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BLADDERSCAN PRIME
OPERATIONS & MAINTENANCE MANUAL

BLADDERSCAN®

BLADDERSCAN PRIME

OPERATIONS & MAINTENANCE MANUAL

Effective: December 3, 2015

Caution: Federal (United States) law restricts this
device to sale by or on the order of a physician.

CONTACT INFORMATION

To obtain additional information regarding your BladderScan system,
please contact Verathon® Customer Care or visit verathon.com/contact-us.

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OVERVIEW

PRODUCT DESCRIPTION

The BladderScan Prime instrument provides noninvasive measurement of urinary bladder volume. The instrument calculates the bladder volume using patented NeuralHarmonics® technology. Volume measurements made with NeuralHarmonics technology are based on a more complex, multifaceted image of the bladder.

Bladder volume, mode (male, female, and small child), directional aiming with real-time feedback, battery status and usage rate indicators are displayed on the LCD.

The system also includes a battery charger for the custom, user-replaceable lithium-ion batteries included with the system.

Stored exams can be accessed at any time using the console display.

STATEMENT OF INTENDED USE

The BladderScan Prime system is an ultrasound device intended to be used for measuring the urine volume in the bladder noninvasively.

NOTICE TO ALL USERS

The BladderScan Prime system should be used only by individuals who have been trained and authorized by a physician or the institution providing patient care. Users should read this entire manual prior to using the system. Do not attempt to operate this instrument until you thoroughly understand all instructions and procedures in this manual.

STATEMENT OF PRESCRIPTION

Caution: Federal (United States) law restricts this device to sale by or on the order of a physician.

ESSENTIAL PERFORMANCE

Essential performance is the system performance necessary to achieve freedom from unacceptable risk. The essential performance of the BladderScan Prime system is to produce ultrasonic output energy, display ultrasonic images, and display numerical values for bladder volume. The instrument shall not produce unintended or excessive probe surface temperature.

SAFETY INFORMATION

ULTRASOUND ENERGY SAFETY

To date, exposure to pulsed diagnostic ultrasound has not been shown to produce adverse effects. However, ultrasound should be used prudently, and total patient exposure should be kept *as low as reasonably achievable* (ALARA). Following the ALARA principle, ultrasound should only be used by medical professionals when clinically indicated, using the lowest possible exposure times necessary to obtain clinically useful information. For more information on ALARA, please refer to the American Institute of Ultrasound in Medicine publication, *Medical Ultrasound Safety*.

The ultrasound output power of the BladderScan Prime system is not user adjustable and is limited to the minimum level necessary for effective performance. For more information about acoustic output levels, see the Product Specifications chapter on page 76.

CONTRAINDICATIONS

The BladderScan Prime system is not intended for fetal use or for use on pregnant patients, patients with open skin or wounds in the suprapubic region, or patients with ascites.

CAUTIONS & WARNINGS

Warnings indicate that injury, death, or other serious adverse reactions may result from use or misuse of the device. *Cautions* indicate that use or misuse of the device may cause a problem, such as a malfunction, failure, or damage to the product. Throughout the manual, pay attention to sections labeled *Important*, as these contain reminders or summaries of the following cautions as they apply to a specific component or use situation. Please heed the following warnings and cautions.

PRECAUTIONS

⚠	**CAUTION**
	The console USB and SD ports are designed to support removable storage media. Use these ports with USB flash drives and SD cards only. Do not attempt to use these ports with other devices.

⚠	**CAUTION**
	To avoid damage to cables and accessories, do not excessively twist or bend cables associated with the system.

⚠	**CAUTION**
	To dispose of the instrument or accessories at the end of their useful service life, see the section Device Disposal on page 55. The system and related devices may contain mineral oils, batteries, and other environmentally hazardous materials.

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⚠ CAUTION

To maintain electromagnetic interference (EMI) within certified limits, the system must be used with the cables, components, and accessories specified or supplied by Verathon®. For additional information, see the Components & Accessories and Component Specifications sections. The use of accessories and/or cables other than those specified or supplied may result in increased emissions and/or decreased immunity of the system.

Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC) and must be installed and operated according to the instructions in this manual. For more information, see the Electromagnetic Compatibility section on page 81.

The system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the system should be observed to verify normal operation in the configuration in which it will be used.

This device can radiate radio frequency energy and is very unlikely to cause harmful interference with other devices in the vicinity. There is no guarantee that interference will not occur in a particular installation. Evidence of interference may include degradation of performance in this device or other devices when operated simultaneously. To correct interference, use the following measures:

- Turn devices on and off in the vicinity to determine the source of interference
- Reorient or relocate this device or other devices
- Increase the separation between devices
- Connect the device to an outlet on a circuit different than the other device(s)
- Eliminate or reduce EMI with technical solutions (such as shielding)
- Purchase medical devices that comply with IEC 60601-12 EMC Standards

Be aware that portable and mobile radio frequency communications equipment (cellular phones, etc.) may affect medical electrical equipment; take appropriate precautions during operation.

⚠ CAUTION

Failure to follow these instructions may cause device damage not covered by the warranty:

- Do not immerse the instrument in cleaning or disinfectant solution.
- Ensure that the console is not exposed to water during the probe cleaning procedure.
- Do not subject any part of the instrument to steam, ethylene oxide, radiation, or similar methods of sterilization or autoclaving.
- Do not use bleach-based (sodium hypochlorite) products on the console touchscreen.
- Do not use metal or abrasive brushes. These may scratch the instrument, causing permanent device damage.

Operations & Maintenance Manual: Important Information

WARNINGS

> ⚠️ **WARNING**
>
> Do not use the system on:
> - Fetal patients.
> - Pregnant patients.
> - Patients with open skin or wounds in the suprapubic region.
> - Patients with ascites.

> ⚠️ **WARNING**
>
> Be aware of the following conditions that can affect ultrasound transmission:
> - Catheterization—A catheter in the patient's bladder may affect the accuracy of the bladder volume measurement in two ways: 1) by introducing air into the bladder that may block the ultrasound signal, and 2) by having the catheter-retaining balloon interfere with the volume measurement. However, the volume measurement may still be clinically useful if it is large (detecting a blocked catheter, for example).
> - Abdominal Surgery—Scar tissue, surgical incisions, sutures, and staples can affect ultrasound transmission. Use care when scanning patients who have had abdominal surgery.

> ⚠️ **WARNING**
>
> Accuracy is compromised if you do not obtain an optimal, repeatable image.

> ⚠️ **WARNING**
>
> To reduce the risk of leakage, explosion, fire, or serious injury, note the following when handling the lithium-ion battery included in the system:
> - Do not store the battery in the console for an extended period of time.
> - Never short-circuit the battery by bringing the battery terminals into contact with any other conductive object.
> - Never expose the battery to abnormal shock, vibration, or pressure.
> - Do not disassemble, heat above 60°C (140°F), or incinerate the battery.
> - Keep battery out of reach of children and in original package until ready to use.
> - Dispose of used batteries promptly according to local recycling or waste regulations.
> - If the battery is leaking or its case is cracked, put on protective gloves to handle it, and discard it immediately.
> - Put insulating tape, such as cellophane tape, on the electrodes during transportation.

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WARNING

This product may only be cleaned and disinfected by using the approved processes provided in this manual. Cleaning and disinfection methods listed are recommended by Verathon® based on compatibility with component materials.

WARNING

Cleaning is critical to ensuring the component is ready for disinfection. Failure to properly clean the device could result in a contaminated instrument after completing the disinfection procedure.

WARNING

Availability of cleaning and disinfection products varies by country, and Verathon is unable to test products in every market. For more information, please contact Verathon Customer Care or your local representative. For contact information, visit verathon.com/contact-us.

WARNING

Ensure that you follow the manufacturer's instructions for handling and disposing of the cleaning and disinfection solutions provided in this manual.

WARNING

To reduce the risk of explosion, do not use the system in the presence of flammable anesthetics.

WARNING

To reduce the risk of electric shock or burns, do not use the system in conjunction with high-frequency surgical equipment.

WARNING

In order to maintain electrical safety, use only the provided power supply, battery, and battery charger. Connect the power cord and power adapter to a properly grounded plug, and ensure the disconnect is easily accessible. Use only the accessories and peripherals recommended by Verathon.

Operations & Maintenance Manual: Important Information

WARNING

To reduce the risk of electrical shock, do not attempt to open the system components. This may cause serious injury to the operator or damage to the instrument and will void the warranty. Contact Verathon® Customer Care or your local representative for all servicing needs.

WARNING

To maintain electrical safety, inspect the battery charger for damage prior to each use. Do not use a battery charger with cracks or other damage. If the battery charger is damaged, contact Verathon Customer Care or your local representative.

WARNING

No modification of this equipment is allowed.

WARNING

To reduce the risk of electrical shock or minor burns, ensure 2 m (6 ft) is maintained between the patient and the battery charger, power supply, and power cord. Do not touch the AC/DC power supply while it is in use.

WARNING

Never use the BladderScan Prime system to display the image of biological features other than the bladder.

WARNING

This system is not a diagnostic device and is only intended as a measuring tool.

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INTRODUCTION

To ensure safe and effective operation of the BladderScan Prime system:

- Familiarize yourself with the contents of this manual.
- Watch the tutorial provided on the instrument.

SYSTEM OVERVIEW

BladderScan Prime is a 3D ultrasound system that noninvasively measures bladder volume. The core components of the system are a console with a touch-screen display, an ergonomic probe containing the ultrasound transducer, and a battery charger with rechargeable lithium-ion batteries. There are several accessories and configuration options available for the system, including a mobile cart, a printer, and external memory solutions. For more information, see Components & Accessories on page 8.

Figure 1.   BladderScan Prime System

The BladderScan Prime system includes an onboard tutorial as well as integrated help screens. Scanning is available in a variety of modes that are suited for different patient anatomies: male, female, and small child. In addition, the console features a variety of customizable settings and a saved scans function that allows you to recall, print, or transfer saved exams.

The Prime console also features an optional live imaging prescan mode that enables you to locate the bladder by displaying a B-mode view of the abdomen in real time, prior to completing the volume measurement scan. This option is disabled by default. For more information about enabling this mode, see Configure Exam Settings on page 28.

COMPONENTS & ACCESSORIES

Table 1.   Included System Components & Accessories

INCLUDED SYSTEM COMPONENTS & ACCESSORIES

Console

Probe

Battery

Console base

Battery charger

Power adapter

In-service USB flash drive

Media storage USB flash drive

Power cord
Note: Plug may vary by region

Port cover

Media storage SD card

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Table 2.   Optional System Components & Accessories

OPTIONAL SYSTEM COMPONENTS & ACCESSORIES

Mobile Cart

Printer

Thermal Paper

Additionally, quick reference materials and ultrasound gel may be available for order in your region. For more information, contact Verathon® Customer Care or your local representative or visit verathon.com/contact-us.

SYSTEM FEATURES

CONSOLE FEATURES

The BladderScan Prime console's primary feature is a touch-screen display that allows you to perform scans, manage scan results, and customize settings. The console also provides controls for adjusting brightness and volume and activating the system or putting it in standby mode. A rechargeable battery is inserted into one side of the console, and the other side features a selection of ports for connecting system components and accessories such as external, removable media storage devices. You may also customize your console by adding an optional printer, attaching the console base, or mounting the console on a mobile cart.

Figure 2.   Console Features

Table 3.   Console Features

PART NAME	PURPOSE
Main display	Features touch-screen controls of the system user interface.
Battery door	Opens to access and replace the rechargeable battery.
Standby button	Activates the unit or puts it in standby mode. When the unit is active, an LED next to the Standby button is illuminated.
Volume control	Adjusts volume up or down.
Brightness control	Adjusts the main display to be brighter or dimmer.
Probe cable port	Connects the system probe and console.
USB ports	Provides connection for external, removable storage media.
Micro USB port	Not functional in this version of BladderScan Prime.
SD card port	Provides connection for external, removable storage media.

Note: The console USB and SD ports are designed to support removable storage media. Use these ports with USB flash drives and SD cards only. Do not attempt to use the ports with other devices.

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PROBE FEATURES

The probe contacts the patient and transmits and receives ultrasound waves, automatically moving its internal transducer 360º to scan twelve planes to produce a three-dimensional image of the bladder. The probe is attached to the console by a cable. After a scan, the probe displays bladder volume and targeting.

Figure 3.   Probe Features

Probe display

Probe cable

Probe button

Probe dome

Table 4.   Probe Features

PART NAME	PURPOSE
Probe button	Starts aiming or scanning when pressed.
Probe display	Displays ready, in progress, and scan results information.
Probe cable	Connects the probe to the console.
Probe dome	Contacts the patient's abdomen and transmits ultrasound.

BATTERY & BATTERY CHARGER FEATURES

The BladderScan Prime system is powered by a lithium-ion battery. The battery charger provided with the system can charge one or two batteries. Removing a discharged battery from the system and replacing it with a fresh battery does not erase any saved exams or system settings.

To provide power to the batteries, the battery charger must be connected to a wall outlet using the power adapter and power cord provided. Use only the battery charger provided with the BladderScan Prime system. Any other battery charger may damage the battery. The battery charger automatically detects whether a lithium-ion battery is being charged. To prevent incorrect insertion of the battery, the console and battery charger have a keyed entry into the battery compartment.

Each battery features a test button that allows you to check the charge level of the battery without inserting it into the console. If you press the **Test** button on the back of the battery, the display next to the test button illuminates to display the approximate charge level: 25%, 50%, 75%, or 100%. Two replaceable batteries ensure the instrument is always available (provided the spare battery is charging when not in use).

Test button
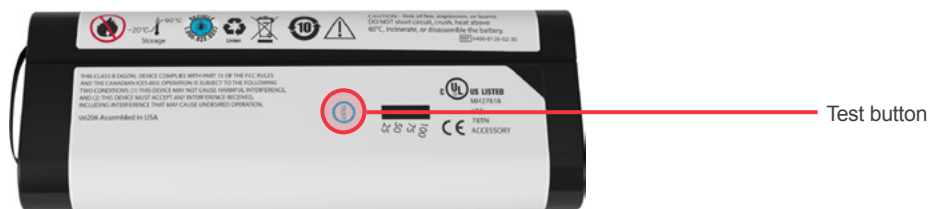
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SYSTEM ICONS

CONSOLE TOUCH-SCREEN ICONS

The console touch-screen displays the interface that controls the BladderScan Prime system. The following icons may appear on the screen, and you may tap them to complete the function associated with the icon.

Table 5.   Touch-Screen Icons

ICON	FUNCTION
	Male—Select if you are scanning a male patient.
	Female—Select if you are scanning a female patient. If you select the Female Patient icon, the instrument asks you if the patient has a uterus.
	Small Child—Select if you are scanning a child who is shorter than 122 cm (48 in) and lighter than 27 kg (60 lbs). *Note: Scanning for this patient type can be disabled on the Exam Settings screen. For more information, see* Configure Exam Settings *on* page 28*.
	Saved Scans—View all scans that are saved to the console.
	Settings—Open the Settings screen.
	Orientation—Select whether the system is located on the patient's right side or left side. *Note: The appearance of this icon varies depending on the patient type you selected (male, female, or small child).*
	B-Mode—View the ultrasound image as pairs of two-dimensional, orthogonal planes from the three-dimensional scan. The contours of detected features are overlaid on the image. *Note: You may disable the display of the detected contours. For more information, see* Configure Exam Settings *on* page 28*.
	C-Mode—View the ultrasound image as a cross-section view of the three-dimensional scan. The C-Mode image consists of a circular region with a crosshair overlay. This image displays the bladder shape and, if detected, the shadow of the pubic bone. The probe displays scan results in C-mode. The console displays scan results in C-mode by default, and B-mode may be selected for any scan.
	Clear—On the Results Screen, clear all scan data within the current exam, but maintain patient information.
	Delete—On the Saved Exam screens, delete a saved exam that is currently being viewed.
	Delete—On the Saved Exam screens, delete a saved exam from the exam list.

ICON	FUNCTION
	Help—Start the onboard tutorial or display screen-sensitive help text.
	Print—Print the scan, self-test, or savings calculation results. *Note: This function is only available if you have attached the optional printer.*
	Done—On the Results screen, save the scan result with the largest volume and return to the Home screen.
	Export Exams—On the Saved Exam screen, move exams from the BladderScan Prime system's internal storage to an external USB drive or SD card. This option is only available if external storage is connected.
	Configure Savings—Customize the values for calculating the cost savings that result from scanning rather than catheterizing patients.
	Back—Return to the previous screen or the Home screen.
	Cancel—On the Results screen, cancel the scan without saving and return to the Home screen.
	Next—Advance to the next screen.
	Play—On the onboard tutorial, play the tutorial.
	Pause—On the onboard tutorial, pause the tutorial.
	Previous—On the onboard tutorial, move to the previous frame of the tutorial.
	Next—On the onboard tutorial, move to the next frame of the tutorial.

CONSOLE BATTERY LEVEL ICONS

The battery level icon is displayed in the Status bar at the top of the touch-screen. The icon and the percentage value next to the icon indicate the remaining battery power. For information about charging the battery, see the procedure Charge the Battery on page 17.
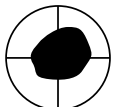
Table 6.   Battery Level Icon

ICON	FUNCTION
	Battery approximately 100% charged.
	Battery approximately 80% charged.
	Battery approximately 60% charged.
	Battery approximately 40% charged.
	Battery approximately 20% charged.
	Battery discharged. Replace or recharge battery immediately.

PROBE ICONS

The following icons may appear on the probe display.

Table 7.   Probe Icons

ICON	FUNCTION
	Ready to Scan Mode—When the patient selection has been made and the system is ready to scan, the probe displays an icon indicating the currently selected patient orientation. The displayed patient orientation icon on the probe is updated when you change the patient orientation on the Before You Scan screen.
	Scan in Progress Mode—When the Home screen is displayed or a scan is in progress, the probe displays the BladderScan logo.
	Results Mode—After a scan has been completed, the probe displays the position of the bladder in relation to the probe and the value of the largest volume acquired in the current exam. *Note: This display can be used to help position the probe. If the bladder is off-center on the probe display, move the probe in the direction of the bladder and scan again.*

SETTING UP

To help you get started, the following topics explain how to assemble the BladderScan Prime instrument:

1. Perform the Initial Inspection

2. Charge the Battery

3. Attach the Probe to the Console

4. Attach the Console Base or Printer

5. Attach the Instrument to the Mobile Cart (Optional)

6. Install the Port Cover (Optional)

7. Insert a Battery

Once the system is assembled, you can configure the BladderScan Prime user settings and add information:

8. Configure General Settings

9. Configure Exam Settings

10. Customize Cost Savings Calculations

11. Configure Printed Report Settings

12. Configure Calibration Settings

ASSEMBLING THE INSTRUMENT

PROCEDURE 1.   PERFORM THE INITIAL INSPECTION

When you receive the BladderScan Prime system, Verathon® recommends that an operator familiar with the instrument perform a full visual inspection of the system for any obvious physical damage that may have occurred during shipment.

1. Carefully open the top of the shipping box. Do not insert anything sharp through the box.

2. Remove the contents and verify that you have received the appropriate components for your system.

3. Inspect the components for damage.

4. If any of the components are missing or damaged, notify the carrier and Verathon Customer Care or your local representative.

PROCEDURE 2. CHARGE THE BATTERY

> ⚠️ **WARNING**
>
> To reduce the risk of leakage, explosion, fire, or serious injury, note the following when handling the lithium-ion battery included in the system:
>
> • Do not store the battery in the console for an extended period of time.
>
> • Never short-circuit the battery by bringing the battery terminals into contact with any other conductive object.
>
> • Never expose the battery to abnormal shock, vibration, or pressure.
>
> • Do not disassemble, heat above 60°C (140°F), or incinerate the battery.
>
> • Keep battery out of reach of children and in original package until ready to use.
>
> • Dispose of used batteries promptly according to local recycling or waste regulations.
>
> • If the battery is leaking or its case is cracked, put on protective gloves to handle it, and discard it immediately.
>
> • Put insulating tape, such as cellophane tape, on the electrodes during transportation.

> ⚠️ **WARNING**
>
> In order to maintain electrical safety, use only the provided battery charger and batteries.

> ⚠️ **WARNING**
>
> To reduce the risk of electrical shock or minor burns, ensure 2 m (6 ft) is maintained between the patient and the battery charger, power supply, and power cords. Do not touch the AC/DC power supply while it is in use.

> ⚠️ **WARNING**
>
> To maintain electrical safety, inspect the battery charger for damage prior to each use. Do not use a battery charger with cracks or other damage. If the battery charger is damaged, contact Verathon® Customer Care or your local representative.

Two lithium-ion batteries are included with the BladderScan Prime system. It is recommended that you charge one battery while the other is in use. Before using the system for the first time, you must fully charge the batteries.

When the BladderScan Prime system is in standby mode, it draws some power from the battery. If you do not plan to use the instrument, remove the battery to prevent it from discharging. When batteries are not in use, they should be stored in the battery charger so they remain fully charged.

1. Before each use, inspect the battery charger, batteries, power adapter, and power cord for damage. If a component is damaged, do not use it. Contact Verathon® Customer Care or your local representative.

2. Connect the power adapter to the power cord.

3. Connect the power adapter to the battery charger.

4. Plug the power supply into a standard wall outlet. Ensure the power cord can be easily disconnected.

5. Insert one or two batteries into the recesses in the battery charger. It is recommended that you charge both batteries when setting up the BladderScan Prime system for the first time.

6. Allow the battery to fully charge. The indicator lights on the battery charger indicate the status:
    • Green solid—Battery is fully charged
    • Green flashing—Battery is fast-charging
    • Yellow solid—Battery charging is suspended or in standby mode
    • Red—Charging error. Contact Verathon Customer Care or your local representative.
    • Off—No battery detected

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PROCEDURE 3. ATTACH THE PROBE TO THE CONSOLE

Once the probe is attached to the console, it can remain attached between uses.

1. Locate the port on the side of the console.

2. Align the probe cable connector with the port on the console.

3. Gently push the connector into the port, until the connector clicks into place and is secure.

Note: Before you connect or disconnect the probe from the console, ensure the console is turned off by removing the battery from the instrument. To disconnect the probe, squeeze the connector brackets and then pull the probe cable connector out of the port. Do not pull on the cable.

Operations & Maintenance Manual: Setting Up

PROCEDURE 4. ATTACH THE CONSOLE BASE OR PRINTER

A console base is included with the system. An optional printer is also available for order. Verathon® recommends that you attach either the console base or the printer, as it provides support for the console and protection to the contacts on the back of the console. This procedure documents how to attach either the console base or printer.

OPTION 1. ATTACH THE CONSOLE BASE

1. Ensure the console is turned off by removing the battery from the instrument.

2. Place the console on a flat stable surface, display side down.

3. Place the console base in the recess as shown.

4. Using a screwdriver with a Phillips bit, attach the console base to the console.

OPTION 2. ATTACH THE PRINTER

1. Ensure the console is turned off by removing the battery from the instrument.

2. Place the console on a flat stable surface, display side down.

3. Inspect the electrical contacts on the console.

4. Place the printer in the recess as shown.

5. Using a screwdriver with a Phillips bit, attach the printer to the console.

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PROCEDURE 5.   ATTACH THE INSTRUMENT TO THE MOBILE CART (OPTIONAL)

The BladderScan Prime system is portable and can be carried or attached to a mobile cart. Installing the system on the optional mobile cart will allow you to move the system, along with related accessories, to the patient examining area or bedside, as necessary.

This procedure provides instructions for mounting the system on the mobile cart. Verathon® recommends that you attach either the console base or the printer to the back of the console prior to completing this procedure. For the purposes of providing clear views of the mount, the console is pictured without either attachment in this procedure.

Figure 4.   Prime Mobile Cart

1.   Assemble the mobile cart according to the instructions included with the cart.

2.   On the mobile stand mount, ensure that the locking pin and quick-release lever are in the unlocked (horizontal) position.

Quick-release lever
in unlocked position

Locking pin in
unlocked position
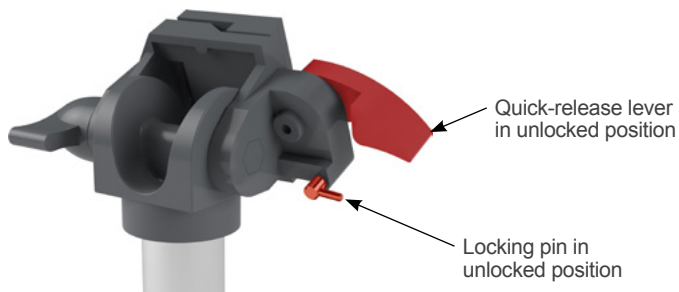
3. Using the orientation shown in the following images, screw the quick-release locking plate to the back panel of the console.

Quick-release locking plate

4. Seat the locking plate of the console on the quick-release mount. When properly situated, the console sits securely on the mount, and the quick-release lever automatically snaps into the locked (down) position.

5. Ensure that the quick-release lever is fully in the locked (down) position. This secures the console in place.

Quick-release lever in locked position

6. Adjust the locking pin to the locked (down) position. This secures the quick-release lever in the locked position.

Locking pin in locked position

ADJUST THE MONITOR ANGLE

Before you start using the console, adjust the angle for optimal viewing. The ideal angle minimizes glare and maximizes visibility.

7. Turn the angle adjustment knob counterclockwise.

Angle adjustment knob
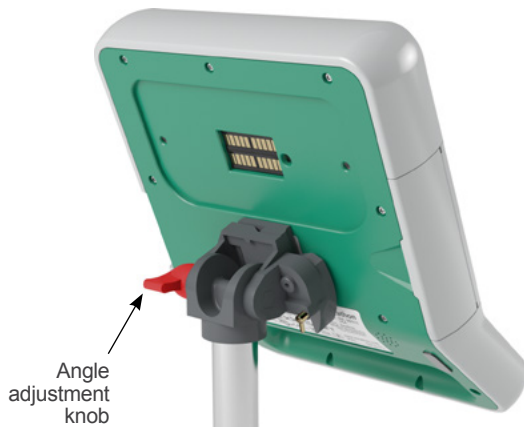
8. Tilt the console to the desired angle.

9. Turn the angle adjustment knob clockwise. This secures the console at the desired angle.

PROCEDURE 6. INSTALL THE PORT COVER (OPTIONAL)

The BladderScan Prime console features a series of ports that allow you to connect external media storage devices, such as SD cards or USB flash drives. If these ports will not be used at your facility, you can hide them by attaching the port cover included with your system. This port cover adheres securely to the console. Once the port cover is installed, you will not be able to save exam results to external media.

Please note that the port cover is not intended to be removed and then reapplied. Once the port cover has been applied, it is semi-permanently attached.

Figure 5.   Console Ports

1. Remove the battery from the BladderScan Prime console.

2. If an external media storage device, such as a USB flash drive or SD card, is inserted in the console, remove it.

3. Clean the console according to the instructions in Clean & Disinfect the System on page 50. A clean surface helps ensure proper adhesion.

4. Allow the console surfaces to dry completely.

5. On the port cover, remove the backing from the two adhesive pads.
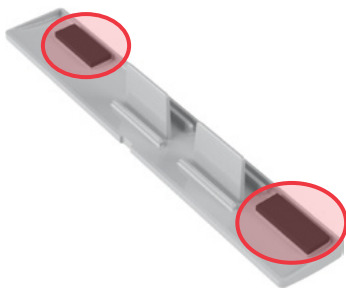
6. Align the port cover with the ports in the console.

7. Insert the port cover into the console, and then press firmly for 30 seconds. This helps ensure good adhesion.

The port cover is now securely attached to the console. If the port cover needs to be removed and then reinstalled, the remaining adhesive may be insufficient to properly reattach the port cover. To order a replacement port cover, please contact Verathon® Customer Care or your local representative.

1. Open the battery door on the console. Pull the door out from the console at the bottom edge; the hinge is on the screen side of the unit.

2. If a battery is already in the console, remove it by pushing the tab down and pulling the battery out.
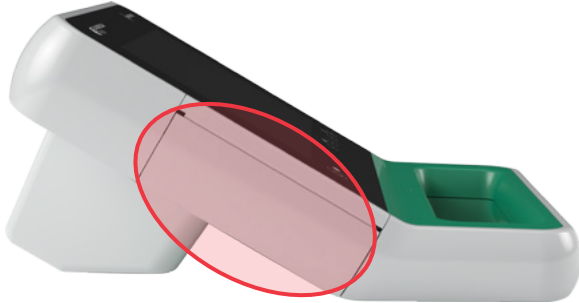
3. Slide a charged battery into the battery well, and then push gently until the battery clicks into place.

    Note: The battery is designed to prevent incorrect installation. If the battery does not slide into the battery well easily, remove the battery, reorient it, and try again. Do not attempt to force the battery into position.
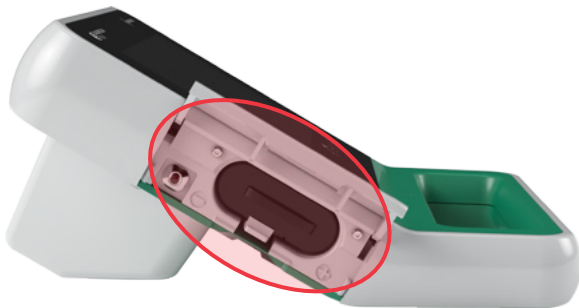
4. Close the battery well door. The system begins startup.

5. Allow the instrument to complete startup. When the system is ready for use, the Home screen appears.
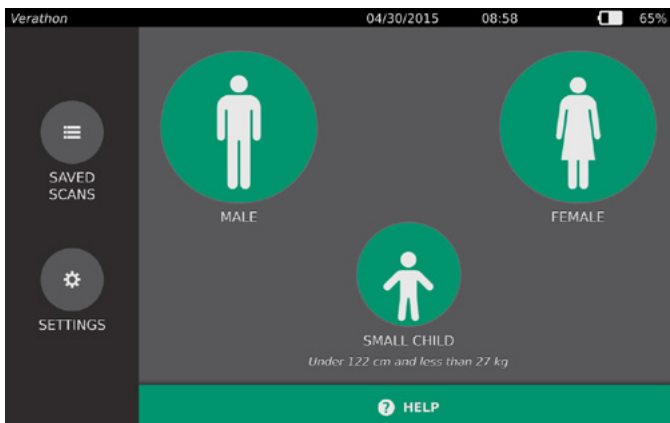
6. If you are completing the initial setup, it is recommended that you continue to the following section in order to customize the system settings. If you do not want to use the BladderScan Prime system immediately, wait for startup to complete and then press the **Standby** button ⏻ to place the system in standby mode.

CONFIGURING SETTINGS

The BladderScan Prime system is configured with default settings that are appropriate for many users. This section contains instructions for modifying the defaults for your facility's needs.

PROCEDURE 1. CONFIGURE GENERAL SETTINGS

1. On the Home screen, tap **Settings**. The Settings screen opens to the General tab.
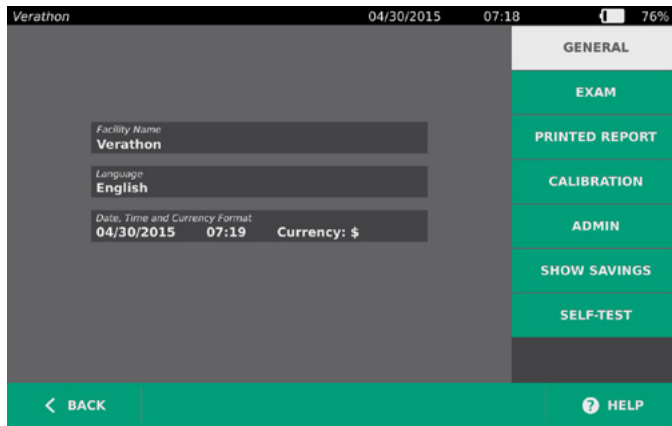
2. On the General tab, tap **Facility Name**, use the virtual keyboard to type a name, and then tap **Enter**. This name is displayed on the status bar at the top of each screen.

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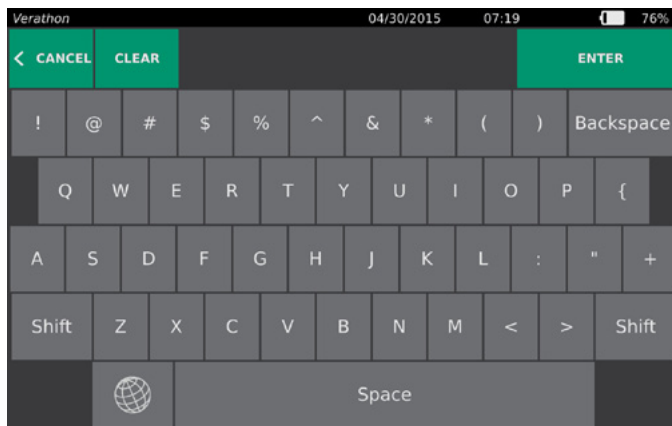
3. Tap **Date, Time and Currency Format**. The Date, Time and Currency screen appears.
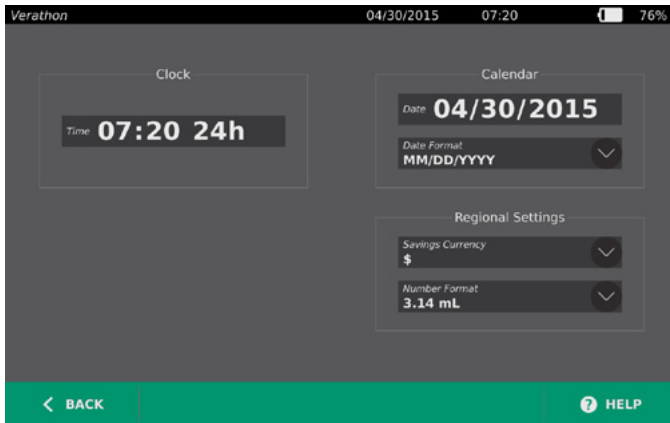
4. In the **Time** field, tap the hour or minutes, vertically swipe to view a value, and then tap the value to select it.

5. In the **Time** field, tap the time format. The time format scrolls through AM, PM, and 24-hour displays. If you select a new time format, the hours and minutes values are updated as necessary.

6. In the **Date** field, tap the month, day or year, vertically swipe to view a value, and then tap the value to select it. Repeat as needed to set the desired month, day, and year.

7. In the **Date Format** field, tap the arrow, and then select the month, day, and year display order. The **Date** field immediately updates to display the selected format.

8. In the **Savings Currency** field, tap the arrow and then select the desired currency. This unit is used when displaying savings as a result of using the BladderScan instrument instead of catheterization.

9. In the **Number Format** field, tap the arrow to select the display format for numeric fields.

10. When you are finished configuring the Date, Time, and Currency settings, tap **Back**.

11. Tap **Admin**. The Settings screen opens the Admin tab.

12. In the **Standby Timer** field, tap the arrow and then select the number of minutes before the instrument goes into standby mode.
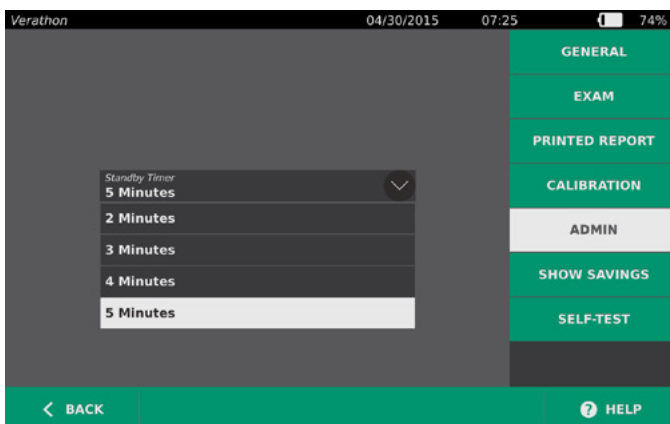
13. When you are finished configuring settings, tap **Back**. This saves your settings and returns the console to the Home screen.

PROCEDURE 2. CONFIGURE EXAM SETTINGS

The BladderScan Prime system is configured with default exam settings. Configurable settings include:

- Enable live imaging prescan
- Display bladder outline on B-mode images
- Show the small child option on the Home screen
- Set the time that live imaging prescan is available

By default, the live imaging prescan feature is disabled. You can modify the defaults for your facility's needs.

1. On the Home screen, tap **Settings**, and then tap **Exam**. The Settings screen opens the Exam tab.
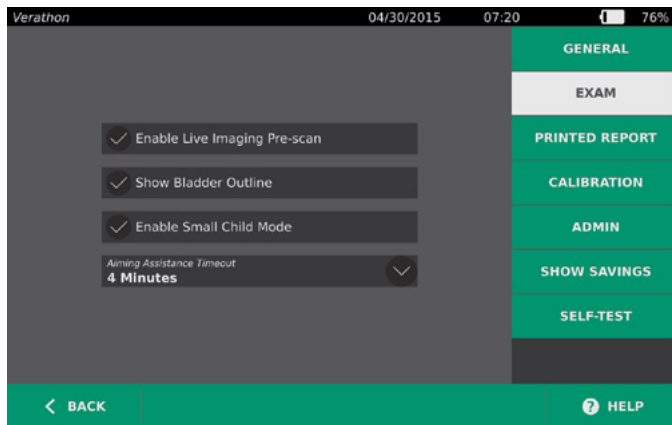
2. Tap the field to update, and then if applicable, select or type new values:
   - **Enable Live Imaging Prescan**—Select to show a real-time B-mode ultrasound preview image while aiming the probe. If this option is enabled, the Aiming Assistance Timeout setting is also visible and configurable.
   - **Show Bladder Outline**—Select to show computed bladder outline graphics on B-mode images.
   - **Enable Small Child Mode**—Select to show the option for scanning children on the Home screen.
   - **Aiming Assistance Timeout**—Select to specify the time after which the aiming display automatically terminates. This option is only visible if Enable Live Imaging Prescan is selected.

3. When you are done, tap **Back**. This saves your settings and returns the console to the Home screen.

PROCEDURE 3.   CUSTOMIZE COST SAVINGS CALCULATIONS

The BladderScan Prime system provides default values for calculating the cost savings that result from scanning rather than catheterizing patients. The default settings can be customized to reflect the rates and costs at your facility. To change the currency used for cost savings calculations, see Configure General Settings on page 26.

Total cost savings from using the BladderScan Prime system are based on the following formula:

Total cost savings = (Catheterizations avoided × Catheterization costs) + (UTIs avoided × UTI costs)

1. On the Home screen, tap **Settings**, and then tap **Show Savings**. The Settings screen opens to the Show Savings tab.
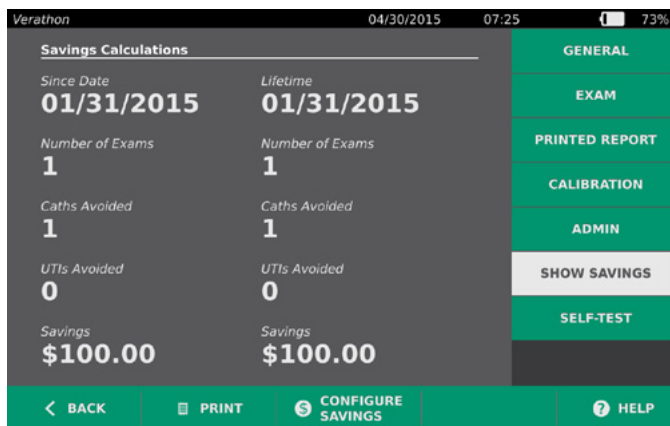
2. Tap **Configure Savings**. The Configure Savings screen appears.

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3. Tap a field to update, and then enter new values. Numeric fields accept decimal input but round to the nearest whole number.

- **UTI Rate**—Select the rate of urinary tract infections (UTIs) resulting from catheterizations.
- **UTI Cost**—Select the cost per UTI at your facility.
- **Catheterization Cost**—Select the cost per catheterization procedure.
- **Catheterization Volume**—Select the volume threshold for catheterization. Scans below the volume threshold are not used in cost savings calculations.

Note: The Reset Calculations button restarts savings calculations as of the date this button is selected. Tapping this button is not required to update savings values.

4. When you are done, tap **Back**. This saves your settings and returns the console to the Show Savings tab of the Settings screen.

5. When you are finished, tap **Back**. This saves your settings and returns the console to the Home screen.

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PROCEDURE 4. CONFIGURE PRINTED REPORT SETTINGS

If a printer is attached to the BladderScan Prime console, you can print scan results. Reports are printed vertically, like a receipt. Scan reports are made up of a number of sections. Some of the sections are optional. You can customize which sections are included in the printed report.

1. On the Home screen, tap **Settings**, and then tap **Printed Report**. The Settings screen opens to the Printed Report tab.
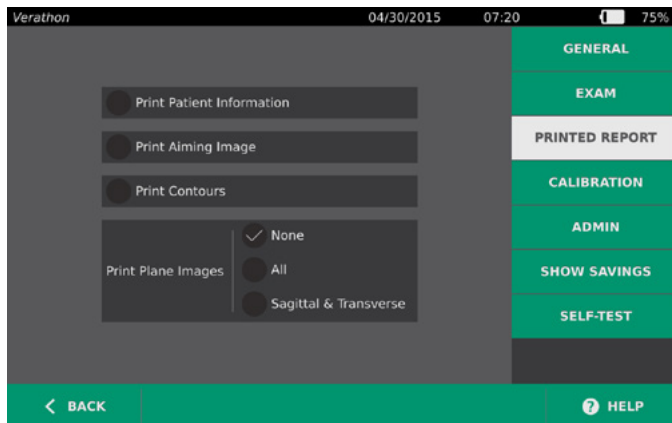
2. Tap the information to include in reports. If a check mark is displayed to the left of the information description, the following information is printed:

    *   **Print Patient Information**—Select to include patient data, including patient ID, name, sex, and date of birth.
    *   **Print Aiming Image**—Select to print the coronal view image computed by the system. The aiming circle and crosshairs are printed as black lines.
    *   **Print Contours**—Select to add contours to the B-mode image.
    *   **Print Plane Images**—Select one of the following B-mode image selections:
        *   **None**—Select to print no B-mode image planes.
        *   **All**—Select to include all 12 B-mode image planes.
        *   **Sagittal & Transverse**—Select to include the two primary B-mode image planes.

3. When you are finished configuring the printed report settings, tap **Back**. This saves your settings and returns the console to the Home screen.

PROCEDURE 5.   CONFIGURE CALIBRATION SETTINGS

Verathon® recommends that you calibrate the probe every 12 months. By default, the BladderScan Prime system reminds you before calibration is due. You can change how early the configuration message is displayed and suppress the configuration reminder entirely.

1. Ensure that the probe is connected to the console.

2. On the Home screen, tap **Settings**.

3. Tap **Calibration**.
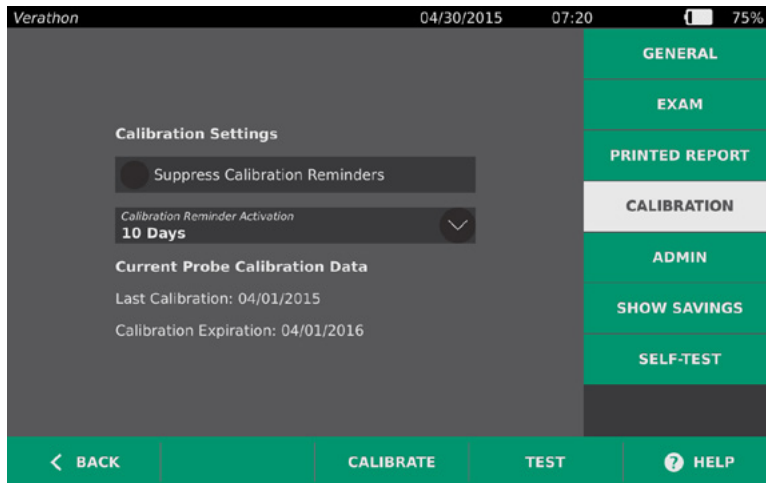
4. If you want to disable calibration reminders, select **Suppress Calibration Reminders**.

5. If you want to adjust when you receive calibration reminders, tap **Calibration Reminder Activation**, and then tap a number of days. This value determines how early the calibration reminder message is displayed on the console prior to the actual calibration due date.

6. When you are done, tap **Back**.

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USING THE INSTRUMENT

⚠️ **WARNING**

Do not use the system on:

- Fetal patients.
- Pregnant patients.
- Patients with open skin or wounds in the suprapubic region.
- Patients with ascites.

⚠️ **WARNING**

Be aware of the following conditions that can affect ultrasound transmission:

- Catheterization—A catheter in the patient's bladder may affect the accuracy of the bladder volume measurement in two ways: 1) by introducing air into the bladder that may block the ultrasound signal, and 2) by having the catheter-retaining balloon interfere with the volume measurement. However, the volume measurement may still be clinically useful if it is large (detecting a blocked catheter, for example).
- Abdominal Surgery—Scar tissue, surgical incisions, sutures, and staples can affect ultrasound transmission. Use care when scanning patients who have had abdominal surgery.

⚠️ **WARNING**

To reduce the risk of explosion, do not use the system in the presence of flammable anesthetics.

⚠️ **WARNING**

To reduce the risk of electric shock or burns, do not use the system in conjunction with high-frequency surgical equipment.

The following section explains how to perform a scan, as follows:

1. Start the System

2. Prepare for the Exam

3. Input Patient Information or Operator ID (Optional)

4. Measure Bladder Volume

5. Review Exam Results

6. Print, Save, or Exit an Exam

7. View Cost Savings

After the exam has been saved, you can manage saved exam results as follows:

8. Recall a Saved Exam

9. Delete a Saved Exam

10. Export Saved Exams

MEASURING BLADDER VOLUME

PROCEDURE 1. START THE SYSTEM

1. If a charged battery is inserted in the console and the screen is blank, then the instrument is in standby mode. Press the **Standby** button (⏻).

   If the system has a discharged battery or a battery is not inserted, insert a charged battery.

2. Allow the instrument to start. The Home screen appears when the instrument is fully started.
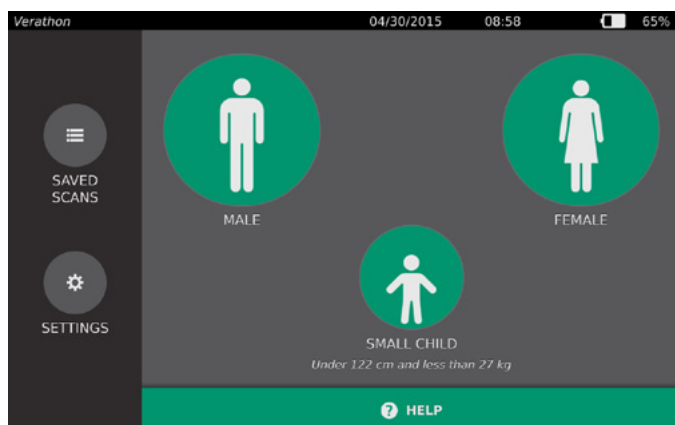
Note: If you do not wish to use the system immediately, wait for startup to complete, and then press the Standby button (⏻).

PROCEDURE 2. PREPARE FOR THE EXAM

1. Ensure you are familiar with the instrument touch-screens and probe displays. For more information about the components and user interface, see the Introduction chapter on page 7.

2. Check the instrument battery icon to ensure the battery has sufficient power.

   Note: If the battery icon is 20% full or less, replace the battery with a fully charged battery before proceeding.

3. Ensure that the instrument has been properly cleaned according to the instructions in the Cleaning & Disinfecting chapter on page 48.

4. On the Home screen, tap the appropriate procedure button, **Male**, **Female**, or **Small Child**.

5. If the patient is female, ask the patient if she has a uterus. On the console screen, answer the question appropriately for the female patient.

6. On the Before You Scan screen, select whether you are standing on the patient's left or right side. The currently selected orientation is displayed in dark text on a white background.
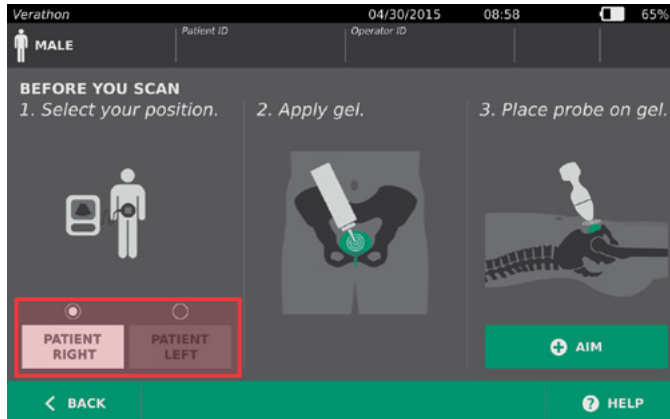
PROCEDURE 3. INPUT PATIENT INFORMATION OR OPERATOR ID (OPTIONAL)
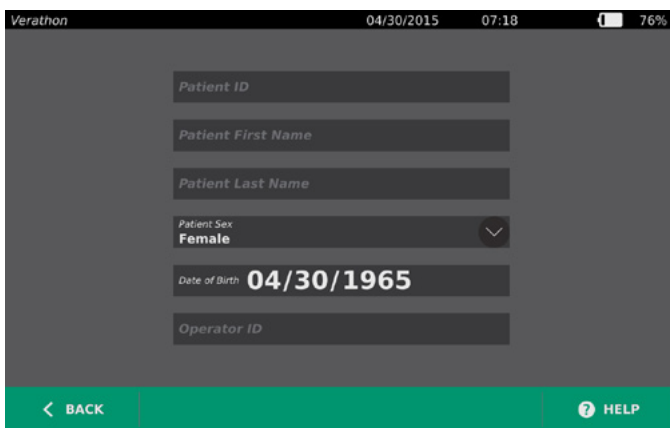
The BladderScan Prime system lets you enter the following patient information:

- Patient ID
- First name
- Last name
- Sex
- Date of birth

Once entered, the Patient ID displays on appropriate BladderScan Prime screens. Patient information can also be printed on reports.

The Operator ID may also be updated at this time. The Patient ID and Operator ID fields are displayed at the top of many screens. You can tap the field and update Patient or Operator ID information whenever the field is visible.

1. On the Before You Scan screen, tap **Patient ID**. The Patient and Operator ID screen appears.

2. On the Patient Data screen, tap **Patient ID**, use the virtual keyboard to type a value, and then press **Enter**.

3. Tap **Patient First Name**, and then use the virtual keyboard to enter the patient's first name.

4. Tap **Patient Last Name**, and then use the virtual keyboard to enter the patient's last name.

5. Tap **Patient Sex**, and then tap the sex for the patient.

6. In the **Date of Birth** field, tap the month, day, or year, vertically swipe to view a value, and then tap the value to select it. Repeat as needed to set the desired month, day, and year.

7. Tap **Operator ID**, and then use the virtual keyboard to enter or update the operator's identifying information.

8. When you are finished inputting the patient's information, tap **Back**.

PROCEDURE 4.   MEASURE BLADDER VOLUME

Use one of the following options to measure bladder volume:

- Option 1: Prescan Disabled
- Option 2: Prescan Enabled

By default, the BladderScan Prime system has prescan disabled. To enable prescan, see Configure Exam Settings on page 28.

OPTION 1. PRESCAN DISABLED

1. With the patient lying in a supine position and with the abdominal muscles relaxed, palpate the patient's pubic bone.

2. Place an ample quantity of ultrasound gel, with as few air bubbles as possible, midline on the patient's abdomen, approximately 3 cm (1 inch) above the pubic bone.

3. Hold the probe by grasping it with the probe cable running up your wrist and forearm.

4. Gently press the probe onto the lower abdomen through the gel. The probe cable should be oriented at 90 degrees to the sagittal plane of the patient.

Sagittal plane

90°

Probe cable

5. If you are scanning an obese patient, lift as much abdominal adipose tissue out of the way of the instrument as possible. Apply more pressure to the probe in order to reduce the amount of adipose tissue through which the ultrasound must pass.

6. Ensure that there are no air gaps between the probe and the patient's skin and that you are applying enough pressure to maintain adequate skin contact until the scan is complete.

7. Target the bladder by manipulating the probe.
    *   Angle the probe slowly side to side.
    *   Point the probe slightly downward toward the tail bone (coccyx) and angle the probe along the body's midline.

8. Press and release the probe Scan button, or tap **Scan** on the Scanning Preview screen. The scanning process begins.
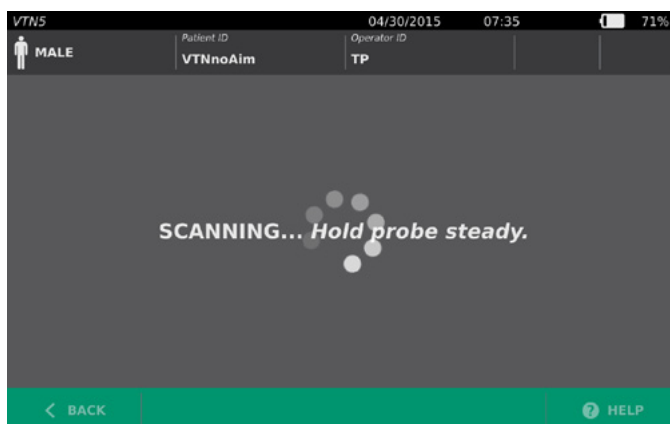
9. Hold the probe steady while the scan is in process. When you hear the end-scan tone, the scan is complete.

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You can locate the bladder with or without a bladder outline to assist with aiming. By default, the BladderScan Prime system has the bladder outline display turned on. To disable the bladder outline, see Configure Exam Settings on page 28.

1. With the patient lying in a supine position and with the abdominal muscles relaxed, palpate the patient's pubic bone.

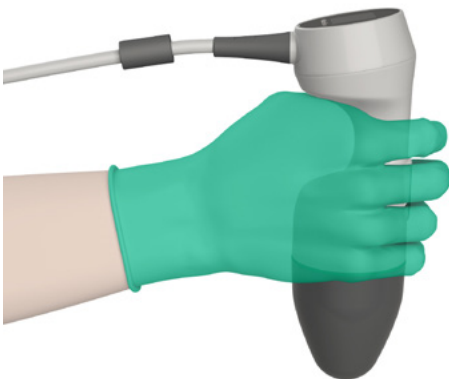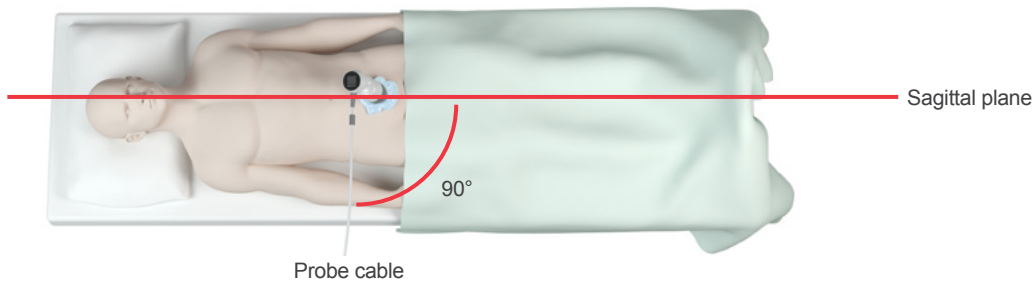2. Place an ample quantity of ultrasound gel, with as few air bubbles as possible, midline on the patient's abdomen, approximately 3 cm (1 inch) above the pubic bone.
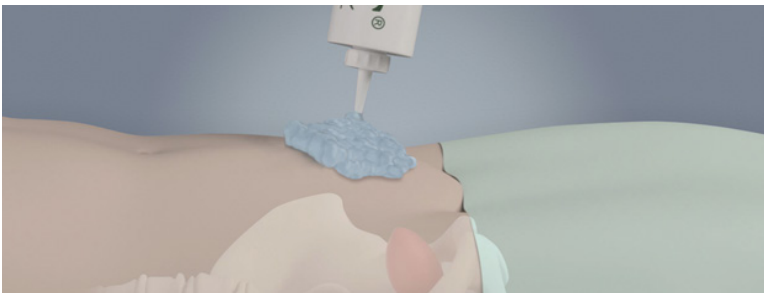
3. Hold the probe by grasping it with the probe cable running up your wrist and forearm.
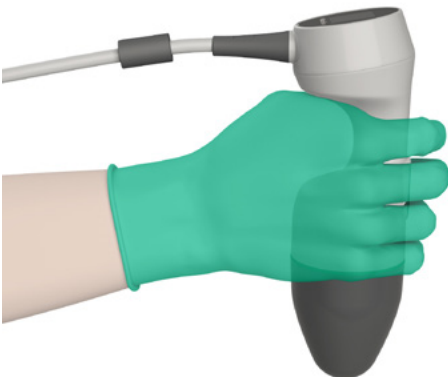
4. Gently press the probe onto the lower abdomen through the gel. The probe cable should be oriented at 90 degrees to the sagittal plane of the patient.

5. If you are scanning an obese patient, lift as much abdominal adipose tissue out of the way of the instrument as possible. Apply more pressure to the probe in order to reduce the amount of adipose tissue through which the ultrasound must pass.

6. Ensure that there are no air gaps between the probe and the patient's skin and that you are applying enough pressure to maintain adequate skin contact until the scan is complete.

7. Press and release the probe Scan button or tap **Aim** on the Before You Scan screen. A real-time B-mode ultrasound image appears on the console screen.

8. Target the bladder by manipulating the probe.
   - Angle the probe slowly side to side. Center the dark (bladder) area relative to the vertical green line on the aiming screen.
   - Point the probe slightly downward toward the tail bone (coccyx) and angle the probe along the patient's midline to obtain the largest possible dark (echo free) area.
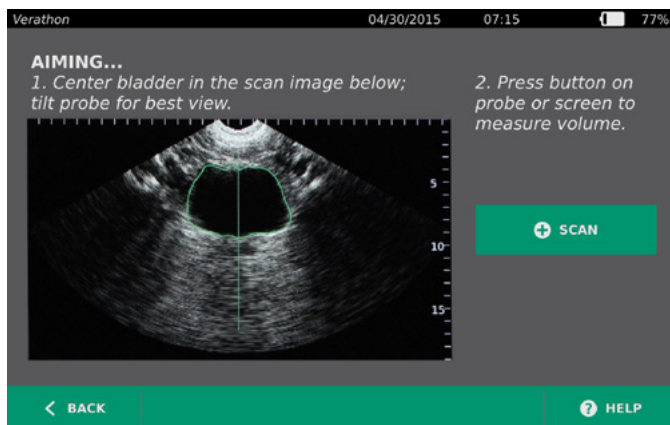
9. Press and release the probe Scan button again, or tap **Scan** on the Scanning Preview screen. The scanning process begins.
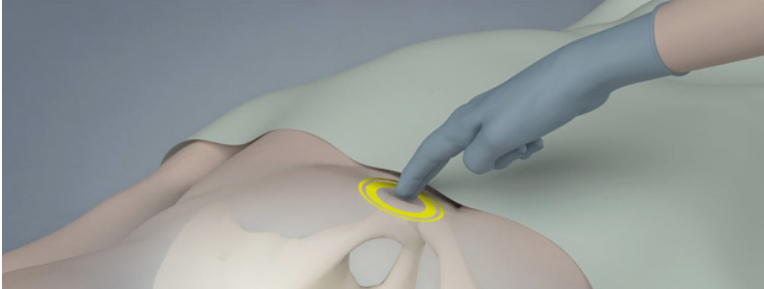
10. Hold the probe steady while the scan is in process. When you hear the end-scan tone, the scan is complete.

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PROCEDURE 5. REVIEW EXAM RESULTS

This section describes the procedures that can occur after the scan. Perform the procedures that are applicable for your installation.

The accuracy range for the instrument is determined by using the following calculation: ± (15% ± 15 mL).

For example, if the volume measurement is 250 mL, the accuracy range is calculated as follows:
250 mL × 15% = 38 mL
38 + 15 mL = 53 mL
250 ± 53 mL = **197–303 mL**
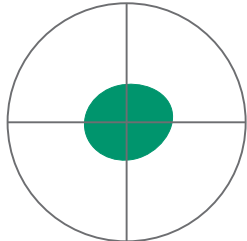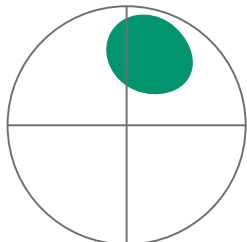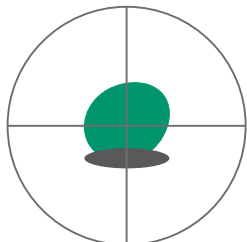
CONFIRM AIM

1. When the Results screen appears, assess the accuracy of the scan as follows:

Table 8.   Bladder Measurement Accuracy

RESULT	INDICATOR(S)	EXAMPLE
Successful	If the scan is successful and "on target," the bladder appears in the center of the crosshairs.	
Off-target	If the scan is unsuccessful or "off-target," the bladder is not centered in the crosshairs. If you are viewing the crosshairs on the probe, move or point the probe in the direction of the bladder on the display.	
Pubic bone interference	If the scan includes the pubic bone, the display indicates that the pubic bone is inside the image cone. If this occurs, you may want to re-aim and re-scan. Although the bladder may be shown as centered in the image cone and your measurement may be complete, there is a possibility the pubic bone is obscuring part of the bladder. By re-aiming and re-scanning you can ensure you have captured the bladder fully inside the image cone.	

Note: If the instrument displays a greater than symbol (>) preceding the volume measurement, apply less pressure and rescan the patient. The greater than symbol may also appear if two sides of the bladder wall are outside the image cone as a result of a bladder that is larger than the ultrasound scan.

2. If you want to rescan the patient, on the Results screen, tap **Scan**.

Repeat the scanning procedure as necessary to correct a less-than-optimal scan or validate the initial measurement.

Note: A maximum of five scans can be stored in scan history. If more then five scans are performed, the oldest scan is deleted to accommodate the newest scan.

3. When you are finished scanning, you can review the results in B or C modes. (C-mode is displayed by default.) You can save scan results, and you can print scan results if you have the printer installed.

VIEW B-MODE IMAGES

4. If you want to view B-mode images, tap the B-mode icon. Dual-pane B-mode images of the scan appear.
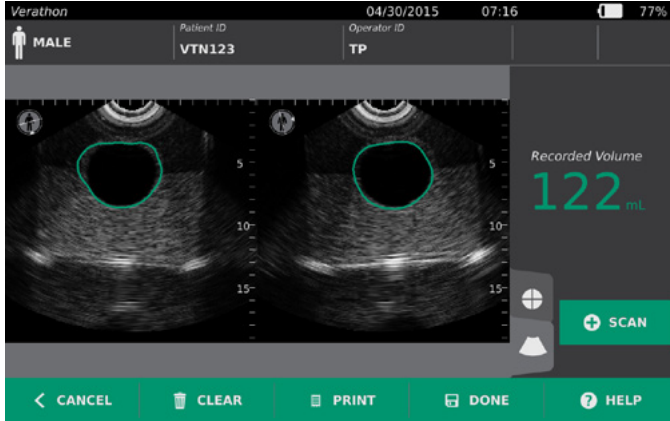
In the top-left corner of each of the B-mode images, the line through the human figure icon indicates the currently displayed plane.

5. Horizontally swipe the B-mode display to navigate through the scan planes.

VIEW MULTIPLE SCANS

When you perform more than one scan, the Results screen displays the largest volume obtained. Below the largest volume measurement, the screen indicates the most recent scan volume.
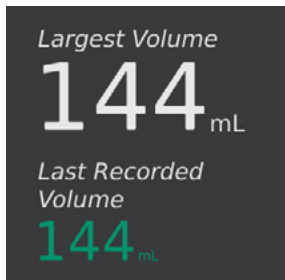
The Scan History dots show which scan in a series of scans is currently displayed.

Note: A maximum of five scans can be stored in scan history. If more then five scans are performed, the oldest scan is deleted to accommodate the newest scan.

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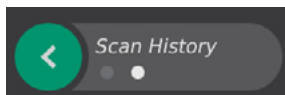
6. If you want to show individual scan measurements, tap the **Scan History** arrow.

7. Tap the scan measurement number to see the scan display.

   Note: The scan appears in the selected mode.

8. Continue to the following procedure, Print, Save, or Exit an Exam.

PROCEDURE 6.   PRINT, SAVE, OR EXIT AN EXAM

1. If you want to record patient information, tap **Patient ID** and then add patient information using the virtual keyboard. Once an exam is saved, you cannot add patient information.

2. If you want to print the exam results, tap **Print**.

   Note: You can customize the information to be printed. The report always contains the largest measurement and the exam date and time. For more information about adding and customizing information to be printed, see Configure Printed Report Settings *on page 31.*

3. If you want to save the exam results, tap **Done**. If there are multiple scans for the patient, the system stores the largest measurement.

4. If you want to exit without saving the exam results, tap **Cancel**.

   For information about viewing, deleting, and exporting saved exams, see the section Managing Saved Exams on page 45.

5. Press the **Standby** button ⏻ to place the system in standby mode. Allow sufficient time for the instrument to enter standby mode.

PROCEDURE 7.   VIEW COST SAVINGS

The BladderScan Prime system calculates and displays information related to cost savings, catheterizations avoided, and UTIs avoided. The Savings Calculations screen lists the number of exams, catheterizations avoided, UTIs avoided, and savings.

The default settings can be customized to reflect the rates and costs at your facility. For more information on customizing savings preferences, see Customize Cost Savings Calculations on page 29.

The system calculates savings since the most recent calculation reset and for the life of the instrument. You can show, configure, and reset cost savings at any time.

1. On the Home screen, tap **Settings**.
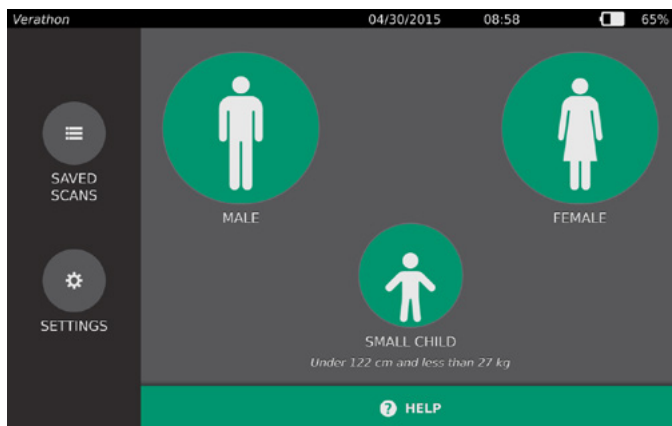
2. Tap **Show Savings**. The Settings screen opens to the Show Savings tab.
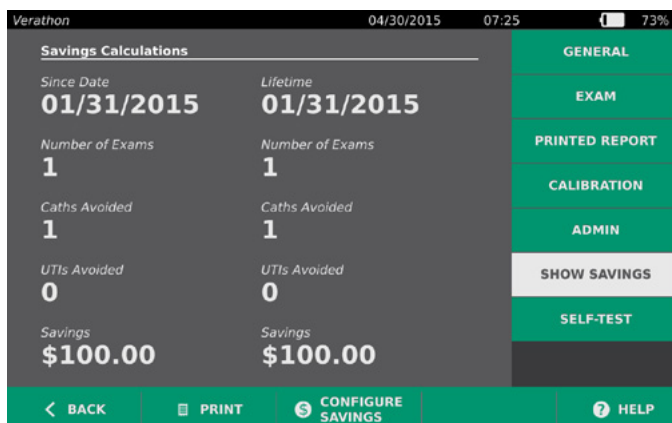
3. If you have a printer and want to print the savings calculations, tap **Print**.

4. When you are finished viewing the savings calculations, tap **Back**. The console returns to the Home screen.

MANAGING SAVED EXAMS

The BladderScan Prime system can store saved exams on the BladderScan Prime instrument or external devices such as USB drives and SD cards. If you scan the patient multiple times during an exam, the system saves the largest measurement.

If no external devices are attached, the BladderScan Prime system stores saved exams on the instrument. If the BladderScan Prime system runs out of internal storage, the system warns you before deleting old exams to make room for new ones.

If a USB drive or SD card is attached, the BladderScan Prime system stores saved exams on the USB drive or SD card. If an attached USB drive or SD card runs out of storage space, the system allows you to switch drives or cards.

You can move exams from the BladderScan Prime system's internal storage to an external USB drive or SD card. For more information, see the procedure Export Saved Exams

> **IMPORTANT**
>
> The console USB and SD ports are designed to support removable storage media. Use these ports with USB flash drives and SD cards only. Do not attempt to use the ports with other devices.

PROCEDURE 1.   RECALL A SAVED EXAM

Once you have saved an exam, it can be recalled using the Saved Exam screen. The Saved Exam screen displays scans saved on the BladderScan Prime system's internal memory if no external storage devices are attached. If a USB drive or SD card is attached, the Saved Exam screen displays scans saved on the attached storage device.

If there are multiple scan results in the exam, the system stores and displays the largest measurement.

SORT OR SCROLL SCANS

1. On the Home screen, tap **Saved Scans**. The Saved Exam screen opens, displaying a list of exams saved on the default media. Each of the rows on this list corresponds to an exam.
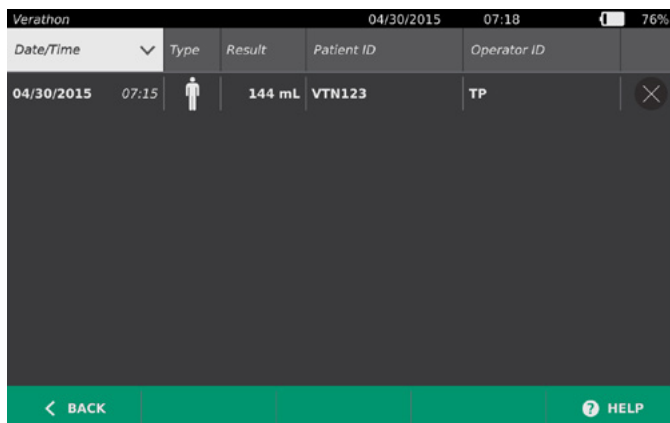
2. If you want to sort exams using a different value, tap a sortable field header.

   The field headers let you sort the exam list using the following fields. The columns may be sorted in ascending or descending order. The currently selected sorting field is highlighted in white, and an arrow icon indicating the direction of the sort is shown next to the column label.
   - Date/Time
   - Patient ID
   - Operator ID

3. If you want to scroll through the exam list, vertically swipe the screen.

4. If you want to view an exam, tap anywhere along the exam's row. When an exam is selected for review, the results screen for the exam is displayed.

PROCEDURE 2.   DELETE A SAVED EXAM

1. On the Home screen, tap **Saved Scans**. The Saved Exam screen opens, displaying a list of exams saved on the default media. Each of the rows on this list corresponds to an exam.
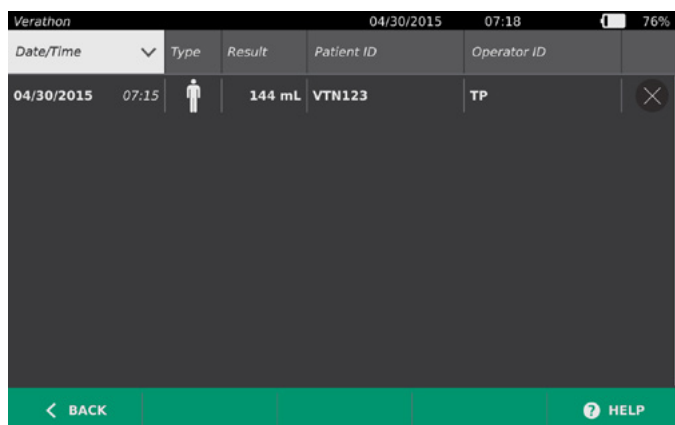
2. If it is not visible in the list, sort or scroll saved exams to display the one you want. For more information on finding exams, see Recall a Saved Exam on page 45.

3. Tap the **Delete** button ⊗ at the right end of the exam row.

4. On the confirmation dialog box, tap **Yes**.

*Note: You may also delete a saved exam that is currently being viewed. To delete an opened exam, at the bottom of the screen, tap **Delete**.*

PROCEDURE 3. EXPORT SAVED EXAMS

Use the following procedure to move exams from the BladderScan Prime system's internal storage to an external USB drive or SD card.

By default, saved scans are retained in the BladderScan Prime system's internal storage. When you insert a USB drive or SD card into the BladderScan Prime console, the system immediately begins viewing the new media for saved scans. If no scans have previously been saved to the external media, the Saved Exam screen appears blank. Scans you have saved on the system's internal memory have not been lost and can be exported to the new media by selecting the Export Exams option.

Scans are saved with unique file names, so saving new scans does not overwrite exams already stored on the USB drive or SD card.

Exported scan information is stored in PDF and graphic formats, so it can be viewed on other devices. Each scan is stored on a folder on the USB drive or SD card. Each folder contains:

- A PDF document containing:
  - Patient information
  - C-mode view of the scan
  - B-mode views of the scan
- Individual graphic files, in PNG format, for each B-mode plane of the scan.
- A graphic file, in PNG format, for the C-mode view of the scan.

1. Insert a USB drive or SD card into the port on the right side of the console.

   Note: Insert only one USB drive or SD card at a time. If you insert multiple devices, the console recognizes only the first device.

2. On the Home screen, tap **Saved Scans**. The Saved Exam screen opens.
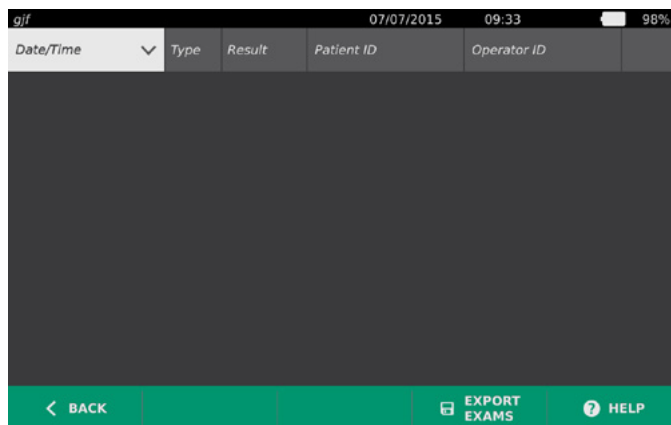
3. Tap **Export Exams**.

4. A verification screen appears. Tap **Enter** to confirm you want to move exams stored on the console to the external storage device. Do not remove the USB drive or SD card until export is complete.

Operations & Maintenance Manual: Using the Instrument

CLEANING & DISINFECTING

IMPORTANT

Failure to follow these instructions may cause device damage not covered by the warranty:

- Do not immerse the instrument in cleaning or disinfectant solution.
- Ensure that the console is not exposed to water during the probe cleaning procedure.
- Do not subject any part of the instrument to steam, ethylene oxide, radiation, or similar methods of sterilization or autoclaving.
- Do not use bleach-based (sodium hypochlorite) products on the console touchscreen.
- Do not use metal or abrasive brushes. These may scratch the instrument, causing permanent device damage.

⚠️ **WARNING**

This product may only be cleaned and disinfected by using the approved processes provided in this manual. Cleaning and disinfection methods listed are recommended by Verathon® based on compatibility with component materials.

⚠️ **WARNING**

Availability of cleaning and disinfection products varies by country, and Verathon is unable to test products in every market. For more information, please contact Verathon Customer Care or your local representative. For contact information, visit verathon.com/contact-us.

⚠️ **WARNING**

Ensure that you follow the manufacturer's instructions for handling and disposing of the cleaning and disinfection solutions provided in this manual.

⚠️ **WARNING**

Cleaning is critical to ensuring the component is ready for disinfection. Failure to properly clean the device could result in a contaminated instrument after completing the disinfection procedure.

Cleaning and disinfecting the BladderScan Prime system is an important part of using and maintaining the system. Prior to each use, ensure all system components have been cleaned and disinfected according to the guidance provided in Table 9.

The following table describes the risk assessment for each system component, including the Spaulding's/CDC classification for the minimum required disinfection level.

Table 9.   BladderScan Prime System Risk Assessment

COMPONENT	PACKAGED	USE	SPAULDING'S/CDC CLASSIFICATION	CLEAN	DISINFECTION LEVEL	
					Low	High
Console	Nonsterile	Reusable	Noncritical	X		
Probe Cable	Nonsterile	Reusable	Noncritical	X		
Probe	Nonsterile	Reusable	Noncritical		X	

X   *Checked boxes show minimum disinfection level requirement.*

☐   *Shaded areas indicate that the disinfection level is not required or compatible with the device materials.*

☐   *Unshaded areas show permissible levels of disinfection based on compatibility with the device materials.*

BEST PRACTICES

Cleaning is the removal of all visible soil or contaminants from the exterior surfaces of the device, and *disinfection* is the process of destroying pathogenic organisms or rendering them inert. When cleaning, ensure all foreign matter is removed. This allows the active ingredients of the chosen disinfection method to reach all the surfaces of the device.

To significantly reduce the amount of effort needed to clean the system, do not let contaminants dry on any system component. Contaminants tend to become securely attached to solid surfaces when dried, making removal more difficult.

Change gloves as directed in the procedure or if gloves become soiled.

When using a wipe cleaning or disinfection method, please adhere to the following best practices:
- Always wipe in the direction from a clean surface towards a dirty surface.
- Minimize overlap on the wiping pattern.
- If a wipe becomes dry or soiled, replace it with a fresh one.
- Do not reuse dry or soiled wipes.
- Use a new wipe as instructed in the cleaning and disinfection procedures.

COMPATIBILITY & AVAILABILITY

The availability of the cleaning and disinfection products provided in this manual varies by region; ensure that you select products in accordance with your local laws and regulations.

The following solutions have demonstrated cleaning or disinfection efficacy and material compatibility with the system components:

- Metrex® CaviWipes™
- Metrex® CaviCide™

The following solutions have demonstrated material compatibility with the system components, but they have not been tested for efficacy:

- Johnson & Johnson® Cidex OPA
- Johnson & Johnson® Cidex Plus
- Clorox Healthcare® Bleach Germicidal Cleaner
- Clorox Healthcare® Hydrogen Peroxide Cleaner
- 6% Hydrogen Peroxide (generic)

- Metrex® Metricide 14™
- Metrex® Metricide 28™
- GAMA Healthcare Clinell® Universal Wipes
- Ecolab® Cliniwipe,™ hard surface wipes (70% IPA)
- GE Septiwipes

PROCEDURE 1. CLEAN & DISINFECT THE SYSTEM

⚠ **WARNING**

Cleaning is critical to ensuring the component is ready for disinfection. Failure to properly clean the device could result in a contaminated instrument after completing the disinfection procedure.

Use this procedure in order to clean the BladderScan Prime probe, probe cable, or console. Review the information in the Best Practices and Compatibility & Availability sections before completing this procedure.

CLEAN THE CONSOLE

1. Ensure the console is in standby mode by pressing the **Standby** button ⏻. Allow sufficient time for the instrument to enter standby mode.

2. Put on new gloves.

3. Using a dry paper towel or soft cloth, wipe any ultrasound gel completely off the console.

4. Using Metrex® CaviWipes,™ wipe all surfaces of the console, ensuring all surfaces have been covered.
    - If a wipe becomes dry or soiled, use a new wipe to continue.
    - If wiping the console causes the screen to turn on, allow the console to automatically return to standby mode, which may take up to 5 minutes.

5. Allow the console to air dry, and continue to the following section, Clean the Probe Cable & Probe Display.

CLEAN THE PROBE CABLE & PROBE DISPLAY

6.   Using a new Metrex® CaviWipes,™ wipe the entire probe cable and probe display until all visible contaminants are removed.

CLEAN THE PROBE

7.   Later in this procedure, you will use cold, running water. Position the console near the sink so the probe can reach the water later when needed, but ensure the console is far enough away to stay dry.

8.   Using a dry paper towel or soft cloth, wipe any ultrasound gel completely off the probe.

9.   Using Metrex® CaviCide,™ spray the lower portion of the probe (including button and label) until visibly wet, and hold for **2 minutes**. Spray additional solution as needed to ensure that the probe remains wet for the full 2 minutes.

10.   Spray a soft-bristled brush with Metrex® CaviCide™ until the brush is thoroughly wet.

11.   Using the brush, scrub the recesses around the probe button, dome gasket, and label for **30 seconds each**.
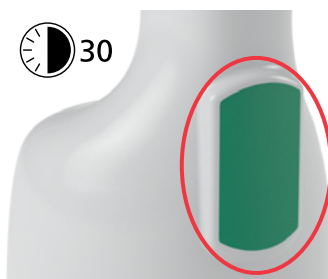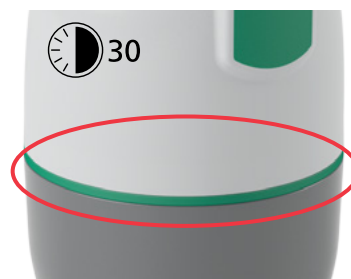
| Probe button | Probe dome gasket | Probe label |
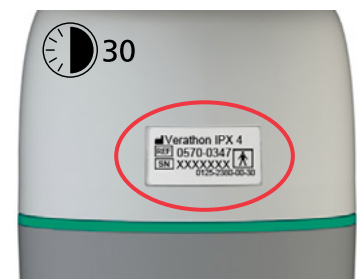
12. Using cold, running water, rinse the lower portion of the probe for **1 minute**. While rinsing, use the brush to scrub the button, dome gasket, and label recess.

13. Using a new Metrex® CaviWipes,™ wipe the probe from the display toward the dome for at least **30 seconds**. Use a spiral pattern as indicated in the figure below. Repeat this process, using a new wipe each time, to achieve the minimum cleaning time of **30 seconds**.

Start here with new wipe

Dispose of wipe
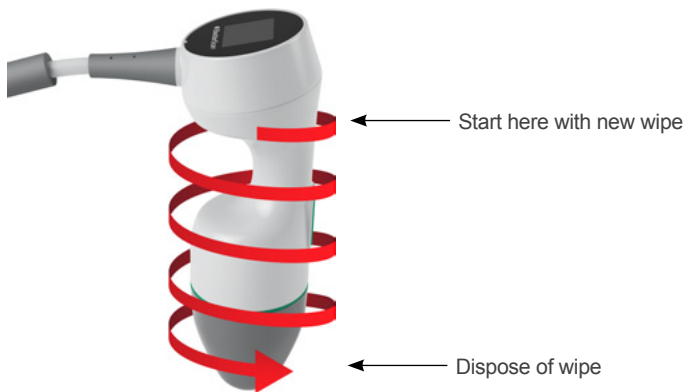
14. Visually inspect the probe for contamination, paying particular attention to recessed or grooved areas. If the probe is visually contaminated, repeat Step 9 though Step 13 until no contamination remains.

15. Allow the probe to air dry.

Note: If you are using a cart, place the probe into the cart with the dome facing upwards. This helps prevent the dome from coming in contact with the cart.

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16. Continue to the following section, Disinfect the Probe. Low-level disinfection of the probe dome is required between uses.

DISINFECT THE PROBE

Low-level disinfection of the probe dome (the gray area at the end of the probe) is required between uses.

Table 10.   Low-Level Disinfection Methods for the Probe

PRODUCT	LEVEL	CONDITIONS
Metrex® CaviWipes™	Low-level disinfect	**Exposure:** Remain wet for **3 minutes**.

17. Remove the gloves used in the cleaning portion of the procedure, and then put on new gloves.

18. Using a low-level disinfectant from Table 10, wipe the probe dome with the disinfection product according to the conditions in Table 10. The exposure period is 3 minutes. Using a new wipe, rewipe the probe dome as needed to ensure that it remains visibly wet for the duration of the exposure period. You may use multiple wipes as necessary; do not reuse wipes.
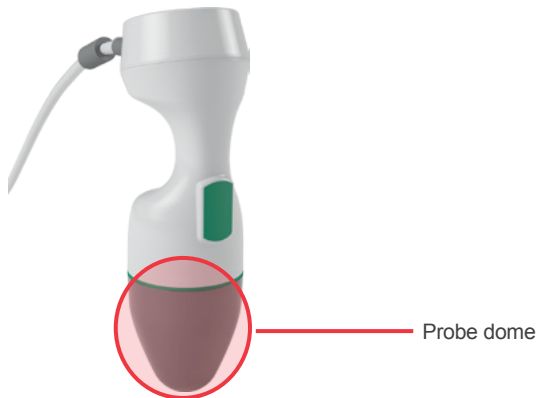
Probe dome

19. Allow the probe to air dry.

Note: If you are using a cart, place the probe into the cart with the dome facing upwards. This helps prevent the disinfected probe dome from coming in contact with the cart.
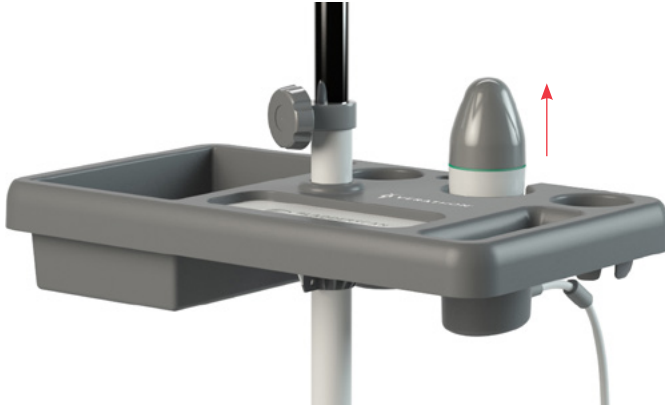
Cleaning and disinfection is complete. The system is ready for use on a patient.

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MAINTENANCE & SAFETY

REGULAR INSPECTIONS

Verathon® recommends that the BladderScan Prime system be certified annually by an authorized BladderScan service representative or Verathon service center. Certification service includes comprehensive inspection and testing of the instrument. For more information, please contact your authorized BladderScan Service Center, your local BladderScan distributor, or Verathon Customer Care.

WEEKLY INSPECTIONS

Once a week, you should inspect the console, probe, probe cable, power supply, power cords, batteries, and plugs for damage or cracks. Cracks that allow the ingress of fluid into the console or probe may affect the performance of the instrument. Other than the maintenance included in this manual, all service and repairs must be completed by an authorized BladderScan service representative or Verathon service center. For more information, contact Verathon Customer Care or your local representative.

SYSTEM SOFTWARE

Verathon may release software upgrades for the BladderScan Prime system. Software upgrades are supplied directly by Verathon or an authorized representative. For information about how to upgrade the device software, see Update the Software on page 59.

Do not perform any software upgrades from third-party vendors or attempt to modify the existing software. Doing so may damage the system and void the warranty.

DEVICE DISPOSAL

The BladderScan Prime instrument and related devices may contain mineral oils, batteries, and other environmentally hazardous materials. When the instrument has reached the end of its useful service life, return the device and related accessories to a Verathon Service Center for proper disposal. Alternatively, follow your local protocols for hazardous waste disposal.

MAINTENANCE

The following procedures explain how to load printer paper, test and calibrate the BladderScan Prime instrument, and update system software.

PROCEDURE 1. LOAD THERMAL PAPER INTO THE PRINTER

⚠️ **WARNING**

To avoid the risk of injury, when the printer door is open:

- Do not touch the printer mechanism or print head, which may be hot from recent printing.
- Do not touch the surface of the paper cutter.

The BladderScan Prime instrument senses the presence of paper and automatically displays a message when the printer is out of paper.

1. Slide the printer door toward you. Placing your thumb on the outside of the printer and squeezing can facilitate easy opening.

2. Rotate the door down to open.

3. If this is the first time you are loading the printer, there may be a sheet of paper in the printer mechanism. Remove the paper sheet.

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4. Place a roll of Verathon® thermal paper (part 0800-0319) inside the door as shown so that the loose end of the paper exits on the top of the roll, on the side closest to the console.

5. Hold the paper end so that the it will protrude from the top of the printer, and then close the printer door. Ensure that the door clicks into place.

6. Tear off any excess paper protruding from the printer. For best results, pull the paper diagonally, starting the cut on one side of the paper, and finishing on the other.

It is recommended that you clean the printer contacts on both the printer and the console when the printer is disconnected from the console, but not more frequently than once per year except in case of malfunction. For more information about cleaning the printer contacts, see Step 6 through Step 9 of the procedure

The BladderScan Prime self-test function completes self-diagnostic testing on the following:

- Internal memory (and external devices, if any)
- Hardware components, including the console, installed battery, probe, and printer, if attached
- BladderScan Prime software

1. On the Home screen, tap the **Settings** icon, and then tap **Self-Test**. The Settings screen opens to the Self-Test tab. The most recently completed self-test appears on the screen.
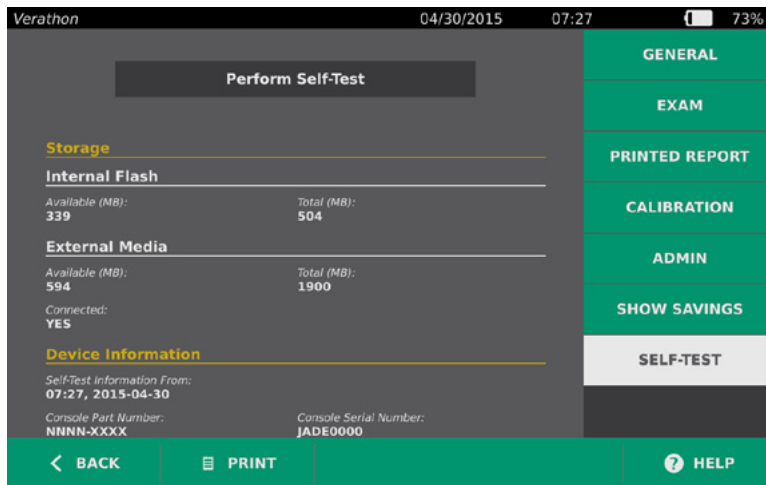
2. If you want to print the displayed self-test results before running a new test, tap **Print**.

3. To run a new self test, tap **Perform Self-Test**. The instrument completes the self-test and prints the results automatically.

4. Scroll through the on-screen test results by vertically swiping with your finger on the touch-screen.

5. If the screen indicates any failed tests or abnormal results, contact Verathon® Customer Care or your local representative.

6. When you are finished viewing the test results, tap **Back**. The console returns to the Home screen.

PROCEDURE 3.   UPDATE THE SOFTWARE

From time to time, you may receive software updates for your BladderScan Prime system. Use the following procedure to install updated software.

Software updates retain system settings and exam information.

1. Ensure that the probe is attached to the console.

2. If a charged battery is inserted in the console and the screen is blank, then the instrument is in standby mode. Press the **Standby** button ⏻. If the system has a discharged battery or a battery is not inserted, insert a charged battery.

3. Ensure that the instrument's battery is at least 50% charged.

4. Insert the USB drive or other device containing a valid software update package into the console.

5. On the Home screen, tap **Settings**.

6. Tap **Admin**, and then tap **Update Software**.
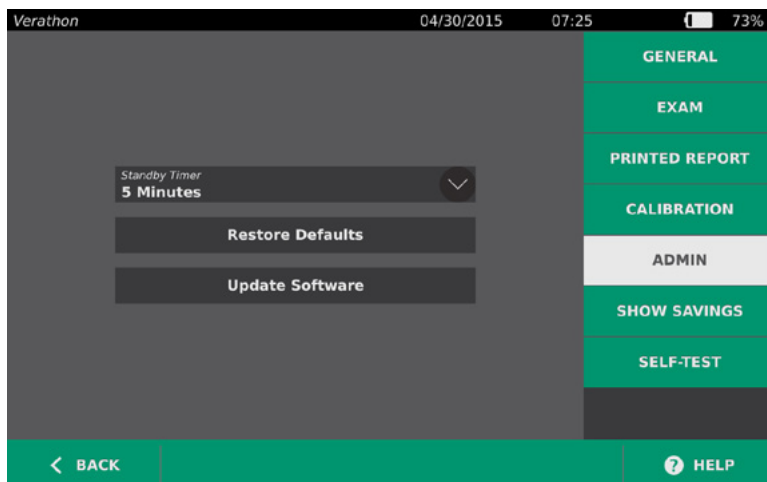
7. On the confirmation dialog box, tap **Start Update**. The system begins updating the software. Do not remove the software upgrade media.

When the update is complete, a message on the console indicates that the update was successful. The BladderScan Prime system restarts.

PROCEDURE 4. CALIBRATE THE INSTRUMENT

Verathon® recommends that you calibrate the system every 12 months. When calibration is recommended, a reminder message appears on the Home screen. If calibration is not performed by the recommended date, the instrument may still be used to take scans, but performance may be compromised.

Calibration should be performed by authorized personnel only. If you are not trained to perform calibration, you must send your instrument to an authorized Verathon service center for calibration. Contact Verathon Customer Care for more information.

Calibration reminders can be turned off, and the reminder period can be customized. For information on changing calibration settings, see the procedure Configure Calibration Settings on page 32.

Calibration options are available only when a probe is attached to the console.

A test of the probe's mechanical components is also available. It is recommended that you run the probe mechanical test as part of a regular maintenance schedule, after the probe has been accidentally dropped, or when the probe has been in storage for an extended period of time.

To perform this procedure, you must have a calibration tank designed for the BladderScan Prime instrument. For more information or to order the calibration tank, contact Verathon Customer Care or your local representative.

1. Place the calibration tank on a flat, non-reflective surface, and then remove the lid.

2. Using the notches to position the spiral-shaped target correctly, place the target in the container.

3. Pour clean, room temperature water into the container, filling to the top of the textured section.

4. Minimize the amount of air bubbles in the water and on the target.
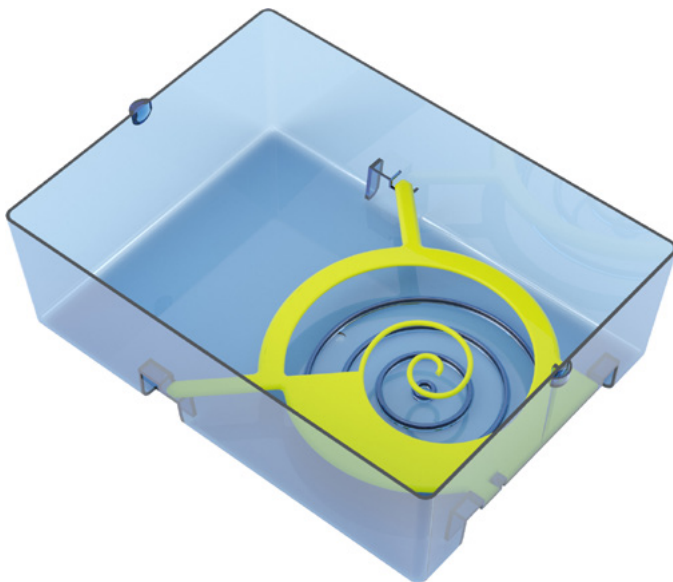
5. Replace the lid onto the calibration container.

6. Place the probe into the cutout in the calibration tank lid. Ensure that the tip of the probe is submerged in the water.

7. Align the probe button with the notch in the calibration tank lid exactly as shown—installation in another orientation may result in failure to calibrate.
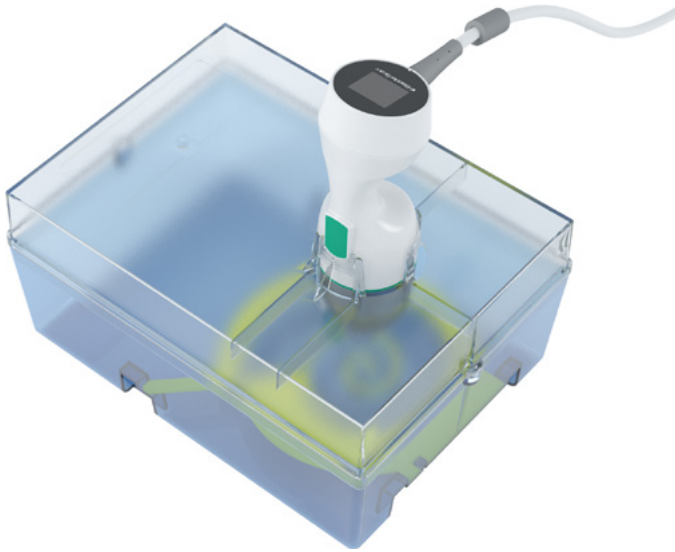
8. On the Home screen, tap **Settings**.

9. Tap **Calibration.**
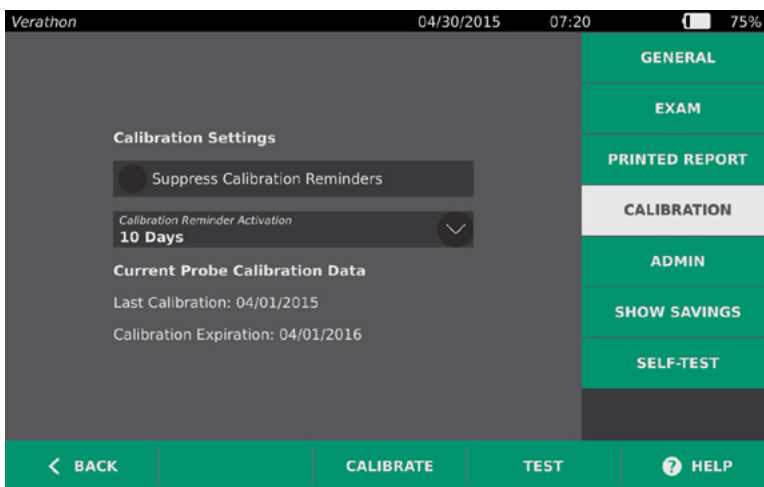
10. When the calibration tank and probe are in position, tap **Calibrate**. A screen of instructions appears.

11. Review the instructions, and then tap **Calibrate**.

Note: Once the calibration process has started, do not press the Standby button or disconnect the probe from the console.

The instrument begins to scan and analyze the data in order to ensure that it meets the calibration parameters. A message and process indicator appear while calibration is in process.
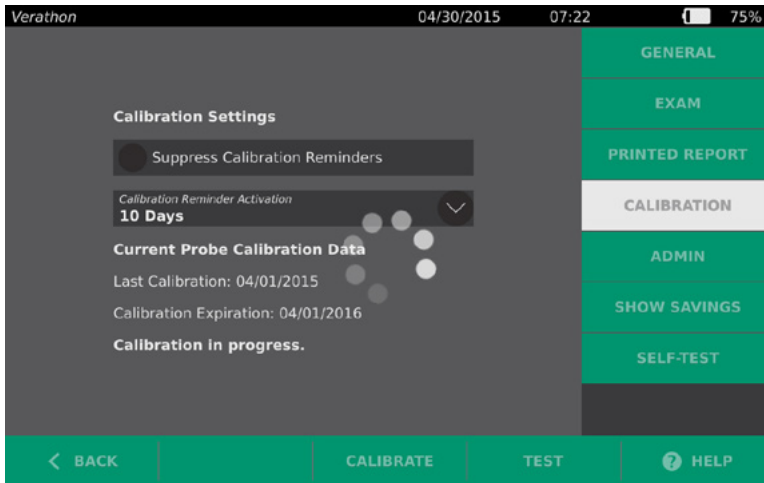
- If calibration is successful, a message on the console indicates that the probe has passed, and the Last Calibration and Calibration Expiration dates are updated.
- If calibration fails, a message on the console indicates calibration failure.

12. If a calibration failure occurs:

- Ensure that the calibration chamber has sufficient water.
- Minimize the amount of air bubbles in the water and on the target.
- Verify that the probe is seated properly in the calibration lid.

13. Tap **Calibrate** to begin recalibration. If repeat calibration failures occur, contact Verathon® Customer Care.

14. When you are done, tap **Back**.

15. Remove the probe from the calibration lid, and then dry it with a clean, soft cloth.

PROCEDURE 5.   TEST THE PROBE

Use the following procedure to test the probe's mechanical components and transducer. A calibration tank is not required to perform this procedure.

1. On the Home screen, tap **Settings**.

2. Tap **Calibration**, and then tap **Test**.
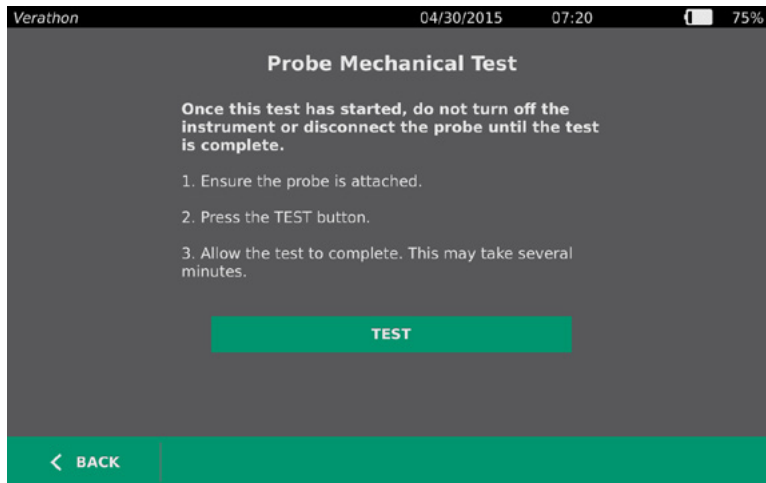
3. Review the test instructions, and then tap **Test**.

   Note: Once the test process has started, do not press the Standby button or disconnect the probe from the console.

   The instrument begins to test probe components. A message and process indicator appear while the test is in process.
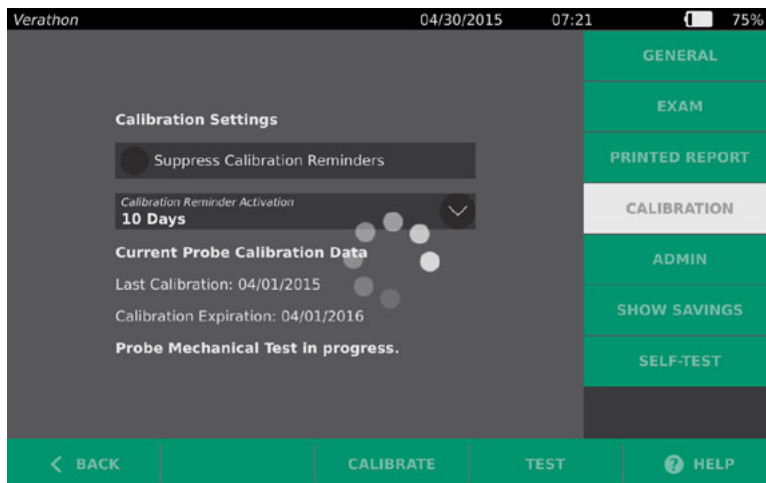
- If the probe passes the test, a message on the console indicates that the probe has passed.
- If probe fails the test, a message on the console indicates failure. Contact Verathon® Customer Care.

4. When you are done, tap **Back**.

Operations & Maintenance Manual: Maintenance & Safety

HELP & TROUBLESHOOTING

HELP RESOURCES

PROCEDURE 1. WATCH THE ONBOARD TUTORIAL

The BladderScan Prime system includes an onboard tutorial. It is recommended that you watch the tutorial prior to using the system. Use the tutorial to:

- Use the console scanning-related screens
- Position and aim the probe
- Save or print scan results
- Work with saved scans

The tutorial does not include an audio track.

Note: The setting and configuration screens include access to screen-specific online help text. To see help text on any setting or configuration screen, tap **Help***.*

1. On the Home, Before You Scan, Results, or Saved Scans screens, tap **Help**. The Tutorial Control screen opens, and the tutorial begins to play.
   - If you start the tutorial from the Home screen, the entire tutorial plays.
   - If you start the tutorial from any other screen, the tutorial begins at the relevant section.
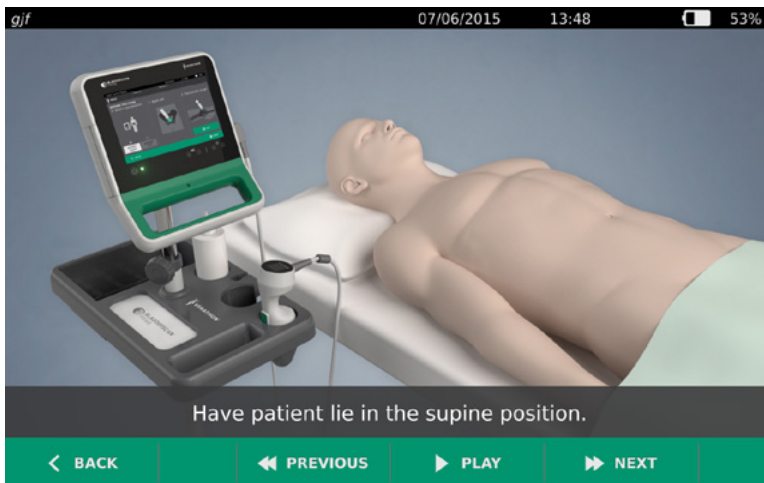
2. While the tutorial is playing you can:
   - View the previous frame of the tutorial (tap **Previous**)
   - View the next frame of the tutorial (tap **Next**)
   - Pause the tutorial (tap **Pause**) or continue the tutorial when paused (tap **Play**)
   - When you are done viewing the tutorial, tap **Back**.

CUSTOMER SERVICES RESOURCES

Verathon® provides several customer service resources, described in the table below.

RESOURCE	DESCRIPTION
In-service USB	USB flash drive included with your system that shows how to use the instrument.
Onboard help tutorial	A training module installed on your BladderScan is available by pressing **Help** from the Home, Aiming, and Results screens.
Onboard help text	Screen-specific online help text is available by pressing **Help** from setting and configuration screens.
Phone support	Please refer to the list of Customer Care resources available at verathon.com/contact-us

DEVICE REPAIR

The BladderScan Prime system components are not user-serviceable. Verathon® does not make available any circuit diagrams, component parts lists, descriptions, or other information that would be required for repairing the device and related accessories. All service must be performed by a qualified technician.

If you have any questions, contact Verathon Customer Care or your local representative.

⚠️ **WARNING**

To reduce the risk of electrical shock, do not attempt to open the system components. This may cause serious injury to the operator or damage to the instrument and will void the warranty. Contact Verathon Customer Care for all servicing needs.

⚠️ **WARNING**

No modification of this equipment is allowed.

TROUBLESHOOTING PROCEDURES

PROCEDURE 1. TROUBLESHOOT CONSOLE POWER ISSUES

1. If the instrument does not turn on, the battery may be dead or discharged. Replace a discharged battery with a fully-charged battery.

2. If the battery charge is too low for the instrument to function, recharge the battery according to the instructions in the procedure Charge the Battery on page 17.

3. If the instrument has stopped responding even with a charged battery, perform a system reset by pressing and holding the reset button for three seconds. The reset button is located next to the battery well.

4. If the instrument does not respond, contact Verathon® Customer Care.

PROCEDURE 2. TROUBLESHOOT PROBE CONNECTION ISSUES

If the console displays an error message indicating that the probe is not attached, use this procedure in order to troubleshoot the issue.

1. Put the console in standby mode by pressing the **Standby** button ⏻. Allow sufficient time for the instrument to enter standby mode.

2. Press the **Standby** button ⏻ again to activate the BladderScan Prime system. Allow sufficient time for the instrument to activate.

3. If the message still appears, replace the battery according to the instructions in the procedure Insert a Battery on page 25.

4. If the message still appears, contact Verathon Customer Care.

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PROCEDURE 3.   TROUBLESHOOT PROBE AIMING ISSUES

If a scan or aiming during prescan is unsuccessful or "off-target" and moving the probe in the expected direction of the bladder moves the bladder further off-target, use this procedure in order to troubleshoot the issue.

1. On the Before you Scan screen, verify that the selected position accurately reflects your position in relation to the patient.
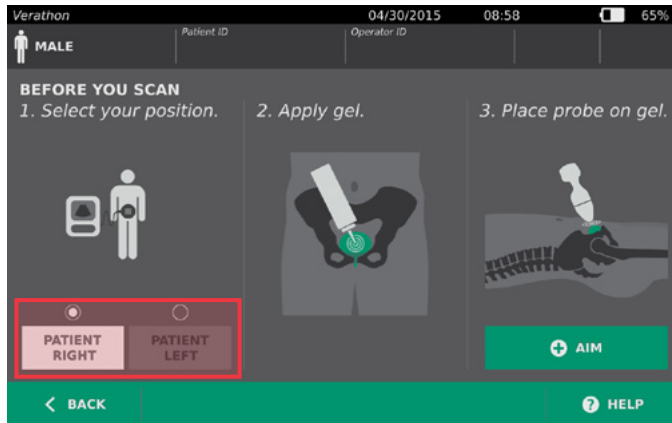
2. Hold the probe by grasping it with the probe cable running up your wrist and forearm.
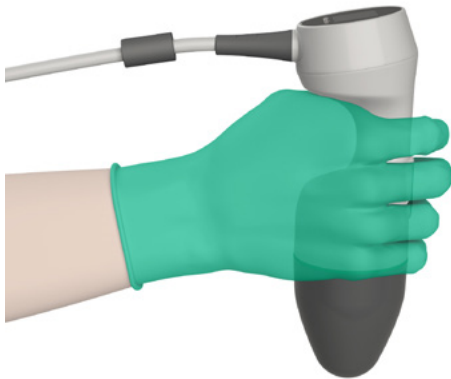
3. With the probe midline on the patient, ensure that the probe cable is oriented at 90 degrees to the sagittal plane.

Operations & Maintenance Manual: Help & Troubleshooting

4. Look at the display on the top of the probe. Ensure that the head of the icon points in the same direction as the head of the patient.

5. After verifying the selected orientation, probe placement, and probe display, rescan the patient. Hold the probe steady while the scan is in process. For detailed scanning instructions, see Measure Bladder Volume on page 37.
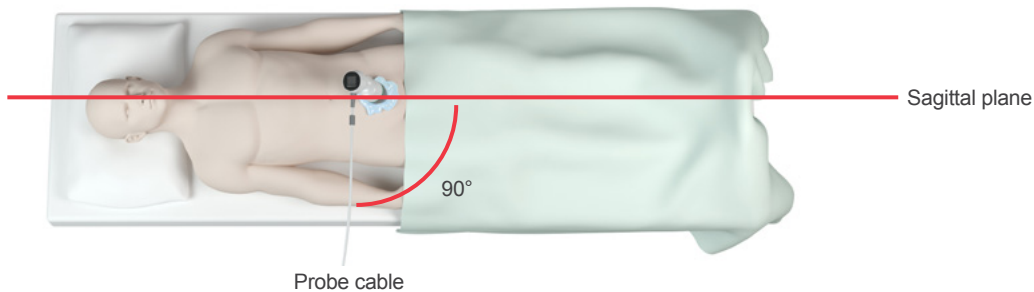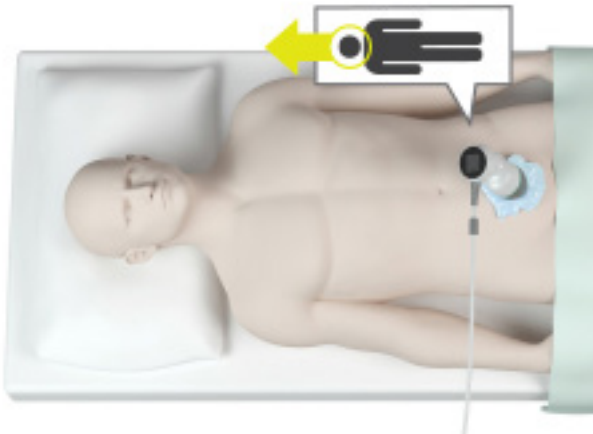
PROCEDURE 4. RESTORE FACTORY DEFAULTS

Use the following procedure to restore the original settings for the BladderScan Prime instrument. This procedure might be used, for example, when the instrument is being sent to a new department and customized settings and saved scans from the original department are no longer required.

Note: Running this procedure removes all user information—including customized system settings, cost savings calculations, and saved scans—from the instrument. Do not restore factory defaults if you want to retain this information.

1. On the Home screen, tap **Settings**.

2. Tap **Admin**, and then tap **Restore Defaults**.
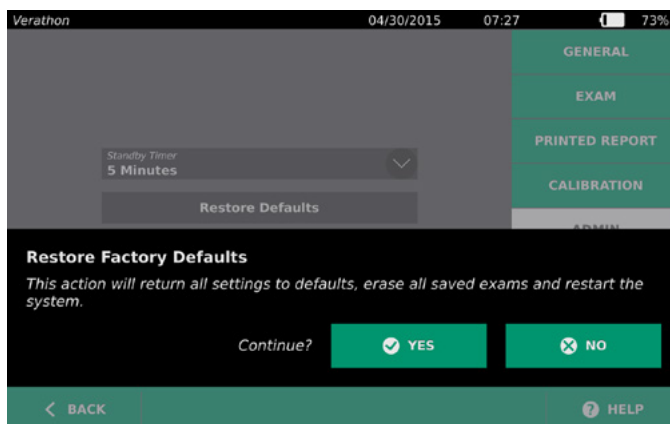
3. If you want to restore the system defaults, tap **Yes**. The BladderScan Prime instrument restores factory settings, and then restarts.

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PROCEDURE 5.   TROUBLESHOOT PRINTER POWER ISSUES

⚠️ **WARNING**

To avoid the risk of injury, when the printer door is open:

- Do not touch the printer mechanism or print head, which may be hot from recent printing.
- Do not touch the surface of the paper cutter.

IMPORTANT

To avoid damaging the equipment, remove the battery prior to connecting or disconnecting the printer or console base.

If the printer is not responding when **Print** is tapped on the console, then you may need to inspect and clean the electrical contacts.

1. Ensure the battery is removed from the instrument.

2. If the console is mounted on a mobile stand, do the following:
    - Securely hold the console so that it does not fall.
    - Move the locking pin to the unlocked (horizontal) position.
    - Move the quick-release lever to the unlocked (horizontal) position.

    The console is released from the mobile stand.

Quick-release lever
in unlocked position

Locking pin in
unlocked position
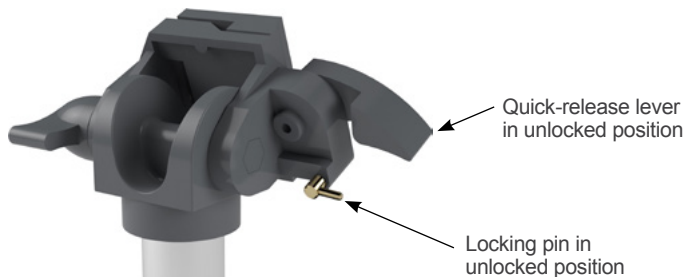
3. Place the console screen-side-down on a flat, non-abrasive surface.

4. Using a screwdriver with a Phillips bit, unscrew the two screws securing the printer to the console. Stop unscrewing when you encounter resistance; the screws are not designed to be completely removed from the printer.

5. Lift the printer away from the console.

6. Using a cotton swab dipped in 70% isopropyl alcohol (IPA), clean the individual contacts on the printer. Do not push the contact sideways or any farther than halfway down.

   Note: Use only the minimum amount of IPA necessary to clean the contacts. Ensure that excess IPA does not enter the interior of the printer.

Printer contacts

7. Inspect the printer contacts and verify the following:
   • The contacts are clean and free from corrosion, lint, or debris.
   • The contacts appear to be straight.
   • The contacts are uniformly spaced.

8. Repeat Step 6 in order to clean the corresponding contacts on the console.
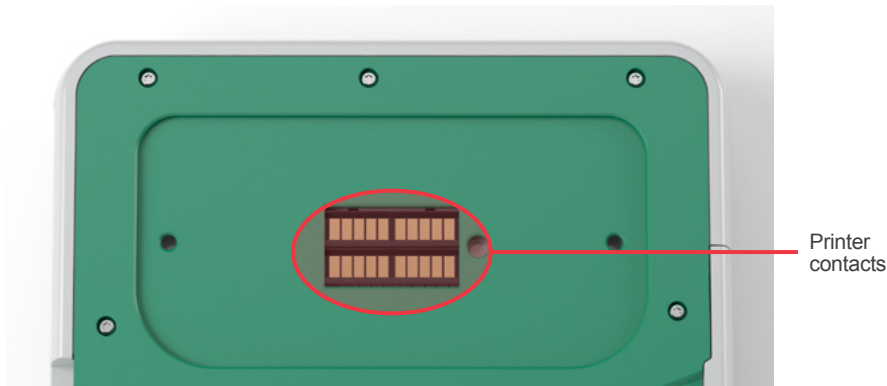
Printer contacts

9. Allow the contacts on the console and the printer to dry completely, and then reattach the printer to the console according to the instructions in the procedure Attach the Console Base or Printer on page 20.

10. If you would like to reattach the console to a mobile stand, complete the procedure Attach the Instrument to the Mobile Cart (Optional) on page 21.

11. If the printer continues to be unresponsive, contact Verathon® Customer Care.

PROCEDURE 6. TROUBLESHOOT IRREGULAR PRINTOUTS

⚠️ **WARNING**

To avoid the risk of injury, when the printer door is open:
- Do not touch the printer mechanism or print head, which may be hot from recent printing.
- Do not touch the surface of the paper cutter.

If the printer is producing irregular printouts, you may need to clean the print head.

1. Ensure that the console is in standby mode by pressing the **Standby** button ⏻. Allow sufficient time for the instrument to enter standby mode.

2. Slide the printer door upward to unlock it, and then rotate the door down to open.

3. If a thermal paper roll is in the printer, remove it.

4. Using a cotton swab dipped in isopropyl alcohol (IPA), wipe along the length of the print head. Do not use your fingers or any hard or abrasive surfaces to clean the print head.
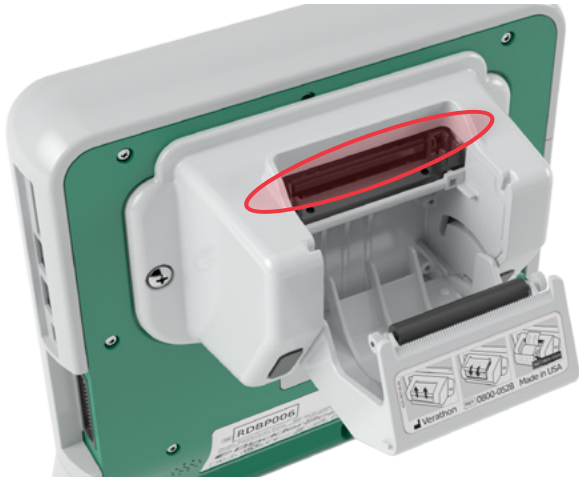
5. Allow the print head to dry completely.

6. Ensure that there is no lint or visible debris on the print head.

7. Verify the position of the printer driver roller in the printer door:
   • The printer driver roller plastic bushings should rest inside the light gray plastic clips in the printer door as shown. The white gear should be outside the clip.
   • If the printer driver roller has fallen out of the gray clips, replace the driver roller according to the instructions in the procedure Replace the Printer Drive Roller on page 74.

8. Load the thermal paper and close the printer door according to the instructions in the procedure Load Thermal Paper into the Printer on page 56.

9. If the printer continues to produce irregular printouts, contact Verathon® Customer Care.

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PROCEDURE 7. CLEAR A PAPER JAM

If the printer is jammed, use this procedure in order to remove the paper jam.

1. Ensure that the console is in standby mode by pressing the **Standby** button ⏻. Allow sufficient time for the instrument to enter standby mode.

2. Slide the printer door upward to unlock it, and then rotate the door down to open.

3. Pull the paper gently in order to release the paper jam. If necessary, pull any ripped or folded paper out of the printer and remove any bits of paper that have been separated from the roll.

4. Verify the position of the printer driver roller in the printer door:

   • The drive roller plastic bushings should rest inside the light gray plastic clips in the printer door as shown. The white gear should be outside the clip.

   • If the printer driver roller has fallen out of the gray clips, replace the driver roller according to the instructions in the procedure Replace the Printer Drive Roller on page 74.

5. Load the thermal paper and close the printer door according to the instructions in the procedure Load Thermal Paper into the Printer on page 56.

6. If the paper on the outside of the printer is ripped or torn, tear it off, pulling to one side to aid in cutting.

7. If you cannot release the paper jam or the printer continues to jam, please contact Verathon® Customer Care.

PROCEDURE 8.   REPLACE THE PRINTER DRIVE ROLLER

The printer drive roller can fall out if the printer is dropped. When the drive roller has fallen out, printing may be irregular or not occur at all. You may be unable to close the printer door.

1. Ensure that the console is in standby mode by pressing the **Standby** button ⏻. Allow sufficient time for the instrument to enter standby mode.

2. Slide the printer door upward to unlock it, rotate the door down to open, and then remove the paper roll.

3. Look for the printer drive roller inside the light gray plastic clips in the printer door.

4. If the printer drive roller has fallen out, place the drive roller as shown with the white gear on the right and the black plastic bushings on the drive roller centered on the light gray clips in the printer door.

5. Push down on the drive roller and ensure that it snaps into the light gray clips in the printer door and is held in place on both sides.

6. Load the thermal paper and close the printer door according to the instructions in the procedure Load Thermal Paper into the Printer on page 56.

7. If the printer continues to malfunction, contact Verathon® Customer Care.

WARRANTY

Verathon® warrants the BladderScan Prime system against defects in material and workmanship as long as it is covered by the Standard Warranty. Pursuant to this warranty, a service center authorized by Verathon will repair or replace units that prove to be defective during the warranty period.

Our policy is to honor product warranties and to perform services only on products purchased from an authorized Verathon entity. If you purchase a Verathon product or system components from unauthorized entities or if the original factory serial number has been removed, defaced, altered, or if the product is past its expiration date, your Verathon warranty will be invalidated. Purchasing Verathon products from unauthorized entities could result in receipt of products or system components that are counterfeit, used, expired, defective, or not intended for use in your region.

The unit must be used in accordance with the instructions contained in this manual. The warranty does not apply if the unit was misused or modified by anyone other than an authorized service center. Consumable items are not covered in this warranty and should be used in conformance with Verathon product specifications, as provided in the Product Specifications chapter on page 76.

For further details, consult your original purchase agreement for additional warranties. Warranty conditions may differ in some countries outside the United States. Contact your local distributor for specific warranty terms.

DISCLAIMER OF ADDITIONAL WARRANTIES

There are no understandings, agreements, representations of warranties expressed or implied (including warranties of merchantability or fitness for a particular purpose) other than those set forth in the preceding Warranty section. The contents of this manual do not constitute a warranty.

Certain regions disallow certain limitations on applied warranties. The purchaser should consult state law if there is a question regarding this disclaimer. The information, descriptions, recommendations, and safety notations in this manual are based upon Verathon experience and judgment with BladderScan Prime systems. The contents of this manual should not be considered to be all-inclusive or to cover all contingencies.

PRODUCT SPECIFICATIONS

SYSTEM SPECIFICATIONS

OVERALL SYSTEM SPECIFICATIONS

Table 11.   General System Specifications

ITEM	SPECIFICATION	
General Specifications		
Classification	Internally powered, Type BF	
Expected product life	Console	7 years
	Probe	7 years
	Printer	7 years
	Battery charger	7 years
Ingress protection (IP) against water	Console	IPX0
	Probe	IPX4
	Printer	IPX0
	Battery charger	IPX0
	Battery	IPX0
Operating Conditions		
Use	Indoor	
Temperature	+10 to +40°C (50 to 104°F)	
Relative humidity	20 to 75%	
Ambient air pressure	+700 hPa to 1060 hPa	
Storage Conditions		
Use	Indoor	
Temperature	-10 to +60°C (14 to 140°F)	
Relative humidity	20 to 80%	
Ambient air pressure	+600 hPa to 1060 hPa	

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Table 12.   Ultrasound Acoustic Output Parameters

Values in this table are the maximum readings obtained from three test results.

ACOUSTIC OUTPUT			MI	$I_{SPTA.3}$ (mW/cm²)	$I_{SPPA.3}$ (W/cm²)
Global Maximum Value			0.424	0.253	11.3
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	0.705		
	W_o	(mW)		1.027	0.635
	f_c	(MHz)	2.70	2.83	2.83
	z_{sp}	(cm)	3.00		3.20
	Beam dimensions	x_{-6} (cm)			0.325
		y_{-6} (cm)			0.346
	PD	(μsec)	0.839		0.728
	PRF	(Hz)	408		408
	EDS	Az. (cm)		5.40	
		Ele. (cm)		1.50	
TIS/TIB/TIC range			0.0-1.0*		

*   Both MI and TI values are below 1.0.

ACCURACY SPECIFICATIONS

Table 13.   Accuracy Specifications

SPECIFICATION	DESCRIPTION
Bladder volume range	0 to 999 mL
Volume accuracy	± (15% ± 15 mL)

The accuracy specifications assume the instrument is being used according to the instructions provided by Verathon® while scanning a tissue-equivalent phantom.

COMPONENT SPECIFICATIONS

CONSOLE SPECIFICATIONS

Table 14.   Console Specifications

ITEM	SPECIFICATION
General Specifications	
Height	125 mm (4.92 in)
Width	227 mm (8.94 in)
Depth	259 mm (10.20 in)
Weight	1770 g (3.90 lbs)
Display	1280 x 800 pixels
Electrical Specifications	
Input	Verathon Supplied Battery, 11.7 V DC
Output	USB Ports, 5 V DC at 100 mA maximum from each port
Insulation	Type BF

PROBE SPECIFICATIONS

Table 15.   Probe Specifications

ITEM	SPECIFICATION
General Specifications	
Height	196 mm (7.70 in)
Width	62 mm (2.43 in)
Depth	62 mm (2.43 in)
Weight	580 g (1.28 lbs)
Display	144 x 168 pixels
Cable	1.8 m (6.0 ft)

PRINTER SPECIFICATIONS

Table 16.   Printer Specifications

SPECIFICATION	DESCRIPTION
General Specifications	
Height	70 mm (2.76 in)
Width	164 mm (6.45 in)
Depth	90 mm (3.54 in)
Weight (without paper)	352 g (0.78 lbs)
Resolution	8 dots/mm (203 dots/in)
Dot size	0.125 mm by 0.12 mm (0.005 in by 0.005 in)
Printing width	48 mm (1.89 in), or 384 dots/line

BATTERY SPECIFICATIONS

The BladderScan Prime system is provided with two lithium-ion batteries. A battery symbol on the instrument LCD is always present, indicating how much power remains and when the battery needs to be changed. You can change the battery whenever necessary.

Removing a discharged battery and replacing it with a fresh battery should not erase any saved exams or system settings. In the event any system settings change, reset them using the instructions in the Configuring Settings chapter on page 26.

Use only the battery charger provided with the system. Any other battery charger may damage the batteries.

Table 17.   Battery Specifications

CONDITION	DESCRIPTION
General Specifications	
Battery type	Lithium Ion (Li-Ion)
Height	23 mm (0.89 in)
Width	151 mm (5.94 in)
Depth	59 mm (2.32 in)
Weight	326 g (0.72 lbs)
Electrical Specifications	
Battery life	A fully charged battery will typically provide over 24 hours of normal operating use between charges
Charging time	2.5 hours (typical)
Rated capacity	4.6 Ah, 51 Wh
Nominal voltage	11.1 V
Max charging voltage	12.6 V

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BATTERY CHARGER SPECIFICATIONS

Table 18.   Battery Charger Specifications

SPECIFICATION	DESCRIPTION
General Specifications	
Height	58 mm (2.30 in)
Width	124 mm (4.89 in)
Depth	175 mm (6.89 in)
Weight	385 g (0.85 lbs)
Electrical Specifications	
Input voltage	24 V DC
Input frequency	DC
Input current	2.5 A
Input connection	2.5 mm (0.1 in), center positive
Output	18 V DC max, 4 A max
Insulation	Protection Class III
Fuses	No user replaceable fuses

POWER ADAPTER SPECIFICATIONS

Table 19.   Charger Power Adapter Specifications

SPECIFICATION	DESCRIPTION
Electrical Specifications	
Input voltage	100–240 V AC, single phase
Input frequency	50–60 Hz
Input current	1.4 A max
Input connection	IEC C13 connection, line cord plug NEMA 5-15 (North America), AS 3112 (Australia), CEE 7/4 (Europe), BS 1363 (United Kingdom)
Output	24 V DC / 0–2.71 A
Insulation	10 Megaohm for 500 V DC
Fuses	Automatic Over Voltage Protection (OVP), Short Circuit Protection (SCP), Over Current Protection (OCP)

ELECTROMAGNETIC COMPATIBILITY

The BladderScan Prime system is designed to be in compliance with IEC 60601-1-2:2007, which contains electromagnetic compatibility (EMC) requirements for medical electrical equipment. The limits for emissions and immunity specified in this standard are designed to provide reasonable protection against harmful interference in a typical facility.

The BladderScan Prime system complies with the applicable essential performance requirements specified in IEC 60601-1 and 60601-2-37. Results of immunity testing show that the essential performance of the system is not affected under the test conditions described in the following tables. For more information about the essential performance of the BladderScan Prime system, see Essential Performance on page 1.

ELECTROMAGNETIC EMISSIONS

Table 20.   Guidance and Manufacturer's Declaration—Electromagnetic Emissions

The BladderScan Prime system is intended for use in the electromagnetic environment specified below. The customer or the user of the BladderScan Prime system should assure that it is used in such an environment.

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
RF emissions CISPR 11	Group 1	The BladderScan Prime system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The BladderScan Prime system is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

ELECTROMAGNETIC IMMUNITY

Table 21.   Guidance and Manufacturer's Declaration—Electromagnetic Immunity

The BladderScan Prime system is intended for use in the electromagnetic environment specified below. The customer or the user of the BladderScan Prime system should assure that it is used in such an environment.

IMMUNITY TESTS	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	In compliance	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	In compliance	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	In compliance	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% Ut (>95% dip in Ut) for 0.5 cycle 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles <5% Ut (>95% dip in Ut) for 5 s	In compliance	Mains power quality should be that of a typical commercial or hospital environment. If the user of the BladderScan Prime system requires continued operation during power mains interruptions, it is recommended that the BladderScan Prime system be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	In compliance	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the BladderScan Prime system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance d (m)** d=1.2 $\sqrt{P}$

Table 21.   Guidance and Manufacturer's Declaration—Electromagnetic Immunity

The BladderScan Prime system is intended for use in the electromagnetic environment specified below. The customer or the user of the BladderScan Prime system should assure that it is used in such an environment.

IMMUNITY TESTS	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	d=1.2 $\sqrt{P}$ 80 MHz to 800 MHz d=2.3 $\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

Note: U$_T$ is the AC mains voltage prior to application of the test level.

At 80 MHz and 800 MHz, the higher frequency range applies.

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BladderScan Prime system is used exceeds the applicable RF compliance level above, the BladderScan Prime system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the BladderScan Prime system.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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RECOMMENDED SEPARATION DISTANCES

Table 22.   Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the BladderScan Prime System

The BladderScan Prime system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BladderScan Prime system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BladderScan Prime system as recommended below, according to the maximum output power of the communications equipment.

RATED MAXIMUM OUTPUT POWER OF TRANSMITTER (W)	SEPARATION DISTANCE ACCORDING TO FREQUENCY OF TRANSMITTER (m)		
	150 kHz to 80 MHz $d=1.2 \sqrt{P}$	80 MHz to 800 MHz $d=1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d=2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

ACCESSORY CONFORMANCE TO STANDARDS

To maintain electromagnetic interference (EMI) within certified limits, the system must be used with the cables, components, and accessories specified or supplied by Verathon®. For additional information, see the Components & Accessories and Component Specifications sections. The use of accessories or cables other than those specified or supplied may result in increased emissions or decreased immunity of the system.

Table 23.   EMC Standards for Accessories

ACCESSORY	LENGTH
AC power cord	2.1 m (6.7 ft)
Power adapter	1.8 m (6.0 ft)

SYMBOL DIRECTORY

The following table explains the industry symbols used to indicate the BladderScan system compliance with international and national standards and regulations.

SYMBOL	MEANING
Warnings & Cautions	
⚠	Warning or Caution—Consult accompanying documents. Read instructions before connecting or operating.
⚡	Risk of electric shock
♨	Hot surface
🚯	Do not incinerate
((•))	Non-ionizing, electromagnetic radiation
Product Use & Specifications	
📖i	Refer to the operations & maintenance manual
🏭	Manufacturer
REF	Catalogue (part) number
SN	Serial number
LOT	Batch code
🌡	Temperature limitation
%	Humidity limitation
→•←	Atmospheric pressure limitation
R$_x$ only	Statement of prescription

SYMBOL	MEANING
	Media storage USB
Shipping & Disposal	
	Quantity per box
	Fragile item, handle carefully
	Keep dry
	Stacking limit by number—Indicates that the items are not to be vertically stacked higher than the specified number of items
	Shipping box is made of corrugated cardboard and should be recycled accordingly
Li-ion	Recycle lithium-ion battery
	Rechargeable Battery Recycling Corporation (RBRC) rechargeable battery recycling information
Standards & Certifications	
CE	CE—Marked in accordance with the Medical Device Directive (MDD)
	UL—Underwriters Laboratories certification mark for electrical shock, fire, and mechanical hazards only
	WEEE—Subject to waste electrical and electronic equipment regulations
EC REP	EC REP—Authorized Representative in the European Community
	EFUP—The environment friendly use period (in years) during which hazardous substances do not leak or mutate under normal use
Electrical & Power	
	Type BF applied part
	This unit is powered by a lithium-ion battery

GLOSSARY

TERM	DEFINITION
A	Ampere
Ah	Ampere hour
ALARA	As low as reasonably achievable
C	Celsius
cm	Centimeter
DC	Direct current
EMC	Electromagnetic compatibility
EMI	Electromagnetic interference
Essential performance	The system performance necessary to achieve freedom from unacceptable risk
ESD	Electrostatic discharge
F	Fahrenheit
g	Gram
GHz	Gigahertz
hPa	Hectopascal
Hz	Hertz
IEC	International Electrotechnical Commission
Image cone	Cone-shaped area in which the probe transmits ultrasound waves
in	Inch
ISPPA	Spatial-peak, pulse-average intensity
ISPTA	Spatial-peak, temporal-average intensity
LCD	Liquid crystal display
m	Meter
MHz	Megahertz
MI	Mechanical index
mL	Milliliter
mm	Millimeter
OCP	Over current protection
OVP	Automatic over voltage protection
RF	Radio frequency
SCP	Short circuit protection
UL	Underwriters Laboratories
UTI	Urinary tract infection
V	Volt
W	Watt
Wh	Watt hour
WEEE	Waste Electrical and Electronic Equipment

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