Baxter

MEDICAL DEVICE CORRECTION

RE: Prismaflex Control Unit software upgrade

November 19, 2019

Dear Healthcare Provider:

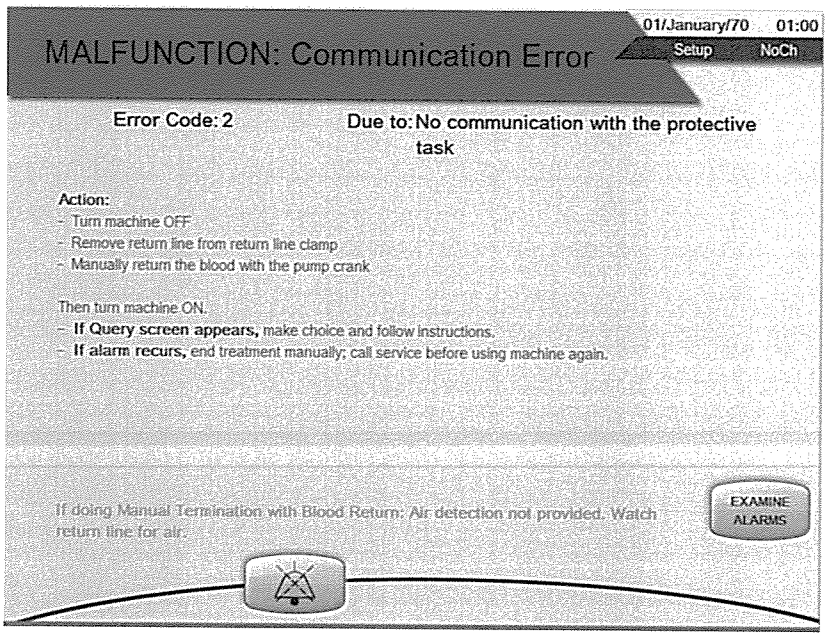
Problem Description

Baxter Healthcare will be upgrading the software on Prismaflex control units to reduce the frequency of communication error alarms. The product codes affected by this issue are listed on page 2. All units with software versions 7.20 and below will be upgraded to version 7.21 or higher, and all units with software versions 8.10 will be upgraded to 8.20* or higher. If the Prismaflex control units at your facility have already been upgraded to software version 7.21 or 8.20, please note that no upgrade is needed.

The upgrade of Prismaflex units from SW 8.10 to 8.20 is already in progress (reference # FA-2019-023- HSA 600:41/01-001/19/02_56). There is no software version below 8.10 in Singapore.

The following actions occur during a communication error alarm:

- The Prismaflex control unit enters a "safe state" by stopping all pumps and closing the return line clamp. Treatment is suspended. The patient's blood does not circulate through the blood flow path.
- Red flashing light
- Recurring high-pitched sound of 10 sound pulses repeated approximately every 8 seconds until muted.
- Malfunction screen appears on the display as pictured below. The instructions to the user are the same for all error codes.



Affected Product (Singapore)

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

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

Hazard Involved

Serious injuries could occur due to communication errors if on-screen instructions are not followed. Communication error alarms may result in interruption of therapy, delay in therapy, or blood loss due to non-restitution of blood in the extracorporeal circuit. In the event of a communication error, the user is instructed to manually return blood in the extracorporeal circuit to the patient. **Baxter has received three adverse event reports in which the clinician's failure to return extracorporeal blood to the patient following a communication error alarm resulted in patient symptoms such as anemia and hypotension necessitating medical intervention.**

Actions to be Taken by Customers

1. Operators may continue to safely use the Prismaflex control units until the upgrade is performed. If a communication error alarm does occur, follow the instructions presented on the graphical user interface and/or in the operator's manual. Please reinforce the importance to manually return the extracorporeal blood to the patient, and re-train users on this process, outlined on page 10:57 of the operator's manual, if necessary.

2. A Baxter representative will contact your facility to determine the correction plan and schedule the upgrade. Your facility will be receiving this upgrade from Baxter at no charge.

3. **If you purchased this product directly from Baxter, complete the enclosed Baxter Customer Reply Form** and return it to Baxter by scanning and e-mailing it to Priscilla Chow at [redacted] or your Baxter local representative. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.

4. 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 according to their instructions.

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

6. If you are a dealer, wholesaler, distributor/reseller, that distributed any affected product to other facilities, please notify your customers of this Medical Device Correction in accordance with your customary procedures.

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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

Baxter

CUSTOMER REPLY FORM

Medical Device Correction

Prismaflex SW 8.10

November 19, 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.