MEDICAL DEVICE FIELD ACTION

October 26, 2023

Dear Directors of Biomedical Engineering and Risk Management:

Baxter Corporation is issuing this communication to address the following issues related to the Novum IQ Large Volume Pump (LVP):

Issue	Description
1	Safety Alert: Potential for Keypad to Malfunction (FA-2023-059)
2	Important Product Information: Updated Operator's Manual Related to Radio-Frequency Identification Devices (FA-2023-060)
3	Urgent Medical Device Correction: Unapproved Adhesive used During Service (FA-2023-061)

The information on the subsequent pages provides the details of each issue, the hazards involved and the actions to be taken.

General Actions to be Taken by Customers

1. Follow the 'Actions to be Taken by Customers' as stated for each issue.

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 response is requested by your distributor or wholesaler, please respond to the supplier according to their instructions.

4. If you distributed 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 communication in accordance with your customary procedures and complete the applicable section on the reply form.

Issue 1 **Potential for a Keypad to Malfunction (FA-2023-059)**

On August 8, 2023, Baxter Corporation issued an Urgent Medical Device Correction for a subset of Novum IQ Large Volume Pumps (LVPs) due to reports of malfunctioning keypads that were identified within a single manufacturing lot. Customers with pumps from this specific lot were contacted. However, because the root cause investigation is in process by the keypad supplier, Baxter Corporation is issuing a Safety Alert for all Novum IQ LVPs to ensure all customers are aware of the potential for a keypad to malfunction.

Specifically, when a pump operator presses a single key on the keypad, the pump may incorrectly register multiple keys (e.g., a user presses the number "8" on the keypad, but the pump registers and displays both an "8" and the adjacent "0"). Hearing a "double beep" after a single key press may be an indication that the pump incorrectly registered the keypad entry.

Baxter is actively engaged with customers regarding pumps impacted by the August 8, 2023 Urgent Medical Device Correction. Actions for all other customers can be found in the "Actions to be Taken by Customers" section of this page below.

Affected Product

Product Code	Product Description	Serial Numbers
40700BAX	Novum IQ Large Volume Pump	All (Note: excluding those serial numbers that were impacted by the August 8, 2023 Urgent Medical Device Correction, which are being replaced)

Hazard Involved

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

Actions to be Taken by Customers

1. Healthcare providers may continue to safely use the Novum IQ Large Volume Pumps while following the Instructions for Use.
2. 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.
3. 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. Any devices that have demonstrated this issue should be removed from use and reported to Baxter Canada Technical Service at 1-877-331-9336, Monday through Friday, between 7:00 am and 3:00 pm Eastern Time, or by email at CA.MEDDEL.CDN.TECH.SERVICES@baxter.com.

Issue 2

Updated Operator's Manual Related to Radio-Frequency Identification Devices (FA-2023-060)

Baxter Corporation has updated the Novum IQ Large Volume Pump (LVP) Operator's Manual to include the risks associated with use of specific Radio-Frequency Identification Devices (RFID) in conjunction with the Novum IQ LVP.

This Important Product Information is to advise operators of these updates in the Operator's Manual as summarized in the 'Actions to be Taken by Customers' section below.

Baxter's Universal Implementation Process (UIP) related to the Novum IQ LVPs already includes an assessment of RFID technology with Novum IQ LVP in the use environment per guidance provided in AIM 7351731 Annex L and the Healthcare Information and Management System Society (HIMSS) in its 'Novum IQ Biomed Discussion Checklist' (UIP T01).

Affected Product

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

Hazard Involved

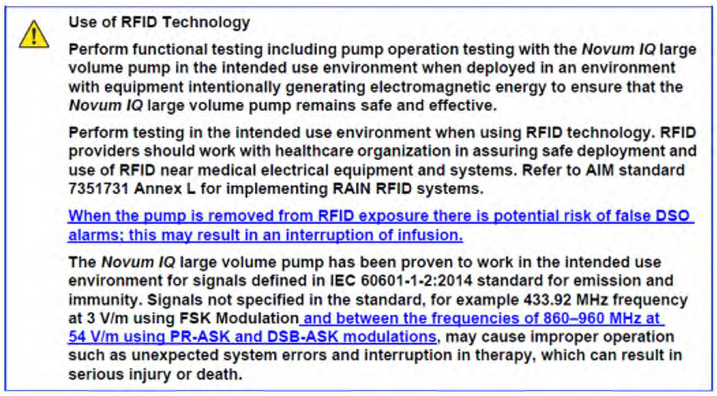
Due to radiofrequency emission standards that RF devices comply with, it is very unlikely that hazardous situations and resultant harm will occur in a clinical setting. The hazardous situations that could result are a delay or interruption of therapy. Baxter has not received any reports of serious injury related to this issue.

Actions to be Taken by Customers

1. Operators may continue to use the Novum IQ LVP by following the updated Operator's Manual. An electronic copy of the Operator's Manual can be accessed at https://service.baxter.com/tsportal/.

2. Customers are advised to read the updates made to the Operator's Manual, which are described below:

   a) The existing warning 'Use of RFID Technology' was revised to include "When the pump is removed from RFID exposure there is a potential risk of false DSO alarms, this may result in interruption of infusion." The revised warning was updated in the existing Section 1.5.1 General Warnings and added to Section 8.19 System Error Alarms.
   b) The existing warning 'Use of RFID Technology' was revised to include the various frequency bands as a cause of system errors. The revised warning was updated in the existing Section 1.5.1 General Warnings and added in Section 8.10 Downstream Occlusion Alarms.



Use of RFID Technology

Perform functional testing including pump operation testing with the *Novum IQ* large volume pump in the intended use environment when deployed in an environment with equipment intentionally generating electromagnetic energy to ensure that the *Novum IQ* large volume pump remains safe and effective.

Perform testing in the intended use environment when using RFID technology. RFID providers should work with healthcare organization in assuring safe deployment and use of RFID near medical electrical equipment and systems. Refer to AIM standard 7351731 Annex L for implementing RAIN RFID systems.

When the pump is removed from RFID exposure there is potential risk of false DSO alarms; this may result in an interruption of infusion.

The *Novum IQ* large volume pump has been proven to work in the intended use environment for signals defined in IEC 60601-1-2:2014 standard for emission and immunity. Signals not specified in the standard, for example 433.92 MHz frequency at 3 V/m using FSK Modulation and between the frequencies of 860–960 MHz at 54 V/m using PR-ASK and DSB-ASK modulations, may cause improper operation such as unexpected system errors and interruption in therapy, which can result in serious injury or death.

Issue 3 **Unapproved Adhesive Used During Service (FA-2023-061)**

Baxter Corporation is issuing an Urgent Medical Device Correction for the Novum IQ Large Volume Pump (LVP) serial number(s) listed below. An unapproved adhesive was used in error during service for the re-installation of the slide clamp assemblies performed at Baxter's Service Centre. The use of the unapproved adhesive may affect the plastic of the slide clamp assembly, which can result in the slide clamp not ejecting properly or the door not opening.

Affected Product

Product Code	Product Description	Serial Numbers
40700BAX	Novum IQ LVP	01A201100064 01A201100088 01A201100105 01A201100124 01A201100126 01A201100147 01A220200390 01A220703920 01A200900365 01A201000229 01A201000357 01A201000426 01A201000450 01A201000530 01A201000533 01A201000585 01A201000618 01A201000707 01A201000754 01A201000801 01A201000845 01A201000862 01A201100011 01A201100033 **will customize list per impacted customer

Hazard Involved

This issue could lead to a delay or interruption of therapy, excessive therapy or insufficient therapy. The harms that could result would depend on numerous therapy- and patient-related factors (the properties of the medication being infused, disease state and age/weight of the patient involved, the care area where they are treated, the magnitude of the excessive/insufficient therapy, the duration of the delay/interruption, etc.). Baxter has not received any reports of serious injury related to this issue.

Actions to be Taken by Customers	1. Locate the impacted device(s) at your facility listed in the Affected Product table above and remove them from use. Baxter will contact you to arrange the replacement of your impacted Novum IQ LVPs.

Further Information and Support

If you have additional questions or experience quality problems, please contact Baxter Canadian Technical Service at 1-877-331-9336, Monday through Friday, between 7:00 am and 3:00 pm Eastern Time, or by email at CA.MEDDEL.CDN.TECH.SERVICES@baxter.com.

Health Canada has been notified of the issues described in this communication.
We apologize for any inconvenience this may cause you and your staff.

Kindly please complete and return the enclosed Baxter Customer Reply Form to acknowledge receipt of this communication.

Sincerely,

Christine Gladwell

Christine Gladwell
Senior Director, Quality
Baxter Corporation – Canada

Enclosure: Baxter Customer Reply Form