URGENT MEDICAL DEVICE CORRECTION

July 14, 2025

Dear Director of Biomedical Engineering or Clinical Engineering and Director of Nursing:

Baxter is issuing an Urgent Medical Device Correction for the **Novum IQ** large volume pump (LVP) due to the following two issues:

1) There is a potential for underinfusion when transitioning from a lower to a higher flow rate (e.g., rate change or bolus). Specifically, the risk occurs when the second flow rate is more than double the first flow rate. For example, an increase from a 30 mL/hr primary infusion over 12 hours to a 600 mL/hr flow rate for a bolus infusion. The level of underinfusion is variable and is based on the lower infusion rate, the duration the pump has been running at this flow rate, and the magnitude of the rate change. The longer duration the pump has been running at the lower infusion rate and the larger the magnitude of the rate change, the larger the underinfusion would be. In the worst case, no delivery may occur.

   In addition to the corrections listed in the 'Actions to be Taken by Customers' section of this letter, Baxter is working to identify software and/or hardware corrections to address the issue and will contact customers with additional information when available.

2) Baxter has identified an increase in customer reports of over and underinfusion that may be due to set misloading. Failure to properly load the tubing into the pump channel may result in the pump infusing at a rate higher or lower than programmed. Consistent with the instructions for use, customers should ensure that:
   a) The door is fully open before loading the set as pictured on page 5 of enclosed Attachment A.
   b) The tubing is taut and loaded without slack in the pumping channel as pictured on page 7 of enclosed Attachment A, and in Figure 1 below.

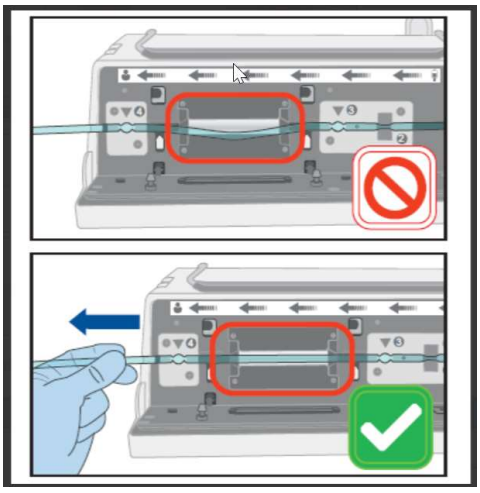

Figure 1

   Baxter is developing a hardware change to reduce misloading of the set and will contact customers to update the pumps when the correction is available.

Customers may continue to use the **Novum IQ** LVP while following the instructions listed in the 'Actions to be Taken by Customers' section of this letter.

Affected Product

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

Hazard Involved

With respect to the first issue (flow rate change), this may lead to the pump delivering at a lower rate than intended (underinfusion). With respect to the second issue (set misloading), this may lead to non-delivery, underinfusion, or overinfusion of the intended solution/medication.

The adverse effects that may result from either issue range from minor or temporary harm to serious injury or death, depending on the patient, the condition being treated, and the fluid, drug, or other treatment being administered. High-risk and vulnerable patient populations may experience higher rates of serious adverse health consequences including hemodynamic instability, cardiac arrhythmias, insufficient sedation, hyperglycemia, and thromboembolic events, among others. From June 2023 through May 2025, Baxter has received 79 reports of serious injury, and two reports of death potentially related to overinfusion or underinfusion.

Actions to be Taken by Customers

1. Users should rely on their clinical judgment. When the delay associated with changing the pump and infusion set would **NOT** prove detrimental to the patient, users should change out the pump and infusion set prior to initiating a bolus infusion or a rate change of greater than 100%.
2. If the delay associated with changing the pump and/or infusion set would prove unacceptable, prior to initiating a bolus infusion or a rate change of greater than 100%, users should move the administration set downstream (towards the patient) approximately 0.5 inches by following steps A through C below.
   A. Please follow the instructions for unloading the set in section 4.4, Unloading an Administration Set, of the **Novum IQ** LVP Operator's Manual (refer to enclosed Attachment A).
      - To prevent free flow, ensure downstream roller clamp is fully closed.
   B. Once unloaded, move the administration set downstream by moving the slide clamp toward the container by 0.5 inches.
   C. After moving the slide clamp, reload the administration set. Please follow the instructions for loading the set in section 4.3, Loading an Administration Set, of the **Novum IQ** LVP Operator's Manual (refer to enclosed Attachment A).
      - Once the tubing has been loaded, the door closed and the slide clamp has been ejected, ensure that the downstream roller clamp is fully open.
   D. **Initiate replacement of the administration set at the first safe opportunity to do so, or check regularly to ensure the infusion proceeds at the expected rate**.
3. To prevent misloading, please follow the instructions for loading the set in section 4.3, Loading an Administration Set, of the **Novum IQ** LVP Operator's Manual (refer to enclosed Attachment A).
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 Pharmacy, Facility Risk Manager, Director of Purchasing/Central Supply, Director of Anesthesia, 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
Attachment A: **Novum IQ** LVP Operator's Manual Excerpt