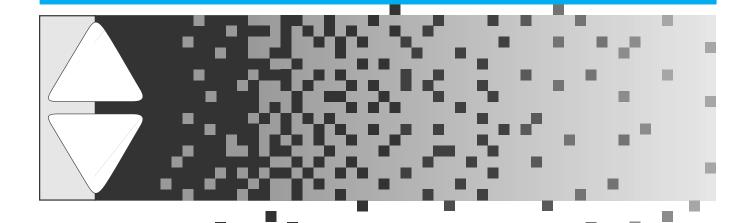
This online version differs from the printed version.
Certain information that is not intended for patients has been removed.





Deltec

SIMS Deltec, Inc., St. Paul, MN 55112 U.S.A.



This manual pertains only to the Deltec CADD-1®, **Model 5100 HFX**, infusion pump.

The issue date of this Operator's Manual is included for the clinician's information. In the event one year has elapsed between the issue date and product use, the clinician should contact SIMS Deltec, Inc. to see if a later revision of this manual is available.

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CADD, CADD-1, Medication Cassette Reservoir and Medication Cassette Reservoir design are SIMS trademarks.

These products are covered by U. S. Patent Nos. 4,559,038; 4,565,542; 4,650,469 and D294,733; other patents pending.

DURACELL® is a registered trademark of DURACELL INC. EVEREADY® ENERGIZER® is a registered trademark of UNION CARBIDE CORP. ULTRALIFE® is a registered trademark of ULTRALIFE Batteries, Inc.

Technical Assistance

If you have comments or questions concerning the operation of the CADD-1® pump, please call this number: **800-426-2448**.

Our staff is available to help clinicians twenty-four hours a day with the programming and operation of the CADD-1® infusion pump.

SIMS Deltec, Inc. 1265 Grey Fox Road St. Paul, Minnesota 55112 U.S.A.

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1.0 INTRODUCTION

The Deltec CADD-1® pump provides measured drug therapy to patients in hospital or outpatient settings. Healthcare professionals should use this manual to learn how to operate the pump.

The purpose of this manual is to familiarize you with the CADD-1® pump's functions, which are described in Section 2; and to instruct you in how to use those functions, which are outlined in detail in Section 3. Section 4 is a reference.

2.0 GENERAL DESCRIPTION OF CADD-1® PUMP OPERATIONS

The CADD-1® Model 5100 HFX ambulatory drug delivery pump is indicated for intravenous, intra-arterial, or subcutaneous infusion (excluding insulin).

Therapy should always be overseen by a physician or a certified, licensed healthcare professional. The patient should be instructed in using and troubleshooting the pump.

The pump's flexibility in programming allows it to be used in a variety of settings, including the home. The pump provides continuous delivery of medication.

- You can program the pump to deliver medication at a constant rate in milliliters per 24-hour period.
- You may also select the **High Flow Mode**. High Flow delivery provides a rate of approximately 90 ml/hr.

2.1 WARNINGS and CAUTIONS

Read this entire Operator's Manual before operating the CADD-1® ambulatory infusion pump.

Failure to properly follow warnings, cautions, and instructions could result in death or serious injury to the patient.

2.1.1 WARNINGS

- Do not use a pump that appears to have been damaged or tampered with, or is not functioning properly.
- Use only drugs and solutions which are stable under delivery conditions experienced during use in the pump. Observe warnings packaged with the Medication Cassette $^{\text{\tiny M}}$ Reservoir or CADD $^{\text{\tiny B}}$ Administration Set.
- Do not use the pump in the presence of flammable anesthetics or explosive gases.
- The pump does not have an air-in-line alarm, an air entrapment mechanism, or an upstream occlusion detector mechanism. Periodic visual inspection is therefore recommended.
- Back-pressure or fluid resistance, which depends upon drug viscosity and catheter size, may result in system delivery inaccuracies.
- Only the CADD® Extension Set with Anti-Siphon Valve must be used with this pump; other extension sets will result in system delivery inaccuracies.
- This pump is capable of being set at a residual volume higher than the capacity of the fluid container. The reservoir-residual volume value should be programmed to reflect the actual volume of the medication being used.
- Avoid dropping the pump or hitting the pump against a hard surface, as this could cause the cassette to become detached and the battery cover to become detached or loose. If the cassette becomes detached, an uncontrolled flow of medication from the fluid container or a reflux of blood may result, which could result in death or serious injury to the patient. If the battery door becomes detached or loose, the battery will not be properly secured; this may result in loss of power, nondelivery of drug, and, depending on the type of drug being administered, death or serious injury.
- If the pump is dropped or hit, inspect the pump to ensure that the cassette did not become detached and the battery cover did not become dislodged. Inspection should include closing the clamp on the tubing, detaching the pump and inspecting the hinges, and checking the clips on the battery door to ensure they are not broken. If there appears to be damage, the patient should be instructed to immediately contact his or her health care provider, the pump should be taken out of service, and Deltec's Customer Service department should be contacted for return authorization. If there appears to be no damage, reattach the cassette following the instructions in the Operator's Manual.

- To prevent the uncontrolled flow of medication, use a CADD® Extension Set with Anti-Siphon Valve, a CADD® Administration Set with integrated anti-siphon valve, or a CADD® Administration Set with an attached Add On Anti-Siphon Valve.
- Use of a syringe with the CADD® Administration Set may result in UNDER-DELIVERY of medication. Syringe function can be adversely affected by variations in plunger dimension and lubricity, which can result in greater force being required to move the plunger. A syringe will lose plunger lubrication as it ages and, as a result, the amount of under-delivery will increase which could, on occasion, be significant. Therefore, the type of medication therapy and delivery accuracy required must be considered when using a syringe with the CADD® pump.

Clinicians must regularly compare the volume remaining in the syringe to the pump's displayed values such as RES VOL and GIVEN in order to determine whether under-delivery of medication is occurring and, if necessary, take appropriate action.

2.1.2 CAUTIONS

- This device is not intended to be used for delivery of blood or cellular blood products.
- This device may interfere with ECG equipment. Monitor ECG equipment carefully when using this device.
- The pump is not sterile. It is not designed to be sterilized. Sterilization could damage the microcomputer and other pump parts.
- The pump should be routinely cleaned and kept free of dirt, liquids, and foreign objects.
- Do not store the pump at temperatures below -40°C (-40°F) or above 55°C (131°F).
- Do not operate the pump at temperatures below $+2^{\circ}\text{C}$ (35°F) or above 40°C (104°F).
- Do not expose the pump to humidity levels above 90% R. H.
- The pump is water resistant. However, total immersion is not recommended because moisture buildup within the case may damage the parts. Do not use pump in the shower, sauna, or steam bath.
- Do not store the pump for prolonged periods with a battery; the battery could leak and damage the pump.
- Avoid using the pump in close proximity to sources of strong static electricity or strong electromagnetic fields.
- The use of a Deltec Pump Pouch is recommended. If the pump is dropped or inadvertently hit against a hard surface, the pump pouch is designed to minimize the need for servicing.

2.2 Physical Description of the Pump and Accessories

The following diagram, Figure 1, illustrates the CADD-1® pump and its major functions.

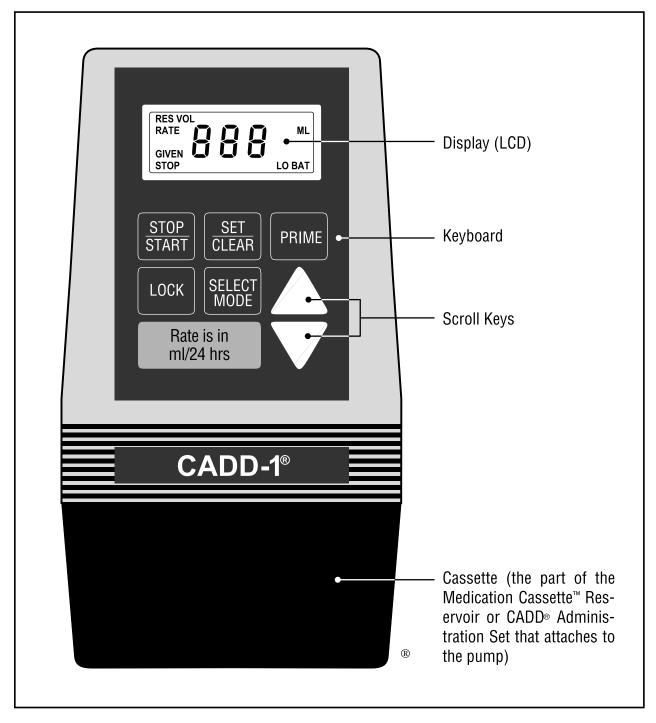


Figure 1. The CADD-1® pump.

2.2.1 Items Packaged with the Pump

Packaged with the pump are the following accessories:

- 1 Battery (9-volt)
- 1 50 ml Medication Cassette[™] Reservoir (non-sterile, for demonstration only)
- 1 Carrying case
- 1 Carrying pouch
- 1 Operator's Manual with warranty information

The following products are also compatible with the CADD-1® pump:

- Medication Cassette[™] Reservoir (50- or 100-ml), to be used with the Extension Set with Anti-Siphon Valve
- CADD® Administration Set with integrated or Add On Anti-Siphon Valve
- Pump Pouches

2.2.2 Description of the Function Keys and Display Panel

This is the pump's display panel; the screen which shows the pump's various functions or modes and the values you program for them. In this manual, the term "display" is synonymous with display panel or LCD.

Press and hold the STOP/START key to start or stop pump delivery.

Use the SET/CLEAR key for programming, setting or resetting, and clearing of numbers in the computer's memory.

Use the PRIME key to fill the tubing and to remove air bubbles from the fluid path.

Use the LOCK key to lock out or limit the patient's operation of the pump.

Use the SELECT MODE key to view the various modes, such as the Continuous Rate and RES VOL modes. When the pump is in the Stop or Start mode, and you press and release the SELECT MODE key, the pump will display each mode in succession. You will have to press the SELECT MODE key each time you wish to access another mode. (See Section 3.9, "Reviewing the CADD-1® Programming Modes".)

Use the up or down SCROLL keys to increase or decrease the numeric value shown on the pump's display.

2.2.3 Description of the Medication Cassette[™] Reservoir or CADD[®] Administration Set

The CADD-1[®] pump may use a detachable, single use Medication Cassette^{$^{\text{TM}}$} Reservoir for holding the drug. They are available in 50 ml and 100 ml sizes.

A CADD® Administration Set may also be used to deliver medication from IV bags of various sizes.

The procedures for attaching and removing the cassette (the part of the Medication Cassette $^{\text{\tiny M}}$ Reservoir or CADD $^{\text{\tiny B}}$ Administration Set that attaches to the pump) are located in Section 3.

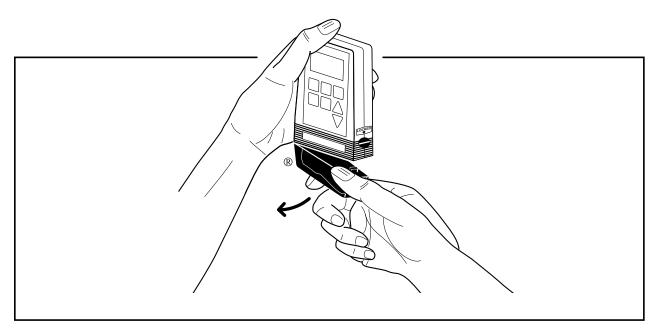


Figure 2. Discard a used Medication Cassette[™] Reservoir or CADD[®] Administration Set immediately.

2.3 Understanding the Delivery Modes

This section introduces the three delivery modes that appear on the CADD-1® HFX pump display: (1) the Continuous Rate (ML) Mode; (2) the Milliliters Given (ML GIVEN) Mode; and (3) the Reservoir-Residual Volume (RES VOL) Mode. Further details concerning these delivery modes are introduced in Section 3.3, "Programming the CADD-1® Pump for Continuous Rate Delivery."

2.3.1 Description of the Continuous Rate Mode

Programming the pump in the Continuous Rate Mode permits a steady infusion rate. (See Figure 3.) In this mode, you can program the pump to deliver medication at a constant rate in milliliters per 24-hour period.

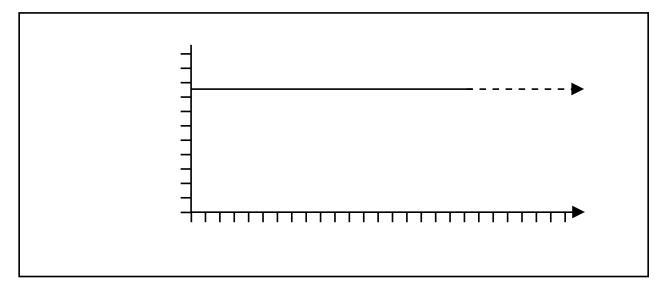


Figure 3. The Continuous Rate Mode.

2.3.2 Description of the High Flow Mode

You may also select the **High Flow Mode**. High Flow delivery provides a rate of approximately 90 ml/hr.

2.3.3 The Continuous Rate (ML)

The delivery rate in ML (milliliters in a 24-hour period) is the constant rate at which the pump delivers medication. The delivery rate range is from 1 ml to 299 ml/24 hours in 1 ml increments. If you program a delivery rate of 000 ml, delivery will not occur.

2.3.4 The Milliliters Given (ML GIVEN)

The ML GIVEN refers to the number of milliliters delivered since the ML GIVEN register was last cleared.

The number of milliliters in ML GIVEN accumulates from 000 to 999 and then automatically resets to 000. Please note that the ML GIVEN counter functions in a way that is similar to your automobile's odometer. After the ML GIVEN counter reaches 999, it will start at 000 again and continue counting.

2.3.5 The Reservoir-Residual Volume (RES VOL)

The Reservoir-Residual Volume (RES VOL) refers to the initial amount of medication (in milliliters), contained in the fluid container, that you wish to deliver. You must enter that amount into the computer's memory to determine the amount of medication remaining in the fluid container. [See Section 3.3.1, "Setting the Reservoir-Residual Volume (RES VOL)".]

3.0 OPERATOR INSTRUCTIONS

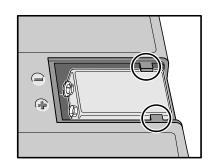
This section describes how to operate the CADD-1® pump. It contains detailed, step-by-step instructions that will enable you to perform the following tasks:

•	Installing a battery and observing the Power up Test (Section 3.1)
•	Preparing to program the pump (Section 3.2)
•	Setting the reservoir-residual volume (Section 3.3.1)
•	Setting the continuous rate (Section 3.3.2)
•	Programming for High Flow delivery (Section 3.4)
•	Attaching the Cassette (Section 3.5.2)
•	Priming the tubing (Section 3.6)
•	Setting the lock levels (LL0, LL1, or LL2) (Section 3.7)
•	Starting and stopping the pump (Section 3.8)
•	Reviewing the CADD-1® programming modes (Section 3.9)

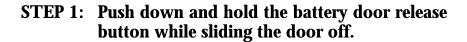
3.1 Installing or Replacing the Battery

Use a new, 9-volt alkaline or lithium battery to power the pump. (See Section 4.5.2, "General Specifications," for further information regarding batteries.)

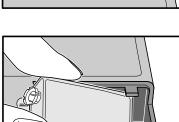
WARNING:



As soon as you install the battery, the pump will be on; there is no On/Off switch. In order to install or replace a battery, be sure to place the pump in the **Stop mode**. Then, follow these steps:

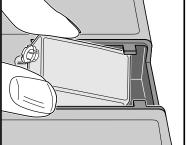






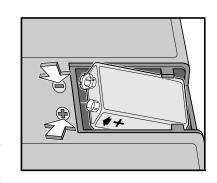
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STEP 3: Install the battery in the compartment (bottomend first).

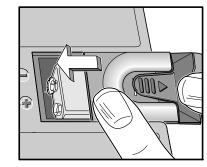


NOTE:

Use a new, 9-volt alkaline or lithium battery to power the pump. You may use any alkaline battery, including DURACELL® Alkaline MN 1604 and EVEREADY® ENERGIZER® Alkaline #522, for example; or, use the ULTRALIFE® Lithium U9VL battery. You may also use an external power source to run the pump.

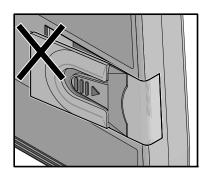


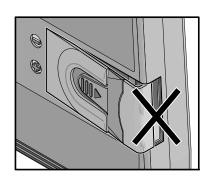
STEP 4: Place the battery door halfway over the battery compartment and press the battery into the compartment by pushing down on top of the door with your thumb.

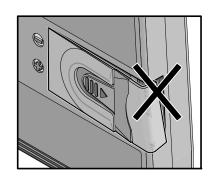


STEP 5: Slide the door closed. Ensure that the door is latched by trying to remove the door without pressing the release button.

WARNING:







The power up sequence will start, and the pump will go through an electronic self-test, which lasts about 50 seconds. All of the display indicators and the software revision level will appear briefly.

STEP 6: Begin operation of the current program by pressing and holding the STOP/START key to enter the Start mode (Section 3.8), or proceed to Section 3.2 to program the pump.

NOTE:

The battery's life is dependent on the amount of medication delivered and the temperature. At the infusion rate of one 50 ml Medication Cassette^{$^{\text{M}}$} Reservoir per day, an alkaline battery will usually last about seven days. If you use an ULTRALIFE^{$^{\text{M}}$} lithium battery, you will have power for approximately ten days. **Be sure to stop the pump before removing the battery, or up to 10 ml of solution may not be accounted for by the ML GIVEN function.** A battery's power will be quickly depleted at temperatures below $+10^{\circ}\text{C}$ (50°F).

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3.2 Preparing to Program the CADD-1® Pump

The CADD-1® pump must be in Lock Level 0 (LL0) in order to program the pump.

You will need to perform three steps to ensure that the pump is in Lock Level 0 (LL0):

- 1. Make sure that the pump is in the Stop mode.
- 2. Determine the current lock level of the pump.
- 3. Change the lock level to Lock Level 0 (LL0)

When the pump is set at LL0, you are ready to turn to Section 3.3, "Programming the CADD-1® Pump." Section 3.6, "Programming the Patient Lock Levels (LL0, LL1, and LL2)" provides more information about the pump's lock levels.

NOTE:

STEP 1: Make sure the pump is in the Stop mode.

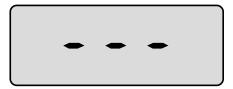
When the pump is in the Stop mode, the word "STOP" flashes in the lower left corner of the display, and you will hear three beeps every 5 minutes. If the pump is in the Stop mode, go to Step 2.



• Press and hold the STOP/START key.



You will hear a single beep, and three dashes will appear one-by-one on the pump's display.



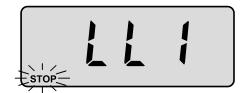
• Release the STOP/START key after the third dash appears and you hear a second beep.

STEP 2: Determine the current lock level of the pump.

• Press and release the LOCK key.



This example shows that the pump is in Lock Level 1.



STEP 3: Change the lock level to Lock Level 0 (LL0).

• Press the up or down SCROLL key until LL0 appears on the display.





• Press the LOCK key.



The display shows "000."



• Press the up SCROLL key (** text omitted from online version**) on the pump's display.



NOTE:

(** text omitted from online version**)



• Press the LOCK key to enter the new lock level into the pump's memory.



• Press the LOCK key again to verify that you are in LL0.





• Press the LOCK key two more times in succession to return to the RES VOL display, which is the starting point for infusion or for programming the pump.





3.3 Programming the CADD-1® Pump for Continuous Rate Delivery

NOTE:

3.3.1 Setting the Reservoir-Residual Volume (RES VOL)

The pump's computer memory keeps track of the amount of the drug infused; and the display automatically shows the calculated amount of the drug in milliliters that remain in the fluid container.

You must enter the initial volume (ml) of the drug, contained within the fluid container, into the pump's memory.

There is a warning alarm when the calculated number of milliliters remaining is at or below 5 milliliters. When RES VOL reaches 0 ml, a continuous alarm signals that the fluid container is empty, and the pump stops automatically.

You may program the reservoir-residual volume to a maximum of 999 ml when using large capacity bags.

NOTE:

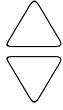
• Press the SELECT MODE key until "RES VOL" appears on the display.



This example shows a RES VOL setting of 100 ml with the pump in the Stop mode.



• Press the SCROLL keys to set the value for the volume contained in the fluid container.



• Press the SET/CLEAR key within 15 seconds to set the value.



NOTES:

3.3.2 Setting the Continuous Rate (ML)

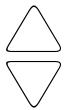
The delivery rate in ML (milliliters in a 24-hour period) is the constant rate at which the pump delivers medication. The delivery rate range is from 001 ml/24 hrs to 299 ml/24 hrs in 1 ml increments/24 hrs.

 Press and release the SELECT MODE key until RATE and ML appear on the display with a number within the range 001 to 299 ml.





• Press the SCROLL keys to the number of milliliters of medication you wish to deliver in a 24-hour period.



• Press and release the SET/CLEAR key within 15 seconds to set the rate.



NOTE:

3.3.3 Reviewing the ML GIVEN (ML GIVEN)

The ML GIVEN mode displays the total milliliters delivered since the mode was last cleared, including the quantities delivered in the Continuous Rate and High Flow modes. The number of milliliters in ML GIVEN increases from 000 to 999 and then automatically resets to 000. Please note that the ML GIVEN counter functions in a way that is similar to your automobile's odometer. After the ML GIVEN counter reaches 999, it will start at 000 again and continue counting.

This ML GIVEN display shows that 50 milliliters have been given.



NOTE:

• Press and release the SET/CLEAR key to clear the ML GIVEN value and to reset the display at 000.



This completes the programming of the CADD-1® pump for the Continuous Rate mode. To verify that you have programmed the values for each mode correctly, press and release the SELECT MODE key to review each value.

3.4 Programming the CADD-1® Pump for High Flow Delivery

You can select High Flow Mode so the pump delivers medication at a rate of approximately 90 ml/hr. Once you select the High Flow Mode and start the pump, you cannot change the Lock Level or view any other values. High Flow delivery will continue until you stop the pump or until the reservoir-residual volume (RES VOL) reaches zero.

In order to program the pump for high flow delivery, follow this procedure:

- Confirm that the pump is in the Stop mode and in Lock Level 0. Set the reservoir-residual volume as described in Section 3.3.1. Attach the cassette and prime the fluid path as described in Sections 3.5 and 3.6.
- Press and hold the PRIME key until three P's appear on the display. Release the PRIME key.



Press and hold the SCROLL key until (** text omitted **)





• Press and release the PRIME key. "HI F" will appear on the display.





 Press and release the STOP/START key to start the delivery of medication.



NOTE:

•	Press and release the STOP/START or SET/CLEAR key to stop the pump.
CAUT	TION:

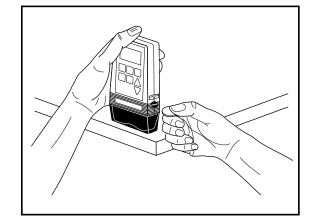
3.5 Attaching and Removing the Cassette

3.5.1 Removing a Used Cassette

WARNING:

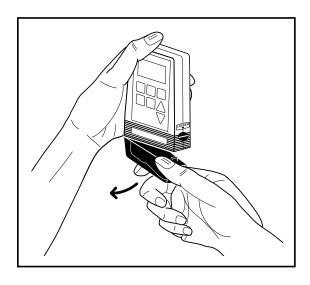
To remove the cassette, follow these steps:

- Place the pump with the cassette attached in an upright position on a firm, flat surface.
- Insert a coin into the slot in the locking button and turn it one-quarter turn **clockwise**. The locking button will pop out when you unlock the cassette.



- Disengage the cassette hooks from the pump hinge pins.
- Discard the used Medication Cassette[™] Reservoir or CADD® Administration Set.

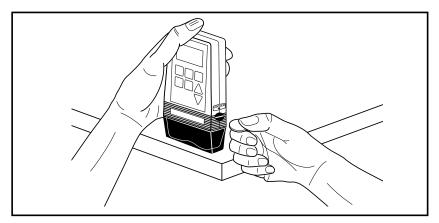


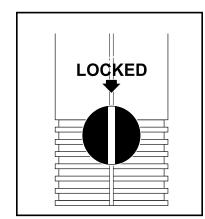


3.5.2 Attaching the Cassette

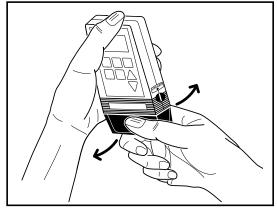
Obtain a new, filled Medication Cassette[™] Reservoir, or CADD® Administration Set attached to a nonvented fluid container. Refer to the instructions for use supplied with the product for preparing the product for use.

- Ensure that the fluid path tubing is closed with the clamp.
- Insert the cassette hooks into the hinge pins on the pump and place the pump upright on a firm, flat surface.





- Press down on the pump so the cassette fits tightly against the bottom of the pump. Lock the cassette in place by inserting a coin into the slot in the locking button, pushing the button in; and then turn the coin one-quarter turn **counterclockwise** until a definite stop is felt.
- Gently twist and pull on the cassette to make sure it is firmly attached.



WARNING:

3.6 Priming the CADD-1® Pump Tubing

To use the Prime mode, be sure that the pump is in the Stop mode and in either Lock Level 0 (LL0) or Lock Level 1 (LL1). You cannot prime the tubing in Lock Level 2 (LL2).

WARNING:

NOTE:

• Press and hold the **PRIME** key. You will hear a single beep, and the letters "**PPP**" will appear one-by-one on the display.



• After PPP appears, and you hear a second, single beep, release the PRIME key.



• Press and hold the PRIME key again to fill the fluid path and to eliminate air bubbles. You will hear a short beep each time the pump goes through a delivery cycle.



NOTES:

WARNING:

3.7 Programming the Patient Lock Levels (LL0, LL1, and LL2)

The CADD-1® pump has three different lock levels. They appear on the pump's display as "LL0," "LL1," and "LL2." **The purpose of the lock level function is to permit programming of the pump and to restrict patient use of the keyboard.** The lock levels function in this way: (1) **LL0** permits you to program the pump; (2) **LL1** permits the patient to have limited control of the pump; and (3) **LL2** permits the patient to have only minimal control of the pump. Before the pump is given to the patient, the lock level must be reset to LL1 or LL2 to prevent the patient from having complete access to all programming and operating functions.

NOTE:

The clinician may permit the patient to change the continuous delivery rate by changing the lock level to LL1. The clinician sets the maximum continuous rate while the pump is in Lock Level 0.

In Lock Level 1, when in the Stop mode, the patient can change the continuous rate by pressing the SELECT MODE key until RATE and ML appear on the display. By using the SCROLL keys, the patient can either scroll up to the maximum continuous rate allowed by the clinician or scroll down to a lower rate.

When the desired rate appears on the display, the patient presses the SET/CLEAR key to set the new rate. If the SET/CLEAR key is not pressed within 15 seconds, the pump will deliver at the previous rate.

The following table shows which keys are active in the different lock levels.

Lock Level	Description		
LLO	Use this lock level for programming the pump's functions.		
LL1	In the Continuous Rate mode, the patient may decrease the MI rate or increase it up to the value that had been programmed in Lock Level 0. In addition, the patient may prime the tubing and reset the RES VOL to the original programmed value.		
LL2	The patient may stop or start the pump and clear the RES VC alarm.		
LL0, LL1, LL2	If the RES VOL on the display is "000," the patient may reset the RES VOL by pressing the SET/CLEAR key. To display the current lock level, be sure the pump is in the Stop mode; and then press and release the LOCK key.		

Table 1. Control Limits of the CADD-1[®] Pump.

To find and change the lock level, make sure that the pump is in the Stop mode. When the pump has stopped, the word "STOP" will flash on the lower left

corner of the display. In this example, the display shows a RES VOL setting of 100 ml with the pump in the Stop mode. You will hear three beeps every 5 minutes as a reminder that the pump is in the Stop mode.



• Press and release the LOCK key once to determine the current lock level, which will appear on the display for 15 seconds. In this example, the display shows "LL2."



• Press either SCROLL key to select the desired lock level (either LL0, LL1, or LL2).



• Once you have selected the desired lock level, press the LOCK key again. The display shows "000."



• Scroll to (** text omitted from online version**)
You should not let the patient know this code, in order to prevent the patient from programming the pump.



• Press the LOCK key again to complete the final step in the locking sequence. The display will return to the previous display. In this example, the display shows a RES VOL setting of 100 ml with the pump in the Stop mode.





• Press the LOCK key again to verify that the pump has been set at the correct lock level. Press the LOCK key two more times in succession to return to the RES VOL display, which is the starting point for infusion.



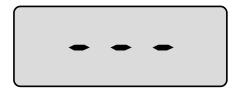
NOTE:

3.8 Starting and Stopping the Pump

To **start** the pump, follow these steps:

STEP 1: Press and hold the STOP/START key. Three dashes appear on the display; then they disappear one-by-one.



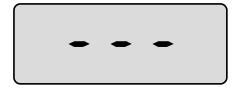


STEP 2: Release the STOP/START key after the last dash disappears, and the pump beeps; then the word "STOP" disappears from the display, and all of the programmed modes appear for your review one after the other.

To **stop** the pump, follow these steps:

STEP 1: Press and hold the STOP/START key. Three dashes will appear one-by-one on the pump's display.





STEP 2: After the third dash appears, release the STOP/START key. The word "STOP" will flash on the display. In this example, the display shows a RES VOL value of 28 ml.



3.9 Reviewing the CADD-1® Programming Modes

Drug delivery begins in the Start mode. When the pump is in the Start mode, programming is not possible, but you can review the pump's programming modes. To review each mode in succession, press and release the SELECT MODE key after each mode appears on the display.

While the pump is scrolling through the modes, the following applies:

- The pump maintains its pumping rate.
- The ML blinks when RES VOL and GIVEN appear on the display but stops blinking when RATE appears.

4.0 REFERENCE SECTION

4.1 Glossary

This term refers to the removal of air from the fluid path by suction.

A trademark acronym for Computerized Ambulatory Drug Delivery.

The device that allows the pump to operate with large capacity IV bags. For instance, by attaching a CADD® Administration Set to the pump, you could use a 250 ml flexible plastic IV bag.

The portion of the Medication Cassette $^{\text{\tiny TM}}$ Reservoir or CADD $^{\text{\tiny ®}}$ Administration Set which attaches to the pump.

When you program the pump in the Continuous Rate mode, you permit the patient to receive medication at a constant rate.

The portion of the delivery system, consisting of the fluid container, tubing, and catheter, which contains medication.

When you program the pump in the High Flow mode, you permit the patient to receive medication at the approximate rate of 90 ml/hr.

A warning message that appears on the display to inform you that there is "high pressure" in the pump's system. You will hear an oscillating alarm as a warning.

The screen or viewing area on the pump that displays modes, values, and the conditions of operation. In this manual, the term "display" is synonymous with LCD.

A signal on the display that indicates low power in the battery. As long as the indicator is blinking, the pump will continue to operate, but you should change the battery soon. If the LO BAT indicator stays on continuously, you should change the battery immediately.

This term refers to a keyboard LOCK setting that restricts the patient's operation of the pump. You program the pump in Lock Level 0 (LL0); you permit the patient to have some control of drug delivery in Lock Level 1 (LL1); and in Lock Level 2 (LL2), you permit the patient to have only minimal control.

The container that holds the medication. You must use a CADD® Extension Set with Anti-Siphon Valve when using the Medication Cassette[™] Reservoir.

The electronic device that controls the pump.

A condition, method, or state of operation. For example, you may program a specific mode, such as the RES VOL mode.

This term refers to the catheter being open or unobstructed.

Press this key to purge air from the fluid path. You should perform that procedure before you attach the tubing to the indwelling catheter. When you press the PRIME key, three P's will appear on the display.

This term refers to the smallest volume of medication that the pump can deliver.

See RES VOL.

The term refers to the amount of medication (in milliliters) that was initially programmed for delivery. When an alarm signals that the residual volume is low, RES VOL blinks on the display.

Two triangular shaped keys used to increase or decrease the numeric value shown on the display.

4.2 Pump Maintenance and Cleaning

CAUTION:

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 nine parts water)
- Alcohol, USP (93%)
- Isopropyl Alcohol, USP (99%)
- 1. Dampen a soft, lint-free cloth with cleaning solution. Apply the solution to exterior surface of the pump.
- 2. Wipe the entire surface dry with another soft, lint-free cloth. Allow the pump to dry completely before use.

4.3 Equipment Exposure to Radiation or Magnetic Resonance Imaging (MRI)

The CADD-1® infusion pump, Model 5100 HFX, is not affected by exposure to **diagnostic** radiographic and fluoroscopic radiation.

CAUTION:

4.4 Alarms and Troubleshooting Chart

The CADD-1® pump (Model 5100 HFX) has a number of alarms to alert you to conditions that require corrective actions.

The alarms are audible and can be distinguished as shown below and on the following page.

Table 2. Alarms that require corrective actions.

Alarm	Condition	Corrective Action
3 beeps sound when RES VOL reaches 5 ml; the alarm repeats with each 1 ml decrease. RES VOL blinks on the display. Refer to Section 4.4.1.	The ML remaining value is at or below 5 ml.	Prepare to install a new (filled) fluid container.
2 beeps sound each second; RES VOL and STOP blink. Refer to Section 4.4.1.	The fluid container is empty. The ML remaining value is at "000."	 Press the STOP/START key or SET/CLEAR key to stop the alarm and to re- set the delivery volume (RES VOL).
		 Install a new (filled) fluid container.
3 beeps sound every five minutes; LO BAT blinks on display.	The battery power is low, but the pump is operable.	Change battery soon.
A continuous, variable-tone alarm sounds, and LO BAT	The battery power is too low to operate pump; pump operation	Change the battery immediately.
remains on the display	starts.	• Use a new, 9-volt battery.
		 Press the STOP/START key to resume operation.
A continuous, variable-tone alarm sounds. "HI P" appears on the display. Pump delivery stops. Refer to Section 4.4.2.	High pressure caused by an obstruction in the fluid path between the pump and the tip of the access device; for example, a kink in the tubing or a closed clamp.	 Remove the obstruction to continue the operation or press the STOP/START key to shut off the alarm and to put the pump into the Stop mode.

Alarm	Condition	Corrective Action
A continuous, variable- tone alarm sounds; the let- ter E and two numbers appear on the display. (See Note 2 below.)	A controller, microprocessor, or motor fault has occurred. The pump operation stops.	 Close the tubing with the clamp. Remove the pump from service and have it repaired. Call Customer Service: 800-426-2448
All indicators appear on the display; a continuous, variable-tone alarm sounds.	A power-up fault has occurred, or the battery is too low to operate the pump.	 Remove and reinsert the battery; or, Insert a new battery; or, Call Customer Service: 800-426-2448
3 beeps sound every 5 minutes; STOP blinks on the display.	The pump has stopped.	Start the pump if necessary
OFF appears on the RES VOL screen, but RES VOL was not intentionally programmed to OFF. (See programming section for more information on programming RES VOL.)	 The battery might have been removed while the pump was in the Start mode, which can cause the pump to lose its program and default the RES VOL setting to OFF; or, An error might have occurred which would have defaulted the RES VOL setting to OFF. 	 Stop the pump and close the tubing clamp. Remove and reinsert the battery. All indicators will appear. After they disappear, look for either a 1-digit number (the software revision) or a 3-digit number (software revision plus error code): If a 3-digit number appears, remove the pump from service and have it repaired. Call Customer Service: 800-426-2448. If a 1-digit number appears, the pump is still operable; review all screens and reprogram the pump if necessary.

NOTES:

4.4.1 The Reservoir-Residual (RES VOL) Volume Alarm

If the pump is running, the RES VOL numeric value will decrease as the pump delivers the drug until the counter has counted down to 5 ml. At that point, the RES VOL numbers on the display will flash about every two seconds. You will also hear a three-beep alarm, which will reoccur as the pump counts down to 4, 3, 2, and 1 ml. When RES VOL reaches "0" ml, all pumping action ceases, and the pump will automatically enter the Stop mode. You will then hear two short beeps every second until you press particular keys. When you press either the STOP/START key or the SET/CLEAR key, the alarm will be shut off, and the volume setting will return to its original programmed value.

4.4.2 The High Pressure (HI P) Alarm

You will hear a continuous, variable-tone alarm if the delivery pressure within the fluid path becomes excessive. The letters "HIP" will appear on the display. The high pressure alarm activates a switch at the base of the pump. If you find the cause of the alarm and correct the problem, the alarm will stop automatically. If you cannot find the cause, you can shut off the alarm by pressing the STOP/START key. However, the letters "HIP" will remain on the display, and you will hear the alarm again every 5 minutes. When you have corrected the problem, the Stop mode display will replace the HIP display. You may then start the pump again and resume delivery.

4.5 Specifications (Nominal)

4.5.1 Programming Specifications

Delivery Rate Range ... 001–299 ml/24-hour period in 1 ml increments; the high flow rate is 90 ml/hr.

ML GIVEN Range 000-999 ml, 1 ml increments rounded down to nearest ml.

RES VOL Range 001–999 ml rounded up to the nearest ml in 1 ml increments; 000 ml for alarm off.

4.5.2 General Specifications

Medication Cassette[™]

Reservoir Capacity 50 ml or 100 ml.

Pump Operating

Temperature Range .. +2°C to 40°C (35°F to 104°F).

Pump Storage

Temperature Range ...-40°C to 55°C (-40°F to 131°F).

Pump Humidity

Range 10% to 90% Relative Humidity.

Pump Resolution 50 microliters per interval.

Pump Alarms Low battery; pump in Stop mode; controller, microprocessor, or motor fault; improper delivery; power up fault; residual volume; high delivery pressure (28 ± 12 psi).

Bolus volume at occlusion alarm

pressure < 0.25 ml

Power Source 9-volt alkaline battery (use DURACELL® Alkaline MN 1604 or EVEREADY® ENERGIZER® Alkaline #522, for example).

9-volt lithium battery (use ULTRALIFE® Lithium U9VL).

Pump Timing

Accuracy ± 0.1%.

System Delivery

Accuracy ± 6%, nominal.

System Definition System is defined as a CADD® pump with an attached

Medication CassetteTM reservoir and CADD® Extension Set with integral anti-siphon valve, or an attached CADD®

 $Administration \, Set\, with\, integral\, or\, add-on\, anti-siphon\, valve.$

4.6 Limited Warranty

SIMS Deltec, Inc. ("Manufacturer") warrants to the Original Purchaser that the infusion pump (not including accessories) are free from defects in materials and workmanship under normal use, if used in accordance with this Operator's Manual, for one year from date of sale to Original Purchaser. THERE ARE NO OTHER WARRANTIES. Subject to the conditions of and upon compliance with this limited warranty, the Manufacturer will repair or replace at its option without charge (except for a minimal charge for postage and handling) any infusion pump (not including accessories) which is defective during such one-year period.

The following conditions, procedures, and limitations apply to the Manufacturer's obligation under this warranty:

- **A. Parties Covered by this Warranty:** This warranty extends only to the Original Purchaser of the infusion pump. This 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 a record of date of purchase.
- **B.** Warranty Performance Procedure: Notice of the defect must be made in writing or by telephone to Customer Service Department, SIMS Deltec, Inc., 1265 Grey Fox Road, St. Paul, MN 55112, (800) 426-2448. Notice to SIMS Deltec, Inc. must include date of purchase, model and serial number, and a description of the defect in sufficient detail to facilitate repairs. Authorization must be obtained prior to returning the pump. The defective pump must be properly packaged and returned to SIMS Deltec, Inc., postage prepaid. Any loss or damage during shipment is at the risk of the sender.
- **C. Conditions of Warranty:** The warranty is void if the pump has been 1) repaired by someone other than SIMS Deltec, Inc. or its authorized agent; 2) altered so that its stability or reliability is affected; 3) misused; or, 4) damaged by negligence or accident. Misuse includes, but is not limited to, use without compliance with the operator's manual of the infusion pump or use with non-approved accessories. 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. Removal or damage to the serial number will invalidate this warranty.
- **D.** Limitations and Exclusions: Repair or replacement of an infusion pump or component part is the EXCLUSIVE remedy offered by the Manufacturer. The following exclusions and limitations shall apply:
 - 1. No agent, representative, or employee of the Manufacturer has authority to bind the Manufacturer to any representation or warranty, expressed or implied. THERE IS NO WARRANTY OF MERCHANTABILITY OR FITNESS OF THE INFUSION PUMP FOR ANY PARTICULAR PURPOSE.
 - 2. The infusion pump can only be used under the supervision of medical personnel whose skill and judgment determine the suitability of the infusion pump for a particular medical treatment.
 - 3. 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.

E. Computer Program License:

- 1. The infusion pump is intended to be used in conjunction with a particular Licensed Computer Program supplied by Manufacturer and use of any other program or unauthorized modification of a Licensed Computer Program shall void Manufacturer's warranty as set forth above.
- 2. The Original Purchaser and any users authorized by the Original Purchaser are hereby granted a nonexclusive, nontransferable license to use the Licensed Computer Program only in conjunction with the single pump supplied by Manufacturer. The Licensed Computer Program is supplied only in machine-readable object code form and is based upon Manufacturer's proprietary confidential information. No rights are granted under this license or otherwise to decompile, produce humanly readable copies of, reverse engineer, modify or create any derivative works based upon the Licensed Computer Program.
- 3. All other terms and conditions of this Limited Warranty shall apply to the Licensed Computer Program.

THE MANUFACTURER DISCLAIMS RESPONSIBILITY FOR THE SUITABILITY OF THE INFUSION PUMP FOR A PARTICULAR MEDICAL TREATMENT OR FOR ANY MEDICAL COMPLICATIONS RESULTING FROM THE USE OF THE INFUSION PUMP. THE MANUFACTURER SHALL NOT BE RESPONSIBLE FOR ANY INCIDENTAL DAMAGES OR CONSEQUENTIAL DAMAGES TO PROPERTY, LOSS OF PROFITS, OR LOSS OF USE CAUSED BY ANY DEFECT OR MALFUNCTION OF THE INFUSION PUMP.

This warranty gives the Original Purchaser specific legal rights, and the Original Purchaser may have other legal rights which may vary from state to state.

Deltec

SIMS Deltec, Inc., St. Paul, MN 55112 U.S.A.





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