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VitaScan LT

USB Ultrasound Bladder Scanner

User and Service Manual

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4.5.4	24th-Nov-17	MW 24th-Nov-17	MW 24th-Nov-17	MW 24th-Nov-17	Added Easy-mode, Setup GUI update.	
4.5.4	17th-Jan-18	MW 17th-Jan-18	MW 17th-Jan-18	MW 17th-Jan-18	Included Probe ID in INI file	29,30,31
4.5.4	8th-Feb-18	MW 8th-Feb-18	MW 8th-Feb-18	MW 8th-Feb-18	Amended Warranty policy for US market.	32
4.5.4	9th-Oct-18	MW 9th-Oct-18	MW 9th-Oct-18	MW 9th-Oct-18	Added Acer Switch 3 as tablet option Added Discard Pubic bone feature	5, 12
4.5.4	4th-Jul-19	MW 4th-Jul-19	MW 4th-Jul-19	MW 4th-Jul-19	Updated text and images to VitaScan v2 probe	
4.5.4	25th-Oct-19	MW 25th-Oct-19	MW 25th-Oct-19	MW 25th-Oct-19	Updated text and images to VitaScan v2 probe	19,20,28
4.5.4.14	7th-Jan-20	MW 7th-Jan-20	MW 7th-Jan-20	MW 7th-Jan-20	Updated Accuracy on Phantom Specs, and required software	4, 11

Contacting Vitacon:

In Europe:

Office Address:

Vitacon AS
Vegamot 8B
7049 Trondheim, Norway
E-mail: sales@vitacon.com
http://www.vitacon.com

In North America:

Vitacon US
600 Twelve Oaks Center
Drive Suite 685, Wayzata
MN 55391, USA
E-mail: info@vitacon.us
http://www.vitacon.us

Manufacturer:

UAB Vitacon LT
Naujoji g. 12-525
Alytus 63250
Lithuania

PN: 6100-500

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Limited Warranty

Vitacon warrants that the VitaScan LT Ultrasound Bladder Scanner 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 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 LT Ultrasound Bladder Scanner, 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 LT Ultrasound Bladder Scanner. Neither Vitacon nor its local representatives will accept, nor be bound by any other form of guarantee concerning the VitaScan LT Ultrasound Bladder Scanner 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 LT 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 LT is a B-mode ultrasonic 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 LT automatically calculates the estimated bladder volume in milliliters and displays it on a screen.

VitaScan LT 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 LT 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 LT. 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 a medical professionals when clinically indicated, using the lowest exposure times possible commensurate with clinical utility.

The ultrasonic output power of the VitaScan LT 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 , note this link may change over time).

Statement of Intended Use:
The VitaScan LT 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 LT is not intended for fetal use or pregnant patients.

Warning: Exposure of 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 LT instrument is used in the presence of flammable anesthetics.

First Time Users:
We advise new operators to use the VitaScan LT on patients with moderately full bladders, rather than initially attempting to locate nearly empty bladders.

Caution:

The VitaScan LT 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 catheter can reflect ultrasound signals that can lead to 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.

Caution:

It is recommended to operate this equipment only on battery power if you are using the software on a non-medical grade computer.

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 Ultrasound Bladder Scanner.
- 3D ultrasound scanner & PC running Windows 10 OS
- USB ultrasound probe connection
- Bladder volume calculations in large digits
- Storage of ultrasound images

Unpacking and Inspection

- There are no special unpacking instructions, but be careful not to damage the instrument when unpacking it. When unpacking the VitaScan LT 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 LT. Save the damaged shipping carton and packing material for the carrier's inspection and contact the respective carrier. If there is any damage on the scanner equipment, contact Vitacon.
- If there is no shipping damage, continue removing the VitaScan LT from the shipping case. Save the box and packing materials; they will be needed when returning the VitaScan LT 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 foam inserts to ensure safe shipment of the VitaScan LT. Save these for future shipment of the unit for service or calibration.

Content of the packaging:

- VitaScan v.2 probe
- USB Memory stick with Application Software and User & Service Manual
- VitaScan v.2 probe holder
- Installation guide in English

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

Warning:

Do not have VitaScan LT connected to any device while stored in the original soft case container.

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 electronic waste:
VitaScan LT 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.

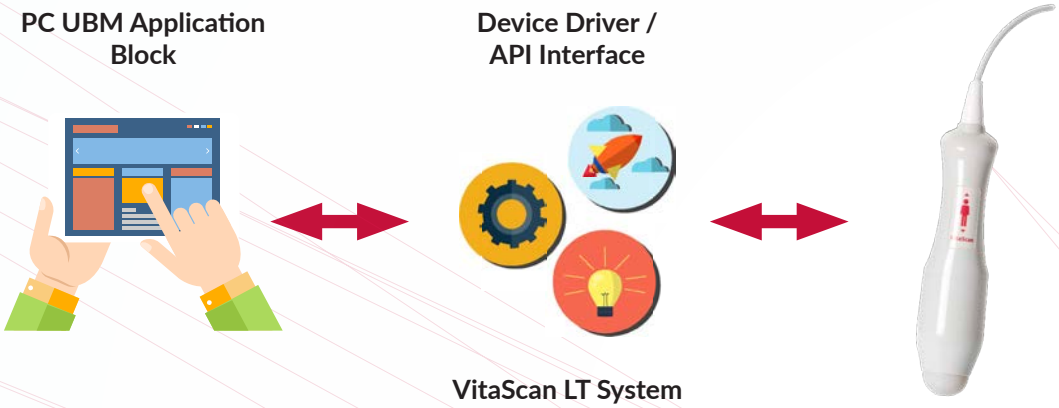
Technical Specifications - Vitascan v.2

- Volume range: ..... 0 – 1000 ml
- Accuracy ..... ± 7.5% on volumes greater than 100 ml[1]
  ..... ± 7.5 ml on volumes less than 100 ml[1]
- Frequency: ..... 3.40 MHz
- Acoustic Output: ..... MI 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: ..... 130 degrees
- Max detection depth: ..... 100, 160 or 230 mm
- Max probe temperature: ..... 35°C @ 22°C ambient temperature
- Dimension ..... (L x W x H) 18.5 x 4.5 x 4.5 cm (7.3 x 1.8 x 1.8 in.)
- Weight incl. cable: 0.36kg (0.79lb)
- IP rating: IPX7
- Power Supplied by ..... USB port: 0.5A @ 5V
- Operating conditions: ..... +10°C to + 45°C, 10 % - 80 % relative humidity
- Storage temperature: ..... -30°C to +50°C
- PC requirements: ..... Windows 10 OS
- PC Input method: ..... Mouse, keyboard and touchscreen

[1] Accuracy specifications in accordance with stated instructions, scanning on Vitacon phantom and using software version 4.5.4.14 and above.

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.



Number	Features	Specifications
1	USB Scanner	VitaScan v.2
2	Tablet/Computer	Lamina T-1022
3	Software version 4.5.4 or higher	VitaScan LT
4	USB Memory stick With Software & Documentation	

About the System Software

The VitaScan LT system contains software that controls its operation. Vitacon will provide you with a USB Memory stick containing the software. Typically new software provides new capabilities.

About the Ultrasound System

The VitaScan LT System includes: USB Probe, and tablet computer Lamina T-1022. For electrical safety reasons you should always power tablet with only battery power.

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. Run Tablet on battery (internal electrical source) whenever integrity of the external protective earth conductor arrangement is in doubt.

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

To avoid the risk of electrical shock, always disconnect the USB Cable from the PC 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 Tablet/Computer output connector (like USB port and others) 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; call Vitacon or your local representative; turn off the system.

Equipment Safety

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

Caution:

- Use the system on with only battery power, do not use while charging.
- 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 LT 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 battery terminals.
- Always charge the tablet 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 behaviour. 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 colour 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 LT if its head or cable is damaged.
- Do not use the VitaScan LT 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 LT that has been immersed in liquid.

Safety and Performance Summary

The VitaScan LT 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 LT 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 the possible hazard of explosion if the VitaScan LT 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

IPX7 Water submersion

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 Scanhead. Smooth the gel out and remove any air bubbles, which may block ultrasound transmission.

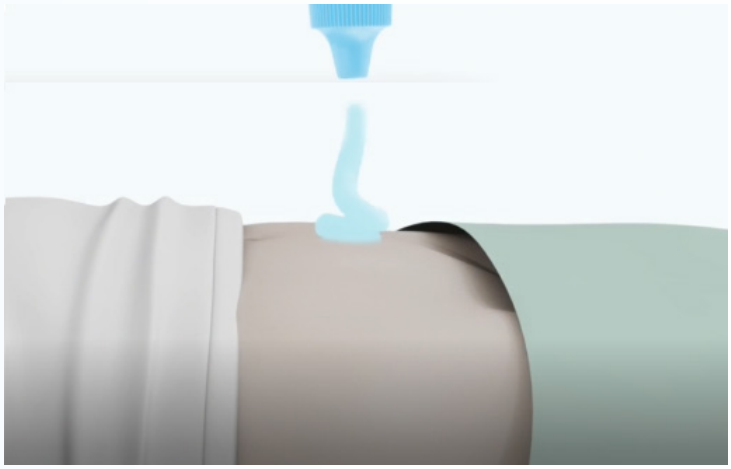
Using Ultrasound Gel Pad:

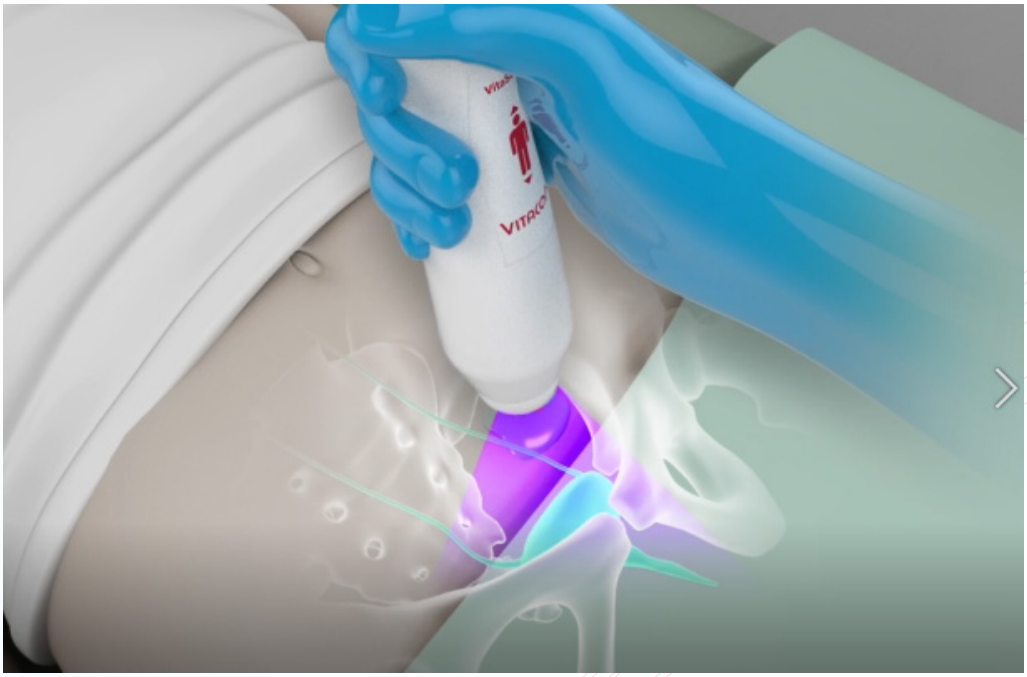
Sometimes it may be convenient to use ultrasound transmission Gel pad. The Gel pad is an easy-to-use coupling medium.

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 LT is a Medical Electric Equipment and therefore needs special precautions regarding EMC. VitaScan LT 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.

Monthly Accuracy Check:

Caution:

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

Each month, or whenever accuracy assessment is desired or in question, the accuracy of the VitaScan LT should be tested using the following procedure:

- 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 form the pre-void measurement and compare to the voided volume.
- Take a measurement on a Vitacon Phantom.
- The measured volume should be within a range ± 7.5% on volumes greater than 100 ml[1]
- or ± 7.5 ml on volumes less than 100 ml[1]

[1]Accuracy specifications in accordance with stated instructions, scanning on Vitacon phantom.

No annual Inspection and Maintenance is required on your VitaScan LT. If the Monthly Accuracy Check fails, you should:

- Perform an online integrity and calibration service using a Calibration Test Tool; or
- Perform an off-line verification test using a Verification Test Tool; or
- Contact your local dealer to learn about options for sending in the device for manufacturer calibration.

Care, Cleaning and Disinfecting

Clean the VitaScan LT 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 probe 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 with a clean soft cloth dampened with sterile water or cleaning solution. Carefully dry the VitaScan 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 LT to steam sterilization or ethylene oxide sterilization.
- Do not immerse the instrument in any cleaning or disinfecting solution.

VitaScan LT Application Software Installation

Before use on patient:

Read the User Manual which is on the USB Memory stick, and follow user instructions for the scan-procedure.

System Requirements :

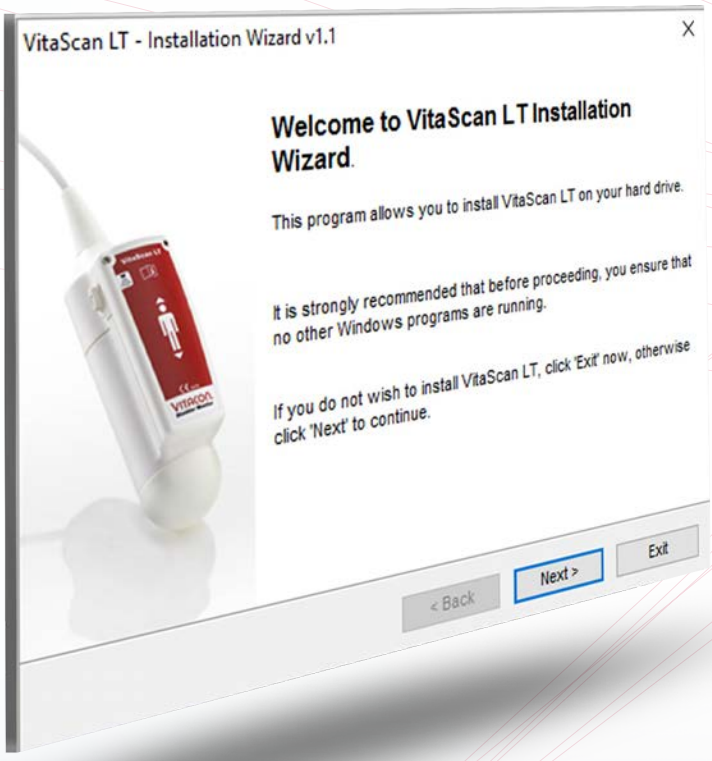
- Windows 10 Operating System, 32 or 64 bit.
- The minimum recommended system configuration is 1GB RAM & 1.3 GHz processor speed.
- VitaScan USB Probe (Firmware version 4.04 or higher)
- Tablet/Computer type: Lamina T-1022.
- USB 2.0 port to source 500mA @ 5V
- Medical Isolation Device – e.g. Tripp Lite IS150HG (N/A) or Noratel IMEDe 150 (Int'l)

Note:

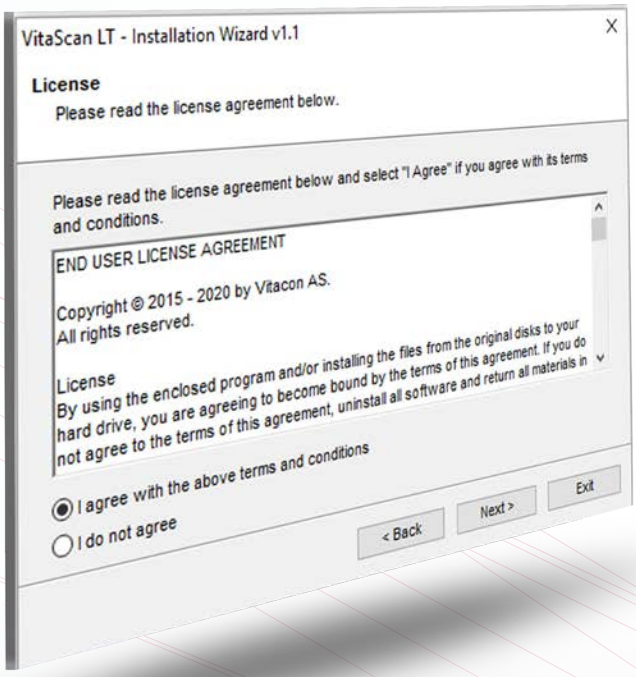
Installing VitaScan LT Application Software on Windows 10 Operating System requires the operator is logged in as "Administrator".

Installation of the VitaScan LT application

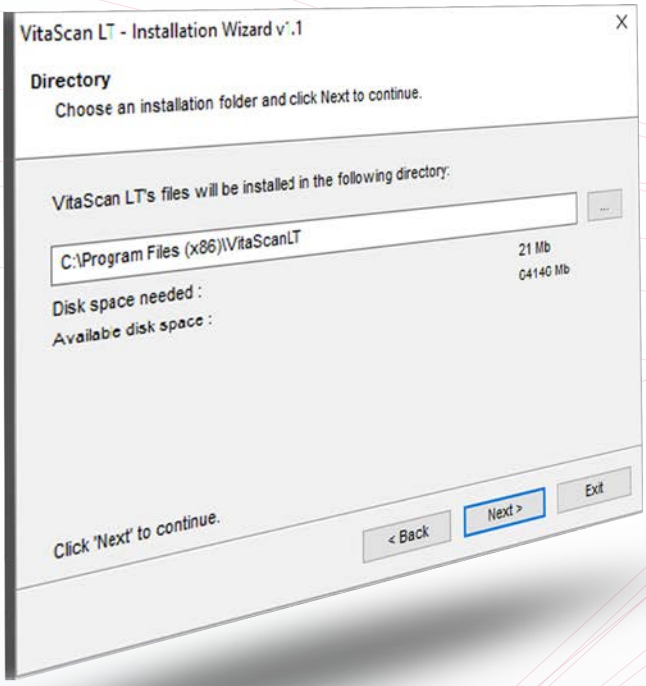
- Open the folder to view the "VitaScan_LT_Installer" files on the USB Memory stick
- Run the VitaScan_LT_Installer.exe file
- Press Next.



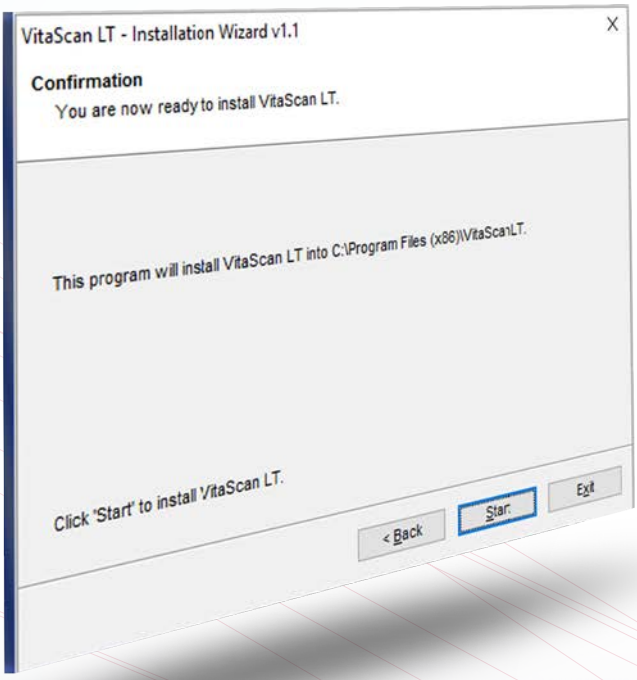
- The “Next” button gets enabled when user chooses to accept the license agreement terms and conditions.



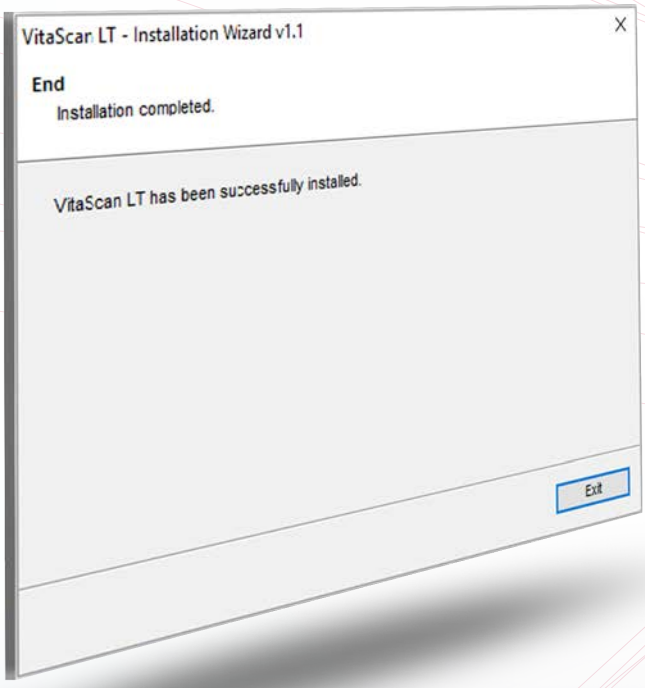
- Press Next, (It is recommended to install in the default director)



- Press Start.



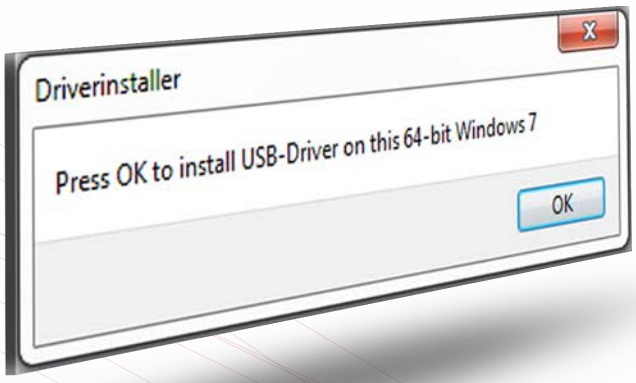
- Press Next.



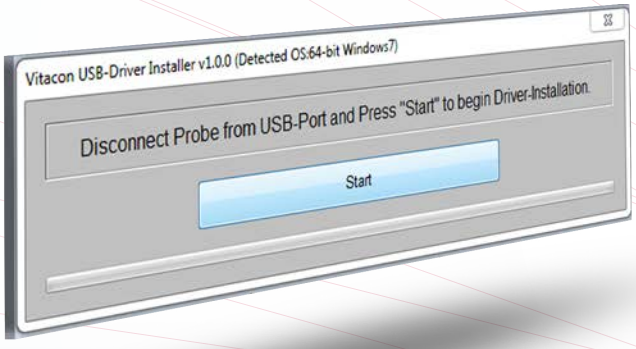
- Finish the installation by pressing Exit.
- After a successful installation a VitaScan LT icon will appear on your desktop.

USB driver Installation

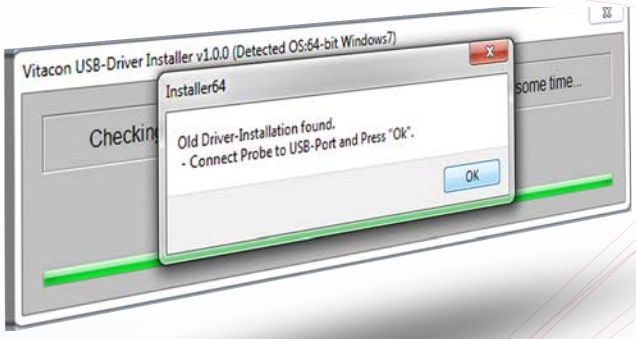
- VitaScan LT installation requires installation of the USB driver for the VitaScan LT.
- Press ‘OK’.



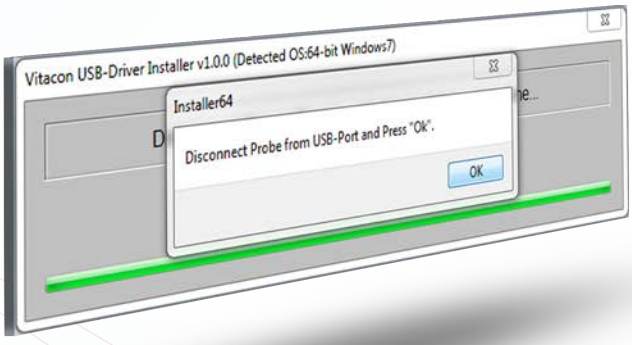
- Press ‘Start’ to start the installation process.



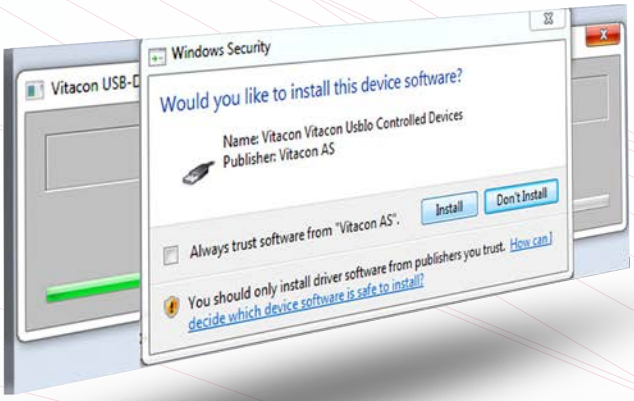
- Connect the probe in the USB-port and press ‘OK’.



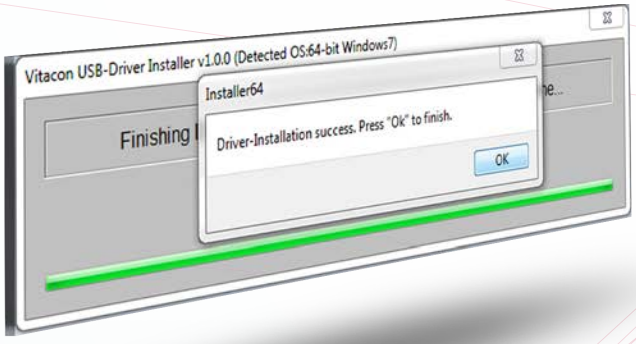
- Disconnect the probe from the USB-port and press ‘OK’.



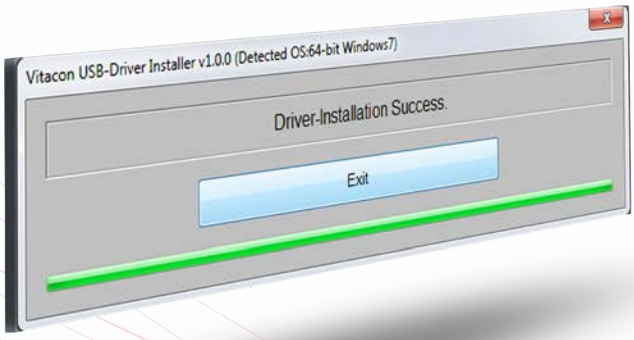
- Press ‘Install’ to proceed the installation process.



- Press ‘OK’, to finish the installation process.



- Press ‘Exit’, to end the installation process.



Note:

If the PC has more than one USB port, please connect the probe to each different USB port while you are logged in as an “Administrator”. The USB driver will be automatically installed and the probe well recognized on whatever port it could be connected. The driver installation will not occur automatically if you are not logged in as an “Administrator”. The USB driver installation takes some time, please wait for Windows to display a successful installation message for each USB port.

User Guide

This section illustrates different features of the VitaScan LT PC Software application and guides you through the application.

This application interacts with VitaScan v.2 Probe, Vitascan LT, for data acquisition.

The Application displays real time images to the user to locate the bladder.
Once the scan is completed, the user can save the scanned images with patient information.

Ultrasound Bladder Scanner Application Software is developed to work on Windows 10 operating system.

PC Software Application Key Features

- Manage patient scan image data
- Displaying images of patient's scans, along with calculated urine volume
- Printable Report for a patient data
- Compatibility with Windows 10 Operating Systems
- Rich Graphical User Interface and easy navigation
- VitaScan LT is configured to work for "No. Of Sectors To Scan" = 6, 12 or 24.

Note:

Installing VitaScan LT Application Software on Windows 10 Operating System requires the operator is logged in as "Administrator".

Application Features

- Pre-Scan image
- Scanned images
- Includes patient information with scanned images

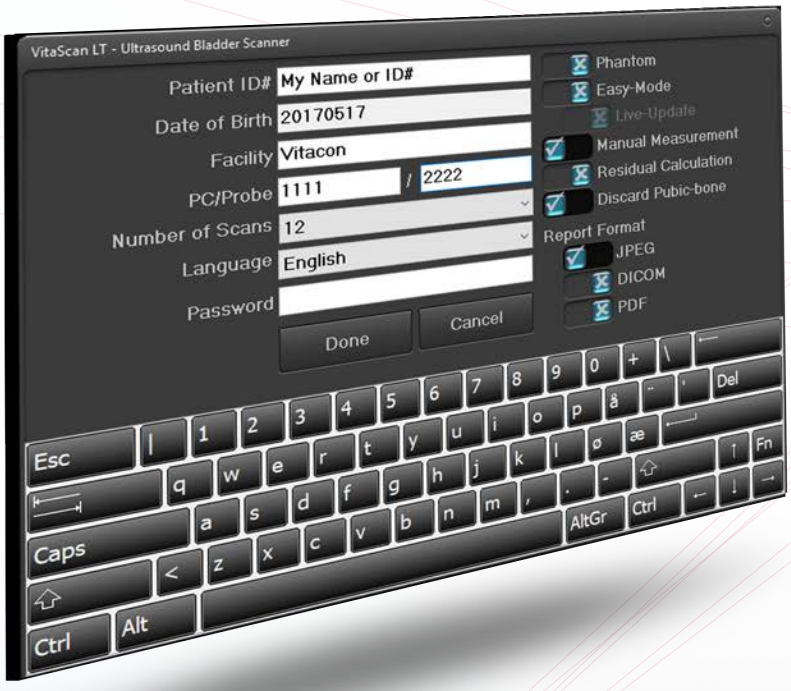
Run VitaScan LT application

- Make sure the VitaScan v.2 probe is inserted to the computer USB port.
- Press the VitaScan LT Icon on your Desktop to start the application.
- All users should view a 2 minute user guide video “How to perform a successful scan” before proceeding. Press play button to start user instruction video. To watch video in other languages; go to setup and change to preferred operational language.
- **Easy-Mode** will estimate bladder volume from Pre-Scan with typical < 20% accuracy.

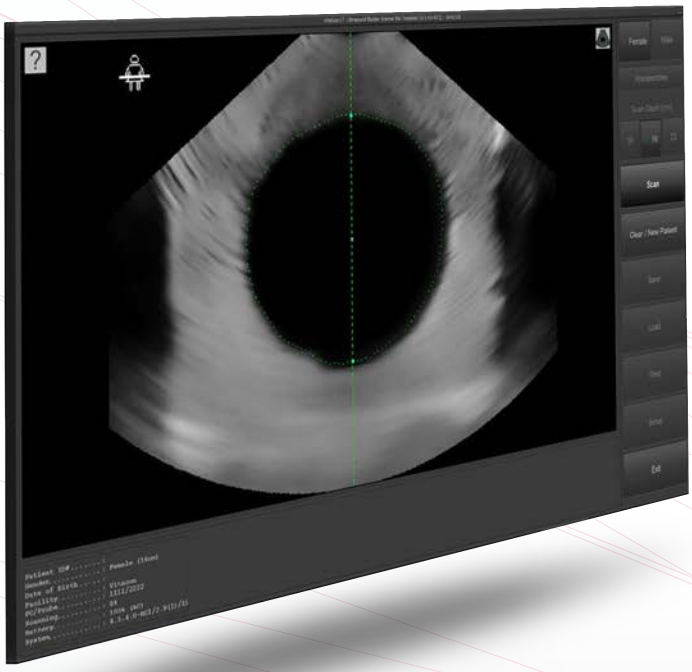
- Before scanning, select Setup. In Setup, you can configure your application.
  - ☐ Set Patient ID, date of birth, facility, set pc and probe serial number.
  - ☐ Set Number of Scan. Choose between 6, 12 or 24 slices
  - ☐ Select Language.
  - ☐ Password – see page 31
  - ☐ Enable Phantom mode when scanning on Vitacon phantom.
  - ☐ Easy-Mode utilize measurement in 1 slice (Horizontal) only
    - Live-Update utilize live update of volume readings
  - ☐ Manual Measurement of measured volume. Utilize correction of 2 slices –Vertical and Horizontal slices.
  - ☐ Residual Calculation utilize saving of pre-void result and post voided result to calculate voided volume

- Set Report Format:
  - JPEG: Saving a test report as JPEG
  - PDF: Saving a test report as PDF
  - DICOM: Saves a test report as DICOM file with these DICOM attributes:
    - PatientID: “as in setup”
    - Patient Birth Date: “as in setup”
    - Patient Sex: “as selected”
    - Study Date: “Current Date”
    - Study Time:” Current Time”
    - Study Modality: “XC”
    - Study Description: “VitaScan LT – Ultrasound Bladder Scanner”

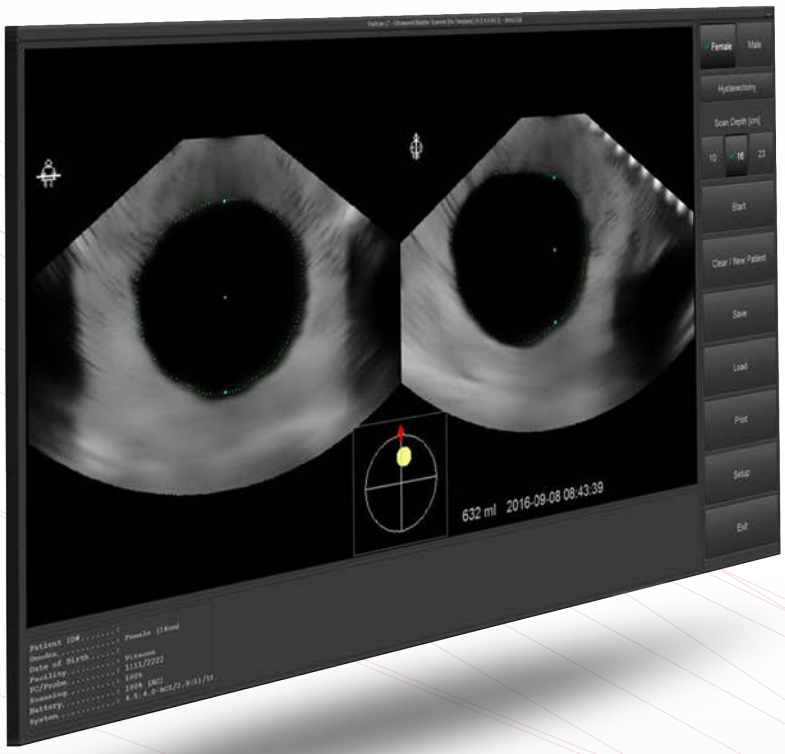
- By default, on power up, the gender will be “Female” and scan depth is set to 16 cm.
- Select Male or Female without/with Hysterectomy.
- Scan Depth (cm) options:
  - 10 cm: designed for paediatric
  - 16 cm: designed for adults (default)
  - 23 cm: designed for obese
- Press the “Start” to start pre-scan to locate the bladder.

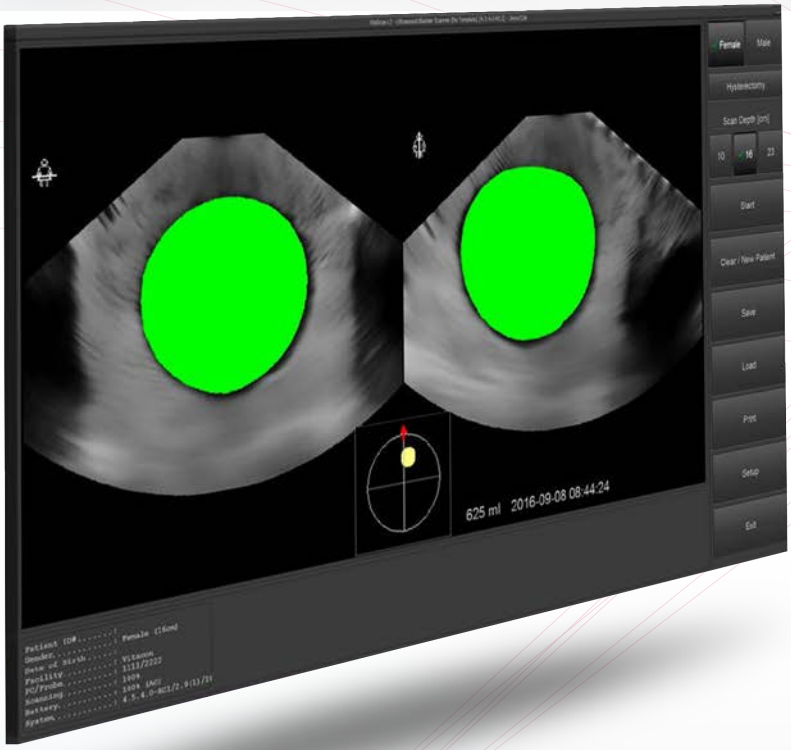


- When you have located the bladder, as in the picture above, press “Scan” to start scanning. NOTE: Do not move the VitaScan probe until scanning is 100% done.
- The results will appear as shown below. The left picture shows the horizontal scan, and the right picture shows the vertical scan. The lower cross hair picture shows the top view of the bladder in yellow.
- The cross hair will display a guiding arrow in what direction the user will have to move or tilt the probe for a more accurate scan. When the cross hair manages to hit the bladder, the system is satisfied with the result. NOTE: For optimal result, the cross hair should hit center of the bladder.



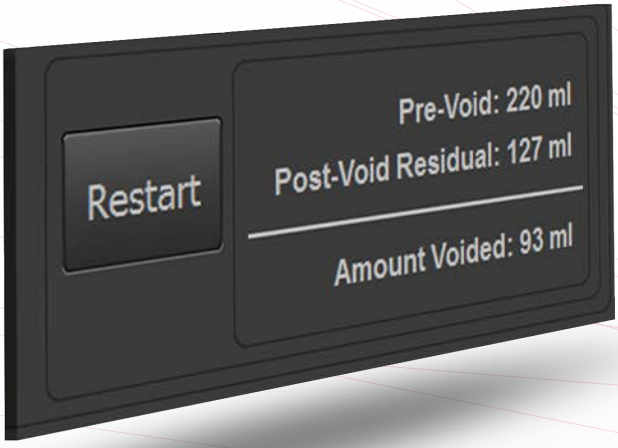
- Software allows you to save pre-void result and post-void result. This allows the software to calculate the voided volume. This mode is default. To turn off, unselect Residual Calculation in Setup.



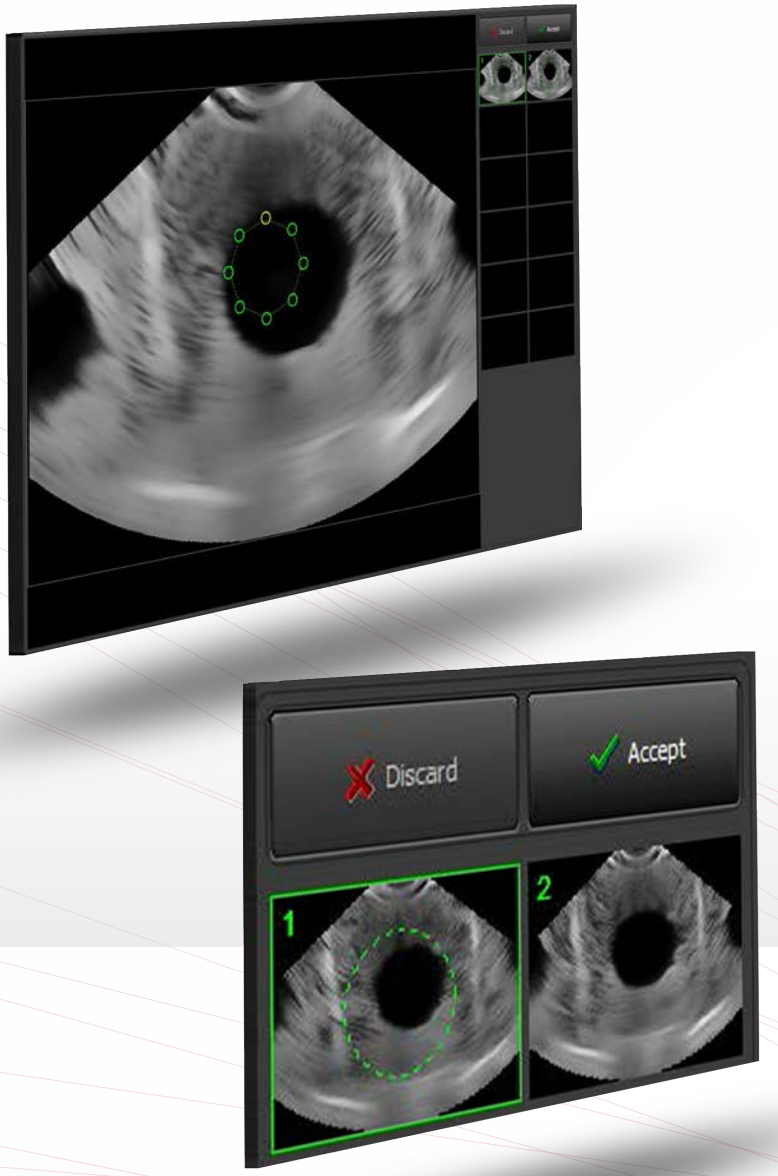


- When you are pleased with the pre-void result, press “Accept as Pre-Void”, press “Discard” to do a new scan.

- The patient will have to empty the bladder. The user will have to do a new scan and accept this result as Post-Void Residual. The amount for urine emptied is displayed as Amount voided.



- Manual Measurement is default. To turn off, unselect Manual Measurement in Setup.
- Manual Measurement allows you to determine the bladder wall. By pressing the button “Manual Measurement” you will then enter a new windows were images of the bladder is displayed.



- The green circle or bladder contour will be displayed. Drag and drop the small green circles on the bladder wall. On left side you see thumbnails of the images you can alter. Clicking on the various thumbnails you can switch between the different slices.

When an alteration has been performed, a green circle is displayed on the thumbnail. When you are finished with the manual measurement, press “Accept”. If you want to start all over again press
“Manual Measurement” again.

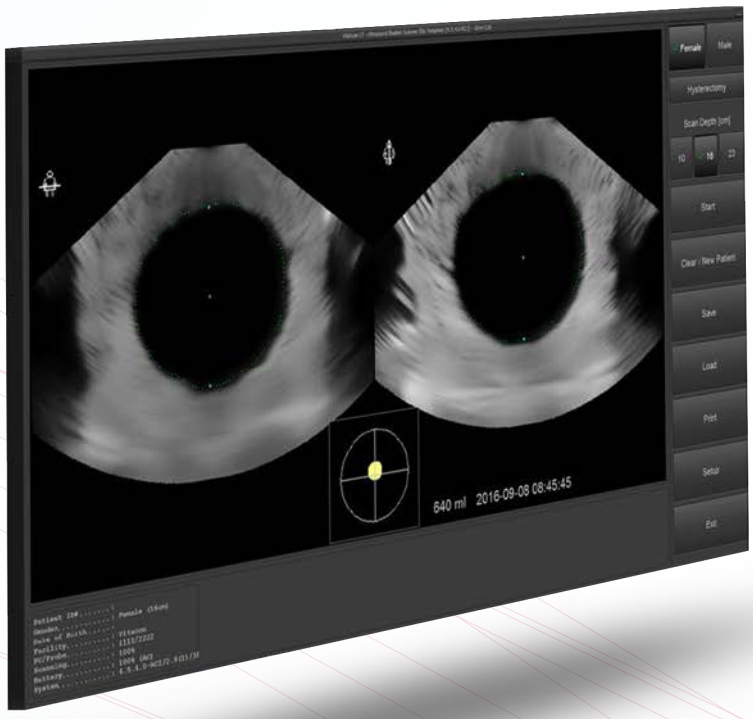
In setup, you may choose between following Manual Measurement modes:

Simple: Correction of two images starting from a green circle.

Simple-Contour: Correction of two images starting from the green bladder-edge contour.

Advanced: Correction of ALL images starting from a green circle.

Advanced-Contour: Correction of ALL images starting from the green bladder-edge contour.

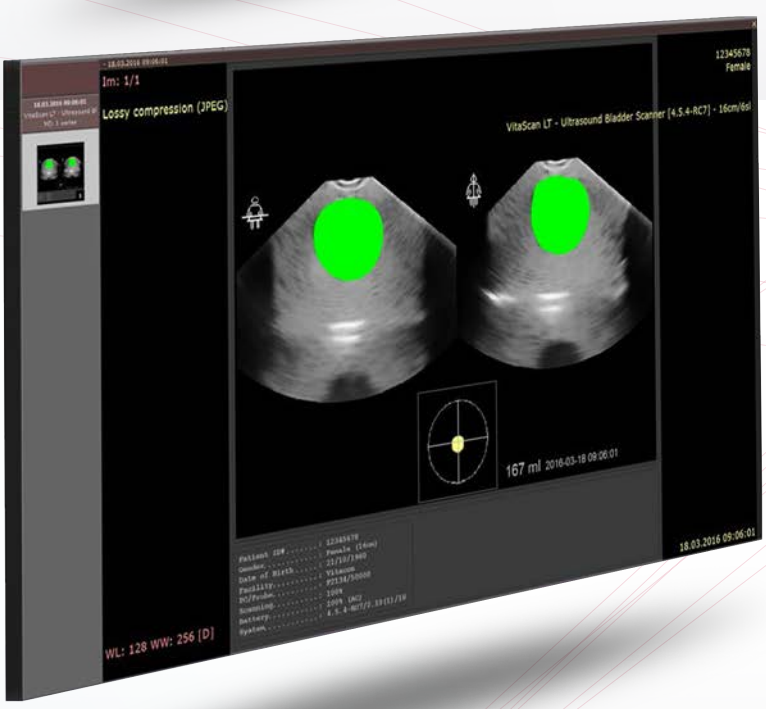


- The Measurement can be saved by pressing “Save”. This will generate an exact image of what you see, including patient information and the volume result. The default name for a saved file is a timestamp which will have the form “20190108 094853”. This means the Measurement was done on the Date: 2019/Jan/08 Time: 09:48:53. You may change this to another name, if desired.

- The result can also be printed by pressing “Print”. It will give you the option to select a printer and chose if you want to print the picture in a landscape or normal orientation.
- To load an old scan, press, “Load” and select the scan you want to see. It will load the picture from the hard disk.

- To exit the application press “Exit” and “Yes”.

- When Dicom is selected as report format in Setup. User has to press Save to generate a report. Dicom file will contain the following Dicom attributes: PatientID: “as in setup”, Patient Birth Date: “as in setup”, Patient Sex: “as selected”, Study Date: “Current Date”, Study Time:” Current Time”, Study Modality: “XC”, Study Description: “VitaScan LT – Ultrasound Bladder Scanner”. And an image of results, transversal image and sagittal plain is displayed.



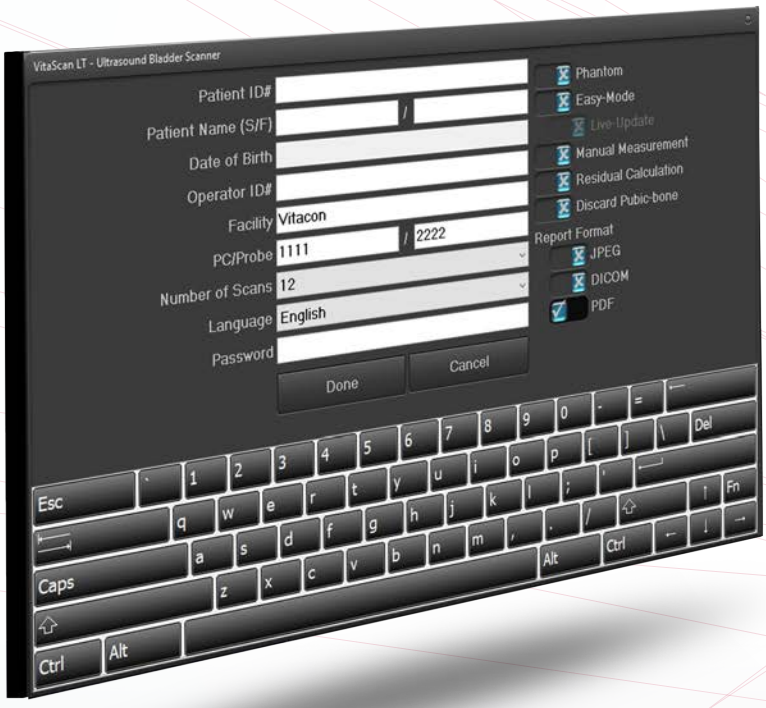
Discard Pubic bone

- In setup Discard Pubic bone function can be turned off. (By default set to on).

  When this fuction is enabled: sectors around pubic bone area will not be used in volumed calculation. This ensures the user will not get a pubic bone interference and recuses the risk to overestimation.

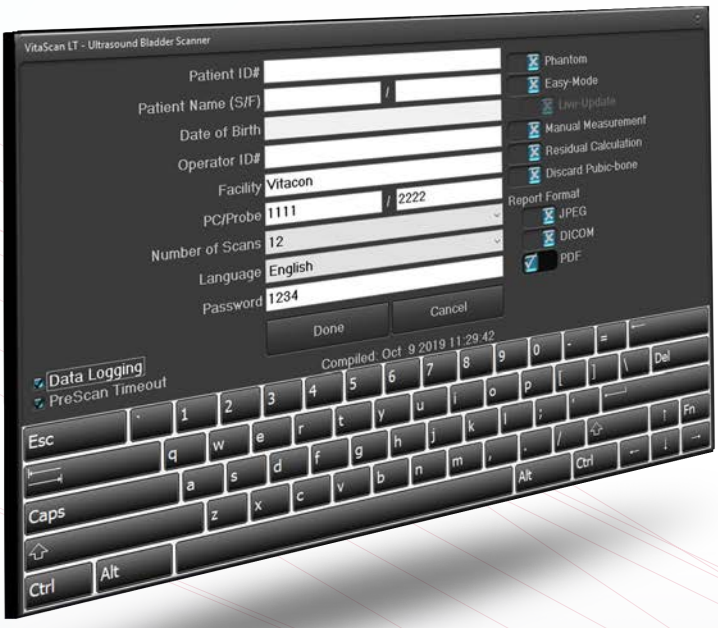
Scanning on Vitacon Phantom

- Before scanning on a Vitacon Phantom enable the “Phantom” box under “Setup”. The Phantom box is disabled as a default setting. I.e. the Phantom box will be turned off when “Setup” is selected or the VitaScan LT application is started.



Other Settings

- Enter Password 1234 to open other settings.



- PreScan Timeout: Disables the 2 min. PreScan timeout
- Data Logging: Enables automatic data logging of measurements. Data is stored with a timestamp in the folder C:\ Documents\Vitacon\VitaScanLT. This option may be used for investigation of issues with image data.

How to run VitaScan LT application remote from INI file

Requires version 4.5.4.6 or higher.

Example:

1) Create and store a VitaScanLT.INI file by TXT editor or another program

Content of the VitaScanLT.INI file:

```
[SETTINGS]
LANGUAGE=English
SERIALNR_PC=Serial number PC/Tablet
SERIALNR_PROBE=Serial number VitaScan LT
HOSPITAL_ID=Hospital name
MANUAL_MEASUREMENT=0
RESIDUAL_CALCULATION=0
DATA_LOGGING=0
SAVE_FORMAT=PDF
SAVE_PATH=C:\Documents\VitaScanLT\Reports
SCAN_COUNT=6
EASY_MODE=0
```

LIVE_UPDATE=0
BLOB_MODE=0
PROBE_ID=0x00000000
PUBICBONE_DISCHARD=1

PATIENT_ID=Patient name PATIENT_DOB= 12/06/87 PATIENT_GENDER=Female
HYSTERECTOMY=0
SCAN_DEPTH_CM=16

TEXT1=
TEXT2=
TEXT3=
TEXT4=

[RESULTS]
SAVE_FILENAME=Patient name

SETTINGS:

- LANGUAGE=English // Set language
- SERIALNR_PC= // Input serial number of PC/Tablet
- SERIALNR_PROBE= // Input serial number of VitaScan LT USB probe
- HOSPITAL_ID= // Hospital name or ID#
- MANUAL_MEASUREMENT=0 // Set to 0 = OFF or 1 = 0N
- RESIDUAL_CALCULATION=0 // Set to 0 = OFF or 1 = 0N
- DATA_LOGGING=0 // Set to 0 = OFF or 1 = 0N
- SAVE_FORMAT=PDF // Set to PDF, JPG or DICOM
- SAVE_PATH= // Set path to an existing folder C:\Documents…..
- SCAN_COUNT=6 // Set to 6, 12, 24 Scans for the Measurement
- EASY_MODE=0 // Set to 0 = OFF or 1 = 0N
- LIVE_UPDATE=0 // Set to 0 = OFF or 1 = 0N
- BLOB_MODE=0 // Set to 0 = OFF or 1 = 0N
- PROBE_ID=0x00000000 // Patient name or ID#
- PUBICBONE_DISCHARD=1 // Date of Birth in any date format
- PATIENT_ID=Patient name // ID number (Set by Vitacon only)
- PATIENT_DOB= // Set to 0 = OFF or 1 = 0N
- PATIENT_GENDER=Female // Set to FEMALE or MALE
- HYSTERECTOMY=0 // Set to 0 = OFF or 1 = 0N
- SCAN_DEPTH_CM=16 // Set to 10, 16 or 23 [depth in cm]
- TEXT1= // Text to be included in Report Header
- TEXT2= // Text to be included in Report Header
- TEXT3= // Text to be included in Report Header
- TEXT4= // Text to be included in Report Header
- SAVE_FILENAME= // Filename of Report
- PROBE_ID= // Probe identification number = 0x00000000

Note:

- «SCAN_COUNT» can be set to 6, 12 or 24 Scan. If not specified or wrong, - 6 will be used.
- «SCAN_DEPTH_CM» can be set to 10, 16 or 23 (if not specified or wrong, - 16 will be used).
- Output “SAVE_PATH” specified must exists, be valid and can be written to.
- Output “SAVE_FILENAME” specified must have a valid filename and can be written to.
- “TEXT 1 to TEXT4” may include information such as Address, Phone number, Reference number, Doctor name or like.

2) **Start VitaScan LT application with the VitaScanLT.INI file from CMD command or another program**

C:\programs\VitaScanLT.exe -IC:\documents\Vitacon\VitaScanLT\VItaScanLT.INI

- Specify both paths where VitaScanLT.exe and VitaScanLT.INI file are located on your computer
- No space between '-I' and path to the INI-filename

3) **SAVE**

Following Reports are stored when pressing SAVE in VitaScan LT application menu:

- Test report on PDF, JPG or DICOM format
- Test result file on TXT format including:

[RESULT]
PATIENT_ID=
SCAN_DEPTH_CM= VOLUME_IN_ML=
SAVE_FILENAME=

Application – Troubleshooting

- **Installation message: Driver not found**
  - ☐ **Uninstall driver**
  - ☐ **Open "Control Panel**
  - ☐ **Select "User Accounts"**
  - ☐ **Select "Change Settings"**
  - ☐ **Drag the selection bar down to "No Warning"**
  - ☐ **Restart the computer**
  - ☐ **Re-install the driver**
- **Device should be configured before running the application.**
  - ☐ **In case of Windows XP OS, the USB driver needs to be configured before the application start.**
- **Application log file and Scan folder images are not getting generated in Windows Vista OS.**
  - ☐ **The log-in user should have access rights to the application folders, or should have administrator rights to the folders.**
- **Scanbutton is deactivated.**
  - ☐ **Press Clear/Restart button, or reset the VitaScan LT by removing USB connection for a few seconds and insert again.**
  - ☐ **Turn off "Power Saving Mode". Set Power Plan of the computer to "High Performance".**
- **Incorrect detection of bladder.**
  - ☐ **Insufficient battery capacity, connect to external safe power supply.**
  - ☐ **Turn OFF "Power Saving Mode". Set Power Plan to "High Performance".**
  - ☐ **Turn OFF "Wireless network connection" on your computer settings.**
  - ☐ **Turn OFF "Bluetooth connection" on your computer settings.**
  - ☐ **Stop "antivirus program" on your computer settings. – if applicable.**
- **ReScan please.**
  - ☐ **Incorrect detection of bladder. Apply more gel on the Scanhead/abdomen, and angle the Scanhead below the pubic bone. Verify that the bladder is placed over the center of the Bladder.**

Warranty and Disclaimer Information

EFFECTIVE: FEBRUARY 1, 2018 FOR US CUSTOMERS

This Warranty applies for the periods defined herein for the Product ("Warranty Period"). VITACON warrants the Products 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 date of purchase, repair or replace any defective Product with new or reconditioned parts or Product that are functionally equivalent or superior to those originally supplied if the fault is due to a manufacturing defect. The Warranty does not cover bundled accessories delivered together with the Product such as: cables, computers, tablets, printers, keyboards, carts, etc. ("Third Party Products"). Third Party Products are covered under the Third Party Manufacturer's warranty and ITACON will act as the liaison for service events between Customer and Third Party Manufacturer's during the Warranty Period.

If Product is repaired or replaced within the Warranty Period for any reason, the original warranty is not extended beyond the initial Warranty Period. In no event will VITACON or its representatives be liable for direct, indirect, special, incidental, or consequential damages arising out of the use of or inability to use the Products, even if advised of the possibility of such damages. Neither VITACON nor its representatives are responsible for any costs, loss of profits, loss of data, or claims by third parties due to use of, or inability to use the Products. Neither VITACON nor its representatives will accept, nor be bound by any other form of guarantee concerning the Products 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.

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 for any unauthorized servicing, disassembly, rebuilding, modification or resale of VitaScan LT 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 LT bladder volume scanner. VitaScan LT 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.

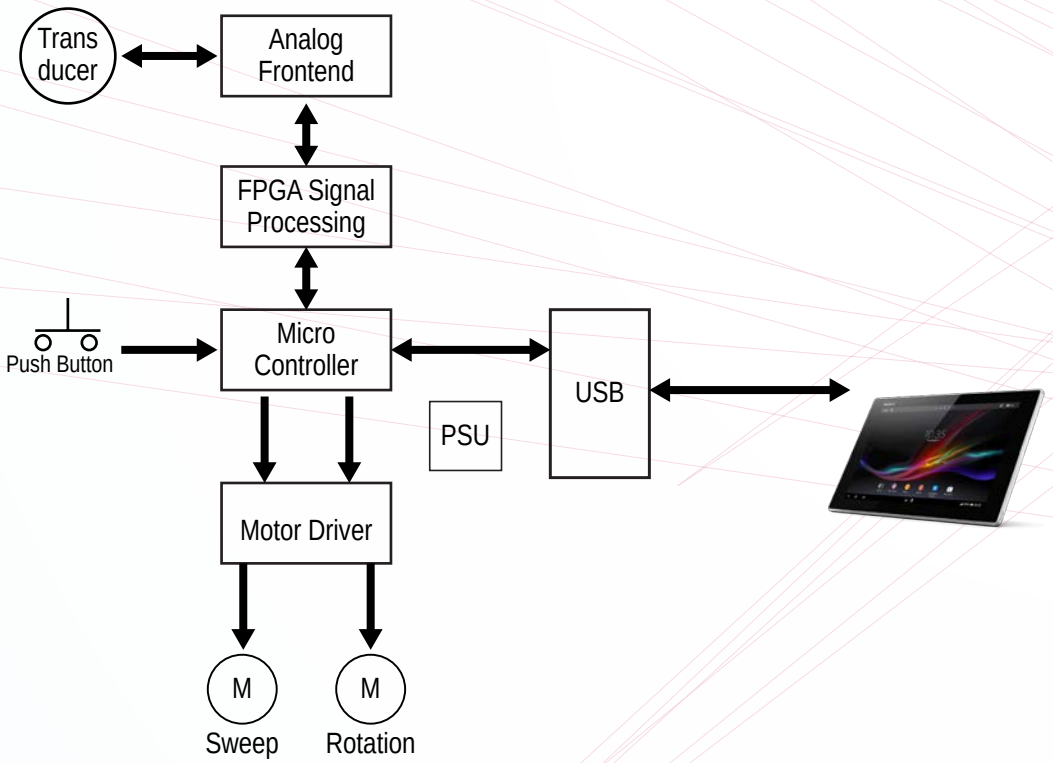
The VitaScan v.2 probe consists of mechanics and electronics. The VitaScan LT contains the mechanical components needed to execute the 3 dimensional scanning of the bladder, and the electronics to obtain the ultrasound image needed to calculate the volume of urine in the bladder both pre and post void.

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 LT bladder scanner system. All modules are physically located inside the VitaScan v.2.

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 LT 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.

Manufacturer:

UAB Vitacon LT
Naujoji g. 12-525
Alytus 63250
Lithuania

CE 2274