URGENT MEDICAL DEVICE CORRECTION

Follow-Up Communication to September 15, 2022, Urgent Medical Device Safety Alert and February 6, 2023, Urgent Medical Device Correction Communication

December 20, 2023

This follow-up letter is to inform customers that Baxter has completed the investigation and identified corrections for the Novum IQ LVP pump related to the previously communicated September 15, 2022 safety alert and the February 6, 2023 device correction.

Dear Directors of Biomedical Engineering and Risk Management:

Problem Description

Baxter Corporation had previously communicated that through internal testing, isolated incidents of overinfusion on the Novum IQ LVP infusion pump were observed during test runs at 0.1 mL/hr after 40 hours of a continuous infusion within the 96-hour set change interval. Baxter also removed the 1W5000 administration set product code from the compatible sets list. To date, there have been no customer complaints related to this observation.

Baxter has completed the investigation and will be making the following changes to the Novum IQ LVP:

1. Update the Novum IQ LVP minimum programmable flowrate (MPFR) from 0.1 to 0.5 mL/hr via a software update, and

2. Update the Novum IQ LVP labeling restricting the use of 2R non-DEHP administration sets to a minimum flow rate of 1.0 mL/hr, specifically for the neonatal population

These changes require supplemental regulatory approval by Health Canada, which is targeted for submission by the end of Q1 2024.

Prior to implementation of this correction, Baxter has provided Risk Mitigations in the **Action to be Taken by Customers** section below. Baxter will support implementation of these risk mitigations at your site.

Affected Product

Product Code	Product Description	Serial Numbers
40700BAX	Novum IQ LVP	All

Hazard Involved

In most patients, the overinfusion is not expected to result in any harm. However, if the device is used to deliver high-alert medications, especially in high risk or neonatal populations, at flow rates below 0.5 mL/hr for all administration sets and 1 mL/hr for 2R administration sets with continuous infusions of durations over 40 hours, significant adverse events may occur. The type and severity of potential adverse events are dependent on the patient's weight, medical condition, medication type and concentration. To date, there have been no reports of adverse events or patient injury associated with this issue.

Actions to be Taken by Customers

1. When the correction becomes available, a local Baxter representative will contact your facility. Your facility will be receiving this correction from Baxter at no charge. Baxter will work with your facility to ensure the safe and timely correction of all devices.

2. Prior to the correction, the following Risk Mitigations should be implemented:

   - For the general population, use a flow rate ≥ 0.5 mL/hr for all administration sets
   - For use of 2R administration sets with neonates, use a flow rate ≥ 1 mL/hr
   - Consider use of an alternative pump (e.g. syringe pump) for flow rates outside these conditions

   If you need to use the Novum IQ LVP at a flow rate outside of the limitations described above then, ensure the IV administration set changes occur at 24-hour intervals.

3. If you purchased the Novum IQ LVP directly from Baxter, complete the enclosed Baxter Customer Reply Form and return it to Baxter by faxing it to 1-888-490-4660 or scanning and e-mailing it to baxter@ptm-health.com. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.

4. 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.

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

6. 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 **complete the applicable section on the reply form.**

Further information and support

If you have additional questions or experience quality problems, please contact your local Baxter representative.

Health Canada has been notified of this action.

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

Sincerely,

Brandon Gingrich
Senior Manager, Quality
Baxter Corporation – Canada

Enclosure: Baxter Customer Follow-Up Reply Form