Baxter

URGENT SAFETY COMMUNICATION

December 29, 2021

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

Problem Description

Baxter is communicating important safety information for Spectrum V8 and Spectrum IQ infusion pumps related to potential reduced or non-delivery of medication, in some cases without alerting the user via pump alarm. This may occur as a result of incorrect administration set setup and/or incomplete resolution of upstream occlusion alarms when using Spectrum V8 and Spectrum IQ infusion pumps.

As described in the Instructions for Use (IFU), it is imperative to fully resolve any upstream occlusion before restarting the pump after an upstream occlusion alarm. Common causes for an upstream occlusion include:

- Improper IV container spiking
- Incomplete blue slide clamp removal from Spectrum keyhole
- Incomplete disengagement of blue slide clamp completely from IV tubing
- Kinked or collapsed IV tubing above Spectrum pump
- Upstream roller clamp (if present) not released
- Improperly vented IV tubing with rigid or semi-rigid containers

After an upstream occlusion alarm, failure to fully resolve any upstream occlusion before restarting the pump can cause the pump to not re-alarm as expected. The pump adjusts occlusion detection after the user acknowledges an upstream occlusion alarm; for the remainder of that infusion, the upstream occlusion alarm will not alarm per its baseline settings. If an upstream occlusion persists after the clinician does not fully resolve the occlusion, the alarm may not recur as expected. The risk is particularly higher when infusing with flow rates below 5 ml/hr. **WARNING: If an upstream occlusion remains after the RUN/STOP key is pressed, the pump may appear to be infusing normally, though it may be infusing below the programmed rate or not infusing at all**. Therefore, **do not press the RUN/STOP key prior to inspecting the IV set line and resolving the occlusion** (refer to Figures 1 and 2 below). This adjustment only affects the current therapy session, as the occlusion detection is reset each time an infusion is started.

Figure 1. Spectrum V8 Upstream Occlusion Alarm Screen

Figure 2. Spectrum IQ Upstream Occlusion Alarm Screen

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As described in the IFU, extended upstream occlusion alarm detection time may also occur at flow rates below 5 mL/hr.

Affected Product

Product Code	Product Description	Serial Numbers
3570009	Spectrum IQ Infusion System with Dose IQ Safety Software	All
35700BAX2	SIGMA Spectrum Infusion System (V8 Platform)	All

Hazard Involved

If the clinician does not resolve an upstream occlusion (partial or full occlusion) prior to infusion restart or does not resolve the upstream occlusion after responding to an upstream occlusion alarm, patient harm may occur from interruption in therapy (due to full occlusion) and/or under-infusion (due to partial occlusion). The potential harm to the patient depends on several factors such as length of therapy delay, medication being infused, volume and rate of infusion, and the patient's underlying status and comorbidities. Based on those factors, the patient may experience no/minimal harm to serious harm, including death. To date, Baxter has received **51 reports of serious injury and three reports of patient death** over five years, potentially associated with this issue.

Actions to be Taken by Customers

1. Clinicians may continue to use Spectrum V8 and Spectrum IQ infusion pumps by following on-screen instructions, 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.

2. Be aware that if an upstream occlusion remains after the RUN/STOP key is pressed, the pump may appear to be infusing normally, though it may be infusing below the programmed rate or not infusing at all.

3. If you suspect that you resumed an infusion without clearing an occlusion, stop the infusion by pressing the RUN/STOP key, clear the occlusion, and restart the infusion.

4. Per the Spectrum IFU, reinforce the importance of completely spiking the IV container, removing the blue slide clamp completely from the keyhole, disengaging the blue slide clamp completely from the IV tubing, checking that the IV tubing is clear of any kinks or collapsed sections, ensuring the roller clamp (if present) is released prior to infusion start, and ensuring that rigid and semi-rigid containers are properly vented. After starting the infusion, verify that drips are flowing in the drip chamber.

5. Per the Spectrum IFU, reinforce that the time to detect an upstream occlusion may be extended if infusing at flow rates below 5 mL/hr. At very low flow rates, it may take several minutes to see drops in the drip chamber.

6. When responding to an upstream occlusion alarm, **do not press the RUN/STOP key prior to inspecting the IV tubing and resolving any occlusions**, as described above. If an upstream occlusion is not fully cleared above the pump and/or within the pumping channel, an upstream occlusion alarm may not reoccur.

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7. An electronic copy of the Operator's Manual can be accessed at https://service.baxter.com/tsportal/.

8. **If you received this communication directly from Baxter, please acknowledge receipt by responding on our customer portal at https://BaxterFieldActionCustomerPortal.onprocess.com/.** Log in to the portal using the account number listed at the top of 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.

9. If you purchased this product from a distributor, please note that responding at the Baxter customer portal is not applicable. If a response is requested by your distributor or wholesaler, please respond to the supplier according to their instructions.

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

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

Further information and support

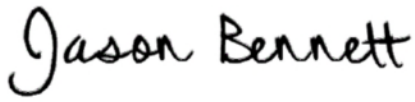
If you have additional questions or experience quality problems, please contact your Baxter sales representative, or Baxter Technical Assistance at 800-356-3454 (choose option 1) Monday through Friday, between 7:00 am and 7:00 pm Eastern Time.

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: 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 appreciate your ongoing patience and commitment to Baxter as we continually strive to ensure all components of the Spectrum system best meet your needs.

Sincerely,



Jason Bennett
Associate Director, Quality
Baxter Healthcare Corporation

Enclosure: Reply Form Instruction Sheet

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