MORE THAN PAIN RELIEF...
SUPERIOR PAIN CONTROL
Become familiar with the amblIT® pump

Solution container

Tubing clamp

Cassette

BOLUS button

ON/OFF switch

Remote BOLUS Switch (optional for select models)

Continuous pumps have FUNCTION button in place of BOLUS button

To solution container

(Side view of cassette)

Cassette shaft

To patient

Tubing clamp

Pump display

RUN/PAUSE button
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SECTION 1 - INTRODUCTION

1.1 Definitions and Symbols

1.1.1 Definitions

ANALGESIA: Relief from pain.

BASAL FLOW RATE: The continuous flow rate. It occurs when the pump is not delivering a bolus. The basal flow rate is adjustable and has units of milliliters per hour (ml/hr).

BOLUS: A volume of medication infused over a relatively short period of time. The bolus is infused at the bolus flow rate. A bolus is delivered when a patient requests it by pushing the BOLUS button or the optional remote BOLUS switch. A bolus is sometime referred to as a PCA bolus. The bolus has units of milliliters (ml). Not available on Continuous pumps.

BOLUS FLOW RATE: The flow rate at which a bolus is delivered. It is a higher flow rate than the basal flow rate. In the ambIT® pump, the bolus flow rate is either 100 ml/hr or 125 ml/hr (pump model dependant). The bolus flow rate is not adjustable.

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.

LOCKOUT TIME: The time between the end of one bolus and the start of the next bolus. The lockout time has units of hours and minutes (hh:mm).

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

PCA: An acronym for patient controlled analgesia. If a pump is in PCA mode and the patient has been prescribed a bolus volume, then PCA allows for a lay user to periodically give the patient a bolus of medication. If the infusion is into the epidural space the PCA is referred to as patient controlled epidural analgesia (PCEA).

VOLUME TO BE INFUSED: The total amount of fluid in the solution container or reservoir to be infused. The volume to be infused has units of milliliters (ml).

WARNING: A warning message contains special safety emphasis and must be observed at all times. Warnings are found at Section 1.2, as well as throughout this document emphasized with grey shading. Failure to observe a warning message is potentially life threatening.

1 The bolus is delivered at a higher flow rate than the basal rate; therefore, for a given volume, the bolus is delivered faster.
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.)


CE symbol certifying that the product complies with the essential requirements of the Medical Device Directive.

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.

The cUL mark applies to products intended for the Canadian market that have been tested and found to comply with the requirements of CAN/CSA 22.1-12, which is the Canadian Electrical Code issued by the Canadian Standards Association.

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.

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.

Medical device

Indicates the date after which the medical device is not to be used.

Indicates the manufacturer’s batch code or lot number so that the batch or lot can be identified.

Indicates the manufacturer’s serial number so that a specific medical device can be identified.

Single-use only (cassettes)

Keep away from heat

Keep dry

Caution: This device is restricted to sale by or on the order of a physician.

Temperature limitation
Section 1 • Introduction

STERILE

DEHP-free fluid path

Not made with natural rubber latex

Indicates which tubing connects to the solution container

Indicates which tubing connects to the patient

Bolus

Program lockout

Bolus lockout time in hours:minutes

Bolus volume in milliliters

Volume in milliliters

Basal infusion rate in ml/hr

Number of boluses delivered

Number of bolus requests

To solution container

(side view of cassette)

To patient

Cassette shaft
Section 1 • Introduction

Elapsed time

Volume to be infused

RUN/PAUSE button

BOLUS button

FUNCTION button

Low/dead battery indicator

Alarm indicator

ambIT® pump display

Pump power on

Pump power off

Battery orientation

Program lockout code

Program lockout mode
1.2 Warnings

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

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 clinical/technical support if pump appears to be operating incorrectly.

All patients should be given a Patient Manual and instructed to read it carefully. The pump must be used only by or on behalf of the person for whom it is prescribed.

Patients should never perform any function or push any button unless instructed by their healthcare provider.

Do not allow the pump to get wet. If the pump is immersed in any liquid, it must be replaced with a new pump.

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).

Never attempt to open the pump case. Only the battery cover may be removed when changing batteries. If the pump is dropped, it must be replaced with a new pump.
This pump is not to be used for infusion of blood or blood products.

This pump is not to be used for infusion of life-sustaining medications.

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.

This pump does not have an air in-line alarm. A cassette with an air elimination filter is available and recommended for intravenous use or where infusion of air would cause a safety hazard.

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.

Use of any remote BOLUS switch other than the approved remote BOLUS switch could result in an inadvertent bolus.

Do not use any other administration set other than the approved ambIT® cassettes. The pump will not function properly with any other administration sets.

Do not use additional untested/unapproved components as their use may lead to under-infusion and the potential of increased pain to the patient.

No modification of this equipment is allowed.

The cassette tubing or BOLUS switch cord may cause strangulation if used improperly.

The pump should not be disassembled 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.

Safety hazards are associated with the interconnection of other infusion systems. Refer to: Terry, Judy (Ed.), Intravenous Therapy, W. B. Sanders Co. 1995, pp 192–193.

A single cassette should not be used for infusion volumes greater than two liters.

In order to minimize the possibility of infection, cassettes should be changed in accordance with your institution’s policies.

Before starting therapy, check that all connections are secure and that there are no leaks in the fluid path.

After the infusion is finished, the pump will give the infusion complete alarm and continue infusing at a KVO rate. The rate is dependent on the basal rate programmed. If the basal rate is 0.5ml/hr or greater, the KVO will be 0.5 ml/hr. If the basal rate is less than 0.5 ml/hr, then the KVO is the basal rate. The KVO is not programmable.
Bolus and infusion history reports should never take the place of good clinical judgment. Always perform a clinical evaluation whenever interpreting these reports.

Infusing viscous solutions (e.g., D25W) into high pressures (e.g., approaching 300mm Hg) may decrease volumetric accuracy.

### 1.2.1 Sterile, Disposable (Single-Use) Administration Set

- Carefully examine each cassette before use. Make sure there are no damaged or missing parts.
- Do not use a cassette if the outer package is torn, punctured, wet or damaged.
- Do not touch the sterile open end of tubing. Use the aseptic technique utilized by your facility.
- Do not re-sterilize cassette.

### 1.2.2 Protection From Air Infusion

- The solution must be provided in a non-vented, collapsible container.
- Remove all air from solution container and tubing before use.
- If infusion of air could cause harm to the patient, the ambIT® pump should be used with air elimination filters because air detection is not provided.

### 1.2.3 Protection From Unintended Bolus

- The unintended bolus volume that could be released into a patient prior to clearing a downstream occlusion may be released by breaking the seal on the connection between the pump and the catheter.
- Breaking the connection between the catheter and the pump may introduce contamination into the fluid path. Do not try to clear the unintended bolus volume if any concerns exist about introducing contamination.
- The maximum unintended bolus volume released into the patient when occluded on the downstream side is between 0.050 and 0.10 ml. One (1) stroke of an infusion is 0.050 ml. Since these amounts are similar, there is no risk of over-infusing and the unintended bolus may not need to be removed.

### 1.2.4 Use of ambIT® Pump in MRI Environment

Safety in MRI not evaluated. The ambIT® pumps have not been evaluated for safety and compatibility in the MRI environment. It has not been tested for heating, migration, or image artifact in the MRI environment. The safety of the ambIT® pumps in the MRI environment is unknown. Scanning a patient who has this device may result in patient injury.
1.3  Indications for Use

1.3.1  Continuous Pumps

The ambIT® Continuous pumps are intended for continuous volumetric delivery of intravenous medicines and/or fluids into patients at a consistent volume for prescriptive treatment by a physician.

1.3.2  Preset Pumps

The ambIT® pumps with Preset settings are intended for use by surgeons and anesthesiologists for the peri-operative and post-operative infusion of local anesthetics and narcotics for pain management and regional anesthesia. Routes of administration include intravenous, subcutaneous, intramuscular, perineural and epidural. The ambIT® pumps with Preset settings are also intended to significantly decrease narcotic use and pain when used to deliver local anesthetics to surgical wound sites or in close proximity to nerves when compared with narcotic only pain management.

1.3.3  PCA Pumps

The ambIT® PCA pump is used to infuse medicines and/or fluids into patients for pain management. Modes of action are intravenous, epidural and/or regional.

1.3.4  Preset*PCA Pump

The ambIT® Preset*PCA pump is used to infuse medicines and/or fluids into patients for pain management. The routes of administration are intravenous, epidural, nerve blocks, and/or local infiltration. The ambIT® Preset*PCA pump is not intended to supersede, augment or replace any other medical device or drug indications for use or intended uses. The ambIT® Preset*PCA pump is intended to be used in the home and in healthcare facilities. The ambIT® Preset*PCA pump is intended to be used by patients 12 years old and above.

1.4  Overview

The ambIT® family of pumps are designed for the ambulatory infusion of fluids and medications in home and healthcare facilities. The pumps have simple controls that are easily operated by both caregivers and patients. References to the remote BOLUS switch apply only to pumps with the remote BOLUS port. See the diagram on inside front cover to determine if pump has a remote BOLUS switch option. The operator position with respect to the device is considered arms length (no more than 0.5 meters direct view).

If any of the acronyms or words are not understood, see the Definitions given in Section 1.1.

There are three categories of ambIT® pumps within this manual: Continuous, Preset and PCA. Continuous pumps allow for continuous infusion. The Preset category of pumps contain up to five programming options on the back of the pump and in the programming steps. All other pumps are PCA pumps. Below are descriptions of these three pump types. See Section 10 for individual pump specifications.
NOTE: Any use of the ambIT® pump other than those indicated in this manual is regarded as an off-label use. The ambIT® pumps are not equipped with an air detection circuit; therefore if infusion of air could cause harm to the patient, it is recommended to use a filtered cassette or air elimination filter.

NOTE: Summit Medical Products, Inc. does not recommend or endorse any one specific medication to be used with the ambIT® family of pumps. The healthcare provider is the sole individual who decides upon the prescribed medication, programmed pump parameters, method and location of infusion.

NOTE: The suitability of this product for use with any specific patient is to be determined solely by the healthcare provider. The healthcare provider should understand the interaction between the infusion characteristics of the pump, the physiological response of a patient to the drug (overall and at the infusion site), the pharmacokinetics of the drug, any potential adverse effects, etc. This patient-specific information should be relied upon to decide if the pump should be used to infuse any medication into any part of the patient’s body. The distributors and Summit Medical Products, Inc. can only provide general guidelines regarding the set up and programming of the pump. They may also provide journal articles referring to applications. They are neither qualified nor permitted to provide specific recommendations for treating any specific patient. In general, to avoid complications, use the lowest flow rate, volume and drug concentration required to produce the desired result.

1.4.1 Continuous Pumps

The ambIT® Continuous family of pumps allow only continuous flow rates (i.e., basal only flow rates). These pumps contain no bolus feature.

1.4.2 PreSet Pumps

The ambIT® PreSet family of pumps allow for the following three types of infusion patterns: (1) basal flow rate only, (2) bolus only, and (3) basal flow rate and bolus.

These pumps simplify pump programming by providing the clinician with the option to choose from up to four (4) preprogrammed infusion protocols (PRO1 - PRO4), or to program infusion parameters individually (PRO5).

NOTE: Some ambIT® pumps with PreSet settings have a limited life of 2,000 ml total infusion. Once 2,000 ml has been reached, the pump will continue to infuse uninterrupted as programmed, until the current infusion program is complete. After the infusion beyond 2,000 ml has been completed, the next time the pump is powered on the ALARM icon (△) and “EEE” will appear in the display, indicating that the pump has reached its end of life and must be replaced.

1.4.3 PCA Pumps

The ambIT® PCA pumps do not include PreSet settings. The clinician may select different delivery profiles, which include: (1) basal flow rate only, (2) bolus only, and (3) basal flow rate and bolus.
1.5 Infusion Patterns

The different parameters of an infusion interact with each other to create an infusion pattern. Examples of the infusion patterns are provided graphically in Figures 1-1 through 1-3 that follow. The flow rates, volumes and lockout times discussed in the graphs are examples only.

**Figure 1-1**

**Basal flow rate only infusion pattern - applicable to all pumps**

For Figure 1-1, the basal flow rate is 10 ml/hr. The maximum available basal flow rate is 20 ml for PreSets and PCA pumps. The maximum available basal flow rate is 125 ml/hr for a Continuous pump.

**Figure 1-2**

**Bolus only infusion pattern - not applicable to Continuous pumps**

The settings for Figure 1-2 are a bolus volume of 10 ml and a lockout time of 30 minutes. After a bolus is requested and delivered, a lockout time begins. A bolus is delivered only when the BOLUS button or remote BOLUS switch is pressed. During the lockout time, the pump will beep when a bolus is requested, but no bolus will be delivered.

**CAUTION:** After programming the pump or clearing the history, a bolus will be delivered, if requested, within one minute. The pump assumes that clearing history or programming/reprogramming indicates that a new therapy is starting.
Figure 1-3

Basal flow rate and bolus infusion pattern - not applicable to Continuous pumps

For Figure 1-3, the settings are a basal flow rate of 10 ml/hr, a bolus volume of 10 ml, and a lockout time of 30 minutes.

**WARNING:** After the infusion is finished, the pump will give the infusion complete alarm and continue infusing at a KVO rate. The rate is dependent on the basal rate programmed. If the basal rate is 0.5 ml/hr or greater, the KVO will be 0.5 ml/hr. If the basal rate is less than 0.5 ml/hr, then the KVO is the basal rate. The KVO rate is not programmable.

**NOTE:** The basal flow rate is discontinued while a bolus is being delivered and resumes once the bolus has been completed.
SECTION 2 - SET UP

(See diagram on inside front cover)

The following steps must be accomplished sequentially to properly set up the pump:

1. Gather required materials (see Section 2.1);
2. Install new, unused, AA alkaline batteries (see Section 2.7);
3. Program the pump (see Section 3);
4. Prime the cassette (see Section 2.3);
5. Verify that the cassette bottom disc is snapped closed before attaching the cassette to the pump (see Section 2.2).
6. Attach the cassette to the pump (see Section 2.4);
7. Attach the long tubing of the cassette to the patient catheter using the aseptic technique utilized by your facility;
8. Start infusion (see Section 4.1); and,
9. Ensure the patient is instructed in the use of the pump and receives a patient manual.

WARNING: Protection from air infusion - The infusion solution must be provided in a non-vented, collapsible container. Remove all air from solution container and tubing before use.

NOTE: It is the responsibility of the healthcare provider to ensure that the lay user/patient is educated in the proper use of the pump.

NOTE: It is the responsibility of the healthcare provider to modify any guidelines provided to the lay user/patient along with the pump as appropriate for the individual patient’s clinical status and medication provided.

2.1 Required Materials

The ambIT® cassette is a sterile, disposable (single-use) administration set. The upstream (short) tubing of the cassette connects to a non-vented, collapsible solution container. Once the cassette has been primed, the downstream extension (long) tubing of the cassette connects to the patient’s access device.

Contact Summit Medical Products, Inc. to obtain a complete list of cassettes.

Accessories such as MediBag™ solution containers and carrying pouches may be added as required by the therapy. Contact Summit Medical Products, Inc. to obtain a complete listing of all optional accessories.
Section 2 • Set Up

WARNING: If an infusion of air could cause harm to the patient, an air elimination filter should be used. The ambIT® cassette may be ordered with or without an integrated air elimination filter.

WARNING: The ambIT® pump requires the use of an ambIT® cassette. Use of cassettes not manufactured by Summit Medical Products, Inc. may cause the pump to malfunction and may cause an over-infusion or an under-infusion.

NOTE: If an ambIT® cassette already has a filter, it is not recommended to use a separate air elimination filter. Using a second filter may cause the pressure to exceed the activation pressure for the pressure switch, causing an occlusion alarm (“OCL” in display and a constant beep).

2.2 ambIT® Cassette

The cassette contains a rotary mechanism that pumps the infusion solution at an accurate and controlled rate.

During cassette priming, fluid will flow freely through the tubing (Figure 1).

After priming, snap the cassette bottom disc into the body of the cassette to close the fluid path. This prevents the free flow of fluid (Figure 2). When primed, the cassette simply snaps onto the pump.

WARNING: Free flow will occur until the cassette bottom disc is snapped in place. No alarm will sound if the cassette bottom disc is not snapped in place. Do not attach the cassette to the patient until the cassette is placed on the pump or the cassette bottom disc is snapped into place. Placing the cassette on the pump will automatically snap the disc in place and prevent free flow.

NOTE: Once the cassette bottom is snapped into place, the rollers engage and compress the tubing, preventing fluid from flowing unless the pump is rotating and moving the fluid. If a downstream occlusion occurs, the pump will alarm and notify the user.

2.3 Priming the Cassette

WARNING: Do not use a cassette if the outer package is torn, punctured, wet or damaged. Do not touch the sterile open ends of the tubing. Use the aseptic technique utilized by your facility.
Step #1  Remove the protective cover from the bottom of the cassette (see illustration at left).

Step #2  Connect the solution container to the short tubing of the cassette using the aseptic technique utilized by your facility.

Step #3  Release all clamps on the tubing.

Step #4  Invert the solution container to allow air to be evacuated before priming the cassette with fluid (see illustration at left).

Step #5  Gently squeeze the solution container to force fluid and air upward through the tubing and cassette. Continue until the solution has completely filled the tubing and all air bubbles have been removed.

Step #6  After priming, close the fluid path by snapping the cassette bottom disc into the cassette body. This will prevent free flow.
WARNING: Failure to properly snap the cassette bottom disc into the cassette body may result in incorrect flow rates or free-flow conditions. Placing the cassette on the pump will snap the cassette disc bottom in place, if it is not done prior.

NOTE: If the cassette bottom disc is snapped closed before the priming process is complete, place the cassette onto the pump (not attached to the patient) and use the instructions below to complete the priming of the cassette.

To remove the air for the Continuous pumps, complete Steps 6a and 6b, as follows:

**Step #6a**  
Set the pump to infuse at 125 ml/hr (see Section 3.4.).

**Step #6b**  
Start the infusion (see Section 4.1). Once all the air has been removed from the cassette tubing and fluid reservoir, stop the pump by pausing the infusion (see Section 4.2). Once all the air has been removed from the cassette tubing and fluid reservoir, pause the infusion, clear the history and program the pump to the desired settings.

To remove the air using the BOLUS button for the PreSet and PCA pumps, complete Steps 6a and 6b, as follows:

**Step #6a**  
Program the pump to deliver a 20 ml bolus (see Section 3.5 for PreSet pumps or 3.6 for PCA pumps).

**Step #6b**  
Start the infusion (see Section 4.1) and press the BOLUS button (see Section 4.5) Once all the air has been removed from the cassette tubing and fluid reservoir, stop the pump by placing it in pause (see Section 4.2). If necessary to remove more than 20 ml of air from the solution container and tubing, boluses can be repeated quickly by clearing the history between each bolus (see Section 5.2). Once all the air has been removed from the cassette tubing and fluid reservoir, clear the history and program the pump to the desired settings.
**Step #7** Bend or break away the wings of the protective cover. Place the protective cover back onto the cassette (insert cassette shaft into octagonal opening). Use the protective cover to rotate the cassette shaft counterclockwise so silver dot makes one full rotation.

**NOTE:** The cassette shaft can also be rotated by hand.

**Step #8** Make sure the patient is instructed in the proper use of the pump.

**NOTE:** The filter bonded to the ambIT® cassette tubing is an air-elimination filter (AEF). The AEF has two membranes. The larger membrane is a hydrophilic membrane and the smaller membrane is a hydrophobic membrane. The hydrophobic membrane will not allow water to flow through it. However, in conjunction with some other liquids, such as organic liquids, water may be permitted to flow through the hydrophobic membrane.

**NOTE:** When the filter is dry, both the hydrophilic membrane and the hydrophobic membrane will allow air through. Once the hydrophilic membrane comes in contact with water (is “wetted”) air will not flow through the membrane until the bubble point is reached. (The bubble point is the pressure required to force air through the wetted hydrophilic membrane).

**NOTE:** Due to the nature of the hydrophilic membrane, it is important to prime the ambIT® cassette without getting water in the filter. This will allow air to flow through very easily. Once the filter is wet, it may be more difficult to prime, because the air has a much smaller area to flow out of (air will only flow out of the smaller hydrophobic membrane).

### 2.4 Attach Cassette to the Pump

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.

**NOTE:** Once the cassette has been properly placed on the pump, free-flow (unimpeded flow due to forces not generated by the pump) cannot occur because the cassette disc bottom has been snapped into place.
2.5 Remove Cassette from the Pump

To remove the cassette, press both cassette release tabs at the same time and lift the cassette off the pump.

CAUTION: Do not remove the cassette while the green run light is blinking. Always place the pump in pause mode first. Failure to do so will cause the pump to sound an alarm when the pump attempts to infuse medication.

2.6 Changing the Fluid Reservoir

WARNING: Not following your facility’s aseptic procedures to properly change the fluid reservoir may contaminate the fluid path. It is beyond the scope of this manual to provide aseptic technique training. If you are unsure of how to perform this task, consult your facility or supervisor.

CAUTION: Do not use a syringe as a fluid reservoir, because under-infusion may occur.

Prior to changing the fluid reservoir, put the pump in pause mode by pushing the RUN/PAUSE button (see Section 4.2). Failure to do so will cause the pump to alarm when the pump attempts to infuse medication.

2.7 Battery Installation and Replacement

The pump is powered by two (2) AA 1.5V batteries.

NOTE: Summit Medical Products, Inc. has not validated all types of batteries (non-alkaline, rechargeable, specific brands, previously-used, etc.); therefore, we 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: Summit Medical Products, Inc. recommends that the batteries be changed at the end of each session or 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.
2.7.1 Battery Installation

To install batteries:

If the pump is in run mode, place the pump in pause mode by pushing the RUN/PAUSE button (see Section 4.2).

**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 insert the batteries according to the illustrations at the left.

**Step #3** Place the battery cap onto the pump as illustrated to the left (OFF symbol (O) on the battery cap slightly to the left of the (I) mark on the pump).

**Step #4** Rotate the battery cap clockwise to the OFF (O) position.

2.7.2 Battery Replacement

**WARNING:** When reinstalling batteries, always verify that the program settings are correct before restarting infusion.

To replace batteries:

**CAUTION:** Verify that the pump is in pause mode before removing the batteries. Failure to do so may cause a 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.

If the pump is in run mode, place the pump in pause mode by pushing the RUN/PAUSE button (see Section 4.2).

**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 insert the batteries according to the instructions in Section 2.7.1.

**Step #3** Place the battery cap onto the pump as illustrated to the left (OFF symbol (O) on the battery cap 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 2.8.

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

2.8  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:

Rotate the battery cap clockwise until the (1) mark on the cover lines up with the (1) mark on the pump.

NOTE: After the power-on self-test, the pump will beep twice and go into pause mode. The clinician can then program the pump or resume current infusion settings.

To power off the pump:

Step #1  If the pump is in run mode, place the pump in pause mode by pushing the RUN/PAUSE button (see Section 4.2).

Step #2  Rotate the battery cap counter-clockwise until the (O) mark on the battery cap lines up with the (1) mark on the pump (see illustration at left).
SECTION 3 - PROGRAMMING INSTRUCTIONS

3.1 General Information

The ambIT® pump must be programmed and have the history cleared before administering any medication or fluid. The pump has two buttons: the RUN/PAUSE button and the BOLUS or FUNCTION button. A specific combination of pressing these buttons programs the pump.

When the pump is in program mode, the RUN/PAUSE button functions as an up arrow (incrementing the displayed value) and the BOLUS or FUNCTION button functions as a down arrow (decrementing the displayed value). Either button can be used to select a value by holding down the button when the desired value is displayed until a beep is heard.

CAUTION: The pump infusion history must be cleared between patients; failure to do so will lead to under-infusion.

NOTE: Holding a button does not increment or decrement any numbers. A button must be pushed and released to increment or decrement any numbers.

NOTE: The pump must be unlocked for programming or reprogramming the pump. "LOC" will appear in the pump display if the pump program is in lockout mode (see Section 6 - "Patient Lockout).

The pump can be reprogrammed after clearing the infusion history (see Section 5.2). The pump must be in pause mode (see Section 4.2) before the pump will enter program mode. See Sections 3.3 through 3.6 for programming instructions.

WARNING: The pump should be programmed by a healthcare provider who has been trained to program and set up the pump. Patients should be instructed not to program the pump or attempt to change the program.

WARNING: After the infusion is finished, the pump will give the infusion complete alarm and continue infusing at a KVO rate. The rate is dependent on the basal rate programmed. If the basal rate is 0.5ml/hr or greater, the KVO will be 0.5 ml/hr. If the basal rate is less than 0.5 ml/hr, then the KVO is the basal rate. The KVO is not programmable.

CAUTION: After clearing history or reprogramming the pump, a bolus is available immediately after starting the infusion.

NOTE: A remote BOLUS switch cannot be used to program the pump.
3.2 ambIT® Pump User Interface

The pump program is determined by selecting the desired parameters during program mode. The pump has two buttons: the RUN/PAUSE button and a BOLUS button or FUNCTION button. The RUN/PAUSE button is located just below the pump display. The BOLUS button or FUNCTION button is located just below the RUN/PAUSE button. An ON/OFF switch is part of the battery cap. See the figure to the left. Pressing and holding both buttons simultaneously for two seconds allows the user to access the program mode. This specific combination of pressing buttons is designed to prevent inadvertent or unauthorized adjustments.

The RUN/PAUSE button is used to start, resume or pause the infusion. The RUN/PAUSE button toggles between run mode and pause mode and will also silence alarms that occurs while the pump is running. A blinking green run light (inside the BOLUS or FUNCTION button), the “ml” icon and the volume infused in the pump display indicates that the pump is infusing. The table in Section 7 of this manual completely describes each alarm and signal.

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

The BOLUS or FUNCTION button is located below the RUN/PAUSE button. For Continuous pumps, when the FUNCTION button is pressed during run mode, the display toggles between displaying volume infused and elapsed time. For PreSet and PCA pumps, when the BOLUS button is pressed during run mode, the pump will deliver the programmed bolus if the infusion protocol allows it. During bolus delivery, the green run light (inside the BOLUS button) will double blink.
### 3.3 Program Options

**To enter program mode:**

**Step #1** Place the pump in pause mode. If the pump is not on, turn it on (see Section 2.8).

**Step #2** Press and hold both buttons for two seconds until one beep is heard.

“PRO” will momentarily appear in the pump display. Depending on the type of pump, a certain icon will flash in the pump display. The remaining steps for programming the pump are described in the following sections:

- Section 3.4 for all Continuous pumps, which have a FUNCTION button in place of the BOLUS button.
- Section 3.5 for all pumps with PreSet settings on the back of the pump, or have a display with PRO and a number blinking. This includes PreSet*PCA pumps.
- Section 3.6 for all pumps with PCA protocols that do not contain PreSet settings on the back of pump, or a screen with PRO that moves to a screen with a blanking number in the display.

### 3.4 Continuous Pump Programming Steps

<table>
<thead>
<tr>
<th>ACTION</th>
<th>AUDIBLE INDICATOR</th>
<th>VISUAL INDICATOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Enter program mode: From pause mode, press and hold both the RUN/PAUSE button and the FUNCTION button until one (1) beep is heard.</td>
<td>One (1) beep</td>
</tr>
<tr>
<td>2</td>
<td>Set flow rate: (A) Press the RUN/PAUSE button to increase the number or press the FUNCTION button to decrease the number (1 - 12). (B) When the desired number appears in the display, press and hold either the RUN/PAUSE button or the FUNCTION button until one (1) beep is heard to accept the setting. (C) Repeat steps 2(A) and 2(B) to set the digit immediately to the left of the decimal point (0 - 9). (D) For rates less than 50 ml/hr: Repeat steps 2(A) and 2(B) to set the digit to the right of the decimal point (0.0 - 0.9).</td>
<td>One (1) beep</td>
</tr>
</tbody>
</table>

**NOTE:** The maximum flow rate is 125 ml.

**NOTE:** If basal rate is programmed to 0, the pump will not go into run mode.
3.5 PreSet Pump Programming Options

The ambIT® pump with preset settings has up to five (5) programs from which the clinician may choose. There may be up to four (4) presets (PRO1 - 4). Only the programs with presets will be available to be selected (e.g., if no parameters were selected for PRO2, it will not appear when scrolling through options). Refer to the table on the back of the pump for the parameter settings for each possible preset protocol (PRO1 - 4). If no table exists and no PRO numbers appear while programming (e.g., PRO2), the pump has no presets and functions as a PCA pump. See Section 3.6. If there is no table, but numbers appear after PRO, either program your own infusion parameters using PRO5 (see Section 3.5.2) or ensure that preset is what is desired by reviewing the preset settings (see Section 3.7).

If you have selected a preset infusion protocol (PRO1 - 4) with more than one infusion volume available, the volume to be infused must be programmed. Refer to the table on the back of the pump for the volume settings available for the program. PRO5 is always available and it allows the programming of a custom basal rate, bolus volume, bolus lockout time and infusion volume combination.

Please refer to the table on the back of your pump for the specific infusion protocols available to you. An example is shown on the following page.

NOTE: The PreSet*PCA pump can be programmed using this section.
NOTE: Summit Medical Products, Inc. makes multiple ambIT® pumps with preset settings. Each model is distinguished by a specific pump color and model number (example: Pump number 220326 is always dark gray). The preset settings for each model can be found on the label on the back of the pump.

<table>
<thead>
<tr>
<th>Program #</th>
<th>Basal Rate (ml/hr)</th>
<th>Bolus (ml)</th>
<th>Lockout Time</th>
<th>Infusion Volume (ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRO1</td>
<td>Specified on back of pump</td>
<td>Specified on back of pump</td>
<td>Specified on back of pump</td>
<td>Specified on back of pump</td>
</tr>
<tr>
<td>PRO2</td>
<td>Specified on back of pump</td>
<td>Specified on back of pump</td>
<td>Specified on back of pump</td>
<td>Specified on back of pump</td>
</tr>
<tr>
<td>PRO3</td>
<td>Specified on back of pump</td>
<td>Specified on back of pump</td>
<td>Specified on back of pump</td>
<td>Specified on back of pump</td>
</tr>
<tr>
<td>PRO4</td>
<td>Specified on back of pump</td>
<td>Specified on back of pump</td>
<td>Specified on back of pump</td>
<td>Specified on back of pump</td>
</tr>
<tr>
<td>PRO5</td>
<td>Set own</td>
<td>Set own</td>
<td>Set own</td>
<td>Set own</td>
</tr>
</tbody>
</table>

NOTE: The graphic shown is an example of a label containing preset information.
### Programming a Preset Infusion Protocol (PRO1 - 4)

<table>
<thead>
<tr>
<th></th>
<th>ACTION</th>
<th>AUDIBLE INDICATOR</th>
<th>VISUAL INDICATOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Enter program mode:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>From pause mode, press and hold both the RUN/PAUSE button and the BOLUS button until one (1) beep is heard.</td>
<td>One (1) beep</td>
<td>“PRO” is displayed for two (2) seconds to indicate that the pump is in program mode. The pump automatically moves to the next screen.</td>
</tr>
<tr>
<td></td>
<td>NOTE: If PRO appears for two seconds, disappears and then a new display appears with a “ml/hr” icon, there are no preset programs. This is PRO5 and the basal rate screen is being displayed. (See Section 3.5.2, step 3.)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Select PRO1 - PRO4:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(A) Press and release the RUN/PAUSE button to scroll up or press and release the BOLUS button to scroll down through PRO numbers 1 - 4.</td>
<td></td>
<td>“PRO” is displayed followed by a flashing number.</td>
</tr>
<tr>
<td></td>
<td>(B) When the desired program number appears in the display, press and hold either button until one (1) beep is heard to accept the setting.</td>
<td>One (1) beep</td>
<td>Program is selected.</td>
</tr>
<tr>
<td></td>
<td>NOTE: If pump has the option to choose a volume, such as the military pump, continue to Step 3. If the selected program has only one infusion volume setting, Step 3 will be skipped. (Refer to the table on the back of your pump for the specific preset infusion protocols available to you.) If there is no table, review the program settings (see Section 3.7).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Set volume to be infused:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(A) Press the RUN/PAUSE button to increase the number or press the BOLUS button to decrease the number.</td>
<td>One (1) beep</td>
<td>“ml” icon is displayed and bag icon flashes.</td>
</tr>
<tr>
<td></td>
<td>(B) When the desired number appears in the display, press and hold either the RUN/PAUSE button or the BOLUS button until one (1) beep is heard to accept the setting.</td>
<td></td>
<td>NOTE: Volume to be infused is displayed in ml.</td>
</tr>
<tr>
<td></td>
<td>NOTE: Volume to be infused is established.</td>
<td></td>
<td>Volume to be infused is established.</td>
</tr>
<tr>
<td>4</td>
<td>Pump returns to pause mode.</td>
<td>Two (2) beeps</td>
<td>Pause icon (II) flashes.</td>
</tr>
</tbody>
</table>

**CAUTION:** After programming the pump, always verify the program settings by performing a program review (see Section 3.7).
### 3.5.2 Programming a Custom Infusion Protocol (PRO5)

<table>
<thead>
<tr>
<th>ACTION</th>
<th>AUDIBLE INDICATOR</th>
<th>VISUAL INDICATOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Enter program mode: From pause mode, press and hold both the RUN/PAUSE button and the BOLUS button until one (1) beep is heard.</td>
<td>One (1) beep</td>
<td>“PRO” is displayed for two (2) seconds to indicate that the pump is in program mode. The pump will automatically move to the next screen.</td>
</tr>
<tr>
<td>2 Select PRO5: Press and release the RUN/PAUSE button to scroll up or press and release the BOLUS button to scroll down through Program numbers 1 - 5 until “PRO5” appears in the display. Press and hold either button until one (1) beep is heard to accept the setting.</td>
<td>One (1) beep</td>
<td>“PRO5” is displayed and the number flashes.</td>
</tr>
<tr>
<td>3 Set basal flow rate:</td>
<td>Number left of decimal point and “ml/hr” icon flash.</td>
<td>Basal flow rate is established.</td>
</tr>
<tr>
<td>(A) Press and release the RUN/PAUSE button to increase the number or press and release the BOLUS button to decrease the number (0 - 20).</td>
<td>One (1) beep</td>
<td>NOTE: Basal flow rate is displayed in ml/hr.</td>
</tr>
<tr>
<td>(B) When the desired number appears in the display, press and hold either button until one (1) beep is heard to accept the setting.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(C) Repeat steps 3(A) and 3(B) to set the digit to the right of the decimal point (0.0 - 0.9).</td>
<td>One (1) beep</td>
<td></td>
</tr>
<tr>
<td>NOTE: The maximum flow rate is 20.0 ml</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 Set bolus volume:</td>
<td>“ml/icon” is displayed. Number left of decimal point and bolus icon flash.</td>
<td>Bolus volume is established.</td>
</tr>
<tr>
<td>(A) Press and release the RUN/PAUSE button to increase the number or press and release the BOLUS button to decrease the number (0 - 20).</td>
<td>One (1) beep</td>
<td>NOTE: Bolus volume is displayed in ml.</td>
</tr>
<tr>
<td>(B) When the desired number appears in the display, press and hold either button until one (1) beep is heard to accept the setting.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(C) Repeat steps 4(A) and 4(B) to set the digit to the right of the decimal point (0.0 - 0.9).</td>
<td>One (1) beep</td>
<td></td>
</tr>
<tr>
<td>NOTE: The maximum bolus volume is 20.0 ml.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NOTE: If bolus volume is set to “0” the next step (5) will be skipped.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>ACTION</td>
<td>AUDIBLE INDICATOR</td>
</tr>
<tr>
<td>---</td>
<td>--------</td>
<td>-------------------</td>
</tr>
</tbody>
</table>
| 5 | Set Bolus lockout time:  
   (A) Press and release the RUN/PAUSE button to increase the time or press and release the BOLUS button to decrease the time. (00:01) to (24:00) hh:mm  
   (B) When the desired lockout time appears in the display, press and hold either button until one (1) beep is heard to accept the setting.  
   (C) If portions of digits displayed are flashing, the option is available to set each digit. Repeat Steps 5(A) and 5(B). | One (1) beep | “hr:min” icon is displayed and the bolus, lock and clock icons flash. |
|   |   |   | NOTE: Bolus lockout time is displayed in hours and minutes. |
|   |   |   | Bolus lockout time is established. |
|   |   |   | Bolus lockout time is established. |
|   | NOTE: The maximum lockout time is 24:00 hr:min. |
| 6 | Set volume to be infused:  
   (A) Press and release the RUN/PAUSE button to increase the number or press and release the BOLUS button to decrease the number.  
   (B) When the desired value appears in the display, press and hold either button until one (1) beep is heard to accept the setting.  
   (C) If portions of digits displayed are flashing, the option is available to set each digit. Repeat Steps 6(A) and 6(B) for each digit. | One (1) beep followed by two (2) beeps | “ml” icon is displayed and bag icon flashes. |
|   |   |   | NOTE: Volume to be infused is displayed in ml. |
|   |   |   | Volume to be infused is established. |
|   |   |   | Volume to be infused is established. |
|   | NOTE: The minimum bag volume is 125 ml and the maximum bag volume is 1,000 ml. |
| 7 | Pump returns to pause mode. | | Pause icon (II) flashes. |

**CAUTION:** After programming the pump, always verify the program settings by performing a program review (see Section 3.7).
### 3.6 PCA Pump Programming Steps

<table>
<thead>
<tr>
<th>ACTION</th>
<th>AUDIBLE INDICATOR</th>
<th>VISUAL INDICATOR</th>
<th>NOTE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Enter program mode:</td>
<td>One (1) beep</td>
<td>“PRO” is displayed for two (2) seconds to indicate that the pump is in program mode. The pump will automatically move to the next screen.</td>
</tr>
<tr>
<td></td>
<td>From pause mode, press and hold both buttons until one (1) beep is heard.</td>
<td>PRO</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Set basal flow rate:</td>
<td>Number left of decimal point and “ml/hr” icon flash.</td>
<td></td>
</tr>
<tr>
<td>(A)</td>
<td>Press and release the RUN/PAUSE button to increase the number or press and release the BOLUS button to decrease the number (0 - 20).</td>
<td>One (1) beep</td>
<td>NOTE: Basal flow rate is displayed in ml/hr.</td>
</tr>
<tr>
<td>(B)</td>
<td>When the desired number appears in the display, press and hold either button until one (1) beep is heard to accept the setting.</td>
<td>120 ml/hr</td>
<td></td>
</tr>
<tr>
<td>(C)</td>
<td>Repeat steps 2(A) and 2(B) to set the digit to the right of the decimal point (0.0 - 0.9).</td>
<td>One (1) beep</td>
<td>Basal flow rate is established.</td>
</tr>
<tr>
<td>3</td>
<td>Set bolus volume:</td>
<td>“ml” icon is displayed. Number left of decimal point and bolus icon flash.</td>
<td></td>
</tr>
<tr>
<td>(A)</td>
<td>Press and release the RUN/PAUSE button to increase the number or press and release the BOLUS button to decrease the number (0 - 20).</td>
<td>One (1) beep</td>
<td>NOTE: Bolus volume is displayed in ml.</td>
</tr>
<tr>
<td>(B)</td>
<td>When the desired number appears in the display, press and hold either button until one (1) beep is heard to accept the setting.</td>
<td>120 ml</td>
<td></td>
</tr>
<tr>
<td>(C)</td>
<td>Repeat steps 3(A) and 3(B) to set the digit to the right of the decimal point (0.0 - 0.9)</td>
<td>One (1) beep</td>
<td>Bolus volume is established.</td>
</tr>
<tr>
<td>NOTE:</td>
<td>If bolus volume is set to “0” the next step (4) will be skipped.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Set Bolus lockout time:</td>
<td>“hr:min” icon is displayed and bolus, lock and clock icons flash.</td>
<td></td>
</tr>
<tr>
<td>(A)</td>
<td>Press and release the RUN/PAUSE button to increase the time or press and release the BOLUS button to decrease the time. (00:01) to (24:00) hh:mm or (00:05) to (12:00) hh:mm depending on the pump.</td>
<td>00:20 hr:min</td>
<td>NOTE: Bolus lockout time is displayed in hours and minutes.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Bolus lockout time is established.</td>
</tr>
</tbody>
</table>
### Section 3 • Programming Instructions

<table>
<thead>
<tr>
<th>ACTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>(C) If portions of the digits displayed are flashing, the option is available to set each digit. Repeat Steps 4(A) and 4(B) for each digit.</td>
</tr>
<tr>
<td>(C) If portions of the digits displayed are flashing, the option is available to set each digit. Repeat Steps 5(A) and 5(B).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>AUDIBLE INDICATOR</th>
<th>VISUAL INDICATOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>One (1) beep</td>
<td>Bolus lockout time is established.</td>
</tr>
<tr>
<td>One (1) beep followed by two (2) beeps</td>
<td></td>
</tr>
<tr>
<td>One (1) beep followed by two (2) beeps</td>
<td></td>
</tr>
</tbody>
</table>

### 5 Set volume to be infused:

- **(A)** Press and release the RUN/PAUSE button to increase the number or press and release the BOLUS button to decrease the number.
- **(B)** When the desired number appears in the display, press and hold either button until one (1) beep is heard to accept the setting.

**NOTE:** Volume to be infused is displayed in ml.

### 6 Pump returns to pause mode.

**CAUTION:** After programming the pump, always verify the program settings by performing a program review (see Section 3.7).
3.7 Program Review

CAUTION: After programming the pump, always verify the program by performing a program review.

NOTE: After turning on, programming, locking or unlocking the pump, the RUN/PAUSE button may also be pressed and immediately released to review the program. After this initial review (“RX”), pressing and releasing the RUN/PAUSE button will start/resume the infusion.

NOTE: The remote BOLUS switch may be used for Program Review.

To review the pump program:

**Step 1:** Place the pump in pause mode.

**Step 2:** Press and release the BOLUS or FUNCTION button.

“RX” will appear in the display and the pump will scroll through each programmed parameter. After the review, the pump will return to pause mode. Pressing the RUN/PAUSE button will start or resume the infusion.
SECTION 4 - OPERATING INSTRUCTIONS

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

4.1 Start Infusion

NOTE: Before starting infusion, the pump must be programmed. See Section 3 - “Programming Instructions” for details.

To begin an infusion, with the pump in pause mode, press and release the RUN/PAUSE button. (Hold for five (5) seconds if a military pump.) The RUN/PAUSE button is located directly below the pump display.

The first time an infusion is started after programming, or after powering on the pump, the program settings will be reviewed. After this review, the pump will return to pause mode.

Press and release the RUN/PAUSE button again to start the infusion. (Hold for five (5) seconds if a military pump.)

The green run light (inside the BOLUS or FUNCTION button) will start to blink, the “ml” and the volume infused will appear in the pump display.

See diagram below for button positions.
4.2 Pause Infusion

To pause the infusion, press and release the RUN/PAUSE button. (Hold for five (5) seconds if a military pump.) The pump will beep two (2) 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 (2) times every four (4) minutes.

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.

NOTE: Pausing the pump temporarily stops the infusion. While in pause mode, the infusion is delayed. This allows for changing the cassette, solution container, or batteries.

4.3 Resume Infusion

To resume the infusion from pause mode, press and release the RUN/PAUSE button. (Hold for five (5) seconds if a military pump.)

The green run light (inside the BOLUS or FUNCTION button) will start to blink, the “ml” 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.

4.4 Silence Alarm

To silence an alarm, press and release the RUN/PAUSE button. (Hold for five (5) seconds if a military pump.) When the alarm has been silenced, the pump will remain in pause mode. Once the cause of the alarm has been corrected, press and release the RUN/PAUSE button to resume the infusion (see Section 4.3). (Hold for five (5) seconds if a military pump.)

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.

NOTE: Most “MA” alarms can be resolved by pressing and releasing the RUN/PAUSE button to silence the alarm. To restart the infusion, press and release the RUN/PAUSE button. If the alarm persists, contact Summit Medical Products, Inc.
4.5  Bolus Activation

NOTE: Continuous pumps have a FUNCTION button instead of a BOLUS button. See Section 4.5a for Continuous pumps.

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

NOTE: When the bolus volume is set to 0 ml, no bolus will be delivered when the BOLUS button is pressed.

NOTE: Flow rate during a bolus is 100 ml/hr or 125 ml/hr, depending on the pump model.

NOTE: The BOLUS button is disabled if the volume to be infused has been delivered. During this time, if the BOLUS button is pressed, the “infusion complete” alarm will sound.

NOTE: A remote BOLUS switch may also be used. Connect the remote BOLUS switch to the pump before placing the pump in run mode.

4.5a  FUNCTION Button Activation

Pressing the FUNCTION button while in run mode will toggle the display between total volume infused and total elapsed (run) time.

NOTE: The maximum volume displayed is 9,999 ml and the maximum time displayed is 999 hours.

NOTE: Elapsed time (run time) will be displayed as hh:mm up to 99:59. After 100 hours, elapsed time will be displayed as hours only, up to 999 hours.
### 4.6 Summary of Operating Controls for Continuous Pumps

<table>
<thead>
<tr>
<th>ACTION</th>
<th>STEPS TO TAKE</th>
<th>AUDIBLE INDICATOR</th>
<th>VISUAL INDICATOR</th>
</tr>
</thead>
</table>
| Start infusion | Program the pump, then press and release the RUN/PAUSE button.  
The RUN/PAUSE button will need to be pushed a second time to start the infusion after the required review has taken place. | One (1) beep | Green run light (inside the FUNCTION button) blinks, and the “ml” (volume infused) and volume infused is in the pump display. |

**NOTE:** If the basal rate was set to 0 while programming the pump, you cannot start the infusion.

**NOTE:** If starting infusion after pausing it, the RUN/PAUSE button only needs to be pressed once.

<table>
<thead>
<tr>
<th>ACTION</th>
<th>STEPS TO TAKE</th>
<th>AUDIBLE INDICATOR</th>
<th>VISUAL INDICATOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pause infusion</td>
<td>Press and release the RUN/PAUSE button.</td>
<td>Two (2) beeps (every four (4) minutes)</td>
<td>Pause icon ( II ) flashes in the display; green run light (inside the FUNCTION button) stops blinking.</td>
</tr>
<tr>
<td>Silence alarm</td>
<td>Press and release the RUN/PAUSE button.</td>
<td>Alarm sound stops</td>
<td>Pause icon ( II ) flashes in the display; green run light (inside the FUNCTION button) stops blinking.</td>
</tr>
<tr>
<td>Function toggle</td>
<td>Press and release the FUNCTION button while in run mode</td>
<td>One (1) beep</td>
<td>Display icon will switch between “ml” and “hr:min”</td>
</tr>
</tbody>
</table>

### 4.7 Summary of Operating Controls for PreSet and PCA Pumps

<table>
<thead>
<tr>
<th>ACTION</th>
<th>STEPS TO TAKE</th>
<th>AUDIBLE INDICATOR</th>
<th>VISUAL INDICATOR</th>
</tr>
</thead>
</table>
| Start infusion | Program the pump, then press and release the RUN/PAUSE button.  
The RUN/PAUSE button will need to be pushed a second time to start the infusion after the required review has taken place. (Hold for five (5) seconds on military pumps.) | One (1) beep | Green run light (inside the BOLUS button) blinks, and the “ml” (volume infused) and volume infused is in the pump display. |

**NOTE:** If starting infusion after pausing it, the RUN/PAUSE button only needs to be pressed once.

<table>
<thead>
<tr>
<th>ACTION</th>
<th>STEPS TO TAKE</th>
<th>AUDIBLE INDICATOR</th>
<th>VISUAL INDICATOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pause infusion</td>
<td>Press and release the RUN/PAUSE button. (Hold for five (5) seconds on military pumps.)</td>
<td>Two (2) beeps (every four (4) minutes)</td>
<td>Pause icon ( II ) flashes in the display; green run light (inside the BOLUS button) stops blinking.</td>
</tr>
<tr>
<td>Silence alarm</td>
<td>Press and release the RUN/PAUSE button. (Hold for five (5) seconds on military pumps.)</td>
<td>Alarm sound stops</td>
<td>Pause icon ( II ) flashes in the display; green run light (inside the BOLUS button) stops blinking.</td>
</tr>
<tr>
<td>Deliver bolus</td>
<td>Press and release the BOLUS button. (Hold for five (5) seconds on military pumps.)</td>
<td>One (1) beep</td>
<td>Green run light (inside the BOLUS button) double blinks.</td>
</tr>
</tbody>
</table>

**NOTE:** Patient may use the BOLUS button on the pump or a remote BOLUS switch to request a bolus.
5.1 Pump Infusion History

To obtain the pump infusion history:

**Step #1**  Place the pump in pause mode.

**Step #2**  Press and hold the BOLUS or FUNCTION button for two (2) seconds until one (1) beep is heard and “HX” is displayed.

<table>
<thead>
<tr>
<th>INFUSION HISTORY</th>
<th>VISUAL INDICATOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total volume infused, including boluses, in ml</td>
<td>“ml” icon</td>
</tr>
<tr>
<td>Total number of boluses delivered</td>
<td>No. and ⌚ icons</td>
</tr>
<tr>
<td>Total number of bolus requests</td>
<td>No. and ⌚ icons</td>
</tr>
<tr>
<td>Elapsed time (time pump has been in run mode since history was cleared)</td>
<td>⌚ and“hr:min” icons</td>
</tr>
</tbody>
</table>

**NOTE:** The PCA and PreSet pumps will cycle through all of the following parameters.

**NOTE:** The Continuous pump will only cycle through volume infused and elapsed time.

**NOTE:** The remote BOLUS switch may be used to review the infusion history.

**NOTE:** After 100 hours, pump will only display hours (not minutes), e.g., 100H
5.2 Clearing Pump Infusion History.

**CAUTION:** Do not clear the infusion history unless the pump is being used for a new infusion or patient, as doing so will allow a bolus immediately once the infusion is started. This may result in over-infusion.

**NOTE:** The infusion history must be cleared between patients.

**NOTE:** The pump must be unlocked for clearing infusion history. “LOC” will appear in the pump display if the pump program is in lockout mode (see Section 6 – “Patient Lockout”).

**NOTE:** The remote BOLUS switch cannot be used to clear the infusion history.

To clear the pump infusion history:

**Step #1** Place the pump in pause mode.

**Step #2** Press and hold the BOLUS or FUNCTION button for two seconds until one beep is heard to enter infusion history mode and “HX” is displayed.

**Step #3** Upon “HX” being displayed, release the BOLUS or FUNCTION button and immediately press and hold the BOLUS or FUNCTION button again until the pump beeps and “HX 0” appears in the pump display. This indicates the infusion history has been cleared.
SECTION 6 - PATIENT LOCKOUT

The pump has been designed with patient lockout features:

**WARNING:** Locking the pump prevents unauthorized tampering with the infusion parameters, and prevents the infusion history from being cleared. The steps required for entering the pump’s program mode should not be revealed to the patient.

### 6.1 Accessing Lockout Mode

The pump’s lockout mode is accessed by following these steps:

**Step #1** Place the pump in pause mode.

**Step #2** Press and hold both buttons for two (2) seconds until one (1) beep is heard and “PRO” appears in the pump display.

**Step #3** Release both buttons and immediately press and release both buttons again. Four (4) dash symbols (-----) will appear in the display.

### 6.2 To Lock the Pump

After accessing lockout mode (see above), enter one lock code number in each digit space of the display, starting from the right. The steps are outlined below:

**Step #1** The first digit space is flashing.

**Step #2** Press and release the RUN/PAUSE button to increase the number or press and release the BOLUS or FUNCTION button to decrease the number.

**Step #3** When the desired number appears in the display, press and hold either button for two (2) seconds until one (1) beep is heard.

**Step #4** Repeat Steps 1 through 3 to program the second through fourth digits.

**NOTE:** The clinician may program one, two, three, or four digits into the pump for the lock code. If programming only one, two, or three digits into the pump for the lock code, when the desired code is programmed (e.g., 12 or 123), press and hold both buttons for two (2) seconds until one (1) beep is heard. This will accept the shortened code and lock the pump program.

After completing lockout mode, the pump will return to pause mode and the lock icon 🗝 will appear in the display. The current infusion can be resumed after reviewing the current program settings (See Section 3.7.)
6.3 To Unlock the Pump

To unlock the pump program, the clinician accesses the lockout mode, as described above. The code previously entered is re-entered into the pump by entering one number into each digit space of the display, starting from the right.

**Step #1** The first digit space is flashing.

**Step #2** Press and release the RUN/PAUSE button to increase the number or press and release the BOLUS or FUNCTION button to decrease the number.

**Step #3** When the desired number appears in the display, press and hold either button for two seconds until one beep is heard.

**Step #4** Repeat Steps 1 through 3 to enter the second through fourth digits.

**NOTE:** If entering only one, two or three digits for the lock code, when the code is entered (e.g., 12 or 123), press and hold both buttons for two seconds until one beep is heard. This will accept the shortened code and unlock the pump program. After unlocking, the pump will return to pause mode. The clinician can now reprogram the pump, clear the history, or verify and resume the current program settings.

**NOTE:** If a code is forgotten, contact Summit Medical Products, Inc. to obtain technical support. (See Section 13.)

**NOTE:** The pump program must be unlocked for programming, reprogramming and clearing the infusion history.

After unlocking the pump, the pump will return to pause mode and the lock icon will disappear from the display.

The current infusion can be resumed after reviewing the current program settings (See Section 3.7.)
### SECTION 7 - ALARMS AND SIGNALS

<table>
<thead>
<tr>
<th>PRIORITY</th>
<th>STATUS</th>
<th>ICON</th>
<th>VISUAL INDICATOR</th>
<th>AUDIBLE INDICATOR</th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>Pump is infusing normally</td>
<td><img src="https://via.placeholder.com/150" alt="icon" /></td>
<td>Green run light (inside the BOLUS or FUNCTION button) blinks, “ml” icon and volume infused is displayed</td>
<td>None</td>
<td>Periodic movement of the cassette gears is normal.</td>
</tr>
<tr>
<td>Low</td>
<td>Bolus infusion</td>
<td><img src="https://via.placeholder.com/150" alt="icon" /></td>
<td>Green run light (inside the BOLUS button) double blinks; bolus icon is in the display</td>
<td>One beep</td>
<td>One beep will sound every time the BOLUS button is pressed during the lockout time. NOTE: Not applicable to continuous pumps.</td>
</tr>
<tr>
<td>Low</td>
<td>Infusion paused</td>
<td><img src="https://via.placeholder.com/150" alt="icon" /></td>
<td>Pause icon flashes in the display; green run light (inside the BOLUS button) is off</td>
<td>Two beeps every four minutes</td>
<td>The battery icon will remain flashing in the display. Replace the batteries as soon as possible.</td>
</tr>
<tr>
<td>Low</td>
<td>Low battery</td>
<td><img src="https://via.placeholder.com/150" alt="icon" /></td>
<td>Battery icon flashes in the display</td>
<td>Five short beeps every four minutes</td>
<td>Press the RUN/PAUSE button to silence the alarm. (Hold for 5 second on military pumps.) The alarm and battery icons will remain displayed. Replace the batteries immediately.</td>
</tr>
<tr>
<td>Low</td>
<td>Dead battery</td>
<td><img src="https://via.placeholder.com/150" alt="icon" /></td>
<td>Battery icon and alarm icon are in the display</td>
<td>Constant tone</td>
<td>Press the RUN/PAUSE button to silence the alarm. (Hold for 5 second on military pumps.) Gently press on top of the cassette to ensure proper placement. Resume infusion.</td>
</tr>
<tr>
<td>Low</td>
<td>Cassette not attached to pump</td>
<td><img src="https://via.placeholder.com/150" alt="icon" /></td>
<td>Alarm icon “MA” are in the display</td>
<td>Constant tone</td>
<td>Release the BOLUS button. Not applicable to Continuous pumps.</td>
</tr>
<tr>
<td>Low</td>
<td>BOLUS button</td>
<td>None</td>
<td>“REL” is in the display</td>
<td>Constant tone</td>
<td>The “infusion complete” alarm will sound every four minutes in pause or run mode.</td>
</tr>
<tr>
<td>High</td>
<td>Infusion complete</td>
<td><img src="https://via.placeholder.com/150" alt="icon" /></td>
<td>Bag icon flashes in the display</td>
<td>One long tone followed by three short beeps; repeats every four minutes</td>
<td>The pump will infuse at a KVO rate (see Section 9) and alarms each time it strokes.</td>
</tr>
<tr>
<td>PRIORITY</td>
<td>STATUS</td>
<td>ICON</td>
<td>VISUAL INDICATOR</td>
<td>AUDIBLE INDICATOR</td>
<td>COMMENTS</td>
</tr>
<tr>
<td>----------</td>
<td>--------------</td>
<td>------</td>
<td>------------------</td>
<td>-------------------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>High</td>
<td>Occlusion</td>
<td>🕉️</td>
<td>“OCL” alarm</td>
<td>Constant beeping only; clears itself if source of occlusion is removed</td>
<td>Press the RUN/PAUSE button to silence the alarm. Press the RUN/PAUSE button to restart the pump. (Hold for 5 second on military pumps.) If unable to resolve (silence) the alarm, contact Summit Medical Products, Inc.</td>
</tr>
<tr>
<td></td>
<td>alarm “OCL”</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High</td>
<td>Malfunction</td>
<td>🕉️</td>
<td>Alarm icon “MA”</td>
<td>Constant tone</td>
<td>Immediately close the tubing clamp. See Section 8 - “Troubleshooting”</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>are in the display</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High</td>
<td>Malfunction</td>
<td>🕉️</td>
<td>Alarm icon “MA1”</td>
<td>Constant tone</td>
<td>Press the RUN/PAUSE button to silence the alarm. (Hold for 5 second on military pumps.) Gently press on top of the cassette to ensure proper placement. Resume infusion.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>are in the display</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High</td>
<td>Malfunction</td>
<td>🕉️</td>
<td>Alarm icon “EE1,”</td>
<td>Ten short beeps</td>
<td>Immediately close the tubing clamp, pause and turn off the pump. Contact Summit Medical Products, Inc. by calling the toll-free number on the pump.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>“EE2,” “EE3,”</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>“EE4,” “EE5,”</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>“EE6,” or “EE7”</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>are in the display</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High</td>
<td>Malfunction</td>
<td>🕉️</td>
<td>Alarm icon “CPU,”</td>
<td>Constant tone</td>
<td>Immediately close the tubing clamp, pause and turn off the pump. Contact Summit Medical Products, Inc. by calling the toll-free number on the pump.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>“RA” or “RO”</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>are in the display</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**NOTE:** Alarms cannot be disabled or modified.

**NOTE:** When batteries are removed, the alarms are cleared. When pump is powered on, it will detect any alarm conditions that are still present.
## SECTION 8 - TROUBLESHOOTING

<table>
<thead>
<tr>
<th>PROBLEM</th>
<th>RESOLUTION</th>
<th>REFERENCE</th>
</tr>
</thead>
</table>
| Cassette will not prime             | • Verify that all tubing clamps are open  
• If a spike cassette is used, verify that the spike is completely inserted into the solution container  
• Verify that the cassette bottom disc has not been snapped into the cassette body | Section 2   |
| Cassette will not attach to pump     | • Verify proper cassette placement onto the pump  
• Verify that the cassette bottom disc has been snapped into the cassette body | Section 2   |
| No display                           | • Verify that the battery cover is in the ON position  
• Verify proper battery placement  
• Replace the batteries | Section 2   |
| “OCL” in display; constant beeping during infusion | Fluid path occlusion -  
• Verify that all tubing clamps are open  
• Check access device patency  
• Check for kinks in the tubing | Section 4   |
| Continuous tone                      | Malfunction -  
• Possible dead battery alarm (battery icon visible); replace the batteries  
• Press on the cassette top to ensure proper placement  
• Check the cassette  
  - Remove the cassette from the pump  
  - Rotate the cassette shaft counter-clockwise one time  
  - Replace the cassette onto the pump  
• Press and release the RUN/PAUSE button to resume infusion  
• If “MA” continues:  
  - Immediately close the tubing clamp  
  - Manufacturer’s service/assistance may be required | Section 7   |
| Blood backed into tubing             | • Verify that the tubing is connected correctly (the patient side is connected to patient and the bag side is connected to the bag)  
• Verify that the pump is in run mode  
• Attempt to clear the tubing by delivering a bolus  
• If unable to clear the tubing by delivering a bolus, close the tubing clamp and replace the cassette  
• If the situation continues, manufacturer’s service/assistance may be required | Section 4   |
## SECTION 9 - SPECIFICATIONS

### 9.1. General Specifications Applicable to All Pumps

<table>
<thead>
<tr>
<th>SPECIFICATION</th>
<th>DETAILS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stroke volume</td>
<td>50 microliters (0.050 ml)</td>
</tr>
<tr>
<td>Volumetric accuracy</td>
<td>+/- 6%</td>
</tr>
<tr>
<td>Pump mechanism</td>
<td>Microprocessor controlled rotary-peristaltic</td>
</tr>
<tr>
<td>Maximum infusion/occlusion pressures</td>
<td>25 +/- 12 Psi</td>
</tr>
<tr>
<td>Maximum activation time of occlusion alarm (minimum rate) at minimum occlusion pressures</td>
<td>4 hours</td>
</tr>
<tr>
<td>Maximum activation time of occlusion alarm (intermediate rate) at maximum occlusion pressures</td>
<td>90 seconds</td>
</tr>
<tr>
<td>Dimensions/weight</td>
<td>2.16 in. X 1.4 in. X 6.875 in. (55 mm x 36 mm x 175 mm) 4.7 ounces (133.2 grams) without batteries 6.4 ounces (181.4 grams) with batteries</td>
</tr>
<tr>
<td>Power supply</td>
<td>Two AA 1.5V batteries</td>
</tr>
<tr>
<td>Battery life (rate dependent)</td>
<td>≥14 Days @ 1 ml/hr or ≥26 hrs @ 20 ml/hr</td>
</tr>
<tr>
<td>KVO rate</td>
<td>KVO = 0.5ml/hr for basal rates ≥0.5 ml/hr. KVO = basal rate for rates &lt;0.5 ml/hr.</td>
</tr>
</tbody>
</table>

### 9.2. Continuous Pump Specifications

<table>
<thead>
<tr>
<th>SPECIFICATION</th>
<th>DETAILS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basal flow rates</td>
<td>0 to 125 ml/hr  (0 to 49.9 in 0.1 ml/hr increments and 50 to 125 in 1.0 ml/hr increments)</td>
</tr>
<tr>
<td>Volumes to be infused (ml)*</td>
<td>25 to 999 ml or 25 to 9999 ml in 1 ml increments</td>
</tr>
<tr>
<td>Display, audible alarms, signals and reports</td>
<td>Run indicator light  Pause indicator  Occlusion downstream  Cassette function indicator  Low battery  Dead battery  Malfunction  Infusion complete</td>
</tr>
<tr>
<td>Operating controls</td>
<td>RUN/PAUSE button  FUNCTION button  ON/OFF twist cap</td>
</tr>
<tr>
<td>History reports</td>
<td>Volume infused  Elapsed time</td>
</tr>
<tr>
<td>Delivery profiles</td>
<td>Basal Rate Only</td>
</tr>
</tbody>
</table>

* Pump dependent
### 9.3. PreSet and PCA Pump Specifications

<table>
<thead>
<tr>
<th>SPECIFICATION</th>
<th>DETAILS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bolus delivery rate*</td>
<td>100 ml/hr or 125 ml/hr</td>
</tr>
<tr>
<td>Basal flow rates</td>
<td>0 to 20 ml/hr in 0.1 ml increments</td>
</tr>
<tr>
<td>Bolus volumes</td>
<td>0 to 20 ml in 0.1 ml increments</td>
</tr>
<tr>
<td>Lockout times (hh:mm)*</td>
<td>00:05 to 12:00 or 00:01 to 24:00</td>
</tr>
<tr>
<td>Volumes to be infused (ml)</td>
<td>25 to 1000 ml</td>
</tr>
<tr>
<td>Display, audible alarms, signals and reports</td>
<td>Run indicator light</td>
</tr>
<tr>
<td></td>
<td>Bolus infusing</td>
</tr>
<tr>
<td></td>
<td>Pause indicator</td>
</tr>
<tr>
<td></td>
<td>Occlusion downstream</td>
</tr>
<tr>
<td></td>
<td>Cassette function indicator</td>
</tr>
<tr>
<td></td>
<td>Low battery</td>
</tr>
<tr>
<td></td>
<td>Dead battery</td>
</tr>
<tr>
<td></td>
<td>Malfunction</td>
</tr>
<tr>
<td></td>
<td>Infusion complete</td>
</tr>
<tr>
<td>Operating controls</td>
<td>RUN/PAUSE button</td>
</tr>
<tr>
<td></td>
<td>BOLUS button</td>
</tr>
<tr>
<td></td>
<td>Remote BOLUS switch (optional)</td>
</tr>
<tr>
<td></td>
<td>ON/OFF twist cap</td>
</tr>
<tr>
<td>History reports</td>
<td>Volume infused</td>
</tr>
<tr>
<td></td>
<td>Boluses delivered</td>
</tr>
<tr>
<td></td>
<td>Boluses requested</td>
</tr>
<tr>
<td></td>
<td>Elapsed time</td>
</tr>
<tr>
<td>Delivery profiles</td>
<td>Basal Rate + Bolus</td>
</tr>
<tr>
<td></td>
<td>Basal Rate Only</td>
</tr>
<tr>
<td></td>
<td>Bolus Only</td>
</tr>
</tbody>
</table>

If the back of your pump contains a program table, please refer to the table for specific infusion processes.

* Pump dependent - not programmable
SECTION 10 - DELIVERY RATE ACCURACY

The ambIT® pump is a pseudo-continuous, positive displacement pump. This means that the pump infuses a specific amount of fluid (0.050 ml) each revolution. The cassette is the pumping mechanism and the pump is the driver. The pump counts the number of revolutions and time between revolutions. For each milliliter (ml) to be infused the pump needs to infuse twenty (20) 0.050 ml shots. The shots or revolutions are spread out over the desired time period to create the correct infusion rate. For a one (1) ml/hr infusion, one of the twenty (20) shots occur every three minutes. This means that volumetric or flow-rate accuracy is dependent on three major things:

1. The volume infused each time the cassette makes a revolution².
2. The time between each revolution³.
3. The counting and displaying of revolutions (i.e., the display shows the correct infusion history information).

The easiest way to test all three items is to connect a cassette to the pump and verify that the pump readout and the amount pumped are the same. It was the objective of the volumetric accuracy testing to show that the pump was volumetrically accurate for minimum (0.1 ml/hr), maximum (20 ml/hr) and median (10 ml/hr) basal flow rates, as well as over the full range of bolus volumes by testing 0.1 ml, 10 ml, and 20 ml boluses.

The cassettes and pumps were set up as described in this manual (see set up of fluid reservoir, cassette and pump on inside front cover) using a collapsible medication bag (Summit MediBag™). A second fluid reservoir (Summit MediBag™) was used to represent the patient and collect the output from the pump. Catheters⁴ and needles⁵ were used to simulate the back pressure that would normally be seen during an infusion. Volumetric accuracy was determined by weighing the inlet bag before the infusion started and then again after the infusion was complete. The difference in weight was converted into volume, based on density. The volume removed from the inlet-fluid reservoir was compared to the reading on the pump display to determine the pump’s accuracy.

As a positive displacement pump, the pressure generated by the pump changes as necessary to provide the set flow rate. If the pump is programmed per guidelines set by the drug manufacturer and/or by following appropriate clinical practice, the volume infused by the pump will be within the range tolerated by the body of the patient.

The Perifix® catheter was chosen as the test catheter because of the gauge size and because the three outlet holes provided a greater back pressure than an open-ended catheter (IV) or a multi-hole (> three hole) fenestrated catheter. The needles were used to show that with very low back pressure the volumetric accuracy is not affected.

² It is important to note that the volume infused each time the cassette makes one (1) revolution is independent of the pump and is completely dependent on the cassette.
³ The timing was validated during the software development and validation. The volumetric accuracy testing verified the timing for the three flow rates and three bolus volumes.
⁴ B.Braun Perifix® epidural catheters 20-gauge were used. Perifix® is a trademark of B.Braun.
⁵ 20-gauge EFD ultra dispensing tips.
It is important to note that for the ambIT® pump virtually all the pressure generated by the pump is to overcome the pressure drop in the catheter and not in the body, which is generally a very large low-pressure area. Thus, the basal flow rate should always be set at the lowest amount required to achieve the desired effect.

Based on the volumetric accuracy testing carried out, as described above, the ambIT® pump met the volumetric accuracy specifications for flow rate and bolus volumes as shown in the table found at Section 10.1 below. Thirty (30) data points were used for each average, except as noted.

### 10.1 Data from Volumetric Accuracy Testing

<table>
<thead>
<tr>
<th>BOLUS</th>
<th>125 ml/hr delivery</th>
<th>100 ml/hr delivery*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>20 ml</td>
<td>10 ml</td>
</tr>
<tr>
<td>Average</td>
<td>0%</td>
<td>1%</td>
</tr>
<tr>
<td>Standard deviation</td>
<td>2%</td>
<td>2%</td>
</tr>
</tbody>
</table>

* 25 samples were used for these values.

<table>
<thead>
<tr>
<th>BASAL FLOW RATE</th>
<th>20 ml/hr</th>
<th>10 ml/hr</th>
<th>0.1 ml/hr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average</td>
<td>1%</td>
<td>-1%</td>
<td>2%</td>
</tr>
<tr>
<td>Standard deviation</td>
<td>2%</td>
<td>2%</td>
<td>2%</td>
</tr>
</tbody>
</table>

The volumetric accuracy described in the table above was generated using specific components and procedures. Thus, if portions of the testing are changed, the volumetric accuracy of the ambIT® pump may also change. Factors that may affect volumetric accuracy are shown below in Section 10.2.
10.2 Factors That May Affect Volumetric Accuracy

<table>
<thead>
<tr>
<th>Changes</th>
<th>Effect</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viscosity of fluid increases as compared to water</td>
<td>Volume infused decreases</td>
<td>This may result in an under-infusion due to the speed at which the fluid flows from the fluid reservoir into the pump. The more viscous the fluid, the greater the under-infusion and lower the flow rate.</td>
</tr>
<tr>
<td>Syringe is used as a fluid reservoir</td>
<td>Volume infused decreases</td>
<td>This may result in an under-infusion due to the speed at which the fluid flows from the syringe into the pump. The more friction required to move the syringe, the greater the under-infusion and lower the flow rate.</td>
</tr>
<tr>
<td>Using a catheter with a gauge smaller than 20 gauge</td>
<td>Volume infused decreases</td>
<td>This may result in an under-infusion due to increased back pressure caused by the restricted fluid path. The pump is designed to be accurate if the back pressure is below 70 kPa (0.7 bar or 10 psi).</td>
</tr>
<tr>
<td>Using a non-collapsible fluid reservoir</td>
<td>Volume infused decreases</td>
<td>This may result in an under-infusion due to the vacuum created as the fluid is removed from the container. The vacuum effect keeps fluid from flowing into the pump.</td>
</tr>
<tr>
<td>Adding microbore tubing to the inlet or outlet side of the cassette</td>
<td>Volume infused decreases</td>
<td>This may result in an under-infusion due to the tubing restricting flow into the pump, or creating significant back pressure on the downstream side of the pump. See comment about using a smaller catheter.</td>
</tr>
</tbody>
</table>

The following graphs show the pump’s delivery accuracy for bolus and basal flow rate infusions. The bolus accuracy is shown at different volumes over a number of sequential bolus events. The basal flow rate accuracy is shown as trumpet curves under different conditions of flow rate and delivery pressures. These graphs are applicable for all ambIT® pump cassettes.

The ambIT® pump uses a rotary peristaltic mechanism to deliver fluid. Each rotation of the peristaltic mechanism delivers 0.050 ml (50 μl) of fluid. During bolus delivery, the pump delivers a prescribed volume at a flow rate of 100 ml/hr or 925 ml/hr, depending on the pump. Bolus accuracy is shown as the percent error for the actual vs. prescribed bolus volume. This error is measured sequentially over a number of bolus events at a minimum bolus volume (0.1 ml) and a maximum bolus volume (20 ml).

During basal delivery, the pump delivers fluid at a prescribed flow rate. The flow rate is controlled by the time interval between rotations of the peristaltic mechanism. The trumpet curves are used to describe the flow rate in basal mode. The trumpet curve defines, for a programmed flow rate, the maximum and minimum percentage variation from the expected flow rate for given time intervals measured from the start-up. Over short time intervals, fluctuations in flow rate have a greater effect on accuracy as represented by the “bell” portion of the trumpet curve. As the time interval increases, short term fluctuations have little effect on accuracy as represented by the narrower portion of the trumpet curve.

The user is directed to these graphs in order to be aware of the delivery profile of the ambIT® pump and to ensure that the delivery profile is acceptable for the drug being infused, the drug’s concentration, and the drug’s rate of delivery.
Section 10 - Delivery Rate Accuracy

**Startup graph (average flow)**

20 ml/hr for 24.83333333333 hours

**20 ml/hr flow rate**

**20 ml/hr + 100 mmHg back pressure**
Section 10 • Delivery Rate Accuracy

20 ml/hr - 100 mmHg back pressure

Supply container below pump 20 ml/hr

0.1 ml/hr flow rate
### Section 10 • Delivery Rate Accuracy

#### 25 0.1 ml bolus volumes

![Graph showing % error vs Bolus number for 0.1 ml bolus volumes]

#### 25 20 ml bolus volumes

![Graph showing % error vs Bolus number for 20 ml bolus volumes]
SECTION 11 - 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. (See Section 11.2 for instructions.)

No maintenance of the pump is required, and no calibration is required. Contact Summit Medical Products, 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.

11.1 Warranty Information

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

This warranty will not apply to ambIT® pumps that have been, in the judgment of Summit Medical Products, 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 Summit Medical Products, Inc. with postage prepaid. The replacement of a pump and cassette will not extend the original term set forth above.
11.2 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 12- 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 Summit Medical remote BOLUS switch. Use of any remote BOLUS switch other than the approved ambIT® PCA remote BOLUS switch manufactured by Summit Medical Products, 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. And that if adjacent or stacked use is necessary, the ambIT® pump and other equipment should be observed to verify normal operation 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 that follow. The emissions group and class of the ambIT® pump is Group 1 and Class B.
Table 12-1. Electromagnetic immunity levels tested and passed by ambIT® pump.

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

Table 12-2. Maximum measured radiated emission levels from the ambIT® pump during operation.

<table>
<thead>
<tr>
<th>Frequency (MHz)</th>
<th>dB(µV/m)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Quasi-peak (limit)</td>
</tr>
<tr>
<td>30 to 230</td>
<td>30</td>
</tr>
<tr>
<td>230 to 1000</td>
<td>37</td>
</tr>
</tbody>
</table>
SECTION 13 - CUSTOMER ASSISTANCE

For customer assistance, please contact your ambIT® distributor, or Summit Medical Products, Inc. at:

Summit Medical Products, Inc.
504 West 8360 South
Sandy, Utah 84070 USA
Toll free: 1-800-444-2728
E-mail: service@ambitpump.com
Website: www.ambitpump.com

European representative:

MT Promedt Consulting GmbH
Altenhofstrasse 80
66386 St. Ingbert
Germany

Importer:

Avanos Medical Belgium bvba
Leonardo da Vincilaan 1
1930 Zaventem, Belgium

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