# Dialysate Composition Verification Procedure

**SERIAL #** _____ **DATE** _____

**MACHINE I.D. #** _____ **MACHINE HOURS** _____

**TECHNICIAN(S)**_____ **INTIALS** _____

**Purpose:** This procedure is used to verify conductivity is calibrated correctly after any conductivity related repair work is performed on a 2008® Series hemodialysis machine.

**Scope:** To instruct Fresenius Medical Care-trained customers, of their responsibility to verify Dialysate Composition, using this procedure. This procedure (or a conductivity procedure that verifies the same data points captured in this document) should be followed after any conductivity related repairs are performed; such as ***repairs related to conductivity problems*** and ***extending the acid/bicarbonate concentrate lines***. If any of the verification steps fail, they must be documented and repaired before the machine can be released for use.

*Note 1: 2008® Series hemodialysis machines include the 2008K, 2008K², 2008K@HOME™ and 2008T.*

*Note 2: The hemodialysis machine mixes acid concentrate, bicarbonate concentrate and RO water to create the final dialysate.*

*Note 3: The composition of the final dialysate is verified with a calibrated conductivity meter.*

*Note 4: If the final dialysate composition is wrong due to a machine mis-modification, the conductivity monitor calibrations and verifications will catch this if the procedures are followed fully.*

**Reference Documents:**

- 2008T Calibration Procedures (P/N 508032)
- 2008T Preventive Maintenance Procedures (P/N 508033)
- 2008K Calibration Procedures (P/N 507296)
- 2008K Preventive Maintenance Procedures (P/N 507297)
- 2008K² Calibration Procedure (P/N 508137)
- 2008K² Preventive Maintenance Procedures (P/N 508138)
- 2008K@home Calibration Procedures (P/N 507664)
- 2008K@home Preventive Maintenance Procedures (P/N 507665)

**Definitions**

- Theoretical Conductivity (TCD)
- Online Clearance (OLC)

**Equipment Required:**

- Calibrated Conductivity/temperature meter
- pH test strip or calibrated pH meter

# Dialysate Composition Verification Procedure

**Machine Preparation:**

Power the machine On and enter service mode

Verify OLC option is set to "YES"

Power the machine Off then On and enter dialysis mode

Connect acid (red) and bicarbonate (blue) wands to concentrates

After the temperature and conductivity have stabilized, connect a calibrated external conductivity/temperature meter to the dialysate lines.

**Note:** If the external meter reads conductivity to the third decimal (thousandths), then the documented conductivity is rounded to the first decimal (tenths).

**Note:** NEO-1 Temperature/Conductivity meters must be grounded for correct conductivity readings.

**Procedure**:

1. Verify acid/bicarbonate compositions were entered correctly.

   Yes ☐ No ☐ Initials: _____ Date: _____

2. Verify the dialysate conductivity **displayed** by the machine corresponds to the external meter (**actual**) within ±0.1 mS/cm.

   Record the displayed reading and external meter readings (Range: DISPLAYED = ACTUAL ± 0.1 mS/cm)

   Display _____ Actual (Meter) _____ Pass ☐ Fail ☐

   Initials: _____ Date: _____

3. Verify the dialysate conductivity displayed by the machine's nominal **TCD** corresponds to the external meter (**actual**) within ±0.4 mS/cm.

   Record the displayed TCD and the external meter readings (Range: TCD = ACTUAL ± 0.4 mS/cm)

   TCD: _____ Actual (Meter) _____ Pass ☐ Fail ☐

   Initials: _____ Date: _____

4. Verify the Dialysate Temperature in dialysis mode. Verify that the dialysate temperature displayed by the machine corresponds to the external meter within 0.3°C at a 500 ml/min dialysate flow rate. Record the **displayed** and external meter readings (**actual**).

   Verify and record temperature (37°C) (Range: DISPLAYED = ACTUAL ± 0.3°C)

   Display _____ Actual (Meter) _____ Pass ☐ Fail ☐

   Initials: _____ Date: _____

5. Verify the pH is between the ANSI/AAMI RD52 standard of 6.9 and 7.6. A pH level outside this range can indicate a serious proportioning of concentrates. Using pH test strips, P/N 335130-01 or a pH meter to perform a pH test on a dialysate sample collected from the machine. Record the results below

   Verify and record conductivity pH (Range: 6.9 – 7.6)

   Measured pH _____ _____ Pass ☐ Fail ☐

   Initials: _____ Date: _____

# Dialysate Composition Verification Procedure

Test the concentrate pumps per Preventive Maintenance Procedures for the applicable model of machine. See reference document section for Fresenius Medical Care part numbers.

AMIN _____ AMAX _____ Pass ☐ Fail ☐

Initials: _____ Date: _____

BMIN _____ BMAX _____ Pass ☐ Fail ☐

Initials: _____ Date: _____

6. If any of the verifications fail, make sure that the acid (red) and bicarbonate (blue) wands are properly connected. Refer to the table below for action to take and document whether or not action was performed.

| If Verification Fails | Action(s) | Performed (YES/NO) |
|---|---|---|
| If acid/bicarbonate compositions were not entered correctly | Enter correct compositions | YES ☐ NO ☐<br>Initials: _____ Date: _____ |
| If conductivity verification fails | Perform the conductivity calibration as per Calibration Manual for the applicable model of machine. | YES ☐ NO ☐<br>Initials: _____ Date: _____ |
| If TCD is ± 0.5 mS/cm | Verify that the acid and bicarbonate input pressure is ≤2 psi if bibag feature is not installed, ≤10 psi if bibag equipped.<br>Perform balance chamber calibration as per Calibration Manual for the applicable model of machine.<br>Perform concentrate pump calibration as per Calibration Manual for the applicable model of machine. | YES ☐ NO ☐<br>Initials: _____ Date: _____ |
| If temperature verification | Perform the temperature calibration as per Calibration Manual for the applicable model of machine. | YES ☐ NO ☐<br>Initials: _____ Date: _____ |
| If pH fails verification | Check the calibration of hydraulic volumes and pressures per Calibration Manual for the applicable model of machine. | YES ☐ NO ☐<br>Initials: _____ Date: _____ |
| If concentrate pumps test fail | Perform acid and bicarbonate pump calibrations and perform test again.<br>Replace pump and perform test again. | YES ☐ NO ☐<br>Initials: _____ Date: _____ |

** Note: If the acid and bicarbonate lines are extended, prime the acid pump and bicarbonate pumps twice (60 strokes) before calibrating.

7. Disconnect the external conductivity/temperature meter from the machine.

8. Perform both self-tests and verify all tests pass.

Pass ☐ Fail ☐ Initials: _____ Date: _____

9. Perform the facility disinfection procedure prior to returning machine to service.

Initials: _____ Date: _____