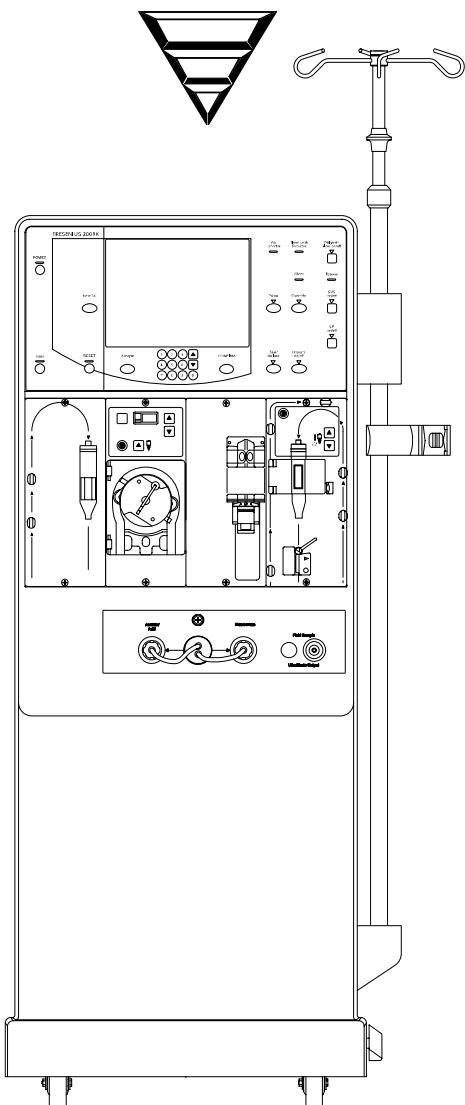


Fresenius USA



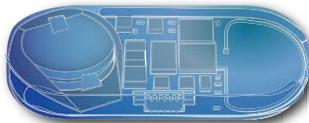
2008K Hemodialysis Machine

Operator's Guide Wireless Wetness Detector

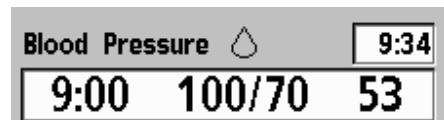
Addendum

Wireless Wetness Detector for Patients

The Wireless Wetness Detector is a disposable device that monitors for leaks. It transmits radio signals to the 2008K hemodialysis machine and alerts the machine when the detector senses a conductive substance like fluid on its sensors.



When the Wireless Wetness Detector option has been set, a gray Drop icon will be displayed in the Dialogue Box. The detector is not activated until the icon is green.



Patient Wireless Wetness Detector Setup During Treatment

Proceed with typical treatment setup (as explained in Chapter 2 of the *2008K Hemodialysis Machine Operator's Manual* P/N 490042), following clinic instructions. Use these instructions before starting the Tx Clock to activate the Wireless Wetness Detector.

1. After preparing the patient's access, create a wetness signal within 10 feet of the machine by touching the metal pattern on the bottom of the detector for at least 3 seconds (see Figure 1) with a conductive surface. Fresenius Medical Care recommends using gauze damp with disinfectant to activate it.

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Warning! Keep access sites uncovered and monitored. Machine alarms do not sound in every blood loss situation.

Warning! Do not touch non-sterile objects to the Wireless Wetness Detector sensor.

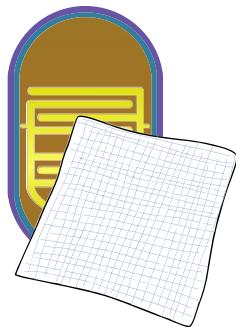
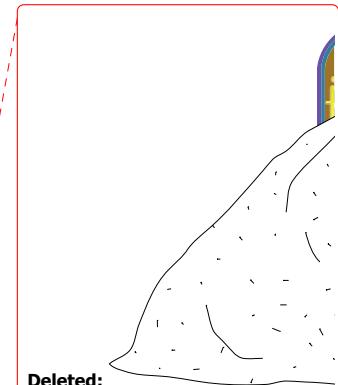


Figure 1 – Create Wetness Signal



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2. The Wireless Wetness Detector will send a wetness signal to the machine. Make sure that an audible alarm sounds and the Status Bar turns red and displays the message “Wetness Detected #1” (see Figure 2).

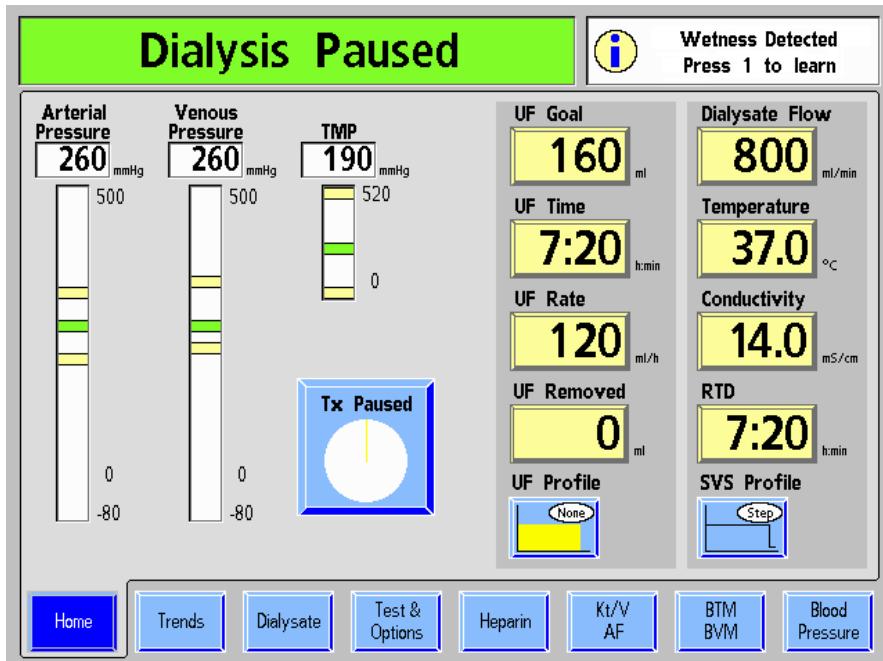


Figure 2 – Home screen: Wetness Detected #1

3. Press the **1** key to learn the Wireless Wetness Detector and clear the alarm. The Drop icon in the Dialogue Box will turn green.
4. Place the detector on the access site bandage and secure it in place with another bandage. The Wireless Wetness Detector will continue to transmit signals to the dialysis machine for the next eight hours.



Warning! Place the detector below the access site on top of no more than two layers of gauze. Failure to do so may allow a blood leak to go undetected. Undetected blood leaks can cause serious injury or death.

5. Touch the **Tx Paused** button and press the **CONFIRM** key. The treatment will begin counting down. If a “Wetness Detected” alarm occurs, it can be cleared with the **RESET** key.



Note: If the machine displays the message “Wetness Detector Not Active”, the Wireless Wetness Detector must be re-activated by touching the metal pattern on the bottom of the detector again.

Note: If a “Wetness Detected” alarm occurs three times within 10 minutes, the Dialogue Box will display the following message: “Press 0 to disable Wetness”. If the **0** key is then pressed, its audible alarm will be deactivated. The Drop icon

in the Dialogue Box will be yellow to show that a Wireless Wetness Detector is disabled.

Note: If the machine displays the message “Wet Low Battery #X”, where the “X” indicates the Wireless Wetness Detector number, that Wireless Wetness Detector must be replaced.

Note: Pressing the **New Tx** key and selecting a new treatment, changing the Blood Sensed status, or running a rinse program will clear Wireless Wetness Detector #1’s association with the machine. If any of those occur, Wireless Wetness Detector #1 must be relearned as explained above.

Using additional Wireless Wetness Detectors

Up to three Wireless Wetness Detectors may be linked to one machine. Wireless Wetness Detectors #2 and #3 must be set in Service Mode and are not patient-specific.

Setting Wireless Wetness Detector Option in Service Mode

The “Wireless Wetness” option must be selected in Service Mode in order to use any Wireless Wetness Detectors. Set the **Wireless Wetness** toggle-button, located in the “Module Options” tab of the “Hardware Options” tab, to Yes.

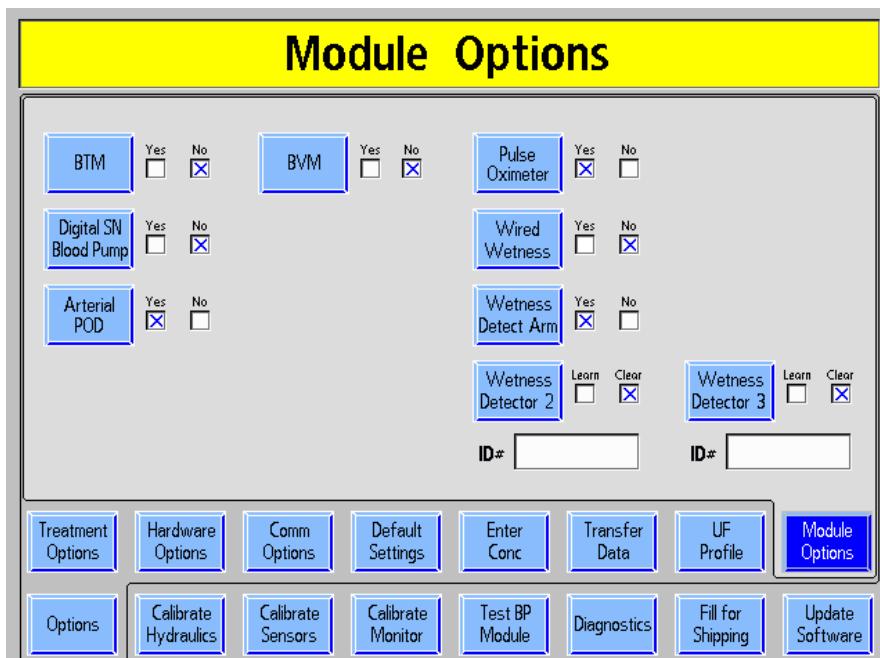


Figure 4 – Service Mode: Options: Module Options screen

Learning Wireless Wetness Detectors #2 and #3 ID's

Wireless Wetness Detectors 2 and 3 are learned only in Service Mode. They are machine specific and do not need to be relearned with every new treatment. To set Wireless Wetness Detectors, go to the “Module Options” screen in Service Mode. Next touch the **Wetness Detector X** toggle-button (where X= 2 or 3) to set it from CLEAR to LEARN, and then press the **CONFIRM** key. When directed by the Status Bar, touch the metal pattern on the bottom of the detector and then release it when indicated. The device's learned ID will appear in the ID box below the button. You may set the other detector by touching its corresponding button and activating it as described above.

Clearing Wireless Wetness Detectors #2 and #3 ID's

To clear a detector's association with the machine, touch that detector's **Wireless Detector** toggle-button to set it from LEARN to CLEAR, and then press the **CONFIRM** key. The ID box will display “0” and the selected Wireless Wetness Detector will no longer be linked to the machine.

When Wireless Wetness Detectors 2 and 3 sense wetness during treatment, they act like Wireless Wetness Detector #1 and may be reset using the **RESET** key. Similarly, if the **0** key is pressed during a detector's third alarm, it will disable the alarming device. That Wireless Wetness Detector must then be relearned in Service Mode.

Wireless Wetness Detector Care

Wireless Wetness Detectors in contact with patients or fluids should be cleaned after every treatment. They can be cleaned with very dilute bleach or other suitable hospital disinfectant. Freshly prepared dilute bleach solution (1:100) is currently recommended by the Center for Disease Control as a suitable disinfectant for the Hepatitis virus. Because surface contamination is the general mode of transmission for this type of virus, thorough cleaning of the Wireless Wetness Detector is essential.

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General Warnings

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This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

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Caution: Changing or modifying the Wireless Wetness Detector without the expressed written consent of Fresenius Medical Care could void the user's authority to operate the equipment.

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