Baxter

Urgent Field Safety Notice

07th March 2017

Dear Customer,

Problem Description

Baxter Healthcare is initiating a field action in order to update software versions of the Prismaflex Control Unit. Baxter has received reports of device operators failing to adhere to the instructions for use pertaining to the safe unloading of disposable sets from the Prismaflex Control Unit. These steps are required to safely disconnect the patient before proceeding to unload the filter set after treatment. If not followed, severe blood loss may occur with a potentially fatal outcome.

Affected Product

Product Code	Product Description	Serial Number
114489	Prismaflex 6.10 Row	All
114870	Prismaflex 7.XX Row	All

Note: Prismaflex Control Units with software version 8.10 already have these safety measures in place and do not need to be updated as part of this device correction.

Hazard Involved

Unloading of the disposable set without following the instructions and warnings on the Prismaflex Control Units may lead to severe blood loss and potentially fatal outcomes.

WARNING!
Unloading or removing the disposable set with the patient still connected will result in severe blood loss. Always ensure patient is disconnected from the disposable set before unloading or removing set from the control unit.

Since 2012, Baxter has received reports of six serious injuries and five patient deaths associated with this issue.

Actions taken by Baxter to avoid reoccurrence of the issue

Through this letter, Baxter is kindly reminding its customers that Prismaflex is designed with specific features to ensure that device operators safely disconnect the patient before proceeding to unload the filter set after treatment. Specific instructions provided in the Operator's manual and displayed on-screen require that, before proceeding with unloading the filter set, the operator must:

- Clamp all lines,

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- Disconnect Access and Return blood line from the blood access device, and
- Verify that all lines are clamped and the patient is disconnected

In addition, Baxter will be releasing an updated software version that will take additional measures to further ensure patient safety. An additional automated test will ensure the operator has clamped the Access and Return blood line. If lines are found not to be clamped, the unload sequence will be stopped and the operator will be notified with a device alarm.

Information and Instructions for the Users and Distributors

- Operators may continue to safely use the affected units by following the instructions provided in the Prismaflex Operator's Manual and the on-screen instructions when unloading the disposable set. Specifically, operators should ensure that all lines are clamped and the patient is disconnected before proceeding with unloading.
- A local Baxter service representative will contact your facility to determine the correction plan and schedule the software upgrade. Your facility will be receiving this software upgrade from Baxter at no charge.
- 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 QA_Dublin@baxter.com or sending it by post to Baxter Healthcare, QA Department, Unit 7 Deansgrange Business Park, Blackrock, Dublin. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.
- Please forward a copy of this letter as appropriate to ensure that all users are aware of this communication.
- If you are a dealer, wholesaler, or distributor/reseller distributing this product to other facilities, please notify your customers of this communication in accordance with your procedures.

Further information and support

For general questions regarding this communication please contact your Baxter Representative.

We apologise for any inconvenience this may cause you and your staff. Baxter's software version update will take additional measures to further ensure patient safety. Baxter is committed to ensuring our products and services consistently meet the highest standards of quality and safety for our patients and healthcare providers.

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The HPRA has been informed about this action.

Sincerely,

Ian Gavigan
Head of CQA UK/Ireland
Baxter Healthcare Ltd.
Deansgrange Business Park
Blackrock
Co. Dublin
Ph: 01 2065500

Attachment: Customer Reply Form

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URGENT DEVICE CORRECTION LETTER DATED 07TH MARCH 2017

Product Family: Prismaflex

Product names: Prismaflex 6.10 Row, Prismaflex 7.XX Row

Product codes: 114489, 114870

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***	_____/____/_____

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