

## DEVICE CORRECTION

February 28, 2017

Dear Healthcare Provider:

**Issue  
Description**

Baxter Healthcare 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.

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 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

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.

**Affected  
Product**

Product Code	Product family	Serial Number
6023014700	Prismaflex System	All
107493	Prismaflex System	All
113082	Prismaflex 4.11	All
114489	Prismaflex 6.10 ROW	All

There are other codes affected globally but not supply or import to Singapore market. Customer should verify with Baxter with if in doubt.

**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.

**There is no similar issue or complaint reported in Singapore.**



**Action to be taken if product was purchased directly from Baxter**

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. If you are a dealer, wholesaler, or distributor/reseller that distributed any product to other facilities, please notify your customers of this device correction in accordance with your customary procedures.
4. 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.

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 software version update will take additional measures to further ensure patient safety.

Sincerely,



Corynn Tan  
QA Manager

Enclosure: Baxter Customer Reply Form  
CC: Chairman of Medical Board & Head(s) of Department