OPERATIONAL OVERVIEW

The following sections provide a high-level overview of how to setup, program, and operate the Spectrum Pump. For detailed instructions, refer to these sections:

- "Preparing the Pump and IV Sets" section, beginning on page 27.
- "Programming the Pump" section, beginning on page 31.
- "Weight Confirmation" section, beginning on page 58.
- "Alarms" section, beginning on page 62.

WARNING: Confirm Safe Operation at Start and Thereafter

Only trained health care professionals can operate Spectrum Generation 2 Operating software. Confirm safe, accurate pump operation at start and periodically thereafter by:

- Ensuring that IV sets or container vents are properly functioning, tubing clamps are in the proper positions, and tubing is free from kinks or signs of collapse outside the pump.
- Observing the drip chamber to verify that there is no flow from the fluid container when the pump is stopped.
- Confirming the drip rate approximates the pump's flow rate during RUN operation.
- Confirming pump settings are as intended.
- Confirming correct: patient, route, dose rate, dose mode, time, and drug/concentration.
- With IV therapy, vital signs and IV access sites are monitored per facility's standard practice of care.
- The Spectrum Generation 2 Operating System is not intended to replace clinician patient observation.
- When using the pump periodic patient monitoring must be performed to ensure that the infusion is proceeding as intended.
- The pump was not designed nor is it intended to detect infiltrations or extravasations.

Never operate the Spectrum unless all of the above safe operations are being practiced.

WARNING: Prevent Inaccuracy

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.
- Operating temperatures outside of 60-90°F for Standard Battery and 60-80°F for Wireless Battery Module.
- Using IV sets longer than is recommended in the Specifications section of this manual.
- Using a dropped, damaged, dirty or wet pump.
- Pressurizing IV bags.
- Positioning IV containers more than 3 feet above or 1 foot below the pump.
- Non-vented IV sets with rigid non-vented containers.
- Vents on sets or burettes left in the closed position.
- Using Microdrip or Minidrip chambers for flow rate settings greater than 200 mL/hr. Doing so may influence flow rate accuracy and cause nuisance air or upstream occlusion alarms.
- Exceeding 500 mL/hr flow rate settings when using sets with backcheck valves. Doing so may influence flow rate accuracy or cause nuisance air-in-line or upstream occlusion alarms. Flow rates above 300 mL/hr may cause fluid to besiphoned from the primary container during piggyback operation (see Secondary Infusion).Not applicable with non-DEHP tubing because 250 mL/hr is the maximum flow rate per warning statement.

WARNING: Follow Epidural Precautions

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.

WARNING: Follow Neonatal and Pediatric Precautions

- 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 (using CONFIGURATIONS/Options mode).

- Prior to connecting to patient, prime IV set, then close roller clamp, load IV set, open slide clamp and roller clamp (if equipped) to avoid possible bolus (0.2 mL) that would result around a door opening/set loading event.

If the pump door is opened with an IV set 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.

CAUTION: Confirm Audio Operation

When pressing the ON key and all other keys, confirm that an audio beep is heard. If sound cannot be heard, discontinue use of the pump and return to SIGMA for service.

CAUTION: Perform Preventative Maintenance Annually

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

CAUTION: Follow Physicians Orders

Federal (USA) law restricts this device to sale or use by, on the order of, or under the supervision of, a physician or other licensed health care practitioner.

CAUTION: Accuracy

Refer to trumpet curves for flow rate accuracy as a function of short infusion durations.See “APPENDIX B - Flow Rate Accuracy” , beginning on page 92.

The upstream occlusion detector may not detect partially occluded tubing. Always check to ensure the IV set’s clamp is not closed above the Spectrum 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: Single Fault Conditions

A bolus of approximately 0.1 mL may be generated as a result of a single fault condition.

CAUTION: 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.

Starting a New Infusion Using the Dose Error Reduction System (DERS)

1. Press the **ON/OFF** button to turn the pump on.
2. If the previous setup needs to be erased, press **YES** soft key when prompted "New Patient?".

   NOTE: 'New Patient?' Prompt – When the pump is turned on and programmed infusion data exists in memory, a screen is displayed asking the operator if the intended use for the pump is for a New Patient. Answering **YES** to this prompt clears the existing infusion data, answering **NO** retains the data and allows the operator to resume the infusion.(See Figure 11.)

Figure 11. New Patient Screen.

3. Load the primed IV set.
4. Select your Care Area.
5. Select drug or fluid. (Type first 2 letters of drug name.)
6. Select and confirm a Concentration if more than one is displayed.
7. Select Delivery Bag (if required).
8. Enter and press **OK** to confirm all required values on the Setup Screen.
9. Confirm that all clamps and vents are in the proper position.
10. Press **RUN/STOP** to start the infusion.
11. Check and confirm proper flow.

Starting a New Infusion using the BASIC Mode

(For use only when drug is not in the Drug Library)

1. Press the **ON/OFF** button to turn the pump on.
2. If the previous setup needs to be erased, press **YES** soft key when prompted "New Patient?", (see "New Patient" prompt above).
3. Load the primed IV set.
4. Select Care Area.
5. Select drug or fluid. (Enter "B" "A" prompts to BASIC Selection)
6. Select Delivery Bag.
7. Select a Dose Mode (default is mL/hr).
8. Enter and press **OK** to confirm all required values on the Setup Screen.
9. Confirm that all clamps and vents are in the proper position.
10. Press **RUN/STOP** to start the infusion.
11. Check and confirm proper flow.

Secondary Infusions

1. Stop the pump if it is running.
2. Lower the primary bag at least 20" below the secondary bag.
3. Open secondary roller clamp.
4. Press the **REVIEW/PROGRAM** soft key.
5. Press the **PROGRAM SECNDRY** soft key.
6. Select drug or fluid for the secondary infusion, (type first 2 letters of drug name).
7. Select and confirm Concentration if more than one is displayed.
8. Press **OK** to select/confirm the secondary delivery bag.
9. Enter and press **OK** to confirm all required values on the setup screen.
10. Confirm that all clamps and vents are in the proper position.
11. Press **RUN/STOP** to begin secondary infusion.
12. Check the flow and confirm drops are falling in secondary drip chamber and no drops falling in the primary drip chamber.