Baxter

Urgent Field Safety Notice

Prismaflex Control Unit, PrisMax
FA-2020-016
Safety Alert

07 Apr 2020

Dear Healthcare Provider:

Problem Description

We want to express our gratitude to you and your colleagues who are on the front lines of the Coronavirus (COVID-19) pandemic. We know this requires extraordinary courage and dedication to adapt to ever-changing challenges and that you are caring for patients in less than ideal circumstances.

We have received questions from clinicians who are exploring modifying their use of Baxter's PrisMax and Prismaflex Control units, in order to minimize exposure to COVID-19-positive patients. For example, clinicians may be using multiple extension lines to extend the length of the tubing set to allow placement of a PrisMax or Prismaflex Control unit outside of the patient's room. There are several significant risks that arise with this practice, which are detailed below in the Hazard Involved section of this letter (on Page 2). To mitigate these risks, users are asked to follow the setup instructions in the Graphical User Interface, as well as the warnings from the PrisMax and Prismaflex Operators Manuals as noted below; otherwise, serious patient harm may occur.

Prismaflex Operator's Manual,
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.

Prismaflex Operator's Manual,
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.

PrisMax Operator's Manual,
WARNING!
Always connect the return line directly to the blood access device. Do not connect additional devices between the return line and/or the blood access device. The use of additional devices, such as three-way valves, stopcocks, or extension lines, may impair return pressure monitoring, and cause damage to blood cells resulting in hemorrhage. Their use can impede the detection of return disconnections which can cause drug delivery inaccuracies and/or failures. The blood access needs to have the

ability to supply blood at the rate ordered and return the blood at the rate ordered without interruptions which will cause clotting.

Affected Product

Product Code	Product Description	Serial Numbers
107493	Prismaflex Control Unit	All
113874		
114870		
955052		
955558	PrisMax System	

Hazard Involved

The following hazards are associated with the use of multiple extension lines to allow placement of a PrisMax or Prismaflex Control unit outside of the patient's room: Baxter cannot guarantee that the use of multiple extension lines will establish and maintain secure connections with PrisMax and Prismaflex sets. The use of extension lines increases the risk of disconnections and interferes with the ability of the PrisMax or Prismaflex Control unit to accurately detect pressure drops in the blood circuit. As a result, vascular access disconnections may go undetected, leading to clinically significant blood loss and fatal exsanguination. Additionally, the use of extension lines increases the blood in the extracorporeal circuit. In the event of non-restitution or clotting of the circuit, this may lead to blood loss beyond what is tolerable for the patient. Other potential risks of multiple extension lines include hypothermia, air embolism, and infection. As of March 27, 2020, there have been no reports of serious injury related to this issue.

Actions to be Taken by Customers

1. Operators can safely use the PrisMax and 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 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 apologise for any inconvenience this may cause you and your staff.

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

Attachment 1: Baxter Customer Reply Form

Confirmation of receipt of communication

(DEVICE SAFETY ALERT 07 APRIL 2020)

DEVICE NAME Prismaflex Control Unit, PrisMax control unit
Product code: 107493, 113874, 114870, 955052 and 955558
Serial numbers: All

Please complete and return one copy of this form per facility either by fax (Fax: 01635 206034) 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.