# FRESENIUS USA

# 2008H & 2008K

# DIASAFE® FILTER

# OPERATOR'S INSTRUCTIONS

FRESENIUS USA
2637 SHADELANDS DRIVE
WALNUT CREEK, CA 94598
(800) 227-2572

# OPERATOR'S INSTRUCTIONS
# FOR THE 2008H & 2008K WITH DIASAFE® 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 2008H or 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® 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® 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® filter at least every 90 days (3 months). After replacing the DIASAFE® filter, perform either the automated test function or a manual pressure holding test AND then perform the DIASAFE® filter integrity test.

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

If your 2008H or 2008K fails one of the above tests, check the external parts of the DIASAFE® filter for leaks and loose connections. Be sure the screw caps and the dialysate quick connectors are tight and are not damaged.

## 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.

**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.

**DIASAFE® 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:** This test should be performed only when the machine is stable and in an alarm free condition. Any alarm during the test invalidates the result. It may be necessary to adjust the alarm window of the conductivity monitor during the test to prevent an alarm.

1. Place the dialysate lines on the shunt. This will spread the TMP alarm limits.
2. Turn the dialysate flow off.
3. Zero the UF Removed.
4. Turn the test valve (on the lower back panel) to the "TEST" position (arrow is the short end).
5. Turn the UF rate to maximum.
6. Turn the UF on until the RMVD reaches 120 ml, then turn the rate down to 2000 ml/hr. If the TMP does not increase by 60 mmHg within 3-1/2 to 4 minutes, the test has failed and the filter should be replaced. In this test the UF pump pulls the dialysate out of the dialyzer and air is pulled in to replace it. When all the dialysate has been replaced by air the TMP should increase. FILLING PROGRAM or HIGH TMP alarms may occur.

Upon completion of this test, the machine may be returned to normal operation in the following way:

1. Turn the test valve handle to the "Dialyze" position.
2. Turn the dialysate flow on and confirm the dialysate flow is set to 500 ml/min.
3. Lift the dialysate shunt door to put the machine into bypass mode. Allow the machine to run this way for 2 minutes while the air is being flushed from the DIASAFE® filter.
4. When this is finished, lower the shunt door and continue with normal pre-dialysis procedure.