Urgent Field Safety Notice

Prismaflex Control Unit
FA-2021-005
Device Correction

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09 February 2021

Dear Healthcare Provider:

Problem Description

Baxter Healthcare Limited is issuing a Device Correction to the user level for the Prismaflex Control Unit due to variability in the 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, none of which occurred in the UK.

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 Control Unit and/or to replace the affected unused PM and spare part kits in your inventory, if applicable. Your facility will be receiving this replacement from Baxter at no charge.

6. **Complete the enclosed Baxter Customer Reply Form and return it to Baxter by emailing to uk_shs_fca@baxter.com.** Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.
7. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.

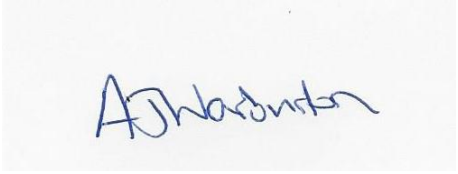
Further information and support

For general questions regarding this communication, contact Baxter at uk_shs_fca@baxter.com

Any adverse reactions or quality problems experienced with the use of these products may be reported to the Prismaflex helpline by calling 0808 1003539.

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

Sincerely,



Andrew Warburton
Business Unit Head UKI, Acute Therapies
Baxter Healthcare Limited

Enclosure: Baxter Customer Reply Form

Baxter

Confirmation of receipt of communication

DEVICE CORRECTION LETTER DATED 09 FEBRUARY 2021

DEVICE NAME Prismaflex control unit
Product code: 107493, 113082, 113874, 114489, 114870, 955052, G5010007, G5064801, G5006203
All serial numbers

Please complete and return one copy of this form per facility either by e-mail (uk_shs_fca@baxter.com) as confirmation that you have received this notification.

Facility Name and Address: *(Please Print)*	
Reply Confirmation Completed By: *(Please Print Name)*	
Title: *(Please Print)*	
Email and/or Telephone Number (Including Area Code):	
Current Location of the Device and Serial Numbers	

Signature/Date: REQUIRED FIELD	_____

Your signature above indicates understanding of the contents of the attached letter, that you performed the actions outlined and disseminated this information, if applicable