CADD™

CADD®-Solis

Ambulatory Infusion Pump

Operator's Manual

Model 2100

This online version differs from the printed version.

Certain information that is not intended for patients has been removed.

smiths medical

The CADD®-Solis ambulatory infusion system is designed to promote patient care and safety for a variety of adult and pediatric patients and clinical care areas, including, but not limited to, post-operative, trauma, critical care, oncology, and labor and delivery. This manual concerns only the CADD®-Solis ambulatory infusion pump. This pump can be programmed with a pump protocol configuration, consisting of a therapy, qualifier, and drug. The pump can deliver medication at a constant rate and/or with a bolus dose.

This manual is intended for clinician use only, do not permit patients to have access to it. The pump has three security levels designed to limit overall patient access and clinician access to certain pump features. Only disclose the pump's security codes to those who are authorized. Patient and unauthorized clinician access to the pump key should also be restricted.

The issue date of this Operator's Manual is included on the back cover. In the event one year has elapsed between the issue date and product use, the clinician should contact Smiths Medical to see if an updated revision of this manual is available.

Technical Assistance

If you have comments or questions concerning the operation of the CADD®-Solis ambulatory infusion pump, please call the number given below. When calling, please specify the pump's software version number. This information is located in the Device Information Report (See *Reports* on page 27).

Our staff at Smiths Medical is available to help twenty-four hours a day with the programming and operation of the CADD®-Solis ambulatory infusion pump.

U.S. Distribution:

Smiths Medical MD, Inc.
1265 Grey Fox Road
St. Paul, MN 55112
1 800.426.2448
+1 651.633.2556
www.smiths-medical.com

European Distribution:

Smiths Medical International Ltd.
WD24 4LG, UK
+44 (0) 1923 246434

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

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

WARNINGS

- This operator's manual should be used by clinicians only. Do not permit patients to have access to this manual, as the information contained would allow the patient complete access to all programming and operating functions.
- To avoid explosion hazard, do not use the pump in the presence of flammable anesthetics or explosive gases.
- For those patients who are likely to be adversely affected by unintended operations and failures, including interrupted medication or fluid delivery from the device, close supervision and provision for immediate corrective action should be provided in order to assure minimum medication delivery interruption. Pump failure will suspend medication delivery, and unintended pump operations could lead to a variety of consequences for the patient.
- If the pump is used to deliver life-sustaining medication, an additional pump must be available, and close supervision and provision for immediate corrective action should be provided to assure minimum medication delivery interruption in the event of a pump failure. Pump failure will suspend medication delivery.
- The pump is not to be used for delivery of blood or cellular blood products, as blood and blood products will be damaged by the pumping mechanism.
- If the pump is dropped or hit, inspect the pump for damage. Do not use a pump that is damaged or is not functioning properly. Contact Smiths Medical Customer Service to return a pump for service.

- Use of a syringe with the CADD® administration set may result in UNDER DELIVERY of medication. Syringe function can be adversely affected by variations in plunger dimension and lubricity, which can result in greater force required to move the syringe plunger. A syringe plunger will lose lubrication as it ages and, as a result, the amount of under-delivery will increase which could on occasion, be significant. Therefore, the type of medication and delivery accuracy required must be considered when using a syringe with the CADD®-Solis pump.

  Clinicians must regularly compare the volume remaining in the syringe to the pump's displayed values such as reservoir volume and given in order to determine whether the under-delivery of medication is occurring and if necessary, take appropriate action.

- 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.

- Do not administer drugs to the epidural space or subarachnoid space unless the drug is indicated for administration to those spaces.

- To prevent the infusion of drugs that are not indicated for epidural space or subarachnoid space infusion, DO NOT use administration sets that incorporate injection sites.

- If a CADD™ medication cassette reservoir or CADD® extension or administration set is used for epidural space or subarachnoid space drug delivery, it is strongly recommended that it be clearly differentiated from those used for other routes of infusion, for example, by color coding, or other means of identification.

- 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.

- Always have new batteries available for replacement. If power is lost, non-delivery of drug will occur.

- There is no pump alarm to alert users that a battery has not been properly installed. An improperly installed battery could result in loss of power and nondelivery of drug.

- Always check the battery compartment for fluid or debris before inserting the batteries and do not allow any fluid or debris to fall into the battery compartment. Fluid or debris in the battery compartment may damage the battery contacts and could result in loss of power and nondelivery of drug.

- If the pump is dropped or hit, the battery door may become broken or damaged. Do not use the pump if the battery door is damaged because the batteries will not be properly secured; this may result in loss of power and nondelivery of drug.

- Follow the instructions for use provided with the CADD™ medication cassette reservoir, CADD® extension set, or CADD® administration set, paying particular attention to all warnings and cautions associated with their use.

- Attach the cassette properly. A detached or improperly attached cassette could result in unregulated gravity infusion of medication from the fluid container or a reflux of blood, which could result in death or injury to the patient.

  If you are using a CADD® administration set or CADD™ medication cassette reservoir that does not have the flow stop feature: you must use a CADD® extension set with anti-siphon valve or a CADD® administration set with either an integral or add-on anti-siphon valve to protect against unregulated gravity infusion that can result from an improperly attached cassette.

- Per general rules of safe practice, always clamp tubing before removing the cassette from the pump. Removing the cassette without closing the clamp could potentially cause unregulated gravity infusion.
- Exercise care when using the clinician bolus function. Since there are no limits on the frequency of delivering a bolus, and since the amount of the bolus can be set as high as 20 mL (or the mg or mcg equivalent), you should not permit the patient to become familiar with the procedure for giving a clinician bolus.
- To prevent the patient from accessing the clinician bolus function, do not let the patient know the security codes.
- Never leave the pump unattended while on the clinician bolus edit screen. You must press "Confirm" or "Deliver" to deliver the programmed value or cancel to leave the screen. Failure to do so could result in serious patient injury or death.
- Do not prime the fluid path with the tubing connected to a patient as this could result in overdelivery of medication or air embolism.
- Ensure that the entire fluid path is free of all air bubbles before connecting to the patient to prevent air embolism.
- The manual mode does not contain programming limits. Be sure to carefully review each parameter to ensure it accurately matches the prescription.
- Ensure that the ± 6% system delivery accuracy specification is taken into account when programming the pump and/or filling the reservoir. Failure to do so may result in medication in the reservoir becoming depleted sooner than expected.
- System delivery inaccuracies may occur as a result of back pressure or fluid resistance, which depends upon drug viscosity, catheter size, and extension set tubing (for example, microbore tubing), and placing the infusion reservoir and/or pump above or below the level of the patient.
- 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.

CAUTIONS

- To avoid damaging the pump's electronics, do not operate the pump at temperatures below 2°C (36°F) or above 40°C (104°F)
- To avoid damaging the pump's electronics, do not store the pump at temperatures below –20°C (–4°F) or above 60°C (140°F). Do not store the pump with a medication cassette reservoir or CADD® administration set attached.
- To avoid damaging the pump's electronics, do not expose the pump to humidity levels below 20% or above 90% relative humidity.
- CADD® 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® pumps must be performed by Smiths Medical or its authorized agents.
- Inspect the AA batteries for damage or wear to the metal or plastic insulation prior to use, or after the pump has been dropped or hit. Replace the batteries if any damage is noted.
- Do not store the pump for prolonged periods with the batteries installed. Battery leakage could damage the pump.
- If the power up results in an error message indicating that the protocol library was lost, do not proceed with using the pump. Follow your facility's procedures for downloading protocol libraries.

- Only use accessories that are specified for use with the CADD®-Solis ambulatory infusion pump.
- If you are using a medication cassette reservoir in which the medication is frozen, thaw at room temperature only. Do not heat in a microwave oven as this may damage the product and cause leakage.
- If the power up results in an error message indicating that the protocol library was lost, do not proceed with using the pump. Follow your facility's procedures for downloading protocol libraries.
- Do not immerse the pump in cleaning fluid or water. Do not allow solution to soak in to the pump, accumulate on the keypad, or enter the battery compartment, USB port, remote dose cord jack, or power jack areas. 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.
- The pump SHOULD NOT BE DIRECTLY IRRADIATED by therapeutic levels of ionizing radiation because of the risk of permanent damage to the pump's electronic circuitry. The best procedure to follow is to remove the pump from the patient during therapeutic radiation sessions or diagnostic levels of radiographic and fluoroscopic radiation. If the pump must remain in the vicinity during a diagnostic or therapy session, it should be shielded, and its ability to function properly should be confirmed following treatment.
- Do not expose the pump directly to ultrasound, as permanent damage to the pump's electronic circuitry may occur.
- Magnetic fields produced by magnetic resonance imaging (MRI) equipment may adversely affect the operation of the pump. Remove the pump from the patient during MRI procedures and keep it at a safe distance from magnetic energy.
- Use of this pump on patients monitored by electronic equipment may cause artifactual interference. As with all electronic equipment, electrical artifacts which affect the performance of other equipment, such as ECG monitors, can occur. The user should check the correct function of the equipment prior to use.
- Do not use the pump in hyperbaric chambers as they will affect how the pump works and may also cause damage to the pump.

Table of Contents

General Description

Introduction

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

Indications

The CADD®-Solis ambulatory infusion pump is indicated for intravenous, intra-arterial, subcutaneous, intraperitoneal, in close proximity to nerves, into an intraoperative site (soft tissue, body cavity/surgical wound site), epidural space, or subarachnoid space infusion. The pump is intended for therapies that require a continuous rate of infusion, patient-controlled demand doses, or both (such as patient-controlled analgesia).

Epidural/Subarachnoid Administration

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

Analgesics

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

Anesthetics

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

WARNING:

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

Symbols

Direct Current (Power Jack)

Consult Instructions for Use

Caution

Class II Equipment

Type CF Equipment

IPX4 Splashproof—water splashed against pump housing will have no harmful effects (see *Cleaning the Pump and Accessories* on p. 44 for additional important information)

Date of Manufacture

REF Catalog Number

SN Serial Number

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

EC REP Authorized Representative in the European Community

AUS REP Australian Representative

Power on/off button

USB port

Remote dose cord jack

Cassette lock/unlock

AA battery location, positive terminal faces up

AA battery location, negative terminal faces up

AA battery location, positive terminal faces up

AA battery location, negative terminal faces up

Symbols on the pump's display

Indicates reservoir volume

Rechargeable battery pack charge level

Rechargeable battery pack charge level, with AC adapter

AA battery charge level

AA battery charge level, with AC adapter

No battery installed, AC power only

Incompatible battery

Incompatible battery, with AC adapter

Pump status is running

Pump status is paused or in KVO

Pump status is stopped

Arrows used in the soft key bar indicating there are more items to see by pressing ▲ or ▼

Arrows used in the soft key bar indicating the top of the menu, press ▼ to move through the menu

Arrows used in the soft key bar indicating the bottom of the menu, press ▲ to move through the menu

Home screen

Indicates keypad is locked

Indicates keypad is unlocked

✓ Appears next to parameter if it has been reviewed and accepted

⇨ Appears on edit screens where a value is scrolled; indicates where the value is being scrolled

▶ Appears on edit screens where there is a menu of options; indicates which setting is being selected

⊘ Indicates the requested action could not be performed (e.g., wrong security code entered)

✚ Appears on PCA dose report to indicate more data is available

Review screen

Appears when the pump is saving an edited parameter

Features of the pump system

The CADD®-Solis ambulatory infusion system delivers break-through advancements in patient-centered pain management infusion solutions. The CADD®-Solis ambulatory infusion pump and CADD®-Solis Medication Safety Software are designed to help promote optimal patient safety, patient care, and a scalable connectivity platform designed to grow with evolving clinical and technology needs.

Patient Safety—Built-in medication delivery safety features and advancements in programming simplicity enable a patient-focused, treatment-orientated infusion system designed to help address medication safety goals and reduce the risk of programming errors:

- State-of-the-art technology designed to meet advanced dose-error reduction guidelines:
  - Initial programming set-up.
  - Dose limits.
  - Indication of overridden soft limits.
  - Configure protocol library to current practices.
  - Software that is simple to operate.
  - Display protocol and drug name at all times.
  - Tracks limit overrides and programming changes.
- Customizable therapy-based protocol libraries deploy user's best practices in all care areas:
  - Facility-defined protocol library includes the therapy, qualifier, drug, unit/concentration, dose limits, and drug delivery parameters.
  - Personalize therapy within user-defined soft and hard limits.
  - Simulates standard flow sheet used in many healthcare facilities.
- Secure access and simple menu structure with soft-key interface and familiar CADD® pump scroll keys:
  - Soft key interface helps make programming and navigating intuitive and easy.
  - Scroll keypad prevents entering values outside of defined program limits.
  - Designate authorized users with levels of security access.

Patient Care—A versatile multi-therapy infusion system designed to support pain management medication delivery needs. The compact, lightweight design promotes patient mobility, which is associated with improved clinical outcomes, reduced length-of-stay, and reduced treatment costs:

- A highly versatile, multi-therapy pain management infusion system:
  - IV PCA, epidurals, nerve blocks, surgical site infusion therapies.
  - Therapies that require a continuous rate of infusion, patient-controlled PCA doses, or both (such as patient-controlled analgesia).
  - Post-op, labor and delivery, trauma, and pediatrics.
- Medication delivery focused on the point of care:
  - Strikingly clear screen displays therapy protocol, drug, medication delivery settings, and status.
  - Color indicators of therapy protocol, pump operating status, and alarms/alerts.
- Immediate access to patient data to assist with patient assessment with on-screen color graphs and trending data:
  - Unique graphs, trend reports and user audit trail facilitate patient-centered care management and promote continuous quality indicators (CQI) processes.
  - Reports include: given and PCA dose counters, PCA dose graph, delivery history and pie chart, delivery log, event log, protocol summary library, device information.
- Human factors design testing to help ensure ease-of-use:
  - Rigorous testing and analysis resulting in an intuitive design with easy to operate controls and high contrast display to help save time and lower the risk of user error.
- Versatile administration set options:
  - Smiths Medical offers a wide variety of CADD® administration sets, featuring exclusive medication cassette reservoirs to promote patient mobility.

Scalable Connectivity—The flexible architectural platform is ideal to grow with your evolving clinical and technology road map.

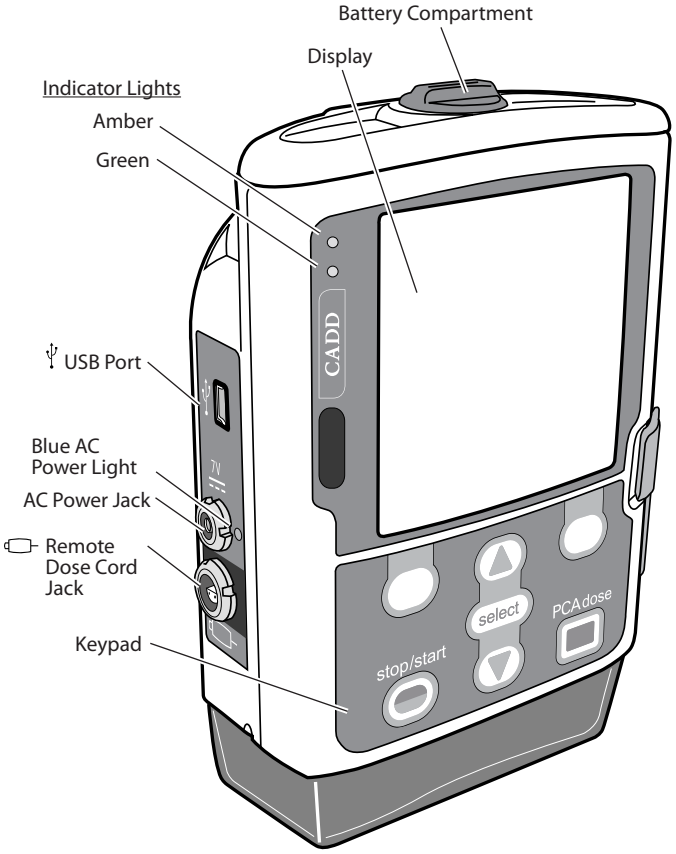
- Flexible design supports future point of care expansion needs:
  - Unique platform provides immediate clinical care benefits and flexibility to sustain our vision of evolutionary IT infrastructure needs.
  - Promotes maximum patient safety, personalized therapy for patient needs, supports best practices and enables continuous quality improvements.

Additional features of the CADD®-Solis ambulatory infusion system:

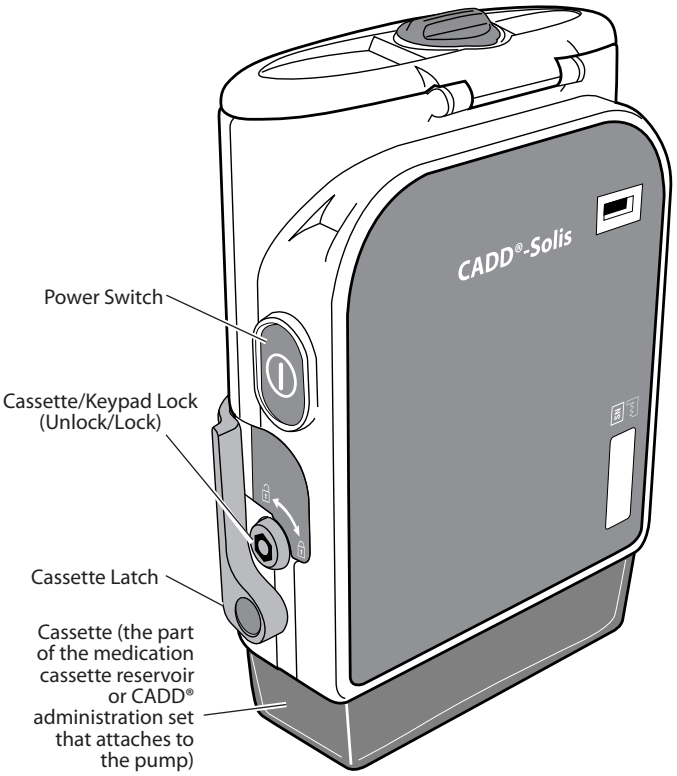
- Use with CADD®-Solis Medication Safety Software to optimize capabilities:
  - Use with CADD®-Solis Medication Safety Software to optimize medication delivery safety features and comprehensive management and analysis capabilities of the CADD®-Solis ambulatory infusion system.
- Firmware design highlights:
  - TALL/short man display style along with units of measurement and/or concentration promotes added safety.
  - Status bar displays reservoir volume status, delivery status, and power status at all times, unless there is an alarm/alert condition, and each indicator is color-coded green, amber or red for an immediate visual indication of pump operating status.
  - Screen title bar with help text helps the user easily identify their location in the pump menu.
  - Alarm/alert screens are color coded to low, medium, and high priority conditions.
  - Therapy, qualifier, drug, concentration/ units, and keypad lock status displayed at all times except when viewing reports or during alarm/alert conditions.
  - Print bar codes and prescription forms.
- Hardware design highlights
  - Cassette latch designed to help easily attach the medication cassette reservoir.
  - PCA dose ▣ key on pump for convenient PCA dose availability while patient is ambulatory.
  - Remote PCA dose cord with LED ergonomically designed to facilitate patient's ease of use.
  - Agile polemount bracket adapter attached to back of pump enhances visibility on IV pole.
  - Three power sources offer versatile and economic options: 4 AA batteries; rechargeable battery pack, and AC power.
  - Integral air-in-line detection to notify user of presence of air-in-tubing.
  - PM (preventative maintenance) reminder available.
  - Splash proof (IPX4) moisture protection.
- Additional highlights
  - User-friendly, easy-to-teach programming/ navigation menu may help shorten staff in-service time and promotes patient bedside care.
  - Three levels of customizable security access levels: keypad code; clinician code; administrator code, allows facility to designate user access.
  - Cassette/keypad lock promotes added safety.
  - On-board library holds up to 500 therapy protocols.
  - Adjustable alarm/alert volumes to meet specific clinical setting needs.
  - Event log holds up to 5,000 events.
  - Clinical, technical, and implementation support are offered 24/7 by Smiths Medical.

Pump Diagram

Front View



Rear View



Description of the Keys, Components, Ports, and Connectors

Indicator Lights

When the pump is powered, one or both of the indicator lights will flash.

Green: The green light flashes to indicate that the pump is running and delivering fluid as programmed.

Amber: The amber light flashes when the pump is stopped, an alarm condition exists, or the battery or the reservoir volume is low. It stays on continuously when the pump is inoperable. The display will briefly describe the alarm condition when the amber light is flashing.

NOTE: At times both lights may flash. This indicates that the pump is running, but there is a condition the clinician should be aware of (e.g., low battery or low reservoir volume).

Display with backlighting

The liquid crystal display (LCD) shows programming information and messages. Backlighting helps keep the display visible in low light. In this manual, "display" is synonymous with display panel or LCD.

After a period in which no keys are pressed, the backlighting turns off and the display goes blank to save battery power (except during an alarm or when an external power source is in use). You may press any key to turn the display back on.

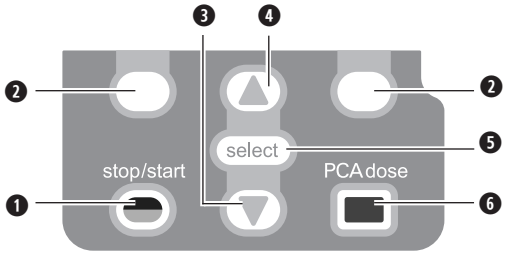
NOTE: When the display is blank, you can determine that the pump is powered by observing either the green or amber (or both) LED indicators periodically flashing.

NOTE: If you press stop/start, the display will reappear with a message asking if you wish to start or stop the pump.

NOTE: If you press PCA dose while the pump screen is blank, the pump will deliver a PCA dose, if available.

Keypad

The keys on the keypad are described below. A key beeps when pressed if it is operable in the current state of the pump. However, the keys will not beep if the key beep function has been turned off in the protocol or the administrator settings.



❶ Starts and stops pump delivery.

❷ Allows you to answer a question on the pump's display. For example, the screen above this key may display "Yes," in which case pressing this key would give the question displayed on the screen an answer of "Yes." Also allows you to navigate through some of the pump's screens (e.g., canceling an action, opening the reports/tasks menus, or backing out of an open screen). Referred to as "soft keys."

❸ Allows you to navigate through the menus on the pump, scrolling down.

❹ Allows you to navigate through the menus on the pump, scrolling up.

❺ Used to select a menu item.

❻ Allows the patient to request a PCA dose, if the remote dose cord is not connected. If the remote dose cord is connected this key will be inactive.

Power Switch

Turns the pump on or off. Press and hold the switch to turn the pump on. Press the switch to turn the pump off and confirm that you want to power down by selecting **Yes**.

Power Jack

You may plug the AC adapter into the power jack. When the AC adapter is plugged in, the blue power light turns on. This light is on regardless of the pump's on or off status. (See *Desktop AC Adapter* on page 15 for more information.)

USB Port

A mini-B USB cord can be attached to the USB port for communications with the CADD®-Solis Medication Safety Software.

Remote Dose Cord Jack

The remote dose cord jack is used for attaching the remote dose cord. (See *Remote Dose Cord* on page 16 for more information.)

Battery Compartment

Four AA batteries or the rechargeable battery pack fit into this compartment. The batteries serve as the primary source of power, or as a backup when the AC adapter is in use. (See *Installing the Batteries* on page 14 for information on how to install the batteries.)

Cassette Latch

This is used to attach the cassette to the pump. When the pump is turned on, it will detect whether the cassette is latched properly. Delivery will stop and an alarm will occur if the cassette becomes unlatched. (See *Attach a Cassette* on page 18 and *Remove a Cassette* on page 19.)

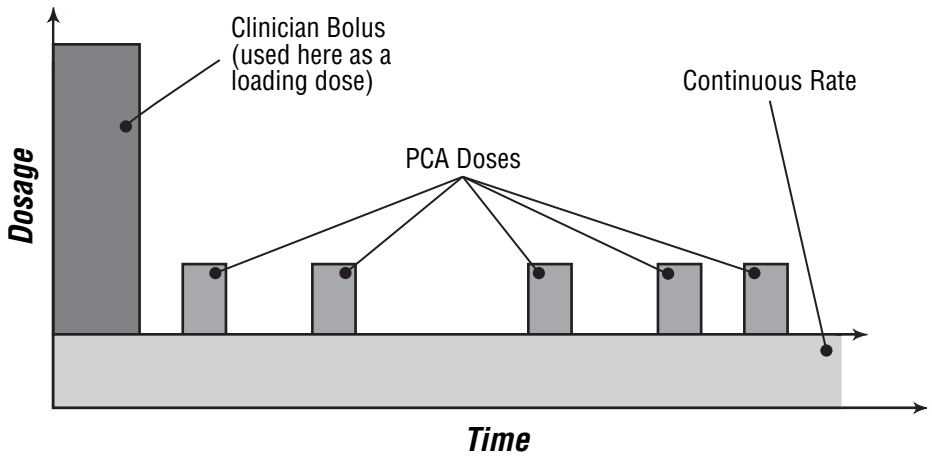
Cassette/Keypad Lock

This allows you to secure the cassette to the pump using the pump key provided. The cassette latch must be latched before it can be locked. The cassette/keypad lock can be configured to unlock only the cassette latch or to unlock the cassette latch as well as the keypad. This is configured by your CADD®-Solis system administrator. (See *Security Settings* on page 21.)

Delivery Methods

The pump provides the following methods of delivery:

- Continuous Rate (see page 30).
- PCA Dose (see page 30).
- Clinician Bolus (see page 22).



Pump Setup

Installing the Batteries

AA 1.5 volt primary (non-rechargeable) alkaline batteries or the Smiths Medical rechargeable battery pack are recommended for use in the CADD®-Solis pump.

NOTE: Smiths Medical does not recommend mixing new and used batteries; doing so may affect low battery alarm times. Always select four new batteries when replacing them.

CAUTION: Inspect the AA batteries for damage or wear to the metal or plastic insulation prior to use, or after the pump has been dropped or hit. Replace the batteries if any damage is noted.

The pump retains all programmed values while the batteries are removed. The pump's batteries must be in place during delivery. If the batteries are removed while the pump is delivering, and an AC adapter is connected, delivery will stop. If an AC adapter is not connected and the batteries are removed, delivery will stop and the pump will lose power.

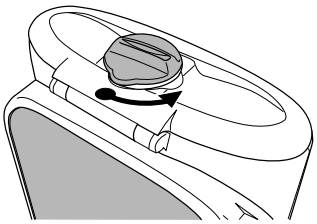
Dispose of used batteries in an environmentally safe manner, and according to any regulations which may apply.

WARNING:

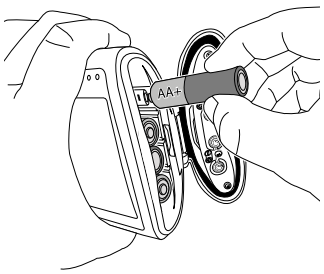
- **Do not use rechargeable NiCd or nickel metal hydride (NiMH) batteries. Do not use carbon zinc ("heavy duty") batteries. They do not provide sufficient power for the pump to operate properly, which could result in death or serious injury to the patient.**
- **Always have new batteries available for replacement. If power is lost, nondelivery of drug will occur and, depending on the type of drug being administered, could result in death or serious injury to the patient.**
- **There is no pump alarm to alert users that a battery has not been properly installed. An improperly installed battery could result in loss of power and nondelivery of drug and, depending on the type of drug being administered, could result in death or serious injury to the patient.**
- **Always check the battery compartment for fluid or debris before inserting the batteries and do not allow any fluid or debris to fall into the battery compartment. Fluid or debris in the battery compartment may damage the battery contacts and could result in loss of power and nondelivery of drug and, depending on the type of drug being administered, could result in death or serious injury to the patient.**
- **If the pump is dropped or hit, the battery door may become broken or damaged. Do not use the pump if the battery door is damaged because the batteries will not be properly secured; this may result in loss of power, nondelivery of drug and, depending on the type of drug being administered, could result in death or serious injury to the patient.**

To install the batteries:

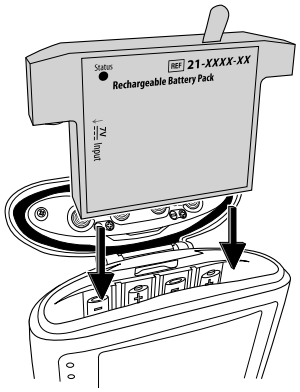
1. Make sure the pump is stopped or powered off. Using your fingers, the pump key, or a coin, turn the knob on the battery door counter-clockwise and open the battery door.



2. Hold the pump at an angle and place 4 AA batteries in the pump, from the bottom up (see picture). Match the + and - markings on the new batteries with the markings on the pump.



OR: If using a rechargeable battery pack, insert it into the pump as shown.



3. Close the battery door and using your fingers, the pump key, or a coin, turn the knob on the battery door clockwise to lock.

   NOTE: If you put the batteries in backwards, the pump will not power up. Check the batteries, making sure to match the + and - markings.

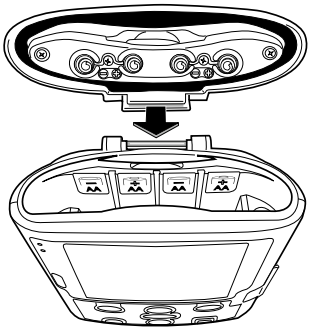
CAUTION: Do not store the pump for prolonged periods with the batteries installed. Battery leakage could damage the pump.

NOTES:

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

Replacing the battery door

If the battery door is removed or needs replacing, simply snap the door onto the bar that is located on the pump (see picture).



Power Up

Press and hold the power switch to turn the pump on. The pump will start the power up sequence during which it will perform various self-tests, test for alarm conditions, and then ask you if you want to start a new patient. Watch for the following during power-up:

- Both the green and amber indicator lights will flash.
- The display will quickly flash gray, then blue. An amber swirl will then fill the display, followed by a CADD®-Solis Ambulatory Infusion System display. Look for any stripes or black or white pixels, which would indicate a faulty display. If you see any indication of a faulty display, remove the pump from service and contact Smiths Medical Customer Service.
- After the power up is completed, listen for the Morse Code "OK" sound (a series of six audible beeps). If you do not hear this sound, there may be a problem with the audible alarms. If you believe there is a problem, remove the pump from service and contact Smiths Medical Customer Service.
- If any issues are found while the pump is performing the self tests, alarms will sound (e.g., if the battery is low or a key on the keypad is stuck in the pressed position).

CAUTION: If the power up results in an error message indicating that the protocol library was lost, do not proceed with using the pump. Follow your facility's procedures for downloading protocol libraries.

Description of pump accessories

CAUTION: Only use accessories that are specified for use with the CADD®-Solis ambulatory infusion pump.

CADD®-Solis Medication Safety Software

The CADD®-Solis Medication Safety Software allows you to create and manage protocol libraries and then import them into the pump. See the installation guide and help files that come with the system for more information.

Desktop AC Adapter

The desktop AC adapter can be used as an alternate source of power for the pump and/or to recharge the rechargeable battery pack. The pump requires that 4 AA batteries or the rechargeable battery pack are installed as a backup while using the AC adapter. You can obtain a desktop AC adapter through the Customer Service department at Smiths Medical. See the desktop AC adapter's instructions for use for more information.

Rechargeable Battery Pack

The rechargeable battery pack is an alternate to using four AA batteries and can be obtained through the Customer Service department at Smiths

Medical. The rechargeable battery pack can easily be recharged with the AC adapter, either inside or outside of the pump. See the rechargeable battery pack's instructions for use for more information.

Cassette

The cassette is the part of the medication cassette reservoir or CADD® administration set that attaches to the bottom of the pump. The following single-use products are compatible with the pump:

- Medication cassette reservoir, used with a CADD® extension set.
- CADD® administration set.

WARNING: Follow the instructions for use provided with the CADD™medication cassette reservoir, CADD® extension set, or CADD® administration set, paying particular attention to all warnings and cautions associated with their use. Incorrect preparation and/or use of these products could result in serious patient injury or death.

NOTE: A CADD® set with free-flow protection must be used in order to prevent free-flow.

NOTE: Smiths Medical recommends that the appropriate supplies needed to replace the cassettes are available in case of a damaged cassette.

NOTE: For detailed instructions and warnings pertaining to the medication cassette reservoir or CADD® administration set, please refer to the instructions for use supplied with the product for preparing the product for use.

Remote Dose Cord

The remote dose cord can be attached to the pump and provided to the patient as an alternative to pushing the PCA dose ▭ key when requesting a PCA dose. The LED on the remote dose cord indicates PCA dose status:

- **Off:** A PCA dose is not available.
- **Flashing:** A PCA dose is available.
- **On:** A PCA dose has been requested and delivery has started.

Refer to the instructions for use provided with the remote dose cord for more information.

Polemount Bracket Adapter

The optional polemount bracket adapter attaches onto the back of the pump. This allows you to attach the pump to an IV pole. Refer to the instructions for use provided with the polemount bracket adapter for information.

Polemount Bracket

The polemount bracket is used along with the polemount bracket adapter to attach the pump to an IV pole. Refer to the instructions for use provided with the polemount bracket for information.

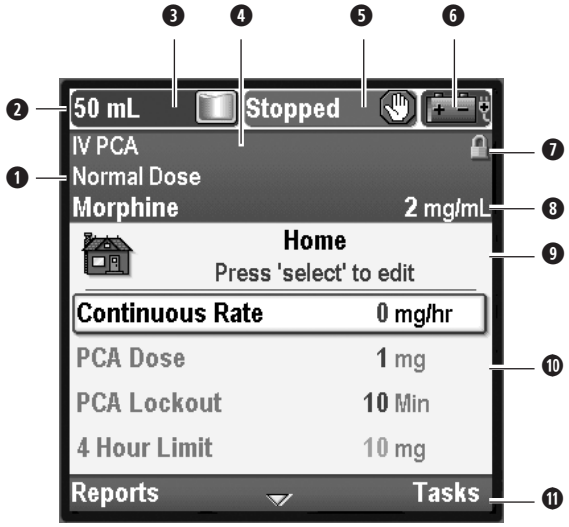
Pump Key

The pump key is used to securely lock the cassette to the pump. It can also be used to lock and unlock the keypad, if allowed by the CADD®-Solis system administrator.

Programming the Pump: General Instructions

The Pump Screen

The screen shots that you will see in this manual are only examples of what might be displayed. The protocols (consisting of therapies, qualifiers, drugs and concentrations, and all associated pump settings) in your pump library will be established by your facility.



❶ The therapy, qualifier, and drug from the current protocol.

❷ The status bar shows the status of the pump. It also displays messages and alerts, for example, if you locked or unlocked the cassette/keypad lock or the keypad, attached a cassette, or reached delivery limit.

❸ The current value of the reservoir volume.

❹ The color of the screen is dependent on how the protocol was set up in the CADD®-Solis Medication Safety Software. If the screen color is black, the protocol has been modified in the administrator settings (see the Administrator Settings Guide for more information) or the pump is in manual mode (see *Manual Mode Programming* on page 32).

❺ The delivery status of the pump—stopped or running.

❻ The type of battery being used and the approximate amount of life it has, as well as AC indication.

❼ Keypad lock status—locked or unlocked. In this example, the keypad is locked.

❽ The units of measurement (mL, mg, or mcg) and the concentration (if units are mg or mcg) for the current protocol.

❾ The name of the screen displayed and help text for the screen, if there is any. This screen, for example, is the home screen.

❿ The work area/contents for the screen being displayed (in this example, the patient specific parameters are on display).

⓫ Options for navigating the pump. These options will change depending on the screen you are on and what functions you are performing with the pump.

Color Display

The CADD®-Solis pump display uses color to help the clinician recognize critical information quickly and easily. For example, your facility may choose to relate a specific color to each protocol in its library. This is customizable by your CADD®-Solis system administrator. Protocols may be color coded in several different ways depending on the needs of your pain management program, including:

- Route of administration (e.g., all epidural protocols may be yellow and used with a pump with a yellow keypad, yellow cassette reservoir or administration set, yellow extension set, and a yellow lockbox).
- Patient type (e.g., all pediatric protocols may be blue).

Or by any other hierarchy which fits the needs of your institution. There are five protocol colors available. The color of the protocol is displayed

in the protocol title bar (❹) as well as the soft key bar (⓫). A protocol displayed in black signifies that the protocol being used is a non-standard protocol or that the pump is programmed using the manual mode (see *Manual Mode Programming* on page 32). Refer to your facility's policies and procedures to understand how colors will be used to identify your protocols.

The pump also uses color to help the clinician recognize the pump's status. The colors blue, green, amber, and red are used in the status bar as well as on alarm screens.

Similar to a traffic control light: green means go, amber indicates caution, and red means stop:

- **Green**—indicates the conditions in the pump are good (e.g., the reservoir volume is above the low reservoir trip point).
- **Amber**—indicates there is a condition to watch, but the current conditions of the pump are satisfactory (e.g., the low reservoir trip point has been reached).
- **Red**—indicates a warning condition that requires immediate attention and that the infusion has stopped (e.g., the reservoir volume has reached zero).

The color **blue** is also used in the status bar to give informational messages (e.g., remote dose cord attached).

To understand how colors relate to alarm screens, refer to the alarms and messages section on p. 36.

Before Programming

Protocol libraries are created with the CADD®-Solis Medication Safety Software and can be imported into the pump by your CADD®-Solis system administrator. Before programming the pump for a patient, make sure the pump contains a protocol library. If you are not using the CADD®-Solis pump with a protocol library, see *Manual Mode Programming* on page 32.

A protocol from the library may be manually edited in the administrator settings. If you are authorized, see the Administrator Settings Guide or contact your facility's CADD®-Solis system administrator for further information.

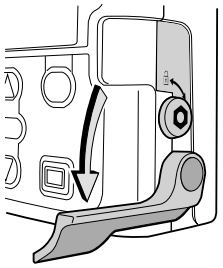
Attach a Cassette

Obtain a new, filled medication cassette reservoir, or CADD® administration set attached to a flexible IV bag. Refer to the instructions for use supplied with the product for information on preparing the product for use.

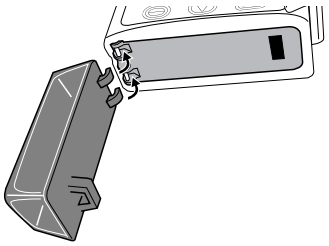
CAUTION: If you are using a medication cassette reservoir in which the medication is frozen, thaw at room temperature only. Do not heat in a microwave oven as this may damage the product and cause leakage.

To attach the cassette to the pump:

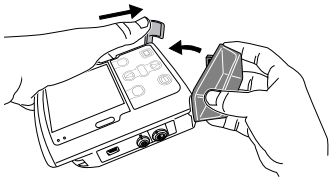
1. Make sure the cassette latch is unlocked and open the cassette latch.



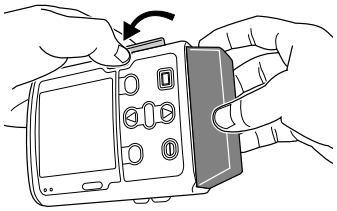
2. Clamp the tubing. Insert the cassette hooks into the hinge pins on the bottom of the pump.



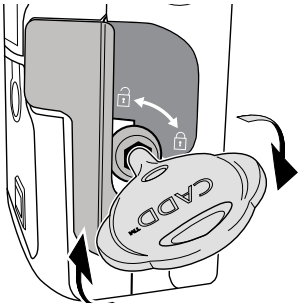
3. Holding the pump in your hands, push down on the cassette latch, and push up on the cassette until it firmly clicks into place.



4. Lift the cassette latch into the closed position. A message will briefly appear in the status bar so you can verify the type of cassette you have attached.



5. Insert the pump key into the cassette/keypad lock and turn clockwise into the locked position.



NOTE: The cassette **must be locked** in order to start the pump. "Cassette Locked" will appear briefly in the status bar.

WARNING: Attach the cassette properly. A detached or improperly attached cassette could result in unregulated gravity infusion of medication from the fluid container or a reflux of blood, which could result in death or injury to the patient.

If you are using a CADD® administration set or CADD™ medication cassette reservoir that does not have the flow stop feature: you must use a CADD® extension set with anti-siphon valve or a CADD® administration set with either an integral or add-on anti-siphon valve to protect against unregulated gravity infusion that can result from an improperly attached cassette. Unregulated gravity infusion can result in death or serious injury.

Remove a Cassette

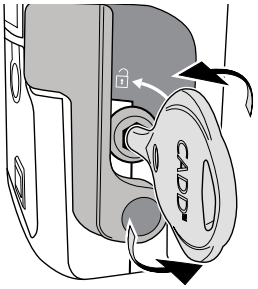
Make sure the pump is stopped before removing the cassette.

WARNING: Per general rules of safe practice, always clamp tubing before removing the cassette from the pump. Removing the cassette without closing the clamp could potentially cause unregulated gravity infusion, which could result in patient injury or death.

To remove the cassette:

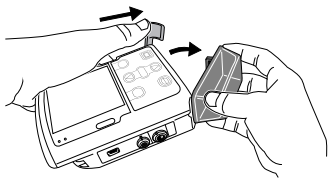
1. Close the tubing clamp.

2. If locked, insert the pump key and turn the cassette/keypad lock counter-clockwise into the unlocked position.



"Cassette Unlocked" will briefly appear in the status bar.

3. Push down on the cassette latch until the cassette detaches.



Start the Pump

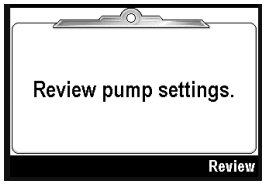
Starting the pump starts delivery. When the pump is running, "Running" will appear with green highlighting on the status bar and the green indicator light will flash. If the pump will not start, a message will appear on the display. Refer to the Alarms and Messages table on page 36.

NOTE: Before starting the pump, ensure correct protocol and patient specific parameters are displayed (see *Patient Specific Parameters* page 29). Also be sure the tubing is primed and the pump is connected to the patient, according to your facility's standards of practice.

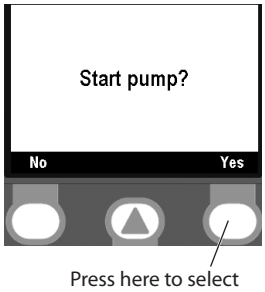
To start the pump:

1. Press stop/start .

NOTE: If the patient specific parameters have not been reviewed and the values have not been accepted, the pump will require you to do so before the pump will run.



2. When "Start Pump?" appears, select **Yes**.



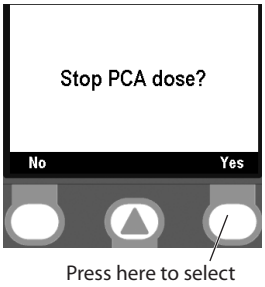
Stop the Pump

Stopping the pump stops delivery. When the pump is stopped, "Stopped" will appear with red highlighting on the status bar and the amber indicator light will flash, while the green indicator light will be off.

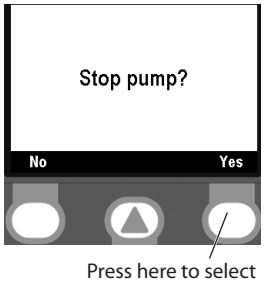
To stop the pump:

1. Press stop/start ⊖.

   NOTE: If a PCA dose or clinician bolus is in progress, "Stop PCA dose?" or "Stop clinician bolus?" will appear. Select **Yes** to stop the dose.



2. When "Stop Pump?" appears, select **Yes**.



Programming and Operation

Security Settings

The security settings are used to limit patient and clinician access to certain programming and operating functions of the pump. The various functions of the pump are protected by three different security codes, and may also be protected by the cassette/keypad lock. The security level table below lists the functions that are available under each security code. The factory default settings for the security codes are as follows:

** Text omitted from online version ** **Administrator Code**: See your CADD®-Solis system administrator.

The keypad code, clinician code, and administrator code can all be customized by the CADD®-Solis system administrator while setting up the protocol using the CADD®-Solis Medication Safety Software, or in the administrator settings. The CADD®-Solis system administrator also determines whether or not to allow use of the cassette/keypad lock to unlock the keypad. See your CADD®-Solis system administrator for more information or to learn the security code you should use if the codes have been customized.

Security Level Table

The keypad code should be used by clinicians who need to set up and manage a protocol for a patient. The clinician code will allow access to all the functions the keypad code allows, as well as the clinician bolus feature. The administrator code will allow access to all functions of the pump and its use should be restricted to the CADD®-Solis system administrator and certain designees. The administrator code gives the user the ability to change protocol ranges and all settings in the pump.

Pump Operations and Programming	Keypad Security Locked		Keypad Security Unlocked		Clinician Security Unlocked		Administrator Security Unlocked	
	Running	Stopped	Running	Stopped	Running	Stopped	Running	Stopped
Stop/Start	•	•	•	•	•	•	•	•
Reset Reservoir Volume				•		•		•
Start PCA Dose	•		•		•		•	
Change (Titrate) Continuous Rate			•	•	•	•	•	•
Change (Titrate) PCA Dose			•	•	•	•	•	•
Change (Titrate)			•	•	•	•	•	•
Change (Titrate) Delivery Amount			•	•	•	•	•	•
Change (Titrate) Max Doses/Hr			•	•	•	•	•	•
Pump Tasks	**Keypad Security Locked**		**Keypad Security Unlocked**		**Clinician Security Unlocked**		**Administrator Security Unlocked**	
	Running	Stopped	Running	Stopped	Running	Stopped	Running	Stopped
Give Clinician Bolus					•		•	
Start New Patient				•		•		•
Start New Protocol/Same Patient				•		•		•
Prime Tubing				•		•		•
Set Time and Date				•		•		•
Adjust Backlight Intensity			•	•	•	•	•	•
Adjust Alarm Volume			•	•	•	•	•	•
View/Clear Reports	•	•	•	•	•	•	•	•
Access Administrator Settings								•

Security Level Table Key Yes [•] No [ ]

Autolock

The CADD®-Solis pump has been designed to meet both safety and usability needs. The autolock feature reduces the chance of non-authorized pump programming.

When the keypad is unlocked using the security code and left unlocked (pushing the right soft key twice from the home screen will ensure that the pump has been locked), the software will eventually lock the keypad. This autolock feature takes affect on the home screen approximately 30 seconds after the last key press. It will take longer on programming or task screens where the user typically needs more time to perform an action (Depending on which screen the pump was left on, it will take up to 4.5 minutes after the last key press, if the pump is not alarming. When the pump is alarming the autolock does not take affect).

If using the key to unlock the keypad while the pump is running, you will be able to edit the program values. You should then relock the keypad using the key.

NOTE: The keypad can always be re-locked by pushing the right soft key twice from the home screen (or once from the tasks menu). As a recommended safety precaution, always be sure to manually lock the pump using this feature.

Tasks

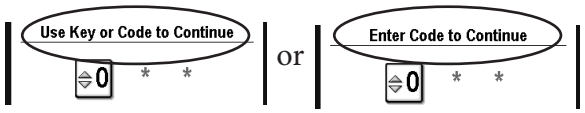
The tasks menu will lead you to most of the pump's operating functions. On this menu, you can perform a range of tasks from giving a clinician bolus, starting a new patient, to changing the date and time, or adjusting the administrator settings. Some of the items on the tasks menu are protected by the various security levels. To learn more about the security codes, see *Security Settings* on page 21.

The following functions can be found on the tasks menu:

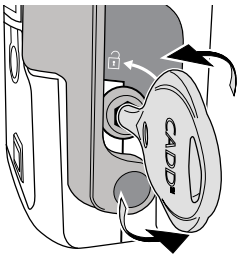
- Give Clinician Bolus
- Start New Patient
- Start New Protocol, Same Patient
- Prime Tubing
- Set Time and Date
- Adjust Backlight Intensity
- Adjust Alarm Volume
- View Reports
- Adjust Admin Settings

Depending on the level of security required and how the CADD®-Solis system administrator has set up the protocol, you may be able to use the cassette/keypad lock to unlock the keypad. When a code or the pump key is required, the pump will always ask for it with one of the following screens:

To unlock the keypad with the pump key, turn the

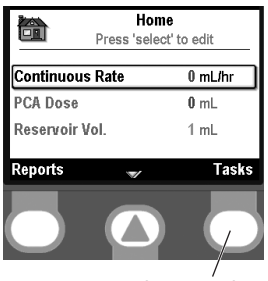


pump key counter-clockwise to put the cassette/keypad lock in the unlocked position.



NOTE: It is possible for the keypad to be locked while the cassette/keypad lock is unlocked. To use the pump key to unlock the keypad, first lock the cassette/keypad lock, and then unlock it.

To access the tasks menu, select **Tasks** on the home screen.



Press here to select

Give Clinician Bolus

A clinician bolus may only be delivered while the pump is running. It allows you to deliver a specified amount of drug, for example, as a loading dose. A clinician bolus cannot be started while a PCA dose is in progress. The amount delivered decreases the reservoir volume and increases the given amount, but does not add to the dose counters or to the delivery limit. A clinician bolus may be stopped in progress.

NOTE: If a clinician bolus is manually stopped by a clinician or automatically stopped by an alarm, power failure, or other condition that stops delivery, the pump will remember what point the bolus was at when it stopped. The next time you choose to give

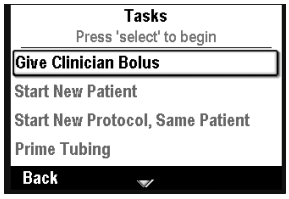
a clinician bolus, it will give you the option to restart the clinician bolus where it left off or to start with a new clinician bolus.

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

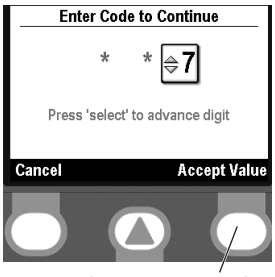
NOTE: The maximum clinician bolus may be limited by the settings in the protocol, which is determined by the CADD®-Solis system administrator.

To start a clinician bolus:

1. Make sure the pump is running. Start the pump if necessary.
2. From the Tasks menu, press ▲ or ▼ until **Give Clinician Bolus** is highlighted, then press select.

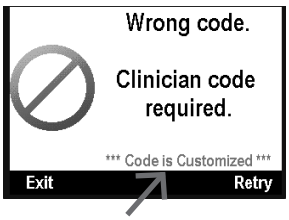


3. Unlock the keypad using the pump key (if allowed) or press ▲ or ▼ to enter the clinician code (or a higher level code). Press select to advance to the next digit. Once the code has been entered, select **Accept Value**.



Press here to Accept Value

NOTE: If you enter a code that you believe is correct and receive a wrong code error, check the screen to see if the clinician code has been customized.

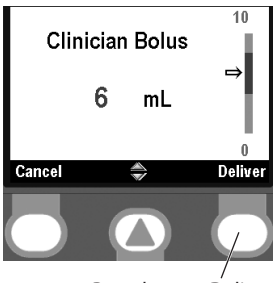


If the code has not been customized, it was entered incorrectly. Retry. If the code has been customized, use the custom clinician code. If you do not know this code, contact your CADD®-Solis system administrator.

WARNING: To prevent the patient from accessing the clinician bolus function, do not let the patient know the security codes. Improper programming could result in serious patient injury or death.

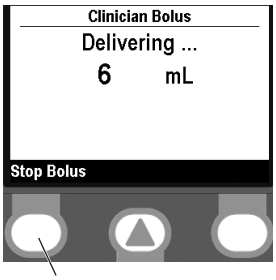
4. Make sure the clinician bolus amount is at the desired value and select **Deliver**.

   NOTE: If you enter a value outside the soft limit, a screen will appear asking you to confirm the soft limit override.



Press here to Deliver

5. The screen will show the amount decreasing as the bolus is delivered. You may stop the bolus at any time by selecting **Stop Bolus**.



Press here to Stop Bolus

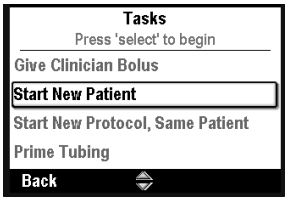
WARNING: Never leave the pump unattended while on the clinician bolus edit screen. You must press "Confirm" or "Deliver" to deliver the programmed value or cancel to leave the screen. Failure to do so could result in serious patient injury or death.

Start New Patient

Each time a new patient is started, it will be recorded in the event log. All other reports will be cleared.

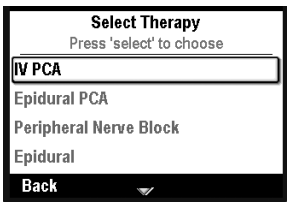
The pump must be stopped and you'll need the keypad code (or a higher level code) or the cassette/keypad lock must be unlocked, if allowed. To start a new patient:

1. From the Tasks menu, press ▲ or ▼ until **Start New Patient** is highlighted and press select.

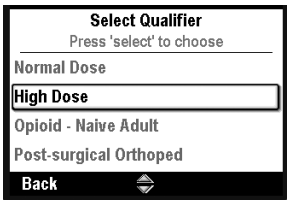


2. Unlock the keypad using the security code or the pump key.

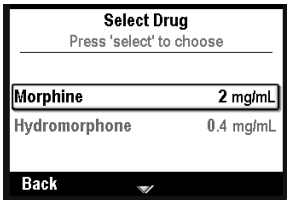
3. Press ▲ or ▼ to highlight the desired therapy and press select.



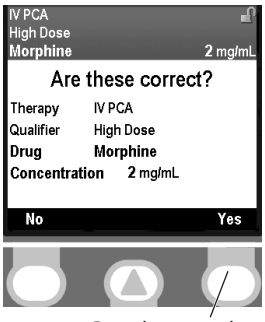
4. Press ▲ or ▼ to highlight the desired qualifier and press select.



5. Press ▲ or ▼ to highlight the desired drug and concentration, and press select.



6. The new protocol will display on the screen and the pump will ask you if you have chosen the correct Therapy, Qualifier, Drug, and Concentration.



Confirm that you have selected the correct Therapy, Qualifier, Drug, and Concentration or Units.

NOTE: If programming in mL, you will not be asked to confirm the concentration.

Selecting **Yes** will program the pump with the protocol you have chosen.

Selecting **No** will bring you back to the **Select Drug** screen. If you desire to change the drug, repeat the process for selecting a new drug. Otherwise, select Back until you reach the screen you desire to change (therapy or qualifier).

Start New Protocol, Same Patient

The process for starting a new protocol for the same patient is much like starting a new patient; however, the event log does not insert a new patient marker (all other reports will be cleared, except the delivery log). See *Start New Patient on page 23* for directions on selecting a therapy, qualifier, and drug for the new protocol.

NOTE: When starting a new protocol, be sure to attach a new reservoir with the proper drug and concentration.

Prime Tubing

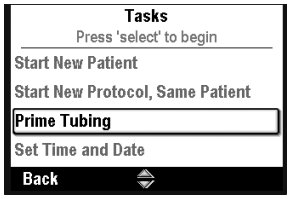
Priming the tubing is done to fill the tubing downstream of the pump with fluid, removing any air bubbles. Prime the tubing before connecting it to the patient's infusion set or indwelling catheter. The pump must be stopped and you'll need the keypad code (or a higher level code) or the cassette/keypad lock must be unlocked.

NOTE: The air detector is disabled while the pump is priming.

WARNING: Do not prime the fluid path with the tubing connected to a patient as this could result in overdelivery of medication or air embolism, which could result in serious patient injury or death.

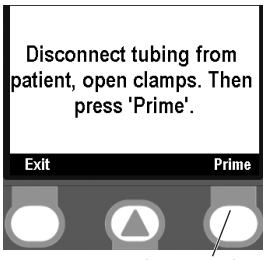
To prime the tubing:

1. From the Tasks menu, press ▲ or ▼ until **Prime Tubing** is highlighted and press select.



2. Unlock the keypad using the security code or the pump key.

3. If you have not already done so, disconnect the tubing from the patient, open clamps, and select **Prime**.



You may stop priming at any time by selecting **Stop Priming**. Otherwise priming will automatically stop once it has primed 10 mL. Continue priming as needed.

WARNING: Ensure that the entire fluid path is free of all air bubbles before connecting to the patient to prevent air embolism. Air embolism could result in serious patient injury or death.

NOTE: If the fluid path contains an air eliminating filter, it is acceptable for air bubbles to be present on the vent side of the filter. See the cassette's instructions for use for more information.

Set Time and Date

The set time and date screen allows you to edit the time and date, as well as to choose a date format. The date format options are Month/Day/Year or Day/Month/Year.

The time option should reflect the current time. The pump shows the time of day in 24-hour time according to the pump's internal clock. The clock is powered by a separate, internal battery which retains the time even when the 4 AA batteries or the battery pack is removed. The pump uses its clock to record the time of events in the delivery and event logs, as well as in other reports.

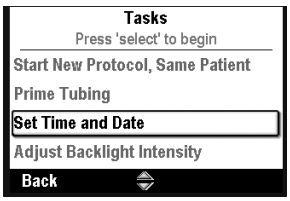
The date option should reflect the current date. The pump uses this feature to record the date of events in the delivery and event logs, in other reports, and to determine when the preventative maintenance (PM) reminder alarms will occur.

NOTE: Protocol information will remain the same regardless of changing the time and/or date during a patient's therapy.

The pump must be stopped and you'll need the keypad code (or a higher level code) or the cassette/keypad lock must be unlocked.

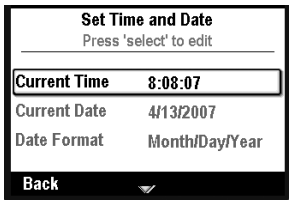
To access the set time and date feature from the tasks menu:

1. Press ▲ or ▼ to choose **Set Time and Date** and press select.



To set the current time:

1. Press ▲ or ▼ until **Current Time** is highlighted and press select.



2. Unlock the keypad using the security code or the pump key.

3. Press ▲ or ▼ to scroll to the correct hour and press select to navigate to the minutes.

4. Press ▲ or ▼ to scroll to the correct minutes and select **Save**.

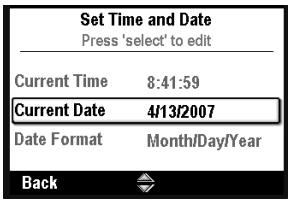
Updating the time and date to daylight savings time.

The pump's time and date will not automatically update during daylight savings. If you live in a geographical area that follows daylight savings time, you will need to manually update the time and date. You may choose to change the time while the pump is currently being used by a patient, or to wait until the patient is finished with therapy.

NOTE: If you update the pump's time while it is being used on a patient, the timestamps in the event and delivery logs will not be updated to reflect daylight savings prior to the change. All events will record the reported time from when the event actually occurred. For your reference, the event log will record the time it was changed.

To set the current date:

1. Press ▲ or ▼ until **Current Date** is highlighted and press select.



2. Unlock the keypad using the security code or the pump key.

3. Press ▲ or ▼ to scroll to the correct month and press select to navigate to the day.

4. Press ▲ or ▼ to scroll to the correct day and press select to navigate to the year.

5. Press ▲ or ▼ to scroll to the correct year and select **Save**.

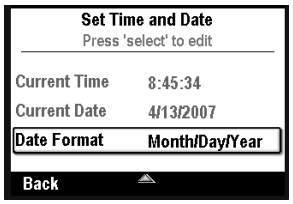
To set the date format:

NOTE: You cannot change the date format without the administrator code.

1. Press ▲ or ▼ until **Date Format** is highlighted and press select.

2. Unlock the keypad using the administrator code.

3. Press ▲ or ▼ to choose either the Month/Day/Year format or the Day/Month/Year format and select **Save**.



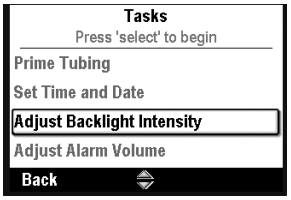
Adjust Backlight Intensity

The backlight intensity feature allows you to adjust the backlight intensity within the range of 1 to 10.

NOTE: Increasing the backlight intensity will shorten the battery life.

To adjust the backlight intensity from the tasks menu:

1. Press ▲ or ▼ to choose **Adjust Backlight Intensity** and press select.



2. Unlock the kepad using the security code or the pump key.

3. Press ▲ or ▼ to scroll from 1 to 10. The pump will display the intensity of each number as it appears. Once you have found the desired backlight intensity, select **Save**.

Adjust Alarm Volume

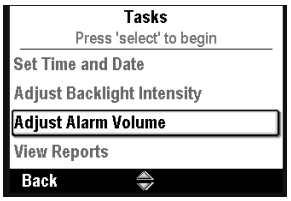
The adjust alarm volume feature allows you to determine the volume of the alarms in the protocol. You may choose between 3 volumes: low, medium, and high.

To adjust the alarm volume from the tasks menu:

1. Press ▲ or ▼ to choose **Adjust Alarm Volume** and press select.

2. Unlock the keypad using the security code or the pump key.

3. Press ▲ or ▼ to choose Low, Medium, or High and select **Save**.



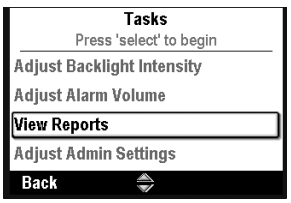
View Reports

The reports screen is used to access a variety of reporting and record-keeping functions.

To access reports from the tasks menu:

1. Press ▲ or ▼ to choose **View Reports** and press select.

   NOTE: Reports may also be accessed from the home screen.



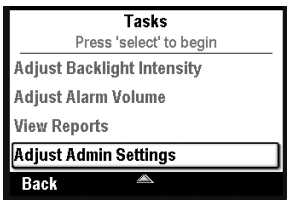
See *Reports* on page 27 for more information.

Adjust Admin Settings

The administrator settings contain pump configurations that are set up by the CADD®-Solis system administrator. Protocol libraries are created using the CADD®-Solis Medication Safety Software. The administrator settings only allow you to make changes to the protocol currently displayed.

To access the administrator settings:

1. From the tasks menu, Press ▲ or ▼ to choose **Adjust Admin Settings** and press select.



   NOTE: You cannot access the administrator settings without the administrator code.

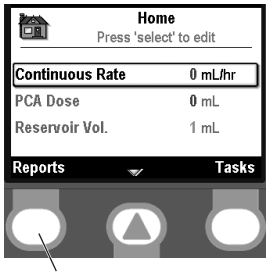
See the Administrator Settings Guide for more information.

Reports

The reports screen is used to access a variety of reporting and record-keeping functions.

You may access the reports from the home screen or the tasks menu. To access the reports from the home screen, select **Reports**.

(To access the reports from the tasks menu, see "View Reports" in the previous section.)



Press here to select

Given and PCA Dose Counters

This screen shows the number of PCA doses given and attempted since the date and time indicated, which is the last time they were cleared manually, or when a new protocol or new patient has been started.

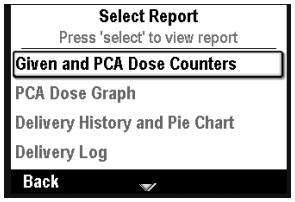
- **Total Given** shows the amount of drug (in programming units) that has been given in continuous rate, clinician boluses, and PCA doses.
- **PCA Doses Given** shows the number of PCA doses actually delivered to the patient, including any doses stopped in progress.
- **PCA Doses Attempted** shows the total number of PCA doses attempted by the patient while the pump was running, including those that were delivered, locked out, and stopped in progress.

The dose counters can be viewed or cleared while the pump is running or stopped.

NOTE: If the PCA dose is not available in the current protocol and has been programmed to not be visible on the home screen, you will only see the "Total Given" when viewing this report.

To view the given and PCA dose counters:

1. From the reports menu, press ▲ or ▼ to choose **Given and PCA Dose Counters** and press select.



To clear the total given:

1. Press ▲ or ▼ until the Total Given section is highlighted.
2. Select **Clear Given**.

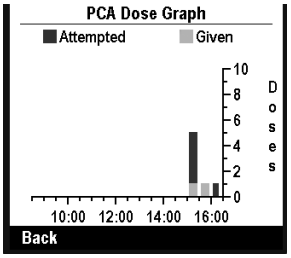
Press here to select

To clear the PCA doses given and attempted:

1. Press ▲ or ▼ until the PCA Doses Given and Attempted section is highlighted.
2. Select **Clear Doses**.

Press here to select

PCA Dose Graph



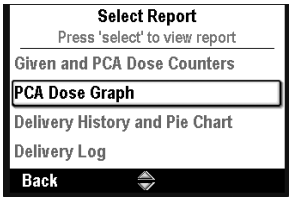
This screen displays the number of doses attempted and given in 30 minute increments starting from the current time to 8 hours in the past or to the start of a new protocol or patient.

In this example, the patient has attempted 7 doses and 2 of those doses were given.

This is a good place to review the number of attempted doses for a particular time frame.

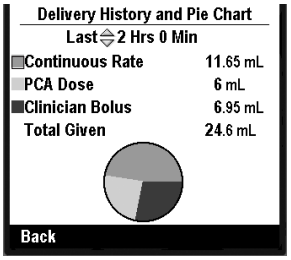
The PCA dose graph can be viewed at any time, with the pump running or stopped.

To view the PCA dose graph:



1. From the reports menu, press ▲ or ▼ to choose **PCA Dose Graph** and press select.

Delivery History and Pie Chart



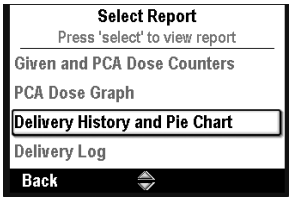
The delivery history and pie chart is a pie chart view of the total given over a specified time frame or to the start of a new patient or protocol. The time frame can be adjusted in various intervals from 30 minutes to 7 days.

Press ▲ or ▼ to view the time chart in the various time frames. This will provide a quick review of the methods of delivery over the interval selected.

The delivery history is displayed in the units for the current protocol.

The delivery history and pie chart can be viewed at any time, with the pump running or stopped.

To view the delivery history and pie chart:



1. From the reports menu, press ▲ or ▼ to choose **Delivery History and Pie Chart** and press select.

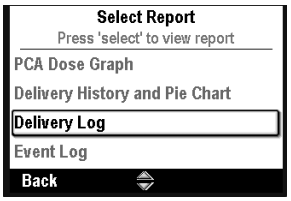
Delivery Log

The delivery log is a subset of the event log and contains information having to do specifically with delivery events. Delivery log information includes:

- PCA dose deliveries.
- Clinician boluses.
- Changes to the patient specific parameters (including continuous rate, PCA dose, PCA dose lockout, delivery limit).
- Manually stopping a PCA dose and/or a clinician bolus.
- Starting a new protocol.
- Pump started, stopped, powered up, and powered down.

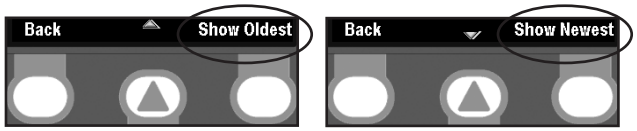
The delivery log is maintained by the pump, and displays all entries since the last time a new patient was started. The delivery log can be viewed at any time, with the pump running or stopped.

To view the delivery log:



1. From the reports menu, press ▲ or ▼ to choose **Delivery Log** and press select.

While viewing the delivery log, you may quickly scroll from the oldest to newest by selecting **Show Oldest** or **Show Newest**.

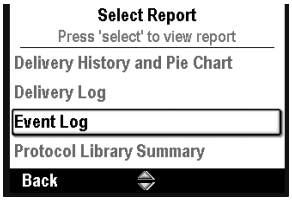


Event Log

The event log records the following types of events: hourly given totals, dose delivery, alarms, error codes, power source changes, cassette changes, protocol library changes, and changes to pump programming or settings. The pump records the time and date of each event, and lists events in order, with the most recent at the bottom of the screen through the last 5000 events.

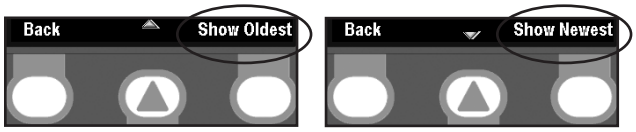
The event log can be viewed at any time, with the pump running or stopped.

To view the event log:



1. From the Reports menu, press ▲ or ▼ to choose **Event Log** and press select.

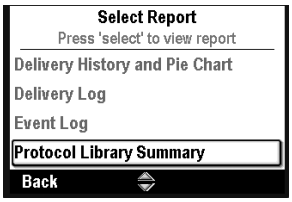
While viewing the event log, you may quickly scroll from the oldest to newest by selecting **Show Oldest** or **Show Newest**.



Protocol Library Summary

The protocol library summary allows you to view the protocol library currently installed in the pump. This screen will tell you the name of the protocol library, the revision, and the number of protocols in the library.

To view the protocol library summary:



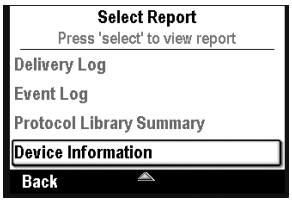
1. From the reports menu, press ▲ or ▼ to choose **Protocol Library Summary** and press select.

Device Information

The device information screen allows you to view the pump's information. On this screen you will find the pump's serial number, software and hardware version numbers, and the last error code (if one exists).

NOTE: Review your facility's procedure for handling error codes (see *Understanding the Alarms and Messages* on page 35 for more information).

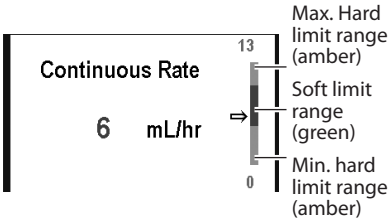
To view the device information:

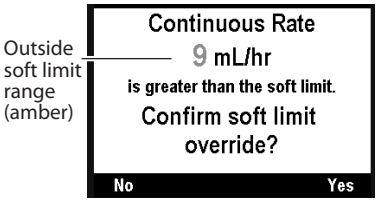


1. From the reports menu, press ▲ or ▼ to choose **Device Information** and press select.

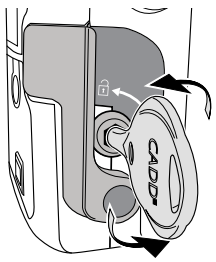
Patient Specific Parameters (Programming Screens)

The patient specific parameters are found on the home screen and can be edited within limits that are set up by the CADD®-Solis system administrator in the protocol. The CADD®-Solis system administrator determines which parameters can be viewed and/or edited on the home screen, as well as the initial values of the parameters. While determining the initial values, the CADD®-Solis system administrator will also set up hard and soft limits which may allow you to modify the parameters as necessary. The soft limits (displayed in green) will be the range most commonly used for the protocol, and the hard limits (displayed in amber) extend to the highest and lowest amount that the CADD®-Solis system administrator chooses to allow for the protocol. If the doctor's orders do not match the initial values, they should be edited to match. Editing the parameters above or below the soft limits will result in a screen that requires you to confirm the soft limit override.





You will need the keypad (or a higher level) code or the pump key to edit the patient specific parameters. The CADD®-Solis system administrator determines if the pump key can be used to unlock the keypad when setting up the protocol.



If the option is available, use the pump key to place the pump in the unlocked position (see picture)

OR

Enter the keypad code (see *Security Settings* on page 21).

NOTE: Using the pump key to unlock the keypad also unlocks the cassette latch (see *Attach a Cassette* on page 18 for more information).

NOTE: When using the pump key to unlock the keypad, be sure to keep the cassette latch in the latched position.

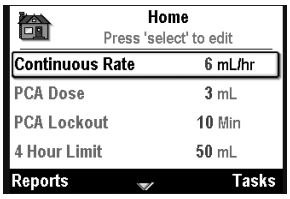
Continuous Rate

The continuous rate is the constant, hourly rate the drug is delivered at while the pump is running.

The continuous rate value can be edited while the pump is running or stopped (if the keypad is unlocked).

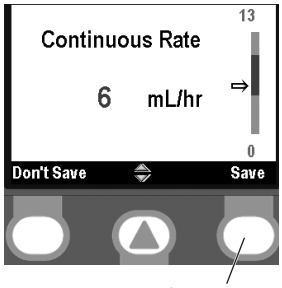
To edit the continuous rate:

1. From the Home screen, press ▲ or ▼ to choose **Continuous Rate** and press select.



2. Unlock the keypad using the security code or the pump key.

3. Press ▲ or ▼ until you reach the desired Continuous Rate and select **Save**.



Press here to Save

PCA Dose

A PCA dose is a bolus of drug delivered by the pump in response to a request from the patient. The patient either presses the PCA dose ■ key on the keypad or presses the remote dose cord button (if attached) to request a PCA dose.

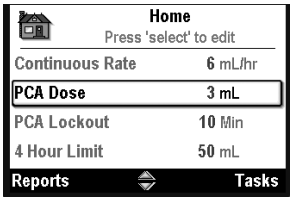
NOTE: If a remote dose cord is attached to the pump, the PCA dose ■ key on the keypad will be inactive.

If the CADD®-Solis system administrator has programmed a PCA dose into the protocol, the patient may start a PCA dose while the pump is running. The amount delivered is added to the amount provided by the continuous rate. Each time the patient requests a PCA dose, the pump will automatically add it to the dose counters screen. If a PCA dose has not been programmed by the CADD®-Solis system administrator, the pump will display the message, "PCA dose not available because no dose programmed."

The PCA dose amount can be edited while the pump is running or stopped (if the keypad is unlocked).

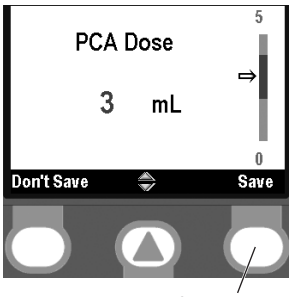
To edit the PCA dose:

1. From the Home screen, press ▲ or ▼ to choose **PCA Dose** and press select.



2. Unlock the keypad using the security code or the pump key.

3. Press ▲ or ▼ until you reach the desired PCA dose and select **Save**.



Press here to Save

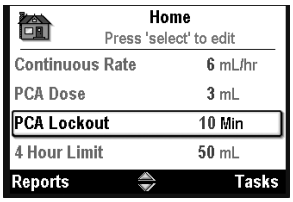
PCA Lockout

A PCA lockout is a program setting that specifies the minimum amount of time that must pass between the start of each PCA dose. If the patient attempts to deliver a PCA dose during the lockout time, "PCA dose not available. Currently locked out." will appear on the display and the pump will not deliver the dose. The parameters for the PCA lockout are determined by the CADD®-Solis system administrator.

The PCA lockout time can be edited while the pump is running or stopped (if the keypad is unlocked).

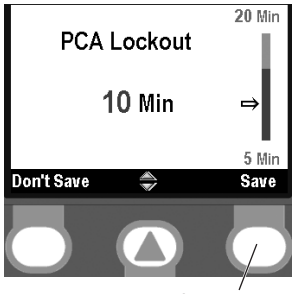
To edit the PCA lockout:

1. From the Home screen, press ▲ or ▼ to choose **PCA Lockout** and press select.



2. Unlock the keypad using the security code or the pump key.

3. Press ▲ or ▼ until you reach the desired PCA lockout time and select **Save**.



NOTES:

- If the delivery limit is reached while a PCA dose is in progress, the PCA dose will not be completed.
- A PCA dose cannot be started while another PCA dose or a clinician bolus is in progress.
- Pressing the remote dose cord button will turn the display back on **AND** deliver a PCA dose (if available). A blank display will not require two key presses to start a PCA dose.

Hourly Limit

The hourly limit is the amount of drug which can be delivered in a specified time frame (1-12 hours). The time frame is determined by your facility's CADD®-Solis system administrator. This limit includes the continuous rate and PCA doses, but does not include clinician boluses.

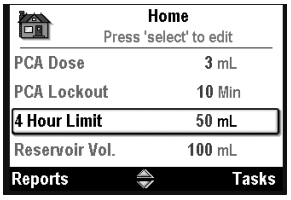
If the delivery limit is reached and a continuous rate is programmed (value other than zero), the status bar will display "Delivery Limit" and the pump will deliver a KVO rate of 0.1 mL/hr. If the delivery limit is reached and no continuous rate is programmed (value = zero), the status bar will display "KVO = 0" and the KVO rate will be zero.

NOTE: If the delivery limit is reached while a PCA dose is in progress, the PCA dose will not be completed.

The hourly limit can be edited while the pump is running or stopped (if the keypad is unlocked).

To edit the hourly limit:

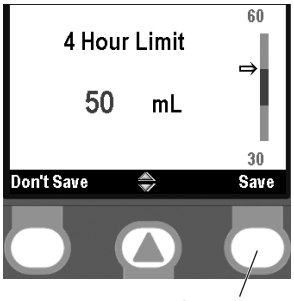
1. From the Home screen, press ▲ or ▼ to choose **X* Hour Limit** and press select.



*X will be the number of hours set up by the CADD®-Solis system administrator. In the example shown, a 4 hour limit is being used.

2. Unlock the keypad using the security code or the pump key.

3. Press ▲ or ▼ until you reach the desired hourly limit amount and select **Save**.



If the hourly limit is not visible on the home screen, your CADD®-Solis system administrator has chosen not to require it. Instead you may be required to program the Max Doses/Hr.

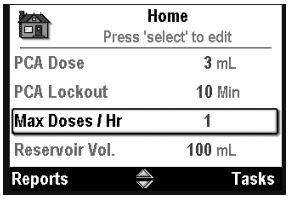
Max Doses/Hr

If the max doses/hr setting is turned on, you may use it to further restrict the number of PCA doses available to the patient in 1 hour. The max doses/hr feature allows you to restrict the PCA doses beyond the PCA lockout time.

The max doses/hr time can be edited while the pump is running or stopped (if the keypad is unlocked).

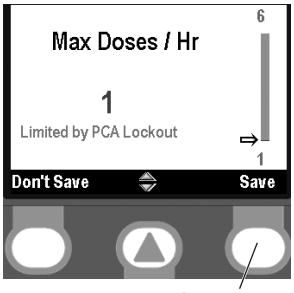
To edit the max doses/hr:

1. From the Home screen, press ▲ or ▼ to choose **Max Doses/Hr** and press select.



2. Unlock the keypad using the security code or the pump key.

3. Press ▲ or ▼ until you reach the desired max doses/hr value and select **Save**.



If max doses/hr is not visible on the home screen, your CADD®-Solis system administrator has chosen not to require it. Instead you may be required to program the hourly limit.

NOTE: If the hourly limit and the max doses/hr settings are not displayed on your programming screen, your facility's CADD®-Solis system administrator has chosen not to require a delivery limit beyond the PCA lockout.

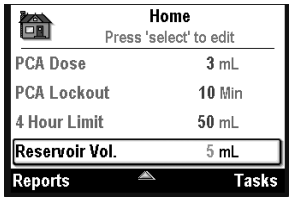
Reservoir Volume

The reservoir volume is a program setting that allows you to set the amount of fluid that is contained in the reservoir. Once you set this number, the software keeps track of how much fluid has been delivered and adjusts the reservoir volume accordingly.

The pump must be stopped, and the keypad unlocked, to adjust the reservoir volume amount.

To edit the reservoir volume:

1. From the Home screen, press ▲ or ▼ to choose **Reservoir Vol.** and press select.



2. Unlock the keypad using the security code or the pump key.

3. Press ▲ or ▼ until you reach the desired reservoir volume and select **Save**.

   You may press select to reset the pump to a default amount which will appear on the screen in blue text, under the current value. In this example, pressing select will reset the reservoir volume to 100 mL.

Manual Mode Programming

The manual mode is for situations when the doctor's orders may not match any of the protocols in the library, or when a protocol library is not available. The screen for the manual mode will always be black in color and the therapy, qualifier, and drug and concentration listing will look like this (see page 17 for a diagram of the pump screen):

NOTE: The protocol title bar may be black even when the pump is not in manual mode if the protocol has been modified in the administrator settings (see the Administrator Settings Guide for more information). Be sure to check the therapy, qualifier, drug, and concentration or units displayed to ensure you are in manual mode.

Unlike protocols that are created and downloaded into the pump by the CADD®-Solis Medication Safety Software System, the manual mode allows you to choose the units (mL, mg, mcg) and concentration, and does not contain any programming limits. Many of the parameters in the manual mode will remain the same as the parameters from the previously used protocol. For example, if the previous protocol had delivery limit set as its delivery limit method, the manual mode will also have delivery limit as its delivery limit method. However, the actual programming limits of the previous protocol will be erased. The hard and soft limits are all set to the factory default, which means the delivery ranges are not limited. See the following chart for details.

NOTE: If the pump was set to the factory default, or if you are using the pump for the first time, the previously selected protocol is the factory default settings. Refer to the table on page 52 to see what the factory default settings are.

If you desire to set programming limits after choosing the manual mode, you may do so. See the Administrator Settings Guide for more information.

The following chart includes the initial settings of the Manual Mode.

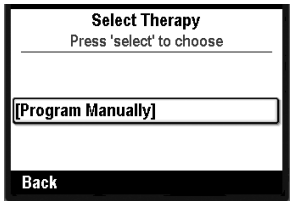
Pump Function	What Changes in the Protocol
Programming Units	User chooses mL, mg, or mcg
Concentration	Range is 0.1–100 mg or/mL or 1–500 mcg/mL
Continuous Rate	Range is 0–30 mL/hour (or mg or mcg equivalent), Default 0
PCA dose	Range is 0–20 mL (or mg or mcg equivalent), Default 0
PCA dose lockout	Range is 1 min–24 hours, Default 1 hr (when PCA dose is programmed).
Delivery limit amount*	Range is 0.1–1000 mL (or mg or mcg equivalent)
Max doses/hour*	Range is 1–60
Reservoir volume	1 mL
Reservoir volume reset value	100 mL
Delivery limit method	Remains the same as the previously used protocol
Reservoir volume low trip point	5.0 mL
Reservoir low alarm type	Remains the same as the previously used protocol
Clinician bolus amount	Range is 0–20 mL (or mg or mcg equivalent)
Delivery limit period	Remains the same as the previously used protocol
Maximum delivery rate	Remains the same as the previously used protocol
Pump stopped alarm type	Remains the same as the previously used protocol
Upstream sensor on/off	Remains the same as the previously used protocol
Downstream sensor sensitivity	Remains the same as the previously used protocol
Air detector on/off	Remains the same as the previously used protocol
Air detector sensitivity	Remains the same as the previously used protocol
Time and date settings	Remains the same as the previously used protocol
PM reminder on/off	Remains the same as the previously used protocol
PM reminder interval	Remains the same as the previously used protocol
Display and sound settings	Remains the same as the previously used protocol
Security settings	Remains the same as the previously used protocol

*Only if feature was used in the previous protocol.

To use the manual mode:

1. Determine whether you are starting a new patient, or starting a new protocol with the same patient. Select the appropriate task from the tasks menu.

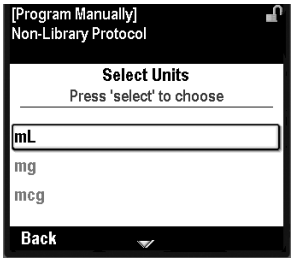
2. On the Select Therapy screen, scroll to the bottom of the therapies until [Program Manually] is highlighted and press (select).



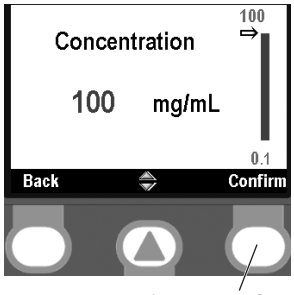
The protocol title bar will be displayed in the color black. Instead of a therapy and qualifier, you will see the Manual Program screen (see page 32).

NOTE: You may need to enter a higher level security code to proceed. If you do not know which code to enter, contact your CADD®-Solis system administrator.

3. Press (▲) or (▼) to select the desired units (mL, mg, mcg) and press (select).

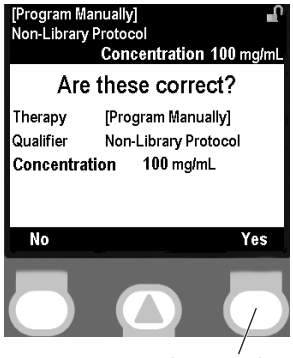


If you selected mg or mcg, press (▲) or (▼) to select the desired concentration and select **Confirm**. If you selected mL, proceed to the next step.



Press here to Confirm

4. The therapy, qualifier, units and concentration, if applicable, that you have selected will now appear. Confirm that you have selected the correct units and concentration and select **Yes**.



Press here to select

NOTE: If the information displayed is incorrect, selecting the left soft key will back you out of each screen, allowing you to start over.

5. The pump will take a moment to set the program before it asks you to review the pump settings. Select **Review**.

6. Carefully review each patient specific parameter.

   If the parameters are not at the desired values, press (select) to edit. (See *Patient Specific Parameters* on page 29 for more information.)

   If the parameters are correct, select **Accept Value**.

   NOTE: When the pump is in the manual mode, only the factory default settings are considered to be within the soft limits. If you edit any of the parameters outside of the factory default, you are exceeding the soft limit range and you will be asked to confirm the soft limit override on each screen (see page 52 for the factory default settings). The parameter and value will be displayed in amber.

   WARNING: The manual mode does not contain programming limits. Be sure to carefully review each parameter to ensure it accurately matches the prescription. Failure to set the manual mode to the correct values could result in serious patient injury or death.

7. Once you have accepted each of the values, follow the instructions on the pump to attach the cassette, prime the set, and start the pump.

NOTE: The manual mode is designed to be used in unusual circumstances when an order is received which is different than any of your standard protocols. Use of the manual mode does not allow you to use all of the medication safety features built into the CADD®-Solis pump. If you find the manual mode is being used frequently, consider contacting your CADD®-Solis system administrator to discuss if additional protocols should be created.

References and Troubleshooting

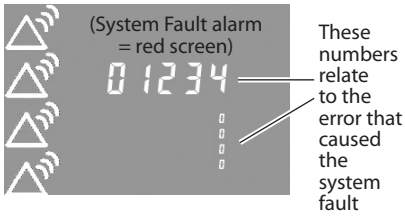
Understanding the Alarms and Messages

There are multiple alarms that the pump can sound. Many of the alarms will give you the option to "acknowledge" or "silence." Choosing to acknowledge the alarm will clear it from the screen; choosing to silence the alarm will keep it on the screen, but silence it for 2 minutes before it sounds again. It will continue until the alarm is acknowledged or resolved.

The alarms may sound different depending on the sound theme selected in the administrator settings. There are 3 different sound themes for the alarms and beeps that the pump makes. The 3 themes are standard, intense, and distinctive. See the Administrator Settings Guide for more information on previewing and selecting the sound themes.

The alarm/message types are as follows:

System Fault Alarm –

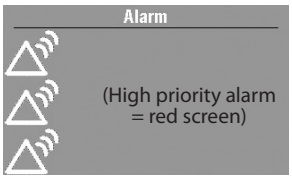


If this screen appears, an unrecoverable error may have occurred, such as a hardware or software fault. The amber indicator light will be continuously illuminated during these conditions and is accompanied by an audible two-tone alarm. If a system fault occurs, the fault should be reported to Customer Service at Smiths Medical MD, Inc. at: 1 800.426.2448 (USA) or Smiths Medical International Ltd at: +44 (0) 1923 246434. To clear this alarm, you must remove power from the pump by opening the battery door and, if necessary, removing the AC power. Turn the pump back on. If the error code does not repeat, Smiths Medical Customer Service may suggest continued use of the pump. However, if the error is persistent, the pump will need to be returned for service.

CAUTION: If the power up results in an error message indicating that the protocol library was lost, do not proceed with using the pump. Follow your facility's procedures for downloading protocol libraries.

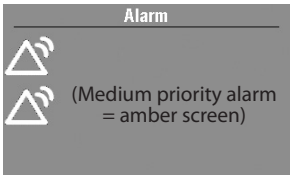
NOTE: Document the error numbers displayed on the system fault screen to help Smiths Medical Customer Service identify the problem.

High Priority Alarm –



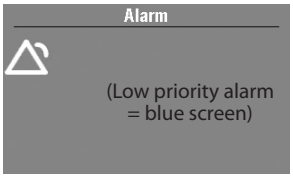
If the pump is running, it will always stop running when a high priority alarm is activated. The alarm is accompanied by a **red** screen, and it will persist until acknowledged by the press of a key on the pump or until the condition that triggered the alarm goes away (e.g., high pressure going down). The alarm can be silenced with a key press and will sound again after 2 minutes if the alarm condition still exists.

Medium Priority Alarm –



If the pump is running, a medium priority alarm will not stop the pump. The alarm is accompanied by an **amber** screen, and it will persist until acknowledged by the press of a key on the pump or until the condition that triggered the alarm goes away (e.g., a remote dose cord is reattached while the pump is running). The alarm can be silenced with a key press and will sound again after 2 minutes if the alarm condition still exists.

Low Priority Alarm –



If the pump is running, a low priority alarm will not stop the pump. The alarm is accompanied by a **blue** screen, and it will persist for 5 seconds, unless it is acknowledged by the press of a key or the condition that triggered the alarm goes away before the 5 seconds have passed.

Informational Message – If the pump is running, an informational priority message will not stop the pump. This message shows up in the status bar, it does not display a new alarm screen. It will persist for 5 seconds and is generally silent, requiring no acknowledgement. Some informational examples are, "Cassette Locked," and "Cassette Unlocked."

Alarms and Messages, Alphabetical List

Alarms and Messages	Alarm Priority	Description / Corrective Action
(Screen is blank and alarm is sounding)	High	The pump was delivering and the batteries were removed or the battery door was opened. The pump has lost power and is no longer delivering. Clear this alarm by turning the pump back on, or the alarm will stop after the power has been off for a minimum of 2 minutes.
A setting was edited, but not saved, and the edit was lost.	Medium	A parameter was being manually edited, but it wasn't saved and the pump reverted to the home screen. Select acknowledge to clear the alarm, and if appropriate, edit the parameter and save.
AC Adapter disconnected.	Low	The AC adapter was disconnected and the pump is being powered by the 4 AA batteries or the rechargeable battery pack. Select acknowledge to clear the alarm or the alarm will automatically clear after 5 seconds. If desired, reconnect the AC adapter.
Air in-line detected. Press 'Acknowledge' then prime tubing.	High	The air detector has detected air in the fluid path; the fluid path may contain air bubbles. The pump was delivering and is now stopped and will not run. Select acknowledge to clear the alarm, then: • If the fluid path contains air bubbles, close the clamps and disconnect the fluid path from the patient. Then follow the instructions for removing air by priming (see *Prime Tubing* on page 24 for more information on priming). Restart the pump.
Battery depleted. Pump stopped.	High	The pump was delivering and is now stopped and the battery power is too low to operate the pump. If the AC adapter is attached, select acknowledge to clear the alarm. • Remove the batteries. • Install 4 new AA batteries or a fully charged rechargeable battery pack. In order to start delivery, good batteries must always be installed, even when an external source of power is connected. • If appropriate, restart the pump.
Battery depleted. Pump will not run.	Medium	The battery power is too low to operate the pump. If the AC adapter is attached, select acknowledge to clear the alarm. • Remove the batteries. • Install a fully charged rechargeable battery pack or 4 new AA batteries. In order to start delivery, good batteries must always be installed, even when an external source of power is connected.
Battery low. Replace battery.	Low	The rechargeable battery pack or the 4 AA batteries are low but the pump is still operable. Select acknowledge to clear the alarm or the alarm will automatically clear after 5 seconds. • Recharge or change the rechargeable battery pack or replace the 4 AA batteries soon.

Alarms and Messages	Alarm Priority	Description / Corrective Action
Battery removed. Pump stopped.	High	The rechargeable battery pack or the 4 AA batteries were removed. The pump was delivering and is now stopped. Select acknowledge to clear the alarm. • Install a fully charged rechargeable battery pack or 4 new AA batteries. In order to start delivery, good batteries must always be installed, even when an external source of power is connected. • If appropriate, restart the pump.
Battery removed. Pump will not run.	Medium	The pump is stopped and the rechargeable battery pack or the 4 AA batteries were removed, but the pump is still powered by the AC adapter. Select acknowledge to clear the alarm. • Install a fully charged rechargeable battery pack or 4 new AA batteries. In order to start delivery, good batteries must always be installed, even when an external source of power is connected.
Cannot start pump with a depleted battery.	Medium	The battery power is too low to operate the pump. In order to start delivery, good batteries must always be installed even when an external source of power is connected. Select acknowledge to clear the alarm. Install 4 new AA batteries or a fully charged rechargeable battery pack. If appropriate, start the pump.
Cannot start pump with a reservoir volume of zero.	Medium	The reservoir volume in the pump is set to zero. Select acknowledge to clear the alarm. Edit the reservoir volume to the correct value. If appropriate, start the pump. See *Patient Specific Parameters* on page 29 for more information about the reservoir volume.
Cannot start pump with rechargeable battery reached end of use.	Medium	The rechargeable battery pack is at the end of its life. It has been discharged and recharged so many times that it is no longer able to hold a good charge. Remove the battery from service. In order to start delivery, good batteries must always be installed even when an external source of power is connected. Select acknowledge to clear the alarm. Install 4 new AA batteries or a new rechargeable battery pack. If appropriate, start the pump.
Cannot start pump without a battery.	Medium	The pump does not have any batteries installed. In order to start delivery, good batteries must always be installed even when an external source of power is connected. Select acknowledge to clear the alarm. Install 4 new AA batteries or a rechargeable battery pack. If appropriate, start the pump.
Cannot start the pump with air in-line. Prime tubing.	Medium	The air detector has detected air in the fluid path directly under the air detector; the fluid path may contain air bubbles. Select acknowledge to clear the alarm, then: • If the fluid path contains air bubbles, close the clamps and disconnect the fluid path from the patient. Then follow the instructions for removing air by priming (see page 24 for more information). • If appropriate, start the pump.

Alarms and Messages	Alarm Priority	Description / Corrective Action
Cannot start pump with an unusable battery	Medium	The batteries installed are either the wrong kind of AA batteries, or you are using a rechargeable battery pack that is not compatible with the pump. In order to start delivery, good batteries must always be installed even when an external source of power is connected. Select acknowledge to clear the alarm. Remove the batteries and install the rechargeable battery pack or 4 new AA batteries. If appropriate, start the pump. For more information on what type of batteries to use, see *Installing the Batteries* on page 14.
Cannot start pump without a latched and locked cassette.	Medium	The pump will not start without a cassette attached. Select acknowledge to clear the alarm. Make sure a cassette is properly attached, then start the pump.
Cassette damaged. Remove cassette.	High	The pump detects the cassette is damaged. Close the tubing clamp and inspect the cassette for damage. The pump is stopped and will not run. Replace cassette if necessary. **NOTE**: You must remove the cassette to continue. **NOTE**: This alarm will also occur if a cassette is attached during one of the following situations: • The pump is set to the factory default and then powered off, then on. • The pump was loaded with new software and then powered off, then on.
Cassette detached. Pump stopped.	High	The cassette was detached while the pump was delivering and the pump is now stopped. Select acknowledge to clear the alarm. Reattach the cassette and, if appropriate, restart the pump.
Cassette locked, but not latched. Unlock and reattach the cassette.	High	The cassette/keypad lock is locked, but there is no cassette attached. The pump is stopped and will not run. Select acknowledge to clear the alarm. Unlock the cassette/keypad lock and reattach the cassette.
Cassette not attached properly. Reattach cassette.	High	The pump detects the cassette is not properly attached. Close the tubing and remove the cassette, then reattach. If the alarm persists, replace the cassette. **NOTE**: You must remove the cassette to continue.
Cassette unlocked. Lock cassette.	Medium	This is a reminder that the cassette is not locked while the pump is delivering. If this alarm is sounding, lock the cassette to clear it.
Cassette was partially unlatched. Fully remove and reattach the cassette.	Medium	The cassette was not completely removed from the pump before it was reattached and, therefore, the pump's sensors are not able to detect the cassette type. Remove the cassette and reattach it, then verify the cassette type in the pump's display. If this alarm persists, replace the cassette. **NOTE**: You must remove the cassette to continue.
Check for empty tubing or reservoir. Pump stopped.	High	The tubing beneath the pump may not contain fluid, or the fluid container may be empty. The pump is stopped and will not run. Select acknowledge to clear the alarm. Check whether the fluid container is empty; or clamp the tubing, remove the cassette, and check for air in the tubing. If the alarm persists after trying the above, it means the pump's pressure sensor is faulty. Remove the pump from service and contact Smiths Medical Customer Service.

Alarms and Messages	Alarm Priority	Description / Corrective Action
Delivery limit reached. (Pump's status bar will read "KVO = 0") OR Delivery limit reached and partial dose delivered. (Pump's status bar will read "KVO = 0")	Low	The programmed delivery limit has been reached, and the pump is not delivering fluid. This alarm occurs when the continuous rate is programmed to 0 mL/hr, and either a PCA dose or the continuous rate has caused the delivery limit to be exceeded. Select acknowledge to clear the alarm or the alarm will automatically clear after 5 seconds. **NOTE**: The status bar display will remain after the alarm has cleared.
Delivery limit reached. (Pump's status bar will read "Del Limit") OR Delivery limit reached and partial dose delivered. (Pump's status bar will read "Del Limit")	Low	The programmed delivery limit has been reached, and the pump is delivering fluid at the KVO rate of 0.1 mL/hr. This alarm occurs when the continuous rate is programmed to greater than 0 mL/hr, and either a PCA dose or the continuous rate has caused the delivery limit to be exceeded. Select acknowledge to clear the alarm or the alarm will automatically clear after 5 seconds. **NOTE**: The status bar display will remain after the alarm has cleared.
Delivery too slow. 1 mL of fluid not delivered.	Medium	The pump is busy with too many activities and does not have sufficient resources to support the programmed delivery rate. The delivery has fallen behind by 1 mL. Select acknowledge to clear the alarm. If this alarm occurs regularly, the pump may be faulty. Remove the pump from use and contact Smiths Medical Customer Service.
Depleted battery is charging.	Low	The rechargeable battery pack is depleted and is being recharged with the AC adapter. Select acknowledge to clear the alarm or the alarm will automatically clear after 5 seconds.
Downstream occlusion. Clear occlusion between pump and patient.	High	The pump has detected high pressure, which may be resulting from a downstream blockage, kink in the fluid path, or a closed tubing clamp. Delivery is paused and will resume if the occlusion is removed. Remove the obstruction to resume operation. Or select **Stop Pump** to stop the pump and silence the alarm for 2 minutes, then remove the obstruction and restart the pump. **NOTE**: To reduce the potential bolus delivery after an occlusion, perform the following: 1. Select **Stop Pump** to stop the pump. 2. Close the distal clamp. If the distal clamp is the cause of obstruction, keep it closed and continue with step 4. 3. Remove the obstruction. 4. Detach the medication cassette reservoir or CADD® administration set from the pump. 5. Open the flow stop feature, if present. 6. Wait 10 seconds. 7. Close the flow stop feature, if present. 8. Reattach the medication cassette reservoir or CADD® administration set to the pump. 9. Open the distal clamp. 10. Review the pump's program. 11. Restart the pump.

Alarms and Messages	Alarm Priority	Description / Corrective Action
External power source faulty. Change power source.	Medium	The AC adapter's output voltage is too high. Select acknowledge to clear the alarm. The AC adapter is faulty, remove from service.
High Flow Admin Set not allowed. Remove cassette.	High	The CADD® high volume administration set cannot be used with the PCA delivery mode. The pump is stopped and will not run. **NOTE**: You must remove the administration set to continue.
Key stuck. Release key or remove power. Pump stopped.	High	A key may be pressed down. The pump is stopped and will not run. Make sure there is nothing pressing on any of the keys. If the alarm persists, close the tubing clamp, remove the batteries to turn off the pump, and remove the pump from use. Contact Smiths Medical Customer Service to return the pump for service.
Lock cassette to start pump.	Medium	The cassette must be locked onto the pump before beginning delivery. If this alarm is sounding, lock the cassette to clear the alarm and the pump will automatically start.
Loss of power occurred while pump was running.	Medium	The pump lost power while it was running. This alarm will occur when the pump restarts. Select acknowledge to clear the alarm and, if appropriate, restart the pump.
Motor service due.	Medium	The pump's motor requires service. Select acknowledge to clear the alarm. Remove the pump from use at the next cassette change and contact Smiths Medical Customer Service to return the pump for service.
New pump settings downloaded. Press 'Acknowledge' then review.	Low	A new protocol was just downloaded into the pump from the CADD®-Solis Medication Safety Software. Select acknowledge to clear the alarm. Review the protocol to ensure the correct one has been downloaded.
PCA dose cord button stuck. Release or remove cord.	High	The PCA remote dose cord button may be pressed down. The pump is stopped and will not run. Make sure there is nothing pressing on the PCA remote dose cord button. If the alarm persists, remove the PCA remote dose cord to clear the alarm and contact Smiths Medical Customer Service. You may continue using the pump with another PCA remote dose cord, or using the PCA dose ▣ button on the pump.
PCA dose cord disconnected.	Medium / Low	**Medium**: The PCA remote dose cord was disconnected from the pump while the pump is delivering. Select acknowledge to clear the alarm or reattach the PCA remote dose cord. **Low**: The PCA remote dose cord was disconnected from the pump while the pump is stopped. Select acknowledge to clear the alarm or the alarm will automatically clear after 5 seconds.
Preventive maintenance due.	Medium	Your facility may have established a maintenance program for the pump, and the pump is due for preventive maintenance. Select acknowledge to clear the alarm and refer to your facility's policy for preventive maintenance.
Protocol library updating. Reselect protocol when update is complete.	Medium	A new or updated library is currently being downloaded into the pump. The pump will not allow you to select any new protocols while this update is in process. Select acknowledge to clear the alarm or it will automatically clear when the update is complete.

Alarms and Messages	Alarm Priority	Description / Corrective Action
Pump does not have a protocol library.	Medium	If the pump had a protocol library the last time it was powered on, but now it does not, you will see this alarm. This would happen if the pump was manually reverted to the factory default, has recently had a software update, or if an attempt to install a protocol library failed. Select acknowledge to clear the alarm and refer to your facility's CADD®-Solis system administrator to download a new protocol library.
Pump settings and patient data lost.	Medium	The pump reverted to the factory default. The pump was either manually reverted to this default, has recently had a software update, or it has not been in use for some time. Select acknowledge to clear the alarm and refer to your facility's CADD®-Solis system administrator to reprogram the pump.
Pump stopped by an alarm that has since cleared.	High	The pump was stopped by another high priority alarm. That alarm was not acknowledged, but the problem has since cleared. Select acknowledge to clear the alarm and restart the pump, if appropriate. The event log has recorded the alarm that stopped the pump. For information on accessing the event log, see *Reports* on page 27.
Pump stopped reminder.	High	This is a reminder that the pump has been stopped and is not delivering. Select acknowledge to clear the alarm. Start the pump, if appropriate. The alarm will repeat in 5 minutes if the pump has not been restarted or powered down.
Rechargeable battery near end of use. Replace battery.	Medium	The rechargeable battery pack is near the end of its life. It has been discharged and recharged so many times that it will soon be at the end of its use. You may continue to use it in this state.
Rechargeable battery reached end of use. Pump will not run.	High	The rechargeable battery pack is at the end of its life. It has been discharged and recharged so many times that it is no longer able to hold a good charge. Remove the battery from service. • Install 4 new AA batteries or a fully charged rechargeable battery pack. In order to start delivery, good batteries must always be installed even when an external source of power is connected.
Reservoir volume is zero. Pump stopped.	High	The reservoir volume has reached 0.0 mL. The pump was delivering and is now stopped and will not run. Select acknowledge to clear the alarm. Install a new fluid container and edit the value of the reservoir volume, if appropriate.
Reservoir volume low.	Medium / Low*	**Medium**: The programmed reservoir volume trip point has been reached indicating the level of fluid in the reservoir is low. Select acknowledge to clear the alarm. **Low**: The reservoir volume value is low, indicating that the level of fluid in the fluid container is low. Select acknowledge to clear the alarm or the alarm will automatically clear after 5 seconds. Prepare to install a new fluid container and edit the value of the reservoir volume, if appropriate.

* The low reservoir alarm can be set to one of two alarm types: "Insistent and One Time Only" alarm (Medium) or "Non-Insistent and Repeating" (Low). The "Insistent and One Time Only" alarm will not reoccur once it has been acknowledged. The "Non-Insistent and Repeating" alarm will repeat at the 75%, 50%, and 25% marks of the Reservoir Low Trip Point.

Alarms and Messages	Alarm Priority	Description / Corrective Action
Unknown cassette type. Remove cassette.	High	The pump detects the cassette is incompatible with the pump. The pump is stopped and will not run. Close the tubing clamp, remove and then reattach the cassette. If the alarm persists, replace the cassette. **NOTE**: You must remove the cassette to continue.
Unusable battery. Pump stopped	High	The batteries installed are either the wrong kind of AA batteries, or you are using a rechargeable battery pack that is not compatible with the pump. The pump was delivering and is now stopped and will not run. Select acknowledge to clear the alarm. Remove the batteries and install a fully charged rechargeable battery pack or 4 new AA batteries. For more information on what type of batteries to use, see *Installing the Batteries* on page 14.
Unusable battery. Pump will not run.	Medium	The batteries installed are either the wrong kind of AA batteries, or you are using a rechargeable battery pack that is not compatible with the pump. Select acknowledge to clear the alarm. Remove the batteries and install a fully charged rechargeable battery pack or 4 new AA batteries. For more information on what type of batteries to use, see *Installing the Batteries* on page 14.
Upstream occlusion. Clear occlusion between pump and reservoir.	High	Fluid is not flowing from the fluid container to the pump, which may be resulting from a kink, a closed clamp, or air bubble in the tubing between the fluid container and pump. Delivery is paused and will resume if the occlusion is removed. Remove the obstruction to resume operation. The alarm will clear when the occlusion is removed. You will be required to acknowledge this alarm after it clears if it has occurred and cleared more than 3 times within 15 minutes.

Cleaning the Pump and Accessories

Cleaning Solutions

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

NOTE: Refer to the instructions for use for each accessory before proceeding with cleaning.

- Soap solution
- Benzalkonium chloride concentrate (0.13%)
- Glutaral concentrate, USP (2%)
- 10% solution of household bleach (one part household bleach to nine parts water)
- Alcohol, USP (93%)
- Isopropyl alcohol, USP (99%)
- Chlorhexidine gluconate (4%)
- PDI Super Sani-Cloth®
- Madacide, MADA Medical
- Virex II made by Johnson Wax
- Coverage Spray and Coverage HB Plus by Steris
- CaviCide® by Metrex
- Quik Fill Compac (A-456-N) by Airkem

CAUTION:

- **Do not immerse the pump in cleaning fluid or water. Do not allow solution to soak in to the pump, accumulate on the keypad, or enter the battery compartment, USB port, remote dose cord jack, or power jack areas. 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.**

1. Dampen a soft, lint-free cloth with cleaning solution. Apply the solution to the exterior surface of the pump or accessory (per manufacturer's instructions). ***Do not allow the solution to soak into the pump or accessory.***

   NOTE: Ensure that debris is not allowed to build up on the pressure plate surface of the pumping mechanism (see the Technical Manual for a diagram of the pumping mechanism). Inspect the air detector sensor slot and remove any debris.

2. Allow the pump to dry completely before use.

Exposure to Radiation or Magnetic Resonance Imaging (MRI)

CAUTION:

- **The pump SHOULD NOT BE DIRECTLY IRRADIATED by therapeutic levels of ionizing radiation because of the risk of permanent damage to the pump's electronic circuitry. The best procedure to follow is to remove the pump from the patient during therapeutic radiation sessions or diagnostic levels of radiographic and fluoroscopic radiation. If the pump must remain in the vicinity during a diagnostic or therapy session, it should be shielded, and its ability to function properly should be confirmed following treatment.**
- **Do not expose the pump directly to ultrasound, as permanent damage to the pump's electronic circuitry may occur.**
- **Magnetic fields produced by magnetic resonance imaging (MRI) equipment may adversely affect the operation of the pump. Remove the pump from the patient during MRI procedures and keep it at a safe distance from magnetic energy.**
- **Use of this pump on patients monitored by electronic equipment may cause artifactual interference. As with all electronic equipment, electrical artifacts which affect the performance of other equipment, such as ECG monitors, can occur. The user should check the correct function of the equipment prior to use.**
- **Do not use the pump in hyperbaric chambers as they will affect how the pump works and may also cause damage to the pump.**

Continuous Rate Scroll Ranges

Units	Starting Value	Increment		Maximum
Milliliters	0	**0.10**		30.00
Milligrams & Micrograms	10% of concentration	**mg only:** Values between 0.01 and 0.5: **mcg only**: Values between 0.1 and 0.5: Values between 0.5 and 100: Values between 100 and 1000: Values greater than 1000:	**0.01** **0.1** **0.1** **1.0** **10.0**	**Concentration x 30**

PCA Dose, Clinician Bolus Scroll Ranges: Milliliters

Milliliters	
increment	max
0.05	20

PCA Dose, Clinician Bolus Scroll Ranges: Milligrams

Concentration mg/mL	Milligrams increment	max
0.1	0.01	2
0.2	0.02	4
0.3	0.03	6
0.4	0.04	8
0.5	0.05	10
1	0.05	20
2	0.10	40
3	0.15	60
4	0.20	80
5	0.25	100
6	0.30	120
7	0.35	140
8	0.40	160
9	0.45	180
10	0.50	200
11	0.55	220
12	0.60	240
13	0.65	260
14	0.70	280
15	0.75	300

Concentration mg/mL	Milligrams increment	max
20	1.00	400
25	1.25	500
30	1.50	600
35	1.75	700
40	2.00	800
45	2.25	900
50	2.50	1000
55	2.75	1100
60	3.00	1200
65	3.25	1300
70	3.50	1400
75	3.75	1500
80	4.00	1600
85	4.25	1700
90	4.50	1800
95	4.75	1900
100	5.00	2000

PCA Dose, Clinician Bolus Scroll Ranges: Micrograms

Concentration mcg/mL	Micrograms increment	max
1	0.05	20
2	0.10	40
3	0.15	60
4	0.20	80
5	0.25	100
6	0.30	120
7	0.35	140
8	0.40	160
9	0.45	180
10	0.50	200
11	0.55	220
12	0.60	240
13	0.65	260
14	0.70	280
15	0.75	300
20	1.00	400
25	1.25	500
30	1.50	600
35	1.75	700
40	2.00	800

Concentration mcg/mL	Micrograms increment	max
45	2.25	900
50	2.50	1000
55	2.75	1100
60	3.00	1200
65	3.25	1300
70	3.50	1400
75	3.75	1500
80	4.00	1600
85	4.25	1700
90	4.50	1800
95	4.75	1900
100	5.00	2000
200	10.00	4000
300	15.00	6000
400	20.00	8000
500	25.00	10000

Technical Description

Standards used in development of the pump

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

Medical Electrical Equipment

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

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

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

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

IEC 60601-1-4 (2000), Medical Electrical Equipment, Part 104: General Requirements for Safety - Collateral Standard: Programmable electrical medial systems.

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

CAN/CSA-C22.2 601.1-M90, Medical Electrical Equipment, Part 1: General Requirements for Safety - November 1990 (Canadian Deviations to IEC 60601-1) Update No. 2 (November 2003).

Electromagnetic Compatibility

RTCA/DO -160E (2004), Radiated Emissions Only, Category M Limit.

EN 60601-1-2 (2001), Medical Electrical Equipment, Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.

IEC 60601-1-2 (Edition 2.1, 2004-11), Medical Electrical Equipment, Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.

IEC 61000-4-2 (2001), Electromagnetic Compatibility (EMC), Part 4-2: Testing and measurement techniques. Electrostatic Discharge immunity test.

IEC 61000-4-3 (2006), Electromagnetic Compatibility (EMC), Part 4-3: Testing and measurement techniques. Radiated, radio frequency, electromagnetic field immunity test.

IEC 61000-4-4 (2004), Electromagnetic Compatibility (EMC), Part 4-4: Testing and measurement techniques. Electrical fast transient/burst immunity test.

IEC 61000-4-5 (2005), Electromagnetic Compatibility (EMC), Part 4-5: Testing and measurement techniques. Surge immunity test.

IEC 61000-4-6 (2004), Electromagnetic Compatibility (EMC), Part 4-6: Testing and measurement techniques. Immunity to conducted disturbances, induced by radio-frequency fields.

IEC 61000-4-8 (2001), Electromagnetic Compatibility (EMC), Part 4-8: Testing and measurement techniques. Power frequency magnetic field immunity test.

IEC 61000-4-11 (2004), Electromagnetic Compatibility (EMC), Part 4-11: Testing and measurement techniques. Voltage dips, short interruptions and voltage variations immunity test.

CISPR11 (2004), Limits and methods of measurement of electromagnetic disturbance characteristics of industrial, scientific and medical (ISM) radio frequency equipment. Amendment 1 (1999) Amendment 2 (2002).

EN 45502-1 (1998), Active implantable medical devices. Part 1. General requirements for safety, marking and information to be provided by the manufacturer.

EN 55011 (1998), Industrial, scientific and medical (ISM) radio frequency equipment - Radio disturbance characteristics - Limits and methods of measurement. Amendment 1 (1999), Amendment 2 (2002)

Miscellaneous Standards

USB 1.1 Universal Serial Bus (USB) Specification, Revision 1.1, September 23, 1998 – USB.org

EN 1041 (1998), Information supplied by the manufacturer with medical devices.

IEC/TR 60878 (2003), Graphical symbols for electrical equipment in medical practice.

EN 980 (2003), Graphical symbols for use in the labeling of medical devices.

IEC 60529 (2001), Degrees of protection provided by enclosures (IP Code).

Specifications (Nominal)

General Pump Specifications

Medication cassette reservoir, part number 21-7002, CADD® extension sets, part number 21-7045, and CADD® administration sets, part number 21-7091 were used to test the pump.

Resolution

Medication cassette reservoir or CADD® administration set, 0.050 mL per pump stroke nominal.

Size

4.1 cm × 10.2 cm × 12.7 cm [1.6 in. × 4 in. × 5 in.] excluding cassette or other accessories.

Weight

595 g [21 oz.] including 4 AA alkaline batteries, excluding other accessories.

Pump Alarms

The following alarms are all considered to be high priority alarms: Battery depleted while delivering; Battery removed while delivering; Battery unusable while delivering; Rechargeable battery end of life; Disposable detached while delivering; Disposable attached improperly; Disposable type high flow administration set; Disposable type invalid; Disposable locked but not latched; Reservoir volume empty; Pressure sensor faulty; Downstream occlusion; Upstream occlusion; Air in line detected; Remote dose cord key stuck; Key stuck; Stop mode reminder; Pump was automatically stopped.

There are an additional 19 medium priority alarms, 8 low priority alarms, and 20 informational messages alerts.

Battery Fallout Alarm

Alarm sounds for 2 minutes if the pump has been powered up for a minimum of 2 minutes. **NOTE**: Only enabled while pump is in run mode.

Battery Status

Battery State	CADD® Pump Status
25%—100%	No alarm
Low battery	Transition to low battery condition; battery low message appears; 3 beeps every 5 min.† LCD backlight will flash for 12 ms during each motor operation.
Depleted battery	Transition to depleted battery condition; battery depleted message appears; pump beeps continuously.††
Shut down	Pump shuts off due to too low operating voltage.

CADD®-Solis pump low battery conditions.

† The pump emits 3 beeps every 5 minutes, and the low battery warning message appears on the pump's display, indicating that the battery power is low, but the pump is operable.

†† The pump emits a continuous, variable-tone alarm, and the depleted battery warning message appears on the display, the battery power is too low to operate the pump, and the pump delivery operation has stopped.

Continuous Delivery Alkaline Battery Life with screen intensity set to 3

Rate	Life	Volume
0.4 mL/hr	260 hrs	104 mL
1 mL/hr	210 hrs	210 mL
5 mL/hr	165 hrs	825 mL
10 mL/hr	150 hrs	1500 mL
30 mL/hr	70 hrs	2100 mL

Continuous Delivery Rechargeable Battery Pack Life with screen intensity set to 3

Rate	Life	Volume
0.4 mL/hr	119 hrs	47.6 mL
1 mL/hr	89 hrs	89 mL
5 mL/hr	88 hrs	440 mL
10 mL/hr	86 hrs	860 mL
30 mL/hr	43 hrs	1290 mL

Classification

CF ♥, Class II □.

Moisture Protection

Splashproof (IPX4) per IEC 60529.

Maximum Infusion Pressure

27.0 psi [1.86 bar].

Maximum Time to Occlusion Alarm

0.1 mL/hr - medication cassette reservoir: 108 minutes. CADD® administration set: 122 minutes.
10 mL/hr - medication cassette reservoir: 44 seconds. CADD® administration set: 122 seconds.

NOTE: Values are nominal and based on actual test data.

Bolus Volume at Occlusion Alarm

0.1 mL/hr - medication cassette reservoir: 0.107 mL. CADD® administration Set: 0.136 mL.
10 mL/hr - medication cassette reservoir: 0.116 mL. CADD® administration set: 0.124 mL.

NOTE: Values are nominal and based on actual test data.

Power Sources

Four AA (IEC LR6) alkaline batteries; AC adapter; rechargeable battery pack.

Charging System for Internal Memory Backup Battery

The internal memory backup battery utilizes lithium manganese dioxide technology. It charges whenever the pump is powered on and has a 10 month memory capacity once it has been charged for 250 hours at 20°C (68°F).

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).

Relative Humidity

20% to 90% relative humidity, non-condensing.

Atmospheric Pressure

70 kPa (10.2 psi) to 106 kPa (15.4 psi).

System Delivery Accuracy

± 6% (nominal). At low infusion rates, this accuracy may not be achieved for short periods. During the total infusion time, the accuracy averages out.

WARNING:

- **Ensure that the ± 6% system delivery accuracy specification is taken into account when programming the pump and/or filling the reservoir. Failure to do so may result in medication in the reservoir becoming depleted sooner than expected. If the pump is being used to deliver critical or life sustaining medication, the interruption in the delivery of medication could result in patient injury or death.**
- **System delivery inaccuracies may occur as a result of back pressure or fluid resistance, which depends upon drug viscosity, catheter size, and extension set tubing (for example, microbore tubing), and placing the infusion reservoir and/or pump above or below the level of the patient. System delivery inaccuracy may result in under or over-delivery of medication, which could result in death or serious injury to the patient.**

System Definition

CADD®-Solis pump with:
- An attached medication cassette reservoir and CADD® extension set or
- an attached CADD® administration set or

CADD®-Solis pump with:
- an attached medication cassette reservoir with flow stop feature and CADD® extension set or
- A CADD® administration set with flow stop feature.

High Pressure Alarm Threshold
18 ± 9 psi [1.24 ± 0.62 bar].

Air Detector Alarm
Sensitivity:
Low - Single bubble greater than 400 µL .
High - Single bubble greater than 150 µL .
Accumulated Air: Greater than 1 mL air over 15 minutes (nominal).

Bolus Accuracy Specification ± 6%
Actual Test Data for Bolus Accuracy at 0.05 mL:

Average	0.0508 mL
% Error	1.6%
Minimum Error %	–3.0%
Maximum Error %	4.2%

Actual Test Data for Bolus Accuracy at 20 mL:

Average	20.108 mL
% Error	0.5%
Minimum Error %	–2.9%
Maximum Error %	4.5%

Maximum Volume Infused Under Single-Fault Conditions
CADD® administration set: 0.15 mL.

Delivery Rate during priming
Approx. 250 mL/hr.

Alarm disabled during priming
Air-In Line.

Delivery Specifications

Reservoir Volume
0 to 9999; programmable in 1 mL increments, displayed in 0.1 mL increments.

Programming Units
Milliliters (mL), milligrams (mg), micrograms (mcg).*

*If programming through the manual mode. Otherwise the programming units are preset through the CADD®-Solis Medication Safety Software.

Concentration
mg/mL:
0.1 to 0.5 mg/mL in increments of 0.1 mg/mL.
0.5 to 1 mg/mL in increments of 0.5 mg/mL.
1 to 15 mg/mL in increments of 1 mg/mL.
15 to 100 mg/mL in increments of 5 mg/mL.

mcg/mL:
1 to 15 mcg/mL in increments of 1 mcg/mL.
15 to 100 mcg/mL in increments of 5 mcg/mL.
00 to 500 mcg/mL in increments of 100 mcg/mL.

Continuous Rate
0 to 30 mL/hr (or the mg or mcg equivalent).

PCA Dose
0 mL to 20 mL (or the mg or mcg equivalent).
Delivery rate (continuous rate + PCA dose): programmable from 40 to 175 mL/hr.

PCA Dose Lockout
1 minute to 24 hours in the following increments:
1 minute for values between 1 and 20 minutes.
5 minutes between 20 minutes and 24 hours.

Max Doses per Hour
1 to 60.

Delivery Limit Amount
0.1 to 1000 mL (or the mg or mcg equivalent) in increments of:
0.01 mL from 0.01 to 0.5 mL.
0.5 mL from 0.5 to 100 mL.
1.0 mL from 100 to 1,000 mL.

Given
0 to 99,999.99 in 0.01 unit increments.

Clinician Bolus
0 mL to 20 mL (or mg or mcg equivalent) delivery rate (continuous rate + clinician bolus): programmable from 40 to 175 mL/hr.

Administrator Settings Specifications

Delivery Limit Method
Delivery limit, max doses per hour, or not in use.

Delivery Limit Period
1 to 12 hours in increments of 1 hour.

Maximum Delivery Rate (combined bolus and continuous)
40 to 175 mL/hr in increments of 1 mL.

Key Beeps
On or off.

Res Vol Low Trip Point
1 to 999 mL in increments of 1 mL.

Res Vol Empty Alarm
Insistent and one time only or non-insistent and repeating.

Pump Stopped Alarm
Informational or high priority.

Air Detector
Turned on or turned off.

Air Detector Sensitivity
Low Sensitivity - Single bubble greater than 400 µL .
High Sensitivity - Single bubble greater than 150 µL .

Alarm Volume
High, medium, or low.

PM (Preventative Maintenance) Reminder
Interval: 1 to 24 months in 1 month increments.
Enable: On or off.

Custom Keypad Code
001 to 899 in increments of 1.

Custom Clinician Code
001 to 899 in increments of 1.

Custom Administrator Code
001 to 899 in increments of 1.

Date Format
US standard (mm/dd/yy) or European standard (dd/mm/yy).

Time
00:00 to 23:59.

Downstream Occlusion Sensitivity
High Sensitivity - once the high pressure alarm threshold is reached, the downstream occlusion alarm is triggered immediately.
Low Sensitivity - once the high pressure alarm threshold is reached, the downstream occlusion alarm is delayed for 2 seconds, this allows for the pressure to settle before a possible alarm (if the pressure settles below the high pressure alarm threshold before the 2 second delay is complete, the alarm will not happen).

Upstream Occlusion Sensor
On or off.
NOTE: The upstream occlusion sensor is automatically disabled during use with medication cassette reservoirs.

Electromagnetic Emissions and Immunity Declarations

Guidance and manufacturer's declaration - electromagnetic emissions		
The CADD®-Solis pump is intended for use in the electromagnetic environment specified below. The customer or the user of the CADD®-Solis 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. 100-240 VAC 50/60Hz to 7VDC switching desktop AC adapter, with an AC power cord length of 1.8 m (6 feet).
2. Rechargeable battery pack.
3. Remote dose cord with a length of 152 cm ± 5 cm (60 in. ± 2 in.).
4. USB cable length of less than 2 m (6.5 feet).

WARNING:

- **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.**

Guidance and manufacturer's declaration - electromagnetic immunity			
The CADD®-Solis pump is intended for use in the electromagnetic environment specified below. The customer or user of the CADD®-Solis 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	± 6 kV contact ± 8 kV air	± 8 kV contact ± 15 kV air (IEC 60601-2-24)	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 line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	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.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The CADD®-Solis pump is intended for use in the electromagnetic environment specified below. The customer or user of the CADD®-Solis 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 outside ISM bands[a]	3 Vrms	Recommended separation distance $d=1.2\sqrt{P}$
Conducted RF IEC 61000-4-6	10 Vrms 150 kHz to 80 MHz in ISM bands[b]	10Vrms	Recommended separation distance $d=1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	$d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 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).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[c] should be less than the compliance level in each frequency range.[d] 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] The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

[b] The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

[c] 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 CADD®-Solis pump is used exceeds the applicable RF compliance level above, the CADD®-Solis pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CADD®-Solis pump.

[d] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the CADD®-Solis pump

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

Rated maximum output power or transmitter W	Separation distance according to frequency of transmitter m			
	150 kHz to 80 MHz outside ISM bands $d=1.2\sqrt{P}$	80 MHz to 800 MHz in ISM bands $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2.5 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.12	0.23
0.1	0.38	0.38	0.38	0.73
1	1.2	1.2	1.2	2.3
10	3.8	3.8	3.8	7.3
100	12	12	12	23

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 The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

NOTE 3 An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Collect Separately

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

In accordance with Directive 2002/96/EC Waste Electrical and Electronic Equipment, residents of the European Union must follow specific disposal or recycling instructions for this product. Contact your local distributor, or visit the following web site for specific instructions:
http://www.smiths-medical.com/recycle/index.html

Non-European Union residents must dispose of or recycle this product (including batteries) in accordance with the local laws or regulations that apply.

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.

Programming Screens/Menus Maps

Patient Specific Parameters and/or Home Screen

Continuous Rate*
PCA Dose*
PCA Lockout*
Hourly Limit*
Max Doses / Hour*
Reservoir Vol.

*If configured in the administrator settings to appear.

Tasks

Give Clinician Bolus
Start New Patient
Start New Protocol, Same Patient
Prime Tubing
Set Time and Date
Adjust Background Intensity
Adjust Alarm Volume
View Reports
Adjust Admin Settings

Reports

Given and PCA Dose Counters
PCA Dose Graph
Delivery History and Pie Chart
Delivery Log
Event Log
Protocol Library Summary
Device Information

Administrator Settings

Delivery
Alarms
Security
Set Time and Date
Display and Sound
Default to Factory Settings

NOTE: See the Administrator Settings Guide for detailed information on navigating the administrator settings menu.

Default Factory Settings

The first time you use the pump, the protocol will be set to the factory default. If you desire to reset the pump to the factory default, you may do so at any time (refer to the Administrator Settings Guide for more information on how to reset the pump to the factory default).

The following chart details the factory default parameters:

Programming Units	mL
Continuous Rate	0 mL/hr
PCA Dose Amount	0 mL
PCA Dose Lockout Period	1 hour
Delivery Limit Method	Not in Use
Reservoir Volume	1 mL
Reservoir Volume Reset Value	100 mL
Reservoir Volume Low trip point	5.0 mL
Reservoir Volume Low Alert Type	Insistent and One Time Only
Repeat Reservoir Volume Empty Alert Type	One Time Only
Clinician Bolus Amount	0 mL
Maximum Fluid Delivery Rate (combined bolus and continuous)	175 mL/hr
Pump Stopped Alert Type	Informational
Upstream Sensor	On
Downstream Occlusion Sensitivity	Low
Air Detector Enabled	Yes
Air Detector Sensitivity	Low
Date Format	mm/dd/yy
Preventative Maintenance Reminder	Off
Sound Volume	High
Unlock Security Code	** Text Omitted **
Clinician Security Code	** Text Omitted **
Administrator Security Code	See your CADD®-Solis system administrator for default security codes
Keypad Security	Code only
Backlight Intensity	3
Color Theme	Black
Sound Theme	Standard
Key Beeps Enabled	Yes
Manual Mode Programming Code	Administrator Code

Accuracy Test Results

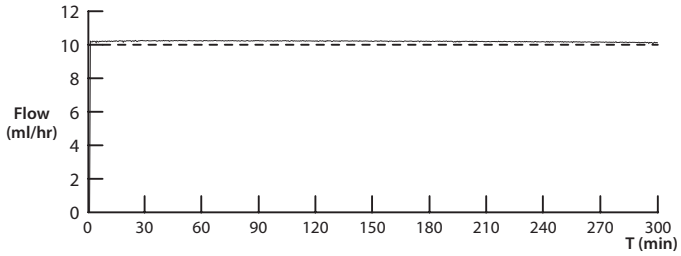
In this device, as with all infusion pumps, the motion of the pumping mechanism and variations in individual disposables cause short-term fluctuations in rate accuracy. The following curves show typical performance of the pump system in two ways:

1. A flow versus time graph during the stabilization period (start-up curves).
2. The accuracy of fluid delivery of particular time periods or 'observation windows' is measured (trumpet curves).

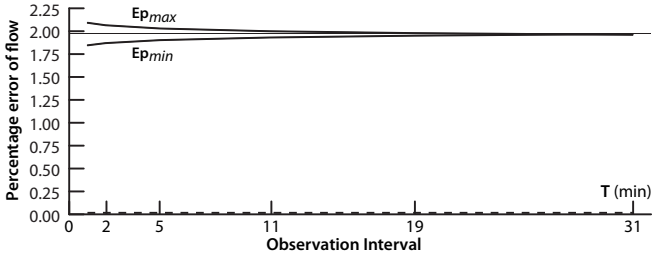
The start-up curve displays flow rate continuously from the start of the infusion. The curve visually represents flow rate uniformity. Trumpet curves are derived from the sixth hour of this data. Tests performed per IEC60601-2-24 standard.

Over long observation windows, short term fluctuations have minimal effect on accuracy as represented by the flat part of the curve. As the observation window is reduced, short term fluctuations have an increasing effect as represented by the "mouth" of the trumpet. Being aware of system accuracy over various observation windows may be of interest when certain drugs are being administered. Short term fluctuations in rate accuracy may have clinical impact depending on the half-life of the drug being infused, both the trumpet curve and drug half-life should be taken into consideration.

Start-up curve over the stabilization period Flow rate: Intermediate (10 mL/hr)



Trumpet Curve over T(2) Period: Intermediate rate (10 mL/hr)



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Limited Warranty

Smiths Medical MD, Inc. (the "Manufacturer") warrants to the Original Purchaser that the CADD®-Solis Ambulatory Infusion Pump ("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 two years 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 two-year period.

The following conditions, procedures, and limitations apply to the Manufacturer's obligation under this warranty:

A. **Parties Covered by this Warranty:** This warranty extends only to the Original Purchaser of the Pump. This warranty does not extend to subsequent purchasers. The Original Purchaser may be a patient, medical personnel, a hospital, or institution which purchases the Pump for treatment of patients. The Original Purchaser should retain the invoice or sales receipt as proof as to the actual date of purchase.

B. **Warranty Performance Procedure:** Notice of the claimed defect must be made in writing or by telephone to the Manufacturer as follows: Customer Service Department, **Smiths Medical MD, Inc.**, 1265 Grey Fox Road, St. Paul, MN 55112, (800) 426-2448 (USA, Canada) or **Smiths Medical International Ltd.** WD24 4LG, UK, +44 (0)1923 246434. 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.

CADD™

Smiths Medical MD, Inc.
St. Paul, MN 55112 USA
1 800.426.2448 (USA)
+1 651.633.2556
www.smiths-medical.com

CE 0473 Rx ONLY

EC REP
Smiths Medical International Ltd.
WD24 4LG, UK
Tel: +44 (0) 1923 246434

AUS REP
Smiths Medical Australasia Pty. Ltd.
61 Brandl Street,
Eight Mile Plains, QLD 4113, Australia.
Tel: +61 (0) 7 3340 1300

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