

**URGENT FIELD SAFETY NOTICE**

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

**R-2014-002**

From:

**B Braun National Organization / Distributor**

To:

**Customer Name**

**Affected Article Codes:**

<b>7102013</b>	<b>7102072</b>
<b>710201C</b>	<b>710207E</b>
<b>710201E</b>	<b>710207F</b>
<b>710201I</b>	<b>710207P</b>
<b>710201S</b>	<b>710207T</b>
<b>710201CV</b>	<b>710207X</b>
<b>710201G</b>	<b>710207EV</b>
<b>710201T</b>	
<b>710201U</b>	
<b>710201XV</b>	
<b>710201D</b>	

**(only use your country specific article code)**


**in which the following spare parts were exchanged**

<b>34560823</b>	<b>Diaphragm Pump</b>
<b>34560831</b>	<b>Valve Block Level Regulation (DP)</b>
<b>3456083A</b>	<b>Valve Block Level Regulation (DP)</b>

**(only use your country specific article code)**

Dear **Sir / Madam**,

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 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<sup>+</sup> dialysis machines is excluded. Potentially affected are only Dialog<sup>+</sup> 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.

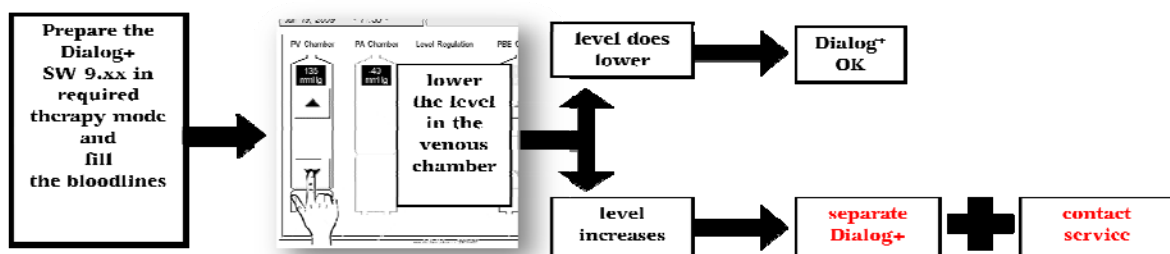
To completely exclude a wrong connection of the tubing in the future, a detailed service instruction will be enclosed to the spare parts valve block level regulation and diaphragm pump.

#### **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<sup>+</sup> 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<sup>+</sup> is working correctly
  - b. if the level increases, the Dialog<sup>+</sup> working faulty, separate and label the Dialog<sup>+</sup> and contact your service technician



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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 **National Competent Authority** 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

**local contact**

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.

Sincerely,

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

...

**Confirmation of Receipt of Field Safety Notice**

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

**R-2014-002**

**Article Code**

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<b>710201CV</b>	<b>7102072</b>	<b>710207EV</b>

**(only use your county specific article code)**

**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+ 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:**

November 13, 2014

**Assembly and Detailed Testing Instruction**

- Dialog+ SW 9.xx

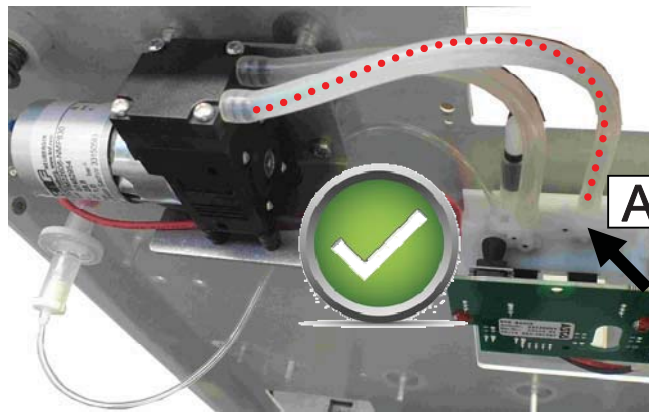
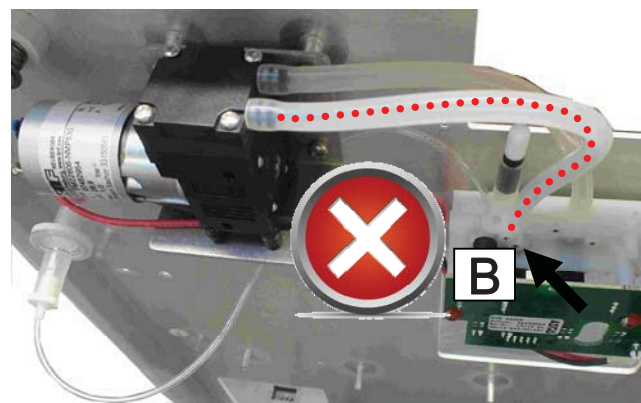
- **Level Regulation Option: Tubing Connection between Diaphragm Pump and Valve Block Level Regulation**

**1. Related Machines**

Dialog+ machines with software 9.xx and a level regulation option.

**2. Assembly and Detailed Testing Instruction**

It is technically possible to connect the two tubes between the diaphragm pump and the valve block level regulation wrongly during a service activity when the diaphragm pump or when the valve block level regulation is replaced, i.e. the tubing can be inverted **B** at the pump or at the valve block. This inverted connection **B** will cause a malfunction of the level regulation system during the required functional check. Only in a single-needle cross-over treatment the intended increasing of the level of the arterial cross-over chamber can actually lead to an air infusion into the patient through the arterial patient connection.

Fig.: Correct connection **A**Fig.: Incorrect connection **B****3. Service Activities**

The correct connection of the tubing **A** shall be ensured after assembly by a visual check, as well as a functional check by increasing and decreasing the levels inside the chambers using the *Up* and *Down* icons in a simulated treatment. The machine shall be released for patient use only if the level regulation works correctly, i.e. the level decreases when the *Down* icon is activated and the level increases when the *Up* icon is activated. This check shall be performed for all chambers of the connected tubing system to ensure the correct function of the option.



**Air infusion possible via the arterial line in Single-Needle Cross-Over mode only!**

- Prepare the machine for a simulated treatment.
- Activate the *Up* and *Down* icons for each chamber.
- Confirm that the levels in the respective chambers actually increase and decrease.

With best regards



For more information please contact your local B. Braun Medical support.

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