
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:

B Braun National Organization / Distributor

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	710200CV	710200E	710200F	710200H	710200IV	710200P
710200R	710200SV	710200W	710200X	710200XV	710200Y	710200ZV

Article codes (only with serial number < 106760)

7102005	710200K	710200L	710200N	710200S	710200T	710200U
---------	---------	---------	---------	---------	---------	---------

Article codes (only with serial number < 500000)

710200A	710200I
---------	---------

Dialog⁺ SW 9.xx Double Pump Machines

Article codes

7102013	710201A	710201C	710201CV	710201E	710201EV	710201G
710201I	710201S	710201SV	710201T	710201U	710201W	710201XV

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



Article codes

7102072	710207D	710207E	710207EV	710207F	710207P	710207T
710207X	710207XV					


(only use your country specific article code group(s))

Description of the Problem, Root Cause and Corrective Measures:

We became aware that it is not completely excluded to interchange the tubing between the valve block level regulation and the diaphragm pump, if the functionality of the level regulation system is not tested as requested in the service manual. This 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.

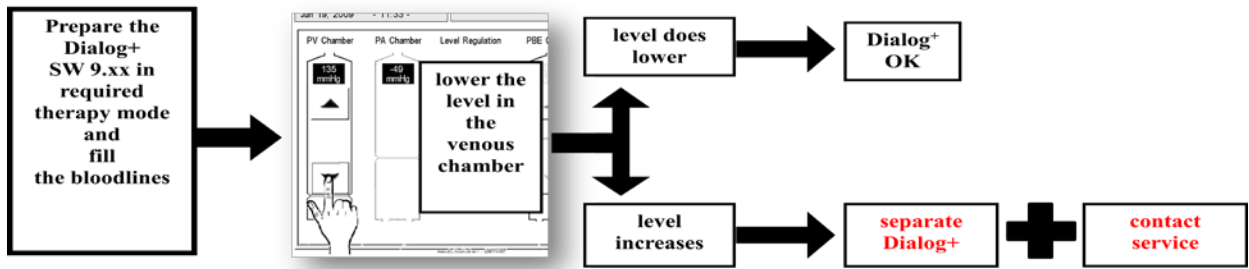
You can easily check your Dialog+ dialysis machines for correct function of the level regulation system during the preparation of the next upcoming treatment. This is possible in any treatment mode.

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

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

National contact

We apologise for the inconvenience caused by this Field Safety Corrective Action / 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 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

Dialog+ SW 9.xx Single Pump Machines

Article codes

710200C 710200CV 710200E 710200F 710200H 710200IV 710200P
710200R 710200SV 710200W 710200X 710200XV 710200Y 710200ZV

Article codes (only with serial number < 106760)

7102005 710200K 710200L 710200N 710200S 710200T 710200U

Article codes (only with serial number < 500000)

710200A 710200I

Dialog+ SW 9.xx Double Pump Machines

Article codes

7102013 710201A 710201C 710201CV 710201E 710201EV 710201G
710201I 710201S 710201SV 710201T 710201U 710201W 710201XV

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

Article codes

7102072 710207D 710207E 710207EV 710207F 710207P 710207T
710207X 710207XV

(only use your country specific article code group(s))

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. 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: