FOR IMMEDIATE RELEASE

BAXTER ISSUES URGENT SAFETY COMMUNICATION TO REINFORCE IMPORTANT SAFETY INFORMATION REGARDING UPSTREAM OCCLUSION ALARMS FOR ALL SPECTRUM V8 AND SPECTRUM IQ INFUSION PUMPS

DEERFIELD, Ill., FEBRUARY 17, 2022 – Baxter International Inc. announced today it has issued an Urgent Safety Communication to reinforce important safety information regarding upstream occlusion alarms for all **Spectrum V8** and **Spectrum IQ** infusion pumps. Incorrect administration set setup and/or incomplete resolution of upstream occlusion alarms may result in reduced delivery or non-delivery of medication, in some cases without alerting the user via pump alarm. Baxter previously communicated this information to customers via an Urgent Safety Communication notification on December 29, 2021.

Customers notified Baxter that the pump was not delivering medication at the programmed rate displayed on the screen, and in some cases was not alarming for upstream occlusions. As described in the Urgent Safety Communication notification, after an upstream occlusion alarm, it is imperative to fully resolve any upstream occlusion before restarting the pump. Failure to do so may cause the pump not to re-alarm as expected, which can lead to interruption in therapy and/or under-infusion. 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. **To date, Baxter has received 51 reports of serious injury and three reports of patient death over five years that may have resulted from incorrect administration set setup and/or incomplete resolution of upstream occlusion alarms.**

Customers may continue to use **Spectrum V8** and **Spectrum IQ** infusion pumps by following on-screen instructions and referencing the Operator's Manual for 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. To help prevent upstream occlusions, it is important to completely spike the IV container, remove the blue slide clamp completely from the keyhole, disengage the blue slide clamp completely from the IV tubing, check that the IV tubing is clear of any kinks or collapsed sections, ensure the roller clamp (if present) is released prior to infusion start, and

ensure that rigid and semirigid containers are properly vented. After starting an infusion, it is important to verify that drips are flowing in the drip chamber, which may take several minutes when infusing at flow rates below 5 mL/hr. If an upstream occlusion remains after the RUN/STOP key is pressed, the pump may appear to be infusing normally but may be infusing below the programmed rate or not infusing at all. If a clinician suspects that they resumed an infusion without clearing an occlusion, they should stop the infusion by pressing the RUN/STOP key, clear the occlusion and restart the infusion.

Baxter will issue a follow-up letter to customers to communicate further details on the actions being taken to address this issue.

Product Code	Product Description	Unique Device Identifier	Serial Number	Manufacturing Date	Release Date	Released Quantity (Units)
35700BAX2	SIGMA Spectrum Infusion System (V8 Platform)	GTIN 00085412498683	All	July 1, 2014 – June 8, 2021	Feb. 5, 2015 - Present	140,674
3570009	Spectrum IQ Infusion System with Dose IQ Safety Software	00085412610900	All	June 29, 2017 - Present	Dec. 6, 2017 - Present	175,028

Spectrum V8 and **Spectrum IQ** are distributed in the United States, Puerto Rico, Canada and certain Caribbean islands. Customers with additional questions can contact their Baxter sales representative or Baxter Technical Assistance at 800-356-3454 (choose option 1) Monday through Friday between 6 a.m. and 6 p.m. Central 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 Monday through Friday between 8 a.m. and 5 p.m. Central Time.
- Emailing 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.

Baxter is voluntarily issuing this Urgent Safety Communication with the knowledge of the U.S. Food and Drug Administration.

About Baxter

Every day, millions of patients, caregivers and healthcare providers rely on Baxter's leading portfolio of diagnostic, critical care, kidney care, nutrition, hospital and surgical products used across patient homes, hospitals, physician offices and other sites of care. For 90 years, we've been operating at the critical intersection where innovations that save and sustain lives meet the healthcare providers who make it happen. With products, digital health solutions and therapies available in more than 100 countries, Baxter's employees worldwide are now building upon the company's rich heritage of medical breakthroughs to advance the next generation of transformative healthcare innovations. To learn more, visit www.baxter.com and follow us on Twitter, LinkedIn and Facebook.

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