Baxter

URGENT MEDICAL DEVICE CORRECTION

RE: Spectrum IQ Infusion Pump software upgrade, Follow-up Communication to June 4, 2021 Urgent Medical Device Correction

August 2, 2021

Dear Directors of Biomedical Engineering, Risk Management, Nursing, and Information Technology:

On June 4, 2021, Baxter issued an Urgent Medical Device Correction letter for all Spectrum IQ infusion pumps. This letter has been updated to include additional information. All updates are in bold.

Problem Description

Two Spectrum IQ infusion pump customers notified Baxter Healthcare Corporation (Baxter) of system errors **occurring in multiple pumps within their fleet** following changes the customers implemented to the configuration of their network and server systems. Gateway Server System performance anomalies resulted in excessive Spectrum IQ pump connectivity errors. An unusually high number of connectivity errors accumulated, placing stress on the pump's processor. The Spectrum IQ pumps recognized this condition as designed and initiated a "watchdog" system error alarm (i.e., EC220, EC221, EC222, and SysEcode0) to notify the user of the issue, causing the pumps to enter a fail-safe mode **which stops all pump processes, including delivery of fluid to the patient**. **The sudden interruption and/or delay of therapy can be especially problematic in situations where vulnerable patient populations are receiving critical medications.** For both customers, the watchdog system errors were resolved by restoring network and server system performance to expected levels.

Since this issue is the result of accumulating connectivity errors, placing stress on the pump's processor, it can take some time (hours or days) for the pump to signal a watchdog system error alarm.

Baxter is developing a software upgrade for all Spectrum IQ infusion pumps. This upgrade 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, therefore **resolving the issue**. Once the software is available, Baxter will be contacting customers to upgrade their infusion pumps.

Affected Product

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

Hazard Involved

Watchdog system errors stop pump processes including delivery of fluid to the patient and may result in delay and/or interruption of therapy. The user is notified via an audio alarm and screen indication that a watchdog system error has occurred. If this error occurs, **the clinician must power cycle the device and reprogram the infusion, as the previously-set infusion parameters will have been cleared.** The potential for harm to the patient depends on several factors such as the length of delay, medication being infused, the volume and rate of the infusion, patient status, and comorbidities. **Depending on these factors, the patient may experience serious adverse health consequences or death.** To date, there have been no reports of adverse events or patient injury associated with this issue.

Actions to be Taken by Customers

1. Operators may continue to use the Spectrum infusion pumps. In order to reduce the likelihood of encountering this issue, **please contact Baxter Technical Assistance in advance of making changes to your network or server infrastructure supporting the pumps or the Baxter Gateway**, as indicated in Baxter's Gateway Server Installation Handoff document which customers receive upon installation. **Changes requiring prior notice are confirmed to be the following**:

    - Any changes to the Gateway servers that require reboot of the servers
    - Server Operating System updates (e.g., patches, security updates, service packs)
    - Hardware infrastructure updates (e.g., changes to the Load Balancer, wireless access points)
    - Maintenance work on the servers (e.g., maintenance of the Oracle database server)

    If you have made changes to your network or server and have not contacted Baxter to discuss these changes, or have questions regarding this issue, please call Baxter Technical Assistance at 800-356-3454 immediately upon receipt of this letter.

2. If a watchdog system error occurs, the user must power cycle the device and reprogram the infusion, as the previously-set infusion parameters will have been cleared. Instructions to reprogram the primary and secondary infusions can be found in the "Programming the Pump" section of the Spectrum Operator's Manual at: https://service.baxter.com/tsportal/. If the error cannot be resolved, contact Baxter Technical Assistance if further support is required.

3. **Clinicians should ensure backup devices are readily available when infusing critical medications where interruptions could cause serious injury or death.**

4. **When the software upgrade is available, a local Baxter service representative will contact your facility to determine the correction plan and schedule the software upgrade.** Your facility will be receiving this software from Baxter at no charge.

5. **If you purchased this product directly from Baxter, 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.

6. If you purchased this product from a distributor, please note that the Baxter customer reply form is not applicable. If a reply form is provided by your distributor or wholesaler, please return it to the supplier according to their instructions.

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

8. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected product to other facilities, please notify your customers of this Urgent Medical Device Correction in accordance with your customary procedures and check the associated box on the reply form.

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