Baxter

SAFETY ALERT

March 27, 2020

Dear Healthcare Provider:

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 and Prismaflex Control 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 or Prismaflex Control 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, 7.xx, G5039912 (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, 7.xx, G5039912 (Page1:7)
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, SW 2.XX, AW8035-B (Page 56 and Page 237)
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.

Affected Product

Product Code	Product Description	Serial Numbers
107493	Prismaflex Control Unit	All
113081		
114870		
115269		
955542		
955792		
955626	PrisMax System	

Hazard Involved

The following hazards are associated with the use of multiple extension lines to allow placement of a PrisMax or Prismaflex Control 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 or Prismaflex Control 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 and Prismaflex Control 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 224-270-5457 or scanning and e-mailing it to fca@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 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 Corporate Product Surveillance at 800-437-5176, between the hours of 8:00 am and 5:00 pm Central Time, Monday through Friday.

The United States Food and Drug Administration (FDA) has been notified of this action. Any adverse events or quality problems experienced with the use of these products may be reported using one of the following options:

- Calling Baxter Product Surveillance at 800-437-5176 between the hours of 8:00 am and 5:00 pm Central Time, Monday through Friday.

- Emailing to Baxter at: corporate_product_complaints_round_lake@baxter.com.
- Reporting to the FDA MedWatch Adverse Event Reporting Program:
  - **Online:** By completing and submitting the report online at: www.fda.gov/medwatch/report
  - **Regular mail or Fax:** Download the form from www.fda.gov/MedWatch/getforms.htm or call 800-332-1088 to request a reporting form, then complete and mail it to the address on the pre-addressed form, or submit by fax to 800-332-0178.

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

Sincerely,

Amy McKernan
Director, Quality
Baxter Healthcare Corporation

cc: Director of ICU
Director of Nursing

Enclosure: Baxter Customer Reply Form