Baxter

URGENT MEDICAL DEVICE CORRECTION

August 8, 2023

Dear Directors of Biomedical Engineering and Risk Management:

Problem Description

Baxter Corporation is issuing an Urgent Medical Device Correction for a subset of Novum IQ large volume pumps (LVP) due to reports of malfunctioning keypads. Specifically, Baxter has received reports of a pump operator pressing a single key on the Novum keypad, but the pump incorrectly registers multiple keys (e.g., a user presses the number “5” on the keypad, but the pump registers and displays both a “5” and the adjacent “6”). Hearing a "double beep" after a single key press may be an indication that the pump incorrectly registered the keypad entry.

Please note that this Urgent Medical Device Correction applies only to a subset of Novum IQ LVPs, which were manufactured with one specific keypad production lot.

Baxter will contact customers regarding the replacement of keypads on affected pumps.

Affected Product

Product Code	Product Description	Serial Numbers
40700BAX	Novum IQ LVP	See Attachment 1

Hazard Involved

The hazards that could result are excessive therapy, insufficient therapy or a delay in therapy. Significant adverse health consequences may occur should the pump operator not recognize the programming error before the infusion begins. Baxter has not received any reports of serious injury related to this issue.

Actions to be Taken by Customers

1. Any devices that have demonstrated this issue should be removed from use and reported to Baxter.
2. Locate the impacted devices at your facility listed in Attachment 1 and remove them from use. Baxter will contact you to arrange service and repair of your impacted Novum IQ LVPs.
3. If continued use of the pump is necessary because no spare pump is available, then the following must be confirmed by the pump operator prior to starting an infusion or initiating a drug titration:
    i. Visually verify that entries made on the keypad were correctly registered on the pump display: drug concentration, dose mode, dose rate, and time are correct prior to starting an infusion or initiating a drug titration.
    ii. Pay additional attention to drug limits, hard, soft and change limits triggered when programming and verify infusion parameters prior to starting an infusion or initiating a drug titration.

4. 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.

5. **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.

6. 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.

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

8. 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
Attachment 1 – Impacted Serial Numbers