Baxter

Urgent Field Safety Notice

EVO IQ Large Volumetric Pump
FA-2020-066
Device Correction

January DD, 2021 *(to be adapted locally)*

Dear Sir/Madam

Affected Product

Product Code	Product Description	Software version	Serial Number
ELVP001UKI	Evo IQ LVP UKI	All versions below V01.04.00.01	All

Problem Description

Baxter Healthcare Corporation is communicating important safety information regarding the administration set loading process for the EVO IQ Large Volumetric Pump (LVP). If the operator incorrectly loads the set into the pumping channel at the site of the pumping mechanism (see Figure 1 below) and fails to follow the operator's manual and on-screen instructions to confirm that drops are falling in the drip chamber, the pump will display that the infusion is running as normal; however, the set may be occluded by the ribs (at the site of the pumping mechanism) and fluid may not be flowing. There is no alert or alarm to notify the user that the pump is not actually infusing.

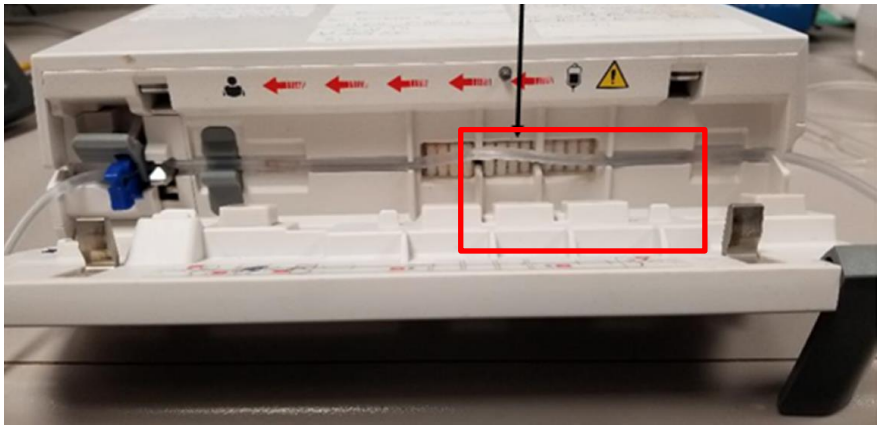

Figure 1. Picture of incorrect set loading across pumping segment

The pump should only be operated by trained personnel. Instructions on how to load the IV set and check for flow at start of the infusion can be found in Section 4.4 of the EVO IQ LVP Operator's Manual (Part # 0719000907E1.

The EVO IQ LVP has a check flow screen requiring the operator to confirm fluid drops are falling in the IV set drip chamber after they have initiated the infusion. The EVO IQ LVP Operator's Manual, Section 4.4, provides step-by-step instructions to correctly load an infusion set and start the infusion. Figure 2 below illustrates correct set loading to ensure the IV set is taut in the tubing channel before closing the door and starting the infusion. Please refer to the enclosed Attachment A for a copy of section 4.4 of the Operator's Manual.

Figure 2. Picture of correct set loading across pumping segment

Baxter will be working with all customers to upgrade the pump software to version V01.04.00.01 or higher to correct this issue. The new software includes an instructional screen to remind the user to check that tubing is inserted correctly through the pumping fingers if no drops are observed (see Figure 3 below).

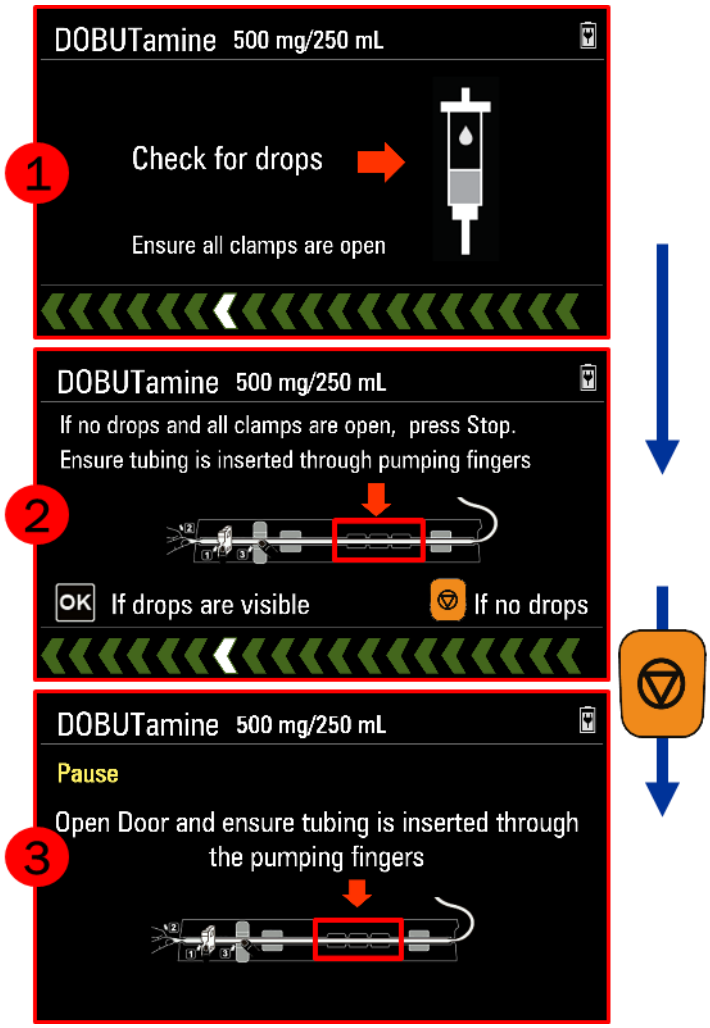

Figure 3. NEW Primary Check Flow Screens

A design review will be completed to determine future updates.

Hazard Involved

If the tubing is not loaded correctly, the hazardous situation of non-delivery of the intended medication may occur. Baxter has received three 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. Operators may continue to safely use the EVO IQ LVP infusion system by following the instructions for use (IFU) within the Operator's Manual and on-screen instructions for correct set loading, and by confirming fluid drops are falling in the IV set drip chamber after initiating the infusion (section 4.4 of the Operator's Manual, see attachment A).

2. 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.

3. **Complete the enclosed Baxter Customer Reply Form and return it to Baxter by faxing it 01635 206034 or scanning / taking a photo and e-mailing it to UK_SHS_FCA@baxter.com.** 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 return it to the supplier according to their instructions.

Further information and support

For general questions regarding this communication, contact Baxter at uk_shs_fca@baxter.com.

Any adverse reactions or quality problems experienced with the use of these products may be reported using one of the following options:

Reporting product quality complaints:

- Call: 01604 704 603
- Fax: 01604 704 688
- Email: uk_shs_qa_complaints@baxter.com

Reporting adverse events with drugs:

- Call: 01635 206 360
- Fax: 01635 206 281
- Email: vigilanceuk@baxter.com

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

Sincerely,

Michael Little
National Sales Manager – Infusion Devices Team
Baxter Healthcare

Attachment 1: Customer Reply Form

Baxter

Confirmation of receipt of communication

(DEVICE CORRECTION LETTER DATED

EVO IQ Large Volumetric Pump
Product code: ELVP001UKI
Serial numbers: All ***(to be completed locally)***
Software version: All versions below V01.04.00.01

Please complete and return one copy of this form per facility by e-mail uk_shs_fca@baxter.com) or Fax (01635 206034) as confirmation that you have received this notification.

A fax cover sheet is not required.

Facility Name and Address:	
Reply Confirmation Completed By: *(Please print name)*	
Title: *(Please print)*	
Email and/or Telephone Number (including Area Code):	

Signature/Date: REQUIRED FIELD	_____

We have received the above-mentioned letter, performed the actions outlined in the letter, and have disseminated the information / documentation to our staff, other services/facilities and customers, as applicable.