Legacy 1400

Operator's Manual

CADD-Legacy® 1400 Pump

Model 1400

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

This operator's manual is for clinician use only.
Read the entire operator's manual before operating the pump.

This manual pertains only to the CADD-Legacy® 1400 pump. There are other CADD-Legacy® pump models available; review the rear label of the pump to ensure it is a CADD-Legacy® 1400 pump before programming. This pump is designed for enteral delivery of medication and can be programmed to deliver a continuous rate, a morning dose, and extra doses.

This manual is intended for clinician use only. Do not permit patients to have access to this manual. The pump has 3 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 on the back cover 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 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-Legacy® 1400 pump, please call the number given below. When calling, please specify the pump's software revision. This information is located on the pump's display during power up.

Our staff at Smiths Medical is available to help clinicians 24 hours a day with the programming and operation of the CADD-Legacy® 1400 pump.

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Read this entire operator's manual before operating the CADD-Legacy® 1400 pump.

Failure to follow the warnings and cautions below could result in return of symptoms, damage to the pump, serious injury, or death in extreme cases.

Please refer to the full prescribing information for DUOPA (carbidopa and levodopa) enteral suspension for indications and usage, contraindications, warnings, precautions, and adverse reactions.

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 compromise patient treatment.
- To avoid explosion hazard, do not use the pump in the presence of flammable anesthetics or explosive gases.
- The CADD-Legacy® 1400 pump and medication cassette reservoir are designed for enteral delivery of medication only. They are *NOT* intended for IV or other parenteral routes of infusion.
- 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 compromise patient treatment.
- Always have new batteries available for replacement. If power is lost, non-delivery of medication will occur.
- 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 and non-delivery of medication.
- 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 and non-delivery of medication.

- System delivery inaccuracies beyond the stated accuracy may occur as a result of back pressure or fluid resistance, which depends upon temperature, medication viscosity, catheter size, extension set tubing, flow rate, and orientation of the pump system.
- Programming the pump at a delivery rate other than what is prescribed will cause over- or under-delivery of medication.
- Clamp the fluid path tubing and/or disconnect the tubing from the enteral access device before removing the medication cassette reservoir from the pump to prevent unintended delivery of medication.
- Use only approved DUOPA medication cassette reservoirs to maintain pump accuracy and assure proper pump operations.
- Use only extension sets approved for use with DUOPA, paying particular attention to all warnings and cautions associated with their use.
- Attach the cassette properly. The cassette is the part of the medication cassette reservoir that attaches to the pump. A detached or improperly attached cassette could result in unintended delivery of medication.
- Do not prime the fluid path with the tubing connected to a patient as this could result in over-delivery of medication.
- 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, as this could compromise patient treatment.
- The use of power supplies and a remote dose cord other than those listed in the electromagnetic emissions declaration may result in increased emissions or decreased immunity of the pump.
- The pump should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the user should verify normal operation of the pump in the configuration in which it is to be used.
- There are potential health hazards associated with improper disposal of batteries, electronics, and contaminated (used) reservoirs and extension sets. Dispose of used batteries, reservoirs, extension sets and other used accessories, or a pump that has reached the end of its useful life, in an environmentally safe manner, and according to any regulations that may apply.

Cautions

- Use only Smiths Medical accessories and replacement parts, as using other brands may adversely affect the operation of the pump.
- 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 the medication cassette reservoir attached. Use the protective cassette provided.
- Do not expose the pump to humidity levels below 20% or above 90% relative humidity.
- Do not sterilize the pump or medication cassette reservoir as this could cause damage.
- When the upstream occlusion sensor is turned off, the pump will not detect occlusions in the medication cassette reservoir. Periodically inspect the medication cassette reservoir for decreasing volume. Undetected occlusions could result in under- or non-delivery of medication.
- Do not use rechargeable NiCd 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.
- Do not store the pump for prolonged periods of time with the batteries installed. Battery leakage could damage the pump.
- Prior to starting medication delivery, inspect the fluid path for kinks, a closed clamp, or other obstruction. An undetected occlusion may result in under- or non-delivery of medication and/or nuisance alarms.
- When you enter a new value, any lockout time already in effect will be cleared. An extra dose or morning dose could be requested and delivered immediately upon starting the pump, which may result in over-delivery of medication.
- 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. Moisture buildup 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 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.
- This pump may interfere with ECG equipment. Monitor ECG equipment carefully when using this pump.
- CADD-Legacy® 1400 pumps are sealed units. A broken or damaged seal will, therefore, be considered conclusive evidence that the pump has been misused and/or altered, which voids any and all warranties. All service and repair of CADD-Legacy® 1400 pumps must be performed by Smiths Medical or its authorized agents.
- Review programming screens when complete to make sure desired programming has been entered. Check to make sure unintended changes were not made to the morning dose, continuous rate, or extra dose volume. If unintended changes were made, go to the appropriate screen and program the desired value.

Table of Contents

1.0 General Description

Introduction

The CADD-Legacy® 1400 pump provides enteral delivery of medication to patients in hospital or outpatient settings. Therapy should always be overseen by a physician or a certified, licensed healthcare professional. As appropriate to the situation, the patient should be instructed in using and troubleshooting the pump.

Indications

The CADD-Legacy® 1400 pump is indicated solely for the enteral delivery of medication contained in a medication cassette reservoir supplied by AbbVie. The medication cassette reservoir attaches to the bottom of the pump.

WARNING: The CADD-Legacy® 1400 pump and medication cassette reservoir are designed for enteral delivery of medication only. They are *NOT* intended for IV or other parenteral routes of infusion. Use of this product for medications or therapies outside the intended use can result in death or serious patient injury.

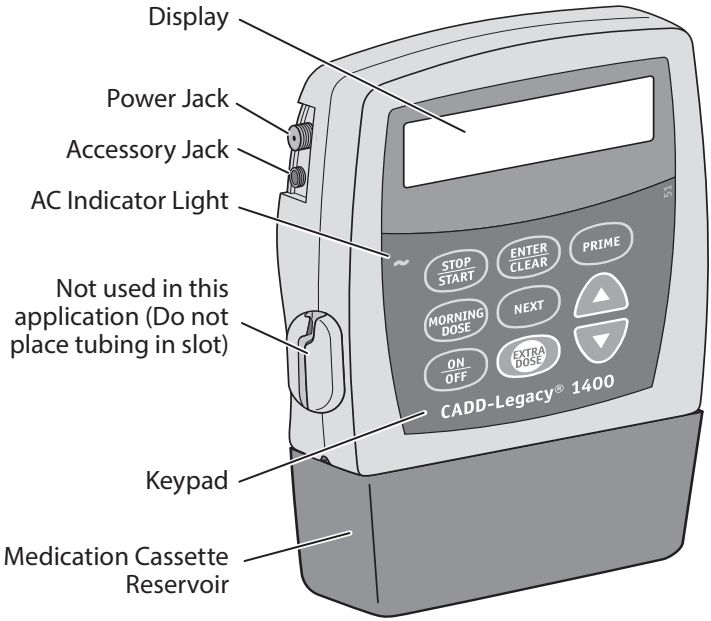
Refer to AbbVie's full prescribing information for DUOPA (carbidopa and levodopa) enteral suspension for indications and usage, contraindications, warnings, precautions, and adverse reactions.

Symbols

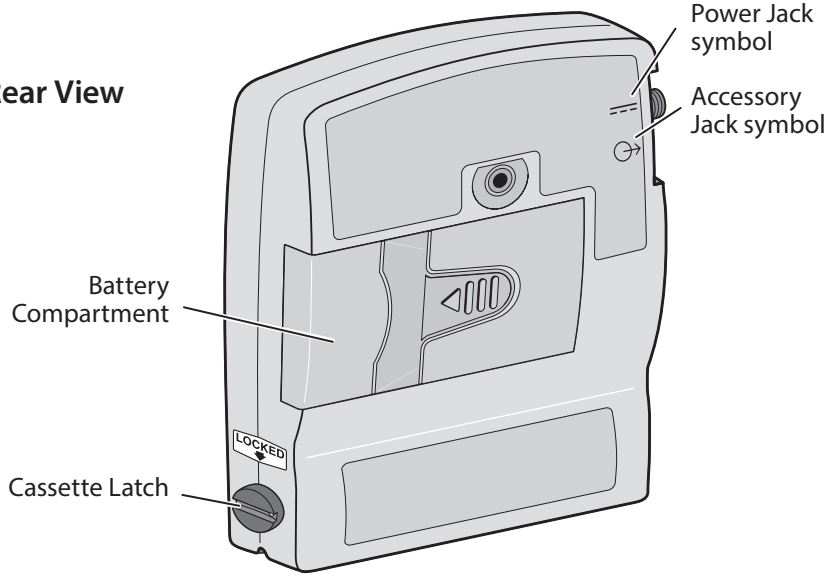
	Direct current (power jack)
	Accessory jack
	Caution
	Class II equipment
	Type CF equipment
IPX4	Splashproof – water splashed against the pump housing will have no harmful effects (see *Cleaning the Pump and Accessories*, Section 5, for additional important information).
REF	Catalog number
SN	Serial number
	Date of manufacture
	Manufacturer
Rx ONLY	**CAUTION:** Federal (USA) law restricts this device to sale by or on the order of a physician.
	Collect separately
	Temperature limitation
	Humidity limitation
	Atmospheric pressure limitation
	MR Unsafe

Pump Diagram

Front View



Rear View



Description of the Keys, Display, and Features

AC Indicator Light

The green indicator light is on when you are using the AC adapter to power the pump.

Display

The liquid crystal display (LCD) shows programming information and messages. In this manual, the term "display" is synonymous with display panel or LCD.

Keypad

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

used to start and stop pump delivery; silences alarms.

used to enter (save) a new value in the pump's memory when programming doses or pump settings or to clear values from record-keeping screens. It is also used to return from the biomed functions to the main screen (see Section 4).

used to fill the tubing with medication.

used to confirm and deliver the morning dose (typically used as a daily loading dose) when the pump is running. When the pump is stopped, it 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.)

used to move from one programming screen to the next without changing the setting or value displayed; silences alarms.

used to "scroll up" or increase a value, or scroll through biomed function settings.

used to "scroll down" or decrease a value, or scroll through biomed function settings.

used to put the pump into a low power state when not in use or back into full power.

used by the patient to deliver a programmed amount of medication upon request (extra dose).

Power Jack

You may plug an AC adapter into the power jack as an alternate source of power. The indicator light on the front of the pump will illuminate when the AC adapter is in use.

Accessory Jack

The accessory jack is used for attaching accessory cables. See the instructions for use supplied with those accessories.

Medication Cassette Reservoir

The medication cassette reservoir is the single-use reservoir designed for use with the CADD-Legacy® 1400 pump. In this manual and on the pump's display, the word "disposable" refers to the medication cassette reservoir. In AbbVie's patient instructions for use, medication cassette reservoir is referred to as DUOPA cassette.

Battery Compartment

Two AA batteries fit into the battery compartment. The AA batteries serve as the primary source of power, or as backup power when an AC adapter is in use.

Cassette Latch

The cassette latch attaches the cassette to the pump. The term "cassette" refers to the part of the medication cassette reservoir that attaches to the bottom of the pump. If the cassette becomes unlatched while the pump is running, delivery will stop and an alarm will occur. If the cassette becomes unlatched while the pump is stopped, an alarm will occur.

Other Features Not Shown

Upstream Occlusion Sensor: The pump contains an upstream occlusion sensor. This feature may be turned on or off (see Section 4, *Biomed Functions*). When the sensor is turned on, and an occlusion in the reservoir is detected, an alarm will sound, delivery will stop, and the display will show **Upstream Occlusion**.

CAUTION: When the upstream occlusion sensor is turned off, the pump will not detect occlusions in the medication cassette reservoir. Periodically inspect the medication cassette reservoir for decreasing volume. Undetected occlusions could result in under- or non-delivery of medication.

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

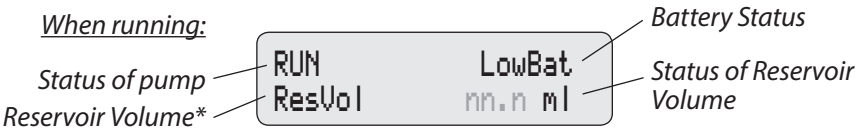
Reservoir Volume Alarm: The reservoir volume alarm indicates when the volume of medication in the medication cassette reservoir is low or depleted. Each time you change the medication cassette reservoir, you may reset the reservoir volume to the originally programmed value. Then, as medication is delivered, the reservoir volume automatically decreases. When the pump calculates that 5 ml remain in the medication cassette reservoir, beeps sound and **ResVol Low** appears on the main screen. This alarm recurs at every subsequent decrease of 1 ml until the reservoir volume reaches 0 ml, at which point the pump stops and the reservoir volume empty alarm sounds.

*NOTE: The default setting for Reservoir Volume is **Not in Use**. The reservoir volume alarm is activated only when a value is programmed into the Reservoir Volume screen. Programming a reservoir volume value is not required for general use, but is available at provider discretion.*

The Main Screen

The main screen is the starting point for programming or viewing the pump's settings.

If no keys are pressed for 2 minutes, the display reverts to the main screen. When the two AA batteries are low, **LowBat** appears on the main screen.



*Does not appear on the main screen if reservoir volume is programmed to **Not In Use**.

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.

Security Codes

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

Text Omitted

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 compromise patient treatment.

Lock Level 0 (LL0) Table

This table lists the operations that are accessible in lock level 0 (LL0) while the pump is stopped and running. LL0 permits complete access to all programming and operating functions.

Pump Operations and Programming	Stopped	Running
	LL0	Any Lock Level
Stop/Start the pump	Yes	Yes
Reset reservoir volume	Yes	***No***
Prime	Yes	***No***
Change the lock level	Yes, w/code	***No***
Change morning dose	***No***	Yes
Start an extra dose	***No***	Yes
Start a morning dose	***No***	Yes
Change continuous rate	Yes	***No***
Change extra dose	Yes	***No***
Clear given amount	Yes	***No***
Biomed Functions		
Access to functions	Yes, w/code	***No***
Extra dose lockout	Yes, w/code	***No***
Morning dose lockout	Yes, w/code	***No***
Upstream occlusion Sensor On/Off	Yes, w/code	***No***

Lock Levels 1 and 2 (LL1, LL2) Table

This table lists the operations that are accessible in lock level 1 (LL1) and lock level 2 (LL2) while the pump is stopped and running. LL1 permits limited control of pump programming and operations. LL2 permits only minimal control of pump operations.

Pump Operations and Programming	Stopped		Running
	LL1	LL2	Any Lock Level
Stop/Start the pump	Yes	Yes	Yes
Reset reservoir volume	Yes	Yes	***No***
Prime	Yes	***No***	***No***
Change the lock level	Yes, w/code	Yes, w/code	***No***
Change morning dose	***No***	***No***	Yes*
Start an extra dose	***No***	***No***	Yes
Start a morning dose	***No***	***No***	Yes
Change continuous rate	Yes*	***No***	***No***
Change extra dose	Yes*	***No***	***No***
Clear given amount	Yes	***No***	***No***

*When in LL1, you can program up to the LL0 value. No programming is allowed in LL2.

2.0 Pump Setup and Programming

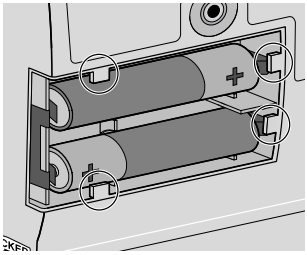
Installing or Replacing the Batteries

Use new, AA alkaline batteries such as DURACELL® or EVEREADY® ENERGIZER® batteries to power the pump. The pump retains all programmed values while the batteries are removed.

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

WARNING:

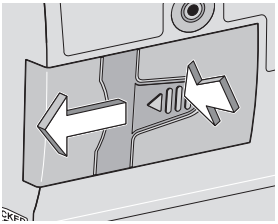
- **Always have new batteries available for replacement. If power is lost, non-delivery of medication will occur, which could compromise patient treatment.**
- **If the pump is dropped or hit, the battery door or tabs may break. Do not use the pump if the battery door or tabs are damaged because the batteries will not be properly secured; this may result in loss of power and non-delivery of medication, which could compromise patient treatment.**



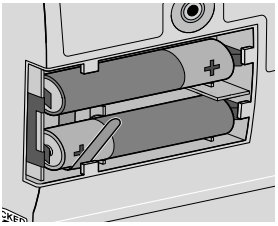
CAUTION: Do not use rechargeable NiCd or nickel metal hydride (NiMH) batteries. Do not use carbon zinc ("heavy duty") batteries. They do not provide sufficient power for the pump to operate properly.

In order to install or replace the batteries, **be sure the pump is Stopped**. Then, follow these steps:

1. Push down and hold the arrow button while sliding the door off.



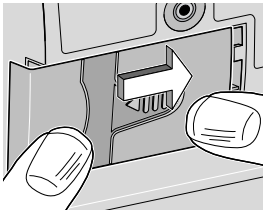
2. Remove the used batteries. Pulling on the end of the battery strap will make battery removal easier.
3. Install the new batteries in the compartment, making sure the battery strap is positioned correctly under the batteries.



NOTE:

- *Be sure to match the polarity markings of the new batteries (+ and –) with those labeled in the battery compartment. If you put the batteries in backwards, the display will remain blank, and you will not hear a beep.*
- *Use two new, AA alkaline batteries to power the pump. You may use any alkaline batteries, including DURACELL® Alkaline and EVEREADY® ENERGIZER® Alkaline, for example.*

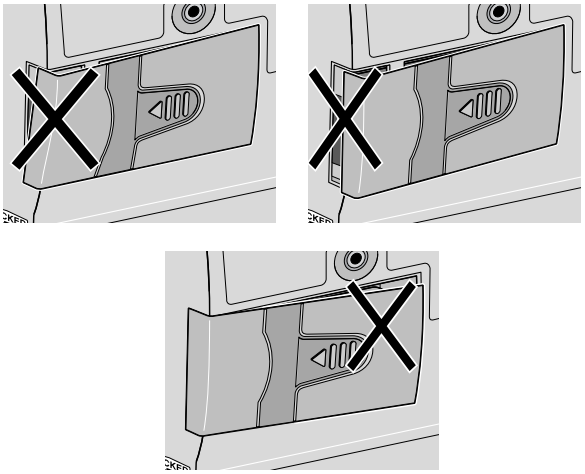
4. Place the battery door over the battery compartment and slide the door closed.



5. Ensure that the door is latched by trying to remove the door without pressing the arrow button.

   NOTE: *The power-up sequence will start, the pump will go through an electronic self-test, and the pump will beep 6 times at the end of the power-up sequence. All of the display indicators, the software revision, and each parameter will appear briefly.*

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 and non-delivery of medication, which could compromise patient treatment.



6. Resume operation of the current program by pressing and holding (STOP START) to start the pump or proceed to program the pump.

NOTE:

- *The life of the batteries is dependent on the amount of medication delivered, delivery rate, battery age, and the temperature.*
- *At the rate of 100 ml per day, alkaline batteries will usually last about 7 days.*
- *The power of the batteries will be quickly depleted at temperatures below 10°C (50°F).*

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

Watching Power Up

When you install the batteries, 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 and last error code ("LEC") if any, will appear. (If an error code appears, the pump should be removed from use and returned for service.)
- The software revision will appear.
- The display will turn on, showing a series of blocks. Look for any blank areas, which would indicate a faulty display.
- The display will turn off briefly.
- The pump's program screens will appear, followed by the current lock level setting. The pump will beep after each screen. If messages appear, see *Messages and Alarms Table,* Section 5 for further explanation and instruction.
- When power up is complete, 6 beeps will sound, and the pump will be stopped on the main screen.

NOTE: *To move quickly through the power-up screens, press* (NEXT) *repeatedly. To skip the automatic review entirely, press* (▼)*. If you attempt to skip screens before the pump is powered up, it will not respond.*

Changing to Lock Level 0 (LL0)

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

1. Make sure the pump is stopped. Press (MORNING DOSE). The current lock level will appear. (If the lock level is already LL0, press (NEXT) to exit.)

Text Omitted

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 compromise patient treatment.

Programming the Pump: General Instructions

WARNING: System delivery inaccuracies beyond the stated accuracy may occur as a result of back pressure or fluid resistance, which depends upon temperature, medication viscosity, catheter size, extension set tubing, and orientation of the pump system.

The procedure for changing a programmed setting is similar for most programming screens.

- Make sure the pump is stopped and in lock level 0.
- To begin programming, start at the main screen and press NEXT.
- To change a setting, press ▲ or ▼ until the desired setting appears. (Press and hold these keys to change values with increasing speed.)
- Press ENTER CLEAR within 25 seconds to confirm a change or the screen will revert to the previous setting.
- If any key other than ENTER CLEAR is pressed, **Value not saved** will appear. Press NEXT to return to the screen being programmed, scroll to the desired value, and press ENTER CLEAR.
- Press NEXT to advance to the next screen.
- To leave a setting unchanged, press NEXT to go to the next screen.

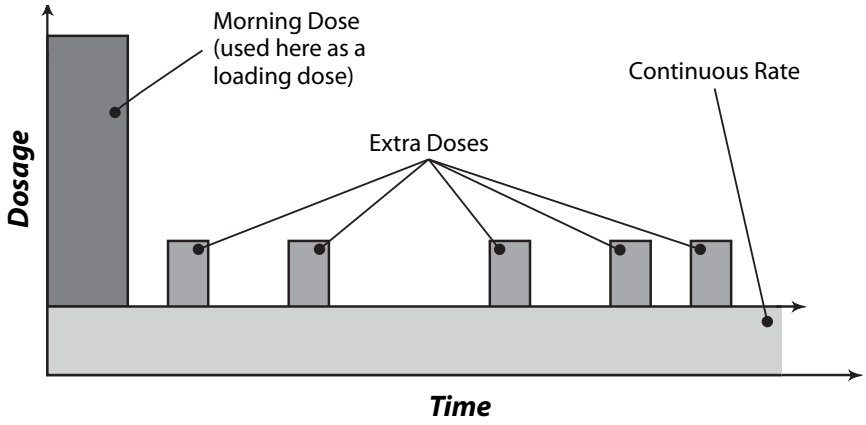
Delivery Methods

WARNING: Programming the pump at a delivery rate other than what is prescribed will cause over- or under-delivery of medication, which could compromise patient treatment. Please refer to the prescribing information for DUOPA for dosage and administration information.

The CADD-Legacy® 1400 pump offers 3 methods of delivery:

- Continuous rate
- Extra dose
- Morning dose

The following graph illustrates the combined delivery methods. The continuous rate, extra dose, and morning dose are programmed as described in this section. Ranges and programming increments are listed in the *Specifications* in Section 5.

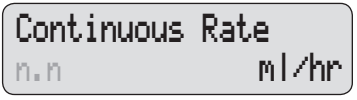


Programming Screens

These are the programming screens for the CADD-Legacy® 1400 pump. Descriptions of the screens follow.

Reservoir Volume (ml)

Continuous Rate (ml/hr)



Extra Dose (ml)

Given (ml)

Reservoir Volume

*NOTE: The default setting for Reservoir Volume is **Not in Use**. Programming a reservoir volume value is not required for general use, but is available at provider discretion.*

If you wish to use the reservoir volume feature, enter the volume of medication contained in the filled medication cassette reservoir. The reservoir volume value decreases as the pump delivers medication or as you prime the tubing. When you change the medication cassette reservoir, reset the reservoir volume value 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).

The reservoir volume value could be set higher than the capacity of the medication cassette reservoir. Be sure to program the reservoir volume to reflect the actual volume in the reservoir.

Continuous Rate

Enter the continuous rate of medication delivery in ml/hr. The maximum rate is 20 ml/hr. 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 Section 2.*

Extra Dose

Enter the amount of medication to be delivered when the patient presses (EXTRA DOSE). If the prescription does not call for an extra dose, enter zero.

NOTE**:** *If you intend to run the pump in lock level 1 so the extra 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 Section 2.*

Given

This screen shows the total amount of medication delivered since the last time this value was cleared. The amount shown is rounded to the nearest 0.05 ml. If this value reaches 99999.95, it automatically returns to 0 and continues counting. When using the pump's (PRIME) key, the amount of medication used is not included in the Given amount.

Other Programming Information

The morning dose should be programmed separately following programming of the above. Information on programming the morning dose can be found later in this section.

Programming Delivery

WARNING: Programming the pump at a delivery rate other than what is prescribed will cause over- or under-delivery of medication, which could compromise patient treatment. Please refer to the prescribing information for DUOPA for dosage and administration information.

To program the pump, enter the prescribed values.

1. Begin at the main screen.

- Make sure the pump is in LL0.
- Make sure **STOPPED** appears on the main screen.
- Press (NEXT) to begin.

2. Enter the reservoir volume (optional – not required for general use)**.**
*NOTE: The default setting for Reservoir Volume is **Not in Use**. Programming a reservoir volume value is not required for general use, but is available at provider discretion.*

- Press (▲) or (▼) to select the volume in the filled medication cassette reservoir. (If you do not wish to use the reservoir volume feature, scroll down to **Not In Use** located before 1 or after 9999.)
- Press (ENTER CLEAR).
- Press (NEXT).

3. Enter the continuous rate.

- Press (▲) or (▼) to select the desired continuous rate.
- Press (ENTER CLEAR).
- Press (NEXT).

4. Enter the extra dose amount.

- Press (▲) or (▼) to select the desired extra dose amount.
- Press (ENTER CLEAR).
- Press (NEXT).

***NOTE:** If required, program the extra dose lockout time, as instructed in Section 4, Biomed Functions.*

5. Clear the amount given.

- Press (ENTER CLEAR) if you wish to clear the amount given.
- Press (NEXT).

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.

Programming a Morning Dose

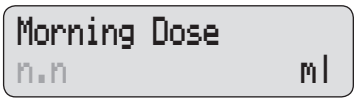
To program a morning dose the pump must be running and a medication cassette reservoir must be attached.

To program a morning dose

1. Make sure the pump is ***running*** and in LL0 or LL1. Start the pump, if necessary.

   NOTE: *In LL0, programming in the full range is possible. In LL1, you can program up to the LL0 value.*

2. Press (MORNING DOSE). The current morning dose value will appear.



3. Press (▲) or (▼) to select the desired morning dose value.
4. Press (ENTER CLEAR) to enter the value into the pump's memory. (If desired, press (MORNING DOSE) again to begin delivering the morning dose.)

Once entered, the morning dose amount is retained in the pump's memory. The patient can then press (MORNING DOSE) **twice** to display and deliver the morning dose.

NOTE: *If required, program the morning dose lockout time, as instructed in Section 4, Biomed Functions.*

Removing a Medication Cassette Reservoir

WARNING: Clamp the fluid path tubing and/or disconnect the tubing from the enteral access device before removing the medication cassette reservoir from the pump to prevent uncontrolled delivery of medication, which could compromise patient treatment.

To remove the medication cassette reservoir from the pump

1. Stop the pump.
2. Close the tubing clamp. If necessary, disconnect the tubing from the enteral access device.
3. Insert a coin into the slot in the cassette latch and turn it clockwise. The latch will pop out when you unlatch the cassette (the part of the medication cassette reservoir that attaches to the bottom of the pump).
4. A continuous alarm will sound and the pump will display **No Disposable, Clamp Tubing** (the pump is not sensing proper cassette attachment). The alarm may be silenced by pressing (STOP START) or (NEXT).
5. Remove the cassette hooks from the pump hinge pins.

Attaching a Medication Cassette Reservoir

Obtain a new, filled medication cassette reservoir.

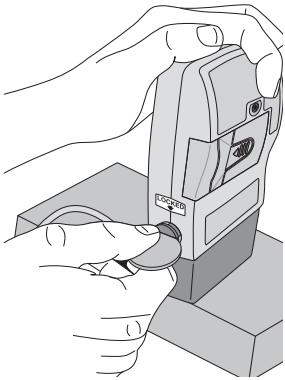
WARNING:

- **Use only approved DUOPA medication cassette reservoirs to maintain pump accuracy and assure proper pump operations.**
- **Use only extension sets approved for use with DUOPA, paying particular attention to all warnings and cautions associated with their use.**

After attaching the medication cassette reservoir, proceed to the reservoir volume screen to reset the value for the volume, and then prime the tubing.

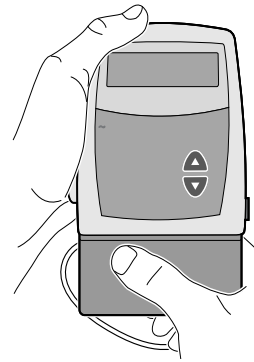
To attach the medication cassette reservoir to the pump

1. Clamp the tubing.
2. Insert the cassette hooks into the hinge pins on the pump.
3. Place the pump upright on a firm, flat surface. Press down so the cassette fits tightly against the pump.



4. Insert a coin into the slot in the cassette latch, push in, and turn counterclockwise until the line on the latch lines up with the arrow on the side of the pump and you feel the latch click into place.

WARNING: Attach the cassette properly. The cassette is the part of the medication cassette reservoir that attaches to the pump. A detached or improperly attached cassette could result in unintended delivery of medication, which could compromise patient treatment.



5. Gently twist, push, and pull on the medication cassette reservoir to make sure it is firmly attached. If the cassette is not secure, repeat the procedure from step 1.

Priming the Tubing and Connecting to the Patient

WARNING: Do not prime the fluid path with the tubing connected to a patient as this could result in over-delivery of medication, which could compromise patient treatment.

The pump must be stopped and in LL0 or LL1 in order to prime the fluid path. If the pump is in LL2, you cannot prime the fluid path.

NOTE: *If you are not changing the medication cassette reservoir but wish to prime the fluid path, you may follow the same procedure.*

1. Make sure the tubing is disconnected from the patient and the tubing clamp is open.
2. Press and hold (PRIME). You will hear a single beep, and the word **Prime** and 3 sets of dashes, each accompanied by a beep, will appear on the display.
3. After **Prime** and 3 sets of dashes appear, release (PRIME).
4. Press and hold (PRIME) again to fill the fluid path. The screen displays **Priming . . .** and you will hear a short beep each time the pump goes through a delivery cycle.

   NOTE: *Medication delivered during priming is subtracted from the reservoir volume, but is not added to the given screen since this amount is not delivered to the patient.*
5. If the tubing is not yet fully primed, press and hold (PRIME) again. If the tubing is primed, press (NEXT) to return to the main screen.

   NOTE: *Each time you press and hold (PRIME), you pump a maximum of 1 ml of medication into the tubing. The pumping action will stop automatically when 1 ml has been delivered. Release (PRIME) if you finish priming the fluid path sooner. If the fluid path is not fully primed, repeat the above priming procedure.*
6. Connect the tubing to the patient's enteral access device.
7. Set the lock level for the patient (see *Setting the Lock Level for the Patient* in this section).

Setting the Lock Level for the Patient

The lock level must be changed to LL1 or LL2 to prevent the patient from having complete access to all programming and operating functions.

NOTE: *You may change the lock level at any time by stopping the pump and following the procedure below.*

To change the lock level

Text Omitted

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 compromise patient treatment.

Programming with Upper Limits, Adjusting Doses in Lock Level 1

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

Programming the pump to use this feature

1. During initial programming in LL0, enter the ***upper limit*** values for the continuous rate, extra dose and/or morning 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, extra dose and/or morning dose to its starting value, then press (ENTER CLEAR).

Adjusting the rate or dose while the pump is in use

- If it becomes necessary to increase or decrease the continuous rate, and/or extra dose during the course of therapy, ***stop*** the pump but ***remain in LL1.***
- To increase or decrease the morning dose, the pump must be ***in LL1***, but it must remain ***running***.

1. To change the continuous rate or extra dose, press (NEXT) until the continuous rate or extra dose screen appears.

   To change the morning dose, press (MORNING DOSE).

2. Press (▲) or (▼) to select the desired value, then press (ENTER CLEAR).

   NOTE: *You will not be able to adjust the continuous rate, extra dose, or morning dose beyond the value originally programmed in LL0.*

3. Restart the pump if appropriate.

3.0 Operating the Pump

Starting the Pump

When you start the pump, programmed values will be automatically reviewed. Then medication delivery will begin as programmed, and **RUN** will appear on the main screen. **If the pump will not start,** a message will appear on the display. Refer to the *Messages and Alarms Table* in Section 5.

CAUTION: Prior to starting medication delivery, inspect the fluid path for kinks, a closed clamp, or other obstruction. An undetected occlusion may result in under- or non-delivery and/or nuisance alarms.

To start the pump

1. Press and hold (STOP START).

   Starting and 3 sets of dashes appear on the display; then the dashes disappear one-by-one, each accompanied by a single beep.

2. Release (STOP START) after the last set of dashes disappears, and the pump beeps. All of the programming screens appear for your review one after the other.

Stopping the Pump

Stopping the pump stops delivery. When the pump is stopped, **STOPPED** will appear on the main screen, and you will hear 3 beeps every 5 minutes.

To stop the pump

1. Press and hold (STOP START).

   Stopping and 3 sets of dashes appear one-by-one on the pump's display, each accompanied by a single beep.

2. Release (STOP START) after the third set of dashes appears and the pump beeps.

Turning the Pump On/Off

When the pump is stopped, you may put the pump into a low power state by turning it off. The pump may be turned off when it is disconnected from the patient and it is going to be stored for short periods of time.

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

To turn the pump off

1. Press and hold (ON/OFF). **Turning off** and 3 sets of dots will appear one-by-one on the pump's display, each accompanied by a single beep.
2. Release (ON/OFF). The display turns off.

To turn the pump on

1. Press and hold (ON/OFF) until the display turns on.
2. Release (ON/OFF). The pump will power up and automatically review all screens.

Starting a Morning Dose

A morning dose may be delivered in any lock level while the pump is running. It allows you to deliver a specified amount of medication, as a loading dose for example.

If the patient attempts to deliver a morning dose during the lockout time, the pump will not deliver the dose. The lockout time is determined by the value entered in Morning Dose Lockout, in biomed functions. The extra dose lockout setting has no effect on morning dose frequency. A morning dose may be stopped in progress.

NOTE: *A morning dose cannot be started while an extra dose or another morning dose is in progress.*

To start a morning dose

To program a morning dose, the pump must be ***running*** and a medication cassette reservoir must be attached.

NOTE: *The* (MORNING DOSE) *key must be pressed twice for morning dose delivery to start.*

1. Make sure the pump is running (in any lock level). Start the pump if necessary.

2. Press (MORNING DOSE).

   The current morning dose value (or the default value of 0 ml) will appear ***UNLESS*** the morning dose is currently locked out (in which case the screen will not appear). If the desired morning dose amount appears in the display, press (MORNING DOSE) **again** to begin delivery.

   NOTE: *If the desired morning dose amount does not appear in the display, program the desired morning dose amount as instructed in Section 2, Pump Setup and Programming.*

   The screen will show the value decreasing as the morning dose is delivered.

Starting an Extra Dose

If an extra dose has been programmed, the patient may start an extra dose while the pump is running. The amount delivered is added to the amount provided by the continuous rate.

If the patient attempts to deliver an extra dose during the lockout time, the pump will not deliver the dose. The lockout time is determined by the value entered in Extra Dose Lockout, in biomed functions.

NOTE: *An extra dose cannot be started while another extra dose or a morning dose is in progress.*

To start an extra dose

1. Make sure the pump is running (in any lock level). Start the pump if necessary.
2. Press (EXTRA DOSE). Two beeps will sound and the pump will begin delivering the extra dose.

   As the extra dose is delivered, the main screen will show **DOSE** in place of **RUN**.

Stopping an Extra Dose or Morning Dose

An extra dose or morning dose can be stopped in progress. The pump may be in any lock level.

To stop an extra dose or morning dose in progress

- Press and hold (STOP START) to stop the pump. All delivery is stopped, including the continuous rate.

Resetting the Reservoir Volume

*NOTE: The default setting for Reservoir Volume is **Not in Use**. Programming a reservoir volume value is not required for general use, but is available at provider discretion.*

To reset the reservoir volume to the value programmed in LL0, the pump may be in any lock level.

1. Stop the pump.
2. Press (NEXT) to display the reservoir volume screen.
3. Press (ENTER CLEAR) to reset the volume to the programmed value.

4.0 Biomed Functions

Overview: Accessing the Biomed Functions and Programming the Lockouts

The biomed functions are pump configurations that are less frequently changed. The biomed functions are accessible only when the pump is stopped and in lock level 0 (LL0).

To access the Biomed Functions

Text Omitted

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 compromise patient treatment.

4. Press (NEXT) to select the setting you wish to view or change, then follow the instructions in this section for the appropriate screen.

   NOTE: *To leave a biomed function setting unchanged, press* (NEXT).

5. To exit the biomed functions, press (NEXT) until you get to the screen that reads, **NEXT for Biomed, ENTER for Main**.

6. Press (ENTER CLEAR) to return to the main screen.

Extra Dose Lockout

The extra dose lockout time determines how often a patient can receive an extra dose of medication. The lockout time is the minimum amount of time which must elapse between the start of one dose and the start of the next.

To program an extra dose lockout time

1. With the pump stopped and in LL0, access biomed functions. (Refer to the beginning of the *Biomed Functions* section for instructions on how to access biomed functions.)
2. Press (NEXT) until **Extra Dose** appears.
3. Press (▲) or (▼) to scroll to the desired lockout time. The default lockout time is 1 hour.

4. Press (ENTER CLEAR) to enter the value.

CAUTION: When you enter a new value, any lockout time already in effect will be cleared. An extra dose could be requested and delivered immediately upon starting the pump, which may result in over-delivery of medication.

Morning Dose Lockout

The morning dose lockout time determines how often a patient can receive a morning dose. The lockout time is the minimum amount of time which must elapse between the start of one dose and the start of the next.

To program a morning dose lockout time

1. With the pump stopped and in LL0, access biomed functions. (Refer to the beginning of the *Biomed Functions* section for instructions on how to access biomed functions.)
2. Press (NEXT) until **Morning Dose** appears.

3. Press (▲) or (▼) to scroll to the desired lockout time.
4. Press (ENTER CLEAR) to enter the value.

CAUTION: When you enter a new value, any lockout time already in effect will be cleared. A morning dose could be requested and delivered immediately upon starting the pump, which may result in over-delivery of medication.

Upstream Occlusion Sensor On/Off

The upstream occlusion sensor can be set to **On** or **Off**. If this screen is set to **On**, and an occlusion in the medication cassette reservoir is detected, an alarm will sound, delivery will stop, and the display will show **Upstream Occlusion**.

CAUTION: When the upstream occlusion sensor is turned off, the pump will not detect occlusions in the medication cassette reservoir. Periodically inspect the medication cassette reservoir for decreasing volume. Undetected occlusions could result in under- or non-delivery of medication.

1. With the pump stopped and in LL0, access biomed functions. (Refer to the beginning of the *Biomed Functions* section for instructions on how to access biomed functions.)
2. Press (NEXT) until **Upstream Sensor** appears.

3. Press (▲) or (▼) to select **Off** or **On**.
4. Press (ENTER CLEAR) to enter the change.

5.0 Reference

Messages and Alarms, Alphabetical List

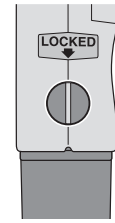
Messages and Alarms	Description / Corrective Action
[No message] TWO-TONE ALARM	With no AC adapter attached, the batteries have been removed while the pump is running. The pump is now stopped and unpowered. Install batteries to silence the alarm. **OR** Batteries were removed within approximately 15 seconds after stopping the pump. Install new batteries to silence the alarm, if desired. Otherwise, the alarm will stop within a short period of time.
[Screen displays current pump status] TWO-BEEPS (LONG-SHORT)	The medication cassette reservoir is not aligned with the pump or medication is not flowing from the medication bag inside the reservoir to the pumping mechanism. Press (STOP START) or (NEXT) to silence the alarm. The pump continues to run. Make sure the medication cassette reservoir is properly aligned with the pump and medication is flowing from the medication bag to the pumping mechanism. Very cold or extremely thick medication may cause this alarm as well. Allow the medication cassette reservoir to thaw to room temperature before attaching to the pump.
Battery Depleted TWO-TONE ALARM	The battery power is too low to operate the pump. The pump is now stopped. • Change the batteries immediately. • Press and hold (STOP START) to restart the pump.
Battery Removed Pump won't run TWO-TONE ALARM	With the AC adapter attached, the AA batteries have been removed while the pump is running, or you have tried to start the pump with depleted batteries. The pump is now stopped. Press (STOP START) or (NEXT) to silence the alarm. Reinstall batteries or install new batteries. Press and hold (STOP START) to restart the pump.

Messages and Alarms	Description / Corrective Action
Error TWO-TONE ALARM	An error has occurred. Remove the pump from service and contact Smiths Medical to return the pump for service.
High Pressure TWO-TONE ALARM	The pump has detected high pressure, which may be resulting from a downstream blockage, kink in the fluid path, or a closed clamp. Remove the occlusion to resume operation. Or, press (STOP START) or (NEXT) to stop the pump and silence the alarm for 2 minutes, then remove the occlusion and restart the pump.
Key pressed, Please release TWO-TONE ALARM	If a key is being pressed, stop pressing it. If the alarm persists, close the tubing clamp and remove the pump from use. Contact Smiths Medical to return the pump for service.
LowBat THREE TWO-TONE BEEPS EVERY 5 MINUTES	The batteries are low, but the pump is still operable. • Change the batteries soon.
Motor Locked, remove all power TWO-TONE ALARM	Batteries are depleted and the pump was powered up with the AC adapter. Install new AA batteries, reconnect the AC adapter, and restart the pump.
No Disposable, Clamp Tubing TWO-TONE ALARM	The disposable (medication cassette reservoir) was removed. The pump is not sensing proper cassette attachment. Clamp the tubing and disconnect from the enteral access device. A medication cassette reservoir must be properly attached in order for the pump to run. Press (STOP START) or (NEXT) to silence the alarm.
No Disposable, Pump won't run TWO-TONE ALARM	You have tried to start the pump without a disposable (medication cassette reservoir) attached. A medication cassette reservoir must be properly attached in order for the pump to run. Press (STOP START) or (NEXT) to silence the alarm.

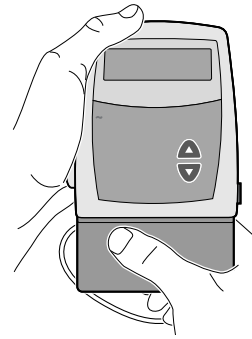
Messages and Alarms	Description / Corrective Action
Power lost while pump was on TWO-TONE ALARM	The pump was running when power was removed. Stop the pump before changing the batteries or removing the power source. Press (STOP START) or (NEXT) to silence the alarm.
Programming Incomplete TWO-TONE ALARM WHEN STARTING THE PUMP	A rate or dose must be programmed to start the pump. Press (STOP START) or (NEXT) to silence the alarm.
Reservoir Volume Empty TWO-TONE ALARM	The reservoir volume has reached 0.0 ml. Press (STOP START) or (NEXT) to silence the alarm. Then install a new medication cassette reservoir if appropriate and reset the reservoir volume.
RUN **ResVol Low** THREE SINGLE BEEPS	The reservoir volume is low. Change the medication cassette reservoir soon. See *Reservoir Volume Alarm* in Section 1 for further details.
Service Due TWO-TONE ALARM	The pump is functional, but is due for service based on clock battery age or total motor revolutions. This screen appears in LL0 for 60 days and then in all lock levels until returned for service.
Upstream Occlusion TWO-TONE ALARM	If the upstream occlusion sensor is set to On and an occlusion in the medication cassette reservoir is detected, the upstream occlusion alarm will sound. Press (STOP START) or (NEXT) to stop the pump and silence the alarm for 2 minutes, then remove the occlusion and restart the pump. You may have to detach the cassette from the pump, then reattach it.
Value not saved	A value was not saved by pressing (ENTER CLEAR). Press (NEXT) to resume programming. Verify all programming screens before moving to the next screen or starting the pump.

What if the pump is dropped or hit?

Immediately do the following:



- Check the cassette latch on the side of the pump and make sure the line on the latch lines up with the arrow on the side of the pump.



- Gently twist, push, and pull on the medication cassette reservoir to make sure it is still firmly attached.
- Check the battery door to make sure it is still firmly attached.

If the medication cassette reservoir or the battery door is loose or damaged, do not use the pump. Immediately stop the pump, close the tubing clamp, and contact Smiths Medical.

WARNING: 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, as this could compromise patient treatment.

- If the pump is accidentally dropped in water, retrieve it quickly, dry it off with a towel, and contact Smiths Medical.

Cleaning the Pump and Accessories

CAUTION:

- **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. Moisture buildup 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.**

NOTE: *Refer to the Instructions for Use for each accessory before proceeding with cleaning.*

The following solutions may be used to clean the pump and accessories, unless otherwise specified:

- Soap solution
- Benzalkonium chloride concentrate (0.13%)
- Glutaral concentrate, USP (2%)
- 10% solution of household bleach (one part household bleach to 9 parts water)
- Alcohol, USP (93%)
- Isopropyl Alcohol, USP (99%)
- Chlorhexidine gluconate (4%)
- PDI Super Sani-Cloth®
- MadaCide, Mada Medical

1. Dampen a soft, lint-free cloth with cleaning solution. Apply the solution to the exterior surface of the pump (per manufacturer's instructions). ***Do not allow the solution to soak into the pump or accessory.***
2. Wipe the entire surface dry with another soft, lint-free cloth. Allow the pump to dry completely before use.

Cleaning the Battery Contacts

Routinely clean the battery contacts, possibly as part of the preventative maintenance cycle, to remove buildup of foreign material on the contacts.

Use the following to clean the battery contacts:

- Cotton swab wetted with Isopropyl Alcohol (70% minimum)

  NOTE: *Do not use an alcohol formulation that contains components other than alcohol and water.*

  OR

- Pre-moistened alcohol swab

1. Using a swab wetted with alcohol, rub the entire battery contact for a minimum of 10 back and forth cycles (20 total wipes over the contact).
2. Using a clean surface of the swab, repeat process for second battery contact.
3. Using a clean swab wetted with alcohol, rub each battery contact again, a minimum of 4 back and forth cycles (8 total wipes over the contact).
4. Allow the contacts to dry completely before use.

Exposure to Radiation, Ultrasound, Magnetic Resonance Imaging (MRI), or Use near ECG Equipment

CAUTION:

- **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 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.**
- **This pump may interfere with ECG equipment. Monitor ECG equipment carefully when using this pump.**

Continuous Rate Scroll Ranges

Starting Value	Increment	Maximum
0.0 ml/hr	**0.1 ml/hr**	**20.0 ml/hr**

Extra Dose, Morning Dose Scroll Ranges

Extra Dose increment	max.
0.1 ml	9.9 ml
Morning Dose increment	**max.**
0.1 ml	20 ml

Technical Description

Standards used in Development of the Pump

The following standards were used in whole or part in the development of the pump:

IEC 60601-1 (1988), (2nd Edition, 1988) Medical Electrical Equipment, Part 1: General Requirements for Safety. Amendment 1 (1991), Amendment 2 (1995).

EN 60601-1 (1990), Medical Electrical Equipment, Part 1: General Requirements for Safety. Amendment A1 (1993), Amendment A13 (1996), Amendment A2 (1995).

IEC 60601-1-2 (2007), Medical Electrical Equipment, Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests.

EN 60601-1-2 (2007), Medical Electrical Equipment, Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests.

The following are reference test methods applied to IEC/EN 60601-1-2:

IEC/EN 61000-4-2, Electromagnetic Compatibility (EMC), Part 4: Testing and measurement techniques. Section 2: Electrostatic Discharge immunity test. Basic EMC Publication.

IEC/EN 61000-4-3, Electromagnetic Compatibility (EMC), Part 4: Testing and measurement techniques. Section 3: Radiated, radio frequency, electromagnetic fields immunity test. Basic EMC Publication.

IEC/EN 61000-4-4, Electromagnetic Compatibility (EMC), Part 4: Testing and measurement techniques. Section 4: Electrical fast transients/bursts immunity test. Basic EMC Publication.

IEC/EN 61000-4-5, Electromagnetic Compatibility (EMC), Part 4: Testing and measurement techniques. Section 5: Surge immunity test. Basic EMC Publication.

IEC/EN 61000-4-8, Electromagnetic Compatibility (EMC), Part 4: Testing and measurement techniques. Section 8: Power frequency magnetic field immunity test.

IEC/EN 61000-4-11, Electromagnetic compatibility (EMC) - Part 4: Testing and measuring techniques - Section 11: Voltage dips, short interruptions and voltage variations immunity tests.

IEC 60601-2-24 (1998), Medical Electrical Equipment, Part 2-24: Particular Requirements for Safety of Infusion Pumps and Controllers.

EN 60601-2-24 (1998), Medical Electrical Equipment, Part 2-24: Particular Requirements for Safety of Infusion Pumps and Controllers.

IEC 60601-1-4 (2000), Medical Electrical Equipment, Part 1: General Requirements for Safety – Collateral Standard: Programmable electrical medical systems.

EN 60601-1-4 (1996), Medical Electrical Equipment, Part 1-4: General Requirements for Safety – Collateral Standard: Programmable electrical medical systems. Amendment A1: 1999.

EN 980 (2008), Graphical symbols for use in the labeling of medical devices.

FCC Part 15 Subpart B, Radiofrequency Devices, Unintentional Radiators.

RTCA/DO -160C, Radiated Emissions Only, Category A & Z Limit.

EN 55011 (2007), Limits and Methods of Measurement of Radio Interference Characteristics of Industrial, Scientific and Medical (ISM) Equipment. Amendment A2: 2007. (Equivalent to CISPR 11: 2003 + Amendment A2: 2006).

CISPR11 (2009), Limits and methods of measurement of electromagnetic disturbance characteristics of industrial, scientific and medical (ISM) radio frequency equipment. Amendment 1 (1996) Amendment 2 (1996).

For **CISPR11** tests, the pump was fitted with an administration set with its inlet connected to a 250 ml bag and its outlet routed back to the bag forming a closed loop system. A total of 6 feet of tubing was used to form the closed loop.

Specifications (Nominal)

General Pump Specifications

Resolution	medication cassette reservoir: 0.05 ml per pump activation nominal
Size	4.1 cm × 9.5 cm × 11.2 cm *[1.6 in. × 3.8 in. × 4.4 in.]* excluding medication cassette reservoir
Weight	392 g *[13.8 oz.]* including 2 AA batteries, empty 100 ml medication cassette reservoir, excluding other accessories
Classification (IEC 60601-1)	CF ♥, Class II □
Moisture protection	Splashproof (IPX4)
Pump alarms	Low battery power; depleted battery power; battery dislodged; pump stopped; pump fault; low reservoir volume; high pressure; disposable not attached when run attempted; motor locked; upstream occlusion; reservoir volume empty; program incomplete; remote dose cord removed; key stuck; disposable detached.
Maximum infusion pressure	40 psi *[2.76 bar]*
Maximum time to occlusion alarm (actual test data)	DUOPA (carbidopa and levodopa) enteral suspension: 10 hours 30 minutes
Bolus volume at occlusion alarm pressure	0.05 ml resolution medication cassette reservoir: <1.1 ml

Power sources ..... AC adapter; Two AA alkaline batteries

Battery life ..... The expected life of 2 AA batteries is 100 hours at 100 ml/16 hours, or approximately 14 days at 10 ml/day (nominal). This estimate is based on laboratory tests conducted at room temperature using two new batteries. Actual battery life will vary depending on the brand of battery, battery shelf life, temperature conditions, and delivery rate. It is recommended that two new AA batteries be kept available for replacement if necessary.

An internal battery powers the clock. When it is depleted, it cannot reliably maintain the clock time. This battery must be replaced by the manufacturer. The internal battery has an expected life of 5 years.

System operating temperature ..... 2°C to 40°C (36°F to 104°F)

System storage and transportation temperature ..... -20°C to 60°C (-4°F to 140°F)
When shipping, use pump case.

System delivery accuracy (DUOPA [carbidopa and levodopa] enteral suspension):

Therapy [1] ..... ± 10%

Continuous rate [2] ..... ± 10% @ flow rates 0.4 ml/hr to 20 ml/hr

Extra dose [2] ..... ± 10%

Morning dose [2, 3] ..... ± 10%

Accessories: 100 ml medication cassette reservoir with 36" 0.10" I.D. tube

[1] Therapy delivery accuracy: program to deliver a 10 ml morning dose with a 5 ml/hr continuous rate and three 3 ml extra doses, with a total of 100 ml of medication delivered. Pumps were evaluated in latch down, upside down, and horizontal position. The medication cassette with DUOPA (carbidopa and levodopa) enteral suspension is initially cold (approx. 2°C). Remove cassette from refrigerator, wait 20 minutes, then conduct the test at nominal temperature. [2]

[2] At nominal temperature (23°C ± 5°C)

[3] An additional -4% change may be seen when cassette starting temperature is 2°C and placed at room temperature (23°C ± 5°C) for 20 minutes prior to use.

WARNING: System delivery inaccuracies beyond the stated accuracy may occur as a result of back pressure or fluid resistance, which depends upon temperature, medication viscosity, catheter size, extension set tubing, flow rate, and orientation of the pump system.

System definition ..... System is defined as a CADD-Legacy® 1400 pump with attached medication cassette reservoir supplied by AbbVie

High pressure alarm ..... 26 ± 14 psi *[1.79 ± 0.97 bar]*

Maximum volume infused under single fault condition ..... medication cassette reservoir: 0.2 ml.

Delivery rate during priming ..... Approx. 125 ml/hr

Delivery Specifications

Reservoir volume .... 1 to 9999 or Not In Use; programmable in 1 ml increments, displayed in 0.1 ml increments
Default: Not In Use

Continuous rate ..... 0 to 20 ml/hr in 0.1 ml/hr increments
Default: 0.1 ml/hr

Extra dose ..... 0 to 9.9 ml in 0.1 ml increments
Delivery rate (continuous rate + extra dose): 40 ml/hr
Default: 0 ml

Given ..... 0 to 99999.95 in 0.05 unit increments

Morning dose ..... 0 to 20.00 ml in 0.1 ml increments
Delivery rate (continuous rate + morning dose): 40 ml/hr
Default: 0 ml

Biomed Functions

Extra dose lockout .. 15 minutes to 24 hours in 15 minute increments
Default: 1 hour

Morning dose
lockout ..... 1 to 24 hours in 1 hour increments
Default: 20 hours

Upstream sensor ..... Off
On
Default: Off

Accuracy Test Results

The following graphs are designed to show flow accuracy of the infusion system plotted against given time periods. The medication cassette reservoir used for flow accuracy tests was supplied by AbbVie.

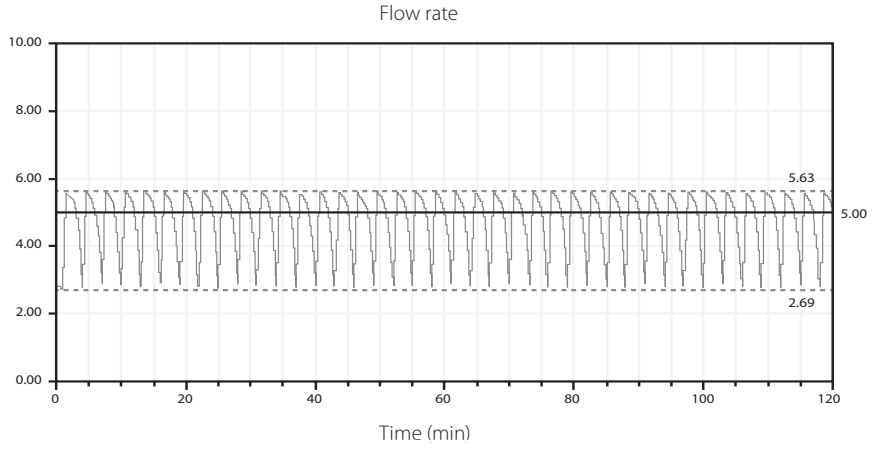
Flow rate immediately following startup

Time Interval: 0.5 min

Total Time: 120 min

Programmed Rate: 5 ml/hr

Reservoir Used: 100 ml medication cassette reservoir



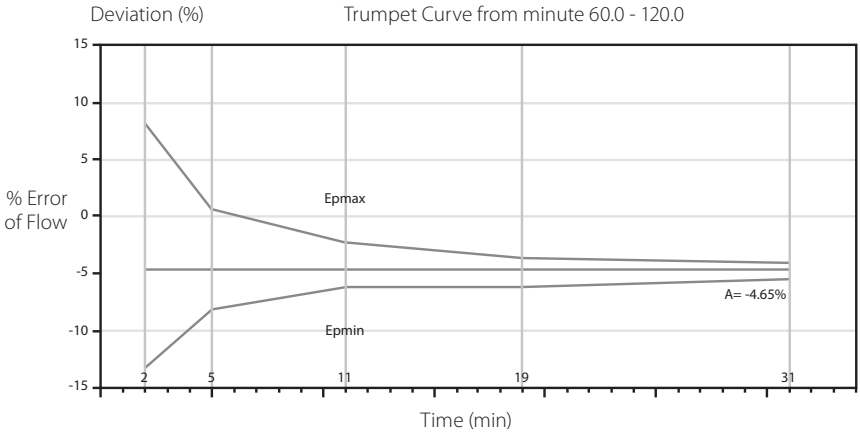
Short term flow rate error

Programmed Rate: 5 ml/hr

Average Flow Rate: 4.76 ml/hr

Mean Flow Error: –4.65%

Reservoir Used: 100 ml medication cassette reservoir



Electromagnetic Emissions and Immunity Declarations

Electromagnetic emissions declaration		
The Pump is intended for use in the electromagnetic environment specified below. The customer or the user of the Pump should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions, CISPR 11	Group 1	The Pump uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions, CISPR 11	Class B	The Pump is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Compliance using:

1. 115VAC/60HZ to 8VDC Power Adapter (US) with a cord length of 274 ± 10 cm *(108 ± 4 in)*.
2. Remote Dose Cord with a length of 152 ± 5 cm *(60 ± 2 in)*.

WARNING:

- **The Pump should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the user should verify normal operation of the pump in the configuration in which it is to be used.**
- **The use of power supplies and a remote dose cord other than those listed in the electromagnetic emissions declaration may result in increased emissions or decreased immunity of the Pump.**

Electromagnetic immunity declaration			
The Pump is intended for use in the electromagnetic environment specified below. The customer or the user of the Pump should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Pump requires continued operation during power mains interruptions, it is recommended that the Pump be powered from an uninterruptible power supply or a battery.
Power frequency 50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	400 A/m (IEC 60601-2-24)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Electromagnetic immunity declaration			
The Pump is intended for use in the electromagnetic environment specified below. The customer or the user of the Pump should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	10 Vrms	Recommended separation distance $d=0.27*P^{1/2}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	10 V/m	$d=0.27*P^{1/2}$ 80MHz to 800 MHz $d=0.54*P^{1/2}$ 800MHz to 2,5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Pump is used exceeds the applicable RF compliance level above, the Pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Pump.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Pump

The Pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Pump as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d=0.27*P^{1/2}$	80 MHz to 800 MHz $d=0.27*P^{1/2}$	800 MHz to 2,5 GHz $d=0.54*P^{1/2}$
0.01	0.03	0.03	0.05
0.1	0.09	0.09	0.17
1	0.27	0.27	0.54
10	0.85	0.85	1.7
100	2.7	2.7	5.4

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Safety Features and Fault Detection

Hardware Safety Features

Key hardware safety features include a watchdog timer circuit, motor driver and motor watchdog circuits, and a voltage detector circuit. Each safety circuit performs a unique function to insure the overall safety of the device.

Watchdog Timer Circuit

The microprocessor must send an appropriate signal to the watchdog circuit at least once per second. If the microprocessor does not, the watchdog circuit will time out and shut down the pump controller.

Watchdog timer circuitry is provided to monitor the status of the microprocessor and disable the motor and enable the audible alarm if the microprocessor fails to function properly. The microprocessor must strobe the watchdog circuit at least once every second in order to prevent the watchdog from performing its reset function. The reset output from the watchdog circuit is a pulse output. This acts to "jump start" the microprocessor. This unique feature allows the microprocessor to test the watchdog circuit on every power-up.

By setting a flag in the memory and not strobing the watchdog, the microprocessor can force a watchdog time-out. After being reset, the microprocessor checks the status flag to see if this was a time-out test. If so, the microprocessor continues normal power-up activities. If the reset occurred when the microprocessor was not expecting it, the microprocessor traps the event, sounds the audible alarm and displays an error message on the LCD.

Motor Driver/Motor Watchdog Circuit

Motor drive circuitry is composed of a series of power FET transistors, passive components, and 2 voltage comparators. Built into the motor drive circuitry is an RC timer which times how long the motor runs each time it is turned on. If the motor runs for more than an average of 3 seconds, the circuit will time out and disable the motor. A unique feature of this circuit is that control lines to and from the microprocessor circuit allow the microprocessor to perform a complete functional test of the motor drive circuit without running the motor. The microprocessor

performs this test function every several minutes to assure its continued functionality. An input from the watchdog circuit prevents motor operation if the watchdog timer expires. The software verifies this function during the watchdog test described above.

Voltage Detector Circuit

Low voltage detection is performed by part of the watchdog circuit and by the microprocessor via software. Three low voltage levels are detected. The first 2 levels are detected by software and the third by hardware. The first level to be reached is the low battery warning threshold which occurs when the battery voltage decays to a nominal value of 2.4 volts when the motor is off or 1.8 volts when the motor is active. An analog to digital converter (ADC) built into the microprocessor allows the microprocessor, via software, to monitor the battery voltage. At the low battery warning threshold, the microprocessor enables a periodic series of beeps and displays a low battery warning message on the LCD. As the voltage operating the motor reaches a nominal value of 4.75 volts, the software disables delivery, places a battery depleted message on the LCD, and enables a constant two tone audible alarm. When the battery voltage decays to a nominal value of 1.0 volts, a hardware reset circuit is triggered which places the microprocessor in reset. This prevents ambiguous microprocessor operation when the battery voltage continues to decay. The hardware reset continues until the battery is completely discharged or until it is removed. Once the pump controller goes into low battery shutdown, only replacing the depleted batteries with new ones will clear the condition.

Software Safety Features

Hardware-related Software Safety Features

Program Memory Check

At power up and at regular intervals thereafter, the program memory is tested by calculating a cyclic redundancy code (CRC) on the program and then comparing it with the CRC stored with the program.

If the stored and calculated CRCs do not match, the software will display a system fault screen, turn on a continuous two-tone audible alarm, and stop all medication delivery.

RAM Memory Check

At power up, the random access memory is checked. A series of bit patterns is written to and read from each address in the RAM. If the read data is different from the written data, the software will display a system fault screen, turn on a continuous two-tone audible alarm, and stop all medication delivery.

Motor Circuit Check

At power up and at regular intervals thereafter, the motor circuit is checked to ensure that no power is being applied to the motor unless the motor is actually on. If the software detects power being applied to the motor at any other time, it will sound a continuous two-tone audible alarm and will no longer attempt to deliver medication. During every pump activation, the software checks to see whether the motor completes one activation. If the motor fails to turn, or fails to complete a cycle, the software will display a system fault screen, turn on a continuous two-tone audible alarm, and stop all medication delivery.

Keyboard Encoder Check

Every time the software receives data from the keyboard encoder, it is checked. If the data is not a valid key press, the software will disregard the key press. The keyboard is designed with redundant switches for PRIME, EXTRA DOSE, and STOP START. The software must detect that both switches are activated before taking any action.

Data Handling Software Safety Features

Data Stored in RAM

Before use, data associated with delivery and stored in RAM is tested by calculating a CRC on the data and then comparing it with the CRC stored with the data. If the stored and calculated CRCs do not match, the software will display a system fault screen, turn on a continuous two-tone audible alarm, and stop all medication delivery.

Data Stored in EEPROM

Before use, data associated with delivery and stored in EEPROM is tested by calculating a CRC on the data and then comparing it with the CRC stored with the data. If the stored and calculated CRCs do not match, the software will display a system fault screen, turn on a continuous two-tone audible alarm, and stop all medication delivery.

Data Stored in NOVRAM

Before use, data associated with delivery and stored in NOVRAM is tested by calculating a CRC on the data and then comparing it with the CRC stored with the data. If the stored and calculated CRCs do not match, the software will display a system fault screen, turn on a continuous two-tone audible alarm, and stop all medication delivery.

Data Used in Calculations

Calculations on data used in some way to control the delivery of medication are performed redundantly.

The two calculated values are then compared. If the two values do not match, the software will display a system fault screen, turn on a continuous two-tone audible alarm, and stop all medication delivery.

Timer Data Registers

The data in the real time clock is checked at regular intervals. If the data is not reasonable, the software will turn on a continuous two-tone audible alarm and stop all medication delivery.

Annual Functional Inspection

Smiths Medical recommends annual functional inspections and tests on the CADD-Legacy® 1400 pump. Contact Smiths Medical to coordinate return and inspection of the pump.

CAUTION: CADD-Legacy® 1400 pumps are sealed units. A broken or damaged seal will, therefore, be considered conclusive evidence that the pump has been misused and/or altered, which voids any and all warranties. All service and repair of CADD-Legacy® 1400 pumps must be performed by Smiths Medical or its authorized agents.

Collect Separately

This product contains electronic and other components (such as batteries) that may contain materials which, if disposed of with general household waste, could be damaging to the environment.

In accordance with Directive 2002/96/EC Waste Electrical and Electronic Equipment, Smiths Medical requires that residents of the European Union return this product for proper disposal at the end of its useful life.

If you are unsure of the proper disposal method, contact your local distributor for specific disposal instructions.

WARNING: There are potential health hazards associated with improper disposal of batteries, electronics, and contaminated (used) reservoirs and extension sets. Dispose of used batteries, reservoirs, extension sets and other used accessories, or a pump that has reached the end of its useful life, in an environmentally safe manner, and according to any regulations that may apply.

Limited Warranty

Smiths Medical ASD, 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: **Smiths Medical ASD, Inc. 1265 Grey Fox Road, St. Paul MN 55112 USA, 1 800.258.5361 (USA)**. 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.

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Appendix A – Pump Programming Quick Reference for Healthcare Providers

This quick reference provides for step-by-step directions for several of the common pump programming tasks performed with the CADD-Legacy® 1400 pump. Additional pump information including warnings, cautions and more information on pump operations is located in the referenced sections of the pump Operator's Manual. Please refer to the full prescribing information for DUOPA (carbidopa and levodopa) enteral suspension for indications and usage, contraindications, warnings, precautions, and adverse reactions.

Begin programming the pump by:

- Attaching a medication cassette reservoir
- Turning on the pump

For instruction on attaching a medication cassette reservoir, see Section 2, *Pump Setup and Programming.*

You will need the following items to complete these steps:

- Pump
- Medication cassette reservoir

Changing to Lock Level 0 (LL0)

Lock level 0 (LL0) allows the health care provider to adjust settings so they are appropriate for the patient. For more information on lock levels descriptions, see Section 1, *General Description.* For more information on changing the lock level, see Section 2, *Pump Setup and Programming.*

Text Omitted

Pump Programming Settings

Program the pump settings to customize the medication delivery inputs for the patient. For more information see Section 2, *Pump Setup and Programming.*

NOTE: *Ensure that the pump is in lock level 0 (LL0) and* STOPPED *appears on the screen.*

1. Press (NEXT). Check for Reservoir Volume / Not in Use on the screen.

   NOTE: Not in Use *is the default setting for the reservoir volume. The reservoir volume feature is not required for use, but is available at provider discretion.*

2. Press (NEXT) again. Check for Continuous Rate / n.n ml/hr on the screen.
3. Press (▲) or (▼) to select the desired continuous rate.
4. Press (ENTER CLEAR).

Pump Status: The continuous rate is now set.

5. Press (NEXT). Check for Extra Dose / n.n ml on the screen.
6. Press (▲) or (▼) to select the extra dose amount.
7. Press (ENTER CLEAR).

Pump Status: The extra dose amount is now set.

8. Press (NEXT). Check for Given / n.n ml on the screen
9. Press (ENTER CLEAR) if you wish to clear the amount given.
10. Press (NEXT).

NOTE: *To change a setting again, press NEXT until the appropriate screen appears. Press (▲) or (▼) to adjust the setting, then press (ENTER CLEAR) to confirm.*

Changing Lockout Times

Program the dose lockout times to customize medication delivery inputs for each patient. Lockout times will determine how often a patient can deliver a morning dose and an extra dose. These values should be determined during titration. For more information on DUOPA titration, refer to the full prescribing information for DUOPA (carbidopa and levodopa) enteral suspension.

The biomed functions allow the health care provider access to the extra dose lockout and morning dose lockout settings. For more information about biomed functions, see Section 4, *Biomed Functions.*

NOTE:

- *Ensure that the pump is in lock level 0 (LL0) and* 

is on the screen.
- *When entering a new lockout value, any lockout time previously in effect will be cleared.*

Text Omitted

Text Omitted

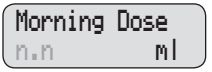
Programming the Morning Dose

Program the morning dose to customize medication delivery for the patient. For more information, see Section 2, *Pump Setup and Programming.*

CAUTION: Review programming screens when complete to make sure desired programming has been entered. Check to make sure unintended changes were not made to the morning dose, continuous rate, or extra dose volume. If unintended changes were made, go to the appropriate screen and program the desired value.

1. The pump must be ***running*** with a cassette attached and in LL0 or LL1. Start the pump, if necessary and confirm the lock level settings.

   NOTE: *In LL0, programming in the full range is possible. In LL1, you can program up to the LL0 value.*

2. Press (MORNING DOSE). 

should appear on the screen.
3. Press (▲) or (▼) to select the desired morning dose volume.
4. Press (ENTER CLEAR) to store the morning dose volume.

Setting the Lock Level

For patient use, the pump must be set to lock level 2 (LL2) or lock level 1 (LL1). For more information on lock levels descriptions, see Section 1, *General Description*. For more information on changing the lock level, see Section 2, *Pump Setup and Programming*.

Text Omitted

Manufacturer:
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St. Paul, MN 55112 USA
Tel: 1 800 258 5361 (USA), +1 614 210 7300
www.smiths-medical.com

Rx ONLY

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smiths medical