Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
مسقط

نتقدم بثقة
Moving Forward with Confidence

رؤية عُمان 2040

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 183 **dated** 30/12/2024 **Regarding SFDA Field Safety Corrective Action of PrisMax from (mfr: Baxter Healthcare SA).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DSC**
- **Director of Pharmacovigilance & Drug Information Dept, DSC**
- **Director of Drug Control Department, DSC**
- **Director of Pharmaceutical Licensing Department, DSC**
- **Director of Central Quality Control Lab., DSC**
- **Supdt. of Central Drug Information**

DSC
مركز سلامة الدواء
Drug Safety Center

ISO 9001:2015 CERTIFIED

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

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Circular No. 183 **/ 2024**

28 -06-1446 H
30 -12-2024

Field Safety Corrective Action of PrisMax from Baxter Healthcare SA.

Source	SFDA- Saudi Food & Drug Authority. https://ade.sfda.gov.sa/Fsca/PublishDetails/233
Product	PrisMax.
Manufacturer	Baxter Healthcare SA.
Local agent	Mustafa Sultan Science & Industry Co. LLC.
The affected products	Software Version: 3.4 For the product Code and serial number, please refer to the attachment.
Reason	It has been identified an issue with the above software version that causes some displayed Effluent dose values to be different than what was actually delivered by the PrisMax system..
Action	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). 3. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: vigilance-md@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General

DSC مركز سلامة الدواء Drug Safety Center

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
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Baxter

Urgent Field Safety Notice

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

24 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 Number
955558	PRISMAX, V2 ROW	102710
955558	PRISMAX, V2 ROW	102716
955558	PRISMAX, V2 ROW	104551
955558	PRISMAX, V2 ROW	104987
955725	PRISMAX V3	PX200295
955725	PRISMAX V3	PX201742
955725	PRISMAX V3	PX201766
955725	PRISMAX V3	PX201876
955725	PRISMAX V3	PX202737
955725	PRISMAX V3	PX203442

955725	PRISMAX V3	PX203445
955725	PRISMAX V3	PX203582
955725	PRISMAX V3	PX203817
955725	PRISMAX V3	PX203820
955725	PRISMAX V3	PX203822
955725	PRISMAX V3	PX203824
955725	PRISMAX V3	PX203827
955725	PRISMAX V3	PX203834
955725	PRISMAX V3	PX203863
955725	PRISMAX V3	PX203866
955725	PRISMAX V3	PX203867
955725	PRISMAX V3	PX203871
955725	PRISMAX V3	PX203927
955725	PRISMAX V3	PX203928
955725	PRISMAX V3	PX203929
955725	PRISMAX V3	PX203937
955725	PRISMAX V3	PX203938
955725	PRISMAX V3	PX203948
955725	PRISMAX V3	PX203949
955725	PRISMAX V3	PX203954
955725	PRISMAX V3	PX203957
955725	PRISMAX V3	PX203958
955725	PRISMAX V3	PX203967
955725	PRISMAX V3	PX203968

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.

Baxter

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 (redwan_hashim@baxter.com & Bandar_Alosaimi@Baxter.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.

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 notify your customers of this notification in accordance with your customary procedures.

Further information and support	For general questions regarding this communication or any product issue you are experiencing, reach out to Baxter contact below:

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

Sincerely,

For Bandar Alosaimi
Title CQA Regional Lead
Baxter A.G

Redwan Hashim

Attachment A: Customer Reply Form