Urgent Field Safety Notice

Prismaflex Control Unit
FA-2021-005
Device Correction

February 2021

Dear Healthcare Provider:

Problem Description

Healthcare Corporation is issuing a Device Correction to the user level for the Prismaflex Control Unit due to variability in the Baxter performance of the tubing in the ARPS (Automatic Repositioning System) Pump Assembly, which may lead to the following alarm situations during or after a system self-test.

	Alarm Situations:
Primary Alarms:	• Malfunction: Prime Self-Test Failure (Code 4), during priming • Malfunction: Self-Test Failure (Code 4), during treatment
Secondary Alarms:	• Caution: TMP Excessive • Advisory: TMP Too high

The Prismaflex Control Unit performs system self-tests during priming and at defined intervals during therapy. Therefore, the above alarm situations may occur during priming or during treatment. In these alarm situations, the Prismaflex Control Unit will default to a safe state and provide on-screen instructions to the user. Customers should follow the on-screen instructions if an alarm appears.

To prevent potential alarm situations, the tubing in the ARPS Pump Assembly for the Prismaflex devices listed below will be replaced with improved tubing.

Affected Product

Product Code	Product Description	Serial Numbers
107493	Prismaflex Control Unit	All
113082		
113874		
114489		
114870		
955052		
G5010007	Preventive Maintenance Kit	
G5064801	ARPS Pump Segment Kit	
G5006203	ARPS Pump Assembly	

Hazard Involved

If an alarm occurs, it may lead to delay or interruption of therapy. In the event that therapy is terminated without returning blood to the patient, blood loss may occur. To date, there have been three reports of serious injury potentially related to this issue.

Actions to be taken by Customers

1. Operators may continue to use the Prismaflex Control Unit according to the instructions in the Operator' Manual until the tubing is replaced within the ARPS Pump Assembly.

2. If an alarm occurs, the Prismaflex Control Unit will default to a safe state and the user should follow the on-screen instructions.

3. Existing pump segments and pump assembly kits in your inventory may be utilized for critical repairs until the improved tubing is provided to your facility. If you need additional parts, please communicate your repair needs to your local Technical Service representative and Baxter will prioritize replacement kits when they are available. If the repairs are not urgent, you may wait to perform the repairs until Baxter contacts you to arrange for the replacement of these products.

4. The tubing in the ARPS Pump Assembly is normally replaced during annual Preventive Maintenance (PM). **If your Prismaflex Control Unit is due for PM, these activities should be delayed until new kits have been provided to your facility**.

5. **A local Baxter service representative will contact your facility** to schedule the replacement of the ARPS tubing within the Prismaflex device and/or to replace the affected unused Preventive Maintenance (PM) and Spare Part kits in your inventory, if applicable. Your facility will be receiving this replacement from Baxter at no charge.

6. **If you purchased this product directly from Baxter, complete the enclosed Baxter Customer Reply Form and return it to Baxter by faxing it, or scanning and e-mailing it.** Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices

7. 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.

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

9. 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 Device Correction in accordance with your customary procedures.

Further information and support

For general questions regarding this communication, contact Baxter.

We thank you for your attention to this important safety information.

Sincerely,

Baxter Healthcare Corporation