Baxter

URGENT MEDICAL DEVICE CORRECTION

April 24, 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

Product Code	Product Family	Serial Numbers	Distribution Dates
107493	Prismaflex System	All	6/15/2006 – 11/17/2015
113081	Prismaflex 5.10 US	All	1/2/2006 – 3/16/2016
114870	Prismaflex 7.XX ROW	All	11/5/2015 – 6/6/2017
115269	Prismaflex 7.XX US	All	11/19/2015 – 12/1/2017
955542	Prismaflex 7.20 US	All	10/19/2017 – 4/5/2018

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 Baxter Customer Reply Form** and return it to Baxter by faxing it to 224-270-5457 or scanning and e-mailing it to fca@baxter.com, **even if you do not have any inventory.** 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.

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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, or original equipment manufacturer (OEM) that distributed any affected product to other facilities, please notify your customers of this Urgent Medical Device Correction in accordance with your customary procedures.

The United States Food and Drug Administration (FDA) has been notified of this action. Any adverse reactions or quality problems experienced with the use of these products may be reported using one of the following options:

- Calling Baxter Corporate Product Surveillance at 800-437-5176 between the hours of 8:00 am and 5:00 pm Central Time, Monday through Friday.
- Emailing to Baxter at: corporate_product_complaints_round_lake@baxter.com.
- Reporting to the FDA MedWatch Adverse Event Reporting Program:
  - **Online:** By completing and submitting the report online at: www.fda.gov/medwatch/report
  - **Regular mail or Fax:** Download the form from www.fda.gov/MedWatch/getforms.htm or call 800-332-1088 to request a reporting form, then complete and mail it to the address on the pre-addressed form, or submit by fax to 800-332-0178.

We apologize for any inconvenience this may cause you and your staff.

Sincerely,

Amy McKernan
Director, Quality
Baxter Healthcare Corporation

Enclosure: Customer Reply Form

cc: Director of Materials Management