

Military PCA Pump

P A T I E N T M A N U A L



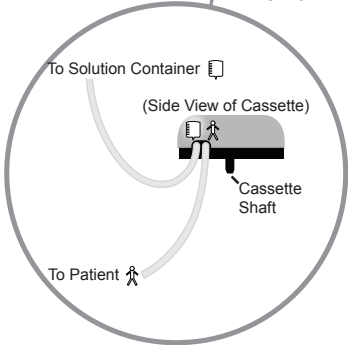
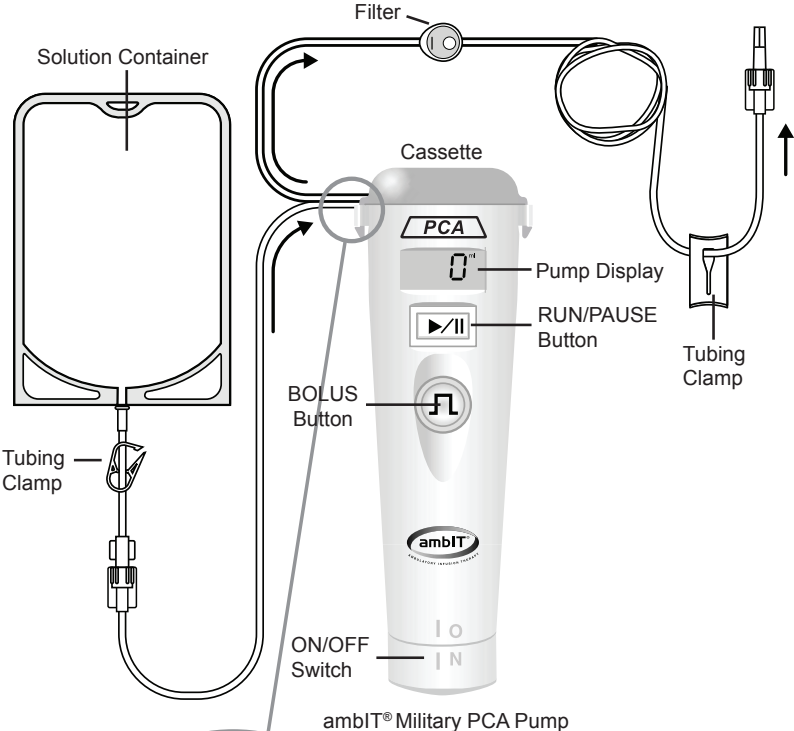
MORE THAN PAIN RELIEF...
SUPERIOR PAIN CONTROL



IPX1



Become Familiar with the ambIT[®] Pump



ambIT[®] Military PCA Pump

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Definitions and Symbols

Warning:

A warning message contains special safety emphasis and must be observed at all times. Failure to observe a **WARNING** message is potentially life threatening.

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.

Note:

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



This international symbol means: Attention, consult accompanying documents.

IPX1

Protected from dripping water.



TYPE BF

This is the IEC symbol for TYPE BF equipment.

- IEC Classification Internally Powered.



The ambIT® Military PCA Pump complies with EN 60601-1:1990 including amendments A1 and A2; IEC 60601-1:1998; IEC 60601-2-24:1998; CAN/CSA C22.2 No. 601-M90 with supplement No. 1-94; UL2601-1:1997 with amendments 1 and 2.



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



NRTL/C

The "NRTL/C" indicator adjacent to the CSA (Canadian Standards Association) Mark signifies that the product has been evaluated to the applicable ANSI/UL and CSA standards, for use in the U.S. and Canada. NRTL (Nationally Recognized Testing Laboratory) is a designation granted by the U.S. Occupational Safety and Health Administration (OSHA) to laboratories which have been recognized to perform certification to U.S. Standards.

Definitions and Symbols



Single-use only (Cassettes)



Keep away from heat



Keep dry



Temperature limitation

STERILE R

Sterilized using irradiation



DEHP-free fluid path



LATEX-free



Indicates which tubing connects to the solution container



Indicates which tubing connects to the patient



Bolus



Program Lockout



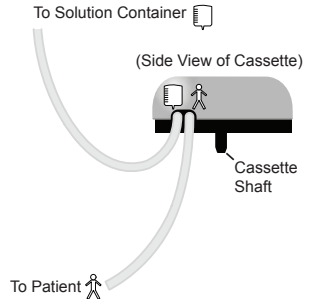
Bolus Lockout Time in hours : minutes



Bolus Volume in milliliters




Volume in milliliters



ml/hr Basal Infusion Rate in ml/hr

No.  Number of Boluses Delivered


No.  Number of Bolus Requests

 Volume to be Infused


 **RUN/PAUSE** Button

 **BOLUS** Button


 Low/Dead Battery Indicator

 Alarm Indicator


 Military PCA Pump Display

 Pump Power **ON**



 Pump Power **OFF**



 Battery Orientation

Warnings

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

This product should only be used by a physician or by a trained individual under direct supervision 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 the person for whom it is prescribed.

Patients should never perform any function or push any button unless instructed by their health care professional.

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: -7°C to 70°C (20°F to 158°F), 10% to 90% relative humidity and 500 hPa to 1060 hPa atmospheric pressure.

Operating conditions: 10°C to 43°C (50°F to 110°F), 10% to 90% relative humidity and 500 hPa to 1060 hPa atmospheric pressure.

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.

This Pump does not have an air in-line alarm. A Cassette with an air elimination filter is available.

Safety hazards such as under infusion may be associated with external radio frequency interference (RFI) or electromagnetic radiation. Typical equipment which may generate such radiation include x-ray machines, MRI equipment, and any other non-shielded electrical equipment.

ambIT® Military PCA Pump Description

Indications for Use

The ambIT® Military PCA Pump is intended for use by a physician or by a trained individual under direct supervision of a physician. The Military PCA Pump is used to infuse medicines and/or fluids into patients primarily for pain management. Modes of action are generally intravenous, epidural and/or regional.

Note:

Any use of the Pump other than those indicated herein is regarded as an off-label use.

Note:

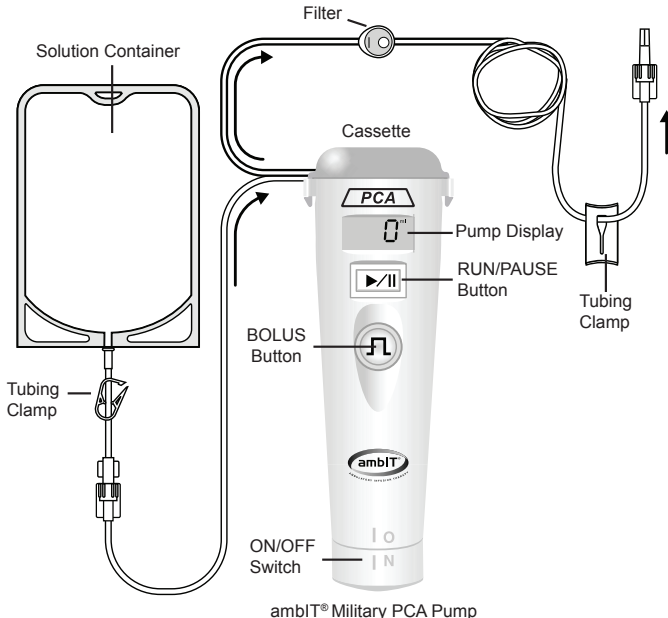
Summit Medical Products, Inc. does not recommend or endorse any one specific medication to be used with the ambIT® Family of Pumps. The medical provider is the sole individual who decides upon the prescribed medication, pump programmed parameters, method and location of infusion.

Pump Control Buttons

The **RUN/PAUSE** button is located just below the Pump display. This button is used to start, pause, or resume the infusion, and to silence alarms. The **RUN/PAUSE** button toggles between **RUN** and **PAUSE**. A blinking green **RUN** light (inside the **BOLUS** button) and "ml" (volume infused) in the Pump display indicate that the Pump is infusing.

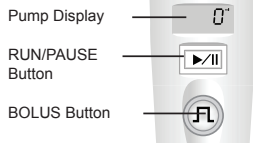
If the infusion is paused, a blinking **PAUSE** symbol (||) appears in the Pump display and two (2) beeps sound every four (4) minutes, indicating that the Pump infusion has been temporarily stopped.

The **BOLUS** button is located below the **RUN/PAUSE** button, and when pressed in **RUN** mode, the Pump will deliver the programmed bolus dose. During bolus delivery, the green **RUN** light (inside the **BOLUS** button) will double blink.



ambIT® Military PCA Pump

Operation



Normal Operation

During normal operation, the green **RUN** light (inside the **BOLUS** button) will start to blink and the “ml” (volume infused) will appear in the Pump display.

Pause Infusion



To **PAUSE** the infusion, press and hold the **RUN/PAUSE** button for five (5) seconds until one (1) beep is heard. The Pump will beep two (2) times, the green **RUN** light will stop blinking, and the **PAUSE** (||) icon will blink in the Pump display. If left in **PAUSE**, the Pump will beep two (2) times every four (4) minutes.

Note:

PAUSE temporarily stops the infusion. While in **PAUSE**, the infusion is delayed. This allows for changing the Cassette, solution container, or batteries.

Resume Infusion



To resume the infusion from **PAUSE**, press and hold the **RUN/PAUSE** button for five (5) seconds. The green **RUN** light (inside the **BOLUS** button) will start to blink, and the “ml” (volume infused) will appear in the Pump display. The infusion will resume at the same point at which the Pump was placed in **PAUSE**.

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**. Once the cause of the alarm has been corrected, press and hold the **RUN/PAUSE** button for five (5) seconds to resume the infusion.

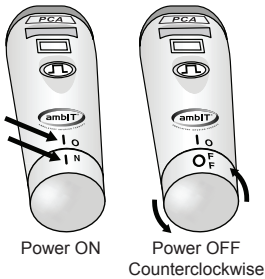
Note:

If the Pump alarms due to downstream pressure (occlusion alarm), and the cause of the alarm is corrected without intervention, the alarm will silence and the Pump will resume the infusion automatically.

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 dose is permitted, the Pump will begin bolus administration. During bolus infusion, the green **RUN** light will double blink. If the **BOLUS** button is pressed during the Bolus Lockout Time, the Pump will beep once, but no bolus will be delivered.



Pump Power ON and 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.

To power OFF the Pump:

STEP 1: Place the Pump in **PAUSE**.

STEP 2: Rotate the battery cover counterclockwise until the (O) mark on the cover lines up with the (I) mark on the Pump. (See illustration at left.)

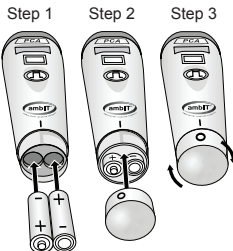
Battery Installation and Replacement

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

Caution:

Summit Medical Products, Inc. has not tested all rechargeable batteries with the Pump; therefore we cannot ensure that a specific rechargeable battery will power the Pump for a period of time. The battery condition and Pump settings will determine how the battery will perform in 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 batteries. We recommend that you change the batteries at the end of each therapy.

The Pump memory is designed to retain program settings and infusion history for up to six (6) months without power. Failure to follow manufacturer's instructions while replacing batteries may result in loss of program settings and report data. Do not store batteries in the Pump.



Battery Installation

To install batteries:

STEP 1: Insert batteries according to illustration at left.

STEP 2: Place battery cover on Pump as illustrated in diagram (**OFF** symbol (O) on cover slightly to the left of the (I) mark on Pump).

STEP 3: Rotate battery cover clockwise to the **OFF** (O) position.

Battery Replacement

To replace batteries:

STEP 1: Place Pump in **PAUSE**.

STEP 2: Rotate battery cover counterclockwise slightly to the left of the **OFF** (O) position until cover stops or meets resistance.

STEP 3: Remove cover and replace batteries as described above.

Resuming Infusion After Battery Replacement

First, power Pump **ON**. Pump will be in **PAUSE** mode.

Press the **RUN/PAUSE** button one (1) time. Pump display will scroll through program settings, then the Pause (II) icon will appear in the display.

Press and hold the **RUN/PAUSE** button for five (5) seconds to resume the current infusion program.

Caution:

Verify that the Pump is in **PAUSE** before removing batteries.














Summary of Operating Controls

To:	Steps to Take	Audible Indicator	Visual Indicator
Start Infusion	Press and hold RUN/PAUSE button for 5 seconds	1 Beep	Green RUN light blinks (inside BOLUS button) and "ml" (volume infused) is in Pump display
Pause Infusion	Press and hold RUN/PAUSE button for 5 seconds	2 Beeps (every 4 minutes)	Pause (II) icon flashing in display; Green RUN light (inside BOLUS button) stops blinking
Silence Alarm	Press and release RUN/PAUSE button	Alarm sound stops	Pause (II) icon flashing in display; Green RUN light (inside BOLUS button) stops blinking
Deliver Bolus	Press and release BOLUS button	1 Beep	Green RUN light double blinks (inside BOLUS button)

Troubleshooting

Problem	Resolution
No display	<ul style="list-style-type: none"> • Verify that Pump power is in the ON position • Verify proper battery placement • Replace batteries
Constant beeping during infusion; "OCL" in display	<p>Fluid path occlusion</p> <ul style="list-style-type: none"> • Verify that tubing clamps are open • Check for kink in tubing
Continuous tone	<p>Malfunction</p> <ul style="list-style-type: none"> • Immediately close tubing clamp • Possible dead battery alarm, replace batteries (battery icon visible) • Gently press on top of Cassette to ensure proper placement • Manufacturer's service/assistance may be required
Blood backed into tubing	<ul style="list-style-type: none"> • Verify that Pump is in RUN mode • Notify healthcare professional

Visible and Audible Alarm and Signal Table

Status	Icon	Visual Indicator	Audible Indicator	Comments
Pump Infusing Normally		Green RUN light (inside BOLUS button) blinking, and "ml" (volume infused) in display	None	Periodic movement of Cassette gears is normal.
Infusion Paused		"Pause" icon blinking in display; Green RUN light off	2 Beeps every 4 Minutes	
Infusion Complete		"Bag" icon blinking	1 Long Tone followed by 3 Short Beeps; repeats every 4 Minutes	"Infusion Complete" alert will sound every 4 minutes.
Bolus Infusion		Green RUN light (inside BOLUS button) double blinks; "Bolus" icon in display	1 Beep	1 beep will sound every time the BOLUS button is pressed during RUN mode.
				
Occlusion Alarm		"Alarm" icon and " OCL " in display	Constant Beeping	Press RUN/PAUSE button to silence alarm. Press and hold RUN/PAUSE button to restart Pump. If unable to resolve (silence) alarm, contact health care professional.
Cassette not Attached to Pump		"Alarm" icon and " MA " in display	Constant Tone	Press RUN/PAUSE button to silence alarm. Gently press on top of Cassette to ensure proper placement. Resume infusion.
Malfunction		"Alarm" icon and " MA " in display	Constant Tone	Immediately close tubing clamp. See Page 8 – <i>Troubleshooting</i> .
Malfunction		"Alarm" icon and " MA1 " in display	Constant Tone	Press RUN/PAUSE button to silence alarm. Gently press on top of Cassette to ensure proper placement. Resume infusion.
Low Battery		"Battery" icon blinking	5 Short Beeps every 4 Minutes	Replace batteries as soon as possible.
Dead Battery		"Battery" icon and "Alarm" icon in display	Constant Tone	Press RUN/PAUSE button to silence alarm. Alarm and battery icons will remain on. Replace batteries immediately.
Malfunction		"Alarm" icon and " EE1 ", " EE2 ", " EE3 ", " EE4 ", " EE5 ", " EE6 ", or " EE7 " in display	10 Short Beeps	Immediately close tubing clamp and turn off Pump. Contact Summit Medical Products, Inc. by calling the toll free number on the Pump.
Malfunction		"Alarm" icon and " CPU ", " RA ", or " RO " in display	Constant Tone	Immediately close tubing clamp and turn off Pump. Contact Summit Medical Products, Inc. by calling the toll free number on the Pump.
BOLUS Button		" REL " in display	Constant Beeping	Release the BOLUS button.

General Care Instructions

The patient should be careful to protect the Pump at all times. The Pump should not be dropped, stored in freezing -7°C (20°F) temperatures, left in direct sunlight, or exposed to excessive heat 70°C (158°F). The Pump should only be operated between 10°C and 43°C (50°F and 110°F).

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

The Pump can be cleaned by wiping its surface with a slightly damp cloth. Use only mild detergent soaps.

To disinfect the Pump, use a cloth slightly dampened with any of the following:

- A fresh solution of one (1) part household bleach to nine (9) parts water
- 70% Isopropyl alcohol
- Equivalent disinfectant product

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 sterile Cassette in any cleaning solutions.

Customer Assistance

For Customer Assistance, please contact your distributor or Summit Medical Products, Inc. at:

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2480 South Main, Suite 212
Salt Lake City, Utah 84115, USA

Toll Free: (877) 352-1888

Phone: (801) 352-1888

Fax: (801) 352-1818

E-mail: service@ambitpump.com

Web Site: www.ambitpump.com



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