

CADD™

CADD®-Solis
Ambulatory Infusion Pump

 **Technical
Manual**
Model 2100

smiths medical

For detailed instructions, specifications, warnings, warranties, and additional information on operating the CADD®-Solis ambulatory infusion pump, please refer to the manuals supplied with the product. If you have additional comments or questions concerning the operations of the CADD®-Solis pump, please call: **1 800.426.2448** (USA) or **+1 651.633.2556**. Our staff is available to help you 24 hours a day with the programming and operation of the CADD®-Solis ambulatory infusion pump.

The issue date of this Technical Manual is included for the user's information. In the event one year has elapsed between the issue date and product use, the user should contact Smiths Medical MD, Inc. to see if a later revision of this manual is available.

The issue date can be found on the rear cover of this technical manual.

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Introduction

The technical manual is intended to provide a basic, but limited, understanding of the mechanical and electrical operation of the CADD®-Solis ambulatory infusion pump to persons familiar with this device. The CADD®-Solis Operator's Manual and CADD®-Solis Administrator's Manual should be used in conjunction with this publication for complete information.

This manual also outlines cleaning and functional testing procedures that can be performed on the CADD®-Solis ambulatory infusion pump.

This technical manual is applicable to the CADD®-Solis ambulatory infusion pump only.

IMPORTANT NOTICE:

CADD®-Solis ambulatory infusion pump operations and safety features are based on a microcomputer design. Inadequate servicing or tampering with the safety features of the pump may seriously affect performance and safety.

For that reason, ALL SERVICING AND REPAIR OF THE CADD®-Solis AMBULATORY INFUSION PUMP MUST BE PERFORMED BY SMITHS MEDICAL MD, INC. OR ITS AUTHORIZED AGENTS.

The manufacturer's warranty agreement shall become null and void if the pump is not used in accordance with the Operator's Manual and Instructions for Use for the pump accessories; or, the pump is serviced by persons other than Smiths Medical or those authorized by Smiths Medical.

Limited Warranty

The limited warranty associated with the CADD®-Solis ambulatory infusion pump can be found in the product literature supplied with the product when originally purchased, which is incorporated herein by reference. SMITHS MEDICAL SPECIFICALLY DISCLAIMS ANY OTHER WARRANTY, WHETHER EXPRESS, IMPLIED OR STATUTORY, INCLUDING, WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR USE. Smiths Medical further disclaims responsibility for the suitability of the system for a particular medical treatment or for any medical complications resulting from the use of the system.

The manufacturer shall not be responsible for any incidental damages or consequential damages to property, loss of profits, or loss of use caused by any defect or malfunction of the system.

If you wish to receive additional information about the extent of the warranty on these products, please contact your Smiths Medical representative or call Customer Service at 1 800.426.2448 (USA) or +1 651.633.2556

All recommendations, information, and literature supplied by Smiths Medical with respect to the CADD® product line are believed to be accurate and reliable, but do not constitute warranties. No agent, representative, or employee of Smiths Medical has authority to bind Smiths Medical to any representation or warranty, expressed or implied.

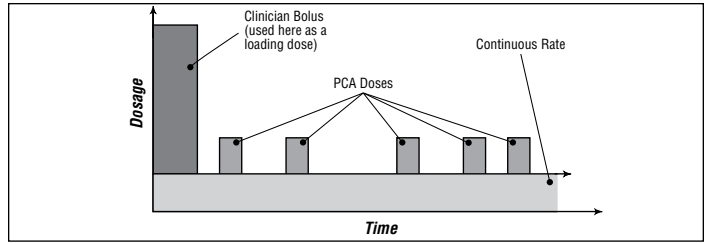
CAUTIONS:

- **The pump SHOULD NOT BE DIRECTLY IRRADIATED by therapeutic levels of ionizing radiation because of the risk of permanent damage to the pump's electronic circuitry. The best procedure to follow is to remove the pump from the patient during therapeutic radiation sessions or diagnostic levels of radiographic and fluoroscopic radiation. If the pump must remain in the vicinity during a diagnostic or therapy session, it should be shielded, and its ability to function properly should be confirmed following treatment.**
 - **Magnetic fields produced by magnetic resonance imaging (MRI) equipment may adversely affect the operation of the pump. Remove the pump from the patient during MRI procedures and keep it at a safe distance from magnetic energy.**
-

CADD®-Solis Pump Overview

Delivery Modes

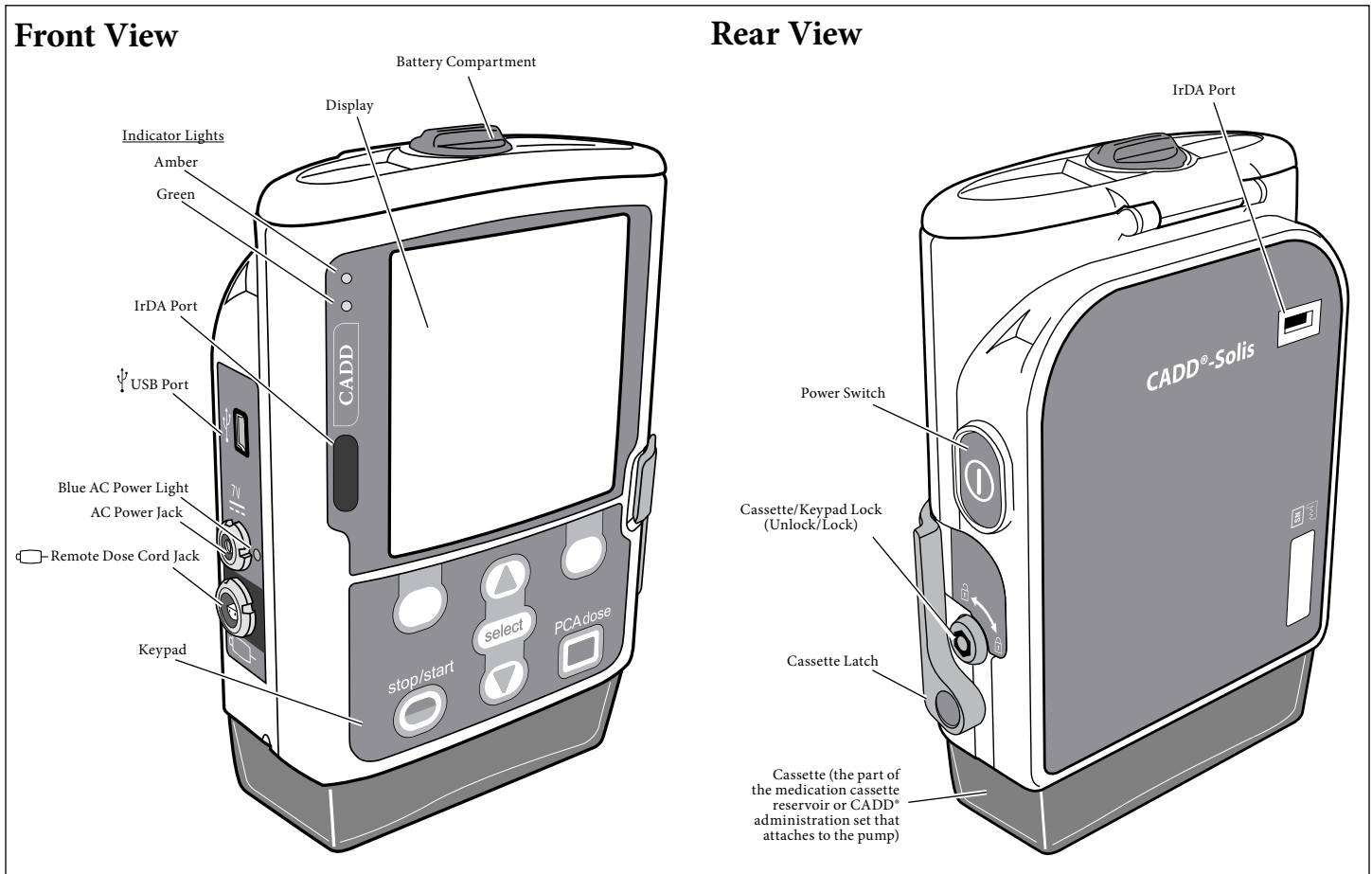
The CADD®-Solis ambulatory infusion pump system provides measured drug therapy to patients in hospital or outpatient settings. The CADD®-Solis ambulatory infusion pump is indicated for intravenous, intra-arterial, subcutaneous, intraperitoneal, in close proximity to nerves, into an intraoperative site (soft tissue, body cavity/surgical wound site), epidural space, or subarachnoid space infusion. Epidural administration is limited to short-term infusion of anesthetics and either long- or short-term infusion of analgesics. Subarachnoid administration is limited to short-term infusion of analgesics.



PCA mode delivery profile.

PCA Delivery Profile

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



Front and back views of the CADD®-Solis ambulatory infusion pump.

PCA Delivery Mode, Continuous Rate Scroll Ranges

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

PCA Delivery Mode, PCA Dose, Clinician Bolus Scroll Ranges: Milliliters

Milliliters	
increment	max
0.05	20

PCA Delivery Mode, PCA Dose, Clinician Bolus Scroll Ranges: Milligrams

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

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

PCA Delivery Mode, PCA Dose, Clinician Bolus Scroll Ranges: Micrograms

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

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

Specifications

General Pump Specifications

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

Resolution

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

Size

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

Weight

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

Pump Alarms



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

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

Battery Fallout Alarm

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

Classification

CF , Class II .

Moisture Protection

Splashproof (IPX4) per IEC 60529.

Maximum Infusion Pressure

27.0 psi [1.86 bar].

Maximum Time to Occlusion Alarm

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

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

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

Bolus Volume at Occlusion Alarm

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

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

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

Power Sources

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

Charging System for Internal Memory Backup Battery

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

System Operating Temperature

2°C to 40°C (36°F to 104°F).

System Storage and Transportation Temperature

-20°C to 60°C (-4°F to 140°F).

Relative Humidity

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

Atmospheric Pressure

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

System Delivery Accuracy

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

WARNING:

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

System Definition

CADD®-Solis pump with:

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

High Pressure Alarm Threshold

18 ± 9 psi [1.24 ± 0.62 bar].

Air Detector Alarm

Sensitivity:

Low - Single bubble greater than 400 μ L.

High - Single bubble greater than 150 μ L.

Accumulated Air: Greater than 1 mL air over 15 minutes (nominal).

Bolus Accuracy Specification $\pm 6\%$

Actual Test Data for Bolus Accuracy at 0.05 mL:

Average	0.0489 mL
% Error	- 2.15%
Minimum Error %	- 5.63%
Maximum Error %	1.2%

Actual Test Data for Bolus Accuracy at 20 mL:

Average	19.6 mL
% Error	- 2.01%
Minimum Error %	- 4.72%
Maximum Error %	.04%

Maximum Volume Infused Under Single-Fault Conditions

CADD® administration set: 0.15 mL.

Delivery Rate during priming

Approx. 250 mL/hr.

Alarm disabled during priming

Air-In Line.

Delivery Specifications**Reservoir Volume**

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

Programming Units

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

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

Concentration

mg/mL:

0.1 to 0.5 mg/mL in increments of 0.1 mg/mL.

0.5 to 1 mg/mL in increments of 0.5 mg/mL.

1 to 15 mg/mL in increments of 1 mg/mL.

15 to 100 mg/mL in increments of 5 mg/mL.

mcg/mL:

1 to 15 mcg/mL in increments of 1 mcg/mL.

15 to 100 mcg/mL in increments of 5 mcg/mL.

100 to 500 mcg/mL in increments of 100 mcg/mL.

Continuous Rate

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

PCA Dose

0 mL to 20 mL (or the mg or mcg equivalent).

Delivery rate (continuous rate + PCA dose): programmable from 40 to 175 mL/hr.

PCA Dose Lockout

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

Max Doses per Hour

1 to 60.

Delivery Limit Amount

0.1 to 1000 mL (or the mg or mcg equivalent) in increments of:

0.01 mL from 0.01 to 0.5 mL.

0.5 mL from 0.5 to 100 mL.

1 mL from 100 to 1,000 mL.

Given

0 to 99,999.99 in 0.01 unit increments.

Clinician Bolus

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

Air Detector Sensitivity

Low Sensitivity - Single bubble greater than 400 uL .

High Sensitivity - Single bubble greater than 150 uL .

Alarm Volume

High, medium, or low.

PM (Preventative Maintenance) Reminder

Interval: 1 to 24 months in 1 month increments.

Enable: On or off.

Custom Keypad Code

001 to 899 in increments of 1.

Custom Clinician Code

001 to 899 in increments of 1.

Custom Administrator Code

001 to 899 in increments of 1.

Date Format

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

Time

00:00 to 23:59.

Downstream Occlusion Sensitivity

High Sensitivity - once the high pressure alarm threshold is reached, the downstream occlusion alarm is triggered immediately.

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

Upstream Occlusion Sensor

On or off.

NOTE: The upstream occlusion sensor is automatically disabled during use with medication cassette reservoirs.

Administrator Settings Specifications

Delivery Limit Method

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

Delivery Limit Period

1 to 12 hours in increments of 1 hour.

Maximum Delivery Rate (combined bolus and continuous)

40 to 175 mL/hr in increments of 1 mL.

Key Beeps

On or off.

Res Vol Low Trip Point

1 to 999 mL in increments of 1 mL.

Res Vol Empty Alarm

Insistent and one time only or non-insistent and repeating.

Pump Stopped Alarm

Informational or high priority.

Air Detector

Turned on or turned off.

Compatible Reservoirs and Administration Sets

- 50-mL or 100-mL medication cassette reservoir, used with the CADD® extension set with anti-siphon valve.
- CADD® administration set with integral anti-siphon valve, with or without bag spike (allows use of flexible plastic bag or sterile vial with injector).
- CADD® administration set with add-on anti-siphon valve and bag spike (allows for gravity priming before attaching the add-on anti-siphon valve).
- CADD® administration set with flow-stop feature, with or without bag spike (allows use of flexible plastic bag or sterile vial with injector).

Remote Dose Cord

Smiths Medical provides a remote dose cord for use by the patient. The push button is a single pole double throw switch (SPDT). When the remote dose cord is attached to the pump, the patient may press the remote dose button to receive a PCA dose. For easy access, the remote dose cord may be fastened to the patient's clothing or bedsheet with the attached clip.

NOTE: To detach the remote dose cord from the pump, grasp the remote dose cord connector and pull back using a straight, steady motion.

CAUTION: Do not twist or turn the connector, or use any instrument to remove it.

For additional specifications refer to the instructions for use provided with the product.

Batteries

Battery Compatibility

Recommended Batteries

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

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

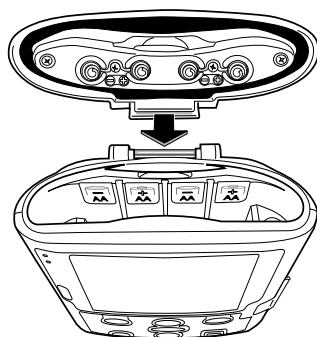
Battery Life

The CADD®-Solis pump has been designed to provide optimal battery life. The expected battery life in the CADD®-Solis pump depends on the following factors:

- Programmed delivery rate.
- Operating temperatures.
- Frequency of use and intensity of display backlighting.
- Duration of using the USB connector.
- Battery type and brand.
- Battery age.

Replacing the battery door

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



Battery Life

The following tables may be used to predict typical alkaline battery and CADD®-Solis rechargeable battery pack life at different delivery rates when used in the CADD®-Solis pump. As expected, battery life decreases as the delivery rate increases. These tables are based on laboratory tests using fresh DURACELL® alkaline batteries and CADD®-Solis rechargeable battery packs in CADD®-Solis pumps while the pumps were operating at room temperature.

Actual battery life may be significantly shorter depending on the operating temperature and the storage conditions of the battery.

Battery life is shortened significantly at very low operating temperatures.

Continuous Delivery Alkaline Battery Life with screen intensity set to 3

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

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

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

Alkaline Batteries

Alkaline batteries should not be stored in a refrigerator. After four years of storage at 21°C (70°F), an alkaline battery retains approximately 86% of its original capacity. Battery life will be shorter if the battery is stored above room temperature. An alkaline battery stored at 43°C (110°F) will discharge down to approximately 80% of its capacity within one year.

Recommended storage conditions are 10°C to 24°C (50°F to 75°F) with no more than 65% relative humidity non-condensing.

The following tables are based on laboratory tests conducted at room temperature using fresh DURACELL® alkaline batteries and a CADD® administration set. Actual battery life will vary depending on the brand of battery, battery shelf life, and temperature conditions.

CADD®-Solis Rechargeable Battery Pack

The Smiths Medical rechargeable battery pack should not be stored in a refrigerator. Recommended storage conditions are 19°C to 25°C (66°F to 77°F).

The battery pack is made up of a lithium-ion cell. When fully charged, its capacity is 1400 mAh.

Each battery pack can sustain a minimum of 500 charge/discharge cycles. Within the operating temperature range [2°C to 40°C (36°F to 104°F)], the battery pack will become fully charged in 4 hours or less.

The battery pack can be recharged using the CADD®-Solis desktop AC adapter. It can be plugged directly into the AC adapter or it will recharge in the CADD®-Solis pump with an AC adapter attached. See the battery pack's instructions for use for more information.

Construction

The pump's housing is made of special high impact plastic, with an internal metallized coating designed to reduce interference from electromagnetic fields and to dissipate electrostatic discharge. It is composed of three sections: the base, cover, and battery housing. The pump housing is sealed to ensure that the pump is water resistant.

NOTE: The CADD®-Solis pump is water resistant (IPX4), but not waterproof.

The battery compartment is accessed through a hinged door on the top of the pump housing. Within the battery compartment is space for 4 AA batteries or the rechargeable battery pack.

The medication cassette reservoir or the administration set is attached to the bottom of the pump by inserting the two hooks on the cassette into the mating hinge pins on the pump. The pump and the cassette can be latched in place by first rotating the latching lever to the furthest downward position. With the latching lever in this position, the cassette will slide smoothly into place when pushed up into the pump. The latching lever can then be rotated back up to its latched position. The cassette is locked into place by inserting a key into the pump's lock and turning the lock into the locked position.

NOTE: The cassette/keypad lock must be unlocked before attempting to unlatch the disposable.

NOTE: The medication cassette reservoir and the administration set are intended for single use only.

The keypad, located on the front housing, is composed of seven membrane switches and is sealed against moisture. All of the keys contain domes to provide a tactile feel when the key is pressed. The keypad keys are sensed by the pump's microprocessor. The top left and top right keys are "soft keys," meaning that they operate based on the messages that are displayed on the screen directly above them.

The liquid crystal display (LCD), also located on the front housing, shows the pump status and programmed settings. The content of the multi-color display is determined by the pump's microprocessor according to status conditions and keypad entries.

The microprocessors and other circuitry which control the pump are located on the printed circuit board.

The board contains three microprocessors and their associated circuitry, motor driver circuitry, and other miscellaneous circuitry. The LCD module contains the liquid crystal display with its associated circuitry, and the backlight module.

The pumping mechanism subassembly contains the motor, gear train, camshaft, valves, expulsor, sensing disk, infrared light source, infrared detector, occlusion sensor, air detector sensor, cassette sensors, lock and latch sensors. The pump's microprocessor controls motor rotation.

Five external ports are utilized for communication and external power input. One of these connectors, the remote dose cord jack, is used for attachment of the remote dose cord. This enables the patient to use the remote dose cord to begin a PCA dose.

The second port is for AC power connection. This port, the AC power jack, can receive input from the AC adapter.

The third port is a USB port. This port can communicate with the CADD®-Solis Medication Safety Software. This jack uses a standard mini-B USB cable to attach to a PC.

The fourth and fifth ports are IrDA ports, designed for future use with the pump.

The keypad is connected to the microprocessor board via a flex circuit tail. Flexible circuitry and discrete wires connect the pumping mechanism, motor, and sensors to the printed circuit boards.

Pumping Operation

Battery Backed RAM

The pump's delivery and record keeping parameters are stored in a battery backed random access memory (RAM). Battery backup is provided by a lithium manganese dioxide rechargeable battery. This battery is designed to provide a minimum of 10 months of back-up power to the memory when the pump is turned off. It takes a maximum of 250 hours with the pump turned on to fully charge a completely discharged back-up battery.

NOTE: This battery charges during normal operational use and does not require 250 hours of charging before use.

The internal rechargeable battery is designed to last for 10 years and provide a minimum of 10 full charge and discharge cycles. The shallower the battery discharge is, the longer the battery will last.

LCD Circuitry

The LCD circuit contains a power supply which provides bias voltage to the LCD panel. The microprocessor disables the LCD drive circuitry when not in use in order to conserve battery power.

An LED backlight is necessary to enable LCD viewing. When the microprocessor enables the LCD, it also enables the LED backlight. A low brightness setting can be used to conserve battery power. Raising the brightness setting of the display will make the display more vibrant at the cost of decreasing pump battery life.

The backlight is shut off by the microprocessor when the LCD is turned off.

LCD backlight will flash for 12 mS during each motor operation.

LED Status Indicators

An amber and a green light emitting diode (LED) are provided on the pump's front panel to provide pump status to the user. Under software control, the LEDs can either flash at a low duty cycle or be on continu-

ously. A flashing indicator typically indicates a normal mode of operation and a steady "on" indicator typically indicates a fault condition.

Audible Alarm Circuitry

The audible alarm circuitry is backed up by a capacitor. The capacitor provides energy for the alarm in the instance where all power is lost while the pump is in the RUN mode. There is enough energy in the capacitor to drive the audible alarm for 2 minutes after the pump has been powered up for 2 minutes or longer.

Power Circuitry

Power for the pump is normally supplied by four AA alkaline batteries, the rechargeable battery pack, or the AC adapter. Alkaline AA batteries have a fairly low internal resistance over their discharge range, which will keep power supply noise low. Other types of batteries, such as carbon-zinc, exhibit high internal resistance, especially near depletion. A voltage drop across the internal resistance occurs when current is drawn by the motor during pump activations. This current is demanded in short pulses when the motor is first turned on and generates large spikes in the battery voltage. This noise can cause the low battery detection circuit to shut down the pump.

Battery Status

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

CADD®-Solis pump low battery conditions.

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

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

Pumping Mechanism

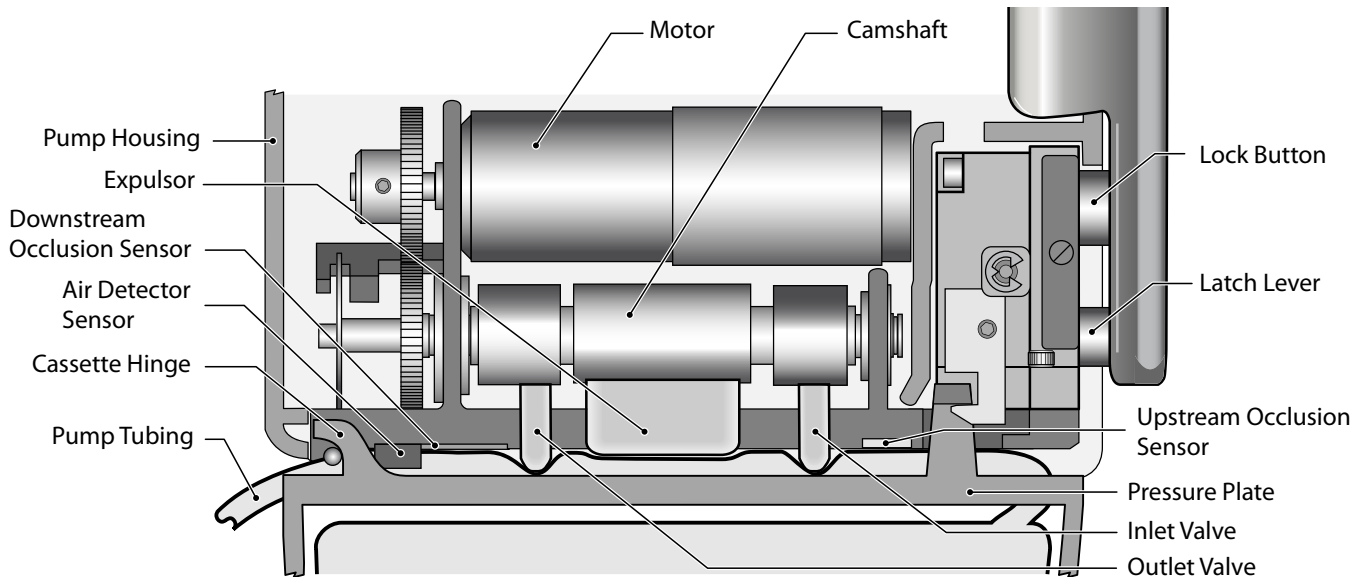
The pumping mechanism is linear peristaltic with two active valves. Pumping occurs when the expulsor presses on the reservoir tubing in sequence with the inlet and outlet valves. At rest, the outlet valve is pressing down fully on the tubing and the expulsor

and inlet valve are retracted. (See figure.)

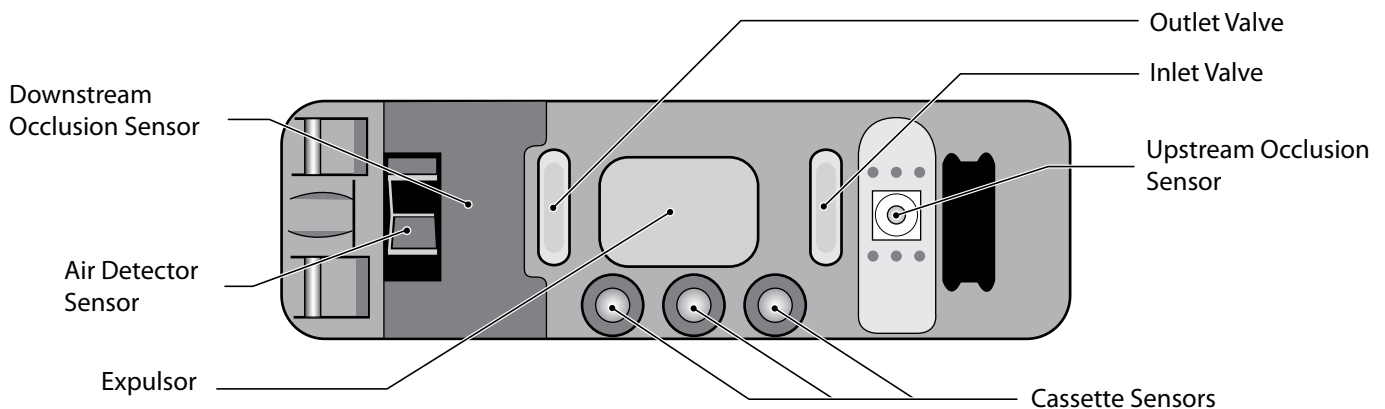
When the microprocessor commands the mechanism to pump, the camshaft begins to rotate, thus controlling the following pump cycle:

1. The inlet valve closes.
2. In synchrony with the expulsor moving down to compress the tubing, the outlet valve opens, expelling fluid.
3. The outlet valve closes.
4. The inlet valve opens as the expulsor is retracted,

A simulated pumping mechanism in a CADD®-Solis pump:



Bottom view:



causing fluid from the reservoir to again fill the pump tubing segment.

5. The camshaft rotation stops after half a revolution and the cycle is completed.

Pumping Characteristics

If the fluid path to the patient becomes blocked, the pump tubing will expand as pumping occurs. When there has been an amount of inflation corresponding to 18 ± 9 psi (1.24 ± 0.62 bar), the downstream occlusion analog sensor trips, whereupon the microprocessor stops the pump mechanism and issues visual and audible alarms. Thus the maximum pressure which can be developed is 27 psi (1.86 bar).

To deliver the amount of drug specified by the parameter settings, the pump's microprocessor causes the pump mechanism to deliver 0.05 mL fluid "pulses" timed according to the desired rate. At rates higher than 15 mL/hr, 2 pulses in succession will be given. Thus, to deliver 20 mL/hr, for example, the microprocessor solves these equations:

Mechanism activations per hr

$$= 20 \text{ mL per hr} / 0.1 \text{ mL per activation}$$

$$= 20 / 0.1$$

$$= 200 \text{ activations per hr}$$

Time (seconds) between activations

$$= 3600 \text{ sec per hr} / \text{number of activations per hr}$$

$$= 3600 / 200$$

$$= 18 \text{ seconds between activation}$$

	Rate (mL/hr)	Volume Resolution (mL)
Cassette or Admin Set	0 - 15 15.1 - 30	0.050 0.100

The microprocessor uses its timer circuits to accurately time the 18 seconds (in this example) between mechanism activations.

Cassette 'Type' Sensor Circuit

The cassette 'Type' sensor system consists of three pins protruding from the bottom of the pump mechanism that interface to the attached administration set and associated circuitry. Each type of administration set designed to work with the CADD®-Solis pump contains a unique 'code' programmed into the set via features molded into the plastic. When a set is latched to the pump, the features press against the pins in the pump mechanism in a pattern unique to that set type.

Latch/Lock Sensor Circuit

Latch and Lock sensors allow the microprocessor to detect the positions of the latch lever and lock button. This prevents attempted fluid delivery when the set is not correctly latched to the pump. In addition, it allows the microprocessor to stop fluid delivery and enable audible and visual alarms if the set is unlatched during fluid delivery.

Hardware and Software Fault Detection

Overview

The CADD®-Solis pump performs self-tests on its hardware and software systems. If a system fault code is displayed, one of the self-tests has failed and there may be something wrong with the pump.

System Fault Alarm

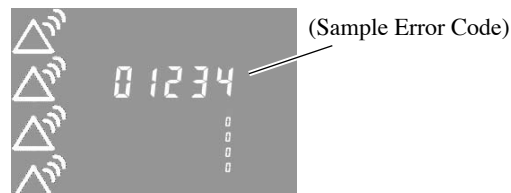
If this screen appears, an unrecoverable error may have occurred, such as a hardware or software fault. The amber indicator light will be continuously illuminated during these conditions and is accompanied by an audible two-tone alarm. If a system fault occurs, the fault should be reported to Customer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

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.

Order of System Fault Alarm Events

1. There is a continuous two-tone audible alarm, the amber LED indicator light will be on continuously, and the display will look like this:



- Record the 5-digit system fault error code for purposes of reporting to Smiths Customer Service.
2. To silence/clear the system fault alarm, open the battery door to remove power. If necessary, remove the AC power.
3. Once the system fault alarm has been silenced/cleared, a record of the system fault error code will still exist. It can be referenced from two places within the pump screens. From the device information report screen, the 5-digit system fault code can be found under the heading, "Last Error Code." It can also be found on the event log report screen under an entry with the heading, "System Fault." The entry in the event log report will remain in memory, and will appear on the event log record until 5,000 new log entries have occurred.

NOTE: Review your facility's procedure for handling error codes.

Cleaning Procedures

Cleaning Solutions

Use only the following solutions to clean the pump and accessories, unless otherwise specified:

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

Cleaning the Pump and Accessories

CAUTION:

- Do not immerse the pump in cleaning fluid or water. Do not allow solution to soak in to the pump, accumulate on the keypad, or enter the battery compartment, USB port, Remote Dose Cord jack, or power jack areas. Moisture buildup inside the pump may damage the pump.
- Do not clean the pump with acetone, other plastic solvents, or abrasive cleaners, as damage to the pump may occur.

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

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

2. Allow the pump to dry completely before use.

Annual Inspection and Testing Procedures

Inspection Recommendation

Smiths Medical recommends annual functional inspection on the CADD®-Solis pump. The following inspection and testing procedures should be performed annually to verify function and accuracy.

NOTE: Persons performing the following tests and procedures should be familiar with the CADD®-Solis pump. Please read the Operator's Manual supplied with the pump before proceeding.

NOTE: Testing procedures should be done through the manual mode.

NOTE: Many of the following tests include steps to unlock the keypad. This step will only be necessary if the keypad is not already unlocked.

CAUTION: CADD® pumps are sealed units. A broken or damaged seal will be considered conclusive evidence that the pump has been misused or altered, and will void all warranties. All service and repair of CADD® pumps must be performed by Smiths Medical MD, Inc. or its authorized agents.

Visual Inspection

- Visually inspect the pump for any damage to the LCD, occlusion sensor seals, valves and expulsor, cassette hinge area, latch handle, lock, cassette sensors (3), keypad, indicator lights, AC power jack, remote dose jack, USB connector, air detector sensor, and housings.
- Check the battery door for proper operation. It should not be cracked or broken. Inspect the battery door seal for proper position.
- Examine the battery compartment for damage or debris. Care must be taken so as not to damage the pump housing or to incur damage to the battery contacts.

Mechanical Inspection

- Press each key on the keypad. Each key should have a distinctive tactile feel. The keys should not feel flat.
- Close and latch the battery door. The battery door should fit snugly in place when it is closed on the pump.
- Attach a medication cassette reservoir or a CADD® administration set to the pump. Check for smooth operation of the latch and make sure the cassette is firmly attached to the pump.
- Lock the cassette by inserting a key into the lock and turning clockwise into the locked position.
- Gently twist and pull on the cassette to make sure it is firmly attached.

NOTE: Persons performing the following procedures should be familiar with the CADD®-Solis pump. Please read the entire Operator's Manual before proceeding.

NOTE: Testing procedures should be done through the manual mode.

Functional Testing

Power Up Check

- Insert 4 AA batteries in the pump and press and hold the ON/OFF key. Observe the LCD during power up. If the system fault screen appears prior to the pump displaying the home screen (see *System Fault Alarm* on p. 17), the pump has experienced an electrical or mechanical fault. If no error message is immediately shown, and six audible beeps occur, the pump has powered up normally. If the new patient marker text appears, select "No." Continue with the latch/lock check.

Latch/Lock Check

- Attach a medication cassette reservoir to the pump. The latch handle should be in an upright position. The status bar should temporarily show "Reservoir Cassette Latched."

- Lock the cassette by inserting a key into the lock and turning clockwise into the locked position. The status bar should temporarily show “Cassette Locked.”
- Unlock the cassette by inserting a key into the lock and turning counter-clockwise into the unlocked position. The status bar should temporarily show “Cassette Unlocked.”
- Unlatch the cassette by moving the latch handle toward you approximately 90 degrees. The status bar should temporarily show “Cassette Unlatched and Removed.”

Cassette Sensor Test

- Attach a CADD® administration set to the pump. Latch the CADD® administration set to the pump. The status bar should temporarily show “Standard Admin Set Latched.”
- Lock the CADD® administration set by inserting a key into the lock and turning clockwise into the locked position. The status bar should temporarily show “Cassette Locked.”
- Unlock the CADD® administration set by inserting a key into the lock and turning counter-clockwise into the unlocked position. The status bar should temporarily show “Cassette Unlocked.” Unlatch the set, the status bar should show “Cassette Unlatched and Removed.”

The following three checks (LCD, motor and reservoir volume is zero alarm) should be performed in the sequence shown.

LCD Check

- Power up the pump by pressing and holding the On/Off key. The display will quickly flash gray, then blue. An amber swirl will then fill the display, followed by a CADD®-Solis Ambulatory Infusion System display. Look for any stripes or black or white pixels, which would indicate a faulty display. After a few seconds, the LCD will display “Do you want to start a new patient?” Double check the LCD for any damage, then select **No**.

- Program the pump to the following parameters:

Continuous Rate	30.0 mL/hr
PCA Dose	0.0 mL
Reservoir Volume	1.0 mL

NOTE: The remaining testing procedures should be performed using a medication cassette reservoir containing fluid and a primed CADD® extension set with anti-siphon valve, a primed CADD® administration set with anti-siphon valve, or a CADD® administration set with flow-stop feature.

Motor and Reservoir Volume is Zero Alarm Checks


- Attach a medication cassette reservoir or CADD® administration set to the pump. Latch and lock the cassette.
- Prime the pump by highlighting **Prime Tubing** from the Tasks Menu, and pressing **select**. Enter the security code. On the priming screen, select **Prime**. The display should show “Reservoir Volume low. Are you sure you want to continue priming?” Select **Yes**.
- The pump should begin to prime. While priming the pump, listen to the motor for excessive noise or grinding sounds. The pump should deliver 1.0 mL. Then the display should show, “Reservoir Volume is zero. Pump Stopped.” Select **Acknowledge**. The reservoir volume in the upper left corner of the display should show 0 mL.

Stopping/Starting the Pump

- Check the stop/start **stop/start** key by pressing it. The display should show, “Reservoir Volume low. Set Reservoir Volume?” Select **Yes**. Enter the security code. Press **select** to reset to 100 mL. Then select **Save**. Review the saved settings, accepting the values and finally selecting **Next**. The display should show, “Start pump?” Select **Yes**. “Pump is starting” should display on the screen. The main screen should appear with “Running” in the status bar, and the green LED indicator light should blink every 3 seconds.
- To stop the pump, press stop/start **stop/start**. When the message “Stop pump?” appears, select **Yes**. The message “Pump is stopping” appears and the amber LED indicator light blinks.


Activation Timing Check

- Check the activation timing by programming the pump with the following values:



Continuous Rate	30.0 mL/hr
PCA Dose	0.0 mL
Reservoir Volume	1.0 mL
- Press stop/start . Select **Yes**. “Pump is starting” should appear on the display. Start a timer at the first motor activation. The display should show “Reservoir Low.” Select **Acknowledge**.
- Count the activations. One activation should occur every twelve seconds. Approximately one minute fifty seconds (1:50) and ten activations later, the reservoir empty alarm should occur. The display should show “Reservoir volume is zero. Pump stopped.” Select **Acknowledge**.

Remote Dose Cord Check

- Attach the remote dose cord.
- Check the remote dose cord button operation by programming the pump with the following values:

Continuous Rate	0.0 mL/hr
PCA Dose	1.0 mL
PCA Lockout	0 hrs 1 min
Reservoir Volume	10.0 mL
- Go to the “Given and PCA Dose Counters” report. Select **Clear Given**.
- Press stop/start . Enter the security code if prompted. Review the saved settings, accepting the values and finally selecting **Next**.
- After “Running” appears on the status bar, press the remote dose cord button and note the time. The pump should beep and begin to deliver. Count the number of pump activations. The pump should make ten double activations. After ten double activations, the display should show a reservoir volume of 9.0 mL. Press the remote dose cord button two more times within the next 1 minute. The pump should not deliver and the message, “PCA Dose not available. Currently locked out.” should display.

Doses Given and Doses Attempted Check

- Stop the pump by pressing stop/start , then select **Yes**. Select **Reports** and highlight “Given and PCA Dose Counters.” The display should show “PCA Doses Given 1, PCA Doses Attempted 3.” (If the above steps have not been followed exactly, different values may appear.)
- Select **Clear Given**. The display should now show 0 mL.
- Press  to move the selection to the PCA Doses Given area. Press **Clear Doses**. The display should show “PCA Doses Given 0, PCA Doses Attempted 0.” (If the above steps have not been followed exactly, different values may appear.)

Air Detector Test

This test will verify the function of the optional air detector. To perform this test, the CADD[®]-Solis pump must have the air detector turned on.

- Check the air detector by programming the pump with the following values:

Continuous Rate	0.0 mL/hr
PCA Dose	1.0 mL
PCA Lockout	0 hrs 1 min
Reservoir Volume	10.0 mL
- Attach an empty medication cassette reservoir or CADD[®] administration set to the pump.
- Latch and lock the cassette to the pump.
- Start the pump.
- The pump should respond with a high priority alarm and the display should read, “Cannot start pump with air-in line. Prime tubing.” Select **Acknowledge** and remove the medication cassette reservoir or CADD[®] administration set.
- Attach a medication cassette reservoir containing fluid and a primed extension set with anti-siphon valve, or a primed CADD[®]-administration set with anti-siphon valve to the pump. Make certain there is no air in the fluid path.
- Latch and lock the cassette to the pump.
- Start the pump.

- Deliver a PCA dose. The pump should deliver the dose without an air detection alarm.

NOTE: 1 minute must have passed since the delivery of the last PCA dose.

Battery Fallout Alarm Test

This test will verify the function of the battery fallout alarm.

- Program the continuous rate to 1.0 mL/hr.
- Attach an empty medication cassette reservoir or CADD® administration set to the pump with air detector off.
- Latch and lock the cassette to the pump.
- Ensure the AC adapter is not connected.
- Start the pump. Allow the pump to run for a minimum of 3 minutes.
- Open the battery door. The pump should respond with a continuous two-tone alarm. Start a stopwatch timer.
- Measure the time the audible alarm is activated. The pump should provide an audible alarm for a minimum of 2 minutes.

LED Indicator Test

This test will verify the function of the LED indicators.

- Attach and lock an empty medication cassette reservoir or CADD® administration set to the pump.
- While in the STOP mode, the Amber LED indicator should blink about every 3 seconds.
- Place the pump in the RUN mode, the Green LED indicator should blink about every 3 seconds.

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

Audible Alarm Check

This test will verify the function of the audible alarm.

- Select Tasks and then Adjust Alarm Volume

from the Main menu.

- Scroll and pause on the three alarm volumes (low, medium, and high). The pump should sound the alarm while you are pausing on each volume.
- Press the up and down arrow keys to verify all 3 audible alarm volumes.

Occlusion Pressure Range Tests

Downstream occlusion and upstream occlusion utilize stored constants for offset and gain to maintain occlusion accuracy.

Downstream Occlusion Pressure Range Test 1

Description:

Pressure is generated by activating the pump mechanism with an attached filled, clamped medication cassette reservoir. The pump is started and a PCA dose is given until the high pressure alarm sounds.

Equipment needed:

Medication cassette reservoir containing distilled water

Procedure:

1. Turn the pump on and attach a medication cassette reservoir containing distilled water to the pump. Latch and lock the cassette.
2. Prime the tubing. The tubing should be filled with fluid to the end of the Luer lock connector. The system **must** be free from air bubbles for this test.
3. Close the clamp on the distal end of the tubing near the female Luer of the medication cassette reservoir.
4. Program the pump to the following parameters:

Units:	Milliliters
Continuous Rate:	0.0 mL/hr
PCA Dose:	1.0 mL
PCA Lockout:	0 hrs 1 min
Reservoir Volume:	10.0 mL

5. Start the pump. When the pump is running, activate a PCA dose, noting when the high pressure alarm is activated.
6. The pump should alarm when the pump delivers between 1 and 2 activations.

Downstream Occlusion Pressure Range Test 2

CAUTION: Safety glasses should be worn while conducting or observing this test.

Description:

An adjustable metered pressure source is connected to the medication cassette reservoir tubing. The pressure is slowly increased until the high pressure alarm sounds.

Equipment needed:

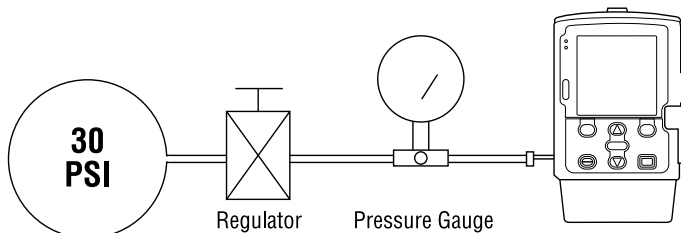
- Pressure gauge, 30 psi \pm 1 psi [2.07 bar \pm 0.07 bar]
- Pressure vessel, partially filled with water
- Pressure regulator, 30 psi [2.07 bar]
- Medication cassette reservoir containing water
- Safety glasses

Procedure:

1. Turn the pump on and attach a medication cassette reservoir to the pump. Latch and lock the cassette.

NOTE: The pressure from the source must be zero when the cassette is attached.

2. Assemble the apparatus as shown.



3. Connect the medication cassette reservoir outlet tube to the metered pressure source.

NOTE: Do not use a CADD® extension set with

anti-siphon valve.

4. Start the pump and run at 30 mL/hr.
5. Slowly increase the back pressure, noting when the high pressure alarm is activated.

NOTE: The pressure may be increased rapidly to 8 psi [0.55 bar], after which the pressure should be increased at 3 psi/min [0.21 bar/min] or less until the alarm sounds.

6. The high pressure alarm should sound between 9 and 27 psi (18 \pm 9 psi) [between 0.62 and 1.86 bar (1.24 \pm 0.62 bar)].

CAUTION: At the completion of the occlusion pressure range test 2, the pressure must be reduced to zero before detaching the cassette from the pump; otherwise, the cassette may rupture. Safety glasses should be worn while conducting or observing this test.

Upstream Occlusion Sensor Test

Description:

The tubing between the fluid reservoir and the pump is occluded while the pump is running until the occlusion alarm sounds.

Equipment needed:

- CADD® administration set with anti-siphon valve
- Tubing clamp (slide clamp or hemostat)

NOTE: Make sure the upstream occlusion sensor is turned on in the Administrator Settings.

Procedure:

1. Spike an appropriate standard I.V. bag.
2. Prime the entire fluid path.
3. Program the pump to deliver a continuous rate of 30 mL/hr.
4. Start the pump.
5. Clamp the tubing halfway between the fluid reser-

voir and the pump.

6. The pump should alarm within three activations after clamping the tubing.

lock connector as possible. This should assure a minimum water loss from the tubing when the syringe is removed.

4. Weigh the entire medication cassette reservoir/extension set assembly and record the weight. This is the **pre-delivery weight** (this weight includes the empty medication cassette reservoir, extension set, and weight of the water).
5. Attach the medication cassette reservoir to the pump. Program the reservoir volume to 20 mL. This value is the **intended delivery volume**. (One mL of water at 20°C weighs 1 gram.) Open the clamp.
6. Program a continuous rate of 0 mL/hr and a PCA dose of 20.0 mL. Start the pump and deliver a PCA dose of 20 mL.
7. Again, secure the clamp as close as possible to the end of the extension set Luer lock connector. Remove the medication cassette reservoir from the pump and weigh the entire medication cassette reservoir/extension set assembly. This is the **post-delivery weight**.
8. Calculate the difference in weight between the pre-delivery weight and the post-delivery weight. This is the **weight of the amount delivered**.
9. Find the difference between the actual delivery volume and the intended delivery volume. This is the **inaccuracy volume**.
10. Divide the inaccuracy volume by the intended delivery volume and multiply by 100. This is the **accuracy error percentage**.
11. If the accuracy error percentage is greater than $\pm 6\%$, repeat the test with a new medication cassette reservoir. If the pump fails a second time, call Smiths Medical MD, Inc.

Accuracy Tests

Calibration is not required in order to maintain delivery accuracy. The pump does not require use of stored calibration values in order to achieve or maintain delivery accuracy.

Gravimetric Accuracy Testing

Description:

A medication cassette reservoir is partially filled with water and weighed. The cassette is then attached to the pump and the pump is set to deliver a certain amount of water. The cassette is then removed and weighed again. The amount of water delivered is compared to the amount that the pump should have delivered.

Nominal system accuracy is given in the technical specifications section for the pump. The nominal test conditions are as follows: degassed water at $25 \pm 5^\circ\text{C}$ without back pressure.

Equipment needed:

- Medication cassette reservoir with attached CADD® extension set **OR**
- Medication cassette reservoir with flow stop feature with attached CADD® extension set
- 50 or 60 mL syringe
- A balance accurate to 0.1 g
- 40 mL of room temperature water

Procedure:

1. Fill the 50 or 60 mL syringe with 40 mL of water.
2. Remove any air from the medication cassette reservoir by aspirating the air with the syringe. Attach the CADD® Extension Set. Prime the tubing so it is filled with fluid to the end of the extension set Luer lock connector.
3. Secure the clamp as close to the extension set Luer

Example:

Pre-delivery Weight	61.1 g
Post-delivery Weight	- 41.6 g
Weight of Amount Delivered	= 19.5 g
Actual Delivery Volume	19.5 mL
Intended Delivery Volume	- 20.0 mL
Inaccuracy Volume	= - 0.5 mL
Inaccuracy Volume	- 0.5 mL
Intended Delivery Volume	÷ 20.0 mL
Accuracy Error	= - 0.025
Accuracy Error	- 0.025
	× 100.00
Accuracy Error Percentage	= - 2.5%

valve. Prime the tubing so it is filled with fluid to the end of the extension set Luer lock.

3. Attach the end of the extension set to the fluid collection device.
4. Attach the cassette to the pump. Program the reservoir volume to 20 mL. This is the **intended delivery volume**. Open all clamps.
5. Program a continuous rate of 0.0 mL/hr and a PCA dose of 20.0 mL. Start the pump and deliver a PCA dose of 20 mL.
6. When delivery is complete, record the volume of fluid delivered. This is the **actual delivery**.
7. Find the difference between the actual delivery volume and the intended delivery volume. This is the **inaccuracy volume**.
8. Divide the inaccuracy volume by the intended delivery volume and multiply by 100. This is the **accuracy error percentage**.
9. If the accuracy error percentage is greater than ± 6%, repeat the test with a new medication cassette reservoir. If the pump fails a second time, call Smiths Medical MD, Inc.

Volumetric Accuracy Testing

Description:

A predetermined amount of water is delivered into a collection device such as a burette or graduated cylinder. The amount of water delivered is compared to the amount that the pump should have delivered.

Nominal system accuracy is given in the technical specifications section for the pump. The nominal test conditions are as follows: degassed water at 25 ± 5°C without back pressure.

Equipment needed:

Medication cassette reservoir with attached CADD® extension set **OR**

Medication cassette reservoir with flow stop feature with attached CADD® extension set

A fluid collection device such as a burette or a Class A, 25 mL capacity graduated cylinder

40 mL of room temperature water

Procedure:

1. Fill the 50 or 60 mL syringe with 40 mL of water. Transfer the water into a medication cassette reservoir.
2. Remove any air from the medication cassette reservoir by aspirating the air with the syringe. Attach the CADD® extension set with anti-siphon

Example:

Actual Delivery Volume	19.5 mL
Intended Delivery Volume	- 20.0 mL
Inaccuracy Volume	= - 0.5 mL
Inaccuracy Volume	- 0.5 mL
Intended Delivery Volume	÷ 20.0 mL
Accuracy Error	= - 0.025
Accuracy Error	- 0.025
	× 100.00
Accuracy Error Percentage	= - 2.5%

CADD®-Solis Pump Cleaning and Functional Testing Checklist

The following checklist is provided as a guide only to assist in establishing documentation of cleaning and functional testing for the CADD®-Solis pump. If service is provided, fill out this sheet and return it with the device.

Serial # _____ Reference # _____ Date _____

(Refer to the Technical Manual procedures.)

I. Visual Inspection

- | | | |
|---|---|--|
| <input type="checkbox"/> LCD | <input type="checkbox"/> Lock | <input type="checkbox"/> Remote dose jack |
| <input type="checkbox"/> Occlusion sensor seals | <input type="checkbox"/> Cassette sensors (3) | <input type="checkbox"/> Air detector |
| <input type="checkbox"/> Valves and expulsor | <input type="checkbox"/> Keypad | <input type="checkbox"/> Pump housing |
| <input type="checkbox"/> Cassette hinge area | <input type="checkbox"/> Indicator lights | <input type="checkbox"/> Battery door |
| <input type="checkbox"/> Latch handle | <input type="checkbox"/> AC power jack | <input type="checkbox"/> Battery compartment |
| <input type="checkbox"/> USB connector | | |

II. Mechanical Inspection

- | | |
|---------------------------------------|---|
| <input type="checkbox"/> Keypad | <input type="checkbox"/> Cassette latch |
| <input type="checkbox"/> Battery Door | <input type="checkbox"/> Cassette lock |

III. Functional Inspection

- | | | |
|--|---|--|
| <input type="checkbox"/> Power-up | <input type="checkbox"/> Dose given/attempted | <input type="checkbox"/> Latch/lock |
| <input type="checkbox"/> Stopping/starting the pump | <input type="checkbox"/> Cassette sensor | <input type="checkbox"/> Activation timing |
| <input type="checkbox"/> Air detector | <input type="checkbox"/> LCD | <input type="checkbox"/> Remote dose cord |
| <input type="checkbox"/> Battery fallout alarm | <input type="checkbox"/> LED indicator | <input type="checkbox"/> Audible alarm check |
| <input type="checkbox"/> Motor and reservoir is zero check | | |

IV. Occlusion Tests (Only need to perform 1 or 2; not both)

Downstream Option 1: Activations before alarm _____

Downstream Option 2: High pressure alarm at _____ psi

Upstream Occlusion Sensor Test

Pass _____ Fail _____

VI. Accuracy Testing (Only need to perform 1 or 2; not both)

Volumetric Accuracy Test

Intended delivery volume	Actual delivery volume	Inaccuracy volume	Accuracy error	Accuracy error percentage
mL	mL	mL		%

Gravimetric Accuracy Test

Pre-delivery weight	Post-delivery weight	Amount delivered	Intended delivery volume	Inaccuracy volume	Accuracy error	Accuracy error percentage
g	g	mL	mL	mL		%

CADD

TM

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