Vitascan cVue/eVue

Ultrasound Bladder Scanner

User and Maintenance Manual

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Vitacon warrants that the Vitascan cVue/eVue/cVue USB Ultrasound Bladder Monitor will substantially conform to published specifications and to the documentation if 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 cVue/eVue USB Ultrasound Bladder Monitor, 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 the use of, or inability to use the Vitascan cVue/eVue USB Ultrasound Bladder Monitor. Neither Vitacon nor its local representatives will accept, nor be bound by any other form of guarantee concerning the Vitascan cVue/eVue USB Ultrasound Bladder Monitor 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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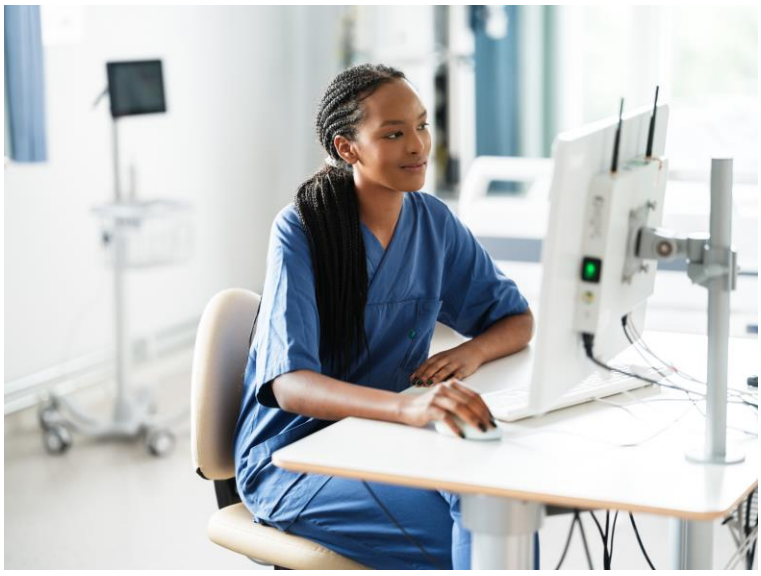


Contents

1 IMPORTANT INFORMATION

1.1 PRODUCT DESCRIPTION

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 cVue/eVue is a B-mode ultrasonic device, 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 cVue/eVue automatically calculates the estimated bladder volume in millilitres and displays it on a screen.

Vitascan cVue/eVue 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.

1.2 ESSENTIAL PERFORMANCE

Essential performance is the device performance necessary to achieve freedom from unacceptable risk. The essential performance of the Vitascan cVue/eVue is to produce ultrasonic output energy and display numerical values for bladder volume. The device has a passively temperature-controlled transducer assembly.

1.3 ENVIRONMENTS OF INTENDED USE

The Vitascan cVue/eVue is intended to be used in professional healthcare environments such as hospitals, clinics, and doctors' offices.

1.4 NOTICE TO ALL OPERATORS

The Vitascan cVue/eVue 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 cVue/eVue. Failure to comply with these instructions may compromise the performance of the device and the safety of the patient.

The user and/or patient in the event of any serious incident involving the device must inform the Vitacon and the competent authority of the Member State in which the user and/or patient is located.

1.5 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 professional when clinically indicated, using the lowest exposure times possible commensurate with clinical utility.

The ultrasonic output power of the Vitascan cVue/eVue 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.

1.6 THE LIFE-CYCLE OF THE VITASCAN CVUE/EVUE

The Lifecycle, period of time, that the Vitascan cVue/eVue can be in service under the operating environment conditions described in this User Manual and remain suitable for use is 7 years.

2 INTENDED USE AND INDICATIONS

2.1 STATEMENT OF INTENDED USE

The Vitascan cVue/eVue is an Ultrasonic Bladder Scanner intended for measuring the urine volume of the bladder non-invasively.

It provides accurate data to aid in the diagnosis of common urological conditions, assesses urinary retention, helps prevent unnecessary catheterization, and to reduce rates of catheter-associated urinary tract infection (CAUTI)

The Vitascan cVue/eVue is applicable in clinical practice to determine bladder volume, time for bladder emptying, and detection of post-void residual volume.

2.2 CONTRAINDICATIONS

The Vitascan cVue/eVue is not intended for two types of patients:

1. A patient must not have abdominal wounds over the midline lower abdominal area.

2. A female patient is not pregnant.

2.3 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.

A bladder scan is a safe, painless, reliable procedure that allows assessing the volume of urine retained within the bladder. Using a scanner instead of urinary catheterization alleviates discomfort, pain, and the introduction of outside pathogens to the patient's bladder. Bladder scanners are the safest option for healthcare providers to use for patients experiencing urine retention for the following indications:

Post-op decreased urinary output. If the patient has undergone an abdominal surgical intervention that may impair the ability to void by causing localized oedema in the abdomen, the oedema may compress the urethra, resulting in partial or complete occlusion.

An enlarged prostate. This condition can impair the patient's ability to void by partially compressing the urethra and occluding the urinary exit pathway.

An urethral stricture. This can impair the patient's ability to fully empty the bladder because the urethral pathway, through which urine exits, is narrowed.

Neurogenic bladder. The patient's inability to void may be due to damaged neural pathways to or from the bladder.

Spinal cord injuries. These conditions can cause urinary retention because of oedema resulting from the injury.

Stroke. A stroke patient may experience an impaired ability to void because of neurologic injuries, such as paralysis or cerebral oedema.

Impaired cognitive ability. This may prevent the patient from correlating the sensation of needing to void with the physical act of voiding.

Renal calculi or renal mass. Renal calculi (kidney stones) or a renal mass may physically obstruct the outflow of urine. Although a bladder scan isn't utilized to diagnose an obstructive mass or stone, occasionally these conditions can be visualized during the scan.

Urinary incontinence. This can result in incomplete emptying of the bladder due to infection, neurologic conditions, or anomalies of the renal structures. A bladder scan can assist the nurse in noting the frequency and volume of retained urine to tailor an individualized bladder retraining program for the patient.

Diabetes. Patients with diabetes may not have the sensation or urge to void.

2.4 PRODUCT FEATURES

- Real-time Ultrasound Bladder Scanner.
- 3D ultrasound scanner.
- USB ultrasound probe connection.
- Bladder volume calculations in large digits.
- Storage of ultrasound images.

2.5 THE BENEFITS OF USING PORTABLE BLADDER ULTRASOUND SCANNERS

2.5.1 BENEFITS TO PATIENTS

- Allows non-invasive measurement of urinary bladder volume.
- Enables appropriate care to be given in the patient's home environment.
- Reduces anxiety and promotes dignity for patients.
- Reduced risk of infection compared with measurement via catheterisation.
- Reduced risk of trauma associated with catheterisation.

2.5.2 OPPORTUNITIES FOR THE SERVICE

- Improved risk management and clinical governance.
- Opportunity to reduce bed days when implemented as part of a wider package of care.
- Potential cost savings related to the reduced number of catheterisations.

3 SAFETY INFORMATION

3.1 SIGNS AND SYMBOLS

In this Manual, warning is used to intensify attention to certain paragraphs. A warning is accompanied with an identification inscription depending on the precaution level:

WARNING:	This is warning of the risky situation that may cause a serious trauma or death if the safety requirements are not observed.
CAUTION:	Indicate that use or misuse of the device may cause a problem, such as a malfunction, failure, or damage to the product. Throughout the manual, pay attention to sections labelled Important, as these contain reminders or summaries of the following cautions as they apply to a specific component or use situation. Please heed the following warnings and cautions.
NOTE:	The note contains important information requiring special attention.

3.2 FIRST TIME USERS:

We advise new operators to use the Vitascan cVue/eVue on patients with moderately full bladders, rather than initially attempting to locate nearly empty bladders.

NOTE:	The user should always follow the ALARA (As Low As Reasonably Achievable) principle. Use the lowest amount of acoustic output power for the shortest duration of time to obtain the necessary clinical diagnostic information. Read this information carefully before you begin operating the Vitascan cVue/eVue scanner.
CAUTION:	The Vitascan cVue/eVue 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. It is recommended to operate this equipment only on battery power.
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.

3.3 RISK OF INACCURATE MEASUREMENTS/RESULTS

When using the Vitascan cVue/eVue be aware of the following conditions which can affect ultrasound transmission and decrease the accuracy of exam results.

- Use care when scanning patients who have had supra-pubic or pelvic surgery. Scar tissue, surgical incisions, sutures, and staples can affect ultrasound transmission and accuracy.
- Do not use the Vitascan cVue/eVue on a patient with open skin or wounds in the suprapubic region.
- Do not use the Vitascan cVue/eVue on a patient with ascites.
- If you scan a patient with a catheter in his/her bladder, the catheter may affect measurement accuracy. However, the information obtained from the measurement could still be clinically useful for detecting problems such as a blocked catheter.

3.4 DISPOSE ELECTRONIC WASTE

Vitascan cVue/eVue 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”.

When the Vitascan cVue/eVue has reached the end of its useful service life, contact Vitacon at the address mentioned at the front of this manual or your local Vitacon distributor to return unwanted products for proper disposal. Alternatively, follow your local protocols for hazardous waste disposal.

3.5 ELECTRICAL SAFETY

This Vitascan cVue/eVue meets EN60601-1, Class II and Type BF isolated patient-applied parts safety requirements.

For maximum safety observe the following warnings and cautions:

WARNING:	To avoid the risk of electrical shock or injury, do not open the Vitascan cVue/eVue enclosure. All internal replacements must be made by a qualified technician. To avoid the risk of injury, do not operate the Vitascan cVue/eVue in the presence of flammable gasses or anaesthetics. 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. To avoid the risk of electrical shock, before using the Vitascan cVue/eVue, inspect the housing and USB cable. Do not use the Vitascan cVue/eVue if these are damaged. To avoid the risk of electrical shock, always disconnect the power cord from the mains supply before cleaning the Vitascan cVue/eVue. 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 console output connector (like USB port and others) and the patient at the same time.

CAUTION:	Although your Vitascan cVue/eVue has been manufactured in compliance with existing EMC/EMI requirements (EN60601-1-2), use of the Vitascan cVue/eVue in the presence of an electromagnetic field can cause degradation of the ultrasound image. If this occurs often, Vitacon suggests a review of the Vitascan cVue/eVue environment. Identify and remove the possible sources of the emissions or move your Vitascan cVue/eVue. Medical Electric Equipment can be affected by portable or mobile RF communication devices. Turn OFF any portable or mobile RF device before operating your Vitascan cVue/eVue. 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 Vitascan cVue/eVue. 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 Vitascan cVue/eVue if an error message appears on the display: note the error code; call Vitacon or your local representative; turn off the Vitascan cVue/eVue.

3.6 EQUIPMENT SAFETY

To protect your ultrasound Vitascan cVue/eVue, scanner, and accessories, follows these precautions.

CAUTION:	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 cVue/eVue 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 battery before using the Vitascan cVue/eVue, to avoid the risk of the Vitascan cVue/eVue turning off while in use.
	Incorrect cleaning or disinfecting of any part of the Vitascan cVue/eVue can cause permanent damage.
	Do not use solvents such as thinner or benzene, or abrasive cleaners on any part of the Vitascan cVue/eVue.
	Do not spill liquid on the Vitascan cVue/eVue.
	Do not use the Vitascan cVue/eVue if it exhibits erratic or inconsistent behaviour. Turn Off the power of the Vitascan cVue/eVue 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 cVue/eVue if its head or cable is damaged.
	To avoid the risk of electrical shock, do not use the Vitascan cVue/eVue that has been immersed in liquid.

3.7 SAFETY AND PERFORMANCE SUMMARY

The Vitascan cVue/eVue 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 cVue/eVue 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.

4 UNPACKING AND INSPECTION

There are no special unpacking instructions but be careful not to damage the device when unpacking it. When unpacking the Vitascan cVue/eVue check for damage during shipment:

- Inspect the shipping carton for damage. If the shipping carton is damaged, carefully continue unpacking the device and note any dents and scratches on the Vitascan cVue/eVue. 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 cVue/eVue from the shipping case. Save the box and packing materials; they will be needed when returning the Vitascan cVue/eVue 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 cVue/eVue. Save these for future shipment of the unit for service or calibration.

4.1 CONTENT OF THE PACKAGING

- Vitascan v.2 probe
- Vitascan cVue/eVue console
- Vitascan v.2 probe holder
- Installation guide in English

4.2 STORAGE

If the Vitascan cVue/eVue 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.

5 TECHNICAL SPECIFICATIONS

5.1 OVERALL DEVICE SPECIFICATIONS

Item	Specification	
General Specifications		
Classification	Internally powered, Type BF	
Expected product life	Console	7 years
	Probe	7 years
	Printer	7 years
	Batteries	7 years
Ingress protection (IP) against water	Console	IPX0
	Probe	IPX7
	Printer	IPX0
	Batteries	IPX0
Operating Conditions - Indoor		
Temperature	+10 - +40º Celsius (50 - 104º Fahrenheit)	
Relative humidity	30% - 75% non-condensing	
Ambient air pressure	700 hPa - 1060 hPa	
Storage Conditions - Indoor		
Temperature	-10 - +60º Celsius (14 - 140º Fahrenheit)	
Relative humidity	15% - 85% non-condensing	
Ambient air pressure	500 hPa - 1060 hPa	
Water resistance	Rated at IPX7 (indicates protected against the effects of temporary immersion in water.)	

Table 1 Overall Device Specifications

5.2 PROBE SPECIFICATIONS

Item	Specification
Length	187 mm (7.48 in)
Diameter	47 mm (1.8 in)
Weight	263 g (1 lbs)
USB Cable	2.3 m (9.2 ft)

Table 2 Probe Specifications

5.3 CONSOLE SPECIFICATIONS

Item	Specification
General Specifications	
Height	125 mm (7.48 in)
Width	227 mm (1.8 in)
Depth	263 m (9.2 ft)
Weight	1770 g (1 lbs)
Electrical Specifications	
Input	100-240 VAC/50-60Hz
Output	USB Port, 5 V DC at 100 mA maximum
Insulation	Type BF

Table 3 Console Specification

5.4 ULTRASOUND OUTPUT PARAMETERS

Item	Description
Maximum ultrasound I_{spta} during a scan	≤ 5.0 m W/cm2
Maximum ultrasound I_{sppa} during a scan	≤ 60.0 W/cm2
Maximum MI (Mechanical Index)	0.22 max
Transducer diameter	17 mm (0.5 inches)
Transducer frequency	3.5 MHz
Transducer bandwidth	75% at 10 dB
Time from 3D scan initiation to result display	< 5 seconds
Penetration depth (in normal European patient)	≥ 20 cm

Table 4 Ultrasound Output Parameters

5.4.1 ULTRASOUND ACOUSTIC OUTPUT PARAMETERS (IEC STANDARD)

MODE: **B mode**

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At surface	Below surface	
Maximum index value*			0.22	$2.21x10^{-3}$		-	-	
Index component value				$2.21×10^{-3}$	$2.21×10^{-3}$	-	-	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)						
	P	(mW)		0.854		-	-	-
	$P_{1×1}$	(mW)		0.205		-	-	
	z_s	(cm)			3.3			
	z_b	(cm)					-	
	z_{MI}	(cm)	3.3					
	$Z_{pii,\alpha}$	(cm)	3.3					
	f_{awf}	(MHz)	3.4	3.4		-	-	-
Other Information	prr	(Hz)	408					
	srr	(Hz)	5.1					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	11.3					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	0.156					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	0.277					
	p_r at Z_{pii}	(MPa)	0.844					
erating Control Conditions	3.4 MHz pulse		•	•	•			

• *MI and TI values are both below 1.0.*

Table 5 Ultrasound Acoustic Output Parameters (IEC Standard)

5.5 ACCURACY SPECIFICATIONS

Specification	Description	
Bladder volume range	0 to 999 mL	
Volume accuracy	greater than 100 mL	± 7.5%
	0–100 mL	± 7.5 mL

Table 6 Accuracy Specifications

The following examples show how the accuracy ranges shown in Table 6 may affect reported volume measurements.

If the measurement is greater than 100 mL, the accuracy range is ± 7.5% and is calculated as follows:

- 240 mL × 7.5% = 18 mL
- 240 ± 18 mL = 222–258 mL

If the measurement is 0–100 mL, the accuracy range is ± 7.5 mL and is calculated as follows:

- 80 mL ± 7.5 mL = 73–88 mL (rounded to the nearest whole number)

The accuracy specifications assume the device is being used according to the instructions provided by Vitacon while scanning a tissue-equivalent phantom.

While the upper threshold of the accuracy range is 1000 mL, the device can detect and display bladder volumes above 1000 mL. Vitacon cannot guarantee the accuracy of measurements outside of the stated specifications.

5.6 BATTERY SPECIFICATIONS

The device includes three lithium-ion batteries. A battery field on the touchscreen display is always present, indicating how much power remains.

Adhere to the following recommendations and guidance:

- Use only the battery charger provided with the device. Any other battery charger may damage the batteries.
- Consider replacement of the battery if the time between battery charges is significantly reduced and is affecting the use of the Vitascan cVue/eVue. Contact Vitacon or your local representative to order replacement batteries.

Safety requirements of the batteries according to standard IES 62133-2 are confirmed by the Test Report #NCT190270291-1

Item	Description
Battery type	Lithium iron phosphate battery (LiFePO4)
Battery life	A fully charged battery will typically provide more than 24 hours of normal operating use between charges
Charging time	3.4 hours (typical)
Rated capacity	3000 mAh, after standard charge and standard discharge
Nominal voltage	3.2 V
Max charging voltage	3.65 V

Table 7 Battery Specifications

5.7 ELECTROMAGNETIC COMPATIBILITY

The Vitascan cVue/eVue is designed to be in compliance with IEC 60601-1-2, which contains electromagnetic compatibility (EMC) requirements for medical electrical equipment. The limits for emissions and immunity specified in this standard are designed to provide reasonable protection against harmful interference in a typical facility.

The Ultrasonic Bladder Scanner Vitascan cVue/eVue complies with the applicable essential performance requirements specified in IEC 60601-1 and 60601-2-37. Results of immunity testing show that the essential performance of the device is not affected under the test conditions described in the following tables.

5.7.1 ELECTROMAGNETIC EMISSIONS

The Vitascan cVue/eVue is intended for use in the electromagnetic environment specified below. The customer or the user of the Vitascan cVue/eVue should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	The Vitascan cVue/eVue uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Vitascan cVue/eVue is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	In compliance	

Table 8 Guidance and Manufacturer's Declaration—Electromagnetic Emissions

5.7.2 ELECTROMAGNETIC IMMUNITY

The Vitascan cVue/eVue is intended for use in the electromagnetic environment specified below. The customer or the user of the Vitascan cVue/eVue should ensure that it is used in such an environment.

IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
± 8 kV contact ± 15 kV air	In compliance	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
± 2 kV for power supply lines 100 kHz repetition frequency	In compliance	Mains power quality should be that of a typical commercial or hospital environment.
± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	In compliance	Mains power quality should be that of a typical commercial or hospital environment.
Radiated RF 3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	In compliance	Interference may occur in the vicinity of equipment marked with the following symbol: 

Table 9 Guidance and Manufacturer's Declaration — Electromagnetic Immunity

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

5.7.3 RECOMMENDED SEPARATION DISTANCES

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

	Separation Distance According To Frequency Of Transmitter (m)		
Rated Maximum Output Power Of Transmitter (W)	**150 kHz to 80 MHz** **d=1.2 √P**	**80 MHz to 800 MHz** **d=1.2 √P**	**800 MHz to 2.5 GHz** **d=2.3 √P**
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

Table 10 Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the Device

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

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

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

5.8 ABOUT THE VITASCAN CVUE/EVUE SOFTWARE

The Vitascan cVue/eVue contains preinstalled software that controls its operation. The Vitacon may offer software upgrades and new features that may improve Vitascan cVue/eVue performance.

The new version of the User & Maintenance Manual will accompany the enhancements, explaining the effects of upgrades and new features on Vitascan cVue/eVue performance.

5.9 DEVICE COMPONENTS

The following components are available for ordering.

Reference Number	Description
100880 MP	Vitascan cVue Bladder Scanner with Mobile Cart
100818	Printer for Vitascan cVue, including housing, pole clamp and cable (optional)
100955B	Barcode scanner, including holder with pole clamp and cable (optional)
100980 CP	Vitascan eVue Bladder Scanner
100560	VitaScan Soft Case with shoulder strap (optional)
100762	Vitascan Mobile Cart with Handle & Basket (optional)
100751	Vitascan Verification Test Tool v.2 probe (optional)

Table 11 Device Components

5.10 SYMBOL DIRECTORY

The following table explains the industry symbols used to indicate the Vitascan cVue/eVue compliance with international and national standards and regulations.

Icon	Explanation
CE 2274	CE mark – Notified body number
UDI-DI	Unique Device Identification
	Consult instructions for use
	Caution Indicates that the instructions for use contain important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
IPX7	Water immersion for transducer from the acoustic window to the junction line.
IPX1	Drip proof for transducer for other parts that may contact the patient, excluding the transducer connector.
IPX0	No protection against water for transducer connector and the main unit.
	Non-ionizing
REF	Type/model of the device
SN	Serial number of the device
	Manufacturer
	The device should not be disposed in landfill.

Table 12 Symbol Directory

5.11 APPLICABLE STANDARDS/APPROVALS

Standard	Title
MDR EU 2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices
EN ISO 14971:2019+A11:2021	Medical devices – Application of risk management to medical devices
EN ISO 13485:2016+ AC:2018+A11:2021	Medical devices- Quality management devices- Requirements for regulatory purposes
EN ISO 14155:2011+AC:2011	Clinical investigation of medical devices for human subjects — Good clinical practice
EN 62304:2006+AC:2008+A1:2015	Medical device software – Software life-cycle processes
EN IEC 60601-1:2006+ A1:2013+ AC:2014 + A2:2021	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 60601-2-37:2008+A11:2011+ A1:2015	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
EN 60601-1-2:2015+A1:2021	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests (IEC 60601-1-2:2014)
EN 60601-1-6:2010+A1:2015	Medical electrical equipment-Part 1-6: General requirements for safety-Collateral Standard: Usability
EN 62304:2006+AC:2008+A1:2015	Medical device software – Software life-cycle processes
EN ISO 10993-1:2009+ AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN 62366-1:2015+AC:2015	Medical devices -- Part 1: Application of usability engineering to medical devices
EN ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer
EN 60529:1991+ A1:2000+A2:2013+AC:2019:	Degrees of protection provided by enclosures (IP code)
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016)
EN ISO 780:2015	Packaging — Distribution packaging — Graphical symbols for handling and storage of packages
EN 62353:2015	Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment

Table 13

6 INTRODUCTION

6.1 DEVICE OVERVIEW

Vitascan cVue/eVue is a 3D ultrasound system that noninvasively measures bladder volume. The core components of the system are a console with a touchscreen display, a probe containing the ultrasound transducer. There are several accessories and configuration options available for the system, including a mobile cart, and external memory solutions.

Figure 1 Vitascan cVue/eVue

The system includes an onboard tutorial. The console features a variety of customizable settings and a saved scans function that allows you to recall, print, or transfer saved exams.

6.2 COMPONENTS & ACCESSORIES

 Vitascan cVue	 Vitascan v.2 Probe	 Thermal Printer Paper  Thermal Printer (optional)  Barcode Scanner (optional)  Power cable C13 with EUR, UK, US or AUS plug
 Vitascan eVue with Thermal Printer	 Vitascan v.2 Probe	 Vitascan Soft Carrying Case with shoulder strap (optional)  Power cable C13 with EUR, UK, US or AUS plug

Figure 2 Components and Accessories

Additionally, quick reference materials and ultrasound gel may be available for order in your region. For more information, contact Vitacon Customer Care or your local representative or visit www.vitacon.com site.

6.3 DEVICE FEATURES

The Power button is constant button on the body of the console and can be pressed at any time. The Scan button is located on the probe.

6.3.1 CONSOLE FEATURES

The console's primary feature is a touchscreen display that allows you to perform scans, manage scan results, and customize settings. It provides controls for adjusting brightness and volume and activating the system or putting it in standby mode. A rechargeable battery is inserted into the console, and the other side features a selection of ports for connecting system components and accessories such as external, removable media storage devices.

Figure 3 Console Features

Part Name	Purpose
Main display	1200x800 pixel display to show real-time ultrasound image, and volume calculation
Probe cable port	USB-C port to connect and power Vitascan v.2 probe
USB port	USB-A port for connecting USB memory stick to save reports, or connect USB barcode scanner for input of patient and operator ID
On/Off button	To turn device on and off. Short press to turn on, long press to turn off

Table 14 Console Features

6.3.2 PROBE FEATURES

The probe contacts the patient and transmits and receives ultrasound waves, automatically moving its internal transducer to scan twelve or twenty-four planes to produce a three-dimensional image of the bladder. The probe is attached to the console by a cable. After a scan, the probe displays bladder volume and aiming.

Figure 4 Probe Features

Part Name	Purpose
Start/Scan button	To start the probe scanning sequence
Probe cable	For power and communication to and from the probe
Probe dome	Contact point for the ultrasound wave to patient lower abdomen

Table 15 Probe Features

6.4 DEVICE ICONS AND BUTTONS

6.4.1 CONSOLE TOUCHSCREEN ICONS

The console touchscreen displays the interface that controls the system. The following icons may appear on the screen, and you may tap them to complete the function associated with the icon.

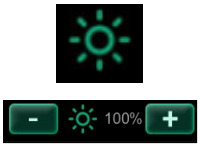
Icon	Function
	Volume button: Adjust volume with plus and minus button
	Screen brightness button: Adjust screen brightness with plus and minus button
	Probe Connectivity Icon: Green indicates the probe is connected; Yellow signifies it is configuring; Red means no probe is connected
	USB Stick Connectivity Icon: Green when the USB Stick is connected
	Battery Status Icon

Table 16 Touchscreen Icons

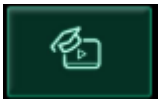
6.5 DISPLAY SCREEN

6.5.1 HOME SCREEN

The Home screen appears when the instrument is turned on. It serves as a starting point for all of the main functions of the device.

The Home screen displays:

Figure 5 Home screen

Button	Function
	Gender Button Adult: Select for patient adult or heavier than 25 kg
	Gender Button Child: Select for Child under 25 kg
	Scan Button: to start Pre-Scanning
	Tutorial Button: To start user tutorial video

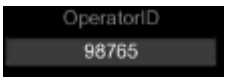
	Settings Button: To enter setup menu
	Patient ID input field: To enter patient information
	Operator ID input field: To enter operator information

Table 17 Button Functions for each Display Screen

6.5.2 PRESCAN SCREEN

The Scan screen appears after you press the Scan button on the probe and displays a progressively updating image of the bladder outline.

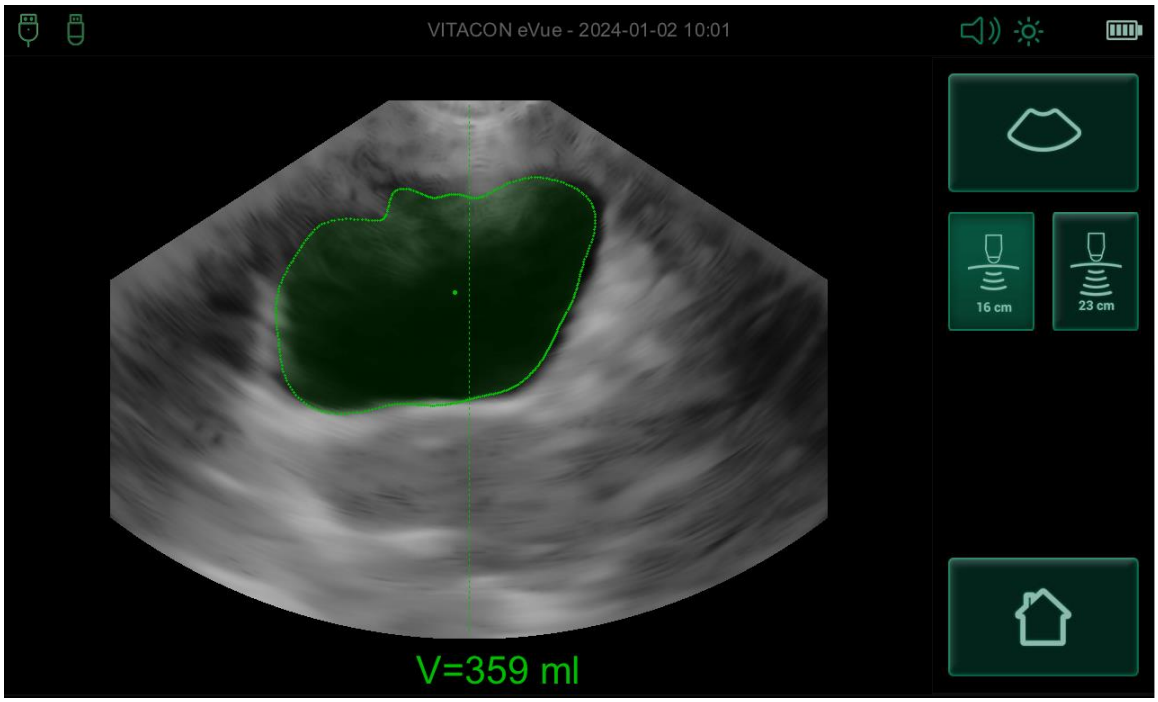


Figure 6 PreScan screen

Button	Function
	Scan button: To start a full 3D scan
	Return to the Home screen.
	16CM scan depth button: To select 16 cm scan depth (Default)
	23CM scan depth button: To select 23 cm scan depth
	The 'V =' result indicates the estimated bladder volume derived from the Pre-Scan

Table 18 Results Screen Button Functions

6.5.3 RESULTS SCREEN

The Results screen appears after pressing the **Scan** button when an ultrasound scan is complete. The display presents the result of the exam: crosshairs, bladder outline, and the calculated bladder volume. You may choose to print this result to the onboard printer and/or save the exam.

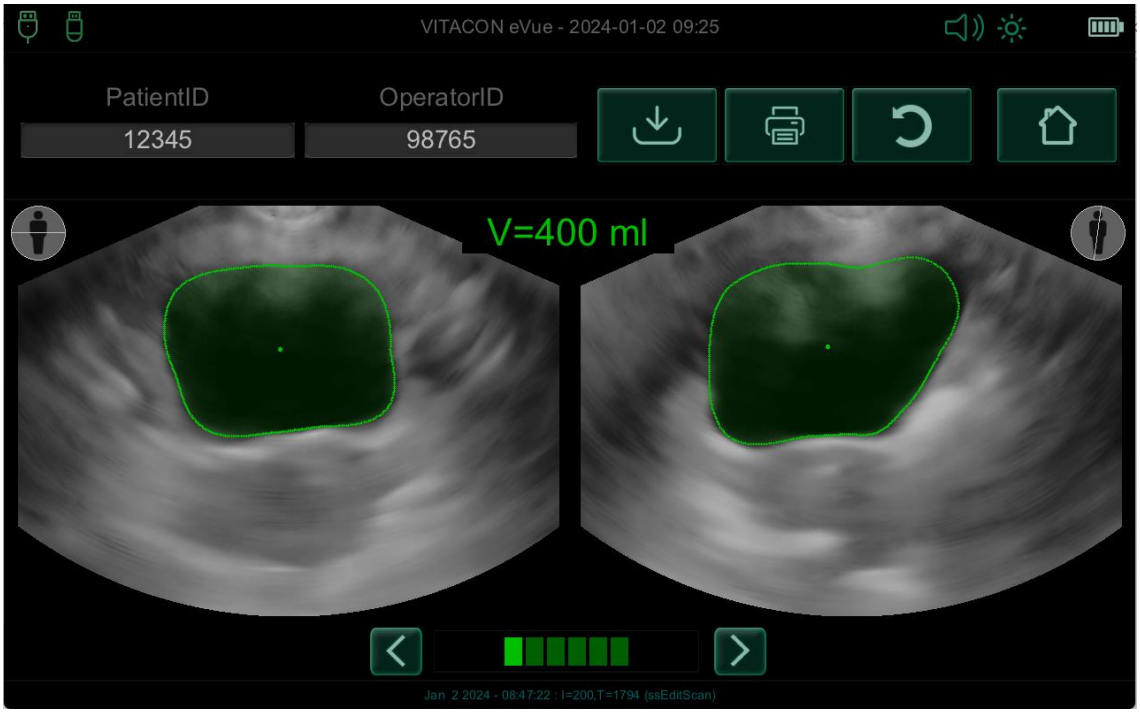


Figure 7 Result screen

Button	Function
	Return to the Home screen.
	Re-Scan Button to preform another scan
	Print Report: Send results to the onboard printer for printing
	Save Button: Use this to save the result on a USB memory stick when inserted, or via Wi-Fi if it is configured
	Navigate through all scanned images using the arrow keys. To view the next scan, use the arrows. Scans that are approved will be displayed with green markings. If a scan appears with yellow markings, this indicates that it should be checked more closely. You can optionally adjust the detection line by pressing it on the screen and then dragging it to the desired position for correction
	Scan Direction Icon: Indicates the direction of the scan for the image

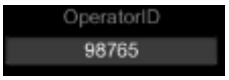
	Patient ID input field: To enter patient information
	Operator ID input field: To enter operator information
	The 'V =' result displays the measured bladder volume

Table 19 Results Screen Button Functions

7 SETTING UP

The device is configured with default settings that are appropriate for many users.

This procedure helps you configure your regional and facility preferences, such as the name of your facility, the language in which your device operates, and your formatting preferences for the time, date, and numbers.

7.1 PERFORM THE INITIAL INSPECTION

When you receive the system, Vitacon recommends that an operator familiar with the system perform a full visual inspection for any physical damage that may have occurred during shipment.

1. Carefully open the top of the shipping box. Do not insert anything sharp through the box.
2. Remove the contents and verify that you have received the appropriate components for your system.
3. Inspect the components for damage.
4. If any of the components are missing or damaged, notify the carrier and Vitacon Customer Care or your local representative.

7.2 POWER CORD

This device is classified as Class II Medical Electrical (ME) Equipment and features internal isolation with screens. It is equipped with a Power Supply Cord that contains three conductors. The third conductor is connected to the Protective Earth contact of the Mains Plug. Please note that in this Power Supply Cord, the third conductor serves as a functional earth and is not intended for protective grounding purposes.

7.3 SAFETY INSTRUCTIONS FOR POWER CORD MANAGEMENT

Important Safety Warning: To ensure your safety and the effective operation of your medical device, it is crucial to position the device in a manner that allows for immediate and easy access to the power cord for disconnection from the mains power supply. Please follow the instructions below carefully:

Procedure for Positioning the Device:

Identify the Power Source: Before setting up the device, identify the nearest mains power outlet you plan to use. Ensure that this power outlet is easily accessible and not obstructed by furniture or other equipment.

Position the Device: Place the device in a location where both the device and the power outlet are within easy reach. Avoid placing the device in a position where you would need to stretch, bend excessively, or move other objects to access the power cord.

Cord Management: Arrange the power cord in a manner that avoids creating trip hazards or placing tension on the plug. Ensure the cord is not entangled or under furniture in a way that would impede quick disconnection.

Accessibility: Confirm that you can easily reach the plug without moving the device or needing to use tools. The plug should be visible and accessible for quick disconnection.

Regular Checks: Periodically inspect the power cord for any signs of damage, wear, or tear. Additionally, verify that the setup maintains the power cord's easy accessibility. Ensure that the positioning of the device has not changed in a manner that obstructs or delays rapid disconnection. It's crucial to address any issues immediately to maintain safety and functionality.

Emergency Procedure Awareness: Familiarize yourself with the procedure for disconnecting the device quickly in case of emergency. Practice this procedure to ensure that you can perform it swiftly and safely.

In Case of Emergency:

Immediate Disconnection: In an emergency, reach for the plug, not the cord, to disconnect the device from the mains power supply. Pull steadily and firmly to remove the plug from the outlet.

Seek Assistance: If you are unable to disconnect the device promptly, or if there is any risk in doing so, seek assistance immediately from another individual or contact emergency services for help.

7.4 CHARGING THE BATTERY

1. Before each use, inspect the power cord for damage. If a component is damaged, do not use it. Contact Vitacon Customer Care or your local representative.
2. Make sure the power cable is securely connected to the console.
3. Plug the cable into a standard wall outlet. Make sure the power cord can be easily disconnected if necessary.
4. The battery indicator LED on the console should light up to indicate that the battery is charging.
5. Allow the battery to charge completely. The first charge should take about 4 hours.

7.5 CONNECTING THE PROBE TO THE CONSOLE

Before you connect or disconnect the probe from the console, ensure the console is turned off. The transducer ports are at the side of the system.

1. Once the probe is attached to the console, it can remain attached between evaluations.
2. Locate the USB-C port on the side of the console.
3. Align the USB probe cable connector with the USB port on the console.
4. Gently push the USB connector into the USB port, until the connector clicks into place and is secure.

7.6 DEVICE POWER ON/OFF

Ensure that the probe is attached to the console.

1. Press the power switch on the front panel to turn on the system.
2. When the system is turned on, the backlight on front panel will on, and the screen will show logo of splash screen.
3. The system will complete the initialization in about 1 minute and go to the **HOME** screen.

7.7 CONFIGURE GENERAL SETTINGS

1. Vitacon recommends keeping the factory default setting. Changing these settings should be performed by operators with good product knowledge.

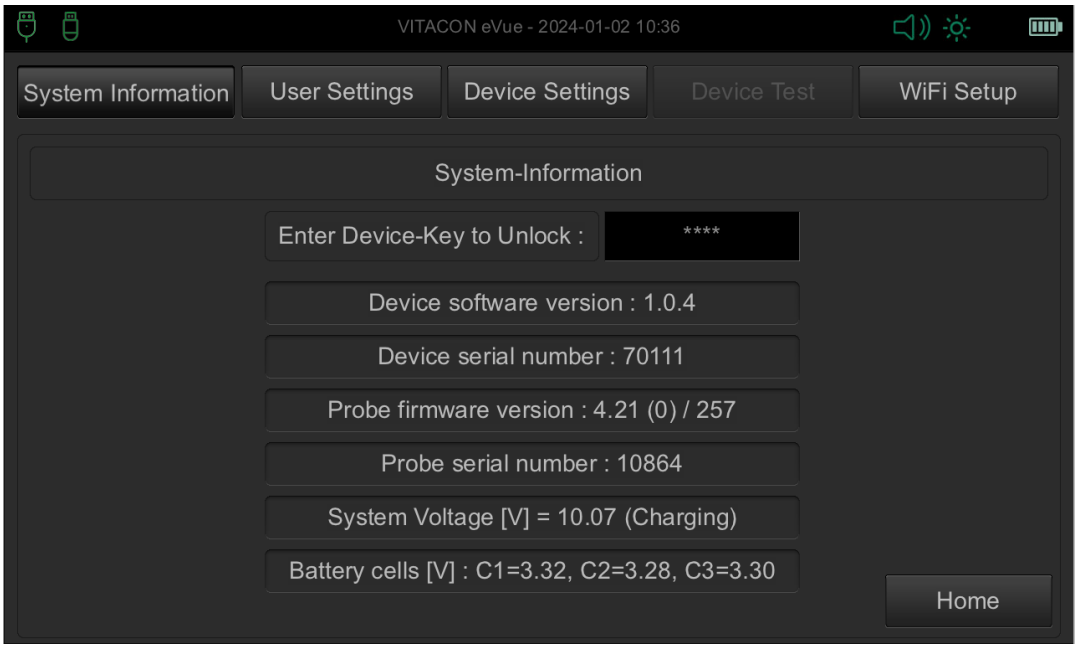


Figure 8 System Information

2. **System Information:** The screen provides an overview of the battery cells' status and system voltage, device software versions, probe firmware version, as well as the device and probe serial numbers. To change the device and probe serial numbers, refer to points 5 and 6 below. To edit the settings, the device key (12345678) must be entered.

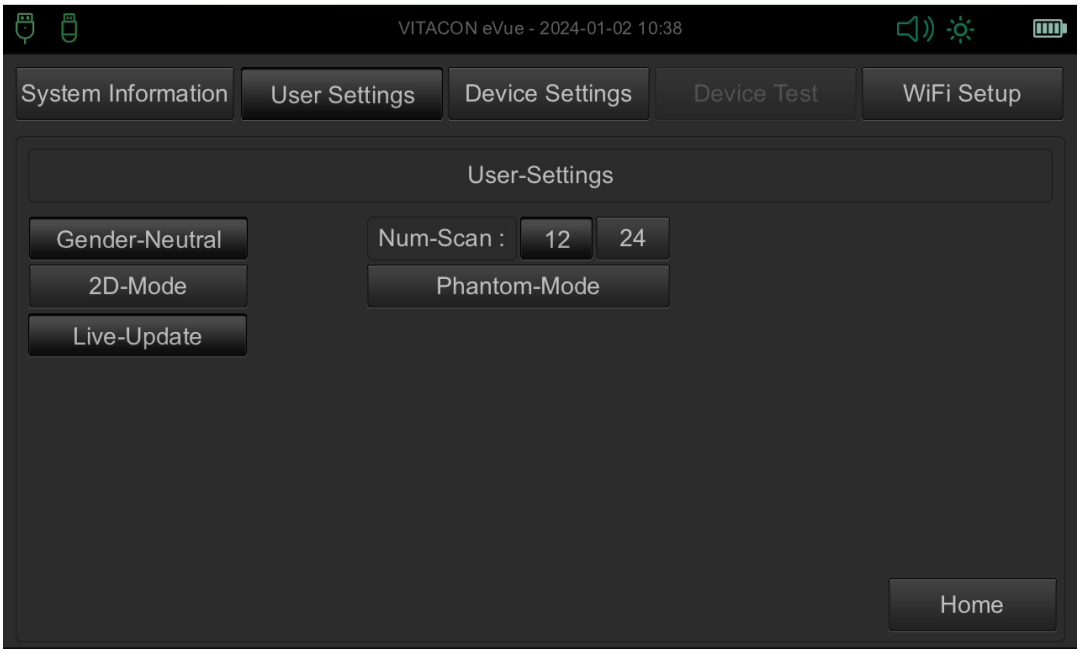


Figure 9 User Settings

3. **User Settings:**
    - Toggle Gender-Neutral option (Default: ON).
    - 2D-Mode (Default: OFF).

- Live-Update (Default: ON).
- Set the number of Scanning sectors (Default: 12).
- Enable phantom mode (Default: OFF)

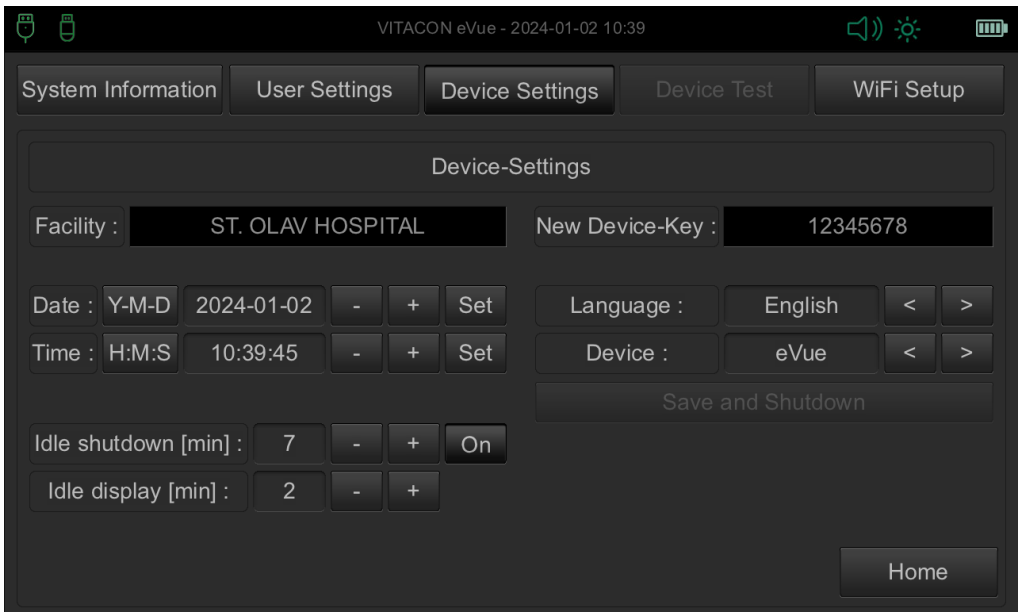


Figure 10 Device Settings

4. **Device Settings:**
   - Facility: Input field.
   - Device Key: Input field for changing the Device Key (Master Key: 24121945).
   - Date and Time setting.
   - Language setting (Default: English).
   - Device: Set device version (Default: cVue or eVue).
   - Battery Management: Set Idle Shutdown (Default: 7 minutes) and Idle Display (Default: 2 minutes).

5. **Device serial number:** Write *DEVICE~XXXX* in the Facility input field where XXXX is the new Device serial number.

   Example: 

6. **Probe serial number**: Write *PROBE~XXXX* in the Facility input field where XXXX is the new Probe serial number.

   Example: 

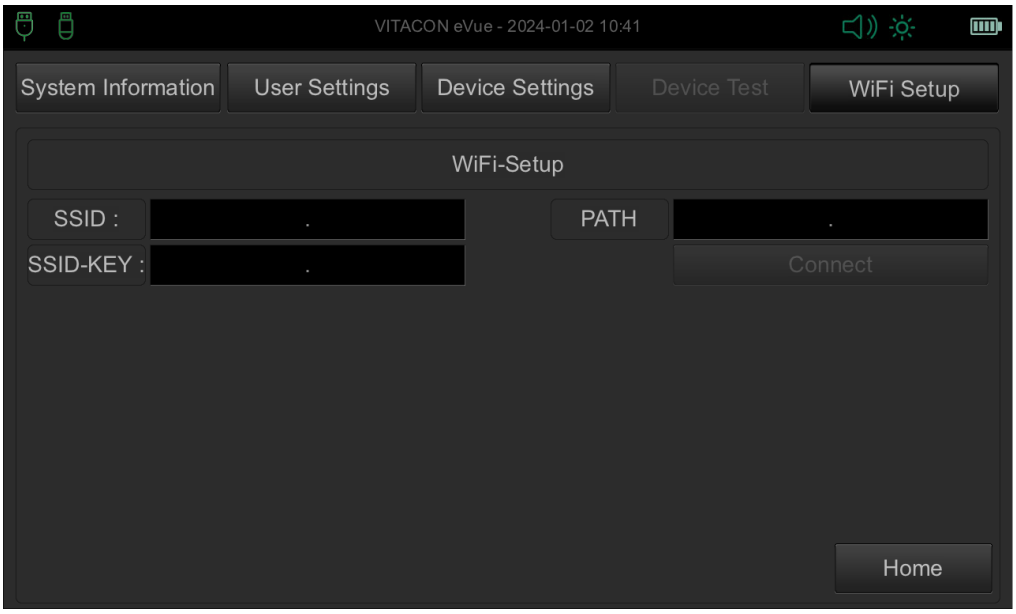


Figure 11 WiFi Setup

7. **Wi-Fi setup:** Set the SSID (Service Set Identifier): This is the unique name you assign to your Wi-Fi network. Set the SSID KEY (Wi-Fi Password): This is the security key for your Wi-Fi network. Specify the PATH for Data Storage: Choose a designated folder within your network where all results or files will be stored.

7.8 CONFIGURE EXAM SETTINGS

You may configure the following exam settings:

1. On the **Setup** screen select the required settings for a new value or mode

- Enable **Phantom mode** when scanning with a Vitacon Phantom
- Enable **2D-Mode**
- Enable **Live-Update**

8 MEASURING BLADDER VOLUME

8.1 PREPARE FOR THE EXAM

Make sure the Vitascan v.2 probe is inserted to the console USB port.

Ensure you are familiar with the device touchscreens and console displays.

1. Press the ON/OFF button to start the application.
2. Allow the device to start. When the device is fully started, the **Home Screen** appears as shown in the following figure.

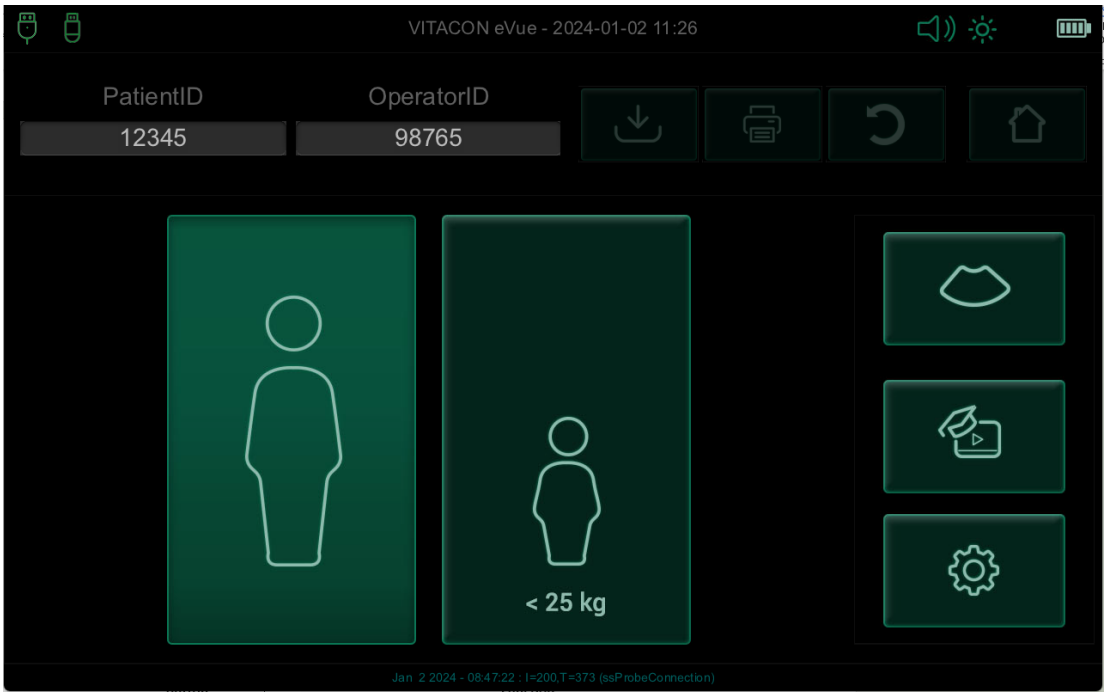


Figure 12 Home Screen

3. Select patient type; Adult or Child then the Scan button will be active.

NOTE:	If the battery status indicator is yellow, it's recommended to connect the power cord to the battery before proceeding.

8.2 MEASURE BLADDER VOLUME

1. Palpate the patient's symphysis pubis and place the **Scan head** midline on the patient's abdomen, approximately 4 cm (1.5 inches) superior to the symphysis pubis, as shown in images below.
2. Apply an ample quantity of ultrasound gel, with as few air bubbles as possible, midline on the patient's abdomen, approximately 3 cm (1 inch) above the pubic bone as shown in images below. Or apply the Gel around the dome of the Scan head. Smooth the gel out and remove any air bubbles, which may block ultrasound transmission.

Figure 13

3. Aim the **Scan head** so the ultrasound is projected toward the expected location of the bladder. For most patients, this means aiming the tip of the **Scan head** toward the patient's coccyx.

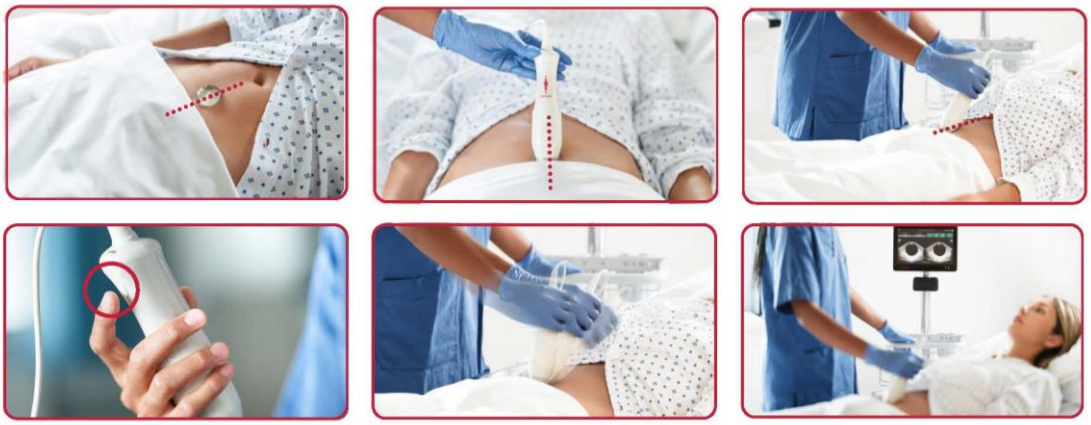


Figure 14 Aiming the tip of the Scan head.

4. Press and release the **Scan** button, located on the **Scan head**. A real-time B-mode ultrasound image appears on the console screen.

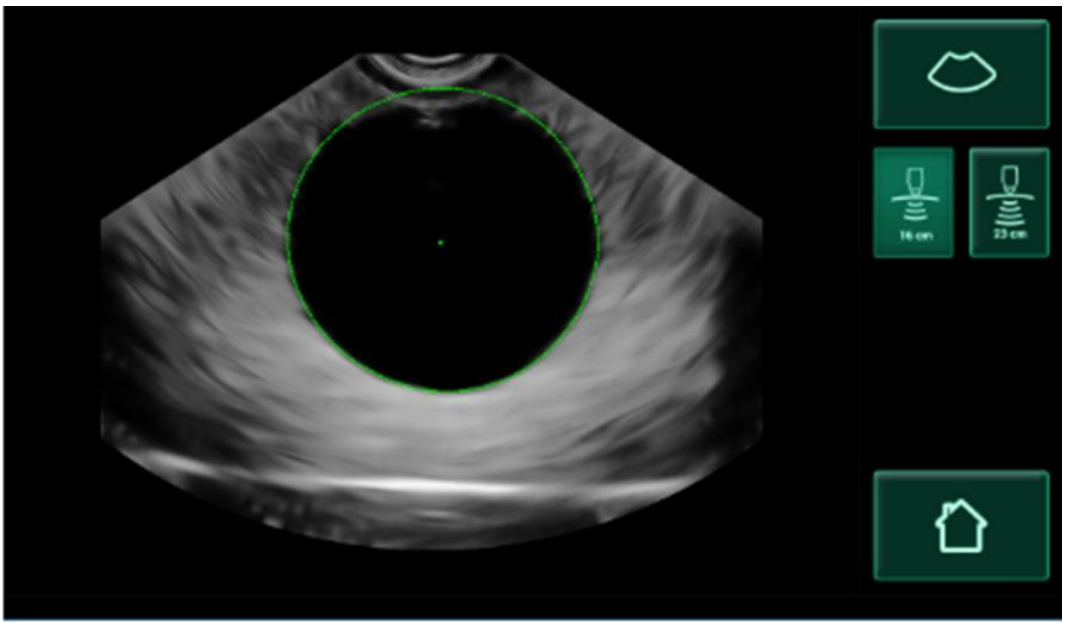


Figure 15 B-mode ultrasound image

5. Target the bladder by doing the following:
   - Angle the probe slowly from the patient's left to right until the dark (bladder) area is cantered on the vertical green line on the aiming screen.
   - Once the bladder is cantered, angle the probe slightly up or down the patient's midline to obtain the largest possible dark area.
6. Once you are finished aiming the probe, press the probe button or tap **Scan** on the screen. The scanning process begins. Hold the **Scan head** steady throughout the scan.

NOTE:	While scanning, avoid making any changes in the position, angle, or pressure of the **Scan head.**

8.3 REVIEW EXAM RESULTS

This section describes the procedures that can occur after the scan.

8.3.1 CONFIRM OR ADJUST AIM

The aiming technique can impact the accuracy of bladder measurement results. If the bladder is partially outside the ultrasound field of view, or if it is obstructed by the pubic bone at certain scanning angles, the actual bladder volume might be greater than the displayed result. To ensure the highest degree of accuracy, the device includes several features designed to assist with the aiming technique and provide confirmation.

1. Upon the appearance of the Results screen, check if the bladder image is encircled by a yellow outline. If this is the case, it indicates that a portion of the bladder was outside the ultrasound field of view, and therefore, the actual bladder volume may be greater than the result shown. In this situation, you should re-aim and rescan the patient. For guidance on how to improve scan results, refer to the table below.

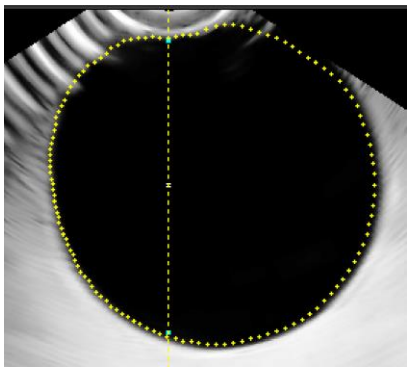


Figure 16 Bladder image is surrounded by a yellow circle.

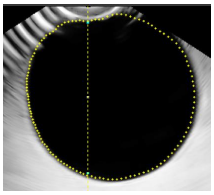
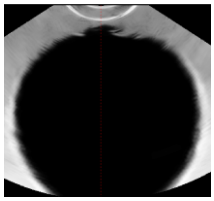
Result	Aiming Guidance	Example
Not centred	If the bladder is not centred in the field of view, you may move or angle the probe towards the direction of the bladder as displayed, to optimize your results.	
Bladder larger than view	If more than one side of the bladder falls outside the field of view, it indicates that multiple portions of the bladder were not included in the scan. In such cases, you can try to capture the entire bladder by rescanning and applying less pressure to the abdomen. However, be aware that if the bladder is larger than the field of view, it may not be possible to capture the entire bladder within a single view.	

Table 20 Aiming Guidance

2. If you want to rescan the patient, on the **Results** screen, tap **Rescan button**.
3. Repeat the scanning procedure as necessary to adjust your aim or confirm the initial measurement.
4. The results will appear as shown below. The left picture shows the horizontal scan, and the right picture shows the vertical scan.

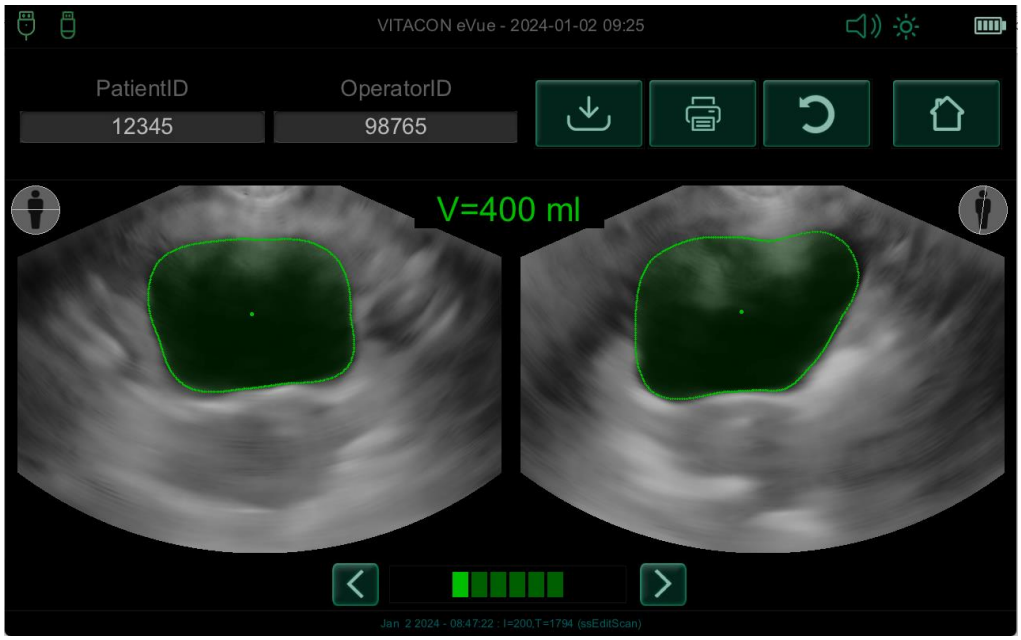


Figure 17 Measurement result

5. After completing the scanning process, you can review the results in B mode. Additionally, you have the options to save and print the scan results.

8.3.2 MANUAL CORRECTION

1. **Manual Correction** Manual enables you to identify the bladder wall. If the automatic detection fails to accurately capture the bladder wall, use your finger to adjust the green line on the screen. The volume measurement will automatically update to reflect these adjustments. The operator has the option to modify one or all images, using arrows to review and correct the detection of the bladder walls.

8.3.3 SAVE MODE

1. Save button will be enabled if a USB memory stick is interested to the device, or if Wi-Fi connectivity is setup correctly. Press the Save button to save the results.

Figure 18 save button.

8.3.4 PRINT MODE

1. The results can also be printed by pressing the 'Print' button.

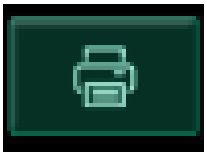


Figure 19 Print button

8.4 SCANNING ON VITACON PHANTOM

- Before performing a scan with a Vitacon Phantom, ensure to enable the 'Phantom-Mode' setting in the Setup menu. Note that the 'Phantom' option is disabled by default, which means it will be turned off each time you access the Setup menu or initiate the Vitascan cVue/eVue application.

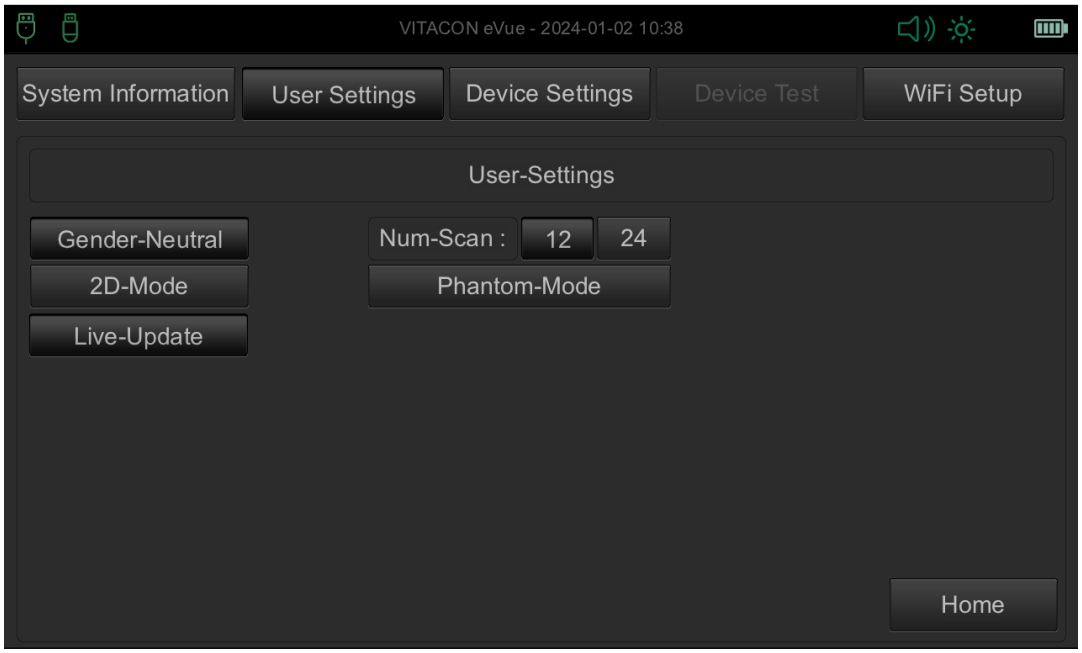


Figure 20 User Settings menu

9 HELP AND TROUBLESHOOTING

9.1 ONBOARD TUTORIAL HELP

The Vitascan cVue/eVue device includes the **Onboard Tutorial** with instructions on how to scan and manage exams. It is recommended that you watch the tutorial prior to using the device. The tutorial does not include an audio track.

1. Press the **ON/OFF** button to start the application.
2. Allow the device to start. When the device is fully started, the **Home Screen** appears.
3. On the **Home Screen** tap the **Tutorial button**. The **Onboard Tutorial** screen opens, and tutorial starts to play.

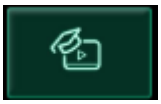


Figure 21 Tutorial Button

9.2 DEVICE REPAIR

The device components are not user serviceable. Vitacon does not make available any circuit diagrams, component parts lists, descriptions, or other information that would be required for repairing the device and related accessories. All service must be performed by a qualified technician. If you have any questions, contact Vitacon Customer Service or your local representative.

9.3 TROUBLESHOOTING

9.3.1 CONSOLE POWER ISSUES

1. If the device does not turn on, the battery may be dead or discharged.
2. If the battery charge is too low for the device to function, recharge the battery.
3. If the device has stopped responding even with a charged battery, contact the Vitacon Customer Service or your local representative.

9.3.2 PROBE CONNECTION ISSUES

1. If the console shows red probe icon **No Probe** indicating that the probe is not attached, use this procedure to troubleshoot the issue.
2. Disconnect the probe and connect again.
3. If the message still appears, contact Vitacon Customer Service or your local representative.

9.3.3 PRINTER PAPER JAM

In the event of a printer jam, follow this procedure to clear the paper jam.

1. Slide the printer door upward to open.
2. Pull the paper gently to clear the paper jam. If necessary, pull any ripped or folded paper out of the printer and remove any bits of paper that have become separated from the roll.
3. Load the thermal paper and close the printer door.
4. If the paper on the outside of the printer is ripped or torn, tear it off, pulling to one side to aid in cutting.
5. If you cannot clear the paper jam or the printer continues to jam, please contact Vitacon Customer Service or your local representative.

10 MAINTENANCE AND SAFETY

10.1 REGULAR INSPECTIONS

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

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

10.2 WEEKLY INSPECTIONS

Once a week, you should inspect the Scan head 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 device. Any apparent faults or cracks must be referred to your authorized VitaScan Service Centre or your local VitaScan distributor.

Once a week, you should inspect the following device components for damage or cracks:

- Console
- Probe
- Probe cable
- Power cord
- Plugs

Cracks that allow the ingress of fluid into the console or probe may affect the performance of the device.

Other than the maintenance included in this manual, all service and repairs must be completed by an authorized Vitacon service representative or Vitacon Service Centre. For more information, contact Vitacon Customer Care or your local representative.

10.3 LOAD THERMAL PAPER INTO THE PRINTER

1. Slide the printer door upward to open.
2. If this is the first time you are loading the printer, there may be a sheet of paper in the printer mechanism. Remove the paper sheet.
3. Place a roll of thermal paper inside the door so that the loose end of the paper exits on the top of the roll, on the side closest to the console.
4. Hold the paper end so that it will protrude from the top of the printer, and then close the printer door. Ensure that the door clicks into place.
5. Tear off any excess paper protruding from the printer. For best results, pull the paper diagonally, starting the cut on one side of the paper, and finishing on the other.

10.4 MONTHLY ACCURACY CHECK

CAUTION:	In the event of changes in the performance of the device, discontinue use and contact your authorized Vitascan Service Centre or your local Vitascan distributor.

Each month, or whenever accuracy assessment is desired or in question, the accuracy of the Vitascan cVue/eVue should be tested using the following procedure:

- Perform a Vitascan Verification Test using the Vitascan Verification Test Software or conduct a VitaScan Calibration using the Vitascan Calibration Software.
- Take a measurement on a Vitacon Phantom.
- For volumes greater than 100 mL, the measurement error should be within ±7.5% of the reading. For volumes less than or equal to 100 mL, the measurement error should be within ±7.5 mL.

10.5 12-MONTH REGULAR INSPECTION AND MAINTENANCE

Vitacon recommends that the Vitascan cVue/eVue to be certified by an authorized Vitascan cVue/eVue service centre once a year. Certification includes comprehensive inspection and testing of the devices to ensure accurate performance in clinical use.

Customers can maintain device certification via Internet by accessing the VitaScan online integrity and filed calibration services. For more information contact your local dealer.

10.6 CARE, CLEANING AND DISINFECTING

Clean the Vitascan cVue/eVue 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 cVue/eVue 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 device thoroughly. To remove all traces of disinfection solution, wipe the Vitascan cVue/eVue with a clean, soft cloth dampened in sterile water or cleaning solution. Carefully dry the Vitascan cVue/eVue with a clean, soft cloth before use. Use appropriate hand protection according to the labelling on the disinfectant to avoid skin reactions.

WORNING:	Do not subject any part of the Vitascan cVue/eVue to steam sterilization or ethylene oxide sterilization. Do not immerse the device in any cleaning or disinfecting solution

10.7 PRECAUTION PROCEDURE FOR CHANGING LIFEPO4 BATTERIES

Warning: Always ensure that you understand and follow the specific instructions regarding battery replacement.

Preparation:

1. Turn Off the Equipment: Ensure that the device is powered off before attempting to replace the battery. Disconnect the device from any external power source.
2. Gather Necessary Tools: Ensure you have a Torx T10 screwdriver for replacement of the battery. Only use LiFePO4 batteries that are compatible with your device.
3. Wear Protective Gear: Consider wearing protective gloves and eyewear to protect against accidental spills, leaks, or other hazards.

Battery Replacement Procedure:

1. Access the Battery Compartment: Carefully locate and unscrew all the screws securing the back panel of the device. Use the Torx T10 screwdriver to avoid damaging the screws or the device casing.

2. Remove the Back Panel: Once all screws are removed, gently lift off the back panel to expose the internal components. Take care not to apply excessive force that could damage the device or its internal parts.
3. Unlock the Battery Compartment: Identify the battery compartment's locking mechanism. Carefully unscrew the screw to open it, then gently release or unlock this mechanism to access the battery.
4. Disconnect the Battery Connector: Locate the battery connector linking the battery to the device's electrical system. Gently grasp the connector (not the wires) and disconnect it by pulling it away from the battery. Ensure this step is performed gently to avoid damaging the connector or the battery terminal.
5. Remove the Old Battery: Carefully disconnect and remove the old battery. Avoid touching battery contacts with metal tools to prevent short circuits.
6. Inspect and Clean: Before installing the new battery, inspect the battery compartment for any signs of damage or corrosion. Clean the compartment if necessary, ensuring it's dry before proceeding.
7. Install the New Battery: Place the new LiFePO4 battery in the compartment, ensuring it is correctly oriented and securely connected according to the device's specifications.
8. Close the Compartment: Reassemble the battery compartment, ensuring all screws are tightened and seals are properly closed to maintain the device's safety and integrity.
9. Dispose of the Old Battery: Follow local regulations and guidelines for the disposal of LiFePO4 batteries. Do not dispose of them in regular trash. Recycling centers or special disposal services for batteries are recommended.

Post-Replacement:

1. Test the Equipment: After replacing the battery, turn on the device to ensure it's operating correctly. Charge the battery by connecting the device to the mains.
2. Document the Replacement: Record the date of the battery replacement and any observations during the process. Keep this information for future reference and maintenance scheduling.

10.8 BEST PRACTICES & INSTRUCTIONS

Cleaning is the removal of all visible soil or contaminants, and disinfection is the process of destroying pathogenic organisms or rendering them inert. When cleaning, ensure all foreign matter is removed. This allows the active ingredients of the disinfectant to reach all the surfaces of the device.

Please adhere to the following best practices:

- Do not let gel or other contaminants dry on the device. This makes removal more difficult.
- Change gloves if they become visibly soiled.
- Always wipe in the direction from a clean surface towards a dirty surface.
- Minimize overlap on the wiping pattern.
- If a towelette becomes dry or soiled, replace it with a fresh one.
- Do not reuse dry or soiled towelettes.

10.8.1 CLEAN THE CONSOLE, PROBE & CABLE

- If the device is on, switch it off.
- Wipe any ultrasound gel completely from the probe.
- Using a wet cloth or a towelette indicated for cleaning medical devices and following the manufacturer's instructions, wipe the console, probe, and probe cable. Repeat as needed to ensure all visible contamination is removed.
- If the console is visibly wet, you may use a clean, soft cloth or paper towel to remove any residual cleaning solution.

10.8.2 DISINFECT THE PROBE

- Using a germicidal towelette that contains an active ingredient class, wipe the probe dome according to the instructions provided by the manufacturer. Re-wipe the area as necessary to ensure that it remains wet for the entire exposure period.
- Allow the probe to air dry. Once cleaning and disinfection are complete, the device is ready for use.

10.9 CUSTOMER SERVICES RESOURCES

Vitacon provides several customer service resources, as described in Table blow.

Resource	Description
Onboard help tutorial	A training module installed on your Vitascan cVue/eVue is available by pressing Tutorial button on the HOME screen.
Online support	Refer to the list of Vitacon Customer Care resources available at www.vitacon.com website.

11 WARRANTY AND DISCLAIMER INFORMATION

11.1 WARRANTY

Vitacon warrants the Vitascan cVue/eVue against defects in material and workmanship of two (2) years from the date of purchase from Vitacon. This warranty is given only to the original purchaser of the Vitascan cVue/eVue.

Pursuant to this warranty, a service centre authorized by Vitacon will repair or replace products which prove to be defective during the warranty period.

This warranty does not cover equipment sold as used.

This warranty does not apply if the product has been damaged by misuse or as the result or service or modification by anyone other than a service centre authorized by Vitacon. The device shall be used in accordance with the instructions contained in this manual.

Consumable items shall be used in conformance with Vitascan product specifications. Consumable items are not covered under this warranty.

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

Warranty extensions are available. For more information, please talk to your local Vitacon representative, or contact Vitacon using the contact information given in the manual.

11.2 DISCLAIMER OF ADDITIONAL WARRANTIES

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

Some states disallow certain limitations on applied warranties. The purchaser, user and patient should consult state law if there is a question regarding this disclaimer.

The information, descriptions, recommendations, and safety notations in this manual are based upon Vitacon experience and judgment. The contents of this manual should not be considered all-inclusive or covering all contingencies.

The physician(s) at your institution directing the use of the Vitascan cVue/eVue is responsible for keeping current with developments in the literature on bladder volume determination. Please direct any questions or problems concerning bladder volume measurement, the use of the device, or interpretation of data, to the responsible physician(s)

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.