BladderScan®
Bladder Volume Instruments

Noninvasive, Accurate, Reliable, Easy to Use

BLADDERSCAN
BVI 3000
OPERATIONS & MAINTENANCE MANUAL

VERATHON®
Trusted and Enduring Medical Solutions

BLADDERSCAN
BVI 3000
OPERATIONS & MAINTENANCE MANUAL

Effective: March 6, 2015

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

CONTACT INFORMATION

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

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TABLE OF CONTENTS

IMPORTANT INFORMATION

OVERVIEW

PRODUCT DESCRIPTION

The BladderScan BVI 3000 is a B-mode ultrasonic instrument, portable and battery-operated, intended for the noninvasive measurement of urinary bladder volume. A mechanical sector-scanning transducer provides cross-sectional images of the bladder from twelve scan planes. Based on these images, the BladderScan instrument automatically calculates the estimated bladder volume in milliliters (ml) and displays it on a screen.

STATEMENT OF INTENDED USE

The BladderScan BVI 3000 projects ultrasound energy through the lower abdomen of the nonpregnant patient to obtain an image of the bladder, which is used to determine bladder volume noninvasively.

ESSENTIAL PERFORMANCE

Essential performance is the system performance necessary to achieve freedom from unacceptable risk. The essential performance of the BladderScan BVI 3000 system is to produce ultrasonic output energy and display numerical values for bladder volume. The system has a passively temperature-controlled transducer assembly.

STATEMENT OF PRESCRIPTION

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

NOTICE TO ALL USERS

The BladderScan BVI 3000 should be used only by individuals who have been trained and authorized by a physician or the institution providing patient care. All operators should read this manual prior to using the instrument. Failure to comply with these instructions may compromise the performance of the instrument.

SAFETY INFORMATION

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 exposure times possible commensurate with clinical utility.

The ultrasonic output power of the BladderScan BVI 3000 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 chapter Product Specifications on page 49.

CONTRAINDICATIONS

The BladderScan BVI 3000 instrument is not intended for fetal use or for use on pregnant patients.

PRECAUTIONS & WARNINGS

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

To ensure safe and reliable operation for the user and patient, please heed the following warnings and cautions.

PRECAUTIONS

CAUTION

The BladderScan BVI 3000 and related devices may contain mineral oils, batteries, and other environmentally hazardous materials. When the instrument and/or accessories have reached the end of their useful service life, see the section Device Disposal on page 47.

CAUTION

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

CAUTION

Failure to adhere to the following when cleaning the control unit or the scanhead may result in permanent equipment damage and void the instrument warranty:

- Ensure that you do not immerse either component in water or a cleaning or disinfecting agent. This may permanently damage the instrument.
- Do not use Cidex® Plus, as it is not recommended for use with Lexan polycarbonate.
- Do not subject any part of the BVI 3000 system to steam sterilization or ethylene oxide sterilization.

CAUTION

Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC) and must be installed and operated according to the instructions in this manual. For more information, see the Electromagnetic Compatibility section on page 54.

To maintain electromagnetic interference (EMI) within certified limits, the BladderScan BVI 3000 system must be used with the cables, components, and accessories specified or supplied by Verathon®. For additional information, see the System Components & Accessories and Component Specifications sections. The use of accessories and/or cables other than those specified or supplied may result in increased emissions and/or decreased immunity of the system.

The BladderScan BVI 3000 system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the system should be observed to verify normal operation in the configuration in which it will be used.

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

- Turn devices on and off in the vicinity to determine the source of interference
- Reorient or relocate this device or other devices
- Increase the separation between devices
- Connect the device to an outlet on a circuit different than the other device(s)
- Eliminate or reduce EMI with technical solutions (such as shielding)
- Purchase medical devices that comply with IEC 60601-1-2 EMC Standards

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

WARNINGS

WARNING

Do not use the BladderScan BVI 3000 instrument on:

- A patient who has open skin or wounds in the suprapubic area.
- A patient with ascites.
- A pregnant patient.

WARNING

Risk of explosion. If you use the BladderScan BVI 3000 instrument in the presence of flammable anesthetics, the hazard of potential explosion exists.

WARNING

When using the instrument, be aware of the following conditions that can affect ultrasound transmission and decrease the accuracy of exam results:

- Abdominal Surgery— Scar tissue, surgical incisions, sutures, and staples can affect ultrasound transmission and accuracy. Use care when scanning patients who have had abdominal surgery
- Catheterization—A catheter in the patient's bladder may affect the accuracy of the bladder volume measurement; however, the volume measurement may still be clinically useful if it is large (detecting a blocked catheter, for example).
- Obesity—Obesity may affect bladder volume measurements. Lift as much abdominal adipose tissue out of the way of the instrument as possible. Apply more pressure to the scanhead to reduce the amount of adipose tissue through which the ultrasound must pass.

Accuracy is compromised if you do not obtain an optimal, repeatable image.

WARNING

Electric shock hazard. Do not attempt to open the system components. This may cause serious injury to the operator or damage to the instrument and will void the warranty. Contact Verathon Customer Care for all servicing needs.

WARNING

Risk of electric shock or burns. Do not use the BladderScan instrument in conjunction with high-frequency surgical equipment.

WARNING

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

WARNING

Availability of cleaning and disinfection products varies by country, and Verathon is unable to test products in every market. For more information, please contact Verathon Customer Care at 1.800.331.2313 or your local representative. For additional contact information, visit verathon.com/contact-us.

WARNING

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

WARNING

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

WARNING

In order to maintain electrical safety, use only the provided medical-approved power supply, battery charger, and batteries.

WARNING

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

WARNING

No modification of this equipment is allowed.

WARNING

The battery charger, power supply, and power cables are not intended for patient contact. Ensure six feet (two meters) is maintained between the patient and these components.

WARNING

Risk of explosion, fire, or serious injury. The BladderScan BVI 3000 system is battery-powered. Failure to note the following when handling the battery may result in serious injury or damage:

- Never short-circuit the battery by bringing the battery terminals into contact with any other conductive object.
- Never expose the battery to abnormal shock, vibration, or pressure.
- Do not disassemble, heat above 60°C (140°F), or incinerate the battery.
- Keep battery out of reach of children and in original package until ready to use.
- If the battery is leaking or its case is cracked, put on protective gloves to handle it, and discard it immediately. Always dispose of used batteries in compliance with all applicable laws and regulations.
- Put insulating tape, such as cellophane tape, on the electrodes during transportation in order to avoid a possible short circuit, fire, or electrical shock.

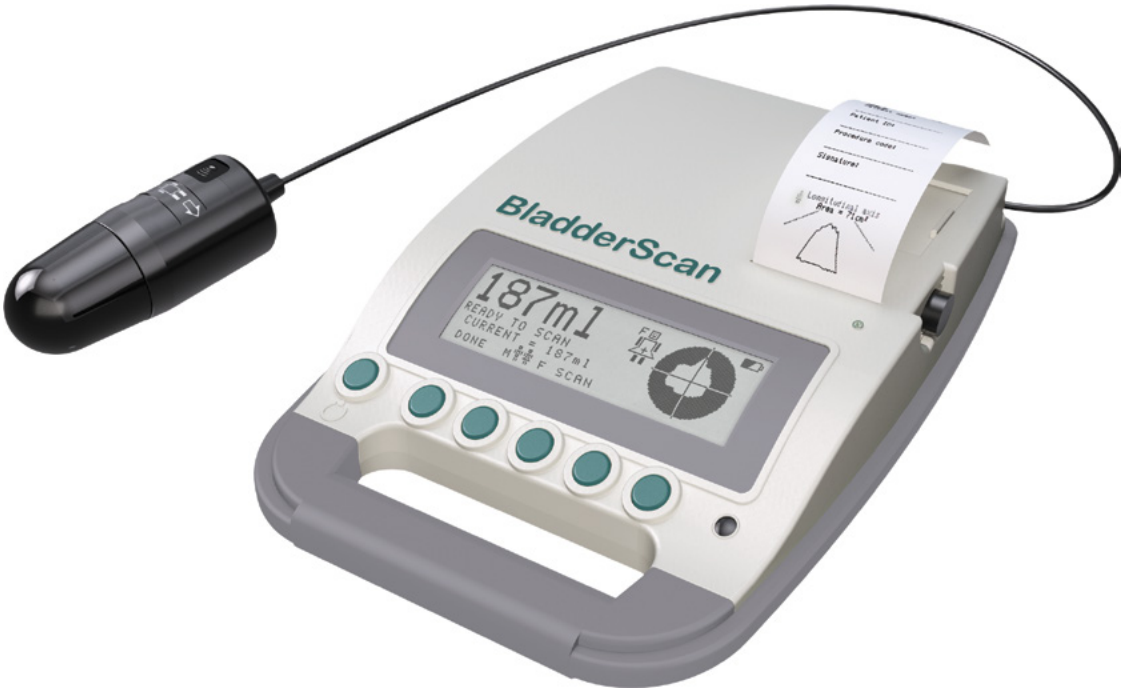
INTRODUCTION

COMPONENTS & FEATURES

The BladderScan BVI 3000 consists of four main components: the scanhead, the control unit, rechargeable batteries, and the battery charger. In addition, you may purchase optional accessories and additional supplies such as ultrasound gel, thermal paper for the printer, a mobile cart, or a carrying case. For more information about available accessories, see System Components & Accessories on page 9 or contact Verathon®.

This section describes the main components and their parts and features.

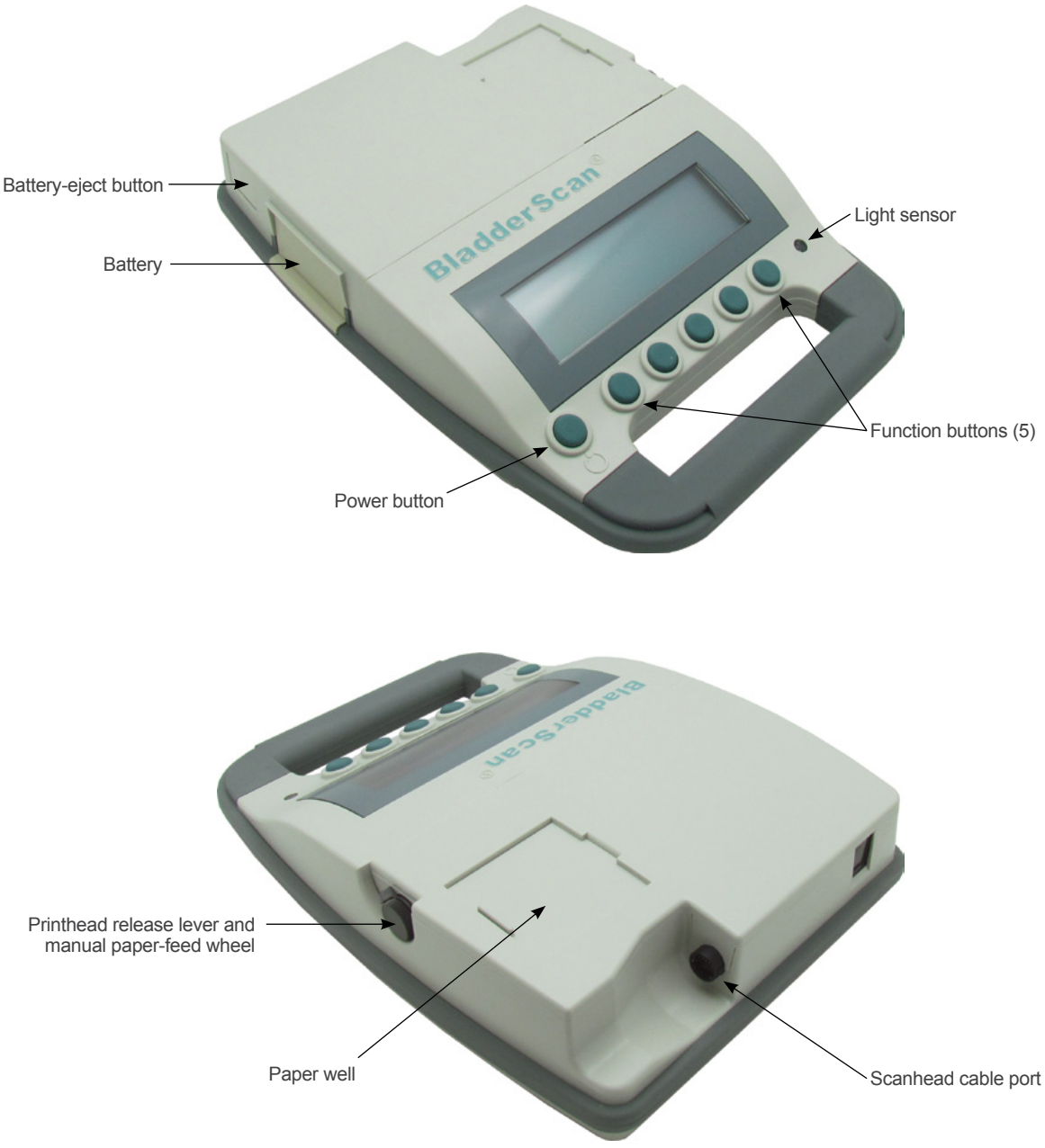
Figure 1. BladderScan BVI 3000 Control Unit and Scanhead



CONTROL UNIT

The control unit provides all operating controls for the scanning procedure by means of six buttons. The measured bladder volume and a target-shaped aiming icon are clearly displayed on the LCD screen, helping the operator to achieve accurate measurement results.

Figure 2. Control Unit Components



SCANHEAD

The scanhead transmits and receives ultrasound, automatically moving its internal transducer 360º to scan twelve planes and produce a three-dimensional image of the urinary bladder. The scanhead is connected to the control unit by means of a cable.

Figure 3. Scanhead Components

BATTERIES & BATTERY CHARGER

Two NiMH rechargeable batteries are included with the BladderScan BVI 3000. One battery can be recharged in the battery charger while the other is being used to power the BVI 3000. This ensures that there is no instrument downtime due to battery charge.

Figure 4. Battery Charger

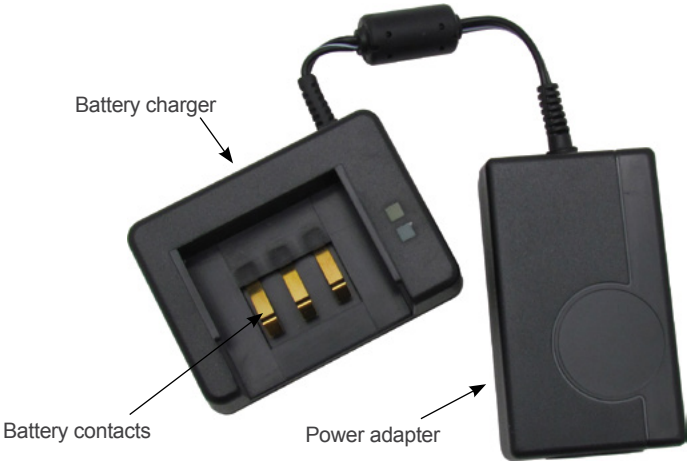
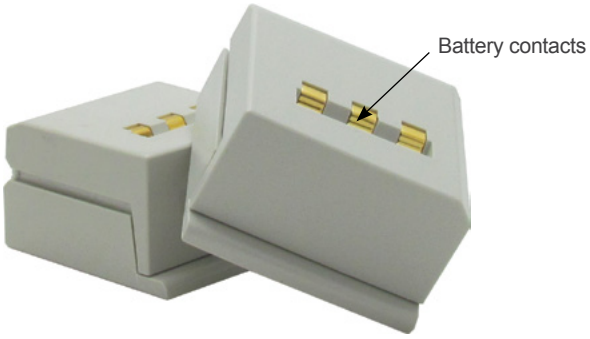


Figure 5. Rechargeable Batteries (2)



SYSTEM COMPONENTS & ACCESSORIES

WARNING

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

Table 1. Components & Accessories

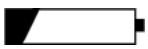
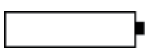
COMPONENTS
BladderScan BVI 3000 control unit
BladderScan BVI 3000 scanhead
BladderScan BVI 3000 battery charger
ACCESSORIES
Battery, 7.2 volt (V), 2 provided
Printer paper
BladderScan BVI 3000 In-Service CD, containing the operations & maintenance manual and a video tutorial
Acoustic coupling gel
Carrying case (Optional)
Mobile cart (Optional)

BUTTONS, ICONS, & CONNECTIONS

BATTERY ICON

The battery icon, located in the upper-right corner of the LCD, indicates the power status of the battery currently installed in your instrument.

Table 2. Battery Icons

ICON STATUS	PERCENT REMAINING	DESCRIPTION
	100%	A fully darkened battery icon indicates that the battery is fully charged and ready for use.
	75%	A battery icon that is almost full indicates a partially discharged battery.
	50%	When the battery icon is half-darkened, the battery is partially discharged. This is the most common display, shown during the majority of the battery's charge life.
	25%	An almost empty battery icon indicates that the battery is nearly discharged. While a few more scans can still be performed, the battery should be replaced at this point.
	0%	When the battery is fully discharged, the battery icon is completely clear and the BVI 3000 does not work. The discharged battery must be replaced with a charged one.

BUTTONS

The five buttons below the LCD screen change functions based on the content currently displayed on the screen. The button marked with the power symbol ⏻ turns the BVI 3000 control unit on or off.

SETTING UP

ASSEMBLING THE INSTRUMENT

PROCEDURE 1. CHARGE THE BATTERIES

WARNING

The battery charger, power supply, and power cables are not intended for patient contact. Ensure six feet (two meters) is maintained between the patient and these components.

WARNING

Risk of explosion, fire, or serious injury. The BladderScan BVI 3000 system is battery-powered. Failure to note the following when handling the battery may result in serious injury or damage:

- Never short-circuit the battery by bringing the battery terminals into contact with any other conductive object.
- Never expose the battery to abnormal shock, vibration, or pressure.
- Do not disassemble, heat above 60°C (140°F), or incinerate the battery.
- Keep battery out of reach of children and in original package until ready to use.
- If the battery is leaking or its case is cracked, put on protective gloves to handle it, and discard it immediately. Always dispose of used batteries in compliance with all applicable laws and regulations.
- Put insulating tape, such as cellophane tape, on the electrodes during transportation in order to avoid a possible short circuit, fire, or electrical shock.

WARNING

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

The BladderScan BVI 3000 draws very little power when it is turned off; however, if you do not plan to use your instrument for several weeks, you should remove the battery to prevent it from discharging.

The battery that is not in use should be stored in the charger so that it remains fully charged. There is no danger of overcharging the battery.

1. To maintain accessibility, plug in the charger only where it can be easily unplugged.

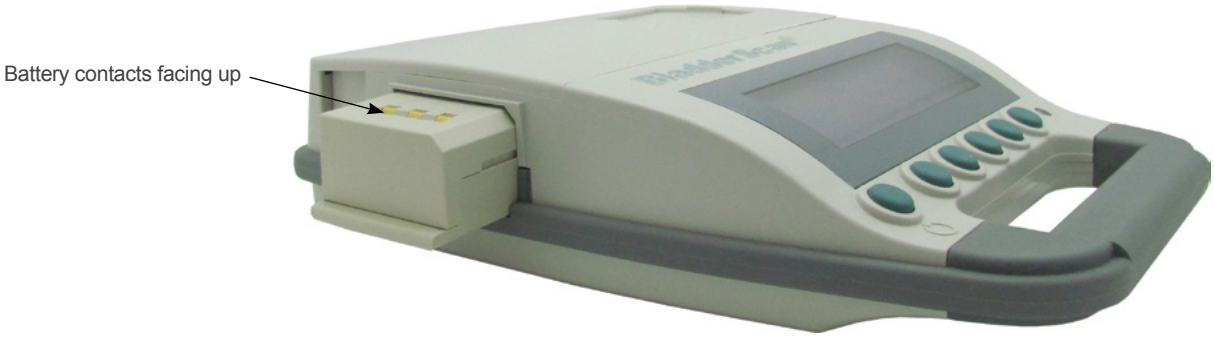
2. Align the battery as shown in the following figure, and then slide the battery into the recess on the top of the charger.

3. Monitor the color indicator lights on top of the battery charger in order to determine the battery's charging status:
   - **Solid Green—**When the battery is low on charge, charging begins in the fast-charge mode. During fast-charge mode, the green light is solid. For a fully discharged battery, fast-charge mode lasts about two to three hours.
   - **Quickly Flashing Green—**When the battery reaches 80% of its charge level, the charger starts to "top off" the charge, and the green light flashes quickly. At this point, you may use the battery in the BVI 3000 instrument.
   - **Slowly Flashing Green—**If the green light flashes slowly upon inserting a battery, then the battery level is too low for fast-charge mode. The charger slowly charges the battery until the power level is high enough to begin fast-charge mode. When the battery power level is high enough, fast-charge mode begins automatically.
   - **Solid Amber—**The amber light indicates that the battery temperature is stabilizing before recharging can begin. This may occur when the battery is taken from a very cold or warm environment, or if the battery is defective. If the light remains amber for over an hour, the battery is defective and must be replaced.

PROCEDURE 2. INSERT OR REMOVE A BATTERY

INSERT A BATTERY

1. Ensure the battery has been properly charged according to the instructions in the procedure Charge the Batteries on page 10.
2. If a battery is already in the control unit, remove it according to the instructions in the following section Remove a Battery.
3. Align the charged battery with the battery well as shown in the following figure.



4. Slide the battery into the well and press until the battery clicks into place.

REMOVE A BATTERY

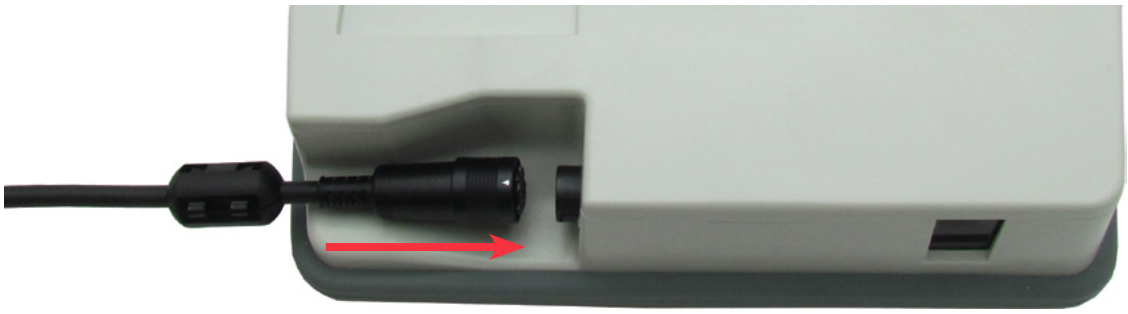
1. Next to the battery well, press the battery-eject button. The battery is released from the control unit.

2. Slide the battery out of the control unit.
3. Recharge or store the removed battery in the charger according to the instructions in the procedure Charge the Batteries on page 10.

PROCEDURE 3. CONNECT THE SCANHEAD TO THE CONTROL UNIT

1. Align the scanhead cable connector so that the arrow is facing up.

2. Press the connector directly into the port until you hear a click.



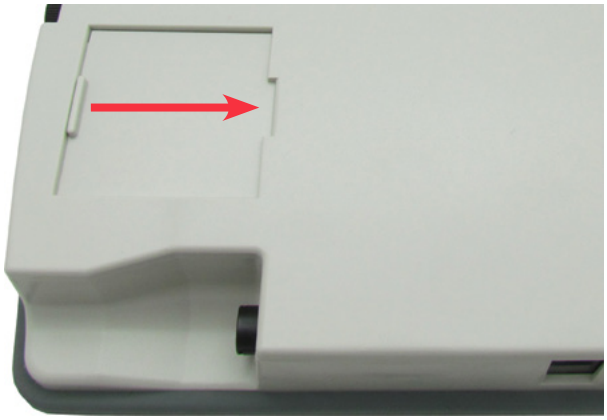
3. If you want to disconnect the scanhead from the control unit, grip the black plastic ring on the cable connector, and then pull straight out. Do not twist the cable or connector.

PROCEDURE 4. LOAD THE THERMAL PAPER ROLL

If the instrument is experiencing a paper jam, see the procedure Clear a Paper Jam on page 44.

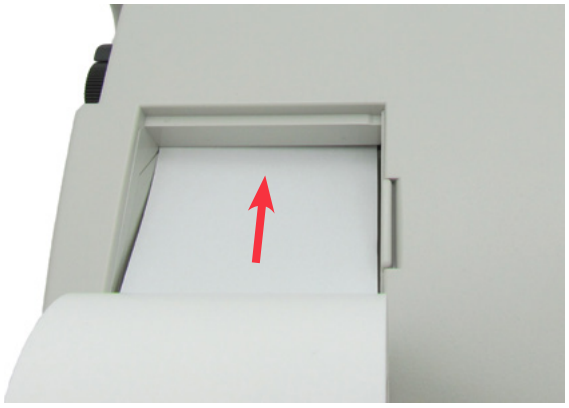
The BladderScan BVI 3000 has an automatic paper-loading mechanism. When you insert the paper roll correctly, the instrument automatically feeds the paper through the instrument and prepares for printing.

1. On the top of the control unit, open the paper well door.



2. If there is an empty paper roll in the paper well, remove it.
3. If you are loading a new paper roll, cut off the first inch of the new paper.
4. Ensure that the end of the paper roll is cut straight. Do not fold the end of the paper roll, cut it diagonally, or cut it to a point.
5. Turn the BVI 3000 on by pressing the power button.
6. Insert the end of a new paper roll, with the thermal side down, into the paper input slot. The BVI 3000 senses the presence of the paper and automatically feeds the paper through the instrument.

   Note: To verify that you are loading the paper with the thermal side down, flick your nail over the paper. If a black mark appears, this is the thermal side.



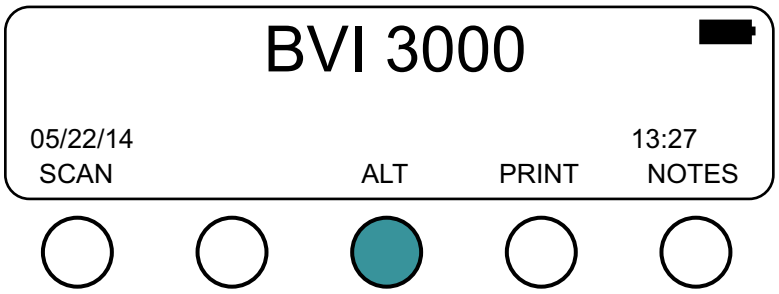
7. Place the paper roll in the paper well.
8. Close the paper well door. The instrument is ready to print.

CONFIGURING USER SETTINGS

PROCEDURE 1. PROGRAM THE NAME

You can customize the BladderScan BVI 3000 instrument by entering your facility or provider name. This information is subsequently included on all printouts of exam results.

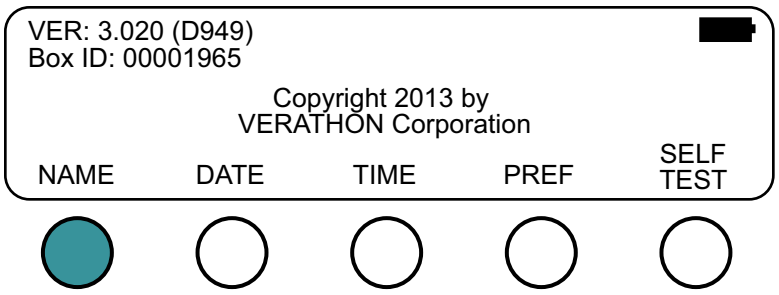
1. Turn the BVI 3000 on by pressing the power button.
2. On the Main Menu screen, press the **ALT** button.



3. If you are prompted, enter your PIN code.

   Note: The default PIN code is 0000. For information about how to change the PIN code, see the procedure Adjust User Preferences *on* page 21.

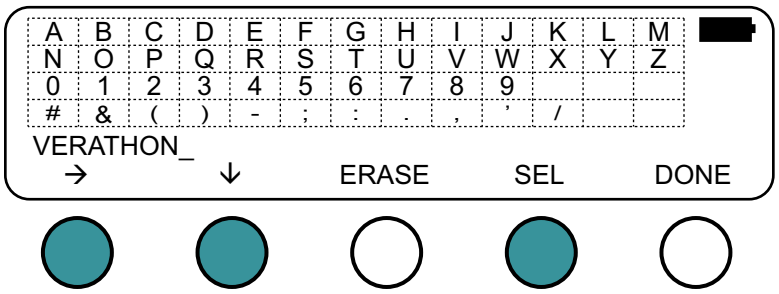
4. On the Alternate Menu screen, press the **NAME** button.



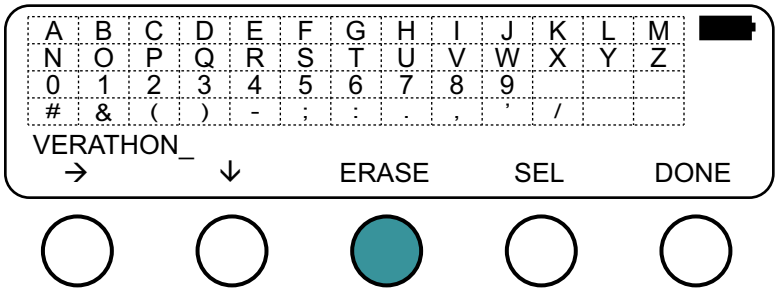
5. On the Name Preset screen, use the right ➔ and down ➔ buttons in order to highlight the character that you would like to enter, and then press the **SEL** button. The character is added to the name below the character grid. Repeat as necessary in order to enter the desired name.

   Note the following:

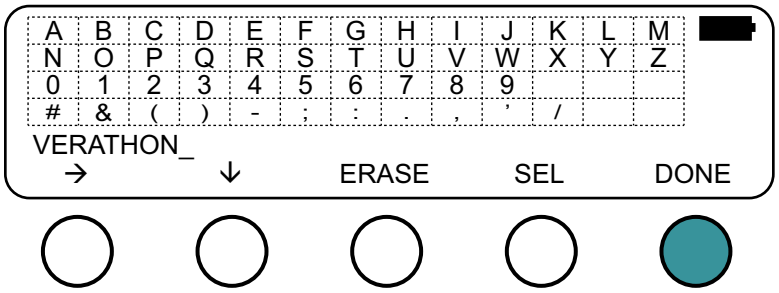
   - *When the cursor reaches the right or bottom edge of the grid, it wraps around to the left or top edge.*
   - *You may use any combination of up to 27 characters when entering the facility name.*
   - *If you would like to enter a space, select any empty character, and then press the* **SEL** *button.*
   - *When the right or down buttons are pressed and held, the cursor moves one character per second.*



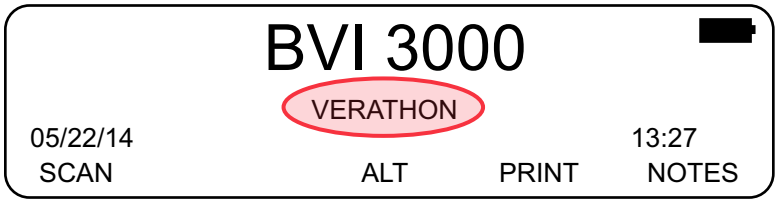
6. If you would like to delete a character, press the **ERASE** button. This deletes the last character entered.



7. When you are finished entering the name, press the **DONE** button.



The name you entered is now displayed on the Main Menu screen.

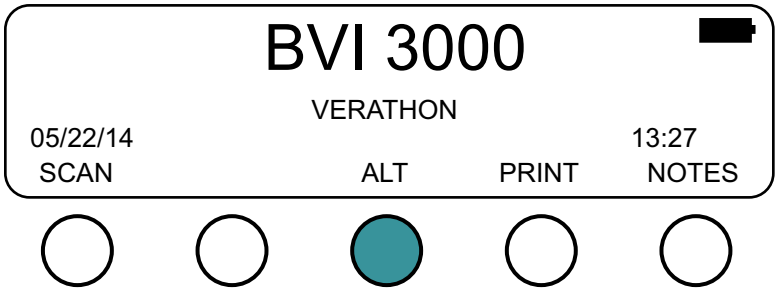


PROCEDURE 2. SET THE DATE

Once set, the BVI 3000 clock recognizes the number of days in each month, including February during leap years. It has its own lithium battery and maintains the correct date and time for at least ten years, even if the rechargeable battery is removed.

This procedure uses the *month/day/year* format for the date setting. If you would like to change the date format, see the procedure Adjust User Preferences on page 21.

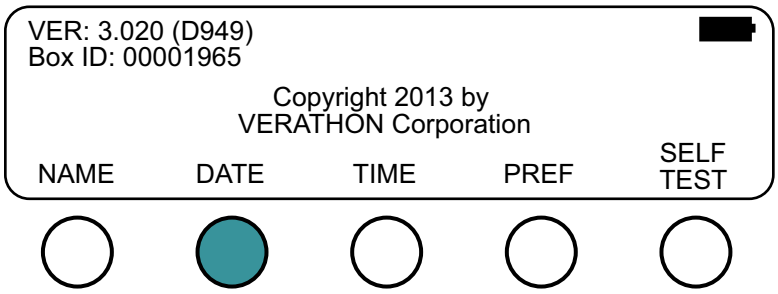
1. Turn the BladderScan BVI 3000 on by pressing the power button.
2. On the Main Menu screen, press the **ALT** button.



3. If you are prompted, enter your PIN code.

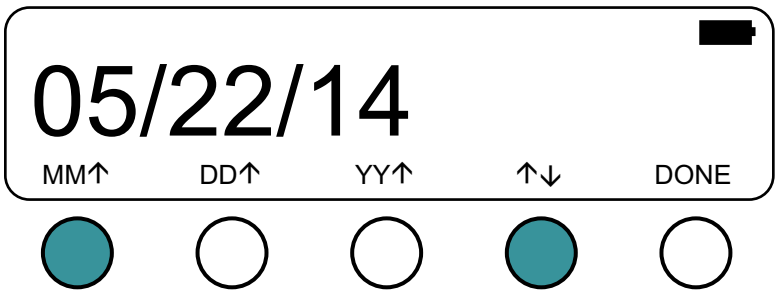
   Note: The default PIN code is 0000. For information about how to change the PIN code, see the procedure Adjust User Preferences on page 21.

4. On the Alternate Menu screen, press the **DATE** button.



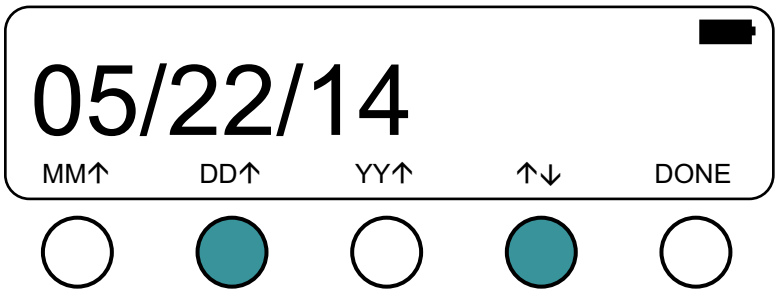
5. On the Date Preset screen, press the ↑↓ button to toggle between increasing or decreasing the month number, and then press the **MM** button until the correct month is displayed.

   Note: Only values from 01 to 12 are allowed.

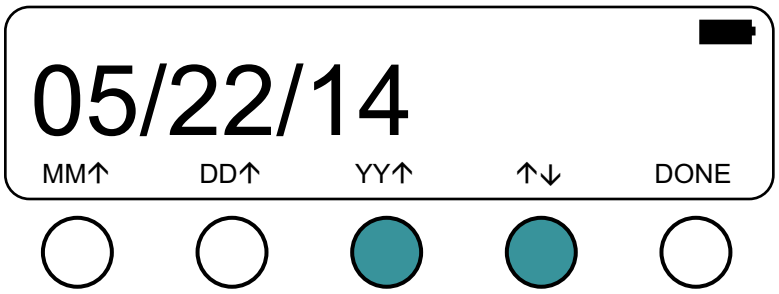


6. Press the ↑↓ button to toggle between increasing or decreasing the day, and then press the **DD** button until the correct day is displayed.

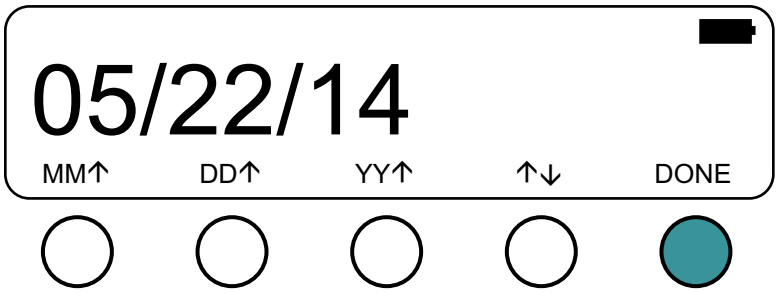
   Note: Only values from 01 to 31 are allowed.



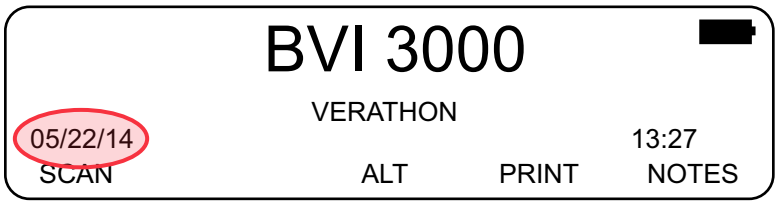
7. Press the ↑↓ button to toggle between increasing or decreasing the year, and then press the **YY** button until the correct year is displayed.



8. When you are finished entering the date, press the **DONE** button.



   The date you entered is now displayed on the Main Menu screen.

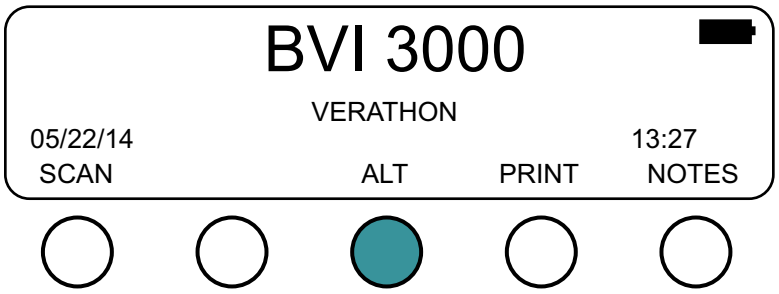


PROCEDURE 3. SET THE TIME

The internal clock is accurate to better than one minute per month at 25°C (77°F). It will operate for at least 10 years from an internal lithium battery. Enter the time in 24-hour format (also known as *military time*).

To convert 12-hour clock time to 24-hour format, if the time is after noon, add 12 hours to the clock time (Example: 3:00 PM + 12 hours = 15:00).

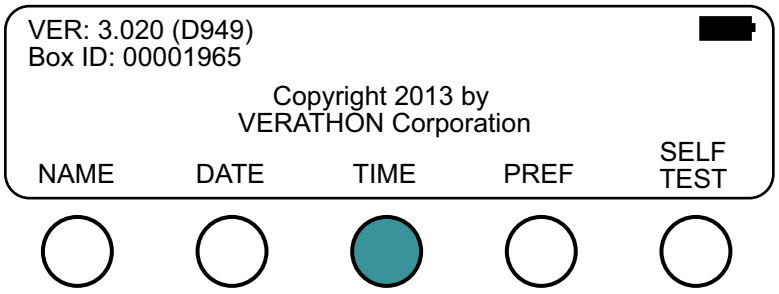
1. Turn the BladderScan BVI 3000 on by pressing the power ⏻ button.
2. On the Main Menu screen, press the **ALT** button.



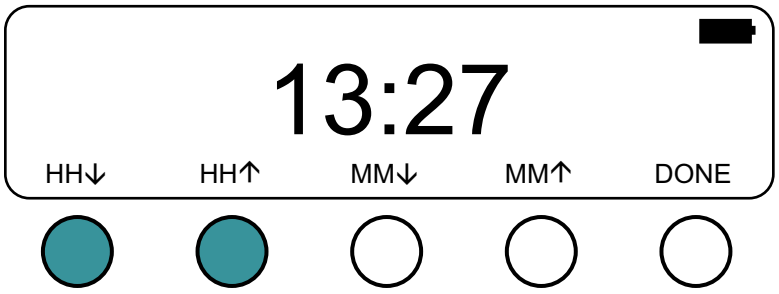
3. If you are prompted, enter your PIN code.

   Note: The default PIN code is 0000. For information about how to change the PIN code, see the procedure Adjust User Preferences *on* page 21.

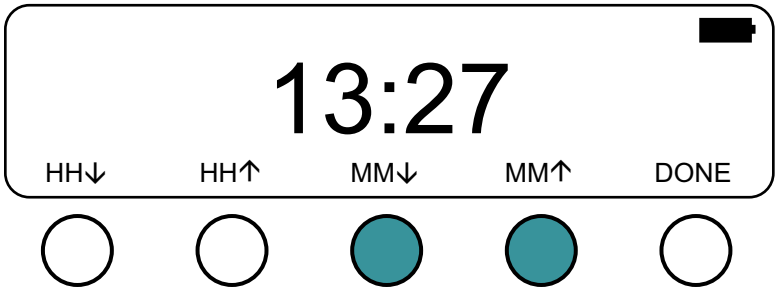
4. On the Alternate Menu screen, press the **TIME** button.



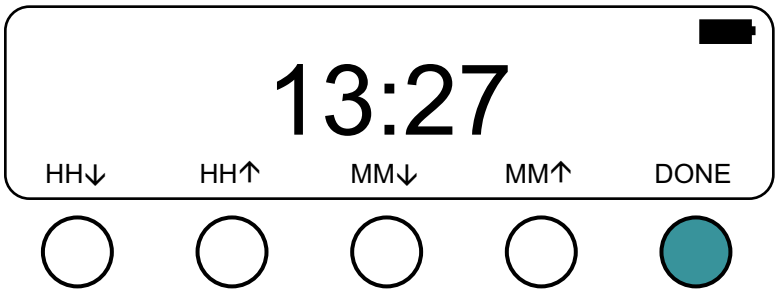
5. On the Time Preset screen, press the **HH↓** button to decrease the hour value, or press the **HH↑** button to increase the hour value.



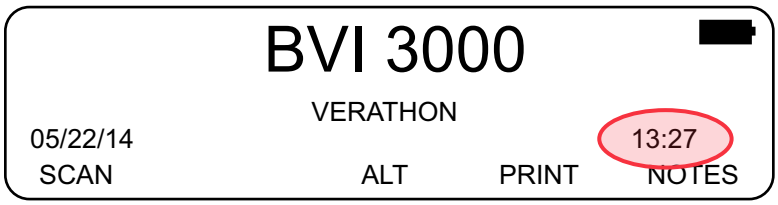
6. Press the **MM↓** button to decrease the minute value, or press the **MM↑** button to increase the minute value.



7. When you are finished entering the time, press the **DONE** button.



The time you entered is now displayed on the Main Menu screen.



PROCEDURE 4. ADJUST USER PREFERENCES

On the Preference screen, various BVI 3000 operating parameters can be customized for personalized use. The following table documents the configurable parameters and their available values.

Table 3. User Preferences

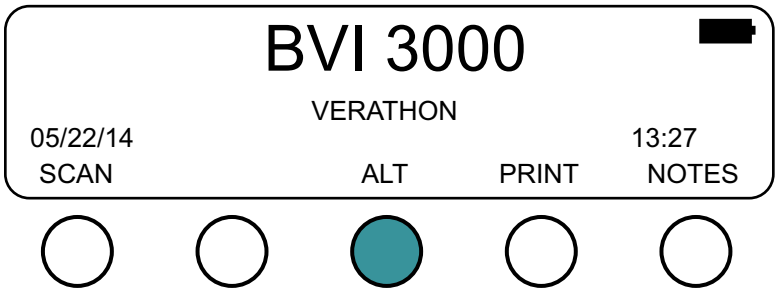
PARAMETER	RANGE OR VALUE	DESCRIPTION
Backlight	AUTO (default)	The backlight turns on and off automatically, depending on the ambient light conditions
	ON	The backlight is always on
	OFF	The backlight is always off
Beep volume	0–9 (default is 5)	Adjusts the instrument volume level up (higher values) or down (lower values)
Language	Multiple languages available	Specifies the language used for displays and printouts
Date	MM/DD/YY	Month, day, year
	DD/MM/YY	Day, month, year
	YY/MM/DD	Year, month, day
Printout	ADD_WALLS (default)	Print grayscale, B-mode images with bladder walls highlighted
	NO_IMAGES	Do not print any B-mode images
	RAW_ONLY	Print grayscale B-mode images without identifying the bladder walls
	WALLS_ONLY	Bladder outline only
	12_PLANES	All 12 scan planes, printed as in the ADD_WALLS mode
Quick	OFF (default)	When you press the PRINT button, the Print screen appears, and you may select whether you would like to print the last scan result, cost savings, or a test print.
	ON	When you are on the Scan Results screen, if you press the PRINT button, the scan results print automatically (the Print screen does not appear).
UTI rate	0–100% (default is 3%)	Percentage of catheterizations that result in UTI; used in cost-savings calculations
UTI cost	0-2000 (default is 680)	Cost to treat a UTI; used in cost-savings calculations
Cath cost	0–20 (default is 3)	Cost of a catheter; used in cost-savings calculations
Cath vol	0–1000 ml (default is 300 ml)	Bladder volume below which catheterization is unnecessary; used in cost-savings calculations
Flash	OFF (default)	Scan results are not saved if instrument is turned off; however, processing time is slightly faster
	ON	Flash memory is enabled, and scan results are saved even the instrument turns off
Time zone	GMT ± 0–12 (default is 0)	This function is currently not used

PARAMETER	RANGE OR VALUE	DESCRIPTION
Contrast Adjust	30–63 (default is 57)	Adjust display contrast ratio; the higher the value, the darker the background *Note: An immediate effect is seen only when adjusting the contrast up. Adjusting the contrast down becomes visible when the instrument is turned off and on again.*
Currency	$	Set the currency for calculating cost savings to dollars
	€	Set the currency for calculating cost savings to euros
	£	Set the currency for calculating cost savings to pounds
	¥	Set the currency for calculating cost savings to yen
Scan count screen	—	Reset the user-controllable scan counter to zero. *Note: There are two scan counters in the BVI 3000. One may be reset by users, and the other may only be reset by an authorized Verathon representative.*
Reset histogram	—	Reset the histogram to being a new analysis of cost savings
Change PIN code	—	Change the PIN code. The current PIN is displayed. Enter the desired PIN, and then press **DONE**.

IMPORTANT

If you change the PIN code, ensure that you record or remember it. If your existing PIN code is lost or forgotten, you must contact Verathon® Customer Care in order to reset it.

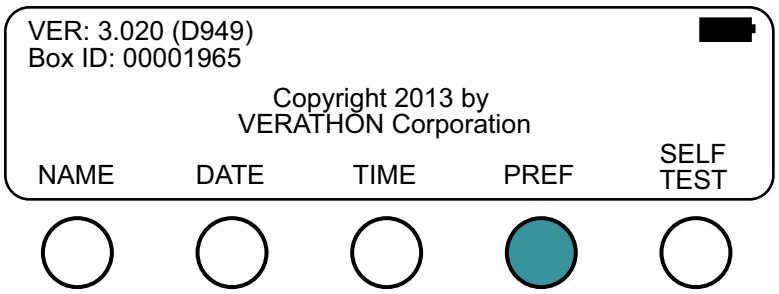
1. Turn the BladderScan BVI 3000 on by pressing the power button.
2. On the Main Menu screen, press the **ALT** button.



3. If you are prompted, enter your PIN code.

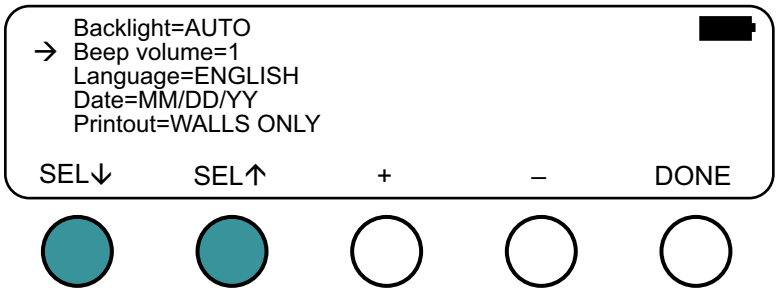
   Note: The default PIN code is 0000.

4. On the Alternate Menu screen, press the **PREF** button.

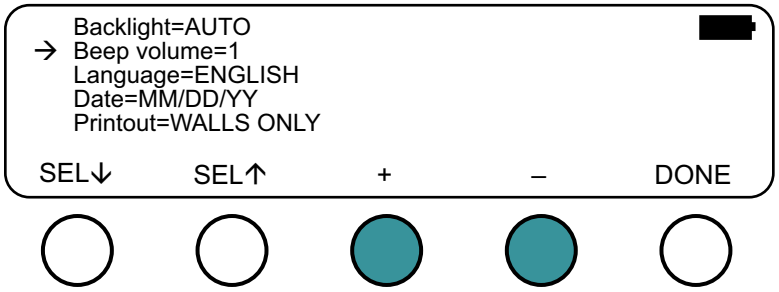


5. On the Preferences screen, select the parameter that you wish to adjust by using the **SEL↓** and **SEL↑** buttons.

   Note: Continue pressing the **SEL↓** *button in order to view additional parameters in the list.*

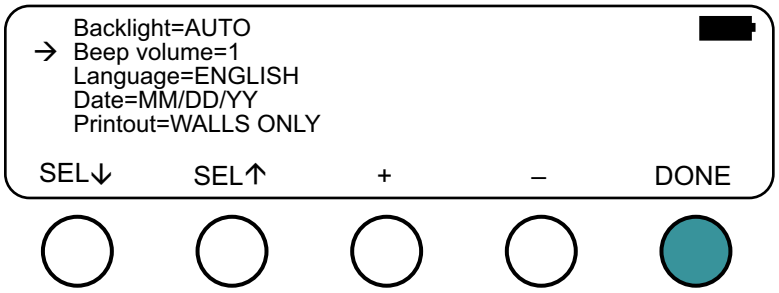


6. When you have selected the parameter you wish to adjust, change the parameter value by pressing the plus **+** or minus **–** buttons.



7. Repeat Step 5 through Step 6 as needed to adjust desired preferences.

8. When you are finished adjusting preferences, press the **DONE** button. Your preferences are saved, and the instrument returns to the Main Menu screen.



USING THE INSTRUMENT

WARNING

Risk of explosion. If you use the BladderScan BVI 3000 instrument in the presence of flammable anesthetics, the hazard of potential explosion exists.

WARNING

Risk of electric shock or burns. Do not use the BladderScan instrument in conjunction with HF surgical equipment.

WARNING

When using the instrument, be aware of the following conditions that can affect ultrasound transmission and decrease the accuracy of exam results.

- Abdominal Surgery— Scar tissue, surgical incisions, sutures, and staples can affect ultrasound transmission and accuracy. Use care when scanning patients who have had abdominal surgery
- Catheterization—A catheter in the patient's bladder may affect the accuracy of the bladder volume measurement; however, the volume measurement may still be clinically useful if it is large (detecting a blocked catheter, for example).
- Obesity—Obesity may affect bladder volume measurements. Lift as much abdominal adipose tissue out of the way of the instrument as possible. Apply more pressure to the scanhead to reduce the amount of adipose tissue through which the ultrasound must pass.

Accuracy is compromised if you do not obtain an optimal, repeatable image.

WARNING

Do not use the BladderScan BVI 3000 instrument on:

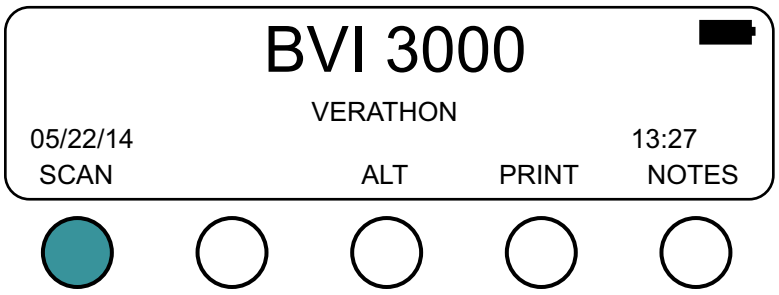
- A patient who has open skin or wounds in the suprapubic area.
- A patient with ascites.
- A pregnant patient.

SCANNING A PATIENT

Verathon® advises new operators to use the BladderScan BVI 3000 on patients with moderately full bladders, rather than initially attempting to locate nearly empty bladders. An in-service training video has been supplied with your instrument. It is recommended that you view the video as a supplement to the procedures provided in this manual.

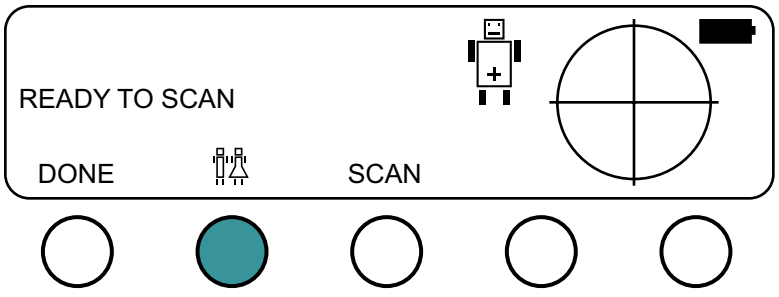
PROCEDURE 1. MEASURE BLADDER VOLUME

1. Ensure the instrument has been properly cleaned according to the instructions in the Cleaning & Disinfecting chapter on page 38.
2. Ensure that the battery is sufficiently charged. If necessary, recharge or replace the battery.
3. Turn the BladderScan BVI 3000 on by pressing the power button.
4. On the Main Menu screen, press the **SCAN** button.



5. On the Scan screen, press the **Male/Female** button in order to select the patient's gender.

   The LCD screen shows a male or a female icon to indicate the gender that is selected. Use the female option only for women who have not undergone a hysterectomy (the female option allows the instrument to exclude the uterus from the measurement, which may resemble the bladder ultrasonically). For all other patients, use the Male option.



6. Have the patient lie in the supine position with abdominal muscles relaxed.
7. Palpate the patient's symphysis pubis (pubic bone).

8. Place an ample amount of gel midline on the patient's abdomen approximately 1 inch (3 cm) above the symphysis pubis.

   Note: Do not spread the gel over the patient's abdomen, and use a sufficiently thick quantity to ensure proper transmission of ultrasound waves.

9. Place the scanhead on the gel on the patient's abdomen, ensuring that on the scanhead, the head of the patient icon (or) points toward the head of the patient.

10. Aim the scanhead toward the expected location of the bladder, as illustrated in the following figures. For most patients, this means aiming the tip of the scanhead toward the patient's coccyx.

Figure 6. View from Patient's Right Side

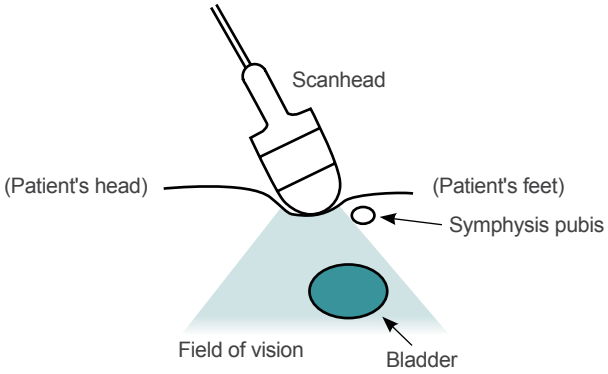
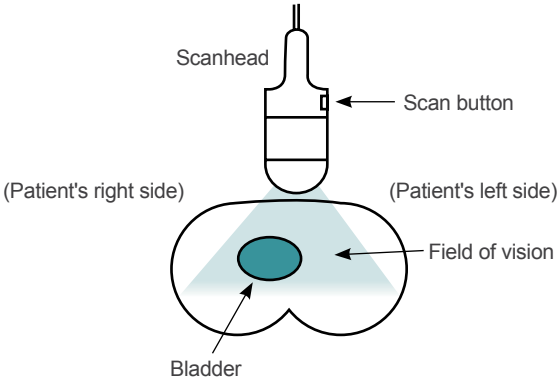
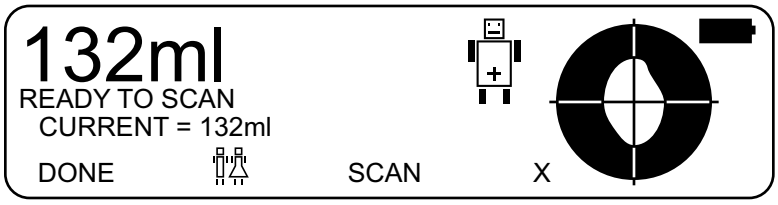


Figure 7. View from Patient's Feet



11. On the scanhead, press and release the scan button. The scan initiates.

12. Hold the scanhead steady throughout the scan. The scanhead clicks once at each of the twelve scan planes. When the scanhead beeps, the scan is complete, and the Aiming screen is displayed.



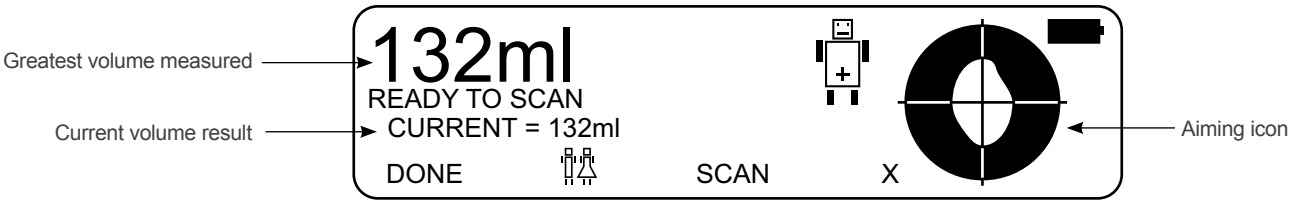
13. If the instrument detects radio frequency interference that could compromise measurement accuracy, the screen displays **RESCAN**. Attempt to locate or disable the source of the outside interference. For more information, see Electromagnetic Compatibility on page 54.

14. Continue to the following procedure, Verify Aim & Accuracy.

PROCEDURE 2. VERIFY AIM & ACCURACY

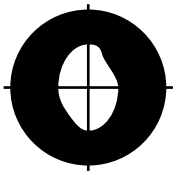
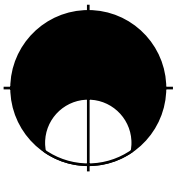
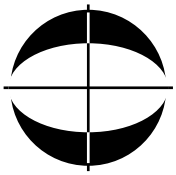
After completing a scan, the BVI 3000 displays two volumes on the Aiming screen: the largest volume measured and the current volume. The light area inside the target-shaped Aiming icon represents the position of the bladder relative to the scanhead.

Figure 8. Aiming Screen



1. Verify that the aim was accurate by comparing the Aiming icon to the results in the following table.

Table 4. Aiming Icons

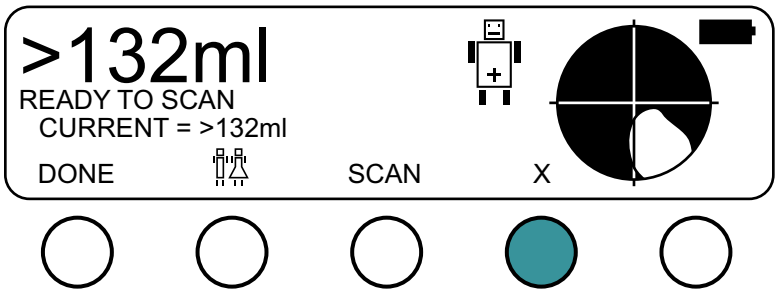
RESULT	AIMING ICON	DESCRIPTION
Accurate		The bladder image is centered on the crosshairs of the Aiming icon. This indicates that the scanhead was properly aimed, and the bladder volume measurement is accurate.
Off-center		The bladder image is not centered on the crosshairs and overlaps one side of the Aiming icon. This indicates that the bladder was outside the scanhead's field of vision. In such cases, the measured volume is lower than the true bladder volume. The BVI 3000 recognizes this condition and displays a greater than (>) symbol before the bladder volume measurement. To achieve an accurate measurement, re-aim the scanhead toward the bladder image, and then repeat the scan.
Volume too high		The bladder overlaps two sides of the Aiming icon. This indicates that the bladder is too large to be fully contained within the scanhead's field of vision. The instrument recognizes this condition and displays a greater than (>) symbol before the bladder volume measurement. In such cases, repositioning or re-aiming the scanhead will do little to improve accuracy; however, this situation arises almost exclusively in patients with very large bladder volumes. At these high volumes, measurements are clinically useful even if they underestimate the true bladder volume.

2. If the aim is accurate, repeat Step 11 through Step 12 of the Measure Bladder Volume procedure in order to determine if you are collecting repeatable results. This helps ensure maximum accuracy.

   Note: The instrument assumes that the largest volume measured is the true bladder volume, because in most cases the largest volume is the most accurate. Exceptions occur when the scanhead is moved during the scan or the incorrect gender was selected. In these situations, the largest volume measurement may be higher than the actual bladder volume, and you should clear the Aiming screen before rescanning the patient.

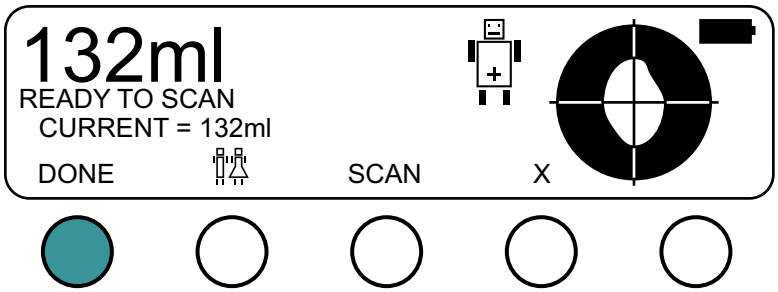
3. If you need to adjust your aim, do the following:
   - Press the **X** button. This clears the inaccurate scan results.

     Note: If your instrument does not have an X button, press the DONE button and then press the SCAN button. This resets the scan.

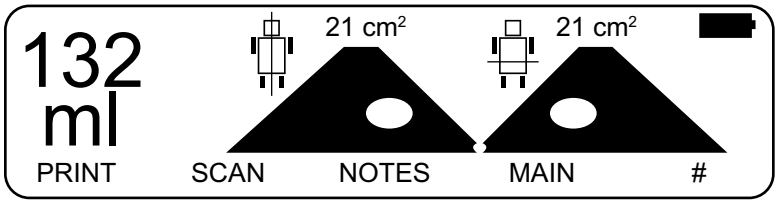


   - Move or angle the scanhead toward the direction of the bladder image on the Aiming icon. For example, if the bladder image is located on the right side of the icon, aim the scanhead so the ultrasound will be projected further to the right.
   - Repeat Step 11 through Step 12 of the Measure Bladder Volume procedure. Verify the accuracy of the scan according to the instructions in this procedure.

4. When you have collected sufficient scans in order to confirm aiming accuracy, press the **DONE** button.



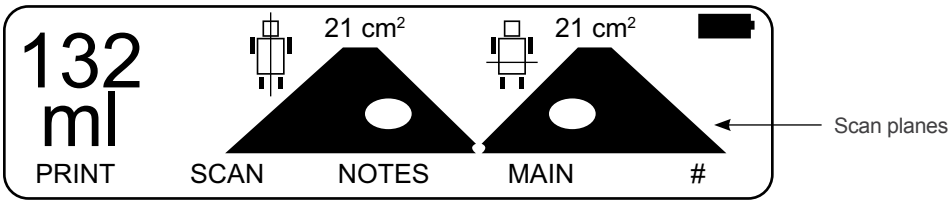
   The Results screen is displayed. Continue to the next procedure, Confirm the Scan Results.



PROCEDURE 3. CONFIRM THE SCAN RESULTS

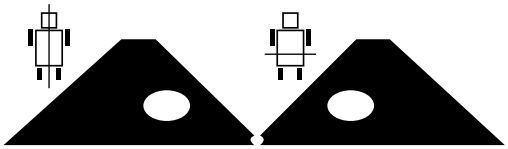
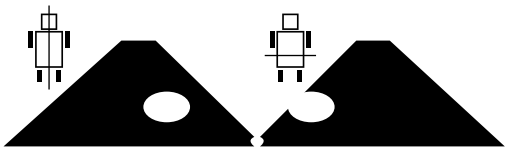
The Results screen displays the longitudinal and horizontal scan planes from the largest image taken during the exam. The light areas represent the bladder. The dark, triangular surfaces, called *scan planes*, represent the scanhead's field of vision.

Figure 9. Results Screen

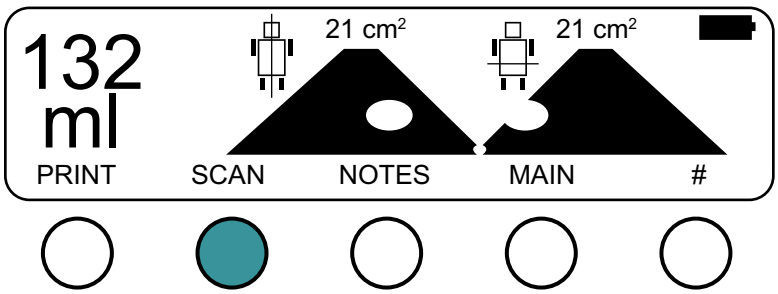


1. Confirm that the aim was accurate by comparing the scan plane results to the results in the following table.

Table 5. Scan Plane Result

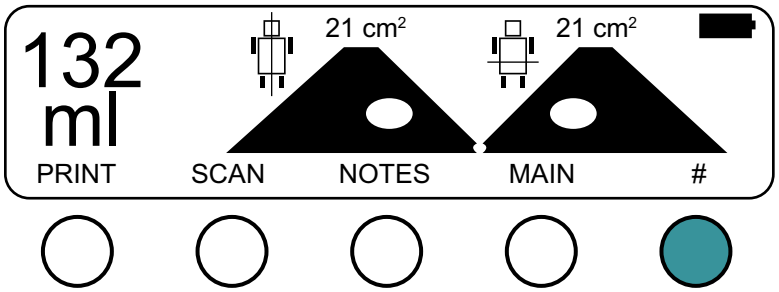
RESULT	SCAN PLANE	DESCRIPTION
Accurate		The light-colored bladder images are completely contained within the dark, triangular scan planes.
Inaccurate		The light surface in either scan plane is overlapping the edge of the black area or appears to be cut off. Part of the bladder was not contained in the scanhead's field of vision, and the measurement may underestimate the patient's bladder volume.

2. If the scan plane result is inaccurate, press the **SCAN** button in order to clear the scan result, and then repeat the procedure Measure Bladder Volume on page 25.

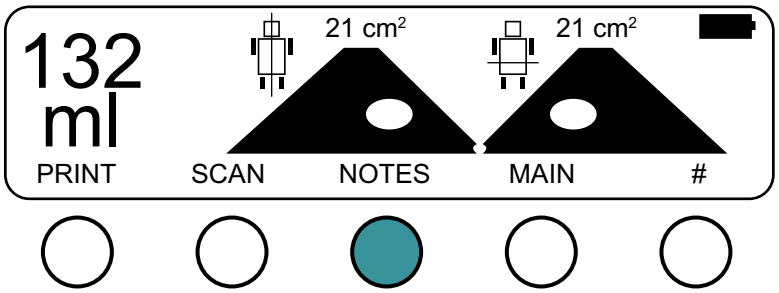


3. If the scan plane result is accurate, do one or more of the following in order to complete the scan and save the results:

   - If you want to add a patient ID number, press the **#** button, and then complete the procedure Add a Patient ID Number (Optional) on page 31.

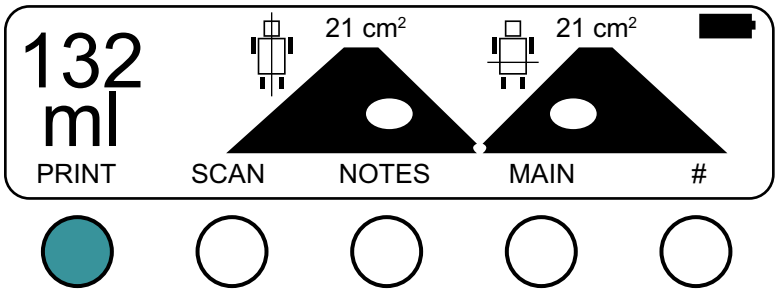


   - If you want to add notes to the scan results, press the **NOTES** button, and then complete the procedure Add Notes (Optional) on page 32.

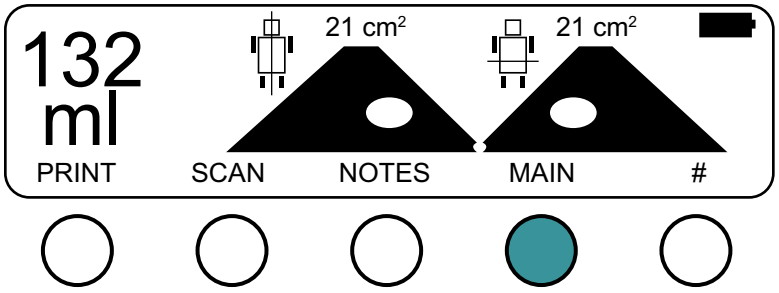


   - If you want to print the scan results, press the **PRINT** button, and then complete the procedure Print the Scan Result (Optional) on page 34.

     Note: If you have enabled the QUICK setting in user preferences, when you press the PRINT button, the instrument automatically prints the scan results without displaying the Print screen. For more information, see the procedure Adjust User Preferences *on* page 21.



   - If you want to save the results and exit to the Main Menu screen, press the **MAIN** button.



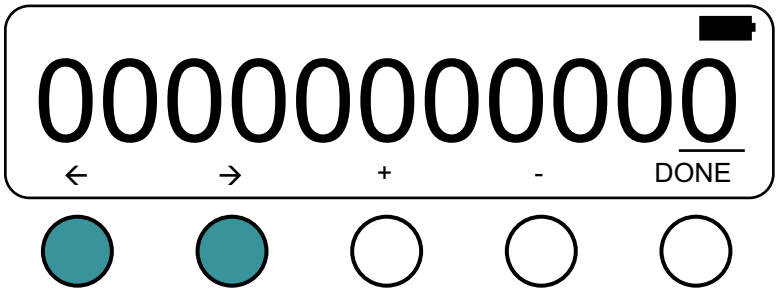
MANAGING SCAN RESULTS

PROCEDURE 1. ADD A PATIENT ID NUMBER (OPTIONAL)

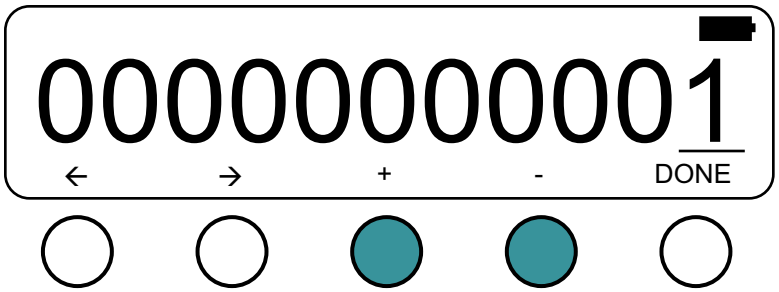
A patient ID number (maximum 10 digits) can be added to the scan result and will be included on the printout. You may access the Patient ID Number screen from the Scan Results screen. The Patient ID Number screen displays 0000000000.

Note: Only press the button marked # when a patient ID number is required. If the # button is used and no patient ID number is entered, the instrument assumes a patient ID number was entered, and 0000000000 will be included on the printout.

1. Using the left ← and right → buttons, select the digit you want to change (the selected digit is underlined).



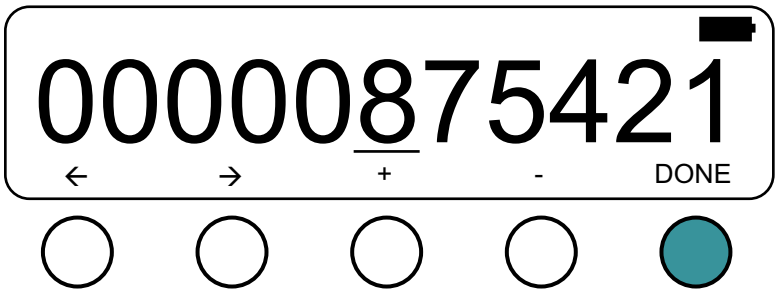
2. Using the plus **+** or minus **–** buttons, increase or decrease the value in order to select the correct digit.



3. Repeat Step 1 through Step 2 until you have entered the complete patient ID number.

4. When you have finished entering the patient ID number, press the **DONE** button.

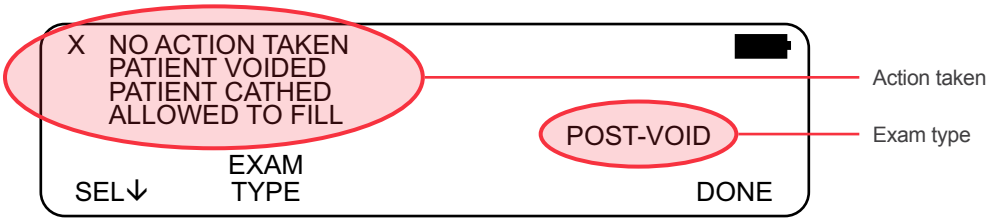
   The instrument returns to the Scan Result screen, and the patient ID number you entered will now be included on the printout of the scan.



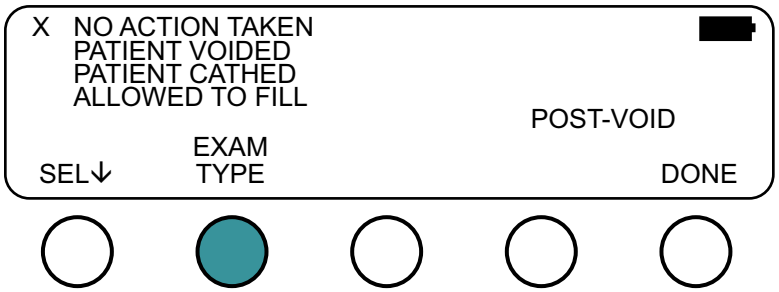
PROCEDURE 2. ADD NOTES (OPTIONAL)

After a scanning procedure has been completed, it is possible to annotate the measurement results, and these annotations will be included on the printout. You may access the Notes screen from the Scan Results screen.

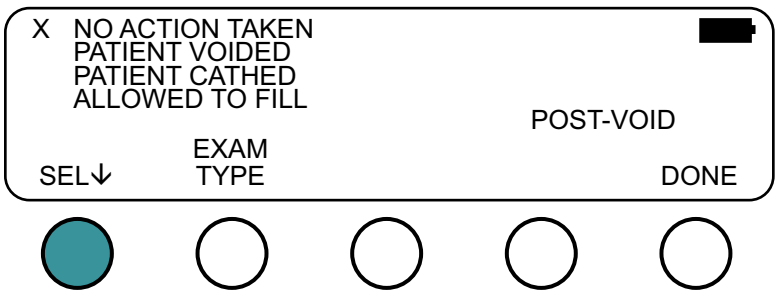
Figure 10. Notes Screen



1. If you would like to change the exam type, press the **EXAM TYPE** button to toggle between options as follows:
   - POST-VOID—The measurement was taken after patient voiding. This exam type is selected by default if the measured bladder volume is less than 100 ml.
   - PRE-VOID—The measurement was taken prior to patient voiding. This exam type is selected by default if the measured bladder volume is between 100 ml and 400 ml.
   - CAPACITY—The measurement was taken prior to patient voiding, and the bladder was filled to maximum capacity. This exam type is selected by default if the measured bladder volume is greater than 400 ml.

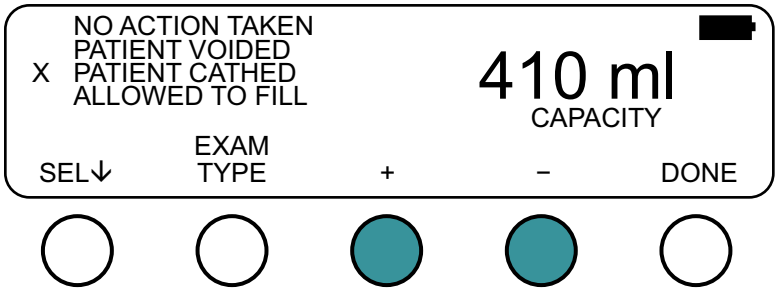


2. If you want to note the action taken as a result of the current bladder volume measurement, press the **SEL↓** button in order to select one of the following options:
   - NO ACTION TAKEN—This option is selected by default.
   - PATIENT VOIDED—The patient was able to void.
   - PATIENT CATHED—The patient's bladder was emptied using a urinary catheter.
   - ALLOWED TO FILL—The patient's bladder was not as full as desired, and voiding was postponed.

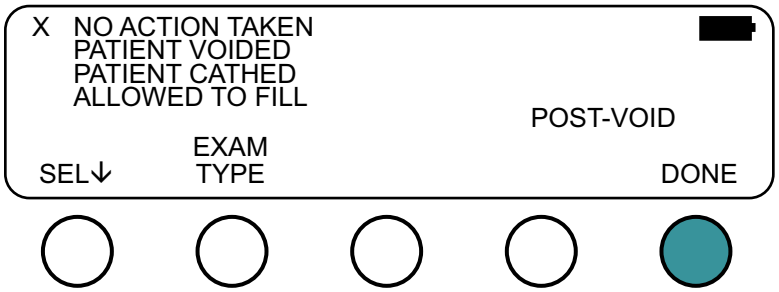


3. If you selected PATIENT VOIDED or PATIENT CATHED in Step 2, enter the amount of urine (rounded to the nearest 10 ml) that was voided or catheterized by pressing the plus **+** and minus **–** buttons.

   Note: By default, the amount of voided or catheterized urine is equal to the volume measured during the scan.



4. When you are finished entering notes, press the **DONE** button.

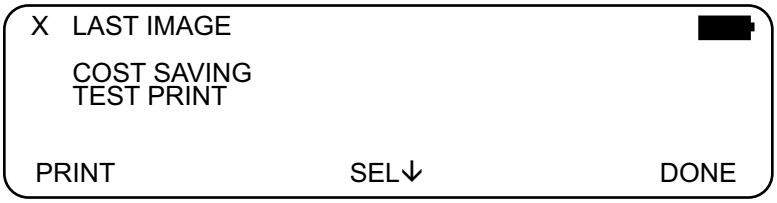


PROCEDURE 3. PRINT THE SCAN RESULT (OPTIONAL)

You may access the Print screen from either the Main Menu screen or the Scan Results screen. For information about adjusting the scan information that appears on the printout, see the procedure Adjust User Preferences on page 21.

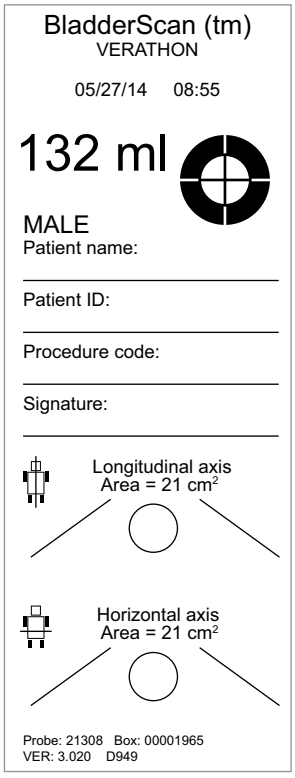
Note: If you have enabled the QUICK setting in user preferences, you cannot access the Print screen from the Scan Results screen. If you are on the Scan Results screen and you press the PRINT button, the instrument automatically prints the scan results without displaying the Print screen.

Figure 11. Print Screen



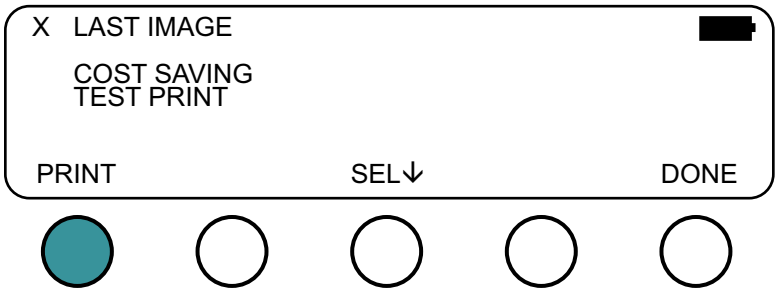
Note: If the facility name, date, and time have not been set, those lines will not be included on the printout.

Figure 12. Printout of Scan Results

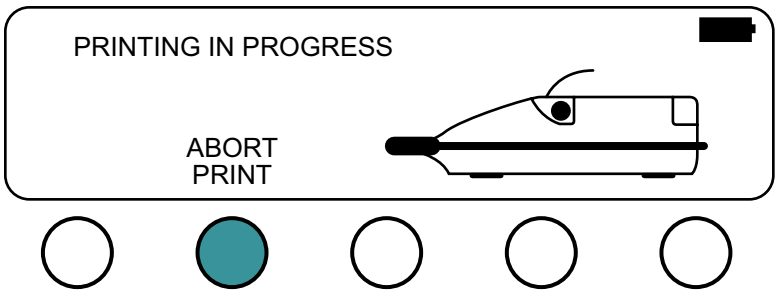


1. On the Print screen, ensure that **LAST IMAGE** is selected. If necessary, press the **SEL↓** button in order to select LAST IMAGE.
2. Press the **PRINT** button.

   Note: Printing takes approximately one minute.



3. If you would like to cancel printing while it is in progress, press the **ABORT PRINT** button.



4. When printing is completed, tear the paper from the instrument by pulling the printout towards the back of the instrument.

5. If desired, create a photocopy of the printout. The BVI 3000 instrument prints on thermal paper. Over time, the printout will fade. For maximum storage life, Verathon® recommends that you create a photocopy of the printout.

PROCEDURE 4. PRINT A HISTOGRAM OF COST SAVINGS (OPTIONAL)

Each volume measurement from a completed scanning procedure is stored in the instrument's memory. Measurement data is stored in one of eleven volume ranges (each with a 100-ml increment). This data is analyzed and can be printed at any time.

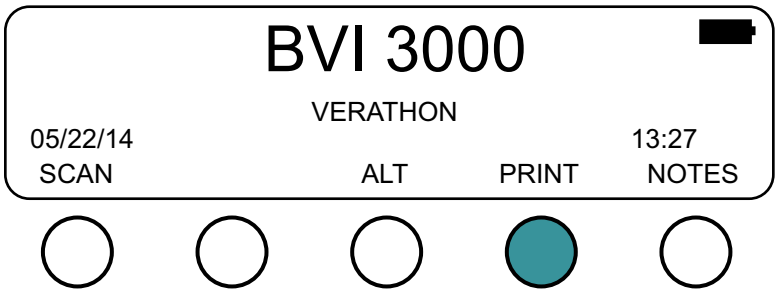
Cost savings are calculated based on the following criteria:

- **Catheterizations avoided**—Urinary catheterization below a certain volume is deemed unnecessary. Thus, by using the BVI 3000, these catheterizations are avoided. The default setting (for volume below which catheterization is unnecessary) is 300 ml.
- **Cost of catheter kits**—The default setting is $3 per kit.
- **UTIs avoided**—Studies indicate that a certain percentage of catheterizations lead to urinary tract infections (UTIs). By avoiding unnecessary catheterizations, the resulting UTIs may be prevented. The default setting (for percent of catheterizations leading to UTIs) is 3%.
- **Cost of UTIs avoided**—Literature suggests that the additional costs associated with treating UTI amount to $680.00 per patient infection. The default setting is $680.

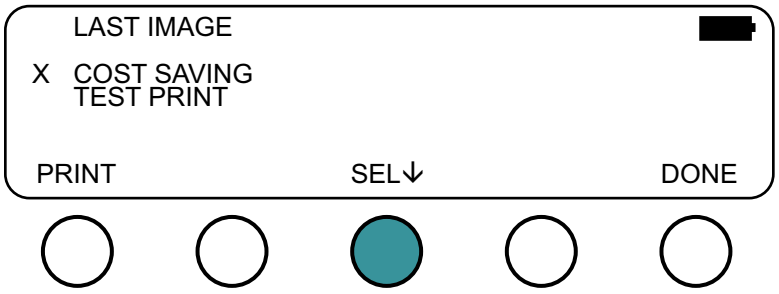
Total cost savings as a result of using the BVI 3000 = (Caths Avoided x Catheter Costs) + (UTIs Avoided x UTI Costs).

For information about adjusting the default values used when calculating the cost savings, see the procedure Adjust User Preferences on page 21.

1. On the Main Menu, press the **PRINT** button.

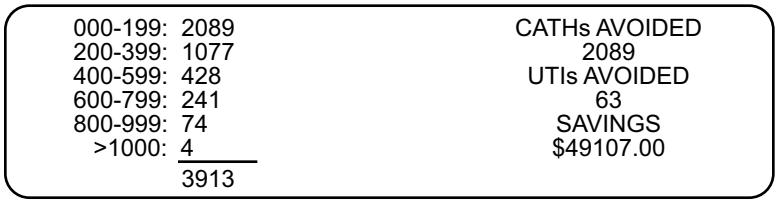


2. On the Print screen, press the **SEL↓** button until Cost Saving is selected.

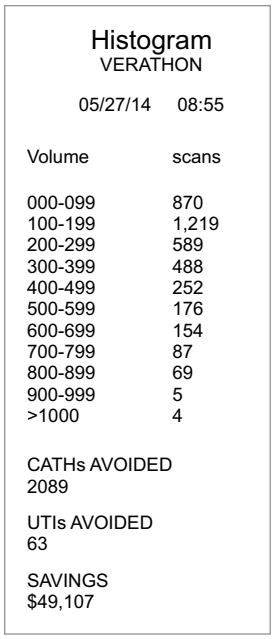


3. Press the **PRINT** button. The instrument begins to print the histogram of cost savings. While the instrument is printing, the cost savings are displayed on the instrument LCD.

   Note: Printing takes approximately one minute.



4. When printing is completed, tear the paper from the instrument by pulling the printout towards the back of the instrument.



Histogram
VERATHON

05/27/14 08:55

Volume	scans
000-099	870
100-199	1,219
200-299	589
300-399	488
400-499	252
500-599	176
600-699	154
700-799	87
800-899	69
900-999	5
>1000	4

CATHs AVOIDED
2089

UTIs AVOIDED
63

SAVINGS
$49,107

5. If desired, create a photocopy of the printout. The BVI 3000 instrument prints on thermal paper. Over time, the printout will fade. For maximum storage life, Verathon® recommends that you create a photocopy of the printout.

CLEANING & DISINFECTING

Routine cleaning and maintenance will help ensure safe and effective operation of the BladderScan BVI 3000 system. Clean and disinfect the instrument before use and between patient exams. For more information, please contact your authorized BladderScan Service Center, your local BladderScan distributor, or Verathon® Customer Care.

WARNING

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

WARNING

Availability of cleaning and disinfection products varies by country, and Verathon is unable to test products in every market. For more information, please contact Verathon Customer Care at 1.800.331.2313 or your local representative. For additional contact information, visit verathon.com/contact-us.

WARNING

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

PROCEDURE 1. CLEAN THE INSTRUMENT

WARNING

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

Cleaning is the removal of all visible soil or contaminants from the exterior surfaces of the device. The device must be cleaned after every use, and cleaning is an essential step before disinfection.

1. Wipe the acoustic coupling gel completely off the scanhead.
2. Use a moistened, soft cloth to remove particulate matter or body fluids that remain on the instrument.
3. Do not re-use cloths or wipes.
4. Allow the device to air dry, or towel dry with a clean dry cloth. Next, you must disinfect the instrument.

PROCEDURE 2. DISINFECT THE INSTRUMENT

IMPORTANT

Failure to heed the following may cause device damage not covered by the warranty:

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

Disinfectants and cleaning methods listed are based on compatibility with product materials, not biological effectiveness. Refer to the instructions from the manufacturer of the disinfectant for guidance on biological effectiveness of the disinfectant.

The following liquid disinfectants and wipes are compatible with the materials used in the instrument:

- A-456® II Disinfectant
- Accel® TB Wipes
- CaviCide®
- CaviWipes®
- Chloro-Sol Spray®
- Clorox® Germicidal Wipes
- Mikro Quat
- Sani-Cloth® Bleach Wipes
- Sani-Cloth® Germicidal Wipes
- Sani-Cloth® Plus Germicidal Wipes
- Sporicidin® Disinfecting Towelettes
- T-Spray II®

The level of disinfection required for a device is based on the type of tissue it contacts during use. Based on the intended use of the BladderScan BVI 3000 system, low-level disinfection is the minimum level required.

1. Ensure the instrument has been properly cleaned according to the procedure Clean the Instrument on page 38.
2. Ensure the disinfectant has not expired.
3. If using a liquid disinfectant, prepare the disinfection solution according to the manufacturer's label instructions, ensuring that you are using the proper concentration.
4. Apply the solution to a soft cloth or wipe.

   Note: Do not spray or apply liquid disinfectants directly to the surface of the device, and do not soak the device in liquids.
5. Wipe the surfaces of the device and allow the surface to remain wet for the required contact duration. Follow the manufacturer's instructions for the appropriate disinfection level contact duration.
6. Do not re-use cloths or wipes.
7. If rinsing or removal of the disinfectant solution from the device is required by the disinfectant manufacturer's instructions, wipe with a clean soft cloth dampened in sterile water. Verathon® recommends wiping the device three separate times to remove all residual disinfectant.
8. Allow the device to air dry, or towel dry the device with a clean, dry cloth.

MAINTENANCE & TROUBLESHOOTING

ANNUAL CERTIFICATION OF CALIBRATION

Verathon® recommends that the BVI 3000 be certified by an authorized Verathon Service Center once a year. Certification service includes a comprehensive inspection and testing of the instrument in order to ensure accurate measurement performance. For more information, please contact the Verathon Service Center or your local distributor.

If the calibration due date for your BVI 3000 has passed, the message “Calibration Due” will appear every time you turn on the instrument. You can still measure bladder volume; however, this message will continue to appear until an authorized Verathon Service Center calibrates the instrument.

PERIODIC INSPECTIONS

WEEKLY INSPECTIONS

Once a week, you should inspect the control unit, scanhead, cable, power supply, power cords, batteries, and plugs for damage or cracks. Cracks that allow the ingress of fluid into the control unit or scanhead may affect the performance of the instrument. Any apparent cracks or faults in the control unit, scanhead, or the cable that links the control unit and the scanhead must be referred to your authorized Verathon Service Center or your local distributor.

MONTHLY ACCURACY CHECK

Each month, or whenever accuracy assessment is desired, you should test the accuracy of the instrument according to the instructions in the procedure Verify Instrument Accuracy on page 47.

DEVICE REPAIR

The BladderScan BVI 3000 system components are completely sealed and not user-serviceable. 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. All service must be performed by a qualified technician.

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

WARNING

Electric shock hazard. Do not attempt to open the system components. This may cause serious injury to the operator or damage to the instrument and will void the warranty. Contact Verathon Customer Care for all servicing needs.

WARNING

No modification of this equipment is allowed.

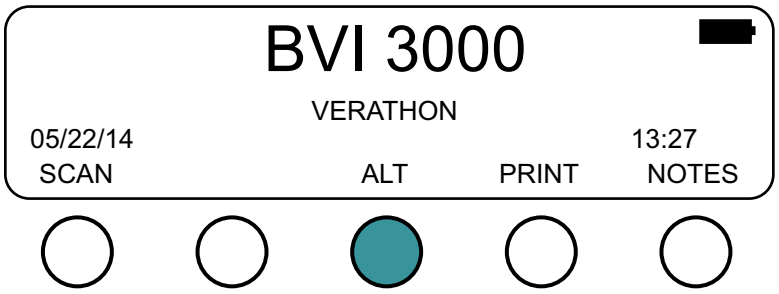
TROUBLESHOOTING

PROCEDURE 1. RUN A SELF TEST

The following tests are completed as part of the self test:

- ROM Test—Program memory
- BUS Test—Microprocessor bus
- NVRAM Test—Non-volatile, battery-backed memory
- SRAM Test—Main memory
- FLASH Test—Flash memory

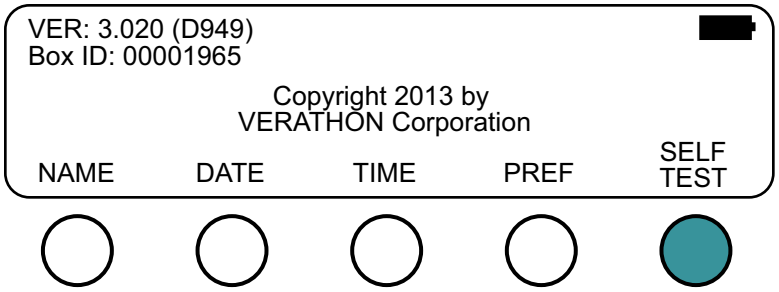
1. Turn the BladderScan BVI 3000 on by pressing the power button.
2. On the Main Menu screen, press the **ALT** button.



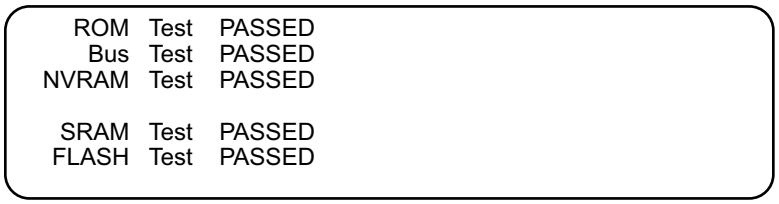
3. If you are prompted, enter your PIN code.

   Note: The default PIN code is 0000.

4. On the Alternate Menu screen, press the **SELF TEST** button. The instrument begins the self test.



As the test is completed, the Self Test screen displays the status of the systems tested. When the test is complete, the instrument returns to the Main Menu screen.



5. If any of the self-test systems does not pass, contact Verathon Customer Care or your local representative.

PROCEDURE 2. TROUBLESHOOT POWER ISSUES

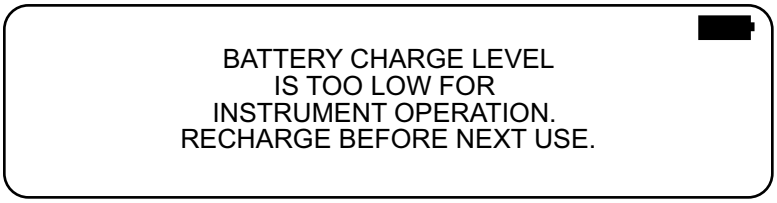
If the instrument does not turn on, this is usually due to a dead or discharged battery and can be fixed simply by replacing the dead battery with a charged one.

1. Check the battery icon in the upper-right corner of the LCD screen.
2. If the battery icon is clear (empty), replace the battery or recharge the current battery. For more information, see Charge the Batteries on page 10.
3. If replacing or charging the battery does not resolve the issue, contact Verathon® Customer Care or your local representative.

PROCEDURE 3. TROUBLESHOOT AN ERROR MESSAGE

BATTERY CHARGE LEVEL

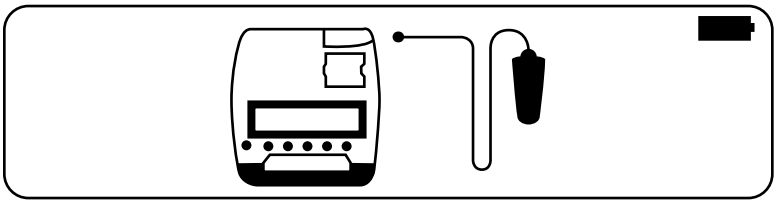
When the battery's charge is too low to allow normal operation (but not too low to permit operation of the internal circuitry) the BVI 3000 displays the following message: BATTERY CHARGE LEVEL IS TOO LOW FOR INSTRUMENT OPERATION. RECHARGE BEFORE NEXT USE.



1. Replace the battery or recharge the current battery. For more information, see Charge the Batteries on page 10.

NO SCANHEAD

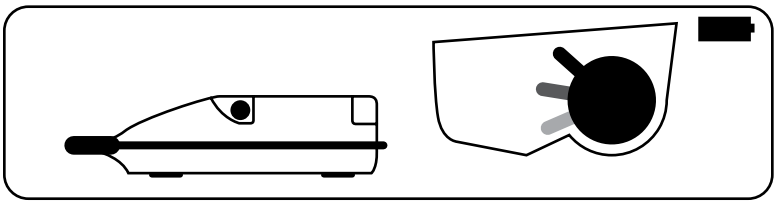
The following image is displayed if the user presses the SCAN button when the scanhead is not connected to the control unit.



1. Connect the scanhead to the control unit according to the instruction in the procedure Connect the Scanhead to the Control Unit on page 13. When the scanhead is properly attached to the control unit, the error disappears, and the instrument operates normally.

PRINTHEAD DISENGAGED

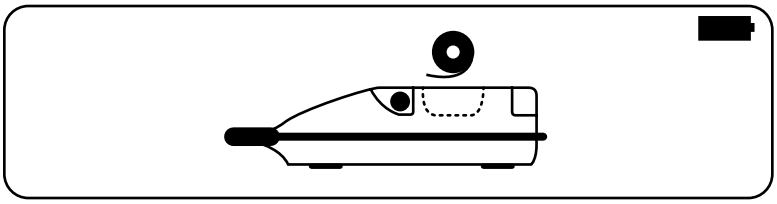
The instrument senses when the printhead is disengaged and displays the following image until the printhead release lever is positioned up as far as it can go.



1. Turn the printhead release lever so that it is pointing to 10 o'clock.

NO PAPER

The BVI 3000 displays the following image when the printer is out of paper.



1. Load paper according to the instructions in the procedure Load The Thermal Paper Roll on page 14.

TOO HOT

The BVI 3000 displays the following message if the printhead overheats.

1. Turn off the BVI 3000, and then wait for the instrument to cool down.
2. Ensure that this is not the result of a paper jam. For more information, see Clear a Paper Jam on page 44.
3. If the printhead continues to overheat, contact Verathon® Customer Care or your local representative.

RESCAN (INTERFERENCE)

The BVI 3000 displays the message RESCAN if it detects interference of sufficient magnitude to possibly compromise measurement accuracy. For more information, see Electromagnetic Compatibility on page 54.

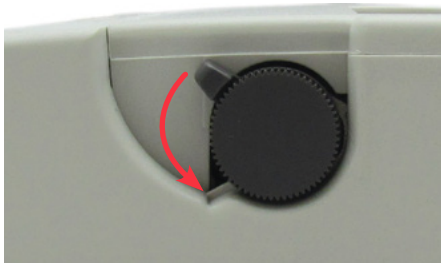
1. Locate the source of the interference.
2. Disable or remove the interference source, or use the BVI 3000 away from the interference source.
3. If these efforts do not restore normal operation, contact Verathon® Customer Care.

PROCEDURE 4. CLEAR A PAPER JAM

IMPORTANT

If the paper jam is inaccessible, do not try to disassemble the printer. Contact your authorized Verathon® Service Center or your local Verathon distributor for service.

1. On the right side of the instrument, next to the paper roll well, lower the printhead release lever.



2. While moving the manual paper-feed wheel counterclockwise, gently pull the paper backward until the paper jam is cleared and the paper roll is free of the instrument.

3. Turn the printhead release lever so that it is pointing to 10 o'clock.

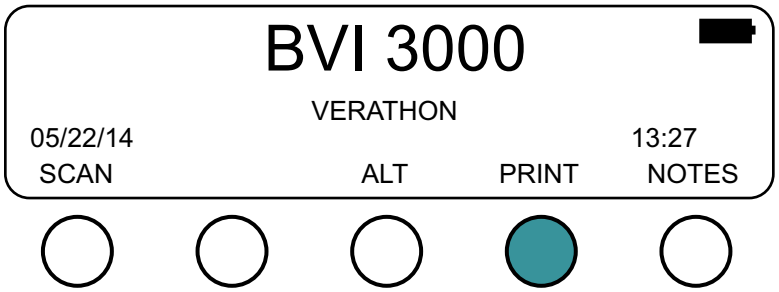
4. Trim any damaged paper off of the paper roll.
5. Ensure that the new end of the paper roll is cut straight. Do not fold the end of the paper roll, cut it diagonally, or cut it to a point.
6. Reload the paper roll according to the instructions in the procedure Load The Thermal Paper Roll on page 14.

PROCEDURE 5. TEST THE PRINTER

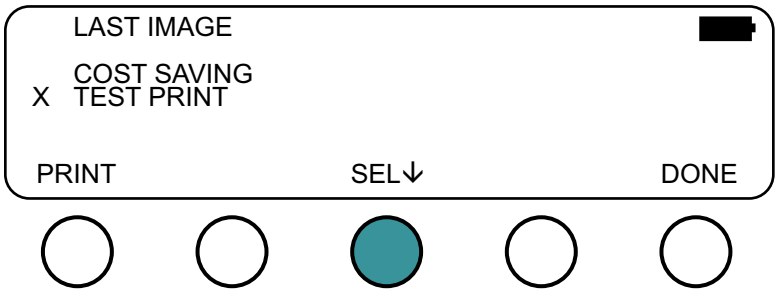
Select this option to test if the built-in thermal printer works. The instrument will print alphanumeric characters and a simple grayscale test pattern.

1. Ensure a paper roll has been inserted into the instrument according to the instructions in the procedure Load The Thermal Paper Roll on page 14.

2. On the Main Menu screen, press the **PRINT** button.

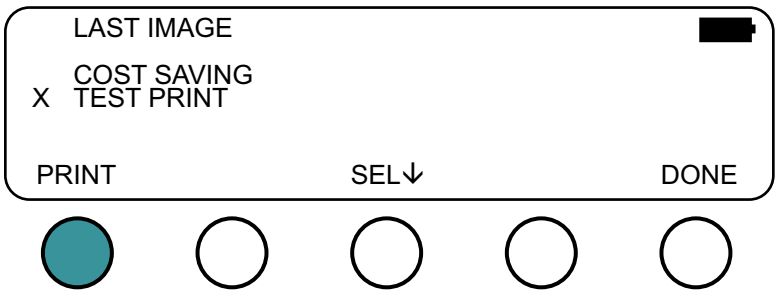


3. On the Print screen, press the **SEL↓** button until TEST PRINT is selected.

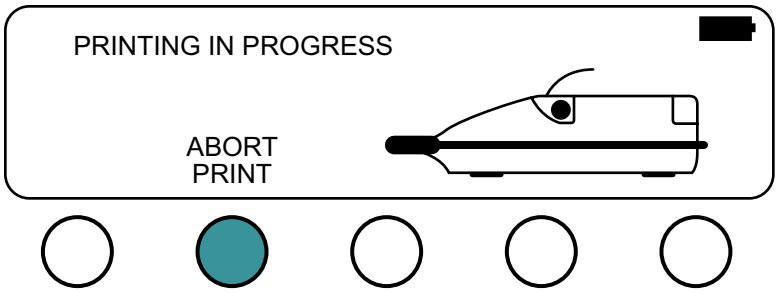


4. Press the **PRINT** button. The instrument begins printing.

   Note: Printing takes approximately one minute.

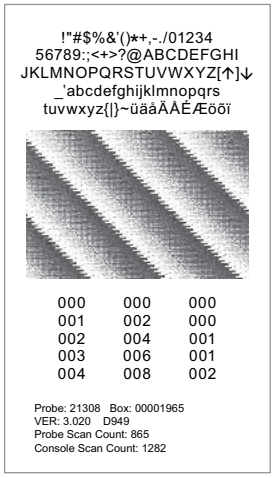


5. If you would like to cancel printing while it is in progress, press the **ABORT PRINT** button.



6. When printing is completed, tear the paper from the instrument by pulling the printout towards the back of the instrument.

7. Ensure that the instrument prints an array of alphanumeric characters and a simple grayscale test pattern.



PROCEDURE 6. VERIFY INSTRUMENT ACCURACY

Measurement accuracy is dependent upon aiming the scanhead so that the bladder falls entirely within the measurement cone and following the proper instructions for use. When confirming measurement accuracy, ensure that you are measuring the bladder volume according to the instructions in this manual.

1. According to the instructions in the chapter Using the Instrument on page 24, measure the pre-void volume of a bladder.
2. Void or catheterize into a measurement beaker. This is called the *voided volume*.
3. According to the instructions in the chapter Using the Instrument on page 24, measure the post-void volume of the bladder. This checks for any post-void residual (PVR).
4. Subtract the post-void measurement collected in Step 3 from the pre-void measurement collected in Step 1. This is called the *measured volume*.
5. Compare the voided volume collected in Step 2 to the measured volume from Step 4.

   If the voided volume is less than 699 ml, the measured volume should be within ± (20% + 20 ml).

   If the voided volume is more than 699 ml, the measured volume should be within ± (25% + 25 ml).
6. If the measured volume is not within the accuracy range, contact Verathon Customer Care or your local representative.

DEVICE DISPOSAL

Disposal of this device in accordance with WEEE requirements can be coordinated through your Verathon® Service Center.

WARRANTY

Verathon® warrants the BladderScan BVI 3000 against defects in material and workmanship for one (1) year from the date of purchase from Verathon Inc. Warranty extensions are available. For more information, contact Verathon Customer Care or your local representative. For contact information, see verathon.com/contact-us.

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 is given only to the original purchaser of the BladderScan instrument. This warranty does not cover equipment sold as used.

This warranty does not apply if the product has been damaged by misuse or as the result of service or modification 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, as provided in the Product Specifications chapter.

Warranty conditions may differ in some countries. Contact your local distributor for warranty terms.

DISCLAIMER OF ADDITIONAL WARRANTIES

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

Some states disallow certain limitations on applied warranties. The purchaser should consult state law if there is a question regarding this disclaimer. The information, descriptions, recommendations, and safety notations in this manual are based upon Verathon experience and judgment, as of June 2014, with respect to the BladderScan BVI 3000 instrument. The contents of this manual should not be considered to be all-inclusive or covering all contingencies.

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

PRODUCT SPECIFICATIONS

SAFETY & PERFORMANCE SUMMARY

- The BladderScan BVI 3000 computes the volume of the urinary bladder based upon twelve, cross-sectional ultrasound images. For maximum accuracy, be sure to hold the scanhead motionless while scanning.
- The most accurate measurements are obtained when the patient rests quietly in the supine position.
- Accuracy is compromised if the user does not obtain an optimal, repeatable image.
- Errors in usage tend to result in the underestimation of bladder volume, except in cases where the scanhead is moved during scanning. In this case, the measurement may overestimate the patient's bladder volume.
- The BladderScan BVI 3000 is not intended for use on pregnant patients.
- The patient being scanned should not have a catheter in his or her bladder. This could create micro bubbles in the bladder, which affect the accuracy of the measurement.
- Do not use the BVI 3000 on patients with open skin or wounds in the suprapubic region.
- Use care when scanning suprapubic and pelvic surgery patients. Scar tissue, surgical incisions, sutures, and staples can affect ultrasound transmission and reflection.
- To conserve power, the BladderScan BVI 3000 turns off automatically when not in use.
- Verathon® recommends that new operators first use the BVI 3000 on patients with moderately full bladders, rather than initially attempting to locate a bladder with a low volume.
- Warning: There is the possible hazard of explosion if the BVI 3000 is used in the presence of flammable anesthetics.

ACCURACY RANGE

Given the tremendous variation of healthy and compromised human anatomy, a guaranteed accuracy specification for the instrument used on humans would be difficult. The accuracy that an individual achieves when using the BVI 3000 depends on properly aiming the scanhead so that the bladder falls entirely within the measurement cone. Ensure that you follow the instructions for use in the chapter Using the Instrument on page 24.

It is suggested that you verify instrument accuracy by scanning a calibrated adult bladder tissue-equivalent phantom (if available) or by completing the procedure Verify Instrument Accuracy on page 47.

Table 6. Scanning Accuracy Range

BLADDER VOLUME	ACCURACY RANGE
0 to 699 ml	± (20% + 20 ml)
700 to 999 ml	± (25% + 25 ml)

COMPONENT SPECIFICATIONS

CONTROL UNIT & SCANHEAD SPECIFICATIONS

Table 7. General Specifications

SPECIFICATION	VALUE
Classification	Electrical Class II, Applied Part BF
Input	Rechargeable nickel–metal hydride (NiMH) battery.
Transient overvoltage	Category II
Integrated printer	Thermal printer
Ingress protection against water	IPX1 (drip-proof, a higher than ordinary level of protection from drips, leaks, and spills)

Table 8. Operating & Storage Conditions

SPECIFICATION	VALUE
Operating Conditions	
Use	Indoor
Ambient temperature range	10–40ºC (50–104ºF)
Atmospheric pressure range	700–1060 hPa
Relative humidity	30–75% non-condensing
Storage Conditions	
Storage	Indoor
Ambient temperature range	-20–60ºC (-4–140ºF)
Atmospheric pressure range	500–1060 hPa
Relative humidity	20–95% non-condensing

Table 9. Ultrasound Acoustic Output Parameters

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

ACOUSTIC OUTPUT			MI	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (W/cm^2)
Global Maximum Value			0.218*	0.0676	2.95
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	0.317		
	W_o	(mW)		0.0676	0.238
	f_c	(MHz)	2.12	2.12	2.12
	z_{sp}	(cm)	2.80		2.80
	Beam dimensions	x_{-6} (cm)			0.367
		y_{-6} (cm)			0.377
	PD	(µsec)	1.17		1.17
	PRF	(Hz)	400		400
	EDS	Az. (cm)		5.46	
		Ele. (cm)		1.20	

TIS/TIB/TIC range	0.0-1.0*
Image Rate	5.55 Hz
M-Lines	72
Sector Angle	120°
Sector Offset	2.035 cm

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

BATTERY CHARGER SPECIFICATIONS

Use only the battery charger supplied. Use of any other charger may damage the battery pack.

The power supply for the battery charger used with the BVI 3000 is tested to IEC 60601-1 requirements and is in compliance with UL and CSA equivalent standards.

The power supply is not intended for direct patient contact. The batteries used in the BVI 3000 are charged separate from the control unit and not during patient use.

Table 10. Battery Charger Specifications

SPECIFICATION	VALUE
Electrical Specifications	
Input voltage	100-120 VAC/North American (LZA-) units 200-250 VAC/European (LZE-) units 100-250 VAC/Universal (LZU-) units
Input frequency	50–60 Hz
Input current	0.39 A/North American (LZA-) units 0.25 A/European (LZE-) units 0.38 A/Universal (LZU-) units
Output	No load to full load at rated voltage. Refer to unit label
Input connection	The power supply employs a direct plug in AC prongs for wall plug-in units
Insulation	The power supply is Class I with basic insulation to each terminal
Environmental Specifications	
Operating temperature	10 to 40°C (50 to 104°F)
Transient overvoltage	Category II
Pollution degree	II
Atmospheric pressure	700 hPa to 1060 hPa
Relative humidity	30 to 75%, non-condensing
Ventilation	The power supply is designed to operate with free air convection.
Earth terminal	The earth terminal provided in this unit is a functional earth terminal, as indicated by the ground symbol on the unit. It is not utilized in the power supply to provide earth protection. Various ground options are available upon request.
Fuses	The fuses used in the power supply are rated at 250 VAC, 2 A, quick acting.

BATTERY SPECIFICATIONS

SPECIFICATION	VALUE
Battery type	Rechargeable nickel–metal hydride (NiMH)
Nominal voltage	7.2 V
Battery service life	>500 cycles (IEC standard), approximately 2 years at 5 cycles per week
Charging time and conditions	160 mA for 16 hours at 20°C (68°F)
Rated capacity	1.6 Ah
Charging voltage	9–32 V DC source
Max weight	195 g (0.43 lbs)
Width	61 mm (2.4 in)
Length	59 mm (2.3 in)
Height	36 mm (1.4 in)

ELECTROMAGNETIC COMPATIBILITY

BladderScan BVI 3000 system is designed to be in compliance with IEC 60601-1-2:2007, which contains electromagnetic compatibility (EMC) requirements for medical electrical equipment. The limits for emissions and immunity specified in this standard are designed to provide reasonable protection against harmful interference in a typical medical installation.

In addition, the BVI 3000 detects outside interference and displays **RESCAN** instead of a volume measurement if the detected interference is of sufficient magnitude to possibly compromise measurement accuracy. If you experience this display repeatedly, see the entry "Rescan (Interference)" in the procedure Troubleshoot an Error Message on page 42.

The BladderScan BVI 3000 system complies with the applicable essential performance requirements specified in IEC 60601-1 and 60601-2-37. Results of immunity testing show that the essential performance of the system is not affected under the test conditions described in the following tables. For more information about the essential performance of the BladderScan BVI 3000 system, see Essential Performance on page 1.

ELECTROMAGNETIC EMISSIONS

Table 11. Guidance and Manufacturer's Declaration—Electromagnetic Emissions

The BladderScan BVI 3000 system is intended for use in the electromagnetic environment specified below. The customer or the user of the BladderScan BVI 3000 system should assure that it is used in such an environment.

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
RF emissions CISPR 11	Group 1	The BladderScan BVI 3000 system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The BladderScan BVI 3000 system is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

ELECTROMAGNETIC IMMUNITY

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

The BladderScan BVI 3000 system is intended for use in the electromagnetic environment specified below. The customer or the user of the BladderScan BVI 3000 system should assure that it is used in such an environment.

IMMUNITY TESTS	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	In compliance	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	In compliance	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	In compliance	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	In compliance	Mains power quality should be that of a typical commercial or hospital environment. If the user of the BladderScan BVI 3000 system requires continued operation during power mains interruptions, it is recommended that the BladderScan BVI 3000 system be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	In compliance	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the BladderScan BVI 3000 system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance d (m)** $d=1.2\sqrt{P}$

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

The BladderScan BVI 3000 system is intended for use in the electromagnetic environment specified below. The customer or the user of the BladderScan BVI 3000 system should assure that it is used in such an environment.

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

Note: U_T is the AC mains voltage prior to application of the test level.

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

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

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BladderScan BVI 3000 system is used exceeds the applicable RF compliance level above, the BladderScan BVI 3000 system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the BladderScan BVI 3000 system.

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

RECOMMENDED SEPARATION DISTANCES

Table 13. Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the BladderScan BVI 3000 System

The BladderScan BVI 3000 system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BladderScan BVI 3000 system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BladderScan BVI 3000 system as recommended below, according to the maximum output power of the communications equipment.

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

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

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

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

ACCESSORY CONFORMANCE TO STANDARDS

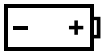
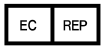
To maintain electromagnetic interference (EMI) within certified limits, the system must be used with the cables, components, and accessories specified or supplied by Verathon®. For additional information, see the System Components & Accessories and Component Specifications sections. The use of accessories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

Table 14. EMC Standards for Accessories

ACCESSORY	MAX LENGTH
AC power cord	2 m (6.6 ft)
Battery charger	—

SYMBOL DIRECTORY

SYMBOL	MEANING
Warnings & Cautions	
	Warning or Caution—Consult accompanying documents. Read instructions before connecting or operating.
	Do not incinerate
	Non-ionizing, electromagnetic radiation
Product Use & Specifications	
	Refer to the operations & maintenance manual
	Manufacturer
	Use-by date
	Use in indoor, dry location only
REF	Catalog (part) number
SN	Serial number
LOT	Batch code
	Temperature limitation
	Humidity limitation
	Atmospheric pressure limitation
Rx Only	Statement of prescription
	Orient scanhead so that icon aligns with the patient's head and feet

SYMBOL	MEANING
	Orient scanhead so that icon aligns with the patient's head and feet
	Scan
	Power on/off
Electrical & Power	
	Class II equipment
	Type BF applied part
	Energy Efficiency Level V
	Battery pack reference part number
	Direct current
	Ground symbol, earth terminal
Standards & Certifications	
	CE—Marked in accordance with the Medical Device Directive (MDD)
	CSA—Canadian Standards Association mark of certification to applicable standards for electromedical equipment
	EC REP—Authorized Representative in the European Community
	RoHS—Meets standards for Restriction of Hazardous Substances (RoHS)
	UL—Underwriters Laboratories certification mark for electrical shock, fire, and mechanical hazards only
	UL—Underwriters Laboratories Recognized Component certification mark in Canada and the United States
	WEEE—Subject to waste electrical and electronic equipment regulations

GLOSSARY

TERM	DEFINITION
6HRLTR6	Battery cell designation
A	Ampere
AC	Alternating current
Ah	Ampere-hour
C	Celsius
CISPR	International Special Committee on Radio Interference
cm	Centimeter
CSA	Canadian Standards Association
DC	Direct current
EMC	Electromagnetic compatibility
EMI	Electromagnetic interference
ESD	Electrostatic discharge
Essential performance	The system performance necessary to achieve freedom from unacceptable risk
F	Fahrenheit
g	Gram
GHz	Gigahertz
HIPAA	Health Insurance Portability and Accountability Act
hPa	Hectopascal
Hz	Hertz
IEC	International Electrotechnical Commission
in	Inch
IPA	Isopropyl alcohol
ISM	Industrial, scientific, and medical
kHz	Kilohertz
kV	Kilovolt
lbs	Pounds
m	Meter
mAh	Milliampere-hour
MDD	Medical Device Directive
MHz	Megahertz
MI	Mechanical index
mm	Millimeter
mW	Milliwatt
NiMH	Nickel-metal hydride
PIN	Personal identification number
PVR	Post-void residual

TERM	DEFINITION
RF	Radio frequency
RH	Relative humidity
RoHS	Restriction of Hazardous Substances
TI	Thermal index
TIB	Thermal index for bone
TIC	Thermal index for the cranium
TIS	Thermal index for soft tissue
UTI	Urinary tract infection
V	Volt
Vrms	Voltage root mean squared
W	Watt
WEEE	Waste electrical and electronic equipment

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