

WetAlert™

Set your mind at ease



2008K@

**2008K@home™ Machine
WetAlert™ Wireless
Wetness Detector
Home User's Guide**



**FRESENIUS
MEDICAL CARE**

RENAL TECHNOLOGIES

2008K@home WetAlert Wireless Wetness Detector Home User's Guide

For software versions 4.14 and above

© Copyright 2012-2014, 2016 Fresenius USA, Inc.—All Rights Reserved

This document contains proprietary information of Fresenius Medical Care Renal Therapies Group, LLC and its affiliates (“Fresenius Medical Care”). The contents of this document may not be disclosed to third parties, copied, or duplicated in any form, in whole or in part, without the prior written permission of Fresenius Medical Care.

Fresenius Medical Care, the triangle logo, 2008K@home, 2008, the @ home logo, and WetAlert are trademarks of Fresenius Medical Care Holdings, Inc., and/or its affiliated companies. All other trademarks are the property of their respective owners.

Caution: *Federal (U.S.) law restricts this device to sale by or on the order of a physician.*

WetAlert device Indications for Use: *The Wireless Wetness Detector is indicated for use with the 2008K@home hemodialysis machine and is an optional accessory to aid in the detection of blood and water leaks during hemodialysis. Home hemodialysis using the detector must be observed by a trained and qualified person as prescribed by their physician.*

2008K@home hemodialysis machine Indications for Use: *the 2008K@home hemodialysis machine is indicated for acute and chronic dialysis therapy in an acute or chronic facility. The 2008K@home hemodialysis machine is also indicated for hemodialysis in the home and must be observed by a trained and qualified person as prescribed by their physician.*

The WetAlert device is for use with the WetAlert Starter Kit (P/N 190893) or the WetAlert Retrofit Kit (P/N 190442) and requires special hardware for the 2008K@home hemodialysis machine.

Table of Contents

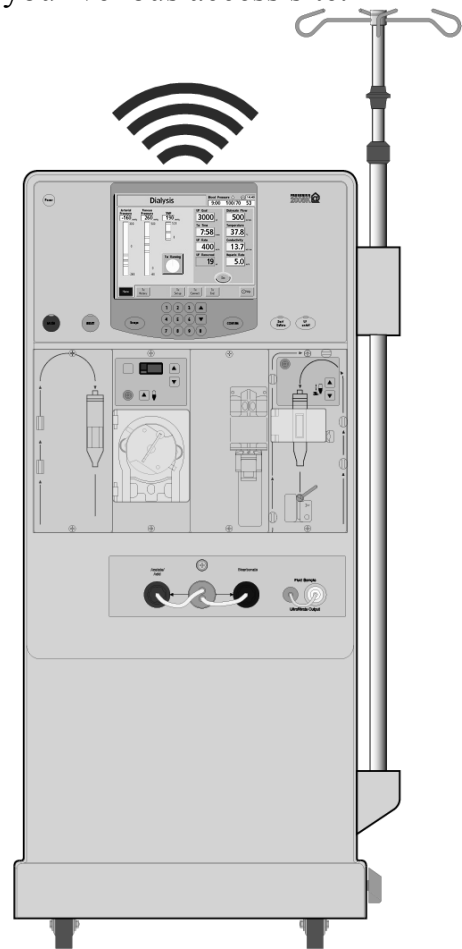
Table of Contents	2
The WetAlert Wireless Wetness Detector	3
Description	3
General Warnings	4
Before Treatment	6
Activating your WetAlert Device.....	8
Activating your WetAlert Device (continued).....	10
Starting Treatment with the WetAlert Device	12
Troubleshooting	14
Restarting a Treatment	16
Reading Drop Icon Status	17
After Treatment.....	18
WetAlert Device Care.....	18
WetAlert Device Storage.....	18
Appendix.....	19
WetAlert Spare Parts	19
WetAlert Device Disposal.....	19
WetAlert Device RF Transmitter Characteristics	19
Quality of Service	19
Manufacturer’s Electromagnetic Compatibility (EMC) Declaration	20
Additional Information	23

The WetAlert Wireless Wetness Detector

Description

The WetAlert wireless wetness detector is a disposable device that can sense blood leaks. During your treatment, the WetAlert device transmits radio signals to your 2008K@home hemodialysis machine and will alert your machine if the device detects a blood leak. During a wetness alarm, your 2008K@home hemodialysis machine will automatically stop the blood pump, close the venous clamp, display a visual alarm, and sound an audible alarm.

The WetAlert device should be placed at your venous access site.



General Warnings

Federal Communication Commission (FCC) Interference Statement

This equipment has been tested and found to comply 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 generates, uses, and radiates 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.

Changing or modifying the WetAlert device without the expressed written consent of Fresenius Renal Therapies could void the user's authority to operate the equipment.

See the Manufacturer's Electromagnetic Compatibility (EMC) declaration in the 2008K@home User's Guide (P/N 490180) or on page 20 of these instructions for more information.



Warning: Radio signals can interfere with the WetAlert device. Particularly no "Ham" or Amateur radio operating in frequency range of 430Mhz to 450Mhz should be used in the vicinity of the WetAlert device. If radio signal interference occurs, the WetAlert device may not detect a blood or fluid leak and therefore your machine will not alarm.

The 2008K@home hemodialysis machine monitors for radio signal interference. If your machine locates interference, it will display a "Wetness No Comm." warning message and an audible alarm will sound. Possible sources of interference include any device operating in the frequency range of 430Mhz to 450Mhz like portable amateur radios, mobile amateur radio located in a vehicle, fixed location amateur radios, and wireless video cameras.

For exact separation distance recommendation, please refer to the Manufacturer's EMC Declaration statement provided in your 2008K@home User's Guide (P/N 490180) or on page 20 of these instructions.



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

Warning: External radio frequency disturbances in the same range as the WetAlert device may prevent you from activating the WetAlert device. If the WetAlert device is not activated, it will not cause the machine to alarm if wetness is detected.

Warning: Do not use devices emitting strong electromagnetic radiation such as portable phones, radio equipment (walkie-talkies, etc.), radio transmitters, and like equipment near your machine. Improper operation may result.

Cellular phones and WiFi-connected devices may be conditionally allowed. However, if any interference is noted, such as false pressure readings that disappear when the external signal is removed, it is recommended to move the cellular phone at least ten feet away from the 2008K@home hemodialysis machine when making or receiving phone calls. If a WiFi-connected device (e.g. laptop computers, tablet devices, smartphones) is found to cause interference, it is recommended to use that device at least four feet away from the 2008K@home hemodialysis machine. For exact separation distance recommendation, please refer to the Manufacturer's EMC Declaration statement provided in the 2008K@home User's Guide (P/N 490180) or on page 20 of these instructions.

Warning: Your machine's modules and internal hydraulics involve fluids. Fluid leaks may cause excess fluid removal from the patient. Correct the problem immediately or take the machine out of service. Spills can cause slips and falls; clean up spills immediately. To contain such spills, the machine should be on a spill-tolerant surface.



Caution: System leaks may occur. Unattended operation of the machine (for example, during disinfection at night) may result in flooding and can cause property damage. Spills can cause damage to carpeting and other surfaces. Clean up spills immediately.

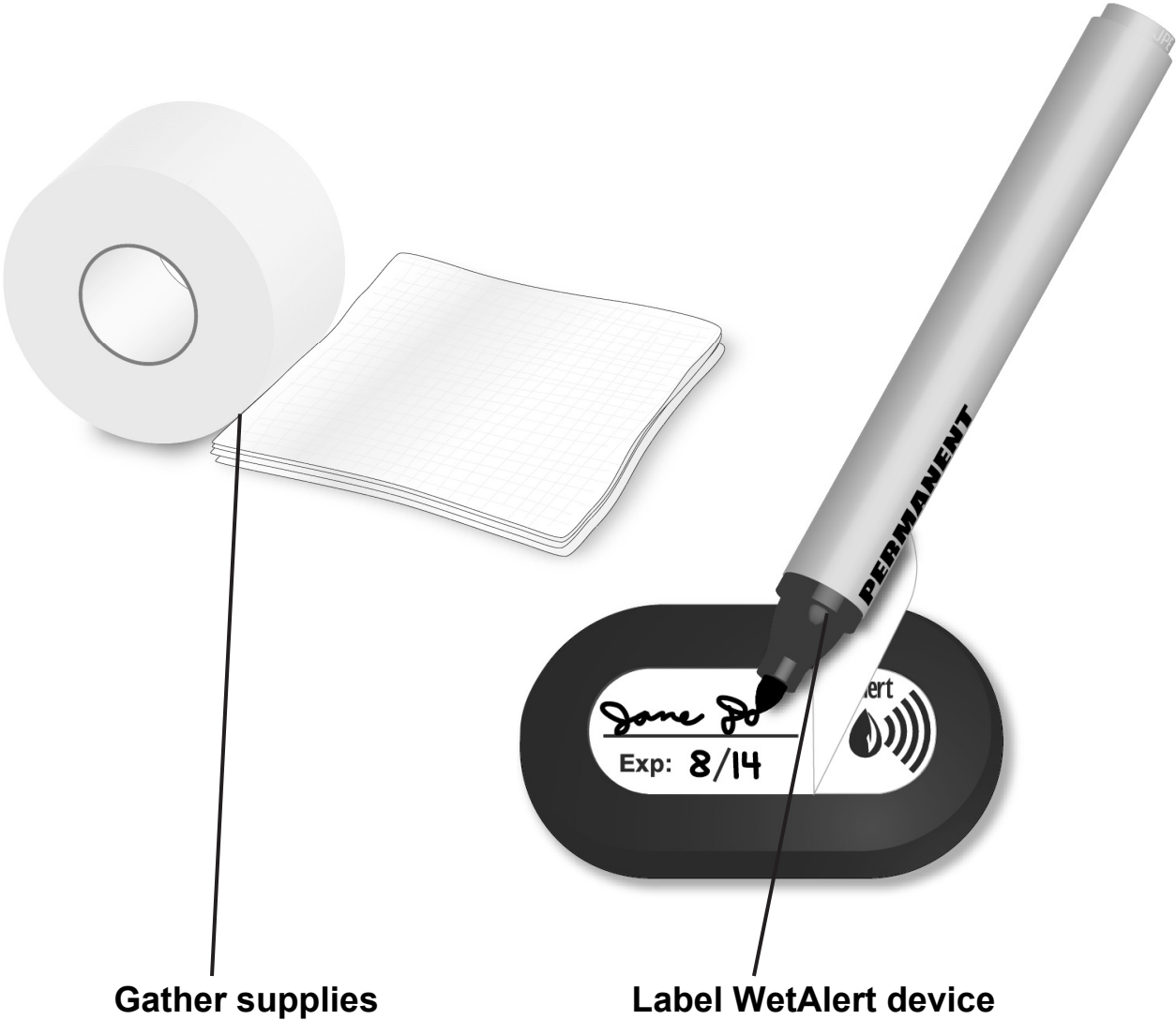
Caution: If the WetAlert device is to be used in a location with more than one WetAlert device equipped machine, the 'In Center' option must be set. See the 2008K@home WetAlert Wireless Wetness Detector In-Center User's Guide (P/N 490181) for more information.



Note: If your machine displays the message "Wetness Low Battery", the WetAlert device must be replaced before your next treatment.

Note: If your machine displays the message "Wetness Not Active", the WetAlert device must be re-activated by touching the metal pattern on the bottom of the device again with a gauze pad damp with 1:100 bleach.

Before Treatment



Gather supplies

Follow your clinic's instructions to set up your 2008K@home hemodialysis machine, using the 2008K@home User's Guide (P/N 490180) as a reference. Use these steps before starting the Tx Clock to activate your WetAlert device.

Supplies Needed:

- 1-2 layers of 2x2 gauze
- 1:100 bleach
- WetAlert device
- Permanent marker (to label the WetAlert device for the first time)
- Tape
- Gloves



Warning: Splashes may occur when using bleach. Use appropriate Personal Protection Equipment (PPE).



Note: Fresenius Renal Therapies recommends using either of the following medical tapes to secure the WetAlert device to the patient:

- 1527-1 (FMC P/N 16-1527-7) Clear 3M Transpore
- 1532-1 (FMC P/N 16-5321-0) White 3M Micropore Plus

Using a stronger (stickier) tape may pull the label off the WetAlert device when removing the tape.

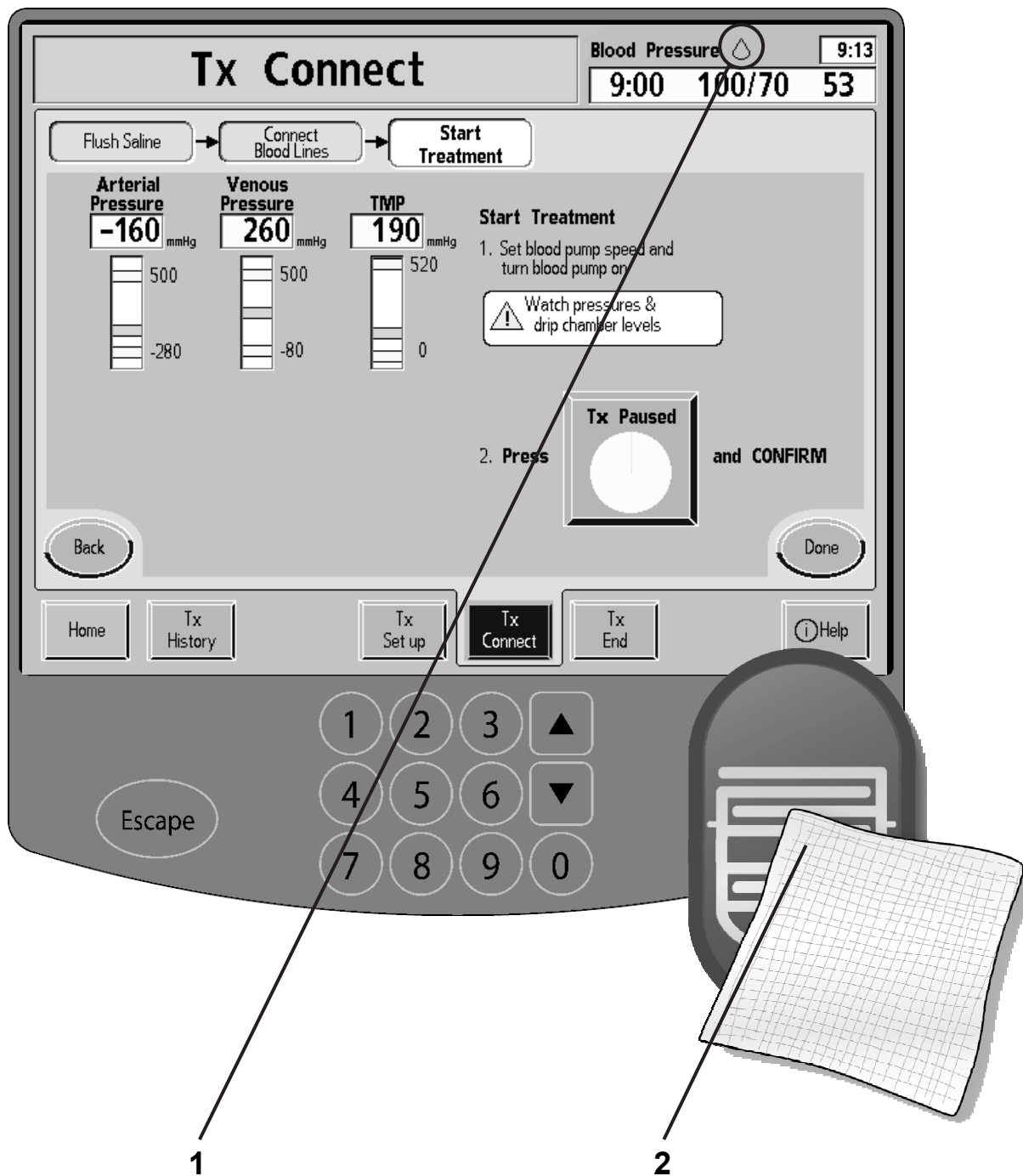
Label WetAlert Device if not yet labeled

Write the patient's name or ID number on the WetAlert label so it is patient-specific. When activating your WetAlert device for the first time, write an expiration (Exp) date of six months from today's date on your device's label. Fresenius Renal Therapies recommends replacing the WetAlert device every six months or when a "Wetness Low Battery" alarm occurs, whichever comes first.


To write on the WetAlert device label:

1. Pull back the label flap to expose the Exp and blank line on the label.
2. Write the name/ID number and the expiration date with a fine-tipped permanent marker.
3. Peel the white plastic backing off the flap to expose the sticky underside of the flap.
4. Firmly press the sticky flap over the label to cover the whole label and protect it.

Activating your WetAlert Device



1 Check for Drop icon

Your 2008K@home hemodialysis machine displays a gray Drop icon  in the Dialogue Box to show that the Wireless Wetness option is set. This means that your machine is searching for a WetAlert device to activate. Look at the Dialogue Box in the upper right corner of the screen. Make sure the Drop icon appears.



Note: If the Drop icon does not appear in the Dialogue Box, your machine is not properly set up to use the WetAlert device. Contact your Home Therapies Nurse for more information.

Your WetAlert device is not activated until the Drop icon is green. The Dialogue Box will remind you to touch your wetness detector when you reach the “Tx Connect: Start Treatment” screen. For more information about the Drop icon, see page 17.

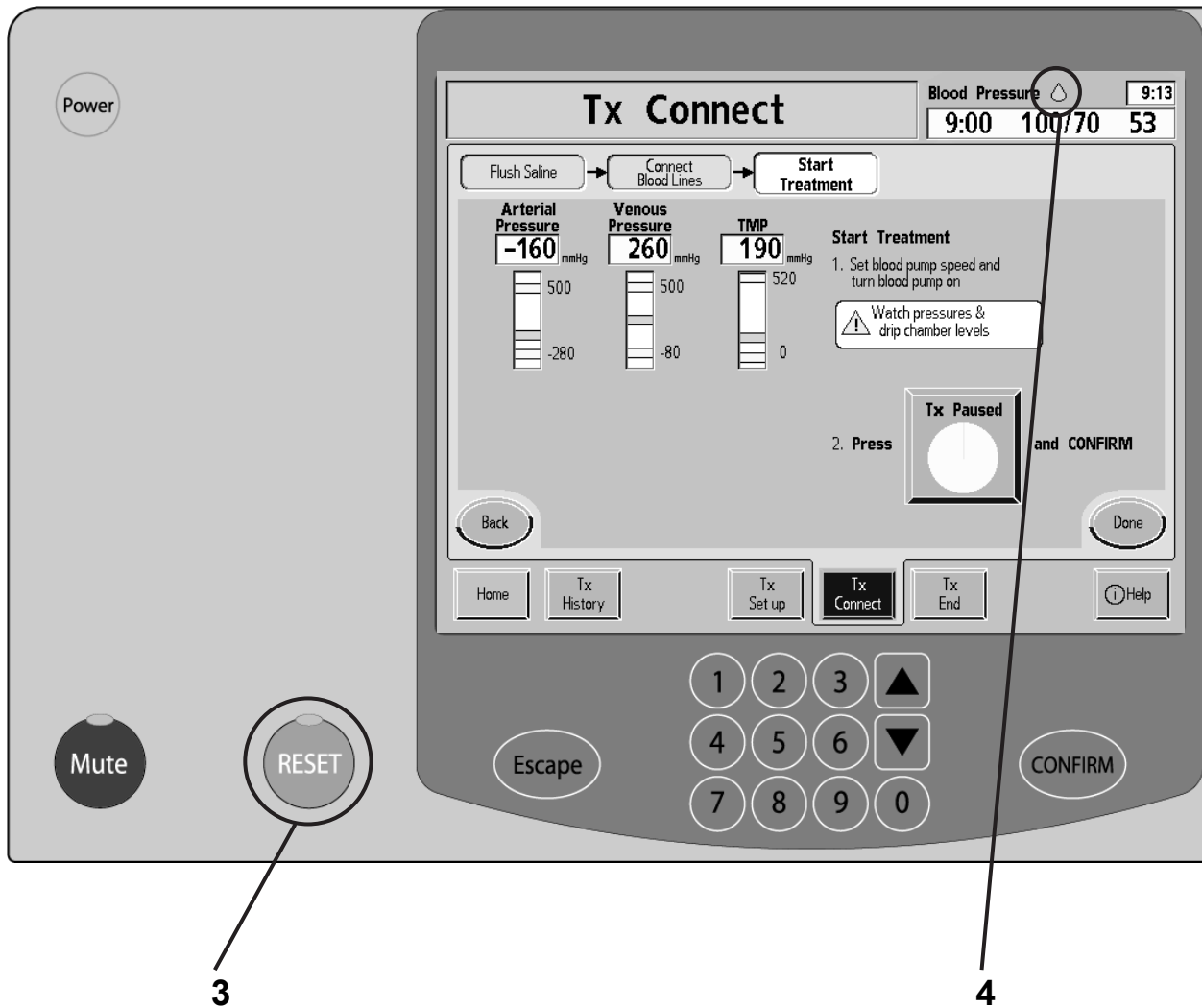
2 Touch detector

To activate your WetAlert device: Create a wetness signal within six feet of your machine by touching the metal pattern on the bottom of the WetAlert device for at least three seconds.



Note: Your WetAlert device will cause an alarm when it comes into contact with conductive fluids like blood or 1:100 bleach. Fresenius Renal Therapies recommends using gauze damp with 1:100 bleach to activate it.

Activating your WetAlert Device (continued)



3 Press **RESET**

Your machine will alarm and display the message “Wetness Detected” in the Status Box. The Drop icon will also turn red. Press the **RESET** key to clear the alarm.



Note: If your machine instead displays the message “Wetness Detected Press 1 to learn,” your machine is not properly set up for use with these instructions. Contact your Home Therapies Nurse for more information.

4 Check for green drop

The Drop icon in the Dialogue Box will turn green, indicating that the WetAlert device is activated. Next you must test the device.



Note: Your 2008K@home hemodialysis machine periodically checks for communication from the activated WetAlert device when the Tx Clock is running. If the machine temporarily loses contact with the WetAlert device, the machine will display a “Wetness No Comm.” warning in the Status Box. Press the **RESET** key to clear the warning and continue. The audible alarm will sound only the first time this warning occurs. Afterward, the machine will display the “Wetness No Comm.” message in the Status Box only.

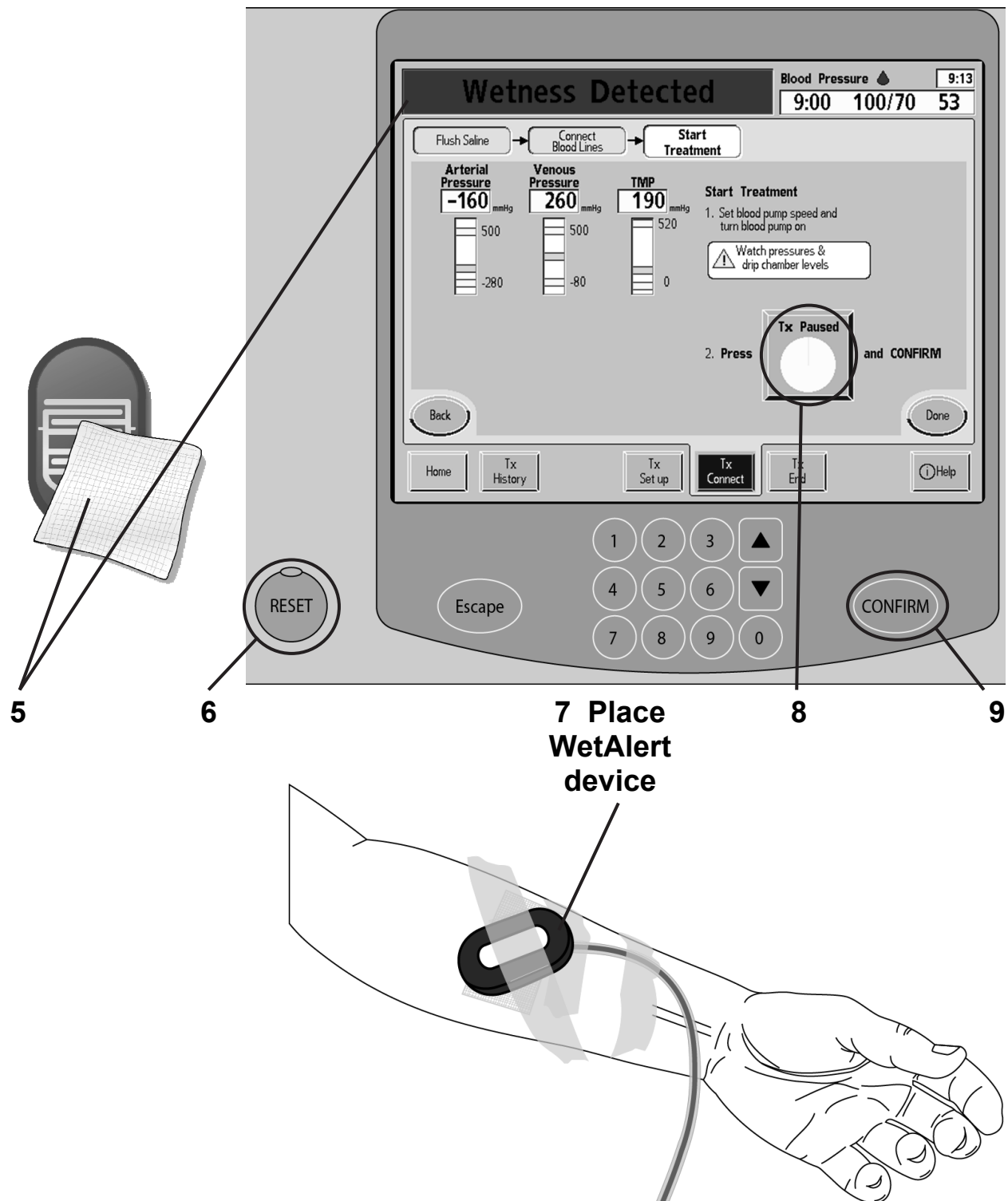
If this warning occurs frequently, either locate and remove the source of radio frequency interference, or discontinue using the WetAlert device. See page 4 for more information on interference. If your machine permanently loses contact with the WetAlert device, it will display a “Wetness Not Active” alarm and sound an audible alarm.

Note: If the same “Wetness Detected” alarm is reset three times within 10 minutes, the Dialogue Box will display the message “Press 0 to disable Wetness Detector.” To continue using the WetAlert device, press the **RESET** key to clear the alarm

Or

Press the **0** key on the Data Entry Keypad to deactivate the device for the remainder of the treatment. The Drop icon in the Dialogue Box will be yellow to show the WetAlert device is deactivated.

Starting Treatment with the WetAlert Device



5 Test WetAlert device

You must make certain your WetAlert device is linked to your machine. Touch the device again to cause a wetness signal. Make sure that an audible alarm sounds and the Status Box turns red and displays the message “Wetness Detected”. The Drop icon in the Dialogue Box will turn red to indicate wetness sensed.



Note: If your device still does not cause an alarm after repeated attempts, you will not be able to use your WetAlert device for this treatment. For more information, see page 16 of the Troubleshooting section.

6 Press **RESET**

Press the **RESET** key to clear the alarm. The Drop icon in the Dialogue Box will turn back to green.

7 Place WetAlert device

Place 1-2 layers of gauze over the secured venous fistula needle. Place the metal pattern bottom side of the WetAlert device on the gauze directly over your venous access site and secure the device with tape.



Warning: Do not use more than two layers of gauze between the access site and the WetAlert device. Do not place tape directly over gauze before placing the device on gauze. Do not use additional bandages or cover the vascular access site with a blanket. Doing so may allow a blood leak to go undetected. Undetected blood leaks can cause serious injury or death.

Warning: When placing the WetAlert device, be careful not to create excessive pressure on the vascular access. Doing so may cause infiltration or damage to the vascular access.

8 Touch **Tx Paused**

9 Press **CONFIRM**

Touch the **Tx Paused** button then press the **CONFIRM** key on the Data Entry Keypad. This will start the Tx Clock. You may continue your treatment as prescribed by your doctor.



Note: If the WetAlert device senses blood, do the following:

1. Press the **Mute** key to silence the alarm.
 2. Correct the condition causing the alarm.
 3. Press the **RESET** key to start the blood pump again.
 4. Clean and dry the WetAlert device with 1:100 bleach (see "WetAlert Device Care" on page 18).
 5. Place the WetAlert device back on the vascular access as described in Step 7 above.
-

Troubleshooting

The following troubleshooting section is a guide to help you troubleshoot WetAlert device alarms, warnings, or advisory messages quickly. For a complete list of alarm messages, please see the Troubleshooting section of the 2008K@home User's Guide (P/N 490180).

Messages shown in the Status Box and Dialogue Box are listed alphabetically. These messages are triggered by conditions and events that occur in your machine during operation. The messages will reset when the condition causing them is corrected. In some cases, you must reset them yourself. The LED light on the **RESET** key will flash if the alarm may be reset.



Note: Doing the recommended action may or may not clear the alarm, warning, or advisory messages displayed. Follow your facility's instructions.

Note: If you have any questions, please call your Home Therapies Nurse.

If additional information exists for an alarm or warning, the **Help** screen-button will flash in the bottom right corner of the touch screen. Your 2008K@home hemodialysis machine will display the following on the "Help" screen:

- Message Meaning
- Action Required

If a message is longer than the space provided allows, use the **Up/Down arrow** (▼/▲) keys on the data entry keypad to scroll up or down to view the rest of the message.

At the end of the Troubleshooting section is also a procedure for restarting your treatment and a table explaining the different WetAlert Drop icon states.

Message	Meaning	Action Required
Press 0 to disable Wetness Detector	The WetAlert device has alarmed three times in ten minutes.	To continue using the WetAlert device that is alarming, press the RESET key. Or, To stop using the alarming WetAlert device, press the 0 key on the Data Entry Keypad. The alarming WetAlert device will no longer be linked to your machine. It will not sense wetness until reactivated with a new treatment.
Touch Wetness Detector	The WetAlert device needs to be activated at this time.	Touch the WetAlert device's metal sensor on the underside then press the RESET key to continue
Wetness Detected	The WetAlert device has sensed wetness.	<ol style="list-style-type: none"> 1. Press the Mute key to silence the alarm. 2. Correct the condition causing the alarm. 3. Press the RESET key to start the blood pump again. 4. Clean and dry the WetAlert device with 1:100 bleach (see "WetAlert Device Care" on page 18). 5. Place the WetAlert device back on the vascular access as described on page 13.
Wetness Low Battery	The WetAlert device's battery is almost empty.	Press the RESET key to clear the alarm. Replace the failing WetAlert device before your next treatment.
Wetness No Comm.	The machine has temporarily lost contact with the WetAlert device.	<p>Press the RESET key to clear the warning. If this warning occurs frequently, either locate and remove the source of radio frequency interference, or discontinue using the WetAlert device. See page 4 for more information on radio interference.</p> <p>To disable this WetAlert device:</p> <ol style="list-style-type: none"> 1. Touch the metal sensor on the underside of the device to cause an alarm and then press the RESET key. 2. Repeat step 1. 3. Touch the metal sensor on the underside of the device to cause a third Wetness Detected alarm. This time press the 0 key on the Data Entry Keypad. The alarming WetAlert device will no longer be linked to your machine. It will not sense wetness until reactivated with a new treatment.
Wetness Not Active	The machine has lost contact with the WetAlert device. Or you must activate the WetAlert device before beginning your treatment.	Touch the metal sensor on the bottom of the WetAlert device to link it to the machine. Press the RESET key to clear the message.

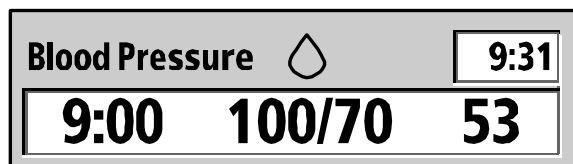
Restarting a Treatment






If your WetAlert device cannot be linked to your machine after repeated tries, another troubleshooting step is to reset your entire treatment before blood is sensed and the Tx Clock is started. Contact your Home Therapies Nurse before attempting this procedure.

To restart your treatment: Press the **Down Arrow (▼)** key on the control panel and the **CONFIRM** key at the same time. Then press the **CONFIRM** key again to confirm a new treatment and re-enter all your parameters. You will be prompted to link a WetAlert device again at the end of the setup process.

Reading Drop Icon Status

The Drop icon in the Dialogue Box indicates whether or not your WetAlert device is ready for your treatment. See the table below for an explanation of each Drop icon status.



Drop Color	Status	Meaning
 No Drop	WetAlert option not set in Service Mode	The Wireless Wetness (WetAlert) option was not set in Service Mode. No WetAlert device can be used during treatment.
 Gray	WetAlert device not yet activated	The Wireless Wetness (WetAlert) option was set in Service Mode, but the device has not been activated yet. Your machine will display “Touch Wetness Detector” in the Dialogue Box when entering the “Tx Connect: Connect” screen from the “Tx Connect: Flush” screen. If the Tx Connect screens are skipped, this message will appear when blood is sensed and you attempt to start the Tx Clock. The WetAlert device is not ready for use during treatment.
 Green	WetAlert device is activated	You have correctly setup the WetAlert device, either during the Tx Connect screens or before running the Tx Clock. The WetAlert device will cause an alarm when it comes into contact with conductive fluids like blood or 1:100 bleach. The WetAlert device is ready for use during treatment.
 Red	Alarm	The enabled WetAlert devices has detected wetness. A blood alarm is occurring. Pressing the RESET key will clear the alarm and the icon will be green. If a device alarms three times within ten minutes, the Dialogue Box will display a message allowing the operator to disable the WetAlert device. Correct the condition causing the alarm before continuing with treatment.
 Yellow	WetAlert device is disabled	The enabled WetAlert devices was disabled (within a period of ten minutes, after its wetness alarm was reset twice, the 0 (zero) key was pressed during the third alarm). The WetAlert device is not active and is not able to detect wetness for the duration of the treatment

After Treatment

WetAlert Device Care

Your WetAlert device should be cleaned after every treatment. WetAlert devices can be cleaned with very dilute (1:100) bleach. 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 WetAlert device is essential.



Caution: Do not use cleaners containing acetone (like nail polish remover) to clean your WetAlert device. Acetone will damage the surface of the WetAlert device's plastic case.

WetAlert Device Storage

Wipe the WetAlert device so it is dry before storing it. The storage location should be at room temperature; do not allow the WetAlert device to freeze. Store the WetAlert device in a clean, dry location away from conductive materials like metal. Storing the WetAlert device on a conductive surface or in a conductive liquid bleach or other disinfectant will reduce the battery life.

Appendix

WetAlert Spare Parts

Additional WetAlert devices (P/N 190988) are a prescription item and must be ordered through Fresenius Renal Therapies Customer Service at (800) 323-5188.

WetAlert Device Disposal

The WetAlert device is not intended for use beyond the life of its battery. Disinfect your WetAlert device before disposing of it. You must comply with all local regulations regarding battery and circuit board recycling.

WetAlert Device RF Transmitter Characteristics

Radio Frequency (RF): 433.92Mhz

Power: 30 microwatts

Effective Range: Up to six feet

Modulation: ASK (Amplitude Shift Keying)

U.S. FCC ID #: UO20906

Canada Certification #: 6776A-0906

The Wireless Wetness Detector System operates a proprietary wireless protocol that does not contain patient specific data and does not support control of the 2008K@home hemodialysis machine. The wireless protocol reports only wetness status. Wireless security for the signal from the wetness detector is assured via internal checksum techniques, timing of the signal data protocol, and a unique 24-bit identification number in each wireless detector.

Quality of Service

The 2008K@home hemodialysis machine monitors for radio signal interference. If the 2008K@home hemodialysis machine detects interference, it will display a “Wetness No Comm.” warning message and an audible alarm will sound. Possible sources of interference include any device operating in the frequency range of 430Mhz to 450Mhz like portable amateur radios, mobile amateur radio located in a vehicle, fixed location amateur radios, and wireless video cameras.

For separation distances, see the Manufacturer's EMC Declaration on the next page.

Manufacturer’s Electromagnetic Compatibility (EMC) Declaration

The 2008K@home hemodialysis machine has been certified to the requirements of ANSI/AAMI/IEC 60601-1-2 within the scope of equipment intended to be used in institutional environments, such as hospitals⁽¹⁾. This certification deems the 2008K@home Hemodialysis Machine to be safe with regards to emissions and immunity to electromagnetic energy when used in institutional environments and does not guarantee against interference upon common household electronics⁽²⁾ when used in the home.

⁽¹⁾ Emissions testing of the machine was performed using the limits for CISPR 11 Group 1, Class A which are specified for equipment intended to be used in institutional environments (such as hospitals) and not in homes (which typically requires Group 1, Class B limits). Therefore, use of the 2008K@home hemodialysis machine in residential environments may result in interference with some types of broadcast receivers such as televisions and radios. Should such interference occur, it will not permanently affect those receivers and can be reduced or eliminated by repositioning of the receiver or the 2008K@home hemodialysis machine.


⁽²⁾ In order to assure the safety of the 2008K@home hemodialysis machine as well as other medical devices when used with the 2008K@home hemodialysis machine in the home environment, a detailed technical analysis was performed. This analysis has shown that the emissions levels of the 2008K@home hemodialysis machine are significantly below the immunity requirements of ANSI/AAMI/IEC 60601-1-2 and therefore are not likely to impact the safe operation of other medical devices used within the proximity.

Guidance and manufacturer’s declaration – electromagnetic emissions		
The 2008K@home hemodialysis machine is intended for use in the electromagnetic environment specified below. The customer or user of the 2008K@home hemodialysis machine should ensure it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF Emissions CISPR 11	Group 1	The 2008K@home hemodialysis machine uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The 2008K@home hemodialysis machine is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: When the 2008K@home hemodialysis machine is used in home environments, it may cause interference with some types of broadcast receivers such as televisions or radios. This interference is not harmful to such equipment and is only temporary. Should such interference occur, it can sometimes be reduced or eliminated by minor repositioning of the 2008K@home hemodialysis machine.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
The 2008K@home hemodialysis machine is intended for use in the electromagnetic environment specified below. The customer or the user of the 2008K@home hemodialysis machine should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air (Level 4)	±8 kV contact ±15 kV air (Level 4)	Can be used in a dry location (minimum 10% relative humidity)
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial and/or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, short interruptions, and voltage variation on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycles 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 seconds	<5 % U_T (>95 % dip in U_T) for 0.5 cycles 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the 2008K@home hemodialysis machine requires continued operation during power mains interruptions, it is recommended that the 2008K@home hemodialysis machine be powered from an uninterruptible power supply or a battery.
Power-Frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity

The 2008K@home hemodialysis machine is intended for use in the electromagnetic environment specified below. The customer or the user of the 2008K@home hemodialysis machine should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the 2008K@home hemodialysis machine, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>If abnormal performance is observed such as TMP alarms or blood leak alarms, additional measures may be necessary, such as re-orienting or relocating the equipment.</p> <p>Recommended separation distance</p> <p>1.2 \sqrt{P}</p> <p>1.2 \sqrt{P} 80 MHz to 800 MHz 2.3 \sqrt{P} 800 MHz to 2.5 GHz</p> <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the 2008K@home hemodialysis machine is used exceeds the applicable RF compliance level above, the 2008K@home hemodialysis machine should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the 2008K@home hemodialysis machine.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

**Recommended separation distances between
portable and mobile RF communications equipment and the 2008K@home
hemodialysis machine**

The 2008K@home hemodialysis machine is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the 2008K@home hemodialysis machine can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 2008K@home hemodialysis machine as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 1.2 \sqrt{P}$	$d = 1.2 \sqrt{P}$	$d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Additional Information

For more information, please contact:

Fresenius Renal Therapies
4040 Nelson Avenue
Concord, CA 94520
(800) 227-2572
www.FMCNA.com

Fresenius Renal Therapies
Canada Technical Support
(888) 709-4411

Manufactured by
Fresenius Renal Therapies
920 Winter Street
Waltham, MA 02451

Indications for Use: The WetAlert wireless wetness detector is indicated for use with the 2008K@home hemodialysis machine and is an optional accessory to aid in the detection of blood and water leaks during hemodialysis. Home hemodialysis using the detector must be observed by a trained and qualified person as prescribed by a physician.

Caution: Federal (US) law restricts these devices to sale by or on the order of a physician.

Note: Read the Instructions for Use for safe and proper use of these devices. For a complete description of hazards, contraindications, side effects, and precautions, see full package labeling available at www.fmcna.com.



Fresenius Renal Technologies
A division of Fresenius Medical Care North America
920 Winter Street
Waltham, MA 02451

For all inquiries and questions,
please contact Technical Services at 1-800-227-2572