

## APPENDIX A - SPECIFICATIONS

### Master Drug Library (MDL) Editor

- PC based, pharmacy edited and controlled, customized in-house list of all IV drugs and manuals, along with their safe delivery parameters
- Care Area enables:
  - same name/same concentration drugs to have different dose rate limits
  - pump configurations for maximum; rate, VTBI, patient weight and occlusion level
- Each drug entry includes, at a minimum, the care area, drug name, concentration, dose rate mode, bolus mode, starting dose rate, soft (able to be exceeded) and hard (not able to be exceeded; an optional setting) dose rate and bolus limits, volume to be infused (VTBI), primary or secondary IV container, and pump screen color.

### Drug Library Transfer

- Transfer via a wireless network connection to a pump using a Wireless Battery Module
- Transfer from the PC directly to a pump via IrDA®

### Standard Gravity IV Sets

Standard gravity IV sets from Baxter or Hospira.

### 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), IrDA Serial Infrared Link Access Protocol v1.1 (IrLAP) and IrDA Serial Infrared Link Management Protocol v1.1 (IrLMP), IrDA Tiny TP v1.1
- Wireless – 802.11b, 802.11b/g
- EIA-RS-232 levels for Asynchronous Transmit/Receive only (RS232)

Specification	Description
AC Power	<p>AC Power Adaptor, low profile, covers only one outlet, Medical Grade (EN60601-1-2):</p> <ul style="list-style-type: none"> <li>■ Input: 100 VAC - 240 VAC, 50-60 Hz / 200 mA</li> <li>■ Output (P/N 35727): 9VDC/1200 mA, short circuit protected</li> <li>■ Output (P/N 35714): 9VDC/800 mA, short circuit protected</li> <li>■ Cord length 3.0 m (~ 9.75 feet)</li> </ul> <p>Use only SIGMA part number 35727 or 35714.</p> <p>The SIGMA Spectrum Infusion Pump is classified according to Medical Electrical Equipment standards as:</p> <ul style="list-style-type: none"> <li>■ Class II Equipment</li> <li>■ Type BF Applied Part</li> <li>■ Continuous Operation</li> </ul>
AC Power Adaptor	Approximate Weight 10 oz
Alarm Volume	Variable (three levels: high, medium and low)
Alarms and Alerts	<ul style="list-style-type: none"> <li>■ Air-In-Line: dual beam ultrasonic detector alarms for large bubbles but allows smaller bubbles to pass. Detects air bubbles &gt; 1” (» 125µL Hospira, » 140µL Baxter), will alarm if &gt; 1 mL* of air in 15 min., &lt; 50µL bubbles are omitted in the summation of the 1 mL.*</li> <li style="padding-left: 20px;">*up to 1.5mL at 60°F</li> <li>■ Downstream Occlusion: automatic restart occurs after the downstream occlusion is cleared. Actuation can be set to Low, 6 ± 4 PSI, Medium, 13 ± 6 PSI or High, 19 ±9 PSI</li> <li>■ Very Low Battery - &lt;15 minutes of battery power remain</li> <li>■ Due for inspection: Preventative Maintenance and/or Network Certification</li> </ul>
Anti-Free-Flow System	Set based, utilizing IV set slide clamp.

Specification	Description
Battery Power and Capacity	<p>Standard Battery</p> <ul style="list-style-type: none"> <li>■ Lithium Ion, 1800 mA/h, 7.4 VDC nominal. SIGMA Part Number, 35724</li> <li>■ Capacity 8 hrs (at 125 mL/hr at the highest backlight settings)</li> <li>■ 12 hr. recharge time</li> <li>■ Charging occurs if AC Power Adaptor is plugged in whether pump is ON or OFF</li> </ul> <p>Wireless Battery Module (802.11b)</p> <ul style="list-style-type: none"> <li>■ Lithium Ion, 1800 mA/h, 7.4 VDC nominal. SIGMA Part Number, 35083</li> <li>■ Capacity 4 hrs (at 125 mL/hr at the highest backlight settings)</li> <li>■ 16 hr. recharge time</li> <li>■ Charging occurs if AC Power Adaptor is plugged in, whether pump is ON or OFF</li> </ul> <p>Wireless Battery Module (802.11b/g)</p> <ul style="list-style-type: none"> <li>■ Lithium Ion, 1800 mA/h, 7.4 VDC nominal. SIGMA Part Number, 35162</li> <li>■ Capacity 4 hrs (at 125 mL/hr at the highest backlight settings).</li> <li>■ 16 hr. recharge time</li> <li>■ Charging occurs if AC Power Adaptor is plugged in, whether pump is ON or OFF</li> </ul>
Display	Color (16 out of a palette of 262,144 possible colors) HRTFT, 240 X 270, LED Front-Lit, 0.2235 mm X 0.2235 mm dot pitch
Dose Modes: Continuous Infusions	mL/hr, mL/kg/min, mL/kg/hr, g/hr, mg/hr, mg/kg/hr, mg/min, mg/kg/min, mg/kg/day, mcg/hr, mg/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
External Interfaces	IrDA (SIR Encoding Protocol. Supports IrOBEX). Additional Asynchronous Serial Port expansion bus available at battery terminals. Software upgrades may be performed through external RS-232.

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 Modes	Primary and Secondary, Multi-Step, and Cyclic TPN
KVO	<p>At the completion of a primary infusion, the pump will infuse at the KVO rate configured per drug in the Drug Library or the current infusion rate, whichever is lower. The default KVO rate is set at 1 mL/hr but may be configured to between 0.5 - 50 mL/hr.</p> <p>At the completion of a secondary infusion program, the pump will run at a fixed KVO rate of 1 mL/hr.</p>
Logging Memory	<ul style="list-style-type: none"> <li>■ AC Power Adaptor, low</li> <li>■ While not in use, the pump's memory will retain the last programmed setup screen for 24 hours.</li> </ul> <p><i>NOTE:</i> Multi-step and cyclic modes are maintained until modified.</p> <ul style="list-style-type: none"> <li>■ Separate pump history log and drug event log</li> <li>■ 10,000 ± event capacity. Once the maximum number of log entries is reached, the data for each new event replaces the data for the oldest event (the data for oldest event is lost)</li> </ul>
Maximum Pump Pressure	28 PSI
Occlusion Pressure	Adjustable: High (19 ±9 PSI), Medium (13 ±6 PSI), and Low (6 ±4 PSI)
Operational Conditions	<p>With Standard Battery</p> <ul style="list-style-type: none"> <li>■ Operating temperature: 60 to 90°F (15.6 to 32.2° C), 20 to 90% relative humidity non-condensing</li> </ul> <p>With Wireless Battery Module</p> <ul style="list-style-type: none"> <li>■ Operating temperature: 60 to 80°F (15.6 to 26.7° C), 20 to 90% relative humidity non-condensing</li> </ul>

Specification	Description												
Overall Size (Pump)	<p>With Standard Battery</p> <ul style="list-style-type: none"> <li>■ Without IV pole clamp – 5.8” H x 4.2” W x 2.5” D</li> <li>■ With IV pole clamp – 5.8” H x 6.4” W x 4.7” D</li> </ul> <p>With Wireless Battery Module</p> <ul style="list-style-type: none"> <li>■ Without IV pole clamp – 6.3” H x 4.2” W x 2.5” D</li> <li>■ With IV pole clamp – 6.3” H x 6.4” W x 4.7” D</li> </ul>												
Pumping Mechanism	Linear peristaltic												
Storage Temperature	<p>With Standard Battery</p> <ul style="list-style-type: none"> <li>■ Storage temperature: -4 to 120°F (-20 to 49°C), 10 to 90% relative humidity non-condensing</li> </ul> <p>With Wireless Battery Module</p> <ul style="list-style-type: none"> <li>■ Storage temperature: -4 to 120°F (-20 to 49°C), 10 to 90% relative humidity non-condensing</li> </ul>												
Timekeeping	<p>Real Time Clock, battery backed, 10-year life</p> <p><i>NOTE:</i> Clock is set to GMT.</p>												
Total Volume	0.1 to 999 mL with 0.1 mL increments from 0.1 to 99.9 mL and 1.0 mL increments from 100 to 999 mL												
Volumetric Accuracy	<p>Accuracy is based on volume collected over one hour using compatible Baxter and Hospira Standard IV Sets.</p> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th></th> <th>BAXTER</th> <th>HOSPIRA</th> </tr> </thead> <tbody> <tr> <td>0.5 – 1.9 mL/hr</td> <td>±0.1 mL/hr</td> <td>±0.1 mL/hr</td> </tr> <tr> <td>2.0 – 800 mL/hr</td> <td>±5%</td> <td>±5%</td> </tr> <tr> <td>801 – 999 mL/hr</td> <td>±5%</td> <td>±10%</td> </tr> </tbody> </table> <p>Specified accuracy is maintained on Baxter Standard IV Sets for up to 96 hours (maximum 12 liters). Hospira Standard IV Sets for up to 72 hours (maximum 9 liters) See “Compatible IV Sets” on page 72.</p>		BAXTER	HOSPIRA	0.5 – 1.9 mL/hr	±0.1 mL/hr	±0.1 mL/hr	2.0 – 800 mL/hr	±5%	±5%	801 – 999 mL/hr	±5%	±10%
	BAXTER	HOSPIRA											
0.5 – 1.9 mL/hr	±0.1 mL/hr	±0.1 mL/hr											
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Specification	Description
Weight	<p>With Standard Battery</p> <ul style="list-style-type: none"> <li>■ Without IV pole clamp – 25.5 oz ±1.0 oz</li> <li>■ With IV pole clamp – 33.5 oz ±1.0 oz</li> </ul> <p>With Wireless Battery Module</p> <ul style="list-style-type: none"> <li>■ Without IV pole clamp – 26.5 oz ±1.0 oz</li> <li>■ With IV pole clamp – 34.5 oz ±1.0 oz</li> </ul>
Wireless Network Interface	<p>Wireless Battery Module (802.11b), SIGMA Part Number 35083</p> <ul style="list-style-type: none"> <li>■ Standard: IEEE 802.11b</li> <li>■ Transmit power: 16 dBm typical</li> </ul> <p>Wireless Battery Module (802.11b/g), SIGMA Part Number 35162</p> <ul style="list-style-type: none"> <li>■ Standard: IEEE 802.11b/g</li> <li>■ Transmit Power: 12 dBm typical</li> </ul>
Wireless Security	<p>WEP (Wired Equivalent Privacy)</p> <ul style="list-style-type: none"> <li>■ Encryption: 64/128-bit (RC4)</li> </ul> <p>WPA/WPA2/802.11i</p> <ul style="list-style-type: none"> <li>■ Encryption: TKIP, CCMP (AES)</li> <li>■ WPA-PSK</li> <li>■ 802.1X authentication</li> <li>■ LEAP (WEP only)</li> <li>■ PEAP/MSCHAPv2</li> <li>■ EAP-TLS</li> </ul>