

Danish Medicines Agency
Axel Heides Gade 1
2300 København S
Att.: Medicinsk Udstyr

22-Mars-2022

Field Safety Notice:

Device Correction- FA-2022-06-PrisMax System - CRRT Patient Parameters Changing Without User Interaction

Product Name: PrisMax, V2, ROW

Product Code: 955558

Serial Numbers: All

Dear Sir/Madam,

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. 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.

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.

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

Our records indicate that 4 customers have received this product in Denmark. For your information, please find attached the communication that is being sent to those customers. The translated version of it will be submitted to you soon.

Should you have any questions, please contact me at *Nordic_RA@baxter.com*.

Yours Sincerely,



Demet Wahlberg
Regulatory Affairs Principal Specialist
Baxter Medical AB

Enclosures

dk-fsca report-fa-2022-006
FA-2022-006- Generic Customer Letter
FA-2022-006 Attachment A (to be adapted)
FA-2022-006 Attachment B (to be adapted)