

**URGENT MEDICAL DEVICE****SAFETY ALERT**

March 30, 2020

Dear Critical Care or ICU Nursing Manager:

**Problem  
Description**

We want to express our gratitude to you and your colleagues who are on the front lines of the Coronavirus (COVID-19) pandemic. We know this requires extraordinary courage and dedication to adapt to ever-changing challenges and that you are caring for patients in less than ideal circumstances.

We have received questions from clinicians who are exploring modifying their use of Baxter's PrisMax Control Units and Prismaflex Hemodialysis Units, in order to minimize exposure to COVID-19-positive patients. For example, clinicians may be using multiple extension lines to extend the length of the tubing set to allow placement of a PrisMax Control Unit or Prismaflex Hemodialysis Unit outside of the patient's room. There are several significant risks that arise with this practice, which are detailed below in the Hazard Involved section of this letter (on Page 2). To mitigate these risks, users are asked to follow the setup instructions in the Graphical User Interface, as well as the warnings from the PrisMax and Prismaflex Operators Manuals as noted below; otherwise, serious patient harm may occur.

**Prismaflex Operator's Manual, Program version 7.xx, G5036005 (Page 1:8 and Page 3:2)****WARNING:**

Always connect the return line directly to the blood access device. Do not connect additional devices between the return line and the blood access device. The use of additional devices, such as three-way valves, stopcocks, or extension lines, may impair return pressure monitoring. Their use can impede the detection of return disconnections, potentially resulting in severe blood loss.

**Prismaflex Operator's Manual, Program version 7.xx, G5036005 (Page1:8)****WARNING:**

During priming and operation, observe the system closely for leakage at joints and connections within the set. Leakage can cause blood loss or air embolism. If leakage cannot be stopped by tightening the connections, replace the set.

**PrisMax Operator's Manual, Program version 2.XX, AW8005-A (Page 58)****WARNING!**

Always connect the return line directly to the blood access device. Do not connect additional devices between the return line and/or the blood access device. The use of additional devices, such as three-way valves, stopcocks, or extension lines, may impair return pressure monitoring, and cause damage to blood cells resulting in hemorrhage. Their use can impede the detection of return disconnections which can

cause drug delivery inaccuracies and/or failures. The blood access needs to have the ability to supply blood at the rate ordered and return the blood at the rate ordered without interruptions which will cause clotting.

**PrisMax Operator’s Manual, Program version 2.XX, AW8005-A (Page 259)**

**WARNING!**

Always connect the return line directly to the blood access device. Do not connect additional devices between the return line and the blood access device. Using additional devices (such as three-way valves, stopcocks, or extension lines) can impede the detection of return disconnections, potentially resulting in severe blood loss.

**Affected Product**

Product Code	Product Description	Serial Numbers
107493	Prismaflex Hemodialysis Unit	All
113081		
113082		
114489		
114870		
955558	PrisMax Control Unit	All

**Hazard Involved**

The following hazards are associated with the use of multiple extension lines to allow placement of a PrisMax Control Unit or Prismaflex Hemodialysis Unit outside of the patient’s room: Baxter cannot guarantee that the use of multiple extension lines will establish and maintain secure connections with PrisMax and Prismaflex sets. The use of extension lines increases the risk of disconnections and interferes with the ability of the PrisMax Control Unit or Prismaflex Hemodialysis Unit to accurately detect pressure drops in the blood circuit. As a result, vascular access disconnections may go undetected, leading to clinically significant blood loss and fatal exsanguination. Additionally, the use of extension lines increases the blood in the extracorporeal circuit. In the event of non-restitution or clotting of the circuit, this may lead to blood loss beyond what is tolerable for the patient. Other potential risks of multiple extension lines include hypothermia, air embolism, and infection. As of March 27, 2020, there have been no reports of serious injury related to this issue.

**Actions to be Taken by Customers**

1. Operators can safely use the PrisMax Control Units and Prismaflex Hemodialysis Units when adhering to the product-specific Operator’s Manual and Graphical User Interface.
2. **If you purchased this product directly from Baxter, complete the enclosed Baxter Customer Reply Form and return it to Baxter by faxing it to 1-888-490-4660 or scanning and e-mailing it to [baxter@ptm-health.com](mailto:baxter@ptm-health.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

distribute this notification to customers and complete the applicable section on the reply form.

**Further  
information  
and support**

For general questions regarding this communication, contact your local Baxter representative.

Health Canada has been notified of this action. We thank you for your attention to this important safety information.

Sincerely,



Linda Lindsay  
Director, Regulatory Affairs & Quality  
Baxter Corporation – Canada

Enclosure: Baxter Customer Reply Form