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BAXTER ISSUES URGENT DEVICE CORRECTION TO REINFORCE IMPORTANT SAFETY INFORMATION REGARDING CLEANING PRACTICES OF ALL SIGMA SPECTRUM INFUSION PUMPS (V6, V8 AND IQ)

DEERFIELD, Ill., OCTOBER 28, 2020 – Baxter International Inc. announced today it has issued an Urgent Device Correction to reinforce important safety information regarding cleaning practices of all **Spectrum** infusion pumps distributed in the United States, Canada, and the Caribbean, as deviations from the specified cleaning methods may impair infusion pump functionality and performance. Baxter previously communicated this information to customers directly in a Safety Alert on April 1, 2020 and subsequently via an Urgent Device Correction notification on August 28, 2020.

Deviations from the cleaning methods described in product-specific Operator's Manuals may lead to residue buildup or corrosion of the electrical pins (e.g. depressed pins) on the infusion pump rear case and battery electrical contacts. This could result in notifications that the user should check the battery, or that batteries are not charging or holding their charge. 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. An undetected or abrupt discontinuation in medication delivery may lead to a delay or interruption of intended treatment. Depending on various factors, including the medication being infused, the volume and rate of the infusion, the route of administration, and patient status and comorbidities, this could result in serious adverse health consequences or death. **To date, Baxter has received 16 reports of serious injuries that may have resulted from improper cleaning practice-related residue buildup and/or corrosion.**

In addition to adhering to the cleaning instructions provided in the Operator's Manuals for the products listed below, Baxter is instructing customers to assess the rear case electrical pins and

battery electrical contacts for residue buildup or corrosion and depressed pins. Baxter is also recommending to have backup devices readily available when infusing critical medications. Additionally, the infusion pumps should be connected to AC power when possible to prevent battery depletion. Finally, Baxter will be clarifying the Instructions for Use (IFU) to recommend a routine inspection to identify signs of residue buildup, corrosion and depressed pins. Once completed, Baxter will issue a written notification to inform customers of the availability of the updated IFU, which will be accessible in Baxter's Global Technical E-Service Center: https://service.baxter.com.

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	

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: 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.

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

About Baxter

Every day, millions of patients and caregivers rely on Baxter's leading portfolio of critical care, nutrition, renal, hospital and surgical products. For more than 85 years, we've been operating at the critical intersection where innovations that save and sustain lives meet the healthcare providers that make it happen. With products, technologies 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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