

Fresenius Medical Care SERVICE BULLETIN

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Equipment: 2008K Hemodialysis Machines
Bulletin: 07-FRK-003 Rev A
Subject: F801 RO and the DIASAFE® PLUS Filter

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1.0 PURPOSE

To clarify how to incorporate an F801 Reverse Osmosis (R.O.) system and a DIASAFE® PLUS filter on a 2008K Hemodialysis machine.

2.0 PROCEDURE

In order to have an F801 R.O. system installed on a 2008K machine with a DIASAFE® PLUS filter, a special lower rear panel must be installed. The process of incorporating these two systems together is outlined as below.

- 1 Remove original lower rear panel.

Note: If a DIASAFE® PLUS filter system is being installed on a 2008K already equipped with an F801 R.O. system, locate the DIASAFE® PLUS filter holder assembly and skip to step 3.

- 2 Remove the DIASAFE® PLUS filter holder assembly noting the location of the three tubing connections to the hydraulics.
- 3 Remove and save the four (4) screws mounting the metal mounting plate to the DIASAFE® PLUS filter holder assembly (see Figure 1).

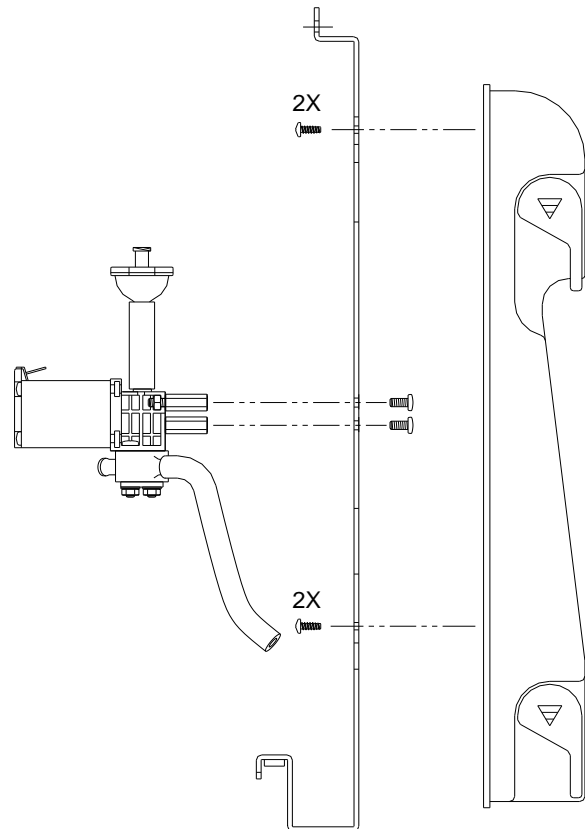


Figure 1

- 4 Remove the tubing connecting the DIASAFE® PLUS filter test valve to the lower tubing block inside the filter holder (see Figure 2). Note the tubing port location.

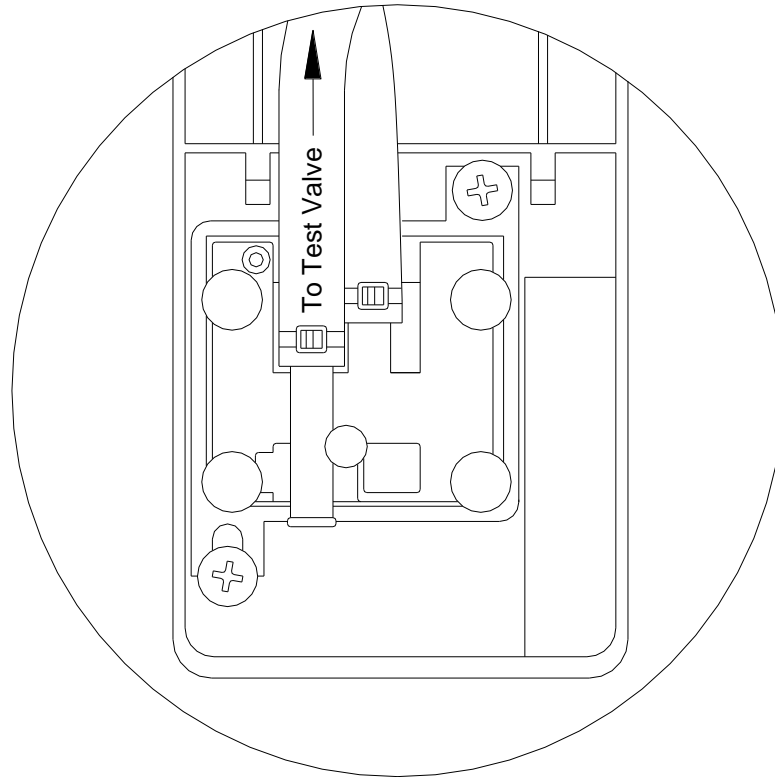


Figure 2

- 5 Slide the remaining tubing out of the metal mounting plate and set the DIASAFE® PLUS filter holder aside.
- 6 Remove and save the two (2) screws holding the test valve to the metal mounting plate (see Figure 1).
- 7 Slide the previously disconnected test valve tubing out of the metal mounting plate and discard the plate.

- 8 Mount the DIASAFE[®] PLUS filter test valve assembly onto the inside of the new rear panel (P/N 190421) using the two (2) saved screws. See Figure 3 for location.

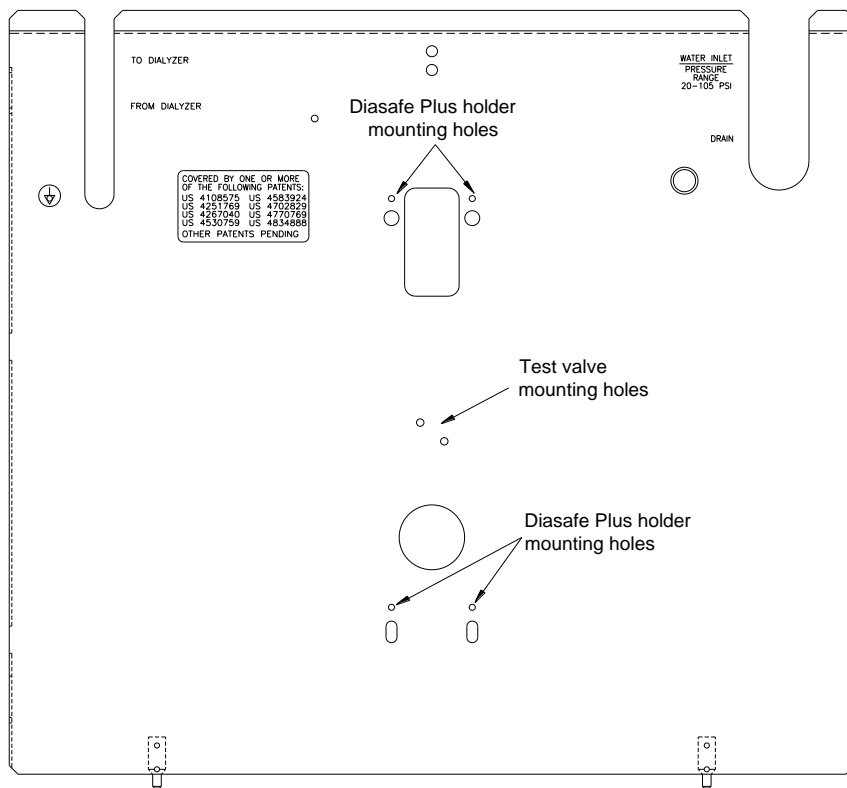


Figure 3

- 9 Thread the tubing removed in step 4 through the round hole of the new rear panel. Note the test valve should be on the inside of the new rear panel.
 - 10 Connect the test valve tube to the lower tubing block inside the filter holder noted in step 4 (see Figure 2 on page 2).
 - 11 Thread the remaining two tubes of the filter holder through the rectangular hole in the new rear panel.
 - 12 Using the four (4) screws saved in step 3; attach the filter holder to the new rear panel. Take care not to pinch tubing.
- Note:** If a DIASAFE[®] PLUS filter system is being installed on a 2008K already equipped with an F801 R.O. system, continue with the installation and testing of the DIASAFE[®] PLUS filter holder assembly and skip the rest of this procedure.
- 13 Using the noted tubing connections in step 2, reconnect the three tubes to their proper locations. Refer to Figure 4 on page 5 for assistance in proper tubing connections.

3.0 INSTALLATION VERIFICATION

DIASAFE® PLUS Integrity Test:

- Turn the machine on and start a rinse program to purge air from the DIASAFE® PLUS filter and the hydraulics.
- Once the rinse completes, go into dialysis mode and bring the machine up to normal operating temperature and conductivity.
- Once the machine is stable, go to the Test and Options screen in dialysis mode and press the Diasafe Test screen button. This will perform an automated test of the DIASAFE® PLUS filter. Confirm the test passes.

Bypass Confirmation Test:

- Start the machine in dialysis mode and wait until the machine is out of bypass (i.e. the inline flow indicator on the blue dialysate line shows flow).
 - Clamp Tube A coming out of the DIASAFE® PLUS filter holder assembly. See Figure 4 on page 5 for proper tube location.
 - Verify that the inline flow indicator shows no flow.
 - If the flow indicator shows that there is flow, determine the source of the failure and repair.

Hydraulic Integrity Test:

- Place the 2008K into the Dialysis mode and perform a self test to verify the integrity of the hydraulics.

Hot Rinse Temperature Test:

- Run a hot rinse cycle and verify that the temperature reaches at least 80.5°C.

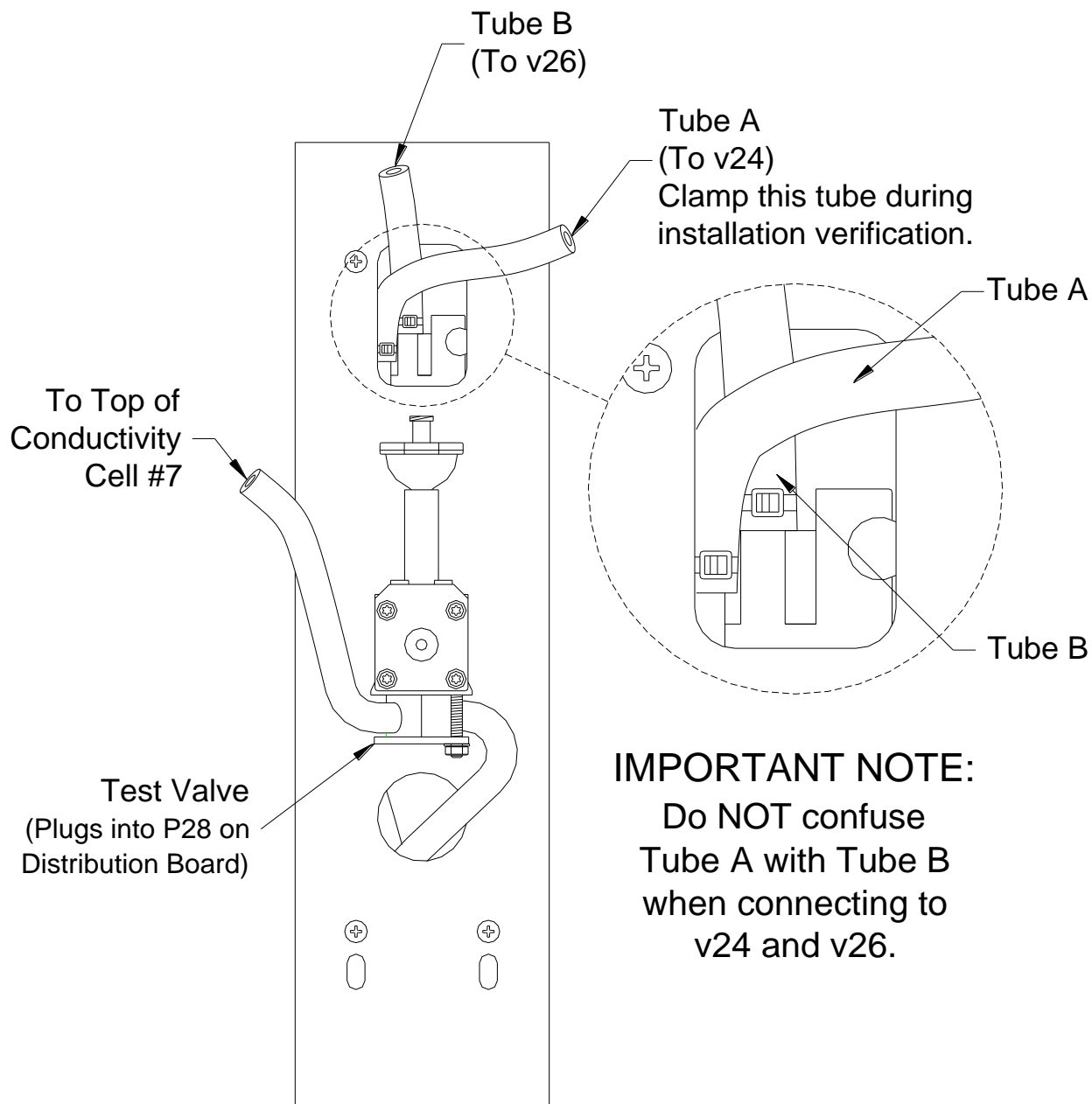


Figure 4

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