

UF Problem Identification Procedure

1.0 **Purpose:**

To establish specific procedures for qualified/trained personnel to follow when attempting to identify Ultrafiltration (UF) problems with the 2008[®] Series Hemodialysis Systems.

2.0 **Reference Documents:**

- UF Problem Identification Checklist – P/N 507162
- Machine Specific Operator's Manual:
 - 2008K Operator's Manual – P/N 490042
 - 2008K² Operator's Manual – P/N 490136
 - 2008K@HOME™ User's Guide – P/N 490180
 - 2008T Operator's Manual – P/N 490122
- Service Confirmation (SC) Form – P/N 500571
- 2008K/K² Troubleshooting Guide – P/N 507298

3.0 **Required Tools:**

- Fresenius Medical Care Test Kit (P/N 150034)
- Barb fitting (P/N 332141-01)
- 2000ml (qty 2) & 500ml (qty 1) graduated cylinders
- 60cc syringe
- 25ml buret
- Pressure meter (i.e. Conductivity/Temperature/Pressure meter)
- Screw type tubing clamp (Cole-Parmer P/N YO-06833-10 or equivalent)

4.0 **Required Supplies:**

- 1000ml bag of saline
- Bloodline
- Dialyzer

5.0 **Procedure:**

Use a **UF Problem Identification Checklist (P/N 507162)** to record data and information. Complete the upper information section completely; this includes machine serial number, current date, machine I.D number, the machine hours, name or names of technicians involved and, for RTG personnel, the Service Confirmation (SC) number.

5.1 **Pressure Holding Tests**

The Pressure Holding Tests must be performed at the onset of UF problems identification and at the completion of the work. Pressure Tests on the 2008K/K²/K@HOME/T machines are automatic with clear test results being displayed following the test. Record "Pass/Fail" on the UF Problem Identification Checklist.

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5.2 Simulated Patient Run

Perform a Simulated Patient Run using the following process:

Note: Setup and prime a bloodline prior to starting the test. For setup and priming instructions, refer to the machine specific Operator's Manual.

1. Set up the dialysis machine as if for a patient treatment. Use a dialyzer with a coefficient similar to that used in the clinic's setting. Make sure the bloodlines and dialysate lines have been primed completely and purged of all air.
2. Set the dialysate flow to 500ml/min.
3. Set the blood flow rate to 300ml/min.
4. Set the temperature to 37°C.
5. Set the UF goal to 1000ml.
6. Set the UF time to 1 hour.
7. With the blood pump running, record the UF rate the machine calculated on the UF Problem Identification Checklist as "**UF Rate**".
8. Using fluid from the machine drain port, fill a 2000ml graduated cylinder with exactly 1500ml of fluid using a 500ml graduated cylinder. This will be the **Simulated Patient** cylinder.
9. An empty 2000ml graduated cylinder will be used to collect the UF output from the machines fluid sample port. This will be the **UF Collected** cylinder.

Note: The machine must be alarm free from this point until the end of the test.

10. Clamp the saline line and stop the blood pump.

Note: The saline line must remain clamped throughout the test.

11. Immerse both ends of the arterial and venous bloodlines into the **Simulated Patient** cylinder making sure the ends are submersed low enough into the cylinder to prevent air from being drawn in. Cover the **Simulated Patient** cylinder to reduce evaporation.
12. Disconnect the tube on the FLUID SAMPLE/ULTRAFILTRATE OUTPUT port and place the end into the empty **UF Collected** cylinder.
13. Turn the blood pump on and start the UF pump. Place a screw type tubing clamp on the venous line just below the line clamp. Adjust the screw clamp to create a venous pressure of approximately +200mmHg. Run an alarm free program.
14. At completion of the program, turn the UF section OFF and open the blood pump door to stop the blood pump. **Remove the blood lines from the Simulated Patient cylinder.**

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Note: For increased accuracy, use a 500ml graduated cylinder in the next step to measure the "Ending Patient".

- Using proper meniscus reading technique (see **Figure 1**), read and record the remaining fluid volume as "**Ending Patient**" on the UF Problem Identification Checklist.

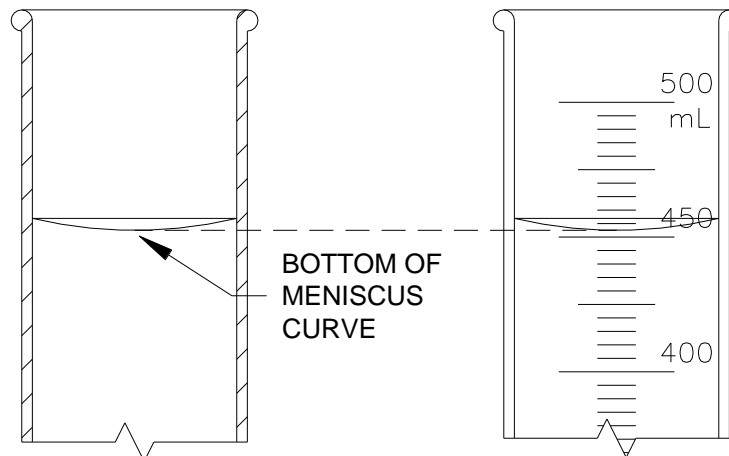


Figure 1 - Meniscus Curve

- Calculate the volume removed from the supply cylinder by using the following formula:

$$(\text{Volume Removed}) = (1500\text{ml}) - (\text{Ending Patient})$$

Record this value on the UF Problem Identification Checklist as "**Volume Removed**".

- Measure the volume of fluid collected from the UF output. Record this value on the UF Problem Identification Checklist as "**UF Collected**".

- Using the following formula, calculate the UF Balance Error:

$$(\text{UF Balance Error}) = (\text{Volume Removed}) - (\text{UF Collected})$$

Record this value as "**UF Balance Error**" on the UF Problem Identification Checklist.

The maximum allowable error is $\pm 30\text{ml}$ for the 1 hour simulated patient run. Record "Pass/Fail" on the UF Problem Identification Checklist.

- Record the UF Removed value from the front panel of the machine as "**UF Counter**" on the UF Problem Identification Checklist.

- Using the following formula, calculate the UF Counter Error:

$$(\text{UF Pump Error}) = (\text{UF Counter}) - (\text{UF Collected})$$

Record this value on the UF Problem Identification Checklist as "**UF Pump Error**".

The maximum allowable error is $\pm 10\text{ml}$ for the 1 hour simulated patient run. Record "Pass/Fail" on the UF Problem Identification Checklist.

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5.3 Verify the UF Pump Stroke Calibration

Without making any adjustments, verify the UF Pump Stroke Calibration. Refer to the Calibration/Installation section of the Technicians Manual for the procedure to verify the fluid volume per pump stroke.

During the UF Pump Stroke Calibration when the Target value reaches zero, the UF pump stops. Measure the fluid collected in the buret. The buret scale should indicate between 0.90 and 1.10ml. This is not the UF pump stroke volume. Using the following formula, calculate the per stroke volume of the UF Pump:

$$(\text{Volume per UF Pump Stroke}) = \frac{25\text{ml} - (\text{Buret Reading})}{24 \text{ strokes}}$$

$$\text{For Example:} \quad \mathbf{1.002\text{ml/stroke}} = \frac{25\text{ml} - (\mathbf{0.95\text{ml}})}{24 \text{ strokes}}$$

Record the ml/stroke volume on the UF Problem Identification Checklist. Round up the recorded value to three decimal places as shown in the example above.

The volume should be between 0.996 and 1.004ml/stroke. Record "Pass/Fail" on the UF Problem Identification Checklist.

5.4 Perform the Positive Pressure Test on the Hydraulics* .

Perform the Positive Pressure Test on the Hydraulics. Refer to Section 12 – Induced Positive Pressure Tests in the 2008K/K² Troubleshooting Guide* (P/N 507298). Record "Pass/Fail" on the UF Problem Identification Checklist.

* The process outlined in Section 12 of the 2008K/K² Troubleshooting Guide (P/N 507298) can be used on all supported 2008 Series hemodialysis machines due the similarity of their hydraulic systems.

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5.5 Perform the Positive Pressure Test on the UF Pump.

Perform the Positive Pressure Test on the UF Pump to confirm the UF Pump pressure holding capability:

1. Machine must be in conductivity with the flow set at 500ml/min and alarm free.
2. Attach the dialysate line quick connects to a shunt assembly with an external pressure meter and a 60cc syringe as illustrated in **Figure 2** below.

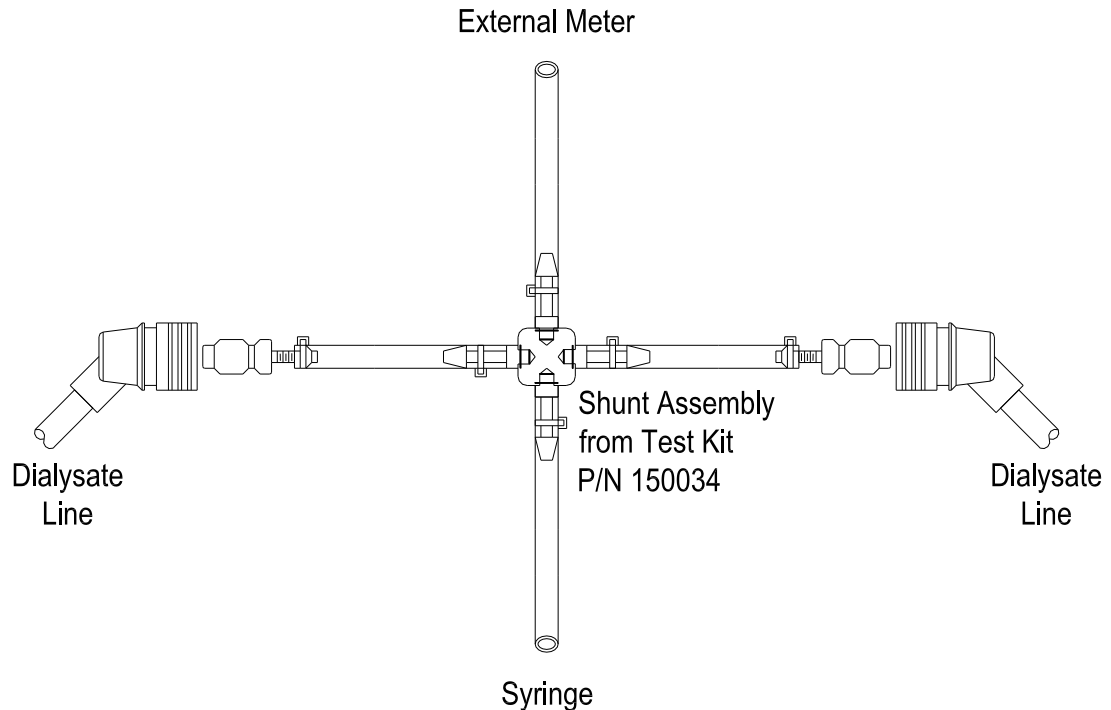


Figure 2

3. Turn the dialysate flow off.
4. Use the syringe to create a positive pressure of about 500mmHg on the external meter and then clamp the line to the syringe. This will cause the TMP to go positive and a low TMP alarm to occur.
5. Remove the output tube from the UF pump. Insure that there is no fluid leaking from the output port.

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6. Verify that the UF check valve is correct (P/N 150123 or P/N 150570) and installed in the proper flow direction.

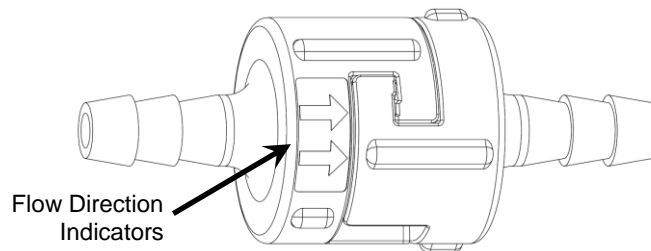


Figure 3 – UF Check Valve
(P/N 150570 shown, P/N 150123 similar)

7. Record the UF Check Valve results as "Pass/Fail" on the UF Problem Identification Checklist.
 8. Relieve the pressure on the syringe by unclamping the tube.
 9. Remove the input tube from the UF pump and connect it to the tubing removed earlier from the UF pump output port using a barb fitting (P/N 332141-01). This will effectively bypass the UF pump and pressure test the UF check valve.
 10. Use the syringe again to create a positive pressure of about 500mmHg on the external meter and then clamp the line to the syringe.
 11. Remove the fluid sample line from the front of the machine and insure that no fluid is leaking through the UF check valve.
 12. Inspect the Pre-UF Pump filter housing for leaks or distortion. Insure that it is present and in good condition. Do not disassemble the filter assembly.
 13. Record the Positive Pressure Test on the UF Pump as "Pass/Fail" on the UF Problem Identification Checklist.
- 5.6 If applicable, record all services performed on an SC (P/N 500571) and attach a copy of the UF Problem Identification Checklist to the SC.**