

Avoset Infusion Pump

Safety Quick Guide

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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.

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Purpose

This Quick Guide provides important guidelines to help you use your Avoset Infusion Pump safely and effectively. Further technical information on Avoset infusion pump and accessories is available in the Avoset Infusion Pump User Manual, contact your service provider for support. The safety information is grouped in functional categories and prioritized as follows:

	<p>Warnings indicate precautions and instructions which, if not followed, may result in personal injury.</p>
	<p>Cautions indicate instructions which, if not followed, may result in damage to the equipment or to the quality of treatment.</p>

Safety Guidelines

Getting Help

If you have questions or concerns about your treatment, contact your physician or other healthcare professional who prescribed the treatment.

If you have questions or concerns about the equipment, contact:

- US toll-free: 1-833-771-2995
- see the website (eitanmedical.com) for other numbers that may be available

Child Safety



Warning

Keep used plastic containers and packaging out of the reach of children and pets. The administration set, infusion container and packaging contains small parts and may contain residual medication.

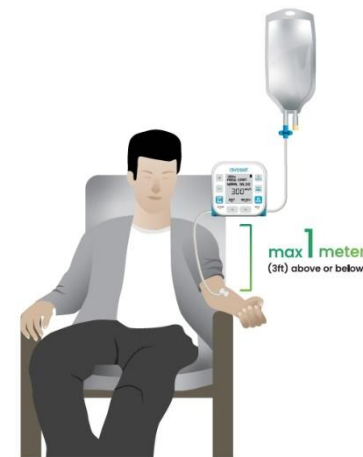
Avoid Deviation from Accuracy



The Avoset infusion pump accuracy is of $\pm 5\%$

Caution

- **Humidity:** Do not use the pump in an environment with humidity above 90% or below 15%. You can find this information on a weather channel, website, or app.
- **Altitude:** Do not use the pump at very high altitudes (above 6096 meters / 20000 ft) or very low altitudes (below -381 meters / -1210 ft).
- **Temperature:** Do not use the pump in temperatures above 40°C / 104F or below 5°C / 41F
- **Placement:** Do not place the pump more than 1 meter (3 ft) above or below the patient's IV insertion point (see figure).
- **Temperature Changes:** Do not use the pump immediately after it was exposed to sudden extreme temperature changes (such as being brought into an air-conditioned room after being left in a hot car). Allow the pump to adjust to the new temperature before use for two hours.
- **Plunger:** Do not push or pull the syringe plunger after the administration set is attached to the pump.



Avoid Exposure to Harmful Use Conditions



Caution

Do not expose the pump to:

- direct sunlight and excessive heat (if you are outdoors, keep the pump shaded)
- steam and boiling water
- lint and dust
- submersion in water or other liquids
- MRI (magnetic resonance imaging) equipment. Remove the pump from the patient during MRI procedures, and keep it at a safe distance.
- therapeutic levels of ionizing radiation such as X-Ray, CT (Computed Topography), CAT (Computed Axial Tomography) scans, or radiation therapy
- portable RF (radio frequency)-enabled equipment (such as wifi routers or Bluetooth speakers) closer than 30 cm (12 in) from the pump
- flammable gas (including anesthetic mixtures or nitrous oxide)

Storage



Caution

Remove batteries for long storage: Do not keep the batteries inside the pump when storing the pump for a long period of time (over 6 months).

Pump Guidelines

When to Not Use the Pump

Not

Do not use the pump or accessories (accessories including Avoset Cradle and Cassette Lock) in these situations:



Warning

- **Damage or Dropping:** Do not use the pump or accessories if they were dropped or appear to be damaged until they have been inspected by a qualified technician.
- **Interface Performance:** Do not use the pump if its interface (including screen messages, audible signals, or physical key functions) does not perform as described in the provided manuals (for example, if there is no sound during an alarm, or if the screen light does not turn on when pressing a key).
- **Training:** Do not Operate the pump if you were not trained how to operate it.

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Caution

Do not use the pump or accessories if any of the following occur:

- The screen does not light up.
- Any area of the screen is not visible, or there are stripes or black and white areas covering parts of the screen.
- When turning on the pump the green and red LED do not light momentarily.
- The Pump technical information does not show on the screen briefly when turning on the pump.

Do Not Do the Following with the Pump

Do not do the following things with the pump or accessories:



Warning

- Do not attempt to modify or disassemble the pump, accessories, administration sets, or the pump mechanism or housing.
- Do not use the pump, medication, or accessories provided by your service provider for anything other than the intended purpose. Misuse may lead to injury.

Administration Set Guidelines

When to Not to Use an Administration Set

Do not use an administration set in these situations:



Warning

- **Usage Time:** Do not use any administration set for longer than 96 hours. If your infusion is expected to exceed 96-hour, make sure to replace the disposable component on time.
- **Damaged or Expired:** Do not use an administration set if the set, its package, or its components are damaged or expired.

Do Not Do the Following with an Administration Set

Do not do the following things:



Warning

- Do not place the administration set on the floor, or anywhere it can accidentally be damaged, or pose a risk of strangulation or entanglement.
- **Single-use only:** Do not clean or sterilize Avoset administration sets for re-use. The sets are intended for single use.
- Do not release or attach an administration set from the pump or to the pump without first clamping the line.

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**Caution**

Do not pull or stretch the administration set tubing when the pump is in use.

Battery Guidelines

Installing and Replacing Batteries



Caution

- **Inspect First:** Do not insert batteries before visually inspecting the battery compartment for liquid or debris. Make sure it is dry and clear of debris (if necessary, clean the pump).
- **Replace All Batteries at Once:** Do not mix new batteries with old ones. Do not use different types of batteries together (for example, rechargeable with alkaline), as it may affect the pump's performance.
- **Do Not Open:** Do not open the battery compartment unless you are changing batteries.
- **Do Not Remove:** Do not remove batteries while infusion is in progress.
- **No Lithium Batteries:** Do not use lithium batteries.
- **Remove for Long Storage:** Do not keep batteries inside the pump when storing the pump for a long period of time (over 6 months).

Setting up a Treatment Safely

Make sure you are aware of the following requirements when setting up a treatment.



Warning

- Always keep a new set of AA batteries available as backup to prevent treatment interruption in case of power loss.
- Always insert a fresh set of batteries when starting a new infusion.
- If the treatment is for life-sustaining medication, always keep a second pump available as a backup. Pay attention to the treatment so that in the event of pump failure, you can switch to the backup pump, minimizing the interruption of medication delivery.

Disposal Guidelines



Warning

Do not dispose of the battery in or near fire.



Caution

- Dispose of the battery, pump, or any other electronic components according to your local laws. Contact your service provider if you are unsure.
- Dispose of used administration sets according to your local laws regarding medical waste. Used administration sets may contain residual medication..
- Dispose of all cleaning/disinfectant materials according to your local laws for infectious waste disposal.

Cleaning and Disinfecting

Between use on different patients, the pump and all of its components need to be first cleaned thoroughly and then disinfected thoroughly, per hospital/medical provider protocol for multiple patient use. If you wish to clean your pump, first contact your service provider to for proper training on the cleaning procedure.

Acceptable cleaning agents are:

- **pump:** 70% IPA (isopropyl alcohol)
- **accessories:** 70% IPA (isopropyl alcohol)
- see the website (eitanmedical.com), as this list may be updated with additional cleaning agents



Warning

Do not clean or disinfect **unless**:

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



Caution

Do not clean or disinfect the pump unless you are trained.



Caution

While cleaning or disinfecting:

- 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. Disinfect only the external parts of the pump.
- Do not allow fluid (including cleaning agents) to enter the pump (including speaker holes, cassette socket, or battery compartment).
- Do not steam autoclave, ethylene oxide sterilize, or immerse any part of the pump in fluid.
- Do not use spray or aerosol cleaners.
- Dispose of all cleaning/disinfectant materials per regulations for infectious waste disposal.

Cleaning the Pump

1. Turn the pump OFF and disconnect it from the patient.
2. Remove the administration set and batteries.
3. Close the battery compartment.
4. Apply the 70% isopropyl alcohol to a cloth, then wring the cloth out to remove excess liquid.
5. Wipe all exterior areas in back-and-forth motions, vertically and horizontally. Perform 3 cycles of the exterior wipe-down, verifying complete coverage of the areas to be cleaned.



Note

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

6. Wipe the pump's cassette slot in vertical or horizontal movements, where possible. Wipe less-accessible areas in bi-directional rotations. Perform 6 cycles of the cassette slot wipe-down, verifying complete coverage of the areas to be cleaned.
7. Let the pump dry for 5 minutes.

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8. Wipe the pump with a clean dry cloth. Inspect the cloth for any residue.



Caution

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

Disinfecting the Pump

1. After cleaning thoroughly, inspect the pump carefully for any residue. If there is any visible soil, repeat the cleaning steps above.
2. Repeat steps 4–8, above.

Cleaning the Accessories

1. Remove accessories from any connections (for example, remove the cradle from the IV stand and remove the pump from the cradle).
2. Apply 70% isopropyl alcohol to a cloth. Wring the cloth out to remove excess liquid.
3. Wipe all exterior areas in back-and-forth motions, vertically and horizontally. Perform 3 cycles of the exterior wipe-down, verifying complete coverage of the areas to be cleaned.

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**Note**

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









4. Let the accessory dry for 5 minutes.
5. Wipe it with a clean dry cloth and inspect the cloth for any residue. (If necessary, repeat cleaning until there is no visible residue on the cloth.)










Disinfecting the Accessories








1. After cleaning thoroughly, inspect the accessories carefully for any residue. If there is any visible soil, repeat the cleaning steps above.
2. Repeat steps 2–5, above.

Symbols and Labelling

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

Symbol	Symbol Title	Location	Description
	Storage Temperature Range	packaging	Safe temperature range for storing packaged device.
	Storage Humidity Range	packaging	Safe humidity range for storing packaged device.
	Atmospheric Pressure Range	packaging	Safe atmospheric pressure range for packaged device.
	Keep Dry	packaging	Product is not waterproof. Keep product dry.
	This Side Up	packaging	Do not store on side or upside down.
	Fragile	packaging	Fragile; handle with care.
	Do not use if package is damaged	packaging	Indicates a medical device that should not be used if the package has been damaged or opened.
	CE	pump back	The product meets Medical Device Regulation concerning medical devices for European Conformity.

Symbol	Symbol Title	Location	Description
	EC Rep	pump back	Authorized representative of European Conformity.
	Direct Current	pump back	The device uses electrical direct current.
	Serial Number	pump back	Serial number for the specific device (unique to each).
	Catalog Number	pump back	Indicates the manufacturer's catalog number so that the medical device can be identified.
	Consult Instructions for Use	Cradle label and Cassette Lock label	Indicates the need for the user to consult the instructions for use.
	Safety (Read Instructions)	pump back	Consulting the accompanying documents is mandatory.
	Date of Manufacture	pump back	Date that the device was produced.
	Manufacturer	pump back	Indicates the name and address of the device manufacturer.
	Defibrillation-proof	pump back	Indicates the device is defibrillation-proof and the degree of protection against electric shock. Equipment type CF applied part.
IP 34	Ingress Protection	pump back	Indicates the device is protected from water spray from any direction.
GTIN	Global Trade Item Number	pump back	Identifying number for these devices.

Symbol	Symbol Title	Location	Description
	Electrical and electronic waste	pump back	Dispose of according to local ordinances.
	MR Unsafe	pump back	Keep away from magnetic resonance imaging (MRI) equipment. The device presents a projectile hazard.
	FCC Logo	pump back	FCC symbol.
	Medical Device	pump back	The device is a medical device.
	Batch Code	pump back	Indicates the manufacturer's batch code so that the batch or lot can be identified.
Rx Only	Prescription	pump back	US Federal law restricts this device to prescription only.
	Battery Orientation	inside pump battery compartment	Shows orientation to insert AA batteries.
	Caution	documentation	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.

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