Intended Use

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

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

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

Conventions

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

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

NOTE: Indicates supplemental information to accompany text.

Summary of Warnings and Cautions

General Warnings

WARNING **Motor Vehicle or Aircraft Use.**

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

WARNING **Hyperbaric Chamber.**

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

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

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

WARNING **Ensure Secure Mounting of Pump During Use and Transport.**

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

WARNING **Battery Handling.**

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

WARNING **Low Battery.**

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

WARNING **Battery Removal.**

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

WARNING **ESD Sensitivity.**

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

WARNING **Adjacent or Stacked Use.**

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

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

WARNING **Pump Storage.**

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

WARNING **Proper Disposal Required.**

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

WARNING **Magnetic Fields.**

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

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

WARNING **Linear Accelerator Radiation.**

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

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

WARNING **Emissions and Immunity.**

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

Procedural Warnings

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

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

WARNING **Environmental Limits**

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

WARNING **Confirm Safe Operation.**

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

Always confirm safe, accurate Pump operation by:

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

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

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

WARNING **Manually Stopping the Pump.**

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

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

WARNING **Do Not Exceed Total Volume.**

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

WARNING **Confirm Drug Library.**

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

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

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

WARNING **Baxter IV Sets.**

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

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

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

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

NOTE: See Operator's Manual: "Downstream Occlusion" for downstream occlusion times and bolus release information.

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

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

WARNING **Flow Rate Inaccuracy.**

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

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

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

WARNING **Priming.**

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

WARNING **Air Bubbles.**

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

WARNING **IV Set Loading.**

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

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

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

WARNING **Bolus.**

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

WARNING **Proper Venting Required.**

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

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

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

Ensure the following:

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

WARNING **Upstream Occlusion Alarm Suspension.**

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

WARNING **Follow Neonatal and Pediatric Procedures.**

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

WARNING **Follow Epidural Procedures.**

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

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

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

WARNING **Unauthorized View or Access.**

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

WARNING **Unintended Delivery.**

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

WARNING **Pressurized Fluid.**

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

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

The analytical related conditions are:

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

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

WARNING **Do Not Reuse Tubing.**

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

WARNING **IV Set Usage.**

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

WARNING **Unloading an IV Set.**

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

WARNING **Radio Frequency Interference.**

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

Procedural Cautions

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

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

CAUTION **Sequester Pumps Pending Evaluation.**

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

CAUTION **Follow Physicians Orders.**

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

CAUTION **BASIC Programming Use.**

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

CAUTION **Accuracy.**

Refer to trumpet curves for flow rate accuracy as a function of short infusion durations. See Operator's Manual: "Flow Rate Accuracy".

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

CAUTION **Upstream Backcheck Valve Use**

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

CAUTION **Pump Orientation.**

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

CAUTION **Use Stable IV Poles.**

Mount Pumps on IV poles that securely hold the Pump.

CAUTION **Keypad Usage.**

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

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

Figure 1. Correct and Incorrect Keypad Usage.

CAUTION **Confirm Audio Operation.**

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

CAUTION **Confirm Display Operation.**

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

CAUTION **Unrecoverable System Error.**

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

CAUTION **Handle AC Power Adaptor With Care.**

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

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

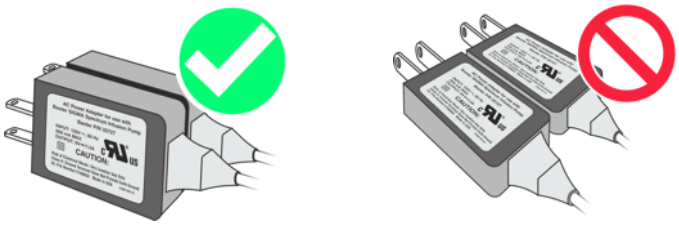

Figure 2. Correct and Incorrect AC Power Adaptor Placement.

CAUTION **Entanglement.**

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

CAUTION **Maintain Battery Charge.**

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

CAUTION **Avoid Bright Natural Sunlight or Artificial Overhead Light.**

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

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

CAUTION **Avoid Overheating.**

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

CAUTION **Static Sensitive Equipment.**

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

CAUTION **Oxygen Enriched Environment.**

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

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

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

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

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

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

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

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

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

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

CAUTION **Perform Preventive Maintenance Annually.**

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

For the safe and proper use of this device refer to the appropriate operator's manuals.