URGENT MEDICAL DEVICE CORRECTION

August 4, 2025

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

Baxter Healthcare Corporation is issuing an Urgent Medical Device Correction for the **Novum IQ** Large Volume Pump (LVP) and **Novum IQ** Syringe Pump (SP) due to software anomalies that may result in a blank Run screen (LVP and SP) and/or false motor movement system error (SP only).

The blank Run screen (LVP and SP) 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 either the **Novum IQ** LVP or SP 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.

Regarding the false motor movement system error (SP only), Baxter has identified a software anomaly in the **Novum IQ** Syringe Pump that results in a false motor movement system error (error code 20602 or 20603). The error can occur only after the user completes specific dose or flow rate changes as identified in Attachment A, when running below the minimum recommended flow rate on a syringe size of 10mL or greater.

Customers can continue to use the **Novum IQ** LVP and **Novum IQ** Syringe Pump 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 software updates to resolve these issues and will contact customers once the software updates are available.

Affected Product

Product Code	Product Description	Serial Numbers	UDI-DI Number
40700BAXUS	**Novum IQ** LVP	All	05413765851797
40800BAXUS	**Novum IQ** Syringe Pump		05413765852428

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 (LVP); the syringe is reloaded while the infusion is running (SP); the pump is power cycled; or the pump is replaced.

With respect to the false motor movement system error, which only occurs on the SP, should this system error occur, it will cause an interruption of therapy, which may lead to significant adverse health consequences depending on the medication being infused and the vulnerability of the patient.

To date, Baxter has received three reports of serious injury related to the blank Run screen anomaly and none related to the false motor movement issue. There is potential for either 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 and **Novum IQ** Syringe Pump 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 a blank Run screen is displayed during an infusion on the **Novum IQ** Syringe Pump, the user should unload, then reload the syringe. If these actions do not resolve the blank screen, both LVP and Syringe Pump users should power-cycle the pump, select "Yes" to the new patient prompt, and reprogram the infusion.

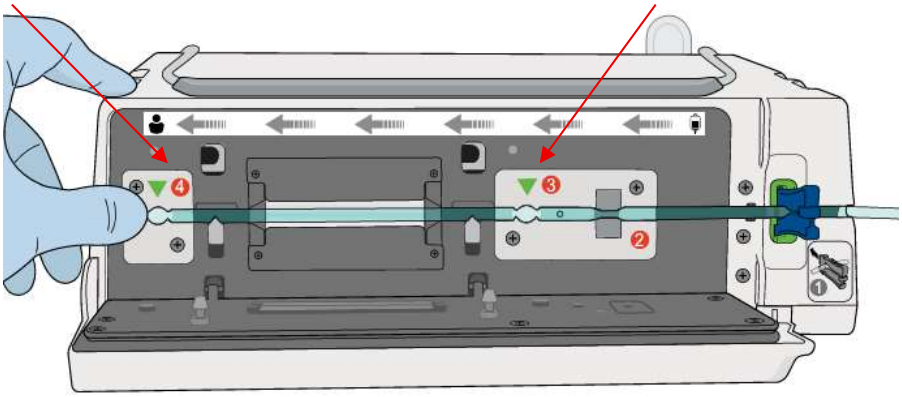

*Figure 1. Red arrows point to load points 3 and 4 on the **Novum IQ** LVP.*

    - To prevent a false motor movement system error, do not program the **Novum IQ** syringe pump to infuse below the Minimum Recommended Flow Rate for a syringe size of 10 mL or greater.

3. 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.
4. 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.
5. Print and post Attachment A in areas frequented by potential users (e.g., break rooms) and where pumps are stored.

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 may cause you and your staff.

Sincerely,

Jason Bennett

Jason Bennett
Senior Director, Quality
Baxter Healthcare Corporation

Enclosure: Baxter Reply Instruction Sheet
Attachment A: Motor Movement Rate Change Failures

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Attachment A
Movement Rate Change Failures

Baxter Healthcare has issued an Urgent Medical Device Correction for **Novum IQ** Syringe Pump due to false motor movement system errors. Baxter has identified a software anomaly that results in a false motor movement system error (error code 20602 or 20603). The error can occur only after the user completes specific dose or flow rate changes as identified in this Attachment A, when running below the minimum recommended flow rate on a syringe size of 10mL or greater.

Compatible Intravenous Syringes	**Initial Rate (mL/hr)**	**New Rate (mL/hr)**
BD 10 mL	0.07	0.06
BD 30 mL	0.11 - 0.12	0.1
BD 50 mL	0.1 - 0.12	0.13
	0.13 - 0.14	0.12 - 0.1
	0.15	0.12 - 0.11
	0.16	0.12
	0.17 - 0.19	0.16 - 0.15
	0.2	0.16
	0.21 - 0.24	0.2
Monoject 12 mL	0.08	0.07
Monoject 35 mL	0.14 - 0.15	0.13 - 0.12
	0.16	0.13
	0.17 - 0.19	0.16
Monoject 60 mL	0.21 - 0.24	0.2

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Attachment A
Movement Rate Change Failures

Compatible Enteral Syringes	Initial Rate (mL/hr)	New Rate (mL/hr)
BD Enteral 10 mL	0.07	0.06
Baxter/Neomed Enfit 12 mL	0.08	0.07
Baxter/Neomed Enfit 20 mL	0.13 - 0.14	0.12
Neomed Enfit 35 mL	0.13 - 0.15	0.12
	0.17 - 0.19	0.16
BD Enteral 50 mL and Baxter Enfit 60 mL	0.1 - 0.12	0.13
	0.13 - 0.14	0.12 - 0.1
	0.15	0.12 - 0.11
	0.16	0.12
	0.17 - 0.19	0.16 - 0.15
	0.2	0.16
	0.21 - 0.24	0.2
Neomed Enfit 60 mL	0.1 - 0.12	0.13
	0.13	0.12 - 0.1
	0.14	0.13 - 0.1
	0.15	0.12 - 0.11
	0.16	0.12
	0.17 - 0.19	0.16 - 0.15
	0.2	0.16
	0.21 - 0.24	0.2