Baxter

EVO IQ Large Volumetric Pump
FA-2020-033

Urgent Field Safety Notice

16th July 2020

Dear Sir/Madam,

Affected Product

Product Code	Product Description	Software Version	Serial Number
ELVP001UKI	EVO IQ LVP	All versions below V01.02.00.04	All

Problem Description

Baxter Healthcare Corporation is issuing a Device Correction for the EVO IQ Large Volumetric Pump (LVP) due to a software error which affects the optional drug modifier feature. The error occurs when multiple drugs within a care area start with the same first letter and have the same exact drug modifier names. If these conditions exist, when one of these drugs are selected on the pump, the available options displayed within that modifier (concentrations, dose modes, etc.) are for multiple drugs, and it is not clear to the user that some of the selections available do not apply to the drug that has been selected. This may lead the user to select a drug set-up or concentration that should not be available for the intended drug. Baxter will be upgrading all pumps to software version V01.02.00.04 or higher to correct this issue.

Hazard Involved

This software error could lead to a delay in therapy if the clinician is confused by the available options on the display screen and attempts mitigation measures. Additionally, selecting an incorrect concentration or dose mode for the intended medication may result in either excessive or insufficient therapy. Potential risk to the patient resulting from excessive, insufficient, or delay of therapy is dependent on various factors, including the medication being infused, the volume and rate of the infusion, the route of administration, patient status and comorbidities. Also, if the incorrect concentration or dose mode is chosen, it may result in the incorrect drug library limits being applied for the selected drug which may not provide the intended safety limits that were set up for that drug. Depending on these factors, the patient may experience serious adverse health consequences. There have been no reports of patient injury or customer complaints related to this issue.

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Baxter is kindly asking that you take the following actions:

Action to be taken by the user

1. Operators may continue to safely use the EVO IQ LVP infusion system until the software upgrade is performed. If the optional feature of drug modifiers is implemented at your facility, please do not set up the same drug modifier for drugs with the same starting letter within the same care area. To review the modifiers in a current drug library, generate a Clinical validation report in the Dose IQ software and review each Care Area, and drugs within each Care Area that are using Modifiers. If modifiers are used, review the modifier name(s) and associated drug names and determine if same modifier names are used for drug names starting with the same letter. If this condition exists, edit the modifier name(s) to ensure they are unique.

2. Should you wish to discuss your current pump configuration, make changes to you current pump configuration or discuss any further details please contact our delegated pharmacist, Dilan Patel on dilan_patel1@baxter.com.

3. Please follow the Instructions for Use (IFU) section 4.1 and do not operate the pump until the pump settings, including drug/concentration, dose mode, dose rate, and time for each drug are checked and confirmed to be correct.

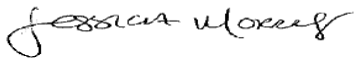
4. A local Baxter service representative will contact your facility to determine the correction plan and schedule the software upgrade. Your facility will be receiving this upgrade from Baxter at no charge.

5. **Please complete the enclosed Baxter customer reply form and return it to Baxter by scanning and e-mailing it to qa_dublin@baxter.com even if you do not have any inventory**. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.

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

We apologise for any inconvenience this action may cause. Should you have any queries, please contact Baxter Dublin Customer Services at shs_customer_services_dublin@baxter.com or phone 01 206 5500.

Yours sincerely,



Jessica Morris
QA Specialist / Responsible Person

Attachment 1: Customer Reply Form