

**Important Safety Message referring to Dialog<sup>+</sup> Machines with DF Option**

Dear customer,

In the past weeks there have been isolated reports on negative deviations in the fluid balance (too high ultrafiltration volume) on some Dialog+ dialysis machines without an alarm. These incidents were only observed on Dialog<sup>+</sup> machines with the dialysis fluid filter option (DF option) that were manufactured after October 16<sup>th</sup>, 2007.

Dialysis machines without DF option and machines with HDF Online option set off an alarm in the case of a malfunction causing a balance deviation.

So far, there have been a total of nine reports about negative deviations in fluid balance amounting to around 1 liter over the entire treatment session; in two instances the patient suffered a drop in blood pressure, but without any further impairment.

Initial results of our investigation suggest that there is a leak at the conductivity sensors on the affected machines. The conductivity sensors are located at the dialysate inlet. Since negative pressure is present during operation, minor quantities of air may enter the dialysis fluid system due to the leak. Due to the design, air intake can only lead to negative deviations in fluid balance on dialysis machines with the DF option (because air collects in the DF filter). This can amount to a maximum of 1000 ml over four hours. There is no risk whatsoever that air will enter the patient's bloodstream.

Corrective measures for machines with DF option:

To exclude a negative fluid balance deviation and thereby prevent any potential hazard to patients, the DF function will have to be bypassed with an adapter until the conductivity sensors can be replaced. The DF filter can be replaced by the bypass adapter prior to a disinfection cycle. After bypassing, machines will set off an alarm in case of a malfunction just like machines without a DF option. Alarm text: "UF-balance? Air entering at dialyzer couplings (code 1026)".

Our service department will be contacting you immediately to implement this action.

A safe operation of the affected machines is currently not guaranteed without the bypassing, as already described. We explicitly point out that we, therefore, cannot assume liability in these cases.

The conductivity sensors will be replaced by a service technician within the next few weeks.

Kurzzeichen:

Datum:

2008-02-28

If you have any questions, our local service manager Mr. *(Please fill in your local contact)* is at your disposal.

We apologize for any inconvenience this situation may have caused you and assure you that the cause of the matter will be remedied immediately.

Please acknowledge receipt by signing this letter and fax it back to us at your earliest convenience.

Thank you for your cooperation!

Best regards,

I acknowledge the receipt of this letter:

*Stamp*

Title, name: \_\_\_\_\_

Telephone number: \_\_\_\_\_

Date, signature: \_\_\_\_\_

Kurzzeichen:

Datum:

2008-02-28