

Urgent Field Safety Notice

PrisMax, V2, ROW
FA-2020-064
Safety Alert

January XX, 2021 (to be adapted locally)

Dear Healthcare Provider (to be adapted locally):

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 (to be adapted locally)

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.

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 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.
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.

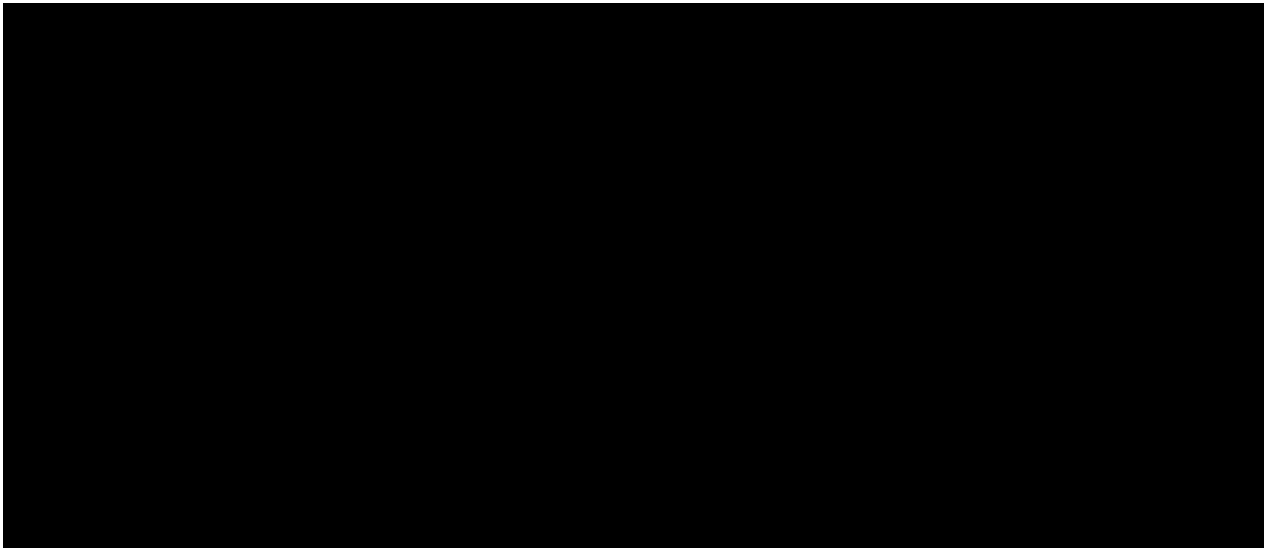
4. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.
5. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected product to other facilities, please distribute this notification to customers and **check the associated box on the reply form (to be adapted locally).**

**Further
information
and support**

For general questions regarding this communication, contact Baxter at **(insert local contact information)**, between the hours of **(insert local information)**.

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

Sincerely,



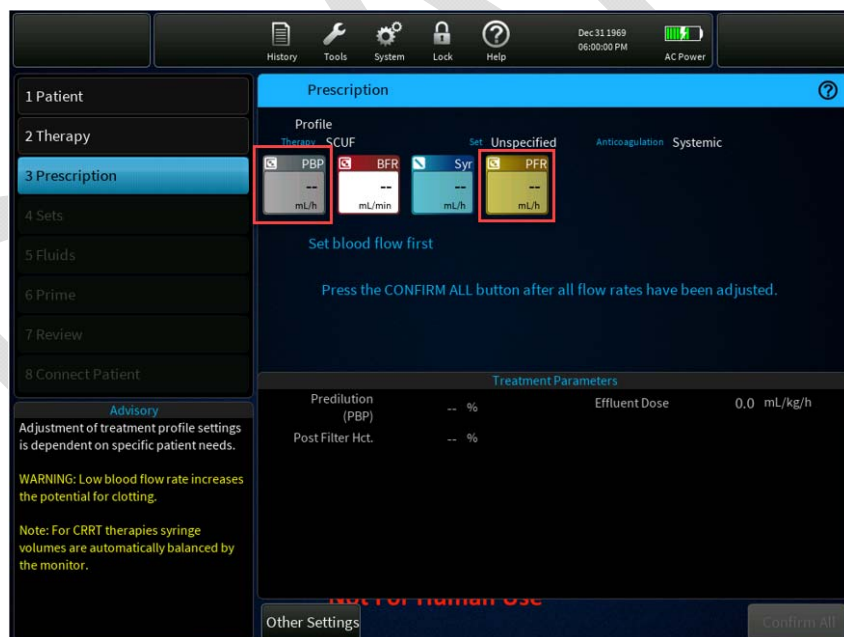
Attachment A: Operator's Manual and Graphical User Interface (GUI) Instructions

PrisMax Operator's Manual: The page number can be adapted locally or removed as needed.

PrisMax Operator's Manual, SW 2.XX, AW8005-A (to be adapted locally)	
PFR: Page 69	<p>Patient Fluid Removal (PFR)</p> <p>Patient Fluid Removal displays the volume of fluid removed from the patient. The Patient Fluid Removal (PFR) charting period is defined in System Configuration. The chart uses a sliding window based on the period selected. History uses a fixed window for charting purposes.</p>
PBP: Page 264	<ul style="list-style-type: none"> The Pre-Blood Pump (PBP) infuses solution into the access line after the patient blood enters the access line and before the blood pump, diluting the blood as it enters the set. To maintain the set blood flow, software increases the blood pump flow to take in the PBP flow. $\text{Blood pump flow} = \text{set blood flow} + \text{PBP flow}$ in milliliters per minute, ml/min.

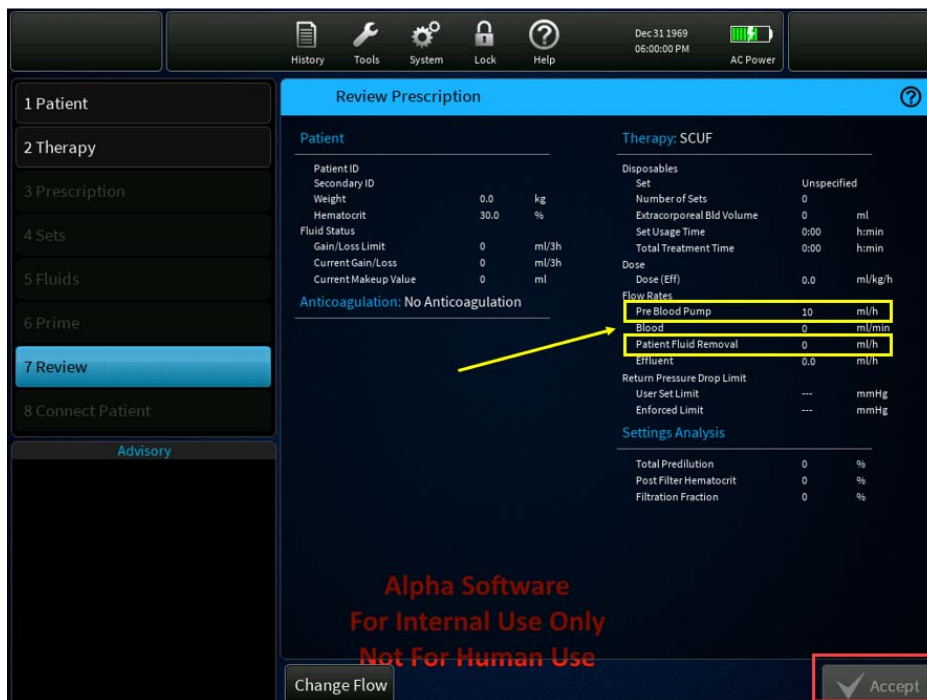
PrisMax Graphical User Interface (GUI):

- Prescription Screen** – Enter the values for Pre-Blood Pump (PBP) shown in gray and the Patient Fluid Removal (PFR) shown in yellow.



Attachment A: Operator's Manual and Graphical User Interface (GUI) Instructions

- Review Screen** – Review the Patient Fluid Removal (PFR) and Pre-Blood Pump (PBP) values have been entered correctly prior to pressing Accept.

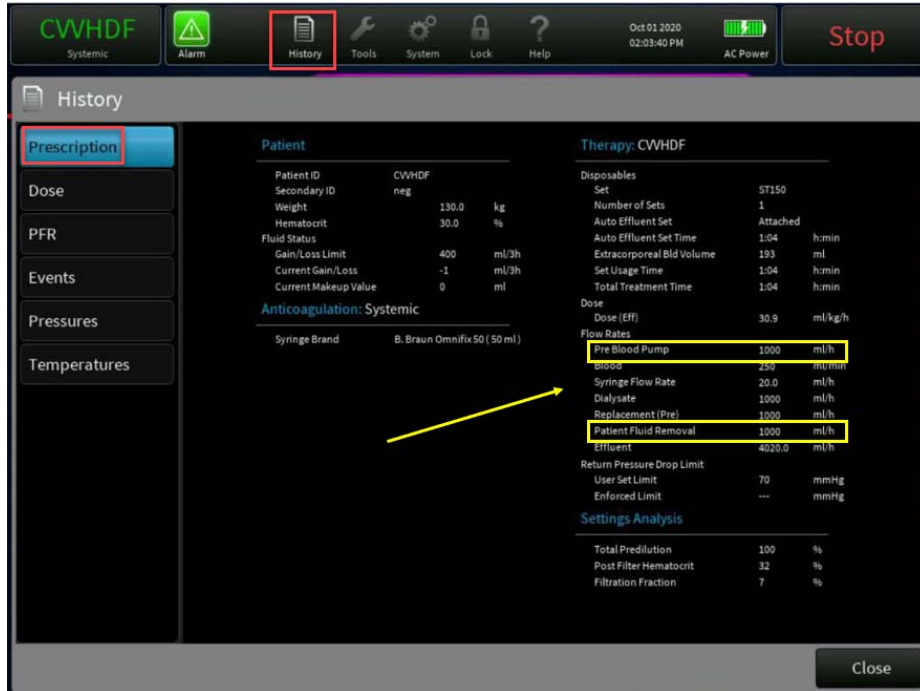


- During Therapy** – PBP is displayed in grey and PFR is displayed in yellow.



Attachment A: Operator's Manual and Graphical User Interface (GUI) Instructions

4. **During Therapy** – Press the History button to view the Prescription where the Patient Fluid Removal and Pre-Blood Pump are spelled out.



5. **During Therapy** – Press the Help button to view the Abbreviations spelled out. PBP abbreviation is displayed initially. To view PFR, scroll down using the scroll bar on the right of the screen (shown on Pg. 5).

