# SERVICE MANUAL
# SIGMA INTERNATIONAL
# MODEL SPECTRUM
# INFUSION PUMP

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Additional copies of this Service Manual
Are available from
SIGMA International, Inc.
711 Park Avenue, Medina, NY USA 14103-0756
(Latest revision will be sent unless otherwise specified)

# Table of Contents

# SECTION 1:
# 1.1 LIMITED WARRANTY

## SIGMA SPECTRUM INFUSION PUMP LIMITED WARRANTY

SIGMA International warrants, to the original purchaser, the SPECTRUM Infusion Pump (hereinafter Pump) to be free from defects in material and workmanship under normal use and service for one year from the date of purchase. SIGMA's obligation under this limited warranty shall be limited to repair or replacement of Pumps, which, upon SIGMA's examination, are found defective in material or workmanship under normal use and service within one year from the date of purchase by the original purchaser. The repair or replacement of any Pump under this limited warranty shall not extend the term of this limited warranty beyond the original term as set forth in this paragraph.

Qualified, trained service personnel must perform all repairs qualifying under this limited warranty. In the event that any Pump is found to be defective during the aforesaid warranty period, the purchaser shall notify SIGMA in writing of any claimed defect within thirty days after such claimed defect is discovered. The Pump claimed to be defective must then be promptly delivered to SIGMA or its designated representative for inspection and repair or replacement, if necessary. Pumps returned to SIGMA must be properly packaged and sent to SIGMA with postage and handling prepaid. Severe pump damage may result if SIGMA shipping cartons and inserts are not used. Shipping cartons and inserts are available at no charge from SIGMA.

This limited warranty shall not apply to defective conditions or damage caused, in whole or in part, by negligence, fluid spills, dropped Pumps, misuse, abuse, improper installation, improper cleaning, alteration, or damage caused by improper shipment to SIGMA. If, after inspection, SIGMA is unable to identify a problem, SIGMA reserves the right to invoice the purchaser for such inspection.

THIS LIMITED WARRANTY IS THE SOLE AND ENTIRE WARRANTY PERTAINING TO THE PUMP AND IS IN LIEU OF AND EXCLUDES ALL OTHER WARRANTIES OF ANY NATURE WHATSOEVER WHETHER EXPRESS, IMPLIED OR ARISING BY OPERATION OF LAW, TRADE, USAGE OR COURSE OF DEALING, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE. ANY AFFIRMATION OF FACT OR PROMISE MADE BY SIGMA SHALL NOT BE DEEMED TO CREATE AN EXPRESS WARRANTY THAT THE PUMP SHALL CONFORM TO THE AFFIRMATION OR PROMISE; ANY DESCRIPTION OF THE PUMP IS FOR THE SOLE PURPOSE OF IDENTIFYING IT AND SHALL NOT BE DEEMED TO CREATE AN EXPRESS WARRANTY THAT THE PUMP SHALL CONFORM TO SUCH DESCRIPTION; ANY SAMPLE OR MODEL IS FOR ILLUSTRATIVE PURPOSES ONLY AND SHALL NOT BE DEEMED TO CREATE AN EXPRESS WARRANTY THAT THE PUMP SHALL CONFORM TO SUCH SAMPLE OR MODEL; AND NO AFFIRMATION, PROMISE, DESCRIPTION SAMPLE OR MODEL SHALL BE DEEMED TO BE PART OF THE PURCHASE OF THE PUMP. THE PURCHASER EXPRESSLY ACKNOWLEDGES THAT THIS LIMITED WARRANTY CONSTITUTES THE PURCHASERS SOLE AND EXCLUSIVE REMEDY WITH RESPECT TO ANY CLAIM OF THE PURCHASER ARISING OR RESULTING DIRECTLY OR INDIRECTLY FROM THE USE OF THE PUMP. IN NO EVENT SHALL SIGMA BE LIABLE HEREUNDER FOR AN AMOUNT THAT EXCEEDS THE PURCHASE PRICE OF THE PUMP. NO PERSON, FIRM OR CORPORATION IS AUTHORIZED TO ASSUME FOR SIGMA ANY LIABILITY IN CONNECTION WITH THE SALE OF THE PUMP.

## SIGMA SPECTRUM BATTERY PACK LIMITED WARRANTY

SIGMA International warrants, to the original purchaser, the SPECTRUM Infusion Pump Battery Pack (hereinafter Battery) to be free from defects in material and workmanship under normal use and service for one year from the date of purchase. SIGMA's obligation under this limited warranty shall be replacement of Batteries, which, upon SIGMA's examination, are found defective in material or workmanship under normal use and service within one year from the date of purchase by the original purchaser. The replacement of any Battery under this limited warranty shall not extend the term of this limited warranty beyond the original term as set forth in this paragraph.

During the aforesaid warranty period, a Battery shall be capable of accepting a full charge, as indicated by a full charge icon and maintaining the specified battery capacity as outlined in section 1.5.

It is normal for battery capacity to decrease over the life of the battery. Beyond the aforesaid warranty period, batteries may exhibit a normal decrease in capacity, depending upon age and usage. If batteries exhibit decreased capacity, they may need to be replaced.

Replacement batteries, purchased separately from SIGMA, International will be subject to the aforesaid one-year warranty.

In the event that any Battery is found to be defective during the aforesaid warranty period, the purchaser shall notify SIGMA in writing of any claimed defect within thirty days after such claimed defect is discovered. The Battery claimed to be defective must then be promptly delivered to SIGMA or its designated representative for inspection and replacement, if necessary. Batteries returned to SIGMA must be properly packaged and sent to SIGMA with postage and handling prepaid.

This limited warranty shall not apply to defective conditions or damage caused, in whole or in part, by negligence, fluid spills, dropped Pumps or Batteries, misuse, abuse, improper installation, improper cleaning, alteration, or damage caused by improper shipment to SIGMA. If, after inspection, SIGMA is unable to identify a problem, SIGMA reserves the right to invoice the purchaser for such inspection.

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## 1.2 SIGMA SPECTRUM INFUSION PUMP WARNINGS AND CAUTIONS

**Definitions:**

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

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.

**Warnings:**

- 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 55071)
  (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 SIGMA OPERATOR'S 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).
  NOTE: Use of any other sets will 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).

**Cautions:**

- 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 Section 1.3, Cleaning and Maintenance, and Section 1.5, Preventative Maintenance.
- Solution spills should be cleaned up, as soon as possible, using a damp cloth or sponge. Dry thoroughly before use. The upstream and downstream sensors tube channel must be kept 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 Section 1.3, Cleaning and Maintenance.

- 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).

- If using filter set, use only filter sets which state specifically in the Operator's Manual instructions that they may be used with pumps.

**Notes:**

| **NOTE:** |
| --- |
| For a list of serviceable parts, call the SIGMA Service Coordinator |

## 1.3 SIGMA SPECTRUM CLEANING

1. **Caution** Always press STOP then OFF and unplug the A.C. Power Adaptor before cleaning.

2. **Caution** DO NOT sterilize by autoclaving, ETO gas or spraying. DO NOT immerse any part of the pump. DO NOT use abrasive cleaners.

3. **Caution** 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.

4. Clean exterior surfaces with pump in upright position. Apply cleaners with a dampened cloth per manufacture's instruction and dilution ratios. DO NOT use spray or aerosol cleaners. A lint free, foam-tipped swab (Chemtronics Foamtip™ or Qosmedix® precision foam tip for example) may be used in the Tube Channel.

5. Visually inspect the tubing channel and remove any foreign material. An obstructed set tubing channel could cause accidental free flow.

6. 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.

7. Dispose of all cleaning/ disinfectant materials per federal, state and local regulations for infectious waste disposal.

**Cleaning**
This pump is designed to be transportable and is recommended to be cleaned and disinfected in accordance with approved facility protocol for multiple patients' usage. A listing of compatible solutions is provided. Turn the pump off and unplug the AC Power Adaptor from the AC power source. Place the pump in an upright position (Keyhole release upward). Apply solutions with a dampened cloth per the manufacturers' instructions using appropriate dilution ratio. Disinfectants should remain on the pump's surface in an even, but not dripping film for the manufacturers' recommended contact time. Open the pump's door using a clean I.V. set with respective slide clamp for the Keyhole match associated with the tubing manufacturer's type of the pump. Clean the speaker vent, power supply connector, door release Keyhole and pumping channel areas with the soft swabs as required. 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. For severe solution spills or contaminated pump product it is recommended that the Battery Pack be removed. The Battery Pack[1., 2.] / cavity area of the pump may be cleaned by wiping down these regions with a dampened cloth as described previously. Dispose of all cleaning materials (including the slide clamp if it is not to be cleaned and disinfected) as required per facility protocol / biohazard policy.

**Examples of Compatible Cleaners:**
(Refer to DOC 11318 for Complete Listing)

**1** 10% solution of bleach and water
**2** Up to 90% Isopropyl alcohol[1]
**3** Caltech Industries Dispatch®
**4** Steris TBQ® and Steris Germicidal Surface Wipes, Product Number 1608-GS
**5** Metrex Cavicide® and Cavi Wipes™
**6** May be others. Contact SIGMA for additional information

1. Alcohols are flammable and should not be use for battery cleaning / disinfection. Always use alcohol in a well-ventilated area.
2. When cleaning the Battery Pack, care should be taken to prevent shorting of the pack's exposed terminals.
3. Do not sterilize this device by autoclaving or ETO gas.
4. Do not immerse any part of this device.
5. Do not use phenolic based cleaners / disinfectants.

## 1.4 SIGMA SPECTRUM INFUSION PUMP SPECIFICATIONS

**Applications**

- Large and small volume parenterals
- Neonatal

**Administration Set**

Compatible with standard gravity IV sets supplied by Hospira® and several other companies, (consult SIGMA for a complete list of compatible standard IV sets).

**Performance**

See Appendix A for additional specifications.

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

| RATE | LOW(6psi) | MEDIUM(13psi) | HIGH(19psi) |
|---|---|---|---|
| 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 |

*With Occlusion 45 inches below the pump and alarm set to LOW, MEDIUM or HIGH.

Trip pressure specifications for downstream occlusions are:

| Pressure Setting | Nominal Value (psi) | Tolerance (psi) |
|---|---|---|
| Low | 6 | ±4 |
| Medium | 13 | ±6 |
| High | 19 | ±9 |

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

**Effect of Fluid Container Height**[1.]
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 graphical presentation is 24" (61 cm). e.g. 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.

[1.] Note: Liquid container must be vented or a collapsible bag.

**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 utilize 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.

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 up 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**

See Appendix A for Additional technical specifications.

- 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.
- Pump operating time on battery power is at least 8 hours at 125ml/hr with the backlight on.* With the optional Wireless Battery Module the specification is at least 4 hours under the same conditions with the wireless interface operating.*
- Computer interface: RS232 port on the back panel and IrDA on front panel. Since the systems pumps may be connected to vary widely, users should consult with SIGMA's Service Department for specific instructions. Users without sufficient electronic background and knowledge of both the SIGMA Spectrum infusion pump and outside devices it may be connected to should never attempt such a connection. To do so otherwise can result in severe damage to the pump.

- 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

**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 | 1998-02 | 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<br>ID: MCQ-50M879 | N/A | FCC approved wireless transmitter/receiver module (Wireless Battery Module Only – SIGMA P/N 35083) |
| FCC Section 15C<br>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

# 1.5 PREVENTIVE MAINTENANCE

## PURPOSE

The purpose of this procedure is to provide a guideline for the Preventative Maintenance of the SIGMA SPECTRUM IV pump.

## SCOPE

The guidelines are to ensure that the SIGMA SPECTRUM IV pump is operating within the specified parameters set forth by SIGMA International, Inc.

## REFERENCES

Preventative maintenance check off sheet (attached at the end of this section).

## EQUIPMENT

1. SIGMA SPECTRUM Infusion Pump
2. IV set of the brand specified on the pump label

NOTE: If the pump is being accuracy tested 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.

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

## DOCUMENTATION

After each operation in this procedure, the findings may be recorded on the Preventative maintenance check off sheet attached at the end of this section.

## PROCEDURE

ALL TESTING AND EVALUATIONS SHALL REQUIRE FLUID AND AIR TEMPERATURE OF 72±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 * may be utilized as an incoming test procedure.

**Preventative Maintenance Schedule**

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

**Visual Inspection**

1. Inspect the pump for visual evidence of damage and or defects to exterior components (i.e. case, keypad and door).
2. The IV set tube channel must be free of foreign materials and dry for both testing and use.

3. Any evidence of damage to or repair of these parts is reason to run the preventative maintenance checks.
4. Verify legibility of all labels.
5. Replace labels as necessary.

**Keypad Test**

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

1. Press the "ON/OFF" key to turn the unit on and observe that the displays indicate the SIGMA Spectrum logo, followed by the "Select Care Area" screen, press BASIC, OK.
2. Press OK to select mL/hr then push the "4", and "6" keys and observe the "Rate mL/hr" field to be "46".
3. Press the "clear" soft key and verify that the rate field is cleared to 0.
4. Enter "7", "8", and "9" keys and observe the "Rate mL/hr" field to be "789".
5. Push "clear" soft key and enter ".", "0" keys and observe the "Rate mL/hr" field to be "0.0"
6. Push "clear" soft key, and press the "▼" key until the 'value given' field is highlighted.
7. Press the left soft key "clr all" and verify that the display menu changes to the "Clear Program Yes/No?" screen, press Yes then the "Care Area Selection" screen will appear

**Upstream (Proximal) Occlusion Sensor Test**

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

1. Press BASIC, OK.
2. Set the flow Rate to 100 mL /hr. Press OK.
3. Set VTBI (volume to be infused) to 13.3 mL. Press OK.
4. Occlude IV set 12" above the pump with a pair of hemostats.
5. 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.
6. The pump may indicate BAG NEAR EMPTY <30 MIN REMAIN. Press the "OK" key to silence this alarm.
7. Verify the pump goes into "UPSTREAM OCCLUSION" alarm prior to infusion complete message.
8. Release the occlusion and restart the pump.

**Downstream (Distal) 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. Select CLR ALL, press YES. Select "Help" softkey.
2. Select OPTIONS, Biomed Configuration, and enter the password. Select Sensor Configuration. Verify that the DS Occlusion Auto Restart is set for "on" and verify US/Air Alarm Confirm is set for "on".
3. Exit the BIOMED OPTION screen.
4. On the OPTIONS screen select User Settings. Select Alarm Settings verify DS Pressure Limit as "med" and exit the User Settings. Exit the OPTIONS screen.
5. Press OK to bypass the Help screen.
6. Select the BASIC key and press OK.
7. Set the Rate to 100 mL/hr and set the VTBI mL to 50 mL.
8. 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.
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 the "OK" key to silence this alarm.
11. Verify the pump displays a "DOWNSTREAM OCCLUSION" alarm at a pressure within the 13-psi ± 6 occlusion trip pressure setting.

**Air Detection Test ***

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

1. Set VTBI limit to 50 mL. Press OK.
2. Push the "RUN / STOP" key.
   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.
3. Introduce a 1" minimum air bubble into the IV set upstream from the pump.
4. Verify the pump goes into "AIR-IN-LINE" alarm. Press RUN/STOP.

**Memory Test** (this assumes you are starting from an all clear point) *****

1. Turn the pump on. May ask New Patient Yes/No? Select No.
2. Push "BASIC" and "OK", "OK".
3. Set a parameter for "RATE" and "VTBI".
4. Turn the pump off.
5. Turn the pump on and press No to the New Patient Yes/No screen. Verify the "RATE" and "VTBI" parameters were saved.

**Recommended Flow Rate Accuracy Test ***

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

1. Set the pump's flow rate to 200 mL/hr.
2. Set the VTBI to 50 mL (length of test ≈ 15 min.) when using a gravimetric method.
3. Set the VTBI 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 collected.
4. Hang the IV bag / container 24" above the pumping mechanism.
5. 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.
6. Load the set into the SIGMA Spectrum pump and close the door.
7. 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.
8. Begin the test by pressing the "RUN" key. Allow the SIGMA Spectrum pump to run until it goes into infusion complete alarm.
   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.
9. Press the "STOP" key to halt the KVO (keep vein open) rate once the pump goes into infusion complete.
10. 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.
11. Observe the actual volume collected either visually or weighed on the scale.
12. When measuring fluid level visually in the graduate, the level is read from the bottom of the fluid meniscus.
13. Acceptance criteria: collected volumes of ± 5%.
14. When measuring with the scale (gravimetric method):
15. Weigh the collection vessel and water using grams as the unit of measure.
16. Empty and dry the collection vessel.
17. Weigh the collection vessel. The difference between the two measured weights is equivalent to the volume delivered.
18. If the collection volume is within the range of ± 5%, the pump is properly calibrated. If not, return the pump to SIGMA International, Inc. 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 low voltage supply cord from the AC power adaptor to the pump unit for signs of abuse such as cuts or exposed conductors.

**Battery Capacity Test**

1. The storage capacity for the battery may be determined by running the Battery Capacity Test.
2. The pump must be connected 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.
3. The pump can be in use while the battery is charging.
4. Use an IV test set in a loop configuration, so that fluid is circulated around the loop.
5. 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.
6. Select the Help softkey, User Settings and select Display Settings, the Display Adjust and then select Backlight Level to “High”. Exit to the OPTIONS screen.
7. Select the Biomed Configuration so that the automatic monitoring of the battery capacity test can be selected. Enter the password and select Pump Testing.
8. Select option for “Battery Life Test”.
9. Follow the display instructions. Enter or verify 125 mL/hr for Rate and turn “Low batt alarm” and “Constant alarm” off.
10. Press the OK key and move the cursor to done press OK.
11. 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, select “OK”.
12. The pump will run until the battery is depleted and will then power off.
13. 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.
14. 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).
15. 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”.
16. 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”.
17. Less battery capacity indicates a battery reaching end of life.
18. See the Battery Removal and Replacement section of this manual for replacement. If a Wireless Battery Module is installed, see the Wireless Battery Module portion of the Battery Removal and Replacement section.

Serial Number: _____ Date:_____

Software Version: _____

Control Number: _____

**Preventative Maintenance Check Off Sheet**

| TEST | PASS | FAIL |
|---|---|---|
| VISUAL INSPECTION | | |
| KEYBOARD TEST | | |
| UPSTREAM (PROXIMAL) OCCLUSION SENSOR TEST | | |
| AIR DETECTION TEST | | |
| DOWNSTREAM (DISTAL) OCCLUSION SENSOR TEST<br>_____PSI OR _____mm/hg | | |
| MEMORY TEST | | |
| FLOW RATE ACCURACY TEST<br>VOLUME OUTPUT _____mL | | |
| BATTERY CAPACITY TEST<br>TIME “Start to dead” = _____HRS _____MIN.<br>TIME “Low to dead” = _____HRS _____MIN. | | |

## 1.6 DOWNLOADING THE HISTORY LOG

### PURPOSE

The purpose of this document is to provide instructions for the extraction of the history (event) log from a SIGMA Model Spectrum Infusion pump.

### SCOPE

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

1. PC running Windows XP or Windows 2000 with enabled IrDA communications
2. Optional Equipment List (if IrDA-equipped PC is not available)
   a. PC running Windows XP or Windows 2000 with SD Card Reader or,
   b. USB External SD Card Reader/Writer, Ezonics™ or equivalent
   c. SD Card, Kingston™ or equivalent, minimum size 512MB
   d. PN 55098 – PDA, PalmOne™ Tungsten™ E2 or equivalent with a file transfer utility installed (McFile version 2.2sigma, or equivalent) for transferring data

### REFERENCES

None.

### DEFINITIONS

- PC – Personal Computer
- IrDA – Infrared Data Association defining a communications protocol for the short-range exchange of data
- PDA – Personal Digital Assistant
- USB – Universal Serial Bus
- SD Card – Secure Digital Card (removable memory)

### PROCEDURE

1. Access the “History Log” option of the Spectrum.
   a. If the pump is running, press STOP and then press the ‘options’ softkey. Otherwise access the ‘options’ softkey from the ‘Need Help’ screen.
   b. Select the ‘User Options’ menu item.
   c. From the USER OPTIONS menu select the “View Information” menu item.
   d. From the VIEW INFORMATION menu select the “History Log” menu item.
   e. From the HISTORY LOG menu select the “Dump History Log” menu item.
   f. Proceed to Step 6.2 or 6.3.

2. Transferring the history log (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 *serial number_date_time.log* in the selected location on the hard drive of the PC (for example, 123456_12-31-06_22-59.log).
    1.2.c.1 The length of time of the transfer will vary based on the number of events in the history log.
    1.2.c.2 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.

3. Transferring the history log (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.
    1.3.e.1 The length of time of the transfer will vary based on the number of events in the history log.
    1.3.e.2 If the pump is unable to establish a link with the PC within 30 seconds, the process will abort.
f. When the transfer is complete a file is created on the PC in the filename format *serial number_date_time.log* on the PDA (for example, 123456_12-31-06_22-59.log). The default location for wireless transfers is to place the files directly on the PC Desktop.
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.

## 1.7 User Options - OPTIONS SCREEN

The SIGMA Spectrum has a number of user-accessible options. This menu is available through the "options" soft-key and is grouped by functionality.

**ALARM SETTINGS**

Audio Volume – The audio volume level of the pump may be set to one of three available levels; LOW, MEDIUM, or HIGH.

Audio Tone – set the type of alarm tone that sounds; Short or Long

Standby delay (hr:min) – Set the length of time to keep the pump in standby (or Hold) after setup of the infusion has completed. Settings are from 00:01 to 99:59 (hr:min). Setting the value to 00:00, or Infinite, results in an infinite Hold period.

Near Empty alert – When enabled, a callback alert is generated when less than 30 minutes of infusion remain. If the initially programmed infusion is less than 30 minutes, the alert shall not be generated regardless of the setting.

DS Pressure Limit – Pressure levels are selectable from three levels; LOW (6psi ±4psi), MEDIUM (13psi ±6psi), and HIGH (19psi ±9psi).

**DISPLAY SETTINGS**

RUN SCREEN OPTIONS – Each of the items in this list may be turned ON or OFF. If enabled, they shall be included in the alternating screens that are displayed while the pump is running.

Audio level indicator – shows L, M, or H (as selected in Audio Volume)
Rate mL/hr – shows the mL/hr infusion rate of the current delivery
Dose rate – shows the dose rate of the current delivery
mL VTBI – shows the remaining Volume To Be Infused, in mL
Time (hr:min) – shows the time remaining in the current infusion, in hr:min format

DISPLAY ADJUST

Backlight Level – The display backlight level may be set to one of four levels (LOW, MEDIUM or HIGH) or OFF. The backlight consumes approximately 400 mW when set to HIGH, therefore, battery life is maximized when the backlight is set to OFF or LOW.

LCD Contrast – The display contrast may be set to any value in the range of 10% to 100%. The contrast setting does not significantly impact battery life.

SETUP OPTIONS

Concentration confirmation – Setting this option ON results in a prompt that requires the operator to confirm that the concentration value selected from a list of concentrations or a user-entered variable concentration is correct.

'New Patient?' Prompt – When the pump is turned on and programmed infusion data exists in memory, a screen is displayed asking the operator if the intended use for the pump is for a New Patient. Answering YES to this prompt clears the existing infusion data, answering NO retains the data and allows the operator to resume the infusion. Setting this option OFF disables this screen.

**VIEW INFORMATION**

PUMP INFORMATION – The pump information screen has the following read-only information that either the user (clinician) or Bio-Medical Engineer may find useful:
Software version – this is the currently installed pump operating software version.
Pressing the "sw info" softkey displays a screen showing the versions of the individual software components that are installed:

- Sharp build
- PIC build

- CPLD build
- SmartBatt Charger build
- Network Module build
- Serial number – The serial number assigned by SIGMA for tracking and device history.
- Tube type – the name of the IV tube set manufacturer that the device is calibrated for use with.

LIBRARY INFORMATION – The library information screen identifies the name of the active drug library in pump memory as well as the date modified, version number, and format indicators.

SHOW CLINICAL ADVISORY – If the current infusion has a Clinical Advisory associated with it, selecting this option will display the advisory. If the current infusion does not have a Clinical Advisory associated with it, this option is not selectable and appears in grey text in the display.

INFUSION INFORMATION – The infusion information screen identifies the infusion specific primary and secondary bag parameters that are not otherwise displayed on the setup screen. The information includes the following information for each bag (if programmed): audio level, near empty alert status (primary only), pressure setting, KVO rate (primary only), and primary siphoning alert or secondary complete alert status (secondary only).

HISTORY LOG – Selecting this option provides access to the event log. Available options for viewing the log are listed below. Note that access to this option is provided only when the pump is not running (delivering). If the pump is running, this option is not selectable and appears in grey text in the display.

- View History Log – select this option to view the entire history log on the pump screen.
- View System Error Log – select this option to view only the system errors recorded in the history log.
- View Drug Error Log – select this option to view only the events associated with programming an infusion; including any drug limits that may have been exceeded during setup.
- Dump History Log – select this option to send the entire history log out of the pump via the IrDA port (reference DOWNLOADING THE HISTORY LOG for instructions).

## 1.8 Biomed Options – OPTIONS SCREEN

The Biomed Options menu may be reached by selecting the “options” softkey. Biomed Configuration is one of the OPTIONS that may be selected. The Bio Medical (Biomed) accessible options require an access password. This access password may be obtained by authorized service personnel. Contact SIGMA International, LLC., Service Department.

Telephone: 1-800-356-3454, or 585-798-3901
Or write:SIGMA International, Inc.
711 Park Avenue
Medina, N.Y. 14103

Email Service Coordinator at: techsupport@sigmapumps.com

**Sensor Configuration**

1. Downstream Occlusion Auto-Restart on/off – Turns on or off the Downstream Occlusion Auto-Restart feature.
2. 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**

**NOTE: Calibration of the device is not recommended to, and should not be performed by, anyone who has not been formally trained by SIGMA personnel on Spectrum calibration procedures.**

**Sensor Calibration**

1. Upstream Sensor – provides utilities for calibrating the upstream sensor and to view the calibration data.
2. Downstream Sensor – provides utilities for calibrating the downstream sensor and to view the calibration data.
3. Slide Clamp Sensor – Calibrates the Keyhole Color Sensor for the specific manufacturer’s slide clamp type.
4. Optical Tube Sensor – Provides access to calibrating the sensor located in the #2 loading position. Also available in this menu are options to View and to perform a Check on the calibration data.

**Pump Calibration**

1. Flow calibration – This option initiates the flow rate calibration process.
2. View flow calibration values – This menu allows the Bio Medical Engineer/Technician to see flow calibration correction values applied during the flow rate calibration process.
3. Calibration prep (break-in) – Operates the pump for a 4-hour period at a rate of 400 mL/hr to provide a break-in period of new pump assembly mechanisms.

## Pump Settings

### Alarm Settings

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

### System Settings

1. Set Time and Date
    a. Time (GMT) – this option is used to set the real-time clock current time (observing Greenwich Mean Time, or UTC).
    b. Date (mm/dd/yyyy) - this option is used to set the real-time clock current date in the indicated format.
2. Hardware Settings – this option is used to select the appropriate audio drive levels to support either a 0.5W or a 1.0W speaker.

## Pump Testing

1. Test Mode – Allows the pump to run at a rate of 100 mL/hr. This is intended for warm-up and will not allow alarm activation in this mode.
2. Battery Test
    a. Battery Life Test - Performs an automated life cycle of the battery to determine its expected period of operation.
    b. Show Battery Test Results – This selection will display the time to LOW BATTERY and PLUG IN Alarm after the Battery Life Test has been conducted.
    c. View Battery Status – provides a display of 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.
3. Flow/Time Test - Operates the pump in a semi-automated method to perform a flow accuracy test over a period of time.
4. Motor Life Test – Allows the pump to run at a rate of 999 mL/hr indefinitely.
5. Flow Cal Test - Performs a semi-automated test of the flow calibration.

## Update Software

1. Drug Library – This option allows updating of the drug library via the IrDA port (not accessible if wireless networking is enabled).
2. Pump Software – This option allows the operating software of the pump to be updated via the serial communications port.

## Network Configuration

See Appendix C – Wireless Network Configuration for details.

1. Network Status – this option shows the current status of the network connection. The following items are available:
    a. 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.
    b. IP Addr – displays the current IP address of the pump.
    c. SIGMA GW – displays the IP address or DNS name of the network host, also known as the Sigma Gateway server.
    d. 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.
    e. Error Message – displays information about any abnormal conditions that may be preventing the pump from accessing or using the network.
2. Transfer Network Status – this option shows the TCP/IP settings of the pump's network connection.
3. Network Settings – this option 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:

   a. 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.
   b. 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.
   c. 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.
   d. 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.

4. 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.
   a. DHCP – (read-only, set via network configuration file) Dynamic Host Control protocol settings, either 'on' or 'of'.
   b. IP – (read-only, set via network configuration file) IP address of pump, either assigned statically or assigned by DHCP server.
   c. Gateway – (read-only, set via network configuration file) IP address of gateway, either assigned statically or assigned by DHCP server
   d. Netmask – (read-only, set via network configuration file) IP netmask, either assigned statically, or assigned by DHCP server.
   e. DNS – (read-only, set via network configuration file) Domain Name Server IP address, either assigned statically, or assigned by DHCP server.
5. Wireless Settings – this option shows the Wireless settings of the pump's network connection.

## 1.9 TROUBLESHOOTING GUIDE

**'CLOCK BATTERY LOW'** – This alert shall appear 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 shall appear 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 will appear on power up when corruption of the stored calibration data has occurred. The pump is prevented from operational use at this point. Return the pump to SIGMA for recalibration.

The following is a list of alert and/or messages that may appear during use of the Spectrum:

### 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:

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

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

### Spectrum "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 |

| Error Code # | Displayed and History Log Language | Description |
|---|---|---|
| 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 |
| 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 |
| 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 |
| 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 |

| Error Code # | Displayed and History Log Language | Description |
|---|---|---|
| 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 |
| 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 |
| 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 |

| Error Code # | Displayed and History Log Language | Description |
|---|---|---|
| 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 |
| 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 smartbattery 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**:**

- Turn the pump off by pressing the “ON/OFF” key.
- Turn the pump off by pressing the “ON/OFF” key and removing the battery for 1 minute.
- A PM 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.

## 1.10 SERVICE

### Return Authorization

Contact SIGMA International, LLC for all service information at:
Telephone: 1-800-356-3454, or 585-798-3901
Or write: SIGMA International, Inc.
711 Park Avenue
Medina, N.Y. 14103
Or:

Email Service Coordinator at: techsupport@sigmapumps.com

Please be prepared to provide the serial number and a description of the difficulty experienced (including all pertinent information such as flow rate, administration set used, and the message displayed at the time of the difficulty).

IMPORTANT: Confirm pump failure as described in this manual before return. Unconfirmed complaints are required to go through Production Testing and Quality Assurance Inspection which will be billed accordingly (See Warranty).

If it is necessary to return the unit for service:

1. Contact the SIGMA International service center above for return authorization (RA) number.
2. A purchase order number or other authorized form of payment will be required on non-warranty repairs before a RA number is issued.
3. If an estimate is required before work is performed, state this when you call in for a RA number.
4. Clearly reference on all applicable documents:
    - 4.1 RA number.
    - 4.2 Purchase order number.
    - 4.3 Written description of problem.
    - 4.4 Name, telephone number, e-mail and mailing address of the following people in your hospital or organization.
        - 4.4.1 Repair Service Manager
        - 4.4.2 Purchasing Manager
        - 4.4.3 Accounts Payable Manager

        (Please note that the above information is required for both the independent biomedical service company and for the pump owner, in cases where SIGMA is not dealing directly with the pump owner.)
    - 4.5 Complete name and address of the hospital or organization.
5. Package pump in the original shipping container (replacement available upon request) and affix the RA number on the outside of the package.
6. Ship pump, freight prepaid, by traceable means to: SIGMA International, LLC.
7. When a device is warranted or under a service agreement, it is returned freight prepaid.
8. Non-warranty repairs are also returned freight prepaid.
9. SIGMA International, Inc. will not be responsible for unauthorized returns or units damaged in shipment due to improper packing.

### Field Service

1. Authorization: Verbal authorization must be obtained in advance, before field service can be performed. Written documentation will also be required.
2. Parts: While under warranty, SIGMA will supply factory trained/authorized service technicians with no charge parts as needed. All defective warranty parts must be returned to SIGMA.

## Battery Removal and Replacement

Should removal of the battery become necessary for any reason, the following procedure may be used. Refer to Section 2, Technical Drawings, for the location of parts.

1. Turn unit OFF if ON.
2. Disconnect the AC Power Adaptor, and lay the SIGMA Model Spectrum 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).
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. **Remove the battery insulating tab** prior to charging the pump's battery or operating the pump.
6. Plug the AC power adaptor into an outlet and charge for 12 hours to assure a full charge.

### Wireless Battery Module Battery Removal and Replacement

***CAUTION***: Static sensitive components will be exposed during this process. Perform this procedure using proper antistatic 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 ¼" flat plate slightly larger than the perimeter of the Wireless Battery Module

1. The wireless battery pack may be removed from the back of the SIGMA Spectrum Infusion Pump according to the first four steps of the above procedure for the standard battery.
2. Once the Wireless Battery Module is removed from the pump place it with the connecting terminals up on the work surface.
3. Using the TORX driver, remove and retain the five TORX head screws from the case.
4. 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.
5. Place the Wireless Battery Module on the flat plate with the bottom (terminal end) of the pack even with the edge of the plate.
6. 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.
7. 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. Slight upward force on the wire end of the connector may help ease component clearance during removal. Do not over stress.
8. The battery may then be removed from the pack.
9. Install the replacement battery in the reverse order of removal.
10. Make sure that the battery is flat inside of the case, the routing of the battery wires is flat across the top of the PCB and that the connector is fully latched in place prior to reassembly.
11. Make sure that the antenna is properly seated in the slot in the case.
12. Make sure that the Wireless Battery Module latching mechanism is properly installed in the case.
13. 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.
14. Place the Wireless Battery Module on the work surface with the terminal side of the battery pack facing up and install the five 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 of the pack.
15. Check the latch mechanism operation to assure that it moves freely when depressed and released.

16. Turn the Wireless Battery Module over and install the last screw into the antenna section of the case and tighten.
17. Replace the Wireless Battery Module back into the pump according to the last three steps of the above procedure for the standard battery.
18. Perform the Battery capacity check of the new battery as indicated in the Preventative 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 disposable center cannot be found.

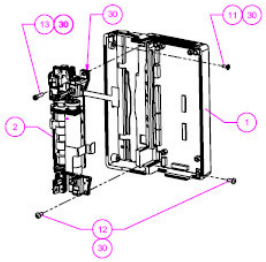
***CAUTION***

**Do not short circuit the battery terminals.**

**Do not disassemble or modify.**

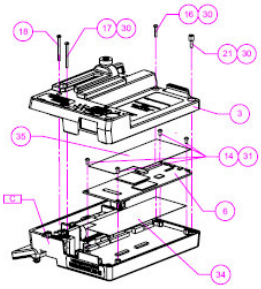
## Section 2: Technical Drawings:

**Assembly, Spectrum Final 35700**

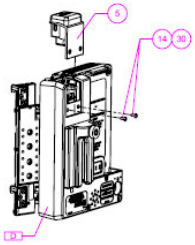


VIEW A

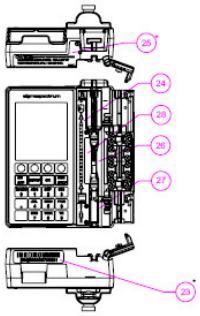
VIEW B



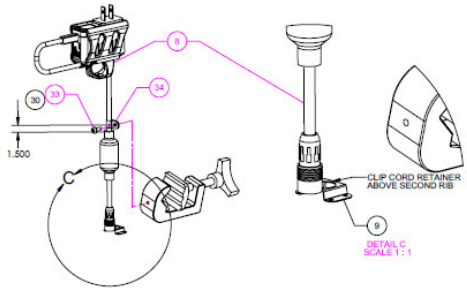
VIEW C



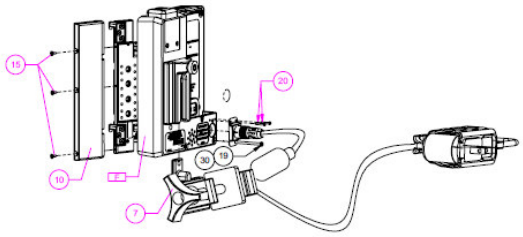
VIEW D



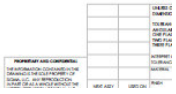
VIEW E




VIEW F



VIEW G



## 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 | |

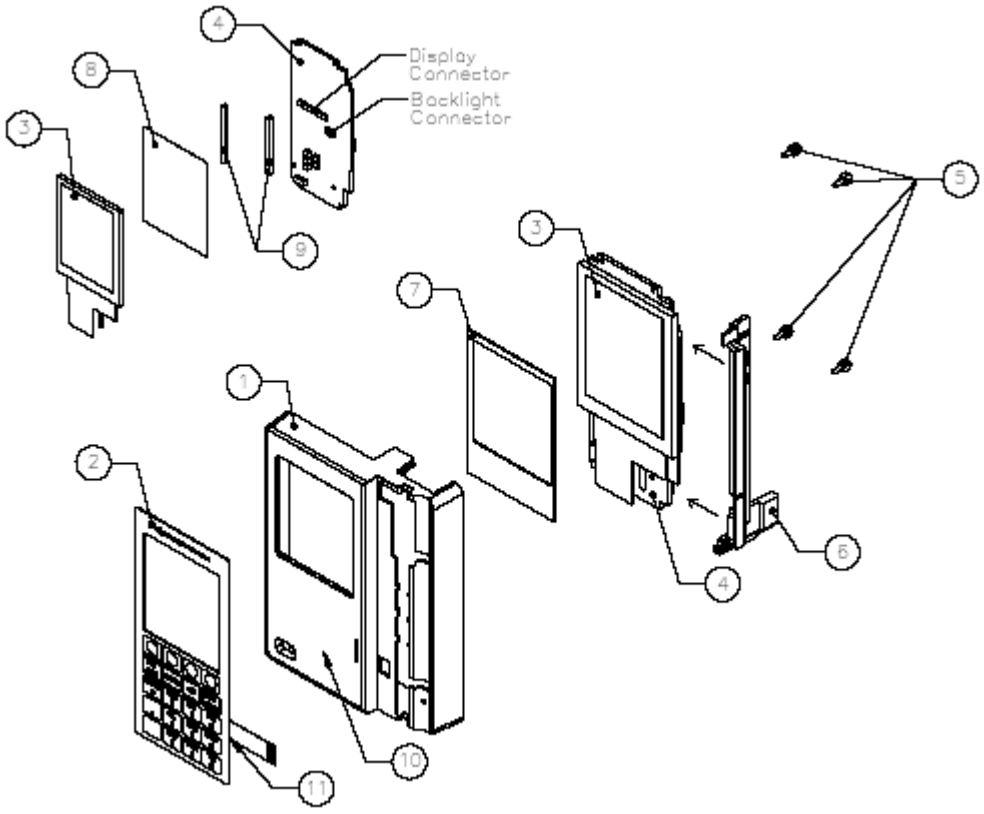
| | |
|---|---|
| 030 | 0.030 |
| 020 | 0.020 |
| 015 | 0.015 |
| 010 | 0.010 |
| -XXX | Thickness |
| Chart C - 41017 | |

| | |
|---|---|
| 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 | |

- * Use 35702 OR 35724

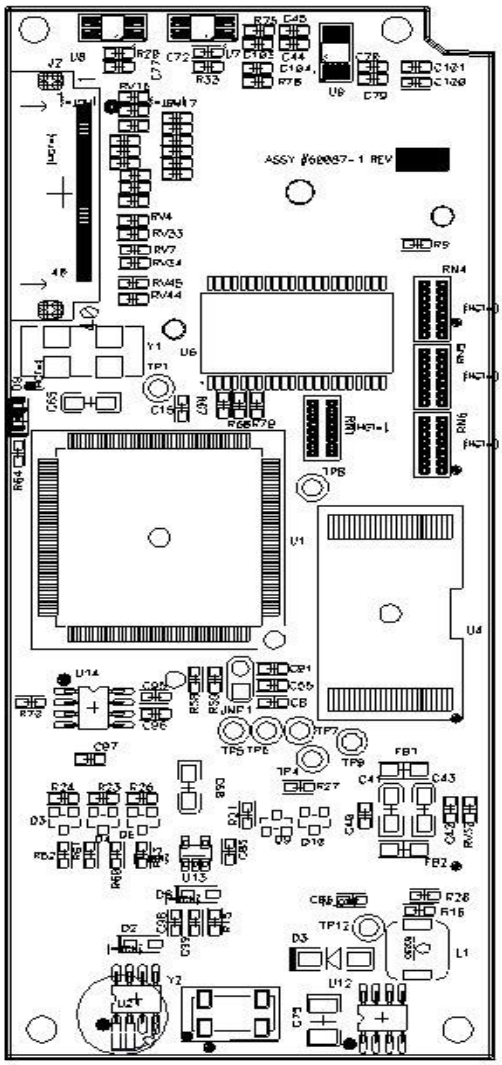
| | | | | | |
|---|---|---|---|---|---|
| | 35 | 1 | 1 | 41085 | SHIELDING, PROCESSOR BOARD |
| | 34 | 1 | 1 | 41084 | SHIELDING,IO BOARD |
| | 33 | 1 | 1 | 86511 | CORD CLIP |
| | 32 | 1 | 1 | 95070 | SCREW, #8-32 x 3/8" LG. |
| | 31 | AR | AR | 85203 | Adhesive, Threadlocker, Loctite 222 |
| | 30 | AR | AR | 90059 | Adhesive, Threadlocker, Hernon 128 |
| | 29 | AR | AR | 85088 | Isopropyl Alcohol |
| Ref. Chart D | 28 | 1 | 1 | 44014 | Shim, Direction of Flow |
| Ref. Chart C | 27 | 1 | 1 | 41017 | Label, Bottom Door Spacer |
| Ref. Chart B | 26 | 1 | 1 | 41016 | Label, Top Door Spacer |
| | 25* | - | 1 | 41015-2 | Label, Tubing ID, Baxter |
| | 25* | 1 | - | 41015-1 | Label, Tubing ID, Hospira (Abbott) |
| Ref. Chart A | 24 | 1 | 1 | 41014 | Label, Direction of Flow |
| | 23* | 1 | 1 | 41013-1 | Label, Serial Number |
| | 23* | 1 | 1 | 41013 | Label, Serial Number |
| | 22 | 1 | 1 | 41007 | Label, Company ID |
| | 21 | 1 | 1 | 95198 | Standoff, Male/Female Hex |
| | 20 | 2 | 2 | 95213 | Screw, 0-48 x 3/8" Threadforming SS |
| | 19 | 1 | 1 | 95063 | Screw, 2-56 x 1-1/4" Phil, PHMS SS |
| | 18 | 1 | 1 | 95212 | Screw, 2-56 x 1" Phil, BHMS Nylon |
| | 17 | 1 | 1 | 95201 | Screw, 2-56 x 1" Phil, PHMS SS |
| | 16 | 1 | 1 | 95196 | Screw, 2-56 x 7/16" Phil, PHMS SS |
| | 15 | 3 | 3 | 95210 | Screw, 2-56 x 1/4" Slotted, FHMS Nylon |
| | 14 | 6 | 6 | 95181 | Screw, 2-56 x 3/16" Phil, PHMS SS |
| | 13 | 1 | 1 | 95200 | Screw, 4-40 x 7/16" SHCS SS |
| | 12 | 2 | 2 | 95015 | Screw, 4-40 x 1/4" Phil, PHMS SS |
| | 11 | 1 | 1 | 95022 | Screw, 4-40 x 3/16" Phil, FHMS SS |
| | 10 | 1 | 1 | 45713 | Cover, Door |
| | 9 | 1 | 1 | 50737 | Cord Retainer |
| | 8 | 1 | 1 | 35714 | Asm, Power Cord w/ Connector |
| | 7 | 1 | 1 | 35712 | Asm, Pole Clamp |
| | 6 | 1 | 1 | 60087-1 | Asm, Processor PCB |
| | 5 | - | 1 | 35709-2 | Asm, Keyhole, Baxter |
| | 5 | 1 | - | 35709-1 | Asm, Keyhole, Hospira (Abbott) |
| | 3 | 1 | 1 | 35701 | Asm, Rear Case |
| | 2 | 1 | 1 | 35703 | Asm, Mechanism/Door |
| | 1 | 1 | 1 | 35708 | Asm, Front Case |
| | ITEM NO. | QUANTITY | | PART NO. | DESCRIPTION |
| | | 35700ABB | | ASSY, FINAL HOSPIRA (ABBOTT) | |
| | | | 35700BAX | ASSY, FINAL BAXTER | |
| | | | | ASSY, WI-FI, FINAL HOSPIRA (ABBOTT) | |
| | | | | ASSY, WI-FI, FINAL BAXTER | |
| BILL OF MATERIALS | | | | | |

**Front Case Assembly 35708**

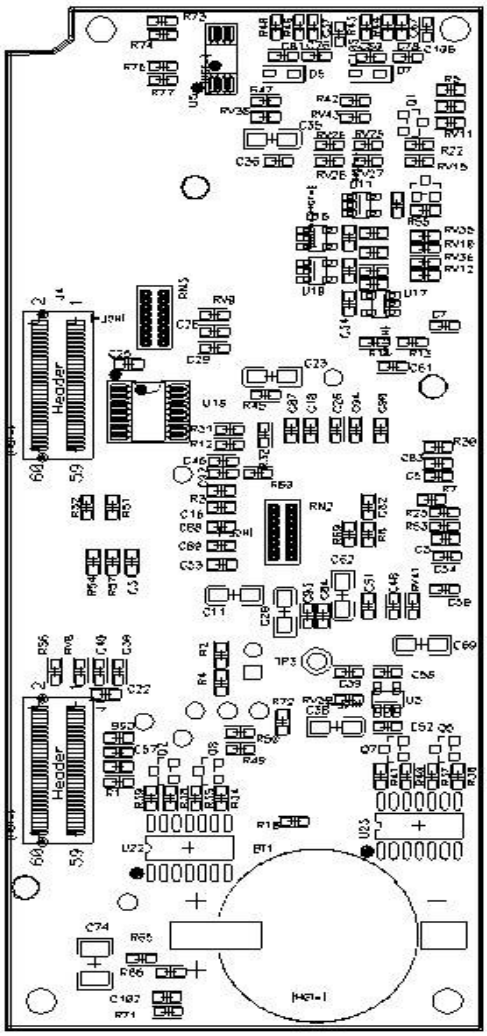



| BILL OF MATERIALS | | | |
|---|---|---|---|
| ITEM NO. | QTY. | PART NO. | DESCRIPTION |
| 1 | 1 | 45700 | Case, Front |
| 2 | 1 | 41001 | Keypad |
| 3 | 1 | 55074-1 | Display |
| 4 | 1 | 60091 | Assembly, I/O PCB |
| 5 | 4 | 95182 | Standoff, Male/Female 2-56 x 4mm |
| 6 | 1 | 45704 | Sealing Wall |
| 7 | 1 | 41002 | Gasket, Display |
| 8 | 1 | 41011 | Insulator, Mylar, Display |
| 9 | 2 | 41010 | Foam Strip Spacer, Display |
| 10 | A/R | 85088 | Isopropyl Alcohol |
| 11 | A/R | 90057 | Adhesive, Dow Corning #3145 RTV |

**Assembly, Processor PCB 60087**

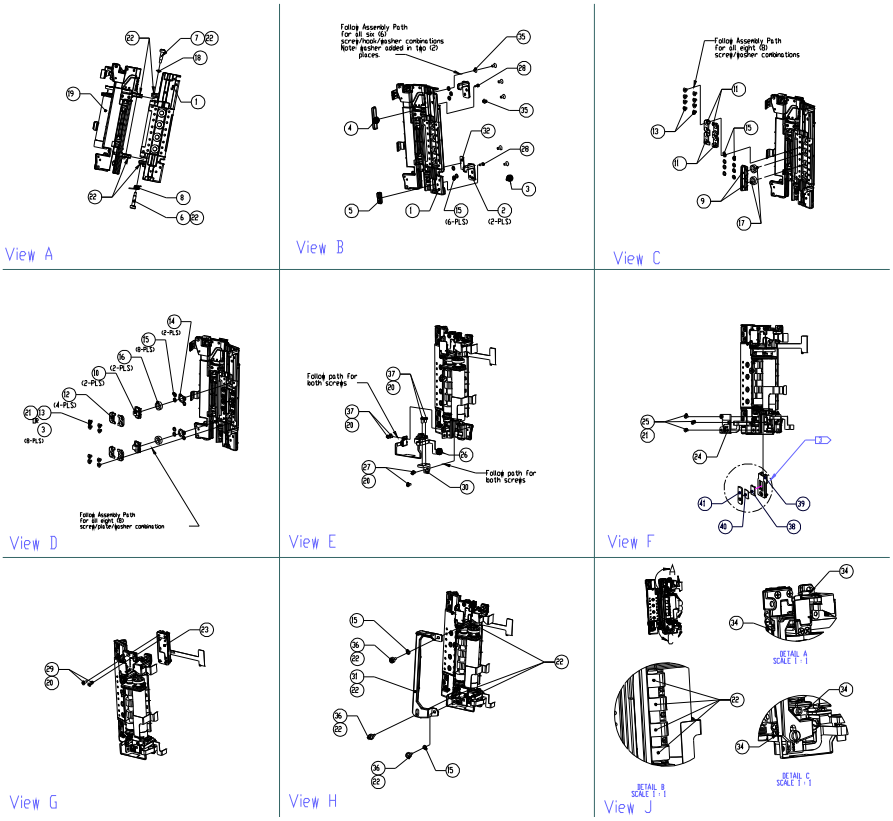


BOTTOM VIEW



TOP VIEW

## Assembly, Mechanism / Door 35703



## Assembly, Mechanism / Door 35703

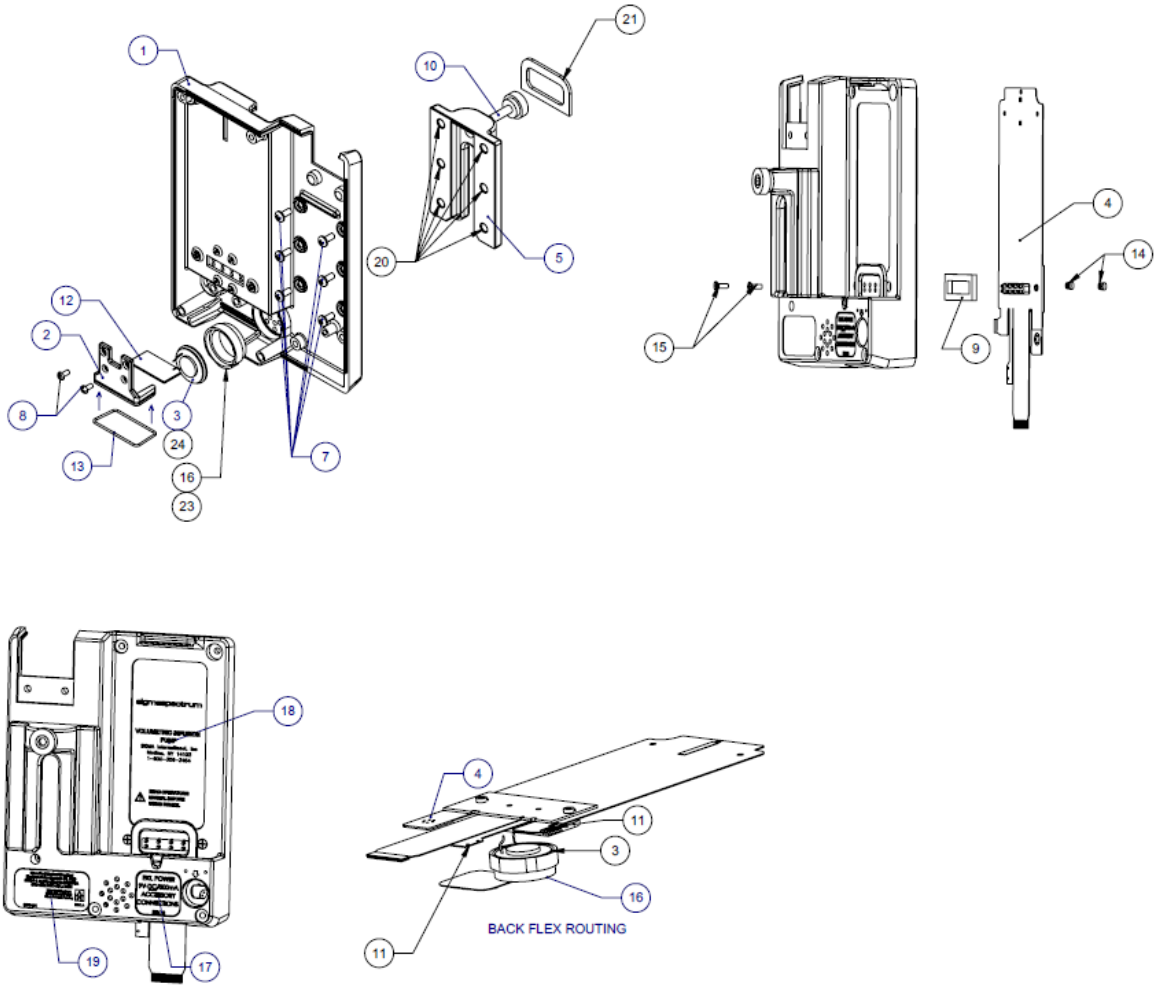
| 95202-030 | .030 |
|---|---|
| 95202-020 | .020 |
| 95202-016 | .016 |
| 95202-014 | .014 |
| 95202-012 | .012 |
| 95202-010 | .010 |
| 95202-008 | .008 |
| 95202-006 | .006 |
| 95202-004 | .004 |
| 95202-002 | .002 |
| PART NO. | THICKNESS(in.) |
| SHIM REF. CHART A | |

| 95203-030 | .030 |
|---|---|
| 95203-024 | .024 |
| 95203-020 | .020 |
| 95203-016 | .016 |
| 95203-014 | .014 |
| 95203-012 | .012 |
| 95203-010 | .010 |
| 95203-008 | .008 |
| 95203-006 | .006 |
| 95203-004 | .004 |
| 95203-002 | .002 |
| PART NO. | THICKNESS(in.) |
| SHIM REF. CHART B | |

| 50731-020 | .020 |
|---|---|
| 50731-015 | .015 |
| 50731-010 | .010 |
| 50731-005 | .005 |
| PART NO. | THICKNESS(in) |
| SHIM REF. CHART C | |

| | | | | |
|---|---|---|---|---|
| | 41 | 1 | 41027 | Force Sensor Gasket |
| see chart C | 40 | 1 | 50731 | Downstream Plate Shim |
| | 39 | 1 | 45712 | Tubing Guide |
| | 38 | 1 | 45732 | Downstream Plate |
| | 37 | 4 | 95214 | Screw, 2-56 x 3/16" Phil, PHMS, Nylon |
| | 36 | 3 | 95134 | Screw, Shoulder, 4-40 x 3/16 x 1/8, w/Patch |
| | 35 | 2 | 95209 | Washer, #4 Countersunk |
| | 34 | 1 | 90061 | Grease, Dow Corning 4 |
| | 33 | A/R | 85088 | Alcohol, Isopropyl |
| | 32 | 1 | 41038 | Label, ID Tag |
| | 31 | 1 | 50812 | Link |
| | 30 | 1 | 50725 | Bracket, Lower Hook Switch |
| | 29 | 2 | 85024 | Screw, 2-56 x 1/4" Phil, FHMS, SS |
| | 28 | 2 | 95216 | Screw, 0-42 x 3/16", Threadforming, SS |
| | 27 | 2 | 95181 | Screw, 2-56 x 3/16" Phil, PHMS, SS |
| | 26 | 1 | 35148 | Asm, Lower Aux Flex |
| | 25 | 3 | 95004 | Screw, 2-56 x 3/16" Phil, FHMS, SS |
| | 24 | 1 | 35147 | Asm, Force Sensor Flex |
| | 23 | 1 | 35711 | Asm, Ultrasonic Sensor |
| | 22 | A/R | 90058 | Grease, Dow Corning 111 |
| | 21 | A/R | 85203 | Adhesive, Threadlocker Loctite, 222 |
| | 20 | A/R | 90059 | Adhesive, Threadlocker, Hernon 128 |
| | 19 | 1 | 35704 | Asm, Mechanism Sub |
| | 18 | 1 | 95184 | Washer, Split Lock #5 |
| | 17 | 2 | 95515 | Spring, Crest to Crest, M3 |
| | 16 | 2 | 95514 | Spring, Crest to Crest, M2 |
| see chart B | 15 | A/R | 95203 | Shim, .125 ID x .187 OD |
| see chart A | 14 | A/R | 95202 | Shim, .250 ID x .375 OD |
| | 13 | 22 | 85240 | Screw, 4-40 x 1/4" Phil, FHMS, SS |
| | 12 | 4 | 50819 | Outside Holder |
| | 11 | 4 | 50818 | Middle Holder |
| | 10 | 2 | 45719 | Pressure Plate, Valve |
| | 9 | 2 | 45718 | Pressure Plate, Finger |
| | 8 | 1 | 95513 | Spring, Door |
| | 7 | 1 | 95186 | Screw, Shoulder 4-40 x 3/8 x 1/8", SS |
| | 6 | 1 | 95007 | Screw, Shoulder 4-40 x 1/2 x 1/8", SS |
| | 5 | 1 | 45708 | Pusher, Force Sensor |
| | 4 | 1 | 45707 | Pusher, Ultrasonic Sensor |
| | 3 | 22 | 95022 | Screw, 4-40 x 3/16" Phil, FHMS, SS |
| | 2 | 2 | 50816 | Hook, Door Latch |
| | 1 | 1 | 50815 | Door |
| ITEM NO. | | QTY. | PART NO. | DESCRIPTION |
| BILL OF MATERIALS | | | | |

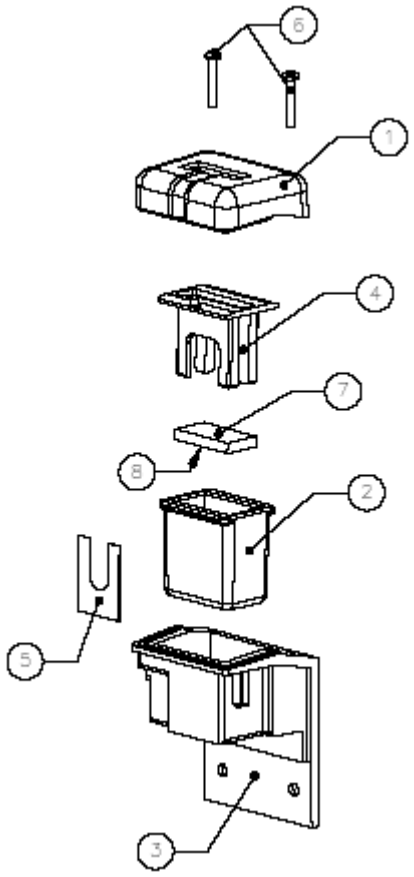
## Assembly, Rear Case 35701




NOTE:
ASSEMBLE PER MWI 35701

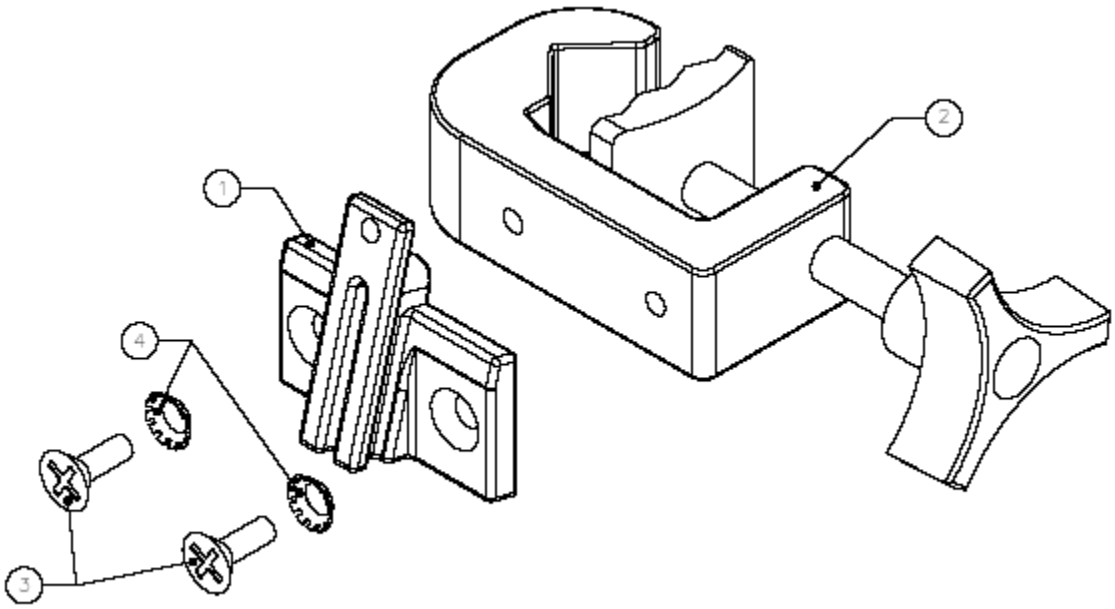
| ITEM NO. | QTY. | PART NO. | DESCRIPTION |
|---|---|---|---|
| BILL OF MATERIALS | | | |
| 1 | 1 | 45701 | Rear Case |
| 2 | 1 | 45705 | Scanner Bracket |
| 3 | 1 | 55069-2 | Speaker, 1W |
| 4 | 1 | 35149 | Assembly, Back Flex |
| 5 | 1 | 45726 | Adaptor, Pump Side |
| 6 | 1 | 30061 | Connector, 6-Pin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

**Assembly, Key Hole 35709**



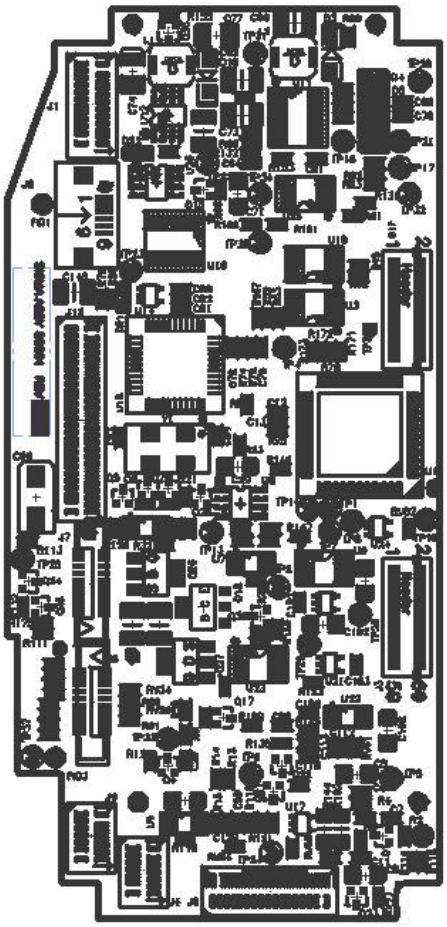

| | | | | | |
|---|---|---|---|---|---|
| 8 | -- | -- | A/R | 90004 | Adhesive, Loctite 454 |
| 7 | -- | -- | 1 | 50728 | Spacer, Slide Clamp |
| 6 | 2 | 2 | 2 | 95213 | Screw, 0-42 x 3/8" Thread Forming, SS |
| 5 | 1 | -- | -- | 41021-1 | Label, Blue Color Sensor |
| 5 | -- | 1 | 1 | 41021 | Label, Red Color Sensor |
| 4 | -- | 1 | -- | 50730-2 | Keyhole Extension - Baxter |
| 4 | 1 | -- | -- | 50730 | Keyhole Extension - Hospira |
| 3 | 1 | 1 | 1 | 45710 | Housing, Slide Clamp Outer |
| 2 | 1 | 1 | 1 | 45711 | Housing, Silde Clamp Inner |
| 1 | -- | -- | 1 | 45709-3 | Key Hole - B.Braun |
| 1 | -- | 1 | -- | 45709-2 | Key Hole - Baxter |
| 1 | 1 | -- | -- | 45709-1 | Key Hole - Hospira |
| ITEM NO. | QUANTITY | | | PART NO. | DESCRIPTION |
| | | | 35709-3 | | Keyhole Assembly - B.Braun |
| | | 35709-2 | | | Keyhole Assembly - Baxter |
| | 35709-1 | | | | Keyhole Assembly - Hospira |
| BILL OF MATERIALS | | | | | |

**Assembly, Pole Clamp 35712**

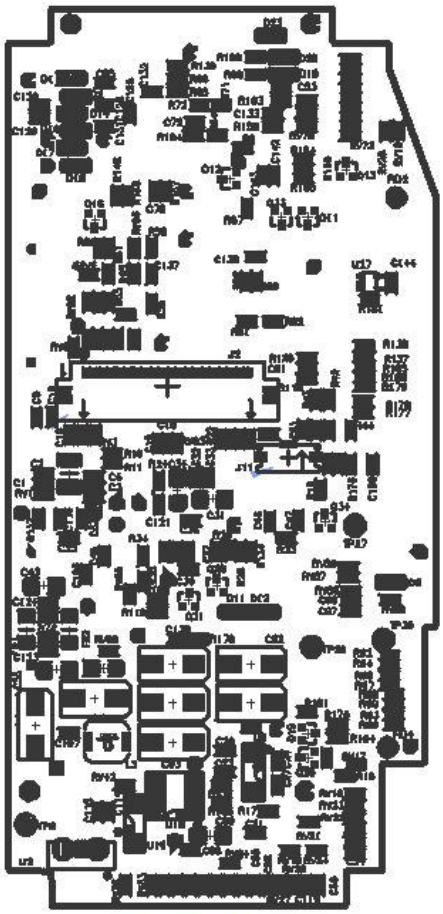



| BILL OF MATERIALS | | | |
|---|---|---|---|
| ITEM NO. | QTY. | PART NO. | DESCRIPTION |
| 1 | 1 | 45727 | POLE SIDE ADAPTOR |
| 2 | 1 | 55041 | C-CLAMP |
| 3 | 2 | 95204 | SCREW, 1/4-20 x 5/8", FHMS, SS |
| 4 | 2 | 95064 | WASHER, 1/4" EXTERNAL TOOTH STAR, SS |

**Assembly, I/O PCB 60091**

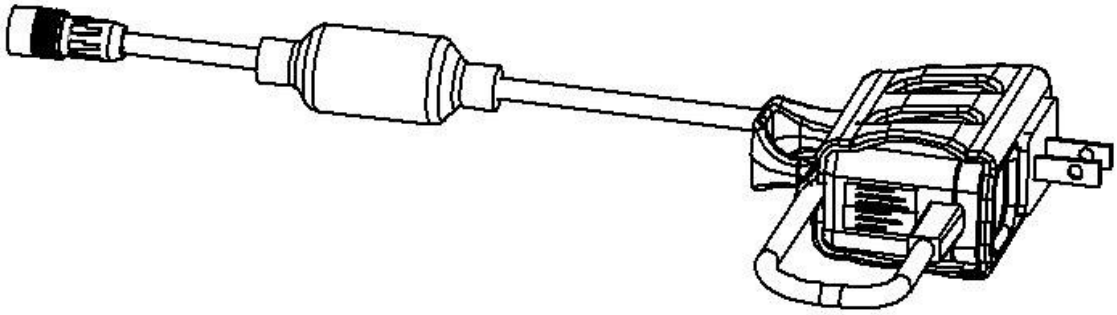


TOP VIEW



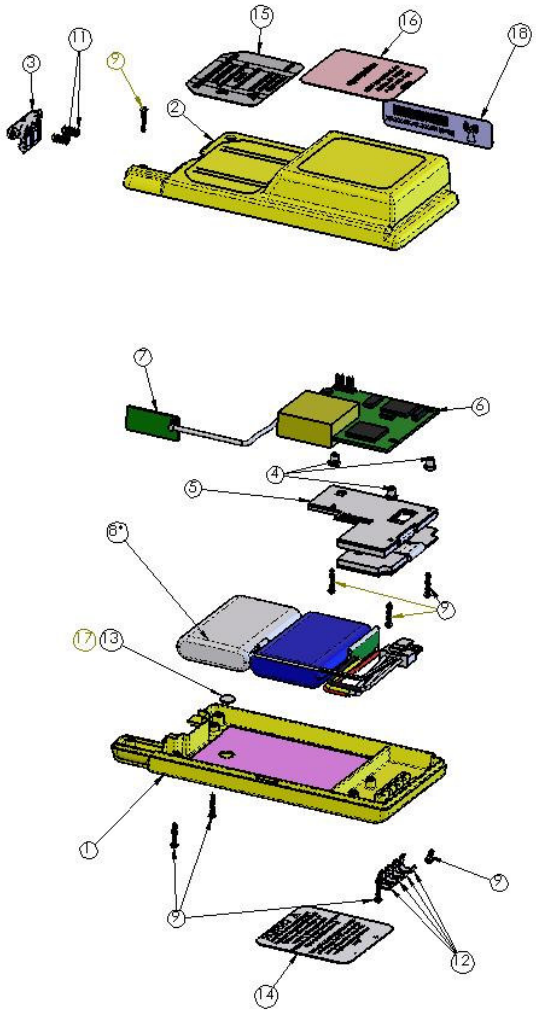
BOTTOM

**Assembly Power Cord 35714**



| ITEM NO. | QTY | P/N | DESCRIPTION |
|---|---|---|---|
| BILL OF MATERIALS | | | |
| 11 | 1 | 45742 | A.C. POWER ADAPTOR PROTECTOR |
| 10 | 1 | 41026 | LABEL, POWER ADAPTOR, MFG |
| 9 | 1 | 41025 | LABEL, POWER ADAPTOR, USE |
| 8 | A/R | 90068 | SOLDER-.020 P3 |
| 7 | A/R | 90067 | PRIMER, LOCTITE 7649 |
| 6 | A/R | 90066 | ADHESIVE, LOCTITE 271 |
| 5 | | | |
| 4 | 1 | 90055 | SHRINK TUBING, .8" ID, POLYOLEFIN |
| 3 | 1 | 25011 | PS FERRITE |
| 2 | 1 | 30115 | CONNECTOR, 6-PIN |
| 1 | 1 | 55079 | POWER SUPPLY |

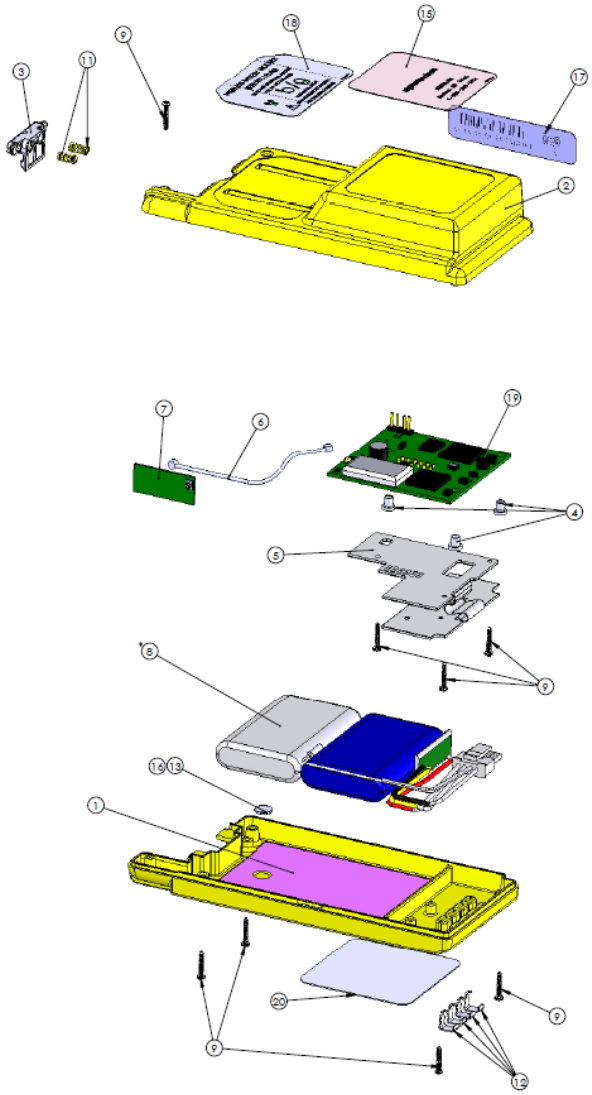
**Assembly, 802.11b Wireless Battery Module**
**35083**




| ITEM NO. | PART NUMBER | DESCRIPTION | Assm QTY |
|---|---|---|---|
| 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 | WI-FI BOARD ASSEMBLY | 1 |
| 6 | 55095 | DIGI MODULE | 1 |
| 7 | 55094 | ANTENNA | 1 |
| 8* | 55075-1 | WI-FI BATTERY PACK | 1 |
| 8* | 55075-2 | Li-Ion Cell Assembly | 1 |
| 9 | 95213 | SCREW, 0-42 x 3/8 SS THREAD FORMING | 8 |
| 10 | 95222 | Screw, 0-42 x 3/16", Thread Forming | 2 |
| 11 | 95507 | SPRING | 2 |
| 12 | 50738 | CONTACT, WIFI BATTERY | 4 |
| 13 | 55024-3 | MAGNET, BATTERY, 0.25 DIA X 0.031 THK | 1 |
| 14 | 41044 | LABEL, WI-FI, CAUTION | 1 |
| 15 | 41045 | LABEL, WI-FI BATTERY, REAR, UPPER | 1 |
| 16 | 41046 | LABEL, WI-FI, BATTERY, REAR, LOWER | 1 |
| 17 | 85081 | ADHESIVE,CYANOACRYLATE,LOCTITE-414 | A/R |
| 18 | 41049 | LABEL, WiFi MAC ADDRESS | 1 |

* Use 55075-1 OR 55075-2

## Assembly, 802.11b/g Wireless Battery Module 35162



| ITEM NO. | PART NUMBER | DESCRIPTION | Assm QTY |
|---|---|---|---|
| 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 | WIRELESS BATTERY PACK | 1 |
| 8* | 55075-2 | Li-Ion Cell Assembly | 1 |
| 9 | 95213 | SCREW, 0-42 x 3/8 SS THREAD FORMING | 8 |
| 10 | 95222 | 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 | LABEL, WIRELESS BATTERY, REAR, UPPER | 1 |
| 19 | 55104 | DIGI-CONNECT WI-EM - b/g | 1 |
| 20 | 41068 | LABEL, CAUTION | 1 |
| 29 | 95213 | SCREW, 0-42 x 3/8 SS THREAD FORMING | 8 |

* USE EITHER 55075-1 OR 55075-2

# Section 3: Theory of Operation

**Case**

- SIGMA Spectrum consists of two case halves, the front and rear case assemblies.

**Front Case Assembly**

- The Front Case assembly is comprised of the front case plastic, display, two circuit boards and the sealing wall. All components of this assembly are fastened with four hex standoffs and four Phillips machine screws.

**Rear Case Assembly**

- The Rear Case assembly consists of the rear case plastic, a back flex circuit, an optional bar-code scan engine with bracket, an external accessory connector and speaker. The back flex circuit is assembled by heat staking it to the rear case. The optional scan engine is assembled with one Phillips machine screw and the external accessory connector is assembled with the hardware provided by the manufacturer.

**Battery Pack**

- The SIGMA Spectrum employs a removable Lithium Ion 7.2V battery pack. This assembly is made of the battery cells, contact pins and the two plastic cases. The battery pack uses both cell and battery pack protection to guard against short-circuit, over voltage and over current. 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.
- ***Standard Battery (P/N 35702)***

  The standard battery is compatible with all SIGMA Spectrum pumps.
- ***802.11b Wireless Battery Module Compatibility (P/N 35083)***


  The 802.1b Wireless Battery Module (P/N 35083) is only compatible with pumps that DO NOT include a ‘G’ preceding the serial number, as shown above.
- ***802.11b/g Wireless Battery Module Compatibility (P/N 35162)***


The 802.1b/g Wireless Battery Module (P/N 35162) is only compatible with pumps that include a 'G' preceding the serial number, as shown above. The 802.11b/g Wireless Battery Module (P/N 35162) should NOT be used with pumps that do not include a 'G' preceding the serial number.

**Pole Clamp**

- The Pole Clamp Assembly (SIGMA P/N 35712) is attached to the pump with a #8-32 x ¼" set screw. The set screw 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-Style Clamp with two ¼-20 x 5/8" Phillips machine screws.

**Tubing Channel/Pump Door**

- The tubing channel consists of a downstream tubing guide, the proximal air/occlusion sensor, pump valves and fingers. These components are designed to facilitate in the proper loading of IV tube. The administration set is loaded by opening the pump door by inserting the slide clamp into the keyhole (loading point # 1) and pressing down until the door opens. Loading must be from the top to bottom of the tubing channel and the tubing should be taught. Load the tubing into loading point # 2 and then loading points # 3 and # 4. Close the door by pressing the upper and lower corners near the door hook areas. Open the slide and roller clamp. To unload sets, push the slide clamp in the keyhole until the door opens and pull tubing out from the bottom of the pump towards the top. Prevent free flow whenever the pump door is open and when the set is out of the pump. This is accomplished by having the set's slide clamp or roller clamp fully closed. When changing IV sets or containers always keep the set's slide clamp or roller clamp fully closed, (except when following standard gravity set priming procedures).

**Set Slide Clamp Sensor**

- A reflective slide clamp sensor is employed to determine if a closed slide clamp is present in the keyhole. If a slide clamp is present in the keyhole, the sensor LED light source will illuminate and detect the presence of the clamp. The sensor component is used to alert 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.

1. Two of the three processors, which we will call the "Sharp" (Processor Board – 60087) and "PIC" " (I/O Board – 60091) are utilized to form a diverse checked redundancy scheme and perform all of the safety critical computations. The scheme is diverse because they are different processor types manufactured by separate, independent manufacturers. Likewise, these processors utilize different software compilers and math libraries, which yields additional independence. This processor pair utilizes 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, it can independently fail the system to a safe state, which includes an audible alarm.

2. 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 method that the SIGMA Spectrum utilizes for pumping fluid is through linear peristaltic cyclical motion, 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. One phase called 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 called the pumping phase of the cycle. 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 an aluminum cast 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 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 for a properly loaded tube and red bar with loading instructions when there is no tube or an improperly placed tube 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 a constant force exerted against 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 and 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

- Air Detection – The air detector utilizes the same sensor hardware as described in the Proximal Occlusion Detection section. The air detection algorithm utilizes 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 to 150µl 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 utilizes a piezoelectric bridge force transducer. A pusher connected to the door assembly assures a constant force exerted against 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 driven 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**

- Spectrum consists of the following factory and field replaceable electronic components (please refer to Spectrum System Diagram in Appendix B):

**AC Power Adaptor / Charger**

- The SIGMA Spectrum infusion pump uses an AC Power Adaptor capable of providing 800 mA at 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 400 mA until the battery voltage reaches 8.4 volts (fully charged voltage). After the battery voltage reaches 8.4 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 first is the charging microcontroller's ability to monitor and control voltage and current applied to the battery. Second, a current clamp circuit is employed to prevent charge currents that would cause charge circuit overheating. Third, battery pack protection circuits within the battery pack itself prevent overheating and over charging.

- The Adaptor side of the A.C. 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 hospital environment. The A.C. 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 old A.C. Power Adaptor. A separate instruction bulletin on how to install the Protector will be send along with the Protector.

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

- **NOTE: IMPROPER REMOVAL MAY DAMAGE THE POWER ADAPTOR.** Remove the Power Adaptor by grabbing the handle of the Protector and pulling it back of 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 power supply.

**Display**

- Spectrum utilizes a: A reflective Highly Reflective Thin Film Transistor (HRTFT) liquid crystal display containing 240 X 270 elements, Color (16 out of a pallet of 262,144 possible colors) HRTFT, 240 X 270, 0.2235 mm X 0.2235 mm dot pitch, Illumination by side mounted LEDs and diffuser. The display employs front lighting utilizing 6 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 from 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 .5 mm flex circuit connectors on the I/O Board.

**I/O Board**

- 60091 – This 10 layer, 0.092 thick 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**

- 60087 - This 10 layer, 0.062 thick 100% surface mount component circuit board distributes input and output (I/O) from the ultrasonic air detector through a 40 pin flex circuit connections that will be 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**

- 35151 – This flex circuit provides connections to two pairs of ultrasonic Piezo crystals (receive and transmit) as well as the secondary tube temperature thermistor. The Ultrasonic Flex is connected to the Processor Board (60087) through a .5 mm pitch, 40-conductor right angle flex connector.

**Upper Aux Flex**

- 35146 – 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 .5 mm pitch, 30-conductor vertical flex connector.

**Lower Aux Flex**

- 35148 - 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 .5 mm pitch, 10-conductor vertical flex connector.

**Force Sensor Flex**

- 35147 - 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 .5 mm pitch, 10-conductor vertical flex connector.

**Backflex**

- 35149 – This flex is connected to the I/O Board (60091) through a .5 mm pitch, 30-conductor vertical flex connector. The Backflex provides the following functions:

1. 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.
2. High-Speed UART Interface / MUX – A digital MUX allows either a smart battery interface which includes an UART, or traditional “dumb” battery connections (Battery type ID resistor and battery thermistor).
3. Battery System Charge Control – An Atmel 8-bit microcontroller is hosted on the backflex. One function of this processor is to control battery charging.
4. Audio Output – The backflex provides connections to a 1-inch moving coil speaker that is used during audio alarms.
5. Temperature Monitor – A temperature sensing thermistor is hosted on the Backflex, which provides internal case temperature to the Spectrum processors.
6. 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.
7. Optional Laser Bar-code Scanner Interface – The optional Laser Bar Code scanner connections are carried from the Atmel processor to a 12 conductor, 1 mm pitch flex circuit tail.
8. Rear Case Connector – The rear case connector circuits are carried from the I/O Board to the rear case connector.

**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 utilizing 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 description of the remainder the keys:

1. ON /OFF Key: Powers up the pump. This key must be pressed for a minimum of 2 seconds to turn the power off preventing unintentionally turning off the pump.
2. OK Key: This key accepts the information currently shown on the pump display and advances the pump program to the next screen.
3. START UP Key: This key is always used to return to the main menu.

4. RUN/STOP Key: This key signals the request to Start or Stop infusions.
5. “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.
6. Alphanumeric Keys 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.
7. The infrared interface (Infra Red 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.

**Rear Case Connector**

- The rear case connector serves three functions. These functions include external power input, Bolus switch connection and an asynchronous data interface.

**Power / Charging Cord**

- External power may be supplied to the SIGMA Spectrum by utilizing a positive locking connector which is connected by the user to the External Power/Accessories rear case receptacle. The SIGMA Spectrum utilizes a medical grade 9VDC output wall power adapter as a power source.

***Digital Data Port***

- *consists of a RS-232 compatible interface. This interface features asynchronous receive, transmit and ground signals. Users can receive/transmit data rates of up to 19.2 Kbps. The RS-232 interface is accessible through the External Power/Accessories rear case connector.*

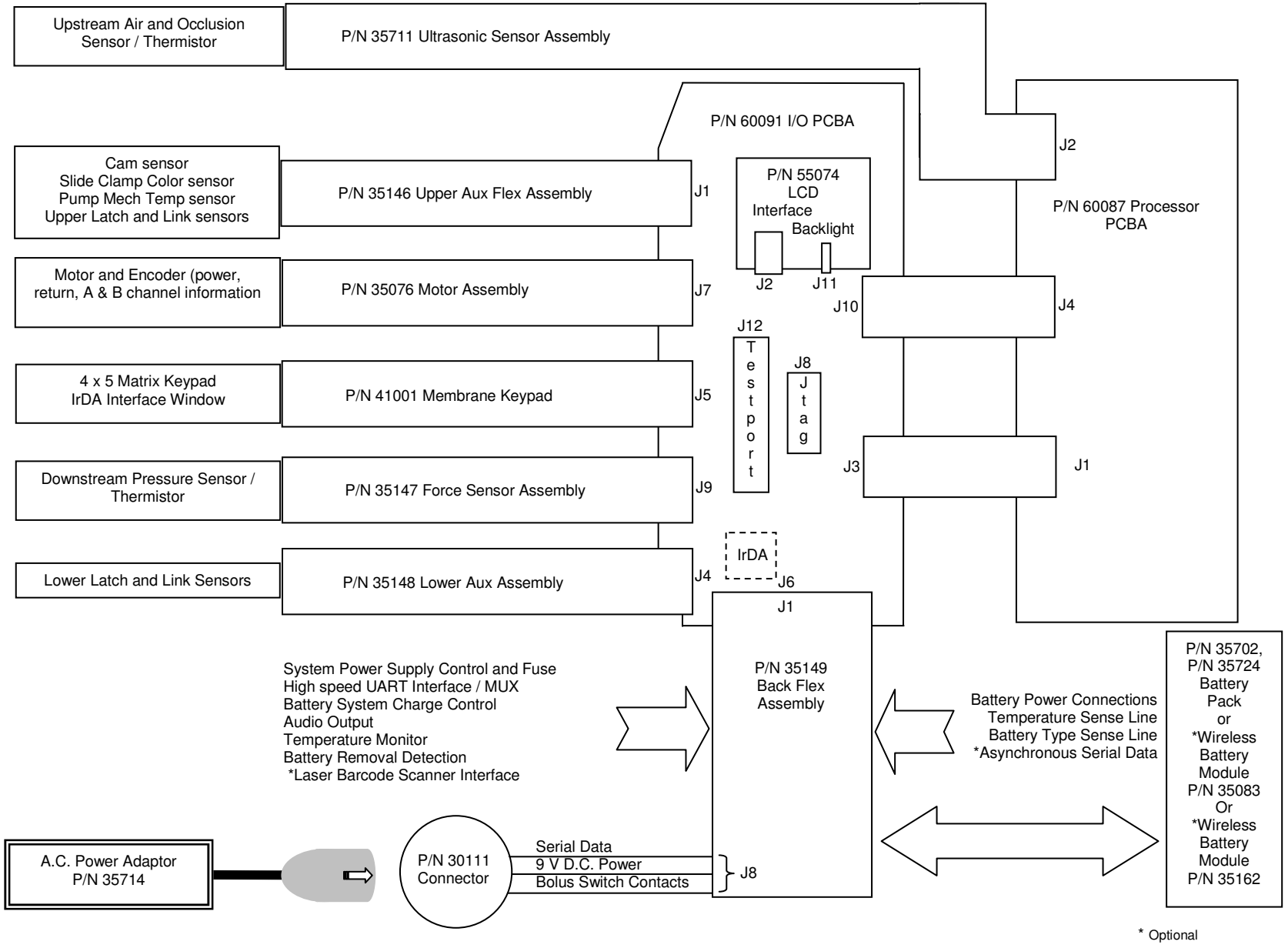
# Appendix A – General Specifications

| | |
|---|---|
| Overall Size (Pump) | 5.8”H x 4.2”W x 2.5”D (without pole clamp),<br>5.8”H x 6.4”W x 4.7”D (with pole clamp) |
| Weight (Pump) | 25.5 oz ± 1.0 oz (with battery), 33.5 oz ± 1.0 oz (with battery and pole clamp), |
| Volumetric Accuracy | Standard IV Sets, Hospira & Baxter: 2-800 mL/hr ± 5%, 1.9 – 0.5 mL/hr ± 0.1 mL/hr, 801-999 mL/hr ± 10% [1,2] ± 5% Baxter Only |
| Infusion Modes | Continuous Primary and secondary |
| Dose Modes | mL/hr, g/hr, mg/hr, mg/kg/hr, mg/min, mg/kg/min, mcg/hr, mcg/kg/hr, mcg/min, mcg/kg/min, ng/min, ng/kg/min, Units/hr, Units/kg/hr, Units/min, Units/kg/min, mUnits/min, meq/hr, meq/kg/hr. |
| Flow Rate | 0.5 to 999 mL/hr with 0.1 mL/hr increments from 0.5 to 99.9 mL/hr and 1.0 mL/hr increments from 100 to 999 mL/hr. |
| KVO | MDL drug configured KVO rate (default rate of 1.0 mL/hr if not configured) or programmed rate (which ever is less) |
| Total Drug Delivered | 0.1 to 9999.9 mL in 0.1 mL increments |
| Timekeeping | Real Time Clock, battery backed, 10 year life. |
| Drug Library Capacity | 1000 Drugs |
| *Logging Memory* | *Separate pump and drug library history logs, minimum of 96 hours each under extreme logging intensive operating conditions[3].* |
| AC Power | A.C. Power Adaptor, Medical Grade (EN60601-1-2), 100 – 240 VAC, 50/60 Hz/200mA, Output: 9V-DC/800mA, short circuit protected, cord length 3.0 m (~ 9.75 feet), leakage current < 10 µA, 10 Watts maximum. |
| Battery Power | Battery (Lithium Ion), 7.2V nominal, 1800mA/h; or 7.2V nominal, 1750mA/h |
| Pumping Mechanism | Linear Peristaltic |
| Battery Capacity | Pump operating time on battery power is at least 8 hours at 125ml/hr with the backlight on (new battery). With a Wireless Battery Module installed the operating time is at least 4 hours under the same conditions with the wireless interface operating. |
| Programming Methods | Manual, *automatic using bar code reader[3]*, Drug Library |
| Display | Color (16 out of a pallet of 262,144 possible colors) HRTFT, 240 X 270, LED Front-Lit ,0.2235 mm X 0.2235 mm dot pitch. |
| Occlusion Pressure | Adjustable: High (19 ± 9 PSI), Medium (13 ± 6 PSI), and Low (6 ± 4 PSI), |
| Maximum Pump Pressure | 36 PSI |
| Operational Conditions | Temperature 60°F - 90F (15.6°C – 32.2°C), 20-90% Relative Humidity non-condensing. |
| Storage Temperature | 14°F - 120°F (-10°C - +49°C), 10-90% Relative Humidity non-condensing. |
| Alarms | Air-in-Line<br>Battery Low, Battery Depleted, Battery Missing and Battery Alert<br>Caution Improper Load<br>Door Open<br>Downstream Occlusion<br>Inactivity<br>Infusion Complete<br>Secondary Complete<br>Slide Clamp Closed<br>Titration Incomplete<br>Upstream Occlusion |
| Alarm Volume | Variable (three levels, high, medium and low) |
| Anti-Free-Flow System | Set based, utilizing IV set slide clamp. |
| External Interfaces | Additional Asynchronous Serial Port expansion bus available at battery terminals. Software upgrades may be performed through external RS-232. |

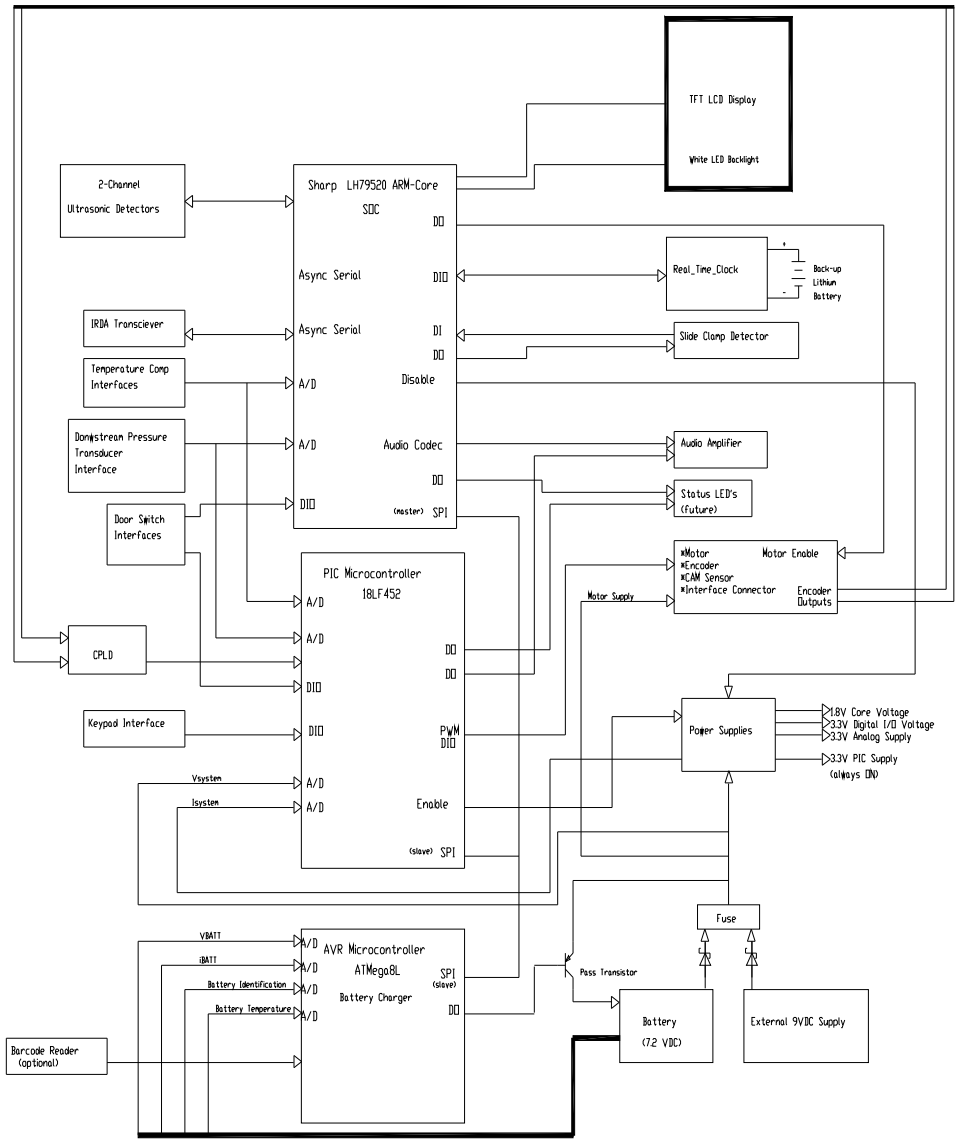
Notes:

1. At approximately 72°F with 95% C.I.
2. The deviation from the nominal flow rate accuracy from +24” to -20” head-height is an influence of a possible -4% in flow rate accuracy when the flow rate is set to 25 mL/hr.
3. Specifications in italics are for future features.

# Appendix B – System Block Diagram



## Appendix B – System Block Diagram (continued)



# APPENDIX C – Wireless Networking

**Introduction:**

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 PDA or 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 or PDA and sent via the IrDA to a pump. After changing the pump's network configuration, the pump may need to be power cycles 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. They include:

**Network Configuration**

1) Network Status – this option shows the current status of the network connection. The following items are available:
   a) 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.
   b) IP Addr – displays the current IP address of the pump.
   c) SIGMA GW – displays the IP address or DNS name of the network host, also known as the Sigma Gateway server.
   d) 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.
   e) 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.
2) 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 PDA or 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=
```

APPENDIX C – Wireless Networking (cont'd)

```
 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=
```

3) Network Settings – this option shows the basic network settings for the pump, and also allows the pump's network connection to be enabled or disable. The following fields item are available:
   a) 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.
   b) 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.
   c) 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.
   d) 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.
4) 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.
   a) DHCP – (read-only, set via network configuration file) Dynamic Host Control protocol settings, either 'on' or 'off'.
   b) IP – (read-only, set via network configuration file) IP address of pump, either assigned statically or assigned by DHCP server.
   c) Gateway – (read-only, set via network configuration file) IP address of gateway, either assigned statically or assigned by DHCP server
   d) Netmask – (read-only, set via network configuration file) IP netmask, either assigned statically, or assigned by DHCP server.
   e) DNS – (read-only, set via network configuration file) Domain Name Server IP address, either assigned statically, or assigned by DHCP server.
5) Wireless Settings – this option shows the Wireless settings of the pump's network connection.
   a) Mode (BSS) – (read-only, set via network configuration file) Basic Service Set (BSS), one of:
      i) Infrastructure (AP)
      ii) Join or Create Ad-Hoc
      iii) Join only Ad-Hoc
      iv) Join any
   b) Name (SSID) – (read-only, set via network configuration file) Service Set Identifier (SSID), or the name of the wireless network to join.
   c) 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.
   d) Security – (read-only, set via network configuration file) the security model to use, one of:
      i) Any
      ii) Open system
      iii) WEP
      iv) WPA pre-shared key
      v) WPA 802.1x
      vi) WEP 802.1x
      vii) LEAP
   e) 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.
   f) Encryption – (read-only, set via network configuration file) the encryption method use on the wireless network:
      i) Any
      ii) WEP
      iii) TKIP
      iv) CCMP (AES)
      v) Open (no encryption)

g) 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.

APPENDIX C – Wireless Networking (cont'd)

h) 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:
i) LEAP
ii) PEAP-MSCHAPv2
i) Username – (read-only, set via network configuration file) user name used to authenticate the pump on the wireless network.
j) 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 the specific pump is permitted to gain access to the network and determine what parts of the network it shall have access to.

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