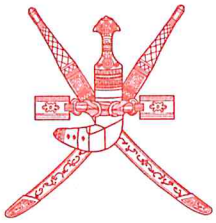
Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs
and Drug Control



سلطنة عمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

To: MUSCAT
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..208.... dated01.12.21.. Regarding NCMDR FSCA of NEXADIA monitor from (mrf: 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

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

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. 208 / 2021

26 -04-1443 H

01 -12-2021

Field Safety Corrective Action of NEXADIA monitor from B. Braun Avitum AG.

Source	NCMDR-National Center for Medical Devices Reporting http://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=15919
Product	NEXADIA monitor.
Description	Software application.
Manufacturer	B. Braun Avitum AG.
Local Agent	Bahwan Health Care Center LLC.
The affected products	Article Code: 7107260, 7107NM201 Article Name: NEXADIA monitor Set, incl. 5 client licenses, NEXADIA monitor 2 Set, incl. 5 client licenses
Reason	In case a customer deviates from the instructions for use of NEXADIA monitor and performs a session data import manually from an external database to NEXADIA monitor in addition to the already automatically performed initial data import, medication, checklist entries and messages can be displayed incorrectly in NEXADIA monitor or by a connected dialysis machine.
Action	1. You may continue to safely use NEXADIA monitor by changing dialysis and demand medication, checklist entries and messages only at NEXADIA monitor as described in the instructions for use in the chapters "Medication", "Messages" and "Checklist". 2. Do not use the manual session data import function in the context menu until the software update is implemented in your facility. 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 contact 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
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

B|BRAUN

B. Braun Avitum AG

Contact:

Mobile:
Phone
E-Mail:
Internet:

Customer
Address

Datum:

Urgent Field Safety Notice

NEXADIA monitor - Software Update

R-2021-004

From:
B Braun National Organization / Distributor

To:
Users, operators and distributors who were supplied with the following products.

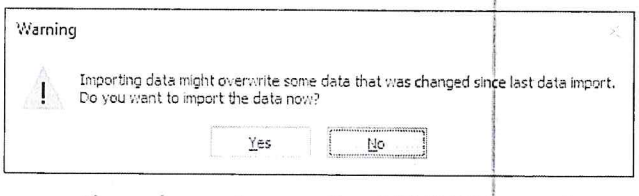
Affected Medical Devices:

Article Code	Article Name	License Number
7107260	NEXADIA monitor Set, incl. 5 client licenses	Select the article code(s) and customer specific license number(s)
7107NM201	NEXADIA monitor 2 Set, incl. 5 client licenses	

Description of the Problem, Root Cause and Corrective Measures

During comprehensive internal testing, we became aware that in case a customer deviates from the instructions for use of NEXADIA monitor and performs a session data import manually from an external database to NEXADIA monitor in addition to the already automatically performed initial data import, medication, checklist entries and messages can be displayed incorrectly in NEXADIA monitor or by a connected dialysis machine.

Whenever a manual session data import is initiated, the following warning is displayed on the NEXADIA monitor screen:



In addition to the above mentioned warning on the NEXADIA monitor screen, the instructions for use of NEXADIA monitor warns to always compare changed data with the written prescription of the physician.

In case a Dialog+ or Dialog iQ dialysis machine is connected to NEXADIA monitor, medication, checklist entries and messages might be displayed also incorrectly by the dialysis machine. Since other dialysis machines do not have a bi-directional data connection with NEXADIA monitor an incorrect display of data by these dialysis machines resulting from the situation described is excluded.

The dialysis therapy parameters are not affected.

There have been no reports referring to the situation described above in the market.

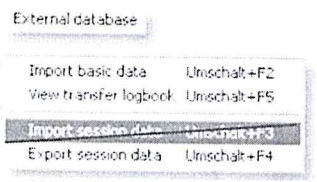
B. Braun Avitum AG is currently developing an updated software and will provide you with it when it becomes available.

Due to this field safety notice, we kindly ask you to take the following measures

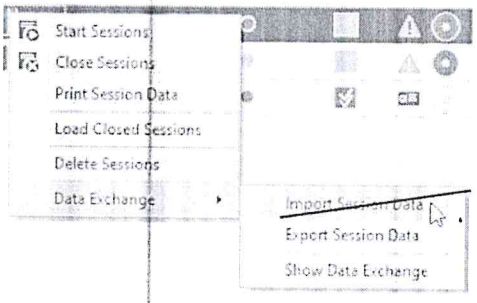
1) Confirm the receipt of this Field Safety Notice on the enclosed confirmation form and return it in a timely manner to the fax number or e-mail address given on the form.
2) You may continue to safely use NEXADIA monitor by changing dialysis and demand medication, checklist entries and messages only at NEXADIA monitor as described in the instructions for use in the chapters "Medication", "Messages" and "Checklist". The instructions for use are accessible in NEXADIA monitor by pressing the F1 key.

   Do not use the manual session data import function in the context menu until the software update is implemented in your facility.

Nexadia monitor software 1.x.x



Nexadia monitor software 2.x.x



B|BRAUN

3) As soon as the software update will be available, your NEXADIA specialist will contact you, provide you with the update and support you in installing it.

Distribution of Information

Please make sure that all users of the above mentioned product in your organisation and other concerned persons are informed about this Field Safety Corrective Action. If you have forwarded the product to a third party, please forward a copy of the Field Safety Notice to them or inform the contact person mentioned below.

Please retain this Field Safety Notice until the update of the NEXADIA monitor is installed at your facility.

The National Competent Authority has been notified of this Field Safety Corrective Action.

If you have any questions regarding this Field Safety Notice, please contact:

National contact

We apologise for the inconvenience caused by this Field Safety Corrective Action and thank you for your understanding and co-operation.

Best regards,

Please fill in your signature, job title, etc. here