Urgent Field Safety Notice

PrisMax, V2, ROW
FA-2020-065
Device Correction

January 2021

Dear Healthcare Provider:

Problem Description

Baxter Healthcare Corporation is issuing a Device Correction for the PrisMax System due to inconsistent variability of the tubing in the ARPS (Automatic Repositioning System) Pump Assembly which may lead to alarm situations during a system self-test and during therapy. This tubing is normally replaced during annual preventative maintenance.

	Alarm Situations:
During System Self-Test	Alarm code B1215 (ARPS Self-Test failure)
During Therapy	B1273 (ARPS Leak), B1215 (ARPS Pressure self-test), B1116 (Return Pressure self-test Failure), B1539 (Access Pod Reposition Failure), B1541 (Effluent Pod Reposition Failure), B1540 (Effluent Filter Pod Reposition Failure)

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

Affected Product

Product Code	Product Description	Serial Numbers
955558	PrisMax, V2, ROW	All serials that were manufactured or received replacement tubing between 1/1/2020 – 12/1/2020.

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 no reports of serious injury related to this issue.

Actions to be taken by Customers

1. Operators may continue to safely use the PrisMax System until the tubing is replaced within the ARPS Pump Assembly.
2. If an alarm occurs, the PrisMax System will default to a safe state and the user should follow the on-screen instructions to end treatment and to contact service.
3. **A local Baxter service representative will contact your facility** to determine the correction plan and schedule the replacement **for the impacted devices only**. Your facility will be receiving this replacement from Baxter at no charge.
4. **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

5. 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.

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

7. 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