Baxter

(SFDA Notification letter)

URGENT DEVICE CORRECTION

Follow-up Letter

June 27th, 2017

Subject: Field Safety Notice – Device correction

Prismaflex Control Unit – Follow-up Letter

Product Names: Prismaflex System, PRISMAFLEX 4.11, PRISMAFLEX 5.00 ROW and PRISMAFLEX 6.10 ROW.

Product Codes: 107493, 113082, 113874 and 114489.

Serial Numbers: All with SW version 6.10

Dear NCMDR Team,

On March 06th, 2017, Baxter Healthcare Corporation issued an Urgent Device Correction Communication in order to update software versions of the Prismaflex Control Unit due to 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. Baxter will be deploying a software update that will prevent such use errors from occurring.

The software update will also correct an issue with Prismaflex software version 6.10, in which the programmed syringe size and brand values for the syringe pump may revert to the "safe default" values of 50 ml-Terumo, when not intended by the operator (when exiting Service or Custom mode). The syringe pump which is used to deliver anticoagulants will automatically operate at the slowest possible relative plunger speed which may result in under-dosing for a 20 or 30 ml installed syringe. This could result in an under-infusion of Anticoagulants administered via the syringe pump, which may increase the risk of clotting of the extracorporeal circuit.

Operators may continue to safely use the affected Prismaflex monitors by following the instructions provided in the Prismaflex Operator's Manual and the on-screen instructions when programming the syringe which would ensure that this issue is detected during set up.

However, in order to ensure that all Operators of Prismaflex equipped with SW version 6.10 know how to handle potential syringe size setting issue that may occur until they have the upgraded SW version, Baxter is providing some instructions on how to best use the Custom mode.

شركة باكستر أيه جي. المكتب العلمي س.ت: ١٠١٠٢٠٦٥٦٦ هاتف ٤٣٤٣٧٠٠ (٩٦٦١١)، فاكس٤٣٤٣٧٧٧ (٩٦٦١١)
ص.ب٢٤٦٩٦٨ الرياض١١٣١٢- المملكة العربية السعودية
Baxter AG Scientific (Rep) Office, C.R. 1010206566 Tel: 966 11 434 3700 Fax: 966 11 434 3777
P.O.Box 246968 Riyadh 11312, Saudi Arabia

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Our records indicate that 01 customer (Our distributor Arabian Medical Marketing Co. (Nawah Healthcare)) received Prismaflex monitors with SW version 6.10 in Saudi Arabia. You can find attached the communication that is being sent to those customers.

Should you have any questions, please contact Ziad Awadallah at +966 11 4343 714.

Yours Sincerely,

Attachment 1: Draft Customer Letter.

شركة باكستر أيه جي. المكتب العلمي س.ت: ١٠١٠٢٠٦٥٦٦ هاتف ٤٣٤٣٧٠٠ (٩٦٦١١)، فاكس٤٣٤٣٧٧٧ (٩٦٦١١)
ص.ب٢٤٦٩٦٨ الرياض١١٣١٢- المملكة العربية السعودية
Baxter AG Scientific (Rep) Office, C.R. 1010206566 Tel: 966 11 434 3700 Fax: 966 11 434 3777
P.O.Box 246968 Riyadh 11312, Saudi Arabia

Attachment 1: Draft Customer Letter

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URGENT DEVICE CORRECTION

Follow-up Letter

June DD, 2017 *(to be adapted locally)*

Subject: Follow up Letter - Prismaflex Control Unit

Dear Healthcare Provider: *(to be adapted locally),*

On Month DD, 2017*(to be adapted locally)*, Baxter Healthcare Corporation issued an Urgent Device Correction Communication in order to update software versions of the Prismaflex Control Unit due to 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. Baxter will be deploying a software update that will prevent such use errors from occurring.
The software update will also correct an issue with Prismaflex software version 6.10 described here-after.

Problem Description

The Prismaflex System Control unit features modes where users and technicians can adjust treatment defaults, including syringe size and brand:

- Service Mode: for technicians (Syringe size)
- Custom Mode: for users (Syringe brand)

In Prismaflex software version 6.10, the programmed syringe size and brand values for the syringe pump may revert to the "safe default" values of 50 ml-Terumo, when not intended by the operator. **In the "safe default" setting, the syringe pump which is used to deliver anticoagulants will automatically operate at the slowest possible relative plunger speed which may result in under-dosing for a 20 or 30 ml installed syringe.**

Hazard Involved

This could result in an under-infusion of Anticoagulants administered via the syringe pump, which may increase the risk of clotting of the extracorporeal circuit.

Actions taken by Baxter to avoid reoccurrence of the issue

Baxter is currently upgrading the software version on the Prismaflex control unit. The issue described here-above being limited to software version 6.10, it is no longer encountered with the updated software. However, before the devices get upgraded, Baxter would like to provide its customers with the following instructions in order to avoid this unintentional reprogramming of the syringe brand and size when leaving Custom mode:

1. Press the "Syringe" button at the "Modify Defaults" main screen.

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2. In the "Syringe Size and Brand" screen, select syringe size and brand as required.

3. Then press the "Exit Custom" button to exit the Custom Mode.

After exiting Custom or Service mode, please follow the instructions below during set up:

1. Verify correct syringe brand and size during set up. This can be done either in the "Install Syringe", "Confirm Syringe Installation" or "Verify Setup" screens. This information is displayed on multiple occasions to make sure the settings are carefully checked against the syringe brand and size used.

2. If the settings do not match the syringe brand and size used, unload the set, reboot the machine, and return to the Prismaflex system startup screen.

3. Call your local Baxter service representative. Access to service mode is required to change syringe size; service mode is only accessible for authorized personnel.

If treatment has already begun prior to noticing that the syringe brand and size has defaulted to the manufacturing defaults, we recommend ending the ongoing treatment and calling Baxter technical service for further support at *(insert local contact information)*

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 programming the syringe which would ensure that this issue is detected during set up.

Baxter is kindly asking its customers to:

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

Attachment 1: Draft Customer Letter

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

3. 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 *(to be adapted locally)*

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.

The Local MOH *(to be adapted locally)* has been informed about this action.

Sincerely,

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

Attachment: Customer Reply Form

Attachment 1: Draft Customer Letter

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Attachment: Customer Reply Form

URGENT DEVICE CORRECTION – FOLLOW-UP LETTER DATED *XX (TO BE COMPLETED LOCALLY)*

Product name: Prismaflex System, PRISMAFLEX 4.11, PRISMAFLEX 5.00 ROW, PRISMAFLEX 6.10 ROW, PRISMAFLEX

Product code: 107493, 113082, 113874, 114489, 6023014700

Serial Numbers: all with SW version 6.10

Please complete and return one copy of this form per facility either by fax (_____) or by e-mail (_____) as confirmation that you have received this notification. A fax cover sheet is not required. ***(Can be adapted locally)***

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 ***(To be adapted locally - for Distributor only)***

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

