MEDICAL DEVICE CORRECTION

June 4, 2019

Dear Healthcare Provider:

Problem Description

Baxter Healthcare has received reports of Prismaflex 8.10 devices with inactive syringe pump during Continuous Renal Replacement Therapy (CRRT) treatment while using Regional Citrate Anticoagulation (RCA). It was determined that there is a potential for the calcium syringe pump to be inactive without the device alarming after a completed change syringe procedure.

Baxter will be upgrading all Prismaflex devices with software version 8.10 to software version 8.20. The new software version will include an enhancement to ensure alarm generation when the issue occurs while performing therapy using the RCA.

However, there is no similar complaint or AE reported in Singapore.

Affected Product (Singapore)

Product Code	Product Family	Serial Numbers
107493	Prismaflex System	All Devices with 8.10 Software
113082	Prismaflex 4.11	All Devices with 8.10 Software
114489	Prismaflex 6.10 ROW	All Devices with 8.10 Software
955052	Prismaflex 8.XX ROW	All Devices with 8.10 Software

Do note: There are other product codes/ models affected globally but not supply in Singapore. Kindly verify with Baxter if in doubt.

Hazard Involved

An inactive pump may result in under delivery of calcium leading to hypocalcemia. Hypocalcemia may potentially result in serious adverse health consequences. There have been two reports of serious injury associated with this issue.

However, there is no similar complaint or AE reported in Singapore.

Actions to be Taken by Customers

1. Clinicians may continue to safely use the Prismaflex devices while utilizing additional caution to ensure that the syringe pump operates as intended after the change syringe procedure, until the software upgrade can be performed. The best way to check if the calcium syringe is running is to listen to the system: the calcium syringe is working in micro bolus mode and not continuously. This means you will hear a low sound pulse from the syringe pump when moving. Additionally, all allowed syringe brands are graded meaning that expected movement over a given time period can be measured and verified. In case the operator identifies a non-moving syringe, a new change syringe procedure shall be performed.

2. Clinicians shall use appropriate syringes when using the Prismaflex device per the operator's manual. See section 15.6.2 Citrate – calcium method. Calcium compensation may need to be increased, depending on how long the calcium pump has been stopped, which is a clinical decision based on the patients ionized and total calcium levels.

3. A local Baxter service representative will contact your facility to arrange for the software upgrade for all Prismaflex devices with current 8.10 software. Your facility will be receiving this software upgrade from Baxter at no charge.

4. If you purchased this product directly from Baxter, Complete the enclosed customer reply form and return it to Baxter by scanning or email. Returning the customer reply form promptly will prevent you from receiving repeat notices.

5. 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 per their instructions.

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

The Health Sciences Authority has been notified of this action. If you have questions regarding this communication or if you have any other questions, please call your Baxter Sales Representative or e-mail to Priscilla Chow at [redacted]

Please kindly report any quality problems or any adverse events associated with the product to the following personnel:

- Please report Product Complaints to singapore_productcomplaint@baxter.com
- Please report Adverse Events to singapore_patientsafety@baxter.com

We sincerely apologize for any inconvenience this communication causes and thank you for your continued support. Baxter's firmware upgrade will take additional measures to further ensure patient safety.

Sincerely,

[redacted]

Corynn Tan
Senior QA Manager

cc: Chairman Medical Board and relevant Head of Departments
Enclosure: Baxter Customer Reply Form

CUSTOMER REPLY FORM

Medical Device Correction

Prismaflex SW 8.10

June 4, 2019

Affected Products:

Product Code	Product family	Serial Number
955052	PRISMAFLEX 8.XX ROW	All
107493	Prismaflex System	All
113082	Prismaflex 4.11	All
114489	Prismaflex 6.10 ROW	All

Please complete and sign this form.
Email a scanned copy to [redacted] or fax it to **+65-6222 9927** as a confirmation that you have received this notification. A cover sheet is not required.

Please ensure that all below information is completed. Responding to this request will prevent unnecessary repeat notifications for this issue.

Please note that ***BAXTER CANNOT PROCESS UNSIGNED FORMS.***

Completed By: _____ **Title:** _____
Print Name

Phone Number: _____

Signature: _____ **Date:** _____/_____/_____
Your signature above indicates understanding of the contents of the attached letter, that you performed the actions outlined and disseminated this information, if applicable.