Avoset Infusion Pump

User Manual

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Technical Assistance	For technical questions and troubleshooting assistance please contact your local agent/distributor, or contact us via email: support@eitanmedical.com.
Serious Incident Reporting	Any serious incident that has occurred in relation to the device should be reported to complaints@eitanmedical.com and to the local competent authority.
Bluetooth License	Avoset is qualified under Bluetooth SIG and has licensee right to use the Bluetooth trademarks.
CE Mark	The CE symbol represents adherence to the Medical Device Regulation 2017/745 of the European Communities concerning medical devices. The electromagnetic compatibility (EMC) requirements are part of the General Safety and Performance Requirements of the Medical Device Regulation.

Terms and Conditions

The Avoset Infusion Pump User Manual is delivered subject to the conditions and restrictions listed in this section. Clinicians, qualified hospital staff, and home users should read the entire User Manual prior to operating the Avoset Infusion Pump in order to fully understand the functionality and operating procedures of the pump and its accessories.

- Healthcare professionals should not disclose to the patient the pump's security code or any other information that may allow the patient access to restricted programming and operating functions.
- Improper use may cause injury or death to the patient.
- Home users of the Avoset Infusion Pump should be instructed on the proper use of this pump. Contact Q Core Medical or your local agent/distributor for training.
- The pump’s warranty will be null and void and the manufacturer will assume no responsibility for incidents which may occur if the product is not used in accordance with product labeling and documentation.

Contact your local agent/distributor as needed.

Prescription Notice

Federal United States law restricts this device for sale by or on the order of a physician only {21CFR 801.109(b) (1)}.

The Avoset Infusion Pump is for use at the direction of, or under the supervision of, licensed physicians and/or licensed healthcare professionals who are trained in the use of the pump and in the administration of parenteral and enteral infusions. The instructions for use presented in this manual should in no way supersede established medical protocol concerning patient care.

Disclaimer

The information in this manual has been carefully examined and is believed to be reliable. No responsibility is assumed for any inadvertent inaccuracies. Q Core Medical reserves the right to make changes to any of its products in order to improve reliability, design and performance. The instructions presented in this manual should in no way supersede established medical protocol concerning patient care. The text and drawings herein are for the purposes of illustration and reference only; the specifications on which they are based are subject to change without notice.

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Chapter 1: Introduction

Product Summary

Intended Use

The Avoset Infusion Pump (*the pump*) is intended for controlled infusion at continuous rate, and/or with an intermittent bolus, and/or with a patient bolus and/or with taper, in the hospital and home environments.

The dedicated administration sets are intended for single-patient use and single-use only.

Indications for Use

Routes	Parenteral (intra-arterial, intra-venous, percutaneous, subcutaneous, perineural, epidural and intraoperative site) and enteral infusions. **Caution** The pump is intended for use with FDA-approved liquid products only.
Patient Populations	The pump is intended for pediatric and adult patients.
Fluids	IV medication (including fluids), Total Parenteral Nutrition (TPN), enteral nutrition, lipids, and epidural medication.
Delivery Modes	Continuous, Intermittent, Taper, and PCA.
Environments	Hospital and home.
Operation Conditions	See **Operation Conditions**.

About This Manual

Intended Audience

This manual is intended for use by medical professionals and patients. Clinicians, qualified hospital staff, and home users should read this user manual prior to operating the Avoset Infusion Pump to make sure they fully understand the functionality and operating procedures of the pump and its accessories.

Document Conventions

Controls and Screen Commands

- Physical controls on the pump are indicated **LIKE THIS** (for example: Press **PRIME**).
- Text displayed on-screen is presented like this `LIKE THIS` (for example, A `PRIMING` indication appears on-screen).

Hazard Information

The following messages in this manual indicate hazard or special information:

	**Warnings** indicate precautions and instructions which, if not followed, may result in personal injury.
	**Cautions** indicate instructions which, if not followed, may result in damage to the equipment or to the quality of treatment.
	**Notes** provide additional information to help obtain optimal equipment performance.

Terms and Abbreviations

Term	Definition
AFFV	Anti-Free-Flow Valve
BLE	Bluetooth Low Energy
DC	Direct Current
DFU	Directions for Use
EMC	Electromagnetic compatibility
EMC	Electromagnetic Compatibility
EMI	Electromagnetic Interference
KVO	Keep Vein Open
ME	Medical Equipment

Term	Definition
mg	milligram
mL	milliliters
MRI	Magnetic Resonance Imaging
NFC	Near Field Communication
PCA	Patient Controlled Analgesia
Rate	the amount of fluid infused in an hour
RF	Radio Frequency
VI	Volume Infused (the amount of volume already infused during the current treatment)
VTBI	Volume to Be Infused (the amount of fluid programmed or remaining to be infused)

Warnings and Safety Precautions

Familiarize yourself with all safety information in this manual and any additional instructions accompanying the disposables and accessories before using the pump.

Note

Safety information specific to particular pump functions appear in the relevant sections of this manual.

General Guidelines

Caution

- Avoid placing the administration set on the floor, or in any other location where it can accidentally be damaged, or pose a risk of strangulation, particularly due to excessive length.
- To avoid damage to the pump and its accessories, keep the equipment away from pests, pets, and unattended children.
- Avoid exposure to sun and excessive heat.
- Avoid exposure to steam and boiling water.
- In addition to following the guidelines for proper usage environment (see **Operating Conditions**), avoid locations with large temperature fluctuations. If the pump is moved to location with a great temperature difference, do not operate immediately. Allow it to adjust to the new temperature.
- Do not clean, disinfect or sterilize any part of the pump by autoclaving, or with ethylene oxide gas. Doing so may damage the pump and void the warranty. Only external parts of the pump should be disinfected.

Warning

- If the pump is dropped or appears to be damaged, do not use it until it has been inspected by trained and qualified technical personnel.
- No modification of this equipment is allowed.

Waste Disposal

Dispose of the packaging, the administration sets, the battery, and any other electronic components in accordance with applicable environmental laws (such as the WEEE Directive for Waste Electrical and Electronic Equipment). Contact your local authority to determine the proper method of disposal.

Warning

- Keep used plastic infusion containers, packaging, and tubing out of the reach of children.
- Dispose of administration sets in a proper manner, considering the nature of residual fluid that may be contained within, in accordance with local disposal practices.
- Do not dispose of the battery in or near fire (see **Recycling & Disposal**).

Explosion Hazard

Caution

Do not use the pump in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.

Electric Shock Hazard

Caution

Access to any internal part of the pump and the performance of any service procedures should be carried out only by a fully trained and qualified service technician, fully trained in operating the pump.

Environmental Safety Precautions

The Avoset Infusion Pump has not been evaluated for compatibility with Extracorporeal Membrane Oxygenation (ECMO) systems.

Proper Use of the Pump

Using the pump not according to its labeling or intended use might result in the following side effects: pain, exacerbation of illness, injury or harm, stroke, electrocution, exsanguination trauma, and death. Although the Avoset Infusion Pump has been designed and manufactured to exacting specifications, it is not intended to replace trained personnel in the monitoring of infusions.

Warning

Home users must be trained before using the pump.

Caution

Clinicians are advised to verify the proper route of delivery, and the patency of the infusion site.

When using the pump, periodic patient monitoring must be performed by a healthcare provider based on clinical practice, to ensure that the treatment is proceeding as expected. For home users in an ambulatory environment, monitoring may be provided by means of a visiting or an on-call nurse, training of patient or relative, or any other means specified by the provider of the devices, based on suitable clinical practice for said environment. The pump is capable of developing positive fluid pressures to overcome widely varying resistances to flow, such as resistance imposed by small-gauge catheters, ports, filters, or intra-arterial infusions. Although the pump is designed to stop fluid flow when an alarm occurs, it is neither designed nor intended to detect infiltrations or extravasations, and such conditions will not trigger an alarm.

Warning

- When using the pump, use only Q Core Medical approved accessory equipment.
- The pump should be used with Q Core Medical administration sets only.
- The use of unsuitable administration sets could impact the function of the pump.
- If auditory and/or visual signals do not perform according to settings, or if the hard keys do not perform as expected, do not use the pump, and contact an authorized technician.
- To prevent potential degradation of performance, do not use any part of the Avoset Infusion Pump any closer than 30 cm (12 inches) from any portable RF communications equipment (including peripherals such as antenna cables and external antennas).
- Do not attempt to disassemble any part of the pump.

Infusion Safety Information

Always read and follow the instructions in this User Manual, and the instructions accompanying the administration set and source container. Carefully follow any label instructions for loading, removing, and reloading the set, as well as the recommended set change interval. For infection control purposes, consider the set change interval recommended by the local Centers for Disease Control and Prevention (CDC), your facility guidelines, and the instructions provided with the administration set.

Administration Set Safety Precautions

- Do not use a damaged or expired administration set or damaged set components or packaging.
- Always refer to the instructions for use that are included.
- Avoset administration sets are for single patient use only. Do not sterilize or clean for re-use.
- ***Do not connect the administration set to the patient while priming.***
- Do not use force when connecting the administration set to the patient.
- Always use the clamps on the administration set to occlude the administration set prior to removing the Avoset administration set cassette from the pump.
- Do not apply pressure or pressurized air to any outlet or tubing connected to the pump. Pressure may destroy sensitive elements.
- Do not pull or stretch the tubing in any section of the administration set when the pump is in use, nor apply pressure to the infusion container.
- Replace the administration set as needed to avoid fluid contamination problems. Replace according to the clinical site's policy of infection control and treatment protocol. Avoset administration sets allow accurate delivery up to 96 hours. If you program rate, dose, or bolus combinations which exceed a 96-hour schedule, make sure that you replace the administration set on time.
- Do not use any disposable components (administration sets, cassettes, etc.) for longer than 96 hours.
- To prevent cross-contamination between patients, never reuse administration sets.
- Do not enter a volume to be infused greater than the amount of fluid available in the container.
- Do not attempt to disassemble or modify an administration set.

Occlusion Pressure Alarm Settings

Low Occlusion sensitivity settings may affect the time for occlusion detection. Make sure that the occlusion pressure is set according to the clinical use case.

Air Detection

- Air detection is an important safety feature of the Avoset Infusion Pump. If the air detection is disabled (OFF), use a set with an air-eliminating filter to prevent patient injury.
- Air detection serves as a safety component. Disabling the air detection hinders the pump's ability to alert on hazardous situations.
- Always ensure that the administration set is primed before starting a treatment.
- Do not infuse non-epidural drugs in the Epidural Delivery mode.
- Use only Epidural Delivery mode to infuse Epidural drugs.

Chapter 2: Welcome to the Avoset Infusion Pump

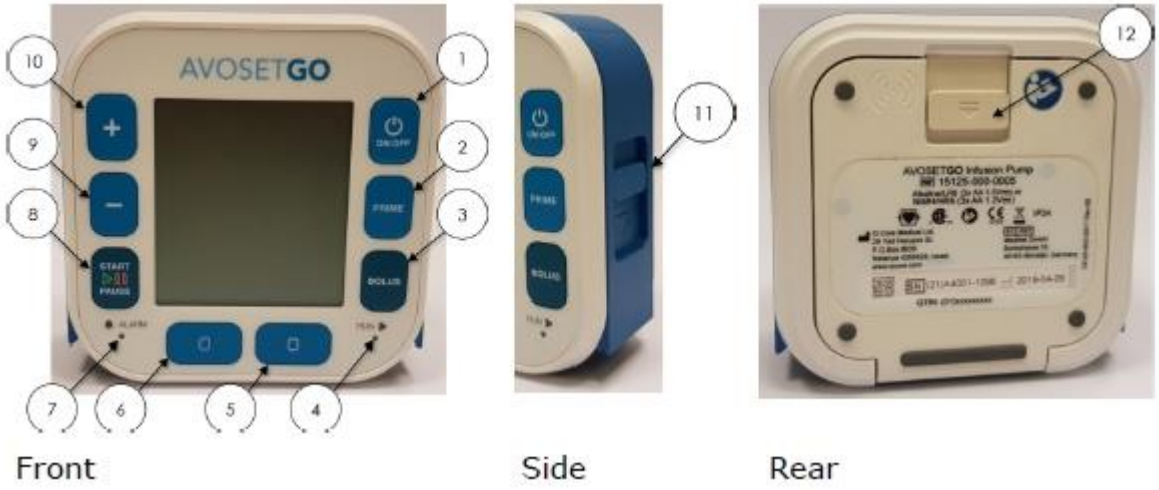
Product Overview

Package Contents

The Avoset Infusion Pump is shipped in package containing:

- 1 pump
- 1 lockbox
- 1 cradle
- 1 AvosetPad (for wireless connection of the pump to other devices
- this user manual

Pump Controls



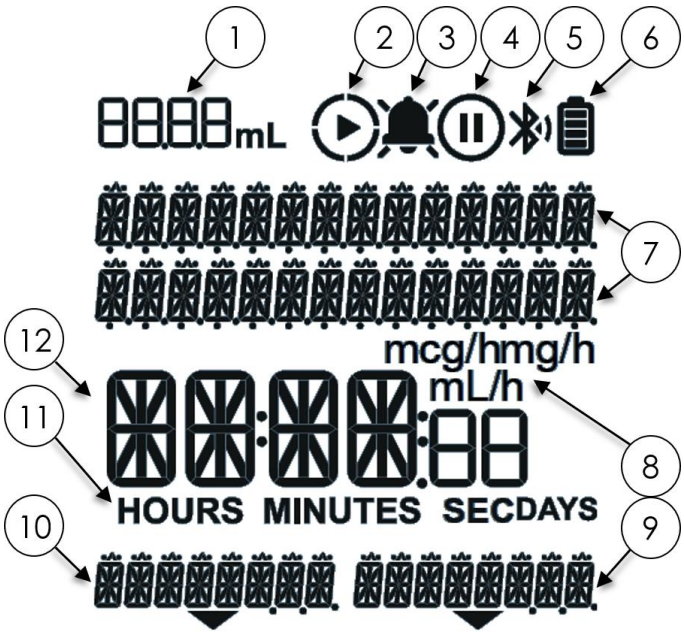
Key	Control Name	Function
1	ON/OFF	Turns the pump ON and OFF.
2	PRIME	Initiates the automatic priming procedure to fill the administration set with fluid and expel air. See **Automatic Priming**.
3	BOLUS	Initiates a PCA dose request.
4	RUN indicator	Electromagnetic compatibility. Flashes green when pump is running.
5	Multi-function button	Electromagnetic Compatibility
6	Multi-function button	Electromagnetic Interference
7	ALARM indicator	Flashes yellow when an alarm appears. See **Alarms**.
8	START/PAUSE	Starts or pauses treatment.

Key	Control Name	Function
9	MINUS	Decreases value.
10	PLUS	Increases value.
11	Administration set cassette release	Releases the administration set cassette from the pump.
12	Battery door release	Opens the battery door.

Caution

Avoid pressing on the screen or controls with excessive force.

Display Layout



Key	Display Element / Icon	Function
1	VTBI	Displays the remaining volume to be infused.
2	RUN	Indicates pump motor operation.
3	ALARM	indicates an active alarm. indicates paused alarm audio. See **Alarms & Troubleshooting**.
4	PAUSED	Flashes when pump operation is paused.
5	Bluetooth connection	the pump is ready to be paired. the pump is paired.

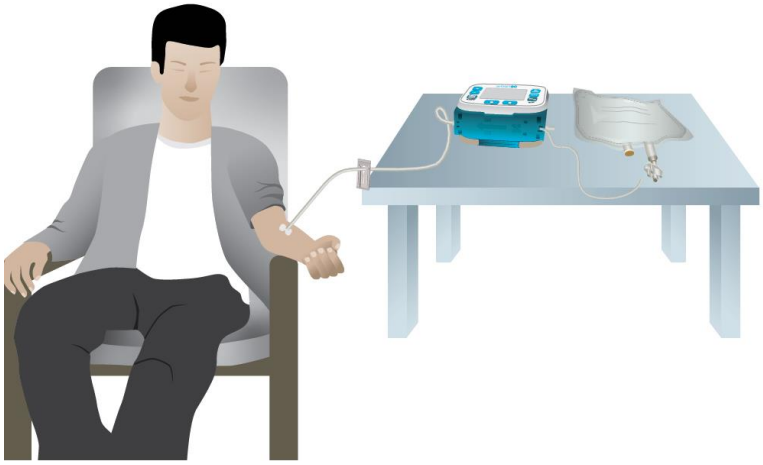
Key	Display Element / Icon	Function
6	Battery status	Indicates the current battery level. batteries are full. batteries are low. 3-minute warning: batteries are depleted. **Caution** Do not start a treatment if the batteries are low. Replace them with fresh batteries.
7	Text	Displays text, such as system messages, prompts and medicine names.
8	Units of measurement (main parameter)	Indicates the main parameter's units of measurements.
9	Right multi-functional button label	Shows what the right multi-functional button does when pressed.
10	Left multi-functional button label	Shows what the left multi-functional button does when pressed.
11	Units of measurement (secondary parameter)	Indicates units of measuring time.
12	Main parameter	Shows the main parameter's current value.

Basic Operation

Introduction

The recommended work-flow for preparing the pump and an administration set for a treatment is:

1. Inserting batteries (**Installing Batteries** on p. 14).
2. Turning the pump ON (**Power ON/OFF** on p. 13).
3. Connecting an administration set to the pump (**Using Administration Sets** on p. 18).
4. Priming the administration set (**Priming** on p. 21).
5. Connecting the administration set to the patient.
6. Starting the treatment (**Starting a Treatment** on p. 24).



Note

When using an administration set with a filter, place the filter under the patient's IV infusion.

Caution

Do not place the pump more than one meter below or one meter above the patient.

First Time Usage/Visual Inspection

1. Make sure that you have all the parts.
2. Examine the pump. Look for cracks in the casing, screen, battery compartment and door, and external parts of the pumping area (particularly the cassette socket). Examine the administration set and/or infusion cassette.

Warning

Do not use the pump, administration set, or infusion cassette if it appears in any way damaged. Contact Technical Support.

Using a Syringe

The pump can be fed from either a treatment bag, cassette, or a syringe.

Note

The pump is compatible with 5 mL to 60 mL syringes.

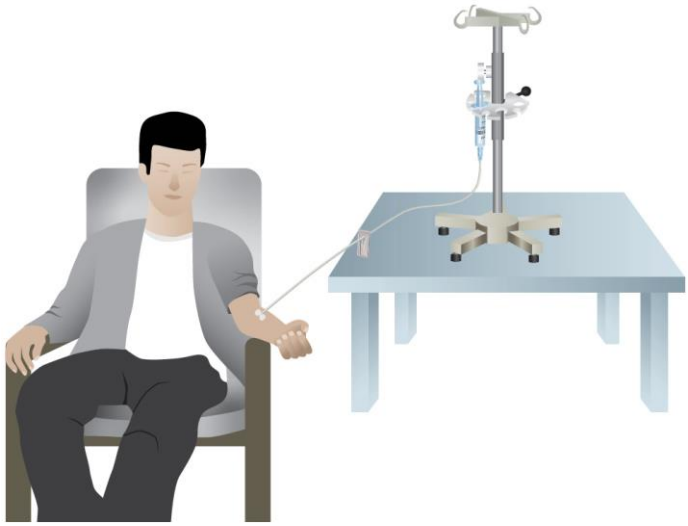
1. Place the pump on a table.
2. Connect a syringe holder to the IV pole.
3. Fill the syringe.
4. Connect the administration set to the syringe.
5. Mount the syringe on its holder. Orient the syringe's luer lock downwards and place the barrel flange on the holder.
6. Connect the administration set to the pump (see **Attaching an Administration Set**).

Caution

Do not push or pull the syringe plunger after the administration set is attached to the pump.

7. Prime the pump (see **Priming**).

8. Connect the administration set to the patient.



Powering ON/OFF

To turn on:

1. Press the **ON/OFF** button.

Caution

When the pump turns ON, it automatically performs a system check, during which the speaker sounds, the screen lights up, the indicators blink, and the unit's serial number and software version briefly appears. If any of the features doesn't function as described, ***do not*** use the pump.

If the pump was turned OFF before completing the previous treatment, a prompt appears: `START NEW BAG OR RESUME?`

- Press **NEW BAG** to reset treatment parameters and begin a new treatment with a new bag.
- Press **RESUME** to retain the VTBI measured before the pump was turned OFF and resume the previous treatment with the existing bag.

The pump turns ON.

Note

The prime prompt can be turned OFF using the Avoset programming tool.

2. If delivery parameters were changed in the previous treatment, the pump prompts: REVIEW NEW PARAMETERS. Press **REVIEW** and confirm all parameters.

   The home screen appears.

Caution

Always review the alarm settings to make sure they are appropriate for the patient. Refer to the Avoset programming tool user guide for details.

To turn off:

1. If the pump is running, press **PAUSE**.
2. Press and hold down the **ON/OFF** button for 3 seconds.

   The pump shuts down.

For emergency shut-off:

1. Disconnect the administration set from the pump to cause an emergency stop.

Note

Settings are saved.

Installing Batteries

The pump is powered by three batteries: Duracell Procell AA Alkaline/PC1500 or Duracell rechargeable 2500mAh.

Note

Always have a set of batteries available for replacement.

Rechargeable batteries should be recharged using an over-the-shelf dedicated charger, in accordance with the charger manufacturer's guidelines.

The pump includes a backup power source to save settings and provide an alarm if the batteries fall out.

Caution

- Never remove the batteries while treatment is in progress!
- Do not use Lithium batteries.
- Always replace all batteries at once; do not install new batteries with old ones.
- Verify that the batteries you install are of the same type (rechargeable/alkaline).
- Before inserting new batteries, check the battery compartment for liquid or debris and clean it if necessary.
- Do not store the pump for a prolonged period with the batteries installed.
- Keep the battery door closed at all times unless actively changing batteries.

1. Turn the pump OFF.

2 3 4 5

2. Open the battery compartment located at the pump's rear by sliding the latch downwards.
3. Remove depleted batteries from the compartment.

Caution

- Remove the batteries from the PLUS end, opposite the compartment's spring.
- Dispose of the depleted batteries in accordance with local environmental guidelines.

4. Install new batteries according to the plus/minus orientation illustration inside the compartment.
5. Close the battery compartment.

Caution

- The battery compartment must be closed to prevent fluid ingress.
- Never use any cleaning solutions on the inside of the battery compartment.

Using the Cradle

The cradle is to attach the pump to an IV pole or bed rail. It can be attached vertically or horizontally while keeping the pump display correctly oriented.

Always attach the cradle first before inserting the pump into the cradle.

Note

For cleaning and maintenance instructions, see **Cleaning and Maintenance**.

1. Position the cradle where desired and tighten the knob.

2. Align the pump with the bottom of the cradle.

3. Press the pump back ***firmly*** until the top latch of the cradle clicks securely into place.

4. To release the pump from the cradle, hold the pump while pushing back firmly on the top latch of the cradle.

Note

Attaching and releasing the cradle is the same when the lockbox is used.

Using Administration Sets

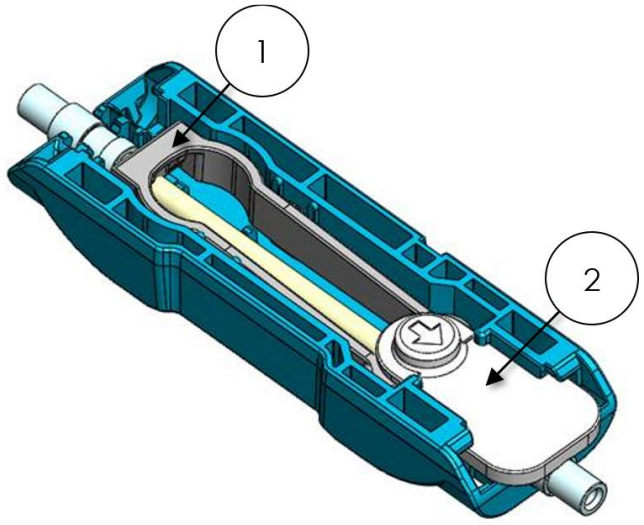
The pump must be used with an approved administration set, which includes the Avoset administration set cassette. This cassette includes a normally closed valve (Anti-Free-Flow Valve) that provides automatic anti-free-flow protection. Opening the valve allows manual priming.

Warning

- To prevent unmonitored free-flow of fluids into the patient, always clamp the administration set before releasing a used administration set cassette, and before installing a new one.
- Never remove the clamp until the administration set has been connected to the pump.
- Never freeze administration sets.
- Attach the administration set cassette to the pump before connecting it to the patient.

Note

The 100 mL Medication reservoir is attached and released by following the same procedures as a regular administration set.

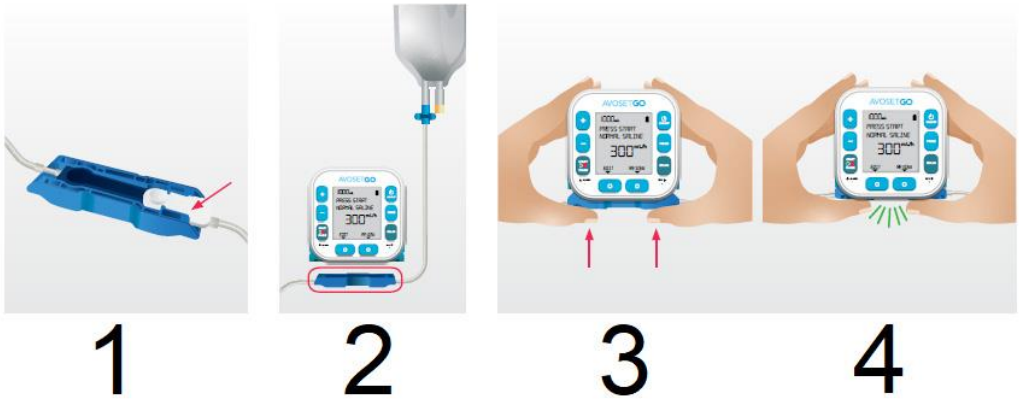


Key	Component Name	Function
1	AFFV (Anti-Free-Flow Valve)	Allows/prevents fluid flow through the set. When pressed (by hand or clip), the valve is open; when released, the valve is closed.
2	AFFV release clip	Keeps the AFFV open while the set is packaged or before attaching the administration set to the pump.

Attaching an Administration Set

Caution

Attach the administration set cassette after the pump is turned ON and ***before*** connecting it to the patient.



1. Remove the AFFV release clip from the new administration set cassette.
2. Orient the cassette so that the flow direction arrow points left, relative to the pump front.
3. Push one side of the cassette into the pump's cassette socket.
   A click sound indicates that one side of the cassette is attached.
4. Push the other side of the cassette into the pump's cassette socket.
   A second click sound indicates that the cassette is fully attached.
5. Open all clamps on the new administration set.

Removing an Administration Set

1. Close all clamps on the used administration set.
2. Disconnect the patient from the administration set.
3. Push down the **RELEASE SLIDE** on the pump's side.
   The used administration set cassette is released.
4. Dispose of the used administration set in accordance with local biohazard disposal guidelines.

Using the Lockbox

Purpose

The lockbox is a transparent secure cover that prevents interference with a medication cartridge, while allowing access to the pump controls and the battery compartment. It can be used with the cradle.

Each lockbox is provided with two keys that are unique to that lockbox.

Note

For cleaning and maintenance instructions, see **Cleaning and Maintenance**.

Attaching the Lockbox

1. Make sure that the cassette is correctly installed.
2. Insert key and turn to the left to unlock (key position is vertical).
3. Slide the lockbox over the pump so that the Avoset logos line up.

4. To lock, press the key in firmly and turn to the right (key position is horizontal) and remove. The key can only be removed if the lockbox is locked.

Removing the Lockbox

1. Insert the key. Push in firmly and turn left.
2. Slide the lockbox up, removing it from the pump.

Priming

Before beginning a treatment, the administration set needs to be primed. Priming expels all the air from the administration set, and fills it with the treatment liquid.

There are two priming methods:

- Automatic: use the pump to prime an administration set that's attached to it.
- Manual: prime an administration set without the pump.

Warning

- Disconnect the administration set from the patient before priming.
- Before priming, check that all clamps are opened and that there is no occlusion.
- Do not allow air into the administration set during priming.
- For either type of priming, always make sure that all air bubbles are expelled before using the set.

Automatic Priming

If possible, ***always use automatic priming***. Automatic priming is available when the pump is turned ON, with an administration set attached to it, either before treatment, or while treatment is paused.

The AIR IN LINE alarm is disabled during automatic priming.

Priming volume is not subtracted from the VTBI, not added to the VI. Therefore, calculate the treatment bag's volume to include patient treatment plus priming volumes.

1. Turn the pump ON (see **Power ON/OFF**).
2. Attach an administration set to the pump (see **Attaching an Administration Set**).
3. Press **PRIME**.

   A prompt appears: `DISCONNECT PATIENT`.

Note

PRIME is available only from the home screen or the paused main screen. It is not available from any other screen or while any notifications are displayed.

4. Disconnect the administration set from the patient.
5. Open all administration set clamps.
6. Press **PRIME**.

   The pump begins to pump fluids from the bag through the administration set. A `PRIMING` indication appears on-screen.
7. Press **STOP** or **START/PAUSE** when the administration set is primed.

   Alternatively, wait for the automatic process to finish: `PRIME COMPLETE` appears on-screen.

8. Press **OK**.
   `CONNECT SET TO PATIENT` appears on-screen.
9. Connect the administration set to the patient

Manual Priming

1. Disconnect the administration set from the patient.
2. Open all administration set clamps.
3. Press and hold the cassette's AFFV valve.
   Treatment fluid flows through the administration set and primes it.
4. Release the AFFV valve when the administration set is primed.
5. Connect the administration set to the patient.

Password Protection

Specific pump features are protected by a password to prevent unauthorized modification. The following features can be locked or unlocked using the Avoset programming tool.

Mode	Password-protected Features
Continuous	Edit Titration Auto prime
Intermittent	Next dosage start time Auto prime
Taper	Immediate taper down Auto prime
PCA (this mode is always locked)	Edit Clinician Dose Auto prime

Note

For details, refer to the Avoset programming tool user guide.

When attempting to modify a locked feature, a password page appears. The password consists of 3 digits.

To unlock a feature:

1. Use the **PLUS** and **MINUS** buttons to set the password's first digit.
2. Press the **OK** function button.

The second digit flashes.

3. Repeat steps 1 and 2 to set the password's 2nd and 3rd digits.
   Press the **CLEAR** function button to reset the entered digit.

4. Press the **OK** function button.
   The feature is unlocked.

Starting a Treatment

Warning

Before starting, always verify that the infusion bag contains the correct drug.

1. Turn the pump ON.
2. Attach an administration set to the pump.
3. Prime the administration set, if necessary.
4. Connect the patient to the administration set.
5. Press **START/PAUSE**.
   The treatment begins.

Reviewing Treatment Parameters

Before beginning a treatment, review the treatment parameters, as described below, to verify they match the patient's prescription.

- Press **REVIEW** to review the parameters.
- Press **NEXT** and **BACK** to browse the parameters.
- From any of the review screen, begin the treatment by pressing **START**.

Delaying the Start

The pump can be programmed for a delayed start. For example, the patient turns the pump ON and presses **START/PAUSE** before the pump was scheduled to be started.

The pump starts delivering the fluid in a KVO rate till the scheduled time is due. On-screen, the time remaining before treatment starts is displayed (`HH:MM`). When treatment begins, the pump changes the infusion rate accordingly.

Ending a Treatment

When the programmed VTBI has been delivered and treatment concludes, `INFUSION COMPLETE` appears on-screen.

Note

except Intermittent, where `TIME TO CHANGE BAG` appears instead of `INFUSION COMPLETE` (see **Change Bag**).

To end a treatment, dismiss the Infusion Complete alarm.

- If KVO is set to zero, `CHANGE BAG OR TURN OFF` appears.
- If KVO is other than zero, the pump continues to deliver liquid at the KVO rate.

Chapter 3: Modes

Introduction

The Avoset Infusion Pump can be operated in four different modes. Operation modes and all program types can be set using the Avoset programming tool.

Note

For details, refer to the Avoset programming tool user guide.

Bluetooth Connection

To program the pump, it must be connected via Bluetooth to a PC or other device.

Connecting to a PC

1. Turn the pump ON.
   The icon turns ON for 2 minutes, during which the pump can be paired.
2. Place the pump on the AvosetPad.
   When connection is established the icon changes to , and `CONNECTED TO PC` appears on-screen.

Connecting to a Mobile Device

1. Turn the pump ON.
   The Home screen appears.
2. Press the **BOLUS** and the **+** buttons simultaneously.
   A 4-digit pin code appears on-screen.
3. Enter the 4-digit pin code in the dedicated mobile application.
   The pump is connected to the mobile device.

Disconnecting

To disconnect the pump from any Bluetooth connection, either:

- Turn the pump OFF.
- Press **DONE** in the Avoset programming tool (after the treatment was sent to the pump).

Continuous Mode

Continuous is the basic infusion operation mode, in which the pump delivers the infusion in a fixed rate.

Manual Programming

Manual programming and operation of the pump is possible in Continuous mode, when the pump has no infusion program installed. If a Continuous infusion program is already installed, its operation parameters can be manually adjusted (see **Edit Continuous Treatment Parameters**).

To program the pump manually:

1. Turn the pump ON.
   The SET RATE screen appears.
2. Set the treatment infusion rate using the PLUS and MINUS keys, then press **OK**.
   The SET VTBI screen appears.
3. Set the VTBI using the PLUS and MINUS keys, then press **OK**.
   A confirmation screen appears, showing the RATE and VTBI values you entered.
4. Press **CONFIRM**.
   The home screen appears, with the prompt `PRESS START` flashing.

Review Continuous Treatment Parameters

Before beginning a treatment, review these treatment parameters:

Parameter (* = optional)	**Description**
Concentration *	Drug concentration
Rate	Amount of fluid delivered per hour
VTBI	Total volume to be infused during treatment
Duration	Treatment duration
KVO *	Keep Vein Open rate
Starts in *	Treatment delay duration (amount of time before starting)

Edit Continuous Treatment Parameters

You can modify continuous treatment parameters before beginning a treatment.

Note

When you edit Continuous mode parameters, the pump retains the changes for future repeated treatments.

To edit continuous treatment parameters:

1. Press **EDIT** on the home screen.
   The SET RATE screen appears.
2. Change the rate using the PLUS and MINUS buttons, and then press **OK** to confirm.
   The SET VTBI screen appears.
3. Change the VTBI using the PLUS and MINUS buttons, and then press **OK** .
   The home screen appears with the message OK blinking.
4. To discard changes, press **BACK**.

Titration

After beginning a continuous treatment, you can edit its Rate and VTBI from the pump's home screen: The changes apply only to the current treatment, and are discarded once the treatment concludes. The pump must be paused before editing Rate and/or VTBI.

To edit the rate during continuous treatment:

1. Press **START/PAUSE**.
   The pump pauses.
2. Press **EDIT** on the home screen.
   The SET RATE screen appears.
3. Change the rate using the PLUS and MINUS buttons, and then press **OK** to confirm.
   The home screen appears.
4. To discard changes, press **OK**.
5. Press **START/PAUSE** to resume treatment.

Continuous Treatment Information

During treatment, press **INFO** to view the current values of the following parameters. Press **NEXT** to browse the parameters, and then return to the home screen:

Parameter (* = optional)	Description
Duration remaining	The amount of time left before the treatment ends
Volume infused	Total volume infused during this treatment ***so far***
VTBI	Total volume to be infused during treatment
KVO *	Keep Vein Open rate

Intermittent Mode

Intermittent mode is used to deliver multiple doses at regular intervals and defined rates. Between doses, a KVO rate is available.

Treatment Interruption in Intermittent Mode

When you pause the pump in Intermittent mode, the way treatment resumes depends on the stage at which it was paused and on the duration of the pause. Here are the most common interruption scenarios and their resulting pump operation profiles.

Scenario	How Treatment Resumes
Treatment is paused during a dose and then resumed before the next dose is scheduled.	The paused dose continues. The next dose is scheduled with a delay of the same duration as the pump's pause.
Treatment is paused during a dose and resumed after the time has come to begin the next dose.	The interrupted dose is skipped. All other doses are postponed by a duration equal to the pause after the scheduled dose was supposed to begin.
Treatment is paused during KVO and resumed ***before*** the next dose is scheduled.	Pump returns to KVO rate and the next dose starts as scheduled.
Treatment is paused during KVO and resumed ***after*** the next dose is scheduled.	Pump immediately begins infusing the next dose. All doses are postponed by a duration equal to the pause after the scheduled dose was supposed to begin.
A new bag is inserted before the last KVO interval elapses. The user pauses the pump, replaces the set, and answer YES to the prompt WAS THE BAG CHANGED?	Pump returns to KVO rate. Dose #1 will be delivered at the end of the current interval.
Bag replacement during a dose. The user pauses the pump, replace the set, and answer YES to the prompt WAS THE BAG CHANGED?	The pump skips the remaining volume, returns to KVO and delivers Dose #1 when the next interval is scheduled.

Reviewing Intermittent Treatment Parameters

Before beginning a treatment, review the treatment parameters:

Parameter (* = optional)	Description
Concentration *	Drug concentration
Dose Rate	Amount of fluid delivered per hour
KVO	Keep Vein Open administration rate
VTBI	Total liquid volume to be infused during treatment, including all doses and all the between doses volume that is delivered in KVO rate
Dose Volume	Volume of each intermittent dose
Dose Interval	Time between a beginning of one dose and the beginning of the following dose
Number of Doses	Total treatment doses
Dose Duration	Intermittent dose delivery duration
Total Duration	Amount of time for the entire treatment, from the start of the first dose till the end of the last KVO
Dose Reminder	(When treatment was paused during KVO) next dose notification
Starts in*	Treatment delay duration

Intermittent Treatment Information

During treatment, press **INFO** to view the current values of the following parameters. Press **NEXT** to browse the parameters, and then return to the home screen:

Parameter	Description
During Dose	
Dose Duration Remaining	The amount of time left before the current dose ends
Total Duration Remaining	The amount of time left before treatment ends
Volume Infused	Total amount of liquid infused during this treatment
VTBI	Liquid volume yet to be infused during this treatment
Dose Volume	Volume of each intermittent dose
Concentration	Drug concentration
KVO	The rate used between doses to keep the vein open
Dose Interval	Time between a beginning of one dose and the beginning of the following dose
Between Dose (in addition to all above)	
Completed Dose X of Y	Number of doses infused (X) and total number of doses (Y) in the current treatment.
Next Dose in	The amount of time left before the next dose begins

Working with Doses

Edit “Next dose in”

In Intermittent mode, when the pump is between doses, you can shorten the time between doses to initiate the next dose sooner.

Note

- This feature can be protected by a password (see **Password-protected Features**).
- Only the current interval is cut short by this feature; subsequent interval lengths remain the same.
- As a result of using this feature, the schedule of subsequent doses changes. The rest of the intervals remain unchanged.

1. Press **START/PAUSE**.
2. Press **INFO**.
   A treatment parameter appears.
3. Press **NEXT** to browse the parameters until `NEXT DOSE IN` appears
4. Press **EDIT**.
   The ENTER PASSWORD screen appears.
5. Enter the password and press **OK**.
6. Modify the parameter using the PLUS and MINUS buttons, and then **OK** to confirm.
   The NEXT DOSE IN screen appears, showing the updated value.
7. To discard changes, press **BACK**.
   The interval cannot be adjusted to be longer than its pre-set value.
8. Press **START/PAUSE** to resume treatment.

Using the Dose Reminder

When the optional Dose Reminder feature is active, and the pump is paused between doses (during KVO), a notification prompts the user to manually resume treatment. The Dose Reminder parameter defines how much time before the next Dose Reminder prompts the user.

Note

- The PUMP IS PAUSED alarm is disabled when Dose Reminder is enabled.
- Dose Reminder is defined or disabled using the Avoset programming tool.

During Dose Reminder, an alarm sounds and an alternating message flashes on-screen: pump is paused and `NEXT DOSE IN XX:XX`. When the dose start time comes, `DOSE DUE NOW` appears.

Changing the Bag

When the last dose of a treatment bag has been delivered, and the pump is in last KVO, a prompt appears on-screen: `TIME TO CHANGE BAG`. The time before the end of the last interval when this prompt appears can be configured via the Avoset programming tool. If the bag is not changed at the appointed time, a prompt appears: `CHANGE BAG NOW`.

1. Replace the depleted treatment bag and set with new ones (see **Using Administration Sets**).
   The message `WAS THE BAG CHANGED?` appears *if* attaching a new set cassette or turning the pump back ON.
2. Press **YES**.
   A message `START NEW INFUSION?` appears.
3. Press **YES**.
   A new cycle of doses begins.

Taper

During a Taper mode treatment, a plateau rate of treatment is maintained, with the option of tapering values up at the beginning and/or tapering them down at the end. Taper mode has an optional programmable KVO rate at the end of the treatment.

Review Taper Treatment Parameters

Before beginning a treatment, review these treatment parameters:

Parameter (* = optional)	**Description**
Plateau Rate	Rate of infusion between tapering phases
Taper Up Duration *	Amount of time rate increases until reaching the plateau rate
Taper Down Duration *	Amount of time rate decreases from the end of the plateau rate
VTBI	Total liquid volume to be infused
Total Duration	Amount of time for the entire treatment
KVO *	Keep Vein Open administration rate
Starts in*	Treatment delay duration

Edit Taper Treatment Parameters

You can modify Taper treatment parameters before beginning a treatment:

1. Press **EDIT** on the home screen.
   The first parameter appears: `VTBI`.
2. Edit the parameter value using the PLUS and MINUS buttons, and then **OK** to confirm.

The next treatment parameter appears.

3. Repeat Step 2 to edit additional Taper treatment parameters.
   The home screen appears, with the prompt `PRESS START` flashing.
4. To discard changes, press **BACK**.
5. Press **START/PAUSE** to resume treatment.

Taper Treatment Information

During treatment, press **INFO** to view the current values of the following parameters. Press **NEXT** to browse the parameters, and then return to the home screen.

Parameter	Description
Total Duration Remaining	The amount of time left before treatment ends
Volume Infused	Total amount of liquid pumped during this treatment
VTBI	Total liquid volume to be infused
Plateau Rate	Rate of infusion between tapering phases
Taper Up Duration	Amount of time rate increases until reaching the plateau
Taper Down Duration	Amount of time rate decreases from the end of the plateau

Immediate Taper Down

This feature, when made available via the Avoset programming tool, allows the user to end the treatment with a gradual decrease in treatment infusion. Immediate Taper Down becomes available after the treatment reaches its plateau, and the button **TAPER D** appears in the home screen.

1. Press **TAPER D**.
   A confirmation message appears: `START TAPER DOWN NOW?`
2. Press **YES**.
   The pump ends the treatment gradually.

Patient Controlled Analgesia (PCA) Mode

PCA mode allows the patient to relieve pain during treatment by releasing high dose (Bolus) medications on demand. Bolus can be infused once in a set amount of time. The duration in which a single bolus is allowed can be reviewed before and during treatment.

- Bolus is available from the **BOLUS** hard button.
- After pressing **BOLUS**, the pump displays a flashing message `BOLUS DELIVERING`. Until the bolus ends, either automatically when it's done or manually by the user, other screens are unavailable.
- During a bolus, press the **START/PAUSE** hard button to pause the pump. When resuming pump operation (by pressing the **START/PAUSE** button again) the pump returns to the basic, and not the bolus rate.
- A new bolus becomes available again after the lockout time ends

Bolus Lockout

After delivering a bolus, a lockout period between boluses prevents the user from requesting any additional boluses until the lockout period elapses. If the user presses **BOLUS** during the lockout period, the pump indicates that it is locked out for x amount of time.

Reviewing PCA Treatment Parameters

Before beginning a treatment, review these treatment parameters:

Parameter (* = optional)	Description
Concentration *	Drug concentration
Loading Dose Volume *	A loading dose is an optional clinician bolus given at the beginning of the treatment. Loading dose is available only when the first treatment is delivered. When repeating the same treatment, Loading Dose is unavailable.
Loading Dose Duration *	
Basal Rate	Infusion rate between bolus doses
VTBI	Drug volume to be infused during this treatment
Lockout Duration	Amount of time between boluses when the user cannot initiate a bolus
Bolus Volume	Volume pumped during a bolus
Max boluses per one hour / Dose limit per xx hours *	Lockout duration limit type
KVO *	Keep Vein Open administration rate
Starts in*	Treatment delay duration

Editing PCA Treatment Parameters

You can modify PCA treatment parameters before or during a treatment.

Note

When you edit PCA mode parameters, the pump retains the changes for future repeated treatments.

1. Press the **EDIT** key on the home screen.
   The ENTER PASSWORD screen appears.
2. Enter the password, then press **OK** (see **Password-Protected Features**).
   The first parameter appears: `BASAL DOSE RATE`.
3. Edit the parameter value using the PLUS and MINUS buttons, and then **OK** to confirm.
   The next treatment parameter appears.
4. Repeat step 3 to edit additional PCA treatment parameters.

The home screen appears, with the prompt PRESS START flashing.

5. Press **BACK** to discard changes.

6. Press **START/PAUSE** to resume treatment.

Reviewing PCA Treatment Information

During treatment, press **INFO** to view the current values of the following parameters. Press **NEXT** to browse the parameters, and then return to the home screen:

Parameter (* = optional)	Description
Lockout Duration	Time until the next bolus is available. When bolus is available, this parameter is not.
Volume Infused	Total amount of liquid infused during this treatment
VTBI	Drug volume yet to be infused during this treatment
Last Clear of Bolus History	Time elapsed since bolus history was last cleared
Bolus Req. X Bolus Giv. Y	Number of boluses requested (X) and number of boluses initiated (Y)
Bolus Volume	Volume pumped during a bolus
Max boluses per one hour / Dose limit per xx hours *	Lockout duration limit type
Concentration *	Drug concentration

Clearing Bolus History

Avoset records and aggregates the number of times bolus was requested and the number of times it was administered. To clear this history:

1. Press **INFO** during PCA treatment.

2. Press **INFO** again.
   A treatment parameter appears.

3. Press **NEXT** to browse the parameters until BOLUS REQ.X BOLUS GIV.Y appears.

Note

This feature is also available when viewing the TOTAL BOLUS INFUSED parameter.

4. Press **CLEAR**.
   Bolus history is cleared

Using Clinician Dose

Clinician dose is an optional way for the clinician to add bolus to the patient during a PCA treatment. To deliver Clinician bolus:

1. Press **CLINIC.B** during PCA treatment.
2. Enter the password, then press **OK**.
3. Set bolus volume using the PLUS and MINUS buttons, and then **OK** to confirm.
   The pump prompts: `GIVE CLINICIAN BOLUS?`
4. Press **YES**.
   The pump indicates: `DELIVERING C. BOLUS`

To quit Clinician Bolus:

1. Press **START/PAUSE** during Clinician bolus.
   Pump operation is paused.
2. Press **QUIT**.
   The pump prompts: `QUIT CLINICIAN BOLUS?`
3. Press **YES**.
   The pump prompts: `RESUME BASAL RATE?`
4. Press **YES**.
   The pump reverts to Basal Rate.

Setting Loading Dose

Loading dose is available only for the first treatment. Consequent treatments start with the basal rate.

If a Loading dose is set in the program:

1. Press **START/PAUSE**.
   Loading dose delivery begins. `LOADING DOSE DELIVERING...` appears on-screen.
2. When Loading dose concludes, the pump proceeds to Basal rate.

To quit Loading Dose:

1. Pause the pump.
   When pausing the pump during Loading dose delivery, `LOADING DOSE PAUSE` appears on-screen and **QUIT** appears next to the left multi-functional button.
2. Press **QUIT**.
   `QUIT LOADING DOSE?` appears on-screen.
3. Press **YES** to abort the Loading dose and proceed to paused Basal rate.
4. Press **NO** to return to paused Loading dose.

Chapter 4: Cleaning and Maintenance

Cleaning and Disinfecting

Between use on different patients, the pump and all of its components need to be first cleaned and then disinfected, per hospital/medical provider protocol for multiple patient use. Wipe the pump and cradle with 1% bleach (final concentration, diluted in water) to clean and disinfect it.

Caution

Only people who are trained in the maintenance of this type of medical device should clean the pump. For home use, patients should be instructed on the correct procedure.

Caution

Before cleaning or disinfecting, verify that:

- The pump is disconnected from the patient.
- The pump is disconnected from all sets and accessories.
- The pump is turned OFF.

Caution

While cleaning or disinfecting:

- Do not allow fluid to enter the housing, speaker holes or battery chamber.
- Do not steam autoclave, ethylene oxide sterilize or immerse any part of the Avoset Infusion Pump in fluid.
- Do not use spray or aerosol cleaners.
- Dispose of all cleaning/disinfectant materials per laws and regulations for infectious waste disposal.

1. Turn the pump OFF and disconnect it from the patient.
2. Remove the administration set and batteries.
3. Dilute the cleaning solution in water to a final concentration of 1%.

4. Apply the solution on a cloth, then squeeze so it won't drip.

Note

To disinfect, repeat the above procedure and wait 1 minute between each wiping cycle.

Verify that the wipe does not dry during the cleaning process. If required, wet the wipe again in the same manner.

5. Wipe all exterior planes areas in back-and-forth motions, vertically and horizontally.
6. Apply 3 cycles of the above locations with normal force, verifying complete coverage of the areas to be cleaned.
7. 7Wipe the pump's pumping area (administration set cassette slot) in vertical or horizontal movements, where possible. Wipe less accessible areas in bi-directional rotations.
8. Apply 6 cycles of the above location with normal force, verifying complete coverage of the areas to be cleaned.
9. Let the pump dry for 10 minutes.
10. Wipe the pump with a clean dry cloth.

Caution

Do not use any cleaning agents when cleaning the battery contacts.

Preventive Maintenance

Note

Apart from visual inspection and cleaning, there is no mandatory maintenance for the pump.

Visual Inspection

Periodically perform a visual inspection of the pump. Look for cracks in the casing, screen, battery compartment and door, and external parts of the pumping area (administration cassette socket).

Functional Tests

The pump may be tested as required.

Required Equipment

- Avoset Infusion Pump
- 100 mL infusion bag (or larger) with water
- 25 mL calibrated graduated cylinder (minimal accuracy ±0.25mL) Class A
- waste bin
- Avoset administration set without filter
- AvosetPad
- PC with the Avoset programming tool installed
- ambient environmental temperature for testing: 20±5 °C (68±10 °F)

Delivery Accuracy Test

1. Replace the pump batteries.
2. Turn the pump ON and verify:
   LCD screen lights up.
   All segments are visible.
   There are no strips and no black/white pixels.
3. Pair the pump with the Avoset programming tool (see **Bluetooth Connection** on page 53) and program the pump with the following settings:

Treatment Settings	
Type	Continuous.
Drug	(any type)
Units	mL
Rate	125 mL/hour
Volume	20 mL
Pump Settings	
Prime Reminder	OFF
Automatic Prime	unlocked
Edit Infusion	unlocked
Air in Line	0.5 mL
Occlusion Sensitivity	high
Occlusion Auto Restart	OFF
KVO Rate	0 mL

4. Attach a new set to the infusion bag.
5. Attach the new set to the pump. Pull the cassette gently to verify it is attached properly.
6. Place the administration set's male luer in the waste bin.

7. Press the **PRIME** button and verify:

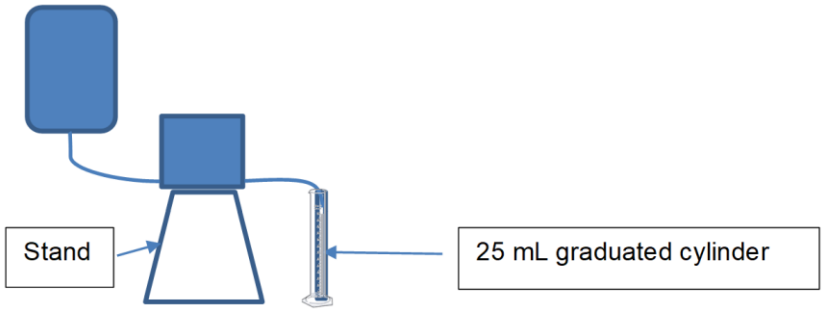
   Pump is priming.
   Administration set has no air bubbles.

8. Place the infusion bag at the same level as the pump.

9. Place the 25 mL graduated cylinder on a levelled surface and adjust the pump to its level.

   The bottom of the pump should be level with the top of the cylinder.

10. Place the administration set's male luer into the cylinder.



11. Press the **START** button and verify:

    The pump is pumping water into the cylinder.
    The Run indicator is blinking green.
    The Run icon is blinking on-screen.

12. Verify that `INFUSION COMPLETE` appears on-screen when treatment concludes.

13. Remove the administration set from the cylinder.

14. Turn the pump OFF.

15. Read the pumped water level on the graduated cylinder. If the volume is between 19 and 21 mL, the pump successfully passed the delivery accuracy test.

Occlusion Detection Test

1. Close the administration set's downstream slide clamp all the way.

2. Place the administration set's male luer in the waste bin.

3. Turn the pump ON.

4. Press the **START** button and verify that `DOWNSTREAM OCCLUSION` appears on-screen after a few seconds.

5. Dismiss the alarm.

6. Open the administration set's downstream slide clamp all the way.

7. Press the **START** button and verify that no Downstream Occlusion alarms appear in the next 2 minutes of treatment.

8. Press the **PAUSE** button.
9. Turn the pump OFF.

Air Detection Test

1. Place the administration set's male luer in the waste bin.
2. Turn the pump ON. If the prompt `WAS THE BAG CHANGED?` appears, press **YES**.
3. Press the **START** button.
4. Flip the infusion bag over to allow air into the administration set. Wait until the air bubble reaches the pump.
5. Verify that the prompt `AIR IN LINE PRIME SET` appears on-screen.
6. Flip the infusion bag over to allow water into the administration set.
7. Prime the administration set.
8. Press the **START** button and verify that no Air in Line alarms appear in the next 2 minutes of treatment.
9. Press the **PAUSE** button.
10. Turn the pump OFF.

Transportation and Storage

The following transport and storage guidelines apply to new pumps and pumps that are stored between patients:

- Store the pump in a clean and dry environment to prevent it from getting dusty or dirty.
- Before storing the pump, disconnect the administration set and remove the batteries.
- The pump can be carried in any orientation within a backpack, a pouch, or by any other means that keeps it enclosed, without risk of parts detaching.

Condition	Minimum	Maximum
Temperature (°C)	-40	60
Humidity (%RH)	15	90
Atmospheric Pressure (kPa)	50	106

When storing the pump for an extended period of time, extract the batteries and store it at a temperature range between 2 ºC (35.6 ºF) and 40 ºC (104 ºF).

Storage at lower or higher temperatures may affect the pump's performance.

After storing the pump in an environment that does not comply with the pump's operating conditions, before operating it again, place it in a suitable operation environment for at least two hours.

Chapter 5: Troubleshooting

During its operation, the Avoset Infusion Pump identifies functional issues and problems as they arise, and notifies the user by:

- On-screen icon
- Flashing indicator, color denotes alarm priority: red for high, yellow for low
- Alarm audio

Note

When a single problem (fault) arises, the maximum volume that can be infused is TBD.

Alarms

Pump alarms are distinct from normal status alerts. They are grouped by their priority:

- Low priority alarms (low volume, 65 dB): treatment continues
- High priority alarms (high volume, 70 dB): treatment is paused

Caution

Pay attention in noisy settings. Auditory alarm signal sound levels that are less than ambient levels can impede operator recognition of alarm conditions.

The pump can alert one or more alarms of the same priority at the same time. High priority alarms are always displayed before low priority alarms.

To pause an alarm audio, press MUTE. The on-screen changes to . Alarm audio resumes after 2 minutes if the issue persists.

Alarms may be accompanied by text to explain the problem:

Alarm Text	Cause	Resolution
High-priority Alarms		
`ERROR 1 REPLACE PUMP`	An unrecoverable error may have occurred, such as a hardware or software fault.	Do not use pump. Turn OFF and contact Service.
`ERROR 2 REPLACE PUMP`	Treatment program error.	Send a new treatment program to the pup.
`ERROR 3 REPLACE PUMP`	The pump detected an internal clock error.	Replace the internal coin (CR2032 Lithium) battery.
`ERROR 4 RELOAD SW`	Software update failure.	Reinstall software.
`ERROR RESTART PUMP`	The pump detected an internal error preventing pump operation.	Restart the pump.

Alarm Text	Cause	Resolution
AIR IN LINE PRIME SET	The pump detected air in the fluid path.	Disconnect the administration set from the patient and prime the administration set.
INFUSION COMPLETE	The VTBI has been delivered.	Dismiss the alarm, then add a new bag or turn the pump OFF.
CASSETTE MISPLACED	Administration set cassette missing or not installed correctly.	Reinstall the cassette.
UPSTREAM OCCLUSION	The pump detected high pressure in the tube connecting the fluid reservoir, which may be a result of an upstream blockage, empty fluid reservoir, kink in the fluid path, or a closed tubing clamp.	Straighten the tube, check for kinks, verify that the administration set is positioned correctly, and un-clamp it. To reduce the potential bolus delivery after an occlusion: 1. Disconnect the patient. 2. Resolve the occlusion. 3. Prime the administration set. 4. Resume the treatment.
DOWNSTREAM OCCLUSION	The pump detected high pressure in the tube connected to the patient, which may be a result of a downstream blockage, kink in the fluid path, or a closed tubing clamp.	
BATTERY DEPLETED	The pump stopped mid-operation: battery power is too low to operate the pump.	Replace the batteries.
(Screen turns OFF)	Batteries were removed or the pump suddenly lost power during operation.	Replace the batteries and make sure that they are installed correctly.
END OF BAG	The tubing beneath the pump may not contain fluid, or the fluid container may be empty, when Air in Line detection is disabled.	If the bag is not empty, disconnect the administration set from the patient, prime the set, then resume the treatment. If the bag is empty, replace it and resume the treatment
CHANGE BAG NOW (Intermittent mode)	The VTBI has been delivered.	Replace the bag.
HIGH TEMPERATURE	Pump is overheating	Turn the pump OFF.
Low-priority Alarms		
ACTION INCOMPLETE	Treatment has not started or an issued action isn't complete, and no key was pressed for a predefined duration.	Address the incomplete action.
PUMP IS PAUSED	Treatment has already started and the pump was paused for 30 seconds.	Press Start if the treatment should be resumed.
LOW BATTERY	Batteries are low.	Replace batteries.
KEY STUCK	A button on the pump was pressed too long or is stuck.	Release the pressed button.
TIME TO CHANGE BAG (Intermittent mode)	Infusion bag is almost empty.	Replace bag.
SW UPDATE FAILED	Pump software update failed.	Restart pump and reload its software.

Alarm Text	Cause	Resolution
PROGRAMMING FAILED	Treatment program was not sent to the pump.	Resend treatment program via the Avoset programming tool.
UNPRIMED SET	The pump detected air in the fluid path directly under the pumping mechanism.	Prime the set.
REPLACE SET	Set cassette failed test.	Remove and reinsert the set.
REMOVE AND REINSERT SET	Set cassette is not properly attached.	Remove and reinsert the set.
CASSETTE IS PRESSED	Set cassette is not properly attached	Remove and reinsert the set.
SHUTDOWN ERROR PROGRAM RESET	An unexpected shut-down occurred.	Start a new treatment with the original values.

Notifications

(TBD??)

Appendix A: Technical Specifications

Specifications

Specification	Value
Display	2.1" x 2.1" LCD
Dimensions (W x H x D)	96 x 96 x 47 mm
Weight (including batteries)	420 g
Pump Mechanism	Avoset Flex Volume straight set technology, volumetric pump
Treatment Modes	Continuous, Intermittent, Taper, PCA
Accuracy	± 5% per IEC 60601-2-24
Power Source	3xAA batteries (disposable/rechargeable)
Battery Types	Alkaline/LR6 (AA, 1.5V) or NiMH/HR6 (AA, 1.2V)
Battery life* @ 1 mL/h	150* hours (alkaline) 140** hours (rechargeable)
Battery life* @ 25 mL/h	120* hours (alkaline) 120** hours (rechargeable)
Battery life* @ 125 mL/h	30* hours (alkaline) 29** hours (rechargeable)
Battery life* @ 300 mL/h	10* hours (alkaline) 10** hours (rechargeable)
* Results of laboratory tests conducted at room temperature using new batteries (Duracell Procell AA Alkaline/PC1500). ** Results of laboratory tests conducted at room temperature using new batteries (NiMH Duracell rechargeable 2500mAh).	
Connectivity	BT, NFC
Disposable Set	DEHP free, Automatic anti-free-flow protection
Container	Medication reservoir, bag, syringe
Ingress Protection	IP24 per IEC 60529
KVO Rate	Supported, 0.1 mL/h increments
Flow Rate	0.1 - 100 mL/h with 0.1 mL/h increments 100 - 300 mL/h with 1 mL/h increments
Volume (VTBI)	0.1 - 9,999 mL with 0.1 mL increments
Upstream Occlusion	3, up to TBD
Downstream Occlusion	1, up to 17.4 psi (1.2 bar/900 mmHg)
Operating Temperature	5 - 40 °C (35.6 - 104 °F)
Maximum Infusion Pressure Generated	2 bar
Priming	Manual or automatic
Defibrillator-proof (recovery time)	Max 1 second

Specification	Value
Infusion Device	Linear, peristaltic
Pump Sensors	• Air in line: Detects both single and accumulated bubbles sized 0.1, 0.5, and 2 mL. Detectable bubble sizes can be configured using the Avoset programming tool. • Upstream/downstream occlusion • Cassette insertion • Temperature: Measures the pump's internal temperature.
Fuse Rating	1.5 A, 24 VDC
Maximum Effective RF Radiated Power	3.99 dBm
Frequency Band of RF Transmission	2.402 – 2.480 GHz as Bluetooth
RF Modulation Type	GFSK
Air Detection Sensitivity Levels	TBD
Expected Service Life	TBD

Operation Conditions

Operate the Avoset Infusion Pump only within the following parameters:

Warning

The pump must operate in the defined temperature specification. Any deviation can affect pump performance.

Condition	Minimum	Maximum
Temperature (°C)	5	40
Humidity (%RH)	15	90
Atmospheric Pressure (kPa)	70	106
Atmospheric Pressure (psi)	10.15	15.4

Note

The pump operation was tested in transient conditions of -20 °C for 20 minutes and found to operate according to specifications. Any deviations from these conditions might result in reduced/inadequate performance.

Service Life

Expected service life for the Avoset Infusion Pump is 6 months.

Typical Bolus Volume after Occlusion

[separate tables for time for max time to occlusion] The following table presents the typical time to a downstream occlusion alarm, and the typical bolus volume after occlusion when occlusion created on the downstream Microbore tubing, 1 meter from the cassette:

Occlusion Detection Sensitivity	Infusion Rate (mL/h)	Typical Bolus Volume after Occlusion (mL)	Maximum Time to Downstream Occlusion Alarm
0.5 bar	25	< 0.15	< 20 sec.
	1	< 0.15	< 10 min.
	0.1	< 0.15	< 55 min.
1.6 bar	25	< 0.3	< 45 sec.
	1	< 0.3	< 16 min
	0.1	< 0.3	< 55 min

Accessory Specs

The following accessories can be ordered from the manufacturer as pump accessories:

- AvosetPad pairing terminal
- Administration sets
- Avoset Lockbox
- Avoset Cradle

Pump Accuracy

The following graphs and curves were derived from the pump accuracy testing procedures described in the IEC 60601-2-24 standard and follows applicable FDA guidance. Testing was performed under normal conditions (specified in IEC 60601-2-24 standard) at room temperature (25 °C, 72 °F).

Note

For details of equipment used in testing, contact support@eitanmedical.com.

Normal conditions to ensure optimal accuracy of ±5 %:

- Fluid level should be at the level of the pump
- No back pressure due to catheter size or difference in height of pump and infusion site
- Room temperature (25 °C)
- Barometric pressure of sea level altitude (101 kPa)
- IV medication with water like fluid characteristics

Infusion under high back-pressure conditions (for example, when using catheters, or other restricting administration set components) may cause the accuracy of the pump flow delivery to deviate from the accuracy stated for normal conditions.

In the Avoset Infusion Pump, as in all infusion systems, external factors may cause fluctuations in rate accuracy. Conditions that can cause flow fluctuations include:

- Fluid characteristics that deviate from water-like characteristics, such as density, viscosity and homogeneity
- Positive and negative pressure, including back pressure
- Environmental temperature above 40 °C or below 5 °C
- In PCA bolus that is less than 1 mL a deviation of +/-0.06 mL can occur
- Position of the infusion container height (any deviation from 50 cm above the pump)
- Pump operation beyond the recommended operating limits

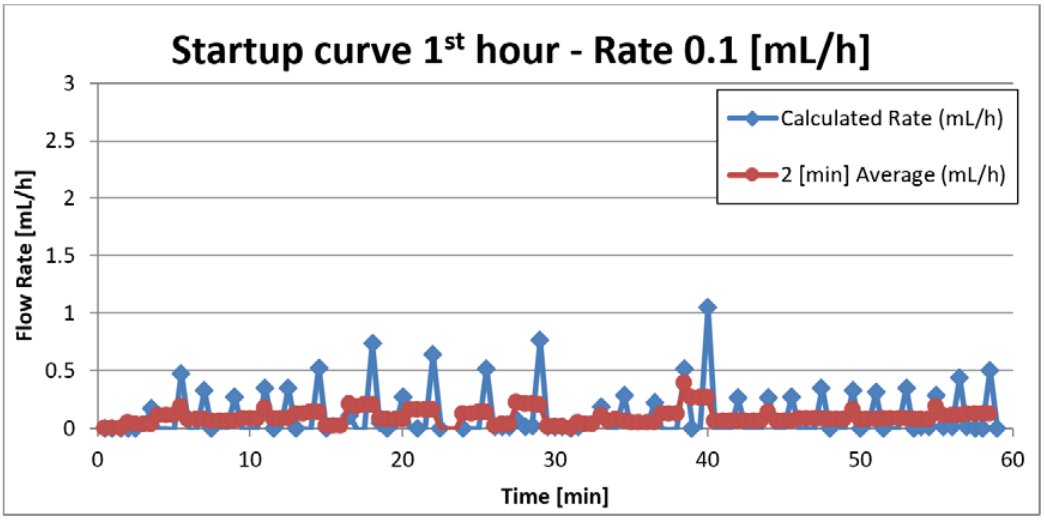
Start-up and Trumpet Graphs

The start-up graphs represent startup flow versus operating time for the first two hours from the start of the infusion. They exhibit the stability of delivery due to mechanical compliance and provide a visual representation of uniformity. Start-up graphs were performed according to the IEC 60601-2-24 standard.

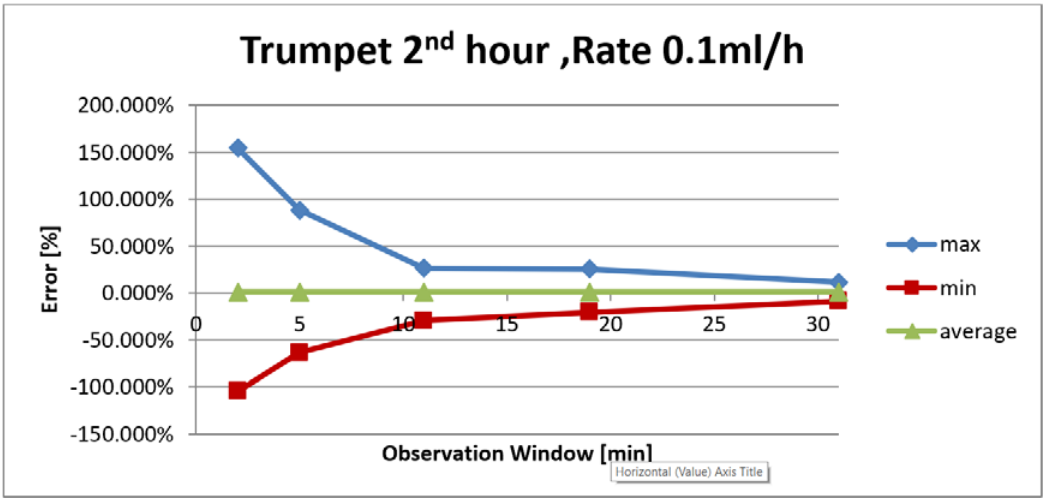
Trumpet curves are named for their characteristic /shape, and are developed in accordance with IEC 60601-2-24. They display the percent flow rate deviation from the programmed rate over time. The horizontal axis represents the observation time intervals.

Over long observation windows, short-term fluctuation has little effect on accuracy, as represented by the flat part of the curve. As the observation window is reduced, short-term fluctuations have a greater effect, as represented by the “mouth” of the trumpet.

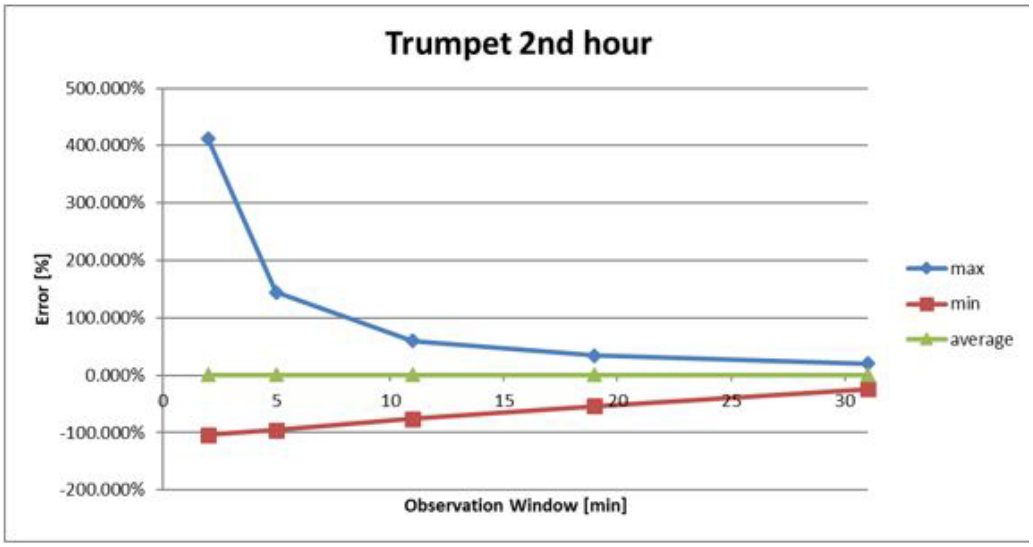
Delivery Startup Graph, First 2 Hours of Test Period, 0.1mL/h



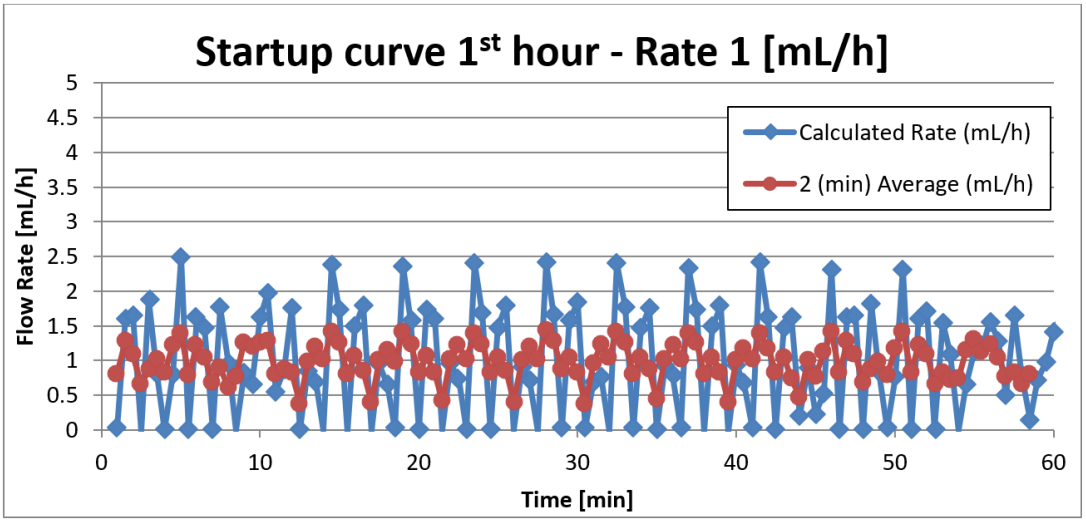
Trumpet Graph, Second Hour of Delivery, 0.1mL/h



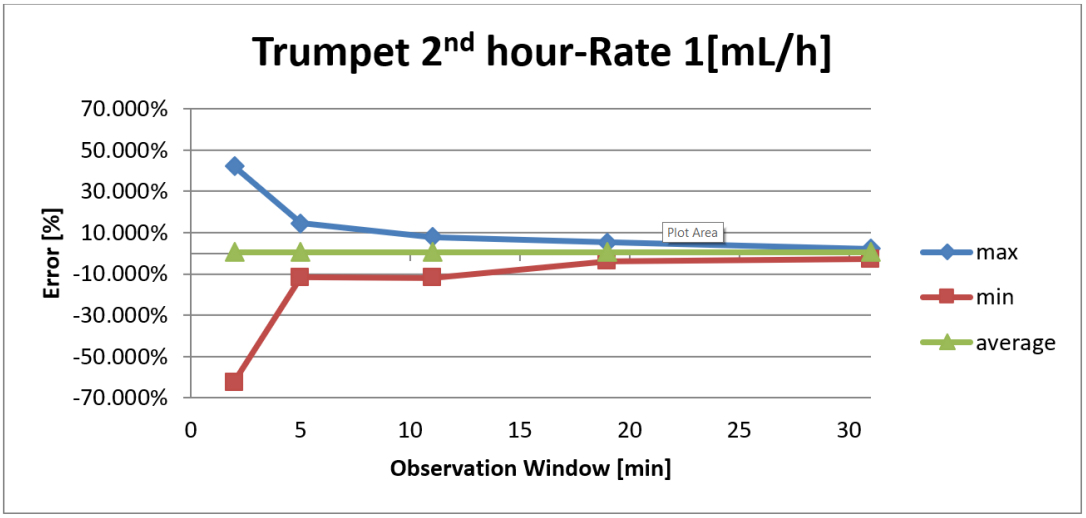
Trumpet Graph, 96th (Last) Hour of Delivery, 0.1 mL/h



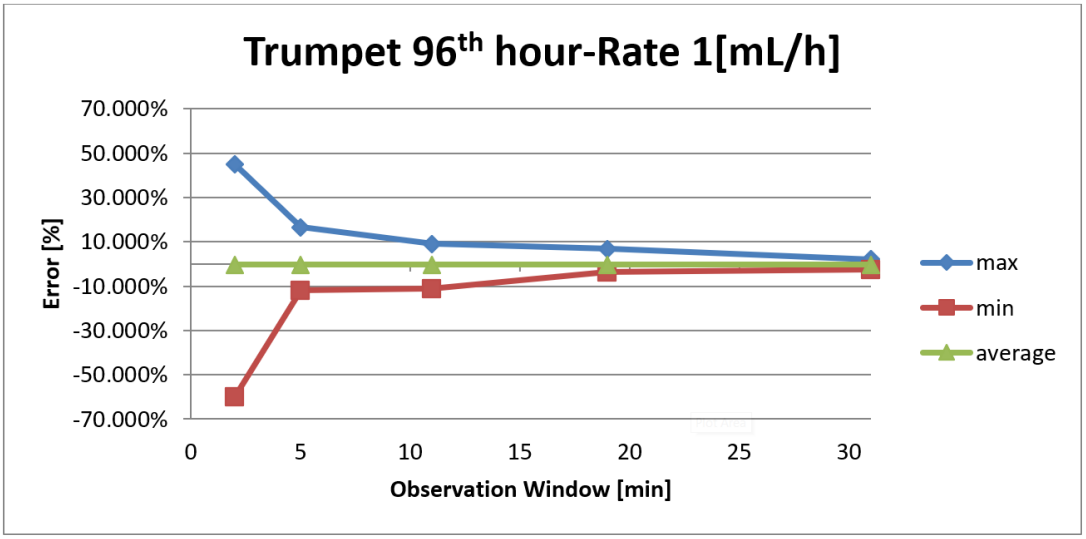
Delivery Startup Graph, First 2 Hours of Test Period, 1 mL/h



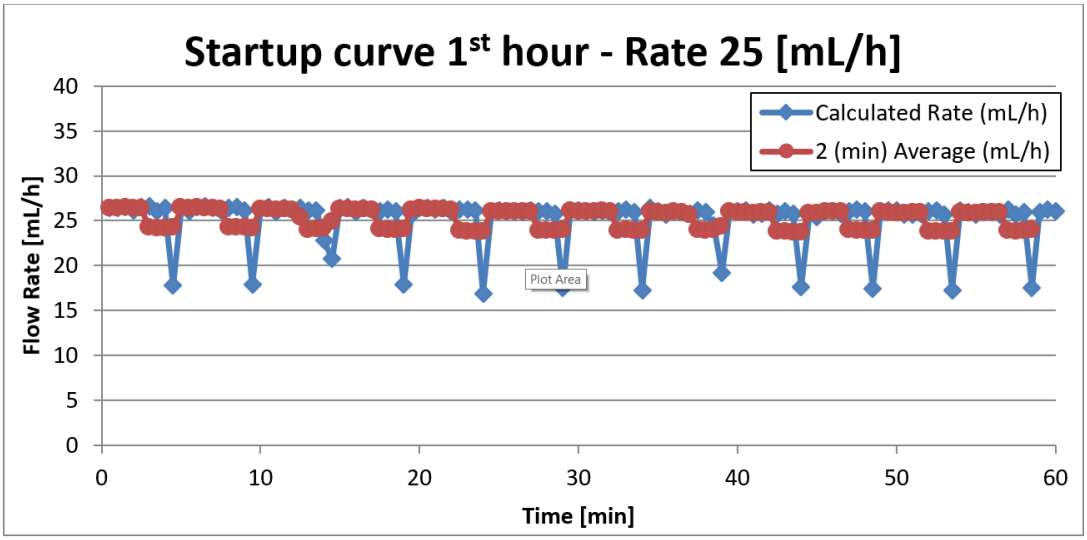
Trumpet Graph, Second Hour of Delivery, 1 mL/h



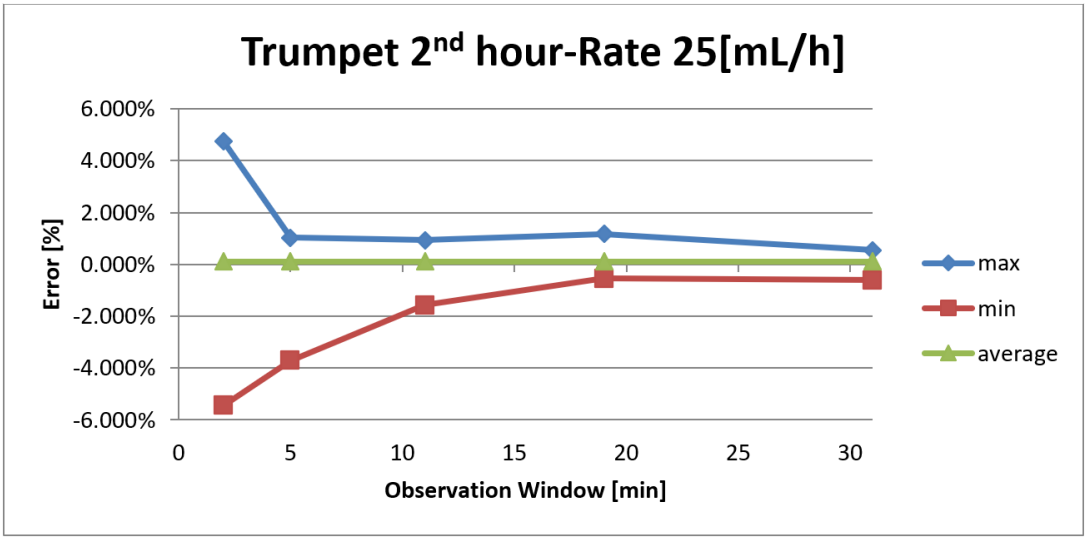
Trumpet Graph, 96th (Last) Hour of Delivery, 1 mL/h



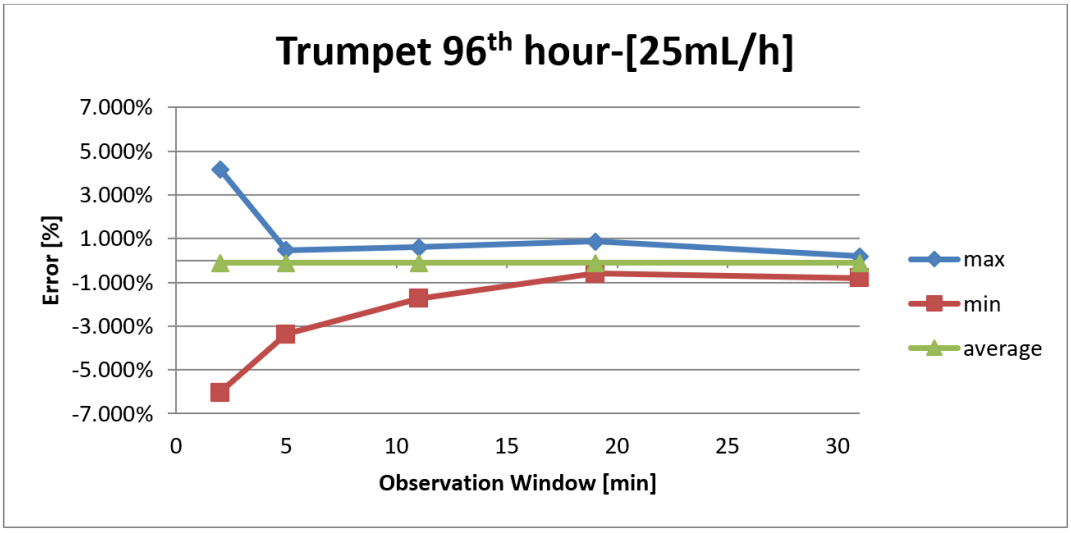
Delivery Startup Graph, First 2 Hours of Test Period, 25 mL/h



Trumpet Graph, Second Hour of Delivery, 25 mL/h



Trumpet Graph, 96th (Last) Hour of Delivery, 25 mL/h



Advanced Settings

These are the parameters that can be set using the Avoset programming tool:

Category	Secondary Parameter	Range	Options
General			
PUMP UNATTENDED		2, 5, 10 min.	N/A
Prime	Prime volume	2–20, 1	N/A
	Prime reminder	N/A	ON/OFF
Audio	Alarm volume	N/A	High (65 dB) Low (45 dB)
	Key sounds	N/A	ON/OFF
Regional	Time offset *	N/A	-6, -5, -4, -3, -2, -1, 0, 1, 2, 3, 4, 5, 6
Password-protected Functions			
Automatic Prime	Continuous	N/A	Locked/Unlocked
	Intermittent	N/A	Locked/Unlocked
	PCA	N/A	Locked/Unlocked
	Taper	N/A	Locked/Unlocked
Continuous Edit Infusion		N/A	Locked/Unlocked
Immediate Taper Down		N/A	Locked/Unlocked
Clear PCA Bolus History		N/A	Locked/Unlocked
Edit Next Dose Start Time		N/A	Locked/Unlocked
Unlock Password		100–999	N/A
Air and Occlusion Alarms			
Air in Line		N/A	OFF, 0.1, 0.5, 2mL
Accumulated Air		N/A	OFF, 1 mL
Occlusion Sensitivity		N/A	High/Low
Occlusion Auto Restart		N/A	N/A

Note

Occlusion alarm threshold is 3 levels for downstream and 1 for upstream.

Category	Secondary Parameter	Range	Options
Advanced Options			
Continuous	KVO rate	0, 0.1–10, 0.1	N/A
	Minimum rate	0.1–99.9,0.1 100–300,1	N/A
	Maximum VTBI	0.1–999.9,0.1 1000–9999,1	N/A
	Minimum VTBI	0.1–999.9,0.1 1000–9999,2	N/A
	Maximum rate	0.1–99.9,0.1 100–300,1	N/A
Intermittent	Time to Change Bag reminder	10, 20, 30 min.	N/A
Taper	KVO rate		N/A
	Intermediate taper down	N/A	N/A
PCA	KVO rate		N/A
	Bolus rate		N/A
* When setting an offset, the pump clock has the same offset as the PC browser. This affects the delayed start time and event log time stamps.			

Event Log

The pump has a log that keep all events monitored by the system. The event log is maintained after the pump is turned OFF.

The event log can be accessed via the Avoset programming tool.

The log can hold 45,000 entries. In a typical infusion, there may be TBD entries. When this is exceeded, new entries overwrite the oldest entries in the log.

Appendix B: Safety and Compliance

Compliance and Classification

This manual has been written in conjunction with the requirements in the International Standard, IEC 60601-2-24 for Medical Electrical Equipment—Part 2-24: *Particular Requirements for Safety of Infusion Pumps and Controllers*. Data presented in the Technical Specification section reflect specific test conditions defined in this standard. Other external factors, such as varying back pressure, temperature, head height, set usage, fluid restrictions, solution viscosity, or combinations of these factors may result in deviations from the performance data presented.

Electromagnetic Compatibility Statement

The system complies with the following radio directives and standards:

- 2014/30/EU EMCD
- 2014/35/EU LVD
- 1999/5/EC R&TTE or 2014/53 RED
- EN 301489-17, EN 301489-3
- EN 300 328 V2.1.1, EN 300 330 V2.1.1
- EN 62479

The Avoset Infusion Pump is designed to conform with the electromagnetic compatibility (EMC) standard IEC 60601-1-2 and to operate accurately in conjunction with other medical equipment which also meets the requirements of this standard. To avoid electromagnetic interference that may affect the operation of the pump, do not use the pump near sources of strong electric and magnetic interference (EMI), such as MRI, CT, diathermy, electromagnetic security systems (e.g., metal detectors), and large electric motors.

Portable and mobile RF communication equipment, such as RF emitters, cellular telephones, 2-way radios, Bluetooth devices, and microwave ovens in close proximity to this device may affect wireless communications with the Infusion pump and/or the operation of the Infusion pump.

This device must not be used with any other antenna or transmitter that has not been approved to operate in conjunction with this device.

Some of these EMI sources (mostly RF emitters) may not be visible and the device can potentially be exposed to fields from these EMI sources without the user's awareness. Special precautions need to be exercised regarding EMC. These include:

- Maintaining a minimum separation distance of 2 1⁄2 ft (3⁄4 m) between the Infusion pump system and portable/mobile RF communications equipment.
- Managing the electromagnetic environment to permit the device to perform as intended without disturbing other equipment.

Note

When programming the pump, the electromagnetic environment includes a PC.

- Separating the device from all other electronic equipment. If the device must be used near other electrical equipment, monitor the equipment to ensure there is no electromagnetic interference.
- Devices should not be used adjacent to or stacked with other equipment. If the device must be used adjacent to or stacked with other equipment, monitor the device to verify normal operation.
- If you identify or suspect that external RF sources or other equipment are influencing device operation (from known or unknown sources), try to (as applicable) increase the pump's distance from the EMI source, re-orient the device, relocate the device, connect the device to a different outlet, contact the biomedical engineering department for additional guidelines concerning electromagnetic immunity or decrease emitting device output power (to 30 dBm).
- Contact the biomedical engineering department for additional information in the service manual concerning operating devices near RF sources.

The EMC limits for the Medical Device Directive 93/42/EEC (EN301489-1/-17 IEC/EN 60601-1-2:2014) are designed to provide reasonable protection against harmful interference in a typical medical installation. The equipment generates, uses and can radiate, radio frequency energy, and if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference with other devices, which can be determined by turning the equipment OFF and ON, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device
- Increase the distance separating between the equipment parts
- Consult the manufacturer or field service technician for help

Electromagnetic Safety Precautions

Do not expose the pump to therapeutic levels of ionizing radiation, as permanent damage to the pump electronic circuitry may occur. It is preferable to remove the pump from the patient during therapeutic radiation sessions.

Do not use the pump in the vicinity of magnetic resonance imaging (MRI) equipment, as magnetic fields may adversely affect the operation of the pump. Remove the pump from the patient during MRI procedures, and keep it at a safe distance from magnetic energy.

Class B Warnings

FCC Statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.

- Connect the equipment to an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician.

CAN ICES-3 (B) / NMB-3 (B)

This Class B digital apparatus complies with Canadian ICES-003.

Cet appareil numérique de classe B est conforme à la norme canadienne ICES-003.

In order to maintain compliance with FCC regulations, shielded cables must be used with this equipment. Operation with non-approved equipment or unshielded cables is likely to result in interference to radio and TV reception.

Modification Statements

FCC Warning

Modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment under FCC Rules.

ISED Warning

Q Core Medical Ltd. n'approuve aucune modification apportée à l'appareil par l'utilisateur, quelle qu'en soit la nature. Tout changement ou modification peuvent annuler le droit d'utilisation de l'appareil par l'utilisateur.

Interference Statement

This device complies with Part 15 of the FCC Rules and Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Wireless Notice

This device complies with FCC/ISED radiation exposure limits set forth for an uncontrolled environment and meets the FCC radio frequency (RF) Exposure Guidelines and RSS-102 of the ISED radio frequency (RF) Exposure rules. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Le présent appareil est conforme à l'exposition aux radiations FCC / ISED définies pour un environnement non contrôlé et répond aux directives d'exposition de la fréquence de la FCC radiofréquence (RF) et RSS-102 de la fréquence radio (RF) ISED règles d'exposition. L'émetteur ne doit pas être colocalisé ni fonctionner conjointement avec à autre antenne ou autre émetteur.

RF Exposure Warnings

This device has been tested for compliance with FCC RF exposure limits in a portable configuration. At least 2 cm of separation distance between the device and the user's body must be maintained at all times. This device must not be used with any other antenna or transmitter that has not been approved to operate in conjunction with this device.

FCC/ ISED Regulatory Notices

Interference Statement

This device complies with Part 15 of the FCC Rules and Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Wireless Notice

This device complies with FCC/ISED radiation exposure limits set forth for an uncontrolled environment and meets the FCC radio frequency (RF) Exposure Guidelines and RSS-102 of the ISED radio frequency (RF) Exposure rules. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Le présent appareil est conforme à l'exposition aux radiations FCC / ISED définies pour un environnement non contrôlé et répond aux directives d'exposition de la fréquence de la FCC radiofréquence (RF) et RSS-102 de la fréquence radio (RF) ISED règles d'exposition. L'émetteur ne doit pas être colocalisé ni fonctionner conjointement avec à autre antenne ou autre émetteur.

Electromagnetic Emission

The Avoset Infusion Pump is intended for use in the electromagnetic environment specified below. The user of the pump should ensure that it is used in such an environment.

Emission Test	Compliance	Electromagnetic Environmental Guidance
RF Emission	CISPR 11 class B	The pump is suitable for use in home and clinical environment.

Electromagnetic Immunity

The Avoset Infusion Pump is intended for use in the electromagnetic environment specified below.

The user should ensure that it is used in the following environment.

Caution

Use of this equipment adjacent to or stacked with other equipment (see below table) should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Test Method	Test Level	Compliance Level	Electromagnetic Environmental Guidance
Electrostatic discharge (ESD) per IEC 61000-4-2	±8 kV contact, ±2 kV, ±4 kV, ±8 kV, ±15 kV air*	±8 kV contact, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated RF EM field immunity per IEC 61000-4-3	10 V/m, 80 MHz –2.7 GHz, 80 % AM at 1 kHz*	10 V/m, 80 MHz –2.7 GHz, 80 % AM at 1 kHz	N/A
Power frequency (50/60 Hz) magnetic field immunity per IEC 61000-4-8	30 A/m*	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
RF wireless communications equipment fields Immunity per IEC 61000-4-3	Frequencies and levels as specified at IEC 60601-1-2, Table 9*	Max. 28 V/m	N/A
Radiated Emission RTCA DO-160G: Section 21 Radiated Emission CISPR 11/ IEC 60601-1-2	Category M Category B	100MHz -6GHz 30MHz -6GHz	
* The pump was tested according to the EMC requirements of IEC 60601-1-2 (fourth edition).			

Applicable IEC Classifications

IEC 6061-1	Medical Electrical Equipment: • internally powered • Class II • Type CF • Continuous operation • IP24 dust- and splash-proof • Not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide
IEC 60601-1-2	Electromagnetic compatibility
IEC 60601-2-24	Infusion pumps and controllers, which classifies the Avoset Infusion Pump as a Type 4 pump (continuous infusion flow, combined with bolus delivery)
IEC 60601-1-8	Requirements for alarm systems in medical electrical equipment and medical electrical systems
IEC 60601-1-11	Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

Other Compliance

Defibrillator Compliance Statement

The Avoset Infusion Pump is equipment type CF Applied Part.

CISPR 11 Classification

The Avoset Infusion Pump is classified as a Class B ME and is meant to be operated in domestic establishments connected to a low voltage power supply network that does not emit strong radio-frequency.

Biocompatibility

All materials in components of the administration sets that are in the fluid pathway have been tested for biocompatibility and are in compliance with applicable international standards ISO 10993-1 for biocompatibility.

Degree of Protection Against Ingress of Water and Dust

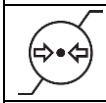
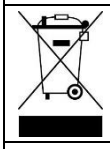
The Avoset Infusion Pump meets the IP24 splash/dust requirements according to IEC 60601-1-11.

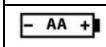
Recycling & Disposal

Dispose of the pump in accordance with local regulations.

Symbols and Labelling

The following table describes the labels and symbols that appear on the pump, accessories, and packaging.

Symbol	Standard and Symbol Number	Symbol Title	Location	Description
CE 0123	93/42/EEC	CE	pump back	The product meets European Community directives concerning medical devices.
EC REP	EN ISO 15223-1:2016	EC Rep	pump back	Authorized representative in the European Community.
⎓	ISO 7000 / IEC 60417, Ref. 5031	Direct Current	pump back	The device uses electrical direct current.
SN	ISO 7000, Ref. 2498	Serial Number	pump back	Serial number for the specific device (unique to each).
REF	ISO 15223-1 5.1.6	Catalog Number	pump back	Indicates the manufacturer's catalog number so that the medical device can be identified.
	ISO 7000, Ref. 0632	Storage Temperature Range	packaging	Safe temperature range for storing packaged device.
	ISO 7000, Ref. 2620	Storage Humidity Range	packaging	Safe humidity range for storing packaged device.
	Symbol 5.3.9 (ISO 7000-2621) of ISO 15223-1:2012	Atmospheric Pressure Range	packaging	Safe atmospheric pressure range for packaged device.
	ISO 7010 M002	Safety (Read Instructions)	pump back	Consulting the accompanying documents is mandatory.
	ISO 7000, Ref. 2497	Date of Manufacture	pump back	Date that the device was produced.
	ISO 15223-1 5.1.1 90/385, 93/42/EEC, 98/79/EC	Manufacturer	pump back	Indicates the name and address of the device manufacturer.
	IEC 60417-5336	Defibrillation-proof	pump back	Indicates the device is defibrillation-proof and the degree of protection against electric shock. Equipment type CF applied part.
IP65	IEC 60529	Ingress Protection	pump back	Indicates the device is protected from dust and splashes.
GTIN		Global Trade Item Number	pump back	Identifying number for these devices.
	WEEE Directive	Electrical and electronic waste	pump back	Dispose of according to local ordinances.
	ISO 7000, Ref. 0621	Fragile	packaging	Fragile; handle with care.
	ISO 7000, Ref. 0626	Keep Dry	packaging	Product is not waterproof. Keep product dry.
		This Side Up	packaging	Do not store on side or upside down.

Symbol	Standard and Symbol Number	Symbol Title	Location	Description
	ISO 15223-1 5.4.4	Caution		Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	IEC 60878:1988 (02-03)	Type B Patient-Applied Part		Indicates a medical device used a patient.
	ISO 15223-1	Use-by Date		Indicates the date after which the medical device is not to be used.
	ISO 15223-1 5.1.5	Batch Code		Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO-15223-1 5.2.8	Do not use if package is damaged		Indicates a medical device that should not be used if the package has been damaged or opened.
	ISO 15223:2016	Prescription		Device requires a prescription.
		Battery Orientation	pump battery compartment	Shows orientation to insert AA batteries.