

BladderScan®

Bladder Volume Instrument



BVI 9400

User's Manual and Quick Reference Guide

BladderScan®

Bladder Volume Instrument



BVI 9400

Quick Reference Guide

1




Turn on the BladderScan® BVI 9400 by pressing the POWER ON/OFF button.

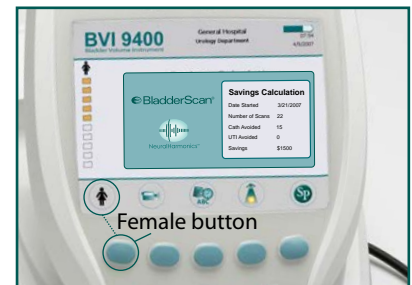


2

Select scanning mode

The BladderScan® BVI 9400 is designed to scan in three patient-specific modes. Select the proper exam mode to ensure the accuracy of your scan. Simply press the button repeatedly until the desired setting appears:

-  Select to scan a male patient, or a female patient who has had a hysterectomy
-  Select to scan a female patient who has not had a hysterectomy
-  Select to scan a small child under 48 inches (122cm) tall and weighing less than 60 lbs (27kg)



3

With the patient supine, apply gel

Have the patient lie in the supine position with 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.



4

Aim toward the bladder

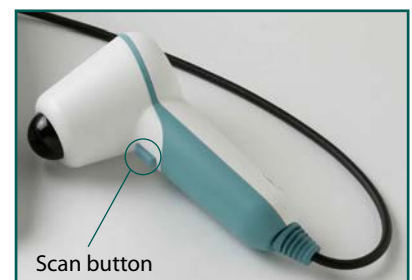
Standing at the patient's right side, place the Probe on the gel and aim toward the expected location of the bladder. For most patients, this means tilting the Probe slightly toward the patient's coccyx (tailbone) so the scan clears the pubic bone.



5

Press the SCAN button

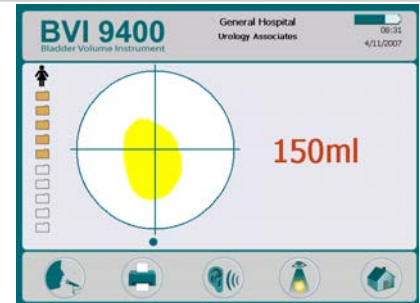
Press the SCAN button, located on the underside of the Probe. As the scan progresses, sections of the bladder will appear on the console screen. When you hear the end-scan tone, the scan is complete.



6

Verify the scan

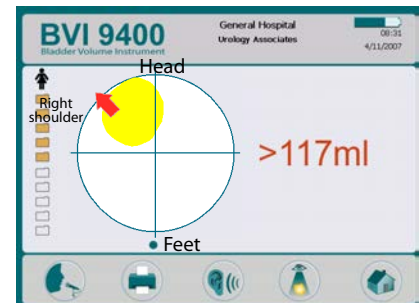
If the scan is **"on target"** all 8 arrows will flash on the Probe screen, and the bladder will be shown in the center of the crosshairs on the Console screen. Since no re-aiming is needed, no arrows will appear on the Console screen.



6a

Re-aiming

If the scan is **"off target"** the Probe will show an arrow indicating the direction to move the Probe to be **"on target."** If the arrow is solid, it means you are slightly **"off target."** If the arrow is flashing, it means you are significantly **"off target"** and must re-aim and re-scan. On the Console, the bladder will not be on the crosshairs, and there will be an arrow pointing in the direction for re-aiming.



6b

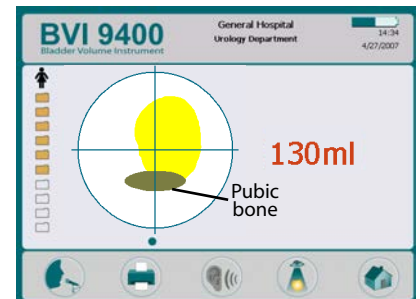
To re-aim

To **re-aim**, note that the small dot at **"6 o'clock"** on the Console target represents the feet of the patient. The **"12 o'clock"** position represents the head of the patient and the upper left quadrant (9-12 o'clock) represents the right shoulder of the patient. This orientation should help you in re-aiming the Probe to capture the complete bladder in the ultrasound **"cone."**

6c

Pubic Bone

You may also see a screen that indicates the pubic bone is **"inside"** the ultrasound cone. If this occurs, you may want to re-aim and re-scan. Although the bladder may be shown as centered in the ultrasound cone, and your measurement could be complete, there is a possibility that the pubic bone is obscuring some of the bladder. By re-aiming, you can ensure you have captured the bladder fully inside the ultrasound cone.



7

Save, review and print exam results

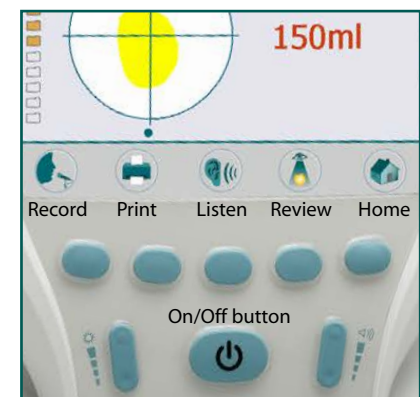
To **save** the exam, you must annotate it.

To **annotate**, press and release the RECORD button on the Console. When you see the RECORD button icon turn to a STOP button icon, record your patient information by speaking into the Probe microphone. Press the STOP button on the Console. When the hourglass icon disappears, press the LISTEN button to replay the annotation.

To **review** the images of your scan, press the REVIEW button (you must first save the exam before you can review it).

To **print** exam results via on-board printer, press the PRINT button.

To **perform another exam**, press the HOME button.



8

Finish exam

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

For ScanPoint® subscribers, logging on to ScanPoint® automatically transfers and saves your annotated exams.

To order additional rolls of paper (0800-0319) or batteries (0400-0066), contact Customer Care at 800.331.2313.

The entire calibration process may take up to 15 minutes. You may calibrate your instrument as often as you like; you do not have to wait for the next scheduled calibration date. However, at a minimum, you must calibrate the instrument every 12 months.

Note: ScanPoint® with QuickPrint is required to calibrate your BladderScan® instrument online. Online calibration is not supported by ScanPoint® LC.

1

Prepare for Calibration

Set up the calibration tank in a location that is within 10 feet of the Battery Charger/Wireless Hub.

Place the calibration tank on a flat, nonreflective surface and remove the lid. Pour clean, room temperature water into the container, filling to the indicator mark. Make sure the water contains a minimal amount of bubbles. Place the spiral-shaped target in the container, using the notches to position target correctly. Replace the lid on the calibration container.



2

Place the probe

Place the Probe in the cutout in the top of the calibration tank. Make sure the black tip of the Probe is submerged in the water.



3

Open ScanPoint® with QuickPrint

From your desktop, open ScanPoint® by double-clicking the ScanPoint® with QuickPrint icon.



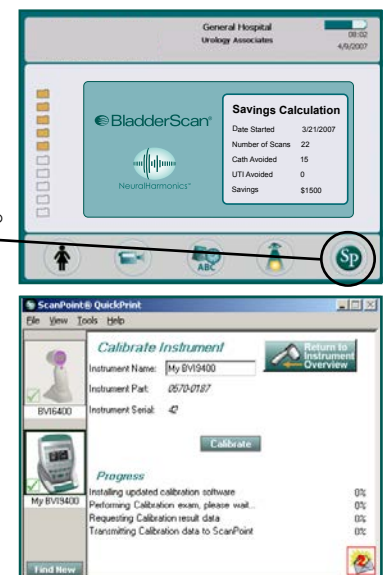
4

Establish BladderScan® - QuickPrint connection

Press the ScanPoint® button on the BladderScan® instrument.

On the QuickPrint screen, click the **FIND NEW** button. When QuickPrint establishes a connection with the BladderScan® instrument, an icon for that device will appear along the left menu.

ScanPoint® button



5

Calibrate instrument

From the Tools menu, select Calibrate Instrument. When the Calibration screen opens, click the CALIBRATE button. ScanPoint® then automatically scans and analyzes the calibration target.

IMPORTANT! Do not remove the Probe from the calibration chamber until four arrows appear on the Probe's LCD screen. Do not disconnect the Charger and Wireless Hub from the computer or otherwise break the connection between the BladderScan® instrument and the ScanPoint® host computer until all processing is complete.

Calibrate

+

Successful calibration

If ScanPoint® was able to locate the calibration target, the instrument analyzes the scan data to ensure that it meets the calibration parameters. If necessary, the instrument automatically rescans the phantom. When calibration is complete, a 'Calibration Successful' message is displayed on your computer.

To print a record of the calibration, click: [Click Here for Printable Certificate of Calibration](#).

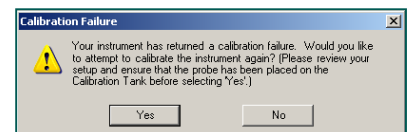


-

Failed calibration

If ScanPoint® was unable to locate the calibration target, it displays an error message and instructs you to ensure that the calibration chamber has enough water and that the Probe is seated properly in the calibration system. You may choose to calibrate again or to quit the calibration process.

NOTE: If you are unable to calibrate, contact your local Verathon Medical representative or Verathon Medical Customer Care at 1.800.331.2313.



6

End calibration

To terminate the calibration procedure and end communication with the ScanPoint®, press the CANCEL (X) button on the BladderScan® instrument.

Remove the Probe from the calibration chamber lid and dry it with a clean, soft cloth.



To order additional rolls of paper (0800-0319) or batteries (0400-0066), contact Customer Care at 800.331.2313.

Intended Use Warnings and Cautions

The BladderScan[®] BVI 9400 should be used only by individuals who have been trained and authorized by a physician or the institution providing the patient care. All users must read the entire BladderScan[®] BVI 9400 User's Manual prior to using the BladderScan[®] BVI 9400. 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: <http://www.verathon.com>, then select the BladderScan[®] > Customer Support links to open a link to this manual and other training materials.

CAUTIONS

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.

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 BladderScan[®] BVI 9400 on a patient with open skin or wounds in the suprapubic region.

Do not use the BladderScan[®] BVI 9400 on a patient 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.

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 the BladderScan[®] BVI 9400 is not user adjustable and is limited to the minimum level necessary for effective performance. Data on acoustic output levels can be found in the "Specifications" section of the BladderScan[®] BVI 9400 User's Manual.

Statement of Prescription

United States federal law restricts the BladderScan[®] BVI 9400 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 the BladderScan[®] BVI 9400 within its intended use throughout an institution. Individual prescriptions for use are not required.

Statement of Intended Use

The BladderScan[®] BVI 9400 projects ultrasound energy through the lower abdomen of the patient to obtain an image of the bladder which is used to calculate bladder volume noninvasively.

CAUTION

Observe the following precautions in the safe use and care of the BladderScan[®] BVI 9400. Hazardous materials present. Assure proper disposal. The BladderScan[®] BVI 9400 and related devices may contain lead, mineral oils, batteries, and other environmentally hazardous materials. When the BladderScan[®] BVI 9400 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[®] BVI 9400 with optional ScanPoint[™] software, 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[®] BVI 9400 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[®] representative, or the Verathon[®] Customer Care Department at 1.800.331.2313.

Assure Proper Distance From Patient

The BVI 9400 battery charger/wireless hub and the computer used to access online ScanPoint[™] image archives (if used) 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.

Contraindications

The BladderScan[®] BVI 9400 is not intended for fetal use or use on pregnant patients.

Specifications - BVI 9400

BladderScan[®] Bladder Volume Instruments are CE marked in accordance with the Medical Device Directive, and the Verathon Inc. Quality system is Quality System Certified to ISA 13485:2003 standards. US 6,884,217 and other US and International Patents Pending.

Range: Adult bladder volume range: 0 to 999 ml; Small child mode: 0-200 ml

Accuracy: The following accuracy specifications assume usage per instructions and scanning a Verathon[®] Tissue Equivalent Phantom.

Bladder volume accuracy: +/- 15%, +/- 15 ml

Specifications - BVI 9400 Continued

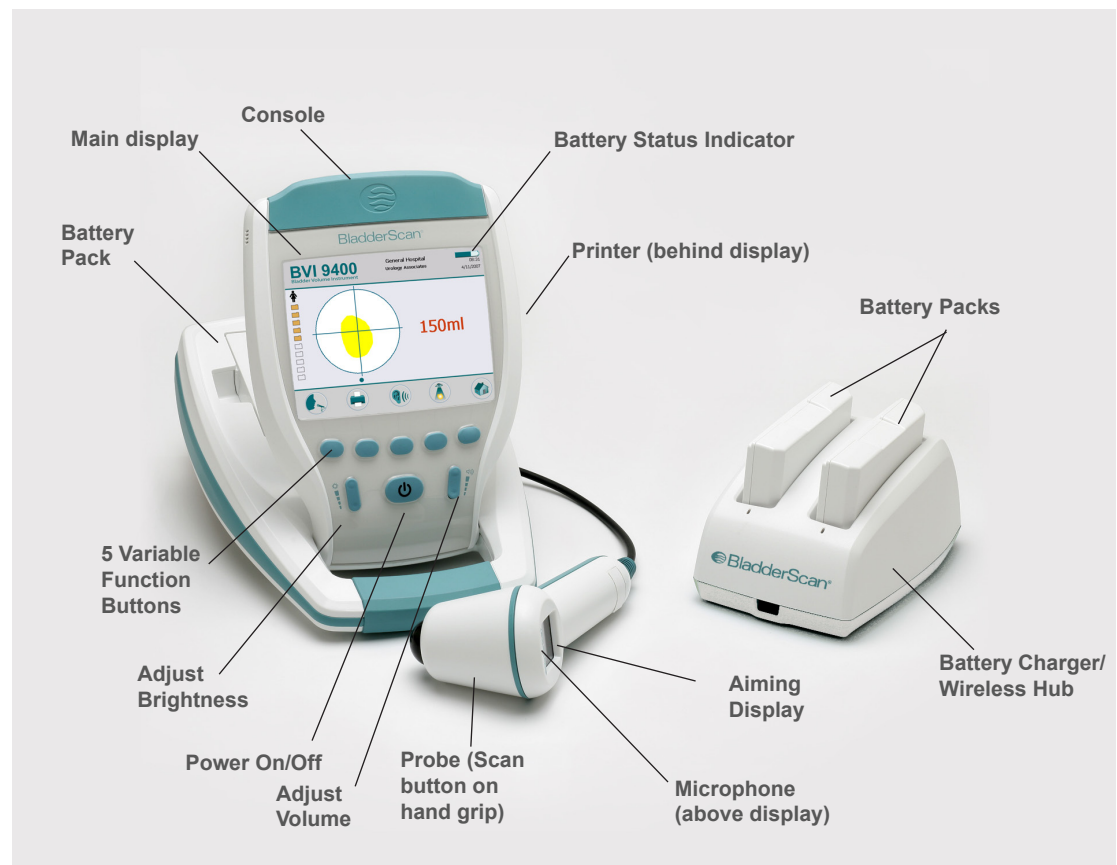
Power: 11.1 v Li Battery Pack (2 Supplied). 3.5 hours continuous use on one charge; Battery indicator

Display: Color LCD

Ultrasound Output Parameters:

- Maximum ultrasound I_{sptad} during a scan: $\leq 5.0 \text{ mW/cm}^2$
- Maximum ultrasound I_{sppad} during a scan: $\leq 60.0 \text{ W/cm}^2$
- Maximum MI (Mechanical Index): 0.95 max
- Transducer diameter: 13 mm (0.512 inches)
- Transducer resonant frequency: 3.0 MHz and 1.74 MHz
- Transducer bandwidth: 75% at 10 dB
- Time from 3D scan initiation to result display: < 3 seconds

Figure 1. BladderScan® BVI 9400 Controls and Indicators



To Charge the Batteries

1. Plug the Battery Charger/Wireless Hub unit into a standard wall outlet.
2. Insert the battery into the recess in the battery charger.
3. Check the colored indicator lights on the battery charger to determine battery status:
 - A. Solid green: Battery is fully charged.
 - B. Amber: Battery is charging.

NOTE

Fully charging the battery may take up to 6 hours.

Batteries may be stored in the charger. There is no danger of overcharging the batteries.

Time and date settings will be lost if the battery is removed from the instrument for longer than five minutes.

Load a Roll of Thermal Paper

To load a new roll of thermal paper:

1. Open the paper compartment door (located on the base of the Console, under the display).
2. Slide the door to the right, then lift the printer door up.
3. Insert the end of a new paper roll with the thermal side down, into the paper slot.

To verify which side is the thermal side, scratch the paper with your finger nail. If a black mark appears, this is the thermal side.

4. Extend the end of the paper past the end of the unit.
5. Rotate the printer door down. Make sure you hear it snap into place.
6. Slide the printer door to the left.
7. Tear the excess paper off.

CAUTION

To avoid paper jams, never fold the end of the paper roll or cut it diagonally or to a point.

NOTE

If the paper will not advance through the printer, open the printer door on the back of the Console and clear the paper jam.

To Record a Voice Annotation

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

The instrument can store ten scans with voice annotations, so you can perform multiple exams on your rounds. If you are using the optional ScanPoint™ with QuickPrint software, you can upload saved exams to your PC. (Refer to the ScanPoint™ with QuickPrint User's Manual for more information).

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.

Cleaning the Instrument

To clean the BladderScan® BVI 9400:

1. Use a 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. Alternatively, 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 the dampened cloth.
4. To remove all traces of disinfectant solution, wipe the instrument with a clean soft cloth dampened in sterile water or potable tap water. 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® BVI 9400 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

Verathon[®] recommends that the BladderScan[®] BVI 9400 be certified by an authorized BladderScan[®] Service Center once a year. Certification service includes comprehensive inspection and testing of the instrument to ensure accurate performance in clinical use.

For more information, please contact your authorized BladderScan[®] Service Center, your local BladderScan[®] distributor, or Verathon[®] Customer Care Department at 1.800.331.2313.

NOTE

ScanPoint[™] Online customers can maintain device certification via the Internet by accessing their ScanPoint[™] account. For more information about using ScanPoint[™] Online, please refer to the ScanPoint[™] with QuickPrint User's Manual.

Weekly Inspections

Once a week, you should inspect the Probe and cable 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 Console, Probe, or the cable that links the Console and the Probe, 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[®] representative or the Verathon[®] Customer Care Department at 1.800.331.2313.

Calibrating the BladderScan[®] BVI 9400 Using the ScanPoint[™] System

You must periodically calibrate your BladderScan[®] BVI 9400 to make sure your instrument is providing the most 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 measurements may be compromised. When calibration is required, a warning appears in the display header.

Device Repair


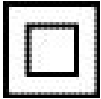



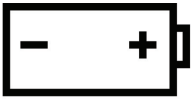
The BladderScan[®] BVI 9400, Probe, and Battery Charger/Wireless Hub are completely sealed. There are no user-serviceable components. Verathon[®] does not make available any type of circuit diagrams, component parts lists, descriptions, or other information that would be required for repairing the device and related accessories. Premium Warranty customers have access to a loaner unit, replacement unit, and free shipping options which vary according to plan. If you have any questions, contact your local Verathon[®] representative or the Verathon[®] Customer Care Department at 1.800.331.2313.

Unit Disposal

The BladderScan® BVI 9400 and related devices may contain lead, mineral oils, batteries, and other environmentally hazardous materials. When the BladderScan® BVI 9400 has reached the end of its useful service life, return the device, Battery Charger/Wireless Hub, and related accessories to a Verathon® Service Center for proper disposal. Alternatively, follow your local protocols for hazardous waste disposal.

Symbol Directory

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

Symbol	Meaning
	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).
	Protection Class II equipment, internally powered equipment.
	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.
 #0400-0066	This unit is powered by a Lithium-Ion battery pack. The Verathon® part number for the batter pack is 0400-0066.

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The BladderScan® technology described in this manual is protected by U.S. Patent Numbers 5,235,985, 6,676,605, 6,884,217 and 6,905,468. The ScanPoint™ technology described in this manual is protected by U.S. Patent Number 6,569,097. Other patents pending.

Information in this *Quick Reference Guide* may change at any time without notice. For the most up-to-date information, see the online manuals at <http://www.verathon.com>. Examples described or illustrated in this *Quick Reference Guide* are fictitious and do not in any way represent real patient or exam data.

Corporate Headquarters

20001 North Creek Parkway
Bothell, WA 98011
USA
800.331.2313 (US and Canada only)
425.867.1348
Fax: 425.883.2896

Verathon Medical (Europe) B.V.

EC REP
Linnaeusweg 11
3401 MS IJsselstein
The Netherlands
+31.30.68.70.570
Fax: +31.30.68.70.512

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BVI 9400

User's Manual

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BladderScan® BVI 9400

Bladder Volume Instrument

User's Manual

For use with consoles purchased or upgraded after August 2013.

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

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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: www.verathon.com Email: customerservice@verathon.com
<div><div>EC</div><div>REP</div></div> 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: http://www.verathon.eu/ Email: customerserviceeu@verathon.nl

For contact information for Verathon subsidiaries, please visit our website at www.verathon.com/ContactUs.htm.

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Company Statement

The team at Verathon® is committed to improving healthcare 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.

Important Information

Product Description

The BladderScan BVI 9400, with patent-pending NeuralHarmonics® technology, is a portable ultrasound instrument that provides a noninvasive measurement of urinary bladder volume. The device consists of an ultrasound probe that scans the patient’s bladder, and a compact, battery-operated console that provides an array of measurement-related information.

BladderScan is quick, accurate, reliable, and easy to use. When the user presses the SCAN button, within seconds, the BVI 9400 measures ultrasonic reflections on multiple planes inside the body and produces a three-dimensional image. Based on this image, the BVI 9400 calculates and displays the bladder volume. A sonographer is not required.

Patent-pending NeuralHarmonics technology (abbreviated from “neural network harmonics”) in the BVI 9400 sharpens accuracy and accelerates speed of measurement. Volume measurements made with NeuralHarmonics technology are more accurate than those from conventional two-dimensional ultrasound, as they are based on a more complex, multifaceted image of the bladder. This technology, applying multispectral analysis to a robust data set, helps reduce margin of error and minimize uncertainty in essential measurements of bladder function.

BladderScan BVI 9400 measurements can be printed via an onboard printer or transmitted, using HIPAA-compliant ScanPoint® image management technology (optional) to your office or facility computer, for viewing, printing, or archiving.

If needed, after a scan has been taken, a unique aiming icon guides the operator to optimal probe placement with a comprehensive, three-dimensional display showing the bladder in two cross-sectional images verifying that a complete scan has been achieved. Bladder volume, patient type, directional aiming with real-time feedback, battery status, and usage rate indicators are all displayed on the device’s LCD screen. The BladderScan BVI 9400 contains an onboard thermal printer that allows the user to print exam results quickly with the press of a button.

A calibration targeting system, consisting of a spiral-shaped calibration target along with a special calibration container, allows the user to easily calibrate the device by scanning a known target.

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.

The BladderScan BVI 9400 system also includes a universal battery charger for the custom, user-replaceable lithium-ion battery incorporated in the system.

The BladderScan BVI 9400 may be mounted on a cart which holds the instrument securely and provides a holder for ultrasound gel and other accessories.

Intended Use Warnings and Cautions

The BladderScan BVI 9400 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 user's manual prior to using the BladderScan BVI 9400. 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: <http://www.verathon.com>, then click on the "Product Materials" tab on the BladderScan BVI 9400 page to open a link to this manual and other training materials.

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 the BladderScan BVI 9400 is not user adjustable and is limited to the minimum level necessary for effective performance. Data on acoustic output levels can be found in the BladderScan BVI 9400 Instrument Specifications.

Statement of Prescription

United States federal law restricts the BladderScan BVI 9400 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 the BladderScan BVI 9400 within its intended use throughout an institution. Individual prescriptions for use are not required.

Statement of Intended Use

The BladderScan BVI 9400 projects ultrasound energy through the lower abdomen of the patient to obtain an image of the bladder which is used to calculate bladder volume noninvasively.

Contraindications

The BladderScan BVI 9400 is not intended for fetal use or for use on pregnant patients.

Warnings & Cautions

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



WARNING! Risk of explosion.

There is a possible risk of explosion if the BladderScan BVI 9400 is used in the presence of flammable anesthetics.



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

The BladderScan BVI 9400 is provided with two lithium ion batteries. Never short circuit the battery pack 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 pack and the BladderScan device.



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

Never expose the battery pack to abnormal shock, vibration, or pressure. The main battery pack’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 BVI 9400 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 BVI 9400 Instrument Specifications.



WARNING! Risk of patient injury.

Do not use the BladderScan BVI 9400 on patients with open skin or wounds in the suprapubic region.



CAUTION! Risk of inaccurate measurements/results.

- Accuracy is compromised if the user does not obtain an optimal, repeatable image.
- The BladderScan BVI 9400 is not intended for use on pregnant patients.
- 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).

When using the BladderScan BVI 9400 be aware of the following conditions which can affect ultrasound transmission and decrease the accuracy of exam results.

- Previous suprapubic or pelvic surgery with resulting scar tissue, surgical incisions, sutures, and staples can affect ultrasound transmission and reflection.
- Do not use the BladderScan BVI 9400 on a patient with open skin or wounds in the suprapubic region.
- Do not use the BladderScan BVI 9400 on a patient with ascites.



CAUTION! Failure to heed the following cautions may cause device damage not covered by the BladderScan BVI 9400 warranty.

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



CAUTION! Observe the following precautions in the safe use and care of the BladderScan BVI 9400.

Hazardous materials present. Assure proper disposal.

The BladderScan BVI 9400 and related devices may contain lead, mineral oils, batteries, and other environmentally hazardous materials. When the BladderScan BVI 9400 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 BVI 9400 with optional ScanPoint® software, 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 BVI 9400 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 representative, or the Verathon Customer Care Department at 1.800.331.2313.

Assure proper distance from patient.

The BVI 9400 battery charger/wireless hub and the computer used to access online ScanPoint image archives (if used) 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! Bluetooth and wireless LAN devices operate within the same radio frequency range and may interfere with one another.

If you are using the BladderScan BVI 9400 Bluetooth link and wireless LAN devices simultaneously, you may experience less than optimal network performance or even lose your network connection. If this happens, you may need to move the BladderScan and ScanPoint host computer to an area away from the 2.4 GHz wireless LAN devices (40 meters/44 yards, or more).



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.

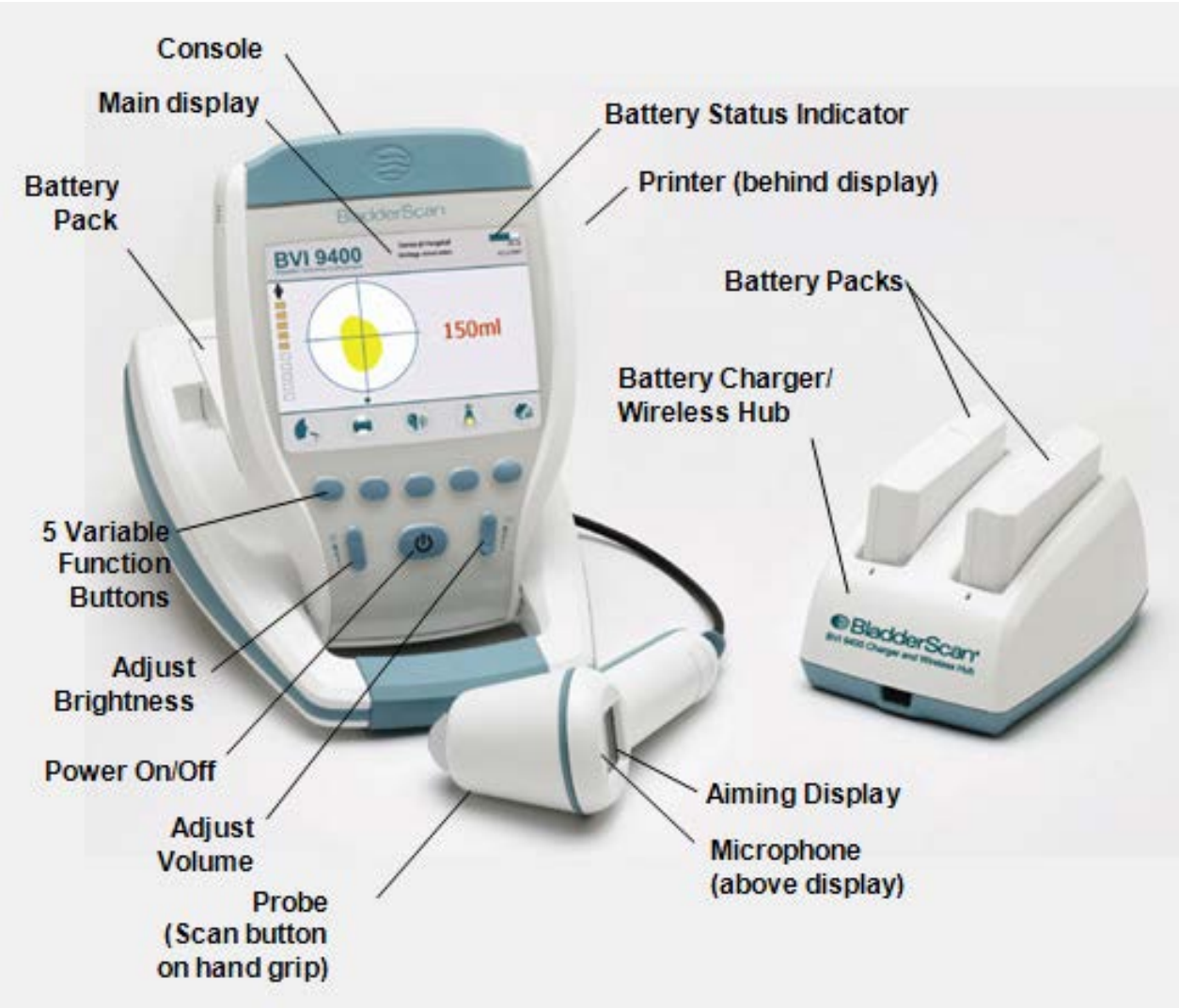
Introducing the BladderScan BVI 9400

- The BladderScan BVI 9400 is designed for simple, intuitive operation. However, to ensure safe and effective operation, before using the device:
- Familiarize yourself with the contents of this manual.
 - Watch the training video provided on the instrument.

BladderScan Parts and Features

The BladderScan BVI 9400 has two main components: the console and the probe. The console and probe are linked by a detachable cable. The BladderScan BVI 9400 controls and indicators are illustrated in Figure 1.

Figure 1. BladderScan BVI 9400 Controls and Indicators



Probe Components

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. The probe is attached to the console by a cable. The probe has three main features:

Part Name	Purpose
SCAN Button	Press to take a scan.
Aiming Display	The LCD displays directional arrows to ensure that the bladder is centered within the image cone.
Microphone	Records voice annotations.

Console Components

The console provides all operating controls for the scanning process by means of 5 variable function buttons. The measured bladder volume and target-shaped aiming icons are clearly displayed on the LCD screen. The console also provides controls for adjusting brightness and volume, turning the power on/off, interfacing with a ScanPoint® host computer (optional), and adjusting user settings and preferences. The console also houses the battery and the printer. The console's controls and features are described in the following table:

Part Name	Purpose
Main Display	Displays the bladder volume measurement, patient type, settings, and instrument status.
Power On/Off	Toggles main power on/off.
Volume	Press to adjust volume up/down on voice annotation playback, start up sound, and "scan complete" tone.
Brightness	Press to adjust display brightness dimmer/brighter.
Five Variable Function Buttons	Depending on device mode, the buttons provide access to all instrument functions for scanning, recording annotations, printing, connecting to ScanPoint (optional), accessing the training video, and setting user preferences.
Printer/Printer Door	Slide to release the printer door.

Battery Charger/Wireless Hub

The BladderScan BVI 9400 is powered by a lithium ion (Li-Ion) battery pack (Figure 2). The battery charger provided with your BVI 9400 can charge two Li-Ion battery packs while simultaneously functioning as the wireless hub linking your BVI 9400 to the ScanPoint® host computer.

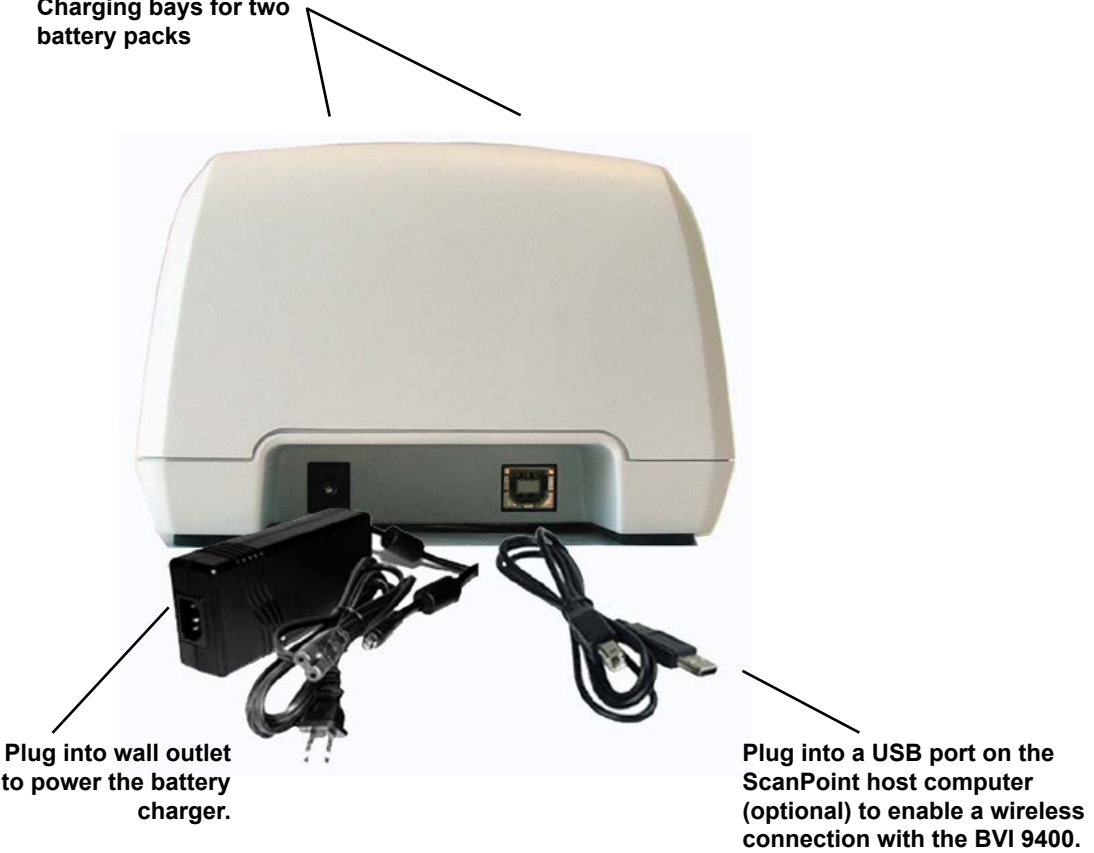
NOTE: Use of ScanPoint software is optional.

- To provide power to the battery packs, the battery charger/wireless hub must be plugged into a wall outlet using the power cord provided.
- To provide wireless communication between the BVI 9400 and the ScanPoint host computer, plug the battery charger/wireless hub USB connector into a USB port on the ScanPoint host computer.

The battery charger/wireless hub maintains an operating distance of up to 120 feet (36 meters) between the ScanPoint computer and the BVI 9400, regardless of barriers such as walls, ceilings, or windows.

Figure 2. Battery Charger & Wireless Hub

Charging bays for two battery packs



Parts and Accessories

Part Number	Description
0570-0190	BVI 9400 Console
0570-0188	BVI 9400 Probe
0570-0351	BVI 9400 Probe (newer)
0570-0193	Battery Charger/Wireless Hub
0400-0066	Lithium-ion Battery (2 provided)
0900-1606	BVI 9400 User's Manual (on In-service CD)
0900-1601	ScanPoint® with QuickPrint User's Manual (on CD)
0900-1446	Quick Reference Card - Bladder Volume Measurement
0900-1447	Quick Reference Card - Calibration
0800-0319	Thermal Paper Roll for the Printer
0900-1500	BladderScan BVI 9400 In-service CD (Includes User's Manuals, Video Tutorial and Quick Reference Cards)
0800-0322	Medical Cart (optional)
0810-0201	Universal Accessory Basket for Medical Cart (optional)
0900-1238	ScanPoint with QuickPrint Software Install CD. NOTE: Use of the ScanPoint software is optional and not required for operation of the BVI 9400.
0620-0340	Calibration Kit (Optional - includes Calibration Container, Calibration Target, etc.)
0800-0005	Acoustic Coupling Gel, 0.25 liter (case of 12)

Getting Started

The previous section provided basic information about the BVI 9400 parts and features. This section provides instructions for setting up your BVI 9400 prior to first use.

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

- Unpack the box and check the components
- Charge and install the batteries
- Customize the display (enter your institution’s name, date, time, and other user data)
- Assemble the medical cart (optional)
- Install the ScanPoint® with QuickPrint software (optional)

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 representative or Verathon Customer Care Department.

- (1) BladderScan BVI 9400 (console and probe)
- (1) Medical cart (optional)
- (1) Universal accessory basket for medical cart (optional)
- (2) Rechargeable lithium-ion batteries
- (1) Battery charger/Wireless hub
- (1) In-service CD (includes user's manuals, video tutorial, and quick reference cards)
- (1) Training pack

Charge the Batteries

Two lithium-ion batteries are included with the BladderScan BVI 9400. One battery can be recharged in the battery charger/wireless hub while the other is installed in the BladderScan instrument. This ensures that there is no instrument downtime. The charger will bring the batteries to a full charge within 6 hours or less.

NOTE: Before using the BladderScan BVI 9400 for the first time, you will need to charge both batteries.

To charge the batteries:

1. Plug the battery charger/wireless hub unit into a standard wall outlet.
2. Insert the battery into the recess in the battery charger.
NOTE: Fully charging the battery may take up to 6 hours. Batteries may be stored in the charger. There is no danger of overcharging the batteries.

3. Check the colored indicator lights on the battery charger to determine battery status:
 - **Solid green:** Battery fully charged.
 - **Amber:** Battery charging.

Install a Battery Pack in the Console



WARNING! Risk of serious injury. If the battery pack is leaking or its case is cracked, put on protective gloves to handle it, and discard it immediately. Always dispose of used battery packs in compliance with all applicable laws and regulations. Put insulating tape, such as cellophane tape, on the electrodes during transportation to avoid a possible short circuit, fire, or electrical shock. Failure to do so could result in serious injury.

To insert a battery pack:

Insert the charged battery into the battery well in the Console, slide it under the ledge and push down gently until the battery clicks into place.
NOTE: The battery pack is designed to prevent incorrect installation. If the battery pack does not slide into the battery well easily, move the battery and try again. Do not force the battery into position.

Battery Care

The BladderScan BVI 9400 draws very little power when it is turned off. However, if you do not plan to use the BladderScan instrument for several weeks, you should remove the battery to prevent it from discharging.
When batteries are not in use, they should be stored in the Battery Charger so they remain fully charged.

Enter the Clinic Name

You can customize your BladderScan 9400 by entering your facility’s name and current date and time. This information will subsequently be included on BladderScan displays and all printouts of exam results.
NOTE: Use of extended-Latin and/or non-Latin characters: The following instructions explain how to enter a facility name that uses only standard Latin characters. Extended Latin characters (tilde, umlaut, accents, circumflex, etc.) and/or non-Latin characters can be entered only by using ScanPoint® with QuickPrint software. To enter a name that uses extended or non-Latin characters, please refer to the instructions in the ScanPoint with QuickPrint User’s Manual.

To enter your clinic's name:



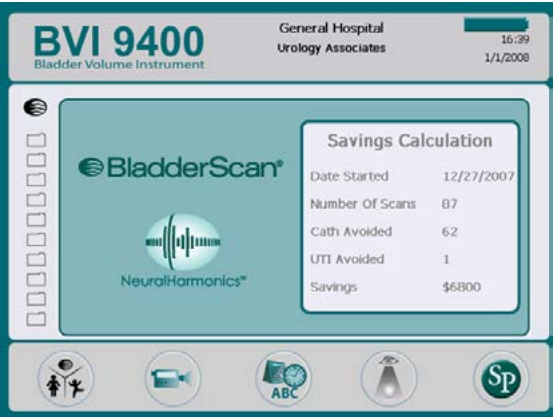
- 1. Turn the BladderScan BVI 9400 on by pressing the POWER button  on the front of the console.
- 2. When the Home screen appears (Figure 3), press the SETTINGS button  to open the Settings screen.

Figure 3. Home Screen






- 3. On the Settings screen (Figure 4), push either the  or  button until **Name** is highlighted (red). Press the  button to open the Name screen.

Figure 4. Settings Screen








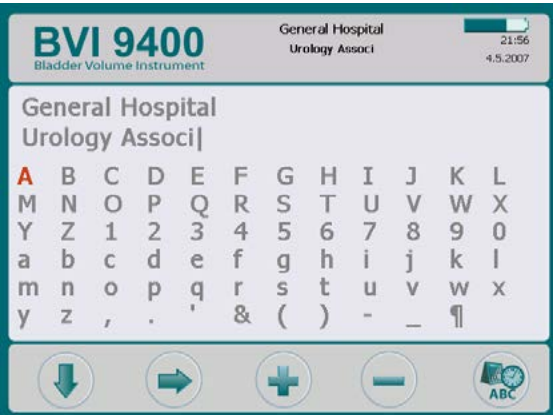
- 4. On the Name screen (Figure 5), use the  and  buttons to move to the desired character. When the desired character is highlighted (red), press the  button to add it to your text. Use the  button to delete characters.
 - To add a space between words, press the blank space below the letter “x”.
 - To add a second line of text use the  character.

Figure 5. Name Screen





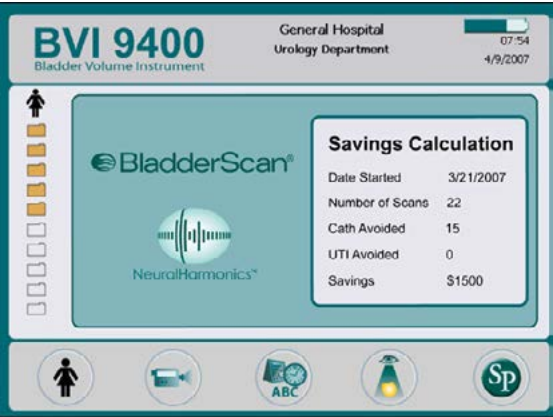
- 5. Continue to select and add characters as needed.
- 6. When finished, press the SETTINGS button  to return to the Settings screen. From the Settings screen, press the HOME button  to return to the Home screen. The facility name will now appear in the display header (Figure 6).

Figure 6. Home Screen



Set the Date and Time

To set the date and time:








- 1. If the BladderScan instrument is turned off, turn the power on by pressing the  button on the front of the console.
- 2. From the Home screen press the SETTINGS button  to open the Settings screen.
- 3. On the Settings screen (Figure 7), push either the  or  button until **Date & Time** is highlighted (red). Press the  button to open the Date & Time screen.

Figure 7. Settings Screen - Date & Time



4. On the Date & Time Select screen (Figure 8), use the  and  buttons to move to the desired unit (hours, minutes, month, day, year).

When the desired unit is highlighted (red):





- Press the  button to increase values.
- Press the  button to decrease values.

Figure 8. Date & Time Select Screen



5. When the time and date are set correctly, press the SETTINGS button  to return to the Settings screen. From the Settings screen, push the HOME button  to return to the Home screen.

NOTES:

- See General Preferences screen for information about setting General Preferences, Savings Preferences, and Self-Test Options.
- General Preferences, Savings Preferences, and Self-Test Options can be accessed from the Settings screen.
- General Preferences include options for: Language, Date Format, Time Format, and Calibration Warning.
- Savings Preferences include: UTI Rate, UTI Cost, Catheterization Cost, Catheterization Volume, Currency, and Savings Calculation.

Load a Roll of Thermal Paper

To load a new roll of thermal paper:

1. Open the paper compartment door (located on the base of the console, under the display).
2. Slide the door to the right, then lift the printer door up.
3. Insert the end of a new paper roll with the thermal side down, into the paper slot.

To verify which side is the thermal side, scratch the paper with your fingernail. If a black mark appears, this is the thermal side.
4. Extend the end of the paper past the end of the unit.
5. Close the door, making sure that you snap it into place, then slide the door to the left.

6. Slide the printer door to the left.
7. Tear the excess paper off.

CAUTION! To avoid paper jams, never fold the end of the paper roll or cut it diagonally or to a point.

NOTE: If the paper appears to be stuck in the printer, open the printer door on the back of the console and clear the paper jam.

Assemble the Medical Cart

NOTE: If you're not using the medical cart, please skip to the next section. Install the ScanPoint® with QuickPrint Software.

The optional medical cart is illustrated in Figure 9.

Medical Cart Parts List

Item No.	Qty	Part Number	Description
1	1	0142-0276	Tray Assembly
2	1	0810-0140	Bracket and Post
3	1	0810-0141	Medical Cart Base
4	4	0261-0107	Screw PH W Lock 25-20 x 1/2
5	1	0260-0357	Fluted Knob 3/8-16 x 1.00
6	4	0810-0142	Caster, 3 inch
7	1	0810-0143	Caster, 3 inch with Brake
8	2	0136-0109	Loctite® 680

Figure 9. Medical Cart
PN: 0800-0322



To assemble the medical cart (Figure 10)

1. Align and press one 3-inch caster with brake (Item 7) and four 3-inch casters (Item 6) into medical cart base (Item 3).
2. Align through round hole in bracket and post (Item 2) bracket to through hole in medical tray (Item 1).
3. Insert bracket and post (Item 2) into square relief in bottom of medical tray assembly (Item 1).
4. Insert four screws (Item 4) through bracket and post (Item 2) into molded inserts in medical tray (Item 1); tighten securely.
5. Place the tray assembly with the bracket and post into the medical cart base (Item 3).

NOTE: If a permanent attachment of the tray assembly and post to the medical cart base is required, refer to the Loctite® option below before inserting the post into the base.

- 6. Place device in foot prints on medical tray (Item 1).
- 7. Screw the fluted knob (Item 5) through bracket and post (Item 2) bracket round hole and hand tighten.

Loctite® option:

- 1. Place medical cart base on level floor.
- 2. Open 2 tubes of Loctite 680 by snapping off the tips of the tubes.
- 3. Apply the Loctite 680 all around the tapered portion of the post. Use all of the contents of both tubes. Complete coverage of the taper is not necessary as the Loctite will spread upon insertion into the base.
- 4. Slide the post into the hole in the base with a twisting motion and press down firmly.
- 5. Wipe off excess Loctite with paper towel and discard towel as waste.
- 6. Allow post and base to sit undisturbed for 3 hours.

To attach the BVI 9400 to the medical cart, refer to the instructions on the next page.

A universal accessory basket (P/N 0810-0201) (Figure 11) is available for the medical cart to provide additional storage capacity.

Figure 10. Medical Cart Assembly

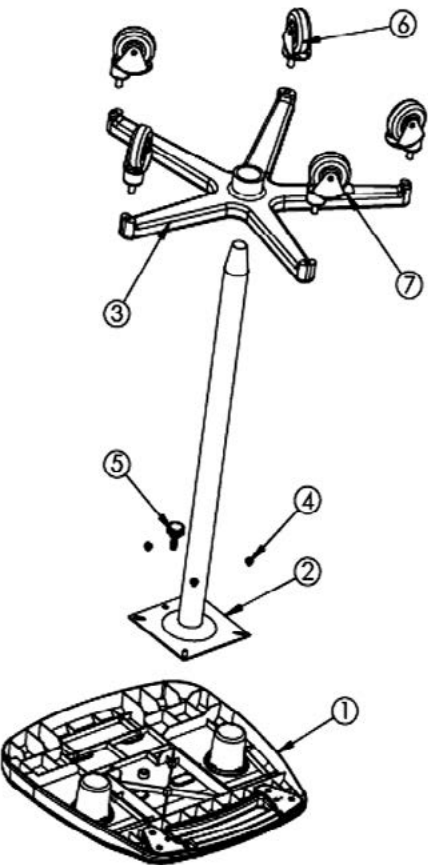


Figure 11. Universal Accessory Basket P/N 0810-0201 (Optional)



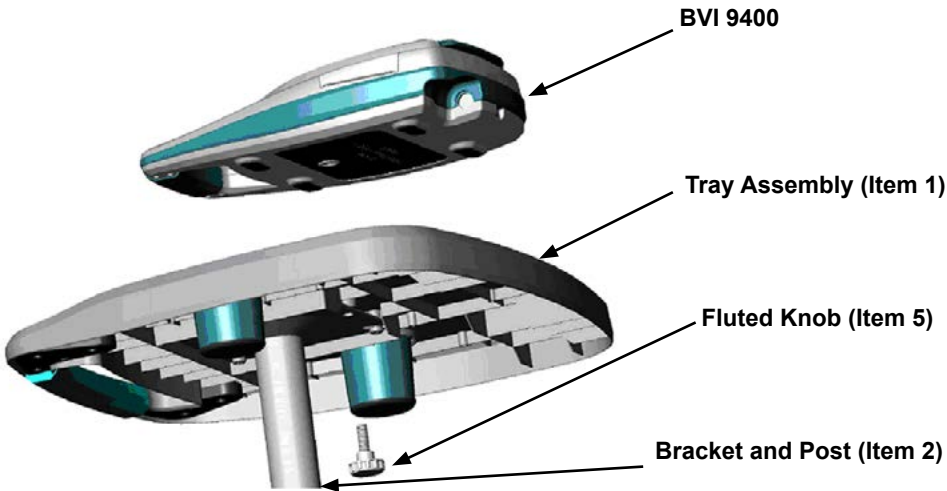
Install the BladderScan on the Optional Medical Cart

Your BladderScan BVI 9400 is completely portable and can be easily moved and positioned for convenient use. Installing the BVI 9400 on the optional mobile cart will allow you to move the BladderScan along with related accessories to the patient examining area or bedside as necessary.

To install the BVI 9400 on the medical cart:

NOTE: For medical cart assembly instructions and parts list, refer to previous pages in this section.

Figure 12. Attaching the BVI 9400 to the Medical Cart



To install the BVI 9400 to the medical cart, screw the fluted knob (Item 5) through bracket and post (Item 2) bracket round hole and tray assembly (Item 1), and into the mounting hole on the bottom of the device. Hand tighten (Figure 12).

Install the ScanPoint with QuickPrint Software (Optional)


Optional ScanPoint® with QuickPrint software is designed to mesh seamlessly with your BladderScan devices. The BVI 9400 automatically downloads exam data to the ScanPoint host computer via a wireless connection enabled by the battery charger/wireless hub - allowing further viewing, analysis, archiving, and report generation.

To install ScanPoint with QuickPrint, insert the ScanPoint with QuickPrint install CD into your computer's CD drive and follow the on-screen prompts. Please refer to the separate user's manual provided with ScanPoint with QuickPrint for complete installation and operating instructions.



Watch the Training Video

The training video provides an overview of how to perform an ultrasound scan of the bladder using the BladderScan BVI 9400. The video is approximately 5 minutes long. The training video:

- can be found on the In-service CD and at the Verathon® Web site: <http://www.verathon.com/Training%20Videos.htm>.
- is available for review anytime on the BladderScan BVI 9400 by pushing the  button from the Home screen
- may also be found at www.verathon.com/BladderScan.htm.

Displays, Controls, and Indicators






Console Displays and Button Functions

The console LCD presents user information and prompts that vary depending on the current device function.

The 5 buttons below the display have variable functions according to device mode. Button functions are indicated by icons in the display footer, immediately above each button.

Battery Status Indicator

A battery status indicator appears in the header of all BVI 9400 screens. Depending on the state of the battery, one of the following symbols will be displayed:

-  Battery is fully charged.
-  Battery is 50% to 75% charged.
-  Battery is 25% to 50% charged.
-  Battery is nearly depleted and can power only a few more scans.
-  Battery is fully depleted and must be changed.

Home Screen

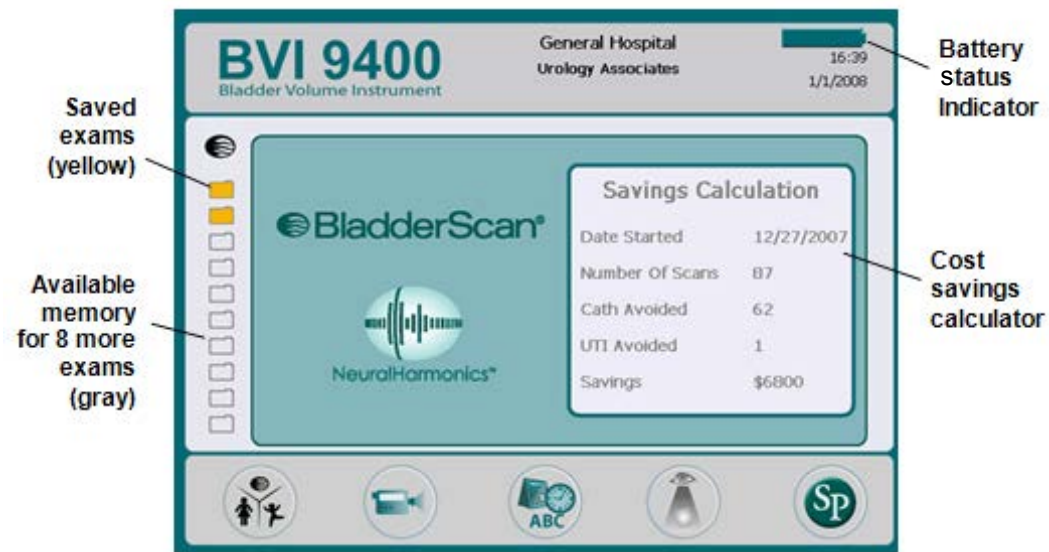
The Home screen appears when the BVI 9400 is first powered on. The Home screen serves as a starting point for all of the main functions of the instrument.

The Home screen displays:

- In the header: Your clinic's name and a battery status indicator.
- In the center panel: A list of saved exam results (10 maximum) saved in chronological order. Yellow folders hold saved exams. Grey folders represent empty spaces still available for saving exam results.

A cost saving summary. Displays the savings to your organization due to using the BladderScan BVI 9400 rather than catheterization. The values used to calculate the savings are user-variable and are entered from the Savings Preference screen.
- In the footer: Five variable-function buttons.

Figure 13. Home Screen



Home Screen Buttons

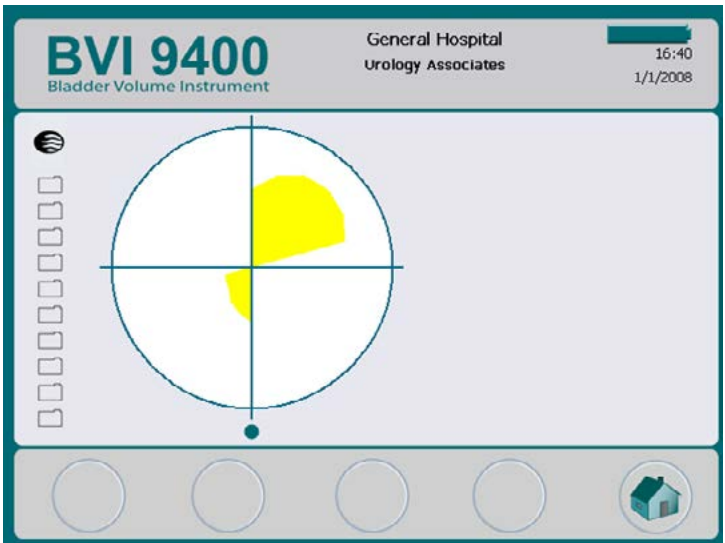
Button	Function
	Single button with three modes. Available when "small child" mode is set to "on." When performing an exam, press the button repeatedly until the desired setting appears above the saved exams folders:
	<ul style="list-style-type: none">Select the small child icon to scan a patient with height less than 48 inches (122 cm) tall and weight less than 60 lbs (27 kg).
	<ul style="list-style-type: none">Select the female icon to scan a female patient who has not had a hysterectomy.
	<ul style="list-style-type: none">Select the BladderScan icon to scan all other patients.
	Replaces single button when small child mode is set to "Off." Press button to toggle between female icon and BladderScan icon.
	<ul style="list-style-type: none">Select the female icon to scan a female patient who has not had a hysterectomy.
	<ul style="list-style-type: none">Select the BladderScan icon to scan all other patients.
	Press to view the training video.
	Press to open the Settings screen (set the time, date, institution name, and user preferences).
	Press to review a previously-saved exam. (This button is gray (inactive) if there are no previously saved exams to review.)
	Press to initiate communication with the ScanPoint® host computer. Saved and annotated exams being held on the BVI 9400 will be automatically uploaded to the ScanPoint computer. (ScanPoint must be installed and open. Use of ScanPoint software is optional.)

Scan Screen

The Scan screen (Figure 14) appears after you press the SCAN button on the Probe and displays a progressively updating image of the bladder outline. When the ultrasound measurement is complete, the Results screen opens automatically.

Four buttons below the display do not function during the scan.

Figure 14. Scan Screen



Results Screen Buttons

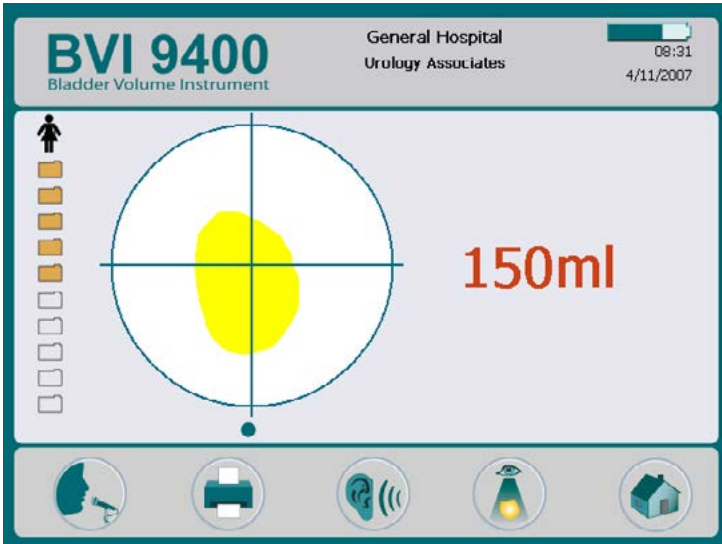
Button	Function
-	No function.
-	No function.
-	No function.
-	No function.
	HOME: Press to cancel the scan and return to the Home screen.

Results Screen

The Results screen (Figure 15) appears automatically when an ultrasound scan is complete.

The display presents the result of the exam: crosshairs, bladder outline, and the calculated bladder volume. You may choose to print this result to the onboard printer and/or to record a voice annotation to save the exam. After the annotation is recorded, the PLAY and REVIEW buttons become active and the newly recorded exam appears on the main display as an orange folder icon.

Figure 15. Results Screen



Results Screen Buttons

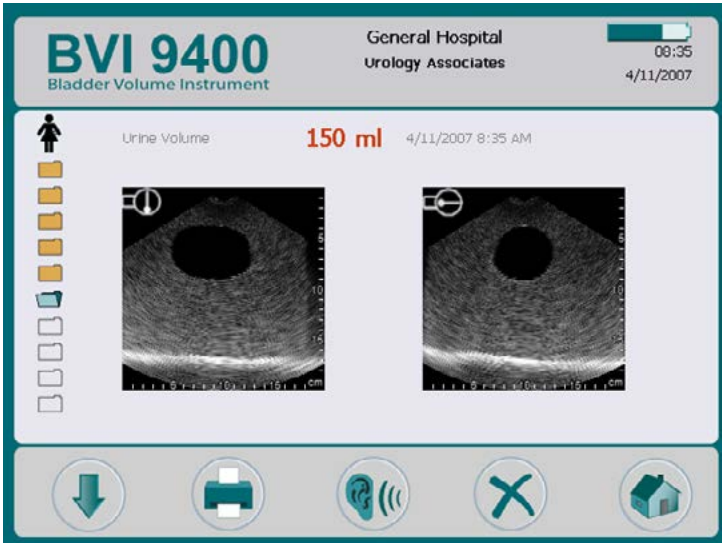
Button	Function
	RECORD: Press to record a voice annotation (up to 15 seconds long). When the (10) folders are full the first recorderd folder will be overwritten.
	PRINT: Press to print exam results.
	PLAY: Press to listen to a previously recorded voice annotation.
	REVIEW SCREEN: Press to open the Review screen. This button is inactive if there are no previously saved exams to review.
	HOME: Press to return to the Home screen.

Review Screen

The Review screen (Figure 16) opens when you select a saved exam (yellow folder icon) to review.

The display shows the ultrasound images associated with the selected exam. A green open-folder icon indicates which exam is being viewed. While reviewing saved exams, the buttons below the display allow you to print, replay, or delete exam data.


Figure 16. Review Screen





Review Screen Buttons

Button	Function
	SELECT: Press to select the next exam in the list.
	PRINT: Press to print the results for the currently selected exam on the onboard printer. While printing is in progress an hourglass icon appears on the display.
	PLAY: Press to play a previously recorded voice annotation. The button is inactive if no voice annotations have been saved.
	DELETE: Press to delete the currently selected exam.
	HOME: Press to return to the Home screen.

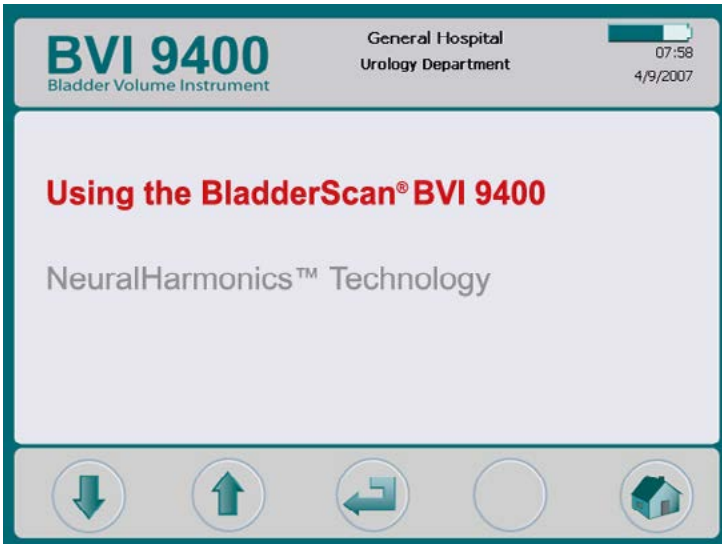
Tutorial Screen

To open the Tutorial Screen (Figure 17) press the  button from the Home screen (Figure 13).





The Tutorial screen presents a menu of training modules. To select a title, press either the  or  button until the desired title is highlighted (red). Press the ENTER button to go to the Video Viewing screen.

NOTE: The SCAN button (on the probe) is disabled during module playback.



Figure 17. Tutorial Screen



Tutorial Screen Buttons

Button	Function
	SELECT NEXT: Press to select the next title.
	SELECT PREVIOUS: Press to move back to the previous title.
	ENTER: Press to open the Video Viewing screen.
--	No function
	HOME: Press to return to the Home screen.

Video Viewing Screen




To view the video press the  button on the Tutorial screen (Figure 17), then the  button on the Video Viewing screen (Figure 18).

NOTE: The SCAN button is disabled during video playback.


Figure 18. Video Viewing Screen




Video Viewing Screen Buttons

Button	Function
-	No function.
	PLAY/PAUSE: Press to start video playback. Press to pause. Press again to resume playback.
	BACK: Return to the Tutorial screen.
-	No function.
	HOME: Press to return to the Home screen.

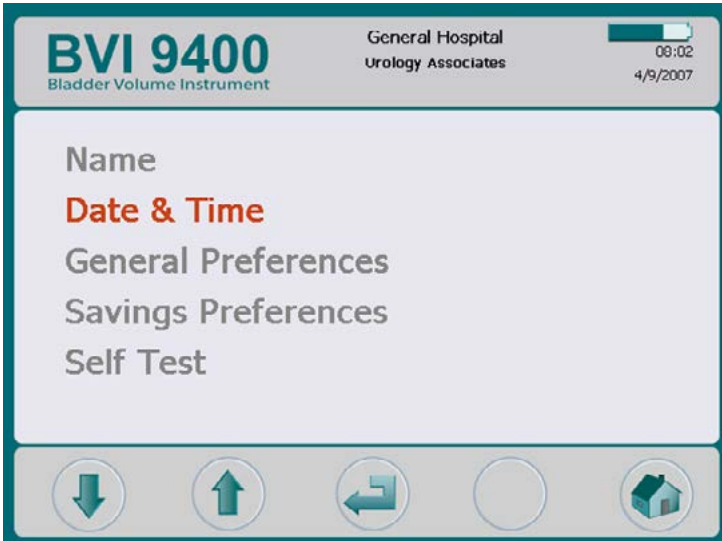
Settings Screen

To open the Settings screen (Figure 19), push the SETTINGS button  on the Home screen.





The display presents a list of user-configurable settings: Name, Time & Date, General Preferences, Savings Preferences, and Self-Test. Use the Up/Down arrows to move through the list of setup options. To select an option, press the ENTER button .

NOTE: When the Settings screens are open, the SCAN button (on the probe) is disabled.

Figure 19. Settings Screen Start Menu



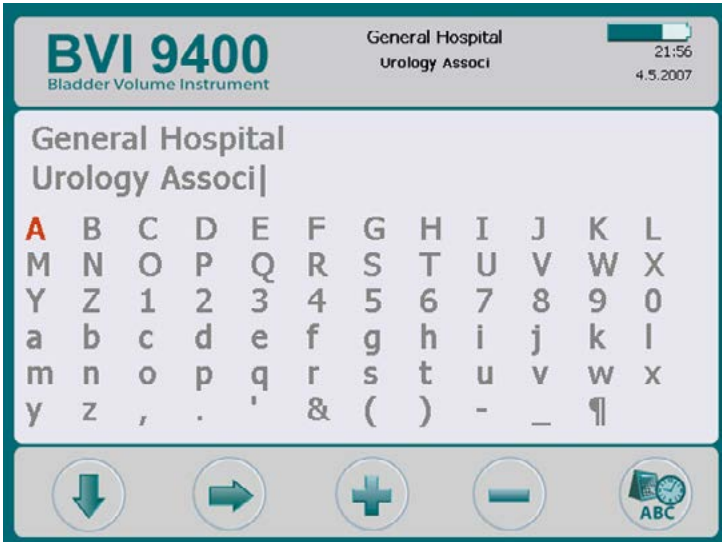
Settings Screen Buttons

Button	Function
	SELECT NEXT: Press to select the next setting in the list.
	SELECT PREVIOUS: Press to select the previous setting in the list.
	ENTER: Press to select the highlighted setting.
-	No function.
	HOME: Press to return to the Home screen.






Name Screen

This screen allows you to select the appropriate alpha-numeric characters for entering your healthcare institution's name.

Figure 20. Name Screen



Name Screen Buttons

Button	Function
	Press to move down in the grid.
	Press to move to the right in the grid.
	Press to add the highlighted character.
	Press to delete one character.
	HOME: Press to return to the Home screen.





Date & Time Screen

This screen allows you to adjust the date and time.

NOTE: If the time display is set to show a 24-hour clock, the hour units are 0 - 23. If the clock is set to show a 12-hour clock, the hour units are 1 AM - 12 AM Noon and 1 PM - 12 PM Midnight.

Referring to the example shown in Figure 21:

To change the time from 8:17 AM to 11:30 AM:

- 1. Press the  button until the 8 is highlighted.
- 2. Press the  button 3 times until the time digits display **11:17 AM**.
- 3. Press the  button until the **17** is highlighted.
- 4. Press the  button repeatedly until the minutes display **30**.

The time setting is now 11:30 AM.







- 5. Press the SETTINGS button  to save this entry and return to the Setup screen.

Figure 21. Date & Time Screen



Date & Time Screen Buttons

Button	Function
	Press to move back one changeable unit.
	Press to move forward to the next changeable unit, in this case: hours, minutes, AM/PM, month, day, year.
	Press to add and/or toggle digits as appropriate (hours, minutes, AM/PM, month, day, year).
	Press to subtract or toggle digits as appropriate.
	Press to save the current date & time setting and return to the Setup screen.

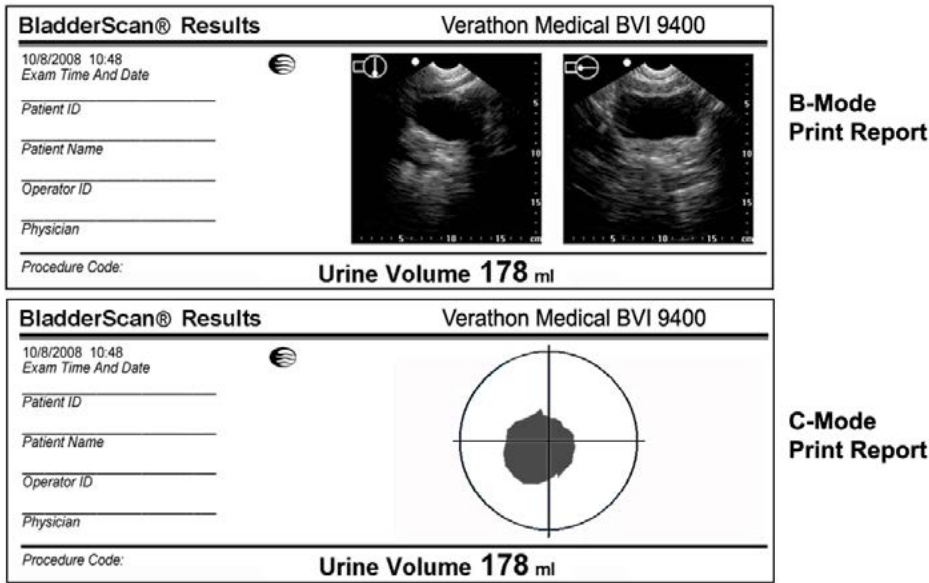
General Preferences Screen

This screen displays a list of available settings and their current values.

Available settings:

- **Language:** English (default), Chinese Simplified, Chinese Traditional, Czech, Danish, Dutch, Finnish, French, German, Greek, Italian, Hungarian, Japanese, Korean, Norwegian, Portuguese (European), Spanish, Swedish, Turkish.
- **Date Format:** mm/dd/yyyy; dd.mm.yyyy; yyyy-mm-dd.
- **Time Format:** 12-hour or 24-hour.
- **Calibration Warning:** On (default), Off. When “On” is selected, a calibration warning will appear in the display header when the device requires calibration.
- **Print Report Type:** (Figure 22) Toggle between C-mode images (bladder in crosshairs) and B-mode images (image of bladder and abdominal space below probe).

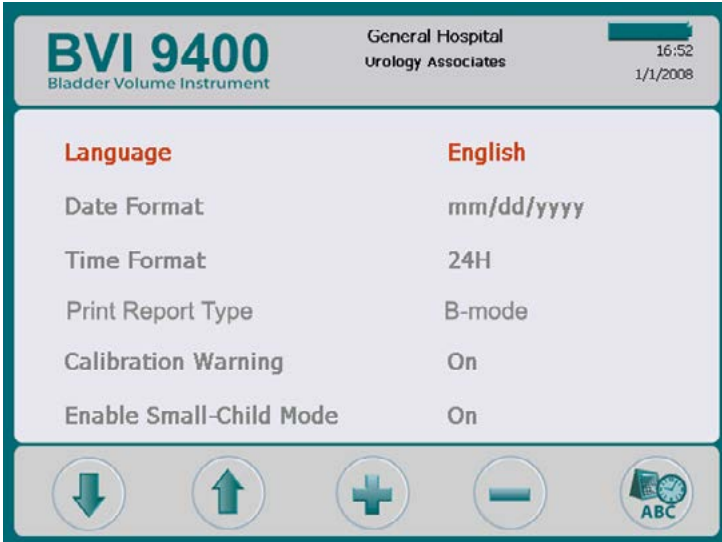
Figure 22. B-Mode and C-Mode Print Reports



- **Enable ScanPoint:** On (default), Off. Select “Off” to disable ScanPoint.
- **Enable Small-Child Mode (SCM):** On (default), Off. Select “Off” to disable small child mode.

NOTE: If use of the small child mode is rare in your practice, you may want to turn that option off.

Figure 23. General Preferences Screen



General Preferences Screen Buttons

Button	Function
	SELECT PREVIOUS: Press to select the previous setting in the list.
	SELECT NEXT: Press to select the next setting in the list.
	For settings with a list of options, press to select the next option.
	For settings with a list of options, press to select the previous option.
	Press to save the current options and return to the Setup screen.

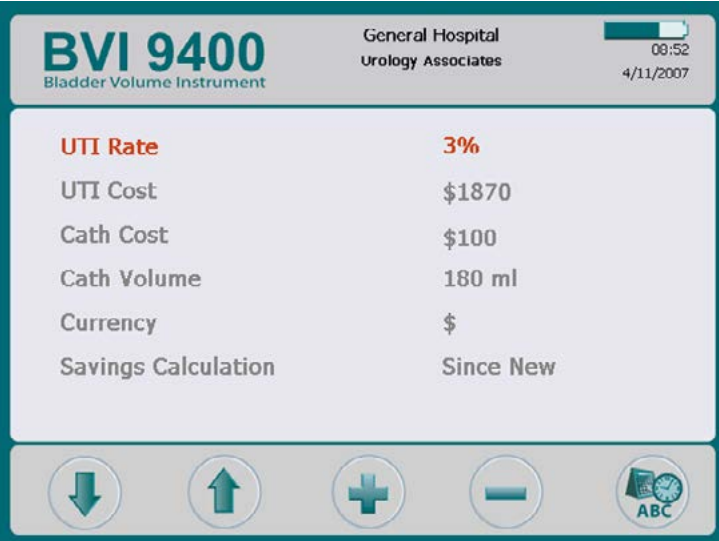
Savings Preferences Screen

To open the Savings Preferences screen (Figure 24), select Savings Preferences from the Settings screen menu (Figure 19). Use this screen to enter base values used to calculate the savings to your organization from using the BladderScan BVI 9400 rather than catheterization.

Preferences lists and options:

- UTI Rate: 1% to 100% in increments of 1%
- UTI Cost: \$10 to \$10,000 in increments of \$10
- Catheter Cost: \$1 to \$1000 in increments of \$1
- Catheter Volume: 20 ml to 1000 ml in increments of 20 ml
- Currency: \$ / € / £ / ¥
- Saving Calculation: Since New, Since 1/1/2006, Reset Now, Print Since New, Print Recent, Hide Savings

Figure 24. Savings Preferences Screen



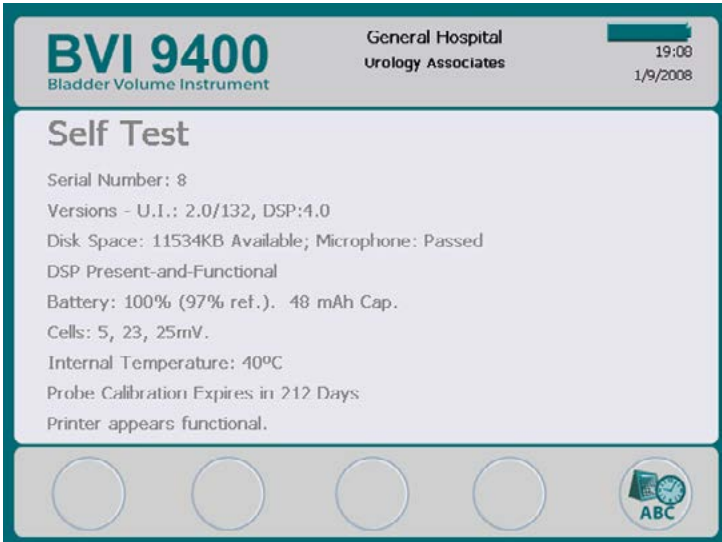
Savings Preferences Screen Buttons

Button	Function
	SELECT PREVIOUS: Press to select the previous setting in the list.
	SELECT NEXT: Press to select the next setting in the list.
	For settings with a list of options, press to select the next option.
	For settings with a list of options, press to select the previous option.
	Press to save the current options and return to the Setup screen.

Self-Test Screen

To open the Self-Test screen (Figure 25), select Self-Test from the Settings menu (Figure 19). The Self-Test screen will open and testing begins automatically.

Figure 25. Self-Test Screen



Self-Test Screen Buttons

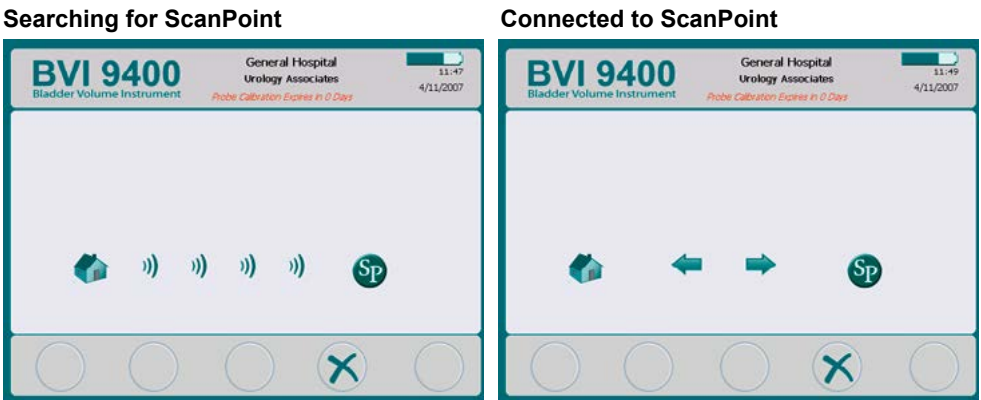
Button	Function
--	No function.
--	No function.
--	No function.
--	No function.
--	No function.
	Press to return to the Setup screen.

ScanPoint Screen

NOTE: Useful if optional ScanPoint® software is installed on a PC.

To open the ScanPoint screen, press from the Home screen (Figure 13). The ScanPoint screens display information about the status of the link between the BladderScan instrument and the ScanPoint host computer (Figure 26).

Figure 26. ScanPoint Screens



ScanPoint Screen Buttons

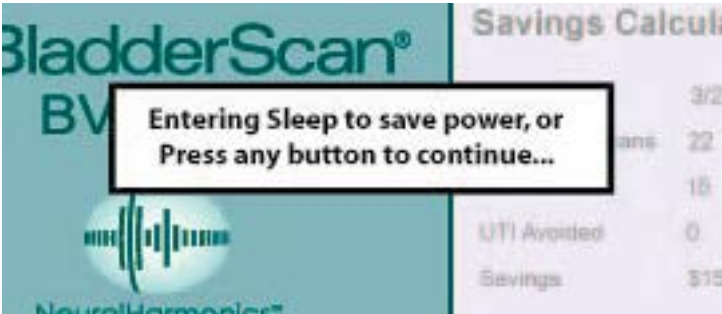
Button	Function
--	No function.
--	No function.
--	No function.
	CANCEL: Cancels the current action and ends communication with the ScanPoint host computer.
--	No function.

Sleep Mode

To conserve battery power, the BladderScan BVI 9400 shuts itself down automatically when not in use (goes into “sleep”).

The sleep mode helps preserve battery power. After four minutes of idle time, a sleep mode alert message displays for 15 seconds (Figure 27). While the message is displayed, press any button to keep the console awake and dismiss the message. After 15 seconds, the console goes to sleep. To wake the instrument from sleep, simply press the power button.

Figure 27. Sleep Mode Screen



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 BVI 9400).
- 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 is 1/4 or less full, replace the battery with a freshly-charged battery before proceeding. Place the discharged battery in the battery charger to recharge.

- 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 BVI 9400 on:

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




Measuring Bladder Volume

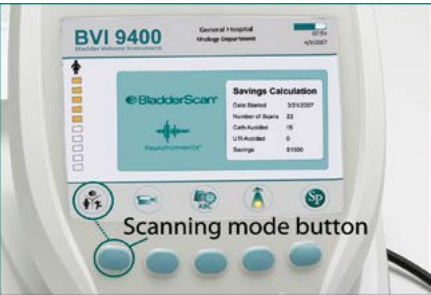
1. Turn on the BVI 9400.

Turn on the BVI 9400 by pressing the On/Off button.



2. Select the exam mode.

-  Select to scan a patient with height less than 48 inches (122 cm) tall and weight less than 60 lbs (27 kg).
-  Select to scan a female patient who has not had a hysterectomy.
-  Select to scan all other patients



3. With the patient supine apply gel.

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

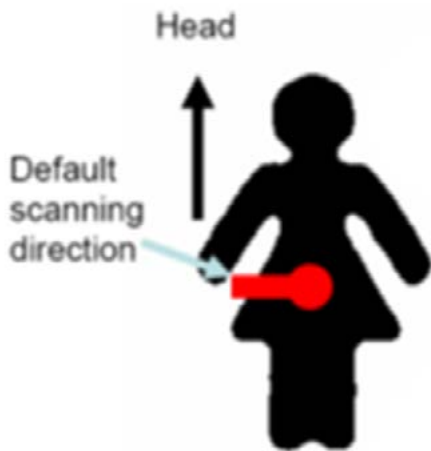


4. Palpate the patient's symphysis pubis (pubic bone).

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.

5a. Orient the probe during placement.

Stand to the right of the patient. The probe handle should point toward you.



5b. Aim toward the bladder.

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.

For maximum accuracy, be sure to hold the Probe motionless while scanning.



6. Press the SCAN button.

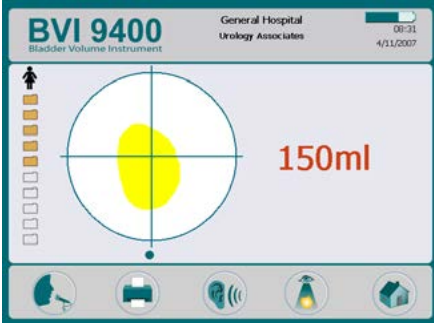
Press the SCAN button, located on the underside of the probe. As the scan progresses, sections of the bladder will appear on the console screen. When you hear the end-scan tone, the scan is complete.

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



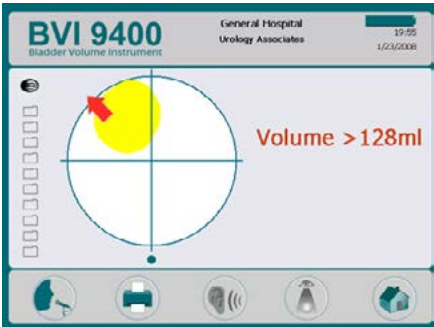
7. Verify the scan.

If the scan is "on target" the probe will display eight arrows. On the console display, the bladder will appear in the center of the crosshairs.



7a. Re-aiming.

If the scan is "off-target" the probe will show an arrow (solid or flashing) indicating the direction to move the probe to be "on target." If the arrow is solid, it means you are slightly "off target" and it is strongly recommended that you re-aim and re-scan. If the probe shows a single flashing arrow, you must re-aim and re-scan. In either case, the bladder will not be in the crosshairs.



7b. To re-aim.

Note that the crosshairs correspond to the anatomy of the patient as follows:

- The small dot at the base of the crosshairs represent the feet of the patient.
- The top of the crosshairs represents the patient's head.
- The upper left quadrant represents the patient's right shoulder.

This orientation should help you in re-aiming the probe to capture the complete bladder fully in the image cone.

7c. Pubic bone.

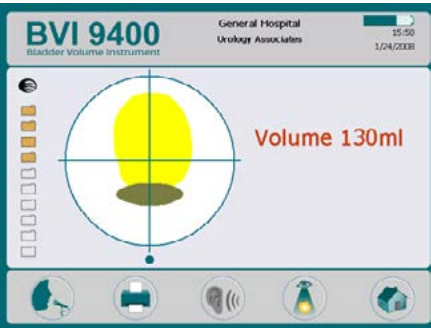
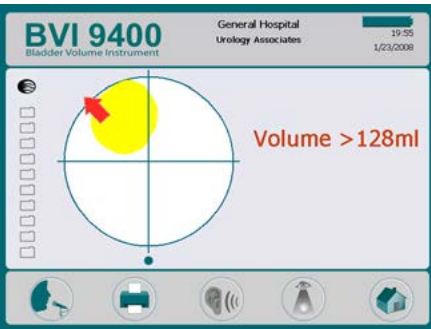
You may also see a display indicating that the pubic bone is inside the image cone. If this occurs, you may want to re-aim and re-scan. Although the bladder may be shown as centered in the image cone, and your measurement may be complete, there is a possibility that the pubic bone is obscuring part of the bladder. By re-aiming and re-scanning you can ensure you have captured the bladder fully inside the image cone.

8. Save, review, and print exam results.

- **To save the exam** you must annotate it.
- **To annotate**, press and release the RECORD button on the console. When you see the RECORD button icon change to a STOP button icon, record the patient information by speaking into the probe microphone. When the hourglass icon disappears, press the LISTEN button to replay the annotation.
- **To review** the scan images, press the REVIEW button. (You must first save the exam before you can review it).
- To print exam results via the onboard printer, press the PRINT button.
- **To perform another exam**, press the HOME button.

9. Finish the exam.

Once you have completed the scan, wipe the ultrasound gel off the patient and the probe. For ScanPoint® subscribers, logging onto ScanPoint automatically transfers and saves your annotated exams to your Windows® computer.



Additional Scanning Tips

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

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

Volume reading will be affected by:

- The presence of scar tissue
- The presence of a catheter
- Overly obese patients

NOTE: The symbol (>) also occurs anytime two sides of the bladder wall are outside the image cone that is with a relatively large bladder or very full bladder, especially in a skinny subject (where the scanhead is naturally close to the bladder because there is so little in between.) So, in many cases there will be no operator error when this symbol occurs; it's just the result of a big/full bladder that is larger than the ultrasound scan.

With obese patients, lift as much abdominal adipose tissue out of the way of the instrument as possible. Apply more pressure to the BladderScan BVI 9400 instrument 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 probe and the patient's skin.
- 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).

Recording a Voice Annotation

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

The instrument can store ten scans with voice annotations, so you can perform multiple exams on your rounds. If you are using the optional ScanPoint® with QuickPrint software, you can upload saved exams to your PC. (Refer to the ScanPoint with QuickPrint user's manual for more information).

Record a voice annotation.

- 1. Press the RECORD button (microphone). A STOP button is now displayed.
- 2. The microphone is located just above the aiming display on the probe. Hold the microphone approximately 6 inches (15 cm) from your mouth when you are recording the annotation, 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.

- 3. When you have finished your annotation, press the STOP button. An hour glass will be displayed while your annotation and exam are updated and stored. After the annotation has been saved, to listen to your annotation, press the LISTEN button.

If you are not satisfied with the recording, press RECORD again to record a new annotation.




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.
- 4. When you are satisfied with your recording, wait while the instrument automatically accepts and stores the recording with the exam results. The volume displayed on the LCD screen disappears, and the instrument is ready to perform another measurement.
 - 5. If you are using the BVI 9400 in conjunction with the optional ScanPoint® with QuickPrint software, you can view exam results and annotations on your PC. Please refer to the ScanPoint with QuickPrint user’s manual for more information.



Deleting a Saved Exam

Saved exams are indicated by yellow folder icons along the left edge of the display. To delete a saved exam:

- 1. Open the Review Screen. (From the Home Screen press )
- 2. Press the  button until the desired exam is highlighted (blue).
- 3. Press the  button to delete the exam.

Printing

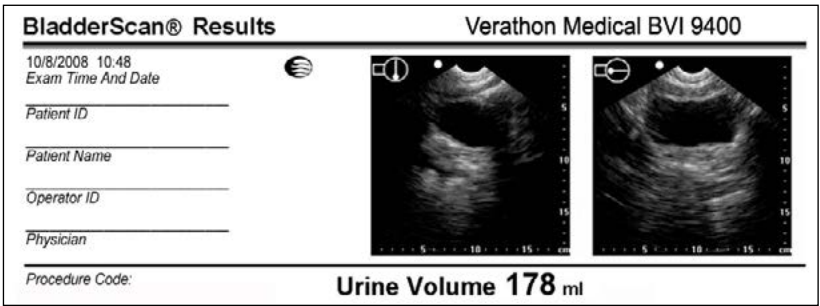
You can use the onboard printer on the BVI 9400 to print the ultrasound images captured during the scan (Figure 28 is an example).

To print exam results press the PRINT button immediately following the exam.

Entering Additional Information

The label provides fields for Patient ID, Patient Name, Operator, and Physician. This information must be entered manually.

Figure 28. Exam results printout using the onboard printer



NOTE: If the facility name, date, and time have not been set, those lines will be skipped on the printout.

The BVI 9400 prints on thermal paper, which fades over time. For maximum storage life, Verathon® recommends that you photocopy the printout.

Histogram of Cost Savings

Each volume measurement from a completed scanning procedure is stored in the memory of the BladderScan BVI 9400 in one of eleven volume ranges (each with a 100 ml increment). This data is analyzed and can be displayed on the BVI 9400 at any time. The Cost Savings screen lists: Date Started, Number of Scans, Cath Avoided, UTI Avoided, Savings.


Cost savings criteria

Cost savings are based on the following criteria:

- **Catheterizations avoided:** Urinary catheterization is deemed unnecessary. Thus, by using the BVI 9400, these catheterizations are avoided. The default setting (for volume below which catheterization is unnecessary) is 200 ml.
- **UTIs avoided:** Studies indicate that a certain percentage of catheterizations lead to urinary tract infections (UTIs).

By avoiding unnecessary catheterizations, the resulting UTIs are thereby avoided. The default setting (for percent of catheterizations leading to UTIs) is 3%.

- **Associated UTI costs:** Literature suggests that the additional costs associated with treating UTIs amounts to \$1875.00 per patient infection. The default setting is \$1870.00.
- **Cost of catheter kits:** The default setting is \$3.00 per kit.
- **Total cost savings from using the BVI 9400 =**
(Catheterizations avoided x catheter costs) + (UTIs avoided x UTI costs)

NOTE: The default settings can be customized to reflect the rates and costs at your facility by selecting from the Home screen:  (SETTINGS) > SAVINGS PREFERENCES. See Savings Preferences Screen for more information on customizing savings preferences.

Cleaning and Maintenance

Cleaning the BladderScan BVI 9400

1. Use a 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. Alternatively, 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 the 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.

Regular Inspections and Maintenance

Verathon recommends that the BVI 9400 be certified by an authorized BladderScan Service Center once a year. Certification service includes comprehensive inspection and testing of the instrument to ensure accurate performance in clinical use. For more information, please contact your authorized BladderScan Service Center, your local BladderScan distributor, or Verathon Customer Care Department. Please refer to the contact information at the beginning of this manual.







NOTE: ScanPoint® Online customers can maintain device certification via the Internet by accessing their ScanPoint® account. For more information about using ScanPoint Online, please refer to the ScanPoint with QuickPrint user's manual.

Weekly inspections

Once a week, you should inspect the probe and cable 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 console, probe, or the cable that links the console and the probe, must be referred to your authorized BladderScan Service Center, your local BladderScan distributor, your local Verathon representative, or the Verathon Customer Care Department.

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

Using the Built-in Self-Test Utility

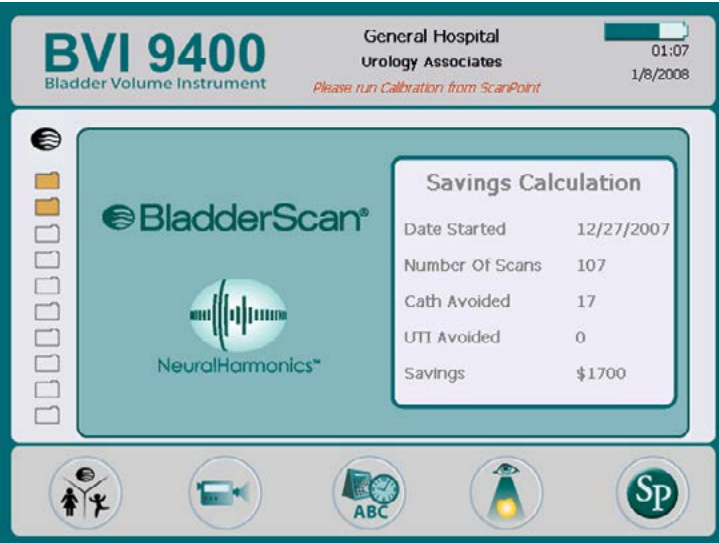
- The BVI 9400 can perform a number of self-diagnostic tests. To access the Self-Test utility:
1. From the Home screen, press the SETTINGS button: 
 2. When the Settings screen opens, press the  or  buttons until SELF TEST is highlighted (red), then press  to open the Self-Test screen.
 3. When the Self-Test screen opens, testing begins automatically with the display providing status and results.
 4. When the test is complete, press the SETTINGS button  to return to the Settings screen, then press the HOME button  to return to the Home screen.
 5. If any test results were failed or abnormal, contact your authorized BladderScan representative, or contact the Verathon Customer Care Department.

Calibrating the BladderScan BVI 9400 Using the ScanPoint System

You must periodically calibrate your BladderScan BVI 9400 to make sure your instrument is providing the most 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 measurements may be compromised.

When calibration is required, a warning appears in the display header (Figure 29).

Figure 29. Calibration Warning



If you do not have ScanPoint® with QuickPrint, you must send your instrument to an authorized Verathon® service center for calibration. Contact your Verathon Customer Care Center for more information. For contact information, please see the front of this manual.

Self-calibration

Self-calibration requires the ScanPoint with QuickPrint system and a calibration kit for the BVI 9400 (P/N 0620-0340). For instructions on software requirements and installation, please refer to the ScanPoint with QuickPrint User's Manual.

The entire calibration process takes approximately 15 minutes. ScanPoint Online plans allow for calibration of the instrument as often as you like. You do not need to wait until the next scheduled calibration date. However, at a minimum, you must calibrate the instrument once every 12 months.

Device Repair

The BladderScan BVI 9400, probe, and battery charger/wireless hub are completely sealed. There are no user-serviceable components. 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.

Premium warranty customers have access to a loaner unit and free shipping options which vary according to plan.

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

Unit Disposal


The BladderScan BVI 9400 and related devices may contain lead, mineral oils, batteries, and other environmentally hazardous materials. When the BladderScan BVI 9400 has reached the end of its useful service life, return the device, battery charger/wireless hub, and related accessories to a Verathon Service Center for proper disposal. Alternatively, follow your local protocols for hazardous waste disposal.

Troubleshooting

Help Resources


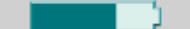


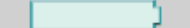






Verathon® provides an extensive array of customer service resources, described in the table below.

You can obtain copies of this manual, quick reference cards, and clinical studies by visiting the Verathon Web site at www.verathon.com or by contacting your Verathon representative.

Resource	Description
BladderScan BVI 9400 In-service CD	CD included with your BVI 9400 that shows how to use the BladderScan.
Onboard training modules	Training modules installed on your BladderScan are available by pressing the  button from the Home Screen. Available titles include: Using the BladderScan BVI 9400 and NeuralHarmonics® Technology.
BladderScan BVI 9400 Quick Reference Cards	Summary of procedures for using the BladderScan system.
Clinical Studies	Scientific papers on BladderScan use.
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• Provides customers a HIPAA compliant solution for data storage.• Automatic software upgrades.• Access to real-time troubleshooting from Verathon.
Premium Warranty	A Verathon device warranty plan that provides all the benefits of ScanPoint Online (preceding paragraph) and also: <ul style="list-style-type: none">• All repairs performed free of charge.• Instrument insurance: A perpetual warranty against outdated technology with free upgrade/ replacement when your device is no longer manufactured.• Free loaner program.• Free shipping.
Verathon Web site	www.verathon.com includes many in-service training resources. From the Verathon Home page, select “BladderScan.” On the BladderScan page, select the appropriate model (BVI 9400) and then click on the "Product Materials" tab.
Phone support	In North America, call: 1.800.331.2313. International customers, please refer to the list of Customer Care resources found at www.verathon.com/ContactUs.htm .

Icons on the BladderScan Console

The following icons may appear on the instrument's LCD screen.

Symbol	Meaning
Battery power level:	
	Indicates a fully-charged battery.
	Indicates a battery 50% to 75% charged.
	Indicates a battery 25% to 50% charged.
	Almost depleted. Can power a few more scans.
	Replace immediately.
	(Green Solid arrow) The bladder is contained within the image cone (cone-shaped area in which the probe transmits ultrasound waves), but not centered. You may be able to obtain a more accurate measurement by re-aiming the probe in the direction indicated by the arrow.
	(Red Solid arrow) If the condole shows a red arrow you must re-aim and re-scan.
	The patient is a small child with height less than 48 inches (122 cm) tall and weight less than 60 lbs (27 kg).
	The patient is a female patient who has not had a hysterectomy.
	Select to scan all other patients.
	The bladder is too large to be contained within the image cone, or the bladder contains more than 999 ml of urine.

Diagnosing Problems

Instrument Does Not Turn On

If the instrument does not turn on, this is usually due to a dead or discharged battery and can be remedied by replacing the dead battery with a charged battery. Check the battery icon in the upper right corner of the LCD display. If the battery icon does not display any power segments, replace the battery.

When the battery charge is too low to allow normal operation (but not too low to permit operation of the internal circuitry) the device displays the following message:

BATTERY CHARGE LEVEL IS TOO LOW FOR INSTRUMENT OPERATION. RECHARGE BEFORE NEXT USE

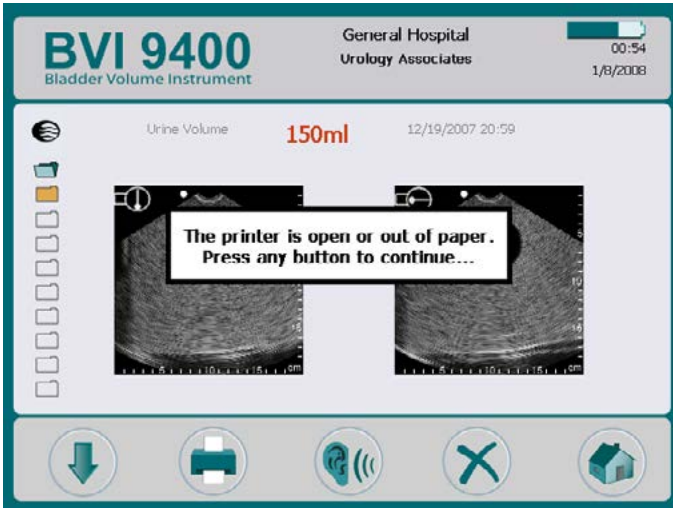
In this case, the battery must be recharged or replaced with a charged one.

Printer Problems

No paper

The BladderScan BVI 9400 senses the presence of paper and automatically displays this image when the printer is out of paper (Figure 30).

Figure 30. Printer Out of Paper Screen



For instructions on loading paper, review the onboard training module or refer to the section in this manual titled, *Load a Roll of Thermal Paper*.

Too hot

The BVI 9400 displays the message TOO HOT if the print head overheats. In this case, turn off the BVI 9400 immediately. This condition may be the result of a paper jam.

Clearing a paper jam

If the paper will not advance through the printer, open the printer door on the back of the console and clear the paper jam.

Warranty

Verathon Inc. warrants the BladderScan BVI 9400 against defects in material and workmanship as long as it is covered by the Premium Warranty.

Pursuant to this warranty, a service center authorized by Verathon® will repair or replace units that prove to be defective during the warranty period.

This warranty 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 in this warranty and should be used in conformance with Verathon product specifications.

For further details, consult your Premium Warranty. Warranty 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.

Certain regional authorities disallow certain limitations on applied or implied warranties. The purchaser, user, and patient should consult applicable 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 instruments as of July 2013. 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 BVI 9400 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.

Parts and Accessories

BladderScan BVI 9400 System Components

The following components are included with your BladderScan BVI 9400 system.

Part Number	Description
0570-0190	Console - Controls the transmission and reception of ultrasound to measure a patient's bladder volume
0570-0188	Probe - Transmits and receives ultrasound to measure a patient's bladder volume
0570-0351	Probe (newer) - Transmits and receives ultrasound to measure a patient's bladder volume
0570-0193	Battery Charger/Wireless Hub
0400-0066	Rechargeable Batteries (2 included)
0800-0319	Roll of Thermal Paper: Properly-sized paper for the onboard Printer.
0620-0340	Calibration Kit (optional - requires ScanPoint® with QuickPrint software)
0800-0322	Medical Cart (optional)
0810-0201	Universal Accessory Basket for Medical Cart (optional)
0900-1606	BladderScan BVI 9400 User's Manual (on In-service CD)
0900-1500	BladderScan BVI 9400 In-service CD (with user's manuals, video tutorial, and quick reference cards)
0900-1601	ScanPoint with QuickPrint User's Manual (on In-service CD)
0900-1446	Quick Reference Cards - Demo/Use
0900-1447	Quick Reference Cards - Calibration

To order any of the above parts, contact your authorized Verathon sales representative or contact the Verathon Customer Care Department at 1.800.331.2313.

Product Specifications

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:

Specification	Standard
International Electrotechnical Commission	EN/IEC 60601-1 Amendments 1 and 2 and EN/IEC 60601-1-2 (EMC)
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® with QuickPrint Help menu (select PRIVACY AGREEMENT).

Electromagnetic Effects

There are no restrictions on the use of BladderScan BVI 9400 due to its electromagnetic characteristics. Both the emissions from the 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 55011:2009 for Group 1, Class A equipment (per EN/IEC60601-1-2, 36.201.1.7).

BladderScan BVI 9400 is suitable for use in industrial, scientific, and medical (ISM) environments, and in domestic environments under the jurisdiction of a healthcare professional. An indication of adverse electromagnetic effects from BladderScan BVI 9400 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 BVI 9400 will operate normally in the proximity of other potential interference sources, and has 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.

Bluetooth® wireless technology

- The Bluetooth technology used in the BladderScan BVI 9400 is compliant with:
- Bluetooth Specification as defined and approved by The Bluetooth Special Interests Group.
 - Logo certification with Bluetooth wireless technology as defined by The Bluetooth Special Interest Group.

BladderScan BVI 9400 Instrument Specifications

For technical performance assessment in an acoustic laboratory, the probe cannot be immersed in water.

Item	Specification
Input	Lithium-ion battery pack. Verathon® P/N 0400-0066.
Output	No load to full load at rated voltage. Refer to unit label.
Insulation	The power supply is Class I with basic insulation to each terminal.
Transient overvoltage	Category II
Weight	5.2 lb (2.36 kg) (with battery)
Display	13.36cm W x 10.13cm H (5.26" W x 3.99" H) (640 x 480 pixels, 120 dpi)
Integrated printer	Thermal label printer
Language	English, Chinese Simplified, Chinese Traditional, Czech, Danish, Dutch, Finnish, French, German, Greek, Italian, Hungarian, Japanese, Korean, Norwegian, Portuguese (European), Spanish, Swedish, Turkish

Ultrasound Output Parameters

Item	Specification
Maximum ultrasound I _{spta} (Spatial Peak Temporal Average derated) during a scan	≤ 5.0 m W/cm2
Maximum ultrasound I _{sppa} (Spatial Peak Pulse Average derated) range during a scan	≤ 60.0 W/cm2
Maximum MI (Mechanical Index)	0.95 max
TIS/TIB/TIC range	0.0 - 4.0
Transducer diameter	13 mm (0.512 inches)
Transducer resonant frequency	3.0 MHz and 1.74 MHz
Transducer bandwidth	75% at 10 dB
Time from 3D scan initiation to result display	< 3 seconds
Penetration depth (in normal North American patient)	≥ 15 cm

Accuracy Specifications

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

Specification	Description
Bladder volume accuracy	± 15%, ± 15 ml (on a Verathon tissue-equivalent phantom)
Bladder volume range	0 - 999 ml (0-200ml in small child scan mode)

BladderScan BVI 9400 Operating Conditions

The BladderScan BVI 9400 is designed to function properly within the following specifications:

Condition	Description
Use	Indoor
Ambient temperature range	+10 - +40° Celsius (+50 - +104° Fahrenheit)
Atmospheric pressure range	700 hPa - 1060 hPa
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)

BladderScan BVI 9400 Storage Conditions

The BladderScan BVI 9400 is designed for storage under the following conditions:

Condition	Description
Storage	Indoor
Ambient temperature range	-20 - +60° Celsius (-4 - +140° Fahrenheit)
Atmospheric pressure range	500 hPa - 1060 hPa
Relative humidity	20% - 95% non-condensing

BladderScan BVI 9400 Displays, Controls, and Indicators

The BladderScan BVI 9400 provides the following controls, connectors, and features:

Instrument Buttons

POWER ON/OFF, BRIGHTNESS (▲/▼), VOLUME (▲/▼). SCAN and RECORD buttons are on the probe. Five buttons below the console LCD vary depending on current instrument mode as follows:

Screen/Mode	Active Buttons
Splash Screen Screen(s) that display during boot-up to show boot-up process is proceeding properly.	None.
Home Screen Appears when the instrument is first turned on.	POWER, SCAN: opens Aim/Scan screen, (1) PATIENT TYPE: toggle between three modes: small child, female with uterus, all other patients, (2) TUTORIAL: opens tutorial screen, (3) SETUP: opens Setup screen, (4) REVIEW: opens the review screen, (5) ScanPoint®: transmits saved exams to ScanPoint.
Scan Screen Appears when the operator presses and holds the SCAN button.	POWER: No function SCAN: Press to take a scan. Buttons (1) - (5): No action.
Results Screen Appears when the operator releases the SCAN button (after aiming).	POWER, SCAN: opens Aim/Scan screen, (1) RECORD: press to record, release to replay, (2) PRINT: print to onboard label printer, (3) PLAY: press to play voice annotations, otherwise, no function, (4) REVIEW: opens review screen if a voice annotation has been recorded. Otherwise, no function, (5) HOME: return to Home screen.
Review Screen Review, replay, print, or delete saved exams	POWER, SCAN, (1) NEXT: select next exam in memory, (2) PRINT: print to onboard printer, (3) PLAY: replay voice annotation for currently selected exam, (4) DELETE: delete currently selected exam, (5) HOME: return to Home screen.
Tutorial Screen View the menu of training modules.	POWER, (1) Skip back one chapter, (2) Play/Pause, (3) Skip forward one chapter, (4) No function, (5) Home (return to Home screen).
Video Viewing Screen The video viewing screen.	POWER, (1) No function, (2) Play/Pause, (3) Return to Tutorial screen, (4) No function, (5) Home (return to Home screen).

Screen/Mode	Active Buttons
Settings Screen Start screen for editing clinic name, date & time, general preferences, savings preferences, and self-test options.	POWER, (1) Select next setting in list, (2) Select previous setting in list, (3) Enter (proceed to the selected screen), (4) No action, (5) Home (return to Home screen). Settings: Name, Date/Time, General Preferences, Savings Preferences, Self-Test.
Name Screen Displays alpha-numeric characters for entering information.	POWER, (1) Move down, (2) Move right, (3) Add currently selected character, (4) Delete currently selected character, (5) Return to main setup screen.
Date & Time Screen Allows the user to set the date and time	POWER, (1) Move forward to next changeable unit, (2) Move back to previous changeable unit, (3) Add/toggle units as appropriate, (4) Decrease/toggle units as appropriate, (5) Save current date/time entries and return to main setup screen.
General Preferences Screen Set preferences for language, time and date format, time zone	<p>POWER, (1) Select next setting in list, (2) Select previous setting in list, (3) Select next option/Enter, (4) Select previous option, (5) Home (return to Home screen).</p> <p>Preferences list and options: <u>Languages</u>: English (default), Chinese Simplified, Chinese Traditional, Czech, Danish, Dutch, Finnish, French, German, Greek, Italian, Hungarian, Japanese, Korean, Norwegian, Portuguese (European), Spanish, Swedish, Turkish. <u>Date format</u>: mm/dd/yyyy, dd.mm.yyyy, yyyy-mm-dd <u>Time</u>: 12-hour, 24-hour <u>Calibration Warning</u>: On (default), Off. When "On" is selected, a calibration warning will appear in the display header when the device requires calibration. <u>Enable ScanPoint</u>: On (default), Off. Select "Off" to disable ScanPoint. <u>Enable Small Child Mode (SCM)</u>: On (default), Off. Select "Off" to disable small child mode. <u>Print Report Type</u>: Print Recent, Print Since New</p>
Savings Preferences Screen Set preferences for UTI Cost Savings Tracking	<p><u>UTI Rate</u>: 1% - 100% in increments of 1% <u>UTI Cost</u>: \$10 - \$100,000 in increments of \$10 <u>Catheter Volume</u>: 20 ml - 1,000 ml in increments of 20 ml <u>Currency</u>: \$ / € / £ / ¥ Catheter Cost: \$1 to \$1000 in increments of \$1 <u>Savings Calculation</u>: Since New, Since 1/1/2006, Reset Now, Print Since New, Print Recent, Hide Savings.</p>
Self-Test Screen	POWER, (1) Scroll down, (2) Scroll up, (3) No function, (4) No function, (5) SETUP (Go back to setup screen).
ScanPoint® Screen (NOTE: Available only when ScanPoint is installed on instrument.)	POWER, (1) No function, (2) No function, (3) No function, (4) CANCEL, (5) No function.

Instrument Display

The instrument display is divided into three horizontal panes:




- The center pane is the main display area. The user interface for the center pane varies depending on device mode.
- The header pane displays the institution name, date, time, and a battery status icon.
- The footer pane displays icons that indicate button functions (described in the preceding table).

Screen/Mode	Display
Splash Screen	Screen(s) that display during boot-up to show boot-up process is proceeding properly.
Home Screen	Memory indicator, correct scanning technique graphic table.
Scan Screen	Appears when the operator presses the SCAN button. As bladder volume is calculated, the display refreshes and updates until the scan is complete.
Results Screen	Appears when a scan is complete. Prominently displays calculated bladder volume, patient type, available memory, and animated print icon (if print is pressed).
Review Screen	Review currently saved exams. Saved exam folders on left (currently selected folder is yellow) and ultrasound images associated with selected exam.
Tutorial Screen	Access to the tutorial video.
Setup Screen	Lists available setting screens.
Name Screen	A grid of alpha-numeric characters.
Date & Time Screen	The date and time.
Preferences Screen	List of available settings and their current values.
Self-Test Screen	Displays test progress and results.
ScanPoint® Screen	When ScanPoint with QuickPrint is installed on the instrument: Displays status information about the ScanPoint communication. For example, when uploading an exam it displays a progress bar.










BladderScan BVI 9400 Icons

The BladderScan BVI 9400 uses the following icons:

Instrument Icons



Icon	Description
	Empty Exam Folder
	Current Exam Folder
	Saved Exam Folder
	Tutorial Video
	Device Setup Options
	Review Saved Exams
	Enable ScanPoint Connection
	Start Recording Voice Annotation
	Stop Recording Voice Annotation
	Print Results
	Play Voice Annotation
	Return to Home Screen
	Move Down
	Delete or Cancel

Instrument Icons (cont'd)

Icon	Description
	Move Up
	Select / Enter Current Item in List
	Move Right
	Play Video
	Pause Video
	Add or Increase the Current Item
	Delete or Decrease the Current Item
	Button Not Available
	Mode Selection




Orientation Icons

Orientation markers are displayed in the B-mode images displayed in review and on the printed results.

Icon	Description
	Sagittal
	Transverse

Mode Icons

The current acquisition mode is indicated by one of the icons shown in the following table.

Icon	Description
	Male/Female (no uterus)
	Female
	Small Child

Battery Charger/Wireless Hub Specifications

The battery charger/wireless hub is powered from a standard wall outlet (adaptable to international power standards). The battery charger/wireless hub can charge two batteries simultaneously.

Operating Conditions

The following are proper operating conditions for the battery charger/wireless hub:

Specification	Description
Use	Indoor
Ambient temperature range	+5 - +40° Celsius (+41 - +104° Fahrenheit)
Atmospheric pressure range	700 hPa - 106o hPa
Relative humidity	30% - 75% non-condensing
Water resistance	Rated at IPX 0 (ordinary equipment without protection against ingress of water)
Computer connection	USB 2.0
Charger	Powered by a desktop DC power supply.
Input voltage	100 - 240 VAC RMS
Input frequency	50 - 60 Hz
Input current	1 Amp max
Input connection	2 wire IEC 60320 C7
Output	9v at 1 Amp
Insulation	Class II with double insulation
Fuses	250 VAC, 2A, quick acting
Testing	CSA 60950-1-03/UL 60950-1

Storage Conditions

Condition	Description
Storage	Indoor
Ambient temperature range	-20 - +60° Celsius (-4 - +140° Fahrenheit)
Atmospheric pressure range	500 hPa - 1060 hPa
Relative humidity	20% - 95% non-condensing

Battery Specifications







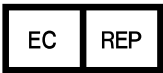






The BladderScan BVI 9400 is provided with two lithium-ion batteries. A battery icon on the instrument display is always present indicating how much power remains and when the battery needs to be changed. The user can change the battery whenever necessary. Removing a discharged battery and replacing with a fresh battery should not erase any saved exams or user settings. In the event any user settings change, reset them by following the instructions in the Getting Started section of this manual. Use only the battery charger provided with the BVI 9400. Any other battery charger may damage the battery pack.


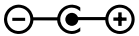











The batteries meet the following specifications:

Condition	Description
Battery type	Lithium-ion
Battery life	A fully charged battery can provide approximately 30 exams within a 24-hour period.
Charging time	Charging time offline will take no more than six hours from an empty battery to a full charge.
Rated capacity	5200 mAh
Normal voltage	11.1 V
Max charging voltage	12.6 V
Max weight	350 g
Width	3.11 in (79 mm)
Length	4.65 in (118 mm)
Thickness	0.91 in (23 mm)

Symbol Directory

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

Symbol	Meaning
	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 electrical equipment
	Type BF applied part with EN/IEC-60601-1.
	CE marked in accordance with the Medical Device Directive (MDD). Number refers to Notified Body.
	Canadian Standards Association (CSA) mark of certification to United States standards for electromedical equipment.
	Tested to Federal Communications Commission Requirements
	European Representative
	This unit is powered by a lithium-ion battery pack.
	Warning or Caution - consult accompanying documents. Read instructions before connecting or operating. Pay special attention.
	Manufacturer of the Product
	Manufactured date
	Serial #
	Temperature range -20° C to +60° C

Symbol	Meaning
	Energy Efficiency Level V
	Connector Polarity Mark
	TUV - Safety approval mark for components or subassemblies
	GS - German safety approval showing conformity with the German Equipment Safety Law
	Danger of electric shock
	Power
	USB
	Lithium-ion batteries in shipping package
	Flammable
	Fragile
	Limited power source
	Eljintek - Manufacturer of the switching power supply.
	Symbols assigned to GMN for CSA inspector audits.

Glossary

Term	Meaning
Aiming Arrows	Arrows that appear on the LCD screen to indicate the location of the bladder relative to the probe. Eight arrows displayed (aiming in different directions) means that you are on target.
Battery Charger/ Wireless Hub	The unit that charges the lithium-ion batteries that power the BladderScan instrument. It simultaneously receives and sends information from/to a BVI 9400 instrument within communication range.
BladderScan	The BladderScan instrument transmits ultrasound energy to produce an image of the patient's bladder and determine bladder volume.
Calibration Kit	Tools for calibrating your BladderScan instrument. The calibration container has a spiral-shaped target which provides a known reference shape. The calibration of the instrument to this known reference assures the accuracy of volume measurements.
Console	The main BladderScan device that provides operating controls and communicates with the user via images and text displays on an LCD screen.
Coupling Medium	A substance, such as ultrasound gel, that enhances the transmission of ultrasound waves.
Flashing Aiming Arrows on the Probe	Indicate the bladder is not inside the image cone and the probe needs to be redirected. The arrow shows the direction to move or tilt the probe to improve the measurement. Re-aiming is required.
HIPAA	Health Insurance Portability and Accountability Act, enacted by the US Congress in 1996.
Image Cone	During a bladder volume measurement, this is the cone-shaped area in which the probe transmits ultrasound waves.
Instrument	In this manual, refers to the BladderScan BVI 9400. The BladderScan instrument transmits ultrasound energy to produce an image of the patient's bladder and determine bladder volume.
LCD Screen	The LCD (liquid crystal display) screen on the BladderScan console that displays the bladder volume measurement, instrument status, and other exam settings and information.
NeuralHarmonics® Technology	A patent-pending ultrasound technology that sharpens accuracy and accelerates speed of three-dimensional ultrasound bladder volume measurements.
Probe	The handheld part of the BladderScan instrument that transmits ultrasound energy to the patient.

Term	Meaning
SCAN Button	Located on the underside of the BladderScan probe, this button is used to initiate the measurement.
ScanPoint® Imaging Technology	The software and online service provided by Verathon® that prints exam results, maintains patient records, displays ultrasound images from exams, downloads software updates, and calibrates the BladderScan instrument.
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 exams results.
Sleep Mode	When the BladderScan instrument shuts down to conserve energy. Press any button to turn on the instrument.
Solid Aiming Arrow	Indicates the bladder is inside the image cone but is not completely centered. The arrow shows the direction to move or tilt the probe to improve the measurement. Re-aiming is recommended but not required.
Supine Position	Refers to the patient laying on his/her back with their face upward.
Suprapubic	The area above the pubic bone.
Symphysis Pubis	The front of the pelvis where the pubic bones meet.
Ultrasonic	Involving ultrasound. Ultrasound is sound at frequencies above the range that can be heard by the human ear.

BladderScan® BVI 9400

Bladder Volume Instrument

User's Manual Addendum

IMPORTANT! The present User's Manual (BladderScan® BVI 9400 User's Manual - PN: 0900-2864-04-60) has the following changes as of July 28, 2013:

- Page 17: "Parts and Accessories"
Add new part: 0570-0351, Probe.
- Page 19: "Caution! Possible device damage! DO NOT remove the battery for any reason while the BVI 9400 is on. Doing so will damage the instrument. Always turn off the BVI 9400 before removing the battery."
This caution no longer applies. Due to a software change, the battery may be removed while the unit is on; however, the unit will lose power and if a scan was in progress it will be lost.
- Page 21: "Set the Date and Time The clock can hold the current time and date setting for up to five minutes after the battery is removed. Time and date settings will be lost if the battery is removed from the instrument for longer than five minutes."
This statement no longer applies as the clock is now backed up by a long-lasting lithium ion battery.
- Page 42: "Memory Optimization During Power Down"
This section no longer applies.
- Page 43: "Before You Begin the Exam: Note: Time and date settings will be lost if the battery is removed from the instrument for longer than five minutes."
This statement no longer applies as the clock is now backed up by a long-lasting lithium ion battery.
- Page 47: "Note The BVI 9400 is able to scan rapidly and repeatedly throughout the day. If however scans are taken quickly, in rapid succession, over a 30 minute period, some slowing in performance may be noticed. While this may occur rarely, it is normal for the instrument."
Due to a software change, the performance of the instrument as described above no longer applies.
- Page 57: "Disclaimer of Additional Warranties"
Date of "December 2007" should be amended to July 2013.
- Page 60: "BladderScan BVI 9400 System Components"
Add new part: 0570-0351, Probe.

BladderScan BVI 9400
BladderScan BVI 9600
AortaScan AMI 9700

User's Manual Addendum

Important! This addendum is effective as of November 1, 2013.

Scan Counter Feature

BladderScan® BVI 9000 Series instruments and AortaScan® AMI 9700 Aortic Measurement Instruments are equipped with a scan counter feature that counts all scan button pushes that are captured by the console. The scan count can be viewed on the Self Test screen. It is designed to enable clinical users or service technicians to determine the number of scans the device has performed over its lifetime. It counts all scans taken with the instrument, including air scans and practice scans. The counter advances automatically after each scan.

To ensure reliability, a backup copy of the scan count is stored in device memory. If both the scan counter and its backup copy are corrupted, the scan counter will automatically reset to a zero value. If one of the storage locations fails, the text "EEPROM Failed" will be added to the DSP status line of the self-test function. In the event of an EEPROM failure, the counter will continue to work but will not have a backup copy stored in the instrument. To restore the scan counter function with backup storage, please contact your Verathon® service representative or Verathon Customer Care at 800.331.2313 or +1.425.867.1348.

