Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

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. 53..... dated 23/3/22. Regarding NCMDR FSN of Prismaflex Control Unit, PrisMax from (mrf: Baxter Healthcare).

Copy to:

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

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control
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
dgpa_dc Email: dg-padc@moh.gov.om

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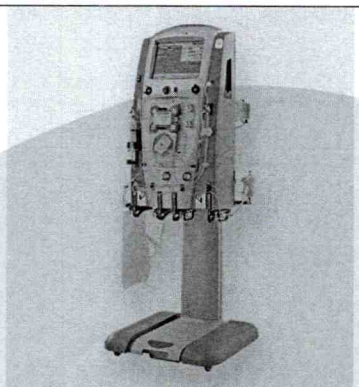
Circular No. 53 / 2022

20-08-1443 H
23-03-2022

Field Safety Notice of Prismaflex Control Unit, PrisMax from Baxter Healthcare.

Source	NCMDR- Nationa Center for Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=16055
Product	Prismaflex Control Unit, PrisMax.
Description	Haemodialysis system
Manufacturer	Baxter Healthcare
Local Agent	Mustafa Sultan Science & Industry Co LLC.
The affected products	Attached.
Reason	Modifying the use of Baxter's PrisMax and Prismaflex Control units, in order to minimize exposure to COVID-19-positive patients.
Action	1. Operators can safely use the PrisMax and Prismaflex Control Units when adhering to the product-specific Operator's Manual and Graphical User Interface. 2. Contact the local agent for remedial action.
Product Picture	
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 contact E-mail: Med-device@moh.gov.om

/ Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

PADC
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Directorate General of Pharmaceutical Affairs & Drug Control

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

Baxter

Urgent Field Safety Notice

Prismaflex Control Unit, PrisMax
FA-2020-016
Safety Alert

April 13th, 2020

Dear Healthcare Provider,

Problem Description

We want to express our gratitude to you and your colleagues who are on the front lines of the Coronavirus (COVID-19) pandemic. We know this requires extraordinary courage and dedication to adapt to ever-changing challenges and that you are caring for patients in less than ideal circumstances.

We have received questions from clinicians who are exploring modifying their use of Baxter's PrisMax and Prismaflex Control units, in order to minimize exposure to COVID-19-positive patients. For example, clinicians may be using multiple extension lines to extend the length of the tubing set to allow placement of a PrisMax or Prismaflex Control unit outside of the patient's room. There are several significant risks that arise with this practice, which are detailed below in the Hazard Involved section of this letter (on Page 2). To mitigate these risks, users are asked to follow the setup instructions in the Graphical User Interface, as well as the warnings from the PrisMax and Prismaflex Operators Manuals as noted below; otherwise, serious patient harm may occur.

Prismaflex Operator's Manual, 7.xx, G5039912 (Page 1:8 and Page 3:2)
WARNING:
Always connect the return line directly to the blood access device. Do not connect additional devices between the return line and the blood access device. The use of additional devices, such as three-way valves, stopcocks, or extension lines, may impair return pressure monitoring. Their use can impede the detection of return disconnections, potentially resulting in severe blood loss.

Prismaflex Operator's Manual, 7.xx, G5039912 (Page1:7)
WARNING:
During priming and operation, observe the system closely for leakage at joints and connections within the set. Leakage can cause blood loss or air embolism. If leakage cannot be stopped by tightening the connections, replace the set.

PrisMax Operator's Manual, SW 2.XX, AW8035-B (Page 56 and Page 237
WARNING!
Always connect the return line directly to the blood access device. Do not connect additional devices between the return line and/or the blood access device. The use of additional devices, such as three-way valves, stopcocks, or extension lines, may impair return pressure monitoring, and cause damage to blood cells resulting in hemorrhage. Their use can impede the detection of return disconnections which can cause drug delivery inaccuracies and/or failures. The blood access needs to have the ability to supply blood at the rate ordered and return the blood at the rate ordered without interruptions which will cause clotting.

Affected Product

Product Code	Product Description	Serial Numbers
107493	Prismaflex Control Unit	All
113080		
113081		
113082		
113874		
114489		
114870		
115269		
115270		
115271		
955052		
955433		
955542		
955633		
955685		
955792		
955626	PrisMax System	
955558		

Hazard Involved

The following hazards are associated with the use of multiple extension lines to allow placement of a PrisMax or Prismaflex Control unit outside of the patient's room: Baxter cannot guarantee that the use of multiple extension lines will establish and maintain secure connections with PrisMax and Prismaflex sets. The use of extension lines increases the risk of disconnections and interferes with the ability of the PrisMax or Prismaflex Control unit to accurately detect pressure drops in the blood circuit. As a result, vascular access disconnections may go undetected, leading to clinically significant blood loss and fatal exsanguination. Additionally, the use of extension lines increases the blood in the extracorporeal circuit. In the event of non-restitution or clotting of the circuit, this may lead to blood loss beyond what is tolerable for the patient. Other potential risks of multiple extension lines include hypothermia, air embolism, and infection. As of March 27, 2020, there have been no reports of serious injury related to this issue.

Actions to be Taken by Customers

1. Operators can safely use the PrisMax and Prismaflex Control Units when adhering to the product-specific Operator's Manual and Graphical User Interface.
2. **If you purchased this product directly from Baxter, complete the enclosed Baxter Customer Reply Form** and return it to Baxter by scanning and e-mailing it to ziad_awadallah@baxter.com. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.
3. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.
4. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected product to other facilities, please distribute this notification to customers.

Baxter

Further information and support

For general questions regarding this communication, contact Baxter at +971 504339369, between the hours of 9:00 am and 6:00 pm, Sunday through Thursday.

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

Sincerely,

Ziad Awadallah, CQA Manager Gulf, Baxter AG.
P.O. Box 64332 Dubai, UAE
Phone : +971 45 196346
E-mail : ziad_awadallah@baxter.com

Attachment 1: Customer Reply Form

Baxter

Confirmation of receipt of communication

(DEVICE SAFETY ALERT MARCH 4, 2022)

DEVICE NAME Prismaflex Control Unit, PrisMax control unit
Product code: 955725, 955052
Serial numbers: ALL

Please complete and return one copy of this form per facility by e-mail Ahmed_albalaasi@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.