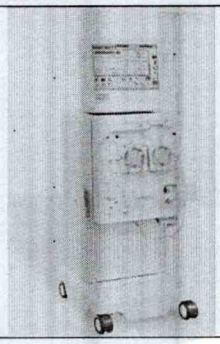
Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
مسقط

Circular No. 6 / 2022

21 -06-1443 H
24 -01-2022

Field Safety Notice of Dialog dialysis machine from B. Braun Avitum AG.

Source	NCMDR-National Center for Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=15993
Product	Dialog dialysis machine.
Description	Haemodialysis system.
Manufacturer	B. Braun Avitum AG.
Local agent	Bahwan Healthcare Center.
The affected products	Conductivity sensors: article code 3456102A (Conductivity Sensor (BIC) - VERSION 2) article code 3456103A (Conductivity Sensor (END) - VERSION 2) of batches 4/21 and 5/21 that have been installed in the following medical devices since 2021-06-15 in the course of a service call: Dialog dialysis machines with software 5.xx, 6.xx and 7.xx Dialog+ dialysis machines with software 8.xx and ≤ 9.18
Reason	Limited number of connection pieces of the bicarbonate and end conductivity sensors may show hairline cracks.
Action	1. A qualified technician will immediately check your potentially affected machines. If your machines are serviced by one of your in-house technicians, the inspection can also be carried out by your own technicians. 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

PADC
المديرية العامة للصيدلة والرقابة الدوائية
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

Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
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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.6/2022**. dated** 24/1/2022 **Regarding NCMDR Field Safety Notice of Dialog dialysis machine from (mfr: B. Braun Avitum AG).**

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
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Kingdom of Saudi Arabia
Saudi Food & Drug Authority
Medical Devices Sector
قطاع الاجهزة الطبية

NCMDR
National Center for Medical Devices Reporting
المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

NCMDR Recall

Reference Number: mdprc 011 01 22 000 Back
Date submitted: 1/11/2022

Manufacturer:	B. Braun Avitum AG
Device Type:	Dialog dialysis machine
Description:	Haemodialysis system
Medical Device Identifier:	Conductivity sensors: article code 3456102A (Conductivity Sensor (BIC) - VERSION 2) article code 3456103A (Conductivity Sensor (END) - VERSION 2) of batches 4/21 and 5/21 that have been installed in the following medical devices since 2021-06-15 in the course of a service call: Dialog dialysis machines with software 5.xx, 6.xx and 7.xx Dialog+ dialysis machines with software 8.xx and ≤ 9.18
Reason of Field Safety Corrective Action:	Limited number of connection pieces of the bicarbonate and end conductivity sensors may show hairline cracks.
Remedy Action:	A qualified technician will immediately check your potentially affected machines. If your machines are serviced by one of your in-house technicians, the inspection can also be carried out by your own technicians. You have received a service information (FSI) describing the appropriate procedure.
Athorized Representative/Importer/Distributor:	Medical supplies & Services Co.Ltd Mediserv
Report Source:	NCMDR
Source Ref. Number:	5B1762CAC5263
SFDA Comments:	SFDA urges all hospitals that have devices subjected to FSCA, to contact the company.
Attachments:	B BRAUN.pdf

View History