

Appendix-E

Standard Pump Operations



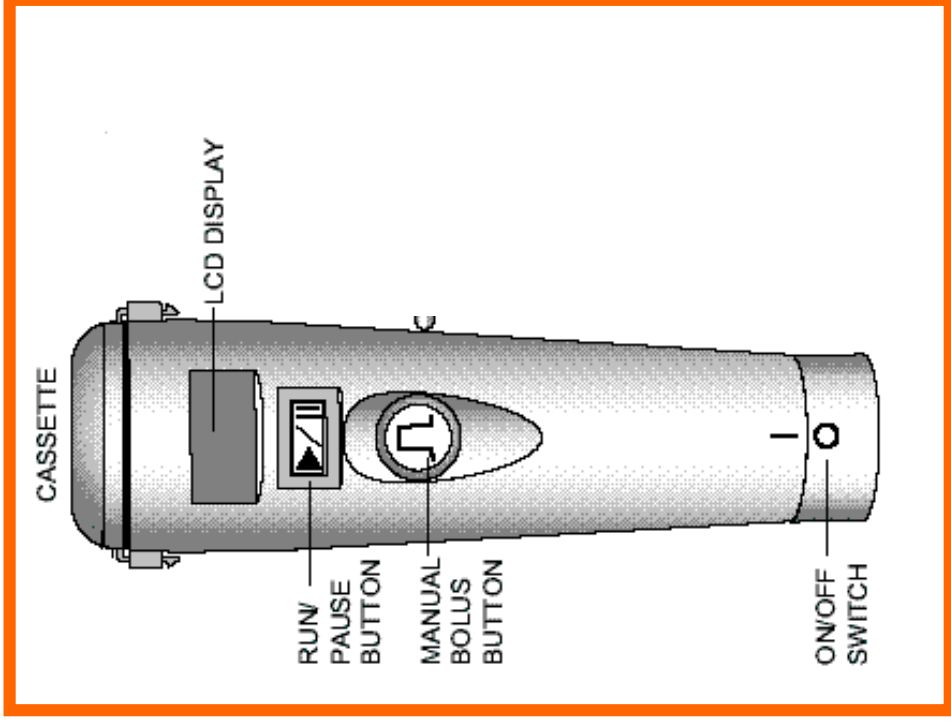
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ambIT® MARAA PCA Pump

Description

- Microprocessor controlled
- Can be programmed to provide standard PCA therapies
- Provides treatment history
- Optional Remote Bolus button available
- Powered by two disposable alkaline “AA” batteries
- Light-weight



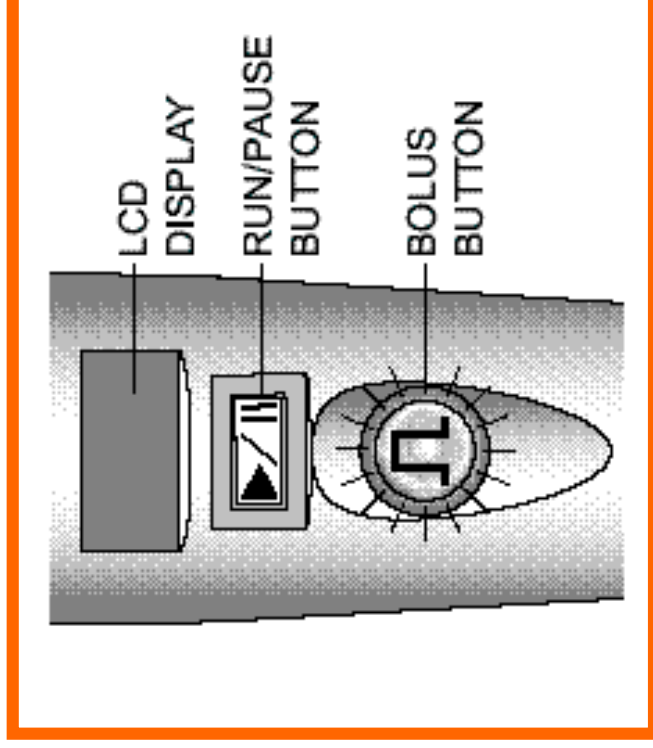
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Description

The ambIT® PCA Pump has two buttons used for programming and operating the pump



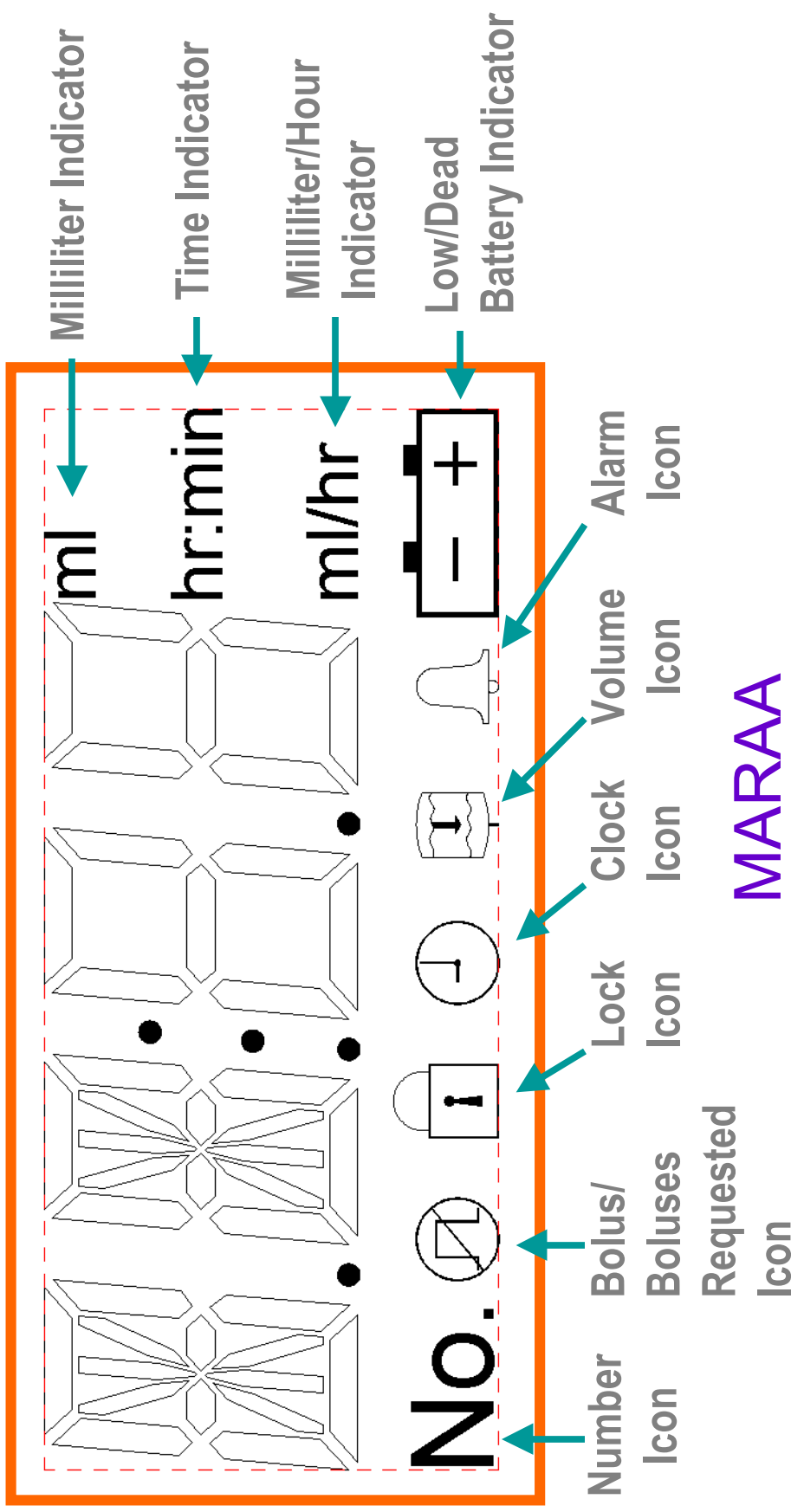
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Description

The LCD Display features:



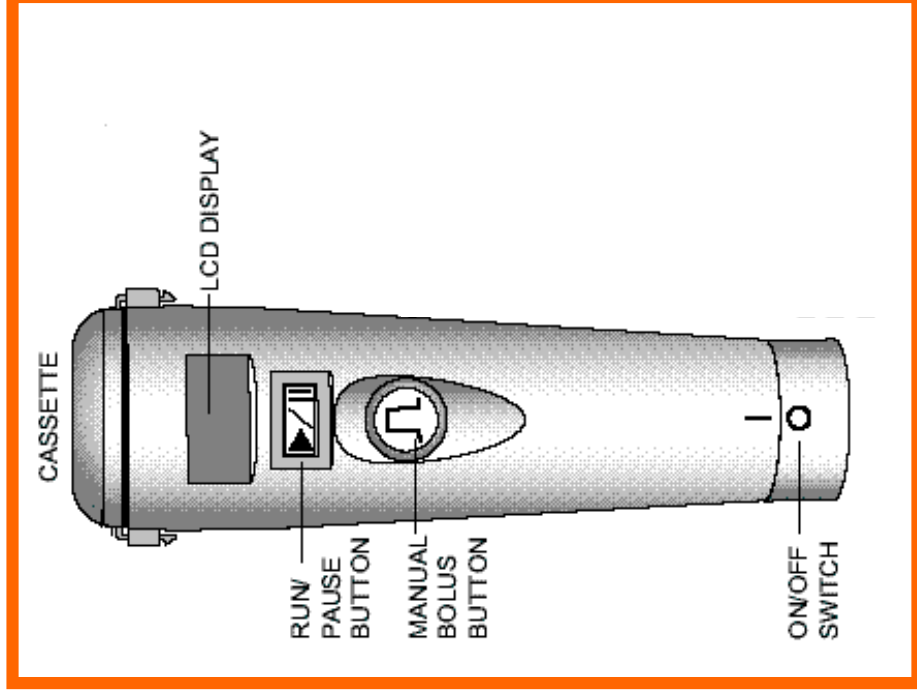
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Description

The Run/Pause Button toggles between Run and Pause. The Run/Pause Button is used to start, pause or resume the infusion and to silence any alarm.

A Green Run light (inside the Manual Bolus Button) will blink once every second during infusion
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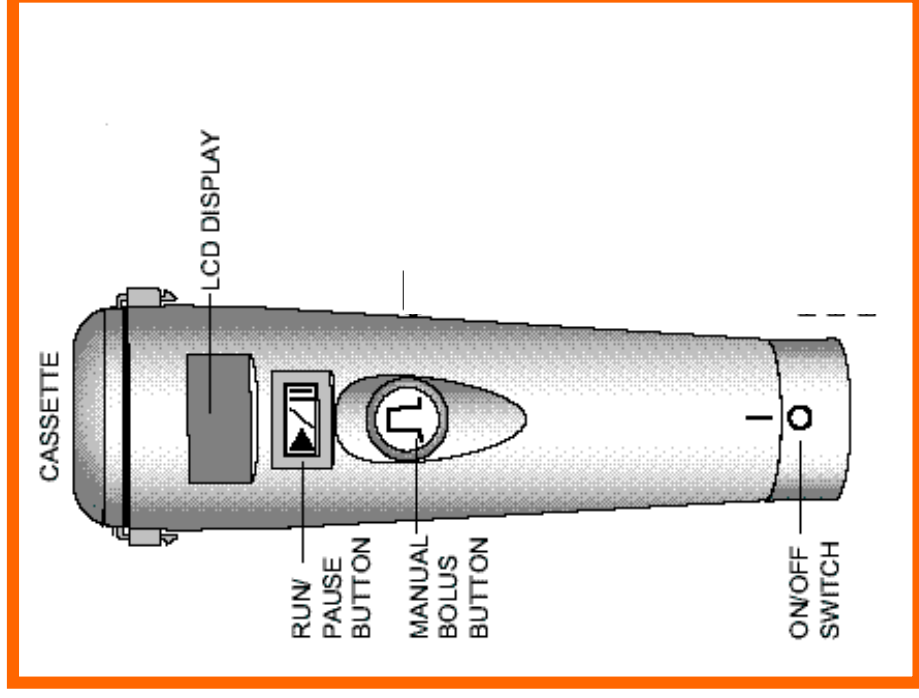
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Description

When the Bolus Button is pressed during the infusion, the pump will deliver the pre-programmed Bolus volume

During Bolus delivery, the green Run light (inside the Bolus button) will blink twice every second



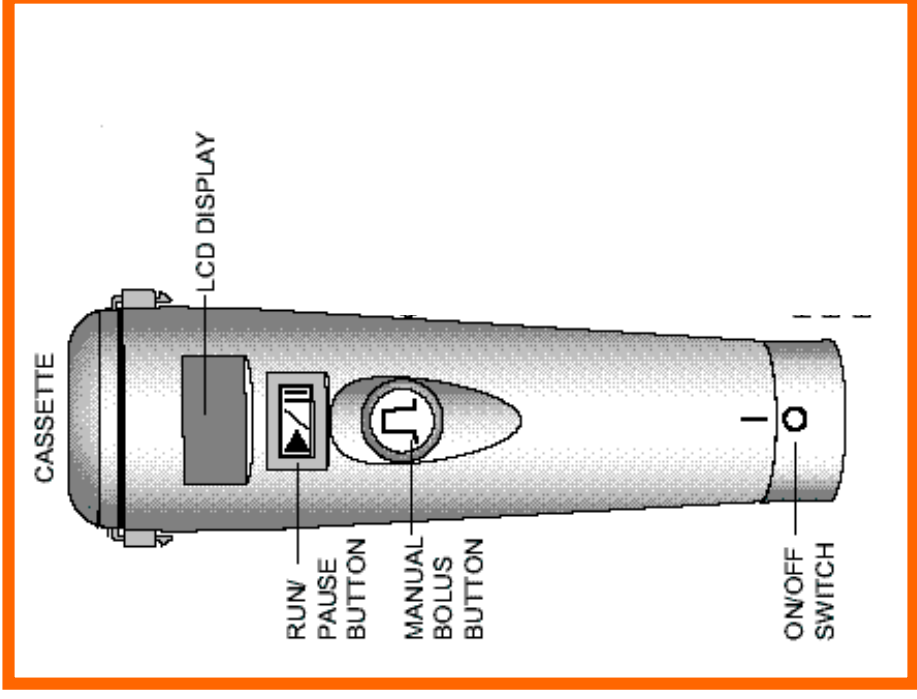
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Pump Description

The Off/On Switch of the ambIT® PCA Pump is also the battery cap



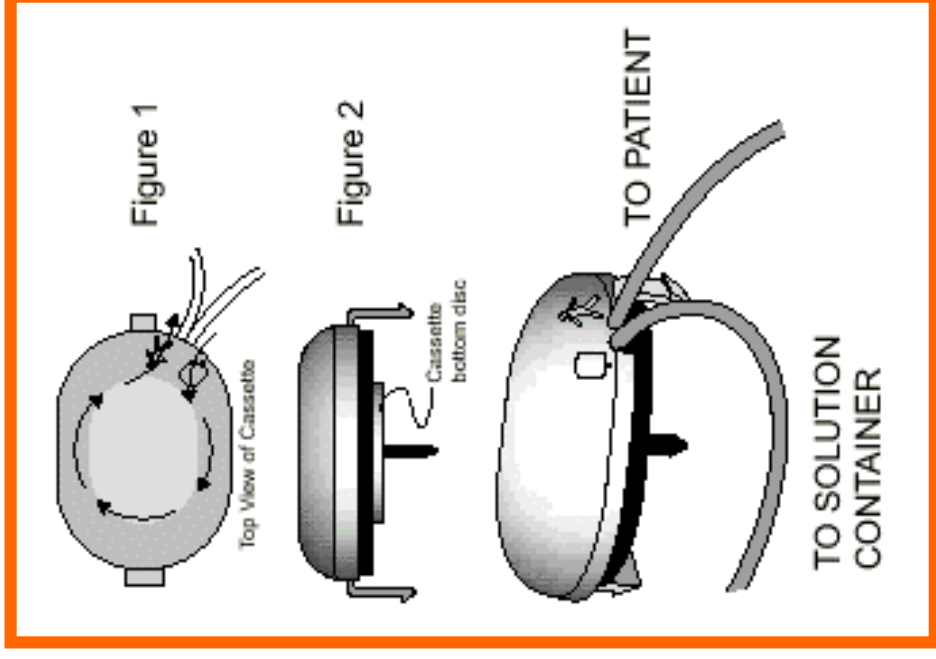
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Cassette Description

- The pump cassette is a single use, sterile, disposable set.
- The cassette is a rotary peristaltic pump.
- The medications are infused at 0.050 mL per stroke or revolution (20 strokes/mL).
- The time between strokes determines the flow rate. Example: at 1 mL/hr the pump strokes once every 3 minutes.



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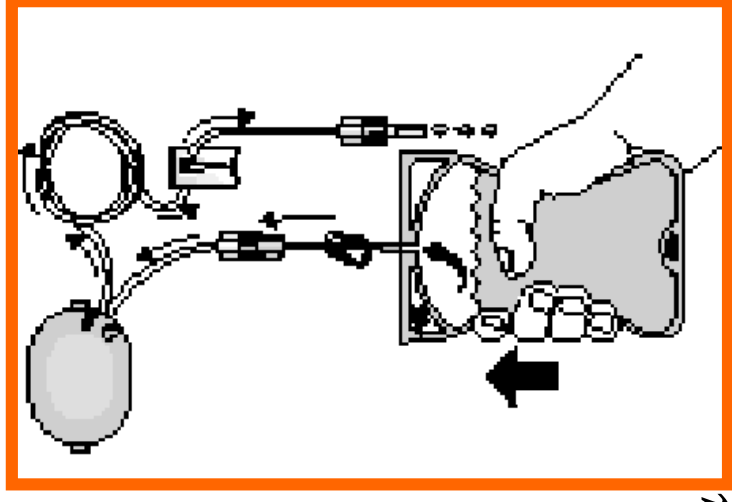
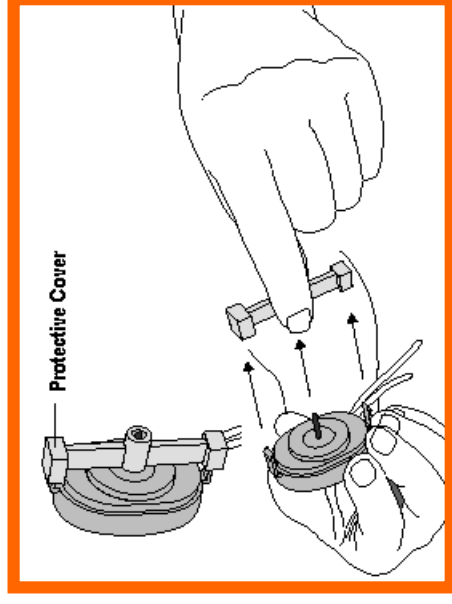
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Priming Cassette

During cassette priming, fluid will freeflow through the cassette and tubing until the priming process has been completed. **To prime the cassette:**

- ① Remove protective cover from bottom of cassette
- ② Connect the solution container to cassette using aseptic technique
- ③ Release all clamps on tubing



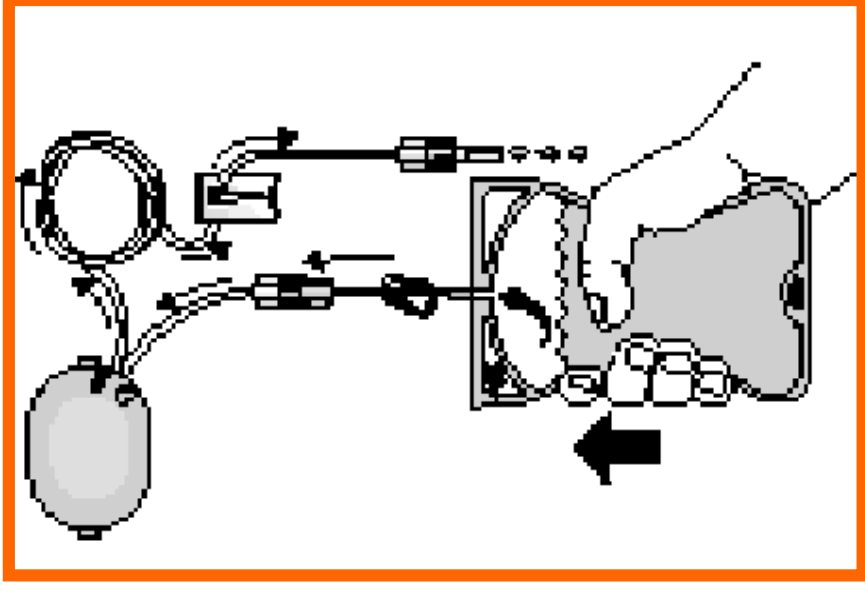
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Priming Cassette

- ④ Invert the solution container to allow the air to be evacuated first before priming the Cassette with fluid.
- ⑤ Gently squeeze the container to force fluid and air upward through the tubing and Cassette. Continue until fluid has completely filled the tubing and all air bubbles have been removed

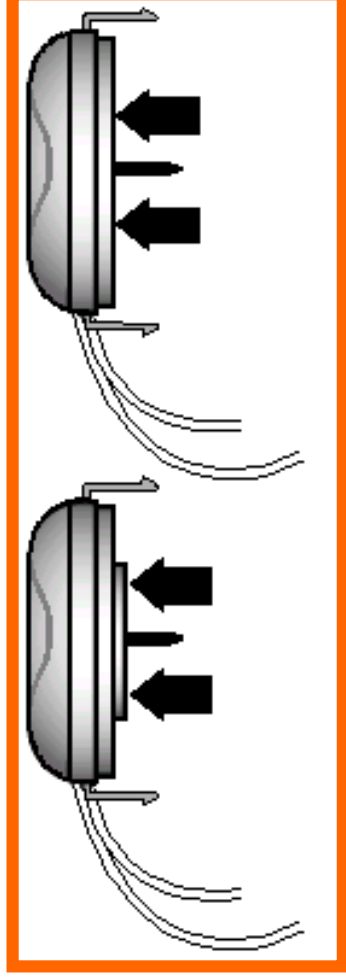


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- ⑥ When the cassette and tubing are primed, snap the cassette bottom disc into the cassette body.



**This will close the fluid path,
preventing freeflow on or off the pump.**

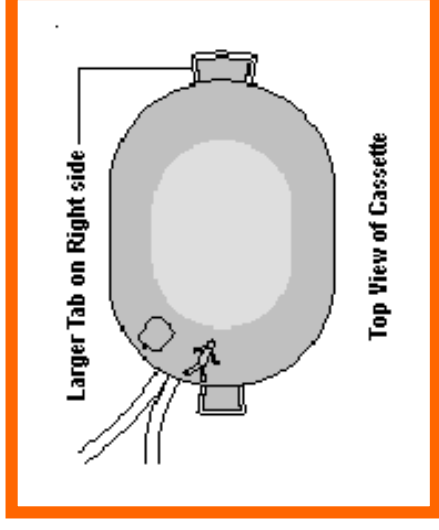
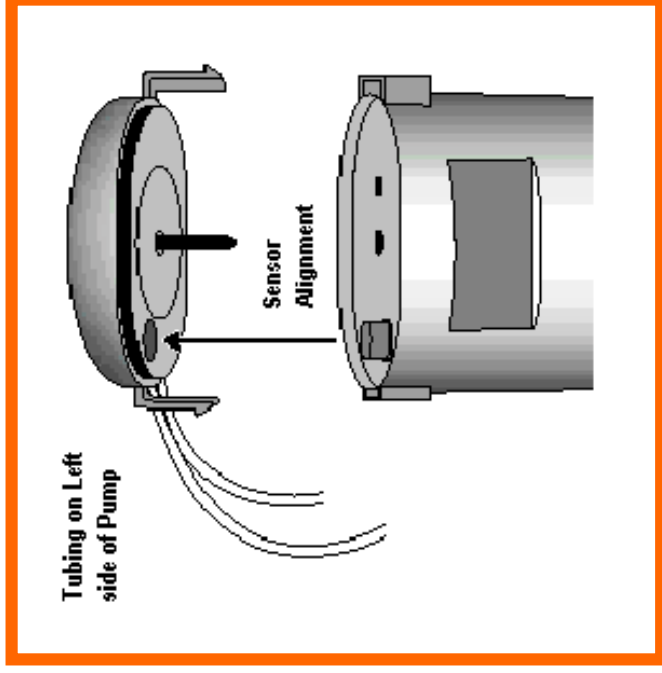
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Attach Cassette to Pump

- Gently squeeze tabs on the cassette to attach onto the pump.



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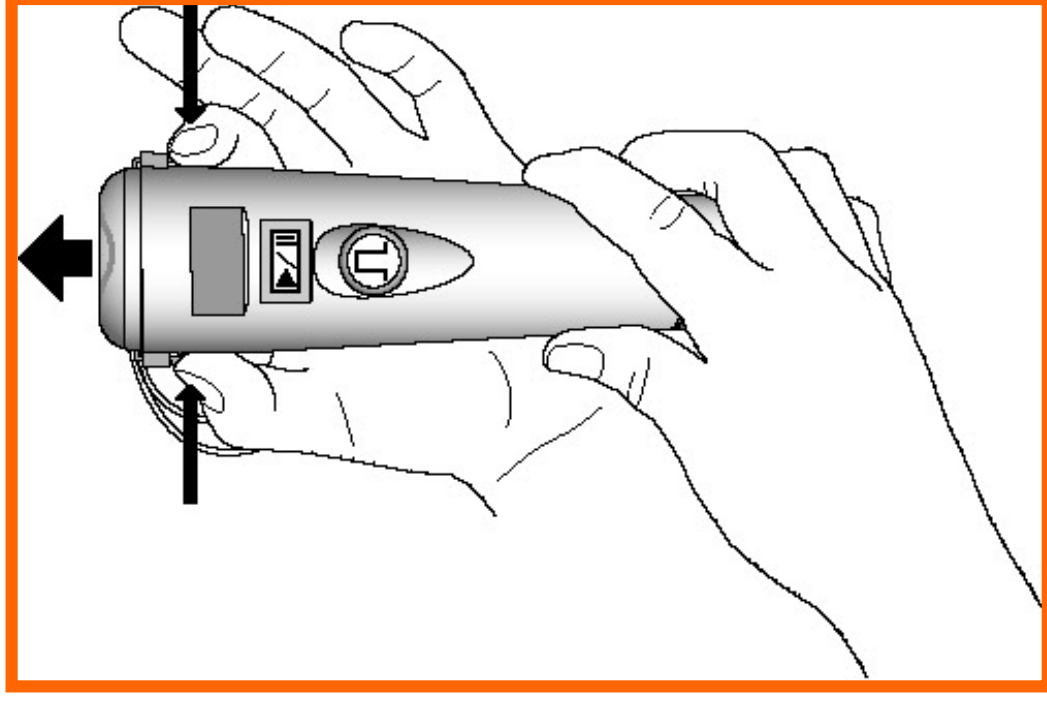
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Remove Cassette from Pump

- **To remove the cassette, press both cassette release tabs at the same time and lift the cassette off the Pump.**

Do not remove cassette while the green run light is blinking. first place pump in pause



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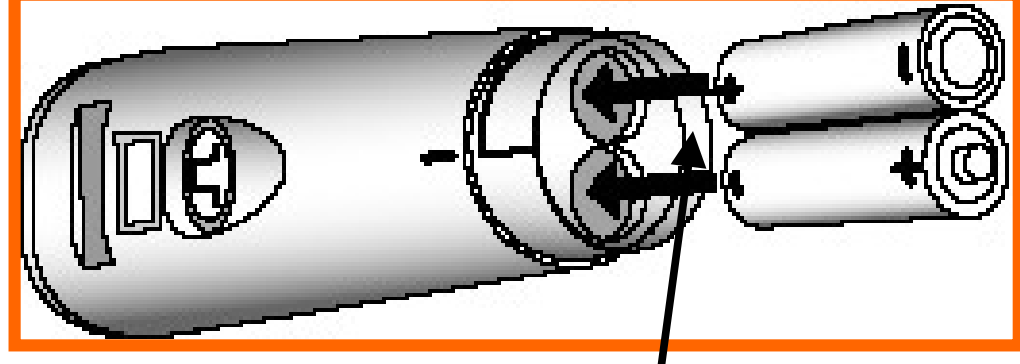
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Battery Installation

Step 1

- **Insert batteries**

Note: Orientation of batteries is shown here



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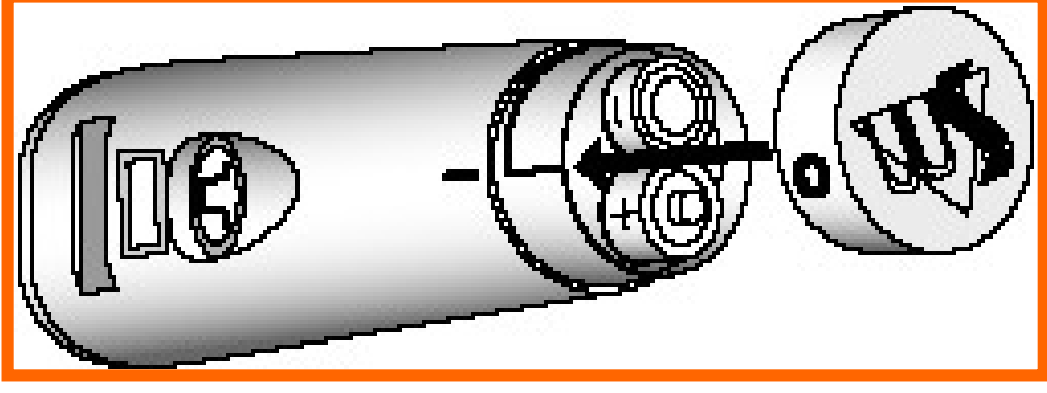
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ambIT® PCA & LPM Pump

Battery Installation

Step 2

- Place battery cover on pump (Off symbol (O) on cover slightly to left of the (|) mark on pump)

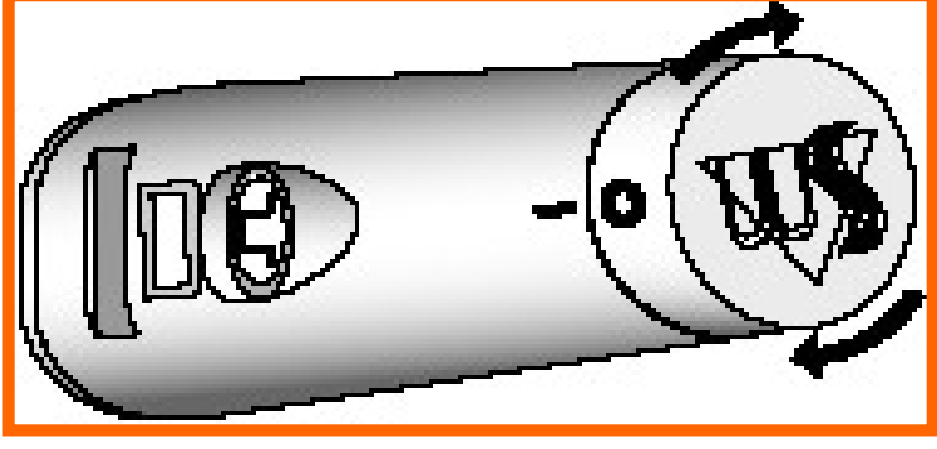


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ambIT[®] PCA & LPM Pump Battery Installation

Step 3

- Rotate battery cover clockwise to the off (O) position



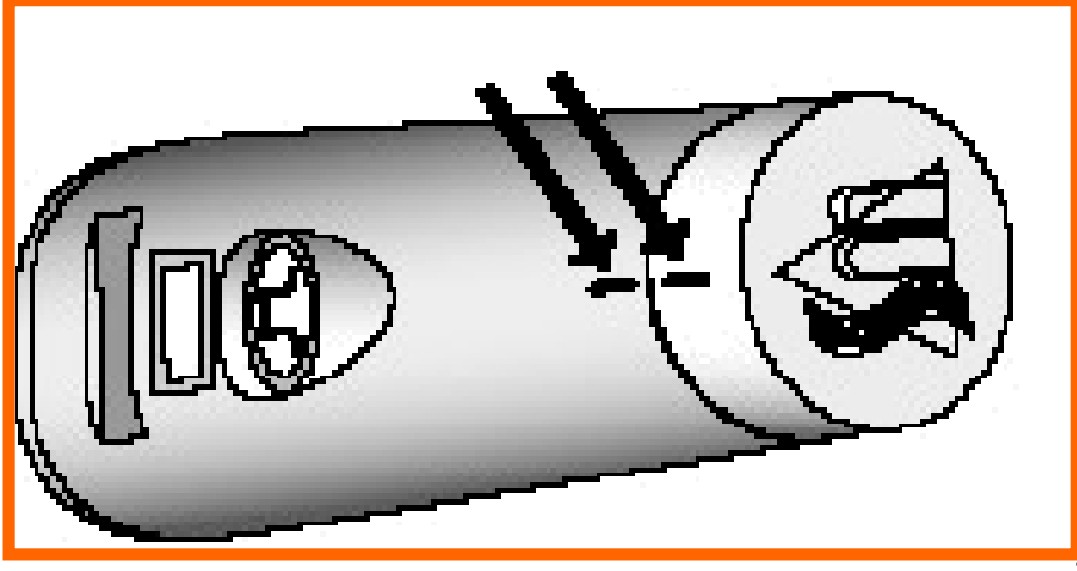
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ambIT[®] PCA & LPM Pump

Power On and Off

The pump's power is turned on by rotating the battery cover clockwise until the "slash" (/) mark on the cover lines up with the (|) mark on the pump.



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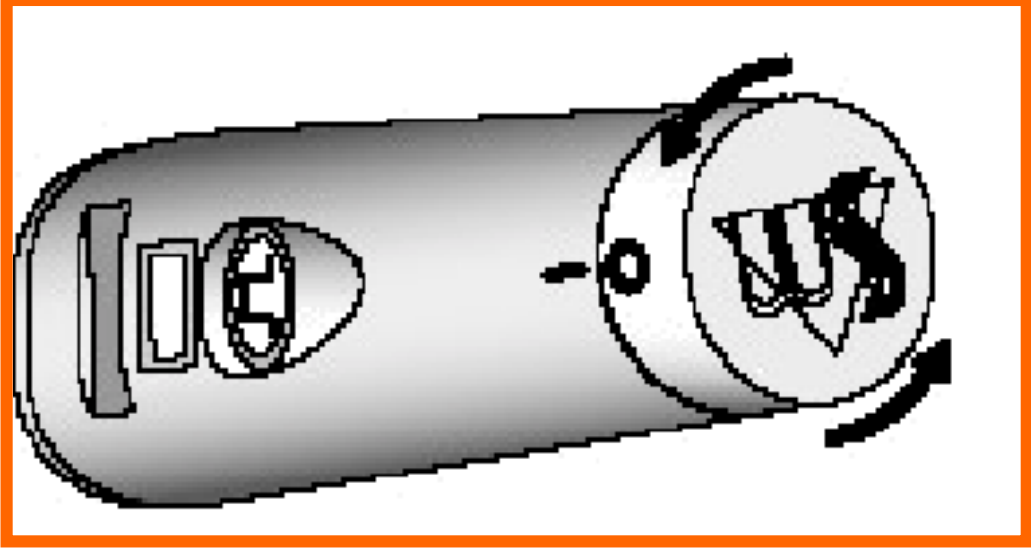
Power On and Off

To turn the pump off:

- Place the pump in pause
- Rotate the battery cover counterclockwise until the (O) mark on the cover lines up with the (|) mark on the pump.

Turning off pump without placing the pump in pause may cause loss pump history.

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Battery Replacement

To Replace Batteries:

- Place the pump in pause
- Rotate battery cover counterclockwise (slightly to the left of off (O), until the cover meets resistance)
- Remove cover and install batteries

After reinstalling batteries and pressing the Run/Pause button, the Pump will scroll through current program settings before resuming operation.

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Programming Steps

The ambIT® PCA Pump must be programmed before administering therapy

Program Parameters

- Basal infusion rate
- Bolus volume
- Bolus lockout time
- Volume to be infused

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Program Parameters

Basal Infusion Rate

The flowrate continuously provided by the pump

Rate is expressed in milliliters per hour (ml/hr)

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Program Parameters

Bolus Volume

The amount of drug infused
upon request by pressing
the Bolus button (infused at
100 mL/hr)

Bolus volume is expressed
in milliliters (mL)

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Program Parameters

Bolus Lockout Time

The time period after the last bolus delivery during which another bolus is not allowed

Bolus Lockout Time is expressed in hours and minutes (HH:MM)

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Program Parameters

Volume to be Infused

The total amount of fluid to be infused

When this amount has been infused, the “Infusion Complete” alert (1 long tone followed by 3 short beeps) will sound and the “bag” icon in the Pump display will appear. The pump will beep every four minutes after an infusion is complete.

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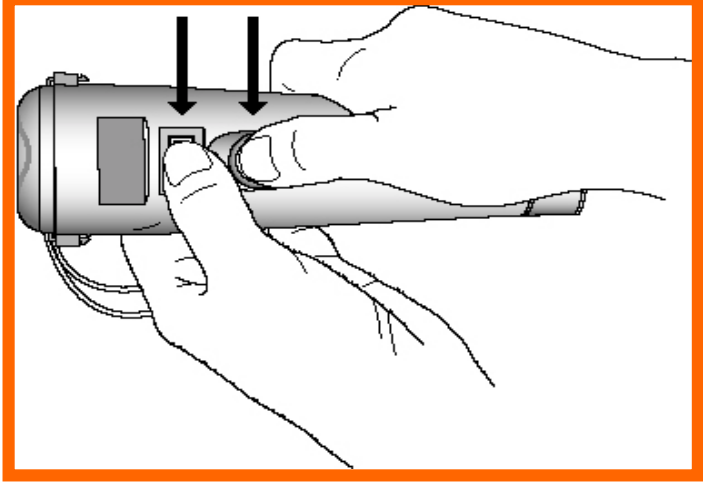
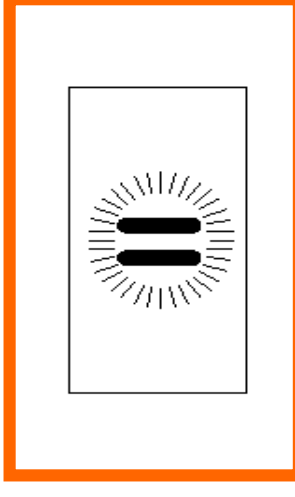
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Programming the Pump

To enter the Programming Mode:

- **Verify the pump is in the pause mode**
- **Press and hold both the Run/Pause and Bolus buttons simultaneously for two (2) seconds until one (1) beep sounds**



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Programming the Pump

➤ “PRO” will appear in the pump display



- ❖ The manual bolus button must be used to program the ambIT® PCA Pump
- ❖ The Pump must be unlocked in order to program the pump

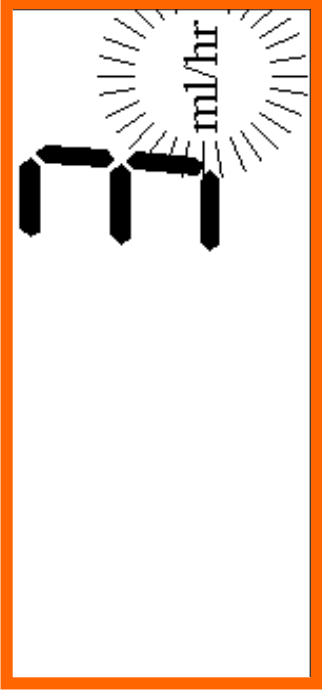
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Programming the Pump

Program Basal Infusion Rate:

- The “ml/hr” symbol will blink in the pump display
- 
- The image shows a close-up of the pump's LCD display. The display is rectangular with a black background and white text. The number '3' is displayed in a large, bold, digital font. To the right of the '3' is the unit 'ml/hr'. A small, white, vertical bar is positioned to the right of the '3', indicating a blinking cursor. The entire display area is enclosed in a thin orange border.
- The rate can be increased or decreased by using the Run/Pause button ↑ or the Bolus button ↓
 - When the desired rate appears in the display, press and hold either the Run/Pause or the Bolus button for two (2) seconds and one (1) beep sounds

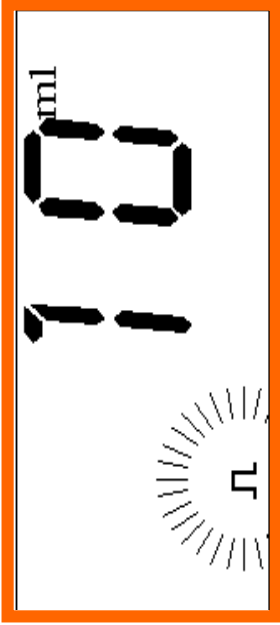
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Programming the Pump

Program Bolus Volume:

- The Bolus icon will blink in the pump display
- 
- The Bolus volume can be increased or decreased by using the Run/Pause button **↑** or the Bolus button **↓**
 - When the desired volume appears in the display, press and hold either the Run/Pause or the Bolus button for two (2) seconds and one (1) beep sounds

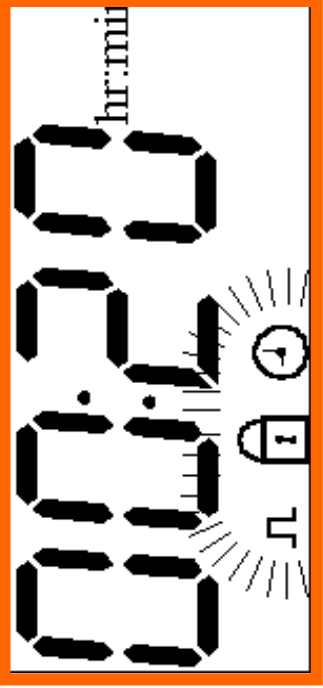
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Programming the Pump

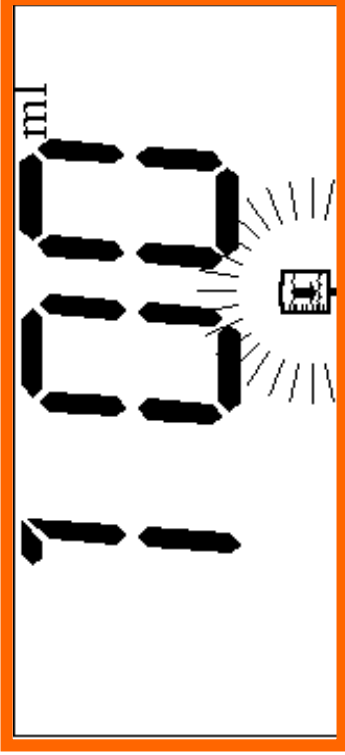
Program Bolus Lockout Time:

- The bolus icon, lock icon and clock icon will blink in the Pump display
- 
- The Bolus Lockout Time can be increased or decreased by using the Run/Pause button **↑** or the Bolus button **↓**
 - When the desired time appears in the display, press and hold either the Run/Pause or the Bolus button for two (2) seconds and one (1) beep sounds

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Programming the Pump

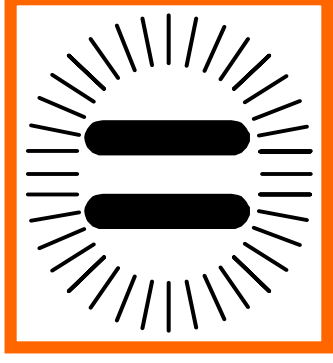
Program Volume to be Infused:

- The Bag icon will blink in the Pump display
- 
- The image shows a digital display with the number '1000' in a large, black, seven-segment font. To the right of the number is the unit 'ml'. Further to the right is a small icon of a medical bag with radiating lines emanating from it, indicating it is active or blinking. The entire display area is enclosed in a thin black border, which is itself inside a thicker orange border.
- The Volume to be Infused parameter can be increased or decreased by using the Run/Pause button ↑ or the Bolus button ↓
 - When desired volume appears in display, press and hold either the Run/Pause or the Bolus button for two (2) seconds and one (1) beep sounds

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Programming the Pump

- The pump will return to the pause mode
- To begin the programmed infusion, press the Run/Pause button



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Delivery Profiles

Infusion (basal) Rate with PCA Bolus

Set the:

- Infusion (basal) Rate
- Bolus Volume
- Bolus Lockout Time
- Volume to be Infused

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Delivery Profiles

Infusion (basal) Rate only

Set the:

- **Bolus Volume to “0”**
- **Infusion (basal) Rate (ml/hr)**
- **Volume to be Infused**

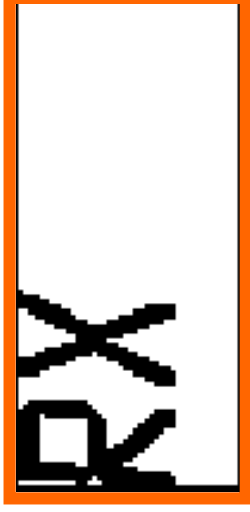
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Program Review

To perform a program review, place the Pump in Pause, then press the Bolus button



The pump will scroll through each setting to verify proper program settings

The remote bolus switch can be used to review the pump program






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Program Review

Program Review

Symbols	Parameters
ml/hr	Infusion Rate
Bolus Icon  and ml	Bolus Volume
Bolus  Lock  and Clock  Icons	Bolus Lockout Time
Bag Volume  Icon and ml	Volume to be Infused

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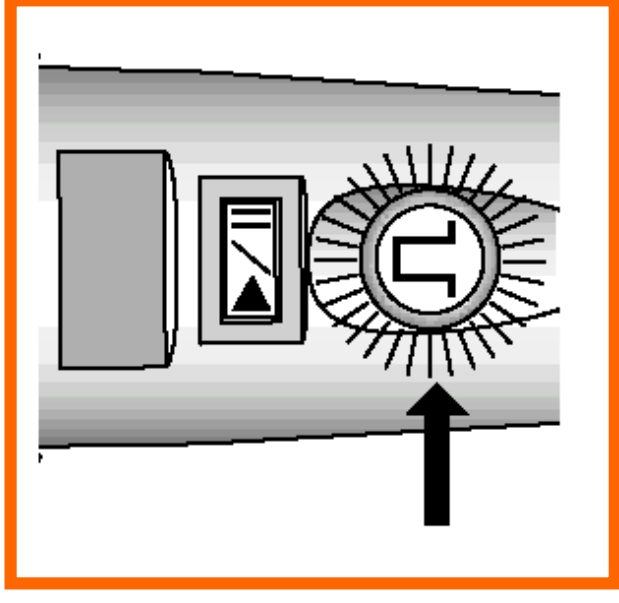
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Pump Operation

Start Infusion

- Push and release the Run/Pause button to initiate infusion
- The green run light (inside the Bolus button) will start to blink and the “ml” (volume infused) will appear in the pump display
- Periodic movement of the cassette gears is normal



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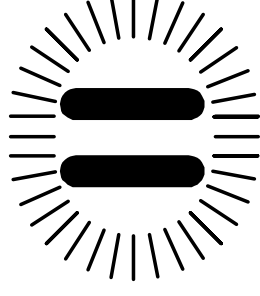
Pump Operation

Pause Infusion

- During infusion, push the Run/Pause button to pause the infusion



- Pump will beep twice, 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 minutes

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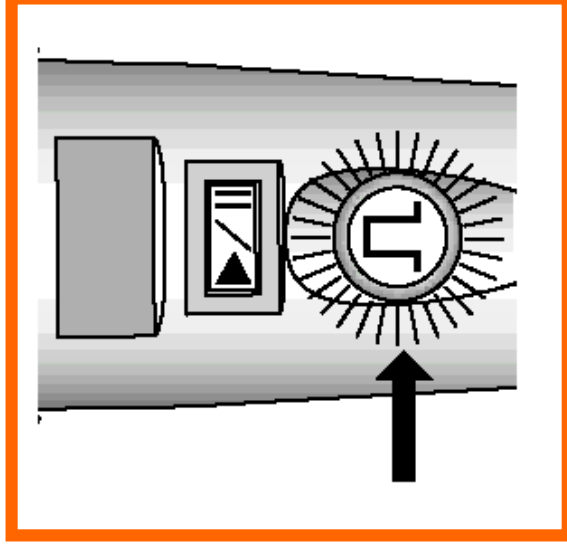
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Key Features Pump Operation

Resume Infusion

- To resume infusion after the pump is put in pause, push the Run/Pause button
- The display will show the “ml” (volume Infused) and the green run light will start to blink

The infusion will resume at the same point as when the pump was placed in pause



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Key Features Pump Operation

Silence Alarm

- Push the Run/Pause button to silence an alarm



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Key Features Pump Operation

PCA Bolus Activation

- Every time the Bolus button is pressed during the infusion, the pump will beep one (1) time.
- During bolus infusion, the green run light will double blink
- Flow rate during PCA bolus is 100ml / hr
- The remote bolus switch may be used to activate a bolus dose



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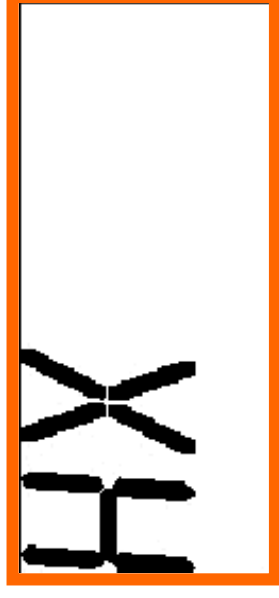
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Key Features Pump History

Infusion History Reports

To obtain an infusion history report:

- Place the pump in pause
- Press and hold down the Bolus button for two (2) seconds, until one (1) beep sounds
- “HX” will appear in pump display indicating the pump history mode



The remote bolus switch may be used to review the pump infusion history

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


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Key Features Pump History

Infusion History Reports

The pump will display the pump infusion history

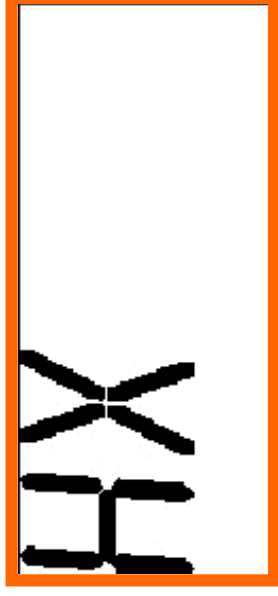
Infusion History	Visual Indicators
Total volume infused including boluses in ml	ml
Total number of boluses actually delivered	No. and 
Total number of bolus requests	No. and  Icon
Elapsed Time	 and hr:min **After 100 hours, Pump will only display hours (not minutes)

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Key Features Pump Reports

Clearing Pump History Reports

- Place the pump in pause
- Press and hold down the Bolus button for two (2) seconds (obtaining the pump history mode)



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Pump Reports

Clearing Pump History Reports

- Upon entering the pump history mode (HX), release the Bolus button and again press the Bolus button until the “HX 0” appears in the pump display.



- ❖ The manual Bolus button must be used when clearing the pump infusion history
- ❖ The Pump Program must be unlocked in order to clear the pump infusion history

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Patient Lockout Features

Level 1-Software

- The steps required for entering the ambIT® PCA Pump Program mode should not be revealed to the patient.

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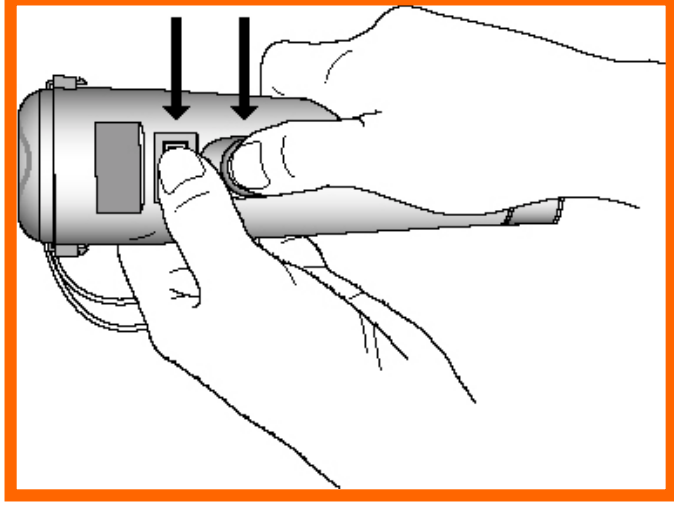
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Patient Lockout Features

Level 2-Access Code

- The software “lockout” mode is accessed by placing the pump in “pause” and entering the pump’s program mode
- Press and hold both the Run/Pause and Bolus buttons simultaneously for two (2) seconds until one (1) beep sounds



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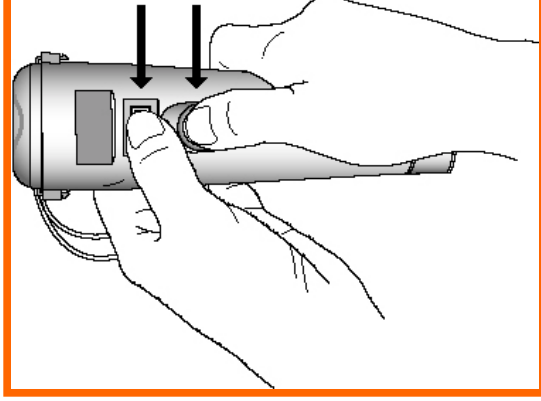
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Patient Lockout Features

Level 2-Access Code

- When the program mode is indicated on the pump's display, the clinician releases and again presses both the Bolus and the Run/Pause buttons simultaneously until one (1) beep sounds
- Four (4) Digit spaces will appear in the display (PCA)
- "LOC" will appear. (LPM)

A rectangular box containing the word "PRO" in a large, pixelated, monospace font.



A rectangular box containing four horizontal dashes "----" in a monospace font, representing four digit spaces.

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Patient Lockout Features

Level 2-Access Code

To Lock the pump

- 1. Enter a lock code between 1-4 digits**
- 2. Use the Run/Pause and Bolus buttons to select the desired number for each space**
- 3. When the desired number appears in the space, press and hold the Run/Pause button or Bolus button for two (2) seconds, until one (1) beep sounds, to select the number**
- 4. Repeat Steps 2 & 3 to program digits 2 through 4**
- 5. When the number for digit space 4 is selected, the Pump will beep (one) 1 time and return to the Pause mode with the “Lock” icon present in the pump display.**

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Patient Lockout Features

Level 2-Access Code

To Lock the pump

- Use the Run/Pause and Bolus buttons so the lock icon appears on the bottom left of the LCD.
- When the lock icon is present press and hold either the Run/pause or Bolus button for two (2) seconds.
- The pump will beep two times and go into pause mode with the lock icon present on the bottom left of LCD.

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Patient Lockout Features

Level 2-Access Code

To Unlock the pump

1. Access the Pump's "Lockout" mode
2. Enter the same lock code used to "Lock" the pump
3. Once the 1-4 digit code is entered into the pump, the pump will beep one (1) time and return to the program mode. The "lock" icon will be absent

***The universal access code is 5__5.**

If only a two (2) digit lock code is desired, the clinician enters the two digits and then presses and holds down both the Run/Pause button and Bolus button for two (2) seconds until two (2) beeps sound and the "lock" icon appears in the display

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Patient Lockout Features

Level 2-Access Code

To Unlock the pump

1. Access the Pump's "Lockout" mode
2. Press either the Run/Pause or the Bolus button so the lock icon disappears from the LCD.
3. Once lock icon is absent from the LCD, press and hold either the Run/Pause or Bolus button for ~ two (2) seconds.
4. The pump will beep twice and will go into pause mode. The "lock" icon will be absent from the LCD.

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General Care Instructions

- Do not drop the pump or allow the pump to get wet
- Operating conditions: 10°C to 43°C (50° F and 110° F)
- Do not store in freezing temperatures: -7°C (20°F)
- Do not expose to direct sunlight or excessive heat 70°C (158°F)

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General Care Instructions

To CLEAN:

The pump can be cleaned by wiping its surface with a slightly damp cloth.

If necessary, mild detergent soaps can be used.

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Dedicated to promoting superior pain control for those in harm's way.

ambIT® MARAA PCA Pump

General Care Instructions

To DISINFECT:

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

- A fresh solution of one part household bleach to nine parts water
- 70% isopropyl alcohol
- Equivalent disinfectant product

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ambIT® MARAA PCA Pump

STORAGE INSTRUCTIONS

To store Pump between patient use:

- **Clear infusion history**
- **Remove batteries**
- **Clean and/or disinfect appropriately**
- **Replace protective cap (pressure switch is delicate and can be easily damaged)**
- **Store pump in a dry, cool place**

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