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The Ministry of Health of the Republic of Armenian

March 07, 2017

Subject: Field Safety Notice – Device correction

Prismaflex Control Unit – Errors in Disconnecting Filter Set

Product Names: Prismaflex 7.XX Row

Product Codes: 114870

Serial Numbers: PA17262

Dear Sir/Madam,

Baxter Healthcare Corporation (ZAO Company «Baxter») 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.

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.

The affected units were distributed between 01/09/2016 and 01/11/2016.

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

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.

Prior to this software update and to ensure that the operators correctly unload the disposable set, Baxter is reminding its customers to follow the instructions provided in the Operator's manual, and displayed on screen, which are as follows:

1. Clamp all lines,

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

Our records indicate that 01 customer have received this product in the Republic of Armenian. For your information, please find attached the communication that is being sent to this customer.

Should you have any questions, please contact Natalia Rybalko,   +7(495) 647-68-07 or by e-mail: (CIS_quality@baxter.com).

Yours Sincerely,

Senior Manager
Country Quality Assurance, Russia/CIS
ZAO Company «Baxter»

Attachment 1: Customer letter

07 march 2017

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March 07, 2017

Dear Healthcare Provider,

Problem Description	Baxter Healthcare Corporation (ZAO Company «Baxter») 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
114870	Prismaflex 7.XX Row	PA17262

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

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set, the operator must:

1. Clamp all lines,
2. Disconnect Access and Return blood line from the blood access device, and
3. 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	1. 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.

2. 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.

3. Complete the enclosed customer reply form, and return it to Baxter by either faxing it to +7(495) 647 68 08 or scanning and e-mailing it to (CIS_quality@baxter.com) or sending it by post to: *ZAO Company «BAXTER» 16A/1, Leningradskoe shosse, 5th floor, Moscow, 125171 Russia*

   Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.

4. Please forward a copy of this letter as appropriate to ensure that all users are aware of this communication.

5. 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, contact Baxter for Service, Monday through Friday, between the hours of 9:00 AM and 18:00 PM Moscow Time or by e-mail: (CIS_quality@baxter.com) or by phone : +7(495) 647 68 07

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        We apologize 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.

The Ministry of Health of the Republic of Armenian has been informed about this action.

Sincerely,

Senior Manager
Country Quality Assurance, Russia/CIS
ZAO Company «Baxter»

07 March 2017

Attachment: Customer Reply Form

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Attachment: Customer Reply Form
URGENT DEVICE CORRECTION LETTER DATED 07 MARCH 2017

Product Family: Prismaflex

Product names: Prismaflex 7.XX Row

Product codes: 114870

> Please complete and return one copy of this form per facility either by fax : +7(495) 647 68 08 or by e-mail: (CIS_quality@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.

☐ We confirm that we have received the above mentioned letter, understood its content and have disseminated this information to our Customers

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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