Baxter

Urgent Field Safety Notice

11th May 2018

Dear Customer,

Problem Description

Baxter Healthcare will be installing new firmware on all Prismaflex control units to address the potential for a small number of these units to exhibit a failure mode with the pump module electronics. The failure mode may result in a "Voltage Out of Range" malfunction alarm, which causes the device to enter a "safe state" and become inoperable until it is serviced. Baxter will be releasing new firmware that will prevent the malfunction from occurring.

Affected Product

Product Code	Product family	Serial Numbers
955052	PRISMAFLEX 8.XX ROW	All
114870	Prismaflex 7.XX Row	All

Hazard Involved

The "Voltage Out of Range" malfunction alarm causes the Prismaflex control unit to enter a "safe state" by stopping all pumps and closing the return line clamp. This failure mode can occur at any time during use and may result in an interruption and/or delay in therapy. Patient harm is not expected as the blood may be manually returned to the patient. There have been no reports of serious injury associated with this issue.

Actions to be Taken by Customers

1. Operators may continue to safely use Prismaflex control units that have not exhibited the “Voltage Out of Range” malfunction alarm.
2. A local Baxter service representative will contact your facility to determine the correction plan and schedule the firmware upgrade. Your facility will be receiving this firmware upgrade from Baxter at no charge.
3. Complete the enclosed customer reply form, and return it to Baxter by either faxing it to 01 206 5577 or scanning and e-mailing it to ga_dublin@baxter.com or sending it by post to Baxter Healthcare Ltd., CQA, Unit 7 Deansgrange Business Park, Blackrock, Co. Dublin, A94 XD50. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.
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 notify your customers of this Urgent Field Safety Notice in accordance with your customary procedures.

Further information and support

For general questions regarding this communication, contact Baxter your local Baxter Representative.

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

The HPRA has been informed about this notice.

Sincerely,

Niamh Farrelly
CQA Manager
Baxter Healthcare
Unit 7 Deansgrange Business Park
Blackrock
Co. Dublin

Attachment: Customer Reply Form

Attachment: Customer Reply Form
URGENT DEVICE CORRECTION LETTER DATED 10TH MAY 2018

Product Family: Prismaflex

Product names: Prismaflex 7.XX Row, Prismaflex 8.XX Row

Product codes: 114870, 955052

Please complete and return one copy of this form per facility either by fax (01 206 5577) or by e-mail (qa_dublin@baxter.com) as confirmation that you have received this notification. A fax cover sheet is not required.

Customer Confirmation

We confirm that that we have have received the above mentioned letter, understood its content and have disseminated this information to our staff, other services and facilities.

Facility Name and Address: *(Please Print)*	
Product code and Serial Number of Machine	
Reply Confirmation Completed By: *(Please Print Name)*	
Title: *(Please Print)*	
Email and/or Telephone Number (Including Area Code):	
Signature/Date: ***REQUIRED FIELD***	_____/____/_____