

ambIT[®] Pump

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



MORE THAN PAIN RELIEF...
SUPERIOR PAIN CONTROL



TYPE BF

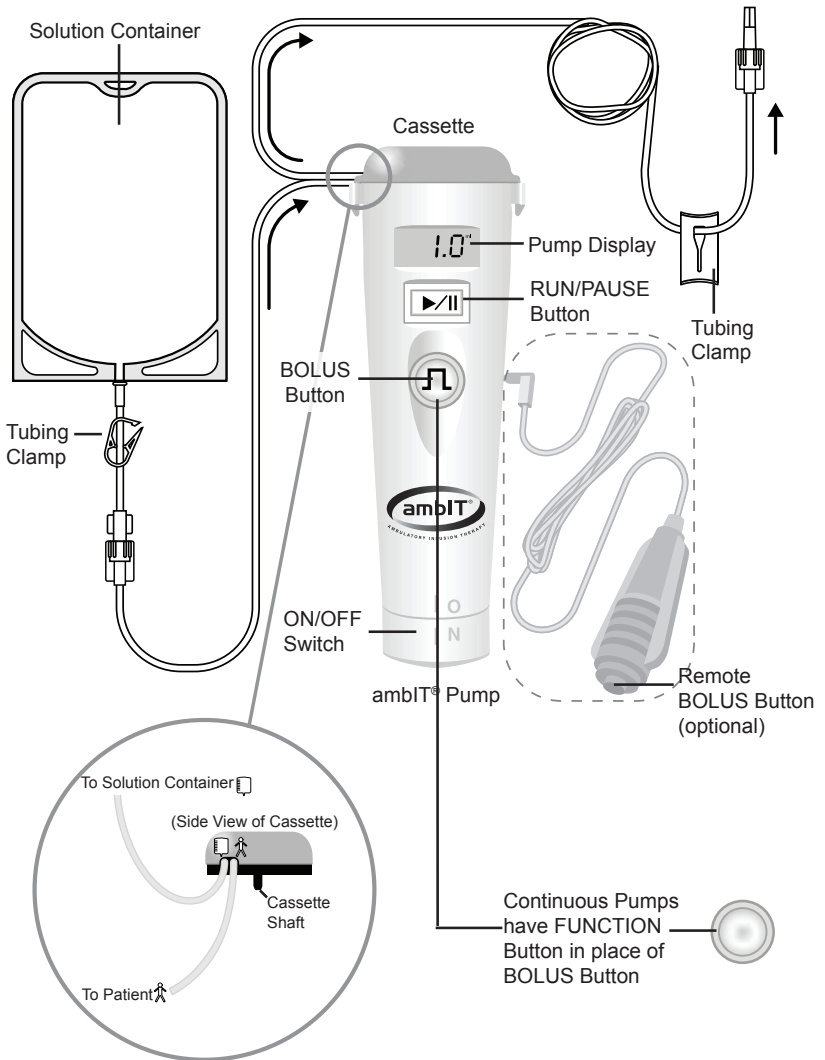


NRTL/C

IPX1 IP22



Become Familiar with the ambIT® Pump



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Warnings

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.

This Pump must be used only by the person for whom it is prescribed.

Never perform any function or push any button unless instructed by your 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.

Never attempt to open the Pump case. Only the battery cover may be removed when changing batteries.

Do Not Drop Pump. If pump is dropped, it must be replaced with a new Pump.

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.

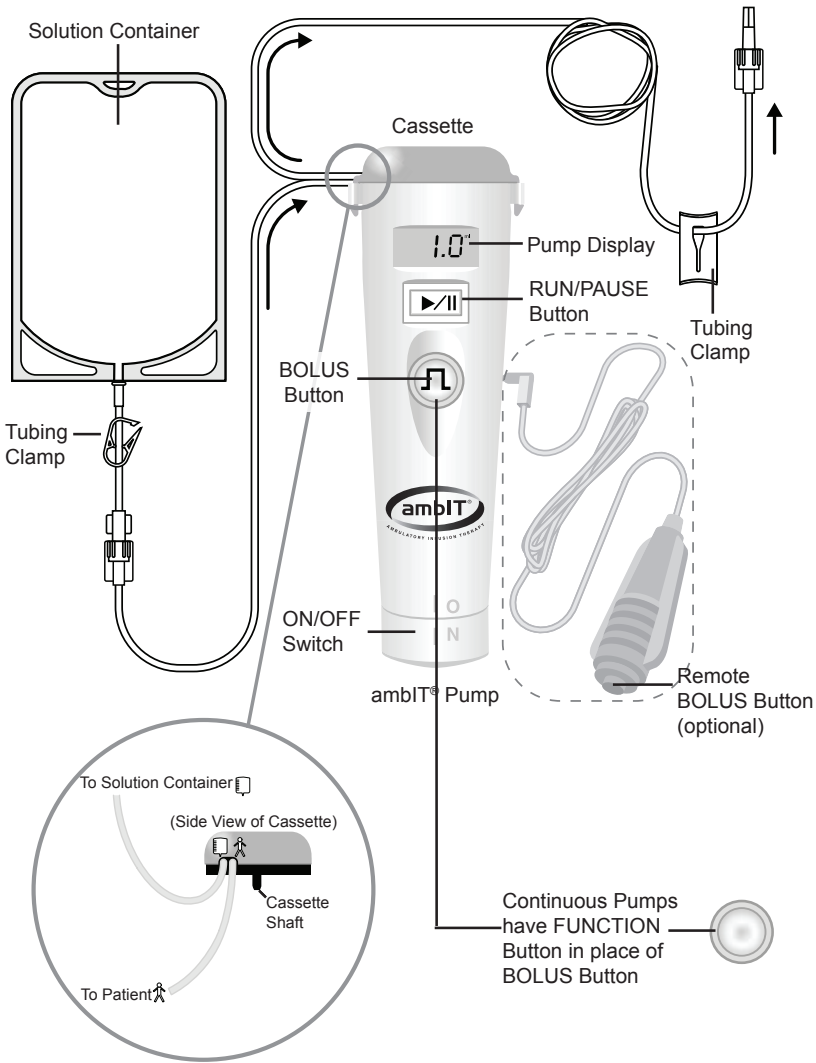
This Pump does not have an air in-line alarm. A Cassette with an air elimination filter is available.

No modification of this equipment is allowed.

Cassette tubing or bolus chord may cause strangulation if used improperly.

Do not tamper with the pump.

Keep out of reach of animals or children.



Welcome to the ambIT Pump Family

You have been provided with this manual to better assist you in your therapy goals. Your doctor has prescribed an ambIT Infusion Pump to best assist you with your personal needs. There are a variety of different ambIT pumps, some that have bolus buttons, and some that do not. The difference between these buttons are shown on the previous page. Your pump is also equipped with notifications that sometimes are referred to as alarms and alerts. We have provided a table for you to become familiar with on pg 8.

The ambIT Family of pumps are used for infusing antibiotics, chemotherapy, pain medications, and other therapies. In general, our pumps are not used for life sustaining medications. These highly accurate electromechanical devices are capable of assisting you with your therapy goals while allowing you the freedom to move about. Please do not tamper with your pump. Your doctor has programmed it to deliver a very precise amount of medication, and tampering with it may inhibit any prescribed therapies.

This manual will help you understand how to activate the BOLUS/ FUNCTION button, power on and off the pump, start infusion, stop or pause infusion, change batteries, and respond to alarm notifications. This pump is capable of more functions but if you have not been trained by your healthcare provider then please do not attempt any function other than what this manual provides. Any other operations such as changing the reservoir bag, administration set, etc. are under the responsibility of your healthcare professional to provide training if it is applicable to your needs.

This is an ambulatory pump; as such you are free to walk around with your pump if it's not against your doctor's orders. Your pump is designed to not interfere with electronics in your home, and is easy to have with you while doing most activities. Please do not shower with your pump. While it will repel water, it is not intended to be fully submerged, and it's life span will diminish if not treated properly.

What to Expect?


When the pump is running or infusing there will be a number in the display and a green light flashing in the BOLUS or FUNCTION button (See Diagram). You will periodically hear a small noise as it infuses medication.

If the display shows a pause symbol or two lines flashing, it is in pause mode and is not infusing medication. To resume your infusion therapy simply press and release the RUN/PAUSE button

If you have any questions regarding your pump, you may contact Summit Medical Products, Inc. (see pg 9). Please keep in mind that we cannot answer therapy specific questions.

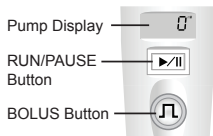
Your Pump's Control Buttons

All of our ambIT pumps have similar 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 MODE and PAUSE MODE. A blinking green RUN light (inside the BOLUS or FUNCTION button) and "ml" (volume infused) in the Pump display indicate that the Pump is infusing.

If the infusion is paused, a flashing PAUSE icon () will appear in the Pump display and two (2) beeps sound every four (4) minutes, indicating that the Pump infusion has been temporarily stopped.

The BOLUS or FUNCTION button is located below the RUN/PAUSE button. When the FUNCTION button is pressed during RUN MODE, the pump will toggle between total volume infused and RUN time. When the BOLUS button is pressed during RUN MODE, the pump will deliver the programmed bolus dose. During bolus delivery, the green RUN light (inside the BOLUS button) will double blink.

We know you'll find your ambIT experience positive during your therapy and we'd love to hear your feedback. To share your story, please contact us at service@ambitpump.com.



Operation

Normal Operation

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

Pause Infusion



To pause the infusion, press and release the RUN/PAUSE button (hold for five (5) seconds if a military pump). The Pump will beep two (2) times, the green RUN light will stop blinking, and the PAUSE icon () will flash in the Pump display. If left in PAUSE MODE, the Pump will beep two (2) times every four (4) minutes.

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.



Resume Infusion

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

The green RUN light (inside the BOLUS button) will start to blink, and “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 MODE.



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, press and release the RUN/PAUSE button (hold for five (5) seconds if a military pump) 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 (Not Applicable to Pumps with FUNCTION Button)

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.

Note:

A Remote BOLUS button may also be used. Connect the Remote BOLUS to the Pump before placing the Pump in RUN MODE.



The FUNCTION Button

The FUNCTION button is located on the Pump directly below the RUN/PAUSE button. When the FUNCTION button is pressed during RUN MODE, the display will toggle between Total Volume Infused and Run Time.

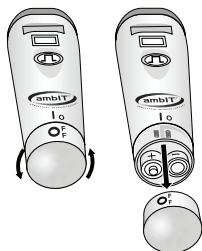
Battery Installation and Replacement

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

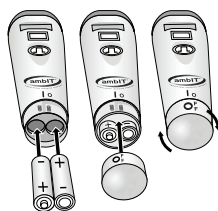
Caution:

Summit Medical Products, Inc. has not validated all types of batteries (non-alkaline, rechargeable, 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 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 or rechargeable batteries. The manufacturer recommends that the batteries be changed 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 the manufacturer's instructions while replacing batteries may result in loss of program settings and report data. Do not store batteries in the Pump.



Remove Battery Cover



Insert Batteries and Replace Cover

To Install Batteries:

- STEP 1:** Rotate the battery cover counterclockwise slightly to the left of the OFF (O) position, until the cover stops or meets resistance.
- STEP 2:** Remove the cover and insert the batteries according to the illustration at left.
- STEP 3:** Place the battery cover onto the Pump as illustrated in the diagram (OFF symbol (O) on the cover slightly to the left of the (I) mark on the Pump).
- STEP 4:** Rotate the battery cover clockwise to the OFF (O) position.

To Replace Batteries:

- STEP 1:** Place the Pump in PAUSE MODE (see "Pause Infusion" on pg 4).
- STEP 2:** Rotate the battery cover counterclockwise slightly to the left of the OFF (O) position, until the cover stops or meets resistance.
- STEP 3:** Remove the cover and replace the batteries according to the instructions above.
- STEP 4:** Power ON the Pump according to the instructions below.

After battery replacement and power ON, the Pump will be in PAUSE MODE, with the PAUSE icon (II) flashing in the display.

Press and release the RUN/PAUSE button. The Pump display will scroll through the program settings, then the PAUSE icon (II) will again flash in the display.

Press and release the RUN/PAUSE button (hold for five (5) seconds if a military pump) a second time to resume the current infusion program.

Caution:

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

Pump Power ON and OFF

To power ON the Pump:

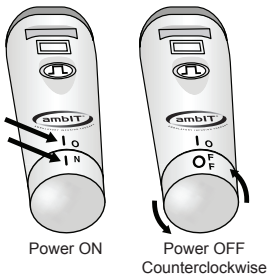
Rotate the battery cover clockwise until the (I) mark on the cover lines up with the (I) mark on the Pump.

Note:

After the power on self-test, the Pump will beep twice and go into PAUSE MODE. The clinician can then program the Pump or resume current infusion settings.

To power OFF the Pump:











- STEP 1:** Place the Pump in PAUSE MODE.
- 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).



Summary of Operating Controls

To:	Steps to Take	Audible Indicator	Visual Indicator
Start Infusion	Press and release the RUN/PAUSE button	1 Beep	Green RUN light (inside the BOLUS button) blinks, and "ml" (volume infused) is in the Pump display
Pause Infusion	Press and release the RUN/PAUSE button (hold for five (5) seconds if military pump).	2 Beeps (every 4 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	Press and release the BOLUS button	1 Beep	Green RUN light (inside the BOLUS button) double blinks

Troubleshooting and Alarm Table

Status	Icon	Visual Indicator	Audible Indicator	Resolution
No Display	None	None	None	<ul style="list-style-type: none"> • Verify that the battery cover is in the ON position • Verify proper battery placement • Replace the batteries
Occlusion Alarm		ALARM icon and "OCL" are in the display	Constant Beeping	<ul style="list-style-type: none"> • Verify that all tubing clamps are open • Check for kinks in the tubing • 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.
Blood backed into tubing	None	None	None	<ul style="list-style-type: none"> • Verify that the Pump is in RUN MODE • Notify healthcare professional
Pump Infusing Normally	 	Green RUN light (inside the BOLUS/ FUNCTION button) blinks, and "ml" (volume infused) is in the display	None	No action is required
Infusion Paused		PAUSE icon flashes in the display; Green RUN light is off	2 Beeps every 4 Minutes	To resume infusion, press the RUN/ PAUSE button.
Infusion Complete		BAG icon flashes in the display	1 Long Tone followed by 3 Short Beeps; repeats every 4 Minutes	Place The Pump in Pause Mode If your pump needs to be programmed for another infusion, contact your physician.
Bolus Infusion	 	Green RUN light (inside the BOLUS button) double blinks; BOLUS icon is in the display	1 Beep	No action is required. Bolus will be delivered.
Low Battery		BATTERY icon flashes in the display	5 Short Beeps every 4 Minutes	Replace the batteries per instructions on page 5.
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 on. Replace the batteries immediately.

If you encounter any alarms or occurrences other than what is provided in Table above, please place the pump in pause mode (see pg 4) and notify Summit Medical Products, Inc. (contact information is located on pg 9) or a healthcare professional.

General Care Instructions

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

Transport and storage conditions: -25°C without relative humidity control; and 70°C at relative humidity up to 93%, non-condensing.

Operating conditions: +5°C to +40°C; relative humidity range of 15% to 93%, non-condensing; and an atmospheric pressure of 700 hPa to 1060 hPa.

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 use. To clean and 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 healthcare provider, 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

E-mail: service@ambitpump.com

Web Site: www.ambitpump.com

EC	REP
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European Representative:

Medical Technology Promedt Consulting GmbH
Altenhofstraße 80
66386 St. Ingbert
Germany

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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.



Consult Instructions for use.

IPX1

Protected from dripping water.

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.



TYPE BF

This is the IEC symbol for TYPE BF equipment.

- IEC Classification Internally Powered.



The ambIT® Pump complies with ES 60601-1 2012 Edition 1 including amendment 1; CSA C22.2 NO. 60601-1:2014 Ed.3; IEC 60601-1:2005+CO RR.1:2006+CORR.2:2007+AM1:2012; IEC 60601-1-6 2013 Ed. 3.1; IEC 60601-1-8 2012 Ed. 2.1; IEC 60601-1-11 2010; 60601-2-24 2012 Ed. 2; IEC 62304 2006 Ed. 1; IEC 62366:2007 (First Edition) +A1:2014; IEC 60601-1-2:2007 (Third Edition_2007-03)



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.



This international symbol means: Attention, consult accompanying documents.



Single-use only (Cassettes)



Keep away from heat



Keep dry

R_{only}

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



Temperature limitation

STERILE

Sterilized using irradiation



DEHP-free fluid path



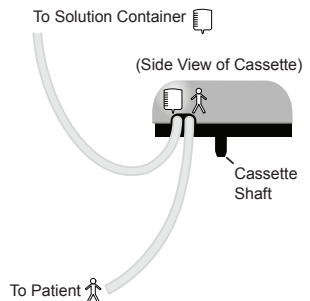
Not made with natural rubber latex



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



Volume in milliliters



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

ambIT® Infusion Pump is a trademark of:



**SUMMIT MEDICAL
PRODUCTS**

FINDING BETTER WAYS TO CARE FOR PEOPLE™