Baxter

URGENT MEDICAL DEVICE SAFETY ALERT

September 15, 2022

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 is currently under investigation. To date, 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.

Baxter is continuing to investigate the issue to identify the root cause and corrective actions.

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. 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. Operators may continue to use the Novum IQ LVP. **Please ensure that every operator of this device is made aware of this Urgent Medical Device Safety Alert.**

2. Consider an alternate low flow infusion device for **delivering high-alert medications to high risk or neonatal populations** if the prescription requires a continuous infusion with flow rate below 1 mL/hr for a duration greater than 40 hours.

3. **If you purchased this product 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 Safety Alert 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 Reply Form