

URGENT FIELD SAFETY NOTICE

**Dialog⁺ SW 9.xx Two Pump Machines (incl. HDF online)
in which level regulation spare parts were exchanged**

R-2014-002

From:

BBraun Medical Ltd.
Avitum Division,
3 Naas Road Industrial Park,
Dublin 12.

To:

XXXXXX

Affected Article Codes:

7102072


in which the following spare parts were exchanged

34560831	Valve Block Level Regulation (DP)
3456083A	Valve Block Level Regulation (DP)

17/11/2014

Dear All,

In the context of our continuous post market surveillance it became known to us that following the exchange of the valve block level regulation and/or the diaphragm pump by a service technician an interchanged connection of the tubing between these components cannot be completely excluded, if the functionality is not tested as requested in the service manual. This results in an incorrect function of the manual level regulation.

Only in 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 above mentioned components were exchanged during a technical service.

Only one single case was reported in which the tubing was wrongly connected by the customer's service technician. The functional test requested in the service manual was not performed completely in this case. There was neither an air infusion nor any other consequences for patient, user or third party.

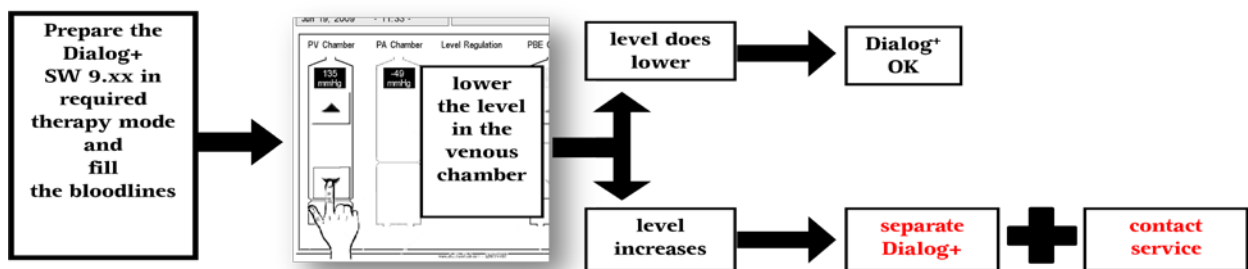
To completely exclude a wrong connection of the tubing in the future, a detailed service instruction will be enclosed to the spare parts valve block level regulation and diaphragm pump.

Actions to be taken by you:

To check whether your Dialog+ SW 9.xx - Two Pump Machines (incl. HDF online) do not have the described failure, we ask you NOT to perform any SN/CO therapy before you have tested the correct function of the manual level regulation.

You can easily check for correct function during preparation of the next upcoming treatment. This is possible in any treatment mode. Please act according to the following steps:

1. Prepare the Dialog+ in the required therapy mode and fill the bloodlines. The venous chamber should be half-full.
2. Lower the level in the **venous chamber** by pressing the function key
3. Observe the level in the venous chamber
 - a. if the level lowers, the Dialog+ is working correctly
 - b. if the level increases, the Dialog+ working faulty, separate and label the Dialog+ and contact your service technician



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. You will be informed as soon as the modified product is available.



The HPRA has been notified of the Field Safety Corrective Action.

We are available to personally answer any questions you may have regarding this issue and the proposed actions. Please contact:

Fiona Duggan – Business Unit Manager - 0860480332

Mark Power – Service Engineer - 0860480368

Brendan Reilly -Service Engineer - 0860458301

We kindly ask you to confirm the receipt of this information by completing the attached form and returning it by fax to the indicated fax number.

We apologize for the inconvenience caused.

Yours Sincerely,

Fiona Duggan
Hospital Business Unit Manager



Confirmation of Receipt of Field Safety Notice

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R-2014-002

Article Code

7102072

**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 17/11/2014 concerning the Dialog+ SW 9.xx with two pumps (incl. HDF online). The Field Safety Notice was communicated within our organization.

We also confirm that we checked our machines with the following result:

- Test passed in all machines
- Test failed in _____ machines
(Please fill in the number of machines in which the test failed)

Name: _____

Telephone Number _____

Date and Signature: _____

Stamp: