Urgent Device Correction

Follow-Up Communication to April 1, 2020, Safety Alert regarding Spectrum Infusion Pumps

August 28, 2020

Dear Directors of Biomedical Engineering, Risk Management, Nursing, and Environmental Services:

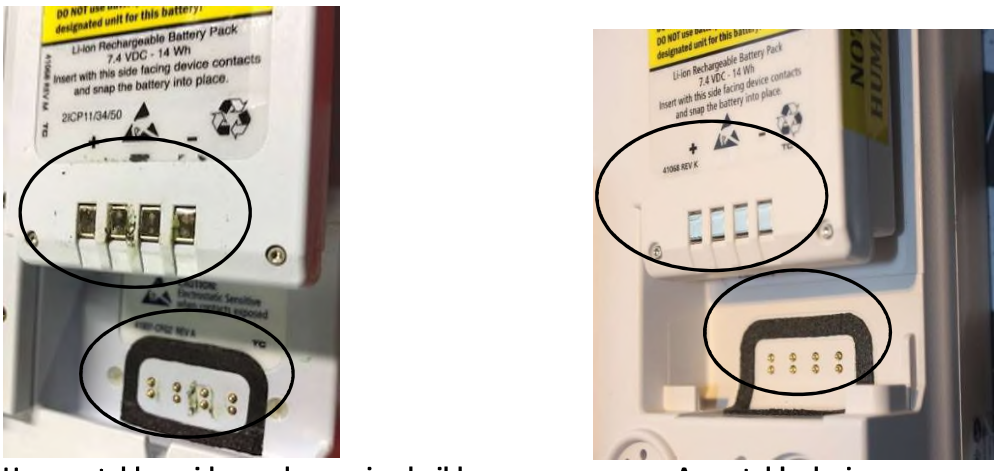
Problem Description

This is a follow-up communication to the Safety Alert Baxter previously issued on April 1, 2020, to reinforce important safety information regarding cleaning practices of Spectrum Infusion Pumps. Deviations from the cleaning methods described in the product-specific Operator's Manual may lead to residue buildup or corrosion of the electrical pins (i.e., depressed pins) on the pump rear case and battery electrical contacts (refer to Figure 1). This could result in check battery alarms, batteries not charging, and/or batteries not holding their charge, situations where the pump may alarm, alert, or otherwise notify the user of a potential issue. **If a device has residue buildup or corrosion, and is running solely on battery power, the pump may shut down without alarming or alerting the user.**

To prevent residue buildup or corrosion of the battery and/or electrical pins, users must adhere to the cleaning instructions provided in the Operator's Manual on the pages listed below. It is important that users comply with the entire cleaning method to ensure proper functionality and performance of the pump, which includes removal of the battery as specified, proper drying of the electrical contacts after cleaning, and using only Baxter-specified cleaning fluids.

- 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 F): pages 10-2 – 10-7

Baxter will be clarifying the Spectrum Instructions for Use (IFU) to emphasize that deviations from the specified cleaning methods may impair pump functionality and performance. The IFU will also recommend a routine inspection process for the electrical pins on the pump rear case and battery electrical contacts to identify signs of residue buildup or corrosion.



Unacceptable residue and corrosion buildup **Acceptable device**

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

Affected Product

Product Code	Product Description	Serial Number
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 16 reports of serious injuries, which may have resulted from improper cleaning-practice-related residue buildup 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 https://service.baxter.com. In addition, **a full list of approved cleaning agents can be accessed at www.spectrumIQ.com/resources.html.**

2. Please inspect all pumps at your facility to assess the electrical pins on the pump rear case and the battery electrical contacts for residue buildup or corrosion. If corrosion or residue buildup is identified, please contact Baxter to service the device.

3. Baxter will be updating the Instructions for Use to recommend a routine inspection process for the electrical pins on the pump rear case and the battery electrical contacts. Once the updated Instructions for Use are made available, Baxter will issue a written notification to inform customers of the availability of the updated IFU. The updated IFU may be accessed online at the Baxter Global Technical E-Service Center at URL: https://service.baxter.com.

4. Clinicians should ensure backup devices are readily available when infusing critical medications where interruptions could cause serious injury or death.

5. To maintain the battery properly, please ensure the pumps are plugged into AC power when possible to prevent battery depletion.

6. **If you purchased this product directly from Baxter, complete the enclosed Baxter customer reply form and return it to Baxter by e-mailing it to fca@baxter.com, even if you do not have any inventory**. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices. If you do not return the customer reply form, you will receive a phone call from OnProcess Technology on behalf of Baxter to confirm your receipt of this notification.

7. 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.

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

9. 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.

10. This notification should be carried out to the user level.

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.

The United States Food and Drug Administration (FDA) has been notified of this action. 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

Vijay Jayaraman
Director, Quality
Baxter Healthcare Corporation

Enclosure: Baxter Customer Reply Form
Safety Alert Communication dated April 1, 2020