Baxter

# SAFETY ALERT

**IMPORTANT: Safety Information Regarding the Cleaning of the Spectrum Infusion Pump, Especially the Battery Compartment and Battery Contacts**

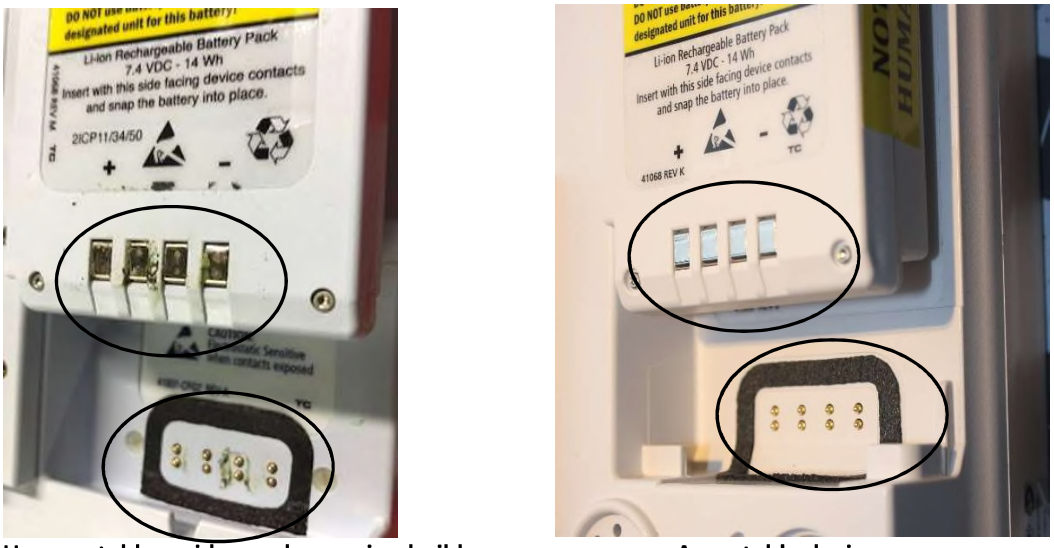
April 1, 2020

Dear Directors of Biomedical Engineering and Risk Management:

**Problem Description**

Baxter is communicating important safety information regarding cleaning practices of the Spectrum Infusion Pumps. Deviations from the cleaning methods described in the product-specific Operator's Manual may lead to residue build-up or corrosion of the electrical pins on the pump rear case and battery electrical contacts (refer to Figure 1). **If a device has residue build-up or corrosion, and is running solely on battery power, the pump may shut down without alarming or alerting the user.** To prevent residue build-up or corrosion of the battery and/or electrical pins, users must adhere to the cleaning instructions provided in the Operator's Manuals on the pages listed below. While specific topics within the cleaning method can be reiterated - such as proper drying of the electrical contacts after cleaning, removal of the battery as appropriate, and using only Baxter-specified cleaning fluids - it is important to be compliant to the entire cleaning method to ensure proper functionality and performance of the pump.

- V6 Operator's Manual (41018 - 6.05/6.2.4, Revision H): pages 79 – 80
- V8 Operator's Manual (41018v0800, Revision O): pages 119 – 123
- Spectrum IQ Operator's Manual (41018v0900, Revision E): pages 10-2 – 10-7




**Unacceptable residue and corrosion build up** **Acceptable device**

*Figure 1: Pictures of the electrical pins and battery contacts with and without corrosion*

**Affected Product**

| Product Code | Product Description | Serial Numbers |
|---|---|---|
| 35700BAX | SIGMA SPECTRUM Infusion System (V6 Platform) | All |
| 35700ABB | | |
| 35700BAX2 | SIGMA SPECTRUM Infusion System (V8 Platform) | |
| 3570009 | Spectrum IQ Infusion System with Dose IQ Safety Software | |

**Hazard Involved**

An undetected or abrupt discontinuation in delivery of medication may lead to a delay or interruption of intended treatment. Potential risk to the patient resulting from an interruption or delay of therapy depends on several factors, including the medication being infused, the volume and rate of the infusion, the route of administration, and patient status and comorbidities. Depending on these factors, the patient may experience serious adverse health consequences, or death. **To date, Baxter has received six reports of serious injuries related to an interruption in delivery of medication associated with pump shutdown, which may have resulted from improper-cleaning-practice-related residue build-up and/or corrosion**.

**Actions to be Taken by Customers**

1. Operators may continue to safely use the infusion pumps while following the instructions for cleaning provided in the Operator's Manual. An electronic copy of the Operator's Manual can be accessed at www.service.baxter.com. In addition, **a full list of approved cleaning agents can be accessed at www.spectrumIQ.com/resources.html**.

2. During the next cleaning of these pumps, please identify if there is any corrosion or other residue build-up on the battery and/or electrical pins of the device and clean per the cleaning instructions. If corrosion or residue build-up persists after cleaning, please ensure the pump is serviced.

3. **If you purchased this product directly from Baxter, complete the enclosed Baxter Customer Reply Form** and return it to Baxter by faxing it to 224-270-5457 or scanning and e-mailing it to fca@baxter.com. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.

4. If you purchased this product from a distributor, please note that the Baxter customer reply form is not applicable. If a reply form is provided by your distributor or wholesaler, please return it to the supplier according to their instructions.

5. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.

6. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected product to other facilities or end users, please distribute this notification to customers and **check the associated box on the reply form.**

**Further information and support**

If you have additional questions or experience quality problems, please contact your Baxter sales representative, or Baxter Technical Assistance at 800-356-3454 (choose option 1) Monday through Friday, between 7:00 am and 7:00 pm Eastern Time.

Any adverse events experienced with the use of these products may be reported using one of the following options:

- Calling Baxter Product Surveillance at 800-437-5176 between the hours of 8:00 am and 5:00 pm Central Time, Monday through Friday.
- Emailing to Baxter at: corporate_product_complaints_round_lake@baxter.com.
- Reporting to the FDA MedWatch Adverse Event Reporting Program:
  - **Online:** By completing and submitting the report online at: www.fda.gov/medwatch/report
  - **Regular mail or Fax:** Download the form from www.fda.gov/MedWatch/getforms.htm or call 800-332-1088 to request a reporting form, then complete and mail it to the address on the pre-addressed form, or submit by fax to 800-332-0178.

We thank you for your attention to this important safety information.

Sincerely,

Vijay Jayaraman 31-MAR-2020

Vijay Jayaraman
Director, Quality
Baxter Healthcare Corporation

Enclosure: Baxter Customer Reply Form