Baxter

Urgent Field Safety Notice

PrisMax
FA Number: FAV-2024-009
Manufacturer: Baxter Healthcare SA (SRN: CH-MF-000026124)
Type of Action: Correction

20th December 2024

Dear Sir/Madam,

Problem Description

Baxter Healthcare Corporation (Baxter) is issuing Correction for the PrisMax Systems listed below that have been upgraded to software version 3.4. Baxter has identified an issue with this software version that causes some displayed Effluent dose values to be different than what was actually delivered by the PrisMax system.

The values sent to the Electronic Medical Records (EMR), Patient Monitoring Systems, history screen, and the operation screens are properly displayed until therapy reaches 24 hours. At the 24 hour mark, the displayed Effluent - Delivered values appear as half of what was actually delivered to the patient. Although the displayed Effluent - Delivered dose is incorrect, the correct amount of effluent gets removed from patients by the device and therapy is performed correctly by the PrisMax system.

Incorrectly displayed Effluent doses may cause the clinician to inappropriately react to the incorrectly displayed delivered dose value and change the treatment prescription unnecessarily.

Affected Product

Product Code	Description	Serial #
955558	PRISMAX, V2 ROW	102710
955558	PRISMAX, V2 ROW	102716
955558	PRISMAX, V2 ROW	104551
955558	PRISMAX, V2 ROW	104987

Hazard Involved

Incorrect display of the dosage information could result in the operator increasing the flow rates to compensate for the incorrectly displayed delivered dose. In this case, the patient will receive more therapy than is necessary. To date, there have been no reports of serious injury related to this issue.

Action to be taken by the user

Baxter is kindly asking that you take the following actions:

1. Stop using your affected PrisMax devices with software v3.4.

2. Baxter is working on a protocol to revert the software on the devices from v3.4 back to v3.3. Once the downgrade is available, a local Baxter representative will contact your facility to determine the correction plan and schedule the downgrade for the impacted device(s). Your facility will be receiving this downgrade from Baxter at no charge.

3. Complete the enclosed customer reply form and return it to Baxter by scanning and e-mailing it to Ireland.CORP.QA@vantive.com. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.

4. 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 or any product issue you are experiencing, contact Baxter at ireland.corp.fa@vantive.com.

The Health Products Regulatory Authority (HPRA) has been notified of this action.

We apologize for any inconvenience this may cause you and your staff.

Sincerely,

Mike Little
Head of Sales UKI
Baxter Healthcare Ltd

Enclosure A: Customer Reply Form

CUSTOMER REPLY FORM related to Product Correction letter dated 20TH December 2024

Product Name: PrisMax

Product code: 955558

Serial Number: 102710, 102716, 104551, 104987

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

Facility Name and Address:	
Reply Confirmation Completed By *(Please Print)*:	
Title *(Please print)*:	
Email and/or Telephone Number (including Area Code):	

Your signature below indicates that you have received the attached letter; performed the actions as outlined in the letter as needed; and disseminated this information to staff and other services or facilities as applicable.

Signature/Date: REQUIRED FIELD	_____