

PadScan HD 5 Plus

Bladder Scanner



User's Manual

Caresono

TRADEMARKS

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INTRODUCTION

The PadScan HD 5 Plus developed and manufactured by Caresono Technology Co., Ltd. Provides noninvasive real-time measurement of urinary bladder volume. The device calculates the bladder volume by using patented ultrasound imaging and measuring technology. When the scan is complete, multiple 2D plane ultrasonic images are acquired in several seconds.

It features:

- *Expert* and *Easy* operating modes.
- Correct, reliable, fast, and simple operation.
- Printouts of ultrasound images with many parameters.
- Portable 8-inch LCD screen(800x600pixels)
- Power supply available by AC adapter and a built-in battery.

Intended Use

The PadScan HD 5 Plus is used for measuring the urine volume in the bladder noninvasively by projecting ultrasound energy through the lower abdomen of the patient to obtain images of the bladder.

Contraindications

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

- To prevent cross-infection, do not use on patients with open skin or wounds in the suprapubic region.
- This device is not intended for fetus use or for use on pregnant patients.
- 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.

Declaration of electromagnetic compatibility

PadScan HD 5 Plus in use 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 5 Plus under strong electromagnetic environments, close to generator, X-ray device, dental and physical therapy equipment, broadcasting stations, or buried cables, etc... may appear signal interference in the image. Stop using the PadScan HD 5 Plus until removal of the electromagnetic interference.

Warning: Shared power supply may appear abnormal images. 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.

The PadScan HD 5 Plus Bladder Scanner has been tested and found to comply with the electromagnetic compatibility (EMC) limits for medical devices to IEC 60601-1-2:2014, IEC 60601-1-2-37:2007 + A1: 2015. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

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 ventilation
- 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: Users 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.

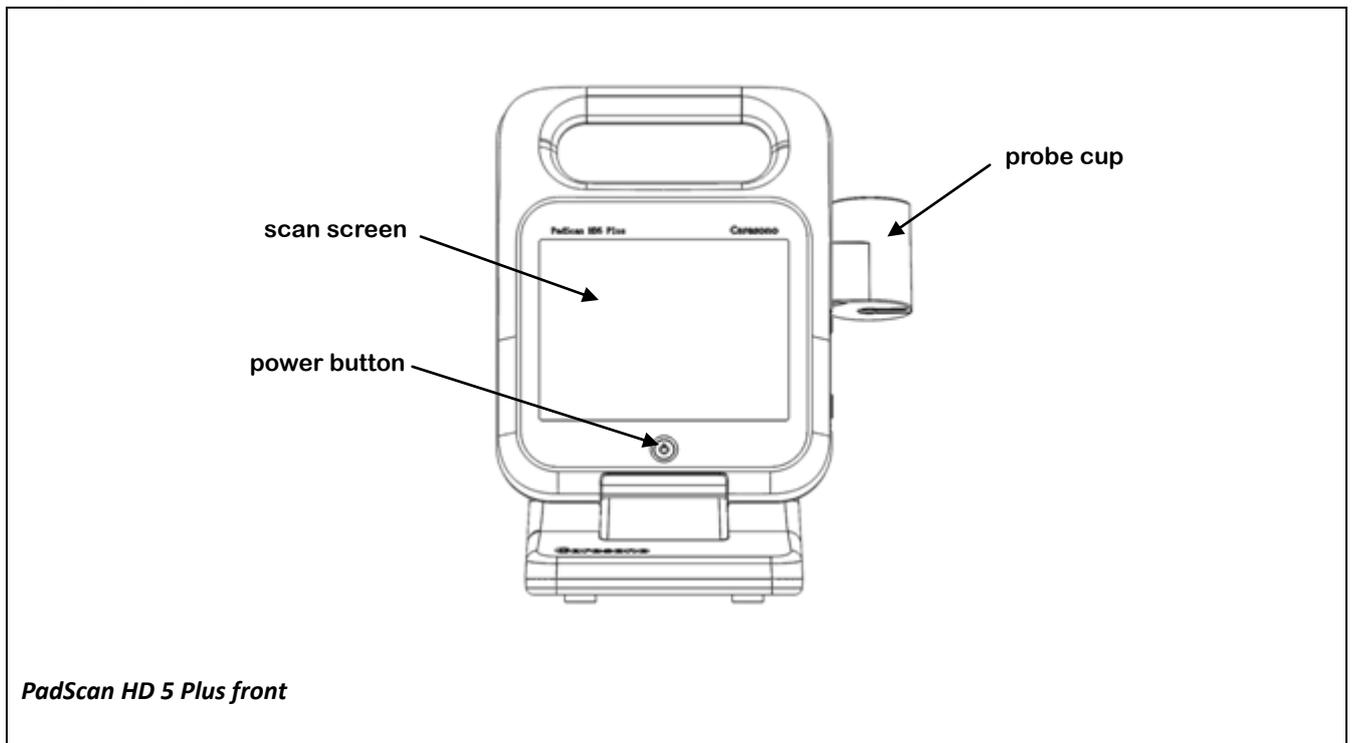
Warning: This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

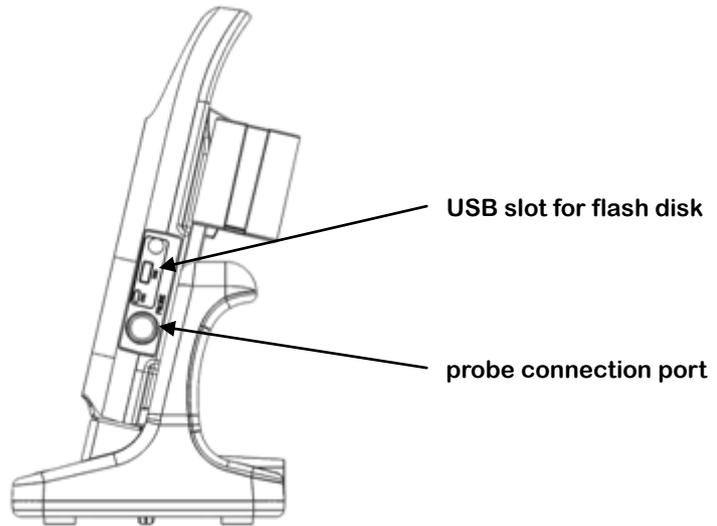
EQUIPMENT UNPACKING AND INSTALLATION

Unpacking

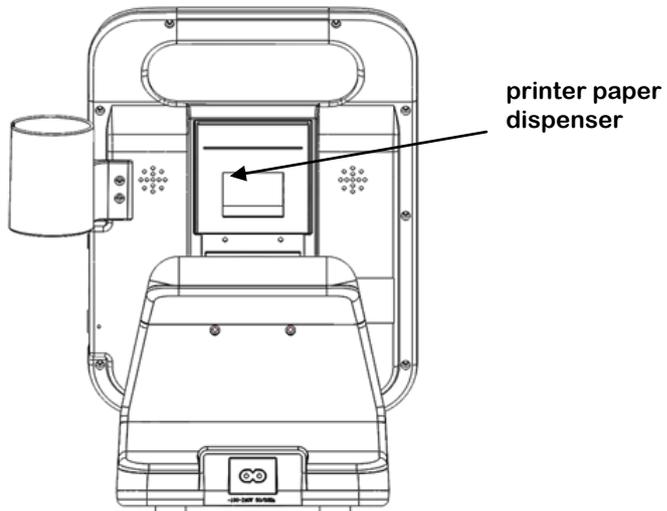
When you receive a PadScan HD5 plus, perform a full visual inspection of the device for any obvious physical damage that may have occurred during shipment, and then check the components and accessories against the packing list. A standard PadScan HD 5 Plus system is included with:

- 1 main unit
- 1 N2/2.5MHz 3-D Mechanical sector scanning probe
- 1 docking station
- 1 Li-ion battery: Model: SNLB-159
- 1 probe cup
- 2 keys of the carry case
- 1 thumb screws M3*6
- 2 socket head cap screws M3*6
- 1 USB data line
- 1 power line
- 1 U-Disk
- 1 printer paper
- 1 user manual
- 1 Packing list
- 1 Carry case
- Screwdriver





PadScan HD 5 Plus side connection ports

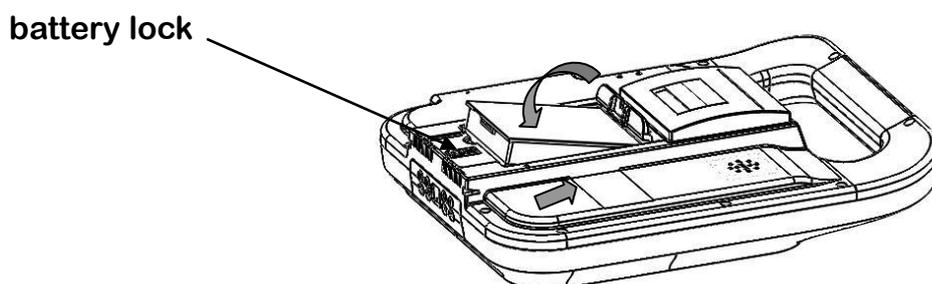


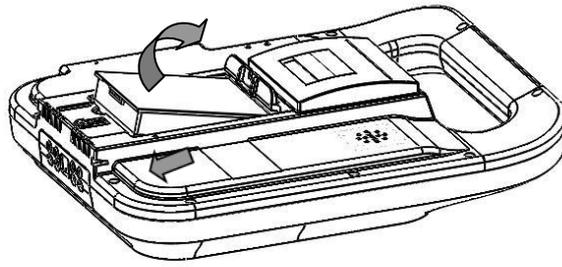
PadScan HD 5 Plus back

Installation

1. Battery Insertion and Removal:

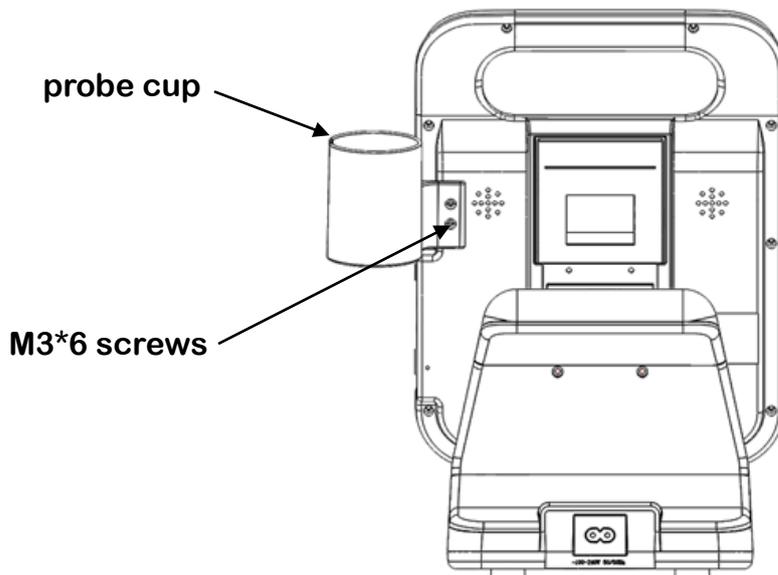
Slide the battery lock downward. Insert the battery into (or remove it from) the battery compartment, and then slide the lock back into the place.





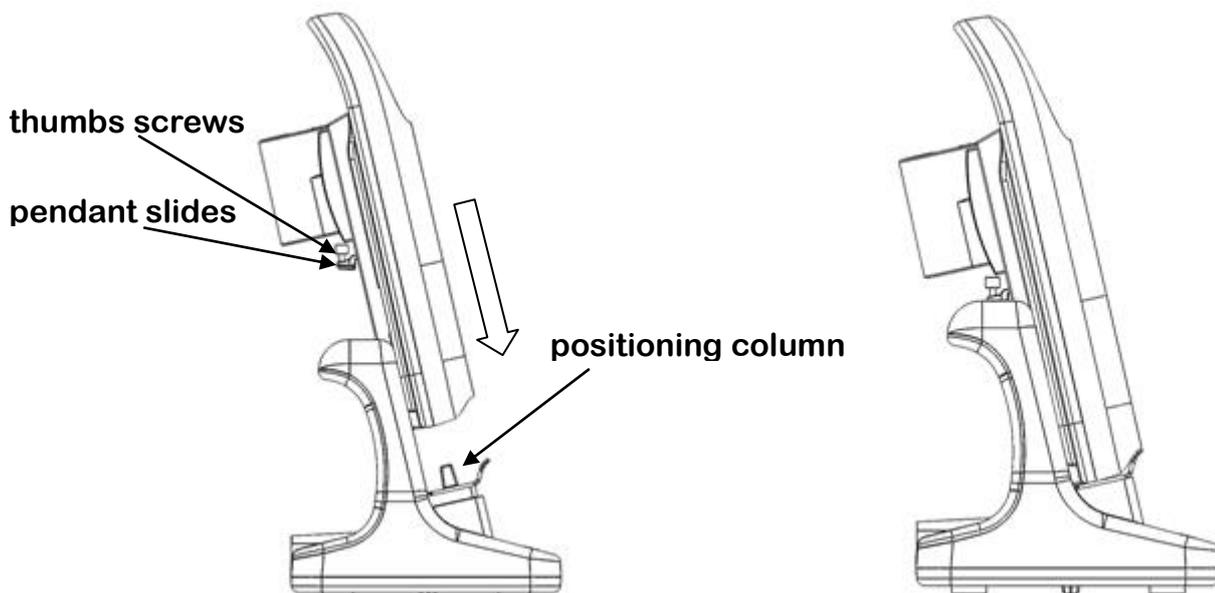
2. Probe Cup Installation and Removal

Align the screw hole of probe cup with the one on main unit as shown in the figure, then tighten the two M3*6 screws using a screwdriver.

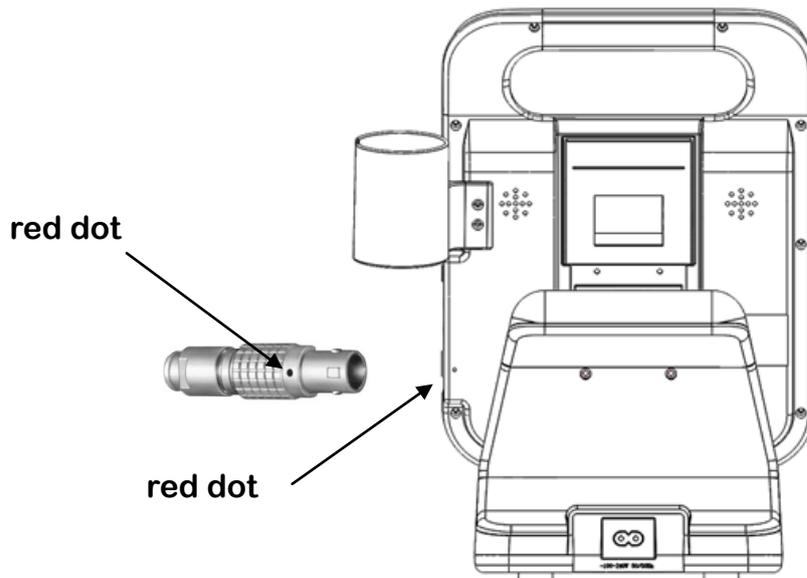


3. Connect the main unit to the docking station

As shown in the figure, gently slide the main unit along the entry on the docking station until the main unit clicks in place, taking the positioning column as reference. Secure the main unit by fixing its pendant slides into the slot on the docking station with the thumbs screws.



4. Attach the probe to the main unit
Align the red dot on the main unit with the black dot on the probe, and gently insert the probe into the main unit.



5. Plug the AC input plug of the adapter into a power outlet. when the indicator light on the DC output turns green, it indicates it is working properly.

Battery Charging and Status

1. Insert 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 orange light on the main unit indicates that the battery requires charging, while the green light indicates that it is fully charged.

Power Supply

PadScan HD 5 Plus is powered by two interchangeable methods: AC adapter and a built-in battery.

By AC Adapter

1. Before each use, inspect the adapter for damage; verify the EPS is in the specified range.
2. Connect the adapter to the docking station.
3. Place the main unit onto the docking station.
4. The light indicator turning green indicates that it is functioning.
5. Turn on the main unit.

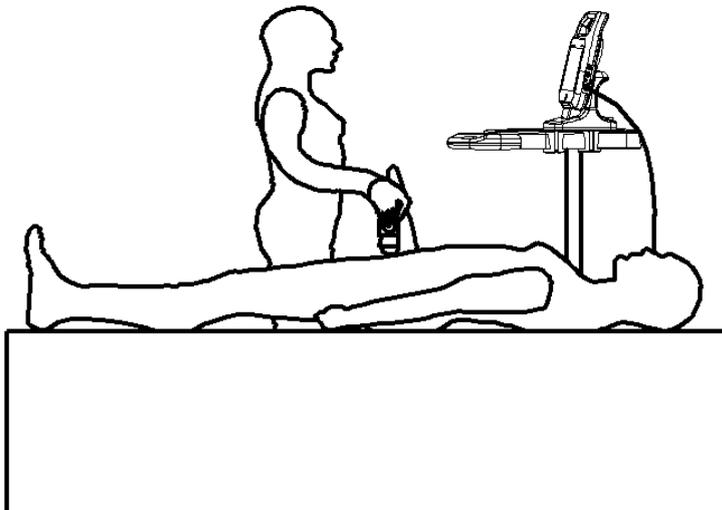
Warning: Use only CARESONO supplied power adapters. Ensure a tight connection between the power cord and the connectors.

By Battery

1. Insert the battery into the main unit as described on page 9.
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 first and the most important step in obtaining correct volume measurements. The bladder is located in the lower abdomen, below the navel while approximately 3 cm above the pubic bone. Place an ample quantity of ultrasound gel on the patient's abdomen and the probe before each scan. Press the probe as below onto the lower abdomen through the gel.

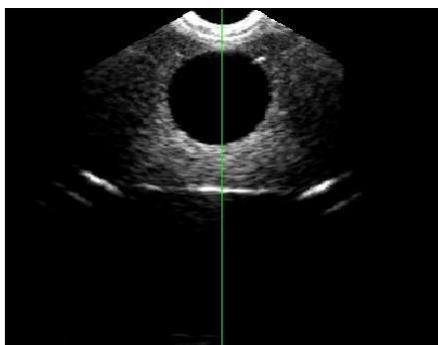


NOTE: the probe button should always be pointed toward the patient's head.

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



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, center the bladder area (dark area within green outlines) relative to the vertical green line. It indicates that the bladder is centered if the center line is green or it is off centered if orange.

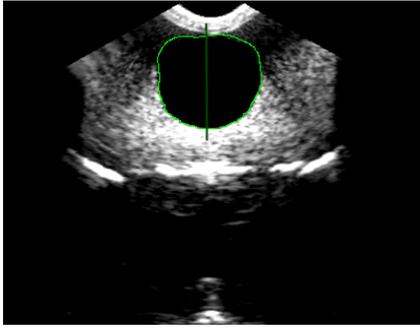


Figure 1: correct position (expert mode)

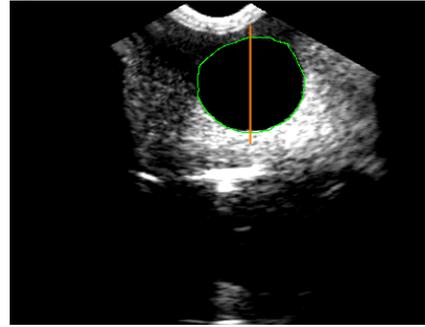


Figure 2: incorrect position (expert mode)

In easy mode, center the bladder area relative to the vertical center line. If the bladder area is green, the scan is on target and successful; while if the bladder area is orange, the scan is off target and unsuccessful.

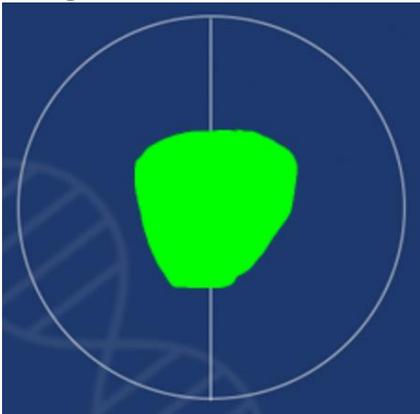


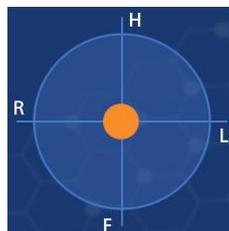
Figure 3: correct position (easy mode)



Figure 4: incorrect position (easy mode)

If the bladder is off centered to the right relative to the center line, move the probe toward the left slowly; if the bladder is off centered to the left relative to the center line, move the probe toward the right slowly;

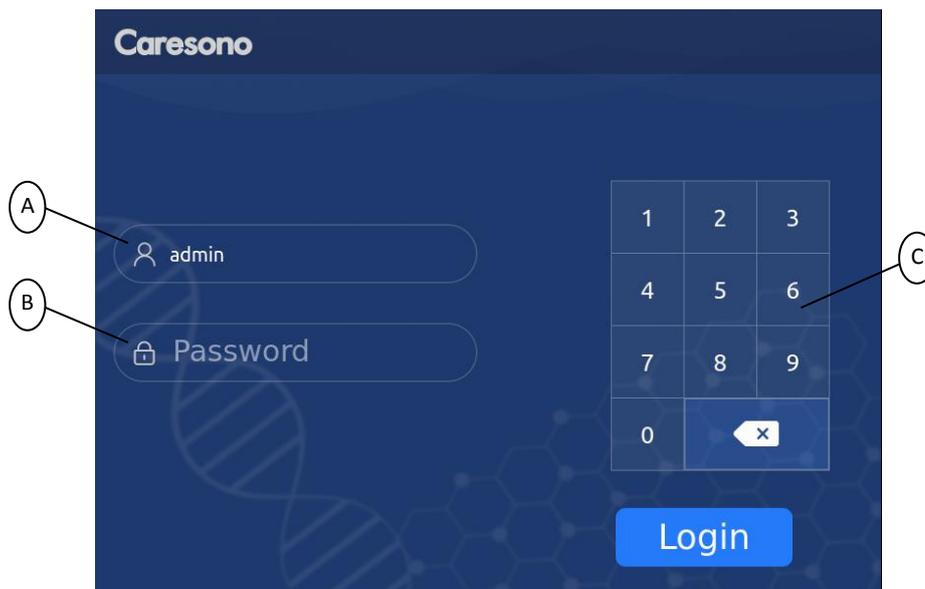
In both Expert and Easy modes, a projection of the bladder in the crosshair is displayed at the right side on the screen. It helps re-aim and re-scan. (You can enable/disable this function from SETUP menu>Display>Projection ON/OFF)



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

PADSCAN HD 5 PLUS SCANNER SCREENS AND BUTTONS

Login Screen

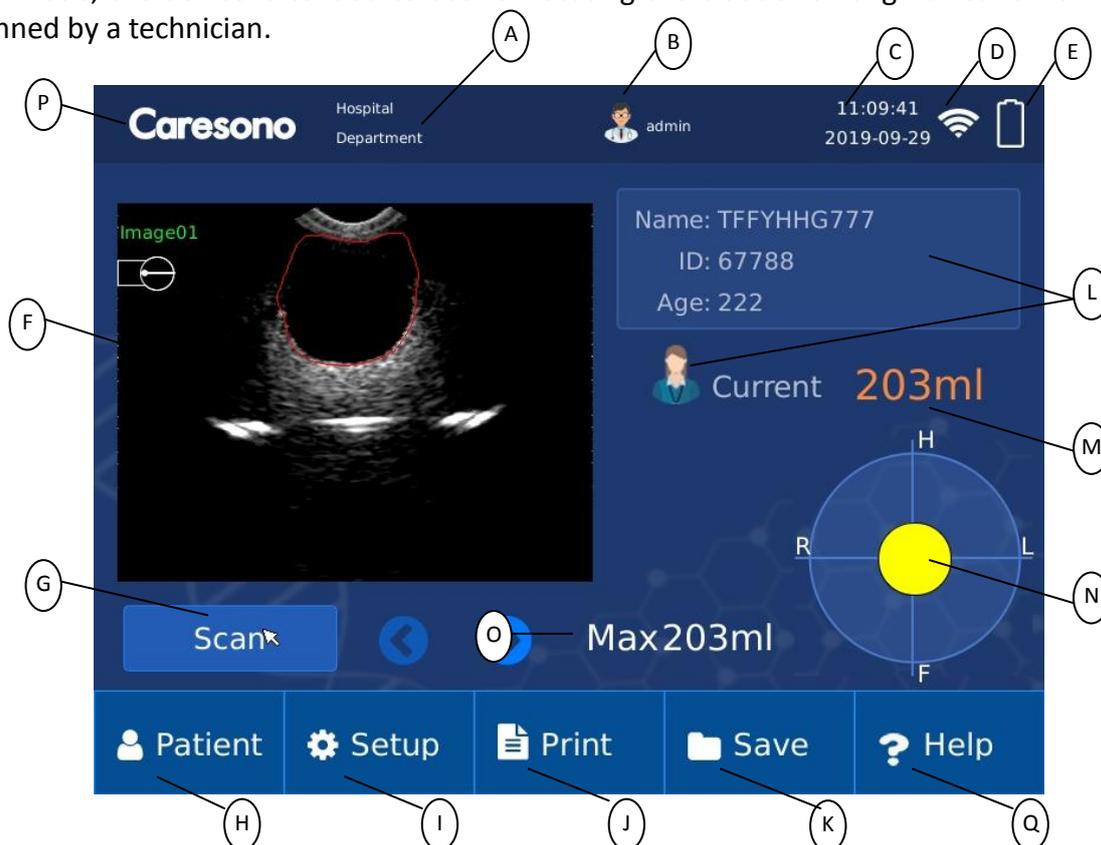


A	Operator: Tap to select user ID
B	Password: Tap to type password
C	Keyboard:use for typing
Login	Tap when ID and password are complete

Home Screen

Expert Mode

Under this mode, the device is tended to use for locating the bladder through a real-time 2D ultrasound image scanned by a technician.



A:	Hospital/Clinic and Department
B:	Admin User
C:	Date and Time
D:	WiFi
E:	Battery status indicator
F:	Ultrasound Image displayed area
G:	Scan icon
H:	Tap to add new or review patient data (see page 14)
I:	Tap to enter Setup menu
J:	Tap to print current scan
K:	Tap to save current scan
L:	Patient information
M:	Current Volume
N:	Projection of probe aiming (Optional)
O:	Maximum Volume displayed (Optional)
P:	Caresono company logo
Q:	Tap to enter instructional video

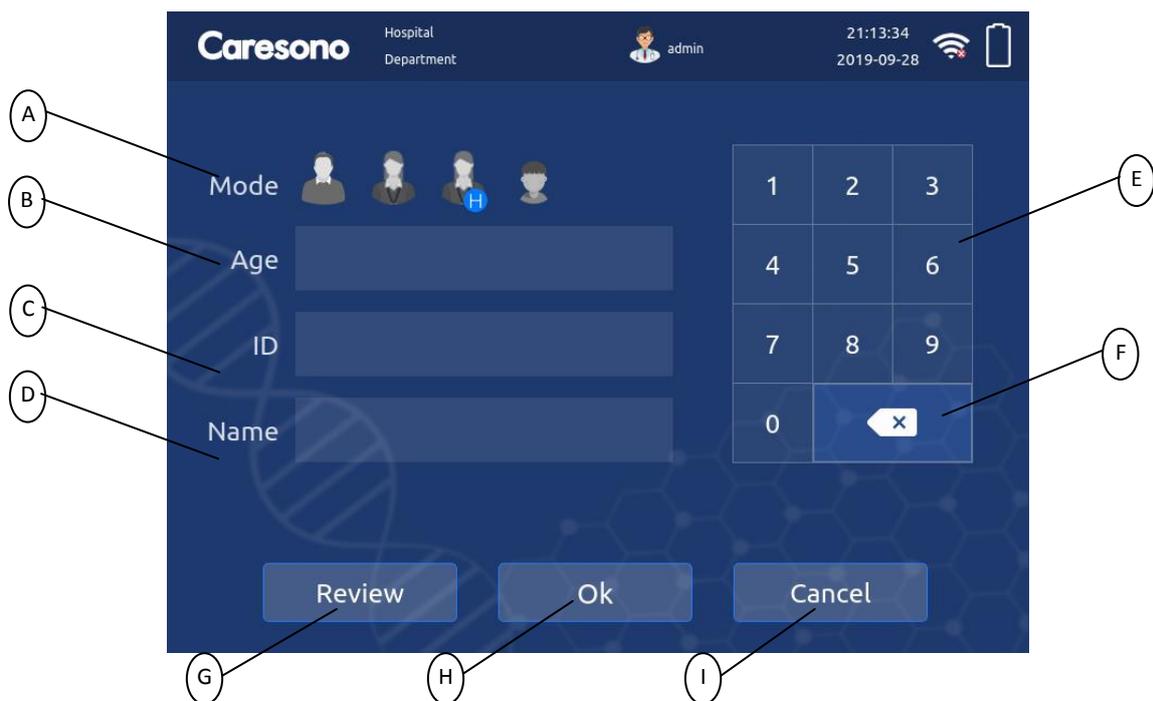
Easy Mode

It is designed to provide the guidance to help find the correct location of the bladder, but not to provide a real-time 2D scanned image.



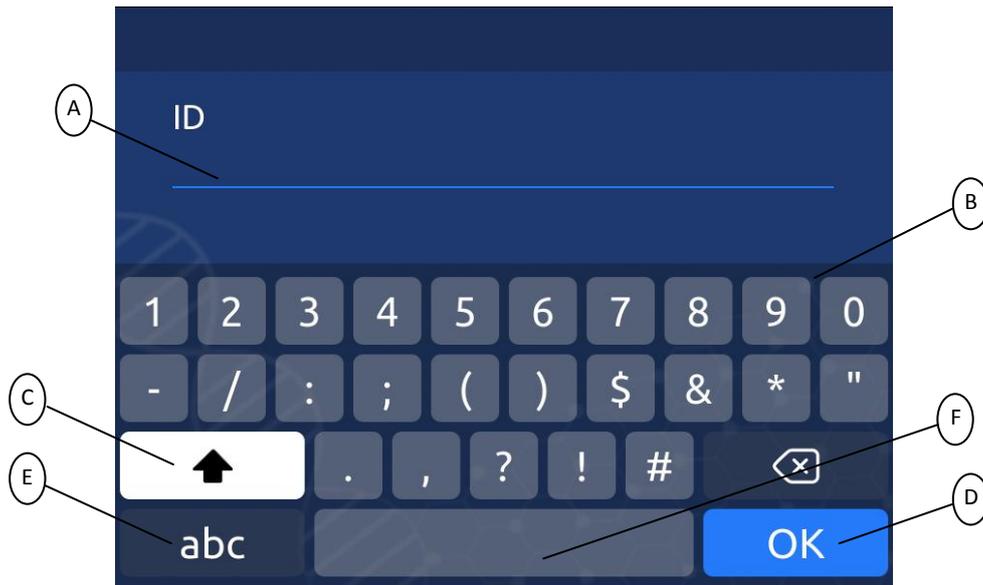
A:	Crosshair
B:	Profile of the urine bladder

Patient Information Screen



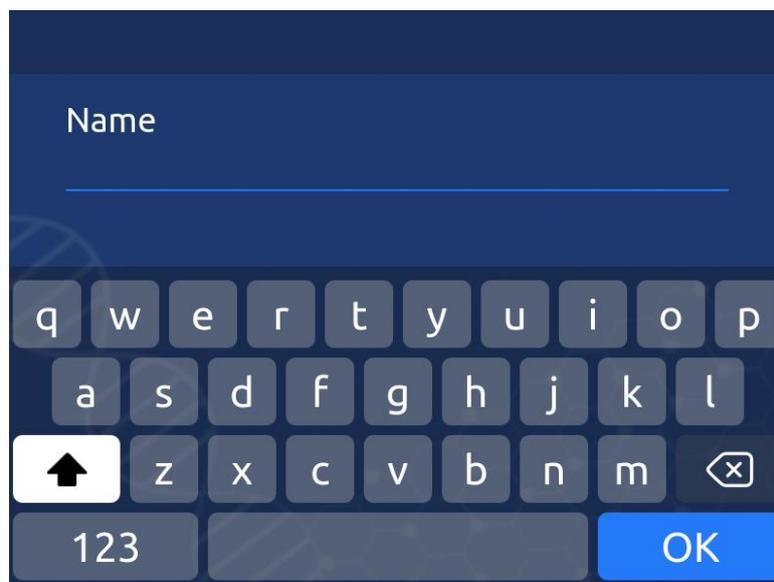
A:	Tap Mode and then icon [<i>male</i>  , <i>female</i>  , <i>female with hysterectomy</i>  , or <i>child</i>  (under 120cm tall and weighing less than 25kg)]
B:	Tap to add Patient Age
C:	Tap to add Patient ID
D:	Tap to add Patient Name
E:	Keyboard for typing age
F:	Tap to clear content
G:	Tap to enter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

Virtual keyboard to enter Patient ID



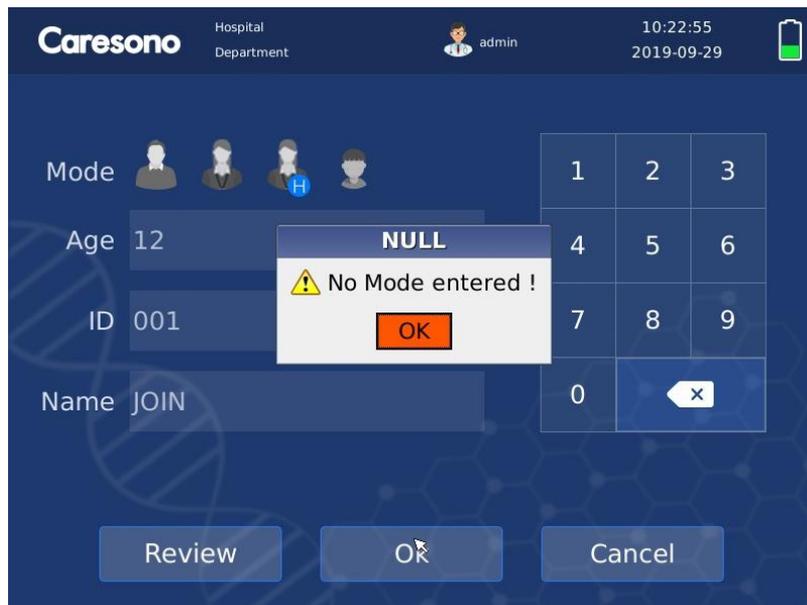
A:	Input patient ID
B:	Virtual keyboard
C:	Caps lock
D:	Confirm the content entered
E:	Switch between words and numbers
F:	Backspace

Virtual keyboard to enter patient Name



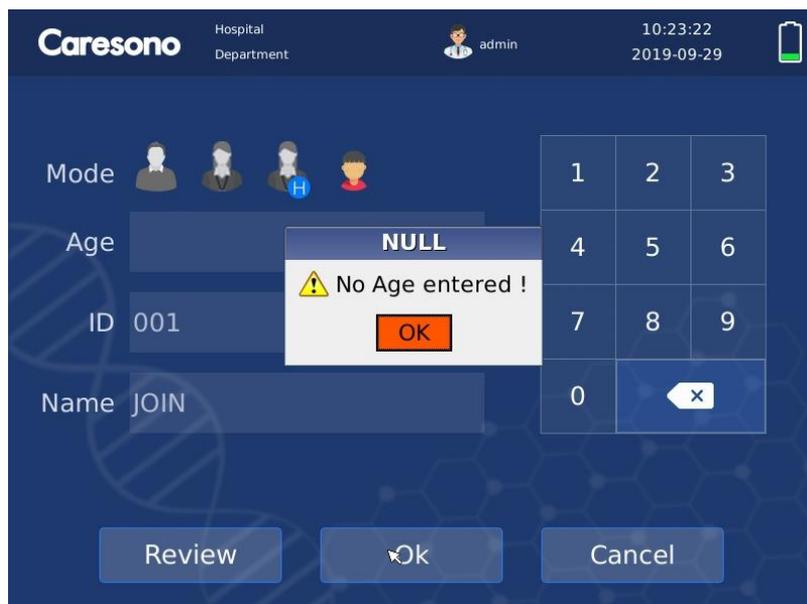
NOTE: The patient information must be entered correctly and completely, otherwise the following dialog box will appear if any of it is not entered:

A. On the Patient Information screen, there are four options available in the Mode icon; It is required to tap one of them or the following dialog box will appear on the screen;



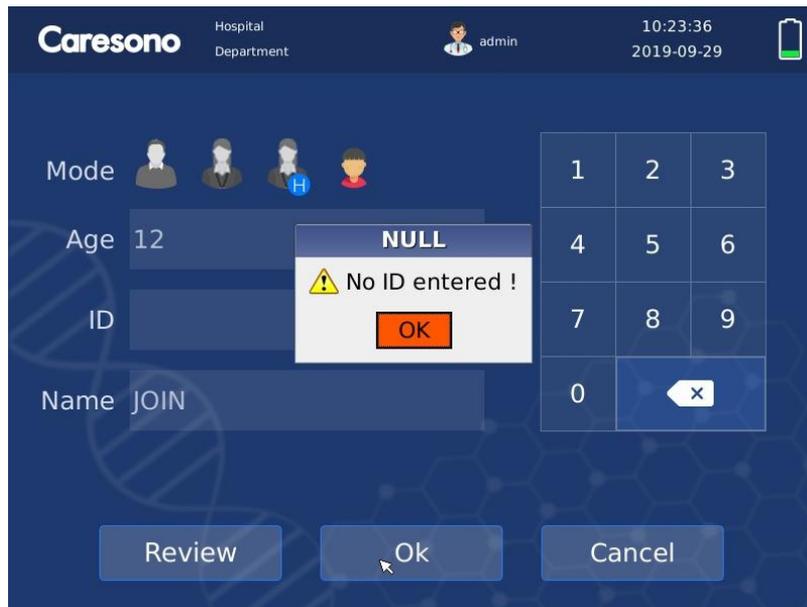
Null: No Mode entered

B. On the Patient Information screen, age can be entered at a maximum of 3-digit number; It is required to enter or the following dialog box will appear on the screen;



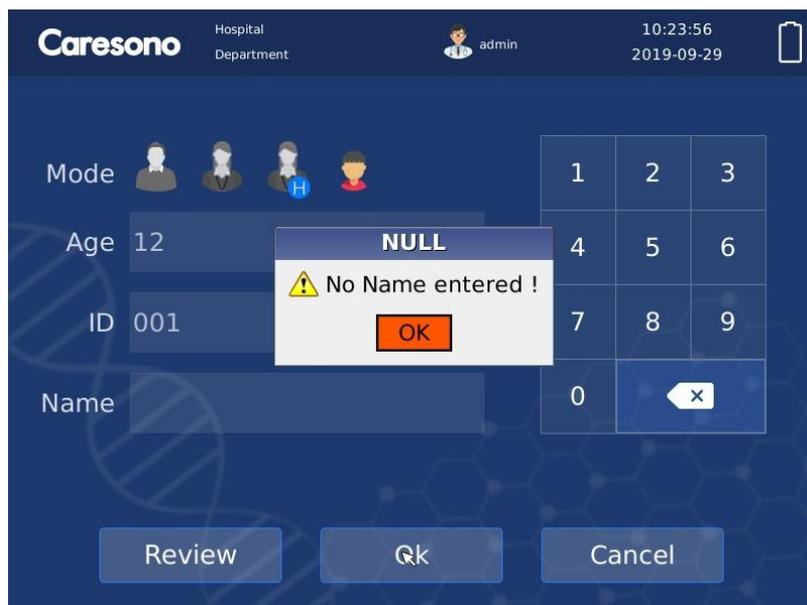
Null: No Age entered

- C. On the Patient Information screen, ID can be entered at a maximum of 12-digit number; It is required to enter or the following dialog box will appear on the screen;



Null: No ID entered

- D. On the Patient Information screen, Name can be entered at a maximum of 12-digit number; It is required to enter or the following dialog box will appear on the screen;



Null: No name entered

NOTE: If you want to go to the Home screen, tap the **OK** after you are finished entering all information requested.

Save and Review Patient Data

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

NOTE: If you want to save the scan results to Patient Data Management, you must select the patient mode at least in the Patient Information screen before scan. Then you can review the saved exam in the Patient Data Management.

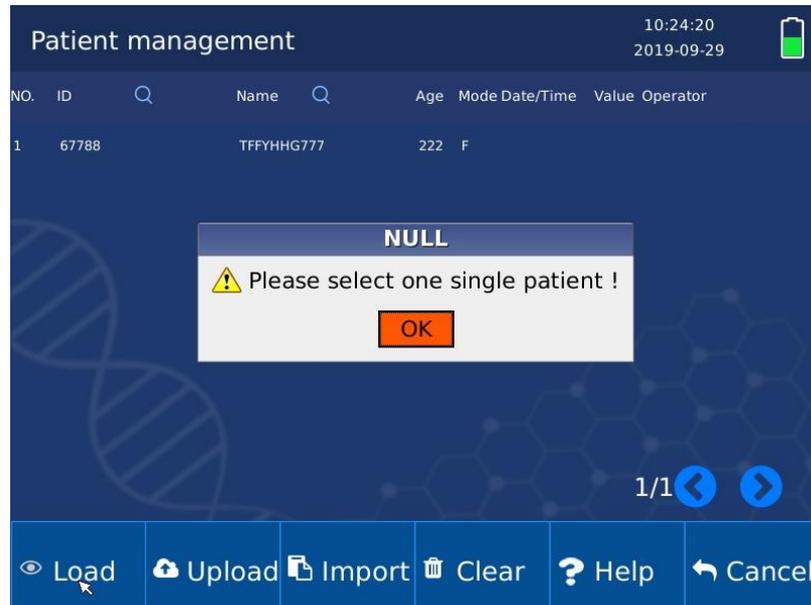
- Tap  on the Home screen and then tap  to enter Patient Data Management screen.
- Tap the line in the patient list then tap  to review the data.
- Tap  or  to move through the pages of patient information.



A:	Sequence Number
B:	Patient ID or tap it to search for the specific patient through ID entered
C:	Patient Name or tap it to search for the specific patient through Name entered
D:	Patient Age
E:	Patient Mode
F:	Time and Date
G:	Urine Volume
H:	Operator Name
I:	Selected Patient
J:	Review more details about the selected patient
K:	Upload through WIFI or USB
L:	Rescan or modify the selected patient
M:	Clear the scan result
N:	Previous page
O:	Next page
P:	Back to the previous screen
Q:	Tap to enter instructional video

Load Patient Data

- If you want to review all scanned results and records for one patient, select the patient and tap **Load** to enter the Patient Data Management screen
- If you haven't selected or select two or more patients, the following dialog will appear on the screen.



Null:please select one single patient

Upload patient data through USB or WIFI

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



NOTE: It takes about 1 seconds to export the scan results for one patient to the USB flash disk.

NOTE: Do not remove the USB flash disk while the export is in process.

NOTE: If you want to export the patient data through WiFi, ensure that the WiFi network is reliable

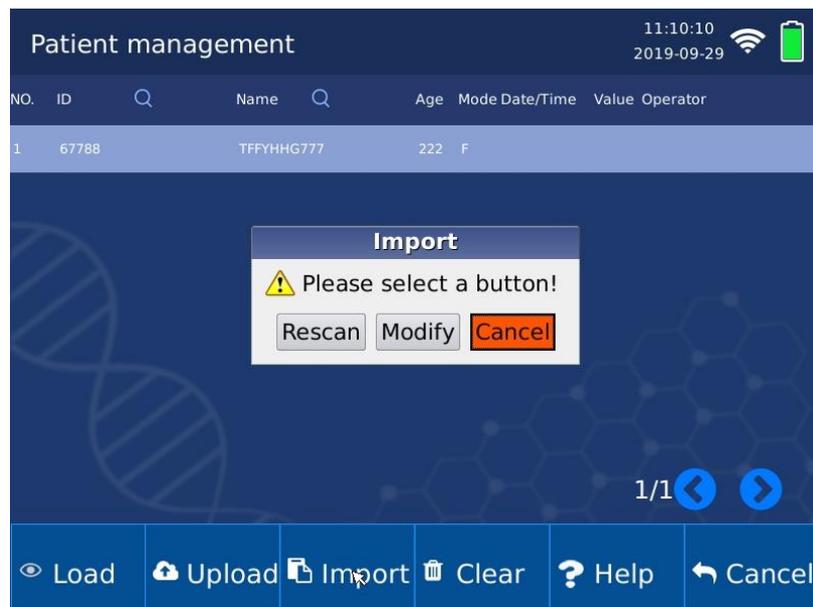
and connected well with the device.

NOTE: Do not turn off the device while the export through WiFi is in process; The time that is needed to complete the process depends on the local network.

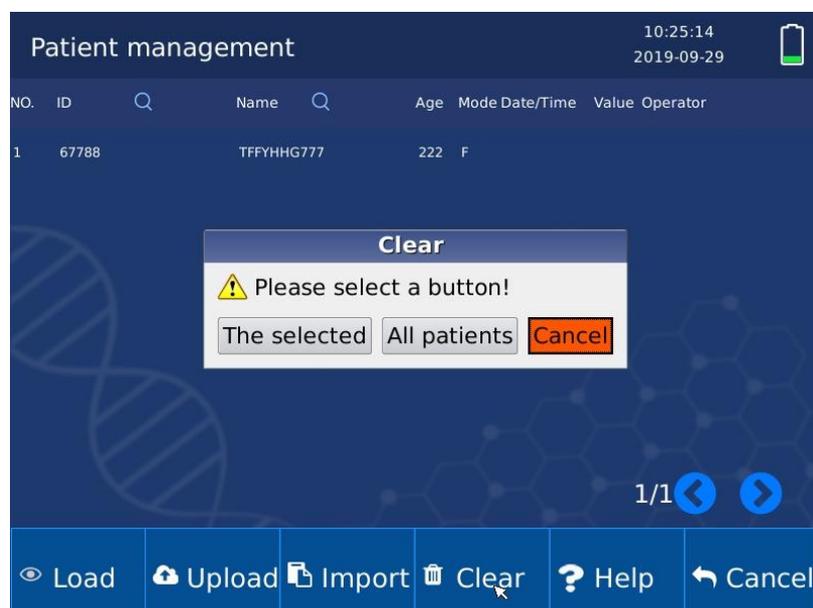
Import Patient Data

- If you want to modify the patient information that has been stored, or to rescan the patient, select the patient record on the list and tap **Import**.

NOTE: If you want to modify the patient information that has been stored, tap **Modify**.
If you want to rescan the patient whose information has been stored, tap **Rescan**

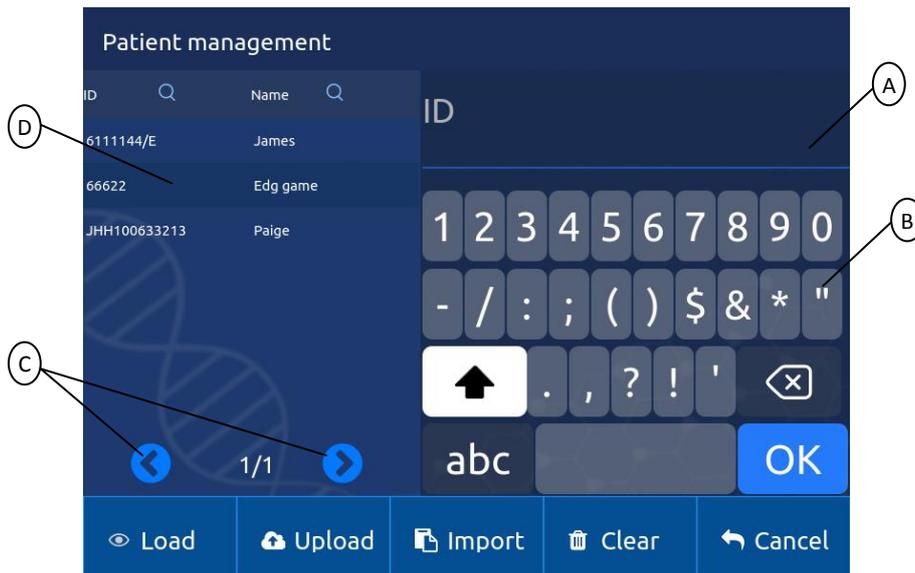


- Tap  to clear patient data.
- Tap Clear to clear up the selected or all patients' scan results.



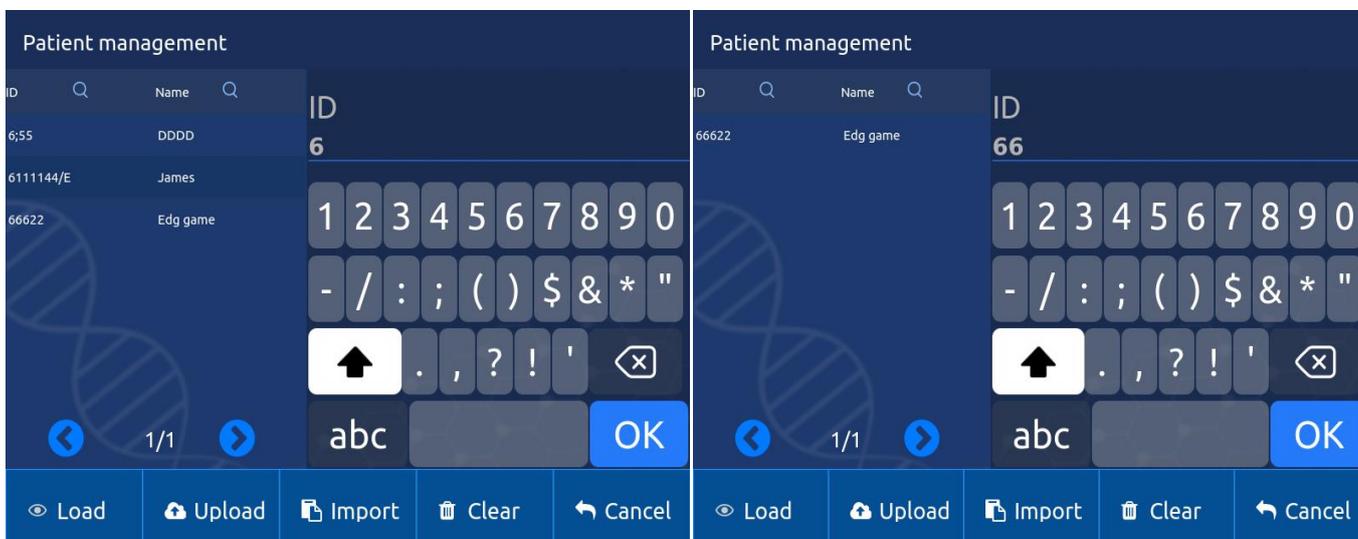
ID and Name Search

Tap **ID** or **Name** to enter the Search screen; The following Search as example is performed through ID.



NOTE: On the Search screen, you may upload or delete patient scans on a batch basis

If you enter the ID to be Searched, the display area on the left side will appear all patient data that satisfies your request.



Patient Data Management

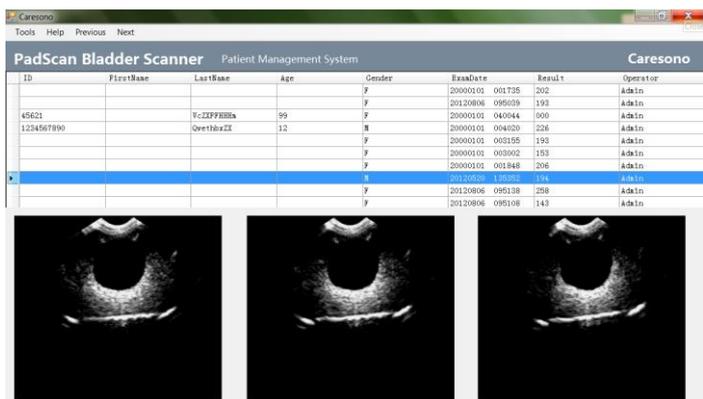
Connect to PC

- Install HD 5 Plus’s software in the PC.
- Connect HD 5 Plus with a computer through the USB cable, whose one end inserting the mini USB port of HD5 Plus.
- Tap  in the Home screen and then tap  to enter Patient Data Management screen.
- Run <Patient Data Management> software in the PC.
- Do not remove the USB cable while the export is in process.



Patient Data Management

- Select [Tools]->[Sync Data] to upload the patient data from HD 5 Plus 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

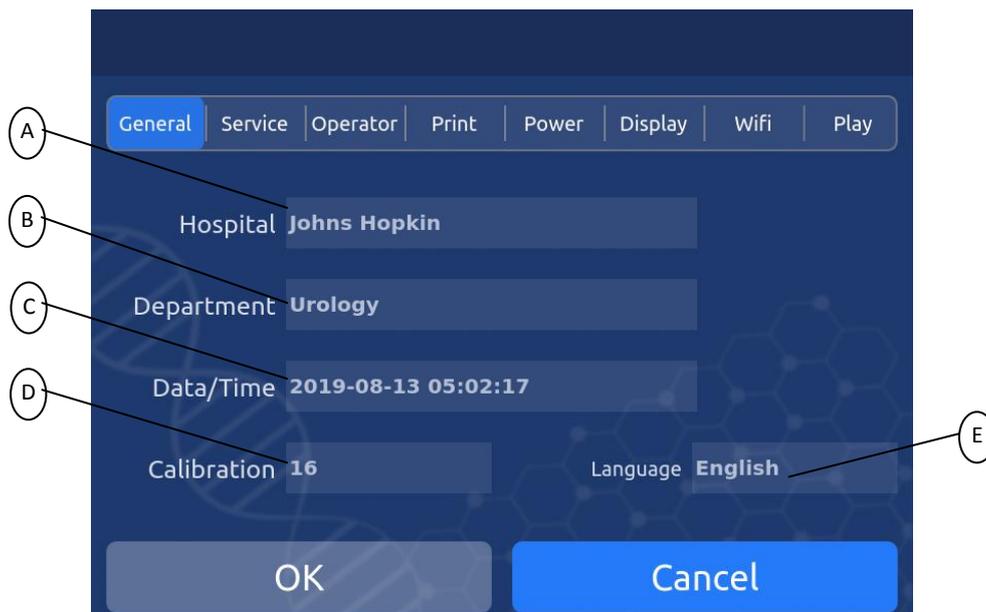
Setup Screen

Tap  on the Home screen to configure the system.



A: General

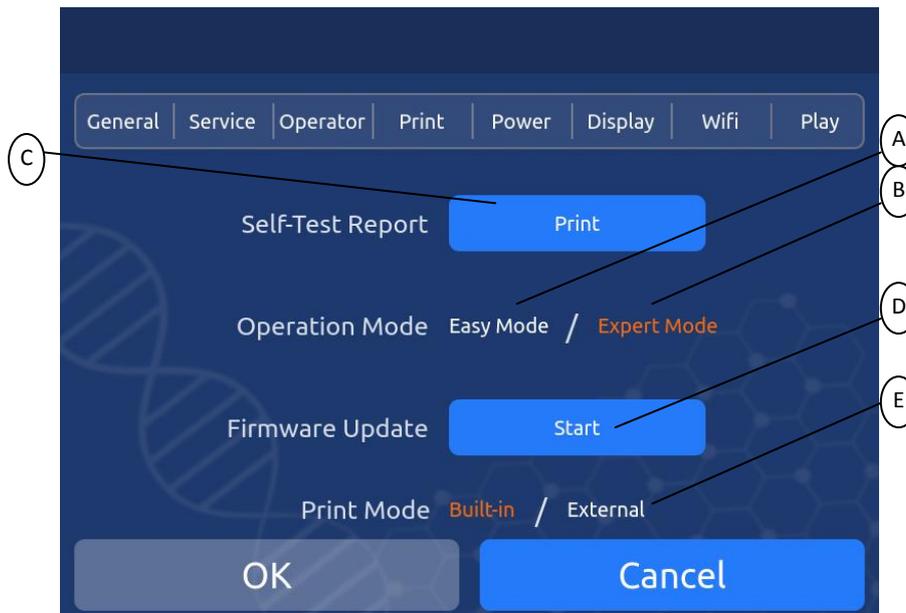
Tap  to add basic information and to start probe calibration if necessary (see page 33 for calibration information).



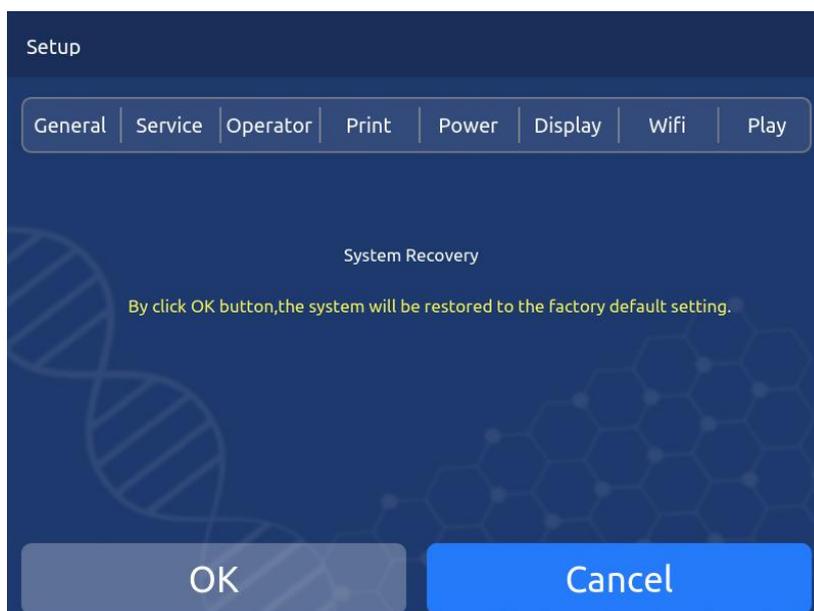
A:	Tap to add the clinic/hospital name. A maximum of 12 letters can be added.
B:	Tap to add the department name. A maximum of 12 letters can be added.
C:	Tap to add date and time.
D:	Tap to start calibration (see page 24 for more information on how to calibrate)
E:	Tap for Language selection.

B. Service

Tap **Service** to select the operation mode (**Expert** or **Easy**) or to restore all settings to default . A password is required before any changes are made on 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
E:	Tap name for Built in printer
F:	Tap name for External printer



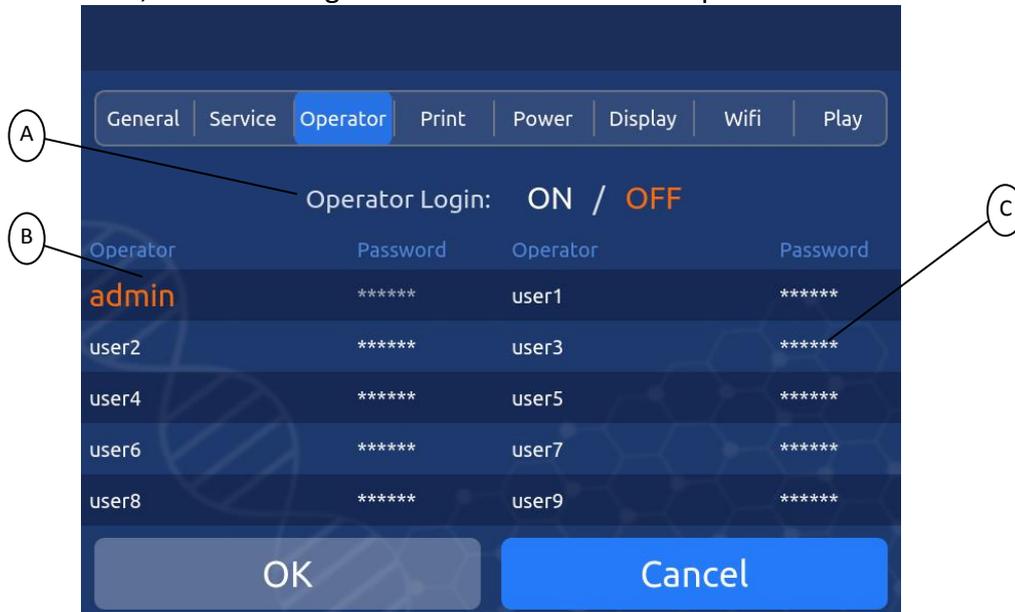
NOTE: If you perform the **System Recovery**, the following settings will get back to defaults:

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

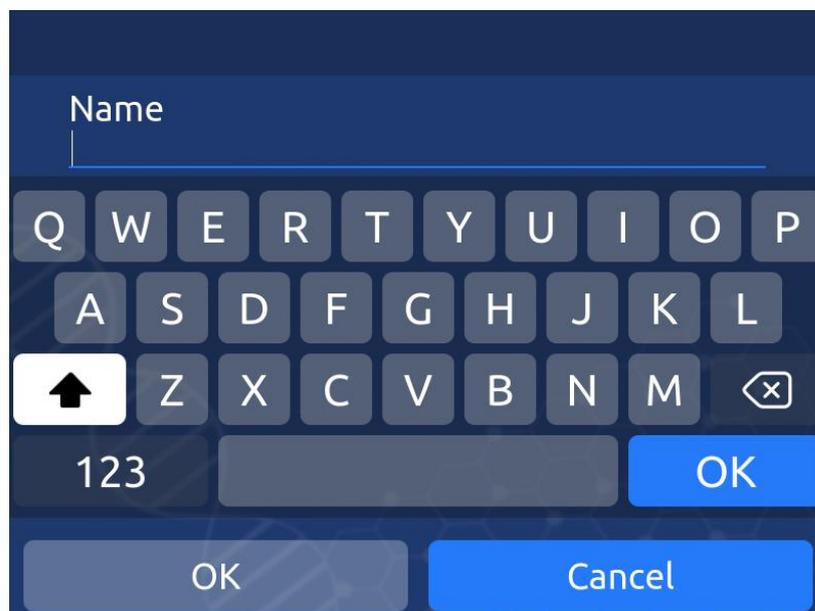
Tap **Operator** to enter the system Administrators Access screen. A maximum of 10 users can be added in this field with user names and passwords. Administrators can modify users' passwords and names in this screen.

Tap **Operator Login: ON / OFF** to turn ON or OFF the procedure of logging in the entire system through passwords. If it's turned off, the access is granted for all users without passwords.

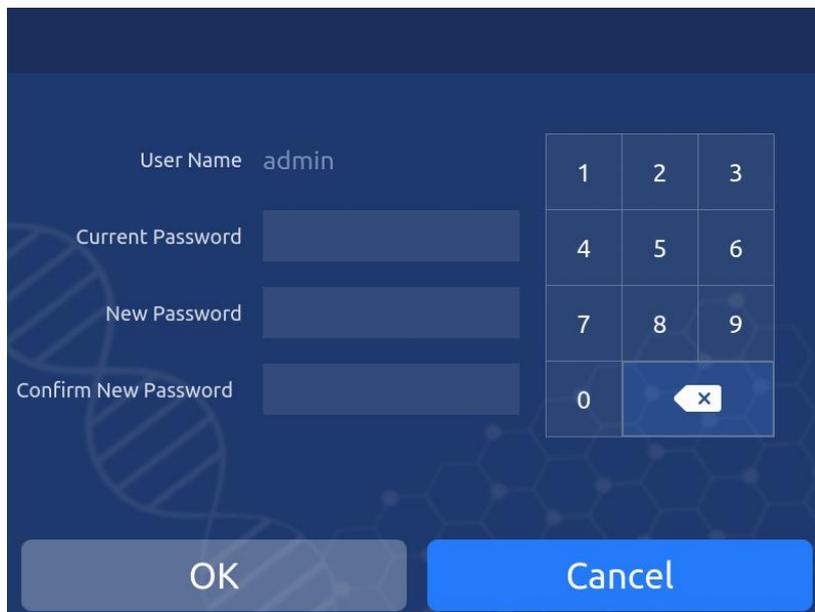


A:	Operator log in (ON/OFF)
B:	User's Name
C:	User's Password

Tap **User** and the Name Input screen appears. Input the operator's name in this field.



Input the user's password in this field.

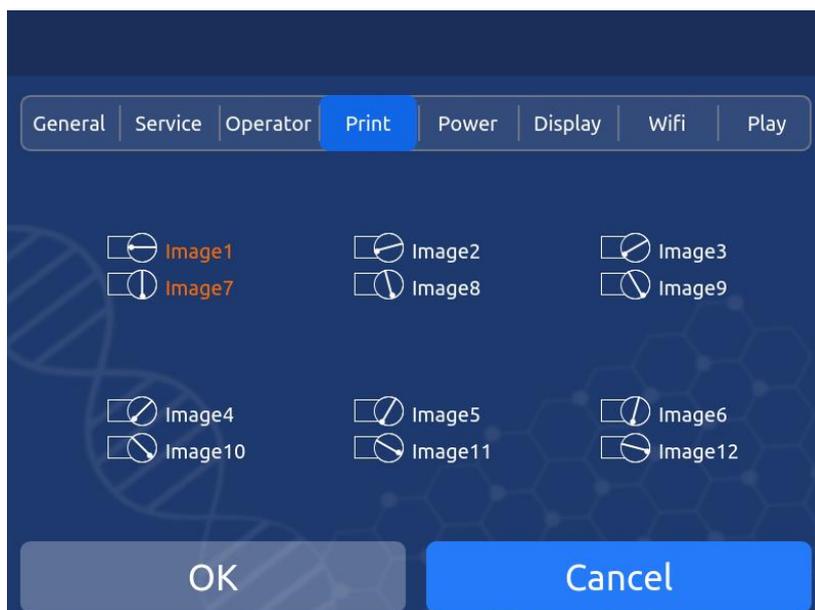


NOTE: The device is configured with default administrator password: 123456 and user password is: 000000.

NOTE: If you tap **OFF** to disable **Operator Login** under Setup screen, the login procedure through password will be canceled when you start the device.

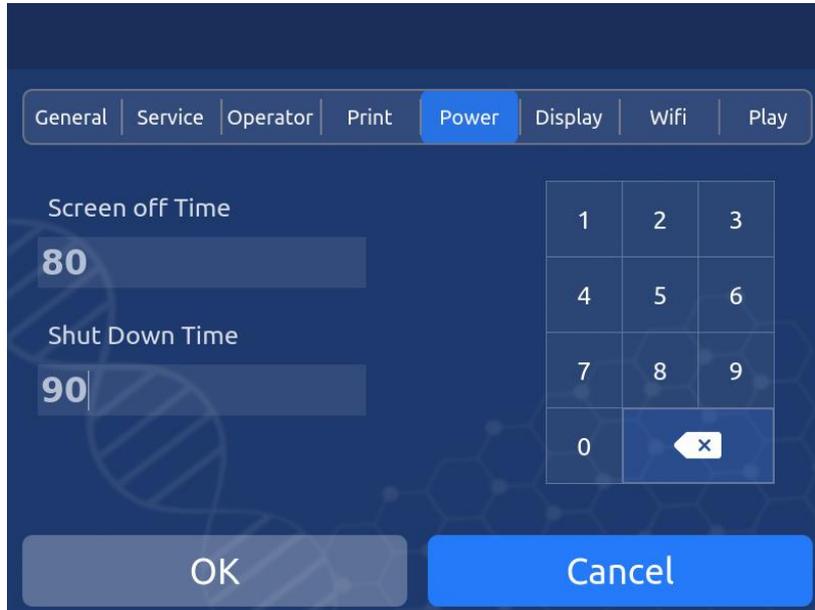
D. Print

Tap **Print** to perform the **Print** settings and pick up one from 6 image groups to print out. (example: *Image 1&7, Image 2&8, etc...*). Each group contains two cross-sectional images.



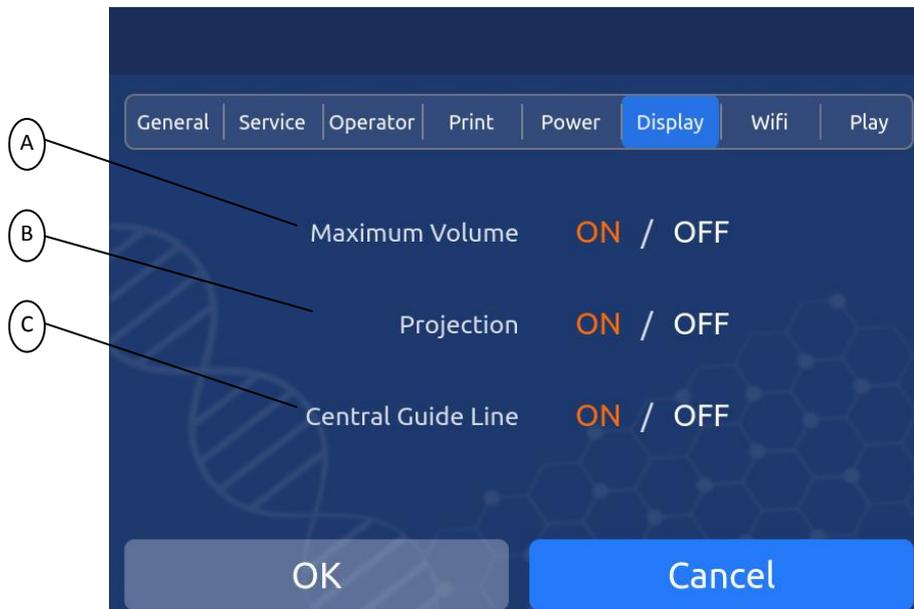
E. Power

Tap **Power** to perform the **Power** settings for the system. Input the time (in minutes) in the **Screen Off Time** field to place the whole system in standby mode input the screensaver activation time (in minutes). Input the time (in minutes) in the **Shut Down Time** field to automatically power off the whole system.



F. Display

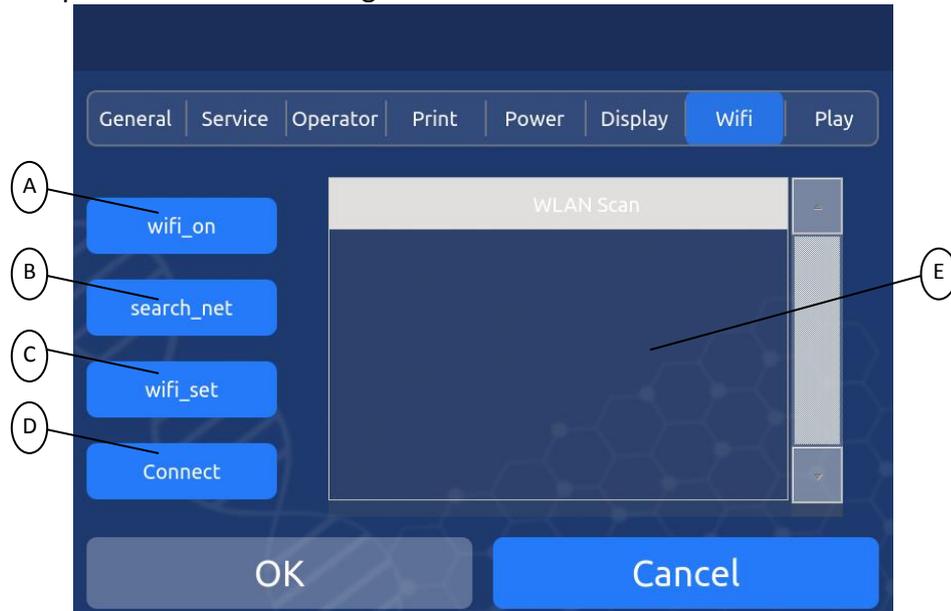
Tap **Display** to perform the **Display** settings on Home screen. Tap **ON** or **OFF** to enable or disable the features.



A:	Display the largest volume obtained for the patient on Home screen.
B:	Display crosshair of project icon guide on Home screen
C:	Display central guide line in Expert mode

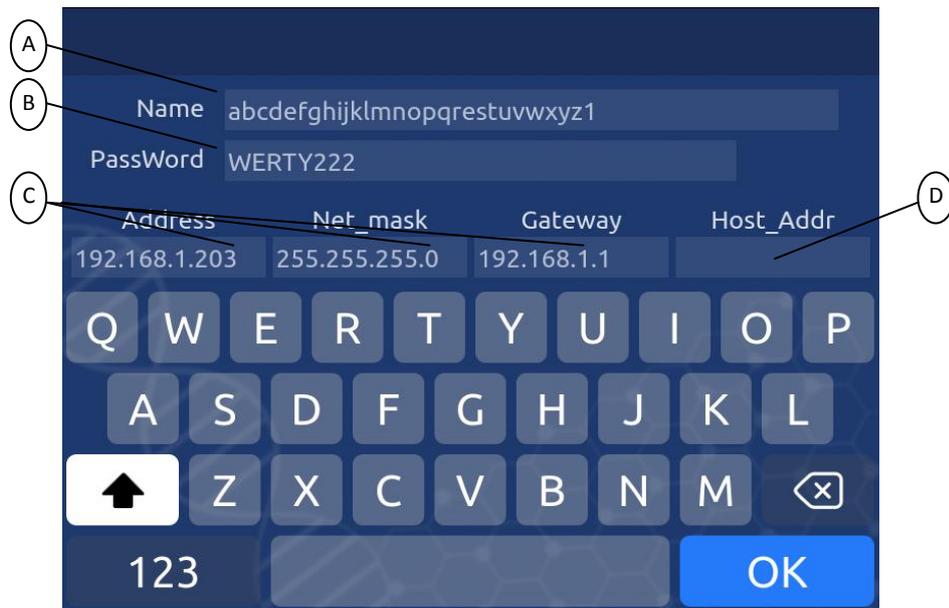
G. WiFi

Tap **Wifi** to perform the Wifi settings.



A:	Turn on/off WiFi
B:	Tap to search for WiFi signals
C:	Perform the configurable settings to connect with WiFi successfully
D:	Tap to connect the WiFi after the WiFi is settled with account number
E:	WiFi signals refreshed area

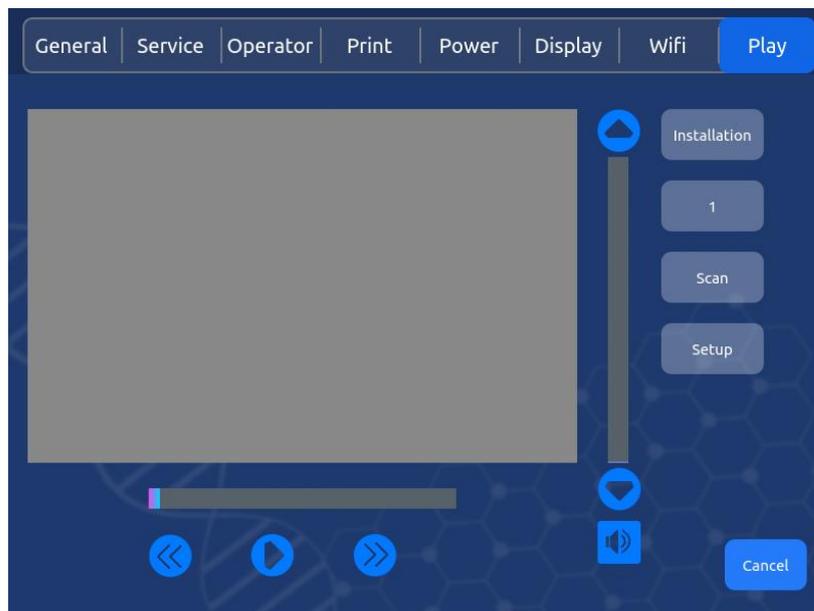
Set up WiFi



A:	add the WiFi's account number
B:	add the WiFi's password
C:	add the device's IP address, net_mask, gateway by hand
D:	add the host's IP address

H. Play

Tap **Play** to display onboard tutorial about installation, setup, operation and data transmission.



A	Tutorial 1	Installation
B	Tutorial 2	Scan
C	Tutorial 3	Setup
D	Tutorial 4	Data Transmission and Management

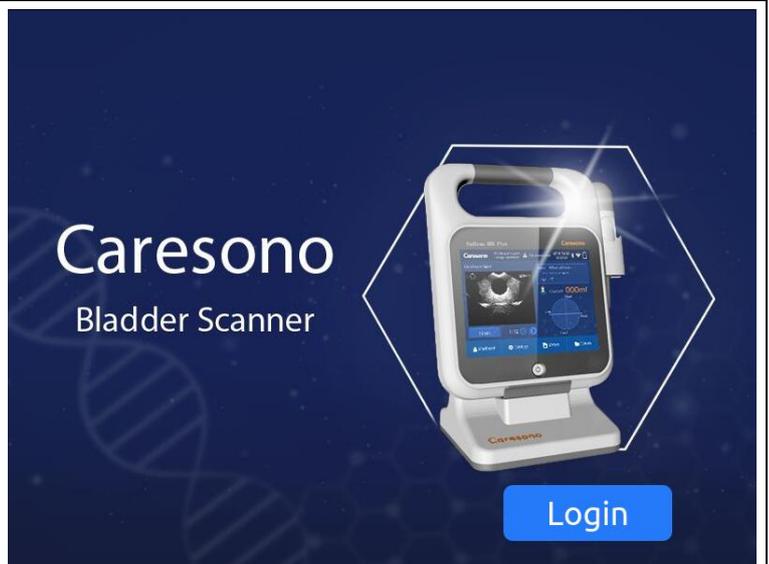
QUICK GUIDE ON HOW TO PERFORM THE PADSCAN HD 5 BLADDER SCANNER

More details about screens can be found on page 13.

1. Login

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

NOTE: If you tap **OFF** to disable **Operator Login** under Setup screen, the login procedure through password will be canceled



2. Add Patient Information

Tap **Patient** to add patient information.



Tap **Mode** and select the appropriate icon.



Tap **ID**, **Age**, **Name** to add corresponding information about the patient.



Tap **OK** when you are finished.

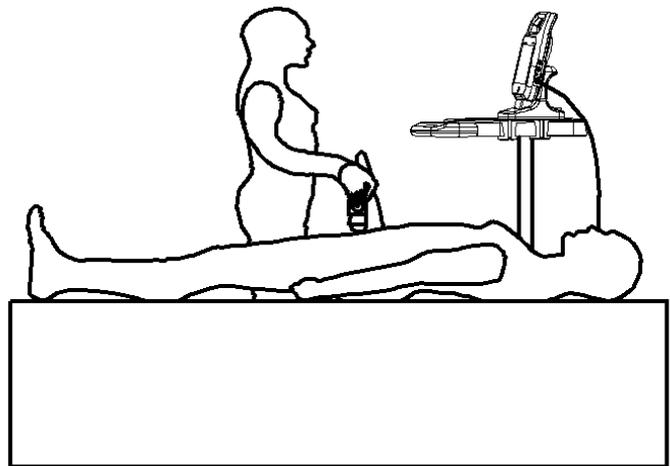


3. Prepare Patient and Position Probe

Let the patient lie in a 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.

Gently press the probe onto the lower abdomen through the gel and ensure the probe's button is oriented at the patient's head.



4. Pre-Scan and Scan

Pre-Scan in **Expert mode:**

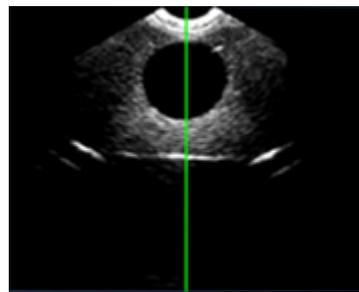
Press and release the button on the probe to start the Pre-scan process (you could view a real-time ultrasound image of the bladder once the process begins). Angle the probe along the body's middle line and tilt it slightly side to side to ensure the bladder area at maximum is centered. Once the bladder is located, press and release the button on the probe again to start the automatic scanning and calculation.

Lift the probe once you hear it sounds 'beep' tone. The bladder volume will be displayed on the screen immediately after the scan is complete in around 5 seconds.

Pre-Scan in **Easy Mode:**

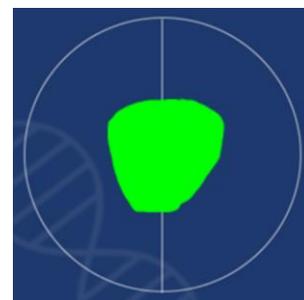
Press and release the button on the probe to start the Pre-scan process (you could view a real-time sectional image of the bladder once the process begins) Angle the probe along the body's middle line and tilt it slightly side to side to ensure the bladder area at maximum is centered relative to the vertical line. Once the bladder is located, press and release the button on the probe again to start the automatic scanning and calculation.

Lift the probe once you hear it sounds 'beep' tone. The bladder volume will be displayed on the screen immediately after the scan is complete in around 5 seconds.



Scan analysis in progress

Scan analysis complete



Scan analysis in progress

Scan analysis complete

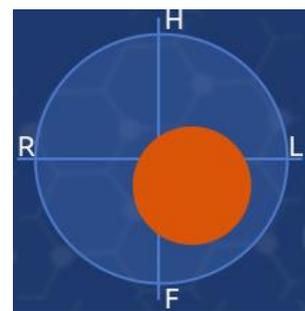
NOTE: Hold the Probe steady while the scan is in process.
Any movement of the probe during the scan will impair the accuracy of the measurement.

5. Re-aim and re-scan

If the scan was on target, the bladder projection will appear in the center of the crosshairs shown as the top right picture.

If the scan was off target, the bladder projection will appear not in the center of the crosshairs shown as the right bottom picture.

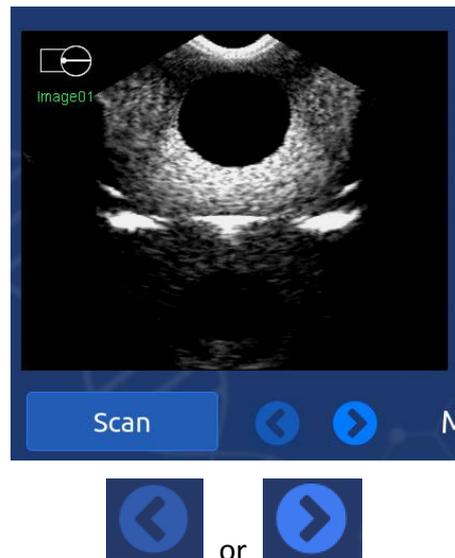
Please refer to Appendix C. of re-aiming.



6. View the scanned images

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

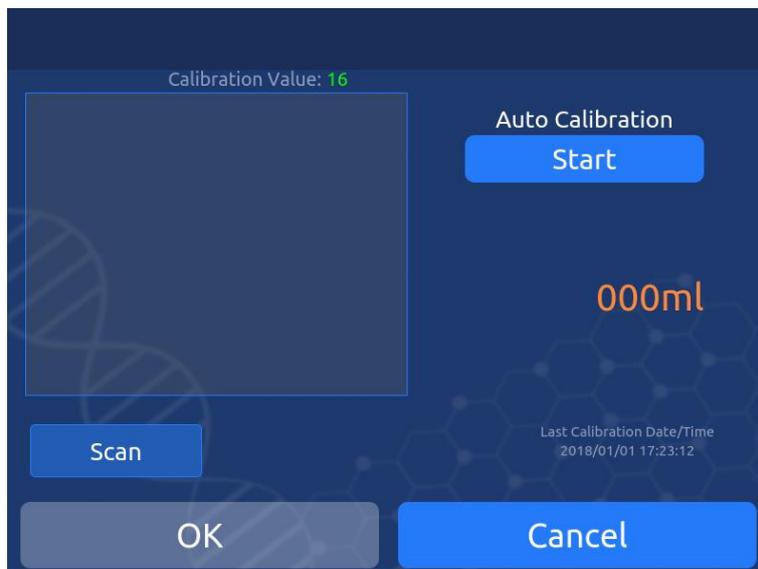
Tap the **LEFT** or **RIGHT** arrows to view the six groups of images.



<p>7. Save Information</p> <p>Tap SAVE to save the exam data and results.</p>	 A blue rectangular button with a white folder icon and the text "Save" in white.
<p>8. Print</p> <p>Tap PRINT to print the scan results. The printout contains the patient's name, ID code, age, scan mode, scan time, bladder volume, and two ultrasound images.</p>	 A blue rectangular button with a white printer icon and the text "Print" in white.

CALIBRATION

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 Plus screen, tap **SETUP>GENERAL>CALIBRATION** to enter the calibration screen.
5. Tap **Start** 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 24.
8. A last calibration date and time will be displayed on the screen after the calibrations succeed.
9. Tap **OK** 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 Plus 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 32.
- 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 33.

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: ≤ 7 second
- 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 consumption: $< 120\text{VA}$
- Dimensions: 220x280x68mm
- Weight: approximately 2600g (including the probe)
- Battery capacity: 2600mA
- Battery charge time: 2 hours;
- Battery life: 2hours continuous scanning, 5 hours standby.
- Languages: English

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

Operating Conditions

Temperature: $+5^{\circ}\text{C}$ to $+40^{\circ}\text{C}$

Relative humidity: 30% to 75%

Pressure: 70kPa to 106kPa

Transportation and Storage Conditions

Temperature: -40°C to $+55^{\circ}\text{C}$

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.

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

PadScan HD 5 Plus in use will not interfere with other wired, wireless equipment and/or other electrical equipment.

Warning: Use of the PadScan HD 5 Plus under strong electromagnetic environments, close to generators, X-ray devices, 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 Plus, or increasing the separation between the PadScan HD 5 Plus 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: $TI < 0.1$;

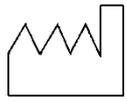
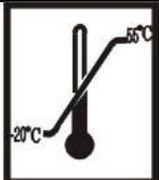
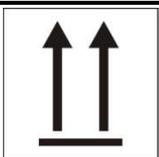
Mechanical index: $MI < 0.5$.

Standards

This device is designed and manufactured in strict accordance with:

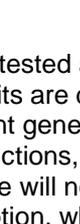
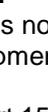
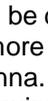
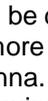
- EN 60601-1-1:2006+A1:2013/IEC 60601-1-1:2005+A1:2012 “Medical electrical equipment - Part 1: General requirements for basic safety and essential performance”
- EN 60601-1-2:2015/IEC 60601-1-2:2014 “ Medical electrical equipment-Part 1-2:General requirements for basic safety and essential performance-Collateral Standard: Electromagnetic disturbances-Requirements and tests”
- IEC 60601-2-37:2007+A1:2005 “Medical electrical equipment-Part 2-37:Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment”
- Type B, Class II protection to the risk of electric shock
- 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>
 <p>Reference user's manual</p>	

APPENDIX A: LABELING

Main Unit Labeling

Name	Bladder Scanner		
Safe mode	Type B	Model	PadScan HD 5 Plus
Power Consumption	14V  3.5A	FCC ID: 2AUG5-HD5PLUS	
SN	BS/XXXXXXXX		 WARNING
	XXXX-XX		
 Caresono Technology Co., Ltd. 4th Floor, No. 11 Building, Initiating Zone, Instruments and Meters Industry Base, Near Port Industry Zone, Dandong, Liaoning, China			
  MEQUIPEX Feldstrasse 39, 4813 Altmuenster Austria			

Probe Labeling



FCC Statement

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.

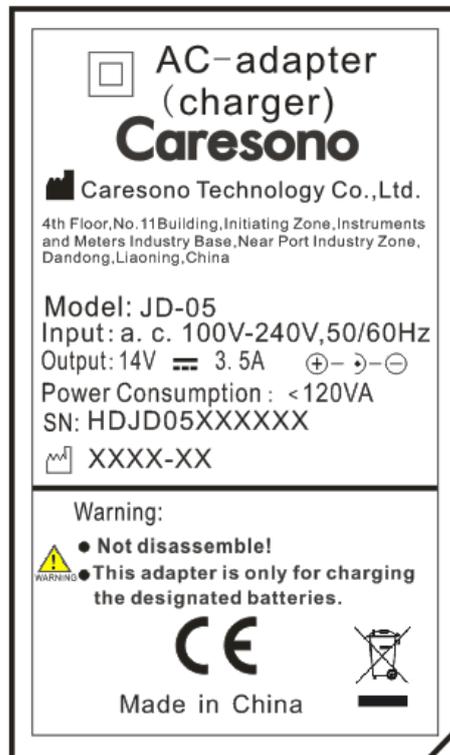
§ 15.21 Information to user.

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

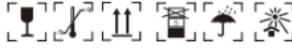
This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

The antenna(s) used for this transmitter must be installed to provide a separation distance of at least 20 cm from all persons and must not be co-located or operating in conjunction with any other antenna or transmitter.

Adapter Labeling



Package labeling



MEQUIPEX Bernhard Kern
 Feldstrasse 39, 4813 Altmünster Austria
 Tel: +43 (650) 7352000 Fax: +43 (650) 7352005
 E-mail: info@caresono.com

MODEL: _____ Q.TY: 1
 GW /NW: _____ DIMS: 470*400*270 (mm³)

Digital Diagnostic Ultrasound Devices



Storage and transportation condition:
 Temperature: -40 C - +55 C
 Relative humidity range: 10%-80%
 Atmospheric pressure range: 50KPa-106KPa
 CE 0182



Storage and transportation condition:
 Temperature: -40 C - +55 C
 Relative humidity range: 10%-80%
 Atmospheric pressure range: 50KPa-106KPa
 CE 0182



Digital Diagnostic Ultrasound Devices

MODEL: _____ Q.TY: 1
 GW /NW: _____ DIMS: 470*400*270 (mm³)

Caresono Technology Co., Ltd.
 4th Floor, NO.11 Building, Initiating Zone, Instruments
 and Meters Industry Base, Near Port Industry Zone,
 Dandong, Liaoning 118009, China
 Tel: 0086-415-6279782 Fax: 0086-415-3191279
 www.caresono.com.cn E-mail: info@caresono.com



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

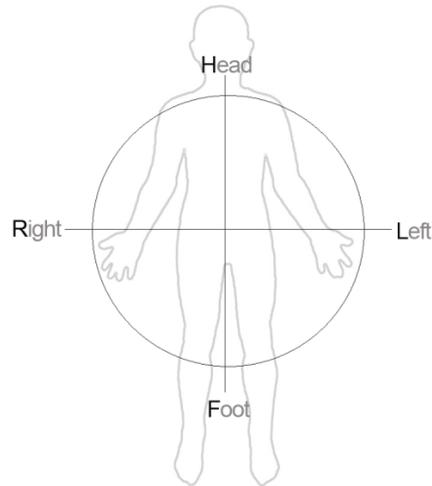
Table 201.103

Acoustic output reporting table

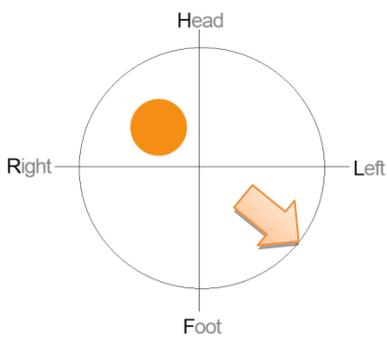
B Mode

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)						
	fawf (MHz)	2.3872	2.3872				2.3872
	Dim of Aaprt	X(cm)		0.547			0.547
Y(cm)			0.547			0.547	
Other Information	td (μs)	0.6738					
	Prr (Hz)	1256					
	Pr at max Ipi (MPa)	0.6904					
	deq at max Ipi (cm)						
	Ipa. oat max MI (W/cm ²)	9.0458					
	Focal Length	FLx(cm)					
FLy(cm)							
Operating Control Conditions	Depth (cm)	--	--			--	
	Focus (cm)	--	--			--	
	Frequency (MHz)	--	--			--	
	...						

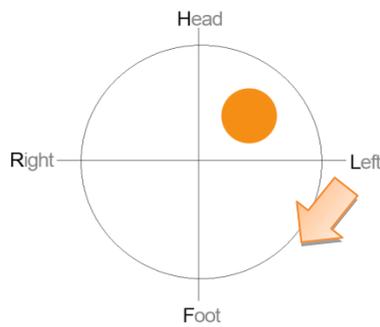
APPENDIX C: RE-AIMING GUIDE



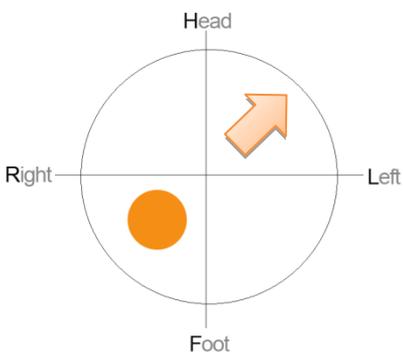
The above crosshair diagram shows the four points to consider when scanning the bladder. The projection guiding icon shows the bladder position after scanning. If the orange icon is not centered, you may need to re-aim and re-scan. The following images show how to re-aim.



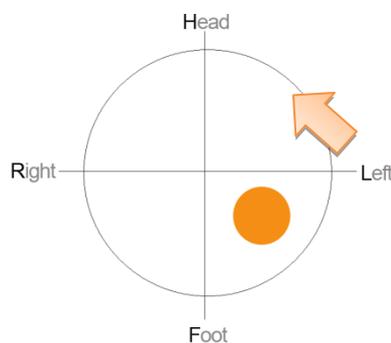
Move the probe to down to the left



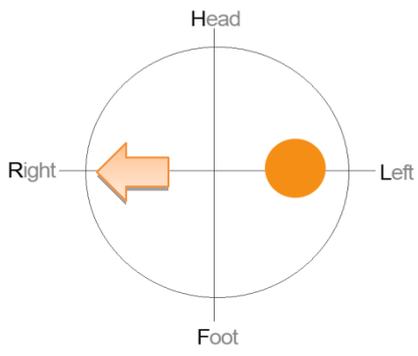
Move the probe to down to the right



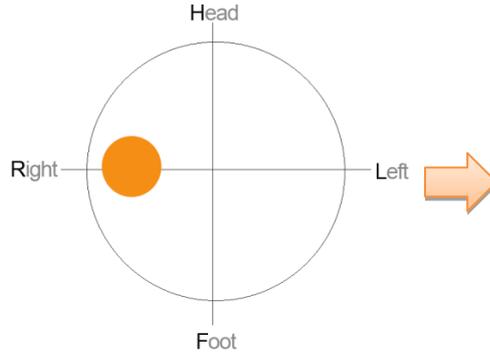
Move the probe to up to the left



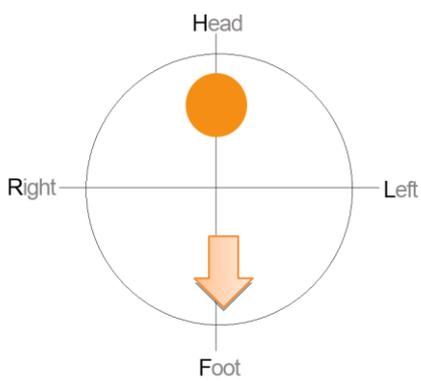
Move the probe to up to the right



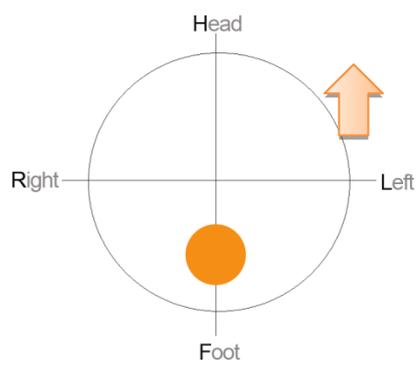
Move the probe to the right



Move the probe to the left



Move the probe down



Move the probe up