Urgent Field Safety Notice

PrisMax, V2, ROW
Follow-Up FA-2020-064
Device Correction

May 2021

Dear Healthcare Provider

Problem Description

This is a follow up communication to the Safety Alert Baxter previously issued on January 2021, to inform clinicians of reports of users who have confused the acronyms for Pre-Blood Pump (PBP) and Patient Fluid Removal (PFR) when entering prescriptions on the PrisMax Graphical User Interface (GUI). The acronyms for PBP and PFR are defined in the Operator's Manual as well as during therapy on the Graphical User Interface (GUI) screen. Please refer to the enclosed Safety Alert for additional details.

Though the acronyms for PBP and PFR are defined in the Operator's Manual as well as during therapy on the GUI screen, Baxter will be updating the PrisMax System software to clarify the prescription settings on the GUI screen to prevent confusion in the future. Baxter will also be updating the PrisMax Operator's Manual to align with the updated screens and wording.

Affected Product

Product Code	Product Description	Serial Numbers
955558	PrisMax V2, ROW	All

Hazard Involved

Incorrect therapy settings could lead to unintended excessive fluid removal during treatment. This has the potential to lead to hypotension. To date, Baxter has received four reports of serious injury related to this issue.

Actions to be Taken by Customers

1. Until the software is updated, operators should continue to use the PrisMax System per the instructions in the Operator's Manual. Refer to the enclosed Attachment A for guidance.

2. Baxter is in the process of developing and validating the new PrisMax software. Once the new software becomes available, Baxter Service will contact customers to arrange for the upgrade of the system software.

3. **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.** 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.

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 distribute this notification to customers and **check the associated box on the reply form.**

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

Enclosure:
Safety Alert dated January, 2021
Attachment A: Operator's Manual and Graphical User Interface (GUI) Guidance
Baxter Customer Reply Form

Baxter

Confirmation of receipt of communication

***DEVICE NAME*:** PrisMax, V2, ROW
Product code: 955558
Serial numbers: all

Please complete and return one copy of this form per facility as confirmation that you have received this notification.

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

Signature/Date: REQUIRED FIELD	_____

We have received the above-mentioned letter, performed the actions outlined in the letter, and have disseminated the information / documentation to our staff, other services/facilities and customers, as applicable.