

URGENT MEDICAL DEVICE CORRECTION

April 29, 2025

Dear Director of Biomedical Engineering or Clinical Engineering:

Baxter 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% when started after 2 hours and 30 minutes in standby mode or with pump powered off. 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
40700BAX	Novum IQ LVP	All

Hazard Involved

If the pump infuses at a lower rate than intended, in most cases, minor or temporary harm may occur. In the high-risk populations, serious and critical adverse health consequences may occur, depending on factors such as the patient condition and medication being infused.

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. Enclosed is an informational poster for your facility.
4. **If you purchased this product directly from Baxter, complete the enclosed Baxter Customer Reply Form** and return it to Baxter by faxing it to 1-855-767-4572 or scanning and e-mailing it to

fca_canada@baxter.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 or wholesaler, please note that responding on the Baxter customer reply form is not applicable. If a response is requested by your distributor or wholesaler, please respond to them according to their instructions.
6. 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.
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 Correction may cause you and your staff.

Sincerely,



Brandon Gingrich
Associate Director, Quality and Regulatory
Baxter Corporation – Canada

Enclosure: Baxter Customer Reply Form
Informational Poster Regarding Standby Mode

NOVUM IQ Large Volume Pump Informational Poster Regarding Standby Mode

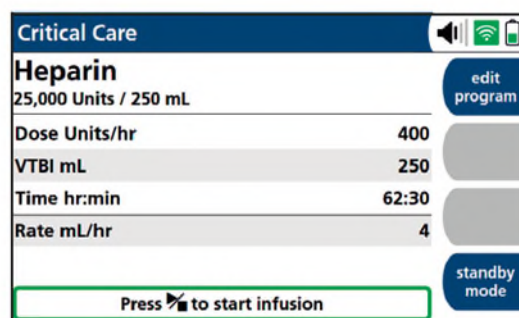
The **Novum IQ** Large Volume Pump Operator's Manual, Section 5.11.1, *Placing the Pump in Standby Mode*, indicates that the pump can be placed in standby mode for 1 minute to 12 hours.

5.11.1 Placing the Pump in Standby Mode

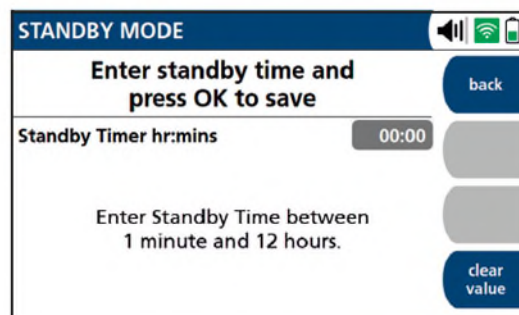
To place the pump in Standby Mode (before running infusion):

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.)



Critical Care	
Heparin	
25,000 Units / 250 mL	
Dose Units/hr	400
VTBI mL	250
Time hr:min	62:30
Rate mL/hr	4
Press to start infusion	
standby mode	



STANDBY MODE	
Enter standby time and press OK to save	
Standby Timer hr:min	00:00
Enter Standby Time between 1 minute and 12 hours.	
back	
clear value	

CAUTION: In accordance with Baxter's Urgent Medical Device Correction issued April 29, 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.