sigmaspectrum

Service Manual

35700ABB & 35700BAX

SIGMA, LLC
711 Park Avenue
Medina, New York 14103
v 800 356 3454
f 585 798 3909
www.sigmapumps.com

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Medina, New York 14103
v 800 356 3454
f 585 798 3909
www.sigmapumps.com

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INTRODUCTION AND SAFETY

Intended Device Use

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

The Spectrum and Spectrum with Master Drug Library are suitable for many user facility applications such as, but not limited to, hospitals, outpatient care areas, homecare and ambulatory care services.

The Spectrum and Spectrum with Master Drug Library are intended to reduce operator interaction through automated programming, thereby helping to reduce errors associated with complex device programming. Parameter programming requires trained healthcare professional confirmation of limits and drug therapy to physician's directive.

Related Documents

The following documents also pertain to the Spectrum and Spectrum with Master Drug Library:

- Operator’s Manual P/N 41018
- MDL User Manual P/N 41020

Listings & Certifications

Standard	Version	Description
UL 60601-1	2003	UL Standard for Safety Medical Electrical Equipment, Part 1: General Requirements for Safety First Edition
CAN/CSA C22.2 NO 601.1-M90	1990	Medical Electrical Equipment – Part 1: General Requirements for Safety General Instruction No 1: with UL60601-1 Supplement I
IEC 60601-2-24	1998–2002	Medical Electrical Equipment – Part 2 –24: Particular Requirements for Safety of Infusion Pumps and Controllers First Edition
EN 60601-1	1990	Medical Electrical Equipment Part 1: General Requirements for Safety Includes Amendments + A1(93) + A2(95)
FCC Section 15C ID: MCQ-50M879	N/A	FCC approved wireless transmitter/receiver module (wireless battery module only – SIGMA P/N 35083)
FCC Section 15C ID: MCQ-50M1538	N/A	FCC approved wireless transmitter/receiver module (wireless battery module only – SIGMA P/N 35162)

See the SIGMA Spectrum Operator's Manual (P/N 41018) for specific flow rate accuracy (trumpet curve) information and electromagnetic compatibility compliance levels.

NRTL – Intertek Testing Services NA Inc. Reference Control Number 3063464

Contacting SIGMA Technical Support

Contact SIGMA, LLC for all service information at:

Telephone:1-800-356-3454

Email: techsupport@sigmapumps.com

Conventions

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

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

NOTE: Additional information to clarify or strengthen wording.

Summary of Warnings and Cautions

WARNING:

- THIS EQUIPMENT IS NOT SUITABLE FOR USE IN THE PRESENCE OF A FLAMMABLE ANAESTHETIC MIXTURE WITH AIR OR OXYGEN OR NITROUS OXIDE.
- LITHIUM BATTERY (SIGMA P/N 55075)
(LOCATION: BT1 ON PCBA P/N 60087)
DANGER OF EXPLOSION IF THE BATTERY IS INCORRECTLY REPLACED. REPLACE ONLY WITH THE SAME OR EQUIVALENT TYPE RECOMMENDED BY SIGMA. REFERENCE THIS MANUAL FOR DISPOSAL INSTRUCTIONS.
- DO NOT SHORT CIRCUIT THE BATTERY TERMINALS, DISASSEMBLE OR MODIFY BATTERY PACKS.
- DO NOT DISPOSED OF BATTERIES OR BATTERY PACKS IN FIRE.
- ANY PUMP THAT HAS BEEN DROPPED OR IS OTHERWISE VISIBLY DAMAGED MUST NOT BE USED. Discontinue use immediately and refer to a qualified Service Technician for inspection and repair prior to further use.
- USE ONLY IV ADMINISTRATION SETS THAT ARE LISTED ON SIGMA COMPATIBLE SET LISTING (see Operator's Manual for listing). Use of any other sets may result in malfunction or inaccurate delivery.
- DO NOT USE IF ROOM OR PUMP TEMPERATURE IS BELOW 15°C (60°F) OR ABOVE 32°C (90°F).

CAUTION:

- Federal (USA) law restricts this device to sale by or on the order of a physician or other licensed practitioner.
- Operate only on the AC line voltage for which the AC power adaptor is marked.
- The AC power adaptor should be plugged in during storage to maintain proper battery charge level.
- Disconnect from AC power source and remove the battery pack prior to servicing this pump.
- Routine cleaning and periodic maintenance is needed to assure that the pump remains safe and functional. Refer to “Service and Maintenance” on page 26, and “Preventive Maintenance” on page 31.
- Clean up solution spills as soon as possible using a damp cloth or sponge. Dry thoroughly before use. Keep the upstream and downstream sensors’ tube channels clean and dry at all times during pump operation. Do not use hard or sharp objects to clean sensor tube channel areas. Failure to comply with this requirement may cause the pump to fail. Refer to “Service and Maintenance” on page 26.
- Static sensitive electronics used in SIGMA infusion pumps may be damaged by electrostatic discharge. Service technicians must follow proper ESD procedures when working on pumps. Refer to MIL-STD-1686 for protective handling procedures.
- Do not use a pen or any other sharp object to actuate the keyboard switches. Replace torn or punctured membranes immediately, to assure solutions won't internally damage the membrane switch and prevent proper operation of the SIGMA Spectrum. (Replacement should only be performed by authorized personnel).
- Use only filter sets that are specifically listed in the Operator's Manual for use with Spectrum pumps.

NOTE: For a list of serviceable parts, contact SIGMA.

DESIGN AND THEORY OF OPERATION

Case

SIGMA Spectrum consists of two case halves: front and rear case assemblies.

Front Case Assembly

The front case assembly is comprised of the following primary components:

- Front case
- Display
- Two circuit boards

The circuit boards of this assembly are fastened with four hex standoffs and four Phillips machine screws.

Rear Case Assembly

The rear case assembly consists of the following primary components:

- Rear case
- Back flex circuit
- Power connector
- Speaker

The back flex circuit is adhered to the rear case. The power connector is assembled to the rear case.

Battery Pack

The SIGMA Spectrum employs a removable lithium ion 7.2V battery pack. This assembly consists of the battery cells, contact pins and the two plastic case halves. The battery pack uses both cell and battery pack protection to guard against short-circuit, over voltage and over current conditions. The battery terminals are slightly recessed to minimize the possibility that the terminals may be shorted on a conductive surface. The battery pack is labeled to identify it and provide handling / disposal information as necessary for user safety.

There are three battery types:

- P/N 35724 - standard battery
- P/N 35083 - 802.11b wireless module
- P/N 35162 - 802.11g wireless module.

The standard battery (P/N 35724) and 802.11b wireless module (P/N 35083) are compatible with all SIGMA Spectrum pumps.

The 802.11g wireless module (P/N 35162) is only compatible with wireless G compatible pumps.

Wireless G compatible pumps are identified by the letter G preceding the serial number on the pump (see Figure 1.). Pumps that do NOT have a letter G preceding the serial number (see Figure 2.) are not compatible with the 802.11g wireless module (P/N 35162).

Figure 1. Serial Number for Pump Compatible with the 802.11b/g Wireless Battery Module (P/N 35162)

Figure 2. Serial Number for Pump NOT Compatible with the 802.11b/g Wireless Battery Module (P/N 35162)

Pole Clamp

The pole clamp assembly (SIGMA P/N 35712) is attached to the rear of the pump. A thumbscrew is used to lock the pole clamp assembly to the SIGMA Spectrum pump. The pole clamp assembly is comprised of an anodized aluminum C-clamp and a slide mount receptacle bracket. The bracket is attached to the C-clamp with two 1/4-20 x 5/8" Phillips machine screws.

Double Rotating Pole Clamp Assembly (Accessory)

The Double Rotating Pole Clamp Assembly (SIGMA P/N 35743) is an accessory to the Spectrum infusion pump. The double rotating feature of the Double Rotating Pole Clamp enables the pump to be offset on the left or right side of the single (standard) IV pole. The clamp can also be clamped to hospital bedside rail diameters ranging from 0.75" to 1.25". Refer to the cleaning section of this manual for compatible cleaners. Refer to the installation manual (SIGMA P/N 41092) on how to install the clamp on the pump. The dimension of the clamp is less than 7.0" long X2.5" wide. The weight of the clamp is less than 1.2 lbs.

CAUTION: Always operate the pump in vertical direction with the key hole at the top of the pump.

Tubing Channel/Pump Door

The tubing channel consists of

- Proximal air/occlusion sensor
- Pump valves and fingers
- Downstream tubing guide

These components are designed to facilitate in the proper loading of the IV tube.

Set Slide Clamp Sensor

A reflective slide clamp sensor is employed to determine whether a closed slide clamp is present in the keyhole. If a slide clamp is present in the keyhole, the sensor LED light source illuminates and detects the presence of the clamp. The sensor component alerts the user that a closed slide clamp is present in the keyhole when the user presses the **RUN/STOP** key.

Processing Architecture

The SIGMA Spectrum employs three computational processors.

- Two of the three processors, "Sharp" (Processor Board – 60087) and "PIC" (I/O Board – 60091), form a diverse checked redundancy scheme and perform all of the safety critical computations. The scheme is diverse because they are different processor types manufac-

tured by separate, independent manufacturers. Likewise, these processors use different software compilers and math libraries, which yields additional independence. This processor pair uses a master/slave checked redundancy scheme where safety critical computations are computed by the master processor and checked by the slave processor. If either processor's check calculation does not match its own computation or if a fault condition is detected, the processor can independently fail the system to a safe state, which includes an audible alarm.

- The third processor is used to charge the battery (Backflex – 35149), interface to the bar-code scanner, and pass asynchronous data through the rear case connector.

Pumping Mechanism

Physical Method

The SIGMA Spectrum uses a linear peristaltic motion to pump the fluid. That is, the tubing is repeatedly squeezed to create fluid pressure and thereby flow of fluid.

Operation

There are two phases of the pumping cycle:

- Fill phase
- Pumping phase

The fill phase allows the tubing to be filled from the proximal or "upstream" end of the pump. The second phase of the cycle is the pumping phase. The pump consists of two valves, one of which occludes the administration set tubing at all times. The proximal valve occludes the tubing during the pumping phase of the cycle. Similarly, the distal valve occludes the tubing during the fill phase of the cycle. There are two "fingers" whose function is to squeeze fluid towards the distal end of the pump, thereby creating fluid pressure and fluid flow during the pumping phase of the cycle. During the fill phase of the cycle, the fingers are in a position that allows maximum volume of fluid to fill the tubing proximal to the distal valve.

Pumping Mechanism Assembly

This assembly is comprised of a cast aluminum chassis and doorplate assembly. The motor, cams, pumping fingers, upstream sensor and downstream sensor are also part of this assembly. All components are fastened with standard, Phillips and socket head machine screws.

Motor

The motor is connected to the I/O Board (60091) through a 10-conductor, 1 mm pitch flex circuit.

Motor Drive

The motor drive circuitry will only allow the motor to run in a clockwise direction, which creates fluid flow from the proximal end of the pump to the distal end of the pump. Both the PIC and Sharp processors have the ability to independently remove power from the motor through independent hardware switches, thereby halting the pump in the event that single fault condition is detected. There are two mechanisms for detecting rotation of the motor. The first rotation sensing mechanism is the two-channel encoder, which can sense motor angular velocity as well as rotation direction. The second rotation sensing mechanism is the once-per-revolution hall effect sensor. These two sensing

mechanisms eliminate the possibility of incorrect sensing motor velocity after a detectable single fault condition.

Motor and Gear Drive

SIGMA Spectrum employs a 16 mm DC motor, encoder and planetary gearbox. The output shaft of the gearbox is coupled to the pump drive camshaft by two identical gears, thereby creating a 1:1 drive ratio between the camshaft and output of the gearbox. Motor speed is controlled by a closed-loop pulse width modulation (PWM) drive system that derives its power directly from the battery or 9VDC source when the AC power adapter is connected.

Fluid Temperature

Physical properties of administration set tubing are subject to the effects of fluid temperature. In general, colder temperatures can cause negative flow rate errors in an uncompensated system. Similarly, hotter temperatures can cause positive flow rate errors in an uncompensated system. The SIGMA Spectrum employs a temperature compensation system to maintain flow rate accuracy over the operating temperature range of the device. Approximate fluid temperature is measured by two negative temperature coefficient thermistors, one proximal to the pumping mechanism and one distal to the pumping mechanism. The proximal sensor is housed by the upstream sensor assembly. The distal sensor is located in the lower tubing guide, just below the distal occlusion sensor. Both sensors are calibrated at the factory, and are used to check each other for single fault failure conditions. The output of both thermistors are filtered and fed to A/D converters for processing by Spectrum processors for compensating pump motor speed to maintain flow rate accuracy.

Upstream Sensors

Optical Tube Sensor

The optical tube sensor consists of a light emitting diode (LED) emitting infrared light and a phototransistor. The LED and phototransistor are located at the bottom of the ultrasonic sensor housings, facing opposite to each other. This position is marked as load point 2 and is indicated in red color next to the “direction of flow” label inside the pump door. The optical tube sensor detects that an IV set is loaded at load point 2 to assist in proper loading of the IV set into the pump. It must recognize the presence or absence of the IV tube. The sensor is activated only when the door is open. If the IV tube is properly placed in the space between the LED and phototransistor, the infrared light is diffracted and the phototransistor outputs a high voltage. If there is no IV tube present, the phototransistor receives continuous infrared light and a low voltage is output.

The software monitors the output voltage and displays a green bar with a check mark to indicate a properly loaded tube or a red bar with loading instructions when there is no tube or if the tube is improperly placed in the sensor. This sensor is calibrated through a biomed option.

Proximal Occlusion Detection

The proximal occlusion sensor consists of two pairs of ultrasonic transmitters and receivers. A “pusher” connected to the door assembly assures that a constant force is exerted to push the administration set tubing against the sensor housing. The transmitted ultrasonic signal is a constant wave

(CW) signal centered at a nominal 293 KHz. This signal is generated by exciting a piezoelectric crystal near its natural resonant frequency. The ultrasonic signal propagates from the sensor housing laterally through the administration set tubing. The ultrasonic receiver is a piezoelectric crystal matched in frequency to the transmitter. The differential output of the receiver is amplified, envelope detected, and filtered before being presented to a 12-bit A/D converter where it is converted to a 12-bit digital word. Three samples are taken for each pump revolution. The digital words are processed by the SIGMA Spectrum processor and fed into a detection algorithm. The detection algorithm compares successive samples and looks for a trend of decreasing signal amplitude caused by a reduction in pressure against the sensor housing. If the trend continues through a predetermined threshold over a predetermined unit of time, a proximal occlusion is declared and a visual and audible alarm is presented to the user.

Air Sensor

The air detector uses the same sensor hardware as described in the Proximal Occlusion Detection section. The air detection algorithm uses an “air” threshold that is set by a calibration routine at the factory. If the signal amplitudes received by both sets of ultrasonic receivers are below the air threshold, an air alarm is declared and a visual and audible alarm is presented to the user. The SIGMA Spectrum air sensor is designed to detect air bubbles greater than 1 inch of tubing (125–150 µl depending on tubing calibration).

Downstream Sensors

Set Loading

The downstream sensor consists of a channel piezoelectric bridge force transducer and is located between loading points 3 and 4 inside the pump door. This sensor has two basic functions. The first is to acknowledge an IV administration set as being installed at load points 3 and 4. Acknowledgement is identified on the display with a third green bar and check mark. The second function is to detect distal occlusions.

Distal Occlusion Detection

The distal occlusion sensor uses a piezoelectric bridge force transducer. A pusher connected to the door assembly assures that a constant force is exerted to push the administration set tubing against the sensor housing. The detection algorithm compares successive samples and looks for a trend of increasing/decreasing signal amplitude caused by a increase/reduction in pressure against the sensor housing. Four samples are taken for each pump revolution. The differential output of the force transducer is amplified, envelope detected, and filtered before being presented to a 12-bit A/D converter where it is converted to a 12-bit digital word. The digital words are processed by the SIGMA Spectrum processor and fed into a detection algorithm. The detection algorithm compares the received signal levels to thresholds set by the user selected occlusion alarm trip points. If the received signal exceeds the trip points, a distal occlusion alarm is declared and a visual and audible alarm is presented to the user.

Audible Alarm Device and System

The audible alarm device is a 1-inch moving coil speaker. The speaker is driven by two separate audio paths, one by the Sharp and one by the PIC. Either the Sharp or PIC can independently sound an audio alarm tone if an alarm occurs or a fault is detected.

Electronic Components

AC Power Adaptor / Charger

The SIGMA Spectrum infusion pump uses an AC power adaptor capable of providing 9 VDC. The power adaptor connects to Spectrum via a positive locking connector, which will reduce the possibility of accidental disconnection. When the AC power adaptor is plugged into an AC receptacle, the lithium ion battery pack will be charged. Normal charger operation occurs as follows: If the battery requires charging, the Spectrum battery charger will initially maintain the battery at a constant current of approximately 250 mA (400 mA if pump is non-wireless or wireless is turned off). After the battery voltage reaches a nominal charge of 8.3 volts, the charger maintains this voltage until the charging current supplied to the battery is less than 60 mA. The battery charge cycle is completed and will terminate. There are three mechanisms employed to prevent overcharging of the battery:

- The charging microcontroller's ability to monitor and control voltage and current applied to the battery.
- A current clamp circuit is employed to prevent charge currents that would cause charge circuit overheating.
- Battery pack protection circuits within the battery pack itself prevent overheating and over charging.

The adaptor side of the AC power adaptor is equipped with a Protector (P/N 45742). The Protector is a plastic enclosure which snaps onto the adaptor. The purpose of the Protector is to protect the adaptor from damage during use in a hospital environment. The AC power adaptor with the Protector can be used on wall outlet and pole mount power strip receptacles. The Protector comes installed with the pump. The Protector cannot be removed from the adaptor once it is installed. The Protector can be ordered separately as an accessory for installing on an old AC power adaptor. A separate instruction bulletin on how to install the Protector is sent along with the Protector.

The Protector is compatible with the cleaners mentioned in this Service Manual. Refer to "SIGMA Spectrum Cleaning" on page 26 of this Service manual for cleaning methods and compatible cleaners that can be used on the Protector.

CAUTION: **IMPROPER REMOVAL MAY DAMAGE THE AC POWER ADAPTOR.** Remove the AC power adaptor by grabbing the handle of the Protector and pulling it back off the receptacle. Do not pull the cord to unplug the Adaptor from the receptacle. Improper twisting or pulling of the connector or cord may damage the AC power adaptor.

Display

Spectrum uses a highly reflective thin film transistor (HRTFT) liquid crystal display containing:

- 240 X 320 pixels (240 x270 are active)
- Color HRTFT - 16 out of a palette of 262,144 possible colors
- 0.2235 mm X 0.2235 mm dot pitch
- Illumination by side mounted LEDs and diffuser.

The display employs front lighting using six white LEDs. Brightness of the LED front light is controlled by a constant current source implemented on the 60091 I/O Board. The display can be easily viewed while mounted to an IV pole, with viewing distances up to 15 feet and a minimum viewing angle of ±30 degrees from a line perpendicular to the display plane. The display has two flex circuit connections: The first 50-conductor flex circuit carries digital display and control data as well as power for the display. The second 5-conductor display flex circuit carries power for the back light. Both of these flex circuits connect to 0.5 mm flex circuit connectors on the I/O Board.

I/O Board

This 10-layer, 100% surface-mount component circuit board distributes input and output (I/O) from all sensors (except the ultrasonic air detector) through flex circuit connections that will be discussed in detail below. The I/O board also receives the keypad, motor and display flex circuit signals. The I/O board hosts A/D converters and discrete I/O to interface to the Spectrum sensors.

Processor Board

This 10-layer, 100% surface mount component circuit board distributes input and output (I/O) from the ultrasonic air detector through a 40-pin flex circuit connection (detailed below). Additionally, the processor board hosts the Sharp processor, which controls the HRTFT display, and performs most of the primary computations for Spectrum. The processor board also hosts the real-time clock (RTC) chip and lithium back-up battery for the RTC, Flash and static RAM memory.

Flex Circuits

- **Ultrasonic Flex —** This flex circuit provides connections to two pairs of ultrasonic piezoelectric crystals (receive and transmit) as well as the secondary tube temperature thermistor. The Ultrasonic Flex is connected to the processor board (60087) through a 0.5 mm pitch, 40-conductor, right angle flex connector.
- **Upper Aux Flex —** This flex circuit provides connections to the upper door latch and link discrete signals, once per revolution hall effect sensor, and slide clamp sensor signals. The upper aux flex is connected to the I/O board (60091) through a 0.5 mm pitch, 30-conductor, vertical flex connector.
- **Lower Aux Flex —** This flex circuit provides connections to the lower door latch and link discrete signals. The lower aux flex is connected to the I/O board (60091) through a 0.5 mm pitch, 10-conductor, vertical flex connector.
- **Force Sensor Flex —** This flex circuit provides connections to the distal force sensor and the primary tube temperature thermistor. The force sensor flex is connected to the I/O board (60091) through a 0.5 mm pitch, 10-conductor, vertical flex connector.
- **Backflex —** This flex is connected to the I/O board (60091) through a 0.5 mm pitch, 30-conductor, vertical flex connector. The backflex provides the following functions:

- System power supply control and fuse – A 2.5 Amp surface-mount primary power fuse is mounted on this flex circuit. Additionally, four dual battery contacts are also on this flex circuit.
- High-Speed UART Interface / MUX – A digital MUX allows either a smart battery interface that includes an UART, or traditional "dumb" battery connections (battery type ID resistor and battery thermistor).
- Battery System Charge Control – An Atmel 8-bit microcontroller is hosted on the back-flex. One function of this processor is to control battery charging.
- Audio Output – The backflex provides connections to a 1-inch moving coil speaker that is used during audio alarms.
- Temperature Monitor – A temperature sensing thermistor is hosted on the backflex, which provides internal case temperature to the Spectrum processors.
- Advanced Battery Removal Detector – A magnetic reed relay is housed on the backflex, and provides an early or advanced battery disconnection warning to the Spectrum processors.

Keypad

The keypad consists of 19 user-actuated keys. Keys 1–9 also have alpha designations A–Z (in groups of 3 starting at the 1 key, with the exception that the 9 key has alpha designation "YZ"), a "0" key, a decimal point, 4 soft keys, a RUN/STOP key, and an ON/OFF key. The keypad is constructed of polyester dome keypad material with a circuit layer and adhesive layer. The keypad is edge sealed to prevent fluid intrusion between the layers of the keypad. The keypad is connected to the I/O board through a 10-conductor 1-mm pitch flex circuit. The following is a detailed description of the keys:

- ON /OFF: Powers up the pump.
- OK: This key accepts the information currently shown on the pump display and advances the pump program to the next screen.
- SETUP: This key is used to access the Care Area Selection screen.
- RUN/STOP: This key signals the request to Start or Stop infusions.
- Soft keys: Four multi-function keys. Can be used in conjunction with the display to perform any software programmable function including but not limited to Bolus operations, navigation arrows, help screens etc.
- Alphanumeric 1-9: These keys may be used to enter numeric sequences including real numbers with decimal point. Alphabetic strings may also be entered using the alphabetic groupings of characters found on these keys.

The infrared interface (Infrared Data Association) utilizes the IrDA protocol that can connect to personal computers and personal digital assistants (PDAs) that employ the IrDA standard. This digital interface can transmit and receive data at rates of up to 115 thousand bits per second (115Kbs). The IrDA interface is accessible through the SIGMA Spectrum keypad that is located on the front case assembly. The IrDA port operates at distances of up to 3 meters assuming a direct line of sight within a 15-degree conic section.

Power Connector

The power connector serves two functions:

- External power input
- Asynchronous data interface

Pump Specifications

Applications

- Large and small volume parenterals
- Neonatal

Administration Set

Compatible with standard gravity IV sets supplied by Baxter® and Hospira® and several other companies. (Visit www.sigmapumps.com for a full listing).

Performance

Downstream occlusion time to alarm for occlusion pressures adjusted to LOW (6 psi), MEDIUM (13 psi), and HIGH (19 psi)[1]:

Rate	Low (6 psi)	Medium (13 psi)	High (19 psi)
5 mL/hr	<5 min.	<10 min.	<20 min
100 mL/hr	<15 sec.	<20 sec.	<40 sec.
Max. Bolus	0.25 mL	0.50 mL	0.80 mL

All safety related sensing systems are automatically checked for proper operation periodically during setup and pump running conditions. Faults are identified by SYSTEM ERROR codes.

See the Specifications section of the Operator's Manual for additional specifications.

Effect of Fluid Container Height[2]

The performance of the infusion pump will be influenced by the forces of gravity on the fluid being administered to the patient. When a fluid container is positioned above or below the patient's administration site, pressure forces associated with the fluid's head-height (distance measured from the center of the pumping mechanism to the top of the fluid in the source container) will cause deviations in the nominal specification for device flow rate accuracy. The nominal head-height used for the flow rate and the graphical presentation is 24" (61 cm). For example, the deviation from the nominal flow rate accuracy from +24" to -20" (-51 cm) head-height has an influence of a possible -4% in flow rate accuracy when the flow rate is set to 25 mL/hr.

Bolus Accuracy

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

1.With Occlusion 45 inches below the pump and alarm set to LOW, MEDIUM or HIGH.
2.Liquid container must be a vented or collapsible bag.

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

In either mode, the time is entered in minutes and seconds (min:sec). Limits are placed on the minimum and maximum amount of time for the bolus delivery. The limit constraints are contained within the software of the Spectrum pump and are necessary to control the maximum or minimum flow rate of the bolus infusion.

The accuracy of the bolus volume is dependent upon the resultant flow rate that is obtained from the calculation of volume to be delivered in the time requested. For example, if the maximum bolus volume is 300 mL, the maximum flow rate is obtained with a bolus time of 18:02 (min:sec) or a flow rate of approximately 999 mL/hr. Using this maximum bolus volume, and delivering the volume in the shortest amount of time, the mean value of 302 mL ±5% may be expected. Whereas using a minimum bolus volume (.5 mL), and delivering the volume in a reasonably short amount of time (1 minute), the mean value of .52 mL ±16% may be expected.

Technical

- Type of pump - volumetric infusion pump.
- Operating principle - linear peristaltic
- Patient leakage: <15 micro amps, normal condition; <50 micro amps, single fault condition.
- Battery type: 7.2-volt battery pack consisting of (2) 3.6V/1.8 Ampere-hr rechargeable lithium ion, or 7.2-volt battery pack consisting of (2) 3.7V/1.75 Ampere-hr rechargeable lithium ion.
- Alarms:
  - Air-In-Line
  - Downstream Occlusion
  - Upstream Occlusion
  - Door Open, Door Not Latched
  - Low and Depleted Battery
  - AC Applied / Removed
  - Battery Not Detected
  - Infusion Complete
  - Secondary Complete
  - Secondary Delivery
  - Primary Delivery
  - User Inactivity
  - Unload Set Caution
  - System Errors
  - Incomplete Titration Entry
  - Slide Clamp Closed

NOTE: For additional technical specifications, refer to the SIGMA Spectrum Operator's Manual.

CONFIGURATION OPTIONS

The Spectrum pump has two sets of configuration options:

- User Options
- Biomed Options

NOTE: For a description of the User options, refer to the SIGMA Spectrum Operator's Manual.

BioMed Options

Biomed Options allow the Biomedical Technician access to certain pump functions and settings. This section will describe the options available to the technician.

NOTE: Biomedical Technicians should access ONLY the options listed in this section, unless otherwise Authorized.

To access the BioMed Options menu:

1. Press the OPTIONS soft key.
2. Select BioMed Options from the options list and press OK.

NOTE: The Bio Medical (BioMed) option menu requires an access password. This access password may be obtained by authorized service personnel.

Contact SIGMA LLC Service Department.

Telephone: 1-800-356-3454, or 585-798-3901

Or write:

SIGMA LLC
711 Park Avenue
Medina, N.Y. 14103

Email Service Coordinator at:

techsupport@sigmapumps.com

The BioMed Options menu has six categories:

- Sensor Configuration
- Calibration
- Pump Settings
- Pump Testing
- Update Software
- Network Configuration

Sensor Configuration

- Downstream Occlusion Auto-Restart on/off - Turns on or off the Downstream Occlusion Auto-Restart feature.
- US /Air alarm confirmation on/off - When this selection is set to on, the user must acknowledge the air-in-line alarm with a key-press before the RUN key will be accepted to resume the infusion.

Calibration Menu

The Calibration Menu provides access to sensor calibration data. There are 4 sensors in this menu and, the biomed personnel can access the sensor data in these menus.

NOTE: Calibration of the device shall be performed by technicians that have been formally trained by SIGMA personnel on Spectrum calibration procedures ONLY.

Sensor Calibration

- Upstream Sensor
  - View Calibration Values - Provides a utility to view the Upstream Sensor calibration data that follows.
    - Upper Freq (kHz)
    - Upper Power Level
    - Upper Reading
    - Lower Freq (kHz)
    - Lower Power Level
    - Lower Reading
- Downstream Sensor
  - View Calibration Data - Provides a utility to view the Downstream Sensor calibration data.
    - Current Reading
    - No-Tube Reading
    - Digit Pot Setting
    - Scale Factor
    - Scale Offset
- Slide Clamp Sensor
  - View Calibration Data - Provides a utility to view the Slide Clamp Sensor and No Slide Clamp calibration data.
    - Red %
    - Green %
    - Blue %
  - View Current Readings - Provides a utility to view the **current** Slide Clamp sensor data.
    - Red %
    - Green %
    - Blue %

        - Red Hz
        - Green Hz
        - Blue Hz
    - Optical Tube Sensor
        - View Calibration Data - Provides a utility to view the Optical Tube Sensor calibration data.
            - No Tube VDC
            - Tube VDC

Pump Calibration

- View flow calibration values - Allows the Biomedical Engineer/Technician to view flow calibration correction values applied during the flow rate calibration process.

View All Calibration

- View All Calibration - Allows the Biomedical personnel to view all of the sensor calibration data previously discussed along with Cam Calibration data from one scrollable menu. This data can be scrolled through by pressing the Next or Prev soft keys.
    - Cam Calibration Data
        - cam_offset:
        - f_offset

Pump Settings

Pump Settings allows the Biomed personnel to enable and disable the following alarms.

Alarm Settings:

- Phase Complete Alarm - Turn this option on to sound audio tone at the completion of the secondary, loading dose, and bolus infusions.

System Settings:

- Set Time and Date
    - Time (GMT) - Sets the real-time clock current time (observing Greenwich Mean Time, or UTC).
    - Date (mm/dd/yyyy) - Sets the real-time clock current date in the indicated format.
- PM Due Settings
    - PM Due Notification ON/OFF
    - Date - mm/dd/yyyy

Pump Testing

- **Battery Test**
  - Battery Life Test - performs an automated life cycle of the battery to determine its expected period of operation.
  - Show Battery Test Results - Displays the time to LOW BATTERY and PLUG IN Alarm after the Battery Life Test has been conducted.
  - View Battery Status - Displays the voltage reading (VDC) of the battery. The motor may also be run to observe the battery status under load; however, alarms are not activated with the exception of the Depleted Battery alarm.
  - View Internal Charger Status - Displays the status of the battery charger.
    - Build - This is the Battery Charger Controller (BCC) Version Number.
    - State - When AC power is applied the status is Charging/Charged and when AC power is not present the status is Off
    - Voltage - This is the battery voltage.
  - View Smart Battery Status -
    - Build - This is the Battery Charger Controller (BCC) Version Number.
    - State - AC in = Charging battery and AC out = Off.
    - Voltage - This is the battery voltage.
    - Current - This is the current draw during charging measured and displayed in milli-amperes (mA).
    - Output - This is the Charge output displayed in percentage (%).
    - Temp - Is the battery temperature displayed in Celsius (C).

Update Software

- **Drug Library** - Allows updating of the drug library via the IrDA port (not accessible if wireless networking is enabled).
- **Pump Software** - Allows the operating software of the pump to be updated via the serial communications port.

Network Configuration

- **Network Status** - Shows the current status of the network connection. The following items are available:
  - MAC Addr - Displays the Media Access Control (MAC) address of the pump. This address is associated with the wireless battery module connected to the pump.
  - IP Addr - Displays the current IP address of the pump.
  - SIGMA GW - Displays the IP address or DNS name of the network host, also known as the Sigma Gateway server.
  - Network Status - Displays the current status of the wireless radio and network connection. If the wireless radio is connected to a network, the relative receive level will be reported as a percentage. While the radio is disabled or booting, pump event information is not buffered or sent to the network host. Network drug library updates are only available when the pump is connected to a host.
  - Error Message - Displays information about any abnormal conditions that may be preventing the pump from accessing or using the network.
- **Transfer Network Status** - This option shows the TCP/IP settings of the pump's network connection.

- **Network Settings** - Shows the basic network settings for the pump, and also allows the pump's network connection to be enabled or disable. The following items are available:
  - Networking - Allows the pump's network connection to be turned on or off. This setting is stored in the pump after the pump is turned off, although the pump's network connection is always turned off when the pump power is turned off, including when the pump is turned off but in battery charge mode.
  - Sigma GW - (read-only, set via network configuration file) The IP address or DNS name of the network host, also known as the Sigma Gateway server. Either this item or 'Multicast' may be set, but not both.
  - Multicast - (read-only, set via network configuration file) The IP address of the multicast group that the pump joins to learn the location of the host. Either this item or 'Sigma GW' may be set, but not both.
  - Device ID - (read-only, set via network configuration file) The facility-defined device identifier for this pump. This value should be unique for each pump on a facility's network.
- **TCP/IP Settings** - Shows the TCP/IP settings of the pump's network connection. If Dynamic Host Control Protocol (DHCP) is enabled, the current settings as configured by the DHCP server will be shown.
  - DHCP - (read-only, set via network configuration file) Dynamic Host Control protocol settings, either 'on' or 'off'.
  - IP - (read-only, set via network configuration file) IP address of pump, either assigned statically or assigned by DHCP server.
  - Gateway - (read-only, set via network configuration file) IP address of gateway, either assigned statically or assigned by DHCP server
  - Netmask - (read-only, set via network configuration file) IP netmask, either assigned statically or assigned by DHCP server.
  - DNS - (read-only, set via network configuration file) Domain Name Server IP address, either assigned statically or assigned by DHCP server.
- **Wireless Settings** - Shows the wireless settings of the pump's network connection.

  NOTE: See "Wireless Networking" on page 21 for additional instruction.

- **Sleep and Location Settings** - This allows the BiomedTechnician to view the settings configured in the MDL for how often the Spectrum Pump does a Drug Library Check in the following modes:
  - Clinical / Biomed Mode (on)
  - AC Sleep Mode
  - Battery Sleep Mode

WIRELESS NETWORKING

The Sigma Spectrum Infusion Pump offers an optional wireless battery module (SIGMA P/N 35083) providing an 802.11b wireless networking capability, and an optional wireless battery module (SIGMA P/N 35162) providing an 802.11b/g wireless networking capability. In conjunction with a host computer system, the pump Drug Library can be updated to a new library and pump status information may be sent via a wireless network connection to a host.

The pump includes a number of networking parameters that must be configured for the pump to access and use the wireless network.

When a new pump is first received from Sigma, the BioMed department must configure each pump's network parameters as described below. The BioMed department will need to coordinate with the facility's IT department to determine the proper settings for the network parameters.

These network parameters are changeable by sending a configuration file to the pump via an IrDA interface. The pump can also send its current network configuration file to a PC or PDA via the IrDA. A PC with an IrDA interface can be used to program multiple pumps with the same configuration. The network configuration file is a simple text file that can easily be edited on a PC and sent via the IrDA to a pump. After changing the pump's network configuration, the pump may need to be power cycled for the net settings to take effect.

Each pump stores its configuration information in non-volatile memory, so that even if it loses all power sources (AC and battery) its settings are not lost.

The following is a description of the parameters required in order for the wireless interface module to work properly with the host. These parameters may be accessed and reviewed as previously indicated in the BioMed Options portion of this manual.

Network Configuration

Network Status

This option shows the current status of the network connection. The following items are available:

- MAC Addr – displays the media access control (MAC) address of the pump. This address is associated with the wireless battery module connected to the pump.
- IP Addr – displays the current IP address of the pump.
- SIGMA GW – displays the IP address or DNS name of the network host, also known as the SIGMA Gateway server.
- Network Status – displays the current status of the wireless radio and network connection. If the wireless radio is connected to a network, the relative receive level will be reported as a percentage. While the radio is disabled or booting, pump event information is not buffered or sent to the network host. Network drug library updates are only available when the pump is connected to a host.
- Error Message or Network Information – displays status information or error conditions about any abnormal conditions that may be preventing the pump from accessing or using the network.

Transfer Network Status

This option allows the pump's network configuration to be sent or received via the pump's IrDA port, to or from an IrDA compatible PC. The pump's network configuration may also be reset, clearing any configured network passwords, returning the pump's network configuration to the pump's default. To configure a pump for use with a facility's network the pump's network configuration file may be modified and sent to the pump via IrDA. The pump serial number located in the network configuration file must match the serial number of the pump it is being sent to, otherwise the pump will prevent use of the configuration file. Note that certificate-based authentication modes are not supported. The default network configuration file, available by pressing 'send' on this screen on a pump after pressing 'reset' to reset the configuration, can be found below:

```
SN=XXXXXX
# Pump serial number - must match SN of receiving pump

# SIGMA Spectrum Settings

[NETWORK CONFIGURATION]
# DHCP=0 DHCP disabled - IP, GATEWAY, NETMASK, and DNS must be valid
# DHCP=1 DHCP enabled - IP, GATEWAY, NETMASK, and DNS must be blank
DHCP=1
IP=
GATEWAY=
NETMASK=
DNS=
# Leave either SIGMAGW or MULTICAST blank
# SIGMAGW set to DNS name or IP address of SIGMA gateway server
SIGMAGW=SIGMAPUMPGW
# MULTICAST group default is 239.237.12.87
MULTICAST=
# DEVICEID set to device alias
#  Limited  to  20  alpha-numeric  characters  (0-1,A-Z,a-z),  blank  is
acceptabl
DEVICEID=

[WIFI CONFIGURATION]
# BSS=0 Infrastructure mode (Access point)
# BSS=1 Join or Create Ad-Hoc (peer-to-peer)
# BSS=2 Join only Ad-Hoc (peer-to-peer)
# BSS=3 Join any
BSS=3
# SSID= set to wireless network name
SSID=sigma_pumps
# CHANNEL=0 search channels
CHANNEL=0
# SECURITY=0 Any available security method
# SECURITY=1 Open system (no-encryption)
# SECURITY=2 WEP shared key
# SECURITY=3 WPA pre-shared key
# SECURITY=4 WPA with 802.1x authentication
# SECURITY=5 WEP with 802.1x authentication
# SECURITY=6 LEAP
SECURITY=0
# WEPKEYINDEX=0-3
```

```
WEPKEYINDEX=0
# WEPKEY may be blank or 10 (64-bit) or 26 (128-bit) hex (0-1 and a-f)
characters long
WEPKEY=
# WPAENCRYPTION=0 Any
# WPAENCRYPTION=1 WEP
# WPAENCRYPTION=2 TKIP
# WPAENCRYPTION=3 CCMP (AES)
# WPAENCRYPTION=4 Open (no encryption)
WPAENCRYPTION=0
# WPAPSK must be blank if WPA PSK is not used
# WPAPSK may 64 hex (0-1 and a-f) characters long to specify a PSK
# WPAPSK may be 8-63 ascii characters long to specify a passphrase
WPAPSK=
# EAP Authentication 32-bit bitmask (decimal format, hex for reference
only)
# 0      (0x00000000) - None
# 1      (0x00000001) - LEAP
# 2      (0x00000002) - PEAP
# 4      (0x00000004) - TLS
# 8      (0x00000008) - TTLS
# 256    (0x00000100) - GTC
# 512    (0x00000200) - MD5
# 1024   (0x00000400) - MSCHAPv2
# 2048   (0x00000800) - OTP
# 65536  (0x00010000) - CHAP
# 131072 (0x00020000) - MSCHAP
# 262144 (0x00040000) - MSCHAPv2
# 524288 (0x00080000) - PAP
AUTHENTICATION=0
# IDENTITY= 802.1x Identity (username)
IDENTITY=
# PASSWORD= 802.1x Password
PASSWORD=
```

Network Settings

This option shows the basic network settings for the pump, and also allows the pump's network connection to be enabled or disabled. The following fields are available:

- Networking – allows the pump's network connection to be turned on or off. This setting is stored in the pump after the pump is turned off, although the pump's network connection is always turned off when the pump power is turned off, including when the pump is turned off but in battery charge mode.
- SIGMA GW – (read-only, set via network configuration file) the IP address or DNS name of the network host, also known as the Sigma Gateway server. Either this item or 'Multicast' may be set, but not both.
- Multicast – (read-only, set via network configuration file) the IP address of the multicast group that the pump joins to learn the location of the host. Either this item or 'SIGMA GW' may be set, but not both.
- Device ID – (read-only, set via network configuration file) the facility-defined device identifier for this pump. This value should be unique for each pump on a facility's network.

TCP/IP Settings –

This option shows the TCP/IP settings of the pump's network connection. If Dynamic Host Control Protocol (DHCP) is enabled, the current settings as configured by the DHCP server will be shown.

- DHCP – (read-only, set via network configuration file) Dynamic Host Control protocol settings, either 'on' or 'off'.
- IP – (read-only, set via network configuration file) IP address of pump, either assigned statically or assigned by DHCP server.
- Gateway – (read-only, set via network configuration file) IP address of gateway, either assigned statically or assigned by DHCP server
- Netmask – (read-only, set via network configuration file) IP netmask, either assigned statically or assigned by DHCP server.
- DNS – (read-only, set via network configuration file) Domain Name Server IP address, either assigned statically or assigned by DHCP server.

Wireless Settings

This option shows the Wireless settings of the pump's network connection.

- Mode (BSS) – (read-only, set via network configuration file) Basic Service Set (BSS), one of:
  - Infrastructure (AP)
  - Join or Create Ad-Hoc
  - Join only Ad-Hoc
  - Join any
- Name (SSID) – (read-only, set via network configuration file) service set identifier (SSID), or the name of the wireless network to join.
- Channel – (read-only, set via network configuration file) wireless network channel (1-11) to use, or 'search' if all channels are to be scanned for the configured wireless network.
- Security – (read-only, set via network configuration file) the security model to use, one of:
  - Any
  - Open system
  - WEP
  - WPA pre-shared key
  - WPA 802.1x
  - WEP 802.1x
  - LEAP
- WEP Key – (read-only, set via network configuration file) the WEP key index (0-3) and the 10 (64-bit) or 26 (128-bit) hex characters WEP key. If the entire WEP key can not be displayed on the screen, then an ellipsis, "…" is displayed at the end of the displayable portion.

- Encryption – (read-only, set via network configuration file) the encryption method use on the wireless network:
  - Any
  - WEP
  - TKIP
  - CCMP (AES)
  - Open (no encryption)
- WPA PSK – (read-only, set via network configuration file) WPA pre-shared key, may be either an 8-63 character pass-phrase, or up to 64 hex characters long for a pass-key. Use of the pass-key, versus a pass-phrase, will reduce the amount of time needed by the pump to connect to the wireless network. If the entire WPA PSK can not be displayed on the screen, then an ellipsis, "…" is displayed at the end of the displayable portion.
- Authentication – (read-only, set via network configuration file) the allowable inner and outer EAP modes used for wireless network authentication, one or more of the following:
  - LEAP
  - PEAP-MSCHAPv2
- Username – (read-only, set via network configuration file) user name used to authenticate the pump on the wireless network.
- Password – (read-only, set via network configuration file) password used to authenticate the pump on the wireless network.

Network Interface Information

A MAC address is supplied for each Wireless Battery module. Because the radio is located in the battery module, the MAC address is associated with the radio and therefore the wireless battery module, not the pump that it is attached to. The MAC address for each battery module is assigned at the factory and cannot be changed. The address is located on the side label of each wireless battery module.

When a Spectrum pump is turned on, assuming it is properly configured, it will attempt to locate and connect to the wireless network. It is the responsibility of the host network to verify that the specific pump is permitted to gain access to the network and to determine to what parts of the network the pump will have access.

Contact SIGMA LLC for further information pertaining to suggested host requirements and/or details needed for network implementations.

SERVICE AND MAINTENANCE

CAUTION: Electric shock hazard.

There are no user serviceable parts. Do not remove the case. Refer servicing to SIGMA trained and qualified service personnel.

Required Maintenance and Frequency

- Maintenance consists of routine cleaning and annual performance evaluations as described in the service manual.
- Pumps suspected of being damaged must be tested for proper performance before being returned to patient use. This includes pumps that have been physically damaged, dropped or those that have fluid intrusion.
- A PM or Network expiration due date may be entered in the BIOMED options. A “Due for Inspection” reminder will appear with the power ON display followed by the normal programming screens. At power off, a due for inspection display will appear prior to pump shutdown.

SIGMA Spectrum Cleaning

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

Compatible Cleaners

- 10% solution of bleach and water
- Up to 90% Isopropyl alcohol
- Caltech Industries Dispatch®
- Steris TBQ® and Steris Germicidal Surface Wipes, Product Number 1608-GS
- Metrex Cavicide® and Cavi WipesTM
- Contact SIGMA for additional information

Refer to DOC 11318 for complete listing.

Cleaning the Pump

CAUTION:

- Always press **STOP** then **OFF** and unplug the AC power adaptor before cleaning.
- DO NOT sterilize by autoclaving, ETO gas or spraying. DO NOT immerse any part of the pump. DO NOT use abrasive cleaners.

- DO NOT use phenolic-based cleaners or disinfectants; extended use may cause damage to the keyboard, case and any other plastic component of the SIGMA Spectrum.
- DO NOT use spray or aerosol cleaners. A lint-free, foam-tipped swab (Chemtronics FoamtipTM or Qosmedix® precision foam tip for example) may be used in the tube channel.
- Alcohols are flammable and should not be used for battery cleaning / disinfection. Always use alcohol in a well-ventilated area.
- When cleaning the battery pack, care should be taken to prevent shorting of the pack's exposed terminals.
- Dispose of all cleaning/disinfectant materials per federal, state and local regulations for infectious waste disposal.

To clean the pump:

1. Turn the pump off and unplug the AC power adaptor from the power source.
2. Place the pump in an upright position (keyhole release upward).
3. Apply the compatible cleaning agent with a dampened cloth per the manufacturer's instructions using appropriate dilution ratio.

   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.
4. Open the pump's door using a standard IV set's slide clamp.
5. Clean the speaker vent, power adaptor connector, door release, keyhole and pumping channel areas with soft swabs.
6. Apply solutions sparingly to the swabs and wipe down the necessary areas.

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

   NOTE: For severe solution spills it is recommended that the standard battery/ wireless battery module be removed. The battery pack cavity area of the pump may be cleaned by wiping down those regions with a dampened cloth as described previously.
7. Visually inspect the tubing channel and remove any foreign material. An obstructed set tubing channel could cause accidental free flow.
8. Subsequent disinfecting is recommended using the same application technique. Disinfectants should remain on the pump surface in an even, but not dripping, film for the manufactures' recommended contact time. Wipe dry or air-dry after completion of contact time period before pump reuse.
9. Dispose of all cleaning materials (including the slide clamp) as required per facility protocol/biohazard policy.

Battery Removal and Replacement

Should removal of the battery become necessary for any reason, the following procedure may be used. Refer to “Appendix A: Technical Drawings” on page 51 for the location of parts.

1. Turn unit off, if on.
2. Disconnect the AC power adaptor, and lay the pump on its front. Use a protective surface, such as plastic foam, to prevent damage to the keypad window.
3. Remove the screw located in the upper right-hand corner of the SIGMA Spectrum battery (if equipped).[1]
4. Depress the release mechanism found in the top center portion of the battery and pull away from the back of the unit.
5. Install the battery by placing the battery insulation tab over the terminals and then gently sliding the battery down the back of the case and inserting the bottom of the battery into the pocket, then pivoting it into the latch.

   Make sure the latch is engaged to retain the battery.
6. Remove the battery insulating tab prior to charging the pump’s battery or operating the pump. .
7. Plug the AC power adaptor into an outlet to begin charging.

Wireless Module Battery Cell Removal and Replacement

CAUTION: Static sensitive components will be exposed during this process. Perform this procedure using proper anti-static techniques in an EOS/ESD safe work area. Failure to do so may result in component failure or degradation.

Tools Required:

- TORX – T5 driver
- 1/8” to 1/4” flat plate slightly larger than the perimeter of the wireless battery module

1. Turn unit off, if on.
2. Disconnect the AC power adaptor, and lay the pump on its front. Use a protective surface, such as plastic foam, to prevent damage to the keypad window.
3. Remove the screw located in the upper right hand corner of the wireless battery module (if equipped).[1]
4. Depress the release mechanism found in the top center portion of the battery and pull away from the back of the unit.
5. After the wireless battery module is removed from the pump place it with the connecting terminals up on the work surface.

1.SIGMA does not recommend re-installation of the battery-securing screw.

6. Using the TORX driver, remove and retain the four TORX head screws from the case. (Wireless modules purchased prior to 2008 may have five torx head screws on this side of the case).
7. Turn the wireless battery module over so that the terminals are now towards the work surface and remove and retain the one remaining TORX head screw at the top of the antenna housing.
8. Place the wireless battery module on the flat plate with the bottom (terminal end) of the pack even with the edge of the plate.
9. Carefully open the case starting at the top of the case and fold it open towards the bottom as if it were hinged at the bottom. **NOTE**: There is a flex cable attaching the two halves at the bottom of the case. Take care not to over stress it.
10. Disconnect the four-pin connector from the battery cables to the PCB inside of the wireless battery module by pressing the release latch on the connector and carefully pulling the connector apart. Do not over stress.
11. The battery may then be removed from the pack.
12. Remove the backing from the adhesive tape on the battery cells and press into the case.
13. Make sure that the battery is flat inside the case, the routing of the battery wires is flat across the top of the PCB and the connector is fully latched in place prior to reassembly.
14. Make sure that the antenna is properly seated in the slot in the case.
15. Make sure that the wireless battery module latching mechanism is properly installed in the case.
16. Carefully fold the case halves back together, making sure that all internal components are aligned properly and that the case will close fully without interferences.
17. Place the wireless battery module on the work surface with the terminal side of the battery pack facing up and install the TORX screws. Tighten snug, do not over tighten. The case halves should fit tightly together along the seams. If not, check for loose screws or internal interferences inside the pack.
18. Check the latch mechanism operation to assure that it moves freely when depressed and released.
19. Turn the wireless battery module over and install the last screw into the antenna section of the case and tighten.
20. Install the battery by placing the battery insulation tab over the terminals and then gently sliding the battery down the back of the case and inserting the bottom of the battery into the pocket, then pivoting it into the latch.

    Make sure the latch is engaged to retain the battery.
21. Remove the battery insulating tab prior to charging the pump's battery or operating the pump.
22. Plug the AC power adaptor into an outlet to begin charging.
23. Perform the battery capacity check of the new battery as indicated in the Preventive Maintenance procedure included in this manual.

Battery Disposal

The SIGMA Spectrum contains a lithium-ion rechargeable battery pack. It should not be disposed of in trash or in fire. It is a recyclable product and should be disposed of properly. Return to SIGMA for disposal if an authorized disposal center cannot be found.

CAUTION:

- Do not short circuit the battery terminals.
- Do not disassemble or modify.

Returning Equipment

Contact SIGMA LLC for all service information at:

Telephone: 1-800-356-3454
Email: techsupport@sigmapumps.com

NOTE: Confirm pump failure as described in this manual prior to return. Evaluation time may be billed at SIGMA's discretion for unconfirmed complaints.

If it is necessary to return the unit for service:

- Visit www.sigmapumps.com or phone 1-800-356-3434 to obtain a Return Authorization (RA) number for service. A Purchase Order (PO) number is required for Return Authorization
- Be prepared to provide the following information:
  - Device model
  - Device serial number
  - Purchase order number
  - Description of problem
  - Name and telephone number of contact person in your hospital or organization
  - Complete hospital or organization name and address
  - Any other pertinent information such as flow rate, administration set part number used, and the message displayed at the time of the difficulty
- Prior to returning device for service, clean and disinfect the pump in accordance with the cleaning procedure provided in this manual.
- Package the pump in the original shipping container (replacement available upon request) and affix the RA number on the outside of the package.
- Ship pump, freight prepaid, by traceable means to: SIGMA LLC.
- SIGMA LLC will not be responsible for unauthorized returns or units damaged in shipment due to improper packing.

PREVENTIVE MAINTENANCE

To ensure that the SIGMA Spectrum IV pump is operating within the specified parameters set forth by SIGMA LLC, perform the preventive maintenance tests in this section according to the maintenance schedule below. After each operation in this procedure, record the results on a copy of the Preventive Maintenance Check Sheet at the end of this section.

NOTE: Service School Training is available, but not required, for performance of this Preventive Maintenance Procedure. Contact TechTraining@sigmapumps.com for information.

Preventive Maintenance Schedule

- Preventive maintenance is recommended a minimum of once annually on all pumps in service.
- Preventive maintenance should be performed after any user facility maintenance.
- Preventive maintenance test should also be carried out whenever a pump is dropped, or suspected of having been otherwise damaged.

Equipment Required

- SIGMA Spectrum Infusion Pump
- IV set of the brand specified on the pump label

  NOTE: If the pump is being tested for accuracy following a clinical problem, it is essential to test with an IV set of the same catalog number and lot number as that in use when the problem occurred.

- IV container (250, 500 or 1000 mL) to be used as pumping source
- Collection vessel used should be a class “A” graduate during a volumetric test
- Any collection vessel may be used for a gravimetric test (output is weighed)
- Pressure gauge
- Electronic balance scale with 0.1 gram readability (only for gravimetric flow rate testing)

Preventive Maintenance Tests

CAUTION: All testing and evaluations require fluid and air temperature of 72°F ±2°F.

NOTE: The brand of IV sets being tested must be compatible with the pump under test. The proper IV set calibration is listed on the label located on the top of the pump.

NOTE: Sections identified with an asterisk (*) may be used as incoming test procedures.

Visual Inspection

1. Inspect the pump for visual evidence of damage and/or defects to exterior components (i.e. case, keypad and door).
   - The IV set tube channel must be free of foreign materials and dry for both testing and use.
   - Any evidence of damage to, or repair of, these parts is reason to run the preventive maintenance checks.
2. Verify legibility of all labels.
3. Replace labels as necessary.

Determine Software Version and Serial Number

When you press the **ON/OFF** key to turn the unit on, the Power Status screen displays the current software version and serial number. You can also view pump and software information from the User Option menu:

1. From the Select Care Area screen, press **OPTIONS**.
2. Select **User Options**, and press **OK**.
3. Select **View Information** and press **OK**.
4. Select **Pump Information** and press **OK** to display the Pump Info screen.
5. Record the software version and serial number on the Preventive Maintenance Check Sheet.

Keypad Test

The Spectrum keypad and display may be checked for proper operation as follows (The 1, 2, 3, and 5 keys will be verified during subsequent testing):

1. Press the **ON/OFF** key to turn the unit on. Select any **Care Area** and Press **OK**.
2. Select any **Drug Name** and Press **OK.**
3. Press **OK** to select **Primary Bag** and Press **OK** to select mL/hr, and then enter “4” and “6” using the keypad and observe the **Rate mL/hr** field to be “46”.
4. Press the **CLEAR** soft key and verify that the **Rate mL/hr** field is cleared to 0.
5. Enter “7”, “8”, and “9” using the keypad and observe the **Rate mL/hr** field to be “789”.

6. Press the **CLEAR** soft key and enter "." and "0" using the keypad and observe the Rate mL/hr field to be "0.0"
7. Press the **CLEAR** soft key, and press the▼ key until the **Volume Given** field is highlighted.
8. Press the **Clear Program** soft key and verify that the display menu changes to the Clear Program Yes/No? screen. Press **Yes**. Then the Care Area Selection screen appears.

Upstream (Proximal) Occlusion Sensor Test

NOTE: The IV line and gauge must be free of air. The test fixture must consist of only compatible IV tubing as specified on the label at the top of the pump. Softer tubing between the pump and the gauge, or air in the line can result in inaccurate results.

NOTE: Confirm test failures with a new unused IV set.

1. Press the **ON/OFF** key to turn the unit on. Select any **Care Area** and Press **OK.**
2. From the Drug List select **BASIC** and then press **OK**.
3. Select Primary Bag and press **OK**.
4. For **Mode** select **mL/hr** and press **OK**.
5. Set the Rate to **100mL/hr** and press **OK.**
6. Set **VTBI mL** to **13.3** mL and press **OK**.
7. Load the IV set in accordance with the directions on the **LOAD SET** screen on the pump.
8. Occlude IV set 12" above the pump with a pair of hemostats.
9. Push the **RUN/STOP** key to start the pump.

   NOTE: Pumps with v6.00.00 and later software versions will display a CHECK FLOW screen once the pump is started. For purposes of this test, press **YES** to proceed to the normal Run screen.

10. The pump may indicate BAG NEAR EMPTY <30 MIN REMAIN. Press **OK** to silence this alarm.
11. Verify that the pump goes into UPSTREAM OCCLUSION alarm prior to the infusion complete message.
12. Release the occlusion and restart the pump.

Downstream (Distal) Occlusion Sensor Test*

If performing this test immediately following the Upstream (Proximal) Occlusion Sensor Test Press the Stop button and continue this test from Step 1. If this is a Stand alone test Turn the Pump ON and continue the test starting with Step 2.

NOTE: Confirm test failures with a new unused IV set.

1. Press the **Clear Program** soft key, Clear Program confirmation window appears, press **YES**.
2. Press the **OPTIONS** soft key, select **BioMed Options**, and enter the password.
3. Select **Sensor Configuration** and press **OK**.

4. Verify that **DS Occlusion Auto Restart** is set for "on" and verify **US/Air Alarm Confirm** is set for "on".
5. Press the **EXIT** soft key two times to return to the **OPTIONS** screen.
6. On the options screen, select **User Options** and press **OK.**
7. On the User Options screen, select **Alarm Settings** and press **OK**.
8. Set the **DS Pressure Limit** to "med".
9. Press the **EXIT** soft key three times to leave the Alarm Settings, User Options, and Options screens.
10. Select a **Care Area** and press **OK**.
11. Press **OK** again and the desired drug list will appear, select **BASIC** and then press **OK**.
12. Select **Primary Bag** and press **OK**.
13. For **Mode** select **mL/hr** and press **OK**.
14. Set the **Rate** to **100 mL/hr** and set the **VTBI mL** to **50 mL**.
15. (Skip this step if IV set is already loaded in pump) Load the IV set in accordance with the directions on the **LOAD SET** screen on the pump.
16. Connect a pressure gauge to the end of a fluid-filled new IV set with a length of ≈48" of tubing between the pump and gauge.
17. Press the **RUN/STOP** key to start the pump.

    NOTE: Pumps with v6.00.00 and later software versions will display the Check Flow screen once the pump is started. For purposes of this test, press **YES** to proceed to the normal Run screen.

18. The pump may indicate BAG NEAR EMPTY <30 MIN REMAIN. Press **OK** to silence this alarm.
19. Verify the pump displays a **DOWNSTREAM OCCLUSION** alarm at a pressure within the 13-psi ±6 occlusion trip pressure setting.
20. Remove the IV set from the gauge and ensure the pump Auto Restarts.
21. Press the **RUN/STOP** key to stop the pump and Remove pressure gauge and re-set the test IV set to continue to the next test.

Air Detection Test*

If continuing this test from the Down Stream (Distal) Occlusion Sensor Test Start with Step 9, if you wish to conduct a standalone test start with step 1.

NOTE: Confirm test failures with a new unused IV set.

1. Press the **ON/OFF** key to turn the unit on. Select any **Care Area** and Press **OK.**
2. From the Drug List, select **BASIC** and then press **OK**.
3. Select Primary Bag and press **OK**.

4. For **Mode** select **mL/hr** and press **OK**.
5. Set the Rate to **100mL/hr** and press **OK**.
6. Set **VTBI mL** to **50** mL and press **OK**.
7. Press the **RUN/STOP** key.

   NOTE: Pumps with v6.00.00 and later software versions will display the Check Flow screen once the pump is started. For purposes of this test, press **YES** to proceed to the normal Run screen.

8. Introduce a 1" minimum air bubble into the IV set upstream from the pump.
9. Verify the pump goes into AIR-IN-LINE alarm, and press **RUN/STOP**.

Memory Test

This test assumes you are starting from an all-clear point.

1. Press the **ON/OFF** key to turn the unit on and Select any **Care Area** and Press **OK.**

   NOTE: If the New Patient Yes/No? prompt appears, press **YES**.

2. From the Drug List, select **BASIC** and then press **OK**.
3. Select Primary Bag and press **OK**.
4. For **Mode** select **mL/hr** and press **OK**.
5. Set the Rate to **100mL/hr** and press **OK**.
6. Set **VTBI mL** to **50** mL and press **OK**.
7. Press the **ON/OFF** key to turn the pump off.
8. Turn the pump on and press **NO** to the New Patient Yes/No screen.
9. Verify that the **Rate** and **VTBI** parameters were saved.

Recommended Flow Rate Accuracy Test*

NOTE: Confirm test failures with a new unused IV set.

1. Press the **ON/OFF** key to turn the unit on. Select any **Care Area** and Press **OK.**
2. From the Drug List, select **BASIC** and then press **OK**.
3. Select Primary Bag and press **OK**.
4. For **Mode** select **mL/hr** and press **OK**.
5. Set the Rate to **200mL/hr** and press **OK**.
6. Set **VTBI mL** to **50** mL and press **OK**.(length of test >15 min.) when using a gravimetric method.

   - Set the **VTBI mL** to **40** mL using a 50 mL Class A graduate collection vessel when the volumetric test method is chosen. If a larger Class A graduate is used, a VTBI that is at least 80% of the collection vessel's maximum capacity should be used.

7. Hang the IV bag/container 24” above the pumping mechanism.
8. Connect a new IV set to the IV container and prime the set completely. Remove all air from the tubing, being sure the drip chamber is at least half full.
9. Load the set into the pump and close the door.
10. Place the end of the IV set in the collection vessel so that the fluid output end will not be below the fluid level that is to be collected.

    The set should be primed so that fluid is at the end of the IV set, but none has dripped into the graduate before starting the test.
11. Begin the test by pressing the **RUN** key. Allow the pump to run until it goes into infusion complete alarm.
12. Press the **STOP** key to halt the KVO (keep vein open) rate once the pump goes into infusion complete.
13. If test is interrupted by any alarms except air, the test can be continued as long as the pump was observed by the tester to have not been in STOP for more than ten minutes.
14. Observe the actual volume collected either visually or weighed on the scale.
15. **When measuring fluid level visually in the graduate**, read the level from the bottom of the fluid meniscus.

    Acceptance criteria: collected volumes of ±5%.
16. **When measuring with the scale (gravimetric method):**

    a. Weigh the collection vessel and water using grams as the unit of measure.

    b. Empty and dry the collection vessel.

    c. Weigh the collection vessel. The difference between the two measured weights (in g) is equivalent to the volume delivered (in mL).

    If the collection volume is within the range of ±5%, the pump is properly calibrated. If not, return the pump to SIGMA LLC for re-calibration.

AC Power Adaptor Safety Analysis

1. Inspect the SIGMA P/N 35714 AC power adaptor for signs of abuse such as cracks in the housing or bent AC main prongs.
2. Verify green LED is lit.
3. Inspect the cord from the AC power adaptor to the pump unit for signs of abuse such as cuts or exposed conductors.

Battery Capacity Test

The storage capacity for the battery may be determined by running the Battery Capacity Test.

1. Connect the pump to the AC power line for at least 12 hours prior to the test, to allow the battery to attain full charge.

   NOTE: If a wireless battery module is installed, the pump must be connected to the AC power line for at least 16 hours prior to the test.

   The pump can be in use while the battery is charging.

2. Use an IV test set in a loop configuration, so that fluid is circulated around the loop.
3. Turn on the pump and load the IV set into the pump following the display prompts to assure that it is properly loaded.

   NOTE: If the IV set is not properly loaded, the test results will be invalid.

4. Press the **OPTIONS** soft key, select **User Options**, select **Display Settings**, and select **Display Adjust**.
5. Set the **Backlight Level** to High.
6. Press **EXIT** to return to the Options screen.
7. Select the **BioMed Options**, and enter the password.
8. Select **Pump Testing**.
9. Select **Battery Test**.
10. Select option for **Battery Life Test** the "Load Tube Into Pump & Push OK To Continue" confirmation window appears. Press **OK**.
11. Follow the display instructions:
    - Enter or verify 125 mL/hr for Rate
    - Turn Low batt alarm off
    - Turn Constant alarm off.
12. Press the **OK** key and move the cursor to **Done** and press **OK**.
13. Be sure that the pump is unplugged and the current battery level indicates a fully charged battery (between 8.0V and 8.3V). If battery is fully charged, press **OK**.

    The pump will run until the battery is depleted and will then power off.

14. After the battery is depleted, plug in the pump's AC power adaptor and power the pump up or power the pump up with a fully charged battery.

    When the pump is plugged in, it will display the time from the start of the test to depleted battery and it will also display time from low battery to depleted battery (in hr:min format).

Pass criteria for a used battery

≥6 hours from “Start to dead” and ≥31 minutes from “Low to dead”.

NOTE: If a wireless battery module is installed, the pump used battery pass criteria is ≥3 hours from “Start to dead” and ≥31 minutes from “Low to dead”.

Pass criteria after installation of a new battery

≥8 hours from “Start to dead” and ≥31 minutes from “Low to dead”.

NOTE: If a wireless battery module is installed, the pump new battery pass criteria is ≥4 hours from “Start to dead” and ≥31 minutes from “Low to dead”.

The battery capacity is less than the pass criteria, the battery is reaching end of life. See the Battery Removal and Replacement section of this manual for replacement. If a wireless battery module is installed, see “Wireless Module Battery Cell Removal and Replacement” on page 28.

Preventive Maintenance Check Sheet

Serial Number: _____ Date:_____

Software Version:_____

Control Number:_____

Test	Pass	Fail
Visual Inspection		
Keyboard Test		
Upstream (Proximal) Occlusion Sensor Test		
Air Detection Test		
Downstream (Distal) Occlusion Sensor Test _____psi or _____mm/hg		
Memory Test		
Flow Rate Accuracy Test Volume Output _____mL		
Battery Capacity Test Time “Start to dead” = _____Hrs. _____Min. Time “Low to dead” = _____Hrs. _____Min.		

TROUBLESHOOTING

- **Clock Battery Low –** This alert appears when the real-time (internal) clock battery level is getting low. At this time the replacement of this battery is not user-serviceable and the pump must be returned to SIGMA for battery replacement.
- **Battery (Very) Low – Send Pump For Repair –** This alert appears during a Low Battery alarm when, through a tutorial-based system of user prompts, it has been determined that the external power cord or supply is damaged and may need to be serviced or replaced.
- **Memory Has Been Reset** - This screen appears on power up when the stored calibration data has been corrupted. The pump is prevented from operating at this point. Return the pump to SIGMA for recalibration.

Battery Charger Error Code Descriptions

Following is a list of errors that may be displayed during battery charge mode (when the pump is powered off and connected to the external power supply):

Displayed Error Code #	Displayed and History Log Language	Description
1	“Not Charging”	The battery charger has powered off
2	“Charger Timeout”	Charger could not detect a battery
3	“Over Volt”	Battery voltage above maximum
4	“Temperature”	Temperature of battery is too high
5	“High Latch Error”	Battery cell error
6	“ADC Voltage Error”	Battery voltage changed too quickly
7	“ADC Error”	Battery charger hardware error
8	“Current Error”	Charge current error
9	“Comm Error”	Battery communication error
10	“Comm Timeout”	Battery communication timeout
11	“Error: 11”	An unknown charger error occurred

Battery charger error codes may be cleared by performing the following steps:

1. Remove the external power supply.
2. Remove the battery for 1 minute.
3. Install the battery again and connect the external power supply.

   If the charge error repeats, return the pump to SIGMA for service.

System Error Code Descriptions

A series of error codes are generated by the software of the SIGMA Spectrum Infusion Pump, then displayed on the pump. The following error codes are intended to help the biomedical engineer to identify problems encountered during operation of the pump for assistance in repair of the product.

Error Code #	Displayed and History Log Language	Description
100	PIC Error	Error of unknown type
101	PIC Msg CRC Error	CRC failure
102	PIC Not Responding	Not responding
103	PIC Msg Rcv CRC Er	Message receive CRC error
104	PIC Receive Ovrflow	Receive overflow
105	PIC Motor Error	Motor failure flag
106	PIC Index Error	Index failure flag
107	PIC CAM Error	CAM failure flag
108	PIC COM Error During Run	COM failure flag
109	PIC Encoder Error	Encoder failure flag
110	PIC counts Per Cam Error	Counts per CAM failure flag
111	Pulse dmnd too high	Pulse demand too high for interval mode
112	Pulse dmnd too low	Pulse demand too low for PWM mode
113	PIC ROM CRC Error	ROM CRC error
114	Sensor disparity (slow)	Motor is slowing down

Error Code #	Displayed and History Log Language	Description
115	Sensor disparity (fast)	Motor is speeding up
116	Motor without PWM	Motor movement without PWM
117	PWM MAX	Max PWM for too many revs
201	Bad Motor Msg Tag	Bad motor message tag
202	Bad SPI Msg Tag	Bad SPI message tag
203	Bad Alarm Msg	Bad alarm message
204	Bad Sensor Msg	Bad sensor message tag
205	Bad Battery Msg	Bad battery message tag
206	Bad IrDA Task Msg	Bad IrDA message tag
210	SPI PIC Timeout	SPI PIC timeout
211	SPI 3202 Timeout	SPI 3202 timeout
212	Sensor Task Timeout	Sensors task wait timeout
213	Battery Task Timeout	Battery task wait timeout
220	Pump Task Starved	Pump task starved
221	User Task Starved	User task starved
222	KwikPeg Task Starved	KwikPeg task starved
223	Keypad Task Starved	Keypad task starved
224	SPI Task Starved	SPI task starved
225	Motor Task Starved	Motor task starved
226	Sens Task Starved	Sensors task starved
227	IrDA Task Starved	IrDA task starved
228	Batt Task Starved	Battery task starved

Error Code #	Displayed and History Log Language	Description
230	Diag Task Starved	Diagnostic task starved
231	Set Mech task Starved	Set mechanism task starved
232	Unknown Tsk Checked In	Unknown task checked in
233	Network Task Starved	Network task starved
240	Key Buffer is Full	Key buffer is full
300	Fail to enable US sensor	fail to enable US sensor (GPI bit 2)
301	US upper avg high	Bad US upper reading average (>MAX FLUID)
302	US lower avg high	Bad US lower reading average
303	Bad upper US rdg	Bad US upper transducer reading (<>ADC)
304	Bad Lower US rdg	Bad US lower transducer reading
305	DS rdng out of range (low)	DS reading out of range (low)
306	DS rdng out of range (high)	DS reading out of range (high)
307	DS pot no adjust	Digital pot failure
308	Inv sensor specified	Invalid sensor specified
309	No-tube rdg too high	No-tube reading too high
310	Upper US stuck high	No-drive upper ultrasonic high
311	Lower US stuck high	No-drive lower ultrasonic high
312	Upper US no adjust	Reduced-drive upper ultrasonic high
313	Lower US no adjust	Reduced-drive lower ultrasonic high
314	DS no-tube elevated	DS reading remains high after tube removal

Error Code #	Displayed and History Log Language	Description
320	Latch Switch Error	Hook switches do not agree
321	Link Switch error (up)	Upper link switch not activating
322	Link Switch Error (low)	Lower link switch not activating
323	Color Sensor Error: TMO	color sensor failure (PIC timeout)
324	Color Sensor Error: FRQ	Color sensor failure (frequency)
330	Bad Upstream A/D	Bad upstream A/D converter
331	Bad Downstream A/D	Bad downstream A/D converter
332	Bad Battery A/D	Bad battery A/D converter
340	Bad Battery Sample	Bad battery sample reading
341	Positional Interrupt Error	failed to receive positional interrupt
342	Sharp CAM Error	Sharp detected CAM failure
343	Motor High Rate Error	Motor high rate failure
344	Motor Low Rate Error	Motor low rate failure
345	Thermistor Disparity	Thermistor disparity
346	Thermistor ADC Error	Thermistor ADC fail
347	Check Battery	Battery is defective
348	No Upstream Sensor Poll	Upstream sensor not being polled
349	No Downstream Sensor Poll	Downstream sensor not being polled
350	Optical Snsr Rail Error	Optical tube detector ADC failure
351	Clean Load Pt. #2	Optical sensor needs cleaning
352	Opitcal Snsr Toggle Error	Optical sensor toggle check failure
401	NVM Sema Timeout	NVM resource semaphore timeout

Error Code #	Displayed and History Log Language	Description
402-411	NVM write error: x (1-10)	NVM write failed
412	User NVM CRC Error	NVM CRC check failed (user data)
413	Cal NVM CRC Error	NVM CRC check failed (cal data)
414	Wrong NVM structure	NVM version # doesn't match expected version#
500	Red. Calc: Unknown	
501	Red. Calc: Rate	Rate calculation data error
502	Red. Calc: Bolus Rate	Bolus rate calculation data
503	Red. Calc: Set Mech	Set mechanism state calculation data
504	Red. Calc: Baseline poly	Baseline polynomial data
505	Red. Calc: Temp poly	Temperature polynomial data
506	Red. Calc: Startup	Startup ln function data
507	Red. Calc: Downstream	Downstream algorithm
508	Red. Calc: Upstream	Upstream data
510	Cannot calc drug lmts	Unable to calculate drug limits
511-529	Improper Units: 1-19	Unimplemented rate/conc units combination
530	Flow Cal out of Range	Flow calibration out of range
540	Bad Tube Type	Tube type incorrect or not selected
601	Sharp Code Corrupted	Code CRC failed
602	CPLD Invalid	CPLD ID wrong
603	Timebase Invalid	Sharp or PIC osc. frequency is wrong
604	Sharp ALU Failure	ALU failure

Error Code #	Displayed and History Log Language	Description
610	Bad drug lib CRC	Drug library CRC failed
611	Bad drug lib data	Bad drug library data
612	Invalid Drug Lib Version	Bad drug library version
615	Cannot read from RTC	Cannot read from RTC
901	Invalid bag specified	Invalid bag specified
902-909	Invalid delivery mode: 1-8	Invalid mode specified
910	Bad infusion parameters	Invalid running parameters
911-913	Invalid Pump State: 1-3	Invalid pump state
914	Alarm Screens Disabled	Alarm screens disabled outside
915	Invalid Pump Rate	Pump rate outside limits
920	Invalid log memory space	Tried to go to out of bounds memory
921	Invalid log memory find	Tried to find memory in out of bounds space
922	History Log que full	History log que buffer full of biomed mode
930	Invalid Screen	Invalid screen
931	C Library Exit	C Library system exit function called
932	Invalid Result	Invalid result
933	Bad care area index	Bad profile/care area index
934	No Rate/Volume Specified	Pump started with no specified rate or volume
935	Could Not Create Bit Map	Could not create bitmap
940	Invalid Sharp Version	Wrong sharp version

Error Code #	Displayed and History Log Language	Description
941	Invalid PIC Version	Wrong PIC version
942	Invalid CPLD Version	wrong CPLD version
943	Invalid AVR Version	Wrong AVR version
944	Invalid Smart Battery version	Wrong smart battery version
955	Invalid NETWORK version	Wrong network version
990	Invalid Data	Undefined error

System Error codes may be cleared by using one or more of the following methods:

1. Turn the pump off by pressing the ON/OFF key.
2. Turn the pump off by pressing the ON/OFF key and removing the battery for 1 minute.
3. Preventive maintenance should be performed on pumps exhibiting error codes that are clearable. If no error codes are observed after the test, the pump may be returned for use.

LOGGING

The SIGMA Model Spectrum Infusion pump provides three logs that can be used when troubleshooting issues with the pump:

- History Log – contains the entire history log for the pump.
- System Error Log – contains only the system errors recorded in the history log.
- Drug Error Log – contains only the events associated with programming an infusion; including any drug limits that may have been exceeded during setup.

You can view these logs on the pump screen from the User Options menu (see the User options section of the SIGMA Spectrum Operator's Manual).

Downloading the History Log

In addition to viewing the logs on the pump screen, you can send the entire history log out of the pump via the Infrared Data Association (IrDA) port using the Dump History Log option.

NOTE: This procedure applies to the transfer of the history (event) log contents from a SIGMA Spectrum Infusion pump with V5.00.06 Operating Software to a PC via the IrDA port.

Equipment List

- Personal computer (PC) running Windows XP or Windows 2000 with enabled IrDA communications
- Optional equipment list (if IrDA-equipped PC is not available)
  - PC running Windows XP or Windows 2000 with SD Card Reader or,
  - USB external SD card reader/writer, Ezonics™ or equivalent
  - SD card, Kingston™ or equivalent, minimum size 512MB
  - PN 55098 – PDA, PalmOne™ Tungsten™ E2 or equivalent with a file transfer utility installed (McFile version 2.2sigma, or equivalent) for transferring data

Procedure

To download the history log:

1. Access the History Log option on the pump:
   a. If the pump is running, press **STOP**, press **HELP** and press **OPTIONS**.
   b. Select the **User Options** menu item.
   c. From the User Options menu, select the **View Information**.
   d. Select **History Log**.
   e. Select **Dump History Log**.
   - **If you are transerring the log directly to a PC**, proceed to step 2.
   - **If you are transerring the log to a PDA then to a PC**, proceed to step 3.

2. Transfer the history log using the pump-to-PC method:
   a. Position the pump near the PC such that the IrDA ports of both devices are in an unobstructed line-of-sight orientation with a distance of no greater than 3 feet between them.
   b. Observe the pump prompt and press the **OK** key on the pump keypad to begin the transfer process.
   c. When the transfer is complete, a file is created in the filename format serialnumber_date_time.log in the selected location on the hard drive of the PC (for example, 123456_12-31-06_22-59.log).

      The length of time of the transfer will vary based on the number of events in the history log.

      If the pump is unable to establish a link with the PC within 30 seconds, the process will abort.
   d. Power off the Spectrum pump.
   e. Skip to step 4.
3. Transfer the history log using the pump-to-PDA-to-PC method:
   a. Insert the SD card into the PDA.
   b. Turn on the PDA.
   c. Select the McFile (or equivalent) application.
   d. Line up the beaming port of the PDA and the IrDA port of the pump. The beaming port of the PDA is usually at the top of the device and the IrDA port of the pump is the rectangular window on the bottom left corner of the pump.
   e. Observe the pump prompt and press the OK key on the pump keypad to begin the transfer process.

      The length of time of the transfer will vary based on the number of events in the history log.

      If the pump is unable to establish a link with the PDA within 30 seconds, the process will abort.
   f. When the transfer is complete, a file is created on the PDA in the filename format serialnumber_date_time.log (for example, 123456_12-31-06_22-59.log).
   g. Follow the prompts on the PDA to store the received file.
   h. Transfer the SD card from the PDA to the SD card reader on the PC.
   i. Power off the Spectrum pump.
   j. Power off the PDA.
4. View/Print the log contents
   a. Locate the text file on the PC and double-click it to open it.

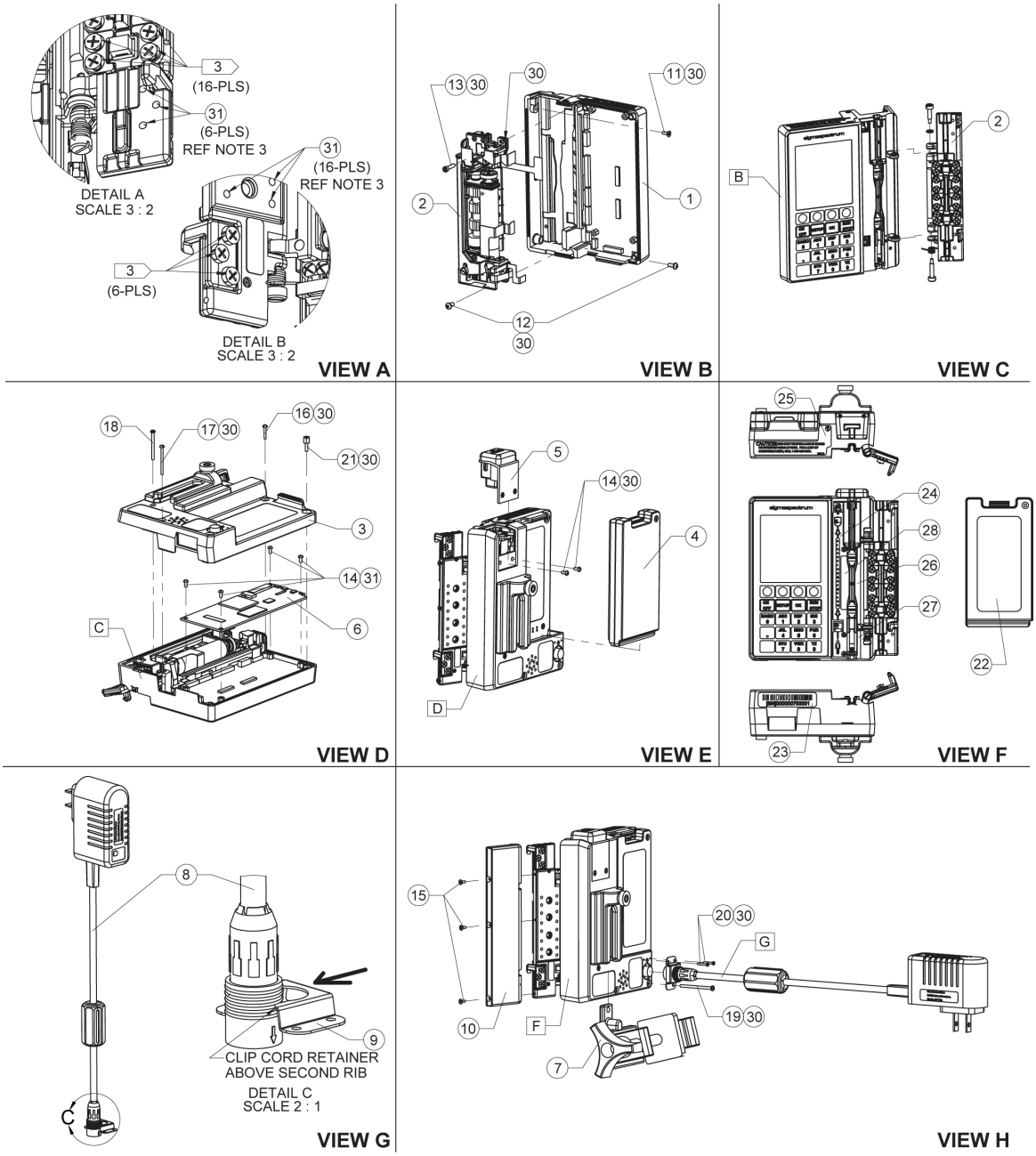
Files that have the `*.log` extension may require selection of software to "Open with...". Typically, Microsoft® Wordpad may be used to open even the longest history log files.

b. Confirm that the file is readable.

NOTE: History log can be in excess of 300 pages in the default text format. Another option is to copy the file contents into another application (such as Microsoft® Word) that will allow better arrangement of the file contents into a format more suitable for printing.

APPENDIX A: TECHNICAL DRAWINGS

Figure 3 Assembly, Spectrum Final 35700



020	0.020
015	0.015
010	0.010
005	0.005
003	0.003
-XXX	Thickness
Chart A - 41014	

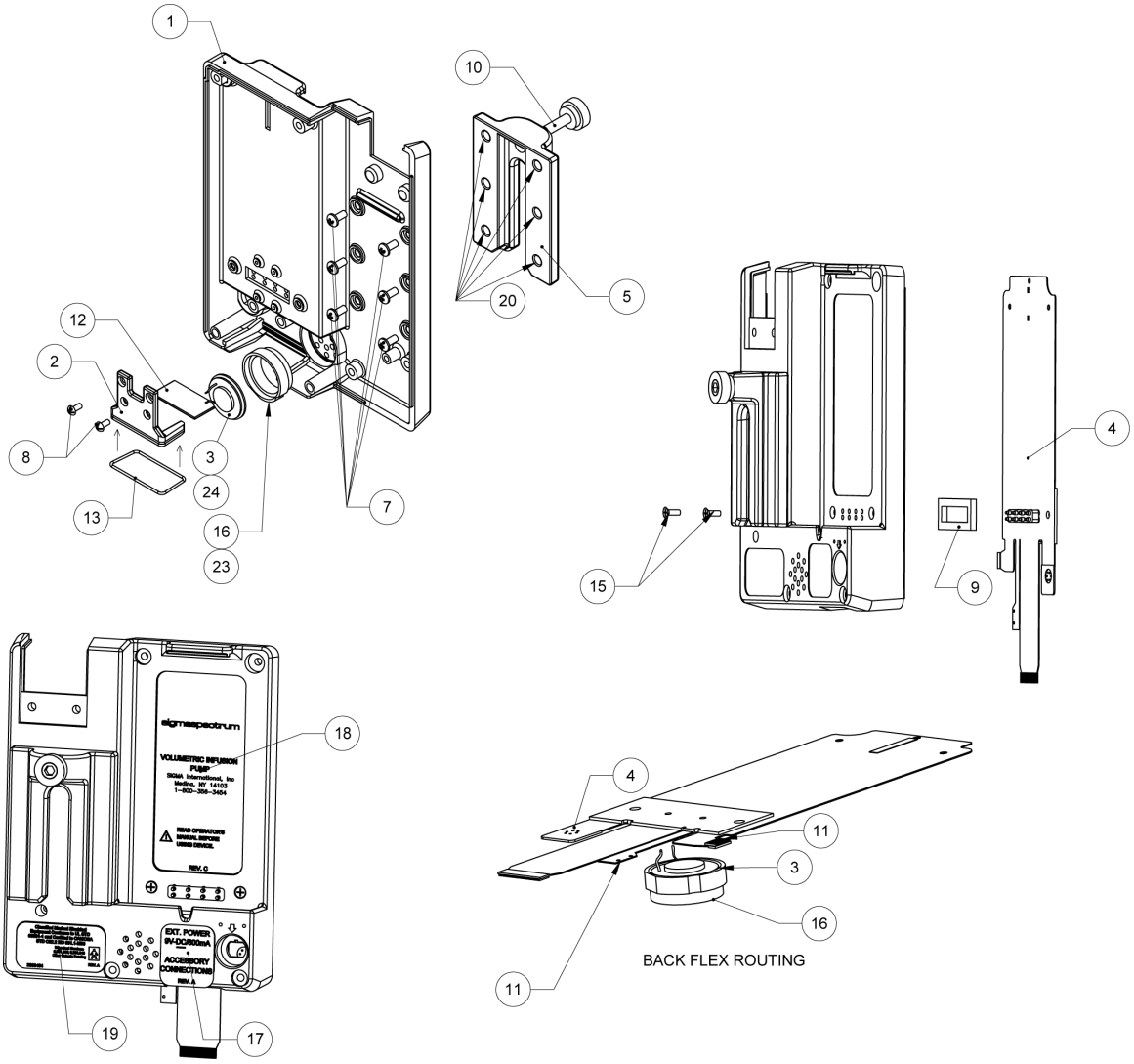
030	0.030
020	0.020
015	0.015
010	0.010
-XXX	Thickness
Chart B - 41016	

030	0.030
020	0.020
015	0.015
010	0.010
-XXX	Thickness
Chart C - 41017	

032	0.032
022	0.022
017	0.017
012	0.012
009	0.009
007	0.007
005	0.005
003	0.003
002	0.002
-XXX	Thickness
Chart D - 44014	

	ITEM NO.	QUANTITY			PART NO.	DESCRIPTION
		35700ABB				ASSY, FINAL HOSPIRA (ABBOTT)
			35700BAX			ASSY, FINAL BAXTER
				35700BBR		ASSY, FINAL B. BRAUN
	BILL OF MATERIALS					
	31	AR	AR	AR	85203	Adhesive, Threadlocker, Loctite 222
	30	AR	AR	AR	90059	Adhesive, Threadlocker, Hernon 128
	29	AR	AR	AR	85088	Isopropyl Alcohol
Ref. Chart D	28	1	2	2	44014	Shim, Direction of Flow
Ref. Chart C	27	1	1	1	41017	Label, Bottom Door Spacer
Ref. Chart B	26	1	1	1	41016	Label, Top Door Spacer
	25	-	-	1	41015-3	Label, Tubing ID, B. Braun
	25	-	1	-	41015-2	Label, Tubing ID, Baxter
	25	1	-	-	41015-1	Label, Tubing ID, Hospira (Abbott)
Ref. Chart A	24	1	1	1	41014	Label, Direction of Flow
	23	1	1	1	41013	Label, Serial Number
	22	1	1	1	41007	Label, Company ID
	21	1	1	1	95198	Standoff, Male/Female Hex
	20	2	2	2	95213	Screw, 0-42 x 3/8" Thread Forming, SS
	19	1	1	1	95063	Screw, 2-56 x 1 1/4" Phil, PHMS SS
	18	1	1	1	95212	Screw, 2-56 x 1", Phil, BHMS, Nylon
	17	1	1	1	95201	Screw, 2-56 x 1" Phil, PHMS SS
	16	1	1	1	95196	Screw, 2-56 x 7/16" Phil, PHMS SS
	15	3	3	3	95210	Screw, 2-56 x 1/4" Slotted, FHMS Nylon
	14	6	6	6	95181	Screw, 2-56 x 3/16" Phil, PHMS SS
	13	1	1	1	95200	Screw, 4-40 x 7/16" SHCS SS
	12	2	2	2	95015	Screw, 4-40 x 1/4" Phil, PHMS SS
	11	1	1	1	95022	Screw, 4-40 x 3/16" Phil, FHMS SS
	10	1	1	1	45713	Cover, Door
	9	1	1	1	50737	Cord Retainer
	8	1	1	1	35714	Asm, Power Cord w/ Connector
	7	1	1	1	35712	Asm, Pole Clamp
	6	1	1	1	60087	Asm, Processor PCB
	5	-	-	1	35709-3	Asm, Keyhole, B. Braun
	5	-	1	-	35709-2	Asm, Keyhole, Baxter
	5	1	-	-	35709-1	Asm, Keyhole, Hospira (Abbott)
	4	1	1	1	35702	Asm, Battery
	3	1	1	1	35701	Asm, Rear Case
	2	-	-	1	35703-3	Asm, Mechanism/Door, B.Braun
	2	1	1	-	35703	Asm, Mechanism/Door
	1	1	1	1	35708	Asm, Front Case

Figure 4. Assembly, Rear Case 35701

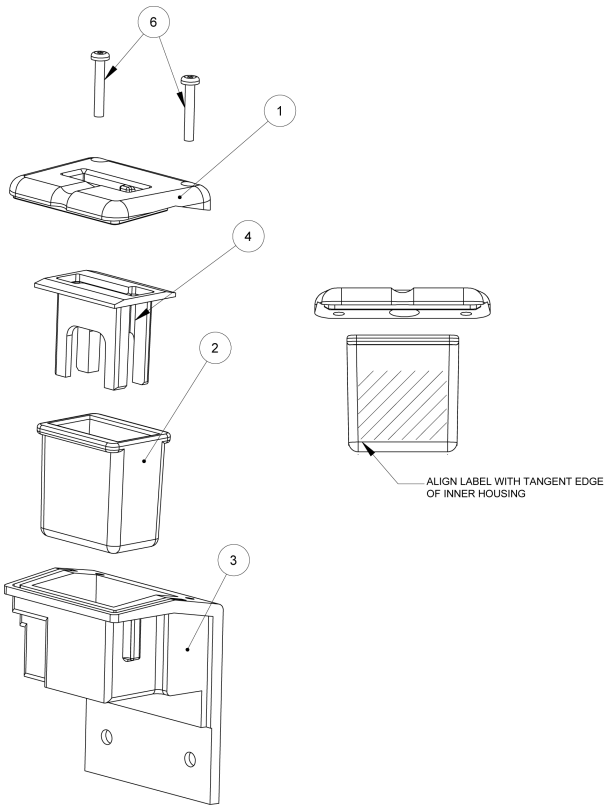


ASSEMBLE PER MWI 35701

24	A/R	85095	Hot Melt Glue
23	A/R	85081	Loctite 406
22	A/R	85088	Isopropyl Alcohol
21	1	41041	Gasket, Battery
20	A/R	90059	Adhesive, Hernon 128
19	1	41009	Label, Certification
18	1	41007	Label, Company ID
17	1	41004	Label, Power/Bolus
16	1	45741	Speaker mount
15	2	95210	Screw, 2-56 x 1/4" FHMS, Phil, Nylon
14	2	95219	2-56 Threaded Insert
13	1	41022	O-Ring, Scanner Bracket
12	1	45728-1	Scanner Window, Clear
11	A/R	90047	Kapton Tape
10	1	95057	Screw, 8-32 x 17/32", LG, THUMB SCREW, SS
9	1	41003	Gasket, Back Flex
8	2	95181	Screw, 2-56 x 3/16" PHMS, Phil, SS
7	6	95015	Screw, 4-40 x 1/4" PHMS, Phil, SS
6	1	30061	Connector, 6-Pin Power/Bolus
5	1	45726	Adaptor, Pump Side
4	1	35149	Assembly, Back Flex
3	1	55069-2	Speaker, 1W
2	1	45705	Scanner Bracket
1	1	45701	Rear Case
ITEM NO.	QTY.	PART NO.	DESCRIPTION

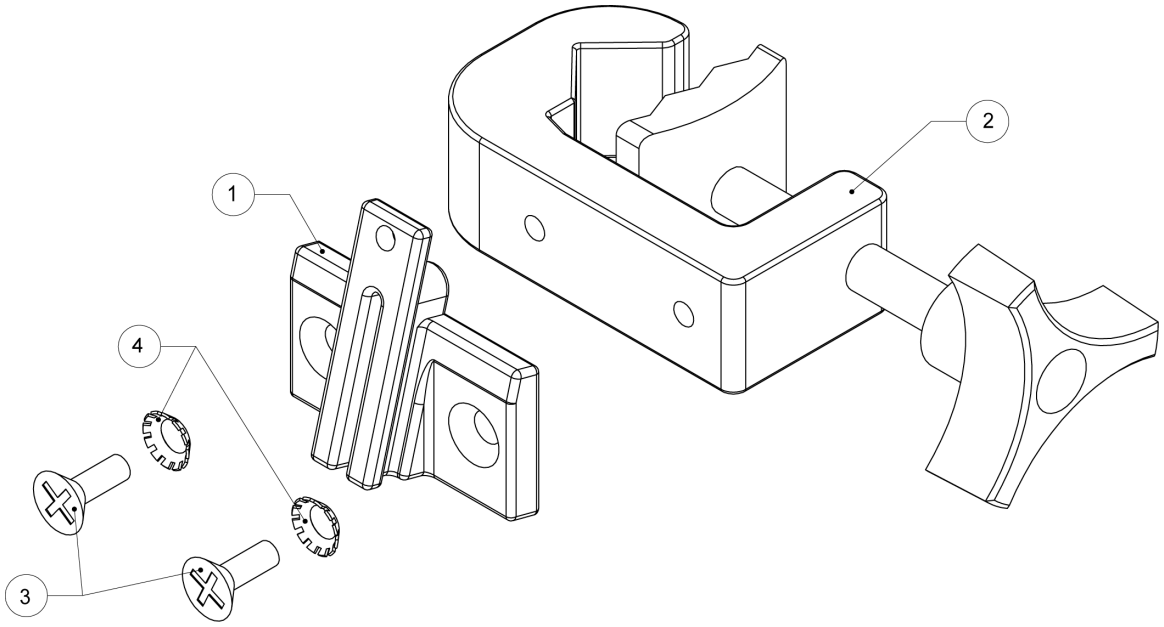
BILL OF MATERIALS

Figure 5. Assembly, Key Hole 35709



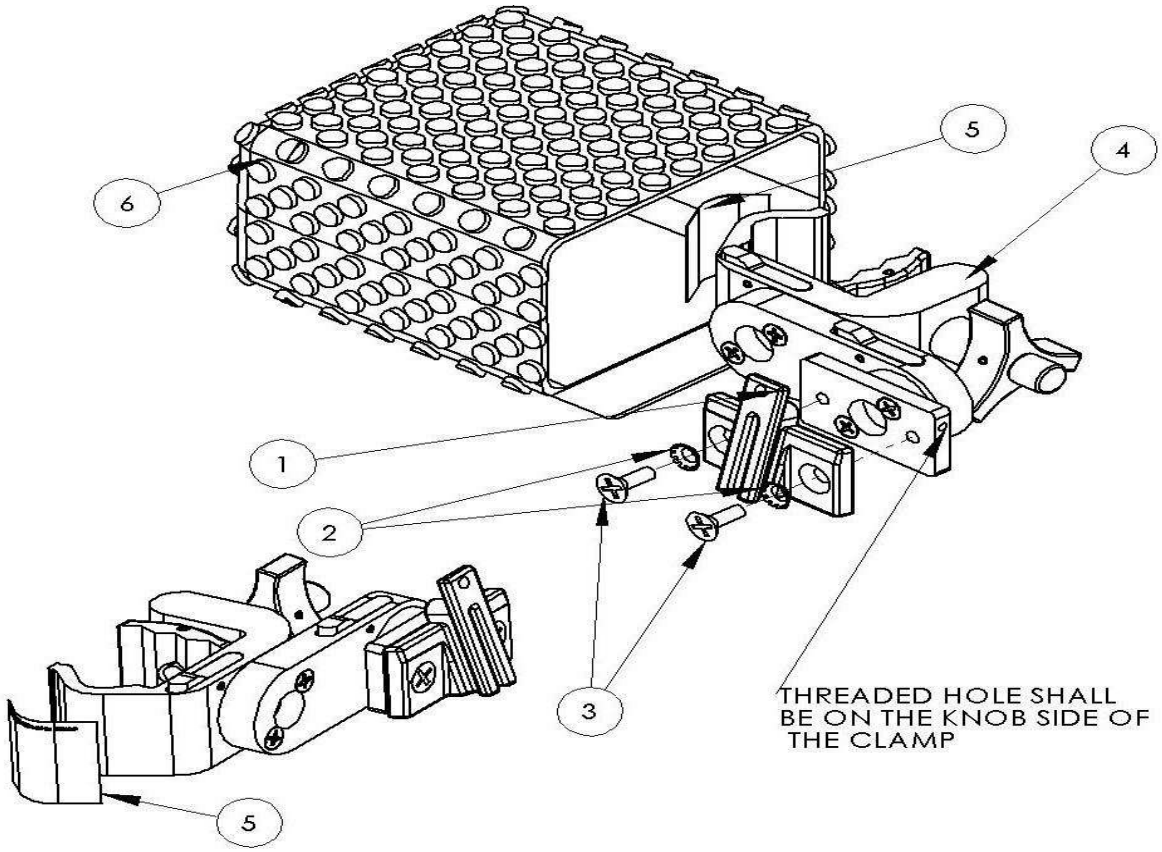
Item No.	Part No.	Description	Quantity			
6	95213	Screw, 0-42 x 3/8” thread Forming, SS	2	2		2
5	41021-1	Label, blue color sensor	1	-	-	1
5	41021	Label, red color sensor	-	1	1	-
4	50730-2	Keyhole extension - Baxter	-	1	-	1
4	50730	Keyhole extension - Hospira	1	-	1	-
3	45751	Housing, Slide Clamp Outer Baxter PCA (2433 Dark Blue)	-	-	-	1
3	45710	Housing, Slide Clamp Outer (2253 Robin Egg Blue)	1	1	1	-
2	45711	Housing, Slide Clamp Inner	1	1	1	1
1	45750	Keyhole - Baxter PCA (2433 Dark Blue)	-	-	-	1
1	45709-3	Keyhole - B.Braun (2253 Robin Egg Blue)	-	-	1	-
1	45709-2	Keyhole - Baxter PCA (2253 Robin Egg Blue)	-	1	-	-
1	45709-1	Keyhole - Hospira (2253 Robin Egg Blue)	1	-	-	-
		Keyhole Assembly - Baxter PCA Pump				35709-4
		Keyhole Assembly - B.Braun			35709-3	
		Keyhole Assembly - Baxter		35709-2		
		Keyhole Assembly - Hospira	35709-1			

Figure 6. Assembly, Pole Clamp 35712



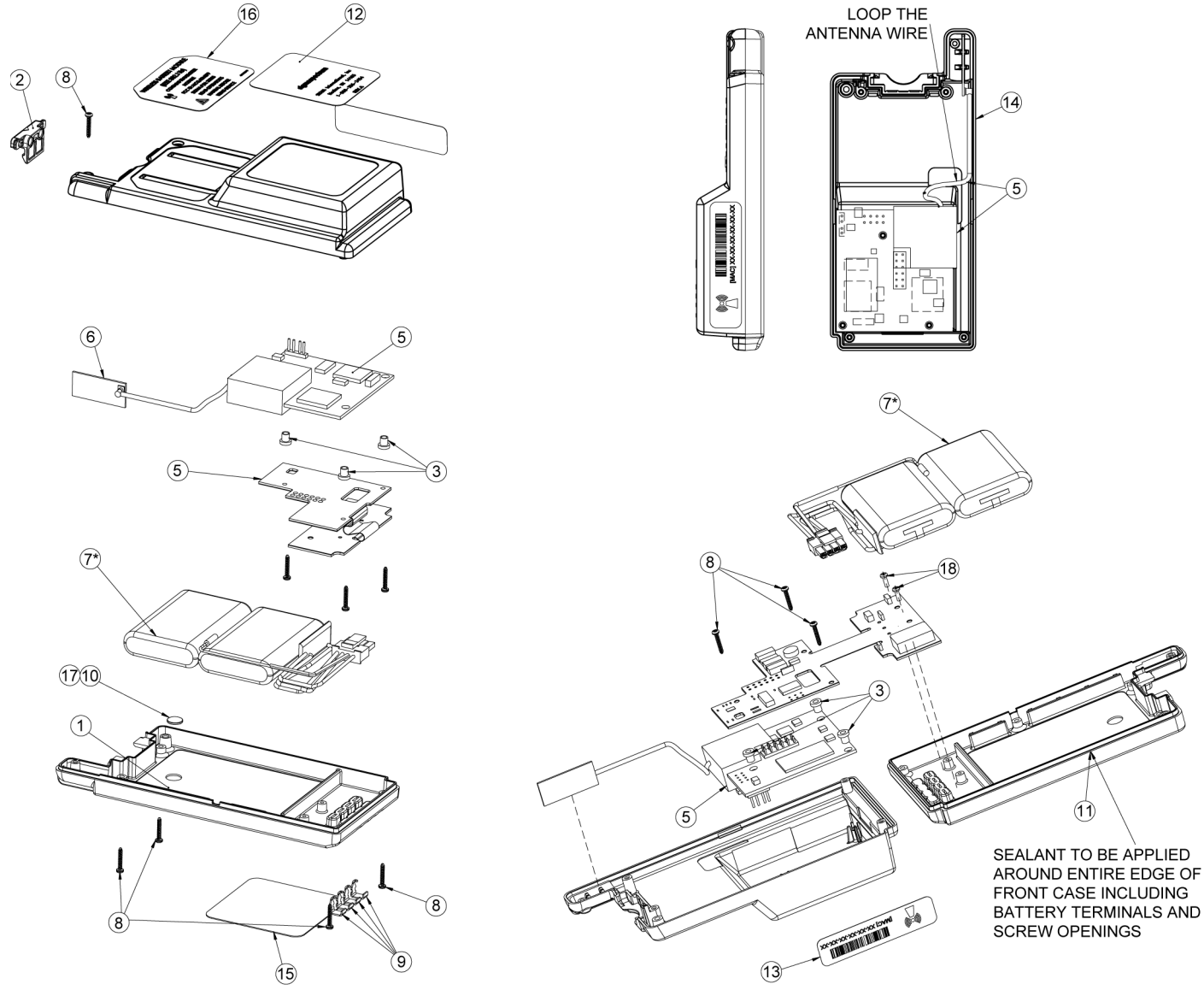
Item No.	Part No.	Description	Quanity
1	45727	Pole Side Adaptor	1
2	55041	C-Clamp	1
3	95204	Screw, 1/4-20 x 5/8", FHMS, SS	2
4	95064	Washer, 1/4” External Tooth Star, SS	2

Figure 7. Assembly, Double Rotating Pole Clamp 35743



Item No.	Part No.	Description	Quanity
1	45727	Pole Side Adaptor	1
2	95064	Lockwasher, 1/4 Countersink, SS	1
3	95204	Screw, 1/4-20 x 5/8”	3
4	55129	Double Rotating Pole Clamp	1
5	41093	Pump Orientation Label	1
6	-	Pryor Products, PAC-1360, Bubble Bag	1

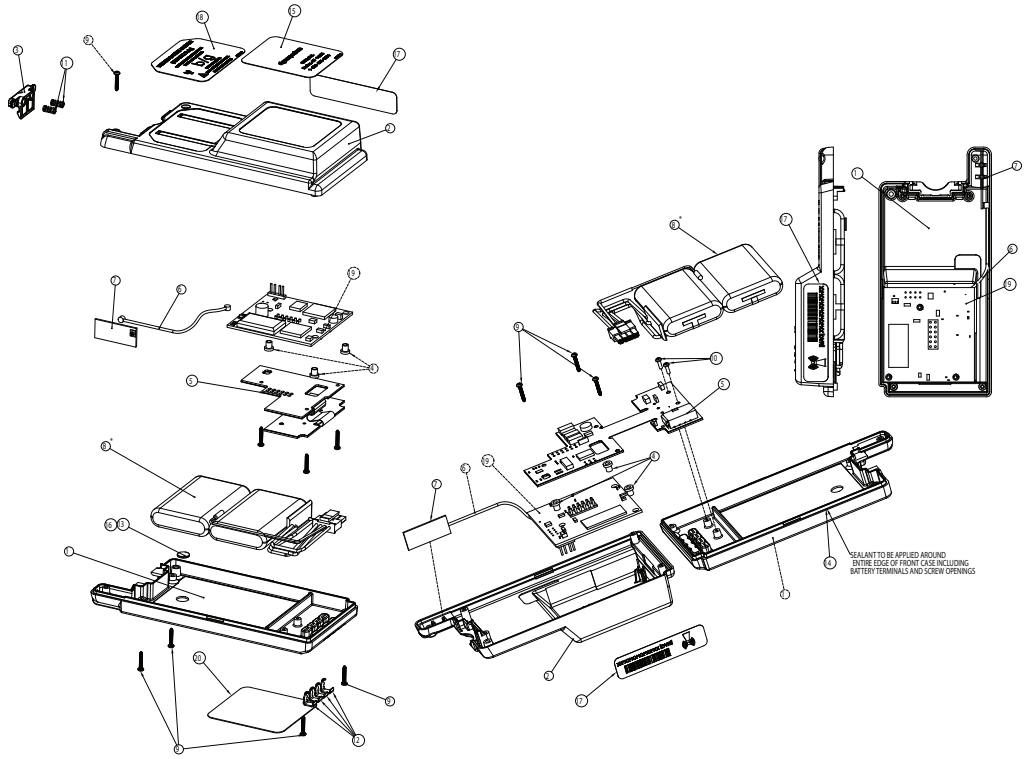
Figure 8. Assembly, 802.11b Wireless Battery Module 35083



Item No.	Part No.	Description	Quanity
1	45737	Battery Case - Front	1
2	45739	Latch, Battery	1
3	95065	Spacer, Nylon 6/6, White	3

Item No.	Part No.	Description	Quanity
4	60128	Assembly, Wireless Flex	1
5	55095	Digi Module	1
6	55094	Antenna	1
7*	55075-1 or 55075-2	Battery Pack	1
8	95213	Screw, 0-42 x 3/8 SS Thread Forming	8
9	50738	Contact, Wireless Battery	4
10	55024-3	Magnet, Battery, 0.25 DIA x 0.031 THK	1
11	90058	Lubricant & Sealant Dow Corning 111	A/R
12	41046	Label, Battery, Rear, Lower	1
13	41049	Label, Wireless Battery Module	1
14	45738-2	Battery Case - Rear	1
15	41068	Label, Caution	1
16	41045	Label, Wi-Fi Battery, Rear, Upper	1
17	85081	Adhesive, Cyanoacrylate, Loctite-414	1
18	95222	Screw, 0-42 x 3/16 Torx PH Threadforming	2

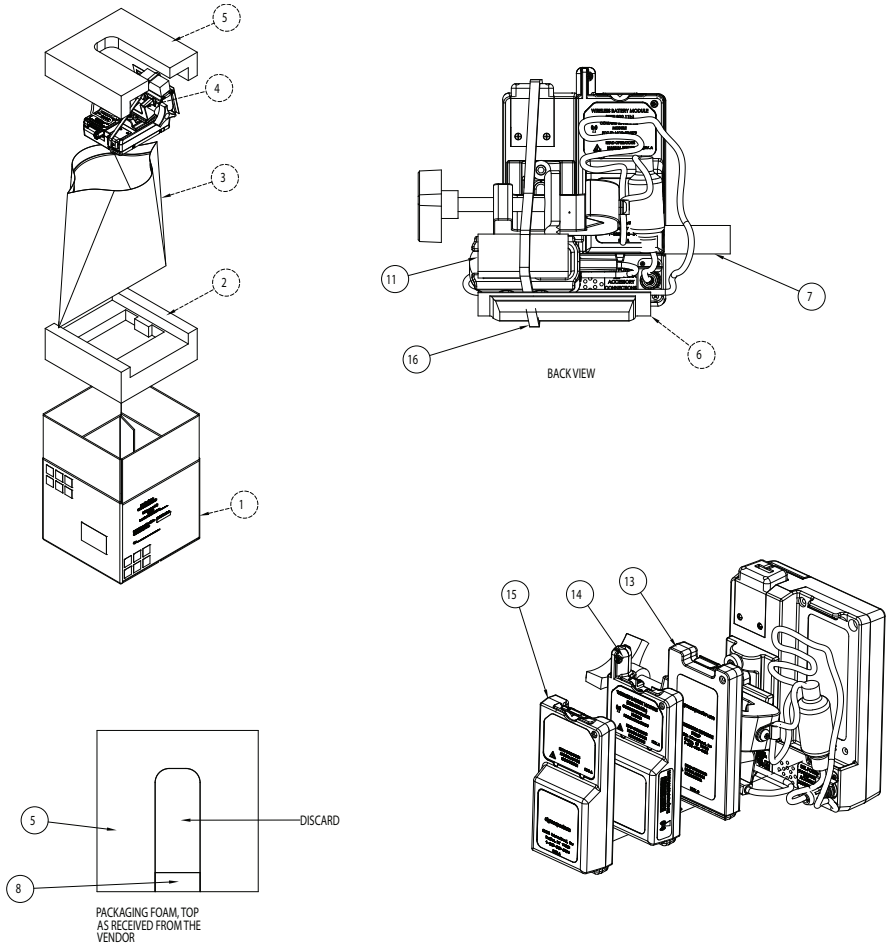
Figure 9. Assembly, 802.11b/g Wireless Battery Module 35162



Item No.	Part No.	Description	Quantity
1	45737	Battery Case - Front	1
2	45738	Battery Case - Rear	1
3	45739	Latch, Battery	1
4	95065	Spacer, Nylon 6/6, White	3
5	60128	Assembly, Wireless Flex	1
6	55105	Antenna Wire	1
7	55094	Antenna	1
8*	55075-1 or 55075-2	Battery Pack	1

Item No.	Part No.	Description	Quantity
9	95213	Screw, 0-42 x 3/8 SS Thread Forming	8
10	95222 S	Screw, 0-42x 3/16, Thread Forming	2
11	95507	Spring, Compression	2
12	50738	Contact, Battery	4
13	55024-3	Magnet, Battery, 0.25 DIA x 0.031 THK	1
14	90058	Lubricant & Sealant Dow Corning 111	1
15	41046	Label, Battery, Rear, Lower	1
16	85081	Adhesive, Cyanoacrylate,Loctite-414	A/R
17	41049	Label, Wireless Battery Module	1
18	41069	Lable, Wireless Battery, Rear, Upper	1
19	55104	Digi-Connect Wi-Em - b/g	1
20	41068	Label, Caution	1

Figure 10. Packaging Assembly 35716



Item No.	Part No.	Description	Quantity
1	98009	Packing Box	1
2	98010	Packaging Foam, Bottom	1
3	98012	Anti-Static Bag	1
4	35700	Spectrum Final Assembly	1
5	98011	Packaging Foam, Top	A/R
6	98013	Silica Gel Pack	A/R
7	41034	Battery Insulation Tab	A/R

Item No.	Part No.	Description	Quantity
8	98011-1	Packaging Foam, AC Power Adaptor	A/R
9	N/A	Packing Tape 2"	1
10	41018	Operator's Manual	1
11	41019	Service Manual	1
12	85088	Alcohol, Isopropyl	1
*13	35724	Assembly, Battery	1
*14	35083	Wireless Battery Module	1
*15	35724	Li-Ion Battery Assembly	1
16	98014	Rubber Band	1