FOR IMMEDIATE RELEASE

Media Contact
Andrea Johnson, (224) 948-5353
media@baxter.com

Investor Contact
Clare Trachtman, (224) 948-3085

BAXTER ISSUES URGENT MEDICAL DEVICE CORRECTION TO REINFORCE IMPORTANT SAFETY INFORMATION REGARDING DOSE IQ SAFETY SOFTWARE DESKTOP APPLICATION VERSION 9.0.X

DEERFIELD, Ill., SEPTEMBER 10, 2021 – Baxter International Inc. announced today it has issued an Urgent Medical Device Correction regarding an issue identified in the **Dose IQ** Safety Software desktop application version 9.0.x that may impact the software's functionality. Baxter previously communicated this information to customers to reinforce important safety information and mitigation plans via an Urgent Medical Device Correction notification on July 7, 2021.

The **Dose IQ** Safety Software is stand-alone PC software that interacts with the **Spectrum IQ** infusion pumps but does not reside on the pumps themselves. The identified software defect creates a mismatch between linked drug identifiers (IDs) in the **Dose IQ** user interface (UI) and the binary drug library (BDL) loaded onto the **Spectrum IQ** pump. As a result, a linked drug ID may appear in the **Dose IQ** UI but may not appear in the BDL on the pump. The software defect could also cause a linked drug that was previously deleted to remain in the BDL loaded onto the pump, but not appear in the **Dose IQ** UI. This issue may result in improperly configured drugs within the drug library.

The scope of this issue is limited to drug libraries initially created with version 9.0.x of the **Dose IQ** Safety Software desktop application and does not impact customers who began creating drug libraries with **Dose IQ** version 9.1.x. This issue may lead to a delay in therapy, under-infusion or over-infusion of medication, with impact to the patient depending on several factors including length of delay, medication being infused, the volume and rate of the infusion, patient status and comorbidities. **To date, Baxter has received one report of serious injury potentially associated with this issue.**

Customers may continue to use **Dose IQ** Safety Software with the **Spectrum IQ** infusion pump. If a customer cannot find the desired drug concentration and delivery mode while programming the pump, the pump may be programmed using Basic Mode. Customers should also immediately notify their Pharmacy department of the missing drug configuration in the BDL on the pump. If their Pharmacy department discovers the missing drug configuration in the BDL is present in the **Dose IQ** UI, and is potentially related to this issue, they should contact Baxter Technical Assistance at 800-356-3454.

Baxter is developing a stand-alone validated software tool that will identify linked drug IDs within each drug library affected by this issue. The validated software tool is currently expected to be available early in the fourth quarter of 2021, and Baxter will work with customers to correct errors in the drug library. Additionally, Baxter will upgrade affected customers to **Dose IQ** version 9.1.1 or higher.

Product Code	Product Description	Software Version
35723V091	Dose IQ Safety Software used with Spectrum IQ Infusion Pump 3570009	All drug libraries initially created with version 9.0.x

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.

###