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

- Solution container
- Tubing clamp
- Cassette (to solution container)
- Cassette shaft
- To patient
- Pump display
- RUN/PAUSE button
- ON/OFF switch
- Remote BOLUS switch (optional)
- Tubing clamp
- BOLUS button
- ambIT® Pump
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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 in PCA mode. 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).

**BOLUS/DOSE FLOW RATE**: The flow rate at which a bolus or dose is delivered. It is a higher flow rate than the basal flow rate. In the ambIT® PIB pumps, the bolus flow rate varies from 210 ml/hr to 125 ml/hr, depending on the energy left in the battery. Flow rate accuracy is not affected by the bolus flow rate. See Section 1.4.1 for an explanation of how the bolus flow rate changes. The bolus/dose 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.

**DOSE**: A volume of medication infused over a relatively short period of time and is programmed to occur at regularly scheduled intervals. Sometimes a dose is referred to as a PIB or as a PIEB. In this manual, the term “dose” will be used when discussing either PIB or PIEB. The dose has units of milliliters (ml).

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

**INTERVAL LIMIT (“IL”)**: The maximum amount that can be delivered within a dose interval, or, if there is no dose programmed, it is the maximum bolus volume allowed to be programmed. This setting is only applicable to PIB + PCA (“P+P”) mode for PIB-IL pumps.

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

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

**P+P**: An acronym for a combination of programmable intermittent bolus (“PIB”) and patient controlled analgesia (“PCA”) and allows for dose volumes occurring at set intervals, as well as optional boluses.

---

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

2 The dose is delivered at a higher flow rate than the basal rate; therefore, for a given volume, the dose is delivered fast.
**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).

**PIB (PIb)**: An acronym for programmable intermittent bolus. If the infusion is into the epidural space, the PIB or PIb is referred to as programmable intermittent epidural bolus (PIEB or PIEb). Within this manual, when referring to the pump itself, “PIB” is used; when referring to the dose, display or mode, “PIb” is used.

**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.

### 1.1.2 Definition of Symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Consult instructions for use." /></td>
<td>International symbol meaning “Attention, consult accompanying documents.”</td>
</tr>
<tr>
<td><img src="image" alt="IEC symbol for “Type BF Applied Part.”" /></td>
<td>IEC symbol for “Type BF Applied Part.” (IEC Classification: Internally powered.)</td>
</tr>
<tr>
<td><img src="image" alt="CE" /></td>
<td>CE symbol certifying that the product complies with the essential requirements of the Medical Device Directive.</td>
</tr>
</tbody>
</table>

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3 In some publications, the PIb is referred to as an “automated bolus” or “automated mandatory bolus.” This usage is less common than PIb or PIEb.
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.

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

Indicates the manufacturer’s batch code 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)
Section 1 • Introduction

Keep away from heat

Keep dry

Rx only

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

Temperature limitation

Sterilized using irradiation

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

To patient

To solution container

Cassette shaft (side view of cassette)
<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>$\text{ml}$</td>
<td>Bolus volume in milliliters</td>
</tr>
<tr>
<td>$\text{ml/hr}$</td>
<td>Basal infusion rate in ml/hr</td>
</tr>
<tr>
<td>No. $\text{\ø}$</td>
<td>Number of boluses delivered</td>
</tr>
<tr>
<td>Volume to be infused</td>
<td></td>
</tr>
<tr>
<td>No. $\text{\ø}$</td>
<td>Number of bolus requests</td>
</tr>
<tr>
<td>$\text{\ø}/\text{II}$</td>
<td>RUN/PAUSE button</td>
</tr>
<tr>
<td>$\text{\ø}$</td>
<td>BOLUS button</td>
</tr>
<tr>
<td>$-$, $+$</td>
<td>Low/dead battery indicator</td>
</tr>
<tr>
<td>$\text{\ø}$</td>
<td>Alarm indicator</td>
</tr>
<tr>
<td>ambIT® pump display</td>
<td></td>
</tr>
<tr>
<td>Pump power on</td>
<td></td>
</tr>
<tr>
<td>Pump power off</td>
<td></td>
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Section 1 • Introduction

Battery orientation

PIb mode

PCA mode

P+P mode

Program lockout code

Program lockout mode

Pump program mode

Review pump program

Infusion history report

Pump infusion history cleared

Bolus button on

Bolus button off
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.

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.

When the desired volume to be infused has been delivered, the empty solution container must be changed. Failure to do so will result in cessation of fluid delivery.

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

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.
• For IV applications, the ambIT® PIB pumps should be used with air elimination filters because air protection 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 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® PIB Pumps in MRI Environment

Safety in MRI not evaluated. The ambIT® PIB 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 PIB pumps in the MRI environment is unknown. Scanning a patient who has this device may result in patient injury.

1.3 Indications for Use

The ambIT® PIB pumps are used to infuse medicines and/or fluids into patients primarily for pain management.

The routes of administration are generally intravenous, epidural, and/or regional.

The ambIT® PIB pumps are not intended to supersede, augment, or replace any other medical device or drug indications for use or intended uses.

The ambIT® PIB pumps are intended to be used in the home and in healthcare facilities.

NOTE: Any use of the pump other than those indicated above is regarded as an off-label use. The ambIT® PIB 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® PIB pumps. The healthcare provider is the sole individual who decides upon the prescribed medication, pump programmed 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 Product Description

1.4.1 Product Overview

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

The ambIT® PIB pumps are unique pumps. There are three different modes of operation. The first mode is PCA. The second mode is Pib4. The third mode is Pib and PCA (P+P). The three different modes allow for the following five types of infusion patterns: (1) basal flow rate only, (2) bolus only, (3) basal flow rate and bolus, (4) dose only, (5) dose and bolus.

In PCA mode, the pump can be programmed in basal flow rate mode, bolus only, or basal flow rate and bolus. In PCA mode the parameters available are (1) basal flow rate5, (2) bolus volume6, (3) lockout time7, (4) activation/deactivation of bolus button (KIDS-PIB pump only), and (5) volume to be infused8.

The Pib mode is added to simplify programming a dose-only therapy. Therefore, in Pib mode the pump can only be programmed to deliver doses. The programmed parameters available in Pib mode are (1) dose volume, (2) dose interval and (3) volume to be infused.

In P+P mode, the pump can be programmed to deliver a dose only, a bolus only, or a dose and a bolus. The programmed parameters available are (1) dose volume9, (2) dose interval10, (3) bolus volume11, (4) lockout time, (5) activation/deactivation of bolus button (KIDS-PIB pump only), (6) volume to be infused and, if a PIB-IL pump, (7) interval limit.

4 Pib stands for programmable intermittent boluses, but in order to avoid confusion, we refer to all automatically delivered boluses as doses and PCA boluses as boluses.
5 The units for the basal flow rate are milliliter per hour (ml/hr). When the basal flow rate is set to zero (0.0) the PCA program is set to bolus only.
6 The unit for the bolus volume is milliliter (ml). When the bolus volume is set to zero (0.0) the PCA program is set to basal flow rate only.
7 The units for the lockout time are hours and minutes (hh:mm). The lockout time is bypassed automatically if the bolus volume is set to zero (0.0).
8 The volume to be infused unit is milliliter (ml). It is the reservoir volume. It is required to be programmed in all modes.
9 The dose volume unit is milliliter (ml). If it is set to zero (0.0), the interval time is bypassed automatically and the dose volume can be set to bolus-only mode.
10 The dose interval or interval units are hours and minutes (hh:mm).
11 If the bolus volume is set to zero (0.0), then the lockout time is automatically bypassed and the pump will only deliver doses (like Pib mode).
The goal of the bolus or dose is to infuse the medication at an increased rate — mimicking an injection as much as possible. The purpose of the increased rate is generally to flood a greater area with analgesic medication or to increase the concentration of the medication. The flow rate at which the ambIT® PIB pump infuses a bolus or dose is dependent on the energy state of the batteries.

The bolus/dose infusion rate will be 210 ml/hr until the low battery alarm is activated if a new, unused set of AA alkaline batteries are used at the start of the infusion. After the low battery alarm is activated, the bolus/dose infusion rate may be reduced from the 210 ml/hr to about 180 ml/hr. On a new, unused set of alkaline batteries, the low battery alarm will not be reached until at least 500 ml have been infused. If one or both batteries have been previously used, non-alkaline batteries are used, or the pump is repeatedly cycled off and on, the bolus/dose infusion rate may drop to a minimum of 125 ml/hr prior to the low battery alarm being activated. The purpose of allowing the infusion rate to drop is to maximize battery life. The pump will NOT inform the user that the bolus/dose infusion rate has dropped. No other parameters are affected as the batteries are depleted.

**CAUTION:** If the medication being infused requires the bolus/dose infusion rate to be 210 ml/hr, only new alkaline batteries should be used and the batteries should be changed immediately when the low battery alarm occurs.

**CAUTION:** Repeatedly cycling the pump off and on may cause the bolus/dose infusion rate to drop below 210 ml/hr. In extreme cases, the bolus/dose infusion rate could drop as low as 125 ml/hr.

A new, unused set of alkaline batteries will infuse at 210 ml/hr. For a minimum of 500 ml, the bolus and dose flow rate will be 210 ml/hr. Once the batteries have been depleted, the flow rate may decrease. The lowest flow rate the pump will reach is 125 ml/hr.

The different parameters for each mode interact with each other to create an infusion pattern. Examples of the infusion patterns for the different modes are provided graphically in Figures 1-1 through 1-6 that follow. The flow rates, volumes, lockout times, and intervals listed are examples only.

**NOTE:** For the Australian PIB PCA, the maximum average infusion rate is limited to 20 ml/hr. While these graphs represent what occurs in all cases, the actual program settings shown in examples may not be available in all models.
Section 1 • Introduction

Figure 1-1

Basal flow rate only (PCA mode) infusion pattern

For Figure 1-1, the basal flow rate is 10 ml/hr. The maximum available basal flow rate is 20 ml.

Figure 1-2

Bolus only (PCA mode) infusion pattern

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: Right after programming the pump or clearing history, a bolus will be delivered if requested. The pump assumes that clearing history or programming/reprogramming a new therapy is starting.

NOTE: When using the KIDS-PIB pump, the BOLUS button on the pump may be activated to allow a bolus administration directly from the BOLUS button or deactivated to require the use of a remote BOLUS switch to administer a bolus.
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.

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

For Figure 1-4, the settings are a dose volume of 25 ml and a dose interval of 90 minutes.

**NOTE:** An optional dose can be delivered at the start of an infusion by pushing the BOLUS button within 60 seconds of the start of an infusion. For the Australian PIB-PCA, the optional dose is only available after the infusion history has been cleared. When using the KIDS-PIB pump, the BOLUS button on the pump may be activated to allow a bolus administration directly from the BOLUS button or deactivated to require the use of a remote BOLUS switch to administer a bolus.
Boluses are available after a lockout time. In the example used in Figure 1-5 and Figure 1-6, the dose volume is 20 ml, the dose interval is 90 minutes, the bolus volume is 10 ml, and the lockout time is 30 minutes.

Automated doses are scheduled at a set interval. An optional dose is available at the start of a new infusion if the BOLUS button is pushed within 60 seconds. Unlike in PCA mode, if the BOLUS button is not pushed, the bolus is NOT available until the lockout time has expired. If a bolus is requested and delivered, the lockout time may delay the dose until the lockout time has expired. A lockout time occurs immediately after either a bolus or dose. The third dose in Figure 1-5 has been delayed by a little over five minutes, so instead of occurring at the 180-minute mark, the third dose occurs at about the 185-minute mark. The dose stays delayed for the rest of the therapy.

NOTE: Figure 1-5 does not apply to the PIB-IL pump; see Figure 1-7 and Figure 1-8 for PIB-IL P+P infusion pattern.

NOTE: When using the KIDS-PIB pump, the BOLUS button on the pump may be activated to allow a bolus administration directly from the BOLUS button or deactivated to require the use of a remote BOLUS switch to administer a bolus.
Figure 1-6

Dose and bolus (P+P mode) infusion pattern of multiple dose delays

(PIB-PCA, KIDS·PIB and Australian PIB-PCA pumps only; does not apply to the PIB-IL)

Each time a dose is delayed; it is added to the previous delays. In Figure 1-6, the second dose is delayed by about 10 minutes (first dose delay), from 90 minutes to 100 minutes. This means that the third dose should have occurred at 190 minutes, but due to the second delay of a little over 5 minutes (second dose delay), the third dose occurs at a little over 195 minutes. If no other delays occur, then all the remaining doses will be delayed by the sum of the first and second dose delays, or a little over 15 minutes.

NOTE: Figure 1-6 does not apply to the PIB-IL pump; see Figure 1-7 for PIB-IL infusion pattern of multiple dose delays.
Figure 1-7

Dose and bolus (P+P mode) infusion pattern of multiple boluses

(Figure 1-7 only applies to the PIB-IL pump)

As shown in Figure 1-7, the total volume infused during the interval is reset to zero at the beginning of each interval. As each bolus and dose is delivered, the total volume infused during the interval is increased (see bold line). If the volume infused during the interval reaches the interval limit (See Figure 1-8) or bolus delivery would overlap the end of a dose interval (See Figure 1-7), then the bolus is stopped immediately.

NOTE: The undelivered portion of the bolus will not be delivered later.
NOTE: The total volume is controlled by the IL over the dose interval. This means it is possible for the bolus and dose to be delivered back-to-back (i.e., the bolus at the end of one dose interval and the dose at the start of the next dose interval).

NOTE: From the start of one dose to the start of the next dose (dose interval), the IL is maintained, but over a time that covers the end of one dose interval and the start of the next dose interval, the volume set for the IL may be exceeded. (This situation is shown in Figure 1-7. The total volume infused from the time the bolus is started at the end of the first dose interval to the time at the end of the first bolus in the second dose interval, may exceed the IL. See Figure 1-8 below.)

Figure 1-8
(Figure 1-8 only applies to the PIB-IL pump)
1.4.2 ambIT® Pump User Interface

The pump has two buttons: the RUN/PAUSE button and the BOLUS button. The RUN/PAUSE button is located just below the pump display. The BOLUS button is located just below the RUN/PAUSE button. See figure to the left.

An ON/OFF switch is part of the battery cap. See figure to the left.

The pump program is determined by selecting the desired parameters during the program mode. Pressing and holding the pump’s RUN/PAUSE button and BOLUS button 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 program 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. The RUN/PAUSE button will also silence any alarm that occurs while the pump is running. A blinking green run light (inside the BOLUS button) and “ml” (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.

When the BOLUS button is pressed during run mode, the pump will deliver the programmed bolus. When using the KIDS-PIB pump, the BOLUS button on the pump may be activated to allow a bolus administration directly from the BOLUS button or deactivated to require the use of a remote BOLUS switch to administer a bolus. During bolus delivery, the green run light (inside the BOLUS button) will double blink.

1.4.3 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 (see figure to the upper left).

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 (see figure to the bottom left). 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. 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 (see Section 2), 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.
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.

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 (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.
WARNING: It is recommended that an air elimination filter be used for IV applications to protect them from air embolisms. The ambIT® cassette can 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 sterile open ends of the tubing. Use the aseptic technique utilized by your facility.

WARNING: The cassette must be primed before use by removing all air from the solution container and tubing.
To prime the cassette, follow these steps:

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 BOLUS button to complete the priming of the cassette.

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

Step #6a
Set the pump to deliver a 20 ml bolus (see Section 3.2.1).

Step #6b
Start the pump (see Section 4.1.1) and push 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 repeatedly initiated by clearing the history (see Section 5.2) between each bolus.

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 counter-clockwise so silver dot makes one full rotation.

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

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.
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® filtered 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 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 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 (1) part of the history to be lost, (2) possible under-infusion, and (3) the pump to sound an alarm when the pump attempts to infuse medication.
2.6 Changing 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 the aseptic technique training. If you are unsure of how to perform this task, consult your facility or supervisor.

**WARNING:** Do not use a syringe as a fluid reservoir, because under-infusion will occur.

Prior to changing the fluid reservoir put the pump in pause mode (see Section 4.2 for instructions). 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 AA 1.5V batteries. Alkaline batteries are recommended and have been used to develop the data in this manual.

**CAUTION:** 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 cover counter-clockwise slightly to the left of the OFF (O) position, until the cover stops or meets resistance.
2.7.2 Battery Replacement

WARNING: When reinstalling batteries, always verify correct program settings before restarting infusion.

Step #2
Remove the cover and insert the batteries according to the illustrations at left.

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

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

To replace batteries:

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

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 cover counter-clockwise slightly to the left of the OFF (O) position, until the cover stops or meets resistance.

Step #3
Remove the cover and insert the batteries according to the instructions in Section 2.6.1.

Step #4
Power on the pump according to the instructions in Section 2.6.3.

After the batteries are replaced and the pump is powered on, the pump will return to pause mode.
Press and release the RUN/PAUSE button to review the current program settings.

Press and release the RUN/PAUSE button a second time to resume the current infusion program.

### 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 cover clockwise until the (I) mark on the cover lines up with the (I) mark on the pump.

**NOTE:** After the power-on self-test, the pump will beep twice and go into pause mode. 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 cover counter-clockwise until the (O) mark on the cover lines up with the (I) 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 button. A specific combination of pressing these buttons sets the pump program.

When the pump is in program mode, the RUN/PAUSE button functions as an up arrow (incrementing the value of the blinking number) and the BOLUS button functions as a down arrow (decimating the value of the blinking number). Both the RUN/PAUSE button and the BOLUS button can be used to select a value by holding either button when the desired value is displayed.

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

NOTE: Holding the RUN/PAUSE button or BOLUS button does not increment or decrement any numbers. The buttons must be pushed and released to increment or decrement any numbers.

There are three different modes that may be programmed into the ambIT® PIB pumps:

- PCA\textsuperscript{13} mode: This mode allows for boluses only, basal flow rate only\textsuperscript{14}, or bolus and basal flow rate combined. (See Section 3.2.1 for parameters and programming instructions.)

- PIb\textsuperscript{15} mode: This mode allows the patient to receive regularly occurring doses of medication. These are delivered automatically at regularly preprogrammed intervals. These doses replace the continuous basal rate of the PCA mode. There is not a patient-controlled bolus option in this mode (see Section 3.2.2 for parameters and programming instructions.)

- P+P mode: This mode allows for boluses only, doses only, or combined doses and boluses. (See Section 3.2.3 for parameters and programming instructions.)

\textsuperscript{13} PCA is 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 or healthcare provider 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).

\textsuperscript{14} Also referred to as a continuous infusion.

\textsuperscript{15} Also referred to as PIEB. See definitions in Section 1.
3.2 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 2.7).

Step #2

Press and hold both the RUN/PAUSE button and the BOLUS button for two seconds until one beep is heard.

“PRO” will momentarily appear in the pump display, after which the pump mode -- Plb, PCA, or P+P -- will flash in the pump display, indicating that the pump mode can be changed. The remaining steps for programming the pump are described in Sections 3.2.1 through 3.2.3.

The pump can be reprogrammed during infusion, without clearing the infusion history, by placing the pump in pause mode and then entering program mode. See Section 3.2.1 through 3.2.3 for programming steps.

The pump can be reprogrammed after clearing the infusion history (see Section 5.2 – “Clearing Pump Infusion History”) by entering program mode and selecting the desired parameters.

When attempting to program/reprogram the pump, “LOC” will appear in the pump display if the pump program is in lockout mode (see Section 6 – “Patient Lockout”).

The pump program must be unlocked for programming/reprogramming and clearing the infusion history.

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.

CAUTION: After clearing history or reprogramming the pump a bolus (in PCA mode) or dose (in Plb or P+P modes) is available immediately after starting the infusion.

NOTE: The remote BOLUS switch cannot be used to program the pump.

3.2.1 PCA Mode

PCA mode allows for bolus-only, basal-only or bolus with basal flow rates.

3.2.1.1 PCA Mode Program Parameters and Definitions

- The basal flow rate is the continuous flow rate. It occurs when the pump is not delivering a bolus in PCA mode. The basal flow rate is adjustable and has units of milliliters per hour (ml/hr).
A bolus is 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).

Bolus/dose flow rate is the flow rate at which a bolus or dose is delivered. It is a higher flow rate than the basal flow rate. In the ambIT® PIB pumps, the bolus flow rate varies from 210 ml/hr to 125 ml/hr, depending on the energy left in the battery. Flow rate accuracy is not affected by the bolus flow rate. See Section 1.4.1 for an explanation of how the bolus flow rate changes. The bolus/dose flow rate is not adjustable.

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

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

The volume to be infused is the total amount of fluid in the solution container or reservoir to be infused. The volume to be infused has units of milliliters (ml).

**NOTE:** When programming in PCA mode, if the tens and/or ones digits are already set to the desired setting, press both the BOLUS button and the RUN/PAUSE button to accept the setting and move on to the next step. This option is not available when a parameter is programmed to its maximum value.

See Section 1.4.1 for an explanation of the patterns of flow available in PCA mode; specifically, bolus-only, basal-only, and bolus with basal flow rates (Figures 1-1 through 1-3).

16 The bolus is delivered at a higher flow rate than the basal rate; therefore, for a given volume, the bolus is delivered faster.
### 3.2.1.2 PCA Mode Programming Steps

<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 beep is heard.</td>
<td>One beep</td>
<td>“PRO” is displayed for two seconds to indicate that the pump is in program mode.</td>
</tr>
<tr>
<td>2 Select PCA: Press the RUN/PAUSE button to scroll up or press the BOLUS button to scroll down through the program modes until “PCA” appears in the display. Press and hold either the RUN/PAUSE button or the BOLUS button until one beep is heard to accept the setting.</td>
<td>One beep</td>
<td>“PCA” flashes in the display. Mode is established.</td>
</tr>
<tr>
<td>3 Set basal flow rate: (A) Press the RUN/PAUSE button to increase the number or press the BOLUS button to decrease the number. (B) When the desired number appears in the display, press and hold either the RUN/PAUSE button or the BOLUS button until one beep is heard to accept the setting. Repeat the steps 3(A) and 3(B) to set the digit to the right of the decimal point.</td>
<td>One beep</td>
<td>Number left of decimal point and “ml/hr” flash. NOTE: Basal flow rate is displayed in ml/hr. The number to the right of the decimal point and “ml/hr” flash. Basal flow rate is established.</td>
</tr>
<tr>
<td>4 Set bolus volume: (A) Press the RUN/PAUSE button to increase the number or press the BOLUS button to decrease the number. (B) When the desired number appears in the display, press and hold either the RUN/PAUSE button or the BOLUS button until one beep is heard to accept the setting.</td>
<td>One beep</td>
<td>Letter “b,” numbers left of decimal point, “ml” and bolus icon flash. NOTE: Bolus volume is displayed in ml.</td>
</tr>
</tbody>
</table>

**NOTE:** The limits for basal flow rate are 0.0 to 20.0 ml.
## Section 3 • Programming Instructions

<table>
<thead>
<tr>
<th>ACTION</th>
<th>AUDIBLE INDICATOR</th>
<th>VISUAL INDICATOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repeat the steps 4(A) and 4(B) to set the digit to the right of the decimal point.</td>
<td>Letter “b” is displayed and the number to the right of decimal point, “ml,” and bolus icon flash. Bolus volume is established.</td>
<td></td>
</tr>
</tbody>
</table>

**NOTE:** The limits for bolus volume are 0.0 to 50.0 ml. The range of bolus volumes may be limited by the basal flow rate chosen.

<table>
<thead>
<tr>
<th>5</th>
<th>Set lockout time:</th>
</tr>
</thead>
<tbody>
<tr>
<td>(A) Press the RUN/PAUSE button to increase the time or press the BOLUS button to decrease the time.</td>
<td>“LOT” and symbols are displayed for two seconds to indicate that the pump is in lockout mode, “hr:min” is displayed and the bolus, lock and clock icons, as well as the numbers in the hr section will flash.</td>
</tr>
<tr>
<td>(B) When the desired lockout time appears in the display, press and hold either the RUN/PAUSE button or the BOLUS button until one beep is heard to accept the setting.</td>
<td>One beep</td>
</tr>
</tbody>
</table>

**NOTE:** Lockout time is displayed in hours and minutes.

<table>
<thead>
<tr>
<th>Repeat the steps 5(A) and 5(B) to set the digits in the minutes section.</th>
<th>“hr:min” is displayed and bolus, lock and clock icons, as well as numbers in the min section, flash.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lockout time is established.</td>
</tr>
</tbody>
</table>

**NOTE:** If bolus volume is set to “0,” this step will be skipped.

**NOTE:** The limits for lockout time are 00:01 to 24:00 hh:mm. This range may be limited by the basal flow rate and/or bolus volume chosen.

<table>
<thead>
<tr>
<th>6</th>
<th>STEP 6 APPLIES ONLY TO THE KIDS • PIB PUMP:</th>
</tr>
</thead>
<tbody>
<tr>
<td>If programming the PIB*PCA or Australian pump, skip Step 6 and proceed to Step 7.</td>
<td>“boff” or “bon” will blink until selected</td>
</tr>
</tbody>
</table>

Activate/Deactivate bolus button:
(A) Press and release either the RUN/PAUSE button or the BOLUS button to toggle between “boff” (bolus button off) and “bon” (bolus button on).
<table>
<thead>
<tr>
<th>ACTION</th>
<th>AUDIBLE INDICATOR</th>
<th>VISUAL INDICATOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>(B) Press and holder either the RUN/PAUSE button or the BOLUS button to select either “boff” or “bon.”</td>
<td></td>
<td>“boff” or “bon” will stop blinking for 2-3 seconds before moving to next step.</td>
</tr>
<tr>
<td>(B) When the desired number appears in the display, press and hold either the RUN/PAUSE button or the BOLUS button until one beep is heard to accept the setting.</td>
<td></td>
<td>Active or deactive status is selected.</td>
</tr>
<tr>
<td>Repeat the steps 7(A) and 7(B) to set the digits in the tens and ones section.</td>
<td>One beep</td>
<td></td>
</tr>
</tbody>
</table>

7 Set volume to be infused:

(A) Press the RUN/PAUSE button to increase the number or press the BOLUS button to decrease the number.

(B) When the desired number appears in the display, press and hold either the RUN/PAUSE button or the BOLUS button until one beep is heard to accept the setting.

NOTE: Bag volume limits are 1 to 1000 ml.

Volume to be infused is established.

One beep followed by two beeps  

Pump returns to pause mode.

Pause icon flashes.

Note: To confirm program settings, access “RX” by pressing and releasing the BOLUS button. After scrolling through the programmed settings, the pump will automatically return to pause mode.
### 3.2.2 PIb Mode

**NOTE:** PIb stands for programmable intermittent bolus or automatic bolus; however, to avoid confusion, this manual uses the term “dose” when referring to PIb or PIEb. (see Definitions in Section 3.2.2 below).

PIb mode allows the patient to receive regularly occurring doses of medication. These doses are delivered automatically at regular intervals. There is not a PCA bolus option in this mode (see Section 3.2.2 for programming instructions).

#### 3.2.2.1 PIb Mode Program Parameters and Definitions.

- A dose is a volume of medication infused over a relatively short period of time\(^{17}\) and is programmed to occur at scheduled intervals. Sometimes a dose is referred to as a programmed intermittent bolus (PIb) or as a programmed intermittent epidural bolus (PIEb)\(^ {18}\). In this manual, the term “dose” will be used when discussing either PIb or PIEb. The dose has units of milliliters (ml).

- The bolus/dose rate is the flow rate at which a bolus or dose is delivered. It is a higher flow rate than the basal flow rate. In the ambIT® PIB pumps, the bolus flow rate varies from 210 ml/hr to 125 ml/hr, depending on the energy left in the battery. Flow rate accuracy is not affected by the bolus/dose flow rate. See Section 1.4.1 for an explanation of how the bolus flow rate changes. The bolus/dose flow rate is not adjustable.

- Interval or dose interval is the time between the start of one dose and the start of the next dose. The dose interval has units of hours and minutes (hh:mm).

- PIb is an acronym for patient-intermittent bolus. If the infusion is into the epidural space, the PIb is referred to as patient-intermittent epidural bolus (PIEb)

- The volume to be infused is the total amount of fluid in the solution container or reservoir to be infused. The volume to be infused has units of milliliters (ml).

**NOTE:** When programming in PIb mode, if the tens and/or ones digits are already set to the desired setting, press both the BOLUS button and RUN/PAUSE button to accept the setting and move on to the next step. This option is not available when a parameter is programmed to its maximum value.

See Section 1.4.1 for an explanation of the pattern of flow available in PIb mode; specifically, dose only (Figure 1-4).

---

\(^{17}\) The dose is delivered at a higher flow rate than the basal rate; therefore, for a given volume, the dose is delivered faster.

\(^{18}\) In some publications, the PIB is referred to as an “automated bolus” or “automated mandatory bolus.” This usage is less common than PIB or PIEB.
### 3.2.2.2 PIb Mode Programming Steps

<table>
<thead>
<tr>
<th>ACTION</th>
<th>AUDBLE 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 beep is heard.</td>
<td>One beep</td>
<td>“PRO” is displayed for 2 seconds to indicate that the pump is in program mode.</td>
</tr>
<tr>
<td>2 Select PIb: Press the RUN/PAUSE button to scroll up or press the BOLUS button to scroll down through program modes until “PIb” appears in the display. To accept the setting, press and hold either the RUN/PAUSE button or the BOLUS button until one beep is heard.</td>
<td>One beep</td>
<td>“PIb” flashes in the display. Mode is established.</td>
</tr>
<tr>
<td>3 Set dose volume: (A) Press the RUN/PAUSE button to increase the number or press the BOLUS button to decrease the number. (B) When the desired number appears in the display, press and hold either the RUN/PAUSE button or the BOLUS button until one beep is heard to accept the setting and move onto the next digit. Repeat steps 3(A) and 3(B) to set the digit to the right of the decimal point (00.0 to 00.9).</td>
<td>One beep</td>
<td>The letter “d,” the number left of decimal point, and the “ml” icon flash. NOTE: Dose volume is displayed in ml. Letter “d” is displayed, and number right of decimal point and “ml” flash. Dose volume is established.</td>
</tr>
<tr>
<td>4 Set dose interval time: (A) Press the RUN/PAUSE button to increase the dose interval time or press the BOLUS button to decrease the dose interval time.</td>
<td></td>
<td>“INT” is displayed for two seconds to indicate that the pump is in dose interval mode. “hr:min” and clock icons and the hours section flash.</td>
</tr>
</tbody>
</table>

**NOTE:** The limits for dose volume are 0.0 to 50.0 ml.
### Section 3 • Programming Instructions

<table>
<thead>
<tr>
<th>ACTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>(B) When the desired dose interval time appears in the display, press and hold either the RUN/PAUSE button or the BOLUS button until one beep is heard to accept the setting and move onto the next digit. Repeat steps 4(A) and 4(B) to set the digits in the minutes section.</td>
</tr>
<tr>
<td>(B) When the desired number appears in the display, press and hold either the RUN/PAUSE button or the BOLUS button until one beep is heard to accept the setting and move onto the next digit. Repeat steps 5(A) and 5(B) to set the digits in the tens and ones sections.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>AUDIBLE INDICATOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>“hr:min” and clock icons and minutes section flash.</td>
</tr>
<tr>
<td>“ml” is displayed, and bag icon and the hundreds digit flash.</td>
</tr>
<tr>
<td>“ml” is displayed, and bag icon and the respective digits flash.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>VISUAL INDICATOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>“hr:mm”.</td>
</tr>
<tr>
<td>Volume to be infused is displayed in ml.</td>
</tr>
<tr>
<td>Volume to be infused is established.</td>
</tr>
</tbody>
</table>

- **NOTE:** Dose interval time is displayed in hours and minutes (hh:mm).

- **NOTE:** If dose volume is set to “0,” this step will be skipped.

- **NOTE:** The minimum dose interval time is dependent on the dose volume chosen. The maximum dose interval is always 24:00 (hh:mm).

5 Set volume to be infused:

(A) Press the RUN/PAUSE button to increase the number or press the BOLUS button to decrease the number.

(B) When the desired number appears in the display, press and hold either the RUN/PAUSE button or the BOLUS button until one beep is heard to accept the setting and move onto the next digit.

- **NOTE:** Bag volume limits are 1 to 1,000 ml.

- **NOTE:** To confirm program settings, access “RX” by pressing and releasing the BOLUS button. After scrolling through the programmed settings, the pump will automatically return to pause mode.

- Pump returns to pause mode.
- One beep followed by two beeps
- Pause icon flashes.
3.2.3 P+P Mode

P+P stands for patient-intermittent bolus (PIb) combined with patient-controlled analgesia (PCA). This mode contains dose volumes occurring at set intervals, as well as optional boluses. It is important to understand how the P+P mode functions. Below is an explanation.

3.2.3.1 P+P Mode Programming Parameters and Definitions

- In the PIB-IL, a maximum interval limit is set. This limits the maximum dose and maximum bolus that can be programmed.

- A bolus is 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).

- The bolus/dose flow rate is the flow rate at which a bolus or dose is delivered. It is a higher flow rate than the basal flow rate. In the ambIT® PIB pump, the bolus flow rate varies from 210 ml/hr to 125 ml/hr, depending on the energy left in the battery. Flow rate accuracy is not affected by the bolus flow rate. See Section 1.4.1 for an explanation of how the bolus flow rate changes. The bolus/dose flow rate is not adjustable.

- The dose is a volume of medication infused over a relatively short period of time and is programmed to occur at scheduled intervals. Sometimes a dose is referred to as a programmed intermittent bolus (PIb) or as a programmed intermittent epidural bolus (PIEb). In this manual, the term “dose” will be used when discussing either PIb or PIEb. The dose has units of milliliters (ml).

- The interval or dose interval is the time between the start of one dose and the start of the next dose. The dose interval has units of hours and minutes (hh:mm).

- In general, the lockout time is the time between the end of one after a bolus or dose and the start of the next bolus or dose. The lockout time has units of hours and minutes (hh:mm).

- The volume to be infused is the total amount of fluid in the solution container or reservoir to be infused. The volume to be infused has units of milliliters (ml).

See Section 1.4.1 for an explanation of the patterns of flow available in P+P mode: specifically, bolus-only, dose-only and bolus plus dose (Figures 1-2 and 1.4 through 1-6).

---

19 The bolus is delivered at a higher flow rate than the basal rate; therefore, for a given volume, the bolus is delivered faster.
20 The dose is delivered at a higher flow rate than the basal rate; therefore, for a given volume, the dose is delivered fast.
21 In some publications, the PIB is referred to as an “automated bolus” or “automated mandatory bolus.” This usage is less common than PIB or PIEB.
NOTE: When programming in P+P mode, if the tens and/or ones digits are already set to the desired setting, press both the BOLUS button and the RUN/PAUSE button to accept the setting and move on to next step. This option is not available when a parameter is programmed to its maximum value.

### 3.2.3.2 P+P Mode Programming Steps

<table>
<thead>
<tr>
<th>ACTION</th>
<th>AUDIBLE INDICATOR</th>
<th>VISUAL INDICATOR</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1</strong></td>
<td>Enter program mode: From pause mode, press and hold both the RUN/PAUSE button and the BOLUS button until one beep is heard.</td>
<td>One beep</td>
</tr>
<tr>
<td><strong>2</strong></td>
<td>Select P+P: Press the RUN/PAUSE button to scroll up or press the BOLUS button to scroll down through the program modes until “P+P” appears in the display. Press and hold either the RUN/PAUSE button or the BOLUS button until one beep is heard to accept the setting.</td>
<td>One beep</td>
</tr>
<tr>
<td><strong>3</strong></td>
<td><strong>STEP 3 APPLIES ONLY TO THE PIB-IL PUMP:</strong> If programming the PIB*PCA or Australian pump, skip Step 3 and proceed to Step 4. Set interval limit (“IL”):</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 beep</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 beep is heard to accept the setting.</td>
<td></td>
</tr>
<tr>
<td><strong>4</strong></td>
<td>Set dose volume: (A) Press the RUN/PAUSE button to increase the number or press the BOLUS button to decrease the number.</td>
<td></td>
</tr>
</tbody>
</table>

NOTE: Dose volume can be programmed only to the maximum of the IL setting.

NOTE: Bolus volume can be programmed only to the IL setting minus the dose volume setting.
### Section 3 • Programming Instructions

<table>
<thead>
<tr>
<th>ACTION</th>
<th>AUDIBLE INDICATOR</th>
<th>VISUAL INDICATOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>(B) When the desired number appears in the display, press and hold either the RUN/PAUSE button or the BOLUS button until one beep is heard to accept the setting. Repeat steps 4(A) and 4(B) to set the digit to the right of the decimal point.</td>
<td>One beep</td>
<td>NOTE: Dose volume is displayed in ml.</td>
</tr>
<tr>
<td><strong>NOTE:</strong> Dose volume is displayed in ml.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>NOTE:</strong> Letter “d” is displayed, and number to the right of the decimal point and “ml” flash. Dose volume is established.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>5</strong> Set dose interval time:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(A) Press the RUN/PAUSE button to increase the interval time or press the BOLUS button to decrease the dose interval time.</td>
<td></td>
<td>“INT” is displayed for two seconds to indicate that the pump is in dose interval mode.</td>
</tr>
<tr>
<td>(B) When the desired dose interval time appears in the display, press and hold either the RUN/PAUSE button or the BOLUS button until one beep is heard to accept the setting. Repeat steps 5(A) and 5(B) to set the digits in the minutes.</td>
<td>One beep</td>
<td>“hr:min” and clock icon and the hours section flash.</td>
</tr>
<tr>
<td><strong>NOTE:</strong> Dose interval time is displayed in hours and minutes (hh:mm).</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>NOTE:</strong> “hr:min”, clock icon, and numbers in the minute section flash. Dose interval time is established.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>6</strong> Set bolus volume:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(A) Press the RUN/PAUSE button to increase the number or press the BOLUS button to decrease the number.</td>
<td></td>
<td>Letter “b,” numbers left of decimal point, “ml” and bolus icon flash.</td>
</tr>
<tr>
<td>(B) When the desired number appears in the display, press and hold either the RUN/PAUSE button or the BOLUS button until one beep is heard to accept the setting.</td>
<td>One beep</td>
<td>NOTE: Bolus volume is displayed in ml.</td>
</tr>
<tr>
<td><strong>NOTE:</strong> If dose volume is set to “0,” this step will be skipped.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>NOTE:</strong> The minimum dose interval is dependent on the dose volume set. The maximum dose interval is 24:00 (hh:mm).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACTION</td>
<td>AUDIBLE INDICATOR</td>
<td>VISUAL INDICATOR</td>
</tr>
<tr>
<td>--------</td>
<td>------------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>Repeat steps 6(A) and 6(B) to set the digit to the right of the decimal point (00.0 to 00.9).</td>
<td>Letter “b” is displayed, and number right of decimal point, “ml” and bolus icon flash.</td>
<td>Bolus volume is established.</td>
</tr>
</tbody>
</table>

**NOTE:** The limits for the bolus volume are 0.0 to 50.0 ml. The maximum bolus available may be dependent on the dose volume and/or interval chosen.

7 Set lockout time:
(A) Press the RUN/PAUSE button to increase the lockout time or press the BOLUS button to decrease the lockout time.

(B) When the desired lockout time appears in the display, press and hold either the RUN/PAUSE button or the BOLUS button until one beep is heard to accept the setting.

Repeat steps 7(A) and 7(B) to set the digits in the minutes section.

NOTE: The maximum and minimum limits for the lockout time are dependent upon the dose volume, dose interval time and/or the bolus volume programmed.

8 **STEP 8 APPLIES ONLY TO THE KIDS • PIB PUMP:**

If programming the PIB*PCA, PIB-IL or Australian pump, skip Step 8 and proceed to Step 9.

Activate/Deactivate bolus button:
(A) Press and release either the RUN/PAUSE button or the BOLUS button to toggle between “boff” (bolus button off) and “bon” (bolus button on).

“boff” or “bon” will blink until selected.

NOTE: Lockout time is displayed in hours and minutes.

NOTE: If bolus volume is set to “0” this step will be skipped.

“hr:min” is displayed, and bolus, lock, and clock icons, as well as numbers in the minutes section, flash.

Lockout time is established.
### Section 3 • Programming Instructions

<table>
<thead>
<tr>
<th>ACTION</th>
<th>AUDIBLE INDICATOR</th>
<th>VISUAL INDICATOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>(B) Press and holder either the RUN/PAUSE button or the BOLUS button to select either “boff” or “bon.”</td>
<td></td>
<td>“boff” or “bon” will stop blinking for 2-3 seconds before moving to next step.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Active or deactive status is selected.</td>
</tr>
<tr>
<td>9</td>
<td>Set volume to be infused:</td>
<td></td>
</tr>
<tr>
<td>(A) Press the RUN/PAUSE button to increase the number or press the BOLUS button to decrease the number.</td>
<td>One beep</td>
<td>“ml” is displayed, and bag icon and first digit to the left flash.</td>
</tr>
<tr>
<td>(B) When the desired number appears in the display, press and hold either the RUN/PAUSE button or the BOLUS button until one beep is heard to accept the setting.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Repeat steps 9(A) and 79B) to set the digits in the tens and ones sections.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NOTE: Bag volume limits are 1 to 1,000 ml.</td>
<td></td>
<td>“ml” is displayed. Bag icon and respective digit flashes. Volume to be infused is established.</td>
</tr>
<tr>
<td>Pump returns to pause mode.</td>
<td>One beep followed by two beeps</td>
<td>Pause icon flashes.</td>
</tr>
<tr>
<td>NOTE: To confirm program settings, access “RX” by pressing and releasing the BOLUS button. After scrolling through the programmed settings, the pump will automatically return to pause mode.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
3.3 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 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.
### 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. 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 will review the program settings (“RX”) when either the RUN/PAUSE button or the BOLUS button is pressed. After this review, the pump will return to pause mode.

Press and release the RUN/PAUSE button again to start the infusion.

The green run light (inside the BOLUS button) will start to blink, the “ml” icon and the volume infused will appear in the pump display. Please refer to Sections 4.1.1, 4.1.2, and 4.1.3 for instructions on receiving infusions for different modes.

#### 4.1.1 PCA Mode Start Infusion

The bolus can be delivered immediately by pushing the BOLUS button after placing the pump in run mode after changing the setting or clearing the history. The lockout time is from the end of a bolus to the start of the next bolus.

For the Australian PIB-PCA, a bolus can only be delivered in the first 60 seconds if the infusion history is cleared.

#### 4.1.2 PIb Mode Start Infusion

The first PIb dose is delivered after the dose interval with the following exception:
If the BOLUS button is pushed within 60 seconds of placing the pump in run mode after changing the settings or clearing the history, the dose is delivered immediately instead of waiting for the dose interval to elapse.

**For the Australian PIB-PCA, a dose can only be delivered in the first 60 seconds if the infusion history is cleared.**

### 4.1.3 P+P Mode Start Infusion

The first dose is delivered after the dose interval and the first bolus is not available until after a lockout time has expired (see Section 1.4.1 for flow patterns), with the following exception:

If the BOLUS button is pushed within 60 seconds of placing the pump in run mode after changing the settings or clearing the history, the dose is delivered immediately instead of waiting the length of the dose interval, if a dose has been programmed. If there is no dose programmed, the first bolus can be requested after the lockout time has elapsed.

**For the Australian PIB-PCA, a dose can only be delivered in the first 60 seconds if the history is cleared.**

### 4.2 Pause Infusion

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

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

To silence an alarm, press and release the RUN/PAUSE button. When the alarm has been silenced, the pump will remain in pause mode. Once the cause of the alarm has been corrected, resume the infusion (see Section 4.3).

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.

4.5 Bolus Activation

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

NOTE: The bolus activation function is only available in PCA and P+P modes.

NOTE: If the bolus volume is set to 0.0 ml, no bolus will be delivered when the BOLUS button is pressed.

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.

NOTE: When using the KIDS-PIB pump, the BOLUS button on the pump may be activated to allow a bolus administration directly from the BOLUS button or deactivated to require the use of a remote BOLUS switch to administer a bolus.
### 4.6 Summary of Operating Controls

<table>
<thead>
<tr>
<th>ACTION</th>
<th>STEPS TO TAKE</th>
<th>AUDIBLE INDICATOR</th>
<th>VISUAL INDICATOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Review and verify program settings</td>
<td>While the pump is in pause mode, press and immediately release the BOLUS button</td>
<td>One beep</td>
<td>“RX” - display cycles through each programmed parameter</td>
</tr>
<tr>
<td>Start infusion</td>
<td>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.</td>
<td>One beep</td>
<td>Green run light (inside the BOLUS button) blinks, the “ml” icon and volume infused is in the pump display.</td>
</tr>
</tbody>
</table>

**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 beeps (every four 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.</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 (PCA and P+P modes only)</td>
<td>Press and release the BOLUS button.</td>
<td>One 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. When using the KIDS® PIB pump, the BOLUS button on the pump may be activated to allow a bolus administration directly from the BOLUS button or deactivated to require the use of a remote BOLUS switch to administer a bolus.

<table>
<thead>
<tr>
<th>ACTION</th>
<th>STEPS TO TAKE</th>
<th>AUDIBLE INDICATOR</th>
<th>VISUAL INDICATOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deliver dose at the start of an infusion after changing settings or clearing history (PIb and P+P modes only)</td>
<td>Press and release the BOLUS button within 60 seconds of starting the infusion.</td>
<td>One beep</td>
<td>Green run light (inside the BOLUS button) blinks, and “ml” (volume infused) is in the pump display.</td>
</tr>
</tbody>
</table>

**NOTE:** For the Australian PIB®PCA, a bolus or dose can only be delivered in the first 60 seconds if the history is cleared.
SECTION 5 - INFUSION HISTORY REPORTS

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 button for two seconds until one beep is heard and “HX” is displayed.

NOTE: All history will be retained in every mode. When viewing the infusion history, only the current mode’s history will be viewed, along with the total volume infused, and the total elapsed time since the last time the pump was cleared; e.g., if the pump is in PCA mode, no dose information will be seen. To view specific history parameters for any mode, the pump must be in that mode.

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

5.1.1 PCA Mode Infusion History

<table>
<thead>
<tr>
<th>INFUSION HISTORY</th>
<th>VISUAL INDICATOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current delivery mode</td>
<td>PCA</td>
</tr>
<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 **After 100 hours, pump will only display hours (not minutes), e.g., 100H</td>
</tr>
</tbody>
</table>
5.1.2 PIb Mode Infusion History

<table>
<thead>
<tr>
<th>INFUSION HISTORY</th>
<th>VISUAL INDICATOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current delivery mode</td>
<td>PIb</td>
</tr>
<tr>
<td>Total volume infused in ml</td>
<td>“ml” icon</td>
</tr>
<tr>
<td>Total number of doses delivered</td>
<td>No. icon</td>
</tr>
<tr>
<td>Elapsed time (time pump has been in run mode since</td>
<td></td>
</tr>
<tr>
<td>history was cleared)</td>
<td>⌛ and “hr:min”</td>
</tr>
<tr>
<td></td>
<td>** icons</td>
</tr>
<tr>
<td></td>
<td>** After 100 hrs, pump will only display hours (not</td>
</tr>
<tr>
<td></td>
<td>minutes), e.g., 100H</td>
</tr>
</tbody>
</table>

5.1.3 P+P Mode Infusion History

<table>
<thead>
<tr>
<th>INFUSION HISTORY</th>
<th>VISUAL INDICATOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current delivery mode</td>
<td>P+P</td>
</tr>
<tr>
<td>Total volume infused, including boluses, in ml</td>
<td>“ml” icon</td>
</tr>
<tr>
<td>Total number of doses delivered</td>
<td>No. 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</td>
<td></td>
</tr>
<tr>
<td>history was cleared)</td>
<td>⌛ and “hr:min”</td>
</tr>
<tr>
<td></td>
<td>** icons</td>
</tr>
<tr>
<td></td>
<td>** After 100 hrs, pump will only display hours (not</td>
</tr>
<tr>
<td></td>
<td>minutes), e.g., 100H</td>
</tr>
</tbody>
</table>

The displayed parameters indicate the history since the last time the pump history was cleared, as explained in Section 5.2.
5.2 Clearing Pump Infusion History.

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

**NOTE:** The infusion history must be cleared between patients or when the reservoir bag has been changed.

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

**NOTE:** When attempting to clear the pump infusion history, “LOC” will appear in the pump display if the pump program is in lockout mode (see Section 6 – “Patient Lockout”).

**NOTE:** The BOLUS button on the pump must be used to clear the infusion history (the remote BOLUS switch cannot be used).

To clear the pump infusion history:

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

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

**Step #3**
When “HX” is displayed, release the BOLUS button and immediately press and hold the BOLUS 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:** The steps required for entering the pump’s program mode should not be revealed to the patient. This prevents unauthorized tampering with the infusion parameters, and prevents the infusion history from being cleared.

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**

Enter program mode by pressing and holding both the RUN/PAUSE button and the BOLUS button for two seconds until one beep is heard and “PRO” appears in the pump display.

**Step #3**

Release both buttons and immediately press and release both the RUN/PAUSE button and the BOLUS button again. Four 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 space of the display, starting from the right. The steps are outlined below:

**Step #1**

The first digit space is flashing.

**Step #2**

Press the RUN/PAUSE button to increase the number or press the BOLUS button to decrease the number.

**Step #3**

When the desired number appears in the display, press and hold either the RUN/PAUSE button or the BOLUS button for two seconds until one 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 the RUN/PAUSE button and the BOLUS button for two seconds until one 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 3.3.)

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 space of the display, starting from the right.

Step #1
The first digit space is flashing.

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

Step #3
When the desired number appears in the display, press and hold either the RUN/PAUSE button or the BOLUS 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 the RUN/PAUSE button and the BOLUS button 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.
### 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="image1.png" alt="Icon" /></td>
<td>Green run light (inside the BOLUS 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="image2.png" 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 run mode.</td>
</tr>
<tr>
<td>Low</td>
<td>Infusion paused</td>
<td><img src="image3.png" 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="image4.png" 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. 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="image5.png" 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. 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="image6.png" alt="Icon" /></td>
<td>Alarm icon and “MA” are in the display</td>
<td>Constant tone</td>
<td>Press the RUN/PAUSE button to silence the alarm. Gently press on top of the cassette to ensure proper placement. Resume infusion.</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>Release the BOLUS button</td>
</tr>
</tbody>
</table>
### 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>High</td>
<td>Infusion complete</td>
<td><img src="image" 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 “infusion complete” alarm will sound every four minutes in pause or run mode. \nNOTE: In the Australian PIB-PCA, while the pump is in run mode, the alarm will occur every eight (8) seconds.</td>
</tr>
<tr>
<td>High</td>
<td>Occlusion alarm “OCL”</td>
<td><img src="image" alt="Icon" /></td>
<td>“OCL” and alarm icon are in the display</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. If unable to resolve (silence) the alarm, contact Summit Medical Products, Inc.</td>
</tr>
<tr>
<td>High</td>
<td>Malfunction</td>
<td><img src="image" alt="Icon" /></td>
<td>Alarm icon and “MA” are in the display</td>
<td>Constant tone</td>
<td>Immediately close the tubing clamp. See Section 8 - “Troubleshooting”</td>
</tr>
<tr>
<td>High</td>
<td>Malfunction</td>
<td><img src="image" alt="Icon" /></td>
<td>Alarm icon and “MA1” are in the display</td>
<td>Constant tone</td>
<td>Press the RUN/PAUSE button to silence the alarm. Gently press on top of the cassette to ensure proper placement. Resume infusion.</td>
</tr>
<tr>
<td>High</td>
<td>Malfunction</td>
<td><img src="image" alt="Icon" /></td>
<td>Alarm icon and “EE1,” “EE2,” “EE3,” “EE4,” “EE5,” “EE6” or “EE7” are in the display</td>
<td>Ten short beeps</td>
<td>Immediately close the tubing clamp and turn off the pump. Contact Summit Medical Products, Inc. by calling the toll-free number on the pump.</td>
</tr>
<tr>
<td>High</td>
<td>Malfunction</td>
<td><img src="image" alt="Icon" /></td>
<td>Alarm icon and “CPU,” “RA” or “RO” are in the display</td>
<td>Constant tone</td>
<td>Immediately close the tubing clamp and turn off the pump. Contact Summit Medical Products, Inc. by calling the toll-free number on the pump.</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 8 |
**SECTION 9 - SPECIFICATIONS**

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stroke volume bolus</td>
<td>50 microliters</td>
</tr>
<tr>
<td><strong>Bolus/dose delivery rate</strong></td>
<td>210 ml/hr</td>
</tr>
<tr>
<td>Volumetric accuracy</td>
<td>+/- 6%</td>
</tr>
<tr>
<td>Interval limit (IL)</td>
<td>0 to 50 ml in 1 ml steps</td>
</tr>
<tr>
<td>Basal flow rates</td>
<td>0 to 20 ml/hr in 0.1 ml/hr steps</td>
</tr>
<tr>
<td>Dose volumes</td>
<td>0 to 50 ml in 0.1 ml steps</td>
</tr>
<tr>
<td>Dose interval times (hh:mm)</td>
<td>00:01 to 24:00 in one minute increments</td>
</tr>
<tr>
<td>Bolus volumes</td>
<td>0 to 50 ml in 0.1 ml steps</td>
</tr>
<tr>
<td>Lockout times (hh:mm)</td>
<td>00:01 to 24:00 in one minute increments</td>
</tr>
<tr>
<td>Volumes to be infused (ml)</td>
<td>1 to 1000</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)</td>
</tr>
<tr>
<td></td>
<td>4.7 ounces (133.2 grams) without batteries</td>
</tr>
<tr>
<td></td>
<td>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>
</tbody>
</table>

**Display, audible alarms, signals and reports**
- Run indicator light
- Bolus infusing
- Pause indicator
- Occlusion downstream (25 +/- 12 psi)
- Cassette not mounted on pump
- Low battery
- Dead battery
- Malfunction
- Boluses requested
- Infusion complete
<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<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>Doses delivered</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>PIb+PCA</td>
</tr>
<tr>
<td></td>
<td>PCA</td>
</tr>
<tr>
<td></td>
<td>PIb</td>
</tr>
<tr>
<td>Estimated life span of pump</td>
<td>Approximately 2 years with an infusion rate of one liter per month.</td>
</tr>
</tbody>
</table>

** Rate varies. See Section 1.4.1 for how the rate varies.

This device is restricted to sale by or on the order of a physician.
SECTION 10 - DELIVERY RATE ACCURACY

The ambIT® PIB pumps are pseudo-continuous, positive displacement pumps. 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 revolution.
2. The time between each revolution.
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/dose volumes by testing 0.1 ml, 25 ml, and 50 ml boluses/doses.

The cassettes and pumps were set up as described in the clinician 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. Catheters 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.

---

22 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.
23 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/dose volumes.
24 B.Braun Perifix® epidural catheters 20-gauge were used. Perifix® is a trademark of B.Braun.
25 20-gauge EFD ultra dispensing tips.
It is important to note that for the ambIT® PIB pumps, 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 and bolus/dose amounts 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® PIB-PCA pump met the volumetric accuracy specifications for flow rate and bolus volumes as shown in the table found at Section 10.1. Thirty (30) data points were used for each average value found in Section 10.1 below.

### 10.1 Data from Volumetric Accuracy Testing

<table>
<thead>
<tr>
<th>Bolus/Dose</th>
<th>Flow Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 ml</td>
<td>20 ml/hr</td>
</tr>
<tr>
<td>25 ml</td>
<td>10 ml/hr</td>
</tr>
<tr>
<td>0.1 ml</td>
<td>0.1 ml/hr</td>
</tr>
<tr>
<td>Average</td>
<td>2%</td>
</tr>
<tr>
<td>Standard deviation</td>
<td>2.4%</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® PIB pumps 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>Changes</td>
<td>Effect</td>
<td>Comments</td>
</tr>
<tr>
<td>---------------------------------</td>
<td>-----------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Adding microbore tubing to the</td>
<td>Volume</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</td>
</tr>
<tr>
<td>inlet or outlet side of the</td>
<td>infused</td>
<td>side of the pump. See comment about using a smaller catheter.</td>
</tr>
<tr>
<td>cassette</td>
<td>decreases</td>
<td></td>
</tr>
</tbody>
</table>

The following graphs show the pump’s delivery accuracy for dose, bolus and basal flow rate infusions. The dose and bolus accuracy is shown at different volumes over a number of sequential bolus/dose 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® PIB pumps use a rotary peristaltic mechanism to deliver fluid. Each rotation of the peristaltic mechanism delivers 0.050 ml (50 μl) of fluid. During bolus/dose delivery, the pump delivers a prescribed volume at a flow rate of 210 ml/hr accuracy. The accuracy is shown as the percent error for the actual vs. prescribed bolus/dose volume. This error is measured sequentially over a number of bolus/dose events at a minimum bolus/dose volume (0.1 ml) and a bolus/dose 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
Supply container below pump 20 ml/hr

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

#### 25  0.1 ml bolus/dose volumes

![Graph of 0.1 ml bolus/dose volumes showing % error against Bolus number.](image)

#### 25  20 ml bolus/dose volumes

![Graph of 20 ml bolus/dose volumes showing % error against Bolus number.](image)
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:

- Gap on sides of pump.
- Gap between cap and pump.
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. 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 below. 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>
<th>Quasi-peak (limit)</th>
<th>Actual value (pass/fail)</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 to 230</td>
<td>30</td>
<td>30</td>
<td>23.85 (pass)</td>
</tr>
<tr>
<td>230 to 1000</td>
<td>37</td>
<td></td>
<td>29.31 (pass)</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 Vinciäan 1
1930 Zaventem, Belgium
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Finding better ways to care for people™

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