Baxter

Urgent Field Safety Notice

COLLEAGUE PUMP, EVO IQ LVP, EVO IQ SYR
FA-2021-008
Safety Alert

March 2021

Dear Sir/Madam,

Problem Description

The COVID-19 pandemic has resulted in clinical practice changes to address care of patients infected with SARS-CoV-2. Specifically, intravenous (IV) infusion pumps have been moved into the hallways outside of patient rooms, resulting in the use of multiple extension sets distal to the infusion pump. This practice was noted and communicated to the industry by an article titled Clinical Experiences Keeping Infusion Pumps Outside the Room for COVID-19 Patients | Institute for Safe Medication Practices on the ISMP website dated April 2020. The article can be found at https://www.ismp.org/news/ismp-second-newsletter-special-edition-focuses-infusion-pump-extension-sets-conserve-ppe.

In response to these clinical practice changes, Baxter is communicating important safety information regarding the practice of using multiple extension sets with infusion pumps listed in the affected product section of this letter. Increasing the length of IV tubing between the pump and the patient will result in varying increases in outlet pressure and/or decreases in intake pressure, which could lead to unknown and undetectable reductions in forward flow and flow rate accuracy.

Hazard Involved

Clinicians should be advised that the use of multiple extension sets may lead to flow rate or titration inaccuracies which may subsequently result in over infusion, under infusion, delay or an interruption in therapy. Any potential harm to the patient would depend on several factors such as length of delay or interruption in therapy, the volume and rate of the infusion, patient status, and comorbidities. In order to support flow rate accuracy and ensure that patients are receiving the expected medication dosing, the IV pump system and infusion bags should be at the proper heights relative to the patient and to one another, as specified in the product-specific Operator's Manual. To date, Baxter has received one report of serious injury related to the use of multiple extension sets and improper hanging height.

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Additionally, use of multiple extension sets could increase the opportunity for accidental disconnections and could result in infusion of contaminated IV fluids and/or blood loss. Any potential harm to the patient from such accidental disconnections would depend on several factors, such as the type and content of the IV fluid, type of IV access, and whether contamination occurs before or at the point of care.

Baxter is dedicated to supporting clinicians who are on the front lines treating COVID-19 patients. **To mitigate these risks, users must follow the warnings and instructions listed in the product-specific Operator's Manuals in the enclosed Attachment A; otherwise, serious patient harm may occur.**

Affected Product (to be adapted locally)

Product Family	Product Code	Serial Numbers
COLLEAGUE SINGLE CHANNEL	Refer to Attachment B	All
COLLEAGUE SINGLE CHANNEL CXE		
COLLEAGUE SINGLE CHANNEL MONO		
COLLEAGUE TRIPLE CHANNEL		
COLLEAGUE TRIPLE CHANNEL CXE		
COLLEAGUE TRIPLE CHANNEL MONO		
EVO IQ LVP		
EVO IQ SYR		

Action to be taken by the user

Baxter is kindly asking that you take the following actions:

1. Operators may continue to safely use Baxter infusion pumps according to the warnings and instructions in the product-specific Operator's Manual. An electronic copy of the Operator's Manual for each affected product can be accessed at https://service.baxter.com (to be adapted locally).

2. Complete the enclosed customer reply form and return it to Baxter by either faxing it to (insert local contact information) or scanning and e-mailing it to (insert local contact information) or sending it by post to (insert local contact information), 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.

3. Please forward a copy of this letter to other facilities or departments within your institutions to ensure that those locations are aware of this action.

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 are a dealer, wholesaler, or distributor/reseller that distributed any product to other facilities, please notify your customers of this communication in accordance with your customary procedures.

Further information and support (to be adapted locally)	For general questions regarding this communication, contact Baxter at (insert local contact information), between the hours of (insert local information).

The local Ministry of Health (MOH) has been notified of this action. (to be adapted locally)

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

Sincerely,

Name (to be adapted locally)
Title (to be adapted locally)
Baxter Healthcare Corporation (to be adapted locally)

Enclosure:

Attachment A: Baxter Infusion Pumps – Operator's Manual Excerpts (to be adapted locally)

Attachment B: Affected Product Codes (to be adapted locally)

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CUSTOMER REPLY FORM

(SAFETY ALERT DATED XXXXXX (TO BE COMPLETED LOCALLY)

Product Name: (to be adapted locally)
Product code: (to be adapted locally)
Batch Number: (to be adapted locally)

Please complete and return one copy of this form per facility either by fax (Fax :_____) or by e-mail (_____) as confirmation that you have received this notification.

A fax cover sheet is not required. ***(Can be adapted locally)***

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

☐ We have received the above-mentioned letter and have disseminated this information to our staff, other services and facilities.

☐ We have received the above-mentioned letter and have disseminated this information to customers/Home Patients. ***(to be adapted locally)***

☐ We have received the above-mentioned letter and we ask Baxter to disseminate this information to customers/Home Patients. ***(to be adapted locally)***

Signature/Date: REQUIRED FIELD	

Your signature above indicates understanding of the contents of the attached letter, that you performed the actions outlined and disseminated this information, if applicable.