

Urgent Field Safety Notice

**PrisMax Systems
FA-2022-006
Device Correction**

March XX, 2022 *(to be adapted locally)*

Dear Healthcare Provider: *(to be adapted locally)*

Problem Description Baxter Healthcare Corporation is issuing a Device Correction to the user level for the PrisMax System. This correction is due to software anomalies occurring during use. If the operator initiates therapy by entering a value other than the default value for the patient Gain/Loss Limit or the Return Pressure Drop Limit (RDL) and uses the Same Patient function, the PrisMax System will return the patient Gain/Loss Limit or the RDL to the default value, rather than the non-default value entered at the initiation of treatment. The PrisMax System interface will display the original values once treatment is restarted but does not have an alert to inform the user of the change. The RDL value will be returned to the original value immediately upon selecting the Same Patient function. The Gain/Loss Limit value will be returned to the original value when the patient weight and/or hematocrit is changed during treatment. These anomalies only occur if the Same Patient function is used when changing the disposable set.

Baxter will be upgrading the software on all affected PrisMax units to resolve these anomalies.

Affected Product
(to be adapted)

Product Code	Product Description	Serial Numbers
955558	PRISMAX, V2 ROW	All serial numbers
955725	PRISMAX V3 CONTROL UNIT ROW	All serial numbers

Hazard Involved If the patient Gain/Loss Limit returns to the default value without direct manipulation by the operator, this may lead to fluid imbalance (hypo/hypervolemia). If the RDL returns to the default, this may lead to a delay in detection of a return disconnection. These may, in turn, lead to an interruption of therapy. To date, there have been no reports of serious injury related to this issue.

Actions to be taken by Customers

- Operators may continue to safely use the PrisMax System. To ensure patient safety, there are two approaches to address the anomalies:
 - Approach 1: Choose new patient at every filter set change. This will require re-input of all prescription settings and therapy will begin without prescription settings and treatment data from the previous filter set.
 - Approach 2: Choose Same Patient when changing a filter set. Check and correct the Gain/Loss Limit or RDL **prior to starting treatment**.
 - See Attachment A to change the Gain/Loss Limit
 - See Attachment B to change the RDL

The device should only be used by a trained operator per the instructions in the Operator’s Manual.

2. **Please keep a copy of this communication with the Operators Manual and ensure that every operator of this device is made aware of this Device Correction.**
3. **When the software upgrade becomes available, a local Baxter Service representative will contact your facility** to determine the correction plan and schedule the upgrade for impacted devices. Your facility will be receiving this upgrade from Baxter at no charge.
4. If you purchased this product directly from Baxter, complete the enclosed customer reply form and return it to Baxter by either faxing it to [\(insert local contact information\)](#) or scanning and e-mailing it to [\(insert local contact information\)](#) or sending it by post to [\(insert local contact information\)](#), even if you don't have any inventory. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.
5. 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.
6. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.
7. 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 at [\(insert local contact information\)](#), between the hours of [\(insert local information\)](#).

The local Ministry of Health (MOH) has been notified of this action. [\(to be adapted locally\)](#)

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

Sincerely,

Name [\(to be adapted locally\)](#)

Title [\(to be adapted locally\)](#)

Baxter Healthcare Corporation [\(to be adapted locally\)](#)

Enclosure: Baxter Customer Reply Form

Attachment A: How to check Gain/Loss Limit

Attachment B: How to check Return Pressure Drop Limit (RDL)



Confirmation of receipt of communication
(DEVICE CORRECTION LETTER DATED XX (TO BE COMPLETED LOCALLY))

DEVICE NAME PRISMAX SYSTEM
Product code: 955558 - 955725
Serial numbers: (to be completed locally)

Please complete and return one copy of this form per facility either by fax (Fax : _____) or by e-mail (_____) as confirmation that you have received this notification.
A fax cover sheet is not required.
(Can be adapted locally)

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	_____
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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.