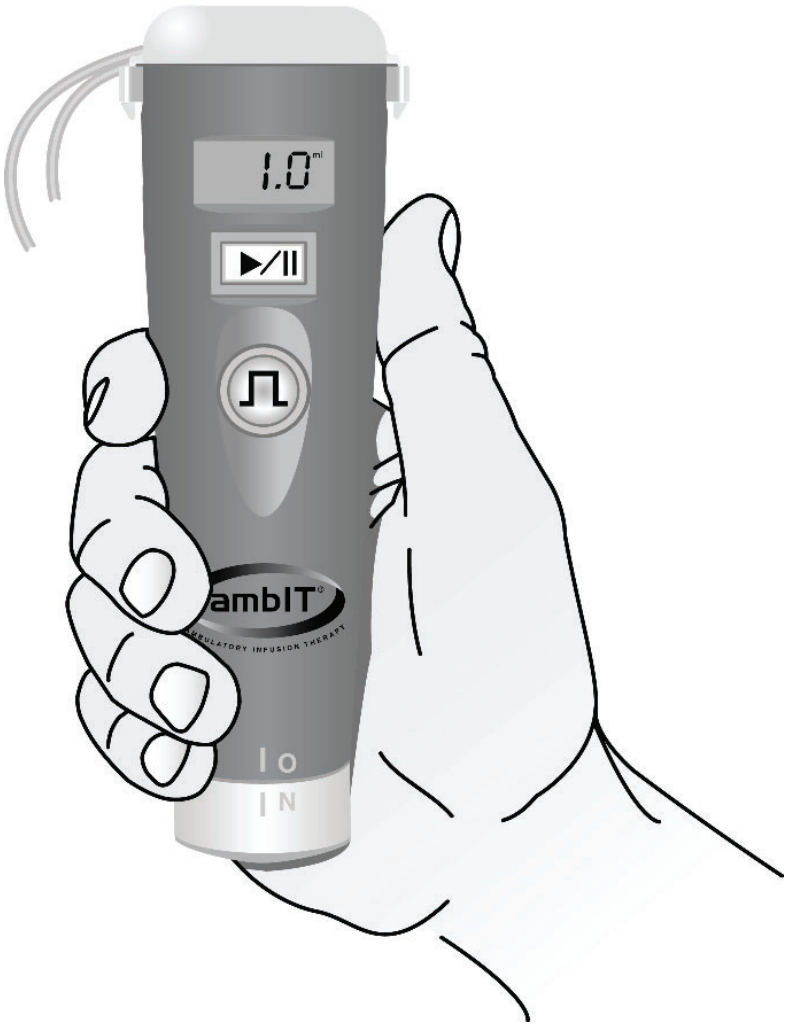
ambIT® PIB · PCA v1.5 Pump

C L I N I C I A N M A N U A L



ambIT®
AMBULATORY INFUSION THERAPY

MORE THAN PAIN RELIEF...
SUPERIOR PAIN CONTROL

TYPE BF

IP22

Summit Medical Products

Become familiar with the ambIT® pump

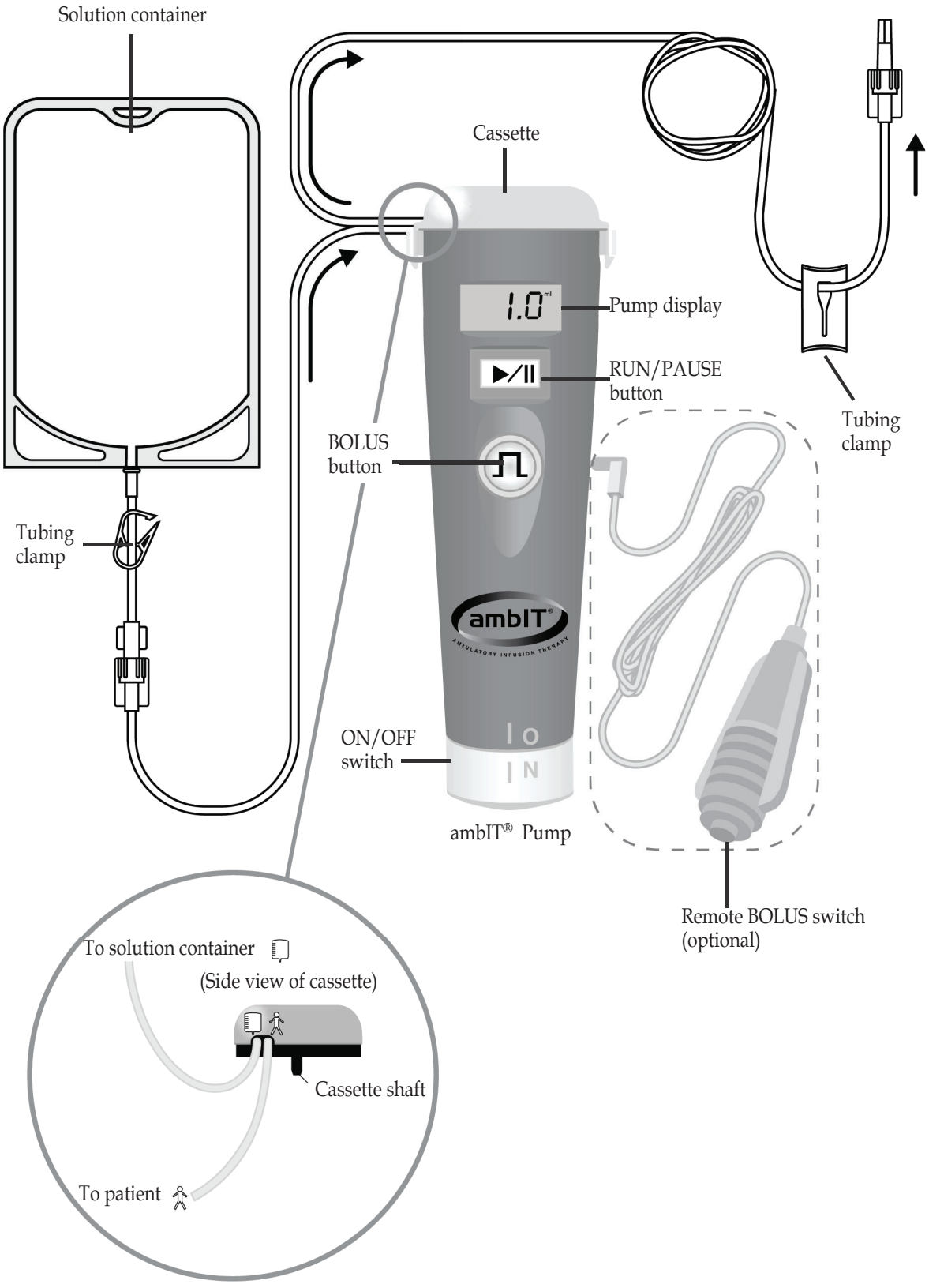


Table of Contents

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.[1] 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 · PCA v1.5 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.

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[2] 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).

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.

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

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.

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).[3] Within this manual, when referring to the pump itself, "PIB · PCA v1.5" 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

Consult instructions for use.

International symbol meaning "Attention, consult accompanying documents."

IEC symbol for "Type BF Applied Part." (IEC Classification: Internally powered.)

The ambIT® pump complies with ES 60601-1:2012, 1st Edition, including Amend. 1; CSA C22.2 NO. 60601-1:2014, 3rd Edition; IEC 60601-1:2005, including Corr. 2:2007 and Amend. 1:2012; IEC 60601-1-6:2013, Edition 3.1; IEC 60601-1-8:2012, Edition 2.1; IEC 60601-1-11:2015; 60601-2-24:2012, Edition 2; IEC 62304:2006, 1st Edition; IEC 62366:2007, 1st Edition, and Amend. 1:2014; IEC 60601-1-2:2014, 4th Edition, 2014-02.

IP22

Protected against insertion of fingers and will not be damaged or become unsafe during a specified test in which it is exposed to vertically or nearly vertically dripping water.

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.

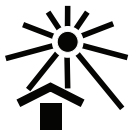
Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.

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)



Keep away from heat

Keep dry

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

Temperature limitation

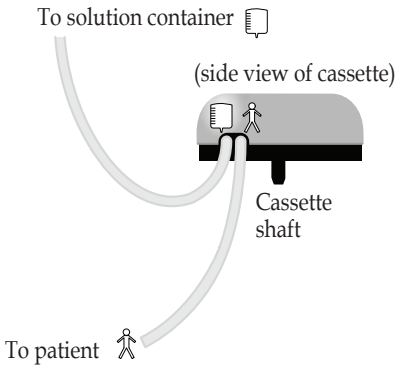
Sterilized using irradiation

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

Bolus volume in milliliters

ml

Volume in milliliters

ml/hr

Basal infusion rate in ml/hr

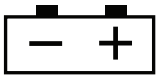
Number of boluses delivered

Number of bolus requests

Volume to be infused

RUN/PAUSE button

BOLUS button



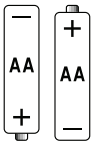
Low/dead battery indicator

Alarm indicator

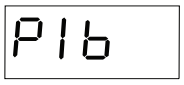
ambIT® pump display

Pump power on

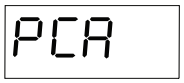
Pump power off



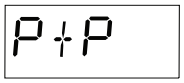
Battery orientation



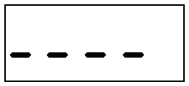
PIb mode



PCA mode



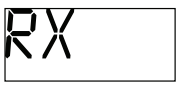
P+P mode



Program lockout code

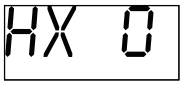
Program lockout mode

Pump program mode



Review pump program

Infusion history report



Pump infusion history cleared

1.2 Warnings

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

Read instructions before use. The pump must be used strictly in accordance with these instructions.

Safe use of this pump is the primary responsibility of the user. The user is responsible for monitoring this pump. Contact clinical/technical support if pump appears to be operating incorrectly.

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

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

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

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

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

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

Never attempt to open the pump case. Only the battery cover may be removed when changing batteries. If the pump is dropped, it must be replaced with a new pump.

This pump is not to be used for infusion of blood or blood products.

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

Failure to follow manufacturer's instructions while replacing batteries may result in loss of program settings and report data. Dispose of batteries properly after use.

Contact the local authorities to determine the proper method of disposal of potentially biohazardous parts and accessories.

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

Safety hazards with the ambIT® pump, including under-infusion, may be associated with external radio frequency (RF) interference or electromagnetic radiation. Typical equipment that may generate such radiation includes x-ray machines, magnetic resonance imaging (MRI) equipment, and any other non-shielded electrical equipment.

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

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

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

No modification of this equipment is allowed.

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

The pump should not be disassembled by any user. If equipment is tampered with to the point it is ineffective, consult the prescribing physician.

Keep out of reach of animals or children.

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

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

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

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 · PCA v1.5 pump 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 · PCA v1.5 Pump in MRI Environment

Safety in MRI not evaluated. The ambIT® PIB · PCA v1.5 pump has 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 · PCA v1.5 pump 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 · PCA v1.5 pump is 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 · PCA v1.5 pump is not intended to supersede, augment, or replace any other medical device or drug indications for use or intended uses.

The ambIT® PIB · PCA v1.5 pump is 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 · PCA v1.5 pump is 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 · PCA v1.5 pump. 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 · PCA v1.5 pump is a unique pump. There are three different modes of operation. The first mode is PCA. The second mode is PIb[4]. 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 rate[5], (2) bolus volume[6], (3) lockout time[7], and (4) volume to be infused[8].

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.

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.

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 volume[9], (2) dose interval[10], (3) bolus volume[11], (4) lockout time, and (5) volume to be infused.

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 · PCA v1.5 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.

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).

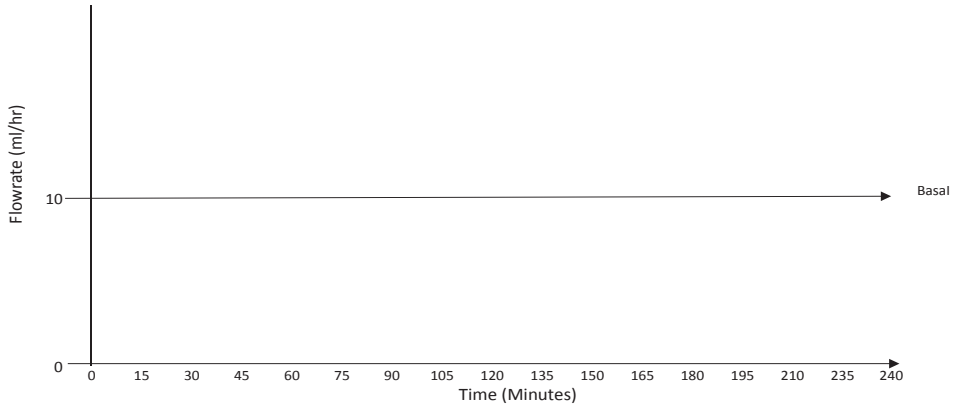


Figure 1-1

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.

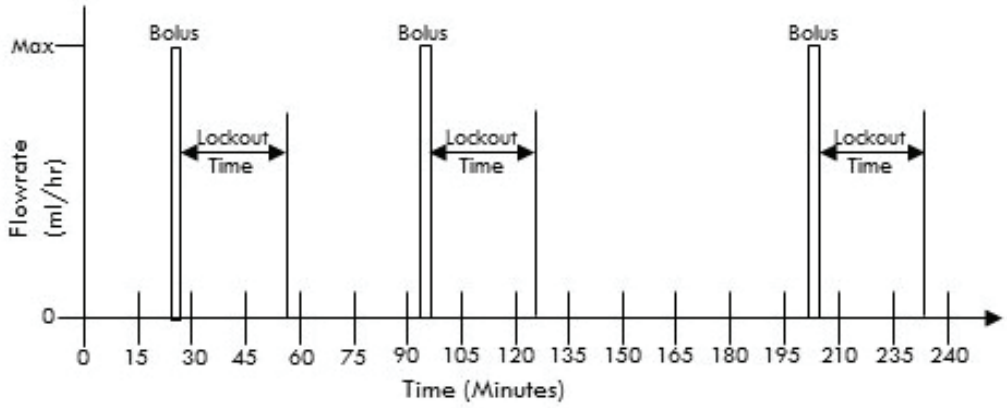


Figure 1-2
Bolus only (PCA mode) infusion pattern

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.

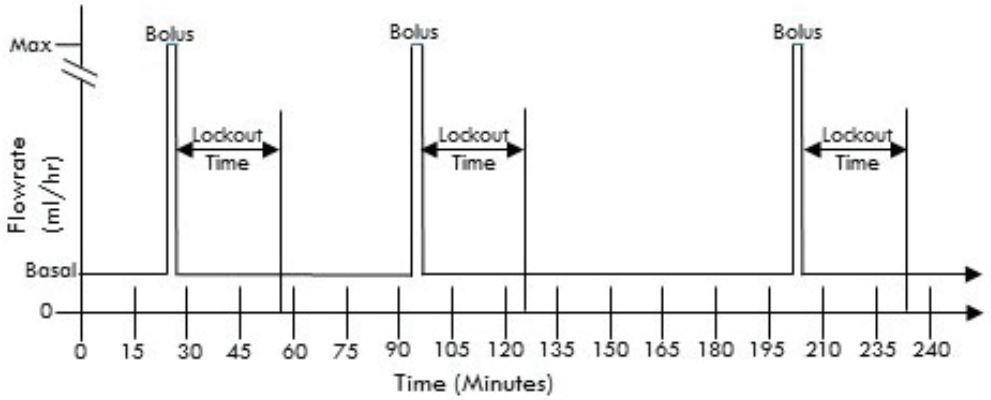


Figure 1-3

Basal flow rate and bolus (PCA mode) infusion pattern

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.

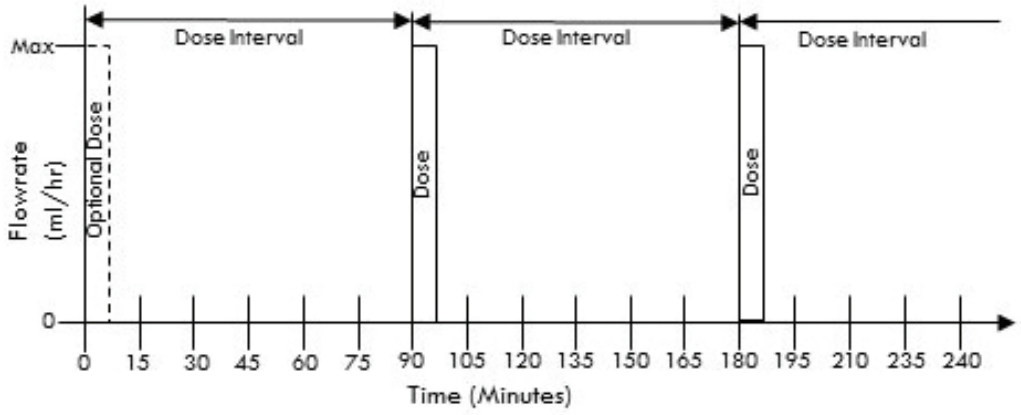


Figure 1-4

Dose only (PIb mode) infusion pattern

The settings for Figure 1-4 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.

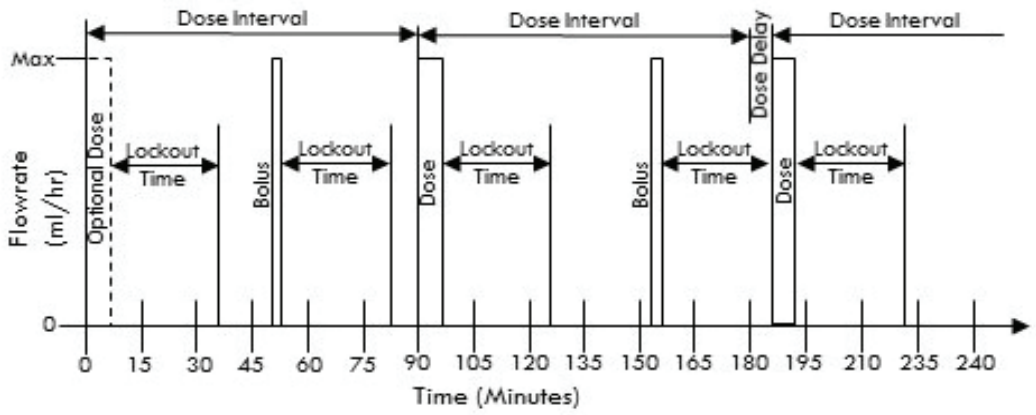


Figure 1-5

Dose and bolus (P+P mode) infusion pattern

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[12]. 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.

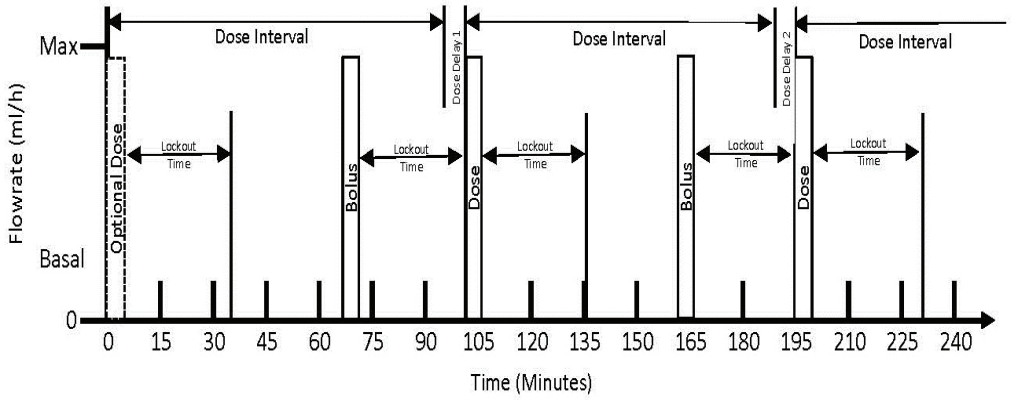


Figure 1-6

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

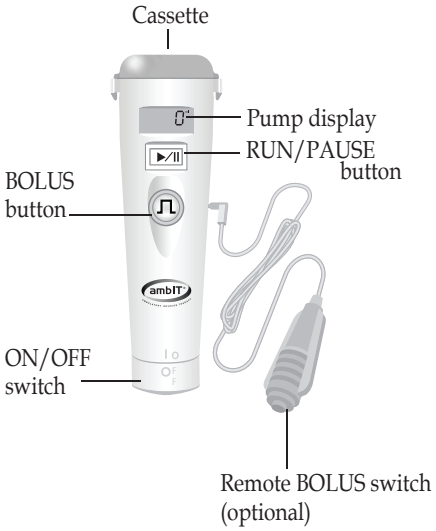
Each time a dose is delayed, it is added to the previous delays. In Figure 1-6, the second dose is delayed by about 10 minutes (first dose delay), from 90 minutes to 100 minutes. This means

12 The purpose of the lockout time is two-fold: (1) to allow the medication to work before the patient can receive additional medication and (2) to space out doses and boluses to prevent the patient receiving a harmful amount of medication.

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.

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.

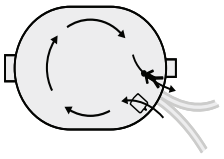
The pump program is determined by selecting the desired parameters during the program mode. Pressing and holding the pump's RUN/PAUSE button and BOLUS button simultaneously for two seconds allows the user to access the program mode. This specific combination of pressing buttons is designed to prevent 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 (ll) appears in the pump display and two beeps sound every four minutes, indicating that the pump infusion has been temporarily stopped.

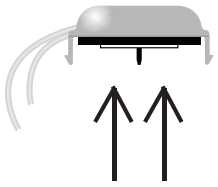
When the BOLUS button is pressed during run mode, the pump will deliver the programmed bolus. During bolus delivery, the green run light (inside the BOLUS button) will double blink.

1.4.3 ambIT® Cassette

Top view of cassette



Cassette bottom disc



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 upper figure to the 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 lower figure to the 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.

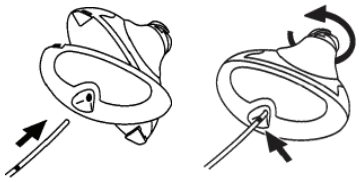
NOTE: Once the cassette bottom is snapped into place (see Section 2), the rollers engage and compress the tubing, preventing fluid from flowing unless the pump is rotating and moving the fluid. If a downstream occlusion occurs, the pump will alarm and notify the user.

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.

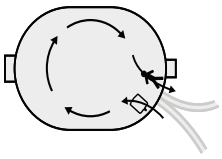
WARNING: It is recommended that an air elimination filter be used for IV applications to protect them from air embolisms. The ambIT® cassette can be ordered with or without an integrated air elimination filter.

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.

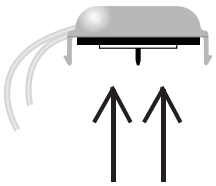
NOTE: If an ambIT® cassette already has a filter, it is not recommended to use a separate air elimination filter. Using a second filter may cause the pressure to exceed the activation pressure for the pressure switch, causing an occlusion alarm ("OCL" in display and a constant beep delayed for 3 minutes).

2.2 ambIT® Cassette

Top view of cassette



Cassette bottom disc



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 upper figure to the 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 lower figure to the 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 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.

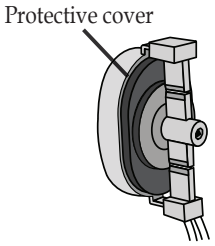
WARNING: The cassette must be primed before use by removing all air from the solution container and tubing.

WARNING: Do not connect the cassette to the patient until the cassette has been primed, the cassette has been connected to the pump, and the pump has been programmed to the desired therapy and checked per hospital protocol.

CAUTION: Verify that all connections are secure, all clamps are opened, and that there are no leaks in the fluid path before starting therapy.

If the filled solution container is not going to be used immediately, clamp the tubing and cap the connector with the protective cap provided to prevent contamination.

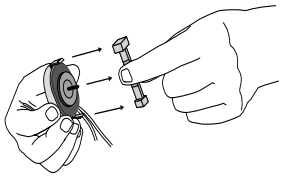
Always verify that the cassette bottom disc is snapped closed before attaching the cassette to the pump.



To prime the cassette, follow these steps:

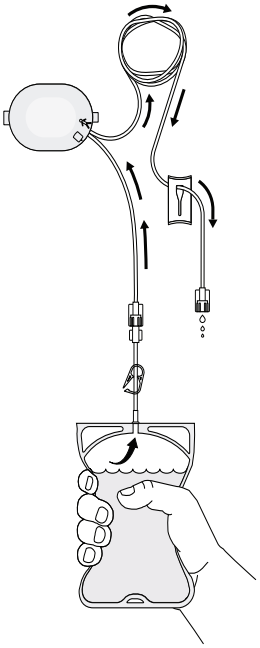
Step #1

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

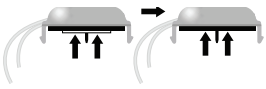
Release all clamps on the tubing.

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.

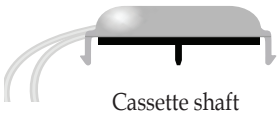


Step #6

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.

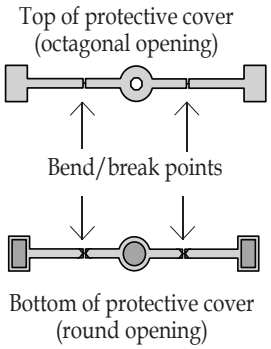
NOTE: If the cassette bottom disc is snapped closed before the priming process is complete, place the cassette onto the pump (not attached to the patient) and use the BOLUS button to complete the priming of the cassette.



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).

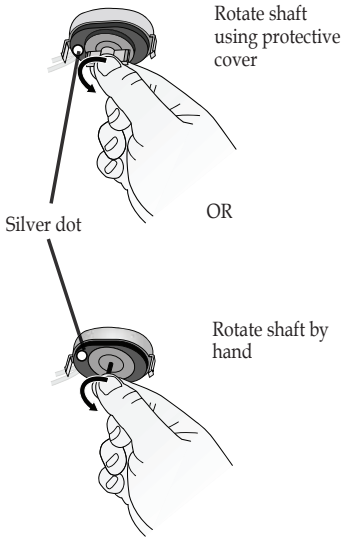


Step #6b

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.

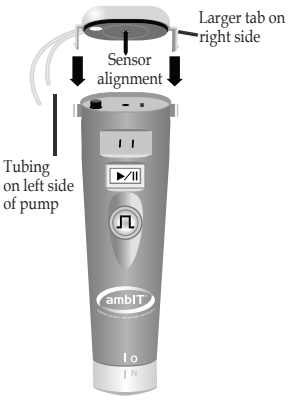
NOTE: The cassette shaft can also be rotated by hand.

NOTE: Most "MA1" and "CASS" 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).

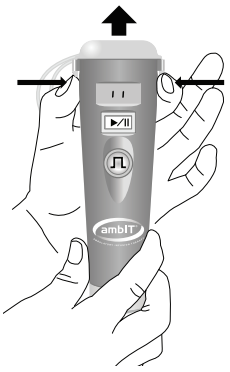


ambIT® pump

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.

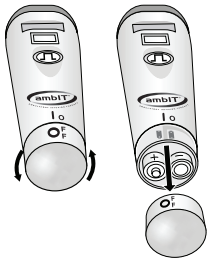
CAUTION: Summit Medical Products, Inc. has not validated all types of batteries (non-alkaline, rechargeable, specific brands, previously-used, etc.); therefore, we cannot ensure that any specific battery will power the pump for a specific period of time. The battery condition and pump settings will determine 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:

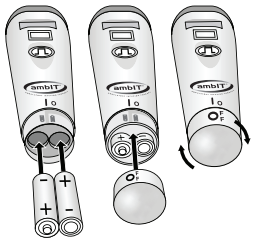


Remove battery cover

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.



Insert batteries and replace cover

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.

2.7.2 Battery Replacement

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

To replace batteries:

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

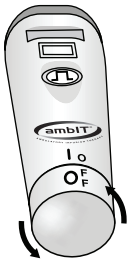
NOTE: After the power-on self-test, the pump will beep twice and go into pause mode. The clinician can then program the pump or resume current infusion settings.

Power ON

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).



Power OFF counter-clockwise

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® PIB · PCA v1.5 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 to increase the value displayed by pressing and immediately releasing the button. The BOLUS button serves to decrease the value displayed by pressing and immediately releasing the button. No beep will be heard in either function.

Pressing the RUN/PAUSE button and holding for two seconds until a beep is heard accepts the parameter entered and continues to the next step in programming.

Pressing the BOLUS button and holding for two seconds until a beep is heard moves the display backward in order to review or make correction during programming. The pump display will move to the previous screen without changing parameters. The BOLUS button can be used in this manner until returning to the initial display screen, at which time it will not function to move backwards.

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 · PCA v1.5 pump pumps:

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

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 a s patient controlled epidural analgesia (PCEA).
14 Also referred to as a continuous infusion.
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 -- PIb, 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.

Changes to previous programming screens may be made during programming by pressing the BOLUS button for two seconds until a beep is heard. The immediately previous screen will be displayed. This may be repeated until the initial screen is reached.

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 PIb 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.[16] 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 · PCA v1.5 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 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 the RUN/ PAUSE button until a beep is heard 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.

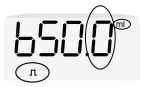
See Section 1.4.1 for an explanation of the patterns of flow available in PCA mode; specifically, bolus-only, basal-only, and bolus with basal flow rates (Figures 1-1 through 1-3).

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

NOTE: If at any point during programming the user needs to move backward in the display, refer to instructions found at 3.2.1.3.

	ACTION	AUDIBLE INDICATOR	VISUAL INDICATOR	
1	Enter program mode: From pause mode, press and hold both the RUN/PAUSE button and the BOLUS button until one beep is heard.	One beep	"PRO" is displayed for two seconds to indicate that the pump is in program mode.	
2	Select PCA: Press and release the RUN/PAUSE button to scroll up or press and release the BOLUS button to scroll down through the program modes until "PCA" appears in the display. Press and hold the RUN/PAUSE button until one beep is heard to accept the setting.	One beep	"PCA" flashes in the display. Mode is established.	
3	Set basal flow rate: (A) Press and release the RUN/PAUSE button to increase the number or press and release the BOLUS button to decrease the number.	One beep	Number left of decimal point and "ml/hr" flash.	
	(B) When the desired number appears in the display, press and hold the RUN/PAUSE button until one beep is heard to accept the setting.		NOTE: Basal flow rate is displayed in ml/hr.	
	(C) Repeat the steps 3(A) and 3(B) to set the digit to the right of the decimal point.		The number to the right of the decimal point and "ml/hr" flash. Basal flow rate is established.	
	(D) If during programming, you need to move backwards in the display to a previous setting, press and hold the BOLUS button until one beep is heard.		Each time the BOLUS button is pressed, the display moves backward one screen to enable review or correction.	
	NOTE: The limits for basal flow rate are 0.0 to 20.0 ml.			

	ACTION	AUDIBLE INDICATOR	VISUAL INDICATOR	
4	Set bolus volume: (A) Press and the RUN/PAUSE button to increase the number or press and release the BOLUS button to decrease the number.		Letter "b," numbers left of decimal point, "ml" and bolus icon flash.	
	(B) When the desired number appears in the display, press and hold the RUN/PAUSE button until one beep is heard to accept the setting.	One beep	NOTE: Bolus volume is displayed in ml.	
	(C) Repeat the steps 4(A) and 4(B) to set the digit to the right of the decimal point.		Letter "b" is displayed and the number to the right of decimal point, "ml," and bolus icon flash. Bolus volume is established.	
	(D) If during programming, you need to move backwards in the display to a previous setting, press and hold the BOLUS button until one beep is heard.		Each time the BOLUS button is pressed, the display moves backward one screen to enable review or correction.	
	NOTE: The limits for bolus volume are 0.0 to 50.0 ml.			
5	Set lockout time: (A) Press and release the RUN/PAUSE button to increase the time or press and release the BOLUS button to decrease the time.		"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.	 
	(B) When the desired lockout time appears in the display, press and hold the RUN/PAUSE button until one beep is heard to accept the setting.	One beep	**NOTE**: Lockout time is displayed in hours and minutes.	
	(C) Repeat the steps 5(A) and 5(B) to set the digits in the minutes section.		"hr:min" is displayed and bolus, lock and clock icons, as well as numbers in the min section, flash. Lockout time is established.	

	ACTION	AUDIBLE INDICATOR	VISUAL INDICATOR	
	(D) If during programming, you need to move backwards in the display to a previous setting, press and hold the BOLUS button until one beep is heard.		Each time the BOLUS button is pressed, the display moves backward one screen to enable review or correction.	
	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.			
6	Set volume to be infused:			
	(A) Press and release the RUN/ PAUSE button to increase the number or press and release the BOLUS button to decrease the number.		"ml" is displayed, and the bag icon and first section flash.	
	(B) When the desired number appears in the display, press and hold the RUN/PAUSE button until one beep is heard to accept the setting.	One beep	NOTE: Volume to be infused is displayed in ml.	
	(C) Repeat the steps 6(A) and 6(B) to set the digits in the tens and ones section.		"ml" is displayed. The bag icon and respective digit flash.	
			Volume to be infused is established.	
	(D) If during programming, you need to move backwards in the display to a previous setting, press and hold the BOLUS button until one beep is heard.		Each time the BOLUS button is pressed, the display moves backward one screen to enable review or correction.	
	NOTE: Bag volume limits are 1 to 1000 ml.			
	Pump returns to pause mode.	One beep followed by two beeps	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.	

3.2.1.3 Moving Backward in Display While Programming

The user can move backward in the display. This functions as follows:

- Pushing and holding the BOLUS button held until a beep is heard causes the currently blinking value to be accepted (i.e., stored in memory) and the value to the left on the display to start to blink so that it can be changed.
- If the leftmost value is blinking and the BOLUS button is pushed and held until a beep is heard, then the value is accepted (i.e., stored in memory) and the display changes the preceding parameter. For example if the left most value of the bolus lockout time (hours) is blinking and the BOLUS button is pushed and held held until a beep is heard, the hours value is accepted and the display changes to the previous parameter (bolus volume) and the right most digit blinks (tenths digit).
- If the basal rate left most digit (tens digit: 0,1X, 2X) is blinking and the BOLUS button is held until a beep is heard, then the value is accepted and the pump shows the mode selected "PCA".
- If the mode (PCA) is blinking and the BOLUS button is held until a beep is heard, the mode is accepted and the pump displays the first parameter for that mode and the left most value is blinking.

NOTE: If the mode is blinking, then the BOLUS button functions the same as the RUN/PAUSE button.

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 · PCA v1.5 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/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 PIb mode, if the tens and/or ones digits are already set to the desired setting, press the RUN/PAUSE and the BOLUS buttons at the same time until a beep is heard 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

NOTE: If at any point during programming the user needs to move backward in the display, refer to instructions found at 3.2.2.3.

	ACTION	AUDIBLE INDICATOR	VISUAL INDICATOR	
1	Enter program mode: From pause mode, press and hold both the RUN/PAUSE button and the BOLUS button until one beep is heard.	One beep	"PRO" is displayed for 2 seconds to indicate that the pump is in program mode.	
2	Select PIb: Press and release the RUN/PAUSE button to scroll up or press and release the BOLUS button to scroll down through program modes until "PIb" appears in the display. To accept the setting, press and hold the RUN/PAUSE button until one beep is heard.	One beep	"PIb" flashes in the display. Mode is established.	
3	Set dose volume: (A) Press and release the RUN/PAUSE button to increase the number or press and release the BOLUS button to decrease the number.	One beep	The letter "d," the number left of decimal point, and the "ml" icon flash.	
	(B) When the desired number appears in the display, press and hold the RUN/PAUSE button until one beep is heard to accept the setting and move onto the next digit		NOTE: Dose volume is displayed in ml.	
	(C) Repeat steps 3(A) and 3(B) to set the digit to the right of the decimal point (00.0 to 00.9).		Letter "d" is displayed, and number right of decimal point and "ml" flash. Dose volume is established.	
	(D) If during programming, you need to move backwards in the display to a previous setting, press and hold the BOLUS button until one beep is heard.		Each time the BOLUS button is pressed, the display moves backward one screen to enable review or correction.	
	NOTE: The limits for dose volume are 0.0 to 50.0 ml.			

	ACTION	AUDIBLE INDICATOR	VISUAL INDICATOR	
4	Set dose interval time: (A) Press and release the RUN/PAUSE button to increase the dose interval time or press and release the BOLUS button to decrease the dose interval time.		"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.	
	(B) When the desired dose interval time appears in the display, press and hold the RUN/PAUSE button until one beep is heard to accept the setting and move onto the next digit.		NOTE: Dose interval time is displayed in hours and minutes (hh:mm).	
	(C) Repeat steps 4(A) and 4(B) to set the digits in the minutes section.		"hr:min"and clock icons and minutes section flash.	
			Dose interval time is established.	
	(D) If during programming, you need to move backwards in the display to a previous setting, press and hold the BOLUS button until one beep is heard.		Each time the BOLUS button is pressed, the display moves backward one screen to enable review or correction.	
	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 and release the RUN/PAUSE button to increase the number or press and release the BOLUS button to decrease the number.		"ml" is displayed, and bag icon and the hundreds digit flash. Volume to be infused is displayed in ml.	
	(B) When the desired number appears in the display, press and hold the RUN/PAUSE button until one beep is heard to accept the setting and move onto the next digit.	One beep	"ml" is displayed, and bag icon and the respective digits flash.	

	ACTION	AUDIBLE INDICATOR	VISUAL INDICATOR	
	(C) Repeat steps 5(A) and 5(B) to set the digits in the tens and ones sections. (D) If during programming, you need to move backwards in the display to a previous setting, press and hold the BOLUS button until one beep is heard.		Volume to be infused is established. Each time the BOLUS button is pressed, the display moves backward one screen to enable review or correction.	
	NOTE: Bag volume limits are 1 to 1,000 ml.			
	Pump returns to pause mode.	One beep followed by two beeps	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.			

3.2.2.3 Moving Backward in Display While Programming

The user can move backward in the display. This functions as follows:

- Pushing and holding the BOLUS button held until a beep is heard causes the currently blinking value to be accepted (i.e., stored in memory) and the value to the left on the display to start to blink so that it can be changed.
- If the leftmost value is blinking and the BOLUS button is pushed and held until a beep is heard, then the value is accepted (i.e., stored in memory) and the display changes the preceding parameter. For example if the left most value of the bolus lockout time (hours) is blinking and the BOLUS button is pushed and held held until a beep is heard, the hours value is accepted and the display changes to the previous parameter (bolus volume) and the right most digit blinks (tenths digit).
- If the basal rate left most digit (tens digit: 0,1X, 2X) is blinking and the BOLUS button is held until a beep is heard, then the value is accepted and the pump shows the mode selected "PCA".
- If the mode (PCA) is blinking and the BOLUS button is held until a beep is heard, the mode is accepted and the pump displays the first parameter for that mode and the left most value is blinking.

NOTE: If the mode is blinking, then the BOLUS button functions the same as the RUN/PAUSE button.

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

- A bolus is a volume of medication infused over a relatively short period of time.[19] 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 · PCA v1.5 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[20] 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)[21]. 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).

NOTE: When programming P+P mode, if the tens and/or ones digits are already set to the desired setting, press the RUN/PAUSE and the BOLUS buttons at the same time until a beep is heard 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.

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.

3.2.3.2 P+P Mode Programming Steps

NOTE: If at any point during programming the user needs to move backward in the display, refer to instructions found at 3.2.3.3.

	ACTION	AUDIBLE INDICATOR	VISUAL INDICATOR	
1	Enter program mode: From pause mode, press and hold both the RUN/PAUSE button and the BOLUS button until one beep is heard.	One beep	"PRO" is displayed for two seconds to indicate that the pump is in program mode	
2	Select P+P: Press and release the RUN/PAUSE button to scroll up or press and release the BOLUS button to scroll down through the program modes until "P+P" appears in the display. Press and hold the RUN/PAUSE button until one beep is heard to accept the setting	One beep	"P+P" flashes in the display. Mode is established.	
3	Set dose volume: (A) Press and release the RUN/PAUSE button to increase the number or press and release the BOLUS button to decrease the number.	One beep	Letter "d," number left of decimal point, and "ml" flash.	
	(B) When the desired number appears in the display, press and hold the RUN/PAUSE button until one beep is heard to accept the setting.		**NOTE:** Dose volume is displayed in ml.	
	(C) Repeat steps 3(A) and 3(B) to set the digit to the right of the decimal point.		Letter "d" is displayed, and number to the right of the decimal point and "ml" flash. Dose volume is established.	
	(D) If during programming, you need to move backwards in the display to a previous setting, press and hold the BOLUS button until one beep is heard.		Each time the BOLUS button is pressed, the display moves backward one screen to enable review or correction.	

	ACTION	AUDIBLE INDICATOR	VISUAL INDICATOR	
4	Set dose interval time: (A) Press and release the RUN/PAUSE button to increase the interval time or press and release the BOLUS button to decrease the dose interval time.		"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.	 
	(B) When the desired dose interval time appears in the display, press and hold the RUN/PAUSE button until one beep is heard to accept the setting.	One beep	**NOTE:** Dose interval time is displayed in hours and minutes (hh:mm).	
	(C) Repeat steps 4(A) and 4(B) to set the digits in the minutes.		"hr:min", clock icon, and numbers in the minute section flash. Dose interval time is established.	
	(D) If during programming, you need to move backwards in the display to a previous setting, press and hold the BOLUS button until one beep is heard.		Each time the BOLUS button is pressed, the display moves backward one screen to enable review or correction.	
	NOTE: If dose volume is set to "0," this step will be skipped. **NOTE:** The minimum dose interval is dependent on the dose volume set. The maximum dose interval is 24:00 (hh:mm).			
5	Set bolus volume: (A) Press and release the RUN/PAUSE button to increase the number or press and release the BOLUS button to decrease the number.		Letter "b," numbers left of decimal point, "ml" and bolus icon flash.	
	(B) When the desired number appears in the display, press and hold the RUN/PAUSE button until one beep is heard to accept the setting.	One beep	**NOTE:** Bolus volume is displayed in ml.	
	(C) Repeat steps 5(A) and 5(B) to set the digit to the right of the decimal point (00.0 to 00.9).		Letter "b" is displayed, and number right of decimal point, "ml" and bolus icon flash. Bolus volume is established.	

	ACTION	AUDIBLE INDICATOR	VISUAL INDICATOR	
	(D) If during programming, you need to move backwards in the display to a previous setting, press and hold the BOLUS button until one beep is heard.		Each time the BOLUS button is pressed, the display moves backward one screen to enable review or correction.	
	NOTE: The limits for the bolus volume are 0.0 to 50.0 ml.			
6	Set lockout time:			
	(A) Press and release the RUN/ PAUSE button to increase the lockout time or press and release the BOLUS button to decrease the lockout time.		"LOt" is displayed for two seconds to indicate that the pump is in lockout mode.	
			"hr:min" is displayed, and bolus, lock and clock icons, as well as numbers in the hour section, flash.	
	(B) When the desired lockout time appears in the display, press and hold the RUN/PAUSE button until one beep is heard to accept the setting.	One beep	**NOTE:** Lockout time is displayed in hours and minutes. **NOTE:** If bolus volume is set to "0" this step will be skipped.	
	(C) Repeat steps 6(A) and 6(B) to set the digits in the minutes section.		"hr:min" is displayed, and bolus, lock, and clock icons, as well as numbers in the minutes section, flash. Lockout time is established	
	(D) If during programming, you need to move backwards in the display to a previous setting, press and hold the BOLUS button until one beep is heard.		Each time the BOLUS button is pressed, the display moves backward one screen to enable review or correction.	
	NOTE: The maximum limit for the lockout time is dependent upon the dose volume, dose interval time and/or the bolus volume programmed.			
7	Set volume to be infused:			
	(A) Press and release the RUN/ PAUSE button to increase the number or press and release the BOLUS button to decrease the number.		"ml" is displayed, and bag icon and first digit to the left flash.	
	(B) When the desired number appears in the display, press and hold the RUN/PAUSE button or the BOLUS button until one beep is heard to accept the setting.	One beep	NOTE: Volume to be infused is displayed in ml.	

	ACTION	AUDIBLE INDICATOR	VISUAL INDICATOR	
	(C) Repeat steps 7(A) and 7(B) to set the digits in the tens and ones sections. (D) If during programming, you need to move backwards in the display to a previous setting, press and hold the BOLUS button until one beep is heard.		"ml" is displayed. Bag icon and respective digit flashes. Volume to be infused is established. Each time the BOLUS button is pressed, the display moves backward one screen to enable review or correction.	
	NOTE: Bag volume limits are 1 to 1,000 ml.			
	Pump returns to pause mode.	One beep followed by two beeps	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.			

3.2.3.3 Moving Backward in Display While Programming

The user can move backward in the display. This functions as follows:

- Pushing and holding the BOLUS button held until a beep is heard causes the currently blinking value to be accepted (i.e., stored in memory) and the value to the left on the display to start to blink so that it can be changed.
- If the leftmost value is blinking and the BOLUS button is pushed and held until a beep is heard, then the value is accepted (i.e., stored in memory) and the display changes the preceding parameter. For example if the left most value of the bolus lockout time (hours) is blinking and the BOLUS button is pushed and held held until a beep is heard, the hours value is accepted and the display changes to the previous parameter (bolus volume) and the right most digit blinks (tenths digit).
- If the basal rate left most digit (tens digit: 0,1X, 2X) is blinking and the BOLUS button is held until a beep is heard, then the value is accepted and the pump shows the mode selected "PCA".
- If the mode (PCA) is blinking and the BOLUS button is held until a beep is heard, the mode is accepted and the pump displays the first parameter for that mode and the left most value is blinking.

NOTE: If the mode is blinking, then the BOLUS button functions the same as the RUN/PAUSE button.

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.

SECTION 4 - OPERATING INSTRUCTIONS

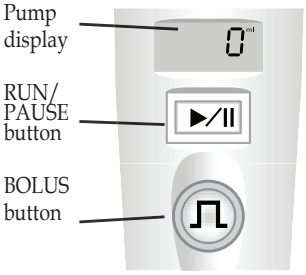
NOTE: All operating instructions are the same for the three modes of the ambIT® PIB·PCA v1.5 pump except "Start Infusion" (Section 4.1). Please read respective sections within Section 4.1 to understand how each mode starts infusion.

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

4.1 Start Infusion

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

To begin an infusion, with the pump in pause mode, press and release the RUN/PAUSE button. 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.

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.

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.

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 (❙❙) 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: In the case of an OCC alarm due to downstream pressure (occlusion alarm), the pump will display a visual alarm initially. An audible alarm is delayed for 3 minutes. If the occlusion is not remedied within 3 minutes, the audible alarm will sound. If the cause of the alarm is corrected within the 3 minute delay, the audible 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.

4.6 Summary of Operating Controls

ACTION	STEPS TO TAKE	AUDIBLE INDICATOR	VISUAL INDICATOR
Review and verify program setttings	While the pump is in pause mode, press and immediately release the BOLUS button	One beep	"RX" - display cycles through each programmed parameter
Start infusion	Program the pump, then press and release the RUN/PAUSE button. The RUN/PAUSE button will need to be pushed a second time to start the infusion after the required review has taken place.	One beep	Green run light (inside the BOLUS button) blinks, the "ml" icon and volume infused is in the pump display.
NOTE: If starting infusion after pausing it, the RUN/PAUSE button only needs to be pressed once.			
Pause infusion	Press and release the RUN/PAUSE button.	Two beeps (every four minutes)	Pause icon (II) flashes in the display; green run light (inside the BOLUS button) stops blinking.
Silence alarm	Press and release the RUN/PAUSE button.	Alarm sound stops	Pause icon (II) flashes in the display; green run light (inside the BOLUS button) stops blinking.
Deliver bolus (PCA and P+P modes only)	Press and release the BOLUS button.	One beep	Green run light (inside the BOLUS button) double blinks.
NOTE: Patient may use the BOLUS button on the pump or a remote BOLUS switch to request a bolus.			
Deliver dose at the start of an infusion after changing settings or clearing history (PIb and P+P modes only)	Press and release the BOLUS button within 60 seconds of starting the infusion.	One beep	Green run light (inside the BOLUS button) blinks, and "ml" (volume infused) is in the pump display.

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

INFUSION HISTORY	VISUAL INDICATOR
Current delivery mode	PCA
Total volume infused, including boluses, in ml	"ml" icon
Total number of boluses delivered	No. and icons
Total number of bolus requests	No. and icons
Elapsed time (time pump has been in run mode since history was cleared)	and** "hr:min" icons ** After 100 hours, pump will only display hours (not minutes), e.g., 100H

5.1.2 PIb Mode Infusion History

INFUSION HISTORY	VISUAL INDICATOR
Current delivery mode	PIb
Total volume infused in ml	"ml" icon
Total number of doses delivered	No. icon
Elapsed time (time pump has been in run mode since history was cleared)	and** "hr:min" icons ** After 100 hours, pump will only display hours (not minutes), e.g., 100H

5.1.3 P+P Mode Infusion History

INFUSION HISTORY	VISUAL INDICATOR
Current delivery mode	P+P
Total volume infused, including boluses, in ml	"ml" icon
Total number of doses delivered	No. icon
Total number of boluses delivered	No. and icons
Total number of bolus requests	No. and icons
Elapsed time (time pump has been in run mode since history was cleared)	and** "hr:min" icons ** After 100 hours, pump will only display hours (not minutes), e.g., 100H

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 and release the RUN/PAUSE button to increase the number or press and release 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

PRIORITY	STATUS	ICON	VISUAL INDICATOR	AUDIBLE INDICATOR	COMMENTS
Low	Pump is infusing normally		Green run light (inside the BOLUS button) blinks, "ml" icon and volume infused is displayed	None	Periodic movement of the cassette gears is normal.
Low	Bolus infusion	 	Green run light (inside the BOLUS button) double blinks; bolus icon is in the display	One beep	One beep will sound every time the BOLUS button is pressed during run mode.
Low	Infusion paused		Pause icon flashes in the display; green run light (inside the BOLUS button) is off	Two beeps every four minutes	
Low	Low battery		Battery icon flashes in the display	Five short beeps every four minutes	The battery icon will remain flashing in the display. Replace the batteries as soon as possible.
Low	Dead battery	 	Battery icon and alarm icon are in the display	Constant tone	Press the RUN/PAUSE button to silence the alarm. The alarm and battery icons will remain displayed. Replace the batteries immediately.
Low	Cassette not attached to pump		Alarm icon and "CASS" are in the display	Constant tone	Press the RUN/PAUSE button to silence the alarm. Gently press on top of the cassette to ensure proper placement. Resume infusion.
Low	BOLUS button	None	"REL" is in the display	Constant tone	Release the BOLUS button

PRIORITY	STATUS	ICON	VISUAL INDICATOR	AUDIBLE INDICATOR	COMMENTS
High	Infusion complete		Bag icon flashes in the display	One long tone followed by three short beeps; repeats every four minutes	The "infusion complete" alarm will sound every four minutes in pause or run mode.
High	Occlusion alarm "**OCL**"		"**OCL**" and alarm icon are in the display	Delayed 3 minutes; Constant beeping only; clears itself if source of occlusion is removed	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.
High	Malfunction		Alarm icon and "CASS" are in the display	Constant tone	Immediately close the tubing clamp. See Section 8 - "Troubleshooting"
High	Malfunction		Alarm icon and "MA1" are in the display	Constant tone	Press the RUN/PAUSE button to silence the alarm. Gently press on top of the cassette to ensure proper placement. Resume infusion.
High	Malfunction		Alarm icon and "EE1," "EE2," "EE3," "EE4," "EE5," "EE6" or "EE7" are in the display	Ten short beeps	Immediately close the tubing clamp and turn off the pump. Contact Summit Medical Products, Inc. by calling the toll-free number on the pump.
High	Malfunction		Alarm icon and "CPU," "RA" or "RO" are in the display	Constant tone	Immediately close the tubing clamp and turn off the pump. Contact Summit Medical Products, Inc. by calling the toll-free number on the pump.

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

Problem	Resolution	Reference
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 after 3 minutes 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 "MA1" or "CASS" 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 9 - SPECIFICATIONS

Specification	Details
Stroke volume bolus	50 microliters
**Bolus/dose delivery rate	210 ml/hr
Volumetric accuracy	+/- 6%
Interval limit (IL)	0 to 50 ml in 1 ml steps
Basal flow rates	0 to 20 ml/hr in 0.1 ml/hr steps
Dose volumes	0 to 50 ml in 0.1 ml steps
Dose interval times (hh:mm)	00:01 to 24:00 in one minute increments
Bolus volumes	0 to 50 ml in 0.1 ml steps
Lockout times (hh:mm)	00:01 to 24:00 in one minute increments
Volumes to be infused (ml)	1 to 1000
Pump mechanism	Microprocessor controlled rotary-peristaltic
Maximum infusion/occlusion pressures	25 +/- 12 Psi
Maximum activation time of occlusion alarm (minimum rate) at minimum occlusion pressures	4 hours
Maximum activation time of occlusion alarm (intermediate rate) at maximum occlusion pressures	90 seconds
Dimensions/weight	2.16 in. X 1.4 in. X 6.875 In. (55 mm x 36 mm x 175 mm) 4.7 ounces (133.2 grams) without batteries 6.4 ounces (181.4 grams) with batteries
Power supply	Two AA 1.5V batteries
Battery life (rate dependent)	≥14 Days @ 1 ml/hr or ≥26 hrs @ 20 ml/hr
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

Specification	Details
Operating controls	RUN/PAUSE button BOLUS button Remote BOLUS switch (optional) ON/OFF twist cap
History reports	Volume infused Doses delivered Boluses delivered Boluses requested Elapsed time
Delivery profiles	PIb+PCA PCA PIb
Estimated life span of pump	Approximately 2 years with an infusion rate of one liter per month.

** 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 · PCA v1.5 pump 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[22].

2. The time between each revolution[23].

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[24] and needles[25] 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 · PCA v1.5 pump, virtually all the pressure generated by the pump is to overcome the pressure drop in the catheter and not in the body, which is generally a very large low-pressure area. Thus, the basal flow rate 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 v1.5 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

	Bolus/Dose			Flow Rate		
	50 ml	**25 ml**	**0.1 ml**	**20 ml/hr**	**10 ml/hr**	**0.1 ml/hr**
Average	2%	2%	-2%	0%v	0%	3%
Standard deviation	2.4%	2.6%	3.8%	2%	2.6%	2%

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 · PCA v1.5 pump may also change. Factors that may affect volumetric accuracy are shown below in Section 10.2.

10.2 Factors That May Affect Volumetric Accuracy

Changes	Effect	Comments
Viscosity of fluid increases as compared to water	Volume infused decreases	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.
Syringe is used as a fluid reservoir	Volume infused decreases	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.
Using a catheter with a gauge smaller than 20 gauge	Volume infused decreases	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).
Using a non-collapsible fluid reservoir	Volume infused decreases	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.

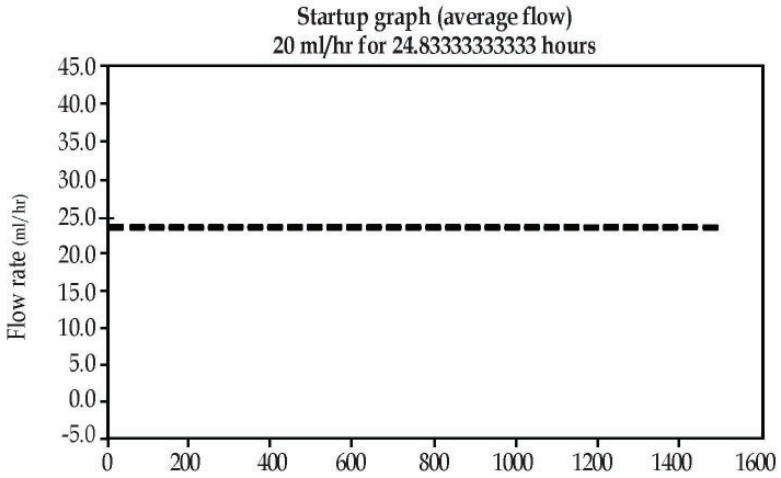
Changes	Effect	Comments
Adding microbore tubing to the inlet or outlet side of the cassette	Volume infused decreases	This may result in an under-infusion due to the tubing restricting flow into the pump, or creating significant back pressure on the downstream side of the pump. See comment about using a smaller catheter.

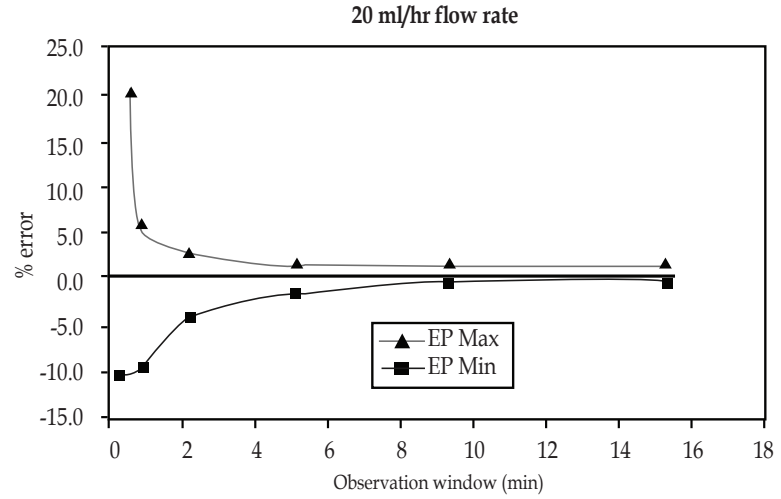
The following graphs show the pump's delivery accuracy for dose, bolus and basal flow rate infusions. The dose and bolus accuracy is shown at different volumes over a number of sequential bolus/dose events. The basal flow rate accuracy is shown as trumpet curves under different conditions of flow rate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

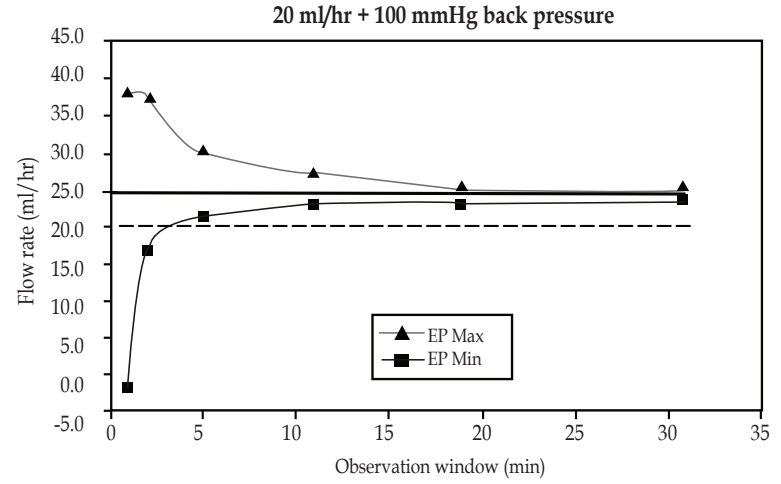
The ambIT® PIB · PCA v1.5 pump use a rotary peristaltic mechanism to deliver fluid. Each rotation of the peristaltic mechanism delivers 0.050 ml (50 µl) of fluid. During bolus/dose delivery, the pump delivers a prescribed volume at a flow rate of 210 ml/hr accuracy. The accuracy is shown as the percent 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.

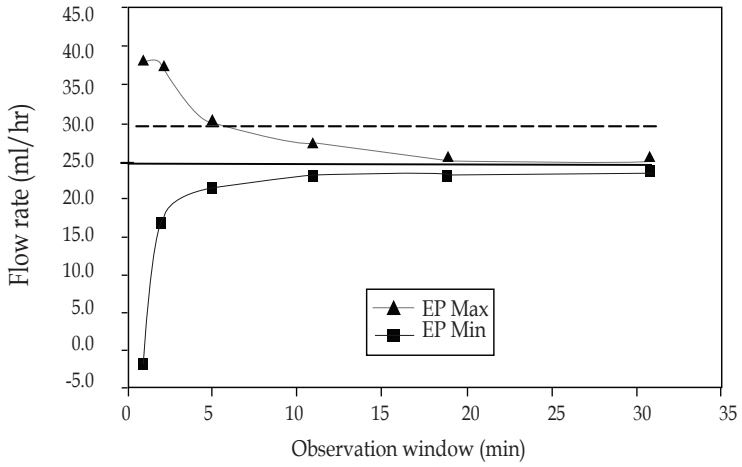
The user is directed to these graphs in order to be aware of the delivery profile of the ambIT® pump and to ensure that the delivery profile is acceptable for the drug being infused, the drug's concentration, and the drug's rate of delivery.


Startup graph (average flow)
20 ml/hr for 24.83333333333 hours
Flow rate (ml/hr)
45.0
40.0
35.0
30.0
25.0
20.0
15.0
10.0
5.0
0.0
-5.0
0
200
400
600
800
1000
1200
1400
1600

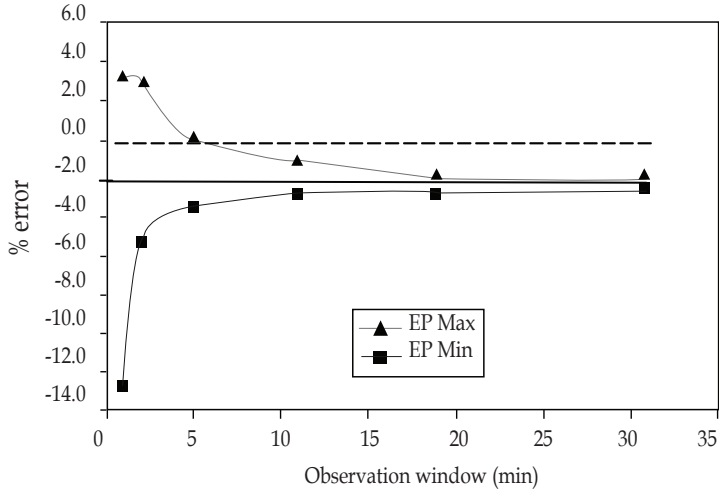

20 ml/hr flow rate
% error
25.0
20.0
15.0
10.0
5.0
0.0
-5.0
-10.0
-15.0
EP Max
EP Min
0
2
4
6
8
10
12
14
16
18
Observation window (min)


20 ml/hr + 100 mmHg back pressure
Flow rate (ml/hr)
45.0
40.0
35.0
30.0
25.0
20.0
15.0
10.0
5.0
0.0
-5.0
EP Max
EP Min
0
5
10
15
20
25
30
35
Observation window (min)

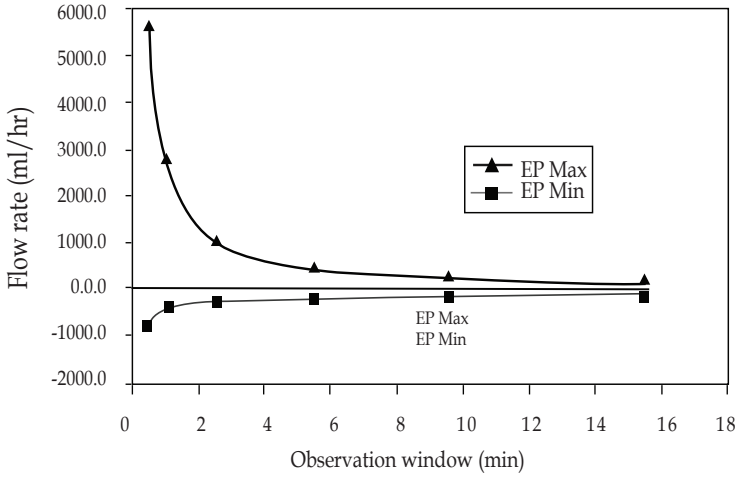
20 ml/hr - 100 mmHg back pressure



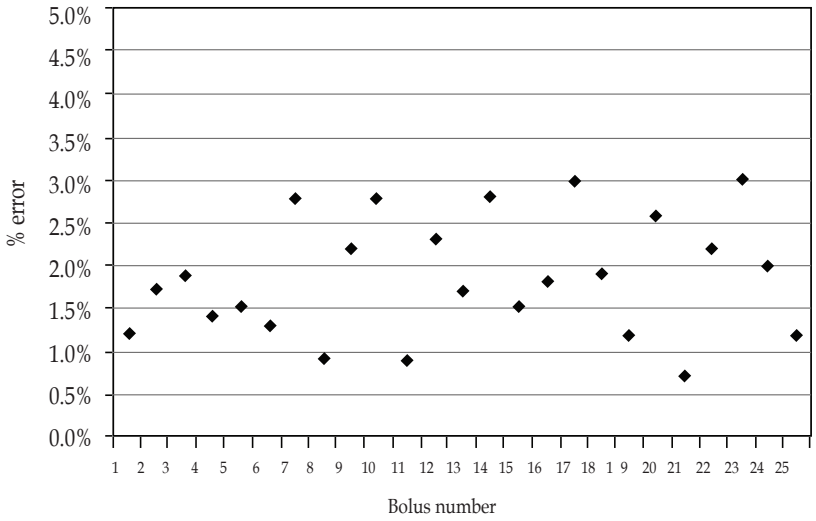
Supply container below pump 20 ml/hr



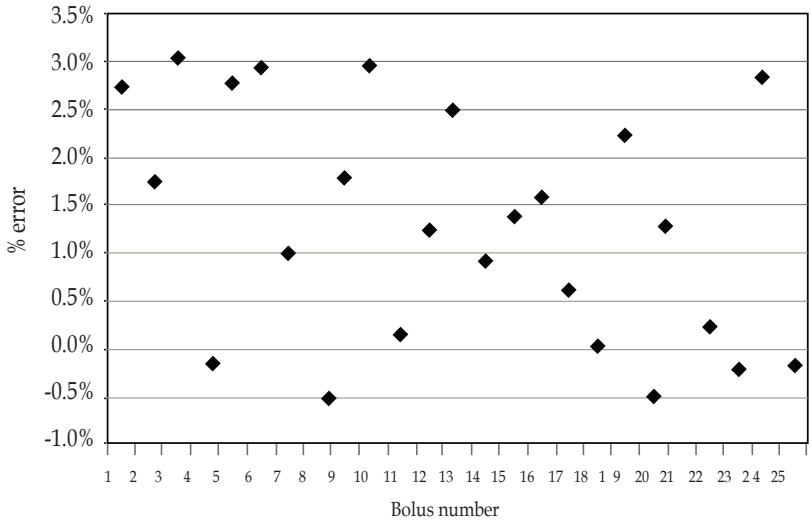
0.1 ml/hr flow rate



25 0.1 ml bolus/dose volumes



25 20 ml bolus/dose volumes



SECTION 11 - GENERAL CARE INSTRUCTIONS

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

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

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

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

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

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

No sterilization of the pump is required. Disinfect the pump before and after every patient use, procedure, and/or transfer of patients. (See Section 11.2 for instructions.)

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

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

11.1 Warranty Information

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

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

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

11.2 Cleaning and Disinfecting Instructions

Step #1

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

- A fresh solution of one (1) part household bleach to nine (9) parts water;
- Rubbing alcohol (70% Isopropyl alcohol);
- 3% Hydrogen peroxide; or
- Equivalent solution (i.e., quaternary ammonium).

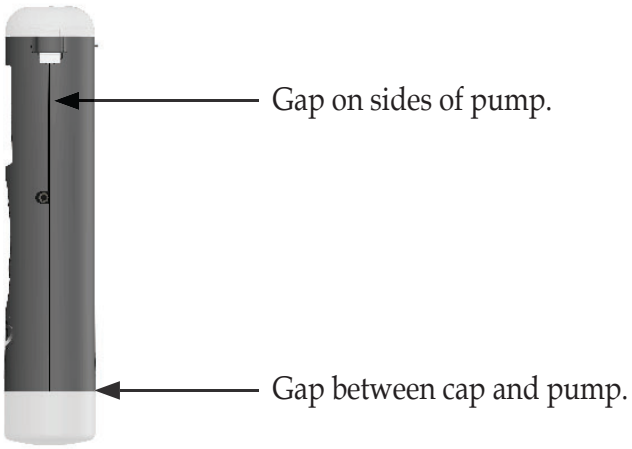
NOTE: Follow directions on the household cleaner label or consult the CDC or EPA website.

Step #2

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

Step #3

Clean the gaps:



SECTION 12 - ELECTROMAGNETIC IMMUNITY (EMC)

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

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

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

WARNING: The ambIT® pump should not be used adjacent to or stacked with other equipment. 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.

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

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

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

SECTION 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: (877) 352-1888
Phone: (801) 352-1888
Fax: (801) 352-1818
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