

**MEDICAL DEVICE CORRECTION**

May 8, 2018

Dear Healthcare Provider:

**Problem  
Description**

Baxter Healthcare will be installing new firmware on all Prismaflex control units to address the potential for a small number of these units to exhibit a failure mode with the pump module electronics. The failure mode may result in a "Voltage Out of Range" malfunction alarm, which causes the device to enter a "safe state" and become inoperable until it is serviced. Baxter will be releasing new firmware that will prevent the malfunction from occurring.

**Affected  
Product  
(Singapore)**

List of product code affected/ supplied in Singapore:

Product Code	Product family	Serial Numbers
955052	PRISMAFLEX 8.XX ROW	All
114489	PRISMAFLEX 6.10 ROW	All
107493	PRISMAFLEX SYSTEM	All
113082	PRISMAFLEX 4.11	All

**Affected  
Product  
(Globally)**

List of product codes affected globally:

Product Code	Product family	Serial Numbers
955433	PRISMAFLEX CHINA	All
955052	PRISMAFLEX 8.XX ROW	All
114870	Prismaflex 7.XX Row	All
955542	Prismaflex 7.20 US	All
115271	PRISMAFLEX 8.XX KOREA	All
115269	Prismaflex 7.XX US	All
114489	PRISMAFLEX 6.10 ROW	All
107493	PRISMAFLEX SYSTEM	All
113080	PRISMAFLEX 4.11 CHINA	All
113081	PRISMAFLEX 5.10 US	All
113082	PRISMAFLEX 4.11	All
113874	PRISMAFLEX 5.00 ROW	All

**Hazard  
Involved**

The "Voltage Out of Range" malfunction alarm causes the Prismaflex control unit to enter a "safe state" by stopping all pumps and closing the return line clamp. This failure mode can occur at any time during use and may result in an interruption and/or delay in therapy. Patient harm is not expected as the blood may be manually

returned to the patient. There have been no reports of serious injury associated with this issue.

**Actions to be  
Taken by  
Customers**

1. Operators may continue to safely use Prismaflex control units that have not exhibited the "Voltage Out of Range" malfunction alarm.
2. A local Baxter service representative will contact your facility to determine the correction plan and schedule the firmware upgrade. Your facility will be receiving this firmware upgrade from Baxter at no charge.
3. If you purchased this product directly from Baxter, Complete the enclosed customer reply form and return it to Baxter by scanning and e-mailing it to [priscilla\\_chow@baxter.com](mailto:priscilla_chow@baxter.com) . Returning the customer reply form promptly will 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.

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 [priscilla\\_chow@baxter.com](mailto:priscilla_chow@baxter.com).

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](mailto:singapore_productcomplaint@baxter.com)
- Please report Adverse Events to [singapore\\_patientsafety@baxter.com](mailto: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,



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 Control Units

May 8, 2018

### 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 [priscilla\\_chow@baxter.com](mailto:priscilla_chow@baxter.com) 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: \_\_\_\_\_  
*Print Name*

Title: \_\_\_\_\_

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.*