



Operator's Manual

SPECTRUM IQ INFUSION SYSTEM WITH DOSE IQ SAFETY SOFTWARE

3570009

Spectrum IQ Infusion System Version 9
Dose IQ Safety Software Version 9



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1

User Assistance Information

1.1 Numbers to Call for Assistance

Baxter Technical Assistance: 1.800.356.3454

Baxter Technical Assistance: MedinaTechSupport@baxter.com

Model Number:3570009

Safety Information

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The following documents also pertain to the **Spectrum IQ** Infusion System with **Dose IQ** Safety Software:

- **Spectrum IQ** Infusion System Operator's Manual (P/N 41018v0900, 41018v0900FRE)
- **Spectrum IQ** Infusion System Service Manual (P/N 41367v0900, 41367v0900FRE)
- **Spectrum IQ** Infusion System Portal Access Instruction (P/N 41366v0900, 41366v0900FRE)
- **Spectrum IQ** Infusion System Installation and Maintenance Manual (P/N 41019v0900, 41019v0900FRE)

2.1 Indications for Use

The **Spectrum IQ** Infusion System with **Dose IQ** Safety Software is intended to be used for the controlled administration of fluids. These may include pharmaceutical drugs, blood, blood products. The intended routes of administration consist of the following clinically accepted routes: intravenous, arterial, subcutaneous or epidural . The **Spectrum IQ** Infusion System with **Dose IQ** Safety Software is intended to be used in conjunction with legally marketed and compatible intravenous administration sets and medications provided by the user.

The **Spectrum IQ** Infusion System with **Dose IQ** Safety Software is suitable for a variety of patient care environments such as, but not limited to, hospitals and outpatient care areas.

The **Spectrum IQ** Infusion System with **Dose IQ** Safety Software is intended to reduce operator interaction through guided programming, including a way to automate the programming of infusion parameters and documentation of infusion therapies. This is intended to aid in the reduction of pump programming errors.

The **Spectrum IQ** Infusion System with **Dose IQ** Safety Software is intended to be used by trained healthcare professionals.

2.2 Regulatory Information

- Tested and conforms to IEC 60601-1, ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012,
- Certified to CAN/CSA STD C22.2 NO 601.1, CSA C22.2 No.60601-1:14

2.3 Warnings

WARNING







A WARNING is a statement that alerts you to potential serious injury, death, serious adverse reactions or safety hazards associated with the use or misuse of the Spectrum IQ Infusion System.

Pay careful attention to the specific, point-of-use warnings located throughout this Operator's Manual and to the following general warnings.

NOTE: Specific, point-of-use warnings may not be repeated in this section. They appear within procedures to provide additional information to protect the user and draw attention to potential immediate harm.

2.3.1 General Warnings

Warnings – General

| WARNING | |
|---|---|
|  | <p>Hyperbaric Chamber</p> <p>Do not use the Spectrum IQ Infusion Pump with Dose IQ in a hyperbaric chamber. Use in a hyperbaric Chamber can cause the device to operate improperly, resulting in serious injury or death.</p> <p>Operate the pump outside of hyperbaric chambers only.</p> |
|  | <p>Motor Vehicle or Aircraft Use</p> <p>Do not use the Spectrum IQ Infusion Pump with Dose IQ Safety Software in a motor vehicle or aircraft.</p> <p>This device has not been tested or evaluated for use in motor vehicles or aircraft (e.g., ambulance or MedFlight helicopter).</p> <p>Use in a motor vehicle or aircraft can cause the device to operate improperly.</p> |
|  | <p>AC Power Adaptor</p> <p>Do not use any AC power adaptor that is not specified for this equipment. Using AC power adaptors that are not intended for the Spectrum IQ can cause improper operation resulting in serious injury or death.</p> <p>Use only Baxter-approved AC power adaptors.</p> <p>Disconnect AC Power Adaptor to disconnect from main.</p> |
|  | <p>Pump Mounting During Use and Transport</p> <p>Secure the pump to an IV pole during use or transportation.</p> <p>Improperly securing the pump can damage the equipment and cause interruption in therapy resulting in personal injury or death.</p> <p>The following conditions are to be met for securing the Spectrum IQ Infusion System to the IV pole:</p> <ul style="list-style-type: none"> ■ Pump must be secured to IV pole during use and transportation. ■ Mount pumps to IV pole by centering the pole in the clamp and turning the mounting knob clockwise. ■ Never exceed 210 cm (83 in) from floor to IV pole top and limit bag volume at this extended height to <1 liter (1000 mL). ■ While transporting pump over inclined and or declined surfaces, hold IV pole to provide stability and avoid the IV pole and carrier from tipping over. |

Warnings – General (continued)

WARNING



Battery Handling

Do not short circuit battery terminals, disassemble or modify battery packs, or dispose of improperly.

Failure to handle battery properly can cause damage to the equipment and may result in personal injury or death.

Follow safety precautions and label instructions when handling battery packs.



Low Battery

Do not transport a patient using the pump on battery power when the battery icon is red.

Make sure the pump battery is fully charged when transporting a patient during therapy.



Battery Removal During Infusion

Do not remove the battery module for any reason during an infusion.

This can cause the pump to shut off and cause an interruption in therapy.

Remove battery module only when pump is not in use.



Static Sensitive Equipment

Do not touch the battery pin set on the rear case of the pump without being grounded.

Damage to the equipment may result from electrostatic discharge.

Use a ESD grounding strap while pins are exposed.



Adjacent or Stacked Use

Do not use the pump adjacent to or stacked with other equipment as this can result in improper operation.

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.



Pump Storage

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



Proper Disposal Required

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

Warnings – General (continued)

WARNING



Magnetic Fields

Do not expose the pump to strong magnetic fields such as those generated by MRI equipment.

Strong magnetic fields can cause improper operation, interrupting therapy, resulting in serious injury or death.

Operate the pump in areas that are free from strong magnetic fields.



Linear Accelerator Radiation

Do not expose the Spectrum IQ Infusion Pump to linear accelerator radiation.

Linear accelerator radiation may cause the device to malfunction, interrupting therapy, resulting in personal injury or death.

Conduct therapy only when a safe distance from linear acceleration devices.



Emissions and Immunity

Do not use accessories, transducers, or cables other than those specified by Baxter.

This can result in increased electromagnetic emissions or decreased electromagnetic immunity of the equipment, and improper functioning of the pump or other devices, interrupting therapy, resulting in serious injury or death.

Use only Baxter-specified accessories on this device.



Combustion Possible

Do not over heat, see storage and use temperatures.

Lithium-ion batteries might experience thermal runaway or cell rupture leading to combustion, resulting in serious injury or death.

Charge the battery only with the Spectrum IQ Pump and Baxter approved AC Power adaptor.

Warnings – General (continued)

WARNING



Current Drug Library

Do not put the pump into service for patient use until the most current Drug Library is loaded and the network configuration file is loaded. Failure to do so can result in risk of death or serious injury.

The Spectrum IQ Infusion Pump (new or serviced) is shipped with original factory defaults. All customized Drug Library and network configuration files have been cleared.

Pumps with no drug library loaded will only have Basic Mode operation available.

For a pump being returned from Service:

- Always verify the current Drug Library is loaded.
- Always verify network configuration file is loaded.
- To load the Drug Library and network configuration file refer to the Spectrum IQ Infusion System Installation and Maintenance Manual (P/N 41019v0900, 41019v0900FRE).

Do not return the pump for use until all preventive maintenance tests have been successfully performed.

To load the Drug Library file refer to the Spectrum IQ Infusion System Installation and Maintenance Manual (P/N 41019v0900, 41019v0900FRE).



Operation is Limited to Baxter Trained Operators

Do not operate the Spectrum IQ infusion pump with the Dose IQ Safety Software unless users have been trained in safe system operation and in safe IV therapy practices.

Pump owners have sole responsibility for operator training and testing even when Baxter personnel assist in the training.

Improper operation can result in serious injury or death to the patient.

Make sure that personnel are trained to use the device properly.



Environmental Limits

Do not use the Spectrum IQ Infusion System outside of the specified environmental limits.

Operating the pump outside of appropriate environmental conditions can cause the pump to fail, resulting in serious injury or death.

See the Operational Conditions section of the manual for specific environmental operating conditions.

Warnings – General (continued)

WARNING**Confirm Safe Operation**

Do not operate the Spectrum IQ Infusion System until following conditions are met:

- Infusion administration sets or fluid container vents are functioning.
- Infusion administration set clamps are in the proper positions.
- Infusion administration set is not kinked or collapsed outside the pump.
- There is no flow observed in the drip chamber while the pump is stopped
- Drip rate approximates the pump flow rate when the pump is running.
- Patient, route, and drug are correct before starting infusion.
- Pump settings, including drug/concentration, dose mode, dose rate, and time are correct.
- Alarm settings that are appropriate for the care area.
- A hazard can exist if different alarm presets are used for the same or similar equipment in any single care area.
- Vital signs and infusion administration set access sites are monitored per the facility's standard practice of care.
- Infusion is monitored to make sure that it is delivered as intended.
- Battery status is checked periodically and the battery is replaced if necessary.

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

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

Failure to meet the conditions above could result in an inaccurate or improper infusion delivery, resulting in serious injury or death.

**Manually Stopping the Pump**

When you cannot STOP the pump by pressing :

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

Warnings – General (continued)

WARNING



Improper Shutdown

In the event of an improper shutdown, Pump will generate an **IMPROPER SHUTDOWN** alarm when subsequently powered on and will require reprogramming of infusion parameters.

An improper shutdown occurs when the pump is unexpectedly shutdown occurs due to total power loss.



Do Not Exceed Total Volume

Do not exceed total volume contained in the IV bag when programing a multi- step (single) infusion.

Exceeding the total volume can result in an air embolism, or interruption or delay in therapy, resulting in serious injury or death.

Make sure that the IV bag is properly filled to the specified volume only.

Make sure that the pump is programmed with the specified volume



Baxter IV Sets

- Abide by the Warnings and flow rate settings for Baxter IV Sets as indicated per the Compatible IV Sets List and compatible set labeling. Refer to the Resource section of the Baxter website at www.spectrumIQ.com/resources.html or call Baxter Technical Support at 800.356.3454 for the Compatible IV Sets List.



Low Flow Rate Accuracy/Continuity

At flow rates of 1.9 mL/hr or below, flow rate accuracy is +/- 0.1 mL/hr. When higher accuracy is required, consider an alternate infusion device

Warnings – General (continued)

WARNING**Flow Rate Inaccuracy**

Rate accuracy can be affected by variations in head height, back pressure or any combination thereof. Fluid viscosity and ambient temperature contribute to this variation. 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.
- Using any set outside of its specifically labeled flow rate range, set change interval, operational environment range, or other labeled parameters.

**Priming**

Do not use an unprimed infusion administration set.

Failure to fully prime an infusion administration set can result in accidental air infusion, causing serious injury or death.

Follow proper procedures for priming the administration set and removing air.

**Air Bubbles**

Make sure that air has been removed from all backcheck valves.

Failure to properly prime and remove all air bubbles from backcheck valves in primary infusion administration set may cause the valve to malfunction, resulting in secondary fluid flow into the primary container, resulting in serious injury or death.

Follow proper procedures for priming the administration set and removing air.

Warnings – General (continued)

WARNING



IV Set Loading

Do not reverse the IV set or load the set improperly.

Improper or reverse loading will result in a no flow to the patient condition, possible back flow of blood into the IV set, and occlusion or air-in-line alarms, which may interrupt therapy and cause serious injury or death.

- Load the IV set according to instructions in the manual.



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 set 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.



Bolus

When an administration set is loaded, the door is closed and the slide clamp is removed, a fluid bolus will occur (maximum of 0.2 mL).



Proper Venting Required

Do not use sets with non-vented drip chambers or rigid containers with improperly functioning vents.

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, resulting in serious injury or death.

Use only properly vented drip chambers or properly vented rigid containers.

Warnings – General (*continued*)

WARNING



Time to Upstream Occlusion at Lower Flow Rates

The time to detect an upstream occlusion may be extended if infusing at flow rates below 5 mL/hr. At 1 ml/hr, time to detect upstream occlusion may extend up to 7 hours

Make sure that:

- 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).

Warnings – General (continued)

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.

Ensure 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.

Use of the Spectrum IQ Infusion Pump outside the environmental limits, noted in Appendix A as “Operational Conditions” might cause performance issues with the Spectrum IQ Infusion Pump, 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.

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.

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.

Time to detect an upstream occlusion may be extended if infusing at flow rates below 5 mL/hr. At 1 mL/hr, time to detect upstream occlusion may extend up to 7 hours.

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).**

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.

Warnings – General (continued)

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.

**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.

**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.

**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.

Warnings – General (continued)

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 m (39.37 in) from the point of the downstream occlusion to the Spectrum IQ 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 m (39.37 in) test administration set contained one Y injection site (no filters or other components).
- Testing was at the nominal room temperature $22.2^{\circ}\text{C} \pm 1.1^{\circ}\text{C}$ ($72^{\circ}\text{F} \pm 2^{\circ}\text{F}$).

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 H Default Settings on page H- 1*.



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.



IV Set Usage

Do not use an IV set for longer than the manufacturer's labeled set change interval.

Use of expired sets may adversely affect flow rate accuracy or cause infections leading to serious injury or death.

Make sure that IV sets are used according to manufacturer's instructions.

Warnings – General (continued)

WARNING**Radio Frequency Interference**

The Spectrum IQ Infusion System meets the electromagnetic compatibility (EMC) requirements as specified in the International Electrotechnical Commission's (IEC) 60601-1-2: 2014 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 *Appendix F Immunity – Separation Distances on page F- 9.* for the recommended minimum distance.

NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

**Use of RFID Technology**

Perform functional testing including pump operation testing with the Spectrum IQ Pump in the intended use environment when deployed in an environment with equipment intentionally generating electromagnetic energy to ensure the LVP remains safe and effective.

Perform testing in the intended use environment when using RFID technology. RFID providers should work with healthcare organization in assuring safe deployment and use of RFID near medical electrical equipment and systems. Refer to AIM standard 7351731 Annex L for implementing RAIN RFID systems.

The LVP has been proven to work in the intended use environment for signals defined in IEC 60601-1-2:2014 standard for emission and immunity. Signals not specified in the standard, for example 860-960 MHz frequency at 54 V/m using DSB-ASK Modulation, may cause improper operation such as unexpected system errors and interruption in therapy, which can result in serious injury or death.

**Power strips**

Spectrum IQ should be attached to electrical outlets and power strips that are not connected to other electrical equipment. Doing so can result in a reduced level of safety. Refer to IEC 60601-1:2012 for requirements of ME systems

2.4 Cautions

CAUTION



A **CAUTION** is a statement that alerts you to a problem or unsafe practice which, if not avoided, can cause potential minor or moderate personal injury or damage to the system and surrounding property.

2.4.1 General Cautions

Cautions – General

CAUTION



Service Personnel Must be Trained by Baxter

Servicing the Spectrum IQ 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.

NOTE: Pump should not be serviced while in use on a patient.



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 the Spectrum IQ Infusion Installation and Maintenance Manual (41019v0900, 41019v0900FRE) for complete information.



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.



Follow Physician's Orders

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

Cautions – General (*continued*)

| CAUTION | |
|---|--|
|  | <p>Avoid Bright Natural Sunlight or Artificial Overhead Light</p> <p>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:</p> <ul style="list-style-type: none"> ■ Increase the distance between the pump and the light source. ■ Move the pump to an adjacent location. |
|  | <p>Avoid Overheating</p> <p>When operating the pump, keep out of bright sunlight or direct heat sources to prevent overheating.</p> |
|  | <p>Basic Programming Use</p> <p>Basic programming should only be used when the desired drug or concentration is not available in the facility's drug library.</p> |
|  | <p>Accuracy</p> <p>Refer to trumpet curves for flow rate accuracy as a function of short infusion durations. <i>See Appendix B Flow Rate on page B- 1.</i></p> <ul style="list-style-type: none"> ■ 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. |
|  | <p>Upstream Backcheck Valve Use</p> <p>When connecting a secondary administration set, ensure the primary administration set contains an upstream backcheck valve.</p> |
|  | <p>Pump Orientation</p> <ul style="list-style-type: none"> ■ 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. |
|  | <p>Use Stable IV Poles</p> <p>Do not mount the pump on an IV pole that is not stable.</p> <p>Mounting the pump on a non-stable IV pole can cause an interruption in therapy if the pump becomes dislodged because of the pole.</p> <p>Mount pumps on IV poles that securely hold the pump.</p> |

Cautions – General (continued)

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.



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.



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.



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.



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.

Cautions – General (*continued*)

| CAUTION | |
|---|---|
|  | <p>Handle AC Power Adaptor With Care</p> <ul style="list-style-type: none"> ■ 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. |
|  | <p>Entanglement</p> <p>Do not allow AC power adaptor cable to become entangled with IV administration set tubing.</p> <p>Tangled lines can be a trip hazard or cause accidental disconnection.</p> <p>Always route IV administration set tubing and the AC power adaptor cable so that they are separated. Use the supplied strap to secure excess power cord length.</p> |
|  | <p>Maintain Battery Charge</p> <p>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.</p> |
|  | <p>Static Sensitive Equipment</p> <ul style="list-style-type: none"> ■ 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. |
|  | <p>Oxygen Enriched Environment</p> <p>This equipment is not suitable for use in the presence of a Flammable Anesthetic Mixture with Air or with Oxygen or Nitrous Oxide.</p> <p>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.</p> |
|  | <p>ECG Artifacts Related to the Use of the Spectrum IQ Infusion System</p> <p>Peristaltic infusion pumps may produce what is known as piezoelectric artifacts on ECG monitors and similar types of monitoring instruments. The Spectrum IQ 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 setup and/or connection of electrodes, leads or equipment. See the ECG monitoring system documentation for recommendations on proper setup including electrode connections, site preparation, monitor system setup and electrode placement.</p> |

Cautions – General (*continued*)

CAUTION



Cleaning the Pump and Pump Accessories

- Always wear gloves when cleaning the 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 or buzzer vent) or severe damage may occur.
- Do not spray solutions directly onto 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 the exposed terminals of the battery packs.
- Do not immerse any part of the pump or battery in cleaning agents or other liquids.
- 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.



Preventive Maintenance Tests

All testing and evaluations require fluid and air temperature of 22.2°C ±1.1°C (72°F ±2°F).



Battery Maintenance

- Always maintain the battery module following the recommended instructions in *See Cleaning the Battery Module, page 10- 5.*
- Test batteries for proper performance annually.
- Test batteries whenever damage from drops, fluid intrusion and other causes are suspected.



Recyclable Battery Pack- Dispose of Properly.

The Spectrum IQ 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.

Cautions – General (*continued*)

CAUTION



Static Sensitive Components

- Static sensitive components will be exposed during this process. Perform this procedure using proper anti-static techniques in an EOS/ESD (Electrical Over-Stress/Electrostatic-Sensitive Discharge) safe work area.
- Failure to do so may result in component failure or degradation.

System Components

| Topic | Page |
|---|------|
| System Components | 3-1 |
| Theory of Operation | 3-2 |
| Spectrum IQ Infusion System Illustrations | 3-3 |
| Pump Icons | 3-9 |
| Keys Used to Program and Operate the Pump. | 3-10 |
| Symbols Glossary | 3-14 |

3.1 System Components

The **Spectrum IQ** Infusion System comprises of the following components:

- **Spectrum IQ** infusion pump (Part Number P/N 3570009 or P/N 36010)
- Pole Clamp (P/N 35712) or Double Rotating Pole Clamp (P/N 35743)
- AC Power Adaptor (P/N 30205)
- 802.11a/b/g/n WBM (P/N 35223 or P/N 36010)
- **Dose IQ** Safety Software used by pharmacists to establish which drugs can be administered by the infusion pump, along with associated Care Areas and infusion delivery parameters for each drug
- **Spectrum IQ** Infusion System with **Dose IQ** Safety Software User Manual (P/N 41020v090, 41020v090FRE)
- **Spectrum IQ** Infusion System Operator's Manual (P/N 41018v0900, 41018v0900FRE)
- **Spectrum IQ** Infusion System Service Manual (P/N 41367v0900, 41367v0900FRE)
- **Spectrum IQ** Infusion System Installation and Maintenance Manual (P/N 41019v0900, 41019v0900FRE)

3.2 Theory of Operation

The **Spectrum IQ** Infusion System is a large volume parenteral infusion pump.

The tubing channel and the mating door occlude tubing when the door is closed.

The pump uses internal gears and cams to manipulate fingers and valves to squeeze the administration set tubing peristaltically and to pump the prescribed infusion.

The **Spectrum IQ** Infusion System automatically calculates the pumping rate and time based upon the order information that the user enters.

The order entered parameters all contribute to this calculation, including volume to be infused (VTBI), time, drug concentration, dose mode, loading or bolus doses, delays or rate changes, patient metrics, and units of measurement.

3.2.1 Sensors

In order to mitigate over-infusion and under-infusion to patients the **Spectrum IQ** Infusion System uses sensors to check the key clamp, the IV tubing set, and the door.

The key clamp sensor optically checks for when the correct key clamp is place.

When the slide clamp on the IV set is pressed down into the key hole, the pump door opens with a spring mechanism.

At the upstream end of the pump there are sensor that use ultrasonic signals to monitor set properties.

The upstream ultrasonic sensors can indicate when gases or air is present in IV line, tubing absence, or tubing collapse from pressure drop that can occur from upstream occlusion.

Downstream of the fingers is a sensor sensitive to pressure produced by the tubing.

Downstream occlusions that cause pressure and expansion in tubing increase the force to this sensor.

Tubing temperature is monitored by the furthest downstream sensor.

Door latch and spring release states are monitored by mechanical sensors.

3.2.2 Wireless Battery Module

The pump uses a wireless battery module. The pump will self test to ensure that a wireless battery module is attached.

The Wireless Battery Module (WBM) communicates wirelessly with the local wireless network.

The WBM communicates with the pump by data connections at the electrical contacts on the battery and pump.

The pump has internal memory independent of the battery. The rechargeable battery is a back-up for when there is no AC power, and the battery recharges when the pump is plugged in to an AC outlet.

3.3 Spectrum IQ Infusion System Illustrations

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

- Front view of the **Spectrum IQ** infusion pump. *See Figure 3-1 Spectrum IQ Infusion Pump- Front View.*
- Front view of the **Spectrum IQ** infusion pump with the door open. *See Figure 3-2 Front View with Door Open.*
- Rear view of the **Spectrum IQ** infusion pump without battery. *See Figure 3-3 Spectrum IQ Infusion Pump- Rear View without Battery.*
- Rear view of the **Spectrum IQ** infusion pump with battery. *See Figure 3-4 Spectrum IQ infusion Pump - Rear View with Battery.*
- Screen display features of the **Spectrum IQ** infusion pump. *See Figure 3-5 Spectrum IQ Infusion Pump- Screen Display Features.*

Spectrum IQ Infusion Pump – Front View

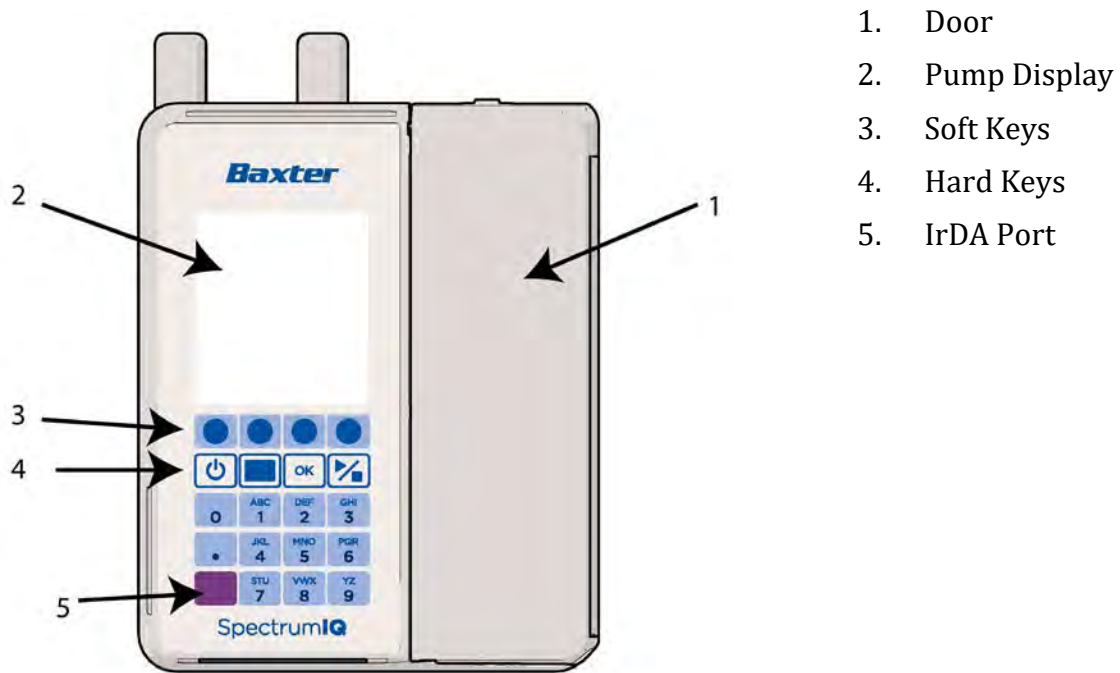


Figure 3-1. Spectrum IQ Infusion Pump- Front View

Spectrum IQ Infusion Pump – Front View with Door Open

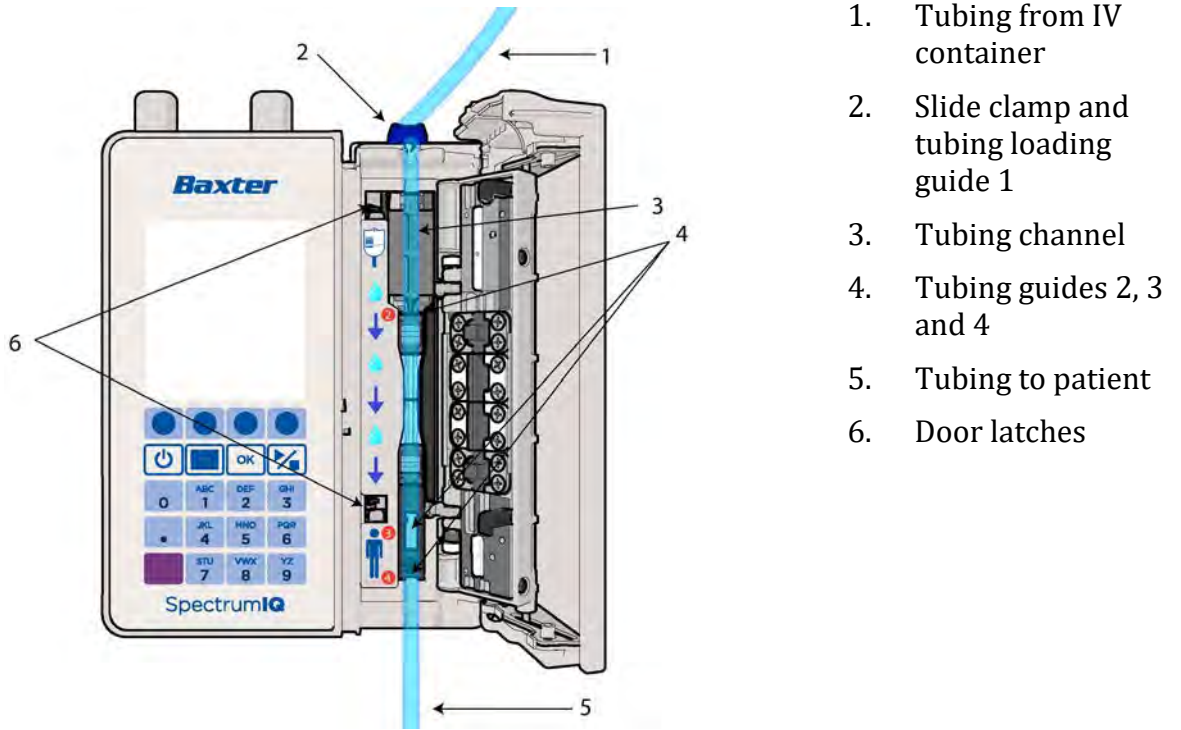


Figure 3-2. Front View with Door Open

Spectrum IQ Infusion Pump – Rear View without Battery

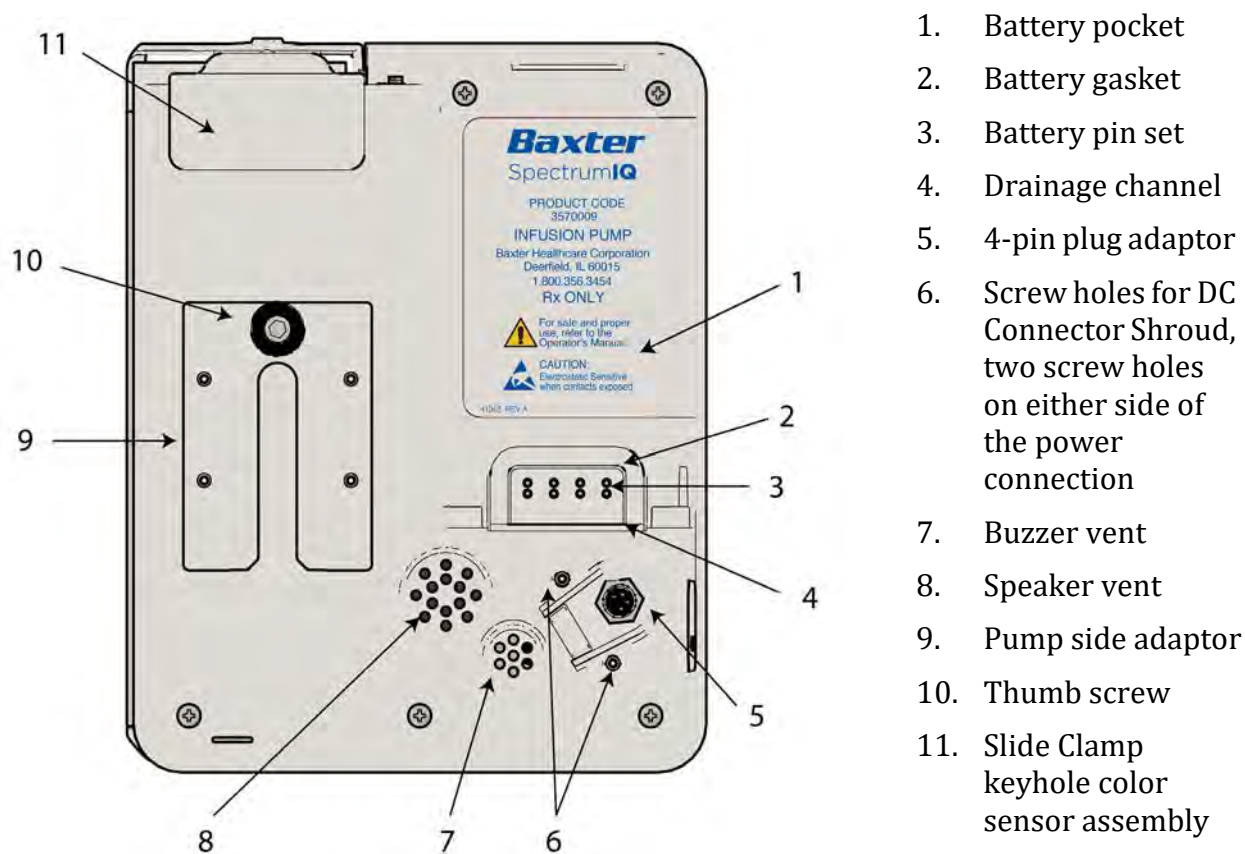


Figure 3-3. Spectrum IQ Infusion Pump- Rear View without Battery

Spectrum IQ Infusion Pump – Rear View with Battery

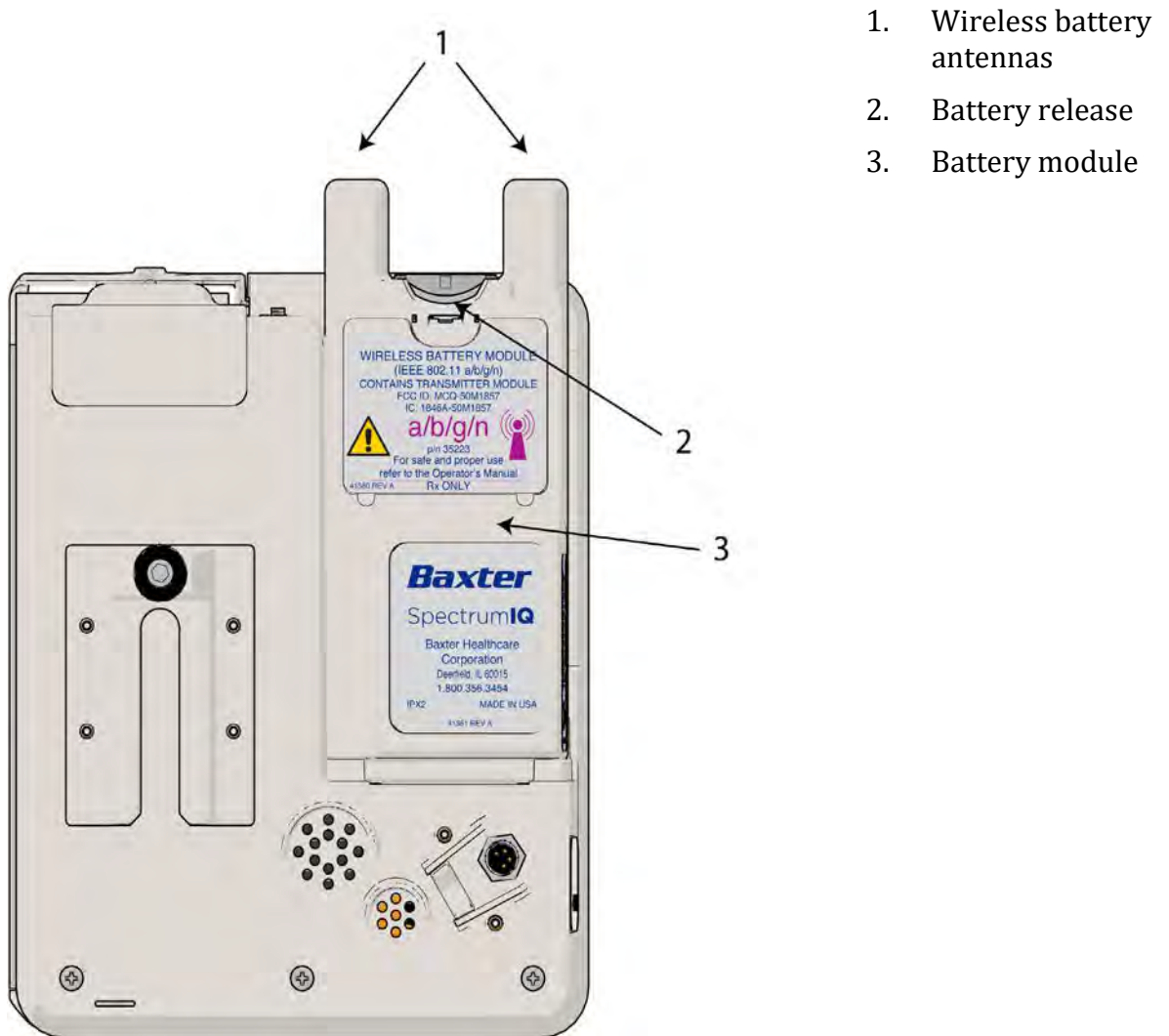
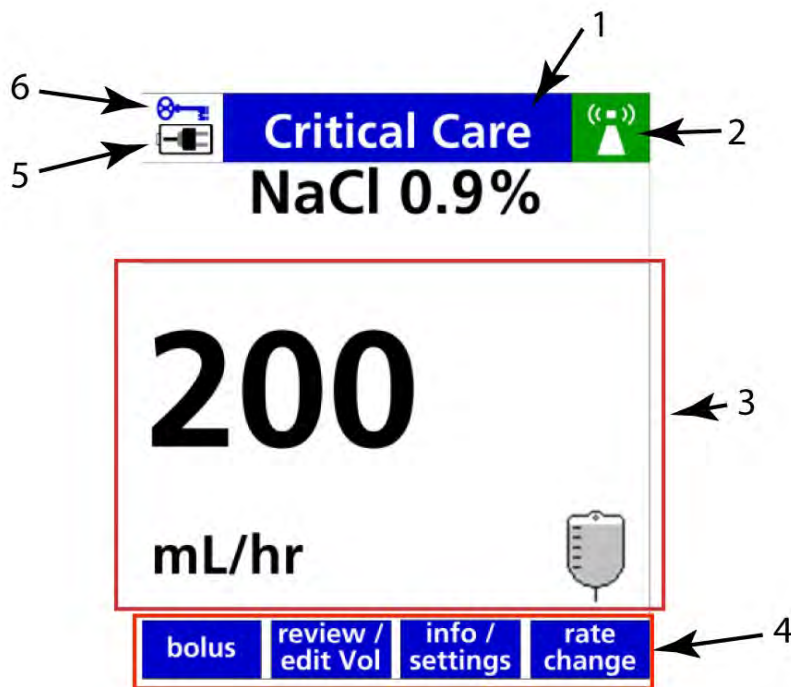


Figure 3-4. Spectrum IQ infusion Pump - Rear View with Battery

Spectrum IQ Infusion Pump –Screen Display Features





















1. Title bar
2. Network status. For more information, See *Pump Icons*, page 3- 9.
3. Infusion Running screen status indicator
4. Soft key labels. For more information, See *Keys Used to Program and Operate the Pump*, page 3- 10.
5. Power status. For more information, See *Pump Icons*, page 3- 9.
6. Keypad lock status. For more information, See *Keypad Lock*, page 8- 161.

Figure 3-5. Spectrum IQ Infusion Pump- Screen Display Features










3.4 Pump Icons

Table 3-1. Icons on Pump Screen

| Icon | Description | Icon | Description | Icon | Description |
|---|--|---|--|---|---|
|  | 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 <i>battery is depleted or missing</i> 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 Dose IQ safety software and is not adjustable on the pump to the selected drug or setting. |  | Secondary Callback feature is active. |  | Secondary infusion is active. |

3. System Components

Table 3-1. Icons on Pump Screen

| Icon | Description | Icon | Description | Icon | Description |
|---|-----------------------------|---|----------------------------|---|-------------------------------------|
|  | Primary infusion is active. |  | Audio Level Indicator. |  | Upstream Occlusion Alarm Suspended. |
|  | Alarm Audio is paused. |  | HIGH Soft Limit Indicator |  | LOW Soft Limit Indicator |
|  | | | High Priority Alarm Bar. | | |
|  | | | Medium Priority Alarm Bar. | | |
|  | | | Low Priority Alarm Bar. | | |

3.5 Keys Used to Program and Operate the Pump

3.5.1 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.

Table 3-2. Pump Soft Keys








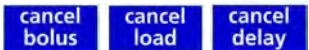











| Soft Key | Screen | Description |
|-------------------|---|--|
| Up/Down Arrows |  | Press to advance cursors up or down and/or select alternate choices. |
| Right/Left Arrows |  | Press to advance cursors left or right. |
| accept order |  | Press to accept order received from EMR. |
| accept program |  | Press to confirm all auto-programmed values from EMR. |

Table 3-2. Pump Soft Keys

| Soft Key | Screen | Description |
|---|---|---|
| accept value |  | Press to accept auto-programmed value that exceeds a soft limit. |
| back |  | Press to go back to the previous screen. |
| bolus |  | Press to access the Bolus setup. |
| cancel bolus cancel load cancel delay |  | Press to cancel bolus, loading dose or delayed start. |
| cancel |  | Press to cancel and return to the previous screen. |
| care area |  | Press to return to Care Area selection screen. |
| clear xxxx |  | Press to erase the highlighted parameter entry (xxxx= parameter label). |
| clear program |  | Press to selectively clear primary infusion, secondary infusion, or both. |
| clr step |  | Press to clear one step of Multi-Step Programming mode. |
| continue |  | Press to continue to the next screen. |
| decline order |  | Press to decline order received from EMR that exceeded hard limit. |
| dose change |  | Press to change dose. |
| edit program |  | Press to edit one or more auto-programmed values from EMR. |
| edit value |  | Press to edit auto-programmed value that exceeds a soft limit. |
| hold |  | Press to place the pump in Standby mode. |

3. System Components

Table 3-2. Pump Soft Keys





















| Soft Key | Screen | Description |
|-------------------------|---|---|
| info/settings |  | Press to select additional pump features related to alarm settings, display settings or information view. |
| no |  | Press to answer “no” to the prompt. |
| not in library |  | Press to program in Basic mode. |
| options menu |  | Press to access the User Options and Biomed Options menu |
| page down |  | Press to scroll down one page. |
| page up |  | Press to scroll up one page. |
| program manually |  | Press to bypass scanning pump and program manually. |
| program pri/sec |  | Press to display the Setup screen when the pump is stopped. |
| program secndry |  | Press to setup a Secondary infusion. |
| rate change |  | Press to change infusion rate (for mL/hr modes only). |
| reset program |  | Press to restart the Multi-Step and Cyclic TPN (Total Parenteral Nutrition) programs to the beginning of the program. |
| reject order |  | Press to reject order received from EMR. |
| review |  | Press to display Setup screen when pump is running. |
| review bolus |  | Press to display bolus setup screen when pump is delivering a bolus. |
| review/edit VTBI |  | Press to display setup screen and edit volume to be infused (VTBI) when pump is running. |




Table 3-2. Pump Soft Keys

| Soft Key | Screen | Description |
|------------------------------------|---|--|
| review load |  | Press to display loading dose setup screen when pump is delivering a loading dose or during primary setup. |
| review primary review secondary |  | Press to view values in the Setup screen. |
| silence |  | Press to pause the audio alarm for 2 minutes Press any key to pause alarm tone. |
| taper down |  | Press to enable a Cyclic TPN program to taper down automatically. |
| yes |  | Press to confirm prompt. |

3.5.2 Hard Keys


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

Table 3-3. Pump Hard Keys

| Hard Keys | | |
|-----------|---|---|
| ON/OFF |  | Press to power the pump on or off. |
| SCAN |  | Press to display barcode screen for updates and back association. |
| OK |  | Press to confirm entries and advance cursors. |

3. System Components

Table 3-3. Pump Hard Keys

| Hard Keys | | |
|---|---|--|
| RUN/STOP |  | Press to start or stop the infusion. |
| ALPHANUMERIC 0-9, A-Z and Decimal Point | | <p>Programming screens enable numbers and drug selection screens enable letters.</p> <ul style="list-style-type: none"> ■ Press the key multiple times to enter a letter. ■ Example: press the 2 key one time for the letter D or press the 5 key three times to enter the letter O. |

3.6 Symbols Glossary

Table 3-4. Standards Developing Organization (SDO)




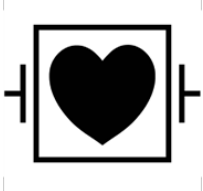




| Established Symbols | Title and number | Title and Reference Number | Meaning |
|---|--|-------------------------------|---|
| Rx ONLY | FDA - Alternative to Certain Prescription Device Labeling Requirements. | N/A | Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician or other licensed practitioner. |
|  | Packaging - Pictorial marking for handling of goods ISO 780:1999. | THIS WAY UP - ISO 7000- 0623. | Indicates correct upright position of the transport package. |
|  | Graphical symbols - Safety colours and safety signs - Registered safety signs (ISO 7010:2011). | ISO 7010-W001. | General Warning Sign. |

Table 3-4. Standards Developing Organization (SDO)

| Established Symbols | Title and number | Title and Reference Number | Meaning |
|---|---|---------------------------------------|--|
|  | International Electrotechnical Commission (IEC). | IEC 60417-5032. | Alternating Current. |
|  | International Electrotechnical Commission (IEC). | IEC 60417-5336. | Defibrillation-Proof Type CF Applied Part. |
|  | International Electrotechnical Commission (IEC). | IEC 60417-5140. | Non-ionizing electromagnetic radiation. |
|  | Underwriters Laboratories (UL). | N/A | Recognized by Underwriters Laboratories (UL) to both Canadian and U.S. requirements. |
|  | Packaging - Pictorial marking for handling of goods ISO 780:1999. | FRAGILE ISO 7000-0621. | Contents of the transport package are fragile therefore it shall be handled with care. |
|  | Packaging - Pictorial marking for handling of goods ISO 780:1999. | KEEP AWAY FROM RAIN ISO 7000-0626. | Transport package shall be kept away from rain. |
| IPX2 | Degrees of protection provided by enclosures (IP Code) - IEC 60529. | N/A | Ingress Protection Marking. |

3. System Components

Table 3-4. Standards Developing Organization (SDO)





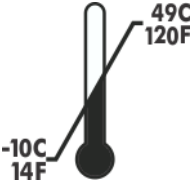



| Established Symbols | Title and number | Title and Reference Number | Meaning |
|---|---|--|--|
|  | ANSI/ESD S8.1 - ESD Awareness Symbols | ESD Susceptibility. | Electrostatic Sensitive when contacts exposed. |
|  | International Electrotechnical Commission (IEC). | IEC 60417-5172. | CLASS II EQUIPMENT. |
|  | ISO. | ISO 7000-1135. | Recyclable, dispose of properly. |
|  | Underwriters Laboratories (UL). | UL Classification Mark for Canada and the United States. | UL Classified (Canada & USA). |
|  | Packaging - Pictorial marking for handling of goods. ISO 780:1999. | TEMPERATURE LIMITS. ISO 7000-0632. | Indicates temperature limits within which the transport package shall be stored and handled. |
|  | ISO 7000 Graphical symbols for use on equipment. | Measure humidity ISO 7000-0224. | Shipping Label - Humidity Sensitive Equipment. |

Table 3-4. Standards Developing Organization (SDO)

| Established Symbols | Title and number | Title and Reference Number | Meaning |
|---|---|---|---|
|  | Packaging - Pictorial marking for handling of goods ISO 780:1999. | KEEP AWAY FROM SUNLIGHT ISO 7000-0624. | Transport package shall not be exposed to sunlight. |
|  | International Electrotechnical Commission (IEC). | ISO 7010-M002. | On ME EQUIPMENT "Follow instructions for use". |

4

Battery Module Compatibility

| Topic | Page |
|-------------------------------|------|
| Battery Replacement | 4-2 |
| Battery Maintenance | 4-2 |

The following battery types are compatible with **Spectrum IQ** Infusion Systems:

- P/N 35223 and P/N 36010 - 802.11a/b/g/n Wireless Battery Module (WBM)

This device complies with part 15 of the Federal Communication Commission (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 can cause improper operation.

- Only Baxter trained service personnel can remove the battery packs from the wireless battery module.

4.1 Battery Replacement

CAUTION



Recyclable Battery Pack – Dispose of Properly

The Spectrum IQ 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 can be obtained from Baxter Healthcare. Contact Baxter Technical Support. *See Battery Module Compatibility, page 4- 1.*

4.2 Battery Maintenance

For battery maintenance information, refer to the **Spectrum IQ** Infusion System Installation and Maintenance Manual (41019v0900, 41019v0900FRE).

Setting up the Pump

| Topic | Page |
|--|------|
| Unpacking the Pump | 5-1 |
| Incoming Pump Tests | 5-2 |
| Connecting and Disconnecting the AC Power Adaptor. | 5-2 |
| Charging the Battery | 5-4 |
| Configuring User Options | 5-6 |

5.1 Unpacking the Pump

The **Spectrum IQ** Infusion System packaging is designed to provide protection to the pump for transportation and storage.

To unpack the pump:

1. Remove the **Spectrum IQ** Infusion System from the protective anti-static bag.
2. Remove the clamshell end caps.

NOTE: Save all packaging materials for reuse when returning the product for repair or warranty replacement.

3. Discard the silica desiccant package.
4. Pull the battery tab away from the battery pocket. *See Figure 5-1 Pull battery tab straight out.*

NOTE: Do not attempt to charge the battery with the battery tab in place.

5. Fully charge the battery prior to use.

NOTE: The approximate time to initially charge the battery is 16 hours tolerance values vary at 24 minutes at 22.2°C ±1.1°C (72°F ±2°F).

5. Setting up the Pump

NOTE: For more information: See *Charging the Battery*, page 5- 4.



Figure 5-1. Pull battery tab straight out

5.2 Incoming Pump Tests

Baxter recommends that the following tests be performed on pumps returned from service repair.

See “Preventive Maintenance Pump Tests” section in the “Installation and Maintenance Manual” (41019v0900, 41019v0900FRE).

- Downstream Occlusion Sensor Testing
- Upstream Occlusion Sensor Testing
- Gravimetric or Volumetric Flow Rate Accuracy Test
- Air Detection Test

5.3 Connecting and Disconnecting the AC Power Adaptor

NOTE: User is to be within 1m (39.37 in) of the pump while operating the device to be in view of the screen.

NOTE: Do not block the area around the AC power adaptor. Blocking the adaptor can cause difficulty when plugging in and unplugging.

WARNING



AC Power Adaptor

Do not use any AC power adaptor that is not specified for this equipment.

Using AC power adaptors that are not intended for the Spectrum IQ Infusion System can cause improper operation resulting in serious injury or death.

Use only Baxter-approved AC power adaptors.

Disconnect AC Power Adaptor to disconnect from main

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.

To connect the AC Power Adaptor:

1. Plug the AC Power Adaptor into a 120 VAC wall outlet.
2. Verify that the plug icon appears in the title bar of the pump display. *See Figure 5-2 Plug Icon.*
 - The plug icon and the battery icon will alternate while the battery is charging.
 - Do not use the pump if the plug icon does not appear. Return the pump for service.



Figure 5-2. Plug Icon

5. Setting up the Pump

To disconnect the AC Power Adaptor:

NOTE: Do not pull on the cord when removing the AC power adaptor.

1. Grasp the strain relief on the power cord with thumb and forefinger.
2. Pull the AC Power Adaptor away from the outlet in a straight direction. *See Figure 5-3 Removing AC Power Adaptor.*

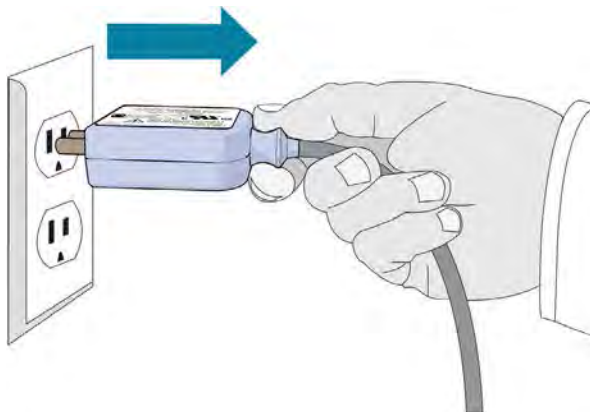


Figure 5-3. Removing AC Power Adaptor

5.4 Charging the Battery

To charge the battery:

1. Dock the battery to the back of the pump.
2. Plug AC Power Adaptor into a 120 VAC outlet.

NOTE: The pump charges the battery whether it is powered on or off.

NOTE: The AC Power Adaptor has a locking cord connection at the pump, to prevent accidental disconnection from the pump.

For battery power and capacity specifications *See Appendix A Pump Specifications on page A- 2.*

For a list of the icon symbols used and their descriptions, *See Pump Icons, page 3- 9.*

WARNING



Battery Handling

Do not short circuit battery terminals, disassemble or modify battery packs, or dispose of improperly.

Failure to handle battery properly can cause damage to the equipment and may result in personal injury or death.

Follow safety precautions and label instructions when handling battery packs.



Low Battery

Do not transport a patient using the pump on battery power when the battery icon is red.

Make sure the pump battery is fully charged when transporting a patient during therapy.



Battery Removal During Infusion

Do not remove the battery module for any reason during an infusion.

This can cause the pump to shut off and cause an interruption in therapy.

Remove battery module only when pump is not in use.



Static Sensitive Equipment

Do not touch the battery pin set on the rear case of the pump without being grounded.

Damage to the equipment may result from electrostatic discharge.

Use an ESD grounding strap while pins are exposed.

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 Spectrum IQ 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.

5.5 Configuring User Options

The **Spectrum IQ** Infusion System has two sets of configuration options:

- User Options- Pump settings that can be updated by a Baxter trained user.
- Biomed Options- Pump settings that are password protected and only accessible by a Baxter trained Biomedical Engineer.
 - The Biomed Options are configured by a Baxter trained Biomed. These options are described in the **Spectrum IQ** Infusion System Service Manual (P/N 41367v0900, 41367v0900FRE).

WARNING



Operation is Limited to Baxter Trained Operators



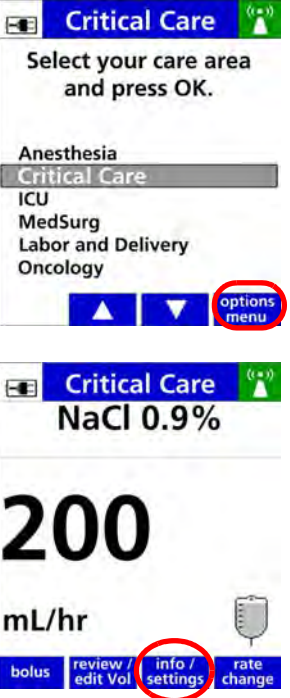
Do not operate the Spectrum IQ Infusion System with the Dose IQ Safety Software unless users have been trained by Baxter in safe system operation and in safe IV therapy practices.

Pump owners have sole responsibility for operator training and testing even when Baxter personnel assist in the training.

Improper operation can result in serious injury or death to the patient.




Make sure that personnel are trained to use the device properly.

Table 5-1. Accessing the user Options Menu

| Steps | Screens |
|---|--|
| <p>1. Press  to power on the pump.</p> |  |
| <p>The Care Area screen displays.</p> <p>2. Press the options menu soft key from the Care Area selection screen.</p> <p>or if an infusion is running:</p> <p>3. Press the info/settings soft key from the RUN screen or Pump Stopped screen This directly accesses the User Options menu. (Proceed to step 4.)</p> |  |

5. Setting up the Pump

Table 5-1. Accessing the user Options Menu

| Steps | Screens |
|---|--|
| <p>4. Press the soft arrow keys to select User Options.</p> <p>5. Press .</p> |  |
| <p>6. The User Options menu appears with 3 options:</p> <ul style="list-style-type: none"> ■ Alarm Settings. <i>See Alarm Settings, page 5- 9.</i> ■ Display Settings. <i>See Display Settings, page 5- 12.</i> ■ View Information. <i>See View Information, page 5- 17.</i> <p>NOTE: Accessing the User Options from the RUN screen is different from accessing the User Options from the Care Area or the Pump Stopped screen.</p> <p>NOTE: Inactivity or an update to the settings returns the screen to the RUN screen.</p> |  |

5.5.1 Alarm Settings

Table 5-2. Alarm settings





Alarm settings can be preset in the **Dose IQ** Safety Software.

The info/setting menu during a **RUN** or **Pump Stopped** screen displays a lock icon  when a setting is preset.

NOTE: A preset setting cannot be changed on the pump.

NOTE: The default of Alarm Settings in the **Dose IQ** Safety Software allows the alarm settings to be adjusted at the pump.

NOTE: In normal operation, internal battery power will retain alarm settings for more than 30 seconds. In case of battery failure, all user alarm settings restore after failure except for downstream occlusion auto- restart, which is configured to “on” after restart.

| Setting | Description | Screen |
|-------------------------------|---|---|
| Audio Volume | <p>The audio volume of the pump has three levels: low, med and high.</p> <p>To adjust the Audio Volume:</p> <ol style="list-style-type: none"> 1. Press arrow soft keys to select the volume level. 2. Press . |  |
| Standby delay (hr:min) | <p>Standby (or Hold) time after the setup of the infusion are from 00:01 to 96:00 (hr:min). Setting the value to 00:00 or Infinite results in an infinite hold period.</p> <p>To set the Standby delay:</p> <ol style="list-style-type: none"> 1. Press numeric keypad to enter the hold time. 2. Press  to save entry. |  |

5. Setting up the Pump

Table 5-2. Alarm settings

Alarm settings can be preset in the **Dose IQ** Safety Software.

The info/setting menu during a **RUN** or **Pump Stopped** screen displays a lock icon  when a setting is preset.

NOTE: A preset setting cannot be changed on the pump.

NOTE: The default of Alarm Settings in the **Dose IQ** Safety Software allows the alarm settings to be adjusted at the pump.

NOTE: In normal operation, internal battery power will retain alarm settings for more than 30 seconds. In case of battery failure, all user alarm settings restore after failure except for downstream occlusion auto- restart, which is configured to “on” after restart.



| Setting | Description | Screen |
|--------------------------|--|--|
| Near- Empty alert | <p>Near- Empty alert has 2 settings: on or off. An on Near- Empty alert displays when 30 minutes or less of infusion remains.</p> <p>NOTE: The alert will not generate when the initially-programmed infusion is less than 30 minutes.</p> <p>To set the Near- Empty alert:</p> <ol style="list-style-type: none"> 1. Press the arrow soft keys to set the alarm. 2. Press . |  |

Table 5-2. Alarm settings



Alarm settings can be preset in the **Dose IQ** Safety Software.

The info/setting menu during a **RUN** or **Pump Stopped** screen displays a lock icon  when a setting is preset.

NOTE: A preset setting cannot be changed on the pump.

NOTE: The default of Alarm Settings in the **Dose IQ** Safety Software allows the alarm settings to be adjusted at the pump.

NOTE: In normal operation, internal battery power will retain alarm settings for more than 30 seconds. In case of battery failure, all user alarm settings restore after failure except for downstream occlusion auto- restart, which is configured to “on” after restart.

| Setting | Description | Screen |
|--|--|--|
| DS Pressure Limit (Downstream Occlusion Pressure Limit) | <p>The DS Pressure limit has three levels:</p> <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) <p>To set the DS Pressure limit:</p> <ol style="list-style-type: none"> 1. Press the arrow soft keys to set the pressure limit. 2. Press . |  |

5. Setting up the Pump

Table 5-2. Alarm settings



Alarm settings can be preset in the **Dose IQ** Safety Software.

The info/setting menu during a **RUN** or **Pump Stopped** screen displays a lock icon  when a setting is preset.

NOTE: A preset setting cannot be changed on the pump.

NOTE: The default of Alarm Settings in the **Dose IQ** Safety Software allows the alarm settings to be adjusted at the pump.

NOTE: In normal operation, internal battery power will retain alarm settings for more than 30 seconds. In case of battery failure, all user alarm settings restore after failure except for downstream occlusion auto- restart, which is configured to “on” after restart.

| Setting | Description | Screen |
|-----------------------------------|---|--|
| DS Occlusion Auto Restarts | <p>The DS Occlusion Auto Restart has 2 settings: on or off.</p> <p>The DS Occlusion Auto Restarts limit is set in the Dose IQ Safety Software.</p> <p>The limit is from 1 to 9.</p> <p>Default for this setting is on.</p> <p>To set the DS Occlusion Auto Restart:</p> <ol style="list-style-type: none"> 1. Press the arrow soft keys to select on or off. 2. Press . <p>To Reset the number of restarts:</p> <ol style="list-style-type: none"> 1. Press the reset restarts soft key. <p>For more details on this feature See <i>Appendix D Downstream Occlusion on page D- 1</i>.</p> |  |

5.5.2 Display Settings

The Display Settings menu can be accessed from the User Options screen. It has two options:

- **RUN screen Options**- Allows users to select the information displayed on the **RUN** screen.
- **Display Adjust**- Changes the back-lighting on the screen.

Display Settings: RUN screen Options

Each of the items on this list can be set to **on** or **off**.

When an option is set to **on**: The information will be displayed in the alternating **RUN** screens during the infusion.

NOTE: Press the exit soft key to return to the previous menu.



Figure 5-4. Display Settings

5. Setting up the Pump

Table 5-3. RUN Screen Options











| Settings | Description | Screen |
|-------------------------------------|---|--|
| <p>Audio Level Indicator</p> | <p>The settings for the Audio Level Indicator are on or off.</p> <p>When set to on, the RUN screen will show an icon to indicate the volume setting of low, med or high.</p> <p>To display the Audio Level Indicator:</p> <ol style="list-style-type: none"> 1. Press the arrow soft keys to set it on or off. 2. Press . <p>Factory default setting is off.</p> |  <p>RUN SCREEN OPTIONS</p> <p>Using ▲▼, select the setting and push OK</p> <p>Audio Level Indicator on ▲▼</p> <p>*Rate mL/hr on</p> <p>*Dose rate on</p> <p>*mL - VTBI off</p> <p>*Time [hr:min] off</p> <p>[*setting N/A in Cyclic TPN Mode]</p> <p>exit ▲▼</p> |
| <p>Rate mL/hr</p> | <p>The settings for the Rate mL/ hr indicator are on or off.</p> <p>When set to on, the RUN screen will show the infusion rate (mL/hr).</p> <p>To display the Rate mL/ hr Indicator:</p> <ol style="list-style-type: none"> 1. Press the arrow soft keys to set it on or off. 2. Press . <p>Factory default setting is on.</p> |  <p>RUN SCREEN OPTIONS</p> <p>Using ▲▼, select the setting and push OK</p> <p>Audio Level Indicator on</p> <p>*Rate mL/hr on ▲▼</p> <p>*Dose rate on</p> <p>*mL - VTBI off</p> <p>*Time [hr:min] off</p> <p>[*setting N/A in Cyclic TPN Mode]</p> <p>exit ▲▼</p> |

Table 5-3. RUN Screen Options

| Settings | Description | Screen |
|-------------------------|---|---|
| <p>Dose rate</p> | <p>The settings for the Dose Rate indicator are on or off.</p> <p>When set to on, the RUN screen will show the dose rate of the infusion (e.g., mcg/kg/min).</p> <p>To display the Dose Rate Indicator:</p> <ol style="list-style-type: none"> 1. Press the arrow soft keys to set it on or off. 2. Press . <p>Factory default setting is on.</p> |  |



5. Setting up the Pump

Table 5-3. RUN Screen Options

| Settings | Description | Screen |
|-----------------------------|--|---|
| <p>mL - VTBI</p> | <p>The settings for the mL- VTBI indicator are on or off.</p> <p>When set to on, the RUN screen will show the remaining Volume to be Infused (mL).</p> <p>To display the mL- VTBI Indicator:</p> <ol style="list-style-type: none"> 1. Press the arrow soft keys to set it on or off. 2. Press . <p>Factory default setting is off.</p> |  <p>The screenshot shows the 'RUN SCREEN OPTIONS' menu with the following settings: Audio Level Indicator (on), *Rate mL/hr (on), *Dose rate (on), *mL - VTBI (off), and *Time [hr:min] (off). The *mL - VTBI setting is highlighted with a blue bar and a downward arrow. At the bottom, there is an 'exit' button and two arrow keys.</p> |
| <p>Time (hr:min)</p> | <p>The settings for Time (hr:min) indicator are on or off.</p> <p>When set to on, the RUN screen will show the time remaining in the current infusion, in hr:min format.</p> <p>To display the Time (hr:min) Indicator:</p> <ol style="list-style-type: none"> 1. Press the arrow soft keys to set it on or off. 2. Press . <p>Factory default setting is off.</p> |  <p>The screenshot shows the 'RUN SCREEN OPTIONS' menu with the following settings: Audio Level Indicator (on), *Rate mL/hr (on), *Dose rate (on), *mL - VTBI (off), and *Time [hr:min] (off). The *Time [hr:min] setting is highlighted with a blue bar and a downward arrow. At the bottom, there is an 'exit' button and two arrow keys.</p> |

Display Settings: Display Adjust

Table 5-4. Display Settings: Display Adjust

| Settings | Description | Screen |
|-----------------------|--|---|
| Display Adjust | <p>The settings for the display backlight brightness levels are 1 through 10 and OFF. 10 is the brightest setting and OFF turns the backlight off.</p> <p>To display the Display Adjust Indicator:</p> <ol style="list-style-type: none"> 1. Press the arrow soft keys to set it on or off. 2. Press . <p>NOTE: The back light consumes approximately 400 mW when set to maximum brightness.</p> <p>Factory default setting is 10.</p> <p>Press the exit soft key until the screen returns to the Care Area selection screen, the RUN screen or the Pump Stopped screen.</p> |  |

5.5.3 View Information

The View Information menu can be accessed from the User Options screen. It has five options: See *Figure 5-5 View information screen*.

1. Pump Information
2. Library Information
3. Show Clinical Advisory
4. Infusion Information
5. History Log

5. Setting up the Pump

NOTE: Not all options are accessible at all times. The option will be in gray when it is not available.

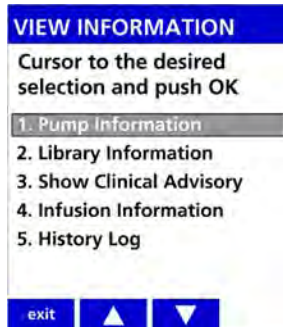




Figure 5-5. View information screen

Table 5-5. View Information Options

| Settings | Descriptions | Screens |
|-----------------------------------|---|---|
| <p>Pump Information</p> | <p>The Pump Information screen shows the following read-only information:</p> <ul style="list-style-type: none"> ■ SW Ver – The software version. ■ Serial number – The serial number assigned by Baxter for tracking and device history. ■ Wireless Module – Wireless protocol. <p>Press the sw info soft key to display the versions of the individual software components that are installed.</p> <ul style="list-style-type: none"> ■ SW Ver. – The software version. ■ Sharp- Subversion build of Sharp processor. ■ PIC – Peripheral Interface Controller version. ■ CPLD – Complex Programmable Logic Device version. ■ Int. Batt Charger- Internal Battery Charger version. ■ SmartBatt Charger- WBM battery version. ■ Network Module- Status. |  |
| <p>Library Information</p> | <p>The Library Information screen identifies the name of the Active drug library in pump memory. It also displays:</p> <ul style="list-style-type: none"> ■ Name ■ Date Modified ■ Version (Ver) ■ Dose IQ Safety Software Version Number ■ Number of Drugs ■ Number of Care Areas ■ Number of Advisories ■ Number of Modifiers |  |

5. Setting up the Pump

Table 5-5. View Information Options


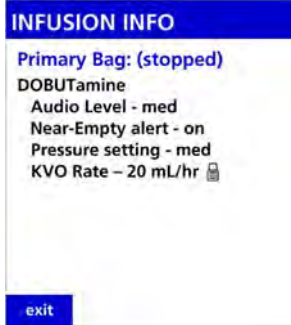

| Settings | Descriptions | Screens |
|-------------------------------|---|---|
| Show Clinical Advisory | <p>NOTE: Available only when the pump is running.</p> <p>This screen shows the clinical advisory for the drug that has been configured in the Dose IQ Safety Software.</p> <p>NOTE: If a drug does not have an advisory configured in the drug library, the option will be gray and not available to select.</p> |  |

Table 5-5. View Information Options



| Settings | Descriptions | Screens |
|-----------------------------|---|---|
| Infusion Information | <p>NOTE: Available only when the pump is running an infusion.</p> <p>The Infusion Information screen shows the infusion-specific primary and secondary bag parameters that are not otherwise displayed on the Setup screen.</p> <p>The information includes the following information for each bag (if programmed):</p> <ul style="list-style-type: none"> ■ Audio Level ■ Near-Empty Alert status (primary only) ■ Pressure Setting ■ KVO rate (primary only) ■ Primary siphoning alert or Secondary Complete alert status (secondary only) |  |
| History Log | <p>NOTE: Available only when the pump is not running an infusion.</p> <p>Selecting this option provides access to the event log.</p> <p>Available options are:</p> <ul style="list-style-type: none"> ■ View History Log – Select this option to view the entire history log on the pump screen. ■ Dump History Log – Select this option to send the entire history log out of the pump using the IrDA port. <p>NOTE: Refer to the Logging section of the Spectrum IQ Infusion System Installation and Maintenance Manual (P/N 41019v0900, 41019v0900FRE).</p> |  |

6

Servicing the Pump

| Topic | Page |
|------------------------------|------|
| Servicing the Pump | 6-1 |

6.1 Servicing the Pump

| CAUTION | |
|---|---|
|  | <p>Service Personnel Must be Trained by Baxter</p> <p>Servicing the Spectrum IQ Infusion System is restricted to qualified, Baxter trained, service personnel who employ Baxter authorized parts and procedures. Use of other parts and servicing procedures is prohibited.</p> <p>NOTE: Pump should not be serviced while in use on a patient.</p> |
|  | <p>Perform Preventive Maintenance Annually</p> <p>Pumps should be tested for proper performance annually and also whenever damage from drops, fluid intrusion and other causes is suspected. See the Installation and Maintenance Manual (P/N 41019v0900, 41019v0900FRE) for complete information.</p> |

Preventive Maintenance is performed to check the functioning of alarms and the operational safety of the device.

Preventive Maintenance is performed by qualified, Baxter-trained, service personnel.

Refer to the **Spectrum IQ** Infusion System Installation and Maintenance Manual (P/N 41019v0900, 41019v0900FRE) or contact Baxter Technical Support for pump service needs. See *Numbers to Call for Assistance, page 1- 1.*

7

Preparing the Pump and IV sets

| Topic | Page |
|---|-------------|
| Mounting the Pump on an IV Pole | 7-2 |
| Preparing and Priming an IV Set | 7-4 |
| Loading an IV Set | 7-6 |
| Unloading an IV Set | 7-12 |
| Secondary Infusion Setup | 7-13 |

7.1 Mounting the Pump on an IV Pole

WARNING



Pump Mounting During Use and Transport

Secure the pump to an IV pole during use or transportation.

Improperly securing the pump can damage the equipment and cause interruption in therapy resulting in personal injury or death.

The following conditions are to be met for securing the Spectrum IQ Infusion System to the IV pole:

- Pump must be secured to IV pole during use and transportation.
- Mount pumps to IV pole by centering the pole in the clamp and turning the mounting knob clockwise.
- Never exceed 210 cm (83 in) from floor to IV pole top and limit bag volume at this extended height to <1 liter (1000 mL).
- While transporting pump over inclined and or declined surfaces, hold IV pole to provide stability and avoid the IV pole and carrier from tipping over.

CAUTION



Use Stable IV Poles

Do not mount the pump on an IV pole that is not stable.

Mounting the pump on a non-stable IV pole can cause an interruption in therapy if the pump becomes dislodged because of the pole.

Mount pumps on IV poles that securely hold the pump.



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.



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.

To mount the pump on an IV pole:

NOTE: Do not place the pump face down on a hard surface.

NOTE: When using a multi-pump carrier with only one pump, mount the pump on the center pole.

NOTE: Avoid resting the pump on the carrier plate when using a multi- pump carrier.

NOTE: Mount the pump on an IV pole by holding the pump in one hand.

1. Center the pole clamp onto the IV pole.
2. Turn the mounting knob of the pole clamp clockwise to tighten.
3. Plug the pump's AC Power Adaptor into a powered outlet.

7.2 Preparing and Priming an IV Set

WARNING



Priming

Do not use an unprimed infusion administration set.

Failure to fully prime an infusion administration set can result in accidental air infusion, causing serious injury or death.

Follow proper procedures for priming the administration set and removing air.



IV Set Usage

Do not use an IV set for longer than the manufacturer's labeled set change interval.

Use of expired sets may adversely affect flow rate accuracy or cause infections leading to serious injury or death.

Make sure that IV sets are used according to manufacturer's instructions.



Flow Rate Inaccuracy

Rate accuracy can be affected by variations in head height, back pressure or any combination thereof. Fluid viscosity and ambient temperature contribute to this variation. 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 Infusions, page 8- 94*.
- Using any set outside of its specifically labeled flow rate range, set change interval, operational environment range, or other labeled parameters.

To prepare and prime an IV set:

1. Follow the instructions on the IV set package to spike and prime the set.
2. Spike the bag and fill the drip chamber to the fill to line located on the drip chamber.
3. Hang the IV container, leaving a distance of 61 cm (24 in) between the top of the container and the center of the pump.
4. Position and close the roller clamp 33.2–38.1 cm (13–15 in) below the upper Y injection site.
 - If there is no upper Y injection site, close the roller clamp 48.3–53.3 cm (19–21 in) below the drip chamber.
5. Prime the IV set by opening the roller clamp half way and slowly priming the tubing.
6. Invert and tap the upper backcheck valve and Y injection sites as fluid is flowing, until all air is removed.
7. 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.
 - Make sure the roller clamp is 48.3–50.3 cm (19–21 in) below the drip chamber.

7.3 Loading an IV Set

WARNING



Roller Clamps

To prevent uncontrolled gravity flow:

- Make sure that the roller clamp below the pump is in the closed position before unloading a primed infusion administration set.
- Make sure that the administration set slide clamp is closed, providing “set-based, anti-free flow” protection before opening the pump door.
- Close the set’s roller clamp during IV container changes. Open the roller clamp only after the pump door is closed.

Failure to do so can cause uncontrolled free flow of medication, resulting in serious injury or death.



Slide Clamps

To prevent uncontrolled gravity flow:

- Make sure that the slide clamp is closing the line before opening the door, or during and after infusion administration set unloading.
- Make sure the slide clamp is securely closed to prevent free flow.

Failure to do so can cause uncontrolled free flow of medication, resulting in serious injury or death.

CAUTION



Accuracy

Refer to trumpet curves for flow rate accuracy as a function of short infusion durations. See *Appendix B Flow Rate on page B- 1*.

- 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.
 - Make sure that 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  to power on the pump.
3. Visually track the tubing from the drip chamber through the closed slide clamp.
4. With the tear drop cutout pointing down insert the slide clamp into the keyhole (loading guide 1) at the top of the pump. *See Figure 7-1 Insert Slide Clamp.*

NOTE: Inserting the slide clamp properly is the only way to open the pump door.

NOTE: Do not grasp the top of the door and attempt to pry open.

NOTE: Loading guide 1 is the keyhole. The slide clamp must remain in the keyhole during IV set loading and reloading.

NOTE: An alarm sounds when slide clamp is removed during set loading, and reloading the IV set will be required.



Figure 7-1. Insert Slide Clamp

7. Preparing the Pump and IV sets

5. Push down on the slide clamp until the door opens.
6. Gently hold the slide clamp in the keyhole.

NOTE: When the door opens confirm that the bar on the pump screen is green for Load Guide1.

NOTE: Tubing should now be in front of the loading channel and not behind the door. See Figure 7-2 Tubing in front of the loading channel.

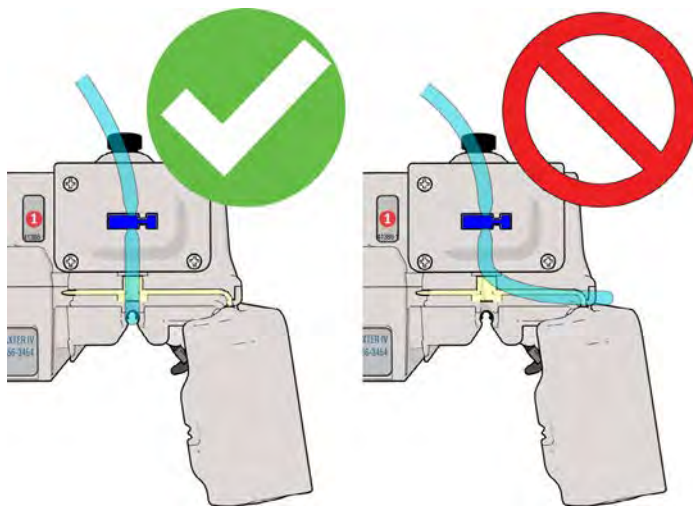


Figure 7-2. Tubing in front of the loading channel

WARNING



IV Set Loading

Do not reverse the IV set or load the set improperly.

Improper or reverse loading will result in a no flow to the patient condition, possible back flow of blood into the IV set, and occlusion or air-in-line alarms, which may interrupt therapy and cause serious injury or death.

- Load the IV set according to instructions in the manual.

7. Observe the Direction of Flow diagram. See Figure 7-3 Direction of flow label and Load Set into guide.

8. Visually inspect the tubing channel to make sure it is free of dirt and debris.
9. Load the primed IV set tubing from the top to the bottom of the tubing channel. Make Sure that:
 - The tubing follows the Direction of Flow diagram. See *Figure 7-3 Direction of flow label and Load Set into guide*.
 - The tubing is routed from the slide clamp directly into the top of the tubing channel.
 - The tubing is loaded 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.
10. Push the tubing into load guide 2 and confirm that the bar is green for load guide 2. See *Figure 7-3 Direction of flow label and Load Set into guide*.

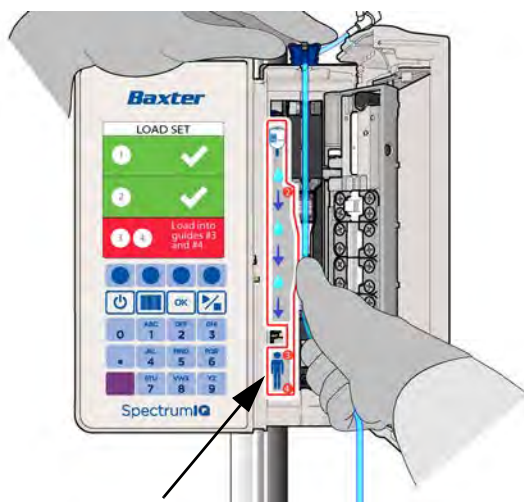


Figure 7-3. Direction of flow label and Load Set into guide

11. Push the tubing into load guides 3 and 4 and confirm that the bar is green for load guides 3 and 4. See *Figure 7-4 Properly loaded tubing*.

NOTE: The tubing is properly loaded when the screen displays:

- Three green bars.
- Check marks for all four loading guides.

7. Preparing the Pump and IV sets

- Close door instruction prompts.

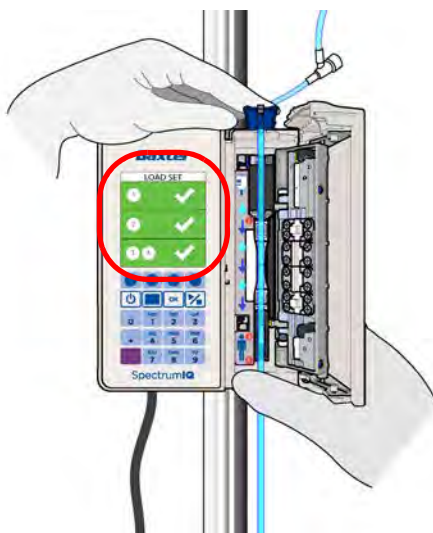


Figure 7-4. Properly loaded tubing

12. Close the door by pressing the upper and lower corners near the key pad. *See Figure 7-5 Proper door closing.*



Figure 7-5. Proper door closing

13. Remove and open the slide clamp from the keyhole per the prompts on the screen:
 - Hold the tubing down on both sides of the keyhole with one hand.
 - Pull the slide clamp straight up and out with the other hand.

- The slide clamp is open when it moves freely on the tubing.

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 0.2 mL).

14. Open the lower roller clamp and confirm that no drops are flowing within the drip chamber. *See Figure 7-6 Open roller clamp confirm no drops.*
 - If drops are flowing in drip chamber, remove the pump from service .

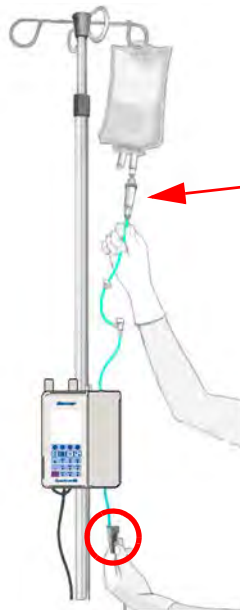


Figure 7-6. Open roller clamp confirm no drops

15. 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, make sure that the IV lines are traced from the IV container to the pump and from the pump to the patient.

NOTE: Follow the facility's procedure for labeling IV tubing.

16. Attach the IV set to the patient access site.

7. Preparing the Pump and IV sets

17. Prime all additional IV sets or add-ons prior to attaching to the existing infusion.

NOTE: The pump is unable to detect any air that may be present in the additional IV lines when another IV set or add-on is added to the existing infusion below the pump.

NOTE: The pump's downstream occlusion pressure base IV line may be affected when other infusions are added to an existing running infusion using separate IV sets below the pump.

NOTE: Make sure that drugs using the same IV set are compatible with one another.

7.4 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. Press  to stop the infusion when the pump is running.
2. Close the roller clamp to prevent free flow.
3. Close the slide clamp.
4. Push the slide clamp into the keyhole until the door opens. *See Figure 7-1 Insert Slide Clamp.*

NOTE: 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.

5. Gently hold the slide clamp in the keyhole.

NOTE: Pull the tubing out and up from the bottom of the pump towards the top.

Do not unload the IV tubing from the top of the pump. This prevents the slide clamp from inadvertently opening.

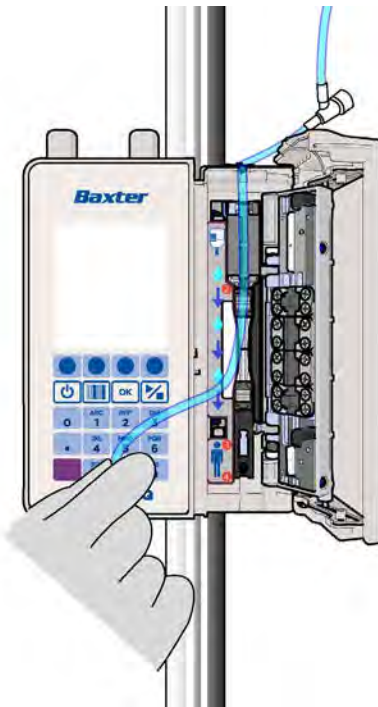


Figure 7-7. Unload Tubing from bottom to top

7.5 Secondary Infusion Setup

Follow the setup steps below to setup the a primary and a secondary infusion bags and IV sets. To program a secondary infusion See *Secondary Infusions*, page 8- 94.

7. Preparing the Pump and IV sets

NOTE: The **Spectrum IQ** Infusion System does not infuse a primary and secondary infusion at the same time.

WARNING



Air Bubbles

Make sure that air has been removed from all backcheck valves.

Failure to properly prime and remove all air bubbles from backcheck valves in primary infusion administration set may cause the valve to malfunction, resulting in secondary fluid flow into the primary container, resulting in serious injury or death.

Follow proper procedures for priming the administration set and removing air.

CAUTION



Upstream Backcheck Valve Use

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

To prepare the pump for a secondary infusion:

1. Use a primary set with an upper Y injection site and backcheck valve.
2. Prepare primary and secondary bags and IV sets.
3. Make sure the roller clamp on the secondary IV set is closed.
4. Connect the secondary set to the primary set's upper Y injection site.
5. Lower the primary bag by fully extending the hanger approximately 31.75 cm (12.5 in) below the secondary bag. *See Figure 7-8 Secondary Infusion setup - Fully extended Hanger (not to scale).*

NOTE: 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.

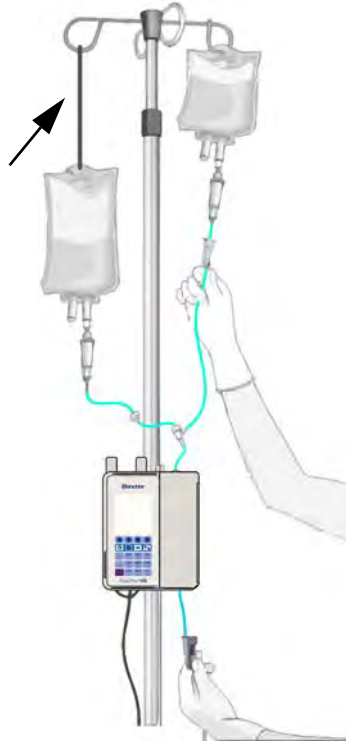


Figure 7-8. Secondary Infusion setup - Fully extended Hanger (not to scale)

6. Confirm proper vent position, if applicable.
7. To program the secondary infusion on the pump, *See Secondary Infusions, page 8- 94.*

8

Programming the pump

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| Infusion Programming Options | 8-4 |
| Infusion Delivery Modes | 8-5 |
| Dose Error Reduction System (DERS) Programming | 8-6 |
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8. Programming the pump

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| Activating a Drug Library on a Pump with a Wireless Battery Module. | 8-163 |

8.1 Programming the Pump

NOTE: All screen shots are examples only.

NOTE: Always follow the physician/ pharmacist's orders.

NOTE: Confirm all program entry with the physician/ pharmacist's orders.

NOTE: Drugs are configured specifically for each care area.

NOTE: User is to be within 1m (39.37 in) of the pump while operating the device to be in view of the screen.

8.2 Pump Safety Features

Electronic Medical Record (EMR) System Integration Capability

This system allows integration with an EMR system, which enables auto-programming of infusion parameters and auto-documentation of infusion therapy information.

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.

Single Step Rate or Dose Change Limits

NOTE: Set at 500% for Anesthesia and OR Care Areas.

Each facility's drug library can be programmed with limits for the percentage of a dose or rate change made in one programming step for each specific drug.

If an attempt is made to program a dose or rate (mL/hr) change that exceeds the facility's pre-configured limit in a single step, the single step dose or rate change alert displays, indicating the percentage of a dose or rate change made in one programming step.

Confirmation by the user is needed to proceed.

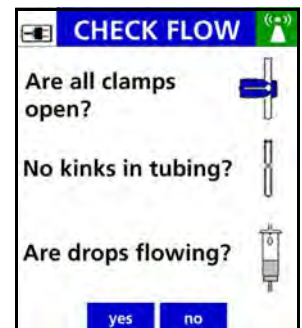


Primary Check Flow Error Prevention

NOTE: Does not apply to Anesthesia and OR Care Areas.

This screen displays at the start of the infusion. The clinician must make sure that:

- All clamps are open.
- There are no kinks in the tubing that might prevent flow.
- Drops are flowing in the drip chamber.

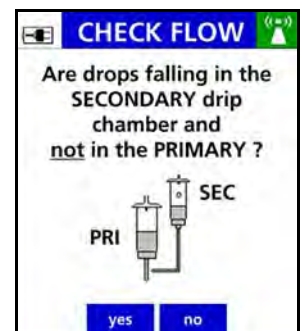


Secondary Check Flow Error Prevention

NOTE: Does not apply to Anesthesia and OR Care Areas

This screen displays at the start of the secondary infusion. The clinician must make sure that:

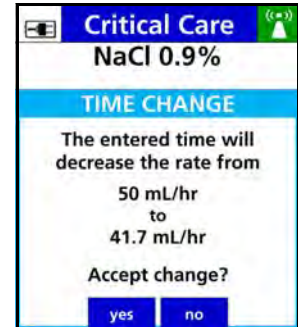
- Drops are falling within the secondary drip chamber (SEC) and not in the primary drip chamber (PRI).



8. Programming the pump

Time Change Alert

If an attempt is made to program a time change 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.



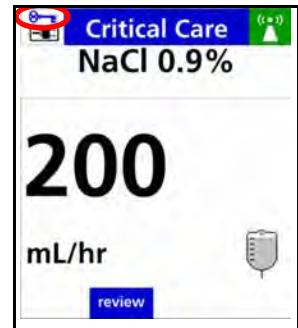
Keypad Lock

Locking the keypad prevents unauthorized activation of specific key entries.

A key icon is displayed in the title bar of the infusion screen when the keypad lock is engaged.

The Keypad lock is configured in the drug library.

See Keypad Lock, page 8- 161.



mL/hr Change confirmation

If a drug is configured in the drug library with a continuous dose mode (non mL/hr mode) and the user attempts to change or enter a rate (mL/hr) value, a mL/hr Change confirmation screen displays, requiring the user to confirm this entry.

An additional safety feature to prevent mL/hr entry for drugs configured with a continuous dose mode (non mL/hr mode) is available. *See Rate (mL/hr) Entry Disabled, page 8- 106.*



8.3 Infusion Programming Options

The **Spectrum IQ** Infusion System provides the following options for programming infusions:

- **Auto-programming (AP)**

A **Spectrum IQ** Infusion System that is integrated with the hospital's EMR system allows infusion parameters to be auto-programmed from the patient's order in the EMR.

The drug, concentration, dose and volume are automatically populated into the **Spectrum IQ** Infusion System within the Dose Error Reduction System (DERS).

Auto-programming in combination with DERS is intended to reduce pump programming errors.

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

The pump always defaults to DERS.

DERS uses predetermined dosing information stored in the facility's configured drug library using **Dose IQ** Safety Software.

This **Dose IQ** Safety Software controls limits for the dose, rate, volume, time and other infusion parameters for specific drugs.

For information on programming the pump using DERS, *See Dose Error Reduction System (DERS) Programming, page 8- 6.*

- **Basic Mode**

Drug library limits (DERS) do not exist in Basic Mode.

Basic Mode requires the user to manually specify a dose mode, rate, volume, time, and other parameters for the infusion.

Safety features available in Basic Mode are: Patient Weight Limits, Primary Check Flow, Secondary Check Flow, and Single Step Dose or Rate Change Limits.

For information on programming the pump using Basic mode, *See Basic Mode Programming, page 8- 138.*

8.4 Infusion Delivery Modes

The following infusion delivery modes are available with the **Spectrum IQ** 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 VTBI 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.

- **Volume/ Time**

An IV drug therapy prescribed as a total volume completely administered over a set duration of time.

8.5 Dose Error Reduction System (DERS) Programming

The **Spectrum IQ** Infusion System defaults directly to DERS when the Pump is powered on.

The **Dose IQ** Safety Software allows the facility to configure a drug library with predefined drugs, concentrations, dose modes, dosing limits, and other infusion parameters for each Care Area. Using this method may reduce the risk of pump programming errors.

WARNING



Confirm Safe Operation

Do not operate the Spectrum IQ Infusion System until following conditions are met:

- Infusion administration sets or fluid container vents are functioning.
- Infusion administration set clamps are in the proper positions.
- Infusion administration set is not kinked or collapsed outside the pump.
- There is no flow observed in the drip chamber while the pump is stopped.
- Drip rate approximates the pump flow rate when the pump is running.
- Patient, route, and drug are correct before starting infusion.
- Pump settings, including drug/concentration, dose mode, dose rate, and time are correct.
- Alarm settings that are appropriate for the care area.
- A hazard can exist if different alarm presets are used for the same or similar equipment in any single care area.
- Vital signs and infusion administration set access sites are monitored per the facility's standard practice of care.
- Infusion is monitored to make sure that it is delivered as intended.
- Battery status is checked periodically and the battery is replaced if necessary.

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

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

Failure to meet the conditions above could result in an inaccurate or improper infusion delivery, resulting in serious injury or death.

WARNING



Confirm Drug Library

Do not operate the Spectrum IQ Infusion System unless the Dose IQ Safety Software Administrators have:

- Tested and validated their drug library per their facility's procedures before implementation, to ensure configuration and workflow reflect clinical practice.
- Confirmed the correct drug library is selected when transferring the drug library to pumps.

Do not operate the Spectrum IQ Infusion System unless the users have:

- Confirmed the correct drug library is active on the pump.

Failure to meet the conditions above could result in an inaccurate or improper infusion delivery, resulting in serious injury or death.



Manually Stopping the Pump

When you cannot STOP the pump by pressing :

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

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.






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.

8.6 Starting an Infusion

NOTE: Make sure that all the entries match the physician/ pharmacist orders.

Table 8-1. To start an infusion

| Steps | Screen All screens shots are examples only |
|--|--|
| <p>1. Press  to power on the pump.</p> |  |
| <p>The New Patient or Care Area screen (go to step 4) displays.</p> <p>NOTE: The pump retains previously programmed infusion values up to 24 hours after power off.</p> <p>New Patient screen:</p> <p>2. Press the yes soft key to clear the previously programmed infusion values and go to the Care Area screen.</p> <p>NOTE: When a new drug is required for the same patient, press the yes soft key. The total given will be reset to zero.</p> <p>Press the no soft key to retain the previously programmed infusion values for the same patient.</p> |  |

8. Programming the pump

Table 8-1. To start an infusion



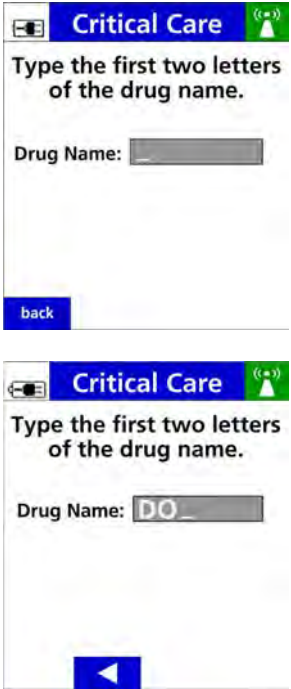






| Steps | Screen All screens shots are examples only |
|--|--|
| <p>3. Press the arrow soft keys to select the Care Area.</p> <p>Press .</p> |  |
| <p>The Drug Search screen displays.</p> <p>4. Press the alphanumeric hard key(s) to enter the first two letters of the drug name.</p> <p>Press the key multiple times to enter the drug letter.</p> <p>Example:</p> <ul style="list-style-type: none"> - Press the 2 key one time for the letter D. - Press the 5 key three times to enter the letter O. <p>Press the back arrow soft key to clear entry errors.</p> <p>5. Select prescribed drug</p> |  |

Table 8-1. To start an infusion

| Steps | Screen All screens shots are examples only |
|--|--|
| <p>The Drug Selection screen shows a list of drugs based on the letters entered in the previous step.</p> <p>NOTE: A selection has to be made in this screen to continue programming.</p> <p>6. Press the arrow soft keys to move the cursor to the correct drug name.</p> <p>7. Press .</p> <p>NOTE: If a prescribed drug is not listed in the drug selection screen, request that the drug be added to the Spectrum IQ Infusion System drug library per the facility's procedures.</p> |   |
| <p>Depending on the setup of the drug in the Dose IQ Safety Software, additional screens can be displayed before the Drug Setup screen.</p> <p>For more information: <i>See Table 8-2 Optional screens before drug setup screen.</i></p> | |
| <p>The Drug Setup screen displays.</p> <p>This screen displays the Care Area and the Drug Selection.</p> <p>NOTE: All entries will be at 0 or will be at a default value and require input or confirmation to continue.</p> <p>8. Press the alphanumeric hard keys to enter the parameters of the infusion (when not defaulted values).</p> <p>9. Press  to confirm entry.</p> <p>NOTE: The screen will vary based on infusion type.</p> |  |
| <p>10. Press RUN/ STOP .</p> | |

8. Programming the pump

Table 8-1. To start an infusion


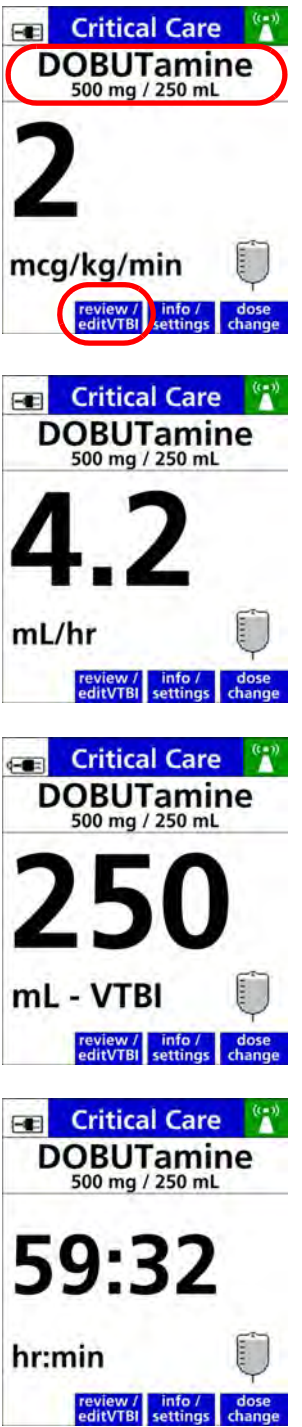
| Steps | Screen All screens shots are examples only |
|---|--|
| <p>The infusion begins.</p> <p>The Check Flow screen displays.</p> <p><i>See Table 8-62 Primary Check Flow Trouble Shooting. and See Table 8-63 Secondary Check Flow Trouble Shooting.</i></p> <p>11. Check the flow by:</p> <ul style="list-style-type: none"> ■ Opening the clamps. ■ Visually check that there are no kinks or collapses in the tubing outside of the pump. ■ Visually check drops are flowing in the drip chamber. <p>NOTE: At very low rates, it takes several minutes to see drops.</p> <ul style="list-style-type: none"> ■ Making sure vents are open (when applicable). <p>12. Press yes when the flow is confirmed.</p> <p>NOTE: Press no when there is no visual confirmation of drops flowing.</p> <p>13. <i>See Table 8-62 Primary Check Flow Trouble Shooting.or See Table 8-63 Secondary Check Flow Trouble Shooting.</i></p> <p>The Bag Infusing screen displays: Primary or Secondary.</p> |  |

Table 8-1. To start an infusion

| Steps | Screen All screens shots are examples only |
|---|--|
| <p>The RUN screen displays.</p> <p>NOTE: RUN screen varies on infusion type.</p> <p>The title bar area of the screen always shows Care Area and drug being delivered.</p> <p>The information section then alternates with information about the infusion.</p> <p>NOTE: See <i>Display Settings, page 5- 12.</i> for the options of displayed information on these alternating screens.</p> <p>NOTE: Press the review/edit VTBI soft key to view the infusion status.</p> |  <p>The screenshots show the following information:</p> <ul style="list-style-type: none"> Screen 1: DOBUTamine 500 mg / 250 mL, 2 mcg/kg/min. The 'review/edit VTBI' soft key is circled in red. Screen 2: DOBUTamine 500 mg / 250 mL, 4.2 mL/hr. The 'review/edit VTBI' soft key is circled in red. Screen 3: DOBUTamine 500 mg / 250 mL, 250 mL - VTBI. The 'review/edit VTBI' soft key is circled in red. Screen 4: DOBUTamine 500 mg / 250 mL, 59:32 hr:min. The 'review/edit VTBI' soft key is circled in red. |

8. Programming the pump

NOTE: Based on the drug setup in the drug library, the screens below can display before the Drug Set up screen.

Table 8-2. Optional screens before drug setup screen


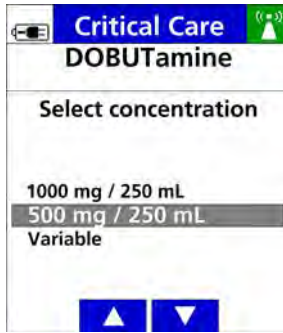
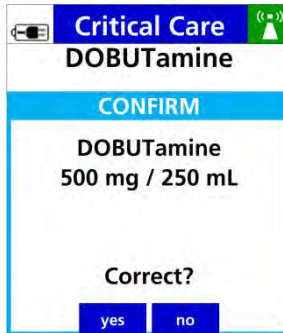



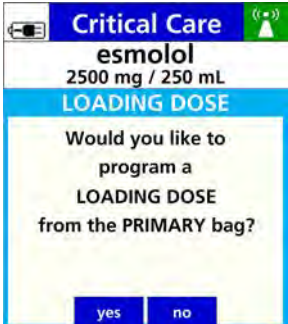
| Steps | Screens All screen shots are examples only |
|---|---|
| <p>A drug may be configured with modifiers. If so, the Modifier Selection screen displays.</p> <p><i>See Modifiers, page 8- 15.</i></p> |  |
| <p>A drug that is configured with multiple concentration options will show a Concentration Selection screen.</p> <p><i>See Table 8-5 To program a primary continuous infusion with fixed drug amount and total volume.</i></p> |  |
| <p>The Confirm Concentration screen displays the concentration selected.</p> <ol style="list-style-type: none"> 1. Press the yes soft key to continue. 2. Press the no soft key to go back to the previous screen. |  |

Table 8-2. Optional screens before drug setup screen

| Steps | Screens All screen shots are examples only |
|---|---|
| <p>If a drug is configured with an advisory in the drug library, a Clinical Advisory screen displays.</p> <ol style="list-style-type: none"> 1. Press the continue soft key to acknowledge. <p><i>See Table 8-35 Clinical Advisory.</i></p> |  |
| <p>If a drug is configured to have multiple delivery bag options a Select delivery bag screen displays.</p> <ol style="list-style-type: none"> 1. Press the arrow soft keys to select the delivery bag. 2. Press  to confirm. <p><i>See Delivery Bag, page 8- 20.</i> <i>See Secondary Infusions, page 8- 94.</i> <i>See Multi-step Programming, page 8- 48.</i></p> |  |
| <p>If a drug is configured with a loading dose option the Loading Dose screen displays.</p> <ol style="list-style-type: none"> 1. Press the yes soft key to program a loading dose for this drug. Press the no soft key to advance to Drug Set up screen. <p><i>See Table 8-9 Programming a Loading Dose.</i></p> |  |

8.7 Modifiers

A modifier is 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.

8. Programming the pump

When a modifier is in use, an asterisk (*) is displayed next to the drug name on the pump Infusion Running screen.

The programming workflow on the pump is as follows:



Table 8-3. To Program an Infusion with Modifiers






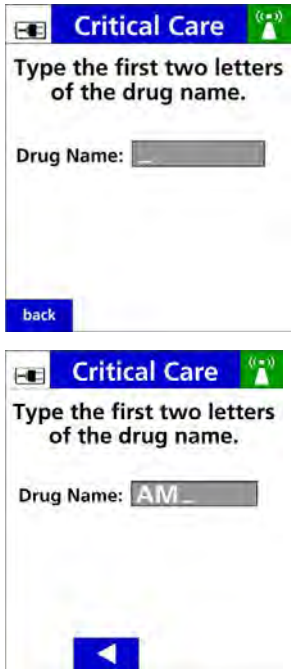
| Steps | Screens All screen shots are examples only |
|---|---|
| 1. Press  to power on the pump. |  |
| <p>The New Patient or Care Area screen (go to step 4) displays.</p> <p>NOTE: The pump retains previously programmed infusion values up to 24 hours after power off.</p> <p>New Patient screen:</p> 2. Press the yes soft key to clear the previously programmed infusion values and go to the Care Area screen. <p>NOTE: When a new drug that is required for the same patient, press the yes soft key. The total given will be reset to zero.</p> <p>Press the no soft key to retain the previously programmed infusion values for the same patient.</p> |  |

Table 8-3. To Program an Infusion with Modifiers

| Steps | Screens All screen shots are examples only |
|---|--|
| <p>3. Press the arrow soft keys to select the Care Area.</p> <p>4. Press  .</p> |  |
| <p>The Drug Search screen displays.</p> <p>5. Press the alphanumeric hard key(s) to enter the first two letters of the drug name. Press the key multiple times to enter the drug letter.</p> <p>Example: Press the 1 key one time for the letter A. Press the 5 key one times to enter the letter M.</p> <p>Press the back arrow soft key to clear entry errors.</p> |  |

8. Programming the pump

Table 8-3. To Program an Infusion with Modifiers









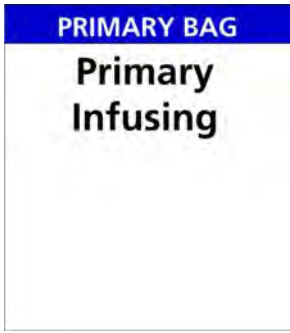

| Steps | Screens All screen shots are examples only |
|--|--|
| <p>The Drug Selection screen shows a list of drugs based on the letters entered in the previous step.</p> <p>NOTE: A selection has to be made in this screen to continue programming.</p> <p>6. Press the arrow soft keys to move the cursor to the correct drug name.</p> <p>7. Press .</p> <p>NOTE: If a prescribed drug is not listed in the drug selection screen, request that the drug be added to the Spectrum IQ Infusion System drug library per the facility's procedures.</p> |   |
| <p>The Select Modifier screen displays the list of modifiers available for the drug selected.</p> <p>8. Press arrow soft keys to move the cursor to the correct modifier.</p> <ul style="list-style-type: none"> Press back to go to the Drug Selection screen. <p>9. Press  to select.</p> <p>NOTE: If a drug has multiple concentrations for the modifier selected, the Concentration selection screen will display.</p> |  |

Table 8-3. To Program an Infusion with Modifiers

| Steps | Screens All screen shots are examples only |
|---|---|
| <p>The Drug Setup screen displays the concentration and/ or modifier name at the top.</p> <p>Complete the entry of all parameters.</p> <p>10. Press  to begin the infusion.</p> |  <p>The screenshots show the 'Critical Care' screen for 'amiodarone' (360 mg / 200 mL, Slow Load, Primary Bag). The top screenshot shows default values: Dose mg/min: 0, VTBI mL: 0, Time hr:min: 00:00, Rate mL/hr: 0. The bottom screenshot shows programmed values: Dose mg/min: 1, VTBI mL: 200, Time hr:min: 06:00, Rate mL/hr: 33.3. A red circle highlights the drug name and concentration in the top screenshot.</p> |

8. Programming the pump

Table 8-3. To Program an Infusion with Modifiers

| Steps | Screens All screen shots are examples only |
|--|--|
| <p>The infusion begins.</p> <p>The Check Flow screen displays.</p> <p>11. Check the flow by:</p> <ul style="list-style-type: none"> ■ Opening the clamps. ■ Visually check that there are no kinks or collapses in the tubing outside of the pump. ■ Visually check drops are flowing in the drip chamber. <p>NOTE: At very low rates, it takes several minutes to see drops.</p> <ul style="list-style-type: none"> ■ Making sure vents are open (when applicable). <p>12. Press yes when the flow is confirmed.</p> <p>NOTE: Press no when there is no visual confirmation of drops flowing.</p> <p><i>See Table 8-62 Primary Check Flow Trouble Shooting. and</i> <i>See Table 8-63 Secondary Check Flow Trouble Shooting.</i></p> <p>The Bag Infusing screen displays: Primary or Secondary.</p> |   |
| <p>The RUN screen displays. An asterisk (*) after the drug name indicates a modifier has been used.</p> <p>NOTE: Press the review/edit VTBI soft key to view the Drug Setup screen.</p> |  |

8.8 Delivery Bag

The delivery bag selection determines how the drug will be programmed and delivered on the **Spectrum IQ** Infusion System.

The delivery bag options are configured in the drug library with one of the following options:

- **Primary or Secondary**
A drug can be programmed as a primary infusion, multi-step primary infusion, or secondary infusion. User selection on the pump is required.
- **Primary Only, Secondary not allowed**
A drug can only be programmed as a primary infusion and cannot be interrupted by a secondary infusion. Delivery bag is defaulted to primary and not editable on the pump.
- **Primary Only, Secondary allowed**
A drug can only be programmed as a primary infusion and may be interrupted by a secondary infusion. Delivery bag is defaulted to primary and not editable on the pump.
- **Secondary Only**
A drug can only be programmed as a secondary infusion. Delivery bag is defaulted to secondary and is not editable on the pump.
- **Multi-step (Primary Only)**
A drug can be programmed with up to 10 sequential steps with individual infusion volume and dose or rate. Automatic transition occurs between each step. Delivery bag setting is defaulted to multi-step primary and is not editable on the pump.

8.9 Confirming Patient Weight and BSA

The optional patient weight and BSA confirmation feature allows the clinician to confirm the initial value entered by re-entering the same value.







The system will make sure the values entered are the same.

When the values do not match, the clinician is prompted to re-enter the values.

8. Programming the pump

This feature is available when enabled in the drug library for the selected Care Area.

Table 8-4. To Confirm Patient Weight or BSA

| Steps | Screens All screens are examples only |
|---|--|
| <p>1. Enter Patient Weight.</p> <p>2. Press  to confirm.</p> <p>NOTE: The Patient Weight value entered is checked against the lower and upper weight limits configured for this Care Area. See <i>Table 8-37 Patient Weight/ BSA Limit</i>.</p> |  <p>The screenshot shows the 'Critical Care' header, drug name 'DOBUTamine', concentration '500 mg / 250 mL', and 'Primary Bag'. The 'Patient Weight kg' is set to 70. Other fields include 'Dose mcg/kg/min' (0), 'VTBI mL' (0), 'Time hr:min' (00:00), and 'Rate mL/hr' (0). At the bottom, there are buttons for 'clear program', 'clear weight', and a prompt 'Press OK to confirm weight'.</p> |
| <p>When the confirmation function is enabled in the drug library, a Patient Weight entry double confirmation screen displays. The initial weight entry is not displayed.</p> <p>3. Re-enter the Patient Weight.</p> <p>4. Press  to confirm.</p> <p>When the value entered matches the initial weight entry, the Drug Setup screen returns.</p> |  <p>The screenshot shows the 'Critical Care' header, drug name 'DOBUTamine', and concentration '500 mg / 250 mL'. The 'Patient Weight kg' field is masked with four asterisks (****). Below it, a 'Confirm Patient Weight kg' field shows '70'. At the bottom, there are buttons for 'cancel', 'clear weight', and a prompt 'Press OK to confirm weight'.</p> |
| <p>When the value does not match the initial entry, a Values Differ pop-up message will appear.</p> <p>5. Press  .</p> <p>6. Re-enter the value.</p> |  <p>The screenshot shows the 'Critical Care' header, drug name 'DOBUTamine', and concentration '500 mg / 250 mL'. A yellow pop-up message box is displayed in the center with the text 'VALUES DIFFER! Enter value again'. Below the pop-up, there are buttons for 'cancel', 'clear weight', and a prompt 'Press OK to confirm weight'.</p> |

8.10 Continuous Infusions

A continuous infusion is an IV drug therapy prescribed as a continuous dose rate.

The IV therapy continues to infuse at set dose rate until the infusion is discontinued or the VTBI has been completed.

Rate changes may be programmed as needed.

A Loading Dose or Bolus may also be programmed in this infusion.

Continuous drugs may be configured and programmed with the following:

- **Concentration Type:**
 - Fixed (Drug Amount and Total Volume)
 - Variable concentration
 - Standard (Drug Amount per 1 mL)
- **Delivery method:**
 - Primary or Secondary
 - Bolus Dose
 - Loading Dose
 - Primary Multi-step
 - Cyclic TPN
- **Dose Mode type:**
 - Weight-based
 - Non-weight-based

8.10.1 Fixed (Drug Amount and Total Volume)

The drug is configured in the drug library with a defined drug amount and diluent volume.

These parameters cannot be changed during pump programming. For example, Drug X, 500 mg/250 mL.

8. Programming the pump

Table 8-5. To program a primary continuous infusion with fixed drug amount and total volume






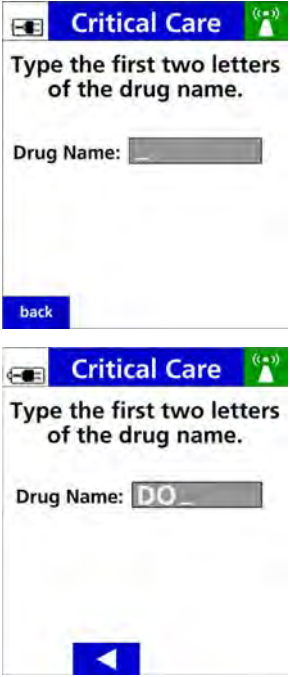
| Step | Screens All screen shots are examples only |
|---|--|
| 1. Press  to power on the pump. |  |
| 2. The New Patient or Care Area screen (go to step 4) displays. NOTE: The pump retains previously programmed infusion values up to 24 hours after power off. New Patient screen: 3. Press the yes soft key to clear the previously programmed infusion values and go to the Care Area screen. NOTE: When a new drug that is required for the same patient, press the yes soft key. The total given will be reset to zero. Press the no soft key to retain the previously programmed infusion values for the same patient. |  |

Table 8-5. To program a primary continuous infusion with fixed drug amount and total volume

| Step | Screens All screen shots are examples only |
|--|--|
| <p>4. Press the arrow soft keys to select the Care Area.</p> <p>5. Press .</p> <p>The Drug Search screen appears.</p> |  |
| <p>The Drug Search screen displays.</p> <p>6. Press the alphanumeric hard key(s) to enter the first two letters of the drug name.</p> <p>Press the key multiple times to enter the drug letter.</p> <p>Example:</p> <p>Press the 2 key one time for the letter D.</p> <p>Press the 5 key three times to enter the letter O.</p> <p>Press the back arrow soft key to clear entry errors.</p> |  |

8. Programming the pump

Table 8-5. To program a primary continuous infusion with fixed drug amount and total volume





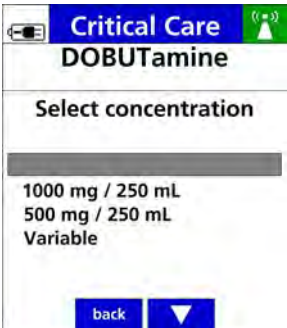
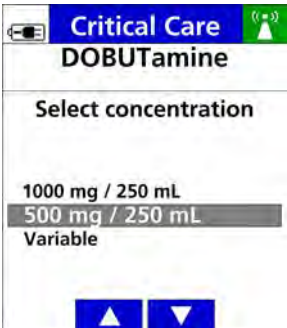
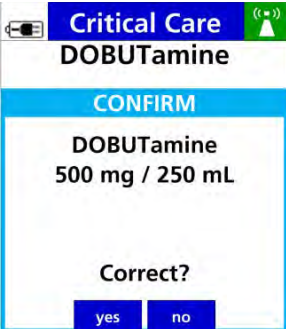



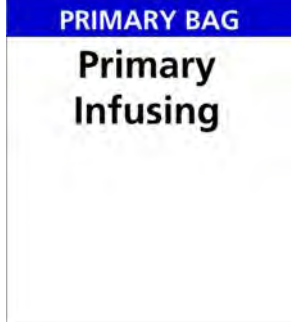
| Step | Screens All screen shots are examples only |
|--|---|
| <p>The Drug Selection screen shows a list of drugs based on the letters entered in the previous step.</p> <p>A selection has to be made in this screen to continue programming.</p> <ol style="list-style-type: none"> Press the arrow soft keys to move the cursor to the correct drug name. Press . <p>NOTE: If a prescribed drug is not listed in the drug selection screen, request that the drug be added to the Spectrum IQ Infusion System drug library per the facility's procedures.</p> |   |
| <p>If a drug that has multiple concentrations configured in the drug library for that care area, a Concentration Selection screen displays.</p> <ol style="list-style-type: none"> Press the arrow soft keys to move the cursor to the correct drug concentration. Press . <ul style="list-style-type: none"> Press the back soft key to go to the Drug Selection screen. |   |

Table 8-5. To program a primary continuous infusion with fixed drug amount and total volume

| Step | Screens All screen shots are examples only |
|--|--|
| <p>The Confirm Concentration screen displays. This screen displays the selected concentration.</p> <p>11. Press the yes soft key to continue to the Drug Setup screen.</p> <p>Press the no soft key to go back to the Concentration Selection screen.</p> |  |
| <p>The Drug Setup screen displays the concentration and/ or modifier name at the top.</p> <p>Complete the entry for all parameters.</p> <p>12. Press  to begin the infusion.</p> |  |

8. Programming the pump

Table 8-5. To program a primary continuous infusion with fixed drug amount and total volume

| Step | Screens All screen shots are examples only |
|--|--|
| <p>The infusion begins.</p> <p>The Check Flow screen displays.</p> <p>13. Check the flow by:</p> <ul style="list-style-type: none"> ■ Opening the clamps. ■ Visually check that there are no kinks or collapses in the tubing outside of the pump. ■ Visually check drops are flowing in the drip chamber. <p>NOTE: At very low rates, it takes several minutes to see drops.</p> <ul style="list-style-type: none"> ■ Making sure vents are open (when applicable). <p>14. Press yes when the flow is confirmed.</p> <p>NOTE: Press no when there is no visual confirmation of drops flowing.</p> <p><i>See Table 8-62 Primary Check Flow Trouble Shooting. or See Table 8-63 Secondary Check Flow Trouble Shooting.</i></p> <p>The Bag Infusing screen displays: Primary or Secondary.</p> |   |
| <p>The RUN screen displays. <i>See Display Settings, page 5- 12.</i></p> | |

WARNING



Low Flow Rate Accuracy/Continuity

At flow rates of 1.9 mL/hr or below, flow rate accuracy is +/- 0.1 mL/hr. When higher accuracy is required, consider an alternate infusion device.

WARNING



Time to Upstream Occlusion at Lower Flow Rates

The time to detect an upstream occlusion may be extended at flow rates below 5mL/hr. At 1 ml/hr, time to detect upstream occlusion may extend up to 7 hours.

Make sure that:

- 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).



Manually Stopping the Pump

When you cannot **STOP** the pump by pressing :

1. Close the roller clamp below the pump.
2. Insert the slide clamp into the keyhole.
3. Push the slide clamp down until the door opens.

8. Programming the pump

Table 8-6. Weight Based Entry











| Steps | Screens All screen shots are examples only |
|---|---|
| <p>1. Enter Patient Weight.</p> <p>2. Press  to confirm.</p> <p>NOTE: When configured in the drug library a Patient weight Entry confirmation screen displays and requires user to confirm weigh/ BSA. See step 3.</p> <p>If confirmation is not required this screen will display. Go to step 5.</p> <p>Patient weight will be checked against the limits in the drug library. <i>See Table 8-37 Patient Weight/ BSA Limit.</i></p> |  |
| <p>Patient Weight Entry Confirmation.</p> <p>3. Re-enter the Patient Weight.</p> <p>4. Press .</p> <p>NOTE: The initial weight entry is not displayed. <i>See Table 8-7 Programming a Primary Continuous Infusion with Variable Concentration.</i></p> |  |
| <p>5. Enter the dose (for drugs configured with a dose mode) or flow rate value (for rate-based drugs).</p> <p>6. The rate (mL/hr) calculates when the dose is entered.</p> <p>7. Press  to confirm.</p> <p>NOTE: The dose entered is checked against the lower and upper dose limits configured for this drug.</p> <p>8. A limit alert will appear when the value entered exceeds configured limits. <i>See Table 8-39 Dose/Rate Limits.</i></p> |  |

Table 8-6. Weight Based Entry

| Steps | Screens All screen shots are examples only |
|---|--|
| <p>9. Enter the Volume to be Infused (VTBI).</p> <p>NOTE: Do not enter a VTBI amount that exceeds the volume in the container.</p> <p>10. Press  to confirm.</p> |  |
| <p>NOTE: The Time parameter is automatically calculated when the VTBI is confirmed.</p> <p>NOTE: Review the parameters of the infusion to make sure they are correct.</p> <p>11. Press  to start the infusion.</p> |  |

8.10.2 Variable Concentration

Variable concentration setups are used when drug concentrations are not standardized.

Variable concentrations allow clinicians to specify the Drug Amount and Diluent Volume during pump programming.

The calculated concentration is checked against concentration limits configured in the drug library.

8. Programming the pump

Table 8-7. Programming a Primary Continuous Infusion with Variable Concentration






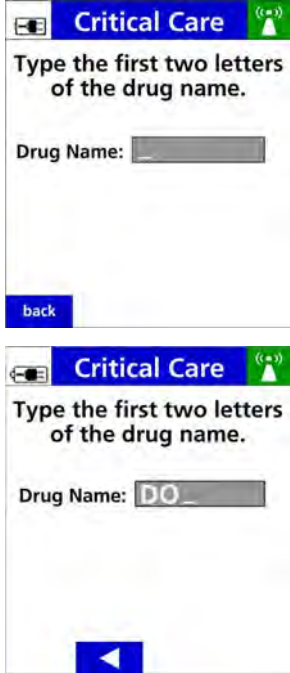


| Steps | Screens All screen shots are examples only |
|--|---|
| <p>1. Press  to power on the pump.</p> |  |
| <p>2. The New Patient or Care Area screen (go to step 4) displays.</p> <p>NOTE: The pump retains previously programmed infusion values up to 24 hours after power off.</p> <p>New Patient screen:</p> <p>3. Press the yes soft key to clear the previously programmed infusion values and go to the Care Area screen.</p> <p>NOTE: When a new drug that is required for the same patient, press the yes soft key. The total given will be reset to zero.</p> <p>Press the no soft key to retain the previously programmed infusion values for the same patient.</p> |  |
| <p>4. Press the arrow soft keys to select the Care Area.</p> <p>5. Press .</p> <p>The Drug Search screen appears.</p> |  |

Table 8-7. Programming a Primary Continuous Infusion with Variable Concentration

| Steps | Screens All screen shots are examples only |
|--|---|
| <p>The Drug Search screen displays.</p> <p>6. Press the alphanumeric hard key(s) to enter the first two letters of the drug name.</p> <p>Press the key multiple times to enter the drug letter.</p> <p>Example:</p> <p>Press the 2 key one time for the letter D.</p> <p>Press the 5 key three times to enter the letter O.</p> <p>Press the back arrow soft key to clear entry errors.</p> |  |
| <p>The Drug Selection screen shows a list of drugs based on the letters entered in the previous step.</p> <p>NOTE: A selection has to be made in this screen to continue programming.</p> <p>7. Press the arrow soft keys to move the cursor to the correct drug name.</p> <p>8. Press .</p> <p>NOTE: If a prescribed drug is not listed in the drug selection screen, request that the drug be added to the Spectrum IQ Infusion System drug library per the facility's procedures.</p> |  |

8. Programming the pump

Table 8-7. Programming a Primary Continuous Infusion with Variable Concentration


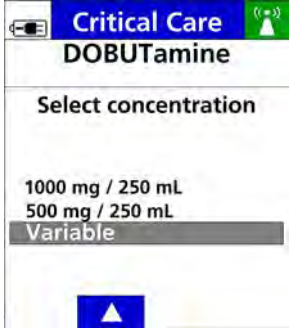






| Steps | Screens All screen shots are examples only |
|--|---|
| <p>The Concentration Selection screen displays. Select Variable when a concentration is not listed as an option.</p> <p>9. Press arrow keys to move the cursor to Variable.</p> <p>10. Press .</p> |  |
| <p>The Total Drug Amount entry screen displays.</p> <p>11. Enter the Total Drug Amount.</p> <p>12. Press .</p> |  |
| <p>13. Enter the Bag Volume.</p> <p>14. Press  to confirm.</p> |  |

Table 8-7. Programming a Primary Continuous Infusion with Variable Concentration

| Steps | Screens All screen shots are examples only |
|---|--|
| <p>The Confirm Concentration screen displays the concentration entered.</p> <p>15. Press the yes soft key to confirm the concentration entered.</p> <p>16. Press the no soft key to return to the concentration Selection screen.</p> <p>NOTE: The concentration entered is checked against the lower and upper concentration limits configured for this drug.</p> <ul style="list-style-type: none"> ■ If the value entered exceeds the configured limits a limit alert will display. <i>See Table 8-34 Summary of Safety Alerts.</i> |  |
| <p>The Drug Setup screen displays the required parameters to be entered.</p> <p>Follow the steps from <i>See Table 8-6 Weight Based Entry.</i></p> <p>Follow <i>See Table 8-1 To start an infusion. Steps 11-12.</i></p> |  |

8.10.3 Standard (Drug Amount per 1 mL)

Standard concentration setups are used when drug concentrations are fixed, but there is not a predefined drug amount or diluent volume available.

The standard concentration is configured as drug amount/mL.

To program a primary continuous infusion with a standard drug amount per 1mL.

8. Programming the pump

Table 8-8. Programming a Primary Continuous Infusion with Standard Drug Amount per 1mL






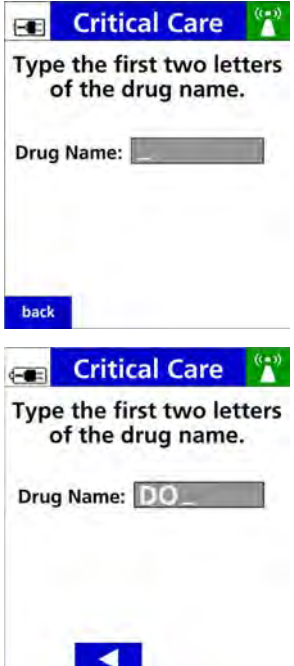
| Steps | Screens All screen shots are examples only |
|--|--|
| <p>1. Press  to power on the pump.</p> |  |
| <p>2. The New Patient or Care Area screen (go to step 4) displays.</p> <p>NOTE: The pump retains previously programmed infusion values up to 24 hours after power off.</p> <p>New Patient screen:</p> <p>3. Press the yes soft key to clear the previously programmed infusion values and go to the Care Area screen.</p> <p>NOTE: When a new drug that is required for the same patient, press the yes soft key. The total given will be reset to zero.</p> <p>Press the no soft key to retain the previously programmed infusion values for the same patient.</p> |  |

Table 8-8. Programming a Primary Continuous Infusion with Standard Drug Amount per 1mL

| Steps | Screens All screen shots are examples only |
|--|--|
| <p>4. Press the arrow soft keys to select the Care Area.</p> <p>5. Press  .</p> <p>The Drug Search screen appears.</p> |  |
| <p>The Drug Search screen displays.</p> <p>6. Press the alphanumeric hard key(s) to enter the first two letters of the drug name.</p> <p>Press the key multiple times to enter the drug letter.</p> <p>Example:</p> <p>Press the 2 key one time for the letter D.</p> <p>Press the 5 key three times to enter the letter O.</p> <p>Press the back arrow soft key to clear entry errors.</p> |  |

8. Programming the pump

Table 8-8. Programming a Primary Continuous Infusion with Standard Drug Amount per 1mL





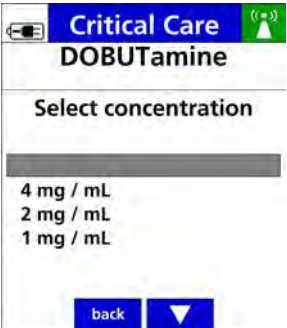
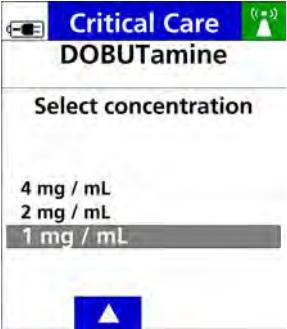
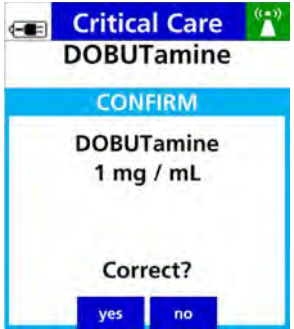


| Steps | Screens All screen shots are examples only |
|---|---|
| <p>The Drug Selection screen shows a list of drugs based on the letters entered in the previous step.</p> <p>NOTE: A selection has to be made in this screen to continue programming.</p> <p>7. Press the arrow soft keys to move the cursor to the correct drug name.</p> <p>8. Press .</p> <p>NOTE: If a prescribed drug is not listed in the drug selection screen, request that the drug be added to the Spectrum IQ Infusion System drug library per the facility's procedures.</p> |   |
| <p>The Concentration Selection screen displays the concentration(s) configured for the drug selected.</p> <p>9. Press arrow soft key to select drug concentration.</p> <p>10. Press  to select.</p> <p>NOTE: The concentration displayed in the patient order and medication bag label should be expressed as drug amount/mL as displayed on the pump's Concentration Selection screen.</p> <ul style="list-style-type: none"> The calculated concentration of the drug amount and volume must equal the standard concentration displayed on the pump. |   |

Table 8-8. Programming a Primary Continuous Infusion with Standard Drug Amount per 1mL

| Steps | Screens All screen shots are examples only |
|---|--|
| <p>The Confirm Concentration screen displays the concentration selected.</p> <p>11. Press the yes soft key to confirm selection.</p> <ul style="list-style-type: none"> ■ Press the no soft key to return to the Concentration Selection screen |  |
| <p>The Drug Setup screen displays the required parameters. To enter required parameters: <i>See Table 8-6 Weight Based Entry.</i></p> <p>12. Press .</p> <p>The Check Flow screen then the RUN screen displays.</p> |  |

8.11 Loading Dose Programming

A loading dose is a comparatively large dose delivered at the beginning of an infusion.

Loading dose programming is available when enabled in the **Dose IQ** Safety Software and is available for primary continuous delivery mode only.

Loading dose amount limits and time limits are configured in the **Dose IQ** Safety Software.

The configured loading dose is intended to be delivered from the same primary IV drug container.

8. Programming the pump

Table 8-9. Programming a Loading Dose


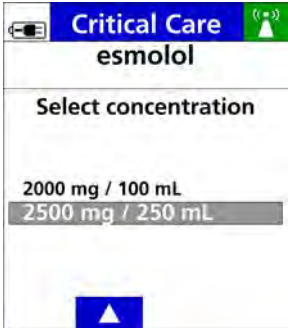
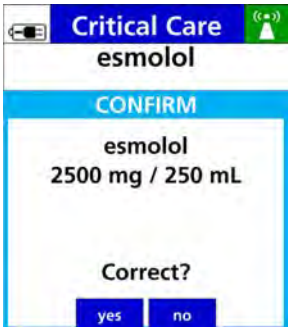
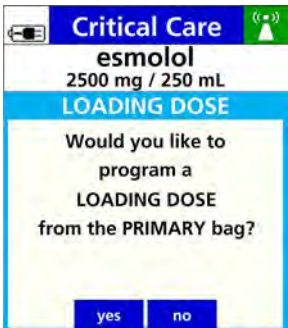






| Steps | Screens All screen shots are examples only |
|--|---|
| <p><i>See Table 8-8 Programming a Primary Continuous Infusion with Standard Drug Amount per 1mL. Steps 1-8.</i></p> | |
| <p>The Concentration Selection screen displays the concentration(s) configured for the drug selected.</p> <ol style="list-style-type: none"> Press arrow soft key to select the drug concentration. Press  to select. |  |
| <p>The Confirm Concentration screen displays the concentration selected.</p> <ol style="list-style-type: none"> Press the yes soft key to confirm. <ul style="list-style-type: none"> Press the no soft key to return to the Concentration Selection screen. |  |
| <p>The Loading Dose prompt is displayed.</p> <ol style="list-style-type: none"> Press the yes soft key to program the Loading Dose. <ul style="list-style-type: none"> Press the no soft key to advance to the Primary Setup screen. |  |

Table 8-9. Programming a Loading Dose

| Steps | Screens All screen shots are examples only |
|---|---|
| <p>The Loading Dose Setup screen displays weight-based loading dose.</p> <p>5. Enter the Patient Weight.</p> <p>6. Press  to confirm.</p> |  |
| <p>The Patient Weight Entry Confirmation screen displays.</p> <p>7. Re-enter the Patient Weight.</p> <p>8. Press .</p> <p>NOTE: The initial weight entry is not displayed. <i>See Table 8-4 To Confirm Patient Weight or BSA.</i></p> |  |
| <p>The Loading Dose Setup screen displays.</p> <p>9. Enter the loading dose Amount.</p> <p>10. Press  to confirm.</p> <p>NOTE: The amount entered is checked against the amount limits configured. <i>See Table 8-40 Loading Dose Limits.</i></p> |  |

8. Programming the pump

Table 8-9. Programming a Loading Dose









| Steps | Screens All screen shots are examples only |
|--|--|
| <p>The Time parameter is now highlighted.</p> <p>11. Enter the Time (duration) for the loading dose.</p> <p>12. Press  to confirm.</p> <p>NOTE: The Time entered is checked against the time limits configured.</p> <p>NOTE: The time unit is defaulted to minutes. A time in seconds soft key option will appear when:</p> <ul style="list-style-type: none"> - No default starting time is configured in the drug library for the drug. - Programming in seconds is configured in the drug library. <p>Minutes to Seconds- A dose that has the time in seconds:</p> <hr/> <ul style="list-style-type: none"> ■ Press the clear time soft key. ■ Press  to confirm the zero time value. The time in seconds soft key will be displayed. ■ Press the time in seconds soft key. The Time Unit Change confirmation screen displays. ■ Press the yes soft key to confirm the change to seconds. <ul style="list-style-type: none"> - Press the no soft key to reject this change. <p>The Time unit is changed to SECONDS.</p> <p>Seconds to Minutes:</p> <hr/> <p>To change the time unit to minutes:</p> <p>1. Press the time in minutes soft key to change back to minutes.</p> |    |

Table 8-9. Programming a Loading Dose

| Steps | Screens All screen shots are examples only |
|--|---|
| <p>The calculated loading dose rate (mL/hr) is displayed.</p> <p>2. Press program primary to continue.</p> <ul style="list-style-type: none"> ■ To change to the loading dose setup: Press the edit load soft key. Press the cancel load soft key to cancel the loading dose. |  <p>Critical Care (0:00)</p> <p>esmolol 2500 mg / 250 mL</p> <p>LOADING DOSE SETUP</p> <p>Patient Weight kg 70 Amount mcg/kg 500 Time minutes 1 Rate mL/hr 210</p> <p>Press 'program primary' to set up maintenance infusion</p> <p>cancel load edit load program primary</p> |
| <p>The Primary Setup screen displays required parameters.</p> <p>3. See <i>Table 8-5 To program a primary continuous infusion with fixed drug amount and total volume.</i> to complete the programming of the primary infusion.</p> <ul style="list-style-type: none"> ■ For a weight-based loading dose, the patient weight is entered in the loading dose setup screen and is not editable in the primary setup screen. ■ The VTBI value includes the total volume of the drug being delivered, which includes the loading dose. ■ To review the loading dose setup, press the review load soft key. <p>4. Press .</p> |  <p>Critical Care (0:00)</p> <p>esmolol 2500 mg / 250 mL</p> <p>Primary Bag</p> <p>Patient Weight kg 70 Dose mcg/kg/min 50 VTBI mL 250 Time hr:min 11:55 Rate mL/hr 21</p> <p>Total given 0</p> <p>clear program review load</p> |
| <p>The Check Flow screen displays.</p> <p>See <i>Table 8-1 To start an infusion.</i> Steps 11-12.</p> | |

8. Programming the pump

Table 8-9. Programming a Loading Dose

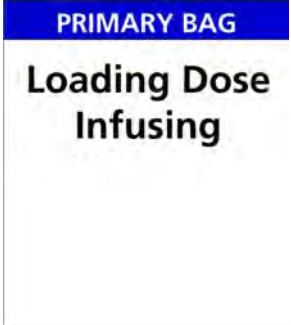


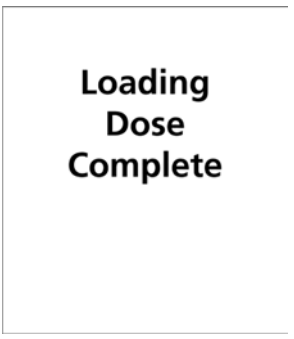

| Steps | Screens All screen shots are examples only |
|--|--|
| <p>The Loading Dose RUN screen shows:</p> <p>Loading Dose Infusing.</p> <p>Amount Given value.</p> <p>This value increments until the total loading dose amount programmed has been delivered.</p> <p>Press the cancel load soft key to cancel the loading dose.</p> <p>The primary infusion will automatically begin when the loading dose is canceled.</p> <p>Press the review load soft key to review the loading dose setup.</p> |  <p>The first screenshot shows the 'PRIMARY BAG' screen with the text 'Loading Dose Infusing'.</p>  <p>The second screenshot shows the 'Critical Care' screen for 'esmolol 2500 mg / 250 mL' with a large '18.3' and the text 'mcg/kg given Loading Dose'. Soft keys for 'cancel load', 'review load', and 'info / settings' are visible.</p>  <p>The third screenshot shows the 'Critical Care' screen for 'esmolol 2500 mg / 250 mL' with a large '500' and the text 'mcg/kg given Loading Dose'. Soft keys for 'cancel load', 'review load', and 'info / settings' are visible.</p> |

Table 8-9. Programming a Loading Dose

| Steps | Screens All screen shots are examples only |
|---|---|
| <p>At the completion of the loading dose, the Loading Dose Complete screen displays.</p> <p>The primary infusion begins automatically at the completion of the loading dose.</p> <p>The Primary Infusing screen displays.</p> |  <p>The screenshot shows a white background with the text "Loading Dose Complete" centered in a bold, black, sans-serif font.</p> |
| <p>The Primary Infusion RUN screen displays.</p> <p>For RUN screen display options See <i>Display Settings, page 5- 12</i>.</p> |  <p>The screenshot shows a white background with a blue header bar containing "Critical Care" and a green status icon. Below the header, the drug name "esmolol" is displayed in bold black text, followed by "2500 mg / 250 mL". The dose "50" is shown in a very large, bold black font. Below the dose, the units "mcg/kg/min" are displayed. At the bottom, there are four blue buttons labeled "bolus", "review / editVTBI", "info / settings", and "dose change".</p> |

8.12 Bolus Dose Programming

A bolus dose is a comparatively large dose that may be given at any time during the infusion.

Bolus dose programming is available when enabled in the **Dose IQ** Safety Software and configured with amount limits and time limits.

Bolus dose programming is available for primary or secondary Continuous delivery mode.

To program a bolus dose in Basic mode See *Table 8-60 To Program a Bolus Dose in Basic Mode*. For bolus dose programming with volume/time infusions See *Table 8-30 To Program a Bolus Dose (volume/ time)*.

The bolus dose is intended to be delivered from the same IV drug container.

8. Programming the pump

Table 8-10. Bolus Dose Programming











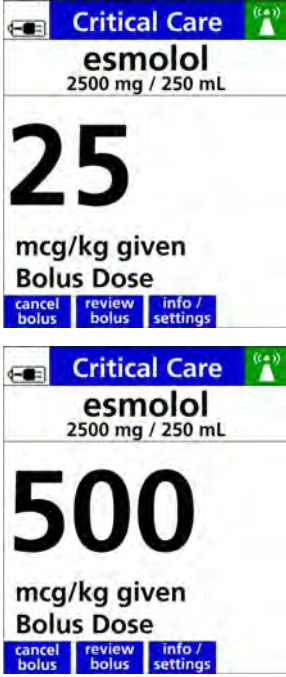

| Steps | Screens All screen shots are examples only |
|--|---|
| <p>1. Press  and the Pump Stopped screen will display.</p> <p>or</p> <p>during an infusion on the RUN screen,</p> <p>2. Press the bolus soft key.</p> |  <p>The screenshot shows the 'Pump Stopped' screen for 'esmolol 2500 mg / 250 mL'. At the bottom, there are four soft keys: 'bolus', 'review', 'info / settings', and 'clear program'. The 'bolus' key is circled in red.</p>  <p>The screenshot shows the 'Bolus Setup' screen for 'esmolol 2500 mg / 250 mL'. The dose is set to '50 mcg/kg/min'. At the bottom, there are four soft keys: 'bolus', 'review / edit VTBI', 'info / settings', and 'dose change'. The 'bolus' key is circled in red.</p> |
| <p>The Bolus Setup screen displays.</p> <p>3. Enter the bolus dose Amount to be given.</p> <p>4. Press  to confirm.</p> <p>NOTE: The amount entered is checked against the amount limits configured. <i>See Table 8-46 Bolus Limits.</i></p> |  <p>The screenshot shows the 'Bolus Setup' screen for 'esmolol 2500 mg / 250 mL'. The 'Amount mcg/kg' is set to '500' and 'Time minutes' is '0'. At the bottom, there are four soft keys: 'cancel bolus', 'Press OK to confirm amount', and 'clear amount'. The 'cancel bolus' and 'clear amount' keys are circled in red.</p> |

Table 8-10. Bolus Dose Programming

| Steps | Screens All screen shots are examples only |
|--|---|
| <p>The Time parameter is highlighted.</p> <p>5. Enter the time duration for the bolus dose.</p> <p>6. Press  to confirm.</p> <p>NOTE: The time entered is checked against the time limits configured.</p> <p>NOTE: To enter time duration in seconds.</p> |  |
| <p>The calculated bolus dose rate (mL/hr) is displayed.</p> <p>7. Press  to begin delivery of the bolus dose.</p> <ul style="list-style-type: none"> ■ Press the edit bolus soft key to change to the bolus dose setup. ■ Press the cancel bolus soft key to cancel the bolus dose. |  |
| <p>The Bolus Infusing screen displays that the bolus dose has started. The Bolus Dose RUN screen displays.</p> <p>NOTE: If a bolus setup was programmed from the Pump Stopped screen, a Check Flow screen will appear prior to the Bolus Infusing screen.</p> |  |

8. Programming the pump

Table 8-10. Bolus Dose Programming

| Steps | Screens All screen shots are examples only |
|---|---|
| <p>The Bolus Dose RUN screen shows the amount given value. This value increments until the total bolus dose amount programmed is delivered.</p> <ul style="list-style-type: none"> ■ Press the cancel bolus soft key to cancel the bolus dose. <ul style="list-style-type: none"> NOTE: Primary infusion will automatically resume. ■ Press the review bolus soft key to view the bolus dose setup. |  |
| <p>At completion of the bolus dose, the Bolus Complete screen is followed by the Primary Infusing RUN screen.</p> <p>NOTE: The primary infusion automatically resumes after the bolus dose is completed.</p> |  |

8.13 Multi-step Programming

Multi-step Programming allows the drug to be programmed as a primary continuous infusion with up to 10 sequential steps, each of which can have an individual infusion volume, dose or rate.

Each step must be within the dose rate limits defined in the drug library.

Multi-step programming is available for drugs configured in the **Dose IQ** Safety Software with the following delivery bag options:

- Primary Only, Multi-step
- Primary or Secondary

Multi-step is also available with Basic mode programming.

WARNING



Do Not Exceed Total Volume

Do not exceed total volume contained in the IV bag when programming a multi- step (single) infusion.

Exceeding the total volume can result in an air embolism, or interruption or delay in therapy, resulting in serious injury or death.

Make sure that the IV bag is properly filled to the specified volume only.

Make sure that the pump is programmed with the specified volume

8. Programming the pump

Table 8-11. To Program a Multi-step infusion






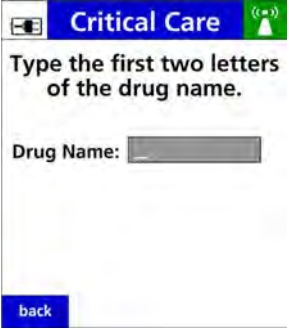
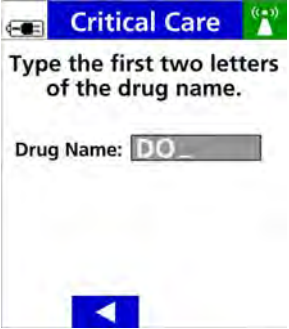


| Steps | Screens All screen shots are examples only |
|---|---|
| <p>1. Press  to power on the pump.</p> |  |
| <p>The New Patient or Care Area screen (go to step 4) displays.</p> <p>NOTE: The pump retains previously programmed infusion values up to 24 hours after power off.</p> <p>New Patient screen:</p> <p>2. Press the yes soft key to clear the previously programmed infusion values and go to the Care Area screen.</p> <p>NOTE: When a new drug that is required for the same patient, press the yes soft key. The total given will be reset to zero.</p> <p>Press the no soft key to retain the previously programmed infusion values for the same patient.</p> |  |
| <p>3. Press the arrow soft keys to select the Care Area.</p> <p>4. Press .</p> |  |

Table 8-11. To Program a Multi-step infusion

| Steps | Screens All screen shots are examples only |
|--|---|
| <p>The Drug Search screen displays.</p> <p>5. Press the alphanumeric hard key(s) to enter the first two letters of the drug name. Press the key multiple times to enter the drug letter. Example:</p> <ul style="list-style-type: none"> - Press the 2 key one time for the letter D. - Press the 5 key three times to enter the letter O. <p>Press the back arrow soft key to clear entry errors.</p> <p>Drug Selection screen displays</p> <p>6. Select prescribed drug.</p> |  <p>The screenshot shows the 'Critical Care' screen with the instruction 'Type the first two letters of the drug name.' The 'Drug Name' field is empty. A 'back' button is visible at the bottom.</p>  <p>The screenshot shows the 'Critical Care' screen with the instruction 'Type the first two letters of the drug name.' The 'Drug Name' field contains 'DO'. A left arrow button is visible at the bottom.</p> |
| <p>The Select delivery bag screen can appear when configured with multiple delivery bag options.</p> <p>7. Press the arrow soft keys, move the cursor to Multi-step (Primary only).</p> <p>8. Press  to select.</p> <p>NOTE: If delivery bag was configured as Primary Only, Multi-step, the Drug Setup screen will appear. <i>See next step.</i></p> |  <p>The screenshot shows the 'MedSurg Drug A' screen with the instruction 'Select delivery bag'. Three options are listed: 'Primary Bag', 'Secondary Bag', and 'Multi-step (Primary only)'. The 'Multi-step (Primary only)' option is highlighted. A 'clear program' button with an up arrow is visible at the bottom.</p> |

8. Programming the pump

Table 8-11. To Program a Multi-step infusion











| Steps | Screens All screen shots are examples only |
|--|--|
| <p>The Step 1 Drug Setup screen shows the Step Indicator Bar at the top with Step 1 highlighted (white tab).</p> <p>9. Enter the required parameters for Step 1.</p> <p>Do not program the VTBI (total from all steps) higher than total volume contained in the IV bag.</p> <p>10. Press .</p> |   |
| <p>A pop-up message will display after each step is entered and confirmed.</p> <p>11. Press  to program the next step.</p> <ul style="list-style-type: none"> ■ Press  to start the infusion. ■ Pressing the hold soft key pauses the infusion. |  |
| <p>The Step 2 Drug Setup screen displays.</p> <p>The Step Indicator Bar shows Step 1 in a white box.</p> <p>The white tab highlights Step 2.</p> <p>12. Enter the required parameters for Step 2.</p> <p>13. Press  to advance to the next step.</p> |  |

Table 8-11. To Program a Multi-step infusion

| Steps | Screens All screen shots are examples only |
|--|---|
| <p>The Step 3 Drug Setup screen displays.</p> <p>The Step Indicator Bar now shows Step 1 and Step 2 in white boxes, The white tab highlights Step 3.</p> <p>14. Enter the required parameters for Step 3.</p> <p>15. Press  to advance to the next step.</p> <ul style="list-style-type: none"> ■ To review the steps programmed, See <i>Table 8-12 To Review Steps Programmed for Multi- step infusion.</i> <p>16. Continue programing all steps using the instructions above.</p> |  |

8. Programming the pump

Table 8-11. To Program a Multi-step infusion









| Steps | Screens All screen shots are examples only |
|---|--|
| <p>17. Press  to start the infusion.</p> <ul style="list-style-type: none"> ■ Check Flow Screen displays. <i>See Table 8-1 To start an infusion.</i> ■ The Program Infusing screen displays showing the step that is infusing. |  |
| <p>The RUN screen displays. The Step number, dose, rate, VTBI remaining and time remaining in alternating screens.</p> <p>The step will be delivered in the sequence programmed.</p> <p>An automatic transition occurs from one step to the next.</p> <p>For RUN screen display options. <i>See Display Settings, page 5- 12.</i></p> |  |

Table 8-12. To Review Steps Programmed for Multi- step infusion:

| Steps | Screens All screen shots are examples only |
|---|--|
| <p>At the Setup screen</p> <p>or</p> <p>Press  when the pump is infusing.</p> <ol style="list-style-type: none"> 1. Press the review soft key. 2. Press the up arrow soft key to move to the top of the screen. <ul style="list-style-type: none"> ■ The Step Indicator Bar is selected when it is highlighted gray. 3. Press the left and right arrow soft keys, to move the white tab to the step to be reviewed. |   |
| <p>NOTE: To edit a value:</p> <ul style="list-style-type: none"> ■ Press the soft arrow keys to go to the step. ■ Press  . <p>NOTE: Edits to a value can only be made when pump is stopped.</p> |  |

8. Programming the pump

Table 8-13. To clear a Step Multi- step infusion




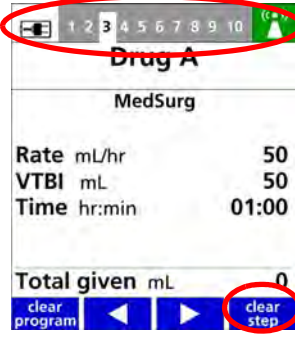




| Steps | Screens All screen shots are examples only |
|--|--|
| <p>At the Setup screen or</p> <p>Press  when the pump is infusing.</p> <ol style="list-style-type: none"> 1. Press the review soft key: 2. Press the up arrow soft key to go to the top of the screen. <p>The Step Indicator Bar is selected when it is highlighted gray.</p> |  |
| <ol style="list-style-type: none"> 3. Press left and right arrow soft key to move the cursor to the white tab of the step to be cleared. 4. Press . 5. Press the clear step soft key. <p>All Values will clear to 0.</p> <p>NOTE: The last step programmed is the only step that can be cleared. An infusion cannot run when there are empty steps in a Multi-step program.</p> |  |

Table 8-14. To reset the Multi-step program

| Steps | Screens All screen shots are examples only |
|---|--|
| <p>A Multi-step program can be reset to Step 1 at any point during the infusion.</p> <ol style="list-style-type: none"> 1. Press . 2. Press the reset program soft key. |  |
| <p>The Program Stopped screen displays Step 1.</p> <ol style="list-style-type: none"> 3. Press  to restart the infusion at Step 1. |  |

8.14 Cyclic TPN

Total Parenteral Nutrition (TPN) therapy is delivered over a set infusion time that includes a period of escalating delivery rates up to a maintenance rate, then a period of tapering down from the maintenance rate until the infusion time has been completed.

The pump automatically calculates the following infusion schedule based on the infusion time programmed and the total volume to be infused:

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

8. Programming the pump

Cyclic TPN programming is only available when it is configured in the **Dose IQ** Safety Software.

Table 8-15. To Program a Cyclic TPN Infusion










| Steps | Screens All screen shots are examples only |
|---|---|
| <p>1. Press  to power on the pump.</p> |  |
| <p>The New Patient or Care Area screen (go to step 4) displays.</p> <p>NOTE: The pump retains previously programmed infusion values up to 24 hours after power off.</p> <p>New Patient screen:</p> <p>2. Press the yes soft key to clear the previously programmed infusion values and go to the Care Area screen.</p> <p>NOTE: When a new drug that is required for the same patient, press the yes soft key. The total given will be reset to zero.</p> <p>Press the no soft key to retain the previously programmed infusion values for the same patient.</p> |  |
| <p>3. Press the arrow soft keys to select the Care Area.</p> <p>Press .</p> |  |

Table 8-15. To Program a Cyclic TPN Infusion

| Steps | Screens All screen shots are examples only |
|--|---|
| <p>The Drug Search screen displays.</p> <p>4. Press the alphanumeric hard key(s) to enter the first two letters of the drug name. Press the key multiple times to enter the drug letter. Example:</p> <ul style="list-style-type: none"> – Press the 7 key two times for the letter T. – Press the 6 key onetime to enter the letter P. <p>Press the back arrow soft key to clear entry errors.</p> <p>The Drug Selection screen shows a list of drugs based on the letters entered in the previous step.</p> <p>NOTE: A selection has to be made in this screen to continue programming.</p> <p>5. Press the arrow soft keys to move the cursor to the correct drug name.</p> <p>6. Press .</p> <p>If a prescribed drug is not listed in the drug selection screen, request that the drug be added to the Spectrum IQ Infusion System drug library per the facility’s procedures.</p> |  |
| <p>TPN is selected.</p> <p>The Delivery Mode selection screen displays the delivery modes for TPN.</p> <p>7. Press the arrow soft key to move the cursor to Cyclic TPN</p> <p>8. Press .</p> |  |

8. Programming the pump

Table 8-15. To Program a Cyclic TPN Infusion







| Steps | Screens All screen shots are examples only |
|---|--|
| <p>The Cyclic TPN Setup screen displays the required parameters to be entered or confirmed.</p> <p>9. Enter the required VTBI.</p> <p>10. Press  to confirm VTBI.</p> |  |
| <p>The Prog Time (program time) parameter will be highlighted.</p> <p>11. Enter the Prog Time (hr:min).</p> <p>12. Press  to confirm time.</p> <p>The time values and units are displayed directly below to confirm entry.</p> |  |

Table 8-15. To Program a Cyclic TPN Infusion

| Steps | Screens All screen shots are examples only |
|---|---|
| <p>The completed setup screen displays the:</p> <ul style="list-style-type: none"> ■ Programmed parameters entered. ■ Main Rate. ■ Time duration for the Ramp up, Main step and Taper down. <p>NOTE: Confirm that the programmed values are correct and are in the proper sequence per physician/ pharmacist's order.</p> <p>13. Press  to begin the infusion.</p> <p>14. The Check Flow screen displays.</p> |  |

8. Programming the pump

Table 8-15. To Program a Cyclic TPN Infusion







| Steps | Screens All screen shots are examples only |
|---|--|
| <p>The Cyclic TPN RUN screen displays the step that is infusing.</p> <p>The phases of Ramping up, Main Step, and Tapering Down will automatically transition.</p> <p>The time remaining in the infusion and the volume remaining is displayed.</p> <p>A green INFUSING indicator continually flashes to indicate that the infusion is running.</p> <p>To review the program status, press the review soft key.</p> |  <p>The screenshots show the following details:</p> <ul style="list-style-type: none"> Top Screenshot (Ramping Up): MedSurg TPN, Ramping Up 12:00 hr:mm remain, 1000 mL remaining, INFUSING, review, info / settings, taper down. Middle Screenshot (Main Step): MedSurg TPN, Main Step 10:48 hr:mm remain, 944 mL remaining, INFUSING, review, info / settings, taper down. Bottom Screenshot (Tapering Down): MedSurg TPN, Tapering Down 01:12 hr:mm remain, 56 mL remaining, INFUSING, review, info / settings. |

Table 8-16. To Begin Early Taper Down (Cyclic TPN)

| Steps | Screens All screen shots are examples only |
|---|---|
| <p>From the RUN screen,</p> <ol style="list-style-type: none"> 1. Press the taper down soft key. <p>The Taper Down confirmation screen displays.</p> <ol style="list-style-type: none"> 2. Press the yes soft key to begin early taper down. |  |
| <p>The RUN screen will display Tapering Down and the time remaining in the step.</p> <p>NOTE: When early taper down is activated during the Ramping up step, the tapering down will begin with the corresponding taper down step of equal delivery rate.</p> <ul style="list-style-type: none"> ■ When early taper down is activated during the Main Step, the first taper down step will begin immediately. |  |

8. Programming the pump

Table 8-17. To Reset the Cyclic TPN Program


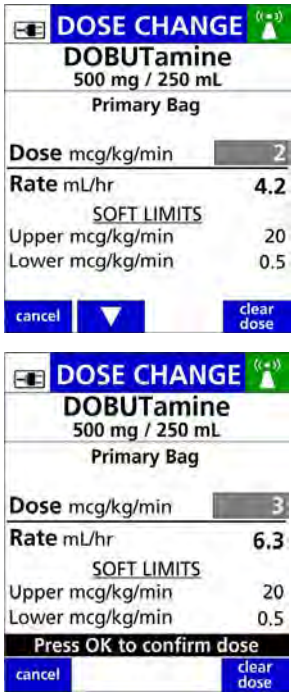
| Steps | Screens <i>All screen shots are examples only</i> |
|--|--|
| <p>The Cyclic TPN program may be reset back to the Ramp up step.</p> <ol style="list-style-type: none">1. Press .2. Press the reset program soft key. |  |
| <p>The Program Stopped screen now displays Start.</p> <p>The time remaining is reset to the total program time.</p> |  |

8.15 Dose or Rate Change During an Infusion (Titration)

A dose or rate change may be programmed without stopping the infusion.

- A dose change option is available for drugs configured with all continuous dose modes except for mL/hr.
- A rate change option is available for drugs configured with a mL/hr dose mode.

Table 8-18. To Change a Dose While an Infusion is Running

| Steps | Screens All screen shots are examples only |
|---|--|
| <p>1. Press the dose change soft key.</p> |  |
| <p>The DOSE CHANGE screen displays the current dose highlighted. The soft limits are displayed in the lower portion of the screen</p> <p>2. Enter the new dose.</p> <p>3. Press OK to confirm.</p> <p>The rate (mL/hr) value is automatically updated as the new dose is entered.</p> <p>NOTE: To cancel the change, press cancel soft key to return to the RUN screen.</p> |  |
| <p>The dose entered is checked against the lower and upper dose limits configured for this drug. A limit alert will appear if the value entered exceeds configured limits. See Table 8.25 Safety Alerts That May Appear During Programming.</p> | |

8. Programming the pump

Table 8-18. To Change a Dose While an Infusion is Running










| Steps | Screens All screen shots are examples only |
|---|--|
| <p>4. Press  to begin delivery of the new dose or rate.</p> |  |
| <p>NOTE: A Dose Change Alert screen will appear when a dose change entered exceeds the percent limit configured for an incremental increase or decrease from the current dose or rate.</p> <p><i>See Table 8-39 Dose/Rate Limits.</i></p> |  |

Table 8-19. To Change the Rate while an Infusion is Running

| Steps | Screens All screen shots are examples only |
|---|---|
| <p>1. Press the rate change soft key.</p> |  <p>The screenshot shows the 'Critical Care' screen for 'NaCl 0.9%'. The current rate is '200 mL/hr'. At the bottom, there are four soft keys: 'bolus', 'review / editVTBI', 'info / settings', and 'rate change'. The 'rate change' key is circled in red.</p> |
| <p>The Rate Change screen displays. The current rate is highlighted. The soft limits are displayed in the lower portion of the screen.</p> <p>NOTE: To cancel the change, press cancel soft key to return to the RUN screen.</p> <p>2. Enter the new rate.</p> <p>3. Press  to confirm.</p> |  <p>The screenshot shows the 'RATE CHANGE' screen for 'NaCl 0.9%'. It indicates 'Primary Bag' and 'Rate mL/hr' with a value of '200'. Below this, 'SOFT LIMITS' are listed: 'Upper mL/hr' at 500 and 'Lower mL/hr' at 50. At the bottom, there are 'cancel' and 'clear rate' soft keys.</p> |
| <p>The rate entered is checked against the lower and upper rate limits configured for this drug. A limit alert will appear if the value entered exceeds configured limits.</p> | |

8. Programming the pump



Table 8-19. To Change the Rate while an Infusion is Running

| Steps | Screens All screen shots are examples only |
|---|--|
| <p>4. Press  to begin delivery of the new rate.</p> |  |
| <p>NOTE: A Rate Change Alert screen will appear when a rate change entered exceeds the percent limit configured in the drug library for an incremental increase or decrease from the current rate.</p> <p><i>See Safety Alerts That May Appear During Programming, page 8- 107.</i></p> |  |

8.15.1 Changing the VTBI (Volume To Be Infused) During an Infusion





The Volume To Be Infused (VTBI) of a continuous infusion may be changed without stopping and interrupting the infusion.

Table 8-20. To Change the VTBI while an infusion is Running

| Steps | Screens All screen shots are examples only |
|--|---|
| <p>1. Press the review/edit VTBI soft key.</p> |  |
| <p>The Setup screen displays for review.</p> <p>2. Press the edit VTBI soft key.</p> <p>The VTBI field is now highlighted.</p> |  |

8. Programming the pump

Table 8-20. To Change the VTBI while an infusion is Running

| Steps | Screens All screen shots are examples only |
|---|--|
| 3. Enter the new VTBI. 4. Press  to confirm. 5. Press  to begin delivery with the new VTBI. |  |
| The RUN screen displays with the new VTBI. |  |

8.16 Amount/Time (Intermittent) Infusions

An Amount/Time Infusion is an IV drug therapy prescribed as a total dose amount completely administered over a set duration of time.

Amount/Time drugs may be configured and programmed in these ways:

- Concentration Type:
 - Fixed (Drug Amount and Total Volume)
 - Variable Concentration
 - Standard (Drug Amount per 1 mL)
- Delivery Method:
 - Primary
 - Secondary



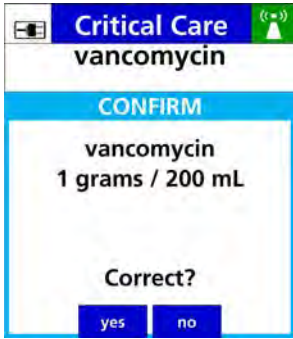
- Dose Mode Type:
 - Non weight-based
 - Weight-based
 - Body Surface Area (BSA) based

8.16.1 Fixed (Drug Amount and Total Volume)

The drug is configured in the drug library with a defined drug amount and diluent volume. These parameters cannot be changed during pump programming.




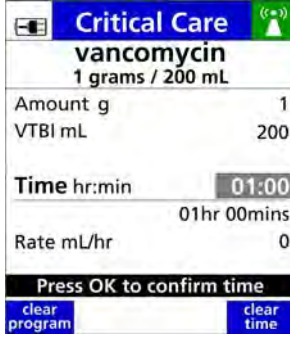

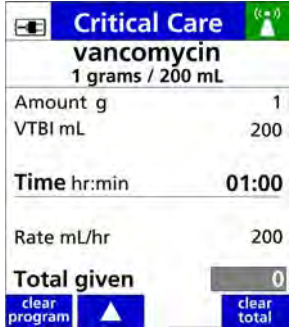
- For Example: Drug X, 1 g/50 mL

Table 8-21. To program a Primary Amount/ Time Infusion with a Fixed Drug amount and Total Volume

| Steps | Screens All screen shots are examples only |
|--|---|
| 1. See Table 8-1 To start an infusion. Steps 1-6. | |
| <p>The Concentration Selection screen displays the concentration(s) configured for the selected drug.</p> <p>2. Press the arrow soft keys to move the cursor to the correct drug concentration.</p> <p>3. Press  to select.</p> |  |
| <p>The Confirm Concentration screen displays the concentration selected.</p> <p>4. Press the yes soft key to confirm the concentration.</p> <p>or</p> <ul style="list-style-type: none"> ■ Press the no soft key to return to the Concentration Selection screen. |  |

8. Programming the pump

Table 8-21. To program a Primary Amount/ Time Infusion with a Fixed Drug amount and Total Volume

| Steps | Screens All screen shots are examples only |
|---|---|
| <p>The Select delivery bag screen will appear when the delivery bag was configured as Primary Or Secondary in the drug library for this drug.</p> <p>Press the arrow soft keys to move the cursor to Primary Bag.</p> <p>Press  to select.</p> <p><i>See Delivery Bag, page 8- 20.</i></p> |  |
| <p>The Drug Setup screen displays. The Time field is highlighted.</p> <p>5. Enter the time duration and press .</p> <p>NOTE: When entering time (hr:min) values, the time values and units are displayed directly below to confirm values.</p> <ul style="list-style-type: none"> The time entered is checked against the lower and upper time limits configured for this drug. A limit alert will appear when the value entered exceeds configured limits. <p><i>See Safety Alerts That May Appear During Programming, page 8- 107.</i></p> |  |
| <p>The cursor moves to the Total given field.</p> <p>6. Press  to begin the infusion.</p> <p>NOTE: <i>See Priming Volume Adjustment, page 8- 78.</i></p> <p>The Check Flow screen displays.</p> |  |
| <p>RUN screen displays.</p> | |

8.16.2 Variable Concentration


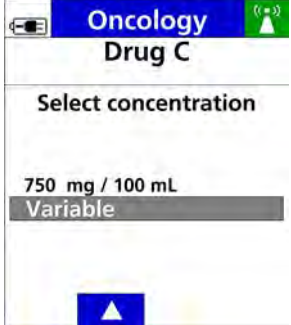

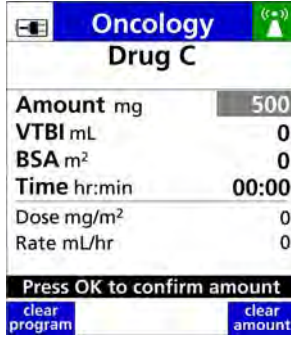
Variable Concentration setups are used when drug concentrations are not standardized. This allows the clinician to specify the Drug Amount and Diluent Volume during pump programming. The calculated concentration is checked against concentration limits configured in the drug library.

The following dose mode types are available for Variable Concentration:

- Non weight-based
- Weight-based
- Body Surface Area (BSA) based

NOTE: Confirm that all programmed values are correct per the physician/ pharmacist's order.

Table 8-22. To Program a Primary Amount/Time Infusion with a Variable Concentration and BSA Based Mode

| Steps | Screens All screen shots are examples only |
|--|---|
| 1. See Table 8-1 To start an infusion. Steps 1-11 | |
| <p>The Concentration Selection screen displays the concentration(s) configured for the selected drug.</p> <p>2. Press the arrow soft keys to move the cursor to Variable.</p> <p>3. Press  to select.</p> |  |
| <p>The Drug Setup screen displays the required parameters.</p> <p>4. Enter the drug Amount.</p> <p>5. Press  to confirm.</p> |  |

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Table 8-22. To Program a Primary Amount/Time Infusion with a Variable Concentration and BSA Based Mode


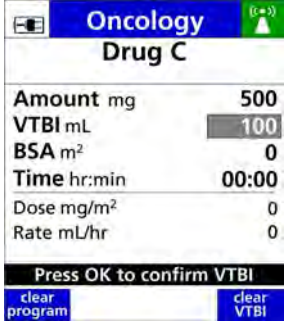







| Steps | Screens All screen shots are examples only |
|---|---|
| <p>The VTBI is highlighted.</p> <p>6. Enter the Volume to Be Infused (VTBI).</p> <p>7. Press  to confirm.</p> |  |
| <p>The Confirm Concentration screen displays the concentration entered.</p> <p>8. Press the yes soft key to confirm the concentration entered.</p> <ul style="list-style-type: none"> Press the no soft key to clear the entry and return to the Drug Setup screen. <p>NOTE: The concentration is checked against the lower and upper concentration limits configured for this drug. A limit alert will appear when the values entered exceeds configured limits.</p> |  |
| <p>The BSA field will be highlighted.</p> <p>9. Enter the patient's BSA.</p> <p>10. Press  to confirm.</p> <p>NOTE: The BSA value is checked against the lower and upper BSA limits configured for this Care Area.</p> |  |

Table 8-22. To Program a Primary Amount/Time Infusion with a Variable Concentration and BSA Based Mode

| Steps | Screens All screen shots are examples only |
|--|--|
| <p>The Dose (mg/m²) is calculated and checked against the dose limits configured.</p> <p><i>See Safety Alerts That May Appear During Programming, page 8- 107.</i></p> <p>11. Enter the time duration.</p> <p>12. Press  to confirm.</p> <p>NOTE: The time entered is checked against the lower and upper time limits configured for this drug. A limit alert will appear when the value entered exceeds configured limits.</p> |  |
| <p>The cursor moves to the Total given field.</p> <p>13. Press  to begin the infusion.</p> <p><i>See Priming Volume Adjustment, page 8- 78.</i></p> <p>The Check Flow screen displays.</p> |  |
| <p><i>See Table 8-1 To start an infusion. Steps 11-12</i></p> | |

8.16.3 Standard Concentration (Drug Amount per 1 mL)

Standard Concentrations are typically used for drugs where the concentration is fixed, but no drug amount or total volume is specified.

The Drug Amount is required to be entered while programming the pump.

The VTBI will be calculated based on the standard concentration configured.

The following dose mode types are available for Standard Concentration:

- Non weight-based
- Weight-based

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- BSA based

NOTE: Confirm that all programmed values are correct and in the proper sequence per the physician/ pharmacist's orders.

Table 8-23. To Program a Primary Amount/Time Infusion with a Standard Concentration in Weight-based Mode












| Steps | Screens All screen shots are examples only |
|---|---|
| 1. See Table 8-1 To start an infusion. Steps 1-11. | |
| <p>The Concentration Selection screen displays the concentration(s) configured for the Drug selected.</p> <ol style="list-style-type: none"> Press the arrow soft key to move the cursor to standard concentration. Press  to select. |  <p>The screenshot shows the 'MedSurg Drug S' interface with a 'Select concentration' menu. Two options are listed: '750 mg / 100 mL' and '2 mg / mL'. The '2 mg / mL' option is highlighted with a grey bar. A blue arrow key is visible at the bottom.</p> |
| <p>The Confirm Concentration screen displays the concentration selected.</p> <ol style="list-style-type: none"> Press the yes soft key to confirm the concentration. Press the no soft key to return to the Concentration Selection menu. |  <p>The screenshot shows the 'MedSurg Drug S' interface with a 'CONFIRM' overlay. It displays 'Drug S 2 mg / mL' and asks 'Correct?'. At the bottom, there are 'yes' and 'no' buttons.</p> |
| <p>The Drug Setup screen displays the required parameters.</p> <ol style="list-style-type: none"> Enter the drug Amount. Press  to confirm. |  <p>The screenshot shows the 'MedSurg Drug S' interface with a 'Drug S 2 mg/mL' header. Below are several fields: 'Amount mg' (200), 'VTBI mL' (0), 'Patient Weight kg' (0), 'Time hr:min' (00:00), 'Dose mg/kg' (0), and 'Rate mL/hr' (0). At the bottom, there are 'clear program' and 'clear amount' buttons.</p> |

Table 8-23. To Program a Primary Amount/Time Infusion with a Standard Concentration in Weight-based Mode

| Steps | Screens All screen shots are examples only |
|---|--|
| <p>The VTBI is calculated based on the Standard concentration. The Patient Weight field is highlighted.</p> <p>7. Enter the Patient Weight.</p> <p>8. Press  to confirm.</p> <p>The Patient Weight value entered is checked against the lower and upper weight limits configured for this Care Area. <i>See Delayed Run, page 8- 103.</i></p> |  <p>The screenshot shows the 'MedSurg' screen for 'Drug S' with a concentration of 2 mg/mL. Fields include Amount (200 mg), VTBI (100 mL), Patient Weight (70 kg, highlighted), Time (00:00), Dose (0 mg/kg), and Rate (0 mL/hr). Buttons for 'clear program', 'clear weight', and 'Press OK to confirm weight' are visible.</p> |
| <p>The Patient Weight, the Dose (mg/kg) is calculated and checked against the dose limits configured.</p> <p>9. Enter the time duration.</p> <p>10. Press  to confirm.</p> <p>The time entered is checked against the lower and upper time limits configured for this drug.</p> <p>A limit alert will appear when the value entered exceeds configured limits.</p> <p><i>See Safety Alerts That May Appear During Programming, page 8- 107.</i></p> |  <p>The screenshot shows the 'MedSurg' screen for 'Drug S' with a concentration of 2 mg/mL. Fields include Amount (200 mg), VTBI (100 mL), Patient Weight (70 kg), Time (00:30, highlighted), Dose (00hrs 30mins), and Rate (0 mL/hr). Buttons for 'clear program', 'clear time', and 'Press OK to confirm time' are visible.</p> |
| <p>The cursor moves to the Total given field.</p> <p>Press  to begin the infusion.</p> <p><i>See Priming Volume Adjustment, page 8- 78.</i></p> <p>The Check Flow screen displays.</p> |  <p>The screenshot shows the 'Oncology' screen for 'Drug C' with a concentration of 500 mg / 100 mL. Fields include Amount (500 mg), VTBI (100 mL), BSA (2 m²), Time (00:30), Dose (250 mg/m²), Rate (200 mL/hr), and Total given (0). Buttons for 'clear program', 'clear total', and an up arrow are visible.</p> |
| <p><i>See Table 8-1 To start an infusion. Steps 1-10</i></p> | |

8.17 Priming Volume Adjustment

The Priming Volume Adjustment feature provides the option to automatically adjust parameters based on the volume (in mL) used to manually prime the IV tubing.

This feature is only applicable for amount/time primary infusions, and is only available during initial programming with an initial IV set load or reload.

The priming volume adjustment feature is available when enabled in the drug library for the selected Care Area.

Table 8-24. Adjust the Priming Volume





| Steps | Screens All screen shots are examples only |
|--|--|
| <i>See Table 8-1 To start an infusion. Steps 1-11</i> | |
| 11. Enter the parameters. 12. Press  to confirm. The cursor moves to the Total given field. |  |

Table 8-24. Adjust the Priming Volume

| Steps | Screens All screen shots are examples only |
|---|---|
| <p>The Priming Volume Adjustment screen displays. This allows the adjustment of the total volume that was used to prime the tubing.</p> <p>Four options are available:</p> <ul style="list-style-type: none"> ■ back <ul style="list-style-type: none"> – Press the back soft key to return to the previous screen to review the program. ■ yes <ul style="list-style-type: none"> – Press the yes soft key to adjust the parameters of the programmed infusion with the priming volume displayed. ■ no <ul style="list-style-type: none"> – Press the no soft key to decline and return to the setup screen. ■ edit <ul style="list-style-type: none"> – Press the edit soft key to edit the priming volume displayed. – Enter the priming volume. <ul style="list-style-type: none"> – Press <input type="button" value="OK"/> to confirm. – The allowable range is 0.5 mL to 30 mL. – Press yes soft key to adjust the parameters of the programmed infusion with the priming volume displayed. | <p>The screenshots show the following sequence of actions:</p> <ol style="list-style-type: none"> Initial screen: "Adjust Amount, VTBI, and Time for priming volume ? (20 mL)". Buttons: back, yes, no, edit. After pressing 'edit': "Adjust Amount, VTBI, and Time for priming volume ? (20 mL)". Buttons: cancel, clear mL. After entering '15': "Adjust Amount, VTBI, and Time for priming volume ? (15 mL)". Buttons: cancel, clear mL. Final screen: "Adjust Amount, VTBI, and Time for priming volume ? (15 mL)". Buttons: back, yes, no, edit. |

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Table 8-24. Adjust the Priming Volume

| Steps | Screens All screen shots are examples only |
|---|---|
| <p>When the priming volume adjustment is accepted, the setup screen displays the adjusted parameters.</p> <p>Press  to begin the infusion.</p> <p>The Check Flow screen displays.</p> |  |
| <p>See Table 8-1 To start an infusion. Steps 11-12</p> | |






8.18 Line Flush

The Line Flush feature allows delivery of any residual volume in the IV container at the completion of an amount/time infusion.

- The maximum volume limit per line flush is configured in the drug library.
- Line flush delivers at the same rate as the current programmed infusion rate.
- The line flush function may be performed up to three times.
- Line flush volume can be set from 1 mL to 100 mL.

A primary line flush is always available at the completion of a primary amount/time infusion. A secondary line flush is only available when the secondary callback alarm is enabled.

Table 8-25. To Flush a Primary Line

| Steps | Screens All screen shots are examples only |
|--|---|
| <p>At the completion of a primary amount/time infusion, the INFUSION COMPLETE screen displays.</p> <p>It shows that the infusion is now running at a KVO rate.</p> <p>1. Press  to stop the infusion.</p> |  |
| <p>The Line Flush screen displays.</p> <p>It provides the option to deliver any residual volume remaining in the IV container.</p> <p>2. Press the yes soft key to flush the primary line.</p> |  |
| <p>The Flush Primary Line screen displays.</p> <p>3. Enter the estimated residual volume in the Flush Amount field</p> <p>4. Press  to confirm.</p> <p>NOTE: The maximum volume limit for the flush amount is configured in the drug library for each amount/time drug. This may be set from 1 mL to 100 mL.</p> <ul style="list-style-type: none"> The Flush Rate remains the same as the current programmed infusion. |  |

8. Programming the pump

Table 8-25. To Flush a Primary Line







| Steps | Screens All screen shots are examples only |
|--|--|
| <p>The Flush Time is displayed.</p> <p>5. Press  to begin the line flush.</p> |  |
| <p>The Primary Flushing screen displays. That shows that a primary line flush has started.</p> <p>This is immediately followed by the line flush RUN screen.</p> |  |
| <p>The Check Flow screen displays.</p> | |

Table 8-25. To Flush a Primary Line

| Steps | Screens All screen shots are examples only |
|--|--|
| <p>The line flush RUN screen indicates that the primary line flush is in progress.</p> <p>The infusion rate is displayed as well as the volume remaining.</p> <p>The volume remaining decreases until the line flush is completed.</p> |  |
| <p>At the completion of the line flush the Line Flush Complete screen displays.</p> <p>It shows that the infusion is running at a KVO rate.</p> <p>6. Press  to stop the infusion.</p> <p>A Line Flush screen will be displayed, providing the option to flush the primary line again.</p> <p>A line flush can be done up to three times.</p> |  |

8. Programming the pump

Table 8-26. To Flush a Secondary Line









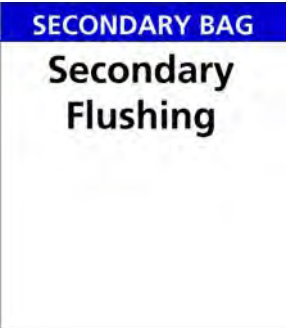

| Steps | Screens- All screens are examples only |
|---|---|
| <p>At the completion of a secondary amount/time infusion with the Secondary Callback Alarm enabled, the SECONDARY COMPLETE screen will be displayed. This indicates that the infusion is running at a secondary KVO rate of 1 mL/hr or the infusion rate (if lower than 1mL/hr).</p> <p>1. Press  to stop the infusion.</p> |  |
| <p>A Line Flush screen displays. It provides the option to deliver any residual volume remaining in the IV container.</p> <p>2. Press the yes soft key to flush the secondary line.</p> |  |
| <p>The Flush Secondary Line screen displays.</p> <p>3. Enter the estimated residual volume in the Flush Amount field.</p> <p>4. Press  to confirm.</p> |  |

Table 8-26. To Flush a Secondary Line

| Steps | Screens- All screens are examples only |
|---|---|
| <p>The Flush Time is displayed.</p> <p>5. Press  to begin the line flush.</p> |  |
| <p>The Secondary Check Flow screen displays.</p> <p>Press the yes soft key when these observations are confirmed.</p> |  |
| <p>The Secondary Flushing screen is displayed.</p> |  |
| <p>The Line Flush RUN screen displays.</p> <p>It shows that the secondary line flush is in progress.</p> <p>The infusion rate is displayed as well as the volume remaining.</p> <p>The volume remaining decreases until the line flush is completed.</p> <p>The secondary line flush may be performed up to three times.</p> |  |

8.19 Rate Change during an amount / time infusion

A rate change may be programmed without stopping the infusion. When changing the infusion rate, the new rate entered is checked against the rate limits established in the drug library. The lower and upper rate limits are determined by the starting VTBI programmed and the time limits configured for the drug.

Table 8-27. To program a Rate Change during an amount / time infusion





| Steps | Screens All screen shots are examples only |
|---|---|
| <p>1. Press the rate change soft key from the RUN screen.</p> |  |
| <p>The rate change screen appears with the current rate highlighted. The soft limits are displayed in the lower portion of the screen.</p> <p>To exit this screen and return to the RUN screen, press cancel soft key.</p> <p>2. Enter the new rate.</p> <p>3. Press <input type="button" value="OK"/> to confirm.</p> |  |

Table 8-27. To program a Rate Change during an amount / time infusion

| Steps | Screens All screen shots are examples only |
|---|---|
| <p>The rate entered is checked against the lower and upper rate limits configured for this drug. A limit alert will appear if value entered exceeds configured limits. See <i>Dose/Rate Limits</i>, page 8-110.</p> | |
| <p>4. Press  to begin delivery of the new rate.</p> <p>RUN screen displays.</p> |  |

8.20 Volume/Time Infusions

A Volume/Time Infusion is an IV drug therapy prescribed as a total volume completely administered over a set duration of time. Rate changes may be programmed as needed. See *Table 8-19 To Change the Rate while an Infusion is Running*.

A Bolus may also be programmed in Volume/Time infusions.

Volume/Time drugs may be configured and programmed in the following ways:

- **Configuration Type:**
 - Fixed (Starting Volume and Starting Time)
 - Variable
- **Delivery Method:**
 - Primary or Secondary
 - Bolus Dose

8. Programming the pump

8.20.1 Fixed Configuration

In the Fixed configuration type, the drug is configured in the drug library with a defined starting volume and time. For example, Drug X, 1000 mL/8 hrs. These parameters may be changed during pump programming.

Table 8-28. To Program a Primary Volume/ Time Infusion with Fixed starting Volume and Time









| Steps | Screens All screen shots are examples only |
|--|---|
| 1. See <i>To start an infusion</i> , page 8- 9. | |
| <p>The Configuration Selection screen displays the configurations available for the selected drug.</p> <p>2. Press the arrow soft keys, move the cursor to the correct drug configuration</p> <p>3. Press  to select.</p> |  |
| <p>The Drug Setup screen shows the required parameters for the selected configuration.</p> <p>NOTE: A Delivery Bag is configured as Primary or Secondary, a Delivery Bag Selection screen will appear before the Drug Setup screen is displayed. See <i>Delivery Bag</i>, page 8- 20.</p> |  |
| <p>4. Press  to confirm volume.</p> <p>NOTE: To edit the volume, press the clear volume soft key and enter the correct value.</p> | |

Table 8-28. To Program a Primary Volume/ Time Infusion with Fixed starting Volume and Time

| Steps | Screens All screen shots are examples only |
|--|--|
| <p>5. Press  to confirm time.</p> <p>NOTE: Press the clear time soft key to edit the time.</p> |  |
| <ul style="list-style-type: none"> ■ The cursor moves to the Total given field. <p>6. Press  to begin the infusion.</p> |  |
| <p><i>See Table 8-1 To start an infusion. Steps 12-15.</i></p> | |

8. Programming the pump

8.20.2 Variable Configuration

Variable configuration setups are used when drug volume and time duration are not standardized. This allows the clinician to specify Volume and Time during pump programming. The volume and time values are checked against the limits configured in the drug library.

Table 8-29. To Program Volume/ Time Infusion with a Variable Configuration


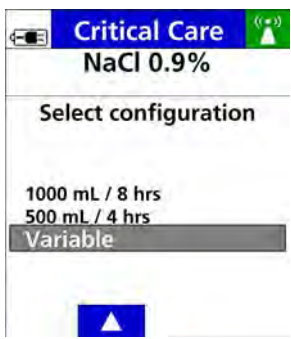

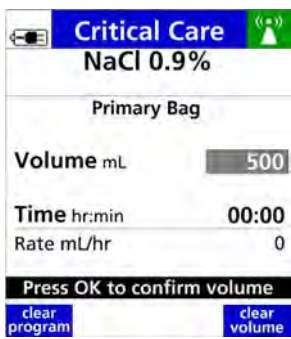




| Steps | Screens All screen shots are examples only |
|---|---|
| 1. See <i>To start an infusion, page 8- 9.</i> | |
| <p>The Configuration Selection screen displays the configurations available for the drug.</p> <p>2. Press the soft arrow Key to select Variable.</p> <p>3. Press .</p> |  |
| <p>The Drug Setup screen display the required parameters.</p> <p>4. Enter the Volume.</p> <p>5. Press  to confirm.</p> |  |
| <p>The Time parameter is now highlighted.</p> <p>6. Enter the Time.</p> <p>7. Press  to confirm time.</p> |  |

Table 8-29. To Program Volume/ Time Infusion with a Variable Configuration

| Steps | Screens All screen shots are examples only |
|--|---|
| <p>The cursor now moves to the Total given field.</p> <p>Confirm that all programmed values are correct.</p> <p>8. Press  to begin the infusion.</p> |  |
| <p><i>See Table 8.6 Starting an Infusion. Steps 12-15</i></p> | |

8.20.3 Bolus Dose Programming (volume/ time)

A Bolus dose for a volume/time infusion can be programmed at any time after the infusion has started.

8. Programming the pump

The Bolus dose may be programmed while the infusion is running or stopped. Bolus dose programming is either enabled or disabled in the **Dose IQ** Safety Software.

Table 8-30. To Program a Bolus Dose (volume/ time)

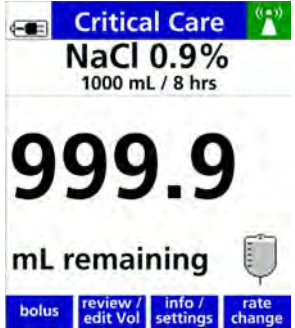








| Steps | Screens All screen shots are examples only |
|--|---|
| <p>A volume/time infusion has been programmed and is infusing.</p> <ol style="list-style-type: none"> 1. Press the bolus soft key. |  <p>The screenshot shows the 'Critical Care' interface with a patient icon and signal strength indicator. The drug is 'NaCl 0.9%' with a rate of '1000 mL / 8 hrs'. A large '999.9' is displayed, with 'mL remaining' below it and a syringe icon. At the bottom, there are four soft keys: 'bolus', 'review / edit Vol', 'info / settings', and 'rate change'.</p> |
| <p>The Bolus Setup screen displays.</p> <ol style="list-style-type: none"> 2. Enter the amount to be delivered. 3. Press  to confirm. <p>NOTE: The amount entered is checked against the limits configured in the drug library.</p> <p>Press the cancel bolus soft key to cancel the bolus and resume the infusion.</p> <p>Press the clear amount soft key to clear amount.</p> |  <p>The screenshot shows the 'Critical Care' interface with the same patient icon and signal strength indicator. The drug is 'NaCl 0.9%' with a rate of '1000 mL / 8 hrs'. The screen is titled 'BOLUS SETUP'. It has two input fields: 'Amount mL' with a value of '250' and 'Time minutes' with a value of '0'. At the bottom, there is a prompt 'Press OK to confirm amount' and two soft keys: 'cancel bolus' and 'clear amount'.</p> |

Table 8-30. To Program a Bolus Dose (volume/ time)

| Steps | Screens All screen shots are examples only |
|---|---|
| <p>The Time parameter is highlighted.</p> <p>4. Enter the Time duration for the bolus.</p> <p>5. Press  to confirm.</p> <p>NOTE: The time entered is checked against the limits configured in the drug library.</p> <p>NOTE: The time unit is defaulted to minutes.</p> <p>NOTE: A time in seconds soft key will appear when:</p> <ul style="list-style-type: none"> ■ There is not a starting time configured in the drug library for the selected drug. ■ Programming in seconds is allowed for the drug. <p>To change time units to seconds:</p> <ul style="list-style-type: none"> ■ Press the time in seconds soft key. <p>Press the cancel bolus soft key to cancel the bolus and resume the infusion.</p> <p>Press the clear time soft key to clear the time entry.</p> |  <p>The screenshots show the 'Critical Care' screen for 'NaCl 0.9%' at '1000 mL / 8 hrs' in 'BOLUS SETUP' mode. The 'Amount mL' is set to 250. In the first screenshot, 'Time minutes' is 0, and the 'time in seconds' soft key is circled in red. In the second screenshot, 'Time minutes' is 30. Both screens have 'cancel bolus' and 'clear time' soft keys at the bottom.</p> |

8. Programming the pump

Table 8-30. To Program a Bolus Dose (volume/ time)

| Steps | Screens All screen shots are examples only |
|---|---|
| <p>6. Press  to begin the bolus dose.</p> <p>Press the cancel bolus soft key to cancel the bolus and resume the infusion.</p> <p>Press the edit bolus soft key to change the entry.</p> |  <p>The screen shows 'Critical Care' at the top with a signal strength icon. Below it is 'NaCl 0.9%' and '1000 mL / 8 hrs'. The main heading is 'BOLUS SETUP'. A table lists: Amount mL: 250, Time minutes: 30, Rate mL/hr: 500. At the bottom, it says 'Press  to begin bolus dose.' and has two buttons: 'cancel bolus' and 'edit bolus'.</p> |
| <p>The infusion Bolus RUN screen displays the amount of bolus given.</p> <p>NOTE: The amount given will increase until the total bolus amount that was programmed has been delivered.</p> <p>NOTE: The primary infusion will resume automatically when the bolus dose has been completely delivered.</p> <p>Press the cancel bolus soft key to cancel the bolus and resume the infusion.</p> <p>Press review bolus soft key to review the entry.</p> <p>Press the info/ settings soft key for the options menu.</p> |  <p>The screen shows 'Critical Care' at the top with a signal strength icon. Below it is 'NaCl 0.9%' and '1000 mL / 8 hrs'. A large '1' is displayed in the center. Below the '1' is 'mL given Bolus Dose'. At the bottom, there are three buttons: 'cancel bolus', 'review bolus', and 'info / settings'.</p> |

8.21 Secondary Infusions

Secondary infusions are delivered through an established pathway of a primary infusion. The delivery bag configured in the drug library for the drug selected determines whether or not secondary infusion is available. *See Delivery Bag, page 8- 20.*


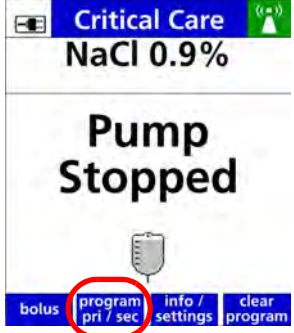
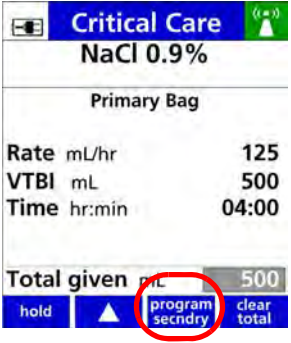


A secondary infusion can only be programmed when the pump is stopped.

Flow rates above 300 mL/hr may cause fluid to be siphoned from the primary container during a secondary infusion.

NOTE: Rates that exceed 300 mL/hr require the primary to be clamped off to prevent concurrent flow.

For preparing the pump and proper pump setup, See *Secondary Infusion Setup*, page 7- 13.

Table 8-31. To program a Secondary Infusion

| Steps | Screens All screen shots are examples only |
|---|---|
| <ol style="list-style-type: none"> Press  to STOP the primary infusion. The Pump Stopped screen displays. Press the program pri/sec soft key. |  |
| <p>The drug setup screen is displayed.</p> <ol style="list-style-type: none"> Review and confirm primary infusion parameters. Press the program secndry soft key. |  |
| <ol style="list-style-type: none"> Search for drug. See <i>Table 8-1 To start an infusion</i>. | |
| <p>Concentration Selection screen displays the concentrations configured for the drug selected.</p> <ol style="list-style-type: none"> Press the arrow soft key to the correct drug concentration. Press  to select. |  |

8. Programming the pump

Table 8-31. To program a Secondary Infusion






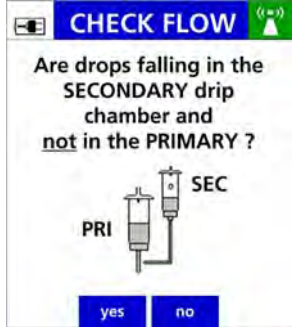


| Steps | Screens All screen shots are examples only |
|---|---|
| <p>The Confirm Concentration screen displays the concentration selected.</p> <p>7. Press the yes soft key to confirm the concentration selected, or</p> <ul style="list-style-type: none"> ■ Press the no soft key to return to the Concentration Selection screen. |  |
| <p>The Drug Setup screen displays the required parameters to be entered and confirmed.</p> <p>A watermark “2” is displayed on the screen, showing that this program is for a secondary infusion.</p> <p>8. Enter the required parameters displayed.</p> |  |
| <p>9. Enter the VTBI.</p> <p>10. Press  to confirm.</p> <p>NOTE: A pop-up message displays a reminder that the secondary VTBI should equal the secondary bag volume.</p> <ul style="list-style-type: none"> ■ This confirms that the entire contents of the secondary container is delivered. |  |
| <p>The cursor moves to the Total given field.</p> <p>11. Press .</p> <p>NOTE: The Total given field includes the volume given from the primary infusion.</p> | |

Table 8-31. To program a Secondary Infusion

| Steps | Screens All screen shots are examples only |
|---|---|
| <p>Secondary Check Flow screen is displayed.</p> <p>12. Check the flow and confirm that:</p> <ul style="list-style-type: none"> ■ Drops falling in the secondary drip chamber (SEC). ■ No drops are falling in the primary drip chamber (PRI). <p>13. Press the yes soft key when all of the above conditions are confirmed.</p> <ul style="list-style-type: none"> – Press the no soft key when no drops are observed and See <i>Table 8-63 Secondary Check Flow Trouble Shooting</i>. <p>The Secondary Infusing screen displays.</p> <p>It shows that the secondary infusion has started. This is immediately followed by the RUN screens</p> |  |

8. Programming the pump

Table 8-31. To program a Secondary Infusion

| Steps | Screens All screen shots are examples only |
|--|--|
| <p>The infusion RUN screen displays.</p> <p>It shows the rate, VTBI remaining, and time remaining in alternating screens.</p> <p>A secondary bag icon is also displayed on the RUN screen.</p> <p><i>See Display Settings, page 5- 12.</i></p> <p>To view the infusion status, press the review/edit VTBI soft key.</p> |  <p>The screenshot shows a blue header with 'SECONDARY BAG' in white. Below the header, the text 'Secondary Infusing' is displayed in a large, bold, black font.</p> |
| <p>The RUN screen displays.</p> |  <p>The first screenshot shows the 'Critical Care' header, 'ceFAZolin 1 grams / 50 mL', and a large '100 mL/hr' rate. Below the rate are three soft keys: 'review/editVTBI', 'info/settings', and 'rate change'. A secondary bag icon is visible in the bottom right.</p> <p>The second screenshot shows the same header and drug information, but with a large '50 mL - VTBI' displayed. The soft keys and bag icon are also present.</p> |

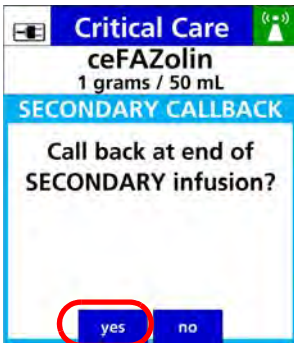


8.22 Secondary Callback

Secondary Callback is an audio and visual notification at the completion of the secondary infusion. A Secondary Complete screen displays, and indicates that the pump is infusing at a KVO rate of 1 mL/hr or the infusion rate (if lower than 1mL/hr). The primary infusion must be restarted manually.

The Secondary Callback feature is available when it is configured in the drug library for the drug selected. Possible configurations are:

- Never - Secondary Callback will not be available.
- Required - Secondary Callback is automatically on.
- Optional - The user has the option to enable the Secondary Callback during pump programming.

Table 8-32. To Program a Secondary Callback

| Steps | Screens All screen shots are examples only |
|---|---|
| 1. See <i>Secondary Infusions</i> , page 8- 94. Step 1-12 | |
| <p>The cursor moves to the Total given field.</p> <p>The secondary call back screen displays.</p> <ul style="list-style-type: none"> ■ It provides the option to enable the secondary callback feature. <p>2. Press the yes soft key to enable secondary callback.</p> |  |
| <p>The drug setup screen is displayed.</p> <p>Make sure that the programmed parameters are correct.</p> <p>3. Press  to begin the secondary infusion.</p> |  |

8. Programming the pump

Table 8-32. To Program a Secondary Callback

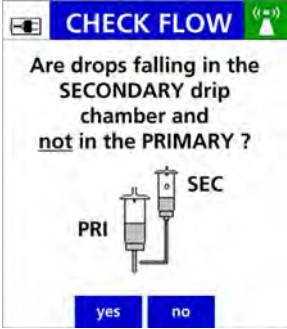
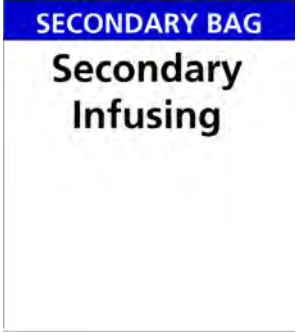











| Steps | Screens All screen shots are examples only |
|---|---|
| <p>Secondary Check Flow screen is displayed.</p> <p>4. Check the flow and confirm that:</p> <ul style="list-style-type: none">■ There are drops falling in the secondary drip chamber.■ No drops are falling in the primary drip chamber. <p>5. Press the yes soft key when all of the above conditions are confirmed.</p> <p>The Secondary Infusing screen displays.</p> |  |

Table 8-32. To Program a Secondary Callback

| Steps | Screens All screen shots are examples only |
|---|---|
| <p>The RUN screen displays.</p> <p>The rate, VTBI remaining, and time remaining in alternating screens.</p> <p>A telephone icon and secondary bag icon are also displayed in alternating screens.</p> <p>See <i>Display Settings, page 5- 12.</i> for RUN screen display options.</p> <p>To view the infusion status, press the review/edit VTBI soft key.</p> |  <p>SECONDARY BAG Secondary Infusing</p>  <p>Critical Care  ceFAZolin 1 grams / 50 mL 100 mL/hr  review / info / rate editVTBI settings change</p>  <p>Critical Care  ceFAZolin 1 grams / 50 mL 50 mL - VTBI  review / info / rate editVTBI settings change</p> |
| <p>At the completion of a secondary infusion the SECONDARY COMPLETE screen shows that the infusion is running at a secondary KVO rate of 1 mL/hr or the infusion rate (if lower than 1mL/hr)</p> <p>6. Press  to stop the infusion.</p> |  <p>  ceFAZolin 1 grams / 50 mL SECONDARY COMPLETE Press  to stop 1 mL/hr KVO silence</p> |

8. Programming the pump

Table 8-32. To Program a Secondary Callback




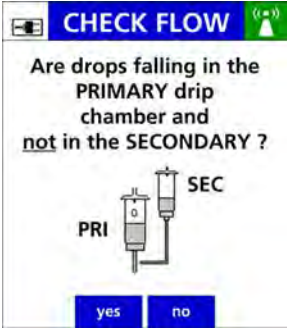






| Steps | Screens All screen shots are examples only |
|--|---|
| <p>The Select Infusion screen displays.</p> <p>Two options are available:</p> <ul style="list-style-type: none"> ■ To restart the primary infusion, press the Review PRIMARY soft key to review the primary setup screen. ■ To setup another secondary infusion, press the SECONDARY soft key. |  |
| <p>Review PRIMARY is pressed:</p> <p>The primary setup screen displays the watermark “1” for the primary infusion.</p> <p>Press  to restart the primary infusion.</p> |  |
| <p>The Check Flow screen displays.</p> <p>Make sure that drops are seen in the primary drip chamber and not in the secondary drip chamber.</p> <ul style="list-style-type: none"> ■ Press the yes soft key when drops are visible in the primary drip chamber. ■ Press the no soft key when no drops are visible in the primary drip chamber. |  |
| <p>When no is pressed, the Clamp Line screen displays to instruct the user to clamp the secondary line.</p> <p>Press  to confirm.</p> |  |

Table 8-32. To Program a Secondary Callback

| Steps | Screens All screen shots are examples only |
|---|---|
| <p>When the SECONDARY soft key is pressed to:</p> <p>The Select Infusion screen displays.</p> <p>Press the arrow soft keys to select:</p> <p>New Drug</p> <ol style="list-style-type: none"> 1. Press . ■ The Drug Selection screen will display or the last secondary infusion that was programmed. 2. Press . 3. Press  to begin infusion |  |
| <p><i>See Secondary Infusions, page 8- 94. Steps 14-15</i></p> | |

8.23 Delayed Run

The optional Delayed Run feature allows the clinician to delay the start of a programmed infusion.

The delay time can be from one minute to twelve hours. This feature is available when enabled in the drug library for the drug selected.

The delay time is entered during pump programming. The pump will begin infusing after time delay has expired.

8. Programming the pump

The clinician will need to respond to the Check Flow screen when the infusion begins.

Table 8-33. To Program a Delayed Run Infusion







| Steps | Screens All screen shots are examples only |
|--|--|
| 1. See Table 8-1 To start an infusion. Steps 1-11. | |
| <p>The drug setup screen displays the required parameters to be entered or confirmed.</p> <p>2. Enter the required parameters.</p> <p>The cursor moves to the Total given field.</p> <p>3. Press the up arrow soft key, move the cursor to the Delay field.</p> |  |
| <p>4. Enter the Delay time.</p> <p>5. Press <input type="button" value="OK"/> to confirm.</p> |  |

Table 8-33. To Program a Delayed Run Infusion

| Steps | Screens All screen shots are examples only |
|---|--|
| <p>The cursor moves to the Total given field.</p> <p>6. Press  to begin the delay timer.</p> <p>The Delay Running screen displays the delay time remaining. The delay time remaining continues to decrease until it reaches zero.</p> <p>NOTE: Press the cancel delay to cancel the delay at any time. This will be followed by the Pump Stopped screen.</p> <ul style="list-style-type: none"> ■ The delay timer can also be paused by pressing . ■ A Delay Stopped screen will display. |  |
| <p>At the end of the delay time the Delay Complete pop up window displays.</p> <p>It shows that the delay time has expired.</p> <p>This is immediately followed by the Check Flow screen and the infusion begins.</p> <p>Follow the steps to confirm flow.</p> |  |

8.24 Rate (mL/hr) Entry Disabled

Entry in the Rate (mL/hr) field may be disabled for a Care Area in the drug library, for drugs configured with a continuous non-mL/hr dose mode. This prevents errors in programming the rate (mL/hr) field when the drug is intended to be programmed with a dose mode.



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

Rate (mL/hr) may not be edited, display only.

Figure 8-1. Rate (mL/hr) entry disabled



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

Rate (mL/hr) field may be edited.

Figure 8-2. Rate (mL/hr) entry enabled

8.25 Safety Alerts That May Appear During Programming

Programming an infusion using the Dose Error Reduction System (DERS) provides additional safety alerts that are not available when programming in Basic mode.

Table 8-34. Summary of Safety Alerts

| Safety Alert | DERS Programming | Basic Mode Programming |
|---|------------------|------------------------|
| Initial Programming | | |
| Clinical Advisory | x | |
| Concentration Soft/Hard Limits | x | |
| Patient Weight/Body Surface Area (BSA) Soft/Hard Limits | x | x (weight only) |
| Dose/Rate Soft/Hard Limits | x | |
| Loading Dose Soft/Hard Limits | x | n/a |
| Amount or Time Soft/Hard Limits | x | n/a |
| Time Change | x | x |
| Pump Rate Hard Limits | x | x |
| Infusion Running | | |
| Single Step Rate/Dose Change Alert | x | x (fixed at 101%) |
| Dose/Rate Soft/Hard Limits | x | |
| Bolus Soft/Hard Limits | x | |
| Pump Hard Rate Limits | x | x |

Initial Programming Alerts

Table 8-35. Clinical Advisory


| Description | Screen |
|---|---|
| <p>A Clinical Advisory may be configured for each drug in the Dose IQ Safety Software.</p> <ul style="list-style-type: none"> ■ Provides additional information prior to programming and delivery of the drug. ■ Press the continue soft key to acknowledge the Advisory and proceed with programming. |  |

Table 8-36. Concentration Limits

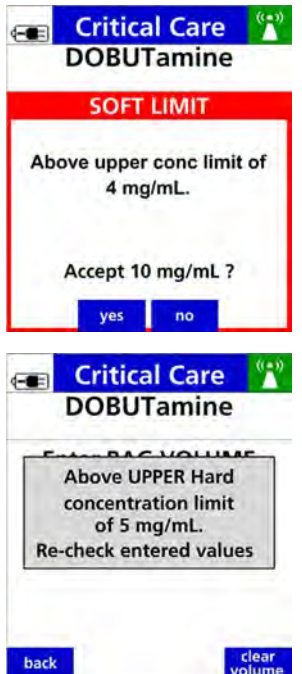
| Description | Screen |
|---|---|
| <p>Concentration Limits are only applicable for a variable concentration drug.</p> <p>Soft Limit:</p> <ul style="list-style-type: none"> ■ Drug amount and volume entered exceeds a lower or upper concentration soft limit configured for the drug. ■ Press the yes soft key to accept. ■ Press the no soft key to re-enter. <p>Hard Limit:</p> <ul style="list-style-type: none"> ■ Concentration entered exceeds a hard limit. ■ Reprogramming is required. |  |

Table 8-37. Patient Weight/ BSA Limit

| Description | Screen |
|--|--------|
| <p>Soft Limit:</p> <ul style="list-style-type: none"> ■ Patient weight/BSA entered exceeds a lower or upper weight soft limit configured for the Care Area. ■ Press the yes soft key to accept. ■ Press the no soft key to re-enter patient weight. <p>Hard limit:</p> <ul style="list-style-type: none"> ■ Patient weight entered exceeded a hard limit. ■ Re-entry of patient weight is required. | |

Table 8-38. Patient weight/ BSA Double Confirmation

| Description | Screen |
|---|--------|
| <p>Applicable when patient weight or BSA confirmation is enabled for the Care Area.</p> <ul style="list-style-type: none"> ■ Patient weight or BSA must be re-entered, and must match the original value entered. ■ The original value entered is masked. | |

8. Programming the pump

Table 8-39. Dose/Rate Limits




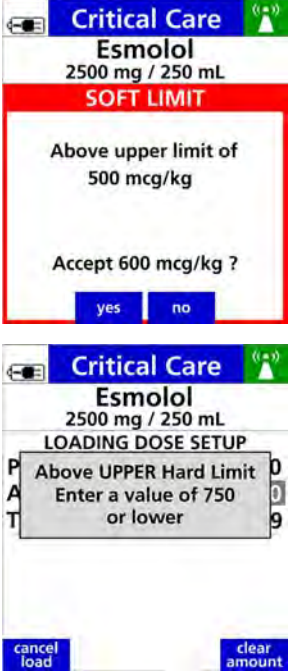
| Description | Screen |
|---|---|
| <p>Soft Limit:</p> <ul style="list-style-type: none"> ■ Dose or Rate entered exceeds a lower or upper soft limit configured for the drug. ■ Press the yes soft key to accept or the no soft key to reprogram. ■ After pressing the yes soft key, the drug name, dose and rate accepted will be displayed in red. |  |
| <p>Soft Limit - RUN screen</p> <p>The RUN screen is displayed, with the drug name and the dose or rate displayed in red.</p> <ul style="list-style-type: none"> ■ The HI indicator is displayed when the dose is above the upper soft limit. ■ The LO indicator is displayed when the dose is below the lower soft limit. |  |
| <p>Hard Limit</p> <p>Dose or Rate entered exceeds a lower or upper hard limit configured for the drug.</p> <p>NOTE: The user cannot proceed and reprogramming of the dose or rate is required.</p> |  |

Table 8-40. Loading Dose Limits

| Description | Screen |
|---|--|
| <p>Soft Limit:</p> <ul style="list-style-type: none"> ■ Loading dose amount or time entered exceeds a lower or upper soft limit configured for the drug. ■ Press the yes soft key to accept, or the no soft key to reprogram. <p>Hard Limit:</p> <ul style="list-style-type: none"> ■ Loading dose amount or time entered exceeds a lower or upper hard limit configured for the drug. ■ Reprogramming of the amount or time is required. |  |

8. Programming the pump

Table 8-41. Amount or Time Limits


| Description | Screen |
|---|---|
| <p>Amount and Time limits are configured for an amount/time drug in the Dose IQ Safety Software.</p> <p>Soft Limit:</p> <ul style="list-style-type: none"> Amount or time entered exceeds a lower or upper soft limit configured for the drug. Press the yes soft key to accept, or the no soft key to reprogram. <p>Hard Limit:</p> <ul style="list-style-type: none"> Amount or time entered exceeds a lower or upper hard limit configured for the drug. Reprogramming is required. |  <p>The screenshots show the following text:</p> <p>Screen 1 (Soft Limit): Critical Care Vancomycin. SOFT LIMIT. Below lower limit of 250 mg. Accept 200 mg? yes no</p> <p>Screen 2 (Hard Limit): Critical Care Vancomycin. Amount mg 2500. Above UPPER Hard Limit Enter a value of 2000 or lower. Rate mL/hr 0. Total given mL 0. clear program clear amount</p> |

Table 8-42. Time Change

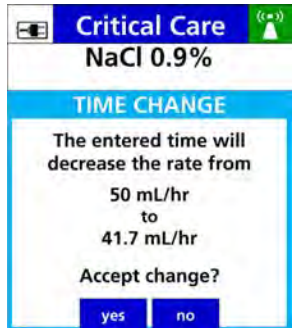
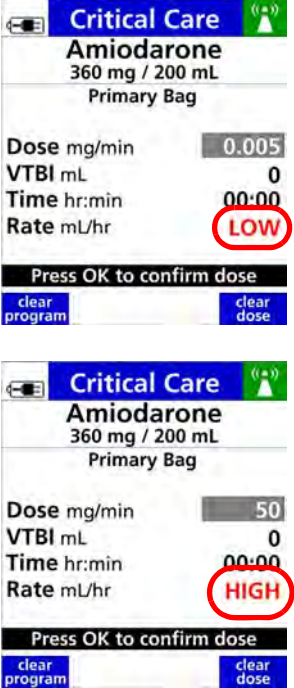
| Description | Screen |
|--|--|
| <p>When the time is changed with a rate and VTBI already programmed, a time change alert will display the corresponding change in dose rate or infusion rate in a mL/hr mode infusion.</p> |  <p>The screenshot shows the following text:</p> <p>Screen: Critical Care NaCl 0.9%. TIME CHANGE. The entered time will decrease the rate from 50 mL/hr to 41.7 mL/hr. Accept change? yes no</p> |

Table 8-43. Pump Rate Hard Limits

| Description | Screen |
|--|--|
| <ul style="list-style-type: none"> ■ The rate field will display LOW in red when the dose entered results in a calculated rate that is lower than the pump rate hard limit of 0.5 mL/hr. ■ The rate field will display HIGH in red when the dose entered results in the calculated rate that is higher than the pump rate hard limit of 999 mL/hr. <p>Reprogramming is required.</p> |  <p>The screenshots show the 'Critical Care' screen for 'Amiodarone 360 mg / 200 mL Primary Bag'. The top screenshot shows a 'Dose mg/min' of 0.005 and a 'Rate mL/hr' of 0.005, with 'LOW' displayed in red in a red circle. The bottom screenshot shows a 'Dose mg/min' of 50 and a 'Rate mL/hr' of 50, with 'HIGH' displayed in red in a red circle. Both screens include 'clear program' and 'clear dose' buttons and a 'Press OK to confirm dose' prompt.</p> |

8. Programming the pump

Infusion Running Alerts.

Table 8-44. Single Step Dose/Rate Change Alert


| Description | Screen |
|---|---|
| <p>NOTE: Set at 500% for Anesthesia and OR Care Areas</p> <p>NOTE: Each facility's drug library can be programmed with limits for the percentage of a dose or rate change made in one programming step for each specific drug.</p> <ul style="list-style-type: none"> ■ The alert shows when a dose rate or change entered exceeds the percent limit configured for an incremental increase or decrease from the current dose or rate. ■ Press the yes soft key to accept, or Press no soft key to reprogram. |  |

Table 8-45. Dose/ Rate Limits

| Description | Screen |
|--|--------|
| <p><i>See Table 8-39 Dose/Rate Limits.</i></p> | |

Table 8-46. Bolus Limits

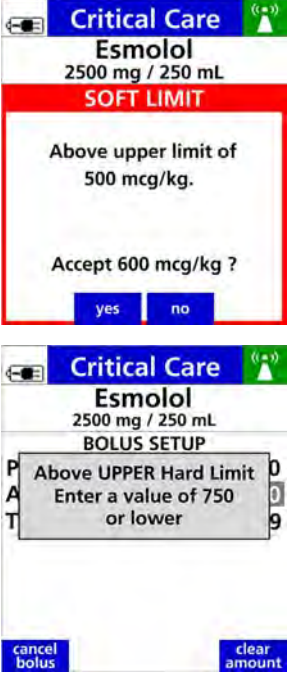
| Description | Screen |
|---|--|
| <p>Soft Limits:</p> <ul style="list-style-type: none"> ■ The alert shows when a bolus dose amount or time entered exceeds a lower or upper soft limit configured for the drug. ■ Press the yes soft key to accept, or the no soft key to reprogram. <p>Hard Limits:</p> <ul style="list-style-type: none"> ■ The alert shows when a bolus dose amount or time entered exceeds a lower or upper hard limit configured for the drug. ■ Reprogramming of the amount or time is required. |  |

Table 8-47. Pump Rate Hard Limits

| Description | Screen |
|---|--------|
| <p><i>See Table 8-47 Pump Rate Hard Limits.</i></p> | |

8.26 Auto-Programming

Auto-programming is the ability to populate infusion parameters from the patient’s order in the electronic medical record (EMR) into the **Spectrum IQ** Infusion System.

Auto-programming is available when the **Spectrum IQ** Infusion System is integrated with the hospital’s electronic medical record system (EMR).

The patient’s medication order in the EMR orders are entered by the physician, validated by pharmacy and confirmed by the clinician when sent to the pump. The clinician then initiates sending the order to the **Spectrum IQ** Infusion System.

8. Programming the pump

The drug, concentration, dose and volume are automatically populated into the **Spectrum IQ** Infusion System within the Dose Error Reduction System (DERS). Infusion status information is auto-documented back into the EMR system. Auto-programming in combination with DERS is intended to reduce pump programming errors.





NOTE: The following functions are not available with Auto-programming. They must be programmed manually.

- Loading Dose
- Bolus Dose
- Volume/Time, Cyclic TPN and Multi-step delivery modes
- Order updates to Basic programmed infusion

NOTE: Always confirm the entry with the physician/ pharmacist's order.

8.26.1 Associate the Pump to the EMR

Table 8-48. To associate the Pump to the EMR

| Steps | Screens All screen shots are examples only |
|--|---|
| <p>1. Follow the facility’s procedure for:</p> <ul style="list-style-type: none"> ■ bar-code scanning of the patient’s wristband and medication. ■ confirming the order in the patient’s medication administration record in the EMR system. ■ Preparing the EMR system to scan and associate the Spectrum IQ Infusion System to the patient’s medication order. | |
| <p>2. Press  to power ON the pump.</p> <p>3. Clear all previous programmed infusions (when the New Patient screen displays).</p> <p>NOTE: Make sure to use this pump to infuse the medication scanned in Step 1.</p> | |
| <p>The Select Care Area screen is displayed.</p> <p>4. Press the arrow soft keys to select care area.</p> <p>5. Press .</p> |  |
| <p>The Spectrum ID barcode screen displays.</p> <p>The barcode screen will appear when auto-programming is enabled in the care area.</p> <p>Scan the Spectrum ID barcode to associate the pump with the patient’s order in the EMR.</p> |  |
| <p>6. Follow the facility’s EMR procedure to send the patient’s medication order to the Spectrum IQ Infusion System.</p> | |

8. Programming the pump

8.26.2 Accept or Reject an Order

Table 8-49. To accept or reject an Order








| Steps | Screens All screen shots are examples only |
|--|---|
| <p>The Order Received screen displays the drug name, concentration, delivery bag and patient weight.</p> <ol style="list-style-type: none"> Press the accept order soft key. <p>NOTE: Press the reject order soft key to reject an order. The Care Area selection screen will display.</p> <p>When the drug is not available in the pump's drug library See <i>Table 8-55 To Auto Program in Basic Mode.</i></p> <p>NOTE: When a patient weight value is greater than 100 kg, there is a potential for discrepancy in the precision of values displayed between the pump and in the EMR system.</p> <p>NOTE: Patient weight values sent from the EMR retain the original precision; however, the pump will not display decimal values for patient weights greater than 100 kg.</p> |  |
| <p>The Drug Setup screen displays the infusion parameters that are auto-populated from the patient's medication order.</p> <ol style="list-style-type: none"> Press the accept program soft key. <p>NOTE: To edit one or more parameters, press the edit program soft key.</p> <ul style="list-style-type: none"> ■ Patient Weight or BSA values cannot be edited on the pump. ■ Confirm the programmed values. |  |

Table 8-49. To accept or reject an Order

| Steps | Screens All screen shots are examples only |
|---|---|
| <p>The cursor moves to the Total given field.</p> <p>3. Press  to begin the infusion.</p> |  |
| <p>When  is pressed, the infusion will start and the Check Flow screen is displayed.</p> |  |
| <p>The RUN screen displays the dose, rate, VTBI and time remaining in alternating screens.</p> <p><i>See Display Settings, page 5- 12. for RUN screen display options.</i></p> |  |
| <p>4. Follow the facility’s procedure to complete the required steps in the EMR system to validate that the administration has begun.</p> | |

8.26.3 Auto-programming Secondary Infusions

A secondary infusion may be auto-programmed when a primary infusion has been previously programmed and is active on the pump.

8. Programming the pump

NOTE: Confirm all entries with the physician/ pharmacist's orders.

Table 8-50. To Auto-program a Secondary Infusion:









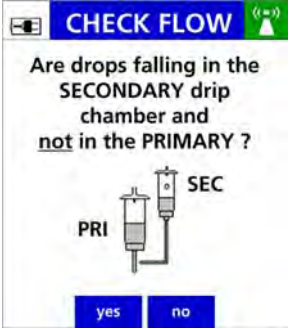

| Steps | Screens All screen shots are examples only |
|---|--|
| <p>A primary infusion has been auto-programmed, and is running on the pump.</p> <ol style="list-style-type: none"> Press  to stop the primary infusion. Press the program pri/sec soft key. The Drug Setup screen displays. Press the program secndry soft key. <p>NOTE: Follow the facility's procedure for bar-code scanning of the patient's wristband and medication, and for confirming the order in the patient's medication administration record in the EMR system. Prepare the EMR system to scan and associate the Spectrum IQ Infusion System to the patient's medication order.</p> |   |
| <p>The Spectrum ID barcode screen displays.</p> <ol style="list-style-type: none"> Scan the Spectrum ID barcode displayed. This will associate the pump with the patient's order in the EMR. <p>Follow the facility's EMR procedure to send the patient's medication order to the Spectrum IQ Infusion System.</p> |  |

Table 8-50. To Auto-program a Secondary Infusion:

| Steps | Screens All screen shots are examples only |
|--|---|
| <p>The Order Received screen displays the drug name, concentration, and delivery bag.</p> <p>5. Press the accept order soft key to continue.</p> |  |
| <p>The Drug Setup screen displays the infusion parameters that are auto-populated from the patient's medication order.</p> <p>The "2" watermark on the screen indicates that this is a secondary infusion.</p> <p>6. Press the accept program soft key to continue.</p> <p>NOTE: Press the edit program soft key to edit the values.</p> |  |
| <p>The cursor will move to the Total given field.</p> <p>7. Prepare the Secondary infusion:</p> <ul style="list-style-type: none"> ■ Connect the secondary set to the primary set's upper Y injection site. ■ Lower the primary bag by fully extending the hanger. ■ Open the secondary roller clamp. <p>8. Press  to begin the infusion.</p> |  |

8. Programming the pump




Table 8-50. To Auto-program a Secondary Infusion:

| Steps | Screens All screen shots are examples only |
|---|--|
| <p>The Secondary Check Flow screen is displayed.</p> <p>9. Check the flow and confirm that:</p> <ul style="list-style-type: none"> ■ There are drops falling in the secondary drip chamber. ■ There are no drops falling in the primary drip chamber. <p>10. When both of these conditions are confirmed, press the yes soft key. This will display the Secondary Infusing screen, followed by the RUN screens.</p> <p>When no drops are observed, press the no soft key and follow the additional screen instructions. <i>See Table 8-63 Secondary Check Flow Trouble Shooting.</i></p> |  |
| <p>The RUN screen displays.</p> <p>For RUN screen display options <i>See Display Settings, page 5- 12.</i></p> <p>11. Follow the facility's procedure to complete the required steps in the EMR system to validate that the administration has begun.</p> |  |

8.26.4 Auto-programming Order Updates





When a patient’s medication order has been updated in the EMR and verified by pharmacy, this update may be applied to the current infusion using auto-programming. This is applicable for updates to the patient weight, patient BSA, dose, rate and VTBI. Follow the facility’s policy for order updates with auto-programming.

Table 8-51. Auto Programming an Order update

| Steps | Screens All screen shots are examples only |
|---|---|
| <p>NOTE: Follow the facility’s procedure for bar-code scanning of patient’s wristband, medication and for confirming the order in the patient’s medication administration record in the EMR system</p> | |
| <p>A primary infusion has been auto-programmed and is running on the pump.</p> <ol style="list-style-type: none"> 1. Press the  hard key. 2. Prepare the EMR system to scan and associate the Spectrum IQ Infusion System to the patient’s medication order. |  |
| <p>Follow the facility’s EMR procedure to send the patient’s medication to the Spectrum IQ Infusion System.</p> <p>The Order Received screen displays.</p> <p>This shows that an Order Update has been received for the current infusion.</p> <ol style="list-style-type: none"> 3. Press the accept order soft key to accept the update. |  |

8. Programming the pump

Table 8-51. Auto Programming an Order update



| Steps | Screens All screen shots are examples only |
|---|---|
| <p>The Drug Setup screen displays the updated values.</p> <p>4. Press the accept program soft key.</p> |  |
| <p>5. Press  to begin the updated infusion.</p> <p>6. Check Flow Screen will display.</p> |  |
| <p>The Primary Infusing screen displays and is immediately followed by the RUN screen.</p> <p>The RUN screen displays the updated information.</p> <p>For RUN screen display options See <i>Display Settings, page 5- 12</i>.</p> |  |

8.26.5 Back-Associating an Infusion

A manually programmed infusion already in progress can be linked back to the patient order in the EMR system. This will enable auto-documentation of infusion status information such as volume infused or time initiated depending on your EMR. It will also allow for auto-programming of subsequent order when needed.

Drugs that are manually programmed within the **Dose IQ** software may be back-associated into an existing patient order in the EMR system.

Table 8-52. To Back Associate an Infusion

| Steps | Screens (all screens are examples only) |
|--|--|
| <p>NOTE: Follow the facility’s procedure for bar-code scanning of the patient’s wristband and medication, and for confirming the order in the patient’s medication administration record in the EMR system. Prepare the EMR system to scan and associate the Spectrum IQ Infusion System to the patient’s medication order.</p> | |
| <p>A manually programmed infusion is running.</p> <ol style="list-style-type: none"> 1. Press the  key to display the Spectrum ID barcode screen. 2. Scan the Spectrum ID barcode displayed, to associate the pump with the patient’s order in the EMR. |  |

8. Programming the pump

8.26.6 Safety Alerts During Auto-Programming

Upon receiving and accepting an auto-programmed infusion, the **Spectrum IQ** Infusion System checks the parameters received from the EMR against the **Dose IQ** Safety Software for any values that are outside the allowed safety limits.

Table 8-53. Soft Dose Rate Limits when Auto- Programming




| Steps | Screens All Screens are examples only |
|---|---|
| <p>1. See Table 8-48 To associate the Pump to the EMR. Steps 1-5.</p> | |
| <p>The Order Received screen displays the drug name, concentration and infusion type.</p> <p>Review to make sure the information is correct.</p> <p>2. Press the accept order soft key.</p> |  |
| <p>A Soft Limit Alert screen will display the soft limit value that was exceeded and the ordered dose.</p> <p>3. Press the accept value soft key to accept the ordered dose.</p> <p>4. Press the edit value soft key to make a change. To edit the value, proceed to Step 5.</p> <p>The reject order soft key returns to the Care Area selection screen.</p> |  |
| <p>The Drug Setup screen displays the accepted value in red.</p> <p>5. Press the accept program soft key to confirm all parameters (proceed to Step 6), or</p> <p>6. Press the edit program soft key to edit one or more parameters.</p> |  |

Table 8-53. Soft Dose Rate Limits when Auto- Programming








| Steps | Screens All Screens are examples only |
|---|---|
| <p>When the edit value soft key (step 2) or the edit program soft key (step 3) is pressed, the parameters in the Drug Setup screen can be edited.</p> <p>7. Edit parameters.</p> <p>8. Press  to confirm.</p> <p>9. Press .</p> |  |
| <p>10. Check Flow screen displays.</p> | |

Table 8-54. Hard Limits when Auto Programming

| Steps | Screens All screen shots are examples only |
|---|---|
| <p><i>See Table 8-48 To associate the Pump to the EMR.</i> Steps 1-5 to associate the pump and send the order from the EMR system.</p> <p>A hard limit alert will only appear when a modifier is required to be selected on the pump and the ordered values are valid for at least one modifier. When ordered values exceed a hard limit for a modifier selected, a hard limit alert will appear.</p> | |
| <p>The Order Received screen displays the drug name, concentration, and infusion type.</p> <p>11. Confirm the order.</p> <p>Press the accept order soft key to accept.</p> |  |

8. Programming the pump

Table 8-54. Hard Limits when Auto Programming

| Steps | Screens All screen shots are examples only |
|---|--|
| <p>The Modifier Selection screen displays a list of available modifiers.</p> <p>12. Press the arrow soft keys, move the cursor to the modifier.</p> <p>13. Press  to select.</p> |  |
| <p>When ordered values exceed a hard limit for a selected modifier, a Hard Limit Alert will appear.</p> <p>14. Press the reject order soft key.</p> <p>Make sure the order and modifier selected are correct, and resend the order from the EMR.</p> <p>NOTE: Follow the facility's procedure for managing hard limits observed on the pump.</p> |  |




8.26.7 Auto-Programming in Basic Mode

Auto-programming using the **Spectrum IQ** Infusion System's Basic Mode is available when a scanned medication is not found in the pump's **Dose IQ** Safety Software. Contact pharmacy for updates to the pump's drug library.

The drug, concentration, dose and volume are automatically populated into the **Spectrum IQ** Infusion System's Basic mode from the patient's medication order in the EMR. Drug specific safety limits are not available when auto-programming in Basic Mode.





NOTE: Workflows for auto documentation after programming in Basic Mode may vary depending on EMR vendor.

Table 8-55. To Auto Program in Basic Mode

| Steps | Screens All screen shots are examples only |
|--|--|
| <p>1. See Table 8-48 To associate the Pump to the EMR. Step 1-5 to associate the pump, select the Care Area and scan the pump.</p> | |
| <p>The Order Received screen is displays. It shows that the drug is not found in the pump’s drug library. The drug name and concentration are displayed.</p> <p>2. Press the accept order soft key to continue.</p> <p>NOTE: Press the reject order soft key to cancel and return to the Care Area selection screen.</p> <p>An advisory message displays. Advising that drug-specific safety limits are not available in Basic Mode.</p> <p>3. Press the yes soft key to continue in Basic Mode.</p> |   |
| <p>The Drug Setup screen displays the infusion parameters that are auto-populated from the patient’s medication order. The drug name and concentration are displayed on a gray background showing that the pump is programmed in Basic Mode.</p> <p>4. Make sure that the values are correct.</p> <p>5. Press the accept program soft key.</p> <p>To edit one or more parameters: Press the edit program soft key.</p> |  |

8. Programming the pump





Table 8-55. To Auto Program in Basic Mode

| Steps | Screens All screen shots are examples only |
|--|---|
| <p>The cursor moves to the Total given field.</p> <p>Make sure that all programmed values are correct.</p> <p>6. Press  to begin the infusion.</p> |  |
| <p>The infusion will start and the Check Flow screen is displayed.</p> <p>7. Check the flow and confirm:</p> <ul style="list-style-type: none"> ■ All clamps are open. ■ There are no kinks or collapses in the tubing outside the pump. ■ Drops are flowing in the drip chamber. <p>NOTE: At very low rates, it may take several minutes to see drops.</p> <ul style="list-style-type: none"> ■ Vents are open (when applicable). <p>8. Press the yes soft key when all of the above conditions are confirmed.</p> <p>When no drops are observed, press the no soft key and follow the additional screen instructions. <i>See Table 8-62 Primary Check Flow Trouble Shooting.</i></p> |  |
| <p>The RUN screen displays the dose, rate, VTBI and time remaining in alternating screens.</p> <p>The gray background indicates that the infusion is programmed in Basic Mode.</p> <p><i>See Display Settings, page 5- 12. for RUN screen display options.</i></p> |  |

8.26.8 Auto-Programming Order Error Messages

An **Order Error Message** will appear when an order received from the EMR cannot be auto-populated on the pump.

Table 8-56. Auto- Programming Order Error Message

| Error Message | Condition | Resolution |
|---|--|--|
|  | <p>The drug ordered is not available in the Care Area selected on the pump.</p> <p>This drug is available in another Care Area on the pump.</p> | <ol style="list-style-type: none"> 1. Press  to clear this message. 2. Make sure the Care Area selected on the pump is correct. 3. When not correct, select the correct Care Area and resend order. 4. When correct, proceed to program manually. 5. Contact pharmacy for updates to the pump's drug library. |
|  | <p>A parameter in the drug order does not match the drug library on the pump.</p> <p>This message is specific to the following mismatch parameters:</p> <ul style="list-style-type: none"> ■ Concentration ■ Concentration units ■ Drug amount units ■ Dose rate units | <ol style="list-style-type: none"> 1. Press  to clear this message. 2. Confirm order in the EMR with prescriber/pharmacy. 3. Obtain new order in EMR and resend or proceed to program manually. 4. Contact pharmacy for updates to the pump's drug library. |

8. Programming the pump

Table 8-56. Auto-Programming Order Error Message











| Error Message | Condition | Resolution |
|--|--|--|
|  | <p>A parameter is missing from the drug order received.</p> <p>This message is specific to the following parameters:</p> <ul style="list-style-type: none"> ■ Dose amount ■ Rate ■ Drug Amount ■ Concentration volume ■ VTBI ■ Patient weight ■ Patient BSA | <ol style="list-style-type: none"> 1. Press  to clear this message. 2. Confirm order in the EMR with prescriber/pharmacy. 3. Obtain new order in EMR and resend or proceed to program manually. |
|  | <p>A parameter value received exceeds the hard limit set in the pump's drug library.</p> <p>This message is specific to the following parameters:</p> <ul style="list-style-type: none"> ■ Patient weight ■ Patient BSA ■ Drug amount ■ Dose ■ Rate ■ Infusion time ■ Concentration | <ol style="list-style-type: none"> 1. Press  to clear this message. 2. Confirm order in the EMR with prescriber/pharmacy. 3. Obtain new order in EMR and resend 4. Contact pharmacy for updates to the pump's drug library. |

Table 8-56. Auto- Programming Order Error Message

| Error Message | Condition | Resolution |
|---|--|--|
|  | <p>A parameter value received exceeds the pump's hard limit.</p> <p>This message is specific to the following parameters:</p> <ul style="list-style-type: none"> ■ Patient weight ■ Patient BSA ■ Rate ■ Infusion time ■ VTBI ■ Drug amount ■ Dose ■ Concentration ■ Concentration volume | <ol style="list-style-type: none"> 1. Press  to clear this message. 2. Confirm order in the EMR with prescriber/pharmacy. 3. Obtain new order in EMR and resend. |
|  | <p>An invalid order is received from the EMR that may be caused by a technical system issue.</p> | <ol style="list-style-type: none"> 1. Press  to clear this message. 2. Confirm order in the EMR with prescriber/pharmacy. 3. Resend order from the EMR. 4. When unsuccessful with second attempt, proceed to program manually. |
|  | <p>The order received requires the drug to be delivered as a primary infusion; however the drug is configured as 'secondary only' in the pump's drug library.</p> | <ol style="list-style-type: none"> 1. Press  to clear this message. 2. Confirm order in the EMR with prescriber/pharmacy. 3. Resend order from the EMR or proceed to program manually. 4. Contact pharmacy for updates to the pump's drug library. |

8. Programming the pump

Table 8-56. Auto- Programming Order Error Message



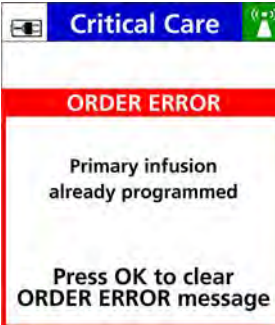

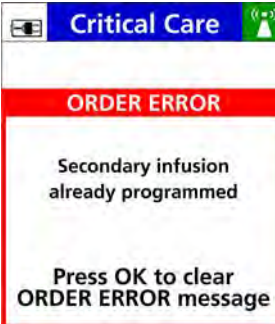

| Error Message | Condition | Resolution |
|---|---|--|
|  | <p>The order received requires the drug to be delivered as a secondary infusion; however the drug is configured as 'primary only' in the pump's drug library.</p> | <ol style="list-style-type: none"> 1. Press  to clear this message. 2. Confirm order in the EMR with prescriber/pharmacy. 3. Resend order from the EMR or proceed to program manually. 4. Contact pharmacy for updates to the pump's drug library. |
|  | <p>A primary infusion is already programmed on the pump. User selects to program a secondary however order received is for a primary infusion.</p> | <ol style="list-style-type: none"> 1. Press  to clear this message. 2. Confirm order in the EMR with prescriber/pharmacy. 3. Resend order from the EMR or proceed to program manually. |
|  | <p>A secondary infusion is already programmed on the pump. User select to program a primary however order received from the EMR is for a secondary infusion.</p> | <ol style="list-style-type: none"> 1. Press  to clear this message. 2. Make sure order in the EMR with prescriber/pharmacy. 3. Resend order from the EMR or proceed to program manually. |

Table 8-56. Auto- Programming Order Error Message







| Error Message | Condition | Resolution |
|---|--|--|
|  | <p>A secondary infusion is already programmed on the pump. A primary infusion order is received; however the primary drug is configured not to allow a secondary infusion with it.</p> | <ol style="list-style-type: none"> 1. Press  to clear this message. 2. Confirm order in the EMR with prescriber/pharmacy. 3. Resend order from the EMR or proceed to program manually. 4. Contact pharmacy for updates to the pump's drug library. |
|  | <p>User attempts to program a new order and order received indicates a rate change; however no infusion is currently programmed.</p> | <ol style="list-style-type: none"> 1. Press  to clear this message. 2. Confirm order in the EMR with prescriber/pharmacy. |
|  | <p>Order received indicates an order update; however update order contains same values as current infusion programmed.</p> | <ol style="list-style-type: none"> 1. Press  to clear this message. 2. Confirm order in the EMR with prescriber/pharmacy. 3. Resend updated order from the EMR. |

Table 8-56. Auto- Programming Order Error Message












| Error Message | Condition | Resolution |
|--|---|---|
|  | <p>Order received indicates an order update; however drug ordered does not match current infusion programmed.</p> | <ol style="list-style-type: none"> 1. Press  to clear this message. 2. Confirm order in the EMR with prescriber/pharmacy. |
|  | <p>Primary infusion is running, user presses the  key and receives a secondary infusion order.</p> | <ol style="list-style-type: none"> 1. Press  to clear this message. 2. Make sure order in the EMR is a secondary infusion. 3. Press . 4. Press program pri/sec soft key. 5. Press program secndry soft key. 6. The barcode screen displays to resend order from the EMR. |

Table 8-56. Auto- Programming Order Error Message

| Error Message | Condition | Resolution |
|--|--|---|
|  | <p>Primary infusion is stopped; user presses the  key and receives a secondary infusion order.</p> | <ol style="list-style-type: none"> 1. Press  to clear this message. 2. Press program pri/sec soft key. 3. Press program secndry soft key. 4. The barcode screen displays to resend order from the EMR. |
|  | <p>An order update is received for an infusion currently programmed:</p> <ul style="list-style-type: none"> ■ in Basic mode. ■ with a valid drug, however a new drug library file has been sent out but not activated on the pump. | <ol style="list-style-type: none"> 1. Press  to clear this message. 2. Proceed to manually program update order. |

8.26.9 Line Check Notification


Line Check notification may be displayed on the pump when initiated from the facility's EMR system.

NOTE: The facility's EMR system may not have this feature.

8. Programming the pump

This feature supports the user in identifying the **Spectrum IQ** Infusion System that is delivering the infusion being checked on the EMR.

Table 8-57. Line Check Notification

| Description | Screen |
|--|---|
| <p>An EMR LINE CHECK feature displays for a running infusion or a Pump Stopped:</p> <p>A running infusion will display LINE CHECK on the top bar with alternating magenta and white background every 500 ms.</p> <p>The Line Check notification will be cleared after:</p> <ul style="list-style-type: none">■ 30 seconds after Line Check screen.■ Press any key.■ Opening the pump door.■ Alarm condition occurs. |  |

8.27 Basic Mode Programming

Basic Mode is a method of programming a continuous infusion when the drug or concentration is not available in the facility's drug library. Drug library limits do not exist.

Basic Mode requires the user to manually specify a dose mode, rate, volume, time or other parameters for the infusion.

Safety features available in Basic Mode are: Patient Weight Limits, Primary Check Flow, Secondary Check Flow and Single Step Rate or Dose Change Limit.

When the pump is running in Basic Mode, "Basic Mode" displays on a gray background in the pump display.

Basic Mode may be accessed by entering BA in the Drug Search screen and selecting Basic from the drug list.

After two unsuccessful attempts at searching for a drug the **not in library** soft key displays.

Pressing the soft key **not in library** enters Basic Mode programming.

CAUTION



Basic Mode Programming Use

Basic Mode programming should only be used when the required drug or concentration is not available in the facility's drug library.

Basic Mode can be programmed with the following methods:

- mL modes (mL/hr, mL/kg/min, mL/kg/hr)
- Dose modes (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)

8. Programming the pump

8.27.1 To Program the pump in Basic Mode with mL/ hr

Table 8-58. To Program the pump in Basic Mode with mL/ hr





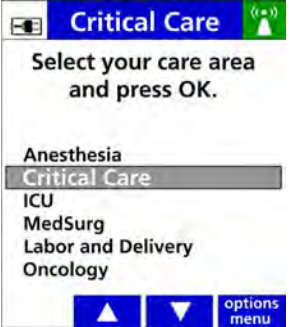
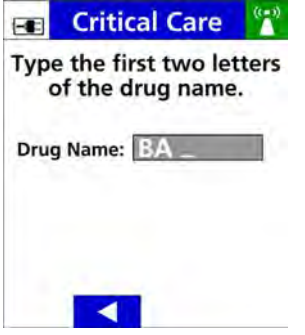


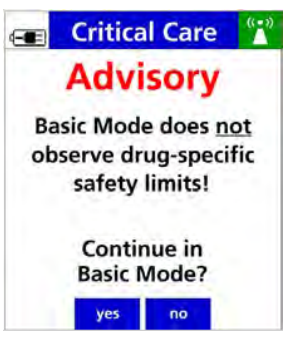

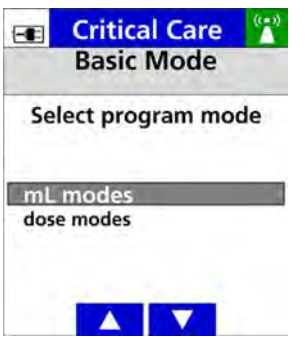
| Steps | Screens All screen shots are examples only |
|--|---|
| <p>1. Press  to power on the pump.</p> |  |
| <p>2. The New Patient or Care Area screen (go to step 4) displays.</p> <p>NOTE: The pump retains previously programmed infusion values up to 24 hours after power off.</p> <p>New Patient screen:</p> <p>3. Press the yes soft key to clear the previously programmed infusion values and go to the Care Area screen.</p> <p>NOTE: When a new drug that is required for the same patient, press the yes soft key. The total given will be reset to zero.</p> <p>Press the no soft key to retain the previously programmed infusion values for the same patient.</p> |  |
| <p>4. Press the arrow soft keys to select the Care Area.</p> <p>5. Press .</p> <p>The Drug Search screen appears.</p> |  |

Table 8-58. To Program the pump in Basic Mode with mL/ hr

| Steps | Screens All screen shots are examples only |
|--|---|
| <p>The Drug Search screen is displayed.</p> <p>6. Press the alphanumeric hard keys and enter the letters BA. B is obtained by pressing the 1 key twice, and A is obtained by pressing the 1 key one time. When an incorrect letter is selected, use the back arrow soft key to clear it and enter the correct letter.</p> |  |
| <p>The Drug Selection screen shows a list of drug names beginning with BA.</p> <p>7. Press the arrow soft keys to move the cursor to the word BASIC</p> <p>8. Press  to select</p> |  |
| <p>An Advisory message shows.</p> <p>This message tells the user that drug-specific limits are not available when programming in Basic Mode.</p> <p>9. Press yes soft key to proceed to Basic Mode.</p> |  |
| <p>The Select program mode screen displays.</p> <p>10. Press the arrow soft keys to move the cursor to mL modes.</p> <p>11. Press  to select.</p> |  |

8. Programming the pump

Table 8-58. To Program the pump in Basic Mode with mL/ hr



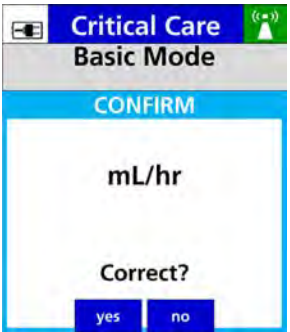











| Steps | Screens All screen shots are examples only |
|--|---|
| <p>The Select mode screen displays.</p> <p>12. Press the arrow soft keys, move the cursor to mL/hr.</p> <p>13. Press  to select.</p> |  |
| <p>The Confirm screen displays the mode selected.</p> <p>14. Press the yes soft key to confirm.</p> |  |
| <p>The Select delivery bag screen displays.</p> <p>15. Press the arrow soft keys to select delivery bag.</p> <p>16. Press  to select.</p> |  |
| <p>The Drug Setup screen displays with the required parameters.</p> <p>The Rate field is highlighted.</p> <p>17. Enter the Rate (mL/hr).</p> <p>18. Press  to confirm.</p> |  |

Table 8-58. To Program the pump in Basic Mode with mL/ hr

| Steps | Screens All screen shots are examples only |
|---|--|
| <p>The cursor moves to the VTBI parameters.</p> <p>19. Entered the VTBI.</p> <p>20. Press  to confirm.</p> |  |
| <p>The cursor moves to the Total given field.</p> <p>21. Press  to begin the infusion.</p> |  |


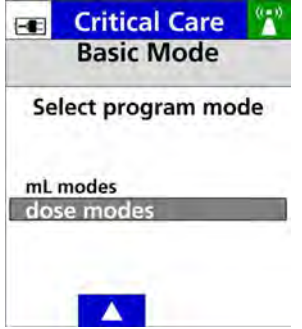

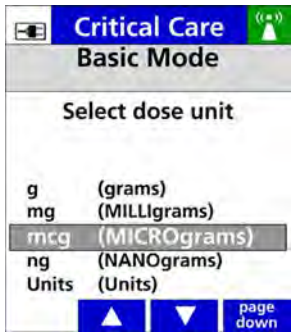


8. Programming the pump

Table 8-58. To Program the pump in Basic Mode with mL/ hr

| Steps | Screens All screen shots are examples only |
|---|---|
| <p>When  is pressed, the infusion will start and the Check Flow screen will be displayed.</p> <p>22. Check the flow and confirm that:</p> <ul style="list-style-type: none"> ■ All clamps are open. ■ There are no kinks or collapses in the tubing outside the pump. ■ Drops are flowing in the drip chamber. <p style="padding-left: 40px;">NOTE: At very low rates, it may take several minutes to see drops.</p> <ul style="list-style-type: none"> ■ Vents are open (when applicable). <p>23. Press the yes soft key if all of the above conditions are confirmed.</p> <p>Press the no soft key if no drops are observed and follow the screen instructions. <i>See Table 8-62 Primary Check Flow Trouble Shooting.</i></p> |  |
| <p>The RUN screen displays the rate, VTBI and time remaining in alternating screens.</p> <p>For RUN screen display options <i>See Display Settings, page 5- 12. .</i></p> |  |

8.27.2 To Program the Pump in Basic Mode with a Dose Mode

Table 8-59. To Program the Pump in Basic Mode with a Dose Mode

| Steps | Screens All screen shots are examples only |
|---|---|
| <p>1. See Table 8-58 To Program the pump in Basic Mode with mL/hr. Steps 1-9</p> | |
| <p>The Select program mode screen displays.</p> <p>2. Press the arrow soft keys, move the cursor to dose modes.</p> <p>3. Press  to select.</p> |  |
| <p>The Select dose unit screen displays.</p> <p>4. Press the arrow soft keys to move the cursor to the dose unit that matches the order.</p> <p>5. Press  to select.</p> <p>Dose unit is the unit of measure for the dose mode.</p> |  |
| <p>The Select weight type entry screen displays.</p> <p>6. Press the arrow soft keys to move the cursor to the weight type that matches the dose mode in the order.</p> <p>7. Press  to select.</p> <p>Examples:</p> <ul style="list-style-type: none"> ■ mcg/kg/min = weight based ■ mg/hr = non-weight based |  |

8. Programming the pump

Table 8-59. To Program the Pump in Basic Mode with a Dose Mode


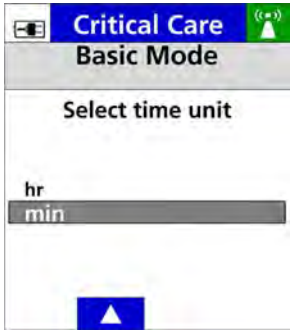
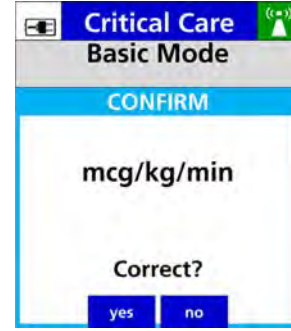

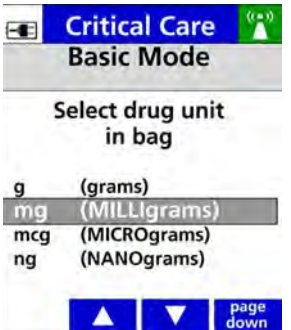

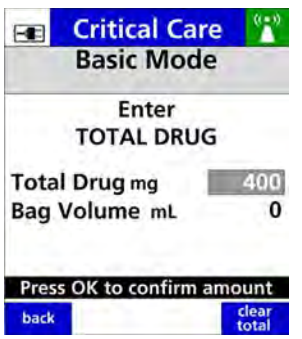


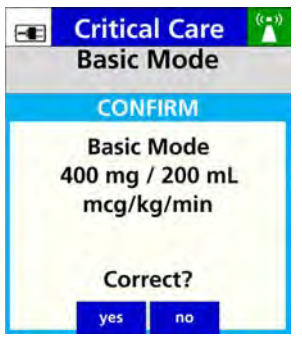





| Steps | Screens All screen shots are examples only |
|--|---|
| <p>The Select time unit screen displays.</p> <p>8. Press the arrow soft keys to move the cursor to the time unit that matches the dose mode in the order.</p> <p>9. Press  to select.</p> <p>Example:</p> <ul style="list-style-type: none"> ■ mcg/kg/min = min |  |
| <p>The Confirm screen displays the dose mode selected.</p> <p>10. Press the yes soft key to confirm the dose mode.</p> <ul style="list-style-type: none"> ■ Press the no soft key to return to the Select dose unit screen. |  |
| <p>The Select drug unit in bag screen displays.</p> <p>This is the unit of measure for the drug amount in the IV bag.</p> <p>11. Press the arrow soft keys, move the cursor to the drug unit.</p> <p>12. Press  to select.</p> |  |

Table 8-59. To Program the Pump in Basic Mode with a Dose Mode

| Steps | Screens All screen shots are examples only |
|--|---|
| <p>The Total Drug amount entry screen displays.</p> <p>13. Enter the Total Drug amount.</p> <p>14. Press  to confirm.</p> |  |
| <p>The Total Bag volume entry screen displays.</p> <p>15. Enter the Total Bag volume.</p> <p>16. Press  to confirm.</p> |  |
| <p>The Confirm screen displays the concentration entered and the dose mode selected.</p> <p>17. Press the yes soft key to confirm.</p> |  |
| <p>The Select delivery bag screen displays.</p> <p>18. Press the arrow soft keys to select delivery bag.</p> <p>19. Press  to select.</p> |  |

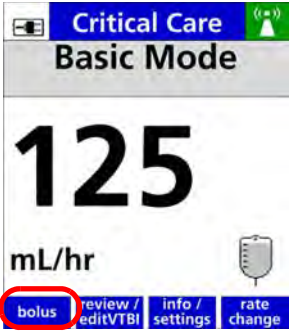
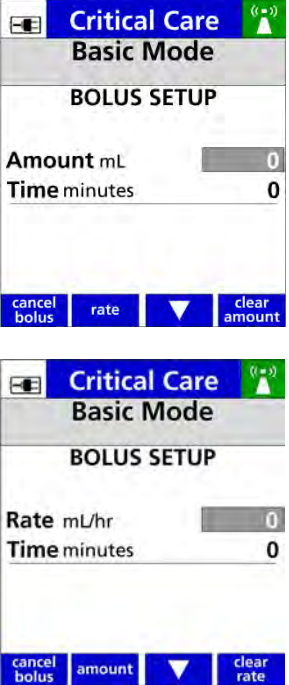
8. Programming the pump

Table 8-59. To Program the Pump in Basic Mode with a Dose Mode

| Steps | Screens All screen shots are examples only |
|---|--|
| <p>The Drug Setup screen displays the required parameters to be entered.</p> <p>20. Enter the required parameters displayed.</p> <p>21. Next, the cursor moves to the Total given field.</p> <p>NOTE: Follow physician and pharmacist orders when entering parameters.</p> <p>22. Press  to begin infusion.</p> |  |
| <p>The Check Flow screen displays.</p> | |
| <p>The RUN screen displays the rate, VTBI and time remaining in alternating screens.</p> <p>For RUN screen display options <i>See Display Settings, page 5- 12.</i></p> |  |

8.27.3 To Program a Bolus Dose in Basic Mode

Table 8-60. To Program a Bolus Dose in Basic Mode

| Steps | Screens All screen shots are examples only |
|---|--|
| <p>The infusion is running in Basic Mode. Press the bolus soft key to program a bolus dose.</p> |  <p>The screenshot shows the 'Critical Care Basic Mode' interface. At the top, it says 'Critical Care Basic Mode'. Below that, a large '125' is displayed, followed by 'mL/hr'. At the bottom, there are four soft keys: 'bolus' (circled in red), 'review / edit VTBI', 'info / settings', and 'rate change'.</p> |
| <p>The Bolus Setup screen displays. Enter the bolus Amount and Time in the fields provided.</p> <ul style="list-style-type: none"> Press the rate soft key to program a bolus using a Bolus Rate (mL/hr) and Time. <p>For additional information on bolus dose programming See <i>Table 8-10 Bolus Dose Programming</i>.</p> |  <p>The top screenshot shows the 'Critical Care Basic Mode' interface with 'BOLUS SETUP' at the top. It has two input fields: 'Amount mL' with a value of '0' and 'Time minutes' with a value of '0'. At the bottom, there are four soft keys: 'cancel bolus', 'rate', a dropdown arrow, and 'clear amount'.</p> <p>The bottom screenshot shows the same interface but with 'Rate mL/hr' as the input field, also with a value of '0'. The soft keys at the bottom are 'cancel bolus', 'amount', a dropdown arrow, and 'clear rate'.</p> |

8. Programming the pump

8.27.4 Programming in Basic Mode Using the Not in the library soft key

Table 8-61. Programming in Basic Mode Using the Not in the library soft key


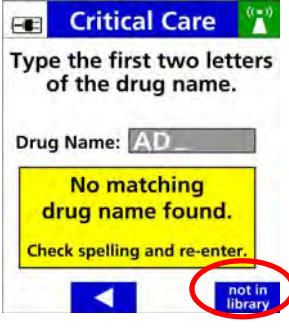
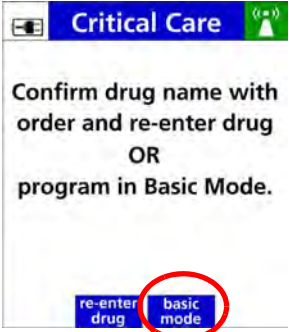


| Steps | Screens All Screens are examples only |
|--|---|
| 1. See Table 8-58 To Program the pump in Basic Mode with mL/hr. Steps 1-9 | |
| <p>The Drug Search screen is displayed.</p> <p>2. Press the alphanumeric hard key(s) to enter the first two letters of the drug name.</p> <p>A pop-up message will appear when there are no matching drug names starting with the first two letters entered.</p> <p>3. Press the back arrow soft key to clear.</p> <p>4. Re-enter the first two letters of the drug name.</p> |  |
| <p>When the second attempt results in no matching drug names found, a not in library soft key displays.</p> <p>5. Press the not in library soft key.</p> |  |
| <p>A confirmation screen displays.</p> <p>6. Press the Basic mode soft key to begin programming in Basic mode.</p> <p>or</p> <p>7. Press the re-enter drug soft key to re-enter the drug name.</p> |  |

Table 8-61. Programing in Basic Mode Using the Not in the library soft key

| Steps | Screens All Screens are examples only |
|--|--|
| <p>An Advisory message displays.</p> <p>It shows that drug-specific limits are not available when programming in Basic mode.</p> <p>8. Press yes soft key to proceed in Basic mode.</p> |  |
| <p>The Select program mode screen displays.</p> <ul style="list-style-type: none"> ■ To program the pump using Basic Mode with mL modes. See <i>Table 8-58 To Program the pump in Basic Mode with mL/ hr.</i> ■ To program the pump using Basic Mode with a dose mode, See <i>Table 8-59 To Program the Pump in Basic Mode with a Dose Mode.</i> |  |

8.28 Check Flow When Starting an Infusion




A Check Flow screen will appear at the start of an infusion to make sure that the infusion is flowing.

A Check Flow screen will not appear for a Care Area with the word Anesthesia (case insensitive) or a Care Area with the word OR (uppercase) in its name.

A Primary Check Flow screen will appear at the start of a primary infusion, and a Secondary Check Flow screen will appear at the start of a secondary infusion.


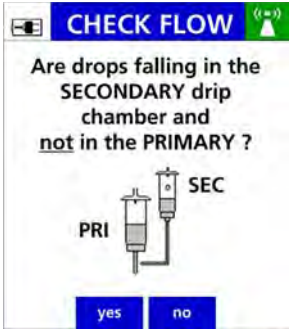
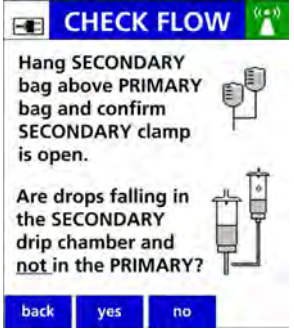
8.28.1 Primary Check Flow Trouble Shooting

Table 8-62. Primary Check Flow Trouble Shooting

| Steps | Screens All screen shots are examples only |
|---|---|
| <p>After pressing , the infusion will start and the Primary Check Flow screen is displayed.</p> <ol style="list-style-type: none"> Check the flow and confirm that: <ul style="list-style-type: none"> All clamps are open. There are no kinks or collapses in the tubing outside the pump. Drops are flowing in the drip chamber. <p>NOTE: At very low rates, it may take several minutes to see drops.</p> <ul style="list-style-type: none"> Vents are open (when applicable). <p>Press the yes soft key when all of the above conditions are met.</p> <ol style="list-style-type: none"> Press the no soft key when no drops are flowing. |  |
| <p>An instructional screen displays requesting the user open all clamps and to check for kinks in the tubing and for clogged catheters.</p> <p>The Primary Check Flow screen displays.</p> |  |

8.28.2 Secondary Check Flow

Table 8-63. Secondary Check Flow Trouble Shooting

| Steps | Screens All screen shots are examples only |
|--|--|
| <p>After pressing , the infusion will start and the Secondary Check Flow screen is displayed.</p> <ol style="list-style-type: none"> Check the flow and confirm that: <ul style="list-style-type: none"> ■ Drops falling in the secondary drip chamber. ■ No drops falling in the primary drip chamber. Press the no soft key when no drops are observed. Press the yes soft key when the above conditions are confirmed. |  |
| <p>A screen displays providing additional instructions for setup of the secondary and primary bags.</p> <ul style="list-style-type: none"> ■ Confirm that the secondary is above the primary. ■ Confirm that all clamps are open on the secondary infusion line. <ol style="list-style-type: none"> Press the yes soft key when drips are observed in secondary drip chamber and not in the primary. Press the no soft key when there are not drops are observed in the secondary drip chamber. <ul style="list-style-type: none"> ■ The Clamp Line screen appears. |  |

8. Programming the pump

Table 8-63. Secondary Check Flow Trouble Shooting








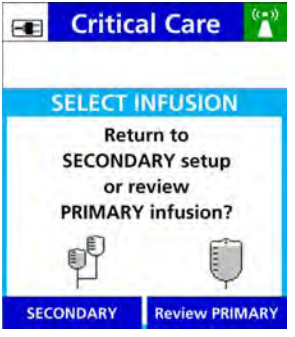




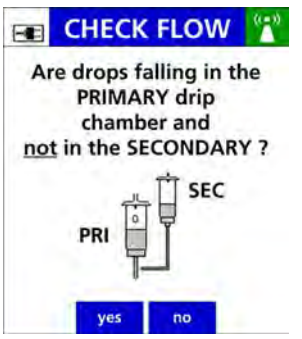
| Steps | Screens All screen shots are examples only |
|--|--|
| <p>The CLAMP LINE screen displays.</p> <p>Providing instructions to apply a clamp to the primary line above the upper Y site.</p> <p>5. Press  to after the primary line is clamped.</p> <p>6. Press  to acknowledge that the secondary callback alarm will appear when the secondary infusion completes.</p> <p>The secondary infusion will continue, and the RUN screen will appear.</p> |   |
| <p>The SECONDARY COMPLETE screen displays when the secondary infusion is complete.</p> <p>7. Press  to stop the infusion.</p> |  |
| <p>The SELECT INFUSION screen is displayed.</p> <p>8. Press the Review PRIMARY soft key to review the primary Setup screen.</p> <p>9. Press  to start the primary infusion.</p> <p>NOTE: To setup another secondary infusion, press the SECONDARY soft key. See Table 8-32 To Program a Secondary Callback.</p> |  |

Table 8-63. Secondary Check Flow Trouble Shooting

| Steps | Screens All screen shots are examples only |
|---|---|
| <p>The REMOVE CLAMP alarm screen displays.</p> <p>10. Remove the clamp from the primary line.</p> <p>11. Press  to confirm that clamp is remove.</p> |  |
| <p>The Primary setup screen is displayed.</p> <p>The “1” watermark indicates that the setup is for the primary infusion.</p> <p>Make sure that all programmed values are correct.</p> <p>12. Press  to start the primary infusion.</p> |  |
| <p>The CHECK FLOW screen displays.</p> <p>Press the yes soft key when drops are flowing in the primary drip chamber.</p> <p>Press the no soft key when no drops are flowing.</p> <p><i>See Table 8-32 To Program a Secondary Callback.</i></p> |  |

8.29 View and Clear the Total Given Volume

The total given volume field displays the volume (mL) that has been delivered for the current programmed infusion(s).

When a secondary infusion is programmed, the total given volume would be the total volume of both primary and secondary infusions delivered.

8. Programming the pump

Record the value of the total given volume when necessary.

This value cannot be recalled after the value has been cleared.

Table 8-64. View And Clear given Volume During Running Infusion






| Steps | Screens All screen shots are examples only |
|---|--|
| <p>At the RUN screen:</p> <ol style="list-style-type: none"> 1. Press the review/edit VTBI soft key from the RUN screen while the infusion is running. |  |
| <p>The Infusion Review screen is displays. Record the value of the Total given volume when required.</p> <ol style="list-style-type: none"> 2. Press the clear total soft key to clear the Total given volume displayed. <p>When cleared, the Primary Infusing screen displays and a pop- up displays that the Total given has been cleared.</p> |  |

Table 8-65. View and Clear Given Volume while infusion is stopped

| Steps | Screens All screen shots are examples only |
|--|--|
| <ol style="list-style-type: none"> Press the  key. Press the program pri/sec soft key. |  |
| <p>The Infusion Review screen is displayed. Record the value of the Total given volume when required.</p> <ol style="list-style-type: none"> Press the clear total soft key to clear the Total given volume displayed. <p>The Total given will display zero.</p> |  |

8.30 Clear Program

A programmed infusion may be cleared during programming setup, or when the infusion stopped.

8. Programming the pump

A primary, secondary or both programs can be cleared.

Table 8-66. Clearing a Program



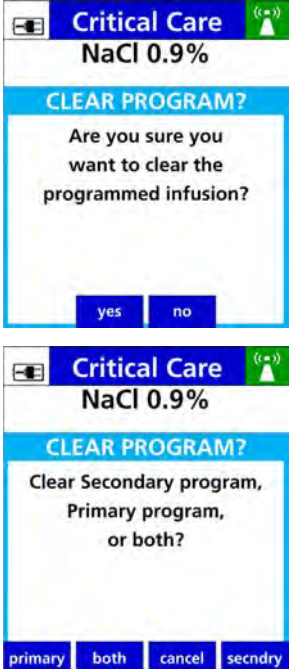
| Steps | Screens All screen shots are examples only |
|---|--|
| <p>From a running infusion:</p> <ol style="list-style-type: none"> 1. Press  key and the Pump Stopped screen displays. 2. Press the clear program soft key. <p>From the Setup screen:</p> <ol style="list-style-type: none"> 1. Press the clear program soft key. |  <p>The top screenshot shows the 'Pump Stopped' screen. At the top, it says 'Critical Care' and 'NaCl 0.9%'. Below that, 'Pump Stopped' is displayed in large text. A soft key bar at the bottom contains 'bolus', 'program pri / sec', 'info / settings', and 'clear program' (circled in red).</p> <p>The bottom screenshot shows the 'Setup' screen. At the top, it says 'Critical Care' and 'NaCl 0.9%'. Below that, 'Primary Bag' is displayed. The screen shows 'Rate mL/hr' at 125, 'VTBI mL' at 0, and 'Time hr:min' at 00:00. At the bottom, it shows 'Total given mL' at 0. A soft key bar at the very bottom contains 'clear program', an up arrow, a down arrow, and 'clear VTBI'.</p> |

Table 8-66. Clearing a Program

| Steps | Screens All screen shots are examples only |
|--|---|
| <p>The Clear Program? confirmation screen displays.</p> <p>Primary Only:</p> <p>Press the yes soft key to clear the programmed infusion.</p> <p>Press the no soft key to keep the infusion and go back to the Set Up or Pump Stopped screen.</p> <p>Primary and secondary infusions that are programmed press the:</p> <ul style="list-style-type: none"> ■ primary soft key to clear the primary infusion only. ■ secndry soft key to clear the secondary infusion only. ■ both soft key to clear both infusions. ■ cancel soft key to keep all infusions programmed and go back to the Set Up or Pump Stopped screen. |  <p>The top screenshot shows a confirmation screen titled "CLEAR PROGRAM?" with the question "Are you sure you want to clear the programmed infusion?" and two soft keys: "yes" and "no".</p> <p>The bottom screenshot shows a confirmation screen titled "CLEAR PROGRAM?" with the question "Clear Secondary program, Primary program, or both?" and four soft keys: "primary", "both", "cancel", and "secndry".</p> |

8.31 Placing the Pump in Standby Mode (Hold)

A programmed infusion can be placed on standby (hold) for a specified time set in the alarm settings. *See Alarm Settings, page 5- 9.*

Inactivity Alarm will occur when no action is taken when the standby time has expired.

8. Programming the pump






Press  at any time when the pump is in standby mode to start the pump. Any key pressed when the pump is in standby mode will cancel the standby mode.

Table 8-67. Placing the Pump in Standby Mode

| Steps | Screens All screen shots are examples only |
|--|---|
| <p>After programming the pump the:</p> <p>Total given field is highlighted gray.</p> <p>The hold soft key displays.</p> <ol style="list-style-type: none"> Press the hold soft key to place the pump in standby mode. |  |
| <p>A pop-up screen displays every two (2) seconds to show the pump is on standby.</p> <p>The Alarm Settings can be programmed with a hold time <i>See Alarm Settings, page 5- 9.</i></p> <p>The time will be displayed in the pop- up.</p> <p>An indefinite hold time will show a dashed line in the pop- up.</p> <ol style="list-style-type: none"> Press  at any time while the pump is in standby mode to start the pump. <p>Any other key pressed while the pump is in standby mode will cancel the standby mode.</p> <p>Inactivity Alarm will occur when no action is taken within two (2) minutes after the stand by has expired.</p> |   |

8.32 Keypad Lock

The keypad lock code is the default key code or a unique number to the facility that is configured in the drug library.

The keypad icon will be in the title bar when the keypad is locked. *See Figure 8-3 Keypad locked Icon.*

Locking the keypad prevents unauthorized access of specific key entries.

They keypad may be locked in two ways:

- **Manually**- by entering the keypad lock code.
- **Automatically**- by enabling the Auto Keypad Lock feature in the drug library.



Figure 8-3. Keypad locked Icon

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.

8. Programming the pump

Table 8-68. Automatic Keypad Lock




| Description | Screen |
|--|---|
| <p>Automatic Keypad Lock is configured by the Care Area in the Drug Library.</p> <p>The keypad locks automatically 60 Seconds after the  key is pressed.</p> <ul style="list-style-type: none"> A key icon is displays above the battery/AC power icon. <p>NOTE: The review soft key is available to view the infusion setup screen. All other keys are disabled.</p> <p>To unlock the keypad, enter the keypad lock code using the numeric keypad.</p> |  |

Table 8-69. Manual Keypad Lock

| Description | Screen |
|---|---|
| <p>From the RUN screen:</p> <ol style="list-style-type: none"> Enter the keypad lock code using the numeric keypad. <ul style="list-style-type: none"> A pop up message displays to confirm that the keypad is locked. A key icon is displays above the battery/AC power icon. <p>NOTE: The review soft key is available to view the infusion setup screen. All other keys are disabled.</p> To unlock the keypad, enter the keypad lock code using the numeric keypad. |  |

8.33 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 can receive a new drug library any time the pump is on and connected to the network, or when Sleep Mode is enabled in Dose IQ Safety Software and the pump is on or off with a 25% or greater battery level charge. Pump does not need to be plugged in.

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.

The drug library will be placed in the queued position while an infusion is running. If the pump is turned on, or not running, it automatically activates the 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.

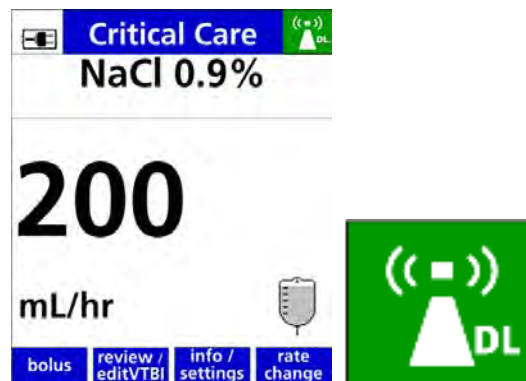


Figure 8-4. Queued drug library

8. Programming the pump

Table 8-70. To see, or activate, the new queued library that is available from the Infusion Running screen

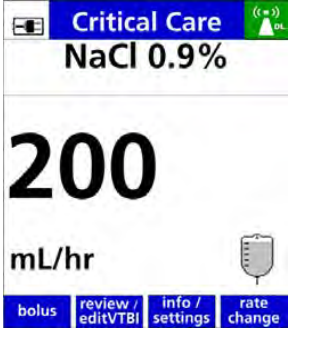



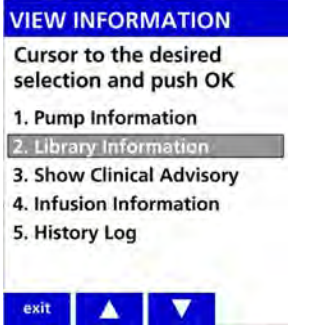



| Description | Screen |
|--|---|
| <p>1. Press the info/settings soft key.</p> |  |
| <p>The User Options menu is displayed.</p> <p>2. Press the arrow soft keys to select View Information.</p> <p>3. Press .</p> |  |
| <p>The View Information menu is displayed.</p> <p>4. Press the arrow soft keys to select Library Information.</p> <p>5. Press .</p> |  |

Table 8-70. To see, or activate, the new queued library that is available from the Infusion Running screen

| Description | Screen |
|--|--|
| <p>The Library Information screen displays the current active drug library information and the queued (new) drug library that is ready to be activated.</p> <p>6. Press exit to return to the RUN screen.</p> |  |
| <p>7. Press the Clear Program soft key to clear the infusion when the current infusion is complete or discontinued, and activate the queued drug library.</p> | |
| <p>The Update Drug Lib screen displays. That shows the new drug library is active.</p> <p>8. Press  to continue.</p> |  |

Alarms

| Topic | Page |
|--|------|
| Alarms | 9-1 |
| Secondary Alarm Management Systems | 9-4 |
| Alarm Priority | 9-5 |
| Troubleshooting Alarm Causes | 9-31 |
| Managing Bolus Before Occlusion (Downstream) Release | 9-32 |
| Battery Warning Levels | 9-32 |

9.1 Alarms

The **Spectrum IQ** Infusion System will display alarms when specific conditions exist.

The alarms are an audio tone and/or an alarm message displayed on the pump screen.

The message states the reason for the alarm and contains instructions for clearing the alarm.

When multiple alarm conditions occur simultaneously, the system communicates the highest priority alarm condition per the table below. (Lowest number takes priority, alarms with the same number are at the same priority level and cannot occur simultaneously).

When an Alarm cannot be cleared, the pump must be serviced by a Baxter-trained biomed, or returned to Baxter for service.

Table 9-1. Alarm Priority

| Alarm | Priority |
|-----------------------------|----------|
| 1. SYSTEM ERROR | HIGH |
| 2. DEPLETED BATTERY | HIGH |
| 3. IMPROPER SHUTDOWN | HIGH |

9. Alarms

Table 9-1. Alarm Priority

| Alarm | Priority |
|---|-----------------|
| 3. DOOR NOT FULLY LATCHED | HIGH |
| 3. LOAD SET SEQUENCING | HIGH |
| 3. RE-LOAD SET | HIGH |
| 3. CLOSE CLAMP RELOAD SET | HIGH |
| 3. DOOR OPEN WHILE PUMP IS RUNNING | HIGH |
| 3. SLIDE CLAMP DETECTED | HIGH |
| 3. INSERT SLIDE CLAMP | HIGH |
| 3. REMOVE PRIMARY CLAMP | HIGH |
| 3. INFUSION COMPLETE | HIGH |
| 3. SECONDARY COMPLETE | HIGH |
| 3. DOWNSTREAM OCCLUSION | HIGH |
| 3. UPSTREAM OCCLUSION | HIGH |
| 3. AIR IN LINE | HIGH |
| 3. AIR STILL DETECTED | HIGH |
| 3. MAX AIR DETECTED | HIGH |
| 3. VALUE ENTRY TIME OUT | HIGH |
| 4. REMOVE CLAMP | MEDIUM |
| 5. VERY LOW BATTERY | MEDIUM |
| 6. BATTERY MISSING | MEDIUM |
| 7. CHECK BATTERY | MEDIUM |
| 8. CLOSE DOOR TO POWER OFF | LOW |
| 9. LOW BATTERY | LOW |
| 10. BAG NEAR EMPTY | LOW |
| 10. INACTIVITY | LOW |
| 10. UNABLE TO RUN | LOW |

WARNING**Audio Alarm**

Make sure that audio alarm volumes on the pump are at a level that can be heard over the ambient noise in the facility.

Do not use different alarm presets for the same or similar equipment in any single area.

Failure to have the proper audio can result in an alarm not being attended to in a timely manner and can result in death or serious injury.

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.

**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.

For full list of alarms and trouble shooting see Spectrum IQ Infusion System Installation and Maintenance Manual (P/N 41019v0900, 41019v0900FRE).

NOTE: All alarms associated with the **Spectrum IQ** Infusion System are classified as “technical”. No physiological alarms are generated by this device.

9.1.1 Escalating Alarm Volume

An alarm that is not acknowledged within two minutes will result in an increase in volume.


The alarm volume will increase to the next volume level.

The alarm will continue until the maximum volume is reached, unless otherwise specified.

9.1.2 Pausing an Alarm Tone

Press the silence soft key or any key on the keypad to pause the audio tone for two (2) minutes.

After two minutes the alarm tone will resume.

Pressing the  key will cause the pump to shut down.

9.1.3 Clearing an Alarm

To clear an alarm, follow the prompts and instructions in the alarm message.

The alarm clears after the alarm condition has been corrected and all of the prompts and instructions have been followed.

Resolve the alarm per the instructions on the screen to clear the alarm and pause the audio tone.

9.1.4 Clinician Alert Tone

The Clinician Alert Tone will occur if an action is not accepted or needs confirmation during programming the pump.

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

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

9.1.5 Back up Alarm

A unique alarm tone, separate from high, medium and low priority alarm tones, will be observed in the event either:

- Power from both the AC mains and the Wireless Battery Module (WBM) are removed when the pump is turned on.
- Failure of the WBM occurs when no AC mains power is connected and the pump is turned on.

9.2 Secondary Alarm Management Systems

Third party secondary alarm management systems are intended to serve as a parallel, redundant, forwarding mechanism of pump alarms to a designated display device in real time. These systems are intended to be used as a secondary alarm.

They do not replace direct monitoring and management of alarms on the infusion pumps.

The Secondary Alarm System (Alerts & Alarms Routing feature) sends Alarm Start and Stop messages from registered wireless connected infusion pumps to the Network Host (Gateway Server), which then translates those messages and routes them to a 3rd party Alarms Management system for further distribution to Alarm Reporting devices.

The pump's Wireless Battery Module (WBM) provides these alerts and alarm status messages in response to queries to it, or broadcasts them when they occur.

Due to potential delays and interference inherent in wireless communication, the Secondary Alarm System is not to be used as a replacement for direct bedside viewing of the state of the infusion pump or clinical observation of the patient.

9.3 Alarm Priority

High priority alarms require immediate operator response. High priority alarms are indicated by a flashing red alarm bar at the top of the pump screen. Infusion stops for a high priority alarm. *See Figure 9-1 High priority alarm.*



Figure 9-1. High priority alarm

Medium priority alarms require prompt operator response. Medium priority alarms are indicated by a flashing yellow bar at the top of the pump screen. *See Figure 9-2 Medium priority alarm.*



Figure 9-2. Medium priority alarm

Low priority alarms are conditions where operator awareness is required. Low priority alarms are indicated by a yellow bar at the top of the pump screen. *See Figure 9-3 Low priority alarm.*



Figure 9-3. Low priority alarm

High Priority Alarm Messages

Air in line

Air has been detected in the loaded administration set. Infusion has stopped. *See Figure 9-4 Air in line Alarm.*



Figure 9-4. Air in line Alarm

To resolve AIR IN LINE ALARM


NOTE: ALWAYS make sure that all clamps are closed before opening the door and unloading the IV set from the pump to prevent free flow.

1. Close the roller clamp to prevent free flow.
2. Open the door to assess the IV set for air by:
 - Check the tubing in the tubing channel for the presence of air.
 - Check the tubing above and below the pump for the presence of air.
 - Check for an upstream occlusion from kinks in the tubing and closed clamps.
 - Make sure that the IV line is free of air and kinks.
3. Unload the IV set to remove the air if necessary.
 - Follow facility policy and procedures to remove the air manually.
4. Reload the IV set per instruction on the screen.
5. Close the pump door.

If air is no longer detected by the pump, the **Continue Infusion** screen appears. See *Figure 9-5 Continue Infusion Screen*.



Figure 9-5. Continue Infusion Screen

6. Open the slide clamp and roller clamp.
7. Press  to resume infusion.

Air Still Detected

When the pump door is closed after an Air-in-Line alarm and air is detected in the loaded administration. See *Figure 9-6 Air Still Detected*.




Figure 9-6. Air Still Detected

To resolve Air Still Detected

NOTE: ALWAYS make sure that all clamps are closed before opening the door and unloading the IV set from the pump to prevent free flow.


1. Close the roller clamp to prevent free flow.

9. Alarms

2. Open the door to assess the IV set for air by:
 - Check the tubing in the tubing channel for the presence of air.
 - Check the tubing above and below the pump for the presence of air.
 - Check for an upstream occlusion from kinks in the tubing and closed clamps.
 - Make sure that the IV line is free of air and kinks.
3. Unload the IV set to remove the air if necessary.
 - Follow facility policy and procedures to remove the air manually.
4. Reload the IV set per instruction on the screen.
5. Close the pump door.
6. Confirm the IV line has been assessed.
7. Open the slide clamp and roller clamp.
8. Press  to resume the infusion.

OR

To continue the infusion:

1. Press the confirm soft key. The **Continue Infusion** screen appears.
2. Press  to continue the infusion.

If using multiple pumps:

NOTE: Confirm correct IV line when checking for the presence of air.

NOTE: If IV line removal is required, confirm correct IV line before removing IV line to assess for air.

WARNING



Priming

Do not use an unprimed infusion administration set.

Failure to fully prime an infusion administration set can result in accidental air infusion, causing serious injury or death.

Follow proper procedures for priming the administration set and removing air.

Max Air Detected Alarm

The pump will alarm when approximately 1 mL of accumulated air has been detected in 15 minutes. See *Figure 9-7 Max Air Detected*.




Figure 9-7. Max Air Detected

To resolve Max Air Detected:

NOTE: ALWAYS ensure that all clamps are closed before opening the door and unloading the IV set from the pump to prevent free flow.

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. Close all clamps 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.

If air is no longer detected by the pump, the **Continue Infusion** screen appears.

1. Confirm that the line has been assessed.
2. Open the slide clamp and roller clamp.
3. Press  to resume the infusion.

Clean Load Point #2

Displays when the pump detects foreign matter in the tubing channel at Load Point 2. *See Figure 9-8 Clean Load Point #2.*



Figure 9-8. Clean Load Point #2

To resolve Clean Load #2:

1. Close the roller clamp to prevent free flow.
2. Open the door.
3. Remove the IV set.
4. Look for debris or foreign matter at Load Point 2. *See Figure 9-9 Load Point 2.*

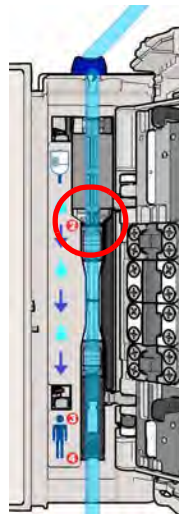


Figure 9-9. Load Point 2

5. Remove debris and clean the tubing channel.
6. See *Cleaning the Spectrum IQ Infusion System and Battery Module*, page 10- 2.

NOTE: Return the pump for service to qualified personnel in the facility when alarm does not clear or repeats.

Close Door

When the administration set is successfully loaded the pump will prompt the user to close the pump door. See *Figure 9-10 Close Door Alarm*.



Figure 9-10. Close Door Alarm

To resolve Close Door:

1. Close the Pump door by pressing the top and bottom of the door.
2. Use the indents on the door as a guide. See *Figure 7-5 Proper door closing*.

Door Not Fully Latched

The pump door is open while an IV tube is loaded in the tubing channel. *See Figure 9-11 Door Not Fully Latched.*



Figure 9-11. Door Not Fully Latched

To resolve Door Not Fully Latched Alarm:

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 door by pressing the top and bottom of the door.

NOTE: Use the indents on the door as a guide *See Loading an IV Set, page 7- 6.*

Door Open

The pump door is open while an IV tube is loaded in the tubing channel. See *Table 9-12 Door Open*.



Figure 9-12. Door Open

To resolve Door Open:

1. Close the roller clamp.
2. Close the door or unload the tubing.

NOTE: Unload the tubing by pulling it out and up from the bottom of the pump towards the top. See *Unloading an IV Set*, page 7- 12.

Downstream Occlusion Alarm

Displays when the pump detects an occlusion below the pump. The infusion is stopped. See *Figure 9-13 Downstream Occlusion*.

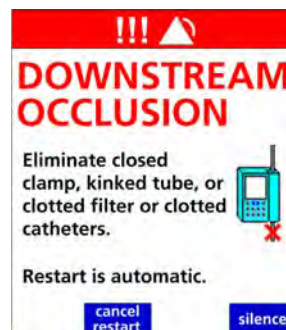


Figure 9-13. Downstream Occlusion



9. Alarms



To resolve Downstream Occlusion Alarm:

1. Assess the IV tubing below the pump.
2. Assess the IV access site.
3. Eliminate any 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.

NOTE: Auto-restart must be enabled for the Care Area.

To cancel auto-restart and start manually:

1. Press the **cancel restart** soft key.
2. Assess the IV access site.
3. Eliminate a closed clamp, kinked tubing, positional catheter, clotted catheter, clogged IV filter or other source of occlusion below the pump.
4. Press  and then  to restart the infusion.

NOTE: If the occlusion has been eliminated and “Press  then press ” does not appear on the screen, clear the alarm by closing the roller clamp and reloading the set.

Reset Setting

The downstream occlusion pressure limit setting was changed on the pump from the default setting. *See Alarm Settings, page 5- 9.*

See DS Pressure Limit (Downstream Occlusion Pressure Limit) on page 5-6, when the clear program is pressed to clear current program, a RESET SETTING screen appears. *See Figure 9-14 Reset setting.*



Figure 9-14. Reset setting

1. Press **yes** soft key to reset setting back to the care area default setting.
2. Press **no** soft key to retain current settings.

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.

See Appendix D Downstream Occlusion on page D- 1.

Infusion Complete (KVO) Alarm

Displays when the primary infusion has been completed (VTBI reaches zero) and the infusion has started running at the KVO (Keep Vein Open) rate.


9. Alarms

The KVO rate running is either the configured KVO rate in the drug library or the current infusion rate, whichever is lower. See *Figure 9-15 Infusion Complete (KVO)*.



Figure 9-15. Infusion Complete (KVO)

To resolve Infusion Complete (KVO) Alarm:

1. Press  to stop the KVO infusion.
 - The Set Up screen displays.
 2. Continue infusion as prescribed.
-

Reload Set

Displays when the pump door is closed and the IV tube has not been loaded in the correct or in all the load points within the tubing channel. See *Figure 9-16 Reload Set*.

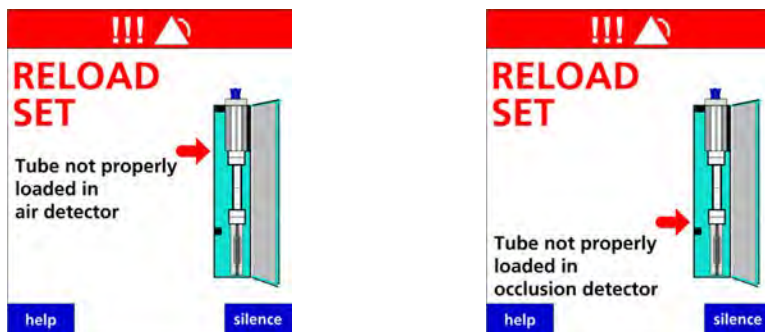


Figure 9-16. Reload Set

To resolve Reload set:

1. See *Loading an IV Set*, page 7- 6.
-

Remove Primary Clamp

Displays when a Secondary infusion has complete.The review **PRIMARY** soft key is pressed after a secondary infusion has been completed with the primary line clamped See *Figure 9-17 Remove Primary Clamp*.



Figure 9-17. Remove Primary Clamp

To resolve Remove Primary Clamp:

1. Remove the clamp from the primary line.
2. Press to confirm clamp is removed.


Secondary Infusion Complete

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. See *Figure 9-18 Secondary Infusion Complete*.



Figure 9-18. Secondary Infusion Complete

To resolve Secondary Infusion Complete:

1. Press  to stop the KVO infusion.
 - The **Set up** screen displays.
 2. Continue infusion as prescribed.
-

Slide Clamp Detected



Displays when the pump detects a slide clamp in the keyhole after  has been pressed. See *Figure 9-19 Slide Clamp Detected*.



Figure 9-19. Slide Clamp Detected

To resolve Slide Clamp Detected:

1. Remove slide clamp from the keyhole.
2. Press .

 - If slide clamp not present in keyhole and the alarm occurs, inspect for debris.

NOTE: An alarm that re-occurs: send the pump for service to qualified personnel.


Upstream Occlusion Alarm

Displays when the pump detects an occlusion above the pump. *See Figure 9-20 Upstream Occlusion Alarm.*



Figure 9-20. Upstream Occlusion Alarm

To eliminate the occlusion or flow restriction:

1. Check and open any or all of the following:
 - slide clamp.
 - burette vent.
 - vent on drip chambers with rigid or semi rigid containers.
2. Check and eliminate kinked or collapsed IV tubing outside the pump.
3. Verify that the occlusion has been eliminated.
4. Press  to start the infusion.
5. Verify that the drop rate is consistent with the programmed rate.

If unable to locate an occlusion, *See Troubleshooting Alarm Causes, page 9- 31.*

Suspension of the Upstream Occlusion Alarm

When enabled in the drug library for the selected drug, the user has the option to temporarily suspend the upstream occlusion alarm for this drug if the occlusion assessed was considered to be a false alarm.

The suspension prompt appears when the check flow is confirmed after two consecutive upstream occlusion alarms.

See Figure 9-21 Suspend all Upstream Occlusion alarm.



Figure 9-21. Suspend all Upstream Occlusion alarm

1. Press **yes** to suspend the alarm.
 - The **RUN** screen will display the suspension Icon. See Figure 9-22 Icon for Upstream Occlusion Suspension.

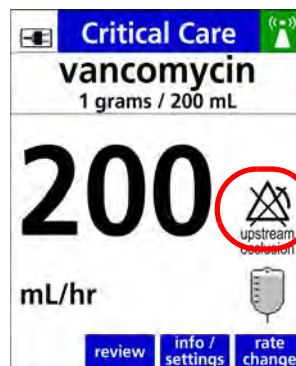



Figure 9-22. Icon for Upstream Occlusion Suspension

The upstream occlusion alarm will be re-enabled automatically when:

-  is pressed.
- The door is opened.
- The infusion transitions from secondary to primary.
- Any alarm condition that stops the pump.

- The pump is powered **OFF** and then back **ON**.

WARNING



Time to Upstream Occlusion at Lower Flow Rates

Time to detect an upstream occlusion may be extended if infusing at flow rates below 5 mL/hr and decreasing to 1 mL/hr. At 1 mL/hr, time to detect upstream occlusion may extend up to 7 hours. Make sure that:

- 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).



Proper Venting Required

Do not use sets with non-vented drip chambers or rigid containers with improperly functioning vents.

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, resulting in serious injury or death.

Use only properly vented drip chambers or properly vented rigid containers.

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.

Ensure 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.

Use of the Spectrum IQ Infusion System outside the environmental limits, noted in Appendix A as “Operational Conditions” might cause performance issues with the Spectrum IQ 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.

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.

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.

Time to detect an upstream occlusion may be extended if infusing at flow rates below 5 mL/hr. At 1 mL/hr, time to detect upstream occlusion may extend up to 7 hours

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).

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.




Value Entry Timeout

Displays when entered value is not confirmed within ten seconds of entering value. The previous value is restored.



Figure 9-23. Value Entry Time Out

To resolve a Value Entry Time Out:

1. Press  to dismiss alarm.
 2. Re-enter Value.
 3. Press  to Confirm.
 4. Press  to begin new value entered.
-

Clock Battery Low

Displays when the real-time (internal coin cell battery) clock (RTC) battery is low *See Figure 9-24 Clock Battery Low.*



Figure 9-24. Clock Battery Low

To resolve a Clock Battery Low Alarm:

1. Return the pump to Baxter for service.
-



Close Clamp Reload Set

Displays when an IV set is loaded into the pump before the pump has completely powered on and clamp is not inserted into the keyhole. *See Figure 9-25 Close Clamp Reload Set.*



Figure 9-25. Close Clamp Reload Set

To resolve a Close Clamp Reload Set:

1. Unload the IV set.
2. Press  to power off the pump.
3. Press  to power on the pump.
4. After the pump has completely powered on, reload the IV set. *See Loading an IV Set, page 7-6.*


Improper Shutdown

Displays when data is lost from the previously programmed infusion.



Figure 9-26. Improper Shutdown

To resolve Improper Shutdown:

1. Press  to clear the message.
2. Re-program the infusion, if needed.

WARNING



Improper Shutdown

In the event of an improper shutdown, Pump will generate an **IMPROPER SHUTDOWN** alarm when subsequently powered on and will require reprogramming of infusion parameters.

An improper shutdown occurs when the pump is unexpectedly shutdown occurs due to total power loss.

System Error

Displays when the pump detects an internal fault.

NOTE: See Spectrum IQ Infusion System Installation and Maintenance Manual (P/N 41019v0900, 41019v0900FRE) for list of all system errors.



Figure 9-27. Numeric system error (example only)


To resolve a system error:

NOTE: Record the programming parameters before the pump is powered off.

Follow the directions on the screen:

-
1. Power off the pump.
 2. Power on the pump.

Should an audio alarm occur with no direction on the screen:

1. Disconnect the battery module from the pump
2. Unplug the AC Power Adaptor from the AC outlet.
3. Wait approximately 5 or more seconds.
4. Reconnect the battery module.
5. Plug the AC Power Adaptor into an AC power outlet.
6. Press .

7. If neither procedure clears the error return the pump 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.

Medium Priority Alarms

Battery Missing

Displays when the pump does not detect an installed battery module. *See Figure 9-28 Battery Missing.*

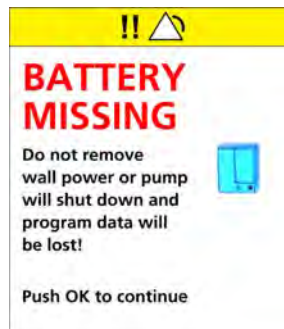



Figure 9-28. Battery Missing

To resolve a Battery Missing Alarm:

1. Confirm battery module is installed.
2. Latch battery into place.
3. Press  to continue.

Low Priority Alarm

Bag near Empty

Displays when there is less than or equal to 30 minutes of the programmed infusion time remaining in the currently programmed infusion. *See Figure 9-29 Bag Near Empty.*

NOTE: This alarm is configurable in the **Dose IQ** Safety Software, and is available for primary continuous infusions.

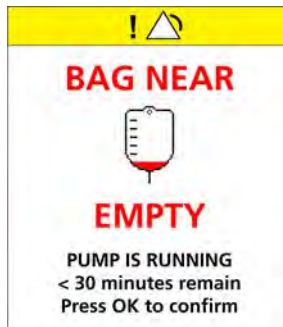



Figure 9-29. Bag Near Empty

To Resolve Bag Near Empty Alarm:

1. Press  to acknowledge and clear the alarm.
-

Inactivity Alarm

Displays when the pump has been inactive for 2 minutes and no action has been taken. See *Figure 9-30 Inactivity Alarm*.




Figure 9-30. Inactivity Alarm

To Resolve Inactivity Alarm:

1. Press any key to pause the alarm.
2. Continue infusion entry.

Unable to Run

When the  key is pressed and:

- An administration set is not loaded.
- Infusion parameters are not confirmed.
- Secondary infusion is started with no primary infusion programmed.

See Figure 9-31 *Unable to Run*.



Figure 9-31. Unable to Run

To resolve a Unable to Run alarm:

1. Press any key to dismiss.
2. Complete the actions on screen to continue with infusion.

9.4 Troubleshooting Alarm Causes

Check the following items to prevent alarms:

- Use only compatible IV sets as labeled and identified on the **Spectrum IQ** Infusion System. See *Compatible IV Sets*, page 11- 1.
- 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.
 - This prevents 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 to fill line.
- 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 module charge.
- Use the medium or high Downstream (DS) Occlusion Pressure Limit setting at flow rate settings above 500 mL/hr to avoid downstream occlusion alarms that are created by IV set pulsation.

9.5 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.


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

WARNING



Low Battery

Do not transport a patient using the pump on battery power when the battery icon is red.

Make sure the pump battery is fully charged when transporting a patient during therapy.

Low Battery

Displays when the low battery alarm threshold is reached. Prior to 30 minutes of battery power remaining. See Figure 9-32 Low Battery.



Figure 9-32. Low Battery

To resolve Low Battery Alarm:

1. Plug the AC Power Adaptor into an AC outlet to recharge the Battery Module.

NOTE: The Low Battery alarm appears prior to 30 minutes of battery power remaining.

The pump sounds a triple-beep audio alarm every 5 seconds.

Press  to temporarily suspend this alarm.

The suspended Low Battery Alarm:

- Shows the status of the battery displays in the alert bar.

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- Every 5 minutes an audible alarm is made. to remind the user of the Low Battery status.

The alarm volume increases and the troubleshooting tutorial automatically begin when the pump is not plugged in or the alarm is not acknowledged after 2 minutes.

Very Low Battery

The Very Low Battery alert displays when the battery has a minimum of 15 minutes of runtime remaining. *See Figure 9-33 Very Low Battery.*

In a Very Low Battery Alarm state

- The Very Low Battery message flashes.
- The back light dims to reduce battery usage.



Figure 9-33. Very Low Battery

To resolve a Very Low battery:

1. Plug the AC Power Adaptor in immediately.
2. The tutorial to check the AC Power Adaptor will automatically begin.

The pump sounds a triple-beep audio alarm every 5 seconds.

Press to temporarily suspend this alarm.

The suspended Very Low Battery Alarm:

- Shows the status of the battery displays in the alert bar.

- Every 5 minutes an audible alarm is made to remind the user of the Very Low Battery status.
 - The alarm volume increases and the troubleshooting tutorial automatically begin when the pump is not plugged in or the alarm is not acknowledged after two (2) minutes.

Battery Depleted

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

The Battery Depleted alarm displays when battery level is fully depleted and 3 minutes of power remain.

In a Battery Depleted Alarm state:

- The alarm changes to a high Priority alarm.
- The Battery Depleted.
- The pump has stopped running and will shut off in 3 minutes if not plugged into a power outlet.

Displays when the battery module is fully depleted and unable to power the pump. *See Figure 9-34 Battery Depleted.*



Figure 9-34. Battery Depleted

To resolve Battery Depleted Alarm:

1. Change the wireless battery module out with a fully charged battery.
- or
2. Plug the pump's AC power adaptor into an AC outlet.
 3. Confirm that the adaptor's power cord connector is attached to the pump.

10

Cleaning and Storage

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10.1 Cleaning and Storage

The **Spectrum IQ** 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 the 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 or buzzer vent) or severe damage may occur.
- Do not spray solutions directly onto 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 the exposed terminals of the battery packs.
- Do not immerse any part of the pump or battery in cleaning agents or other liquids.
- 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.

10.2 Compatible Cleaners

The list of compatible cleaning materials is in the Resource section of the Baxter website (www.spectrumIQ.com/resources.html), or call Baxter Technical Support at 800.356.3454.

10.2.1 Cleaning the Spectrum IQ Infusion System and Battery Module

Refer to the facility's protocol for the frequency of cleaning the pump.

Tools Needed

- Gloves (or facility-required Personal Protective Equipment (PPE)).

- Compatible cleaning solution. *See Compatible Cleaners, page 10- 2.*
- Lint-free cloth - to clean.
- Lint-free towel - to dry.
- Lint-free, foam tipped swab (do not use a cotton swab).
- Slide clamp.
- Soft Brush.

10.2.2 Before Cleaning the Pump, Battery Module or Components

- Power off the pump before cleaning the pump or any components.
 - Unplug the AC Power Adaptor from the power source.
 - Remove the battery module. (set aside for cleaning).

NOTE: Remove the battery module to ensure proper cleaning of the battery terminals and prevent any power from being applied to pump circuitry while liquid cleaning solution is present, which may cause corrosion.

- Do not use rigid cleaning instruments.
- Do not spray solutions directly on the pump and its accessories.
- Visually Inspect the Pump, battery module and components for damage.
 - Damage includes but is not limited to: cracks, cuts or dents.

NOTE: Do not use damaged equipment. Send to Biomed for repair.

- Sensors can be damaged if cleaning is not performed in a careful manner.
- Prior to performing any maintenance on the Pump, read each maintenance procedure completely.

10.2.3 Cleaning the Pump

To clean the front and sides of the pump:

1. Remove the pole clamp from the back of the pump.
 - Loosen the thumb screw on the pump side adaptor (back of the pump).
 - Slide the pump off of the pole clamp.
2. Place the pump in an upright position (keyhole assembly upward).
3. Apply the compatible cleaning agent to a lint-free cloth.

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NOTE: Use dilution ratio per the cleaning agent's manufacturer's instructions.

NOTE: Do not spray solutions directly onto the pump.

4. Wring out any excess cleaning solution from the lint-free cloth.

NOTE: Make sure the cloth is damp, not dripping. This prevents fluid from seeping into component areas of the pump.

5. Wipe down the front and sides 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. A minimum of two wipes will be required to keep the surface visibly wet for the duration of the contact time.

6. Wipe the pump dry and allow to fully air-dry.

To clean the Tubing Channel:

7. Open the Pump's door using a compatible IV set's slide clamp.

NOTE: If the Keyhole requires cleaning, this must be done by a Baxter-trained technician.

8. Visually inspect the tubing channel.
9. Remove any foreign material. An obstruction in the tubing channel could cause free flow.
10. Wipe down the surface of the door and the tubing channel area.
11. Apply cleaning solution to a lint-free, foam tipped swab (do not use a cotton swab).
12. Blot the swab onto a dry lint-free towel to remove excess cleaning solution.
13. Carefully swab down the tubing channel.

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

NOTE: Do not allow cleaning fluids to seep into or between the pump components.

14. Allow the tubing channel to air dry.

To clean the back for the pump.

NOTE: Do not contact the battery gasket with the cleaning swab.

NOTE: Do not allow moisture to permeate the terminal pins.

15. 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.
16. Wipe down the speaker vent, the buzzer vent, and the battery pocket.
17. Using the swab, carefully wipe battery terminal pins.

NOTE: Make sure the drainage channel in the battery pocket is clean and clear of any debris.

18. Allow the back of the pump to air dry.

Drying the pump:

NOTE: Keep the pump powered off, the AC Power Adaptor unplugged from a power source, and the battery module off the pump until all cleaning liquids have completely evaporated from the entire pump.

19. Allow the pump to air dry.
20. Allow additional drying time when in a cold or humid environment.
21. Allow the cleaning liquids to completely evaporate from the pump.
22. Allow time for fluids that may have seeped into or between pump components to dry.

WARNING



Proper Disposal Required

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

10.2.4 Cleaning the Battery Module

To clean the battery module:

1. Remove the Battery Module from the pump.
2. Apply the compatible cleaning agent to a lint-free cloth.

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

NOTE: Use dilution ratio per the cleaning agent's manufacturer's instructions.

3. Wring out any excess cleaning solution from the lint-free cloth.

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4. Make sure the cloth is damp, not dripping. This prevents fluid from seeping into component areas of the battery module.
5. Disinfectants should remain on the module's surface in an even, but not dripping, film for the recommended contact time for the compatible cleaning agents. A minimum of two wipes will be required to keep the surface visibly wet for the duration of the contact time.
6. Wipe the casing of the battery module.
7. Carefully inspect and clean any debris from around the battery terminals.
8. Wipe the battery terminal pins with a damp cloth. Use care to avoid damaging the pins.
9. Blot dry the battery terminal pins with a dry cloth.
10. Allow the Battery Module to completely air dry before replacing on the pump.
11. Dispose of all cleaning materials as required per facility protocol/biohazard policy. The **Spectrum IQ** Infusion System will display alarms when specific conditions exist.

10.2.5 Cleaning the Power Adaptor

To clean the AC power Adaptor:

1. Power off the pump.
2. Unplug the AC Power Adaptor from the power source.
3. Using a screwdriver, remove the DC connector cover
4. Unscrew the retaining nut to disconnect the AC power adaptor connector from the pump
5. Grasp the four-pin power connector by the connector body and remove it by pulling it straight from the back of the pump. Do not pull on the power cord.
6. Visually inspect the AC Power Adaptor for damage to the:
 - AC Power Adaptor Module
 - AC Power Cord
 - AC Power Cord Adaptor Retainer

NOTE: Damage included but is not limited to: cracks, bent prongs, cuts or exposed wires or dents.

NOTE: Do not use a damaged AC Power Adaptor. Send a damaged AC Power Adaptor to a technician for repair or replacement.

7. Apply the compatible cleaning agent to a lint-free cloth.

NOTE: Do not spray solutions directly on the AC adaptor.

NOTE: Use dilution ratio per the cleaning agent's manufacturer's instructions.

8. Wring out any excess cleaning solution from the lint-free cloth.
9. Wrap the cloth on the AC Power Adaptor cord and clean the full length of the cord.
10. Wipe the power cord housing and the connector.
11. Wipe the AC Power Adaptor pins. Use care to avoid bending or damaging the pins.
12. Allow the AC Power Adaptor to air dry thoroughly.

NOTE: Make sure the AC Power Adaptor is completely dry.

13. Align the pins and screw on the retaining nut to connect the AC power adaptor connector to the pump.
14. Using a screwdriver, attach the DC connector cover.
15. Connect the AC Power Adaptor to the pump. Plug the AC Power Adaptor into a working wall outlet.
16. Verify that a plug icon appears on the pump's display, indicating that the pump has detected AC power.
17. Dispose of all cleaning materials as required per facility protocol/biohazard policy.

10.2.6 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.
3. Slide the pump off of the pole clamp.
4. Turn the mounting knob counter clockwise to remove the pole clamp from the IV pole.
5. Apply cleaning agent to a dampened cloth per the manufacturer's instructions.

NOTE: Use dilution ratio per the cleaning agent's manufacturer's instructions.

6. Wipe the entire pole clamp including the screw mechanism.
7. Use a soft brush to clear debris from the screw mechanism.
8. Air dry the pole clamp thoroughly before replacing it onto the pump.
9. Dispose of all cleaning materials as required per facility protocol/biohazard policy.

10.2.7 Pump Handling, Transport and Storage

- Do not handle, transport or store pumps in a manner in which any heavy or sharp objects could impact the keypad.
- Use care when handling, transporting and storing pumps to prevent physical damage.

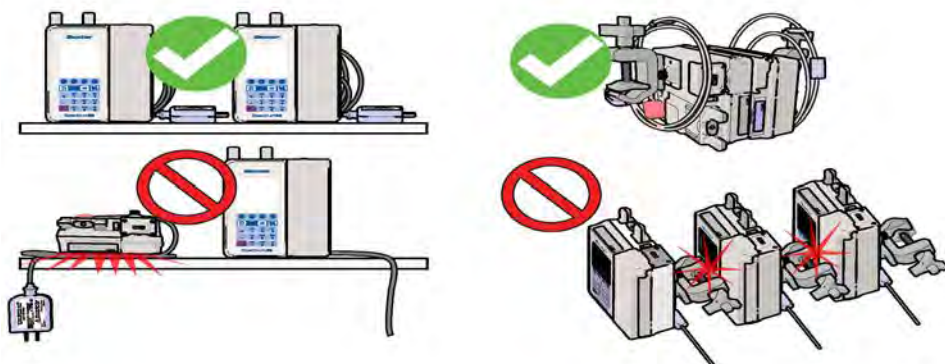


Figure 10-1. Pump Handling, Transport and Storage

11

Compatible IV Sets

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| Compatible Baxter IV Sets | 11-1 |

11.1 Compatible Baxter IV Sets

The **Spectrum IQ** Infusion System is designed to operate with compatible standard gravity IV sets. Refer to the Resource section of the Baxter website at www.spectrumIQ.com/resources.html for a list of compatible IV sets, or call Baxter Technical Support at 800.356.3454.

12

Accessories

| Topic | Page |
|---------------------------|-------------|
| List of Accessories | 12-1 |

12.1 List of Accessories

Table 12-1. List of Accessories

| Baxter Part Numbers | Description |
|----------------------------|--|
| 2M0811 | 4 Pump Vertical Carrier |
| 2M0812 | 6 Pump Vertical Carrier |
| 2M0814 | 3 Pump Horizontal Carrier With Handle |
| 2M0815 | 4 Pump Horizontal Carrier With Handle |
| 2M0811CA | 4 Pump Vertical Carrier for Canada |
| 2M0812CA | 6 Pump Vertical Carrier for Canada |
| 2M0814CA | 3 Pump Horizontal Carrier With Handle for Canada |
| 2M0815CA | 4 Pump Horizontal Carrier With Handle for Canada |



Specifications

| Topic | Page |
|-------------------------------|------|
| Drug Library | A-1 |
| Pump Specifications | A-2 |

A.1 Drug Library

The **Dose IQ** Safety Software is a Microsoft Windows based software program that is used to configure a facility-specific drug library. The software generates a drug library file that is transferred to a **Spectrum IQ** Infusion System.

The development of a drug library is the first step in implementing a Dose Error Reduction System (DERS) to be used with the **Spectrum IQ** Infusion System.

The drug library includes pharmaceutical drugs, blood and blood products, and fluids. Each drug record is associated with one or more Care Areas, and includes a Drug Name and Concentration, Delivery Mode, Delivery Bag, Dose Mode, and Upper and Lower (Hard and Soft) Limits.

Care Areas are a method of grouping drugs usually associated with a specific hospital area, unit or patient population. Settings for a Care Area include patient weight and BSA limits, EMR integration, downstream occlusion pressure setting, enable/disable mL/hr programming, and priming volume adjustment.

A.1.1 Drug Library Transfer

The Drug Library Transfer allows the user to:

- Transfer the drug library using a wireless network connection to a pump.
- Transfer the drug library from the PC directly to a pump using Infrared Data Association (IrDA).

A.1.2 Standard Gravity IV Sets

The **Spectrum IQ** Infusion System uses standard gravity IV sets from Baxter. *See Compatible IV Sets, page 11- 1.*

A.1.3 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 802.11a, IEEE 802.11b, IEEE 802.11g, IEEE 802.11n

A.2 Pump Specifications

Table A-1. Pump Specifications

| Specification | Description |
|-------------------------|--|
| AC Power Adaptor | AC Power Adaptor, low profile, covers only one outlet, Medical Grade (EN60601-1-2:2014): <ul style="list-style-type: none">■ Input (P/N 30205): 100-240 VAC, 50 / 60 Hz / 300 mA Max■ Output (P/N 30205): 9 VDC/1000 mA, short circuit protected■ Cord length 3.0 m (approximately 9.75 ft) Use only Baxter P/N 30205. |
| Alarm Volume | setup (three levels: high, medium and low). For more detail, <i>See Default Settings, page H- 1.</i> |
| Alarm Tone | Alarm tones available are: <ul style="list-style-type: none">■ Classic Tones■ Modern Tones |

Table A-1. Pump Specifications

| Specification | Description |
|-------------------------------------|--|
| <p>Alarms and Alerts</p> | <ul style="list-style-type: none"> ■ Air In Line: dual-beam ultrasonic detector alarms for large bubbles but allows smaller bubbles to pass. ■ • Detects air bubbles >1 in (approximately 140 µL based on a nominal tubing ID of 0.103" for normal (72 ±2°F) temperatures) ■ • Detects >1 mL of accumulated air over 15 min, at normal (72 ±2°F) and hot (90±2°F) temperatures. ■ • Detects >1.5 mL of accumulated air over 15 min, at cold (60 ±2°F) temperatures. <p style="margin-left: 40px;">NOTE: Air bubbles >= 50 µL are counted towards accumulated air. Air bubbles < 10 µL are excluded towards accumulated air. When detected, air bubbles < 50 µL and > 10 µL are counted as 50 µL towards accumulated air. This algorithm was tested using 35 µL air bubbles.</p> <ul style="list-style-type: none"> ■ 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 ±27 kPa (6 ±4 psi) – Medium, 89 kPa ±41 kPa (13 ±6 psi) – High, 131 kPa ±62 kPa (19 ±9 psi) ■ Very Low Battery: ≤15 minutes of battery power remaining. ■ Due for inspection: Preventive Maintenance and/or Network Certification. |
| <p>Anti-Free-Flow System</p> | <p>Set based, utilizing IV set slide clamp.</p> |

Table A-1. Pump Specifications

| Specification | Description |
|---|---|
| <p>Battery Power and Capacity</p> | <p>802.11a/b/g/n WBM</p> <ul style="list-style-type: none"> ■ Lithium Ion, 7.4 VDC nominal. Baxter P/N 35223 and P/N 36010 ■ 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 and Wi- Fi on) ■ Capacity 3.1 hrs (at 999 mL/hr at highest backlight setting on and Wi-Fi on) ■ 16 hr. recharge time at 22.2°C ±1.1°C (72°F ±2°F) ■ Charging occurs if AC Power Adaptor is plugged in, whether the pump is on or off |
| <p>Display</p> | <p>Color LCD</p> |
| <p>Device Classification</p> | <p>The Spectrum IQ Infusion System is classified according to Medical Electrical Equipment standards as:</p> <p>Class II Equipment Type CF Applied Part</p> <p>NOTE: Applied part is IV Administration Set</p> <p>Continuous Operation</p> <p>Disinfect according to Cleaning and Storage on page 277.</p> <p>Not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.</p> <p>IPX2 - Water protection (offers protection from dripping water when the device is rotated 15 degrees any direction from vertical for at least 10 minutes.</p> |
| <p>Dose Modes: Continuous Infusion</p> | <p>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</p> |

Table A-1. Pump Specifications

| Specification | Description |
|---|--|
| 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 |
| Conversion Factor | <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).</p> <p>To calculate rate from an entered dose, the following formulas are applied:</p> <ul style="list-style-type: none"> ■ General: $\text{Rate} = \frac{\text{Dose}}{\text{Concentration}}$ ■ Weight based $\text{Rate} = \frac{\text{Dose} \times \text{Patient Weight}}{\text{Concentration}}$ <p>To calculate dose from an entered rate, the following formulas are applied:</p> <ul style="list-style-type: none"> ■ General $\text{Dose} = \text{Rate} \times \text{Concentration}$ ■ Weight based: $\text{Dose} = \frac{\text{Rate} \times \text{Concentration}}{\text{Patient Weight}}$ ■ To calculate rate from an entered volume to be infused and entered time of infusion, the following formula is applied: $\text{Rate} = \frac{\text{Volume to be Infused}}{\text{Time of Infusion}}$ |
| External Interfaces | IrDA (SIR Encoding Protocol) |

Table A-1. Pump Specifications

| Specification | Description |
|--------------------------------|--|
| 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, Amount/Time (Primary and Secondary), and Volume/Time |
| 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.</p> <p>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 or the infusion rate (if lower than 1mL/hr).</p> |
| 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 style="margin-left: 40px;">NOTE: 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 displays system errors and drug limit violation events in red font on the pump screen. ■ In case of the Spectrum IQ Infusion System being powered down the pump history log will be maintained and a time stamp will be added to the log recording the beginning and end of the down time. ■ After a total loss of power the contents of the log will not be lost. ■ Minimum 4,500 Event Log Capacity. <p style="margin-left: 40px;">NOTE: 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> |

Table A-1. Pump Specifications

| Specification | Description |
|--|---|
| <p>Low-Flow Continuity</p> | <p>The maximum period of no-flow is 90 seconds at a flow rate of 0.5 mL/hr.</p> <p>The maximum period of no-flow is 90 seconds with a bolus volume that does not exceed 15 µL over a 5 second sample volume interval at a flow rate of 0.5-1.0 mL/hr inclusive.</p> |
| <p>Maximum Allowable pressure while in downstream occlusion</p> | <p>207 kPa (30 psi)</p> |
| <p>Downstream Occlusion Pressure</p> | <p>Adjustable</p> <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) |
| <p>Operational Conditions</p> | <p>With 802.11a/b/g/n WBM</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. Atmospheric Pressure: 66kPa to 102kPa <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <p style="text-align: center; background-color: #0056b3; color: white; margin: 0;">WARNING</p> <p>Environmental Limits</p> <p>Do not use the Spectrum IQ Infusion System outside the specified environmental limits.</p> <p>Operating the pump outside of appropriate environmental conditions can cause the pump to fail, resulting in serious injury or death.</p> <p>See the Operational Conditions section of the manual for specific environmental operating conditions.</p> </div> |
| <p>Storage and Packing Conditions</p> | <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 |

Table A-1. Pump Specifications

| Specification | Description | | | | | | |
|-----------------------------------|--|------|----------|-----------------|------------|-----------------|-----|
| Overall Size (Pump) | <p>With Wireless Battery Module</p> <ul style="list-style-type: none"> ■ Without IV pole clamp: <ul style="list-style-type: none"> – Height 18.4 cm (7.4 in) – Width 13.7 cm (5.2 in) – Depth 8.673cm (3.3 in) ■ With IV pole clamp: <ul style="list-style-type: none"> – Height 19.1 cm (7.4 in) – Width 19.7 cm (7.7 in) – Depth 14.0 cm (5.5 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 Spectrum IQ Infusion System, which stops the pump motor and results in an alarm) | | | | | | |
| Timekeeping | <p>Real Time Clock, battery-backed, 7-year life</p> <p>NOTE: Clock is set to GMT.</p> | | | | | | |
| 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 (DEHP) | <p>Accuracy is based on volume collected over one hour using compatible Baxter DEHP 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 <i>Compatible IV Sets, page 11- 1.</i></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% | | | | | | |

Table A-1. Pump Specifications

| Specification | Description | | | | | | | | | |
|---------------------------------------|---|------------|----------|------------|----------------|------|----------|-----------------|------|---------|
| Volumetric Accuracy (non-DEHP) | <p>Accuracy is based on volume collected over one hour using compatible Baxter non- DEHP Standard IV Sets.</p> <table border="1" data-bbox="691 453 1385 611"> <thead> <tr> <th data-bbox="691 453 922 506">Rate</th> <th data-bbox="922 453 1153 506">Accuracy</th> <th data-bbox="1153 453 1385 506">Tubing use</th> </tr> </thead> <tbody> <tr> <td data-bbox="691 506 922 558">10 -125 mL/ hr</td> <td data-bbox="922 506 1153 558">±10%</td> <td data-bbox="1153 506 1385 558">≤ 36 hrs</td> </tr> <tr> <td data-bbox="691 558 922 611">126- 250 mL/ hr</td> <td data-bbox="922 558 1153 611">±10%</td> <td data-bbox="1153 558 1385 611">≤ 4 hrs</td> </tr> </tbody> </table> <p><i>See Compatible IV Sets, page 11- 1.</i></p> | Rate | Accuracy | Tubing use | 10 -125 mL/ hr | ±10% | ≤ 36 hrs | 126- 250 mL/ hr | ±10% | ≤ 4 hrs |
| Rate | Accuracy | Tubing use | | | | | | | | |
| 10 -125 mL/ hr | ±10% | ≤ 36 hrs | | | | | | | | |
| 126- 250 mL/ hr | ±10% | ≤ 4 hrs | | | | | | | | |
| Weight | <p>Wireless Battery Module = 155.19g Pump alone (no WBM or pole clamp) = 861.97g Pump with Wireless Battery Module</p> <ul style="list-style-type: none"> ■ Without IV pole clamp: 1.235 kg (45.6 oz ± 1.0 oz) ■ With IV pole clamp: 1.462 kg (51.6 oz ±1.0 oz) | | | | | | | | | |

Table A-1. Pump Specifications

| Specification | Description |
|-----------------------------------|--|
| Wireless Network Interface | 802.11a/b/g/n WBM, Baxter P/N 35223 or P/N 36010 <ul style="list-style-type: none"> ■ Frequency: 2.4 Ghz, 5.0 Ghz ■ Standard: IEEE 802.11a, IEEE 802.11b, IEEE 802.11g, IEEE 802.11n ■ Typical Transmit Power: <ul style="list-style-type: none"> – 12 dBm @ 1 Mbps – 12 dBm @ 11 Mbps – 12 dBm @ 6 Mbps – 12 dBm @ 54 Mbps |
| Wireless Security | WEP (Wired Equivalent Privacy) <ul style="list-style-type: none"> ■ Encryption: 64/128-bit (RC4) WPA/WPA2/802.11i <ul style="list-style-type: none"> ■ Encryption: TKIP, CCMP (AES) Wireless Security <ul style="list-style-type: none"> ■ WPA-PSK ■ WPA2-PSK ■ 802.1X authentication <ul style="list-style-type: none"> – LEAP (WEP only) – PEAP/MSCHAPv2 – EAP-FAST – EAP-TLS – EAP-TTLS/PAP – EAP-TTLS/MSCHAPv2 |

B

Flow Rate

| Topic | Page |
|---|------|
| Effect of Fluid Container Height | B-1 |
| Effect of Back Pressure | B-2 |
| Effect of High Viscosity Fluids | B-3 |
| Flow Profile | B-3 |
| Standard Conditions | B-3 |
| Baxter Administration Set Accuracy Graphs | B-5 |

B.1 Effect of Fluid Container Height

The performance of the **Spectrum IQ** Infusion System is influenced by the forces of gravity on the fluid being administered to the patient.

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) 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).

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

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

- 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%.

B.2 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 nominal accuracy by -10%. Negative back pressure of -100 mmHg may increase flow rate, causing a deviation in nominal accuracy of 10% in Baxter IV Sets.

WARNING



Abide by the Warnings and flow rate settings for Baxter IV Sets as indicated per the Compatible IV Sets List and compatible set labeling. Refer to the Resource section of the Baxter website at www.spectrumIQ.com/resources.html or call Baxter Technical Support at 800.356.3454 for the Compatible IV Sets List.



Low Flow Rate Accuracy/Continuity

At flow rates of 1.9 mL/hr or below, flow rate accuracy is +/- 0.1 mL/hr. When higher accuracy is required, consider an alternate infusion device.



Flow Rate Inaccuracy

Rate accuracy can be affected by variations in head height, back pressure or any combination thereof. Fluid viscosity and ambient temperature contribute to this variation. 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.
- Using any set outside of its specifically labeled flow rate range, set change interval, operational environment range, or other labeled parameters.

B.3 Effect of High Viscosity Fluids

When infusing, with high viscosity fluids, flow rate accuracy may be affected. For example, when delivering Parenteral Nutrition (Amino Acid with Dextrose solution) in Cyclic TPN mode, flow accuracy may deviate from nominal accuracy by up to 5% as compared to a lower viscosity fluid, such as Normal Saline, delivered in a continuous infusion where nominal accuracy is maintained.

B.4 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, page B- 5.*

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.

B.5 Standard Conditions

- Ambient Temperature: 22.2°C ±1.1°C (72°F ±2°F)
- Fluid Temperature: 22.2°C ±1.1°C (72°F ±2°F)
- Solution Container Head Height: 610 ± 51 mm (24 in. ± 2 in.)
- Test Solution: Deionized Water, ISO Class III

B. Flow Rate

- Distal Positive Pressure (Back pressure): 0 mmHg
- Needle: 18 Gauge or equivalent as per IEC 60601-2-24: 2012 Clause 201.12.1.102

Set Type: Compatible DEHP IV set, or equivalent. For a list of compatible IV sets, *See Compatible IV Sets, page 11- 1.*

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 **Spectrum IQ** 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 **Spectrum IQ** 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 **Spectrum IQ** Infusion System for short- and long-term operation.

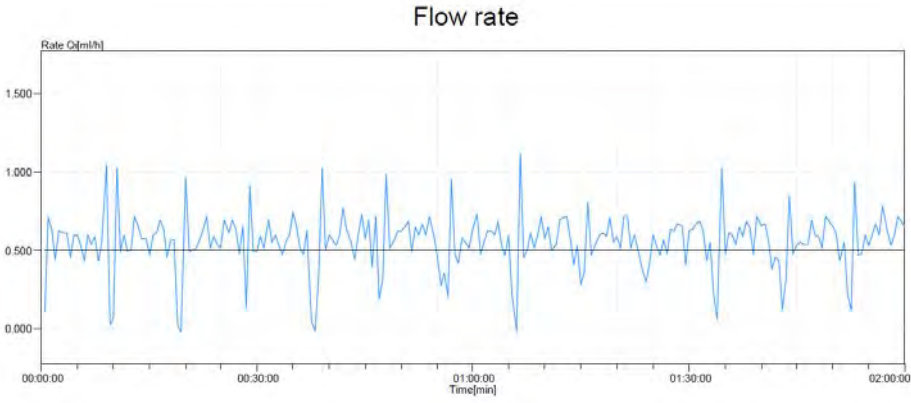
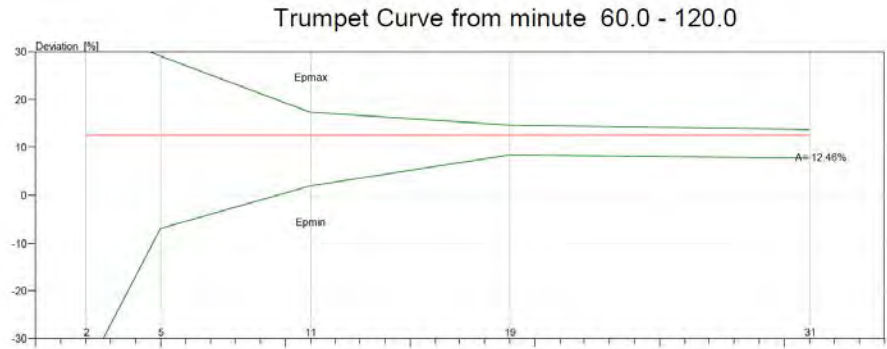
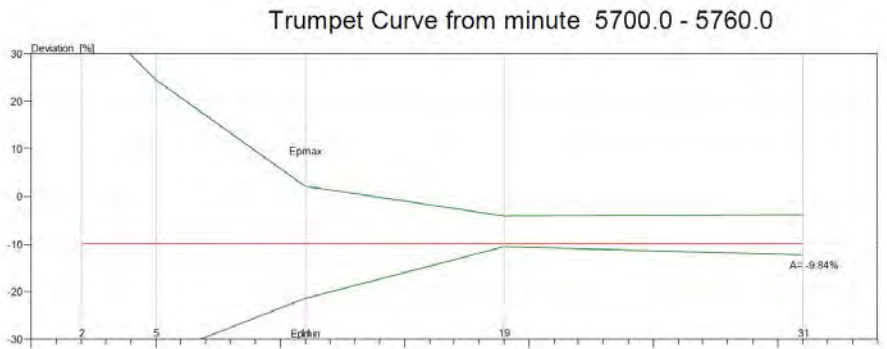
Data has been acquired through the testing of one pump equipped with one administration set.

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 0.5 mL/hr (minimum selectable rate), 1 mL/hr (minimum rate as defined by standard), 25 mL/hr (intermediate rate as defined by standard) and 999 mL/hr (maximum selectable rate) for the Spectrum IQ Infusion System.

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

B.6 Baxter Administration Set Accuracy Graphs

Table B-1. Accuracy Tests

| Description | Graph |
|--|---|
| <p>Start Up Curve 0.5mL/hr (1st 2hrs) SET:1C8109s</p> |  <p style="text-align: center;">Flow rate</p> |
| <p>Trumpet Curve 0.5mL/hr (2nd Hr) SET: 1C8109s</p> |  <p style="text-align: center;">Trumpet Curve from minute 60.0 - 120.0</p> |
| <p>Trumpet Curve 0.5mL/hr (96th hr) SET:1C8109s</p> |  <p style="text-align: center;">Trumpet Curve from minute 5700.0 - 5760.0</p> |

B. Flow Rate

Table B-1. Accuracy Tests (continued)

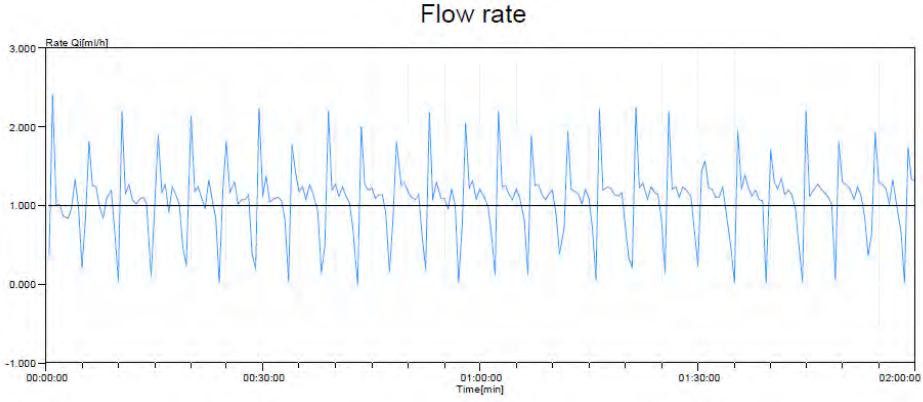
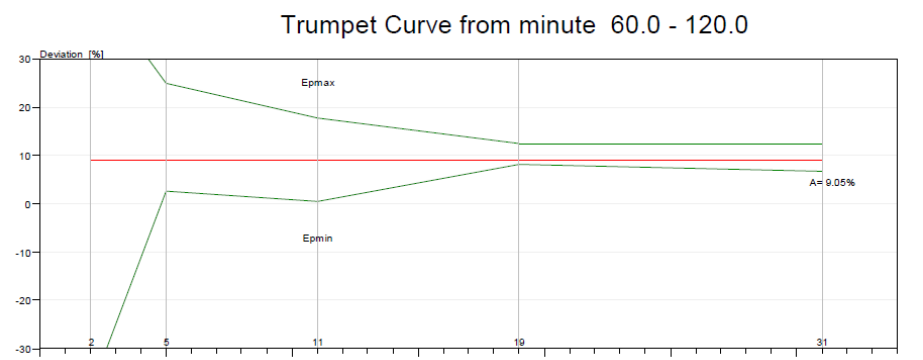
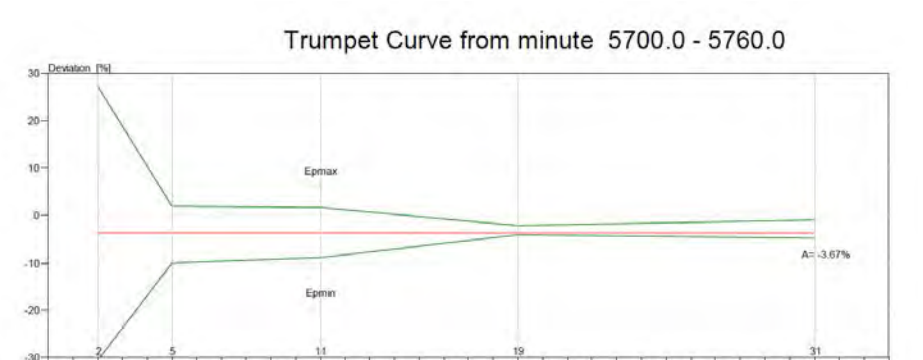
| Description | Graph |
|---|---|
| <p>Start Up Curve 1mL/hr (1st 2hrs) SET: 1C8109s</p> |  <p style="text-align: center;">Flow rate</p> |
| <p>Trumpet Curve 1mL/hr (2nd hr) SET: 1C8109s</p> |  <p style="text-align: center;">Trumpet Curve from minute 60.0 - 120.0</p> |
| <p>Trumpet curve 1mL/hr (96th hr) SET: 1C8109s</p> |  <p style="text-align: center;">Trumpet Curve from minute 5700.0 - 5760.0</p> |

Table B-1. Accuracy Tests (continued)

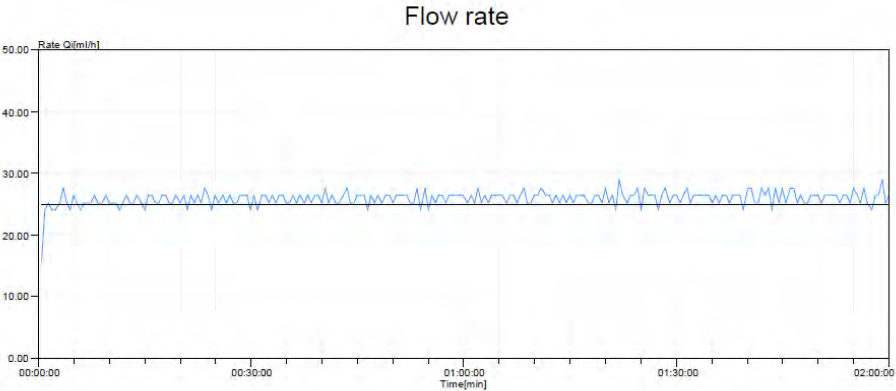
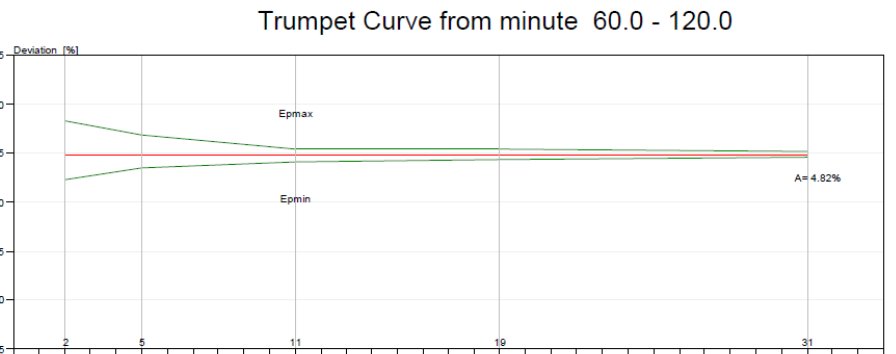
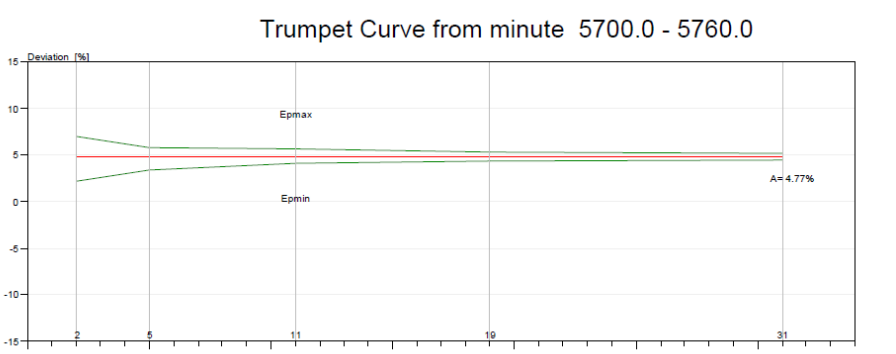
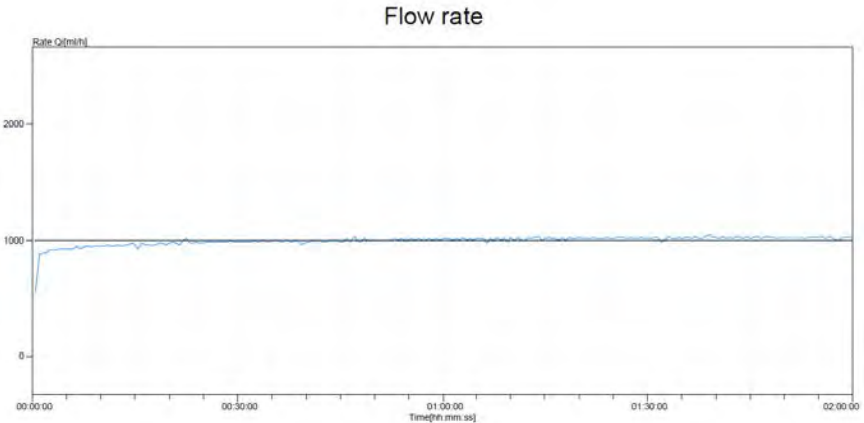
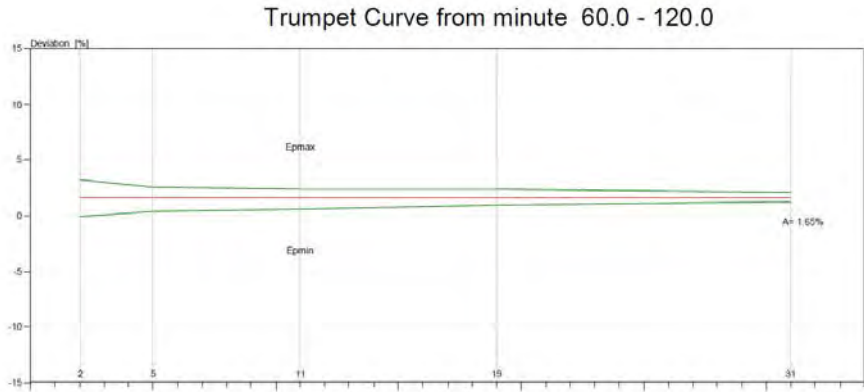
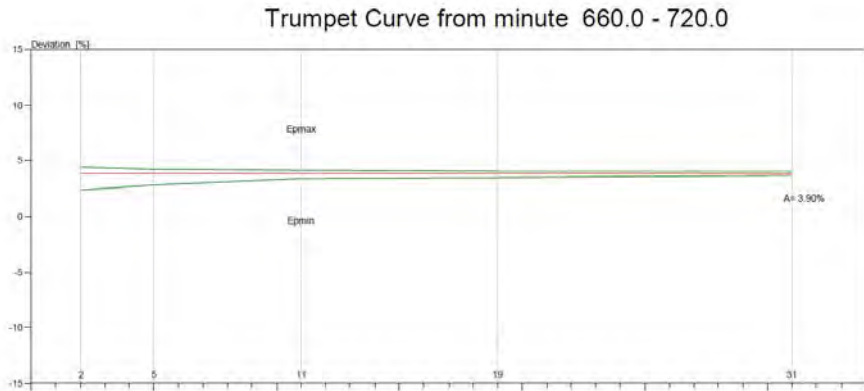
| Description | Graph |
|---|---|
| <p>Start Up Curve 25 mL/hr (1st 2hrs) SET: 1C8109s</p> |  <p style="text-align: center;">Flow rate</p> |
| <p>Trumpet Curve 25 mL/hr (2nd hr) SET: 1C8109s</p> |  <p style="text-align: center;">Trumpet Curve from minute 60.0 - 120.0</p> |
| <p>Trumpet Curve 25 mL/hr (96th hr) SET: 1C8109s</p> |  <p style="text-align: center;">Trumpet Curve from minute 5700.0 - 5760.0</p> |

Table B-1. Accuracy Tests (continued)

| Description | Graph |
|---|---|
| <p>Start Up Curve 999 mL/hr (1st 2 hrs) SET: 1C8109s</p> |  <p>The graph titled "Flow rate" plots Rate Q (ml/hr) on the y-axis (0 to 2000) against Time (hr, min, sec) on the x-axis (00:00:00 to 02:00:00). The flow rate starts at 0, rises sharply to approximately 1000 ml/hr within the first minute, and then remains stable with minor fluctuations around 1000 ml/hr for the remainder of the two-hour period.</p> |
| <p>Trumpet Curve 999 mL/hr (2nd hr) SET:1C8109s</p> |  <p>The graph titled "Trumpet Curve from minute 60.0 - 120.0" plots Deviation (%) on the y-axis (-15 to 15) against Time (min) on the x-axis (2 to 31). It shows a central line with upper and lower bounds labeled Epmax and Epmid. The deviation is relatively constant, and a value of A= 1.65% is indicated on the right side of the plot.</p> |
| <p>Trumpet Curve 999 mL/hr (12th hr) SET: 1C8109s</p> |  <p>The graph titled "Trumpet Curve from minute 660.0 - 720.0" plots Deviation (%) on the y-axis (-15 to 15) against Time (min) on the x-axis (2 to 31). It shows a central line with upper and lower bounds labeled Epmax and Epmid. The deviation is relatively constant, and a value of A= 3.90% is indicated on the right side of the plot.</p> |

Bolus Accuracy

| Topic | Page |
|----------------------|------|
| Bolus Accuracy | C-1 |

C.1 Bolus Accuracy

The **Spectrum IQ** 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 (available for Basic modes only) or a specific amount to be delivered in a certain amount of time.

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.

C. Bolus Accuracy

When tested in accordance with IEC 60601-2-24: 2012 Clause 201.12.1.105, the following are the minimum, maximum and mean deviations in bolus volume for each corresponding setting.

Table C-1. Bolus Volume with DEHP Administration Sets

| Set Type | Test | Bolus Delivery | Bolus Time | Bolus Rate | Delivery Accuracy |
|----------|----------------------|----------------|------------|------------|-------------------|
| DEHP | Minimum Bolus Volume | 0.5 mL | 20 seconds | 90 mL/hr | ±20% |
| DEHP | Maximum Bolus Volume | 999 mL | 60 minutes | 999 mL/hr | ±10% |

Table C-2. Bolus Volume with N-DEHP Administration Sets

| Set Type | Test | Bolus Delivery | Bolus Time | Bolus Rate | Delivery Accuracy |
|----------|----------------------|----------------|------------|------------|-------------------|
| N- DEHP | Minimum Bolus Volume | 0.5 mL | 20 seconds | 90 mL/hr | ±20% |
| N- DEHP | Maximum Bolus Volume | 250mL | 60 minutes | 250 mL/hr | ±10% |

D

Downstream Occlusion

| Topic | Page |
|-----------------------------|------|
| Time to Occlusion | D-1 |
| Bolus Volume | D-1 |

D.1 Time to Occlusion

At the minimum downstream occlusion setting and minimum flow rate of 0.5 mL/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 0.5 mL/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.

D.2 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 m (39.37 in) from the point of the downstream occlusion to the Spectrum IQ 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 m (39.37 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 *Downstream Occlusion, page D- 1.*

Upstream Occlusion

| Topic | Page |
|-----------------------------|------|
| Time to Occlusion | E-1 |

E.1 Time to Occlusion

At the minimum flow rate of 1mL/hr, the time for activation of the upstream occlusion alarm in the event of an upstream occlusion, that creates a complete blockage of flow, at 12" above the pump prior to starting an infusion on a new test set, is 52 minutes or less for at least 51% of alarms (95% Confidence Interval), with a maximum time for alarm activation of 7 hours in the event of an upstream occlusion, that creates a complete blockage of flow, at 24" above the pump prior to starting an infusion on a new test set.

| WARNING | |
|---|--|
|  | <p>Time to Upstream Occlusion at Lower Flow Rates</p> <p>Time to detect an upstream occlusion may be extended if infusing at flow rates below 5 mL/hr. At 1 ml/hr, time to detect upstream occlusion may extend up to 7 hours.</p> <p>Make sure that:</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). |

Electromagnetic Compatibility

| Topic | Page |
|---|------|
| Emissions | F-1 |
| Immunity – ESD, Transient/Burst, Voltage Disparity and Magnetic Field | F-4 |
| Immunity – Conducted and Radiated | F-7 |
| Immunity – Separation Distances | F-9 |

F.1 Emissions

WARNING



Emissions and Immunity

Do not use accessories, transducers, or cables other than those specified by Baxter.

This can result in increased electromagnetic emissions or decreased electromagnetic immunity of the equipment, and improper functioning of the pump or other devices, interrupting therapy, resulting in serious injury or death.

Use only Baxter-specified accessories on this device.

WARNING



Radio Frequency Interference

The Spectrum IQ Infusion System meets the electromagnetic compatibility (EMC) requirements as specified in the International Electrotechnical Commission's (IEC) 60601-1-2:2014 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*, page F- 9. for the recommended minimum distance.

NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.



Use of RFID Technology

Perform functional testing including pump operation testing with the Spectrum IQ Pump in the intended use environment when deployed in an environment with equipment intentionally generating electromagnetic energy to ensure the LVP remains safe and effective.

Perform testing in the intended use environment when using RFID technology. RFID providers should work with healthcare organization in assuring safe deployment and use of RFID near medical electrical equipment and systems. Refer to AIM standard 7351731 Annex L for implementing RAIN RFID systems.

The LVP has been proven to work in the intended use environment for signals defined in IEC 60601-1-2:2014 standard for emission and immunity. Signals not specified in the standard, for example 860-960 MHz frequency at 54 V/m using DSB-ASK Modulation, may cause improper operation such as unexpected system errors and interruption in therapy which can result in serious injury or death.



Power strips

Spectrum IQ should be attached to electrical outlets and power strips that are not connected to other electrical equipment. Doing so can result in a reduced level of safety. Refer to IEC 60601-1:2012 for requirements of ME systems.

Guidance and manufacturer's declaration – electromagnetic emissions –
for all equipment and systems

| <p>The Spectrum IQ 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.</p> | | |
|--|--|---|
| Emissions test | Compliance | Electromagnetic environment – guidance |
| RF emissions CISPR 11 | Group 1 | The Spectrum IQ 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 Spectrum IQ 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. |
| Harmonic Current Emissions IEC 61000-3-2 | Class A | |
| Voltage Flicker IEC 61000-3-3 | <ul style="list-style-type: none"> ■ the value of Pst not greater than 1.0; ■ the value of Plt not greater than 0.65; ■ the value of d(t) during a voltage change not exceeding 3.3% for more than 500 ms; ■ the relative steady-state voltage change, dc, not exceeding 3.3%; ■ the maximum relative voltage change dmax, not exceeding 6% | |

F.2 Immunity – ESD, Transient/Burst, Voltage Disparity and Magnetic Field

Guidance and manufacturer’s declaration – electromagnetic immunity – for all equipment and systems

The **Spectrum IQ** 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) | ±8 kV contact | ±8 kV contact | Floors should be wood, concrete or ceramic tile. |
| IEC 61000-4-2 | ±15 kV air | ±15 kV air | Floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Electrical fast transient/burst | ±2 kV for power supply lines | ± 2kV for power supply lines | Supply power quality should be that of a typical commercial or hospital environment. |
| IEC 61000-4-4 | ±1 kV for input/output lines | Not applicable | |
| Surge | ±1 kV differential mode | ±1 kV differential mode | Supply power quality should be that of a typical commercial or hospital environment. |
| IEC 61000-4-5 | ± 2kV common mode | Not applicable | |

| Guidance and manufacturer's declaration – electromagnetic immunity – for all equipment and systems (<i>continued</i>) | | | |
|---|--|--|--|
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | 0% 120 VAC for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° | 0% 120 VAC for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° | Supply power quality should be that of a typical commercial or hospital environment. During a power interruption the user of the Spectrum IQ Infusion System is to make sure, that the pump is powered from an uninterrupted power supply or the internal battery be fully charged to provide unit power as specified in this operator's manual. |
| | 0% 120 VAC for 1 cycle | 0% 120 VAC for 1 cycle | |
| | 70% 120 VAC (30% dip in 120 VAC) for 30 cycles | 70% 120 VAC (30% dip in 120 VAC) for 30 cycles | |
| | 0% 120 VAC for 300 cycles | 0% 120 VAC for 300 cycles | |
| Power frequency (50/60Hz) magnetic field IEC 61000-4-8 | 30 A/m | 30 A/m | Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment. |

NOTE: The pump was tested to the requirements of IEC 60601-1-2: 2014 Ed 4 and IEC 60601-2-24:2012.

NOTE: The essential performance of the pump is volumetric accuracy. Loss or degradation of volumetric accuracy due to EM disturbances may cause injury to the patient.

WARNING



Magnetic Fields

Do not expose the pump to strong magnetic fields such as those generated by MRI equipment.

Strong magnetic fields can cause improper operation, interrupting therapy, resulting in serious injury or death.

Operate the pump in areas that are free from strong magnetic fields.

WARNING



Adjacent or Stacked Use

Do not use the pump adjacent to or stacked with other equipment as this can result in improper operation.

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.

CAUTION



ECG Artifacts Related to the Use of the Spectrum IQ Infusion System

Peristaltic infusion pumps may produce what is known as piezoelectric artifacts on ECG monitors and similar types of monitoring instruments. The Spectrum IQ 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 setup and/or connection of electrodes, leads or equipment. See the ECG monitoring system documentation for recommendations on proper setup including electrode connections, site preparation, monitor system setup and electrode placement.




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.

F.3 Immunity – Conducted and Radiated

| Guidance and manufacturer’s declaration – electromagnetic immunity – for all life-supporting equipment and systems | | | |
|---|---|------------------|---|
| The Spectrum IQ 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 $d = 1.2\sqrt{P}$ |
| | 10 Vrms 150 kHz to 80 MHz in ISM bands ^b | 6 Vrms | $d = 1.2\sqrt{P}$ |

F. Electromagnetic Compatibility

| Guidance and manufacturer's declaration – electromagnetic immunity – for all life-supporting equipment and systems (<i>continued</i>) | | | |
|--|--------------------------|-----------------------------|--|
| Radiated RF IEC 61000-4-3 | 3 Vm 80 MHz to 2.7GHz | 10 V/m 80 MHz to 2.7 GHz | $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). ^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:  |
| <p>Note 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> | | | |

Guidance and manufacturer's declaration – electromagnetic immunity –
for all life-supporting equipment and systems (*continued*)

^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 27.83 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 2.7 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. Abnormal performance requires that, additional measures may be necessary, such as reorienting or relocating the pump. If clinically necessary manually regulate the flow in accordance to the facility's processes and procedures.

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

F.4 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 **Spectrum IQ** 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.

F. Electromagnetic Compatibility

| 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 The above separation distances were calculated :

$$d = 1.2\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$$

$$d = 2.3\sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$$

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 The ISM compliance level in the ISM frequency band between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.7 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.

NOTE 2 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 3 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 27.83 MHz; and 40.66 MHz to 40.70 MHz.

NOTE 4 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 5 The guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

F. Electromagnetic Compatibility

| | | | |
|--|--|---|--|
| <p>Proximity Fields from RF wireless communications equipment</p> <p>IEC 61000-4-3</p> | <p>TEST LEVEL REQUIRED</p> <p>IEC 60601-1-2:2014 Ed.4.0</p> <p>Table 9</p> | <p>TEST LEVEL MET</p> <p>IEC 60601-1-2:2014 Ed.4.0</p> <p>Table 9</p> | <p>Portable and mobile RF communications equipment should be used no closer to any part of the pump, including cables, than the recommended separation of 0.3m for the wireless communication services listed in IEC 60601-1-2:2014 Ed.4.0 Table 9, shown below.</p> |
|--|--|---|--|

Note 1 The above test levels were met with the 802.11 a/b/g/n WBM, Baxter P/N 35223 and P/N 36010 installed and operating.

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 27.83 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 2.7 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.

WARNING



Linear Accelerator Radiation

Do not expose the Spectrum IQ Infusion System to linear accelerator radiation.

Linear accelerator radiation may cause the device to malfunction, interrupting therapy, resulting in personal injury or death.

Conduct therapy only when a safe distance from linear acceleration devices.



Low/ Very Low Battery Alarm Instructions

| Topic | Page |
|---|------|
| Low / Very Low Battery Alarm Instructions | G-1 |

G.1 Low / Very Low Battery Alarm Instructions

The Low Battery and Very Low Battery alarms provide on-screen trouble shooting instructing the user to connect the Pump to an external power supply.

The instructions state to connect the AC adaptor to a wall outlet and that the power cord is properly connected to the **Spectrum IQ** Infusion System.

G.1.1 Low Battery Alarm Instructions

Displays when the low battery alarm threshold is reached. Prior to 30 minutes of battery power remaining.

The pump displays the following screen-by-screen instructions when the Low Battery alarm is activated and not acknowledged within two (2) minutes, or when the help soft key is pressed.

NOTE: When the pump is plugged into AC power correctly, the Low Battery Alarm message will be dismissed.

G.1.2 Very Low Battery Alarm Instructions

The Very Low Battery alert displays when the battery has a minimum of 15 minutes of runtime remaining.

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

G. Low/ Very Low Battery Alarm Instructions

NOTE: When the pump is plugged into a power outlet. The Very Low Battery Alarm message will be dismissed.



Default Settings

| Topic | Page |
|--|------|
| Factory Settings for Pump Software | H-1 |
| Basic Configurations | H-2 |

H.1 Factory Settings for Pump Software

Some settings can be controlled by the drug library, as indicated in the tables in this section.

The settings below are hard defaults that cannot be changed by the user programming the pump, unless noted otherwise.

Table H-1. User Options – Alarm Settings

| Feature | Original Factory Default | User Options | Ability to be Controlled by the Drug Library? |
|--------------|--------------------------|--|---|
| Audio Volume | Medium | Low [45 dB(A) SPL at 1m], Medium [>45dB(A) at 1m and <[65dB(A) SPL at 1m], High [65 dB(A) SPL at 1m] | Yes (Drug Level Configuration) |
| Audio Tone | Legacy Tones | N/A | Yes Modern Tones |

H. Default Settings

Table H-1. User Options – Alarm Settings (continued)

| Feature | Original Factory Default | User Options | Ability to be Controlled by the Drug Library? |
|---|--------------------------|--------------------------------|---|
| 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) |
| <p>* 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 always default back to the drug library setting.</p> | | | |

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

| Feature | Original Factory Default | Ability to be Controlled by the Drug Library? |
|---|-------------------------------|---|
| Infusion Running screen Options: <ul style="list-style-type: none"> ■ Audio Level Indicator ■ Rate mL/hr* ■ Dose rate* ■ mL – VTBI* ■ Time (hr:min*) *Setting not applicable in Cyclic TPN | Off On On Off Off | No No No No No |
| Display Adjust | 10 (highest level) | No |

H.2 Basic Configurations

A Basic infusion provides non-DERS based infusion programming.

DERS does 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, Single Step Rate Change of 101%, Patient Weight Limits and Patient Weight Double Confirmation.

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 H-3. Basic Mode Fixed Settings

| Basic Configuration Settings | Fixed Settings |
|------------------------------|-----------------------------------|
| Allow Bolus | Yes |
| Allow Loading Dose | Not Available |
| Bolus Amount Units | Dependent on Dose Mode Programmed |
| 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 H-4. Basic Mode Configurable Settings

| Basic Configuration Settings | Default Settings | Configurable in Drug Library |
|-------------------------------------|---|--|
| Audio Alarm | High [≥ 65 dB(A) SPL at 1m], Medium [> 45 dB(A) at 1m and < 65 dB(A) SPL at 1m], Low [45 dB(A) SPL at 1m]. | No |
| Bag Near Empty Alarm | On, Off | No |
| Delivery Bag | Primary Bag, Secondary Bag | No |
| Dose Mode | Clinician can select | No |
| Upstream Occlusion Alarm Suspension | On | Yes See the description of "Upstream Occlusion Alarm Suspension" in <i>See High Priority Alarm Messages, page 9- 6.</i> |

Table H-5. 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. |

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A

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