CADD-PLUS®

Ambulatory Infusion Pump

Model 5400
Operator's Manual

Deltec

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

sims **SMITHS INDUSTRIES**
Medical Systems

This manual pertains **only** to the Deltec CADD-PLUS®, **Model 5400,** 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-PLUS® 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-PLUS® infusion pump.

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CONTENTS

1.0   INTRODUCTION

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

The purpose of this manual is to familiarize you with the CADD-PLUS® 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-PLUS® PUMP OPERATIONS

The CADD-PLUS® Model 5400 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 clinician may program the pump in either of two modes: the Continuous mode or the Intermittent mode. In the Continuous mode, the pump delivers medication at a constant rate; in the Intermittent mode, it delivers medication at regular, preset intervals.

2.1   WARNINGS and CAUTIONS

Read this entire Operator's Manual before operating the CADD-PLUS® 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.

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- 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°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-PLUS® pump and its major functions.
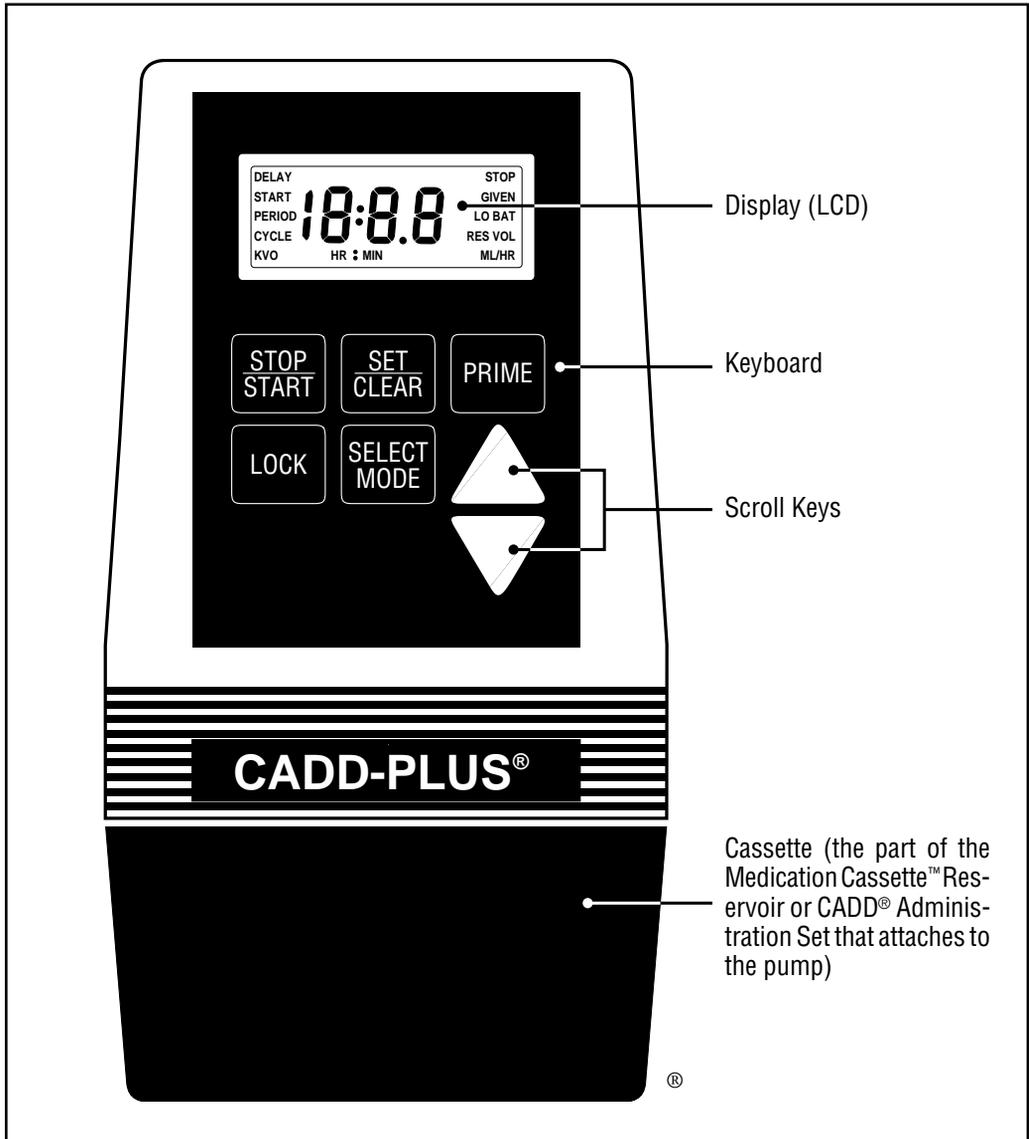
Figure 1.   The CADD-PLUS® pump.

2.2.1   Items Packaged with the Pump

Packaged with the pump are the following items:
- 1   Battery (9-volt)
- 1   50 ml Medication Cassette™ Reservoir (nonsterile, 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-PLUS® 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 of numbers in the computer's memory. You also use this key for setting the Continuous or Intermittent mode.

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.

SELECT MODE Key. Use the SELECT MODE key to view the various delivery and programming modes, such as Continuous or Intermittent delivery and RES VOL. 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-PLUS® Programming Modes.")

SCROLL Keys. 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-PLUS® pump may use a detachable Deltec, 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.
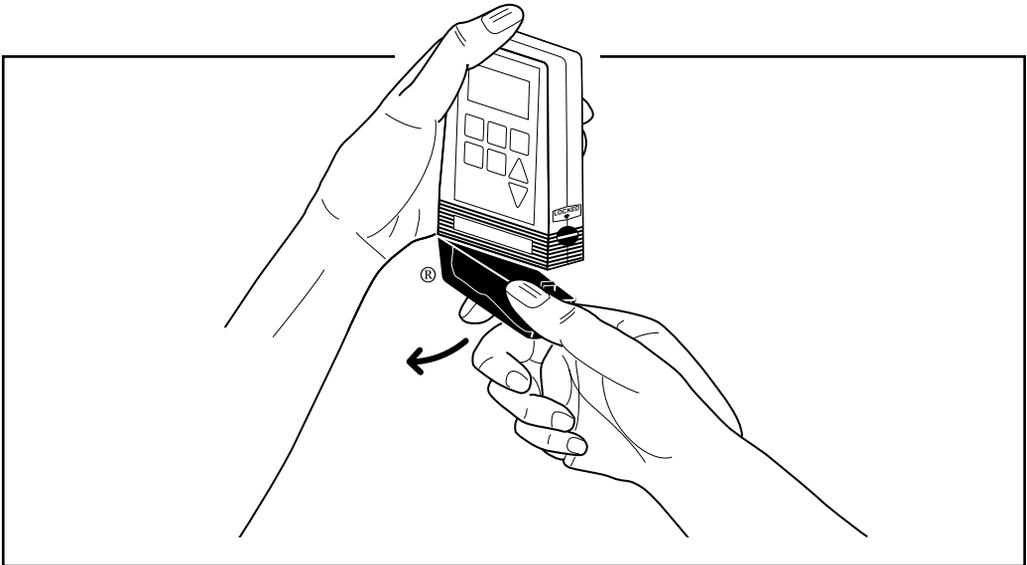
Figure 2.   Discard a used Medication Cassette™ Reservoir or CADD® Administration Set immediately.

2.3 Understanding the Delivery Modes

This section introduces the two delivery modes and their associated programming modes that appear on the CADD-PLUS® pump display: (1) the Continuous (C) delivery mode; and (2) the Intermittent (I) delivery mode. Further details concerning these delivery modes are introduced in Section 3.3, "Programming the CADD-PLUS® Pump for Continuous Delivery," and Section 3.4, "Programming the CADD-PLUS® Pump for Intermittent Delivery."

2.4 Description of the Continuous Delivery Mode

Programming the pump in the Continuous delivery mode (C 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 hour.
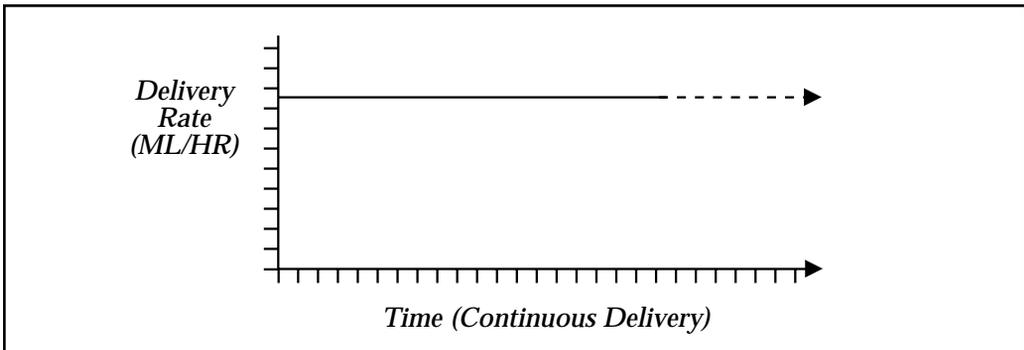
Figure 3.   The Continuous delivery mode.

2.4.1 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 3.3.2, "Setting the Reservoir-Residual Volume (RES VOL)."]

2.4.2   Continuous Rate (ML/HR)

The delivery rate 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 75.0 ml/hr in 00.1-ml/hr increments. If you program a delivery rate of 00.0 ml/hr, delivery will not occur.

2.4.3   The Amount GIVEN (GIVEN)

GIVEN refers to the number of milliliters that have been delivered since the GIVEN register was last cleared.

The number of milliliters in GIVEN accumulates from 000 to 999 and then returns to 000. Please note that the GIVEN counter functions in a way that is similar to an automobile's odometer. After the GIVEN counter reaches 999, it will start at 000 again and continue counting, which is especially important if you plan to use more than 1,000 milliliters of solution.

2.5   Description of the Intermittent Delivery Mode

Programming the pump in the Intermittent delivery mode (I mode) permits the infusion of a prescribed volume of drug (delivery volume) over a specified time period (delivery PERIOD). You can repeat that program in a cycle of up to 24 hours (delivery CYCLE). When you are not infusing a drug dose, you may also program the pump for a KEEP VEIN OPEN (KVO) function. The pump will then deliver a minimal amount of a drug to maintain catheter patency. Finally, you may also program the pump for a time delay (DELAY START) before starting drug infusion. (See Figure 4.)
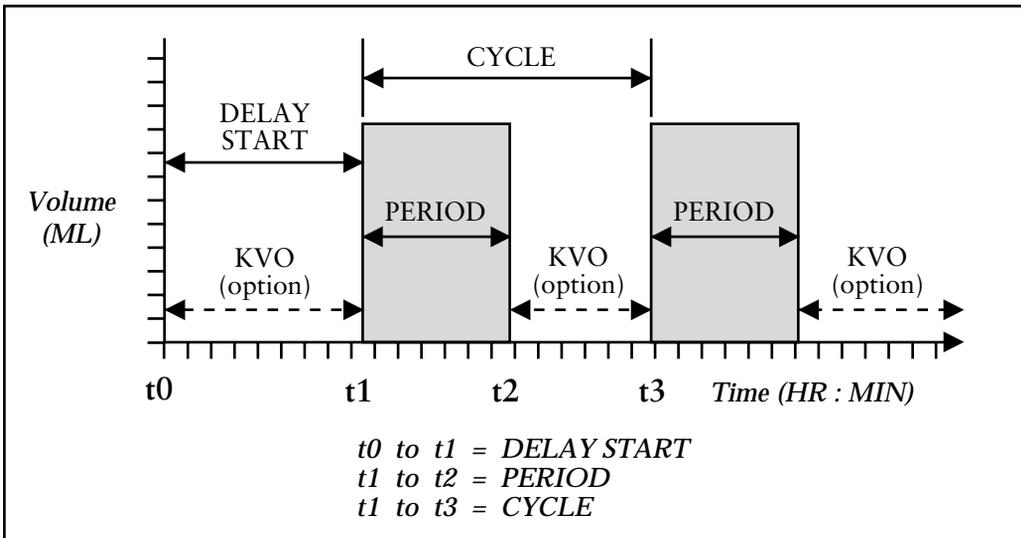
Figure 4.   The Intermittent delivery mode.

2.5.1   The Reservoir-Residual Volume (RES VOL)

The reservoir-residual volume (RES VOL) refers to the initial amount of medi-
cation (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 3.4.2, "Setting the
Reservoir-Residual Volume (RES VOL)."]

2.5.2   The Delivery Volume (ML)

The display will show the current delivery volume, which is the specific amount
of medication in milliliters that the pump will deliver during the PERIOD. The
delivery range is from 00.1 ml to 150.0 ml in 00.1 ml increments. If you pro-
gram a delivery volume of 0.00 ml, the pump will deliver medication at the
KVO rate.

2.5.3   The Delivery PERIOD (PERIOD)

You may program a specific amount of time, called the PERIOD, during which
the patient will receive a prescribed volume of a drug. (See Figure 4.) The display
will show the HR:MIN and PERIOD indicators that denote the current setting
for the PERIOD. The effective delivery rate (ML) during the PERIOD (HR:MIN)
may never exceed 75 ml/hr. The PERIOD range is from 10 minutes to 12 hours.
The PERIOD is programmable in 10-minute increments.

2.5.4   The Delivery CYCLE (CYCLE)

To repeat delivery of a preset volume (ML), it is necessary to program the pump for a delivery CYCLE. (See Figure 4.) You will see the current CYCLE time in hours and minutes on the display. You can program the CYCLE from 20 minutes to 12 hours and 10 minutes. The CYCLE is programmable in 10-minute increments. The minimum amount of time for the CYCLE is the amount of time programmed for the PERIOD plus 10 minutes. The special, 24-hour CYCLE mode permits the delivery PERIOD to repeat once a day.

2.5.5   The KEEP VEIN OPEN (KVO) Rate

Setting the KVO rate is an **optional** function. Usually, you program the pump for a KVO rate when you wish to deliver a minimal amount of drug to help maintain catheter patency; consequently, you may use the KVO function between infusion periods and during the DELAY START. (See Figure 4.) The KVO setting is active between each PERIOD and during the DELAY START unless the KVO rate has been set at 00.0.

2.5.6   The DELAY START Function (DELAY START)

The DELAY START function, an **optional** feature, delays the start of a drug delivery sequence. (See Figure 5.) The DELAY START function ranges from 10 minutes to 12 hours, and you can program it in 10-minute increments. If you program the DELAY START function for "0" hours and "0" minutes, a delay
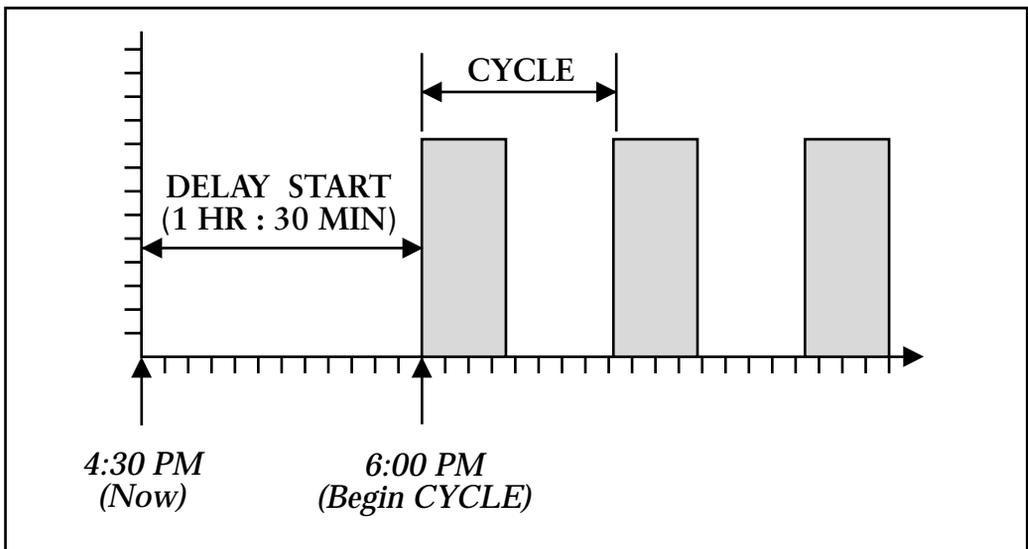
Figure 5.   The DELAY START function.

will not occur, and the pump will begin its delivery immediately. For example, if it is 4:30 pm, and you do not want the delivery of the drug to begin until 6:00 pm, you would program the DELAY START for 1HR:30MIN, which means that the delivery would not begin until 6:00 pm.

2.5.7   The CYCLE GIVEN (CYCLE GIVEN)

CYCLE GIVEN shows the time that has elapsed since the last dose began. CYCLE GIVEN is automatically set to 00:00 when the clinician programs a new drug delivery profile or a new DELAY START time. When the pump is started, CYCLE GIVEN waits until the DELAY START time, if any, passes. Then it begins to count in 1-minute increments (or 1-hour increments in the 24-hour mode) until it equals the programmed delivery CYCLE. At that point, CYCLE GIVEN automatically resets to 00:00 and a new cycle begins.

If the pump is stopped at any time during the cycle, CYCLE GIVEN stops counting. When the pump is restarted, CYCLE GIVEN resumes counting at the same point in the cycle at which it was stopped.

NOTE:
If necessary, you can reset the CYCLE GIVEN in LL0 or LL1. To do this, display the DELAY START screen and press SET/CLEAR. Even if the DELAY START is 00:00, the CYCLE GIVEN will clear to 00:00 and a new cycle will begin when the pump is restarted.

2.5.8   The Amount GIVEN (GIVEN)

GIVEN refers to the number of milliliters that have been delivered since the GIVEN register was last cleared.

The number of milliliters in GIVEN accumulates from 000 to 999 and then returns to 000. Please note that the GIVEN counter functions in a way that is similar to an automobile's odometer. After the GIVEN counter reaches 999, it will start at 000 again and continue counting, which is especially important if you plan to use more than 1,000 milliliters of solution.

3.0   OPERATOR INSTRUCTIONS

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

Operating Instructions

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.)

If the pump is in **Lock Level 1 or Lock Level 2** when you replace the battery, the pump will remain in either the Intermittent mode or the Continuous mode, whichever was active before the old battery was removed. (See Section 3.7 for more information about the pump's lock levels.)

If the pump is in **Lock Level 0** when you install a battery, the display will pause on "𝐿" for Continuous mode, or "𝐼" for Intermittent mode. To resume power-up, you must confirm the mode (see step 6, below.)

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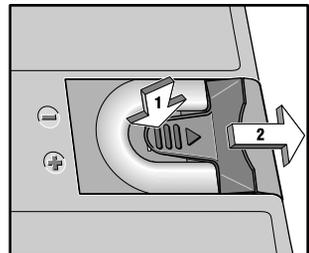
STEP 3: Install the battery in the compartment (bottom-end first).

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. You may also use an external power source to run the pump.
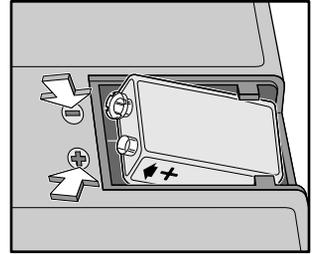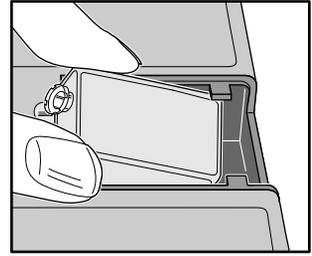
STEP 4: Place the battery door halfway over the battery compartment and press the battery into the compartment by pushing down on top of the door with your thumb.
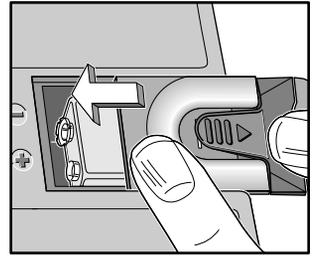
STEP 5: Slide the door closed. Ensure that the door is latched by trying to remove the door without pressing the release button.

WARNING:

If a gap is present anywhere between the battery door and the pump housing, the door is not properly latched. If the battery door becomes detached or loose, the batteries will not be properly secured; this could 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.
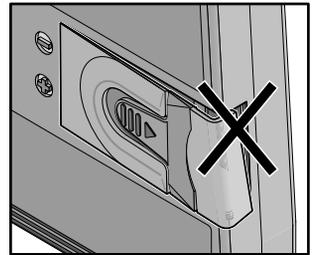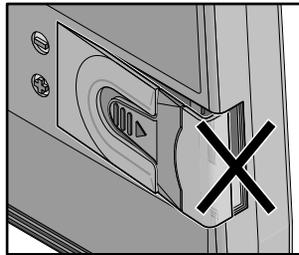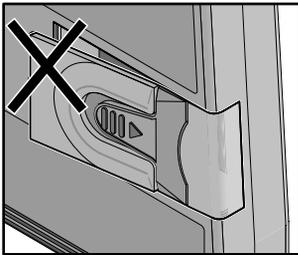
If the pump is in LL1 or LL2, the power-up sequence will start and the pump

will go through an electronic self test. **All of the display indicators, the software revision level, and each parameter will appear briefly.**

If the pump is in LL0, all of the display indicators and software revision level appear, then the display will pause on either

           " *!* " (Intermittent mode) or " *L* " (Continuous mode).

If the desired mode is displayed, press the SET/CLEAR key to continue the power-up sequence. (If the mode must be changed, press the SELECT MODE key so the desired mode appears, then press the SET/CLEAR key. The power-up sequence will continue.)

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.**

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™ Reservoir per day, an alkaline battery will usually last about seven days. If you use an ULTRALIFE® Lithium U9VL 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°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-PLUS® Pump

The CADD-PLUS® 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).

When the pump is set at LL0, you are ready to turn to Section 3.3, "Programming the CADD-PLUS® Pump." Section 3.7, "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, 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 upper right 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.

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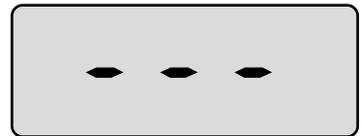
- Release the STOP/START key after the third dash appears and you hear a second beep.

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

LOCK

- Press and release the LOCK key.

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

$$LL1$$

STOP

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.

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- 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.

`LOCK`

```
 L L 0            STOP
```

- 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.

`LOCK`

```
 1 0 0           STOP
               RES VOL
```

3.3 Programming the CADD-PLUS® Pump for Continuous Delivery

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

3.3.1 Selecting the Continuous Delivery Mode

Remove the battery compartment cover and lift the battery at the contact end until the contacts disengage. Reinstall the battery and replace the cover. The power-up sequence will start, and the pump goes through an electronic self-test. All of the display indicators, an error code (if any), and the software revision level will appear briefly.

The display will show either of these figures:

Continuous mode (**C** mode)

or

Intermittent mode (**I** mode)

If the pump is in the Continuous mode,

- Press the SET/CLEAR key to retain the Continuous mode setting in the pump's memory and to continue the power-up sequence. Near the end of the self-test, the pump will display the Continuous mode functions: ML/HR, GIVEN, and RES VOL. A series of beeps indicates that the power-up sequence has been completed.

- Go to Section 3.3.2, "Setting the Reservoir-Residual Volume (RES VOL)."

If the pump is in the Intermittent mode,

- Press the SELECT MODE key to change the pump display from the Intermittent mode to the Continuous mode.
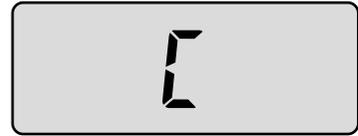
- Press the SET/CLEAR key to enter the Continuous mode setting into the pump's memory and to continue the power-up sequence. Near the end of the self-test, the pump will display the Continuous mode functions: ML/HR, GIVEN, and RES VOL. A series of beeps indicates that the power-up sequence has been completed.

- Go to Section 3.3.2, "Setting the Reservoir-Residual Volume (RES VOL)."

3.3.2 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 3 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 1,500 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 the SELECT MODE key until "RES VOL" appears on the display.

  SELECT MODE

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

  STOP

  100 RES VOL

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

- Press 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. However, this "OFF" relates only to the RES VOL function. The pump will continue to operate. 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.

3.3.3 Setting the Continuous Delivery Rate (ML/HR)

The continuous delivery rate in ML/HR is a constant rate at which the pump delivers medication. The delivery rate range is from 00.1 ml/hr to 75.0 ml/hr in 00.1-ml/hr increments.

- Press and release the SELECT MODE key until ML/HR appears on the display with a number within the range 00.0 to 75.0 ml/hr.

- Press the SCROLL keys until the desired delivery rate appears on the pump's display. This example shows a continuous delivery rate of 25.0 ml/hr.

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

NOTE:
If you do not press the SET/CLEAR key within 15 seconds, the pump's memory will retain the previous delivery rate.

3.3.4 Reviewing the GIVEN Mode

The GIVEN mode displays the total milliliters delivered since the mode was last cleared, including the quantities delivered in either the Continuous or Intermittent modes. The number of milliliters in 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 GIVEN counter reaches 999, it will start at 000 again and continue counting. This GIVEN display shows that 148 milliliters have been given.

NOTE:
The pump does not include the amount primed when calculating the total milliliters given.

- Press and release the SELECT MODE key until GIVEN appears on the display with a number in the range of 000 to 999.

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

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

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3.4 Programming the CADD-PLUS® Pump for Intermittent Delivery

NOTE:

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

3.4.1 Selecting the Intermittent Delivery Mode

Remove the battery compartment cover and lift the battery at the contact end until the contacts disengage. Reinstall the battery and replace the cover. The power-up sequence will start, and the pump goes through an electronic self-test. All of the display indicators, an error code (if any), and the software revision level will appear briefly.

The display will show either of these figures:

Continuous mode (**C** mode)

or

Intermittent mode (**I** mode)
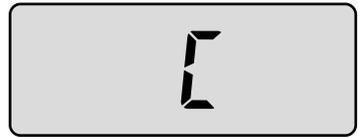
If the pump is in the Intermittent mode,

- Press the SET/CLEAR key to retain the Intermittent mode setting in the pump's memory and to continue the power-up sequence. Near the end of the self-test, the pump displays the Intermittent mode functions: ML, PERIOD, CYCLE, KVO ML/HR, DELAY START, CYCLE GIVEN, GIVEN, and RES VOL. A series of beeps indicates that the power-up sequence has been completed.

- Go to Section 3.4.2, "Setting the Reservoir-Residual Volume (RES VOL)."

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If the pump is in the Continuous mode,

- Press the SELECT MODE key to change the pump display from the Continuous mode to the Intermittent mode.
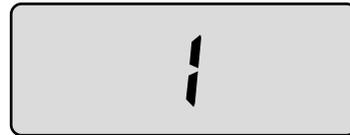
- Press the SET/CLEAR key to enter the Intermittent mode setting into the pump's memory and to continue the power-up sequence. Near the end of the self-test, the pump displays the Intermittent mode functions: ML, PERIOD, CYCLE, KVO ML/HR, DELAY START, CYCLE GIVEN, GIVEN, and RES VOL. A series of beeps indicates that the power-up sequence has been completed.

- Go to Section 3.4.2, "Setting the Reservoir-Residual Volume (RES VOL)."

3.4.2 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 3 milliliters. When RES VOL reaches 0 ml, a continuous 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 1,500 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.*

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

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

- Press the SCROLL keys to set the value for the volume contained in the reservoir.
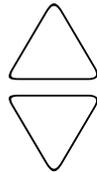
- Press the SET/CLEAR key within 15 seconds to set the value.

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. However, this "OFF" relates only to the RES VOL function. The pump will continue to operate. 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.*

3.4.3 Setting the Delivery Volume (ML)

- Press and release the SELECT MODE key until ML appears on the display with a number in the range of 00.0 to 150.0.

- Press the SCROLL keys until the desired delivery volume appears on the pump's display.
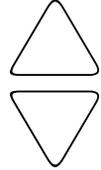
This example shows an Intermittent delivery volume of 50.0 ml.

50.0 ML

- Press the SET/CLEAR key within 15 seconds to enter the delivery volume.

NOTES:

(1) If you do not press the SET/CLEAR key within 15 seconds, the pump's memory will retain the previous delivery volume.

*(2) If you hear a variable-tone alarm, you have programmed a delivery volume that is too large for the currently programmed PERIOD (**PERIOD-too-Short Alarm**). The pump will automatically go to the PERIOD mode, displaying the minimum time that is acceptable for the new delivery volume. You may now use the SCROLL and SET/CLEAR keys as described in Section 3.4.4 to program a new PERIOD. If you do not program a new PERIOD, you will hear the PERIOD-too-Short Alarm again in 15 seconds.*

3.4.4 Setting the Delivery PERIOD (PERIOD)

- Press and release the SELECT MODE key until HR:MIN and PERIOD appear on the display, with a number in the range of 0:10 to 12:00.

- Press the SCROLL keys until the desired PERIOD appears on the pump's display.
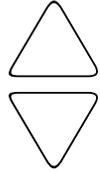
This example shows a PERIOD of 1 hour.

- Press the SET/CLEAR key within 15 seconds to enter the delivery PERIOD.

NOTES:

(1) If you do not press the SET/CLEAR key within 15 seconds, the pump's memory will retain the previous delivery PERIOD.

*(2) If you hear a variable-tone alarm, you have programmed the time of the delivery PERIOD to be too long for the delivery CYCLE (**CYCLE-too-Short Alarm**). In that event, the pump will automatically go to the CYCLE mode, displaying the minimum time that is acceptable for a delivery CYCLE. You may now use the SCROLL and SET/CLEAR keys as described in Section 3.4.5 to program a new CYCLE. If you do not program a new CYCLE, you will hear the CYCLE-too-Short Alarm again in 15 seconds.*

3.4.5 Setting the Delivery CYCLE (CYCLE)

- Press and release the SELECT MODE key until HR:MIN and CYCLE appear on the display, with a number in the range of 0:20 to 12:10 or 24:00.

- Press the SCROLL keys until the desired CYCLE appears on the pump's display.
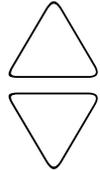
This example shows a CYCLE of 6 hours.

CYCLE **6:00** **STOP**
HR : MN

- Press the SET/CLEAR key within 15 seconds to enter the delivery CYCLE.

SET CLEAR

NOTE:
If you do not press the SET/CLEAR key within 15 seconds, the pump's memory will retain the previous delivery CYCLE.

3.4.6 Setting the KEEP VEIN OPEN (KVO) Function

- Press and release the SELECT MODE key until KVO and ML/HR appear on the display with a number in the range or 00.2 to 10.0, or 00.0.

SELECT MODE

- Press the SCROLL keys until the desired KEEP VEIN OPEN rate appears on the pump's display.

This example shows a KEEP VEIN OPEN rate of 00.2 ml/hr.

STOP
00.2
KVO **ML/HR**

- Press the SET/CLEAR key within 15 seconds to enter the KVO rate.

SET CLEAR

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NOTE:

If you do not press the SET/CLEAR key within 15 seconds, the pump's memory will retain the previous KVO rate.

3.4.7 Setting the DELAY START (DELAY START)

- Press and release the SELECT MODE key until DELAY START and HR:MIN appear on the display with a number in the range of 0:10 to 12:00, or 0:00.

SELECT
MODE

- Press the SCROLL keys until the desired DELAY START time appears on the pump's display.
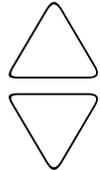
This example shows a DELAY START of 1 hour, 30 minutes.

```
DELAY
START   1:30    STOP

      HR : MN
```

NOTE:

If you do not wish to use the DELAY START feature, set the DELAY START to "0:00."

- Press the SET/CLEAR key within 15 seconds to enter the DELAY START time.

SET
CLEAR

NOTE:

If you do not press the SET/CLEAR key within 15 seconds, the pump's memory will retain the previous DELAY START time.

3.4.8 Reviewing the CYCLE GIVEN Mode

The CYCLE GIVEN display shows the elapsed time in the current delivery CYCLE. Once a new DELAY START or drug delivery sequence is programmed, the CYCLE GIVEN counter automatically resets itself to "0" hours and "0" minutes. The CYCLE GIVEN display cannot be manually reset.

- Press and release the SELECT MODE key until CYCLE GIVEN and HR:MIN appear on the display. The number 0:00 will appear on the display if you have changed the pump's program or DELAY START. A number between 0:00 and the current delivery CYCLE will appear on the display if the program has not been altered.

3.4.9 Reviewing the GIVEN Mode

The GIVEN mode displays the total milliliters delivered since the mode was last cleared, including the quantities delivered in the Continuous and Intermittent modes. The number of milliliters in 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 GIVEN counter reaches 999, it will start at 000 again and continue counting. This GIVEN display shows that 148 milliliters have been given.

NOTE:

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

- Press and release the SELECT MODE key until GIVEN appears on the display with a number in the range of 000 to 999.

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

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

3.5 Attaching and Removing the Cassette

3.5.1 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 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.

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.
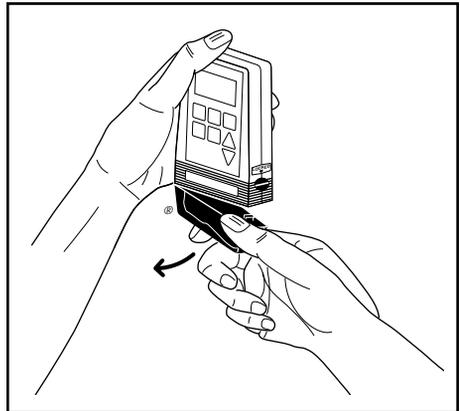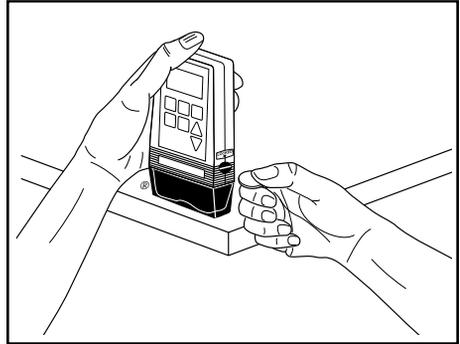
3.5.2 Attaching the Cassette

Obtain a new, filled Medication Cassette™ Reservoir, or CADD® Administration Set attached to a non-vented 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.

LOCKED
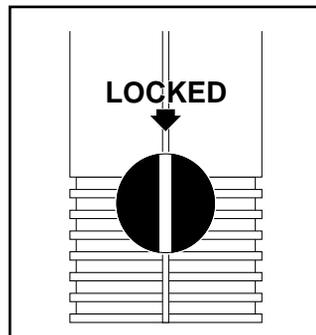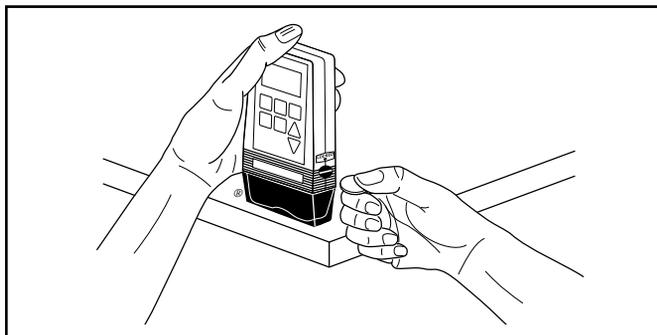
- Press down on the pump so the cassette fits tightly against the bottom of the pump. Lock the cassette in place by inserting a coin into the slot in the locking button, pushing the button in; and then turn the coin one-quarter turn **counter-clockwise** until a definite stop is felt.

- Gently twist and pull on the cassette to make sure it is firmly attached.
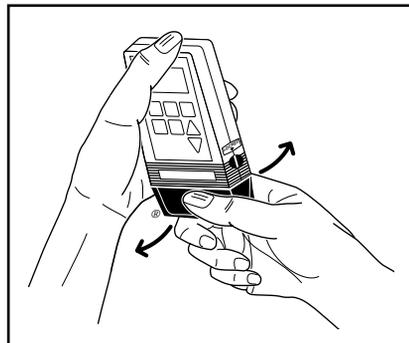
WARNING:

It is essential that you attach the cassette properly. When you attach the cassette properly, the coin 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 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.

3.6 Priming the CADD-PLUS® 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.

$$PPP$$

- Release the PRIME key after PPP appears and you hear a second, single beep.

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 priming delivery cycle.
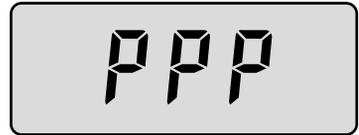
NOTES:

(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.

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

The CADD-PLUS® 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: **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 3.5.2, "Attaching the Cassette.")

In the Intermittent mode, the clinician may permit the patient to change the DELAY START time by changing the lock level to LL1. The clinician sets the DELAY START time while the pump is in Lock Level 0.

In Lock Level 1, when in the Stop mode, the patient can change the DELAY START time by pressing the SELECT MODE key until DELAY START appears on the display. By using the SCROLL keys, the patient can enter the new DELAY START time.

When the desired time appears on the display, the patient presses the SET/ CLEAR key to set the new DELAY START time. If the SET/CLEAR key is not pressed within 15 seconds, the pump will begin delivery after the previous DELAY START time.

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

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

Lock Level	Description
LL0	Use this lock level for programming the pump's functions.
LL1	In the Continuous mode, the patient may prime the tubing and reset the RES VOL to the original programmed value. In the Intermittent mode, the patient may program the DELAY START function, prime the tubing, and reset the RES VOL to the original programmed value.
LL2	The patient may only start or stop the pump and clear the RES VOL alarm.
LL0, LL1, LL2	If the RES VOL value 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.

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 upper right 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. In this example, the display shows "LL2."

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

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

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- 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:
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.

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.
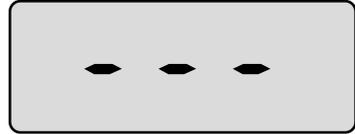
STOP
START

STEP 2:   Release the STOP/START key after the last dash disappears, and the pump beeps; then the word "STOP" disappears from the display. 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 display.

STOP
START

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.

028   STOP
RES VOL

3.9   Reviewing the CADD-PLUS® Programming Modes

Drug delivery begins in the Start mode. When the pump is in the Start mode, programming is not possible, but there can be a review of 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.

- "RES VOL" stops blinking on the display while you are reviewing the program modes.

4.0 REFERENCE SECTION

4.1 Glossary

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

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.

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

Cycle Given. A mode which tells you how much time has elapsed in the current CYCLE.

Delay Start. A programming mode that you use to postpone an infusion period. This function adds a delay to the start of a drug delivery sequence.

Delivery Cycle. The amount of time that you can program into the pump to repeat a dose of medication.

Delivery Volume. The prescribed amount of medication that you infuse within a specified period of time.

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.

Intermittent Mode (I Mode). This is the mode that permits you to deliver medication at a periodic rate.

KVO (Keep Vein Open) Rate. An optional program mode that you may use after the regular infusion period has ended to permit you to deliver a minimal amount of drug to maintain a positive flow.

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. A signal on the display that indicates low power in the battery.

Lock Level. 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.

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.

Period. The amount of time, in hours and minutes, during which the pump will deliver a specified quantity of medication (in milliliters).

Prime Key. Press this key to purge air from the fluid path.

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

Reservoir-Residual Volume. See *RES VOL.*

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.

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

4.2   Pump Maintenance and Cleaning

CAUTIONS:
- ***Do not immerse the pump in cleaning fluid or water. Do not allow solution to soak into the pump, accumulate on the keypad, or enter the battery compartment.***
- ***Do not clean the pump with acetone, other plastic solvents, or abrasive cleaners.***

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.

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

The CADD-PLUS® infusion pump, Model 5400, 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-PLUS® pump (Model 5400) 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/conditions that require corrective actions.

Alarm/Condition	Cause	Corrective Action
The display blinks when RES VOL reaches 5 and 4 ml. Refer to Section 4.4.1.	The ML remaining value is at or below 5 ml.	Prepare to install a new (filled) fluid container.
You hear 3-second, 6-second, or 9-second variable-tone beeps. Refer to Section 4.4.1.	The ML remaining value is at 3 ml, 2 ml, or 1 ml.	Prepare to install a new (filled) fluid container.
2 beeps sound each second; RES VOL is displayed continuously and STOP blinks on the display.	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 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 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 below.)	A controller, microprocessor, or motor fault has occurred. The pump operation stops.	• Close the tubing. • Remove the pump from service and have it repaired. Call Customer Service: **800-426-2448.**

Reference

Table 2—*continued*.

Alarm/Condition	Cause	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 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.
After installing a battery, "C" or "I" remains on the display	The pump is in LL0 and is requiring you to confirm the mode (C = Continuous, I = Intermittent).	• If the desired mode is displayed, press SET/CLEAR. • To change the mode, press SELECT MODE, then SET/CLEAR. • If it is intended that the pump run in LL1 or LL2, change the lock level after power-up.
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: Volume =

Reference

*00.0; PERIOD = 12:00; CYCLE = 12:10; DELAY START = 00:00; CYCLE GIVEN = 00:00; KVO ML/HR = 00.0; ML GIVEN = 000; RES VOL = OFF; ML/HR = 00.0; Mode = Intermittent; and Lock Level 0 or Lock Level 1 revert 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 numbers on the display will flash about every two seconds. When RES VOL reaches 3 ml, you will hear a 3-second variable-tone alarm. At 2 ml you will hear a 6-second variable-tone alarm, and at 1 ml you will hear a 9-second variable-tone alarm. 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 Continuous

GIVEN Range .... 000–999 ml in 1-ml increments rounded down to nearest ml.

RES VOL Alarm Range ..... 000–1,500 ml in 1-ml increments rounded up to the nearest ml; 000 ml for alarm off.

ML/HR Range .... 0.00–75.0 ml/hr in 00.1-ml increments.

4.5.2 Intermittent

ML Range .... 0.00–150.0 ml, 00.1-ml increments.

PERIOD Range .... 10 min– 12 hr, 10-min increments.

CYCLE Range .... 20 min–12 hr:10 min, 10-min increments; and 24 hours for a 24-hour cycle.

KVO ML/HR Range .... 00.2–10.0 ml/hr, 00.1-ml increments; and 00.0 when not using KVO.

DELAY START Range .... 10 min–12 hr, 10-min increments, and 0 hr:00 min when not using DELAY START.

CYCLE GIVEN Range ...... 0 min–12 hr:10 min, in 1-min increments; and 0 to 24 hours, in 1-hour increments, when CYCLE is programmed in 24-hour mode.

GIVEN Range .... 000–999 ml in 1-ml increments rounded down to the nearest ml.

RES VOL Alarm Range ..... 000–1,500 ml in 1-ml increments rounded up to the nearest ml; 000 ml for alarm off.

4.5.3 General

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.

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 (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 an 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.

Reference

1
PLUS
PCA

*Use CADD® pump
accessories carrying
this symbol*

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