



Fresenius Medical Care

SERVICE BULLETIN

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Equipment: 2008H Hemodialysis Machines
Bulletin: 08-FRH-001 Rev A
Subject: Blood Pressure Module Preventive Maintenance Update

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1.0 PURPOSE

To inform all Field Service and Technical Support personnel of an update to the Internal Blood Pressure Module section in the 2008H Preventive Maintenance Procedures P/N 500558 Rev I. This Service Bulletin replaces FSB# 04-FRH-001, 05-FRH-001 and 06-FRH-002.

2.0 SCOPE

The update to the 2008H Preventive Maintenance Procedures involves Section 3.22 Internal Blood Pressure Module.

3.0 PROCEDURE

Section 3.22 Internal Blood Pressure Module has been updated to include additional Blood Pressure Module types. Use the following pages to replace the existing procedures in the 2008H Preventive Maintenance Procedures revision I.

If there are any questions regarding this bulletin, contact Fresenius Technical Support at 800-227-2572 x7003.

3.22 INTERNAL BLOOD PRESSURE MODULE

If the machine is equipped with an internal blood pressure module (Figure 2), test it as follows:

1. Connect the pressure tubing from the module to the 700cc port on the Test Device. Ensure the tubing fits snugly on the ports.
2. Place the machine in Service mode as follows:
 - Press the POWER touchpad to turn the machine Off.
 - On the back of the Monitor Unit, place the red Service switch in the Up position (Figure 2).
 - Press the POWER touchpad again to turn the machine On. The screen will display:

```
→CALIBRATION  
  DIAGNOSTICS  
  OPTIONS
```

3. Press the SET touchpad to select CALIBRATION, then press the down arrow touchpad to indicate the Colin Module test:

```
CALIBRATION SELECT:  
13 VOLT HI LO DETECT  
14 DEAERATION PRESSUR  
15 FLOW RELIEF PRESSR  
16 CLOCK  
17 FILL FOR SHIPPING  
→ TEST COLIN MODULE
```

NOTE

The name Colin refers to one of the manufacturer of the blood pressure module used in the Fresenius 2008H machine.

4. Press the SET touchpad. The screen will display:

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→INFLATION SPD TEST
  DEFLATION SPD TEST
  AIR LEAKAGE TEST
  CALIBRATE MODE
```

5. Press the Up and Down arrows if needed to select INFLATION SPD TEST. Press SET. The blood pressure module will pressurize the Test Device and report the times:

```
INFLATION SPEED TEST
TIME TO 250MMHG =
CUFF PRESSURE = ×
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NOTE

If the display also shows TIME TO 300MMHG, disregard the value; it is for reference only and is no longer used.

6. When the test is complete, use the table below to verify that the Time to 250 value is within range dependant upon the module type installed.

Module Type	Time to 250
M400	≤ 7.3 seconds
M2000	≤ 10.0 seconds
M2600	≤ 10.0 seconds
TM-2910	≤ 10.0 seconds
SunTech	≤ 11.0 seconds

NOTE

The deflation speed test is not applicable to the SunTech module. Skip to step 10.

7. Move the pressure tubing to the 220cc port on the Test Device.
8. Press SET to return to the blood pressure module test menu. Press the Up and Down arrows as needed to select DEFLATION SPD TEST and press SET.
9. The blood pressure module will depressurize (deflate) the Test Device and report the deflation speed at various pressures in mmHg per second. Use the table below to verify that the values reported are within the following ranges dependant upon the module type installed.

Pressure (mmHg/sec)	M400		M2000		M2600		TM-2910		SunTech	
	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max
RATE AT 240	4.3	6.2	4.4	6.7	4.4	6.7	3.5	7.5	NA	NA
RATE AT 160	4.3	6.2	4.4	6.7	4.4	6.7	3.5	7.5	NA	NA
RATE AT 80	3.3	5.2	3.0	5.2	3.0	5.2	3.5	7.5	NA	NA
RATE AT 40	2.6	4.4	2.4	4.6	2.4	4.6	3.5	7.5	NA	NA

10. Move the pressure tubing back to the 700cc port on the Test Device.
11. Press the SET touchpad to return to the blood pressure module test menu. Press the Up and Down arrows as needed to select AIR LEAKAGE RATE and press SET.
12. The blood pressure module will pressurize the Test Device as indicated by a rise in the CUFF PRESSURE displayed to approximately 200. An internal timer is then activated automatically. Any change in the pressure being held will show on the CUFF PRESSURE line of the display:

AIR LEAKAGE TEST
LEAK RATE =
CUFF PRESSURE = ×

13. At the end of the AIR LEAKAGE TEST, the pressure is automatically released and the LEAK RATE in mmHg for a 3-minute test is displayed. Use the table below to verify that the Leak Rate value is within range dependant upon the module type installed.

Module Type	Leak Rate
M400	<15mmHg
M2000	<15mmHg
M2600	<15mmHg
TM-2910	<30mmHg
SunTech	<8mmHg

14. Disconnect the pressure tube from the Test Device and connect it to a mercury manometer or similar pressure meter accurate to within ± 1 mmHg.
15. Calibration Check:

For the M400, M2000, TM-2910 & SunTech

- a) Press the SET touchpad to return to the blood pressure module test menu. Press the Up and Down arrows as needed to select CALIBRATION MODE and press SET.
- b) The blood pressure module will pressurize the line. When the pressure shown on the display screen and on the external meter stabilizes, verify that they agree within ± 3 mmHg

For the M2600

- a) From the blood pressure module test menu press the Up and Down arrows as needed to select AIR LEAKAGE RATE and press SET.
- b) The blood pressure module will pressurize the Test Device as indicated by a rise in the CUFF PRESSURE displayed to approximately 200mmHg. An internal timer is then activated automatically.
- c) When the pressure shown on the display screen and on the external meter stabilizes, verify that they agree within ± 3 mmHg.
- d) At the end of the AIR LEAKAGE RATE test, the pressure is automatically released.

CAUTION

Do not exceed 330 mmHg in the following step. The blood pressure module may be damaged if this pressure is exceeded.

16. Over-Pressure Relief Check:

For the M400 & TM-2910 While still pressurized from calibration check, remove the hose from the external meter and connect it to a large syringe (60cc) that has its plunger pulled back. Use the syringe to over-pressurize the blood test module while watching the display carefully. Verify that at between 320 (310mmHg for TM-2910) and 330mmHg indicated on the display screen, the pressure is automatically released.

For the M2000, M2600 & SunTech Due to the microprocessor control of these devices, the over-pressure relief check does not need to be conducted. In fact, an over-pressure relief test could permanently damage these modules.

17. Place the machine in normal operating mode again:

- Press the POWER touchpad to turn the machine Off.
- Place the red Service switch to the Down position.