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BAXTER ISSUES URGENT MEDICAL DEVICE CORRECTION FOR ALL SPECTRUM IQ INFUSION PUMPS TO REINFORCE IMPORTANT SAFETY INFORMATION REGARDING BEST PRACTICES FOR CUSTOMER-INITIATED IT NETWORK UPDATES

DEERFIELD, Ill., AUGUST 24, 2021 – Baxter International Inc. announced today it has issued an Urgent Medical Device Correction for all **Spectrum IQ** infusion pumps to reinforce important safety information when customers implement changes to their network configuration and server systems. Baxter previously communicated this information to customers via an Urgent Medical Device Correction notification on June 4, 2021 and a follow-up communication with updated information on August 2, 2021.

Two **Spectrum IQ** infusion pump customers notified Baxter of system errors occurring in multiple pumps within their fleets following changes the customers implemented to the configuration of their network and server systems. Gateway Server System performance anomalies resulted in multiple pump connectivity errors, placing stress on the pump's processor. When this occurs, pumps initiate a "watchdog" system error alarm to notify the user of the issue, causing the pump to enter a fail-safe mode which stops all pump processes, including delivery of fluid to the patient. For both customers, the watchdog system errors were resolved by restoring network and server system performance to expected levels. **To date, there have been no reports of adverse events or patient injury associated with this issue.** However, depending on several factors, such as the length of delay, medication being infused, the volume and rate of the infusion, patient status, and comorbidities, the patient may experience serious adverse health consequences or death.

Baxter is developing a software upgrade for all **Spectrum IQ** infusion pumps that will assist how the pump responds to unstable network and server systems by reducing the stress on the pump's memory and processing functions if this occurs. The updated software is currently expected

to be available early in the fourth quarter of 2021, and Baxter will work with customers to schedule the software upgrades. To reduce the likelihood of encountering this issue, Baxter is asking customers to contact Baxter Technical Assistance at 800-356-3454 in advance of making changes to their network or server infrastructure supporting the pumps or the Baxter Gateway. Changes requiring prior notice can be found in the Urgent Medical Device Correction communication and in Baxter's Gateway Server Installation Handoff document, which customers receive upon installation. Additionally, Baxter recommends that customers ensure backup devices are readily available when infusing critical medications.

Product Code	Product Description	Serial Numbers
3570009	Spectrum IQ Infusion System with Dose IQ Safety Software	All

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 Medical 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 90 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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