Urgent Field Safety Notice

Prismaflex Control Unit
FA-2019-050
Device Correction

October XX, 2019 (to be adapted locally)

Dear Healthcare Provider:

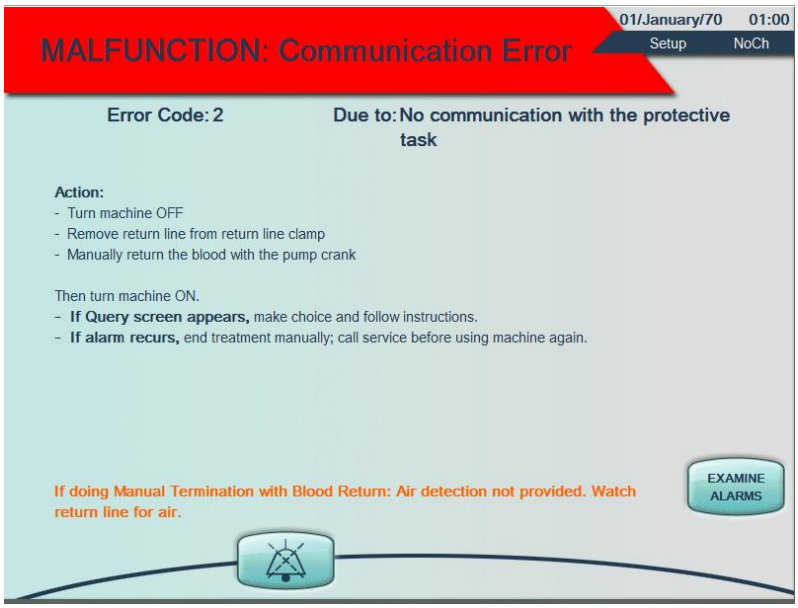
Problem Description

Baxter Healthcare will be upgrading the software on Prismaflex control units to reduce the frequency of communication error alarms. The product codes affected by this issue are listed on page 2. All units with software versions 7.20 and below will be upgraded to version 7.21 or higher, and all units with software versions 8.10 will be upgraded to 8.20* or higher (to be adapted locally). If the Prismaflex control units at your facility have already been upgraded to software version 7.21 or 8.20, please note that no upgrade is needed. Globally, Baxter has received complaints related to this issue at a rate of 1.4 alarms per 1,000 therapies.

**The upgrade of Prismaflex units from SW 8.10 to 8.20 is already in progress (reference # FA-2019-023)* (to be adapted locally)

The following actions occur during a communication error alarm:

- The Prismaflex control unit enters a “safe state” by stopping all pumps and closing the return line clamp. Treatment is suspended. The patient’s blood does not circulate through the blood flow path.
- Red flashing light
- Recurring high-pitched sound of 10 sound pulses repeated approximately every 8 seconds until muted.
- Malfunction screen appears on the display as pictured below. The instructions to the user are the same for all error codes.



Affected Product (to be adapted locally)

Product Code	Product Family
106913	Prismaflex System
107493	Prismaflex System
113082	PRISMAFLEX 4.11
113874	PRISMAFLEX 5.00 ROW
114489	PRISMAFLEX 6.10 ROW
114870	PRISMAFLEX 7.XX ROW
955052	PRISMAFLEX 8.XX ROW
6023014700	Prismaflex System

Hazard Involved

Serious injuries could occur due to communication errors if on-screen instructions are not followed. Communication error alarms may result in interruption of therapy, delay in therapy, or blood loss due to non-restitution of blood in the extracorporeal circuit. In the event of a communication error, the user is instructed to manually return blood in the extracorporeal circuit to the patient. **Baxter has received three adverse event reports in which the clinician's failure to return extracorporeal blood to the patient following a communication error alarm resulted in patient symptoms such as anemia and hypotension necessitating medical intervention.**

Actions to be Taken by Customers

1. Operators may continue to safely use the Prismaflex control units until the upgrade is performed. If a communication error alarm does occur, follow the instructions presented on the graphical user interface and/or in the operator's manual. Please reinforce the importance to manually return the extracorporeal blood to the patient, and re-train users on this process, outlined on page 10:57 (to be adapted locally) of the operator's manual, if necessary.

2. A local Baxter service representative will contact your facility to determine the correction plan and schedule the upgrade. Your facility will be receiving this upgrade from Baxter at no charge. (to be adapted locally)

3. **If you purchased this product directly from Baxter, 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.

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 distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.

6. 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 Medical Device Correction in accordance with your customary procedures.

Further information and support

For general questions regarding this communication, contact Baxter at (insert local contact information), between the hours of (insert local information).

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

Sincerely,

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

Enclosure: Baxter Customer Reply Form

Baxter

Confirmation of receipt of communication

*(DEVICE CORRECTION LETTER DATED XX **(to be completed locally)***

DEVICE NAME Prismaflex Control Unit
Product code: ***(to be completed locally)***
Serial numbers: ***…. (to be completed 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.
(to be adapted locally)

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.