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

سلطنة عمان
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. 24 **dated** 07/02/12 **Regarding NCMDR Field Safety Notice of Prismaflex Control Unit from (mfr: 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**

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

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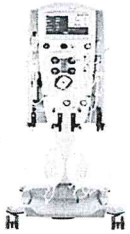
Circular No. 24 / 2021

24-06-1442 H
07-02-2021

Field Safety Notice of Prismaflex Control Unit from Baxter Healthcare.

Source	NCMDR- National Centre for Medical Devices Reporting- SFDA http://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=15527
Product	Prismaflex Control Unit (Hemodialysis Units, Renal, Continuous Replacement Therapy).
Manufacturer	Baxter Healthcare.
Local agent	Mustafa Sultan Science & Industry Co LLC.
The affected products	1- Prismaflex Control Unit: - Product Code: 107493, 113082, 113874, 114489, 114870, 955052 - Serial Numbers: All 2- Preventive Maintenance Kit: - Product Code: G5010007 - Serial Numbers: All 3- ARPS Pump Segment Kit: - Product Code: G5064801 - Serial Numbers: All 4- ARPS Pump Assembly: - Product Code: G5006203 - Serial Numbers: All
Reason	A variability in the performance of the tubing in the ARPS (Automatic Repositioning System) Pump Assembly, may lead to alarm situations (See attached FSN) during or after a system self-test.
Action	1. Please refer to "Actions to be taken by Customers" section in the attached FSN. 2. Contact the local agent for remedial action.
Product image	
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: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General

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

Baxter

Urgent Field Safety Notice

Prismaflex Control Unit
FA-2021-005
Device Correction

February 01, 2021

Dear Healthcare Provider:

Problem Description

Baxter Healthcare Corporation is issuing a Device Correction to the user level for the Prismaflex Control Unit due to variability in the performance of the tubing in the ARPS (Automatic Repositioning System) Pump Assembly, which may lead to the following alarm situations during or after a system self-test.

	Alarm Situations:
Primary Alarms:	• Malfunction: Prime Self-Test Failure (Code 4), during priming • Malfunction: Self-Test Failure (Code 4), during treatment
Secondary Alarms:	• Caution: TMP Excessive • Advisory: TMP Too high

The Prismaflex Control Unit performs system self-tests during priming and at defined intervals during therapy. Therefore, the above alarm situations may occur during priming or during treatment. In these alarm situations, the Prismaflex Control Unit will default to a safe state and provide on-screen instructions to the user. Customers should follow the on-screen instructions if an alarm appears.

To prevent potential alarm situations, the tubing in the ARPS Pump Assembly for the Prismaflex devices listed below will be replaced with improved tubing.

Affected Product

Product Code	Product Description	Serial Numbers
107493	Prismaflex Control Unit	All
113082		
113874		
114489		
114870		
955052		
G5010007	Preventive Maintenance Kit	
G5064801	ARPS Pump Segment Kit	
G5006203	ARPS Pump Assembly	

Hazard Involved

If an alarm occurs, it may lead to delay or interruption of therapy. In the event that therapy is terminated without returning blood to the patient, blood loss may occur. To date, there have been three reports of serious injury potentially related to this issue.

Actions to be taken by Customers

1. Operators may continue to use the Prismaflex Control Unit according to the instructions in the Operator' Manual until the tubing is replaced within the ARPS Pump Assembly.
2. If an alarm occurs, the Prismaflex Control Unit will default to a safe state and the user should follow the on-screen instructions.

3. Existing pump segments and pump assembly kits in your inventory may be utilized for critical repairs until the improved tubing is provided to your facility. If you need additional parts, please communicate your repair needs to your local Technical Service representative and Baxter will prioritize replacement kits when they are available. If the repairs are not urgent, you may wait to perform the repairs until Baxter contacts you to arrange for the replacement of these products.

4. The tubing in the ARPS Pump Assembly is normally replaced during annual Preventive Maintenance (PM). **If your Prismaflex Control Unit is due for PM, these activities should be delayed until new kits have been provided to your facility**.

5. **A local Baxter service representative will contact your facility** to schedule the replacement of the ARPS tubing within the Prismaflex Control Unit and/or to replace the affected unused PM and spare part kits in your inventory, if applicable. Your facility will be receiving this replacement from Baxter at no charge.

6. **If you purchased this product directly from Baxter, complete the enclosed Baxter Customer Reply Form and return it to Baxter** by emailing it to Ahmed_Albalaasi@Baxter.com . Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.

7. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.

8. 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 Device Correction in accordance with your customary procedures.

Further information and support For general questions regarding this communication, contact Baxter at Ahmed_albalaasi@Baxter.com, phone 0551048777 between the hours of 8:00 AM – 5:pm

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

Sincerely,

Enclosure: Baxter Customer Reply Form