



QCore[®] Sapphire Pump Clinician Training Program

April 2015

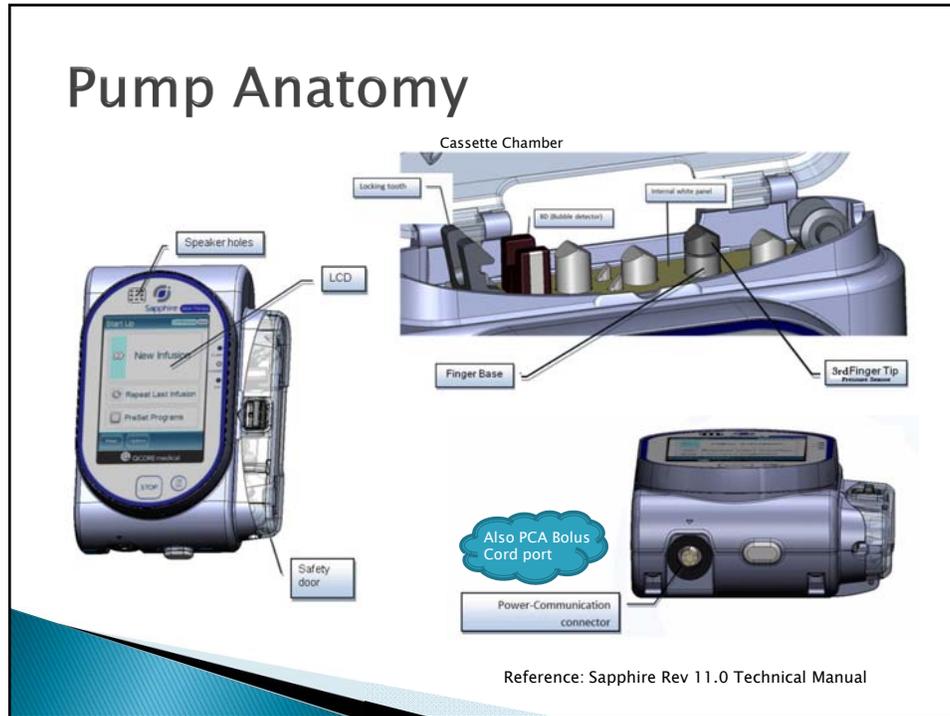
Goals for training

▶ Goals

- Review pump functionality, sets and accessories
- Understand key process steps for
 - Starting an infusion
 - Stopping an infusion
 - Changing a container
 - Re-programming the pump
 - Troubleshooting alarms

▶ Expectations

- Stay together
- Stay on task
- One conversation at a time
- Write questions on a comment card



Sapphire Features

- ▶ Modes
 - Continuous
 - Intermittent
 - Multi-Step
 - PCA
 - TPN
 - Epidural- turned off
- Only programs in the selected mode, at the time of Medium Lock level activation, will be accessible to the patient

The photograph shows the pump's interface with the following menu options visible on the screen:

- Continuous
- Intermittent
- Multi-step
- PCA
- TPN
- Epidural

Sapphire Features Cont.

- ▶ On Screen troubleshooting
 - Guides users through resolving alarms
- ▶ Occlusion auto re-start*
 - An occlusion alarm will occur if a detected occlusion isn't resolved within 40 seconds
- ▶ Infusion near end*
 - Alarm will sound 10 minutes before the end of therapy to alert patient to gather disconnect supplies
 - Requires patient to acknowledge alarm by pressing OK, infusion continues through alarm

*HomeMed specific configuration setting (changes to configuration will not be saved after powering off the pump)

Sapphire Features Cont. JCT2

- ▶ Priming*
 - **No longer need to hold to prime**
 - Auto configured priming volume of 8 mL
- ▶ KVO Settings*
 - Continuous 0 mL/h
 - PCA- 0 mL/h
 - TPN- 3 mL/h
 - MultiStep- 3 mL/h
- ▶ Backlight*
 - Set to partial- screen will dim after 30 seconds
 - Touch screen to turn backlight back on

*HomeMed specific configuration setting (changes to configuration will not be saved after powering off the pump)

Slide 6

JCT2 Not adding air detection setting here
Tharp, Jamie, 3/25/2015

Sapphire Pump and Accessories

1. AC Power Cord—

standard accessory

2. Mini Cradle

3. Bolus Cord

4. External Battery Pack

- Requires 6 AA batteries
- Emergency use only

Optional Accessories

Pump Accessories



Sapphire Battery Info

▶ Internal Rechargeable Battery

- Charge time 4h (100%), 2.5 h (80%)
- Charge light flashes while charging, solid light when charged
- ALL Patients should be coached to **plug in at night** (like their cell phone)
- External battery pack available for emergency preparedness for high need patients

▶ Sapphire Battery Life by Rate

Flow Rate mL/hr.	Average Nominal Time of Operation (h:mm)		
	Backlight Illumination Level		
	Off	Partial	On
1	47:58	34:18	15:28
5	47:46	32:47	15:40
50	41:59	30:58	15:06
125	30:53	23:37	13:25
350	25:25	20:38	12:40
600	25:30	23:06	11:50
800	24:18	21:55	11:53
900	16:27	15:17	8:52
950	8:02	7:03	6:00
975	7:32	5:33	4:00
999	3:17	2:36	1:33

Reference: Sapphire Rev 11.0 User Manual

Sapphire External Battery Pack (EBP)

- ▶ External Pack Charge Capabilities
 - Pump operation with EPB at 125 mL/h= 15-20 hours
- ▶ EBP is connected properly if the external battery icon shows on the pump (right corner)
- ▶ LED at the bottom of the EBP is illuminated
 - Replace batteries when light flashes
- ▶ Detach the EBP when regular power supply restored and wall charging available
- ▶ Strap included for IV pole hanging



Reference: QCore Sapphire EBP Package Insert

Pump Authorization Levels

Authorization (Lock) Levels	Features Available in Level
Low- do not plan to use regularly 9990	Stop (and resume) the pump Power on and off Administer Patient bolus Use the view menu
Medium*- Code =8880	All of above and... Start an infusion Use Preset program feature Use Restart last program feature Prime View bolus rate (PCA) Unlock Patient Lock Status
High- Issued by HomeMed	All of above and... Start Infusions using NEW infusion feature View/Edit parameters Access Configuration menu Create/Edit Preset programs Use All PCA options Change the infusion mode (w/ passcode entry) Administer Clinician bolus (w/ passcode entry)
Technician-	Access to pump testing and configuration for equipment staff

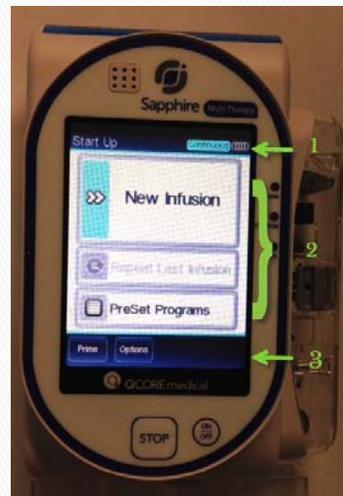
*Patients will only receive the Medium lock level code

Sapphire Infusion Modes

Mode	Description	Notes
Continuous	Delivers and infusion as a constant, programmed rate	No KVO available in HomeMed's configuration
Intermittent	Delivers infusions at intermittent, pre-set intervals	Commonly used for high frequency antibiotic dosing (e.g. nafcillin)
Multi-Step	Delivers the infusion in a set of 1 to 25 steps	KVO= 3mL/hr Possible uses for IVIG or continuous programs (1 step) requiring KVO
PCA	Delivers a basal pre-set rate either alone or in addition to PCA boluses	
TPN	Delivers an infusion at a constant rate, with optional tapering at the beginning and end of the infusion	Can also be used for continuous infusion therapies (where KVO allowable) in addition to TPN program

Start Up Screen

- ▶ **Components**
 1. **Indicator Bar**
 - Power Status
 - Mode
 2. **Main Screen**
 - New Infusion
 - Repeat Infusion
 - PreSet Programs
 3. **Toolbar**
 - Prime
 - Options (Requires High Passcode)
 - Delivery Mode selection
 - Pump Configurations
 - Alarms, General Settings, Regional settings, Test system
 - View



Pump Status Indicators

▶ Status LEDs

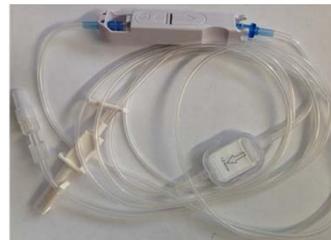
1. Alarm
 - Red LED= Alarm is occurring
2. Charge
 - Yellow LED (flashing)= Battery is charging
 - Yellow LED (steady on)= Pump is connected to main power and battery is fully charged
3. Run
 - Green LED= Pump is running



Tubing Sets

▶ Tubing set components

- Cassette
- Anti-free flow valve (AFFV)–
 - Shipped OPEN for gravity priming (not advised)
 - Automatically in CLOSED position after removal from pump
- Filter (if available)
 - Filter should be below the vascular access site



▶ Y-Site

- CLAVE Y-site for needle free connections–NOT available with current 1.2 micron filter microbore tubing
- Bifurcated extension set will be required for patients with Y-site medication admin

Starting a New Infusion in the Home

- ▶ Inspect tubing and medication dose
- ▶ Spike bag
- ▶ Insert Tubing
- ▶ Power Pump On
- ▶ Confirm Battery Use
- ▶ Select #1, resume program
- ▶ Review Program
- ▶ Prime set, press and HOLD purge key
- ▶ Connect to patient
- ▶ Select Change
- ▶ Press #1 for new container
- ▶ Press Start

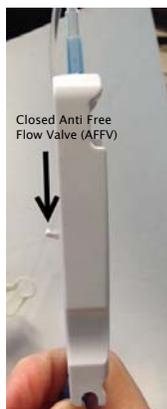
Gemstar Steps-OLD

- ▶ Inspect tubing and medication dose
- ▶ Power Pump On*
- ▶ Open Door
- ▶ Insert cassette
- ▶ Close Door
- ▶ Spike Bag
- ▶ Select PreSet Programs
- ▶ Select Program name
- ▶ Confirm program
- ▶ Prime set (single push of button)
- ▶ Connect to patient
- ▶ Press Start

Sapphire Steps-NEW

*Power on before inserting tubing to allow pump fingers to self adjust without administering drug to patient

Insert Tubing



Seat saddle on metal anchors



Engage Metal Locks



Secured Cassette

Prime Tubing



Select to Prime



Safety Check Message



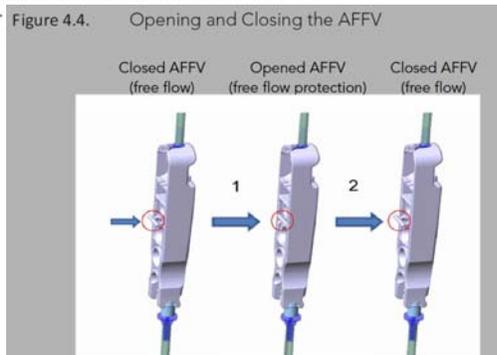
Countdown while priming

*Press [Finish Prime] or hard [STOP] key to stop early

Prime Tubing (manually)

> To prime the administration set manually:

1. Open all the clamps on the administration set.
2. To allow free flow, open the AFFV by pushing it in and down, towards the center of the Q Core administration cassette (#1 in Figure 4.4).
3. Fill the entire administration set with fluid, so that the fluid displaces all air in the administration set.
4. To block free flow, close the AFFV by pushing it up and away from the center of the cassette (#2 in Figure 4.4).



Reference: Sapphire Rev 11.0 User Manual

Start Using PreSet Program



*Compare to Drug Label

HomeMed will not be using “New Infusion” –OR– “Repeat Last Infusion” options for programming the pump. These options do not allow programs to be named and have different configuration limitations.

Run Screen

1. Indicator bar
 - PreSet Program Name
 - Action Wheel
 - Delivery Mode
 - Battery Indicator
2. Main display–infusion status
3. Toolbar–all buttons visible, but access could be restricted based upon authorization level



Run Screen Overview

Example Display

Toolbar Options from Run Screen

Toolbar—all buttons visible, but access could be restricted by authorization level

- ▶ Bolus (Clinician)—
 - Requires High lock level
 - Not recommended in the field
 - Configuration limited to 1 mL/h bolus, so any programmed bolus will only administer at 1 mL/h



Run Screen Tool Bar

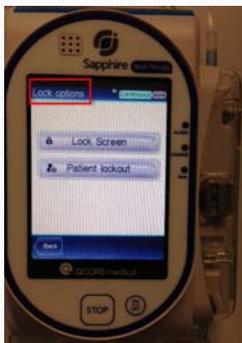
Toolbar Options from Run Screen Cont.

- ▶ View/Edit
 - Clear Volume Infused— not needed with PreSet program (previous VI auto cleared)
 - View System— Infusion values, alarm volume, occlusion, authorization level, delivery mode, air detector information, date, time, software version, serial number



View System

Toolbar Options from Run Screen Cont.



Lock Options

- ▶ Lock-
 - Lock Screen- (No Code Required)
 - prevents inadvertent touch changes
 - Patient lockout- (Medium Code Required)
 - ideal for securing screen/infusion while wearing in a carry case or around children
- ▶ Pause-
 - to temporarily interrupt infusion
 - 5 minute call back
 - May also pause using the hard "STOP" key below the touchscreen



Pause Infusion

Messages /Warnings



Lock Level Restriction
Prevented Clinician Bolus During Infusion



Infusion Stop Alert
Active Confirmation Required

***Teaching moment for patients:** Alert means they won't be able to start where this infusion is leaving off, new program will think it is equal to a new dose

General Use Information

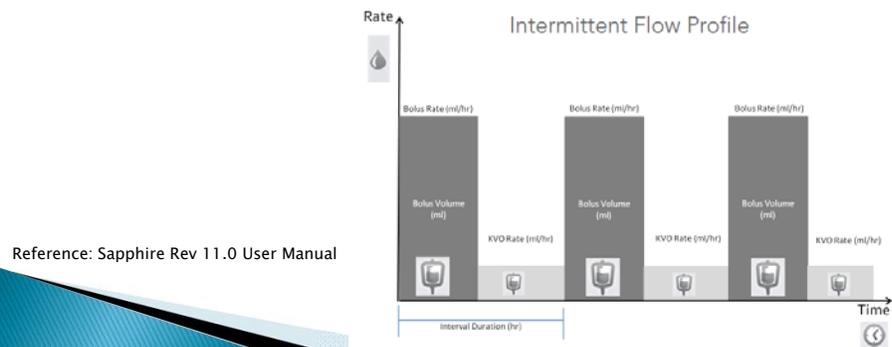
- ▶ Optimum bag height above the pump is 20 inches (50 cm)
- ▶ Educate patients to charge the pump each night

Continuous Mode Review

- ▶ **Rate**= speed at which the fluid is infused
- ▶ **VTBI**= Volume to be infused (does not include priming volume)
- ▶ **Time**= period of time over which the fluid is infused
- ▶ **KVO** rate is preset at 0 mL/h. (HomeMed setting)
 - KVO not available in Cont Mode to prevent over/under dosing of High Risk Medications infusing at low rates
- ▶ **Bolus**
 - Available in High Lock Level
 - **Warning to Clinicians**- Do not enter a bolus
 - Configured to 1 mL/h max (Safety Step to prevent significant alteration of intended dose/rate)
 - Patient cannot use this key with Medium level passcode

Intermittent Mode Review

- ▶ **VTBI**= Volume of bag to be infused (Total volume– priming volume)
- ▶ **Dose**= the amount of each dose
- ▶ **Dose Rate**= continuous rate at which the dose is delivered
- ▶ **Interval Duration**= time from the start of one dose to the start of the next dose (Dose+KVO)
- ▶ **KVO**= The rate of fluids delivered between doses to prevent line occlusion (0–20 mL/h allowable)



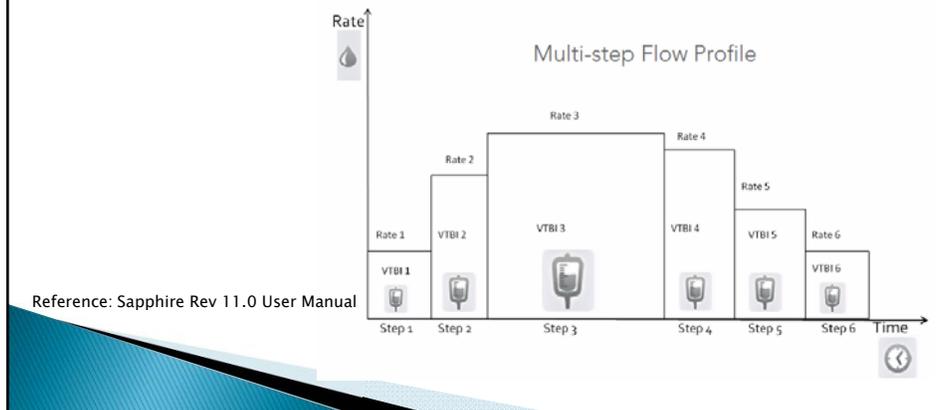
Intermittent Mode Review Cont.

Intermittent Screen Display

- ▶ **VI/Total**= is the volume that has been infused over the total VTBI in the bag
- ▶ **Time to dose**= Time remaining until the end of the current interval (Dose left + KVO)
 - When Paused, the time to the next dose is paused and not displayed
- ▶ **Time left**= Time remaining until the end of the entire infusion
- ▶ **Infusions always start with the dose (bolus). Patients should take note of dose times and time bag changes appropriately.**

Multi-Step Mode Review

- ▶ **VTBI**= total amount of fluid to be infused in a given step
- ▶ **Rate**= speed at which the fluid is infused in a given step
- ▶ **Time**= the period of time over which the fluid is infused
- ▶ Allowable to program in VTBI+Rate or VTBI+Time

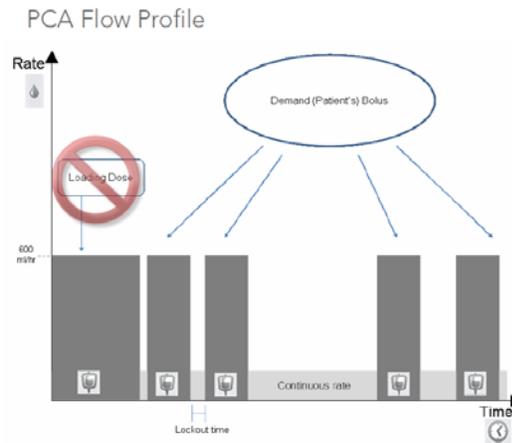


PCA Mode Review-General

- ▶ **VTBI**= Volume of bag to be infused (Total volume- priming volume)
- ▶ **Continuous Rate**= Basal Rate
- ▶ **Demand Bolus**= Patient bolus dose (volume)
- ▶ **Bolus Lockout**= Time between end of one bolus and start of next
- ▶ **Bolus Limit**= # Bolus per fixed time period
 - 1 and 4 hour limit ranges available with PreSet program (4h hour only with New Infusion from Main Screen)
 - Max Allowable # based upon time between boluses (lockout), and bolus administration time (at rate of 125 mL/h)

PCA Mode Review–General cont.

- ▶ HomeMed Not recommending Loading Dose use, because most patients are transferring from an inpatient PCA to home PCA



Reference: Sapphire Rev 11.0 User Manual

PCA Mode Review–Bolus Options

- ▶ Automatically in Patient Lock while running
- ▶ No alerts display on the pump when a bolus request is denied during the lockout period
- ▶ Review of bolus history (administered vs. attempts) is available in Bolus History Menu
- ▶ User able to pause and quit a bolus with Medium Lock level
 - Quitting bolus allows user to resume basal rate infusion
 - Bolus history shows that partial bolus volume given

PCA Display



PCA Screen Shot

- ▶ C Rate= Continuous Rate (does not display during bolus admin)
- ▶ VTBI= Volume of Bag to be infused
- ▶ Lock out time= time remaining until next bolus available
- ▶ Time left= Time left of bag infusion
- ▶ Bolus [] mL=patient bolus from touch screen
 - (requires pump to be unlocked)
- ▶ Bolus History= displays pump settings and bolus info

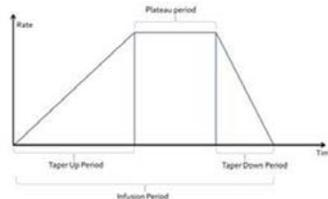
PCA Bolus Administration

- ▶ When a bolus is available, Patient administered bolus can be given in 2 ways
 - **Pump Touchscreen Administered bolus** (requires patient to unlock Patient Lock with Medium Level Code)
 - **PCA Bolus Cord** (does not require pump to be unlocked)



TPN Mode Review

- KVO rate is preset at 3 mL/h.
- Max Taper 3 hours up and 3 hours down
- **Cannot** edit infusion program (with High level passcode) while the pump is infusing.
- Pump displays **Plateau rate** during program review.
 - Plateau (Max Infusion) Rate Calculation, based upon the formula for an area of a trapezoid
 - HomeMed TPN spreadsheet updated to reflect this calculation change



$$VTBI = \left(\frac{\text{Plateau Period} + \text{Infusion Period}}{2} \right) \text{Max Rate}$$

Example: VTBI = 2000mL, Taper up= 1 hr, Taper down = 1 hr, Infusion period = 9 hr

$$2000 = \left(\frac{7 \text{ hours} + 9 \text{ hours}}{2} \right) \text{Max Rate}$$

Max Rate = 250 mL/hr

Reference: Sapphire Rev 11.0 User Manual

Viewing Event Logs

Viewing the Events Log

The Events log screen enables you to view a record of all events audited by the system. You can view a list of all events, or only the events that occurred on a specific day.

> To view events that occurred on a specific day:

1. From the Options menu, select **View**.
2. On the View screen, select **Events log**.
3. On the Events log screen, select **By date**.
4. Using the keypad, enter values for the day (2 digits), the month (2 digits), and the year (2 digits). (When U.S. format is set, the order is month, day, and year.)

i To navigate directly to a component of the date (e.g., day), press the component.

5. On the toolbar, press **OK**.
A list of events is displayed.

i If no events occurred on the selected day, a blank screen is displayed.

> To view all events:

1. From the Options menu, select **View**.
2. On the View screen, select **Events log**.
3. On the Events log screen, select **All events**.
A list of events is displayed.

Viewing Bolus History

This screen, which appears only in the PCA and PCEA infusion modes, provides a summary of all bolus-related events that occurred during a specified time frame.

i When a PCA or Epidural infusion is running, the Bolus history screen can be accessed by pressing the **View/Edit** function key, and then (from the View/Edit screen) selecting **Bolus history**.

Reference: Sapphire Rev 11.0 User Manual

Changing a Container

- ▶ Press Stop
- ▶ On tubing change day–prime tubing by HOLDing purge key
- ▶ Connect to patient
- ▶ Press Change
- ▶ Press #1 for new container
- ▶ Confirm Program
- ▶ Press Start

- ▶ Press Stop or Pause
- ▶ Press Quit, Quit
- ▶ Press PreSet Program*
- ▶ Select Name of Program
- ▶ Review against drug label
- ▶ Press Ok
- ▶ On tubing change day–prime tubing by selecting Prime
- ▶ Press Start

Gemstar Steps–OLD

Sapphire Steps–NEW

*Do NOT select repeat last infusion

Changing Modes

- ▶ Press Stop or Pause
- ▶ Press Quit, Quit
- ▶ Press Options
- ▶ Enter High Authorization code
- ▶ Select Mode
- ▶ Press PreSet Program
- ▶ Select the desired program name
- ▶ Review against drug label
- ▶ Press Ok
- ▶ On tubing change day–prime tubing by selecting Prime
- ▶ Press Start to infuse

Discouraged in the home–Requires patient to use High lock level passcode

Remove tubing from pump

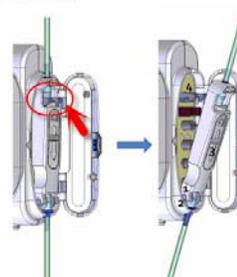
> To remove the Q Core administration cassette:

1. Close all clamps on the administration set.
2. Disconnect the patient from the administration set.
3. Open the safety door (Opening the Safety Door on page 52).
4. Loosen the cassette by raising the metal lock that secures it to the pump (#4 in Figure 4.3).
5. Pull out the cassette, and close the safety door.

HomeMed Notes:

- Recommended to remove tubing before turning pump OFF
- The AFFV is automatically CLOSED upon cassette removal

Figure 4.3.



Reference: Sapphire Rev 11.0 User Manual

Power Off



Turning the Pump Off

Pressing the **On/Off** hard key for 5 consecutive seconds turns the pump off. Alternatively, press the **On/Off** hard key, and then, from the Attention screen, press **Off**.



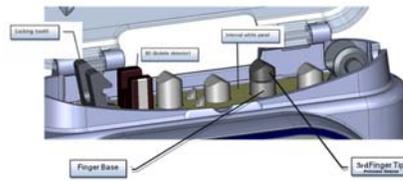
After operating the pump with <math><1\text{ mL/h}</math> flow rate, you will be prompted to remove the administration cassette before turning off the pump.

Reason: When powering down, the pump fingers self adjust and may deliver small amount of medication at greater than 1 mL/h rate

Reference: Sapphire Rev 11.0 User Manual

Cleaning the pump in the home

- ▶ Pump
 - Can be wiped with a damp cloth (**mild detergent** or **70% Isopropyl Alcohol (IPA)** allowable)
- ▶ LCD Screen
 - A **mild detergent** or **70% IPA** may be used
 - Wipe thoroughly with a soft, clean dry cloth
 - Do not use ketone or aromatic solvents on screen
- ▶ Internal white panel (under pump door)
 - Should be kept free from dirt and foreign objects
 - If necessary use **mild detergent** or **70% IPA** on a cotton tipped applicator around the pump fingers
- ▶ Sensor Fingers
 - Clean the finger tips with a slightly damp cloth or sponge only
- ▶ Bubble Detector
 - Self Cleaning with loading/removal of tubing
 - May clean with cotton tipped applicator
 - Use a **mild detergent** or **70% IPA** and wipe thoroughly with a soft, clean cloth



Reference: Sapphire Rev 11.0 Tech Manual

Troubleshooting

Alert Type	MESSAGE
Description and Action Required	<ul style="list-style-type: none"> ➢ A condition of medium severity that should be attended to as soon as possible ➢ Auditory alarms sound and screen displays reason and recommended action ➢ Infusion continues to operate during alert (unless infusion complete) ➢ Available action keys on touchpad <ul style="list-style-type: none"> • Mute–silences alarm for 2 minutes • Ok–confirms message and returns to previous screen
Examples	Low battery Door opened Infusion near end Infusion complete Pump inactive

Troubleshooting

Alert Type	ALARMS		
	Level 1	Level 2	Level 3
Description and Action Required	➤ Pump Shuts Down	➤ Infusion stops and cannot be resumed	➤ Infusion stops but may be resumed
Examples	<ul style="list-style-type: none"> ✓ Battery Depleted ✓ Internal Error 	<ul style="list-style-type: none"> ✓ Mechanical error ✓ Pump fault ✓ Battery Reminder 	<ul style="list-style-type: none"> ✓ Air in line ✓ Cassette misplaced ✓ Occlusion- Upstream/ Downstream ✓ Flow Error ✓ Insufficient Battery

Troubleshooting, Common Issues

Issue	Pump is NOT Charging
Problem	<ul style="list-style-type: none"> ➤ Probable Causes- <ul style="list-style-type: none"> • The charge has become disconnected from the mini-cradle or the power supply • The charger is not working
Solution	<ul style="list-style-type: none"> ✓ Confirm all power connections are in place ✓ Connect the charger to a different power supply (outlet) and reconnect it to the pump. ✓ If the Charge is not functioning properly, replace it

Troubleshooting, Common Issues

Issue	Recurring Air in Line
Problem	<ul style="list-style-type: none"> ➤ Probable Causes– <ul style="list-style-type: none"> • Treatment is near end • Therapy prone to foaming or effervescence • Air detection settings are too sensitive
Solution	<ul style="list-style-type: none"> ✓ Minimize shaking prior to administration and allow adequate time for product to warm to room temperature ✓ Close clamps, remove administration cassette from pump and prime the set manually. Replace set if manual prime unsuccessful ✓ Clean Bubble Detector ✓ Air detection settings can only be modified by HomeMed

Troubleshooting, Common Issues

Issue	Recurring Occlusion
Problem	<ul style="list-style-type: none"> ➤ Probable Causes– <ul style="list-style-type: none"> • Occlusion issue has not been properly resolved
Solution	<ul style="list-style-type: none"> ✓ Close clamps, remove administration cassette from pump, disconnect from patient and prime the set manually ✓ Replace the administration set ✓ Change the infusion site ✓ Assess catheter for thrombus and treat appropriately

Questions?

- ▶ Contact HomeMed at [800-862-2731](tel:800-862-2731) to speak with an onsite clinician