Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
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 81 **dated** 06/06/2024 **Regarding NCMDR Field Safety Notice of multiFiltratePRO from (mfr: Fresenius Medical Care).**

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

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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Ministry of Health
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سلطنة عُمان
وزارة الصحة
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مسقط

Circular No. 81 **/ 2024**

29 -11-1445 H
06-06-2024

Field Safety Notice of multiFiltratePRO from Fresenius Medical Care.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21060
Product	multiFiltratePRO.
Description	Acute renal failure dialysis machine.
Manufacturer	Fresenius Medical Care.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	- Article no. M205001 - Software versions 6.02 and 5.02
Reason	A software issue was identified in multiFiltratePRO software versions 6.02 and 5.02. This issue affects the initial functional test of the machine, known as the T1-Test, which occurs prior to setting up the device for treatment.
Action	1. Customers are advised to continue operating the above-affected devices according to the guidelines in the attachment. 2. Fresenius Medical Care will provide stickers to be placed on the machine monitor. These stickers will serve as a reminder for displaying important message in the attachment, please contact your Fresenius Medical Care distributor to obtain these stickers and ensure they are visibly attached to each affected device. 3. The manufacturer is in the process of developing a software update to rectify this error. However, until the update is available and installed, please adhere carefully to the instructions provided in the attachment. 4. 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: Med-device@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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@DSCPHO Email: dscpho@moh.gov.om

FRESENIUS
MEDICAL CARE

Field Safety Notice

multiFiltratePRO (article no. M205001) – Software error during initial functional test may lead to incomplete machine testing

Date: May 13th, 2024

Dear Valued Customer,

During product development activities at Fresenius Medical Care, a software issue was identified in *multiFiltratePRO* software versions 6.02 and 5.02. This issue affects the initial functional test of the machine, known as the T1-Test, which occurs prior to setting up the device for treatment.

The T1-Test rigorously evaluates both software and safety-related components such as the Blood Leak Detector (BLD) and machine-controlled clamps to ensure they are functioning correctly. If a malfunction is detected during this test, an error message is displayed on the touchscreen, and the user is prompted to repeat the T1-Test by pressing a software button to verify the respective defect.

However, due to the software error, when the T1-Test is repeated using this touchscreen button, the test does not properly re-evaluate the components. Instead, it erroneously passes the test, allowing the setup of disposables and the commencement of treatment, even if a critical safety-related component is faulty or has limited functionality.

For example, if there is a defect in the Blood Leak Detector (BLD), the *multiFiltratePRO* device may fail to detect a blood leak during treatment. This could lead to significant, undetected blood loss without triggering the necessary alarms.

To date, Fresenius Medical Care has not received any complaints or reports of incidents related to this specific software issue.

Our records indicate that you are using a *multiFiltratePRO* device with software version 5.02 or 6.02. We advise continuing to operate these affected devices according to the following guidelines:

- If the machine identifies a defective component during the T1-Test, do not attempt to repeat the T1-Test **by pressing the error message using the button on the touchscreen.**
- Instead, **restart the machine by turning it off and then on again.** This action will ensure the T1-Test is executed fully.
- Should the T1-Test detect a defective component after the machine restart, please refrain from using the device and immediately contact a Fresenius Medical Care Service Technician to verify and confirm the machine's functionality.

To aid in compliance with these instructions, Fresenius Medical Care will provide stickers to be placed on the machine monitor. These stickers will serve as a reminder, displaying the message:

"**If initial FUNCTIONAL TEST fails, do not repeat test via software button, but TURN OFF machine and RESTART the device.**"

Please contact your Fresenius Medical Care representative to obtain these stickers and ensure they are visibly attached to each *multiFiltratePRO* machine with software version 5.02 or 6.02 .

We are in process of developing a software update to rectify this error as quickly as possible. However, until the update is available and installed, please adhere carefully to the instructions provided above.

We sincerely apologize for any inconvenience this may cause and appreciate your cooperation. Fresenius Medical Care is committed to upholding the highest standards of quality and safety for our patients and healthcare providers.

Please distribute this Safety Notice throughout your organization and ensure that all affected machines are marked with the provided notice/sticker.

Should you have any additional questions or require further assistance, please do not hesitate to contact:

Dirk Etzdorf (Dirk.Etzdorf@freseniusmedicalcare.com)

Sincerely yours,

Donna Hua

Vice President
Quality & Regulatory, Critical Care & Ventures

Marco Zimmer

Vice President
International MD Vigilance & PMS