

# MEMO

To: All Hospital Coordinators, Managers & Directors

From: Andrea Raynak, Director Nursing Practice

Date: August 1, 2023

RE: Urgent Medical Device Correction- Baxter Corporation, Novum IQ Large Volume Pump

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Good evening,

Please be advised Baxter Corporation has issued an urgent medical device correction for our current intravenous pump, the Novum IQ Large Volume Pump. This notice has been issued due to the potential for internal screws becoming loose and further, damaging the pumping mechanism valves. This damage has the potential to lead to the over infusion of the intravenous solution.

Prior to initiating an intravenous infusion, please complete the following;

1. Confirm the pumping mechanism valves (two visible white valves when the pump door is open) are not stuck, ensure they move up and down.

While the pump is infusing, please monitor the following;

1. Listen for any atypical sounds coming from the pump.

If the pumping mechanism valves appear to be stuck and/or there is any atypical noise noted, bring the pump to your Patient Care Manager. Ensure the pump is labeled and a biomedical requisition is complete.

Please see attached poster for visual representation.

Quality care and patient safety is of utmost importance. Baxter Corporation is working diligently to resolve the issue. Further communication will come once the issue is resolved.



# Urgent Medical Device Correction:

Affecting all Baxter Novum IQ large volume pumps(LVP)

## Problem: Over infusion or delay in IV therapy

- Follow the steps below to ensure correct functioning of the IV pump:

Step 1	Step 2
Confirm pumping mechanism valves (2 white valves when door is open) are not stuck and move up and down. See figure below.	Listen for any atypical sounds coming from the pump.

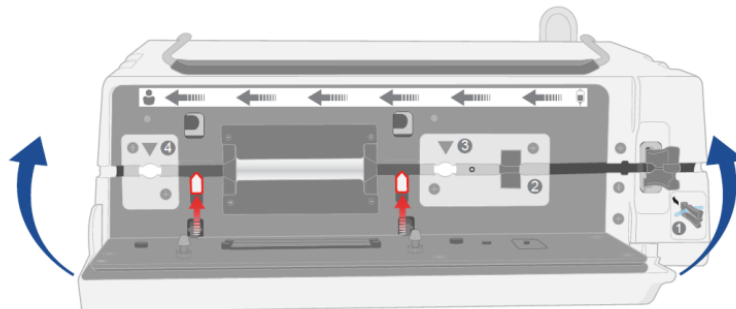


Figure 1: Rotate Door Open and Shut to confirm Valve movement

## If any issues are identified:

- Label the pump with a biomedical requisition and bring the pump to your manager

# URGENT MEDICAL DEVICE CORRECTION

July 26, 2023

Dear Directors of Biomedical Engineering and Risk Management:

**Problem Description** Baxter Corporation is issuing an Urgent Medical Device Correction for the Novum IQ large volume pump (LVP) due to the potential for internal screws becoming loose and damaging the pumping mechanism valves. A loose screw within the Novum LVP device that results in damage to the pumping mechanism valves can cause an over infusion.

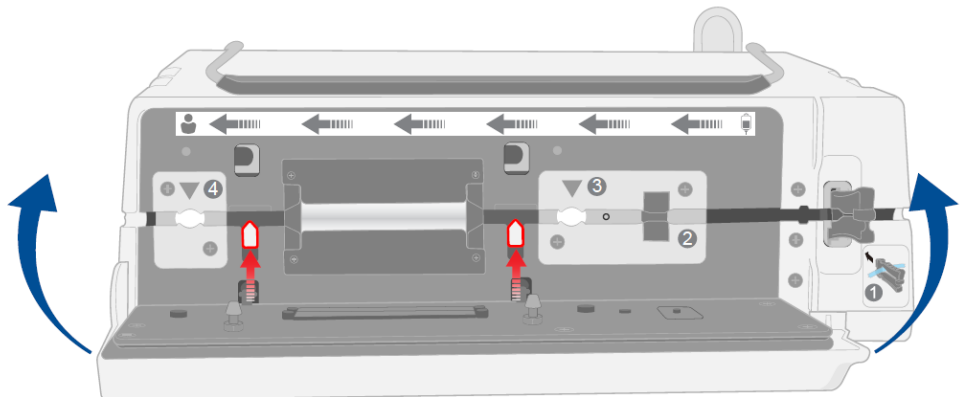
Once available, a correction to the pumps will be applied to assure affected screws do not inadvertently loosen as a result of the identified conditions.

Affected Product	Product Code	Product Description	Serial Numbers
	40700BAX	Novum IQ LVP	All

**Hazard Involved** A loose screw within the Novum IQ LVP device can result in over infusion, a delay of therapy, an interruption of therapy or an electrical hazard. These hazardous situations may result in harm to a patient depending on several factors such as length of therapy delay, medication being infused, volume and rate of infusion, and the patient's underlying status and comorbidities. Baxter has received two complaints related to this issue, including one report of serious injury that is potentially associated with this issue.

**Actions to be Taken by Customers**

1. Operators may continue to use the Novum IQ LVP. Prior to use, confirm pumping mechanism valves (outlined in red in Figure 1) are not stuck and move up and down as the Novum IQ LVP door is rotated open and shut. If the mechanism valves are stuck or not moving up and down with the rotation of the door, immediately discontinue the use of the device.



*Figure 1: Rotate Door Open and Shut to confirm Valve movement*



2. In certain cases, a screw that has become loose inside a pump could result in a rattling sound when the pump gets transported or otherwise moved. If you hear an atypical sound-- such as a rattling sound-- coming from inside a pump that is being moved or transported, immediately discontinue the use of the device.
3. **When the correction becomes available, a local Baxter representative will contact your facility.** Your facility will be receiving this correction from Baxter at no charge. Baxter will work with your facility to ensure the safe and timely correction of all devices.
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 1-888-490-4660 or scanning and e-mailing it to [baxter@ptm-health.com](mailto:baxter@ptm-health.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, please note that the Baxter customer reply form is not applicable. If a reply form is provided by your distributor or wholesaler, please return it to the supplier according to their instructions.
6. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.
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 may cause you and your staff.

Sincerely,

DocuSigned by:  
*Azmina Kanji*  
EF2BAC6CB0A346A...

Azmina Kanji  
Manager, Quality Systems  
Baxter Corporation – Canada

Enclosure: Baxter Customer Reply Form