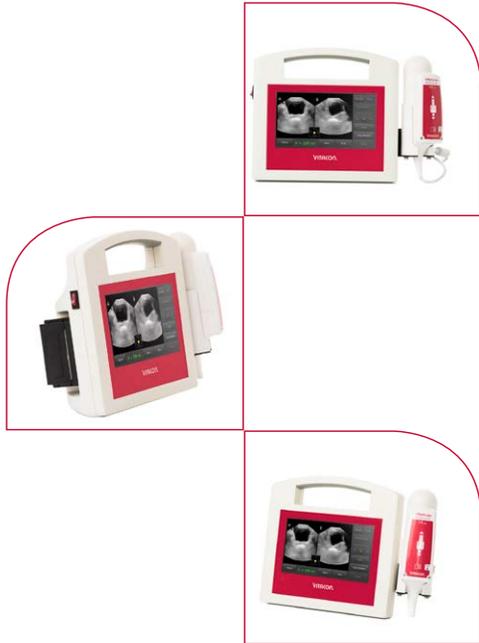




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VitaScan PD Ultrasound Bladder Scanner

User and Service Manual

Version 1.0.3 | Date: 11th of December 2017.



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Limited Warranty

Vitacon warrants that the VitaScan PD will substantially conform to published specifications and to the documentation, provided that it is used for the purpose for which it was designed. Vitacon will, for a period of twenty-four (24) months from the date of purchase, replace or repair any defective device, if the fault is due to a manufacturing defect. In no event will Vitacon or its local representatives be liable for direct, indirect, special, incidental, or consequential damages arising out of the use of or inability to use the VitaScan PD, even if advised of the

possibility of such damages. Vitacon or its local representatives are not responsible for any costs, loss of profits, loss of data, or claims by third parties due to use of, or inability to use the VitaScan PD. Neither Vitacon nor its local representatives will accept, nor be bound by any other form of guarantee concerning the VitaScan PD other than this guarantee. Some jurisdictions do not allow disclaimers of expressed or implied warranties in certain transactions; therefore, this statement may not apply to you.

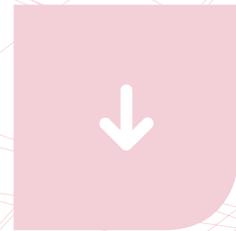
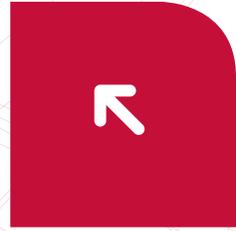
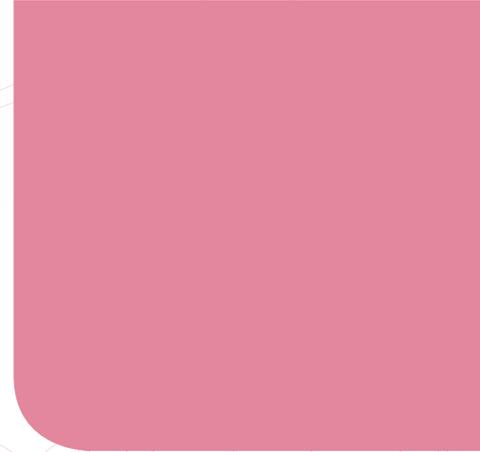
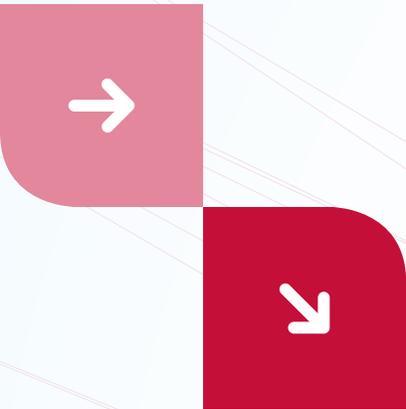


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Introduction

VitaScan PD - Ultrasound Bladder Scanner

Real-time bladder scanning is a safe and easy, non-invasive method to measure bladder volume. Bladder scanning measures ultrasonic reflections within a patient's body and differentiates the urinary bladder from the surrounding tissues.

The VitaScan PD is a B-mode ultrasound instrument, portable and battery operated, intended for the non-invasive measurement of urinary bladder volume. A mechanical sector scanning transducer

provides cross-sectional images of the bladder from up to twenty-four scan planes. Based on these images the VitaScan PD automatically calculates the estimated bladder volume in milliliters and displays it on a screen.

VitaScan PD is applicable in many clinical areas to determine bladder volume, time for bladder emptying and detection of post-void residual volume (PVR).

A real-time image of the bladder during pre-scan makes it easier to detect the bladder before scanning.

Important Information

Notice To All Operators:

The VitaScan PD 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 VitaScan PD. Failure to comply with these instructions may compromise the performance of the instrument and the safety of the patient.

output levels can be found in the section titled, "Technical Specifications" in this manual.

It is recommended that users read the Health Canada Guidelines for the Safe Use of Diagnostic Ultrasound before using this, or any other diagnostic ultrasonic device. (http://www.hc-sc.gc.ca/ewh-semt/alt_formats/hecs-sesc/pdf/pubs/radiation/01hecs-secs255/01hecs-secs255-eng.pdf, note this link may change over time).

Biological Safety:

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

Statement of Intended Use:

The VitaScan PD projects ultrasound energy through the lower abdomen of the patient to obtain an image of the bladder. This image is used to determine bladder volume noninvasively.

The ultrasound output power of the VitaScan PD is not user-adjustable and is limited to the minimum level necessary for effective performance. Data on acoustic

Contraindications

The VitaScan PD is not intended for fetal use or pregnant patients.



Warning: Exposure to low power diagnostic ultrasound has not been shown to produce adverse effects. However, medical professionals should use ultrasound only when clinically indicated.



Warning: There is the hazard of possible explosion if the VitaScan PD instrument is used in the presence of flammable anesthetics.

First time users We advise new operators to use the VitaScan PD on patients with moderately full bladders, rather than initially attempting to locate nearly empty bladders.



Caution:

The VitaScan PD should not be used on a patient with open skin or wounds in the suprapubic region.

- The manual measurement function should be used on patients with catheters, as a catheter can reflect ultrasound signals that can lead to an inaccurate volume measurement.
- User care with suprapubic/pelvic surgery patients, Scar tissue, incisions, sutures, and staples affect ultrasound transmission and reflection.
- Accuracy may be affected for patients with ascites or free floating fluid in the peritoneum.

Indications for Use

This manual is directed toward the reader who is familiar with Ultrasound techniques. Sonography training and clinical procedures are not included here. This manual is not intended as training material for the principles of ultrasound, anatomy, scanning techniques, or applications. You should be familiar with all of these before attempting to read this manual or using the device.

Product Features

- Real-time 3D Ultrasound Bladder Scanner.
- Automatic Urinary Bladder volume calculation in large digits
- Storage of ultrasound images
- Simple, intuitive software with Touch-Screen support

- Large for storage of Patient Records and Images
- Touch Screen
- USB port to save on external memory device
- Integrated carry handle
- Battery operated

Unpacking and Inspection

There are no special unpacking instructions, but be careful not to damage the instrument when unpacking it. When unpacking the VitaScan PD to check for damage during shipment:

- Inspect the shipping carton for damage. If the shipping carton is damaged, carefully continue unpacking the instrument and note any dents and scratches on the VitaScan PD. Save the damaged shipping carton and packing material for the carrier's inspection and contact the respective carrier. If there is any damage to the scanner equipment, contact Vitacon.
- If there is no shipping damage, continue removing the VitaScan PD from the shipping case. Save the box and packing materials; they will be needed when returning the VitaScan PD to Vitacon for recalibration or future service.
- Verify that all items listed on the packing list have been received and are in good condition.

Note:

This box contains specifically designed inserts to ensure safe shipment of the VitaScan PD. Save these for future shipment of the unit for service or calibration.

The content of the packaging:

This box contains specifically designed inserts to ensure safe shipment of the VitaScan PD. Save these for future shipment of the unit for service or calibration.

- VitaScan PD, VitaScan LT ultrasound probe and probe holder.
- USB Memory stick with User & Service Manual, certificates and application notes
- VitaScan PD console
- VitaScan LT Ultrasound probe
- Thermal Printer
- User Manual
- Power cord

Storage

If the system is to be stored, pack it in the original container, and keep it in an environment free of corrosive material, fluctuations in temperature and humidity, and vibration and shock.

Storage Requirements:

Storage temperature from -30°C to 50°C

Relative humidity of 20% to 90% @ 30°C, non-condensing

Atmospheric pressure from 700 hPa to 1060 hPa

As with most electronic equipment, the unit should be operated in a dry area within normal temperature limits (+10°C to +45°C, 10% - 80% humidity).

Dispose of electronic waste:

VitaScan PD complies with the WEEE Directive (2002/96/EC) marking requirements.

The affixed label indicates that you must not discard this Medical Electric Equipment in domestic household waste. Product category: With reference to the equipment types in WEEE directive annex IA, this product is classed as category 8 "Medical Devices". To return unwanted products, contact Vitacon at the address mentioned at the front of this manual or your local VitaScan distributor.

Technical Specifications

- Display type.....LCD Touchscreen Display
- Input method..... Touchscreen
- Volume range 0 - 1000 ml
- Accuracy..... +/- 10 % of reading, +/- 20 ml
- Frequency 2.35 MHz
- Acoustic OutputMI max: 0.38, Power: 0.25 mW/cm²
- Thermal Index - TI < 0.02
- Scanning method..... Sector, 180 degrees
- Rotation positions..... 6, 12 or 24 rotating positions
- Sweep angle 110 degrees
- Max detection depth.....100, 160 or 230 mm
- Max probe temperature.....35°C @ 22°C ambient temperature
- IP rating IPX1
- Input Voltage100 ~ 240VAC, 50 ~ 60Hz
- Dimension.....(D x W x H) 7.5 x 29.5 x 21 cm - 3.0 x 11.6 x 8.3 in
- Weight 2.0 kg - 4.4 lbs
- Operating conditions..... +10°C to + 45°C, 10 % - 80 % relative humidity
- Storage temperature.....-30°C to +50°C

¹ Accuracy referred to measurements on Vitacon Phantoms only.



AC/DC Adaptor

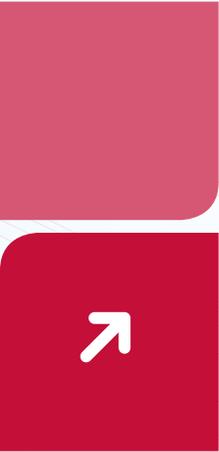
Input		Output	
Input range	100-240VAC	Maximum Power	25W
Frequency	50 - 60Hz	Nominal output	15V DC
Input current	0.7- 0.35A	Output current	Max 1.66A

Number	Item	Specifications
1	Rated Capacity (minimum)	7500mAH with 0.2C Charging & 0.2C Discharging
2	Nominal Capacity	75000mAH with 0.2C Charging & 0.2C Discharging
3	Normal Voltage	11.1V
4	Open circuit voltage when shipped	11.40V - 11.85V
5	Charge ending voltage	12.60V
6	Discharge ending voltage	9.0V
7	Charge current	0.4 C
8	Charging time	2.0 - 2.5 hours

Table 0-0 Battery Specifications

Product Upgrades and Updates

Vitacon may offer software upgrades and new features that may improve system performance. User and Service Manual updates, explaining the effects of upgrades and new features on system performance, will accompany the upgrades.



VitaScan PD

System Familiarization Introduction

The VitaScan PD is an Ultrasound Urinary Bladder Scanner System. The VitaScan PD consists of an inbuilt LCD Display with Touch Screen input and utilizes a VitaScan LT Ultrasound Probe.

Front View

The front view of the VitaScan PD is as shown in the figure below:



- 1 Touch Display
- 2 Ultrasound prob
- 3 ON/OFF button



Back View

The back view of the VitaScan PD is as shown in the figure below:



1 VESA mount - 75 x 75 mm

2 Probe holder mount

3 Thermal printer

4 DC Power Inlet - 15V



Left Side View

The left side view of the VitaScan PD is as shown in the figure below:

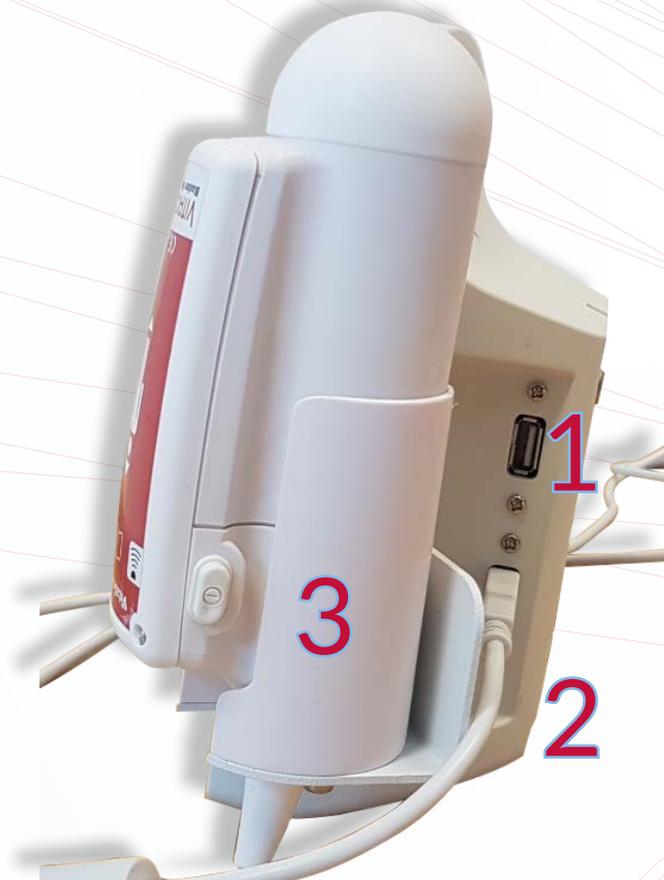


- 1 Power On/Off switch
- 2 Thermal printer



Right Side View

The right side view of the VitaScan PD is as shown in the figure below:



- 1 USB port for external USB memory stick
- 2 USB port for VitaScan LT probe
- 3 Probe holder

About the System Software

Vitacon will provide software updates on micro SD card. Typically, the new software provides new capabilities.

Electrical Safety

This system meets EN60601-1, Class I and Type BF isolated patient-applied parts safety requirements. This system complies with the applicable medical equipment requirements published in the European Norm Harmonized Standards, Underwriters Laboratories (UL) and the Canadian Standards Association (CSA).

For maximum safety observe the following warnings and cautions:



Warning:

To avoid the risk of electrical shock or injury, do not open the system enclosure. All internal replacements must be made by a qualified technician.

To avoid the risk of injury, do not operate the system in the presence of flammable gasses or anesthetics.

To avoid the risk of electrical shock, use only properly grounded equipment.

Shock hazards exist if the power supply is not properly grounded. Grounding reliability can only be achieved when equipment is connected to a receptacle marked "Hospital Only" or "Hospital Grade" or the equivalent. The grounding wire must not be removed or defeated. Connect equipotential ground terminal whenever integrity of the external protective earth conductor arrangement is in doubt.

To avoid the risk of electrical shock, before using the VitaScan PD, inspect the housing, cable, and probe. Do not use the VitaScan PD if these are damaged.

To avoid the risk of electrical shock, always disconnect the power inlet before cleaning the system.

To avoid the risk of electrical shock, do not use any transducer that has been accidentally immersed in any liquid, or has been immersed in any liquid for cleaning or any other purpose.

To avoid the risk of electrical shock, do not touch USB port or Ethernet port and the patient at the same time.

Caution:



Although your system has been manufactured in compliance with existing EMC/EMI requirements (EN60601-1-2), use of the system in the presence of an electromagnetic field can cause degradation of the ultrasound image. If this occurs often, Vitacon suggests a review of the system environment. Identify and remove the possible sources of the emissions or move your system.

Medical Electric Equipment can be affected by portable or mobile RF communication devices. Turn OFF any portable or mobile RF device before operating your system.

Electrostatic discharge (ESD), or static shock, is a naturally occurring phenomenon. ESD is common in conditions of low humidity, which can be caused by heating or air conditioning.

Static shock is a discharge of electrical energy from a charged body to a lesser or non-charged body. The degree of discharge can be significant enough to cause damage to a transducer or an ultrasound system. The following precautions can help reduce ESD: anti-static spray on carpets, anti-static spray on linoleum, and anti-static mats.

Do not use the system if an error message appears on the display: note the error code; turn off the system; call Vitacon or your local representative.

Equipment Safety

To protect your ultrasound system, scanner and accessories follow these precautions.

Caution:

- To avoid the risk of excessive heating or damage to the system, use the system in a well-ventilated environment.
- If the operating environmental temperature exceeds 25°C, limit scans to 5 minutes and allow a 10 minute cooling period between scans.
- Excessive bending or twisting of cables can cause a failure or intermittent operation.
- Do not submerge the VitaScan PD in any solution, follow the cleaning instructions.
- To avoid damaging the power supply, verify the power supply input is within the correct voltage range.
- Do not short the USB or Ethernet terminals.
- Always charge the battery before using the system, to avoid the risk of the system turning off while in use.
- Incorrect cleaning or disinfecting of any part of the system can cause permanent damage.
- Do not use solvents such as thinner or benzene, or abrasive cleaners on any part of the system.
- Do not spill liquid on the system.
- Do not use the system if it exhibits erratic or inconsistent behavior. Turn Off the power of the system and call Customer Service.
- Do not dispose of the battery in fire.
- Immediately discontinue use of the battery if, while using, charging or storing the battery, the battery emits an unusual smell, feels hot, changes color or shape, or appears abnormal in any other way. Contact a customer service representative if any of these problems are observed.
- Do not use the VitaScan PD if probe head or cable is damaged.
- Do not use the VitaScan PD if there is evidence of leakage of internal liquids. Wash hands immediately in warm, soapy water. Consult the MSDS on Polypropylene Glycol for additional information/precautions.
- To avoid the risk of electrical shock, do not use any VitaScan PD that has been immersed in liquid.**Note:**

Safety and Performance Summary

Safety and Performance Summary

The VitaScan PD computes the volume of the urinary bladder based upon twenty-four cross-sectional ultrasound images (or less). For maximum accuracy, be sure to hold the Scan head 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 Scan head is moved during scanning. In this case, the measurement may overestimate the patient's bladder volume.

The patient being scanned should not have a catheter in his/her bladder. This could create micro bubbles in the bladder, which affect the accuracy of the measurement.

Do not use the VitaScan PD 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.



Warning

There is a possible hazard of explosion if the VitaScan PD is used in the presence of flammable anesthetics.

Labeling Symbols



CE mark – Notified body no.2274



Warning, consult accompanying documents



Test Agency Certification Mark - North America



Read the documentation



BF type (Body Floating)



Ultrasound radiation



WEEE - Waste Electrical and Electronic Equipment



Drip proof



Alternating current input

Applicable Standards/Approvals

The VitaScan PD Bladder Monitor conforms with following standards:

CSA C22.2 NO 60601-1-08: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

IEC 60601-1 Medical Electrical Equipment - Part 1: General requirements for safety, 1988: A1 1991-11, A2 1995

CSA C22.2 NO. 60601-1-2A-03 (R2006) [EN 60601-1-2 (2001) + A1 (2006)]: Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests

IEC 60601-1:2005, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2 ed. 4.0 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

EN 60601-1-2:2007 Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

IEC 60601-2-37, Medical Electrical Equipment, Part 2-37: Particular Requirements for the basic safety and essential performance of ultrasonic equipment, Ed. 2.0, 2007-08

ISO 14971:2007 Medical devices – Application of risk management to medical devices

US FDA 510(k) market approval: K121689

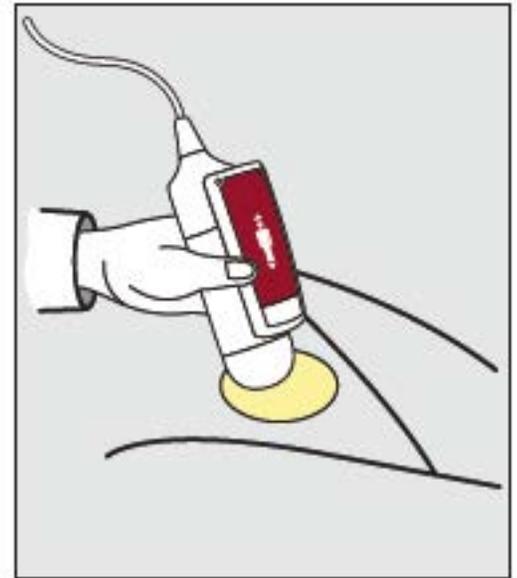
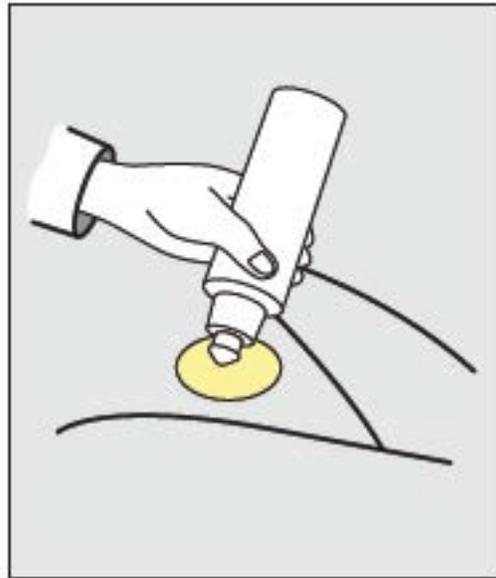
Applying the Ultrasound Gel

Palpate the patient's symphysis pubis (pubic bone) and apply the Gel immediately superior to the patient's symphysis pubis, as shown in images below. Or apply the Gel around the dome of the Probe. Smooth the gel out and remove any air bubbles, which may block ultrasound transmission.

Using Ultrasound Gel Pad:

Sometimes it may be convenient to use ultrasound transmission Gel pad. The Gel pad is an easy-to-use coupling medium.

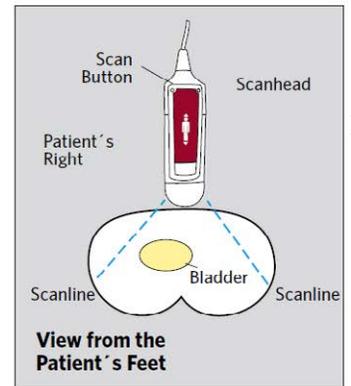
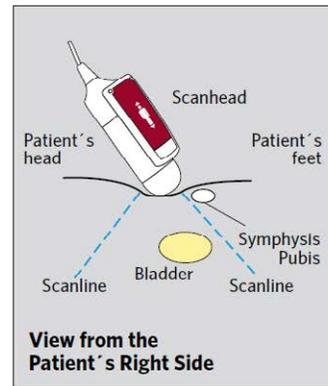
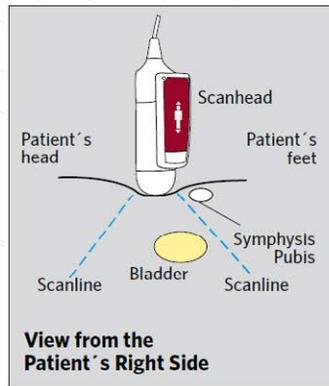
To apply the ultrasound Gel Pad, peel back the foil lid of the individual gel pad package, exposing the gel pad.



Measuring Bladder Volume

Palpate the patient's symphysis pubis and place the Scanhead midline on the patient's abdomen, approximately 4 cm (1.5 inches) superior to the symphysis pubis, as shown in images below.

- Aim the Scanhead so the ultrasound is projected toward the expected location of the bladder. For most patients, this means aiming the tip of the Scanhead toward the patient's coccyx.
- Press and release the scan button, located on the Scanhead.
- Locate the bladder.
- Press and release the scan button and hold the Scanhead steady throughout the scan.



Note:

While scanning, avoid making any changes in the position, angle or pressure of the Scanhead.

Regular Inspections and Maintenance

VitaScan PD is a Medical Electric Equipment and therefore needs special precautions regarding EMC. VitaScan PD needs to be installed and put into service according to the EMC information provided in the accompanying documents.

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

Weekly Inspections:

Once a week, you should inspect the Scanhead and cable for physical faults or cracks. Cracks that allow the leakage or ingress of fluid may affect the safety and/or the performance of the instrument. Any apparent faults or cracks must be referred to your authorized VitaScan Service Center or your local VitaScan distributor.



Figure 0-1 Home Screen

- Tap on the screen, to navigate through the screen.
- Tap Woman or Man option
- For Woman tap Hysterectomy if needed
- Tap Scan Depth option
- Tap Start to start Prescan and locate the bladder.
- Tap Restart to start a new scan
- Tap Setup to enter setup menu

Scan Operation

To make a measurement, press the Start button in the Home Screen. The Prescan displayed as shown below.

Scan Operation

To make a measurement, press the Start button in the Home Screen. The Prescan displayed as shown below.



Figure 0-2 PreScan

- Tap SCAN to start scanning of the whole bladder.
- Tap Restart to stop pre-scan.
- Tap Icon  to colorize the detected area.

Scan Operation

To make a measurement, press the Start button in the Home Screen. The Prescan displayed as shown below.



Figure 0-3 Result

- Tap Start to do a new scan
- Tap Clear/Restart to clear screen
- Tap Print to print result
- Tap Save to save result to USB memory stick. (Only enabled when USB-memory stick is connected)
- Tap Adjust to adjust result. (Adjustment might be needed if bladder edge is not detected properly)

Adjust result



Figure 0-3 Result

- Tap  to Adjust transversal plane. (Move blue marker points to bladder edge)
- Tap  to Adjust sagittal plane. (Move blue marker points to bladder edge)
- Tap Done to end adjustment

Adjust result



Figure 0-5 Setup

- Tap H:M:S to toggle between Hour - Minutes - Second. Change setting by - or +
- Tap Y-M-D to toggle between Year - Month - Day. Change setting by - or +
- Tap “6”, “12”, or “24” to Set a number of slices in a scan.
- Easy-Mode (toggle between Yes or No) to set only one slices in a scan.
- Tap Live-Update to set continuous reading
- Phantom (toggle between Yes or No) to measure on Vitacon bladder phantom



Vitacon will upon request make available other technical documentation, which will assist qualified technical personnel to repair the equipment. Repair should be performed only by Vitacon authorized service organization.

Manufacturer:

U AB Vitacon LT
Naujoji g. 12-525, Alitauš 62401 Lithuania