Baxter

Urgent Medical Device Correction

Baxter Abacus Order Entry & Calculation Software – Risk of Medication Error

June 22, 2022

Dear Directors of Pharmacy and Nursing:

Problem Description

Baxter Healthcare Corporation is issuing an Urgent Medical Device Correction to notify our customers of a field action due to the potential risk of medication error when using the Abacus Order Entry & Calculation software listed below. The Abacus Order Entry & Calculation software is commonly used with ExactaMix automated compounding devices (ExactaMix 1200 and ExactaMix 2400). The Abacus software functionality allows users with administrative permission to access and modify label templates. Modifying label templates may lead to incorrect information on the final printed bag label (e.g., wrong infusion rate, incorrect patient name, etc.). Although the Abacus Configuration Guide provides instructions and warnings on how to safely modify label templates, it is Baxter's recommendation that customers contact Baxter Technical Services for assistance when changing a label template.

Due to the potential risk of errors that can occur when customers access and modify label templates, Baxter will be performing a software upgrade to remove the ability of all Abacus users to modify label templates. To ensure patient safety, customers should contact Baxter Technical Service for any modifications to label templates.

Affected Product

Product Code	Product Description	Serial Numbers	UDI	Release Dates
8300-0167	Abacus V3.1 CE	NA	NA	20-May-2013
8300-0168	Abacus V3.1 SE		NA	20-May-2013
8300-0169	Abacus V3.1 ME		NA	20-May-2013
8300-0191	Abacus V3.2 CE		NA	17-Dec-2015
8300-0192	Abacus V3.2 SE		NA	17-Dec-2015
8300-0193	Abacus V3.2 ME		NA	17-Dec-2015
8300-3391	Abacus V3.3 CE		(01)05413765577345(10)3.3.2.1	20-Sep-2019
8300-3392	Abacus V3.3 SE		(01)05413765577352(10)3.3.2.1	20-Sep-2019
8300-3393	Abacus V3.3 ME		(01)05413765577369(10)3.3.2.1	20-Sep-2019

Hazard Involved

There are multiple fields within the bag label template that can be modified; therefore, the potential harm is highly variable depending on which field has been modified incorrectly. Having incorrect values or patient name on the final printed bag labels of compounded medications may cause serious harm, especially in high-risk patients. In the event incorrect information is printed on the bag label from Abacus (for example, if the infusion rate is incorrect) there is a possibility that a patient may have electrolyte

abnormalities (e.g., hyperkalemia, which could lead to cardiac arrythmias), glucose issues (e.g., hyperglycemia), and/or fluid overload related complications. There are required pharmacist checks typical of standard pharmacy and clinical practice which mitigate the risk of harm. To date, there have been five potentially related complaints with no reports of patient harm associated with this issue.

Actions to be Taken by Customers

1. Baxter recommends that customers discontinue making updates to bag label templates and to contact Baxter Technical Support if updates to bag label templates are needed. Please 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**. Please ensure your facility processes include pharmacy checks during the compounding process as well as a nursing check.

   Below are the safety notices related to order outputs and bag label templates currently in all versions of the Abacus User Guide and Abacus Configuration Guide.

   In the Abacus Software Version 3.3 User Guide (Pages i-ii) and Abacus Software Version 3.3 Configuration Guide (pages i-ii):

WARNING!

Patient injury, including death, can occur as a result of:

- **Mismatches between test configurations and production configurations. Contact Technical Services for assistance in the creation of a test environment. Always verify that test configurations cannot be used in the production environment.**
- **Mismatches between user expectations and configuration settings. After completing your installation do not change ANY configuration settings without first obtaining assistance from Technical Services.**
- **Incorrectly configured non-standard ordering practices. If your facility requires ordering practices outside those contained in the ASPEN guidelines for TPN, contact Technical Services for assistance in correctly implementing these non-standard ordering practices.**
- **Incorrect use of this product, including off-label use. Contact Technical Services for assistance and training in the correct use of this product within industry-approved pharmacy processes.**
- **Misapplication of therapy to patient type. Contact Technical Services for assistance in using this product for multiple patient types.**
- **Misapplication of therapy type. Contact Technical Services for assistance in using this product for multiple therapy types.**

WARNING!

- Incorrectly implemented non-standard ordering practices. Always verify with a pharmacist orders that deviate from standard institution practice.
- Inappropriate warning limit settings. After completing your installation, do not change ANY warning limits without first obtaining assistance from Technical Services.
- Mismatches between user expectations and configuration settings. Review all customized formulary data, labels, and reports thoroughly with a pharmacist and assistance from Technical Services prior to use.
- Mismatches between user expectations and the entered order. Have a pharmacist thoroughly review the order and all order outputs for safety.
- Particulate in products administered to patients. Visually inspect all solutions for particulate prior to and during administration.
- Mismatches between user expectations and user-entered information. Have a pharmacist thoroughly review all user-configured data.
- Mismatches between user expectations and configuration settings. Proper use of user permissions and user logon is expected.

Additionally, in the Abacus software version 3.3 Configuration Guide (pages 6-32):

6.5.1 Formatting Labels

WARNING

Label changes can result in patient harm. All changes, even those completed by Technical Services, must be tested and reviewed by a responsible clinician prior to use in a live environment.

Tip! Contact Technical Services before changing a label if you are unfamiliar with doing so.

2. Baxter will communicate to customers when the software upgrade becomes available. At that time additional instructions to obtain the software upgrade will be provided.

3. **If you received this communication directly from Baxter, please acknowledge receipt by responding on our customer portal at https://BaxterFieldActionCustomerPortal.onprocess.com/.** Log in to the portal using the account number located on the enclosed reply form instruction sheet. Acknowledging receipt of this notification will prevent you from receiving repeat notices. If you do not complete the acknowledgement, you will receive a phone call from OnProcess Technology on behalf of Baxter to confirm your receipt of this notification.

4. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.

Further information and support	For general questions regarding this communication, contact Baxter Technical Service at 800-678-2292, between the hours of 8:00 am and 7:00 pm Eastern Time, Monday through Friday.

The United States Food and Drug Administration (FDA) has been notified of this action. Any adverse events or quality problems experienced with the use of these products may be reported using one of the following options:

- Calling Baxter Product Surveillance at 800-437-5176 between the hours of 8:00 am and 5:00 pm Central Time, Monday through Friday.
- Emailing to 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.

We apologize for any inconvenience this may cause you and your staff.

Sincerely,

Nicolas Vanhaelen

Nicolas Vanhaelen
Director, Product Quality
Baxter Healthcare Corporation

Enclosure: Reply Form Instruction Sheet