



English

vTitan Corporation Private Limited

***Accuflow* VE Syringe Pump**

User Manual



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Declaration of Language Translation:

AccufLOW VE Syringe Pump comes to you as a package, complete with labels, user manual and related documents, all of which are in English. The product targets the customers who are proficient in the language and can read the instructions and understand the product better. This user manual will be supplied in the local language on request.

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Device Information

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Software Version

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Emergency Controller (EC) Pump Software Version: **2.0.1**

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1. Pump Description

1.1 Intended Use

Accuflo VE Syringe Pump is intended for use in adult and pediatric patients for the intermittent or continuous intravenous infusion of parenteral fluids and medications. It shall be used by the healthcare professionals.

1.2 Target Patient Population

The syringe pump is intended for use in adults and pediatric patients, excluding neonates, for intravenous administration of medication.

1.3 Intended User and User Qualification

The pump is intended for use by trained healthcare professionals only.

The trained healthcare professionals are doctor, physician, registered nurse, and staff nurse. A trained technician must perform the complete set-up of the pump before use in a clinical setting.

1.4 Intended Use Environment

This product is intended to be operated by trained healthcare professionals in healthcare facilities, outpatient and medical transport environments.

1.5 Indications For Use

The pump is indicated for the following uses:

- In the administration of fluids requiring precisely controlled infusion rates including lipids, drugs, antibiotics and other therapeutic fluids
 - By the following delivery route: intravenous
 - By the following delivery modes: rate mode, dosage rate mode, volume / duration mode and multi-step mode
- In critical care, anesthesia and pediatric applications or other healthcare facilities, outpatient and medical transport environments where the use of the syringe infusion pump can be monitored or supervised by a clinician.

This includes but is not limited to: outpatient departments, emergency.

1.6 Contraindications

The pump is contraindicated for:

- Neonates
- Enteral feeding
- ECMO use: Do not use on the inlet side of Extracorporeal Membrane Oxygenation (ECMO) systems where the negative pressure is greater than negative 100 mmHg as the high negative pressures can result in uncontrolled fluid flow.

1.7 Clinical Benefits

The syringe infusion pump does not provide a direct therapeutic effect. Its clinical benefit is indirect and arises from enabling the safe, accurate, and controlled administration of prescribed medicinal products and fluids in accordance with the intended therapy.

- **Accurate and Controlled Drug Delivery:** The use of the device enables accurate and controlled delivery of prescribed medications and fluids at defined infusion rates, thereby reducing the risk of dosing errors (e.g., over-infusion or under-infusion), which may otherwise lead to adverse clinical outcomes or reduced therapeutic effectiveness.
- **Continuity of Therapy:** By enabling continuous, bolus, and keep vein open infusion modes, the device facilitates uninterrupted delivery of therapy, thereby reducing the risk of treatment interruption or delay that could negatively impact the patient's clinical condition.
- **Detection of Hazardous Situations:** The incorporation of alarm systems for conditions such as occlusion, infusion completion, and system errors enables timely detection of clinically relevant hazardous situations, supporting prompt clinical intervention and thereby reducing the risk of under-delivery, over-delivery, or delayed therapy and associated patient harm.

1.8 Side Effects

- **Local Irritation:** If problems arise with the infusion site, the patient may have localised discomfort, or there may be reduced absorption of the medicine and a loss of symptom control.
- **Infection:** Local reactions such as pain, inflammation or infection can cause discomfort and interfere with the delivery and absorption of the medicines.
- **Tissue Damage:** Local inflammation and irritation when the same infusion site is repeatedly being used might result in tissue injury.

1.9 Important Points in an Emergency

If the patient complains of any discomfort while infusion is in progress, then stop the infusion immediately. Resume the infusion once the patient feels better. If the issue persists, disconnect the pump and inform the manufacturer.

2. Labels and Symbols

2.1 Description of the User Manual

Read this entire manual before using the Accuflow VE Syringe Pump. Failure to follow the instructions and important information contained in this manual, or improper / inadequate troubleshooting can lead to death or serious injury. Warnings, cautions and other safety information can be found in the below section, and throughout the manual. If you have additional questions about information in the user manual, you may contact the local distributor or vTitan directly. Keep this manual where it can be reached easily.



Caution!

Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor injury, product malfunction or damage to the product.



Warning!

Indicates a potential hazard or unsafe practice that, if not avoided, could result in death, serious injury or damage to the product.

2.2 User Responsibility

This user manual is intended to provide important information for the proper operation, maintenance, cleaning and disinfection of the pump. Failure to follow these instructions may result in:

- Decreased efficiency of operation
- Detrimental effects on the health of the patient, the user or other persons

Note:

- The user is responsible for checking the pump for broken / worn cables and to inform the manufacturer for service / repair / replacement.
- Before and after use of every patient, the pump should be cleaned as per the cleaning procedure specified in this manual.
- The pump must be checked periodically up to the expected service life of 7 years.
- A defective pump should not be used.
- Parts that are broken, missing, plainly worn, distorted or contaminated (used syringes, IV sets) should be replaced immediately.
- Neither this pump nor any of its parts should be repaired in any manner other than in accordance with written instructions provided by vTitan.
- The pump must not be altered without the prior written approval of the vTitan Quality Assurance Department.
- The pump shall be connected to an uninterrupted power source.
- Use only power source indicated on the label and **Section-18** of this manual.
- The pump parameters should be modified only by authorized persons. Avoid unauthorized persons to access the pump to avoid loss of parameter setting.
- Batteries should be replaced by vTitan authorized service personnel only. Replacement of batteries by inadequately trained personnel could result in potential hazards.

2.3 Safe Handling

2.3.1 General

- Make sure that the introductory training on the pump is given by a vTitan sales representative or by a vTitan authorized person.
- If the pump is dropped or subjected to external forces, stop using the pump and have it tested by a vTitan service personnel.
- Avoid external loads on the plunger head sensor. Protect the pump against moisture.
- Dispose the used batteries, used syringes, IV sets, or a pump that has reached the end of its useful life, in an environmentally safe manner, and in accordance with any regulations that may apply.
- Do not modify this pump without authorization of the manufacturer. If this pump is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the pump.
- Any unauthorized modification of the pump may cause a safety hazard, which might lead to patient injury or death. Use only vTitan supplied service / replacement parts. Unauthorized modification and / or the use of unauthorized service / replacement parts will void the warranty.
- This syringe pump is not intended for the administration of blood or blood products. Use of this device to deliver blood or blood components may result in damage to red blood cells.

2.3.2 Transport and storage

- Do not hold the pump by the drive head during transport.
- Pumps stored at temperatures below the defined storage conditions range must be kept at room temperature for at least one hour before being powered on.
- Do not store the pump with the drive head extended.

2.3.3 Set-up and start-up

- For mobile use (patient transport within the clinic and outside the clinic) ensure secure mounting or positioning of the pump. Changes of position and strong vibrations can cause minor changes in the delivery characteristics.
- Ensure that the pump is properly positioned and secured.
- Place the pump as close to the patient's infusion site as possible.
- Before powering on, check the pump. In particular, inspect the barrel clamp and plunger jaws for dirt, damage, missing parts and ensure that they function correctly.
- Pay attention to audible and visible alarms and the lighting up of the LEDs during the self-test.
- Fully charge the battery before the first use.
- Always verify the stability of the object to which the pump is mounted (for instance, an IV pole) before using the pole clamp. If the pole clamp is not adequately tightened, it might cause damage to the pump or cause the pump to fall.

2.3.4 Control

- Stand in front of the pump to operate it. This ensures that you can reach all control elements and that the display is clearly visible.
- Only connect the patient once the syringe has been positioned correctly and the syringe plunger head is being correctly held by the jaws. Ensure adequate protection against free-flow when changing syringes in order to avoid an unwanted dose administration.
- Only use vTitan approved syringes on the pump. Use of unapproved syringes would result in erroneous infusion, occlusion detection/alarms and inappropriate bolus delivery.
- Always confirm that the syringe size and model displayed on the pump match the size and model loaded onto the pump. Use of unapproved syringes may cause improper pump operation, resulting in inaccurate fluid delivery or occlusion sensing or other potential hazards.
- Use the smallest syringe size necessary to deliver the fluid or medication. Using a large syringe at very low flow rates may cause improper pump operation, delayed occlusion sensing, larger post occlusion bolus at higher occlusion limit settings, delivery inaccuracies, or other potential hazards.
- Do not select a syringe size or model that is different from the syringe loaded on the pump. Wrong syringe selection may lead to improper pump operation, inaccurate fluid delivery, incorrect occlusion detection, under-infusion or over-infusion.
- Position the infusion line to the patient so that it does not have any kinks.
- To avoid air embolism, always purge all air from the syringe and infusion lines before connecting to the patient.
- Ensure that installation in rooms used for medical purposes is done in accordance with any regulations that may apply.
- To avoid risk of explosion, never use the pump in the presence of flammable anesthetics, oxygen enriched atmospheres, or explosive gases.
- Always check the plausibility of the values shown on the display.
- Ensure that there is additional patient supervision (e.g. monitoring) if life-sustaining drugs are administered.
- Do not apply any force to the plunger head during delivery as this could trigger an alarm.
- When administering highly effective drugs, have a second pump ready for the drug.
- Avoid mechanical effects on the pump. If the pump is moved while in operation, the set delivery rate may exceed / not be reached.
- Monitor the administration of highly effective drugs accordingly.
- When using the pump near equipment that can cause higher interference emissions (e.g. electro surgical pumps, magnetic resonance imaging units, mobile telephones) keep the pump at the recommended safe distance away from such equipment.
- The volume of the pump's acoustic alarms can be adjusted for the environmental conditions. This ensures that the alarms are clearly audible.
- Friction and compliance of the syringe plunger tip affect delivery start up and flow continuity. The bigger the syringe, the greater the friction and compliance. Use a smaller syringe when running at a lower rate.
- During lower flow rates, because of syringe stiction, there may be a deviation in accuracy or erroneous occlusion may be detected.

- Make sure that the plunger jaws securely capture the syringe plunger. If the syringe is not properly secured, it could result in uncontrolled fluid flow to the patient.
- Do not initiate or continue infusion if the IV cannula is not properly secured. An unsecured cannula may become dislodged, resulting in infiltration, extravasation, unintended bolus delivery, or interruption of therapy.
- The IV insertion site shall be visually inspected at regular intervals for signs of swelling, leakage, redness, or infiltration during infusion.
- Do not touch the plunger head during operation.
- Check the fluid pathway periodically for leaks. Leaks in the system may cause fluid loss, resulting in under-delivery and might also cause contamination.
- Turn off fluid flow to patient in tubing via clamp or stopcock before loading or unloading a syringe. Uncontrolled fluid flow can occur when infusion set is not clamped or turned off, resulting in inappropriate delivery rate.
- After the completion of infusion, always disconnect the pump from the patient to prevent unintended delivery or backflow.
- When an alarm occurs, check the pump's status and handle the alarm as soon as possible. If the alarms do not conform with the actual situation, contact your service personnel.
- Failure of the alarm system may result in the user not being alerted to critical conditions such as occlusion, empty syringe, low battery, or device malfunction. The user shall ensure continuous monitoring of the infusion and patient condition during operation.

2.4 Electrical connection

- Do not use the pump if the plug has visible damage.
- Do not use an extension cable that has not been approved for use with the pump.
- Position the power cable so that it does not present a trip hazard.
- Do not touch the patient and the conductive part simultaneously.
- Make sure that the ME (Medical Electrical) equipment is connected to an appropriate power source.
- An additional multiple socket outlet or extension cord should not be connected to the ME system.
- Connect only items that have been specified as part of the ME system or that have been specified as being compatible with the ME system.
- Service personnel should disconnect the power cord before servicing the pump.

2.5 Storage Precautions

- Handle the pump with care during storage.
- Store the pump in a cool, dry place. The storage area must be clean and organized.
- Clean and disinfect the pump prior to storage.

2.6 AC Power Supply Precautions

Check that the AC power supply voltage corresponds to the value indicated on the label at the bottom of the pump. Do not exceed the permitted voltage. The power outlet must remain accessible at all times to allow emergency power supply disconnection.



CAUTION:

- The pump should only be connected to the AC power supply with the power cord supplied by vTitan.
- Do not use an extension cord when connecting the pump to the AC power supply.
- Pump must be plugged into a medical grade power strip if one is used.

2.7 Battery Precautions

The pump uses a Lithium-ion rechargeable battery.

The following actions may cause leakage, overheating, smoke, explosion or fire; which could result in deterioration of performance, failure, damage to the equipment or injury to the user:

- Incorrect handling of a Lithium-ion battery.
- Replacement of the battery by inadequately trained personnel.

2.8 Electrostatic Discharge (ESD) Precautions

Electronic components and semiconductors can be destroyed by electrostatic discharge (ESD). In particular, components made with metal oxide semiconductor (MOS) can be damaged from direct or indirect discharges. Damage caused by ESD may not be immediately identifiable, and malfunctions can even occur after a longer period of operation.

Exceeding and / or repeating the test level attained in guidance & manufacturer's declaration on EMC may permanently damage the pump and / or cause serious malfunctions (for example, loss of communication and system failures).

The following environmental conditions related to electrostatic sensitive components (ESD standards) must be observed:

- Floors coated with wood, tiles or concrete
- Relative humidity of at least 30%

If it is not possible to guarantee this environment, the following additional precautions must be taken:

- Use of anti-static equipment
- Preliminary user discharge
- Anti-static clothing

The best precaution is preliminary user discharge on a grounded metal object such as a rail, a pole or a metal part located at the rear of the pump.

For maintenance operation performed on the pump, place the pump on a conductive working surface, and wear a special ESD conductive wristband.

2.9 Precautions for Pump Position



WARNING:

- If using multiple syringe pumps and it is not clinically feasible to have all pumps level with the distal tip of the catheter (or the site of fluid delivery), place the high risk or life-sustaining medications as close to level with the distal tip of the catheter as possible. When infusing multiple high risk or life-sustaining medications, consider placing the ones infusing at the lowest rates as close to the level with the distal tip of the catheter as possible.
- Minimize the height difference between the pump and the patient and avoid changes in the height of the pump to prevent unintended fluctuations in the flow rate.

2.10 Precautions for the use of Extension Sets

Use extension sets which have the smallest internal volume or “dead space” to minimize residual volumes between the syringe and the patient when administering medications or fluids at low infusion rates (e.g., less than 5 mL/hr, and especially flow rates less than 0.5 mL/hr). This reduces the amount of time it takes for fluid to reach the patient, maintains delivery accuracy, and reduces occlusion detection times.

For example:

- Tubing internal diameter: Small bore or microbore tubing is recommended when infusing at low rates
- Tubing length: Tubing length should be minimized, when possible
- Filters: Internal volume (dead space) of in-line filters should be minimized
- Connection sites: The number of connection sites such as stopcocks and Y-sites should be limited, and high risk or life-sustaining solutions should be connected as close to the intravenous access site as possible.



CAUTION:

- Avoid use of extension sets with ports containing high pressure valves.
- High pressure valves require additional pressure (e.g., 50-200 mmHg) to open and allow fluid flow. These high pressure valves may cause a significant delay in infusion followed by a sudden bolus once the valve is opened, particularly at low infusion rates (e.g., less than 5 mL/hr, and especially flow rates less than 0.5 mL/hr).

2.11 Labels and Symbols



Should product repair or part replacement become necessary, please call or make a written request for service to the nearest vTitan Regional Service Centre. Only vTitan trained personnel should carry out the service, maintenance or repair of this product.



This pump is not intended for use in oxygen rich, flammable anaesthesia gases and other flammable substance or gas mixtures environment. The manufacturer is not responsible for any malfunction resulting from improper use, faulty maintenance, improper repair, damage, or alteration by anyone other than vTitan

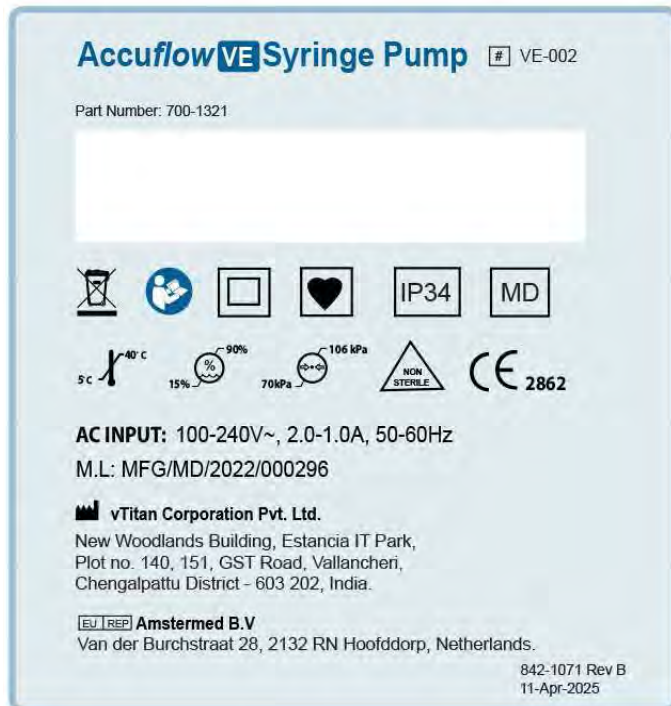


- Inspect cables thoroughly for any cracks / damages prior to usage on a patient.
- Ensure that the electrical wall socket at the pump usage site is properly grounded.
- Confirm that the AC mains socket meets the relevant local safety standard.
- Unplug the equipment from wall socket before cleaning / maintenance / service.
- The pump should not be moved while operating.
- To avoid explosion, do not use this pump in the presence of flammable gases or flames. Operation of any electrical instruments in such environments constitutes a safety hazard.
- To avoid any personal injury, do not dismantle the pump.
- To avoid injury to the operator and prevent damage to the pump, inspect the mains for any earth leakage voltage, before turning on the system.

- The pump should not be used near high frequency surgical equipment.
- Use only power cord provided with the pump. Using other power cords may increase electrical emission or decrease electrical immunity of this pump.
- Internal components of this pump are electrostatic sensitive. Please do not touch the connector pins while inserting the electrode to the connectors.
- Avoid using portable RF communication equipment near this pump. This may affect the pump performance.
- Verify that the pump usage site supply voltage corresponds to the power supply voltage range. See **"Section 18 - Technical Specifications"**. Place the pump on an even surface.
- Avoid mechanical shocks and vibration to the pump.
- No user serviceable parts inside. Do not attempt to service the pump except the simple troubleshooting method mentioned in this user manual. For any other servicing please contact the authorized service center / service personnel.
- Do not allow any liquid to enter inside the pump.
- Unplug the power cord when the pump is not in use.
- Pay attention while using the pump.

Product Label

842-1071



Part Number	Labels	Description
842-1045		Refer to manual Label
842-1013		Use only approved syringes Label

Symbols on the Product and Packaging

Symbols	Description
	Manufacturer
	Refer instruction manual
	Class II device
	Type CF applied part
	Unique Device Identifier
	Medical Device
	Indicates a potential hazard or unsafe practice that, if not avoided, could result in death, serious injury or damage to the product
	Batch code
	Date of manufacture
	Model Number
	Serial Number
	Authorized Representative

Symbols	Description
	Fragile, handle with care
	Keep dry
	Keep away from sunlight
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	This way up
	Maximum 4 boxes
	Do not use if package is damaged and consult instructions for use
	Non Sterile
	Ingress protection against solid objects over 2.5mm, e.g. tools & wires, ingress protection against water splashed from all directions, limited ingress permitted.
	Do not dispose with household waste
	Caution
	Alternating current
	Non-ionizing electromagnetic radiation
	Rechargeable battery
	Device complies with 2017/745 (MDR)

3. Preparing the Syringe Pump for Use

3.1 Unpacking the Pump

For contents, refer the packaging box.

Despite the careful packaging, the potential risk of damage during transport exists. Upon delivery, please ensure that all items are present and are intact.

Do not open if the pack is damaged and upon opening if you find any damage on the pump, do not use it. Please contact the service department at vTitan Corporation Pvt. Ltd at the earliest.

Unpack the pump and store all the packing materials in a safe manner. They are specially designed to protect the pump and will help in repacking if you ever need to ship your pump. All the accessory details are marked in the individual package.



Image 1 - Accuflow VE Syringe Pump - Packaging Box



Image 2 - Accuflow VE Syringe Pump - Box Contents



Do not unpack the pump if the package is damaged or in wet condition.

3.2 Before First Use

Charge the pump fully before using it for the first time. You can check the charge status using the battery indicator. The pump is pre-configured and can be used immediately.



Allow the pump to reach the ambient temperature for operation (approx. 20 °C) for about an hour, if it has previously been transported or stored under very hot or cold conditions.

4. Operation

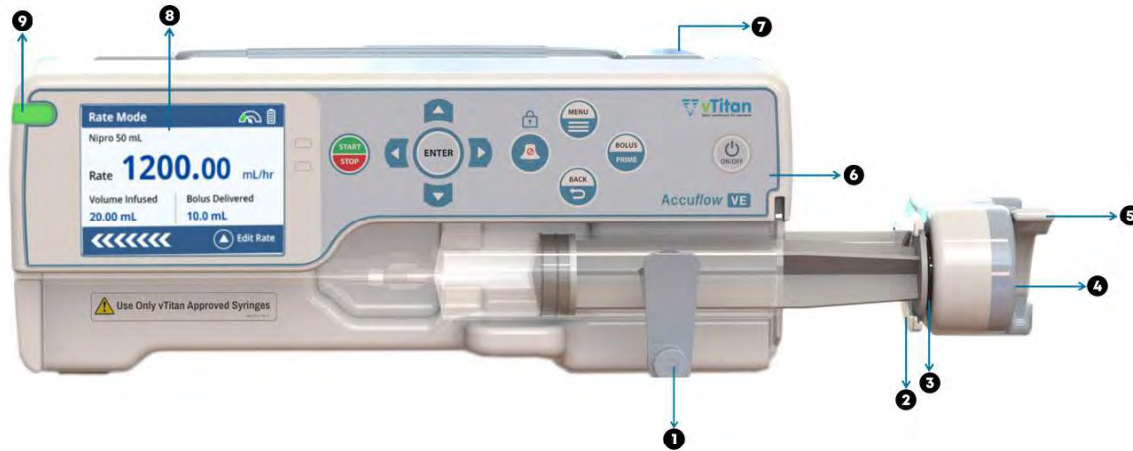


Image 3 - Accuflow VE Syringe Pump Front View

S.No	Name	Description
01	Barrel clamp	Holds the syringe barrel securely in place
02	Plunger jaws	Holds the syringe plunger securely in place
03	Syringe contact switch	Checks if the syringe is in contact with the syringe plunger
04	Plunger head	Holds the syringe plunger to deliver fluid at the programmed rate.
05	Plunger lever / Clutch	Pushes the plunger forward after loading the syringe and starting the delivery
06	Overlay	Consists of keys for programming the parameters and performing the operations
07	Handle	Helps in carrying the pump
08	Display	Shows the pump operating and status information
09	LEDs	Indicate pump status, alarms and battery charging conditions



Image 4 (a) - Accuflow VE Syringe Pump Side View



Image 4 (b) - Accuflow VE Syringe Pump Side View



Image 5 - Accuflow VE Syringe Pump Rear View

S.No	Name	Description
10	Pole clamp Mount	Used to attach the pump to the pole clamp if needed
11	AC Power Connector Port	To connect the power cord to provide power supply to the pump

4.1 Key Functionality

Symbol	Functionality
	To power on and power off the pump, Switch to standby mode
	To mute the audio alarm momentarily, To activate and deactivate the keylock
	To prime before the start of infusion, To administer a bolus when the infusion is in progress
	To go to previous screen, To clear the entries
	To start and stop the infusion To pause and resume the infusion
	To access the functions listed under menu
	To scroll the menus, To set the values, Up toggle to edit the parameters, Enter key to confirm the entries
	LED lights to indicate the status of the pump • Green Corner LED while Infusing • Cyan LED for Programming and Caution Alarms • Yellow LED for Warning Alarms • Red Corner LED for Emergency Alarms

4.2 Icons on the Pump's Display

Icons	Description
	Battery Status 4 bars - 75% to 100%
	Battery Status 3 bars - 50% to 75%
	Battery Status 2 bars - 25% to 50%
	Battery Status 1 bar - < 25%
	Battery Low
	Pump connected to AC power supply
	Normal, pressure is within the set occlusion pressure level
	Increasing, pressure is increasing and nearing the set occlusion pressure level
	Occlusion, pressure reached the set occlusion pressure level
	Keypad locked

4.3 Abbreviations

Abbreviation	Description
A	ampere
AC	Alternating Current
AM	Amplitude Modulation
AP	Access Point
cc	cubic centimeters
°C	degree Celsius
EM	Electromagnetic
ESD	Electrostatic Discharge
g	gram
hr	hour
Hz	Hertz
IEC	International Electrotechnical Commission
IP	Internet Protocol / Ingress Protection
IV	Intravenous
kg	kilogram
kPa	kilopascal
kV	kilovolt
KVO	Keep Vein Open
LCD	Liquid Crystal Display

Abbreviation	Description
LED	Light Emitting Diode
m	metre
MAC	Media Access Control
mAh	milliampere-hour
mcg	microgram
ME	Medical Electrical
mEq	milliequivalents
mg	milligram
MHz	Megahertz
min	minute
mmHg	millimetre of mercury
mmol	millimole
ng	nanogram
RF	Radio Frequency
s	second
SSID	Service Set Identifier
V	volt
VTBI	Volume To Be Infused
Wi-Fi	Wireless Fidelity

4.4 Procedure to Use the Syringe Pump - Pump Programming

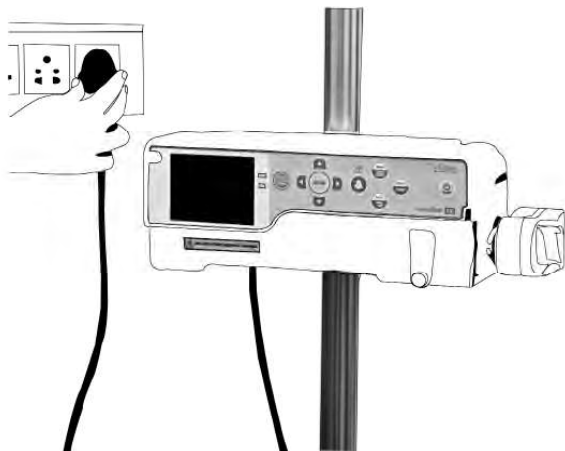
4.4.1 Power On and Self Test

Open the packaging box. It consists of Accuflow VE Syringe Pump (1 No.) and power cord (1 No.)

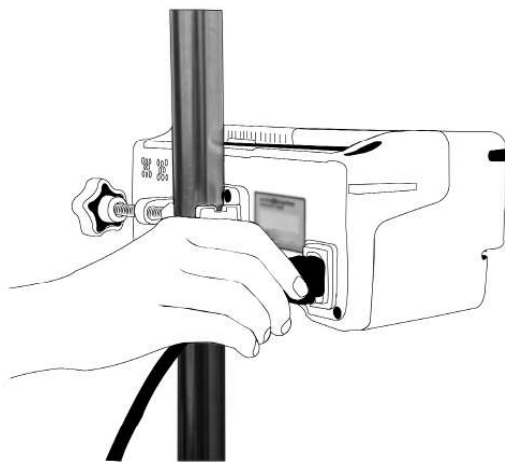
Connect the pump to the AC mains through the power cord or it can be battery - operated.

Connecting the Power Cord

Step 1: Connect the power cord to the AC mains supply.



Step 2: Connect the other end of the power cord to the connector port on the pump.



Step 3: Switch on the power supply.

Note: The pump comes with a power cord. vTitan suggests to use the same length of power cord to avoid any electrical disturbances. The user may contact the manufacturer / dealer / distributor / authorized service provider for power cord replacement.

Power on the pump using the on / off key.

The pump automatically runs a “Self Test” of all the modules. If any alarm is raised during the “Self Test”, the pump displays the alarm condition and the resolution on-screen.



4.4.2. Load Syringe

Once the “Self Test” is complete, the pump displays the syringe load procedure on-screen (when the syringe is not loaded).

1. Hold the clutch and pull the plunger head to the right.
2. Pull the barrel clamp and turn.
3. Load the syringe onto the pump and ensure that the flange of the syringe is secure in the groove provided.
4. Place the barrel clamp on the syringe.
5. Hold the clutch and move the plunger head towards the syringe end.
6. Ensure that the plunger head touches the plunger end of the syringe.
7. Release the clutch.

If the syringe is loaded properly, the pump automatically moves to the syringe selection screen.

If the barrel clamp or the plunger head is not in place, the proper placement (in animation) is displayed on-screen. If the syringe is loaded before power on, the pump displays a syringe selection screen after the "Self Test".



4.4.3. Syringe Selection

After successful syringe load, the pump auto-detects the syringe size and displays it on-screen. Select the syringe make from the options using up and down toggle and press enter to confirm. If the intended syringe make is not displayed on the list, then select "Other" option and proceed.

Always ensure that the syringe size displayed on-screen is correct. To edit the syringe size, press back key whenever required. The syringe size is highlighted. Modify the syringe size using up and down toggle and press enter to confirm.



Note: Use only vTitan approved syringes - Nipro, Becton Dickinson (BD) Luer-Lok™ Tip Syringe and HMD Dispo Van. If the loaded syringe make is not displayed on the list, "Other" option can be selected. Please note that use of unapproved syringes may cause improper pump operation resulting in inaccurate fluid delivery or other potential hazards.

4.4.4. Enter Rate

The pump displays the syringe make and size on-screen and the infusion rate is highlighted. Edit the infusion rate if needed and start the infusion using the start key.



4.4.5. Priming

If priming the IV line is required, use the prime feature after syringe selection.

Press the prime key and the pump displays the prime screen. Ensure that the IV line is not connected to the patient during the priming procedure.

Press and hold the prime key to remove the air bubbles. The pump displays the priming volume on-screen.



Note: Press enter key to acknowledge the alarm (before 5 seconds auto-disposable time) and proceed further whenever needed.

Once the air bubbles are removed, release the prime key. The pump then reverts to the previous screen from where the prime key is pressed after 3 seconds. Enter the inputs and start the infusion using the start key.

During priming, when the priming volume reaches 10% of the syringe size, the pump stops priming and displays the alarm. Press the Prime key to initiate priming again.

4.4.6. Infusing

During infusion, the pump displays the rate, volume infused and bolus delivered on-screen.



During infusion, to edit the rate, press the up toggle and the rate becomes editable. Edit the rate and start the infusion by pressing the start key. The infusion is delivered at a new rate only when the start key is pressed after editing the rate.

When editing the rate during infusion, if the rate is not within the limits, the pump displays the field alert on-screen.

4.4.7. Bolus

To deliver Bolus, press the bolus key. The pump displays the bolus screen.

Press and hold bolus key for manual bolus or press left toggle to enter the inputs for auto bolus. To edit the bolus rate, press up toggle, edit the bolus rate and confirm.



4.4.7.1 Manual Bolus

To deliver manual bolus, press and hold the bolus key. The pump displays bolus volume infused and bolus rate on-screen. Release the bolus key after the required bolus dose has been delivered. Once the Bolus is complete, the pump reverts to the infusing screen after 3 seconds.



During bolus delivery, the pump stops the bolus when the bolus volume reaches 10% of the syringe size. The pump prompts the user with an alarm and reverts to the infusing screen after 5 seconds.



To administer another bolus, press bolus key once, press and hold the bolus key to deliver the manual bolus.

Note: If the bolus rate is less than the infusion rate, the bolus is delivered at the bolus rate. To deliver bolus at a higher rate, edit the infusion rate / bolus rate and ensure that the bolus rate is higher than the infusion rate.

4.4.7.2. Auto Bolus

Press left toggle to enter the input parameters for auto bolus.

The pump displays 10% of syringe size volume in bolus volume field, default bolus rate depending upon syringe size in bolus rate field and auto-calculated bolus duration in bolus duration field.



If required, edit the bolus volume and bolus duration. The bolus rate will be auto-calculated. After the input entry, press bolus key to deliver the auto bolus. The pump displays the bolus volume infused on-screen.

The screen displays the 'Auto Bolus' mode. At the top, there is a header bar with the title 'Auto Bolus' and a pump icon. Below the header, the 'Bolus VI' is set to '1.5 mL'. Underneath, a table shows 'Bolus Vol' as '5.0 mL', 'Bolus TR' as '14 secs', and 'Bolus Rate' as '900 mL/hr'. At the bottom, there are five left-pointing chevrons indicating navigation options.

During bolus delivery, if the user wants to stop the bolus, they shall press the stop key. Once the bolus is completed / stopped, the pump shall revert to the infusing screen after 3 seconds.

The screen displays the 'Auto Bolus Stopped' mode. It has the same layout as the 'Auto Bolus' screen, with a header bar, 'Bolus VI' of '1.5 mL', and a table showing 'Bolus Vol' (5.0 mL), 'Bolus TR' (14 secs), and 'Bolus Rate' (900 mL/hr). The bottom navigation bar with five chevrons is also present.

4.4.8. Menu

To access the functions, use the Menu key. Press the up and down toggle to select the functions.

The screen displays the 'Menu' mode. It features a list of settings: 'Bed ID' (SICU-003), 'Total Volume Infused', 'Rate Mode' (which has a green checkmark), 'Volume / Duration Mode', and 'Dosage Rate Mode'. At the bottom, there is a blue bar with an 'ENTER' button and the word 'Select'.

Bed ID

On selecting the bed ID from menu, the pump will display the care area list. Select the care area from the list using up and down toggle, press enter key to select the care area, then the pump will display the bed number list. Select the bed number from the list using up and down toggle and confirm the bed number by pressing enter key.

Note: By default, "None" only will be displayed in care area list. Add / edit / delete the care area and bed number in the app. The updated care area list and bed numbers will be sent to the pump via the application.

A maximum of 20 care area names and 100 bed numbers will be stored.

During first power on, bed ID will not be displayed in any screen.

If the care area and bed number is selected from the menu, then the pump will display the bed ID on rate mode programming screen, infusing screen, infusion paused screen, infusion completed screen, infusion stopped screen, KVO On screen and KVO stopped screen.

If the user selects 'None', bed ID will not be displayed in any screen.

4.4.9. Total Volume Infused

It is the total volume infused into the patient. It gets accumulated over multiple drug programs and infusion modes. The value gets cleared only when the user clears the total volume infused from the menu (or) when the pump is powered off. The pump displays the total volume infused on-screen. Press the enter key to clear the total volume infused.



Note: The total volume infused value rolls over to zero after reaching the limit (999999 mL).

Note: Clearing the total volume infused value under "Menu" is allowed only during the programming, infused paused / stopped / completed states. During infusion, only viewing the total volume infused to the patient is allowed.

4.4.10. Volume / Duration Mode

The pump displays the syringe size on volume field, default / programmed rate on rate field and auto-calculated duration on duration field. Editing the volume and duration input is permitted and rate is auto-calculated. Start the infusion using the start key. The pump then infuses at the new auto-calculated flow rate.



The pump displays the rate, volume to be infused, volume infused and time remaining on the infusing screen.

Volume / Duration Mode

Nipro 50 mL

Rate **300.00** mL/hr

VTBI mL	VI mL	TR min : sec
50.00	0.14	9 : 57

Navigation arrows: <<<<<<

During infusion, infusion paused and infusion complete states, use the right toggle to check the bolus volume delivered. Then, press the left toggle to move to the volume infused screen. If there is no user action, the pump reverts to the volume infused display after 3 seconds.

Volume / Duration Mode

Nipro 50 mL

Rate **300.00** mL/hr

VTBI mL	Bolus mL	TR min : sec
50.00	10.00	9 : 57

Navigation arrows: <<<<<<

During input entry, if the auto-calculated rate is not within the limits, the value on rate field is displayed as zero and the field alert is displayed on-screen. Edit the volume / duration if required and ensure that the rate is within the limits.

Volume / Duration Mode

Volume 800.00 mL

Duration 100 : 09 : 10 hr : min : sec

Rate 000.00 mL/hr

Calculated rate not within limits, Edit values

Note: Volume Limit - 0.1 to 999 mL, Duration Limit - 10 seconds to 500 hours. Autocalculated rate cannot be modified.

4.4.11. Dosage Rate Mode

When dosage rate mode is selected, the pump displays the default concentration unit (mg/mL), patient info (kg) and dosage unit (mg/kg/min) on-screen. Press enter and move to the next screen.

The screenshot shows the 'Dosage Rate Mode' screen. At the top, there is a title bar with 'Dosage Rate Mode' and a list icon. Below this, there are three columns: 'Conc. Unit', 'Patient Info', and 'Dosage Unit'. The 'Conc. Unit' column displays 'mg/mL', the 'Patient Info' column displays 'kg', and the 'Dosage Unit' column displays 'mg/kg/min'. At the bottom, there are two buttons: 'Edit' (with an up arrow icon) and 'Confirm' (with an 'ENTER' icon).

4.4.11.1. Concentration and Dosage Units

Note:

Amount Limit - 0.01 to 999999 (For mg, mcg, ng, g, mEq, mmol, kcal, mU, unit)

Diluent Limit - 0.1 to 999 mL

Concentration Limit - 0.01 to 999999 (For mg, mcg, ng, g, mEq, mmol, kcal, mU, unit)

Weight Limit - 1 to 500 kg

Body Surface Area (BSA) Limit - 1 to 6.5 m²

Dosage Limit - 0.01 to 99999 (For mg, mcg, ng, g, mEq, mmol, kcal, mU, unit)

4.4.11.2. Dosage Rate Mode –Unit Edit

To edit the unit, press the up toggle.

This screenshot is identical to the one above, showing the 'Dosage Rate Mode' screen with 'mg/mL' for Concentration Unit, 'kg' for Patient Info, and 'mg/kg/min' for Dosage Unit. The 'Edit' and 'Confirm' buttons are at the bottom.

In the unit selection screen, press the up / down toggle to scroll the options, press the right / left toggle to edit the next / previous parameter. Then press the enter key to confirm the units and move to the next input entry screen.

Dosage Rate Mode 

Conc. Unit	Patient Info	Dosage Unit
mg/mL	kg	mg/kg/min

 Edit Next Parameter
  Confirm

Dosage Rate Mode 

Conc. Unit	Patient Info	Dosage Unit
mcg/mL	kg	mcg/kg/min

 Confirm

Dosage Rate Mode 

Amount	1000.00 mg
Diluent	100.00 mL
Concentration	10.00 mg/mL
Patient Info	110.00 kg

 Select

Once the inputs are entered, start the infusion using the start key. The pump displays the dosage, rate and drug concentration on-screen.

Dosage Rate Mode  

Nipro 50 mL Conc 10.00 mg/mL

Dosage **1.00** mg/kg/min

Rate	Volume Infused
660.00 mL/hr	0.43 mL







Note: Bolus is disabled for Dosage Rate Mode. Parameters cannot be edited during infusion.

4.4.12. Multi-Step Mode

Multi-Step mode is a non-standard delivery pattern. The infusion takes place in specified steps (at a certain rate for a certain duration). Enter the rate and duration input parameters. The pump displays 2 steps, at 1 mL/hr for 1 hr each by default.

Steps	Rate (mL/hr)	Dur (hr : min : sec)
1	90.00	0 : 10 : 00
2	100.00	0 : 20 : 00

During input entry, if the entered input parameter is not within the limits, the pump displays the field alert on-screen.

Steps	Rate (mL/hr)	Dur (hr : min : sec)
1	0000.01	1 : 15 : 15

Once the inputs are entered, start the infusion by pressing the start key. Now, the pump displays the rate and volume infused.

Rate 1 **90.00** mL/hr

Volume Infused: 0.04 mL | Time Remaining: 09 min : 59 sec

Rate 2 **100.00** mL/hr

Volume Infused: 2.31 mL | Time Remaining: 18 min : 38 sec

During infusion, use the left toggle to check the previous step infusions. Press right toggle to move to the current step infusion. If there is no user action, the pump reverts to the current step infusing screen after 3 seconds.

Multi-Step Mode

Nipro 50 mL Total Steps : 2

Rate 1 **90.00** mL/hr

Volume Infused: **15.00 mL** Time Remaining: **00 min : 00 sec**

Navigation arrows: <<<<<<

When a step is complete, the pump automatically proceeds with the next step infusion. When all the programmed steps are complete, the pump prompts the user with an emergency alarm “Infusion Complete”.

For an intimation after each step is completed, go to system settings and enable the step complete alarm. When a step is complete, the pump prompts the user with an emergency alarm “Step Complete”. Once the alarm is acknowledged by pressing the enter key, the pump displays the next step input parameters. Either press the enter key to continue the next step infusion or press the back key to edit the parameters.

Step Complete

Nipro 50 mL Total Steps : 2

Rate 2 **100.00** mL/hr

Volume Infused: **0.00 mL** Time Remaining: **20 min : 00 sec**

Buttons: (BACK) Edit (ENTER) Continue

Multi-Step Mode

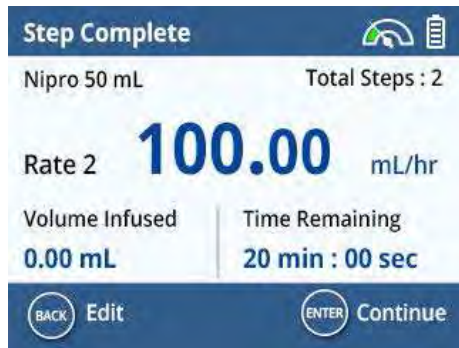
No of Steps : 2

Steps	Rate (mL/hr)	Dur (hr : min : sec)
1	90.00	0 : 10 : 00
2	100.00	0 : 20 : 00

Button: (START) Start Infusion

Note: Only the upcoming steps can be edited.

During step complete state, use the left toggle to check the previous step infusions. Then press the right toggle to move to the current step infusion. If there is no action, the pump reverts to the current step complete screen after 3 seconds.



When KVO is enabled, the pump displays Step Complete KVO On screen.



During KVO, to edit the KVO rate, press up toggle and the KVO rate becomes editable. Edit the KVO rate when required and start the KVO by pressing start key.

Press stop key to stop the KVO. The pump displays KVO stopped screen for 3 seconds, then reverts to the step complete screen. At step complete state, either continue the next step infusion using enter key or edit the parameters using back key.



While editing the KVO rate, if the KVO rate is greater than the infusion rate or when the KVO rate is not within the limits (0.1 to 5 mL/hr), the pump displays the field alert. If any key press action is not performed before or after edit, the pump reverts to the KVO infusing screen after 3 seconds.



When the syringe is empty, the pump raises an emergency alarm. After acknowledgement, the pump displays infusion stopped screen.

Note:

Number of steps that can be configured - 1 to 10.

Default number of steps is 2. If the number of steps is edited, the pump displays 1 mL/hr in rate input field and 1 hr in duration input field for all the edited number of steps.

Duration Limit - 10 seconds to 99 hours (for each step).

The maximum volume that can be infused in each step is 999 mL. During the rate and duration input entry, if the auto-calculated VTBI exceeds 999 mL, the pump displays the field alert "Calculated VTBI not within limits, Edit values".

Bolus is disabled for Multi-Step mode. Parameters cannot be edited during infusion.

4.5. Occlusion Pressure

Default occlusion pressure is level 3. The pump displays 5 pressure levels on-screen. If the occlusion pressure level is to be changed, select the pressure level using up and down toggle and press the enter key to confirm. The pump reverts to the menu screen.

Occlusion Pressure	
Level 1	100 mmHg
Level 2	300 mmHg
Level 3	500 mmHg
Level 4	700 mmHg
Level 5	900 mmHg

ENTER Confirm

Note: During infusion, the pressure icon is displayed on-screen.

Note: After the occlusion is removed, the bolus volume released (i.e., the amount of fluid that had been collected in the tubing during occlusion) shall be atmost 0.5 mL.

4.6. KVO

KVO is disabled by default. Enable the KVO whenever needed. The default KVO rate is 0.1 mL/hr. To edit the KVO rate, press down toggle, edit the KVO rate and press enter key to confirm.
 Programmable KVO Rate: 0.1 - 5 mL/hr.

KVO	
Disable	
Enable	

ENTER Confirm

KVO	
Disable	
Enable	
KVO Rate	0.1 mL/hr

▼ Edit KVO Rate ENTER Confirm

KVO	
Disable	
Enable	
KVO Rate	0.1 mL/hr

ENTER Confirm

Note: While editing the KVO rate, if the KVO rate is not within the limits, the pump displays the field alert on-screen.

The image shows two screenshots of the 'KVO' screen. The top screenshot shows 'KVO Rate' set to '3.0 mL/hr' with a red alert box stating 'Enter KVO rate ≤ Inf rate 3.00 mL/hr'. The bottom screenshot shows 'KVO Rate' set to '0.0 mL/hr' with a red alert box stating 'Enter KVO rate - 0.1 to 5 mL/hr'. Both screens have 'Disable' and 'Enable' buttons at the top.

4.7. Drug

Select the drug from the list using up and down toggle and confirm by pressing the enter key.

The image shows the 'Drug' selection screen. It has a list of drugs: 'No Drug', 'Nitroglycerin', 'Dopamine', 'Heparin', and 'Propofol'. At the bottom, there is a blue bar with an 'ENTER' button and the text 'Confirm'.

Note: A maximum of 200 drug names can be stored. The pump displays 20 drugs by default. Adding / editing / deleting the drug name in the application is allowed. The updated drug list is sent to the pump via the application.

If the drug name is selected from the menu, then the pump displays the drug name on the infusing screen.

4.8. Keylock

When keylock under the menu is selected, the pump displays the instruction to lock / unlock the pump on-screen. From any screen (Programming / Infusing), press and hold alarm silencing key for more than 2 seconds to lock / unlock the pump.



When the pump is locked, the lock icon is displayed (flashing) on-screen for indication.

4.9. System Settings

Under system settings, the pump displays Wi-Fi enable / disable, step complete alarm, alarm sound, screen brightness, date, time, bed ID update, drug list update, syringe list update, configuration, history log transfer, preventive maintenance cycle and pump information. Select any of the options, modify and press the enter key to confirm.



Wi-Fi is disabled by default. To enable Wi-Fi, select "Enable" using up and down toggle and press enter key to confirm. When Wi-Fi is disabled, the options 'Drug List Update', 'Syringe List Update', 'Configuration' and 'History Log Transfer' will not appear in System Settings.



The step complete alarm is disabled by default. During multi-step infusion, if an intimation is required after each step is completed, enable the step complete alarm. When a step is complete, the pump prompts the user with an emergency alarm “Step Complete”.



While using the pump for the first time, the alarm sound level will be level 5 and screen brightness level will be level 3. The pump displays 5 levels on-screen. To change the level, select the level using up and down toggle and press the enter key to confirm. The pump reverts to the System Settings screen.

Note: While powering on the pump, the previously programmed alarm sound and screen brightness levels will be stored and retained in the pump.

Note: While editing the date, the number of days input shall be restricted based on the entered month and year. The pump shall provide an invalid keypress tone when the user tries to enter the input beyond the limits.

4.9.1. Drug List Update

To update the drug list in the pump, connect to the ad hoc network (pump SSID, key and QR code displayed on-screen).

Note: Please refer **Section 4.17.1 (g)** for additional information.



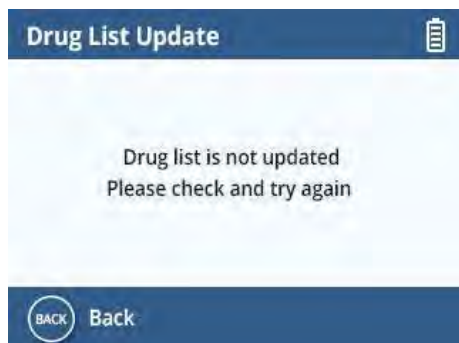
The progress bar indicates that the update is in progress.



Once it is completed, the pump displays the update status. Press enter to shutdown the pump.



If the update fails, the message "Drug list is not updated" appears on-screen. Press the back key. Now, repeat the above steps to update the drug list in the pump.



4.9.2. Configuration

After selecting the Configuration option under Menu, press the enter key to confirm. Now, the pump acts as an AP (Access Point). Configure the network details in the pump via the app by either scanning the QR code or entering the SSID and key manually. Once the configuration is complete, press the enter key to shutdown the pump.



Note: Please refer **Section 4.17** for additional information.

4.9.3. History Log Transfer

The pump stores the last seven days' log details. The logs are transferred to the application.

To transfer the history log, connect to the ad hoc network (key, QR code and pump SSID are displayed on-screen).



The progress bar indicates that the update is in progress.



Once it is completed, the pump displays the update status. Press enter to shutdown the pump.



If the update fails, press the back key. Now, repeat the above steps to transfer the history log.



Note: Please refer **Section 4.17.2** for additional information.

4.9.4. Pump Information

The pump displays the device name, MC (microcontroller) version, model number, serial number and date on which PMC (Preventive Maintenance Cycle) was completed.



4.9.5. Syringe List Update

To update the syringe list in the pump, connect to the ad hoc network by either scanning the QR code via app or entering the SSID and key manually in the app (QR code, key and SSID shall be displayed on-screen).



The progress bar indicates that the update is in progress.



Once it is completed, the pump displays the update status. Press enter to shutdown the pump.



If the update fails, the message "Syringe list is not updated" appears on screen. Press the back key. Now, repeat the above steps to update the syringe list in the pump.



Note: Please refer **Section 4.17.3 (d)** for additional information.

4.9.6. Bed ID Update

To update the bed ID in the pump, connect to the ad-hoc network by either scanning the QR code via app or selecting the SSID from the drop-down and enter the security key details manually in the app (QR code, SSID, and key shall be displayed on-screen). The progress bar indicates that the update is in progress. Once it is completed, the message will be displayed on-screen. Press enter key to shutdown the pump.

Note: Please refer **Bed ID Configuration - Updating the Bed ID List in the Pump (page 71)** for additional information.



Once it is completed, the pump displays the update status. Press enter to shutdown the pump.



If the update fails, the message “Bed ID is not updated” appears on screen. Press the back key. Now, repeat the above steps to update the bed ID in the pump.



4.10. History Log

The pump displays the events along with the date and time stamp on-screen. If an infusion or an alarm event is selected by pressing the enter key, the pump displays the detailed information.

The pump displays the last 100 events.

The pump stores the last seven days' information (approx. 2 MB). Perform the history log transfer procedure as mentioned in **Section 4.9.3** to transfer the logs to the application. Retrieve the logs via the app in .csv file format for analysis.



4.11. Infusion Paused

To pause the infusion, press the stop key. The pump displays infusion paused on-screen. During infusion paused,

1. Press the start key to resume the infusion
2. Press menu key to access the menu functions
3. Change the syringe, select syringe make, check the input parameters and press the start key to resume the infusion

Note: In multi-step mode, editing the upcoming steps is allowed.

Note: If the syringe is changed, the volume infused value displayed on the infusing screen will be additive in all the infusion modes.

If stop key is pressed during KVO enabled, the pump displays Infusion Paused KVO On screen.



To edit the KVO rate, press up toggle and the KVO rate becomes editable. Edit the KVO rate and start the KVO by pressing start key when required.

Press stop key to stop the KVO. The pump displays KVO stopped screen for 3 seconds and then reverts to the infusion paused screen. At infusion paused state, performing any of the actions mentioned above is allowed.



While editing the KVO rate, if the KVO rate is greater than the infusion rate or when the KVO rate is not within the limits (0.1 to 5 mL/hr), the pump displays the field alert. If any key press action is not performed before or after edit, the pump reverts to the KVO infusing screen after 3 seconds.

4.12. Syringe Empty

When the syringe is empty, the pump raises an emergency alarm.



If the syringe is removed, the pump displays load syringe screen. If the alarm is acknowledged, the pump displays infusion stopped screen.

4.13. Syringe Disengaged

During infusion, if the syringe is disengaged, the pump raises an emergency alarm and the infusion is stopped.



On acknowledging the alarm, select the syringe make, check the parameters and resume the infusion.

During Infusion Paused KVO On and Step Complete KVO On, if the syringe is disengaged, the pump prompts the user with an emergency alarm and the KVO infusion is stopped.



4.14. Infusion Complete

When the entered input volume has been delivered / multi-step infusion is complete, the pump prompts the user with an emergency alarm.



If the alarm is acknowledged, the pump displays infusion complete on-screen.



During KVO enabled, the pump displays Infusion Complete KVO On screen.



4.15. Pump on Standby

To retain the programmed inputs and start the infusion later, use standby feature.

Press on / off key. Then press the left toggle to switch to standby mode.



The default standby time is 24 hours. To edit the standby time, press up toggle, edit the standby time (5 min to 24 hr) and press enter key to confirm. If the edited standby time is not within the limits, the pump displays the field alert on-screen.



Press on / off key to cancel standby mode.

The pump displays the standby time remaining on-screen. The pump prompts when the standby time is elapsed. On acknowledging the alarm by pressing the enter key, either proceed with the programming or switch to standby again if needed.



4.16. Preventive Maintenance Cycle

Preventive Maintenance Cycle should be performed every year to test the keypad, display, audio, LED, RTC, barrel sensor, occlusion sensor, volume accuracy, near end switch test, clutch switch test and battery health.

Select the System Settings option under Menu. Under System Settings, select Preventive Maintenance Cycle. Enter the security pin and perform the tests shown in the list.



Preventive maintenance should be performed by trained and qualified technical personnel only.

Note: Please refer **980-1095 Accuflow VE Syringe Pump Service Manual** for additional information.

4.17. Configuration Application

Points to remember

- Accuflow VE Syringe Pump Configuration application will be provided by vTitan. The configuration should be performed by vTitan personnel or vTitan authorized personnel.
- The tablet with the Accuflow VE Syringe Pump Configuration Application will hereinafter be referred to as 'Tablet', which also acts as a server.
- Accuflow VE Syringe Pump Configuration Application will hereinafter be referred to as 'Application'.

Installation steps for the Configuration Application

Step 1: The Accuflow VE Syringe Pump Configuration Application APK will be shared with the authorized user through the registered email ID. The file will be password-protected.

Step 2: Download the shared APK.

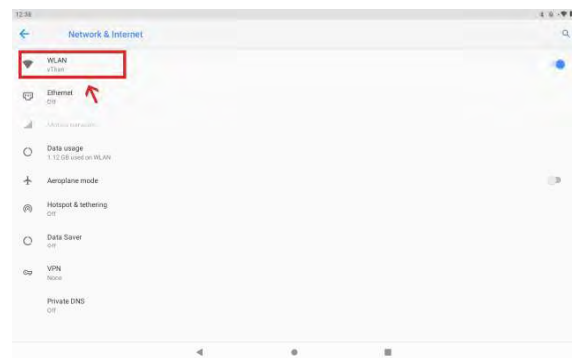
Step 3: Open the downloaded APK file and click "Install" when the pop-up appears.

Step 4: The application will then be installed.

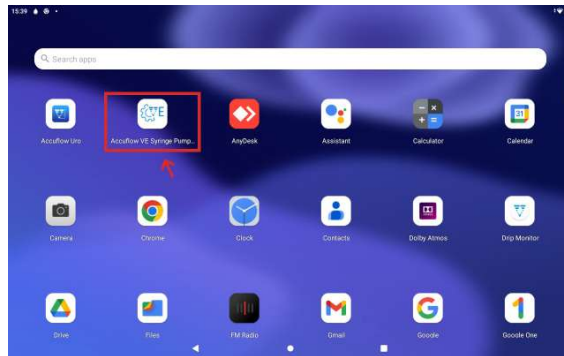
Steps to configure the pump and the tablet

In the tablet

1. Switch on the tablet. Open 'Settings' and enable the Wi-Fi connection.



2. Open the Accuflow VE Syringe Pump Configuration application.



In the pump

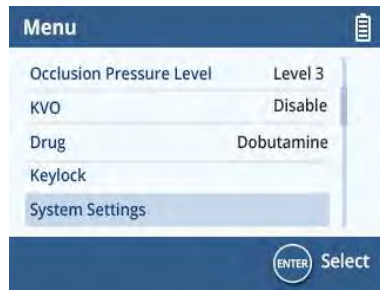
3. Press On/Off key to power on the pump. Load the syringe, select the syringe make and press Enter to confirm.



4. Press Menu key to access menu functions and navigate to system settings.



5. In System Settings, select Configuration.

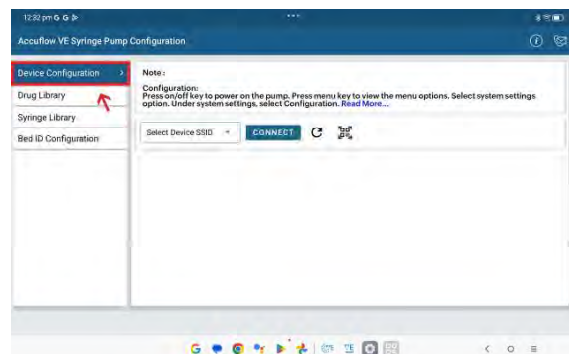


6. Press enter key to configure. The pump displays the SSID (Service Set Identifier), Key and QR code to scan.



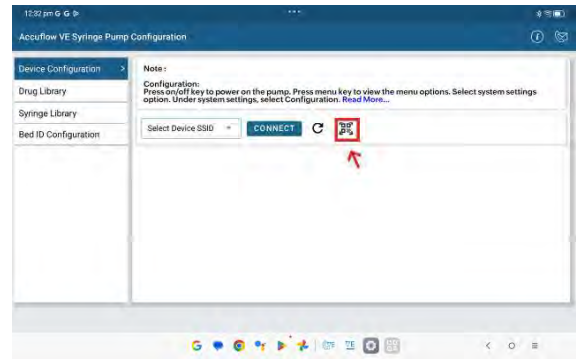
In the tablet

7. Open the Accuflow VE Syringe Pump Configuration Application. Select the 'Device Configuration' on the left pane of the application.

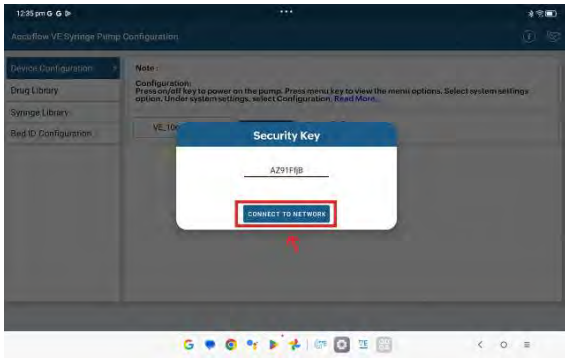
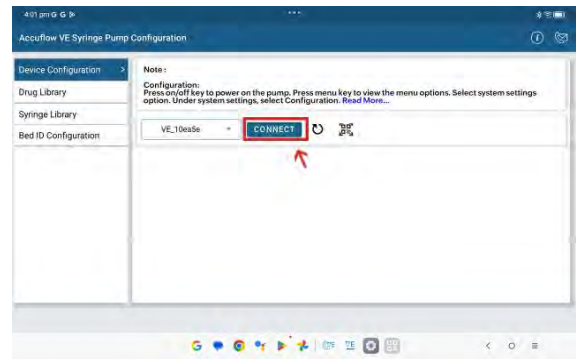
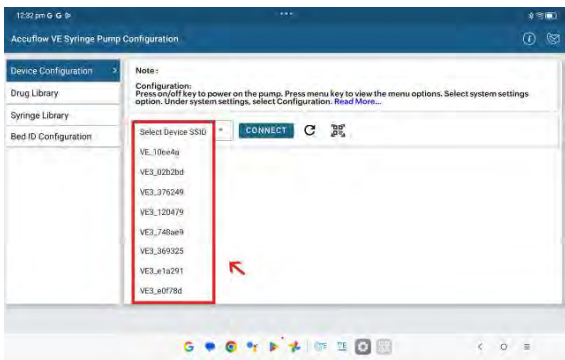
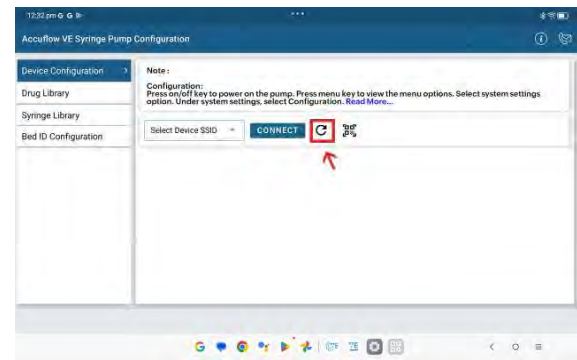


Connect with the pump either by scanning the QR code displayed in the pump or manually selecting the pump's SSID from the list.

8. Scan the QR code displayed in the pump using  and click 'CONNECT' to connect with the pump.

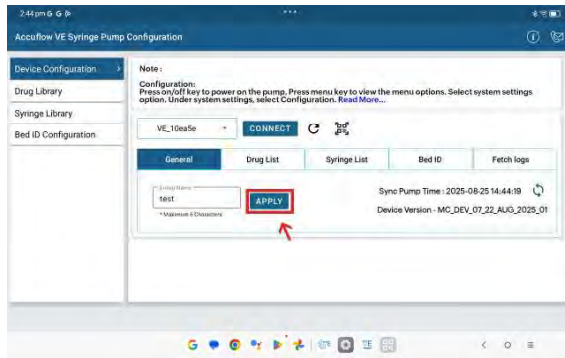


Else, click the  icon. Select the pump ad hoc network name (pump's SSID) from the list and click 'CONNECT'. A pop-up appears to enter the security key. Enter the security key displayed in the pump and click 'CONNECT TO NETWORK' to connect with pump.



Note: Once the 8-digit security key is entered, "CONNECT TO NETWORK" shall be enabled automatically.

9. In the table below, select 'General' option. Modify the pump name if needed and click 'APPLY' to submit the pump name.



Note: Ensure that the pump name is unique for all the pumps.

Note: Drug list, syringe list, Bed ID shall be updated from the configuration screen.

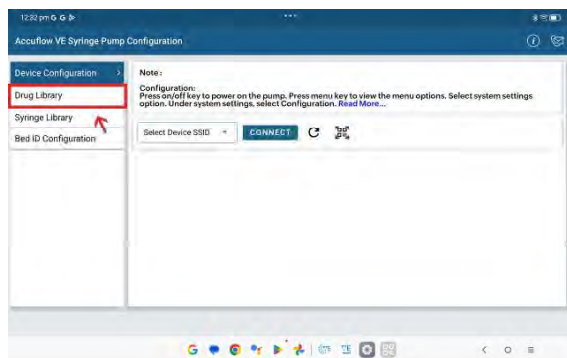
In the pump

10. Once the configuration is complete, press enter key to confirm and shut down the pump.



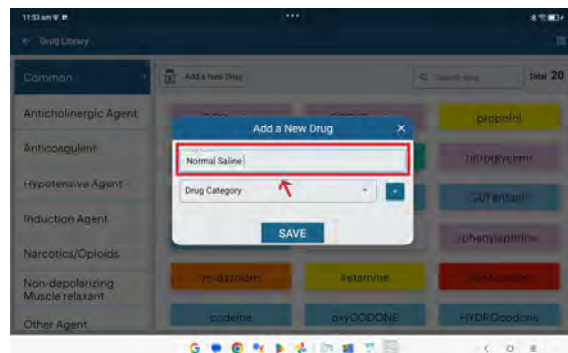
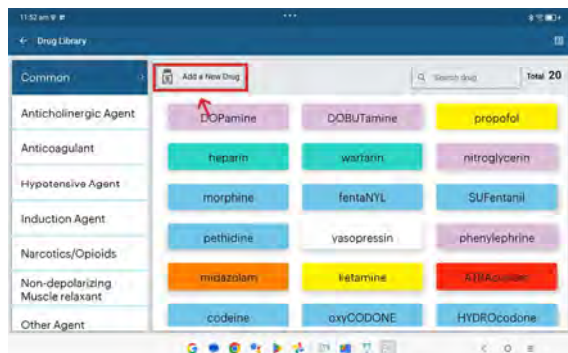
4.17.1 Drug Library

Select the 'Drug Library' on the left pane of the application to access the drug library.

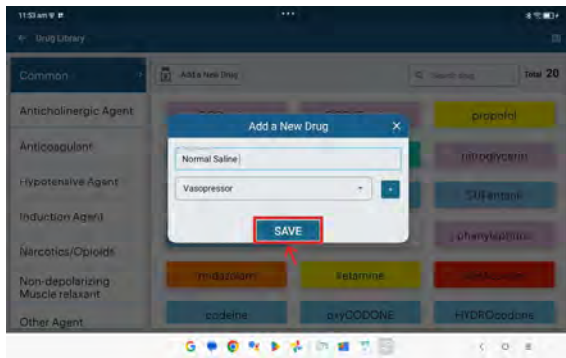


a. Adding a New Drug

Click 'Add a New Drug' at the left corner of the Drug Library screen, enter the drug name and select the drug category from the drop down menu.

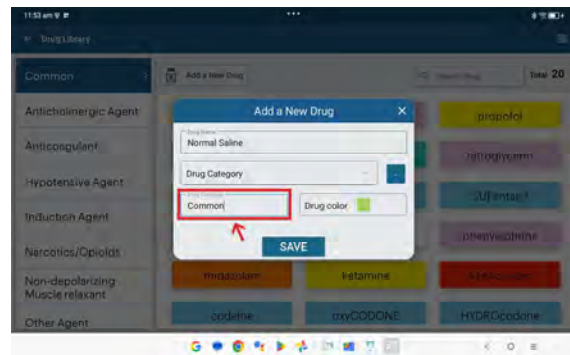
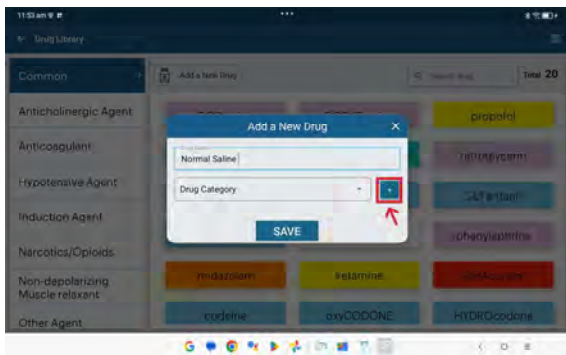


Click "SAVE" to add the details to the drug library.

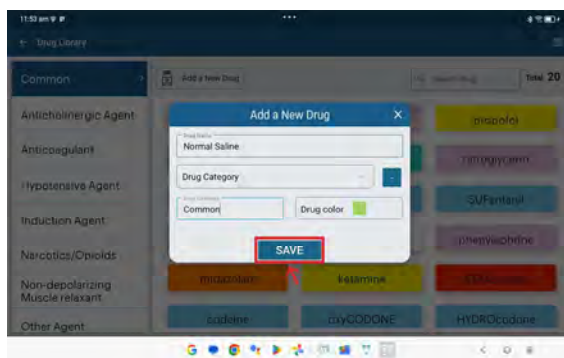
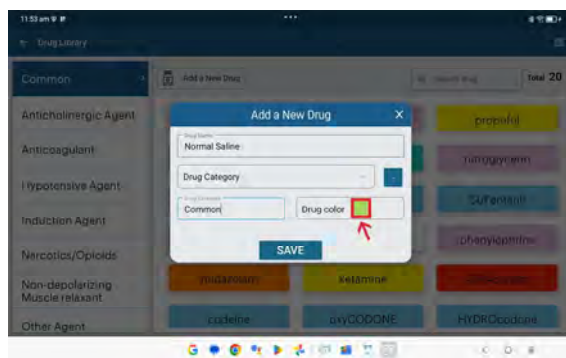


b. Adding a New Drug Category

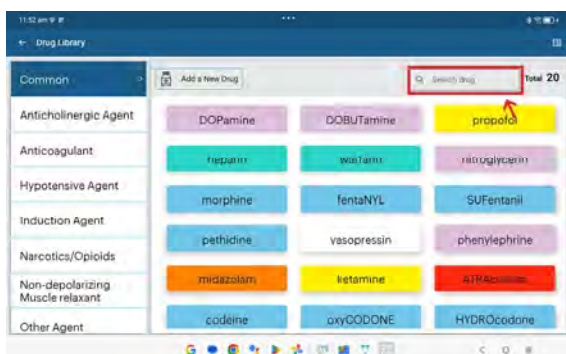
To add a new drug category, click  and enter the drug category.



Select a color and click "SAVE" to add a new drug category to the library.

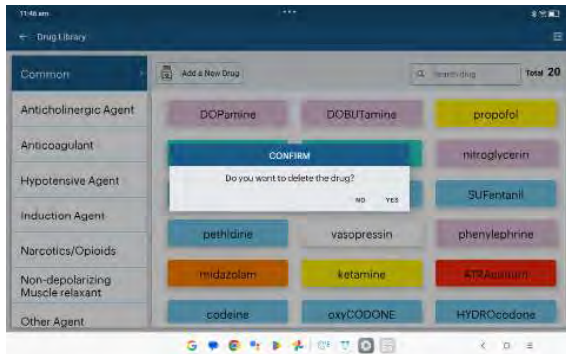


Enter the name of the drug in the search bar at the top right corner of the Drug Library screen to find any drug from the drug library.



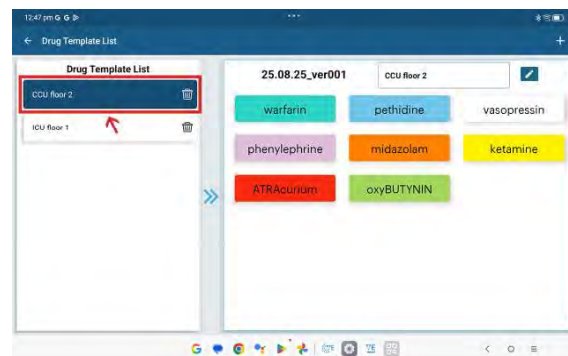
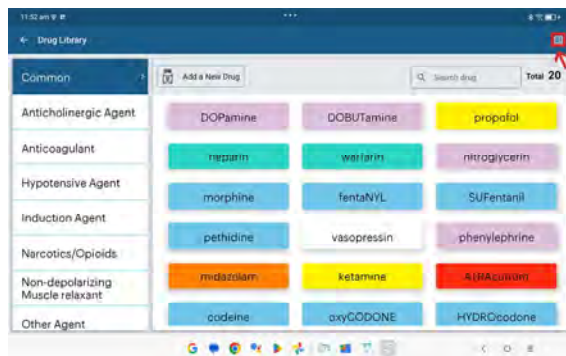
c. Deleting a Drug

To delete a drug, long press the drug that needs to be deleted, confirmation pop-up appears. Click “YES” to delete the drug.



d. Drug Template

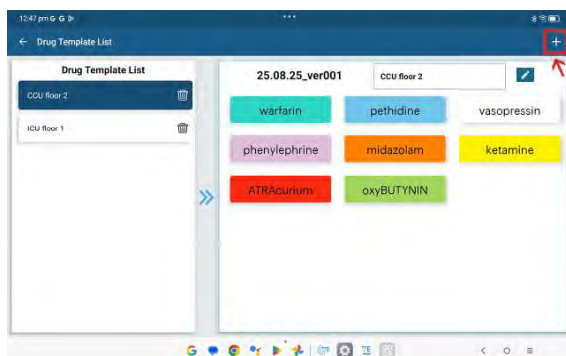
Click  icon on the Drug Library screen to view the Drug Template List. Click the required drug template to view the drugs in the selected drug template.



Note: The user shall click  icon, to edit the template name and click  icon to save the edited detail.

e. Creating a New Drug Template

Click  icon on the Drug Template List screen to create a new drug template.



Click and drag the required drugs to the right to add them to the Drug template, enter the template name and click  icon to create the drug template.



The total number of drugs added to the drug template will be displayed at the top right corner.

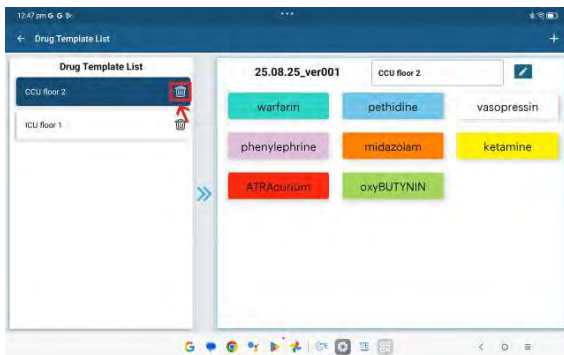


Note: Number of drugs that can be added to the Drug template: 5 to 200

Note: Maximum number of drug templates that can be created: 5

f. Deleting a Drug Template

Click  icon to delete the selected drug template.



A confirmation pop-up appears. Click "YES" to delete the drug template.

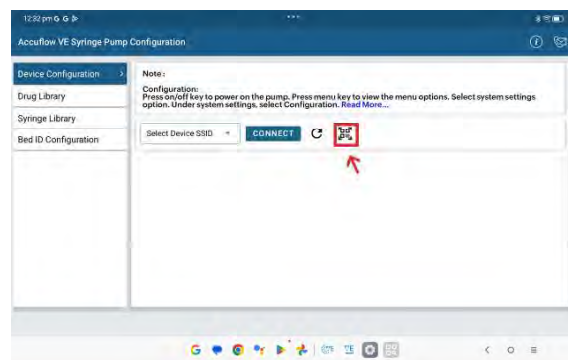
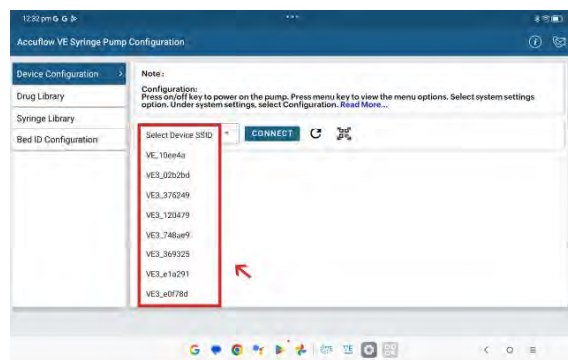
g. Updating the Drug List in the Pump

To update the drug list in the pump, perform the following actions:

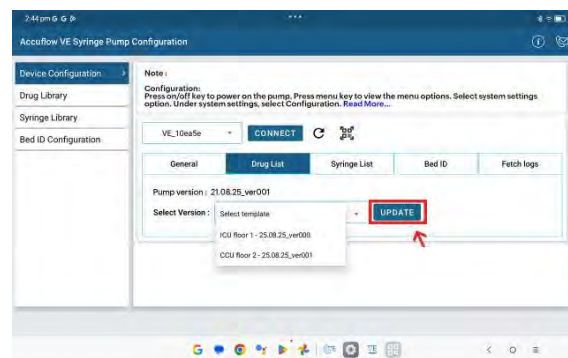
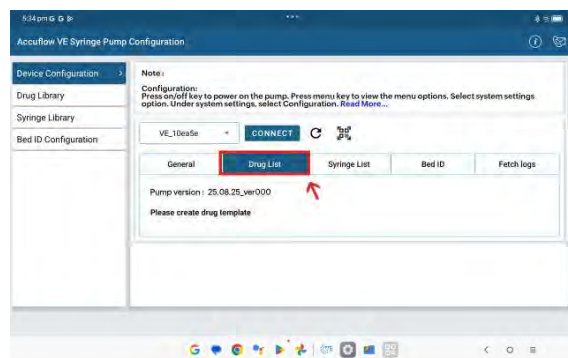
- (i) In the pump, press menu key to view the menu options. Select “System Settings” option.
- (ii) Under “System Settings”, select “Drug List Update”.



- (iii) Either scan the QR code displayed in the pump using  or Click the  icon and select the pump ad hoc network name (pump's SSID) from the list, enter the security key and click 'CONNECT'.



- (iv) In the table below, select ‘Drug List’ option and select the template from the drop-down options and click ‘UPDATE’ to update the drug list in the pump.



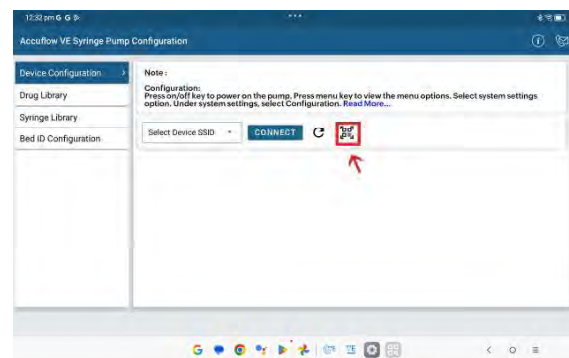
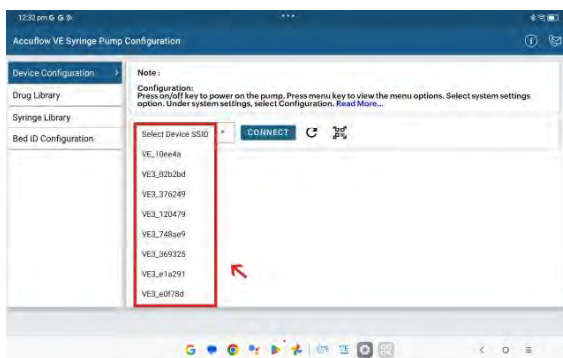
Once the update is completed, press enter key in the pump to shutdown.

4.17.2 Fetch Logs

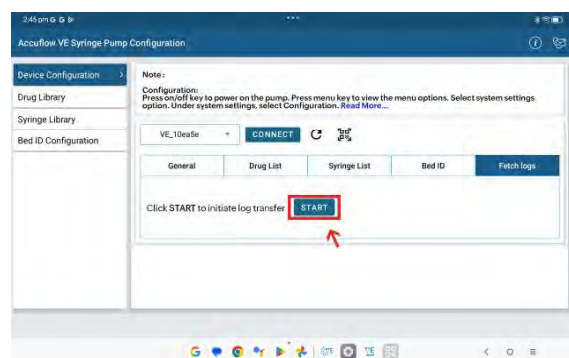
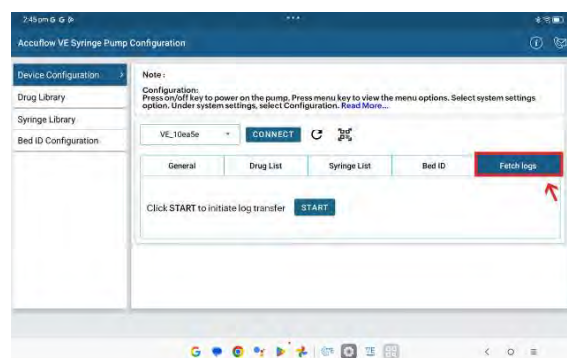
- (i) In the pump, press menu key to view the menu options. Select “System Settings” option.
- (ii) Under “System Settings”, select “History Log Transfer”.



- (iii) Either scan the QR code displayed in the pump using  or Click the  icon and select the pump ad hoc network name (pump's SSID) from the list, enter the security key and click 'CONNECT'.



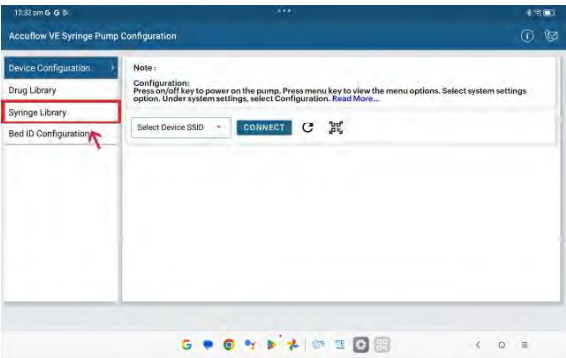
- (iv) In the table below, select 'Fetch logs' option and click “START” to download the logs in .csv format.



Once the log transfer is completed, press enter key in the pump to shutdown.

4.17.3 Syringe Library

Select the 'Syringe Library' on the left pane of the application to access the syringe library.

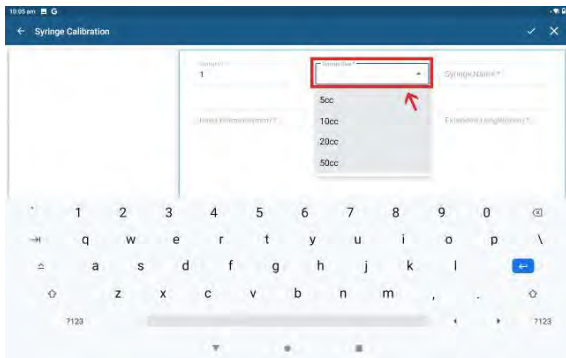


a. Adding a New Syringe Make

Click  icon on the right corner of the syringe calibration screen to add a new syringe make.



Select the syringe size from the drop-down options (5cc, 10cc, 20cc, 50cc).



Once the syringe size is selected, enter the syringe name, inner diameter, closed length and extended length.

Syringe Calibration

Syringe ID: 1 Syringe Size: 50cc Syringe Name: Omnivan

Inner Diameter (mm): Closed Length (mm): Extended Length (mm):

Switch to Technician

Syringe Calibration

Syringe ID: 1 Syringe Size: 50cc Syringe Name: Omnivan

Inner Diameter (mm): Closed Length (mm): Extended Length (mm):

Switch to Technician

Click  icon to add the syringe make.

Syringe Calibration

Syringe ID: 1 Syringe Size: 50cc Syringe Name: Omnivan

Inner Diameter (mm): Closed Length (mm): Extended Length (mm):

Switch to Technician

Click  icon to cancel the addition. A confirmation pop-up appears. Click "YES" to cancel the addition.

Syringe Calibration

Syringe ID: 1 Syringe Size: 50cc Syringe Name: Omnivan

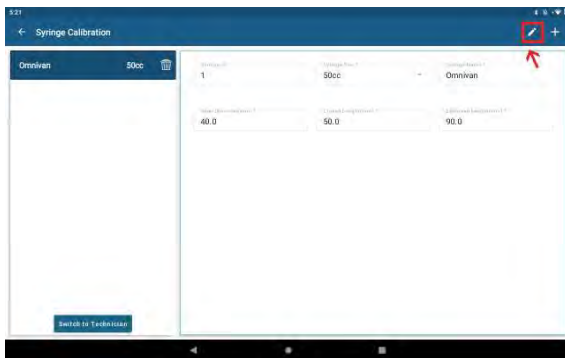
Inner Diameter (mm): Closed Length (mm): Extended Length (mm):

Switch to Technician

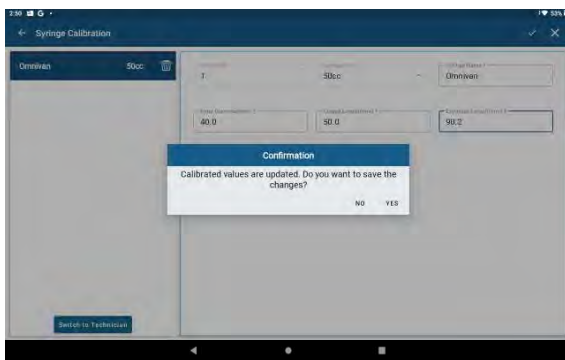
Note: Maximum number of syringe make that can be added: 4

b. Editing a Syringe Make

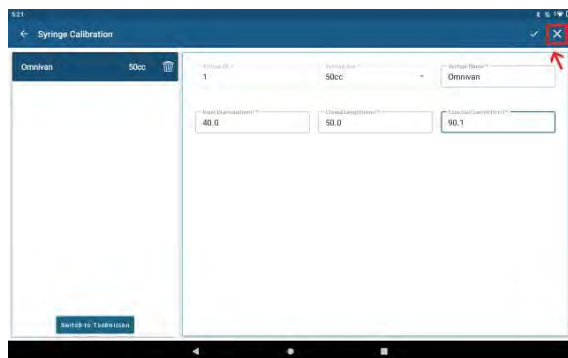
Click  to edit the entered details. Click  to save the edited details.



When the inner diameter, closed length and extended length values are edited, a confirmation pop-up appears. Click "YES" to save the edited details or click "NO" to retain the previously entered values.



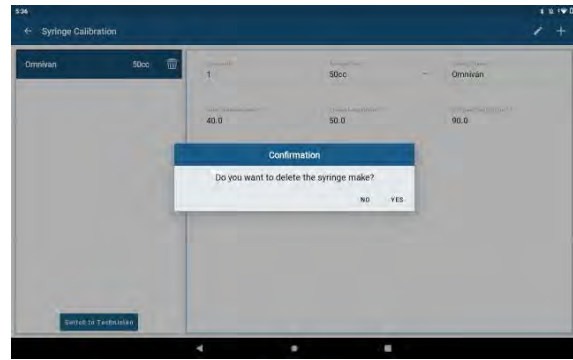
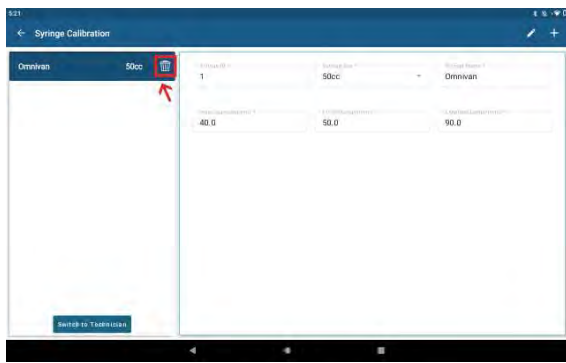
Click  icon to cancel the edit. A confirmation pop-up appears. Click "YES" to cancel.



Note: Syringe size cannot be edited.

c. Deleting a Syringe Make

Click  icon to delete the selected syringe make. A confirmation pop-up appears. Click "YES" to delete the syringe make.



Note: The technician view is intended for use only by vTitan service personnel.

Note: Please refer **980-1095 Accuflo VE Syringe Pump Service Manual** for additional information.

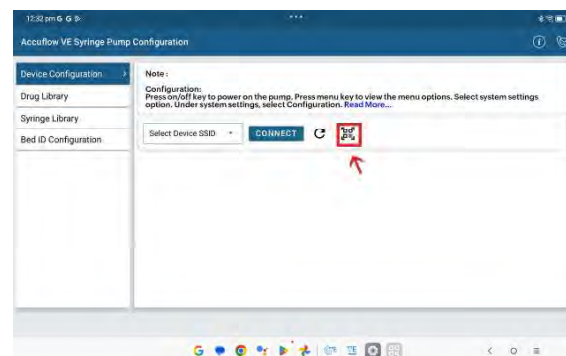
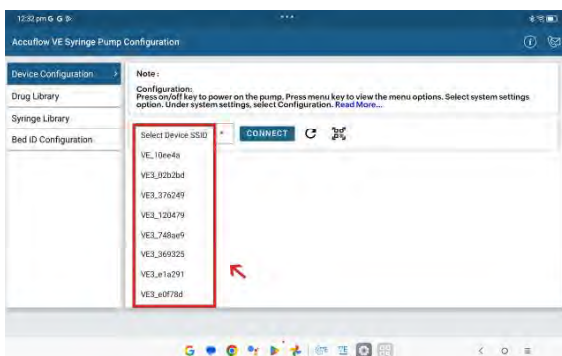
d. Updating a Syringe List in the Pump

To update the newly added syringe make in the pump, perform the following actions:

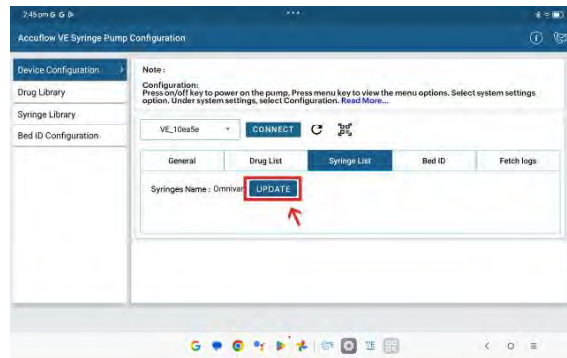
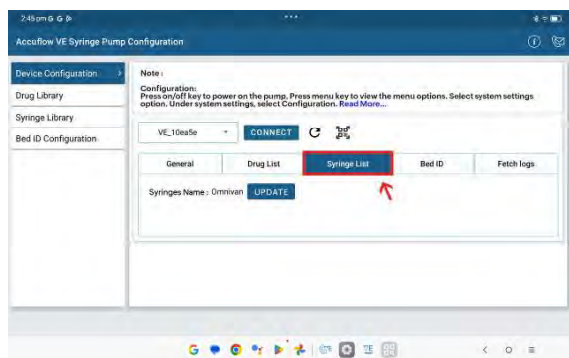
- (i) In the pump, press menu key to view the menu options. Select “System Settings” option.
- (ii) Under “System Settings”, select “Syringe List Update”.



- (iii) Either scan the QR code displayed in the pump using  or Click the  icon and select the pump ad hoc network name (pump's SSID) from the list, enter the security key and click 'CONNECT'.



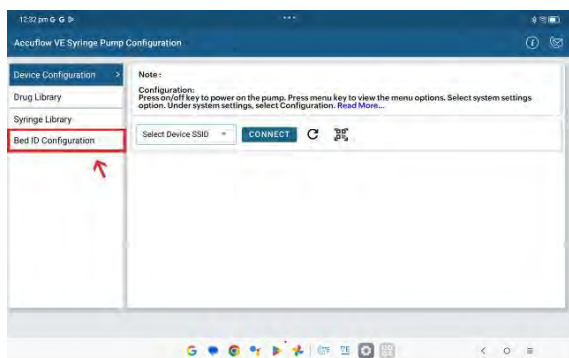
(iv) In the table below, select 'Syringe List' option and click 'UPDATE' to update the syringe list in the pump.



Once the update is completed, press enter key in the pump to shutdown.

Bed ID configuration

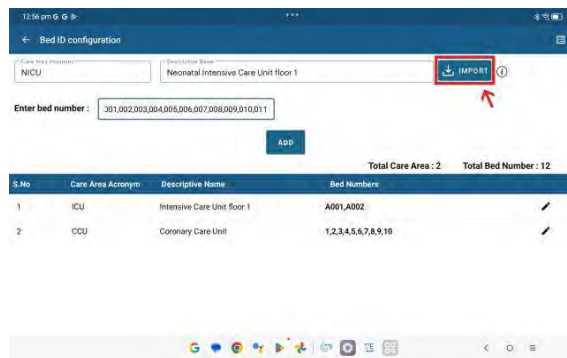
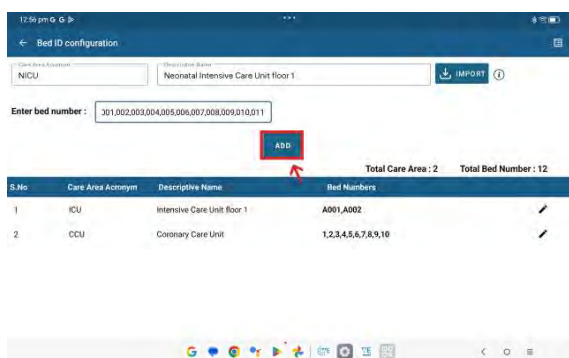
Select the 'Bed ID Configuration' on the left pane of the application to access the bed ID configuration.



a. Adding care area and bed number

Enter the Care Area Acronym, Descriptive Name, and Bed Numbers, and click the "ADD" button to save the details. Otherwise, click the "IMPORT" button to upload a CSV file. The CSV file shall contain a predefined list of care areas and their associated bed numbers.

Once the details are added, the configured care areas and corresponding bed numbers shall be displayed in the summary table.



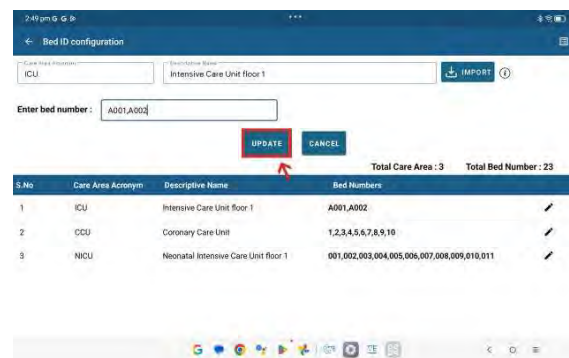
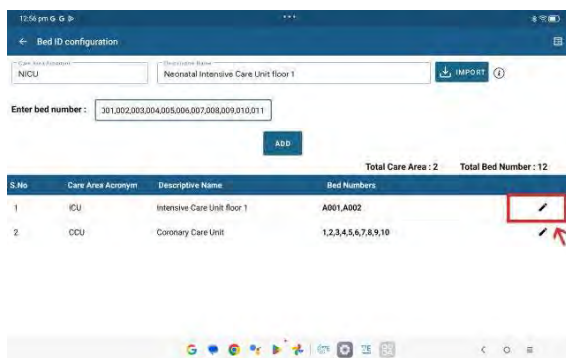
Note: The total number of care areas and bed numbers configured are displayed at the top-right of the table.

Click ⓘ icon to view the rules of the CSV file . A pop-up shall appear.



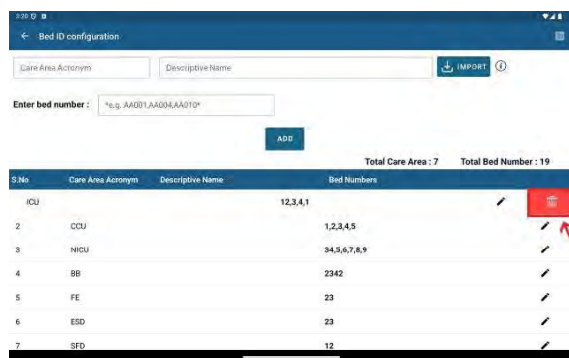
b. Editing care area and bed number

Click ✎ icon in the summary table to edit the entered details. Click “UPDATE” button to save the edited details and “CANCEL” button to discard the changes.



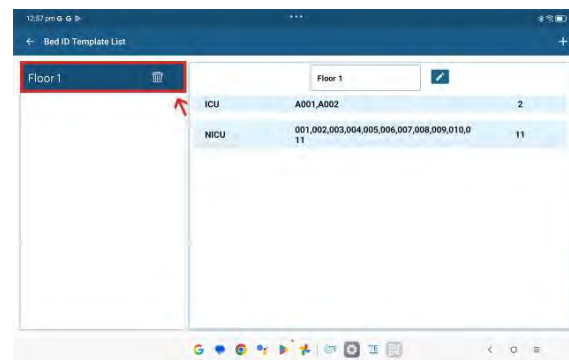
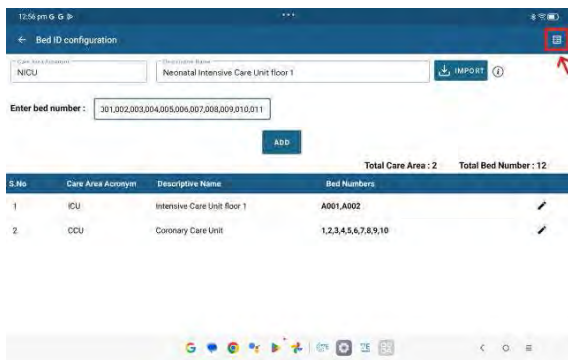
c. Deleting care area and bed number

Click the care area that needs to be deleted, swipe left and click the 🗑 icon. The confirmation pop-up shall appear. Click “YES” to delete the care area.



d. Bed ID Template

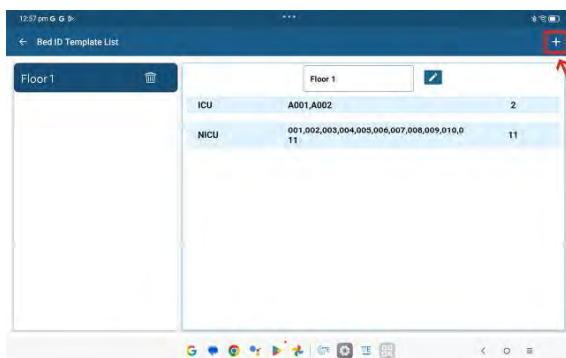
Click 📄 icon on the Bed ID Configuration screen to view the Bed Template List. Click the required Bed ID template to view the care area and bed number in the selected Bed ID template.



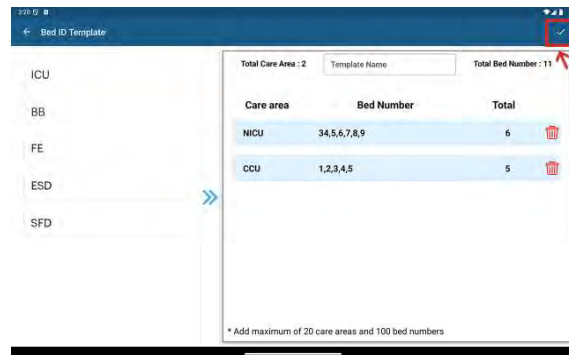
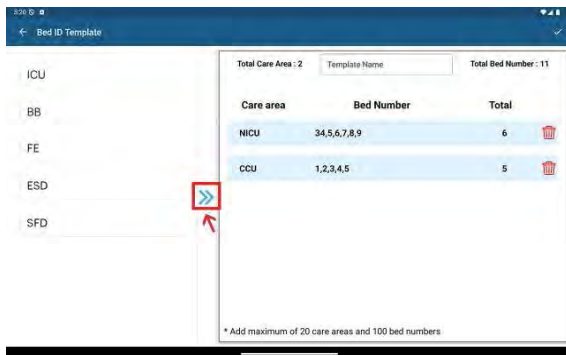
Note: The user shall click  icon, to edit the template name and click  icon to save the edited detail.

e. Creating a New Bed ID Template

Click  icon on the Bed ID template List screen to create a new Bed ID template.



Click and drag the required care area to the right to add them to the Bed ID template, enter the template name and click  icon to create the Bed ID template.



Note: The user shall click  icon to delete the care area from the template.

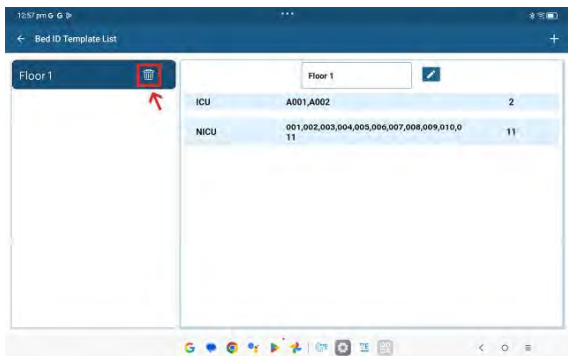
The total number of care areas and bed numbers added to the template shall be displayed at the top left corner and top right corner respectively.

Note: Maximum of 20 care areas and 100 bed numbers can be added to the template.

Note: Maximum number of bed ID templates that can be created: 20

f. Deleting a Bed ID Template

Click  icon to delete the selected Bed ID template. A confirmation pop-up appears. Click “YES” to delete the Bed ID template.



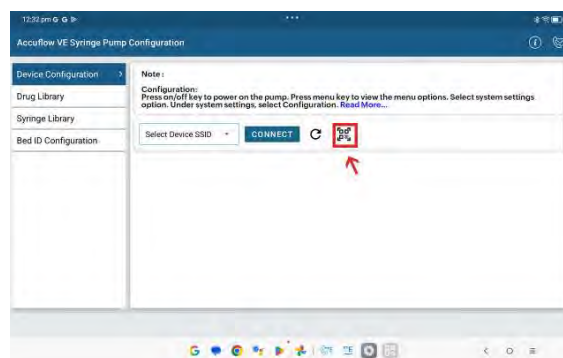
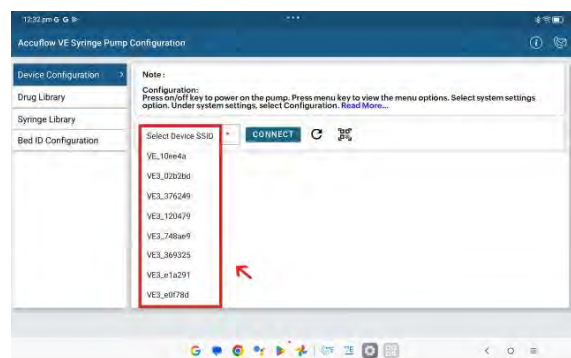
g. Updating the Bed ID List in the Pump

To update the bed ID in the pump, perform the following actions:

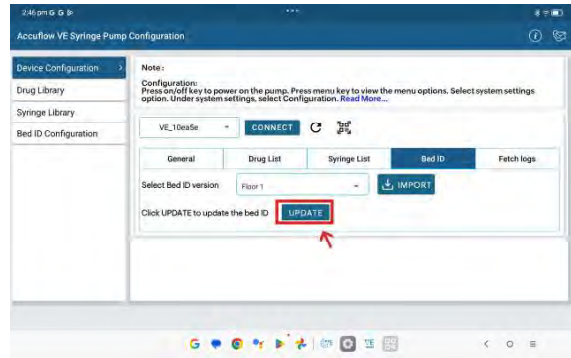
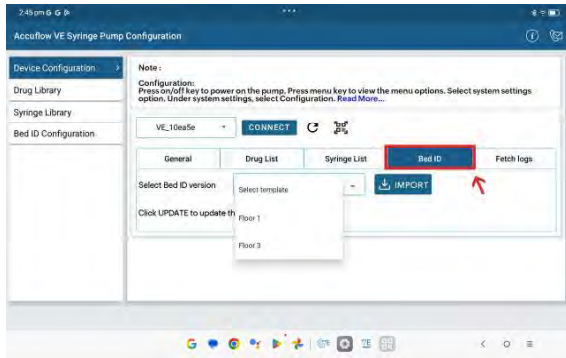
- (i) In the pump, press menu key to view the menu options. Select “System Settings” option.
- (ii) Under “System Settings”, select “Bed ID Update”.



- (iii) Either scan the QR code displayed in the pump using  or Click the  icon and select the pump ad hoc network name (pump's SSID) from the list, enter the security key and click 'CONNECT'.



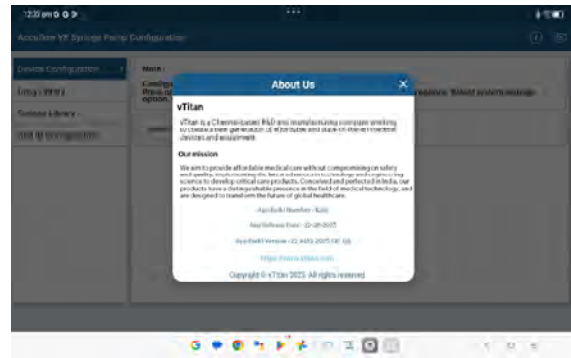
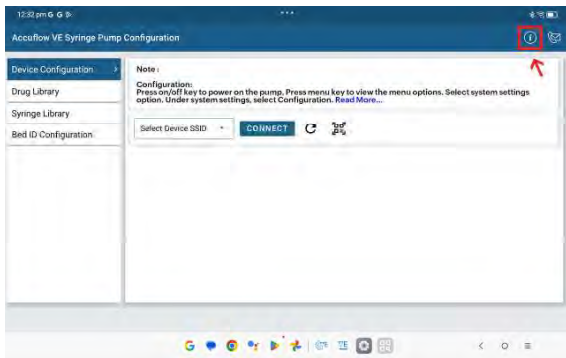
(iv) In the table below, select 'Bed ID' option and click "IMPORT" button or select the template from the drop-down options and click 'UPDATE' to update the Bed ID in the pump.



Once the update is completed, press enter key in the pump to shutdown.

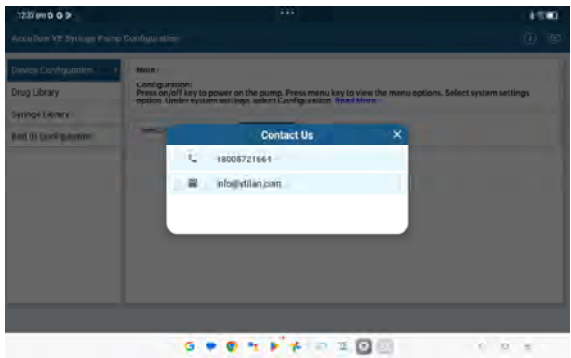
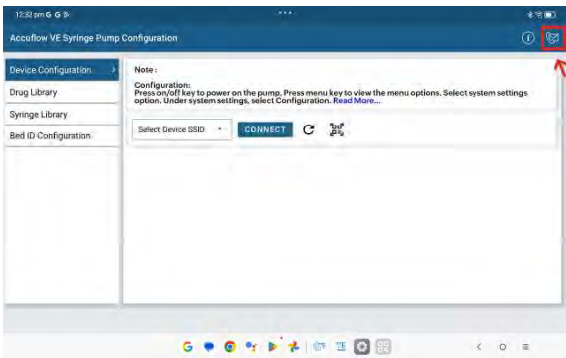
4.17.4 About Us

Click the  icon to view information about the company, App Build Number, App Release Date and App Build Version.



4.17.5 Contact Us

Click the  icon to view the contact details.



4.17.6 Display Messages (Configuration Application)

S.No	Scenario	Message
Device Configuration		
1	Connect - On success and get pump name is success	Success: Device name fetched
2	Connect to VE - On Failure (Failed to get response)	Error: Unable to fetch pump name
3	Connect to VE - On Failure (Timeout)	Error: Unable to get pump name
4	Pump Name - Save - Validation Error	Error: Pump name should contain at least one character
5	Pump Name - Save - Failed to update the pump	Error: Pump name not updated
6	Pump Name - Save - On Success	Success: Pump name updated
7	When there is no data transfer from the pump	<Pump Name> is not available
8	Connect - Timeout / any issue in android to connect with Wi-Fi	Something came up. The application has cancelled the request to choose a device.
9	When Wi-Fi is not turned on in tablet	Turn Wi-Fi on ENABLE
10	When location is not turned on in tablet	Turn location on ENABLE
11	QR scan - On Failure (Timeout)	Not a valid QR
12	QR scan - On Failure (Failed to get response)	Scanning failed
13	QR scan - On success	Scanned successfully
14	General - Sync Pump Time - On Success	Success: Date and Time updated
15	General - Sync Pump Time - On Failure	Error: Date and Time update failed
16	General - Sync Pump Time - Date and Time mismatch / when tablet's date and time is set prior to app release date	Error: Date and Time mismatch
17	Connect - Without selecting pump SSID	Please select the pump SSID
18	Connect to VE - On Failure (Timeout)	Error: Unable to get date and time
19	Drug Library Update - Unable to get pump's drug template version	Error: Unable to get pump's drug template version
20	Drug Library Update - No newly added drug template	Please create drug template
21	Drug Library Update - Newly added drug template available - On success	Drug List updated successfully
22	Drug Library Update - Newly added drug template available - On Failure	Drug List failed to update

S.No	Scenario	Message
23	Fetch Logs - On Success	Log Transferred Successfully
24	Fetch Logs - On Failure	Log Transfer Failed
25	Syringe Make Update - No newly added syringe	No Syringe Makes Available
26	Syringe Make Update - Newly added syringe available - On success	Syringe List updated successfully
27	Syringe Make Update - Newly added syringe available - On failure	Syringe List failed to update
28	Bed ID Update - No newly added bed ID template	Please create Bed ID template
29	Bed ID Update - When no bed ID template selected	Please select the Bed ID template
30	Bed ID Update- Import - Error in the uploaded file	Unable to read data from the file
31	Bed ID Update - When bed ID template selected - On success	Bed ID updated successfully
32	Bed ID Update - When bed ID template selected - On Failure	Bed ID update failed
Drug Library		
33	Input validation	Drug name should contain at least 3 characters
34	Input validation- When the user enters the drug name that already exists	Drug name already exists
35	Delete the last item from the list	Cannot delete. Drug Library should have at least one entry
36	To delete a drug	Do you want to delete the drug?
37	Drug name - Save - Validation - If the drug name field is empty	Please enter drug name
38	Drug category - Save - Validation - If the drug category field is empty	Please select drug category
39	New Drug category addition - Save - Validation - If the drug category field is empty	Drug category should contain at least 3 characters
40	Drug color - Save - Validation - If the drug category field is empty	Please select drug color
41	Drug addition - Save - On success	Drug added successfully
42	Drug addition - New drug category addition - On success	Drug name and drug category added successfully

S.No	Scenario	Message
43	Drug addition - New drug category addition - On failure	Drug Name and drug category addition failed
44	Drug deletion - On success	Drug deleted successfully
45	Drug entered in the search bar is not present in the drug library	Drug not found
Drug Template		
46	Maximum number of entries reached	Maximum number of entries allowed is 200
47	To delete a drug template	Do you want to delete the drug template?
48	When less than 5 drugs are added to a drug list template	Minimum 5 drugs should be selected
49	If the user tries to create more than 5 drug templates	Maximum 5 drug template allowed
50	Drug Template - On success	Drug Template created successfully
51	Input Validation - If the template name field is empty	Template name cannot be empty
52	Input Validation - Edit Template name - on success	Template name updated
53	Input Validation- When the user enters the template name that already exists	Template name already exists
Bed ID configuration		
54	Input validation - If the care area acronym is empty	Care Area Acronym should contain at least one character
55	Input validation - When the user enters none in the input fields of care area acronym and bed number	The value 'None' is not allowed
56	Input validation – when the user enters more than 5 characters in the Individual Bed Number field	Individual Bed Number cannot exceed 5 characters
57	If the user wants to cancel the edit	Do you want to cancel ?
58	If the user exits the edit screen without saving the changes	Changes will not be saved. Do you want to exit?
59	Input validation- When the user enters the care area acronym that already exists	Care Area Acronym already exists
60	To delete a care area	Do you want to delete the Care Area?
61	Care Area addition - On success	Care Area added successfully
62	Care Area delete - On success	Care Area deleted successfully
63	Care Area edit - On success	Care Area updated successfully
64	Input validation- When the user enters the bed number that already exists	Added Care Area after removing duplicate bed numbers

S.No	Scenario	Message
65	Input validation – when the user adds more than 50 bed numbers in a care area	Cannot add more than 50 bed numbers per Care Area
66	Input Validation - If the bed number field is empty	Bed number cannot be empty
Bed ID Template		
67	If the user tries to create more than 20 bed ID templates	Maximum 20 Bed ID template allowed
68	If the user tries to add more than 20 care areas	Maximum of 20 Care Areas is allowed
69	If the user tries to add more than 100 bed numbers	Maximum of 100 Bed Numbers is allowed
70	When a user attempts to create a Bed ID template without assigning a Care Area	Bed ID template cannot be empty
71	Input Validation - If the template name field is empty	Template name cannot be empty
72	Input Validation - Edit Template name - on success	Template name updated
73	Input validation- When the user enters the template name that already exists	Template name already exists
74	Bed ID Template - On success	Bed ID template created successfully
75	To delete a bed ID template	Do you want to delete the Bed ID template?
Syringe Library		
76	Syringe Size - Save - Validation - If the syringe size field is empty	Please select Syringe Size
77	Input validation - In user view and technician view	Syringe name should contain at least 3 characters
78	Input validation - In user view and technician view	Inner Diameter cannot be empty
79	Input validation - In user view and technician view	Closed Length cannot be empty
80	Input validation - In user view and technician view	Extended Length cannot be empty
81	Input validation - When the user enters syringe make and size that already exists	The make and size already exists
82	Input validation - When the user enters Nipro, BDLuerLok, Dispovan, Others and None in the syringe name field	Syringe Name not allowed
83	Input validation - When the user enters only dot(.) or any values less than 1 in any of the input fields	Invalid entry

S.No	Scenario	Message
84	Input validation - When the user enters value greater than 40.0 in inner diameter field	Inner diameter cannot exceed 40.0mm
85	Input validation - When the user enters value greater than 150.0 in closed length field	Closed length cannot exceed 150.0mm
86	Input validation - When the user enters value greater than 150.0 in extended length field - In user view and technician view	Extended length cannot exceed 150.0mm
87	Input validation - When the user enters greater value in closed length field than extended length field - In user view and technician view	Closed length must be smaller than Extended length
88	Input validation - In technician view	FL Thickness cannot be empty
89	Input validation - In technician view	PL Thickness cannot be empty
90	Input validation - In technician view	Slope cannot be empty
91	Input validation - In technician view	Offset Counts cannot be empty
92	Input validation - In technician view	Ret Count <xx> cannot be empty
93	Input validation - In technician view	Level <xxx> Threshold cannot be empty
94	Input validation - In technician view	Maximum allowable load cannot be empty
95	Input validation - In technician view	Window size <xx> cannot be empty
96	Input validation - In technician view	Chk Window size <xx> cannot be empty
97	Input validation - When the user enters value greater than 3.00 in FL thickness - In technician view	FL thickness cannot exceed 3.0mm
98	Input validation - When the user enters value greater than 3.00 in PL thickness - In technician view	PL thickness cannot exceed 3.0mm
99	If the user tries to add more than 4 syringes	Only 4 syringes will be allowed
100	If the user enter wrong password in technician view	Incorrect password
101	Add syringe make - Save - On Failure	Syringe Addition failed
102	Edit syringe make - Save - On success	Syringe details updated successfully

S.No	Scenario	Message
103	To delete a syringe make	Do you want to delete the syringe make?
104	If the user wants to cancel the edit or add	Do you want to cancel ?
105	If the user exits the edit screen without saving the changes	Changes will not be saved. Do you want to exit?
106	Add syringe make - Save - On Success	Syringe added successfully
107	Edit syringe make - Save - On Failure	Syringe details update failed
108	If the user wants to switch to technician view while editing in user view	Action not allowed
109	When no syringe make is added	Custom syringe make not found
110	Edit syringe make - Save - Validation - When the user edits the values.	Calibrated values are updated. Do you want to save the changes?
111	When the user enter wrong password more than 5 times - Technician view	Too many attempts! Try again after 5 minutes.
112	Password, Current password, New password, Confirm new password - Input validation - Technician view	Field cannot be empty
113	When the user enter wrong current password - Technician view	Incorrect current password
114	When the user entered new password and confirm new password are different - validation - Technician view	Passwords do not match. Please re-enter.
115	If the user entered new password is less than 8 characters - Input validation - Technician view	Password should contain 8 characters
116	Change password - Submit - On Success	Password changed successfully

5. Pump Shutdown

Press on / off key. Then press the enter key to shutdown the pump.



6. Alarms

Alarms are audio as well as visual. The visual display of alarms includes alarm messages as well as LED indication.

Note: The alarm condition and the resolution is displayed on the header and footer of the screen in the respective colors based on the alarm category.

The priority of the alarms and alerts will be in the following order from highest to lowest precedence: Emergency alarm, Warning alarm, Caution alarm and Alerts.

The pump uses an intelligent alarm system with three levels: Caution, Warning, and Emergency. In the event of multiple alarm conditions, the system gives precedence to the Emergency alarms. Other alarms (Caution and Warning) are queued and displayed only after any active Emergency alarms are resolved.

Within each alarm category (e.g., within Emergency alarms), the pump follows a predefined internal order of priority.



Note:

- When power is lost for less than or equal to 30 s, the alarm settings prior to the power loss will be restored automatically.
- If there is no power supply and the battery is depleted, the pump will shut down. In that case, there will be an emergency buzzer to alert the user.
- The duration of audio pause or alarm pause will be 2 minutes.
- Maximum setting of alarm signal sound pressure level (volume level): 70 dB



6.1. Emergency

Emergency alarms cause infusion termination and need immediate user action.

In case of Unit Malfunction, System Errors, the pump needs to be returned to the biomed.

Emergency Alarms has E1## as code (For Unit Malfunction and System Error); Red corner LED flashing with audible alarm indicates emergency conditions.

E102 UNIT MALFUNCTION

Nipro 50 mL

Rate **10.00** mL/hr

Volume Infused

20.00 mL

Bolus Delivered

10.0 mL

Use Alternate Device

Press

**E151 SYSTEM ERROR**

Nipro 50 mL

Rate **10.00** mL/hr

Volume Infused

20.00 mL

Bolus Delivered

10.0 mL

Use Alternate Device

Press

**OCCCLUSION DETECTED**

Nipro 50 mL

Rate **10.00** mL/hr

Volume Infused

20.00 mL

Bolus Delivered

10.0 mL

Clear Occlusion

Press

**INFUSION COMPLETE**

Nipro 50 mL

Rate **300.00** mL/hr

VTBI mL

50.00

VI mL

50.00

TR min : sec

00 : 00

Reprogram pump

Press

**INFUSION COMPLETE KVO ON**

Nipro 50 mL

Rate **300.00** mL/hr

VTBI mL

50.00

VI mL

50.00

TR min : sec

00 : 00

Reprogram pump

Press



STEP COMPLETE  

Nipro 50 mL Total Steps : 2

Rate 1 **90.00** mL/hr

Volume Infused | Time Remaining
15.00 mL | **00 min : 00 sec**

Press 

STEP COMPLETE KVO ON  

Nipro 50 mL Total Steps : 2

Rate 1 **90.00** mL/hr

Volume Infused | Time Remaining
15.00 mL | **00 min : 00 sec**

Press 

INFUSION COMPLETE  

Nipro 50 mL Total Steps : 2

Rate 2 **100.00** mL/hr

Volume Infused | Time Remaining
33.33 mL | **00 min : 00 sec**

Reprogram Pump Press 

INFUSION COMPLETE KVO ON  

Nipro 50 mL Total Steps : 2

Rate 2 **100.00** mL/hr

Volume Infused | Time Remaining
33.33 mL | **00 min : 00 sec**

Reprogram Pump Press 

SYRINGE EMPTY  

Nipro 50 mL

Rate **10.00** mL/hr

Volume Infused | Bolus Delivered
20.00 mL | **10.0 mL**

Replace Syringe Press 



During power on, if the battery cycle count crosses 300 cycles, the pump raises an alarm. Press enter key to acknowledge the alarm. The pump shuts down. Then, handover the pump to biomed to replace the battery.



During power on or during infusion, if the watchdog is reset, the pump raises an alarm. Press enter key to acknowledge the alarm. Then the pump shall move to shutdown screen.



6.2. Warning

Warning Alarms do not terminate infusion but need user acknowledgement.

Warning Alarms have Yellow LED flashing with audible alarm.

The pump displays the syringe near empty alarm when the near end switch is triggered.

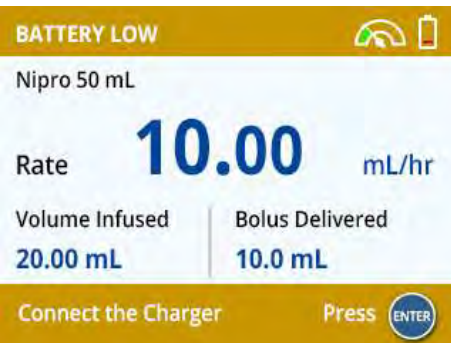


The pump displays the infusion near end alarm before two minutes of time remaining.



Note: During battery charging, if the battery temperature exceeds limits ($\geq 55^{\circ}\text{C}$), the charging will be suspended and the pump raises a warning alarm.

During discharge, if the battery temperature exceeds the limits ($> 60^{\circ}\text{C}$), the pump raises a warning alarm.



Note: When the battery level reaches 20%, a low-battery warning alarm will be triggered. After the alarm is acknowledged, the warning alarm will occur 2 times at 15-minute intervals. Once these two warnings have been issued, the alarm will repeat every 5 minutes until the battery is fully depleted.



During power on, if the battery cycle count goes beyond 250 cycles, the pump prompts the user with an alarm. Press the enter key to acknowledge the alarm. Also, press on / off key to shutdown the pump and handover the pump to biomed to check the battery.

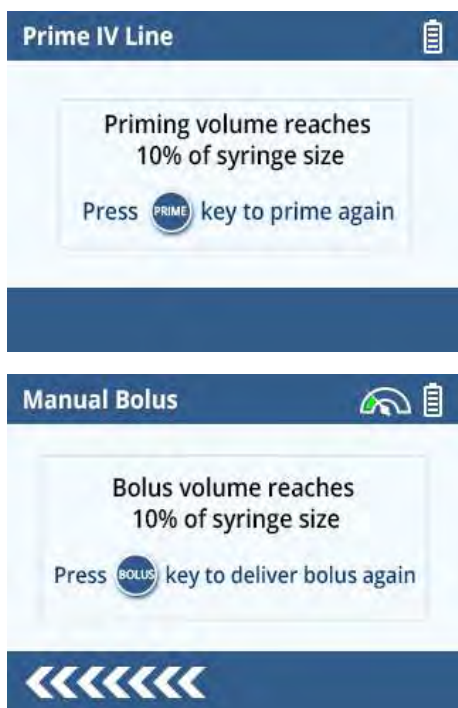


If the Preventive Maintenance Cycle alarm is enabled, the pump displays the alarm every year after every power on. Press the enter key to acknowledge the alarm. Contact your biomed or vTitan authorized service personnel to perform PMC.



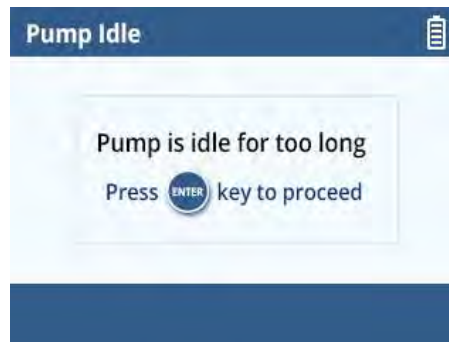
6.3. Caution

Caution alarms are low priority alarms to alert the user.



Note: To acknowledge the alarm, press enter key (before 5 seconds auto-disposable time) and proceed further whenever needed.

When the pump is idle for about 2 minutes during programming, infusion paused, infusion complete, the pump raises an alarm. The alarm is not auto-disposable. Press the enter key to proceed.



During infusion, if the flow rate exceeds by 10% of programmed rate due to occlusion, the pump alerts with an alarm. Check the IV line and press enter to proceed.



During syringe load, if the clutch half nut switch fails, the pump alerts with an alarm. Hold the clutch and pull the plunger head to the right. Move the plunger head towards the syringe end and ensure that the plunger head touches the plunger end of the syringe before releasing the clutch. Then press enter to proceed.



6.4 Field Alerts

When the input is not within the limits, the pump displays a field alert on-screen.

S.No	SCENARIO	FIELD ALERT DISPLAY
01	Rate not within the limits - 5 mL syringe loaded (Rate mode)	Enter rate - 0.1 to 100 mL/hr
02	Rate not within the limits - 10 mL syringe loaded (Rate mode)	Enter rate - 0.1 to 300 mL/hr
03	Rate not within the limits - 20 mL syringe loaded (Rate mode)	Enter rate - 0.1 to 500 mL/hr
04	Rate not within the limits - 50 / 60 mL syringe loaded (Rate mode)	Enter rate - 0.1 to 1200 mL/hr
05	Rate not within the limits - 5 mL syringe loaded (Editing rate while infusing)	Enter rate - 0.1 to 100 mL/hr
06	Rate not within the limits - 10 mL syringe loaded (Editing rate while infusing)	Enter rate - 0.1 to 300 mL/hr
07	Rate not within the limits - 20 mL syringe loaded (Editing rate while infusing)	Enter rate - 0.1 to 500 mL/hr
08	Rate not within the limits - 50 / 60 mL syringe loaded (Editing rate while infusing)	Enter rate - 0.1 to 1200 mL/hr
09	Bolus rate not within the limits - 5 mL syringe loaded	Enter bolus rate - 50 to 300 mL/hr
10	Bolus rate not within the limits - 10 mL syringe loaded	Enter bolus rate - 50 to 600 mL/hr
11	Bolus rate not within the limits - 20 mL syringe loaded	Enter bolus rate - 50 to 900 mL/hr
12	Bolus rate not within the limits - 50 / 60 mL syringe loaded	Enter bolus rate - 50 to 1500 mL/hr
13	Bolus volume not within the limits - 5 mL syringe loaded	Enter bolus volume - 0.1 to 5 mL
14	Bolus volume not within the limits - 10 mL syringe loaded	Enter bolus volume - 0.1 to 10 mL

S.No	SCENARIO	FIELD ALERT DISPLAY
15	Bolus volume not within the limits - 20 mL syringe loaded	Enter bolus volume - 0.1 to 20 mL
16	Bolus volume not within the limits - 50 / 60 mL syringe loaded	Enter bolus volume - 0.1 to 50 mL
17	Bolus duration not within the limits	Enter bolus duration - 1 s to 60 mins
18	Auto calculated bolus rate not within the limits	Calculated rate not within limits, Edit values
19	Volume not within the limits	Enter volume - 0.1 to 999 mL
20	Duration not within the limits	Enter duration - 10 s to 500 hr
21	Auto calculated rate not within the limits	Calculated rate not within limits, Edit values
22	Entered input is not within the limits	Enter parameters within limit
23	Amount not within the limits - For mg, mcg, ng, g, mEq, mmol, kcal, unit, mU	Enter amount - 0.01 to 999999 <mg>*
24	Diluent not within the limits	Enter diluent - 0.1 to 999 mL
25	Auto calculated concentration not within the limits	Calculated conc. not within limits, Edit values
26	Patient info -weight not within the limits	Enter weight - 1 to 500 kg
27	Patient info - BSA not within the limits	Enter BSA - 1 to 6.5 m ²
28	Dosage not within the limits - For mg, mcg, ng, g, mEq, mmol, kcal, unit, mU	Enter dosage - 0.01 to 99999 <mg/kg/min>*
29	Auto calculated rate not within the limits	Calculated rate not within limits, Edit values
30	Rate not within the limits - 5 mL syringe loaded	Enter rate - 0.1 to 100 mL/hr
31	Rate not within the limits - 10 mL syringe loaded	Enter rate - 0.1 to 300 mL/hr

S.No	SCENARIO	FIELD ALERT DISPLAY
32	Rate not within the limits - 20 mL syringe loaded	Enter rate - 0.1 to 500 mL/hr
33	Rate not within the limits - 50/60 mL syringe loaded	Enter rate - 0.1 to 1200 mL/hr
34	Duration not within the limits (For each step)	Enter duration - 10 s to 99 hr
35	VTBI not within limits	Calculated VTBI not within limits, Edit values
36	KVO rate not within limits	Enter KVO rate - 0.1 to 5 mL/hr
37	KVO rate greater than infusion rate	Enter KVO rate $\leq$ Inf rate x.xx mL/hr
38	Standby time not within the limits	Enter standby time - 5 mins to 24 hrs
39	Entered input value reached upper limit	Value reached upper limit

* Units may vary

LED Functionality

S.No	Condition	Visual Signal				Audible Signal	User Confirmation
		Green Corner LED	Red Corner LED	Yellow LED	Cyan Blue LED		
1	Power On and POST	Yellow and Cyan Blue lit together Then Green, Yellow and Cyan Blue lit in sequence				-	No
2	Programming / Shutdown	Off	Off	Off	Lit	Invalid key press for wrong entry	No
3	Pump Running	Lit	Off	Off	Off	-	No
4	Standby	Flashing	Off	Off	Off	-	No
5	Infusion Paused / Infusion Stopped / KVO Stopped / Bolus Stopped / Completed	Off	Flashing	Off	Off	-	No
6	Log Transfer / PM Cycle	Off	Off	Off	Flashing	-	No
7	Emergency Alarms	Off	Flashing	Off	Off	High Priority	Yes
8	Warning Alarms	Off	Off	Flashing	Off	Medium Priority	Yes
9	Caution Alarms	Off	Off	Off	Lit	Low Priority	No
10	Battery Charging Indication (Pump powered off)	Flashing	Off	Off	Off	-	No
11	Battery Charging Complete (Pump powered off)	Lit	Off	Off	Off	-	No

6.5. Emergency Alarms List

In case of emergency alarms, return the pump to the biomed and use an alternate pump.

DISPLAY	CODE	CAUSE
Unit Malfunction	E102	Occlusion sensor wire breakage
	E103	Infusion failed due to error from microcontroller
	E104	Battery not found
	E105	SM bus error
	E106	Emergency controller communication fault
	E107	Emergency controller UART error
	E108	Prime failed
	E109	Speaker fault
	E110	POST failed
	E111	I2C communication error
	E112	Not able to read / write to the external flash
	E113	Battery cycle count exceeded the limit
System Error	E151	Motor stalled / fatal following error
	E152	Battery hot
	E153	Infusion start failed - Infusion start parameters set wrongly
	E154	Battery environment condition failure
	E155	Battery charge failed
	E156	Battery depleted
	E157	Battery data corrupted
	-	Watchdog reset

7. Time to Occlusion

The time to occlusion table shows the time to alarm according to the specific pressure, flow rate and the syringe.

Note:

0.1 mL/hr = Minimum Selectable Rate; 1 mL/hr = Minimum Rate; 5 mL/hr = Intermediate Rate.

Test condition: Temperature: 20°C ±2°C, Administration set: VEIN-O-LINE Extension Set (with male luer lock and 3-way stopcock), Romsons 200 cm

SYRINGE MAKE & SIZE	FLOW RATE (mL/hr)	OCCCLUSION LEVEL	TIME TO ALARM
HMD Dispo Van 5 cc	0.1	L1	> 45 min
		L5	> 10 hr
	1	L1	20 min
		L5	> 1 hr
	5	L1	3 min
		L5	15 min
Nipro 5 cc	0.1	L1	> 45 min
		L5	> 10 hr
	1	L1	20 min
		L5	> 1 hr
	5	L1	3 min
		L5	15 min
Becton Dickinson (BD) Luer-Lok™ Tip Syringe 5 cc	0.1	L1	> 45 min
		L5	> 10 hr
	1	L1	20 min
		L5	> 1 hr
	5	L1	3 min
		L5	15 min
HMD Dispo Van 10 cc	0.1	L1	> 1 hr
		L5	> 12 hr
	1	L1	20 min
		L5	> 1 hr
	5	L1	5 min
		L5	20 min

SYRINGE MAKE & SIZE	FLOW RATE (mL/hr)	OCCLUSION LEVEL	TIME TO ALARM
Nipro 10 cc	0.1	L1	> 1 hr
		L5	> 12 hr
	1	L1	20 min
		L5	> 1 hr
	5	L1	5 min
		L5	20 min
Becton Dickinson (BD) Luer-Lok™ Tip Syringe 10 cc	0.1	L1	> 1 hr
		L5	> 12hr
	1	L1	20 min
		L5	> 1 hr
	5	L1	5 min
		L5	20 min
HMD Dispo Van 20 cc	0.1	L1	> 1 hr
		L5	> 15 hr
	1	L1	20 min
		L5	> 1 hr
	5	L1	5 min
		L5	25 min
Nipro 20 cc	0.1	L1	> 1 hr
		L5	> 15 hr
	1	L1	20 min
		L5	> 1 hr
	5	L1	5 min
		L5	25 min

SYRINGE MAKE & SIZE	FLOW RATE (mL/hr)	OCCLUSION LEVEL	TIME TO ALARM
Becton Dickinson (BD) Luer-Lok™ Tip Syringe 20 cc	0.1	L1	> 1 hr
		L5	> 15 hr
	1	L1	20 min
		L5	> 1 hr
	5	L1	5 min
		L5	25 min
HMD Dispo Van 50 cc	0.1	L1	> 3 hr
		L5	> 25 hr
	1	L1	40 min
		L5	> 2 hr
	5	L1	6 min
		L5	>30 min
Nipro 50 cc	0.1	L1	> 3 hr
		L5	> 25 hr
	1	L1	40 min
		L5	> 2 hr
	5	L1	6 min
		L5	>30 min
Becton Dickinson (BD) Luer-Lok™ Tip Syringe 50 cc	0.1	L1	> 3 hr
		L5	> 25 hr
	1	L1	40 min
		L5	> 2 hr
	5	L1	6 min
		L5	> 30 min

Note: The occlusion pressure tolerance is as follows:

Level 1: 100 mmHg (50 to 200 mmHg)

Level 2: 300 mmHg $\pm$ 100 mmHg

Level 3: 500 $\pm$ 100 mmHg

Level 4: 700 $\pm$ 100 mmHg

Level 5: 900 $\pm$ 100 mmHg

Post occlusion bolus reduction

Using post occlusion bolus reduction, the pump withdraws the plunger a predetermined amount to reduce “stored” bolus in the syringe. However, this feature does not totally eliminate the occlusion bolus. Occlusion bolus will vary greatly with occlusion limit setting, syringe size, and the fluid infused. The post-occlusion bolus reduction feature decreases bolus on occlusion release to less than 0.6 mL.



Larger syringe sizes at high occlusion setting may produce a post occlusion bolus larger than 0.6 mL due to excessive syringe plunger tip compliance.

8. Unintended Bolus Volume Data (at 5 mL/hr)

Syringe Size	L1	L5
5 cc	≤ 0.15 mL	≤ 0.60 mL
10 cc	≤ 0.15 mL	≤ 0.55 mL
20 cc	≤ 0.2 mL	≤ 0.30 mL
50 cc	≤ 0.25 mL	≤ 0.45 mL

9. Start up and Trumpet Curves

Significance in clinical practice

Trumpet curves show the recorded maximum and minimum deviations in flow rate compared to the delivery rate per time interval. In clinical practice, the trumpet curve makes it easier for the treating doctor to decide if the pump is sufficiently precise for the administration of the desired drug.

- Reconcile drugs with short half lives, in particular, with the delivery accuracy in this period on the trumpet curve.

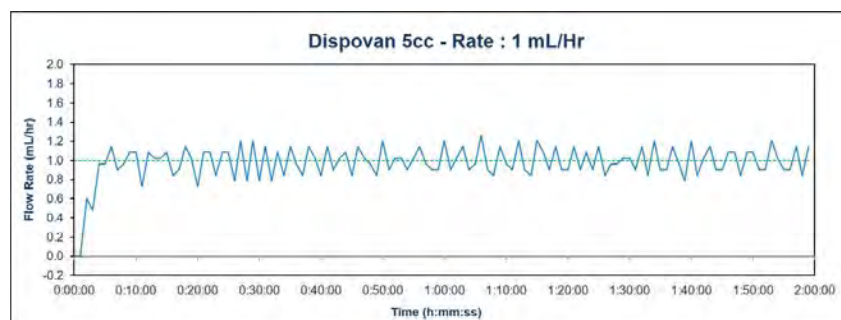
The physiological effect of the drug can be affected by the flow and the disposable article.

- Ensure that the prescription is in line with the start-up/trumpet curve and the set flow rate.

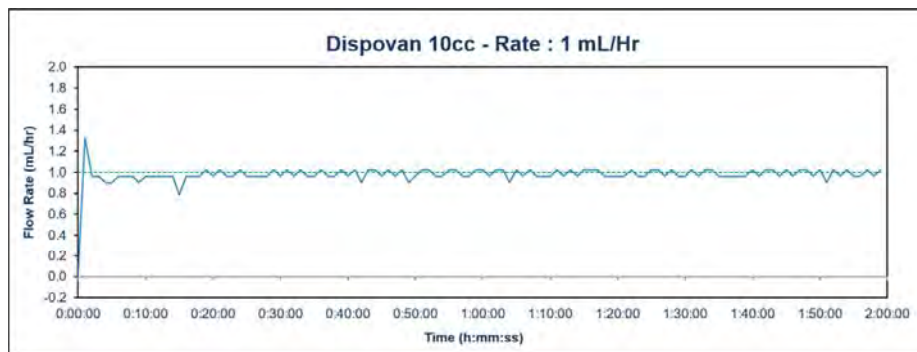
Typical start up and trumpet curves

Start up curves

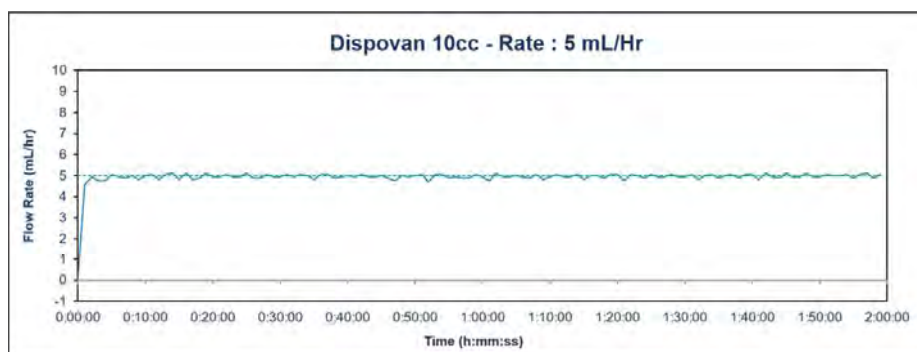
Start up curve at 1 mL/hr: HMD Dispo Van 5 cc



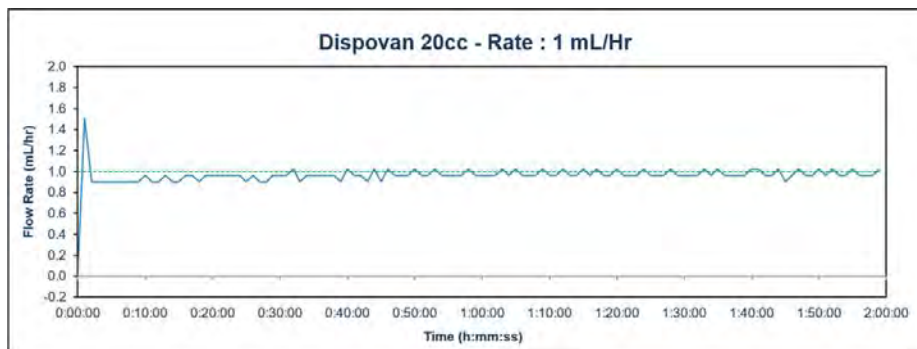
Start up curve at 1 mL/hr: HMD Dispo Van 10 cc



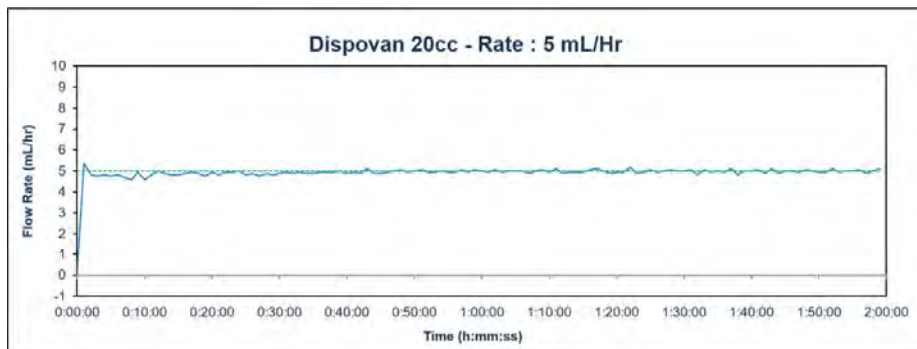
Start up curve at 5 mL/hr: HMD Dispo Van 10 cc



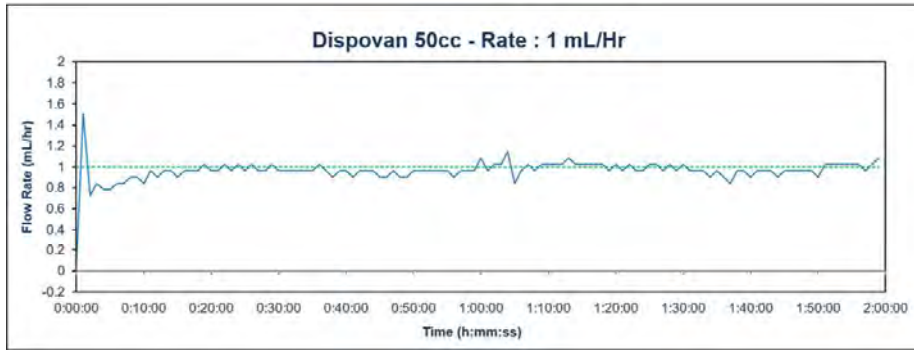
Start up curve at 1 mL/hr: HMD Dispo Van 20 cc



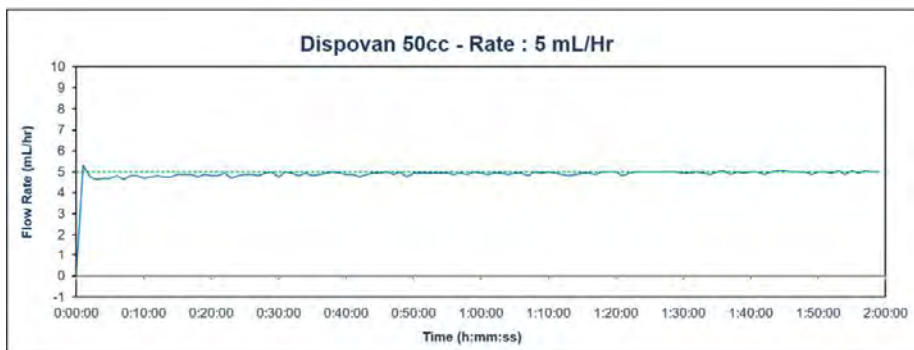
Start up curve at 5 mL/hr: HMD Dispo Van 20 cc



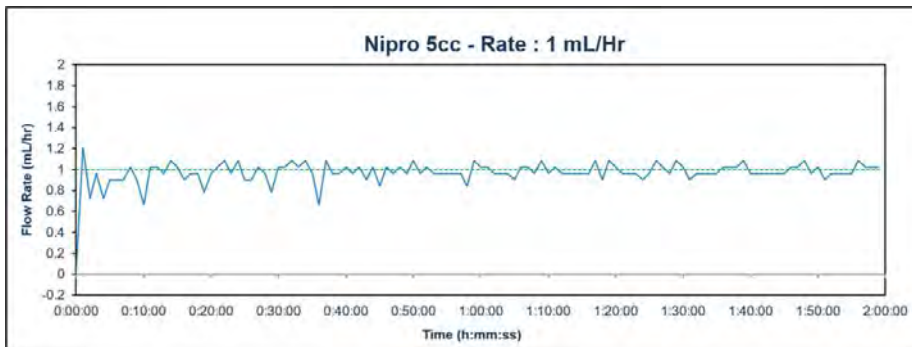
Start up curve at 1 mL/hr: HMD Dispo Van 50 cc



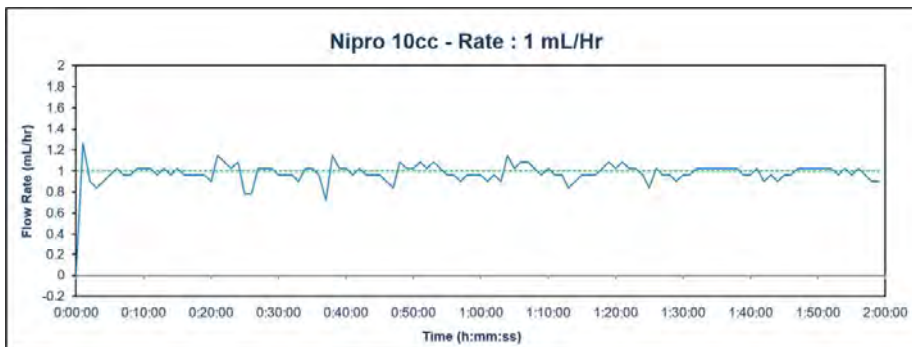
Start up curve at 5 mL/hr: HMD Dispo Van 50 cc



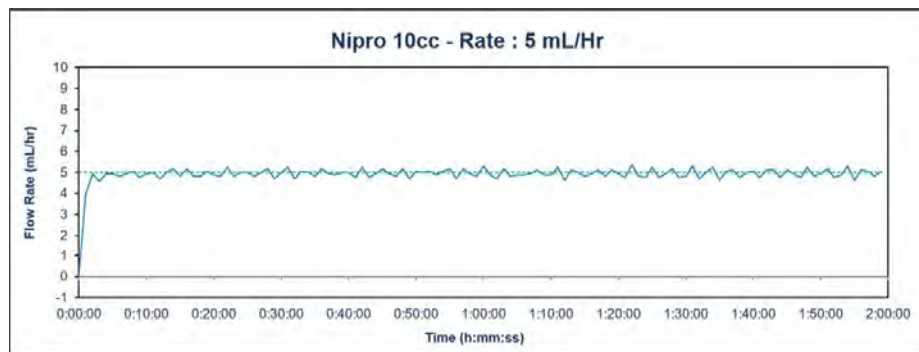
Start up curve at 1 mL/hr: Nipro 5 cc



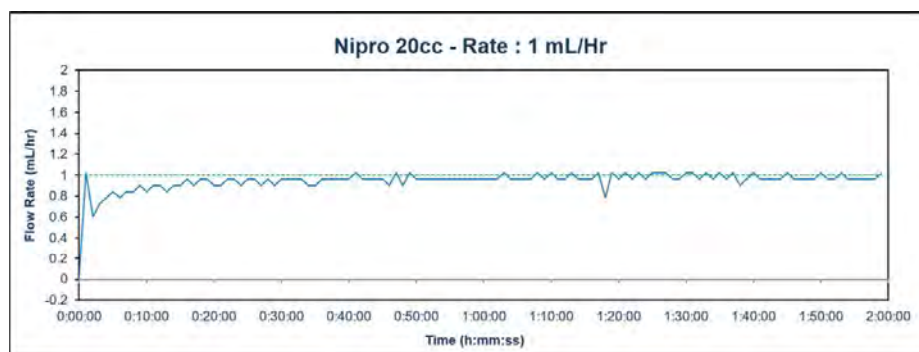
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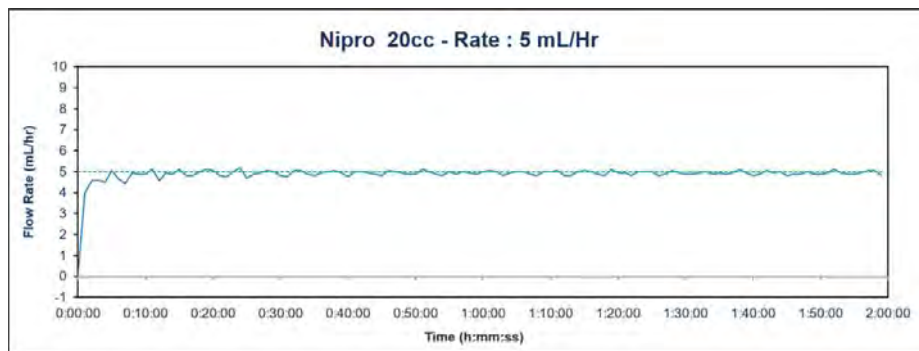
Start up curve at 5 mL/hr: Nipro 10 cc



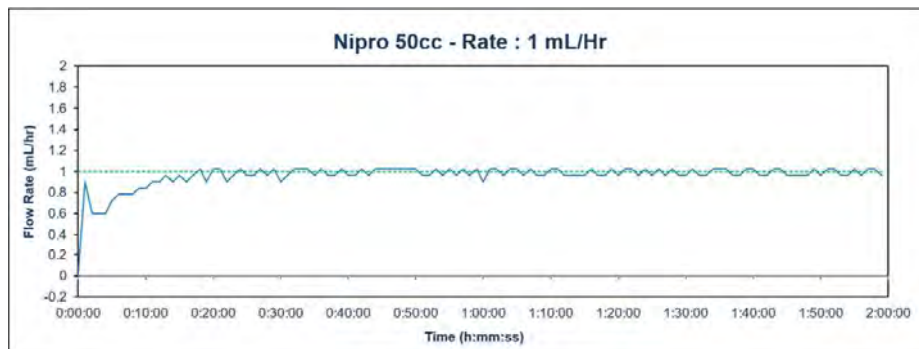
Start up curve at 1 mL/hr: Nipro 20 cc



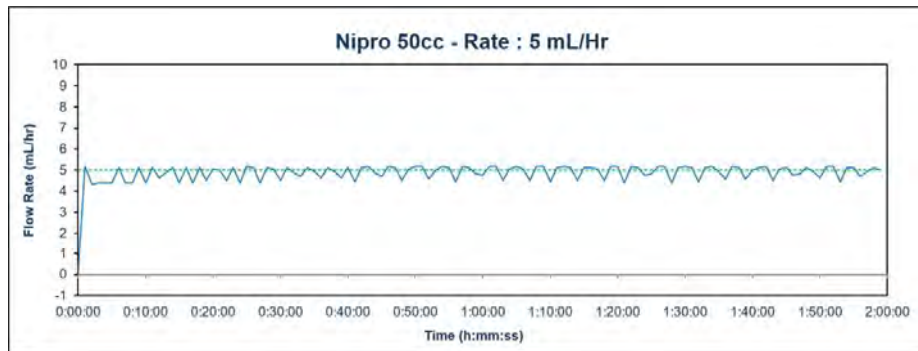
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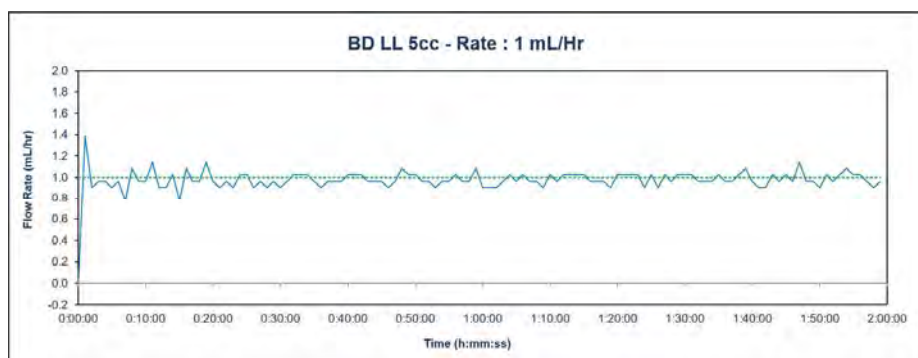
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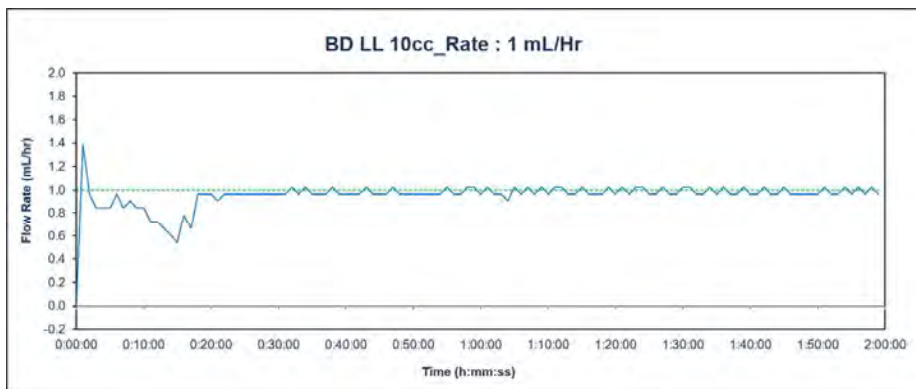
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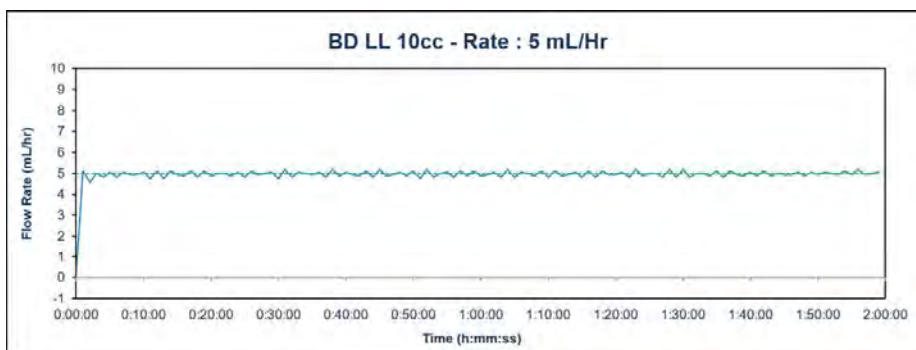
Start up curve at 1 mL/hr: Becton Dickinson (BD) Luer-Lok™ Tip Syringe 5 cc



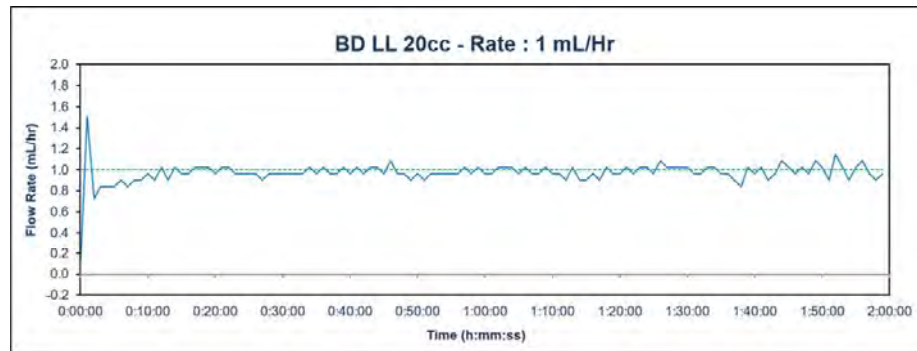
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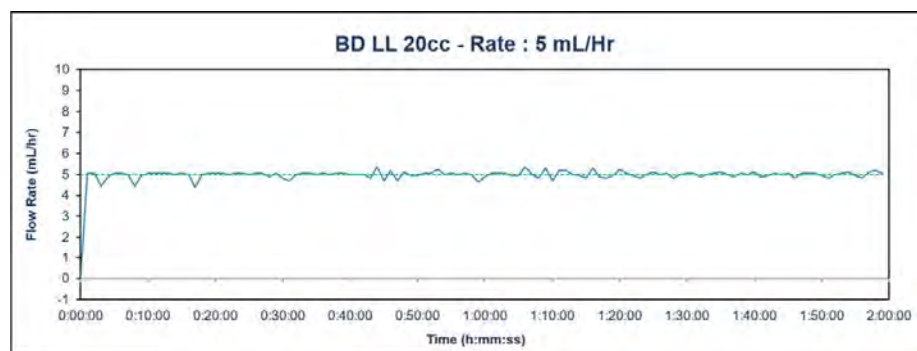
Start up curve at 5 mL/hr: Becton Dickinson (BD) Luer-Lok™ Tip Syringe 10 cc



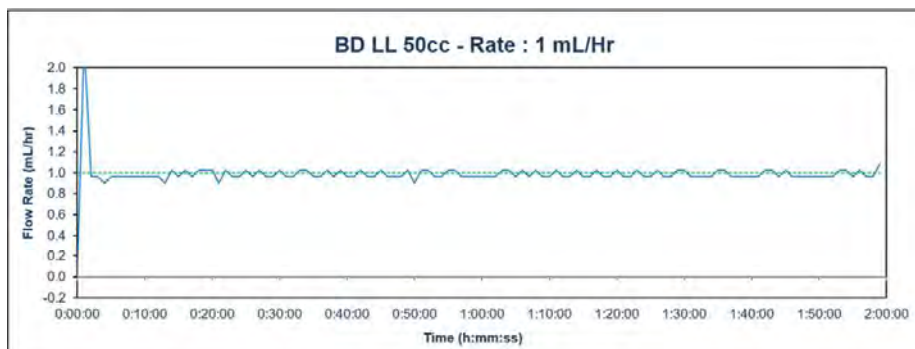
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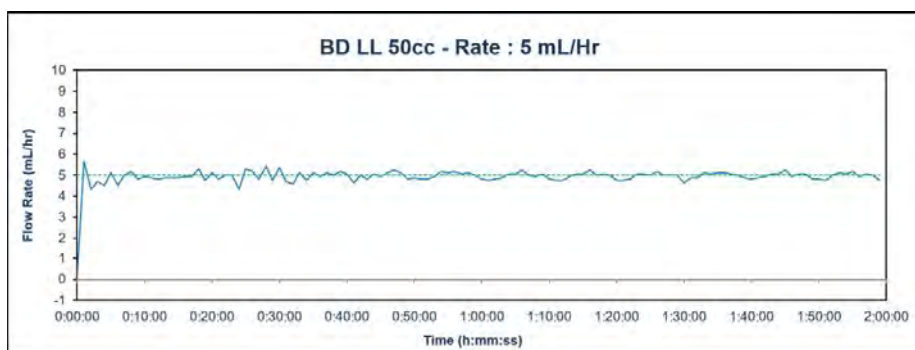
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Start up curve at 1 mL/hr: Becton Dickinson (BD) Luer-Lok™ Tip Syringe 50 cc

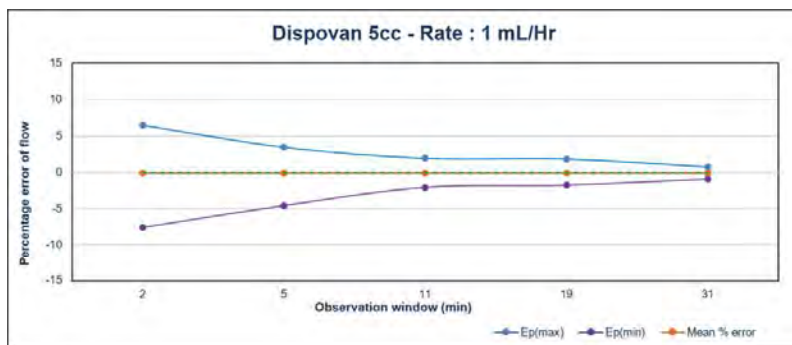


Start up curve at 5 mL/hr: Becton Dickinson (BD) Luer-Lok™ Tip Syringe 50 cc

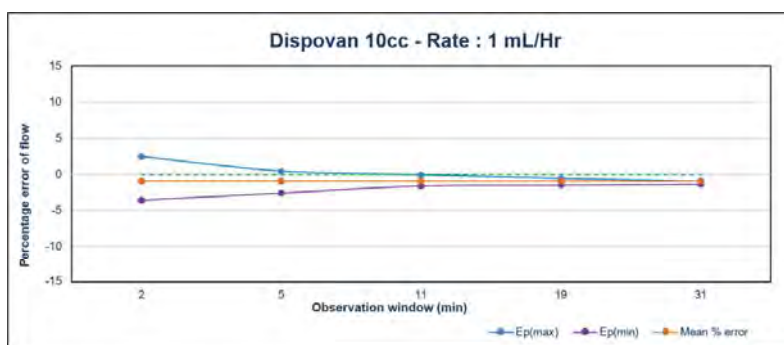


Trumpet Curves

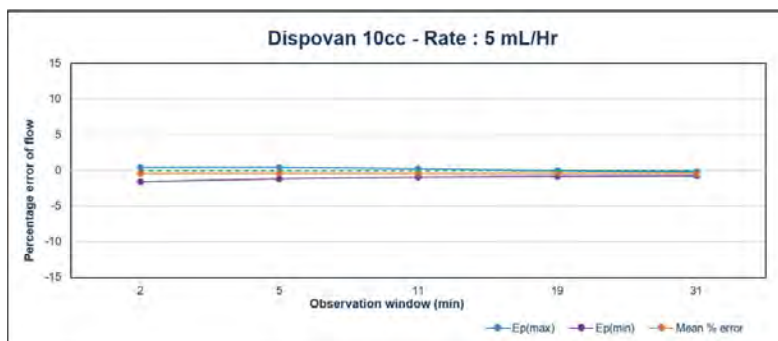
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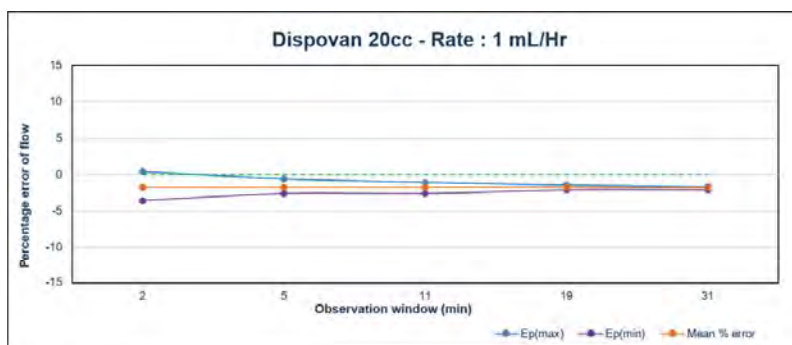
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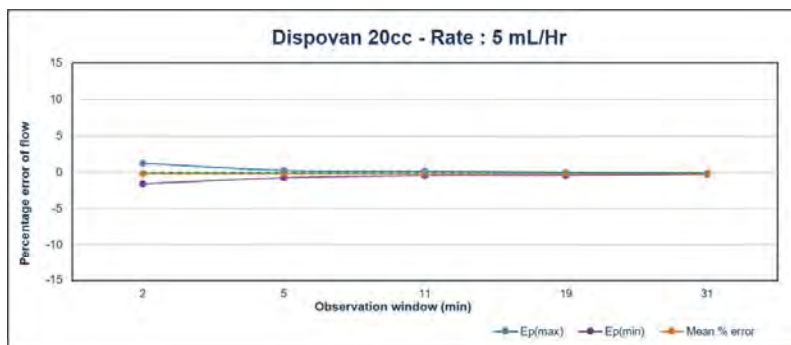
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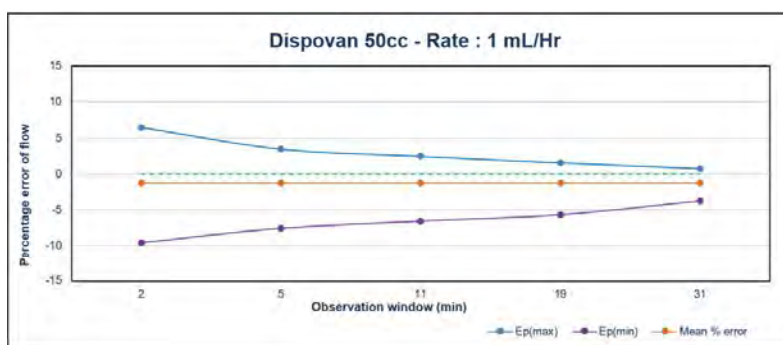
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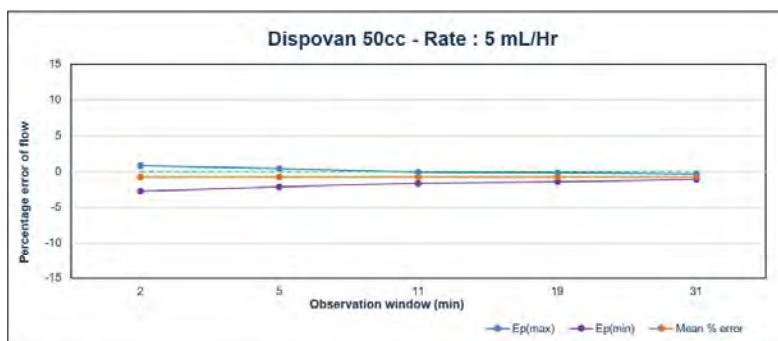
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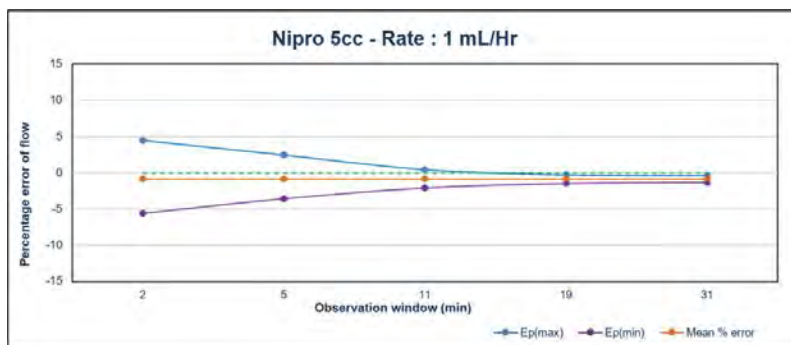
Trumpet curve at 1 mL/hr: HMD Dispo Van 50 cc



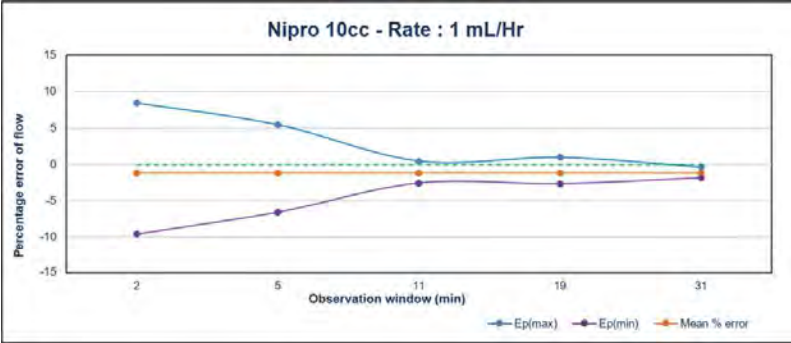
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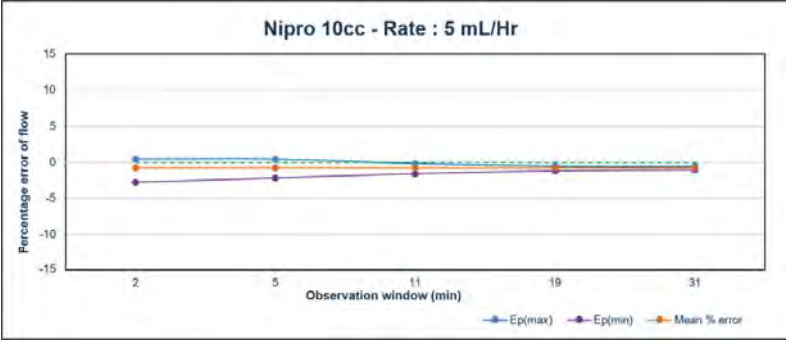
Trumpet curve at 1 mL/hr: Nipro 5 cc



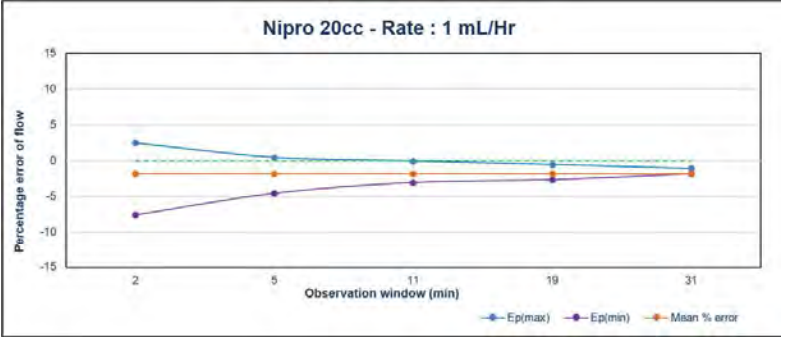
Trumpet curve at 1 mL/hr: Nipro 10 cc



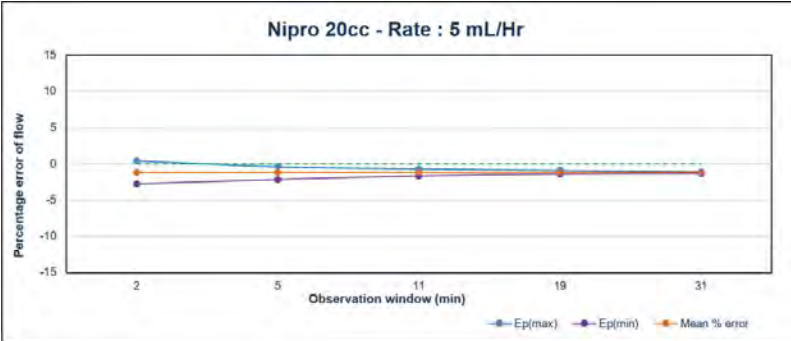
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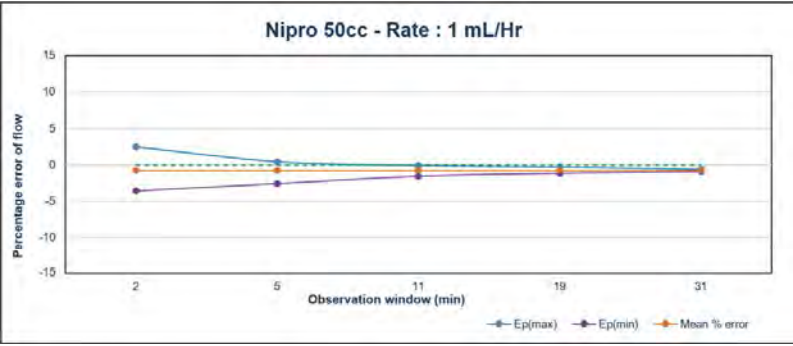
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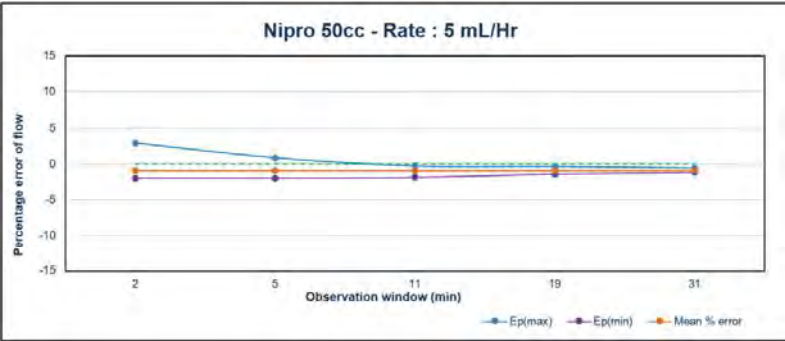
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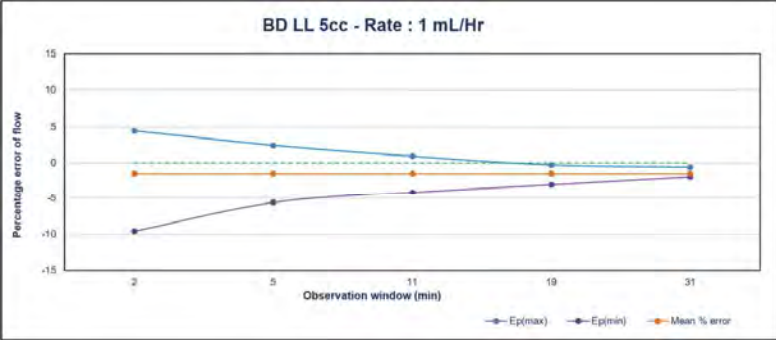
Trumpet curve at 1 mL/hr: Nipro 50 cc



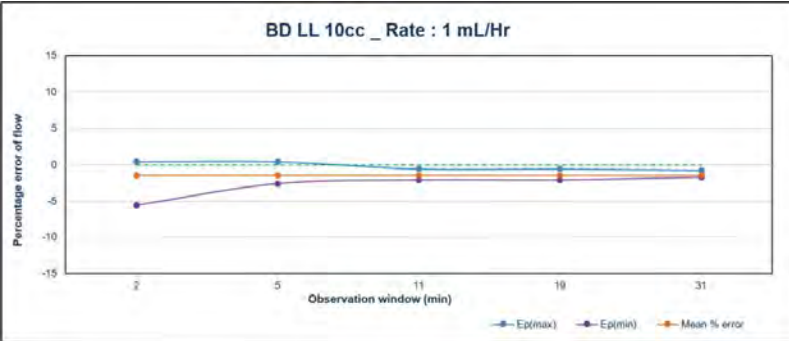
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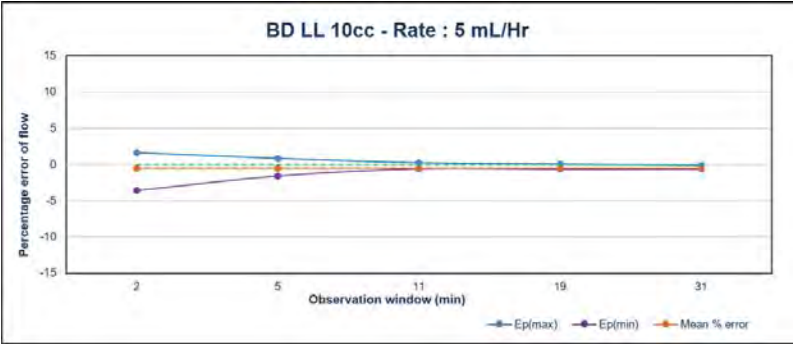
Trumpet curve at 1 mL/hr: Becton Dickinson (BD) Luer-Lok™ Tip Syringe 5 cc



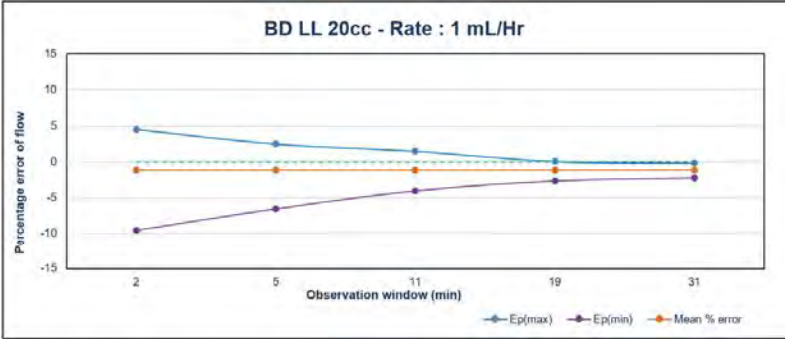
Trumpet curve at 1 mL/hr: Becton Dickinson (BD) Luer-Lok™ Tip Syringe 10 cc



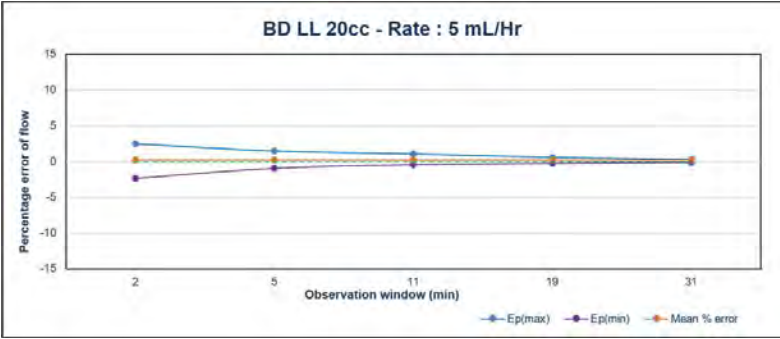
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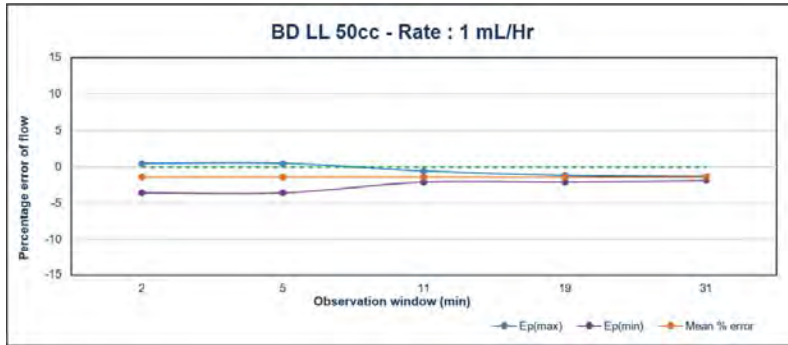
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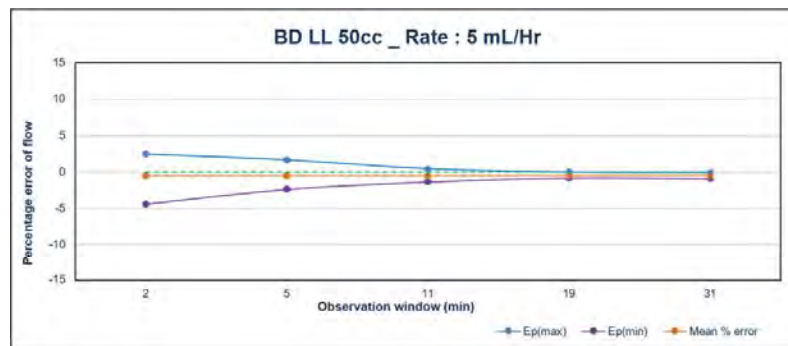
Trumpet curve at 5 mL/hr: Becton Dickinson (BD) Luer-Lok™ Tip Syringe 20 cc



Trumpet curve at 1 mL/hr: Becton Dickinson (BD) Luer-Lok™ Tip Syringe 50 cc



Trumpet curve at 5 mL/hr: Becton Dickinson (BD) Luer-Lok™ Tip Syringe 50 cc



Note: Every syringe has certain tolerances in start-up behaviour (depending on the syringe manufacturer, syringe plunger material, siliconisation of the cylinder etc.).

In order to keep the delay as short as possible, the syringe should be as small as possible and the plunger moved before the syringe is inserted in order to work through the rubber stopper's breakloose force behaviour.

The device is equipped with start acceleration, which enables a quick infusion start after each syringe change.

Note: Always use the device with the smallest possible syringe, provided the therapy permits this.

This is particularly important if highly concentrated or life-sustaining drugs with short half-lives are to be infused at low infusion rates.

When infusing at low rates and with large syringes, there can be deviations from the pump's technical data, which can lead to delivery deviations, delayed startup behaviour and longer alarm times in the event of system occlusions (pressure alarms).

Flow rates below 1 mL/hr are supported by the device but not recommended. Accuracy and alarm response at these rates may vary. The recommended rate for 5 mL, 10 mL, 20 mL and 50 mL syringes is ≥ 1 mL/hr.

These graphs show the accuracy and uniformity of flow over time. Take into account:

- The delivery behaviour and the delivery accuracy are fundamentally affected by the type of syringe used (disposable item).
- Deviations from the pump technical data cannot be ruled out for competitors' syringes.

Note: The system accuracy is normally $\pm 2\%$ of the volume, measured using the trumpet curve test method according to IEC 60601-2-24 at a rate of 5 mL/hr (at $20\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$) and using the recommended syringes.

Start up curves	
Measurement interval	$\Delta t = 0.5\text{ min}$
Measurement duration	$T = 120\text{ min}$

Trumpet curves (Measured values for second hour in each case)	
Measurement interval	$\Delta t = 0.5\text{ min}$
Observation interval	$p \times \Delta t\text{ [min]}$

10. Cleaning

Power off the pump and gently wipe the pump with alcohol swabs.

The cleaning agents / solutions should not contain any of the ingredients like acetaldehyde, acetone, ammonia, benzene, hydroxyl-toluene, methylene chloride or ozone.

Cleaners containing N-alkyl ethyl benzyl dimethyl ammonium chloride may not be used as well. This will apply to all contact areas like overlay keys and the display.

Corrective Maintenance

If the pump does not work well, we advise to control that there is not a fault in the commands.

In case the pump is submitted to mechanical and external solicitations, for example after a heavy fall, or if the pump is submitted to liquids, or to strong overheating (for example direct light of the sun, fire), or if some parts of the cover are broken, or if some connectors or cables are consumed, the equipment and the accessories should be handled by the qualified personnel.

Maintenance by the User

- Regularly maintain and check the pump and its parts.
- When using the pump after a prolonged period of inactivity, confirm normal and safe operation beforehand.

Daily Checks

- Do not store the pump where there is dust.
- When not in use, turn off the power.
- Check for drug spillage. Wipe the device regularly.
- Check if the battery is charged.
- Check for any physical damage or broken parts.
- During every power on, check if the LED indicators are working properly.
- Check for any unusual noise or vibrations.
- Check if any object is stuck in the moving parts.

Weekly Checks

- Check the plunger jaws for breakage.
- Make sure to retrieve logs.

Monthly Checks

- Check if the date and time settings are correct.
- Check the battery health.

Yearly Checks

- Perform the Preventive Maintenance Cycle checks.
- Check for the legibility of the labels on the device.

11. Troubleshooting

Issue	Recommended Actions
The pump is unstable when mounted.	• Check that the rotating pole clamp is fastened
The pump is damaged, the parts are broken or if there are any abnormalities (like unusual noise, excessive heat or smoke).	• Remove the power cord • Contact your biomed or your vTitan sales representative immediately
The pump has been dropped or was subjected to a force that might have caused internal damage.	• Do not use the pump • Contact your biomed or your vTitan sales representative
The pump does not start after pressing Start key	• Connect the pump to the AC power supply to check if the battery is fully discharged • Contact your biomed or your vTitan sales representative
There is drug spillage while infusion is in progress	• Do not use the pump • Contact your biomed or your vTitan sales representative

Issue	Recommended Actions
Flow rate variance is higher than flow rate accuracy	• Check the infusion line configuration • Check the fluid viscosity • Check that the fluid temperature is within the recommended range • Contact your biomed or your vTitan sales representative
Keypad / LEDs are not working properly	• Check the condition and operation of the keys. • Check the LEDs • Contact your biomed or your vTitan sales representative
Display is not working properly	• Contact your biomed or your vTitan sales representative
Battery is not working properly	• Check the battery health in PM cycle test • If the battery cycle count exceeded, contact your biomed or your vTitan sales representative
The syringe is not detected	• Check if the syringe is loaded properly • If the issue persists, contact your biomed or your vTitan sales representative
Alarm sounds are not heard properly	• Ensure that the volume settings in the device are appropriately adjusted • Ensure there is no blockage in the speaker holes • Contact your biomed or your vTitan sales representative
The clutch gets disengaged	• Contact your biomed or your vTitan sales representative
The power supply indicator does not light up	• Connect the pump to the AC power supply • If the issue persists, contact your biomed or your vTitan sales representative
The pump shuts down on its own	• Connect the pump to the AC power supply • If the issue persists, contact your biomed or your vTitan sales representative
The software freezes in between the operation	• Restart the pump • If the issue persists, contact your biomed or your vTitan sales representative
The battery alarm is ON even though the pump has been correctly charged.	• Check the AC power voltage • Contact your biomed or your vTitan sales representative
The pump powers off when it is disconnected from the AC power supply	• If the battery is depleted, charge the battery • Contact your biomed or your vTitan sales representative

Do's and Don'ts

Do's	Don'ts
Keep the syringe pump and infusion site dry	Do not expose the pump to direct sunlight or extreme temperatures
Confirm that the syringe is properly loaded in the pump	Do not place the pump next to hot or flammable substances
Always confirm the set parameters before pressing the start button	Do not immerse the syringe pump in water
Keep all medication in a safe place away from children	Do not drop the syringe pump
Check the condition of the pump before using it	Do not cover the pump
Clean the pump as per the cleaning procedure specified in this manual	Do not use a defective pump
Use and store the pump in the operating and storage conditions specified in this manual	Do not use damaged power cord
Mount the pump on a stable pole clamp	Do not move the pump while infusion is in progress
Perform regular maintenance checks	Do not use an electric dryer to dry the pump

12. Storage

The pump shall be stored in a dry place. Store the pump under the temperature and humidity limits specified in **Section 18** of this manual.

Please refer **Section 20.5** for additional information related to pump storage.

13. Service

- Do not attempt to dismantle / service the pump.
- In case of any malfunction contact the dealer / manufacturer.
- Only company representative / service personnel are authorized to perform any service.
- Please do not perform any modifications on the pump.
- The manufacturer / dealer / representative shall not responsible for any unauthorized service / repair / modification on this pump.

14. Maintenance Requirements

To ensure that the pump continues to operate normally, follow the instructions below:

- Preventive maintenance should be performed by trained and qualified technical personnel in compliance with the technical manual and procedures. Only authorized service personnel should attempt to repair the pump.
- The qualified personnel must be informed if the pump is dropped or if any malfunctions occur. In this case, do not use the pump and contact your biomedical department or vTitan
- Failure to comply with these maintenance procedures could damage the pump and lead to a functional failure. Internal inspection of the pump requires compliance with special procedures to avoid damage to the pump.

If the pump needs upgrading, vTitan or its representative will provide relevant instructions. It is the healthcare facility's responsibility to follow vTitan's instructions.

15. Device Lifetime

To ensure the pump continues to operate normally, follow the instructions below:

- 300 cycles of battery recharge.
- The pump can be used up to 7 years if the user / buyer enters a service and maintenance plan with the manufacturer once the first 300 cycles of battery recharge is completed.

16. Requirements

16.1. General Requirements

Specification	Description
Life Cycle	The device can be used up to 7 years if the user / buyer enters a service and maintenance plan with the manufacturer once the first 300 cycles of battery recharge is completed.
Operating Temperature Range	The device can be operated from +5 °C to +40 °C
Storage Temperature Range	The device can be stored from -10°C to +50°C
Operation Humidity Range	The device can be operated from 15% to 90% humidity

Specification	Description
Storage Humidity Range	The device can be stored from 10% to 90% humidity
Operating Atmospheric Pressure Range	The device can be operated from 70 kPa to 106 kPa atmospheric pressure
Storage Atmospheric Pressure Range	The device can be stored from 50 kPa to 106 kPa atmospheric pressure
RoHS	The entire device hardware complies to RoHS Directive 2011/65/EU (RoHS 2) supplemented by 2015/863/EU
Applied Part	Type CF

16.2. Basic Hardware Requirements

Specification	Description
Microcontroller	480 MHz, 32-bit ARM Cortex M7 MCU
Safety Microcontroller	32 MHz, 32-bit ARM Cortex M0 MCU
Wi-Fi Module	2.4 GHz / 5 GHz Module, wireless network processor
Wi-Fi Certification	CE, FCC, ISED, MIC, Wi-Fi CERTIFIED Chip
Battery type	Lithium ion, 4S1P, 3200 mAh
Battery charge duration	5 hours (approx.)
Battery runtime	Up to 13 hours
Power down mode	800 uAmps
Active mode	During Charging mode 1.2 Amps (Max)
Active mode (Battery)	0.3 Amps (During Infusion) 0.6 Amps (During Occlusion)
Battery shelf life duration (idle state)	3 months

Specification	Description
RTC power supply	Non-rechargeable coin cell
RTC Accuracy	±10 seconds per month
Internal Adapter	19 VDC, 2.1 Amps, Medical Grade
Maximum output Voltage	19 VDC (Adapter) 16.8 VDC (Battery)
Charge current accuracy	±2%

16.3. Software and User Interface Requirements

Software Requirements

Specification	Description	
Operating System	Android 11 and above	
Communication	Wi-Fi	
API (Application Programming Interface) Requirements	Accuflex VE Syringe Pump Configuration application	- IDE: Android Studio Meerkat 2024.3.1 - Java Runtime Environment: 21 - Android SDK: 30 and above

User Interface Requirements

Specification	Description
LCD Display	3.5-inch 320x240 pixel resolution
LED Light indication for status of the pump	- Green Corner LED while Infusing - Cyan LED for Programming and Caution Alarms - Yellow LED for Warning Alarms - Red Corner LED for Emergency Alarms
Keypad	11 dedicated membrane switches to get user input
System Settings	The system setting feature allows the user to modify the alarm sound, screen brightness and the number of drugs from the master list
Battery Status	If the battery cycle count goes beyond 250 cycles, the pump shall prompt the user with an alarm
Alarm Management	The pump is designed to raise 3 categories of alarms classified as - Caution - Warning - Emergency
Auditory Feedback	The pump is equipped with a speaker to provide auditory feedback to the user. The speaker is used for key press feedback and audio feedback for alarms
Infusion Programming - Selecting syringe make and size	- The user selects the make and size (auto detected by software) of the syringe to proceed with the Infusion programming - The user will select the syringe make from the list of supported syringes. - The pump will allow the user (caregiver) to configure (enable / disable) the syringes to be used from the master list of syringes supported by vTitan - The pump enables the user to program an infusion by entering the infusion rate
Pairing pump with application	Establishes a wireless connectivity (Wi-Fi) module to transmit data between the pump and the Android application for log transfer, drug list update, syringe list update and bed ID update.

16.4. Safety and Security Requirements

Specification	Description
Battery Safety Feature	OVP, OCP, SCP, thermal shut down protection, charge over current protection, Input over current protection, battery overvoltage protection The hardware allows charging of the battery only in the temperature range of 0-45 °C
Emergency Microcontroller	If main battery and adapter fail, the emergency controller that monitors it shall trigger secondary buzzer
Fuse	The hardware provides fuse for limiting currents in case of short circuits on the board
External Watchdog	The hardware shall have an independent watchdog circuit that will reset the micro controller if it hangs
Supply Monitoring	The hardware shall have an external supervisory that will reset the micro controller if any power on reset or Brown-out reset occurs

17. Member States the Pump is to be Sold

Apart from India, the pump is to be sold in the following EU countries:

Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden.

18. Technical Specifications

Note: The delivery accuracy, pressure alarm and alarm reaction times apply at room temperature and with water as the test material. Different media viscosities and temperatures may lead to deviations.

PARAMETER	VALUE
Dimensions	275 x 120 x 108 mm (L x W x H)
Weight	2.3 kg
Display	3.5 inch Colour LCD
Syringe Capacities	5, 10, 20, 50 / 60 mL

PARAMETER	VALUE
Flow Rate Range	0.1 - 100 mL/hr (5 mL syringe) 0.1 - 300 mL/hr (10 mL syringe) 0.1 - 500 mL/hr (20 mL syringe) 0.1 - 1200 mL/hr (50 / 60 mL syringe)
VTBI Range	0.1 – 999 mL
Accuracy	Mechanical Accuracy: $\pm 1\%$ Flow Rate Accuracy: $\pm 2\%$ (as per IEC 60601-2-24 standard)
Bolus	Manual and Auto Bolus
Bolus Rate	50 - 300 mL/hr (5 mL syringe) 50 - 600 mL/hr (10 mL syringe) 50 - 900 mL/hr (20 mL syringe) 50 - 1500 mL/hr (50 / 60 mL syringe)
KVO Rate	0.1 – 5 mL/hr
Drug List	>200 Drugs (Preloaded and Configurable)
Mode of Operation	Continuous
Infusion Modes	Rate Mode, Volume / Duration Mode, Dosage Rate Mode, Multi-Step Mode
Occlusion Setting	5 levels (100 – 900 mmHg)
Alarms	Occlusion, Syringe Disengaged, Syringe Near Empty, Syringe Empty, Infusion Near End, Infusion Complete, Unit Malfunction, System Error
Maximum volume infused under single fault conditions	≤ 1 mL
Maximum infusion pressure generated	1000 mmHg
Screen Lock Function	Available
Mains Power	100 - 240 V AC, 50 - 60 Hz
Battery	Li-Ion Battery Rating: 3200 mAh Operating Time: Upto 13 hr (at 5mL/hr) Charging Time: 5 hr (approx.)

PARAMETER	VALUE
Communication	Wireless connectivity (Wi-Fi)
Operating Conditions	Temperature: 5 to 40 °C Relative Humidity: 15 to 90 % Atmospheric Pressure: 70 kPa to 106 kPa
Storage and Transportation Conditions	Temperature: -10 to 50 °C Relative Humidity: 10 to 90 % Atmospheric Pressure: 50 kPa to 106 kPa
Warranty	2 years from the date of shipment
Product Classification	Class IIb, according to REGULATION (EU) 2017/ 745
Safety Classification	
Ingress Protection	IP34
Electrical Safety Class	Class II, according to EN 60601-1
Protection from Electric Shock	Type CF

Note: The infusion accuracy tests and occlusion pressure tests are performed in accordance with IEC 60601-2-24:2012 (test temperature: 20°C ± 2°C).

Note: When storing the pump, ensure that the following conditions are met.

- The pump should not be splashed with water.
- Store the pump where air pressure, temperature, humidity, ventilation, sunlight, dust, salty / sulfurous air, etc. do not give any negative side effect.
- Do not store or transport the instrument on a slope or uneven surface or in an area where it is subject to vibrations or instability.

19. Electromagnetic Compatibility

Medical electrical pumps are subject to special precautionary measures with regard to electromagnetic compatibility (EMC). They must be installed and used in accordance with the EMC information contained in this document.

The device meets the requirements of IEC 60601-1-2.



Warnings:

The use of this pump next to or stacked with other equipment should be avoided, as this could result in incorrect operation. If use in the manner described above is necessary, this device and the other equipment should be observed to ensure that they are working properly.

Portable RF communications equipment (including peripheral devices such as antenna cables and external antennas) should be used no closer than 0.5 m to any part of the device including cables specified by the manufacturer. Otherwise, the performance of this device may be negatively impacted.

The use of accessories, converters and cables that are not specified or provided by the manufacturer of this device can lead to increased electromagnetic emissions or decreased electromagnetic immunity of this device and improper operation.

This device is intended for use in professional healthcare facility environment only. If it is used in special environment, such as magnetic resonance imaging environment, the equipment / system may be disrupted by the operation of nearby equipment.

19.1 Electromagnetic Interference Emissions

Guidance and manufacturer's declaration – Electromagnetic Emissions for all ME Equipment and ME Systems		
EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Conducted Emissions CISPR 11	Group 1	The device uses RF energy only for internal operation. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment.
Radiated Emissions CISPR 11	Class A	The device is suitable for use in professional healthcare facilities and similar environments. It complies with Class A emission limits intended for industrial and medical environments.

Guidance and manufacturer's declaration – Electromagnetic Emissions for all ME Equipment and ME Systems

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Harmonic Emissions IEC 61000-3-2	Conforms	The device complies with the limits for harmonic current emissions specified in IEC 61000-3-2.
IEC 61000-3-3 Voltage Fluctuations / Flicker Emissions	Conforms	The device complies with the limits for voltage fluctuations and flicker specified in IEC 61000-3-3.

19.2 Electromagnetic Immunity

Guidance and manufacturer's declaration – Electromagnetic Immunity

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Electrostatic discharge (ESD) IEC 61000-4-2	Contact discharge ± 8 kV	±6 kV without disturbance ±8 kV temporary disturbance with automatic recovery	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
	Air discharge ± 15 kV	±6 kV without disturbance ±15 kV temporary disturbance with automatic recovery	
Radiated RF EM Fields IEC 61000-4-3	3 V/m (80 MHz to 2.7 GHz)	3 V/m	Portable RF communication equipment should be used no closer than the recommended separation distance.
Electrical fast transient / burst IEC 61000-4-4	±2 kV on AC power lines	± 2 kV	Mains power quality should be that of a typical commercial or hospital environment.

Guidance and manufacturer's declaration – Electromagnetic Immunity

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Conducted RF disturbances IEC 61000-4-6	3 Vrms (150 kHz to 80 MHz), 80% AM at 1 kHz	3 Vrms outside ISM bands 6 Vrms within ISM bands	The device should maintain normal operation in the presence of conducted RF disturbances on power or signal lines.
Power frequency magnetic field (50 / 60 Hz) IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields should be at levels typical of those found in professional healthcare environments.
Voltage dips and short interruptions IEC 61000-4-11	0% UT (0.5 cycle), 0% UT (1 cycle), 70% (30% dip) UT (25 cycles), 0% UT (250 cycles)	0% UT (0.5 cycle), 0% UT (1 cycle), 70% (30% dip) UT (25 cycles), 0% UT (250 cycles)	If continuous operation is required during power interruptions, the device should be powered from an uninterruptible power supply or battery.
NOTE 1 UT is the AC mains voltage prior to application of the test level.			

Recommended separation distances between portable and mobile RF communications equipment and Accuflow VE Syringe Pump

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

RATED MAXIMUM OUTPUT POWER OF TRANSMITTER (W)	SEPARATION DISTANCE ACCORDING TO FREQUENCY OF TRANSMITTER (m)	
	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.23
0.1	0.38	0.73
1	1.2	2.3
10	3.8	7.3

For transmitters at a maximum output power not listed above, the recommended separation distance in meters (m) can be determined 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 higher frequency range applies.

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

20. Battery Maintenance

Battery Type: Li-ion battery

Operating Time: Up to 13 hr

20.1 Battery Operation

The pump is typically operated by AC (mains) power.

The pump contains an internal rechargeable battery that is continually charged as long as the pump is connected to AC power. If the AC power is disconnected while the pump is turned on, the pump automatically starts operating on the internal battery.

The internal battery is intended to allow infusions of medications and fluids when an external power outlet is not available or when the patient is being moved.

20.2 Charging the Battery

If the “Battery Low” message is displayed, plug the pump into a power outlet for recharging. The battery indicator remains on continuously while charging. If the pump is plugged into an outlet and fails to charge the battery, or the pump has been stored for longer than two months without charging, contact vTitan service personnel for information on how to test and / or service the battery.

20.3 Battery Depletion

When the battery becomes fully depleted, all infusions stop, and a “Battery Depleted” alarm appears on-screen and the alarm is audible. For a fully depleted battery, plug in the AC power cord, turn the pump off to clear the alarm, and then turn the pump back on. Leave the pump plugged in for at least 6 hours to completely recharge the battery.

20.4 Replacing the Battery

During power on, if the battery cycle count crosses 300 cycles, the pump raises an alarm “Battery Cycle Count Exceeded”.

Press the Enter key to shutdown the pump. Then, handover the pump to biomed or vTitan service personnel to replace the battery.

20.5 Pump Storage

Keep the pump’s battery in charged condition if the pump is stored for a period of more than 2 months. Connect the pump to the power cord once in a month till the battery status indicator shows full. Do not leave the pump with the power cord connected after the full battery storage indicator.

To extend the pump’s life, store the pump under conditions mentioned in **Section 18 - Technical specifications**.

21. Packing List

DESCRIPTION	QUANTITY
Syringe Pump	1 no.
Power Cord	1 no.

22. Warranty

vTitan Corporation Pvt. Ltd. (the manufacturer) warrants to the original purchaser that the Accuflow VE Syringe Pump (the pump), not including accessories, shall be free from defects and materials and workmanship under normal use, if used in accordance with this instructions for use, for a period of two (2) year from the actual date of sale to the original purchaser.

There are no other warranties implied.

This warranty does not cover normal wear and tear and maintenance items, and specifically excludes batteries, IV sets, extension sets or any other accessory items or equipment used with the pump.

The pump being repaired by someone other than the authorized personnel or use of unauthorized service / replacement parts will void the warranty. Removal or damage to the seal will also void the warranty.

Subject to the conditions of and upon compliance with this limited warranty, the manufacturer will repair or replace at its option without charge (except for a minimal charge for postage and handling) any pump (not including accessories) which is defective if a claim is made during such a two year period.

Note: Any serious incident that has occurred in relation to the pump should be reported to the manufacturer and the competent authority of the Member state in which the user and / or patient is established.

23. Declaration of Medical Substances

By design, this vTitan product does not incorporate any medicinal substances.

24. Disposal

Dispose the pump according to local disposal and recycling laws.



This pump must not be disposed of with household waste; it must be taken to a collection point for electrical and electronic equipment.

Some parts of the pump contains material which must be disposed in special areas designated by the local health authorities or other local regulations at the end of the pump's life cycle.

In particular, the pump contains the following material and / or components:

1. Enclosure & Accessories: Contains non-biodegradable plastic material and Metal Parts.
2. Pump Assembly: Contains PCB Assemblies, Copper wires with PVC sleeves, Steel springs & Steel Screws and nuts.
3. PCB Assembly: Contains Semiconductors, Glass Epoxy material and metals Tin, Silver, Gold & Copper.

The Manufacturer and the Distributor do not accept any responsibility for the disposal of equipment or parts discarded by the user and the related costs.

25. Additional Information

- All operations for this pump are mentioned in this user manual. No special operating instructions are required for the intended use of this pump.
- Inspect the wires and connectors before and after every use. If any part needs replacement, then inform the dealer / manufacturer for spare.
- Inform the dealer / manufacturer if the labels on the pump are peeled off.
- Frequently used functions for this pump are the User Interface Keypad, Barrel clamp, Plunger Lever and Plunger Head
- Use only CE approved syringes and IV sets.
- IV sets will not be provided by the manufacturer.
- If the pump / software freezes while using, then the physician shall restart the pump manually.

26. Technical Support

vTitan Corporation Pvt. Ltd.

New Woodlands Building, Estancia IT Park,
Plot no. 140, 151, GST Road, Vallancheri,
Chengalpattu District - 603 202, India.

Email: support@vtitan.com

Website: www.vtitan.com

Toll Free Number: 18005721664

27. Notified Body

Intertek Medical Notified Body AB

Torshamnsgatan 43, Box 1103
SE-164 22 Kista
Country : Sweden

28. Product Details

Product Name - Accuflow VE Syringe Pump

Designed and Developed in India

Manufacturing License Number: MFG/MD/2022/000296

Model Number: VE-002