

URGENT MEDICAL DEVICE CORRECTION

August 7, 2025

Dear Director of Biomedical/Clinical Engineering, Director of Nursing, and Director of Pharmacy:

Baxter Corporation is issuing an Urgent Medical Device Correction for the **Novum IQ** Large Volume Pump (LVP) due to software anomalies that may result in a blank Run screen.

The blank Run screen occurs with multiple software anomalies. For example, this issue can occur when a user attempts to silence a downstream occlusion (DSO) alarm at the same time the device is automatically restarting the infusion (i.e., clearing the alarm condition). A blank Run screen on the **Novum IQ** LVP will not interrupt the ongoing therapy, which will continue to run to completion, but the user will not be able to adjust the ongoing therapy.

Customers can continue to use the **Novum IQ** LVP while following the instructions listed in the 'Actions to be Taken by Customers' section of this letter. While providing patient care involving high-risk medications and/or critical illness, users should consider utilizing an alternate pump, if available and appropriate for the patient's treatment.

Baxter is developing a software update 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

With respect to the blank Run screen, an interruption of therapy will be required should the user need to adjust therapy settings. Excessive or insufficient therapeutic effects may occur in the interim period while either the pump door is opened or closed while the infusion is running, the pump is power cycled, or the pump is replaced.

To date, Baxter has received three reports of serious injury related to the blank Run screen anomaly. There is potential for the defect to result in death or serious injury.

Actions to be Taken by Customers

1. Users should rely on their clinical judgment. When providing patient care involving high risk medications and/or critical illness, users should consider utilizing an alternate pump, if available and appropriate for the patient's treatment.
2. If an alternate pump is not available or appropriate for patient care involving high risk medications and/or critical illness, you may continue to use the **Novum IQ** LVP consistent with the following actions:
 - If a blank Run screen is displayed during an infusion on the **Novum IQ** LVP, the user should open the door, press the tubing into load point 3, then load point 4, to turn the light green (pictured in Figure 1 below), and close the door. If these actions do not resolve the blank screen, users should power-cycle the pump, select "Yes" to the new patient prompt, and reprogram the infusion.

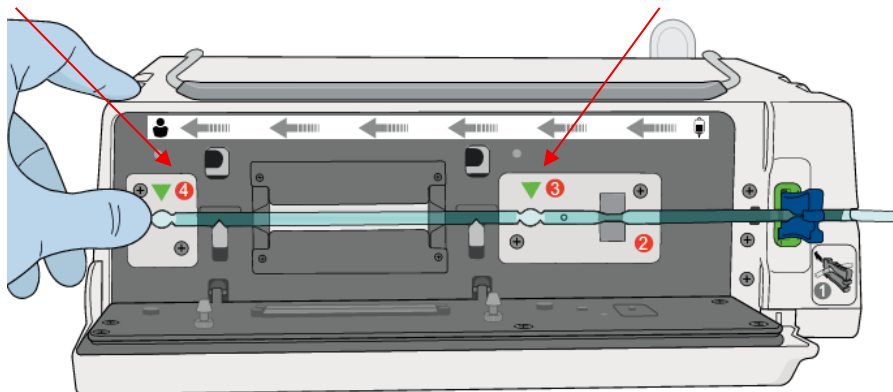


Figure 1. Red arrows point to load points 3 and 4 on the **Novum IQ** LVP.

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 1-855-767-4572 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.
4. 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.
5. Please forward a copy of this communication to the Chief Medical Officer, Medical Director, Director of Anesthesia, Facility Risk Manager, Director of Purchasing/Central Supply, and any other departments within your institution who use the affected product.
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 Correction may cause you and your staff.

To provide a helpful and centralized resource for customers impacted by ongoing Novum IQ Large Volume Pump (LVP) field actions, Baxter has uploaded a summary of all current Novum IQ LVP field actions to our Novum IQ LVP Important Safety Updates website, including applicable remediation steps and links to associated customer letters. Please note that your facility would have previously received the official customer communication for all field actions that you are impacted by.

This page will be maintained and updated with any relevant information pertaining to Novum IQ LVP field actions, in addition to communication via our standard channels.

Please visit <https://www.baxter.ca/novum-iq-large-volume-pump-important-safety-updates> to view the information.

Sincerely,

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

Enclosure: Baxter Customer Reply Form