

OPERATOR'S
MANUAL

CADD Prizm[®] VIP

Model 6100 and 6101

Ambulatory

Infusion

Pump



This manual concerns **only** the CADD-Prizm® VIP (Variable Infusion Profile) Model 6100 and Model 6101 ambulatory infusion pumps. The pump has the following delivery modes:

PCA	PCA 6210 (all revision letters)
Continuous	CONTIN 6220 (all revision letters)
TPN	TPN 6230 (all revision letters)
Intermittent	INTERMT 6240 (all revision letters)

This manual is intended for clinician use only. Do not permit patients to have access to this manual. The pump has three security levels designed to limit patient access. Do not disclose the pump's security codes or any other information that would allow inappropriate access to programming and operating functions.

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 Smiths Medical MD, Inc. to see if a later revision of this manual is available.

Technical Assistance

If you have comments or questions concerning the operation of the CADD-Prizm® pump, please call the number given below. When calling, please specify the pump's software module. This information is located in the pump's start-up screen.

Our staff at Smiths Medical MD is available to help clinicians twenty-four hours a day with the programming and operation of the CADD-Prizm® infusion system.

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

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

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 a pump for service.
- 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 required to move the syringe plunger. A syringe plunger will lose 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 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.

- 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 administer drugs to the epidural space or subarachnoid space unless the drug is indicated for those spaces.
- To prevent the infusion of drugs that are not indicated for epidural space or subarachnoid space infusion, DO NOT use administration sets that incorporate injection sites.
- If a Medication Cassette Reservoir, CADD™ Extension Set or CADD™ Administration Set is used for epidural space or subarachnoid space drug delivery, it is strongly recommended that it be clearly differentiated from those used for other routes of infusion, for example, by color coding, or other means of identification.
- When the Air Detector is not installed, or is installed but turned off, the pump will not detect air in the fluid path. It is recommended that you periodically inspect the fluid path and remove any air to prevent air embolism.
- Follow the Instructions for Use provided with the Medication Cassette Reservoir and CADD™ Extension Set, or the CADD™ Administration Set, paying particular attention to all warnings and cautions associated with their use.
- When the Upstream Occlusion Sensor is turned Off, the pump will not detect occlusions upstream (between pump and fluid container). It is recommended that you periodically inspect the fluid path for kinks, a closed clamp, or other upstream obstructions. Upstream occlusions may result in under- or non-delivery of medications.
- Do not disclose to the patient the pump's security codes or any other information that would allow the patient complete access to all programming and operating functions.
- Ensure that the $\pm 6\%$ System Delivery Accuracy specification is taken into account when programming the pump and/or filling the Medication Cassette Reservoir. Failure to do so may result in medication in the reservoir becoming depleted sooner than expected.
- 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.
- Always have new batteries available for replacement. If power is lost, non-delivery of drug will occur.

- There is no pump alarm to alert users that a battery has not been properly installed or has become dislodged. An improperly installed or dislodged battery could result in loss of power and non-delivery of drug.
- If the pump is dropped or hit, the battery door may become broken or damaged. Do not use the pump if the battery door is damaged because the battery will not be properly secured; this may result in loss of power or non-delivery of drug.
- When you enter a new Demand Dose Lockout time, any lockout time in effect will be cleared. A Demand Dose could be requested and delivered immediately upon starting the pump, resulting in over-delivery.
- When you enter a new Max Doses per Hour value, any lockout time in effect will be cleared. A Demand Dose could be requested and delivered immediately upon starting the pump, resulting in over-delivery.
- Exercise care when using the Clinician Bolus function. Since there are no limits on the frequency of delivering a bolus, and since the amount of the bolus can be set as high as 20 ml (or the mg or mcg equivalent), you should not permit the patient to become familiar with the procedure for giving a Clinician Bolus.
- To prevent the patient from accessing the Clinician Bolus function, do not let the patient know the Clinician Bolus code.
- Always close the fluid path tubing with the clamp before removing the cassette from the pump to prevent unregulated gravity infusion.
- Attach the cassette properly. A detached or improperly attached cassette could result in unregulated gravity infusion of medication from the fluid container or a reflux of blood.

If you are using a Deltec administration set medication cassette reservoir that does not have the flow stop feature (reorder number does not start with 21-73xx): you must use a CADD™ Extension Set with anti-siphon valve or a CADD™ Administration Set with either an integral or add-on anti-siphon valve to protect against unregulated gravity infusion that can result from an improperly attached cassette.

- Do not prime the fluid path with the tubing connected to a patient as this - could result in over-delivery of medication or air embolism.
- Ensure that the entire fluid path is free of all air bubbles before connecting to the patient to prevent air embolism.

- If Demand Doses are currently locked out, changing the Date and/or Time will cancel the lockout period. This will allow a Demand Dose to be requested and delivered as soon as you restart the pump, resulting in over-delivery.

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 -20°C (-4°F) or above 60°C (140°F). Do not store the pump with a Medication Cassette Reservoir or CADD™ Administration Set attached.
- Do not expose the pump to humidity levels below 10% or above 90% relative humidity.
- Do not store the pump for prolonged periods with the battery installed. Battery leakage could damage the pump.
- If you are using a Medication Cassette Reservoir in which the medication is frozen, thaw at room temperature only. *Do not heat in a microwave oven* as this may damage the product and cause leakage.
- 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, Data In/Out jack, Power jack or Air Detector port area. Moisture build-up inside the pump may damage the pump.
- Do not clean the pump with acetone, other plastic solvents, or abrasive cleaners, as damage to the pump may occur.
- Do not expose the pump to therapeutic levels of ionizing radiation as permanent damage to the pump's electronic circuitry may occur. 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.
- Do not expose the pump directly to ultrasound, as permanent damage to the pump's electronic circuitry may occur.
- Do not use the pump in the vicinity of magnetic resonance imaging (MRI) equipment as magnetic fields 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.

- Do not use the pump near ECG equipment as the pump may interfere with the operation of the equipment. Monitor ECG equipment carefully when using this pump.
- Do not sterilize the pump.
- Do not use the pump in the presence of flammable anesthetics or explosive gases.
- Use only Smiths Medical MD 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.

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Section 1: General Description and Basic Operations

Introduction

The CADD-Prizm® ambulatory infusion pump provides measured drug therapy to patients in hospital or outpatient settings. Therapy should always be overseen by a physician or a certified, licensed healthcare professional. As appropriate, the patient should be instructed in using the pump.

Indications

The CADD-Prizm® pump is indicated for intravenous, intra-arterial, subcutaneous, intraperitoneal, epidural space, or subarachnoid space infusion.

PCA (Patient-Controlled Analgesia) delivery is used for therapies that require a continuous rate of infusion, patient-controlled demand doses, or both, such as patient-controlled analgesia.

Continuous delivery allows the infusion of drug at a constant, programmed rate.

TPN (Total Parenteral Nutrition) delivery allows the infusion of nutritional solutions or other fluids, with optional tapering at the beginning and end of infusion.

Intermittent delivery allows the infusion of a specific volume of drug at a regular, programmed interval.

Epidural/Subarachnoid Administration

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

Analgesics

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

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

Anesthetics

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

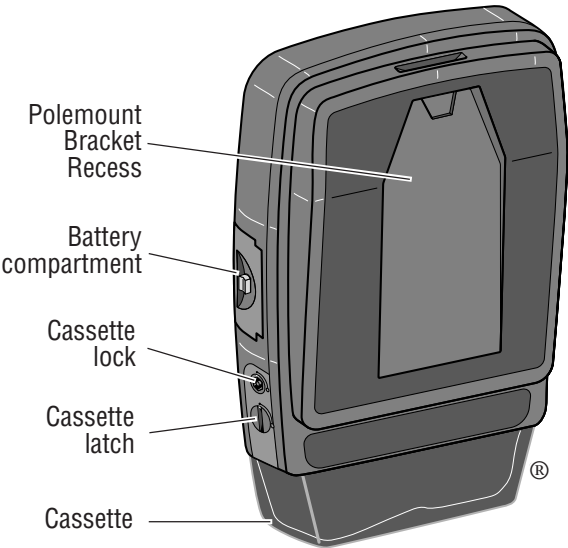
WARNING:

- Do not administer drugs to the epidural space or subarachnoid space unless the drug is indicated for administration to those spaces. Drugs not intended for epidural or subarachnoid space infusion could result in death or serious injury to the patient.
 - To prevent the infusion of drugs that are not indicated for epidural space or subarachnoid space infusion, DO NOT use administration sets that incorporate injection sites. The inadvertent use of injection sites for infusion of such drugs may cause death or serious injury to the patient.
 - If a Medication Cassette Reservoir, CADD™ Extension Set or CADD™ Administration Set is used for epidural space or subarachnoid space drug delivery, it is strongly recommended that it be clearly differentiated from those used for other routes of infusion, for example, by color coding, or other means of identification. Drugs not intended for epidural or subarachnoid space infusion could result in death or serious injury to the patient.
-

Pump Diagram



Front View



Rear View

Description of Keys, Display and Features

Indicator Lights

Green: The green light blinks approximately every 3 seconds when the pump is running and delivering fluid as programmed.

Amber: The amber light flashes when the pump is stopped or an alarm condition exists. It stays on continuously when the pump is inoperable. The display briefly describes the condition.

If both lights blink, delivery is still occurring but a condition exists of which you should be aware (for example, a low battery). Look at the display for a brief description of the condition.

Display with backlighting

The liquid crystal display (LCD) shows programming information and messages. Backlighting helps keep the display visible in low light.

After a period of no key presses, backlighting turns off and the display blanks to save battery power (except during an alarm or when an external power source is in use). Press any key to turn the display back on.

NOTE: If you press , the display will reappear with a message asking if you wish to start or stop the pump; press  or . Do not use  to turn the display back on; this may deliver an inadvertent dose.

Keypad

The keys on the keypad are described below. A key beeps when pressed if it is operable in the current lock level.

-  starts and stops pump delivery.
-  is used to view or change the pump's current lock level. Lock levels are used to limit patient access to certain programming and operating functions. (See Lock Levels, this section.) This key is also used to access the Clinician Bolus in the PCA delivery mode.
-  is the "Help" key. It is used to display help for a screen or an alarm message. (See Getting Help, this section.)
-  is used to enter, or save, a new value in the pump's memory when programming new pump settings. It is also used to select an item from the Options Menu (Section 4) or Biomed Toolbox Menu (Section 5).

NEXT

is used to move from one programming screen to the next without changing the setting or value displayed. It is also used to return from the Biomed Toolbox Menu to the Options Menu, or from the Options Menu to the main screen. (See Sections 4 and 5.)



is used only in the PCA delivery mode. It allows the patient to deliver a programmed amount of medication upon request.



is used to access the Options Menu, which contains such features as time, date, and the Event Log. (See Section 4, Options.)



allows you to answer “yes” to a question on the pump’s display, “scroll up” or increase a value (for example, a dose amount), or scroll through items on a menu.



allows you to answer “no” to a question on the pump’s display, “scroll down” or decrease a value, scroll through items on a menu, or cancel printing.

Power jack

You may plug a CADD™ External Power Source (EPS) System Power Pack or an AC Adapter into the Power jack as an alternate source of power.

Data In/Out jack

The Data In/Out jack is used for attaching the following accessories:

- **Interface Cable** for printing reports
- **Remote Dose Cord** for remote operation of the dose key
- **Modem cable** for communications

For more information on the Remote Dose Cord, printing or communications, see the instructions for use provided with those products.

Air Detector Port Cover

This encloses the Air Detector port when the Air Detector is not attached.

Air Detector accessory (optional)

The Air Detector attaches to the pump in the area shown in the diagram. If air is detected in the part of the tubing that passes through the Air Detector, an alarm sounds and delivery stops. (See Section 6 for Air Detector specifications.) The pump may be customized to require an Air Detector. (See Section 5, Biomed Toolbox.) If an Air Detector is attached but not required, it may be turned off.

WARNING: When the Air Detector is not installed, or is installed but turned off, the pump will not detect air in the fluid path. It is recommended that you periodically inspect the fluid path and remove any air to prevent air embolism. Air embolism could result in death or serious injury to the patient.

Cassette

The cassette is the portion of the Medication Cassette Reservoir or CADD™ Administration Set that attaches to the bottom of the pump. The following single use products are compatible with the CADD-Prizm® pump:

- Medication Cassette Reservoir (50 or 100 ml), used with a CADD™ Extension Set
 - CADD™ Administration Set
 - CADD-Prizm™ High Volume Administration Set, for rates up to 350 ml/hr (not for use in PCA mode)
-

WARNING: Follow the Instructions for Use provided with the Medication Cassette Reservoir and CADD™ Extension Set, or the CADD™ Administration Set, paying particular attention to all warnings and cautions associated with their use. Incorrect preparation and/or use of these products could result in serious patient injury or death.

Polemount Bracket recess

The optional Polemount Bracket slides into the recess on the back of the pump, allowing you to attach the pump to an IV pole.

Battery compartment

The 9 volt battery fits into this compartment. The 9 volt battery serves as the primary source of power, or as a backup when an EPS System power pack or AC Adapter is in use.

Cassette latch

This attaches the cassette (the part of the Medication Cassette Reservoir or CADD™ Administration Set that attaches to the pump) to the pump. The pump detects whether the cassette is latched properly. Delivery will stop and an alarm will occur if the cassette becomes unlatched.

Cassette lock

This allows you to secure the cassette to the pump using the key provided. The cassette *must* be latched before it can be locked. In the PCA delivery mode, the cassette *must* be locked onto the pump or the pump will not run.

Downstream Occlusion Sensor (Not Shown)

The pump contains a downstream occlusion sensor. When a downstream occlusion (between pump and patient) is detected, an alarm will sound, delivery will stop, and the display will show “High Pressure.”

Upstream Occlusion Sensor (Model 6101 only; Not Shown)

The pump contains an upstream occlusion sensor. This feature may be turned on or off (see Section 5, Biomed Toolbox). When the sensor is turned on, and an upstream occlusion (between pump and fluid container) is detected, an alarm will sound, delivery will stop, and the display will show “Upstream Occlusion.”

WARNING: When the Upstream Occlusion Sensor is turned off, the pump will not detect occlusions upstream (between pump and fluid container). It is recommended that you periodically inspect the fluid path for kinks, a closed clamp, or other upstream obstructions. Upstream obstructions may result in under- or non-delivery of medications to the patient. If undetected, these occlusions could lead to death or serious injury to the patient.

Reservoir Volume Alarm (Not Shown)

Reservoir Volume is a feature that indicates when the fluid in the fluid container is low or depleted. Each time you change the fluid container, you may reset the Reservoir Volume to the originally programmed volume. Then, as medication is delivered, the Reservoir Volume automatically decreases.

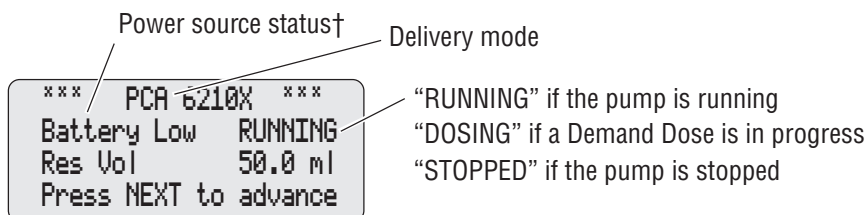
Medication Cassette Reservoir or CADD™ Administration Set: When the pump calculates that 5 ml remain in the fluid container and a “Reservoir Volume Low” message appears. This alarm recurs at every subsequent decrease of 1 ml until the Reservoir Volume reaches 0 ml, at which point the pump stops.

CADD-Prizm™ High Volume Administration Set: When the pump calculates that 25 ml remain in the fluid container, beeps sound and “Reservoir Volume Low” appears. This alarm recurs at every subsequent decrease of 5 ml until the Reservoir Volume reaches 0 ml, at which point the pump stops.

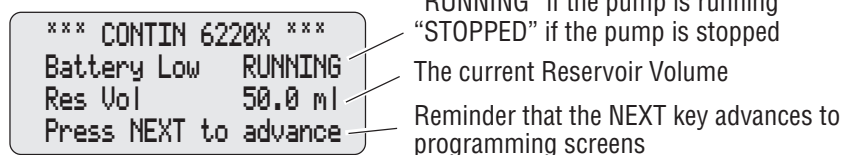
The Main Screen

The main screen is the starting point for programming or viewing the pump's settings. If no keys are pressed, the display will eventually revert to the main screen. The main screen within each delivery mode displays information about the delivery status, as shown below.

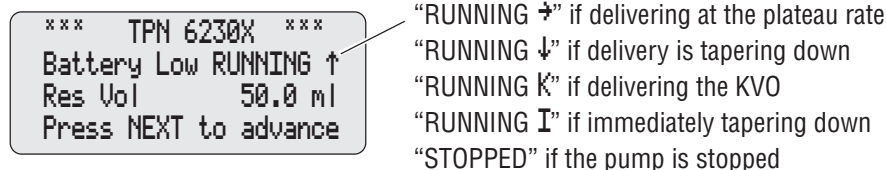
PCA Delivery Mode



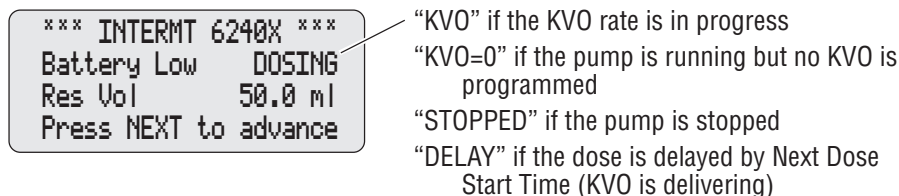
Continuous Delivery Mode



TPN Delivery Mode



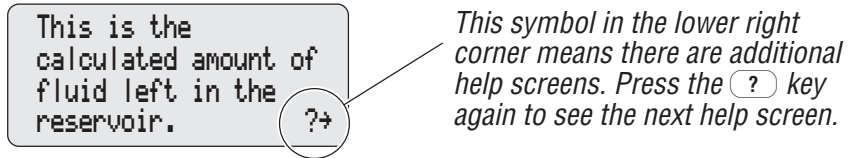
Intermittent Delivery Mode



† The Power Source Status will only display when the 9 volt battery is low, unless the pump has been customized to *always* show the type of power source in use. (See Biomed Toolbox, Section 5.)

Getting Help Using the Key

For more information about a screen or message on the pump's display, press the  key to view help screens. Help screens describe what you see on the display. They may also explain why a screen or message appeared and what to do next.



- To page through all the help screens, press  repeatedly. The original screen will reappear when no further help is available.
- To exit help, press any key (other than the  key). This will bring you back to the original screen.
- If a help screen tells you to press a certain key, first exit help, then press that key.

Help screens are lock level dependent. If the pump's current lock level prevents access to a certain function, the function will not be described in the help screens.

Lock Levels

Lock levels are used to limit patient access to certain programming and operating functions. The table on the next page lists the functions that are accessible in Lock Level 0 (LL0), Lock Level 1 (LL1), and Lock Level 2 (LL2). When a function is accessible, the key associated with the function beeps when pressed. If a function is not accessible, the pump ignores the key press and a beep does not sound. Section 2, Pump Setup and Programming, describes how to change the lock level.

AutoLock

AutoLock is one of the Options. This feature automatically changes the lock level from LL0 to LL1 or LL2 when the pump is started (instead of requiring you to manually change the lock level before giving the pump to the patient). See Section 4 for more information on using AutoLock.

Security Codes

The following security codes are preset by the manufacturer for the clinician's use:

**** Text Omitted from Online Version ****

WARNING: Do not disclose to the patient the pump's security codes or any other information that would allow the patient complete access to all programming and operating functions. Improper programming could result in death or serious injury to the patient.

Customizing the Security Codes

If it becomes necessary to change the Lock Level Code, Access Code, and Biomed Toolbox Code to ensure that a patient will be unable to access these features, you may customize the Lock Level Code in the Biomed Toolbox. (See Section 5.) Customizing the Lock Level Code will not affect the Clinician Bolus Code.

Lock Level Table

This table shows the features that can be accessed in each lock level. LL0 permits complete access to all programming and operating features. LL1 permits limited programming and access, and LL2 permits only minimal access.

Pump Operations and Programming	Stopped		
	LL0	LL1	LL2
Stop/Start the pump	Yes	Yes	Yes
View Help screens	Yes	Yes	Yes
Print	Yes	Yes	Yes
Reset Reservoir Volume	Yes	Yes	Yes
Reset Infusion Profile (TPN)	Yes	Yes	Yes
Change the lock level	Yes, w/code	Yes, w/code	Yes, w/code
Change the program	Yes	Within LL0 Limits†	No
Change Next Dose Start Time (INTERMT)	Yes	No	No
Clear Given amount	Yes	Yes	No
Clear Dose Counters (PCA)	Yes	Yes	No
Options			
Immediate Taper-Down (TPN)	Yes, programmable	Yes, programmable	Yes, not programmable
Prime	Yes	Yes	No
Time Remaining, view (INTERMT)	Yes	Yes	Yes
Extended History, view (PCA)	Yes	Yes	Yes
Change Delivery Modes	Yes, w/code	No	No
AutoLock	Yes	View only	View only
Time	Yes	View only	View only
Date	Yes	View only	View only
Air Detector On/Off	Yes	View only	View Only
Event Log, view	Yes	Yes	Yes
Biomed Toolbox	Yes, w/code	No	No

† In PCA and CONTIN delivery modes

Section 2: Pump Setup and Programming

Installing a Battery

Use a new, 9 volt alkaline or lithium battery such as the DURACELL® Alkaline MN 1604, the EVEREADY® ENERGIZER® Alkaline #522 or the ULTRALIFE® Lithium U9VL battery. The pump retains all programmed values while the battery is removed. If the pump is running, you may connect an external power source to keep the pump running for 3 minutes while you change the battery.

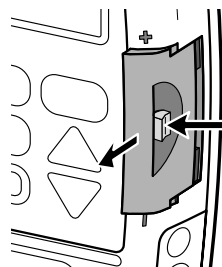
Dispose of used batteries in an environmentally safe manner, and according to any regulations which may apply.

WARNING:

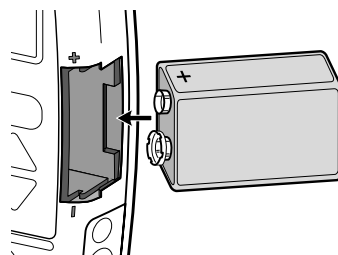
- Do not use rechargeable NiCad or nickel metal hydride (NiMH) batteries. Do not use carbon zinc (“heavy duty”) batteries. They do not provide sufficient power for the pump to operate properly, which could result in death or serious injury to the patient.
 - Always have new batteries available for replacement. If power is lost, non-delivery of drug will occur and, depending on the type of drug being administered, could result in death or serious injury to the patient.
 - There is no pump alarm to alert users that a battery has not been properly installed or has become dislodged. An improperly installed or dislodged battery could result in loss of power and non-delivery of drug and, depending on the type of drug being administered, could result in death or serious injury to the patient.
 - If the pump is dropped or hit against a hard surface, the battery door may become broken or damaged. DO NOT USE the pump if it has been damaged in this way because the battery will not be properly secured; this may result in loss of power, non-delivery of drug, and, depending on the type of drug being administered, death or serious injury.
-

To install a battery

1. Make sure the pump is stopped. Press the button on the battery door and slide the battery door forward. Remove the used battery.



2. Match the + and - markings on the new battery with the markings on the pump. Insert the battery. The pump will beep if the battery is inserted correctly.
3. Replace the battery door.



NOTE: If you put the battery in backwards, the display will remain blank. Reinsert the battery, making sure to match the + and - markings.

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

NOTE:

- Battery life is dependent on the amount of medication delivered, delivery rate, battery age, temperature, frequent screen display and backlighting and frequent printing.
- The power of the battery will be quickly depleted at temperatures below +10°C (50°F).

Watching Power Up

When you install a battery, the pump will start its power up sequence during which it performs self-tests and displays programmed values. Watch for the following:

- Pump model number, last error code (“lec”), if any, and serial number (“sn”) will appear.
- The delivery modes contained in the pump and its software version will appear. Make sure the desired delivery modes are displayed.
- The display will turn completely on. Look for any stripes, which would indicate a faulty display.
- If no Air Detector is attached, “No Air Detector attached” will appear. The pump’s program screens will appear, followed by screens showing the lock level setting. AutoLock setting (if in use), Air Detector status (if an Air Detector is attached), time, and date. You may need to confirm certain settings before power up will continue. If messages appear, see the Alarms and Messages Table in Section 6 for further explanation and instructions.
- When power up is complete, “Power Up Successful” will appear, six beeps will sound, and the pump will be stopped.
- Make sure the pump is in the desired delivery mode. If not, change the delivery mode before programming (Section 4, Options).

NOTE:

- When the pump is powered up in Lock Level 0 with an Air Detector attached, the pump will automatically turn on the Air Detector (the Air Detector setting in Options will change to “Turned On.”)
- To move quickly through the power up screens, press  repeatedly. To skip the automatic review entirely, press .

Changing the Lock Level

Before programming the pump, make sure the lock level is LL0. LL0 allows the clinician to access all programming and operating functions.

To change the lock level

1. Make sure the pump is stopped.
Press **LOCK**. The current lock level will appear. (If the pump is already in the desired lock level, press **NEXT** to exit.)

Lock Level
LL2

2. Press **Y** or **N** until the desired lock level appears.

Lock Level
LL0

3. Press **LOCK** again. "000" will appear.

NOTE: If <Custom> appears on the screen, the Lock Level Code has been customized. Enter the custom Lock Level Code in the next step.

Lock Level Code
000

4. Press **Y** or **N** until the Lock Level Code "061" (or the custom code) appears.

Lock Level Code
061

WARNING: Do not disclose to the patient the pump's security codes or any other information that would allow the patient complete access to all programming or operating functions. Improper programming of the pump could result in death or serious injury to the patient.

5. Press **LOCK** to set the new lock level. Watch the display to verify that the correct lock level is being entered. If you do not see this message, the lock level has not changed. Repeat the above steps.

Lock Level
LL0
<Changing...>

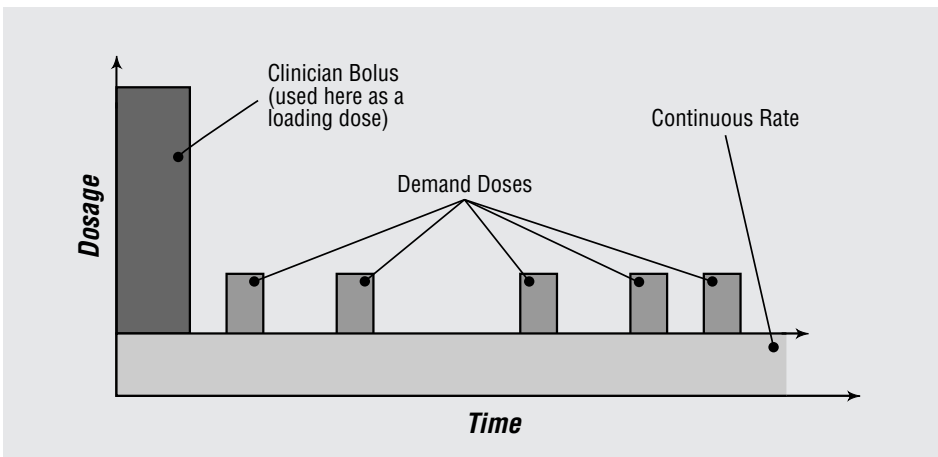
NOTE: To check the lock level, press **LOCK**. The current lock level will appear. To return to the screen you were on, press **NEXT**.

PCA Delivery Method

The PCA delivery method provides the following methods of delivery:

- **Continuous Rate**
- **Demand Dose**, activated by the patient
- **Clinician Bolus**, a dose activated by the clinician.

You may program each of the methods individually or in combination with each other. The following graph illustrates the combined delivery methods. Ranges and programming increments are listed in the Specifications in Section 6.



PCA Programming Screens

These are the programming screens for the PCA delivery method. Descriptions of the screens follow.

PCA Main Screen

```
*** PCA 6210X ***
                STOPPED

Press NEXT to advance
```

Reservoir Volume

```
Reservoir Volume
  ⬆ 100.0 ml

<Range: 1 - 9999>
```

Units

```
Units
  ⬆ Milligrams

<Range: mg or ml>
```

Concentration
(ml, mg or mcg)

```
Concentration
  ⬆ 1.0 mg/ml

<Range: 0.1 - 100>
```

Continuous Rate

```
Continuous Rate
  ⬆ 5.00 mg/hr

<Range: 0 - 30.00>
```

Demand Dose

```
Demand Dose
  ⬆ 2.50 mg

<Range: 0 - 9.90>
```

Demand Dose Lockout

```
Demand Dose Lockout
  ⬆ 15 Min

<Range: 5 min-24 hr>
```

Max. Doses per Hour

Max Doses Per Hour
 ⬆ 2
 <Range: 1 - 4>

Dose Counters

Dose Counters
 Given/Attempt: 0/ 0
 since 06/08/05 10:35
 Press ENTER to clear

(Units) Given

Milligrams Given
 0.00 mg
 since 06/08/05 10:35
 Press ENTER to clear

Air Detector (review)

Air Detector
 Required
 <Review Only>

New Patient Marker (optional)

To insert New Patient
 Marker and clear
 Extended History press
 ENTER

Reservoir Volume

Enter the volume of fluid contained in a filled fluid container. The Reservoir Volume value decreases as the pump delivers fluid or you use the priming feature. When you change the fluid container and reset the Reservoir Volume, the value resets to the value entered on this screen. If you do not wish to use the Reservoir Volume feature, scroll down to “Not In Use” (located before 1 and after 9999 in the range of values).

Units

Enter the programming units. Possible settings are milliliters and milligrams. Micrograms will also be one of the choices if the Micrograms settings in the Biomed Toolbox is “On.” When you change the Units, the pump requires you

to enter or verify the Continuous Rate and Demand Dose. If the units are mg or mcg, you must also enter the Concentration. Changing the Units clears the amount Given and the Extended History.

Concentration

If Units are mg or mcg, enter the concentration of drug in mg/ml or mcg/ml. When you enter a new Concentration, the pump requires you to enter a new Continuous Rate and Demand Dose.

Continuous Rate

Enter the continuous rate of medication delivery (in mg/hr, ml/hr, or mcg/hr, depending on the Units). The maximum rate is 30 ml/hr or the mg or mcg equivalent. If the prescription does not call for a Continuous Rate, enter zero.

NOTE: If you intend to run the pump in Lock Level 1 so the Continuous Rate can be varied, you should enter the maximum allowable rate while programming in Lock Level 0. After programming, you may then change to Lock Level 1 and decrease the rate to its starting value. See Programming with Upper Limits, Adjusting Doses in LL1 at the end of this section

Demand Dose

Enter the amount of drug to be delivered when the patient presses the  key (or the Remote Dose Cord button, if attached). If the prescription does not call for a Demand Dose, enter zero.

NOTE: If you intend to run the pump in Lock Level 1 so the Demand Dose can be varied, you should enter the maximum allowable dose while programming in Lock Level 0. After programming, you may then change to Lock Level 1 and decrease the dose to its starting value. See Programming with Upper Limits, Adjusting Doses in LL1 at the end of this section.

Demand Dose Lockout

If you programmed a Demand Dose, enter the minimum amount of time that must elapse between the time one Demand Dose starts and the time the next Demand Dose starts. This lockout period is unaffected by removal of the battery or stopping of the pump.

Max Doses Per Hour

This screen appears only if Max Doses Per Hour is “On” in the Biomed Toolbox. If you programmed a Demand Dose, enter the maximum number of Demand Doses allowed in any one-hour period. The possible values may be limited by the Demand Dose Lockout time you entered. If the Demand Dose Lockout is one hour or greater, this screen will not appear. The actual lockout time will be determined by either the Demand Dose Lockout or the Max Doses Per Hour, whichever is more restrictive. The Max Doses Per Hour limit is unaffected by removal of the battery or stopping of the pump.

NOTE: The number shown on this screen may be outside of the range; this can happen when the Demand Dose Lockout time is changed but the Max Doses Per Hour number is not adjusted. If you scroll through the numbers, only numbers within the range will appear.

Dose Counters

This screen appears if you programmed a Demand Dose. It shows the number of Demand Doses given and attempted since the date and time indicated, which is the last time they were cleared. (If the counters reach 999, they automatically return to zero and continue counting.) Even if these counters show zeroes, you should clear this screen during programming to update the time and date markers.

- **Given** shows the number of Demand Doses actually delivered to the patient, including doses stopped in progress.
- **Attempt** shows the total number of Demand Doses attempted by the patient while the pump was running, including doses that were delivered, locked out, and stopped in progress.

(Units) Given

This screen shows the total amount of drug delivered since the time and date indicated, which is the last time this value was cleared. The amount shown is rounded to the nearest 0.01 mg, ml, or mcg. (If this value reaches 99999.99, it automatically returns to 0 and continues counting. For concentrations of 0.5, 0.4, 0.3, 0.2 and 0.1 mg/ml, the value changes at 49999.99, 39999.99, 29999.99, 19999.99, and 9999.99 mg respectively.) The Given amount does not include drug delivered with the priming feature. Even if this screen shows zero, you should clear this screen during programming to update the time and date markers.

Air Detector Status

This screen appears only if an Air Detector is attached to the pump. It indicates whether the Air Detector is required, turned on, or turned off.

New Patient Marker

This screen appears only if the Extended History is “On” in the Biomed Toolbox. When you add a New Patient Marker, an event is added to the Event Log to indicate the pump was programmed for a new patient, and any previous information contained in the Extended History is cleared.

Options Specific to the PCA Delivery Mode

The Extended History option is available in the PCA delivery mode, which allows you to view dosing information either during a specified time period or hour by hour (see Section 4, Options).

PCA Programming Example

WARNING: Ensure that the $\pm 6\%$ System Delivery Accuracy specification is taken into account when programming the pump and/or filling the Medication Cassette Reservoir. Failure to do so may result in medication in the reservoir becoming depleted sooner than expected. If the pump is being used to deliver critical or life sustaining medication, the interruption in the delivery of medication could result in patient injury or death.

Medication is provided in a 100 ml Medication Cassette Reservoir at a concentration of 1.0 mg/ml. The patient should receive medication continuously at 5.0 mg/hr. Patient-activated doses of 2.5 mg are allowed, with a 15 minute lockout time between doses, and a maximum of 2 doses per hour.

Before programming:

- Stop the pump and change the Lock Level to LL0 as described in Section 1.
- Select the PCA delivery mode as described in Changing Delivery Modes in Section 4. If the pump is already in the PCA delivery mode, you may select it again to clear all programming screens to their default settings.

For a full description of each programming screen, see the preceding pages.

1. Begin at the main screen

```

*** PCA 6210X ***
      STOPPED
Press NEXT to advance
  
```

- Make sure the pump is in LL0.
- Make sure PCA and STOPPED appear on the main screen.
- Press **NEXT** to begin.

2. Enter the Reservoir Volume

```

Reservoir Volume
  100.0 ml
<Range: 1 - 9999>
  
```

- Press **▲** or **▼** to select the desired volume. (If you do not wish to use the Reservoir Volume feature, scroll down to “Not In Use” located before 1.)
- Press **ENTER**.

3. Enter the Units

To accept the current programming Units, press **ENTER**.

Units
 ⬆ Milligrams
 <Range: mg or ml>

Change Units
 to Milligrams?
 Press Y or N

Or, to change the units:

- Press **Y** or **N** to select the desired programming units.
- Press **ENTER**.
- Press **Y** to confirm the change.

NOTE: If the prescription calls for milliliters, enter Milliliters and skip to step 5.

4. Enter the Concentration of the drug

This screen will not appear if the units are milliliters; go to step 5.

Concentration
 ⬆ 1.0 mg/ml
 <Range: 0.1 - 100>

Change Concentration
 to 1.0 mg/ml?
 Press Y or N

- Press **Y** or **N** to select the desired concentration. (If you cannot select the desired concentration, it may have been turned off in the Biomed Toolbox)
- Press **ENTER**.
- Press **Y** to confirm the change.

NOTE: If you change the Concentration, you *must* enter the Continuous Rate and Demand Dose.

5. Enter the hourly Continuous Rate

Continuous Rate
 ⬆ 5.00 mg/hr
 <Range: 0 - 30.00>

- Press **Y** or **N** to select the desired rate.
- Press **ENTER**.

NOTE: If “Change Rate to...?” appears, you must confirm the rate because the Units or Concentration was changed, or the rate is greater

than or equal to 100 mg/hr or mcg/hr. Press **Y** to confirm, or press **N** and re-enter the rate.

6. Enter the Demand Dose amount

Demand Dose
 $\updownarrow$ 2.50 mg
 <Range: 0 - 9.90>

- Press **Y** or **N** to select the desired amount.
- Press **ENTER**.

NOTE: If “Change Demand Dose to...?” appears, you must confirm the dose because the Units or Concentration was changed, or the dose is greater than or equal to 100 mg or mcg. Press **Y** to confirm, or press **N** and re-enter the dose.

7. Enter the Demand Dose Lockout time

If Demand Dose is zero, this screen will not appear; go to step 10.

Demand Dose Lockout
 $\updownarrow$ 15 Min
 <Range: 5 min-24 hr>

- Press **Y** or **N** to select the desired lockout time between doses.
- Press **ENTER**.

WARNING: When you enter a new Demand Dose Lockout time, any lockout time in effect will be cleared. A Demand Dose could be requested and delivered immediately upon starting the pump, resulting in over-delivery, which could result in death or serious injury to the patient.

8. Enter the Max Doses Per Hour

This screen will appear only if the Max Doses Per Hour function is on. If Demand Dose is zero or the Lockout is one hour or greater, this screen will not appear; go to step 10.

Max Doses Per Hour

2

<Range: 1 - 4>

NOTE: The number shown on this screen may be outside of the range; this can happen when the Demand Dose Lockout time is changed but the Max Doses Per Hour number is not adjusted. If you scroll through the numbers, only numbers within the range will appear.

- Press **▲** or **▼** to select the maximum number of doses per hour.
- Press **ENTER**.

WARNING: When you enter a new Max Doses per Hour value, any lockout time in effect will be cleared. A Demand Dose could be requested and delivered immediately upon starting the pump, resulting in over-delivery, which could result in death or serious injury to the patient.

9. Clear the Dose Counters

If Demand Dose is zero, this screen will not appear; go to step 10.

Dose Counters

Given/Attempt: 0/ 0

since 06/08/05 10:35

Press ENTER to clear

- Press **ENTER** if you wish to clear the counters; even if the counters are zero, this updates the time and date markers.

10. Clear the units Given

Milligrams Given
0.00 mg
since 06/08/05 10:35
Press ENTER to clear

- Press **ENTER** if you wish to clear the amount given; even if the amount is zero, this updates the time and date markers.

11. Verify the Air Detector status

This screen will appear only if an Air Detector is installed.

Air Detector
Required
<Review Only>

- Make sure the setting is correct. **NOTE:** If the Air Detector is not required, this screen will show whether it is turned on or off.
- Press **NEXT** to continue. If you need to correct the Air Detector setting, see Section 4, Options.

12. Enter a New Patient Marker (optional)

This screen will appear only if the Extended History is on.

If you do not wish to add a New Patient Marker, press **NEXT**.

To insert New Patient
Marker and clear
Extended History press
ENTER

Clear Extended
History and insert
New Patient Marker?
Press Y or N

If you wish to add a New Patient Marker to the Event Log,

- Press **ENTER**.
- Press **▲Y**. This will clear the Extended History from the last patient and add a marker to the Event Log. The main screen will reappear.

13. Review the program

Press **NEXT** repeatedly to review the programming screens. If you need to reprogram a setting, press **NEXT** until the appropriate screen appears and change the setting as described in this section.

14. Prepare the Pump for the Patient

Follow the instructions for attaching a cassette, priming, changing the lock level, and attaching the pump to the patient (Section 3).

PCA: Programming with Upper Limits, Adjusting Doses in Lock Level 1

If a prescription allows for the Continuous Rate or Demand Dose to be adjusted during the course of therapy, you may wish to operate the pump in LL1. Then, when necessary, you can adjust the Continuous Rate or the Demand Dose values up to the maximum value that was programmed in LL0.

Programming the pump to use this feature

The following example shows how to set an upper Demand Dose limit of 5.00 mg with a starting value of 2.50 mg. The same procedure is used to set an upper limit and starting value on the Continuous Rate screen.

1. During initial programming in LL0, enter the **upper limit** values for the Continuous Rate and/or Demand Dose. (These will be the maximum values when the pump is in LL1.)
2. After you are finished programming, change the lock level to LL1.
3. Decrease the Continuous Rate or Demand Dose to its starting value, then press **ENTER**. “Range: Limited” indicates you cannot increase the value beyond the maximum programmed in LL0.

Demand Dose
⬆ 5.00 mg
<Range: 0 - 9.90>

Demand Dose
⬆ 2.50 mg
<Range: Limited>

Adjusting the rate or dose while the pump is in use

If it becomes necessary to increase the Continuous Rate or Demand Dose during the course of therapy, stop the pump but *remain in LL1*.

1. Press **NEXT** until the Continuous Rate or Demand Dose screen appears.
2. Press **▲** or **▼** to select the desired value, then press **ENTER**. “Range: Limited” indicates you cannot increase the value beyond the maximum.
3. Restart the pump if appropriate.

Demand Dose
⬆ 3.00 mg
<Range: Limited>

PCA: Starting a Clinician Bolus

A Clinician Bolus may be delivered in any lock level while the pump is running. It allows you to deliver a specified amount of drug, as a loading dose for example. Lockout settings have no affect on Clinician Bolus frequency. However, a Clinician Bolus cannot be started while a Demand Dose is in progress. The amount delivered decreases the Reservoir Volume and increases the Given amount, but does not add to the Dose Counters. A Clinician Bolus may be stopped in progress.

WARNING: Exercise extreme care when using the Clinician Bolus function. Since there are no limits on the frequency of delivering a bolus, and since the amount of the bolus can be set as high as 20 ml (or the mg or mcg equivalent), you should not permit the patient to become familiar with the procedure for giving a Clinician Bolus. Improper programming could result in death or serious injury to the patient.

To start a Clinician Bolus

1. Make sure the pump is running (in any lock level). Start the pump if necessary.
2. Press **LOCK**.
3. Press **▼** until the Clinician Bolus Code “997” appears on the display.
4. Press **LOCK** again.

Clinician Bolus Code
997

WARNING: To prevent the patient from accessing the Clinician Bolus function, do not let the patient know this code. Improper programming could result in death or serious injury to the patient.

5. Press **▲** or **▼** to select the desired amount.
6. Press **ENTER** or **DOSE**.

Clinician Bolus
⬆ 10.00 mg
Range <0 - 20.00>

NOTE: If you enter a value of 100, a screen will appear asking you to

confirm the value. Press **Y** to confirm, or **N** to re-enter the value.

7. The screen will show the amount decreasing as the bolus is delivered.

Clinician Bolus
10.00 mg
<Delivering...>

PCA: Starting a Demand Dose

If a Demand Dose has been programmed, the patient may start a Demand Dose while the pump is running. The amount delivered is added to the amount provided by the Continuous Rate. Each time the patient requests a Demand Dose, the pump will automatically add it to the Dose Counters screen. If no Demand Dose has been programmed, the pump will display the message “Dose not delivered, No Dose programmed.”

If the patient attempts to deliver a Demand Dose during the lockout time, “Dose Not Delivered, Dose Locked Out” will appear on the display and the pump will not deliver the dose. The lockout time is determined by the Demand Dose Lockout time or the Max Doses Per Hour, *whichever limits dose frequency more*. The attempt will be added to the “Attempts” counter on the Dose Counters screen.

NOTES:

- A Demand Dose cannot be started while another Demand Dose or a Clinician Bolus is in progress.
- Even if the display has automatically blanked, pressing the  key will turn the display back on and deliver a Demand Dose (if available).

To start a Demand Dose

1. Make sure the pump is running (in any lock level). Start the pump if necessary.
2. Press  (or the button on the Remote Dose Cord, if attached). Two beeps will sound and the pump will begin delivering the Demand Dose.

As the Demand Dose is delivered, the main screen will show “DOSING” in place of “RUNNING.”

Demand Dose
Started

NEXT to continue

```
*** PCA 6210X ***
Low Battery  DOSING
Res Vol      47.0 ml
Press NEXT to advance
```

PCA: Stopping a Demand Dose or Clinician Bolus

A Demand Dose or Clinician Bolus can be stopped in progress. The pump may be in any lock level. A Demand Dose that has been stopped will remain recorded on the Dose Counter screen under “Given/Attempt.”

To stop a dose while the pump is running

1. Press .
One beep will sound and the message “Stop Demand Dose?” or “Stop Clinician Bolus?” will appear.
2. Press  to stop the dose and to cancel the remainder of the dose. “Demand Dose Stopped” or “Clinician Bolus Stopped” will appear.
3. When “Stop the Pump?” appears,
 - press  to remain running, or
 - press  to stop the pump.

Stop Demand Dose?

Press Y or N

Demand Dose
Stopped

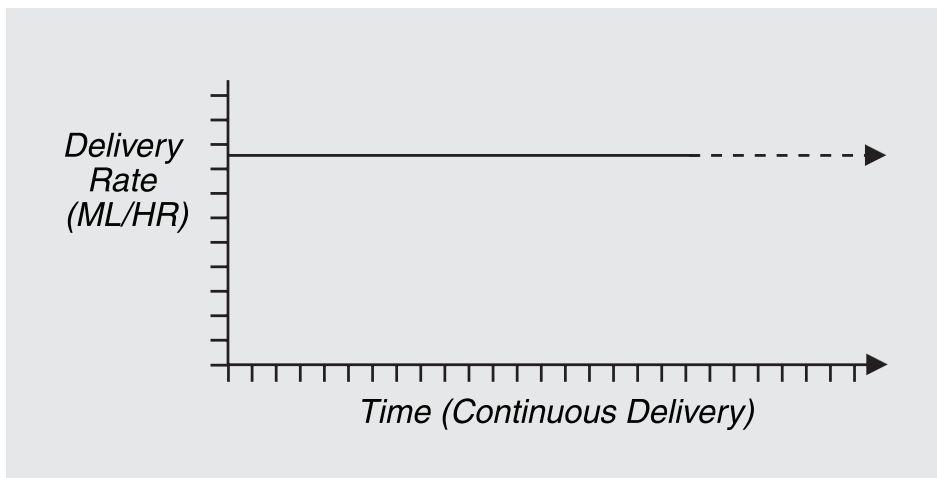
Stop the Pump?

Press Y or N

Continuous Delivery Method

The Continuous delivery method provides a continuous rate of delivery in milliliters per hour.

The following graph illustrates the Continuous delivery method:



Programming Screens for Continuous Delivery

The following are the programming screens for the Continuous Delivery method. Descriptions of the screens follow.

Continuous Main Screen

```
*** CONTIN 6220X ***
                        STOPPED
Press NEXT to advance
```

Reservoir Volume

```
Reservoir Volume
  ⬆ 100.0 ml
<Range: 1 - 9999>
```

Continuous Rate

```
Continuous Rate
  ⬆ 0.5 ml/hr
<Range: 0.1 - 350.0>
```

Milliliters Given

Milliliters Given
0.0 ml
since 01/08/05 10:35
Press ENTER to clear

Air Detector (review)

Air Detector
Required
<Review Only>

Reservoir Volume

Enter the volume of fluid contained in a filled fluid container. The Reservoir Volume value decreases as the pump delivers fluid or you use the priming feature. When you change the fluid container and reset the Reservoir Volume, the value resets to the value entered on this screen. If you do not wish to use the Reservoir Volume feature, select “Not In Use” (located before 1 and after 9999 in the range of values).

Continuous Rate

Enter the continuous rate of medication delivery in ml/hr. The maximum rate is 350 ml/hr.

Rates above 125 ml/hr require a CADD-Prizm™ High Volume Administration Set. Rates above 250 ml/hr also require an AC Adapter or a Power Pack.

NOTE: If you intend to run the pump in Lock Level 1 so the Continuous Rate can be varied, you should enter the maximum allowable rate. After programming, you may then decrease the rate to its starting value. See Programming with Upper Limits, Adjusting Rate in LL1 at the end of this section.

Milliliters Given

This screen shows the total amount of drug delivered since the time and date indicated, which is the last time this value was cleared. The amount shown is rounded to the nearest 0.1 ml. (If this value reaches 99999.9, it automatically returns to 0 and continues counting.)

The Given amount does not include drug delivered with the priming feature. Even if this screen shows zero, you should clear this screen during programming to update the time and date markers.

Air Detector Status

This screen appears only if an Air Detector is attached to the pump. It indicates whether the Air Detector is required, turned on, or turned off.

Continuous Programming Example

WARNING: Ensure that the $\pm 6\%$ System Delivery Accuracy specification is taken into account when programming the pump and/or filling the Medication Cassette Reservoir. Failure to do so may result in medication in the reservoir becoming depleted sooner than expected. If the pump is being used to deliver critical or life sustaining medication, the interruption in the delivery of medication could result in patient injury or death.

Medication is provided in a 100 ml Medication Cassette Reservoir. The patient should receive medication continuously at 0.5 ml/hr.

Before programming:

- Stop the pump and change the Lock Level to LL0 as described in Section 1.
- Select the Continuous (CONTIN) delivery mode as described in Changing Delivery Modes in Section 4. If the pump is already in the CONTIN delivery mode, you may select it again to clear all programming screens to their default settings.

For a full description of each programming screen, see the preceding pages.

1. Begin at the main screen

```
*** CONTIN 6220X ***
                STOPPED
Press NEXT to advance
```

- Make sure the pump is in LL0.
- Make sure CONTIN and STOPPED appear on the main screen.
- Press **NEXT** to begin.

2. Enter the Reservoir Volume

```
Reservoir Volume
  100.0 ml
<Range: 1 - 9999>
```

- Press **▲** or **▼** to select the desired volume. (If you do not wish to use the Reservoir Volume feature, scroll down to “Not In Use” located before 1.)
- Press **ENTER**.

3. Enter the hourly Continuous Rate

Continuous Rate
 ⚡ 0.5 ml/hr
 <Range: 0.1 - 350.0>

- Press **▲** or **▼** to select the desired rate.
- Press **ENTER**.

4. Clear the Milliliters Given

Milliliters Given
 0.0 ml
 since 01/08/05 10:35
 Press ENTER to clear

- Press **ENTER** if you wish to clear the milliliters given; even if the amount is zero, this updates the time and date markers.

5. Verify the Air Detector status

This screen will appear only if an Air Detector is installed.

Air Detector
 Required
 <Review Only>

- Make sure the setting is correct.
NOTE: If the Air Detector is not required, this screen will show whether it is turned on or off.
- Press **NEXT** to continue. If you need to correct the Air Detector setting, see Section 4, Options.

6. Review the program

Press **NEXT** repeatedly to review the programming screens. If you need to reprogram a setting, press **NEXT** until the appropriate screen appears and change the setting as described in this section.

7. Prepare the Pump for the Patient

Follow the instructions for attaching a cassette, priming, changing the lock level, and attaching the pump to the patient (Section 3).

CONTIN: Programming with Upper Limits, Adjusting Rate in Lock Level 1

If a prescription allows for the Continuous Rate to be adjusted during the course of therapy, you may wish to operate the pump in LL1. Then, when necessary, you can adjust the Continuous Rate up to the maximum value that was programmed in LL0.

Programming the pump to use this feature

The following example shows how to set an upper Continuous Rate limit of 5.0 ml/hr with a starting value of 2.5 ml/hr.

1. During initial programming in LL0, enter the **upper limit** value for the Continuous Rate. (This will be the maximum value when the pump is in LL1.)
2. After you are finished programming, change the lock level to LL1.
3. Decrease the Continuous Rate to its starting value. “Range: Limited” indicates you cannot increase the value beyond the maximum programmed in LL0.

Continuous Rate
⬆ 5.0 ml/hr
<Range: 0 - 350.0>

Continuous Rate
⬆ 2.5 ml/hr
<Range: Limited>

Adjusting the rate while the pump is in use

If it becomes necessary to increase the Continuous Rate during the course of therapy, stop the pump but **remain in LL1**.

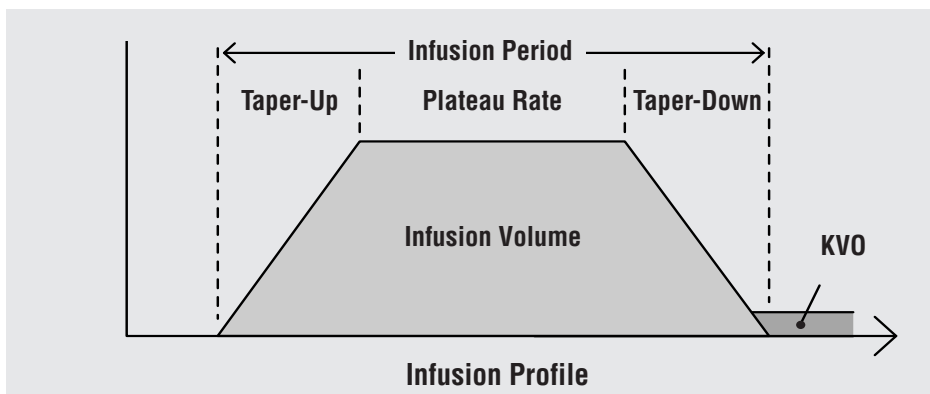
1. Press **NEXT** until the Continuous Rate screen appears.
2. Press **▲** or **▼** to select the desired value, then press **ENTER**. “Range: Limited” indicates you cannot increase the value beyond the maximum.
3. Restart the pump if appropriate.

Continuous Rate
⬆ 5.0 ml/hr
<Range: Limited>

TPN Delivery Method

The TPN delivery method allows high volume delivery of solutions, with optional tapering. Delivery can be gradually increased or “tapered up” at the beginning of the infusion profile, or it can be gradually decreased, or “tapered down” at the end of the infusion profile. When the infusion profile is completed, the pump will beep 9 times. A Keep Vein Open (KVO) rate may be delivered at the end of the infusion profile, depending on the program you have entered.

The following graph illustrates the TPN delivery method:



TPN Delivery

These are the programming screens for TPN Delivery. Complete descriptions of the screens follow.

TPN Main Screen

```
***  TPN 6230X  ***
                STOPPED
Press NEXT to advance
```

Reservoir Volume

```
Reservoir Volume
  ⚡ 1050 ml
<Range: 10.0 - 9990>
```

Infusion Volume

```

Infusion Volume
⬆ 1000.0 ml total
<Range: 10 - 9990>

```

Infusion Period

```

Infusion Period
⬆ 10 hrs 00 min
<Range: 3:00-99:50>

```

Taper-Up Period

```

Taper-Up Period
⬆ 1 hrs 30 min
<Range: 0:00- 9:50>

```

Taper-Down Period

```

Taper-Down Period
⬆ 1 hrs 30 min
<Range: 00:00- 8:20>

```

Plateau Rate (review)

```

Plateau Rate
      117.6 ml/hr
KVO Rate  5.0 ml/hr
<Review Only>

```

Milliliters Given

```

Milliliters Given
      0.0 ml
since 01/08/05 10:35
Press ENTER to clear

```

Air Detector (review)

```

Air Detector
Required
<Review Only>

```

Reservoir Volume

Enter the volume of fluid contained in a filled fluid container. The Reservoir Volume value decreases as the pump delivers fluid or you use the priming feature. The Reservoir Volume programmed should be larger than the Infusion

volume, because of the fluid pumped during priming (see Priming the Tubing, Section 3), and so that automatic KVO delivery occurs at the completion of the infusion profile.

NOTE: If the programmed Reservoir Volume is greater than the Infusion Volume, KVO delivery will automatically begin when the infusion profile is complete. The KVO rate is 5 ml/hr, or 1/10th of the plateau rate. KVO delivery continues until the Reservoir Volume reaches zero, or until the pump is stopped. If the Reservoir Volume is the same as the Infusion Volume, KVO delivery will not occur at the completion of the infusion profile.

When you change the fluid container and reset the Reservoir Volume, the value resets to the value entered on this screen and the infusion profile is reset. The Reservoir Volume cannot be set to less than the programmed Infusion Volume. If you do not wish to use the Reservoir Volume feature, select “Not In Use” (located before 10.0 and after 9990 in the range of values).

Infusion Volume

Enter the total volume of fluid to be delivered. The maximum is 9990 ml. The pump calculates the Plateau Rate based on the Infusion Volume, the existing Infusion Period, and the existing Taper values. If you enter a volume that would cause the Plateau Rate to be greater than the maximum rate of 350 ml/hr or less than the minimum of 10 ml/hr, the pump will automatically lengthen or shorten the Infusion Period and may change the Taper values to accommodate the new volume. A message will appear to show that the pump is adjusting the value. You will then need to confirm the new Infusion Period or enter a different Infusion Period. Entering a new Infusion Volume resets the infusion profile so delivery will start at the beginning of the infusion period.

Infusion Period

Enter the duration for delivery of the Infusion Volume, up to 99 hours 50 minutes. The pump will automatically calculate the rate necessary to deliver the Infusion Volume you entered. You will not be able to select an Infusion Period that would cause the rate of delivery to be greater than 350 ml/hr or less than 10 ml/hr. In addition, the Infusion Period cannot be shorter than the taper periods plus 10 minutes. Entering a new Infusion Period resets the infusion profile so delivery will start at the beginning of the infusion period.

Taper-Up Period

Enter the length of time for the Taper-Up Period, up to 99 hours 40 minutes. The Taper-Up Period becomes part of the overall Infusion Period you entered. If you enter a Taper-Up Period that would cause the Plateau Rate to be greater

than the maximum rate or less than the minimum rate, the pump will automatically lengthen or shorten the Infusion Period to accommodate the new Taper-Up Period. A message will appear to show that the pump is adjusting the value. You will then need to confirm the new Infusion Period or enter a different Infusion Period. Entering a new Taper-Up Period resets the infusion profile so delivery will start at the beginning of the infusion period.

Taper-Down Period

Enter the length of time for the Taper-Down Period, up to 99 hours 40 minutes. The Taper-Down Period becomes part of the overall Infusion Period you entered. If you enter a Taper-Down Period that would cause the Plateau Rate to be greater than the maximum rate or less than the minimum rate, the pump will automatically lengthen or shorten the Infusion Period to accommodate the new Taper-Down Period. A message will appear to show that the pump is adjusting the value. You will then need to confirm the new Infusion Period or enter a different Infusion Period. Entering a new Taper-Down Period resets the infusion profile so delivery will start at the beginning of the infusion period.

Rate Display

Based on the Infusion Volume, Infusion Period, and any programmed tapering, the pump will calculate the rate of delivery that will occur during the plateau portion of the infusion profile. The calculated Plateau Rate and KVO rate (5.0 ml/hr or one tenth of the Plateau Rate) will display on this screen for review only. Rates above 125 ml/hr require a CADD-Prizm™ High Volume Administration Set. Rates above 250 ml/hr also require an AC Adapter or a Power Pack.

Milliliters Given

This screen shows the total amount of drug delivered since the time and date indicated, which is the last time this value was cleared. The amount shown is rounded to the nearest 0.1 ml (If this value reaches 99999, it automatically returns to 0 and continues counting.) The Given amount does not include drug delivered with the priming feature. Even if this screen shows zero, you should clear this screen during programming to update the time and date markers.

Air Detector Status

This screen appears only if an Air Detector is attached to the pump. It indicates whether the Air Detector is required, turned on, or turned off.

Options Specific to the TPN Delivery Mode

The Immediate Taper-Down option is available in the TPN delivery mode (see Section 4, Options).

TPN Programming Example

WARNING: Ensure that the $\pm 6\%$ System Delivery Accuracy specification is taken into account when programming the pump and/or filling the Medication Cassette Reservoir. Failure to do so may result in medication in the reservoir becoming depleted sooner than expected. If the pump is being used to deliver critical or life sustaining medication, the interruption in the delivery of medication could result in patient injury or death.

A total of 1 liter of TPN solution must be delivered to the patient over 10 hours. The TPN bag contains 1050 ml. Delivery should taper up over 1 hour 30 minutes at the beginning of delivery and down over 1 hour 30 minutes at the end of delivery.

Before programming:

- Stop the pump and change the Lock Level to LL0 as described in Section 1.
- Select the TPN delivery mode as described in Changing Delivery Modes in Section 4. If the pump is already in the TPN delivery mode, you may select it again to clear all programming screens to their default settings.

For a full description of each programming screen, see the preceding pages.

1. Begin at the main screen

```

***  TPN 6230X  ***
                STOPPED
Press NEXT to advance
  
```

- Make sure the pump is in LL0.
- Make sure TPN and STOPPED appear on the main screen.
- Press **NEXT** to begin.

2. Enter the Reservoir Volume

```

Reservoir Volume
  1050 ml
<Range: 10.0 - 9990>
  
```

- Press **▲** or **▼** to select the desired volume. (If you do not wish to use the Reservoir Volume feature, scroll down to “Not In Use” located before 10.0.)
- Press **ENTER**.

3. Enter the Infusion Volume

When this screen is first displayed, the third line may show the volume left from the last infusion period. As soon as you begin scrolling to a new Infusion Volume, it will disappear.

```

Infusion Volume
⬆ 1000.0 ml total
<Range: 10 - 9990>
  
```

- Press **▲** or **▼** to select the desired volume.
- Press **ENTER**.

4. Enter the Infusion Period

When this screen is first displayed, the third line may show the amount of time left from the last infusion period. As soon as you begin scrolling to a new Infusion Period, it will disappear.

```

Infusion Period
⬆ 10 hrs 00 min
<Range: 3:00-99:50>
  
```

- Press **▲** or **▼** to select the desired Infusion Period.
- Press **ENTER**.

5. Enter the Taper-Up Period

```

Taper-Up Period
⬆ 1 hrs 30 min
<Range: 0:00- 9:50>
  
```

- Press **▲** or **▼** to select the desired Taper-Up Period.
- Press **ENTER**.

6. Enter the Taper-Down Period

```

Taper-Down Period
⬆ 1 hrs 30 min
<Range: 00:00- 8:20>
  
```

- Press **▲** or **▼** to select the desired Taper-Down Period.
- Press **ENTER**.

7. View the Calculated Rate

```

Plateau Rate
      117.6 ml/hr
KVO Rate   5.0 ml/hr
<Review Only>
  
```

- Both the Plateau Rate and the KVO Rate will be displayed. Press **NEXT** to continue.

8. Clear the Milliliters Given

Milliliters Given
0.0 ml
since 01/08/05 10:35
Press ENTER to clear

- Press **ENTER** if you wish to clear the amount given; even if the amount is zero, this updates the time and date markers.

9. Verify the Air Detector status

This screen will appear only if an Air Detector is installed.

Air Detector
Required

<Review Only>

- Make sure the setting is correct.
NOTE: If the Air Detector is not required, this screen will show whether it is turned on or off.
- Press **NEXT** to continue. If you need to correct the Air Detector setting, see Section 4, Options.

10. Review the program

Press **NEXT** repeatedly to review the programming screens. If you need to reprogram a setting, press **NEXT** until the appropriate screen appears and change the setting as described in this section.

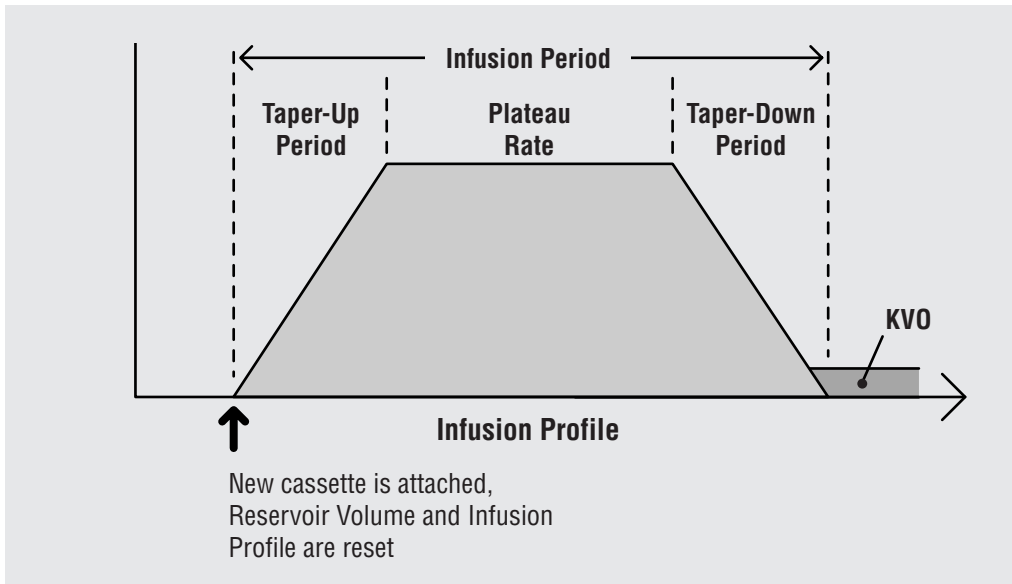
11. Prepare the Pump for the Patient

Follow the instructions for attaching a cassette, priming, changing the lock level, and attaching the pump to the patient (Section 3).

TPN: Starting Daily Infusion

When a new cassette is attached to the pump at the beginning of infusion, the Reservoir Volume should be reset. This will also reset the infusion profile. To do this, follow the instructions in Section 3 for attaching a cassette and answering yes to “Reset Reservoir Volume to — ?” Then when you start the pump, delivery will begin at the start of the infusion period (illustrated below).

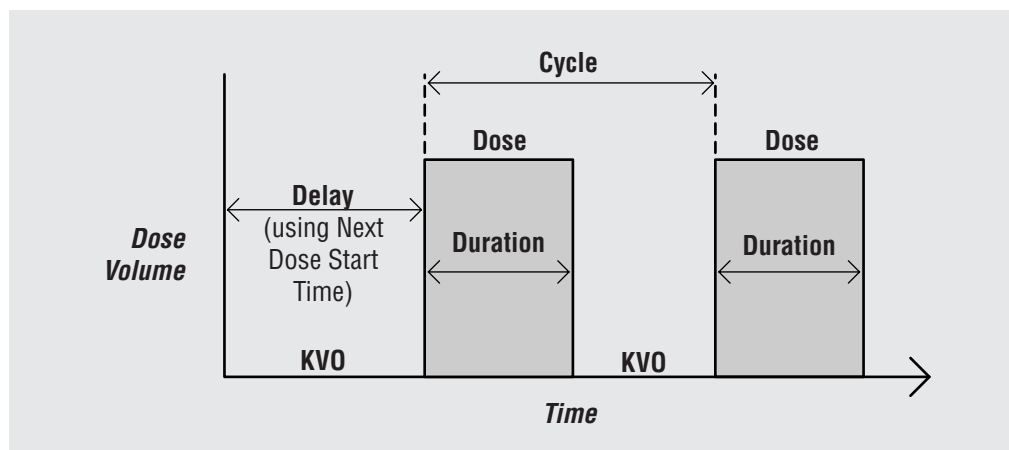
NOTE: Whenever the Reservoir Volume is reset, the infusion profile is also reset so the infusion will start at the beginning.



Intermittent Delivery Method

The Intermittent delivery method delivers a specified dose volume over a specified duration. You may repeat the dose in a cycle of up to 96 hours. The KVO feature allows you to deliver a minimal amount of drug between doses to maintain catheter patency. You may also delay the start of delivery using The Next Dose Start Time feature.

The following graph illustrates the Intermittent delivery method:



Intermittent Delivery Programming Screens

These are the programming screens for Intermittent Delivery. Complete descriptions of the screens follow.

Intermittent Main Screen

```

*** INTERMT 6240X ***
                        STOPPED
Press NEXT to advance
  
```

Reservoir Volume

```

Reservoir Volume
  ⬆ 100.0 ml
<Range: 1 - 9999>
  
```

Dose Volume

Dose Volume
↕ 23.5 ml
<Range: 0.1 - 1000>

Dose Duration

Dose Duration
↕ 1 hrs 00 min
<Range: 00:09-24:00>

Dose Cycle

Dose Cycle
↕ 6 hrs 00 min
<Range: 01:05-96:00>

KVO Rate

KVO Rate
↕ 0.2 ml/hr
<Range: 0.0 - 10>

Next Dose Start Time (optional)

Next Dose Start Time
↕ 20:00 2/21/05
<Range: See Help>

Dose Rate (review)

Dose Rate
50.0 ml/hr
<Review Only>

Milliliters Given

Milliliters Given
0.0 ml
since 01/08/05 10:35
Press ENTER to clear

Air Detector (review)

Air Detector
Required
<Review Only>

Reservoir Volume

Enter the volume of fluid contained in a filled fluid container. The Reservoir Volume value decreases as the pump delivers fluid or you use the priming feature. When you change the fluid container and reset the Reservoir Volume, the value resets to the value entered on this screen. If you do not wish to use the Reservoir Volume feature, select “Not In Use” (located before 1 and after 9999 in the range of values).

Dose Volume

Enter the volume of the dose in milliliters. The maximum volume is 1000 ml. Entering a Dose Volume will automatically reset the cycle and set the Next Dose Start Time to “Immediate.” If you enter a Dose Volume that would cause the rate to be greater than the maximum rate of 350 ml/hr, the pump will automatically lengthen the Dose Duration to accommodate the new volume. You will then need to confirm the new Dose Duration or enter a different duration. The cycle may also be affected if the Dose Duration is lengthened; in this case, you would also need to confirm the new Dose Cycle or enter a different Dose Cycle.

Dose Duration

Enter the duration for delivery of the dose, up to 24 hours. You will not be able to select a duration that would cause the rate of delivery of the programmed Dose Volume to exceed 350 ml/hr. Entering a Dose Duration will automatically reset the Dose Cycle and set the Next Dose Start Time to “Immediate.” Rates above 125 ml/hr require a CADD-Prizm™ High Volume Administration Set. Rates above 250 ml/hr also require an AC Adapter or a Power Pack.

Dose Cycle

The cycle is the time from the start of one dose to the start of the next dose. The programmable values for cycle are based on the Dose Duration. There must be at least 5 minutes between the end of one dose and the start of the next; therefore, the minimum programmable cycle is the Dose Duration plus 5 minutes. The maximum cycle is 96 hours. Entering a cycle automatically sets the Next Dose Start Time to “Immediate.”

KVO Rate

The KVO or “Keep Vein Open” rate is optional. It allows the delivery of a minimal amount of drug up to 10 ml/hr to help maintain catheter patency. If a

Next Dose Start Time is programmed, the KVO rate is active during the initial delay. The KVO rate is also active between doses.

Next Dose Start Time

The Next Dose Start Time is optional. It allows you to delay the start of delivery up to four days by allowing you to select the date and time at which the first dose should begin. The pump must be running at the selected date and time in order for delivery to begin. If a delayed start is not desired, program the Next Dose Start Time to “Immediate” so that delivery will begin as soon as you start the pump.

A Next Dose Start Time can be programmed in Lock Level 0 at any time to delay the start of the next dose, but if a dose is in progress, this will cancel the remainder of the dose. NOTE: During dosing, this screen will show “In Progress.” If a dose is stopped in progress, this screen will show “Interrupted.”

Dose Rate

This screen is for review only. It shows the rate at which the dose will be delivered based on the programmed Dose Volume and Dose Duration.

Milliliters Given

This screen shows the total amount of drug delivered since the time and date indicated, which is the last time this value was cleared. The amount shown is rounded to the nearest 0.1 ml (If this value reaches 99999, it automatically returns to 0 and continues counting.) The Given amount does not include drug delivered with the priming feature. Even if this screen shows zero, you should clear this screen during programming to update the time and date markers.

Air Detector Status

This screen appears only if an Air Detector is attached to the pump. It indicates whether the Air Detector is required, turned on, or turned off.

Options Specific to the Intermittent Delivery Mode

While a dose is being delivered, you can use the Time Remaining option to view the amount of time remaining in both the dose and the current cycle (see Section 4, Options).

Intermittent Programming Example

WARNING: Ensure that the $\pm 6\%$ System Delivery Accuracy specification is taken into account when programming the pump and/or filling the Medication Cassette Reservoir. Failure to do so may result in medication in the reservoir becoming depleted sooner than expected. If the pump is being used to deliver critical or life sustaining medication, the interruption in the delivery of medication could result in patient injury or death.

Medication is provided in a 100 ml Medication Cassette Reservoir. The patient should receive 23.5 ml dose over 1 hour. The dose should be given every 6 hours, with a 0.2 ml/hr KVO rate between doses. The first dose should begin at 8:00 PM tonight.

Before programming:

- Stop the pump and change the Lock Level to LL0 as described in Section 1.
- Select the Intermittent (INTERMT) delivery mode as described in Changing Delivery Modes in Section 4. If the pump is already in the INTERMT delivery mode, you may select it again to clear all programming screens to their default settings.

For a full description of each programming screen, see the preceding pages.

1. Begin at the main screen

```
*** INTERMT 6240X ***
                STOPPED
Press NEXT to advance
```

- Make sure the pump is in LL0.
- Make sure INTERMT and STOPPED appear on the main screen.
- Press **NEXT** to begin.

2. Enter the Reservoir Volume

```
Reservoir Volume
  100.0 ml
<Range: 1 - 9999>
```

- Press **▲** or **▼** to select the desired volume. (If you do not wish to use the Reservoir Volume feature, scroll down to “Not In Use” located before 1.)
- Press **ENTER**.

3. Enter the Dose Volume

Dose Volume
 ⬆ 23.5 ml
 <Range: 0.1 - 1000>

- Press **▲** or **▼** to select the desired volume.
- Press **ENTER**.

4. Enter the Dose Duration

Dose Duration
 ⬆ 1 hrs 00 min
 <Range: 00:09-24:00>

- Press **▲** or **▼** to select the desired duration.
- Press **ENTER**.

5. Enter the Dose Cycle

Dose Cycle
 ⬆ 6 hrs 00 min
 <Range: 01:05-96:00>

- Press **▲** or **▼** to select the desired cycle.
- Press **ENTER**.

6. Enter the KVO Rate

KVO Rate
 ⬆ 0.2 ml/hr
 <Range: 0.0 - 10>

- Press **▲** or **▼** to select the desired KVO rate.
- Press **ENTER**.

7. Enter the Next Dose Start Time

Next Dose Start Time
 ⬆ 20:00 2/21/05
 <Range: See Help>

- Press **▲** or **▼** to select the desired dose start time and date (or “Immediate”).
- Press **ENTER**.

Start next dose in
 3 hrs 27 min on
 2/21/05 at 20:00?
 Press Y or N

- Verify the start time shown on the screen and press **▲** if correct. If you need to re-enter the start time and date, press **▼**.

8. Verify the Dose Rate

Dose Rate
50.0 ml/hr
<Review Only>

- The pump automatically calculates the rate of dose delivery based on the volume and duration you entered. This screen is for review only; press **NEXT** to continue. (If the rate is 125 ml/hr or greater, a CADD-Prizm™ High Volume Administration Set must be used.)

9. Clear the Milliliters Given

Milliliters Given
0.0 ml
since 01/08/05 10:35
Press ENTER to clear

- Press **ENTER** if you wish to clear the amount given; even if the amount is zero, this updates the time and date markers.

10. Verify the Air Detector status

This screen will appear only if an Air Detector is installed.

Air Detector
Required
<Review Only>

- Make sure the setting is correct.
NOTE: If the Air Detector is not required, this screen will show whether it is turned on or off.
- Press **NEXT** to continue. If you need to correct the Air Detector setting, see Section 4, Options.

11. Review the program

Press **NEXT** repeatedly to review the programming screens. If you need to reprogram a setting, press **NEXT** until the appropriate screen appears and change the setting as described in this section.

12. Prepare the Pump for the Patient

Follow the instructions for attaching a cassette, priming, changing the lock level, and attaching the pump to the patient (Section 3).

