

Baxter

Operator's Manual

SIGMA SPECTRUM INFUSION PUMP WITH
MASTER DRUG LIBRARY

35700BAX2

Pump Operating Software Version 8.00

For use with Master Drug Library Version 8



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INTRODUCTION AND SAFETY

Intended Use

The SIGMA Spectrum Infusion Pump with Master Drug Library is intended to be used for the controlled administration of fluids. These may include pharmaceutical drugs, blood, blood products and mixtures of required patient therapy. The intended routes of administration consist of the following clinically accepted routes: intravenous, arterial, subcutaneous, epidural or irrigation of fluid space. The SIGMA Spectrum Infusion Pump with Master Drug Library is intended to be used in conjunction with legally marketed and compatible intravenous administration sets and medications provided by the user.

The SIGMA Spectrum Infusion Pump with Master Drug Library is suitable for a variety of patient care environments such as, but not limited to, hospitals and outpatient care areas.

The SIGMA Spectrum Infusion Pump with Master Drug Library is intended to reduce operator interaction through guided programming, thereby helping to reduce errors. The SIGMA Spectrum Infusion Pump with Master Drug Library is intended to be used by trained healthcare professionals.

Related Documents

The following documents also pertain to the SIGMA Spectrum Infusion System:

- *SIGMA Spectrum Infusion System Service Manual (P/N 41019v0800)*
- *SIGMA Spectrum Infusion System Master Drug Library User Manual*

Regulatory Information

- Tested and conforms to UL STD 60601-1
- Certified to CAN/CSA STD C22.2 NO 601.1-M90

Trademark Information

Product names or trademarks appearing in this manual are the property of their respective owners.

Contacting Baxter Technical Support

Contact Baxter for all technical support and service information at:

Telephone: 800.356.3454

E-mail: MedinaTechSupport@baxter.com

Conventions

WARNING Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate personal injury or property damage. This word is used to also alert against unsafe practices.

NOTE: Indicates supplemental information to accompany text.

Summary of Warnings and Cautions

General Warnings

WARNING **Motor Vehicle or Aircraft Use.**
The SIGMA Spectrum Infusion Pump with Master Drug Library has not been tested or evaluated for use in motor vehicles or aircraft (for example, ambulance or MedFlight helicopter).

WARNING **Hyperbaric Chamber.**
The SIGMA Spectrum Infusion System has not been tested or evaluated for use in a hyperbaric chamber.

WARNING **Only Use the AC Power Adaptor Specified for this Equipment.**
Using other AC Power Adaptors may cause personal injury or damage to equipment.

WARNING **Ensure Secure Mounting of Pump During Use and Transport.**
During use and transport, securely mount Pumps to IV pole by centering the pole in the clamp and turning the mounting knob clockwise. To maintain IV pole stability, never exceed 210 cm (83 in) from floor to IV pole top and limit bag volume at this extended height to <1 liter (1000 cc).

WARNING **Battery Handling.**

- Do not short circuit battery terminals.
- Do not disassemble or modify battery packs.
- Do not dispose of batteries or battery pack in fire.

WARNING **Low Battery.**
Do not use battery operation or transport a patient when the Pump is in a low battery state.

WARNING **Battery Removal.**

- Do not detach the battery during patient therapy.
- Never touch the patient and the Pump at the same time with the battery removed and the Pump connected to the power outlet.

WARNING **ESD Sensitivity.**

Do not touch the battery pin set when the Battery Module is removed.

WARNING **Adjacent or Stacked Use.**

The Pump should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Pump should be observed to verify normal operation in the configuration in which it will be used.

NOTE: The SIGMA Spectrum Infusion System has been tested to operate normally when used stacked or adjacent to other SIGMA Spectrum Infusion Systems.

WARNING **Pump Storage.**

Remove the Battery Module from the Pump when storing the Pump for extended periods.

WARNING **Proper Disposal Required.**

To dispose of this device or the associated administration sets, adhere to local, state, federal and/or other governing regulations.

WARNING **Magnetic Fields.**

The SIGMA Spectrum Infusion System is not designed to be MRI-compatible nor is it intended to be used in this manner. Strong magnetic fields (those beyond the level tested) may cause the device to operate improperly.

Do not expose the Pump to strong magnetic fields such as is common with MRI equipment or in close proximity 60.9 cm (2 ft) of a cathode ray tube (CRT) monitor. Doing so may cause injury to the patient and/or damage to the equipment.

WARNING **Linear Accelerator Radiation.**

The SIGMA Spectrum Infusion System is not designed to be exposed to linear accelerator radiation nor is it intended to be used in this manner. Exposure to radiation of this type may cause the device to operate improperly.

Do not expose the SIGMA Spectrum Infusion System to linear accelerator radiation. Doing so may cause injury to the patient and/or damage to the equipment.

WARNING **Emissions and Immunity.**

The use of accessories or cables other than those specified by Baxter may result in increased Emissions or decreased Immunity of this medical device.

Procedural Warnings

WARNING **Operation is Limited to Trained Operators.**

SIGMA Spectrum Infusion Pump operation is strictly limited to trained operators who are competent in safe SIGMA Spectrum Infusion Pump operation and in safe IV therapy practices. Pump owners have sole responsibility for operator training and testing even when Baxter personnel assist in training processes.

WARNING **Environmental Limits**

Use of the SIGMA Spectrum Infusion System outside the environmental limits, noted in Appendix A as “Operational Conditions” may cause performance issues with the SIGMA Spectrum Infusion System, including but not limited to: under or over infusion, inability to detect upstream or downstream occlusions, inability to charge battery, and/or decreased battery life.

WARNING **Confirm Safe Operation.**

Never operate the SIGMA Spectrum Infusion Pump unless all of the following safe operations are being practiced.

Always confirm safe, accurate Pump operation by:

- Ensuring that IV sets or container vents are properly functioning, that tubing clamps are in the proper positions and that tubing is free from kinks or signs of collapse outside the Pump to prevent undetected upstream occlusions.
- Observing the drip chamber to verify that there is no flow from the fluid container when the Pump is stopped.
- Ensuring the drip rate approximates the Pump's flow rate during RUN operation.
- Ensuring correct patient, correct route and correct drug.
- Ensuring Pump settings, for example; drug/concentration, dose mode, dose rate and time.
- Monitoring vital signs and IV access sites per facility's standard practice of care.
- Monitoring the infusion to ensure that the infusion is delivered as intended.
- Periodically checking battery status and replace if necessary.

The SIGMA Spectrum Infusion System is not intended to replace clinician patient observation.

The Pump was not designed nor is it intended to detect infiltrations or extravasations.

WARNING **Manually Stopping the Pump.**

If the Pump cannot be stopped by pressing the **RUN/STOP** key,

- Close the roller clamp below the Pump.
- Insert the slide clamp into the keyhole.
- Push the slide clamp down until the door opens.

WARNING **Do Not Exceed Total Volume.**

To prevent Air in Line, ensure the total VTBI of all the steps in a multi-step program does not exceed the total volume contained in the IV bag.

WARNING **Confirm Drug Library.**

- Master Drug Library Administrators (MDLAs) should verify the correct Drug Library is installed when deploying the Drug Library to Pumps.
- Master Drug Library Administrators (MDLAs) should verify the Drug Library transfer is successful after deployment.
- Users should verify the correct Drug Library is installed on the deployed Pumps.
- Before implementation, clinical users at each facility must thoroughly test and validate their Drug Library per their facility's procedure to ensure configuration and workflow reflect clinical practice.

WARNING **Use the Specified Manufacturer's IV Set.**

A label located on the top of the Pump indicates the specific type of IV tubing that the Pump has been calibrated for. The use of other manufacturers' brands or type tubing could produce Pump inaccuracies that could be unsafe for patients.

WARNING **Baxter IV Sets.**

1. Minidrip chambers should not be used for flow rate settings greater than 200 mL/hr. Doing so may influence flow rate accuracy and cause air in line or upstream occlusion alarms.
2. When using sets with backcheck valves, flow rate settings should not exceed 500 mL/hr. Doing so may influence flow rate accuracy or cause air in line or upstream occlusion alarms. Secondary flow rates above 300 mL/hr may cause fluid to siphon from the primary container.

NOTE: Not applicable with non-DEHP tubing because 250 mL/hr is the maximum flow rate per warning statement.

3. When using sets with rigid polyethylene lined tubing, as is often used in nitroglycerine sets, flow rate settings should not exceed 500 mL/hr. Doing so may influence flow rate accuracy.
4. Partially occluded filters can cause air in line, upstream occlusion or downstream occlusion alarms or negatively affect flow rate accuracy.
5. Burettes with closed vents or shutoff valves will cause upstream occlusions that may not be detected by the infusion Pump. Rigid unvented containers used with unvented sets or vented sets with vent closed, will cause upstream occlusions that may not be detected by the infusion Pump.
6. When using a buretrol set containing a ball valve in the drip chamber, an upstream occlusion due to a closed ball valve may not be detected by the Pump.
7. Rigid polyethylene lined tubing, as is often used in nitroglycerine sets, may produce as much as 69 kPa (10 psi) downstream occlusion pressure above the lower limit of the SIGMA Spectrum Infusion System specification.
8. Some Sets contain two or more slide clamps. Only the slide clamp on the pumping section or on the section with the main roller clamp should be used for pumping operation and clamp detection. Other slide clamps on the set must be used with the set and need to be observed and controlled by the user. To prevent free flow, the slide clamp on the tubing that is loaded into the Pump should be used to open the Pump door.
9. Blood sets with both clamps closed above the blood filter will cause upstream occlusions that may not be detected by the Pump.
10. Sets containing a manifold may require longer times to detect downstream occlusions.
11. When using the compatible, non-DEHP IV administration sets in the Pump, the following performance limitations must be observed:
 - 11.1. Flow rate accuracy will range $\pm 10\%$ from the expected volume, when evaluated for over a one-hour period and not the $\pm 5\%$ specified for Baxter compatible DEHP IV sets.
 - 11.2. Flow rate range and IV set usage duration for Baxter non-DEHP IV administration sets is limited to:
 - 10 - 125 mL/hr with IV tubing use of not greater than 36 hours
 - 126 - 250 mL/hr with IV tubing use of not greater than 4 hours
 - 11.3. Do not use Baxter compatible non-DEHP administration sets with the SIGMA Spectrum Infusion System for drugs and therapies requiring infusion flow rates and durations outside of the ranges specified above.

11.4. Prior to using the SIGMA Spectrum Infusion System with non-DEHP IV tubing, healthcare professionals should evaluate drugs, prescribed therapies and patient populations.

NOTE: See Appendix D: "Downstream Occlusion" on page 152 for downstream occlusion times and bolus release information.

WARNING **Low Flow Rate Accuracy/Continuity.**

At flow rates of 2 mL/hr or below, flow rate accuracy is ± 0.1 mL/hr. If higher accuracy is required, consider an alternate infusion device.

WARNING **Flow Rate Inaccuracy.**

Rate accuracy can be affected by variations of fluid viscosity, fluid temperature, head height or back pressure, or any combination thereof. In addition to IV set specific warnings, the following can cause flow rate inaccuracies and must be avoided:

- Incompatible brand IV sets and compatible brand IV sets with unusually large or small diameters or unusually stiff materials.
- Using a dropped, damaged, dirty or wet Pump.
- Pressurizing IV bags
- Non-vented IV sets with rigid non-vented containers.
- Vents on sets or burettes left in the closed position when they should be open.
- Using Minidrip chambers for flow rate settings greater than 200 mL/hr. Doing so may influence flow rate accuracy and cause air in line or upstream occlusion alarms.
- Laying the IV container flat. Doing so may influence flow rate accuracy and cause upstream occlusion and air in line alarms.
- Exceeding 500 mL/hr flow rate settings when using sets with backcheck valves. Doing so may influence flow rate accuracy or cause air in line or upstream occlusion alarms.
- Flow rates above 300 mL/hr may cause fluid to be siphoned from the primary container during a secondary infusion. See "Secondary Infusion" on page 58.

NOTE: Not applicable with non-DEHP tubing because 250 mL/hr is the maximum flow rate per warning statement.

WARNING **Priming.**

Prior to connecting to patient, prime IV set following the standard gravity priming instructions included with the administration set, remove all air, close roller clamp and slide clamp, load IV set into the Pump, close the door, open slide clamp and roller clamp.

WARNING **Air Bubbles.**

Failure to prime/remove all air bubbles from backcheck valves in primary sets may cause the valve to malfunction, resulting in secondary fluid flow back up into the primary container.

WARNING **IV Set Loading.**

- Load tubing directly from the slide clamp to the top of the tubing channel. Confirm the tubing from the IV container enters the back of the slide clamp and exits the front of the slide clamp prior to loading the tubing section into the Pump channel.
- Improper or reverse IV set loading will result in a no flow condition to the patient, as well as possible back flow of blood from the IV set into the IV tubing and/or occlusion/air in line alarms.
- Follow the Direction of Flow diagram and screen prompts to load IV set tubing correctly.

WARNING **Do Not Allow Uncontrolled Gravity Flow.**

- Before loading a primed IV set, ensure the roller clamp below the Pump is in the closed position.
- To open the Pump door, the IV set's slide clamp must first be closed (thus providing "set-based anti-free flow" protection).
- Do not open the slide clamp when the door is open or during and after IV set unloading. This can cause dangerous, uncontrolled free flow to occur.
- During IV container changes, always close the set's roller clamp. When the set is in the Pump and the door is closed, the slide clamp can safely be opened. If gravity flow is to be used, the Pump door will be open or the set will be outside the Pump. Verify gravity flow is maintained at the intended rate whenever the Pump door is open and when the set is outside of the Pump.

WARNING **Bolus.**

When an administration set is loaded, the door is closed and the slide clamp is removed, a fluid bolus will occur (maximum of 0.1 mL).

WARNING **Proper Venting Required.**

Upstream occlusions caused by improperly vented glass bottles or burettes may not be detected because of the very slow-building vacuums resulting from these situations.

WARNING **Time to Upstream Occlusion at Lower Flow Rates.**

When infusing at flow rates below 5 mL/hr, the Pump may take an extended period of time to detect an upstream occlusion and sound an alarm.

Ensure the following:

- All clamps are open.
- There are no kinks or collapses in the tubing outside of the Pump.
- Drops are flowing in the drip chamber. Note, at very low rates, it may take several minutes to see drops.
- Vents are open (if applicable).

WARNING **Upstream Occlusion Alarm Suspension.**

- Do not use the Upstream Occlusion Alarm Suspension when delivering critical drugs where the risk of flow stoppage due to an undetected upstream occlusion outweighs that of flow interruption due to alarms where no upstream occlusion is present.
- Do not use Upstream Occlusion Alarm Suspension for drugs delivered in RIGID containers since the flow restriction caused by lack of proper container venting may be difficult to recognize when troubleshooting an alarm condition.
- Only use Upstream Occlusion Alarm Suspension after the operator visually observes positive line flow.

WARNING **Follow Neonatal and Pediatric Procedures.**

- Use 60 drop/1 mL IV sets.
- Configure the Pump with appropriate flow rate, VTBI (Volume To Be Infused), patient weight and occlusion alarm limits.
- Prior to connecting to patient, prime IV set following the standard gravity priming instructions included with the administration set, then close roller clamp, load IV set, open slide clamp and roller clamp to avoid possible bolus (0.2 mL) that would result from a door opening/set loading event.
- If the Pump door is opened while the IV set is connected to a patient, bolusing at door closing must be avoided. Before closing the door, clamp the set below the lower Y injection site. Connect a syringe to the lower Y injection site, close the door, open the slide clamp, collect a 0.085 mL bolus in the syringe and unclamp the set below the Y injection site.

WARNING **Follow Epidural Procedures.**

Epidural administration of drugs other than those indicated for epidural use can result in serious patient injury.

- When administering epidural analgesics, use only catheters specifically labeled for epidural analgesia drug delivery.
- To help prevent accidental infusion of non-epidural drugs, DO NOT USE epidural administration sets that contain injection sites.
- Label the administration container and IV set "EPIDURAL USE ONLY".
- Clearly identify infusion Pumps used for epidural administration.

- Use Keypad Lock to guard against unauthorized Pump access by a patient or family member.

WARNING **Unauthorized View or Access.**

Always guard the keypad lock code from unauthorized view or access. Uncontrolled access by a patient or family member may cause injury to the patient.

WARNING **Unintended Delivery.**

Close the clamp on the secondary line or remove the secondary container administration set to prevent the secondary drug from flowing when the Primary mode is intended.

WARNING **Pressurized Fluid.**

If disconnecting the IV set below the Pump is necessary, close the roller clamp before disconnecting the IV set from the patient to prevent possible exposure by the release of pressurized fluid upon Pump auto-restart.

WARNING **Specifications for Downstream Occlusion detection times and bolus volume, after release of occlusion, are based on specific test conditions.**

The analytical related conditions are:

- A distance of 1.2 m (48 in) from the point of the downstream occlusion to the SIGMA Spectrum Infusion System's Downstream Occlusion sensor (approximately the distance from the IV administration set's exit from the pumping channel to the point of occlusion).
- The 1.2 m (48 in) test administration set contained one Y injection site (no filters or other components).
- Testing was at the nominal room temperature 22.2°C ±1.1°C (72°F ±2°F).

Time to Downstream Occlusion and Bolus Volume release will generally increase under the following conditions: longer distances to the occlusion point, additional fluid volumetric area (from filters or other components within the IV set length), hotter room temperatures and higher Downstream Occlusion Pressure Thresholds or Limits. For additional information on Downstream Pressure Limits, see Appendix G: "Default Settings" on page 162.

WARNING **Do Not Reuse Tubing.**

Do not reload pumped-on tubing (the tubing segment previously used in the pumping channel) into the pumping channel. Doing so will cause alarms and adversely affect flow rate accuracy.

WARNING **IV Set Usage.**

Do not use an IV set for longer than the manufacturer's labeled set change interval to reduce risk of infection and to maintain flow rate accuracy.

WARNING **Unloading an IV Set.**

- Do Not Allow Uncontrolled Gravity Flow.
- Before unloading a primed IV set, ensure the roller clamp below the Pump is in the closed position. To open the Pump door, the IV set's slide clamp must first be closed (thus providing "set-based anti-free flow" protection).
- Do not open the slide clamp when the door is open or during and after IV set unloading. This can cause dangerous, uncontrolled free flow to occur.
- During IV container changes, always close the set's roller clamp. When the set is in the Pump and the door is closed, the slide clamp can safely be opened.
- If gravity flow is to be used, the Pump door will be open or the set will be outside the Pump. Verify gravity flow is maintained at the intended rate whenever the Pump door is open and when the set is outside of the Pump.

WARNING **Radio Frequency Interference.**

The SIGMA Spectrum Infusion System meets the electromagnetic compatibility (EMC) requirements as specified in the International Electrotechnical Commission's (IEC) 60601-1-2 (2001-09) standard for emissions and immunity. There may be potential difficulties if the Pump is not kept separated from other equipment, such as hand-held transmitters, cellular phones and electrosurgical equipment that may generate strong radio frequency interference (RFI). See "Immunity – Separation Distances" on page 153 for the recommended minimum distance.

Procedural Cautions

CAUTION **Service Personnel Must be Trained by Baxter.**

Servicing the SIGMA Spectrum Infusion Pump is restricted to qualified, Baxter trained, service personnel who employ Baxter authorized parts and procedures. Use of other parts and servicing procedures is prohibited.

CAUTION **Sequester Pumps Pending Evaluation.**

Devices that are believed to have malfunctioned and/or were involved in an adverse event should be immediately removed from service and quarantined pending their evaluation and/or returned to Baxter for inspection and service.

CAUTION

Follow Physicians Orders.

Federal (USA) law restricts this device to sale by or on the order of a physician or other licensed practitioner.

CAUTION

BASIC Programming Use.

BASIC programming should only be used when the desired drug or concentration is not available in the facility's Drug Library.

CAUTION

Accuracy.

Refer to trumpet curves for flow rate accuracy as a function of short infusion durations. See Appendix B: "Flow Rate Accuracy" on page 142.

- The upstream occlusion detector may not detect partially occluded tubing.
- Always check to ensure the IV set's clamp is not closed above the Pump and respond appropriately to all primary and secondary check flow prompts.
- Small bore catheters or needles may cause excessive back pressure at high flow rates.
- Size the catheters according to expected flow rate and fluid viscosity.

CAUTION

Upstream Backcheck Valve Use

When connecting a secondary, ensure the primary administration set contains an upstream backcheck valve.

CAUTION

Pump Orientation.

- Always orient the Pump vertically on the IV pole, with the slide clamp keyhole at the top of the Pump.
- Only program the Pump in the upright position.

CAUTION

Use Stable IV Poles.

Mount Pumps on IV poles that securely hold the Pump.

CAUTION

Keypad Usage.

- Only program the device with the pad or tip of a finger.
- Do not use sharp objects to depress keys, such as the tip of a pen or the edge of an ID badge. Doing so may damage the Pump making the keys inoperable.

- If keypad malfunctions, discontinue use immediately and sequester Pump pending inspection.

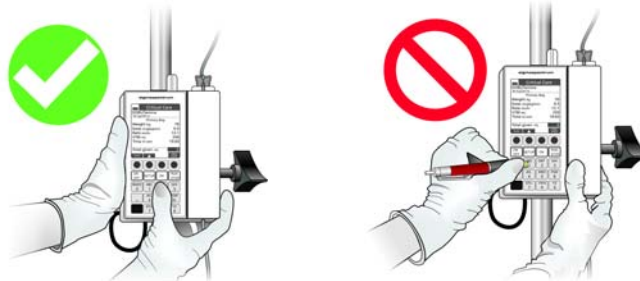


Figure 1. Correct and Incorrect Keypad Usage.

CAUTION Confirm Audio Operation.

Listen for beeps when pressing keys. If sound is not heard, discontinue use of the Pump and refer servicing to qualified service personnel at your facility or return the Pump to Baxter for service.

CAUTION Confirm Display Operation.

Regularly observe the Pump's display. If display abnormalities are observed, discontinue use of the Pump and refer servicing to qualified service personnel at your facility or return the Pump to Baxter for service.

CAUTION Unrecoverable System Error.

If unable to clear a fault condition during a system error occurrence, discontinue using the Pump. Refer to qualified service personnel at your facility or return the Pump to Baxter for service.

CAUTION Handle AC Power Adaptor With Care.

- Do not drop the AC Power Adaptor. It is an electronic device and may break if dropped.
- Do not twist or pull the AC Power Adaptor or cord at an angle. This could bend the prongs.
- Do not unplug the AC Power Adaptor by pulling on the power cord.

- Do not connect two or more AC Power Adaptors side by side (narrow side touching) on a power strip.

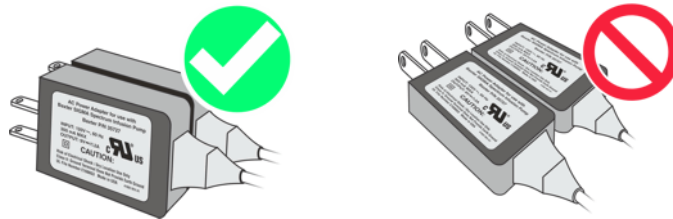


Figure 2. Correct and Incorrect AC Power Adaptor Placement.

CAUTION Entanglement.

Always route IV set tubing and AC Power Adaptor cabling to prevent patient hazard or entanglement. Use the supplied strap to secure excess power cord length. Identify the individual IV set lines when multiple Pumps and routes of administration are practiced.

CAUTION Maintain Battery Charge.

To maintain battery charge, keep the Pump's AC Power Adaptor plugged into a powered outlet whenever possible, including when the Pump is not in use.

CAUTION Avoid Bright Natural Sunlight or Artificial Overhead Light.

Bright Light (equivalent to greater than or equal to 100 watt incandescent bulb) within 30.5 cm (1 ft) above the Pump's keyhole (load point #1) may affect the Pump's ability to recognize the blue slide clamp during set loading. To prevent alarms or continuous system errors:

- Increase the distance between the Pump and the light source.
- Move the Pump to an adjacent location.

CAUTION Avoid Overheating.

When operating the Pump, keep out of bright sunlight or direct heat sources to prevent overheating.

CAUTION Static Sensitive Equipment.

- Wherever possible, eliminate any electro-static producing materials or conditions (dry, low humidity, synthetic materials such as blankets, carpeting, drapes, and so forth).
- The Pump is ESD sensitive when the Battery Module is removed.

CAUTION Oxygen Enriched Environment.

This equipment is not suitable for use in the presence of a Flammable Anesthetic Mixture with Air or with Oxygen or Nitrous Oxide.

NOTE: This statement applies to oxygen enriched environments, such as oxygen tents. It is not meant to apply to patients on breathing tubes. Refer to IEC-60601-2-24.

CAUTION **ECG Artifacts Related to the Use of the SIGMA Spectrum Infusion System.**

Peristaltic infusion Pumps may produce what is known as piezoelectric artifact on ECG monitors and similar types of monitoring instruments. The SIGMA Spectrum Infusion System may produce this effect when the Pump is running at rates in the higher ranges of operation, this may be in the frequency range tracked by the ECG monitor. The appearance of the artifact may be affected by set up and/or connection of electrodes, leads or equipment. See the ECG monitoring system documentation for recommendations on proper set up including electrode connections, site preparation, monitor system set up and electrode placement.

CAUTION **Recyclable Battery Pack. Dispose of Properly.**

The SIGMA Spectrum Infusion System contains a lithium-ion rechargeable battery pack and a replaceable battery cell. Improper disposal can result in hazards to humans or environmental conditions.

- Do not dispose of batteries in trash or in fire. These batteries are recyclable and should be disposed of properly.
- Contact an authorized disposal center or return battery to Baxter for disposal if an authorized disposal center cannot be found.

CAUTION **Cleaning the Pump and Pump Accessories.**

- Always wear gloves when cleaning Pump and Pump accessories.
- Only use Baxter specified compatible cleaning fluids.
- Do not allow fluid to seep inside the Pump (especially through the keyhole, door latches, or rear case speaker vent) or severe damage may occur.
- Do not spray solutions directly on the Pump and Pump accessories.
- Do not autoclave or EtO (ethylene oxide) to sterilize Pumps or Pump accessories.
- Do not apply cleaners directly to battery packs exposed terminals.
- Do not immerse any part of the Pump or battery.
- Do not use phenol-based cleaners/disinfectants. Phenols degrade plastics and membrane switches.
- Do not use abrasive cleaners.
- Do not use rigid cleaning instruments.
- Always use a lint-free, foam tipped swab to clean the tube channel.

- Always dispose of all cleaning materials per federal, state and local regulations for biohazard waste disposal.

CAUTION

Perform Preventive Maintenance Annually.

Pumps should be tested for proper performance annually and also whenever damage from drops, fluid intrusion and other causes is suspected. See *SIGMA Spectrum Infusion System Service Manual (P/N 41019v0800)* for complete information.

SYSTEM COMPONENTS

The SIGMA Spectrum Infusion System is comprised of the following components:

- SIGMA Spectrum Infusion Pump (P/N 35700BAX2)
- Pole Clamp (P/N 35712) or Double Rotating Pole Clamp (P/N 34743)
- AC Power Adaptor (P/N 35727)
- Standard Battery (P/N 35724) or Wireless Battery Module 802.11 b/g (P/N 35162)
- Master Drug Library (MDL) software used by pharmacists to establish which drug may be administered by the infusion pump, along with associated Care Areas and infusion delivery parameters for each drug.
- *SIGMA Spectrum Infusion System Master Drug Library User Manual*
- *SIGMA Spectrum Infusion System Operator's Manual (P/N 41018v0800)*
- *SIGMA Spectrum Infusion System Service Manual (P/N 41019v0800)*

SIGMA Spectrum Infusion System Illustrations

The illustrations in this section present the various features of the SIGMA Spectrum Infusion System. The illustrations are:

- Front view of the SIGMA Spectrum Infusion Pump.
- Front view of the SIGMA Spectrum Infusion Pump with the door open.
- Rear view of the SIGMA Spectrum Infusion Pump without battery.
- Rear view of the SIGMA Spectrum Infusion Pump with battery installed.
- The screen display features of the SIGMA Spectrum Infusion System.

SIGMA Spectrum Infusion Pump, Front View

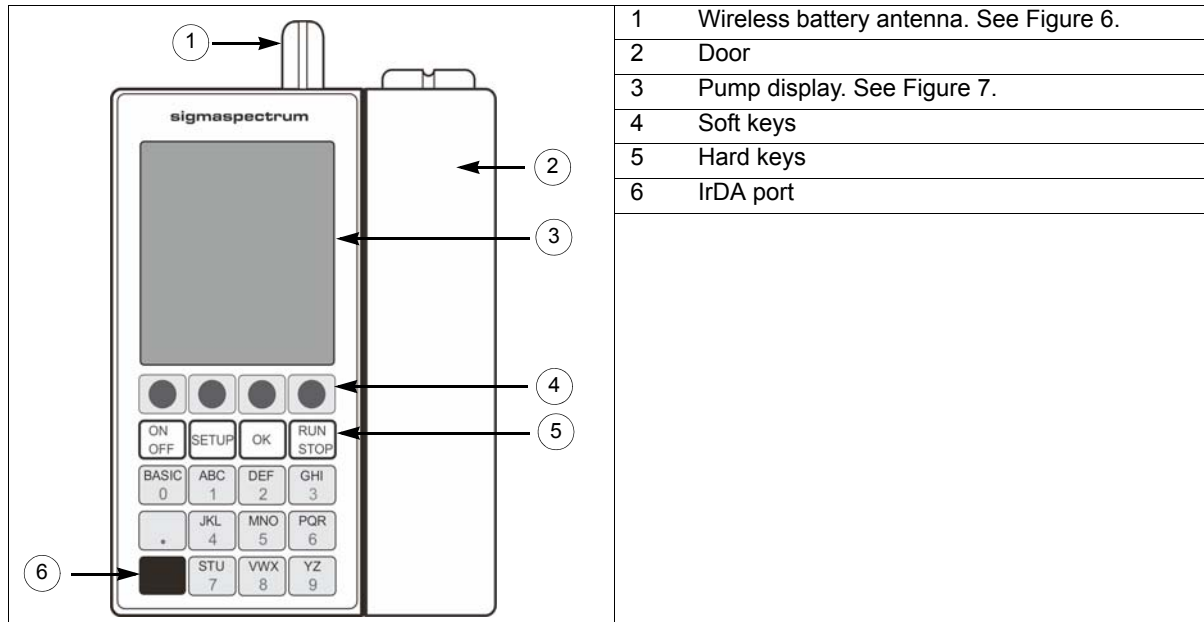


Figure 3. SIGMA Spectrum Infusion Pump, Front View.

SIGMA Spectrum Infusion Pump, Front View with Door Open

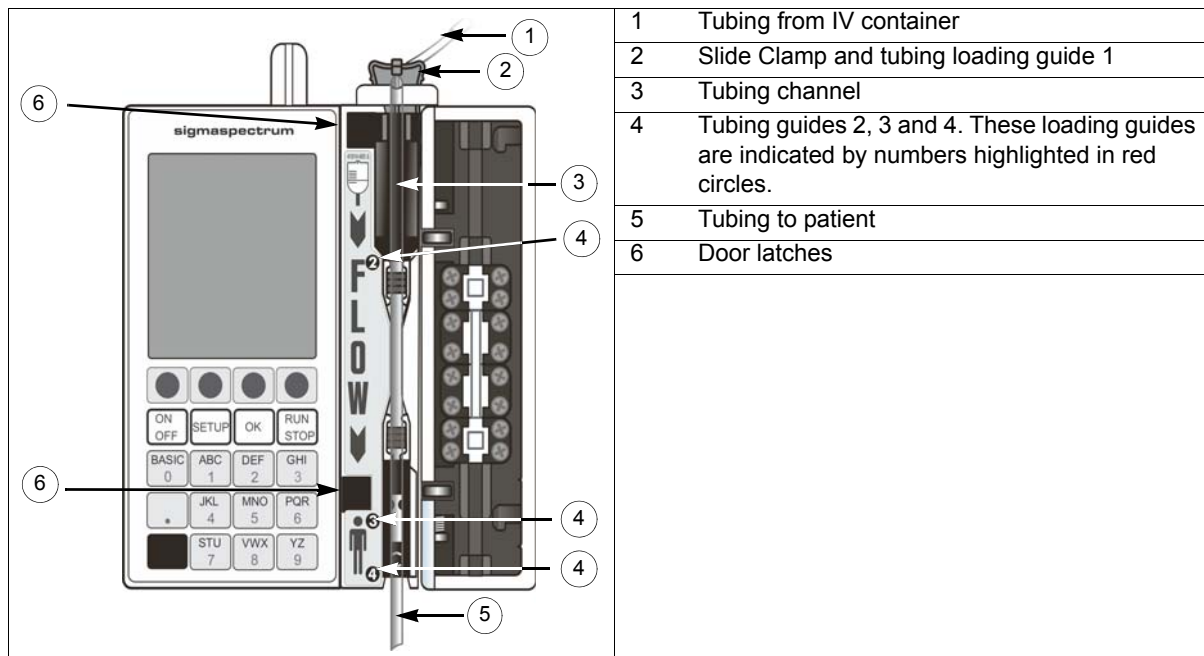


Figure 4. SIGMA Spectrum Infusion Pump, Front View with Door Open.

SIGMA Spectrum Infusion Pump, Rear View Without Battery

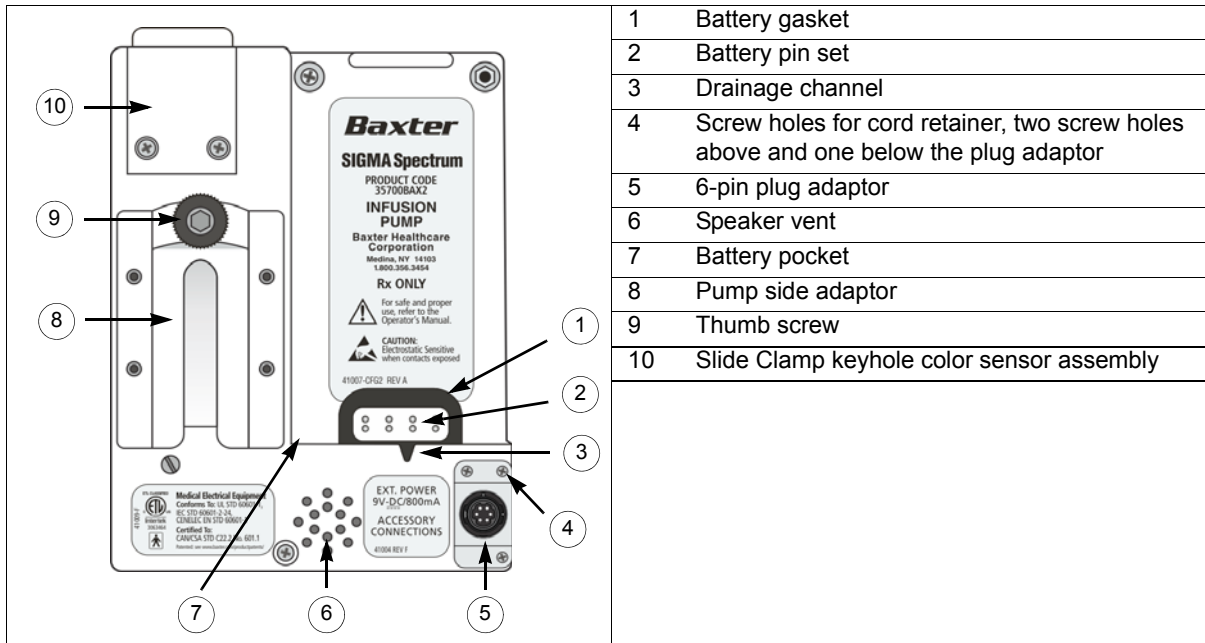


Figure 5. SIGMA Spectrum Infusion Pump, Rear View without Battery.

SIGMA Spectrum Infusion Pump, Rear View with Battery Installed

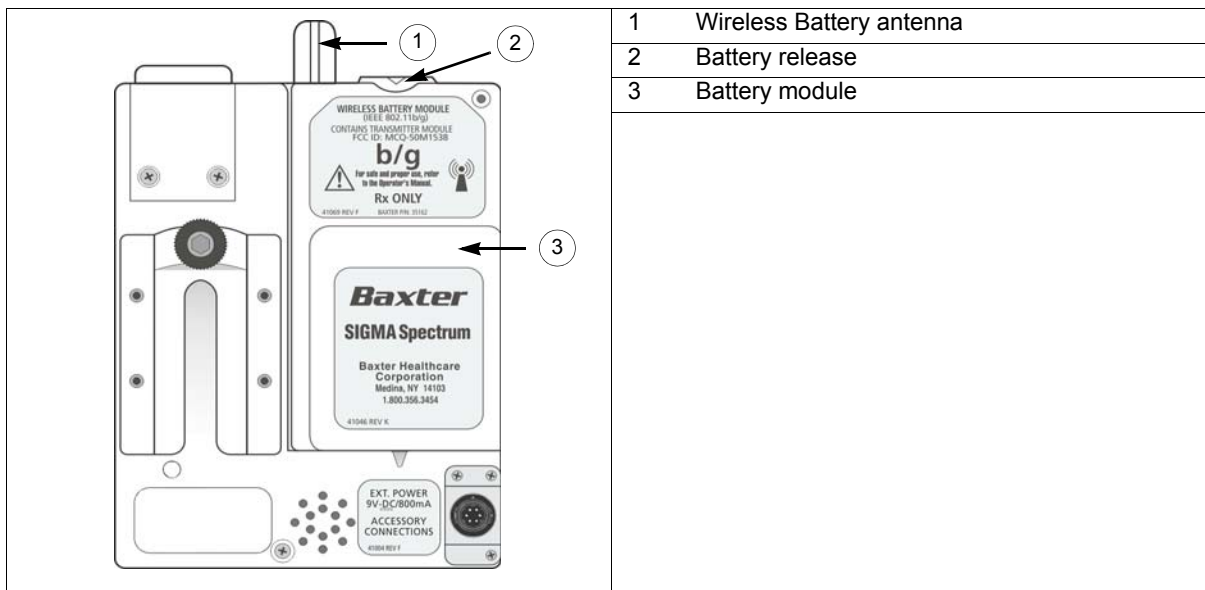


Figure 6. SIGMA Spectrum Infusion Pump, Rear View with Battery Installed.

SIGMA Spectrum Infusion Pump Display Features

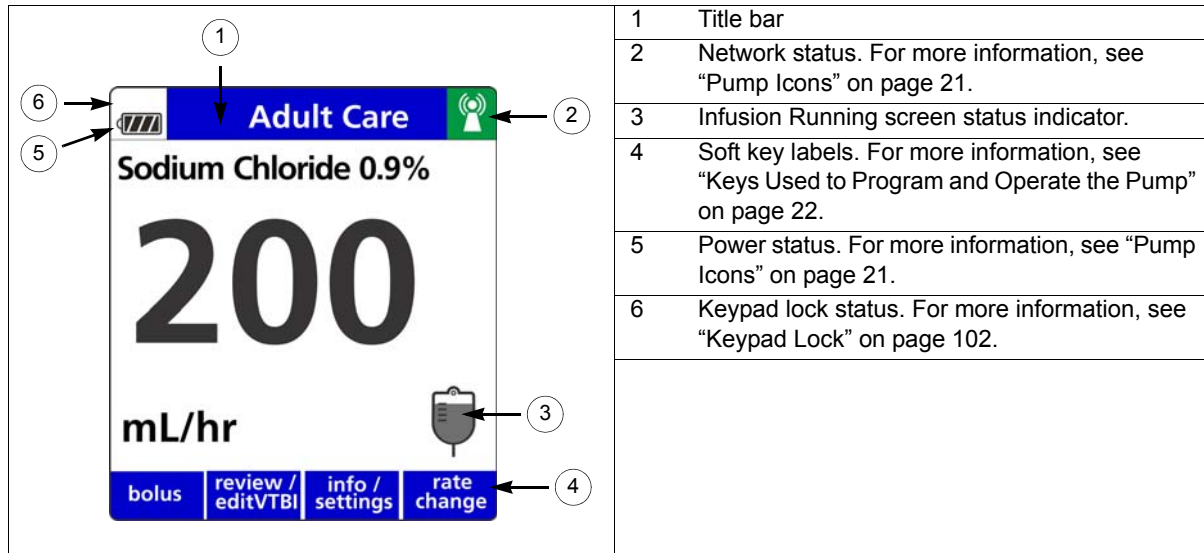
















Figure 7. SIGMA Spectrum Infusion Pump Display Features.

Pump Icons

| | | | | | |
|---|--|--|---|--|---|
|  | Battery is low or very low (Red battery). |  | Battery is 25% charged. |  | Battery is 50% charged. |
|  | Battery is 75% charged. |  | Battery is 100% charged. |  | Battery is installed and the AC Adaptor is connected. On Pumps with Wireless Battery Modules, alternates with one of the battery level icons. |
|  | Battery is depleted or missing (Red battery). |  | AC Adaptor is connected with no battery installed. Alternates with the battery is depleted or missing icon. |  | Initializing the wireless network (Red background). |
|  | Searching for the network and host (Yellow background). |  | Connected to the network (Green background). |  | Network disabled or Wireless Battery Module removed (Gray background). |
|  | Network module error (inverting Red and White background). |  | A new Drug Library has been received and is ready for activation. |  | Keypad is locked. |
|  | Setting has been assigned in the Master Drug Library to the currently selected drug. |  | Callback feature is active. |  | Secondary infusion is active. |
| | |  | Primary infusion is active. | | |
|  | The AC Adaptor is connected and the Wireless Battery Module is being charged. Battery segments (bars) indicate battery charge level (Black battery; White background). |  | Standard Battery is being charged (Black battery; White background). | | |
|  | Wireless Battery Module is fully charged (Black battery with a plug inside; Green background). |  | Battery Error. An error code number may also be displayed. For a description of the error code, refer to the <i>SIGMA Spectrum Infusion System Service Manual (P/N 41019v0800)</i> (Red battery). | | |
|  | AC power is supplied and Battery pack is not installed (Black battery). |  | Initial Pump screen when AC power is supplied and the Pump is powered off. Battery charger is determining the current status of the installed battery (Black battery). | | |

Keys Used to Program and Operate the Pump

Soft Keys

The top row of keys on the keypad are non-labeled keys with various functions, depending on what is displayed on the screen above them.

| Soft Keys | Description |
|---|--|
| Arrows | Press to advance cursors and/or select alternate choices. |
| back | Press to go back to the previous screen. |
| bolus | Press to access the Bolus setup. |
| cancel <label> | Press to cancel indicated <label>. |
| clear <label> | Press to erase the highlighted entry. |
| clear program | Press to selectively clear Primary mode, Secondary mode or both. |
| clr step | Press to clear one step of Multi-Step Programming mode. |
| confirm | Press to confirm prompt. |
| edit | Press to change the flush or priming volume on the flush setup screen. <i>NOTE:</i> This feature is available for Amount/Time only. |
| hold | Press to place the Pump in Standby mode. |
| info/settings | Press to select additional Pump features related to alarm settings, display settings or information view. |
| multi-step | Press to access the Multi-Step Programming mode. |
| no | Press to indicate a negative acknowledgement of a prompt. |
| options menu | Press to access the User Options and Biomed Options selection menu. |
| program pri/sec | Press to display the Setup screen when Pump is stopped. |
| program secndry | Press to set up a Secondary infusion. |
| rate change or dose change | Press to change the flow rate without stopping the Pump. |
| reset program | Press to restart the multi-step and Cyclic TPN programs to the beginning of the program. |
| review | Press to view the Setup screen without stopping the Pump or when the Pump is stopped. |
| review PRIMARY or review SECONDARY | Press to view values in the Setup screen. |
| review/edit VTBI | Press to display the Setup screen and make any necessary edits to the VTBI value when the Pump is running. |

| Soft Keys | Description |
|-------------------|---|
| silence | Press to quiet the audio alarm for 2 minutes. Additionally, any key can be pressed for silence. |
| taper down | Press to enable a Cyclic TPN program to taper down automatically. |
| yes | Press to indicate a positive acknowledgement of a prompt. |















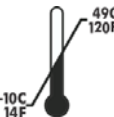

Hard Keys

The bottom four rows on the keypad are the hard keys.

| Hard Keys | Description |
|--|---|
| BASIC (Zero key) | Displays the BASIC Mode CAUTION screen informing the user that BASIC Mode operation does not observe library limits. During programming, this key allows entry of the number zero. |
| ALPHANUMERIC (1-9, A-Z and the decimal point key) | Programming screens enable numbers and drug selection screens enable letters. Press alphanumeric keys once, twice, or three times to select corresponding letters or numbers. |
| OK | Press to confirm entries and advance cursors. |
| ON/OFF | Press to power the Pump on or off. |
| RUN/STOP | Press to start or stop the infusion. |
| SETUP | Press to access drug selection screen from a programming screen or the Pump STOP screen. |

Symbols

Symbols used on the SIGMA Spectrum Infusion System and packaging:

| | | | |
|---|---|---|---|
| Rx ONLY | Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician or other licensed practitioner. | IPX0 | IP code is the degrees of protection provided by an enclosure. IPX0 indicates the enclosure does not protect against ingress of water with harmful effects. |
|  | Consult accompanying documents. Read all instructions before using (ISO 15223-1). |  | CLASS II EQUIPMENT (IEC 60417-5172) |
|  | TYPE BF APPLIED PART (IEC 60417-5333) |  | Direct Current (IEC 60417-5031) |
|  | Alternating Current (IEC 60417-5032) |  | Recyclable, dispose of properly (ISO 7000-1135) |
|  | Non-ionizing electromagnetic radiation (IEC 60417-5140) |  | Intertek ETL Listed (Canada & USA) |
|  | Certified by UL to both Canadian and U.S. requirements |  | Shipping Label - This Way Up |
|  | Shipping Label - Fragile |  | Shipping Label - Humidity Sensitive Equipment |
|  | Shipping Label - Keep Away From Rain |  | Shipping Label - Keep Away From Sunlight |
|  | Shipping Label - Temperature Sensitive Equipment |  | Electrostatic Sensitive when contacts exposed |

NOTE: The SIGMA Spectrum Infusion System enclosure holds IPX0 rating. Protection from spillage and leakage was evaluated per the applicable requirements of IEC 60601-2-24.

Labels

Labels used on the SIGMA Spectrum Infusion System.

NOTE: The actual label may vary with laser mold.



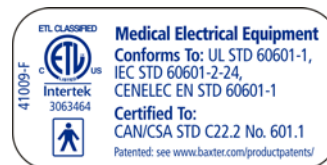
Direction of Flow



Company ID
Located on the back of the Pump case.



Power
Located on the back of the Pump case.



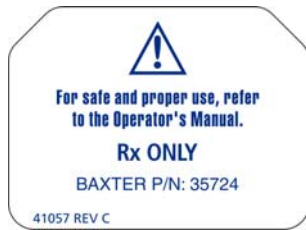
Certification *
Located on the back of the Pump case.



Serial Number
Located on the bottom of the Pump case.



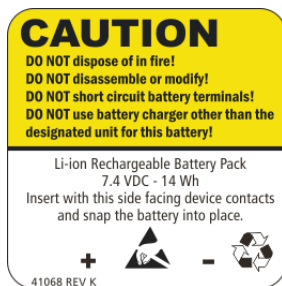
Tubing ID
Located on the top of the Pump case.



Standard Battery
Located on the back of the battery module.



Wireless Battery 802.11b/g
Located on the back of the battery module.



Battery Caution
Located on the front of the battery module.



Company ID
Located on the back of the battery module.



Wireless Battery Module
Located on the side of the battery module.



Field Serviceable (Optional)
Located on the bottom of the Pump case.
Direction on field serviceability for Pumps with and without the field serviceable label is provided during technical training school.



Intertek Certification Label *
Located on the bottom of the front Pump case.



Rebuilt Certification Label *
Located on the bottom of the front Pump case.

* The Certification Label used will vary depending on the Pump configuration.

BATTERY COMPATIBILITY

The following battery types are compatible with all SIGMA Spectrum Infusion Systems:

- P/N 35724 - Standard Battery Module
- P/N 35162 - 802.11b/g Wireless Battery Module

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference and (2) This device must accept any interference received, including interference that may cause undesired operation.

Battery Replacement

CAUTION Recyclable Battery Pack. Dispose of Properly.

The SIGMA Spectrum Infusion System contains a lithium-ion rechargeable battery pack and a replaceable battery cell. Improper disposal can result in hazards to humans or environmental conditions.

- Do not dispose of batteries in trash or in fire. These batteries are recyclable and should be disposed of properly.
- Contact an authorized disposal center or return battery to Baxter for disposal if an authorized disposal center cannot be found.

Replacement batteries may be obtained from the manufacturer. Contact Baxter Technical Support. See "Contacting Baxter Technical Support" on page 1.

Battery Maintenance

For battery maintenance information, refer to the *SIGMA Spectrum Infusion System Service Manual (P/N 41019v0800)*.

SERVICING SIGMA SPECTRUM INFUSION SYSTEM

CAUTION Service Personnel Must be Trained by Baxter.

Servicing the SIGMA Spectrum Infusion Pump is restricted to qualified, Baxter-trained, service personnel who employ Baxter authorized parts and procedures. Use of other parts and servicing procedures is prohibited.

CAUTION Perform Preventive Maintenance Annually.

Pumps should be tested for proper performance annually and also whenever damage from drops, fluid intrusion and other causes is suspected. See *SIGMA Spectrum Infusion System Service Manual (P/N 41019v0800)* for complete information.

To check the correct functioning of alarms and operational safety of the device, have preventive maintenance performed by qualified service personnel.

Refer to the *SIGMA Spectrum Infusion System Service Manual (P/N 41019v0800)* or contact Baxter Technical Support for Pump service needs; including circuit diagrams, component part lists, descriptions, calibration instructions, or other information. See "Contacting Baxter Technical Support" on page 1.

SETTING UP THE PUMP

Unpacking the Pump

The SIGMA Spectrum Infusion System is packaged to provide protection to the Pump during transportation and storage.

To unpack the Pump:

1. Remove the SIGMA Spectrum Infusion Pump from the protective anti-static bag, and remove the protective foam end caps.
2. Save all packaging materials for reuse. This is advised in the event that product repair or warranty replacement is necessary.
3. Discard the desiccant package.
4. A battery tab isolates the battery voltage from the Pump during transportation and distribution. Remove the tab prior to charging the Pump's battery or operating the Pump. To remove the battery tab, pull the tab away from the Battery pocket. See Figure 8.

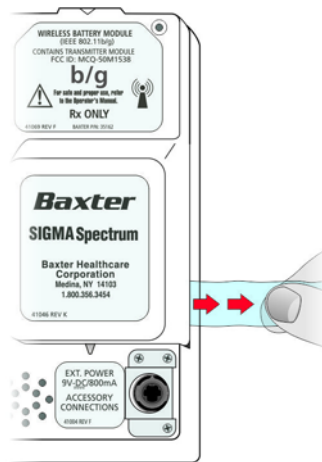


Figure 8. Battery Tab.

NOTE: Ensure that the battery is fully charged prior to use. For more information, see “Connecting and Disconnecting the AC Power Adaptor” on page 30 and “Charging the Battery” on page 31.

Connecting and Disconnecting the AC Power Adaptor

When plugged into a powered wall outlet, the AC Power Adaptor charges the Pump's battery. The AC Power Adaptor has a locking cord connection to prevent inadvertent disconnection from the Pump.

WARNING Only Use the AC Power Adaptor Specified for this Equipment.

Using other AC Power Adaptors may cause personal injury or damage to equipment.

CAUTION Handle AC Power Adaptor With Care.

- Do not drop the AC Power Adaptor. It is an electronic device and may break if dropped.
- Do not twist or pull the AC Power Adaptor or cord at an angle. This could bend the prongs.
- Do not unplug the AC Power Adaptor by pulling on the power cord.
- Do not connect two or more AC Power Adaptors side by side (narrow side touching) on a power strip.

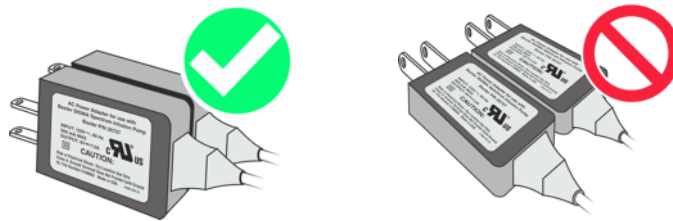


Figure 9. Correct and Incorrect AC Power Adaptor Placement.

To connect the AC Power Adaptor:

1. Plug the AC Power Adaptor into a 120 VAC wall outlet.
2. Confirm that the green LED on the AC Power Adaptor is lit. See Figure 10.



Figure 10. AC Power Adaptor P/N 35727.

3. Verify that the plug icon appears on the Pump display. See Figure 11.



Figure 11. External Power Icon.

If the icon does not appear, do not use the Pump and have it serviced.

To disconnect the AC Power Adaptor:

- » Pull the AC Power Adaptor away from the outlet in a straight direction.

Charging the Battery

WARNING Low Battery.

Do not use battery operation or transport a patient when the Pump is in a low battery state.

WARNING Battery Handling.

- Do not short circuit battery terminals.
- Do not disassemble or modify battery packs.
- Do not dispose of batteries or battery pack in fire.

WARNING Battery Removal.

- Do not detach the battery during patient therapy.
- Never touch the patient and the Pump at the same time with the battery removed and the Pump connected to the power outlet.

WARNING ESD Sensitivity.

Do not touch the battery pin set when the Battery Module is removed.

CAUTION Maintain Battery Charge.

To maintain battery charge, keep the Pump's AC Power Adaptor plugged into a powered outlet whenever possible, including when the Pump is not in use.

CAUTION Recyclable Battery Pack. Dispose of Properly.

The SIGMA Spectrum Infusion System contains a lithium-ion rechargeable battery pack and a replaceable battery cell. Improper disposal can result in hazards to humans or environmental conditions.

- Do not dispose of batteries in trash or in fire. These batteries are recyclable and should be disposed of properly.
- Contact an authorized disposal center or return the battery to Baxter for disposal if an authorized disposal center cannot be found.

The Pump's battery is charging whenever the AC Power Adaptor is plugged into a powered outlet and is connected to the Pump. It is not necessary to power on the Pump to charge the battery.

Ensure that the battery is fully charged prior to first use. The approximate time to initially charge the battery is as follows:

- Standard Battery charge time: 12 hours
- Wireless Battery Module charge time: 16 hours

For battery power and capacity specifications, see Appendix A: "Specifications" on page 135.

For a list of the icon symbols used and their descriptions, see "Pump Icons" on page 21.

Configuring User Options

The SIGMA Spectrum Infusion System has two sets of configuration options:

- User options
- Biomed options

For a description of the Biomed options, refer to the *SIGMA Spectrum Infusion System Service Manual (P/N 41019v0800)*.

WARNING Operation is Limited to Trained Operators.

SIGMA Spectrum Infusion Pump operation is strictly limited to trained operators who are competent in safe SIGMA Spectrum Infusion Pump operation and in safe IV therapy practices. Pump owners have sole responsibility for operator training and testing even when Baxter personnel assist in training processes.

To access the User Options menu:

From the Care Area selection screen:

1. Press the **options menu** soft key.
2. Select **User Options** from the menu and press **OK**.

From the RUN or STOPPED screen:

- » Press the **info settings** soft key.

The User Options menu has three categories, which are described in the sections that follow:

- Alarm Settings
- Display Settings
- View Information

Alarm Settings

- **Audio Volume.** The audio volume of the Pump has three levels: LOW, MEDIUM and HIGH. To adjust the Audio Volume, use the arrow soft key to select the desired volume level and press **OK**.

Audio Volume may be preset in the Master Drug Library. The default setting is "Use Pump Setting", which is adjustable at the Pump.

- **Audio Tone.** The audio tone has two settings: short and long. To adjust the audio tone, use the arrow soft key to select the desired tone and press **OK**.
- **Standby (hr:min).** Set the length of time to keep the Pump in Standby (or Hold) after setup of the infusion has been completed. Settings are from 00:01 to 99:59 (hr:min). Setting the value to 00:00, or Infinite, results in an infinite Hold period.
- **Near Empty alert.** When enabled, a Near Empty alert is displayed when 30 minutes or less of infusion remains. If the initially-programmed infusion is less than 30 minutes, the alert is not generated, regardless of the setting.

Near Empty alert has three options in the Drug Library: On, Off and "Use Pump Setting". The default setting is "Use Pump Setting", which is adjustable at the Pump.

- **DS Pressure Limit (Downstream Occlusion Pressure Limit).** The DS Pressure limit has three levels:
 - Low, 41 kPa \pm 27 kPa (6 \pm 4 psi)
 - Medium, 89 kPa \pm 41 kPa (13 \pm 6 psi)
 - High, 131 kPa \pm 62 kPa (19 \pm 9 psi)

To adjust the DS Pressure Limit, use the arrow soft key to select the desired level and press **OK**.

The default Pressure Limit may be preset for a Care Area in the Drug Library. The default setting is "Use Pump Setting", which is adjustable at the Pump.

NOTE: An icon is displayed next to any configuration item in the Options menu (User or Biomed) where the setting has been assigned in the Drug Library. See Figure 12.



Figure 12. MDL Icon.

Display Settings

- **Run Screen Options.** Each of the items in this list may be set to On or Off. If enabled, they are included in the alternating screens that are displayed while the Pump is running.
 - Audio level indicator – Shows L, M, or H (as selected in Audio Volume).
 - Rate mL/hr – Shows the mL/hr infusion rate of the current delivery.
 - Dose rate – Shows the dose rate of the current delivery.
 - mL VTBI – Shows the remaining Volume To Be Infused, in mL.
 - Time (hr:min) – Shows the time remaining in the current infusion, in hr:min format.
- **Display Adjust.** The display backlight brightness level may be adjusted from 1 to 10 (10 being the highest) or set to Off. The backlight consumes approximately 400 mW when set to maximum brightness; therefore, battery life is maximized when the backlight is set to Off.

To adjust display brightness:

1. Access the User Options menu screen:
 - From the Care Area selection screen, press the **options menu** soft key. Then use the arrow soft keys to select **User Options** and press **OK**.
 - From the Infusion Running screen, press the **info settings** soft key.
2. Using the arrow soft keys, select **Display Settings** and press **OK**. The Display Settings menu screen appears.
3. Using the arrow soft keys, select **Display Adjust** and press **OK**. The Display Adjust screen appears.
4. Using the arrow soft keys, raise or lower the brightness to the desired level.
5. After selecting the desired brightness level, press **OK** to save the level and exit the Display Adjust screen.
6. Press the **exit** soft key as needed to return to the Care Area selection screen or Infusion Running screen.

View Information

- **Pump Information.** The Pump Information screen shows the following read-only information:
 - SW (software) Version
 - Serial number – The serial number assigned by Baxter for tracking and device history.

- Tube type – The name of the IV tube set manufacturer that the device is calibrated for use with.
- Wireless Module

From the Pump Information screen, press the **sw info** soft key to display the Software Version screen, which shows the versions of the individual software components that are installed.

- SW Version
 - Sharp
 - PIC
 - CPLD
 - SmartBatt Charger build
 - Network Module
- **Library Information.** The Library Information screen identifies the name of the Active Drug Library in Pump memory as well as the Name, Date Modified, Version Number, Format Indicators, Drugs, Care Areas and Advisories (or modifiers, depending on MDL version).
 - **Show Clinical Advisory.** If the current infusion has a clinical advisory associated with it, selecting this option will display the advisory. If the current infusion does not have a clinical advisory associated with it, this option is not selectable and appears in grey text in the display.
 - **Infusion Information.** The Infusion Information screen identifies the infusion-specific primary and secondary bag parameters that are not otherwise displayed on the Setup screen. The information includes the following information for each bag (if programmed): audio level, Near-Empty Alert status (primary only), pressure setting, KVO rate (primary only) and primary siphoning alert or secondary complete alert status (secondary only).
 - **History Log.** Selecting this option provides access to the event log. Available options for viewing the log are listed below.

NOTE: Access to this option is provided only when the Pump is not running (delivering). If the Pump is running, this option is not selectable and appears in grey text in the display.

- View History Log – Select this option to view the entire history log on the Pump screen.
- View System Error Log – Select this option to view only the system errors recorded in the history log.
- View Drug Error Log – Select this option to view only the events associated with programming an infusion; including any drug limits that may have been exceeded during setup.
- Dump History Log – Select this option to send the entire history log out of the Pump using the IrDA port. Refer to the Logging section of the *SIGMA Spectrum Infusion System Service Manual (P/N 41019v0800)*.

PREPARING THE PUMP AND IV SETS

Mounting the Pump on an IV Pole

To mount the Pump on an IV pole:

WARNING Ensure Secure Mounting of Pump During Use and Transport.

During use and transport, securely mount Pumps to IV pole by centering the pole in the clamp and turning the mounting knob clockwise. To maintain IV pole stability, never exceed 210 cm (83 in) from floor to IV pole top and limit bag volume at this extended height to <1 liter (1000 cc).

CAUTION Use Stable IV Poles.

Mount Pumps on IV poles that securely hold the Pump.

CAUTION Pump Orientation.

- Always orient the Pump vertically on the IV pole, with the slide clamp keyhole at the top of the Pump.
- Only program the Pump in the upright position.

CAUTION Maintain Battery Charge.

To maintain battery charge, keep the Pump's AC Power Adaptor plugged into a powered outlet whenever possible, including when the Pump is not in use.

1. Mount the Pump on an IV pole by holding the Pump in one hand, centering the pole in the clamp and with the other hand, turning the mounting knob clockwise.

When using a three-pump carrier, avoid resting the Pump on the carrier plate. Attach to the center pole if no other Pumps are attached.

2. Plug the Pump's AC Power Adaptor into a powered outlet, if available.
3. Select a compatible IV set. See "Compatible IV Sets" on page 125.

NOTE: Select only IV sets made by the manufacturer listed on top of the Pump. IV sets must be of standard stiffness and diameter.

Preparing and Priming an IV Set

WARNING Use the Specified Manufacturer's IV Set.

A label located on the top of the Pump indicates the specific type of IV tubing that the Pump has been calibrated for. The use of other manufacturers' brands or type tubing could produce Pump inaccuracies that could be unsafe for patients.

WARNING

Priming.

Prior to connecting to patient, prime IV set following the standard gravity priming instructions included with the administration set, remove all air, close roller clamp and slide clamp, load IV set into the Pump, close the door, open slide clamp and roller clamp.

WARNING

IV Set Usage.

Do not use an IV set for longer than the manufacturer's labeled set change interval to reduce risk of infection and to maintain flow rate accuracy.

To prepare and prime an IV set:

1. Follow the instructions on the IV set package to spike and prime the set.
2. Hang the IV container, leaving a distance of 61 cm (24 in) between the top of the container and the center of the Pump.
3. Position and close the roller clamp 30.5 - 35.5 cm (12 - 14 in) below the upper Y injection site.
 - If there is no upper Y injection site, close the roller clamp 45.7 - 50.8 cm (18 - 20 in) below the drip chamber.
4. Spike the bag and fill drip chamber approximately halfway or to the fill IV line located within the drip chamber.
5. Prime the IV set by opening the roller clamp half way and slowly prime the tubing. As fluid is flowing, invert and tap the upper backcheck valve and Y injection sites until all air is removed.
6. When the IV tubing is completely primed, position and close the slide clamp halfway between the upper Y injection site and the closed roller clamp. Ensure the roller clamp is 45.7 - 50.8 cm (18 - 20 in) below the drip chamber.

Loading an IV Set

WARNING

Do Not Allow Uncontrolled Gravity Flow.

- Before loading a primed IV set, ensure the roller clamp below the Pump is in the closed position.
- To open the Pump door, the IV set's slide clamp must first be closed (thus providing "set-based anti-free flow" protection).
- Do not open the slide clamp when the door is open or during and after IV set unloading. This can cause dangerous, uncontrolled free flow to occur.
- During IV container changes, always close the set's roller clamp. When the set is in the Pump and the door is closed, the slide clamp can safely be opened. If gravity flow is to be used, the Pump door will be open or the set will be outside the Pump. Verify gravity flow is maintained at the intended rate whenever the Pump door is open and when the set is outside of the Pump.

CAUTION Accuracy.

Refer to trumpet curves for flow rate accuracy as a function of short infusion durations. See Appendix B: "Flow Rate Accuracy" on page 142.

- The upstream occlusion detector may not detect partially occluded tubing.
- Always check to ensure the IV set's clamp is not closed above the Pump and respond appropriately to all primary and secondary check flow prompts.
- Small bore catheters or needles may cause excessive back pressure at high flow rates.
- Size the catheters according to expected flow rate and fluid viscosity.

NOTE: Follow all loading steps as stated when reloading an IV set.

To load an IV set:

1. Inspect the section of the IV set below the slide clamp that is to be loaded or reloaded into the Pump. Ensure it is free of kinks, bends or creases.

WARNING Do Not Reuse Tubing.

Do not reload pumped-on tubing (the tubing segment previously used in the pumping channel) into the pumping channel. Doing so will cause alarms and adversely affect flow rate accuracy.

2. Press **ON/OFF** to power on the Pump.
3. Visually track the tubing from the drip chamber through the closed slide clamp.
4. Orient the slide clamp (with the tear drop cutout pointing down) and insert it into the keyhole (loading guide 1) at the top of the Pump. See Figure 13.



Figure 13. Inserting the Slide Clamp into Load Guide 1.

NOTE: Inserting the slide clamp properly is the only way to open the Pump door. Load guide 1 is the keyhole. The slide clamp must remain in the keyhole during the IV set loading and reloading. If the slide clamp is removed during set loading, the Pump will alarm and reloading the IV set will be required.

5. Press down until the door opens.
6. Continue to gently hold the slide clamp in the keyhole. The slide clamp must remain in the keyhole during set loading.

NOTE: Tubing should now be in front of the loading channel and not behind the door. See Figure 14.

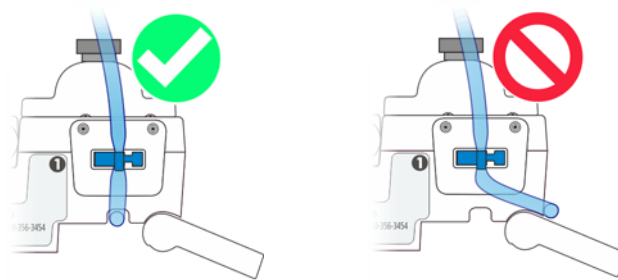


Figure 14. Slide Clamp Inserted at Load Guide 1 with Proper Tubing Placement.

WARNING IV Set Loading.

- Load tubing directly from the slide clamp to the top of the tubing channel. Confirm the tubing from the IV container enters the back of the slide clamp and exits the front of the slide clamp prior to loading the tubing section into the Pump channel.
- Improper or reverse IV set loading can result in a no flow condition to the patient, as well as possible back flow of blood from the IV set into the IV tubing and/or occlusion/air in line alarms.
- Follow the Direction of Flow diagram and screen prompts to load IV set tubing correctly.

7. Observe the Direction of Flow diagram, which is to the left of the pumping mechanism. See Figure 15.

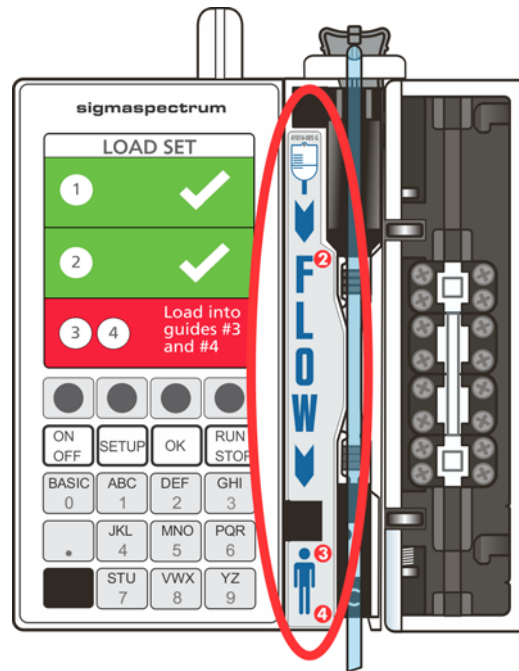


Figure 15. Direction of Flow Diagram.

8. Load the primed IV set tubing from the top to the bottom of the tubing channel.

NOTE: Before loading the tubing, ensure that the tubing channel is free of dirt and debris.

- Ensure that the tubing follows the Direction of Flow diagram.
 - Ensure that the tubing is routed from the front of the slide clamp directly into the top of the tubing channel.
 - Load the tubing without slack. This prevents the tubing from getting caught in the door or from being loose in the Pump.
 - Do not use excessive force when inserting the administration set into the channel.
9. Push the tubing into load guide 2 and confirm that the display is green for load guide 2. See Figure 15.
 10. Push the tubing into load guides 3 and 4 and confirm that the display is green for load guides 3 and 4.

The tubing is properly loaded when the screen displays three green bars and check marks for all four loading guides. See Figure 16.

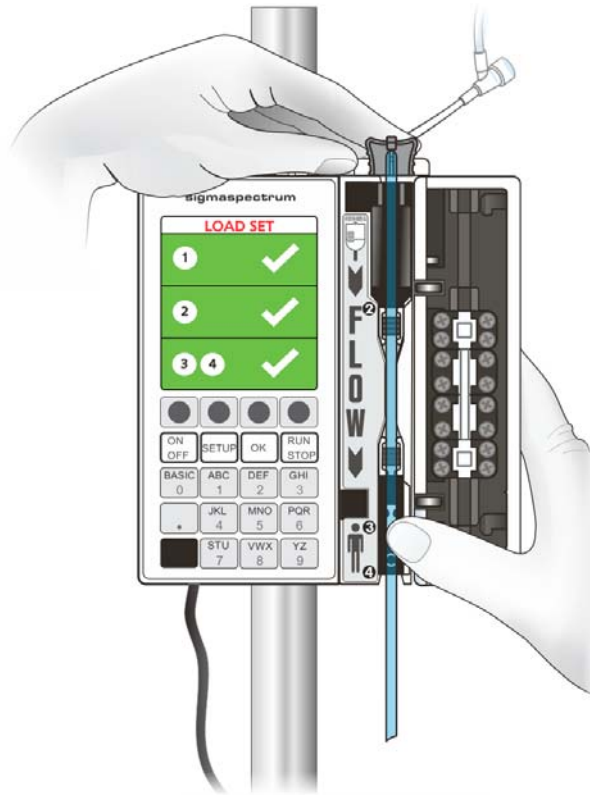


Figure 16. IV Set Loaded in the Tubing Channel.

11. Close the door by pressing the upper and lower corners near the door latches. See Figure 17.

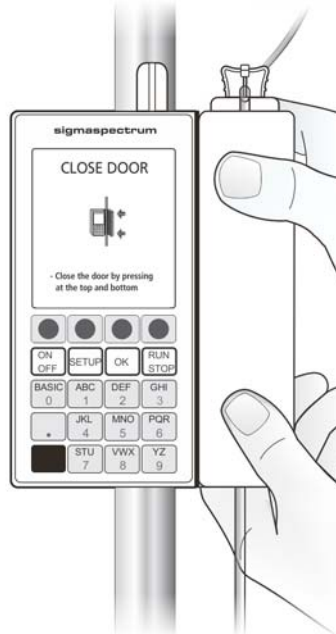


Figure 17. Proper Door Closing.

WARNING Bolus.

When the administration set is loaded, the door is closed and the slide clamp is removed, a fluid bolus will occur (maximum of 0.1 mL).

12. Remove and open the slide clamp from the keyhole by holding the tubing down on both sides of the keyhole with one hand and removing the slide clamp up and out with the other hand. The slide clamp is open when it moves freely on the tubing.

13. Open the lower roller clamp and confirm that no drops are flowing within the drip chamber. If drops are visible, remove the Pump from service. See Figure 18.

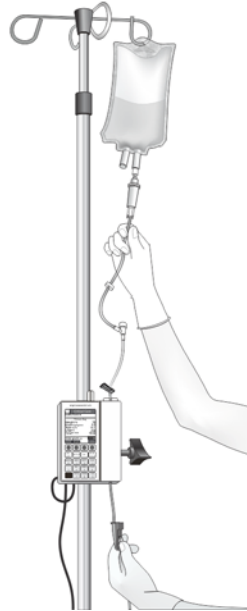


Figure 18. Open Roller Clamp.

14. Trace the IV line from the IV container to the Pump and from the Pump to the patient to confirm correct route.

NOTE: When using multiple Pumps, ensure that the IV lines are traced from the IV container to the Pump and from the Pump to the patient. Follow the facility's procedure for labeling IV tubing.

15. Attach the IV set to the patient access site.
16. Prime all additional IV sets or add-ons prior to attaching to the existing infusion.
 - If another IV set or add-on is added to the existing infusion below the Pump, the Pump is unable to detect any air that may be present in the additional IV lines.
 - If other infusions are added to an existing running infusion using separate IV sets below the Pump, the Pump's downstream occlusion pressure base IV line may be affected.
 - Always ensure that drugs using the same IV set are compatible with one another.

Unloading an IV Set

WARNING Unloading an IV Set.

- Do Not Allow Uncontrolled Gravity Flow.
- Before unloading a primed IV set, ensure the roller clamp below the Pump is in the closed position. To open the Pump door, the IV set's slide clamp must first be closed (thus providing "set-based anti-free flow" protection).
- Do not open the slide clamp when the door is open or during and after IV set unloading. This can cause dangerous, uncontrolled free flow to occur.
- During IV container changes, always close the set's roller clamp. When the set is in the Pump and the door is closed, the slide clamp can safely be opened.
- If gravity flow is to be used, the Pump door will be open or the set will be outside the Pump. Verify gravity flow is maintained at the intended rate whenever the Pump door is open and when the set is outside of the Pump.

To unload an IV set:

1. If the Pump is running, press **STOP** to stop the infusion.
2. Close the roller clamp to prevent free flow.
3. Push the slide clamp into the keyhole until the door opens.

NOTE: When opening the Pump door, use only the slide clamp on the tubing loaded into the Pump to prevent free flow. Use of a slide clamp from another IV set can cause dangerous, uncontrolled free flow to occur when the door is opened.

4. With the slide clamp resting in the keyhole, using one hand, pull the tubing out and up from the bottom of the Pump towards the top. This ensures the slide clamp will not be inadvertently opened when removed from the keyhole. See Figure 19.

NOTE: To prevent the slide clamp from inadvertently opening, do not unload the IV tubing from the top of the Pump.

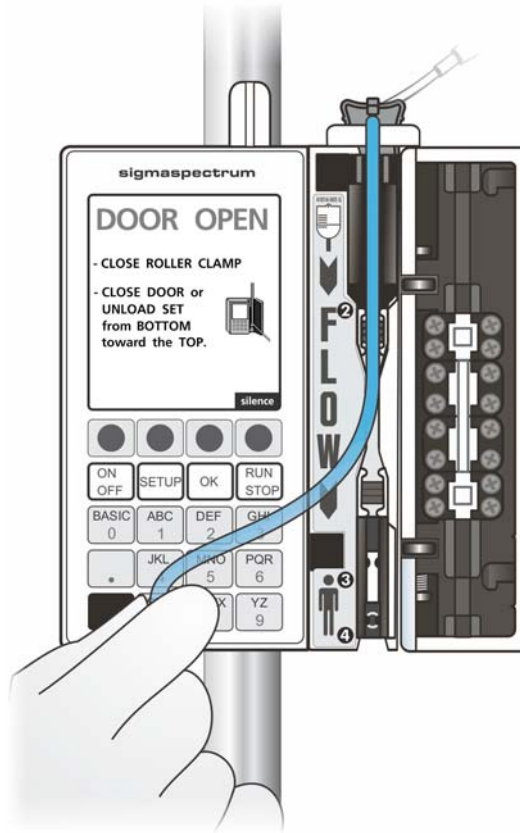


Figure 19. Remove the IV Set.

Secondary Infusion Setup

If the infusion is to include both a primary and a secondary bag and IV sets, follow these steps to set up the bags and the IV sets.

NOTE: The SIGMA Spectrum Infusion Pump does not infuse a primary and secondary infusion at the same time.

To prepare the Pump for a secondary infusion:

1. Prepare primary and secondary bags and IV sets.

WARNING **Air Bubbles.**

Failure to prime/remove all air bubbles from backcheck valves in primary sets may cause the valve to malfunction, resulting in secondary fluid flow back into the primary container.

CAUTION **Upstream Backcheck Valve Use**

When connecting a secondary, ensure the primary administration set contains an upstream backcheck valve.

2. Use a primary set with an upper Y injection site and backcheck valve.
3. Ensure the roller clamp on the secondary IV set is closed.
4. Connect the secondary set to the primary set's upper Y injection site. Lower the primary bag by fully extending the hanger approximately 50.8 cm (20 in) below the secondary bag. This provides the secondary bag with a gravity advantage. It also causes the primary set's backcheck valve to close.

NOTE: Secondary bag height must be 61 cm (24 in) from the top of the secondary bag to the center of the Pump.

5. Confirm proper vent position, if applicable.
6. To program the secondary infusion, see "Secondary Infusion" on page 58.

PROGRAMMING THE PUMP

Pump Safety Features

- **Dose Error Reduction System (DERS)**

This system uses predetermined dosing information stored in the facility's configured Drug Library to control the dose, rate, volume, time and other infusion parameters for specific drugs. Programming using this method may reduce the risk of programming errors.

- **Primary Check Flow Error Prevention**

(does not apply to Anesthesia and OR Care Areas)

The screen displays at the start of the infusion to ensure that there are no closed clamps or kinks in the tubing that might prevent flow and that drops are flowing in the drip chamber. See Figure 20.

- **Secondary Check Flow Error Prevention**

(does not apply to Anesthesia and OR Care Areas)

During Secondary setup, a pop-up displays to verify that the Secondary VTBI (Volume To Be Infused) equals the secondary bag volume. See Figure 21.

The screen displays to verify that drops are falling in the secondary drip chamber and not in the primary drip chamber. See Figure 22.

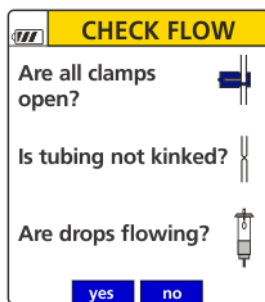


Figure 20. Primary Check Flow Screen.

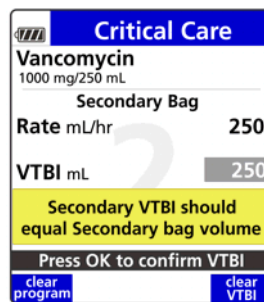


Figure 21. Secondary Bag Volume Confirmation Pop-up.

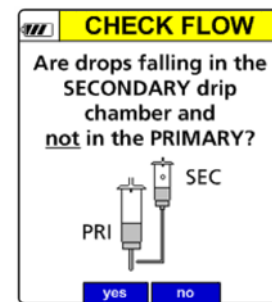


Figure 22. Secondary Check Flow Screen.

- **Single Step Rate or Dose Change Limits**

(set at 500% in Anesthesia and OR Care Areas)

The screen displays an alert to indicate that in a single programming step, a pre-configured percentage limit has been exceeded. See Figure 23.

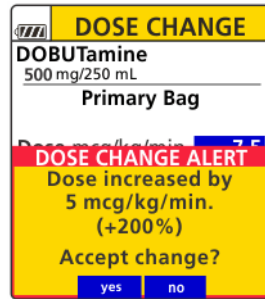


Figure 23. Single Step Dose Change Alert.

■ **Time Change Alert**

If the time is changed with a rate and VTBI already programmed, a time change alert will display the corresponding change in dose rate or infusion rate in an mL/hr mode infusion. See Figure 24.

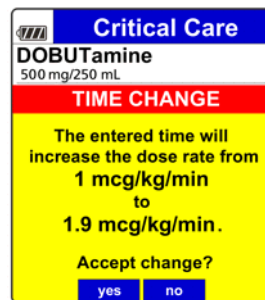


Figure 24. Time Change Alert.

■ **Keypad Lock**

Locking the keypad prevents unauthorized activation of specific key entries. For information on using the Keypad Lock feature, see Keypad Lock on page 102.

Infusion Programming Options

The SIGMA Spectrum Infusion System provides two options for programming infusions:

■ **Dose Error Reduction System (DERS)**

For information on programming the Pump using DERS, see Dose Error Reduction System (DERS) Programming on page 50.

■ **BASIC Mode**

For information on programming the Pump using BASIC mode, see BASIC Mode on page 96.

Infusion Delivery Modes

The following infusion delivery modes are available with the SIGMA Spectrum Infusion System using this operating software:

- **Amount/Time Infusion.** An IV drug therapy prescribed as a total dose amount completely administered over a set duration of time.
- **Continuous Infusion.** An IV drug therapy prescribed as a continuous dose rate. The IV therapy continues to infuse a set dose rate until the infusion is discontinued or the volume to be infused has been completed. Rate changes may be programmed as needed. A Loading Dose or Bolus may also be programmed in this infusion.
- **Cyclic TPN.** An IV drug therapy that requires a flow rate (mL/hr) ramp-up to a main (mL/hr) rate for a prescribed period of time and then a tapering down of the rate until total infusion time has completed.
- **Multi-step.** Multi-step mode allows the drug to be programmed on the Pump with up to 10 individual infusion rate steps. Automatic transition occurs between each step. Each step must be within the Drug Library defined dose rate limit.

Activating a Drug Library on a Pump with a Wireless Battery Module

Activating a Drug Library is the process of replacing the current Drug Library or deploying a new Drug Library. The Pump will receive a new Drug Library any time the Pump is on and at the Drug Library check interval specified in the Drug Library.

When a new Drug Library is received, it is placed in a “queued” position in the Pump. While the new Drug Library is queued, the current Drug Library remains the active Drug Library. When all infusions are cleared and the Pump is returned to the Care Area screen, the queued Drug Library is automatically made active.

While a Drug Library is queued, an icon will appear in the upper right corner of the Pump screen. See Figure 25.



Figure 25. Queued Drug Library Icon.

To see, or activate, the new queued library that is available from the Infusion Running screen:

1. Press the **info/settings** soft key.
2. Press the arrow soft keys to select **view information** and press **OK**.

The Library Information screen displays the current active Drug Library information and the queued (new) Drug Library that is ready to be activated. See Figure 26.

3. Press the **exit** soft key to return to the Infusion Running screen.

4. Stop the Pump and clear the infusion program to make the queued Drug Library active. See Figure 27.

NOTE: Once a Drug Library is queued, the user cannot prevent the queued library from being activated.

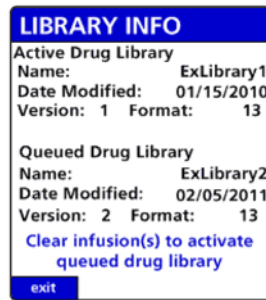


Figure 26. Drug Library Information Screen.



Figure 27. Drug Library Update Screen.

Dose Error Reduction System (DERS) Programming

NOTE: The SIGMA Spectrum Infusion Pump defaults directly to DERS when powered on.

WARNING

Confirm Safe Operation.

Never operate the SIGMA Spectrum Infusion Pump unless all of the following safe operations are being practiced.

Always confirm safe, accurate Pump operation by:

- Ensuring that IV sets or container vents are properly functioning, that tubing clamps are in the proper positions and that tubing is free from kinks or signs of collapse outside the Pump to prevent undetected upstream occlusions.
- Observing the drip chamber to verify that there is no flow from the fluid container when the Pump is stopped.
- Ensuring the drip rate approximates the Pump's flow rate during RUN operation.
- Ensuring correct patient, correct route and correct drug.
- Ensuring Pump settings, for example; drug/concentration, dose mode, dose rate and time.
- Monitoring vital signs and IV access sites per facility's standard practice of care.
- Monitoring the infusion to ensure that the infusion is delivered as intended.
- Periodically checking battery status and replace if necessary.

The SIGMA Spectrum Infusion System is not intended to replace clinician patient observation.

The Pump was not designed nor is it intended to detect infiltrations or extravasation

WARNING

Confirm Drug Library.

- Master Drug Library Administrators (MDLAs) should verify the correct Drug Library is installed when deploying the Drug Library to Pumps.
- Master Drug Library Administrators (MDLAs) should verify the Drug Library transfer is successful after deployment.
- Users should verify the correct Drug Library is installed on the deployed Pumps.
- Before implementation, clinical users at each facility must thoroughly test and validate their Drug Library per their facility's procedure to ensure configuration and workflow reflect clinical practice.

CAUTION

Confirm Audio Operation.

Listen for beeps when pressing keys. If sound is not heard, discontinue use of the Pump and refer servicing to qualified service personnel at your facility or return the Pump to Baxter for service.

CAUTION

Confirm Display Operation.

Regularly observe the Pump's display. If display abnormalities are observed, discontinue use of the Pump and refer servicing to qualified service personnel at your facility or return the Pump to Baxter for service.

To program the Pump using DERS:

1. Press **ON/OFF** to power on the Pump.
2. The New Patient screen may display.

The Pump retains previously programmed infusion values up to 24 hours after power off. The New Patient screen will display at power on to allow use of the previously programmed values or allow a new infusion to be programmed.

3. At the New Patient screen:
 - Press the **yes** soft key to clear the previously programmed infusion values and allow programming a new infusion.

NOTE: If it is the same patient, but a new drug is required, press the **yes** soft key. As a result, the Total given will be reset to zero.

- Press the **no** soft key to retain the previously programmed infusion values. See Figure 28.



Figure 28. New Patient Screen.

4. Press the arrow soft keys to select the Care Area and press **OK**. See Figure 29.

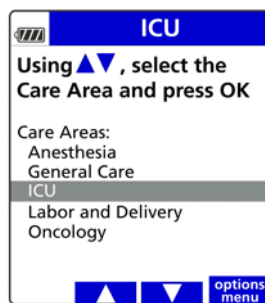


Figure 29. Select Care Area Screen.

- Select the drug from the Drug Library using the keypad, press the alphanumeric hard key(s) labeled with the desired letter(s) to enter the first two letters of the drug name. If an incorrect letter is displayed, use the back arrow soft key to clear and reenter the correct letter. See Figure 30. All drug names beginning with those two letters appear.

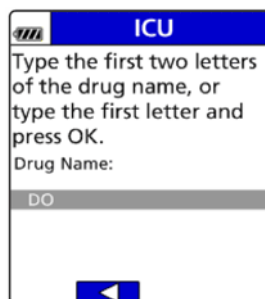


Figure 30. Drug Name Search Screen.

NOTE: "D" is obtained by pressing the 2 key one time and the "O" is obtained by pressing the 5 key three times (similar to phone texting).

5. Press the arrow soft keys to move the cursor to the desired drug name and press **OK**. See Figure 31.

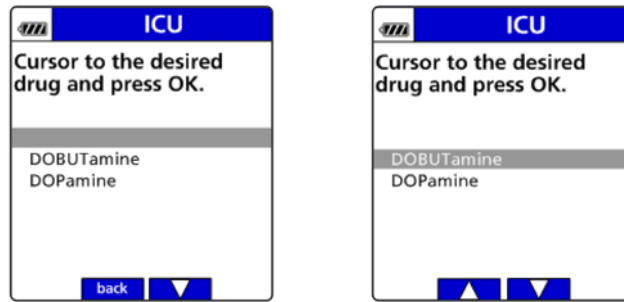


Figure 31. Drug Identification and Drug Selection Screen.

If the drug is not listed, follow the facility's procedure to request the drug be added to the Pump.

NOTE: After selecting a drug and concentration (if applicable), a clinical advisory may display. A clinical advisory is configured in the Drug Library by drug. It is an advisory that displays important information related to the delivery of a drug.

6. Move the cursor to the correct drug concentration (if more than one is offered) and press **OK**. See Figure 32.

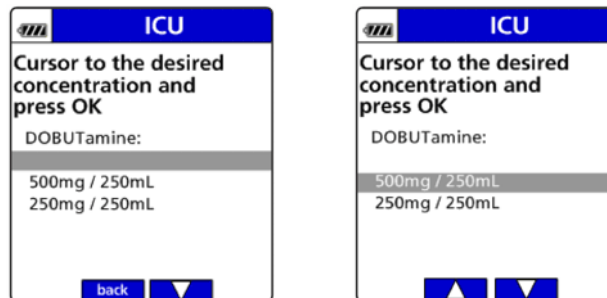


Figure 32. Drug Concentration Selection Screens.

7. Once a concentration is selected, confirm the selected drug concentration. See Figure 33.

NOTE: The confirmation box appears only when a drug concentration is selected from a list or when a concentration is entered manually to a drug that has been assigned a Variable concentration in the Drug Library.

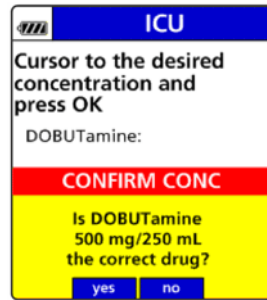


Figure 33. Confirm Concentration Screen.

8. Press the **yes** soft key to continue or the **no** soft key to reselect.
9. Enter all required values and press **OK** after each entry on the Setup screen. See Figure 34.
10. Enter patient weight if applicable.
11. Enter the dose or flow rate value and press **OK**.
12. Enter the VTBI (Volume To Be Infused) in mL.
13. Verify that the VTBI equals the volume in the container and press OK.
14. Confirm the calculated infusion time.
15. Confirm the Total given mL value or press the **clear total** soft key to erase it.

NOTE: VTBI counts down to zero, while Total given counts from zero up.

16. Review the values of the drug displayed on the screen to ensure correctness. See Figure 35.

WARNING Low Flow Rate Accuracy/Continuity.

At flow rates of 2 mL/hr or below, flow rate accuracy is +/- 0.1 mL/hr. If higher accuracy is required, consider an alternate infusion device.

| Critical Care | |
|-----------------------------|--------------|
| DOBUtamine 500 mg/250 mL | |
| Primary Bag | |
| Patient Weight kg | 0 |
| Dose mcg/kg/min | 0 |
| Rate mL/hr | 0 |
| VTBI mL | 0 |
| Time hr:min | 00:00 |
| Total given mL 0 | |
| clear program | clear weight |

Figure 34. Primary Bag Setup Screen.

| ICU and CCU | |
|-----------------------------|-------------|
| DOBUtamine 500 mg/250 mL | |
| Primary Bag | |
| Patient Weight kg | 75 |
| Dose mcg/kg/min | 0.5 |
| Rate mL/hr | 1.1 |
| VTBI mL | 250 |
| Time hr:min | 222:14 |
| Total given mL 0 | |
| hold | clear total |

Figure 35. Completed Primary Bag Setup Screen.

Prompts that may appear during programming

- The Weight/BSA Confirmation screen** is set up in the Drug Library. The patient weight or BSA parameter must be re-entered to confirm the value was entered correctly. If the weight or BSA values do not match, the Values Differ popup message is displayed. Press **OK** and enter an accurate value.

While programming an infusion, a dialog box will appear if the dose rate limits defined in the Drug Library for the drug are exceeded.

- Soft limit advisory** is an alert that the dose or the mL/hr rate has been programmed to exceed the facility's pre-configured limit in the Drug Library or the programming exceeded the Pump's limit.

Soft dose rate or mL/hr limits may be exceeded by pressing **OK** followed by pressing the **yes** soft key to accept the dose rate displayed in the dialog box. If the values are accepted, they will appear in red on the Infusion Running screen.

- Hard dose or mL/hr limits** is an alert that the dose or the mL/hr rate has been programmed to exceed the facility's pre-configured hard limits in the Drug Library or that the programming exceeded the Pump's hard limits. Hard limits cannot be exceeded (see the Flow Rate specification in Appendix A: "Specifications" on page 135). The Pump will not start or infuse with entered values. Re-enter rates within hard limits.
 - If the dose rate entered exceeds the hard mL/hr rate limit defined in the Pump, **HIGH** will be displayed. See Figure 36.
 - If the dose rate entered is lower than the hard mL/hr rate limit defined in the Pump, **LOW** will be displayed. See Figure 37.
 - Press **OK** to view a dialog box which identifies the actual limit. Press **OK** to clear the dialog box.

- Re-enter the dose rate and press **OK** to confirm.



Figure 36. Dose Rate Exceeds the Hard mL/hr Rate Limit.



Figure 37. Dose Rate is Lower Than the Hard mL/hr Rate Limit.

- Single Step Rate or Dose Change (Rate alert)** – Dose or mL/hr rate entered is increased or decreased by a percentage (set in the Drug Library) above or below the current rate.
 - Press the **yes** soft key to accept or the **no** soft key to decline the change displayed in the dialog box.
 - In BASIC mode, the rate advisory is set for an increase (+) of 101% and a decrease (-) of 51% and cannot be changed.
 - When programming using DERS the default is set for an increase (+) of 101% and a decrease (-) of 51% and is configurable in the MDL for all Care Areas except “Anesthesia” or “OR”.
 - The rate advisory is set for an increase (+) of 500% and a decrease of (-) 99% if the selected Care Area name contains “Anesthesia” or “OR” and cannot be changed.

17. After selection and review of all values, select one of the following actions:

- To start the infusion, ensure that the slide clamp and roller clamp are open and press **RUN**.
- To put the Pump in Standby mode, press the **hold** soft key.
- To set up a secondary infusion (enabled using the Drug Library), press the **program** **secndry** soft key.

For instructions on setting up a secondary infusion, see Secondary Infusion on page 58.

18. Once **RUN** is pressed, the infusion will start and either the Primary or Secondary Check Flow screen is displayed. Check the flow and confirm:

- All clamps are open.
- There are no kinks or collapses in the tubing outside of the Pump.
- Drops are flowing in the drip chamber. Note, at very low rates, it may take several minutes to see drops.
- Vents are open (if applicable).

If drops are falling in the drip chamber, press the **yes** soft key. See Figure 38.

If no drops are falling in the drip chamber, press the **no** soft key and follow the screen prompts. The Infusion Running screen appears, indicating that the infusion is running. See Figure 39.

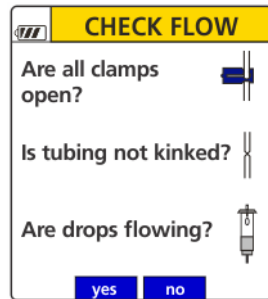


Figure 38. Primary Check Flow Screen.

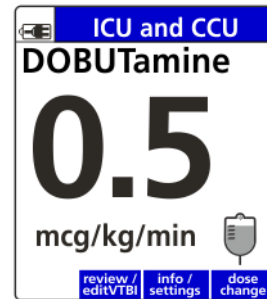


Figure 39. Infusion Running Screen.

WARNING Time to Upstream Occlusion at Lower Flow Rates.

When infusing at flow rates below 5 mL/hr, the Pump may take an extended period of time to detect an upstream occlusion and sound an alarm.

Ensure the following:

- All clamps are open.
- There are no kinks or collapses in the tubing outside of the Pump.
- Drops are flowing in the drip chamber. Note, at very low rates, it may take several minutes to see drops.
- Vents are open (if applicable).

WARNING Manually Stopping the Pump.

If the Pump cannot be stopped by pressing the **RUN/STOP** key,

- Close the roller clamp below the Pump.
- Insert the slide clamp into the keyhole.
- Push the slide clamp down until the door opens.

To change the rate or dose while the Pump is running:

- » Press the **rate change** soft key or the **dose change** soft key.

To clear the total given while the Pump is running:

1. Press the **review/edit VTBI** soft key to view infusion information.
2. Press **clear total** to clear the total volume given.

To clear the total given while the Pump is stopped:

1. Press **STOP**.

2. Press the **review** or **program pri/sec** soft key to display the Setup screen.
3. Press the **clear total** soft key to clear the total given.

To change the rate while the Pump is stopped:

1. Press **STOP**.
2. Press the **review** or **program pri/sec** soft key to display the Setup screen.
3. Press the arrow soft keys to select the desired value.
4. Enter the new rate value.
5. Press **OK** to confirm.
6. Press **RUN** to resume the infusion.

Secondary Infusion

To program a secondary infusion:

1. Prepare the IV sets and container for a secondary infusion using the steps in Secondary Infusion Setup on page 46.
2. Follow the steps for programming the primary bag infusion as described in either Dose Error Reduction System (DERS) Programming on page 50 or BASIC Mode on page 96.

NOTE: The SIGMA Spectrum Infusion Pump does not deliver a primary and secondary infusion at the same time.

3. Press the arrow soft keys to select a primary bag or a secondary bag and press **OK**. See Figure 40.

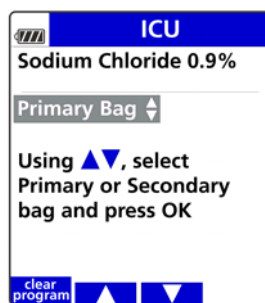


Figure 40. Bag Selection Screen.

NOTE: The bag selection prompt does not appear if the selected drug has been specifically assigned in the Drug Library as:

- ◆ Primary only, Secondary Not Allowed
 - ◆ Secondary only
 - ◆ Primary only multi-step
 - ◆ Cyclic
4. When finished programming the Pump for the primary infusion and before running the infusion, press the **program secndry** soft key to begin programming the secondary bag. See Figure 41.

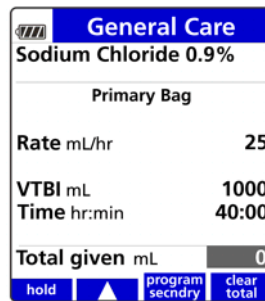


Figure 41. Programmed Primary Setup Screen Showing Program Secndry Soft Key.

5. If the Pump is running, press **STOP**. See Figure 42. The Pump Stopped screen will appear.
6. On the Pump Stopped screen, press the **program pri/sec** soft key. See Figure 43. The Setup screen appears.
7. On the Setup screen, press the **program secndry** soft key. See Figure 44.

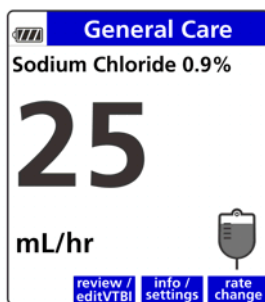


Figure 42. Infusion Running Screen.

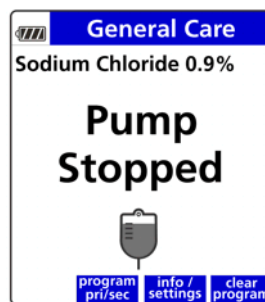


Figure 43. Pump Stopped Screen.

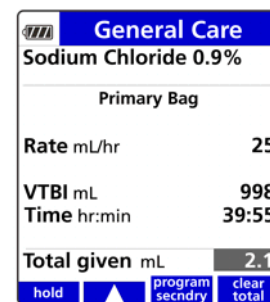


Figure 44. Programmed Primary Setup Screen Showing program secndry Soft Key.

8. If the drug is to be delivered using the DERS, select the drug from the Drug Library:

NOTE: The drug must be pharmacy/hospital-approved and configured in the Drug Library for secondary delivery.

- Using the keypad, enter the first two letters of the drug name. All drug names beginning with those two letters will appear. See Figure 45.

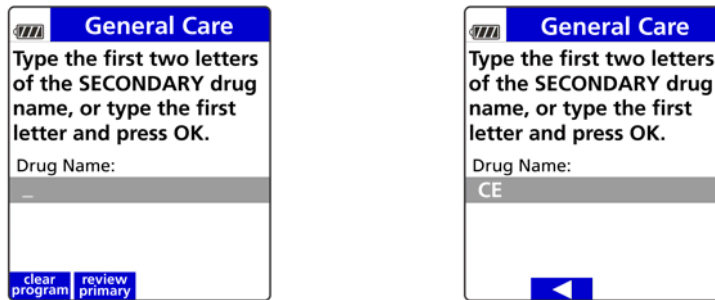


Figure 45. Secondary Drug Identification Screens.

- Press the arrow soft keys to move the cursor to the desired drug name and press **OK**. See Figure 45.
- Press **OK** to select the secondary bag or press the arrow soft keys to change to the primary bag, if needed. See Figure 46.
 - Confirm the values on the Setup screen:
 - Confirm the drug and concentrations are correct (if selected).
 - Enter all required values and press **OK** after each entry.

NOTE: Secondary VTBI should equal the secondary bag volume to avoid infusion of residual amounts of the secondary bag at primary flow rates.

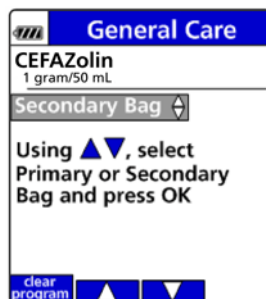


Figure 46. Secondary Bag Selection Screen.

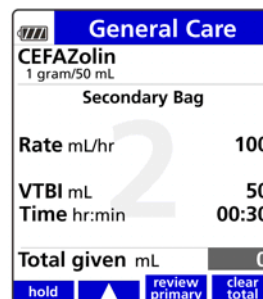


Figure 47. Secondary Bag Setup Screen.

NOTE: A watermark is displayed behind the value to help distinguish the Secondary (2) Setup screen from the Primary (1) Setup screen. See Figure 47. This watermark does not appear on primary-only infusions.

11. To start the Secondary Infusion:

- Connect the secondary set to the primary sets upper Y injection site.
- Lower the primary bag by fully extending the hanger.
- Open the secondary roller clamp.
- Press **RUN** to begin the secondary infusion.

12. Once **RUN** is pressed, the infusion will start and the Secondary Check Flow screen is displayed. Confirm there are no drops falling in the primary drip chamber and there are drops falling in the secondary drip chamber. See Figure 48.

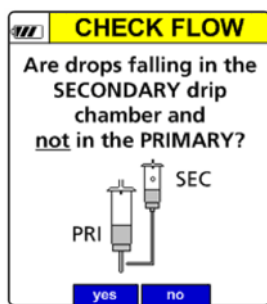


Figure 48. Secondary Check Flow.

If the **yes** soft key is pressed, the Secondary infuses as programmed until completion with automatic transition to primary (unless Secondary Callback is **ON**).

The Secondary icon (two IV bags) on the Secondary Run screen denotes the secondary is running. See Figure 49.



Figure 49. Secondary Run Screen with Secondary Icon.

If the **no** soft key is pressed on the Secondary Check Flow screen, ensure the secondary IV bag is hung above the primary IV bag. Confirm the secondary clamp is open and drops are falling in the secondary drip chamber and not in the primary?

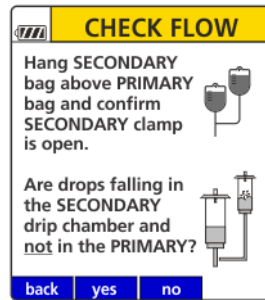


Figure 50. Secondary Check Flow Instruction Screen.

- If the **yes** soft key is pressed, the Secondary infuses as programmed until completion with automatic transition to primary (unless Secondary Callback is **ON**).
- If the **no** soft key is pressed, apply clamp to primary IV line above upper Y injection site (see Figure 51.), and press **OK** to confirm primary IV line is clamped. See Figure 52.

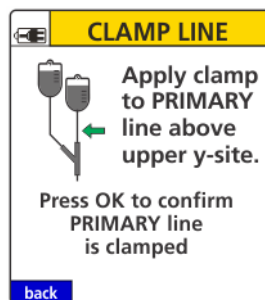


Figure 51. Primary IV Line Instruction Screen.

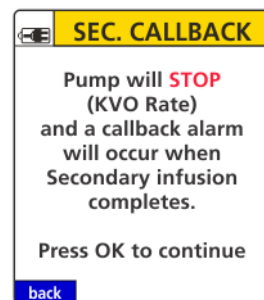


Figure 52. Primary IV Line Confirmation Screen.

NOTE: If the primary IV line is clamped, the secondary infuses until completion and the rate will decrease to a KVO (Keep Vein Open) rate with alarm. See Figure 53.

13. At the completion of the secondary infusion, if secondary callback has been applied, the Secondary Complete notification screen will display.
14. Press **STOP**.

NOTE: If the drug is configured as an Amount/Time infusion, the Line Flush dialog will be displayed. See Secondary Line Flush on page 93.

15. At the Select Infusion screen:

- Press the **SECONDARY** soft key to return to the secondary setup. See Figure 54. This allows reprogramming of the last secondary infusion or programming with a new drug. See Figure 55.
- Press the **review PRIMARY** soft key to return to the primary infusion. See Figure 54.

16. After reviewing the primary program, remove clamp on primary IV line, if applicable, and press **RUN**.

NOTE: When the secondary infusion is complete, close the clamp on the secondary IV line above the upper Y injection site or remove the IV bag and tubing to prevent any remaining drug in the secondary bag from being delivered at the primary delivery rate.

Upon completion of the secondary infusion and once the transition is made to the primary infusion, a Primary icon (one IV bag) replaces the Secondary icon (two IV bags) on the Infusion Running screen.



Figure 53. Secondary Complete Alarm Screen.

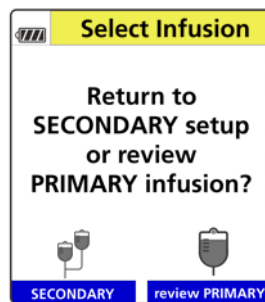


Figure 54. Select Infusion Screen.

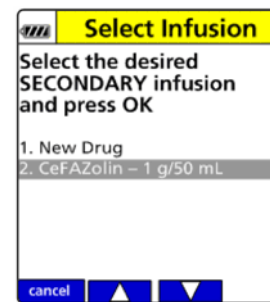


Figure 55. Secondary Infusion Drug Selection Screen.

17. In the event the secondary IV bag is still attached, confirm flow from primary drip chamber (**yes/no**).

- If the **yes** soft key is pressed, Primary infuses as programmed.
- If the **no** soft key is pressed, close clamp on secondary IV line. Press **OK** to confirm secondary IV line is clamped.

Clearing the Secondary Infusion to Return to the Primary Infusion

To clear the secondary infusion to return to the primary infusion:

1. Press **STOP**.
2. Press the **clear program** soft key.

NOTE: When the program is cleared, the Total Given is reset to zero and is not retrievable.

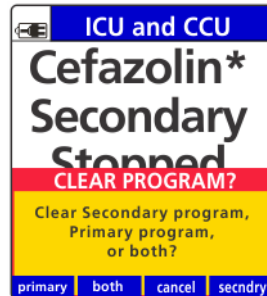


Figure 56. Clear Program Screen.

3. Press the **secndry** soft key.
4. Press the **yes** soft key to clear the secondary program.

WARNING Unintended Delivery.

Close the clamp on the secondary IV line or remove the secondary container administration set to prevent the secondary drug from flowing when the Primary mode is intended.

5. Close the clamp on the secondary IV line above the upper Y injection site or remove the secondary container and IV tubing.
6. Press **OK** to continue. The Primary Review screen appears.
7. To start the infusion press **RUN**.

Once **RUN** is pressed, the infusion will start and the Primary Check Flow screen is displayed. Check the flow and confirm:

- All clamps are open
- There are no kinks or collapses in the tubing outside of the Pump
- Drops are flowing in the drip chamber. Note, at very low rates, it may take several minutes to see drops.
- Vents are open (if applicable).

If drops are falling in the drip chamber, press the **yes** soft key.

If no drops are falling, press the **no** soft key and follow the screen prompts.

Secondary Callback

Secondary Callback is an audio and visual notification at the completion of the secondary infusion. During this time, the infusion will infuse at a KVO rate of 1 mL/hr and cannot be changed.

The Master Drug Library allows Secondary Callback configuration as **REQUIRED**, **OPTIONAL**, or **NEVER**:

■ If **REQUIRED**:

The Pump will display the Callback dialog box and the Pump will drop to the KVO Rate at the completion of the secondary infusion and sound an audio alarm. This alarm must be acknowledged before making a transition to the primary infusion. Review the primary infusion or return to and manage the secondary setup.

■ If **OPTIONAL**:

The Pump will display the Callback dialog box upon completion of programming the secondary infusion. If during the infusion, secondary callback is desired, press the **info settings** soft key to change callback status during secondary infusion. Press the **yes** soft key to receive a callback at the end of the infusion. Press the **no** soft key to automatically transition to the primary infusion.

■ If **NEVER**:

The Pump will automatically transition to the primary infusion upon completion of the secondary infusion.

To select Secondary Callback:

1. When finished programming a secondary infusion, if Secondary Callback is enabled as optional (per drug in the Drug Library), a dialog box is displayed asking if a callback is needed at the completion of the secondary infusion. See Figure 57.

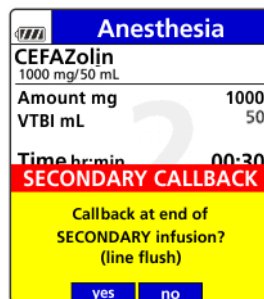


Figure 57. Secondary Callback Dialog Box.

- If **yes** is pressed, a callback icon (a picture of a telephone) is displayed on the Secondary Infusion Running screen to indicate that the callback feature is active. The Callback icon alternates with the Secondary icon (picture of two IV bags) during the secondary infusion. See Figure 58.



Figure 58. Alternating Infusion Running Screens with Secondary Callback Enabled.

- If **no** is pressed, the callback icon will not be displayed and the Pump will automatically transition to the primary infusion upon completion of the secondary infusion.

At the completion of the secondary infusion, if secondary callback is active, the Pump will run at a KVO rate (1 mL/hr) and a Secondary Complete notification screen will display. See Figure 59.

2. Press **STOP**.
3. Select the infusion:
 - Press the **SECONDARY** soft key to return to the secondary setup screen. This allows reprogramming of the last secondary infusion or programming with a new drug.
 - Press the **review PRIMARY** soft key to return to the primary infusion. See Figure 60.
 - After reviewing the primary program, if the primary IV line is clamped, remove the clamp on the primary IV line and press **RUN**.



Figure 59. Secondary Complete: KVO Alarm.

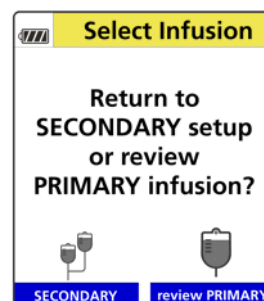


Figure 60. Select Infusion Screen.

Loading Dose

A loading dose is an initial higher dose of a drug delivered once at the start of an infusion.

- A loading dose is enabled using the Drug Library and infuses at the beginning of an infusion.
- A loading dose amount, time and limits can be assigned to a drug in the Drug Library.

To program a loading dose:

1. If the drug has been configured in the Drug Library to allow a loading dose, a prompt is displayed after the drug and concentration (if the drug has more than one concentration) has been selected. See Figure 61.

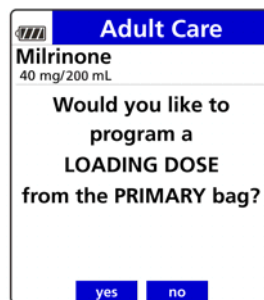


Figure 61. Loading Dose Prompt Screen.

- If the **yes** soft key is pressed, the Loading Dose Setup screen is displayed. See Figure 62.
- If the **no** soft key is pressed, the Primary Setup screen is displayed.

NOTE: The loading dose may be accepted or declined.

The following Drug Library configuration will result in the appearance of a **time in seconds** soft key. See Figure 62.

- No start time.

- No lower hard limit in minutes.

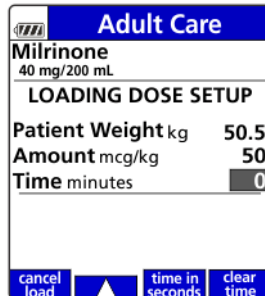


Figure 62. Loading Dose Setup Screen
Showing Time In Seconds Soft Key.

The following Drug Library configuration will result in the absence of a **time in seconds** soft key. See Figure 63 and Figure 64.

- Start time in minutes.
- Lower hard limit in minutes.



Figure 63. Loading Dose Setup Screen
Without Time In Seconds Soft Key.

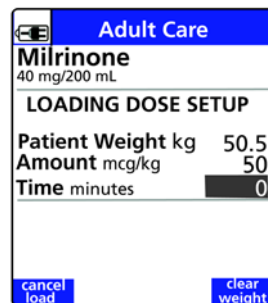


Figure 64. Loading Dose Setup Screen
Without Time In Seconds Soft Key.

2. Enter all required values, pressing **OK** after each entry.

NOTE: If the time in minutes has already been filled in and you wish to change the program from minutes to seconds, press the **clear time** soft key and press **OK** to accept the zero. The **time in seconds** soft key will appear.

- When Loading Dose Setup is complete, press the **program primary** soft key to begin programming of the primary infusion. See Figure 65.

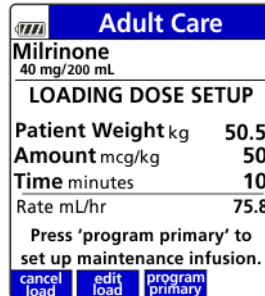


Figure 65. Loading Dose Setup Screen Complete.

- Enter all required values, pressing **OK** after each entry, to complete setup of the primary program.
- To start the infusion, ensure that the slide clamp and roller clamp are open and press **RUN** to start the delivery of the Loading Dose.

Once **RUN** is pressed, the infusion will start and the Primary Check Flow screen is displayed. Check the flow and confirm:

- All clamps are open.
- There are no kinks or collapses in the tubing outside of the Pump.
- Drops are flowing in the drip chamber. Note, at very low rates, it may take several minutes to see drops.
- Vents are open (if applicable).

If drops are falling in the drip chamber, press the **yes** soft key.

If no drops are falling, press the **no** soft key and follow the screen prompts.

NOTE: If additional action is required:

- To cancel the Loading Dose during infusion, press the **cancel load** soft key on the Infusion Running screen.
- To review the loading dose during the infusion, press the **review load** soft key.

NOTE: Once the delivery of the loading dose has started, no changes to the loading dose values can be made.

Once the loading dose is complete, the **review load** soft key is not available.

The Loading Dose Infusion Running screen shows the amount of drug delivered (number value will increase).

At the completion of the Loading Dose, transition to the Primary Infusion rate is automatic.

Bolus

A Bolus is a higher dose of a drug and can be delivered throughout the infusion.

- A bolus is configured per drug in the Drug Library but is always available in BASIC mode.
- A bolus can be programmed while the Pump is stopped or while infusing.

To program a bolus:

1. Press the **bolus** soft key. See Figure 66.

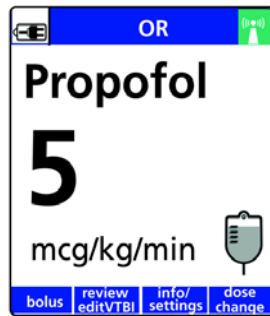


Figure 66. RUN screen for drug with bolus enabled.

2. The Bolus Setup screen appears. See Figure 67.
 - Enter the bolus amount and press **OK** to confirm.



Figure 67. Bolus Setup screen.

- The **Time** field is now highlighted. See Figure 68.

The following Drug Library configuration will result in the appearance of a **time in seconds** soft key. See Figure 68.

- No default start time.

- No lower hard limit in minutes.



Figure 68. Bolus Setup screen showing the Time In Seconds Soft Key.

The following Drug Library configuration will result in the absence of a **time in seconds** soft key. See Figure 69.

- Start time in minutes.
- Lower hard limit in minutes.

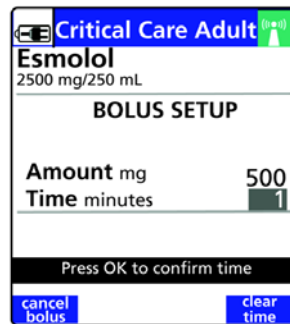


Figure 69. Bolus Setup Screen Without Time In Seconds Soft Key.

NOTE: If the time in minutes has already been filled in and you wish to change the program from minutes to seconds, press the **clear time** soft key and press **OK** to accept the zero. The time in seconds soft key will appear.

3. Enter all required values and press **OK** after each entry.
4. Press **RUN** to start the bolus delivery. If infusion was previously stopped, ensure that the slide clamp and roller clamp are open.

NOTE: If additional action is required:

- To cancel the Bolus Dose during infusion, press the **cancel bolus** soft key on the Infusion Running screen.

- To review the Bolus Dose during the infusion press **review bolus** soft key.

NOTE: Once the delivery of the Bolus Dose has started, no changes to the Bolus Dose parameters can be made.

Once the Bolus dose is complete, the **review bolus** soft key is not available.

The Bolus Dose Infusion Run screen shows the amount of drug delivered (number value will increase).

At the completion of the Bolus Dose, transition to the Primary Infusion rate is automatic.

Multi-Step

Multi-step programming allows the drug to be programmed on the Pump with up to 10 individual infusion rate steps. Automatic transition occurs between each step. Each step must be within the Drug Library defined Dose Rate limits.

WARNING Do Not Exceed Total Volume.

To prevent Air in Line, ensure the total VTBI of all the steps in a multi-step program does not exceed the total volume contained in the IV bag.

Multi-Step Programming is allowed when programming in one of the following:

- DERS (for drugs configured with the following delivery bag)
 - Primary Only Multi-Step, only available during primary delivery
 - Primary or Secondary
- BASIC

NOTE: Multi-step programming is not available as a secondary infusion and is not available for the primary bag when a secondary infusion exists in memory.

To use Multi-Step Programming:

1. Press **ON/OFF** to power on the Pump.
2. If the New Patient screen displays:
 - Press the **yes** soft key to clear the previously programmed infusion values and allow programming of a new infusion.
 - Press the **no** soft key to retain the previously programmed infusion values.
3. Press the arrow soft keys to select the Care Area and press **OK**.

If the drug is to be delivered using the Drug Library, select the drug as described in Dose Error Reduction System (DERS) Programming on page 50.

If the drug is to be delivered using the BASIC mode:

- Using the keypad, enter the letters **BA**, select **BASIC** and press **OK**.

- At the bag selection screen, select **Primary Bag** and press the **multi-step** soft key to enter the Multi-Step Programming.

NOTE: The Multi-Step Program is not available for the primary bag when a secondary program exists in memory.

NOTE: If the drug has been configured in the Drug Library as a "Primary Only Multi-step" infusion, bag selection will be bypassed and the Multi-Step Program setup screen will be displayed. See Figure 70.

NOTE: Multi-Step Program is not available as a secondary infusion.

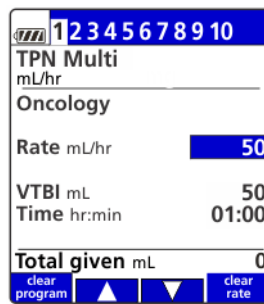


Figure 70. Multi-Step Setup Screen.

- Enter the infusion parameters as described in the BASIC or DERS programming sections. See Dose Error Reduction System (DERS) Programming on page 50 or see BASIC Mode on page 96.

NOTE: Always verify current program parameters for each step prior to starting a new infusion.

A step indicator bar is located at the top of the screen. The bar shows which steps within the program have parameter values programmed (a small white highlight) and which step is currently being viewed (a tabbed white highlight). See Figure 71.



Figure 71. Multi-Step Screen with Step Programmed.

6. When the setup of an individual step has been completed and “Total given” is highlighted on the programming screen, press **OK** to advance and program the next step.

NOTE: A maximum of 10 steps may be programmed. Only one step is necessary to start a program, however, it must be the first and only programmed step. The Pump will not start if programming is incomplete in any step.

NOTE: If additional action is required:

- To view the setup value for any programmed step use the up arrow soft key to navigate to the step indicator bar located at the top of the setup screen. Then using the left and right arrow soft keys move from step to step.

NOTE: A one-second delay exists from the time a step is selected when its setup value is displayed to allow rapid scrolling along the step bar.

- To change any setup value when the Pump is stopped, press the **review** or **program pri/sec** soft key and navigate to the step and press **OK** to move to the values that must be changed.
- To view any programmed step while the Pump is running, press the **review** soft key. No values can be changed with the exception of the Total given value, which can be cleared by pressing the **clear total** soft key.

7. To start the infusion, ensure that the slide clamp and roller clamp are open and press **RUN**.

Once **RUN** is pressed, the infusion will start and the Primary Check Flow screen is displayed. Check the flow and confirm:

- All clamps are open.
- There are no kinks or collapses in the tubing outside of the Pump.

- Drops are flowing in the drip chamber. Note, at very low rates, it may take several minutes to see drops.
- Vents are open (if applicable).

If drops are falling in the drip chamber, press the **yes** soft key.

If no drops are falling, press the **no** soft key and follow the screen prompts.

The Infusion Running screen appears showing the mL/hr (or dose rate, if applicable) and alternates with the program step indicator screen. See Figure 72.

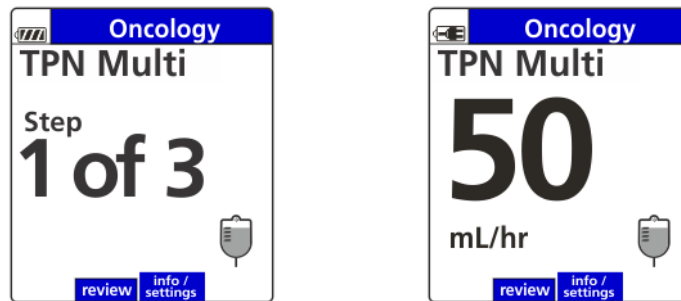


Figure 72. Alternating Multi-Step Infusion Running Screens.

The Pump will automatically advance to programmed steps while infusing.

NOTE: Any value missing within the program is identified in a popup message when the user starts the Pump.

The program is complete when all programmed steps have been delivered. The program schedule automatically resets itself and may be restarted without entering or re-entering any setup.

8. The program will be retained indefinitely during power-off cycles until reset. To reset the program, press the **reset program** soft key from the program stopped screen. See Figure 73.

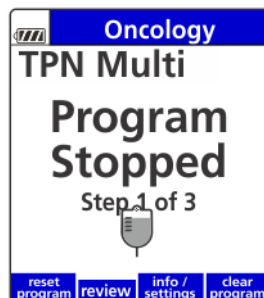


Figure 73. Multi-Step Stop Screen Showing reset program Soft Key.

To end the multi-step program:

- » At anytime during the infusion or, at the end while infusion complete displays, press **STOP** and press the **clear program** soft key to clear the entire program.

To retain the existing program in memory and restart at the same step, or after infusion complete (returns to Step 1):

1. Press **STOP**.
2. Press **ON/OFF** to power off the Pump.

When the Pump is powered back on, the same program will be retained in memory until the **clear program** soft key is pressed.

To clear the entire multi-step program:

- » Press the **clear program** soft key and answer **yes** to the confirmation screen.

To clear the last step in the multi-step program:

1. Ensure that the Pump is stopped.
2. Press the **review** or **program pri/sec** soft key.
3. Press the arrow soft keys to scroll to the desired step in the step bar.

NOTE: Press the **clr step** soft key. The last step of the program is the only step that can be cleared.

Cyclic TPN

Cyclic TPN delivers TPN (Total Parenteral Nutrition) over a prescribed period of time in an automatic ramp-up infusion rate to a main rate before tapering down. This process increases the delivery rate at the start of an infusion and decreases the delivery rate at the end of the infusion.

The Pump calculates the ramp-up and taper-down rates once the duration and total volume of the infusion are entered. The infusion schedule is calculated containing the rates and volumes for:

- 10 ramp-up steps consisting of 10% of the total infusion time.
- The main delivery rate accounts for 80% of the infusion time.
- 10 taper-down steps for the remaining 10% of the total infusion time.

Cyclic TPN is only available for Continuous Infusions.

To program Cyclic TPN:

1. Press **ON/OFF** to power on the Pump.
2. Press the arrow soft keys to select the Care Area and press **OK**.
3. Type "TP" and select TPN from the Drug Library.
4. Select **Cyclic TPN** and press **OK**.

NOTE: Cyclic TPN may be identified differently in your Drug Library per your facility.



Figure 74. Cyclic TPN Setup Screen.



Figure 75. Cyclic TPN Programmed Screen.



Figure 76. Cyclic TPN Running Screen.

5. Enter the VTBI and verify the entered volume equals the volume of the container and press **OK**. See Figure 74.
6. Enter the program time and press **OK**.
7. The screen displays with main rate, VTBI, prog time, ramp up time, main step time, taper down time and Total given mL. See Figure 75.

NOTE: Once the TPN program starts delivery, no changes to the infusion parameters can be made.

8. To start the infusion, ensure that the slide clamp and roller clamp are open and press **RUN**.
Once **RUN** is pressed, the infusion will start and the Primary Check Flow screen is displayed. Check the flow and confirm:
 - All clamps are open.
 - There are no kinks or collapses in the tubing outside of the Pump.
 - Drops are flowing in the drip chamber. Note, at very low rates, it may take several minutes to see drops.
 - Vents are open (if applicable).

If drops are falling in the drip chamber, press the **yes** soft key.

If no drops are falling, press the **no** soft key and follow the screen prompts.

9. Observe mL remaining value and green **INFUSING** icon. See Figure 76.

NOTE: If additional action is required:

- To display program status, press the **review** or **program pri/sec** soft key.
- To go back to the previous screen, press the **return** soft key.
- To begin early taper down, press the **taper down** soft key.
A Taper Down confirmation dialog box displays on the screen. Confirm by pressing the **yes** soft key.

- To start the program from the beginning when the Pump is stopped, press the **reset program** soft key.
10. At completion, the Pump infuses at KVO rate. Press **STOP** to automatically reset the program from the beginning.

Dose Change or Rate Change of a Continuous Infusion

During a Continuous Infusion, if the dose or rate change exceeds the limits defined in the Drug Library, a dialog box is displayed. See Prompts that may appear during programming on page 55.

To change dose without stopping the Pump:

1. Press the **dose change** soft key. See Figure 77.
2. The current dose is displayed along with the dose soft limits. Observe the displayed dose soft limits. See Figure 78.

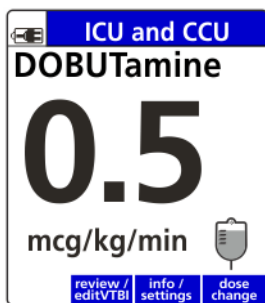


Figure 77. Infusion Running Screen.

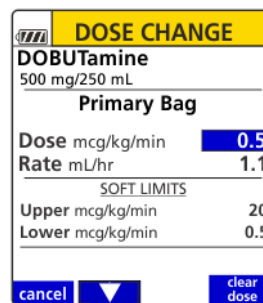


Figure 78. Dose Change Screen.

3. Enter a new dose. See Figure 79.

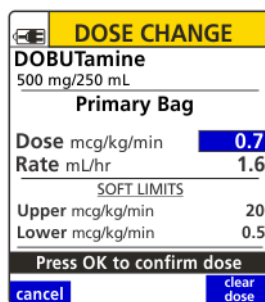


Figure 79. Dose Change Screen with New Dose.

4. Press **OK** to confirm entered dose.

If soft limits are exceeded, press the **yes** soft key to accept the new value or the **no** soft key to return to the previous value.

NOTE: Values exceeding the hard limits set in the Drug Library will not be accepted by the Pump.

5. Observe the change in the mL/hr rate based on the new dose entry.
6. Press **RUN** to begin delivery at the new dose rate.

To change rate mL/hr without stopping the Pump:

1. At the Infusion Running screen, press the **rate change** soft key. See Figure 80.

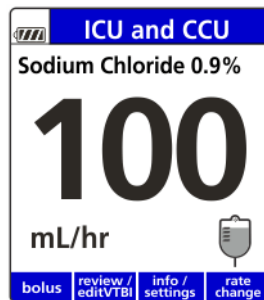


Figure 80. Infusion Running Screen.

2. Observe the displayed mL/hr soft limits. See Figure 81.
3. Enter a new mL/hr flow rate. See Figure 81.
4. Press **OK** to confirm new flow rate. See Figure 81.

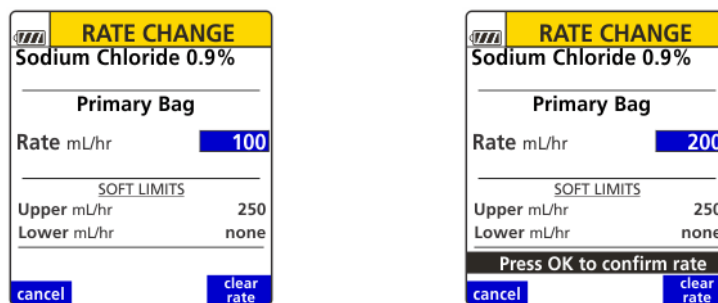


Figure 81. Rate Change Screen.

If soft limits are exceeded, press the **yes** soft key to accept the new value or the **no** soft key to return to the prior value.

NOTE: Values exceeding the hard limits set in the Drug Library will not be accepted by the Pump.

5. Press **RUN** to begin delivery at the new flow rate.

Changing the VTBI Without Stopping the Pump

To change VTBI without stopping the Pump:

1. At the Infusion Running screen, press the **review/edit VTBI** soft key. See Figure 82.



Figure 82. Infusion Running Screen.

2. At the Review screen, press the **edit VTBI** soft key. See Figure 83.
3. Enter new value and verify the VTBI is equal to or less than the volume in the container. See Figure 83.
4. Press **OK to confirm VTBI**. See Figure 83.

- Press **RUN** to begin delivery of the new VTBI.

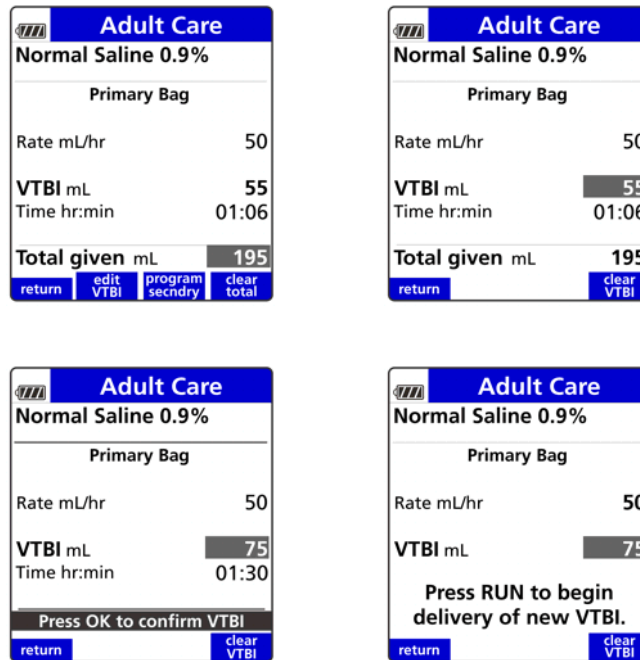


Figure 83. VTBI Review Screens.

Delayed Run

If Delayed Run is enabled (per drug in the Drug Library), the start of any programmed infusion may be delayed up to 12 hours.

To set up a delayed run:

- On the Infusion Setup screen, enter any value between 1 minute and 12 hours (00:01 to 12:00, hr:min) for the delay run parameter and press **OK**.
- After the infusion programming is complete and the set is loaded, press **RUN** to begin the infusion delay timer. The delay running screen is displayed with the remaining delay time shown in a flashing format.
- When the delay time period expires, the Pump begins delivery of the programmed infusion. Primary Check Flow will display.
- An inactivity alarm will occur after 2 minutes and Primary Check Flow confirmation will be required.

To stop or cancel the delay timer:

While the delay timer is running, it can be stopped or cancelled.

1. To stop the delay timer, press **STOP**. The display updates to **DELAY STOPPED** and the delay timer is paused and no longer flashes. To restart the delay timer, press **RUN**.
2. To cancel the delay, press the **cancel** soft key. The remaining delay time is cleared and the display updates to **PUMP STOPPED**.

To change the remaining delay time:

1. Press **STOP**.
2. Press the **review/program** soft key to display the setup screen.
3. Move the cursor to the delay value, enter the new desired delay time and press **OK**.

NOTE: The new delay time is immediately applied. The delay time value may not be cleared while the delay is running.

4. Press **RUN** to start the delay timer.

Confirming Weight and BSA

The Weight or BSA confirmation screen (set up in the Drug Library), requires the patient weight or BSA parameter to be re-entered to confirm that the value was entered correctly. If the weight or BSA values do not match, the Values Differ popup message is displayed. Press **OK** and enter an accurate value. See Figure 84. Also see Figure 85.

NOTE: **Important.** For the drug products mentioned, refer to the manufacturers' package insert for full prescribing information which may include boxed warnings.



Figure 84. Weight Confirmation Screen.

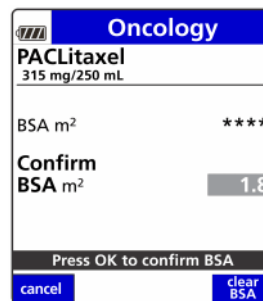


Figure 85. BSA Confirmation Screen. See important note on page 82.

The flow rate (mL/hr) will be auto calculated based on the patient weight and dose entered.

Amount/Time Infusion

Amount/Time programming is used for drug therapies that require a prescribed drug dose amount to be delivered over a set duration of time.

NOTE: Amount/Time is not available in BASIC mode.

NOTE: **Important.** For the drug products mentioned, refer to the manufacturers' package insert for full prescribing information which may include boxed warnings.

Amount/Time drugs may be entered as:

- Primary and or secondary infusions
- Fixed amount (for example, 1000 mg/250 mL)
- Standard concentration - drug amount/mL (for example, 10 mg/mL)
- Variable concentration
- Weight based infusions (for example, 70 mg/kg)
- Body Surface Area (BSA) (for example, 2 mg/m²)

To program an Amount/Time Infusion:

1. Select Care Area. Press **OK**.
2. Select the drug from the Drug Library using the keypad. Press the alphanumeric hard key(s) labeled with the desired letter(s) to enter the first two letters of the drug name. All drug names beginning with those two letters appear.
3. If the selected drug has modifiers, scroll to the desired modifier and press **OK**.

NOTE: A Modifier is used to differentiate drug therapies on the Pump based on dose modes, concentrations, limits, or configuration settings. An asterisk (*) displays next to the drug name on the Pump Infusion Running screen to indicate a Modifier is in use.

4. Select and confirm concentration if more than one concentration is displayed.
5. Press the arrow soft keys to choose the primary or secondary bag. If selected in the Drug Library, the required delivery mode will automatically display on the programming setup screen.

To program a Fixed Drug Amount:

These values may not be changed at the Pump and represent the entire dose. For example, 1000 mg/250 mL. See Figure 86.

1. Enter duration of infusion. Press **OK**.



Figure 86. Fixed Drug Amount Parameters Screen.

Infusion rate mL/hr is calculated and displayed.

NOTE: After **RUN** is pressed, the VTBI cannot be edited in any Amount/Time infusion.

2. To start the infusion, ensure that the slide clamp and roller clamp are open and press **RUN**.

Once **RUN** is pressed, the infusion will start and the Primary or Secondary Check Flow screen is displayed. Check the flow and confirm:

- All clamps are open.
- There are no kinks or collapses in the tubing outside of the Pump.
- Drops are flowing in the drip chamber. Note, at very low rates, it may take several minutes to see drops.
- Vents are open (if applicable).

If drops are falling in the drip chamber, press the **yes** soft key.

If no drops are falling, press the **no** soft key and follow the screen prompts. See Figure 87.

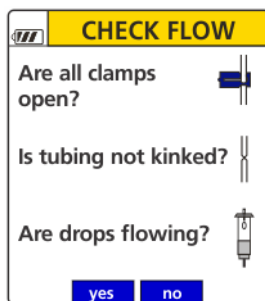


Figure 87. Primary Check Flow Screen.



Figure 88. Infusion Running Screen.



Figure 89. Infusion Status Screen.

NOTE: If additional action is required:

- To display infusion status while the Pump is infusing, press the **review/edit VTBI** soft key from the Infusion Running screen. See Figure 88. Also see Figure 89.
- To change the mL/hr rate while stopped, press the **review** or **program pri/sec** soft key. Press the arrow soft key to scroll up to change the rate.
- To change mL/hr rate while running, press the **rate change** soft key and enter the new rate.

To program a Standard Concentration - Drug Amount/mL:

The standard concentration may not be changed at the Pump. For example: 4 mg/mL.

1. Enter drug amount. Press **OK**.
2. Confirm standard concentration and press **OK**. See Figure 90. Also see Figure 91.

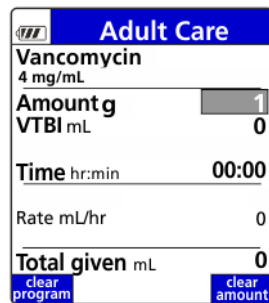


Figure 90. Standard Concentration Setup Screen.

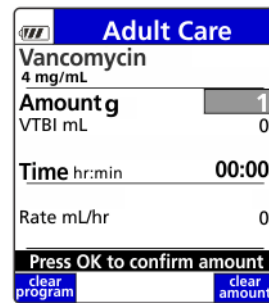


Figure 91. Standard Concentration Confirmation Screen.

NOTE: VTBI is automatically calculated and displayed.

NOTE: After **RUN** is pressed, the VTBI cannot be edited in any Amount/Time infusion.

3. Enter duration of infusion. Press **OK**. See Figure 92.
 - Dose is calculated and displayed. See Figure 93.

- Infusion rate mL/hr is calculated and displayed. See Figure 93.

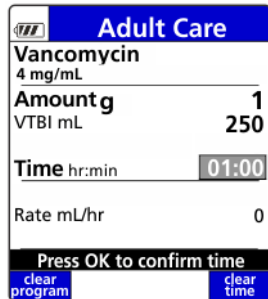


Figure 92. Enter Duration of the Infusion.



Figure 93. Dose and Infusion Rate Calculated by the Pump.

- To start the infusion, ensure that the slide clamp and roller clamp are open and press **RUN**. Once **RUN** is pressed, the infusion will start and either the Primary or Secondary Check Flow screen is displayed. Check the flow and confirm:
 - All clamps are open.
 - There are no kinks or collapses in the tubing outside of the Pump.
 - Drops are flowing in the drip chamber. Note, at very low rates, it may take several minutes to see drops.
 - Vents are open (if applicable).

If drops are falling in the drip chamber, press the **yes** soft key. See Figure 94.

If no drops are falling, press the **no** soft key and follow the screen prompts. See Figure 94.

NOTE: If additional action is required:

- To display infusion status while the Pump is infusing, press the **review** soft key from the Infusion Running screen. See Figure 95. Also see Figure 96.
- To change the mL/hr rate while stopped, press the **review** or **program pri/sec** soft key. Press the arrow soft keys to change the rate.

- To change mL/hr rate while running, press the **rate change** soft key and enter the new rate.

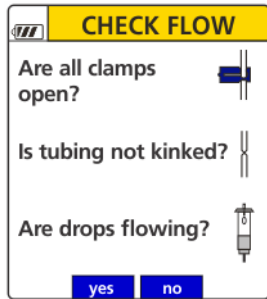


Figure 94. Primary Check Flow Screen.



Figure 95. Infusion Running Screen.

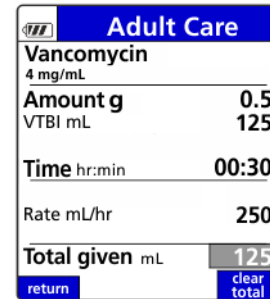


Figure 96. Infusion Status Screen.

To program a Variable Concentration:

Drug amount and diluent volume (VTBI mL) are entered during Pump programming.

- Enter drug amount. Press **OK**. See Figure 97.
- Enter VTBI. Press **OK**. See Figure 98.

NOTE: After **RUN** is pressed, the VTBI cannot be edited in any Amount/Time infusion.

The CONFIRM ADMIXTURE dialog box is displayed. Press the **yes** soft key to confirm. See Figure 99.

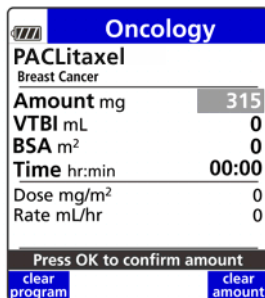


Figure 97. Enter Drug Amount. See important note on page 83.

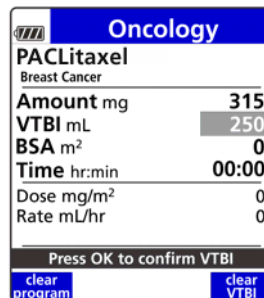


Figure 98. Enter VTBI. See important note on page 83.

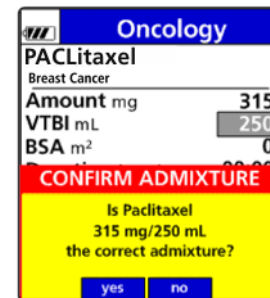


Figure 99. Confirm Admixture Dialog Box. See important note on page 83.

- Enter patient's weight or BSA if required. Press **OK**. See Figure 100.
- Enter duration of infusion. Press **OK**. See Figure 101.
 - Dose (if weight or BSA based) is calculated and displayed. See Figure 102.

- Infusion rate mL/hr is calculated and displayed. See Figure 102.

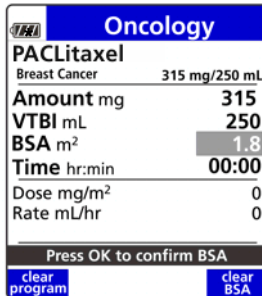


Figure 100. Enter Patient Weight or BSA. See important note on page 83.



Figure 101. Enter Duration of Infusion. See important note on page 83.

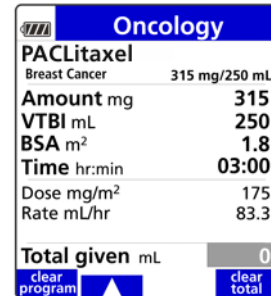


Figure 102. Dose and Rate Calculated by the Pump. See important note on page 83.

- To start the infusion, ensure that the slide clamp and roller clamp are open and press **RUN**.

Once **RUN** is pressed, the infusion will start and either the Primary or Secondary Check Flow screen is displayed. Check the flow and confirm:

- All clamps are open.
- There are no kinks or collapses in the tubing outside of the Pump.
- Drops are flowing in the drip chamber. Note, at very low rates, it may take several minutes to see drops.
- Vents are open (if applicable).

If drops are falling in the drip chamber, press the **yes** soft key. See Figure 103.

If no drops are falling, press the **no** soft key and follow the screen prompts. See Figure 103.

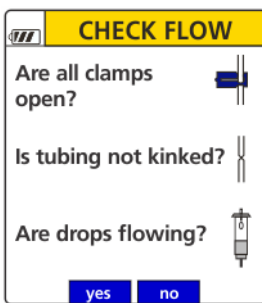


Figure 103. Primary Check Flow Screen.



Figure 104. Infusion Running Screen. See important note on page 83.

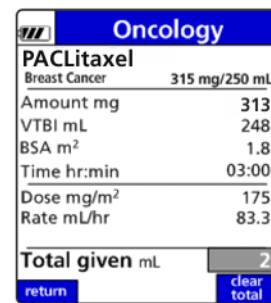


Figure 105. Infusion Status Screen. See important note on page 83.

NOTE: If additional action is required:

- To display infusion status while the Pump is infusing, press the **review** soft key from the Infusion Running screen. See Figure 104. Also see Figure 105.
- To change the mL/hr rate while stopped, press the **review** or **program pri/sec** soft key. Press the arrow soft key to change the rate.
- To change mL/hr rate while running, press the **rate change** soft key and enter the new rate.

Priming Volume

The Priming Volume feature is only applicable for Amount/Time primary infusions and only available during initial programming and IV set load or reload.

NOTE: Priming Volume adjustment allows a more accurate infusion of the actual fluid volume (VTBI) in the container after subtraction of the priming volume. This feature helps prevent early container depletion, which may result in air in line alarms at the end of the primary infusion. The infusion rate remains the same.

NOTE: The Pump does not prime the IV set. Priming needs to be done manually. See Preparing and Priming an IV Set on page 36.

To adjust the priming volume:

1. Follow the display prompts to load or reload the set properly.

NOTE: Priming Volume adjustment is available only after an IV set load or reload at the start of the infusion. Priming is done off the Pump by gravity.

NOTE: The Pump does not prime the set.

2. Select one of the following actions:

- Press the **yes** soft key to accept the priming volume displayed.
- Press the **no** soft key to decline the priming volume displayed.
- Press the **edit** soft key to change amount (mL). See Figure 106.

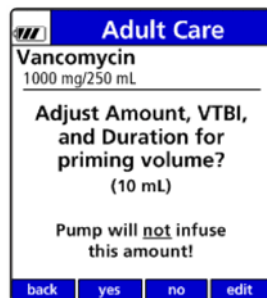


Figure 106. Priming Volume Adjustment Screen.

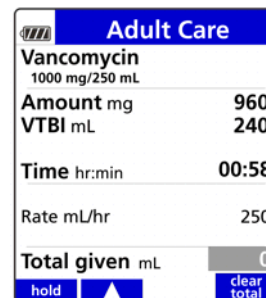


Figure 107. Review Screen for Priming Volume Adjustment.

If **yes** is pressed, priming volume is adjusted, the drug amount, VTBI and duration are adjusted accordingly and display on the review screen. See Figure 107.

3. Press **OK** to confirm.
4. To start the infusion, ensure that the slide clamp and roller clamp are open and press **RUN**.

Once **RUN** is pressed, the infusion will start and the Primary Check Flow screen is displayed. Check the flow and confirm:

- All clamps are open.
- There are no kinks or collapses in the tubing outside of the Pump.
- Drops are flowing in the drip chamber. Note, at very low rates, it may take several minutes to see drops.
- Vents are open (if applicable).

If drops are falling in the drip chamber, press the **yes** soft key.

If no drops are falling, press the **no** soft key and follow the screen prompts.

Line Flush

Line Flush feature allows delivery of any residual drug volume remaining in the IV container of a primary Amount/Time infusion.

- The Line Flush feature is enabled in the Drug Library.
- Line Flush infuses at the same rate as the last programmed infusion rate.
- The Line Flush feature may be repeated up to three times.
- Line Flush volume can be set to between 1 mL and 100 mL.
- Line Flush is only available for Amount/Time infusions.
- Line Flush volume is set in the Drug Library and can be changed at the Pump.

To flush the primary line:

1. At the completion of the primary infusion, press **STOP**.

A dialog box displays to enable the line flush. See Figure 108.

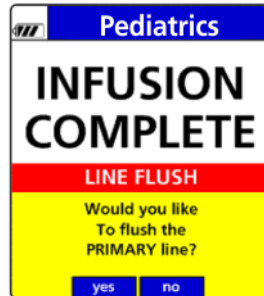


Figure 108. Primary Infusion Line Flush Dialog Box.

2. Press the **yes** soft key to deliver the residual volume (flush the line). Press the **no** soft key to decline the flush.
3. Enter the desired flush amount to be delivered and press **OK**. See Figure 109.

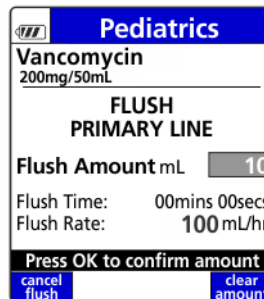


Figure 109. Enter Primary Line Flush Volume.

The Pump will deliver the Line Flush amount at the mL/hr rate of the previous infusion.

NOTE: If additional action is required:

To change the line flush volume (mL) after entering and confirming it, press the **clear amount** soft key.

4. To start the infusion, ensure that the slide clamp and roller clamp are open and press **RUN**.
Once **RUN** is pressed, the infusion will start and the Primary Check Flow screen is displayed. Check the flow and confirm:
 - All clamps are open.
 - There are no kinks or collapses in the tubing outside of the Pump.

- Drops are flowing in the drip chamber. Note, at very low rates, it may take several minutes to see drops.
- Vents are open (if applicable).

If drops are falling in the drip chamber, press the **yes** soft key.

If no drops are falling, press the **no** soft key and follow the screen prompts.

The volume remaining and an indicator that the IV line is being flushed are displayed. See Figure 110.



Figure 110. Primary Line Flush Status Screen.

Line Flush will continue until the entered flush volume has been delivered or the air in line detector senses air. See Figure 111.

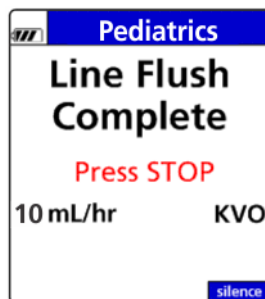


Figure 111. Primary Line Flush Complete Screen.

Secondary Line Flush

NOTE: **Important.** For the drug products mentioned, refer to the manufacturers' package insert for full prescribing information which may include boxed warnings.

At the completion of the secondary infusion a dialog box will be displayed to enable the line flush only if:

- Yes is pressed to request the secondary callback on the dialog box or,
- Secondary Callback has been configured as required in the Drug Library

NOTE: In the Optional setting, if no is selected to a callback, Secondary Line Flush will not be available.

The Secondary Line Flush feature allows delivery of any residual fluid volume remaining in the IV container of a secondary Amount/Time infusion.

- Line Flush is available for secondary infusions when the Secondary Callback feature is set to Required or Optional in the Drug Library.
- Line Flush infuses at the same rate as the last programmed infusion rate.
- Line Flush feature may be repeated up to three times.
- Line Flush volume can be set to between 1 mL and 100 mL.
- Line Flush is only available for Amount/Time infusions.
- Line Flush volume is set in the Drug Library and can be changed at the Pump.

To flush the secondary line:

1. At the completion of the secondary infusion, the Secondary Complete screen will display if the secondary callback has been enabled or configured for this drug in the Drug Library. See Figure 112. Also see Figure 113.

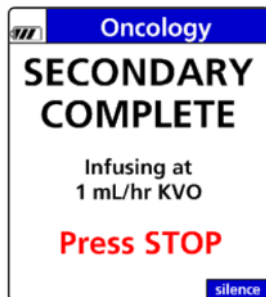


Figure 112. Secondary Complete Alarm.

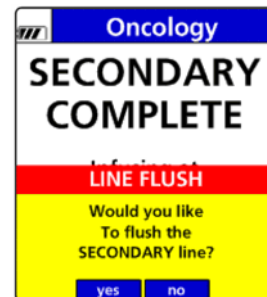


Figure 113. Secondary Complete: Line Flush Dialog Box.

2. Press the **yes** soft key to deliver the residual volume (line flush). Press the **no** soft key to decline the flush.

3. Enter the desired flush amount to be delivered and press **OK**. See Figure 114.

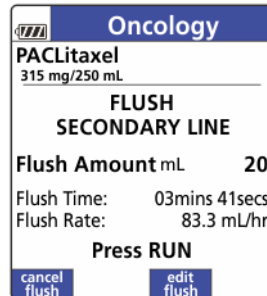


Figure 114. Enter Secondary Line Flush Volume. See important note on page 93.

The Pump will deliver the Line Flush at the mL/hr rate of the previous infusion.

NOTE: If additional action is required, to change the Line Flush amount (mL) after entering and confirming it, press the **edit flush** soft key.

4. To start the infusion, ensure that the slide clamp and roller clamp are open and press **RUN**.

Once **RUN** is pressed, the infusion will start and the Secondary Check Flow screen is displayed. Check the flow and confirm:

- All clamps are open.
- There are no kinks or collapses in the tubing outside of the Pump.
- Drops are flowing in the drip chamber. Note, at very low rates, it may take several minutes to see drops.
- Vents are open (if applicable).

If drops are falling in the drip chamber, press the **yes** soft key.

If no drops are falling, press the **no** soft key and follow the screen prompts.

The Infusion Running screen will show the amount of volume remaining and an indicator that the line is being flushed. See Figure 115.

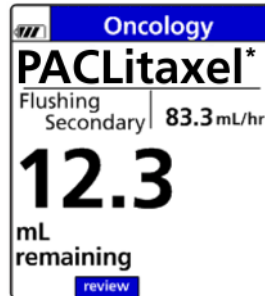


Figure 115. Secondary Line Flush Status Screen. See important note on page 93.

The Line Flush will continue until the entered flush volume has been delivered or the air in line detector senses air. See Figure 116.

- When no additional flushes are available (maximum of 3), a Select Infusion screen displays to return to the Secondary Setup or Review Primary infusion. See Figure 117.

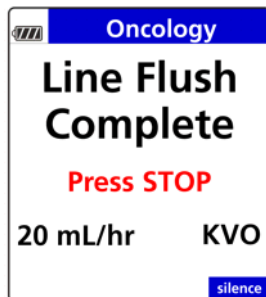


Figure 116. Secondary Line Flush Complete Screen.

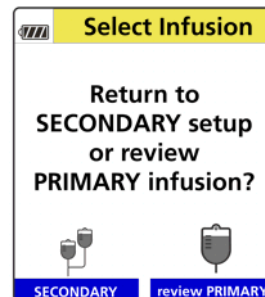


Figure 117. Select Infusion Screen.

Changing the Rate of an Amount/Time Infusion

NOTE: During an Amount/Time Infusion, a dialog box is displayed if the limits defined in the Drug Library for the selected drug are exceeded.

- Values exceeding the Soft Limits can be accepted by pressing the **yes** soft key or declined by pressing the **no** soft key displayed in the dialog box.
- Hard limits cannot be exceeded. Re-enter values within hard limits.

NOTE: **Important.** For the drug products mentioned, refer to the manufacturers' package insert for full prescribing information which may include boxed warnings.

To Change rate mL/hr without stopping the Pump:

1. At the Infusion Running screen, press the **rate change** soft key. See Figure 118.
2. Observe the displayed mL/hr soft limits. See Figure 119.

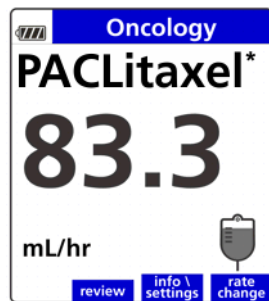


Figure 118. Infusion Running Screen. See important note on page 96.

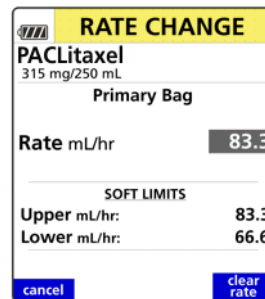


Figure 119. Rate Change Screen. See important note on page 96.

3. Enter a new mL/hr flow rate.
4. Press **OK** to confirm.

BASIC Mode

BASIC mode is a method of programming a continuous infusion where Drug Library limits do not exist.

BASIC mode allows the user to manually specify a dose mode, rate, volume, time or other parameters for the infusion.

Safety features available in BASIC mode are: Primary Check Flow, Secondary Check Flow and Single Step Rate or Dose Change.

When the Pump is running in BASIC, "BASIC MODE" appears on a red background in the title bar of the Pump display.

To program the Pump using the BASIC mode:

1. Press **ON/OFF** to power on the Pump.
2. At the New Patient screen:
 - Press the **yes** soft key to clear the previously programmed infusion values and allow programming a new infusion.

- Press the **no** soft key to retain the previously programmed infusion values. See Figure 120.



Figure 120. New Patient Screen.

3. Press the arrow soft keys to select the Care Area and press **OK**. See Figure 121.

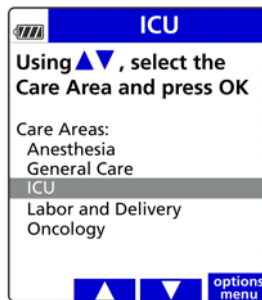


Figure 121. Select Care Area Screen.

4. Using the keypad, enter the letters **BA**, select BASIC and press **OK**. See Figure 122.

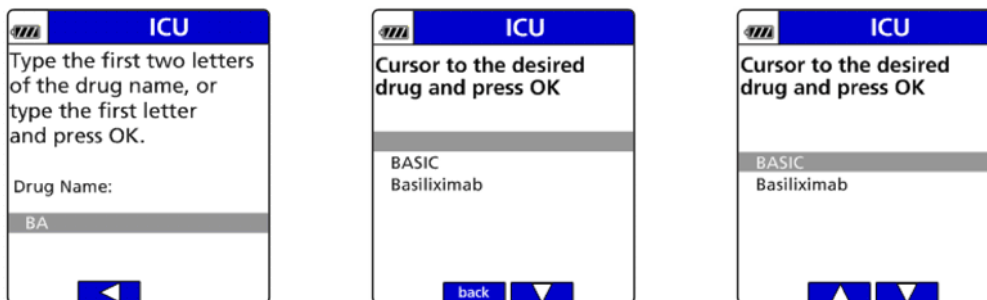


Figure 122. Selecting BASIC at Drug Identification Screen.

- Press the arrow soft keys to select Primary or Secondary bag setup and press **OK**. See Figure 123.
- Press the arrow soft key to select a dose mode and press **OK**. See Figure 124. Also see Figure 125. If a dose mode is selected, entering a concentration will be required.



Figure 123. BASIC Mode - Bag Selection Screen.



Figure 124. BASIC Mode - Dose Rate Selection Screen.



Figure 125. Arrow Soft Keys used to scroll through Dose Modes.

- To enter a concentration, press the arrow soft keys to select a unit of measurement (for example, mg, mcg, g and so forth). Press **OK**. See Figure 126.



Figure 126. BASIC Concentration Unit Selection Screen.

8. Enter a unit amount and press **OK**. See Figure 127.

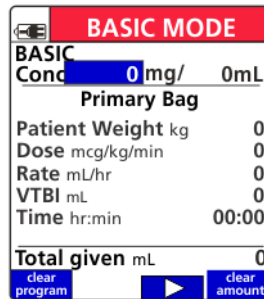


Figure 127. BASIC Concentration Unit Amount Selection Screen.

9. Enter diluent amount and press **OK**. See Figure 128.



Figure 128. BASIC Concentration Diluent Amount Selection Screen.

10. Enter patient weight if applicable.
11. Enter the dose or flow rate value and press **OK**.
12. Enter the VTBI (Volume To Be Infused) in mL.
13. Verify the VTBI equals the volume in the container and press **OK**.
14. Confirm the calculated infusion time.
15. Confirm the Total given mL value or press the **clear total** soft key to erase it.

NOTE: VTBI counts down to zero, while Total given counts from zero up.

16. To start the infusion, ensure that the slide clamp and roller clamp are open and press **RUN** to begin the infusion.

17. Once **RUN** is pressed, the infusion will start and either the Primary or Secondary Check Flow screen is displayed. Check the flow and confirm:

- All clamps are open.
- There are no kinks or collapses in the tubing outside of the Pump.
- Drops are flowing in the drip chamber. Note that at very low rates, it may take several minutes to see drops.
- Vents are open (if applicable).

If drops are falling in the drip chamber, press the **yes** soft key.

If no drops are falling in the drip chamber, press the **no** soft key and follow the screen prompts.

Placing the Pump in **STANDBY (Hold)**

Place the Pump in standby to prevent the Inactivity Alarm for the period of time specified in Alarm Settings in the menu option. The default setting is set to an infinite period of time, however, this value may be changed from 1 minute up to 99 hours and 59 minutes.

To place the Pump in standby:

1. Load the set and complete the infusion programming.

Once programming has been completed and the highlight is on the Total Given mL value, a message is displayed stating that the Pump may either be started or placed in standby.

2. To place the Pump in standby, press the **hold** soft key. See Figure 129.

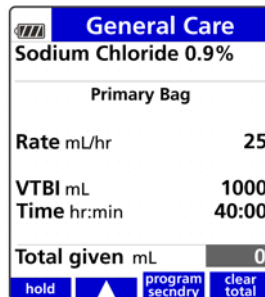


Figure 129. hold Soft Key.

When standby is activated, **IN STANDBY** is displayed in a flashing format. See Figure 130.

NOTE: If the standby period is set to infinite, the time value in the display will be replaced with a dashed line.

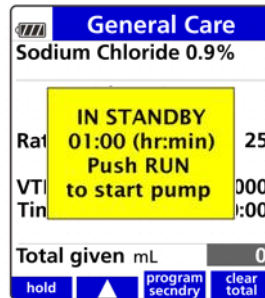


Figure 130. In STANDBY Message.

3. While the Pump is in standby, press **RUN** at any time to begin the infusion.

NOTE: Pressing any other key or opening the Pump door cancels standby mode.

4. To start the infusion, ensure that the slide clamp and roller clamp are open and press **RUN**.
Once **RUN** is pressed, the infusion will start and the Primary Check Flow screen is displayed. Check the flow and confirm:
 - All clamps are open
 - There are no kinks or collapses in the tubing outside of the Pump
 - Drops are flowing in the drip chamber. Note, at very low rates, it may take several minutes to see drops.
 - Vents are open (if applicable).

If drops are falling in the drip chamber, press the **yes** soft key.

If no drops are falling, press the **no** soft key and follow the screen prompts.

To place a Pump in standby after an infusion has started:

1. Press **STOP**.
2. Press the **review/program** soft key.
3. Press the **hold** soft key.

Keypad Lock

Locking the keypad prevents unauthorized keypad use. The keypad can be locked in two ways:

- Manually by entering the keypad lock code.
- Automatically by activating the Auto Keypad Lock feature in the Drug Library.

WARNING Unauthorized View or Access.

Always guard the keypad lock code from unauthorized view or access. Uncontrolled access by a patient or family member may cause injury to the patient.

Automatic keypad lock:

- » When configured in the Drug Library, the keypad will lock automatically by activating the Auto Keypad Lock feature by Care Area.

The keypad will lock 60 seconds after the **RUN** key is pressed.

To manually lock the keypad:

- » While the Pump is infusing, enter the keypad lock code 429. A popup message appears briefly indicating that the keypad has been locked. See Figure 131.

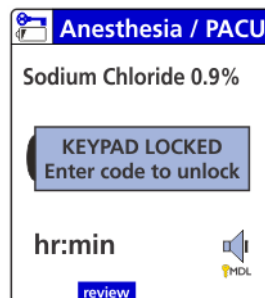


Figure 131. Keypad Lock Popup Message.

The Keypad Lock icon appears in the upper left corner of the screen when the Pump is locked. See Figure 132.



Figure 132. Keypad Lock Icon.

Pressing any key while the keypad is locked causes the same popup message to be displayed. See Figure 131.

NOTE: 429 is the default keypad lock code. Refer to the Library Configurations section in the *SIGMA Spectrum Infusion System Master Drug Library User Manual* to change the keypad lock code. The keypad lock code is set hospital-wide in the Drug Library and may be 1 to 4 digits long (1-9 only; zero cannot be used).

To unlock the keypad:

- » Re-enter the keypad lock code 429. The Keypad Lock icon disappears.

NOTE: If the keypad is unlocked while reviewing setup and the Pump is not stopped, the keypad will automatically relock upon returning to the Infusion Running screen.

NOTE: Pressing the **STOP** key while the keypad is locked will not stop the Pump. To stop the Pump, re-enter the keypad lock code and press **STOP**.

To view infusion setup while the keypad is locked:

- » Press the **review** soft key or the **review/edit VTBI** soft key. No values can be changed and, therefore, navigation from value to value is not allowed while the keypad is locked.

Certain alarm conditions can be silenced and cleared while the keypad is locked.

For more information about the keypad lock feature, refer to the Care Area Configurations section in the *SIGMA Spectrum Infusion System Master Drug Library User Manual*.

ALARMS

The SIGMA Spectrum Infusion System will display alarms when specific conditions exist. Depending on the priority, these alarms can be an audio tone and/or an alarm message displayed in red on the Pump screen. The message states the reason for the alarm and contains prompts for clearing the alarm.

CAUTION Confirm Audio Operation.

Listen for beeps when pressing keys. If sound is not heard, discontinue use of the Pump and refer servicing to qualified service personnel at your facility or return the Pump to Baxter for service.

CAUTION Confirm Display Operation.

Regularly observe the Pump's display. If display abnormalities are observed, discontinue use of the Pump and refer servicing to qualified service personnel at your facility or return the Pump to Baxter for service.

NOTE: The following shows some of the alarms that use the drug audio alarm setting entered in the MDL when the drug is selected at the Pump: Inactivity; Air in line; Max Air Detected; Upstream Occlusion; Downstream Occlusion; Bag Near Empty; Slide Clamp Detected; KVO; Air Still Detected. See Figure 133. Also see Figure 134.

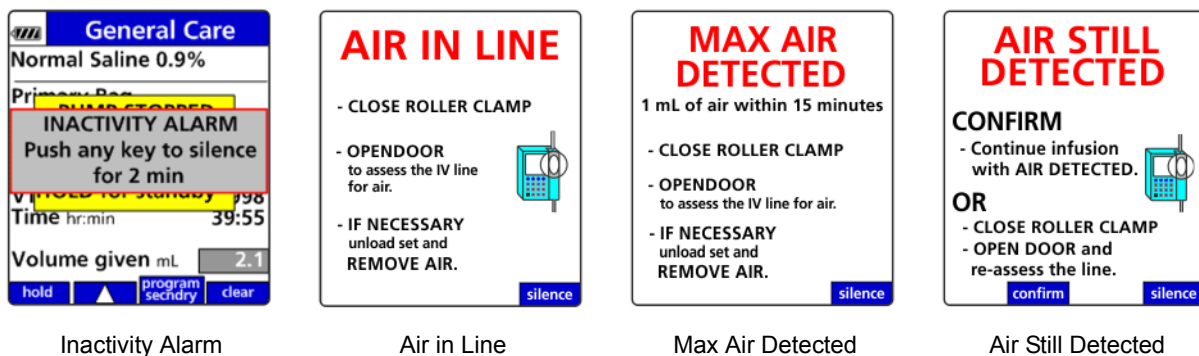


Figure 133. Example Audio Alarm Messages.



Figure 134. Example Audio Alarm Messages.

Silencing an Alarm Tone

To silence the audio tone for an alarm, press the **silence** soft key or any key on the keypad. This silences the alarm tone for 2 minutes. If the alarm has not been cleared after 2 minutes, the alarm tone will resume.

NOTE: Pressing the ON/OFF key will cause the Pump to shutdown.

Clearing an Alarm

To clear an alarm, follow all of the prompts and instructions in the alarm message. The alarm clears after the alarm condition has been corrected and all of the prompts followed.

Clinician Alert Tone

When programming the Pump, the Clinician Alert Tone will occur if an action is not accepted or needs confirmation.

The Clinician Alert Tone is a triple beep tone that occurs every 10 seconds.

To silence the Clinician Alert Tone, enter the necessary information until the action is accepted or enter a confirmation.

Alarm Messages

| Alarms | Action |
|---------------------------|--|
| <p>AIR IN LINE</p> | <p>The AIR IN LINE screen displays if the Pump detects air in the loaded IV tubing. To prevent free flow, ALWAYS ensure all clamps are closed before opening the door and unloading the IV set from the Pump.</p> <p>View and assess the IV line for air:</p> <ol style="list-style-type: none"> 1. Close the roller clamp to prevent free flow. 2. Open the door to evaluate the IV set. 3. Check the tubing in the tubing channel for the presence of air. 4. Check the tubing above and below the Pump for the presence of air. 5. Check for an upstream occlusion from kinks in the tubing and closed clamps. 6. Confirm the IV line is free of air and kinks. 7. Unload the IV set to remove the air if necessary. 8. Follow facility policy and procedures to remove the air manually. 9. Reload the IV set. 10. Close the Pump door. <p>If air is no longer detected by the Pump:</p> <ol style="list-style-type: none"> 11. Open the slide clamp and roller clamp. 12. Press RUN to resume infusion. <p>If using multiple Pumps:</p> <ul style="list-style-type: none"> ■ Confirm correct IV line when checking for the presence of air. ■ If IV line removal is required, confirm correct IV line before removing. <p>WARNING Priming. Prior to connecting to patient, prime IV set following the standard gravity priming instructions included with the administration set, remove all air, close roller clamp and slide clamp, load IV set into the Pump, close the door, open slide clamp and roller clamp.</p> |

| Alarms | Action |
|----------------------------------|---|
| <p>AIR STILL DETECTED</p> | <p>The AIR STILL DETECTED screen displays if the Pump still detects air in the loaded IV tubing when the door is closed after an AIR IN LINE alarm.</p> <p>Reassess the IV line for air</p> <ul style="list-style-type: none"> ■ Ensure all clamps are closed before opening the door and unloading the IV set from the Pump. <ol style="list-style-type: none"> 1. Close the roller clamp to prevent free flow. 2. Open the door to evaluate the IV set. 3. Check the tubing in the tubing channel for the presence of air. 4. Unload the IV set to remove the air if necessary. 5. Follow facility policy and procedures to remove the air manually. 6. Reload the IV set. 7. Close the Pump door. 8. Confirm the IV line has been assessed. 9. Open the slide clamp and roller clamp. 10. Press RUN to resume the infusion. <p>OR</p> <p>To continue the infusion:</p> <ol style="list-style-type: none"> 1. Press confirm and continue the infusion with air detected. 2. Press RUN to continue the infusion. <p>If using multiple Pumps:</p> <ul style="list-style-type: none"> ■ Confirm correct IV line when checking for the presence of air. ■ If IV line removal is required, confirm correct IV line before removing. <p style="text-align: center;">WARNING Priming.</p> <p>Prior to connecting to patient, prime IV set following the standard gravity priming instructions included with the administration set, remove all air, close roller clamp and slide clamp, load IV set into the Pump, close the door, open slide clamp and roller clamp.</p> |

| Alarms | Action |
|--|---|
| MAX AIR DETECTED | <p>The Pump will alarm when approximately 1 mL of accumulated air has been detected in 15 minutes.</p> <p>To prevent free flow, ALWAYS ensure all clamps are closed before opening the door and unloading the IV set from the Pump.</p> <ol style="list-style-type: none"> 1. Close the roller clamp to prevent free flow. 2. Open the door to evaluate the IV set. 3. Check the tubing in the tubing channel for the presence of air. 4. Check the tubing above and below the Pump for the presence of air. 5. Ensure all clamps are closed before unloading the IV set from the Pump. 6. Unload the IV set. 7. Follow facility policy and procedures to remove the air manually. 8. Reload the set. 9. Close the Pump door. 10. Confirm the line has been assessed. 11. Open the slide clamp and roller clamp. 12. Press RUN to resume the infusion. <p style="text-align: center;">WARNING Priming.</p> <p>Prior to connecting to patient, prime IV set following the standard gravity priming instructions included with the administration set, remove all air, close roller clamp and slide clamp, load IV set into the Pump, close the door, open slide clamp and roller clamp.</p> |
| AUDIO | <p>The audio alarm may be silenced for 2 minutes by pressing any key or the silence soft key.</p> |
| BAG NEAR EMPTY < 30 minutes remain | <p>Displays when there is less than 30 minutes of the programmed infusion time remaining in the currently programmed infusion.</p> <ul style="list-style-type: none"> ■ Press OK to acknowledge and clear the alarm. |
| BATTERY ALERT | <p>Displays when the Battery Module will not charge. In order to prevent interruption to the infusion, do not unplug the AC Power Adapter from the Pump.</p> <ol style="list-style-type: none"> 1. Press OK to acknowledge and clear the alarm. 2. Replace the Battery Module after the current infusion ends. |
| BATTERY DEPLETED | <p>Displays when the Battery Module is fully depleted and unable to power the Pump.</p> <p>To recharge the Battery Module and continue the infusion:</p> <ol style="list-style-type: none"> 1. Plug the Pump's AC Power Adapter into an AC outlet. 2. Confirm that the adaptor's Power Cord Connector is attached to the Pump. |

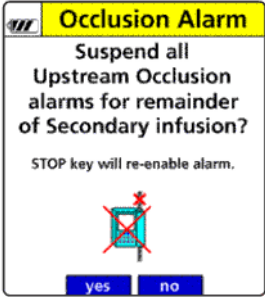

| Alarms | Action |
|-------------------------------|--|
| BATTERY MISSING | <p>Displays when the Pump cannot detect an installed Battery Module.</p> <ul style="list-style-type: none"> ■ Confirm that the Battery Module is properly installed and securely latched into the Pump. |
| CLEAN LOAD POINT #2 | <p>Displays when the Pump detects foreign matter in the tubing channel at Load Point 2.</p> <ol style="list-style-type: none"> 1. Observe there is no debris or foreign matter at Load Point 2. 2. If observed, remove debris and clean the tubing channel. See “Cleaning the Pump” on page 120. 3. If the alarm repeats, return the Pump for service to qualified personnel at your facility. |
| CLOCK BATTERY LOW | <p>Displays when the real-time (internal coin cell battery) clock (RTC) battery is low.</p> <ul style="list-style-type: none"> ■ Return the Pump to qualified personnel at your facility or to Baxter for service. |
| CLOSE CLAMP RELOAD SET | <p>Displays when an IV set is loaded into the Pump before the Pump has completely powered on.</p> <ol style="list-style-type: none"> 1. Unload the IV set. 2. Press ON/OFF to power off the Pump. 3. Press ON/OFF to power on the Pump. 4. After the Pump has completely powered on, reload the IV set. See “Loading an IV Set” on page 37. |
| DOOR NOT FULLY LATCHED | <p>Displays when the Pump’s door is closed but not fully in the locked position.</p> <ol style="list-style-type: none"> 1. Close the roller clamp below the Pump. 2. Open the door by inserting the slide clamp into the keyhole. 3. Re-load the IV set following the on-screen prompts. 4. Close the Pump’s door by pressing the upper and lower corners near the door latches. See “Loading an IV Set” on page 37. |
| DOOR OPEN | <p>Displays when the Pump’s door is open while an IV tube is loaded in the tubing channel.</p> <ol style="list-style-type: none"> 1. Close the roller clamp. 2. Assess the IV line for air. 3. Close the door. <p>OR</p> <ul style="list-style-type: none"> ■ Unload the tubing by pulling it out and up from the bottom of the Pump towards the top. See “Unloading an IV Set” on page 44. |

| Alarms | Action |
|--|---|
| DOWNSTREAM OCCLUSION | <p>Displays when the Pump detects an occlusion below the Pump.</p> <ol style="list-style-type: none"> 1. Assess the IV tubing below the Pump. 2. Assess the IV access site. 3. Eliminate a closed clamp, kinked tubing, positional catheter, clotted catheter, clogged IV filter or other sources of occlusion below the Pump. 4. Once the occlusion has been resolved, the Pump will automatically restart. <p style="text-align: center;">WARNING Pressurized Fluid.</p> <p>If disconnecting the IV set below the Pump is necessary, close the roller clamp before disconnecting the IV set from the patient to prevent possible exposure by the release of pressurized fluid upon Pump auto-restart.</p> |
| DOWNSTREAM PRESSURE LIMIT - RESET SETTING | <p>The downstream occlusion pressure limit differs from Care Area default (set in the Drug Library).</p> <p>Select the yes soft key to reset to the default setting, or</p> <p>Select the no soft key to keep the current setting.</p> |
| INACTIVITY ALARM | <p>Displays when the Pump has been inactive for 2 minutes and no action has been taken.</p> <ol style="list-style-type: none"> 1. Follow the on-screen prompts. 2. Resume or restart the Pump by pressing RUN. |
| IMPROPER SHUTDOWN | <p>Displays when data is lost from the previously programmed infusion.</p> <ol style="list-style-type: none"> 1. Press OK to clear the message. 2. Re-program the infusion, if needed. |
| LOAD SET | <p>Displays on loading of the IV set into the tubing channel.</p> <ul style="list-style-type: none"> ■ Follow the on-screen prompts to load the IV set properly. See "Loading an IV Set" on page 37. |
| LOW BATTERY | <p>Displays when the low battery alarm threshold is reached. There is less than 30 minutes of battery power remaining.</p> <ol style="list-style-type: none"> 1. Plug the AC Power Adaptor into the Pump. 2. Plug the AC Power Adaptor into an AC outlet as soon as possible to recharge the Battery Module. |
| CLOSE DOOR REMOVE CLAMP | <p>Displays when ON/OFF is pressed to power off the Pump while the door is open or the slide clamp is in the keyhole.</p> <p>Before the Pump powers off:</p> <ol style="list-style-type: none"> 1. Remove the slide clamp from the keyhole. 2. Close the Pump door. |

| Alarms | Action |
|---|--|
| <p>PRIMARY INFUSION COMPLETE</p> | <p>Displays when the Primary Infusion VTBI has counted down to zero.</p> <ul style="list-style-type: none"> ■ The Pump is running at a Keep Vein Open rate (KVO rate) or the actual infusion rate, whichever is lower. ■ The Drug Library default KVO rate is set at 1 mL/hr in the Drug Library. |
| <p>RELOAD SET</p> | <p>Displays when the Pump door is closed and the IV tube has not been loaded in the correct order or in all the load points within the tubing channel.</p> <ul style="list-style-type: none"> ■ Unload and reload the IV set. See “Loading an IV Set” on page 37 and “Unloading an IV Set” on page 44. |
| <p>REMOVE CLAMP FROM PRIMARY</p> | <p>Displays at the completion of a secondary infusion if no is selected during the Secondary Check Flow tutorial and yes is selected in response to Clamp Applied? during tutorial. See “Secondary Infusion” on page 58.</p> <p>At the end of a secondary infusion:</p> <ol style="list-style-type: none"> 1. Press the review Primary soft key. 2. Remove applied clamp from primary line. |
| <p>SECONDARY INFUSION COMPLETE</p> | <p>Displays when the programmed secondary VTBI has counted down to zero and secondary callback is applied by either the Drug Library or has been selected. The Pump runs at KVO rate.</p> <p>If Secondary Callback is unavailable or not selected, the Pump transitions to the delivery of the primary program.</p> |
| <p>SLIDE CLAMP DETECTED</p> | <p>Displays when the Pump detects a slide clamp in the keyhole.</p> <ol style="list-style-type: none"> 1. Remove slide clamp from the keyhole. 2. Press RUN. 3. If slide clamp not present in keyhole and the alarm occurs, inspect for debris. 4. If the alarm re-occurs, send the Pump for service to qualified personnel at your facility. |

| Alarms | Action |
|----------------------------|---|
| <p>SYSTEM ERROR</p> | <p>Displays when the Pump detects an internal fault.</p> <p><i>NOTE:</i> Record the programming parameters before the Pump is powered off.</p> <p>Follow the directions displayed on the screen to:</p> <ul style="list-style-type: none"> ■ Power off the Pump and then power on the Pump. <p>Should an audio alarm occur with no direction on the screen:</p> <ol style="list-style-type: none"> 1. Disconnect the battery from the Pump and unplug the AC Power Adaptor from the AC outlet. 2. Wait approximately 5 or more seconds, reconnect the battery and plug the AC Power Adaptor into an AC power outlet. 3. Press ON. 4. If neither procedure clears the fault, return the Pump for service. <p style="text-align: center;">CAUTION Unrecoverable System Error.</p> <p>If unable to clear a fault condition during a system error occurrence, discontinue using the Pump. Refer to qualified service personnel at your facility or return the Pump to Baxter for service.</p> |

| Alarms | Action |
|----------------------------------|---|
| <p>UPSTREAM OCCLUSION</p> | <p>Displays when the Pump detects an occlusion above the Pump.</p> <p>To eliminate the occlusion or flow restriction:</p> <ol style="list-style-type: none"> 1. Check and open any of the following: <ul style="list-style-type: none"> ● Closed slide clamp ● Closed burette vent ● Closed vent on drip chambers with rigid or semi rigid containers 2. Check and eliminate kinked or collapsed IV tubing outside the Pump. 3. Verify the occlusion has been eliminated. 4. Press RUN to start the infusion. 5. Verify the drop rate is consistent with the programmed rate. <p><i>NOTE:</i> If unable to locate an occlusion, see “Troubleshooting Alarm Causes” on page 116.</p> <p>WARNING Time to Upstream Occlusion at Lower Flow Rates.</p> <p>When infusing at flow rates below 5 mL/hr, the Pump may take an extended period of time to detect an upstream occlusion and sound an alarm.</p> <p>Ensure the following:</p> <ul style="list-style-type: none"> ● All clamps are open. ● There are no kinks or collapses in the tubing outside of the Pump. ● Drops are flowing in the drip chamber. Note, at very low rates, it may take several minutes to see drops. ● Vents are open (if applicable). <p>WARNING Proper Venting Required.</p> <p>Upstream occlusions caused by improperly vented glass bottles or burettes may not be detected because of the very slow-building vacuums resulting from these situations.</p> |

| Alarms | Action |
|---|---|
| <p>UPSTREAM OCCLUSION ALARM SUSPENSION</p> | <p>A drug configuration in the Drug Library that allows the clinician to temporarily suspend the upstream occlusion alarm on the Pump if the alarm is considered to be a false alarm. See "Troubleshooting Alarm Causes" on page 116.</p> <p>The suspension prompt appears after two consecutive upstream occlusion alarms and a positive confirmation on the check flow display screen. See Figure 135.</p> <p>This dialog allows the user to suspend the alarm for the currently programmed infusion. The upstream occlusion alarm will be re-enabled automatically when:</p> <ol style="list-style-type: none"> STOP is pressed. The door is opened. The infusion transitions from Secondary to Primary. Any alarm condition that stops the Pump and when the Pump is powered OFF and then back ON. <p>WARNING Upstream Occlusion Alarm Suspension.</p> <ul style="list-style-type: none"> Do not use the Upstream Occlusion Alarm Suspension when delivering critical drugs where the risk of flow stoppage due to an undetected upstream occlusions outweighs that of flow interruption due to alarms where no upstream occlusion is present. Do not use Upstream Occlusion Alarm Suspension for drugs delivered in RIGID containers since the flow restriction caused by lack of proper container venting may be difficult to recognize when troubleshooting an alarm condition. Only use Upstream Occlusion Alarm Suspension after the operator visually observes positive line flow. <p>Upstream Occlusion Suspension feature is enabled for all drugs, by default, in the Drug Library.</p> <div style="display: flex; justify-content: space-around; align-items: center;">   </div> <p>Figure 135. Upstream Suspension Prompts: Primary and Secondary Infusions.</p> |

| Alarms | Action |
|----------------------------|---|
| Value Entry Timeout | Displays when entered value is not confirmed within ten seconds of entering value. The previous value is restored. <ol style="list-style-type: none"> 1. Re-enter desired value. 2. Press OK to confirm entered value. |
| VERY LOW BATTERY | Displays when less than half of the low battery capacity remains. <ol style="list-style-type: none"> 1. Plug the AC Power Adaptor in immediately. 2. Follow the tutorial to check the AC Power Adaptor will automatically begin. See Appendix F: "Low / Very Low Battery Alarm Instructions" on page 159. |

Troubleshooting Alarm Causes

Check the following items to prevent alarms:

- Use only compatible IV sets as labeled and identified on the SIGMA Spectrum Infusion Pump. See "Compatible IV Sets" on page 125.
- Remove all air from IV sets. Slowly prime the IV line while inverting and tapping air from all Y injection sites and backcheck valves.
- Do not administer extremely cold or hot solutions.
- Warm solutions to room temperature before use to help prevent upstream occlusion or air in line alarms caused by out-gassing of micro bubbles.
- Effervescent, foamy, or frothy solutions can result in upstream occlusion alarms.
- Invert (do not shake) IV bags that need to be mixed.
- Fill drip chambers half way.
- Do not reload pumped-on tubing (the tubing segment previously used in the pumping channel) into the pumping channel.
- Keep the pumping channel clean, dry and free of dirt and debris.
- Avoid empty IV containers by properly setting VTBI values.
- Plug in the Pump's AC Power Adaptor to maintain battery charge.
- Use the medium or high DS Pressure Limit (Downstream Occlusion Pressure Limit) setting at flow rate settings above 500 mL/hr to avoid downstream occlusion alarms that are created by IV set pulsation.

Managing Bolus before Occlusion (Downstream) Release

When a downstream occlusion alarm occurs, pressure and a small volume of <0.98 mL of fluid (the "bolus") builds up between the Pump and the point of occlusion. When it might be harmful to infuse the bolus into the patient, simultaneously withdraw 0.9 mL of fluid from the lower Y injection site of the IV set and eliminate the source of the occlusion.

Battery Warning Levels

The Pump provides three warning levels as the battery capacity decreases while operating on battery power. These levels are:

- Low Battery
- Very Low Battery
- Battery Depleted

When the Low Battery and Very Low Battery alarms are activated, a set of on-screen instructions automatically pops up to guide the user through the process. For more information, see Appendix F: "Low / Very Low Battery Alarm Instructions" on page 159.

If the Pump is not plugged in, the battery will continue to slowly discharge even if the Pump is powered off.

Low Battery

When the battery is low, the Pump sounds a triple-beep audio alarm every 5 seconds. Press **OK** to temporarily suspend this alarm. While suspended, the Low Battery status will be indicated in the alert bar and a tone will be generated once every 5 minutes to remind the user of the Low Battery status. See Figure 136.

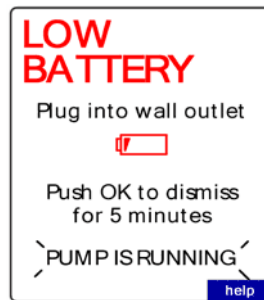


Figure 136. Low Battery Alarm.

If the Pump is not plugged in or the alarm is not acknowledged after 2 minutes, the alarm volume increases and the troubleshooting tutorial automatically begins.

NOTE: When the Low Battery warning initiates, a minimum of 30 minutes of runtime remains.

Very Low Battery

If the battery level drops below the low-battery level, the message changes to Very Low Battery and begins to flash. The back light also dims to reduce battery usage. See Figure 137.

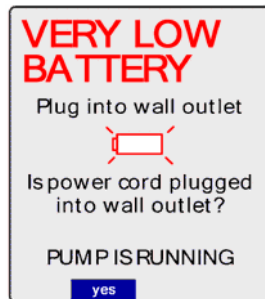


Figure 137. Very Low Battery Alarm.

NOTE: When the Very Low Battery warning initiates, a minimum of 15 minutes of runtime remains.

Battery Depleted

If the battery level drops below the Very Low Battery level, the message changes to Battery Depleted. See Figure 138.



Figure 138. Battery Depleted Alarm.

The Pump will stop running. If the Pump is not plugged in within 3 minutes, the Pump will shut itself off.

CLEANING AND STORAGE

The SIGMA Spectrum Infusion System should be cleaned and disinfected for each patient use according to facility protocol.

CAUTION Cleaning the Pump and Pump Accessories.

- Always wear gloves when cleaning Pump and Pump accessories.
- Only use Baxter specified compatible cleaning fluids.
- Do not allow fluid to seep inside the Pump (especially through the keyhole, door latches or rear case speaker vent) or severe damage may occur.
- Do not spray solutions directly on the Pump and Pump accessories.
- Do not autoclave or use EtO (ethylene oxide) to sterilize Pumps or Pump accessories.
- Do not apply cleaners directly to battery packs exposed terminals.
- Do not immerse any part of the Pump or battery.
- Do not use phenol-based cleaners/disinfectants. Phenols degrade plastics and membrane switches.
- Do not use abrasive cleaners.
- Do not use rigid cleaning instruments.
- Always use a lint-free, foam tipped swab to clean the tube channel.
- Always dispose of all cleaning materials per federal, state and local regulations for biohazard waste disposal.

Compatible Cleaners

For a complete list of compatible cleaning materials refer to DOC 11318 on the Baxter website (www.sigmapumps.com).

- 10% Solution of Clorox[®] Regular-Bleach and 90% Water
- Clorox Commercial Solutions[®] Clorox[®] Germicidal Wipes
- Up to 90% Isopropyl Alcohol (IPA)
- Dispatch[®] Hospital Cleaner Disinfectant Towels With Bleach
- Coverage[®] Plus Germicidal Surface Wipes
- Coverage Spray TB Plus Ready to use Disinfectant and Decontaminant
- CaviCide[®] Disinfectant/Decontaminant Cleaner
- CaviWipes[®] Disinfectant/Decontaminant Cleaner
- EnVerros Sanimaster 4[®]
- A-456 II Disinfectant Cleaner
- PDI[®] Sani-Cloth[®] AF Germicidal Disposable Wipe

- PDI® Sani-Cloth® Bleach Wipes
- Super Sani-Cloth® Germicidal Disposable Wipe
- Opti-Cide3® Surface Disinfectant Wipes
- Opti-Cide3® Disinfectant and Cleaner Solution
- Sklar Disinfectant Solution
- DisCide® Ultra Disinfecting Towelettes
- 3M™ HB Quat Disinfectant Cleaner Concentrate
- MicroKill Plus Germicidal Wipes
- Oxivir TB Wipes

Cleaning the Pump

Do not use rigid cleaning instruments or spray solutions directly on the Pump and its accessories.

NOTE: Refer to the facility's protocol for the frequency of cleaning the Pump.

To clean the Pump:

1. Power off the Pump and unplug the AC Power Adaptor from the power source.
2. Remove the battery module.

NOTE: It is important to remove the battery module to ensure proper cleaning of the battery terminals, as well as to prevent any power from being applied to Pump circuitry while liquid cleaning solution is present, which may cause corrosion.

3. If a pole clamp is attached to the Pump, remove the pole clamp by loosening the thumb screw on the Pump side adaptor (back of the Pump) and slide the Pump off of the pole clamp.
4. Place the Pump in an upright position (keyhole assembly upward).

NOTE: Do not soak any portion of the Pump with liquid cleaners. All cleaning applicators should be damp, not dripping.

5. Apply the compatible cleaning agent to a lint-free cloth. Use appropriate dilution ratio per the manufacturer's instructions.
6. Ring out any excess cleaning solution from the lint-free cloth to ensure it is damp, not dripping. This prevents fluid from seeping into component areas of the Pump.

NOTE: Disinfectants should remain on the Pump's surface in an even, but not dripping, film for the recommended contact time for the compatible cleaning agents.

7. Wipe down the outside of the Pump.

NOTE: When cleaning the back of the Pump, lightly wipe the battery terminal pins with a damp cloth. Blot dry immediately (do not wipe dry), using a clean dry lint-free towel. Do not allow moisture to permeate the terminal pins or the seal.

8. Apply cleaning solution to a lint-free, foam tipped swab (do not use a cotton swab). Blot the swab onto a dry lint-free towel to remove excess cleaning solution.
9. Wipe down the speaker vent, battery pocket.
10. Ensure that the drainage channel in the battery pocket is clean and clear of any debris.
11. If the keyhole needs cleaning, send the Pump to the Biomed for proper cleaning.
12. Open the Pump's door using a compatible IV set's slide clamp.
13. Using a fresh lint-free, foam tipped swab, (do not use a cotton swab), apply cleaning solution to swab. Blot the swab onto a dry lint-free towel to remove excess cleaning solution.

NOTE: Do not attempt to clean inside latch holes adjacent to the Direction of Flow label.

NOTE: When cleaning the tubing channel, do not allow cleaning fluids to seep into or between the Pump components.

14. Wipe down the surface of door and tubing channel areas.
15. Visually inspect the tubing channel and remove any foreign material. An obstruction in the tubing channel could cause free flow.
16. Clean the battery module following the steps in "Cleaning the Battery Module" on page 122.
17. Wipe the Pump dry and allow to air-dry in the open air before Pump reuse.

NOTE: The Pump should remain powered off and the AC Power Adaptor unplugged from a power source until all cleaning liquids are completely evaporated from the entire Pump. Allow time for fluids that may have seeped into or between Pump components to dry. The battery module should remain off the Pump until air drying is complete.

NOTE: Allow additional drying time when in cold or humid environments.

18. Dispose of all cleaning materials (including the slide clamp) as required per facility protocol/biohazard policy.

WARNING Proper Disposal Required.

To dispose of this device or the associated administration sets, adhere to local, state, federal and/or other governing regulations.

Cleaning the Battery Module

To clean the battery module:

1. Remove the Battery Module from the Pump.
2. Apply cleaning agent with a dampened cloth per the manufacturer's instructions using appropriate dilution ratio.

NOTE: Do not spray solutions directly on the Battery Module or the exposed battery terminals.

3. Carefully inspect and clean any debris from around the battery terminals.
4. Dry Battery Module thoroughly before replacing into the Pump.
5. Dispose of all cleaning materials as required per facility protocol/biohazard policy.

Cleaning the AC Power Adaptor

To clean the AC Power Adaptor:

1. Power off the Pump and unplug the AC Power Adaptor from the power source.
2. Disconnect the power cord from the Pump.
3. Apply cleaning agent to a dampened cloth per the manufacturer's instructions using appropriate dilution ratio. Do not spray solutions directly on the AC Power Adaptor.
4. Wrap the cloth on the AC Power Adaptor cord and clean the full length of the cord.
5. Wipe the power cord housing and the connector, and carefully clean the AC Power Adaptor prongs.
6. Dry the AC Power Adaptor thoroughly.
7. Inspect the AC Power Adaptor for visual evidence of damage such as cracks, bent prongs, cuts or exposed wires or dents:
 - AC Power Adaptor Module
 - AC Power Adaptor Cord
 - AC Power Cord Adaptor Retainer
8. If no signs of damage are found, plug the AC Power Adaptor into a working wall outlet. If signs of damage are found, discontinue use and return the AC Power Adaptor to qualified service personnel at your facility for service.
9. Verify green LED on the AC Power Adaptor is lit while plugged in and a plug icon appears on the Pump's display.
10. Dispose of all cleaning materials as required per facility protocol/biohazard policy.

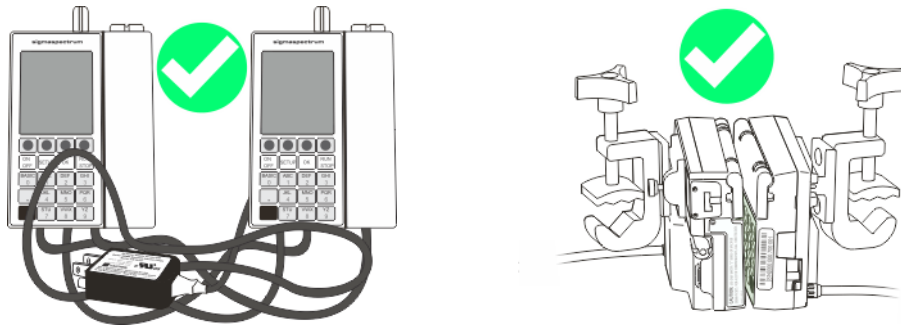
Cleaning the Pole Clamp

To clean the pole clamp:

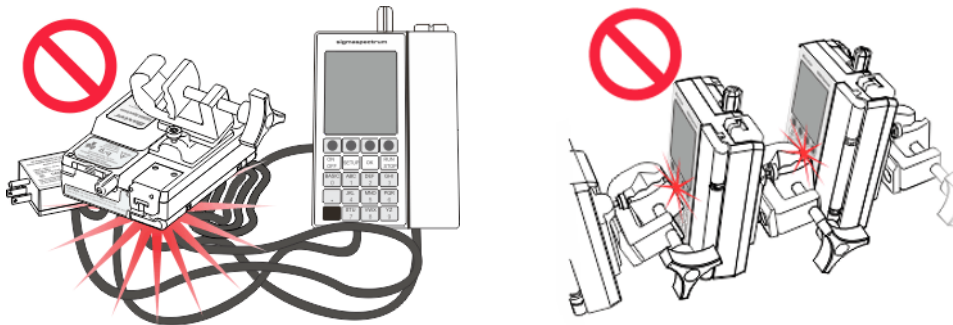
1. Power off the Pump and unplug the AC Power Adaptor from the power source.
2. Loosen the thumb screw on the back of the Pump and slide the Pump off of the pole clamp.
3. If the pole clamp is still attached to an IV pole, turn the mounting knob counter clockwise to remove.
4. Apply cleaning agent to a dampened cloth per the manufacturer's instructions, using appropriate dilution ratio.
5. Wipe the entire pole clamp including the screw mechanism.
6. Use a soft brush to clear debris from the screw mechanism.
7. Dry the pole clamp thoroughly before replacing it onto the Pump.
8. Dispose of all cleaning materials as required per facility protocol/biohazard policy.

Pump Handling, Transport and Storage

- Do not handle, transport or store Pumps in ways that might result in physical damage.
- Avoid handling, transporting and storing Pumps in a manner in which the pole clamp of another Pump, or other heavy or sharp objects could impact the keypad.



Proper Pump Handling, Transport and Storage.



Improper Pump Handling, Transport and Storage.

Figure 139. Pump Handling, Transport and Storage.

WARNING Pump Storage.

Remove the Battery Module from the Pump when storing the Pump for extended periods.

WARNING Ensure Secure Mounting of Pump During Use and Transport.

During use and transport, securely mount Pumps to IV pole by centering the pole in the clamp and turning the mounting knob clockwise. To maintain IV pole stability, never exceed 210 cm (83 in) from floor to IV pole top and limit bag volume at this extended height to <1 liter (1000 cc).

COMPATIBLE IV SETS

Compatible Baxter IV Sets

The following is a partial listing of the Baxter IV Sets compatible with the SIGMA Spectrum Infusion Systems that have been calibrated for Baxter IV set tubing. For a full listing of compatible sets refer to DOC 11182 on the Baxter website (www.sigmapumps.com) or call Baxter Technical Support at 800.356.3454.

WARNING IV Set Usage.

Do not use an IV set for longer than the manufacturer's labeled set change interval to reduce risk of infection and to maintain flow rate accuracy.

NOTE: In the IV Set List, noted superscripts reference specific warnings provided at the end of the compatible set list. See "Compatible Baxter IV Sets – WARNINGS " on page 129.

All sets must include a Blue Slide Clamp on the section of the set to be placed into the Pump. See Figure 140.



Figure 140. Blue Slide Clamp.

| No. | Brief Description |
|--|--|
| Primary Set Macro (10 drops/mL) | |
| 1C8109s | Solution Set, 101" (2.6 m), Male Luer Lock Adapter |
| 1C8160s | Solution Set, 69" (1.8 m) Male Luer Lock Adapter |
| 1C8296s | Solution Set, 125" (3.2 m), Male Luer Lock Adapter |
| 1C8727s | CLEARLINK System, CONTINU-FLO Solution Set, 113" (2.9 m), 3 Luer Activated Valves, Male Luer Lock Adapter with Retractable Collar ² |
| 2C6255s | CLEARLINK System, CONTINU-FLO Solution Set, 89" (2.3 m), 2 Luer Activated Valves, Male Luer Lock Adapter, Large Bore 4-Way Stopcock Extension Set, 34" (86 cm), Vol. 5.4 mL, 2 Luer Activated Valves, Male Luer Lock Adapter ^{2, 8} |
| 2C6401s | Interlink® System, Solution Set, Injection Site, Lever Lock Cannula, Luer Lock Adapter, 76" (1.9 m) |
| 2C6419s | Interlink® System, Solution Set with DUO-VENT Spike, 92" (2.3 m), Injection Site, Male Luer Lock Adapter |

| No. | Brief Description |
|---|---|
| 2C6541s | CONTINU-FLO Solution Set with DUO-VENT Spike, 106" (2.7 m), 3 Injection Sites, Male Luer Lock Adapter ^{2, 8} |
| 2C8401s | CLEARLINK System, Solution Set, 76" (1.9 m), Luer Activated Valve, Male Luer Lock |
| 2C8419s | CLEARLINK System, Solution Set with DUO-VENT Spike, 92" (2.3 m), Luer Activated Valve, Male Luer Lock Adapter |
| 2C6519s | CONTINU-FLO Solution Set, 89" (2.2 m), 2 Injection Sites, Male Luer Lock Adapter with Retractable Collar ² |
| 2C6537s | INTERLINK System, CONTINU-FLO Solution Set, 110" (2.8 m), 3 Injection Sites, Male Luer Lock Adapter ² |
| 2C6931s | Interlink® System, Continu-Flo® Solution Set, Length 89" (2.3 m), 2 Injection Sites, Male Luer Lock Adapter, 3-Port Manifold with Check Valves Vol. 1.0 mL, Large Bore 4-Way Stopcock Extension Set Vol. 6.2 mL, Length 41" (104 cm), 2 Injection Sites, Male Luer Lock Adapter ^{2, 8, 10} |
| 2C8515s | CLEARLINK System, CONTINU-FLO Solution Set, 106" (2.7 m), Luer Activated Valve, Male Luer Lock Adaptor with Retractable Collar ² |
| 2C8519s | CLEARLINK System, CONTINU-FLO Solution Set, 112" (2.8 m), 2 Luer Activated Valves, Male Luer Lock Adaptor ² |
| 2C8537s | CLEARLINK System, CONTINU-FLO Solution Set, 109" (2.8 m), 3 Luer Activated Valves, Male Luer Lock Adapter with Retractable Collar ² |
| 2C8541s | CLEARLINK System, CONTINU-FLO Solution Set with DUO-VENT Spike, 105" (2.7 m), 3 Luer Activated Valves, male Luer Lock Adapter with Retractable Collar ^{2, 8} |
| 3C0062s | INTERLINK System, CONTINU-FLO Solution Set, 89" (2.3 m), 2 Injection Sites, Male Luer Lock Adapter, Large Bore 4-way Stopcock Extension Set, 34" (89 cm), Vol. 5.4 mL, 2 Injection Sites, Male Luer Lock Adapter ^{2, 8} |
| 3C0134s | CLEARLINK System, CONTINU-FLO Solution Set, 88" (2.2 m), 2 Luer Lock Adapter with Retractable Collar, Large Bore 4-way Stopcock Manifold Extension Set, 32" (81 cm), 4.6 mL, Luer Activated Valve, Male Luer Lock Adapter with Retractable Collar ^{2, 8, 10} |
| Primary Set Minidrip (60 drops/mL) | |
| 2C6402s | Interlink® System, Solution Set, 76" (1.9 m), Injection Site, Lever Lock Cannula Male Luer Lock Adapter ¹ |
| 2C6424s | Solution Set, 92" (2.3 m), 2 Injection Sites, Male Luer Lock Adapter ¹ |
| 2C8402s | CLEARLINK System, Solution Set, 76" (1.9 m), Luer Activated Valve, Male Luer Lock Adapter ¹ |
| 2C6546s | CONTINU-FLO Solution Set, 105" (2.7 m) 3 Injection Sites, Male Luer Lock Adapter with Retractable Collar ^{1, 2, 8} |

| No. | Brief Description |
|---|---|
| 2C8546s | CLEARLINK System, CONTINU-FLO Solution Set, 105" (2.7 m), 3 Luer Activated Valves, Male Luer Lock Adapter with Retractable Collar ^{1, 2, 8} |
| 2C8548s | CLEARLINK System, Vented CONTINU-FLO Solution Set, 104" (2.6 m), 2 Luer Activated Valves, Male Luer Lock Adapter with Retractable Collar ^{1, 2} |
| Primary Filter Set Macro (10 or 20 drops/mL) | |
| 1W5000s | INTERLINK System - Solution Set (20 drops/mL), Injection Site, 15 Micron Disc Filter, Male Luer Lock Adapter 100" (2.5 m) long ⁴ |
| 1W5019s | Solution Set (20 drops/mL), 15 Micron Disc Filter, Male Luer Lock Adapter 93" (2.4 m) long ⁴ |
| 2C6571 | CONTINU-FLO Solution Set (10 drops/mL), 105" (2.7 m), 0.22 Micron High Pressure, Extended Life Filter, 2 Injection Sites, Male Luer Lock Adapter with Retractable Collar ^{2, 4} |
| 2C8571 | CLEARLINK System, CONTINU-FLO Solution Set (10 drops/mL), 104" (2.6 m), 0.22 Micron High Pressure Extended Life Filter, 2 Luer Activated Valves, Male Luer Lock Adapter with Retractable Collar ^{2, 4} |
| Primary Filter Set Minidrip (60 drops/mL) | |
| 2C6572 | Continu-Flo Solution Set, 105" (2.7 m), 0.22 Micron High Pressure Extended Life Filter, 2 Injection Sites, Male Luer Lock Adapter ^{1, 2, 4} |
| Buretrol Minidrip (60 drops/mL) | |
| 2C7562s | INTERLINK System BURETROL Solution Set, 115" (2.9 m) 150 mL Valveless Burette, 4 Injection Sites, Male Luer Lock Adapter with Retractable Collar ^{1, 5, 8} |
| 2C7564 | INTERLINK System, BURETROL Solution Set, 105" (2.7 m) 150 mL Burette, Drip Chamber Filter Valve, 3 Injection Sites, Male Luer Lock Adapter with Retractable Collar ^{1, 4, 5, 8} |
| 2C8860 | CLEARLINK System, Buretrol Solution Set, 88" (2.2 m), 150 mL Burette, Burette Chamber Filter Valve, 3 Luer Activated Valves, Male Luer Lock Adapter with Retractable Collar ^{1, 4, 5, 8} |
| 2C8862 | CLEARLINK System, Buretrol Solution Set, 115" (2.9 m), 150 mL Burette, 4 Luer Activated Valves, Male Luer Lock Adapter with Retractable Collar ^{1, 5, 8} |
| 2C8864 | CLEARLINK System, BURETROL Solution Set, 105" (2.7 m), 150 mL Burette, Drip Chamber Filter Valve, 3 Luer Activated Valves, Male Luer Lock Adapter with Retractable Collar ^{1, 4, 5, 8} |

| No. | Brief Description |
|---|--|
| Y-Type Blood Set (10 drops/mL) | |
| 2C6750Hs | INTERLINK System, Y-Type Blood /Solution Set, 115" (2.9 m), Standard Blood Filter, 170 to 260 Micron Filter, Injection Site, Male Luer Lock Adapter ^{4, 9} |
| 2C8750s | CLEARLINK SYSTEM, Y-Type Blood/Solution Set with Standard Blood Filter, 112" (2.8 m), 170 to 260 Micron Filter, Luer Activated Valve, Male Luer Lock Adapter ^{4, 9} |
| Nitroglycerin Set (10 drop/mL) | |
| 1C8043s | Nitroglycerin Set with DUO-VENT Spike, 133" (3.4 m), PVC Tubing Segment, Male Luer Lock Adapter with Retractable Collar ^{3, 7} |
| Nitroglycerin Set (60 drop/mL) | |
| 2C7551s | CLEARLINK System, Nitroglycerin Set with DUO-VENT Spike, 103" (2.6 m), PVC Tubing Segment, Injection Site, male Luer Lock Adapter ^{1, 3, 7} |
| 2C8851s | CLEARLINK System, Nitroglycerin Set with DUO-VENT Spike, 103" (2.6 m), PVC Tubing Segment, Luer Activated Valve, Male Luer Lock Adapter ^{1, 3, 7} |
| No. | Brief Description - Non-DEHP Sets |
| Primary Set Macro (10 drops/mL) | |
| 2H8401 | CLEARLINK System Non-DEHP Solution Set, 76" (1.9 m), Luer Activated Valve, Male Luer Lock Adapter with Retractable Collar ¹¹ |
| 2H8519 | CLEARLINK System, Non-DEHP CONTINU-FLO Solution Set, 96" (2.4 m), 2 Luer Activated Valves, Male Luer Lock Adapter with Retractable Collar ¹¹ |
| 2H8537 | CLEARLINK System, Non-DEHP CONTINU-FLO Solution Set, 109" (2.8 m), 3 Luer Activated Valves, Male Luer Lock Adapter with Retractable Collar ¹¹ |
| 2H8454 | CLEARLINK System, Non-DEHP CONTINU-FLO Solution Set, 68" (1.7 m), 2 Luer Activated Valves, Male Luer Lock Adapter with Retractable Collar, Non-DEHP Large Bore 4-Way Stopcock Extension Set, 59" (1.5 m), Volume 8.7 mL, Large Bore 4-Way Stopcock manifold, Luer Activated Valve, Male Luer Lock Adapter with Retractable collar ^{8, 10, 11} |
| Primary Set Minidrip (60 drops/mL) | |
| 2H8546 | CLEARLINK System, Non-DEHP CONTINU-FLO Solution Set, 105" (2.7 m), 3 Luer Activated Valves, Male Luer Lock Adapter with Retractable Collar ^{1, 8, 11} |
| Primary Filter Set Macro (10 drops/mL) | |
| 2H8480 | CLEARLINK System, Non-DEHP Solution Set with DUO-VENT Spike, 102" (2.6 m), 0.22 Micron High Pressure Extended Life Filter, Luer Activated Valve, Male Luer Lock Adapter ^{4, 8, 11} |
| 2H8486 | CLEARLINK System, Non-DEHP Solution Set, 108" (2.7 m), 1.2 Micron Downstream Filter, Luer Activated Valve, Male Luer Lock Adaptor ^{4, 8, 11} |

| No. | Brief Description - Non-DEHP Sets |
|---|--|
| Buretrol Minidrip (60 drops/mL) | |
| 2H8862 | CLEARLINK System, Non-DEHP BURETROL Solution Set, 115" (2.9 m), 150 mL Valveless Burette, 4 Luer Activated Valves, Male Luer Lock Adaptor with Retractable Collar ^{1, 5, 8, 11} |
| 2H8864 | CLEARLINK System, Non-DEHP BURETROL Solution Set, 105" (2.7 m) 150 mL Burette, Drip Chamber Filter Valve, 3 Luer Activated Valves, Male Luer Lock Adapter with Retractable Collar ^{1, 4, 5, 8, 11} |
| IV Fat Emulsion Administration Set (10 or 60 drops/mL) | |
| 2C1145 | Non-DEHP IV Fat Emulsion Administration Set, 10 drop/mL, 86" (2.2 m) ¹¹ |
| 2C1146 | Non-DEHP IV Fat Emulsion Administration Set, 60 drop/mL, 86" (2.2 m) ^{1, 11} |
| Special Use (10 drops/mL) | |
| 2C8858 | CLEARLINK System, Paclitaxel Set, 107" (2.7 m), Polyethylene Lined Tubing, Non-DEHP Pump Segment, 0.22 Micron Downstream High Pressure Filter, Luer Activated Valve, Male Luer Lock Adapter ^{3, 4, 7, 11} |
| 2C8875 | CLEARLINK System, Solution Set with DUO-VENT Spike, 103" (2.6 m), Polyethylene Lined Tubing, Non-DEHP Pump Segment, Luer Activated Valve, Male Luer Lock Adaptor ^{3, 7, 11} |

Buretrol, Clearlink, CONTINU-FLO and Interlink are all registered names/trademarks associated with Baxter International Inc.

Compatible Baxter IV Sets – WARNINGS

NOTE: The numbers in the warning correspond with the superscript reference numbers found in the compatible IV set list.

WARNING Baxter IV Sets.

1. Minidrip chambers should not be used for flow rate settings greater than 200 mL/hr. Doing so may influence flow rate accuracy and cause air in line or upstream occlusion alarms.
2. When using sets with backcheck valves, flow rate settings should not exceed 500 mL/hr. Doing so may influence flow rate accuracy or cause air in line or upstream occlusion alarms. Secondary flow rates above 300 mL/hr may cause fluid to siphon from the primary container.

NOTE: Not applicable with non-DEHP tubing because 250 mL/hr is the maximum flow rate per warning statement.

3. When using sets with rigid polyethylene lined tubing, as is often used in nitroglycerine sets, flow rate settings should not exceed 500 mL/hr. Doing so may influence flow rate accuracy.
4. Partially occluded filters can cause air in line, upstream occlusion or downstream occlusion alarms or negatively affect flow rate accuracy.
5. Burettes with closed vents or shutoff valves will cause upstream occlusions that may not be detected by the infusion Pump. Rigid unvented containers used with unvented sets or vented sets with vent closed, will cause upstream occlusions that may not be detected by the infusion Pump.
6. When using a buretrol set containing a ball valve in the drip chamber, an upstream occlusion due to a closed ball valve may not be detected by the Pump.
7. Rigid polyethylene lined tubing, as is often used in nitroglycerine sets, may produce as much as 69 kPa (10 psi) downstream occlusion pressure above the lower limit of the SIGMA Spectrum Infusion System specification.
8. Some Sets contain two or more slide clamps. Only the slide clamp on the pumping section or on the section with the main roller clamp should be used for pumping operation and clamp detection. Other slide clamps on the set must be used with the set and need to be observed and controlled by the user. To prevent free flow, the slide clamp on the tubing that is loaded into the Pump should be used to open the Pump door.
9. Blood sets with both clamps closed above the blood filter will cause upstream occlusions that may not be detected by the Pump.
10. Sets containing a manifold may require longer times to detect downstream occlusions.
11. When using the compatible, non-DEHP IV administration sets in the Pump, the following performance limitations must be observed:
 - 11.1. Flow rate accuracy will range $\pm 10\%$ from the expected volume, when evaluated for over a one-hour period and not the $\pm 5\%$ specified for Baxter compatible DEHP IV sets.
 - 11.2. Flow rate range and IV set usage duration for Baxter non-DEHP IV administration sets is limited to:
 - 10 -125 mL/hr with IV tubing use of not greater than 36 hours
 - 126 - 250 mL/hr with IV tubing use of not greater than 4 hours
 - 11.3. Do not use Baxter compatible non-DEHP administration sets with the SIGMA Spectrum Infusion System for drugs and therapies requiring infusion flow rates and durations outside of the ranges specified above.

- 11.4. Prior to using the SIGMA Spectrum Infusion System with non-DEHP IV tubing, healthcare professionals should evaluate drugs, prescribed therapies and patient populations.

NOTE: See Appendix D: "Downstream Occlusion" on page 152 for downstream occlusion times and bolus release information.

WARNING Use the Specified Manufacturer's IV Set.

A label located on the top of the Pump indicates the specific type of IV tubing that the Pump has been calibrated for. The use of other manufacturers' brands or type tubing could produce Pump inaccuracies that could be unsafe for patients.

ACCESSORIES

Tandem Carrier

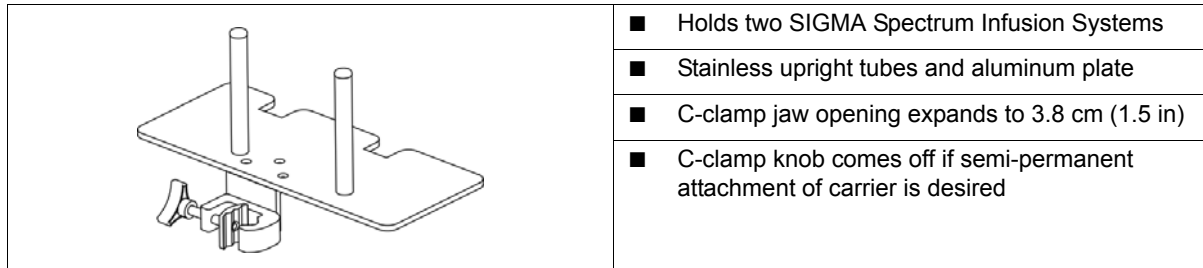


Figure 141. Baxter P/N 55092NS.

Three-Pump Carriers

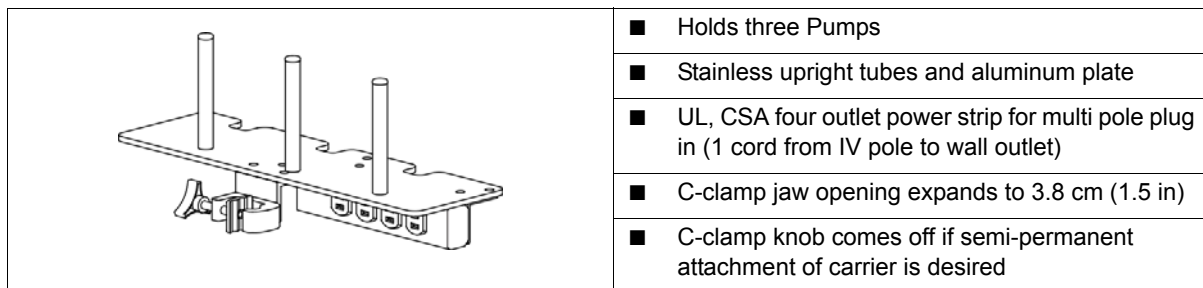


Figure 142. Baxter P/N 55093.

CAUTION

Use Stable IV Poles.

Mount Pumps on IV poles that securely hold the Pump.

Multi-Pole

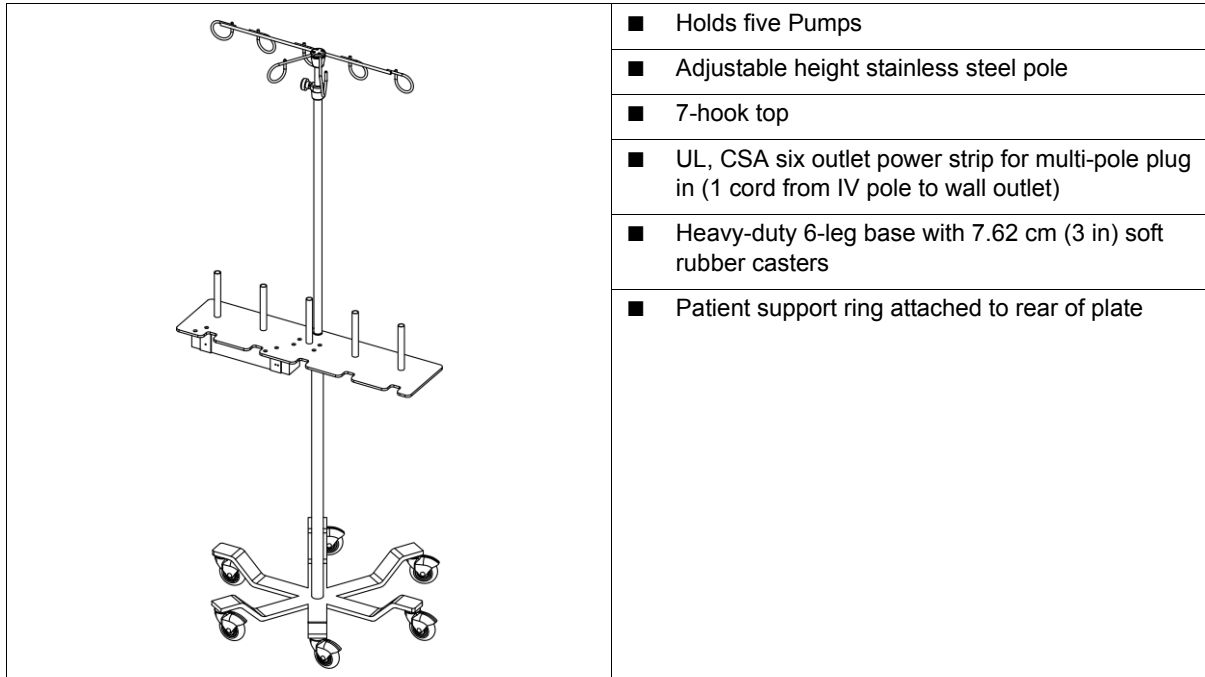


Figure 143. Baxter P/N 55088-1.

WARNING Ensure Secure Mounting of Pump During Use and Transport.

During use and transport, securely mount Pumps to IV pole by centering the pole in the clamp and turning the mounting knob clockwise. To maintain IV pole stability, never exceed 210 cm (83 in) from floor to IV pole top and limit bag volume at this extended height to <1 liter (1000 cc).

CAUTION Entanglement.

Always route IV set tubing and AC Power Adaptor cabling to prevent patient hazard or entanglement. Use the supplied strap to secure excess power cord length. Identify the individual IV set lines when multiple Pumps and routes of administration are practiced.

Double Rotating Pole Clamp Assembly

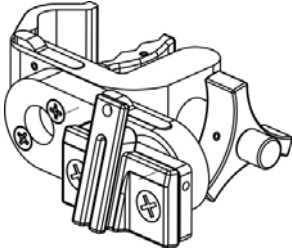
| | |
|---|---|
|  | <ul style="list-style-type: none">■ The double rotating feature of Double Rotating Pole Clamp enables the Pump to be offset on left or right side of the single (standard) IV pole diameters ranging from 1.9 to 3.18 cm (0.75 to 1.25 in). |
| | <ul style="list-style-type: none">■ The clamp can also be clamped to hospital bedside rail diameters ranging from 1.9 to 3.18 cm (0.75 to 1.25 in). |
| | <ul style="list-style-type: none">■ Mount the clamp on the IV pole by rotating the triangular knob clockwise. The cylindrical protrusion on the triangular knob helps to rotate the knob faster. |
| | <ul style="list-style-type: none">■ The Pump mounted on the adaptor can be rotated clockwise or counterclockwise in 90° increments by pressing the lever located on the arm. |
| | <ul style="list-style-type: none">■ The Pump can be offset by the length of the arm by rotating the arm in clockwise or counterclockwise in 90° increments by pressing the lever located on the body of the clamp. |
| | <ul style="list-style-type: none">■ Refer to the cleaning section of this manual for compatible cleaners. See “Compatible Cleaners” on page 119. |
| | <ul style="list-style-type: none">■ Refer to the installation manual on how to install the clamp on the Pump. |
| | <ul style="list-style-type: none">■ The weight of the clamp is less than 0.54 kg (1.2 lb). |
| <ul style="list-style-type: none">■ The dimension of the clamp is less than 17.7 cm (7.0 in) long × 6 cm (2.5 in) high × 11.4 cm (4.5 in) wide. | |

Figure 144. Baxter P/N 35743.

CAUTION

Pump Orientation.

- Always orient the Pump vertically on the IV pole, with the slide clamp keyhole at the top of the Pump.
- Only program the Pump in the upright position.

APPENDIX A: SPECIFICATIONS

Master Drug Library (MDL)

The SIGMA Master Drug Library (MDL) is a Microsoft Windows based software program that allows the ability to configure a Drug Library for the SIGMA Spectrum Infusion Pump. The Drug Library includes all drugs, including blood, blood components and IV fluids. Each drug record consists of the Care Area name, Drug Name and Concentration, Programming mode, Delivery Bag, Dose mode, and Upper and Lower (Hard and Soft) Limits and Starting rates, where applicable.

The Care Area enables:

- Same name/same concentration drugs to have different dose rate limits
- Configurations for Patient Weight and BSA Limits, Downstream Occlusion Pressure settings, Priming Volume adjustments and Auto Keypad Lock

Drug Library Transfer

The Drug Library Transfer allows the user to:

- Transfer the Drug Library using a wireless network connection to a Pump with a Wireless Battery Module
- Transfer the Drug Library from the PC directly to a Pump using IrDA

Standard Gravity IV Sets

The SIGMA Spectrum Infusion Pump uses standard gravity IV sets from Baxter.

Standards

- IEC60601-1, including collateral standards; Third Party Notified Body Testing (Reference Electromagnetic Compatibility Tables)
- IrDA Serial Infrared Physical Layer Link Specification v1.4 (IrPHY)
- Wireless – IEEE 802.11b and IEEE 802.11g

Pump Specifications

| Specification | Description |
|-----------------------|--|
| AC Power | <p>AC Power Adaptor, low profile, covers only one outlet, Medical Grade (EN60601-1-2):</p> <ul style="list-style-type: none"> ■ Input (P/N 35727): 115 VAC \pm15%, 50 - 60 Hz / 300 mA Max ■ Output (P/N 35727): 9 VDC/1200 mA, short circuit protected ■ Cord length 3.0 m (approximately 9.75 ft) <p>Use only Baxter P/N 35727.</p> |
| Alarm Volume | <p>Variable (three levels: high, medium and low). For more detail, see Appendix G: "Default Settings" on page 162.</p> |
| Alarms and Alerts | <ul style="list-style-type: none"> ■ Air In Line: dual-beam ultrasonic detector alarms for large bubbles but allows smaller bubbles to pass. <ul style="list-style-type: none"> ● Detects air bubbles >2.5 cm (>1 in) (approximately 140 μL in Baxter sets) ● Detects >1 mL of accumulated air over 15 min., excluding <10 μL bubbles, at room temperature ● Detects >1.5 mL of accumulated air over 15 min., excluding <10 μL bubbles, at 15.5°C (60°F) ■ Downstream Occlusion: When the Downstream Occlusion Automatic Restart is enabled, automatic restart occurs after the downstream occlusion is cleared. Actuation can be set to: <ul style="list-style-type: none"> ● Low, 41 kPa \pm27 kPa (6 \pm4 psi) ● Medium, 89 kPa \pm41 kPa (13 \pm6 psi) ● High, 131 kPa \pm62 kPa (19 \pm9 psi) ■ Very Low Battery: \leq15 minutes of battery power remaining ■ Due for inspection: Preventive Maintenance and/or Network Certification |
| Anti-Free-Flow System | <p>Set based, utilizing IV set slide clamp.</p> |

| Specification | Description |
|---------------------------------------|--|
| Battery Power and Capacity | <p>Standard Battery</p> <ul style="list-style-type: none"> ■ Lithium Ion, 7.4 VDC nominal. Baxter P/N 35724 ■ Capacity at intermediate rate 8 hrs (at 25 mL/hr at the highest backlight settings) ■ Capacity 8 hrs (at 125 mL/hr at the highest backlight settings) ■ 12 hr. recharge time ■ Charging occurs if AC Power Adaptor is plugged in, whether the Pump is on or off <p>Wireless Battery Module (802.11b/g)</p> <ul style="list-style-type: none"> ■ Lithium Ion, 7.4 VDC nominal. Baxter P/N 35162 ■ Capacity at intermediate rate 5 hrs (at 25 mL/hr at the highest backlight settings) ■ Capacity 4 hrs (at 125 mL/hr at the highest backlight settings) ■ 16 hr. recharge time ■ Charging occurs if AC Power Adaptor is plugged in, whether the Pump is on or off |
| Display | Color LCD |
| Device Classification | <p>The SIGMA Spectrum Infusion System is classified according to Medical Electrical Equipment standards as:</p> <ul style="list-style-type: none"> ■ Class II Equipment ■ Type BF Applied Part ■ Continuous Operation ■ Disinfect according to "Cleaning and Storage" on page 119. ■ Not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide. ■ IPX0 Enclosure does not protect equipment against ingress of water with harmful effects. Tested for safety in the event of fluid spillage/leakage in accordance with IEC 60601-2-24:1998. |
| Dose Modes: Continuous Infusions | mL/hr, mL/kg/min, mL/kg/hr, g/hr, mg/hr, mg/kg/hr, mg/min, mg/kg/min, mg/kg/day, mcg/hr, mcg/kg/hr, mcg/min, mcg/kg/min, mcg/kg/day, ng/min, ng/kg/min, Units/hr, Units/kg/hr, Units/min, Units/kg/min, mUnits/min, mUnits/kg/hr, mUnits/kg/min, mEq/hr, mEq/kg/hr, mmol/hr, mmol/kg/hr |
| Dose Modes: Loading Dose and Bolus | mL, mL/kg, g, g/kg, mg, mg/kg, mcg, mcg/kg, ng, ng/kg, Units, Units/kg, mUnits, mUnits/kg, mEq, mEq/kg, mmol, mmol/kg |
| Dose Modes: Amount/Time Infusions | mL, mL/kg, g, g/kg, g/m ² , mg, mg/kg, mg/m ² , mcg, mcg/kg, mcg/m ² , Units, Units/kg, Units/m ² , mEq, mEq/kg, mmol, mmol/kg |

| Specification | Description |
|-------------------------|---|
| Conversion Factors | <p>Conversion factors are applied as appropriate to calculate rate or dose (that is, 60 minutes = 1 hour, 1000 mcg = 1 mg, and so forth). To calculate rate from an entered dose, the following formulas are applied:</p> <ul style="list-style-type: none"> ■ General: $Rate = \frac{Dose}{Concentration}$ ■ Weight based: $Rate = \frac{Dose \times Patient\ Weight}{Concentration}$ <p>To calculate dose from an entered rate, the following formulas are applied:</p> <ul style="list-style-type: none"> ■ General: $Dose = Rate \times Concentration$ ■ Weight based: $Dose = \frac{Rate \times Concentration}{Patient\ Weight}$ <p>To calculate rate from an entered volume to be infused and entered time of infusion, the following formula is applied:</p> $Rate = \frac{Volume\ to\ be\ Infused}{Time\ of\ Infusion}$ |
| External Interfaces | IrDA (SIR Encoding Protocol) |
| Flow Rate | 0.5 to 999 mL/hr with 0.1 mL/hr increments from 0.5 to 99.9 mL/hr and 1.0 mL/hr increments from 100 to 999 mL/hr |
| Infusion Delivery Modes | Continuous (Primary and Secondary), Multi-Step, Cyclic TPN, and Amount/Time (Primary and Secondary) |
| KVO | <p>At the completion of a primary infusion, the Pump will infuse at the KVO rate configured per drug in the Drug Library or the current infusion rate, whichever is lower. The default KVO rate is set at 1 mL/hr but may be configured to between 0.5 and 50 mL/hr.</p> <p>At the completion of a secondary infusion program, the Pump will run at a fixed KVO rate of 1 mL/hr.</p> |

| Specification | Description |
|--|--|
| Logging Memory | <ul style="list-style-type: none"> ■ While not in use, the Pump's memory will retain the last programmed setup screen for 24 hours. <p><i>NOTE:</i> Multi-step and cyclic modes are retained until using the clear program soft key.</p> <ul style="list-style-type: none"> ■ The Pump history log can be filtered to only display the logged system error events or the logged drug error events. ■ Minimum 4,500 Event Log Capacity. <p><i>NOTE:</i> An event is any user-confirmed data entered into the Pump. Once the maximum log file size is reached, the data for each new event replaces the data for the oldest event (the data for the oldest event is lost).</p> |
| Low-Flow Continuity | The maximum period of no-flow is 90 seconds at a flow rate of 0.5 mL/hr. |
| Maximum Allowable pressure while in downstream occlusion | 207 kPa (30 psi) |
| Downstream Occlusion Pressure | Adjustable <ul style="list-style-type: none"> ■ Low, 41 kPa ±27 kPa (6 ±4 psi) ■ Medium, 89 kPa ±41 kPa (13 ±6 psi) ■ High, 131 kPa ±62 kPa (19 ±9 psi) |
| Operational Conditions | <p>With Standard Battery</p> <ul style="list-style-type: none"> ■ Operating temperature: 15.6 to 32.2°C (60 to 90°F), 20 to 90% relative humidity non-condensing <p>With Wireless Battery Module</p> <ul style="list-style-type: none"> ■ Operating temperature: 15.6 to 26.7°C (60 to 80°F), 20 to 90% relative humidity non-condensing |

WARNING

Environmental Limits

Use of the SIGMA Spectrum Infusion System outside the environmental limits, noted in Appendix A as "Operational Conditions" may cause performance issues with the SIGMA Spectrum Infusion System, including but not limited to: under or over infusion, inability to detect upstream or downstream occlusions, inability to charge battery, and/or decreased battery life.

| | |
|--------------------------------|--|
| Storage and Packing Conditions | <p>With Standard Battery</p> <ul style="list-style-type: none"> ■ Storage temperature: -10 to +49°C (14 to 120°F), 10 to 90% relative humidity non-condensing <p>With Wireless Battery Module</p> <ul style="list-style-type: none"> ■ Storage temperature: -10 to +49°C (14 to 120°F), 10 to 90% relative humidity non-condensing |
|--------------------------------|--|

| Specification | Description | | | | | | |
|------------------------|--|------|----------|-----------------|------------|-----------------|-----|
| Overall Size (Pump) | <p>With Standard Battery</p> <ul style="list-style-type: none"> ■ Without IV pole clamp: <ul style="list-style-type: none"> ● Height 14.7 cm (5.8 in) ● Width 10.6 cm (4.2 in) ● Depth 6.35 cm (2.5 in) ■ With IV pole clamp: <ul style="list-style-type: none"> ● Height 14.7 cm (5.8 in) ● Width 16.76 cm (6.6 in) ● Depth 11.93 cm (4.7 in) <p>With Wireless Battery Module</p> <ul style="list-style-type: none"> ■ Without IV pole clamp: <ul style="list-style-type: none"> ● Height 16 cm (6.3 in) ● Width 10.6 cm (4.2 in) ● Depth 6.35 cm (2.5 in) ■ With IV pole clamp: <ul style="list-style-type: none"> ● Height 16 cm (6.3 in) ● Width 16.76 cm (6.6 in) ● Depth 11.93 cm (4.7 in) | | | | | | |
| Pumping Mechanism | Linear peristaltic | | | | | | |
| Single Fault Condition | A maximum bolus of 0.56 mL may be generated as a result of a Single Fault Condition (a failure of the SIGMA Spectrum Infusion Pump, which stops the Pump motor and results in an alarm). | | | | | | |
| Timekeeping | Real Time Clock, battery-backed, 10-year life <i>NOTE:</i> Clock is set to GMT. | | | | | | |
| Total Volume | 0.1 to 9999 mL with 0.1 mL increments from 0.1 to 99.9 mL and 1.0 mL increments from 100 to 9999 mL | | | | | | |
| Volumetric Accuracy | <p>Accuracy is based on volume collected over one hour using compatible Baxter Standard IV Sets.</p> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th>Rate</th> <th>Accuracy</th> </tr> </thead> <tbody> <tr> <td>0.5 – 1.9 mL/hr</td> <td>±0.1 mL/hr</td> </tr> <tr> <td>2.0 – 999 mL/hr</td> <td>±5%</td> </tr> </tbody> </table> <p>Specified accuracy is maintained on Baxter Standard IV Sets for up to 96 hours (maximum 12 liters). See “Compatible IV Sets” on page 125.</p> | Rate | Accuracy | 0.5 – 1.9 mL/hr | ±0.1 mL/hr | 2.0 – 999 mL/hr | ±5% |
| Rate | Accuracy | | | | | | |
| 0.5 – 1.9 mL/hr | ±0.1 mL/hr | | | | | | |
| 2.0 – 999 mL/hr | ±5% | | | | | | |

| Specification | Description |
|----------------------------|---|
| Weight | <p>With Standard Battery</p> <ul style="list-style-type: none"> ■ Without IV pole clamp: 0.722 kg (25.5 oz ±1.0 oz) ■ With IV pole clamp: 0.949 kg (33.5 oz ±1.0 oz) <p>With Wireless Battery Module</p> <ul style="list-style-type: none"> ■ Without IV pole clamp: 0.751 kg (26.5 oz ± 1.0 oz) ■ With IV pole clamp: 0.978 kg (34.5 oz ±1.0 oz) |
| Wireless Network Interface | <p>Wireless Battery Module (802.11b/g), Baxter P/N 35162</p> <ul style="list-style-type: none"> ■ Frequency: 2.4 Ghz ■ Standard: IEEE 802.11b, IEEE 802.11g ■ Typical Transmit Power: <ul style="list-style-type: none"> 18 dBm @ 1Mbps 16 dBm @ 11 Mbps 14 dBm @ 6 Mbps 12 dBm @ 54 Mbps |
| Wireless Security | <p>WEP (Wired Equivalent Privacy)</p> <ul style="list-style-type: none"> ■ Encryption: 64/128-bit (RC4) <p>WPA/WPA2/802.11i</p> <ul style="list-style-type: none"> ■ Encryption: TKIP, CCMP (AES) ■ WPA-PSK ■ 802.1X authentication ■ LEAP (WEP only) ■ PEAP/MSCHAPv2 ■ EAP-FAST ■ EAP-TLS ■ EAP-TTLS/PAP ■ EAP-TTLS/MSCHAPv2 |

APPENDIX B: FLOW RATE ACCURACY

Effect of Fluid Container Height

The performance of the SIGMA Spectrum Infusion Pump will be influenced by the forces of gravity on the fluid being administered to the patient. When a fluid container is positioned above or below the patient's administration site, pressure forces associated with the fluid's head-height (distance measured from the center of the Pump to the top of the fluid in the source container) will cause deviations in the nominal specification for device flow rate accuracy. The nominal head-height used for the flow rate specification is 610 ±51 mm (24 ±2 in). (Reference: AAMI ID26:2004, Sub-clause 50.102.)

NOTE: The fluid container must be vented or a collapsible bag.

Always hang the fluid container such that the level of fluid in the container is 610 ±51 mm (24 ±2 in) above the center of the infusion Pump.

As an example, flow rate accuracy may deviate by up to -4% from the nominal accuracy when operating at 25 mL/hr delivery rate with a -50 cm (-20 in) fluid head-height, resulting in a flow rate accuracy of +5% to -9%.

Effect of Back Pressure

Positive back pressure can influence the flow rate accuracy of the infusion. Back pressure equivalent to 300 mmHg may reduce the flow rate, causing a deviation in accuracy by -9%. Negative back pressure of -100 mmHg may increase flow rate, causing a deviation in accuracy of 7% in Baxter IV Sets.

WARNING Baxter IV Sets.

1. Minidrip chambers should not be used for flow rate settings greater than 200 mL/hr. Doing so may influence flow rate accuracy and cause air in line or upstream occlusion alarms.
2. When using sets with backcheck valves, flow rate settings should not exceed 500 mL/hr. Doing so may influence flow rate accuracy or cause air in line or upstream occlusion alarms. Secondary flow rates above 300 mL/hr may cause fluid to siphon from the primary container.

NOTE: Not applicable with non-DEHP tubing because 250 mL/hr is the maximum flow rate per warning statement.

3. When using sets with rigid polyethylene lined tubing, as is often used in nitroglycerine sets, flow rate settings should not exceed 500 mL/hr. Doing so may influence flow rate accuracy.
4. Partially occluded filters can cause air in line, upstream occlusion or downstream occlusion alarms or negatively affect flow rate accuracy.

5. Burettes with closed vents or shutoff valves will cause upstream occlusions that may not be detected by the infusion Pump. Rigid unvented containers used with unvented sets or vented sets with vent closed, will cause upstream occlusions that may not be detected by the infusion Pump.
6. When using a buretrol set containing a ball valve in the drip chamber, an upstream occlusion due to a closed ball valve may not be detected by the Pump.
7. Rigid polyethylene lined tubing, as is often used in nitroglycerine sets, may produce as much as 69 kPa (10 psi) downstream occlusion pressure above the lower limit of the SIGMA Spectrum Infusion System specification.
8. Some Sets contain two or more slide clamps. Only the slide clamp on the pumping section or on the section with the main roller clamp should be used for pumping operation and clamp detection. Other slide clamps on the set must be used with the set and need to be observed and controlled by the user. To prevent free flow, the slide clamp on the tubing that is loaded into the Pump should be used to open the Pump door.
9. Blood sets with both clamps closed above the blood filter will cause upstream occlusions that may not be detected by the Pump.
10. Sets containing a manifold may require longer times to detect downstream occlusions.
11. When using the compatible, non-DEHP IV administration sets in the Pump, the following performance limitations must be observed:
 - 11.1. Flow rate accuracy will range $\pm 10\%$ from the expected volume, when evaluated for over a one-hour period and not the $\pm 5\%$ specified for Baxter compatible DEHP IV sets.
 - 11.2. Flow rate range and IV set usage duration for Baxter non-DEHP IV administrations sets is limited to:
 - 10 - 125 mL/hr with IV tubing use of not greater than 36 hours
 - 126 - 250 mL/hr with IV tubing use of not greater than 4 hours
 - 11.3. Do not use Baxter compatible non-DEHP administration sets with the SIGMA Spectrum Infusion System for drugs and therapies requiring infusion flow rates and durations outside of the ranges specified above.
 - 11.4. Prior to using the SIGMA Spectrum Infusion System with non-DEHP IV tubing, healthcare professionals should evaluate drugs, prescribed therapies and patient populations.

NOTE: See Appendix D: "Downstream Occlusion" on page 152 for downstream occlusion times and bolus release information.

WARNING **Low Flow Rate Accuracy/Continuity.**

At flow rates of 2 mL/hr or below, flow rate accuracy is ± 0.1 mL/hr. If higher accuracy is required, consider an alternate infusion device.

WARNING **Flow Rate Inaccuracy.**

Rate accuracy can be affected by variations of fluid viscosity, fluid temperature, head height or back pressure, or any combination thereof. In addition to IV set specific warnings, the following can cause flow rate inaccuracies and must be avoided:

- Incompatible brand IV sets and compatible brand IV sets with unusually large or small diameters or unusually stiff materials.
- Using a dropped, damaged, dirty or wet Pump.
- Pressurizing IV bags.
- Non-vented IV sets with rigid non-vented containers.
- Vents on sets or burettes left in the closed position when they should be open.
- Using Minidrip chambers for flow rate settings greater than 200 mL/hr. Doing so may influence flow rate accuracy and cause air in line or upstream occlusion alarms.
- Laying the IV container flat. Doing so may influence flow rate accuracy and cause upstream occlusion and air in line alarms.
- Exceeding 500 mL/hr flow rate settings when using sets with backcheck valves. Doing so may influence flow rate accuracy or cause air in line or upstream occlusion alarms.
- Flow rates above 300 mL/hr may cause fluid to be siphoned from the primary container during a secondary infusion. See "Secondary Infusion" on page 58.

NOTE: Not applicable with non-DEHP tubing because 250 mL/hr is the maximum flow rate per warning statement.

Flow Profile

The graphs presented in this section represent the variation in flow rate that is recorded from the time an infusion is started to the end of a two-hour period. See "Baxter Administration Set Accuracy Graphs" on page 146. Each graph is intended to provide a picture of the "general stability" with time of the infusion and is commonly called a "start-up curve". The techniques and methods of test and generation are detailed in IEC 60601-2-24, *Medical electrical equipment – Part 2-24: Particular requirements for the safety of infusion pumps and controllers*.

CAUTION **Accuracy.**

Refer to trumpet curves for flow rate accuracy as a function of short infusion durations.

- The upstream occlusion detector may not detect partially occluded tubing.

- Always check to ensure the IV set's clamp is not closed above the Pump and respond appropriately to all primary and secondary check flow prompts.
- Small bore catheters or needles may cause excessive back pressure at high flow rates.
- Size the catheters according to expected flow rate and fluid viscosity.

Standard Conditions

- Ambient Temperature: 22.2°C (72°F ± 2°F)
- Fluid Temperature: 22.2°C (72°F ± 2°F)
- Solution Container Head Height: 610 ± 51 mm (24 in ± 2 in)
- Test Solution: Deionized Water, ISO Class III
- Distal Positive Pressure (Back pressure): 0 mmHg
- Needle: 18 Gauge or equivalent as per Sub-Clause 50.102 of IEC 60601-2-24
- Set Type: Compatible DEHP IV set, or equivalent. For a list of compatible IV sets, see "Compatible IV Sets" on page 125.

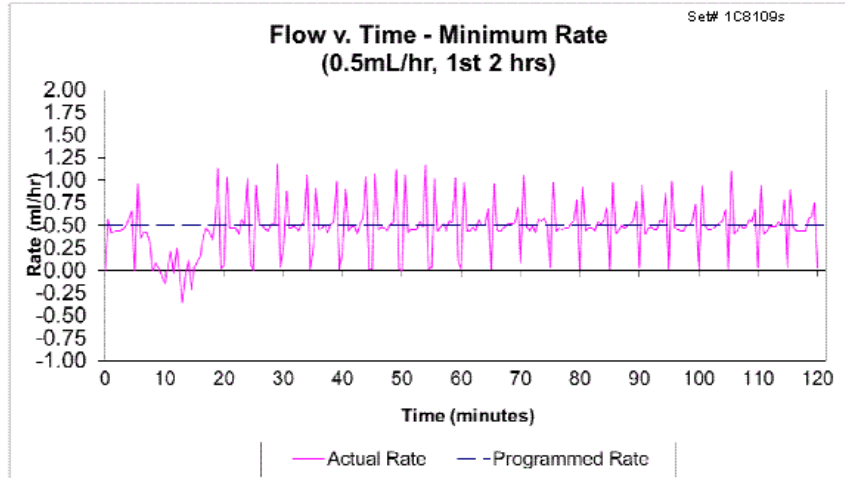
The percent variation of mean flow rate accuracy over a specific observation period may be quantified with the use of a trumpet graph. Using the rationale for development of a statistical trumpet graph as defined in IEC 60601-2-24, a presentation of the SIGMA Spectrum Infusion System mean flow over a specific measurement interval is provided.

NOTE: It is important for the clinician to understand the pharmacological influence of specific drugs based on concentrations and patient response when used in conjunction with the SIGMA Spectrum Infusion System.

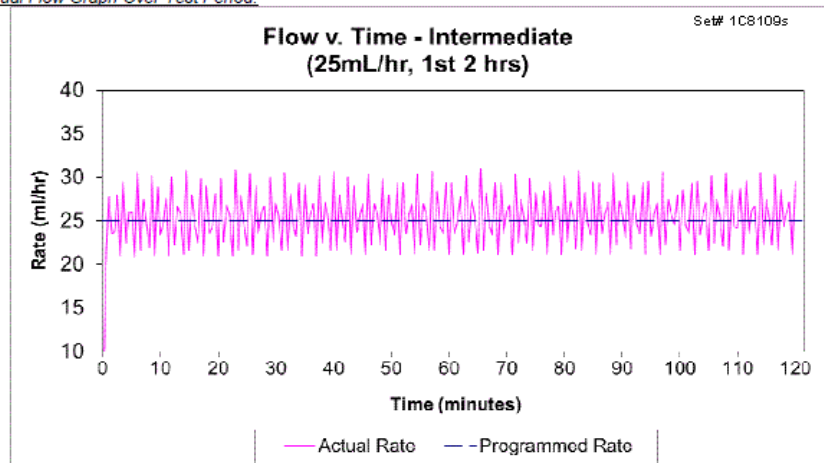
Pumping mechanisms produce fluctuation in fluid flow by design based on the specific mechanism type (peristaltic, piston, rotary, and so forth), electronic control system and other factors related to the administration set's characteristics. Specific flow profiles are helpful in determining the correct clinical application for the infusion pump. Data is presented as requested by the applicable standards and represents the typical flow rate function of the SIGMA Spectrum Infusion System for short- and long-term operation. To facilitate visualization of the flow inconsistencies that are typical of most infusion pumps, the start-up graphs and trumpet curves are extended to include the minimum rate (0.5 mL/hr) and intermediate rate (25 mL/hr) for the SIGMA Spectrum Infusion System.

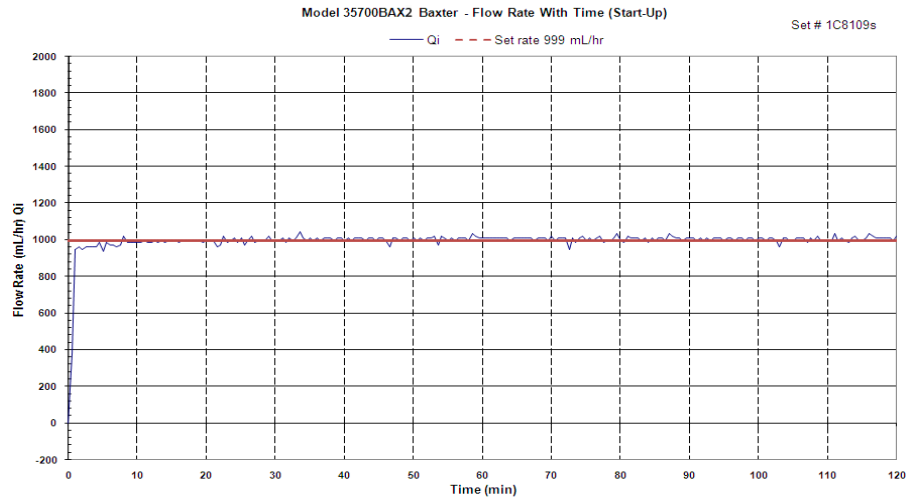
NOTE: The SIGMA Spectrum Infusion System is best classified as a "Volumetric Infusion Pump" as defined by the applicable standards. Reference IEC 60601-2-24 and AAMI ID26:2004, Medical electrical equipment – Part 2: Particular requirements for the safety of infusion pumps and controller.

Baxter Administration Set Accuracy Graphs

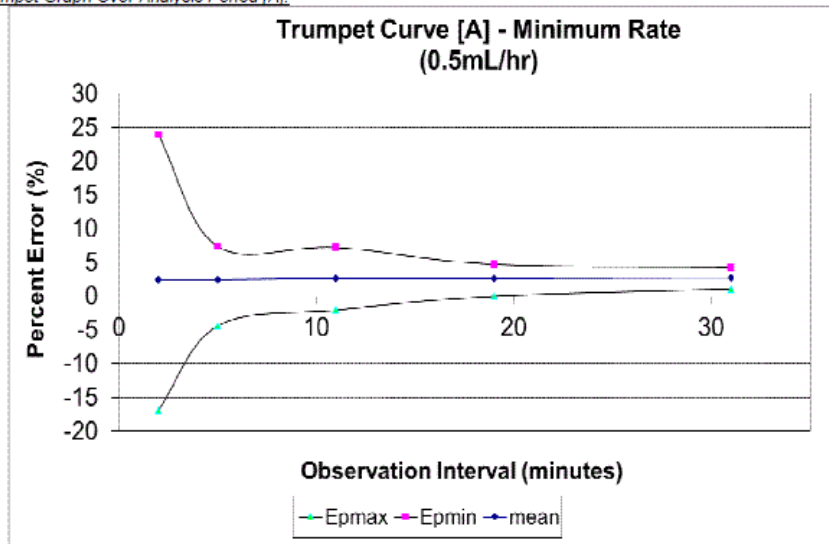


Actual Flow Graph Over Test Period:

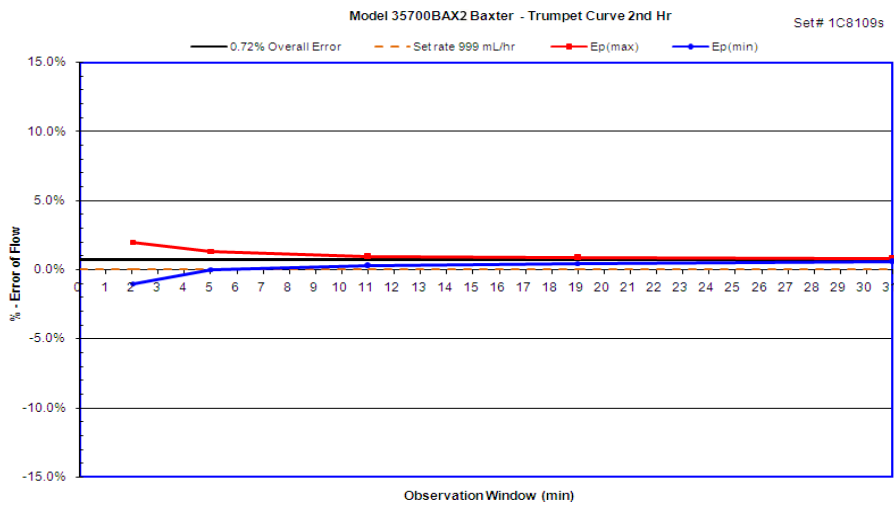
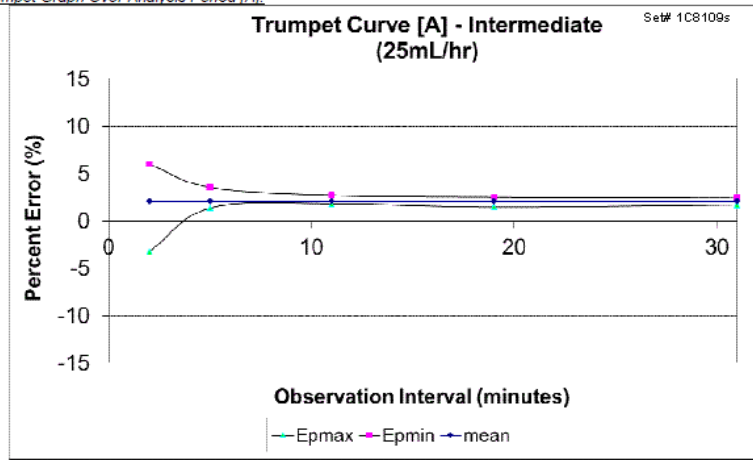




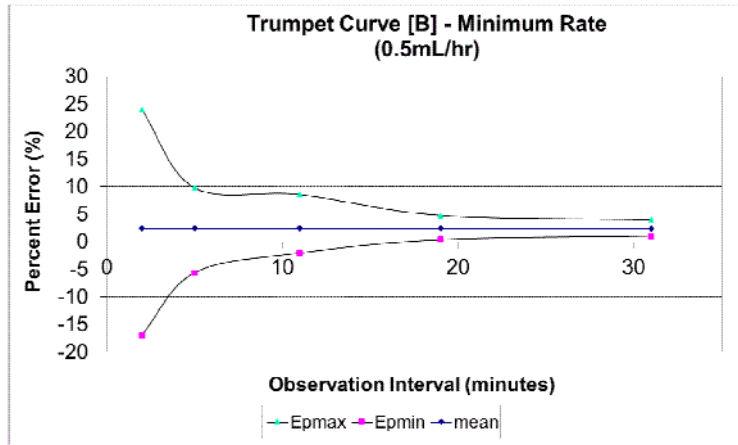
Trumpet Graph Over Analysis Period [A]:



Trumpet Graph Over Analysis Period [A]:

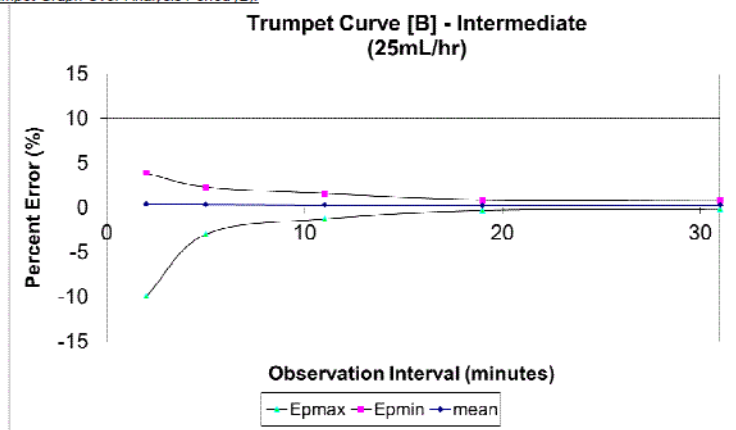


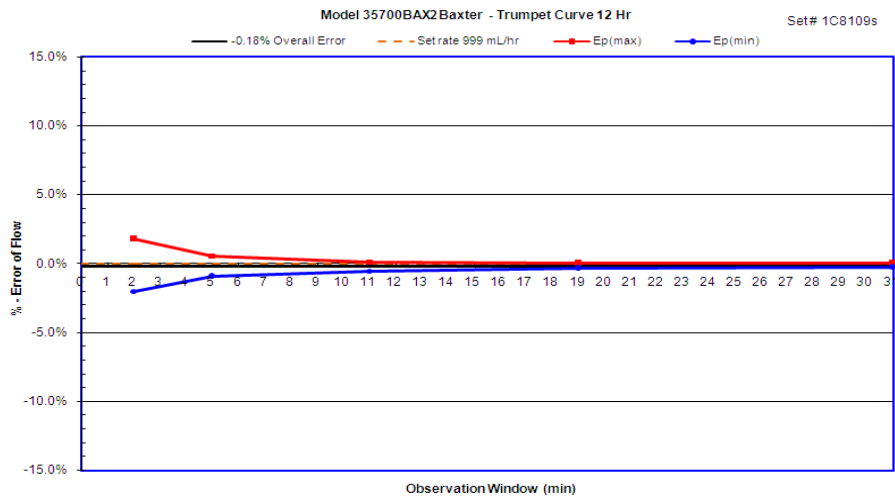
Trumpet Graph Over Analysis Period [B]:



The measured % Error was within the Rated % Error of $\pm 5\%$

Trumpet Graph Over Analysis Period [B]:





APPENDIX C: BOLUS ACCURACY

The SIGMA Spectrum Infusion System may have an optional bolus mode of operation. This feature allows the user to perform a BOLUS SETUP action. To utilize this feature, the Pump must be programmed with either a specific rate or a specific amount to be delivered in a certain amount of time.

If the Pump is currently operating in mL/hr delivery mode, the bolus rate value is entered in mL/hr and the volume is entered in milliliter (mL). If the Pump is operating in a non-mL/hr delivery mode (for example, mcg/kg/min), the bolus amount would be entered in mcg/kg; however, the **mL/hr** soft key may be pressed in the setup screen to enter the bolus information in mL/hr format.

In either mode, the time is entered in minutes by default, but it can be programmed in seconds if needed. Limits are placed on the minimum and maximum amount of time for the bolus delivery. The limit constraints are contained within the software of the SIGMA Spectrum Infusion System and are necessary to control the maximum or minimum flow rate of the bolus infusion.

The accuracy of the bolus volume is dependent on the resultant flow rate that is obtained from the calculation of volume to be delivered in the time requested. For example, if the bolus volume is 300 mL, the maximum flow rate is obtained with a bolus time of approximately 18 minutes or a flow rate of approximately 999 mL/hr. Using this bolus volume and delivering the volume in the shortest amount of time, the mean value of 300 mL \pm 5% may be expected, whereas using a minimum bolus volume (0.5 mL) and delivering the volume in a short amount of time (1 minute), the mean value of 0.5 mL \pm 16% may be expected.

When tested in accordance with IEC 60601-2-24: 1998 Clause 50.106, the following are the minimum, maximum and mean deviations in bolus volume for each corresponding setting:

| Bolus Delivery (mL) | Bolus Time (min) | Bolus Rate (mL/hr) | Mean Deviation from Set Value | Percentage Deviation from Set Value | Maximum Positive Deviation | Maximum Negative Deviation |
|---------------------|------------------|--------------------|-------------------------------|-------------------------------------|----------------------------|----------------------------|
| 0.5 | 1 | 30 | 0.015 | 6.02 | 7.11% | 9.52% |
| 300 | 18 | 999 | -6.939 | -2.51 | 1.83% | 4.47% |

APPENDIX D: DOWNSTREAM OCCLUSION

Time to Occlusion Alarm

At the minimum downstream occlusion setting and minimum flow rate of 0.5mL/hr, the time for activation of the downstream occlusion alarm is 20 minutes or less for at least 51% of alarms (95% Confidence Interval), with a maximum time for alarm activation of 1.5 hours.

At the Maximum downstream occlusion setting and minimum flow rate of 0.5mL/hr, the time for activation of the downstream occlusion alarm is 2.5 hours or less for at least 51% of alarms (95% Confidence Interval), with a maximum time for alarm activation of 5 hours.

The maximum time for activation of the downstream occlusion alarm at the intermediate flow rate of 25 mL/hr is 50 seconds at the minimum occlusion threshold setting. It is 3 minutes at the maximum occlusion alarm threshold setting.

Bolus Volume

The maximum bolus volume generated as a result of operation at 25 mL/hr and reaching the minimum downstream occlusion alarm threshold is 0.25 mL.

The maximum bolus volume generated as a result of operation at 25 mL/hr and reaching the maximum downstream occlusion alarm threshold is 0.8 mL.

WARNING

Specifications for Downstream Occlusion detection times and bolus volume, after release of occlusion, are based on specific test conditions.

The analytical related conditions are:

- A distance of 1.2 m (48 in) from the point of the downstream occlusion to the SIGMA Spectrum Infusion System's Downstream Occlusion sensor (approximately the distance from the IV administration set's exit from the pumping channel to the point of occlusion).
- The 1.2 m (48 in) test administration set contained one Y injection site (no filters or other components).
- Testing was at the nominal room temperature 22.2°C ±1.1°C (72°F ±2°F).

Time to Downstream Occlusion and Bolus Volume release will generally increase under the following conditions: longer distances to the occlusion point, additional fluid volumetric area (from filters or other components within the IV set length), hotter room temperatures and higher Downstream Occlusion Pressure Thresholds or Limits. For additional information on Downstream Pressure Limits, see Appendix G: "Default Settings" on page 162.

APPENDIX E: ELECTROMAGNETIC COMPATIBILITY

Emissions

WARNING Emissions and Immunity.

The use of accessories or cables other than those specified by Baxter may result in increased Emissions or decreased Immunity of this medical device.

WARNING Radio Frequency Interference.

The SIGMA Spectrum Infusion System meets the electromagnetic compatibility (EMC) requirements as specified in the International Electrotechnical Commission's (IEC) 60601-1-2 (2001-09) standard for emissions and immunity. There may be potential difficulties if the Pump is not kept separated from other equipment, such as hand-held transmitters, cellular phones and electrosurgical equipment that may generate strong radio frequency interference (RFI). See "Immunity – Separation Distances" on page 158 for the recommended minimum distance.

| Guidance and manufacturer's declaration – electromagnetic emissions – for all equipment and systems | | |
|---|------------|---|
| The SIGMA Spectrum Infusion System is intended for use in the electromagnetic environment specified below. The customer or user of the Pump should assure that it is used in such an environment. | | |
| Emissions test | Compliance | Electromagnetic environment - guidance |
| RF emissions CISPR 11 | Group 1 | The SIGMA Spectrum Infusion System 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 A | The SIGMA Spectrum Infusion System is suitable for use in all establishments other than domestic and those directly connected to a low-voltage power supply network that supplies buildings used for domestic purposes. |

Immunity – ESD, transient/burst, voltage disparity and magnetic field

| Guidance and manufacturer's declaration – electromagnetic immunity – for all equipment and systems | | | |
|---|--|--|---|
| The SIGMA Spectrum Infusion System is intended for use in the electromagnetic environment specified below. The customer or user of the Pump should assure that it is used in such an environment. | | | |
| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment - guidance |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±6 kV contact ±8 kV air | ±2 kV contact ±6 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. See Note 1. |
| 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 | Supply power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ±1 kV differential mode ±2 kV common mode | ±1 kV differential mode Not applicable | Supply 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% 120 VAC (>95% dip in 120 VAC) or 0.5 cycle 40% 120 VAC (60% dip in 120 VAC) for 5 cycles 70% 120 VAC (30% dip in 120 VAC) for 25 cycles <5% 120 VAC (>95% dip in 120 VAC) for 5 sec | <5% 120 VAC (>95% dip in 120 VAC) or 0.5 cycle 40% 120 VAC (60% dip in 120 VAC) for 5 cycles 70% 120 VAC (30% dip in 120 VAC) for 25 cycles <5% 120 VAC (>95% dip in 120 VAC) for 5 sec | Supply power quality should be that of a typical commercial or hospital environment. If the user of the SIGMA Spectrum Infusion System requires continued operation during power interruption, it is recommended that the Pump be powered from an uninterrupted power supply or the internal battery be fully charged to provide unit power as specified in this operator's manual. |
| Power frequency (50/60Hz) magnetic field IEC 61000-4-8 | 3 A/m | 400 A/m | Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment. |

Note1: For levels 2, 3 and 4, a clearable alarm will occur with interruption of flow.

NOTE: The Pump was tested to the requirements of IEC 60601-1-2:2001/A1:2004, Ed 2 and IEC 60601-2-24:1998.

NOTE: The essential performance of the Pump is volumetric accuracy.

WARNING **Magnetic Fields.**

The SIGMA Spectrum Infusion System is not designed to be MRI-compatible nor is it intended to be used in this manner. Strong magnetic fields (those beyond the level tested) may cause the device to operate improperly.

Do not expose the Pump to strong magnetic fields such as is common with MRI equipment or in close proximity 60.9 cm (2 ft) of a cathode ray tube (CRT) monitor. Doing so may cause injury to the patient and/or damage to the equipment.

WARNING **Adjacent or Stacked Use.**

The Pump should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Pump should be observed to verify normal operation in the configuration in which it will be used.

NOTE: The SIGMA Spectrum Infusion System has been tested to operate normally when used stacked or adjacent to other SIGMA Spectrum Infusion Systems.


CAUTION **ECG Artifacts Related to the Use of the SIGMA Spectrum Infusion System.**

Peristaltic infusion pumps may produce what is known as piezoelectric artifact on ECG monitors and similar types of monitoring instruments. The SIGMA Spectrum Infusion System may produce this effect when the Pump is running at rates in the higher ranges of operation, this may be in the frequency range tracked by the ECG monitor. The appearance of the artifact may be affected by set up and/or connection of electrodes, leads or equipment. See the ECG monitoring system documentation for recommendations on proper set up including electrode connections, site preparation, monitor system set up and electrode placement.

CAUTION **Static Sensitive Equipment.**

- Wherever possible, eliminate any electro-static producing materials or conditions (dry, low humidity, synthetic materials such as blankets, carpeting, drapes, and so forth).
- The Pump is ESD sensitive when the Battery Module is removed.

Immunity – Conducted and Radiated

| Guidance and manufacturer's declaration – electromagnetic immunity – for all life-supporting equipment and systems | | | |
|---|--|-------------------|--|
| The SIGMA Spectrum Infusion System is intended for use in the electromagnetic environment specified below. The customer or user of the Pump should assure that it is used in such an environment. | | | |
| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment - guidance |
| Conducted RF IEC 61000-4-6 | 3 Vrms 150 kHz to 80 MHz in ISM bands ^a | 3 Vrms | 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. Recommended separation distance $d = 1.2 \cdot \sqrt{P}$ |
| Radiated RF IEC 61000-4-3 | 10 Vrms 150 kHz to 80 MHz in ISM bands ^b 10 V/m 80 MHz to 2.5 GHz | 10 Vrms 10 V/m | $d = 1.2 \cdot \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \cdot \sqrt{P}$ 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). ^b Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^c should be less than the compliance level in each frequency range. ^d Interference may occur in the vicinity of the equipment marked with the following symbol:  This excludes the Wireless Battery Module, Baxter P/N 35162. |

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 6.756 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 ISM compliance level in the ISM frequency band 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 3K is used in calculating the recommended separation distance for transmitters in these frequency ranges.

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

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

Immunity – Separation Distances

Recommended separation distance between portable and mobile RF communications equipment and the equipment or system – for all life-supporting equipment and systems

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

| Rated maximum output power of transmitter W | Separation distance according to frequency of transmitter m | | | |
|--|--|---|--|---|
| | 150 kHz to 80 MHz outside ISM bands $d = 1.2\sqrt{P}$ | 150 kHz to 80 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 | .23 |
| 0.1 | 0.38 | 0.38 | 0.38 | .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 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 power 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 6.756 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 the transmitters in the ISM frequency band 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 The guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

WARNING Linear Accelerator Radiation.

The SIGMA Spectrum Infusion System is not designed to be exposed to linear accelerator radiation nor is it intended to be used in this manner. Exposure to radiation of this type may cause the device to operate improperly.

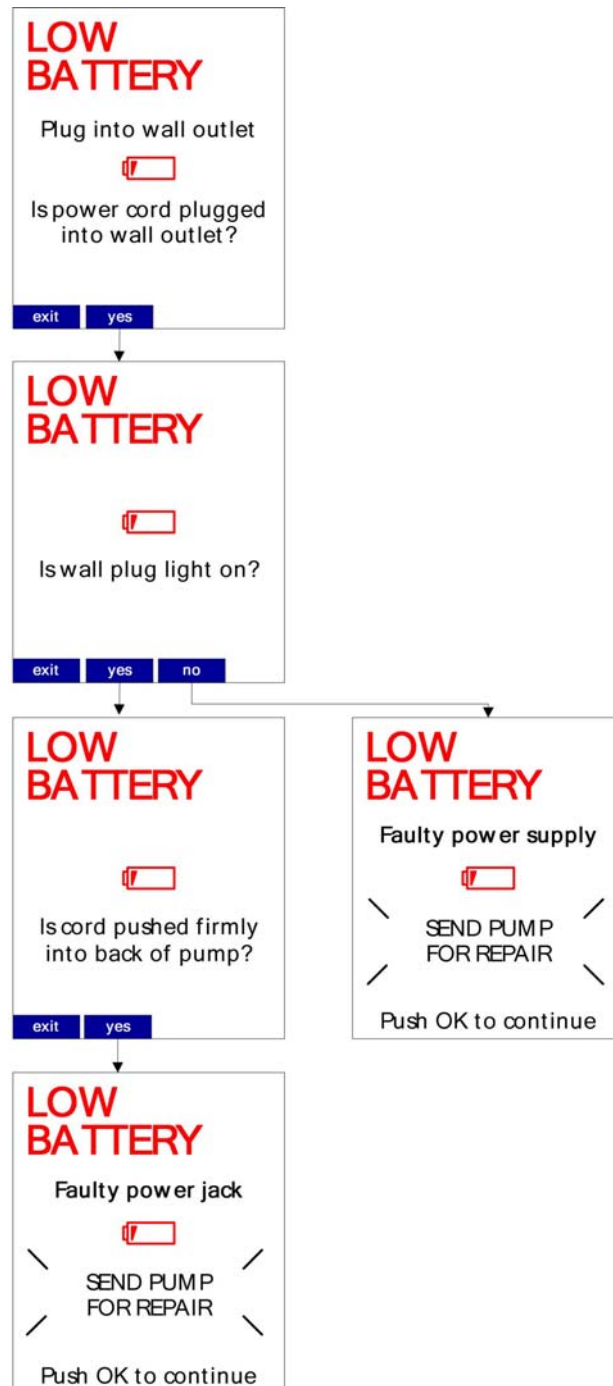
Do not expose the SIGMA Spectrum Infusion System to linear accelerator radiation. Doing so may cause injury to the patient and/or damage to the equipment.

APPENDIX F: LOW / VERY LOW BATTERY ALARM INSTRUCTIONS

The Low Battery and Very Low Battery alarms provide on-screen step-by-step instructions for confirming that the external power supply is connected to the wall outlet, the power light is illuminated and the power cord is properly connected to the SIGMA Spectrum Infusion Pump.

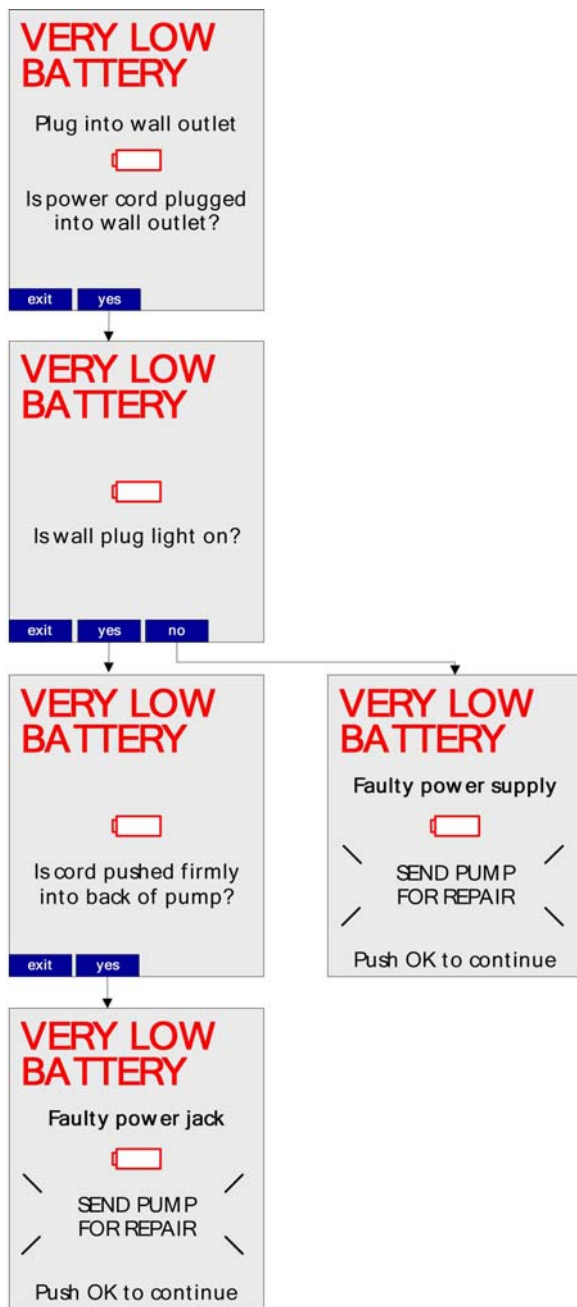
Low Battery Alarm Instructions

The Pump displays the following screen-by-screen instructions when the Low Battery alarm is activated.



Very Low Battery Alarm Instructions

The Pump displays the following screen-by-screen instructions when the Very Low Battery alarm is activated.



APPENDIX G: DEFAULT SETTINGS

Factory Settings for Pump Software

Once a user changes these defaults, they will remain at the most current setting. Some settings can be controlled by the Drug Library, as indicated in the tables in this section. These settings are hard defaults that cannot be changed by the clinician programming the Pump, unless noted otherwise.

Table 1. User Options - Alarm Settings.

| Feature | Original Factory Default | User Options | Ability to be Controlled by the Drug Library? |
|--|--------------------------|--------------------------------|---|
| Audio Volume | Medium | Low, Medium, High | Yes (Drug Level Configuration) |
| Audio Tone | Long | Long, Short | No |
| Standby Delay | Infinite | Infinite, Specified Time frame | No |
| Bag Near Empty Alarm | Off | On, Off | Yes (Drug Level Configuration) |
| DS Pressure Limit (Downstream Occlusion Pressure Limit) | Medium | Low, Medium, High | Yes* (Care Area Level Configuration) |
| *DS Pressure Limit can be set in the Drug Library by Care Area. The user still retains the ability to change this setting at the Pump level, but the Pump will default back to the Drug Library setting. | | | |

Table 2. User Options - Display Settings - SETUP Options.

| Feature | Original Factory Default | Ability to be Controlled by the Drug Library? |
|---------------------------------------|--------------------------|---|
| Infusion Running Screen Options: | | |
| Audio Level Indicator | Off | No |
| Rate mL/hr* | On | No |
| Dose rate* | On | No |
| mL - VTBI* | Off | No |
| Time (hr:min*) | Off | No |
| *Setting not applicable in Cyclic TPN | | |
| Display Adjust | 10 (highest level) | No |

BASIC Configurations

A BASIC infusion provides non-DERS based infusion programming.

DERS limits do not exist when using BASIC mode. BASIC mode allows the user to manually specify an mL/hr rate, dose mode, dose rate and volume to be infused, among other parameters. It does possess the following safety features: Check Flow at Run, Secondary Error Prevention and Single Step Rate Change of 101%.

CAUTION BASIC Programming Use.

BASIC programming should only be used when the desired drug or concentration is not available in the facility's Drug Library.

Table 3. BASIC Fixed Settings.

| BASIC Configuration Settings | Fixed Settings |
|------------------------------|--------------------|
| Allow Bolus | Yes |
| Allow Loading Dose | No |
| Bolus Amount Units | mL |
| Bolus Time Units | Minutes or Seconds |
| Completion Alarm | Not Available |
| Delayed Run | Not Available |
| KVO Rate | 1 mL/hr |
| Secondary Callback | Never |
| Single Step Rate Change | 101% |

Table 4. BASIC Settings Configurable on the Pump.

| BASIC Configuration Settings | Default Settings |
|------------------------------|----------------------------|
| Audio Alarm | High, Medium, Low |
| Bag Near Empty Alarm | On, Off |
| Delivery Bag | Primary Bag, Secondary Bag |
| Dose Mode | Clinician can select |

Table 5. BASIC Settings Configurable in the Drug Library.

| BASIC Configuration Settings | Default Settings |
|-------------------------------------|--|
| Upstream Occlusion Alarm Suspension | Feature Available. See the description of "Upstream Occlusion Alarm Suspension" in "Alarm Messages" on page 107. |

Table 6. Dose Modes Available in BASIC Mode.

| BASIC Configuration Settings | Default Settings |
|-----------------------------------|--|
| Any Infusion while in BASIC Mode. | mL/hr, mL/kg/min, mL/kg/hr, g/hr, mg/hr, mg/kg/hr, mg/min, mg/kg/min, mg/kg/day, mcg/hr, mcg/kg/hr, mcg/min, mcg/kg/min, mcg/kg/day, ng/min, ng/kg/min, Units/hr, Units/kg/hr, Units/min, Units/kg/min, mUnits/min, mUnits/kg/hr, mUnits/kg/min, mEq/hr, mEq/kg/hr, mmol/hr, mmol/kg/hr. |

GLOSSARY

The acronyms and abbreviations used throughout this manual are defined below.

| | |
|----------------------|--|
| 802.11 b/g | Wireless local Area Network implemented in accordance with the following standards: IEEE 802.11b and IEEE 802.11g |
| A/D | Analog to Digital |
| A/D Converter | Analog to Digital Converter. A device that converts a continuous quantity to a discrete time digital representation. |
| A/m | Ampere per meter |
| AAMI | Association for the Advancement of Medical Instrumentation |
| AC | Alternating Current |
| Admixture | Two substances combined into one final fluid or drug solution. |
| AES | Advanced Encryption Standard |
| Amount/Time Infusion | Drug therapies that require a prescribed drug dose amount to be delivered over a set duration of time. |
| AP | Access Point |
| ASCII | American Standard Code for Information Interchange. A character-encoding scheme. |
| AVR | A series of 8 and 32 bit flash micro-controllers manufactured by Atmel Corporation. |
| BASIC | A method of programming a continuous infusion where Drug Library limits are not present. |
| BCC | Battery Charger Controller |
| BDL | Binary Drug Library. A BDL file is created and saved using the MDL software, and the file is transferred to the SIGMA Spectrum Infusion Pump. |
| BF | Body Floating. A medical safety standard rating. Type BF for devices that have conductive contact with the patient, or having medium- or long-term contact with the patient. |
| Binary | Content that is interpreted by another program that understands how it is formatted. |
| Biomed | Biomedical Technician: A trained super-user with access privileges to the SIGMA Spectrum Infusion Pump and who performs all non-manufacturer Pump maintenance. |
| Bolus | The administration of a drug at a higher dose than the current continuous infusion over a set duration of time. |
| BSA | Body Surface Area; expressed in square meter (m ²) |
| BSS | Basic Service Set |
| C | Celsius |
| CAN/CSA | Canada/Canadian Standards Association |
| Care Area | A way of grouping drugs usually associated with a specific hospital area, unit or patient population; for example, ICU, Anesthesia, Pediatrics |
| cc | Cubic Centimeter |
| CCMP (AES) | Counter Mode CBC-MAC Protocol (Authenticate and Encrypt) |
| CD | Compact Disc |

| | |
|---------------------|--|
| CISPR | Special International Committee on Radio Interference |
| Clinical Advisory | Clinical notes pertaining to a drug. |
| cm | Centimeter |
| Continuous Infusion | IV drug prescribed by continuous dose rate and not dependent on a set duration of time. |
| CPLD ID | Complex Programmable Logic Device Identification |
| CQI | Continuous Quality Improvement |
| CRC | Cyclic Redundancy Check: An error-detecting code commonly used in digital networks and storage devices to detect accidental changes to raw data. |
| CRT | Cathode Ray Tube |
| Cyclic | An IV drug therapy that requires a flow rate (mL/hr) ramp-up over a set duration of time to a main rate (mL/hr) for a set duration of time and then tapers down (mL/hr) for the remainder of the infusion. |
| dBm | The power ratio in decibels (dB) of the measured power referenced to one milliwatt (mW) |
| DC | Direct Current |
| DEHP | Bis(2-ethylhexyl) phthalate. A plasticizer used to make IV tubing flexible. |
| DERS | Dose Error Reduction System |
| DHCP | Dynamic Host Configuration Protocol. Automates the assignment of IP addresses. |
| Distal | Downstream of the pump. Farthest from the center or midline of the body or trunk or from the point of attachment. |
| DL | Drug Library |
| DNS | Domain Name System |
| Dongle | A device that attaches to a computer to control access to a particular application. |
| DS | Downstream Occlusion |
| DTIM | Data Traffic Indication Message |
| ea | Each |
| EAP | Extensible Authentication Protocol |
| ECG | Electrocardiography |
| EMC | Electromagnetic compatibility |
| EOS/ESD | Electrical Over-Stress/Electrostatic Discharge |
| Epidural | Drugs administered into the epidural space. |
| ESD | Electrostatic Discharge |
| EtO Sterilizer | A type of sterilizer for medical equipment that uses ethylene oxide vapor. |
| F | Fahrenheit |
| FAST | Flexible Authentication via Secure Tunneling |
| FCC | Federal Communications Commission |
| FCC ID | Federal Communications Commission equipment authorization identifier consisting of a three-character grantee code and a product code. |
| ft | Foot |
| g | Grams |

| | |
|--------------------|---|
| GHz | Gigahertz |
| GMT | Greenwich Mean Time |
| GW Server | Gateway. A server, or system of servers, that act as the central point of communication for all network communication to or from a SIGMA Spectrum Infusion System. Provides a web based user interface where biomedical engineers can register and manage pumps, pharmacists can distribute, and monitor the distribution of, drug libraries, and pharmacists or nursing managers can generate CQI reports. |
| Hard Limit | Limits that cannot be exceeded. |
| Head Height | The distance measured from the center of the Pump to the top of the fluid in the source container. |
| Hr | Hour |
| HRTFT | Highly Reflective Thin Film Transistor |
| HTM | HyperText Markup |
| Hyperbaric Chamber | A room that allows an individual to breathe 100% pure oxygen at greater than 1 standard atmosphere of pressure. |
| Hz | Hertz |
| ICU | Intensive Care Unit |
| IEC | International Electrotechnical Commission |
| IEEE | Institute of Electrical & Electronic Engineers |
| in | Inch |
| IO/PCB | Input Output/Printed Circuit Board |
| IP Address | Internet Protocol Address. A 4 byte value with 4 numbers ranging from 0 – 255 separated by decimals, that is unique for each smart IV pump and other devices on a network. For example: 192.168.3.43 or 10.1.33.41. |
| IPX0 | IP code indicates the degrees of protection provided by an enclosure. IPX0 indicates the enclosure does not protect against ingress of water with harmful effects. |
| IrDA | Infrared Data Association. A low-level communications protocol used to communicate using infrared with similarly equipped devices such as desktop or laptop computers. |
| IrOBEX | IrDA Object Exchange |
| ISM | Industrial, scientific and medical |
| ISM P | Institute for Safe Medication Practices |
| IT/IS | Information Technology/Information Systems |
| IV | Intravenous |
| KB | Kilobyte |
| Kbs | Thousand bits per second |
| kg | Kilogram |
| kHz | Kilohertz |
| kPa | Kilopascal; unit of pressure in the Metric system. |
| kV | Kilovolts |

| | |
|----------------|--|
| KVO | Keep Vein Open: A minimal but continuous flow rate of fluid at the completion of an infusion to keep the vein open. |
| LEAP | Lightweight Extensible Authentication Protocol |
| LED | Light Emitting Diode |
| Li-Ion | Lithium-Ion |
| Linked Drug | Drugs that have exactly the same parameters and are used by two or more Care Areas. |
| Loading Dose | A higher initial dose of a drug that is delivered over a set duration of time at the beginning of a continuous infusion. |
| LVP Pump | Large Volume Parenteral Pump. |
| m ² | Square Meter; units for representing Body Surface Area (BSA) |
| mA | milli-Amps; 1/1000 (10 ⁻³) of an amp |
| MAC Address | Media Access Control Address. A 6 byte, 12 hex character, unique identifier for each device on a network. These addresses are globally unique. |
| Mbps | Megabits per second |
| mcg | Microgram; 1/1000000 (10 ⁻⁶) of a gram |
| MDL | Master Drug Library. The MDL is a PC-based software tool used to enter and configure facility-specific intravenous drugs for therapy delivery by the SIGMA Spectrum Infusion Pump. |
| MDLA | Master Drug Library Administrator: Person responsible for creating, editing and maintaining the Drug Library. |
| Med Surg | Medical Surgical |
| mEq | Milliequivalent; 1/1000 (10 ⁻³) of an equivalent |
| mg | Milligram; 1/1000 (10 ⁻³) of a gram |
| MHz | Megahertz |
| min | Minute |
| mL | Milliliter; 1/1000 (10 ⁻³) of a liter |
| mL/hr | Milliliter per hour |
| mm | Millimeter |
| mmHg | Millimeters of mercury; a unit of pressure |
| mmol | Millimole; 1/1000 (10 ⁻³) of a mole |
| Modifier | A facility defined text descriptor used to differentiate drug therapies on the Pump when it has distinctive uses, dose modes, concentrations, limits, or configuration settings. |
| MRI | Magnetic Resonance Imaging. Used in radiology to visualize internal structures of the body in detail. |
| MSCHAPv2 | Microsoft Challenge-Handshake Authentication Protocol version 2 |
| mUnits | Milliunits; 1/1000 (10 ⁻³) of an international unit |
| MUX | Multiplexer: A device that selects one of several analog or digital input signals and forwards the selected input into a single line. |
| mW | Milliwatt |

| | |
|-------------|--|
| Neonatal | Pertaining to the first four weeks of life |
| ng | Nanogram; 1/1000000000 (10 ⁻⁹) of a gram |
| NIST | National Institute of Standards and Technology |
| Non-DEHP | Flexible IV tubing that does not use DEHP plasticizer. |
| OR | Operating Room |
| oz | Ounce |
| P Multi | Primary Only Multi-step |
| P No S | Primary Only, Secondary Not Allowed |
| P w/S | Primary Only, Secondary Allowed |
| P/N | Part Number |
| P/S | Primary or Secondary |
| PAC | Protected Access Credentials |
| PAP | Password Authentication Protocol |
| PC | Personal Computer; used to install the MDL application. |
| PCB | Printed Circuit Board |
| PDA | Personal Digital Assistant: A mobile device that functions as a personal information manager and can be used to transfer the Binary Drug Library file (BDL) to the SIGMA Spectrum Infusion Pump. |
| PDF | Portable Document Format: A file format that has captured all the elements of a printed document as an electronic image that you can view, navigate, print or forward. |
| PEAP | Protected Extensible Authentication Protocol |
| Pediatric | Medical care of infants, children, and adolescents |
| PEM | Privacy Enhanced Mail |
| PIC | I/O processor: (I/O Board – 60091-CFG2) Microchip PIC 16F family micro-controller with on-chip A/D convertor used for controlling and monitoring motor speed. |
| PM | Preventive Maintenance |
| PO | Purchase Order |
| Proximal | Upstream of the Pump. Closest to the center or midline of the body or trunk, nearer to the point of attachment. |
| PSI | Pounds per Square Inch |
| PSK | Pre-shared key |
| PWM | Pulse Width Modulation. Used to control power to internal devices. |
| QA | Quality Assurance |
| QoS | Quality of Service |
| RA | Return Authorization |
| RAM | Random Access Memory |
| Rate Change | The capability of the device to change programmed parameters “on the fly” while an infusion is in progress. Rate change is applied, clinically, to adjust an infusion to receive a desired therapeutic effect. |
| RF | Radio Frequency |

| | |
|--------------------|--|
| RFI | Radio Frequency Interference |
| RFID | Radio-frequency identification |
| RTC | Real Time Clock |
| RTLS | Real Time Location Services |
| Rx | Prescription |
| S | Secondary |
| SD | Secure Digital |
| SDS | Simple Data Structure |
| sec | Seconds |
| Sharp | Primary processor: (Processor Board – 60087-1) SHARP LH79520 micro-controller with on-chip A/D convertor used for user interaction and infusion programming. |
| SIGMA | SIGMA International General Medical Apparatus |
| SIR | Serial Infrared |
| Single Error Event | An event (or an error) which occurs once, is cleared and the user is not able to duplicate the event. |
| Soft Keys | Non-labeled keys at the top of the Pump keypad with various functions, depending on what is displayed on the screen directly above them. |
| Soft Limit | Limits that, if exceeded, will generate an alert notifying the user and requiring the user to reject or accept the value entered. |
| SPI | Serial Peripheral Interface |
| SSID | Service Set Identifier. The name of an individual wireless local area network. Can be public, in which the SSID is broadcast for all to see on the WLAN, or private, in which the SSID is not broadcast. A private SSID requires that each connecting device must know the SSID ahead of time. |
| TCP | Transmission Control Protocol |
| TKIP | Temporal Key Integrity Protocol. Used for WPA/WPA2 Security. |
| TLS | Transport Layered Security |
| TPN | Total Parenteral Nutrition: A way of supplying all the nutritional needs of the body by bypassing the digestive system and dripping nutrient solution directly into a vein. |
| TSB | Technical Service Bulletin. External communication of technical information updates. |
| TTLS | Tunneled Transport layered Security |
| UART | Universal Asynchronous Receiver/Transmitter |
| UDP | User Datagram Protocol |
| UL STD | Underwriters Laboratories Standard |
| US | Upstream |
| USB | Universal Serial Bus |
| UTC | Coordinated Universal Time |
| V | Version |
| V/m | Volts per meter |
| VAC | Volts of Alternating Current |
| VDC | Volts of Direct Current |

| | |
|---------|---|
| VLAN | Virtual local area network |
| Vrms | Volts root mean square |
| VTBI | Volume To Be Infused |
| WBM | Wireless Battery Module |
| WEP | Wired Equivalent Privacy. Wireless Frequency Security Method. |
| WLAN | Wireless Local Area Network |
| WPA PSK | Wireless Protected Access - Pre Shared Key |
| μ | Micro |
| μL | Microliter |

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