Baxter

URGENT MEDICAL DEVICE CORRECTION

May 29, 2023

Dear Directors of Pharmacy, Biomedical Engineering, Risk Management, Nursing and Nurse Educators:

Problem Description

Baxter Corporation has identified a defect in the Dose IQ Safety Software used with Novum IQ Large Volume Pump (LVP) that affects a drug library file that has been migrated from a Spectrum Large Volume infusion pump to a Novum IQ LVP drug library. This defect results in an **invalid initial setting** for the **air in line threshold** for any new Care Area created in which none of the settings are changed. Existing Care Areas from the migrated drug library are not impacted.

If a drug library with this issue is installed on a Novum IQ LVP and the pump user accesses the **Air in Line** alarm setting in the **User Options** menu within the affected Care Area, a **non-halting system error** will occur. The pump will continue to infuse, however it will require a restart for the user to interact with the pump.

Additionally, the pump will set the air in line threshold to 200 µL for the affected Care Area, instead of the intended default threshold of 100 µL.

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

Baxter has identified the root cause of the issue and is authoring a software update to address it. Once available, Baxter will be providing a software upgrade to all affected Dose IQ Safety Software to resolve this software issue.

NOTE: This issue only affects the Care Area's Air in Line threshold setting for any new Care Area created. Drug settings are not impacted in the new Care Area.

Affected Product

Product Code	Product Description	Software Version
DOSEIQW0001	Dose IQ Safety Software	All existing versions as of date of this letter

Hazard Involved

When a drug library with an invalid Air In Line threshold value is used on the Novum IQ LVP, it can result in a potential delay in therapy, interruption in therapy, or an unexpected air bubble size (between 100 and 200 µL) potentially passing to the patient. There have been no events of death or serious injury related to this issue reported to Baxter to date.

Actions to be Taken by Customers

1. For users that have previously migrated libraries from Spectrum IQ to Novum IQ LVP, operators may continue to use the Dose IQ Safety Software by taking the steps below. **Please ensure every operator of this device is made aware**

of this Urgent Medical Device Correction and to complete the steps below immediately.

i. In the Dose IQ Web software, generate a **Clinical Validation Report** for the drug library currently used on the infusion pumps.

ii. Review configuration setting for each individual Care Area. (*See Figure 1)*

Care Area: Medical/Surgical

Care Area																	
																	LVP
Care Area Type	Patient weight lower hard limit (kg)	Patient weight lower soft limit (kg)	Patient weight upper soft limit (kg)	Patient weight upper hard limit (kg)	BSA lower hard limit (m^2)	BSA lower soft limit (m^2)	BSA upper soft limit (m^2)	BSA upper hard limit (m^2)	Required weight / BSA value confirmation	Pump	EMR Integration	Auto keypad lock	Downstream occlusion pressure default	Downstream occlusion auto-restart attempts	Priming Volume (mL)	Allow mL/hr programming	Threshold for air in line detection (µL)	LVP drugs in care area
Standard									On	Novum IQ LVP	Off	Off	Medium	5		Off		1

Figure 1

iii. Under the **Threshold for air in line detection (µL),** if the value shows **blank**, this care area is affected. If there is a value displayed in this field (50, 100, 200 or 400), this care area is not affected.

iv. To correct a care area with a **blank** value, please do the following:

a) Access the **Care Area page** in Dose IQ Web software

b) Select **Edit care area** button (*See Figure 2*)

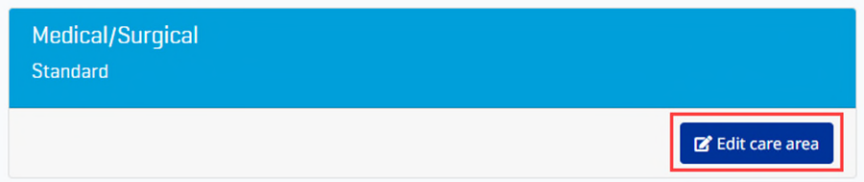

Figure 2

c) In the **Care Area Name** field, rename the Care Area name. (e.g. add an alphanumeric character) (*See Figure 3*)

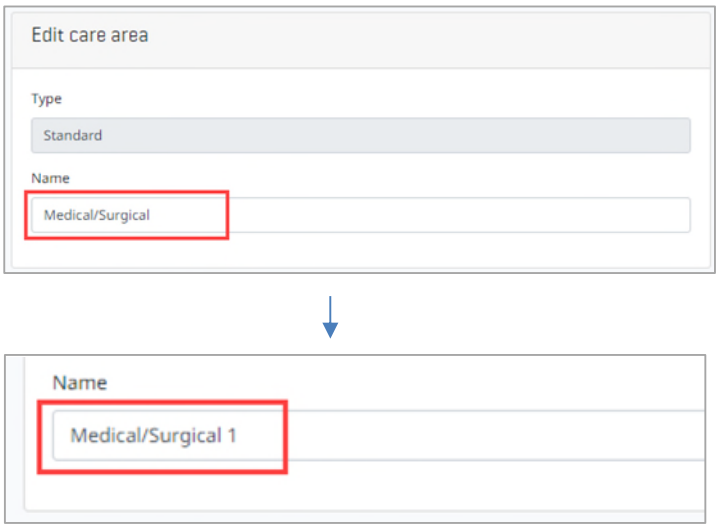

*Figure **3***

NOTE: For OR or Anesthesia, a space is required between the name OR or Anesthesia and the new character. (E.g. OR 1, or Anesthesia 1)

d) Next, select the **LVP settings** tab (*See Figure 4*)
e) View the **Threshold for air in line detection** setting. (*See Figure 4*)
Note: The value of **100 µL** will be displayed. (*See Figure 4*)

f) From the dropdown menu, select the required threshold if different from the displayed **100 µL** (*See Figure 4*)

g) Click **Update** to confirm and save setting (*see Figure 4*)
NOTE: Repeat steps iv a) to g) for each Care Area that may be affected.

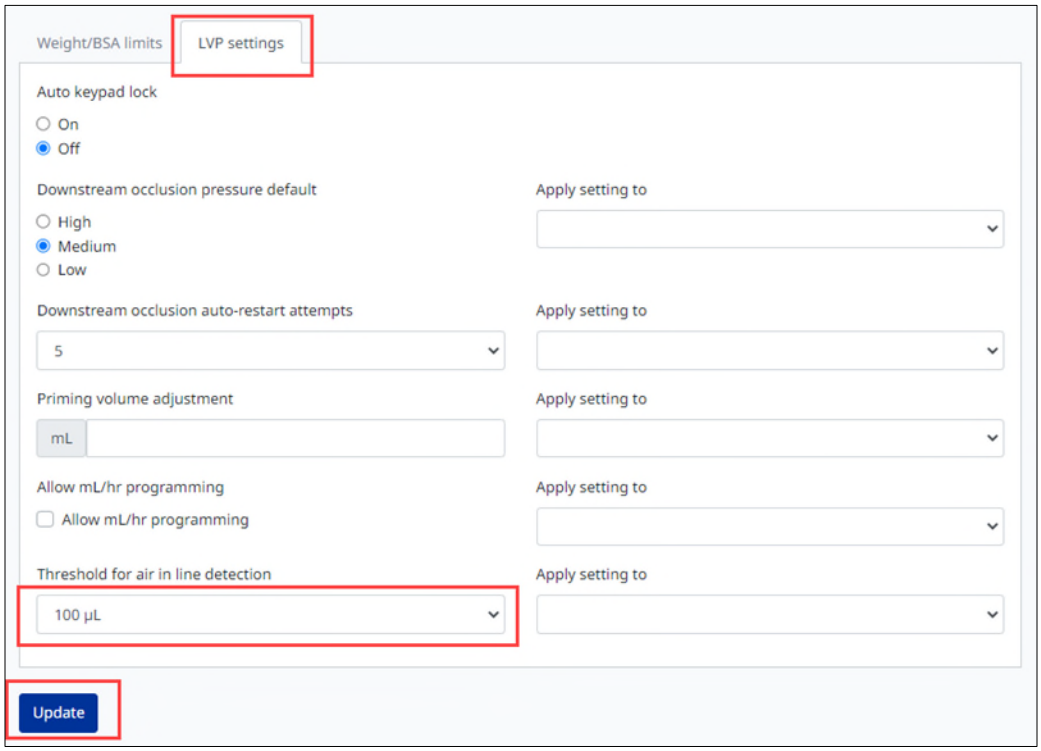

Figure 4

h) Next, follow the steps to generate a new BDL file using the **BDL Exports** function from the **Dashboard** page.
i) Review the Clinical Validation Report (see Step ii above) and confirm the **Threshold for air in line detection (µL)** values are correct for all care areas and no blanks are observed.

j) Create the new BDL file

k) **Transfer the new BDL file** to all infusion pumps in your hospital fleet.
Note: The new BDL file must be transferred to all pumps to resolve this issue.

2. **When creating a Care Area in the future:**
    a) Upon creating the new Care Area name, select **Edit care area** button within the new Care Area. (*See Figure 5*)

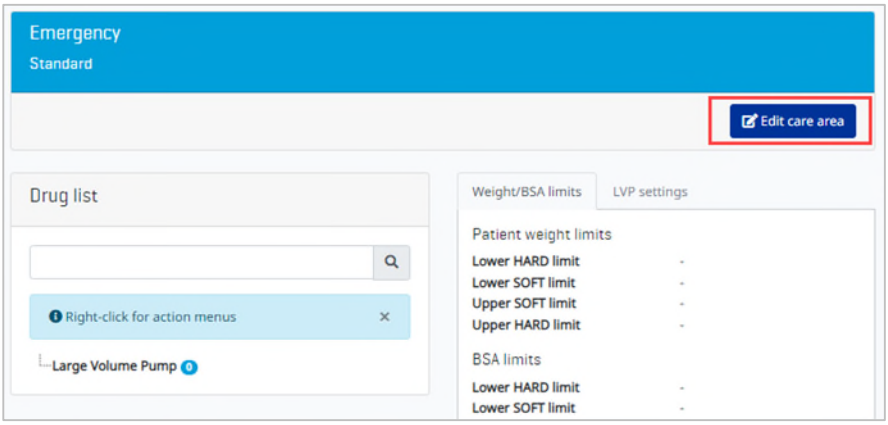

Figure 5

    b) Next, select the **LVP settings** tab (*see Figure 6*)
    c) View the **Threshold for air in line detection** setting. (*See Figure 6*)
    d) From the dropdown menu, select the required threshold if different from the displayed **100 µL** (*see Figure 6*)
    e) Click **Update** to confirm and save setting (*see Figure 6*)

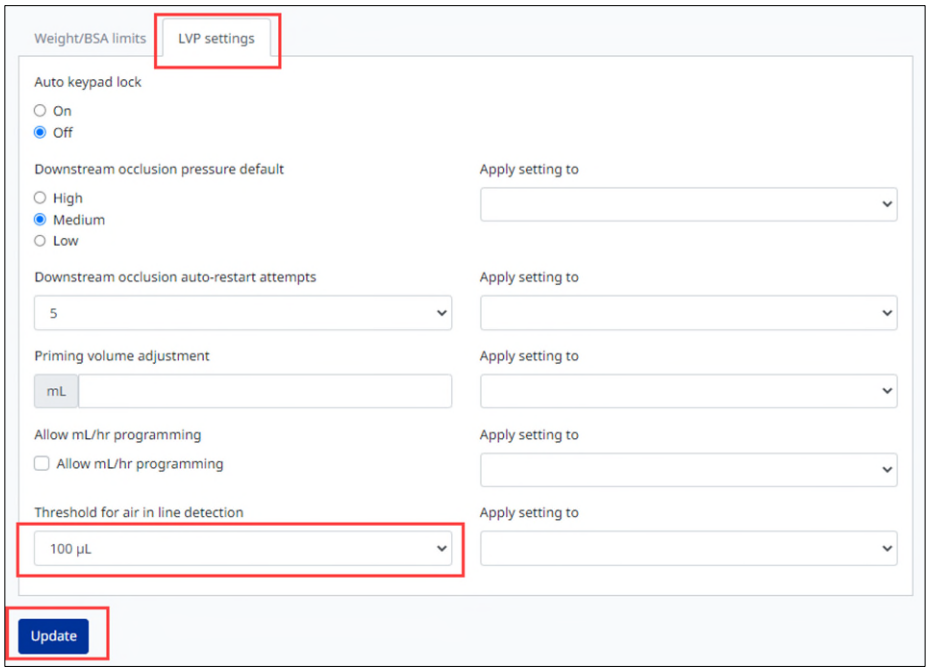

Figure 6

3. When the software upgrade becomes available, a local Baxter representative will contact your facility. 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 affected Dose IQ Safety Software.

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 share the Dose IQ Safety Software with other facilities or departments within your institution, please forward a copy of this communication to them.

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