Baxter

URGENT MEDICAL DEVICE CORRECTION

Follow-Up Communication to October 20, 2022, Urgent Medical Device Correction Communication

December 7, 2022

Dear Directors of Biomedical Engineering and Risk Management:

On October 20, 2022, Baxter Corporation issued an Urgent Medical Device Correction communication regarding the Novum IQ Large Volume Pump (LVP) related to two different software issues that occur during use. Baxter Corporation is issuing a follow-up communication to the user level for an additional software issue and to notify customers that a software correction is now available.

Problem Description

The Novum IQ LVP may not execute bolus initiations/cancellations or titration adjustments as expected by the user. This issue was identified during internal testing of the software correction for the previous two software issues communicated in the October 20, 2022 letter. To date, there are no reported customer complaints.

There are three potential scenarios in which this software error could occur:

In the first scenario, the user cancels the programmed bolus before completion. **If the software error occurs**, the pump does not return to the maintenance delivery rate as expected and continues to deliver at the bolus rate until the full programmed bolus volume is delivered. The display incorrectly indicates a return to the maintenance rate. After completion of the bolus volume, the pump stops without a high priority alarm as expected. The inactivity alarm will sound after 2 minutes.

In the second scenario, when the user initiates a bolus, **if the software error occurs**, the pump will fail to apply the bolus rate, instead delivering at the previously programmed maintenance rate while incorrectly displaying the bolus rate programmed by the user.

In the third scenario, **if the software error occurs** during rate titration, the newly programmed rate will not be applied. The pump will continue to incorrectly deliver at the previous rate while displaying the new rate programmed by the user.

Baxter has approved an updated software version and will be providing the software upgrade to all affected Novum LVPs to resolve these software issues.
This updated software, version 1.1.6, will address the issue communicated in this letter, as well as the incorrect volume delivered, and the 'Air Still Detected' Alarm workflow issues communicated in the previous letter dated October 20, 2022.

Affected Product

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

Baxter

Hazard Involved

This issue may lead to the hazardous situations of unintended bolus delivery, interruption of therapy, insufficient therapy and/or excessive therapy. The potential for harm to the patient depends on several factors such as the medication being infused, the volume and rate of the infusion, patient status and comorbidities, etc. To date, there have been no reported complaints or patient injury associated with this issue.

Actions to be Taken by Customers

1. **Please immediately upgrade all Novum IQ LVPs to software version 1.1.6 found on the Technical Service Portal (https://service.baxter.com/tsportal/).** Your facility will be receiving this upgrade from Baxter at no charge. Baxter will work with your facility to ensure the safe and timely upgrade of all devices.

2. **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.

3. 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.

4. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.

5. 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:
Brandon Gingrich
D4CB1DA1D2FC4DA...

Brandon Gingrich
Senior Manager, Quality
Baxter Corporation – Canada

Enclosure: Baxter Customer Reply Form