Prismaflex Control Unit
FA-2021-005 Follow Up
Device Correction

September, 2021 *(to be adapted locally)*

Dear Biomedical Engineer: *(to be adapted locally)*

On February 2021, Baxter Healthcare Corporation issued the enclosed Device Correction communication to notify users of variability in the performance of the tubing in the Prismaflex Automatic Repositioning System (ARPS) Pump Assembly, which may lead to alarm situations during or after a system self-test. Baxter is continuing to contact customers to replace the ARPS Pump Assembly tubing in impacted Prismaflex Control Units.

Baxter now has inventory to replace the existing unused Prismaflex preventive maintenance kits, pump segments, and pump assemblies in your inventory with those containing improved tubing.

Affected Product

(to be adapted locally)

Product Code	Product Description	Serial Numbers
G5010007	Preventive Maintenance Kit	All
G5064801	ARPS Pump Segment Kit	
G5006203	ARPS Pump Assembly	

A local Baxter service representative will contact your facility to replace the affected unused PM and spare part kits in your inventory.

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 it and emailing it. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.

We apologize for any inconvenience this may cause you and your staff and look forward to continuing to serve your needs.

Sincerely,

Amy McKernan *(to be adapted locally)*
Director, Quality *(to be adapted locally)*
Baxter Healthcare Corporation *(to be adapted locally)*

Enclosures: Baxter Customer Reply Form

Device Correction communication dated January 28, 2021 *(to be adapted locally)*

Baxter

(Customer communication)

CUSTOMER REPLY FORM related to Follow Up Correction letter dated XXXXXX *(to be completed locally)*

DEVICE NAME Prismaflex preventive maintenance kits, pump segments, and pump assemblies

Product code: G5010007, G5064801, G5006203

Lot numbers: ***…. (to be completed locally)***

Please complete and return one copy of this form per facility either by fax (Fax :_____) or by e-mail (_____) as confirmation that you have received this notification. A fax cover sheet is not required. ***(Can be adapted locally)***.

Facility Name and Address:	
Reply Confirmation Completed By *(Please Print)*:	
Title *(Please print)*:	
Email and/or Telephone Number (including Area Code):	

Please check boxes as appropriate: *(to be adapted locally)*

☐ We do not have any of the affected lots in our inventory.

☐ We do have the affected lots in our inventory and products have been quarantined.

Please list the quantity of the specific lot(s) to be returned below*:

Product Code	Lot number	Quantity in units to be returned

*You may attach an additional sheet if required.

(Below paragraph to be removed locally if not applicable)

☐ I would like Baxter to contact my patients and will provide support as needed

☐ I will contact my home patients directly and will provide information to Baxter as it becomes available.

Your signature below indicates that you have received the attached letter; performed the actions as outlined in the letter as needed; and disseminated this information to staff and other services or facilities as applicable.

Signature/Date: REQUIRED FIELD	_____

(Customer communication)

TO BE COMPLETED BY BAXTER PERSONNEL *(Below paragraph to be removed locally if needed)*

Number of product effectively received:

Justification (if discrepancy):