Urgent Field Safety Notice

Evo IQ Large Volumetric Pumps (LVP)
FA-2024-065
Manufacturer: Baxter Healthcare SA (BHSA) (Single Registration Number: CH-MF-000026124)
Type of Action: Correction

November 2024

Dear Healthcare Provider

Problem Description

Baxter Healthcare Corporation is issuing an Urgent Medical Device Correction for EVO IQ Large Volumetric Pumps (LVP) listed below due to a potential issue with occlusion alarms not being triggered. This issue occurs after a downstream occlusion (DSO), or upstream occlusion (USO) initially alarms during an infusion, and the clinician tries to troubleshoot the alarm by opening the door, assessing the IV tubing, and closing the door without resolving the occlusion. This will cause the pump to re-baseline the occlusion pressure and future occlusion alarms may be delayed. Additionally, if the user opens and closes the door multiple times without resolving the initial triggered occlusion, it will eventually result in the alarm not being triggered but the pump will continue to appear that it is infusing. In addition, for DSO alarms when the pump door is closed the dynamic infusion pressure display on the pump screen will reset to show no pressure or less pressure is built up in the line (since it was reset when the pressure sensor re-baselined when the pump door was closed).

Baxter is developing a software update and will contact all customers to upgrade the pumps once the upgrade is available.

Affected Product

Product Code	Description	Lot Number	GTIN Number
ELVP001GRC	EVO IQ LVP GRC	All	05413765584831
ELVP001UKI	EVO IQ LVP UKI	All	05413765574412

Hazard Involved

If an upstream or downstream occlusion alarm occurs and is not properly resolved, the issue described above could lead to a delay in therapy, interruption of therapy, and insufficient therapy. Serious adverse health consequences may occur if the patient does not receive the intended dose of the prescribed medication. The resulting harm would depend on multiple patient- and therapy-related factors, the infusion settings, the duration of the delay or interruption, and the magnitude of the underdose. To date, there have been two complaints reported associated with this issue, however, there have been no reports of serious injury associated with this issue.

Action to be taken by the user

Baxter is kindly asking that you take the following actions:

1. Customers can continue to use the impacted EVO IQ LVPs while following the Operator's Manual and ensuring proper resolution of an occlusion. The EVO IQ LVP pump will operate as intended when the USO/DSO is cleared, this issue only occurs when the USO/DSO is not cleared. Details related to occlusions are already contained in the Operator's Manual under the following sections:
    - For pressure setting selection guidelines, refer to section 6.2.1, "Occlusion Pressure".
    - Guidelines for downstream occlusion resolution can be found in section 9.3, "Resolving a Downstream Occlusion Alarm" and section A.3, "Occlusion Alarms" for time to occlusion alarm.
    - An electronic copy of the Operator's Manual can be accessed at https://service.baxter.com/tsportal/

Users should also monitor the drip chamber when restarting any infusion to observe for drops as stated in Section 4. General Options "Checking the Flow". If drops are not observed, the user should stop the pump and look for potentially unresolved occlusions (upstream or downstream depending on the preceding alarm that resulted in the opening of the door).

Per standard clinical practice, users should continue to monitor the "Volume To Be Infused" and the volume delivered while therapy is in progress. This is especially true after a downstream occlusion has occurred to observe for mismatches between the volume the pump says is delivered and the amount actually removed from the IV bag. If the total dose is not delivered upon the "VTBI Complete" alarm, users should check the set-up for occlusions and if none, reprogram the pump and deliver the remaining volume as necessary.

2. A Baxter representative will contact your facility when the correction becomes available.

3. Complete the enclosed customer reply form and return it to Baxter by either faxing it or scanning and e-mailing, or sending it by post, even if you don't have any inventory. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.

4. 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

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

6. 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 Correction in accordance with your customary procedures.

Further information and support	For general questions regarding this communication or any product issue you are experiencing, contact Baxter.

We apologize for any inconvenience this may cause you and your staff.

Sincerely,

Baxter Healthcare Corporation