Baxter

URGENT MEDICAL DEVICE CORRECTION

RE: Dose IQ Safety Software Upgrade

July 7, 2021

Dear Directors of Pharmacy, Biomedical Engineering, and Risk Management:

Problem Description

Baxter Healthcare Corporation has identified a software issue in the Dose IQ Safety Software desktop application. The Dose IQ Safety Software is stand-alone PC software that interacts with the Spectrum IQ infusion pumps (product code 3570009) but does not reside on the pumps themselves. The 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 onto 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. Please note this issue does not impact customers who began creating drug libraries with Dose IQ version 9.1.x.

Baxter is developing a stand-alone validated software tool which will identify linked drug IDs within each facility's drug library affected by this issue. We will be working with customers to correct errors identified by the software tool. Additionally, we will be upgrading affected customers to Dose IQ version 9.1.1 or higher.

Affected Product

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

*This issue does not affect the Spectrum IQ Infusion Pump, but the stand-alone Dose IQ software that is used to create the BDL file.

Hazard Involved

This issue may lead to the hazardous situations of either a delay in therapy, under-infusion, or over-infusion of medication. The harm to the patient will depend on several factors such as 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.

Actions to be Taken by Customers

1. If customers are not experiencing this issue, they may continue to use Dose IQ Safety Software with the Spectrum IQ infusion pump.
2. In the event the user cannot find the desired drug concentration and delivery mode while programming the pump, the pump may be programmed using Basic Mode. Additionally, the Pharmacy department should be notified of the missing drug configuration in the BDL on the pump. If Pharmacy discovers the missing drug configuration in the BDL is present in the Dose IQ UI, and is potentially

related to this issue, please contact Baxter Technical Assistance at the phone number listed below.

3. When the stand-alone validated software tool is available, a Baxter representative will contact your facility to determine the correction plan. Baxter will utilize the validated software tool to work with customers to correct errors in the drug library. Additionally, affected customers will be upgraded to Dose IQ version 9.1.1 or higher. Your facility will be receiving this software upgrade from Baxter at no charge.

4. **Complete the enclosed Baxter Customer Reply Form** and return it to Baxter by e-mailing it to fca@baxter.com**.** Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices. If you do not return the customer reply form, you will receive a phone call from OnProcess Technology on behalf of Baxter to confirm your receipt of this notification.

5. 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 If you have additional questions or experience quality problems, please contact your Baxter sales representative, or Baxter Technical Assistance at 800-356-3454 (choose option 1) Monday through Friday, between 7:00 am and 7:00 pm Eastern Time.

The United States Food and Drug Administration (FDA) has been notified of this action. 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 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 appreciate your ongoing patience and commitment to Baxter as we continually strive to ensure all components of the Spectrum system best meet your needs.

Sincerely,

Vijay Jayaraman

Vijay Jayaraman
Director, Quality
Baxter Healthcare Corporation

Enclosure: Baxter Customer Reply Form