Baxter

URGENT MEDICAL DEVICE CORRECTION

Follow-Up Communication to September 15, 2022, Urgent Medical Device Safety Alert Communication

February 6, 2023

On September 15, 2022, Baxter Corporation issued an Urgent Medical Device Safety communication regarding the Novum IQ Large Volume Pump (LVP). This letter has been updated to include additional information regarding corrective actions. All updates are in **bold**.

Dear Directors of Biomedical Engineering and Risk Management:

Problem Description

Through ongoing internal testing, Baxter Corporation has observed isolated incidents of overinfusion on the Novum IQ LVP infusion pump during test runs at 0.1 mL/hr after 40 hours of a continuous infusion within the 96-hour set change interval. These data indicate that Novum IQ LVP performs appropriately at flow rates of 1 mL/hr and greater during the 96-hour continuous infusion set change interval; the performance between 0.1 mL/hr and 1 mL/hr during that 96-hour interval **was** under investigation. **Up until the date of this follow-up letter**, there have been no customer complaints related to this observation.

This issue may lead to the hazardous situation of overinfusion at flow rates less than 1 mL/hr after 40 hours of a continuous infusion.

Based on Baxter's investigation, all of the sets on the Novum IQ LVP Compatible Sets list are acceptable to use at rates below 1mL/hr except for 1W5000 (INTERLINK SYSTEM, SOLUTION SET (20 DROPS/ML), INJECTION SITE, 15 MICRON DISC FILTER, MALE LUER LOCK ADAPTER). Product code 1W5000 will be removed from the Novum IQ LVP List of Compatible Sets.

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 1 mL/hr for continuous infusions of durations over 40 hours, significant adverse events may occur. **This risk is decreased by the removal of the 1W5000 product code**. 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. **Customers should immediately discontinue the use of the 1W5000 product code when using the Novum IQ LVP. Contact your Baxter Clinical Representative or Baxter Medical Information at 1-855-584-1368 or medinfocanada@baxter.com to discuss an alternate compatible set option for your therapy needs. Please note that Baxter is in the process of**

removing the 1W5000 product code from the Novum IQ LVP Compatible Sets List. This list can be accessed at https://service.baxter.com.

2. **Customers who have ordered the 1W5000 product code for use with the Novum IQ LVP should contact Baxter Customer Care to arrange the return of these sets. Baxter Customer Care can be reached at 1-888-719-9955, Monday through Friday, between the hours of 8:00 AM and 6:00 PM Eastern Time.**

3. Operators **who are not using the 1W5000 product code and using another compatible set** may continue to use the Novum IQ LVP. **Please ensure that every operator of this device is made aware of this Urgent Medical Device Correction.**

4. **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.

5. 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.

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

7. 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,

DocuSigned by:
Brandon Gingrich
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Brandon Gingrich
Senior Manager, Quality
Baxter Corporation – Canada

Enclosure: Baxter Customer Follow-Up Reply Form

