Baxter

Urgent Field Safety Notice

14th January 2021

Dear Customer,

Problem Description

In an effort to keep you informed of important product information that can help ensure the safe and effective use of our products, Baxter Healthcare is issuing a Safety Alert for the PrisMax System. Baxter has received reports of users who have confused the acronyms for Pre-Blood Pump (PBP) and Patient Fluid Removal (PFR) when entering the prescriptions on the PrisMax Graphical User Interface (GUI).

During setup, the user needs to enter the Pre-Blood Pump (PBP) and the Patient Fluid Removal (PFR) flow rates. **Please ensure the appropriate values are entered in the respective fields.** Color coding and an additional help button are available for further support when entering the prescription. Please confirm the entered Pre-Blood Pump and Patient Fluid Removal values on the Review screen. Switching these two flow rates may result in excessive fluid removal from the patient.

The acronyms for PBP and PFR are defined in the Operator's Manual as well as during therapy on the GUI screen. Refer to the enclosure for details.

To ensure patient safety, the device should only be used by a trained operator.

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. There have been two reports of serious injury related to this issue, none of which occurred in Ireland.

Actions to be Taken by Customers

1. To ensure patient safety, the device should only be used by a trained operator per the instructions in the Operator's Manual. **Please ensure that every operator of this device is made aware of this Safety Alert.**

2. **If you purchased this product directly from Baxter, complete the enclosed Baxter Customer Reply Form and return it to Baxter by emailing qa_dublin@baxter.com.** Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.

3. 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.

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

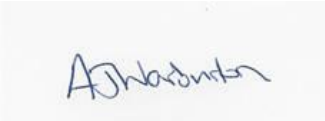
5. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected product to other facilities, please notify your customers of this Device Correction in accordance with your customary procedures.

Further information and support

For general questions regarding this communication, contact Baxter Dublin Customer Services at shs_customer_services_dublin@baxter.com or phone 01 206 5500.

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

Sincerely,



Andrew John Warburton
Acute Business Management
UK & Ireland

Enclosure:
Baxter Customer Reply Form
Attachment A: Operator's Manual and Graphical User Interface (GUI) Instructions