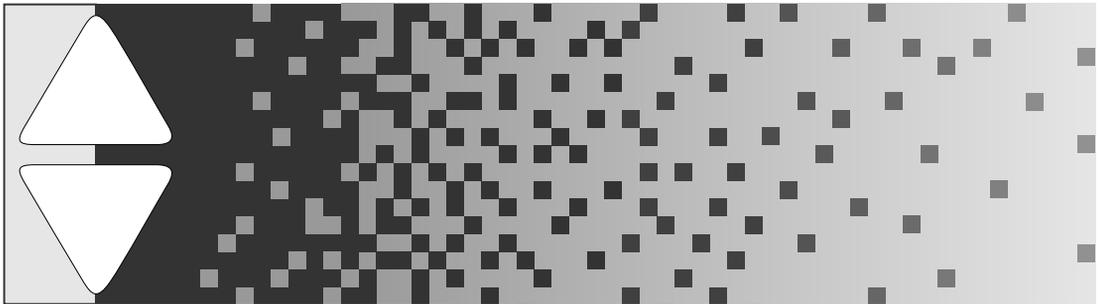# CADD-TPN®

Ambulatory Infusion System

Model 5700
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-TPN®, **Model 5700,** ambulatory infusion system.

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-TPN® system, 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-TPN® infusion system.

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

CONTENTS

1.0   INTRODUCTION

The Deltec CADD-TPN® Model 5700 Ambulatory Infusion System consists of a pump and its related accessories.

The purpose of this manual is to help you, the healthcare professional, to become familiar with the CADD-TPN® pump and its associated 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 general reference section, containing other important information.

You should review these operating instructions carefully before using the CADD-TPN® pump and its accessories. You should also become familiar with all warnings and caution advisories to learn how to operate the system properly.

2.0   GENERAL DESCRIPTION OF THE CADD-TPN® SYSTEM AND ITS ACCESSORIES

The CADD-TPN® Model 5700 system is designed primarily for the administration of nutritional and other solutions or fluids intravenously. The system can also be used for intra-arterial and intraperitoneal infusion therapies.

Therapy should always be overseen by a physician or a certified, licensed healthcare professional. The patient should be instructed in using and trouble-shooting the pump. If used properly according to the instructions contained in this manual, the pump provides programmed delivery of solutions at controlled rates for continuous and "tapering" modes. The pump's flexibility allows it to be used in a variety of settings, including the home.

2.1 WARNINGS and CAUTIONS

**Read this entire Operator's Manual before operating the CADD-TPN®
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

- This Operator's Manual should be used by clinicians only. Do not permit
  patients to have access to this manual, as the information contained
  would allow the patient complete access to all programming and operating
  functions. Improper programming could result in death or serious injury
  to the patient.

- For those patients who are likely to be adversely affected by unintended
  operations and failures, including interrupted medication or fluid delivery
  from the device, close supervision and provision for immediate corrective
  action should be provided.

- If the pump is used to deliver life-sustaining medication, an additional
  pump must be available.

- The pump is not to be used for delivery of blood or cellular blood
  products.

- If the pump is dropped or hit, inspect the pump for damage. Do not use
  a pump that is damaged or is not functioning properly. Contact Customer
  Service to return the pump for service.

- Prior to starting infusion, inspect the fluid path for kinks, a closed clamp,
  or other upstream obstructions, and remove any air to prevent air
  embolism.

- Do not use rechargeable NiCad or nickel metal hydride (NiMH) batteries.
  Do not use carbon zinc ("heavy duty") batteries.

- Always have extra new batteries available for replacement.

- Ensure that the battery door is securely latched.

- Ensure that the cassette is properly attached.

- Close the fluid path tubing with the clamp before removing the

administration set from the pump.

- Use only CADD-TPN* Administration Sets with an Add On Anti-Siphon Valve to protect against: unregulated gravity infusion that can result from an improperly attached reservoir, and delivery inaccuracies.

- System delivery inaccuracies may occur as a result of back pressure or fluid resistance, which depends upon drug viscosity, catheter size, and extension set tubing (for example, microbore tubing).

- Do not prime the fluid path with the tubing connected to a patient.

- For detailed instructions and warnings pertaining to administration sets, please refer to the instructions supplied with those products.

- Frozen medication must be thawed at room temperature only. Do not heat the administration set in a microwave oven.

2.1.2 CAUTIONS

- Do not operate the pump at temperatures below +2°C (36°F) or above 40°C (104°F).

- Do not store the pump at temperatures below -40°C (-40°F) or above 55°C (131°F). Do not store the pump with the administration set attached.

- Do not expose the pump to humidity levels above 90% relative humidity.

- Do not store the pump for prolonged periods with the batteries installed.

- Do not immerse the pump in cleaning fluid or water or 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.

- Do not expose the pump to therapeutic levels of ionizing radiation.

- Do not expose the pump directly to ultrasound.

- Do not use the pump in the vicinity of magnetic resonance imaging (MRI) equipment.

- Do not use the pump near ECG equipment.

- Do not sterilize the pump.

- Do not use the pump in the presence of flammable anesthetics or explosive gases.

- Use only Deltec accessories as using other brands may adversely affect the operation of the pump.

- Check appropriate medication stability for time and temperature to assure stability with actual pump delivery conditions.

2.2 Physical description of the pump display, function keys, and set plate

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

Figure 1. CADD-TPN® pump display, function keys, and set plate.
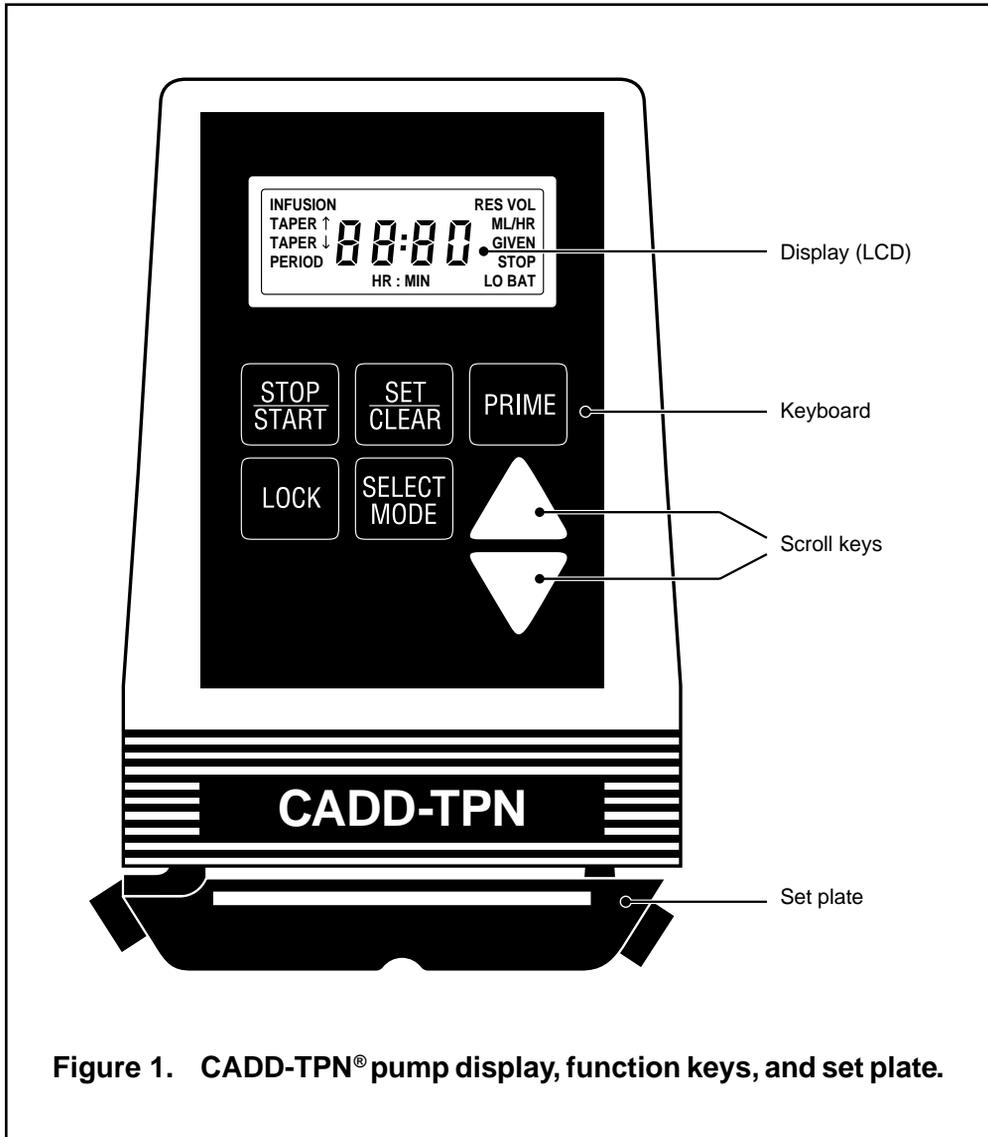
2.3 Description of the pump display and function keys

Liquid Crystal Display (LCD). The screen or display panel that shows the pump's various control functions and the values you program for the pump operation. In this manual, the term "display" is synonymous with display panel or LCD.

STOP/START Key. The STOP/START key is used to start and stop the pump's pumping action.

SET/CLEAR Key. The SET/CLEAR key is used to enter new settings or programming values into the computer's memory. This key is also used to clear or remove the volume given (ML GIVEN).

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

LOCK Key. Use the LOCK key to restrict changes in the pump's operation and to find out which lock level the pump is in.

SELECT MODE Key. Use the SELECT MODE key to display the pump's programmed values; for example, reservoir-residual volume (RES VOL), infusion volume, infusion period, taper-up period, taper-down period, infusion rate, and volume given. 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.

SCROLL Keys. Use the up or down SCROLL keys to increase or decrease the pump operating values, which will appear on the pump's display. If you press and hold a SCROLL key, you can scroll through the operating values rapidly.

2.4   System components and accessories

The CADD-TPN® system consists of the following components:

- CADD-TPN® pump, including
  - Carrying case
  - Battery (9-volt)
  - Operator's Manual with warranty information
  - Set plate (non-sterile - for demonstration purposes only)

- External Power Source (EPS) System, including
  - AC adapter
  - Power pack (rechargeable)
  - Battery adapter
  - Battery door (notched)

- Backpack (with shoulder strap)

Other accessories:

- CADD-TPN® Administration Set (0.2 µ air-eliminating filter and Add On Anti-Siphon Valve)
- CADD-TPN® Administration Set (1.2 µ air-eliminating filter and Add On Anti-Siphon Valve)
- One-Liter Pump Pouch

2.5   Description of the CADD-TPN® Administration Set

The administration set is used to connect the fluid container to the patient's access device. You must use the Add On Anti-Siphon Valve supplied with the administration set. The anti-siphon valve provides free flow protection, allows one-way fluid delivery, and ensures pump accuracy. If the Add On Anti-Siphon valve is not used, delivery inaccuracies of approximately 2.5% are possible.

Figure 2.   Administration set without connections to the fluid container or patient access device.

Figure 3.   The administration set plate is inserted in the bottom of the pump.
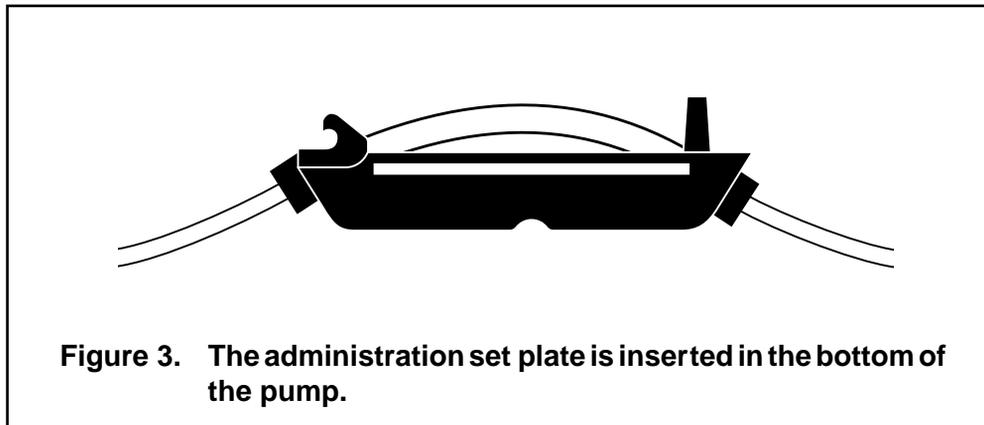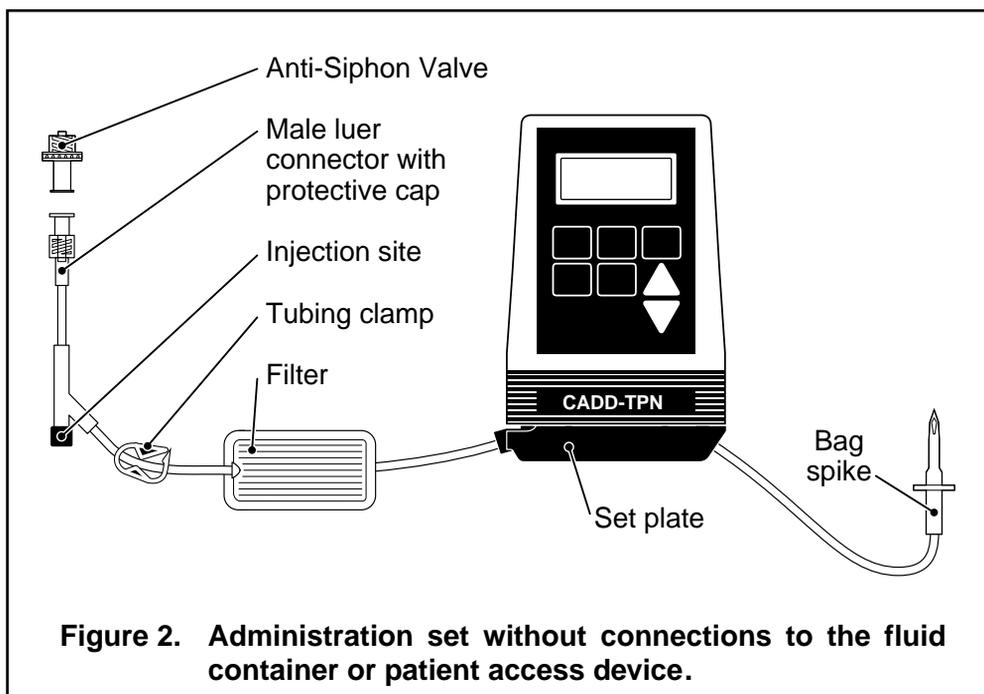
The administration set includes either a 0.2 µ or a 1.2 µ air-eliminating filter, which is designed to remove air bubbles from the fluid path. However, periodic visual inspection is recommended.

Procedures for attaching (or removing) the administration set are described in Section 3.3 and 3.4. Priming the administration set is described in Section 3.5.

2.6 Understanding the continuous infusion mode and the tapering modes

The CADD-TPN® pump delivers solutions at continuous infusion rates, which may include a programmable feature called "tapering." With tapering, infusion rates are gradually increased at the beginning of an infusion period, and/or are gradually decreased at the end of an infusion period.

The pump can deliver solutions at a continuous infusion rate of 10–400 ml/hr with the power pack; or, it can deliver solutions at a continuous rate of 10–250 ml/hr with a 9-volt battery. An example of continuous infusion (without any tapering) is illustrated in Figure 4. Two liters of solution are delivered during a 10-hour infusion period at a continuous infusion rate of 200 ml/hr (Figure 4).

Figure 4.   Continuous infusion rate delivery of 2 liters of solution during a 10-hour infusion period.
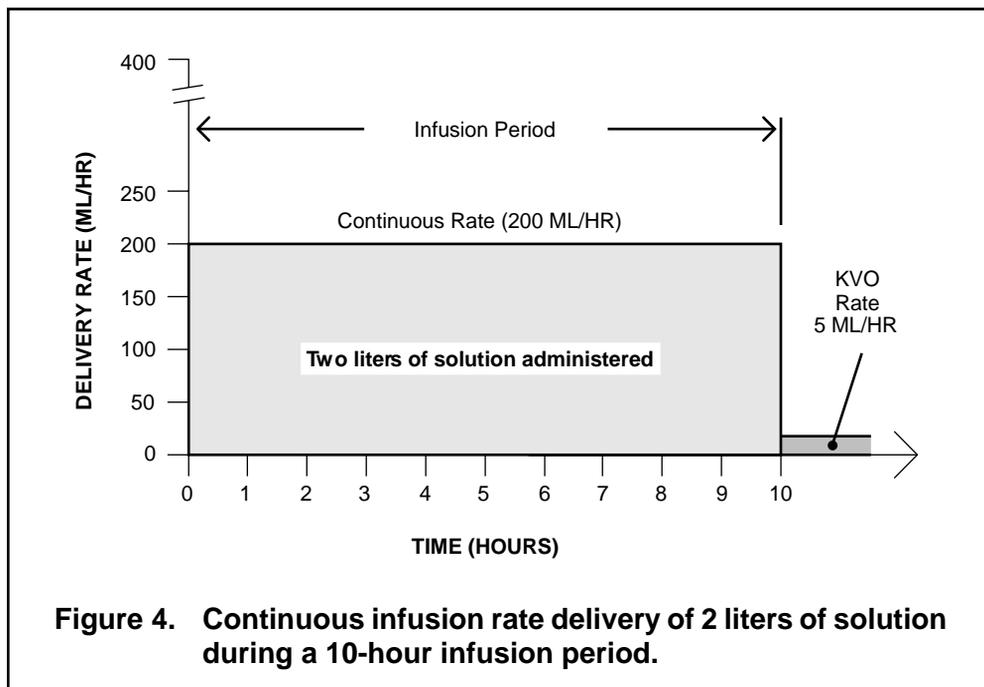
In addition, the CADD-TPN® pump can be programmed for gradual changes (tapering) in the infusion rate at the beginning and/or end of the programmed infusion period. Infusion rate changes can be made to occur very slowly or quickly, depending on how the pump is programmed. An example of tapering when two liters of solution are delivered during a 10-hour infusion period is shown in Figure 5. The pump slowly increases the infusion rate in the first

hour of infusion. Between the second and ninth hours of infusion, the solution is delivered at the continuous rate of 222 ml/hr. In the last hour, the infusion rate decreases.

Figure 5. Automatic tapering. Two liters of solution are delivered during a 10-hour infusion period by gradually increasing and decreasing the rate of delivery.
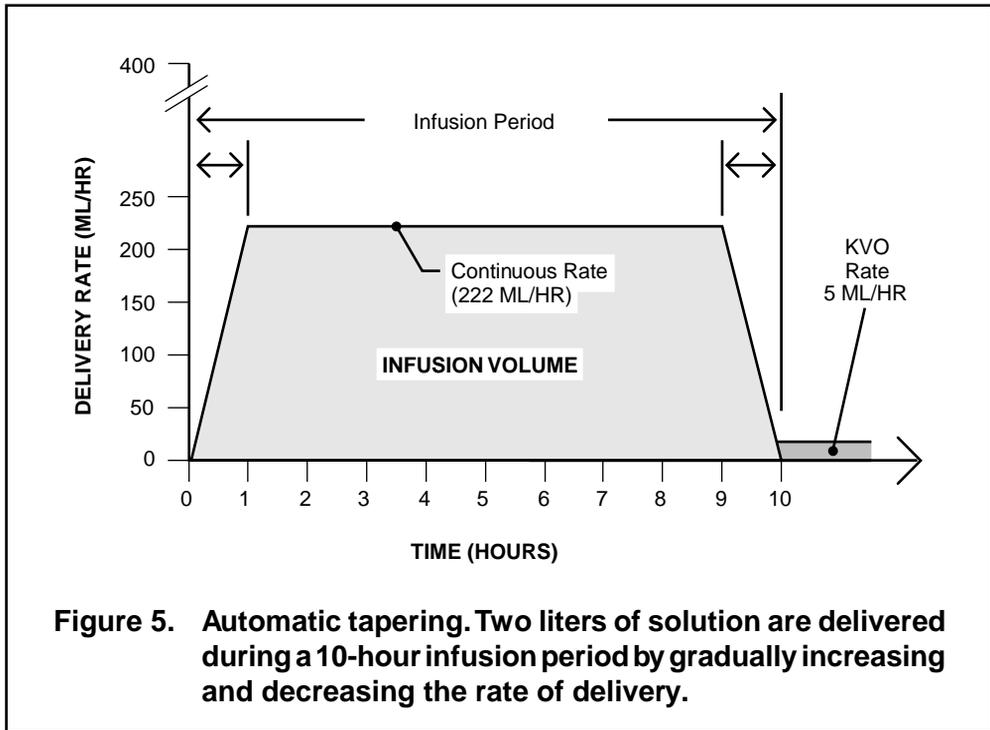
NOTES:

(1) *The clinician determines whether the patient requires tapering.*

(2) *After the taper-down period, the rate of infusion automatically switches to 5 ml/hr (if applicable). This rate is referred to as the **KVO (KEEP VEIN OPEN)** infusion rate. It permits a minimal amount of solution to flow after the regular infusion volume has been delivered; and it occurs until the RES VOL value is "0000", or the pump enters the Stop mode.*

If you intend to use the KVO mode, be sure that the volume in the fluid container is sufficient for your needs. **You must make sure that the RES VOL value is large enough to include the priming volume and, if applicable, the KVO delivery.** *(See Section 3.7.2.)*

3.0 OPERATOR INSTRUCTIONS

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

3.1 Installing or replacing the battery and observing the pump power-up test

NOTE:

The pump can also be powered by the External Power Source (EPS) System. (See Section 3.8.)

CAUTION:

If your delivery rate is more than 250 ml/hr, you must use the power pack instead of a 9-volt battery to power the pump.

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, nondelivery of drug, and, depending on the type of drug being administered, death or serious injury to the patient could result.*

- *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, nondelivery of drug, and, depending on the type of drug being administered, death or serious injury to the patient.*

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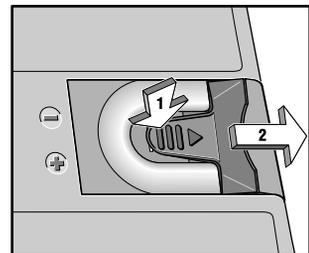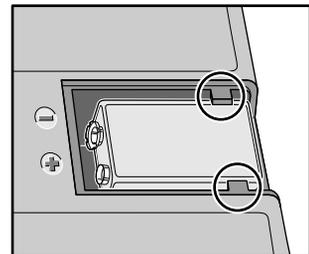
STEP 3: Install the battery in the compartment (bottom-end first).
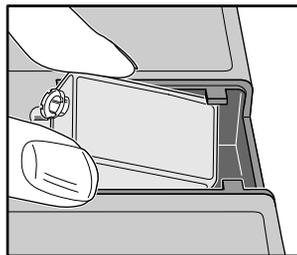
NOTE:

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. (See Section 3.8.)
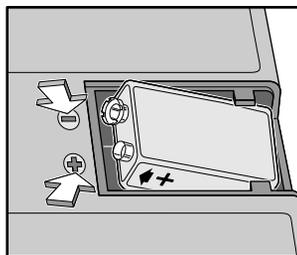
STEP 4: Place the battery door halfway over the battery compartment and press the battery into the compartment by pushing down on top of the door with your thumb.
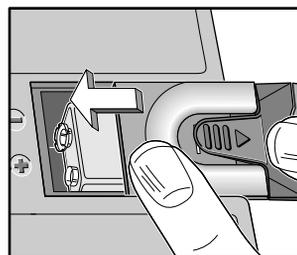
STEP 5: Slide the door closed. Ensure that the door is latched by trying to remove the door without pressing the release button.

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, nondelivery of drug, and, depending on the type of drug being administered, death or serious injury to the patient.
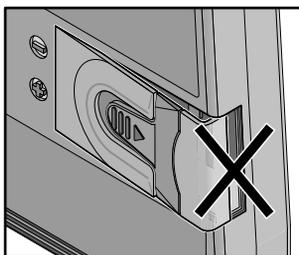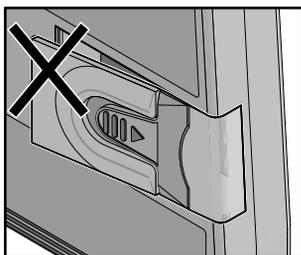
The power-up sequence will start, and the pump will go through an electronic self-test, which lasts about 50 seconds. All of the display indicators and the

software revision level will appear briefly.

STEP 6: Begin operation of the current program by pressing and holding the STOP/START key to enter the Start mode (Section 3.7.3), or proceed to Section 3.2 to program the pump.

NOTE:
*You will not be able **to change** the delivery rate until the infusion period has been completed, unless you stop the pump and reprogram in Lock Level 0.*

The battery's life is dependent on the volume of solution delivered and temperature (Section 4.5.2). An alkaline battery will supply enough energy for approximately 6 hours at 250 ml/hr. If you use an ULTRALIFE® lithium battery, you should have power for approximately 18 hours at 250 ml/hr. You **must** use the power pack for rates greater than 250 ml/hr. **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   Programming the CADD-TPN® pump

3.2.1 Preparing to program the CADD-TPN® pump

Before you begin, determine the following:

- The value that should be programmed for **RES VOL**, in milliliters, including the KVO and priming volume (if appropriate). (See Section 3.7.2.)

- The value that should be programmed for the **infusion volume**, in milliliters.

Decide how much time you need:

- The amount of time required to deliver the solution, the **infusion period**, in hours and minutes; and, if you are using the tapering function,

- The amount of time for gradually increasing the rate of delivery, **taper-up period**, in hours and minutes; and

- The amount of time for gradually decreasing the rate of delivery, **taper-down period**, in hours and minutes.

Once you have completed the above steps, you are ready to program the pump. Make sure the pump is in the Stop mode and Lock Level 0.

When the pump is in the Stop mode, the word "STOP" will blink in the lower right corner of the display, and you will hear three beeps every 5 minutes. If the pump is already in the Stop mode, go directly to STEP 2. If not, proceed with STEP 1:

STEP 1:   Press and hold the STOP/START key to stop the pump.

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

- After the third dash appears, you will hear a second beep. Release the STOP/START key.
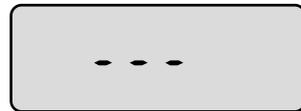
- The word "STOP" flashes on the display, and you will hear three beeps every 5 minutes.

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

- Press and release the LOCK key.

- The current lock level (LL0, LL1, or LL2) will appear on the display for 15 seconds unless you press the LOCK key again.

| LL2 |

To change the lock level to LL0, press the up or down SCROLL key until LL0 appears.

| LL0 |

- Press the LOCK key.

- The display shows "000".

| 000 |

- Press the up SCROLL key until ******** appears on the pump's display.

| |

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

- 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 and also the starting point for programming.

3.2.2 Setting and changing the reservoir-residual volume (RES VOL)

NOTE:

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

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

You must enter the initial volume (ml) of solution, contained within the fluid container, into the pump's memory. You may program the reservoir-residual volume to be any value between 0 ml and 9990 ml.

When the RES VOL decreases to 50 milliliters, that value will blink, and a short alarm will sound (1 beep). With each subsequent 10-ml decrease in RES VOL, a single beep or additional beeps will sound, and the RES VOL value will continue to blink. When RES VOL reaches 0 ml, a continuous alarm will indicate that the fluid container is empty, and the pump will stop automatically.

NOTE:

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

*For example, if you were to program the RES VOL for 1,000 ml, which is the stated capacity of some fluid containers, and actually receive a fluid container with 1,010 ml, the pump would stop its delivery after 1,000 ml had been delivered. The **RES VOL** alarm would beep to indicate that the programmed volume had been delivered. However, the fluid container would still contain about 10 ml of solution. This discrepancy **might** cause you to think that the pump is inaccurate, since fluid containers may contain more fluid than indicated; so, it may be normal to find a small volume of solution left within the fluid path at the end of an infusion schedule.*

Follow these steps to set or change the reservoir-residual volume (**RES VOL**):

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

The display shows the **RES VOL** setting. In this example, the volume of solution that remains in the fluid container is 810 ml, and the pump is **in the Stop mode.**

```
0810  RES VOL
      ML
      STOP
```

- Press the SCROLL keys to change the value of the volume in the fluid container. A beep sounds each time a SCROLL key is pressed. The values will continue to change as long as a SCROLL key is pressed.

- Press the SET/CLEAR key within 15 seconds to set the value for RES VOL.

NOTES:

(1) If you do not press the SET/CLEAR key within 15 seconds after releasing the SCROLL key, the pump will retain the previously programmed RES VOL setting.

(2) Normally, the RES VOL value is displayed while the pump is running.

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

(4) If you do not wish to use the reservoir-residual volume feature, set the RES VOL value to "0000". Thereafter, when RES VOL is displayed, "OFF" will appear on the display, and the RES VOL alarm will not function. There will be no warning when the reservoir-residual volume is low or empty. (See Section 3.7.5.)

3.2.3 Setting and changing the infusion volume (INFUSION ML)

The "**INFUSION ML**" is the volume of solution that is programmed to be delivered to the patient. Infusion volumes from 10 ml up to 9990 ml can be programmed. Follow the steps below for setting or changing the value of the pump's infusion volume:

- Press the SELECT MODE key until "INFUSION ML" appears on the display. The display shows the previous infusion volume setting. In this example, an infusion volume of 1000 ml had been programmed. "STOP" will flash on the lower right corner of the display to show that the pump is not running.

```
INFUSION
1000  ML
      STOP
```

- Press the SCROLL keys to change the infusion volume. A beep will sound each time a SCROLL key is pressed.

- Press the SET/CLEAR key within 15 seconds to set the desired value for the infusion volume.

NOTES:

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

(2) *After pressing the SET/CLEAR key to enter the value of the infusion volume, you can put the pump into the Start mode to begin delivery. If the pump is not put into the Start mode, the pump will remain in the Stop mode, and the RES VOL will automatically appear on the display (after 60 seconds). An alarm will beep every five minutes to indicate that the pump is in the Stop mode.*

NOTE:
A "Rate-too-High" or a "Rate-too-Low" alarm may sound when you program a new infusion volume that is either too high or too low for the current delivery schedule. Press the SET/CLEAR key to clear the error and review Sections 4.4.3 and 4.4.4.

3.2.4 Setting and changing the infusion period (HR:MIN)

The "**INFUSION PERIOD (HR:MIN)**" is the total amount of time programmed for delivery of solution. The infusion period includes the time programmed for continuous and tapered delivery (if tapering is used). Solutions can be delivered over infusion periods that last from 10 minutes to 99 hours and 50 minutes (00:10–99:50). Follow the steps below for setting or changing the value of the INFUSION PERIOD (HR:MIN):

- Press the SELECT MODE key until "INFUSION PERIOD (HR:MIN)" appears on the display. The display shows the previous setting for the infusion period. In this example, an infusion period of 10 hours had been programmed. "STOP" appears at the bottom of the display to show that the pump is not running.

- Press the SCROLL keys to change the value of the infusion period. A beep will sound each time you press the SCROLL key.

- Press the SET/CLEAR key within 15 seconds to set the desired value for the infusion period.

NOTES:

(1) If you do not press the SET/CLEAR key within 15 seconds after releasing the SCROLL key, the pump will retain the previous setting for the infusion period.

(2) After pressing the SET/CLEAR key to enter the value for the infusion period, you can put the pump into the Start mode to begin delivery. If the pump is not put into the Start mode, the pump will remain in the Stop mode, and RES VOL will appear on the display (after 60 seconds). An alarm will beep every five minutes to indicate that the pump is in the Stop mode.

(3) The infusion period is limited by the values programmed for the infusion volume, taper-up period, and taper-down period. ***You may not be able to program the desired infusion period without changing the other values.*** *After changing the other values, and starting the pump, delivery will occur at the new rate.*

If you wish to change the infusion volume, you may also have to change the infusion period, since the new setting for the infusion volume may require a longer or shorter infusion period than the infusion period currently programmed. If that is the case, an alarm will sound, and the pump will display the minimum (or maximum) infusion period required to accommodate the infusion volume you have just programmed. You would then program a new infusion period, based on the new value shown on the display, or reset the infusion volume.

If you wish to program an infusion period that is **shorter** than the one currently programmed, and the pump's current values prevent you from setting the shorter period, you may follow either of these steps:

- Lower the infusion volume; or,

- Shorten the taper-up and taper-down values so that their sum plus 10 minutes is never more than the desired infusion period.

If you wish to program an infusion period that is **longer** than the one currently

programmed, and the pump's current values prevent you from setting the longer period, you may follow either of these steps:

- Increase the infusion volume; or,

- Lengthen the taper-up and/or taper-down values.

3.2.5 Setting and changing the taper-up period (HR:MIN)

The "**Taper-up Period** (**HR:MIN**)" is the total amount of time, at the beginning of an infusion period, when the infusion rate is gradually increased until it reaches the continuous rate. To program a taper-up period, you must program a value for the desired time. This period can last from 0 minutes to 99 hours and 40 minutes (0–99:40). Follow the steps below for setting or changing the value of the taper-up period:

- Press the SELECT MODE key until "**TAPER** ↑" appears on the display. The previous value for the taper-up period is shown on the display. In this example, a taper-up period of 1 hour and 30 minutes had been programmed. "STOP" will appear at the bottom of the display to show that the pump is not running.

TAPER ↑
PERIOD 0 1:30
HR:MIN
STOP

- Press the SCROLL keys to change the taper-up period. A beep will sound each time a SCROLL key is pressed.

- Press the SET/CLEAR key within 15 seconds to set the desired value for the taper-up period.

NOTES:

(1) If you do not press the SET/CLEAR key within 15 seconds after releasing the SCROLL key, the pump will retain the previous setting for the taper-up period.

(2) Set the taper-up period to "00:00" to operate the pump without a taper-up period.

(3) The pump limits the total tapering time, in either or both the taper-up and taper-down modes, to values which are at least 10 minutes less than the total time set for the infusion period.

(4) After pressing the SET/CLEAR key to enter the value for the taper-up

period, you can put the pump into the Start mode. If the pump is not put into the Start mode, the pump will remain in the Stop mode, and RES VOL will appear on the display (after 60 seconds). An alarm will beep every five minutes to indicate that the pump is in the Stop mode.

(5) The taper-up period is limited by the values programmed for the infusion volume and infusion period. You may not be able to program the desired taper-up period without reprogramming the other values. After reprogramming the other values, and starting the pump, delivery will occur at the new rate.

NOTE:

If the pump alarms while programming a new taper up, you have reached the pump's min or max rate. See Sections 4.4.3 and 4.4.4 for detailed information.

3.2.6 Setting and changing the taper-down period (HR:MIN)

The "**Taper-down Period (HR:MIN)**" is the total amount of time, at the end of an infusion period, when the infusion rate is gradually decreased. To program a taper-down period, you must program a value for the desired time. This period can last from 0 minutes to 99 hours and 40 minutes (0–99:40). Follow the steps below for setting or changing the value of the taper-down period:

- Press the SELECT MODE key until "**TAPER ↓**" appears on the display. The display shows the previous setting for the taper-down period. In this example, a taper-down period of 1 hour and 30 minutes had been programmed. "STOP" will appear at the bottom of the display to show that the pump is not running.

- Press the SCROLL keys to change the value of the taper-down period. A beep will sound each time a SCROLL key is pressed.

- Press the SET/CLEAR key within 15 seconds to set the desired value for the taper-down period.

NOTES:

(1) If you do not press the SET/CLEAR key within 15 seconds after releasing the SCROLL key, the pump will retain the previous setting for the taper-down period.

(2) Set the taper-down period to "00:00" to operate the pump without a taper-down period.

(3) After pressing the SET/CLEAR key to enter the value for the taper-down period, you can put the pump into the Start mode to deliver a solution. If the pump is not put into the Start mode, the pump will remain in the Stop mode, and RES VOL will appear on the display (after 60 seconds). An alarm will beep every five minutes to indicate that the pump is in the Stop mode.

(4) The taper-down period is limited by the values programmed for the infusion volume, infusion period, and the delivery rate. You may not be able to program the desired taper-down period without programming the other values. After programming the other values, and starting the pump, delivery will occur at the new rate.

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If the pump alarms while programming a new taper up, you have reached the pump's min or max rate. See Sections 4.4.3 and 4.4.4 for detailed information.

3.2.7 Viewing the continuous infusion rate (ML/HR)

If you wish to view the current rate of delivery (continuous infusion rate), you must do the following:

- Press the SELECT MODE key until ML/HR appears on the display. In this example, the display shows that the pump has a delivery rate of 222 milliliters.

The pump **automatically** calculates the continuous infusion rate in milliliters per hour. It is possible that the values you program for the infusion volume, taper-up period, and taper-down period will result in a delivery rate which is not within the limits of 10 ml/hr and 400 ml/hr. In that event, the pump will adjust one or more values to obtain a valid delivery rate. An alarm will sound, and each new value will appear on the display. Press the SET/CLEAR key to set that value or press the SCROLL keys to change the value; and then press the SET/CLEAR key to set the value. The next time you start the pump, delivery will occur at the new rate.

3.2.8 Resetting the volume delivered (ML GIVEN)

The **ML GIVEN** mode displays the total milliliters of solution delivered since the display was last cleared. The pump must be stopped to reset ML GIVEN. The ML GIVEN can be reset to 0 ml. Follow the steps below to review the ML GIVEN or to reset the ML GIVEN value to 0 ml:

- Press the SELECT MODE key until ML GIVEN appears on the display. In this example, the display shows a volume of 120 ml has been delivered by the pump.

- Press the SET/CLEAR key to clear the ML GIVEN value. A beep sounds to tell you this has happened, and the value "0000" will appear on the pump display. **You cannot clear the ML GIVEN in Lock Level 1 (LL1) or Lock Level 2 (LL2).**

NOTES:

(1) After pressing the SET/CLEAR key to reset the ML GIVEN value, you can put the pump into the Start mode to begin delivery. To place the pump in the Start mode, follow the steps in Section 3.7.3. If the pump is not put into the Start mode, the pump will remain in the Stop mode, and RES VOL will appear on the display (after 60 seconds). An alarm will beep every five minutes to indicate that the pump is in the Stop mode.

(2) The ML GIVEN counter functions in a way that is similar to your automobile's odometer. After the ML GIVEN counter reaches 9990, it will start at 0000 again and continue counting.

This completes the CADD-TPN® pump programming instructions. To verify that you have programmed the correct values for each programming function, press and release the SELECT MODE key to review each value.

3.3   Removing a used administration set

WARNING:

Always close the administration set tubing with the clamp before removing the CADD-TPN® Administration Set from the pump, or unregulated gravity infusion can result, which could result in death or serious injury to the patient.

You will need a coin to remove the administration set plate. To remove the administration set plate, follow these steps:

- Press and hold the STOP/START key to stop the pump if the pump is running.

- **Close the clamps on the administration set, infusion set, and/or indwelling catheter.**

- Disconnect the administration set from the infusion set or indwelling catheter.

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

- Insert a coin in the slot in the pump's locking button and turn it one-quarter turn **clockwise**. The locking button will pop out when you unlock the set plate.

- Disengage the set plate hooks from the pump's hinge pins. (See Figure 6.)

- Discard the used administration set.

Figure 6.   Disengage the administration set plate.
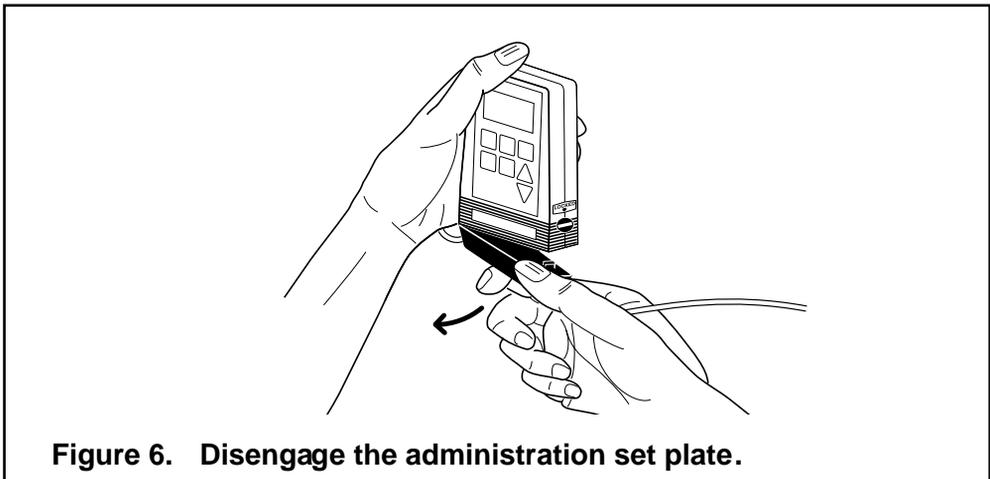
3.4   Preparing and attaching a new CADD-TPN® Administration Set

Before using the CADD-TPN® Administration Set, refer to the *Instructions for Use* supplied with the set for instructions, warnings, and cautions.

Priming must occur before you connect the set to the patient's infusion device or indwelling catheter. (See Section 3.5, this manual.)

To attach the administration set plate to the pump, follow these steps. You will need a coin to attach the administration set plate.

- Ensure that the pump is in the Stop mode.

- Ensure that the administration set tubing clamp is closed.

- Insert the hooks on the set plate into the hinge pins on the pump and place the pump with the set plate in an upright position on a firm, flat surface.

- Press downward on the pump to ensure that the set plate fits tightly against the bottom of the pump. Lock the set plate in place by inserting a coin in the slot in the pump's locking button, pushing the button in; and then turning the button one-quarter turn **counterclockwise** until a definite stop is felt. (See Figure 7.)
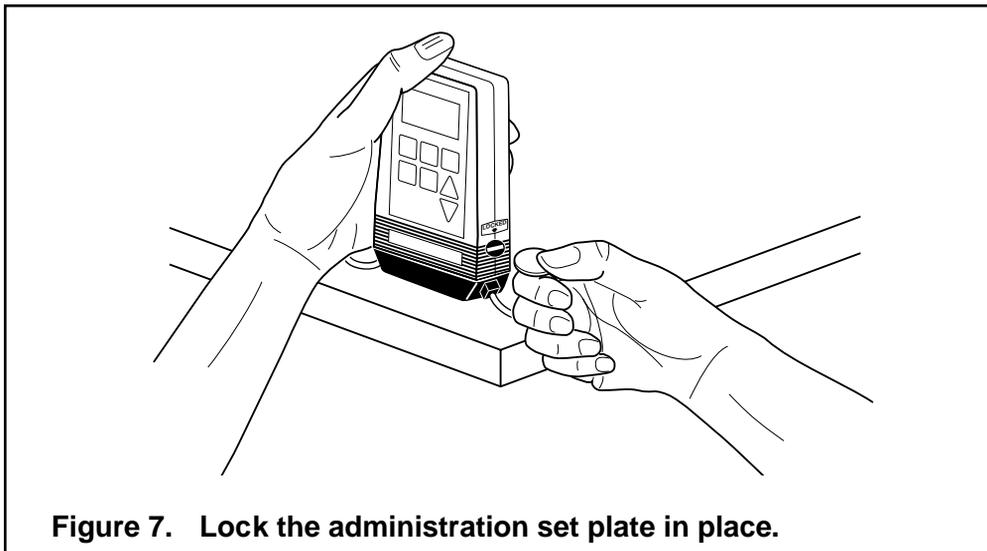
Figure 7.   Lock the administration set plate in place.

- Gently twist and pull on the set plate to make sure it is firmly attached.

WARNING:

It is essential that you attach the set plate properly. When you attach it properly, the slot of the locking button lines up with the arrow on the side of the pump. If you do not attach the set plate properly, an uncontrolled delivery of solution from the fluid container or a reflux of blood may result.

To protect against unregulated gravity infusion or reflux of blood that can result from an improperly attached set plate and could result in death or serious injury to the patient, the anti-siphon valve must be used.

LOCKED
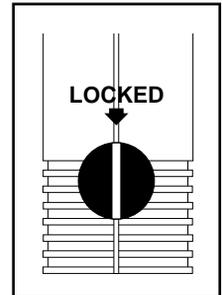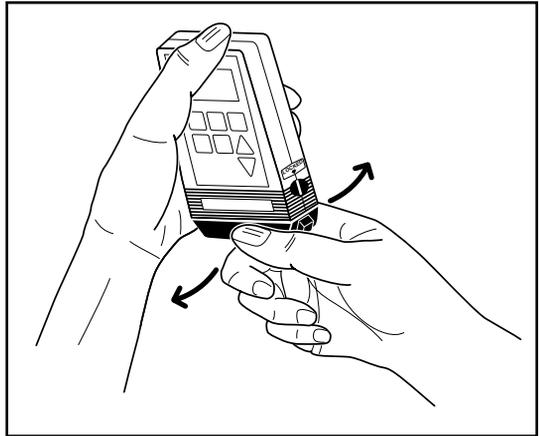
3.5 Priming the administration set and add on anti-siphon valve with the CADD-TPN® pump

Use the **PRIME** key to prime the set before connecting it to the patient. Be sure the pump is in the Stop mode and in either Lock Level 0 (LL0) or Lock Level 1 (LL1). You cannot prime the administration set in Lock Level 2 (LL2).

WARNING:

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

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

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

- 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.

PPP

NOTES:

(1) Each time you press and hold the PRIME key, you pump a maximum of 15 ml of solution. The pumping action will stop automatically when 15 ml have been delivered. If all of the air has not been removed from the tubing, repeat the above priming procedure.

*(2) Priming the administration set tubing subtracts the priming volume from RES VOL but **does not** affect the ML GIVEN amount, since the solution would not have actually entered the patient. Thus, the fluid container must contain more solution than you intend to infuse during the delivery cycle; and the programmed value for RES VOL must be large enough to finish the delivery and also account for the priming volume.*

WARNING:

Do not connect a fluid container that contains air bubbles to the tubing that leads to a patient. Ensure that the fluid path from the rib side of the filter to the end of the anti-siphon valve is free from all air. Air embolism can result in death or serious injury to the patient.

3.6 Selecting and programming the lock levels (LL0, LL1, and LL2)

The CADD-TPN® 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 limit or restrict access to the keyboard.**

- LL0 permits full programming of all aspects of pump operations.

- LL1 permits limited control of the pump.

- LL2 permits minimal control of the pump.

NOTES:

(1) You use the LOCK key to control the use of the keyboard. Do not confuse that procedure with "locking" the set plate onto the bottom of the pump.

*(2) **Before you can program** the CADD-TPN® pump, the pump must be in Lock Level 0 (LL0).*

When the pump is programmed to operate in Lock Level 0, any pump operating value can be changed.

Table 1 (next page) shows the pump operations that apply in each lock level.

Lock Level	Description
LL0	Use this lock level for programming any of the pump's functions. You can start and stop the pump; stop the RES VOL alarm; clear the value for the ML GIVEN; change or reset the value for RES VOL; prime the administration set, taper down immediately; and change lock levels.
LL1	Use this lock level to start and stop the pump; stop the RES VOL alarm; reset the value for RES VOL; prime the administration set; taper down immediately; change lock levels. You **cannot change** the value for RES VOL or clear the ML GIVEN.
LL2	Use this lock level to start and stop the pump; stop the RES VOL alarm; taper down immediately; and change lock levels. You **cannot change** the value for RES VOL or clear the ML GIVEN or prime the pump.
LL0, LL1, LL2	If the RES VOL value on the display is "0000", you may reset the RES VOL by pressing the STOP/START key. All lock levels permit starting and stopping of the pump; clearing the RES VOL alarm; tapering down immediately; and changing of the lock levels.

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

To change lock levels, follow these steps:

- Make sure that the pump is in the Stop mode. When the pump has stopped, the word "STOP" will flash on the lower right corner of the display. In this example, the display shows a RES VOL setting of 200 ml with the pump in the Stop mode.

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

- Press either SCROLL key until you find the desired lock level (either LL0, LL1, or LL2).

- Once you have selected the desired lock level, press the LOCK key again. The display will show "000".

- Press the up SCROLL key until the lock level code **** appears on the pump's display.

- Press the LOCK key again to complete the final step in the locking sequence. The previous display will reappear.

RES VOL
ML
0200 **STOP**

- Press the LOCK key again to verify that the pump has been set at the correct 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:

If you permit 15 seconds to lapse without continuing to press the LOCK key, the locking sequence will be cancelled, and the previous display will appear.

3.7 Operating the CADD-TPN® pump

3.7.1 Summary of programming and record-keeping displays

This section summarizes the displays and alarms that occur when using the CADD-TPN® pump.

The following values provide an example of a programming schedule with KVO delivery:

RES VOL:	2010 milliliters	
Infusion volume:	2000 milliliters	
Infusion period:	10:00 hours	
Taper-up period:	01:00 hour	
Taper-down period:	01:00 hour	

NOTE:

The infusion period includes the programmed times for the taper-up and taper-down periods.

If the above values are programmed, the following will occur:

- The reservoir-residual volume (RES VOL) is automatically displayed while the pump is delivering. In the example above, the display shows that the programmed reservoir-residual volume is 2010 ml.

- The pump will gradually increase its delivery for 1 hour, since a taper-up period has been programmed. The **TAPER** ↑ and **ML** indicators will blink on the display during taper-up delivery.

- After completing the taper-up period, delivery will reach a plateau of 222 ml/hr, and the pump will continue its delivery for 8 hours. **The ML**

indicator will blink during continuous delivery. If you decide to interrupt the delivery, in order to taper down immediately, see Section 3.7.4.

- The pump will **automatically** calculate a continuous delivery rate in milliliters per hour. Based on the program values above, the rate will be 222 ml/hr. To observe the value on the display, press the SELECT MODE key until ML/HR appears.

$$222 \quad \text{ML/HR} \atop \text{STOP}$$

- After 9 hours, the pump will gradually decrease its delivery for 1 hour, since a taper-down period had been programmed. The **TAPER ↓ and ML indicators will appear on the display, and both indicators** will blink during taper-down delivery. As the pump is tapering down, you will hear the RES VOL alarm beep when RES VOL reaches 50 ml; and again at 40 ml; 30 ml; 20 ml; and 10 ml.

- The pump will **automatically** calculate the total number of milliliters delivered (**ML GIVEN**). To observe this value on the display, press the SELECT MODE key until ML GIVEN appears. To clear the value, place the pump in the Stop mode and in LL0; and then press the SET/ CLEAR key. This example shows that 120 milliliters have been delivered.

$$0120 \quad {\text{ML/HR} \atop \text{GIVEN} \atop \text{STOP}}$$

- You will be able to review the milliliters given (ML GIVEN). To read the ML GIVEN value on the display, press the SELECT MODE key until ML GIVEN appears.

NOTE:

*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.*

3.7.2 Using the optional KVO (Keep Vein Open) mode

When the infusion period has been completed, you will hear 9 beeps, and, if applicable, the pump will enter the KVO mode (Keep Vein Open rate of 5 ml/hr). **The KVO delivery rate of 005 ml/hr will be displayed, and the ML indicator will blink.** You must make sure that the RES VOL value is larger than the infusion volume to permit infusion at the KVO rate. In the example above, if the pump was not used to prime the set (*NOTE:* when you gravity prime the set, you must prime the anti-siphon valve with the pump.) the KVO delivery will continue for approximately 2 hours, since the RES VOL setting was 2010 ml, and the infusion volume was 2000 ml. After 2 hours, the RES VOL alarm will signal that the fluid container is empty, and the pump will stop automatically.

CAUTION:

The rate of infusion automatically switches to the KVO rate of 5 ml/hr after the taper-down period is completed; and it continues until the pump enters the Stop mode or until RES VOL = 0000. If you stop the pump during the KVO delivery, see Section 3.7.5 for information on beginning a new infusion period. You <u>will</u> <u>not</u> be able to reset RES VOL until RES VOL = 0000 or OFF if in LL2.

3.7.3 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 will disappear one-by-one.

STEP 2: Release the STOP/START key after the last dash disappears, and the pump will beep; then the word "STOP" will disappear from the display, and all of the programmed modes will appear for your review one after the other. The pump will then be in the Start mode, and delivery will begin.

NOTE:
To make sure that the pump starts at the beginning of an infusion period, refer to Sections 3.7.5 and 3.7.6.

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

STEP 1: Press and hold the STOP/START key. Three dashes will appear one-by-one on the pump's display.
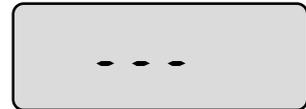
STEP 2: After the third dash appears, release the STOP/START key. The word "STOP" will blink on the display. In this example, the display shows a RES VOL value of 1000 ml.

NOTE:
If the pump is put into the Stop mode during the infusion period, the pump can be started again, and it will restart exactly where the delivery had been interrupted, even if the battery had been removed. If the pump is NOT put in the Stop mode, refer to the following caution:

CAUTION:
If the battery is removed during the infusion period WITHOUT stopping the pump, the precise start-up location will be lost. When the pump is restarted, the delivery of the infusion volume will be up to 10 ml less than had been programmed originally, or the infusion period will be up to 10 minutes less than originally programmed, whichever value is less.

3.7.4 Tapering down immediately

On occasion, it may be necessary for medical reasons to **taper down immediately,** interrupting the schedule for continuous delivery. You will not be able to taper down immediately if the pump is not in the process of delivering solution at the continuous rate; or, if you had not originally programmed a taper-down value. If you wish to taper-down immediately, you should follow these steps:

- Press and hold the STOP/START key to set the pump in the Stop mode.

- Press the SELECT MODE key repeatedly until the ML/HR display appears.

- Press the down SCROLL key. The "**TAPER ↓**" indicator will appear on the display.

NOTE:

*If you press the STOP/START key, LOCK key, PRIME key, SELECT MODE key, or up SCROLL key, while the "**TAPER ↓**" indicator is displayed, tapering down immediately will **not** occur, and the previous ML/HR display will appear.*

- Press the SET/CLEAR key within 15 seconds to initiate the function of tapering down immediately. **Once you press the SET/CLEAR key, you will not be able to return to the continuous rate without reprogramming the pump.**

- Press and hold the STOP/START key to set the pump in the Start mode. The preprogrammed, taper-down infusion rate will begin almost immediately, and the "**TAPER ↓**" and "**ML**" indicators will blink on the display.

3.7.5 Starting the daily infusion

At the beginning of every infusion period, follow these steps:

- Press and hold the STOP/START key to stop the pump if it is
  not stopped.

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

NOTE:
*The RES VOL display must read "0000"
or OFF if the pump is in LL2.*

- Press the SET/CLEAR key to reset the
  RES VOL value.

- Press the SELECT MODE key until INFUSION ML appears
  on the display.

- Press the SET/CLEAR key. **The value
  on the INFUSION ML display will
  not change. This step resets the
  infusion period.**

- Press the SELECT MODE key until ML GIVEN appears on the
  display.

- Press the SET/CLEAR key **in LL0** to reset the value for the ML GIVEN (if
  appropriate). You cannot clear the value for ML GIVEN in LL1.

NOTE:
*If you do not press the SET/CLEAR key within 60 seconds, the
pump **will** return to the RES VOL display.*

- Press and hold the STOP/START key to resume delivery.

3.7.6 Resuming delivery during the infusion period

If you stop the pump in LL0, LL1, or LL2 before the infusion period has been completed, and wish to resume delivery from where it had been interrupted, restart the pump.

• Press and hold the STOP/START key to resume delivery. The pump will continue the delivery from the point where it had been interrupted.

3.8   The External Power Source (EPS) system

Refer to the *External Power Source (EPS) System Instructions for Use* supplied with the product for instructions on equipment set-up and other operational instructions, including specifications and warnings, before using the EPS System with the *CADD-TPN® Ambulatory Infusion System*.

3.9   Using the backpack and storing the system

The backpack is designed for ambulatory use with the pump or for storage of the pump and accessories. The opened backpack with pockets and VELCRO® strips is illustrated below to show how it would be set up for use or storage. (See Figure 8.) Refer to the *Instructions for Use* supplied with the backpack for complete information on using the CADD-TPN® system with the backpack.

Administration set

Fluid container support straps

Fluid container

2700

2400

Filter

Tubing exit

Power pack

Pump

Set plate

Administration set

Tubing exit

AC adapter

Figure 8.   Using the backpack for ambulatory delivery.
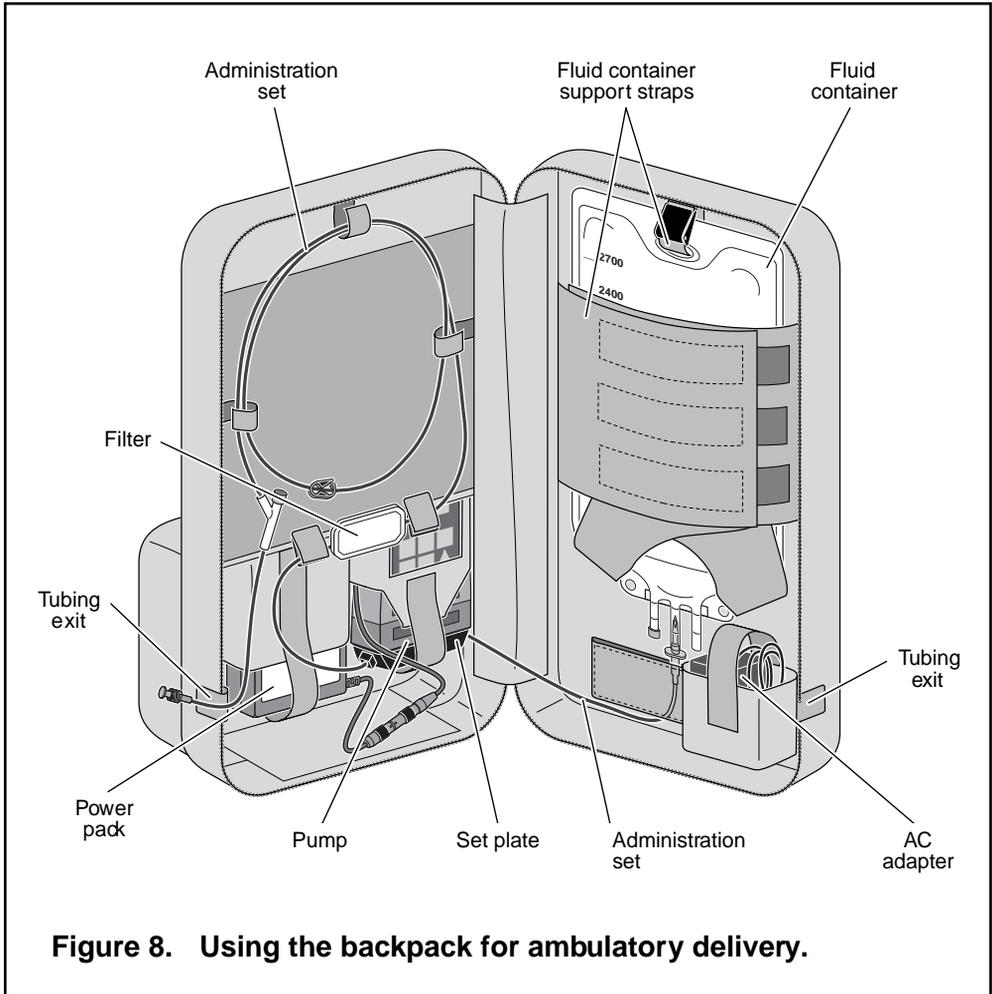
4.0 REFERENCE SECTION

4.1 Glossary

AC Adapter. The electronic device which plugs into an AC outlet to power the pump and to recharge the power pack.

CADD-TPN® Administration Set. An accessory that connects the fluid container to the patient's access device and/or infusion set, consisting of the following components: bag spike, set plate, filter, tubing, clamp, injection site, luer lock connector, add-on anti-siphon valve, and cap.

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

Continuous Rate Delivery. The nontapered portion of the delivery cycle.

Delivery Cycle. The period of time which includes all delivery phases: taper-up, continuous, taper-down, and KVO delivery.

Fluid Container. The reservoir that contains the solution to be delivered.

Fluid Path. The portion of the delivery system that consists of the fluid container, administration set, and access device.

HI P. These three letters appear on the pump's display, with a variable, two-tone alarm, to indicate that high pressure exists in the fluid path.

Infusion. The act of pumping a solution into the patient.

Infusion Period. The prescribed time during which the solution is infused into the patient. This period also includes the time in which continuous delivery and tapering occur but does not include the KVO delivery period.

Infusion Volume. The prescribed volume of solution to be delivered to the patient during the infusion period.

KVO (KEEP VEIN OPEN) Infusion Rate. After the prescribed infusion volume has been delivered, pumping will automatically continue at the KVO infusion rate of 5 ml/hour until RES VOL reaches 0, or the pump stops.

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

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

Lock Level. This term refers to a keyboard LOCK key setting that restricts changes in the pump's operation.

Luer Lock Connector. The fitting which connects the patient's access device and/ or infusion set to the administration set.

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Microprocessor. The electronic device that controls the pump.

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

Power Pack. A device that contains rechargeable batteries. After the power pack is charged by the AC adapter, it can be used to power the pump. The power pack has its own LO BAT alarm.

PRIME Key. This key allows you to pump a small volume of solution (up to 15 ml) through the fluid path to purge air bubbles from the administration set and tubing. The priming procedure occurs before you connect the tubing to the patient's access device.

Pump Resolution. This term refers to the smallest volume of solution that the pump delivers with each pumping operation.

Reservoir-Residual Volume. See RES VOL.

RES VOL. The term refers to the volume of solution (in milliliters) that was initially programmed, or which remains in the fluid container.

Scroll Keys. Two triangular shaped keys which are used to increase or decrease the numeric value of any pump operating value. These values are shown on the display.

Set Plate. The portion of the administration set that attaches to the pump and contains the pumping chamber. The action of the pump on the tubing in the set plate establishes the actual pumping of solution.

Tapering. This term refers to a gradual increase in the infusion rate at the beginning of the infusion period and/or a gradual decrease in the infusion rate at the end of the infusion period.

Taper-up Period. The initial phase of the infusion period when a solution is delivered at an increasing infusion rate. The pump provides an increasing rate during the taper-up period, by gradually increasing the delivery in the first 10 minutes or more of the infusion period.

Taper-down Period. The final phase of the infusion period when a solution is delivered at a decreasing infusion rate. The pump provides a decreasing rate during the taper-down period, by gradually decreasing delivery in the last 10 minutes or more of the infusion period until the KVO rate is reached or the pump stops.

TPN (Total Parenteral Nutrition). This term refers to the intravenous delivery of nutrient solutions that help meet the patient's need for balanced nutrition.

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-TPN® Model 5700 infusion pump is not affected by exposure to **diagnostic** levels of radiographic and fluoroscopic radiation.

CAUTIONS:
- *(1) 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.*
- *(2) 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 a safe distance away from magnetic energy.*

Reference

4.4 Alarms and troubleshooting chart

The CADD-TPN® pump (Model 5700) has a number of alarms to alert you about conditions that require corrective action.

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

Table 2.   Alarms and troubleshooting chart.

Alarm	Condition	Corrective Action
1 beep sounds when RES VOL reaches 50 ml; with each subsequent 10-ml decrease in RES VOL, RES VOL value and ML indicator blink on the display, and a short beep or additional beeps sound. Refer to Section 4.4.1.	The ML remaining value is at or below 50 ml.	Prepare to discontinue therapy; or, use another fluid container if the infusion has not been completed.
2 beeps sound each second; STOP blinks on the display.	The ML value (RES VOL) is at "0000".	• Press any key. This will silence the alarm and reset the reservoir volume. • Remove the used fluid container and install a new (filled) one, if necessary.
3 beeps sound every 5 minutes; LO BAT blinks on display.	The 9-volt battery power is low, but the pump is operable.	Change the 9-volt battery soon.
A continuous, variable tone alarm sounds, and LO BAT remains on the display but does not blink.	The 9-volt battery power is too low to operate the pump; the pump operation stops.	• Change the battery immediately. • Use a new, 9-volt battery; or, refer to Section 3.8 for other power source options. • Press the STOP/START key to resume operations.

Reference

Table 2—*continued.*

Alarm	Condition	Corrective Action
The power pack emits 1 beep every 2 seconds.	LO BAT alarm indicates that the power pack will soon be unable to support pump operation.	• Begin recharging the power pack with the AC adapter; or, • Use a new, 9-volt battery and continue operations; or, refer to Section 3.8 for other power source options.
A continuous, variable-tone alarm sounds, and BAT remains on the display but does not blink; and the power pack emits 1 beep every 2 seconds.	The battery power in the power pack is too low to operate the pump; the pump operation stops.	• Begin recharging the power pack with the AC adapter; or, • Use a new, 9-volt battery and continue operations; or, refer to Section 3.8 for other power source options. • Press the STOP/START key to resume operations.
A continuous, variable-tone alarm sounds. "HI P" appears on the display. Pump delivery stops. Refer to Section 4.4.2.	A high pressure alarm might result from a blockage or kink in the fluid path between the pump and the tip of the access device; or, a tubing clamp might be closed.	• 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. • Press the STOP/START key to resume operations, if necessary.
A continuous, variable-tone alarm sounds. The letter E and two numbers appear on the display. If the battery was removed and reinserted after this alarm occurred, "OFF" will appear on the RES VOL display. (See Note 2 following this table.)	A controller, microprocessor, or motor fault has occurred. The pump operation stops.	• Close the tubing with the clamp. • Remove the pump from service and have it repaired. Call Customer Service: **800-426-2448**.
All indicators appear on the display; a continuous, variable-tone alarm sounds.	A power-up fault has occurred.	• Remove and reinsert the battery; or, • Insert a new 9-volt battery; or, refer to Section 3.8 for other power source options; or, if conditions still exist, • Call Customer Service: **800-426-2448**.

Reference

Table 2—*continued.*

Alarm	Condition	Corrective Action
A series of 9 beeps sound in succession.	The end of the infusion period has been reached. The pump switches to the KVO rate of 5 ml/hr.	Corrective action is **not** necessary.
3 beeps sound every five minutes.	The pump is in the Stop mode.	Start the pump or remove the power source, if appropriate.
A two-tone alarm sounds to signal that the programmed rate of delivery is too high. Refer to Section 4.4.3, the Rate too-High alarm.	A new, larger infusion volume was programmed; or, a new, longer taper-up period was programmed; or, a new longer taper-down period was programmed.	• Press the SCROLL key to select a new value for the **longer** infusion period. • Press the SET/CLEAR key to set the value for the new infusion period, and the alarm will stop.
A two-tone alarm sounds to signal that the programmed rate of delivery is too low. Refer to Section 4.4.4, the Rate too-Low alarm.	A new, smaller infusion volume was programmed; or, a new, shorter taper-up period was programmed; or, a new shorter taper-down period was programmed.	• Press the SCROLL key to select a new value for the **shorter** infusion period. • Press the SET/CLEAR key to set the value for the new infusion period, and the alarm will stop.
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 if 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 operation. All pumping action ceases, and the microprocessor automatically resets the mode settings to these default values: infusion volume = 10 ml, infusion period = 1 hour, taper-up period = 0, taper-down period = 0, RES VOL = OFF; and Lock Level 0 or Lock Level 1 reverts to Lock Level 2. Use the tubing clamp to close the administration set tubing, stop the pump, and call Customer Service: 800-426-2448.*

4.4.1 The reservoir-residual volume (RES VOL) alarm

If the pump is running, the RES VOL value will decrease as the pump delivers the solution. When the computer's calculated reservoir-residual volume is reduced to 50 ml, there will be an audible alarm (1 beep). At that point, the displayed RES VOL numbers will blink about every two seconds. With each subsequent 10-ml decrease in RES VOL, a single beep or additional beeps will sound, and the RES VOL value will continue to blink on the display. When the RES VOL value of "0000" ml is displayed, all pumping action will cease, and the pump will automatically enter the Stop mode. You will then hear two short beeps every second until you shut off the alarm. When you press any key, the alarm will be shut off, and the volume setting will automatically reset to the value programmed. In addition, you may also program the RES VOL value to read "0000". Thereafter, when RES VOL is displayed, "OFF" will appear on the display, and the RES VOL alarm will not sound. (See Sections 3.2.2 and 3.7.5.)

4.4.2 The high pressure (HI P) alarm

You will hear a continuous, variable-tone alarm if the delivery pressure in the fluid path becomes excessively high. The letters "**HI P**" will appear on the display. The high pressure alarm is activated by 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 cancel 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 2 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.

4.4.3 The rate-too-high alarm

After programming the pump, the pump will automatically calculate the continuous delivery rate. If that rate is greater than 400 ml/hr, the "Rate-too-High" alarm (a two-tone alarm) will sound to remind you that the values you programmed exceeded the pump's maximum limit for continuous delivery. The pump will display an acceptable time (infusion period) for delivery at the maximum rate.

When the above display appears, you will have these two options:

• Press the SET/CLEAR key to accept the new value for the infusion period. **Or,**

• Press the SCROLL keys to select an acceptable value for the infusion period, other than the one displayed, and then press the SET/CLEAR key.

Either of the above actions will cancel the alarm.

If you wish to review the programmed values, press and release the SELECT MODE key. Each value will appear on the display in succession.

4.4.4 The rate-too-low alarm

After programming the pump, the pump will automatically calculate the continuous delivery rate. If that rate is lower than 10 ml/hr, the "Rate-too-Low" alarm (a two-tone alarm) will sound to remind you that the values you programmed exceeded the pump's minimum limit for continuous delivery. The pump will display an acceptable time (infusion period) for delivery at the minimum rate.

When the above display appears, you will have these two options:

- Press the SET/CLEAR key to accept the new value for the infusion period. **Or,**

- Press the SCROLL keys to select an acceptable value for the infusion period, other than the one displayed, and then press the SET/CLEAR key.

Either of the above actions will cancel the alarm.

If you wish to review the programmed values, press and release the SELECT MODE key. Each value will appear on the display in succession.

4.5   Specifications (nominal)

4.5.1   Programming specifications

Reservoir-residual
volume[1] .... 0–9990 ml, in 10-ml increments. When the pump is programmed to zero, "OFF" will appear on the display.

Infusion volume .... 10–9990 ml, in 10-ml increments.

Infusion period .... 10 minutes to 99 hours and 50 minutes (99:50), in 10-minute increments.[2] The pump will control variations in the programming schedule to maintain the continuous rate (within the range of 10–400 ml/hr).

Taper-up period .... 0–99 hours and 40 minutes (99:40), in 10-minute increments.[2,3]

Taper-down period .... 0–99 hours and 40 minutes (99:40), in 10-minute increments.[2,3]

Continuous
infusion rate .... 10–250 ml/hr with a 9-volt battery; 10–400 ml/hr with the power pack, or power pack and AC adapter; the rate is established by the programmed values of infusion volume, infusion period, and tapering (if any).

Delivered infusion
volume (ML GIVEN) ...... 0–9990 ml, in 10-ml increments.

Optional KVO
infusion rate .... 5 ml/hr, after the programmed infusion volume has been delivered, and before the pump enters the Stop mode. It is a predefined rate.

Footnotes:

1   This value represents the remaining fluid container volume, which is also the starting fluid container value when infusion begins.
2   The infusion period includes the time required for any tapering. See Section 3.2.4 for additional information on programming the infusion period.
3   The duration of all tapering periods must be at least 10 minutes less than the total infusion period.

Reference

4.5.2 General pump specifications

Resolution . . . . 250 microliters per pump stroke (nominal).

Size . . . . 2.79 cm × 8.89 cm × 13.34 cm (1.1 in × 3.5 in × 5.25 in) including the set plate.

Weight . . . . 368.5 g (13 oz.) including 9-volt battery.

Pump alarms . . . . Low battery power; pump in Stop mode; internal controller, microprocessor, or pump motor fault; improper delivery; power-up fault; low fluid container volume; high delivery pressure (22 ± 12 psi).

Bolus volume at occlusion
alarm pressure . . . . < 2.0 ml.

Power sources . . . . 9-volt alkaline or lithium battery, or the External Power Source (EPS) System.

DURACELL® MN1604 or EVEREADY® ENER-GIZER® #522, 9-volt alkaline batteries can provide power for approximately 6 hours of infusion at a rate of 250 ml/hr. Longer periods of operation can be expected at lower infusion rates.

ULTRALIFE® Lithium U9VL batteries can provide power for approximately 18 hours of infusion, at a rate of 250 ml/hr. Longer periods of pump operation can be expected at lower infusion rates.

The External Power Source (EPS) System's power pack can provide power for approximately 18 hours of infusion at a rate of 250 ml/hr, or approximately 11 hours at 400 ml/hr. Longer periods of pump operation can be expected at lower infusion rates. The power pack can be used to power the pump while it is being charged by the AC adapter. **At rates above 250 ml/hr, the power pack *must* be used.**

Reference

System operating temperature .... +2°C to 40°C (35°F to 104°F).

System storage temperature .... -30°C to 50°C (-22°F to 122°F).

Power pack charging temperature .... +10°C to 35°C (50°F to 95°F).

Pump timing accuracy .... ± 0.1%.

System delivery accuracy .... ± 8% (nominal).

System Definition .... System is defined as a CADD-TPN® pump with an attached CADD-TPN® Administration Set with Add-On Anti-Siphon valve.

4.6   Limited warranty

SIMS Deltec, Inc. (the "Manufacturer") warrants to the Original Purchaser that the infusion pump (the "Pump"), not including accessories, shall be free from defects in materials and workmanship under normal use, if used in accordance with this Operator's Manual, for a period of one year from the actual date of sale to the Original Purchaser. THERE ARE NO OTHER WARRANTIES.

This warranty does not cover normal wear and tear and maintenance items, and specifically excludes batteries, administration sets, extension sets or any other accessory items or equipment used with the Pump.

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 Pump (not including accessories) which is defective if a claim is made 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 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 proof as to the actual date of purchase.

B.   Warranty Performance Procedure: Notice of the claimed defect must be made in writing or by telephone to the Manufacturer as follows: Customer Service Department, SIMS Deltec, Inc., 1265 Grey Fox Road, St. Paul, MN 55112, (800) 426-2448. Notice to the Manufacturer must include date of purchase, model and serial number, and a description of the claimed defect in sufficient detail to allow the Manufacturer to determine and facilitate any repairs which may be necessary. **AUTHORIZATION MUST BE OBTAINED PRIOR TO RETURNING THE PUMP.** If authorized, the Pump must be properly and carefully packaged and returned to the Manufacturer, postage prepaid. Any loss or damage during shipment is at the risk of the sender.

C.   Conditions of Warranty: The warranty is void if the Pump has been 1) repaired by someone other than the Manufacturer 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 not in compliance with the Operator's Manual or use with nonapproved 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 Pump's serial number will invalidate this warranty.

D.   Limitations and Exclusions: Repair or replacement of the Pump or any component part thereof 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.

2. **THERE IS NO WARRANTY OF MERCHANTABILITY OR FITNESS OR USE OF THE PUMP FOR ANY PARTICULAR PURPOSE.**

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

4. 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 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 PUMP FOR ANY PARTICULAR MEDICAL TREATMENT OR FOR ANY MEDICAL COMPLICATIONS RESULTING FROM THE USE OF THE 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 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

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TPN

*Use CADD® pump
accessories carrying
this symbol*