Baxter

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.

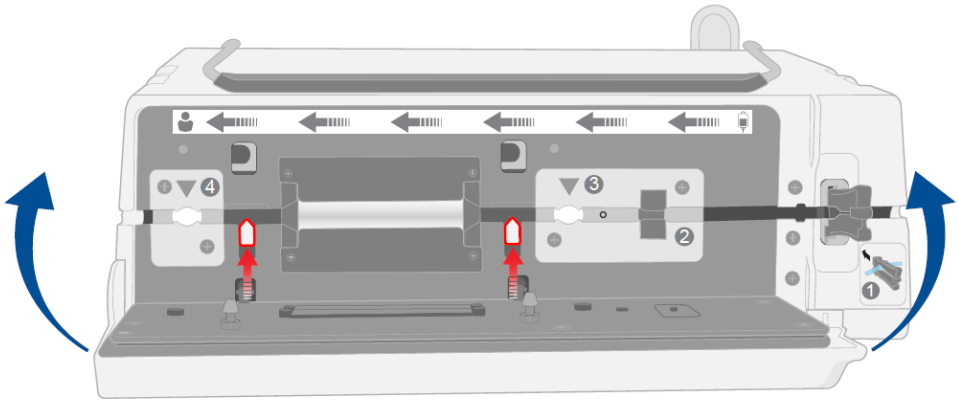

Figure 1: Rotate Door Open and Shut to confirm Valve movement

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. 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
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Azmina Kanji
Manager, Quality Systems
Baxter Corporation – Canada

Enclosure: Baxter Customer Reply Form