BladderScan®

BLADDERSCAN BVI 6400

Operations & Maintenance Manual

VERATHON®

BLADDERSCAN
BVI 6400
Operations & Maintenance Manual

Effective: September 13, 2019

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

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IMPORTANT INFORMATION

OVERVIEW

PRODUCT DESCRIPTION

The BladderScan BVI 6400 bladder volume instrument is a wireless, battery-powered, ultrasound device that provides a noninvasive measurement of urinary bladder volume.

During each scan, the device employs patented VMODE technology to create a three-dimensional image of the bladder, which automatically calculates and displays measurements based upon this image. VMODE measurements tend to be more accurate than those obtained from conventional two-dimensional ultrasound, as they are based on a more complete, multi-faceted image of the bladder.

Optionally, exam results may be transmitted to a personal computer running Scan Point with QuickPrint software via a USB communication cradle. Scan Point with QuickPrint allows the user to archive data, calibrate the device, update software, print, and transfer data through an application-based interface.

STATEMENT OF INTENDED USE

The BladderScan BVI 6400 is an ultrasound device intended to be used for measuring the urine volume in the bladder noninvasively.

ESSENTIAL PERFORMANCE

Essential performance is the system performance necessary to achieve freedom from unacceptable risk. The essential performance of the BladderScan BVI 6400 system is to produce ultrasonic output energy and display numerical values for bladder volume. The system has a passively temperature-controlled transducer assembly.

ENVIRONMENTS OF INTENDED USE

The BladderScan BVI 6400 system is intended to be used in professional healthcare environments such as hospitals, clinics, and doctors' offices.

NOTICE TO ALL USERS

This device should be used only by individuals who have been trained and authorized by a physician or the institution providing patient care. All users must read this entire manual prior to using the device. Do not attempt to operate the device until you thoroughly understand all instructions and procedures in this manual. Failure to comply with these instructions may compromise the performance of the device and the reliability of its measurements.

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 this device 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 32

CONTRAINDICATIONS

This device 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.

WARNINGS & CAUTIONS

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.

WARNINGS

WARNING

This system 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, disinfection, and sterilization 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/support.

WARNING

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

WARNING

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

WARNING

When preparing and using one of the approved cleaning, disinfection, or sterilization solutions, follow the instructions of the solution manufacturer. Pay close attention to the proper dilution and immersion times.

WARNING

In order to maintain electrical safety, use only the provided power adapter, battery, and battery charger.

WARNING

To reduce the risk of electric shock, use only the accessories and peripherals recommended by Verathon.

WARNING

The docking station, charging cradle, power adapter, and power cords are not intended for patient contact. Ensure 2 m (6 ft) is maintained between the patient and these components.

WARNING

Ensure proper distance from patient. When transmitting data to or from your computer, make sure the device, accessories, and computer are outside the patient vicinity (more than 2 m (6 ft) from the patient).

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

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

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 device and will void the warranty. Contact Verathon Customer Care or your local representative for all servicing needs.

WARNING

Use of accessories, transducers and cables other than those specified or provided by Verathon may cause this system to experience electromagnetic malfunctions, including increased emissions or decreased immunity. This may cause improper operation, procedure delays, or both.

WARNING

Portable radio frequency communications equipment (including peripherals such as antenna cables and external antennas) may not be used within 30cm (12inches) of any part of the BladderScan BVI 6400 system, including cables that Verathon specifies or provides for use with the system. If this distance is not maintained, performance of the system may be degraded and image display may be compromised.

WARNING

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

WARNING

No modification of this equipment is allowed.

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:

- 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.

CAUTIONS

CAUTION

When using the system with optional Scan Point software, your computer must be minimally certified to EN/IEC/CSA/UL 60950-1 or 60601-1 standards. This configuration ensures that compliance to the EN/IEC 60601-1 system standard is maintained. Anyone connecting additional equipment to the signal input port or signal output port configures a medical system, and is therefore responsible for ensuring that the system complies with EN/IEC 60601-1. If you need assistance, contact your biomedical staff, local representative, or Verathon Customer Care.

CAUTION

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

- Do not immerse the device in cleaning or disinfectant solution or other liquids.
- Do not subject any part of the device to steam, ethylene oxide, radiation, or similar methods of sterilization or autoclaving.
- Do not use metal or abrasive brushes. These may scratch the device, causing permanent damage.
- Do not use CIDEXPLUS to disinfect the device. CIDEXPLUS will damage the plastic enclosure.

CAUTION

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

CAUTION

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 35.

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 60601-1-2 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.

INTRODUCTION

SYSTEM OVERVIEW

The BladderScan BVI 6400 is a portable, hand-held ultrasound device that scans the patient's bladder. It is battery-powered with an ergonomic design. Using patented VMODE technology, it provides a noninvasive measurement of urinary bladder volume. The display provides aiming assistance and provides an array of bladder measurement information.

The device measures ultrasonic reflections on multiple planes inside the body, producing a three-dimensional image. Based on this image, the device calculates and displays the bladder volume. A sonographer is not required.

Volume measurements made with VMODE ultrasound are more accurate than those from conventional ultrasound, as they are based on a more complex, three-dimensional image of the bladder.

The device includes an integrated microphone for recording voice annotations. Voice annotation allows up to 10 exams to be stored on the device.

BLADDERSCAN BVI 6400

This hand-held, portable device:

- Measures bladder volume noninvasively.
- Takes scans quickly, providing test results in a matter of seconds.
- Is easy to operate: staff members can easily learn to scan patients quickly and accurately.
- Provides the capability to voice annotate each exam (10 seconds to record patient ID and relevant exam information), ensuring that valuable patient and exam data is retained.
- Stores voice-annotated data for up to ten exams.
- Improves efficiency of healthcare professionals who examine multiple patients on their rounds.
- Allows for exam results and images to be downloaded, viewed and printed using the optional Scan Point Image Management Technology.
- Is battery-operated, lightweight, and portable.

SCAN POINT IMAGE MANAGEMENT TECHNOLOGY (OPTIONAL)

You may transmit bladder volume measurements and ultrasound images from your BladderScan device to Scan Point image management software. Scan Point installs on a Windows-based computer and allows viewing, printing, and archiving of patient exam results, including ultrasound images for patient records and reimbursement (when applicable). Exam data and ultrasound images may be printed in a variety of report formats from adhesive labels that may be affixed to patient charts, to full, letter-size formats.

Scan Point can also be used to calibrate your device. The Scan Point image management technology (Scan Point software, license, and accessories) is available with the purchase of many BladderScan systems. Comprehensive service and warranty are provided under the Scan Point Total Reliability Plan.

Note: Plan availability and conditions may differ depending on your location. For more information about terms and availability, contact Verathon Customer Care or your local representative.

Scan Point Local Client (LC) is a stand-alone, non-networked version of the software. It is available for use with this device.

Scan Point with QuickPrint is a network-based version of the application. Archived patient data is stored securely on HIPAA-compliant, Verathon-maintained servers. Users can access records from any Internet-enabled, Windows-based PC. Scan Point with QuickPrint allows users to maintain the most recent software for their devices, to calibrate their devices themselves without having to send them in for service, and also enables remote diagnostics and troubleshooting by Verathon service technicians.

SYSTEM COMPONENTS & ACCESSORIES

REQUIRED SYSTEM COMPONENTS

Table 1. Required System Components and Accessories

PART	DESCRIPTION
	BladderScan BVI 6400 Hand-held, wireless, battery-operated, ultrasound bladder volume instrument.
	Charging cradle Use the charging cradle to charge the device's internal battery. The charging cradle plugs directly into an electrical wall outlet. Before using your device, you must charge it for a minimum of 6 hours.
	BladderScan BVI 6000 series in-service CD Includes the electronic version of this operations and maintenance manual.
	Activation tool If needed, use this tool in order to press the Activation button on the device.

OPTIONAL COMPONENTS & ACCESSORIES

The following optional items are available to enhance the capabilities of your device. Please contact Verathon Customer Care or your local representative for more information on any of the following Verathon products.

Table 2. Optional Components and Accessories

PART	DESCRIPTION
	Scan Point LC Software install CD Installs Scan Point Image Management System on a stand-alone (non-networked) Windows PC. For more information, see Scan Point Image Management Technology (Optional). **Scan Point with QuickPrint Install CD** Installs Scan Point with QuickPrint software on a network-enabled Windows PC. For more information, see Scan Point Image Management Technology (Optional).
	Scan Point docking station Used with Scan Point image management technology. Transmits data from the BladderScan device to the Scan Point host computer and simultaneously recharges the battery.
	Calibration kit (requires Scan Point with QuickPrint software) The calibration tank base holds a spiral-shaped calibration target and 4.2 liters of water. The indentation in the tank lid places the device in a known and repeatable location with respect to the spiral target. Self-calibration takes about 15 minutes.
	Scan Point label writer Prints exam results on adhesive label media. Requires installation of Scan Point software on a Windows PC. The following items are related to the Scan Point label writer: • USB Cable—Connects the Scan Point label writer to the Scan Point host computer. • Power Cord—Connects the Scan Point label writer power adapter to a wall outlet. • Power Adapter—Connects the power cord to the label writer. • Roll of Labels—Labels in roll format properly sized for the Scan Point label writer.
	Battery replacement kit Contains a replacement lithium-ion battery and instructions for installing it.

BUTTONS, PARTS, & ICONS

BUTTONS & PARTS

Figure 1. Buttons and Parts

Table 3. Buttons and Parts

PART	PURPOSE
Scan button	Press to take a scan.
Scanhead	The scanhead transmits and receives ultrasound waves, automatically moving its internal transducer 360° in order to scan twelve different planes, producing a three-dimensional image of the bladder.
Top button	Press to select gender.
Activation button	Press to reactivate the device if the battery becomes completely discharged.
Display	Displays bladder volume measurements and other scan, patient, and device data.
Infrared (IR) window	Enables the device to communicate with a Scan Point-equipped PC via the Scan Point docking station.
Microphone	Speak into the microphone to record voice annotations.

SCREEN ICONS

The following icons may appear on the display.

Table 4. Display icons

ICON	MEANING
	Battery power level.
	Female gender option is selected. Select this option only for women who have not had a hysterectomy. Deselect for all others, male or female.
	Bladder imaging in progress. Hold device steady.
	Solid: Indicates that the bladder was not centered within the ultrasound field of view. However, the bladder volume measurement is still accurate. Re-aiming is optional. **Flashing**: Indicates that the aim was "off target." In order to get an accurate bladder volume measurement, you must re-aim in the direction of the arrow.
	The patient's actual bladder size is larger than the ultrasound field of view.
	Solid: Indicates that a voice annotation is being recorded. **Flashing**: Indicates that the recorded voice annotation is being stored
	Indicates the number of days remaining until the next required calibration.

BATTERY ICON

The battery icon is located in the lower-right corner of the display and indicates the power level of the battery. The device can be charged at any time, but if the battery is completely discharged, it must be recharged before use.

Table 5. Battery status icons

BATTERY ICON	DESCRIPTION
	Battery is fully charged and ready for use.
	Battery is 50–75% charged.
	Battery is 25–50% charged.
	Battery is nearly discharged and may only have enough power for a few scans. Recharge the battery as soon as possible.
	The battery is completely discharged. The device will not work until it is recharged.
	Scrolling segments indicate that the battery is charging.

SETTING UP

To help you get up and running as quickly as possible, the next few pages explain how to:

1. Perform Initial Inspection
2. Charge the Device
3. Activate the Device (Optional)
4. Install Scan Point Software (Optional)

PROCEDURE 1. PERFORM INITIAL INSPECTION

When you receive the device, Verathon recommends that there is a full visual inspection of the system for any obvious physical damage that may have occurred during shipment.

1. Verify that you have received the appropriate components for your system by referring to System Components & Accessories.
2. Inspect the components for damage.
3. If any of the components are missing or damaged, notify the carrier and Verathon Customer Care or your local representative.

PROCEDURE 2. CHARGE THE DEVICE

Please read the Warnings & Cautions section before performing the following task.

Before using your device for the first time, or when the battery becomes completely discharged, you must charge your device battery for approximately 6 hours or until it is fully charged. In this procedure, you set up the charging cradle and use it to charge the battery.

Note: If you have already installed Scan Point on your computer and installed the docking station, then you can use the docking station to charge the device.

When you are not using your device, Verathon recommends that you store it in the charging cradle in order to ensure that the device is always sufficiently charged. The charging cradle cannot overcharge the battery.

1. Plug the charging cradle into an electrical wall outlet.
2. Place the device in the charging cradle. The scrolling-segments battery icon displays, indicating that the device is charging.

   If the battery icon does not appear, then the device was completely discharged. Allow the battery to charge for 2 hours. If the scrolling-segments battery icon does not appear after 2 hours, reactivate the device according to the following procedure.

PROCEDURE 3. ACTIVATE THE DEVICE (OPTIONAL)

Complete this procedure if the battery is completely discharged, or if after 2 hours in the charging cradle the device does not show the scrolling-segments battery icon.

1. Using the tip of the activation tool, press the Activation button located just above the Scan button.
2. Place the device in the charging cradle or docking station until the "full battery" icon is displayed.

Note: When you are not using your device, Verathon recommends that you store it in the charging cradle in order to ensure that your device is always sufficiently charged. The charging cradle cannot overcharge the battery.

PROCEDURE 4. INSTALL SCAN POINT SOFTWARE (OPTIONAL)

If you are using Scan Point Image Management Technology, install it according to the instructions in the Scan Point user's manual. Refer to the manual for further instructions on how to use Scan Point or how to set up and install the Scan Point label writer. For more information, see the section Scan Point Image Management Technology (Optional).

MEASURING BLADDER VOLUME

PERFORMING SCANS

Please read the Warnings & Cautions section before performing the following tasks.

PROCEDURE 1. PREPARE FOR THE EXAM

Before using a BladderScan device, ensure that you are familiar with its parts. For more information, see the Introduction chapter.

If you are a new BladderScan device user, Verathon recommends that you perform your first exam on a patient with a moderately full bladder rather than a nearly empty bladder. A nearly empty bladder can be more difficult to locate.

1. If the patient meets any of the following restrictions, do not use the device for the exam:
   - Fetal patients.
   - Pregnant patients.
   - Patients with open skin or wounds in the suprapubic region.
   - Patients with ascites
2. Ensure that you are aware if the patient has any of the following conditions, which may affect ultrasound transmission and the accuracy of the exam:
   - **A catheter in the bladder**—The presence of a catheter may affect the accuracy of the bladder volume measurement, but the measurement may still be clinically useful (example: detecting a blocked catheter).
   - **Previous suprapubic or pelvic surgery**—Scar tissue, surgical incisions, sutures, and staples can affect ultrasound transmission and reflection.
3. Check the battery icon, and ensure that the battery has sufficient power.
4. Ensure that the device has been properly cleaned according to the instructions in the chapter Cleaning & Disinfecting on page 22.

PROCEDURE 2. MEASURE BLADDER VOLUME

To ensure the highest degree of accuracy, Verathon recommends that you scan the patient's bladder at least three times per exam, in order to ensure the repeatability of your measurements. Repeatability refers to your ability to center the bladder during each measurement, not your ability to obtain exactly the same bladder volume measurement each time. Volume measurements should be close, but need not be identical. If you cannot obtain an optimal, repeatable measurement, the accuracy of the result is compromised.

The device will go into sleep mode 20 minutes after completing the exam. If the device goes to sleep or turns off due to a low battery before you do one of the following, the exam results will be lost:

- Record a voice annotation
- Manually record the exam results
- Transfer the exam results to Scan Point
- Return the device to the charging cradle or docking station

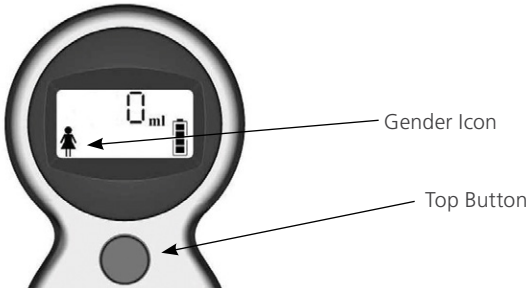
Performing a new exam overwrites any non-annotated exam results. To ensure that patient data is not lost, it is recommended that you record a voice annotation with every exam. The device can save up to 10 voice-annotated exam results. For more information about performing scans, see Scanning Tips.

1. If the device is in a charging cradle or docking station, remove it. The device turns on automatically.

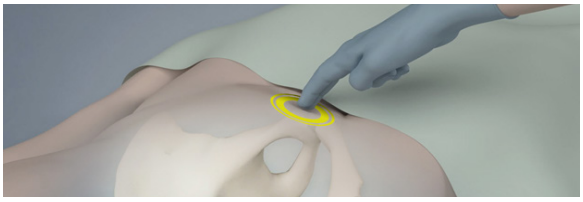
   If the device is not in the charging cradle or docking station and is in sleep mode, press any button. The device turns on.

2. If the patient is a female who has not had a hysterectomy, press the top button until the gender icon is displayed.

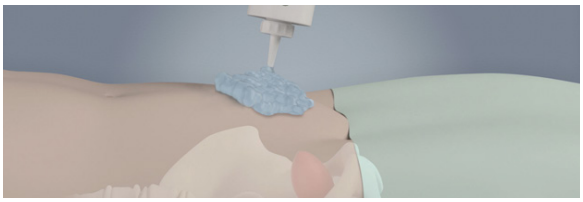
   If the patient is a male, or a female who has had a hysterectomy, press the top button until the gender icon is cleared.



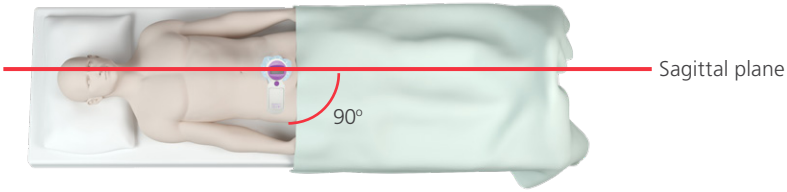
3. With the patient lying in a supine position and with the abdominal muscles relaxed, palpate the patient's pubic bone.



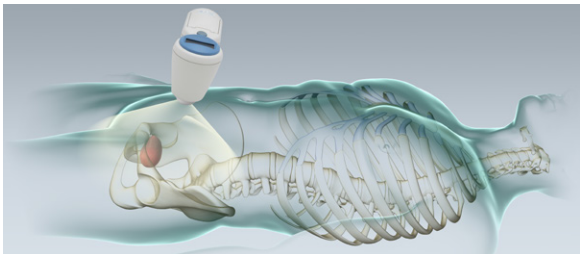
4. Place an ample quantity of ultrasound gel, with as few air bubbles as possible, midline on the patient's abdomen, approximately 3 cm (1 in) above the pubic bone.



5. Standing at the patient's right side, gently press the scanhead onto the lower abdomen through the gel. The device's handle should be oriented at 90 degrees to the sagittal plane of the patient.



6. Aim toward the expected location of the bladder. For most patients, this means angling the device slightly toward the patient's coccyx (tail bone) so the scan clears the pubic bone.



7. Press and release the scan button, located on the underside of the device.

A scanning symbol appears in the upper right corner of the display during the scan.

8. Hold the device steady while scanning; avoid changing its position, angle, or pressure. When you hear the end-scan tone, the scan is complete.

9. View the top half of the display. The bladder volume measurement is displayed in milliliters (mL).

   If a flashing arrow is displayed, then the scan is off-target, and the bladder was mostly outside the ultrasound field of view. Re-aim in the direction indicated by the flashing arrow and perform the scan again.

   If a solid arrow is displayed, then the bladder was mostly inside the ultrasound field of view. The results are satisfactory, but in order to ensure accuracy, Verathon recommends that you re-aim in the direction of the arrow and perform the scan again.

   If no arrow is displayed, then the bladder was completely contained within the ultrasound field of view. The measurement is accurate. Continue with the procedure.

10. If you would like to ensure the highest degree of accuracy, repeat Step 5–Step 9 in order to complete three scans, and then compare the results. It is not necessary that the three exam results be identical, but they should be similar.

11. If you would like record a voice annotation and save the exam, continue to the next step.

    If you do not need a voice annotation, skip to Step 16.

IMPORTANT

If you do not record a voice annotation for the exam, the next exam will overwrite the non-annotated exam. The device can store up to ten voice-annotated scans, so you can perform multiple exams on your rounds.

Non-annotated exam data is lost if the battery is depleted or the device goes into sleep mode. To ensure you do not lose any patient data, it is a good idea to add a voice annotation to every exam.

12. Press and hold the top button until you hear a tone (approximately 3 seconds), and then continue to hold the top button.

13. Hold the microphone approximately 15 cm (6 in) from your mouth and speak clearly. Be sure to include all relevant exam information, such as the patient's name and the name of the person performing the exam. You have 10 seconds to record information.

14. When you have finished recording, release the top button and listen to your annotation play back.

15. If you would like to re-record your annotation, repeat Step 12–Step 14. You can make a new recording only if the device still displays the bladder volume for that particular exam.

    If you are satisfied with the annotation, do not press any buttons. After several seconds, the scanner automatically accepts and stores the annotation with the exam. The microphone icon on the display flashes while the exam and voice annotation are being saved.

16. Wipe the gel off the patient and the scanhead.

17. If you did not save a voice annotation, ensure that you manually record the exam results or transfer the data to Scan Point prior to performing another exam or allowing the device to go into sleep mode.

SCANNING TIPS

IMPORTANT

Hold the device steady while scanning. Movement will result in an inaccurate reading.

Applying too much pressure when scanning will lead to a "greater than" symbol (>) preceding the bladder volume measurement. Apply less pressure and re-scan.

Volume reading will be affected by:

- The presence of scar tissue.
- The presence of a catheter.
- Obese patients—If you are scanning an obese patient, lift as much abdominal adipose tissue out of the way of the device as possible. Apply more pressure with the device in order to reduce the amount of adipose tissue through which the ultrasound must pass.

To ensure accurate results, make sure that:

- There are no air gaps between the scanhead and the patient's skin.
- There are no air bubbles in the ultrasound gel.
- You are holding the device steady while scanning (avoid changing its position, angle, or pressure).
- You are using enough pressure to maintain good skin contact until the scan is complete.
- There is not a catheter in the patient's bladder. The presence of a catheter may affect the accuracy of the bladder volume measurement, but the measurement may still be clinically useful (detecting a blocked catheter, for example).

The following table illustrates typical scanning scenarios and corresponding bladder volume information that may appear on the display.

Table 6. Typical scanning scenarios and displays

SCANNING SCENARIO	EXAMPLE DISPLAY	DESCRIPTION
Optimal scan		In an optimal scan, the bladder is entirely contained within the ultrasound field of view. The display shows: • Bladder volume • No > symbol • No flashing arrow • No solid arrow
Bladder volume is greater than 999 mL		The bladder is entirely contained within the ultrasound field of view but the bladder volume is greater than 999 mL. In this case, the display shows: • A bladder volume of >999 mL • No flashing arrow • No solid arrow
Bladder is too large to be fully contained within the ultrasound field of view		Either the bladder is too large to be contained by the ultrasound field of view, or the user is pressing too hard with the device. The display shows: • Bladder volume with a > symbol • No flashing arrow • No solid arrow Apply less pressure and rescan.
Bladder not centered (optional rescan)		The bladder is entirely contained within the ultrasound field of view but not centered. Rescanning is optional. The display shows: • Bladder volume • A solid arrow indicating re-aiming direction for optional rescan Move device in the direction of the arrow and rescan.
Bladder not centered (rescan required)		Bladder is only partially contained within the ultrasound field of view. A rescan is necessary to ensure accurate bladder volume measurement. The display shows: • Bladder volume • A flashing arrow indicating the re-aiming direction Move device in the direction of the arrow and rescan.

CLEANING & DISINFECTING

Please read the Warnings & Cautions section before performing the following task.

Cleaning and disinfecting this device is an important part of using and maintaining it. Prior to each use, ensure the device has been cleaned and disinfected according to the following procedures.

Remove the device from the docking station or charging cradle to clean and disinfect it.

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 material compatibility with the system components, but they have not been tested for efficacy. For guidance on biological effectiveness of the disinfectant, refer to the instructions from the manufacturer:

- T-Spray II
- Cavicide
- CaviWipes
- Chloro-Sol Spray
- Sani-Cloth Bleach Wipes
- Sani-Cloth Germicidal Wipes
- Clorox Germicidal Wipes
- Sporicidin
- Sporicidin Disinfecting Towelettes

PROCEDURE 1. CLEAN & DISINFECT THE DEVICE

Use this procedure in order to clean and disinfect the device. Review the information in the Best Practices and Compatibility & Availability sections before completing this procedure.

CLEAN THE DEVICE

1. Put on new gloves.
2. After every exam, using a dry paper towel or soft cloth, wipe any ultrasound gel completely off the scanhead.
3. Use a soft, moistened cloth to remove particulate matter or body fluids that remain on the device.
4. Allow the device to air dry or towel dry with a clean dry cloth before disinfecting.
5. Continue to the following section, Disinfect the Device. Low-level disinfection of the scanhead is required between uses.

DISINFECT THE DEVICE

Low-level disinfection of the scanhead is required between uses. Only use disinfectants prior to their expiration date.

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

7. If using a liquid disinfectant, mix the disinfection solution according to the manufacturer's label instructions for the appropriate disinfection level concentration.
8. Apply the solution to a soft cloth or wipe for application. Do not spray or apply liquid disinfectants directly to the surface of the device or soak the device in liquids.
9. Wipe the surfaces of the device, allowing the surface to stay wet for the required contact duration. Follow the manufacturer's instructions for the appropriate disinfection level contact duration.
10. If rinsing or removal of the disinfectant solution from the device is required by the disinfectant manufacturer's instructions, wipe the device with a clean soft cloth dampened in sterile water. Verathon recommends wiping the device three separate times to remove all residual disinfectant.
11. Allow the device to air dry or towel dry with a clean, dry cloth.

MAINTENANCE & TROUBLESHOOTING

REGULAR INSPECTIONS

Prior to each use, inspect the device for cracks, abrasions, gouging, evidence of impact, or other damage. Cracks that allow the ingress of fluid may affect the safety and performance of the device.

IMPORTANT

If you see any physical damage or cracks in the device, discontinue use immediately and contact Verathon Customer Care or your local representative.

CALIBRATING THE DEVICE

You must periodically calibrate your device to ensure that it is providing accurate results. The required frequency of calibration depends on your Total Reliability Plan. Calibrating the device on a regular basis ensures accurate and proper alignment of the device's internal coordinate system.

If you have the calibration kit and Scan Point with QuickPrint, you can easily and quickly calibrate your own device. You may also send your device to an authorized Verathon Service Center.

If you are not using Scan Point with QuickPrint, you must send your device in to an authorized Verathon Service Center for calibration.

To contact Verathon Customer Care about calibration, please visit verathon.com/support.

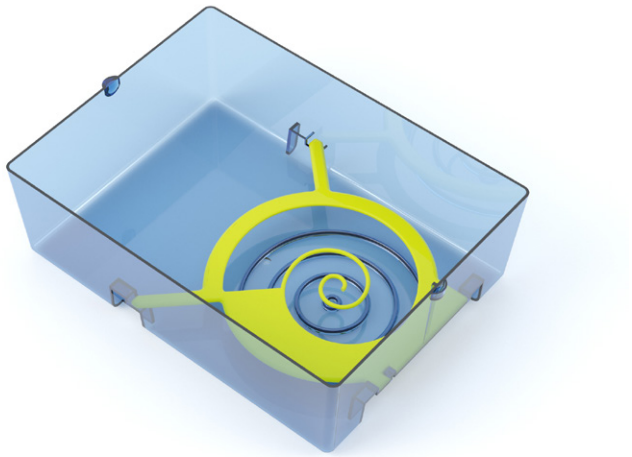
PROCEDURE 1. CALIBRATE THE DEVICE

Calibrating your device ensures that it is providing accurate results, and maintains proper alignment of the device's internal coordinate system. If the device is not calibrated by the prescribed date, the device is disabled and must be calibrated before it can be used again.

1. Place the calibration tank on a flat, non-reflective surface, and then remove the lid.
2. Pour clean, room-temperature water into the tank base, filling to the indicator mark. Ensure that there is a minimal amount of bubbles in the water.

   Note: The tank may need to sit for 24 hours until the water has degassed.

3. Using the notches to position the spiral-shaped target correctly, place the target in the tank base.

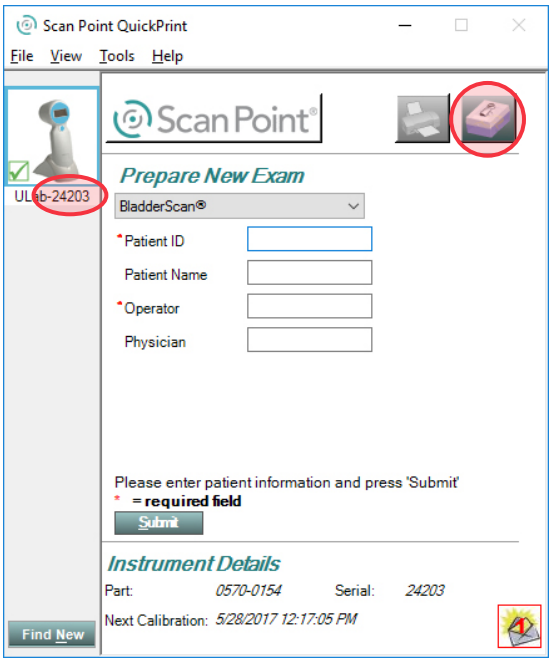


4. Replace the tank lid on the tank base. Ensure that the opening for the scanhead is directly above the spiral target.
5. On the computer, double-click the Scan Point QuickPrint icon. Scan Point with QuickPrint opens.

6. Place the device in the Scan Point docking station. Scan Point connects to the device.

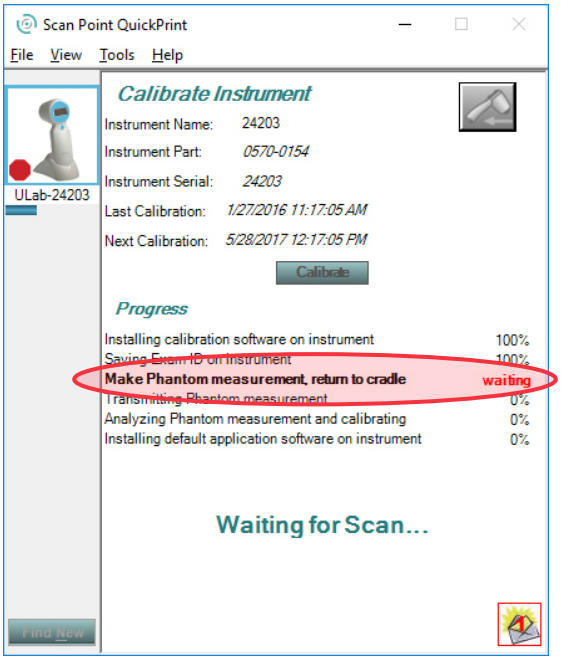
   Note: Software may upload to the device at this time.

7. In Scan Point, select the device, verify that the serial number matches the device you are calibrating, and then click the calibration tank icon.



8. In the Calibrate Instrument window, click the **Calibrate** button. Scan Point prepares the device for calibration.

9. When the text **Make Phantom measurement, return to cradle** is highlighted and the status says **waiting**, remove the device from the Scan Point docking station and place it into the recess in the calibration tank lid. Ensure that the tip of the scanhead is submerged in the water.



10. On the device, press the top button. The device begins to scan the calibration tank.

    Note: Do not remove the device from the calibration tank while scanning is in progress.

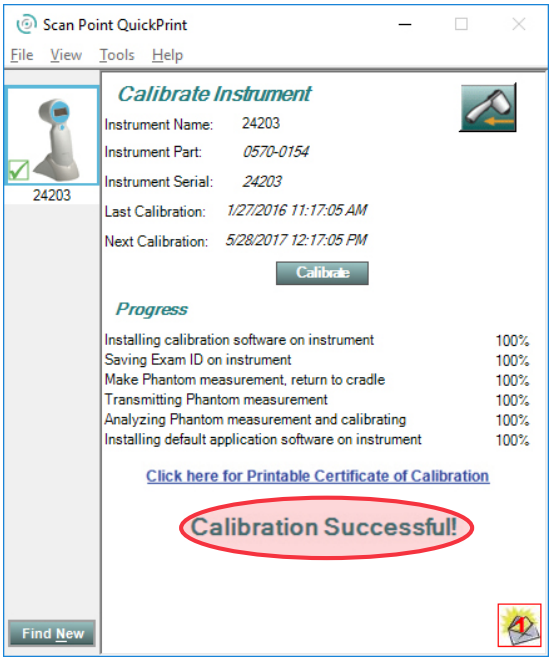
11. When the calibration scan is complete, four arrows appear on the display, and the device plays a melody.

12. Dry the device with a clean, soft cloth, and then return it to the Scan Point docking station. The device transmits the calibration results to Scan Point.

    Note: Do not remove the device from the Scan Point docking station while data is being transferred.

13. If the calibration scan was successful, Scan Point reinstalls the device software, and then the message "Calibration Successful" appears in Scan Point. You may remove the device from the Scan Point docking station.

    If the calibration scan was not successful, then you are prompted to rescan the calibration tank. Ensure that the tank has sufficient water and the target is properly positioned, and then repeat Step 9 through Step 12. After three unsuccessful calibration attempts, you will need to contact Verathon Customer Care in order to continue.



14. If you would like to print a certificate of calibration, in Scan Point, click the link **Click Here for Printable Certificate of Calibration**. The Calibration Report appears.

WARRANTY

Verathon products and software are warranted against defects in material and workmanship according to the Terms and Conditions of Sale. This limited warranty applies as long as it is covered by the Scan Point Total Reliability Plan. Warranty coverage applies to the following system components:

- BladderScan BVI 6400 device
- Scan Point docking station

Additional reusable components purchased either singularly or as a part of a system are warranted separately. Consumable items are not covered under this warranty.

For more information about your warranty or to purchase a Scan Point Total Reliability Plan that extends the limited warranty on your system, please contact Verathon Customer Care or your local representative.

DEVICE REPAIR OR REPLACEMENT

The device is built with a replaceable battery, however, the charging cradle and docking station are completely sealed. Verathon does not make available any type of circuit diagrams, component parts lists, descriptions, or other information that would be required for repairing the device and related accessories.

For additional information or to request service or repairs, contact Verathon Customer Care or your local representative. For contact information, please visit verathon.com/support.

BATTERY REPLACEMENT

This device is built with a replaceable battery.

Note: Older versions of the device may not have a battery door. If your device does not have a battery door, the battery is not replaceable.

Figure 2. Device with replaceable battery

If your battery no longer holds a charge, or requires frequent charging, you may order a battery replacement kit. Instructions for replacing the batteries are included in the replacement kit.

To order a battery replacement kit, or if you have any questions about battery replacement, please contact Verathon Customer Care or your local representative. For more information, please see verathon.com/support.

TROUBLESHOOTING

FREQUENTLY ASKED QUESTIONS

If you are encountering issues when operating your device, review this list of common questions. If you do not find a solution here, contact Verathon Customer Care or your local representative. For contact information, see verathon.com/support.

WHY WON'T MY DEVICE TURN ON?

This problem is usually caused by an unresponsive or discharged battery. Charge the device for a minimum of 6 hours. If the scrolling battery icon does not appear after 2 hours, complete the procedure Activate the Device (Optional). If the device still won't turn on, the battery may need to be replaced.

WHY WON'T MY DEVICE PERFORM A SCAN?

If the device does not perform a scan when you press the scan button, but the battery icon on the display indicates that the battery has some power remaining, one of the following conditions may apply:

- If the battery icon shows only one segment, then the battery power may be too low to perform a scan. See the procedure Charge the Device.
- If the display shows 000, you must calibrate the device before you can continue scanning. See Calibrating the Device.

WHY DID MY DEVICE BEEP?

Beeps indicate an alert or the completion of a normal function. The device may beep in the following situations:

- The device is turned on.
- The device goes into sleep mode in order to conserve battery power.
- The device completes a bladder volume or calibration measurement.
- The device has begun or finished transmitting data to Scan Point.
- The calibration procedure was successfully completed.
- The female gender option is selected or deselected.
- The battery power is low, and the battery requires recharging. In this case, the battery icon will show no power segments. See the procedure Charge the Device.
- The device requires calibration. See Calibrating the Device.

WHY IS THERE A FLASHING ARROW ON THE DISPLAY?

If a flashing aiming arrow appears on the display after a scan, the bladder was not fully within the ultrasound field of view. Adjust your aim in the direction indicated by the arrow, and then rescan the patient. Repeat this process until no flashing arrow appears. When the device is aimed properly, either a solid arrow or no arrow appears with the bladder volume measurement. For more information about the aiming arrows, see the procedure Measure Bladder Volume or the Scanning Tips section.

WHY IS THERE A SOLID ARROW ON THE DISPLAY?

A solid arrow indicates an aiming suggestion. The solid aiming arrow appears on the display when the bladder is not completely centered in the ultrasound field of view. In this case, the measurement is accurate and re-aiming is optional. For more information about the aiming arrows, see the procedure Measuring Bladder Volume or the Scanning Tips.

HELP RESOURCES

Verathon provides an extensive array of customer service resources, described in the table below.

You may obtain copies of this manual, quick reference cards, and clinical studies by visiting the Verathon Web site at verathon.com or by contacting your local representative. To obtain contact information, see verathon.com/support.

Table 7. Troubleshooting help resources

RESOURCE	DESCRIPTION
In-service CD	The CD included with your system provides instructions for using the device.
Clinical studies	Scientific papers on BladderScan use.
Scan Point Online	Scan Point Online provides customers: • The ability to calibrate and certify devices online anytime you wish. • Automatic data backup and archiving (HIPAA compliant). • Automatic software upgrades. • Access to real-time troubleshooting from Verathon.
Phone and Email support	Please refer to verathon.com/support for a list of phone numbers and locations. To request information on our products, or to schedule an on-site demo, please fill out the form found at verathon.com/contact-us

DEVICE DISPOSAL

The system and accessories may contain mineral oils, batteries, and other environmentally hazardous materials. When the device 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.

PRODUCT SPECIFICATIONS

COMPONENT SPECIFICATIONS

DEVICE SPECIFICATIONS

Table 8. BladderScan Device Specifications

GENERAL SPECIFICATIONS	
Bladder volume range:	0–999 mL
Accuracy:	The following accuracy specification assumes usage per instructions, scanning a Verathon tissue equivalent phantom: Bladder Volume: ± (15% + 15 mL) Example for a scanned volume of 160 mL: 160 mL × 15% = 24 mL 24 mL + 15 mL = 39 mL 160 mL ± 39 mL = **121–199 mL**
Scan time:	Less than 5 seconds
Voice annotation interval:	10 seconds
Weight:	Less than 11 oz (309 grams)
Power:	3.7 v lithium-ion rechargeable battery
Display:	Liquid crystal
Water resistance:	Rated at IPX1 (indicates drip-proof, a higher than ordinary level of protection from drips, leaks, and spills)
Expected product life	5 years
OPERATING & STORAGE SPECIFICATIONS	
Operating Conditions	
Temperature:	10°–40°C (50°–104°F)
Relative humidity:	30–75% non-condensing
Atmospheric pressure range:	70–106 kPa
Storage Conditions	
Storage:	Indoor
Ambient temperature range:	-10°–50°C (14°–122°F)
Atmospheric pressure range:	50–106 kPa
Relative humidity:	20–95% non-condensing

Table 9. Ultrasound Acoustic Output Parameters (IEC Standard)

INDEX LABEL			MI	TIS		TIB		TIC
				AT SURFACE	BELOW SURFACE	AT SURFACE	BELOW SURFACE	
Maximum index value			0.251	0.00142		—	—	—
Index component value				0.00142	0.00142	—	—	
Acoustic Parameters	$p_{r,\alpha}$ at Z_{MI}	(MPa)	0.470					
	P	(mW)		0.331		—	—	—
	$P_{1\times1}$	(mW)		0.0851		—	—	
	z_s	(cm)			2.60			
	z_b	(cm)					—	
	Z_{MI}	(cm)	2.60					
	$Z_{pii,\alpha}$	(cm)	2.60					
	f_{awf}	(MHz)	3.50	3.50		—	—	—
Other Information	prr	(Hz)	400					
	srr	(Hz)	5.56					
	n_{pps}	—	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	W/cm²	7.48					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	mW/cm²	0.0857					
	I_{spta} at z_{pii} or z_{sii}	mW/cm²	0.160					
	p_r at z_{pii}	(MPa)	0.644					

Table 10. Ultrasound Acoustic Output Parameters (FDA Standard)

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			0.268*	0.0977	8.06
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	0.501		
	W_o	(mW)		0.339	0.339
	f_c	(MHz)	3.54	3.54	3.54
	z_{sp}	(cm)	2.90		2.90
	Beam dimensions	x_{-6} (cm)			0.306
		y_{-6} (cm)			0.315
	PD	(μsec)	0.658		0.658
	PRF	(Hz)	400		400
	EDS	Az. (cm)		4.75	
		Ele. (cm)		4.75	
TIS/TIB/TIC range			0.0-1.0*		

* *Both MI and TI values are below 1.0.*

CHARGING CRADLE SPECIFICATIONS

The charging cradle is tested to applicable IEC 60601-1 requirements, but it is not intended for direct patient contact. It is designed to operate within the specifications and environmental conditions identified in the following table.

Table 11. Charging Cradle Specifications

GENERAL SPECIFICATIONS	
Input Voltage	90–264 VAC RMS
Input Frequency	47–63 Hz
Input Current	0.5 Amp max
Input Connection	Direct plug-in AC prongs for wall plug-in units
Output	5V at 2.4 Amps
Insulation	Class II with double insulation
Expected product life	5 years
STORAGE SPECIFICATIONS	
Storage	Indoor
Ambient Temperature Range	-10°–50°C (14°–122°F)
Atmospheric Pressure Range	50–106 kPa
Relative Humidity	30–75% non-condensing
Water Resistance	IPX0 (ordinary equipment without protection against ingress of water)

ELECTROMAGNETIC COMPATIBILITY

The system is designed to be in compliance with IEC 60601-1-2, 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 medical installation.

The 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 systems, see Essential Performance on page 1.

ELECTROMAGNETIC EMISSIONS

Table 12. Guidance and Manufacturer's Declaration—Electromagnetic Emissions

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

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
RF emissions CISPR 11	Group 1	The system uses RF energy only for 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 system is suitable for use in a professional healthcare environment.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

ELECTROMAGNETIC IMMUNITY

Table 13. Guidance and Manufacturer's Declaration—Electromagnetic Immunity

The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should ensure 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	± 8 kV contact ± 15 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	Not applicable	Mains power quality should be that of a typical hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not applicable	Mains power quality should be that of a typical hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T; 0.5 Cycle At 0˚, 45˚, 90˚, 135˚, 180˚, 225˚, 270˚ and 315˚ 0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single Phase: at 0˚	Not applicable	Mains power quality should be that of a typical hospital environment. If the user of the system requires continued operation during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply or a battery.
Rated power frequency magnetic fields IEC 61000-4-8	30 A/m	In compliance	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands 150 kHz to 80 MHz 80% AM at 1 kHz	Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of the 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 13. Guidance and Manufacturer's Declaration—Electromagnetic Immunity

The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should ensure 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 2.7 GHz 80% AM at 1 kHz	In compliance	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.

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 cords, components, and accessories specified or supplied by Verathon. For additional information, see the System Components & Accessories and Component Specifications sections. The use of accessories or cords other than those specified or supplied may result in increased emissions or decreased immunity of the system.

Table 14. EMC Standards for Accessories

ACCESSORY	MAX LENGTH
Scan Point docking station cable (USB cable)	2.2 m (7.2 ft)
Charging cradle (power cable from charging cradle to its power supply)	3.65 m (11.97 ft)

GLOSSARY

The following table provides definitions for specialized terms used in this manual or on the product itself. For a full list of caution, warning, and informational symbols used on this and other Verathon products, please refer to the *Verathon Symbol Directory* at verathon.com/symbols.

TERM	DEFINITION
C	Celsius
cm	Centimeter
CSA	Canadian Standards Association
EMC	Electromagnetic compatibility
EMI	Electromagnetic interference
Essential performance	The system performance necessary to achieve freedom from unacceptable risk
ESD	Electrostatic discharge
f_{awf}	Acoustic working frequency (definition 3.4, IEC 62359:2010)
GHz	Gigahertz
HIPAA	Health Insurance Portability and Accountability Act
Hz	Hertz
IEC	International Electrotechnical Commission
Ultrasound field of view	Cone-shaped area in which the scanhead transmits ultrasound waves
in	Inch
IP	Ingress Protection
I_{sppa}	Spatial-peak, pulse-average intensity
I_{spta}	Spatial-peak, temporal-average intensity
kHz	Kilohertz
LCD	Liquid crystal display
m	Meter
MHz	Megahertz
MI	Mechanical index
MPa	Megapascal
mW	Milliwatt
RF	Radio frequency
RMS	Root mean square
TIB	Bone thermal index (definition 3.17, IEC 62359:2010)
TIC	Cranial bone thermal index (definition 3.21, IEC 62359:2010)
TIS	Soft tissue thermal index (definition 3.52, IEC 62359:2010)
UL	Underwriters Laboratories
V	Volt
VAC	Volt alternating current
W	Watt
WEEE	Waste electrical and electronic equipment

VERATHON®