AVANOS*

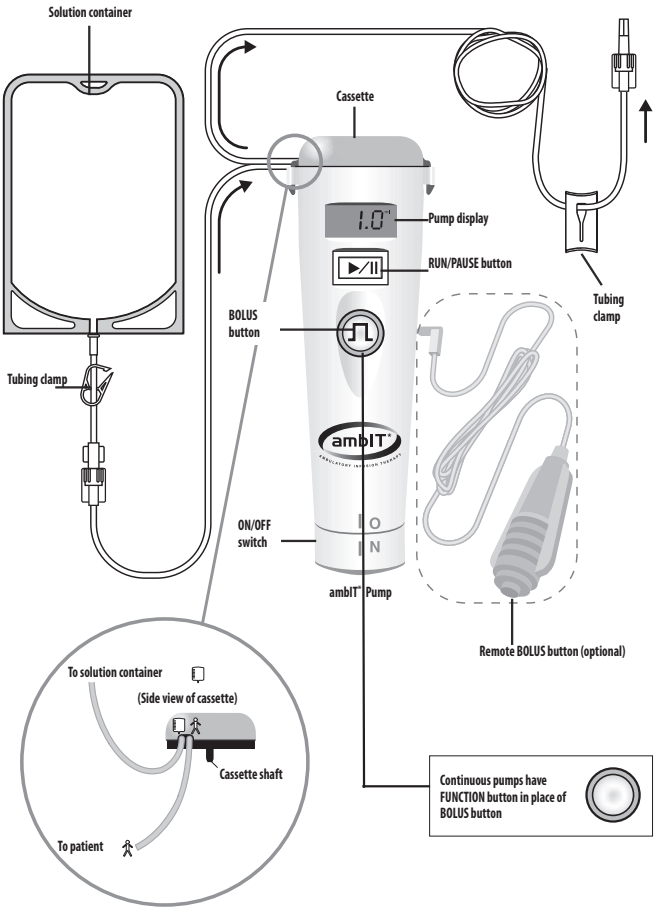
ambIT* PUMP

Patient Manual

ambIT®
AMBULATORY INFUSION THERAPY

Table of Contents

Become familiar with the ambIT* pump



SECTION 1 - INTRODUCTION

1.1 Definitions and Symbols

1.1.1 Definitions

ANALGESIA: Relief from pain.

BASAL FLOW RATE: The continuous flow rate.

BOLUS: A volume of medication infused over a relatively short period of time. If the healthcare provider has prescribed a bolus option, the bolus is delivered when requested by pushing the BOLUS button or the optional remote BOLUS switch.

CAUTION: A caution usually appears in front of a procedure or statement. Failure to observe a caution could result in serious patient or user injury. Cautions are found throughout this document emphasized with grey shading.

DOSE: A volume of medication infused over a relatively short period of time that occurs at regularly scheduled intervals.

INFUSION: The introduction of a saline or other solution via the tubing into the body.

INTERVAL OR DOSE INTERVAL: The time between the start of one dose and the start of the next dose. The dose interval has units of hours and minutes (hr:min).

KINK: A twist or curl of the tubing caused by its doubling or bending upon itself. A kink may stop or reduce the infusion rate (i.e., cause an occlusion; see definition below.)

LOCKOUT TIME: The time between the end of one bolus or dose and the start of the next bolus or dose. The lockout time has units of hours and minutes (hr:min).

ML: Milliliter; one-thousandth of a liter; shown as "ml" on pump and throughout manual.

NOTE: A note highlights information that acts as a reminder or helps explain a concept or procedure.

OCCLUSION: Closure or blockage of the tubing.

PAUSE MODE: The pump is on, but not infusing medication.

PCA: An acronym for patient controlled analgesia.

RUN MODE: The pump is on and infusing medication.

TUBING CLAMPS: A device found on the tubing used to open or close the flow of solution through the tubing. See diagram on inside cover.

WARNING: A warning message contains special safety emphasis and must be observed at all times. Warnings are found at Section 1.3, as well as throughout this document emphasized with grey shading. Failure to observe a warning message is potentially life threatening.

1.1.2 Definition of Symbols

	Consult instructions for use.
	International symbol meaning "Attention, consult accompanying documents."
	IEC symbol for "Type BF Applied Part." (IEC Classification: Internally powered.)
	The ambIT* pump complies with ES 60601-1:2012, 1st Edition, including Amend. 1; CSA C22.2 NO. 60601-1:2014, 3rd Edition; IEC 60601-1:2005, including Corr. 2:2007 and Amend. 1:2012; IEC 60601-1-6:2013, Edition 3.1; IEC 60601-1-8:2012, Edition 2.1; IEC 60601-1-11:2015; 60601-2-24:2012, Edition 2; IEC 62304:2006, 1st Edition; IEC 62366:2007, 1st Edition, and Amend. 1:2014; IEC 60601-1-2:2014, 4th Edition, 2014-02.
	MEDICAL – GENERAL MEDICAL EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1:2005/(R)2012 and CAN/CSA- C22.2 No. 60601-1:2014 | E468072
 NRTL/C	The "NRTL/C" indicator adjacent to the CSA (Canadian Standards Association) mark signifies that the product has been evaluated to the applicable ANSI/UL and CSA standards for use in the U.S. and Canada. NRTL (Nationally Recognized Testing Laboratory) is a designation granted by the U.S. Occupational Safety and Health Administration (OSHA) to laboratories that have been recognized to perform certification to U.S. standards.
IP22	Protected against insertion of fingers and will not be damaged or become unsafe during a specified test in which it is exposed to vertically or nearly vertically dripping water.
	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
EC REP	Indicates the Authorized Representative in the European Community.
	Any natural or legal person established within the Union that places a device from a third country on the Union market.
MD	Medical device
SN	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	CAUTION: This device is restricted to sale by or on order of a physician.
	Indicates which tubing connects to the solution container

	Indicates which tubing connects to the patient
	Bolus
	Program lockout
ml	Volume in milliliters
	Infusion completed
	RUN/PAUSE button
	PAUSE indicator
	BOLUS button
	FUNCTION button
	Low/dead battery indicator
	Alarm indicator
	ambIT* pump display
	Pump power on
	Pump power off

1.2 Clinical Benefits

The clinical benefits of the ambIT* pump and accessories are local or systemic (parenteral) delivery of therapeutic agents into a patient to mitigate post-operative pain, treat cancer (chemotherapy) and infections (antibiotics), and provide nutrition parenterally to patients who cannot feed orally or by enteral means.

1.3 Warnings

- Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
- This pump must be used only for the person for whom it was prescribed.
- Read instructions before use. The pump must be used strictly in accordance with these instructions.
- Safe use of this pump is the primary responsibility of the user. The user is responsible for monitoring this pump. Contact technical/customer support if pump appears to be operating incorrectly. See Section 7.
- Never perform any function or push any button unless instructed by your healthcare provider or by following the instructions in the manual.
- Do not allow the pump to get wet. If the pump is immersed in any liquid, it must be replaced with a new pump.
- Never attempt to open the pump case. Only the battery cover may be removed when changing batteries.
- Do not drop the pump. If the pump is dropped, it must be replaced with a new pump.
- Failure to follow manufacturer's instructions while replacing batteries may result in loss of program settings and report data. Dispose of batteries properly after use.
- Contact the local authorities to determine the proper method of disposal of potentially biohazardous parts and accessories.
- Safety hazards with the ambIT* pump, including under-infusion, may be associated with external radio frequency (RF) interference or electromagnetic radiation. Typical equipment that may generate such radiation includes x-ray machines, magnetic resonance imaging (MRI) equipment, and any other non-shielded electrical equipment.
- The cassette tubing or BOLUS switch cord may cause strangulation if used improperly.
- The pump should not be disassembled or modified by any user. If equipment is tampered with to the point it is ineffective, consult the prescribing physician.
- Keep out of reach of animals or children.
- Parts of the pump, that may come in contact with the patient under normal use, may reach temperatures of 43 °C when operated in a 40 °C temperature environment. Condition of safe use at this temperature is 10 minutes on normal adult skin. The pump must not be left in direct contact with the skin. Do not sleep on the pump or apply pressure over the pump.

SECTION 2 - PRODUCT DESCRIPTION

2.1 Welcome to the ambIT* Pump Family

You have been provided with this manual to better assist you in your therapy goals. Your doctor has prescribed an ambIT* Infusion Pump to best assist you with your personal needs. There are a variety of different ambIT* pumps, some that have bolus buttons and some that do not. The differences between these buttons are described in Sections 3.8 and 3.9. Your pump is also equipped with notifications that sometimes are referred to as alarms and alerts. We have provided a table for you to become familiar with in Section 4.

The ambIT* Family of pumps are used for infusing antibiotics, chemotherapy, pain medications, and other therapies. In general, our pumps are not used for life-sustaining medications. These highly accurate electromechanical devices are capable of assisting you with your therapy goals while allowing you the freedom to move about. Please do not tamper with your pump. Your doctor has programmed it to deliver a very precise amount of medication, and tampering with it may inhibit any prescribed therapies.

This manual will help you understand how to activate the BOLUS/ FUNCTION button, power on and off the pump, start infusion, stop or pause infusion, change batteries and respond to alarms and alerts. This pump is capable of more functions but if you have not been trained by your healthcare provider then please do not attempt any function other than what this manual provides. Any other operations such as changing the reservoir bag, administration set or dressings and removal of catheters, etc. are the responsibility of your healthcare provider.

This is an ambulatory pump; as such you are free to walk around with your pump if it's not against your doctor's orders. Your pump will not interfere with electronics in your home, and is easy to have with you while doing most activities. Please do not shower with your pump. While it will repel water, it is not intended to be fully submerged, and its life span will diminish if not treated properly.

2.2 What to Expect?

When the pump is running or infusing there will be a number in the display and a green light flashing in the BOLUS or FUNCTION button (See illustration in Section 3.1). You will periodically hear the gears turning as the pump infuses medication.

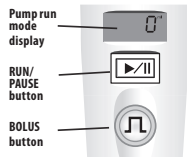
If the display shows a pause symbol or two lines flashing, it is in pause mode and is not infusing medication. To resume your infusion therapy simply press and release the RUN/PAUSE button (see Section 3.6).

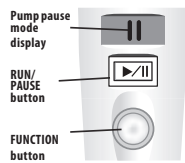
If your healthcare provider has given you the option to request a bolus, pushing the BOLUS button will deliver the additional medication. After a bolus has been delivered, a lockout time occurs during which another bolus will not be given. The primary purpose of the lockout time is to make sure the patient does not receive too much medication if they repeatedly request more. A secondary purpose of the lockout time is to allow the medication to act and relieve the pain prior to infusing any additional medication.

If you have any questions regarding your pump, you may contact technical/customer assistance (see Section 7). Please keep in mind that we cannot answer therapy specific questions.

SECTION 3 - OPERATION

NOTE: Pump display may not be clearly visible in bright light. Shading the display will allow viewing of the display by the user.





3.1 Your Pump's Control Buttons

All of our ambIT* pumps have similar control buttons. The RUN/PAUSE button is located just below the pump display. This button is used to start, pause, or resume the infusion, and to silence alarms. The RUN/PAUSE button toggles between run mode and pause mode.

A blinking green RUN light (inside the BOLUS or FUNCTION button) and "ml" (volume infused) in the Pump display indicate that the Pump is infusing.

If the infusion is paused, a flashing pause icon (II) will appear in the Pump display and two (2) beeps sound every four (4) minutes, indicating that the Pump infusion has been temporarily stopped.

The BOLUS or FUNCTION button is located below the RUN/PAUSE button. When the FUNCTION button is pressed during run mode, the pump will toggle between the amount of medication infused and the total time the pump has been infusing. When the BOLUS button is pressed during run mode, the pump will deliver the programmed bolus. During bolus delivery, the green run light (inside the BOLUS button) will double blink.

We know you'll find your ambIT* experience positive during your therapy and we would love to hear your feedback. To share your story, please contact us at service@ambitpump.com.

3.2 Attach Cassette to Pump

In the event the cassette becomes detached from the pump, it will be necessary to re-attach the cassette. Insert the cassette onto the top of the pump, as shown. Align and gently squeeze the tabs on the cassette to attach to the pump.

3.3 Battery Replacement

The pump is powered by two AA 1.5V batteries. Alkaline batteries are recommended.

CAUTION: Make sure the pump is in pause mode before turning off the pump and removing the batteries. Failure to do so may cause loss of timing and a delay in therapy. The pump will not sound an alarm if it is turned off without being placed in pause mode.

CAUTION: Avanos Medical, Inc. has not validated all types of batteries (non-alkaline, rechargeable, specific brands, previously-used, etc.) and cannot ensure that any specific battery will power the pump for a specific period of time. The battery condition and pump settings will determine how the battery will perform with regard to the pump. For this reason, the time before the low battery alarm occurs and the time between low and dead battery alarms is difficult to predict with non-alkaline or rechargeable batteries.

NOTE: It is recommended that the batteries be changed when the low battery alarm occurs.

The pump memory is designed to retain program settings and infusion history for up to six months without power. Failure to follow the manufacturer's instructions while replacing batteries may result in loss of program settings and report data. Do not store batteries in the pump.

Twist left to unlock battery cap

To replace batteries:

If the pump is in run mode, place the pump in pause mode by pushing the ▶/II RUN/PAUSE button (see Section 3.5).

Step #1

Rotate the battery cap counter-clockwise until the line (I) on the pump is slightly to the right of the OFF (O) position (i.e., until the battery cap stops or meets resistance).

Step #2

Remove the battery cap and remove the batteries according to the illustrations at the left.

Step #3

Insert batteries and replace battery cap

Insert new batteries and replace the battery cap. Place the battery cap onto the pump as illustrated to the left (The OFF (O) symbol on the battery cap will be slightly to the left of the (I) mark on the pump).

Step #4

Rotate the battery cap clockwise to the OFF (O) position.

Power on the pump according to the instructions in Section 3.4.

After the batteries are replaced and the pump is powered on, the pump will return to pause mode.

Press and release the ▶/II RUN/PAUSE button. The current settings will be displayed.

Press and release the ▶/II RUN/PAUSE button a second time to resume the infusion.

3.4 Pump Power On and Off

CAUTION: Always place the pump in pause mode prior to turning the pump off. Failure to do so may cause the therapy to be delayed and/or history to be lost. The pump will not sound an alarm if the pump is not placed in pause mode prior to being turned off.

To power on the pump:

Power ON clockwise

Rotate the battery cap clockwise until the (I) mark on the cover lines up with the (I) mark on the pump.

NOTE: After the power-on self-test, the pump will beep twice and go into pause mode.

To power off the pump:

Power OFF counter-clockwise

Step #1

If the pump is in run mode, place the pump in pause mode by pushing the RUN/PAUSE button (see Section 3.5).

Step #2

Rotate the battery cap counter-clockwise until the (O) mark on the battery cap lines up with the (I) mark on the pump (see illustration at left).

3.5 Pause Infusion

CAUTION: Always place the pump in pause mode prior to turning the pump off. Failure to do so may cause the therapy to be delayed and/or history to be lost. The pump will not sound an alarm if the pump is not placed in pause mode prior to being turned off.

To pause the infusion, press and release the ▶/II RUN/PAUSE button. The pump will beep two times, the green run light will stop blinking, and the pause mode icon (II) will flash in the pump display. If left in pause mode, the pump will beep two times every four minutes.

NOTE: Pausing the pump temporarily stops the infusion. While in pause mode, the infusion is delayed. This allows for changing the batteries and turning off the pump.

3.6 Resume Infusion

To resume the infusion from pause mode, press and release the ▶/II RUN/PAUSE button.

The green run light (inside the BOLUS/FUNCTION button) will start to blink, the "ml" icon and the volume infused will appear in the pump display. The infusion will resume at the same point at which the pump was last placed in pause mode.

3.7 Silence Alarm

To silence an alarm, press and release the RUN/PAUSE button. When the alarm has been silenced, the pump will remain in pause mode. Once the cause of the alarm has been corrected, resume the infusion (see Section 3.6).

NOTE: If the pump sounds an alarm due to downstream pressure (occlusion alarm), and the cause of the alarm is corrected without intervention, the alarm will silence itself and the pump will resume the infusion automatically.

3.8 The BOLUS Button (not applicable to pumps with FUNCTION button)

The BOLUS button is located on the pump directly below the RUN/PAUSE button. Each time the BOLUS button is pressed during the infusion the pump will beep once. If the bolus is permitted (the lockout time has elapsed), the pump will begin bolus administration. During bolus infusion, the green run light will double blink. If the BOLUS button is pressed during the lockout time, the pump will beep once but no bolus will be delivered.

NOTE: The bolus activation function is only available when the physician has prescribed a bolus option.

NOTE: The BOLUS button is disabled if the infusion is complete. During this time, if the BOLUS button is pressed, the "infusion complete" alarm will sound.

NOTE: A remote BOLUS switch may also be used to request a bolus. To connect the remote BOLUS switch to the pump, locate the remote BOLUS switch port on the right side of the pump and open the black rubber plug. Insert the metal tip into the remote BOLUS switch port. Once connected, press and release the black button found at the end of the body of the switch to administer the bolus. See diagram on inside front cover.

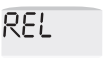
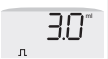
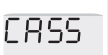
3.9 The FUNCTION Button

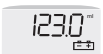
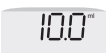
The FUNCTION button is located on the pump directly below the RUN/PAUSE button. When the FUNCTION button is pressed during run mode, the display will toggle between the amount of medication infused and the total time the pump has been infusing.

3.10 Summary of Operating Controls

ACTION	STEPS TO TAKE	AUDIBLE INDICATOR	VISUAL INDICATOR
Start infusion	Press and release the RUN/PAUSE button. The RUN/PAUSE button will need to be pressed again if the pump has just been turned on.	One beep	Green run light (inside the BOLUS button) blinks, the "ml" icon and volume infused is in the pump display.
Pause infusion	Press and release the RUN/PAUSE button.	Two beeps (every four minutes)	Pause icon (II) flashes in the display; green run light (inside the BOLUS button) stops blinking.
Silence alarm	Press and release the RUN/PAUSE button.	Alarm sound stops	Pause icon (II) flashes in the display; green run light (inside the BOLUS button) stops blinking.
Deliver bolus using BOLUS button on pump	Press and release the BOLUS button.	One beep	Green run light (inside the BOLUS button) double blinks.
Deliver bolus using remote BOLUS switch	To connect the remote BOLUS switch to the pump, locate the remote BOLUS switch port on the right side of the pump and open the black rubber plug. Insert the metal tip into the remote BOLUS switch port. Once connected, press and release the black button found at the end of the body of the switch to administer the bolus.	One beep	Green run light (inside the BOLUS button on the pump) double blinks.

SECTION 4 - ALARMS AND TROUBLESHOOTING

STATUS	ICON	PUMP DISPLAY	AUDIBLE INDICATOR	COMMENTS
Blood backed into tubing	None		None	Make sure the green light inside the BOLUS/FUNCTION button is blinking. Contact healthcare professional.
Release BOLUS button	"REL"		Constant tone	Release the BOLUS button
Bolus infusion	 		One beep	Green run light (inside the BOLUS button) double blinks; bolus icon is in the display. One beep will sound every time the BOLUS button is pressed during run mode.
Cassette not attached to pump	"MA" or "CASS" 	 or 	Constant tone	Press the RUN/PAUSE button to silence the alarm. Gently press on top of the cassette to ensure proper placement. (See Section 3.2) Resume infusion.
Dead battery	 		Constant tone	Press the RUN/PAUSE button to silence the alarm. The alarm and battery icons will remain displayed. To continue the infusion, replace the batteries and restart the infusion.

STATUS	ICON	PUMP DISPLAY	AUDIBLE INDICATOR	COMMENTS
Infusion complete			One long tone followed by three short beeps; repeats every four minutes	The “infusion complete” alarm will sound every four minutes whether in pause or run mode. NOTE: In the Australian PIB•PCA, while the pump is in run mode, the alarm will occur every eight seconds.
Infusion paused			Two beeps every four minutes	Green run light (inside the BOLUS button) is off
Low battery			Five short beeps every four minutes	The battery icon will remain flashing in the display. Replace the batteries as soon as possible.
No display	None			• Make sure that the battery cover is in the ON position. • Make sure battery placement is proper. • Replace the batteries. Refer to Section 3.3
Occlusion alarm; constant beeping during infusion	“OCL” 		Constant beeping only; clears itself if source of occlusion is removed	Press the RUN/PAUSE button to silence the alarm. Check tubing and remove any kinks and/or check to make sure tubing clamps are not stopping flow. Press the RUN/PAUSE button to restart the pump. If unable to resolve (silence) the alarm, contact Avanos Medical, Inc.
To confirm the pump is infusing normally	 		None	Green run light (inside the BOLUS/FUNCTION button) blinks. Periodic movement of the cassette gears is normal. No action is required.

NOTE: Alarms cannot be disabled or modified.

NOTE: When the batteries are removed, the alarms are cleared. When the pump is powered on, it will detect any alarm conditions that are still present.

NOTE: Sound pressure level 57.1 dBA at one meter.

NOTE: If you encounter any alarms or occurrences other than what is provided in the preceding table, pause the infusion (see Section 3.5) and notify technical/customer assistance (contact information is located in Section 7) or your healthcare provider.

SECTION 5 - ELECTROMAGNETIC IMMUNITY (EMC)

Mobile RF communications equipment can affect the operation of the ambIT* pump.

The ambIT* pumps that have a remote bolus switch connector should only be used with the remote BOLUS switch. Use of any remote bolus switch other than the approved ambIT* remote BOLUS switch manufactured by Avanos Medical, Inc. (product #220265) could result in an inadvertent bolus. It may also result in increased emissions or decreased immunity of the device.

The ambIT* pump uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

WARNING: The ambIT* pump should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the ambIT* pump and other equipment should be observed to make sure the pump is operating normally in the configuration in which it will be used.

The ambIT* pump is suitable for use in home healthcare and healthcare facility environments.

The purpose of the ambIT* pump is to infuse medication from a fluid reservoir into a patient at a controlled rate (flow rate). The ambIT* pump has been tested to ensure that it is not affected by normal electromagnetic emissions from surrounding electronic devices. However, if the surrounding electronic devices emit excessive electromagnetic emissions, the performance of the ambIT* pump may be degraded. Specifically, the pump display may cease to function until the ambIT* pump is placed in pause and then powered off and back on. The pump will continue to infuse at the correct rate and all other functions will not be compromised.

WARNING: Use of accessories other than those provided by the manufacturer of the ambIT* pump could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ambIT* pump and remote BOLUS switch. Otherwise, degradation of the performance of the ambIT* pump could result.

The ambIT* pump meets the immunity test levels shown in the tables below. The emissions group and class of the ambIT* pump is Group 1 and Class B.

Table 5-1. Electromagnetic immunity levels tested and passed by ambIT* pump.

Phenomenon	Basic EMC Standard Or Test Method	Immunity Test Levels
Electrostatic discharge	IEC 61000-4-2	±2, 4, 6, 8 kV contact ±2, 4, 8, 15 kV air
Radiated RF EM fields	IEC 61000-4-3	10 V/m 80 MHz-2.7 GHz
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz and 60 Hz

Table 5-2. Maximum measured radiated emission levels from the ambIT* pump during operation.

Frequency (MHz)	dB(µV/m)	
	Quasi-peak (limit)	Actual value (pass/fail)
30 to 230	30	23.85 (pass)
230 to 1000	37	29.31 (pass)

SECTION 6 - GENERAL CARE INSTRUCTIONS

WARNING: Pump failure may be caused by the application of cleaning solutions other than those recommended by the manufacturer. Do not immerse the pump or sterilize cassette in any cleaning solutions.

The patient should be careful to protect the pump at all times. The pump should not be dropped.

Transport and storage conditions: -25 °C (-13 °F) without relative humidity control; and +70 °C (+158 °F) at relative humidity of up to 93%, non-condensing.

The pump will warm from the minimum storage/transportation temperature to room temperature (about 20 °C [68 °F]) in approximately 30 minutes. The pump will cool to room temperature from the maximum storage/transportation temperature in about 35 minutes.

Operating conditions: +5 °C to +40 °C (+41 °F to +104 °F); relative humidity range of 15% to 93%, non-condensing; and an atmospheric pressure of 700 hPa to 1060 hPa (10.2 psi to 15.4 psi).

The pump and components should be stored in a dry, cool place until used.

No sterilization of the pump is required. Disinfect the pump before and after every patient use, procedure, and/or transfer of patients.

No maintenance of the pump is required, and no calibration is required. Contact Avanos Medical, Inc. if a functional test is desired.

NOTE: For storing and transporting the pump, a cap should be placed on the pump to protect the pressure switch.

6.1 Warranty Information

Contact your local sales representative for warranty and extended warranty lengths.

This warranty will not apply to amblT* pumps that have been, in the judgment of Avanos Medical, Inc., damaged in whole or in part due to misuse, abuse, negligence, alteration or improper installation, or that have been dropped or used in a manner inconsistent with their labeling and packaging.

To obtain warranty service, the pump and cassette must be returned to Avanos Medical, Inc. with postage prepaid. The replacement of a pump and cassette will not extend the original term set forth above.

6.2 Cleaning and Disinfecting Instructions

Step #1 Dampen a clean rag or paper towel with any household cleaners such as:

A fresh solution of one (1) part household bleach to nine (9) parts water;

Rubbing alcohol (70% Isopropyl alcohol);

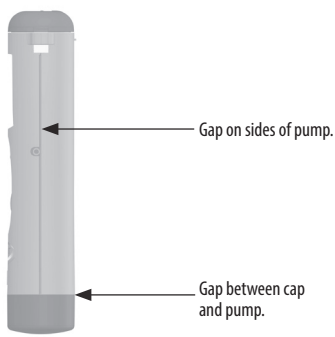
3% Hydrogen peroxide; or

Equivalent solution (i.e., quaternary ammonium).

NOTE: Follow directions on the household cleaner label or consult the CDC or EPA website.

Step #2 Gently wipe and clean the front, back, sides and ends of the pump.

Step #3 Clean the gaps:



SECTION 7 - CUSTOMER ASSISTANCE

For customer assistance, please contact Avanos Medical, Inc. at 1-844-4AVANOS / 1-844-428-2667.

If a serious incident has occurred in relation to the device, it should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established. A serious incident means any incident that directly or indirectly led, might have led or, in case of recurrence, could lead to any of the following: the death of a patient, user or other person, the temporary or permanent serious deterioration of a patient's, user's, fetus or other person's state of health, or a serious public health threat.

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