CADD®

CADD®-Solis 2110

Ambulatory Infusion Pump

Operator's Manual

Software version 4.2

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. The pump can be programmed with a protocol configuration consisting of a therapy, qualifier, and drug. Medication is delivered at a constant rate, and/or with an intermittent bolus, and/or with a patient dose.

This manual concerns CADD®-Solis Ambulatory Infusion Pumps, model 2110, with software version 4.2 (Software package # 97-0582-0402XX-01). Smiths Medical recommends that you maintain the same software version across all CADD®-Solis pump models in your facility.

This operator's manual, the pump, and its accessories are intended for trained clinician use only. Do not permit unauthorized clinicians or 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 security codes to those who are authorized. Access to the pump key should also be restricted. Contact Smiths Medical and/or your facility's policies and procedures for additional training information and materials for the safe and effective use of the pump.

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, contact Smiths Medical to see if an updated version is available.

Technical Assistance

If you have comments or questions concerning the operation of the CADD®-Solis Ambulatory Infusion Pump, call the number given below. When calling, specify the pump software version number. This information is located in the device information report (See *Reports* on page 39).

Smiths Medical is available to help with the programming and operation of the CADD®-Solis Ambulatory Infusion Pump.

If this manual is being viewed electronically, a printed copy is available from Smiths Medical upon request.

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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.

Contraindications

- The pump is not to be used for delivery of blood or cellular blood products, as blood and cellular blood products will be damaged by the pumping mechanism.
- This pump is not to be used in any intra-articular space infusion.

Warnings

- This operator's manual, the pump, and its accessories should be used only by clinicians that have been trained and authorized per your facility's policies and procedures.
- To avoid explosion hazard, do not use the pump in the presence of flammable anesthetics or explosive gases.
- For patients 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 suspends 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 suspends medication delivery.
- The user should ensure that the performance offered by the pump is fit for the intended use and that the pump is not used in any way or for any purpose other than its intended use.
- If the pump is dropped or hit, inspect it for damage. Do not use a pump that is damaged or not functioning properly. Contact Smiths Medical Customer Service to return a pump for service.
- To avoid patient injury and electric shock, remove the pump from patient use prior to any preventative maintenance and servicing of the pump.
- Do not use a syringe with the CADD®-Solis pump. The use of a syringe could result in underdelivery of medication.
- The CADD®-Solis pump and accessories include small component pieces that could pose a choking hazard to young children.
- 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, CADD® extension set, or CADD® administration set is used for epidural space or subarachnoid space drug delivery, it is strongly recommended that it be clearly differentiated from those used for other routes of infusion (for example, by color coding or other means of identification).
- If the air detector is turned off, the pump does not detect air in the fluid path. It is recommended that you periodically inspect the fluid path and remove any air to prevent air embolism.
- The air detector, when turned on, may be set to detect and alarm for air bubbles as small as 150 uL. The High Sensitivity setting and/or filtered sets should be considered for patients and therapies with a risk of harm due to an air embolism.

- When the upstream occlusion sensor is turned off, the pump does not detect occlusions upstream between the pump and the reservoir. Periodic inspection of the fluid path for kinks, a closed clamp, or other upstream obstructions is recommended. Upstream occlusions may result in underdelivery of medication.
- Do not use rechargeable NiCd or nickel metal hydride (NiMH) batteries. Do not use carbon zinc ("heavy duty") batteries. They do not provide sufficient power for the pump to operate properly.
- Always have new batteries available for replacement. If power is lost, nondelivery of drug occurs.
- A rechargeable battery pack that has reached the end of it useful life must be replaced with either another CADD®-Solis rechargeable battery pack or with 4 AA batteries.
- 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.
- A hazard can exist if different alarm styles are used on multiple pumps in the same single care area; for example, a critical care area or operating room. Auditory alarm signal sound levels that are less than ambient levels can hinder operator recognition of alarm conditions.
- A hazard can exist if a user depends on audible alarm indications without a corresponding visual indication. Use of low volume alarm settings or distance from the device can hinder operator recognition of alarm conditions when hearing impairment may be a concern, or when the clinician may be away from the device.
- 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 non-delivery 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.
- Carefully route tubing, cords, and cables to reduce the possibility of patient entanglement or strangulation.
- Attach the cassette properly. A detached or improperly attached cassette could result in unregulated gravity infusion of medication from the reservoir or a reflux of blood.

  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 the tubing before removing the cassette from the pump. Removing the cassette without closing the clamp could potentially cause unregulated gravity infusion.
- Do not disclose pump security codes or any other information that would allow the patient or unauthorized clinician complete access to programming and operating functions.
- Do not leave the pump unattended while unlocked. Many programming functions are accessible while the pump is unlocked.
- Exercise care when using the clinician bolus function. Because there are no limits to the frequency of delivering a bolus, and because the bolus amount may be set as high as 50 mL (or the mg or mcg equivalent), do not permit the patient or an unauthorized clinician 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 deliver the programmed value, or cancel to leave the screen.
- Do not prime the fluid path with the tubing connected to a patient as this could result in overdelivery of medication or air embolism.
- To prevent air embolism, ensure that the entire fluid path is free of all air bubbles before connecting to the patient.
- The remote dose cord is for *patient use only*. Operation by anyone other than the patient may cause overdelivery of medication.
- The manual program mode does not contain programming limits. Carefully review each parameter to ensure it accurately matches the prescription.
- Always carefully review the program on the pump after it has been programmed to verify that the pump is programmed correctly.
- The pump and reusable accessories should be cleaned and disinfected after each patient use and in accordance with this manual and your organization's policies and procedures for reusable, solid surface, non-critical medical devices.
- Ensure that debris is not allowed to build up on the pressure plate surface of the pumping mechanism. Inspect the air detector sensor slot and remove any debris. A blocked air detector sensor may not detect air present in the fluid path.
- 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 beyond ± 6% may occur as a result of back pressure or fluid resistance, which depends upon temperature, drug viscosity, catheter size, extension set tubing (for example, microbore), in-line components (such as filters and needleless access connectors), and placing the infusion reservoir and/or pump above or below the level of the patient. System delivery inaccuracy may result in under or overdelivery of medication. (See *System Delivery Accuracy on page 75* for more information.)
- 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.
- Serious harm to the patient or operator may result from the use of modified parts or parts not authorized by Smiths Medical. Do not modify the system, parts, or accessories.
- The pump should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, you should verify normal operation of the pump in the configuration in which it is to be used.
- Common portable and mobile consumer electronic devices may cause interference with the pump. Observe the pump to verify normal operation. If abnormal performance is observed, it may be necessary to reorient or relocate the pump away from radio frequency transmitting devices.
- To avoid electric shock, do not touch the Power Jack, Remote Dose Cord Jack, USB Port, Battery Terminals, or any other connectors and the patient simultaneously.
- Residential/facility wiring must comply with all applicable electrical codes. Do not bypass power cord connections. Do not remove a prong from the power cord.
- 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.
- Always set the Delivery Limit amount alarm, Reservoir Volume Low alarm, and all other variable alarm settings to clinically appropriate settings. Setting alarm limits to values not clinically safe for the patient may cause patient harm due to a delay in therapy.
- To avoid any potential electrical interference or delivery inaccuracies, power off the pump when the pump is being transported in an aircraft.

Cautions

- Do not operate the pump at temperatures below 2°C (36°F) or above 40°C (104°F) to avoid damaging the electronic circuitry.
- Do not store the pump at temperatures below –20°C (–4°F) or above 60°C (140°F) to avoid damaging the electronic circuitry. Do not store the pump with a CADD™ medication cassette reservoir or CADD® administration set attached.
- If the pump is stored outside of the environmental operating conditions and within the specified environmental storage conditions, allow the pump to warm or cool to operating temperature for at least one hour prior to use to avoid damaging the electronic circuitry.
- Do not expose the pump to humidity levels below 20% or above 90% relative humidity to avoid damaging the electronic circuitry.
- 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.
- Use only Smiths Medical accessories that are specified for use with the CADD®-Solis Ambulatory Infusion Pump, as other brands may adversely affect pump operation.
- If you are using a CADD™ medication cassette reservoir in which the medication is frozen, thaw at room temperature only. Do not heat in a microwave oven as this may damage the product and cause leakage.
- Do not immerse the pump in cleaning fluid or water. Do not allow solution to soak 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 oversaturate the chassis area on the bottom of the pump with cleaning or disinfecting solutions. Oversaturating this area can cause damage to the pump sensors over time.
- Do not clean the pump with acetone, other plastic solvents, or abrasive cleaners, as damage to the pump may occur. Also refer to the instructions for use for each accessory before proceeding with cleaning and disinfecting. Some accessories may have their own list of acceptable cleaning and disinfecting solutions.
- The pump should *not* be directly irradiated by therapeutic levels of ionizing radiation due to 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 electronic circuitry may occur.
- The pump should not be exposed to MRI equipment because the pump is not intended or designed to be used in the MRI environment. Exposing the pump to magnetic fields that exceed the 600 gauss line may cause irreversible damage, rendering the pump inoperable.
- 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 affect how the pump works and may also cause damage to the pump.

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References and Troubleshooting

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General Description

Introduction

The CADD®-Solis Ambulatory Infusion 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, and/or an intermittent bolus, and/or with patient-controlled demand doses.

Contraindications

- The pump is not to be used for delivery of blood or cellular blood products, as blood and cellular blood products will be damaged by the pumping mechanism.
- This pump is not to be used in any intra-articular space infusion.

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.

Smiths Medical has performed neurotoxicological testing using 0.9% saline to represent aqueous drugs infused into epidural and subarachnoid spaces.

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, CADD® extension set, or CADD® administration set is used for epidural space or subarachnoid space drug delivery, it is strongly recommended that it be clearly differentiated from those used for other routes of infusion (for example, by color coding, or other means of identification). Drugs not intended for epidural or subarachnoid space infusion could result in serious patient injury or death.**

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.

Delivery Methods

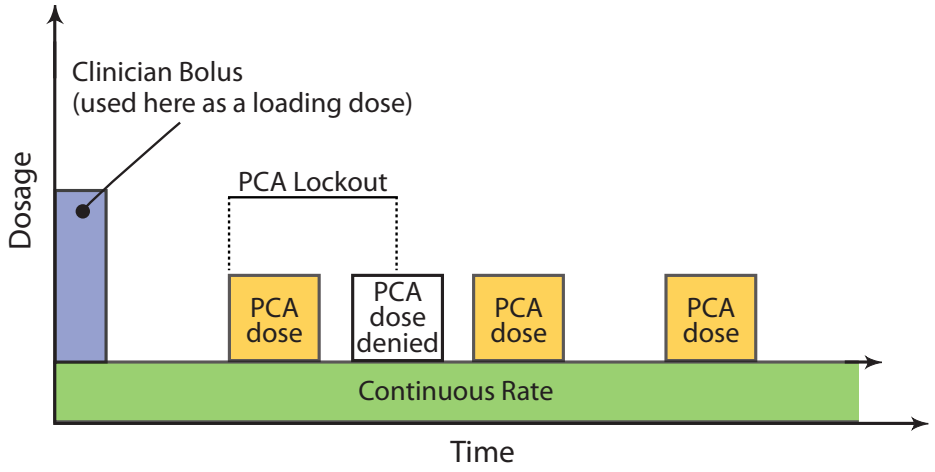
The pump provides the following methods of delivery:

- **Continuous rate:** infusion of drug at a constant, programmed rate

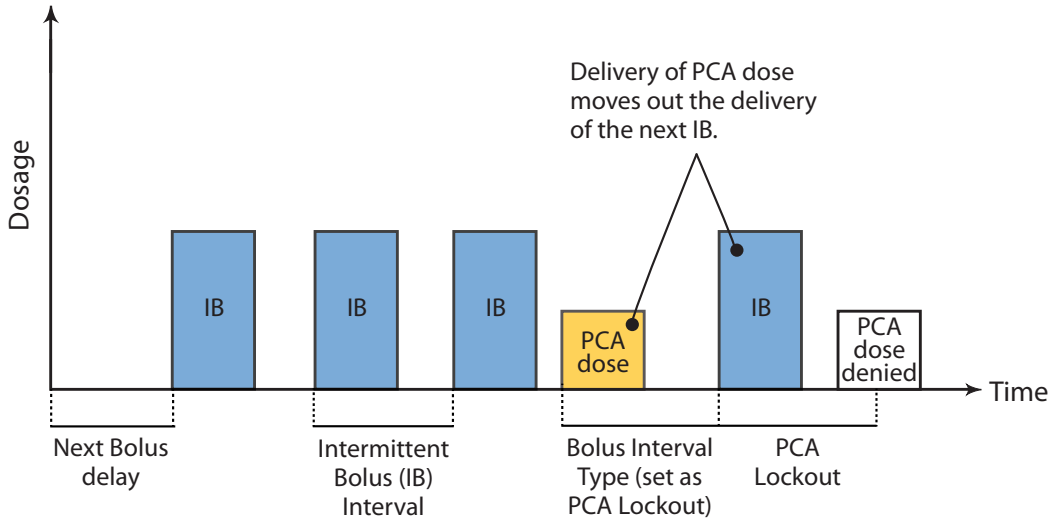
- **Intermittent bolus (IB):** a series of doses automatically delivered at regular, programmed intervals
- **PCA (PCEA) dose:** a demand dose activated by the patient
- **Clinician bolus:** a dose activated by the clinician

Each of the methods may be programmed individually or in combination with each other. The figures below illustrate examples of combined delivery methods. Ranges, programming increments, rates, and volumes are listed in *Specifications (Nominal)* on page 10.

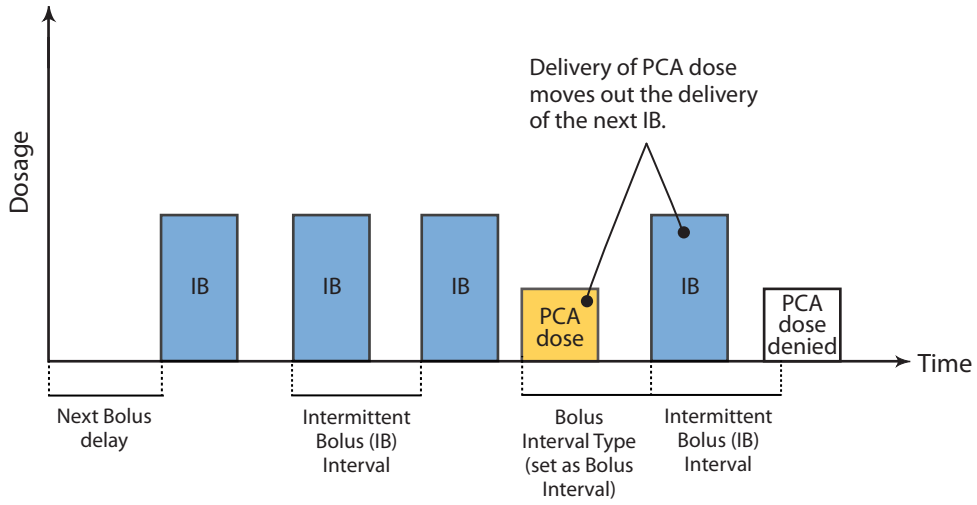
Example 1: Continuous Rate, PCA Doses, and Clinician Bolus



Example 2: Intermittent Boluses (IB) and PCA Doses, with Bolus Interval Type set as PCA Lockout



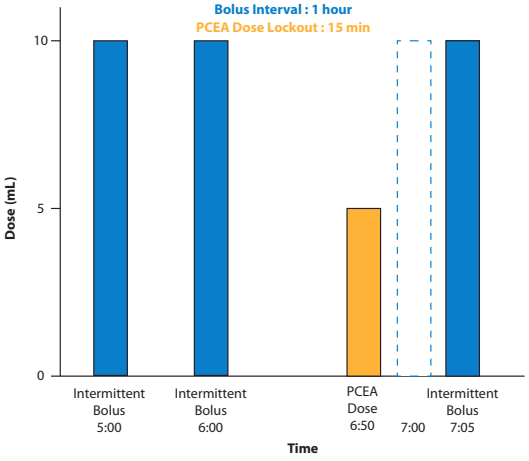
Example 3: Intermittent Boluses (IB) and PCA doses, with Bolus Interval Type set as Bolus Interval



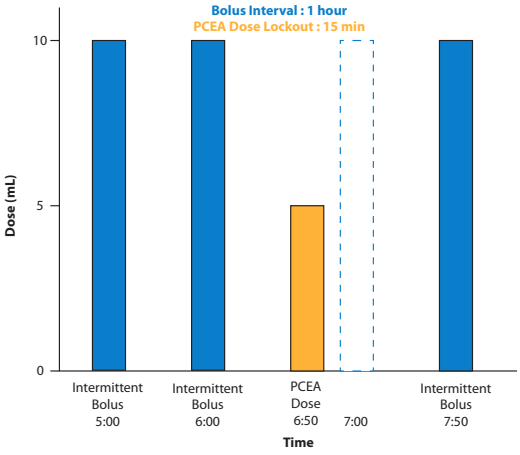
Programming Flexibility

With the CADD®-Solis system, you have the flexibility to delay a PIB following a PCEA dose based on the PIB interval or PCEA dose lock out interval.

Intermittent Bolus Examples

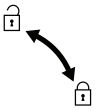


Bolus Interval Type Setting = PCEA Dose Lockout – Intermittent boluses will deliver every hour unless the time between a delivered PCEA Dose and the next scheduled PIB is less than the PCEA Dose Lockout time



Bolus Interval Type Setting = PIB Bolus Interval – Intermittent boluses will deliver every hour unless a PCEA Dose is delivered

Symbols

Symbols on the Pump and Labels			
Symbol	**Definition**	**Symbol**	**Definition**
	**Caution**		Power on/off button
	Follow Instructions for Use (The symbol appears on the device with a blue background.)		Cassette unlock/lock
	Catalog number		Soft key
	Serial number		Up button
	Date of manufacture		Down button
	Manufacturer		Select button
	Authorized representative in the European Community		Start/Stop button
	Temperature limitation		PCA (PCEA) dose button
	Humidity limitation		AA battery location, positive terminal faces up
	Atmospheric pressure limitation		AA battery location, negative terminal faces up
	Type CF applied part		AA battery location, positive terminal faces up
	Class II equipment		AA battery location, negative terminal faces up
IP24	Solid Particulate Protection: Protected from solid foreign objects greater than 12.5 millimeters in diameter. Liquid Ingress Protection: Splashproof - water splashed against the pump housing will have no harmful effects.		USB port
	Collect separately		Direct current (power jack)
Rx ONLY	**Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician.		Remote dose cord jack
	MR Unsafe		

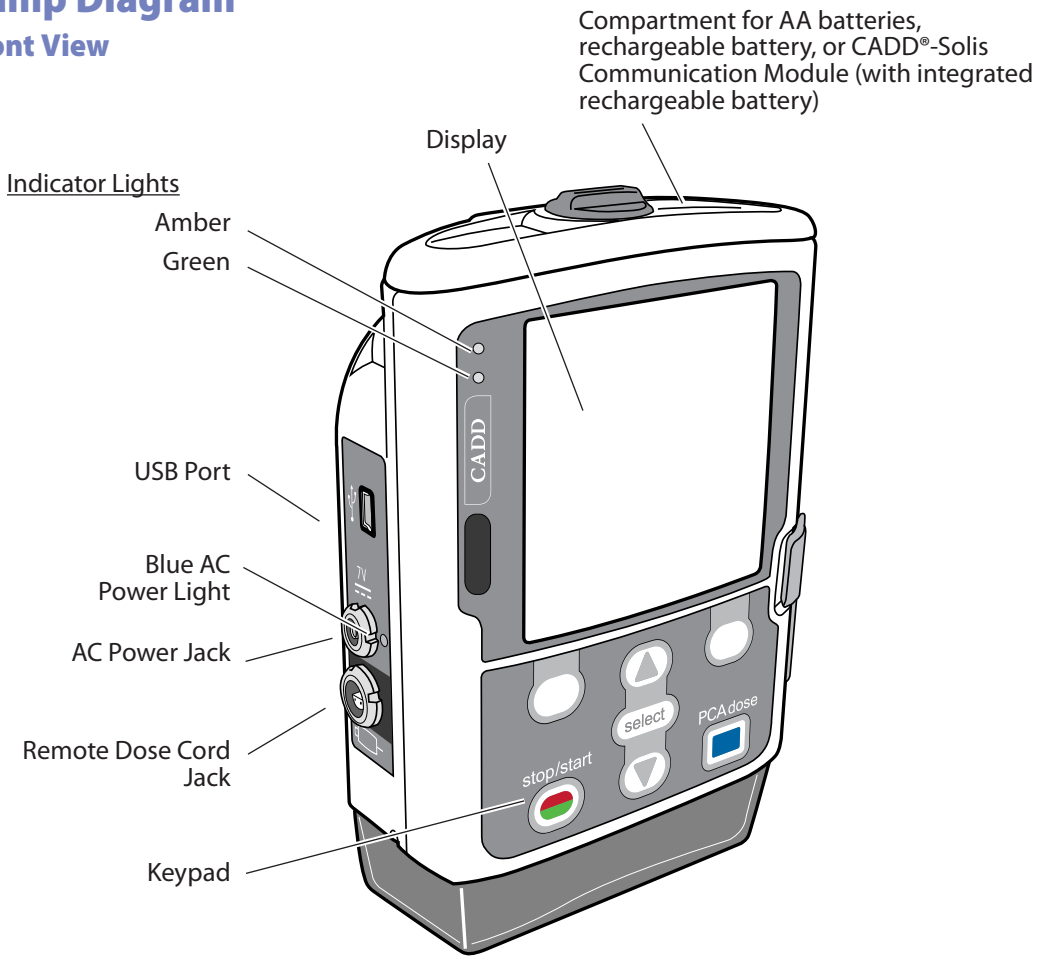
Symbols on the Pump Display	
Symbol	**Definition**
	Reservoir volume
	Charge level of rechargeable battery pack
	Charge level of rechargeable battery pack. AC adapter connected.
	Charge level of AA batteries
	Charge level of AA batteries. AC adapter connected.
	No battery installed, AC power only
	Incompatible battery
	Incompatible battery. AC Adapter connected.
	Wireless Off*
	Wireless On*, not associated with wireless access point
	Wireless On*, associated with wireless access Point
	Wireless On*, associated with wireless access Point, and communicating with PharmGuard® Server
	Pump status is Started or Running.
	Pump status is Paused or in KVO.
	Pump status is Stopped.

Symbol	Definition
	Item highlighted in the work area is at the top of the menu. Press ▼ to scroll down.
	Item highlighted in the work area is at the bottom of the menu. Press ▲ to scroll up.
	Home screen
	Keypad is locked
	Keypad is unlocked
	Appears next to a parameter that was reviewed and accepted.
	On edit screens. Indicates current parameter value. Press ▲ or ▼ to scroll up or down to edit the value.
	On edit screens with a menu of options. Indicates which setting is being selected.
	The requested action can not be performed.
	More data is available. On PCA dose report only.
	Review screen
	Saving
	There are more items to see in the work area. Press ▲ or ▼ to scroll up or down.

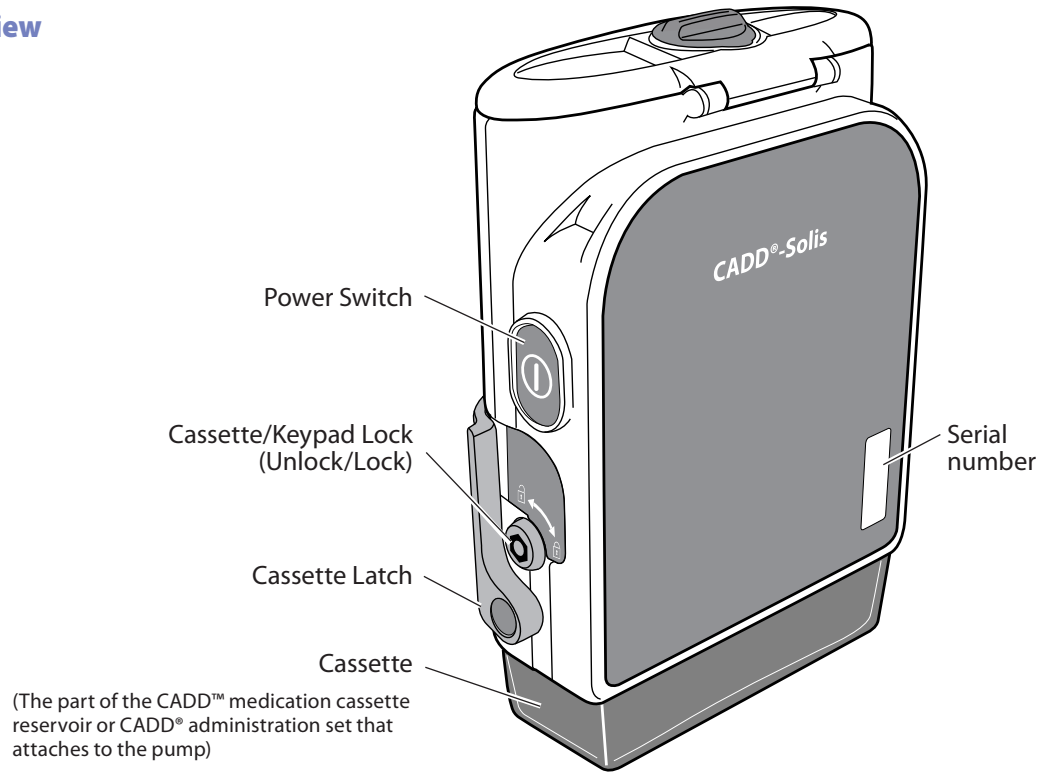
* Visible only when a CADD®-Solis Communication Module is installed.

Pump Diagram

Front View



Rear View



(The part of the CADD™ medication cassette reservoir or CADD® administration set that attaches to the pump)

Pump Components, Ports, and Connectors

Indicator Lights

When the pump is powered, one or both of the indicator lights 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 briefly describes 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 (for example, 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.

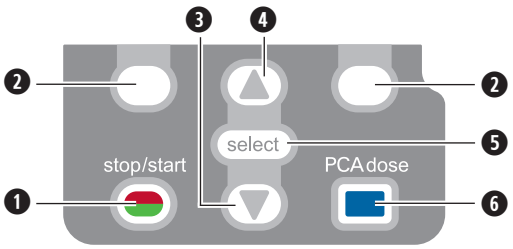
After a period in which no keys are pressed, the backlighting turns off and the display goes blank to save battery power (except during an alarm or when an external power source is in use). To turn the display back on, press any key except the PCA (PCEA) dose key when the PCA (PCEA) dose option is available.

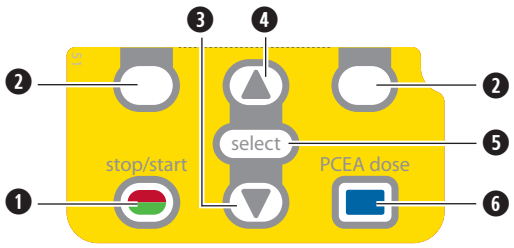
Note:

- When the display is blank, you can determine that the pump is powered by observing either the green or amber (or both) indicator lights periodically flashing.
- Therapies incorporating patient-controlled analgesia are configured with the PharmGuard® Administrator software to display either "PCA" (patient-controlled analgesia) or "PCEA" (patient-controlled epidural analgesia). The examples shown in this manual display only "PCA". However, menus, submenus, and screens on the pump will appear with "PCEA" if they are programmed to do so.
- If you press stop/start, the display reappears with a message asking if you wish to start or stop the pump.
- If you press PCA dose while the pump screen is blank, the pump delivers a PCA dose, if available.

Keypad

The pump has either a gray or yellow 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 do not beep if the key beep function is turned off in the protocol or the PharmGuard® system administrator settings.





1. Starts and stops pump delivery.
2. Referred to as "soft keys." 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 (for example, canceling an action, opening the reports/tasks menus, or backing out of an open screen).
3. Allows you to navigate through the menus on the pump, scrolling down, or decreasing a value.
4. Allows you to navigate through the menus on the pump, scrolling up, or increasing a value.
5. Used to select a menu item.
6. Allows the patient to request a PCA (PCEA) dose if the remote dose cord is not connected, and if the PCA (PCEA) dose option is available. If the remote dose cord is connected, this key is inactive.

WARNING: To avoid electric shock, do not touch the Power Jack, Remote Dose Cord Jack, USB Port, Battery Terminals, or any other connectors and the patient simultaneously.

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.

USB Port

A mini-B USB cord can be attached to the USB port for communications with the PharmGuard® Medication Safety Software. This jack is also used for communications with SureLink® Remote Support Software and the CADD® Solis Network Setup Utility software. For more information, see the documentation that accompanies these software products.

CAUTION: The USB port is intended for communication to the PharmGuard® Medication Safety Software, SureLink® Remote Support Software, and the CADD® Solis Network Setup Utility software only. Do not connect unsupported accessories to the USB port (e.g., charging other devices, attaching a wireless dongle) as this could damage the pump.

Remote Dose Cord Jack

The remote dose cord jack is used for attaching the remote dose cord. (See *Remote Dose Cord on page 18* for more information.)

Battery Compartment

Four AA batteries, rechargeable battery pack, or the CADD® Solis Communication Module (with integrated rechargeable battery) 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 20* 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 detects whether the cassette is latched properly. Delivery stops and an alarm occurs if the cassette becomes unlatched. (See *Attaching a Cassette on page 25* and *Removing a Cassette on page 27.*)

Cassette/Keypad Lock

Secures 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 PharmGuard® system administrator. (See *Security Settings on page 28*.)

Air Detector

The air detector may be turned on or off, depending on facility or therapy requirements (for more information, see the Administrator Settings Guide). If enough air is detected in the part of the tubing that passes the air detector sensor, an alarm sounds and delivery stops. If an air detector is not required, it may be turned off.

WARNING:

- **If the air detector is turned off, the pump does not detect air in the fluid path. It is recommended that you periodically inspect the fluid path and remove any air to prevent air embolism, which could result in serious patient injury or death.**
- **The air detector, when turned on, may be set to detect and alarm for air bubbles as small as 150 uL. The High Sensitivity setting and/or filtered sets should be considered for patients and therapies with a risk of harm due to an air embolism.**

Downstream Occlusion Sensor

The pump contains a downstream occlusion sensor. When a downstream occlusion (between the pump and the patient) is detected, an alarm sounds, delivery stops, and the display shows "Downstream occlusion. Clear occlusion between pump and patient."

Upstream Occlusion Sensor

The pump contains an upstream occlusion sensor. This feature may be turned on or off (for more information, see the Administrator Settings Guide). When an upstream occlusion (between the pump and the reservoir) is detected, an alarm sounds, delivery stops, and the display shows "Upstream occlusion. Clear occlusion between pump and reservoir."

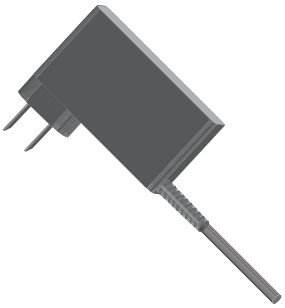
WARNING: When the upstream occlusion sensor is turned off, the pump does not detect occlusions upstream between the pump and the reservoir. Periodic inspection of the fluid path for kinks, a closed clamp, or other upstream obstructions is recommended. Upstream occlusions may result in underdelivery of medication. If undetected, these occlusions could lead to death or serious injury to the patient.

Pump Accessories

CAUTION: Use only Smiths Medical accessories that are specified for use with the CADD®-Solis Ambulatory Infusion Pump, as other brands may adversely affect pump operation.

CADD®-Solis accessories may be obtained through the Customer Service department at Smiths Medical. For detailed instructions and warnings applicable to each accessory, refer to the instructions for use provided with the product. The *Pump Diagram on page 14* illustrates the location of ports, jacks, latches, and compartments used with the accessories.

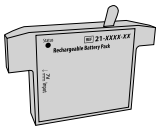
AC Adapter



The AC adapter can be used as an alternate source of power for the pump and/or to recharge the rechargeable battery pack or CADD®-Solis Communication Module with integrated rechargeable battery. The pump requires that 4 AA batteries, rechargeable battery pack, or CADD®-Solis Communication Module with integrated rechargeable battery are installed as a backup while using the AC adapter.

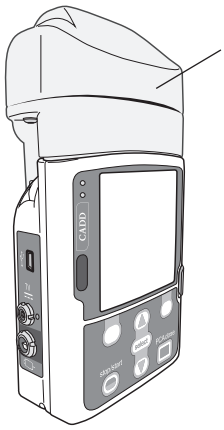
Access to the AC adapter power cords should not be blocked at the AC adapter and at the pump connector so they can be easily disconnected.

Rechargeable Battery Pack



The rechargeable battery pack is an alternative to using four AA batteries. The rechargeable battery pack can be recharged with the AC adapter, either inside or outside of the pump.

CADD®-Solis Communication Module (Models 2130 and 2131)



CADD®-Solis Communication Module with integrated rechargeable battery

The CADD®-Solis Communication Module (optional, contact Smiths Medical for availability) adds wireless features to the pump, allowing the pump to communicate with PharmGuard® Server. With the communication module installed the pump can send event history and receive pump firmware and library updates from the server wirelessly.

The communication module is securely installed in the battery compartment of the pump and includes an integrated rechargeable battery that powers the pump and module. The rechargeable battery is charged via the CADD®-Solis AC Adapter connection to the pump.

If necessary, the pump operator can turn off wireless capabilities of the communication module while still providing power to the pump and without affecting any of the pump's clinical operations.

When installed, the wireless capabilities of the module may be turned on or off via the pump menus (see *Turn Wireless On/Off on page 38*).

For more information about installing the CADD®-Solis Communication Module, see the documentation provided with the module. For configuration of the wireless network settings of the pump and communication module see operators manual for the Network Setup Utility software.

Pump Key

The pump key is used to securely lock a cassette or administration set to the pump. It can also be used to lock and unlock the keypad, if allowed by the protocol setting.

Cassette, Extension Set, Administration Set

The cassette is the part of the CADD™ 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:

- CADD™ medication cassette reservoir with a CADD® extension set
- CADD® administration set
- CADD® high volume administration set (with pump model 2110 only)

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.**
- **Carefully route tubing, cords, and cables to reduce the possibility of patient entanglement or strangulation. Failure to observe this warning could result in patient injury or death.**

Note:

- A CADD® set with free-flow protection must be used in order to prevent free-flow.
- The maximum delivery rate is 500 mL/hr, however, programmed delivery rates exceeding 250 mL/hr require the use of a high volume administration set. Do not manually adjust the delivery rate to override pump programming without written authorization from the prescribing physician.
- Smiths Medical recommends that the appropriate supplies needed to replace the cassettes are available in case of a damaged cassette.
- For detailed instructions and warnings pertaining to the CADD™ medication cassette reservoir or CADD® administration set, refer to the instructions for use supplied with the product for preparing the product for use.

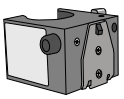
Remote Dose Cord

The remote dose cord can be attached to the pump and provided to the patient as an alternative to pushing the PCA (PCEA) dose ▭ key to request 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.

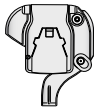
Polemount Bracket

The polemount bracket is used along with the polemount bracket adapter to attach the pump to an IV pole.



Polemount Bracket Adapter

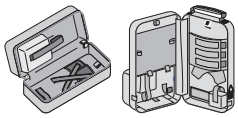
The polemount bracket adapter attaches to the back of the pump so that it can be mounted on an IV pole or in a LockBox. (When a CADD Solis Communication Module is installed, a polemount adapter is integrated with the mounting bracket of the communication module.)



Polemount Swivel

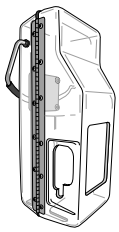
The polemount swivel allows the pump to rotate while it is attached to the CADD®-Solis polemount bracket. With the swivel attached, the pump can be tilted or rotated 230° for easy viewing of the display. The swivel can not be used in a LockBox.

Pouches and Backpacks



Several styles of pump pouches and backpacks are available. They can carry a CADD®-Solis ambulatory infusion pump with either a CADD™ medication cassette reservoir (50 mL to 250 mL) or a flexible, plastic IV bag up to 3 liters.

LockBox



Clear and yellow lockboxes are available to hold both the CADD®-Solis ambulatory infusion pump and a CADD™ administration set or high flow administration set. The pump attaches to the lockbox with a polemount bracket adapter, and the lockbox can be attached to an IV pole. The lockbox allows for viewing of its contents and access to the keypad, remote dose cord jack, and AC power jack.

PharmGuard® Medication Safety Software

PharmGuard® Medication Safety Software is PC software that allows you to create and manage protocol libraries and then send them to the pump. For more information, see the installation guide and online help for PhamGuard® Administrator software and PharmGuard® Point of Care software.

PharmGuard® Server Software

When a CADD®-Solis pump has a CADD®-Solis Communication Module installed (see page page 17), the pump can communicate with a wireless access point at your facilty and to a PharmGuard® Server for reporting and administration purposes. When the CADD®-Solis pump has wireless turned on and a wireless access point is in range, the pump sends history data to the server periodically, and can also receive authorized pump firmware and library updates from the server. For more information, contact your PharmGuard® Server system administrator.

SureLink® Remote Support Software

The CADD®-Solis Ambulatory Infusion Pump is upgradeable (when updates are available from Smiths Medical) using SureLink® Remote Support Software – PC Direct Connect. This application, available separately, may be used to receive available pump software updates from Smiths Medical Customer Service via the Internet and install those updates onto eligible pumps via USB connection. For more information about using SureLink® Remote Support Software, see the documentation provided with the software.

CADD®-Solis Network Setup Utility Software

All wireless and network configuration for the CADD®-Solis Communication Module is set using the CADD®-Solis Network Setup Utility software. This software, available separately, programs the CADD®-Solis Communication Module via USB connection to the CADD®-Solis pump. For more information about using the CADD®-Solis Network Setup Utility Software, see the documentation provided with the software.
The configuration settings are stored by the pump and not the communication module. A pump may be configured for wireless without a communication module installed. The communication module will obtain configuration settings upon pump power up after the communication module is installed in an already configured pump. The communication module settings are not retained once it is removed from a pump.

Pump Setup

Installing the Batteries

Four AA, 1.5 volt primary (non-rechargeable) alkaline batteries (for example, Duracell® PC1500 / MN1500, IEC LR6), the Smiths Medical rechargeable battery pack, or the CADD®-Solis Communication Module (with integrated rechargeable battery) are required for use in the CADD®-Solis pump.

Note: Smiths Medical does not recommend mixing new and used AA batteries because it may affect low battery alarm times. Always use four new batteries when replacing depleted ones.

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 (or the CADD®-Solis Communication Module with integrated rechargeable battery) are removed, but 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 stops. If an AC adapter is not connected and the batteries are removed, delivery stops and the pump loses power. Delivery will not begin without proper batteries installed (with or without an AC adapter).

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

Note:

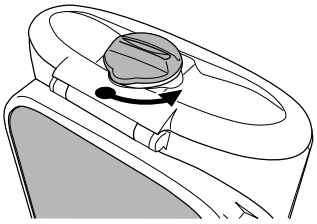
- Battery life is dependent on the amount of medication delivered, delivery rate, battery age, temperature, active display time, and backlight intensity.
- The power of the battery is quickly depleted at temperatures below 10°C (50°F).
- Dispose of used batteries in an environmentally safe manner, and 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 occurs and depending on the type of drug being administered, could result in death or serious injury to the patient.**
- **A rechargeable battery pack that has reached the end of it useful life must be replaced with either another CADD®-Solis rechargeable battery pack, a replacement communication module rechargeable battery, or with 4 AA batteries. Using rechargeable battery packs from other manufacturers could result in fire or explosion.**
- **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 or communication module 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 or rechargeable battery pack:

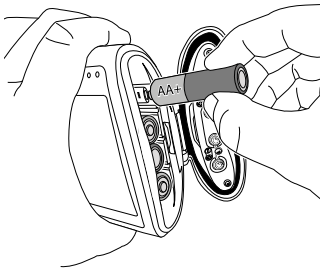
1. Make sure the pump is stopped or powered off. Using your fingers, the pump key, or a coin, turn the knob on the battery door counter-clockwise and open the battery door.



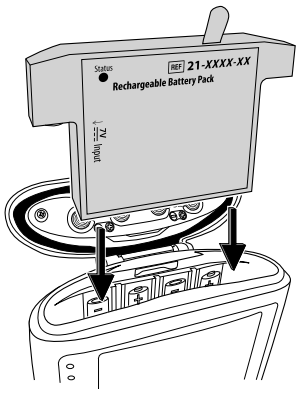
2. Hold the pump at an angle and place 4 AA batteries in the pump, from the bottom up (see picture). Match the + and - markings on the new batteries with the markings on the pump.

   – OR –

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



– OR –



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.

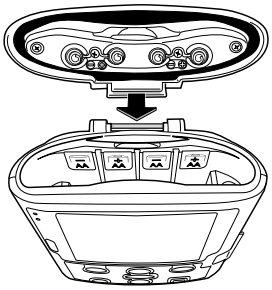
   Note: If you put the batteries in backwards, the pump will not power up. Check the batteries, making sure to match the + and - markings.

To install a CADD®-Solis Communication Module:

See the CADD Solis Communication Module Operator's Manual to install the communication module into the pump.

Replacing the Battery Door

If the battery door is removed or needs replacing (e.g., after removing the CADD®-Solis Communication Module to use AA batteries instead), simply snap the battery 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 starts the power up sequence during which it performs various self-tests and tests for alarm conditions. Watch for the following during power-up:

- Both the green and amber indicator lights flash.
- The display quickly flashes gray, then blue. An amber swirl then fills 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 (for example, 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.

Power Down

Press the power switch to turn the pump off. You must acknowledge the "Power down?" prompt by selecting **Yes.** The pump then powers down.

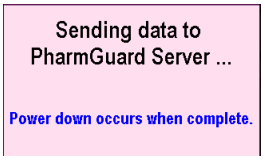
Be aware of the following conditions when the pump is powered down:

- The display is blank.
- Keypad presses are not detected.
- The remote dose cord does not function.
- Medication is not infused.
- Alarm conditions are not sensed.
- Audio alarms do not sound.
- Visual alarms are not displayed.
- Communication with PharmGuard® Medication Safety Software or PharmGuard® Server is not possible.
- If the AC adapter is plugged in, the blue AC power light is on. No other lights are lit.
- The internal battery used to retain time and date does not charge.
- If the pump is connected to AC power and a rechargeable battery pack or a CADD®-Solis Communication module (with integrated battery pack) is installed, the battery continues to charge.

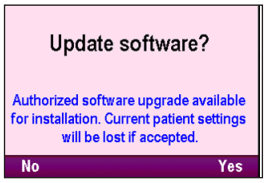
Software Updates

If the pump is equipped with a CADD®-Solis Communication Module and is in communication with PharmGuard® Server, the following may occur before the pump powers down:

- A screen appears briefly to advise you that pump data is being sent to PharmGuard® Server.



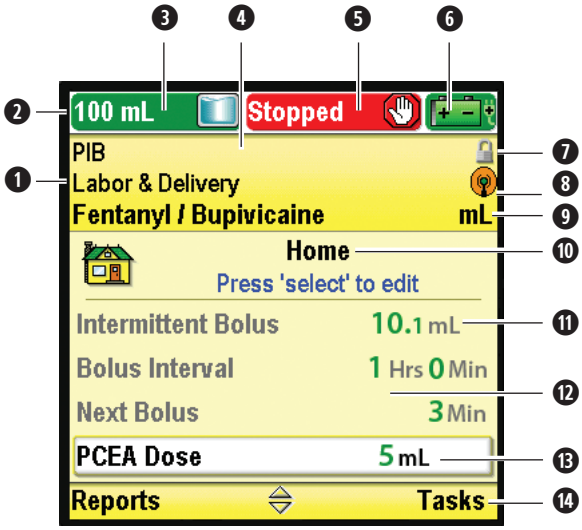
- *If a software update has been sent to the pump by the PharmGuard® Server administrator*, a screen notifies you and you are given the option to accept the update.
  Upon selecting **Yes** to accept the update, and confirming security measures (see *Security Settings* on page 28), it is installed and the pump powers down. If you select **No**, the update is not installed and the pump powers down (you will be given the option again to update the pump the next time it is powered down). For more information, contact your PharmGuard® Server system administrator.



Programming the Pump: General Instructions

The Pump Screen

The sample screens 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.



1. The therapy, qualifier, and drug from the current protocol. Where a long drug name is used, it will scroll from right to left on the pump screen to allow you to view the entire drug name.
2. The status bar shows the status of the pump. It also displays messages and alerts.
3. Current reservoir volume.
4. The color of the screen is dependent on how the protocol is set up in the PharmGuard® Medication Safety Software. If the screen color is black, the protocol has been modified in the PharmGuard® system administrator settings (see the Administrator Settings Guide for more information) or the pump is in manual mode (see *Manual Mode Programming* on page 23).
5. The delivery status of the pump—stopped or running.
6. The type of battery being used and an estimation of the approximate amount of battery life remaining. Also indicates if an AC adapter is in use.

AA batteries.
Fully or near fully charged.

AA batteries with AC adapter.
~50% charge.

Rechargeable battery or Communication Module.
Low battery, <25% charge.

Rechargeable battery or Communication Module with AC adapter.
Depleted battery.

7. Keypad lock status—locked or unlocked.
8. Wireless status indicator (when a CADD®-Solis Communication Module is installed)—Off; On; On and associated with wireless access point; On and not associated with wireless access point; or, On and associated with wireless access point and communicating with PharmGuard® Server.
9. Units of measurement and concentration (if applicable) for the drug or solution in the current protocol.
10. Screen name and help text, if there is any.
11. TALL/short characters improve readability to avoid dosing errors.
12. The work area/contents for the displayed screen
13. Trailing zeros are eliminated to avoid dosing errors.
14. Options for navigating the pump. These options 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.

Protocol Screen Colors

Your facility may choose to relate a specific color to each protocol in its library. This is customizable by your PharmGuard® Medication Safety Software system administrator. Protocols may be color coded in several different ways depending on the needs of your pain management program, including:

- Route of administration (for example, 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 (for example, all pediatric protocols may be blue),
- Or by any other hierarchy which fits the needs of your institution

There are five protocol colors available: purple, yellow, gray, blue, and green.

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 51).

Refer to your facility's policies and procedures to understand how colors are used to identify your protocols.

Pump Status Colors

The pump colors green, amber, red, and blue are used to help the clinician recognize pump status. Similar to a traffic control light: green means go, amber indicates caution, and red means stop:

- **Green:** Pump conditions are satisfactory. Green numbers in the work area indicate that a programmed value falls *within* the soft limit range for the parameter.
- **Amber:** There is a condition to watch, but the current pump conditions are satisfactory. Medium priority alarms and values *outside* soft limits display in amber.
- **Red:** There is a warning condition that requires immediate attention and infusion has stopped. All high priority and system fault alarms display in red
- **Blue:** Low priority alarms and informational messages display in blue.

To understand how colors relate to alarm screens, refer to *Types of Alarms on page 55*.

Before Programming

Protocol libraries are created with the PharmGuard® Medication Safety Software and can be imported into the pump by your PharmGuard® 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 *51*.

A protocol from the library may be manually edited in the PharmGuard® system administrator settings. If you are authorized, see the Administrator Settings Guide or contact your facility's PharmGuard® system administrator for further information. Making edits to the protocol changes the settings for the current protocol only. The edits do not change the settings for any future selections of the protocol from the library.

Attaching a Cassette

WARNING:

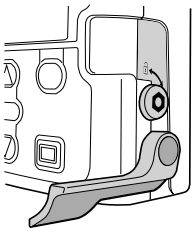
- **Attach the cassette properly. A detached or improperly attached cassette could result in unregulated gravity infusion of medication from the reservoir or a reflux of blood, which could result in death or injury to the patient.**
  If you are using a CADD® administration set or CADD™ medication cassette 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.
- **Carefully route tubing, cords, and cables to reduce the possibility of patient entanglement or strangulation. Failure to observe this warning could result in patient injury or death.**

CAUTION: If you are using a CADD™ 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.

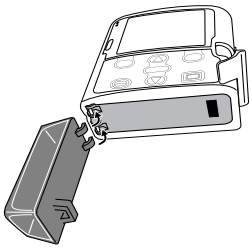
Before attaching a new cassette, make sure the pump is powered on. Once the cassette is attached, the pump automatically displays screens that allow you to verify the cassette type, prime the fluid path, reset the reservoir volume, review pump settings, and/or start the pump.

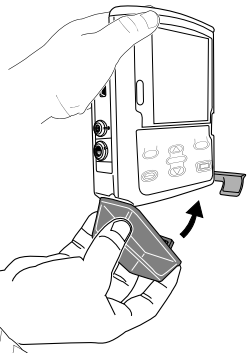
To attach the cassette to the pump:

1. Obtain a new, filled CADD™ 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.
2. Clamp the tubing.
3. Make sure the cassette latch is unlocked and open the cassette latch.



4. Insert the cassette hooks into the hinge pins on the bottom of the pump.



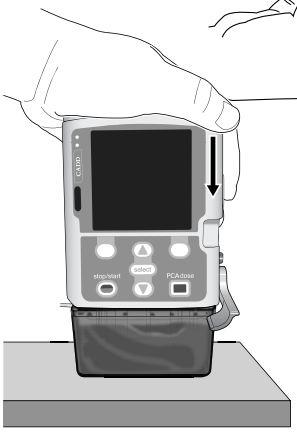


5. Without holding the cassette latch:

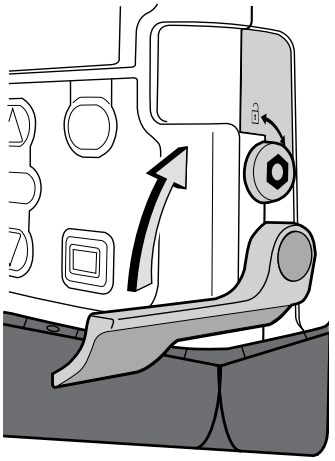
   Push up on the cassette until it firmly clicks into place.

   -OR-

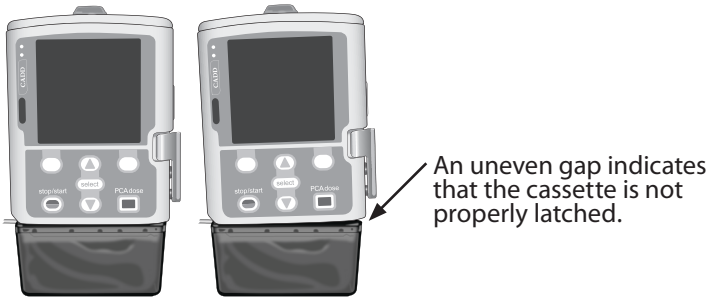
   Place the pump upright on a firm, flat surface, and then press down on the latch side of the pump until the cassette firmly clicks into place.



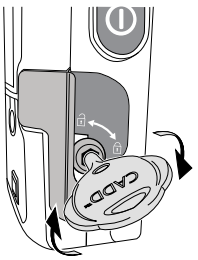
6. Lift the cassette latch into the closed position. You should be able to move the latch into the closed position with minimal to no resistance. If you experience resistance when lifting the cassette latch, DO NOT FORCE the latch. If you are unable to attach the cassette to the pump with minimal to no resistance, the cassette is not in the proper latching position. If the pump does not latch easily, unlatch the cassette and repeat the process. If unsuccessful on the second attempt, do not use the pump. Contact Smiths Medical Customer Service for further assistance.



7. Verify the cassette is attached correctly. Looking from left to right, the top of the cassette should line up evenly with the bottom of the pump and be securely attached. If the cassette is attached incorrectly, there will be an uneven gap between the cassette and the pump, with the gap appearing on the latch side of the pump. If an uneven gap exists, unlatch the cassette and repeat the process. If the gap exists after the second latch-up attempt, do not use the pump. Contact Smiths Medical Customer Service for further assistance.



8. A brief message appears on the pump screen so you can verify the type of cassette you have attached.
9. To lock the cassette, insert the pump key into the cassette/keypad lock and turn it clockwise into the locked position. “Cassette Locked” appears briefly in the status bar.

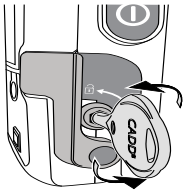


Removing a Cassette

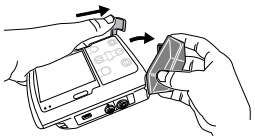
WARNING: Per general rules of safe practice, always clamp the tubing before removing the cassette from the pump. Removing the cassette without closing the clamp could potentially cause unregulated gravity infusion, which could result in patient injury or death.

To remove the cassette:

1. Make sure the pump is stopped before removing the cassette.
2. Close the tubing clamp.
3. If locked, insert the pump key and turn the cassette/keypad lock counter-clockwise into the unlocked position. "Cassette Unlocked" briefly appears in the status bar.



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



Starting the Pump

Starting the pump starts delivery. When the pump is running, "Running" appears with green highlighting on the status bar and the green indicator light flashes. If the pump does not start, a message appears on the display. Refer to the *"Alarms and Messages" on page 58*.

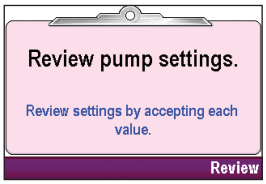
Note: Before starting the pump, ensure correct protocol and patient specific parameters are displayed (see *Patient Specific Parameters* page 45). Also be sure the tubing is primed and the pump is connected to the patient, according to your facility's standards of practice.

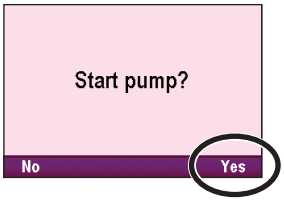
To start the pump:

1. Press stop/start.

   Note: If the patient specific parameters have not been reviewed and the values have not been accepted, the pump requires you to do so before the pump will run. If a clinical advisory note has been defined by your facility for the selected protocol, it will appear after accepting all values. To acknowledge the clinical advisory note, select **OK**. If you have a question about the note, contact your PharmGuard® system administrator.

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





Stopping the Pump

Stopping the pump stops delivery. When the pump is stopped, "Stopped" appears with red highlighting on the status bar, the amber indicator light flashes, and the green indicator light is off.

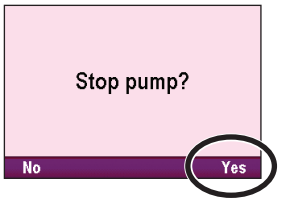
Note: Stopping the pump while an Intermittent Bolus is in progress will cancel the remainder of the Intermittent Bolus dose.

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?" appears. Select **Yes** to stop the dose.

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



Programming and Operation

Security Settings

Security settings are used to limit patient and unauthorized clinician access to certain programming and operating functions of the pump. Pump functions 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:

- **Keypad Code:** 201
- **Clinician Code:** 997
- **Administrator (Admin) Code:** See your PharmGuard® system administrator.

WARNING

- **Do not disclose pump security codes or any other information that would allow the patient or unauthorized clinician complete access to programming and operating functions. Improper programming could result in serious patient injury or death.**
- **Do not leave the pump unattended while unlocked. Many programming functions are accessible while the pump is unlocked, and improper programming could result in serious patient injury or death.**

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

Security Level Tables

- The keypad code is for clinicians who need to set up and manage a protocol for a patient.
- The clinician code allows access to all the functions the keypad code allows, as well as the clinician bolus feature.
- The administrator code allows access to all functions of the pump and its use should be restricted to the PharmGuard® 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) Intermittent Bolus			*	*	*	*	✓	✓
Change (Titrate) Bolus Interval			*	*	*	*	✓	✓
Change Next Bolus			*	*	*	*	✓	✓
Change (Titrate) PCA Dose			*	*	*	*	✓	✓
Change (Titrate) PCA Lockout			*	*	*	*	✓	✓
Change (Titrate) Delivery Limit 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 Time and Date Format								✓
Adjust Backlight Intensity			✓	✓	✓	✓	✓	✓
Adjust Alarm Volume			✓	✓	✓	✓	✓	✓
View/Clear Reports	✓	✓	✓	✓	✓	✓	✓	✓
Turn Wireless On/Off (when a communication module is installed)			✓	✓	✓	✓	✓	✓
Update Software				✓		✓		✓
Access Administrator Settings								✓

Table Key:		
		No
	✓	Yes
	*	Yes. If using a manual mode protocol, the setting depends on the "Manual Programming Security" parameter.

Autolock

The CADD®-Solis ambulatory infusion pump is designed to meet both safety and usability needs. The autolock feature reduces the chance of unauthorized pump programming. When the keypad is unlocked with a security code and left unlocked, the software automatically locks the keypad.

The autolock feature takes affect on the Home screen approximately 30 seconds after the last key press, or when reverting back to the Home screen from other screens. Autolock takes longer on programming or task screens when you typically need more time to perform an action. From some of these screens, it may take up to 4 minutes after the last key press to revert back to the Home screen. If the pump is alarming, autolock does not take affect.

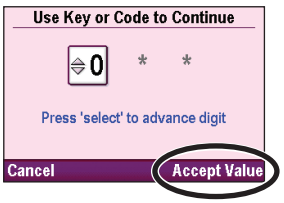
If using the key to unlock the keypad while the pump is running, you should relock the keypad using the key.

Note: The keypad can 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, you should always manually lock the pump using this feature.

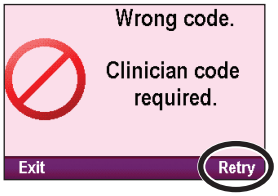
Entering Security Codes

To enter a security code when prompted:

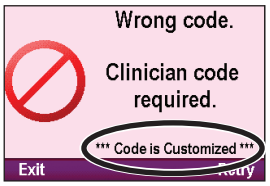
1. Press ▲ or ▼ to scroll up or down to the correct digit. Press select or **Accept Value** to advance to the next digit. Once the complete code has been entered, press select or **Accept Value.**



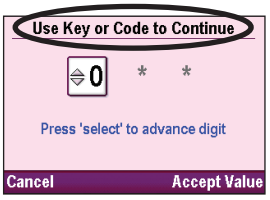
2. If an incorrect code is entered, a wrong code error appears. It includes the security level required to access the function. Select **Retry** to enter the code again.

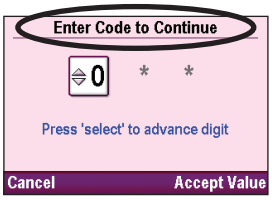


Note: If you enter a code that you believe is correct and receive a wrong code message, check the screen to see if the code has been customized. If the code is not customized, it was entered incorrectly and you should retry. If the code is customized, enter the customized code. If you do not know the code, contact your PharmGuard® system administrator.

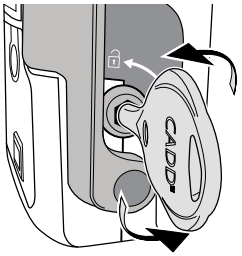


3. Depending on the level of security required and how the PharmGuard® system administrator has programmed the security settings, you may be able to use the pump key to unlock the keypad. When accessing a menu or function that requires a security code, 1 of 2 prompts appears, as shown in the sample screens to the right.





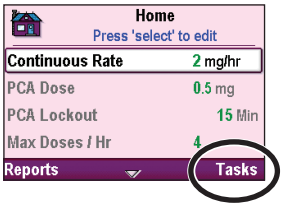
To unlock the keypad with the pump key, turn the pump key counterclockwise.



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.

Tasks

The tasks menu leads 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, turning wireless on/off, or adjusting the PharmGuard® system 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 28. To access the tasks menu, select **Tasks** on the Home screen.



The following functions can be found on the tasks menu:

Tasks
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
Turn Wireless On/Off
Adjust Admin Settings

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 (PCEA) dose or intermittent 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.

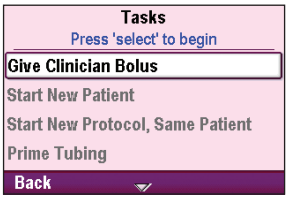
Note: If a clinician bolus is manually stopped by a clinician or automatically stopped by an alarm, power failure, or other condition that stops delivery, the pump remembers what point the bolus was at when it stopped. The next time you choose to give a clinician bolus, it gives you the option to restart the clinician bolus where it left off or to start with a new clinician bolus.

WARNING: Exercise care when using the clinician bolus function. Because there are no limits on the frequency of delivering a bolus, and because the bolus amount may be set as high as 50 mL (or the mg or mcg equivalent), do not permit the patient or an unauthorized clinician 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 PharmGuard® system administrator.

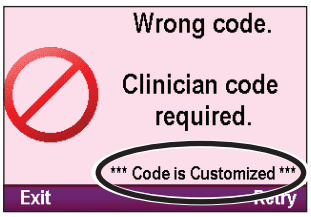
To give a clinician bolus:

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



4. 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 is entered, select **Accept Value.**

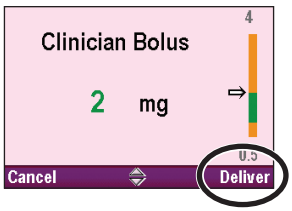
Note: If you enter a code that you believe is correct and receive a wrong code error, check the screen to see if the clinician code is customized. If the code was not customized, it was entered incorrectly. Retry. If the code is customized, use the custom clinician code. If you do not know this code, contact your PharmGuard® 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.

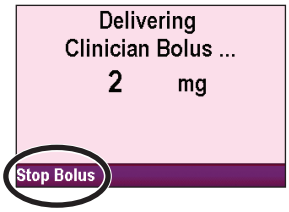
5. Make sure the clinician bolus amount is at the desired value and select **Deliver.**

Note: If you enter a value outside the soft limit, a screen appears asking you to confirm the soft limit override.



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

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

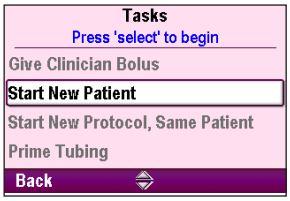


Start New Patient

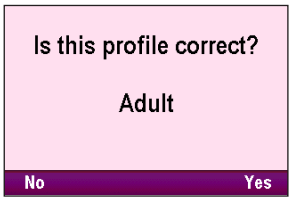
Each time a new patient is started, it is recorded in the event log. All other delivery related reports are cleared.

To start a new patient:

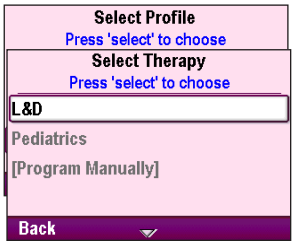
1. Stop the pump if it is running.
2. From the Home screen, select **Tasks.**
3. From the Tasks menu, press ▲ or ▼ until **Start New Patient** is highlighted and press select.



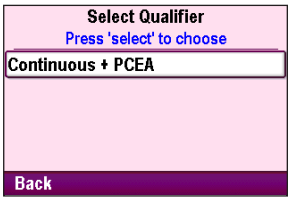
4. If your library was setup to use profiles by the PharmGuard® system administrator, the previously selected profile is shown. Profiles contain a grouping of protocols (e.g., profiles can be defined for specific care areas, etc.). If your desired therapy is contained within the profile shown, select **Yes**, otherwise select **No.** If No is selected, you may press ▲ or ▼ to highlight the desired profile and press select.



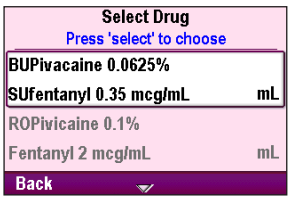
5. The therapies contained within your selected profile are shown. Press ▲ or ▼ to highlight the desired therapy and press select.



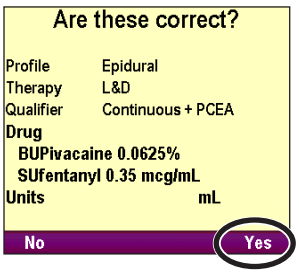
6. Press ▲ or ▼ to highlight the desired qualifier and press select.



7. Press ▲ or ▼ to highlight the desired drug(s) and concentration, and press select.



8. Unlock the keypad using the security code.
9. The new protocol is displayed on the screen and the pump asks if you have selected the correct therapy, qualifier, drug, and concentration.



Confirm that you have selected the correct profile, therapy, qualifier, drug, and concentration or units.

Note: If programming in mL, you are not asked to confirm the concentration.

Select **Yes** to program the pump with the protocol you have chosen. Select **No** to go back to the **Select Drug** screen. If you want to change the drug, repeat the process for selecting a new drug. Otherwise, select **Back** until you reach the screen you want to change (profile, therapy or qualifier). You will be asked to enter a security code after selecting **Back** and reselecting any profile, therapy, qualifier, or drug.

10. You will be prompted to review the pump settings to accept each value before the pump can be started. During the review, the pump settings may be edited if necessary.

    Note: If a clinical advisory note has been defined by your facility for the selected protocol, it will appear after accepting all values. To acknowledge the clinical advisory note, select **OK**. If you have a question about the note, contact your PharmGuard® system administrator.

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 delivery related reports are cleared except the delivery log). See *Start New Patient* on page 32 for directions on selecting a profile, 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

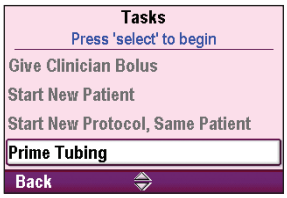
Priming the tubing is done to fill the tubing downstream of the pump with fluid, removing any air bubbles. Prime the tubing before connecting it to the patient's infusion set or indwelling catheter. The pump must be stopped and you must enter the security code or the cassette/keypad lock must be unlocked.

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

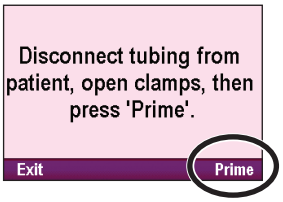
WARNING: Do not prime the fluid path with the tubing connected to a patient as this could result in overdelivery of medication or air embolism, which could result in serious patient injury or death.

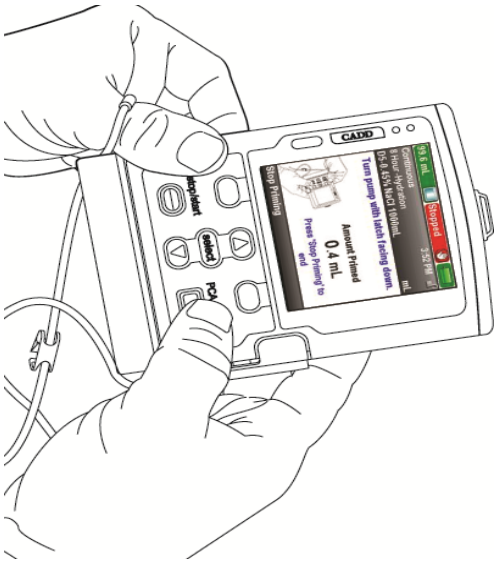
To prime the tubing:

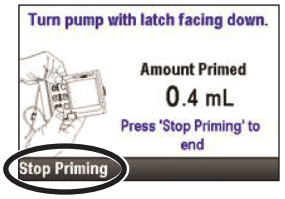
1. From the Home screen, select **Tasks.**
2. From the Tasks menu, press ▲ or ▼ until **Prime Tubing** is highlighted and press select.



3. Unlock the keypad using the security code or the pump key.
4. If you have not already done so, disconnect the tubing from the patient, open clamps, and select **Prime**, and turn pump with latch facing down (as shown below).







You may stop priming at any time by selecting **Stop Priming.** Otherwise priming automatically stops once it has primed 10 mL (or 20 mL if using a high volume administration set). Continue priming as needed.

WARNING: To prevent air embolism, ensure that the entire fluid path is free of all air bubbles before connecting to the patient. 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. For more information, see the administration set or extension set instructions for use.

Set Time and Date

The set time and date screen allows you to view daylight saving time settings and edit the current time and date. Additionally, you can choose a time and date format. The time and date options should reflect the current time and date, and follow the standard format used in your facility.

The pump time and date do not automatically update for daylight saving time unless it has been configured to do so by your PharmGuard® system administrator. If you live in a geographical area that follows daylight saving time, and the pump is not configured to automatically adjust for daylight saving time, you must manually update the time and date. You may choose to change the time while the pump is currently being used by a patient, or wait until the patient is finished with therapy.

Note:

- If you manually update the time while the pump is in use, the timestamps in the event and delivery logs are not updated to reflect daylight saving time prior to the change. All events record the reported pump time from when the event actually occurred. For your reference, the event log records the time when it was changed.
- If the pump is configured to adjust time automatically for daylight saving time, the time will update at the configured time if the pump is in stop mode, or the first time it enters stop mode after the configured time. When the pump clock is changed automatically due to daylight saving time, a message appears on the pump to notify you.

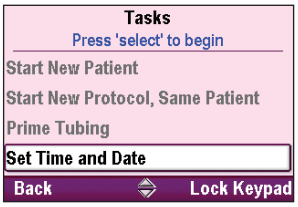
The pump clock is powered by a separate, internal battery that retains the time and date even when the 4 AA batteries, the battery pack, or communication module is removed. The pump uses this feature to record the time and date of events in the delivery and event logs. In addition, the date is used to determine when preventive maintenance alarms occur.

Note:

- The internal battery is rechargeable and automatically recharges when the pump is powered on. If the pump is off for a long period of time, it may not show the correct time and date when it is powered on. Check the time and date, and edit these settings if necessary.
- Protocol information remains the same regardless of changing the time and/or date during a patient's therapy.

To access the set time and date feature:

1. From the Home screen, select **Tasks.**
2. Press ▲ or ▼ to choose **Set Time and Date** and press select.



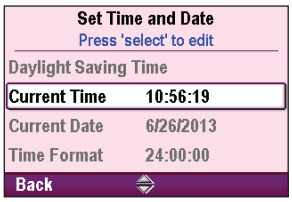
To view the daylight saving time setting:

- Press ▲ or ▼ until **Daylight Saving Time** is highlighted and press select.

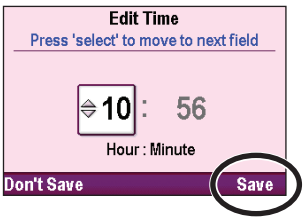
  Depending on how your pump is configured by your PharmGuard® system administrator, the pump either displays when daylight saving time will change (if the pump is set to change for daylight saving time automatically), or that the daylight saving time feature is disabled.

To set the current time:

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



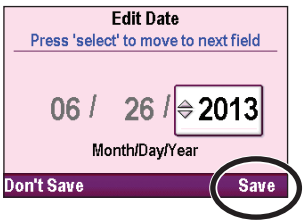
2. Unlock the keypad using the security code or the pump key.
3. Press ▲ or ▼ to scroll to the correct hour and press select to navigate to the minutes.
4. Press ▲ or ▼ to scroll to the correct minutes and select **Save.**



To set the current date:

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

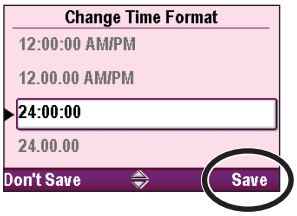
2. Unlock the keypad using the security code or the pump key.
3. Press ▲ or ▼ to scroll to the correct month and press select to navigate to the day.
4. Press ▲ or ▼ to scroll to the correct day and press select to navigate to the year.
5. Press ▲ or ▼ to scroll to the correct year and select **Save.**



To set the time format:

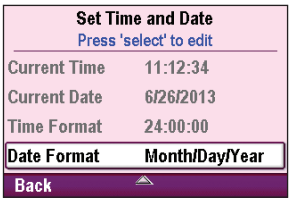
1. Press ▲ or ▼ until **Time Format** is highlighted and press select.

2. Unlock the keypad using the administrator code.
3. Press ▲ or ▼ until the desired time format is highlighted and select **Save.**

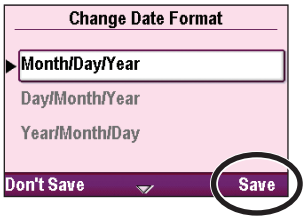


To set the date format:

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



2. Unlock the keypad using the administrator code.
3. Press ▲ or ▼ until the desired date format is highlighted and select **Save.**



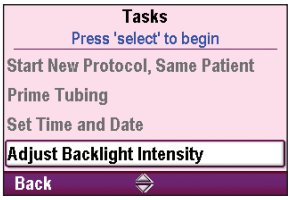
Adjust Backlight Intensity

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

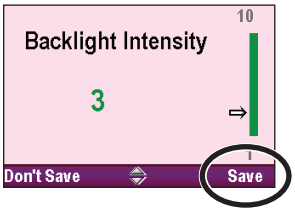
Note: Increasing the backlight intensity shortens the battery life.

To adjust the backlight intensity:

1. From the Home screen, select **Tasks.**
2. Press ▲ or ▼ to choose **Adjust Backlight Intensity** and press select.



3. Unlock the keypad using the security code or the pump key.
4. Press ▲ or ▼ to scroll from 1 to 10. The pump displays the intensity of each number as it appears. Once you have found the desired backlight intensity, select **Save.**



Adjust Alarm Volume

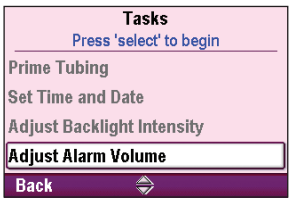
The adjust alarm volume feature allows you to determine the volume of the alarms in the protocol. You may choose between 3 volumes: low, medium, and high.

Note:

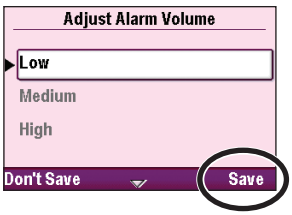
- Use of a pouch, lockbox, or backpack may muffle audible alarms.
- If a high or medium priority alarm exists for 2 or more minutes without being acknowledged, the alarm volume automatically adjusts to "High."

To adjust the alarm volume:

1. From the Home screen, select **Tasks.**
2. Press ▲ or ▼ to choose **Adjust Alarm Volume** and press select.



3. Unlock the keypad using the security code or the pump key.
4. 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:

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

  Note: Reports may also be accessed from the Home screen.

See *Reports* on page 39 for more information.

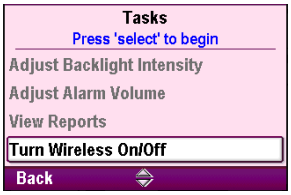
Turn Wireless On/Off

When the pump has a CADD®-Solis Communication Module installed, its wireless radio can be turned off (and on) as necessary. The wireless capabilities are used to allow the pump to communicate to a PharmGuard® Server system (i.e., sending pump data to the server, and receiving pump library and software updates from the server).

Note: The clinical functions of the pump are not affected by the pump's wireless on/off status. Wireless can be turned off or on without affecting pump delivery. When wireless is turned off, the pump retains delivery history data within the pump which will be communicated to the PharmGuard® Server system automatically later when wireless is turned on and connectivity to the server is established.

To turn wireless capabilities on or off:

1. From the Home screen, select **Tasks.**
2. Press ▲ or ▼ until **Turn Wireless On/Off** is highlighted and press select.
3. Press ▲ or ▼ until the desired setting is highlighted and select **Save.**



The wireless indicator in the pump display (below the keypad lock status) shows wireless and connectivity status:

Wireless Off		Wireless Off (white indicator)
Wireless On		Wireless On, not associated with wireless access point (orange indicator)
		Wireless On, associated with wireless access point (orange indicator with green center)
		Wireless On, associated with wireless access point, and communicating with PharmGuard® Server (green indicator with green center)

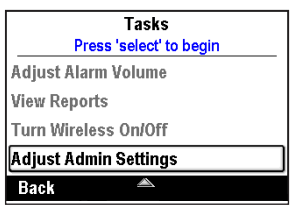
Adjust Admin Settings

The administrator settings contain pump configurations that are set up by the PharmGuard® system administrator. Protocol libraries are created using the PharmGuard® 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 Home screen, select **Tasks.**
2. 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.



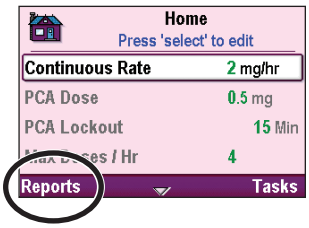
See the Administrator Settings Guide for more information.

Reports

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

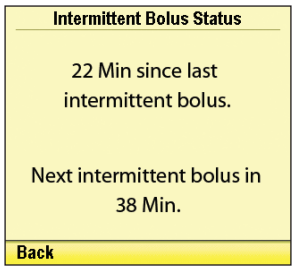
Note: Therapies incorporating patient-controlled analgesia are configured with the PharmGuard® Medication Safety Software to display either "PCA" or "PCEA". Most examples shown in this manual display "PCA". However, menus, submenus, and screens on the pump will appear with "PCEA" if they are programmed to do so.

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.)



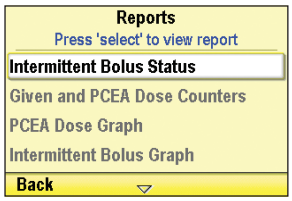
Intermittent Bolus Status

This screen shows the amount of time that has elapsed since the last intermittent bolus, and the amount of time until the next intermittent bolus is due to be delivered.



To view the intermittent bolus status:

1. From the Home screen, select **Reports.**
2. From the Reports menu, press ▲ or ▼ to choose **Intermittent Bolus Status** and press select.



Given and PCA Dose Counters (Given and PCEA 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 was started.

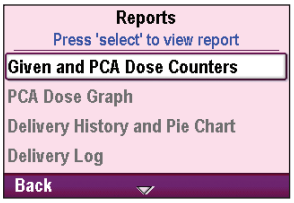
- **Total Given** shows the amount of drug given (in programming units) in continuous rate, clinician boluses, intermittent boluses, and PCA doses. If the programming units are mg or mcg, the total volume of fluid (mL) and amount of drug (mg or mcg) are shown.
- **PCA Doses Given** shows the number of 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, you see only the Total Given when viewing this report.

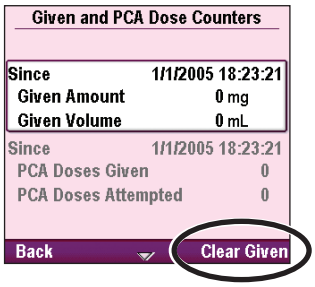
To view the Given and PCA dose counters:

1. From the Home screen, select **Reports.**
2. From the Reports menu, press ▲ or ▼ to choose **Given and PCA Dose Counters** and press select.



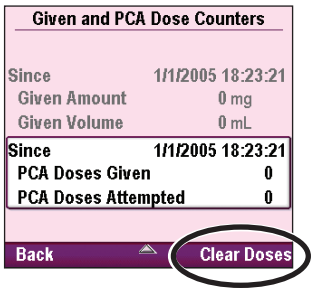
To clear the total given counters:

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



To clear the PCA doses given and attempted counters:

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

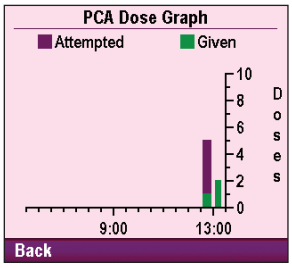


PCA Dose Graph (PCEA Dose Graph)

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

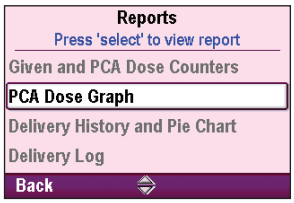
In this example, the patient has attempted 7 doses and 3 of those doses were given.

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



To view the PCA dose graph:

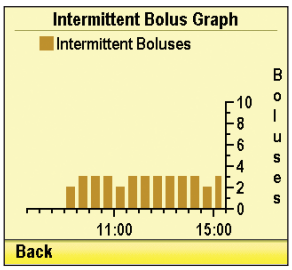
1. From the Home screen, select **Reports.**
2. From the Reports menu, press ▲ or ▼ to choose **PCA Dose Graph** and press select.



Intermittent Bolus Graph

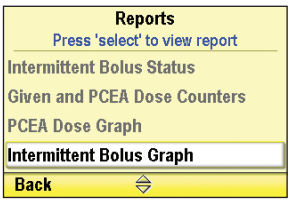
This screen displays the number of intermittent boluses given in 30 minute increments starting from the current time to 8 hours in the past or to the start of a new protocol or patient.

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



To view the intermittent bolus graph:

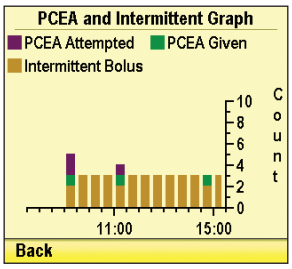
1. From the Home screen, select **Reports.**
2. From the Reports menu, press ▲ or ▼ to choose **Intermittent Bolus Graph** and press select.



PCA and Intermittent Graph (PCEA and Intermittent Graph)

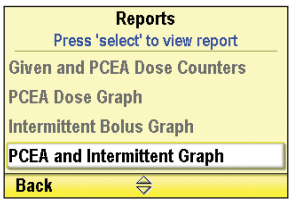
This screen displays the number of intermittent boluses, and the number of PCA doses attempted and given in 30 minute increments starting from the current time to 8 hours in the past or to the start of a new protocol or patient. The PCA and intermittent graph can be viewed at any time, with the pump running or stopped.

In this example, the patient attempted 6 doses and 3 of those doses were given.



To view the PCA and intermittent graph:

1. From the Home screen, select **Reports.**
2. From the Reports menu, press ▲ or ▼ to choose **PCA and Intermittent Graph** and press select.



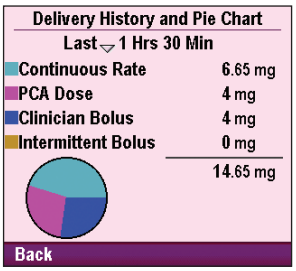
Delivery History and Pie Chart

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 provides a quick review of the methods of delivery over the interval selected.

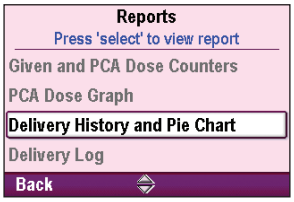
The delivery history is displayed in the units for the current protocol.

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



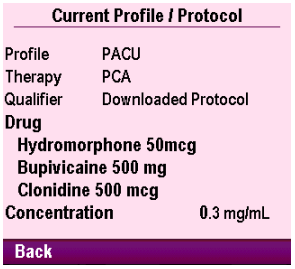
To view the delivery history and pie chart:

1. From the Home screen, select **Reports.**
2. From the Reports menu, press ▲ or ▼ to choose **Delivery History and Pie Chart** and press select.



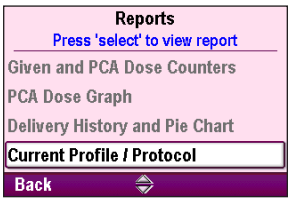
Current Profile / Protocol (if configured)

The Current Profile / Protocol screen shows the profile, therapy, qualifier, drug and units in use based on your selected protocol or manually programmed protocol.



To view the current profile / protocol:

1. From the Home screen, select **Reports.**
2. From the Reports menu, press ▲ or ▼ to choose **Current Profile / Protocol** and press select.



Delivery Log

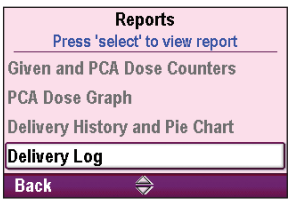
The delivery log is a subset of the event log and contains information having to do specifically with delivery events. Delivery log information includes:

- PCA dose deliveries.
- Clinician boluses.
- Intermittent boluses.
- Changes to the patient specific parameters (including continuous rate, intermittent boluses, 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 Home screen, select **Reports.**
2. From the Reports menu, press ▲ or ▼ to choose **Delivery Log** and press select.



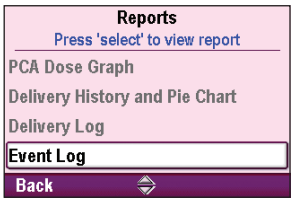
While viewing the delivery log, you may quickly scroll from the oldest to newest by selecting **Show Oldest** or **Show Newest.**

Event Log

The event log records the following types of events: hourly given totals, dose delivery, alarms, error codes, power source changes (including power losses), 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. When the event log reaches 5000 events, and a new event occurs, the oldest event is replaced with the next oldest event in order of occurrence.

The event log can be viewed at any time, with the pump running or stopped. The event log is maintained by an internal back up battery during and after the pump is powered off or when the pump loses power unexpectedly due to removal or depletion of power source (AC adapter, AA alkaline batteries, rechargeable battery pack, or communication module).

To view the event log:



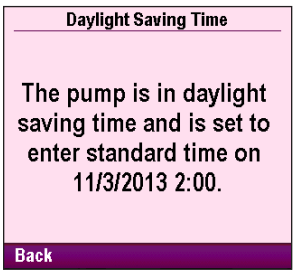
1. From the Home screen, select **Reports.**
2. From the Reports menu, press ▲ or ▼ to choose **Event Log** and press select.

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

Daylight Saving Time

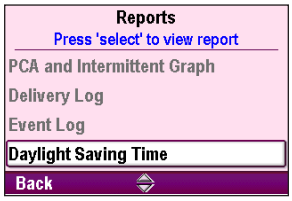
When the pump is configured by your PharmGuard® system administrator to automatically change time due to daylight saving time, this screen displays time change information. If this screen states that the feature is disabled, time can be updated manually on the pump.

For more information about time changes and when automatic time changes will occur on the pump, see page 34.



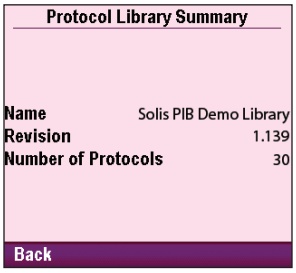
To view the daylight saving time information:

1. From the Home screen, select **Reports.**
2. From the Reports menu, press ▲ or ▼ to choose **Daylight Saving Time** and press select. This option is also available from the Set Time and Date screen.



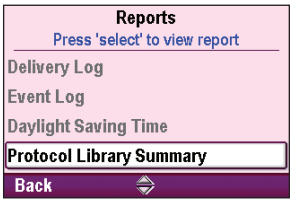
Protocol Library Summary

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

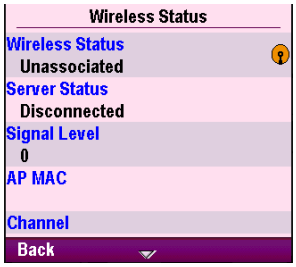


To view the protocol library summary:

1. From the Home screen, select **Reports.**
2. From the Reports menu, press ▲ or ▼ to choose **Protocol Library Summary** and press select.



Wireless Status



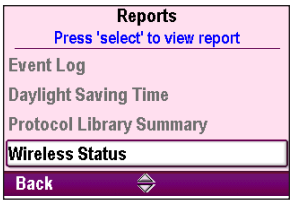
This screen is available only when a CADD®-Solis Communication Module is installed. This report is used by network or systems adminstrators to view the current status of the pump wireless module and its connectivity to the wireless network

If the Communication Module is incompatible with the wireless network configuration programmed in the pump, the status reported on the screen will be "Incompatible Configuration".

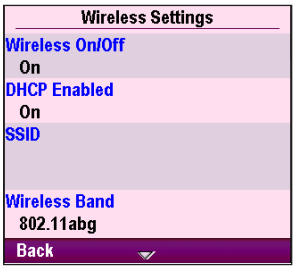
Note: For information about how to turn wireless on/off and viewing basic wireless status, see page 38.

To view wireless status:

1. From the Home screen, select **Reports.**
2. From the Reports menu, press ▲ or ▼ to choose **Wireless Status** and press select.



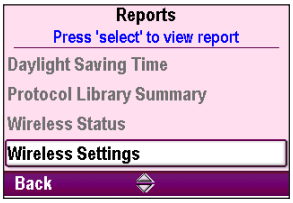
Wireless Settings



This screen is available only when a CADD®-Solis Communication Module is installed. This report is used by network or systems adminstrators to view the configuration settings for the communication module.

Notes:

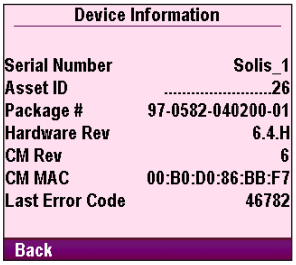
- For information about how to turn wireless on/off and viewing basic wireless status, see page 38.
- Wireless settings can be modified only by network administrators using the CADD®-Solis Network Setup Utility software. For more information, administrators should consult the documentation included with this software.



To view wireless settings:

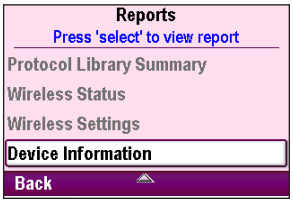
1. From the Home screen, select **Reports.**
2. From the Reports menu, press ▲ or ▼ to choose **Wireless Settings** and press select.

Device Information



The device information screen allows you to view the pump serial number, asset ID, software (package number) and hardware version numbers, and the last error code (if one exists). If a CADD®-Solis Communication Module is installed, the communication module (CM) revision and MAC address is also shown.

Note: Review your facility's procedure for handling error codes (see *Alarms and Messages, Alphabetical List on page 58* for more information).

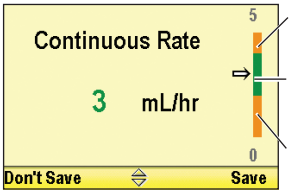


To view device information:

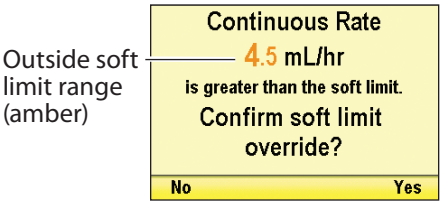
1. From the Home screen, select **Reports.**
2. From the Reports menu, press ▲ or ▼ to choose **Device Information** and press select.

Patient Specific Parameters (Programming Screens)

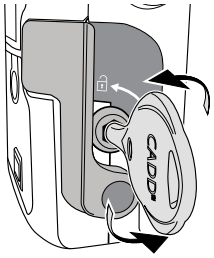
The patient specific parameters are found on the Home screen and can be edited within limits that are set up by the PharmGuard® system administrator in the protocol. The PharmGuard® system administrator determines which parameters can be viewed and/or edited on the Home screen, as well as the initial values of the parameters.



While determining the initial values, the PharmGuard® system administrator also sets up hard and soft limits which may allow you to modify the parameters as necessary. The soft limits (displayed in green) are the range most commonly used for the protocol, and the hard limits (displayed in amber) extend to the highest and lowest amount that the PharmGuard® 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 results in a screen that requires you to confirm the soft limit override.



You need the security code or the pump key to edit the patient specific parameters. The PharmGuard® 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 security code (see *Security Settings* on page 28).



Note:

- Using the pump key to unlock the keypad also unlocks the cassette latch (see *Attaching a Cassette on page 25* for more information).
- When using the pump key to unlock the keypad, be sure to keep the cassette latch in the latched position.

The pump provides the following methods of delivery:

- **Continuous rate:** infusion of drug at a constant, programmed rate
- **Intermittent bolus:** a series of doses activated at regular, programmed intervals
- **PCA dose:** a demand dose activated by the patient
- **Clinician bolus:** a dose activated by the clinician

Each of the methods may be programmed individually or in combination with each other. Ranges, programming increments, rates, and volumes are listed in the specifications section (see *Specifications (Nominal) on page 71*).

Note: Therapies incorporating patient-controlled analgesia are configured with the PharmGuard® Medication Safety Software to display either "PCA" or "PCEA". Most examples in this manual display "PCA". However, menus, submenus, and screens on your pump will appear with "PCEA" if they are programmed to do so.

Intermittent Bolus

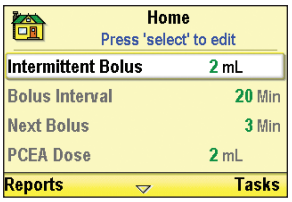
Each intermittent bolus is the infusion of a specific volume of drug at the programmed max delivery rate value. Programming the intermittent bolus is limited by the values of the max delivery rate, bolus interval, and continuous rate. Intermittent boluses are delivered at regular time intervals based on the programmed Bolus Interval, and as allowed by intermittent bolus limits, bolus interval limits, and bolus type. For more information, contact your PharmGuard® system administrator.

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

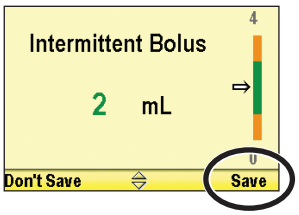
Note: Stopping the pump while an Intermittent Bolus is in progress will cancel the remainder of the Intermittent Bolus dose.

To edit the intermittent bolus:

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



2. Unlock the keypad using the security code or the pump key.
3. Press ▲ or ▼ until you reach the desired intermittent bolus quantity and select **Save.**



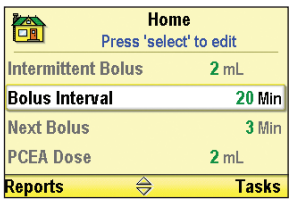
Bolus Interval

The bolus interval is the amount of time that elapses from the beginning of one intermittent bolus to the beginning of the next one. The bolus interval cannot be programmed to a value that would prevent an intermittent bolus from being fully delivered within the bolus interval time period. Programming the bolus interval is limited by values of the max delivery rate, continuous rate, and intermittent bolus. For more information, contact your PharmGuard® system administrator.

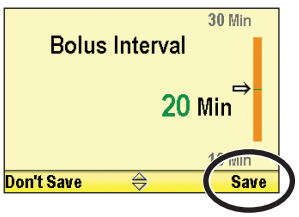
This value can be edited while the pump is running or stopped (if the keypad is unlocked).

To edit the bolus interval:

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



2. Unlock the keypad using the security code or the pump key.
3. Press ▲ or ▼ until you reach the desired bolus interval and select **Save.**



Next Bolus

The Next Bolus setting is the length of time between when the pump starts "Running" until when the first intermittent bolus will be delivered. After the initial intermittent bolus is delivered, Next Bolus functions as a timer to count down the time remaining until the next intermittent bolus is programmed to deliver.

Note: The Next Bolus countdown does not begin until you start the pump by pressing the stop/start button. Once the pump has been started, the countdown continues even if the pump is subsequently stopped.

The Next Bolus setting may be edited to adjust the timing of the next Intermittent Bolus as defined by the bolus interval. This can be done prior to beginning an infusion or during an infusion. For example, a clinician can edit the next bolus setting to 0 minutes to immediately deliver an intermittent bolus. All subsequent intermittent bolus delivery times will be determined by the bolus interval.

Note: When the Next Bolus is programmed to 0 Min and the pump is started, or when the pump is running and the Next Bolus has counted down and reaches 0 Min, the Intermittent Bolus delivery starts, "PIB bolus" is displayed in the status bar, and the Next Bolus time immediately resets to match the programmed Bolus Interval. Because the reset of the Next Bolus time occurs immediately, the value of 0 Min will only be seen if the pump is in stop mode.

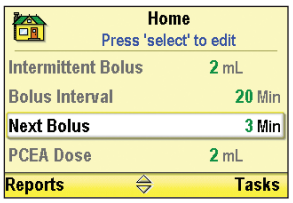
The following are examples of when the pump will deliver the intermittent bolus dose and what the pump will display based on how the bolus interval and the next bolus are programmed. When the pump is started:

- If Bolus Interval is programmed to **1** Hrs and Next Bolus is programmed to **1** Hrs:
  The Intermittent Bolus will occur in 1 hour.
  The status bar will display "Running."
  Next Bolus will display "1 Hrs" and will count down as time passes.
- If Bolus Interval is programmed to **1** Hrs and Next Bolus is programmed to **0** Min:
  The Intermittent Bolus will occur immediately after starting the pump.
  The status bar will display "PIB Bolus."
  Next Bolus will display "1 Hrs" and will count down as time passes.

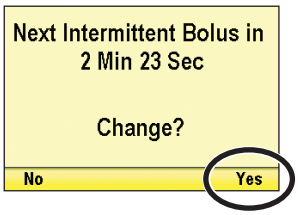
The next bolus option can be edited only when the pump is stopped. The pump must be running at the selected time in order for delivery to begin.

To edit the next bolus:

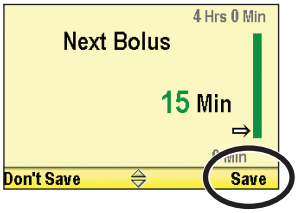
1. From the Home screen, press ▲ or ▼ to choose **Next Bolus** and press select.



   Note: If a protocol was running and medication was delivered, a confirmation screen appears showing the current, programmed setting. Select **Yes** to change the setting.



2. Unlock the keypad using the security code or the pump key.
3. Press ▲ or ▼ until you reach the desired next bolus time and select **Save.**



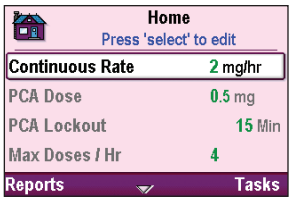
Continuous Rate

The continuous rate is the constant, hourly rate the drug is delivered at while the pump is running. Programming the continuous rate is limited by values of the max delivery rate, bolus interval, and intermittent bolus. For more information, contact your PharmGuard® system administrator.

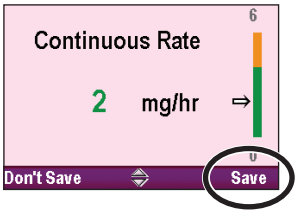
The continuous rate value can be edited while the pump is running or stopped (if the keypad is unlocked).

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 rate and select **Save.**



PCA Dose (PCEA 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.

WARNING: The remote dose cord is for *patient use only*. Operation by anyone other than the patient may cause overdelivery of medication that could result in serious injury or death of the patient.

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

If the PharmGuard® 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 either the continuous rate and/or intermittent bolus. A PCA dose can be delivered during the next bolus countdown.

Note:

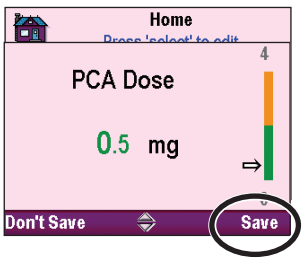
- If the delivery limit is reached while a PCA dose is in progress, the PCA dose will not be completed.
- A PCA dose cannot be started while another PCA dose or a clinician bolus is in progress.
- Pressing the remote dose cord button turns the display back on ***and*** delivers a PCA dose (if available).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

Each time the patient requests a PCA dose, the pump automatically adds it to the dose counters screen. If a PCA dose has not been programmed by the PharmGuard® system administrator, the pump displays 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.**



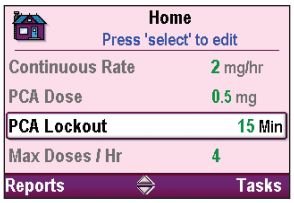
PCA Lockout (PCEA Lockout)

The PCA lockout is the minimum amount of time that must pass after a PCA dose and before the patient can successfully request another PCA dose. It is also the minimum time that must elapse between the time an intermittent bolus starts and the time that the next PCA dose is available.

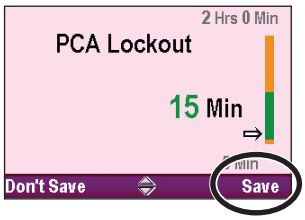
The PCA lockout can be edited while the pump is running or stopped (if the keypad is unlocked).

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.**



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 PharmGuard® 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 displays "Delivery Limit" and the pump delivers 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 displays "KVO = 0" and the KVO rate is zero.

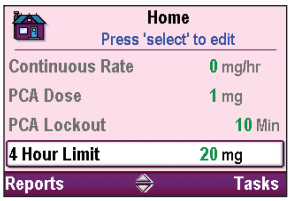
Note: If the delivery limit is reached while a PCA dose is in progress, the dose will not be completed.

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

To edit the hourly limit:

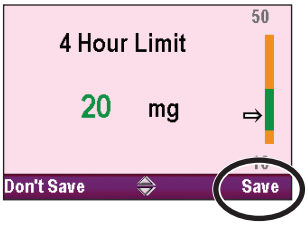
1. From the Home screen, press ▲ or ▼ to choose **X* Hour Limit** and press select.

   *X is the number of hours set up by the PharmGuard® 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 PharmGuard® system administrator has chosen not to require it. Instead you may be required to program the Max Doses/Hr.



Max Doses/Hr

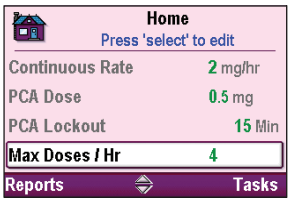
The max doses/hr setting is used to further restrict the number of PCA doses available to the patient in 1 hour. The max doses/hr feature allows you to restrict the PCA doses beyond the PCA lockout time.

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

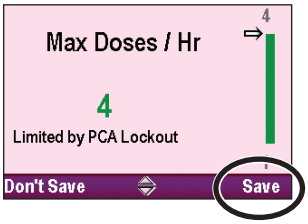
Note: If the hourly limit or the max doses/hr settings are not visible on the Home screen, your facility's PharmGuard® system administrator has chosen not to require a delivery limit beyond the PCA lockout.

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.**



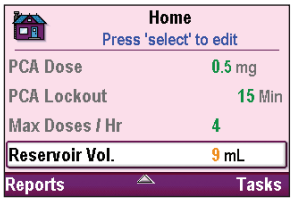
Reservoir Volume

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 is delivered and adjusts the reservoir volume accordingly.

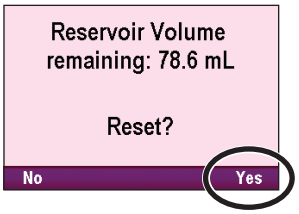
The pump must be stopped to adjust the reservoir volume amount.

To edit the reservoir volume:

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

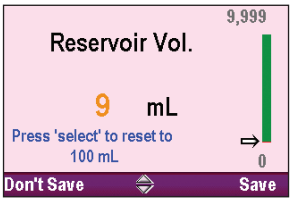


Note: If a protocol was running and medication was delivered, a confirmation screen appears showing the amount remaining in the reservoir volume. Select **Yes** to adjust the reservoir volume.



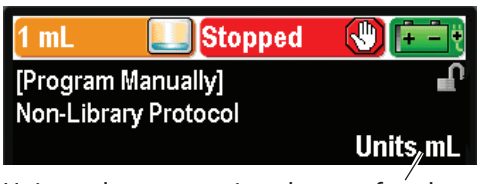
2. Unlock the keypad using the security code or the pump key.
3. Press ▲ or ▼ until you reach the desired reservoir volume and select **Save.**

   You may press select to reset the pump to a default amount which appears on the screen in blue text, under the current value. In this example, pressing select resets 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 is always black in color and the therapy, qualifier, and drug and concentration listing will look like this (see page 23 for a diagram of the pump screen):



Units and concentration chosen after the manual mode is selected.

Note: The protocol title bar may be black even when the pump is not in manual mode if the protocol was 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 PharmGuard® 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 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 are 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 82 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.

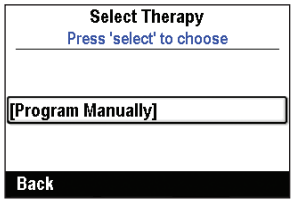
Note: The manual mode is designed to be used in unusual circumstances when an order is received which is different than any of your standard protocols. Use of the manual mode does not allow you to use all of the medication safety features built into the CADD®-Solis pump. If you find the manual mode is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

Manual Mode Initial Settings	
Pump Function	**Protocol Setting**
Programming Units	User selects mL, mg, or mcg
Concentration	User selects if the programming units are mg or mcg. Range is 0.1–100 mg/mL or 1–500 mcg/mL
Continuous Rate On/Off	On
Continuous Rate Limits	Range is 0–100 mL/hour (or mg or mcg equivalent). Value is 0
PCA Dose On/Off	On
PCA Dose Limits	Range is 0–50 mL (or mg or mcg equivalent). Value is 0
PCA Lockout Limits	Range is 1 min–24 hours. Value is 1 hour (when PCA dose is programmed)
Intermittent Bolus On/Off	Off
Intermittent Bolus Limits	Range is 0–50 mL. Value is 0 mL
Bolus Interval Limits	Range is 1 minute–4 hours. Value is 1 hour
Intermittent Bolus Type	Bolus Interval or PCA Lockout. Value is Bolus Interval
Next Bolus	Range is 0 minutes–4 hours. Value is 0 hr
Delivery limit amount*	Range is 0.1–1000 mL (or mg or mcg equivalent)
Max doses/hour*	Range is 1–60. Value is 1
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 0–50 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	On
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

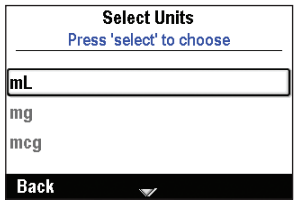
*Only if feature was used in the previous protocol.

To use the manual mode:

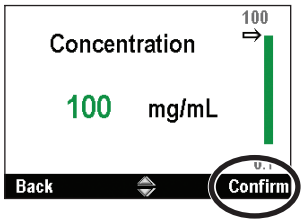
1. Determine whether you are starting a new patient, or starting a new protocol with the same patient. Select the appropriate task from the tasks menu.
2. On the Select Therapy screen, scroll to the bottom of the therapies until **[Program Manually]** is highlighted and press select. The protocol title bar is displayed in the color black. Instead of a therapy and qualifier, you see the Manual Program screen (see page 51).



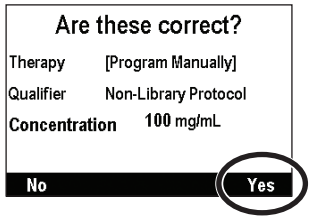
3. Unlock the keypad using the security code.
4. Press ▲ or ▼ to select the desired units (mL, mg, mcg), and then press select.



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

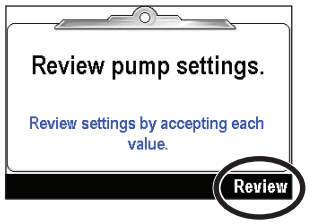


5. The therapy, qualifier, units and concentration, if applicable, that you have selected now appear. Confirm that you have selected the correct units and concentration and select **Yes.**



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

6. The pump takes a moment to set the program before it asks you to review the pump settings. Select **Review.**



7. 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 45 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 will exceed the soft limit range and will be asked to confirm the soft limit override on each screen (see page 82 for the factory default settings). The parameter and value are displayed in amber.

WARNING: The manual mode does not contain programming limits. 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.

8. 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.

Wireless Function (Communication Module)

When the pump has the optional CADD®-Solis Communication Module installed, its wireless capabilities allow the pump to communicate to a PharmGuard® Server system (i.e., sending pump data to the server, receiving pump library updates, and software updates (pump and communication module) from the server). The communication module also features a built in rechargeable battery to power the pump. The communication module is recharged while installed in the pump using the pump AC adapter connected to the pump AC power jack. For installation and additional information, *see the CADD®-Solis Communication Module Operators Manual*.

Note: The wireless feature can be turned off or on without affecting pump delivery. The communication module is an added feature and not required for normal pump operation. Lack of wireless connection to an access point does not impact delivery accuracy.

Functionality of the CADD®-Solis Communication Module:

- PharmGuard® library updates occur without impact to current delivery. The new libraries are effective upon the next "start new patient" setup.
- PharmGuard® software downloads occur without impact to current delivery and only take effect upon the "acceptance" of the new software.
- The communication module allows the pump to send event history and status to the PharmGuard® Server. The events match those from the pump event log.
- Rechargeable battery built into the communication module powers wireless function and pump delivery (four hours run time) when the AC adapter is not used.
- Built in Pole Mount adapter. The mounting bracket of the communication module also provides a built in pole mount bracket.

Heat Reduction Mode:

When the communication module is sending and/or receiving large amounts of data in an operating environment that is near the higher end of the specified operating environment temperature range, wireless functionality may be temporarily limited as a safeguard to prevent overheating. If heat reduction mode occurs, pump function and delivery accuracy are not impacted, only the wireless functionality.

If heat reduction mode is active, the pump Wireless Status Indicator will show,  - Wireless On, not associated with wireless access point.
Move the pump and communication module into a cooler area to expedite cooling and resume wireless functionality.

References and Troubleshooting

Alarms and Messages

The pump can produce multiple alarms. For many of the alarms, you have one or more options available:

- **Acknowledge**—the alarm clears from the screen.
- **Silence**—the alarm stays on the screen, but is silenced for 2 minutes before it sounds again. The alarm continues until it is acknowledged or resolved.
- **Power Down**—available from some select alarms, this option powers the pump down.
- **Stop Pump**— available from some select alarms, this option stops pump delivery.

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

Types of Alarms

System Fault Alarm

If this screen appears, an unrecoverable error may have occurred, such as a hardware or software fault. The amber indicator light is 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 or Smiths Medical International Ltd.

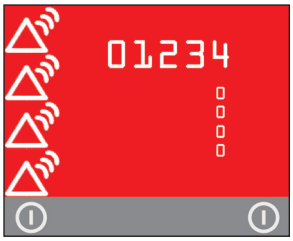
There are two ways to clear this alarm (pump will power down):

• Two key press; separately press the left and right soft keys on the keypad, or press either the left or right soft key and then press the power switch.

Or

• Remove power from the pump by opening the battery door and, if necessary, removing the AC power. Close the battery door and turn the pump back on.

If the error code does not repeat, Customer Service may suggest continued use of the pump. However, if the error is persistent, the pump must be returned for service.



System fault alarm (red).

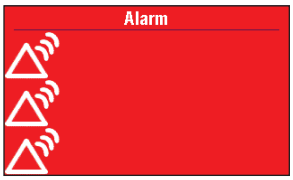
The numbers relate to the error that caused the system fault.

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

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.

High Priority Alarm

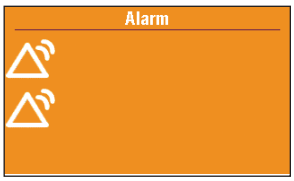
A high priority alarm always pauses or stops the pump if it is running. The alarm is accompanied by a **red** screen, and it persists until acknowledged by the press of a key on the pump or until the condition that triggered the alarm goes away (for example, high pressure). The alarm can be silenced with a key press and will sound again after 2 minutes if the alarm condition still exists.



High priority alarm (red)

Medium Priority Alarm

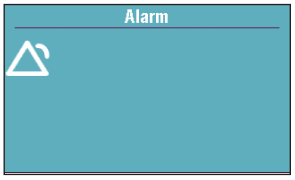
A medium priority alarm does not stop the pump if it is running. The alarm is accompanied by an **amber** screen, and it persists until acknowledged by the press of a key on the pump or until the condition that triggered the alarm goes away. The alarm can be silenced with a key press and will sound again after 2 minutes if the alarm condition still exists.



Medium priority alarm (amber)

Low Priority Alarm

A low priority alarm does not stop the pump if it is running. The alarm is accompanied by a **blue** screen, and it persists 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. (Some low priority alarms persist for longer than 5 seconds.)



Low priority alarm (blue)

Multiple Alarms

The alarm system will maintain and manage multiple alarm conditions at the same time, but will only generate alarm signals from a single alarm at any time. When an alarm of higher priority is activated, its alarm signals will supersede those of any currently active lower priority alarm. When an alarm of equal or lower priority is activated, its alarm signals will follow at the removal of any currently active higher or of equal priority alarm. In this way, the operator awareness of lower or of equal priority alarms may be delayed until existing higher priority alarms are addressed by the operator.

Informational Messages and Signals

An informational priority message does not stop the pump if it is running. This message appears in the status bar, and does not display over any existing screen. It persists for 5 seconds and may be silent, requiring no acknowledgement. Some informational examples are “Cassette Locked” and “Cassette Unlocked.”

When an alarm condition is active, in addition to the visual indication, the pump will sound an audible alarm that is distinguishable from other pump sounds. All audible alarms, no matter the sound theme used, will be distinguishable from other information signals that the device may sound.

The audible informational signals are not impacted by the sound theme settings. Audible informational signals include: key beeps, PCA dose granted beeps, stop mode beeps, informational message beeps, low battery beeps, and power on beeps. The audible characteristics of these informational signals may also be previewed along with the sound themes (see Administrator Settings Guide).

Alarm Algorithms

Most alarm algorithms are based on simple, singular, and unchangeable alarm limits; for example, Reservoir Volume Empty, Remote Dose Cord Disconnected, Delivery Cannot Be Started, Battery Removed, and Disposable Detached.

Alarm algorithms based on user configurable alarm limits are: High/Standard Flow Disposable Not Allowed, Delivery Limit, Reservoir Volume Low, Downstream Occlusion, Upstream Occlusion, Air In-Line, and Stop Mode Reminder.

Other alarm algorithm details included in the table of alarm messages.

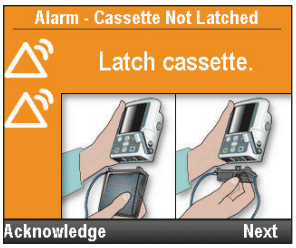
Alarm Help Screens

Additional information may be displayed when certain alarms occur. The help screens describe what you can do to try to solve the current problem that is causing the alarm.

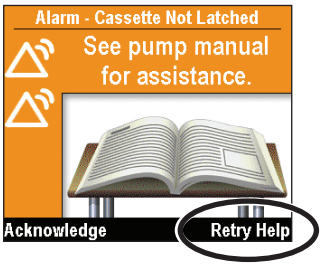
1. When an alarm occurs, select **Silence** to quiet the alarm.

2. If help screens are available for the alarm, “Help” appears above the right soft key. To view the help screens, select **Help.**

3. Follow the applicable instructions provided on the help screen. To page through all available help screens, press **Next** repeatedly. Press **Acknowledge** at any time to exit Help.



4. "Retry Help" appears when no additional help steps are available. To page through the help screens again, press **Retry Help.** The Alarm screen reappears as in Step 2 above. Repeat Steps 2 and 3. When the alarm clears, the help screens will no longer be displayed.



User Position

The user must position themself to ensure alarm visibility and audibility with respect to distance from the device in the expected ambient light and noise conditions.

Note: Perform an alarm risk assessment to determine compatibility with facility alarm policies and care area requirements. If choosing an alternative alarm style, perform a risk assessment to ensure the operator's recognition of the audible alarm.

Note: There is no power interruption limit to the device's ability to restore alarm settings and behavior. The pump will retain alarm state upon power interruption if the alarm condition persists through the power interruption, and alarm algorithms are unaffected by power interruption.

Troubleshooting

Issue	Possible Solution
A continuous two-tone alarm is sounding, and the amber light is lit or flashing.	Delivery has stopped. Read the message on the display and refer to the list of messages in the table below. If the display is blank or contains random characters, the 4 AA batteries , the rechargeable battery pack, or the CADD®-Solis Communication Module with integrated rechargeable battery may be depleted. Install 4 new AA batteries, a fully charged rechargeable battery pack, or attach an AC adapter to charge a rechargeable battery pack or communication module battery.
The pump is sounding persistent audible beeps, and the amber light is flashing.	Look at the message on the display and refer to the list of messages in the table below.
Three beeps sound every 5 minutes.	This may be a reminder that the pump is stopped.
After installing 4 new AA batteries and powering up the pump, no screen appears and no beep sounds.	The batteries may be installed incorrectly. Review the procedure for installing batteries. Be sure to match the polarity (+ and –) markings inside the battery door with the markings on the batteries. If there is still no power, the batteries may be completely depleted. Install 4 new AA batteries.

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 or the CADD®-Solis Communication Module with integrated rechargeable battery was removed, the battery door was opened, or the batteries are too depleated to power the pump. The pump lost power and is no longer delivering. Clear this alarm by turning the pump back on, or the alarm stops after the power is 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 , rechargeable battery pack or the CADD®-Solis Communication Module with integrated rechargeable battery. 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 accumulated 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. If the fluid path contains air bubbles, close the clamps and disconnect the fluid path from the patient. Follow the instructions for removing air by priming (see *Prime Tubing on page 34* 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. If the AC adapter is not attached, select **Power Down** to power down the pump. • Charge the rechargeable battery pack or the CADD®-Solis Communication Module with integrated rechargeable battery. • Install 4 new AA batteries or a fully charged rechargeable battery pack. 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. If the AC adapter is not attached, select **Power Down** to power down the pump. • Charge the rechargeable battery pack or the CADD®-Solis Communication Module with integrated rechargeable battery. • Install 4 new AA batteries or a fully charged rechargeable battery pack. 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, CADD®-Solis Communication Module with integrated rechargeable battery, or 4 AA batteries are low but the pump is still operable. Select **Acknowledge** to clear the alarm or the alarm automatically clears after 5 seconds. Recharge or change the rechargeable battery pack or CADD®-Solis communication module, or replace the 4 AA batteries soon.

Alarms and Messages	Alarm Priority	Description / Corrective Action
Battery removed. Pump stopped.	High	The rechargeable battery pack, CADD®-Solis Communication Module with integrated rechargeable battery, or the 4 AA batteries were removed. The pump was delivering and is now stopped. Select **Acknowledge** to clear the alarm. • Install 4 new AA batteries, a fully charged rechargeable battery pack, or CADD®-Solis communication module. 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, CADD®-Solis Communication Module with integrated rechargeable battery, 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, CADD®-Solis communication module, or 4 new AA batteries. To start delivery, good batteries must always be installed, even when an external source of power is connected.
Cannot start pump. Rechargeable battery has reached end of use.	Medium	The rechargeable battery pack or the rechargable battery integrated with the CADD-Solis Network Comunication Module 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. 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, a new rechargeable battery pack, or the CADD®-Solis Communication Module with a its rechargeable battery replaced. If appropriate, start the pump.
Cannot start pump with a depleted battery.	Medium	The battery power is too low to operate the pump. 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, a fully charged rechargeable battery pack, or attach an AC adapter to charge a rechargeable battery pack or communication module battery. 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 *Reservoir Volume on page 50* for more information about the reservoir volume.
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. Follow the instructions for removing air by priming (see page 34). • If appropriate, start the pump.
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. 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 4 new AA batteries, or fully-charged rechargeable battery pack. If appropriate, start the pump. For more information on what type of batteries to use, see *Installing the Batteries on page 20*

Alarms and Messages	Alarm Priority	Description / Corrective Action
Cannot start pump without a battery.	Medium	The pump does not have any batteries installed. 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, rechargeable battery pack, or the CADD®-Solis Communication Module with integrated rechargeable battery. If appropriate, start the pump.
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. **Note:** This alarm has associated help screens.
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 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 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, the pump's pressure sensor is faulty. Remove the pump from service and contact Smiths Medical Customer Service.
Current settings require high volume set. Change cassette.	High	The delivery-specific parameters are programmed to values that cause the maximum delivery rate to exceed 250 mL/hr, which requires a high volume administration set. The pump is stopped and will not run. Replace the standard volume cassette with a high volume administration set to continue. **Note:** Do not manually adjust the delivery rate to override pump programming without written authorization from the prescribing physician.

Alarms and Messages	Alarm Priority	Description / Corrective Action
Current settings require standard volume set. Change cassette.	High	The CADD® high volume administration set cannot be used with the selected protocol. The pump is stopped and will not run. Replace the high volume administration set with a standard volume cassette to continue. **Note:** Do not manually adjust the delivery rate to override pump programming without written authorization from the prescribing physician.
Delivery limit reached. Partial PCA (PCEA) dose delivered. Running at KVO rate.	Low	The programmed delivery limit has been reached, and the pump is delivering fluid at the KVO rate. This alarm occurs when PCA (PCEA) dose caused the delivery limit to be exceeded. Select **Acknowledge** to clear the alarm or the alarm automatically clears after 5 seconds. **Note:** The status bar display remains after the alarm has cleared.
Delivery limit reached. Running at KVO rate.	Low	The programmed delivery limit has been reached, and the pump is delivering fluid at the KVO rate. This alarm occurs when continuous rate with PCA, or intermittent bolus, caused the delivery limit to be exceeded. Select **Acknowledge** to clear the alarm or the alarm automatically clears after 5 seconds. **Note:** The status bar display remains after the alarm has cleared.
Delivery too slow.	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 2 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 or the CADD®-Solis Communication Module is depleted and is being recharged with the AC adapter. Select **Acknowledge** to clear the alarm or the alarm automatically clears after 5 seconds.
Downstream occlusion. Clear occlusion between pump and patient.	High	The pump detects high pressure, which may be resulting from a downstream blockage, a 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. Press **stop/start** to stop the pump. 2. Close the distal clamp. If the distal clamp is the cause of the obstruction, keep it closed and continue with step 4. 3. Remove the obstruction. 4. Detach the CADD™ 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 CADD™ 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. **Note:** This alarm has associated help screens.

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.
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, and 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. **Note:** This alarm has associated help screens.
Loss of power occurred while running. Replace AA batteries.	Medium	The pump lost power while it was running. This alarm occurs when the pump restarts. 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, rechargeable battery pack, or the CADD®-Solis Communication Module with integrated rechargeable battery. To start delivery, good batteries must always be installed, even when an external source of power is connected. 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 sent to the pump from the PharmGuard® Point of Care Medication Safety Software. Select **Acknowledge** to clear the alarm. Review the protocol to ensure that it is correct.
PCA (PCEA) 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 (PCEA) dose ▣ button on the pump.
PCA (PCEA) 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 automatically clears 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.

Alarms and Messages	Alarm Priority	Description / Corrective Action
Protocol library updating. Reselect protocol when update is complete.	Medium	A new or updated library is currently being downloaded into the pump. You cannot 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.
Pump does not have a protocol library.	Medium	The pump had a protocol library the last time it was powered on, but now it does not. This could happen if the pump was manually reverted to the factory default, 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 PharmGuard® 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 manually reverted to this default, has recently had a software update, or has not been in use for some time. Select **Acknowledge** to clear the alarm and refer to your facility's PharmGuard® 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 page 43.
Pump stopped reminder. When ready, press 'stop/start' key.	High	This is a reminder that the pump is stopped and not delivering. Select **Acknowledge** to clear the alarm. Start the pump, if appropriate. The alarm will repeat in 5 minutes if the pump is not restarted or powered down.
Rechargeable battery near end of use. Replace battery.	Medium	The rechargeable battery pack or the CADD®-Solis Communication Module 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 or the CADD®-Solis Communication Module 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. To start delivery, good batteries must always be installed even when an external source of power is connected.
Remove and reattach cassette.	High	The pump detects a damaged cassette. Close the tubing clamp and inspect the cassette for damage. The pump is stopped and will not run. Replace the cassette if necessary. **Note:** You must remove the cassette to continue. **Note:** This alarm also occurs if a cassette is attached during one of the following situations: • The pump is set to the factory default, powered off, and then powered on. • The pump was loaded with new software, powered off, and then powered on.
Reservoir volume is zero. Pump stopped.	High	The reservoir volume has reached 0.0 mL. The pump was delivering, 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.

Alarms and Messages	Alarm Priority	Description / Corrective Action
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 automatically clears 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" (Medium) or "Non-Insistent and Repeating" (Low). The "Insistent and One Time Only" alarm does not reoccur once it is acknowledged. The "Non-Insistent and Repeating" alarm repeats at the 75%, 50%, and 25% marks of the Reservoir Low Trip Point.
Unknown cassette type. Remove cassette.	High	The pump detects a cassette 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 20.
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 20.
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 an 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 clears when the occlusion is removed. After it clears, you must acknowledge this alarm if it has occurred and cleared more than 3 times within 15 minutes. **Note:** This alarm has associated help screens.
Wireless Module intermittent connection with pump.	High	The internal hardware connection between the CADD®-Solis Communication Module and the pump is intermittent. Select **Power Down** to power down the pump. Service personnel shall attempt to re-install the CADD®-Solis Communication Module and power the pump back up. If the alarm persists, install another communication module or contact Smiths Medical Customer Service to return the pump for service.

WARNING:

- **A hazard can exist if different alarm styles are used on multiple pumps in the same single care area, for example, a critical care area or operating room. Auditory alarm signal sound levels that are less than ambient levels can hinder operator recognition of alarm conditions.**
- **Always set the Delivery Limit amount alarm, Reservoir Volume Low alarm, and all other variable alarm settings to clinically appropriate settings. Setting alarm limits to values not clinically safe for the patient may cause patient harm due to a delay in therapy.**

Note: The measured audible alarm sound pressure level range, as tested in accordance with IEC 60601-1-8, is 53 (±4) dBA for high priority alarms and 50 (±4) dBA for medium priority alarms.

Exposure to Radiation or Magnetic Resonance Imaging (MRI)

CAUTION:

- **The pump should *not* be directly irradiated by therapeutic levels of ionizing radiation due to 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 electronic circuitry may occur.**
- **The pump is considered MR Unsafe and should not be exposed to or used in the MRI environment because the pump is not intended or designed to be used in the MRI environment. Exposing the pump to strong magnetic fields can damage the pump.**
- **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 affect how the pump works and may also cause damage to the pump.**

Cleaning and Disinfecting the Pump and Accessories

WARNING:

- **The pump and reusable accessories should be cleaned and disinfected after each patient use and in accordance with this manual and your organization's policies and procedures for reusable, solid surface, non-critical medical devices. Failure to do so could result in serious patient injury or death.**
- **Ensure that debris is not allowed to build up on the pressure plate surface of the pumping mechanism. Inspect the air detector sensor slot and remove any debris. A blocked air detector sensor may not detect air present in the fluid path, which could result in serious patient injury or death.**

CAUTION:

- **Do not immerse the pump in cleaning fluid or water. Do not allow solution to soak into the pump, accumulate on the keypad, or enter the battery compartment, USB port, remote dose cord jack, or power jack areas. Moisture buildup inside the pump may damage the pump.**
- **Do not oversaturate the chassis area on the bottom of the pump with cleaning or disinfecting solutions. Oversaturating this area can cause damage to the pump sensors over time.**
- **Do not clean the pump with acetone, other plastic solvents, or abrasive cleaners, as damage to the pump may occur. Also refer to the instructions for use for each accessory before proceeding with cleaning and disinfecting. Some accessories may have their own list of acceptable cleaning and disinfecting solutions.**

Note: Refer to the instructions for use for each accessory before proceeding with cleaning.
For optimal efficiency, it is recommended best practice to clean first and then disinfect. All disinfectants require pre-cleaning, except for disinfectant cleaners that are tested to disinfect in the presence of 5% of organic matter.

1. **Inspect the Downstream Occlusion (DSO) seal for damage or wear to the rubber material during cleaning and at each preventative maintenance service.** DSO seals that show signs of cracking or abrasion(s) should be returned to a Smiths Medical Service Center for replacement of the DSO seal, sensor, and bezel.

   If the DSO seal does not have cracking and/or abrasion(s), continue with the following steps to clean and disinfect the pump and accessories, unless otherwise specified in the instructions for use for an accessory:
2. **Clean the pump and its accessories using a *mild detergent soap solution* to remove residuals or contaminated material.** Apply solution to a soft, lint-free cloth and then wipe the pump or accessory. ***Do not allow the solution to soak into the pump or accessory.***
3. **Disinfect the pump and its accessories by applying a *disinfecting solution* (listed below) according to the disinfecting product label instructions.** If using a liquid or spray, apply solution to a soft, lint-free cloth and then wipe the pump or accessory. Follow the disinfectant manufacturer's recommendations for disinfectant contact times. ***Do not allow the solution to soak into the pump or accessory.***

   Acceptable disinfecting solutions for the CADD®-Solis pump and its accessories are listed below.
   Note: For the CADD®-Solis LockBox, use only the Sani-Cloth® Bleach product listed below as other products may affect the transparency of the lockbox.

Product	Manufacturer	EPA Registration Number	Active Ingredient(s)	Contact/ Kill Time
CaviWipes™ *(Do not use with CADD®-Solis LockBox)*	Metrex	46781-8	17.2% Isopropanol	3 minutes
Sani-Cloth® Super *(Do not use with CADD®-Solis LockbBox)*	PDI	9480-4	Dimethyl Benzyl Ammonium Chloride, Dimethyl Ethyl Benzyl Ammonium Chloride	2 minutes
Sani-Cloth® Bleach	PDI	9480-8	0.60% Sodium Hypochlorite	4 minutes

4. **Allow the pump and accessories to dry completely before use**.

Scroll Ranges

Continuous Rate Scroll Ranges			
Units	**Starting Value**	**Increment**	**Maximum**
Milliliters	0	0.1	100
Milligrams only	10% of concentration	Values between 0.01 and 0.5: 0.01	Concentration x 100
Micrograms only	10% of concentration	Values between 0.1 and 0.5: 0.1	Concentration x 100
Milligrams and Micrograms	10% of concentration	Values between 0.5 and 100: 0.1 Values between 100 and 1000: 1.0 Values greater than 1000: 10.0	Concentration x 100

PCA Dose, Clinician Bolus, and Intermittent Bolus Scroll Ranges			
Units	Starting Value	Increment	Max.
Milliliters	0	0.05	50

PCA Dose, Clinician Bolus, and Intermittent Bolus Scroll Ranges: Milligrams					
Concentration (mg/mL)	Increment (mg)	Max. (mg)	Concentration (mg/mL)	Increment (mg)	Max. (mg)
0.1	0.01	5	20	1.00	1000
0.2	0.02	10	25	1.25	1250
0.3	0.03	15	30	1.50	1500
0.4	0.04	20	35	1.75	1750
0.5	0.05	25	40	2.00	2000
1	0.05	50	45	2.25	2250
2	0.10	100	50	2.50	2500
3	0.15	150	55	2.75	2750
4	0.20	200	60	3.00	3000
5	0.25	250	65	3.25	3250
6	0.30	300	70	3.50	3500
7	0.35	350	75	3.75	3750
8	0.40	400	80	4.00	4000
9	0.45	450	85	4.25	4250
10	0.50	500	90	4.50	4500
11	0.55	550	95	4.75	4750
12	0.60	600	100	5.00	5000
13	0.65	650			
14	0.70	700			
15	0.75	750			

PCA Dose, Clinician Bolus, and Intermittent Bolus Scroll Ranges: Micrograms					
Concentration (mcg/mL)	Increment (mcg)	Max. (mcg)	Concentration (mcg/mL)	Increment (mcg)	Max. (mcg)
1	0.05	50	35	1.75	1750
2	0.10	100	40	2.00	2000
3	0.15	150	45	2.25	2250
4	0.20	200	50	2.50	2500
5	0.25	250	55	2.75	2750
6	0.30	300	60	3.00	3000
7	0.35	350	65	3.25	3250
8	0.40	400	70	3.50	3500
9	0.45	450	75	3.75	3750
10	0.50	500	80	4.00	4000
11	0.55	550	85	4.25	4250
12	0.60	600	90	4.50	4500
13	0.65	650	95	4.75	4750
14	0.70	700	100	5.00	5000
15	0.75	750	200	10.00	10,000
20	1.00	1000	300	15.00	15,000
25	1.25	1250	400	20.00	20,000
30	1.50	1500	500	25.00	25,000

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 (2006 + A1:2013 + A11:2011 + A12:2014) Ed3.1, Medical Electrical Equipment, Part I: General Requirements for Safety. Amendment A1 (1993) Amendment A13 (1996) Amendment A2 (1995).

EN 60601-2-24 (2015), Medical Electrical Equipment, Part 2-24: particular Requirements for Safety of Infusion Pumps and Controllers.

IEC 60601-1 (2005 + A1:2012) Ed3.1, Medical Electrical Equipment, Part 1: General Requirements for Safety. Amendment 1 (1991) Amendment 2 (1995).

IEC 60601-2-24 (2012), 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).

ANSI/AAMI ES60601-1 (2005/(R2012) + A1:2012) Ed 3.1, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-1-8 (2012), Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

EN 60601-1-8 (2007 + AC:2010), Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

IEC 62304 (2015), Medical device software - Software life-cycle processes

EN 62304 (2006 + AC:2008), Medical device software - Software life-cycle processes

Electromagnetic Compatibility:

RTCA/DO -160G (2010), Radiated Emissions Only, Category M Limit.

EN 60601-1-2 (2015), Medical Electrical Equipment, Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.

IEC 60601-1-2 (2014), Medical Electrical Equipment, Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.

CISPR11 (2016), Limits and methods of measurement of electromagnetic disturbance characteristics of industrial, scientific and medical (ISM) radio frequency equipment. Amendment 1 (1999) Amendment 2 (2002).

Miscellaneous Standards

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

EU RoHS Directive 2011/65/EU, Restriction of Hazardous Substances in Electrical and Electronic Equipment

REACH Regulation (EC) No.1907/2006, Registration, Evaluation, and Authorization of Chemicals (REACH)

2012/19/EU, Waste Electrical and Electronic Equipment (WEEE)

Essential Performance

The CADD®-Solis pump has the following essential performance characteristics:

The pump delivery will be at the set rate within the declared limits of accuracy under nominal conditions or will provide an alarm.

The pump high priority alarms will remain operable.
The following pump protective systems will be operable or alarm:

- Pump Clock Self-Test
- Motor Safety Circuit Test
- Disposable Detection
- Air Detection
- Occlusion Detection
- Latch/Lock Sensors

Specifications (Nominal)

General Pump Specifications

System definition	CADD®-Solis pump with 1 of the following attached: • Medication cassette reservoir and CADD® extension set • Medication cassette reservoir with Flow Stop feature and CADD® extension set • CADD® administration set • CADD® administration set with Flow Stop feature
Classification	CF ♥ Class II □
Used to test the pump	• CADD™ medication cassette reservoirs, REF 21-7002 and REF 21-7309 • CADD® extension sets, REF 21-7047 and REF 21-7046 • CADD® administration sets, REF 21-7091 and REF 21-7321 • CADD® high volume administration sets, REF 21-7355 and REF 21-7357
Resolution	• CADD™ medication cassette reservoir: 0.05 mL per pump stroke nominal • CADD® administration set: 0.05 mL per pump stroke nominal • CADD® high volume administration set: 0.1 mL per pump stroke nominal
Size	Excluding cassette and accessories: 4.1 cm × 10.2 cm × 12.7 cm 1.6 in × 4 in × 5 in
Weight	Including 4 AA alkaline batteries, excluding other accessories: 595 g 21 oz
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
Maximum surface Temperature (pump, while operating)	48°C (118°F) Maximum
Moisture protection	Splashproof (IPX4) per IEC 60529
Relative humidity	20% to 90% relative humidity, non-condensing
Atmospheric pressure	70 kPa to 106 kPa 10.2 psi to 15.4 psi
Expected Service Life	5 years
Power sources	• AC adapter • CADD®-Solis rechargeable battery pack • CADD®-Solis Communication Module with integrated rechargeable battery • Four AA alkaline batteries (for example, Duracell® PC1500 / MN1500, IEC LR6)
Charging system for internal memory backup battery	The internal memory backup battery uses 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).
Battery fallout alarm	Alarm sounds for at least 2 minutes if the pump has been powered up for a minimum of 4 minutes. **Note:** Alarm enabled while pump is in run mode only.

<table>
<tr><td rowspan="4">Battery status</td><td>Battery State</td><td>CADD®-Solis Pump Status</td></tr>
<tr><td>25% to 100%</td><td>No alarm</td></tr>
<tr><td>Low battery</td><td>• Transition to low battery condition
• Battery low message appears
• Pump emits 3 beeps every 5 min
• Low battery warning message appears on pump display
• Pump is operable
• LCD backlight flashes for 12 ms during each motor operation</td></tr>
<tr><td>Depleted battery</td><td>• Transition to depleted battery condition
• Battery depleted message appears
• Pump emits a continuous, variable-tone alarm
• Depleted battery warning message appears on pump display
• Battery power is too low to operate pump
• Pump delivery operation stops</td></tr>
<tr><td>Shut down</td><td>Pump shuts off due to low operating voltage</td></tr>
</table>

Alkaline battery life with screen backlight intensity set to 3

These estimates are based on laboratory tests conducted at room temperature using new batteries (Duracell® PC1500 / MN1500, IEC LR6). Actual battery life varies depending on the battery brand, shelf life, temperature conditions, delivery rate, and frequency of screen display and backlighting. It is recommended that new batteries be kept available for replacement.

Continuous Delivery		
Delivery Rate (mL/hr)	**Operating Time (hr)**	**Volume Delivered (mL)**
0.4	142	56
1	139	139
5	124	620
10	113	1130
30	69	2070

Intermittent Bolus Delivery				
IB Volume (mL)	**IB Interval (min)**	**Maximum Delivery Rate (mL/hr)**	**Operating Time (hrs)**	**Volume Delivered (mL)**
5	30	40	90	900
10	30	250	104	2080
10	30	500	88	1760

<table>
<tr><td>Rechargeable battery pack life with screen backlight intensity set to 3</td><td>These estimates are based on laboratory tests conducted at room temperature using a new CADD®-Solis rechargeable battery pack. Actual battery life varies depending on the temperature conditions, delivery rate, and frequency of screen display and backlighting. It is recommended that new batteries be kept available for replacement.
<table>
<tr><th colspan="3">Continuous Delivery</th></tr>
<tr><th>Delivery Rate (mL/hr)</th><th>Operating Time (hr)</th><th>Volume Delivered (mL)</th></tr>
<tr><td>0.4</td><td>74</td><td>29</td></tr>
<tr><td>1</td><td>67</td><td>67</td></tr>
<tr><td>5</td><td>60</td><td>300</td></tr>
<tr><td>10</td><td>50</td><td>500</td></tr>
<tr><td>30</td><td>40</td><td>1200</td></tr>
</table>
<table>
<tr><th colspan="5">Intermittent Bolus Delivery</th></tr>
<tr><th>IB Volume (mL)</th><th>IB Interval (min)</th><th>Maximum Delivery Rate (mL/hr)</th><th>Operating Time (hrs)</th><th>Volume Delivered (mL)</th></tr>
<tr><td>5</td><td>30</td><td>40</td><td>71</td><td>710</td></tr>
<tr><td>10</td><td>30</td><td>250</td><td>60</td><td>1200</td></tr>
<tr><td>10</td><td>30</td><td>500</td><td>58</td><td>1160</td></tr>
</table></td></tr>
<tr><td>Pump alarms</td><td>• High priority alarms: Air in line detected, Battery depleted while delivering, Battery removed while delivering, Battery unusable while delivering, Disposable attached improperly, Disposable damaged, Disposable detached while delivering, Disposable locked but not latched, Disposable type high flow administration set not allowed, Disposable type high flow administration set required, Disposable type invalid, Downstream occlusion, Key stuck, Pressure sensor faulty, Pump automatically stopped, Rechargeable battery end of life, Remote dose cord key stuck, Reservoir volume empty, Stop mode reminder, Upstream occlusion, wireless communication module intermittent connection
• Medium priority alarms: 19
• Low priority alarms: 8
• Informational messages/alerts 23</td></tr>
<tr><td>Delivery rate during priming</td><td>• Standard volume cassette tubing: approx. 250 mL/hr
• High flow volume cassette tubing: approx 500 mL/hr</td></tr>
<tr><td>Alarm disabled during priming</td><td>Air-In Line</td></tr>
<tr><td>Maximum infusion pressure</td><td>1.86 bar
27.0 psi</td></tr>
<tr><td>High pressure alarm threshold</td><td>1.24 bar ± 0.62 bar
18 ± 9 psi</td></tr>
<tr><td>Air detector alarm</td><td>High Sensitivity: • Single bubble > 150 µL
• Accumulated air > 2mL over 15 minutes
Low Sensitivity: • Single bubble > 2mL (2000 µL)
• Accumulated air > 4mL over 15 minutes
Note: Bubbles smaller than 50 µL are not included in the accumulated air measurement. Statistical tolerance limits calculated at 95/99 level.</td></tr>
<tr><td>Maximum volume infused under single-fault conditions</td><td>• CADD® administration set: 0.15 mL
• CADD® high volume administration set: 0.30 mL</td></tr>
</table>

Maximum time to occlusion alarm

and

Maximum Bolus volume at occlusion alarm

The pressure build-up that occurs after an occlusion may cause fluid to accumulate or be stored in the line. This extra fluid may be delivered as a bolus when the occlusion is released. For corrective action, see the steps listed under "Downstream occlusion" in the *Alarms and Messages, Alphabetical List on page 58*.

Flow Rate (mL/hr)	Tubing Set	Max. Time to Occlusion Spec. (min)	Max. Bolus at Occlusion Spec. (mL)
0.1	CADD™ medication cassette reservoir REF 21-7002 with CADD® extension set REF 21-7047	≤ 160	≤ 0.25
	CADD® administration set REF 21-7091	≤ 190	≤ 0.30
	CADD® high volume administration set REF 21-7055	≤ 1200	≤ 1.40

Flow Rate (mL/hr)	Tubing Set	Max. Time to Occlusion Spec. (sec)	Max. Bolus at Occlusion Spec. (mL)
10	CADD™ medication cassette reservoir REF 21-7002 with CADD® extension set REF 21-7047	≤ 60	≤ 0.25
	CADD® administration set REF 21-7091	≤ 150	≤ 0.30
	CADD® high volume administration set REF 21-7055	≤ 580	≤ 1.40

System Delivery Accuracy	**± 6% at nominal (at 90/90 tolerance level).** At low infusion rates, stated accuracy may not be achieved for short periods. During the total infusion time, the accuracy averages out. System delivery accuracy is determined under the following nominal conditions: • Infusion rate of 10mL/hr • Ambient temperature of 22 degree C • Fluid viscosity of 0.89 cP (i.e., water) • 0.2 mmHg (0.004 PSI) back pressure (i.e., 2 inch 18Ga needle) • Pump and Reservoir both placed at the same height as the infusion site • CADD Administration Set with Flow Stop Free Flow Protection (i.e., 21-7322-24) Accuracy testing was performed using 22 CADD®-Solis Ambulatory Infusion Pumps and 22 CADD® Administration Sets with Flow Stop Free Flow Protection. All accuracy is stated for a 90/90 tolerance level. **Intermediate Rate** Accuracy testing methods defined in industry standard IEC 60601-2-24 is performed using an `intermediate rate' representative of typical rates for various therapies. The intermediate rate of 10 mL/hr is representative for use with standard volume administration sets. **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 beyond ± 6% may occur as a result of back pressure or fluid resistance, which depends upon temperature, drug viscosity, catheter size, extension set tubing (for example, microbore), in-line components (such as filters and needleless access connectors), 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 patient injury or death.**

Alternate System Configurations at Nominal Conditions	**System Delivery Accuracy**
Flow Stop administration set with air eliminating filter (0.2 µm and 1.2 µm)	-8% to 8%
Non-Flow Stop administration set	-9% to 2%
All 50/100 mL medication cassette reservoirs with 21-7046-24 extension set	-9% to 11%
All 250 ml medication cassette reservoirs with 21-7046-24 extension set	-13% to 8%

Patient Selection
It is important to consider patient selection with regard to clinical factors and environmental factors. These factors can include the route of administration, the prescribed medication, and the system configuration chosen to ensure acceptable delivery accuracy is appropriate for your patient.

Consideration of Continuous Flow at Low Rates
Delivery accuracy is not tested below 10 mL/hr. When intending to deliver therapies that require a low continuous flow rate, consider using another type of infusion pump, such as a syringe pump.

Challenge Conditions
The adjusted flow rate accuracy for non-nominal environmental conditions when using a CADD® Administration Set with Flow Stop Free Flow Protection is summarized below as determined per testing methods defined in industry standard IEC 60601-2-24.

Challenge Conditions	*System Delivery Accuracy*
Pump & reservoir height approximately four feet below the infusion site (backpressure increase of 100mmHg)	-10% to 5%
Backpressure increase of 300mmHg	-17% to -7%
Pump & reservoir height approximately four feet above the infusion site (backpressure decrease of 100mmHg)	-6% to 11%
Reservoir height 0.3 m below pump & infusion site	-12% to 7%
Temperature at 2°C, 20% RH	-12% to -1%
Temperature at 40°C, 90% RH	-10% to 10%
21 Gauge Epidural Catheter	-20% to -1%

Bolus accuracy specification: ± 6%

Tested with CADD® administration set with Flow Stop free flow protection

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 50 mL:	
Average	50.77 mL
% Error	1.55%
Minimum Error %	–0.07%
Maximum Error %	2.35%
Challenge test conditions (min and max % error from set value):	
0.05 mL at 2°C, 20% RH	-14% to -1%
0.05 mL at 40°C, 90% RH	-1% to 12%
50 mL at 2°C, 20% RH	-16% to -7%
50 mL at 40°C, 90% RH	-8% to 2%

Delivery Specifications

Programming units	• Milliliters (mL) • Milligrams (mg) • Micrograms (mcg)
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 • 100 to 500 mcg/mL in increments of 100 mcg/mL
Reservoir volume	0 to 9999 Programmable in 1 mL increments. Displayed in 0.1 mL increments.
Given	0 to 99,999.99 in 0.01 unit increments
Delivery limit amount	0.1 to 1,900 mL (or the mg or mcg equivalent) in increments of: • 0.01 mL from 0.1 to 0.5 mL • 0.1 mL from 0.5 to 100 mL • 1 mL from 100 to 1,000 mL • 10 mL from 1,000 to 1,900 mL
Continuous rate	0 to 100 mL/hr (or the mg or mcg equivalent)
Clinician bolus	• 0 mL to 50 mL (or mg or mcg equivalent) • Delivery rate: 40 mL/hr to the maximum delivery rate in 1 mL increments.
PCA dose	0 mL to 50 mL (or the mg or mcg equivalent) Delivery rate: 40 mL/hr to the maximum delivery rate in 1 mL increments.
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
Intermittent bolus	0 mL to 50 mL (or the mg or mcg equivalent) Delivery rate: 40 mL/hr to the maximum delivery rate in 1 mL increments.
Intermittent bolus interval	0 to 4 hours
Next bolus	0 to 4 hours
Maximum doses per hour	1 to 60

CADD™ Ambulatory Tubing Set Testing	
One representative medication for each of the following routes of delivery was tested for drug interaction with pump disposables. Use any selected drug in accordance with the indications included in the drug package insert. Administration of any drug by the CADD®-Solis ambulatory infusion pump is limited by any warnings, precautions, or contraindications in the drug labeling.	
Route of Delivery	**Drug Tested**
Intravenous, subarachnoid space (intrathecal)	Morphine Sulfate Injection
Intra-arterial	Floxuridine for Injection, USP
Intraperitoneal	Dianeal with dextrose
Epidural space, local infiltration(subcutaneous, perineural, surgical site)	Ropivacaine HCl Injection

Administrator Settings Specifications

KVO rate	• 0 mL/hr if continuous rate is 0 mL/hr • 0.1 mL/hr if continuous rate > 0 mL/hr, with standard administration set • 0.2 mL/hr if continuous rate > 0 mL/hr, with high volume administration set
Bolus interval type	• Bolus interval • PCA lockout
Maximum delivery rate (PCA dose, clinician bolus, intermittent bolus)	• With standard administration set: 250 mL/hr • With high volume administration set: 500 mL/hr • Max. delivery rate = continuous rate + bolus rate (PCA dose *or* clinician bolus *or* intermittent bolus) • Boluses may not be delivered simultaneously
Delivery limit method	• Delivery limit • Max doses per hour • Not in use
Delivery limit period	1 to 12 hours in increments of 1 hour
Pump stopped alarm	• Informational • High priority
Res vol low trip point	1 to 999 mL in increments of 1 mL
Res vol empty alarm	• Insistent and one time only • Non-insistent and repeating
Air detector	• On • Off
Air detector sensitivity	• High • Low
Upstream occlusion sensor	• On • Off **Note:** The upstream occlusion sensor is automatically disabled during use with medication cassette reservoirs.
Downstream occlusion sensitivity	**High Sensitivity:** When the high pressure alarm threshold is reached, the downstream occlusion alarm is triggered immediately. **Low Sensitivity:** When the high pressure alarm threshold is reached, the downstream occlusion alarm is delayed for 2 seconds. This allows for the pressure to stabilize before a possible alarm. If the pressure stabilizes below the high pressure alarm threshold before the 2 second delay is complete, the alarm will not occur.
PM 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 admin. code	001 to 899 in increments of 1
Time format	• 00:00 to 23:59 military • 12-hour AM/PM
Date format	• US standard (month/day/year) • European standard (day/month/year) • International standard ISO 8601:2004 (year/month/day)
Alarm volume	• High • Medium • Low
Key beep	• On • Off

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: 100–240 VAC 50/60 Hz to 7 VDC switching AC adapter, with an AC power cord length of 1.8 m (6 ft); rechargeable battery pack; remote dose cord with a length of 152 cm ± 5 cm (60 in ± 2 in); and a USB cable length of less than 2 m (6.5 ft).

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, you should verify normal operation of the pump in the configuration in which it is to be used.**
- **Common portable and mobile consumer electronic devices may cause interference with the pump. Observe the pump to verify normal operation.**
- **Facility wiring must comply with all applicable electrical codes. Do not bypass power cord connections. Do not remove a prong from the power cord. Failure to comply may result in fire or electrical shock.**

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]	10 Vrms	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 $d = 2.3\sqrt{P}$ 800 MHz 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).[c] 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 output 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 80 MHz 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*
Intermittent Bolus*
Bolus Interval*
Next Bolus*
PCA† Dose*
PCA† Lockout*
Hourly Limit*
Max Doses / Hour*
Reservoir Vol.

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
Turn Wireless On/Off
Adjust Admin Settings

Reports
Intermittent Bolus Status
Given and PCA† Dose Counters
PCA† Dose Graph
Intermittent Bolus Graph
PCEA† and Intermittent Graph
Delivery History and Pie Chart
Current Profile / Protocol
Delivery Log
Event Log
Daylight Saving Time
Protocol Library Summary
Wireless Status**
Wireless Settings**
Device Information

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

* If configured in the PharmGuard® system administrator settings to appear.

** Available when a CADD®-Solis Communication Module is installed.

† The PharmGuard® Medication Safety Software administrator may configure a therapy to display either "PCA" or "PCEA".

‡ 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 is set to the factory default. You may reset the pump to the factory default at any time. Refer to the Administrator Settings Guide for more information on how to reset the pump to the factory default. The factory default is a manual mode programming, see page 51.

The following chart details the factory default parameters:

Parameter	Default Factory Setting
Programming Units	mL
Continuous Rate On/Off	Off
Continuous Rate	0 mL/hr
PCA Dose On/Off	Off
PCA Dose	0 mL
PCA Lockout	1 hour
Intermittent Bolus On/Off	Off
Max Delivery Rate	175 mL/hr (combined bolus + continuous)
Delivery Limit Method	Not in Use
Reservoir Volume	1 mL
Reservoir Reset Volume	100 mL
Clinician Bolus	0 mL
Pump Stopped Alarm Type	Informational
Reservoir Low Trip Point	5.0 mL
Reservoir Low Alarm Type	Insistent and One Time Only
Air Detector On/Off	On
Air Detector Sensitivity	Low
Upstream Sensor On/Off	On
Downsteam Sensor Sensitivity	Low
PM Reminder	Off
Reservoir Empty Alarm Type	One Time Only
Keypad Code	201
Clinician Code	997
Admin Code	See your PharmGuard® system administrator
Manual Programming Security	Admin Code
Keypad Security	Code only
Time Format	24:00:00
Date Format	Month/Day/Year
Backlight Intensity	3
Alarm Volume	High
Sound Theme	Standard
Key Beep On/Off	On
Numeric Format	1,234.56
Color Theme	Black (manual mode programming)

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:

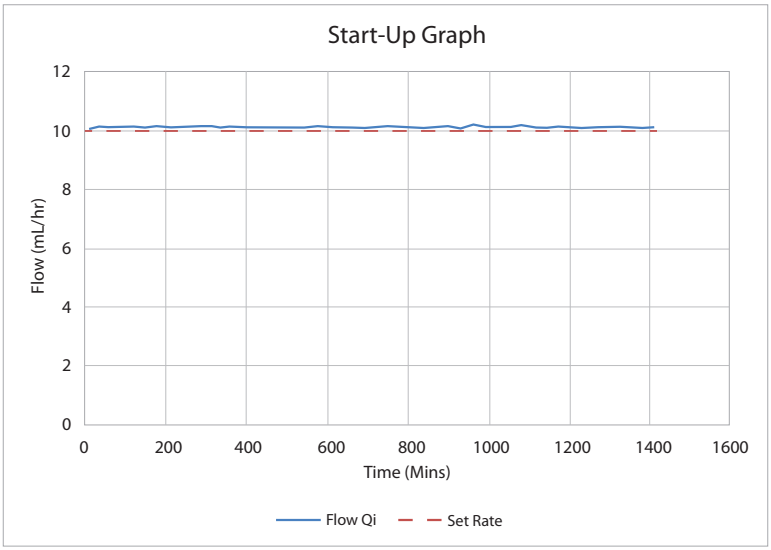
1. A flow versus time graph during the stabilization period (start-up curves).
2. The accuracy of fluid delivery of particular time periods or 'observation windows' is measured (trumpet curves).

The start-up curve displays flow rate continuously from the start of the infusion. The curve visually represents flow rate uniformity. The trumpet curve is derived from the last hour of this data. Tests performed per IEC 60601-2-24 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.

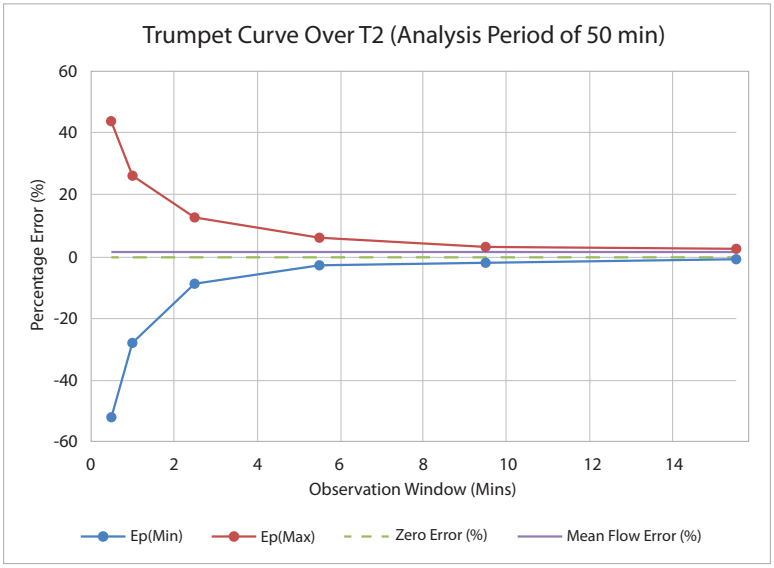
Start-up curves over the stabilization period T(1)

Flow rate (10 mL/hr) CADD® administration set with Flow Stop



Trumpet curves over the analysis period T(2)

Flow rate (10 mL/hr) CADD® administration set with Flow Stop



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