URGENT MEDICAL DEVICE CORRECTION

April 24, 2025

Dear Director of Biomedical Engineering or Clinical Engineering:

Baxter Healthcare Corporation is issuing an Urgent Medical Device Correction for the **Novum IQ** large volume pump (LVP) due to the potential for underinfusion following use of the “standby mode” feature, or if the device is powered off with the set loaded. Keeping the administration set loaded in the pump for an extended period of time may result in an underinfusion on the subsequent infusion due to compression of the set. The risk increases when infusing at higher flow rates after longer duration in standby mode or powered off. Testing has identified that at flow rates above 50 mL/hour, certain infusions may experience flow rate variability of more than 10% after 2 hours and 30 minutes. In the worst-case scenario, 50% underinfusion can be observed at the maximum flow rate of 1200 mL/hour and the maximum standby time of 12 hours. This may lead to underinfusion of infusates, including drugs, IV nutrition, blood, and blood products. Note that even at 10% variability, pediatric patients (infants > 29 days to 2 years) may be at risk of dehydration, inadequate drug therapy, and nutrition, as well as insufficient blood infusion, leading to increased risk of morbidity and mortality.

Customers can continue to use the **Novum IQ** LVP while following the instructions listed below. Baxter is developing a software update and accompanying labeling updates to resolve the issue and will contact customers once the software update is available.

Affected Product

Product Code	Product Description	Serial Numbers	UDI-DI Number
40700BAXUS	**Novum IQ** LVP	All	05413765851797

Hazard Involved

If the pump delivers at a lower rate than intended, adverse effects may range from minor or temporary harm to severe harm, depending on the vulnerability of the target population, the condition being treated, and the fluid, drug, or other treatment being administered. High-risk patients and vulnerable populations may experience serious adverse health consequences including cardiac arrhythmias, hemodynamic instability, insufficient sedation, hyperglycemia, and thromboembolic events, among others.

Actions to be Taken by Customers

1. For flow rates greater than 50 mL/hour, do not exceed a programmed standby time of 2 hours and 30 minutes. Monitor patients frequently to ensure that the appropriate infusion is being delivered.
2. Please remove the set upon powering off the device.
3. Post the enclosed informational poster with **Novum IQ** LVPs in your facility.
4. Acknowledge receipt of this notification by following the instructions on the enclosed reply instruction sheet, even if you have no remaining inventory. Acknowledging receipt will prevent you from receiving repeat notices. If you do not complete the acknowledgement, you will receive a phone call from OnProcess Technology on behalf of Baxter to confirm your receipt of this notification.

5. Please forward a copy of this communication to the Chief Medical Officer, Medical Director, Director of Nursing, Director of Pharmacy, Facility Risk Manager, Director of Purchasing/Central Supply, and any other departments within your institution who use the affected product.

Further Information and Support

For general questions regarding this communication, or if you experience quality problems, please contact your Baxter sales representative, or Baxter Global Technical Services at 800-843-7867 (select option 2, then option 2 again) 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:

- Contacting Baxter Product Surveillance at the Baxter product feedback portal at https://productfeedback.baxter.com, or emailing Baxter at corporate_product_complaints_round_lake@baxter.com
- Reporting to the FDA MedWatch Serious Injury Reporting Program:
    - **Online:** By completing and submitting the report at 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 apologize for any inconvenience this Correction may cause you and your staff.

Sincerely,

Jason Bennett

Jason Bennett
Senior Director, Quality
Baxter Healthcare Corporation

Enclosure: Baxter Reply Instruction Sheet
Informational Poster Regarding Standby Mode

NOVUM IQ Large Volume Pump
Informational Poster Regarding Standby Mode

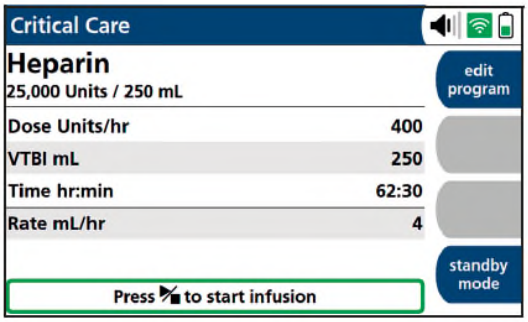
The **Novum IQ** Large Volume Pump Operator's Manual, Section 5.11.1, *Placing the Pump in Standby Mode*, indicates that the pump can be placed in standby mode for 1 minute to 12 hours.

5.11.1 Placing the Pump in Standby Mode

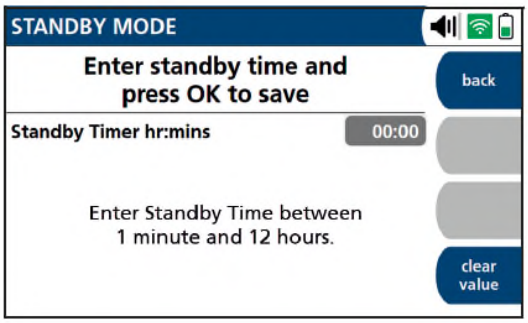
To place the pump in Standby Mode (before running infusion):

Once the programming setup is complete and an administration set is loaded, the **standby mode** soft key appears.

1. Press the **standby mode** soft key to place the **Novum IQ** large volume pump into Standby Mode.



2. The **STANDBY MODE** screen appears.
3. Set the Standby Mode timer. (See *Setting the Standby Mode Timer* on page 5-26.)



CAUTION: In accordance with Baxter's Urgent Medical Device Correction issued April 24, 2025, for flow rates greater than 50 mL/hour, do not exceed a programmed standby time of 2 hours and 30 minutes.

Monitor patients frequently to ensure that the appropriate infusion is being delivered.

Please remove the set upon powering off the device.