FOR IMMEDIATE RELEASE

BAXTER ISSUES URGENT MEDICAL DEVICE CORRECTION FOR SPECTRUM V8 AND SPECTRUM IQ INFUSION PUMPS WITH SPECIFIC SOFTWARE VERSIONS

DEERFIELD, Ill., July 28, 2023 – Baxter International Inc. announced today it has issued an Urgent Medical Device Correction for **Spectrum V8** and **Spectrum IQ** infusion pumps in the U.S. and Puerto Rico that have been upgraded to software versions v8.01.01 and v9.02.01. The Correction is due to an increase in reported false upstream occlusion alarms following the software upgrades. Baxter will be working with customers to revert the software on all affected pumps to the previous software version.

The upgraded software installed on **Spectrum V8** and **Spectrum IQ** infusion pumps may cause an alarm for an upstream occlusion when there is no actual upstream occlusion present. This false alarm may lead to 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.

Baxter representatives are contacting all affected customers to schedule the software reversion. Until the reversion is completed, false upstream occlusion alarms can occur on impacted pumps at a higher rate. Customers can continue to use **Spectrum V8** and **Spectrum IQ** infusion pumps by following on-screen instructions or referencing 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. If a customer is unable to resolve an upstream occlusion alarm, they should unload and reload the set.

This Urgent Medical Device Correction applies to **SIGMA Spectrum** Infusion System (V8 Platform) with product code 35700BAX2 and software version v8.01.01 and **Spectrum IQ** Infusion System with **Dose IQ** Safety Software with product code 3570009 and software version v9.02.01.

Spectrum V8 and **Spectrum IQ** infusion pumps are distributed in the United States, Puerto Rico, Canada and certain Caribbean islands. Only customers in the U.S. and Puerto Rico are affected by this Correction. Customers with additional questions can contact their Baxter sales

representative, or Baxter Technical Assistance at 800-356-3454 (choose option 3) 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:

- 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 Medical Device Correction 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 more than 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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