Become Familiar with the ambIT® Pump

Solution Container

Tubing Clamp

Filter

Cassette

Pump Display

RUN/PAUSE Button

BOLUS Button

ON/OFF Switch

ambIT® Military PCA Pump

To Solution Container

(Side View of Cassette)

Cassette Shaft

To Patient
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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.

Protected from dripping water.

This is the IEC symbol for TYPE BF equipment.
- IEC Classification Internally Powered.


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

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

- *ml/hr*
  - Basal Infusion Rate in ml/hr

- *No. ⌅*
  - Number of Boluses Delivered

- *No. ⌇*
  - Number of Bolus Requests

- **RUN/PAUSE** Button
  - Volume to be Infused

- **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 (\(\text{II}\)) 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.
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 (II) 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 has been 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 (1) 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 (1) 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 (1) 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

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

Troubleshooting

<table>
<thead>
<tr>
<th>Problem</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>No display</td>
<td>• Verify that Pump power is in the ON position</td>
</tr>
<tr>
<td></td>
<td>• Verify proper battery placement</td>
</tr>
<tr>
<td></td>
<td>• Replace batteries</td>
</tr>
<tr>
<td>Constant beeping during infusion; “OCL&quot; in display</td>
<td>Fluid path occlusion</td>
</tr>
<tr>
<td></td>
<td>• Verify that tubing clamps are open</td>
</tr>
<tr>
<td></td>
<td>• Check for kink in tubing</td>
</tr>
<tr>
<td>Continuous tone</td>
<td>Malfunction</td>
</tr>
<tr>
<td></td>
<td>• Immediately close tubing clamp</td>
</tr>
<tr>
<td></td>
<td>• Possible dead battery alarm, replace batteries (battery icon visible)</td>
</tr>
<tr>
<td></td>
<td>• Gently press on top of Cassette to ensure proper placement</td>
</tr>
<tr>
<td></td>
<td>• Manufacturer’s service/assistance may be required</td>
</tr>
<tr>
<td>Blood backed into tubing</td>
<td>• Verify that Pump is in RUN mode</td>
</tr>
<tr>
<td></td>
<td>• Notify healthcare professional</td>
</tr>
</tbody>
</table>
## Visible and Audible Alarm and Signal Table

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