Baxter

URGENT MEDICAL DEVICE CORRECTION

October 20, 2022

Dear Directors of Biomedical Engineering and Risk Management:

Problem Description

Baxter Corporation is issuing an Urgent Medical Device Correction to the user level for the Novum IQ Large Volume Pump (LVP). This correction is related to two different software issues that occur during use. These issues apply to both currently marketed software versions 1.1.3 and 1.1.4 unless otherwise noted below. The issues do not occur for infusions run to completion.

The first issue observed is due to incorrect reported delivered volume while an infusion is running. This incorrect reported volume can occur during a Bolus delivery, Loading Dose cancellation and Volume to be Infused (VTBI) adjustments while the infusion is running. The following scenarios can potentially occur:

For Bolus Delivery

1. The infusion may transition to KVO (keep vein open) prematurely after bolus completion. Furthermore, this transition to KVO is not accompanied with a high priority "Infusion Complete" alarm as expected.

2. The infusion following the bolus may have an incorrect remaining VTBI and can result in insufficient or excessive therapy.
   For example, if a primary infusion is programmed for 100 mL and a Bolus of 10 mL is programmed 20 mL into the primary infusion, the expected remaining VTBI would be 70 mL. In the case of this software issue, the remaining VTBI is incorrectly calculated to be more or less than 70 mL.

   If the remaining volume is less than 70 mL
   a. The subsequent transition to KVO will happen prematurely with an "Infusion Complete" alarm and residual volume in the infusion container.

   If the calculated remaining VTBI is greater than 70 mL
   a. The infusion container will empty stopping the infusion and the user will get an ‘Air in line’ alarm.

3. If bolus delivery is enabled for the Secondary medication and a bolus is performed while the Secondary is infusing, it is possible that a portion of the Secondary drug is delivered at the primary rate and vice versa if Secondary Callback is not enabled.

For Loading Dose, if a loading dose is **cancelled** and the primary infusion is stopped or a VTBI change is applied to the primary infusion

1. The infusion may transition to KVO prematurely. Furthermore, this transition to KVO is not accompanied with a high priority "Infusion Complete" alarm as expected. **This only applies to Novum IQ LVPs**

with software version 1.1.3.

2. The infusion following the loading dose may have an incorrect remaining VTBI on the screen and can result in insufficient therapy. The subsequent transition to KVO may happen prematurely with an "Infusion Complete" alarm and residual volume in the infusion container.

For VTBI adjustment while the infusion is running, if the infusion is stopped or a **subsequent second VTBI change is applied** to the infusion:

1. The infusion may transition to KVO prematurely. Furthermore, this transition to KVO is not accompanied with a high priority "Infusion Complete" alarm as expected. **This only applies to Novum IQ LVPs with software version 1.1.3.**

2. For primary infusions, the infusion may have an incorrect remaining VTBI and can result in insufficient therapy. However, the infusion rate is as programmed and the subsequent transition to KVO is with an "Infusion Complete" alarm.

3. For secondary infusions, it is possible that a portion of the Secondary drug is delivered at the primary rate if Secondary Callback is not enabled.

For all the above scenarios

1. If the issue occurs, the VTBI and 'Total Given' displayed on pump screen may be inaccurate. This inaccurate value is propagated to CQI reports and any Auto-Documentation records in the Electronic Medical record (EMR).

To date, there are two customer complaints potentially related to this issue.

The second issue observed is an unexpected screen transition during the 'Air Still Detected' Alarm workflow. The issue occurs when the user is resolving a high priority 'AIR IN LINE' alarm, elects to continue the infusion and does not clear the air in line. The issue results in cases where the 'Air still Detected' alarm does not occur.

Instead, the pump transitions directly to the 'Line Assessed' screen with high priority alarm visual indicators i.e., alarm banner on display and red flashing beacon light.

Figure 1: Expected and Unexpected Screen Transition During the 'Air Still Detected' Alarm Workflow

Expected 'Air Still Detected' Alarm Screen	Unexpected 'Line Assessed' Screen
	

These alarm visual indicators (alarm banner and red flashing beacon) persist for the remainder of the infusion and do not clear until the user opens the door.
While these alarm visual indicators are present, any alarms of relatively lower priority than the "Air Still Detected" alarm are not presented to the user i.e. displayed or accompanied with an audible alarm such as Upstream or Downstream occlusion alarms. See the Operator's Manual, Table 8-2 General Alarms for the complete list of alarm prioritization.

To date, there are three customer complaints potentially related to this issue.

Baxter is continuing to investigate the issue to identify the root cause and corrective actions. Once available, Baxter will be providing an additional software upgrade to all affected Novum LVPs to resolve these software issues.

Affected Product

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

Hazard Involved

The first issue may lead to the hazardous situations of interruption of therapy, insufficient therapy 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 reports of patient injury associated with this issue.

The second issue may result in the hazardous situations of patient exposure to air in line and/or interruption of therapy. The resultant harm would depend on several factors such as the rate and volume of air entering the patient, the length of interruption, the medication being infused, patient population, status and comorbidities, etc. To date, there have been no reports of patient injury associated with this issue.

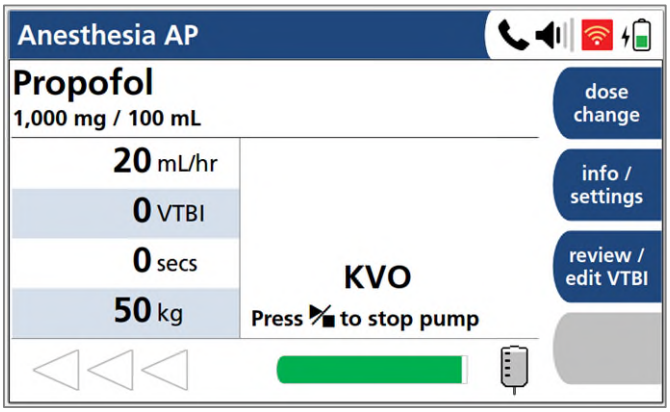
Actions to be Taken by Customers

1. Operators may continue to use the Novum IQ LVP. **Please ensure that all devices are updated to the latest available software version 1.1.4 found on the Technical Service Portal (service.baxter.com) and every operator of this device is made aware of this Urgent Medical Device Correction.** Software version 1.1.4 partially addresses the issues outlined in this letter.

2. For the first issue, operators should:

   Monitor the patient during bolus delivery to completion or minimally at completion to ensure appropriate return to the maintenance rate. Upon completion of the bolus if a premature transition to KVO occurs (See Figure 2).
   - Press the 'run/stop' key to stop the infusion
   - Select 'review / edit VTBI' soft key
   - Select 'edit program'
   - Reprogram the VTBI
   - Press the 'run/stop' key to resume the infusion

Figure 2: Unexpected KVO Screen



Do not perform Bolus delivery or VTBI changes while the Secondary is infusing.

Do not enable bolus delivery for secondary medications in the drug library using Dose IQ Safety Software. When disabled in the drug library, the 'Bolus' soft key is not available during Secondary infusion delivery.
VTBI changes for secondary infusions should be applied before initiating the Secondary infusion.

3. For the second issue for 'Air Still Detected' Alarm workflow, if operators encounter the 'Line Assessed' screen with alarm banner and red flashing beacon (See Figure 3, right image), operators **should not** resume the infusion.

   - Users should open the door,
   - Re-assess the line for air,
   - Remove any residual air in the line per hospital policies

- Close the door again.

Operators should only resume the infusion when the 'Line Assessed' screen **without** alarm banner and red flashing beacon (See Figure 3, left image) is displayed after door closure.

Figure 3: Expected and Unexpected 'Line Assessed' Screen

Expected 'Line Assessed' Screen OK TO RESUME	Unexpected 'Line Assessed' Screen DO NOT RESUME
	

4. **Baxter will communicate when an additional software upgrade beyond 1.1.4 becomes available.** 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.

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