
BladderScan® Bladder Volume Instruments

User's Manual

For:

BladderScan BVI 6100 Bladder Volume Instrument

BladderScan BVI 6400 Bladder Volume Instrument

CAUTION: In the United States, federal law restricts this device to use by or on the order of a physician.

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The BladderScan® technology described in this manual is protected by U.S. Patent Numbers 5,235,985, 6,676,605 and 6,884,217. The ScanPoint® technology described in this manual is protected by U.S. Patent Number 6,569,097. Other patents pending.

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Statement from the CEO

The team at Verathon® is committed to improving health care delivery by putting healthcare providers and their patients first.

Our products support you, the health care provider, by consistently offering accuracy, utility, reliability and excellence.

Please contact us directly at 1.800.331.2313 (USA and Canada only) or 1.425.867.1348, if we can improve our service to you.

Sincerely,

Gerald McMorrow

Gerald McMorrow, CEO and Founder

Important Information

Product Description

BladderScan® BVI 6000 series bladder volume instruments are wireless, battery-powered, ultrasound instruments that provide a noninvasive measurement of urinary bladder volume.

During each scan, BladderScan instruments employ patented V_{MODE}® technology to create a three-dimensional image of the bladder. BladderScan instruments automatically calculate and display measurements based upon this image. V_{MODE} 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 ScanPoint with QuickPrint software via a proprietary wireless connection. ScanPoint with QuickPrint allows the user to archive data, calibrate the device, update software, print, and transfer data through a Web-based interface.

Intended Use Warnings and Cautions

- ♦ All users must read this entire *User's Manual* prior to using the BladderScan instrument. Do not attempt to operate this instrument 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. For the most current version of the *User's Manual*, please visit the Verathon® Web site at verathon.com.

- ♦ BladderScan instruments should be used only by individuals who have been trained and authorized by a physician or the institution providing patient care.

Biological Safety

To date, exposure to pulsed diagnostic ultrasound has not been shown to produce adverse effects. However, ultrasound should be used only by medical professionals when clinically indicated, using the lowest possible exposure times indicated by clinical need.

The ultrasound output power of BladderScan BVI 6000 series instruments is not user adjustable and is limited to the minimum level necessary for effective performance. Data on acoustic output levels can be found in *Product Specifications* beginning on page 40 of this manual.

Statement of Prescription

United States federal law restricts BladderScan BVI 6000 series instruments to use by, or on the order of, a physician. This statement is required per 21 Code of Federal Regulations (CFR) 801.109.

NOTE: It is standard practice to have medical staff authorize the use of a BladderScan instrument within its intended use throughout an institution. Individual prescriptions for use are not required.

Statement of Intended Use

BladderScan® bladder volume instruments project ultrasound energy through the lower abdomen of the patient to obtain an image of the bladder which is used to noninvasively measure urinary bladder volume.

Contraindications

BladderScan instruments are not intended for fetal use or for use on pregnant patients.

Cautions and Warnings

To assure safe and reliable operation for the use and the patient, please read and heed the following warnings and cautions.

WARNING! Risk of explosion.

If you use the BladderScan instrument in the presence of flammable anesthetics, the hazard of potential explosion exists.

WARNING! Risk of explosion, fire, or serious injury.

The BladderScan BVI 6100/6400 is provided with an internal lithium-ion battery. Never short circuit the battery by either accidentally or intentionally bringing the battery terminals into contact with any other conductive object. This could cause serious injury or fire and could also damage the battery and the BladderScan device.

Never expose the battery to abnormal shock, vibration, or pressure. The battery's internal protective covering could fail, causing it to overheat or ignite, resulting in caustic liquid leakage, or explosion or fire, possibly resulting in serious injury.

WARNING! Potential patient hazard.

To date, exposure to low-power, pulsed diagnostic ultrasound has not been shown to produce adverse effects. However, medical professionals should use ultrasound only when clinically indicated, using the lowest exposure times possible to obtain accurate measurements. The ultrasonic output of the BladderScan instrument is not user-adjustable and is limited to the minimum level necessary for effective performance. For more information about the acoustic output levels of this device, please refer to *BladderScan Instrument Specifications* beginning on page 42 of this manual.

CAUTION: Items Affecting Accuracy of Results.

When using the BladderScan BVI 6100/6400 be aware of the following conditions which can affect ultrasound transmission and decrease the accuracy of exam results.

- ♦ Use care when scanning patients who have had supra-pubic or pelvic surgery. Scar tissue, surgical incisions, sutures, and staples can affect ultrasound transmission and accuracy.
- ♦ Do not use the BVI 6100/6400 on patients with open skin or wounds in the suprapubic region.
- ♦ Do not use the BVI 6100/6400 on patients with ascites.
- ♦ If you scan a patient with a catheter in his/her bladder, the catheter may affect measurement accuracy. However, the information obtained from the measurement could still be clinically useful for detecting problems such as a blocked catheter.

CAUTION: Observe the following precautions in the safe use and care of the BladderScan® instrument.

Hazardous materials present. Assure proper disposal.

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

Assure proper computer system configuration.

When using the BladderScan instrument with optional ScanPoint® image management technology, your computer must be minimally certified to EN / IEC / CSA / UL 60950 or 60101-1 standards. This configuration ensures that compliance to the EN/IEC 60601-1-1 system standard is maintained. Anyone connecting additional equipment to the BladderScan instrument signal input port or signal output port configures a medical system, and is therefore responsible for ensuring that the system complies with EN/IEC 60601-1-1. If you need assistance, contact your biomedical staff, Verathon Medical representative, or the Verathon Medical Customer Care Department at 1.800.331.2313.

Assure proper distance from patient.

The BladderScan instrument, accessories, and computer used to access online ScanPoint image archive (if needed) must be placed outside the patient vicinity (more than six feet (2 meters) from the patient). Refer to UL 2601-1 Clause 2 deviation for the definition of patient vicinity.

CAUTION: Risk of Fire and Burns. Regarding the battery, do not disassemble, heat above 60° C (140° F), or incinerate. 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.

Introducing the BladderScan Bladder Volume Instruments

Product Description

The BladderScan® BVI 6100/6400 are portable ultrasound instruments that measure bladder volume. Using patented V_{MODE}® technology, BladderScan BVI 6000 series instruments provide a noninvasive measurement of urinary bladder volume.

The BVI 6100/6400 consists of an ergonomic, battery-powered, handheld probe that scans the patient's bladder. The LCD display provides aiming assistance and displays an array of bladder measurement information.

BladderScan instruments are quick, accurate, reliable, and easy to use. When the user releases the scan button, within seconds, the BladderScan instrument measures ultrasonic reflections on multiple planes inside the body and produces a three-dimensional image. Based on this image, the BladderScan instrument calculates and displays the bladder volume. A sonographer is not required.

Volume measurements made with V_{MODE} ultrasound are more accurate than those from conventional ultrasound, as they are based on a more complex, 3D image of the bladder.

The BladderScan BVI 6400 includes an integrated microphone for recording voice annotations. Voice annotation allows up to 10 exams to be stored on the instrument.

BladderScan Bladder Volume Instruments



BladderScan BVI 6100

PN: 0570-0154

The handheld, portable BladderScan® BVI 6100:

- ♦ Measures bladder volume noninvasively.
- ♦ Provides fast, accurate and reliable results.
- ♦ 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.
- ♦ Allows for exam results and images to be downloaded, viewed and printed using the optional ScanPoint® image management technology.
- ♦ Is battery-operated, lightweight, and portable.



BladderScan BVI 6400

PN: 0570-0167

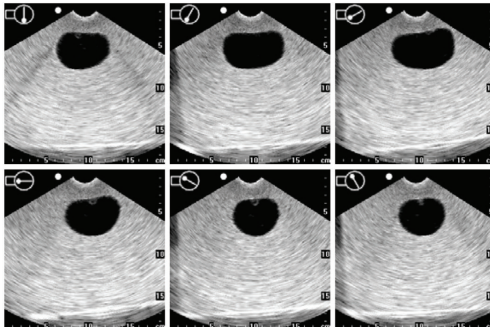
The handheld, portable BladderScan BVI 6400:

- ♦ Measures bladder volume noninvasively.
- ♦ Provides fast, accurate, and reliable results.
- ♦ 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 ScanPoint technology.
- ♦ Is battery-operated and easy to use.

Optional ScanPoint Image Management Technology

Bladder volume measurements and ultrasound images may be transmitted from your device to ScanPoint® image management software. ScanPoint software 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. Figure 1 shows an example of a ScanPoint report.

Figure 1. BladderScan Report for a Physician's Office

BladderScan® Report for Physician's Office			
My Hospital			
Patient Name:	Sam Ple	Upload Date:	Urine Volume: 123 ml
Patient ID:	Sample	08/04/2006	
Chief Complaint:			
<input type="checkbox"/> Urgency	<input type="checkbox"/> Frequency	<input type="checkbox"/> Male	<input type="checkbox"/> Female
<input type="checkbox"/> Dysuria	<input type="checkbox"/> Nocturia	<input type="checkbox"/> Dribbling	<input type="checkbox"/> Urinary Tract Infection
<input type="checkbox"/> Hesitancy	<input type="checkbox"/> Other	<input type="checkbox"/> Slow Stream	<input type="checkbox"/> Urinary Incontinence
Medical History:			
<input type="checkbox"/> History of Urinary Retention		<input type="checkbox"/> Suprapubic Pain or Discomfort	
<input type="checkbox"/> Neurologic Disease			
<input type="checkbox"/> Other:			
Findings:			
<input type="checkbox"/> Urine Volume WNL		<input type="checkbox"/> Elevated Volume	<input type="checkbox"/> Bladder Wall Thickness (Abnormal / Normal)
<input type="checkbox"/> Diverticula (YES / NO)		<input type="checkbox"/> Stones (YES / NO)	
<input type="checkbox"/> Other:			
Impressions:			
<input type="checkbox"/> Urinary Retention		<input type="checkbox"/> Incomplete Bladder Emptying	
<input type="checkbox"/> Other:			
<div style="display: flex; align-items: center;"> <div style="background-color: #008080; color: white; padding: 5px; margin-right: 10px;">CAUTION:</div>  </div>			
Operator:	User	Physician Signature: _____	
Physician:	Doctor		

ScanPoint can also be used to calibrate your BladderScan instrument. The ScanPoint image management technology (ScanPoint software, license, and accessories) is available with the purchase of any BladderScan instrument. Comprehensive service and warranty are provided under the ScanPoint Total ReliabilitySM Plan. For details, please contact your local Verathon Medical representative at 1.800.331.2313.

- ♦ **ScanPoint® Local Client (LC)** is a stand-alone, non-networked version of the software. It is available for use with the BVI 6100, BVI 6400, BVI 9400, and FloPoint® Elite products.
- ♦ **ScanPoint 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. ScanPoint 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.

ScanPoint with QuickPrint is available for use with Verathon BladderScan® BVI 6000 series, BVI 9000 series, and FloPoint Elite products.



Getting Started

To get up and running as quickly as possible, follow this sequence:

- ♦ Unpack the BladderScan® instrument and related accessories.
- ♦ Charge the device in the Charging Cradle. (Instructions begin on page 19)
- ♦ Install optional items as desired (ScanPoint® software and ScanPoint Label Writer)

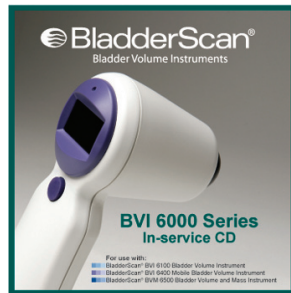
Unpack the Box and Check the Components

Set the shipping container right side up and carefully open the top flaps (do not insert anything sharp through the top of the box). Remove the contents and verify that you have received everything listed below. If anything is missing or damaged, notify your authorized Verathon Medical representative or the Verathon Medical Customer Care Department at 1.800.331.2313.

Part and Part Number	Name and Description
	BladderScan BVI 6100 or BVI 6400: Handheld, wireless, battery-operated, ultrasound bladder volume instrument.
0570-0154 (BVI 6100) 0570-0167 (BVI 6400)	
	Charging Cradle: Use the Charging Cradle to charge the BladderScan instrument's internal battery. The Charging Cradle plugs directly into an electrical wall outlet. Before using your BladderScan device you must charge it for a minimum of six hours.
0270-0234	

Part and Part Number

Name and Description



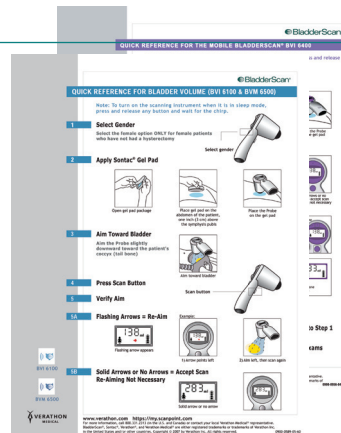
BladderScan BVI 6000 Series In-Service CD:
Includes the electronic version of the BladderScan® User's Manual (this manual), Quick Reference Cards, and the ScanPoint® User's Manual.

0900-0813

**Activation Tool:**

Use to press the Activation button on the instrument if needed.

0130-0181

**BladderScan Bladder Volume Instruments****Quick Reference Cards:**

Provide a summary of essential user instructions.

0900-0589 (BVI 6100)

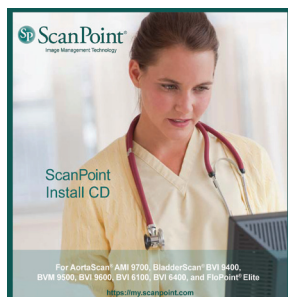
0900-0956 (BVI 6400)

Optional Accessories

The following optional items are available to enhance the capabilities of your BladderScan® instrument. Please contact your Verathon Medical Customer Care Representative (1.800.331.2313) for more information on any of the following Verathon® products.

Part and Part Number

Name and Description



0900-1238

ScanPoint® with QuickPrint Install CD:

Installs ScanPoint with QuickPrint imaging software. Allows viewing, printing, and archiving of patient exam results with a Windows®-based computer. Archived patient data is stored securely on HIPAA-compliant, Verathon-maintained servers. Users can access records from any Internet-enabled Windows®-based PC. ScanPoint 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. ScanPoint with QuickPrint works with all BladderScan 6000 series, 9000 series, and FloPoint® Elite devices.



0570-0168

ScanPoint Docking Station:

(Optional - used with ScanPoint Bladder image management technology). Transmits data from the BladderScan device to the ScanPoint host computer and simultaneously recharges the device battery.



0620-0225

Calibration Kit (Requires ScanPoint with QuickPrint software)

The calibration container holds a spiral-shaped calibration target and 4.2 liters of water. The top has an indentation for the instrument that places it in a known and repeatable location with respect to the spiral target. Self-calibration takes about 15 minutes.



0800-0005

Sontac® Ultrasound Gel

Provides the optimal coupling medium. Performance of the BVI 6000 series instruments has been optimized for use with Sontac Ultrasound Gel. The use of any other coupling gel or medium may compromise the accuracy of readings.

BladderScan Controls and Features

The BladderScan® instrument controls and features are illustrated in Figure 2 and explained in Table 1.

Figure 2. BladderScan Probe Instrument Parts











Table 1. BladderScan Controls and Features

Part Name	Purpose
SCAN button	Press to take a scan.
Probe	The Probe transmits and receives ultrasound waves automatically moving its internal transducer 360° to scan twelve different planes to produce a three-dimensional image of the bladder.
TOP button	Press to select gender.
ACTIVATION button	Press to reactivate the BladderScan instrument if the battery becomes completely discharged.

Part Name	Purpose
LCD Screen	Displays bladder volume measurements and other scan, patient, and instrument data.
Infrared (IR) Window	Enables the BladderScan® instrument to communicate with a ScanPoint®-equipped PC via the Docking Station.
Microphone	Speak into the microphone to record voice annotations (found on BVI 6400 only).

Table 2. Display Icons

Symbol	Meaning
	Battery power level. Please refer to the table on page 19 for a completely description of battery power icons.
	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 instrument steady.
	Flashing arrow indicates that the aim was “off target.” In order to get an accurate bladder volume measurement, you must re-aim the Probe in the direction of the arrow.
	A solid arrow indicates that the bladder was not centered within the scanning cone. However, the bladder volume measurement is still accurate. Re-aiming is optional.
	The patient’s actual bladder size is larger than the scanning cone.
	(BVI 6400 only.) Indicates that a voice annotation is being recorded and stored.
	Indicates the number of days remaining until the next required calibration.

Charging the BladderScan Instrument

Before using your BladderScan® instrument for the first time, and subsequently if the BladderScan instrument becomes completely discharged, you must charge your BladderScan instrument battery for approximately six hours, or until it is fully charged.

To charge the bladder volume instrument:

1. Plug the Charging Cradle into an electrical wall outlet.
2. Place the BladderScan instrument in the Charging Cradle.







The battery icon will begin scrolling, indicating that the instrument is charging. If the battery icon does not appear, then your bladder volume instrument was completely discharged and may need to charge for up to six hours. The battery icon will appear when the bladder volume instrument is charged sufficiently for operation.

NOTE: Alternatively, you can charge the BladderScan instrument in the Docking Station if you have already installed ScanPoint® on your computer, and installed the Docking Station using the Windows® New Hardware Install Wizard.

Battery Power Status Icons

The battery icon is located in the lower-right corner of the bladder volume instrument display and indicates the power level of the battery. You can recharge the bladder volume instrument whenever you like but you must recharge the bladder volume instrument when the power status icon shows only one segment. While charging, the battery icon displays scrolling power segments. The following table provides more information about battery status icons.

Table 3. Battery Status Icons

Battery Icon	Description
	Battery is fully charged and ready for use.
	Battery is 50 - 75% charged.
	Battery power is 25 - 50% charged.
	Battery is nearly discharged. There is enough power for few scans. Recharge the battery as soon as possible.
	The battery is completely discharged. The bladder volume instrument will not work until it is recharged.
	Scrolling segments indicate that the battery is being recharged.

Battery Charging Notes

You may need to reactivate your BladderScan® instrument before charging the battery.

- ♦ If your BladderScan instrument battery is completely discharged.
- ♦ If the “scrolling segments” battery icon does not appear after the BladderScan instrument has been in the cradle for two hours.

To reactivate your BladderScan instrument:

1. Use the tip of the activation tool to press the **ACTIVATION** button. The **ACTIVATION** button is located just above the **SCAN** button (Figure 2).
2. Place the BladderScan instrument in the Charging Cradle or Docking Station until the “full battery” icon is displayed.

NOTE: When you are not using your bladder volume instrument, Verathon recommends that you store it in the Charging Cradle to ensure that your instrument is always sufficiently charged.

The Charging Cradle cannot overcharge the battery.

Installing ScanPoint Image Management Technology

If desired, install ScanPoint® Bladder Image Management Technology,

Please consult your ScanPoint User’s Manual for complete instructions for installation and use of ScanPoint Image Management Technology.

The ScanPoint User’s Manual also includes instructions for setting up and installing the ScanPoint Label Writer.

Measuring Bladder Volume

Preparing for the Exam

Before You Begin the Exam:

- ♦ Make sure you are familiar with the parts of the BladderScan® instrument (see *Introducing the BladderScan Instrument* on page 10).
- ♦ If you are a new BladderScan instrument user, Verathon® recommends that you perform your first exam on a patient with a moderately full bladder, rather than initially attempting to locate and scan a nearly empty bladder.
- ♦ Check the instrument's battery icon to make sure the battery has sufficient power.

NOTE: If the battery icon shows only one segment, fully charge the BladderScan instrument before use.

- ♦ Clean and disinfect the Probe by wiping it gently with a soft cloth soaked in isopropyl alcohol.

Be aware of the following conditions the patient may have that could affect ultrasound transmission and the accuracy of your exam:

- ♦ **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).
- ♦ **Previous suprapubic or pelvic surgery.** Scar tissue, surgical incisions, sutures, and staples can affect ultrasound transmission and reflection.

Do not use the BladderScan instrument on:

- ♦ Patients with ascites.
- ♦ Patients with open skin or wounds in the suprapubic region.
- ♦ Pediatric patients (patients under 60 lbs and under 48" tall).
- ♦ Pregnant patients.

Measuring Bladder Volume

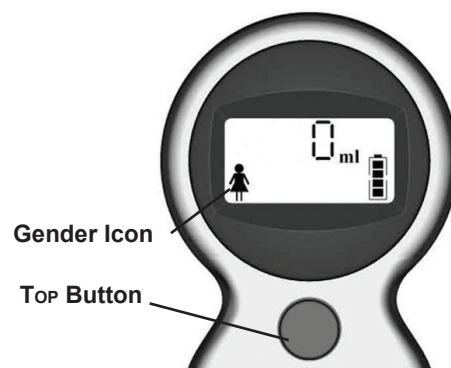
1. Turn on the bladder volume instrument.

If the BladderScan® instrument has been stored in a Charging Cradle or Docking Station, the power comes on automatically when you remove the bladder volume instrument from the cradle.

If the bladder volume instrument has not been stored in the Charging Cradle or Docking Station, it will go into sleep mode to conserve power. If the bladder volume instrument is in sleep mode, press and release any button to turn the power on.

2. Select the patient's gender.

If your patient is a female who has not had a hysterectomy, press the TOP button located below the display. For all other patients, (male or female), press the TOP button again to clear the gender icon from the Console display.



3. With the patient supine, apply gel.

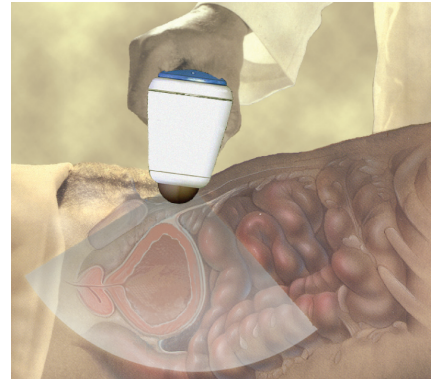
Have the patient lie in the supine position with the abdominal muscles relaxed.

Palpate the patient's symphysis pubis (pubic bone). Place an ample quantity of gel (with as few air bubbles as possible) midline on the patient's abdomen, approximately one inch (3 cm) above the symphysis pubis (pubic bone). Make sure that there are as few air bubbles as possible.



4. Aim toward the bladder.

Standing at the patient's right side, place the Probe on the gel and aim it toward the expected location of the bladder. For most patients, this means angling the Probe slightly toward the patient's coccyx (tail bone) so the scan clears the pubic bone.

**5. Press and release the SCAN button.**

Press and release the SCAN button, located on the underside of the Probe.

A scanning symbol appears in the upper right corner of the LCD screen during the scan:



Hold the Probe steady until the scan is finished. When you hear the end-scan tone, the scan is complete.

After a scan, the bladder volume measurement in milliliters (ml) is displayed in the top half of the screen.



SCAN button

NOTE: To assure the highest degree of accuracy, Verathon® recommends that you scan the patient's bladder at least three times per exam, 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.

6. Verify the scan.

Flashing arrow: If the scan is "off-target," that is, if the bladder was not enclosed within the scanning cone, the display will show a flashing arrow. In this case, you must re-aim the Probe in the direction indicated by the arrow and perform the scan again.



Solid arrow: A solid arrow indicates that the bladder was mostly inside the scanning cone. The results are satisfactory but re-aiming in the direction of the arrow and re-scanning would be advisable to assure accuracy.



No arrow: Indicates that the bladder was completely contained within the scanning cone. The measurement is accurate.



7. Record a Voice Annotation (BVI 6400 only)

After performing an exam, you can record additional information about a patient to be stored with the exam results.

The instrument can store up to ten scans with voice annotations, so you can perform multiple exams on your rounds. If you are using the optional ScanPoint® software, you can upload saved exams to your PC or electronic health record (EHR) system.

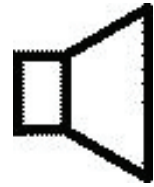
To record a voice annotation:

- Press and hold the TOP (Gender) button until you hear a tone (approximately 3 seconds).
- To record your annotation, continue to hold the TOP button and speak into the microphone (directly above the display) Hold the microphone approximately 6 inches (15 cm) from your mouth and speak clearly.

Be sure to include all relevant exam information, including the patient's name and the name of the person performing the exam. You have 10 seconds to record information.

- When you have finished recording, release the TOP button and listen to your annotation play back. If desired, re-record your annotation.

- d. If you are satisfied with the annotation, do not press any buttons. After several seconds, the BVI 6400 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. You may now begin a new patient exam, if desired.



NOTE: The BVI 6400 will retain at least 10 voice-annotated exams. When the device is full, the message FULL is displayed on the LCD screen. To clear the memory, you may transfer all the voice-annotated exams to ScanPoint®.

IMPORTANT!

- ♦ If you do not record a voice annotation for a particular exam, that exam will be lost and the next exam you perform will overwrite the non-annotated one.
- ♦ If the instrument battery runs low or the instrument goes into sleep mode, any non-annotated exam data is lost. However, the instrument does not erase any annotated exam results when it goes into sleep mode. To make sure you do not lose any patient data, it is a good idea to add a voice annotation to every patient exam.
- ♦ You can make a new recording only if the instrument still displays the bladder volume for that particular exam.

8. Record, review, and print exam results.

If you are using the BVI 6100:

If desired, manually record the bladder volume measurement, because the measurement will be erased when you begin a new exam.

Optionally, you may also choose to view, save, and print exam results using ScanPoint Image Management Technology. Please consult your ScanPoint User's Manual for more information.

IMPORTANT: If you do not return the Probe to the Charging Cradle or Docking Station within 20 minutes of completing the exam, the Probe will go into sleep mode to conserve battery power and bladder imaging data will be erased. To avoid loss of data, promptly download results to ScanPoint, or record a voice annotation (BVI 6400 only).

9. Finish the exam.

Once you have completed the scan, wipe the ultrasound gel off the patient and the Probe.

Additional Scanning Tips

- ♦ **IMPORTANT: Hold the BladderScan® instrument 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
 - Overly obese patients:











With obese patients, lift as much abdominal adipose tissue out of the way of the instrument as possible. Apply more pressure to the BladderScan instrument to reduce the amount of adipose tissue through which the ultrasound must pass.

- ♦ To assure accurate results, make sure that:
 - There are no air gaps between the Probe and the patient's skin.
 - There are no air bubbles in the ultrasound gel.
 - You are **holding the instrument 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).



Table 4 illustrates typical scanning scenarios and corresponding bladder volume information that may appear on the Probe display.

Table 4. Typical Scanning Scenarios and Displays

Scanning Scenario	Example Display	Description
Optimal Scan 		<p>In an optimal scan, the bladder is entirely contained within the scanning cone. The display shows:</p> <p>Bladder volume.</p> <p>No > symbol.</p> <p>No flashing arrow.</p> <p>No solid arrow.</p>
Bladder volume is greater than 999 ml. 		<p>The bladder is entirely contained within the scanning cone but the bladder volume is greater than 999 ml. In this case, the display shows:</p> <p>A bladder volume of >999 ml.</p> <p>No flashing arrow.</p> <p>No solid arrow.</p>
Bladder is too large to be fully contained within the scan cone. 		<p>Either the bladder is too large to be contained by the ultrasound cone, or the user is pressing too hard with the Probe. The display shows:</p> <p>Bladder volume with a > symbol.</p> <p>No flashing arrow.</p> <p>No solid arrow.</p> <p>Apply less pressure and rescan.</p>
Bladder not centered (Optional re-scan) 		<p>The bladder is partially contained within scan cone. Re-scanning is optional. The display shows:</p> <p>Bladder volume.</p> <p>A solid arrow indicating re-aiming direction for optional re-scan. Move Probe in the direction of the arrow and re-scan.</p>
Bladder not centered Re-scan required. 		<p>Bladder is only partially contained within the scan cone. A re-scan is necessary to assure accurate bladder volume measurement. The display shows:</p> <p>Bladder volume.</p> <p>A flashing arrow indicating re-aiming direction. Move Probe in the direction of the arrow and re-scan.</p>

Cleaning and Maintenance

Cleaning and Disinfecting the BVI 6100/BVI 6400

To Clean and Disinfect the Instrument:

1. Use a germicidal wipe or soft cloth dampened with isopropyl alcohol (or an appropriate hospital cleaning agent) to wipe the Probe until it is thoroughly cleaned.
2. If you use a detergent solution to clean the instrument, remove all residual detergent. Dry the instrument with a clean, soft cloth.
3. If the instrument needs to be disinfected, dampen a soft cloth in any glutaraldehyde-based hospital disinfectant solution such as Cidex® or Cidex 7® from Advanced Sterilization Products, or Sporocidin® from Sporocidin International. Wipe the instrument with a dampened cloth.
4. To remove all traces of disinfectant solution, wipe the instrument with a clean soft cloth dampened in sterile water or cleaning solution. Verathon® recommends wiping the device three separate times to remove all residual disinfectant.
5. Thoroughly dry the instrument with a clean, soft cloth before using.

IMPORTANT! Failure to heed the following warnings may cause device damage not covered by the BladderScan® warranty.

- ♦ Do not immerse the instrument in disinfectant solution.
- ♦ Do not use CidexPlus® to disinfect the instrument. CidexPlus® will damage the plastic enclosure.
- ♦ Do not subject any part of the instrument to steam sterilization or ethylene oxide sterilization.

Regular Inspections and Maintenance

Once a week, you should inspect the instrument for physical faults or cracks. Cracks that allow the ingress of fluid may affect the performance of the instrument. Any apparent cracks or faults in the instrument must be referred to your authorized BladderScan Service Center, your local BladderScan distributor, your local Verathon Medical representative, or the Verathon Medical Customer Care Department.

IMPORTANT! If you see any physical faults or cracks in the instrument, discontinue use immediately and contact your local Verathon Medical representative or the Verathon Medical Customer Care Department at 1.800.331.2313.

Calibrating the BladderScan Instrument

You must periodically calibrate your BladderScan® instrument to make sure that it is providing accurate results. Calibrating ensures accurate and proper alignment of the instrument's internal coordinate system. If you do not perform the calibration by the prescribed date, the instrument can still be used to take scans but measurement accuracy may be compromised.

At a minimum, Verathon® requires that you calibrate the instrument every 6 - 12 months, depending on your Total Reliability PlanSM. Calibrating your bladder volume instrument on a regular basis ensures the accuracy of bladder imaging.

If you are using ScanPoint® and if your BladderScan instrument is within 20 days of a required calibration, the Calibration Warning dialog box will appear when you start ScanPoint. Please take prompt action to ensure that your device continues to function properly and accurately.

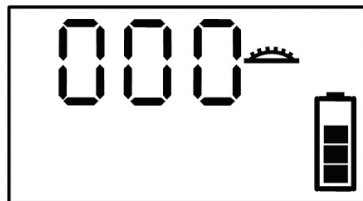
If you are not using ScanPoint with QuickPrint, you must send your instrument in to an authorized Verathon service center for calibration. Contact your Verathon Medical Customer Care Center for more information. For contact information, please see *Contacting Verathon* on page 36.

If you are using ScanPoint with QuickPrint, you can easily and quickly calibrate your own instrument. Please consult your ScanPoint User's Manual for complete instructions.

Displaying the Days Remaining Until Calibration

Your BladderScan instrument tracks the number of days remaining until calibration is necessary. When zero days remain, the instrument is disabled, and you will have to calibrate the instrument before using it again. You will know your instrument is disabled when "000" and the "setting sun" symbol appear on the instrument display (Figure 3).

Figure 3. Calibration Required Display



To display the number of days remaining until calibration:

1. Remove the instrument from the Charging Cradle or Docking Station.
2. Press and hold down the TOP (Gender) button, located on the back of the Probe's handgrip, below the display for five seconds. The number of days remaining until the next required calibration will be displayed.

Device Repair and/or Replacement

The BladderScan® instrument, Battery Charger, and Docking Station are completely sealed, except for some units that feature a replaceable battery, described below. 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.

ScanPoint® Total ReliabilitySM Plan customers have access to loaner units while their instruments are under repair and free shipping options which vary according to plan.

If you have any questions, contact your local Verathon Medical representative or the Verathon Medical Customer Care Department at 1.800.331.2313.

Battery Replacement

Some BladderScan BVI 6000 series instruments were built or refurbished to accommodate a replaceable battery. These units can be identified by the battery replacement door on the handle (Figure 4).

Figure 4. BVI 6000 series instrument with replaceable battery



If your BladderScan instrument battery no longer holds a charge, or if the BladderScan instrument requires frequent charging, a battery replacement kit may be ordered.

- ♦ BladderScan BVI 6000 Li-ion battery replacement kit: **P/N 0270-0435**

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 the Verathon Medical Customer Care Department at 1.800.331.2313.

Unit Disposal

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

Troubleshooting

Help Resources

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

You can obtain copies of this manual, Quick Reference Cards, and clinical studies by visiting the Verathon Web site at verathon.com or by contacting your Verathon Medical representative. A complete listing of contact information is provided on page 36.

Table 5. Troubleshooting Help Resources

Resource	Description
BladderScan® Bladder Volume Instruments In-Service CD	CD included with your device containing User's Manual and Quick Reference Cards.
BladderScan Quick Reference Cards	Summary of procedures for using the BladderScan devices.
Clinical Studies	Scientific papers on BladderScan use available on the Verathon Web site (verathon.com).
ScanPoint® Online	ScanPoint Online provides customers: <ul style="list-style-type: none"> ♦ 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.
ScanPoint Total Reliability SM Plan	A Verathon device warranty plan that provides: <ul style="list-style-type: none"> ♦ All repairs performed free of charge. ♦ Instrument insurance: A warranty against outdated technology with free upgrade / replacement when your device is no longer manufactured. ♦ Free loaner program. ♦ Free shipping.
Verathon Web site	For additional information and in-service training resources, visit bladderscan.com .
Phone support	In North America, call: 1.800.331.2313. International customers, please visit verathon.com and select "Contact Us."

Common Problems

If you are having problems operating your BladderScan® device, review this list of common issues. If you do not find a solution here, contact your authorized BladderScan service center, your local BladderScan distributor or Verathon Medical . In North America, call: 1.800.331.2313. International customers, please refer to “Contact Us” at verathon.com.

Table 6. Common Problems and Solutions

Problem	Meaning
The bladder volume instrument does not turn on.	This problem is usually caused by an unresponsive or discharged battery. Charge the bladder volume instrument for a minimum of six hours. If the scrolling battery icon does not appear after two hours, you will need to activate the bladder volume instrument by pressing the activation button with the Activation Tool. Once activated, place the instrument in the Charging Cradle to continue charging. For more information about charging the battery and activating the instrument, see <i>Charging the BladderScan Instrument</i> on page 19.
The bladder volume instrument is charged but will not scan.	<p>If the bladder volume instrument does not measure bladder volume when you press the SCAN button, but the battery icon on the instrument display indicates that the battery has some power remaining, one of the following conditions may apply:</p> <ul style="list-style-type: none"> ♦ Battery power is too low to perform bladder imaging. In this case, the battery icon will show only one segment. Place the instrument in the Charging Cradle to recharge the battery. (see <i>Charging the BladderScan Instrument</i> on page 19.) ♦ The bladder volume instrument requires calibration. If the display shows “000” as the number of days remaining until calibration, you must calibrate the device before you can continue to perform bladder volume measurements. Please refer to <i>Calibrating the BladderScan Instrument</i> on page 29 for more information.

Problem	Meaning
The bladder volume instrument beeps	<p>The instrument may beep in the following situations. These beeps indicate an alert or completion of a normal instrument function.</p> <ul style="list-style-type: none"> ♦ You turn on the bladder volume instrument. ♦ The device goes into sleep mode to conserve battery power. ♦ The battery power is low, and the battery requires recharging. In this case, the battery icon will show no power segments. Place the instrument in the Charging Cradle or Docking Station to recharge the battery. ♦ You need to calibrate the instrument. Please refer to <i>Calibrating the BladderScan® Instrument</i> on page 29 for more information. ♦ The instrument performs and completes a bladder volume or calibration measurement. ♦ The instrument has begun or finished transmitting data to ScanPoint®. ♦ The calibration procedure was successfully completed. ♦ You select or deselect the female option.
Flashing aiming arrows appear on the LCD display	<p>If flashing aiming arrows appear on the instrument display after a scan, the bladder was not fully within the image cone. Re-adjust your aim in the direction indicated by the arrow and re-scan the patient. Repeat this process until no flashing arrows appear. When the instrument is aimed properly, either a solid arrow or no arrow appears with the bladder volume measurement. For more information about using the aiming arrows, see <i>Measuring Bladder Volume</i> beginning on page 22.</p>
A solid arrow appears on the LCD display	<p>A solid arrow indicates an aiming suggestion. The solid aiming arrow appears on the instrument's LCD display when the bladder is not completely centered in the scanning cone. In this case, the measurement is accurate and re-aiming is optional.</p>
A (>) symbol appears before the bladder volume measurement	<p>If a "greater than" symbol (>) appears before the bladder volume measurement, then the bladder is too large to be fully contained within the image cone. In such cases, the true volume is greater than the measurement displayed and re-aiming the instrument will not help. This situation occurs almost exclusively in patients with extremely high bladder volumes. At these high volumes, measurements are clinically useful even though they underestimate the actual bladder volume.</p>

Warranty

Verathon® Inc. warrants the BladderScan® instrument against defects in material and workmanship as long as it is covered by the ScanPoint® Total ReliabilitySM Plan.

Damage or loss insurance is available as part of the ScanPoint Total Reliability Plan. Pursuant to this Total Reliability Plan, a service center authorized by Verathon will repair or replace units that prove to be defective during the Total Reliability Plan period.

This Total Reliability Plan does not apply if the unit was misused or modified by anyone other than a service center authorized by Verathon.

The unit must be used in accordance with the instructions contained in this manual. Consumable items are not covered under this warranty and should be used in conformance with Verathon product specifications.

For further details, consult your ScanPoint Total Reliability Plan. Total Reliability Plan conditions may differ in some countries outside the United States. Contact your local distributor for 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.

Some states disallow certain limitations on applied warranties. The purchaser, user, and patient should consult state law if there is a question regarding this disclaimer. This information, descriptions, recommendations, and safety notations in this manual are based upon Verathon experience and judgment with BladderScan instrument as of October 2011. The contents of this manual should not be considered to be all-inclusive, or to cover all contingencies.

The physician who directs the use of the BladderScan instrument at the institution where it is in use is responsible for keeping current with clinical research in bladder volume measurements.

Please direct any questions or problems concerning bladder volume measurement, using the instrument, or the interpretation of data to the responsible physician.

Contacting Verathon

The team at Verathon® is committed to modernizing healthcare delivery by putting patients first. Our products support healthcare professionals by providing accuracy, utility, and excellence. For additional product and company information, visit the Verathon Web site at verathon.com. If you have any questions or comments about Verathon products and services, please contact us at:

Table 7. Contacting Verathon

Corporate Headquarters (USA) Verathon Incorporated 20001 North Creek Parkway Bothell, WA 98011 USA	Toll free: 800.331.2313 (US & Canada Only) Tel: 425.867.1348 Fax: 425.883.2896 Web: verathon.com Email: customerservice@verathon.com
Verathon Medical B. V. (Europe) Linnaeusweg 11 3401 MS IJsselstein The Netherlands	Tel: +31.30.68.70.570 Fax: +31.30.68.70.512 Web: verathon.eu Email: customerserviceeu@verathon.nl

Safety and Performance Summary

- ♦ The BladderScan® instrument computes the volume of the urinary bladder based upon twelve cross-sectional ultrasound images. For maximum accuracy, be sure to hold the Probe motionless while scanning.
- ♦ The most accurate measurements are obtained when the patient rests quietly in a supine position.
- ♦ Errors in usage tend to result in the underestimation of bladder volume, except in cases where the Probe is moved during scanning. In this case, the measurement may overestimate the patient's bladder volume.
- ♦ We recommend that new users use the BladderScan instrument to measure patients with moderately full bladders rather than initially attempting to locate a bladder with a low urinary volume.
- ♦ To conserve battery power, the BladderScan instrument shuts itself down automatically when not in use (goes into "sleep" mode).

WARNING! Risk of explosion.

There is a possible risk of explosion if the BladderScan instrument is used in the presence of flammable anesthetics.

WARNING! Risk of patient injury.

Do not use the BladderScan instrument on patients with open skin or wounds in the suprapubic region.

CAUTION: Risk of inaccurate measurements.

- ♦ Accuracy is compromised if the user does not obtain an optimal, repeatable image.
- ♦ The BladderScan instrument is not intended for use on pregnant patients.
- ♦ The patient being scanned should not have a catheter in his/her bladder. This could create microbubbles in the bladder, which will compromise the accuracy of the measurement.
- ♦ Use care when scanning suprapubic and pelvic surgery patients. Scar tissue, surgical incisions, sutures, and staples can affect ultrasound transmission and reflection.

CAUTION: Risk of Fire and Burns. Do not disassemble, heat above 60° C (140° F), or incinerate 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.

Parts and Accessories

BladderScan System Components (BVI 6100 and BVI 6400)

The following components are included with your BladderScan® BVI 6000 series device.

To order any of the following items, contact your authorized Verathon Medical sales representative or contact the Verathon Medical Customer Care Department at 1.800.331.2313.

Table 8. Included Items

Part Number	Description
0570-0154	One of the following: BladderScan BVI 6100
0570-0167	BladderScan BVI 6400
0270-0234	Charging Cradle
0130-0181	Activation Tool
0900-1236	BladderScan Bladder Volume Instruments User's Manual
0900-0813	BladderScan Bladder Volume Instruments In-Service Training CD (with BladderScan Bladder Volume Instruments User's Manual, Quick Reference Cards, and training videos.)
0900-0589	One of the following: BladderScan BVI 6100 Quick Reference Card
0900-0956	BladderScan BVI 6400 Quick Reference Card

Table 9. Optional Items

Part Number	Name and Description
0900-1009	ScanPoint® LC Software Install CD. Installs ScanPoint Image Management System on a stand-alone (non-networked) Windows® PC.
0900-1238	ScanPoint with QuickPrint Install CD. Installs ScanPoint with QuickPrint software on a network-enabled Windows® PC
0570-0168	ScanPoint Docking Station
0570-0178	ScanPoint Label Writer: Prints exam results on adhesive label media. Requires installation of ScanPoint software on a Windows® PC.
0600-0233	USB Cable: Connects the ScanPoint Label Writer to the ScanPoint host computer.
0600-0232	ScanPoint Label Writer Power Cord. Connects the ScanPoint Label Writer power adaptor to a wall outlet.
0275-0002	Power Supply: Connects the power cord to the Label Writer.







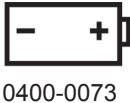
Part Number	Name and Description
0125-0446	Roll of Labels: Labels in roll format properly sized for the ScanPoint® Label Writer.
0800-0255	Acoustic Coupling Gel, 0.25 liter (case of 12)
0270-0435	Battery Replacement Kit

Product Specifications

Symbol Directory

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

Table 10. Symbol Directory

Symbol	Meaning
	Marked in accordance with Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE) (solid bar indicates product was put on the market after 13 August 2005.)
	Class II equipment protected throughout by double insulation or reinforced insulation.
	Type BF applied part with EN/IEC-60601-1.
	CE marked in accordance with the Medical Device Directive (MDD).
	Canadian Standards Association (CSA) mark of certification to United States standards for electromedical equipment.
	Attention. Consult accompanying documents.
	This unit is powered by a Lithium-Ion battery pack. The Verathon® part number is 0400-0073. The battery pack is <u>NOT</u> user-replaceable.

Standards and Regulations Compliance

Verathon® certifies that all units are in compliance with all applicable international and national standards and regulations, including but not limited to the following:

Table 11. Standards and Regulations Compliance

Specification	Standard
International Electrotechnical Commission	EN/IEC 60601-1 Amendments 1 and 2 and EN/IEC 60601-1-2 (EMC)
Safety Standard	EN/IEC 60601-2
Medical Device Directive	MDD 93/42/EEC Annex 1
Canadian Standards Association	C22.2 No. 601.1-M90 (Master Contract No. 177198)
Underwriters Laboratories, Inc.	UL 60601-1
Health Insurance Portability and Accountability Act (HIPAA)	

*For details on Verathon compliance with privacy rules, please refer to the information in the ScanPoint® Help menu (select PRIVACY AGREEMENT).

Per the MDD, BladderScan® instruments are Class IIa devices.

Electromagnetic Effects

There are no restrictions on the use of the BladderScan instrument due to its electromagnetic characteristics. Both the emissions from BladderScan instrument and the susceptibility of this instrument to interference from other sources are within prescribed limits of all applicable standards at the date of manufacture. The emissions test procedure that was used is specified in EN/ IEC55011: 1991 for Group 1, Class A equipment (per EN/IEC60601-1-2, 36.201.1.7).

BladderScan instruments are suitable for use in industrial, scientific, and medical (ISM) environments, and in domestic environments under the jurisdiction of a health care professional. An indication of adverse electromagnetic effects from a BladderScan instrument on another electronic device would be a degradation of performance in the other device when the devices are operated simultaneously. If such interference is suspected, separate the two devices as much as possible, or discontinue simultaneous operation, if practical, and contact Verathon.

BladderScan instruments will operate normally in the proximity of other potential interference sources, and have demonstrated immunity at a field strength of 3 V/m (per EN/IEC 60601-1-2, 36.202.2.1). You do not need to take any other precautions regarding exposure in reasonably foreseeable environmental conditions to magnetic fields, pressure, or variations in pressure, acceleration, or thermal ignition sources.

BladderScan Instrument Specifications

Table 12. BladderScan® Instrument Specifications

Specification	Description
Range	Bladder volume range 0 - 999 ml (BVI 6100, BVI 6400)
Accuracy	The following accuracy specification assumes usage per instructions, scanning a Verathon® Tissue Equivalent Phantom: Bladder Volume: $\pm 15\%$, ± 15 ml
Scan Time	Less than 5 seconds
Voice Annotation Interval	10 seconds (BVI 6400 only)
Weight	Less than 11 oz (309 grams)
Power	3.8v Li Ion rechargeable battery
Display	Liquid crystal
Ultrasound Output Parameters	Maximum SPTA* Intensity: 1.04 mW/cm ² Maximum SPPA* Intensity: 65.0 mW/cm ² Mechanical Index (MI): 0.925 maximum Ultrasound Frequency: 3.7 MHz Scan angle: 120 degrees Mode: V _{MODE} ® (multiple, aligned B-mode images)
Operating Conditions	Temperature: + 50° - + 104° F (+ 10° C to + 40° C)
Atmospheric Pressure Range	70 kPa - 106 kPa
Relative Humidity	30% - 75% non-condensing
Water Resistance	Rated at IPX1 (indicates DRIP-PROOF, a higher than ORDINARY level of protection from drips, leaks, and spills)

*SPTA = Spatial temporal average; SPPA = Spatial peak pulse average

Storage Conditions

BladderScan® BVI 6000 series instruments are designed for storage under the following conditions:

Table 13. BladderScan BVI 6000 Series Storage Conditions

Condition	Description
Storage	Indoor
Ambient Temperature Range	- 4 - + 140° F (- 20 - + 60° C)
Atmospheric Pressure Range	500 hPa - 1060 hPa
Relative Humidity	20% - 95% non-condensing

Charging Cradle Specifications

The Charging Cradle is tested to EN/EN/IEC 60601-1 requirements and is in compliance with UL and CSA equivalent standards. The Charging Cradle is not intended for direct patient contact. It is designed to operate within the specifications and environmental conditions identified in the following tables.

Table 14. Charging Cradle Specifications

Specification	Description
Input Voltage	90-264 VAC RMS
Input Frequency	47-63 Hz
Input Current	2 Amp max
Input Connection	Direct plug-in AC prongs for wall plug-in units
Output	9v at 1 Amp
Insulation	Class II with double insulation

Table 15. Charging Cradle Storage Conditions

Condition	Description
Use	Indoor
Ambient Temperature Range	+ 41 - + 104° F (+ 5 - + 40° C)
Atmospheric Pressure Range	70 kPa - 106 kPa
Relative Humidity	30% - 75% non-condensing
Water Resistance	Rated at IPX 0 (ordinary equipment without protection against ingress of water)

Glossary

Table 16. Glossary

Term	Meaning
Activate	The act of turning on your instrument by placing the activation tool in the opening just above the scan button. When your instrument has been completely discharged, sometimes activation will be necessary.
Activation Tool	The small, metal tool used to activate your instrument.
Aiming arrows	Arrows that appear on the LCD screen to indicate the location of the bladder relative to the Probe. A flashing arrow indicates that you must re-aim the instrument and re-scan the patient to obtain the highest degree of accuracy. A solid aiming arrow means re-aiming is optional.
BladderScan Instrument	The BladderScan® instrument transmits ultrasound energy to produce an image of the patient's bladder and determine bladder volume.
Calibration	Checking the accuracy and function of your BladderScan instrument by comparing it with a known standard.
Charging Cradle	The cradle that is used to charge the battery of the instrument. This cradle plugs directly into an electrical wall outlet.
Docking Station	The cradle that plugs into any personal computer through a standard USB connection and enables the bladder volume instrument to communicate with the computer. This cradle can also be used to recharge the battery of the instrument when the connected computer is turned on.
Coupling Medium	A substance, such as ultrasound gel, that enhances the transmission of ultrasound waves.
Flashing Aiming Arrows	Indicate the bladder is not inside the scan cone and the Probe needs to be redirected. The arrow shows the direction to move or tilt the BladderScan instrument to improve the measurement. Re-aiming is required.
HIPAA	<p>Health Insurance Portability and Accountability Act, enacted by the US Congress in 1996.</p> <p>Title II of HIPAA, the Administrative Simplification provisions (AS), requires the establishment of national standards for electronic health care transactions and national identifiers for providers, health insurance plans, and employers. The AS provisions also address the security and privacy of health data. The standards are meant to improve the efficiency and effectiveness of the nation's health care system by encouraging the widespread use of electronic data interchange in the U. S. health care system.</p>

Term	Meaning
Image Cone	During a bladder volume measurement, this is the cone-shaped area in which the Probe transmits ultrasound waves.
IR Window	The window located at the base of the handgrip which enables the instrument to connect with your computer via the Docking Station.
Labeling	The square label located below the SCAN button on the Probe that provides important product information, including the name, product and serial numbers, and instrument classifications.
LCD Screen	The LCD (liquid crystal display) screen on the BladderScan® instrument that displays the bladder volume measurement, instrument status, and other exam settings and information.
Neurogenic	Caused or affected by the nervous system.
Repeatability	Repeating a scan multiple times in order to assure more accurate exam results.
SCAN Button	Located on the underside of the Probe hand grip, this button is used to initiate the measurement.
ScanPoint® Bladder Imaging Technology	Verathon®-provided software that allows users to display ultrasound images from exams, prints exam results, and maintain patient records.
ScanPoint LC	Verathon-provided software that allows users to display ultrasound images from exams, prints exam results, and maintain patient records on a stand-alone (non-networked) PC.
ScanPoint Online	Verathon-provided software that allows users to display ultrasound images from exams, prints exam results, and maintain patient records on a secure HIPAA, Verathon-maintained server. Patient exam results are accessible from any Internet-enabled PC via a password-protected “myscanpoint” account. The network connection also enables users to calibrate their Verathon devices by themselves, without having to send them in for servicing, allows automatic software updates, and remote diagnostics by Verathon service technicians.
ScanPoint with QuickPrint	ScanPoint with QuickPrint is a software program installed on your computer that communicates with ScanPoint Online to help you quickly and easily download and print exam reports.
Sleep Mode	When the BladderScan shuts down to conserve energy. Press any button to turn on the instrument.
Solid Aiming Arrow	Indicates the bladder is inside the scan cone but is not completely centered. The arrow shows the direction to move or tilt the BladderScan to improve the measurement. Re-aiming is optional but not required.
Supine Position	Refers to the patient laying on their back with their face upward.
Suprapubic	The area above the pubic bone.
Symphysis Pubis	The front of the pelvis where the pubic bones meet.

Term	Meaning
Top (Gender) Button	The button located below the Probe's LCD screen. This button allows the user to select various settings and perform different functions, depending on the device model. For example, it is used to select or deselect the female setting when measuring bladder volume, to record a voice annotation with the BVI 6400, and to display the days remaining until the next required calibration.
Ultrasonic	Involving ultrasound. Ultrasound is sound at frequencies above the range that can be heard by the human ear.