FOR IMMEDIATE RELEASE

BAXTER ISSUES URGENT MEDICAL DEVICE CORRECTION REGARDING POTENTIAL RISK OF MEDICATION ERROR WHEN USING ABACUS ORDER ENTRY AND CALCULATION SOFTWARE

DEERFIELD, Ill., JULY 22, 2022 – Baxter International Inc. announced today it has issued an Urgent Medical Device Correction regarding the potential risk of medication error when using certain product codes for the Abacus Order Entry and Calculation Software. The Abacus software is commonly used with **ExactaMix** automated compounding devices (**ExactaMix** 1200 and **ExactaMix** 2400). Baxter previously communicated about this issue to customers via an Urgent Medical Device Correction notification on June 22, 2022.

Affected Product Codes

Product Code	Product Description	Serial Number	Unique Device Identifier	Release Date
8300-0167	Abacus V3.1 CE	N/A	N/A	May 20, 2013
8300-0168	Abacus V3.1 SE		N/A	May 20, 2013
8300-0169	Abacus V3.1 ME		N/A	May 20, 2013
8300-0191	Abacus V3.2 CE		N/A	Dec. 17, 2015
8300-0192	Abacus V3.2 SE		N/A	Dec. 17, 2015
8300-0193	Abacus V3.2 ME		N/A	Dec. 17, 2015
8300-3391	Abacus V3.3 CE		(01)05413765577345(10)3.3.2.1	Sept. 20, 2019
8300-3392	Abacus V3.3 SE		(01)05413765577352(10)3.3.2.1	Sept. 20, 2019
8300-3393	Abacus V3.3 ME		(01)05413765577369(10)3.3.2.1	Sept. 20, 2019

The Abacus software functionality allows users with administrative permission to access and modify label templates, and the Abacus Configuration Guide provides instructions and warnings for users to safely modify label templates. However, modifying label templates incorrectly may lead to inaccurate information on the final printed bag label, such as the wrong infusion rate or incorrect patient name. There are multiple fields within the bag label template that can be modified, and the **potential harm is highly variable depending on which field has been modified incorrectly.** Having inaccurate information on the final printed bag labels of compounded medications can cause serious harm, especially in high-risk patients. **When incorrect information is printed on the Abacus bag label, there is a possibility it could lead to a patient having electrolyte abnormalities, glucose issues and/or fluid-related complications.** There are required pharmacist and nursing checks typical of standard clinical practice that can help mitigate the risk of harm, in the event there is incorrect information printed on the bag label. **To date, there have been five related complaints with no reports of patient harm associated with this issue.**

Baxter recommends that customers discontinue making updates to bag label templates and contact Baxter Technical Support if updates to bag label templates are needed. Customers should continue to follow the instructions in the Abacus User Guide and Abacus Configuration Guide when creating an order and have a pharmacist thoroughly review all order outputs, including the printed bag label, for accuracy and safety. They should also ensure their facility procedures include pharmacy and nursing checks throughout the parenteral nutrition compounding process.

Baxter is developing an upgraded Abacus software that no longer includes the capability for users to customize bag label templates. Baxter will share instructions with customers for obtaining the software upgrade once it becomes available.

Customers with additional questions can contact their Baxter sales representative or Baxter Technical Assistance at 800-678-2292 Monday through Friday between 7 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, 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.

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

Investor Contact
Clare Trachtman, (224) 948-3020

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