

Urgent Field Safety Notice

COLLEAGUE PUMP, EVO IQ LVP, EVO IQ SYR

FA-2021-008

Safety Alert

Month DD, YYYY (to be adapted locally)

Dear Sir/Madam (to be adapted locally),

**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> (to be adapted locally).

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.

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 [\(to be adapted locally\)](#)



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

Attachment A: Baxter Infusion Pumps – Operator’s Manual Excerpts

(to be adapted locally)

Product Family	Operator’s Manual Excerpts																																
Colleague	<p>(Page 8-9) (to be adapted locally): WARNING</p> <p>There is a risk of under-infusion if a downstream occlusion occurs while an air bubble, 1.9 cm (0.75 inch) or larger, is within the pumping mechanism between the upstream occlusion sensor and the downstream occlusion sensor, but not under the Air in Line sensor. In this particular situation, the pump may not detect air in the line or the downstream occlusion and may continue to pump without delivering medication or alarming.</p> <p>Page 9-3) (to be adapted locally): Technical Specifications</p> <table><tr><th>Component</th><th colspan="4">Description</th></tr><tr><td rowspan="4">Nominal Downstream Occlusion Values for Alarm</td><td colspan="4">Downstream Occlusion Alarm sensitivity is a configurable option.</td></tr><tr><td colspan="4">Rate range in mL/hr</td></tr><tr><td><21</td><td colspan="2">21-200</td><td>>200</td></tr><tr><td>103 mmHg (2 psig)</td><td>207 mmHg (4 psig)</td><td>310 mmHg (6 psig)</td><td>Minimum</td></tr><tr><td></td><td>258 mmHg (5 psig)</td><td>414 mmHg (8 psig)</td><td>569 mmHg (11 psig)</td><td>Moderate</td></tr><tr><td></td><td>465 mmHg (9 psig)</td><td>620 mmHg (12 psig)</td><td>775 mmHg (15 psig)</td><td>Maximum</td></tr></table> <p>(Page 9-7) (to be adapted locally): WARNING</p> <p>Rate accuracy can be affected by variations of fluid viscosity, fluid temperature, head height, or back pressure, or any combination thereof. Additional factors that may influence rate accuracy are administration set configuration and the duration of time the administration set is used.</p>	Component	Description				Nominal Downstream Occlusion Values for Alarm	Downstream Occlusion Alarm sensitivity is a configurable option.				Rate range in mL/hr				<21	21-200		>200	103 mmHg (2 psig)	207 mmHg (4 psig)	310 mmHg (6 psig)	Minimum		258 mmHg (5 psig)	414 mmHg (8 psig)	569 mmHg (11 psig)	Moderate		465 mmHg (9 psig)	620 mmHg (12 psig)	775 mmHg (15 psig)	Maximum
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EVO IQ LVP	<p>Page 1-6 (to be adapted locally): Compatible IV Sets Use of unapproved administration sets can impact the delivery of an infusion. Unapproved sets can cause inaccuracy to properties of an infusion including, flow rate, occlusion detection, or air in line detection.</p> <p>Page A-8 (to be adapted locally):</p> <table><tr><th></th><th>Flow Rate Range</th><th>Accuracy</th></tr><tr><td></td><td>0.1 – 100 mL/h</td><td>±5%*</td></tr><tr><td></td><td>100.1 – 1200 mL/h</td><td>±7.5%*</td></tr></table> <p>*For any one hour period or 0.5 ml delivery (whichever is larger in volume), over 72 hours or maximum 3 liters (maximum volume recommended over a continuous infusion) at least 85% of the observed values (95% confidence) will lie within the limits shown for the indicated settings.</p> <p>Standard conditions:</p> <ul style="list-style-type: none">Ambient temperature: 22°C ± 2°C (71.6°F ±3.6°F)Solution container height: ±508 mm (+20 inches), ±50 mm (±1.97 inches)Distal positive pressure: 0 mmHg <p>The Evo IQ Large Volume Pump will maintain a flow rate volumetric accuracy as listed in table above, when used at the standard environmental conditions as described. The Evo IQ Large Volume Pump should be used at standard conditions whenever possible. If used at non-standard environmental conditions that extend beyond the standard environmental conditions as described above, the flow rate volumetric accuracy may deviate beyond the nominal flow rate volumetric accuracy. The impact of back pressure and environmental temperature on flow rate accuracy is shown in Table A-12 on page A-7 with result based on 25 mL/h flow rate.</p> <p>Page A-9 (to be adapted locally):</p>		Flow Rate Range	Accuracy		0.1 – 100 mL/h	±5%*		100.1 – 1200 mL/h	±7.5%*																							
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Attachment A: Baxter Infusion Pumps – Operator’s Manual Excerpts

(to be adapted locally)

	Time to detect a Downstream Occlusion and a Bolus Volume release will generally increase under the following conditions: longer distances to the occlusion point, additional fluid volumetric area (from filter or other components within the IV set length), hotter room temperatures and higher Downstream Occlusion Pressure Thresholds or Limits.
EVO IQ SRY	<p>Page 1-7 (to be adapted locally): CAUTION Use only administration sets that have an appropriate pressure rating that is greater than the Occlusion Detection setting chosen for the infusion. This may be indicated by the P symbol on the administration set labeling as defined by standard ISO 8536-9, Infusion Equipment for Medical Use - Part 9: Fluid Lines for Single Use with Pressure Infusion Equipment. The accuracy claim in Evo IQ SYR IFU related trumpet curve are made through clearly demonstration of set that was used to obtain the accuracy curve. The impact of distal back pressure on flow rate accuracy was demonstrated in Table A-13.</p> <p>Page A-11 (to be adapted locally): Note Occlusion alarm pressure, alarm delays, and bolus volume may vary depending on test conditions, temperature, and occlusion tube length. Operating the device above the standard test temperature or with longer IV set lengths will cause the time to occlusion alarm to increase.</p>

Attachment B: Affected Product Codes

(To Be Adapted Locally)

Product Family: Colleague P1.7

Product Code	Product Description
2M81517	COLLEAGUE SINGLE CHANNEL MONO
2M81517K	COLLEAGUE SINGLE CHANNEL MONO
2M81537K	COLLEAGUE TRIPLE CHANNEL MONO
2M91617	COLLEAGUE SINGLE CHANNEL CXE
2M91617A	COLLEAGUE SINGLE CHANNEL
2M91637	COLLEAGUE TRIPLE CHANNEL CXE
2M91637A	COLLEAGUE TRIPLE CHANNEL
BRM81517	COLLEAGUE SINGLE CHANNEL MONO
BRM81537	COLLEAGUE TRIPLE CHANNEL MONO
BRM91617	COLLEAGUE SINGLE CHANNEL CXE
BRM91637	COLLEAGUE TRIPLE CHANNEL CXE
CNM81517	COLLEAGUE SINGLE CHANNEL MONO
CNM81537	COLLEAGUE TRIPLE CHANNEL MONO
DNM81517	COLLEAGUE SINGLE CHANNEL MONO
DNM81537	COLLEAGUE TRIPLE CHANNEL MONO
DNM91617A	COLLEAGUE SINGLE CHANNEL
DNM91637A	COLLEAGUE TRIPLE CHANNEL
GNM81517	COLLEAGUE SINGLE CHANNEL MONO
GNM81537	COLLEAGUE TRIPLE CHANNEL MONO
HNM81517	COLLEAGUE SINGLE CHANNEL MONO
HNM81537	COLLEAGUE TRIPLE CHANNEL MONO
PNM81517	COLLEAGUE SINGLE CHANNEL MONO
PNM81537	COLLEAGUE TRIPLE CHANNEL MONO
PNM91617	COLLEAGUE SINGLE CHANNEL CXE
PNM91637	COLLEAGUE TRIPLE CHANNEL CXE
WNM81517	COLLEAGUE SINGLE CHANNEL MONO
WNM81537	COLLEAGUE TRIPLE CHANNEL MONO

Product Family: EVO IQ LVP and EVO IQ SYR

Product Code	Product Description
ELVP001UKI	EVO IQ LVP UKI
ELVP001GRC	EVO IQ LVP GRC
ESYR001GRC	EVP IQ SYR GRC
ESYR001UKI	EVO IQ SYR UKI