
URGENT FIELD SAFETY NOTICE

**Dialog⁺ Dialysis Machines with Software 8.2A
in combination with Option Adimea
Software-Update**

R-2016-004

2016-10-16

From:

B. Braun National Organization / Distributor

To:

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

Affected Medical Devices:

To be specified by the country organisation / distributor according to the machines/options delivered to the individual customer

Description of the Problem, Root Cause and Corrective Measures:

We became aware of a software error in software (SW) 8.2A of the Dialog⁺ dialysis machine affecting the timer/stop watch function. This timer function only serves as a support to the user to remind him of an action that has to be taken by him.

The failure occurs only in SW 8.2A and only in combination with option Adimea. In certain conditions and on rare occasions the warning triggered to remind the user is reset by the machine without user interaction. The user might not be aware that the reminder was triggered at all.

The root cause of this failure is a single error in SW 8.2A. If the error occurs, the warning sounds and the yellow light flashes as intended, but the warning is reset by the machine without user interaction.

If the timer/stop watch function is used to remind the user of the application or change of a medication during therapy, and the reminder fails, the patient might suffer from consequences dependent on the medication intended to be applied.

Since the market introduction of the SW 8.2A in 2010 only one single case was reported recently describing this situation. In this case the concentrate was not changed. The patient did not suffer from any long-term consequences.

The failure has been corrected with software version 8.2B. All Dialog⁺ dialysis machines with software 8.2A and option Adimea must be updated to software 8.2B.

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

1. Until the affected Dialog⁺ machines are updated to software 8.2B either do not use the timer/stop watch function and/or monitor the set reminder independent of the machine.

2. Please confirm the receipt of this FSN by signing the Confirmation of Receipt attached below and send it back to the given fax number.
3. Please make sure that all users of the above mentioned products in your organization and other concerned persons are informed about this Field Safety Notice.
4. In case you have uninstalled option Adimea art. code 7105233 in your stock, put it on hold until your contact partner will support you with the action to be taken.

(Country Organisation / Distributor) will contact you to update your Dialog⁺ machine with software 8.2A and option Adimea to software 8.2B. *(in case of service by country organisation / distributor)*

In case your Dialog⁺ dialysis machines are serviced by your own certified technician *(Country Organisation / Distributor)* will contact you to support you to take the required actions for the update. *(in case of service by certified technician of the customer)*

Distribution of Information

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

Please retain this Field Safety Notice until you have completed all the above measures. The *National Competent Authority* has been notified of the Field Safety Corrective Action/Voluntary Recall.

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

National contact

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

Best regards,

Please fill in your signature, job title, etc here

Confirmation of Receipt of Urgent Field Safety Notice

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Affected Devices (to be amended)

Please fill in this form and return it by fax immediately to the fax number

Please fill in your fax number

We hereby confirm that we are aware of the Field Safety Notice from *date* concerning the Dialog⁺ dialysis machine. The Field Safety Notice was communicated within our organization.

Name: _____

Phone Number _____

Date and Signature: _____

Company Stamp: