

TO:
Customer

FIELD SAFETY NOTICE

Dialog⁺ SW 9.xx Dialysis Machines

**in which the tubing between the level regulation block and the diaphragm pump
had been disconnected/reconnected in the course of any repair and maintenance
measures**

R-2015-004

2015-11-20

From:
BBraun Medical Ireland Ltd.

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

Affected Medical Devices:

The following Dialog+ dialysis machines with level regulation system are potentially affected:

Dialog+ SW 9.xx Single Pump Machines

Article codes

710200C

Dialog+ SW 9.xx Double Pump Machines HDF-Online


Article codes

7102072


Description of the Problem, Root Cause and Corrective Measures:

Subsequent to the previous FSCA/Recall R-2014-002 in which only Dialog+ SW 9.xx machines with two pumps including HDF online machines were affected, we have now become aware through internal laboratory investigations that this can affect all Dialog+ SW 9.xx machines.

Interchanging the tubing between the valve block level regulation and the diaphragm pump might occur during any repair or maintenance measures where it was necessary to disconnect and reconnect the tubing. An interchanged tubing results in an inverse function of the manual level regulation system.

The inverse function becomes relevant if the level regulation system is used to remove air from the venous chamber to remedy an air alarm. Activating the function key  on the Dialog⁺ screen results in a positive pressure in the venous chamber instead of a negative pressure.

The negative pressure would trigger the opening of the safety air clamp (SAKV), but due to the positive pressure caused by the interchanged tubing, the SAKV remains closed. The actual positive pressure is displayed on the screen of the Dialog⁺ machine. If the operator does not recognize the positive pressure and opens the safety air clamp manually with the lever at the clamp, deviating from the description in the instructions for use, air is infused through the venous line. This situation was identified during internal laboratory investigation, and has never been reported from the market. It can only occur if the technician had interchanged the tubing during repair or maintenance measures by mistake and the user acts deviating from the instructions for use.

In a Single-Needle-Cross-Over therapy manually raising the level in the arterial chamber leads to a lowering of the level. If this is not realized by the user, and the function key  is continuously pressed, this can lead to an air infusion through the arterial line.

Ex factory, this failure of the Dialog⁺ dialysis machines is excluded. Potentially affected are only Dialog⁺ dialysis machines in which the tubing between the valve block level regulation and the diaphragm pump had been disconnected and reconnected during maintenance and repair activities.


A Service Information will be distributed to all certified service technicians. It describes the correct assembly of the tubing between the valve block level regulation and the diaphragm pump as well as the correct testing procedure.

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

Do NOT use the manual level regulation in therapy and do NOT perform any SN/CO therapy before you have tested the correct function of the manual level regulation of your Dialog⁺ SW 9.xx machines.

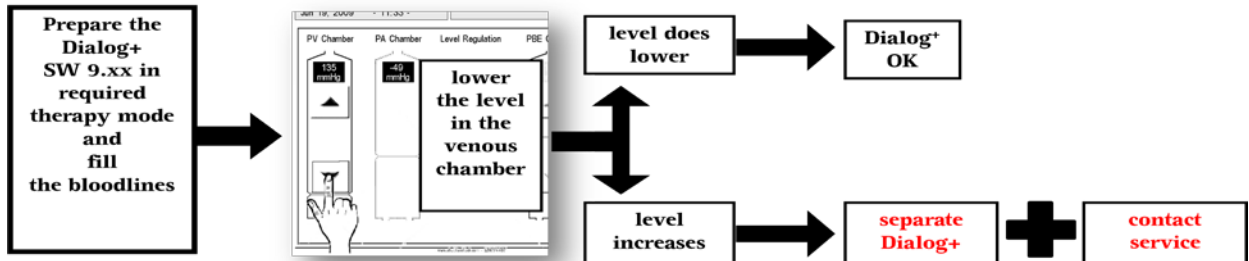
You can easily check your Dialog⁺ dialysis machines for correct function of the level regulation system during the preparation of the next upcoming treatment. This is possible in any treatment mode.

Please check all your above mentioned Dialog⁺ machines according to the following steps:

1. Prepare your Dialog⁺ machine in the required therapy mode as usual.
Fill the bloodlines.
The venous chamber should be half-filled.
2. Lower the level in the venous chamber by pressing the function key .
3. Observe the level in the venous chamber
The level lowers ⇨ the level regulation is working correctly

The level rises ⇒ the level regulation is **NOT** working correctly
↓

Do not use the respective Dialog⁺ machine
Separate and label it
Contact your service technician



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 **Field Safety Notice**. If you have forwarded the products 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 you have completed all the above measures. The HPRA has been notified of the Field Safety Corrective Action.

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

Fiona Duggan
Business Unit Manager – Avitum Division
BBraun Medical Ltd.

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

Best regards,

Fiona Duggan
Business Unit Manager – Avitum Division
BBraun Medical Ltd.

Confirmation of Receipt of Field Safety Notice

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

01 7091889

We hereby confirm that we are aware of the Field Safety Notice from 19/11/2015 concerning the Dialog+ SW 9.xx. The Field Safety Notice was communicated within our organization.

We also confirm that we checked all our above mentioned Dialog+ dialysis machines as described in the Field Safety Notice.

Name: _____

Phone Number _____

Date and Signature: _____

Company Stamp: 