



# VITAcon.

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## **VitaScan PD+** Ultrasound Bladder Scanner

### **User and Service Manual**

Version 2.0.3 | Date: 21. September 2020



Ver/Rel. No	Release date	Mod. By Mod. Date	Rev. by relevant stakeholders Rev. date	Auth. by Auth. date	Remark/Revision details
2.0.3	20-Dec-19	MW	MW	MW	Initial release
		20-Dec-19	20-Dec-19	20-Dec-19	
2.0.3	7-Jan-20	MW	MW	MW	Added required software version page 4.
		7-Jan-20	7-Jan-20	7-Jan-20	
2.0.3	21-Sep-20	MW	MW	MW	Updated accuracy assessment procedure and recommendation (page 15)
		21-Sep-20	21-Sep-20	21-Sep-20	

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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 sixty (60) 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

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# Table of Contents



Tables of Contents .....	1
Introduction .....	2
Important Information .....	2
Indications for Use .....	3
Product Features .....	3
Unpacking and Inspection .....	3
Content of the packaging .....	4
Storage .....	4
Technical Specifications .....	4
AC/DC Adaptor .....	5
Battery .....	5
Product Upgrades and Updates .....	5
System Familiarization .....	6
About the System Software .....	10
Electrical Safety .....	10
Equipment Safety .....	11
Safety and Performance Summary .....	11
Labeling Symbols .....	12
Applicable Standards/Approvals.....	13
Applying the Ultrasound Gel .....	14
Measuring Bladder Volume .....	14
Regular Inspections and Maintenance .....	15
Care, Cleaning and Disinfecting .....	16
Powering up the System .....	16
Scan Operation.....	18
Adjust result.....	20
Setup .....	21
Patient infomation .....	22
Service .....	23
Manufacturer .....	26

## 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.

### 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.

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 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](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).

### 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.

### 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
- Simple, intuitive software with Touch-Screen support

- 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

- VitaScan PD+ Console with thermal printer
- VitaScan v.2 ultrasound probe and probe holder.
- 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 - 10.1 Inch
- Input method ..... Touchscreen
- Volume range ..... 0 – 1000 ml
- Accuracy .....  $\pm 7.5\%$  on volumes greater than 100 ml <sup>1</sup>
- .....  $\pm 7.5$  mL on volumes less than 100 ml <sup>1</sup>
- Frequency ..... 3.40 MHz
- Acoustic Output ..... MI max: 0.38, Power: 0.25 mW/cm<sup>2</sup>
- Thermal Index – TI ..... < 0.02
- Scanning method ..... Sector, 180 degrees
- Rotation positions ..... 12 or 24 rotating positions
- Sweep angle ..... 130 degrees
- Max detection depth ..... 100, 160 or 230 mm
- Max probe temperature ..... 35°C @ 22°C ambient temperature
- IP rating ..... IPX7
- Input Voltage ..... 100 ~ 240VAC, 50 ~ 60Hz
- Dimension ..... (D x W x H) 9 x 27 x 23.5 cm - 3.5 x 10.6 x 9.3 in
- Weight ..... 2.2 kg - 4.8 lbs
- Operating conditions ..... +10°C to + 45°C, 10% - 80% relative humidity
- Storage temperature ..... -30°C to +50°C

<sup>1</sup>Accuracy specifications in accordance with stated instructions, scanning on Vitacon phantom and software version 2.0.3 and above.

### AC/DC Adaptor

#### Input

Input range	100-240VAC
Frequency	50 - 60Hz
Input current	0.7- 0.35A

#### Output

Maximum Power	25W
Nominal output	15V DC
Output current	Max 1.66A

### Battery

Number	Item	Specifications
1	Rated Capacity (minimum)	13200mAH with 0.2C Charging & 0.2C Discharging
2	Nominal Capacity	13200mAH 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	Battery run time	5 - 6 hours
8	Charging time	4 – 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.



### 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 v.2 Ultrasound Probe.

#### Front View

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



- 1 Touch Display
- 2 Ultrasound probe
- 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:

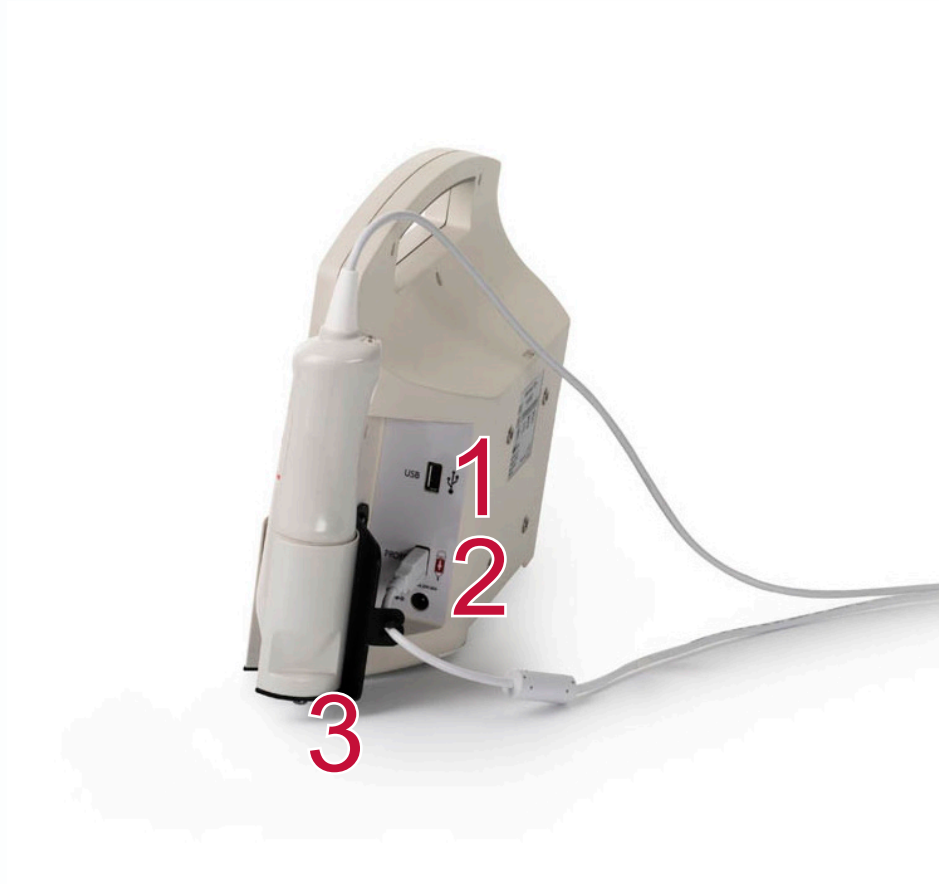


1 Power ON/OFF switch

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 v.2 probe
- 3 Probe holder

### About the System Software

The VitaScan PD+ system contains software that controls its operation. 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.

### 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 under-estimation 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

93/42/EEC Council Directive concerning medical devices

EN ISO 13485:2012+ AC:2012 Medical devices- Quality management systems- Requirements for regulatory purposes

EN ISO 14971:2012 Medical devices – Application of risk management to medical devices

EN ISO 14155:2011 Clinical investigation of medical devices for human subjects — Good clinical practice

EN 60601-1:2006+ AC:2010 + A1:2013 Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance

EN 60601-1-1:2001 Medical electrical equipment. Part 1-1: General requirements for safety. Collateral standard: Safety requirements for medical electrical systems (IEC 60601-1- 1:2000)

EN 60601-1-2:2015 Medical electrical equipment Part 1: General requirements for safety 2.Collateral Standard: Electromagnetic compatibility - Requirements and tests

EN 60601-1-4: 1996+ A1:1999 Medical electrical equipment-Part 1-4 General requirements for safety- Collateral Standard: Programmable electrical medical systems

EN 60601-1-6:2010 Medical electrical equipment-Part 1-6: General requirements for safety- Collateral Standard: Usability

EN 60601-2-37:2008+A11:2011 Medical electrical equipment-Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment)

EN 62304:2006+AC:2008 Medical device software – Software life-cycle processes

EN 62366:2008 Medical Devices. Application of usability engineering to medical devices

EN 60529:1991+A1:2000 Degrees of protection provided by enclosures (IP code)

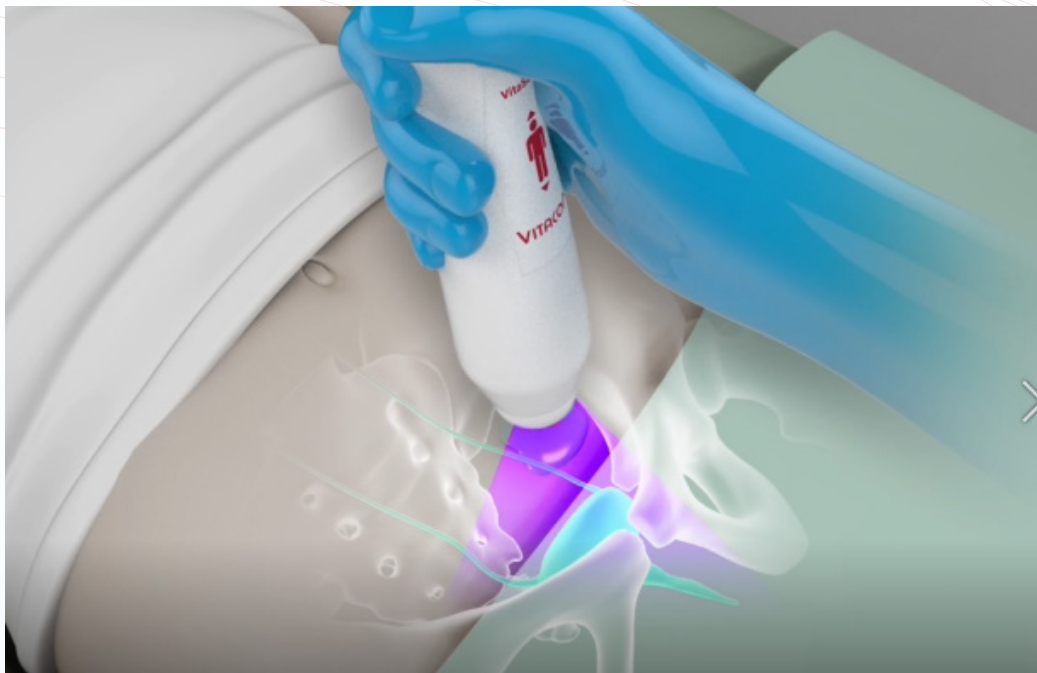
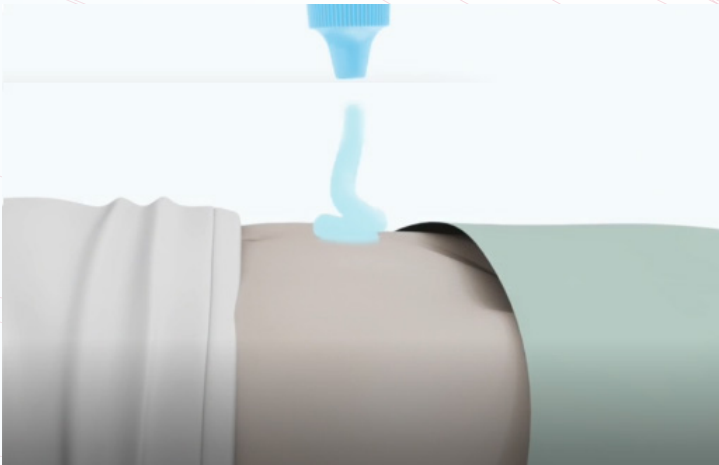
### Applying the Ultrasound Gel

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.

### 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.

## 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.

## Accuracy assessment:



### Caution:

In the event of changes in the performance of the instrument, discontinue use and contact your authorized VitaScan Service Center or your local VitaScan distributor.

Whenever accuracy assessment is desired or in question, the accuracy of the VitaScan should be tested using one of the following procedures:

1. Perform an off-line verification test using a Verification Test Tool; or
2. Perform an online integrity and calibration service using a Calibration Test Tool; or
3. Take a measurement on a Vitacon Phantom.

The measured volume should be within a range  $\pm 7.5\%$  on volumes greater than 100 ml<sup>1</sup> or  $\pm 7.5$  ml on volumes less than 100 ml<sup>1</sup>; or

4. Compare patient measurement

Take a Pre-void measurement of bladder volume.

Void or catheterize into a measuring beaker.

Take a post-void measurement of bladder volume to check for post-void residual (PVR)

Subtract the post-void measurement from the pre-void measurement and compare to the voided volume.

### <sup>1</sup>Accuracy specifications in accordance with stated instructions, scanning on Vitacon phantom.

Vitacon recommends performing an accuracy assessment once a year.

No annual inspection and maintenance is required on your VitaScan PD+. If accuracy assessment fails, you should:

- Contact your local dealer to learn about options for sending in the device for manufacturer calibration and service.

### Care, Cleaning and Disinfecting

Clean the VitaScan PD+ with a soft cloth soaked in a mild liquid detergent solution. Rinse with clean water and carefully dry with a clean soft cloth. Dampen a soft cloth with 70% ethanol. Wipe the probe with the dampened soft cloth and let the ethanol evaporate.

If the VitaScan PD+ needs to be disinfected, we recommend CIDEX® OPA Solution, PDI Sani-Cloth AF3 Germicidal Disposable Wipes, or other comparable disposable wipe designed for use on non-porous plastic surfaces. You may also use any glutaraldehyde based hospital disinfection solution or Clorox Healthcare bleach products. Dampen a soft cloth and wipe the instrument thoroughly. To remove all traces of disinfection solution, wipe the VitaScan PD+ with a clean soft cloth dampened with sterile water or cleaning solution. Carefully dry the VitaScan PD+ with a clean soft cloth before use. Use appropriate hand protection according to the labeling on the disinfectant to avoid skin reactions.



#### Warning:

- Do not subject any part of the VitaScan PD+ to steam sterilization or ethylene oxide sterilization.
- Do not immerse the instrument in any cleaning or disinfecting solution.

### Powering up the System

Running on Mains Power. Push the Mains Switch ON - located at the left-hand side. Press the ON/OFF button on the front. Once the VitaScan PD+ is powered ON, the system boots up and the Home Screen is displayed. Running on Battery: Push the Main Switch OFF – located at the left-hand side.





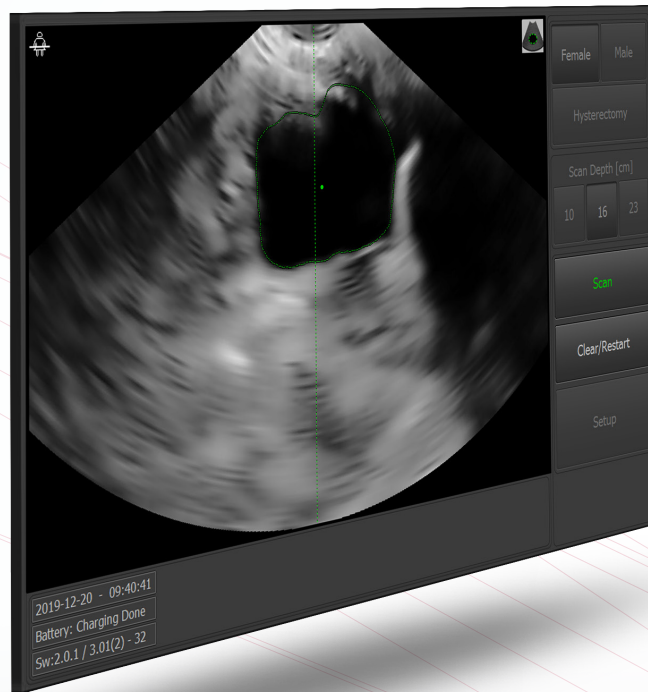
**Figure 0-1 Home Screen**

- 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




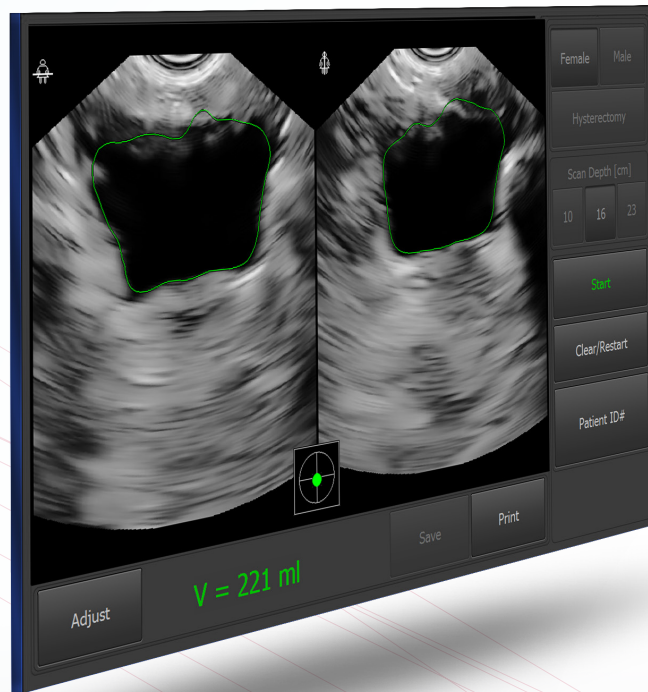
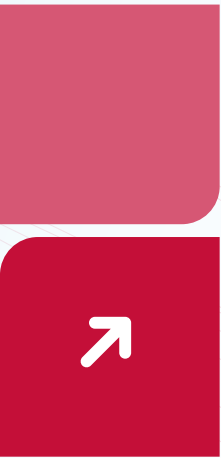
### Scan Operation

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



**Figure 0-2 PreScan**

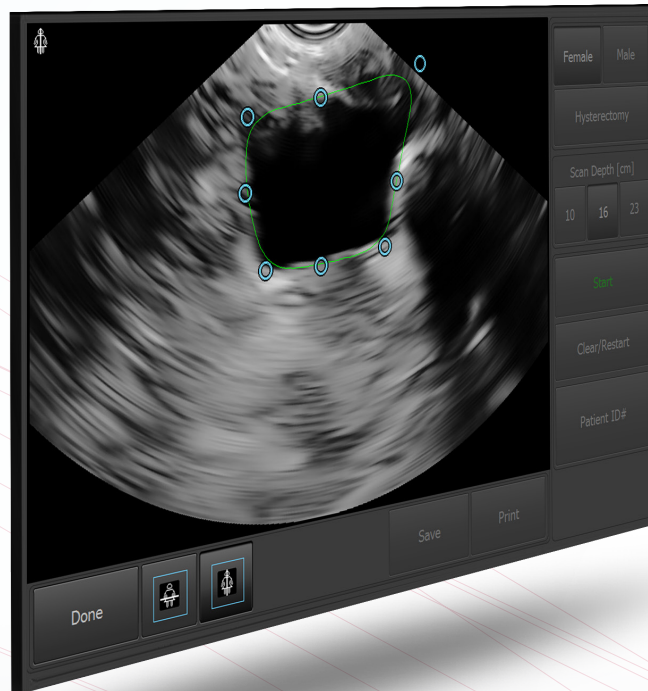
- Tap **Scan** to start scanning of the whole bladder.
- Tap **Restart** to stop pre-scan.
- Tap Icon  to colorize the detected area.





**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 0-4 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

### Setup



**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 in pre-scan
- **Phantom** (toggle between **Yes** or **No**) to measure on Vitacon bladder phantom

### Patient: ID, Name and Facility



**Figure 0-6 Setup**

- Press PatientID to fill in patient ID number
- Press PatientName to fill in patient name
- Press Facility to fill in facility name
- To enable factory default settings: type "DEFAULT" in PatientID field.
- To disable factory default settings: type "DEFAULT" in PatientID field again.

## Service

The Information contained in this service manual is proprietary to Vitacon. It is supplied solely for the convenience of our customers. It may be changed in whole or in part without the written notice.

This manual is not intended as support or any unauthorized servicing, disassembly, rebuilding, modification or resale of VitaScan PD+ by unauthorized third parties.

### Introduction

This section contains the IVBM VUFE technical specification and architectural design description. IVBM VUFE is the electronic module in the VitaScan PD+ bladder volume scanner. VitaScan PD+ is a 3-dimensional ultrasonic scanning device used to measure the bladder volume and quantity of urine remaining in the bladder; safely and comfortably through a non-invasive method.

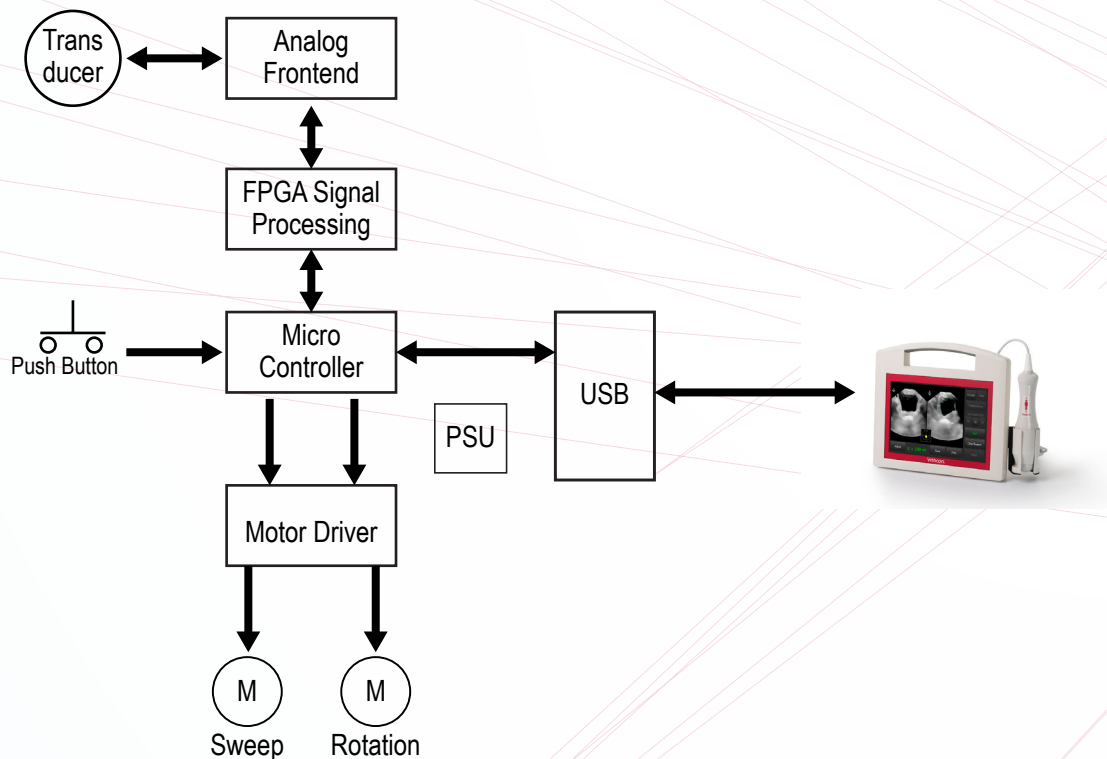
The VitaScan v.2 probe consists of mechanics and electronics. The VitaScan PD+ contains the mechanical components needed to execute the 3 dimensional scanning of the bladder, and the electronics to obtain the ultrasound image needed to calculate the volume of urine in the bladder both pre and post void.

The VitaScan v.2 probe is attached to the computer via a USB connection, which also provides the necessary power to the probe. This document only covers the technical specification for the probe electronics, IVBM VUFE.

### Overview

The drawing below shows an overview of the complete VitaScan PD+ bladder scanner system. All modules are physically located inside the VitaScan PD+.

### Vitascan v.2 Probe



Block diagram for VitaScan v.2 Probe





### Functional Description

The IVBM VUFE is a single element ultrasound scanner with the electronic module and scanning mechanics, designed to fit in a hand held scanner, having the following main functionality:

- USB communication interface for computer
- Ultrasound Pulse generator
- Ultrasound receiver and signal processing
- Motor control and positioning of the ultrasound transducer element

The module is realized in analog and digital hardware, FPGA configuration, and microcontroller firmware. The following are the main parts of the design:

- Microcontroller
- FPGA
- PSU
- USB
- Motor driver
- Analogue Receiver and transmitter

### Microcontroller

The microcontroller is the master in the IVBM VUFE-module, controlling all functionality and safety. It is also a communication interface between the probe and the computer. The microcontroller is a slave with respect to the computer, and will only communicate in response to a command from the computer.

### Microcontroller states of operation:

#### Power up:

At normal power up, a self-test and initiation procedure will start. The FPGA configuration will be cleared and configuration must be downloaded from the computer before ultrasound acquisition may start. The transducer element positions will be initialized.

At power up with the push-button pressed, the module will enter "PROGRAM" mode, waiting for firmware upgrade via the USB connection. This is a maintenance function, and should only be used by trained service personnel.

### Idle:

In Idle state, the module is waiting for a command from the computer or the pushbutton. The current consumption is reduced to an absolute minimum.

### Pre-Scan:

In Pre-Scan mode, the module will move the transducer sweep-motor continuously between the end positions, and ultrasound data for one vector will be transmitted to the computer at each defined position. The rotation-motor is parked in the initial position. This will give the computer the possibility to present a "live" image of the bladder, making it possible to move the VitaScan v.2 probe to the correct position before making a Full-Scan with volume calculation.

### Full-Scan:

In Full-Scan mode, the module will move the transducer sweep-motor from one end position to the other, transmitting ultrasound data for one vector to the computer at each defined position. The rotation motor will then move one step, and a new sweep will be performed. When the rotation motor has moved a total of 180 degrees, and the computer has received a number of vectors defining a set.

### FPGA:

The FPGA (Field Programmable Gate Array) is responsible for all signal-processing in the IVBM VUFE module.

The microcontroller configures the FPGA with "Bitstream" data and configuration data received by the computer.

The microcontroller initiates an "Ultrasound capture sequence" by a Trigger signal. The FPGA will generate an ultrasound pulse according to the configuration data, receive the echo, and send data for the vector to the microcontroller after signal processing.

### PSU:

The PSU (power supply unit) in the IVBM-VUFE module get its input voltage from the USB-connection. The computer will provide all power needed by the IVBM-VUFE module, including motors and transducer that are driven from this module. The power consumption must be lower than the maximum rating of power to be provided by the computers USB port.

### The PSU will provide 4 different voltages:

1.2V: FPGA  
3.3V: Microcontroller,  
5.0V: Analog receiver, Motor driver logic  
Motor: HW-programmable voltage for the motors to be used

### USB:

The USB controller is an integral part of the microcontroller.

The IVBM-VUFE USB will be the SLAVE, and the computer will be MASTER. Implementation of the USB firmware follows the USB 2.0 standard.

### Motor driver:

The motor driver is designed for running Stepper-motors, and consists of three parts:

- A HW part that will transform logical control signals into currents driving the motors.
- A SW part in the microcontroller that will keep track of position of each motor, and generate logical control signals to move the motors to correct positions dependent on operating mode.
- A HW HAL-sensor and magnet to be used as a reference to calibrate sweep-motor position.
- The motor driver is designed to support Full-step, Half-step and Micro-step modes, but for maximum motor-torque the Full-Step mode is used. The motor supply voltage is made HW-programmable to support different step-motors.

### Analog Receiver and Transmitter:

The transmitter is a bipolar “square-wave” pulse transmitter. The voltage level is settable to tree levels by software/configuration data control. The waveform is controlled by a sequence generator in the FPGA. The input signal from the transducer is attenuated by a t/r-switch during the pulse transmit period. The t/r-switch is controlled by a sequencer in the FPGA. The receiving signal is amplified by a TGC-amplifier chain. The gain control signal is set by an analog ramp signal, controlled from the FPGA. The amplified analog receive signal is low-pass filtered by a passive L-C filter before it is fed to the A/D-converter. The A/D converter is clocked from the FPGA. Resolution is 12 bits, and sampling speed is 12.5MHz. The parallel output data is fed to the FPGA for further digital processing.

### Safety Mechanisms:

The following safety mechanisms are implemented in the IVBM VUFE module:

TX-Voltage and Input voltage monitoring

### Software Watchdog:

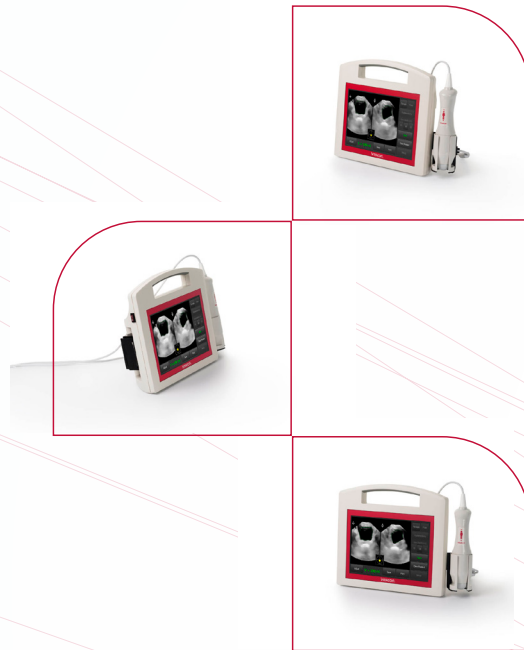
The microcontroller is supervising the voltages in the “main loop” for maximum safety, and a watchdog is supervising the microcontroller program execution.

In case of a SW/HW error that causes abnormal program execution, a HW-reset condition will occur and the High Voltage will be disabled. The HW has a measurement circuit allowing the microcontroller to measure the High Voltage and the Input voltage.

The microcontroller will disable the TX Voltage if the voltage is out of the pre-defined range (+/-10% of set value), and an error will be sent to the computer.

If the Input voltage reaches the minimum value (4.2V), an error message will be sent to the computer.

If the input voltage is too low to drive the IVBM VUFE, a HW-reset condition will occur and the High Voltage will be disabled.



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.



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