Baxter

Urgent Field Safety Notice

PrisMax Systems
FA-2022-006
Device Correction

21st March 2022

Dear Healthcare Provider:

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

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

1. 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. Please complete the enclosed customer reply form and return it to Baxter by e-mailing it to qa_dublin@baxer.com, 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 distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.

Further information and support

For general questions regarding this communication, contact Baxter Dublin Customer Services at shs_customer_services_dublin@baxter.com or phone 01 206 5500.

The local Ministry of Health (MOH) has been notified of this action.

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

Sincerely,

Andrew Warburton
Business Unit Head, Acute Therapies
Baxter Healthcare Ltd

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 FA-2022-006 DATED 21ST MARCH 2022

DEVICE NAME PRISMAX SYSTEM

Product code: 955558 and 955725

Serial numbers: All serial numbers

Please complete and return one copy of this form per facility by e-mail (qa_dublin@baxter.com) as confirmation that you have received this notification.

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	_____

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.