Baxter

Urgent Medical Device Correction

June 15, 2023

Dear Directors of Biomedical Engineering, Risk Management, Nursing, and Nurse Educators:

Problem Description

Baxter is issuing an Urgent Medical Device Correction for the Spectrum V8 and Spectrum IQ infusion pumps listed below due to an increase in reported false upstream occlusion alarms following upgrades to software versions v8.01.01 and v9.02.01. Baxter will be reverting the software on all affected pumps to the previous software versions v8.01.00 and v9.02.00.

Affected Product

Product Code	Product Description	Software Version	Serial Numbers
35700BAX2	SIGMA Spectrum Infusion System (V8 Platform)	v8.01.01	All
3570009	Spectrum IQ Infusion System with Dose IQ Safety Software	v9.02.01	All

Hazard Involved

The upgraded Spectrum pumps may alarm for an upstream occlusion when there is no actual upstream occlusion present. This false upstream occlusion alarm will lead to the hazardous situations of an interruption or delay of therapy. An interruption or delay of therapy may cause serious adverse health consequences in patients who are receiving life-sustaining medications. Baxter has received three reports of serious injury potentially associated with this issue.

Actions to be taken by Customers

1. Operators may continue to use Spectrum V8 and Spectrum IQ pumps by following on-screen instructions, or the infusion setup instructions in the *Preparing the Pump and IV Sets* and *Programming the Pump* sections and upstream occlusion alarm troubleshooting in the *Alarms* section of the Operator's Manual. An electronic copy of the Operator's Manual can be accessed at https://service.baxter.com/tsportal/.

   Please note that false upstream occlusion alarms can occur at a higher rate until the software reversion is completed. If you are unable to resolve an upstream occlusion alarm, unload and reload the set.

2. A Baxter representative will contact your facility to determine the correction plan and schedule the software reversion. The representative will work with you to determine a list of affected serial numbers at your facility. Please note you will be receiving this software reversion from Baxter at no charge.

3. **Please acknowledge receipt of this notification by responding on our customer portal at https://BaxterFieldActionCustomerPortal.onprocess.com even if you do not have any remaining inventory.** Log in to the portal using the account number listed in the enclosed reply form instruction sheet. Acknowledging receipt of this notification will prevent you from receiving repeat notices. If you do not complete the acknowledgement, you will receive a phone call from OnProcess Technology on behalf of Baxter to confirm your receipt of this notification.

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

Further information and support

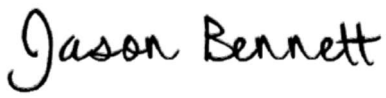
If you have additional questions or experience quality problems, please contact your Baxter sales representative, or Baxter Global Technical Services at 800-356-3454 (choose option 3) Monday through Friday, between 7:00 am and 7:00 pm Eastern Time.

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:

- Emailing Baxter at corporate_product_complaints_round_lake@baxter.com.
- Reporting to the FDA MedWatch Serious Injury Reporting Program:
  - **Online:** By completing and submitting the report online at: https://www.accessdata.fda.gov/scripts/medwatch/
  - **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 apologize for any inconvenience this may cause you and your staff.

Sincerely,



Jason Bennett
Director, Product Quality
Baxter Healthcare Corporation

Enclosure: Baxter Customer Reply Form Instruction Sheet