

PadScan HD 5

Bladder Scanner



User's Manual

Caresono

TRADEMARKS

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Table of Contents

INTRODUCTION	1
Intended Use	1
Contraindications	1
CAUTIONS AND WARNINGS	2
Equipment Checks	2
Pre-scan Checks	2
Scanning Checks	2
Post-scan Checks	2
Maintain Device Safety	2
Maintain Probe Safety	3
Handling the Device	3
In Case of Device Failure.....	3
Manufacturer Declarations	3
EQUIPMENT UNPACKING AND INSTALLATION	4
Unpacking.....	4
Installation	5
Battery Installation and Removal	5
Battery Charging and Status	6
Power Supply	6
Adapter Power Supply	6
Battery Power Supply	6
POSITIONING THE PROBE AND OBTAINING OPTIMAL IMAGES	7
PADSCAN HD 5 SCANNER SCREENS AND BUTTONS	9
Login Screen	9
Main Scanning Screen	9
Expert Mode	9
Easy Mode	10
Patient Information Screen	11
Save and Review Patient Data	12
Export Patient Data	14
Patient Data Management	15
Connect to PC	15
Patient data management	15
Setup Screens	16
A: General.....	16
B: Service	17
C: Operator	18
D: Print.....	20
E: Power.....	20
F: Display	21
USING THE PADSCAN HD 5 BLADDER SCANNER	22
1. Login	22
2. Add Patient Information	22
3. Prepare Patient and Position Probe.....	23
4. Start Scan and Capture Image	23
5. View the scanned images	24
6. Save Information	24
7. Print	24
CALIBRATION	25
TROUBLESHOOTING	27
CLEANING AND PREVENTIVE MAINTENANCE	28
System Cleaning and Maintenance	28
System Cleaning.....	28

System Maintenance	28
Probe Cleaning and Maintenance	28
Cleaning the Probe	28
Probe Maintenance	28
Battery Use and Maintenance	28
Treating and Disposing of Products After Use	29
TECHNICAL SPECIFICATIONS AND GENERAL SYSTEM INFORMATION.....	30
Component Specifications*	30
Operating Conditions.....	30
Transportation and Storage Conditions.....	30
Transporting the System	30
System Storage	31
Declaration of Electromagnetic Compatibility	31
Promulgation of Heat Index and Mechanical Index	31
Standards.....	31
Symbols	32
APPENDIX A: LABELING.....	33
Main Unit Labeling	33
Probe Labeling	33
Adapter Labeling	33
APPENDIX B: ACOUSTIC OUTPUT REPORT	34
APPENDIX C: RE-AIMING GUIDE	35

INTRODUCTION

The PadScan HD 5 by Caresono Technology Co., Ltd. Provides real-time ultrasound imaging and measuring, and also provides non-invasive volume measurement of the bladder. During image scanning, multiple 2D plane ultrasonic images are acquired in several seconds.

It features:

- *Expert* operating mode and *Easy* operating mode.
- Correct, reliable, fast, and simple operation.
- Printouts of ultrasound images with many parameters.
- Portable 8-inch LCD screen (800x600 pixels)
- Combined power supply with AC adapter and a built-in battery.

Intended Use

The PadScan HD 5 projects ultrasound energy through the lower abdomen of the patient to obtain images of the bladder which is used to calculate bladder volume noninvasively.

Contraindications

The PadScan HD 5 is contraindicated for any patient who is not a candidate for ultrasound scanning.

- 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, the catheter may affect measurement accuracy. However, the information obtained from the measurement and real-time ultrasound image could still be clinically useful for detecting problems such as a blocked catheter.

CAUTIONS AND WARNINGS

Read carefully before use

Only trained technicians should operate this device. The operator must read the Owner's manual entirely and refer to any additional training materials before using the device.

- **Check and maintain the device regularly.**
- **Do not disassemble or attempt to repair the device and the probe. ONLY CARESONO-trained technicians may service the unit.**

Equipment Checks

1. Make sure all cables are properly connected.
2. Make sure the device is properly functioning.
3. 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.

Pre-scan Checks

1. Make sure the probe is properly connected.
2. Make sure no water, chemicals, or other materials are on the device.

Scanning Checks

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 the 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, unplug all cables, and power OFF. Contact CARESONO technical support for help.
3. Patients must not touch other electrical equipment during examination.
4. Do not cover the air vent of the device.

Post-scan Checks

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

Maintain Device Safety

This device should avoid the following:

- Spraying water
- High humidity
- Poor draught
- Direct sunlight
- Dust
- Gas with salt or sulfur

- Chemical medicines or gas
- Sudden shaking of the device or drops

Maintain Probe Safety

- Do not immerse the probe in water or any other liquids.
- Keep probe away from heat sources.
- To avoid damaging the cable or transducer connector, handle them with care. Do not bend or pull probe cable.
- It is recommended to use standard ultrasound gel only. Other substances may damage the probe and the probe cable.
- A dirty probe may decrease the accuracy of the system. Keep the probe clean. Use standard detergent or clean water to clean the ultrasound gel off the probe.
- The probes are not interchangeable between units. They are calibrated to specific main units. If changing the probe associated with a machine, it is necessary to calibrate the machine before using.
- Confirm that the probe and cable are normal before and after each examination. A defective probe may cause electric shock to the patient.

Handling the Device

- Always pull out the power plug.
- Drop, shake, or hit the probe may cause malfunction or inaccuracy. Do not drop, shake, or hit the probe or the device.

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.

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

Manufacturer Declarations

WARNING! Changes or modifications not expressly approved by CARESONO could void the user's authority to operate the equipment.

Warning: It is strictly prohibited to perform any modifications to the device without prior permission.

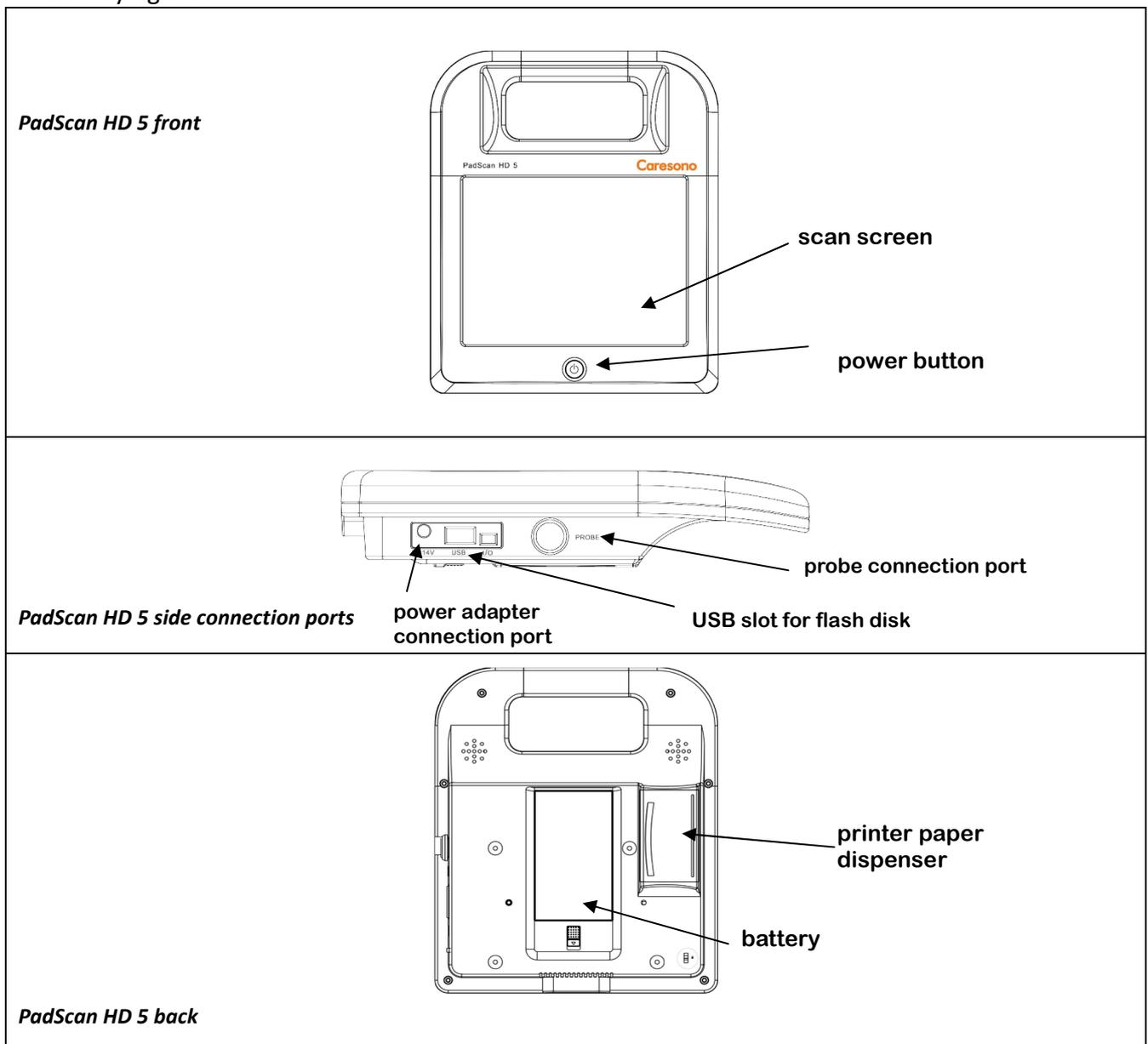
Warning: To ensure the continued safe use of the equipment, modifications must be inspected and tested by approved departments.

EQUIPMENT UNPACKING AND INSTALLATION

Unpacking

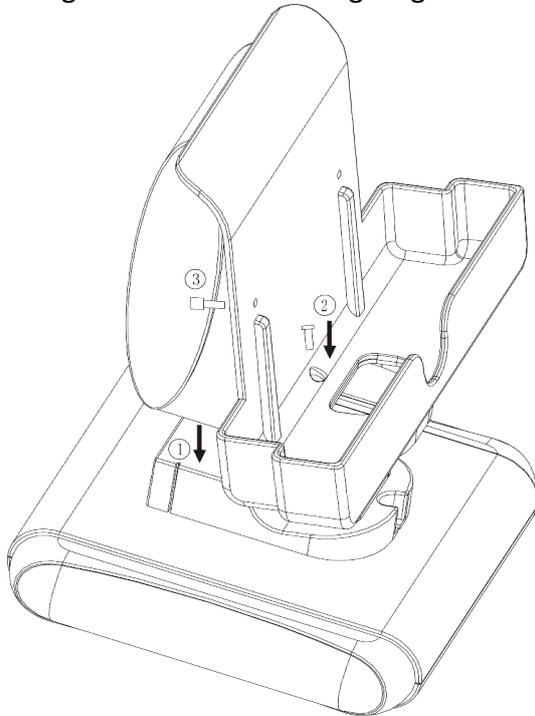
After unpacking, confirm there is no damage due to shipping, and then check the parts against the packing list. The PadScan HD 5 system arrives with:

- 1 main unit with docking station and screws
- 1 Power adapter: AC100-240V±24V 50/60Hz, main unit: DC14V±0.5V
- 1 N2/2.5MHz 3-D Mechanical sector scanning probe
- 1 Ultrasound gel bottle
- 1 Quick Start Guide and 1 Owner's Manual
- 1 Li-ion battery: Model: SP-1196
- 1 Certificate
- 1 Packing list
- 1 Carrying case



Installation

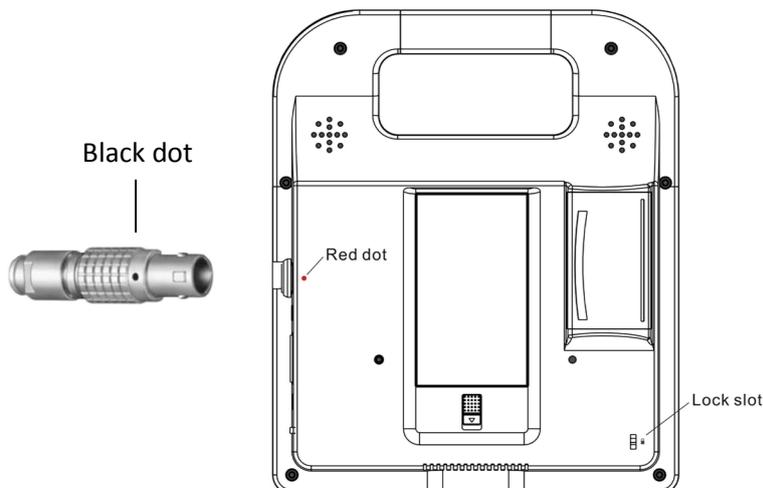
1. Plug the AC input plug of the adapter into a power outlet. Insert the DC output plug of the adapter into the **DC14V** port on the side of the device. The DC output indicator light turns green to signal it is working properly.
2. Connect the main unit to the docking station:
Align the socket on the bottom of the main unit with the docking station and place it into the docking station. See following diagram:



- 1 Insert here.
- 2 Screw in tightly.
- 3 Screw in (when necessary).

PadScan HD 5 docking station installation

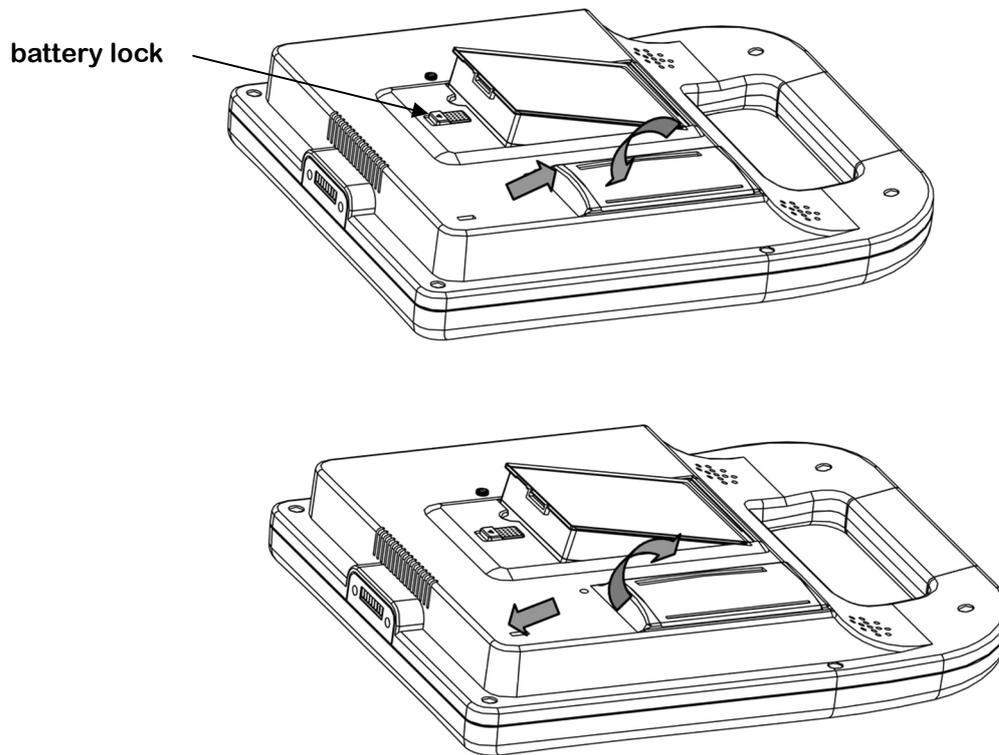
3. Align the red dot on the main unit with the black dot on the probe, and insert the probe into the main unit.



Lock slot: Any notebook security lock is applied to this lock slot on the right down side of the main unit.

Battery Installation and Removal

Slide the battery lock down and lift the battery. Insert (or remove) the battery in the slot, and then slide the lock back into place.



Battery Charging and Status

1. Install the battery into the main unit.
2. Place the main unit securely onto the docking station.
3. Plug the power supply into the power outlet to start charging.
4. Turn ON the scanner.

NOTE: The yellow light indicates the battery requires charging. Green light signals it is fully charged.

Power Supply

PadScan HD 5 power is supplied by two interchangeable methods: adapter and built-in battery.

Adapter Power Supply

1. Check that the adapter is properly functioning; verify the EPS is in the specified range.
2. Insert the AC input plug of the adapter into the base of the power supply.
3. Place the main unit onto the docking station.
4. The light indicator will turn green to signal it is functioning.
5. Turn on the main unit.

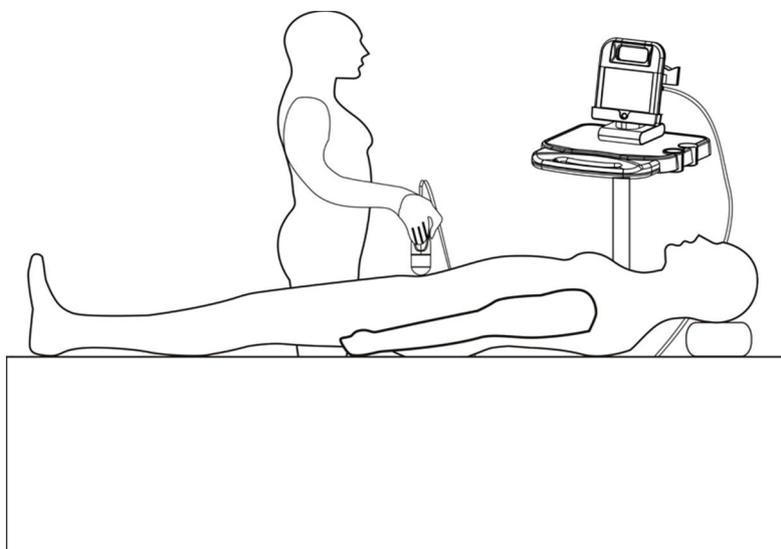
Warning: Use only CARESONO supplied power adapters.

Battery Power Supply

1. Install the battery into the main unit as described on page 6.
2. Press the power button to turn on the main unit.

POSITIONING THE PROBE AND OBTAINING OPTIMAL IMAGES

Locating the position of the bladder is the most important step in obtaining correct volume measurements. The bladder is located in the hypogastrium, below the navel. Coat the hypogastrium of the patient and the probe with ultrasound gel before the scan. Place the probe as illustrated below.

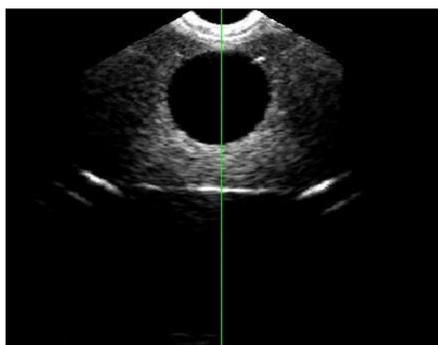


REMEMBER: the probe button should always face up toward the patient's head.

In order to correctly measure the volume of the bladder, grasp the probe as shown here:



A green guideline visible on screen helps center the bladder. ((You can enable/disable this function from SETUP menu>Display>Central guide line ON/OFF))



In expert mode, move the bladder image to the center. Dark green central line indicates the image is centered, while the orange central line indicates the image deviates from the center. See Figure 1 and Figure 2.

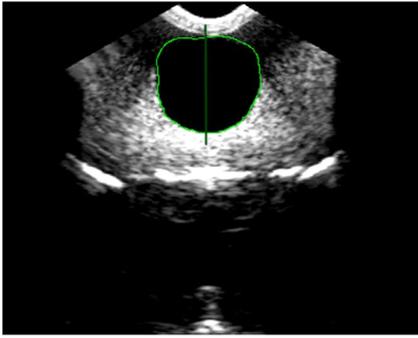


Figure 1: correct position (expert mode)

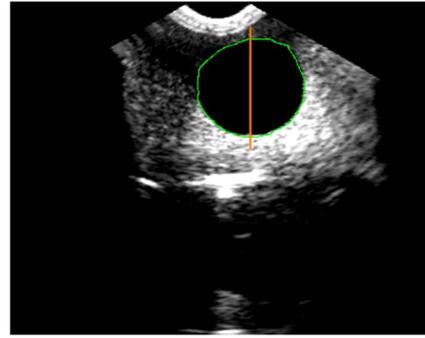


Figure 2: incorrect position (expert mode)

In easy mode, move the bladder image to the center. Dark green central line indicates the image is centered, while the orange central line indicates the image deviates from the center. See Figure 3 and Figure 4.

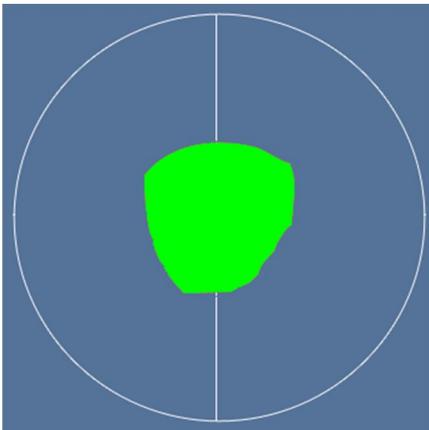


Figure 3: correct position (easy mode)

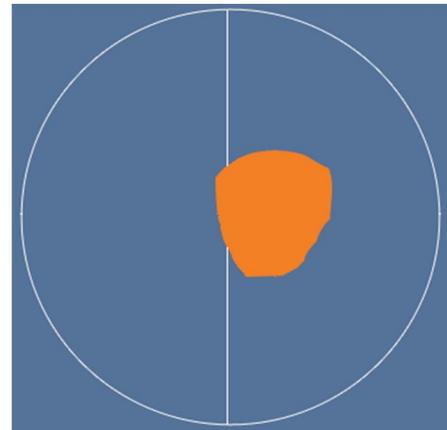


Figure 4: incorrect position (easy mode)

If the central position of the bladder deviates from the central line and to the right of the image, move the probe to the left. The central position of the bladder moves according to the movements of the probe. If the bladder image deviates from the central line and to the left side, move the probe to the right.

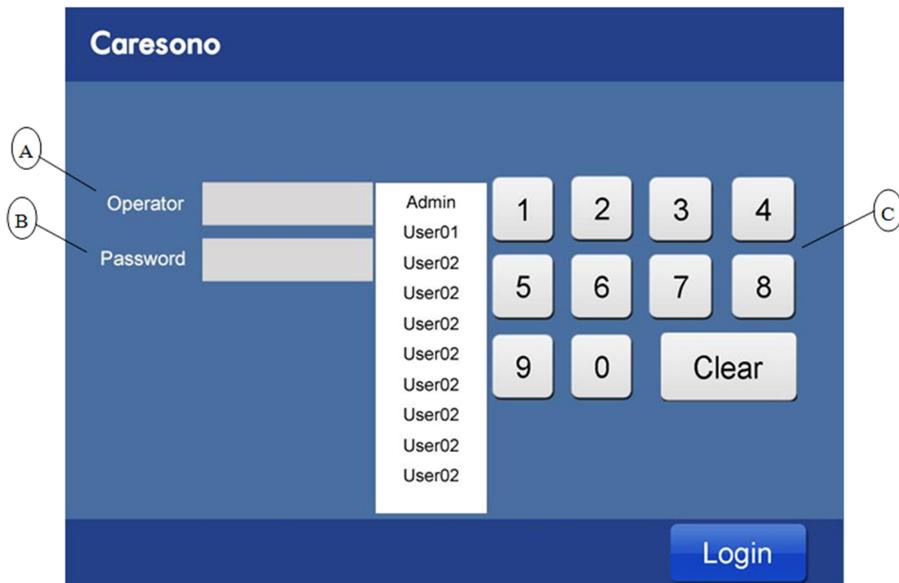
In both Expert mode and Easy mode, a crosshair of project icon guide is displayed at the right side on the screen. It helps re-aim and re-scan. (You can enable/disable this function from SETUP menu>Display>Projection ON/OFF)



Please refer to APPENDIX C: RE-AIMING GUIDE for more information about how to re-aim and re-scan.

PADSCAN HD 5 SCANNER SCREENS AND BUTTONS

Login Screen

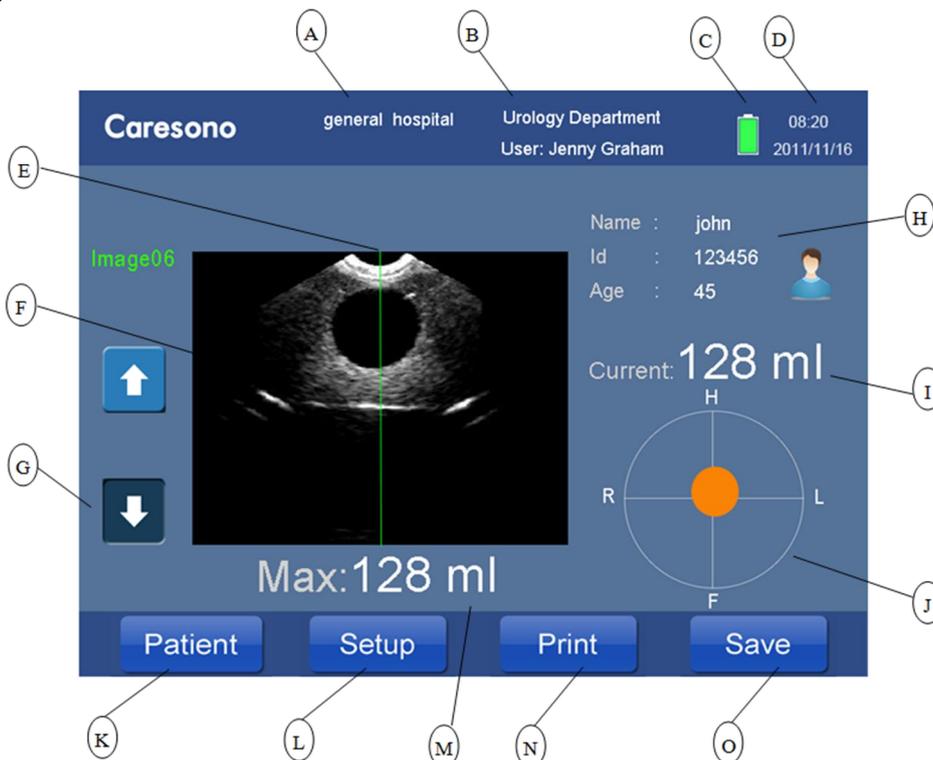


A	Operator: Tap to select user ID
B	Password: Tap to type password
C	Keyboard: use for typing
Login	Tap when ID and password are complete

Main Scanning Screen

Expert Mode

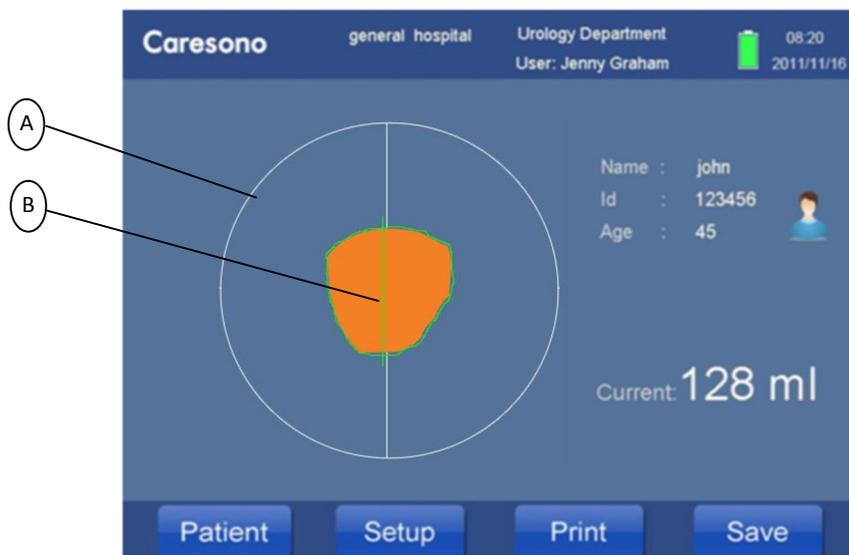
Bladder location for volume measurement is determined by the technician scanning the image. Displays a real-time 2D image.



A:	Hospital/clinic name display
B:	Name of the department and userdisplay
C:	Battery status indicator
D:	Date and time
E:	C guideline
F:	Ultrasound image viewing area
G:	Tap arrows for image review
H:	Patient information display
I:	Current volume display
J:	Projection of probe aiming (Optional)
K:	Tap to add new or review patient data (see page 12)
L:	Tap to enter Setup menu
M:	Maximum Volume display (Optional)
N:	Tap to print current scan
O:	Tap to save current scan

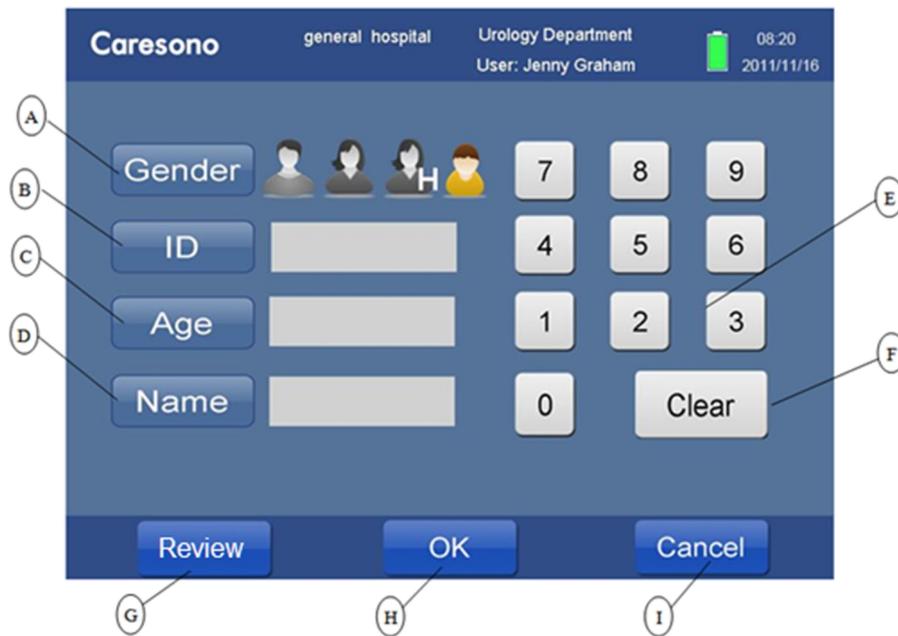
Easy Mode

Provides guidance to help find the correct location of the bladder. Does not provide a real-time 2D scanned image.



A:	Crosshair
B:	Profile of the urine bladder

Patient Information Screen



A:	Tap GENDER and then tap icon [male  , female  , female with hysterectomy  , or child  (under 120cm tall and weighing less than 25kg)]
B:	Tap to add Patient ID
C:	Tap to add Patient Age
D:	Tap to add Patient Name
E:	Keyboard for typing ID and age
F:	Tap to clear content
G:	Tap to enter Patient data management
H:	Tap to confirm content
I:	Tap to cancel screen

Keyboard for entering patient name



A:	Input patient name
B:	Virtual keyboard
C:	Caps lock
D:	Confirm input
E:	Cancel input
F:	Backspace

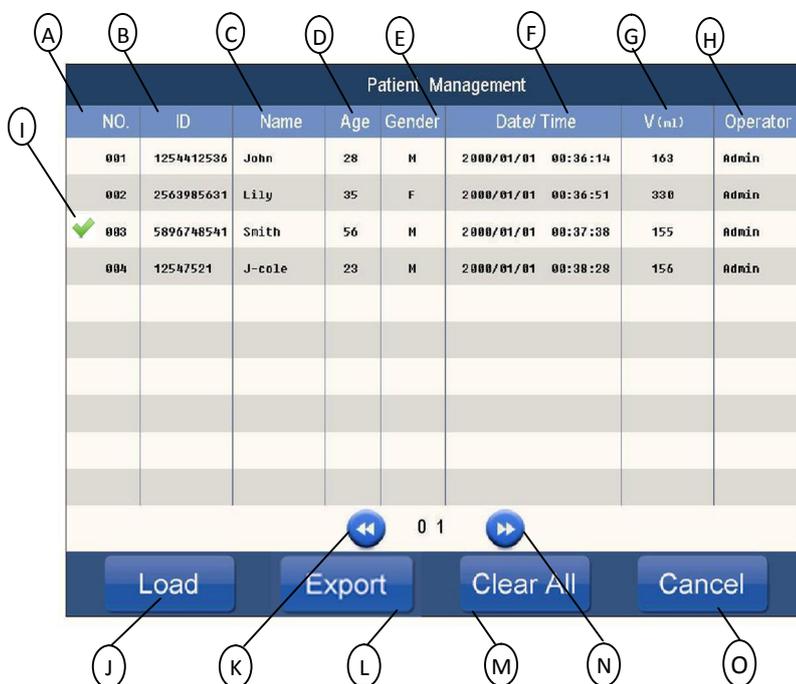
Save and Review Patient Data

- Tap **Save** to save current patient scan to the Patient Data Management.

NOTE: If you want to save the exam to Patient Data Management, before you start to scan the patient, you must at least select the patient gender. Then you can review the saved exam in the patient data management.

NOTE: If the USB flash disk is inserted. The current patient scan will be saved into the USB flash disk instead of the machine's memory.

- Tap **Patient** in the main screen and then tap **Review** to enter patient data management.
- Tap the line in the patient list then tap **Load** to review the data.
- Tap  or  to move through the pages of patient information.



The screenshot shows the 'Patient Management' screen with a table of patient data. Callouts A through O point to specific elements: A (Sequence Number), B (Patient ID), C (Patient Name), D (Patient Age), E (Patient Gender), F (Time and date), G (Urine Volume), H (Operator Name), I (Selected Patient), J (Load selected patient case), K (Previous page), L (Export all patient data to USB Disk), M (Clear all patient data), N (Next page), and O (Back to the previous page).

NO.	ID	Name	Age	Gender	Date/Time	V (ml)	Operator
001	1254412536	John	28	M	2000/01/01 00:36:14	163	admin
002	2563985631	Lily	35	F	2000/01/01 00:36:51	330	admin
003	5896748541	Smith	56	M	2000/01/01 00:37:38	155	admin
004	12547521	J-cole	23	M	2000/01/01 00:38:28	156	admin

A:	Sequence Number
B:	Patient ID
C:	Patient Name
D:	Patient Age
E:	Patient Gender
F:	Time and date
G:	Urine Volume
H:	Operator Name
I:	Selected Patient 
J:	Load selected patient case
K:	Previous page
L:	Export all patient data to USB Disk
M:	Clear all patient data
N:	Next page
O:	Back to the previous page

- Tap **Clear All** to clear all the saved patient data; Or clear synchronization makers. During the process of uploading the saved patient data to the PC patient management software, if you want to re-upload, you need to clear the synchronization makers.



Export Patient Data

- Insert the USB flash disk to the USB slot on the main unit.
- Tap **Export** in the Patient Management screen to export the selected patient data/all patient data to the USB flash disk.



NOTE: It will take about 10 seconds to export one selected patient data to the USB flash disk.

NOTE: Do not remove the USB flash disk during the exporting.

Patient Data Management

Connect to PC

- Install the Driver of HD 5 on the PC.
- Connect the I/O slot of HD 5 main unit to a PC via the USB cable.
- Tap **Patient** in the main screen and then tap **Review** to enter patient data management.
- Run <Patient Data Management> software from PC.
- Do not remove the USB cable during uploading.



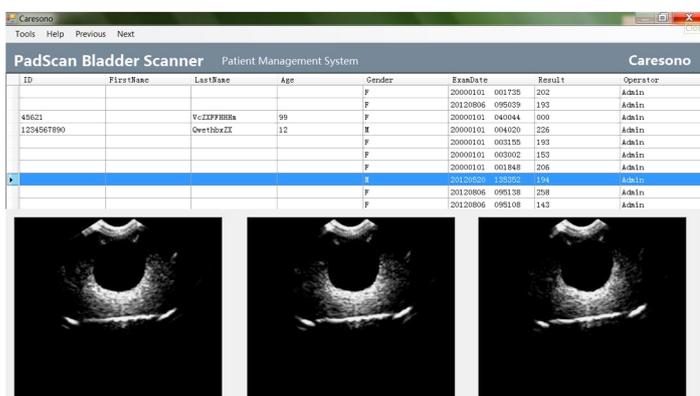
HD 5 main unit

USB Cable

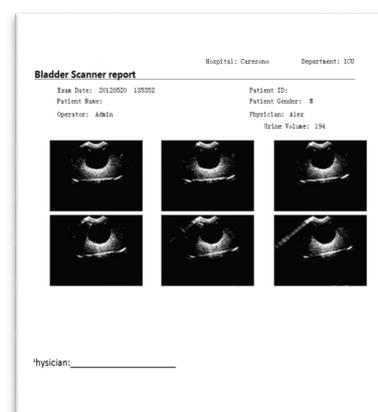
PC

Patient Data Management

- Select [Tools]->[Sync Data] to upload the patient data from HD 5 to <Patient Data Management>.
- Add the Hospital Name, Department Name and Physician Name from [Tools]->[Option].
- Review the ultrasound images of selected patient by click<Previous> and <Next>.
- Print the Bladder Scanner Report from [Tools]->[Print].



Patient Data Management interface



Report printout

NOTE: If you have saved new patient data to HD 5, you need to reboot HD 5 before another attempt of uploading.

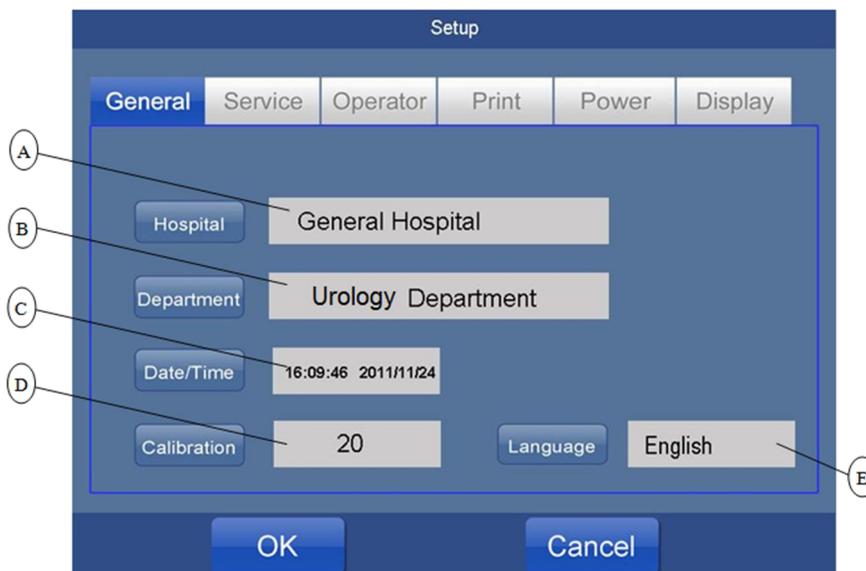
Setup Screens

Tap the  button on the main screen to configure the system.



A: General

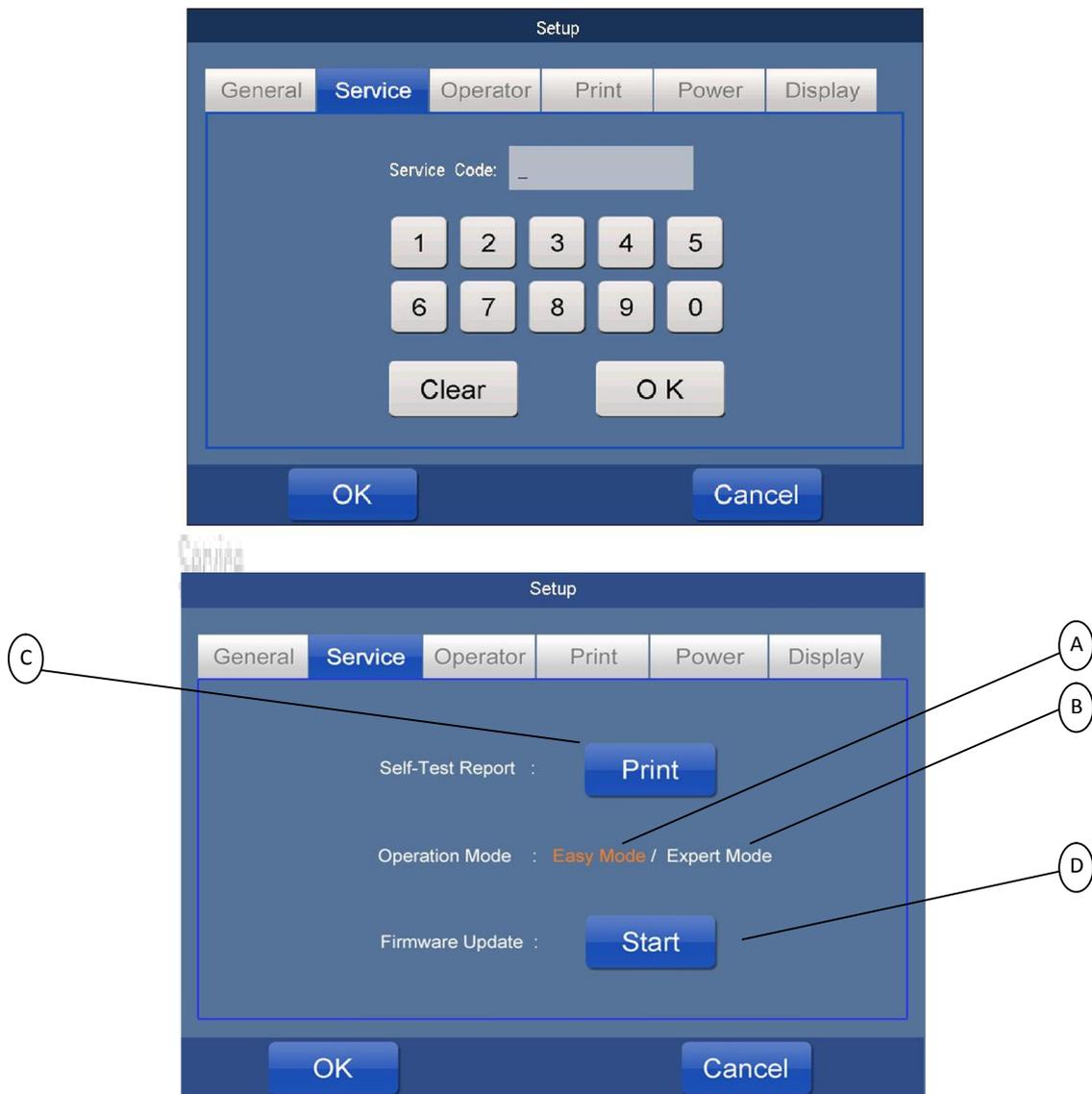
Tap  to add basic information and to start probe calibration if necessary (see page 25 for calibration information).



A:	Tap to add the clinic/hospital name. Up to 25 letters can be added.
B:	Tap to add the department name. Up to 20 names can be added.
C:	Tap to add date and time.
D:	Tap to start calibration (see page 24 for more information on how to calibrate)
E:	Tap for Language selection.

B. Service

Tap **Service** to select the mode of operation or to restore all settings to default factory settings. A password will need to be entered before any changes can be made to these settings.



A:	Tap name for Easy mode
B:	Tap name for Expert mode
C:	Tap [PRINT] to print a self-test report
D:	Tap [START] to enter firmware update



NOTE: If you confirm the System Recovery, the following items will be changed to factory default setting: Hospital Name, Department Name, Calibration Value, Exam mode (Expert Mode), Screen off time, Shutdown time, Operator’s name and password, and screen Display options.

C. Operator

Tap **Operator** to enter the system administrator’s access area. System users (operators) will be set up in this area with a username and password. Up to 10 users can be added to the system. Administrators can modify a user’s password and name in this screen.

Tap **Operator Login: ON / OFF** to turn ON or OFF user login for the entire system. If turned OFF, then access is granted for all users without passwords.

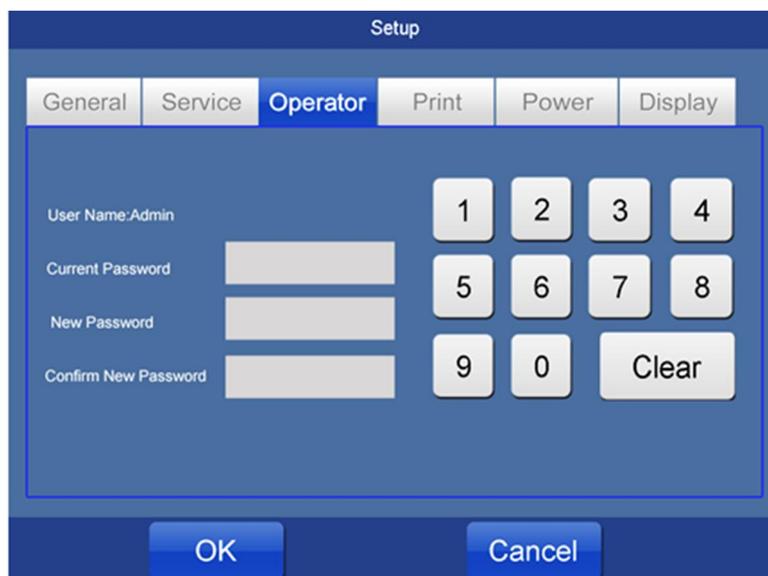


A:	Operator log in (ON/OFF)
B:	User’s Name
C:	User’s Password

Tap the user's name line (*****) to enter the operator's name.



Tap the user's password line (*****) to enter the password.

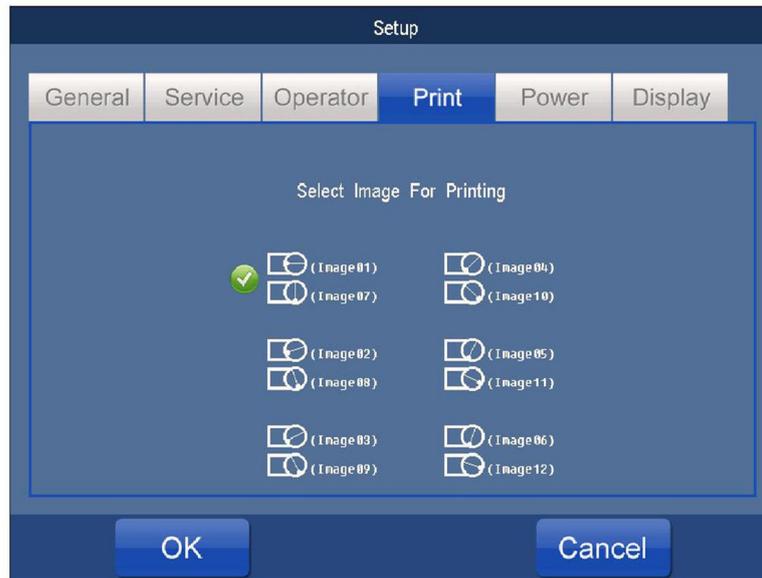


NOTE: The default administrator's password is: 123456. The user's default password is: 000000.

NOTE: If you turn off the LOGIN function from SETUP menu, the login procedure will not be enabled during the start-up.

D. Print

Tap **Print** to select the standard images for each print out. Tap to select 1 of the 6 image groups for printout. (example: *Image 1&7, Image 2&8, etc...*). Each group has two cross-sectional images.



E. Power

Tap **Power** to set up system power settings. Tap the *Screen Off Time* box to input the screensaver activation time (in minutes). Tap the *Shut Down Time* box to input an automatic system power-off time (in minutes).



F. Display

Tap **Display** to set up screen display options. Tap ON or OFF to enable or disable the feature.



A:	Display the maximum volume of current patient's scans on main screen.
B:	Display crosshair of project icon guide on main screen
C:	Display central guide line in expert mode

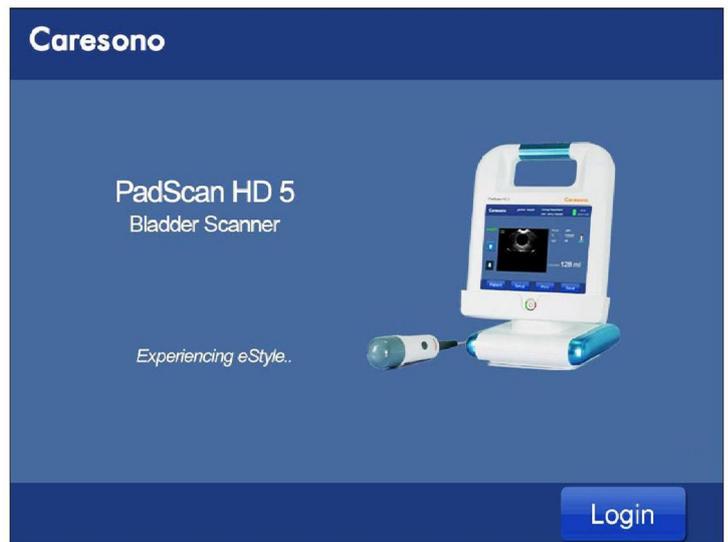
USING THE PADSCAN HD 5 BLADDER SCANNER

Detailed information about screens can be found on page 9.

1. Login

Press the power button to turn on the scanner.
Tap the **LOGIN** button and type the access code.

NOTE: If you turn off the LOGIN function from SETUP menu, the above login procedure will not be enabled.



2. Add Patient Information

Tap the **PATIENT** button to add patient information.

Tap **GENDER** and tap the appropriate gender icon.

Tap **ID**, **AGE**, **NAME** to add the patient's Identification Number, Age, and Name.

Tap **OK** when complete.

Patient

Gender



ID

Age

Name

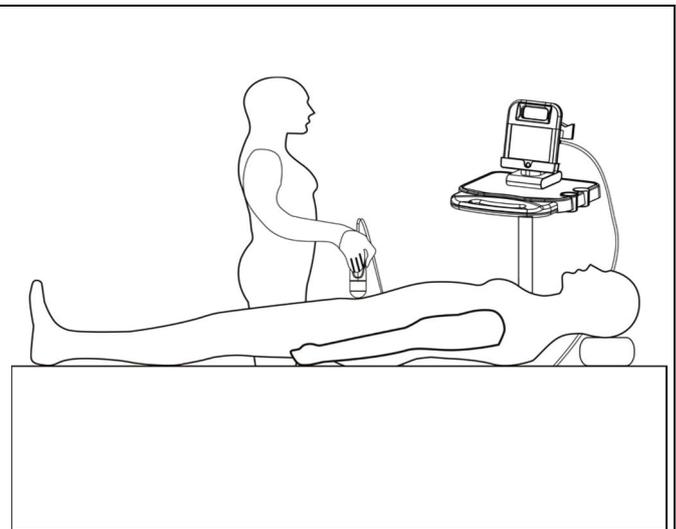
OK

3. Prepare Patient and Position Probe

Invite the patient to take the test. Patient should be in supine position with abdominal muscle relaxed.

Place an ample quantity of ultrasound gel on the patient's abdomen, approximately 3cm above the pubic bone, and on the probe.

Place the probe on the gel covered area and make sure the probe button face up towards the patient's head.



4. Start Scan and Capture Image

Expert mode scan:

Press and release the button on the probe to start Pre-scan (view a real-time image of the bladder). Move and tilt the probe slightly to make sure the image of the bladder is centered and maximum area. Once the location of the bladder is confirmed, press and release the button on the probe again to start calculation.

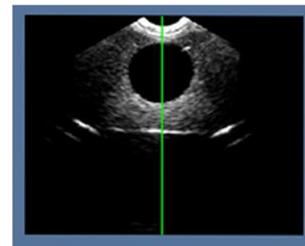
Once the 'beep' sound is heard lift the probe. The screen will display the volume of the bladder. The scanning takes 5seconds to complete.

Easy mode scan:

Press and release the button on the probe to view a sectional real-time image of bladder. Move and tilt the probe slightly to make sure the image of the bladder is in the central position of the crosshair; Once the location of the bladder is confirmed, Press and release the button again on the probe and hold the probe in place during the calculation.

Once the 'beep' sound is heard lift the probe. The screen will display the volume of the bladder. The scanning takes 5 seconds to complete.

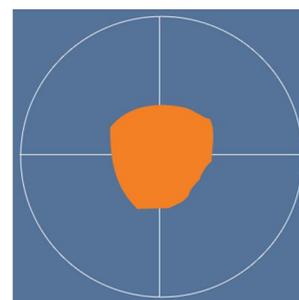
NOTE: Hold the Probe steady while scanning. Movement will impair the accuracy of the measurement.



Scan analysis in progress



Scan analysis complete



Scan analysis in progress



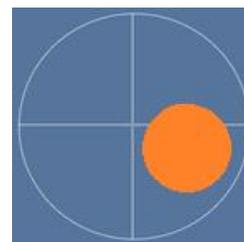
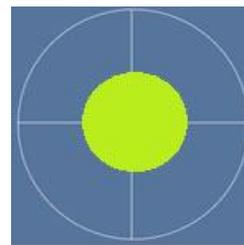
Scan analysis complete

5. Re-aim and re-scan

If the scan position of bladder is centered, a green projection icon of bladder will be shown in the center of the crosshairs on the screen. You will may need to re-scan to find the maximum area of the bladder to achieve the most accurate result.

If the scan position of bladder is not centered, an orange projection icon of bladder will be shown on the crosshair. You must re-aim and re-scan.

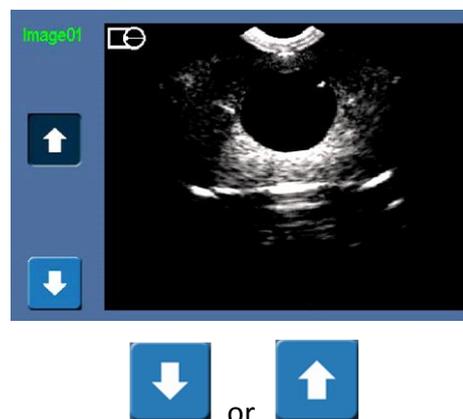
Please refer to Appendix C. of re-aiming.



6. View the scanned images

Once bladder scanning is finished, the bladder volume will be displayed, and six groups of sectional images of the bladder will also be displayed.

Tap the **UP** or **DOWN** arrows to view the six groups of images.



7. Save Information

Tap **SAVE** to save the exam data and results.



8. Print

Tap **PRINT** to print the scan results. The printout contains the name of the patient, the patient ID code, patient age, patient gender, scan time, bladder volume, and two ultrasound images.



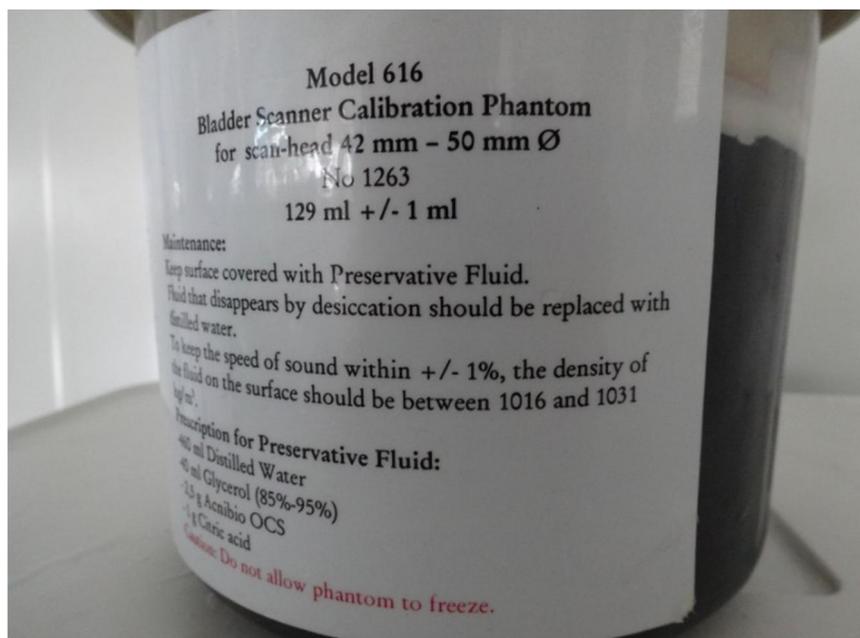
CALIBRATION

Please be kindly noted, out of the proprietary technologies in ultrasound imaging and algorithm in measurement, Caresono PadScan Bladder Scanner HD5 retains clinical supremacy of Zero Calibration during its lifetime. Regarding this, we hereby officially specify:

Within its lifetime clinical application, under the intact condition of both the PadScan Bladder Scanner HD5 main unit and the probe:

1. The operators do not need to do the calibration for clinical measuring precision before their first scan on the patients.
2. The operators do not need to do the calibration for clinical measuring precision during their day to day working.
3. The operators do not need to do the calibration for clinical measuring precision if changing another probe.

If the calibration were the fixed procedure from the hospitals or any type of end-user customers, they could follow the next steps; But please be kindly noted, the phantom model Dansk 616 is the only one model to comply.

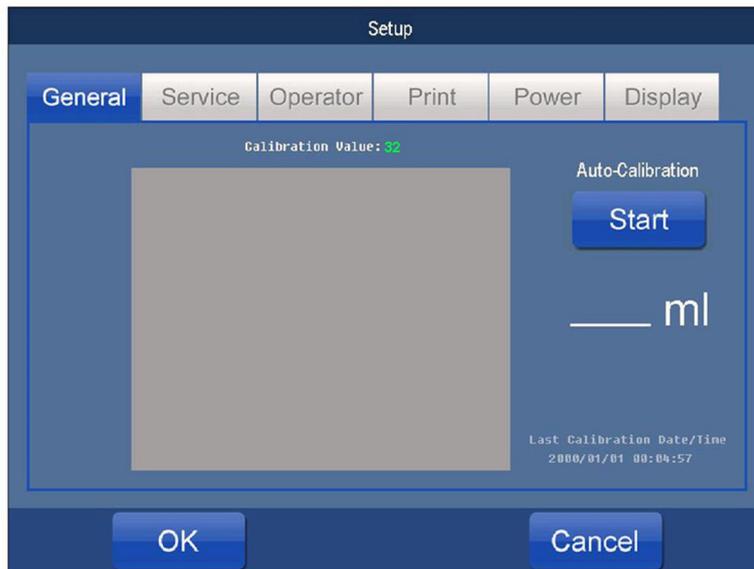


1. Prepare the Dansk Tissue Equivalent Phantom for calibration.
2. Place the probe head into the phantom holder firmly.
3. Align the probe button with the red arrow on the phantom.
4. In the main PadScan HD 5 screen, tap **SETUP>GENERAL>CALIBRATION** to enter the calibration screen.
5. Tap  to start auto calibration. It takes about 2 minutes to finish the calibration.
6. Do not remove the probe during the calibration.
7. The default calibration value is 32.
8. A last calibration date and time will be displayed on the



screen after the calibrations succeed.

9. Tap  to exit.



NOTE:

- You may take a normal scan on the phantom in the calibration mode to verify the calibration result. (Compare the scan volume with the phantom labeling volume.) If the volume values deviate greatly from the acceptable calibration range, perform another calibration.
- The calibration can only be done on Dansk Tissue Equivalent Phantom.
- The Dansk Phantom should be equipped with the probe holder made by Caresono.
- The probe head should be immersed by the water on the phantom surface completely; the probe head should touch the phantom surface.
- The calibration should be done when the main unit is powered on at least 40 minutes.
- The calibration should be done when the AC power is on. (Shouldn't on battery only.)

TROUBLESHOOTING

- Check if the power supply is functioning properly, and the power cord of the main unit is connected and is plugged into the power adapter.
- Check if the probe and main unit are connected correctly.

Symptom	Check/Corrective Action(s)
When power button pressed, the indicator does not turn on and no signal on the display screen visible.	<ol style="list-style-type: none">1. Check the power supply;2. Check the power cord and the plug;3. Check if the power adapter is functioning.
Screen display shows "snow-like" images or mesh interference appears on the screen	<ol style="list-style-type: none">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.

If problems continue, please contact Caresono technical support.

CLEANING AND PREVENTIVE MAINTENANCE

The PadScan HD 5 is **non-immersible**. It should be wiped down with a soft, clean cloth dampened with a cleaning solution such as soap and water, or a mild detergent solution, or as per hospital/clinic cleaning instructions.

Performing regular maintenance will reduce the need for costly repairs. **Check the system and calibration every 24 months or whenever you suspect the system is off calibration.**

System Cleaning and Maintenance

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.
- 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.

System Maintenance

- Operate the system in the environment as outlined on page 28.
- 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 on page 29.

Probe Cleaning and Maintenance

Always clean the probe after use.

Cleaning the Probe

- Check the probe and other cables for signs of damage, such as cracking and/or leaking. If any sign of damage appears, stop using the probe and contact 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.

Probe Maintenance

- Do not scratch the probe.
- Do not drop or bang the probe.
- Use only standard medical ultrasound gel.

Battery Use and Maintenance

- For optimum performance, it is recommended to charge and completely discharge a new battery two to three times before first use.
- Do not step on, drop, drop in water, or puncture the battery. If misuse, abuse, or damage is suspected, or any form of mechanical damage to the casing is visible, then discontinue use and return the battery to CARESONO.
- If a sudden change in the battery's ability to hold a charge or a sudden change in battery life time is noticed, discontinue use and return the battery to CARESONO.
- Keep away from fire.
- The battery should be charged and completely discharged once every two to three months.

NOTE: Always charge a battery that has been in storage for an extended period of time.

Treating and Disposing of Products After Use

- For end of life product, waste electrical and electronic equipment should be collected separately and returned to the designated local recycling service.
- Packaging waste should be collected separately for available national packaging collection and recycling services.

TECHNICAL SPECIFICATIONS AND GENERAL SYSTEM INFORMATION

Component Specifications*

- Probe: 3D mechanical sector
- Standard ultrasonic frequency of operation: 2.5MHz
- Volume measure range: 0ml - 999ml.
- Volume measure accuracy: $\pm 15\%$, $\pm 15\text{ml}$ (On Caresono tissue equivalent phantom)
- Scan time: <5 seconds
- Operation methods: touchscreen
- Tissue Harmonic Imaging (THI)
- Mode of the device: Two modes: expert mode and easy mode
- Patient data storage
- Information print
- Socket of USB flash disk
- Dimensions of the display: 8-inch TFT-LCD
- Power: 50W
- Dimensions: 210x252x52mm
- Weight: approximately 1500g (including the probe)
- Power at the state of charging: 30-120VA;
- Battery capacity: 2200mA
- AC power supply, batteries full charged or supply by the batteries: 30-40VA;
- Battery charge time: 2 hours;
- Battery life: 2hours continuous scanning, 5 hours standby.
- Languages: English, Danish, Dutch, Finnish, French, German, Norwegian, Portuguese, Spanish, Swedish.

**Specifications are subject to change without prior notice.*

Operating Conditions

Temperature: +5°C to +40°C

Relative humidity: 30% to 75%

Pressure: 70kPa to 106kPa

Transportation and Storage Conditions

Temperature: -40°C to +55°C

Relative humidity: 10% to 80%

Pressure: 50kPa to 106kPa

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.

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.

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.

Declaration of Electromagnetic Compatibility

The operation of PadScan HD 5 will not interfere with other wired, wireless equipment and/or other electrical equipment.

Warning: Use of the PadScan HD 5 under strong electromagnetic environments, close to generators, X-ray devices, dentistry physiotherapy equipment, broadcasting stations, or buried cables, etc... may introduce interference signals in the image. It is recommended to correct this by repositioning the PadScan HD 5, or increasing the separation between the PadScan HD 5 and the interfering equipment.

Warning: Shared power supplies may produce distorted images. Eliminate the interference of electromagnetic coupling by means of test and verify.

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

Promulgation of Heat Index and Mechanical Index

Heat index: $PI < 0.1$;

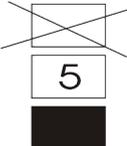
Mechanical index: $MI < 0.1$.

Standards

This device is designed and manufactured in strict accordance with:

- IEC60601-1:2005 "Medical electrical equipment part 1: General requirements for safety"
- IEC 60601-2-2:2006 "Medical electrical equipment -- Part 2-2: Particular requirements for the safety of high frequency surgical equipment"
- Type B, Class II protection to the risk of electric shock
- The environment test is in accordance with the requirements of climate environment test group II, mechanical environment test group II, GB/T 14710-2009 "Environmental requirement and test methods for medical electrical equipment".
- Degree of protection against ingress of water: IPX7(probe), IPX0 (main unit)

Symbols

 <p>Type B device</p>	 <p>Attention! Consult accompanying documents</p>
 <p>Switch ON the general power</p>	 <p>Switch OFF the general power</p>
 <p>Signal output</p>	 <p>CE mark and code of certification body</p>
 <p>Class II Electrical Equipment</p>	 <p>Not for general waste. Dispose of in accordance to local regulations.</p>
 <p>Manufacturer</p>	 <p>Manufacture Date</p>
 <p>Handle with care</p>	 <p>Temperature limit</p>
 <p>Upwards</p>	 <p>Limited layers of storage</p>
 <p>Keep dry</p>	 <p>Keep away from sunlight</p>

APPENDIX A: LABELING

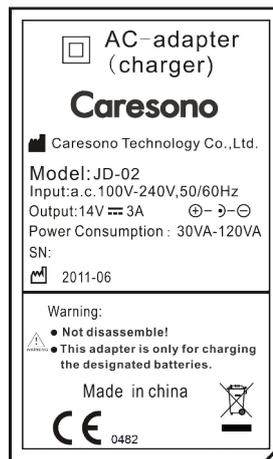
Main Unit Labeling

Name	Bladder Scanner		
Safe mode	Type B	Model	PadScan HD 5
Power Consumption	30VA-120VA	SN	
Power	DC14±0.5V	 0482	  
	2011-12		
 Caresono Technology Co.,Ltd. 4th Floor,NO.11Building,Initiating Zone, Instruments and Meters Industry Base, Near Port Industry Zone, Dandong, Liaoning			

Probe Labeling



Adapter Labeling



APPENDIX B: 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

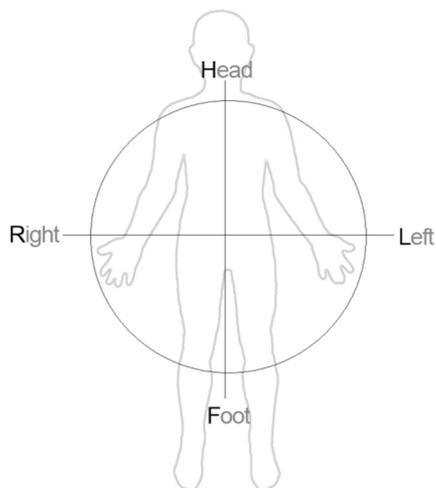
Table 201.103

Acoustic output reporting table

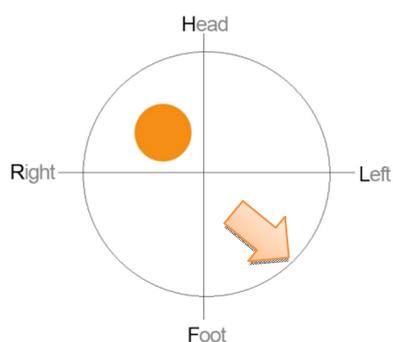
B Mode

Index Label	MI	TIS		TIB	TIC	
		Scan	Non-Scan			Non-Scan
			Aaprt ≤ 1 cm ²	Aaprt > 1 cm ²		
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)					
	fawt (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. α at max MI (W/cm ²)	9.0458				
	Focal Length	FLx(cm)				
FLy(cm)						
Operating Control Conditions	Depth (cm)	--	--		--	
	Focus (cm)	--	--		--	
	Frequency (MHz)	--	--		--	
	...					

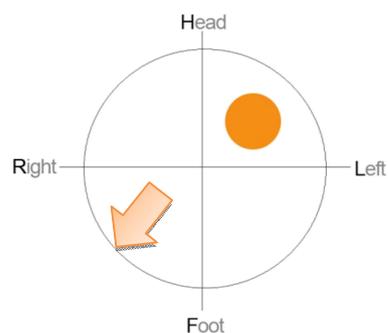
APPENDIX C: RE-AIMING GUIDE



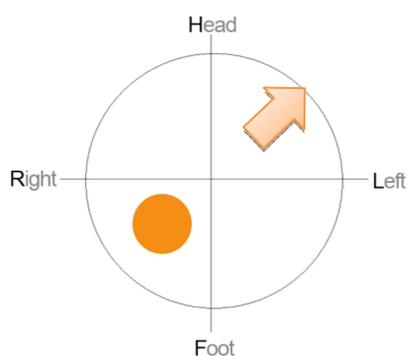
The above crosshair diagram shows the four points to consider when scanning the bladder. The projection guiding icon shows the bladder position after scanning. If the orange icon is not centered, you may need to re-aim and re-scan. The following images show how to re-aim.



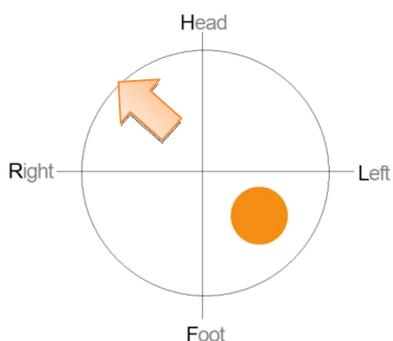
Move the probe to down to the left



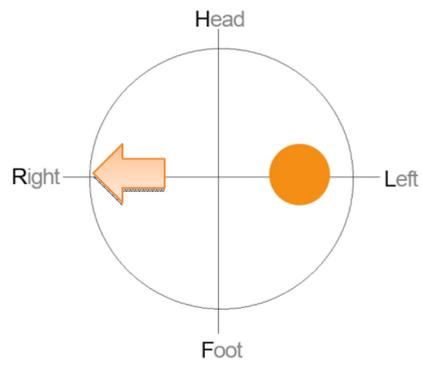
Move the probe to down to the right



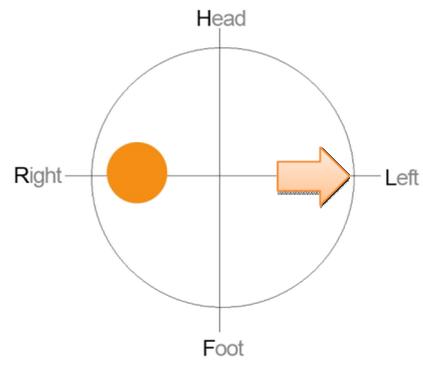
Move the probe to up to the left



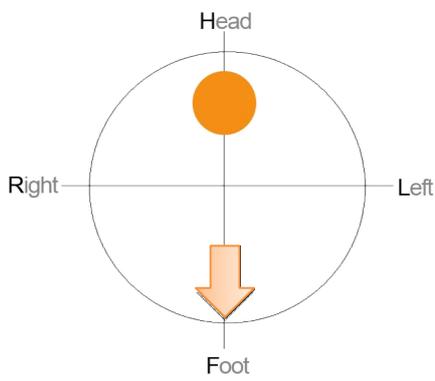
Move the probe to up to the right



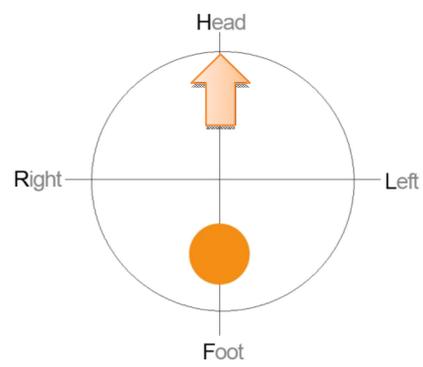
Move the probe to the right



Move the probe to the left



Move the probe down



Move the probe up