CADD™

Operator's Manual

This online version differs from the printed version.

Certain information that is not intended for patients has been removed.

CADD-MS™ 3 Ambulatory Infusion Pump
Model 7400

smiths medical

Updates to the manual

The following updates were made to this version (40-5470-51C) of the *User Manual.* The specific pages affected by the changes are shown.

For your safety, review the manual carefully, including all warnings and cautions. If you don't understand something, contact your clinician, your pump provider, or Smiths Medical.

Summary of updates	Pages
Warning regarding tightening the battery cap	3, 10, 16, 62, 80
Inspecting the battery cap	17, 80
Added illustrations	9,17, 80
WEEE Warning	16, 81
WEEE Statement	81

This manual provides information on programming, using and maintaining the CADD-MS™ 3 Ambulatory Infusion Pump. This manual is intended for clinicians only. DO NOT permit patients to have access to this manual. DO NOT disclose the pump's security pass codes or any other information that would allow inappropriate access to programming and operating functions.

The issue date of this manual is included on the back cover. If your manual is a year or more old, contact Smiths Medical MD, Inc. (or check the web site at www.smiths-medical.com) to see if a newer manual is available.

If you have comments, questions, or problems...

If you have comments or questions about the pump, please call the appropriate number given below. You will be asked for the pump's serial number, which you will find on the back of the pump.

Our staff is available to help you 24 hours a day with programming and operation of the pump.

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Important safety information

WARNING: Read this entire manual before using the CADD-MS™ 3 Ambulatory Infusion Pump. If you do not understand something or have any questions, contact Smiths Medical MD, Inc. Incorrect use of this pump, failure to follow the instructions and important information contained in this manual, or improper/ inadequate troubleshooting can lead to death or serious injury. Warnings, cautions and other important safety information can be found in this section, and in bullet form throughout the manual (indicated by the ⇨ symbol). The Help section (starting on page 51) contains information on troubleshooting the pump and other important information.

Warnings

- ⇨ **This manual is designed for clinicians and contains all of the information needed to fully program the pump.** Do not give this manual to patients as it would allow them complete access to all programming information.
- ⇨ **The CADD-MS™ 3 Ambulatory Infusion Pump is designed for subcutaneous, intravenous, epidural and intrathecal infusion of medication.** DO NOT use with blood or cellular blood products. Use the pump only as instructed in this manual.
- ⇨ **This manual describes how to use and troubleshoot the CADD-MS™ 3 pump. Smiths Medical MD, Inc. does not, however, make any recommendations about any specific programming related to any therapy.** Whether certain features are appropriate for an individual patient must be determined before use. Before using the pump, the patient must receive appropriate training in all its functions and in troubleshooting problems.
- ⇨ **To avoid a risk of explosion**, do not use the pump in the presence of flammable anesthetics or explosive gases.
- ⇨ **System delivery inaccuracies may occur as a result of backpressure or fluid resistance, which depends upon drug viscosity, catheter size, and extension set tubing**.
- ⇨ The CADD-MS™ 3 pump and accessories include small component pieces that **could pose a choking hazard to small children**.
- ⇨ Before going to bed, the patient should **make sure the cartridge contains enough medication to last through the night**. Do not use the **Vibrate** alarm at night. If the patient is a very deep sleeper, they may want to set the audio volume to High (the loudest setting) before going to bed.
- ⇨ **There are potential health hazards associated with improper disposal of batteries, electronics, and contaminated (used) infusion sets and cartridges.** Dispose of used batteries, infusion sets, cartridges, and other used accessories, or a pump that has reached the end of its useful life, in an environmentally safe manner, and according to any regulations that may apply.

2 Important Information

- **If there are any system problems during the self tests, the pump will stop the tests and display an alarm screen letting you know there is a problem. If this happens, do not use the pump.**
- **The cartridge cap, battery cap, and luer connections are not childproof.** Tampering with them can result in over- or under-delivery of medication.
- **The time and date must be set correctly, since delivery factors are time-based, and all history is stored based on time and date**. Occasionally the time will need to be reset, for example, during daylight savings time or to adjust for a different time zone.
- **Do not allow the patient to learn the pass code.** The pass code allows access to all delivery programming and security settings.
- **If you choose not to require pass codes to access the Setup and Delivery Program menus, the patient will have full access to all programming and delivery functions.**
- **Always use the pump's Load feature when starting a new cartridge**. This will assure that the cartridge is properly loaded and the infusion or extension set is filled with medication.
- **Always use aseptic technique, particularly when working with the cartridge, infusion set, catheter and access site to minimize the risk of infections**.
- **The CADD-MS™ 3 pump and cartridge are not a secure system.** Patient must be assessed for appropriateness of pump usage.
- **Always read the Instructions For Use** provided with the medication, cartridge, infusion set, and any other accessory used with the CADD-MS™ 3 pump.
- **To avoid accidentally infusing medication or causing backflow of blood from the access device (or site), disconnect the tubing from the access device (or site) before removing a used cartridge or replacing an infusion set**. Never use the pump's **Load Cartridge** or **Fill Tubing** features while tubing is connected to the patient, or an unintended dose of medication can be delivered.
- **If not properly tightened, medication could leak from the cartridge and tubing connections and disrupt delivery**. Signs of leakage can also mean opportunity for contamination leading to infection.
- **Never use Fill Tubing when the infusion set is connected to the body**, or an unintended dose could be delivered.
- **Always remove all air from the cartridge and infusion set before starting medication delivery. Air bubbles in the system can slow or stop medication delivery**. Check all connections carefully for leaks, as leakage can slow or stop medication delivery to the body, and allow an opening for contamination leading to infection.

- ⇨ **You should provide specific training on delivering a dose**.
- ⇨ **If the pump is dropped or hit against something hard, always inspect it carefully to make sure it is still working properly**. Make sure the display is working correctly, and the cartridge, cartridge cap, battery cap and infusion set are connected correctly. If there is damage to the pump's outer shell (cracks, chips), the pump may no longer be watertight.
- ⇨ **Make sure that the battery cap is fully tightened to avoid an interruption in battery power which can cause the pump to power down and stop the delivery of drug therapy. A prolonged interruption in the delivery of drug therapy can result in serious patient injury or death.**
- ⇨ **If the display has missing or incomplete characters, or if the pump does not seem to be working correctly, stop using the pump immediately**. Contact Smiths Medical MD, Inc. for information on servicing the pump.

Cautions

- ⇨ **Avoid strong electromagnetic fields, like those present with Magnetic Resonance Imaging (MRI) and direct x-ray, as they can affect how the pump works.** If you cannot avoid them, the pump and pouch must be taken off.
- ⇨ **Do not expose the pump directly to ultrasound**.
- ⇨ **Do not use the pump in a hyperbaric chamber** as this may affect how the pump works and may also cause damage to the pump.
- ⇨ **Do not use cell phones within six (6) inches (15 cm) of the pump**. Interference with the pump electronics by cell phones can occur. If a cell phone interferes with the pump, the pump will generate a System Fault alarm.
- ⇨ To avoid damage when storing the pump, first remove the battery and cartridge. Place the pump in the original carton and keep it away from cold, heat, and dampness. After 30 days, any pump programming will be lost and you will need to reprogram it.
- ⇨ The pump may experience problems if operated in conditions where temperatures are lower than 35.6°F (2°C) or higher than 104°F (40°C), when relative humidity (non-condensing) exceeds 90%, and when atmospheric pressure is lower than 10.2 psi (70 kPa) (10,000 feet above sea level) or higher than 15.4 psi (106 kPa). If you experience problems, remove the pump from use.
- ⇨ The pump may be damaged if stored in environments where temperatures are lower than –4°F (–20°C) or higher than 140°F (60°C), when relative humidity (non-condensing) exceeds 90%, and when atmospheric pressure is lower than 10.2 psi (70 kPa) (10,000 feet above sea level) or higher than 15.4 psi (106 kPa).
- ⇨ **Do not use NiCd, nickel metal hydride, carbon zinc (heavy duty), lithium or any rechargeable batteries**. They will not power the pump properly, and the battery life indicator on the home screen may not show the correct amount.

- ⇨ **Use only Smiths Medical MD, Inc. 3 ml Medication Cartridges**; other manufacturers' products will not work with the CADD-MS™ 3 pump.
- ⇨ **Never use abrasive cleaners, solvents, bleach, scouring pads or sharp instruments when cleaning your pump, as they can scratch, discolor or damage the pump's outer shell**. If the display is scratched, it may be difficult to read and you will need to have it replaced. If the outer shell is chipped or cracked, it may no longer be watertight and will require service.
- ⇨ **Never use steam or very hot water (exceeding 120°F [49°C]) in an attempt to sterilize the pump. Never put your pump in the dishwasher**. Exposing the pump to these high temperatures could damage the pump's electronics and result in the need to service your pump.

Explanation of symbols

Below is a list of symbols you will see on the CADD-MS™ 3 pump, packaging, and accessories, as well as explanations of what the symbols mean.

SN	Serial number
	Attention! See instructions for use
	Type CF equipment (protection from electric shock)
IPX8	Watertight when submerged to 8 feet (2.4 meters) for 30 minutes or to 12 feet (3.6 meters) for 3 minutes
	Date of manufacture
	Use by
	On Pump Display: Wait
Rx ONLY	**Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician
REF	Catalog number
CE 0473 or CE	Indicates that the product was designed and manufactured in accordance with applicable standards/guidelines and may be sold in the EU (European Union)

Appears in pump display, with a message, to indicate a question you must answer before programming can continue

Appears in pump display, along with a message, as an indicator of an alarm condition.

Collect separately

Latex free

Press ▲ or ▼ keys to move through menu/settings

Top of menu; press ▼ key to move through menu

Bottom of menu; press ▲ key to move through menu

Approximate volume of medication left in cartridge

Approximate battery life remaining

CR Continuous Rate home screen

AD Automatic Dose home screen

DD Demand Dose home screen

SR Site Reminder home screen

Empty cartridge or low battery

Keep dry

Fragile, handle with care

Keep away from sunlight

Temperature limitation

⇨ Important safety information, warnings and cautions

da Dansk

de Deutsch

el Ελληνικά

en English

es Español

fi Suomi

fr Français

it Italiano

nl Nederlands

no Norsk

pt Português

sv Svenska

5 Important Information

Introduction

The CADD-MS™ 3 Ambulatory Infusion Pump provides measured medication therapy to patients in hospital or outpatient settings. Any medication therapy must be overseen by a physician or certified, licensed healthcare professional.

Indications

The CADD-MS™ 3 pump is a syringe-based ambulatory infusion pump designed for subcutaneous, intravenous, epidural and intrathecal infusion of medication.

Contraindications

The pump is not indicated for anyone who cannot follow the instructions for use or perform basic troubleshooting and maintenance activities associated with ambulatory pump use.

Delivery features

The pump can be used to deliver medication in two ways, as a continuous rate and as an added dose.

Continuous Rate

The pump can be programmed to deliver a steady flow of medication called the **Continuous Rate**. You can program up to 48 time/rate segments per 24 hour period to meet the patient's medication needs throughout the day and night.

Doses

The pump can deliver two types of doses, an Automatic Dose (programmed to deliver a specific dose at a preprogrammed time) as well as Demand Dose (delivered by the patient as needed). You can also program lockout times so that you can control the time between doses.

Other features

The pump has a large display (or screen) where all programming, operating and alarm information is displayed. Programming of the pump is menu-driven, like an ATM or cell phone.

The pump is powered by one AAA (IEC LR03) alkaline battery, which is readily available at most grocery stores, hardware stores, drug stores, and electronic stores. The expected battery life is approximately 2 weeks (battery low alert) at 0.124 ml/hr.

⇨ **Caution: Do not use NiCd, nickel metal hydride, carbon zinc (heavy duty), lithium or any rechargeable batteries**. They will not power the pump properly, and the battery life indicator on the home screen may not show the correct amount.

As long as the pump's labels and outer shell are intact, the pump is watertight to a depth of 8 feet (2.4 meters) for 30 minutes or 12 feet (3.6 meters) for 3 minutes.

Pump and delivery history is automatically tracked by the pump, and can be viewed in the **History** menu (see page 44).

The pump has a Security feature which allows you to lock out the Setup and Delivery Program menus. This feature helps prevent tampering with the programming of the pump.

The pump requires the use of the Smiths Medical 3 ml Medication Cartridge and an infusion set (any manufacturers' infusion set can be used, as long as it has a standard luer lock to connect to the cartridge).

Glossary of Terms

The following is a list of terms used throughout this manual:

Automatic Dose: Automatic Doses are programmed amounts of medication delivered at specific times of the day.

Continuous Rate: The amount of medication delivered continuously over 24 hours a day, providing delivery of medication at all times. The continuous rate is measured in *milliliters per hour* (ml/hr).

Cannula: A small, soft tube or needle, inserted into the body, through which medication is delivered.

Cartridge: The container that holds the medication. The Smiths Medical 3 ml Medication Cartridge looks like a small syringe.

Demand Dose: A Demand Dose is an extra programmed amount of medication initiated by the patient as needed.

Dose: An extra amount of medication given at specified times and or as needed.

Fluid path: The areas inside the cartridge and infusion set that come into direct contact with the medication. These areas include the inside of the tubing and connectors, the inside and tip of the needle and cannula, and the inside and tip of the cartridge. To help protect against infection, never touch or blow directly on any part of the fluid path.

Infusion pump: A small electromechanical medical device designed specifically for delivering precise amounts of medication into the body. The CADD-MS™ 3 pump systems are controlled by two microprocessors (computer chips) which continuously monitor each other to make sure the systems are working properly.

Occlusion: Blockage. Occlusions are associated with the infusion set and/or access site, and mean that medication delivery is stopped. Blockage can be caused by a number of things, including the tubing being pinched or kinked, the cannula or needle being blocked, as well as other reasons.

Pushrod: On the CADD-MS™ 3 pump, the cartridge is attached to the pushrod and, when the pump is started, the motor causes the pushrod to move forward and push medication through the infusion set into the body.

Pump illustrations

Figure 1

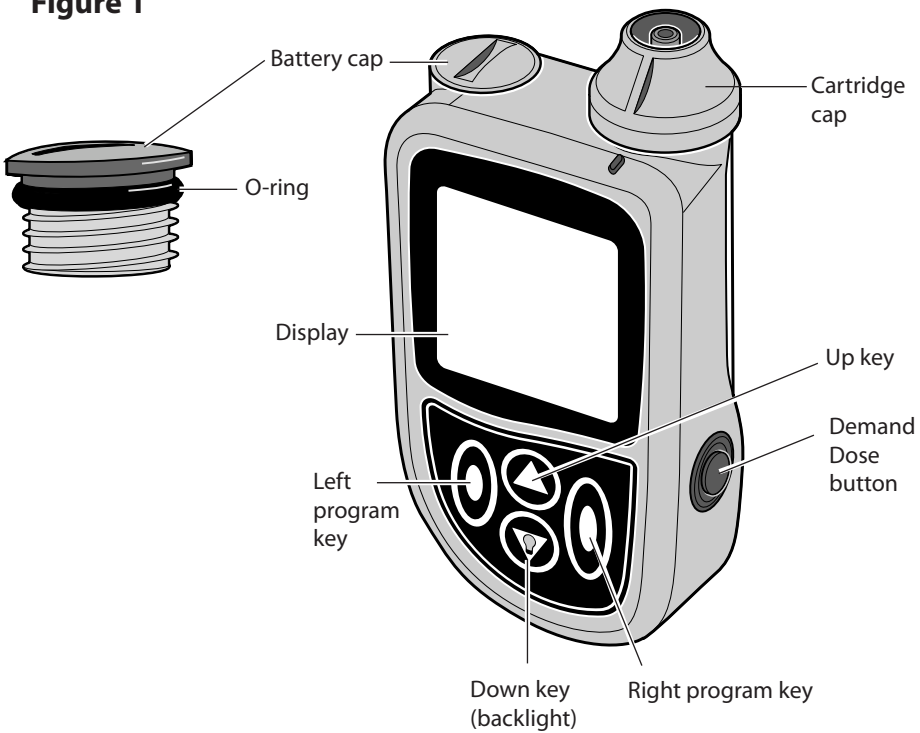
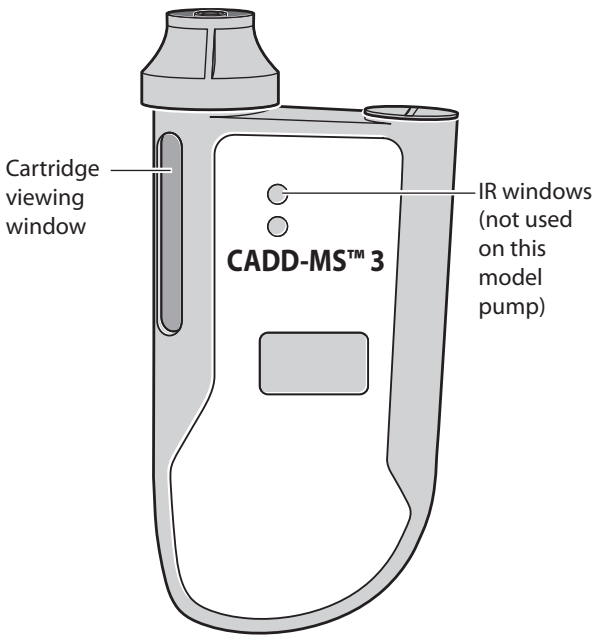


Figure 2



Description of features and buttons

Battery cap with o-ring (Figure 1)
Holds the battery in place in the battery compartment. The pump uses one AAA (IEC LR03) alkaline battery. The approximate amount of battery life is displayed in the home screen, and an alarm is given when battery power is low. Keep extra batteries on hand.

⇨ **Warning: Make sure that the battery cap is fully tightened to avoid an interruption in battery power which can cause the pump to power down and stop the delivery of drug therapy. A prolonged interruption in the delivery of drug therapy can result in serious patient injury or death.**

Display (Figure 1)
The display (also referred to as the screen) shows all the programming, operating and alarm/alert information for the pump.

Programming keys (Figure 1)
There are two keys on the front of the pump right below the display that do not have any names or symbols on them. These are the programming keys. They have different functions, depending on where you are in a menu. In the display right above each key is a short description of what happens if you press it. **(Always look to the display above each key to see what the key is used for.)**

▲ and ▽ keys (Figure 1)
The ▲ and ▽ keys are used to move around in menus, and to program amounts. Whenever you can use the up and down keys, the symbol ▲▼ is shown in the bottom, middle part of the display. When you are at the top or bottom of a menu, only one of the keys can be used, and the symbol will change to ▼ or ▲, respectively.

Demand Dose button (Figure 1)
If Demand Doses are allowed, the user can press the Demand Dose button to initiate a dose.

Cartridge cap (Figure 1)
Once you load a filled cartridge into the compartment, press and turn the cartridge cap over the top of it to hold it firmly in place. You can look at the cartridge viewing window (Figure 2) to make sure the cartridge is properly loaded, and to periodically check the amount of medication left in the cartridge.

Infrared (IR) windows (Figure 2)
The IR windows allow the pump to communicate with a PC or other IR accessory. There is no IR functional capability available with this model pump.

Features

Vibration alert
If you don't want the pump to beep during alarms and alerts, you can program it to vibrate instead. This feature can be used in meetings, classrooms, etc. If you choose Vibrate, the "beep" that accompanies each key press is also disabled. The battery is used much more quickly when you use Vibrate.

Occlusion (blockage) sensor
The occlusion sensor continuously tests for blockage that prevents medication from being delivered.

Cartridge sensor
There is a sensor in the cartridge chamber that has two functions. It senses when a cartridge is correctly loaded in the chamber. If the cartridge becomes loose or detached during use, the sensor causes an alarm to occur. When you load a new cartridge into the pump, the sensor also measures how much medication is in the cartridge, and displays this information in the upper left part of the home screen.

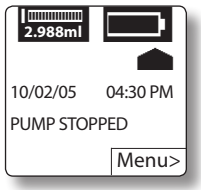
Watertight
As long as the pump's labels and outer shell are intact the CADD-MS™ 3 pump is watertight to a depth of 8 feet (2.4 meters) for 30 minutes or 12 feet (3.6 meters) for 3 minutes.

History
The pump has a History feature that displays a variety of delivery history information.

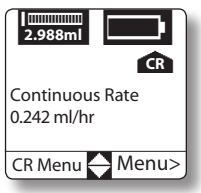
Description of pump display and menus

All programming, operating and alarm/alert information is shown in the display. Programming of the pump is menu driven, like a cell phone or ATM.

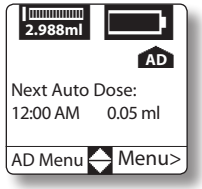
The **Home** screen shows various information relating to pump operation. If all of the delivery types are turned off, the home screen at right is shown. Depending on which features you are using, one or more of the following home screens will be shown:



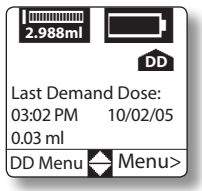
• The **Continuous Rate** (CR) home screen shows the current continuous rate being delivered. This home screen will only be visible if Continuous Rate is set to **Yes** (in use) in both the Setup and Delivery Program menus. You can also access the Continuous Rate menu from this home screen (see page 47).



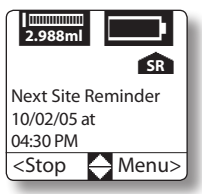
• The **Automatic Dose** (AD) home screen shows when the next automatic dose is scheduled to be delivered. This home screen is only visible if Automatic Dose is set to **Yes** (in use) in both the Setup and Delivery Program menus. You can also access the Automatic Dose menu from this home screen (see page 48). When an Automatic Dose is being delivered, the screen will show, "**Auto Dose Active**".



• The **Demand Dose** (DD) home screen shows the amount, time, and date of the last demand dose programmed. This home screen is only visible if Demand Dose is set to **Yes** (in use) in both the Setup and Delivery Program menus. You can also access the Demand Dose menu from this home screen (see page 49). When a Demand Dose is being delivered the screen will show, "**Demand Dose Active**".



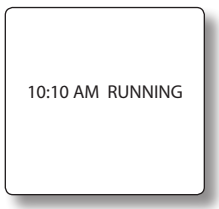
• The **Site Reminder** (SR) home screen shows the date and time of your next programmed site reminder alert. This home screen will only be visible if set to **Yes** (in use) in the **Setup** / **Alerts** menu. If you haven't programmed another site reminder, it shows when the previous one occurred.



A variety of symbols appear on the screen. For example, any time you have to answer a question before proceeding, the question appears on the screen accompanied by [?]. Alarms and alerts are accompanied by [!]. If the pump is performing a task which takes a little time, you will see ⧗.

Screensaver and backlight

The screensaver allows the pump to save on battery power. When you are at the home screen and no keys or buttons are pressed for 15 seconds, the screensaver display appears. The screensaver shows the time and whether the pump is running or stopped. Press any key on the keypad to deactivate the screensaver and return to the home screen. Pressing the ▽ key turns on the screen backlight; the backlight automatically turns off when the screensaver reactivates. You can only turn on the backlight from screensaver. When the motor is running, the backlight blinks.



Menus

To choose a menu item, press the △ or ▽ key to highlight the item you want, then press **Select**.

Editing values

Screens with a single field: press the △ or ▽ key to change a value, then press the < or > key to save it or continue editing or move to another screen.

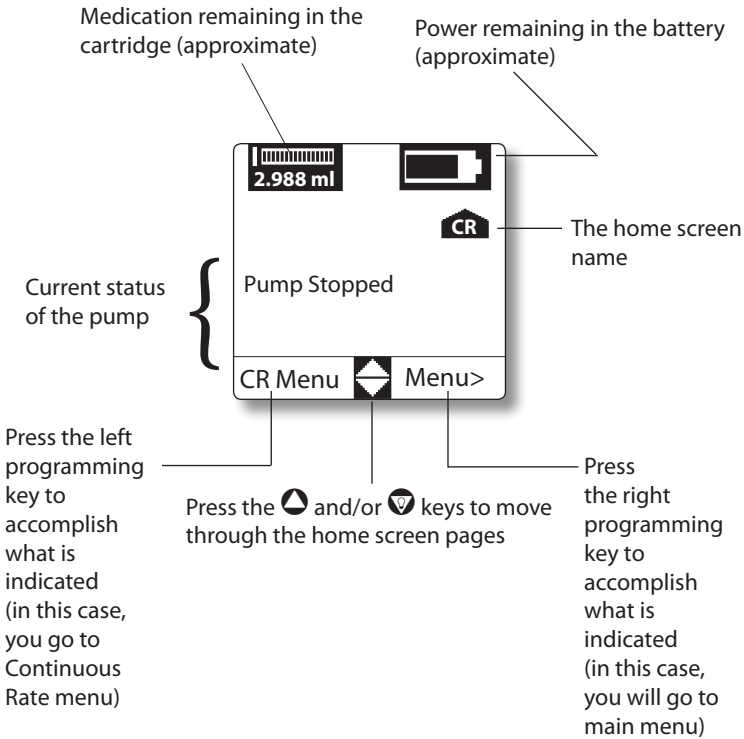
Screens with more than one field: press the > key (**Next**) to move to the field you want to change, and then press the △ or ▽ key to change the value. On some screens pressing the < key (**Done**) will save your changes and move to another screen. On others, pressing the < key (**Back**) will save the value in the field and move to the previous field on the screen. There are two exceptions: 1) where your changes take effect only when you exit the screen, and 2) the New Patient Screen and the Enable Delivery Methods screen.

⇨ **Warning: Because the method of saving values varies by screen, it is essential that you review the program before beginning delivery.**

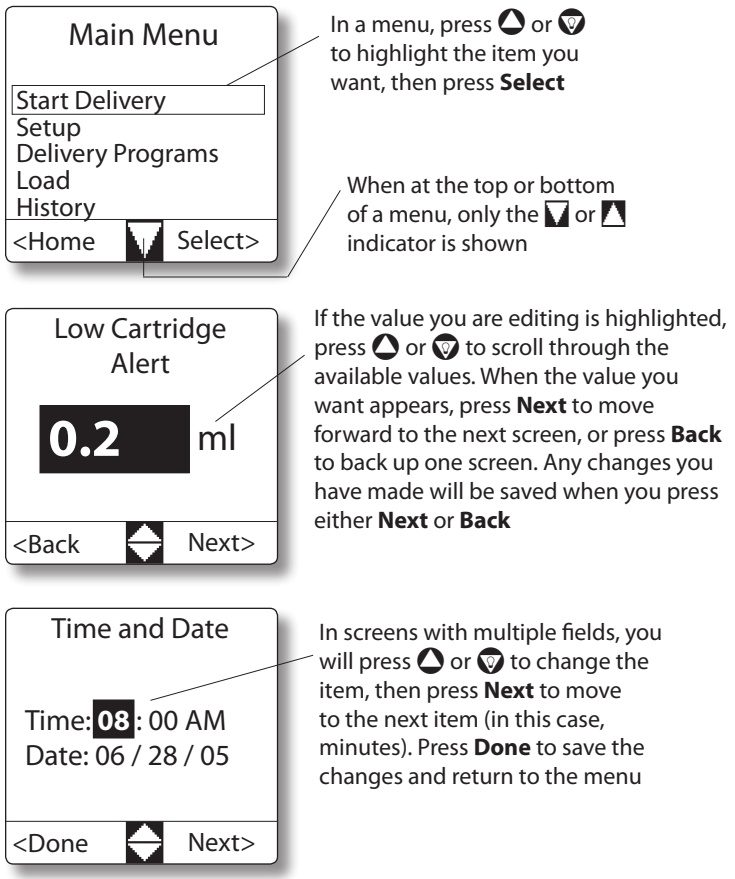
Timeout feature

If you change a value using the △ or ▽ key and then decide you don't want to change it after all, wait 45 seconds and the field will return to its original value. Warning beeps or vibrations will let you know that this is happening.

14 Programming the Pump



Home screen example



Sample screens

Accessories

Smiths Medical offers a variety of products for use with your pump.

Cartridge

You must use the Smiths Medical 3 ml Medication Cartridge (catalog number 21-7450) with the pump. Smiths Medical cartridges are latex free.

⇨ **Caution: Use only Smiths Medical 3 ml Medication Cartridges**. Other manufacturers' products will not work with the CADD-MS™ 3 pump.

Infusion sets

You can use any manufacturer's infusion set as long as it has a standard luer lock to connect to the Smiths Medical 3 ml Medication Cartridge.

Before using the pump for the first time

Inserting a battery, programming the regional settings (if required), and setting the time and date are the first things you need to do when you get the pump. The expected battery life is approximately 2 weeks (battery low alert) at 0.124 ml/hr (the **Vibrate** alert uses up battery power faster).

Insert a battery

1. Put the side of a smooth-edged coin into the slot on the battery cap and turn it counterclockwise (left) to open it (see Figure 3). Remove the old battery (if present). Discard used batteries according to local laws and requirements.

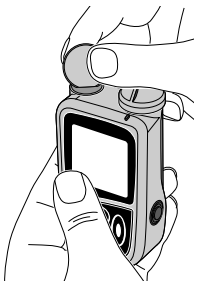


Figure 3

⇨ **Warning: There are potential health hazards associated with improper disposal of batteries, electronics, and contaminated (used) infusion sets and cartridges. Dispose of used batteries, infusion sets, cartridges, and other used accessories, or a pump that has reached the end of its useful life, in an environmentally safe manner, and according to any regulations that may apply.**

2. Insert one AAA (IEC LR03) alkaline battery into the compartment, making sure the + side goes in first (see Figure 4); if you insert the battery wrong, the pump will not start.

Figure 4

⇨ **Caution: Do not use NiCd, nickel metal hydride, carbon zinc (heavy duty), lithium or any rechargeable batteries.** They will not power the pump properly, and the battery life indicator on the home screen may not show the correct amount.

3. Place the battery cap back over the compartment. Push down and turn the cap clockwise (right). Again use a smooth-edged coin to tighten the cap.

⇨ **Warning: Make sure that the battery cap is fully tightened to avoid an interruption in battery power which can cause the pump to power down and stop the delivery of drug therapy. A prolonged interruption in the delivery of drug therapy can result in serious patient injury or death.**

Make sure that the battery cap is fully tightened. The battery cap is fully tightened when the battery cap o-ring is not visible, the cap fits snug, and when you press on the battery cap the pump does not produce a "chirp" (see Figures 5 and 6). If the pump sounds a brief alert ("chirp"), the cap **is not fully tightened** and should be tightened further. If you are unable to tighten the cap and eliminate this chirp, the pump should not be used. Contact your pump provider or Smiths Medical.

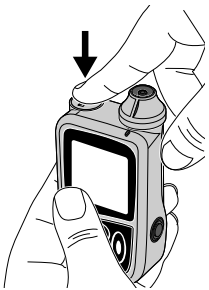


Figure 5

Inspect the Pump's battery cap. The battery cap should be free of damage. If the cap shows signs of wear, such as cracks, or if the slot becomes worn, the battery cap should be replaced before the Pump is used. Contact your Pump provider or Smiths Medical for a replacement battery cap.

If you insert a new battery and the pump doesn't turn on, check to make sure that the battery is in the correct orientation (the + side goes in first. If it still doesn't turn on, try a new battery.

Once the battery is correctly inserted, the pump turns on automatically and performs self tests to make sure all the systems are working properly.

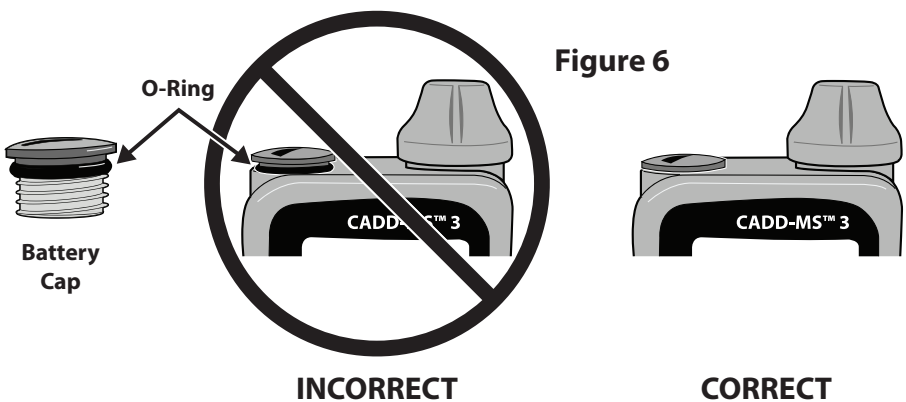


Figure 6

Self Tests

During the self tests, the pump's internal computer performs tests on all the major hardware, computer, and electronic systems.

⇨ **Warning: If there are any system problems during the self tests, the pump will stop the tests and display an alarm screen letting you know there is a problem. If this happens, do not use the pump.**

After installing a new battery, watch the pump's display and verify the following:

- The internal computer's software version appears, as well as the pump serial number and last error code (if any).
- The entire display becomes a darker gray. Look for any blank or incomplete areas, which indicates a broken display. The display then briefly goes blank; if the entire display is not blank, it indicates a broken display.
- The pump's internal computer tests the major hardware, computer and electronic systems. If there is a problem with any system, an alarm occurs and you will not be able to start delivery.

When the self tests are complete, power up ends and the pump beeps six times.

The first time you insert a battery and a new pump performs the self tests, you will see the following alert screens:

• A screen will appear that reads, "**Program Defaulted** Set time and date". Program the current time and date by pressing ▲ and ▼ to set the highlighted value, then pressing **Next** to move through the sequence. When the time and date are correct, press **Done**.

• Next you will see a screen that reads, "**Program Defaulted** You must program the pump". Press **OK**.

• After the pump beeps 6 times, a screen that reads, "**Cartridge removed** Press OK to begin load process" is displayed. Press **OK**; the pump goes to the **Cartridge** menu. If you are ready to load a cartridge, follow the steps indicated starting on page 31. If you aren't ready to load a cartridge yet, press **Done**.

NOTE: The pump has a built-in internal battery that powers the clock and allows the pump to store the programs and history (see page 69) which is charged by the AAA alkaline battery. If your internal battery has not been charged for awhile, you may see a screen that reads, "**Program Defaulted** Setup of cartridge volume required, with no cartridge present, press Next". Make sure no cartridge is loaded into the pump and press **Next**.

Setup

The **Setup** menu is where you perform certain setup functions, such as determining which delivery types should be available, setting the time and date, setting a new patient marker, setting pump security, setting up how the pump alarms for certain features and programming the local formats.

⇨ **Warning: The time and date must be set correctly, since delivery factors are time-based, and all history is stored based on time and date.** Occasionally you will need to reset the time, for example, during daylight savings time or to adjust for a different time zone.

The Setup menu looks different depending on whether the pump is running or stopped. Any menu items associated with delivery will only appear in the menu when the pump is stopped.

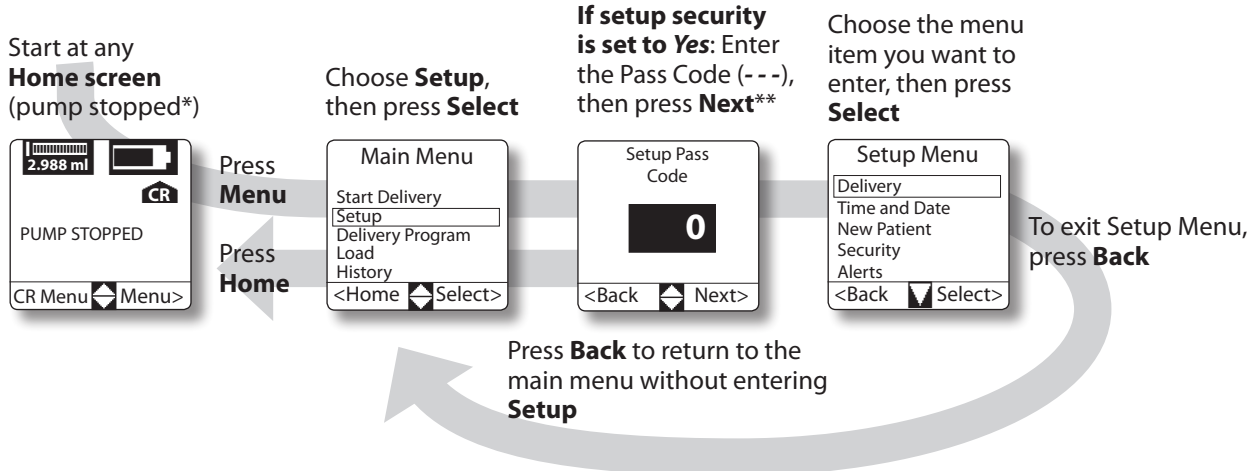
At the home screen, press **Menu**. Press ▽ to choose **Setup**, then press **Select**.

If security is set to **Yes** for the **Setup** menu, you will need to enter a pass code. This is to prevent the patient from having complete access to all pump programming.

⇨ **Warning: Do not allow the patient to learn the pass code.** The pass code allows access to all delivery programming and security settings.

Once inside the menu, you can choose between the various items. Once you have entered a menu item, you can either make a change to an item (use the △ and ▽ keys until the setting you want is displayed, then press **Next**), or press **Next** to accept the displayed value.

Opening the Setup Menu



* If the pump is running when you enter the Setup menu you will not have access to the full menu. Only the Security, Alerts and Local Formats menu items will appear.

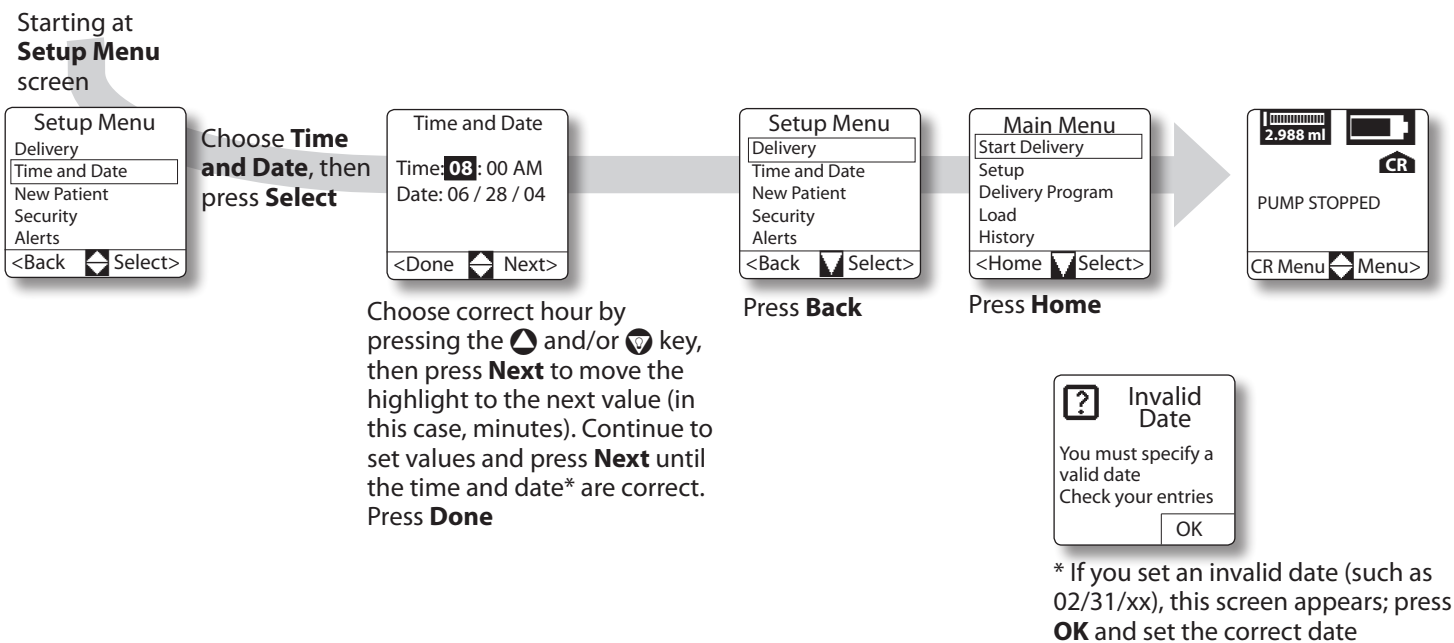
** Once the Pass Code has been entered, it remains in effect until the pump's screensaver activates.

Setup Menu - Time and Date

⇨ **Warning: The time and date must be set correctly, since delivery factors are time-based, and all history is stored based on time and date.** Occasionally you will need to reset the time, for example, during daylight savings time or to adjust for a different time zone.

NOTE: If the pump is programmed to display a site reminder alert (see page 23), resetting the time may cause that alert to occur sooner or later than expected (up to 24 hours), depending on how far forward or back you set the time.

Time and Date is only available when pump is stopped.



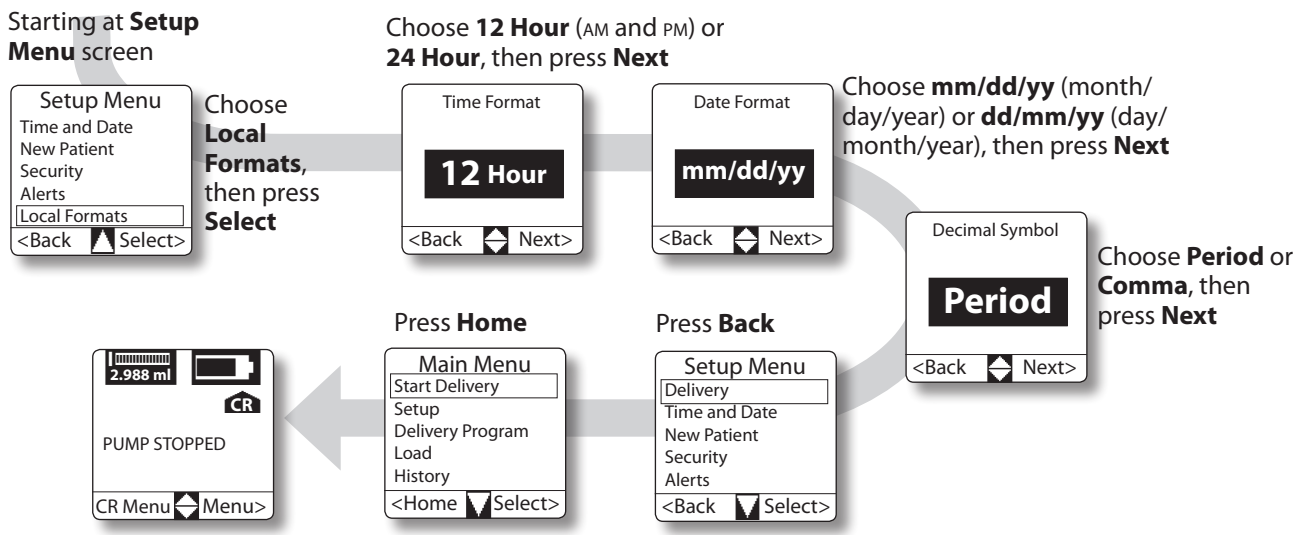
Setup Menu - Local Formats

Local Formats determine how certain things are displayed on the pump.

- Time can be displayed as 12 hour (AM and PM) or 24 hour.
- The date can be displayed as month/day/year (mm/dd/yy) or day/month/year (dd/mm/yy).
- The decimal symbol can be displayed as either a Period (xx.xx) or as a Comma (xx,xx).

When the pump is built, the default settings are: Time format: 12 Hour; Date format: mm/dd/yy; and decimal symbol: Period. If these are correct for your location, you can skip this section. If you use different settings, follow the instructions below.

Local Formats is available whether the pump is running or stopped.



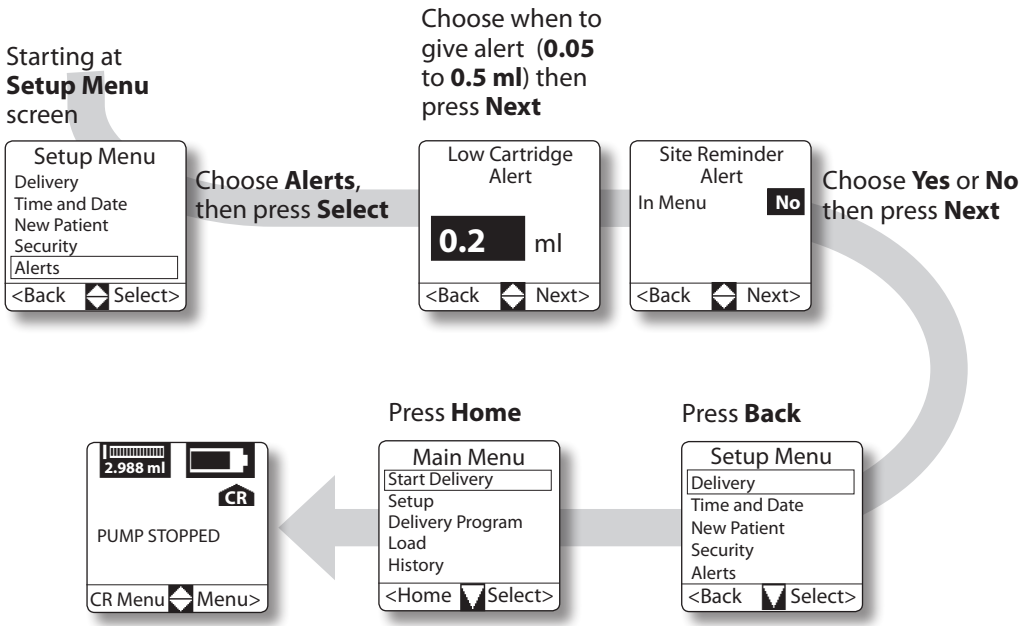
Setup Menu - Alerts

The pump allows you to set up certain alerts associated with treatment considerations, personal preference and safety, and can be personalized uniquely for each user.

Alert for low cartridge: determines when the pump alerts the patient to an almost empty cartridge. Decide how much medication should be left when the alert occurs (0.05 to 0.5 ml). It is factory preset to **0.2 ml**. (Choosing a higher amount will give more time between the low cartridge alarm and the empty cartridge alarm.)

Display site reminder in menu: optional alert determines whether a screen is added to the **Load** menu to set a reminder for when it is time to change the patient's infusion set and/or access site. It is factory preset to **No** (reminder not in use). If set to **Yes**, a Site Reminder home screen is added, which shows the time and date for the next scheduled site change.

Alerts are available whether the pump is running or stopped.


Starting at **Setup Menu** screen
Setup Menu
Delivery
Time and Date
New Patient
Security
Alerts
<Back Select>
Choose **Alerts**, then press **Select**
Choose when to give alert (**0.05** to **0.5 ml**) then press **Next**
Low Cartridge Alert
0.2 ml
<Back Next>
Site Reminder Alert
In Menu No
<Back Next>
Choose **Yes** or **No** then press **Next**
Press **Back**
Setup Menu
Delivery
Time and Date
New Patient
Security
Alerts
<Back Select>
Press **Home**
Main Menu
Start Delivery
Setup
Delivery Program
Load
History
<Home Select>
2.988 ml
CR
PUMP STOPPED
CR Menu Menu>

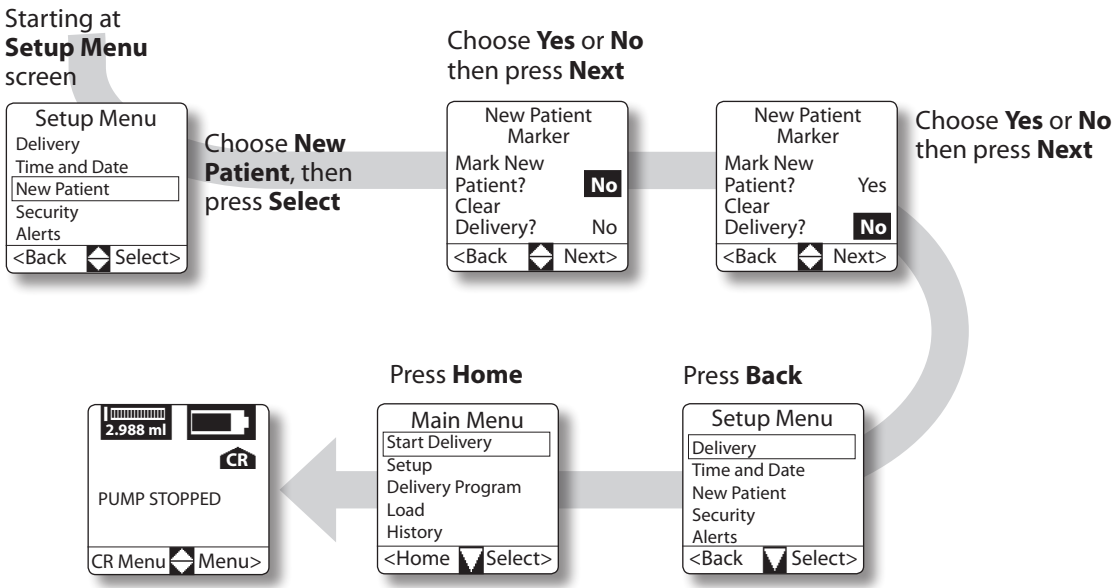
Setup Menu - New Patient

Before beginning to program the delivery specifics, it is recommended that you ready the pump for a new patient. The New Patient feature allows you to set the pump to its default values.

The New Patient feature is only available when the pump is stopped.

Choosing "yes" to mark New Patient will record an event in the History Log and clear all entries from the daily summary log.

Choosing "yes" to Clear Delivery will set all delivery parameters to factory default settings.



Setup Menu - Delivery

Before programming Delivery for a new patient it is recommended that you first use the New Patient feature (as shown on page 25).

In Delivery you will decide which of the three types of delivery methods (Continuous Rate, Automatic Dose and Demand Dose) will be used for the patient, and program delivery Maximums, Dose Duration and Dose Lockout Time.

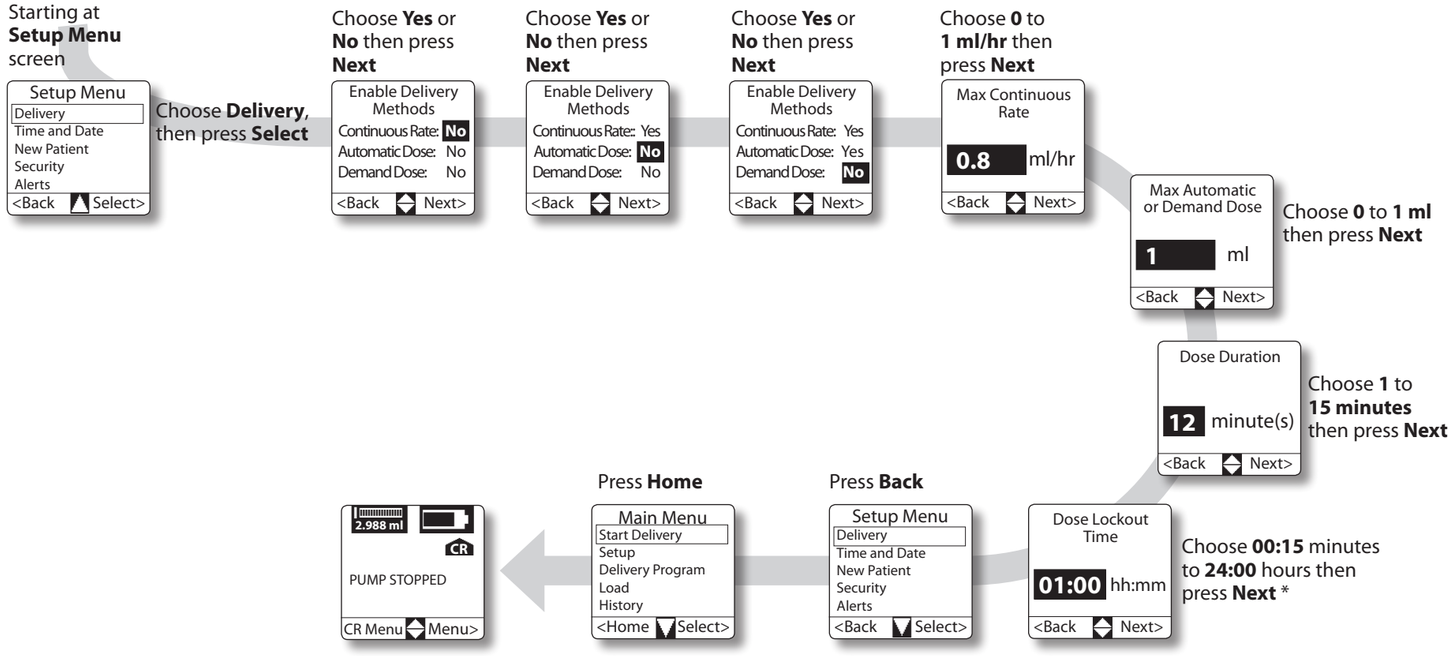
Note: If the pump has already been programmed, you will not be able to set pump values less than what is already programmed.

Dose Duration is the time over which a dose (Automatic and/or Demand) is delivered. You can choose to have the dose delivered over 1 to 15 minutes (programmed in 1 minute increments). The default value is 12 minutes.

The Dose Lockout time is the minimum amount of time that can pass between the start of one dose and the start of the next dose. You can choose a lockout time of 15 minutes to 24 hours (programmed in 15 minute increments). The default value is 1 hour. Dose Lockout time cannot be 0.

Delivery is only available when the pump is stopped.

Note: Dose Duration and Dose Lockout time cannot be equal.



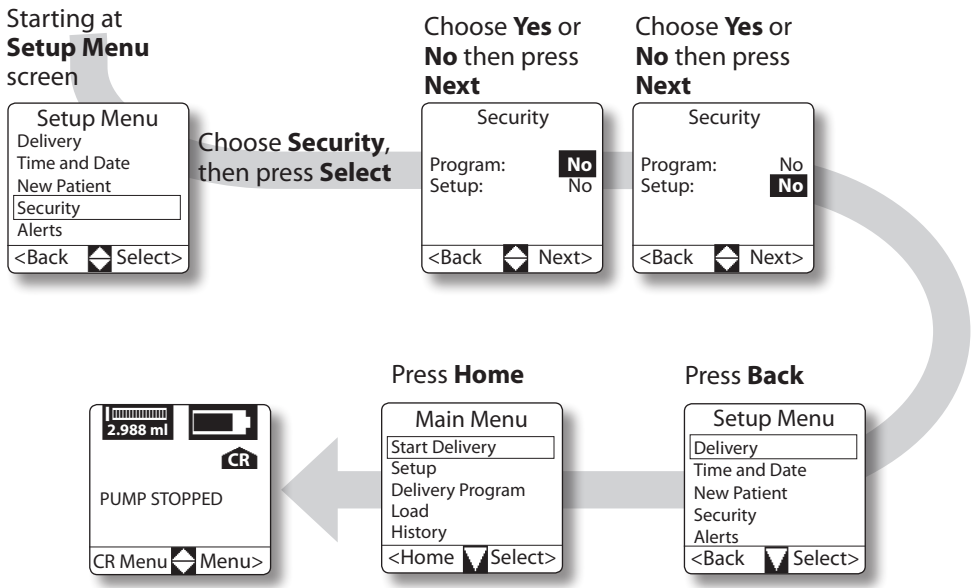
* You cannot program a Dose Lockout that will cause one programmed Automatic Dose to lockout another.

Setup Menu - Security

Security allows you to decide if you want to require pass codes to access the Setup and Delivery Program menus.

Security can be accessed when the pump is running or stopped.

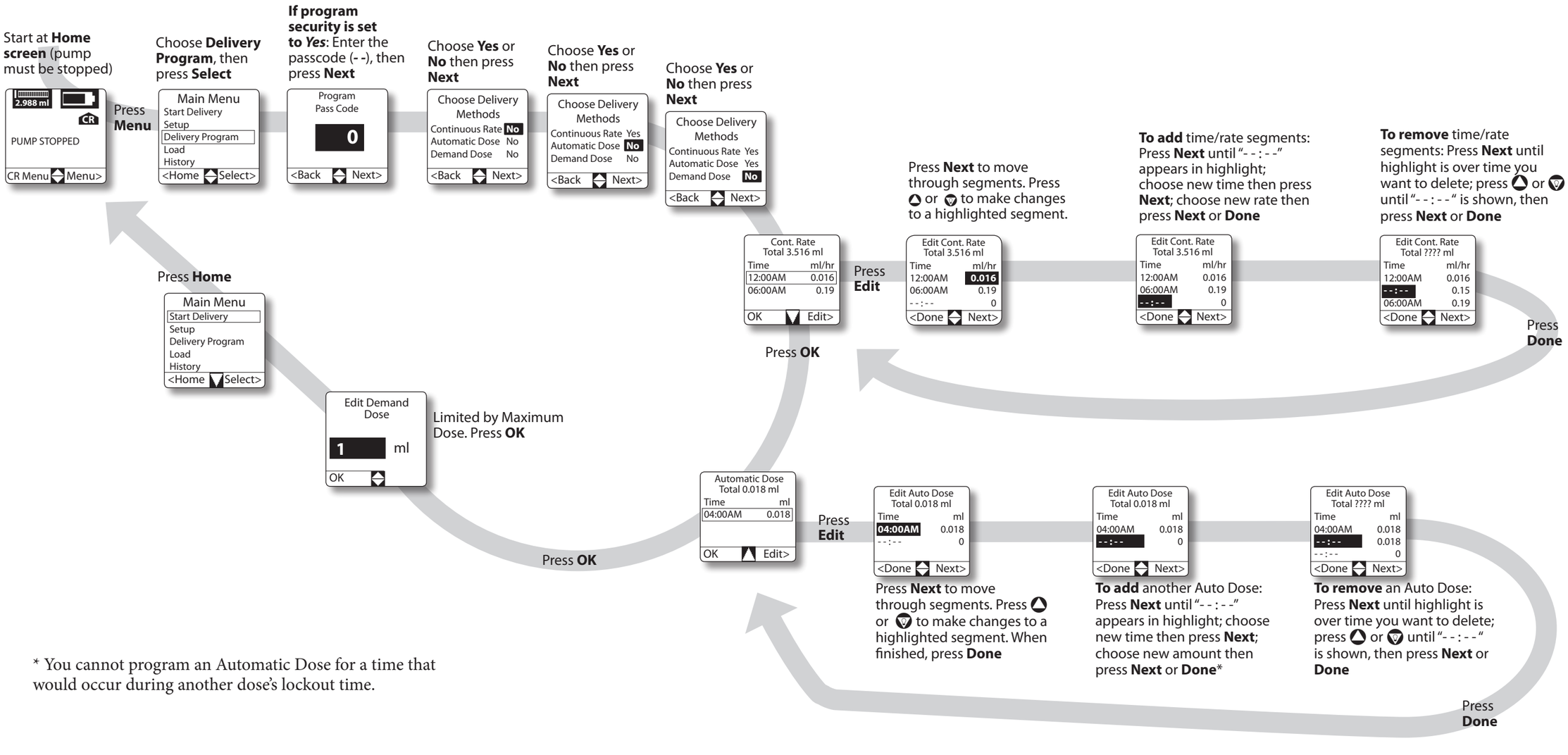
⇨ **Warning: If you choose not to require pass codes to access the Setup and Delivery Program menus, the patient will have full access to all programming and delivery functions.**



Delivery Program

In Delivery Program you program the delivery specifics for your patient: Continuous Rate schedule, Automatic Dose schedule and Demand Dose amount.

Delivery Program only appears in the main menu when the pump is stopped.



* You cannot program an Automatic Dose for a time that would occur during another dose's lockout time.

Loading a cartridge

The **Load** feature in the pump menu takes you through each step needed to load a filled cartridge in the pump and start delivering medication.

⇨ **Warning: Always use the pump's Load feature when starting a new cartridge.** This will assure that the cartridge is properly loaded and the infusion or extension set is filled with medication.

⇨ **Warning: Always use aseptic technique, particularly when working with the cartridge, infusion set, catheter and access site**.

⇨ **Warning: The CADD-MS™ 3 pump and cartridge are not a secure system.** Patient must be assessed for appropriateness of pump usage.

Supplies required

In addition to the pump, you will need:

- One filled Smiths Medical 3 ml Medication Cartridge
- One infusion or extension set with standard female luer connection (for connecting to cartridge)

⇨ **Warning: Always read the Instructions For Use** provided with the medication, cartridge, infusion set, and any other accessory used with the CADD-MS™ 3 Ambulatory Infusion Pump.

1. Filling the cartridge

Use aseptic technique.

Fill the cartridge according to the *Instructions for Use* supplied with the cartridge.

2. Attaching an infusion or extension set and loading a filled cartridge into the pump

⇨ **Warning: To avoid accidentally infusing medication or causing backflow of blood from the access device (or site), disconnect the tubing from the access device (or site) before removing a used cartridge or replacing an infusion set**. Never use the pump's **Load Cartridge** or **Fill Tubing** features while tubing is connected to the patient, or an unintended dose of medication can be delivered.

1. Turn the cartridge cap counterclockwise (left) approximately ¼ turn and remove it from the pump (see Figure 7). If required, remove the used cartridge (you may get the **Cartridge Removed** alert; press **OK**). **NOTE:** turning the cartridge cap may also turn the cartridge, so it may already be disconnected from the pushrod when the cap is removed. If not, turn the cartridge ¼ turn to the left to disconnect it from the pushrod.

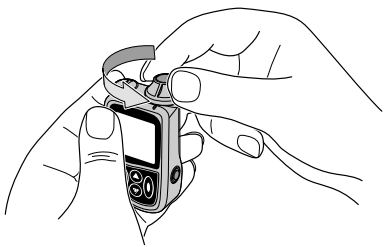


Figure 7

2. Thread the infusion set tubing through the cartridge cap; remove the protective cap from the luer end of the infusion set and insert the luer through the hole in the cap and firmly tighten it onto the tip of the filled cartridge (see Figure 8).

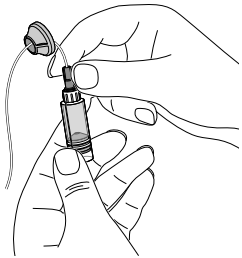


Figure 8

⇨ **Warning: If not properly tightened, medication could leak from the cartridge and tubing connections and disrupt delivery**. Signs of leakage can also mean opportunity for contamination leading to infection.

3. Insert the new cartridge into the cartridge chamber (see Figure 9). Gently turn the cartridge clockwise (right) about ¼ turn to fasten it onto the pushrod (you may need to first turn the cartridge until it drops onto the pushrod).

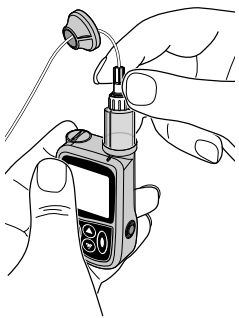
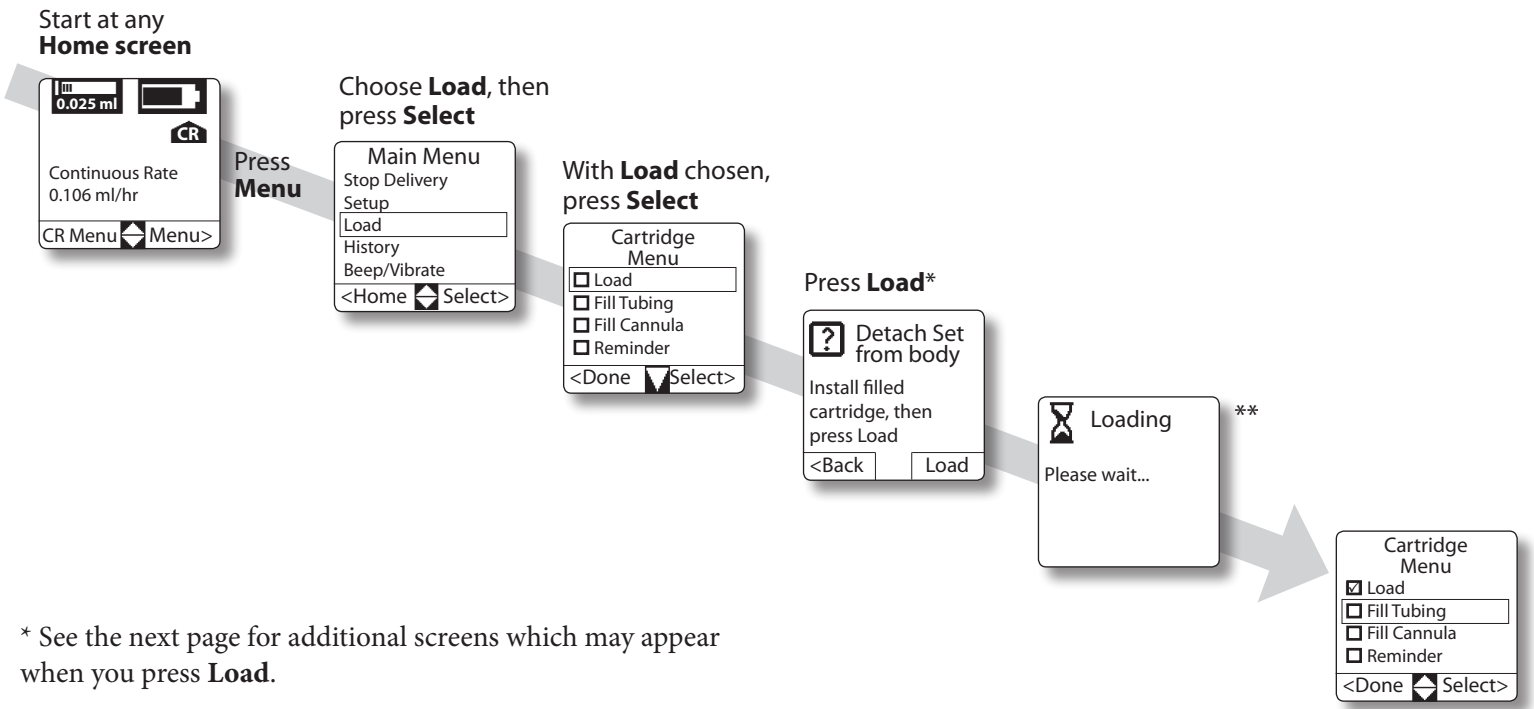


Figure 9

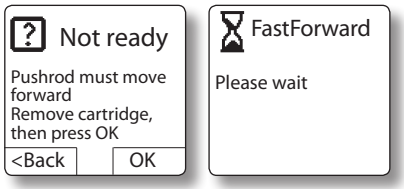
4. Choose **Load** from main menu and open the cartridge menu.

NOTE: You will not be able to load a cartridge that contains less than 0.2 ml (the sensor may have trouble sensing the cartridge amount).



* See the next page for additional screens which may appear when you press **Load**.

** See the next page for additional screens which may appear after the "**Loading**" screen.



* In order for the pump to assure that the cartridge is correctly connected to the pushrod, the pushrod must start in a forward position. If it is not far enough forward when you press **Load, or if you attempt to load a cartridge that contains less than 0.2 ml**, the screens shown at left will appear. Remove the cartridge, then press **OK** (or press **Back** to return to the previous screen). If you press **OK**, the pushrod moves forward, then the screen reads, "Detach set from body, install filled cartridge, then press **Load".** If your cartridge contains less than 0.2 ml, you will need to start with a new filled cartridge. With **Load** still chosen, press **Select**.

** If, during the loading process, you intentionally or accidentally remove the cartridge, or if the cartridge is too full (more than 3 ml), the screens shown at left will appear. The pump needs to check to make sure that the cartridge sensor is working properly.

- If the cartridge is not installed, install it;
- If a cartridge is installed, make sure it is not too full (fill with no more than 3 ml). With the tubing set attached, press down gently on the cartridge (this will push excess medication into the tubing). Press **Confirm**. The pump will confirm that the sensor is working properly. (If the sensor is not working, you will get this message repeatedly and the pump will need to be serviced.) If the sensor is confirmed, remove the cartridge and press **OK**. The pushrod moves forward, then the screen reads, "Detach set from body, install filled cartridge, then press **Load".** With **Load** still chosen, press **Select**.

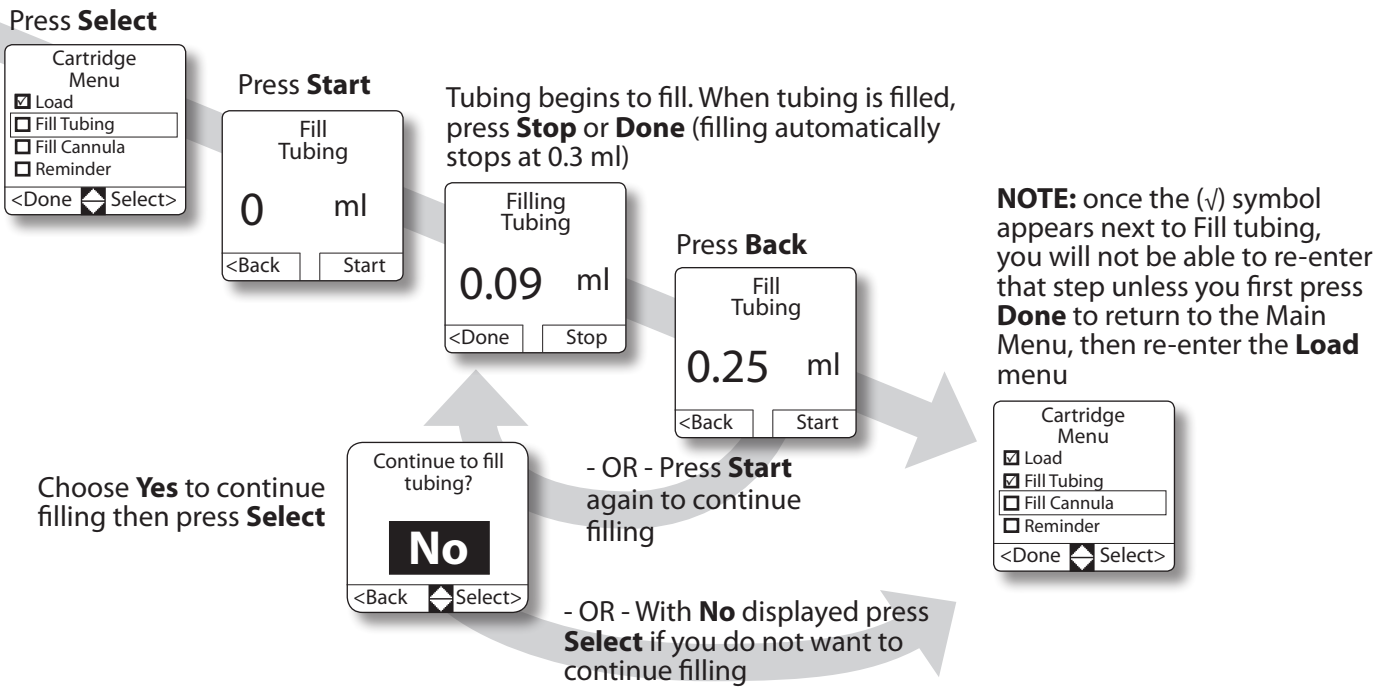
5. Verify, by looking through the cartridge viewing window, that the cartridge is properly attached to the pushrod. **Fasten the cartridge cap back onto the pump. Make sure the rib on the cap lines up with the rib on the pump, indicating the cap is secured (see Figure 10).**

Figure 10

3. Fill the tubing

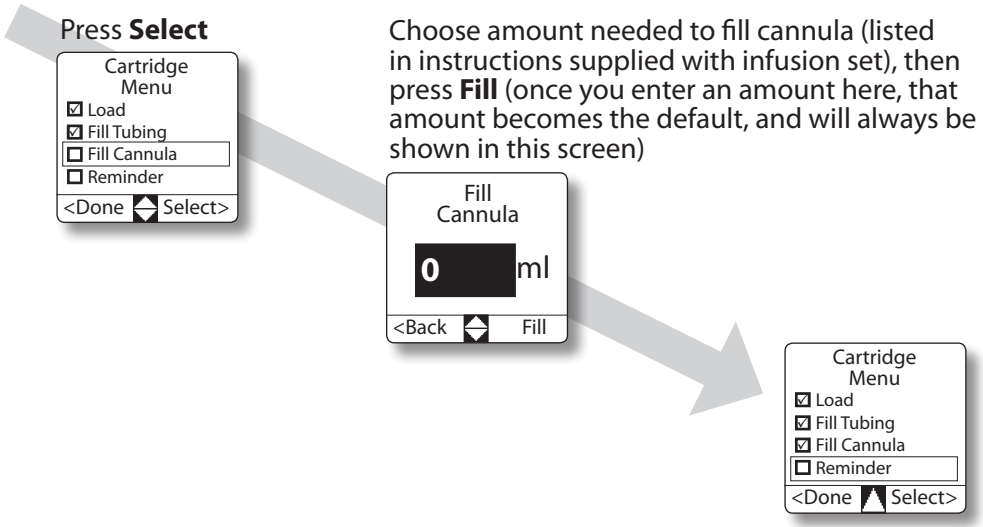
Filling forces medication from the cartridge and pushes air out of the tubing. Filling is complete when you see medication come out of the end of the tubing and all air is removed. The amount of medication used to fill the tubing is not counted as medication delivered to the patient.

⇨ **Warning: Never use Fill Tubing when the infusion set is connected to the body**, or an unintended dose could be delivered.



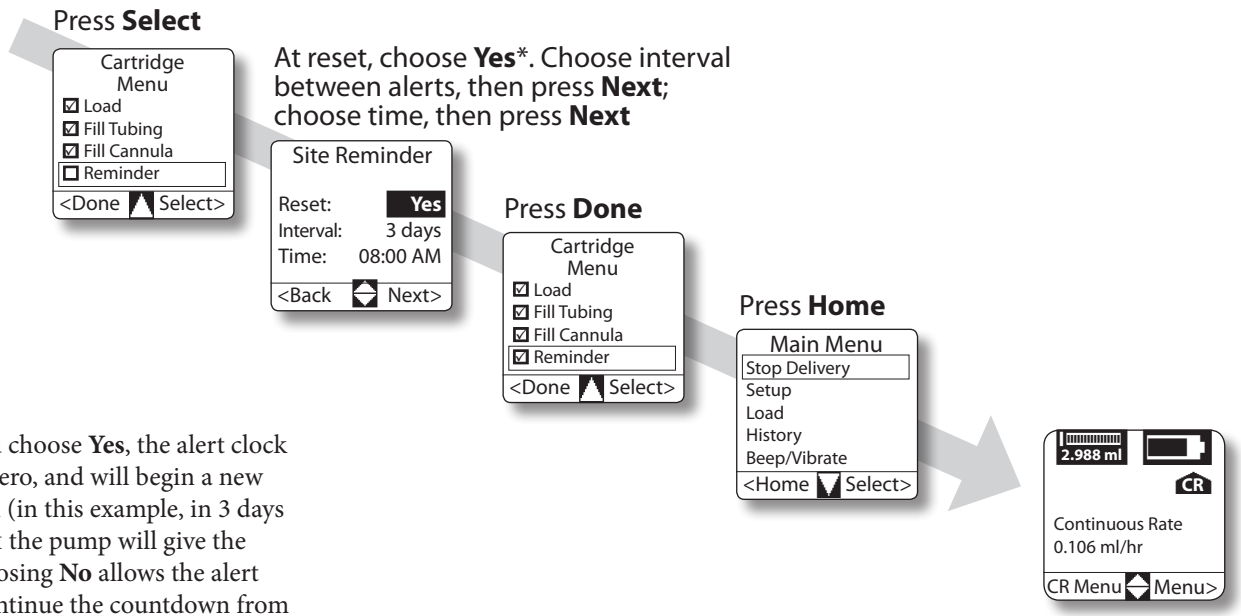
4. Fill cannula

Filling the cannula is an important step if using an infusion set that has a separate needle or cannula that needs priming prior to use. If you do not fill the cannula, there is a delay in medication delivery once the pump is started.



5. Set site change reminder and restart delivery

The Site Change reminder screen appears here if turned on in **Setup / Alerts** (see page 23). Setting the site change reminder will cause the pump to beep (or vibrate) as a reminder that it is time to change the tubing or access site.

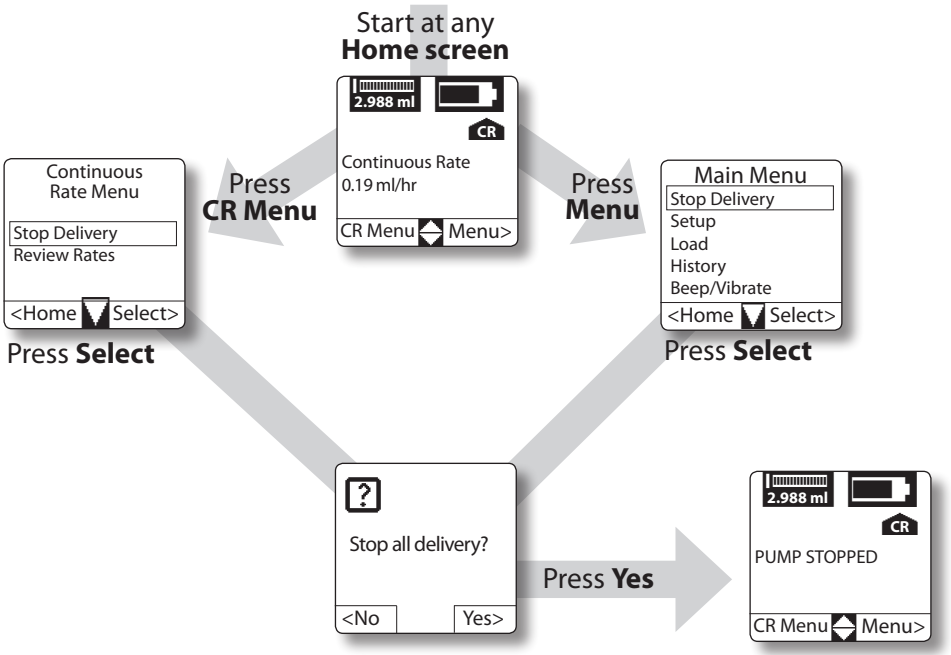


*When you choose **Yes**, the alert clock is reset to zero, and will begin a new countdown (in this example, in 3 days at 08:00 AM the pump will give the alert). Choosing **No** allows the alert clock to continue the countdown from the last time it was reset.

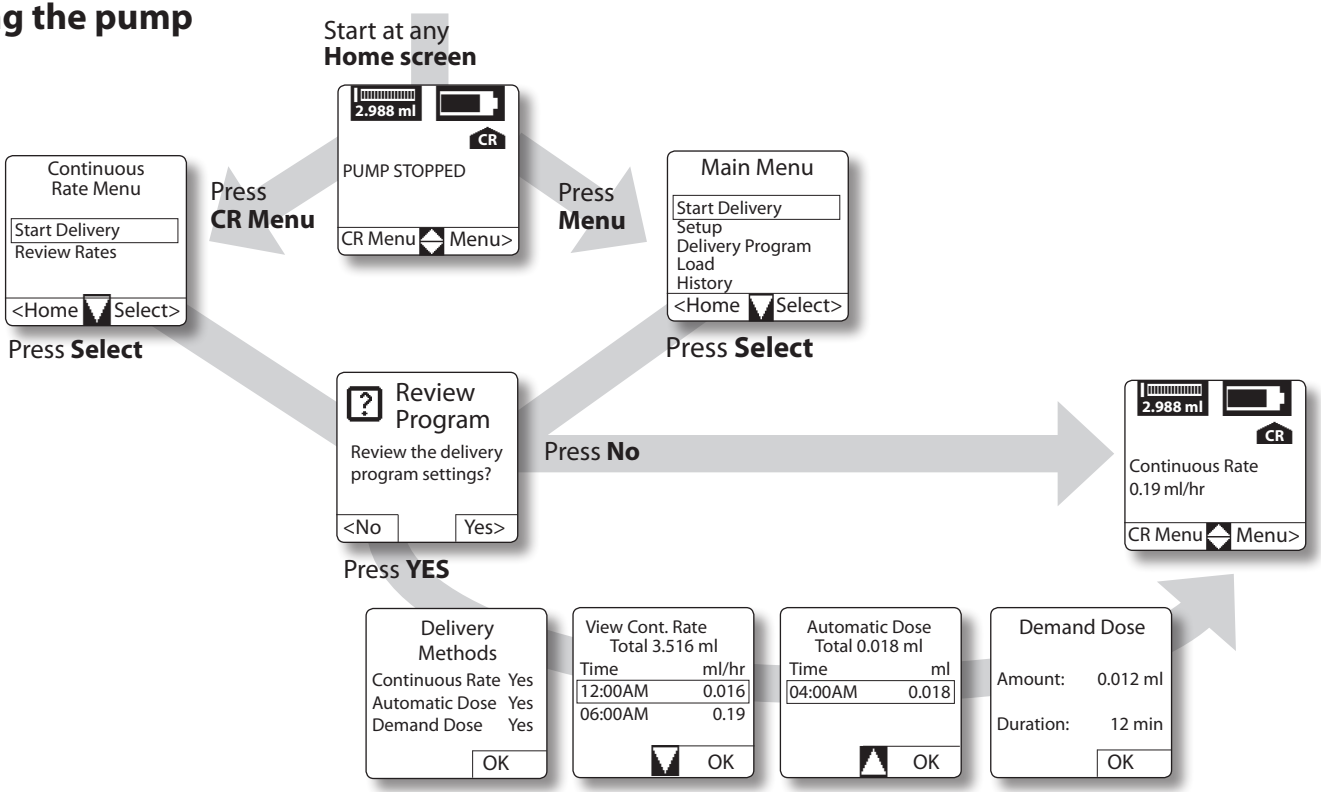
Stopping and starting the pump

You can stop and start the pump from any of the Home screens or in the main menu. The Delivery Program and certain items in the Setup Menu (those having an effect on delivery) can only be accessed if the pump is stopped.

Shown below is how to stop from the CR home screen, although stopping from any of the Home screens will use the same procedure.



Starting the pump



Press **OK** to move through the program review screens. Press ▲ or ▼ to scroll through the continuous rate and automatic dose screens (if needed). Continuous Rate, Automatic Dose and Demand Dose will only appear here if set to **Yes** in both the Setup and Delivery Program menus.

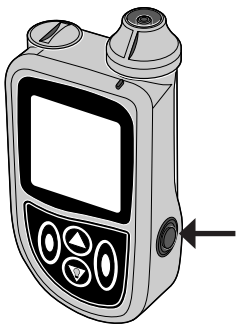
Delivering a Demand Dose

In order to deliver a Demand Dose, the pump must be programmed to allow them in the **Setup** menu (where you will need to program a Lockout time limit and dose duration) as well as in the **Delivery Program** menu (where you will program the amount).

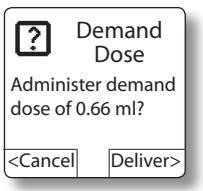
A Demand Dose is initiated by pressing the Demand Dose button on the side of the pump. A Demand Dose can be given only when the pump is running.

If the patient tries to deliver a Demand Dose during the lockout period, the display will show, **"No dose allowed."** If the pump is not programmed to allow Demand Doses, pressing the button will have no effect.

Unlike Automatic Doses, the patient chooses whether or not to deliver a Demand Dose. If the pump is programmed to allow demand doses, the patient can choose to deliver a dose or not, as long as it is not prevented by any Lockout time.



Press Demand Dose button; Demand Dose screen appears



To give the dose, press **Deliver**. If you do not want to give the dose, press **Cancel**.

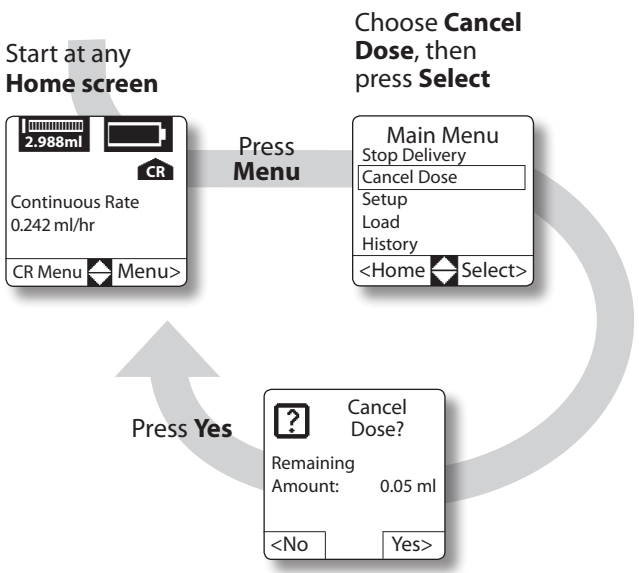
Canceling doses

Doses can be canceled while in progress. The next scheduled Automatic Dose can also be canceled.

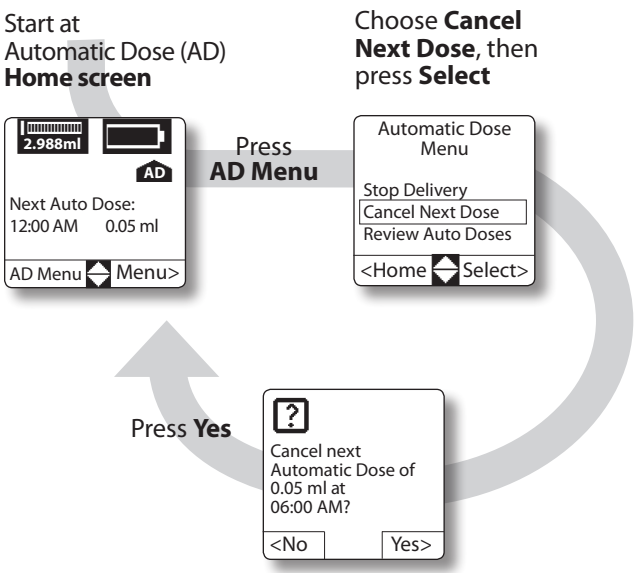
NOTE: Instruct the patient under what circumstances they can cancel a dose.

Stopping the pump will stop any dose in progress. Use the procedures on the following pages to stop delivering a dose **without stopping the pump** (and any continuous rate delivery).

Canceling a dose (Demand or Automatic) while in progress



Canceling next Automatic Dose



History

The pump stores history in two ways:

- As events. The pump stores information for the previous 4000 events.
- By the delivery date. The pump stores delivery information for the previous 90 days.

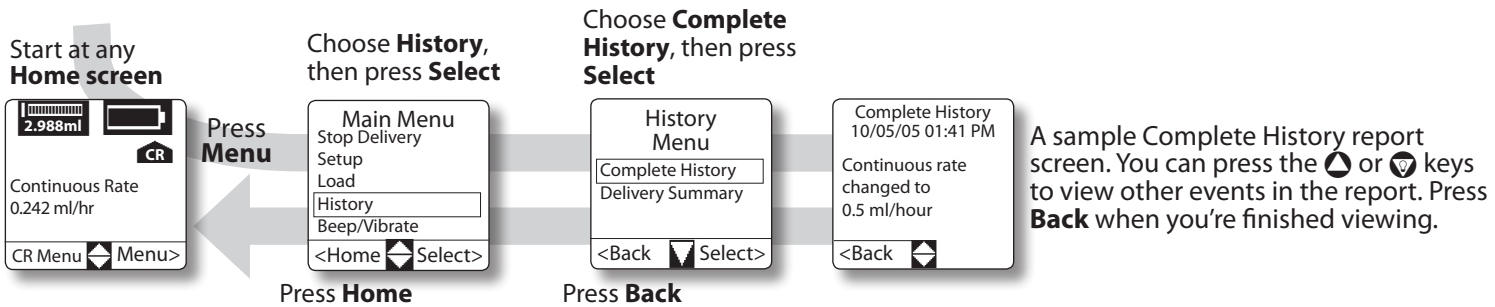
History can be viewed directly on the pump display from the History menu.

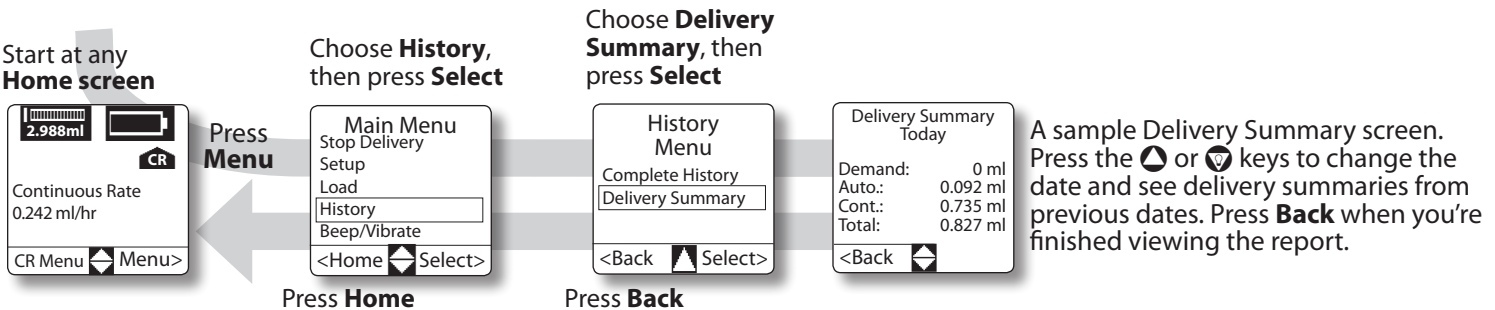
You can scroll through the history reports using the ▲ and ▼ keys in History.

The history reports are:

Complete History: this includes delivery totals, alerts, errors, battery changes, cartridge changes, changes to the pump program, etc. Each event in the complete history report includes the date and time of its occurrence. It includes the last 4000 events.

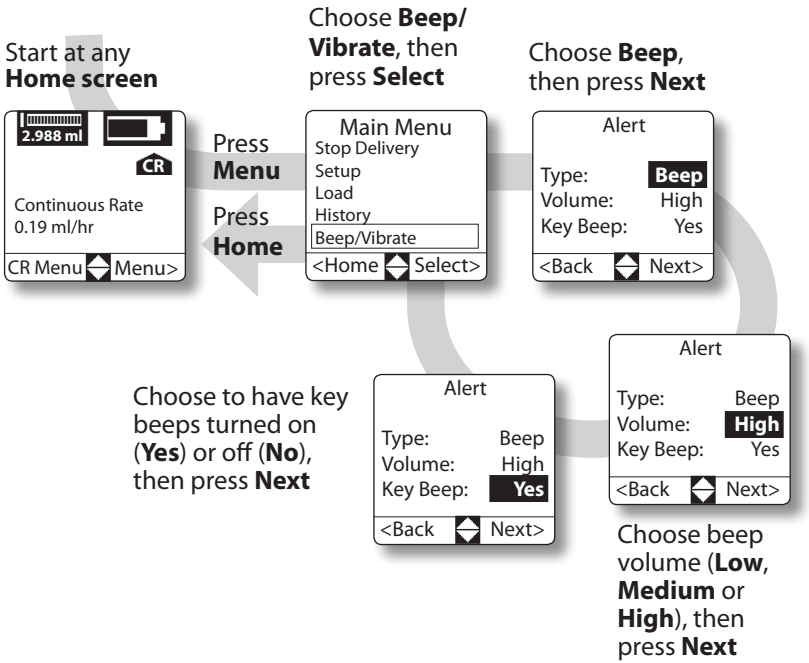
Delivery Summary: this is a **daily** breakdown of medication delivery, and may include the Demand Doses, Automatic Doses, and Continuous Rate delivered and includes a total amount delivered for that day. Only those delivery options that are active (set to **Yes** in the **Setup** and **Delivery Program** menus) will appear in the Delivery Summary.

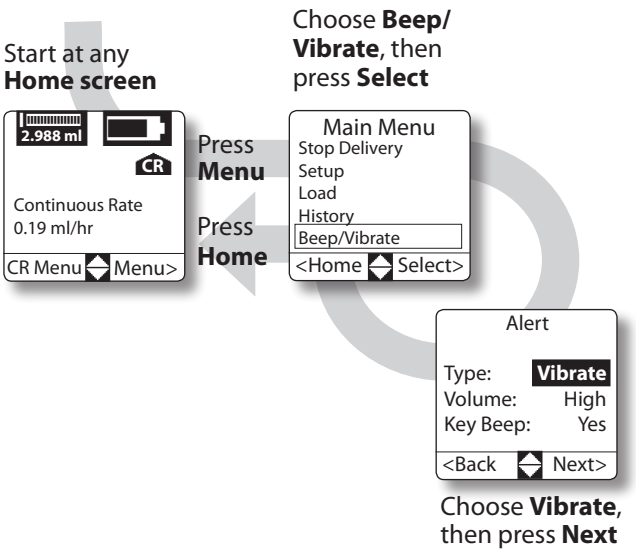

Start at any
Home screen
2.988ml
CR
Continuous Rate
0.242 ml/hr
CR Menu
Menu>
Press
Menu
Main Menu
Stop Delivery
Setup
Load
History
Beep/Vibrate
<Home
Select>
Press Home
Choose History,
then press Select
History
Menu
Complete History
Delivery Summary
<Back
Select>
Press Back
Choose Complete
History, then press
Select
Complete History
10/05/05 01:41 PM
Continuous rate
changed to
0.5 ml/hour
<Back
A sample Complete History report screen. You can press the ▲ or ▼ keys to view other events in the report. Press Back when you're finished viewing.


Start at any
Home screen
2.988ml
CR
Continuous Rate
0.242 ml/hr
CR Menu
Menu>
Press
Menu
Main Menu
Stop Delivery
Setup
Load
History
Beep/Vibrate
<Home
Select>
Press Home
Choose History,
then press Select
History
Menu
Complete History
Delivery Summary
<Back
Select>
Press Back
Choose Delivery
Summary, then
press Select
Delivery Summary
Today
Demand: 0 ml
Auto.: 0.092 ml
Cont.: 0.735 ml
Total: 0.827 ml
<Back
A sample Delivery Summary screen. Press the ▲ or ▼ keys to change the date and see delivery summaries from previous dates. Press Back when you're finished viewing the report.

Beep or Vibrate

Choose **Beep** or **Vibrate*** to signal alarms and alerts. Then, if using **Beep**, decide how loud the beep is and whether you want the pump to beep each time you press a key. **Low** is quietest and **High** is loudest. It is factory preset to **High**.

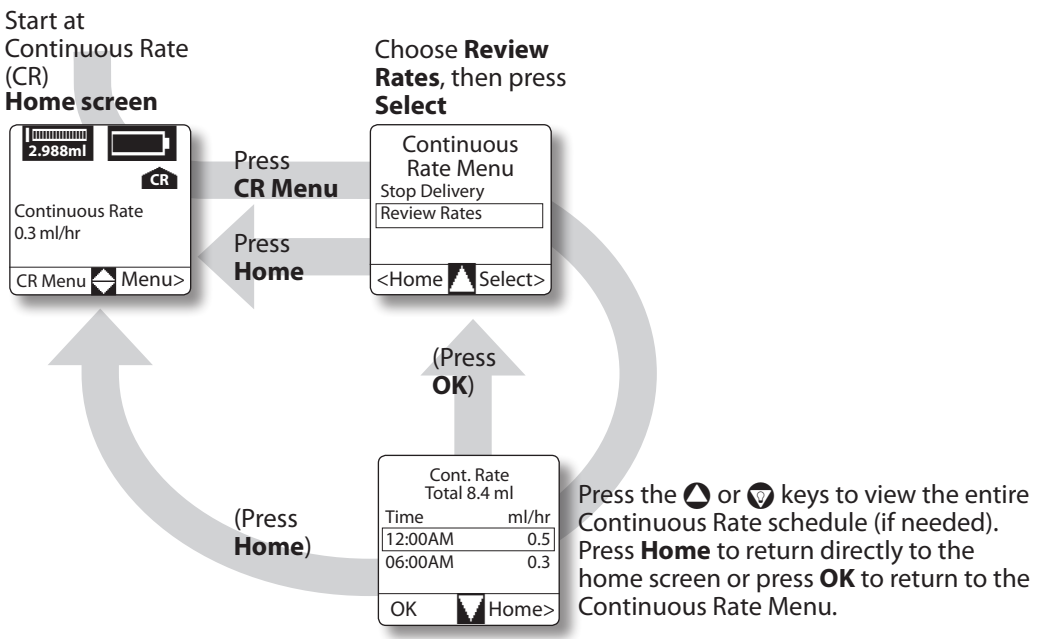




***Note that Vibrate uses up batteries much faster.**

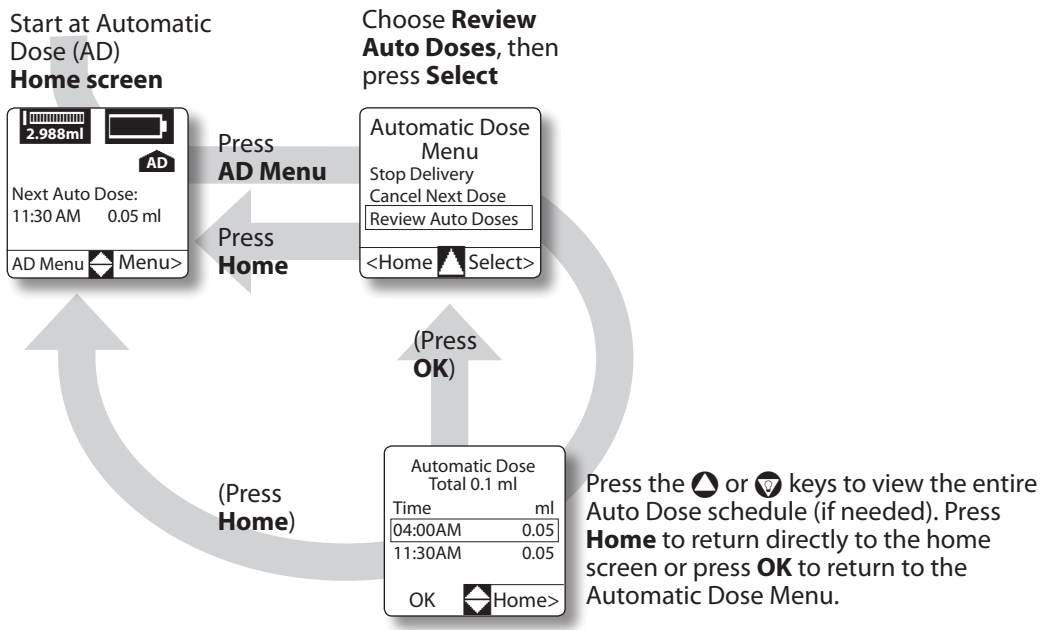
Continuous Rate Menu

If the pump is programmed with a continuous rate, a Continuous Rate Home screen is added. A Continuous Rate Menu is also added, where you can view (but not change) the Continuous Rate schedule.



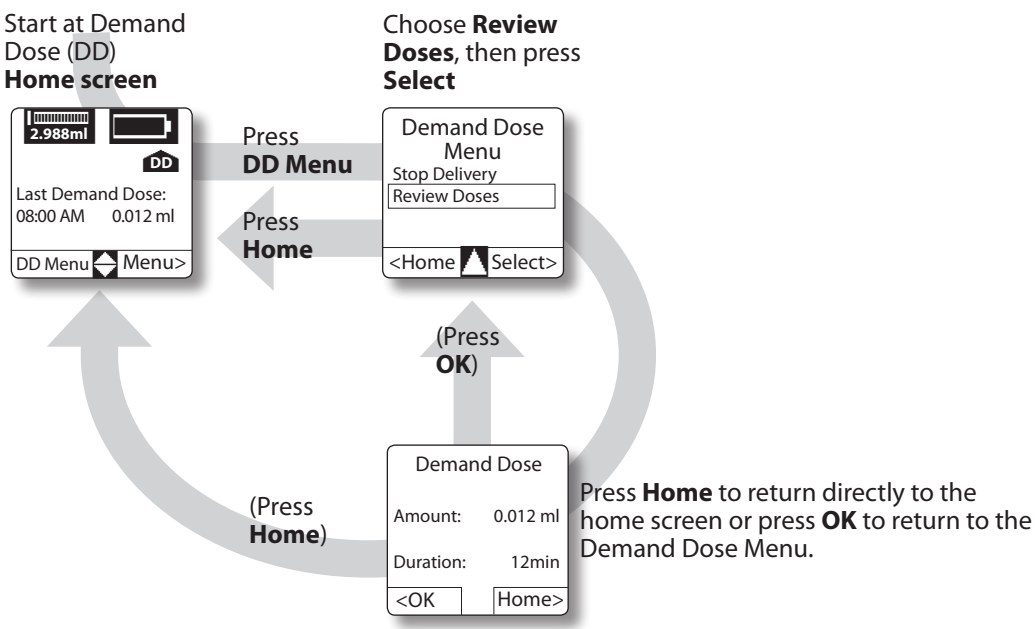
Automatic Dose Menu

If the pump is programmed to deliver automatic doses, an Automatic Dose Home screen is added. An Automatic Dose Menu is also added, where you can view (but not change) the dose schedule and cancel doses. Canceling the next Auto Dose is discussed on page 43.



Demand Dose Menu

If the pump is programmed to allow demand doses, a Demand Dose Home screen is added. A Demand Dose Menu is also added, where you can view (but not change) the dose amount and duration and cancel doses.



About alarms (Beep/Vibrate settings)

The pump can be set to **Beep** or **Vibrate** when an alert or alarm occurs (see page 46). With **Beep** selected, you can also choose whether the pump beeps when you press a key. When **Vibrate** is selected, the pump will not beep (or vibrate) when keys are pressed. (**NOTE:** the battery is used much more quickly when **Vibrate** is programmed.)

There are several types of alarm tones/vibration patterns:

- **Siren alarm:** Indicates pump is not working correctly and must be removed from use.

  Beep: 2 alternating beeps repeated constantly. Remove pump from use.
  Vibrate: Disabled.
- **Continuous alarm:** Indicates a problem which may have caused medication delivery to be stopped. See to alarms immediately.

  Beep: 4 double-beeps, repeating every 10 seconds until you press the appropriate key to silence it.
  Vibrate: 4 double-vibrations, repeated every 10 seconds until you press the appropriate key to silence it.
- **Attention alarm:** Indicates a problem that you need to see to, however it is not serious enough to have stopped delivery. Examples include low cartridge volume, low battery, etc.
  Beep: 4 double-beeps, repeated once per minute.
  Vibrate: 4 double-vibrations, repeated once per minute.
- **Single alarm:** This is a notification alert.
  Beep: pump beeps once.
  Vibrate: pump vibrates once.
- **Stopped alarm:** Indicates the pump is stopped.
  Beep: 3 beeps, repeated every 5 minutes.
  Vibrate: 3 vibrations, repeated every 5 minutes.

You can set the volume of the **Beep** alarm to **Low**, **Medium**, or **High** (see page 46). If a continuous alarm occurs that is not cleared within 5 minutes, the pump will switch between vibrating and beeping at the high setting in order to get your attention.

The backlight automatically lights whenever an alarm or alert occurs.

Troubleshooting

Alarms

Message in display	What it means / Alarm	How to make it stop
Battery depleted Delivery stopped. Insert a new battery.	Delivery stops. The battery does not have enough power for the pump to work. **Siren alarm.**	You must change the battery immediately. Power may be so low that the display goes blank or the pump continuously attempts to restart; always replace the battery whenever this occurs.
Blockage detected No delivery. Check tubing or site for blockage.	Delivery suspended. There is something preventing the medication from being delivered. **Continuous alarm**.	Alarm will recur unless blockage is cleared. Disconnect your infusion set from the access device until the blockage is cleared. Check tubing, making sure it is not kinked; make sure tubing is not trapped in the patient's clothing or pouch. Check cannula, making sure cannula is properly inserted, if applicable. Press **OK**.
Cartridge empty Insert filled cartridge to continue delivery.	Delivery suspended. The cartridge is empty. **Continuous alarm**.	Press **OK**. You must load a new cartridge now.
Cartridge removed Press OK to begin load process.	Delivery suspended. Pump detected that cartridge was removed or not properly installed. **Continuous alarm**.	Press **OK**. Disconnect the tubing from the patient. Correctly load a cartridge onto the pushrod and fill the tubing (see page 32).

Alarms - continued

Message in display	What it means / Alarm	How to make it stop
 **Cartridge very low**	The cartridge is nearly empty. If Continuous Rate delivery is active, it will continue. If Automatic or Demand Dose delivery is active, delivery of doses will not start or will be suspended. **Continuous alarm**.	Press **OK**. There is enough medication to continue delivering the continuous rate for a short time, but not enough to start a dose, or complete a dose that is in process (the dose may be completed when a new cartridge is loaded). You must begin preparation to load a new cartridge.
 **Key stuck** Release key or remove battery.	A key has been pressed continuously for 5 minutes, or a key was pressed during the pump's power up. **Continuous alarm**.	If you are pressing a key, stop pressing it. If you are not pressing a key, remove and reload the battery. If the alarm persists, there may be a problem with the keypad that requires service.
 **System fault** Call for service.	Delivery stops. The pump's computer has detected a problem with the pump. **Siren alarm**.	Disconnect the tubing from the access device. Remove the battery to silence the alarm and contact Smiths Medical MD, Inc. to initiate pump service. Do not use the pump.
 **Battery low** Change battery soon.	This alert occurs only during waking hours (6:00 AM to 10:00 PM). A series of 4 **Attention alarms** given every 4 hours until battery is depleted.	Press **OK**. Change the battery as soon as possible.

Alerts

Message in display	What it means / Alarm	How to make it stop
Cartridge Volume Low Change cartridge soon.	The amount of medication left in the cartridge is low. Alert repeats at intervals until **Cartridge Very Low** alarm occurs. **Attention alarm**.	Press **OK**. Replace the cartridge as soon as practical.
Edit not saved Editing was not saved because an alarm occurred.	An alarm or alert occurred while you were programming/editing a value. **Single alarm**.	Press **OK**. Reprogram the value.
Program Defaulted Setup of cartridge volume required. With no cartridge present, press Next.	The cartridge volume needs to be rechecked to make sure it will be displayed correctly on the home screen. **Attention alarm**.	Remove the cartridge (if present), then press **Next**.
Program Defaulted Set time and date: XX:XX XX XX/XX/XX	The time and date settings in the program have been reset and must be reprogrammed. **Attention alarm**.	Press the ▲ or ▽ key to choose the currently highlighted setting, then press **Next** to move highlight to next setting. When time and date are correct, press **Done**.

Alerts - continued

Message in display	What it means / Alarm	How to make it stop
Program Defaulted You must program the pump.	All pump settings are reset to default values (usually seen with new pumps or when internal battery is discharged). **Attention alarm**.	Press **OK**. Reprogram all pump settings.
Site change reminder x days since site changed. Time for new site?	It is time to change your infusion set and access site. **Attention alarm**.	Press **OK**. Follow the instructions for Loading the cartridge starting on page 31.

Other messages

Message in display	What it means / Alarm	How to make it stop
All Automatic Doses programmed to zero.	You have attempted to start the pump and the Automatic Dose amounts are programmed to zero. **Single alarm.**	Press **OK**. If necessary, go to the Delivery Program menu and program the amount(s) for the Automatic Dose schedule.
All Continuous Rates programmed to zero.	You have attempted to start the pump and all the rates in the Continuous Rate schedule are programmed to zero. **Single alarm**.	Press **OK**. If necessary, go to the Delivery Program menu and program the rate(s) for the Continuous Rate schedule.
Cancel Demand Dose and stop all delivery?	You have tried to stop the pump while a Demand Dose is delivering. **Single alarm**.	To stop the pump and cancel the remainder of the Demand Dose, press **Yes**. To leave the pump running and continue delivering the Demand Dose press **No**.

Other messages - continued

Message in display	What it means / Alarm	How to make it stop
 Demand Dose programmed to zero.	You have attempted to start the pump and the Demand Dose amount is programmed to zero. **Single alarm.**	Press **OK**. If necessary, go to the Delivery Program menu and program the amount for the Demand Dose.
 **Dose Interrupted** Resuming dose .	Dose delivery was interrupted, and will now resume. **Single alarm**.	Press **OK**.
 **Dose Not Completed** Dose Duration expired while delivery was suspended.	Dose delivery was interrupted and the duration has since expired. **Single alarm**.	Press **OK**. The dose will not be completed, and the patient must wait for the dose lockout period to expire before delivering another dose.
 **No cartridge detected** Cartridge missing or overfilled. Install cartridge to confirm sensor.	You have attempted to use the **Load** portion of the load cartridge menu, but no cartridge is detected. It may also mean that you filled the cartridge too full (more than 3 ml). **Single alarm**.	If a cartridge is installed (and with the infusion set attached to the cartridge) press down gently on the cartridge to push excess medication into the tubing. If a cartridge is not installed, install one. Press **Confirm**. If the cartridge sensor is not confirmed, you will need to have the pump serviced.

Other messages - continued

Message in display	What it means / Alarm	How to make it stop
No dose allowed Demand dose is currently locked out.	You attempted to deliver a Demand Dose during the lockout period. **Single alarm**.	Press **OK**. The Demand Dose home screen displays the time that the next dose will be available.
No dose allowed Dose in progress.	You attempted to deliver a Demand Dose while a Demand Dose or Automatic Dose was being delivered. **Single alarm.**	Press **OK**. The Demand Dose home screen displays the time that the next dose will be available.
No dose allowed Cartridge volume is very low.	You attempted to deliver a dose, but the cartridge volume is too low. **Single alarm**.	Press **OK**. Load a new cartridge, then deliver the dose.
Programming Required You must completely review the delivery program.	You have chosen to use a delivery method, but have not reviewed or completed all required programming. **Single alarm**.	Press **OK**. Completely review the delivery program and program the pump as required.
Stop all delivery?	You have tried to stop the pump. **Single alarm.**	To stop the pump, press **Yes.** To leave the pump running, Press **No.**

Other messages - continued

Message in display	What it means / Alarm	How to make it stop
 This will result in a Demand Dose amount of 0 ml.	You have allowed Demand Doses, but programmed the amount to zero. **Single alarm**.	If you want to leave the amount at zero, press **OK**. If you want to reprogram the amount, press **Edit**.
 This will result in an Automatic Dose amount of 0 ml.	You have programmed an automatic dose schedule where at least one of the dose amounts is set to zero. **Single alarm**.	If you want the schedule to run as programmed, press **OK**. If you want to reprogram the schedule, press **Edit**.
 This will result in a time period with a Continuous Rate of 0 ml/hr.	You have programmed a continuous rate where at least one of the rates is zero. **Single alarm**.	If you want the schedule to run as programmed, press **OK**. If you want to reprogram the schedule, press **Edit**.

Cleaning the pump

Routinely clean the pump to prevent buildup of dirt or dried fluids. Try to wipe spills off the pump right away to avoid a sticky buildup, which will be harder to wipe off later.

When cleaning the pump, **ONLY** use a sponge or soft cloth with a solution of warm water and a mild soap, such as liquid dish or hand soap.

Routinely clean the pump to keep it free of dirt, liquids, and foreign objects.

Use any of the following solutions to clean the pump and accessories:

- Soap solution
- Benzalkonium chloride concentrate (0.13%)
- Glutaral concentrate, USP (2%)
- 10 percent solution of household bleach (one part household bleach to 9 parts water)
- Alcohol, USP (93%)
- Isopropyl alcohol, USP (99%)
- Chlorohexidine (70%)
- PDI — Super Sani-Cloth®
- Mada Medical — MadaCide

1. Dampen a soft, lint-free cloth with cleaning solution and wipe the exterior surface of the pump. ***Do not allow the solution to soak into the pump.***
2. Wipe the entire surface dry with another soft, lint-free cloth. Allow the pump to dry completely before use.

Make sure to clean inside the battery or cartridge compartment. Moisten one end of a cotton swab (such as a Q-tip®) and gently clean inside the compartment. Use the dry end of the swab to dry the compartment.

⇨ **Caution: Never use abrasive cleaners, solvents, bleach, scouring pads or sharp instruments when cleaning your pump, as they can scratch, discolor or damage the pump's outer shell**. If the display is scratched, it may be difficult to read and you will need to have it replaced. If the outer shell is chipped or cracked, it may no longer be watertight and will require service.

⇨ **Caution: Never use steam or very hot water (exceeding 120°F [49°C]) in an attempt to sterilize the pump. Never put your pump in the dishwasher**.

Exposing the pump to these high temperatures could damage the pump's electronics and result in the need to service the pump.

Servicing the pump

If the pump becomes damaged or broken, or if it is not working properly, you will need to call Smiths Medical MD, Inc.

Before contacting Smiths Medical, please be sure that you know the pump serial number (located on the back of the pump), and are able to give a brief description of the problem.

In the USA, contact Smiths Medical MD, Inc. Customer Service at

1 800.426.2448

The pump and:

Extreme temperatures

If outside in very cold temperatures for any length of time, instruct the patient to keep the pump next to their body and covered by warm clothing.

Avoid leaving the pump in direct sunlight. Instruct the patient to remove the pump before entering a hot tub, Jacuzzi®, or sauna, as the temperatures may be too high for the pump to operate properly. See Specifications in the Technical Information chapter for appropriate storage and operation temperatures.

Water

As long as the pump's labels and outer shell are intact (no cracks or chips), the pump is watertight. The pump does not need to be removed when showering or bathing. Instruct the patient to dry the pump with a clean towel after it is exposed to water.

If the pump is dropped or hit hard

If the pump is dropped or hit against something hard, it will need to be immediately looked over carefully to make sure it is not damaged. Instruct the patient to disconnect their infusion set from their body and stop delivery until they have made sure the pump is working correctly. The patient should remove the battery, then reinsert it. The pump will perform the self-tests, and alarm if there is a problem.

The patient should make sure the pump display is working correctly. If there are missing or incomplete characters, the pump will need to be serviced.

The patient should look over the pump's outer shell carefully, checking for cracks or chips. If there are cracks or chips, the pump will no longer be watertight. The pump will need to be serviced if there is any damage.

The patient should make sure the cartridge cap and battery cap are in place and secure. Have them check all connections on the cartridge and infusion set. If moisture is present, they must tighten the connectors. If the connectors appear damaged, they must replace the cartridge and infusion set.

- ⇨ **Warning: If the pump is dropped or hit against something hard, it must always be inspected carefully to make sure it is still working properly.** Make sure the display is working correctly, and the cartridge, cartridge cap, battery cap and infusion set are connected correctly. If there is damage to the pump outer shell (cracks, chips), the pump may no longer be watertight.
- ⇨ **Warning: If the display has missing or incomplete characters, or if the pump does not seem to be working correctly, stop using the pump immediately.** Contact Smiths Medical MD, Inc. for information on servicing the pump.
- ⇨ **Warning: Make sure that the battery cap is fully tightened to avoid an interruption in battery power which can cause the pump to power down and stop the delivery of drug therapy. A prolonged interruption in the delivery of drug therapy can result in serious patient injury or death.**

Pump development standards

AAMI ID26: 1998 - Medical Electrical Equipment — Part 2: Particular requirements for the safety of infusion pumps and controllers.

ANSI/AAMI HE48: 1993 - Recommended Practice — Human factors engineering guidelines and preferred practices for the design of medical devices. (February 5, 1988 version) Design guideline.

IEC 60601-1 (Second Edition, 1988) - Medical Electrical Equipment, Part 1: General requirements for safety. Amendment 1 (1991), Amendment 2 (1995).

IEC 60601-1-1 (Second Edition, 1992) - Medical Electrical Equipment, Part 1: General requirements for safety - 1. Collateral standard: Safety requirements for medical electrical systems. Amendment 1 (1995).

IEC 60601-1-2 (2001) - General Requirements for Safety, Part 2 — Electromagnetic compatibility — Requirements and tests. (European Harmonized Standard).

IEC 60601-1-4 (1996) - Medical Electrical Equipment, Part 1: General requirements for safety — 4. Collateral standard: Programmable electrical medical systems.

IEC 60601-2-24 (1998-02) - Medical Electrical Equipment, Part 2–24: Particular requirements for safety of infusion pumps and controllers.

IEC 878 (First Edition, 1988) - Graphical symbols for electrical equipment in medical practice.

IEC 61000-4-2 (1995) - Electromagnetic Compatibility (EMC), Part 4: Testing and measurement techniques. Section 2: Electrostatic Discharge immunity test. Basic EMC Publication.

IEC 61000-4-3 (1995) - Electromagnetic Compatibility (EMC, Part 4: Testing and measurement techniques. Section 3: Radiated, radio frequency, electromagnetic fields immunity test. Basic EMC Publication. Amendment 1 (1998-06).

IEC 61000-4-8 (1993) - Electromagnetic Compatibility (EMC), Part 4: Testing and measurement techniques, Section 8: Power frequency magnetic field immunity test, 1993.

CISPR11 (1990) - Limits and methods of measurement of electromagnetic disturbance characteristics of industrial, scientific and medical (ISM) radio frequency equipment. Amendment 1 (1996; Amendment 2 (1996).

CISPR14 (1993) - International Special Committee on Radio Interference, limits and methods of measurement of radio interference characteristics of household electrical appliances, portable tools and similar electrical apparatus. Amendment 1 (1996).

IEC 529 - Degrees of protection provided by enclosures (IP Code).

RTCA/DO-160D (7/97) - Environmental conditions and test procedures for airborne equipment: SECT 21 — Emissions of radio frequency energy (Radiated Emissions Only — Category M Limit).

UL2601-1 (1998) - Medical Electrical Equipment, Part 1: General requirements for safety.

NOTE: While the pump complies with the above standards, there is no guarantee that interference will not occur in any particular situation. If the pump malfunctions due to interference with radio or cell phones: move the antenna further from the pump and/or increase the distance between the pump and the radio or cell phone.

Guidance and Manufacturer's Declaration — Electromagnetic Emissions		
The pump is intended for use in the electromagnetic environment specified below. The customer or the user of the pump should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment — Guidance**
RF emissions, CISPR 11	Group 1	The 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.
RF emissions, CISPR 11	Class B	The pump is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions, IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions, IEC 61000-3-3	Not applicable	

⇨ **Warning:** Use of accessories other than those indicated or adjacent to other equipment may result in increased emissions or decreased immunity of the pump. The user should verify normal operation of the pump in the configuration and environment in which it is to be used.

Guidance and Manufacturer's Declaration — Electromagnetic Immunity			
The pump is intended for use in the electromagnetic environment specified below. The customer or the user of the pump should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment — Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not applicable Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	Not applicable Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines, IEC 61000-4-11	< 5 % U_T (> 95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 sec	Not applicable Not applicable Not applicable Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Pump requires continued operation during power mains interruptions, it is recommended that the Pump be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	3 A/m	400 A/m (IEC 60601-2-24)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration — Electromagnetic Immunity			
The pump is intended for use in the electromagnetic environment specified below. The customer or the user of the pump should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment — Guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF, IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not applicable	**Recommended separation distance** $d=[3,5/V_1]*P^{½}$
Radiated RF, IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	15 V/m	$d=0.23*P^{½}$ 80MHz to 800MHz $d=0.47*P^{½}$ 800MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. **NOTE 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the pump is used exceeds the applicable RF compliance level above, the pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the pump. [b](Not applicable) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than $[V_1]$ V/m.			

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Pump			
The pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the pump as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum Output Power of Transmitter W	**Separation Distance According to Frequency of Transmitter** m		
	150 kHz to 80 MHz $d=[3,5/V_1]*P^{1/2}$	**80 MHz to 800 MHz** $d=0.23*P^{1/2}$	**800 MHz to 2,5 GHz** $d=0.47*P^{1/2}$
0.01	Not applicable	0.02	0.05
0.1	Not applicable	0.07	0.15
1	Not applicable	0.23	0.47
10	Not applicable	0.74	1.5
100	Not applicable	2.3	4.7
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. **NOTE 1:** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. **NOTE 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Specifications

General specifications (nominal)

Minimum increment of resolution:
0.005 ml per activation

Size:
3.2 in × 1.8 in × 0.95 in (80 mm × 47 mm × 24 mm)

Weight:
Approximately 3.2 oz (90 g) including battery and cartridge

Classification:
Type CF ♥ (protection from electric shock)

Moisture protection:
IPX8 (watertight to a depth of 12 ft [3.64 m] for 3 min, or 8 ft [2.4 m] for 30 min.

Pump alarms/alerts:
Pump stopped, blockage, low battery, dead battery, low cartridge volume, empty cartridge, system fault
Optional alarms/alerts: site change

Maximum infusion pressure:
23 psi

Maximum time to blockage (occlusion) alarm:

	Minimum	Maximum
Intermediate rate: 0.124 ml/hr	12 min	15 min
Minimum rate: 0.002 ml/hr	9.5 hr	19 hr

Bolus volume at blockage (occlusion) release:
Minimum rate: approximately 0.04 ml
Intermediate rate: approximately 0.21 ml

Power source:
One AAA (IEC LR03) alkaline battery.

⇨ **Caution: Do not use NiCd, nickel metal hydride, carbon zinc (heavy duty), lithium or any rechargeable batteries.** They will not power the pump properly, and the battery life indicator on the home screen may not show the correct amount.

Battery life:
The expected battery life is approximately 2 weeks (battery low alert) at 0.124 ml/hr

Data storage time:
An internal battery powers the clock, and allows pump to store program parameters and history. The internal battery is charged by the AAA alkaline battery. Once fully charged (approximately 40 hours after AAA battery installed), the

internal battery maintains pump programming and history for approximately 30 days. The life of the internal battery is 10 years minimum under normal use conditions.

Operating conditions:

Temperature: 2°C to 40°C (35.6°F to 104°F)
Humidity: 90% relative humidity (non-condensing) maximum
Atmospheric pressure: 70 kPa (or 10,000 feet above sea level) to 106 kPa (10.2 psi to 15.4 psi)

⇨ **Caution: Do not use the pump in hyperbaric chambers** as they will affect how the pump works and may also cause damage to the pump.

Transport and storage conditions:

Temperature: –20°C to 60°C (–4°F to 140°F)
Humidity: 90% relative humidity (non-condensing) maximum
Atmospheric pressure: 70 kPa (or 10,000 feet above sea level) to 106 kPa (10.2 psi to 15.4 psi)

System delivery accuracy (ml/hr):

± 3% (nominal). At low delivery rates, this accuracy may not be achieved for short periods. During the total delivery time, the accuracy averages out.

System definition:

CADD-MS™ 3 Ambulatory Infusion Pump with Smiths Medical 3 ml Medication Cartridge and a Unomedical Comfort™ Infusion Set

Blockage (occlusion) alert:

18 psi ± 5 psi

Dose accuracy at set value of 0.002 ml:

± 15% (measurement error ± 10%)

Dose accuracy at set value of 1.0 ml:

-0.12, -0.88%; Average - 0.53% (measurement error ± 0.0005%)

Maximum volume infused under single fault condition:

Less than 0.02 ml

Delivery rate during dose:

Approximately 0.0001 ml per second minimum, 0.016667 ml per second maximum (based on dose amount and dose duration - dose duration configurable from 1 to 15 minutes)

Delivery rate during Fill tubing/Fill cannula:

Approximately 0.01 ml per second

Continuous Rate Delivery Interval:

Every 3 minutes (approximately $^{1}/_{20}$ continuous rate)

Delivery specifications

Main Menu

Setup

Delivery Methods:

Choose to have the following delivery methods available:

Continuous Rate: Yes or No

Default: No

Automatic Dose: Yes or No

Default: No

Demand Dose: Yes or No

Default: No

Maximum Continuous Rate: 0.000 ml/hr to 1.000 ml/hr in 0.002 ml increments

Default: 0.800 ml/hr

Maximum Auto or Demand Dose: 0.000 ml to 1.000 ml in 0.002 ml increments

Default: 1.000 ml

Dose Duration: 1 to 15 minutes in 1 minute increments

Default: 12 minutes

Dose Lockout Time: 00:15 minutes to 24:00 hours in 00:15 (15 minute) increments

Default: 01:00 (1 hour)

Time and Date:

Allows user to set time and date

New Patient:

Mark for new patient: Yes or No

Default: No

Clear Delivery: Yes or No

Default: No

Security:

Delivery Program Menu: Yes or No

Default: Yes

Setup Menu: Yes or No

Default: Yes

Alerts:

Low cartridge volume: Alert at 0.050 ml to 0.500 ml in 0.01 ml increments

Default: 0.2 ml

Display site reminder: Yes or No

Default: No

Regional Settings:

Time Format: 12-hour or 24-hour

Default: 12-hour

Date Format: mm/dd/yy or dd/mm/yy

Default: mm/dd/yy

Decimal Symbol: Decimal shown as Period or Comma

Default: Period

Delivery Program

Delivery Methods: Choose to use the following delivery methods:

Continuous Rate: Yes or No

Default: No

Automatic Dose: Yes or No

Default: No

Demand Dose: Yes or No

Default: No

Continuous Rate Schedule:

Programmable (with a possible 48 time/rate segments)

Time: 12:00 AM to 11:30 PM in 00:30 increments or 00:00 to 23:30 in 00:30 increments

Default: --:--

Rate: 0.000 ml/hr to Continuous Rate Maximum (up to 1.000 ml/hr) in 0.002 ml increments

Default: 0.000 ml/hr

Automatic Dose Schedule:

Programmable (with a possible 24 time/dose segments)

Time: 12:00 AM to 11:30 PM in 00:30 increments or 00:00 to 23:30 in 00:30 increments

Default: --:--

Dose: 0.000 ml to Maximum Dose (up to 1.000 ml) in 0.002 ml increments

Default: 0.000 ml

Demand Dose: 0.000 ml to Maximum Dose (up to 1.000 ml) in 0.002 ml increments

Default: 0.000 ml

Load

User loads cartridge, fills tubing, fills cannula, and selects site change alarm (if displayed)

Fill tubing: Fills in 0.01 ml increments until **Stop** or **Done** is pressed (automatically stops at 0.3 ml).

Fill cannula: 0.000 ml to 0.012 ml in 0.001 ml increments

Default: 0.000 ml initially, then last programmed amount

Site change alert (if displayed - see Alert Specifications):
1 to 5 days in 1 day increments
Default: 3 days

12:30 AM (00:30) to 11:30 PM (23:30) in 00:30 minute increments
Default: 8:00 AM

History

User selects displayed report for viewing

Complete History: last 4000 events, arranged from most recent to oldest

Delivery Summary: last 90 days, arranged from most recent to oldest

Beep/Vibrate

Beep/Vibrate: Beep or Vibrate
Default: Beep

If beep, choose volume: Low, Medium or High
Default: High

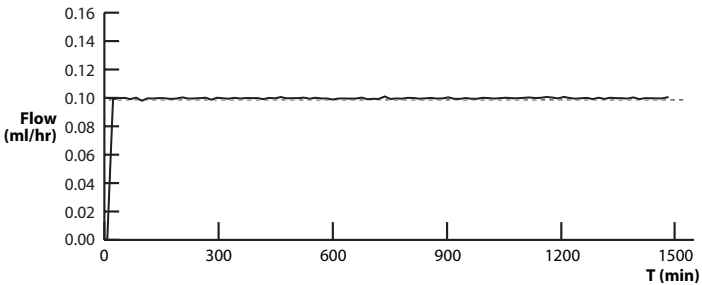
If beep, Key beeps (beep with each key press): Yes or No
Default: Yes

Accuracy test results

The following graphs are designed to show flow accuracy of a pump against given time periods. All graphs were plotted using a Smiths Medical 3 ml Medication Cartridge (21-7450) and Unomedical Comfort™ Infusion Set.

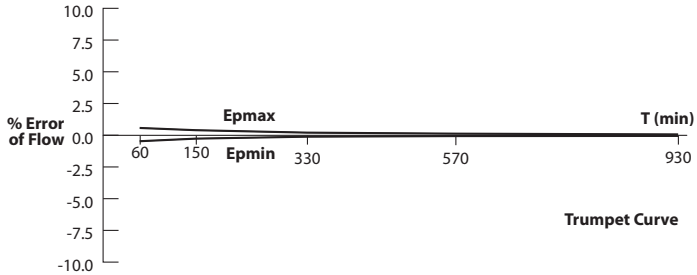
Flow rate from startup

Time interval:	15 seconds
Total time:	1455 minutes
Programmed rate:	0.1 ml/hr



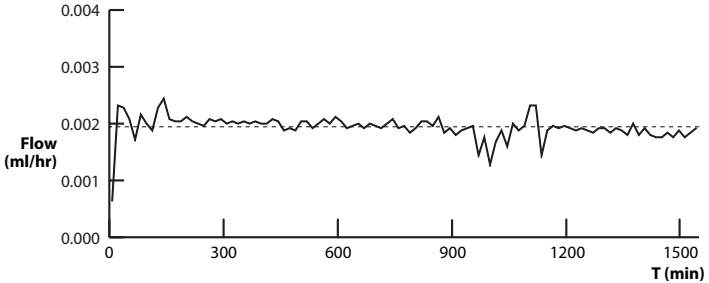
Flow rate error

Programmed rate:	0.1 ml/hr
Average flow rate:	0.1000 ml/hr
Mean flow error:	– 0.01%



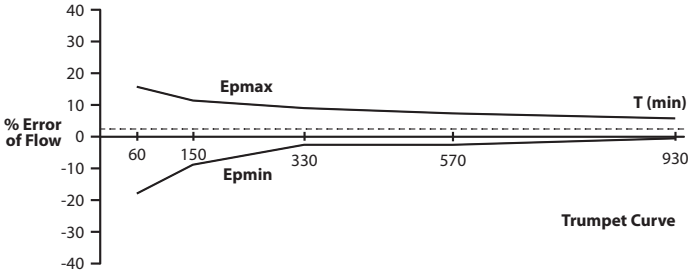
Flow rate from startup

Time interval:	15 minutes
Total time:	1530 minutes
Programmed rate:	0.002 ml/hr



Flow rate error

Programmed rate:	0.002 ml/hr
Average flow rate:	0.0021 ml/hr
Mean flow error:	2.59%



Safety features and fault detection

Hardware safety features

Key hardware safety features include a watchdog timer circuit, motor driver and motor watchdog circuits, and a voltage detector circuit. Each safety circuit performs a unique function to ensure the overall safety of the pump.

Watchdog timer circuit

The microprocessor must send an appropriate signal to the watchdog circuit at least once per minute. If the microprocessor does not send this signal, the circuit initiates a "time out" and shuts down the pump controller.

Watchdog timer circuitry is provided to monitor the status of the microprocessor, disable the motor, and cause the pump to beep if the microprocessor malfunctions. The microprocessor must strobe the watchdog circuit at least once per minute in order to prevent the watchdog from performing its reset function. The microprocessor tests the watchdog circuit on every power up.

By setting a flag in the memory and not strobing the watchdog, the microprocessor can force a watchdog time out. After being reset, the microprocessor checks the status flag to see if this was a time out test. If it was, the microprocessor continues its normal power up routine. If the reset occurred when the microprocessor was not expecting it, the microprocessor traps the event, an alarm is given (either beep or vibrate), and an error message appears in the display.

Motor drive/motor watchdog circuit

Motor drive circuitry is composed of a series of FET transistors, passive components, two voltage comparators and the second microprocessor. The second microprocessor times how long the motor runs each time it is turned on. If the motor runs for longer than the primary microprocessor specifies, the circuit times out and disables the motor. A unique feature of this circuit is that control lines to and from the microprocessor circuit allow the microprocessor to perform the complete functional test of the motor drive circuit without running the motor. The microprocessor performs this test every several minutes to assure its continued functionality. An input from the watchdog circuit prevents motor operation if the watchdog timer expires. The software verifies this function during the watchdog test described above.

Voltage detector circuit

Low voltage detection is performed by part of the watchdog circuit and by the microprocessor via software. Three low voltage levels are detected. The first two levels are detected by software and the third by hardware. The first level to be reached is the Low Battery Warning threshold, which occurs when the battery voltage decays to a point where less than 10% operating time is available. An analog to digital converter (ADC) built into the microprocessor allows the microprocessor, via software, to monitor the battery voltage. At the Low Battery Warning threshold, the microprocessor enables an alarm (either beep or vibrate) and displays the low battery alert in the display. When the battery voltage drops to a point where it is too low to guarantee proper motor operation, the microprocessor via software stops delivery, generates an alarm (either beep or vibrate), and a depleted battery alarm message appears in the display. When the battery voltage drops to a value where operation of the microprocessor cannot be guaranteed, a hardware reset circuit is triggered which places the microprocessor in reset. This prevents ambiguous microprocessor operation as the battery voltage continues to decay. The hardware reset continues until the battery is completely depleted or it is removed. Once the pump controller goes into low battery shutdown, only replacing the depleted battery with a new battery will clear the condition.

Software safety features

Hardware-related software safety features

Program memory check

At power up and regular intervals thereafter, the program memory is tested by calculating a cyclic redundancy code (CRC) on the program and then comparing it with the CRC stored with the program.

If the stored and calculated CRC do not match, the software stops medication delivery, initiates an alarm (either beep or vibrate) and a system fault alarm message appears in the display.

RAM memory check

At power up, the random access memory (RAM) is checked. A series of bit patterns is written to and read from each address in the RAM. If the read data is different from the written data, the software stops medication delivery, initiates an alarm (either beep or vibrate) and a system fault alarm message appears in the display.

Motor circuit check

At power up and at regular intervals thereafter, the motor circuit is checked to ensure that no power is being applied to the motor unless the motor is actually on. If the software detects power being applied to the motor at any other time, it initiates an alarm (either beep or vibrate) and no longer attempts to deliver medication. During every pump activation, the software checks to see whether the motor completes one activation. If the motor fails to turn, or fails to complete an activation, the software stops medication delivery, initiates an alarm (either beep or vibrate) and a system fault alarm message appears in the display.

Keypad encoder check

Every time the software receives data from the keypad, it is checked. If the data is not a valid keypress, the software disregards the keypress.

Data handling and software safety features

Data stored in RAM

Before use, data associated with delivery and stored in RAM is tested by calculating a CRC on the data and then comparing it with CRC stored in the data. If the stored and calculated data do not match, the software stops medication delivery, initiates an alarm (either beep or vibrate) and a system fault alarm message appears in the display.

Data stored in NOVRAM

Before use, data associated with delivery and stored in NOVRAM is tested by calculating a CRC on the data and then comparing it with CRC stored in the data. If the stored and calculated data do not match, the software stops medication delivery, initiates an alarm (either beep or vibrate) and a system fault alarm message appears in the display.

Data used in calculations

Calculations on data used in some way to control delivery of medication are performed redundantly.

The two calculated values are then compared. If the two values do not match, the software stops medication delivery, initiates an alarm (either beep or vibrate) and a system fault alarm message appears in the display.

Timer data registers

The data in the Real Time Clock is checked at regular intervals. If the data is not reasonable, the software stops medication delivery, initiates an alarm (either beep or vibrate) and a system fault alarm message appears in the display.

Inspecting the pump

Other than periodic visual inspection and cleaning of the pump, no testing of the pump is required. The pump's internal software, hardware and dual microprocessors are constantly checked while the pump is operating, and during the self tests performed during power up.

- Visually inspect the pump for any damage to the pump's outer shell. Look for chips or cracks. If the outer shell is chipped or cracked, the pump may no longer be watertight. Visually inspect the cartridge and battery chambers to make sure they are clean and free of foreign objects/materials.
- Visually inspect the display. If there are missing or incomplete characters, or if the display is otherwise damaged, stop using the pump immediately.
- Visually inspect the cartridge cap and battery cap. Make sure they fit properly and tightly on their respective compartments.

⇨ **Warning: Make sure that the battery cap is fully tightened to avoid an interruption in battery power which can cause the pump to power down and stop the delivery of drug therapy. A prolonged interruption in the delivery of drug therapy can result in serious patient injury or death.**

- Make sure that the battery cap is fully tightened. The battery cap is fully tightened when the battery cap o-ring is not visible, the cap fits snug, and when you press on the battery cap the pump does not produce a "chirp" (see Figures 11 and 12). If the pump sounds a brief alert ("chirp"), the cap **is not fully tightened** and should be tightened further. If you are unable to tighten the cap and eliminate this chirp, the pump should not be used. Contact your pump provider or Smiths Medical.

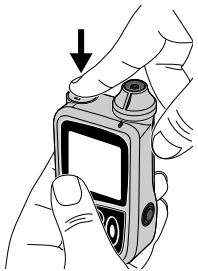
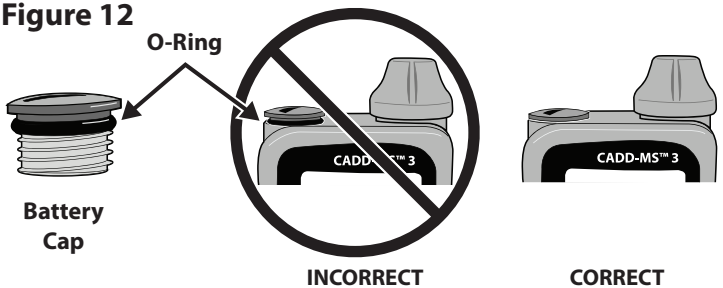


Figure 11

- Inspect the Pump's battery cap. The battery cap should be free of damage. If the cap shows signs of wear, such as cracks, or if the slot becomes worn, the battery cap should be replaced before the Pump is used. Contact your Pump provider or Smiths Medical for a replacement battery cap.

Reference the Cleaning the pump and Servicing the pump sections in the Help section of this manual if you need to clean or return a pump for service.

Figure 12



Collect Separately 

This product contains electrical and electronic components (including batteries) that may contain materials, which if disposed of with general waste, could be damaging to the environment.

In accordance with Directive 2002/96/EC Waste Electrical and Electronic Equipment, residents of the European Union must follow specific disposal or recycling instructions for this product. Contact your local distributor, or visit the following web site for specific instructions:
http://www.smiths-medical.com/recycle/index.html

Non-European union residents must dispose of or recycle this product (including batteries) in accordance with the local laws or regulations that apply.

⇨ **Warning: There are potential health hazards associated with improper disposal of batteries, electronics, and contaminated (used) infusion sets and cartridges. Dispose of used batteries, infusion sets, cartridges, and other used accessories, or a pump that has reached the end of its useful life, in an environmentally safe manner, and according to any regulations that may apply.**

Limited Warranty

Smiths Medical MD, Inc. (the "Manufacturer") warrants to the Original Purchaser that the CADD-MS™ 3 Ambulatory Infusion Pump (the "Pump"), excluding accessories, shall be free from defects in materials and workmanship under normal use, if used in accordance with this Operator's Manual, for a period of one (1) year from the date of purchase by the Original Purchaser. This warranty does not cover normal wear and tear or maintenance and specifically excludes all accessories, including, but not limited to batteries, infusion sets, cartridges, apparel, equipment, computers and printers used with the Pump.

Limitation of Remedies

The Manufacturer will repair or replace without charge (except for postage and handling) any Pump (excluding all accessories) which is determined by the Manufacturer to be defective during the one (1) year warranty period. In the event the Pump is replaced or repaired, the warranty period will not extend beyond the original warranty period. THIS IS THE EXCLUSIVE REMEDY.

Parties Covered:

This Warranty extends only to the Original Purchaser of the Pump. This Limited Warranty does not extend to subsequent purchasers. The Original Purchaser may be a patient, medical personnel, a hospital, or institution which purchases the Pump for treatment of patients. The Original Purchaser should retain the invoice or sales receipt as proof of the actual date of purchase.

Conditions of Warranty:

This warranty is valid only if the Pump is used in accordance with this Operator's Manual. The warranty will be void in the following cases:

1. The Pump has been altered, misused (misuse includes, but is not limited to use not in accordance with this Operator's Manual, used with accessories not approved by the Manufacturer and/or used with a computer program other than that licensed by the Manufacturer) or damaged by neglect or accident;

2. The Pump has not been properly maintained or has been repaired by persons not authorized by the Manufacturer. The Pump is a sealed unit, and the fact that the seal has been broken will be considered conclusive evidence that the Pump has been altered or misused.; or

3. The Pump serial number has been removed or damaged.

Exclusions:

All other warranties, express or implied, are excluded, including but not limited to the warranties of merchantability and fitness for a particular purpose or use. The remedies provided in this Warranty are the exclusive remedies available to the Original Purchaser for any breach of this Warranty and no person has the authority to bind the Manufacturer to any representation, condition or warranty except this Warranty.

The Pump can only be used under the supervision of medical personnel whose skill and judgment determine the suitability of the Pump for a particular medical treatment and patient.

The Manufacturer, its distributors or suppliers shall not be responsible for any incidental, special or consequential damages of any kind or nature caused by or arising out of a defect or malfunction of the Pump.

All recommendations, information, and descriptive literature supplied by the Manufacturer or its agents are believed to be accurate and reliable, but do not constitute warranties.

Warranty Procedure

Notice of the claimed warranty defect must be made in writing, fax or by telephone to the Manufacturer as follows: Smiths Medical MD, Inc., 1265 Grey Fox Road, St. Paul, MN 55112 U.S.A. Telephone: 1 800.426.2448, or if outside the USA contact your local distributor. Original Purchaser must include date of purchase by the Original Purchaser, model and serial number, and a description of the claimed warranty defect in sufficient detail to allow the Manufacturer to determine and facilitate any repairs which may be necessary.

AUTHORIZATION MUST BE OBTAINED PRIOR TO RETURNING THE PUMP. If authorized, the Pump must be properly and carefully packaged and returned to the Manufacturer, postage prepaid. Any loss or damage during shipment is at the risk of the sender.

This Warranty gives the Original Purchaser specific legal rights. The Original Purchaser may have other legal rights which may vary from state to state.

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CE 0473

The products described are covered by one or more of the following: U.S. Patent No. 7,033,338; 7,041,082; and 6,241,704. Other U.S. and foreign patents pending.

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smiths medical