CADD-PCA®

Ambulatory Infusion Pump

Model 5800R
Operator's Manual

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This manual pertains **only** to the Deltec CADD-PCA®, **Model 5800R,** 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.

WARNING:

It is intended that this Operator's Manual only be utilized by clinicians. Do not permit patients to have access to this manual or otherwise disclose to the patient the security code of the pump or any information which would allow the patient to have complete access to all programming and operating functions.

TECHNICAL ASSISTANCE

If you have comments or questions concerning the operation of the CADD-PCA® 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-PCA infusion pump.

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> St. Paul, Minnesota 55112 U.S.A.

CONTENTS

1.0 INTRODUCTION

The Deltec CADD-PCA® 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-PCA® 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-PCA® PUMP OPERATIONS

The Deltec CADD-PCA® pump is indicated for intravenous, subcutaneous, epidural space, or subarachnoid space infusion.

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.

Epidural/Subarachnoid Administration

The selected drug must be used in accordance with the indications included in the package insert accompanying the drug. Administration of any drug by this pump is limited by any warnings, precautions, or contraindications in the drug labeling.

Analgesics Administration of analgesics to the epidural space is limited to use with indwelling catheters specifically indicated for either short-or long-term drug delivery.

Administration of analgesics to the subarachnoid space is limited to use with indwelling catheters specifically indicated for short-term drug delivery.

Anesthetics Administration of anesthetics to the epidural space is limited to use with indwelling catheters specifically indicated for short-term drug delivery.

WARNING:

Administration of drugs to the epidural space or subarachnoid space other than those indicated for administration to the epidu-

ral space or subarachnoid space could result in death or serious injury to the patient.

To prevent the infusion of drugs that are not indicated for epidural space or subarachnoid space infusion, DO NOT use administration sets that incorporate injection sites. The inadvertent use of injection sites for infusion of such drugs may cause death or serious injury to the patient.

If a Medication Cassette™ Reservoir, CADD® Extension Set or CADD® Administration Set is used for epidural space or subarachnoid space drug delivery, it is strongly recommended that it be clearly differentiated from reservoirs, cassettes or administration sets used for other routes of infusion, for example, by color coding, or other means of identification.

2.1 WARNINGS and CAUTIONS

Read this entire Operator's Manual before operating the CADD-PCA® 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™ Reservoir or CADD® 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.

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- 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°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 build-up 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-PCA® pump and its major functions; and the Remote DOSE cord/button.

Display (LCD)

Keyboard

Scroll Keys

CADD-PCA®

Cassette (the part of the Medication Cassette™ Reservoir or CADD® Administration Set that attaches to the pump)

Remote DOSE Cord Adaptor

Remote DOSE Cord/ Button
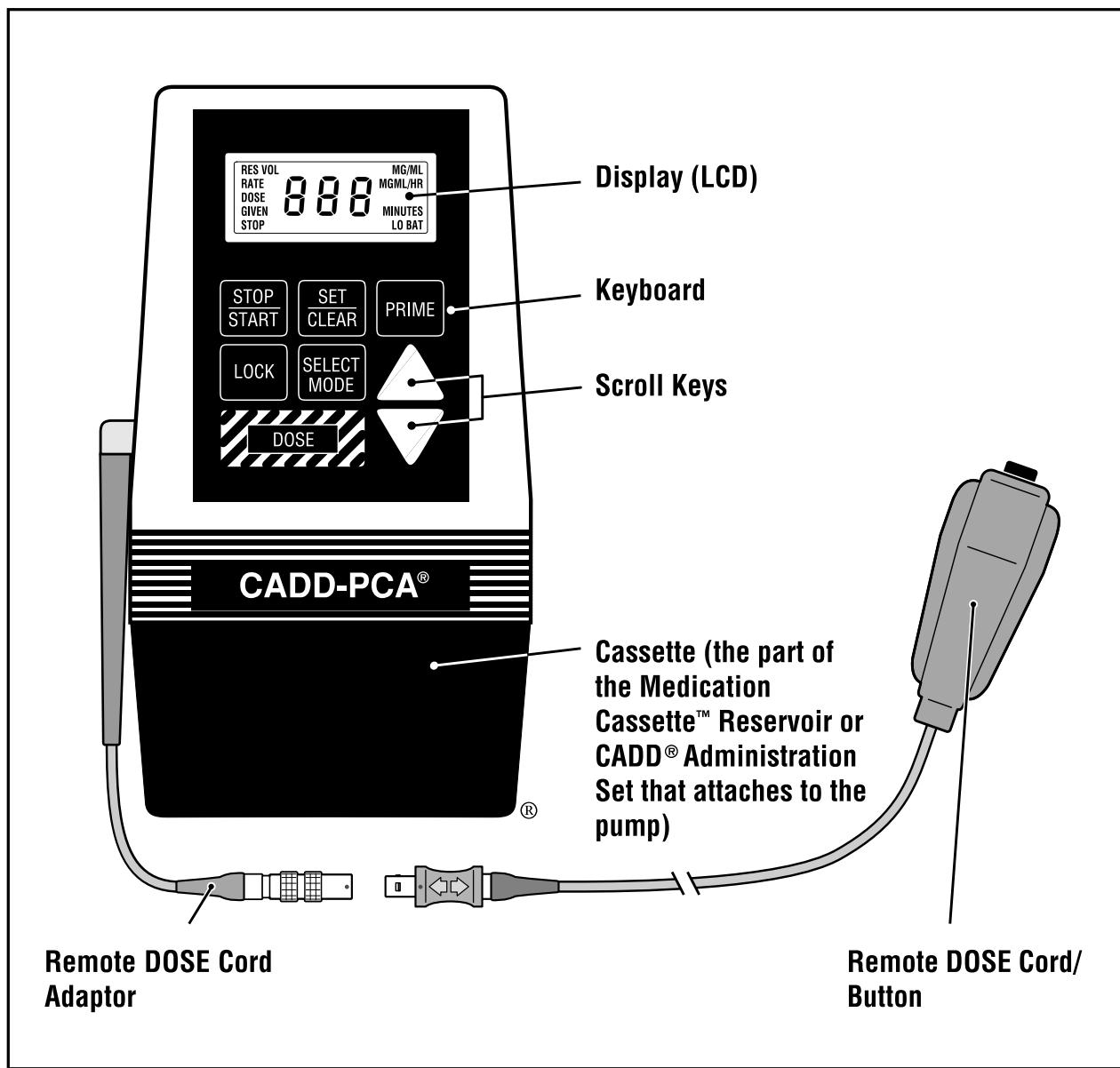
Figure 1. The CADD-PCA® Model 5800R pump with a Remote DOSE cord.

2.2.1 Items Packaged with the Pump

Packaged with the pump are the following accessories:

1 Alkaline battery (9-volt)
1 50 ml Medication Cassette™ Reservoir (nonsterile, for demonstration only)
1 Key
1 Carrying case
1 Carrying pouch
1 Operator's Manual with warranty information
1 Remote DOSE cord/button with attached clip

The following products are also compatible with the CADD-PCA® 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

Liquid Crystal Display (LCD). 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.

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

SET/CLEAR Key. Use the SET/CLEAR key for programming, setting or resetting, and clearing numbers in the computer's memory. The SET/CLEAR key is also used to initiate clinician-activated bolus delivery.

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

LOCK Key. Use the LOCK key to lock out or limit the patient's operation of the pump. In the Start mode, the LOCK key is also used to access the Clinician-Activated Bolus mode.

SELECT MODE Key. Use the SELECT MODE key to view the various modes, such as the Continuous Rate, Dose, Concentration, and RES VOL modes. When the pump is in the Start mode, and you press the SELECT MODE key, the pump will **automatically display** each mode in succession. (See Section 3.8, "Reviewing the Automatic Display.") If the pump is in the Stop mode, and you press the SELECT MODE key, the pump will display the next mode. You will then have to press the SELECT MODE key again to access another mode.

NOTE:
> *If you set the concentration or rate to "00.0," neither mode will appear on the display in the automatic display mode. If you set the dose to "00.0," the dose amount, dose minutes, doses per hour, and doses given will not appear on the display.*

SCROLL Keys. Use the up or down SCROLL keys to increase or decrease the numeric value shown on the pump's display. In the Stop mode, these keys are also used to review the total number of doses the patient attempted to deliver.

DOSE Key. Press the DOSE key to deliver a preprogrammed amount of medication. In the Start mode, this key can be used to initiate the Clinician-Activated Bolus or Patient-Activated Dose. This key is easily identified because it is larger than the others, is colored, and has ridges.

Remote DOSE Cord/Button. Press the Remote DOSE button when the cord is attached to the CADD-PCA® pump to deliver a preprogrammed amount of medication. In the Start mode, this button can be used in place of the DOSE key to initiate the Clinician-Activated Bolus or Patient-Activated Dose.

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

The CADD-PCA® pump may use a detachable, single use Medication Cassette™ 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™ Reservoir or CADD® Administration Set that attaches to the pump) are located in Section 3.4.
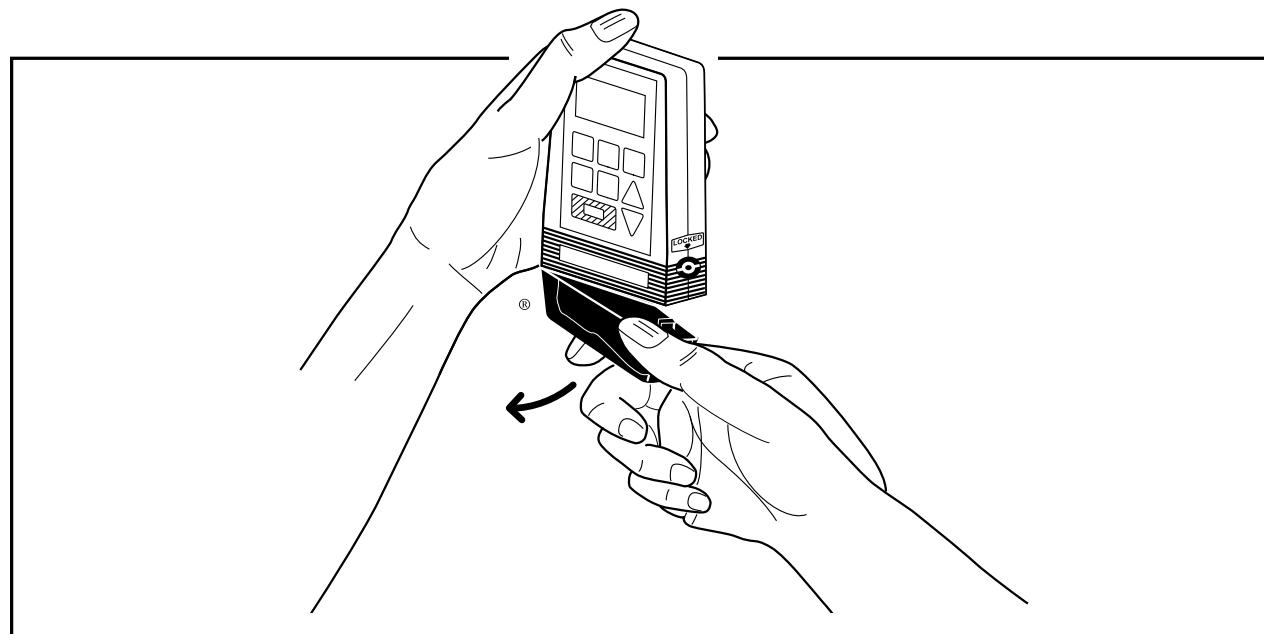
Figure 2. **Discard a used Medication Cassette™ Reservoir or CADD® Administration Set immediately.**

2.3 Understanding the Delivery Modes

The CADD-PCA® pump has three methods, or modes, of delivery: (1) Continuous Rate mode (rate); (2) Patient-Activated Dose mode (dose); and (3) Clinician-Activated Bolus mode (bolus). You may program each of the modes individually or in combination with each other. The following graph, Figure 3, illustrates the combined delivery modes. Further details concerning these delivery modes are introduced in Section 3.3, "Programming the CADD-PCA® Pump." and Section 3.9, "Using the Optional Clinician-Activated Bolus (MG or ML)."
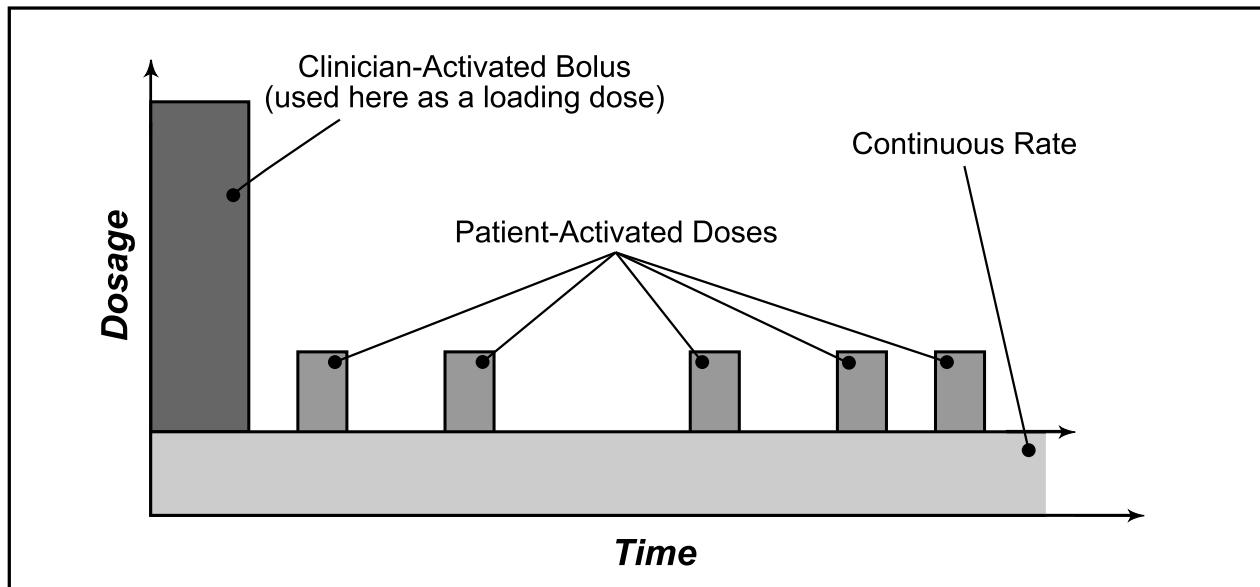
Figure 3. Combined delivery modes. You may program each mode individually or in combination with each other.

2.3.1 Continuous Rate Delivery

In the Continuous Rate mode, you program the pump to deliver medication at a constant rate in your choice of either milligrams per hour or milliliters per hour. You will find the maximum continuous rates and increments listed in the Parameter Settings Table (Section 4.5.1). If you do not wish to deliver medication continuously, you may set the continuous rate to 00.0. The pump may then be programmed to deliver only patient-activated doses or clinician-activated boluses. [See Section 3.3.4, "Setting the Continuous Rate (MG/HR or ML/HR)."]

2.3.2 Patient-Activated Dose Delivery

In the Patient-Activated Dose mode, you can program the pump to deliver a quantity of medication when the patient presses the DOSE key or the Remote DOSE button. You must program the minimum time period between dose activations and the maximum number of doses per hour. You must also program the quantity of the dose. In Lock Level 2, this quantity is fixed. In Lock Level 1, you may adjust the quantity, depending upon the limit set in Lock Level 0. The clinician may set a maximum dose in Lock Level 0 and then reset the pump to Lock Level 1. This will permit the patient to reduce the dose but not to exceed the maximum dose programmed in Lock Level 0. Or, the clinician may set a maximum dose in Lock Level 0, reset the pump to Lock Level 1, and reduce the dose before giving the pump to the patient. The patient can then increase or decrease the dose but cannot exceed the maximum dose programmed in Lock Level 0. You will find the maximum patient-activated dose values and increments listed in the Parameter Settings Table (Section 4.5.1). The amount of medication which the patient-activated delivery provides is in addition to the amount provided by the continuous rate delivery. [See Section 3.3.5, "Setting the Patient-Activated Dose (MG or ML)."]

NOTE:

The clinician determines the amount of the patient-activated dose. When the patient presses the DOSE key or the Remote DOSE button, and delivery occurs, two beeps will confirm delivery.

2.3.3 Clinician-Activated Bolus Delivery (Optional)

In the Clinician-Activated Bolus mode, you can program the pump to deliver a quantity of medication immediately. There is no minimum time between boluses, since the amount of medication is not preprogrammed. Each time you use the bolus function, you must select the quantity again. The amount of medication which the clinician-activated bolus delivery provides is in addition to the amount provided by the continuous rate delivery. [See Section 3.9, "Using the Optional Clinician-Activated Bolus (MG or ML)."]

WARNING:

Exercise extreme care when using this function. Since there are no limits on the frequency of delivering the bolus, and since the amount of the bolus can be set as high as 20 ml, you should not permit the patient to become familiar with the programming. Improper programming could result in death or serious injury to the patient.

3.0 OPERATOR INSTRUCTIONS

This section describes how to operate the CADD-PCA® pump. It contains detailed, step-by-step instructions that will enable you to perform the following tasks in either the Continuous Rate mode, Patient-Activated Dose mode, or the Clinician-Activated Bolus mode:

Operating Instructions

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3.1 Installing or Replacing the Battery
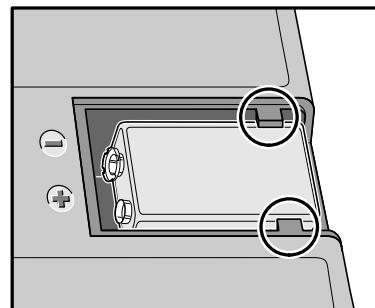
Use a new, 9-volt alkaline or lithium battery to power the pump. (See Section 4.5.3, "General Specifications," for further information regarding batteries.)

NOTES:

(1) In LL1 or LL2, removing the battery resets the patient-activated dose lockout time (which is determined by the programmed DOSE MINUTES or DOSE/HR). After reinserting the battery, the patient must wait the full lockout time before receiving a patient-activated dose. For example, DOSE MINUTES may be programmed to 30 minutes and the patient may request a dose. If the patient removes the battery 15 minutes later and reinserts a battery, he or she must wait another 30 minutes before receiving a patient-activated dose.

(2) In LL0, removing the battery clears the patient-activated dose lockout time. This allows the delivery of a patient-activated dose immediately upon inserting a battery and restarting the pump, regardless of when the previous dose was given.
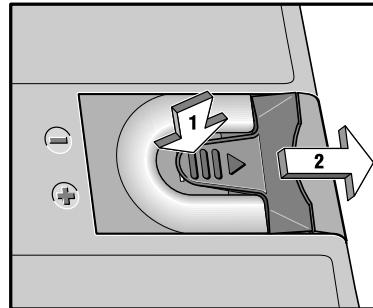
WARNING:

- *Do not use rechargeable NiCad or nickel metal hydride (NiMH) batteries. Do not use carbon zinc ("heavy duty") batteries. They do not provide sufficient power for the pump to operate properly, which could result in death or serious injury to the patient.*
- *Always have new batteries available for replacement. If power is lost, non-delivery of drug, and, depending on the type of drug being administered, death or serious injury to the patient could result.*
- *There is no pump alarm to alert users that the battery has not been properly installed or has become dislodged. An improperly installed or dislodged battery could result in loss of power and non-delivery of drug and, depending on the drug being administered, could result in death or serious injury to the patient.*
- *If the pump is dropped or hit, the battery door or tabs may break. Do not use the pump if the battery door or tabs are damaged because the batteries will not be properly secured; this may result in loss of power, non-delivery of drug, and, depending on the type of drug being administered, death or serious injury to the patient.*
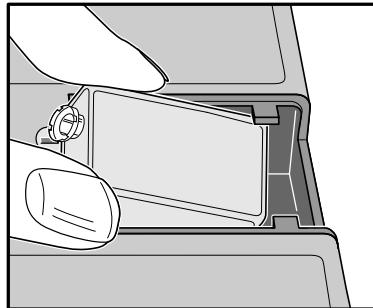
As soon as you install the battery, the pump will be on; there is no On/Off switch. In order to install or replace a battery, **be sure to place the pump in the Stop mode.** Then, follow these steps:
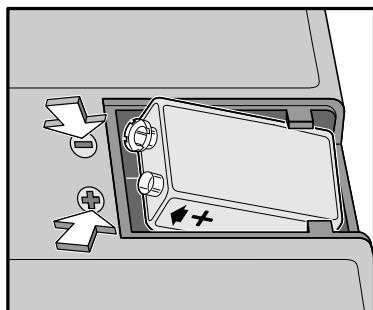
STEP 1:   **Push down and hold the battery door release button while sliding the door off.**

STEP 2:   **Remove the used battery.**

STEP 3:   **Install the battery in the compartment (bottom-end first).**
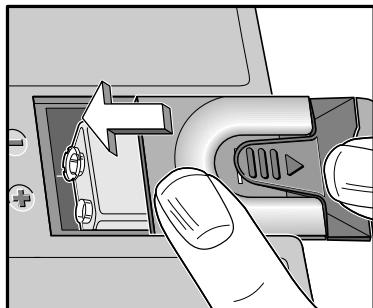
NOTE:

Be sure to match the polarity markings of the new battery (+ and –) with those on the battery compartment. If you put the battery in backwards, the display panel will be blank, and you will not hear a beeping sound.

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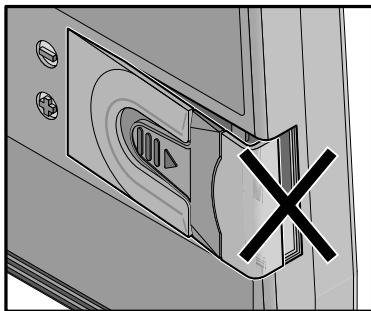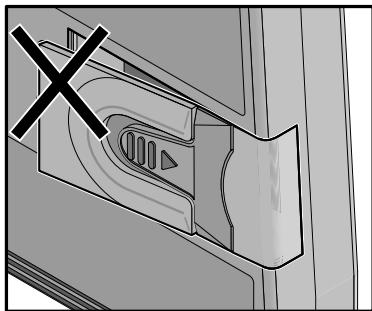
STEP 4:   **Place the battery door halfway over the battery compartment and press the battery into the compartment by pushing down on top of the door with your thumb.**

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

The power-up sequence will start, and the pump will go through an electronic self-test. All of the display indicators, the software revision level, and each parameter will appear briefly.

STEP 6: **Resume operation of the current program by pressing and holding the STOP/START key to enter the Start mode or proceed to Section 3.2 to prepare to program the pump.**

The battery's life is dependent on the amount of medication delivered and the temperature. At the rate of one 50 ml Medication Cassette™ Reservoir per day, an alkaline battery will usually last about seven days. If you use an ULTRALIFE® lithium battery, you will have power for approximately ten days. A battery's power will be quickly depleted at temperatures below +10°C (50°F).

CAUTION:

Do not store the pump for prolonged periods of time with the battery installed. Battery leakage could damage the pump.

3.2 Preparing to Program the CADD-PCA® Pump

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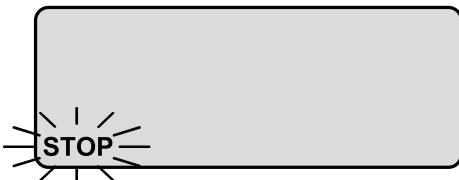
When the pump is set at LL0, you are ready to turn to Section 3.3, "Programming the CADD-PCA® Pump." Section 3.6, "Programming the Patient Lock Levels (LL0, LL1, and LL2)" provides more information about the pump's lock levels.

NOTE:
While you are using the LOCK key to change the lock level, you must proceed to the next step in the sequence within 15 seconds. If you do not perform the next step within 15 seconds, the pump will retain the previous setting.

STEP 1: **Make sure that 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.
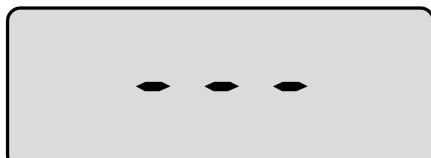
If the pump is in the Stop mode, go to STEP 2.

• Press and hold the STOP/START key.
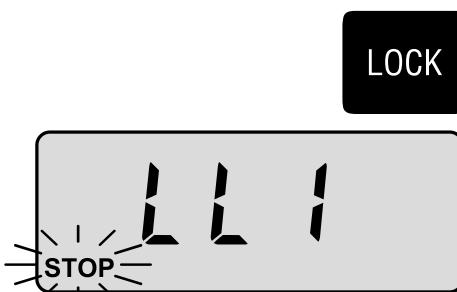
You will hear a single beep, and three dashes will appear one-by-one on the pump's display.

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- 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.**

LOCK

- Press and release the LOCK key.

LL1
STOP
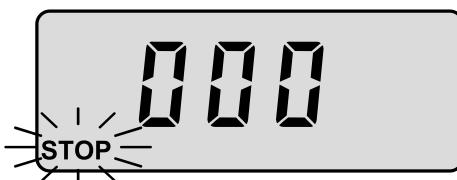
This example shows that the pump is in Lock Level 1.

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

LL0
STOP

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

LOCK

- Press the LOCK key.

000
STOP

The display shows "000."

- Press the up SCROLL key until
  *** Text omitted from online version ***

STOP

NOTE:
      *** Text omitted from online version ***   You should not let the patient know this code, in order to prevent the patient from programming the pump.

LOCK

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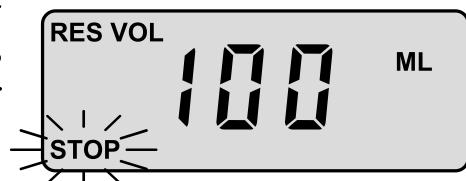
  LOCK

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

  LL0

  STOP

  LOCK

- 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.

  RES VOL
  100 ML
  STOP

3.3 Programming the CADD-PCA® Pump

NOTE:

Make sure that the pump is set in the Stop mode and Lock Level 0 (Section 3.2).

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 are warning alarms when the calculated number of milliliters remaining is at or below 5 milliliters. When RES VOL reaches 0 ml, another alarm signals that the programmed volume of medication has been delivered, and the pump stops automatically.

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

NOTE:

*The pump **does not** actually measure the volume of drug remaining in the fluid container. The number displayed in the Reservoir-Residual Volume mode (RES VOL) is calculated by subtracting the current milliliters of drug given from the initial value you **programmed** for the RES VOL. The term "RES VOL" refers to the amount of drug programmed and **the calculated amount** of drug remaining in the fluid container.*

*For example, if you were to program the RES VOL for 75 ml, and actually put 85 ml into the fluid container, the pump would stop its delivery after 75 ml had been delivered. The RES VOL alarm would beep to indicate that the programmed amount had been delivered. However, the fluid container would still contain about 10 ml of residual volume, which **might** cause you to think that the pump is inaccurate. It is normal to find a small amount of fluid left within the tubing and/or fluid container at the end of an infusion program.*
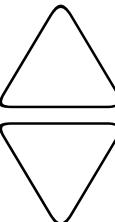
- Press and release the SELECT MODE key until "RES VOL" appears on the display.

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

  SELECT MODE

  RES VOL **100** **ML** **STOP**

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

- Press and release the SET/CLEAR key within 15 seconds to set the value.

  SET CLEAR

NOTES:

(1) If you do not wish to use the reservoir-residual volume feature, set the RES VOL value to "000." Thereafter, when RES VOL is displayed, "OFF" will appear on the display, and the RES VOL alarm will not function. Consequently, there will be no warning that the residual volume is low.

(2) If you do not press the SET/CLEAR key within 15 seconds, the pump will retain the previous RES VOL setting.

(3) Priming the tubing subtracts the priming volume from RES VOL but does not affect the GIVEN amount, since the drug would not have actually entered the patient.

3.3.2 Changing the Units of Measure (MG or ML)
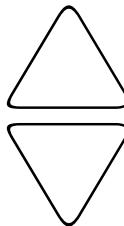
You may program the pump in either MG units or ML units. If you wish to program the pump in MG units, you must program the concentration (MG/ML) for the medication you are using. If you wish to program the pump in ML units (volume), you must program the concentration to 00.0 MG/ML.

MG/ML **00.0** **STOP**

3.3.3 Setting the Concentration (MG/ML)

SELECT
MODE

△

▽

SET
CLEAR

- Press and release the SELECT MODE key until you can see "MG/ML" on the display.

- Press the SCROLL keys to advance to the desired concentration in milligrams/milliliter. If you set the concentration to 00.0, the pump will operate in ML units instead of MG. If you set the concentration to a value other than 00.0, the pump will operate in MG units. Please refer to the Parameter Settings Table (Section 4.5.1).

- Press and release the SET/CLEAR key within 15 seconds to set the concentration.
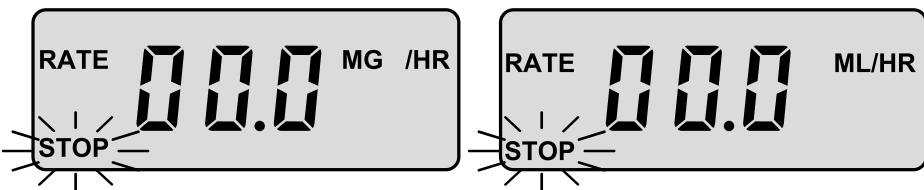
NOTES:

(1) *If you do not press the SET/CLEAR key within 15 seconds, the pump will retain the previous setting for the concentration.*

(2) ***Once the concentration has been set, the rate and dose values will revert to zero, and the pump will automatically display the Rate mode and, subsequently, the Dose mode to permit programming.*** *If you do not reset these modes, an alarm will remind you that you should reset them. Since this alarm has a delay, it allows sufficient time for resetting. You will not be able to start the pump until you have reset the Rate and Dose modes.*

3.3.4 Setting the Continuous Rate (MG/HR or ML/HR)
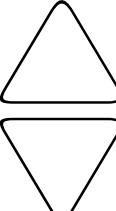
The delivery rate in MG/HR (milligrams per hour) or in ML/HR (milliliters per hour) is the constant rate at which the pump delivers medication. The delivery rate range is from 00.1 ML/HR to 20.0 ML/HR in 00.1 ML/HR increments. If you are programming in MG/HR, the range and increments depend upon the concentration (Section 4.5.1). If you **do not** wish to use continuous delivery, program a continuous rate of 00.0 ML/HR or 00.0 MG/HR, and the continuous rate will become inactive.

Operating Instructions

If you do not see "RATE" on the display, press and release the SELECT MODE key until "RATE" and "MG /HR" or "ML/HR" appear.

RATE *00.0* MG /HR STOP   RATE *00.0* ML/HR STOP

- Press the SCROLL keys to advance to the number of milligrams or milliliters of medication you wish to deliver per hour.

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

SET CLEAR

NOTES:
(1) *If you do not press and release the SET/CLEAR key within 15 seconds, the pump's memory will retain the previous delivery rate.*
(2) **If the concentration has been reset, you can program the Rate mode; thereafter, the pump will automatically advance to the Dose mode.**

3.3.5 Setting the Patient-Activated Dose (MG or ML)
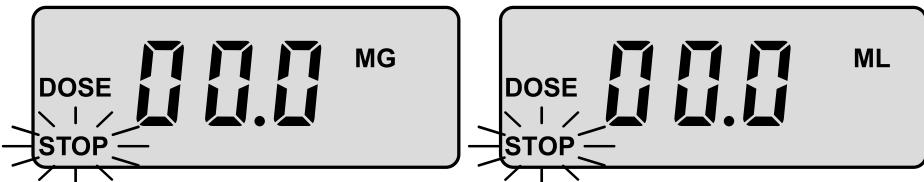
When the patient presses the DOSE key or the Remote DOSE button, the pump delivers an incremental dose. The clinician controls the delivery of incremental doses by setting the **minimum** number of minutes between incremental doses, the **maximum** number of incremental doses per hour, and the amount of the dose.
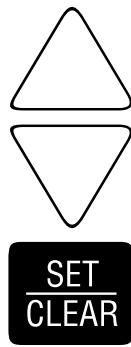
NOTE:
The clinician may allow the patient to vary the dose, in order to have a maximum dose at peak pain time (Section 3.6).

If you do not see "DOSE" on the display, press and release the SELECT MODE key until "DOSE" and "MG" or "ML" appear.

SELECT MODE

DOSE *00.0* MG STOP   DOSE *00.0* ML STOP

- Press the SCROLL keys to advance to the desired dose amount when "DOSE" and "MG" or "ML" appear on the display.

- Press and release the SET/CLEAR key within 15 seconds to set the dose.

NOTE:

If you do not press and release the SET/CLEAR key within 15 seconds, the pump's memory will retain the previous delivery value for the dose.

3.3.6 Setting the Dose Minutes

In this mode, the clinician sets the minimum period of time between incremental doses.
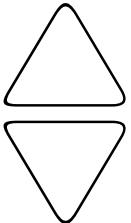
- Press and release the SELECT MODE key until "DOSE" and "MINUTES" appear on the display.

  This display shows that a minimum of 5 minutes have been set between incremental doses.

- Press the SCROLL keys to advance to the minimum number of minutes between doses. If the clinician sets the time for 5 minutes, and the patient presses the DOSE key or the Remote DOSE button again before 5 minutes have elapsed, the pump will **not** deliver the dose.

- Press and release the SET/CLEAR key to set the value.

NOTE:

If you do not press and release the SET/CLEAR key within 15 seconds, the pump's memory will retain the previous value for the dose minutes.

3.3.7 Setting the Doses per Hour

The clinician can limit the number of doses the patient may receive per hour by following these steps:

- Press and release the SELECT MODE key until "DOSE" and "/HR" appear on the display.

    This display shows that 1 dose per hour has been set.

    DOSE **001** /HR
    STOP

- Press the SCROLL keys to advance to the number of doses per hour.

- Press and release the SET/CLEAR key to set the value.

    SET CLEAR

NOTES:
   (1) *If you do not press and release the SET/CLEAR key within 15 seconds, the pump's memory will retain the previous delivery value for the number of doses per hour.*
   (2) *If you have programmed a DOSE MINUTES value larger than 60 minutes, you must program a Doses per Hour value greater than 000. If you program a value of 000 for the Doses per Hour, the pump will not allow any patient-activated doses, even though a DOSE MINUTES value has been programmed.*

3.3.8 Reviewing the Number of Doses Given (DOSE GIVEN) and the Number of Doses Attempted (DOSE)

In order to review the total number of doses actually delivered by the pump, follow these steps:

- Set the pump in the Stop mode.

- Press and release the SELECT MODE key until "DOSE" and "GIVEN" appear on the display.

    SELECT MODE
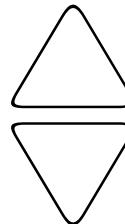
As soon as the DOSE and GIVEN indicators appear on the display, you will be able to read the total number of **actual doses given.**

This display shows that a total of 5 doses were actually given.

In order to review the total number of doses attempted by the patient, do the following:

- Press the up or down SCROLL key.

You will note that the DOSE and GIVEN indicators have been replaced by the DOSE indicator. As soon as the DOSE indicator appears on the display, you will be able to read the total number of **doses attempted.**

This display shows that the patient attempted to deliver a total of 10 doses.
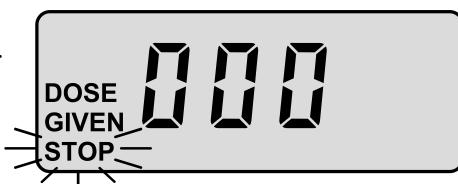
In order to clear the values for **both** actual doses given and attempted doses, follow this procedure in either the Dose Given or Doses Attempted mode:

- Press and release the SET/CLEAR key. The display will show "000."

NOTE:
The number of doses given and the number of doses attempted accumulate from 000 to 999 and then return to 000.

3.3.9 Reviewing the MG GIVEN or ML GIVEN
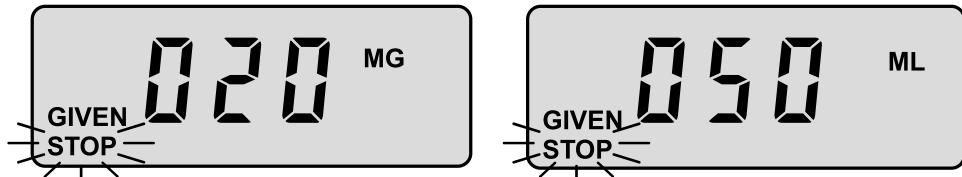
The MG GIVEN or ML GIVEN mode displays the total milligrams or milliliters delivered since the mode was last cleared, including the quantities delivered in the Continuous Rate, Patient-Activated Dose, and Clinician-Activated Bolus modes. The number of milligrams or milliliters in MG GIVEN or ML GIVEN increases from 000 to 999 respectively and then returns to 000. Please note that the MG GIVEN or ML GIVEN counter functions in a way that is similar to your automobile's odometer. After the MG GIVEN or ML GIVEN counter reaches 999, it will start at 000 again and continue counting.

NOTE:

The pump does not include the amount primed when calculating the total milligrams or milliliters given.

- Press and release the SELECT MODE key to until "MG" or "ML" and "GIVEN" appear on the display with a number in the range of 000 to 999.

The MG GIVEN display shows that 20 milligrams have been given. The ML GIVEN display shows that 50 milliliters have been given.

- Press and release the SET/CLEAR key to clear the MG GIVEN or ML GIVEN value and to reset the display at 000. (The MG GIVEN and ML GIVEN values can also be cleared in Lock Level 1.)

This completes the programming of the CADD-PCA® pump for the Continuous Rate and Patient-Activated Dose drug delivery modes. 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 Attaching and Removing the Cassette
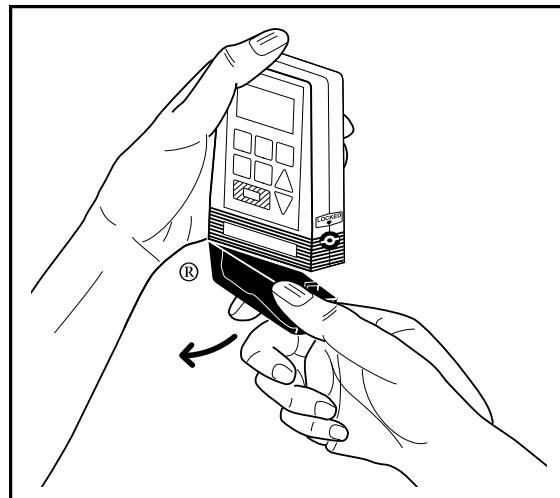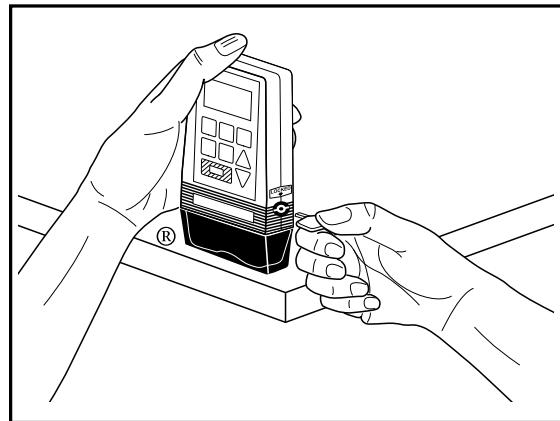
3.4.1 Removing a Used Cassette

WARNING:

Always close the fluid path tubing with the clamp before removing the cassette from the pump to prevent unregulated gravity infusion, which could result in death or serious injury to the patient.

To remove the cassette, follow these steps:

- Place the pump with the cassette attached in an upright position on a firm, flat surface.

- Insert the key 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.
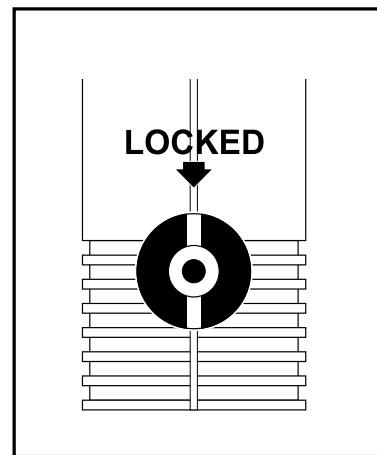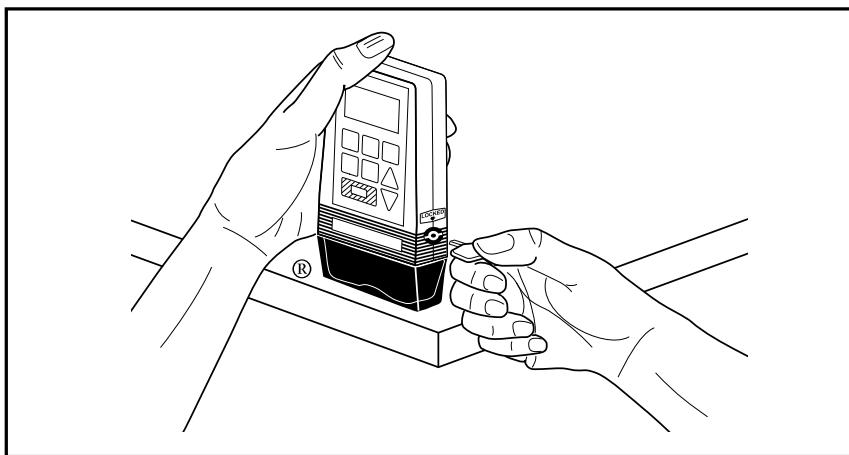
NOTE:

For additional information and cautions associated with the Medication Cassette™ Reservoir or CADD® Administration Set, refer to the package insert which accompanies the product.
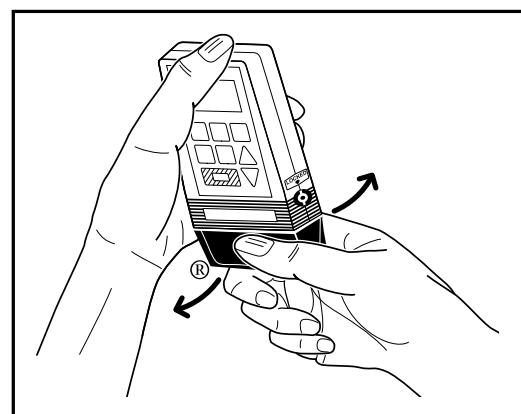
3.4.2 Attaching the Cassette

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 the key provided into the slot in the locking button, pushing the button in; and then turning the key 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:

It is essential that you attach the cassette properly. When you attach the cassette properly, the key slot of the locking button aligns with the arrow on the side of the pump case. If you do not attach the cassette properly, an uncontrolled flow of medication

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from the fluid container or a reflux of blood may result, which could result in death or serious injury to the patient.

To protect against unregulated gravity infusion that can result from an improperly attached cassette, a CADD® Extension Set with Anti-Siphon Valve or a CADD® Administration Set with either an integral or Add On Anti-Siphon Valve must be used.

3.5 Priming the CADD-PCA® 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).
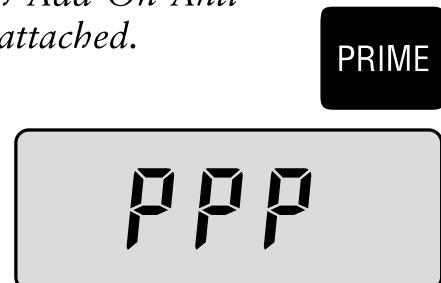
WARNING:

Do not use the Prime mode when the tubing is connected to the patient, as this will result in overdelivery of medication, which could result in death or serious injury to the patient.

NOTE:

Before priming the pump, open all tubing clamps and remove all luer caps. If you are using a Medication Cassette™ Reservoir, make sure a CADD® Extension Set with Anti-Siphon Valve is attached. If you are using a CADD® Administration Set with Add On Anti-Siphon Valve, make sure the anti-siphon valve is attached.

PRIME

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

$$P\ P\ P$$

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

PRIME

- 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:

(1) Each time you press and hold the PRIME key, you pump in a maximum of 0.5 ml of solution into the tubing. The pumping

action will stop automatically when 0.5 ml has been delivered. If all of the air has not been removed from the fluid path, repeat the above priming procedure.

(2) **Priming the tubing subtracts the priming volume from RES VOL but does not affect the GIVEN amount, since the drug would not have actually entered the patient.**

WARNING:

Do not connect a Medication Cassette™ Reservoir or CADD® Administration Set that contains air bubbles to the tubing that leads to a patient. Ensure that the entire fluid path is free of all air bubbles. Air embolism could result in death or serious injury to the patient.

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

The CADD-PCA® 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 access to the keyboard.** The lock levels function in this way: **LL0** permits you to program the pump; **LL1** permits the patient to have limited control of the pump; and **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:
> *You use the LOCK key to control the patient's use of the keyboard. Do not confuse that procedure with the locking of the cassette. (See Section 3.4.2, "Attaching the Cassette.")*

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, MG or ML, and /HR 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.

Similarly, the clinician may permit the patient to change the dose amount by changing the lock level to LL1. The clinician sets the maximum dose amount while the pump is in Lock Level 0.

In Lock Level 1, when the pump is in the Stop mode, the patient presses the SELECT MODE key until DOSE and either MG or ML appear on the display. By using the SCROLL keys, the patient can either scroll up to the maximum dose amount allowed by the clinician or scroll down to a lower amount.
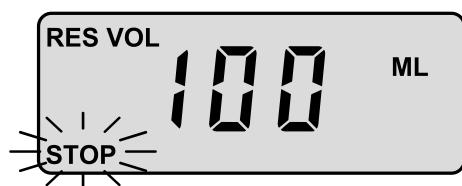
When the desired amount appears on the display, the patient presses the SET/CLEAR key to set the new dose amount. If the patient does not press the SET/CLEAR key within 15 seconds, the pump will deliver at the previous dose amount.

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

Table 1.   Control limits of the CADD-PCA® pump.

Lock Level	Description
LL0	Use this lock level for programming the pump's functions.
LL1	In the Continuous mode, the patient may decrease the MG/HR or ML/HR rate or increase it up to the value that had been programmed in Lock Level 0. The patient may also lower the patient-activated dose amount or raise the dose amount to the upper programmed limit set by the clinician. In addition, the patient may prime the tubing and reset the RES VOL to the original programmed value. The clinician-activated bolus function is operable. The MG GIVEN or ML GIVEN may be cleared.
LL2	The patient may stop or start the pump and clear the RES VOL alarm. The patient-activated dose and clinician-activated bolus functions are operable.
LL0, LL1, LL2	If the RES VOL on the display is "00.0", the patient may reset the RES VOL. To display the current lock level, be sure the pump is in the Stop mode; and then press and release the LOCK key. The clinician-activated bolus function is active in all lock levels.

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.

RES VOL   100   ML
STOP
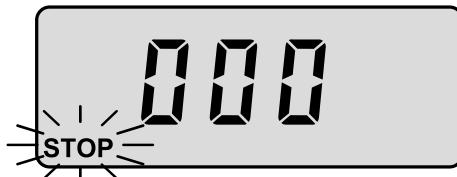
- Press and release the LOCK key once to determine the current lock level. In this example, the display shows "LL2."

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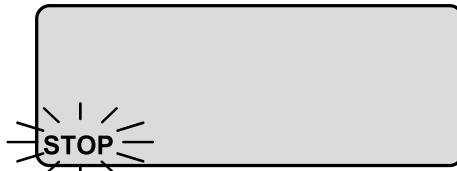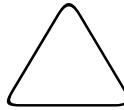
- Press either SCROLL key to select the desired lock level (either LL0, LL1, or LL2).

LL2
STOP

- Press the LOCK key again after you have selected the desired lock level. The display shows "000."
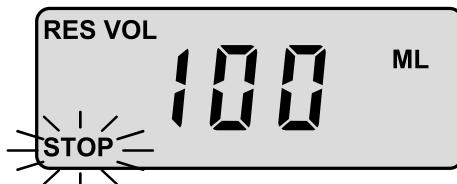
000
STOP

- **** Text omitted from online version **** You should not let the patient know this code, in order to prevent the patient from programming the pump.

STOP

- 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.

LOCK

RES VOL
100 ML
STOP

- 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.

LOCK

NOTE:

Each of the above steps must follow the previous step within 15 seconds. If the correct key is not pressed within 15 seconds, the pump will retain the previous setting.

Operating Instructions

3.7 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.
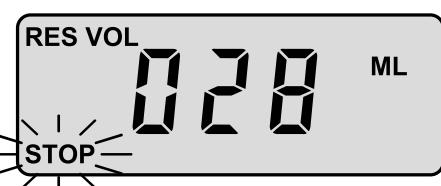
STEP 2:   Release the STOP/START key after the last dash disappears, and the pump beeps; then the word "STOP" disappears from the display, and all of the programmed modes appear for your review one after the other.

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

3.8   Reviewing the Automatic Display

When the pump is in the Start mode, and you press the SELECT MODE key, the pump will automatically scroll through each mode in succession.
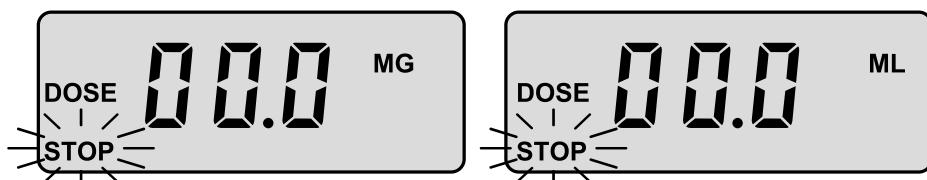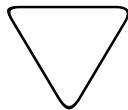
While the pump is scrolling through the modes, the following applies:

- The pump maintains its pumping rate.

- The MG or ML indicator stops flashing on the display.

- Pressing the STOP/START key will stop the automatic display for about 1 minute, after which the display will revert to the RES VOL setting.

- Pressing the SELECT MODE key during the automatic display **after** you have pressed the STOP/START key will enable the pump to continue its automatic display of modes.

3.9   Using the Optional Clinician-Activated Bolus (MG or ML)

The clinician-activated bolus decreases the RES VOL and increases the MG GIVEN or ML GIVEN values. However, it does not increase the DOSE GIVEN counter or the Attempted DOSE counter.
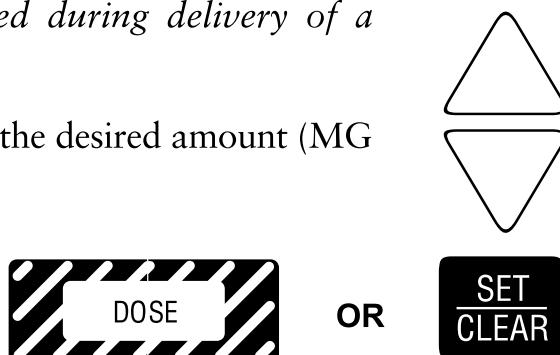
- Set the pump in the Start mode to operate this function (Section 3.7).

- Press the LOCK key; the display shows "000."

- *** Text omitted from online version **** You should not let the patient know this code, in order to prevent the patient from accessing this pump function.

- Press the LOCK key within 15 seconds, and "DOSE," "00.0," and "MG" or "ML" will appear on the display.

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NOTE:

*If "00.0" does not appear on the display, the number displayed represents the amount of medication not delivered during an interrupted clinician-activated bolus. The amount **not** delivered appears because the pump had been set in the Stop mode during a high pressure (**HI P**) alarm that occurred during delivery of a clinician-activated bolus.*

- Press the SCROLL keys to advance to the desired amount (MG or ML) of bolus.

- Press either the DOSE key or the Remote DOSE button or the SET/CLEAR key to begin the clinician-activated bolus.

DOSE   **OR**   SET CLEAR
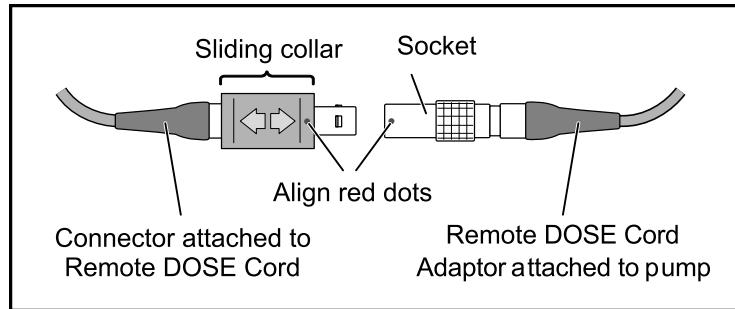
NOTES:

(1) If you do not press the above keys within 15 seconds, each function will revert to its original programmed value.

(2) The pump will operate at its maximum rate, approximately 90 ML/HR. The value on the display will decrease as the bolus is delivered.

(3) If you wish to interrupt the delivery of a clinician-activated bolus, press the STOP/START key. Delivery will cease. The next time you access the clinician-activated bolus option, the bolus amount in the display will be zero, unless the HI P alarm was activated and you pressed the STOP/START key. If the HI P alarm was active during the delivery of the clinician-activated bolus, and you pressed the STOP/START key, you must restart the pump by following the start-up sequence noted above in this section; the remaining bolus amount will appear on the display. If you wish to deliver this amount, you simply press either the SET/CLEAR key, the DOSE key, or the Remote DOSE button. If you wish to deliver a different amount, first scroll to a different value, and then press the SET/CLEAR key, the DOSE key, or the Remote DOSE button to begin the clinician-activated bolus.

3.10 Attaching, Using, and Detaching the Remote DOSE Cord/Button
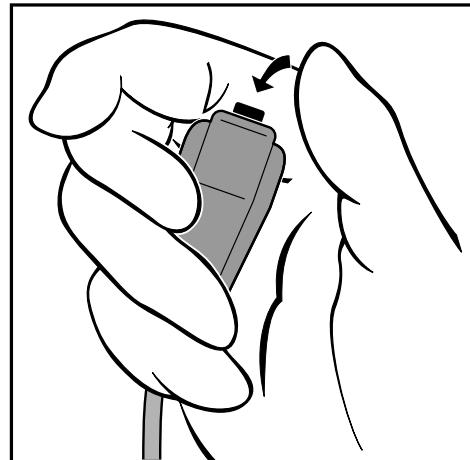
3.10.1 Attaching the Remote DOSE Cord to the Pump

- Align the red dots.

- Insert the connector into the socket and push firmly until it snaps into place. You should not be able to remove the connector from the socket without pulling back on the sliding collar.

3.10.2 Using the Remote DOSE Button to Deliver a Dose or Bolus

The Remote DOSE button operates in the same manner as the DOSE key. When the Remote DOSE cord is attached to the pump, the patient may press either the Remote DOSE button or the DOSE key to receive a patient-activated dose. The clinician may also use either the Remote DOSE button or the DOSE key to deliver a clinician-activated bolus, if desired. For easy access, the Remote DOSE button may be fastened to the patient's clothing or bedsheet with the attached clip.

WARNING:
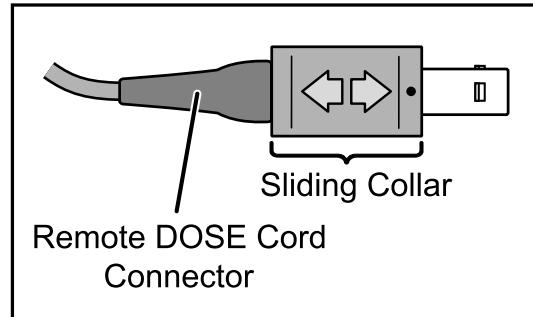
> *Avoid positioning the Remote DOSE cord/button where the button might accidentally be pushed. Accidentally pushing the button may deliver an inadvertant dose, resulting in over-delivery, which could result in death or serious injury to the patient.*

3.10.3 Detaching the Remote DOSE Cord from the Pump

CAUTION:

Do not use excessive force or instruments such as pliers to remove the Remote DOSE cord connector from the socket.

- Grasp the sliding collar on the connector and pull the collar back until you feel it stop.

- Pull the connector out of the socket while continuing to pull back on the sliding collar.

Sliding Collar

Remote DOSE Cord Connector

NOTE:

It is important to keep the connector and socket clean and free of foreign material. (See Section 4.2, "Pump Maintenance and Cleaning," for instructions on cleaning the pump.)

CAUTION:

The Remote DOSE cord must not be used to pick up or carry the pump. Using the cord in this manner could damage the pump or cord.

4.0 REFERENCE SECTION

4.1 Glossary

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

Bolus. An extra amount of medication which may be administered by the clinician. In this manual, the term "bolus" is synonymous with clinician-activated bolus delivery.

CADD®. A trademark acronym for Computerized Ambulatory Drug Delivery.

CADD® Administration Set. 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.

Cassette. The portion of the Medication Cassette™ Reservoir or CADD® Administration Set which attaches to the pump.

Clinician-Activated Bolus Mode. A pump feature that allows the clinician to administer an extra amount of medication.

Continuous Rate Mode. This is the mode that permits you to deliver medication at a constant rate.

Dose. An incremental amount of medication given when the patient presses the DOSE key or the REMOTE DOSE button for relief during peak moments of pain. In this manual, the term "dose" is synonymous with patient-activated dose delivery.

Dose / Hour. This term refers to the maximum number of doses the clinician programs per hour.

Dose Minutes. This term refers to the minimum number of minutes between patient doses.

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

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

Liquid Crystal Display (LCD). 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.

LO BAT. An indicator on the display that shows when battery power is low.

Lock Level. This term refers to a keyboard lock setting that restricts the patient's operation of the pump.

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

Microprocessor. The electronic device that controls the pump.

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

Patency. This term refers to the catheter being open or unobstructed.

Patient-Activated Dose Mode. A pump feature that allows the patient to receive an incremental amount of medication when pressing the DOSE key or the Remote DOSE button for relief during peak moments of pain.

Prime Key. 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.

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

REMOTE DOSE Cord/Button. A detachable cord with a button which can be clipped to the patient's bedsheet or clothing, providing another means of access to the DOSE or bolus functions. The Remote DOSE button operates in the same manner as the DOSE key.

Reservoir-Residual Volume. See *RES VOL.*

RES VOL. The term refers to the volume of medication (in milliliters) that was initially programmed for delivery or that remains in the reservoir.

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

4.2 Pump Maintenance and Cleaning

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. *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.

Reference

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

The CADD-PCA® infusion pump, Model 5800R, is not affected by exposure to *diagnostic* radiographic and fluoroscopic radiation.

CAUTION:

The pump SHOULD NOT BE DIRECTLY IRRADIATED by therapeutic levels of ionizing radiation because of the risk of permanent damage to the pump's electronic circuitry. The best procedure to follow is to remove the pump from the patient during therapeutic radiation sessions. If the pump must remain in the vicinity during a therapy session, it should be shielded, and its ability to function properly should be confirmed following treatment.

Magnetic fields produced by magnetic resonance imaging (MRI) equipment may adversely affect the operation of the pump. Remove the pump from the patient during MRI procedures and keep it at a safe distance from magnetic energy.

4.4   Alarms and Troubleshooting Chart

The CADD-PCA® pump (Model 5800R) has a number of alarms to alert you to conditions that require corrective actions.

The alarms are audible and can be distinguished as shown in Table 2.

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 and ML blink 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 reset the delivery volume (RES VOL). • Install a new (filled) fluid container.
3 beeps sound every 5 minutes; LO BAT blinks on the display.	The battery power is low, but the pump is operable.	Change battery soon.
A continuous, variable-tone alarm sounds, and LO BAT remains on the display.	The battery power is too low to operate pump; pump operation stops.	• Change the battery immediately. • 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.
A continuous, variable-tone alarm sounds; the letter E and two numbers appear on the display. (See Note 2.)	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**.

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Table 2—*continued.*

Alarm	Condition	Corrective Action
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 if condition remains: **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:

(1) *Every time you press an active key, the pump beeps once. The pump will not beep when you press a key that is not operable; for example, when you press a key that is not operable in a selected lock level or that is not used in the selected mode.*

(2) *When the letter "E" and two digits appear, the pump has detected an error in its operations. All pumping action ceases, and the microprocessor automatically resets the mode settings to these default values: Concentration = 01.0 MG/ML; RATE = 00.0 MG/HR; DOSE = 00.0 MG; MG GIVEN = 000 MG; RES VOL = OFF; and Lock Level 0 or Lock Level 1 reverts to Lock Level 2. Call Customer Service: 800-426-2448.*

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 and ML indicators 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 "**HI P**" 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 "**HI P**" 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 HI P display. You may then start the pump again and resume delivery.

4.5 Specifications (Nominal)

4.5.1 Parameter Settings Table

Table 2.   Parameter Settings Table.

MG/ML Conc.	MG Rate Increment	MG/HR Max Rate	MG Dose Increment	MG Max Dose	MG[1] Given Increment	MG Bolus Increment	MG Max Bolus
0.5	0.1	10.0	0.1	3.0	1	0.1	10.0
1	0.1	20.0	0.1	6.0	1	0.1	20.0
2	0.1	40.0	0.1	12.0	1	0.1	40.0
4	0.2	80.0	0.2	24.0	1	0.2	80.0
5	0.5	99.5	0.5	30.0	1	0.5	99.5
10	0.5	99.5	0.5	60.0	2	0.5	99.5
15	1.5	99.0	1.5	90.0	3	1.5	99.0
20	2.0	98.0	2.0	98.0	4	2.0	98.0
25	2.5	97.5	2.5	97.5	5	2.5	97.5
30	3.0	99.0	3.0	99.0	6	3.0	99.0
35	3.5	98.0	3.5	98.0	7	3.5	98.0
40	4.0	96.0	4.0	96.0	8	4.0	96.0
45	4.5	99.0	4.5	99.0	9	4.5	99.0
50	5.0	95.0	5.0	95.0	10	5.0	95.0
55	5.5	99.0	5.5	99.0	11	5.5	99.0
60	6.0	96.0	6.0	96.0	12	6.0	96.0
65	6.5	97.5	6.5	97.5	13	6.5	97.5
70	7.0	98.0	7.0	98.0	14	7.0	98.0
75	7.5	97.5	7.5	97.5	15	7.5	97.5
80	8.0	96.0	8.0	96.0	16	8.0	96.0
85	8.5	93.5	8.5	93.5	17	8.5	93.5
90	9.0	99.0	9.0	99.0	18	9.0	99.0
95	9.5	95.0	9.5	95.0	19	9.5	95.0

MG/ML Conc.	ML Rate Increment	ML/HR Max Rate	ML Dose Increment	ML Max Dose	ML[1] Given Increment	ML Bolus Increment	ML Max Bolus
0	0.1 ml	20 ml/hr	0.1 ml	6.0 ml	1 ml	0.1 ml	20 ml

Footnote: [1] = Rounded down

4.5.2 Programming Specifications

Continuous Rate .... 0–20 ml/hr or 0–99.5 mg/hr, depending on the concentration. (See the Parameter Settings Table, Section 4.5.1.)

Patient-Activated Dose
Intervals .... 5 min–999 min in 1-min increments.

Patient-Activated Doses
per Hour .... 0–12 over the last 60-min period.

Accumulated Delivery .... 0–999 mg or ml, rounded down according to the concentration setting of the device. (See the Parameter Settings Table, Section 4.5.1.)

Number of Patient-Activated
Doses Delivered .... 0–999.

Number of Patient-Activated
Doses Attempted .... 0–999.

RES VOL Range .... 1–999 ml rounded up to the nearest ml in 1-ml increments; 000 = Off.

GIVEN Range .... 0–999 mg or ml. (See the Parameter Settings Table for the range, depending on the concentration, Section 4.5.1.)

Clinician-Activated Bolus .... 0–20 ml or 0–99.5 mg, depending on the concentration. (See the Parameter Settings Table, Section 4.5.1.)

Patient-Activated Dose .... 0–6 ml or 0–99.0 mg, depending on the concentration. (See the Parameter Settings Table, Section 4.5.1.)

Reference

4.5.3 General Specifications

Pump Resolution .... 50 microliters per interval.

Size .... 2.79 cm × 8.89 cm × 16.26 cm (1.1 in × 3.5 in × 6.4 in) including 50 ml Medication Cassette™ Reservoir.

Weight .... 425 g (15 oz.) including battery and empty 50 ml Medication Cassette™ Reservoir.

Pump Alarms .... Low battery; battery depleted; pump in Stop mode; controller, microprocessor, or motor fault; improper delivery; power-up fault; low residual volume; RES VOL = 000; 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 Cassette™ 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.

SIMS **SMITHS INDUSTRIES**
Medical Systems

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