

Customer
Address

Urgent Field Safety Notice

Check and Replacement of Conductivity Sensors Installed as a Spare Part in a Dialog dialysis machine since 2021-06-15

R-2022-001

From:

B Braun National Organization/Distributor

To:

Users, operators, distributors and patients who have received affected conductivity sensors as spare parts and which have been installed in machines listed below in the course of a service call.

Affected Medical Devices:

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

Description of the Problem, Root Cause and Corrective Measures:

We became aware that a limited number of connection pieces of the bicarbonate and end conductivity sensors, manufactured by our supplier, show hairline cracks. This issue was narrowed down to two batches of conductivity sensors that were installed in the above-mentioned Dialog dialysis machines in the course of a service call since 2021-06-15.

Chairwoman of the Supervisory Board:
Anna Maria Braun, LL.M.

Executive Board:
Markus Strotmann (Chairman)
Michael Becker
Dr. Holger Seeberg

Corporate Office: Melsungen
Register Court: Local Court
Fritzlar
HRB 11 263
VAT reg.no. DE210567578
WEEE-reg.-no. DE 95624383

Address:
B. Braun Avitum AG
Schwarzenberger Weg 73-79
34212 Melsungen
Germany

If such a hairline crack occurs, this can potentially lead to a leak and subsequently to a potential balance deviation. The kind of balance deviation depends on whether the Dialog machine is equipped with a dialysis fluid filter or not.

In potentially affected Dialog machines equipped with a dialysis fluid filter or HDF online machines, this might lead to a higher ultrafiltration rate than expected. In Dialog machines without DF filter the hairline cracks might cause a lower ultrafiltration rate than expected. In both cases the optical and acoustical alarm "UF balance? air leakage in dialyz. coupl." (alarm code 1026) is triggered. The more significant the leakage the earlier the alarm occurs.

No balance deviation became known from the market.

In a laboratory setting the worst case scenario was simulated. The excess of ultrafiltration in this worst case simulation was about 600 ml/h in machines with DF filter and the insufficient ultrafiltration about 250 ml/h in machines without DF filter. In the respective mock therapies, the alarm was triggered within the first hour. These extreme situations, artificially created, did neither occur in the field nor in investigations with affected conductivity sensors.

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.

Due to this Field Safety Notice, we kindly ask you to take the following measures:

Please confirm the receipt of this Urgent Field Safety Notice by signing the completely filled in confirmation attached and send it back to the given fax number or e-mail address.

Distribution of Information:

Please make sure that all users of the above mentioned products in your organization and other concerned persons are informed about this Urgent Field Safety Notice.

If you have forwarded the products to a third party, please forward a copy of the Urgent Field Safety Notice to them or inform the contact person mentioned below.

Please retain this Urgent Field Safety Notice until you have completed all the above measures.

The **National Competent Authority** has been notified of the **Field Safety Corrective Action/Recall**.

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

National contact

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

Best regards,

Organization

Please fill in your signature, job title, etc here

Confirmation of Receipt of Urgent Field Safety Notice

Check and Replacement of Conductivity Sensors Installed as a Spare Part in a Dialog dialysis machine since 2021-06-15

R-2022-001

Please complete this form and make sure to return it to the

fax number **xxxxxxx**

or the

e-mail address **xxxxxxx**

We hereby confirm the receipt and the acknowledgement of the Urgent Field Safety Notice dated **2022-xx-xx**.

We confirm the number of conductivity sensors affected in the table below.

Conductivity sensors of batches 4/21 and 5/21	Quantity
In stock as spare part	

Conductivity sensors of batches 4/21 and 5/21 assembled as spare parts in Dialog machines with software 5.xx, 6.xx and 7.xx or Dialog ⁺ machines with software 8.xx and ≤ 9.18 since 2021-06-15		
Serial Number Machine	Software Version	Quantity

The affected conductivity sensors were

handed over to the B. Braun technician at Date: _____.

returned with the respective material return form at Date: _____.

Name Customer: _____

B|BRAUN

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Phone Number Customer: _____

Date and Signature Customer: _____

Stamp:

