clean cloth dampened with isopropyl alcohol (or an appropriate hospital cleaning agent), to clean the device's surface (including the keyboard).
- Control the time of sponging referring to the instructions of the detergents, and the interval time should also meet the clinical requirements.
- Dry the system's surface naturally or dry it with clean cloth referring to the instructions of the detergent label.
- Use soft and wet cloths with neutral detergents to clean the fingerprint or other filth on the display screen.

7.1.2 System maintenance

- Operate the system in the environment as outlined in "1.5".
- After shut down, wait five minutes before restarting the system.
- When the device is not used for a long time, pack the device and store in the environment outlined in "8.1".

7.2 Probe cleaning and maintenance

Please keep the probe clean to ensure the probe work normally and prolong its service life.

7.2.1 Probe cleaning

- 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 CARESONO's technical support department.
- Use a soft cloth dampened with isopropyl alcohol (or an appropriate hospital cleaning agent) to wipe the probe until it is thoroughly cleaned.

7.2.2 Probe maintenance

- Must not hit and drop the probe.
- Choose medical ultrasound gel that accords with national standard. If the ultrasound gel doesn't qualify, it will damage the probe and irritate the skin.

- Clean the probe each time after using it.

7.3 Battery usage and maintenance

- For optimum performance, it is recommended to charge and completely discharge a new battery two to three times before first use.
- The battery can be charged and discharged for hundreds of times， but it will be worn-out. When the work time shortens apparently, please replace it with a new one.
- Do not use, store and charge the battery near the fire.
- Must not short circuit the battery, wet the battery, disassemble the battery, drop the battery and hit the battery.
- The battery should be charged and discharged once every two or three months to prevent the battery invalidation. **Note**: The full battery which has not been used for a long time can discharge slowly. So, you should charge the battery which has not been used for a long time first, and then you can use it.
- If the battery is straining, discolored, heating, smelling or with other abnormal phenomena, stop using the battery at once. Remove it from the device or electricity charger and discard it according to the waste handling regulations.

7.4 Treating and disposing of products after use

The disposal of the waste product and battery should be accord with the local environmental protection regulations. Or contact with our service department.

Chapter Eight Transportation and Storage

8.1 Transporting the system

1. Unplug the power cord and put it in the carrying case.
2. Carefully place the main unit into the corresponding slot of the carrying case. Do not drop, shake or bang the probe or the device.
3. Carefully place the probe into the corresponding slot in the carrying case.
4. Cover the bottle of ultrasound gel tightly to prevent leaks and place it into the corresponding slot in the carrying case.

8.2 Transportation and storage conditions

Temperature: -40℃ to +55℃

Relative humidity: 10% to 80%

Pressure: 50kPa to 106kPa

8.3 Transportation

The labeling of the device packaging fulfills the requirements of **GB191 "Packaging-Pictorial marking for handling of goods"**. Simple shockproof materials are equipped in the carrying case, which are suitable for aviation, railway, highway, or steamship transportation. Keep dry, avoid inversion and collision.

8.4 System storage

1. 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.

2. Keep it in a well-ventilated area away from sunlight or caustic gases.

Chapter Night Checking and Troubleshooting

9.1 Checking

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

2. Check if the probe and main unit are connected correctly.

9.2 Troubleshooting

NO.	**Symptom**	**Check/Corrective Action(s)**
1	When power button pressed, the indicator does not turn on and no signal on the display screen visible.	1. Check the power supply; 2. Check the power cord and the plug; 3. Check if the power adapter is functioning.
2	Snowy noisy or mesh interference appears on the screen.	1. Check the power supply and whether it is interfered by other devices; 2. Check the environment and whether it is the electromagnetic field interfering with the device; 3. Check if the power, the plug of the probe and the sockets are connected well.

9.3 After-sales support form CARESONO

If problems persist, please contact Caresono for support.

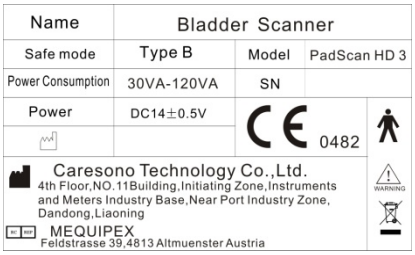
9.4 Maintenance

1. Please perform maintenance by personnel or companies with expertise

2. Please contact the manufacturer for maintenance information in detail

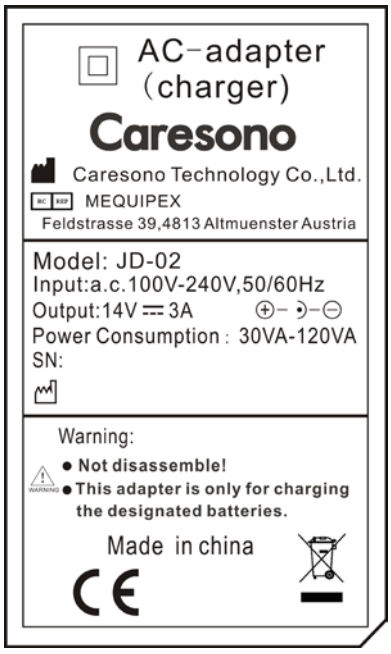
Appendix A: Labeling

HD3 Main unit labeling



HD3 Probe labeling

HD3 Adapter labeling



HD3 Package labeling

AppendixB: Acoustic output report

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

Test Report

Test Report №:RZ1107003 **Samples' Serial №:RZ1107003** **Page 15 of 18**

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	
					*A*aprt <= 1 cm²	*A*aprt > 1 cm²		
Maximum Index Value			0.4616	0.0192				0.0802
Associated Acoustic Parameters	Pr. α	(MPa)	0.7081					
	P	(mW)		2.011				1.850
	min of[Pa(Zs),Ita.a(Zs)]	(mW)						
	Zs	(cm)						
	Zbp	(cm)						
	Zb	(cm)						
	Z at max Ipi, α		0.65					
	deq(Zb)	(cm)						
	f_{awf}	(MHz)	2.3872	2.3872				2.3872
	Dim of Aaprt	X(cm)		0.547				0.547
		Y(cm)		0.547				0.547
Other Information	td	(μs)	0.6738					
	Prr	(Hz)	1256					
	Pr at max Ipi	(MPa)	0.6904					
	deq at max Ipi	(cm)						
	Ipa. αat max MI	(W/cm²)	9.0458					
	Focal Length	FLx(cm)						
		FLy(cm)						
Operating Control Conditions	Depth	(cm)	--	--				--
	Focus	(cm)	--	--				--
	Frequency	(MHz)	--	--				--
	…							