Baxter

Urgent Field Safety Notice

Prismaflex Control Unit
FA-2020-006
Safety Alert

07 Apr 2020

Dear Healthcare Provider

Problem Description

Baxter Healthcare Limited is communicating important safety information regarding the use of connectors with the Prismaflex system. The use of connectors may prevent a secure connection between the return line and the patient's blood access device. To ensure a proper connection, users must follow the Prismaflex Operator's Manual, which lists the following warnings:

WARNING:

⚠ Always connect the return line directly to the blood access device. Do not connect additional devices between the return line and the blood access device. The use of additional devices, such as three-way valves, stopcocks, or extension lines, may impair return pressure monitoring. Their use can impede the detection of return disconnections, potentially resulting in severe blood loss.

WARNING:

⚠ During priming and operation, observe the system closely for leakage at joints and connections within the set. Leakage can cause blood loss or air embolism. If leakage cannot be stopped by tightening the connections, replace the set.

Affected Product

Product Code	Product Description	Serial Numbers
107493	Prismaflex Control Unit	All
113874		
114870		
955052		

Hazard Involved

Baxter Healthcare Limited cannot guarantee connectors will establish and maintain secure connections with Prismaflex sets. Additionally, use of connecting devices with the Prismaflex Control Unit could interfere with the ability of the Prismaflex Control Unit to accurately detect pressure drops in the blood circuit. As a result, vascular access disconnects may go undetected, leading to clinically significant blood loss and fatal exsanguination. Baxter Healthcare Limited has received two reports of serious injury and one report of patient death as a result of blood loss related to the use of a connecting device between the return line and the blood access device.

Actions to be Taken by Customers

1. Operators can safely use the Prismaflex Control Units when adhering to the product-specific Operator's Manual and Graphical User Interface.
2. **Complete the enclosed Baxter Customer Reply Form and return it to Baxter by either faxing it to 01635 206034 or scanning / taking a photo and e-mailing it to UK_SHS_FCA@baxter.com**, **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. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.
4. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.
5. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected product to other facilities, please distribute this notification to customers.

Further information and support

For general questions regarding this communication, email uk_shs_fca@baxter.com.

For any technical questions regarding these machines please contact ICON on 0808 100 3539.

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 704688
- 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 thank you for your attention to this important safety information.

Sincerely,

Sam Nickerson
Business Unit Head, Acute Therapies, UK and Ireland
Baxter Healthcare Ltd.

Enclosure:
Attachment 1: Baxter Customer Reply Form

Baxter

Confirmation of receipt of communication

*(DEVICE SAFETY ALERT **FA-2020-006**) 07 Apr 2020*

DEVICE NAME Prismaflex Control Unit
Product code: 107493, 113874, 114870 & 955052
Serial numbers: All

Please complete and return one copy of this form per facility either by fax (Fax: 01635206034) or by e-mail (uk_shs_fca@baxter.com) 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.