

**FRESENIUS USA**

**2008K**

**DIASAFE PLUS<sup>®</sup> FILTER**

**OPERATOR'S INSTRUCTIONS**

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# OPERATOR'S INSTRUCTIONS FOR THE 2008K WITH DIASAFE PLUS<sup>®</sup> FILTER

**Warning:** With highly permeable dialyzers, ultrafiltration must be carried out only with volume-controlled ultrafiltration.

**Warning:** For the safe execution of hemodiafiltration and dialysis with highly permeable dialyzers it is important that the balancing system of the 2008K Dialysis Machine is operating properly. Operation of the balancing system must be checked before each high-flux or high-efficiency dialysis session using the following automated or manual test. The dialysate delivery machine must be stable and alarm free before beginning these tests.

**Warning:** The use of the DIASAFE PLUS<sup>®</sup> filter does not reduce the need for the routine disinfection of the dialysis machine and treated water (R.O.) distribution system or routine monitoring of the chemical and bacterial water quality. The water and dialysate quality must meet current AAMI Hemodialysis Systems standards. The machine disinfection procedure is unchanged with the DIASAFE PLUS<sup>®</sup> filter present.

**Warning:** Proper functioning of the machine must be verified prior to initiating treatment. Unidentified malfunctions or alarm failure could potentially expose a patient to a risk of injury.

Replace the DIASAFE PLUS<sup>®</sup> filter at least every 90 days (3 months). After replacing the DIASAFE PLUS<sup>®</sup> filter, perform either the automated test function or a manual pressure holding test AND then perform the DIASAFE PLUS<sup>®</sup> filter integrity test.

**Note:** For instructions on replacing the DIASAFE PLUS<sup>®</sup>, refer to P/N 507500.

**Note:** Before performing the DIASAFE PLUS<sup>®</sup> filter integrity test, the Automated or Manual PHT must be performed successfully. This eliminates false failures of the DIASAFE PLUS<sup>®</sup> filter integrity test.

If your 2008K machine fails one of the above tests, check the external parts of the DIASAFE PLUS<sup>®</sup> filter for leaks and loose connections.

## **Automated Test Function**

The procedure to perform the automated test function can be found in the appropriate machines specific operator's manual.

**Note:** This test should be performed before every dialysis treatment to help identify malfunction. The alarm checks are performed first, followed by the Pressure Holding Test (PHT). The PHT verifies the integrity of the volumetric balancing system.

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## **Manual Pressure Holding Test**

1. Place the dialysate lines in the shunt with dialysate flow at 500 ml/min.
2. Set UF rate to 500 ml/hr.
3. Allow the UF pressure to rise until a TMP of 300 (260-340) mmHg is established.
4. Stop the UF pump by turning the UF OFF. Allow the TMP to stabilize.
5. The TMP may change by no more than 60 mmHg within 3 minutes.

## **Automated DIASAFE PLUS<sup>®</sup> Filter Integrity Test. Perform this test Bi-Weekly (Every other week).**

**Note:** Before beginning this test, the Automated or Manual PHT must be performed successfully. This assures the correct operation and integrity of the balancing system.

**Note:** The machine does not need to be alarm free to perform this test.

1. Turn the machine on into dialysis.
2. Verify that the dialysate lines are on the shunt, the dialysate flow is on and that there is no blood sensed.
3. Go to the Test & Options screen, press the "Diasafe Test" button and then Confirm.
4. When the test is complete, verify that the Status line displays "Diasafe Test Passed".
5. If the machine gives the "Diasafe Test Failed" message in the status line, replace the DIASAFE PLUS<sup>®</sup> filter.

**Note:** If the DIASAFE PLUS<sup>®</sup> filter is replaced, run the automated Diasafe test again. If it fails again, the machine must be serviced.

**Note:** For instructions on replacing the DIASAFE PLUS<sup>®</sup>, refer to P/N 507500.