

**Urgent Field  
Safety Notice****Colleague Infusion Pump  
FA-2021-006  
Device Correction**

16th March 2021

Dear Sir/Madam,

**Affected  
Product**

Product Code	Product Description	Serial Numbers
2M91617	COLLEAGUE SINGLE CHANNEL CXE	All
2M81517K	COLLEAGUE SINGLE CHANNEL MONO	
2M91637	COLLEAGUE TRIPLE CHANNEL CXE	
2M81537K	COLLEAGUE TRIPLE CHANNEL MONO	

**Problem  
Description**

Baxter Healthcare has identified that the Colleague P1.7 Large Volumetric Pump (LVP) Operator's Manual and Global Service Manual require updates to include flow rate accuracy claims for non-DEHP administration sets. The current flow rate accuracy claims in the manuals are specific to DEHP administration sets.

Baxter will be updating the Colleague P1.7 Operator's Manual and Global Service Manual to include an addendum, which defines the following requirements for flow rate accuracy specific to non-DEHP administration sets:

Flow Rate Range	DEHP Accuracy	Non-DEHP Accuracy
0.1 to 0.9 mL/hr	±10%*	±15%*
1.0 to 9.9 mL/hr	±7%**	±12%**
10.0 to 800 mL/hr	±5%**	±10%**
801 to 1000 mL/hr		±15%***

1001 to 1200 mL/hr		Not approved for use
<p>*for any one-hour period or for 0.5 mL of delivery. At least 90% of the observed values (95% confidence) will lie within the limits for the indicated settings.</p> <p>**for any one-hour period over 72 hours or 7.2L, whichever occurs first. At least 90% of the observed values (95% confidence) will lie within the limits for the indicated settings.</p> <p>***for any one-hour period over 3 hours. At least 80% of the observed values (95% confidence) will lie within the limits for the indicated setting.</p>		

**Standard Conditions:**

- Ambient Temperature: 23C +/- 2C
- Solution Container height: +508mm (+20 inches)
- Test Solution: Distilled water
- Distal positive pressure: 0 mmHg
- Needle: 18 gauge
- Set Types:
  - DEHP: 2C8537S
  - Non-DEHP: FNC3220N, 2H8537, EMC9608, AMC9667, MRC1012P, ABC1499

Note that flow fluctuations can be caused by unusual conditions or combinations of conditions that may involve, but are not limited to, the following: position of the infusion container, fluid density, positive and negative pressure and the environment. Flow fluctuations are most likely to occur when the conditions mentioned above are exacerbated or when the pump is operated in conditions outside of its normal limits. See the Component Description Table for details.

**!WARNING!**

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.

Baxter does not advise the use of non-DEHP administration sets with the Colleague P1.7 LVP for infusion rates of over 1,000 mL/hr. The Colleague LVP product codes affected by the Operator’s Manual and Global Service Manual updates are listed above (Affected Product Table).

**Hazard Involved**

Use of non-DEHP sets with Colleague P1.7 pumps may result in under infusion at flow rates above 1,000 mL/hr. The harm to the patient will depend on several factors such as the medication being infused, the volume and rate of the infusion, patient status, and comorbidities. To date, there have been no reports of patient injury associated with this issue.



**Actions to be  
Taken by  
Customers**

1. Operators may continue to safely use the Colleague P1.7 LVP with DEHP administration sets. When using non-DEHP administration sets, please be aware of the new flow rate accuracy claims and do not use non-DEHP sets for infusion rates of over 1,000 mL/hr. The new flow rate accuracy label claims are based on testing performed using administration set product codes FNC3220N, 2H8537, EMC9608, AMC9667, MRC1012P, ABC1499. As indicated in the warning statement above, rate accuracy can be affected by a variety of factors including administration set configuration. **Baxter is currently evaluating the impact of additional administration set configurations with the Colleague P1.7 LVP which utilize non-DEHP pump tubing (Please refer to Attachment A for a list of these sets).**
2. Baxter will be updating the Colleague P1.7 Operator's Manual and Global Service Manual to include an addendum, which defines the requirements for flow rate accuracy specific to non-DEHP administration sets. **Please indicate in the Customer Reply Form attached whether you still have this product and require the addendum.**
3. Once the updated Manuals are made available, **Baxter will issue a written notification to inform all customers who have declared they still use this product** that it is available and how to access the addendum on the Baxter Technical Services Portal.
4. **If you purchased this product directly from Baxter, complete the enclosed Baxter Customer Reply Form, scan and return it to Baxter by e-mailing qa\_dublin@baxter.com.** Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.
5. 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.
6. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.
7. 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 Urgent Medical Device Correction in accordance with your customary procedures.

**Further  
information and  
support**

For general questions regarding this communication, contact Baxter Dublin Customer Services at shs\_customer\_services\_dublin@baxter.com or phone 01 206 5500.



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:

- Email: [shs\\_complaints\\_dublin@baxter.com](mailto:shs_complaints_dublin@baxter.com)

Reporting adverse events with drugs:

- Email: [vigilanceuk@baxter.com](mailto:vigilanceuk@baxter.com)

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

Sincerely,

A handwritten signature in black ink, appearing to read 'Michael Little', is positioned above the typed name.

Michael Little  
National Sales Manager – Infusion Devices Team  
Baxter Healthcare

**Enclosures:**

Attachment 1: Customer Reply Form

Attachment 2: Attachment A: Baxter Non-DEHP Administration Pump Set Configurations