

2008K@home User's Guide

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Caution: *Federal (U.S.) law restricts this device to sale only by or on the order of a physician. Frequency, duration, and parameters of treatment are to be determined by the prescribing physician.*

Note: *Not all features are available in all regions.*

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.

Optional bibag system Indications for use: the bibag system is used with three stream proportioning hemodialysis systems equipped with the bibag module such as the 2008K@home machine and is indicated for use in bicarbonate hemodialysis for acute and chronic renal failure. The bibag system is intended for extracorporeal bicarbonate hemodialysis according to a physician's prescription.

Optional 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.

My Treatment Parameters

Use this page for your treatment values as prescribed by your doctor



Warning: You must enter the values prescribed by your doctor. Failure to enter your own prescribed treatment parameters could result in serious injury or death.

The main screen contains the following fields:

- Conc**: []
- Na+**: [] mEq/l
- Dialysate Flow**: [] ml/min
- Bicarbonate**: [] mEq/l
- Temperature**: [] °C
- Syringe**: []
- Heparin Rate**: [] ml/hr
- Stop Heparin**: [] min
- Heparin Bolus**: [] ml
- Dry Weight**: [] kg
- Tx Time**: [] h:min
- Max UF Vol**: [] ml
- Done**: []

The **Blood Pressure** sub-menu includes:

- Blood Pressure Alarm Limits**
 - Upper Sys: [] mmHg
 - Lower Sys: [] mmHg
 - Upper Dia: [] mmHg
 - Lower Dia: [] mmHg
- Blood Pressure Settings**
 - Inflation Pressure: [] mmHg
 - Interval: [] h:min

The **Pulse Alarm Limits** sub-menu includes:

- Upper Pulse: [] /min
- Lower Pulse: [] /min

The **BP rate** sub-menu includes:

- Start/Stop: []
- BP rate: ml/min []
- Up arrow: []
- Down arrow: []

My Treatment Procedures

Use this page for your treatment procedures decided by your clinic



Warning: Your clinic must decide your particular treatment procedures. Failure to follow your clinic's procedures could lead to serious injury or death.

Supplies Needed: _____

Priming Method: _____

Use Heparin Pump (y/n): _____

Testing Conductivity and pH: _____

Testing for Residual Disinfectant: _____

My Dialyzer Coefficient (KUF): ____
Typical Expected TMP: _____

$$\frac{\text{UF Rate}}{\text{Dialyzer Coefficient or KUF}} = \text{Approximate Expected TMP}$$

High/Low Pre Weight Error: _____

UF Additional Volume: _____ ml

Setting the Arterial Drip Chamber Level: _____

Rinsing Back Blood with Saline: _____

Treating Access Site: _____



Note: If you have any questions, you should call your Home Therapies Nurse at: () -

My Cleaning Procedures

Use this page for your cleaning procedures decided by your clinic



Warning: Your clinic must decide your cleaning procedures. Failure to follow your clinic's procedures could lead to serious injury or death.

Bloodline and Dialyzer

Disposal: _____

Rinse – page 156: _____

Frequency: _____

Heat Disinfect – page 164
(recommended daily to disinfect hydraulics or weekly if Chemical/Rinse is run daily):

Frequency: _____

Acid Clean – page 160
(recommended daily to remove bicarbonate build-up):

Frequency: _____

Chemical/Rinse – page 168
(recommended weekly to disinfect hydraulics or daily if Heat Disinfect is run weekly):

Frequency: _____

Acid & Heat Disin – page 174
(recommended daily to disinfect hydraulics and remove bicarbonate build-up):

Frequency: _____

Disinfect Machine Exterior –
page 180 (after every treatment):

Blood Leak Policy: _____

RO System Disinfection –
page 188:

Transducer Contamination
Policy: _____

Frequency: _____

Concentrate Container and
Cap Disinfection – page 186:

Machine Storage Procedure –
page 190: _____

Notes: _____

Reporting Problems



Note: Complaints may be reported directly to Fresenius Medical Care North America by calling our Technical Support Hotline at (800) 227-2572. The Technical Support Hotline is staffed 24 hours a day, 7 days a week.

For U.S. Customers Only

Reporting Adverse Events to the FDA (Food and Drug Administration)

MedWatch is the Food and Drug Administration's reporting system for adverse events. The MedWatch system collects reports of adverse reactions and quality problems associated with FDA-regulated products, such as the 2008K@home hemodialysis machine.

Voluntary reporting by healthcare professionals, consumers, and patients is conducted on a single, one-page reporting form (Form FDA 3500). You may report online at:

<http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm>

or by submitting the MedWatch 3500 form by mail or fax 1-800-332-0178. A copy of form 3500 can be found online at:

<http://www.fda.gov/downloads/Safety/MedWatch/DownloadForms/UCM082725.pdf>

Detailed instructions for reporting Adverse Events are available at:

<http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm095859.htm>

Or call 1-800-FDA-1088 Mon–Fri between 8:00 a.m. and 4:30 p.m. EST.

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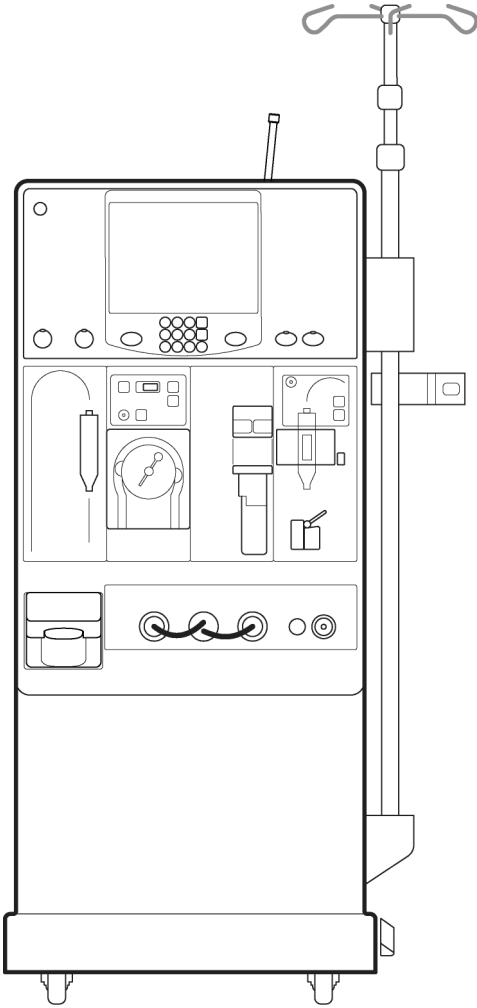
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Chapter 1: Introduction



Welcome “Home”



Welcome “Home”

Welcome to the “Home” version of the 2008K hemodialysis machine. We at Fresenius Medical Care know that life on hemodialysis is not easy, but we have worked hard to make it simpler. New to the “Home” are special features, easy to use Control Panel keys, and simple touch screen menus that guide you through the setup, treatment, and clean up procedures. Carefully following your doctor’s instructions, you have the convenience and freedom of dialyzing in your own home.

Be sure to read and follow all instructions and warnings listed in the manual.

Requirements

You must have adequate and appropriate training to operate your 2008K@home hemodialysis machine. Anyone else who operates this machine must also have adequate and appropriate training. You and your care partner must follow your doctor’s orders when operating this machine. Before using this machine, each operator should be:

- Knowledgeable of hemodialysis procedures and how they affect the body
- Well-practiced in aseptic techniques and other healthcare procedures
- Very familiar with the contents of this manual
- Able to read and understand these instructions and on-screen instructions and menus
- Fully trained and qualified to operate this machine. You and your care partner must be able to tell between normal and abnormal operation

Purpose of the 2008K@home machine

The 2008K@home hemodialysis machine is for short term (acute) and long term (chronic) dialysis treatment in an acute or chronic facility. The 2008K@home hemodialysis machine is also for hemodialysis in the home. In the home, a trained and qualified person as prescribed by your doctor must observe your treatment.

Contraindications (When this machine should not be used)

The 2008K@home hemodialysis machine is contraindicated for use in a home setting where there is inadequate water supply or inadequate water pressure. In other words, you cannot use the 2008K@home hemodialysis machine in your home if you do not have a constant water supply with good pressure. Your water pressure must be at least 20 psi and no more than 105 psi. Your water temperature must be at least 10°C (50°F) and no higher than 25°C (77°F).

Hemodialysis Precautions

Your doctor has prescribed hemodialysis for you. There are risks to hemodialysis, but your doctor believes that hemodialysis is essential for you. It is very important that you follow your prescription to minimize risks associated with hemodialysis. Here are some things you and your doctor should consider:

- During hemodialysis your blood may clot when it is running through the bloodlines (the tubing used to carry the blood to your machine and back to your body). To prevent this, your doctor may prescribe heparin, a drug which prevents clotting (anticoagulant). You should only use the amount prescribed by your doctor to prevent clotting in the bloodlines while avoiding the risk of excessive bleeding.
- Hemodialysis may affect the effectiveness of some medicines. If you are taking any medicines, you should discuss with your doctor any steps you may need to take in order to minimize any effects of hemodialysis on your prescribed medications. The medicine may be removed from your blood more quickly because of hemodialysis. Then the medicine is not as effective. Your doctor should consider these effects and make necessary adjustments in your prescribed medications.

Hemodialysis Complications

Hemodialysis therapy may be associated with complications. In serious cases, permanent injury or death may result. Some of the common complications associated with hemodialysis and the use of hemodialysis equipment are listed below. If you experience any of these or other complications, immediately call your Home Therapies Nurse or doctor. You may need medical care to manage health consequences of these complications.

You must carefully follow your doctor's orders to minimize the risk of these complications. Hemodialysis may cause:

- Excessive removal of fluid (hypovolemia)
- Inadequate fluid volume removed (hypervolemia)
- Low blood pressure (hypotension)
- High blood pressure (hypertension)
- Itching
- Cramping
- Feeling sick to your stomach and throwing up (nausea and vomiting)
- Feeling cold (hypothermia)
- Feeling hot (hyperthermia)
- Anxiety
- Headaches
- Confusion or other changes in your mental status
- Convulsions
- Accidental entry of air into your veins and/or lungs (air embolism)
- Electrolyte abnormalities (changes in the levels of certain minerals in your blood)
- Too much acid (acidosis) or too little acid (alkalosis) in your blood
- Damage to your red blood cells (hemolysis)
- Fever.

Venous Needle Dislodgement

Venous Needle Dislodgement (VND) refers to accidental removal of the needles used to access your blood vessels for hemodialysis. Your level of risk for VND should be assessed during screening for your suitability for home hemodialysis. The most important precaution patients, caregivers and hemodialysis professionals can take against VND is to monitor the access site and keep it visible at all times during dialysis. If the tubing accidentally disconnects or a needle comes out, it can cause severe blood loss which may result in serious injury or death. Do not rely on only machine alarms to monitor for these complications. The machine may not alarm in every needle dislodgement or disconnection. If dislodgement or disconnection occurs, follow your Home Therapies Nurse's advice.

Water Treatment Considerations

The quality of water used for hemodialysis is very important to reduce the risk of infections and exposure to other toxins. You should work with your Home Therapies

Nurse and your clinic to monitor the quality of water to meet the recommended chemical and bacteriologic standards. See Water Quality on page 325 of the “Machine Specifications” section for more information. If you do not follow these standards for water, it may lead to toxic effects over time. Your clinic must create a regular schedule for disinfecting and testing the water treatment system, piping, inlet lines, filters, concentrate feed containers, and the dialysate lines. You must then follow their schedule. This schedule may vary among clinics.

Good practices

Be sure to use all techniques taught to you by your Home Therapies Nurse. These include the following:

- Use aseptic technique
- Tightly connect and monitor all tubing and connections to prevent loss of blood or air entering the bloodlines
- Monitor the ultrafiltration (UF) rate and UF removed
- Monitor your blood pressure, pulse, and general physical status
- Use chemical disinfectants to disinfect your machine and water treatment and distribution systems
- Rinse your machine and water treatment and distribution systems well
- Test for disinfectant in your machine and water treatment and distribution systems every time before using them for treatment.

When the Blood Pressure Module should not be used (Contraindications)

Please refer to training techniques from your Home Therapies Nurse when placing your blood pressure cuff. These health problems may interfere with the use of a blood pressure cuff (timed automatic blood pressure instrument utilizing the oscillometric principle):

- Convulsions
- Irregular (ectopic) beats
- Peripheral circulation problems in your arms and legs
- Severe arrhythmia
- Spasms
- Rapid heartbeat (tachycardia)
- Tremors
- Use of a heart lung machine

Using an incorrectly sized blood pressure cuff may cause inaccurate blood pressure readings.

About This User's Guide

This user's guide is a reference for properly trained users of the 2008K@home hemodialysis machine—it cannot replace formal training by your clinic. It cannot provide or replace clinical advice.

This manual is specially designed for easy readability and understanding. It has illustrated procedures, step-by-step instructions, and a foldout “map” of your machine to help you quickly locate features on your machine. This is called “Your K Map” and it folds out from the inside front cover of this user's guide. When a procedure references a feature not shown, the operator can find the matching letter and location on “Your K Map” to see it. Another helpful reminder in this manual, attention boxes, explained on the next page, keep you on the right track to home hemodialysis.

Attention Boxes



Warning: This symbol warns against an action or situation that could hurt you. If you do not follow these instructions, it can lead to serious injury or death.



Shock Hazard: This symbol means you could get a severe electrical shock if you use the equipment wrong.



Tip Hazard: This symbol means you could tip your machine if you push or pull it wrong.



Caution: This symbol means you will damage your machine if you do not follow instructions.



Note: This symbol means there is extra information about machine features. Notes have helpful information. They may also show instructions for unique cases.

Other Important Symbols you may see on labels



Corrosive Substance Hazard: A corrosive substance hazard warning means that you could get hurt or damage the machine if you use the equipment wrong.



Hot Surface, Fluid, or Vapors Hazard: A hot surface, fluid, or vapors hazard warning means you could get burned if you use the equipment wrong.



Mandatory Action: A command describing required action to maintain safety.



Do not reuse (applies to disposables)



and



ON: This symbol, at the top of the switches on the back of your machine, means the switch is in the ON position.



and



OFF: This symbol, at the bottom of the switches on the back of your machine, means the switch is in the OFF position.



Degree of protection against electric shock:
Type B



Degree of protection against electric shock:
Type CF – Blood Pressure Cuff only



MR Unsafe: An item which poses unacceptable risks to the patient, medical staff or other persons within the MR (Magnetic Resonance) environment.



Protective ground terminal



Ground terminal



Equipotentiality

Related Reading

These documents have more information about your 2008K@home hemodialysis machine:

- 2008K Hemodialysis Machine Operator's Manual (P/N 490042)
- 2008K@home bibag User's Guide (P/N 508340)
- 2008K@home WetAlert Wireless Wetness Detector Home User's Guide (P/N 507939)
- 2008K@home WetAlert Wireless Wetness Detector In-Center User's Guide (P/N 490181)
- 2008K@home Technician's Manual (P/N 490078)
- 2008K@home Calibration Procedures Booklet (P/N 507664)
- 2008K@home Preventive Maintenance Procedures Booklet (P/N 507665)
- 2008K@home Electronic Block Diagrams (P/N 290253)
- 2008K@home Hydraulic Flow Diagrams (P/N 700074)
- 2008K@home Installation Checklist (P/N 490079)
- 2008K@home Installation Checklist Instructions (P/N 507670)
- 2008K@home Field Service Bulletins may be obtained from the Fresenius Medical Care North America (FMCNA) website: www.FMCNA.com or contact your clinic for more information.
- Information on the effectiveness of disinfection procedures is available through Fresenius Medical Care Quality Systems.

Questions? Call Your Home Therapies Nurse

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

Technical Support can also be reached anytime at **(800) 227-2572**.

General Warnings

Read all warnings before beginning your treatment. Additional warning statements for each topic are found throughout the manual.



Warning: Read this entire user's guide before beginning your treatment. You must be familiar with how to use your machine and with the features of this manual. If you do not follow these instructions to install and maintain this equipment, it may cause serious injury or death.



Warning: Your doctor must prescribe your entire hemodialysis treatment, including all of the values listed on the "My Treatment Parameters" sheet. If you use the wrong values, it may cause serious injury or death. Do not use example values shown in machine pictures.



Warning: Headaches and nausea can be caused by dehydration or too much volume removed during hemodialysis. You and your doctor must pay strict attention to the achievement of the prescribed dry weight.

Water Warnings



Warning: Make sure your machine is working correctly before beginning your treatment. If you fail to respond to alarms, it may lead to serious injury or death.



Warning: You must follow all local regulations covering the separation of devices in the water supply. In case of drain back up; you must maintain an air gap between your machine's drain line and its drain.



Warning: Your water must meet quality standards for dialysate (see Water Quality and Dialysate Quality on page 325 of the "Machine Specifications" section for more information). Monitor the water source regularly to detect changes in quality. These changes could have an unfavorable effect on you or your machine. Regularly check for chemicals such as chlorine and chloramines. These chemicals can harm dialysis patients.



Warning: Do not use the 2008K@home hemodialysis machine in your home if you do not have a constant water supply with good pressure. Your water pressure must be at least 20 psi and no more than 105 psi.



Warning: Frequent temperature or water flow alarms may indicate a problem with the water supply. Call a qualified technician if you have these problems.

Concentrates Warnings



Warning: You must properly match your concentrate type to your machine's setup. Failure to do so may cause serious injury or death. Many different concentrate types are available for use in your machine. Concentrates contain various amounts of dextrose, potassium, calcium, sodium, chloride, magnesium, and bicarbonate.



Warning: Use of an acid concentrate intended for a 1:44 mix ratio in any 1:34 proportioning dialysate delivery machine may result in a dialysate with normal conductivity but not at a physiologic pH (low pH). There will be no alarms in this event. Use of improper dialysate may cause injury or death.



Warning: Acid concentrate, bicarbonate concentrate, and water must be of the appropriate quality to ensure safety and performance of the final dialysate are met (see Water Quality, Dialysate Quality, and Concentrate Quality on page 325 of the "Machine Specifications" section for more information).



Warning: The dissolved bibag bicarbonate concentrate must be used within 24 hours of connecting to the dialysis machine. Do not refill the bibag container.



Warning: Your dialysate concentrate jugs must match the concentrate listed in the "Set up" screens. If you use the wrong dialysate, it may cause serious injury or death. Fresenius Medical Care recommends using the concentrate containers provided with your machine to avoid mismatching containers.



Warning: Test the conductivity and approximate pH of the dialysate with an independent device before beginning treatment. Test it also when you change liquid concentrates during your treatment and when switching from the bibag system to liquid bicarbonate*. The wrong conductivity or pH may cause serious injury or death.

*Note: If alternative liquid bicarbonate concentrate sources are used (jugs or central delivery) the end user must ensure the bicarbonate is of appropriate quality and is prepared per manufacturer's instructions.



Warning: Hemolysis of the blood in the dialyzer may occur if the dialysate temperature goes higher than 42°C. Dialysate temperatures must be maintained below this level. Do not return hemolyzed blood.



Warning: The conductivity alarm is an important safety feature of your dialysis treatment. Your concentrate jugs must be full at the beginning of each treatment. You must have enough concentrate for the entire treatment. If your concentrate jugs run low, replace them. Failure to have sufficient concentrate for your entire treatment will prevent you from receiving your prescribed dialysis and may lead to serious injury or death.



Warning: Acid concentrate products are used as one component in mixing dialysate bath. These acid products contain chemical compounds that, after mixing, yield acetate (and citrate in certain products) in the dialysate. (Please refer to the acid concentrate product labeling for specific acetate/citrate amounts.) After diffusion across the dialyzer membrane, acetate (and citrate when present) is metabolized by the liver to serum bicarbonate and adds to the serum bicarbonate that separately results from the diffusion of dialysate bicarbonate across the dialyzer membrane. During dialysis, the dynamic of diffusion and concentration gradients prevent serum bicarbonate concentration from exceeding the dialysate bicarbonate concentration. The bicarbonate concentration of the dialysate is the “bicarbonate” setting on the dialysis machine, and is the bicarbonate dose prescribed by the physician. On the 2008 series hemodialysis machines, the bicarbonate dose may be set in a range between 20 and 40 milliequivalents per liter, but may be set in different ranges in other machines.

When the dialysis session terminates, acetate (and citrate when present) that has not yet metabolized may remain in the blood and will be converted to serum bicarbonate after diffusion ceases, without possibility of diffusion out of the blood. The post dialysis metabolism of acetate (and citrate when present) could thus briefly increase serum bicarbonate concentration above the prescribed bicarbonate concentration of the dialysate. Physicians should consider this possibility in prescribing bicarbonate dose.

Prescription of insufficient bicarbonate may contribute to metabolic acidosis; excessive bicarbonate may contribute to metabolic alkalosis. Both conditions are associated with poor patient outcomes, including increased mortality risk



Warning: Your dialysate flow must be monitored. The flow must be set to your prescribed flow rate. Treatment without proper dialysate flow may cause injury due to minimal removal of waste products from the blood.



Warning: Replace a leaking *bibag* disposable immediately. Spills can cause damage to carpeting and other surfaces. To contain such spills, the machine should be on a spill-tolerant surface. Spills can cause slips and falls; clean up spills immediately.

Machine Warnings



Warning: You must properly disinfect your machine and test for remaining disinfectant before every treatment day.



Warning: Do not use your machine in the presence of flammable substances, like anesthetics, as it may cause explosions which may cause serious injury or death.



Warning: The air detector alarm is a critical safety feature that alerts the user of potential air in the bloodline. You must properly place the venous drip chamber in its holder and set the proper blood/saline level in the venous drip chamber. Avoid overfilling. Failure to follow the instructions in this user's guide can result in severe injury or death. Please contact your physician if you have any questions about the proper operation of the air detector or how to attach the venous bloodline.



Warning: Your machine's Level Detector module must be calibrated for the venous line being used, as your machine is compatible with a number of venous lines. Also, visually check that the Venous Clamp is capable of fully closing the model of bloodline you are using. Failure to do so may cause serious injury or death.



Warning: Check all bloodlines for leaks after your treatment has started. Keep access sites uncovered and monitored. Loose or improper bloodline connections or needles coming out can result in too much blood loss, serious injury and death. Machine alarms may not occur in every blood loss situation.



Warning: The "UF Goal Reached" alert is an important feature of your 2008K@home hemodialysis machine. Reaching your prescribed UF Goal is important. If you do not reach your prescribed UF Goal, it may lead to fluid overload, serious injury and death. The supervising nephrologist and care team is responsible for adequate training and supervisions of hemodialysis and volume removal.



Warning: Do not install the 9-Volt battery backwards in your machine, it will damage your "No Power" alarm.



Warning: You must use sterile transducer protectors between your machine and pressure monitor lines to prevent the transducers from getting wet. If transducer protectors become wet or contaminated with blood, they must be replaced. Wet transducers cause inaccurate pressure readings and may cause injury or death. Disinfect or replace associated parts. Clear monitor lines if they become wet.



Warning: Alarm limits for arterial and venous pressure monitoring, temperature, and conductivity must be maintained within safe physiological limits, prescribed by your doctor.



Warning: Repeated arterial and/or venous pressure alarms may mean poor blood flow or access problems. If you have frequent alarms or a change in alarm patterns, you should call your clinic. Frequent movement can trigger the alarm. Patients should refrain from unnecessary movement during dialysis.



Warning: Check that all lines and tubing are free of kinks to prevent damage to your blood (hemolysis).



Warning: The 2008K@home hemodialysis machine has not been cleared by the FDA for nocturnal use.



Warning: Repeated acid pump alarms may mean acid pump failure. If repeated acid pump alarms occur, stop your treatment and contact a qualified technician. Failure to replace a failed acid pump could cause serious injury.



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 on page 331.



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: Only qualified people from your clinic may use Service Mode. Do not make any changes to your machine with Service Mode. If you enter the wrong options or values, you may cause serious injury or death.



Warning: Never perform maintenance when a patient is connected to your machine. If possible, remove your machine from the treatment area when it is being serviced. Label your machine to make sure that it is not accidentally returned to use before the service work is completed. Disinfect and test your machine when service is done. Test the dialysate for acceptable conductivity and pH values before use.



Warning: Shock hazard. Do not remove machine covers. Refer servicing to qualified personnel. The electrical source must be single phase, three-conductor type provided with a hospital grade receptacle and a ground fault interrupter at 120 Volts, 15 Amps, 60 Hz. The proper polarity and ground integrity must be initially checked and maintained. Plug your machine directly into the electrical outlet; do not use extension cords or power strips.



Warning: When using the *bi*bag system, the acid and bicarbonate pressures must not exceed 10 psi when using a Central Delivery System. It may be necessary to use pressure regulators in order to reach proper conductivity. When not using the *bi*bag system, the maximum supplied pressure is 2 psi.

General Cautions



Caution: Connection to a central acid or bicarbonate feed system requires certain mechanical parts installed. Contact Fresenius Medical Care for more information.



Caution: Only the bags manufactured by Fresenius Medical Care may be used in the *bi*bag connector.



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 page 318.



Caution: Use only your fingers to operate machine keys. Using other objects, such as pens, may result in damage or premature failure.



Caution: Only qualified people authorized by your clinic's medical director or by Fresenius Medical Care may assemble, install, adjust, or repair your machine.



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. Clean up spills immediately.



Caution: Do not squeeze the blood pressure cuff when deflating it. Squeezing the blood pressure cuff may damage your machine's internal blood pressure module.

General Notes



Note: Arterial, venous, and transmembrane pressure monitor alarm limits are automatically set and delayed for pressure to stabilize, but conductivity and temperature alarm limits are calculated for the dialysate composition and may be somewhat adjusted by the operator.



Note: Your machine's screens and user's guide show bloodline model 03-2962-3. If you use a different model bloodline, your clinic must provide instructions for it.



Note: Once the concentrate type has been selected, it may be necessary to add concentrates from the preprogrammed catalog or add an entirely new concentrate. See the "Adding New Concentrates or Changing the Type" section in the 2008K Hemodialysis Machine Operator's Manual P/N 490042.



Note: The Diasafe Plus filter is required when the *bi*bag system is in use.



Note: You must follow all environmental regulations regarding waste disposal and eventual machine disposal. Contact your clinic for more information. Before disposing of your machine, any possible risk of infection from blood borne pathogens must also be eliminated by appropriate disinfection.



Note: A smoke detector should be properly installed in the room you use for dialysis. Follow the manufacturer's instructions. Test your alarm according to the manufacturer's instructions, and replace the battery as specified.



Note: The temperature of the bloodline and the durometer of the tubing affect the ability of the bloodline/blood pump system to prime during setup. Cold tubing may not prime as readily as warm tubing.

Fresenius Medical Care manufactures bloodlines for use with the model 2008K hemodialysis machine. Fresenius Medical Care cannot guarantee the performance of bloodlines not manufactured by Fresenius Medical Care. The prescribing physician must guarantee other bloodlines.



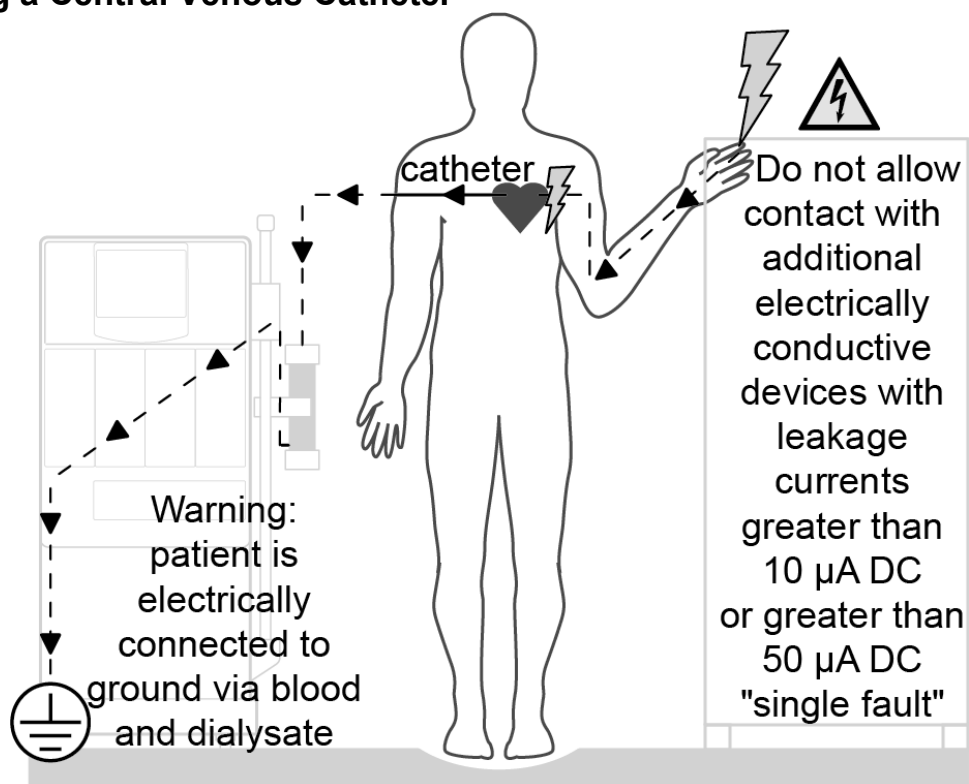
Note: Keep emergency supplies near your machine at all times. Include a flashlight in case of power failure. Check the flashlight regularly for fresh batteries.



Note: The following materials come into contact with purified water, dialysate, or dialysate concentrate:

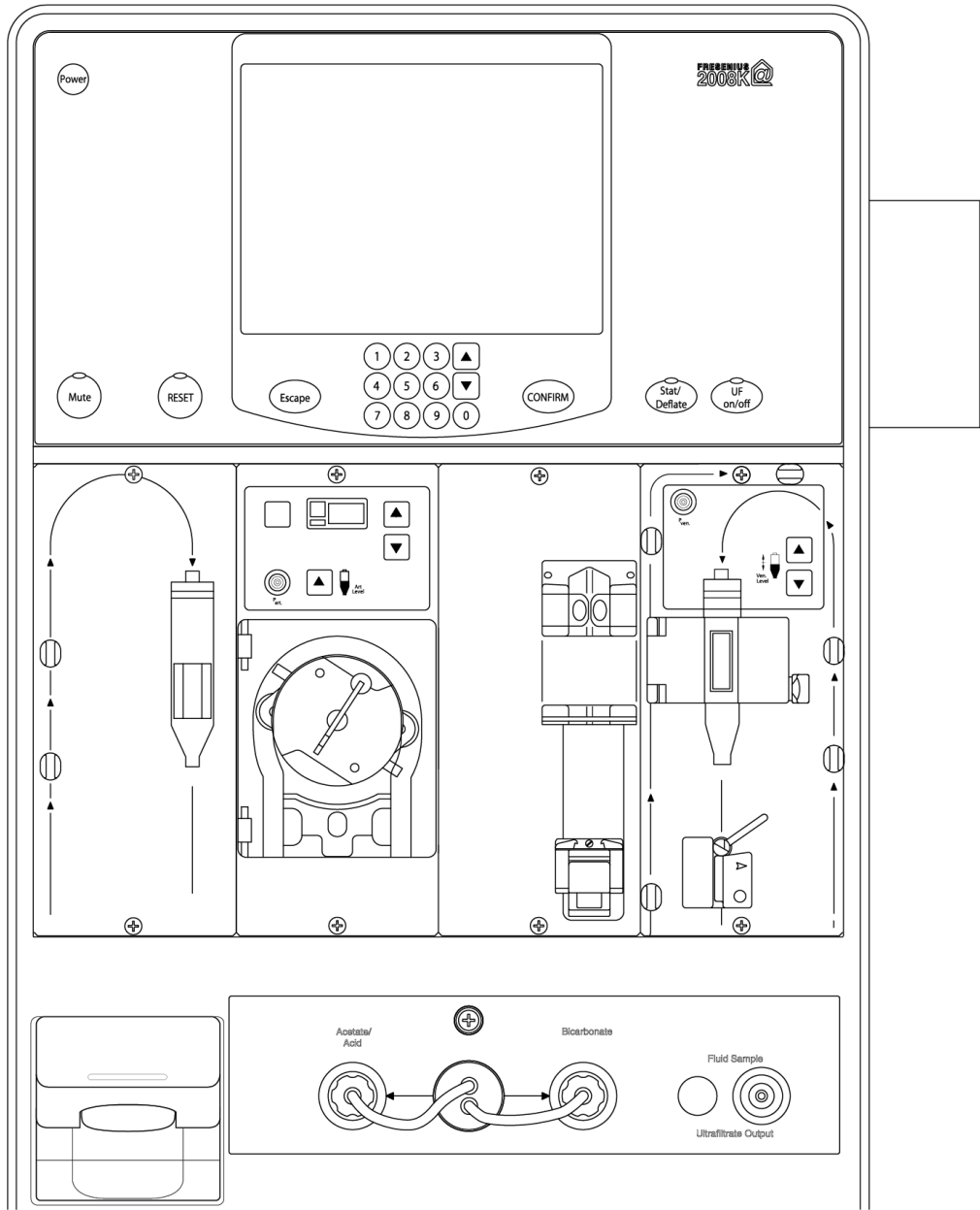
Dyflor (PVDF)	Polypropylene 20% glass fiber (PP-GF20)
Ethylene-propylene terpolymer (EPDM)	Radel 10 & 20% glass fiber (PES)
Forafion (PVDF)	Stainless steel (types 300 & 316)
Glass	Silicone (Si)
Lupolen (PE)	Teflon (PTFE)
Makrolon (PC)	Thermocomp (PES)
Polyethersulfone (PES)	Titanium – TiAl 4 V6
Polyphenylene oxide (PPO)	Ultem (PEI)
Polyphenylene oxide 20% glass fiber (PPO-GF20)	Ultradur+ (PBT)
Polypropylene (PP)	Victrex (PEEK)
	Vinyl chloride polymer (PVC)

Using a Central Venous Catheter



Shock Hazard: Ensure that no conductive electrical devices connected to or near the patient have leakage currents above the maximum CF applied parts limit of 10 μ A DC and 50 μ A DC in a single fault condition. Failure to follow these precautions may result in serious injury or death.

Chapter 2: Overview



2008K@home Hemodialysis Machine Features

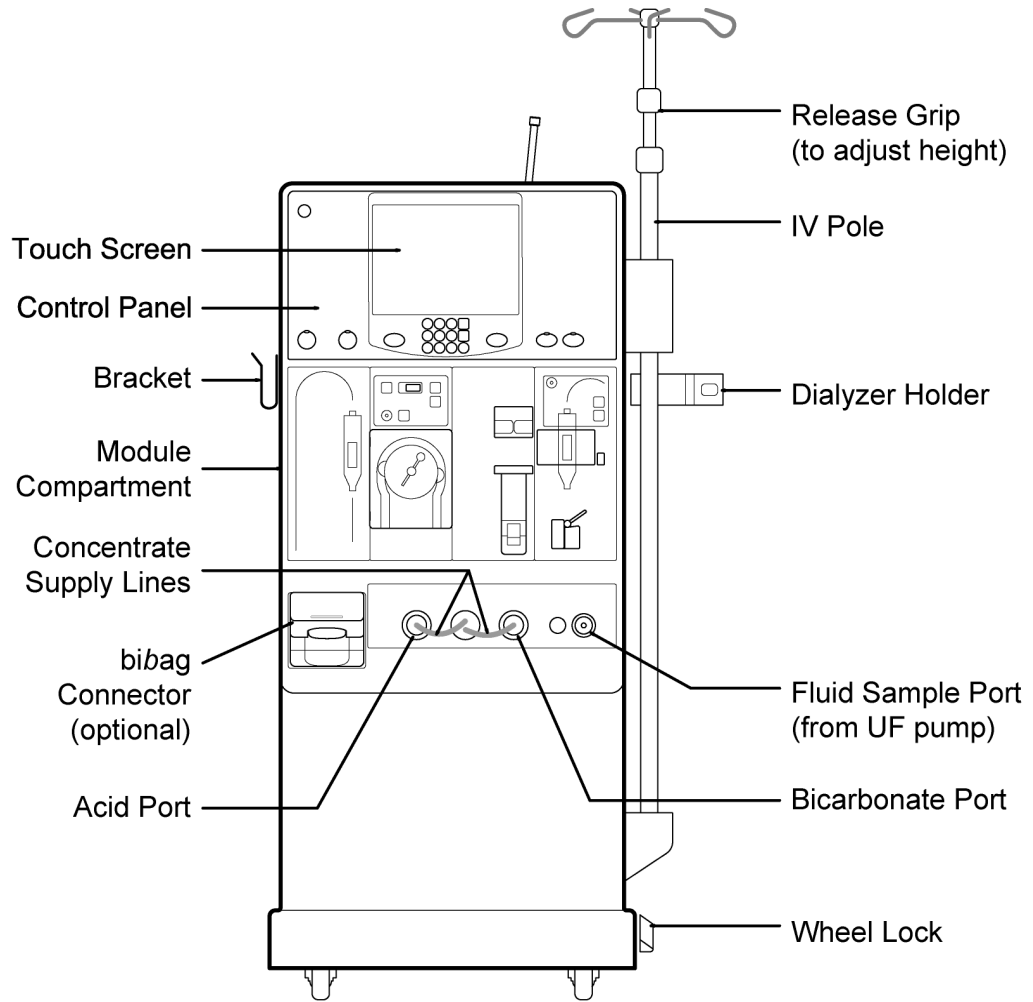
Your 2008K@home hemodialysis machine works like your kidneys: It removes waste from your bloodstream and washes it away. Your 2008K@home hemodialysis machine does this with two flow paths: The blood circuit and the dialysate path.

In the blood circuit, your blood flows constantly from you through a dialyzer and back again. There, waste is filtered out through a semi-permeable membrane before the blood returns to your body. Also during this process, your machine monitors the pressures in the venous and arterial bloodlines, and for the presence of air and blood. Your 2008K@home hemodialysis machine can also add heparin evenly throughout your treatment and use ultrafiltration to remove excess fluid.

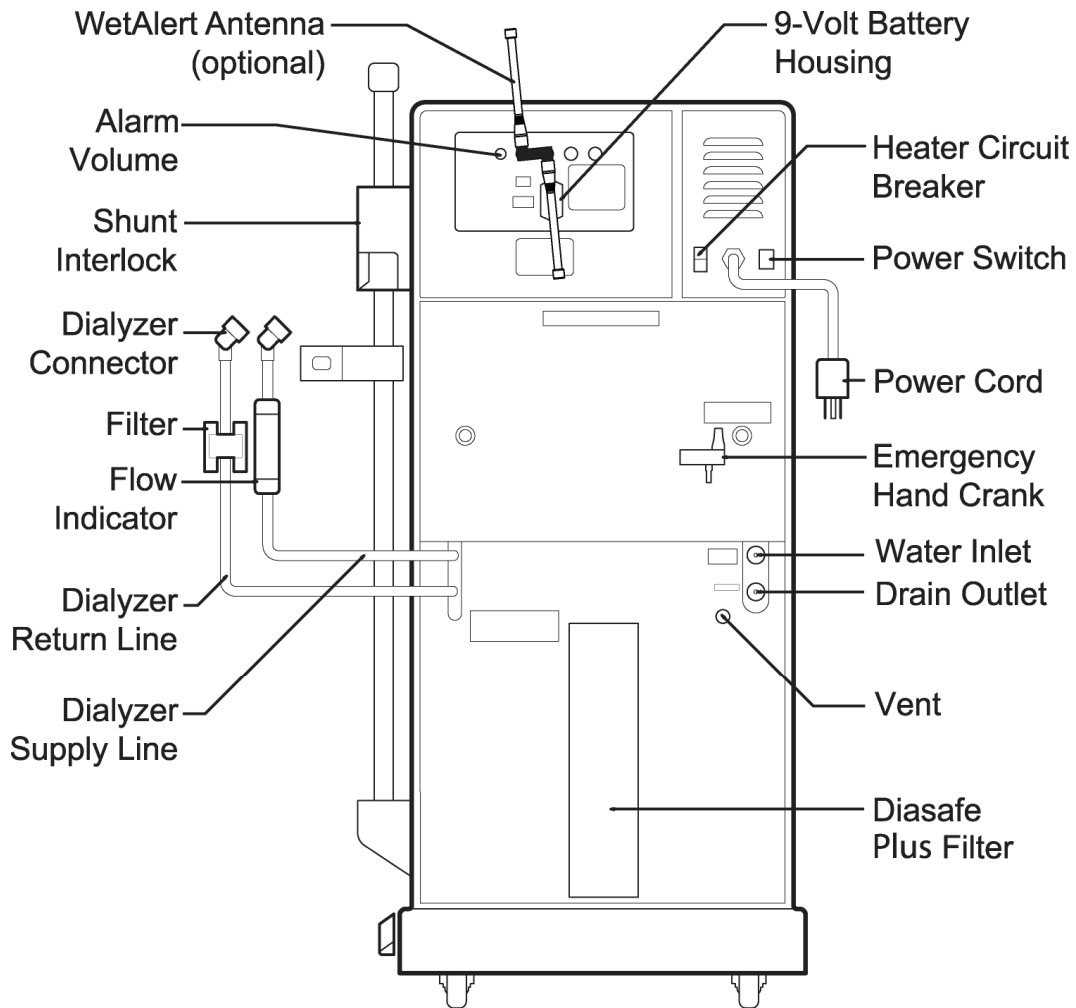
In the dialysate path, your machine first heats purified water and removes air from it. Then your machine mixes in acid and bicarbonate concentrates to make your dialysate. The solution is then pumped to the dialyzer. There it pulls waste from your bloodstream and washes it out the drain. The Balancing Chamber makes certain that the incoming flow of the dialysate is equal to the volume of the outgoing flow to control ultrafiltration from your body.

The Control Panel allows you to set and adjust treatment parameters and monitor your treatment.

Utilities such as water, drain, and electrical connections are all placed on the back of your machine, and out of the way of daily treatment procedures.

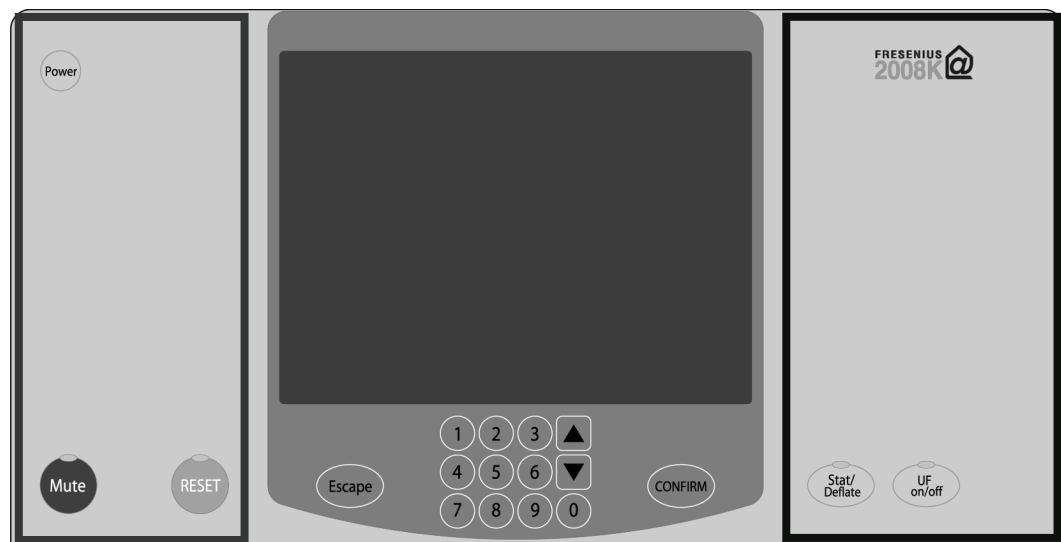


2008K@home Hemodialysis Machine Front View



2008K@home Hemodialysis Machine Rear View

The Control Panel



**Machine
Section**

**Treatment
Section**

**Patient
Section**

Control Panel

The Control Panel is located at the top, front of your machine; it is designed for simple operation and easy clean-up. It features a touch screen and various keys used to operate your 2008K@home hemodialysis machine. The different parts of the Control Panel are grouped into three sections:

Machine Section

Left side of the Control Panel: see page 24.

Treatment Section

Middle of the Control Panel: see page 26.

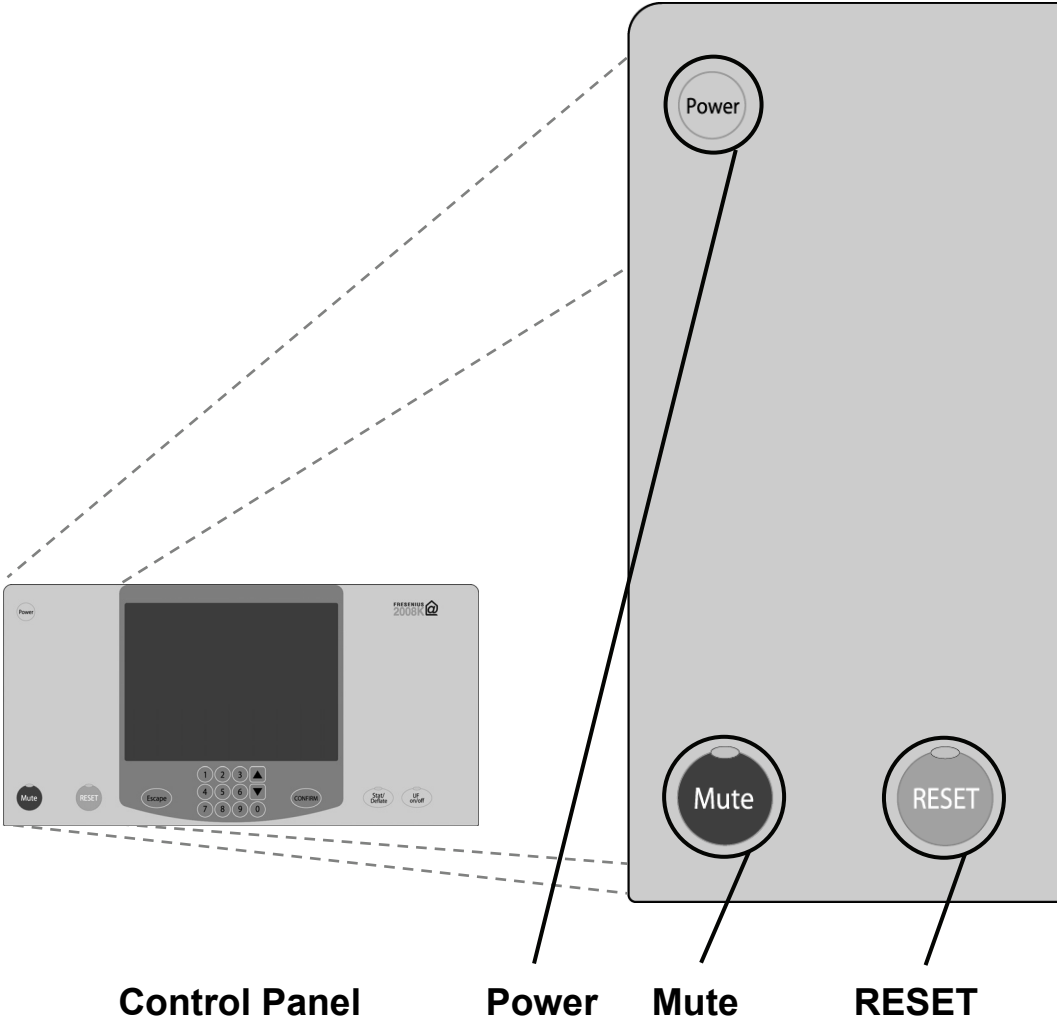
Patient Section

Right side of the Control Panel: see page 34.



Caution: Only use fingertips to press the keys and the touchscreen—pressing keys or the touchscreen with objects may damage your machine.

The Machine Section



Machine Section

The Machine section is located on the left side of the Control Panel. It is responsible for the general operation of your machine. It features three keys:

Power Key

- Press to turn your machine ON
- Press and hold for two seconds to turn your machine OFF



Note: The **Power** key does not interrupt electrical power to your machine. To disconnect completely, use the main power switch on the back or pull the power cord plug.

Mute Key

- Press to silence an alarm for two minutes



Note: The following alarms are muted for an extra four minutes (for a total of six minutes) when using a *bibag* disposable for the bicarbonate source:

- Conductivity Low and Conductivity High
- *bibag*: Cond Low
- Bicarb Cond 2 Low and Bicarb Cond 2 High
- Low Temperature and High Temperature

Note: Your machine may be set to automatically silence certain alarms, see “Emergencies and Alarms,” on page 194. However, the **Mute** key will not silence the “No Power” alarm.

RESET Key

- Press to reset your machine after an alarm
- Press and hold for two seconds to temporarily widen the alarm window for arterial, venous, and transmembrane (TMP) pressures
- During a blood leak, press and hold for three seconds to override the alarm and keep the blood pump running for three minutes

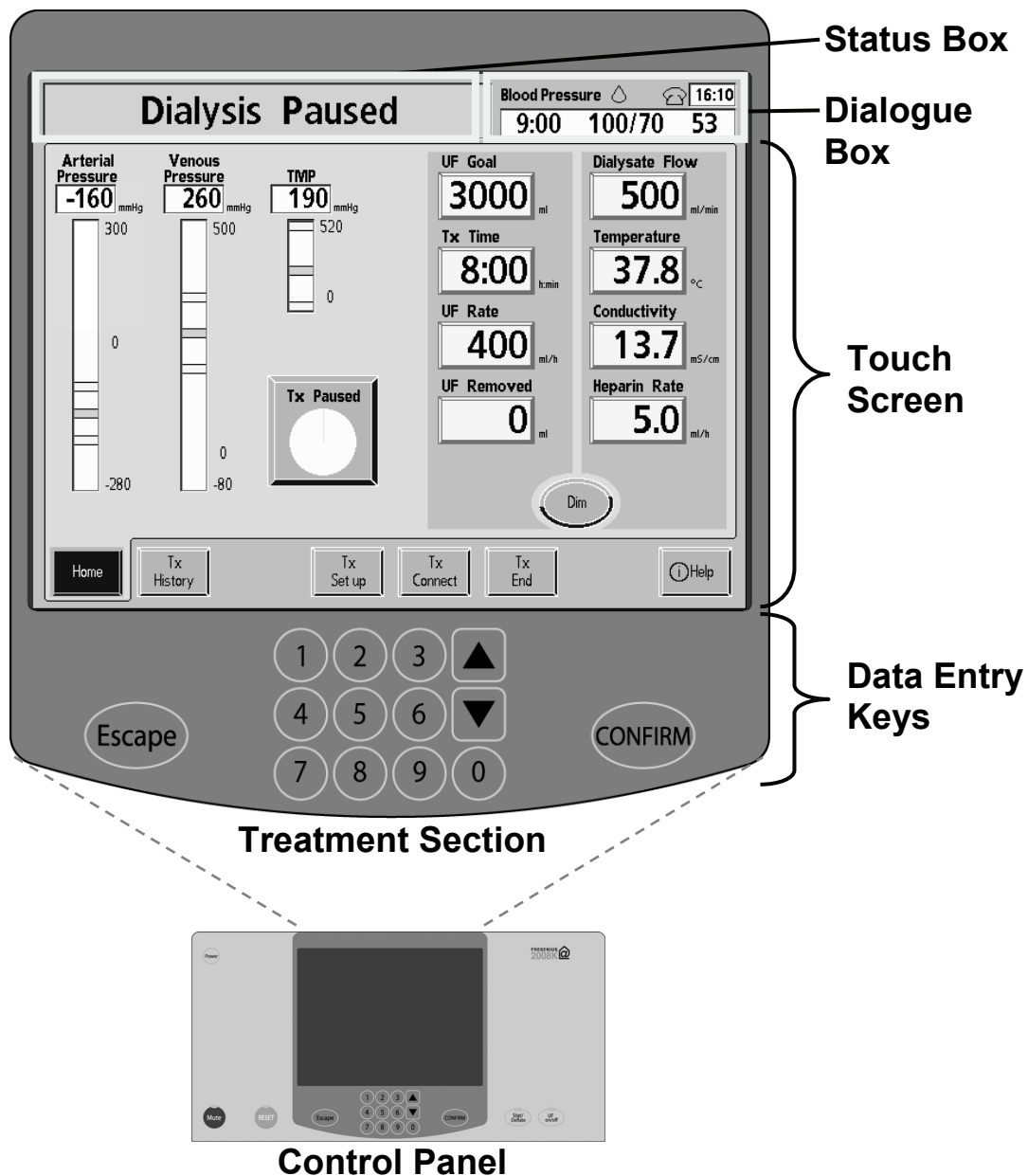


Warning: During an override, your machine’s blood leak detector is inactive. You must monitor your treatment.



Note: The **RESET** key light flashes when a resettable alarm occurs.

The Treatment Section



Warning: The values shown here are for example only. You must use the values prescribed by your doctor. If you use the wrong values, it may cause serious injury or death.

Treatment Section

The Treatment section is located in the middle of the Control Panel. It is used to view and set treatment parameters. It has four different features:

Status Box

See page 30 for a description of the Status Box.

Dialogue Box

See page 32 for a description of the Dialogue Box.

Touch Screen

The Touch Screen is a viewing screen located in the middle of the Control Panel that reacts to fingertip pressure. Using the Touch Screen, you may monitor your treatment and select treatment options with Touch Screen Buttons. The different types of Touch Screen buttons are described on the next page.

Data Entry Keys


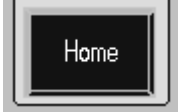








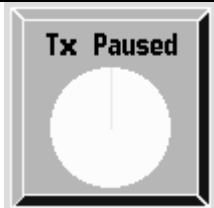

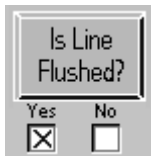

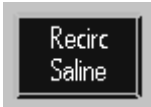
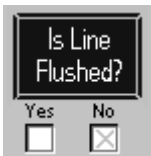

Data entry keys are located in the middle of the Control Panel along the base. They feature **Escape**, **CONFIRM**, number keys, and **Up/Down Arrow (▼/▲)** keys. Data entry keys are used to enter and change treatment parameter values and make selections in various screens. After entering a treatment parameter, you must press the **CONFIRM** key to confirm your selections. The **CONFIRM** key prevents accidental changes. The **Escape** key is used to exit certain screens, stop priming and recirculating functions, and undo parameter changes.

Additionally, pressing the **Down Arrow (▼)** key and **CONFIRM** at the same time will prompt for a 'New Treatment'. Pressing **CONFIRM** again will reset all treatment parameters to their default values as set on the "Rx Parameter" screen.



Note: If you reset all treatment parameters to their default values, you must re-enter your prescription again before starting your treatment.

Touch Screen Buttons

	Normal Light blue or light yellow	Selected Dark blue or dark yellow	Unavailable Gray
Screen-Buttons			
Movement-Buttons	 		 
Parameter-Buttons			
Action-Buttons	  	  	

Buttons Overview

Buttons are specific, identified sites on the Touch Screen that do certain actions when selected. Buttons are drawn to look three-dimensional.

Screen-Buttons

Screen-buttons are light blue rectangles usually located along the bottom or the left side of the Touch Screen. They act as a ‘doorway’ to another screen. When you touch a screen-button, it turns dark blue and you enter its screen. Gray screen-buttons are unavailable options from certain screens.

Movement-Buttons

The light blue oval movement-buttons, **Back** and **Done**, are used to move from screen to screen in various treatment procedures. **Done** moves you to the next screen, while **Back** displays past screens.

A gray movement-button cannot be selected until certain onscreen procedures are complete.

The **Dim** movement-button, located in the “Home” screen, ‘moves’ you to a darkened screen-saver when selected (see page 133).

Parameter-Buttons

Parameter-buttons are light yellow rectangles that display treatment parameters. When you touch a parameter-button, it turns bright yellow. You may then use the data entry keypad to change the parameter it displays. You must press the **CONFIRM** key in order to confirm the change (see page 27).

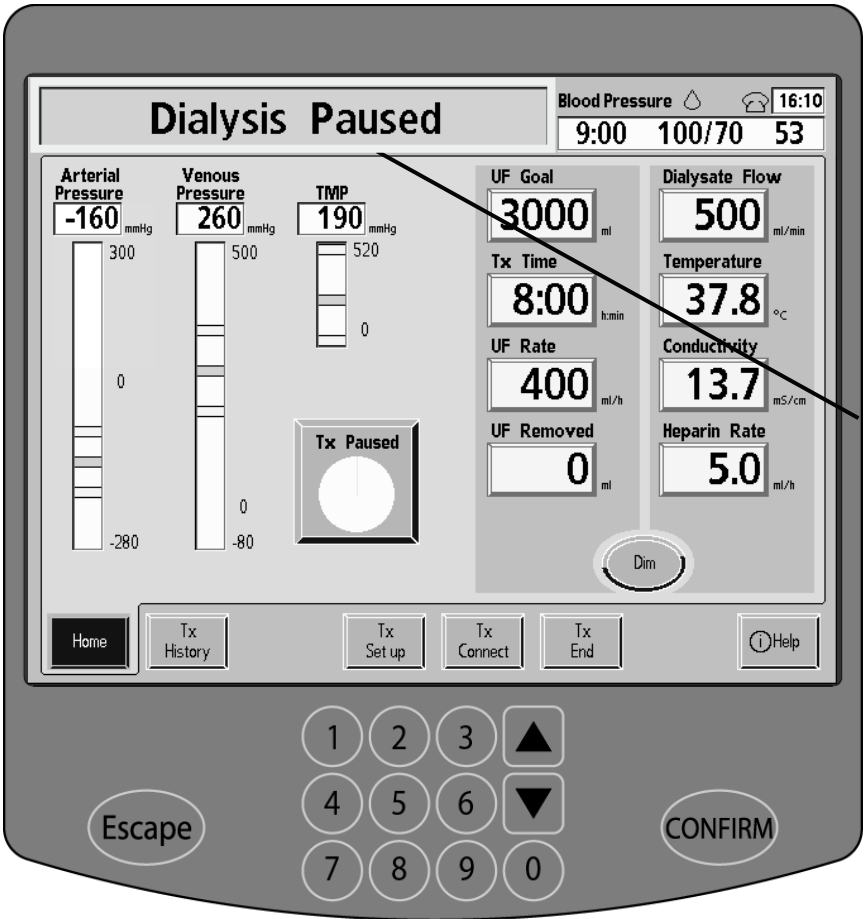
Action-Buttons

Action-buttons are light blue squares or rectangles that become dark blue when selected. You must next press the **CONFIRM** key to activate the button, starting a function of your machine or toggling a value. The button will change back to light blue again. The **Tx Clock** action-button features a pie chart graph that counts down your treatment time when selected and confirmed.



Note: Pressing the **Escape** key before the **CONFIRM** key is pressed will reset parameter-buttons and toggle-buttons to previous settings.

The Status Box



Status Box

Treatment Section

Status Box

The Status Box is located in the top, left corner of the Touch Screen. It displays various operational modes, warnings, alarms, or operator instructions. The Status Box background changes between three different colors to display your machine's conditions:

Green

During normal operation, when no problems have been detected, the Status Box background is green. It displays the current operational mode.

Yellow

When a warning condition exists, the Status Box background changes to yellow, instructing you to enter information or do a certain action. A warning condition, although possibly serious, does not mean an immediate threat to the patient. Warning events do not stop the blood pump, but may sound a two-tone audible warning.

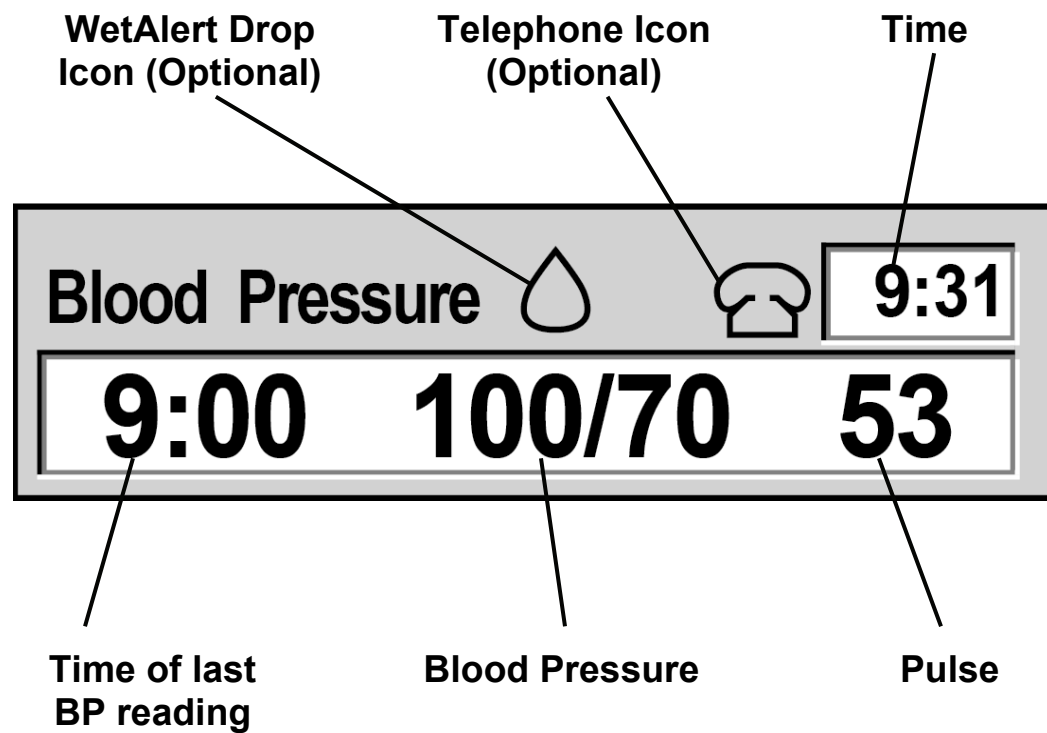
Red

Alarms need your immediate attention. During an alarm event, a steady beeping audible alarm sounds and the Status Box background changes to bright red. There are three types of alarm events:

- Blood – relating to the blood circuit
- Dialysate – relating to the dialysate path
- Other – all other types of alarms

For a description of alarm events and Status Box messages, see “Emergencies and Alarms” on page 194, and “Troubleshooting” on page 224.

The Dialogue Box



Dialogue Box

The Dialogue Box is located in the top right of the Touch Screen. It displays the following:

- The current time; to set the time, see page 77.



Note: Your 2008K@home hemodialysis machine uses a 24-hour clock to display the time. For example, '00:00' is midnight and '13:00' is one o'clock PM.

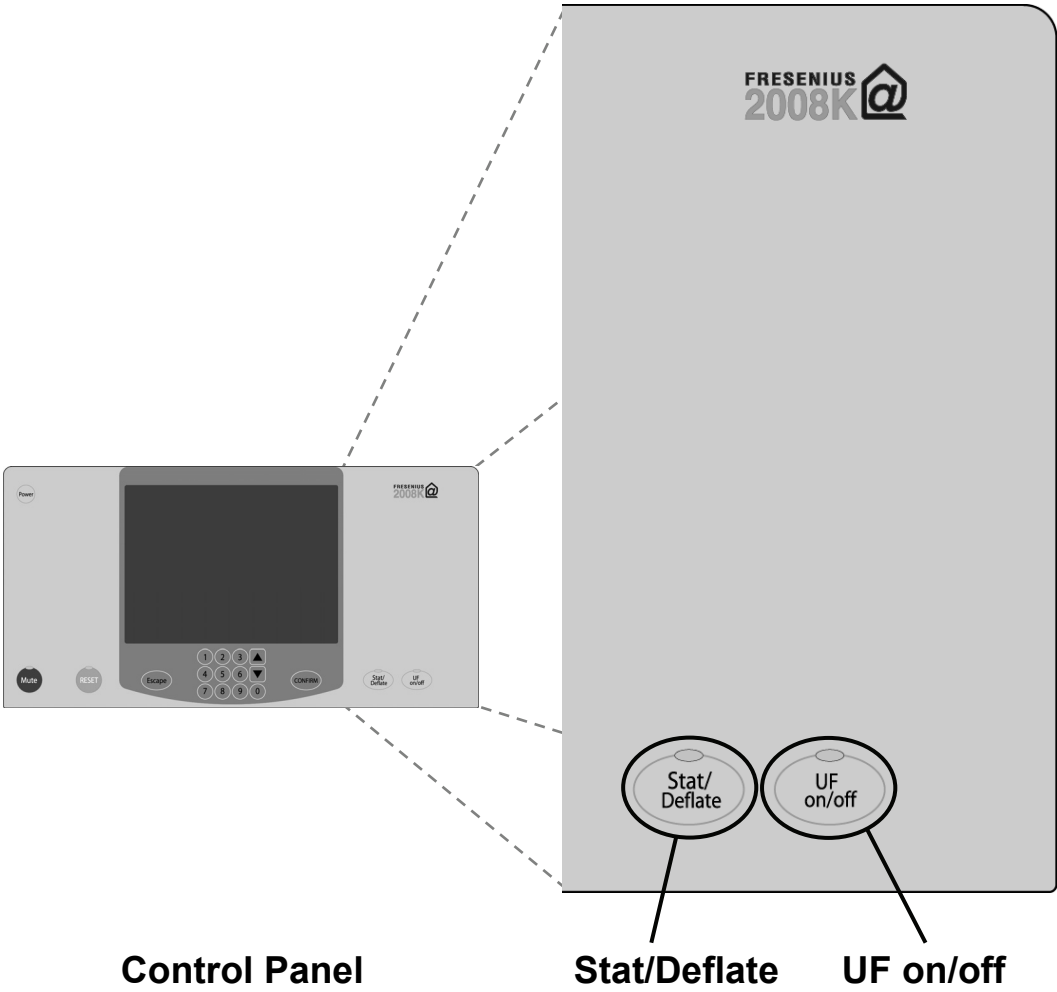
- Blood Pressure (only during treatment): Systolic/
Diastolic
- Pulse (only during treatment)
- Time of last Blood Pressure reading

The Dialogue Box can also instruct in an action or serve as a reminder, working with the Status Box (see page 30). If you try to enter a treatment parameter outside allowed limits, the Dialogue Box displays an advisory message.

The following symbol also appears in the Dialogue Box if set in Service Mode:

- WetAlert Drop Icon (Optional) – This symbol appears if your machine is equipped with the WetAlert wireless wetness detector. See the 2008K@home Home WetAlert Home User's Guide (P/N 507939) for more information.
- Telephone Icon (Optional) – contact your clinic for more information on remote monitoring

The Patient Section



Patient Section

The Patient section is located on the right side of the control panel. It directly relates to the patient. The Patient Section contains two keys:

Stat/Deflate Key

The **Stat/Deflate** key operates the blood pressure module.

- Press to start an immediate (stat) unscheduled blood pressure reading when the cuff is deflated
- Press again to instantly deflate an inflated blood pressure cuff



Caution: Do not squeeze the blood pressure cuff when deflating it. Squeezing the blood pressure cuff may damage your machine's internal blood pressure module.



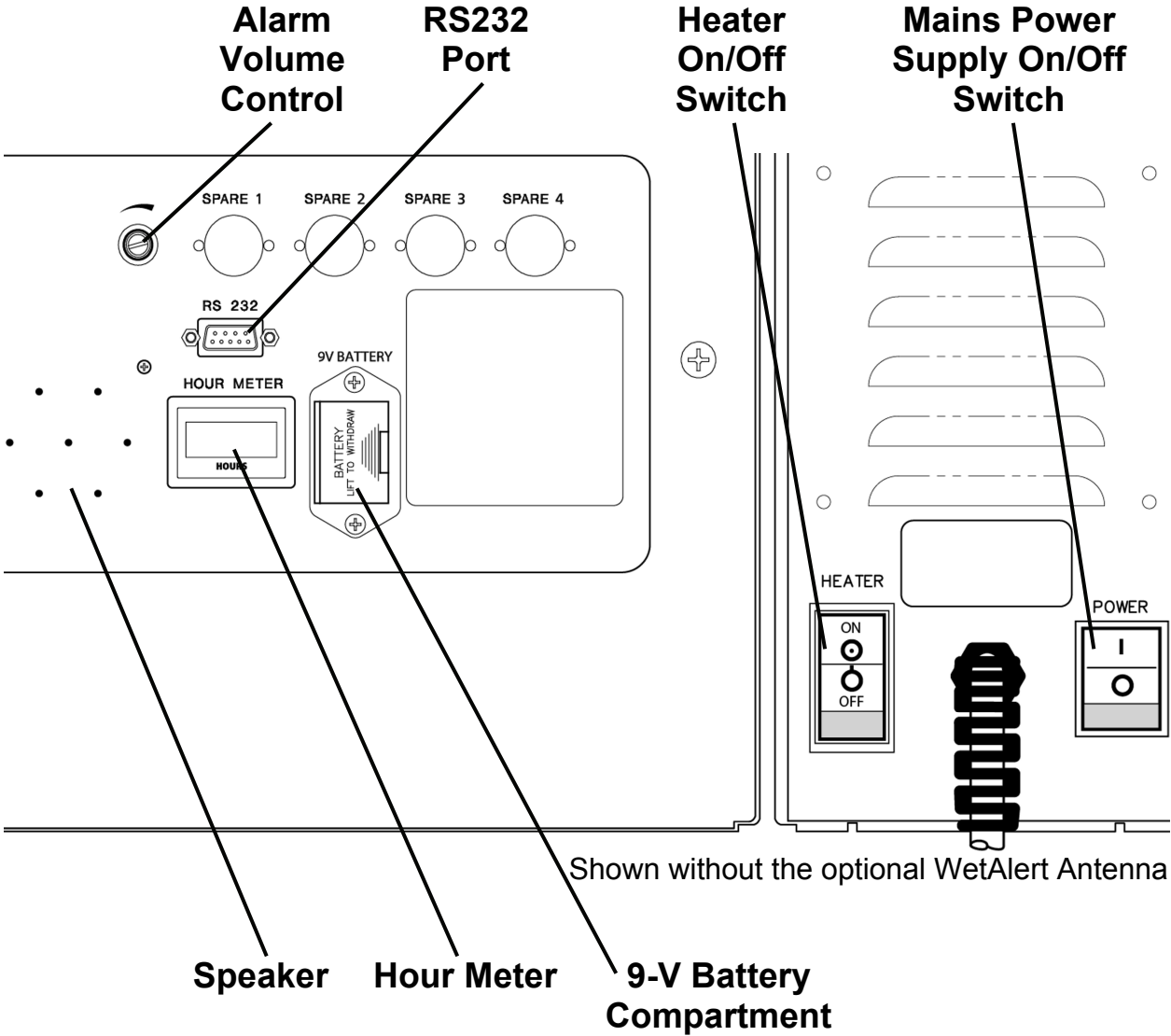
Note: Certain versions of the blood pressure module require a 30 second delay between blood pressure readings.

UF on/off Key

Ultrafiltration (UF) works to remove excess fluids from your body during treatment. During ultrafiltration the green light above the **UF on/off** key is lit. The light will flash when UF is interrupted.

- Press to stop the UF pump if it is on, or turn on the pump if it is off

The Back Panel



Back Panel

The back panel of your 2008K@home hemodialysis machine (at the top of the cabinet, in the back) contains more controls like alarm volume, switches and different connections.

Alarm Volume Control

- Turn the knob to the right to raise the volume
- Turn the knob to the left to lower the volume



Note: Warning tone volume ranges from 75 dBA to 89 dBA (at 1 meter). Alarm tone volume ranges from 67 dBA to 81 dBA (at 1 meter).

RS232 Port

Contact your clinic for more information on using this port.

Heater On/Off Switch

This switch turns the power to the dialysate heater on or off. This switch must be in the ON position during treatment.

Mains Power Supply On/Off Switch

This switch turns the power to the whole machine on or off. This switch must be in the ON position (|) to operate your machine.

Speaker

The speaker makes two different sounds: one is used for high priority alarms, and the other for lower priority warnings.

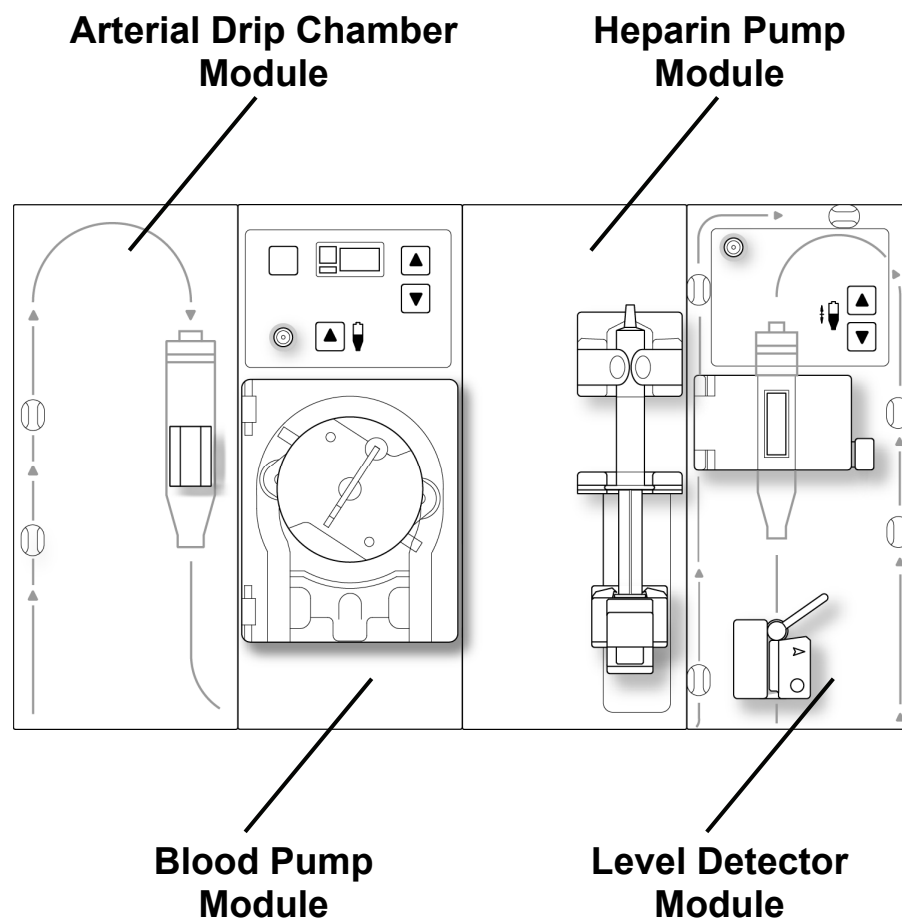
Hour Meter

The Hour Meter displays the number of hours your machine has run over its lifetime. Your clinic will periodically schedule maintenance.

9-V Battery Compartment

The 9-V heavy duty alkaline battery is used when the main power fails. A steady, audible alarm will immediately sound for seven minutes that you cannot silence with the **Mute** key. You can manually silence it by removing this 9-volt battery. See “Replacing the 9-Volt Battery” on page 312 for more information.

The Module Section



Note: This is the standard module setup. The 2008K@home software screens follow this setup in these instructions.

2008K@home Module Section

The specialized modules that move blood from your body to the dialyzer and back again are located just below the Control Panel. The red lines on the modules are guides for the arterial bloodline (from patient to the dialyzer). The blue lines are guides for the venous bloodline (from dialyzer to patient).

Your machine's design simplifies blood tubing paths. It also minimizes the chance of kinking bloodlines.

Standard Setup

The Module Section is usually made up of four different modules:

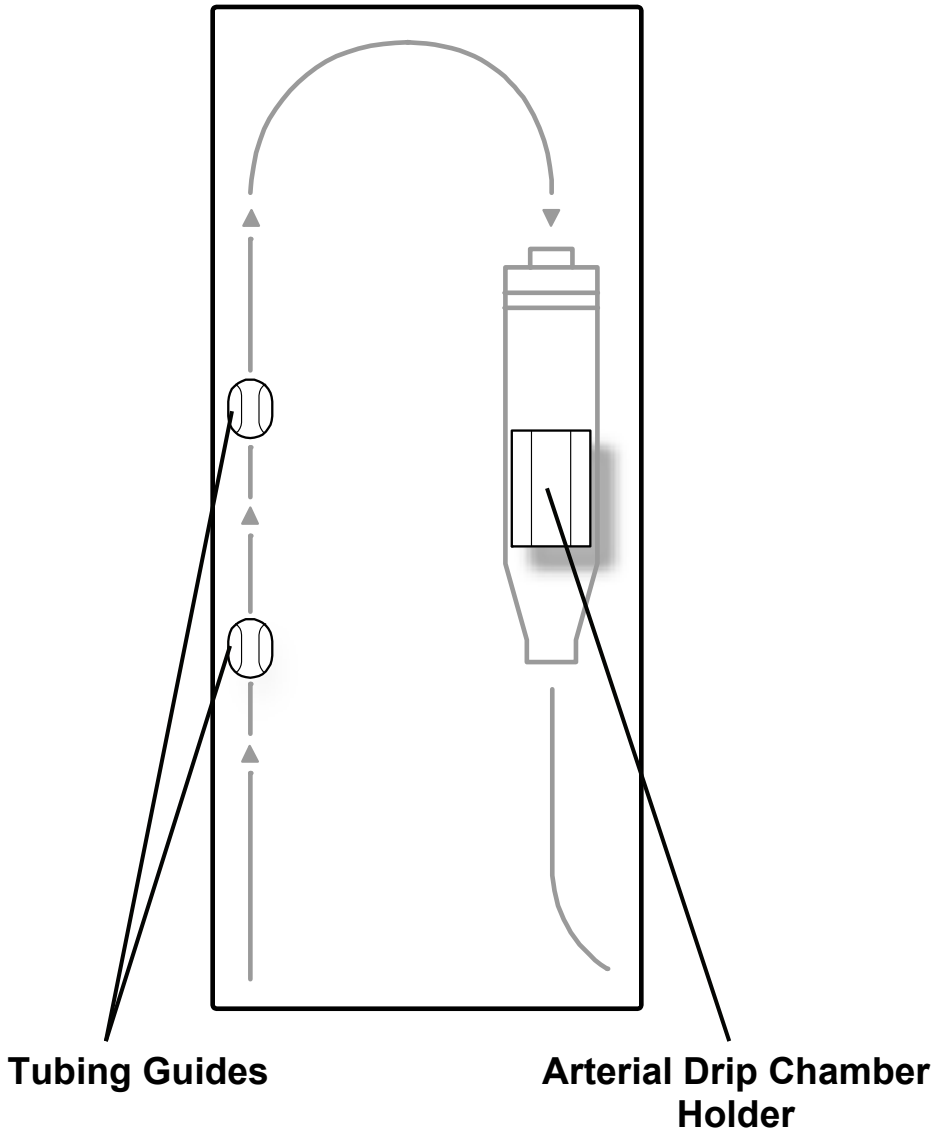
- Arterial Drip Chamber (see page 40)
- Blood Pump (see page 42)
- Heparin Pump (see page 44)
- Level Detector (see page 46)

and a Blood Pressure module inside your machine (see page 48). It is connected to the blood pressure cuff through blood pressure tubing.



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 damage to carpeting and other surfaces. To contain such spills, the machine should be on a spill-tolerant surface. Spills can cause slips and falls; clean up spills immediately.

The Arterial Drip Chamber Module



Drip Chamber Module

The drip chamber module is a panel with guides for blood tubing and a holder for the arterial drip chamber.

Tubing Guides

Press the bloodlines into the tubing guides to help keep blood tubing visible and free from kinks. The red guidelines are for arterial bloodlines. The blue guidelines (shown on the Level Detector Module, see page 46) are for venous bloodlines.

Arterial Drip Chamber Holder

The arterial drip chamber holder keeps the arterial drip chamber in place. Be sure to watch the drip chamber carefully—make sure that the level does not fall too low during treatment.

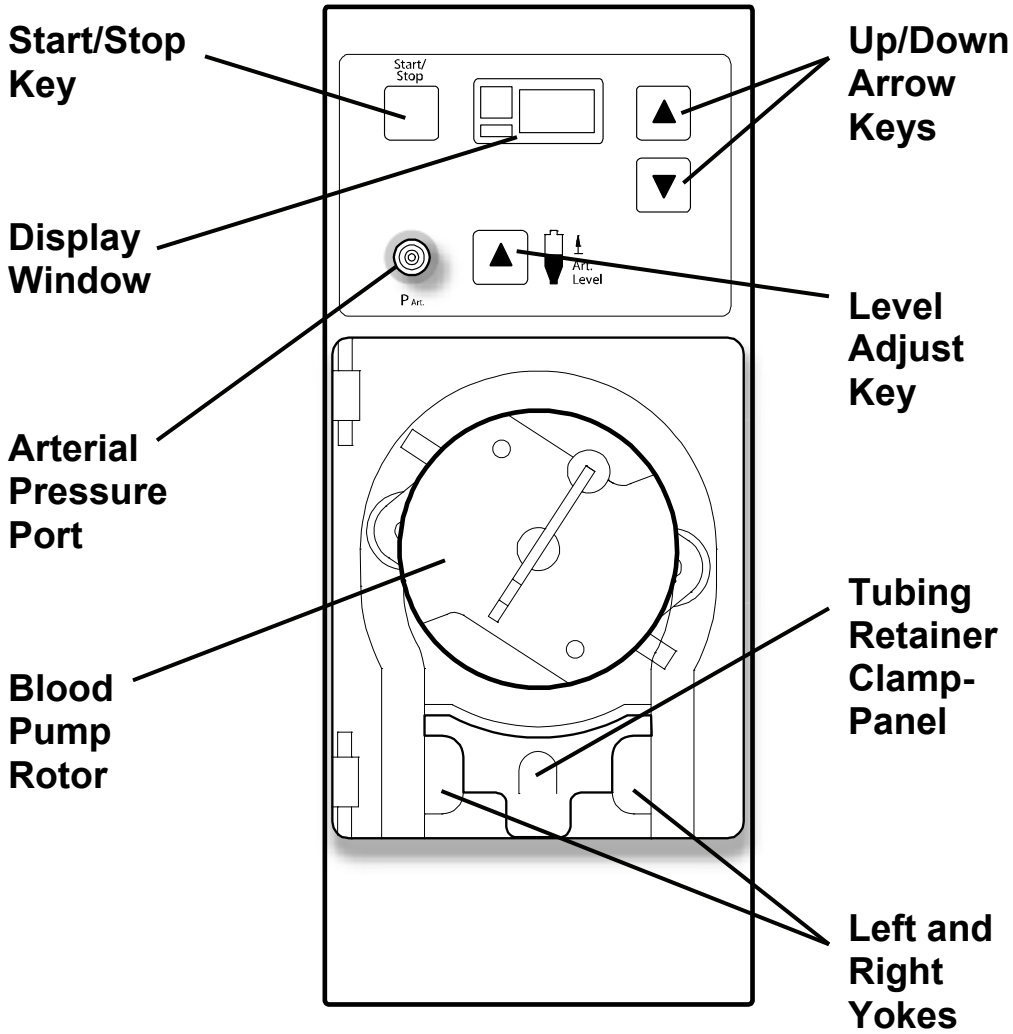


Note: The button used to raise the arterial drip chamber level is located on the Blood Pump module.



Caution: Do not raise the fluid level of the drip chamber so high that the transducer protector becomes wet. Wet transducer protectors must be replaced, as they will cause inaccurate readings and possibly serious injury or death. See “Clearing the Pressure Monitor Line” on page 208.

The Blood Pump Module



Blood Pump Module

The Blood Pump module pumps blood from your body to the dialyzer and back again.

Start/Stop Key

To start the blood pump, press the **Start/Stop** key. Press the **Start/Stop** key again (or open the pump door) to stop the blood pump during operation.

Display Window

The Display Window shows the pump speed in 5 ml/min increments during blood pump operation. When the blood pump door covering the rotor is open, the diameter of the pump segment is shown. The left side of the Display Window features a green light, lit when the pump is running, and a red light for alarms.

Arterial Pressure Port

The Arterial Pressure Port houses a pressure transducer that monitors arterial tubing pressure. This is the arterial pressure displayed on the “Home” screen during treatment.

Blood Pump Rotor

The Blood Pump Rotor turns to move your blood along the tubing. In an emergency the rotor can be turned with a separate hand crank (on the back of your machine) to manually return the blood, see page 212.

Up/Down Arrow Keys

The **Blood Pump Up/Down Arrow (▼/▲)** keys increase or decrease blood pump rotor speed. The Display Window shows the pump speed.

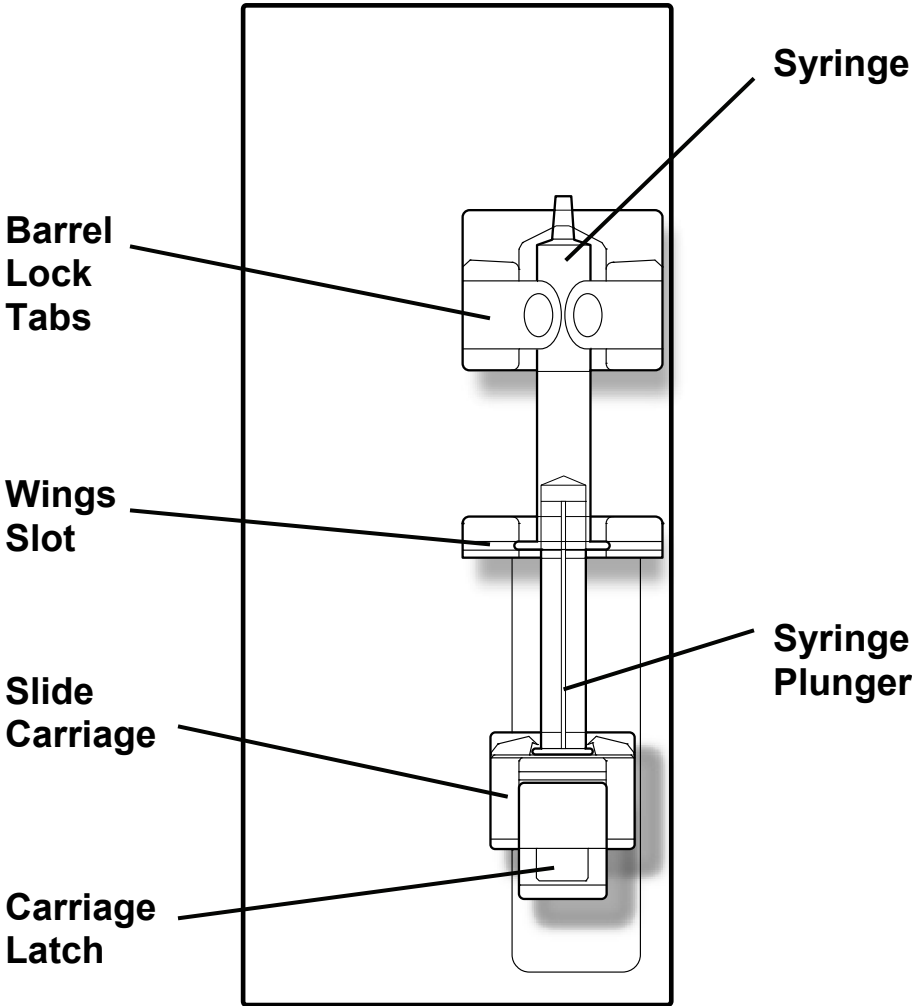
Level Adjust Key

The **Level Adjust (▲)** key can be used only to raise the arterial drip chamber fluid level. To lower the level, see “Clearing the Pressure Monitor Line” on page 208.

Tubing Retainer Clamp-Panel and Yokes

The clamp-panel presses the blood pump segment against the left and right yokes, holding the tubing in place.

The Heparin Pump Module



Heparin Pump Module

The Heparin Pump module pushes (infuses) heparin from a syringe into your blood circuit to slow the blood clotting process. If you enter the rate and stop-time of the infusion in the “Rx Parameter” screen, your 2008K@home hemodialysis machine will automatically add heparin at the set time during treatment.

Syringe and Syringe Plunger

Your 2008K@home hemodialysis machine can fit 10, 12, or 20 ml syringes.

Barrel Lock Tabs and Wings Slot

When the syringe barrel is pressed against the barrel lock tabs, they snap around the syringe to hold it in place. The wings slot supports the base of the syringe barrel.

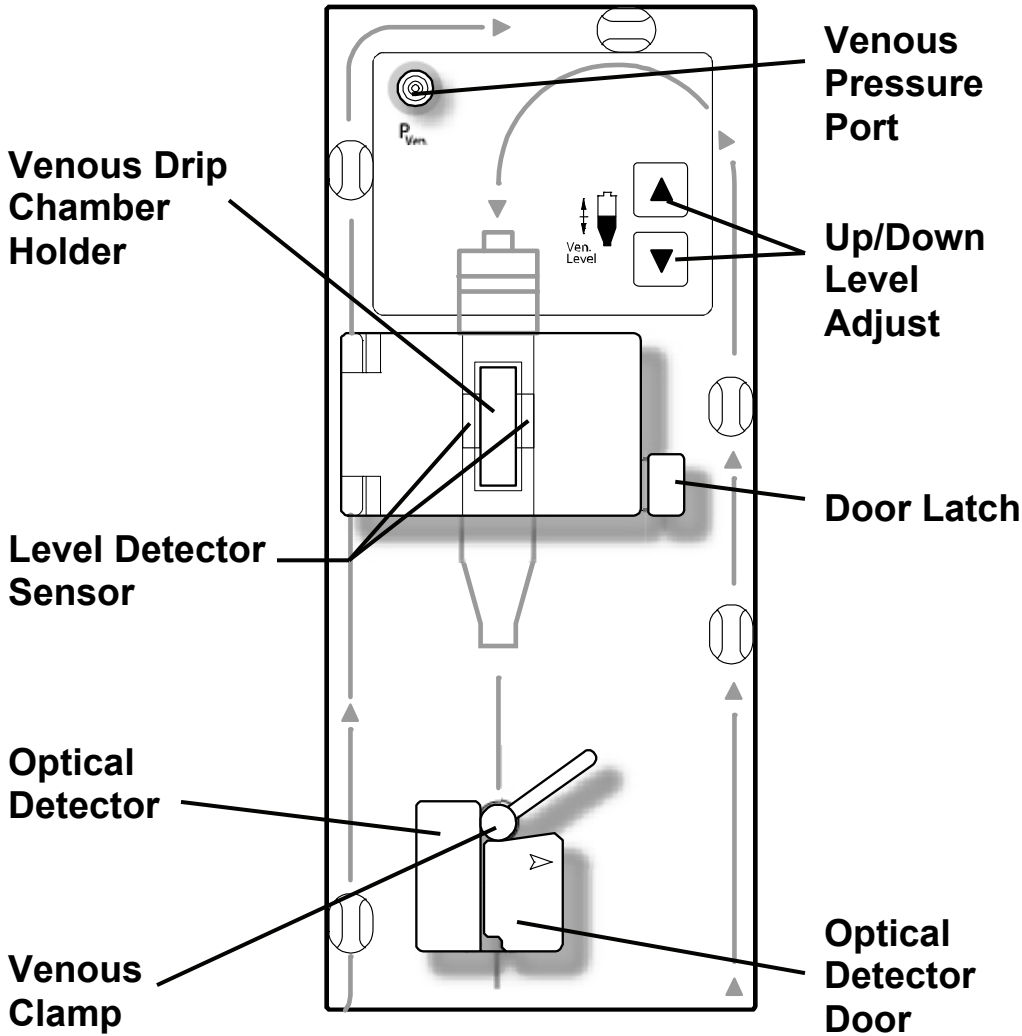
Slide Carriage and the Carriage Latch

The slide carriage holds and pushes up the end of the syringe plunger. Squeezing the carriage latch allows you to manually move the slide carriage and load a syringe.



Note: The heparin pump can be used to infuse heparin manually (by squeezing the carriage latch button while pushing up on the slide carriage), but it is not recommended, as your machine will not register the infusion.

The Level Detector Module



Level Detector Module

The Level Detector module monitors your venous line.

Venous Drip Chamber Holder

The venous drip chamber holder keeps the venous drip chamber in line with the Level Detector Sensor.

Level Detector Sensor

The Level Detector Sensor monitors the blood level in the venous drip chamber. A latching door covers the sensors.

Optical Detector

The optical detector recognizes the difference between blood and saline in the bloodline.

Venous Clamp

The Venous Clamp automatically clamps the venous line during blood alarms or if the venous drip chamber level is too low. Make certain that the Venous Clamp is able to fully close the blood tubing used for treatment.

Venous Pressure Port

The pressure port in the upper left corner houses a pressure transducer that monitors venous tubing pressure. This is the venous pressure displayed on the “Home” screen during treatment.

Up/Down Level Adjust Keys

The **Up/Down (▼/▲) Level Adjust** keys are used to increase or decrease the level of fluid in the venous drip chamber.

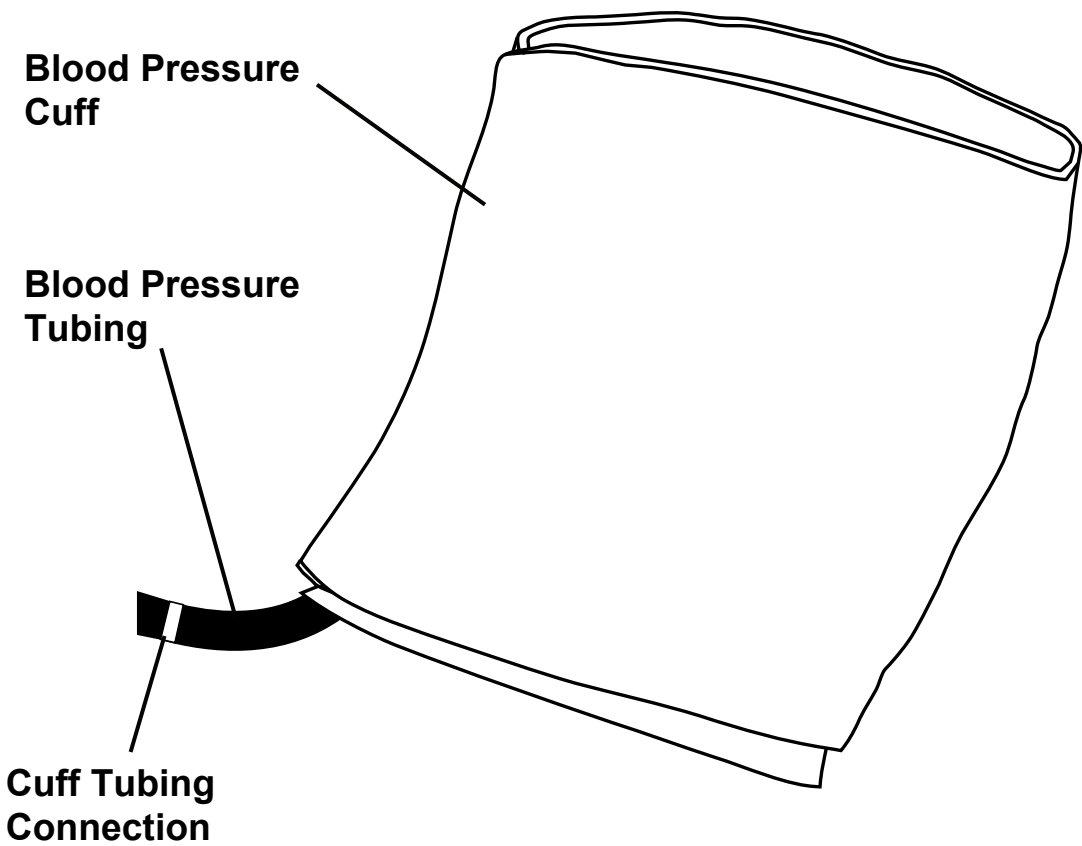


Caution: Do not raise the fluid level of the drip chamber so high that the pressure monitor line and transducer protectors become wet. Wet monitor lines must be cleared and wet transducer protectors must be replaced, as they will cause inaccurate readings and possibly serious injury or death.

Optical Detector Door

The Optical Detector door holds the venous line in place. The door rotates clockwise to open.

The Blood Pressure Module



Blood Pressure Module

The Blood Pressure module is located inside your machine with the pressure tubing running from the back of your machine to the cuff. The module can automatically measure your blood pressure at set times and record the systolic, diastolic, Mean Arterial Pressure (MAP), and pulse values on the “Treatment History” screen. During treatment, both your blood pressure and the last time it was measured are shown in the Dialogue Box (see page 32).

Blood Pressure Cuff

The pressure cuff comes in a variety of sizes to fit small through large adult patients. The adult size comes standard with your 2008K@home hemodialysis machine. It can fit patients with upper arm circumferences of 25 to 35 centimeters (9.8 to 13.8 inches). An optional thigh cuff is also available.

Blood Pressure Tubing

The blood pressure tubing connects the cuff to the Blood Pressure module. Make sure that the line does not kink.

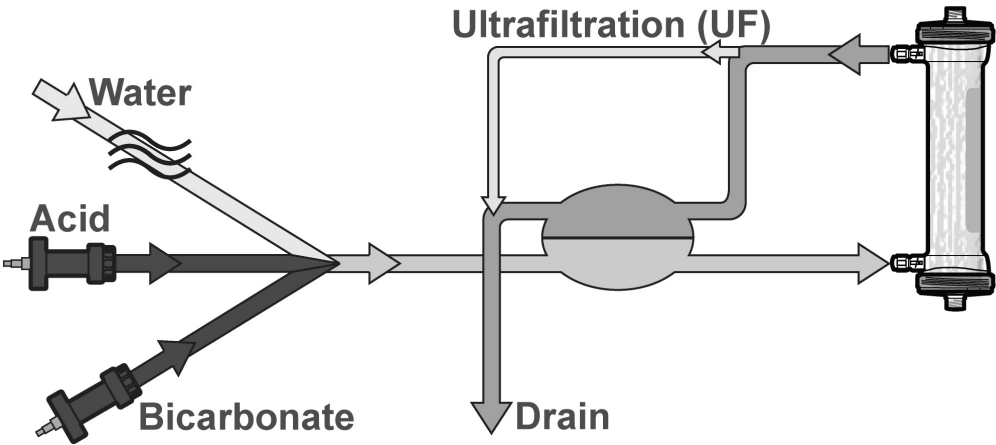
Cuff Tubing Connection

The tubing connection joins the blood pressure cuff to the blood pressure tubing. Pulling on the blood pressure tubing separates the line.

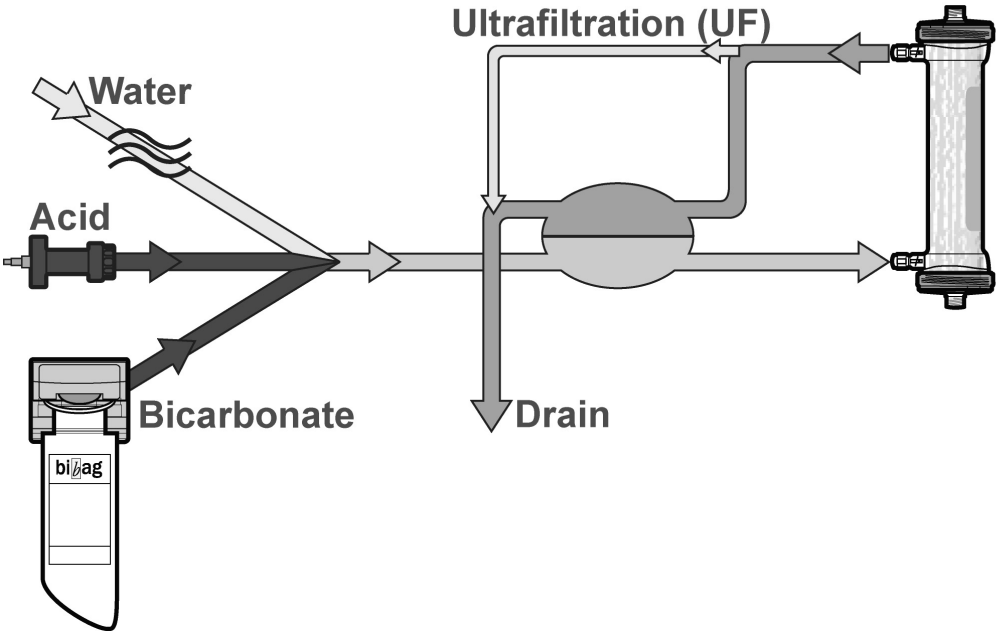


Warning: See “Blood Pressure Module Contraindications,” page 6, if you have any of the following conditions: peripheral circulation problems, severe arrhythmia, ectopic beats, convulsions, spasms, tremors, or tachycardia.

The Dialysate Path



Shown with liquid acid and bicarbonate concentrates



Shown with the optional bibag system

Dialysate Path

The dialysate for your hemodialysis treatment is a solution used to clear waste from your blood. It is made of water, bicarbonate, sodium, potassium, calcium, magnesium, chloride, acetate and dextrose. Your doctor prescribes dialysate to meet your needs.

Your 2008K@home hemodialysis machine is a three-stream dialysate delivery machine. This means it mixes your dialysate from three different sources and sends it to your dialyzer for your treatment. The three main parts of the dialysate are: purified (RO) water, acid concentrate, and bicarbonate concentrate.

After your machine heats and degasses the water, it mixes in the concentrates to form dialysate. Your machine then filters the dialysate with the Diasafe Plus filter (see page 308).

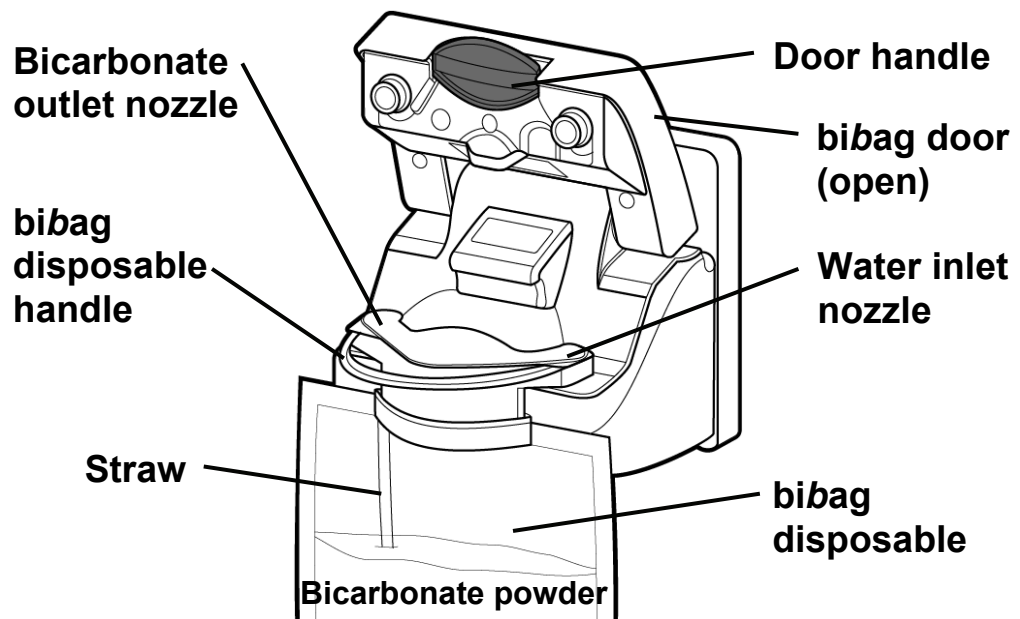
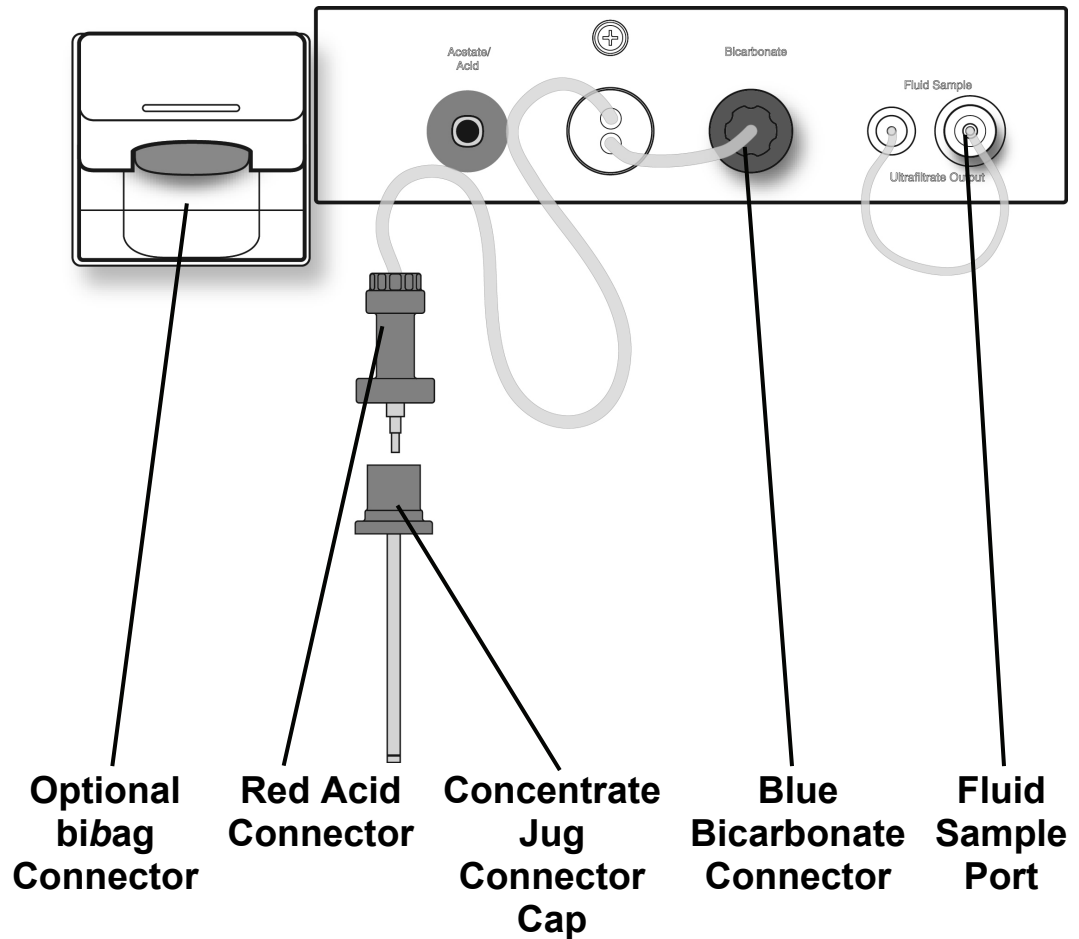
The dialysate then pumps through dialysate lines to the ports on the side of the dialyzer. Meanwhile, your blood pumps through the bloodlines connected at each end of the dialyzer. The blood and dialysate meet in the dialyzer but never touch. The dialysate pulls waste from your bloodstream and then washes it out the drain.

The Balancing Chamber makes sure that the incoming flow of the dialysate is equal to the volume of the outgoing flow to control ultrafiltration from your body. Ultrafiltration (UF) is the process of removing excess fluid during your treatment. The fluid that is removed is called UF Removed and the value is displayed on your machine's "Home" screen.

Dialysate Path With Optional *bibag* connector

The *bibag* connector is part of the *bibag* system. It is a hardware option that allows you to use a dry bicarbonate powder to make dialysate solution for your 2008K@home hemodialysis machine. The bicarbonate powder is contained in a bag called the *bibag* disposable which connects to your machine's dialysate path through the *bibag* connector. Your machine adds purified (RO) water to the bag and pumps out the liquid bicarbonate concentrate to mix with the acid concentrate and more RO water.

Concentrate Connections



Optional *bibag* connector

The *bibag* connector connects the *bibag* disposable to your machine's dialysate path.

***bibag* Door**

The *bibag* door covers the nozzles of the *bibag* connector. When the door is closed with no bag on the *bibag* connector, the nozzles form a loop in the dialysate path so your machine can rinse and disinfect the *bibag* connector. Pressing down on the *bibag* door locks the door in place. Lifting up on the door handle will open the *bibag* door.

Bicarbonate Outlet Nozzle

Your machine pumps the liquid bicarbonate out of the *bibag* disposable through this opening.

Water Inlet Nozzle

Your machine adds purified water to the bicarbonate powder in the *bibag* disposable through this opening.

***bibag* Disposable**

The *bibag* disposable is a bag filled with dry bicarbonate powder. At the top of the bag are special inlet and outlet ports. These ports match up with the nozzles on your machine's *bibag* connector.

The Bicarbonate Outlet Nozzle connects to a straw inside the bag to reach the bottom of the bag.

The handle on the bag allows you to easily lift the *bibag* disposable off the *bibag* connector when you are ready to remove it.

Red acid and blue bicarbonate connectors

The concentrate connectors draw in acid and bicarbonate concentrates from the supply jugs. The concentrate connectors pull out and snap into jugs of acid and bicarbonate concentrates. When connecting, make certain to correctly match red to acid and blue to bicarbonate concentrates.

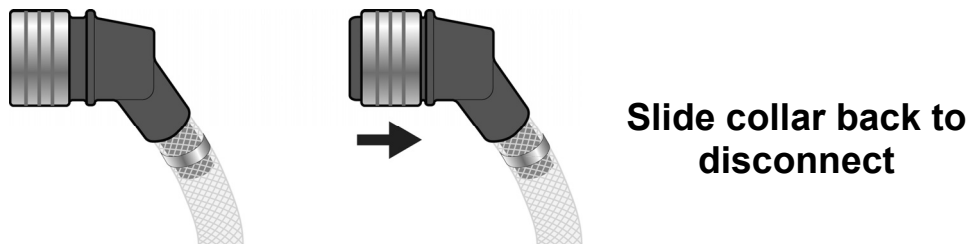
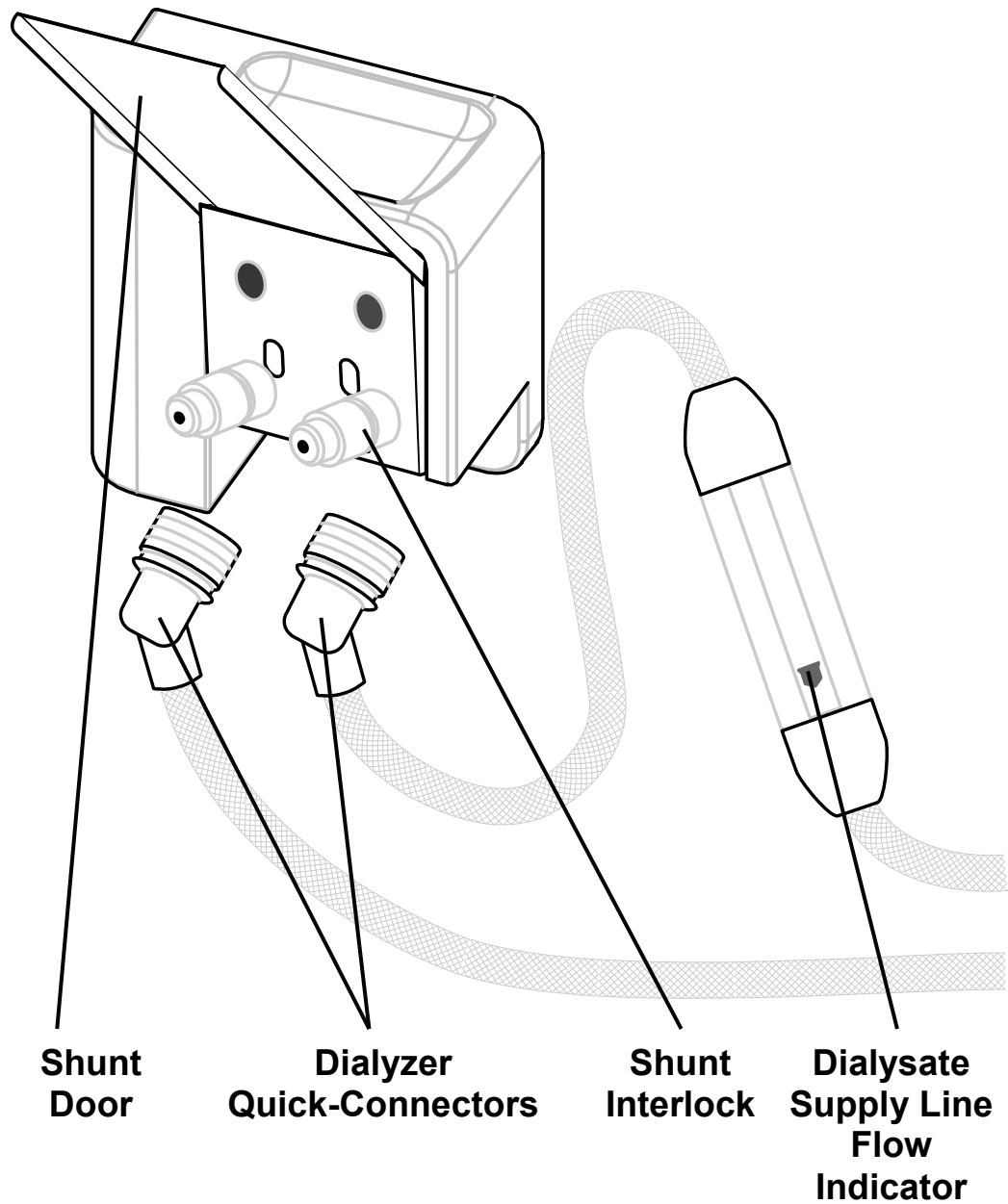
Concentrate Jug Connector Cap

The connector cap snaps onto the top of concentrate jugs. The Acid and Bicarbonate connectors snap into the cap so your machine can pull concentrate from the jugs.



Note: The Fluid Sample Port is also located in this section. It allows the UF pump to be tested. If necessary, ask your clinic for more information.

Dialyzer Connections



Dialysate Path Dialyzer Connections

Your 2008K@home hemodialysis machine's dialysate path leads out of the machine cabinet at the shunt interlock and connects to the dialyzer through the dialyzer lines.

Shunt Interlock and shunt door

The shunt interlock is located on the right side of your machine. It links the dialysate lines when they are snapped onto it.

Lifting the shunt door during dialysis will cause the dialysate to run through your machine only and not the dialyzer. This is called "Bypass Mode." The flow indicator will be still. Your blood will continue to pass through the dialyzer as long as the blood pump is on, but dialysis will not be occurring because the dialysate is not flowing.

Dialyzer Supply Line

The Dialyzer Supply Line has a blue quick-connector. It snaps onto the dialyzer during dialysis or the shunt interlock during rinse programs. When connecting, make sure to correctly match blue to blue.

The dialyzer supply line also features a dialysate flow indicator tube. A moving float in the tube allows you to see when dialysate is running through the lines and the dialyzer.

Dialyzer Return Line

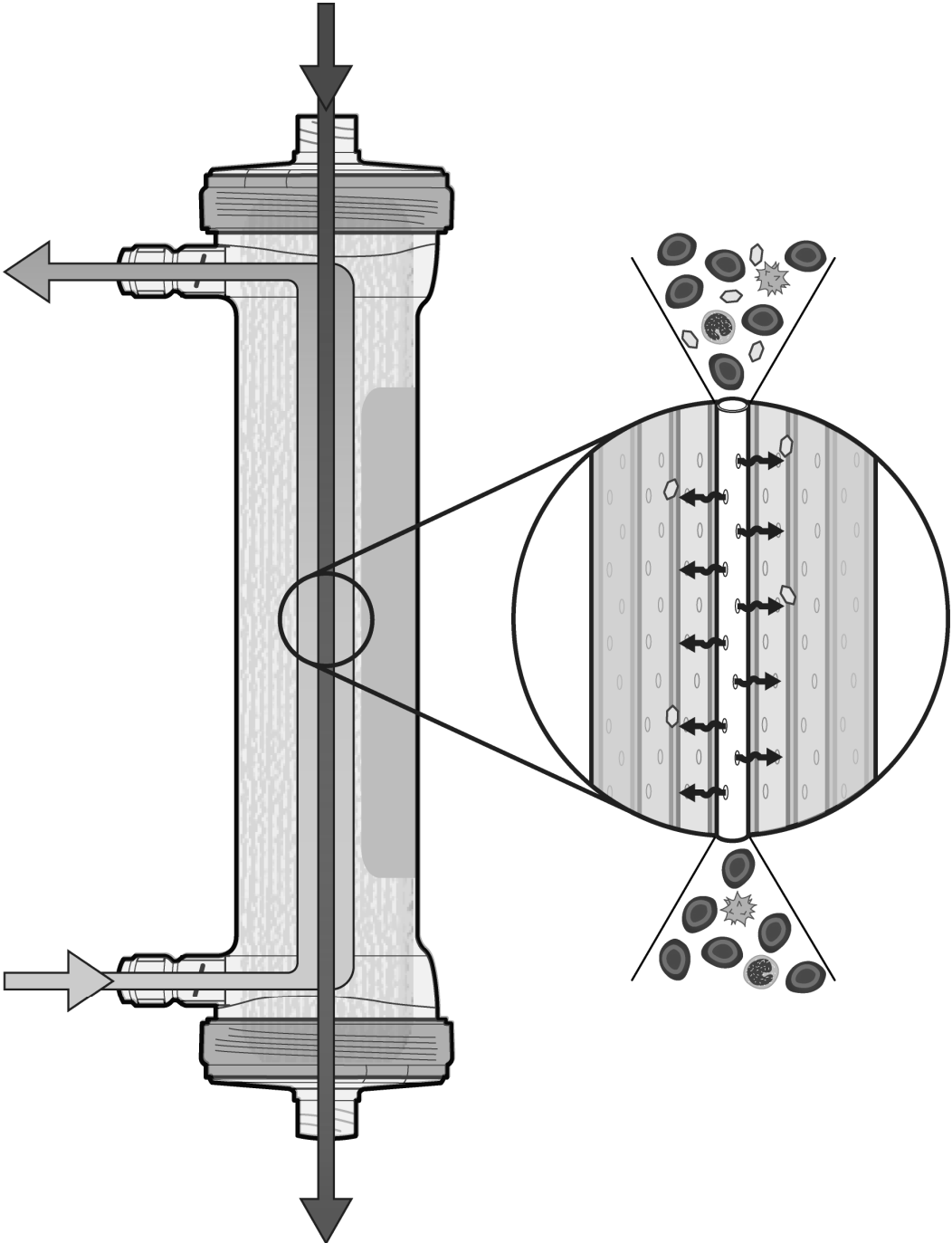
The Dialyzer Return Line has a red quick-connector. It snaps onto the dialyzer during dialysis or the shunt interlock during rinse programs. When connecting, make sure to correctly match red to red.

Quick-Connectors

Push quick-connectors onto the shunt interlock and the dialyzer ports to snap them in place. After making a connection, pull on the connector to make sure it fits tightly.

When disconnecting: slide the metal collar back on the quick-connector to release the connection.

The Dialyzer



The Dialyzer

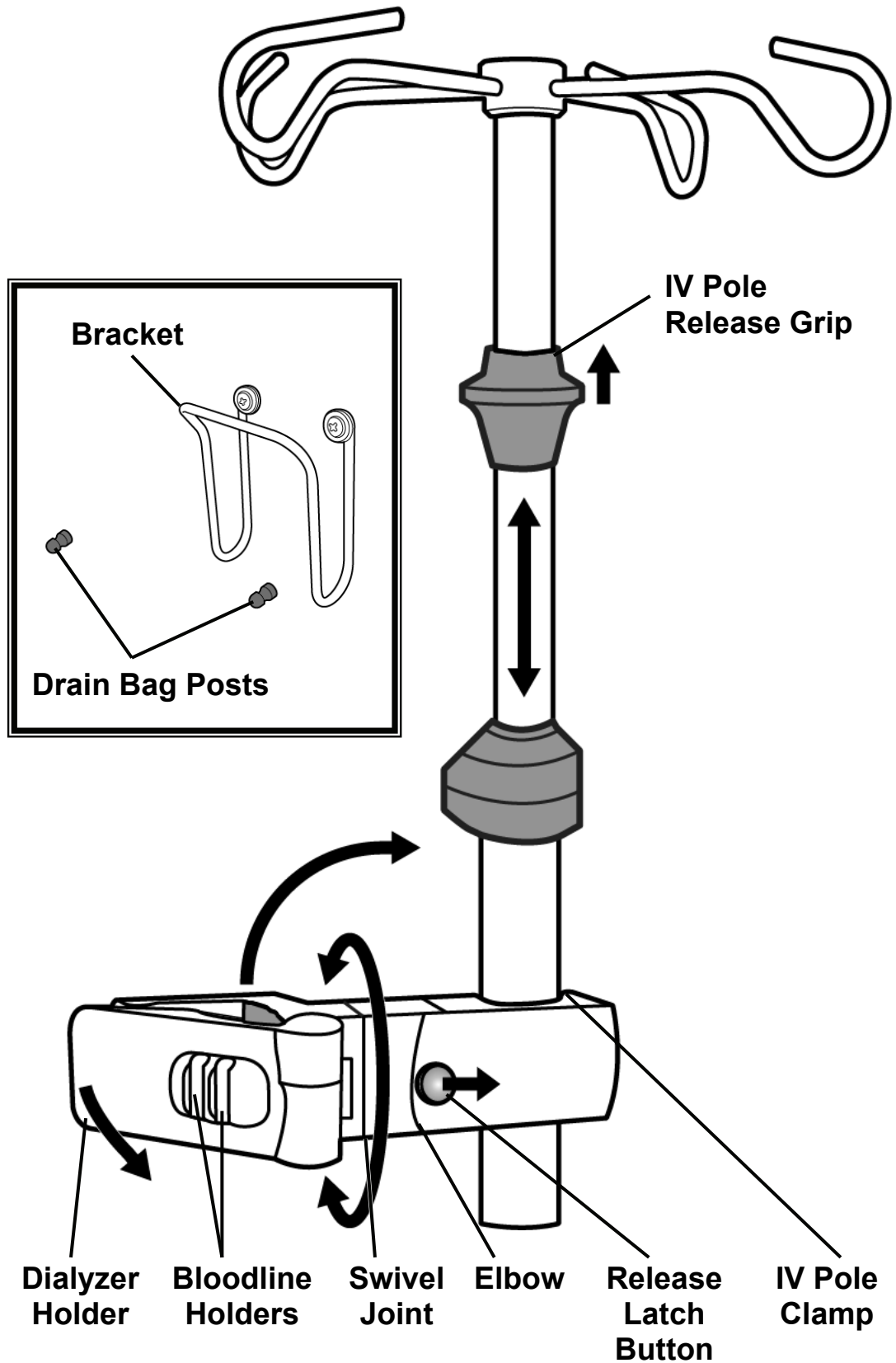
The dialyzer, or ‘artificial kidney,’ is a tube filled with thousands of tiny, synthetic straws. The hollow straws act as a semi-permeable membrane (or filter) because they are full of tiny holes that are too small for blood cells to pass through.

The dialyzer tube chamber is sealed at both ends with the tips of the straws open to allow blood to flow down through the dialyzer’s straws.

The dialysate enters the tube through the dialyzer supply port on the side of the dialyzer (near the bottom of the dialyzer). It flows upward through the dialyzer tube, around the straws. The dialysate flows in the opposite direction from the downward blood flow. This is called ‘counter-current’ flow.

Inside the dialyzer, the dialysate pulls water and the smaller waste particles in your bloodstream through the semi-permeable membrane as your blood flows by. At the same time, electrolytes and minerals from the dialysate enter your bloodstream. This is called diffusion. Your blood continues moving through the dialyzer and is returned to your body. The waste is carried away in the used dialysate, out the dialyzer return port, and run down the drain.

Fixtures



IV Pole

The IV pole is on the right side of your 2008K@home hemodialysis machine. This pole has hooks at the top that are used to hold the saline bag for your treatment. Your Home Therapies Nurse will explain what else you may need to hang from the IV pole.

Near the top of the pole is a black release grip. You can use this grip to adjust the height of your IV pole. Lift up on the grip to slide the top of the IV pole up or down. Let go of the grip to lock the IV pole at its new height.

Dialyzer Holder

The dialyzer holder keeps the dialyzer in place during your treatment. The end of the dialyzer holder swings shut to clamp around a dialyzer. It rotates at the swivel joint on an arm. This is so you can easily flip the dialyzer in the holder during treatment setup and end procedures.

The opposite end of the arm clamps on the IV pole when the arm is straight. To move the arm up or down along the IV pole: slide the Release Latch Button toward the IV pole and bend the arm upward at the elbow. The arm's IV pole clamp will loosen and then the arm can move freely. To clamp the arm on the IV pole, straighten the arm at the elbow again.

The dialyzer holder also has bloodline holders like the tubing guides on your machine's modules. Press the bloodlines into these holders to help keep them visible and free from kinks.

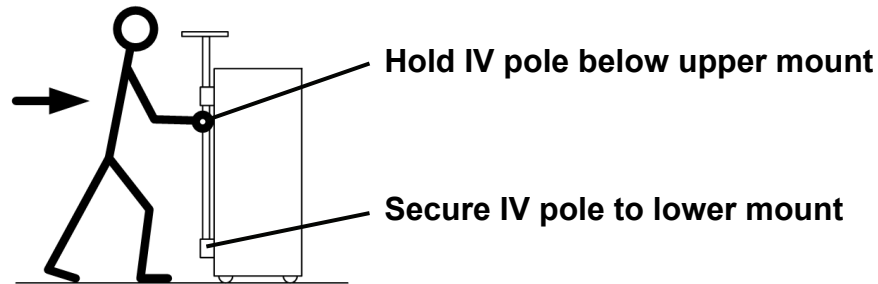
Bracket

The Bracket is on the left side of your machine. You can use it to hang up your bloodlines during setup and treatment.

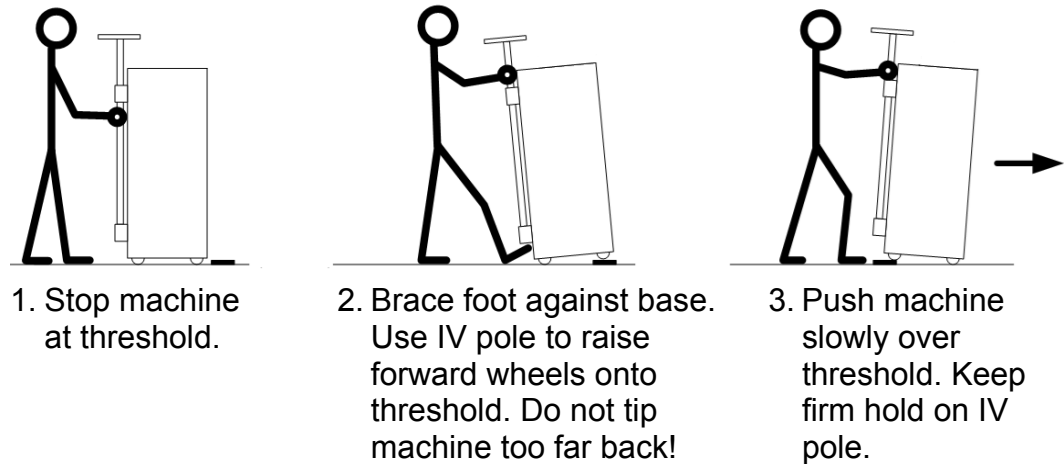
Drain Bag Posts

The Drain Bag Posts are on the left side of your machine below the Bracket. The Drain Bag hangs on these posts during treatment setup.

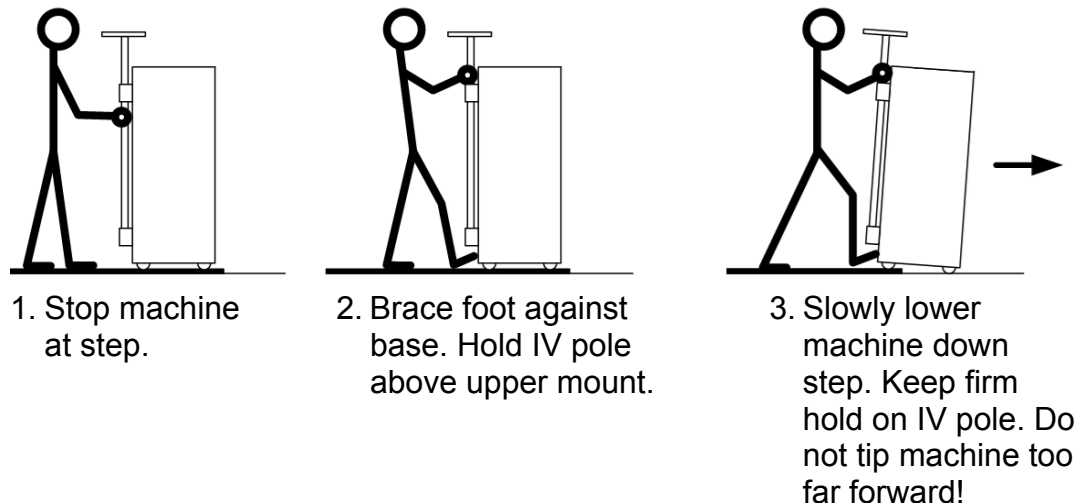
Moving Your Machine



Moving over a $\frac{3}{4}$ inch threshold



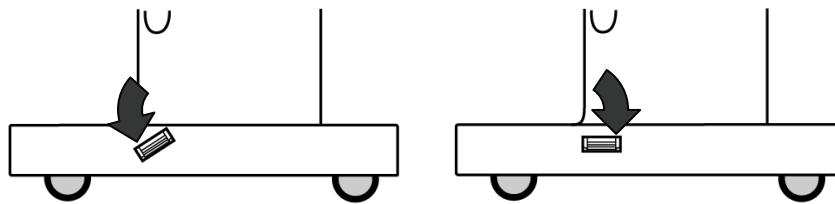
Moving down a $1\frac{1}{2}$ inch step



Moving Your Machine

Your 2008K@home hemodialysis machine has wheels on the bottom to make it easy to move. Before moving your machine, you must make sure the IV pole is secured in its lower mount.

You may need to release the wheel lock before your machine will roll. The wheel lock is on the right side of your 2008K@home hemodialysis machine at the base. To unlock the wheels, press down on the front end of the foot pedal.



Unlocked Wheels

Locked Wheels

Hold the IV pole below its upper mount as a handle to keep control of your machine. Push your machine from the middle when moving it. Be careful when moving your machine.



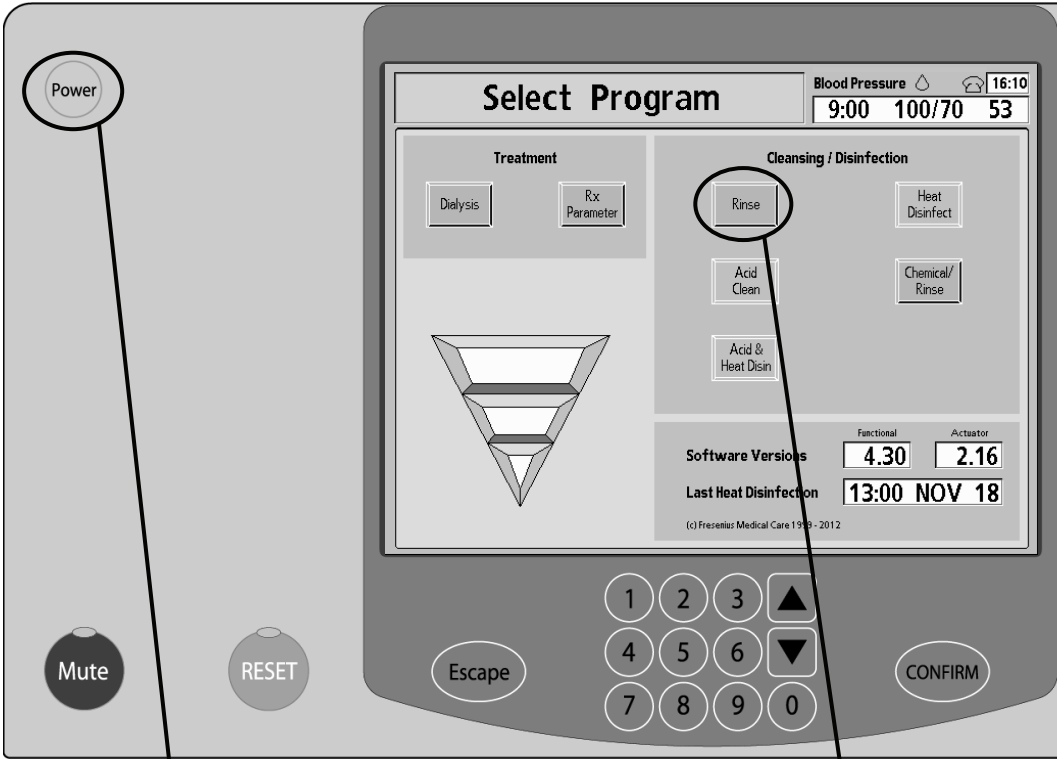
Warning: Tip Hazard. Do not push or lean against machine when the wheel lock is set.



Warning: Be careful not to tip your machine when rolling it over uneven surfaces. Push your machine from the middle when moving it.

To lock the wheels again, push down on the back end of the foot pedal.

Chapter 3: Setting Your Treatment Parameters



Press Power

Rinse if required

Press **Power** (see Your K Map: 'A')

To turn on your 2008K@home hemodialysis machine, press the **Power** key, located in the Machine section of the Control Panel. Your machine will power up and, after about a minute, the “Select Program” screen will appear on the Touch Screen.

Touch **Rinse** if required

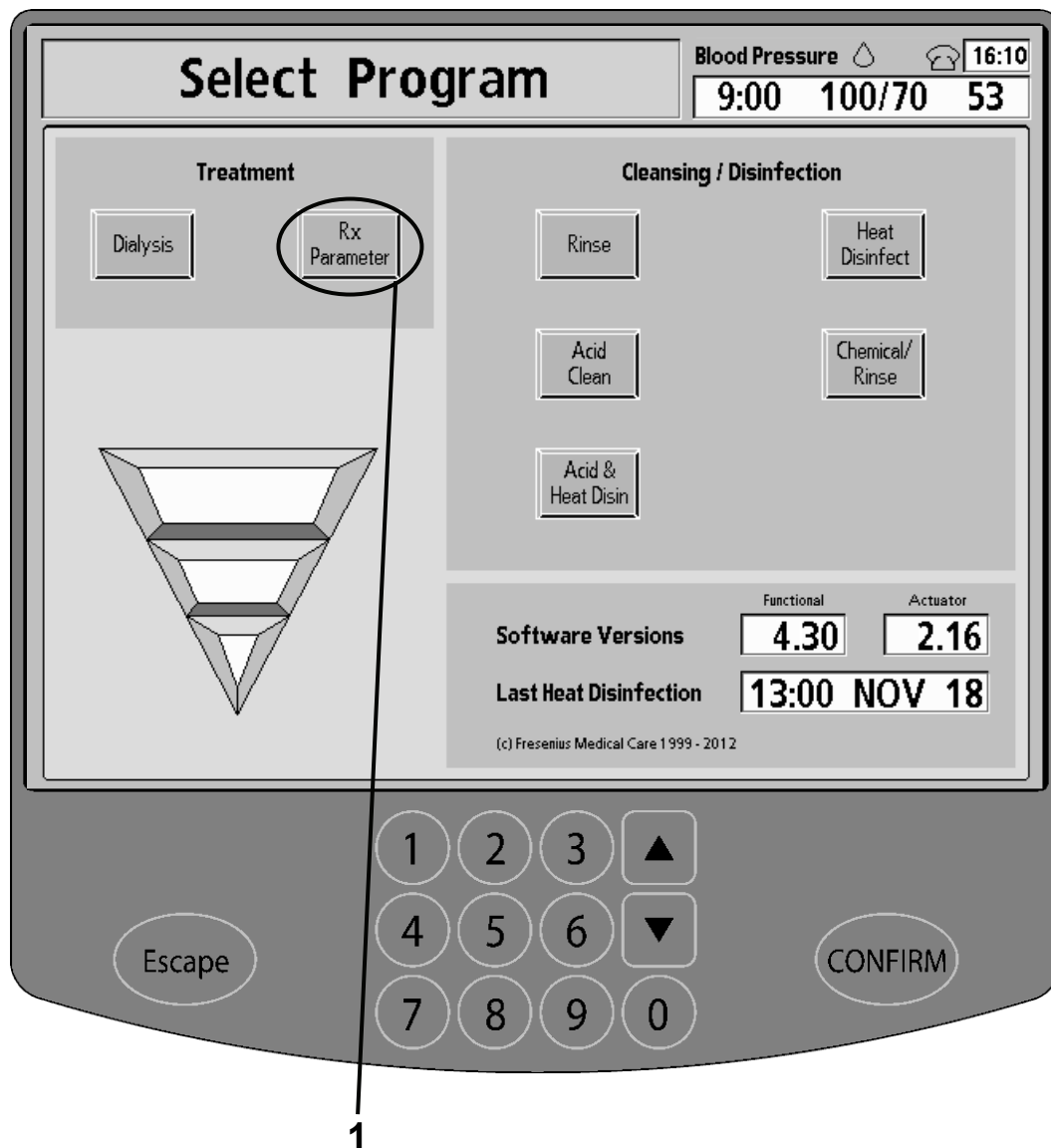


Note: You must complete a rinse cycle on your machine before using it for your treatment if either of the following occurs:

- Your machine is filled with disinfectant
- “Chemical/Rinse” and/or “Rinse” are the only cleaning/disinfection options available on the “Select Program” screen

Select the **Rinse** screen-button to start the rinse cycle (see the “Rinse” section on page 156). When the rinse is finished, you must test your machine for any remaining disinfectant.

Entering Your Prescription



Entering your prescription

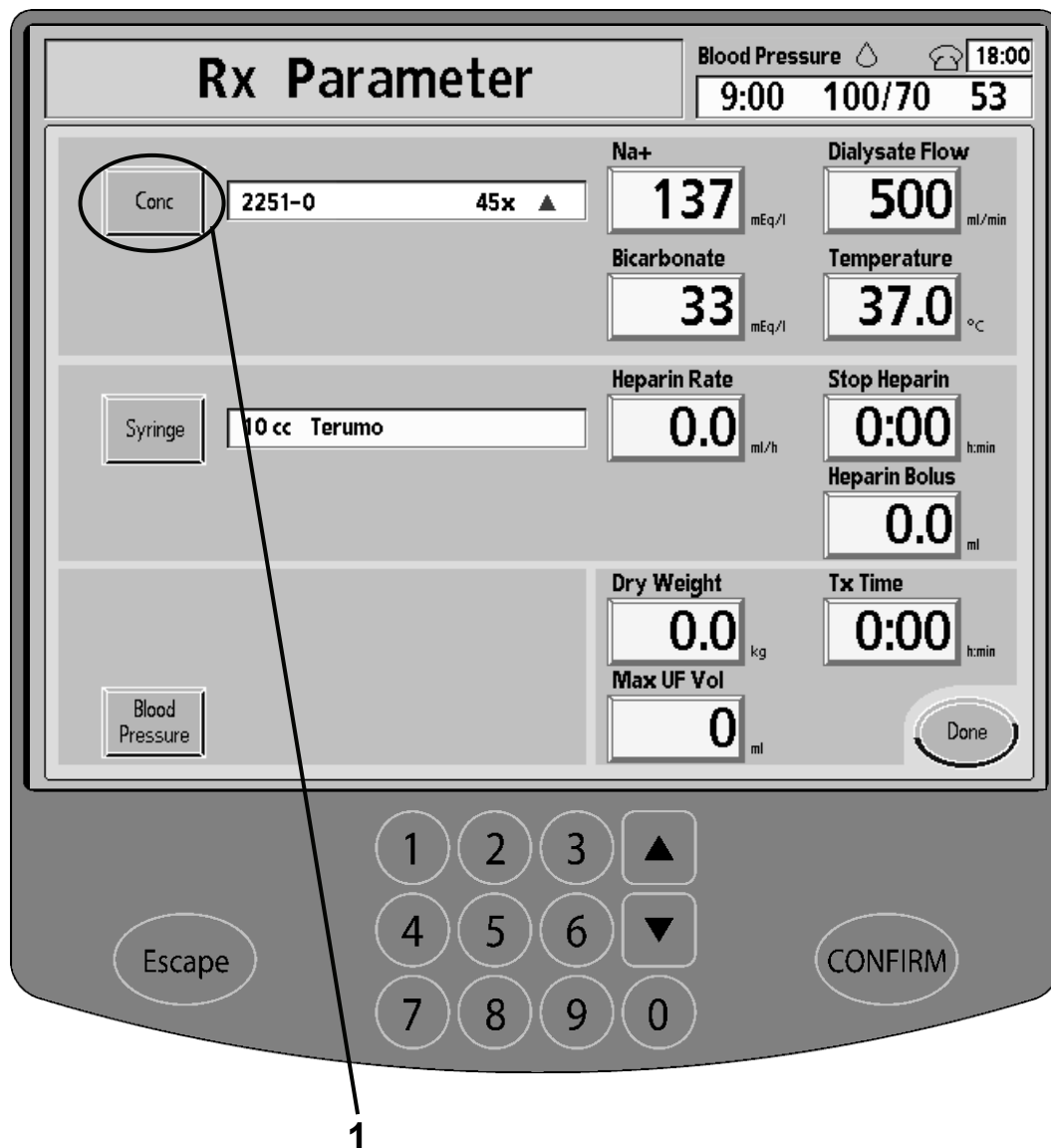
Before you start your first treatment, you will need to enter the treatment parameters that your doctor has prescribed. You will only need to do this once (unless your doctor changes your prescription). These values are then automatically set in Dialysis Mode where you run your treatment. You do not have to re-enter these values there.

The numbered items in the picture on the left match the numbered steps listed on this page. Do each step in order and pay close attention to Note, Caution, and Warning statements.

1 Select **Rx Parameter**

Touch the **Rx Parameter** screen-button to go to the “Rx Parameter” screen.

Selecting Your Concentrate



Warning: The values shown here are for example only. You must use the values prescribed by your doctor. If you use the wrong values, it may cause serious injury or death.

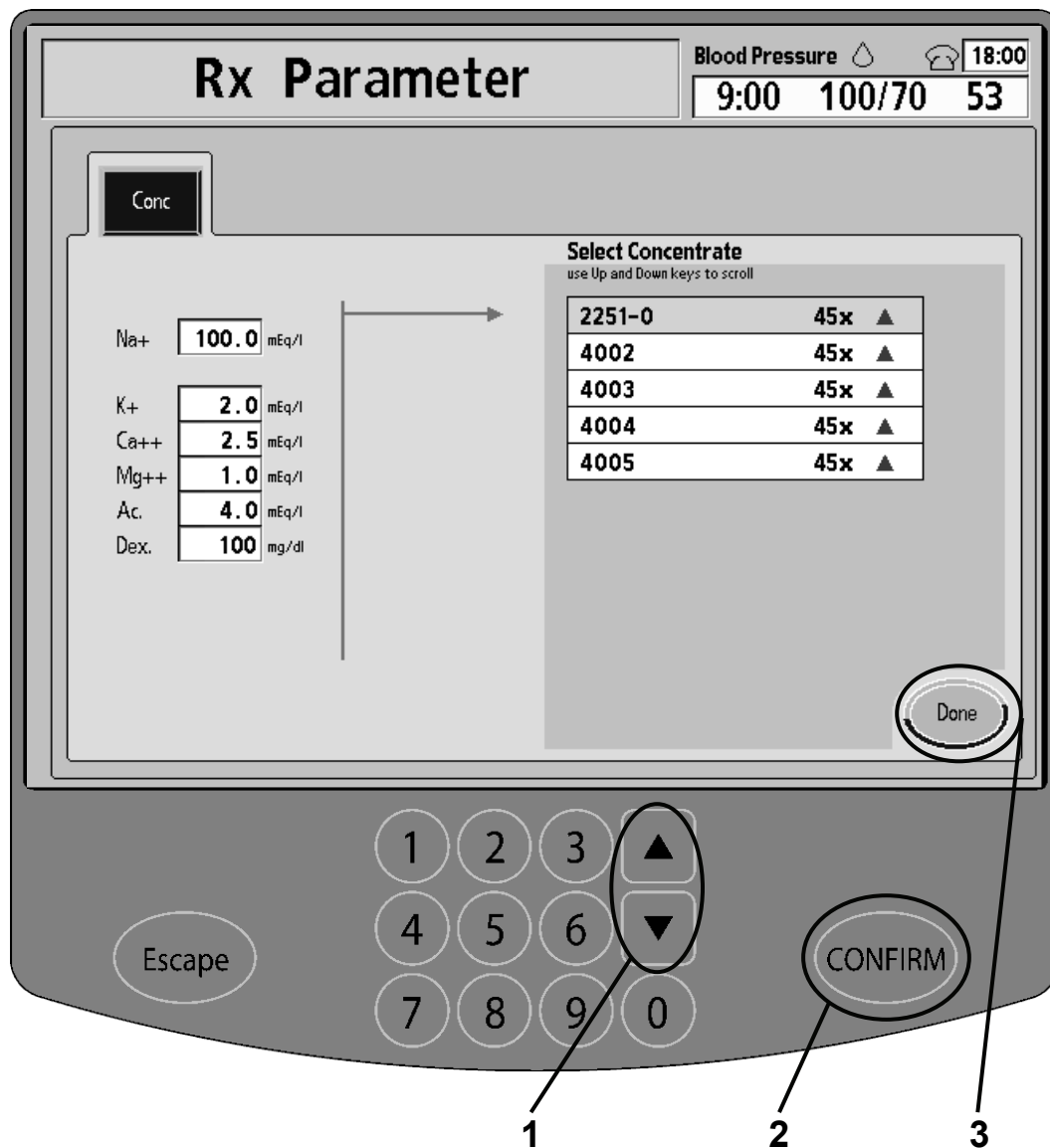
1 Touch **Conc**

The “Rx Parameter” screen contains a list of all the settings and values for your treatment. Here you will need to enter your prescription from your doctor (see “My Treatment Parameters” on page ii). To begin, touch the **Conc** screen-button to go to the “Concentrate Selection” screen.



Warning: The values shown in pictures here are for example only. You must enter the values prescribed by your doctor; see “My Treatment Parameters,” page ii. Failure to enter your own prescribed treatment parameters could result in serious injury or death.

Selecting Your Concentrate (continued)



Warning: The values shown here are for example only. You must use the values prescribed by your doctor. If you use the wrong values, it may cause serious injury or death.

1 Select concentrate

In the “Concentrate Selection” screen, use the **Up/Down Arrow (▼/▲)** keys on the data entry keypad to choose your prescribed concentrate. The selected concentrate is highlighted with a green background. The symbol to the right of the name indicates the concentrate’s family. Match the name and symbol to your prescribed concentrate.



Warning: Your selected concentrate must match your prescribed concentrate and that listed on your concentrate jugs. Selecting the wrong concentrate could cause injury or death.



Note: If your prescribed concentrate is not listed, it will need to be added. Contact your clinic.

If you have incorrectly entered a value, you may press the **Escape** key to reset that value (exiting this screen). You may use the **Escape** key only if you have not already confirmed your values. The **Escape** key is located across from the **CONFIRM** key on the data entry keypad.

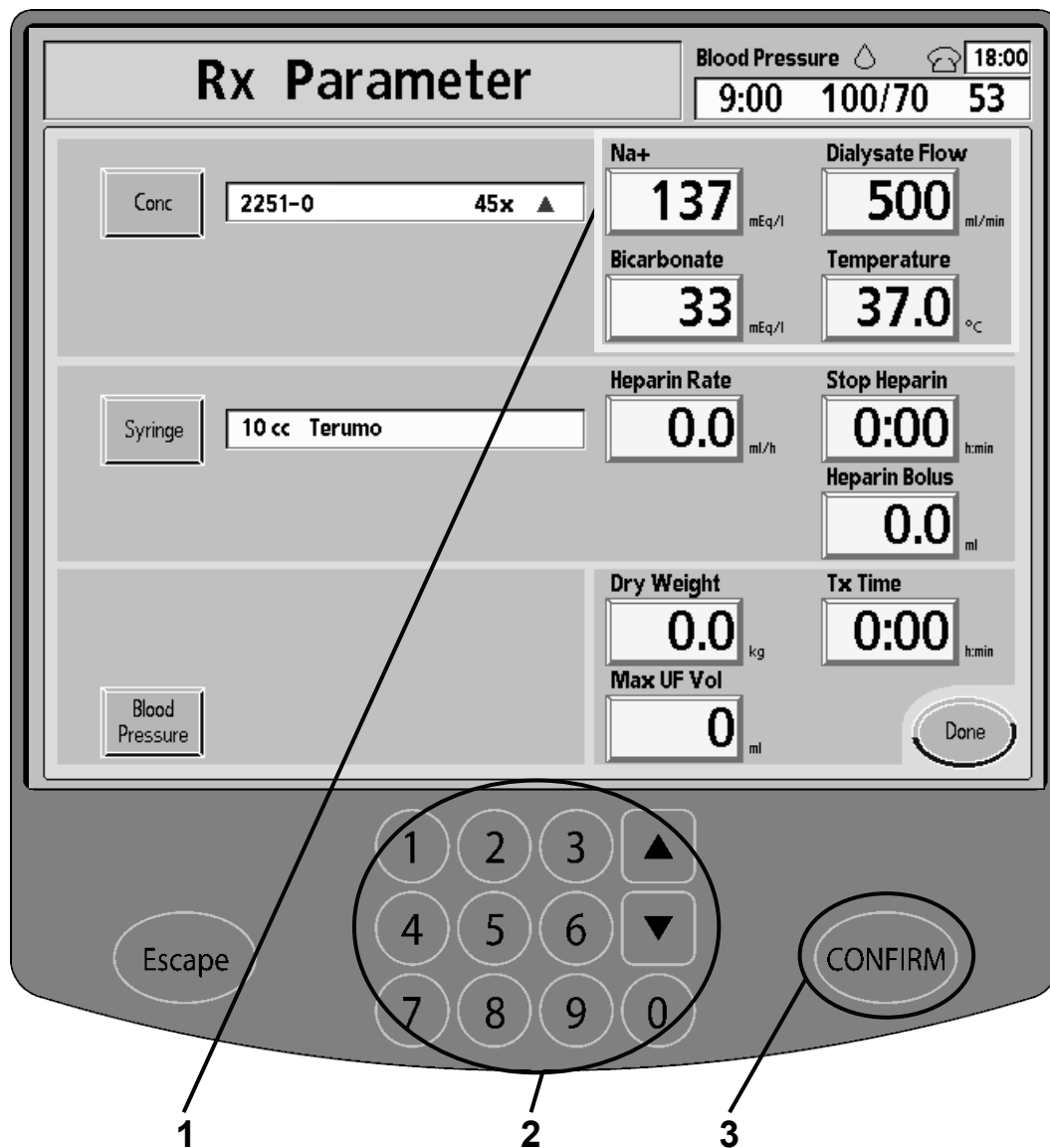
2 Press **CONFIRM**

When your prescribed concentrate is highlighted in green, press the **CONFIRM** key on the data entry keypad to confirm your selection. You will immediately return to the main “Rx Parameter” screen.

3 Touch **Done**

If your correct concentrate is already selected, you may touch the **Done** button to return to the main “Rx Parameter” screen.

Entering Your Dialysate Prescription



Warning: The values shown here are for example only. You must use the values prescribed by your doctor. If you use the wrong values, it may cause serious injury or death.

1 Select parameter

Touch the yellow **Na⁺** button to highlight the dialysate base sodium value. The button color will change to a brighter yellow when active.

2 Enter values

Use the **Up/Down Arrow (▼/▲)** keys or the number keys on the data entry keypad to enter your prescribed **Na⁺** value. Using the procedure demonstrated above, enter the correct “Dialysate Flow,” “Bicarbonate,” and “Temperature” values as prescribed by your doctor.

To enter 2x dialysate autoflow (set in Service Mode), raise the **Dialysate Flow** button value over 800. The button will display ‘2x’ and your machine will set an automatic dialysate flow for you on the dialysis “Home” screen based on your blood pump rate.



Warning: Setting the dialysate flow to a rate that is too low can negatively affect dialyzer clearance and reduce treatment effectiveness. If ‘2x’ selects a flow rate below your prescribed rate, you may manually set the dialysate flow to the desired value.

Warning: Your doctor must prescribe each of the values in the “Rx Parameter” screen. Use the “My Treatment Parameters” sheet on page ii. Using the wrong values could cause injury or death.

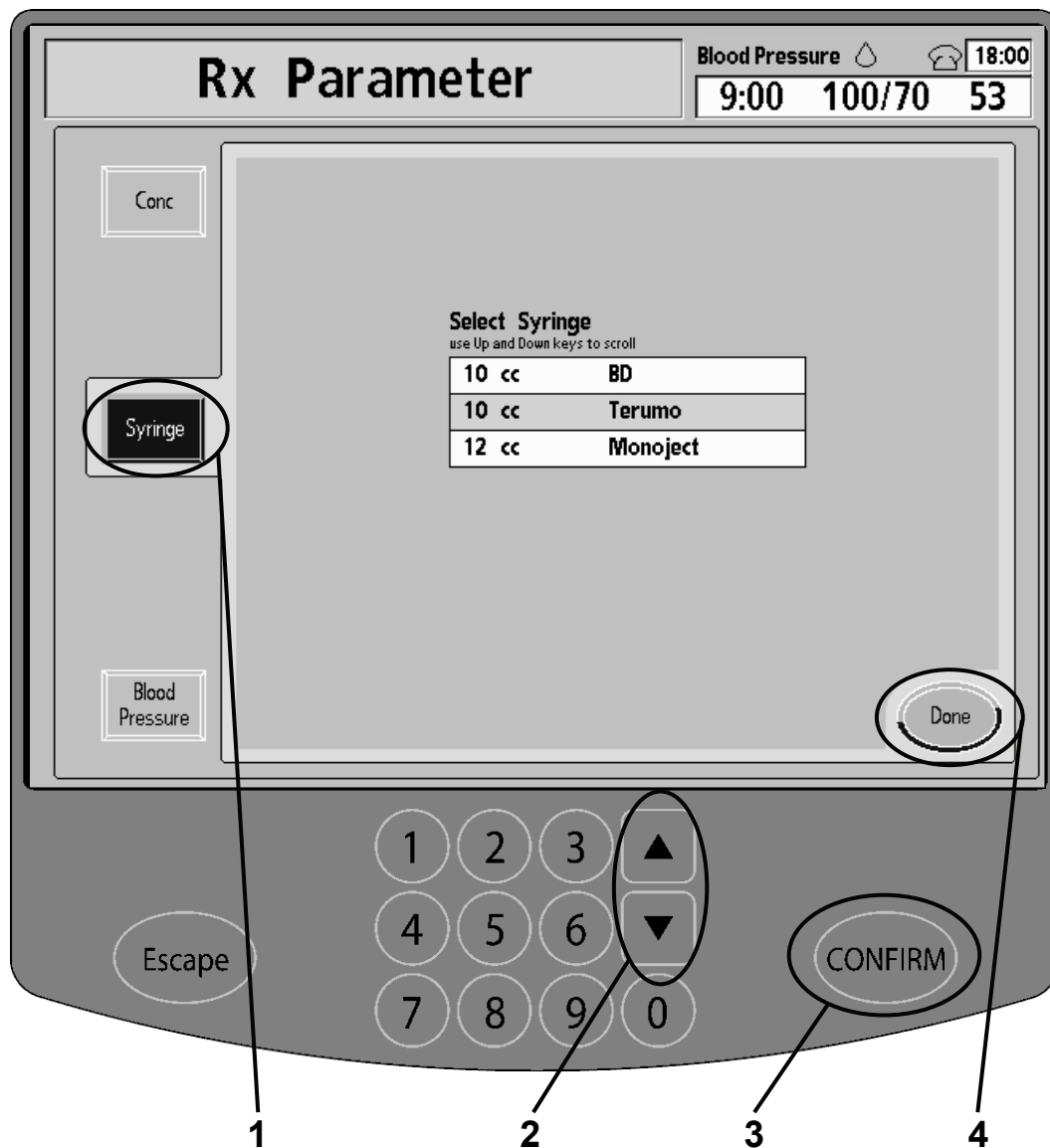


Note: If you incorrectly enter a value, try again or press the **Escape** key (located to the left of the number keypad) to reset the button to its original value.

3 Press **CONFIRM**

When you have entered all of your values, press the **CONFIRM** key to confirm your selections.

Selecting Your Syringe



Warning: The values shown here are for example only. You must use the values prescribed by your doctor. If you use the wrong values, it may cause serious injury or death.



Note: If the heparin buttons are grayed-out, the heparin pump is not available for your treatment. Contact your Home Therapies Nurse for more information.

1 Touch **Syringe**

From the “Rx Parameter” screen, touch the **Syringe** screen-button. Your machine will display the “Syringe Selection” screen.

2 Select syringe

In the “Syringe Selection” screen, use the **Up/Down Arrow (▼/▲)** keys on the data entry keypad to choose the syringe prescribed by your doctor. The selected syringe is highlighted with a green background.

3 Press **CONFIRM**

When your prescribed syringe is highlighted in green, press the **CONFIRM** key to confirm your selection. You will immediately return to the main “Rx Parameter” screen.

4 Touch **Done**

If your correct syringe is already selected, you may touch the **Done** button to return to the main “Rx Parameter” screen.

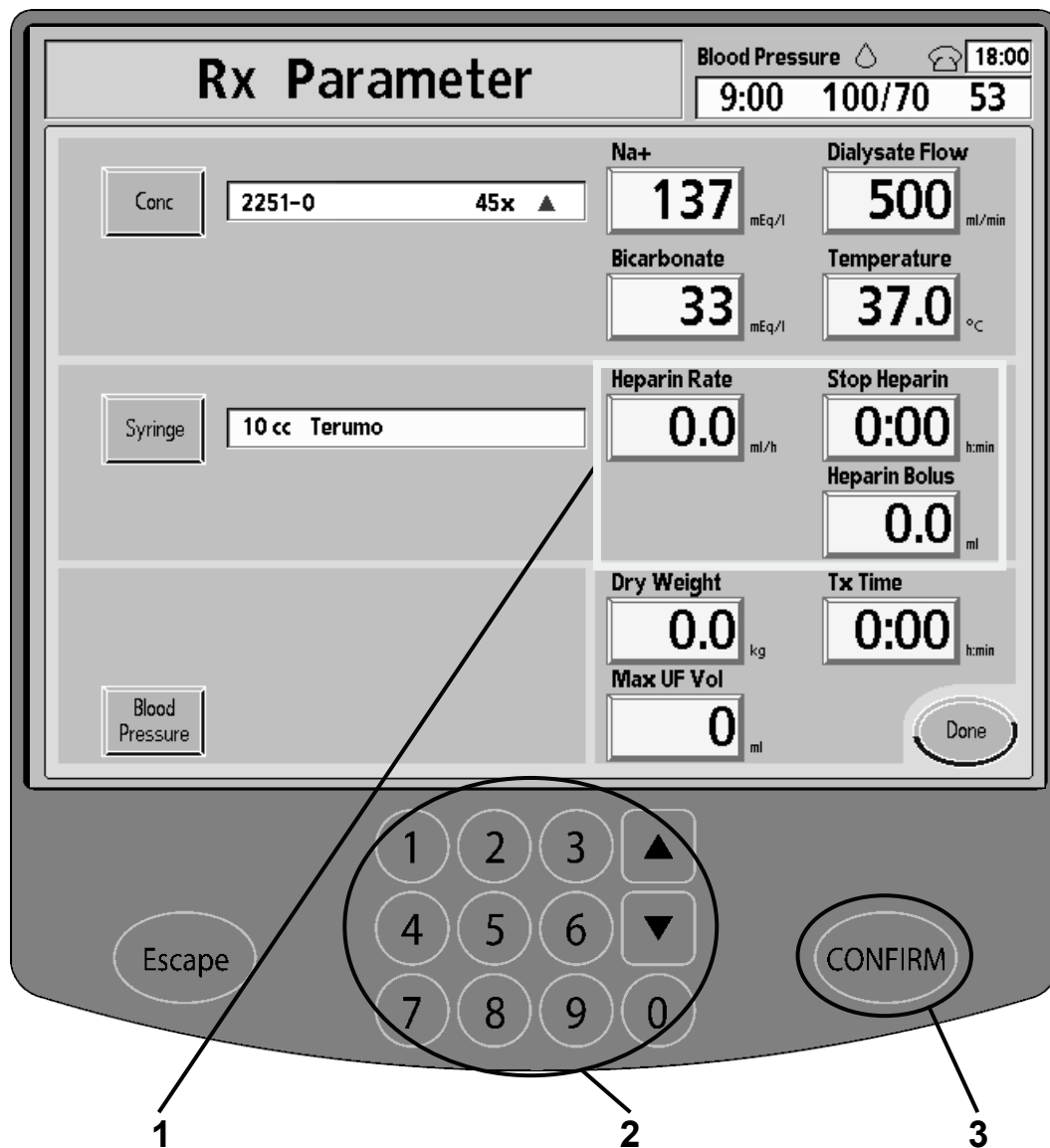


Warning: You must select your prescribed syringe to accurately add heparin during your treatment. Use the “My Treatment Parameters” sheet on page ii.



Note: If your syringe is not in this list, it has not been approved for use on the 2008K@home machine. Contact your Home Therapies Nurse for instructions.

Entering Your Heparin Prescription



Warning: The values shown here are for example only. You must use the values prescribed by your doctor. If you use the wrong values, it may cause serious injury or death.

1 Select parameter

Touch the **Heparin Rate** button to highlight it. The button will change to a brighter yellow when active.

2 Enter values

Use the **Up/Down Arrow** (▼/▲) keys or the number keys on the data entry keypad to enter your prescribed heparin delivery rate.

Using the same method, touch the **Stop Heparin** button and use the data entry keypad to set the length of time before the end of your treatment to stop delivering heparin. If prescribed, touch the **Heparin Bolus** button and use the data entry keypad to set the amount of heparin to be infused all at once.

3 Press **CONFIRM**

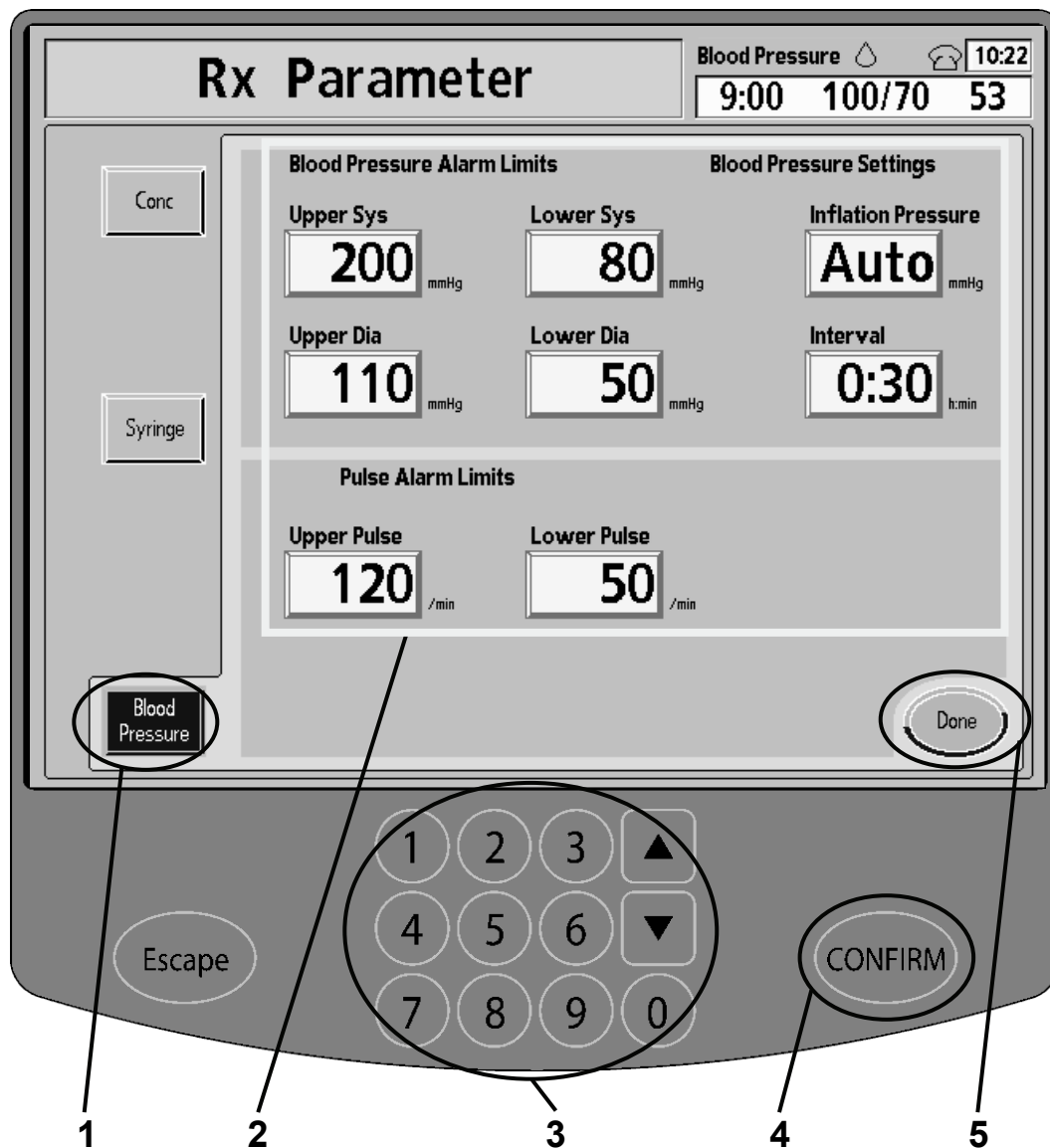
Press the **CONFIRM** key on the data entry keypad to confirm your selections.



Warning: If you do not enter a “Stop Heparin” value, the heparin pump will run at the selected rate until the syringe is empty or your treatment is over. The heparin pump should be monitored to make sure of proper heparin infusion.

Warning: Your doctor must prescribe each of the values in the “Rx Parameter” screen. Use the “My Treatment Parameters” sheet on page ii. Using the wrong values could cause injury or death.

Entering Your Blood Pressure Settings



Warning: The values shown here are for example only. You must use the values prescribed by your doctor. If you use the wrong values, it may cause serious injury or death.

1 Touch **Blood Pressure**

From the “Rx Parameter” screen, touch the **Blood Pressure** screen-button. Your machine will display the “Blood Pressure Monitor Settings” screen.

2 Select parameter

Touch the yellow **Upper Sys** button to highlight your upper systolic blood pressure limit. The button will change to a brighter yellow when active.

3 Enter values

Use the **Up/Down Arrow (▼/▲)** keys or the number keys on the data entry keypad to set your prescribed blood pressure limits.

Using the process explained above, enter the correct values in each button with the data entry keypad. The values are prescribed by your doctor and listed on the “My Treatment Parameters” sheet on page ii.



Warning: Your doctor must prescribe each of the values in the “Rx Parameter” screen. Use the “My Treatment Parameters” sheet on page ii. Using the wrong values could cause injury or death.

4 Press **CONFIRM**

When you have entered all of your prescribed values, press the **CONFIRM** key to confirm your selections.

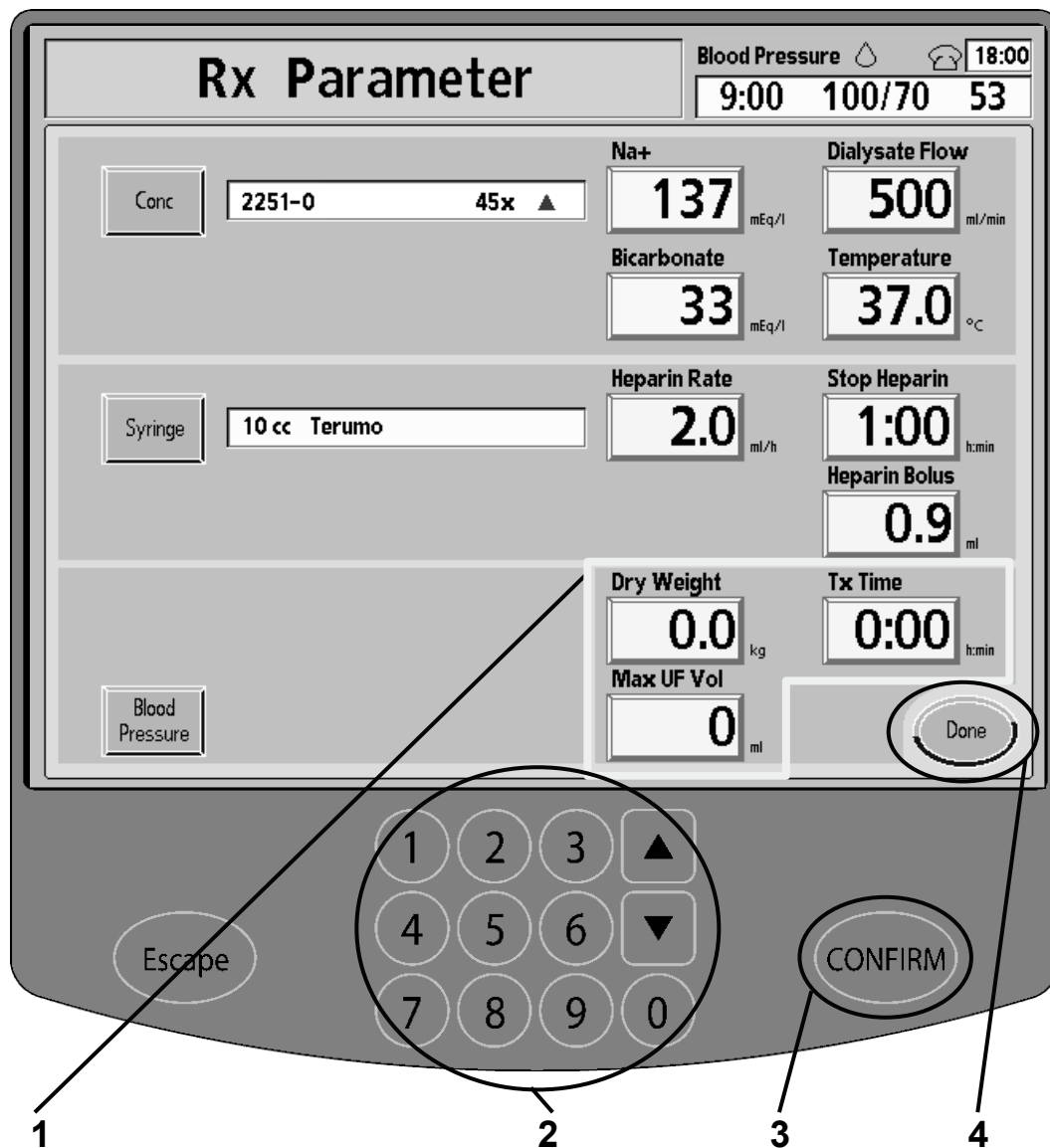
5 Touch **Done**

Touch the **Done** button to return to the main “Rx Parameter” screen.



Note: You may adjust the clock time on this screen. Touch the yellow time box in the upper right corner and use the **Up/Down Arrow (▼/▲)** keys to enter a new time. Press the **CONFIRM** key to confirm the change.

Completing Your Prescription



Warning: The values shown here are for example only. You must use the values prescribed by your doctor. If you use the wrong values, it may cause serious injury or death.

1 Select parameter

Touch the **Dry Weight** button to highlight it.



Note: If your Dry Weight is less than 25 kilograms, your machine will automatically adjust blood pressure ranges. For more information, see the blood pressure module performance limits on page 330.

2 Enter values

Use the **Up/Down Arrow** (▼/▲) keys or the number keys on the data entry keypad to set your dry weight as calculated by your doctor. Next, touch **Tx Time** to highlight it and use the data entry keypad to enter your prescribed length of time on dialysis. Finally, touch **Max UF Vol** to highlight it and use the data entry keypad to enter your maximum ultrafiltration value.



Note: The Max UF Vol is an additional check during the setup process. If your UF Goal (calculated later) is set higher than this value, your machine will alert you.

3 Press **CONFIRM**

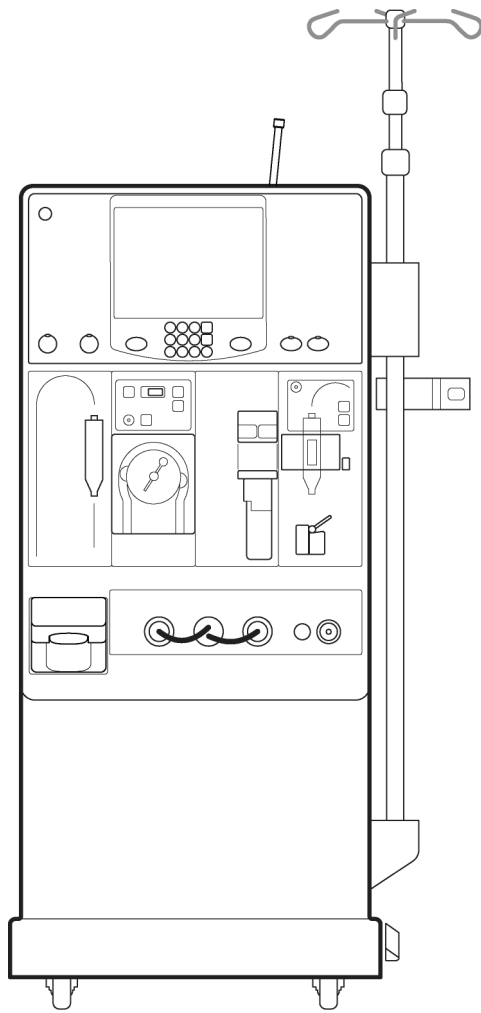
Press the **CONFIRM** key to confirm your selections.

4 Touch **Done**

Review the values on the screen to make sure they match your prescribed values. Touch the **Done** button when all your prescribed values are correctly displayed. You will then automatically return to the “Select Program” screen. Unless your doctor changes your prescription, this is the only time you will need to use these “Rx Parameter” screens. Continue with chapter 4.

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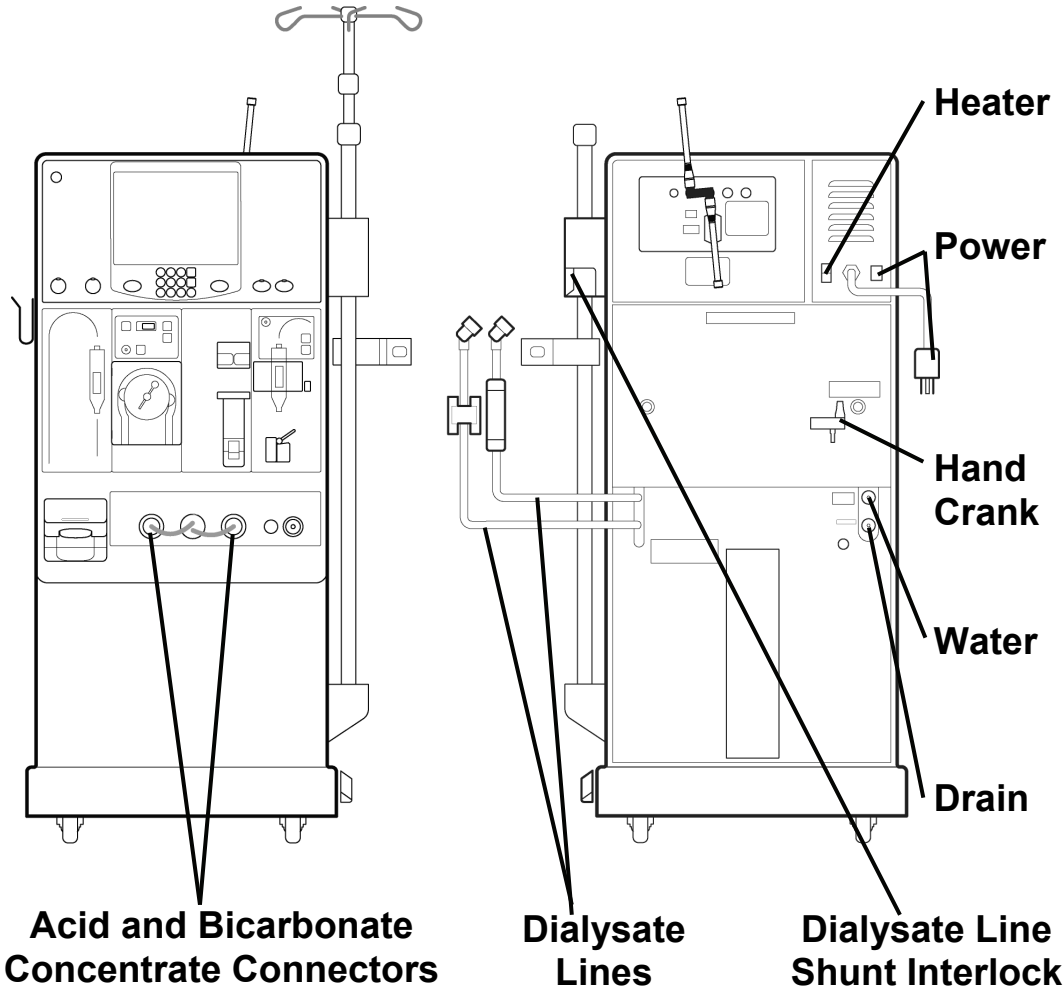
Chapter 4: Your Treatment



TREATMENT

Preparing for Your Treatment

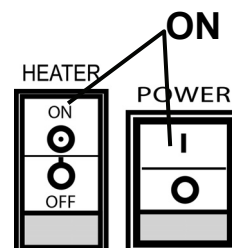
TREATMENT



Getting Started

You must complete the following machine requirements before starting your treatment:

- ✓ Check that the Reverse Osmosis (RO) unit is running and the water supply line is connected to the water inlet
- ✓ Check that the drain line is inserted into a drain with an air gap
- ✓ Check that the power cord is plugged into a grounded, GFI-protected electrical outlet, and the main power switch on the back of your machine is in the ON position
- ✓ Check that the heater switch on the back of your machine is in the ON position
- ✓ Check that the acid concentrate line (red connector) is inserted tightly into the red rinse port
- ✓ Check that the bicarbonate concentrate line (blue connector) is inserted tightly into the blue rinse port
- ✓ If your machine has the optional *bi*bag connector, check that the *bi*bag door is firmly closed
- ✓ Check that the dialysate supply line (blue quick-connector) and the dialysate return line (red quick-connector) are both firmly snapped onto the matching color connectors of the shunt interlock
- ✓ Check that your machine has been recently disinfected, rinsed, tested for traces of disinfectant, and is ready to use
- ✓ Check that the emergency hand crank for the blood pump is readily available
- ✓ Check that all of your supplies are prepared



Warning: If any of the conditions listed above have not been met, you must correct them before continuing with your treatment preparation. Failure to do so may cause injury or death.

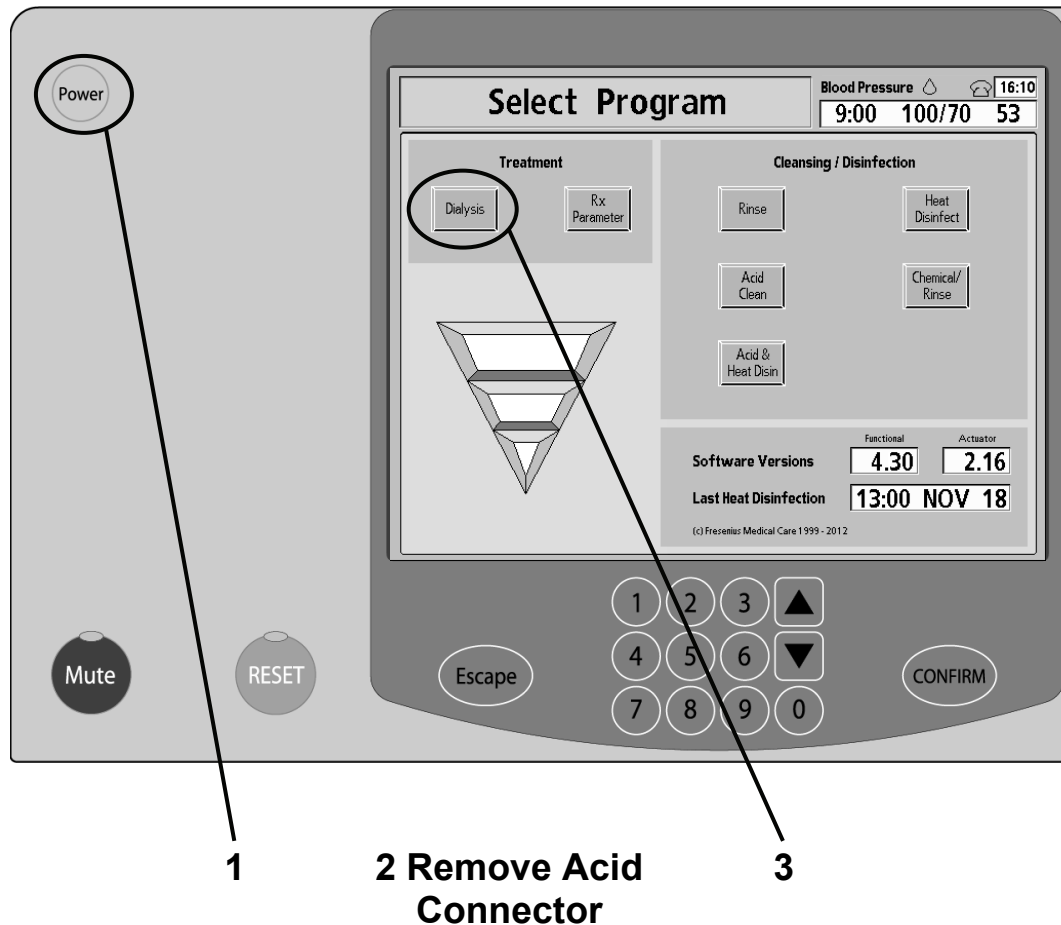
Warning: Mix your bicarbonate according to your clinic's instructions. Make sure your concentrate jugs are full (see the fill level on page 88). If a jug runs out during treatment, it will cause conductivity problems.



Note: The *bi*bag disposable contains a fixed volume of bicarbonate powder. In order to run a treatment with one bag, your doctor should consider set-up time and potential start of treatment delays. See the estimated *bi*bag disposable run time table on page 316 for estimated run times.

Powering up Your 2008K@home Machine

TREATMENT



i **Note:** Software versions 4.30 or later: The “Select Program” screen displays any additional software applications (Apps) that are installed on your 2008K@home hemodialysis machine. The installed apps are listed in the lower left corner of the screen.

1 Press **Power** (see Your K Map: ‘A’)

If your machine is not currently on, press the **Power** key in the Machine section of the Control Panel. Your 2008K@home hemodialysis machine will power up and, after about a minute, the “Select Program” screen will appear on the Display Screen.



Note: If your machine is filled with disinfectant, or if the only cleaning/disinfection option highlighted on the “Select Program” screen is “Rinse” or “Chemical/Rinse,” you must complete a rinse cycle before using it for your treatment. Select and confirm the **Rinse** screen-button to start the rinse cycle (see the “Rinse” section on page 156). When the rinse is finished, you must test your machine for any remaining disinfectant.

Note: If you have missed a scheduled cleaning/disinfecting program, your machine will also remind you with a pop-up message when you touch the **Dialysis** button. You must either press the **CONFIRM** key to continue or press the **Escape** key to cancel and then select the required cleansing/disinfecting program. For more information on the recommended cleaning/disinfection schedule, see “My Treatment Procedures” on page iii.

If you are using the *bi*bag system for treatment

1. Remove the white plastic seal from underneath the water and bicarbonate nozzles of the *bi*bag disposable.
2. Open the *bi*bag door on your machine by lifting up on the dark-gray handle.
3. With the white *bi*bag handle facing outward, hang the bag on the *bi*bag connector nozzles. Close the door, making sure it latches firmly in place. An audible click means the door is closed.

2 Remove **Acid Concentrate Connector** (see Your K Map: ‘H’)

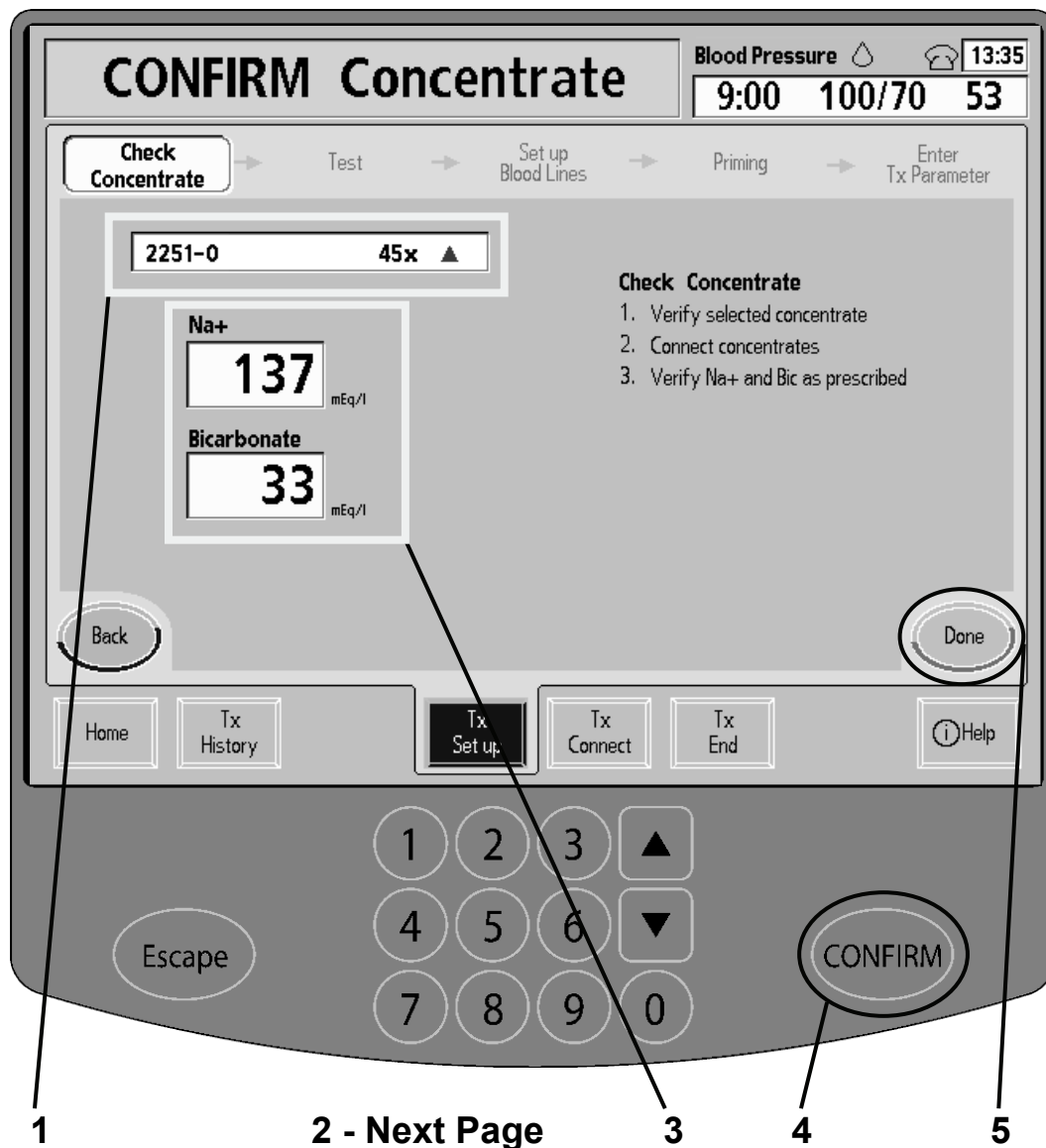
You must pull the red acid connector out of its port on the front of your machine to enter the dialysis screens.

3 Touch **Dialysis**

Touch the **Dialysis** screen-button to go to the “Treatment Set up” screens.

Checking the Concentrates

TREATMENT



Warning: The values shown here are for example only. You must use the values prescribed by your doctor. If you use the wrong values, it may cause serious injury or death.

1 Verify selected concentrate

Check that your prescribed concentrate is listed. If your settings are incorrect, touch the **Back** button. The **Back** button is located in the bottom left corner of the screen, opposite the **Done** button. The **Back** button may be used to go to previous screens.



Warning: The values listed must be those prescribed by your doctor. If you need to make any changes to this screen, turn to “Entering Your Treatment Parameters” on page 64. If you must return to the “Rx Parameter” screens, either touch the **Back** button or restart your machine by holding the **Power** key down for two seconds and then turning your machine back on.

Warning: Your jugs of acid and bicarbonate concentrates must match both your prescription and your machine settings. Make sure they are correct before connecting. Using the wrong concentrates may cause serious injury or death.



Note: Your machine will not allow you to use the *bibag* disposable unless the 45x concentrate family is selected in Service Mode. The blue bicarbonate connector must be inserted into your machine’s blue bicarbonate port during a *bibag*-based treatment.

2 Connect concentrates

Connect the concentrates as shown on the next page.

3 Verify Na⁺ and Bic as prescribed

Check that the sodium (“Na⁺”) and bicarbonate settings are correct. If your settings are incorrect, touch the **Back** button.

4 Press **CONFIRM**

If the values listed are correct, press the **CONFIRM** key.

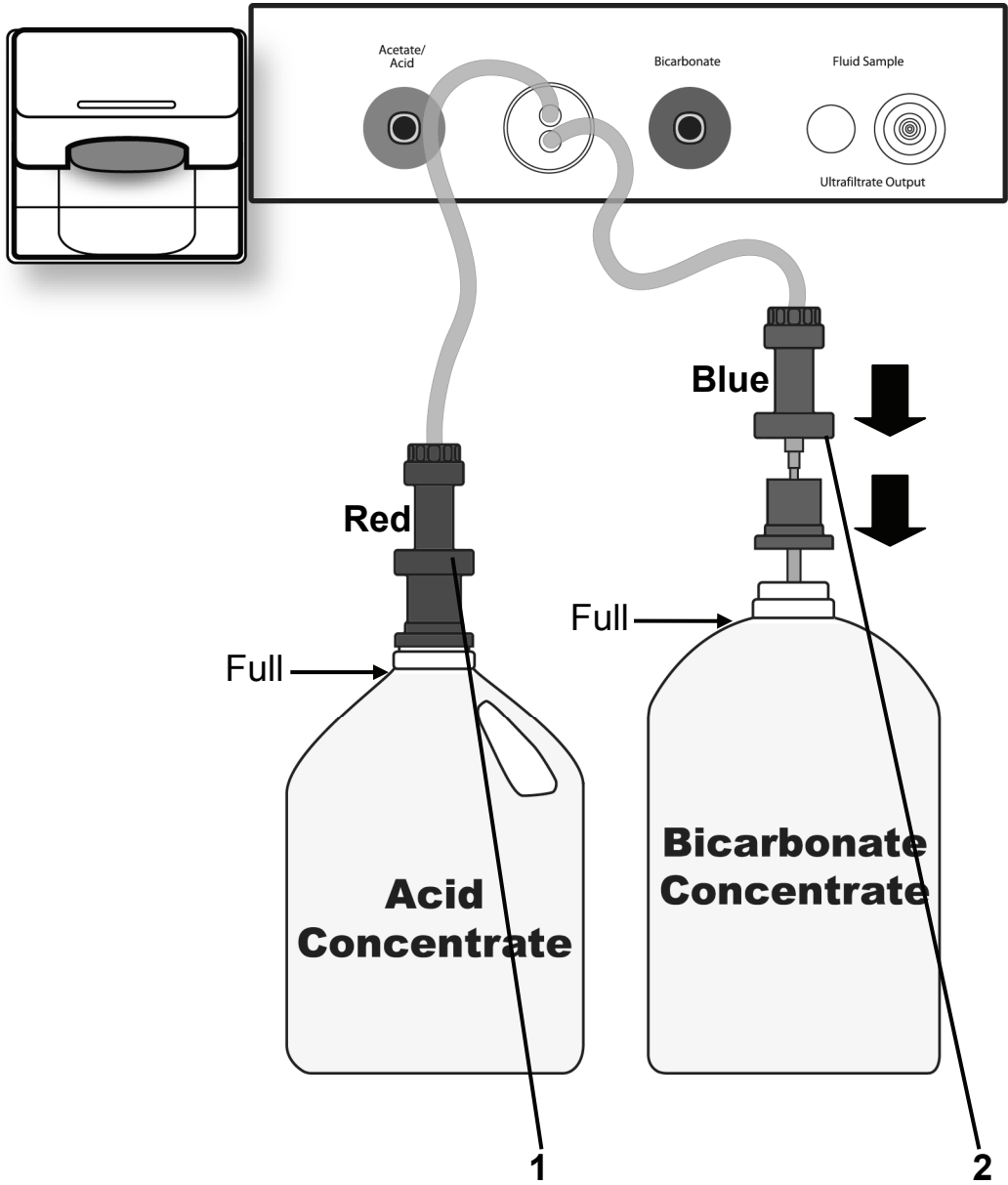


Note: Your machine will display the message “Air Detector Alarm” in the Status Box. This is normal and will be cleared when you prime the bloodlines.

5 Touch **Done**

When you are finished connecting the concentrates, touch the **Done** button. This will take you to the “Test” screen.

Connecting the Concentrates



TREATMENT

1 Connect acid (see Your K Map: ‘H’)

Snap the red acid connector into the red connector cap on a full acid jug.

2 Connect bicarbonate (see Your K Map: ‘I’)



Note: If you are using the *bi*bag system for treatment, do not pull the blue bicarbonate connector out of your machine’s bicarbonate port. Doing so will stop the flow to and from the *bi*bag disposable.

Note: The *bi*bag disposable must hang freely below the *bi*bag connector. Make certain that there are no jugs or other objects obstructing or touching the *bi*bag disposable.

Note: If your machine is set up for Acetate, you will only need to connect the red concentrate connector.

Pull the blue bicarbonate connector from the front of your machine and snap it into the blue connector cap on a full liquid bicarbonate jug.

Your machine will begin mixing the water and bicarbonate and acid concentrates. Your machine’s conductivity and temperature readings should stabilize within ten minutes.



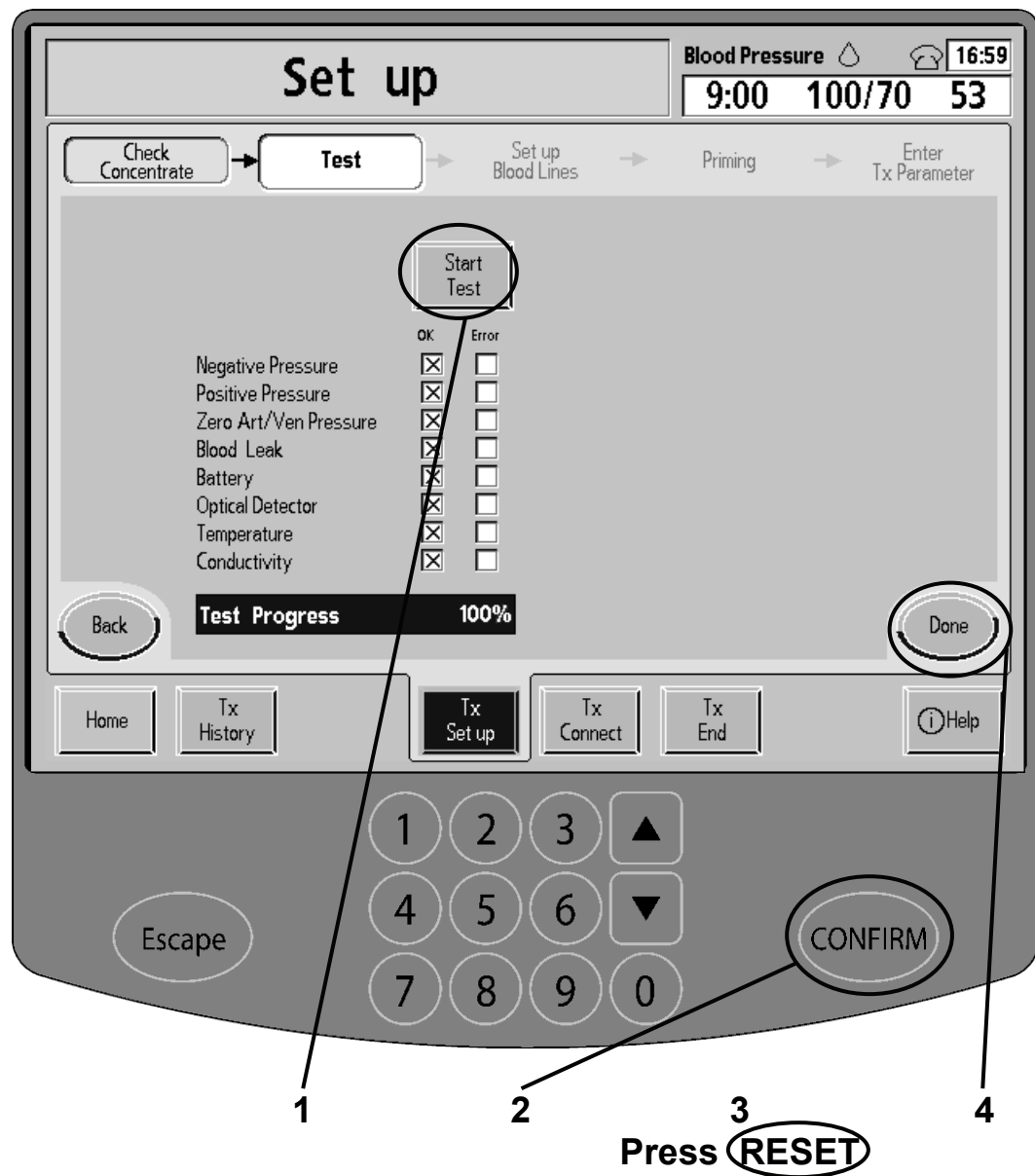
Note: You may check to see when your dialysate conductivity has reached the set range by touching the **Home** screen-button along the bottom of the screen. This will take you to the “Home” screen. The conductivity is displayed in the **Conductivity** parameter-button. Once the conductivity is within the set range, the **Conductivity** button on the “Home” screen will change from red to light yellow. This may take up to ten minutes.

When you are ready to continue, touch the blue **Tx Set up** screen-button along the bottom of the screen. You will return to the previous screen where you confirmed your concentrate values. Now touch the **Done** button to move to the next screen.

Continue following the “Set up” screens on the next page to begin testing your machine.

Testing Your Machine

TREATMENT





Note: If you are using the bibag disposable for your bicarbonate source, wait until conductivity has stabilized before you start testing your machine on this screen.

1 Touch **Start Test**

You must test your machine before each use. The “Test” screen allows you to test the alarm and hydraulic systems. Touch the **Start Test** button.

2 Press **CONFIRM**

Next, press the **CONFIRM** key to begin the automatic test. The Status Box displays each test as it runs. As each test passes, a blue “☑” appears in the “OK” column.

A bar graph along the bottom of the screen will fill to show the tests’ progress.

When all the tests are done, the bar graph will display 100%, your machine will beep, and the Status Box will display the message: “**Test Complete.**”

If any part of the test fails, a red “☒” appears in the “Error” column, an alarm sounds, and the Status Box displays the message: “**Test Failed.**” For a description of errors, see “Troubleshooting” on page 224.



Warning: After you select and confirm the **Start Test** button, your machine will beep. This is a test of the audible alarm system; make certain that the sound occurs. If your machine fails any of these tests and the cause cannot be corrected, or if it fails later tests, it should not be used for treatment. Call your clinic to let them know and to have your machine checked by a qualified technician to correct the problem.

Warning: If your machine has a Diasafe Plus filter, you must test it every other week; see page 310.



Note: To retest your machine, see “The Help Screen” section on page 200.

3 Press **RESET** (see Your K Map: ‘B’)

When the tests are complete, press the **RESET** key to clear the Status Box message.

4 Touch **Done**

When all the tests have successfully passed, touch the **Done** button to continue.

Setting up the Arterial Lines

TREATMENT



1 Insert dialyzer into holder

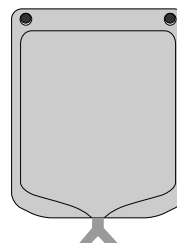


Warning: Use aseptic technique.

Warning: The 2008K@home hemodialysis machine is not designed to be used with re-used dialyzers. You must use a new, sterile dialyzer for every treatment.

2 Hang Drain Bag on posts

Hang the drain bag on the posts on the left side of your machine. The lines should hang below the bag.



3 Snap arterial drip chamber into holder



Note: Do not remove the tape from your bloodlines until necessary to snap them into the machine.

Note: A bracket is provided to help you organize your bloodlines during setup, if necessary.

Use the red guidelines on the module panel to fit the drip chamber in its proper location.

Make certain that the recirculation connector is securely connected to the tubing.



4 Remove Tape 1 and feed pump segment into pump

Tear off only the tape labeled with a red 1 to uncoil the bloodline with the blood pump segment. Follow the instructions on the next page to properly set up the blood pump segment.

5 Remove Tape 2 and connect arterial line to dialyzer

Tear off only the tape labeled with a red 2 to uncoil the dialyzer end of the bloodline. Connect the dialyzer end of the arterial line to the bottom port of the dialyzer. Make certain the connection is tight to prevent blood leaks.

6 Insert line into tubing guides

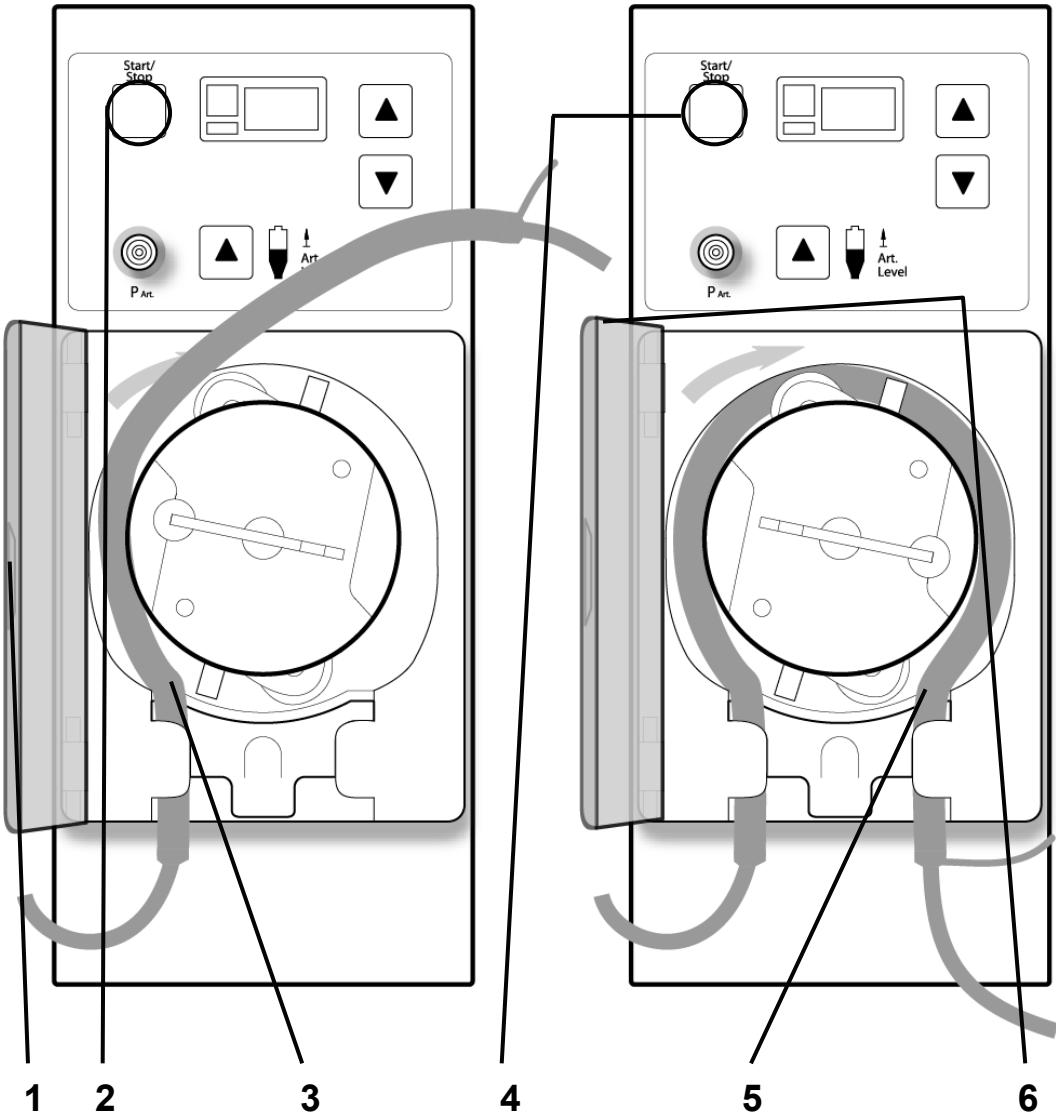
The arterial bloodlines should follow the red guidelines.

7 Touch **Done**

When you have completed these steps, touch the **Done** button to continue.

Fitting the Blood Pump Segment

TREATMENT



1 Open blood pump door

When the blood pump door is open, the Display Window shows the diameter of the blood pump segment. If necessary, set the pump for the diameter of the pump segment by pressing both of the **Blood Pump Up/Down Arrow (▼/▲)** keys at the same time (see Your K Map: ‘E’). When the display flashes, use these keys to select the correct diameter (written on its packaging).

2 Start blood pump to align pump rotor (see Your K Map: ‘D’)

Press and hold the Blood Pump **Start/Stop** key to align the rotor so you can fit the pump segment more easily.



Warning: Keep fingers clear of the blood pump rotor when it is running. Serious injury may occur.

Warning: Inspect the blood pump rotor for proper operation (tubing guide posts not bent, rollers move freely, crank lever moves freely). Bent or loose tubing guide posts can damage bloodlines. Replace rotor if necessary. See page 180 for rotor diagram.

3 Fit first half of pump segment

Use thumb pressure to push the retainer clamp-panel back. Fit the beginning of the pump segment around the first half of the blood pump rotor. Release the clamp-panel to hold the tubing against the left yoke.

4 Start blood pump to re-align pump rotor (see Your K Map: ‘D’)

Press and hold the **Start/Stop** key. The rotor will make one full turn to pull the rest of the segment within the pump housing.

5 Fit second half of pump segment

Release the **Start/Stop** key when the pump segment has been pulled along the track inside the pump housing all the way to the right yoke. Take the remaining portion of the segment and, using thumb pressure again, place it behind the right yoke.

6 Close Pump Door

Release the clamp-panel and close the pump door.



Warning: Make sure the blood pump segment is free of kinks. It must be set correctly into the tubing retainer with both ends beneath the blood pump rotor to reduce kinking.

Setting up the Arterial Lines (screen 2)

TREATMENT



1 Connect patient end of arterial line to the Drain Bag

Make certain the patient end of the arterial line is unclamped and the connection is tight.

2 Connect transducer protector to arterial pressure port (see

Your K Map: 'F')

Make certain the pressure monitor line is unclamped and the connections on both ends of the transducer protector are tight.



Warning: Use a sterile transducer protector between your machine and each pressure monitor line so the transducers do not get wet. Wet transducer protectors must be replaced, as they will cause inaccurate pressure readings.

3 Tighten the red and blue recirc connector

Make certain that both ends of the recirculation connector are securely connected to the tubing.



4 Close saline clamp (S)

The clamp below the saline bag spike should remain open.

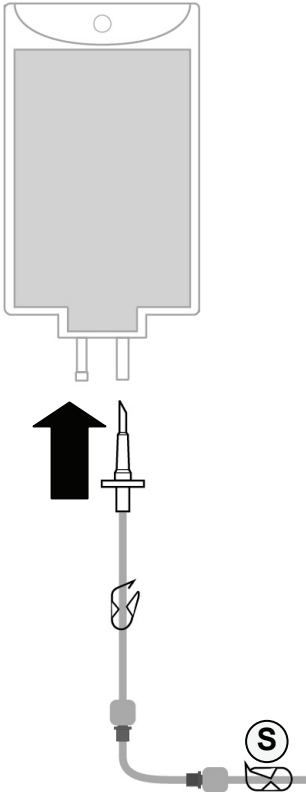
5 Hang Saline Bag

Hang a fresh saline bag on the IV pole.

6 Remove Tape 3 and connect Saline Bag

Tear off only the tape labeled with a red 3 to uncoil the saline line.

Uncap the end of the saline line and insert the spike into the base of the bag as shown to the right.



7 Touch Done

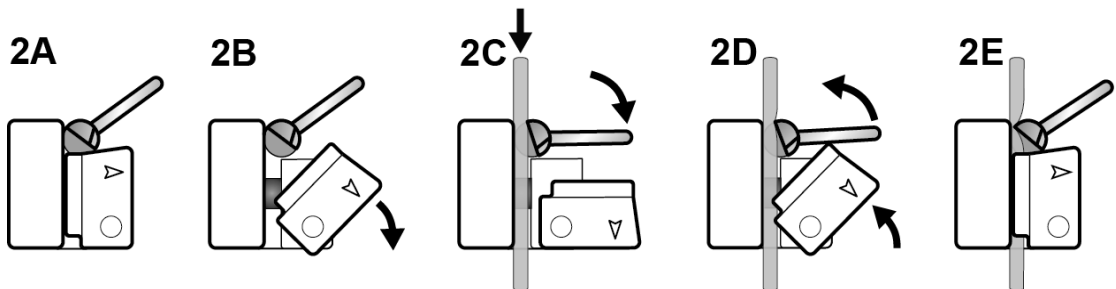
When you have completed these steps, touch the **Done** button to go to the next screen.

Setting up the Venous Lines

TREATMENT



8



1 Roll venous chamber into holder

Open the level detector door and roll the venous drip chamber into its holder. The mark on the chamber must line up with the top of the holder. Close and latch the level detector door.



Warning: If the drip chamber contains a filter, make certain the filter is below the sensor heads.

Warning: The level detector must be calibrated for the venous line model being used. Failure to do so may cause serious injury or death.

2 Insert line into Venous Clamp and Optical Detector (see Your K Map: 'K', 'J')

Follow steps 2A – 2E on the facing page: Rotate the Optical Detector door clockwise and flip the Venous Clamp open. Make certain that you place the bloodline completely into the Venous Clamp. Release the Venous Clamp and rotate the Optical Detector door back over the bloodline.



Warning: The tubing beneath the venous drip chamber must be inserted into the venous line clamp and the optical detector.

3 Connect patient end of venous line to drain bag

4 Remove Tape 4 and connect venous line to top of dialyzer

Tear off only the tape labeled with a blue 4 to uncoil the dialyzer end of the bloodline. Connect the dialyzer end of the venous line to the top port of the dialyzer; make certain every connection is tight.

5 Insert line into tubing guides

The venous bloodlines should follow the blue guidelines.

6 Connect transducer protector to venous pressure port (see Your K Map: 'M')

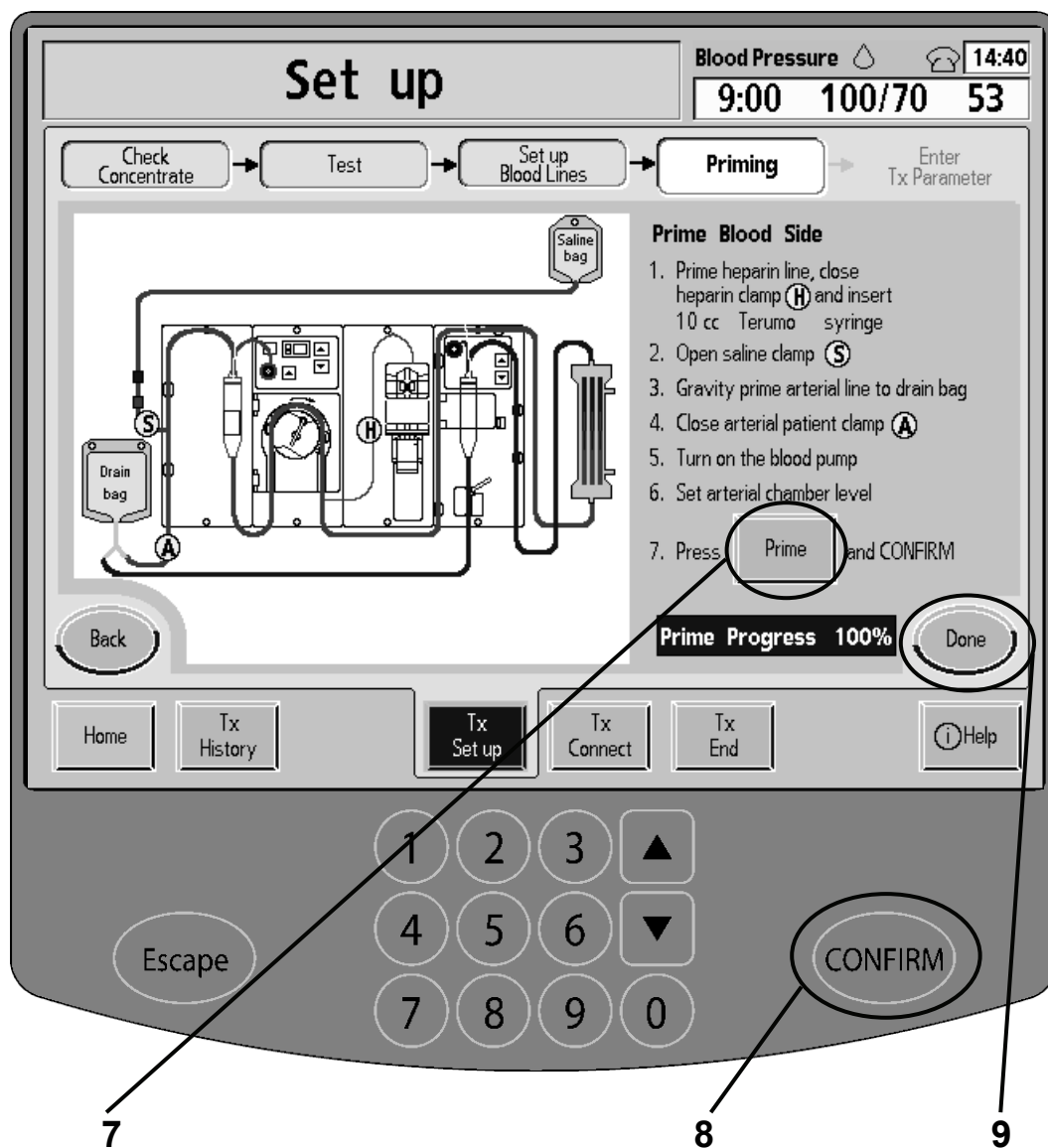
Make certain the pressure monitor line is unclamped and the connections on both ends of the transducer protector are tight.

7 Close both medication clamps (M)

8 Touch Done

Touch the **Done** button when you are ready to continue.

Priming the Blood Side



Note: The syringe type shown in step 1 is for example only. This screen will display the syringe you selected on the “Rx Parameter” screen.

1 Prime heparin line, close heparin clamp **(H)** and insert syringe

If the Heparin pump is used: Insert the Heparin syringe and prime the line as shown on the next page.

If the Heparin pump is not used, do not close the heparin line clamp yet.

2 Open saline line clamp **(S)**

3 Gravity prime arterial patient line to drain bag

4 Close arterial patient line clamp **(A)**

5 Turn on the blood pump (see Your K Map: ‘D’)

To start the blood pump, press the **Start/Stop** key on the Blood Pump module. Set the blood pump speed as directed by your Home Therapies Nurse.

6 Set arterial drip chamber level (see Your K Map: ‘G’)

Use the “My Treatment Procedures” sheet, on page iii, for instructions on setting your drip chamber level.



Warning: The **Level Adjust (▲)** key (see your K Map: ‘G’) on the Blood Pump module can only be used to raise the level in the arterial chamber. Do not press the **Level Adjust (▲)** key so long that the pressure transducer becomes wet. Wet transducer protectors must be replaced to avoid false pressure readings.

7 Touch **Prime**

8 Press **CONFIRM**

When you have completed the previous steps, touch the **Prime** button. Press the **CONFIRM** key to begin running saline through the bloodlines. To help remove air from the bloodline and dialyzer while priming, be sure to:

- Intermittently pinch the bloodline between the blood pump and dialyzer
- Gently tap the dialyzer

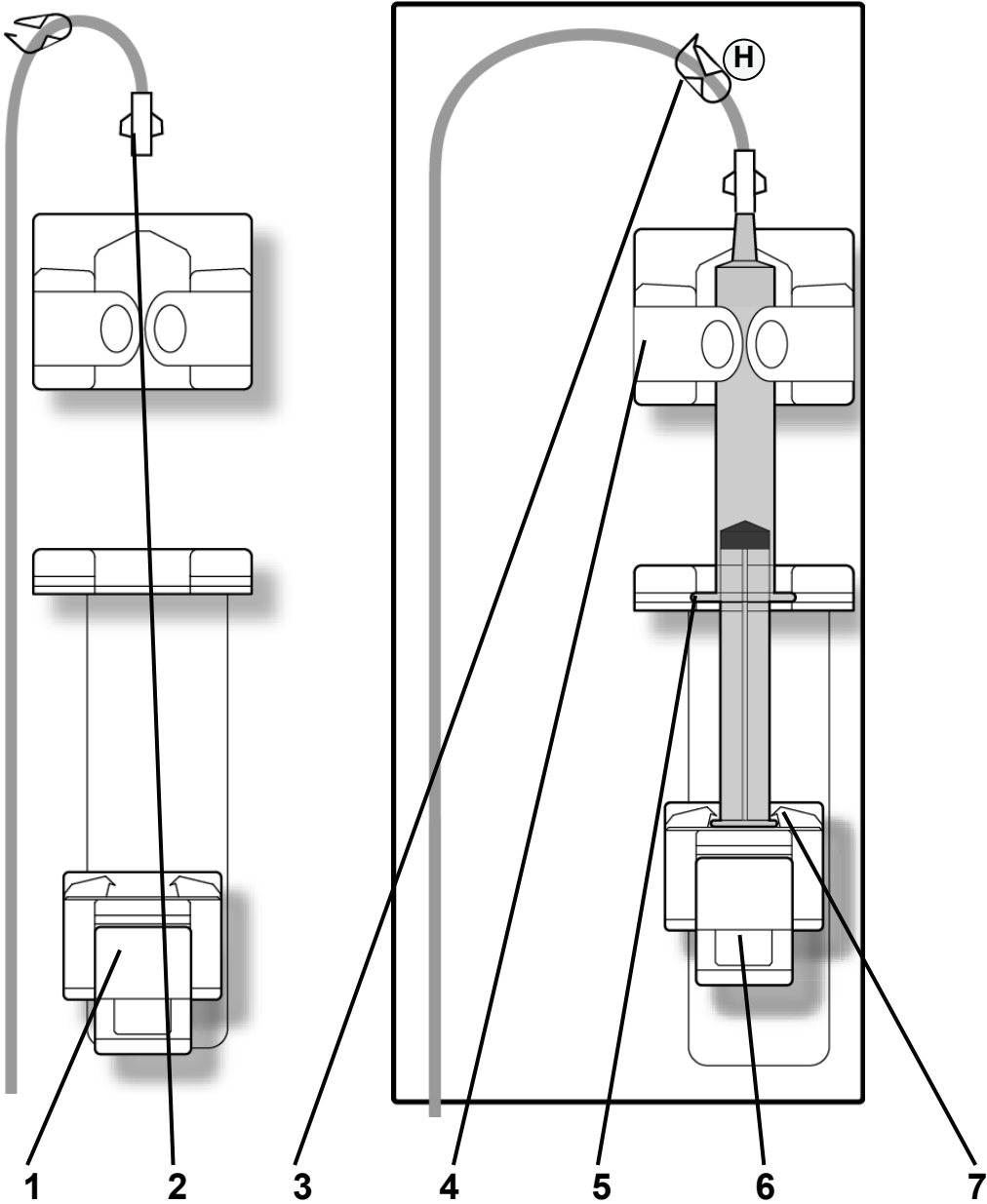
If the Heparin pump is not used, make certain to close the heparin line clamp **(H)** after the heparin line is primed.

9 Touch **Done**

When the priming bar graph shows 100%, the **Done** button will change from gray (unavailable) to blue, touch the **Done** button to continue.

Inserting the Heparin Syringe

TREATMENT



1 Move slide carriage down

If you are using the Heparin Pump: Squeeze the carriage latch and move the slide carriage all the way down to the base of the Heparin Pump module to insert the syringe.

2 Prime Heparin line

Attach your sterile, heparin-filled syringe to the heparin line. Push heparin into the line until the entire length is filled with heparin (primed).



Warning: Only use syringes prescribed by your doctor in the Heparin Pump module. Make sure that there is enough heparin for your entire treatment. Do not load the syringe beyond your prescribed amount.

Warning: The heparin pump is to be used only under positive pressure conditions. Under negative pressure conditions, too much heparin may be infused.

3 Close heparin line clamp (H)



Caution: The syringe must be properly loaded for your machine to add heparin during treatment.

4 Push syringe barrel into barrel lock tabs

Push the syringe barrel against the barrel lock tabs to snap the syringe in place (plunger-end down).

5 Fit syringe into wings slot

Make certain the syringe wings are fitted into the wings slot of the holder.

6 Squeeze carriage latch and move carriage up

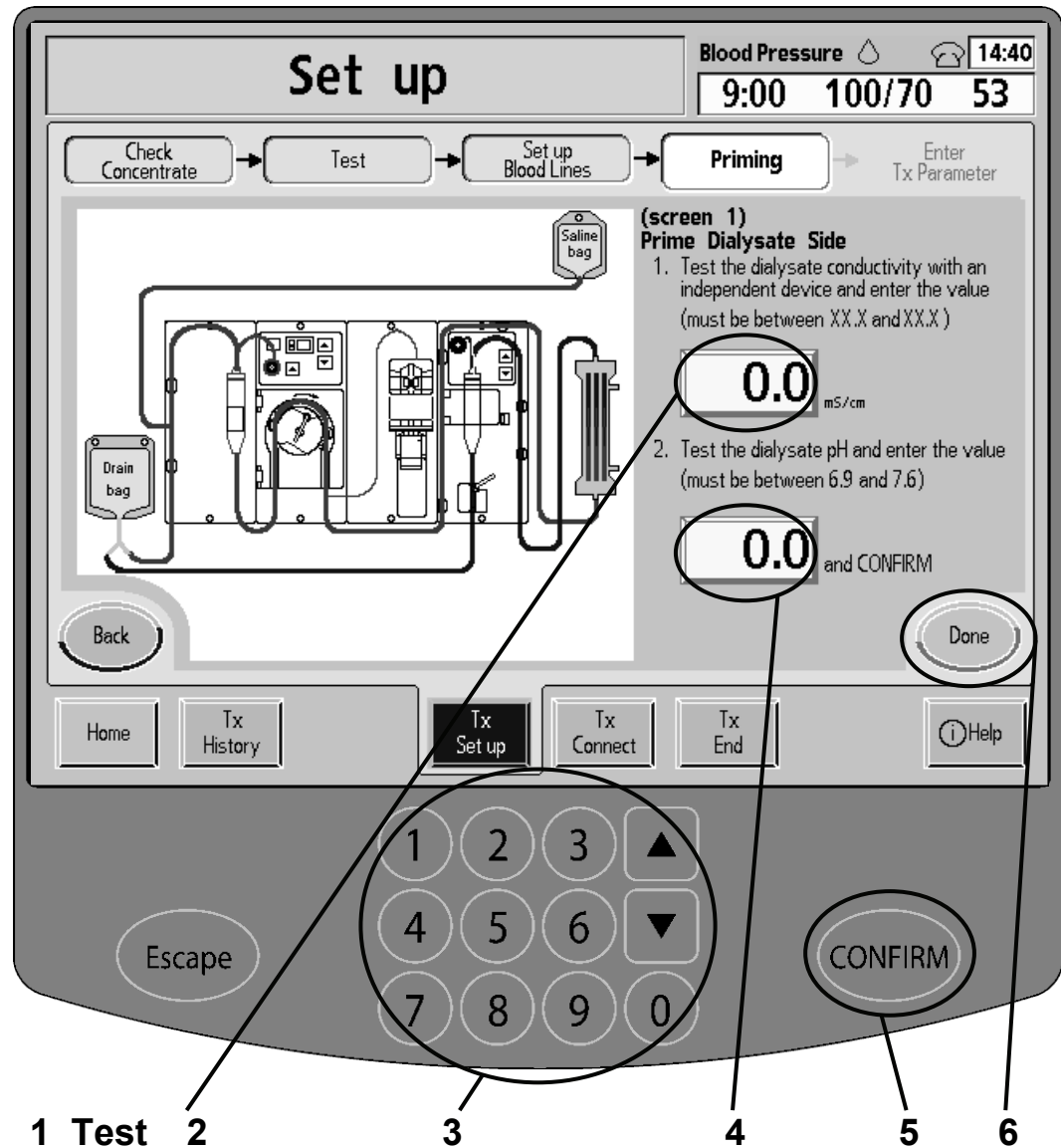
Squeeze the carriage latch and gently slide the carriage upward until it makes contact with the syringe plunger.

7 Close plunger lock tabs over end of syringe plunger

Release the carriage latch, making sure the plunger lock tabs close securely around the end of the syringe plunger.

Testing the Dialysate

TREATMENT



Warning: The values shown here are for example only. You must use the values prescribed by your doctor. If you use the wrong values, it may cause serious injury or death.

1 Test conductivity and pH with an independent meter

Follow the instructions on the next page to test your dialysate for:

- proper conductivity
- pH between 6.9 and 7.6
- residual disinfectant

Test your dialysate as instructed by your clinic, use the “My Treatment Procedures” sheet on page iii for more information.



Warning: After testing the dialysate through independent means (e.g., using a conductivity meter and pH paper or meter), verify that the conductivity is reasonably close to the theoretical value (TCD) and the pH is between 6.9 and 7.6. The machine must also be free of residual disinfectant. If these conditions are not met, do not initiate dialysis.

2 Touch **dialysate conductivity**

Touch the **dialysate conductivity** button to highlight it.

3 Enter values

After you have tested the dialysate for proper conductivity, read the conductivity value from your independent meter. Enter that number using the number pad or **Up/Down Arrow** (▼/▲) keys on the data entry keypad.



Note: If your conductivity or pH values are out of range, the Dialogue Box will alert you. Make sure that the value you entered matches your test reading. If the value is still out of range, take a new dialysate sample to test.

4 Enter dialysate pH

Touch the **dialysate pH** button to highlight it. Using the data entry keypad, enter the pH value from your dialysate test.

5 Press **CONFIRM**

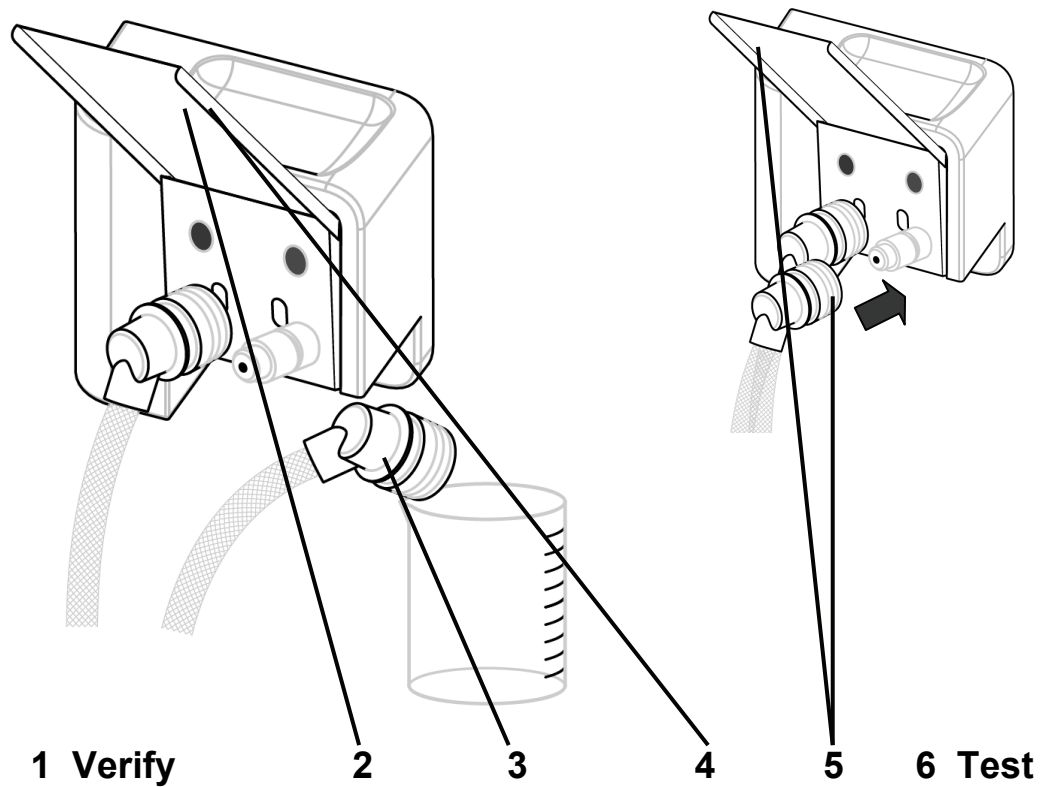
Press the **CONFIRM** key to confirm your selections.

6 Touch **Done**

When your conductivity and pH is within limits, the **Done** button will change from gray (unavailable) to blue. Touch the **Done** button to continue to the next screen.

Testing the Dialysate (continued)

TREATMENT



1 Before testing the dialysate, verify the following:

- ✓ The dialysate lines are on the shunt
- ✓ Your machine's conductivity and temperature readings have stabilized
- ✓ Your independent conductivity meter is properly calibrated
- ✓ You have a clean (non-foam-type) container to collect the dialysate

2 Open the shunt door and unsnap the blue dialysate line

Open the shunt door (see your K Map: 'P'). Remove the blue dialysate line from the shunt and hold the end of the blue dialysate line over your collection container.

3 Rinse container and collect sample for testing

After you close the shunt door, your machine will begin running dialysate through the dialysate line and into the collection container. Collect at least 50 ml then open the shunt door again to stop the dialysate flow. Repeat this step two more times to rinse your collection container to bring it up to the temperature of the dialysate for proper conductivity. Collect a final, third sample for testing.

4 Open the shunt door (see Your K Map: 'P')**5 Snap the blue dialysate line back on the shunt**

With the shunt door open, snap the blue dialysate line back on the shunt. Close the shunt door again.

6 Test the dialysate

See "My Treatment Procedures" on page iii to test the dialysate according to your clinic's instructions for:

- Conductivity - set the meter to read conductivity, introduce the sample to the meter, and observe the readings
- pH - follow the manufacturer's instructions to either use pH paper or a pH meter, then observe the readings
- Residual disinfectant - introduce the sample and observe the readings

Priming the Dialysate Side

TREATMENT

Set up Blood Pressure 14:40
9:00 100/70 53

Check Concentrate → Test → Set up Blood Lines → **Priming** → Enter Tx Parameter

(screen 2)
Prime Dialysate Side

1. Rotate dialyzer
2. Connect blue dialysate line to blue side
3. Connect red dialysate line to red side
4. Close clamp **D** at drain bag
5. Open arterial patient clamp **A**
6. Press **Recirc Saline** and CONFIRM

Blood Line Tests OK Error

Test & Recirc 0% Done

Home Tx History Tx Set up Tx Connect Tx End Help

Escape

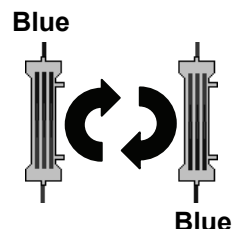
1 2 3 ▲
4 5 6 ▼
7 8 9 0

CONFIRM

6 7

1 Rotate dialyzer

To connect the dialysate lines, first turn the dialyzer upside down so the venous line is on the bottom. Make certain all connections are tight to prevent dialysate or blood leaks.



2 Connect blue dialysate line to venous side of dialyzer

3 Connect red dialysate line to arterial side of dialyzer

Lift up the shunt door (see Your K Map: 'P') and unsnap the dialysate lines from the shunt interlock. Snap the dialysate line quick-connectors to the matching dialyzer connectors: red to red arterial side, blue to blue venous side. Close the shunt door when you are done.



Warning: All quick-connectors must be tightly connected to prevent air from entering the dialysate path or dialysate leaks.

4 Close clamp **(D)** at drain bag

5 Open arterial patient line clamp **(A)**

6 Touch **Recirc Saline**

7 Press **CONFIRM**

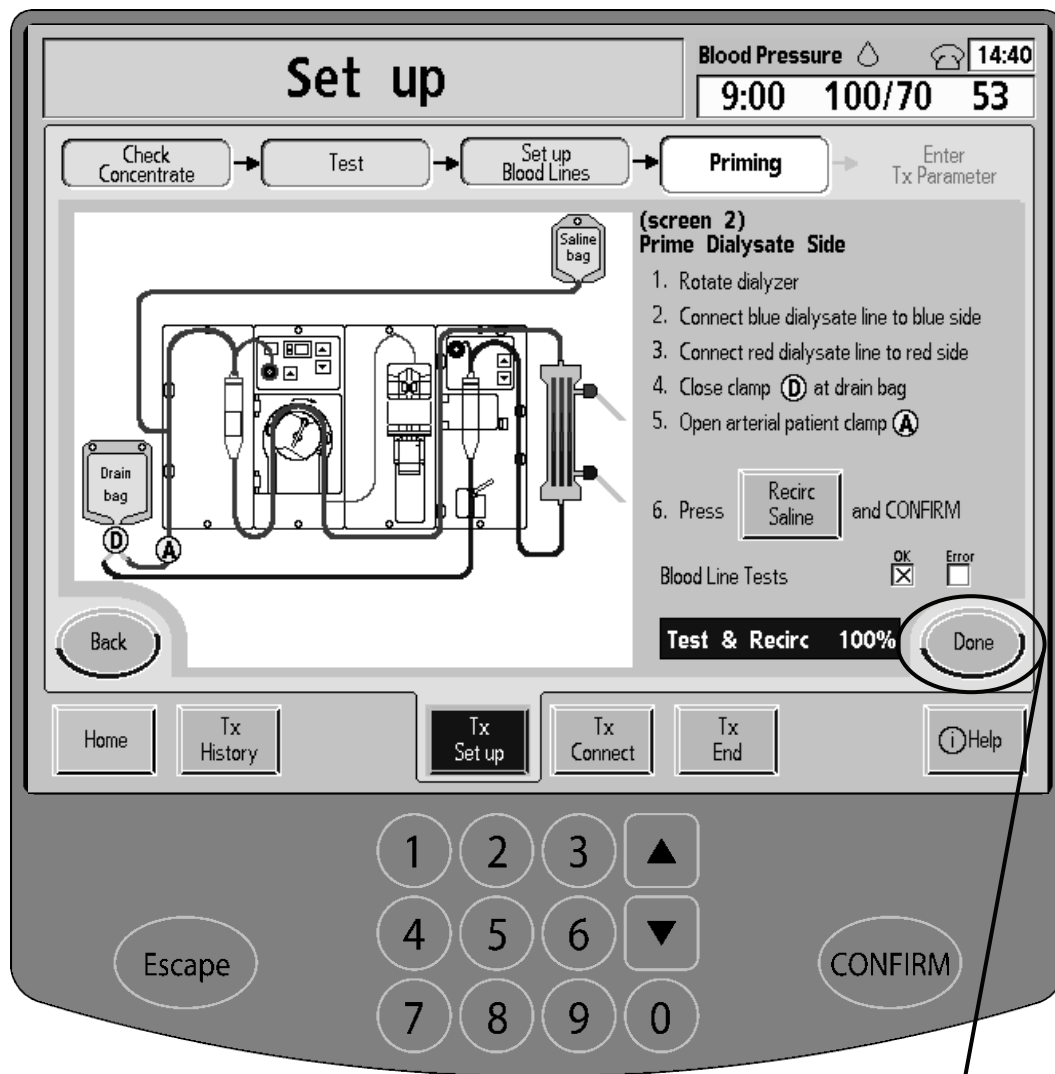
Touch the **Recirc Saline** button then press the **CONFIRM** key. The bloodline test will begin followed by the recirc saline program. A bar graph will fill to show the progress of the test and recirculation program.

The **Recirc Saline** button and **Done** button will be grayed-out as the test runs.

(continued on next page)

Priming the Dialysate Side (continued)

TREATMENT



(continued)

8
Press **RESET**

9

(continued)



Note: If all the air has not been cleared from your dialyzer, turn your dialyzer upside down and right side up again.

Note: Make sure the saline has reached the end of the bloodline when priming.

When your machine passes the bloodline test, a blue “☒” appears in the “OK” column. If any part of the test fails, a red “☒” appears in the “Error” column and the Status Box displays the message: “Test Failed.” For a description of errors, see “Troubleshooting” on page 224.

Your machine will now begin recirculating the saline.

8 Press **RESET** (see Your K Map: ‘B’)

When the recirc saline program is finished your machine will display the message “Recirculating Done” and an alarm will sound. Press the **RESET** key to clear the Status Box message.

9 Touch **Done**

The **Done** button will now be active again. Touch the **Done** button to continue.

Setting Your UF Goal

TREATMENT



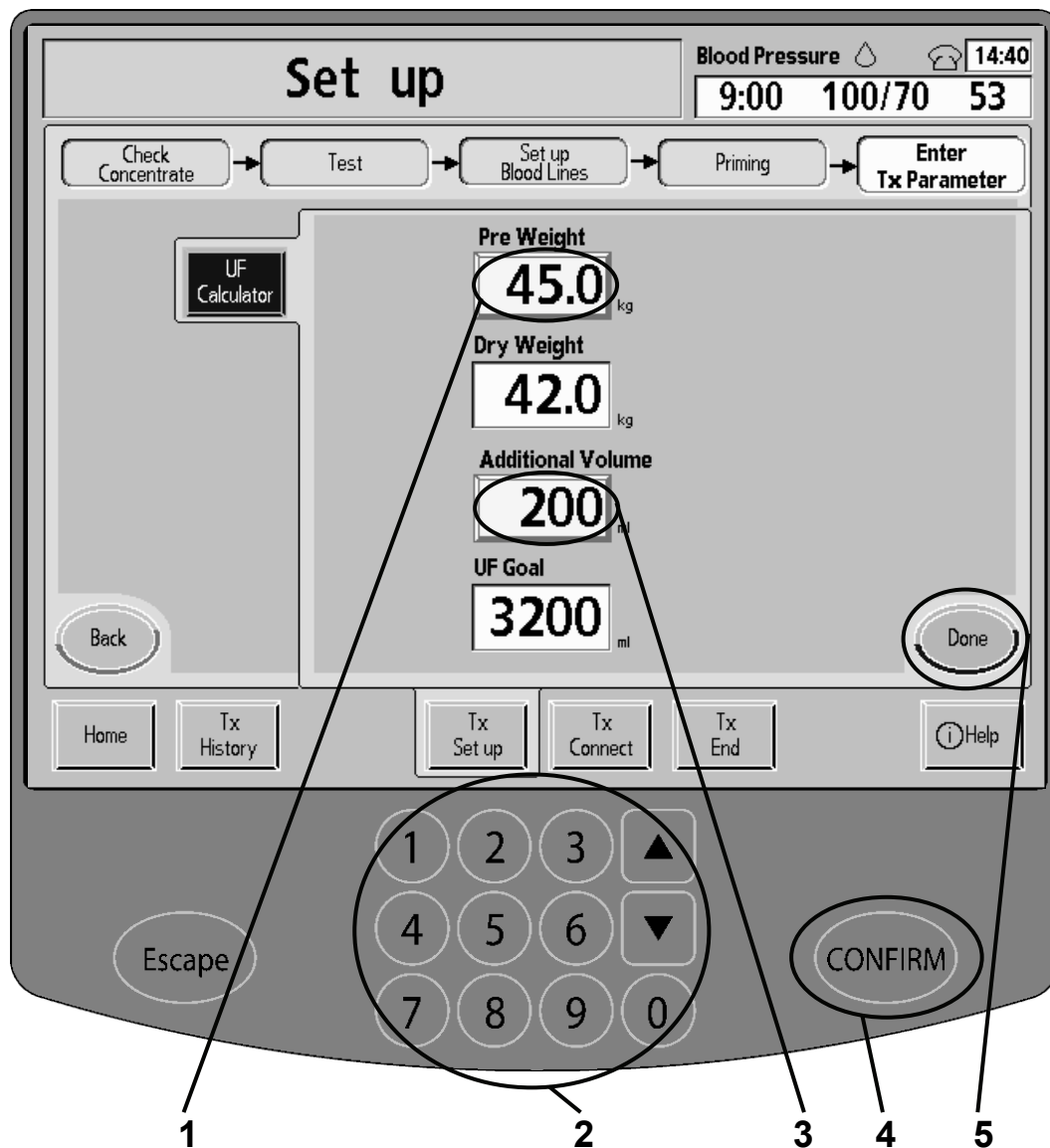
1 Touch **UF Calculator**

Next, you need to set your Ultrafiltration (UF) rate and goal. This is the amount of excess fluid your machine will remove from your body each hour of your treatment. You may either set your own UF Goal or have your machine calculate a value for you.

Using the UF Calculator to calculate your ultrafiltration goal is recommended over setting your own goal. Touch the **UF Calculator** screen-button to go to the “UF Calculator” screen.

UF Calculator

TREATMENT



Warning: The values shown here are for example only. You must use the values prescribed by your doctor. If you use the wrong values, it may cause serious injury or death.

1 Touch **Pre Weight**

Touch the **Pre Weight** button to highlight it.

2 Enter values

Enter your current weight in kilograms using the number pad or **Up/Down Arrow (▼/▲)** keys on the data entry keypad. Your “Dry Weight” is displayed automatically.



Note: Your weight must be measured in kilograms. 2.2 lbs. = 1 kg (kilogram).

Note: If the Dialogue Box displays a message that your pre weight is too high or low, see “My Treatment Procedures” on page iii.

3 Enter Additional Volume

Touch the **Additional Volume** button to highlight it. Using the data entry keypad, enter the amount of fluid you plan on drinking (in milliliters) during treatment.



Note: One fluid ounce is equal to about 30 ml.

Next, use the “My Treatment Procedures” sheet, on page iii, for the volume of saline you will use during treatment. Add that volume to your “Additional Volume.”

4 Press **CONFIRM**

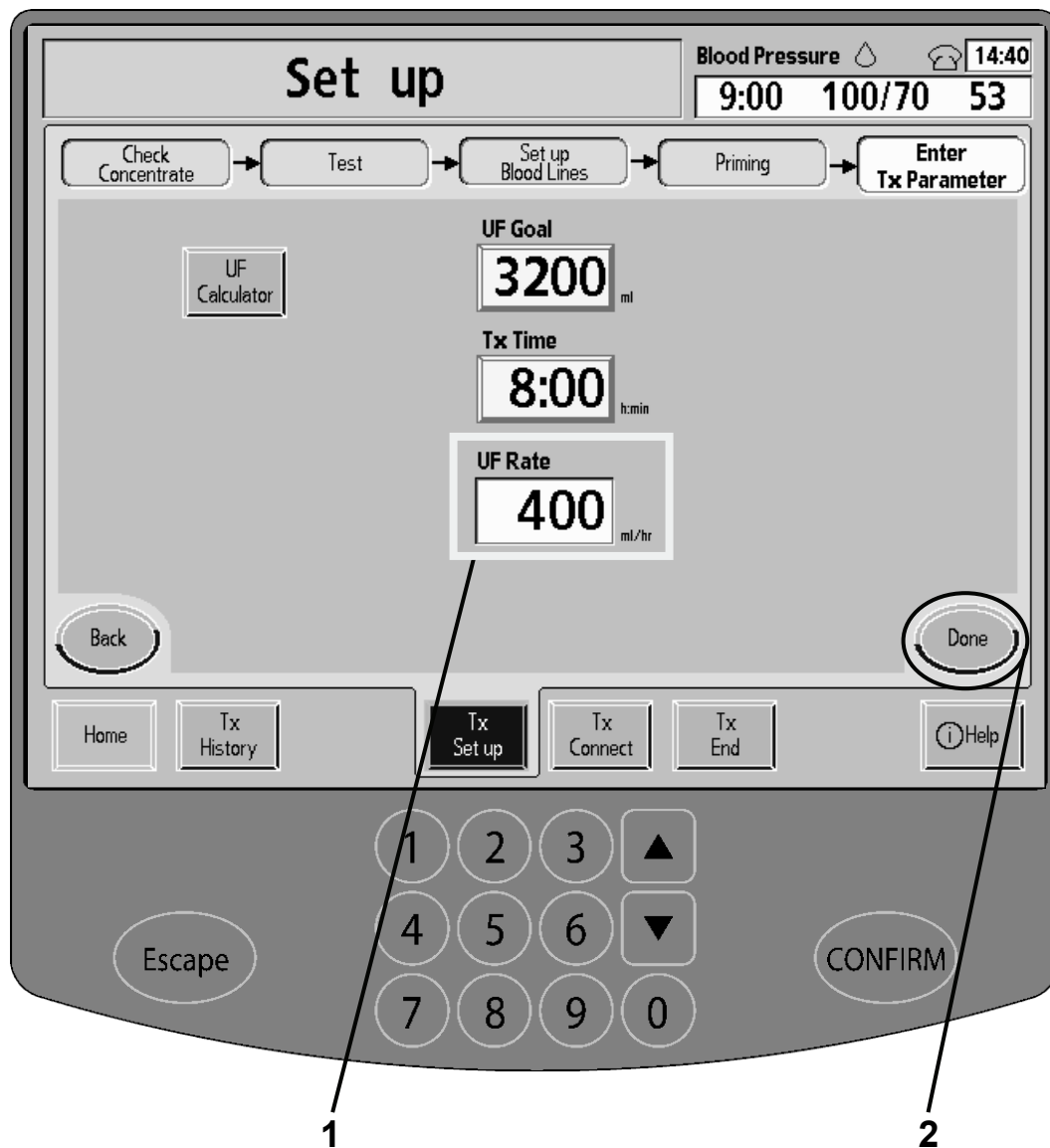
Press the **CONFIRM** key to confirm your selections.

5 Touch **Done**

Touch the **Done** button. Your UF goal will be calculated and displayed on the “UF Goal” screen when you return to it.

New UF Rate Calculated

TREATMENT



Warning: The values shown here are for example only. You must use the values prescribed by your doctor. If you use the wrong values, it may cause serious injury or death.

1 New UF Rate

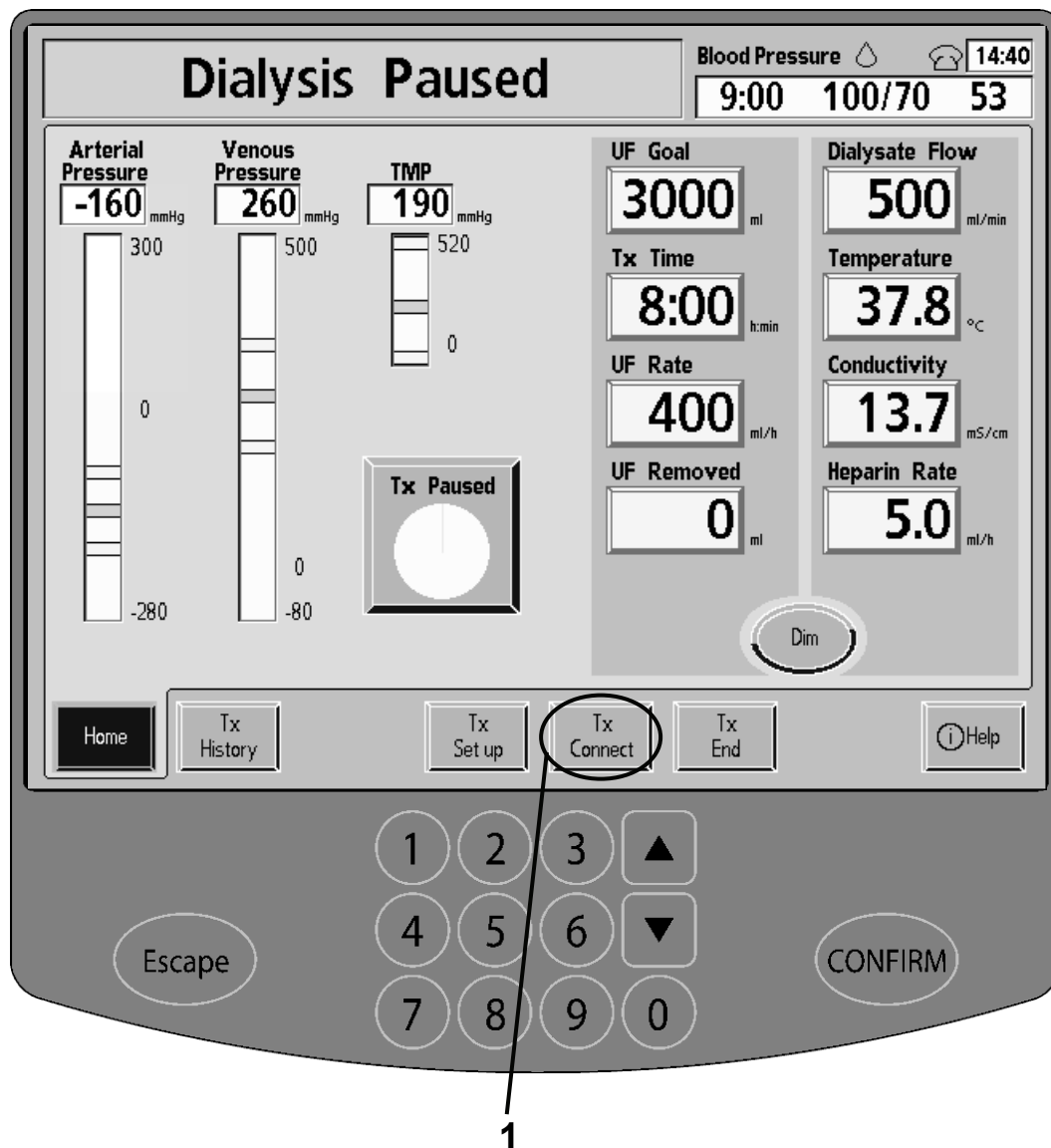
The meter box now shows your calculated UF rate.

2 Touch **Done**

Touch the **Done** button. You will go to the dialysis “Home” screen.

Connecting for Treatment

TREATMENT



Warning: The values shown here are for example only. You must use the values prescribed by your doctor. If you use the wrong values, it may cause serious injury or death.

Connecting Requirements

You must complete the following requirements before connecting for your treatment:

- ✓ Check that your machine has passed all pressure and alarm tests
- ✓ Check that the dialysate is at the proper temperature and conductivity and pH
- ✓ Check that the dialysate is tested and free of traces of disinfectant
- ✓ Check that your machine's bypass mode is functioning correctly by lifting the shunt door (see your K Map: 'P'). The float in the dialysate flow indicator should drop and remain at the bottom of the indicator. An audible alarm should sound (unless it was turned off in Service Mode). Close the shunt door again.



Warning: If any of the conditions listed above have not been met, you must correct them before continuing with your treatment preparation. Failure to do so may cause serious injury or death.

Warning: You must test the conductivity and approximate pH of the dialysate with an independent device before connecting for treatment. Improper conductivity or pH may cause serious injury or death.

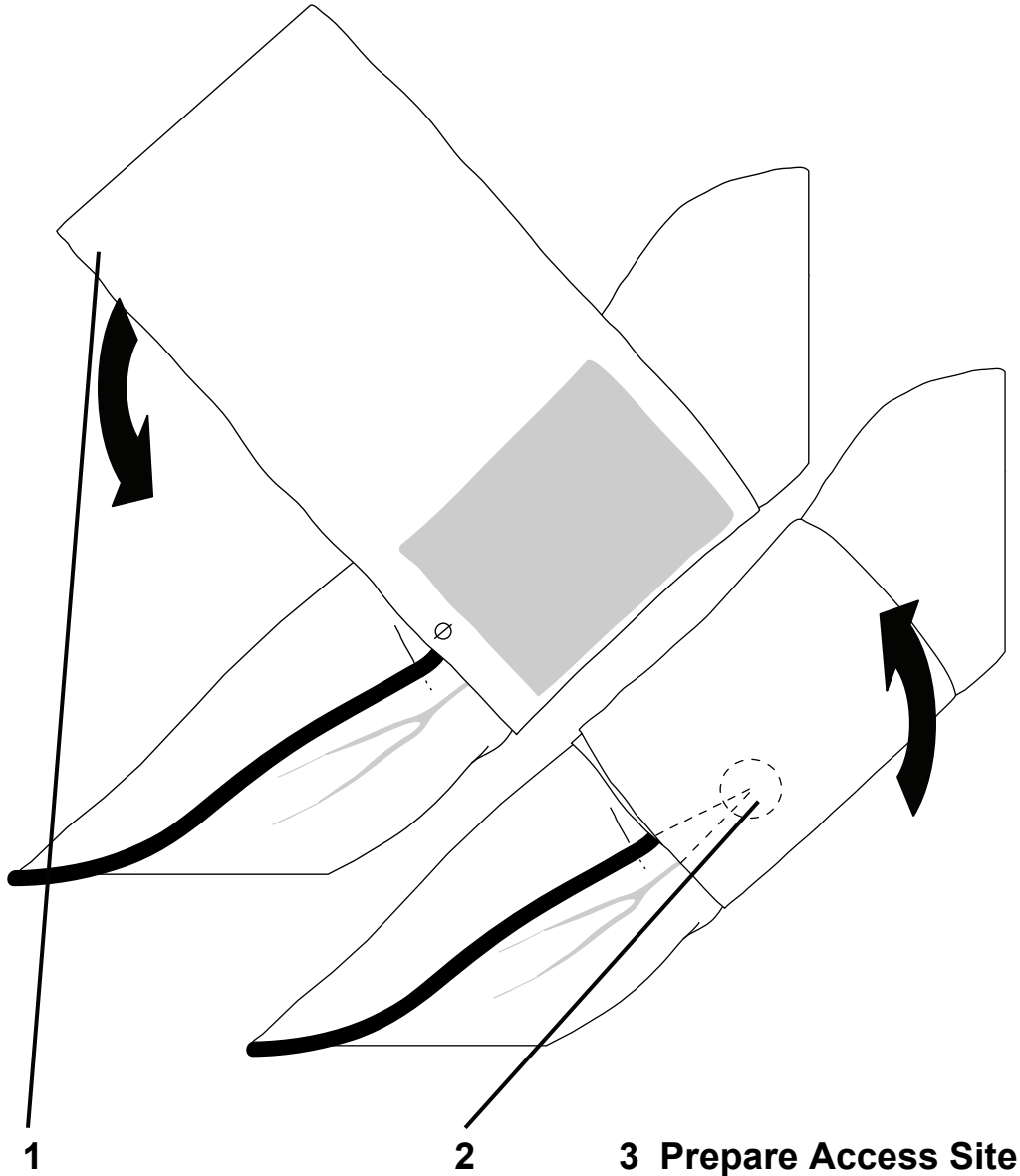
Note: To review pressure and alarm test results, you may touch the **Help** screen-button in the lower right hand corner of the display. See "The Help Screen" on page 200 for more information.

1 Touch **Tx Connect**

From the dialysis "Home" screen, touch the **Tx Connect** screen-button to begin the final connections for dialysis. Next you need to fit the blood pressure cuff and prepare your access site: follow the instructions on the next page.

Fitting the Blood Pressure Cuff

TREATMENT



1 Place blood pressure cuff

At this point in your treatment preparations, you need to put the blood pressure cuff on the limb not used for your access. Roll up your sleeve or pant leg if necessary. Thick clothing may cause inaccurate readings. If you are using the blood pressure cuff on your arm, place the deflated blood pressure cuff on your upper arm 2.5 to 5 cm (1 to 2 inches) above the elbow and level with your heart.



Caution: If you use a thigh blood pressure cuff, follow the manufacturer's instructions.



Note: Do not wear the blood pressure cuff on a limb used for access.

Note: Using blood pressure tubing longer than 10 feet may cause false blood pressure readings.

2 Wrap blood pressure cuff around limb

The cuff should fit snugly but allow enough room for you to slip your fingertip between it and your limb. If on the arm, the pressure tubing must line up with your brachial artery under the cuff, running along the inside of your arm.



Warning: An incorrectly fitted arm cuff may cause inaccurate readings due to improper compression of the brachial artery. Each centimeter above or below your heart level will cause an error of ± 0.8 mmHg.



Caution: Do not squeeze the blood pressure cuff when deflating it. Squeezing the blood pressure cuff may damage your machine's internal blood pressure module.



Note: You may press the Stat/Deflate key (see Your K Map: 'O') in the Patient section of the Control Panel to inflate the cuff and measure your blood pressure. Your blood pressure will continue to be monitored, but will not be recorded until your treatment begins.

3 Prepare access site

Place an underpad beneath your access and follow your clinic's instructions. Use aseptic technique.

Flushing the Lines

TREATMENT

Tx Connect Blood Pressure 14:40
9:00 100/70 53

Flush Saline → Connect Blood Lines → Start Treatment

Flush

1. Stop blood pump
2. Change saline bag
3. Open clamp **(D)** and gravity flush arterial line to drain bag
4. Close arterial clamp **(A)**
5. Start blood pump
6. Run 300 ml into drain bag
7. Stop blood pump
8. Close clamps **(S, D, V)**
9. Press **(9)** and CONFIRM

Is Line Flushed?
Yes No

Back Done

Home Tx History Tx Set up Tx Connect Tx End Help

Escape 1 2 3 4 5 6 7 8 9 0 CONFIRM

9 10 11

1 Stop blood pump (see Your K Map: ‘D’)
To stop the blood pump, press the **Start/Stop** key on the Blood Pump module.

2 Change saline bag
Make certain that you will have enough saline for your entire treatment.

3 Open clamp (D) and gravity flush arterial line to drain bag

4 Close arterial patient clamp (A)

5 Start blood pump (see Your K Map: ‘D’)
To start the blood pump, press the **Start/Stop** key on the Blood Pump module.

6 Run 300 ml saline into drain bag
Watch the saline bag level drop to measure 300 ml.



Warning: You must test the Level Detector system before treatment. To test your machine: Press the **Down (▼) Level Adjust** key (see your K Map: ‘L’) to lower the fluid level in the venous drip chamber. If the blood pump does not stop and the Venous Clamp (see your K Map: ‘K’) does not close, remove your machine from service and call a qualified technician. Press the **Up (▲) Level Adjust** key to raise the venous drip chamber level again.

7 Stop blood pump (see Your K Map: ‘D’)
When the saline bag has drained 300 ml, press the **Start/Stop** key on the Blood Pump module to stop the blood pump.

8 Close clamps (S) (D) (V)

9 Touch **Is Line Flushed?**

10 Press **CONFIRM**

Check that the patient ends of the venous and arterial bloodlines are flushed. There should be no air in the lines going to the drain bag. If the lines are free from air bubbles, touch the **Is Line Flushed?** toggle-button to set it from ‘No’ to ‘Yes’. Press the **CONFIRM** key to confirm the selection.

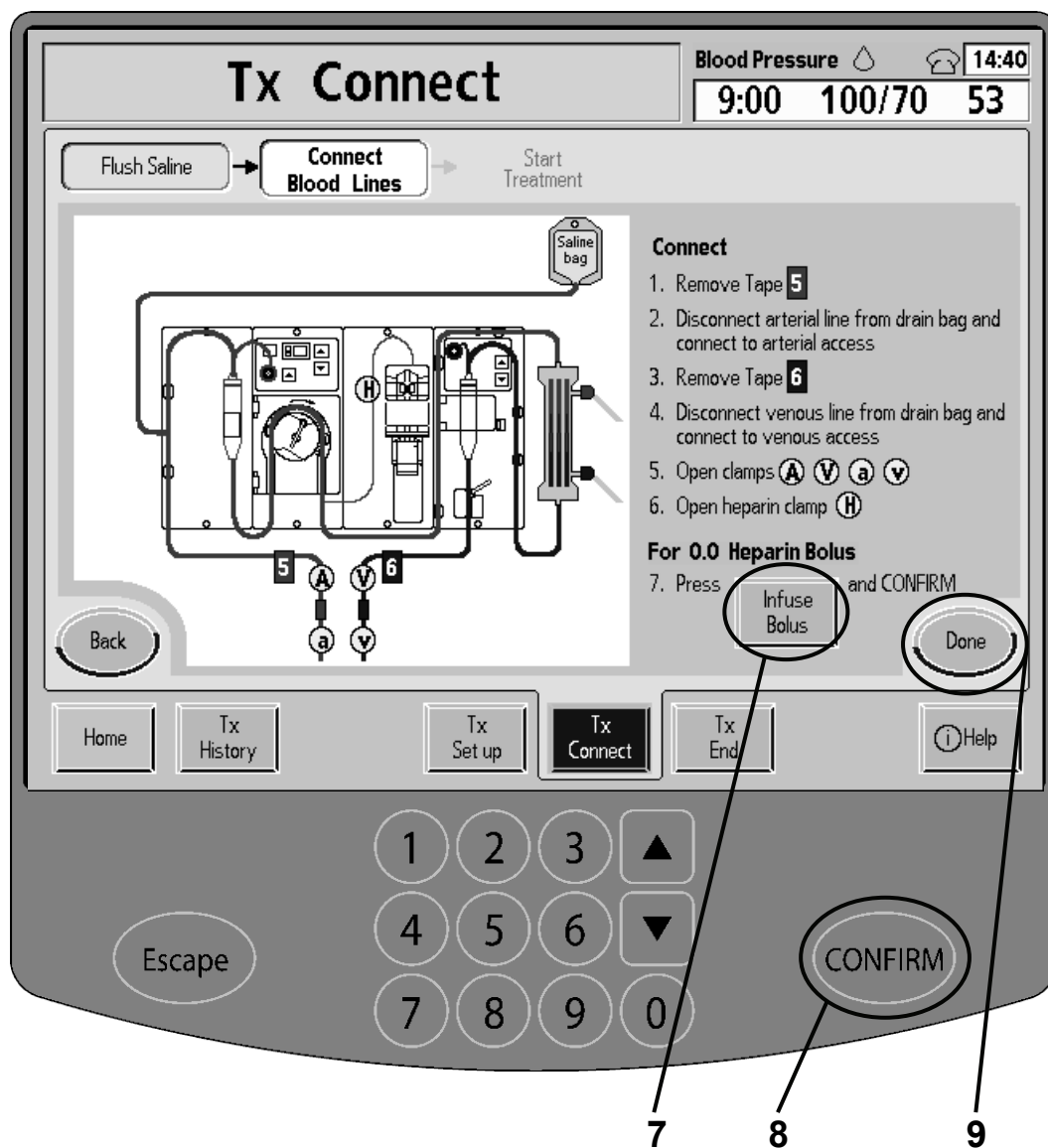
If the lines are not yet flushed, open the clamps from step 8, turn on the blood pump and flush the lines with more saline. Repeat steps 8 - 10 when the lines are flushed.

11 Touch **Done**

Touch the **Done** button when you are ready to continue.

Connecting the Bloodlines

TREATMENT



Warning: The values shown here are for example only. You must use the values prescribed by your doctor. If you use the wrong values, it may cause serious injury or death.

1 Remove Tape 5

Tear off only the tape labeled with a red **5** to uncoil the patient end of the arterial bloodline.

2 Disconnect arterial line from Drain Bag and connect to arterial access**3 Remove Tape 6**

Tear off only the tape labeled with a blue **6** to uncoil the patient end of the venous bloodline.

4 Disconnect venous line from drain bag and connect to venous access

Warning: Check all bloodlines and dialysate lines for leaks after your treatment has started. Keep access sites uncovered and monitored. Improper bloodline connections or needle dislodgements can result in excessive blood loss, serious injury and death. Machine alarms may not occur in every blood loss situation.

Warning: Check all bloodlines for kinking. Improper blood flow may cause hemolysis of the blood.

Warning: Infusing recirculated saline is not recommended. Use fresh, sterile saline, if required.

5 Open clamps (A)(V)(a)(v)

Open all arterial and venous line clamps.

6 Open heparin line clamp (H)**7 Touch **Infuse Bolus** if prescribed****8 Press **CONFIRM****

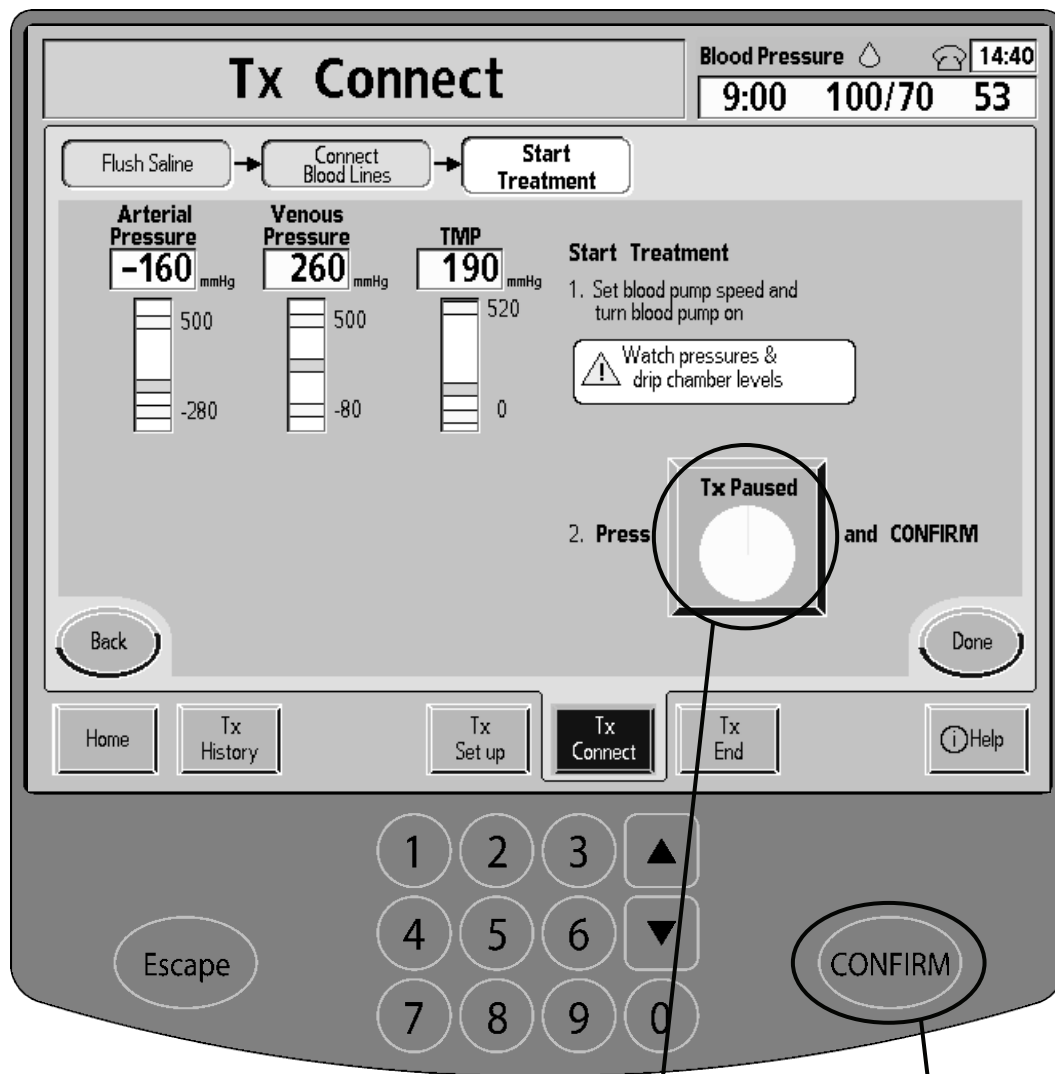
If your machine is set up for a heparin bolus, the **Infuse Bolus** button will be displayed. Make sure that your prescribed amount is displayed. Touch the **Infuse Bolus** button and press the **CONFIRM** key to begin the bolus.

9 Touch **Done**

When you have completed these steps, touch the **Done** button to go to the “Start Treatment” screen.

Starting the Blood Pump

TREATMENT



1 Set blood pump speed and turn blood pump on

2

3

1 Set blood pump speed and turn blood pump on (see Your K Map: ‘D’)

Set the blood pump speed with the **Blood Pump Up/Down Arrow (▼/▲)** keys (see Your K Map: ‘E’). The pump speed is shown in the Blood Pump module Display Window. Next, start the blood pump by pressing the **Start/Stop** key on the Blood Pump module.

Run the blood pump slowly at first, adjusting it with the **Blood Pump Up/Down Arrow (▼/▲)** keys (see Your K Map: ‘E’) on the module until you reach your prescribed rate. Your rate is listed on the “My Treatment Parameters” sheet, on page ii.

The arterial and venous pressures should change steadily. Make certain the pressures do not cross the alarm limits. Watch that the drip chambers do not drain completely. Press the **Level Adjust (▲)** key (see Your K Map: ‘G’) on the Blood Pump module to raise the arterial drip chamber level, if necessary.



Warning: The **Level Adjust (▲)** key can only raise the blood level in the arterial drip chamber. Do not raise the level so high that the transducer protector becomes wet. Wet transducer protectors must be replaced. Failure to do so may cause injury or death.

Warning: Keep fingers clear of the blood pump rotor when it is running. Serious injury may occur.

Warning: Check all bloodline connections for leaks after your treatment has started. Improper bloodline connections could cause blood loss and death. Keep your access site uncovered.



Note: If your machine is set up to use the WetAlert wireless wetness detector, the Dialogue Box will prompt you to activate your device at this time. See the WetAlert Home User’s Guide (P/N 507939) for more information.

2 Touch **Tx Paused**

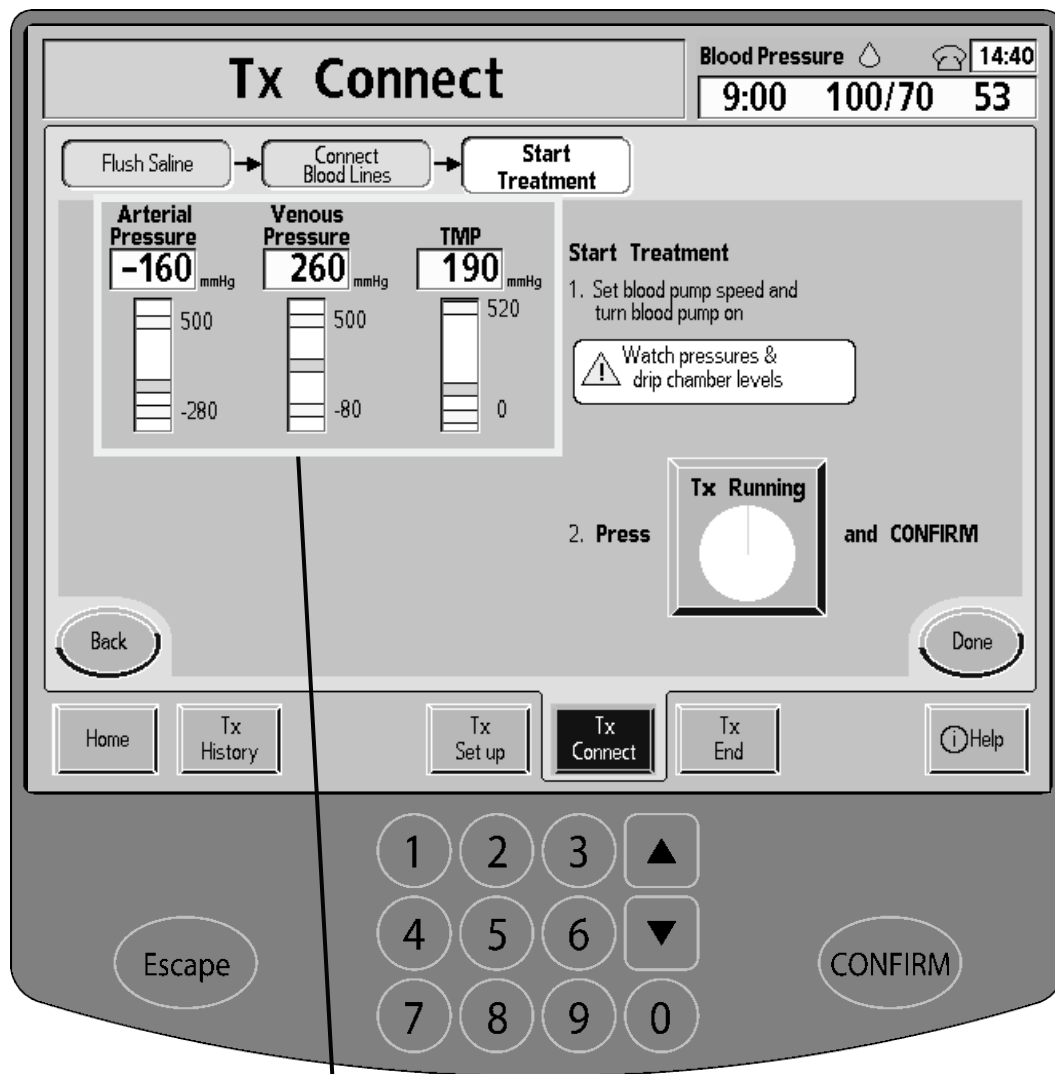
3 Press **CONFIRM**

Touch the **Tx Paused** button then press the **CONFIRM** key. This will start the Tx Clock.

(continued on next page)

Starting the Blood Pump (continued 1)

TREATMENT



(continued) 4

(continued)

“Tx Paused” will change to “Tx Running” and begin counting down your treatment. The heparin pump will begin running if prescribed.

4 Monitor the arterial, venous, and TMP pressures

Your Arterial, Venous and Transmembrane (TMP) pressures are displayed here. Watch that the green pressure level bars do not move outside of the yellow bar limits as your treatment begins. Unusually high or low pressures may be caused by kinks in the blood tubing, clotting, or a needle pressing against a vessel wall.

If pressure readings move outside alarm limits:

- The pressure bar changes to red (after a short delay)
- An alarm sounds
- The blood pump stops
- The Venous Clamp closes
- The Status Box displays an alarm message



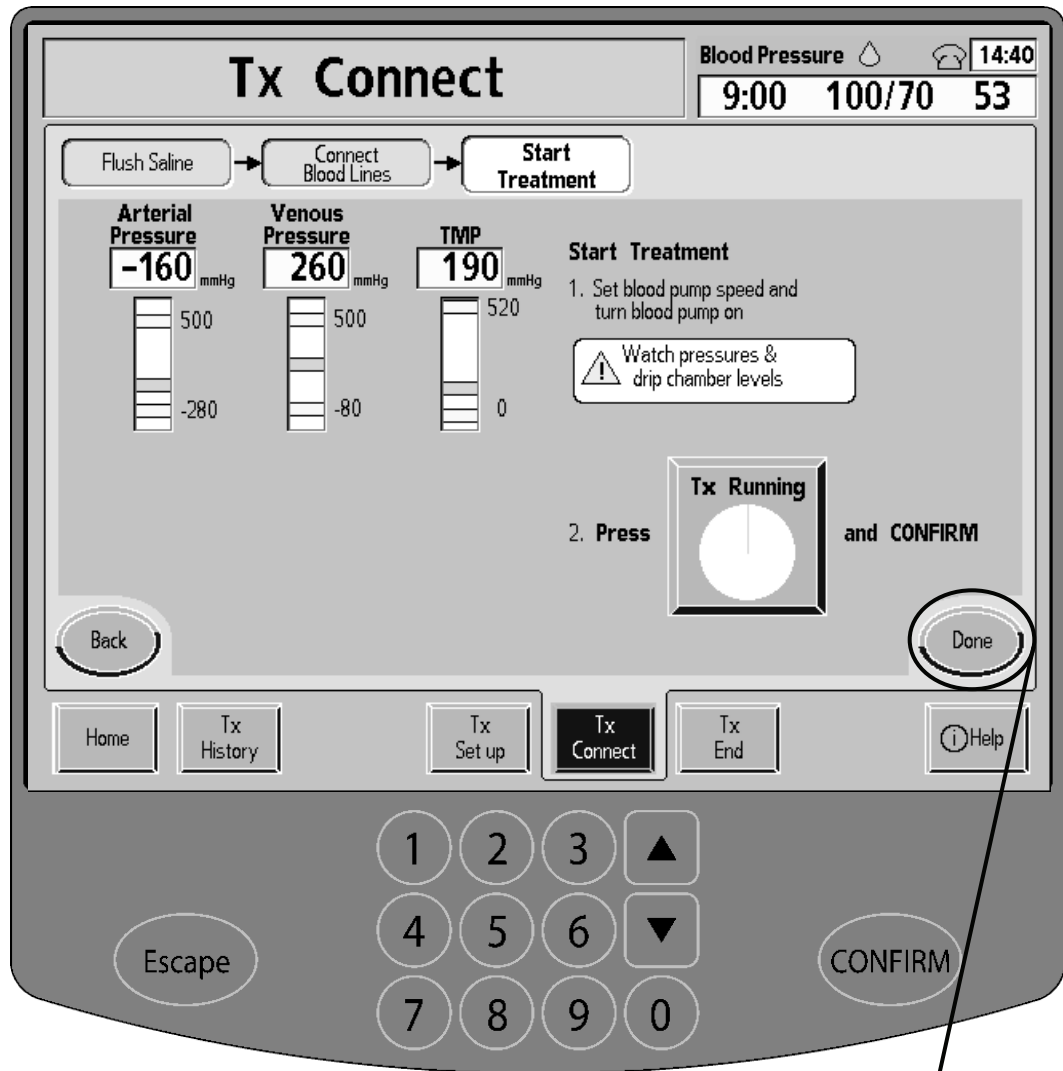
Caution: If you run out of concentrates during treatment, turn the dialysate flow pumps off before replacing a jug or switching from a *bibag* disposable to a jug. The pumps must be off to avoid drawing air into the system, as it can cause dialysate concentrate pump errors. The optional *bibag* connector’s door must be closed with no *bibag* disposable connected. To turn off dialysate flow in the dialysis “Home” screen:

Touch the **Dialysate Flow** button to highlight it, and then use the **Down Arrow (▼)** key on the data entry keypad to set the button to “OFF.” Press the **CONFIRM** key to confirm the selection. Turn dialysate flow back on to your prescribed rate when you resume treatment.

(continued on next page)

Starting the Blood Pump (continued 2)

TREATMENT



(continued)

5

(continued)



Warning: Dialysate leaks in the dialyzer will add to your ultrafiltration rate. Watch the system for fluid leaks. Stop your treatment if you cannot correct any fluid leak quickly. Failure to do so may cause serious injury or death.

Warning: When blood flow is established, check the bloodlines for air. Air must not enter your access lines.

Warning: The pressure changes from an access line separation or needle dislodgement may be too small for your machine to detect. All access sites and connections must be uncovered, properly, secured and checked regularly. Failure to do so may cause serious injury or death.

Warning: After starting dialysis, calculate to see if the TMP corresponds to the dialyzer's ultrafiltration coefficient (KUF). TMP must be closely monitored with the alarm limits. The TMP may not change substantially during UF errors when high permeable dialyzers are in use. A fluctuating TMP may indicate a leak in the dialysate side of the system. Some, but not all, UF errors can be checked by measuring the volumetric accuracy of the UF pump via the fluid sample port using a graduated cylinder. If the cause cannot be corrected quickly, discontinue treatment.



Note: The approximate expected TMP can be calculated from the dialyzer blood KUF and the UF rate:

$$\frac{\text{UF Rate}}{\text{Dialyzer Coefficient or KUF}} = \text{Approximate Expected TMP}$$

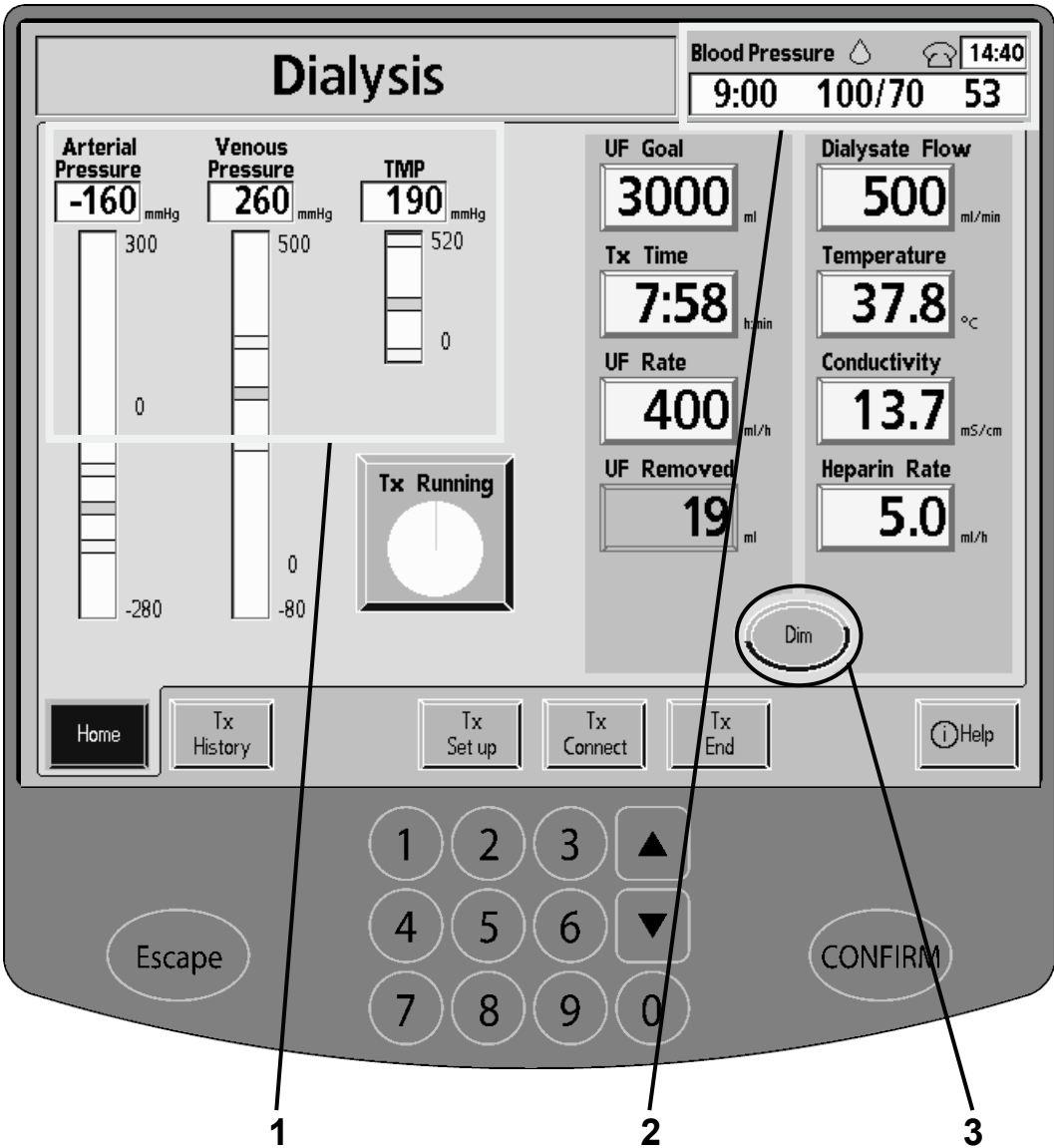
See “My Treatment Procedures” on page iii for your dialyzer's KUF and the expected TMP.

5 Touch **Done**

Touch the **Done** button to go to the dialysis “Home” screen. Continue to monitor your pressures there.

Treatment: The Dialysis Home Screen

TREATMENT



Warning: The values shown here are for example only. You must use the values prescribed by your doctor. If you use the wrong values, it may cause serious injury or death.

1 Monitor the arterial, venous, and TMP pressures

The dialysis “Home” screen displays your information during treatment. Continue to monitor the Arterial, Venous, and Transmembrane (TMP) pressure bar graphs shown on the left side of the Display Screen.

2 Dialogue Box

The Dialogue Box shows your last blood pressure and pulse rate and the time they were measured. The Dialogue Box also displays the current time.

If you have activated the optional WetAlert device for your treatment, the Dialogue Box will show a green Drop icon. A red Drop icon means that wetness is detected. At that time, your machine will stop the blood pump, close the Venous Clamp, sound an alarm, and display a message in the Status Box. Use the “Troubleshooting” section on page 224 to help you clear the alarm. If the Drop icon is yellow, the device is disabled and will not sense wetness. See the WetAlert Home User’s Guide (P/N 507939) for more information.

3 Example: Touch **Dim**

Touch the **Dim** button to darken the screen like a screen-saver. The entire display will be dark except for the clock in the Dialogue Box. You may turn the display back on again by touching anywhere on the screen. Status Box notices automatically turn your display back on.

During Treatment

If you are using the *bi*bag disposable as your bicarbonate source, see the Estimated *bi*bag disposable run time table on page 316 for estimated run times.

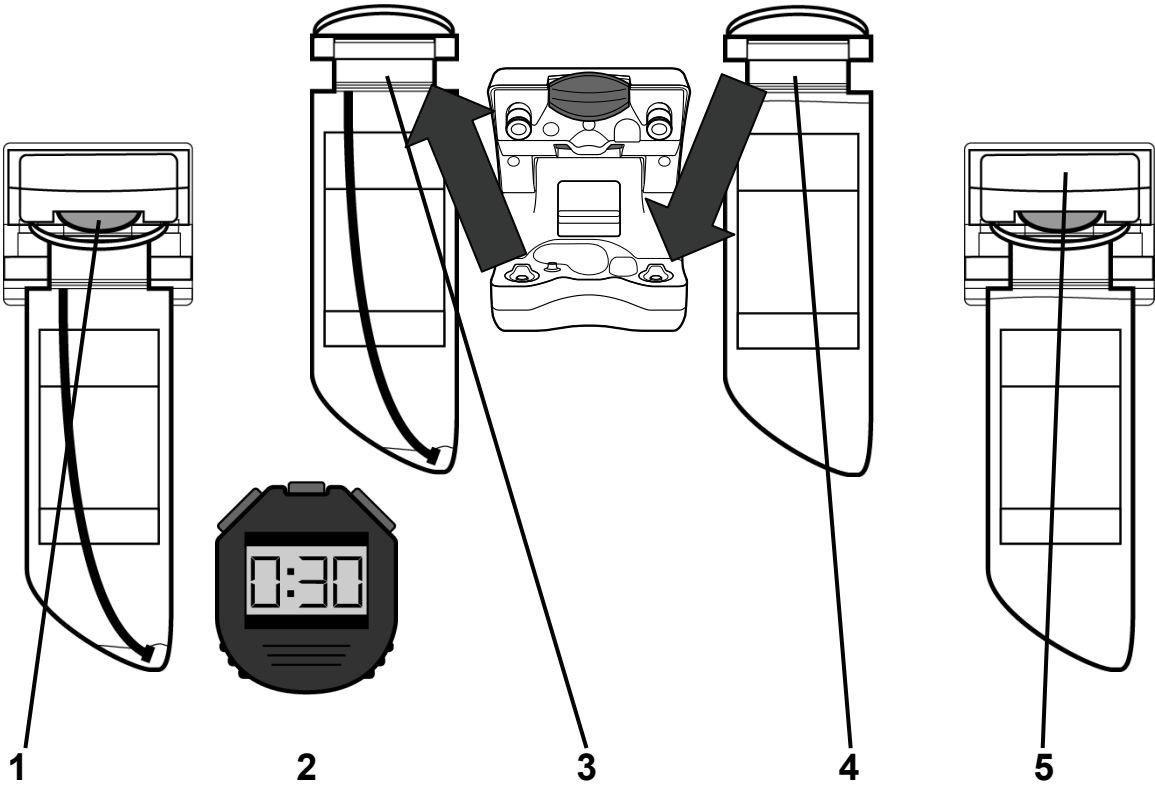


Note: If a “*bi*bag: Cond Low” alarm occurs when there is only about one inch (2.5 cm) of bicarbonate left at the bottom of the *bi*bag disposable, the bag is at the end of its useful life. Replace the bag with a fresh bag (see the next page for instructions).

Continue to page 136 for more information about the time during your treatment.

Changing a bibag Disposable

TREATMENT



Changing a *bibag* disposable during your treatment

If the *bibag* disposable needs to be changed during your treatment, use the following steps:



Note: The **Empty *bibag*** button on the “Conductivity” screen is only for use at the end of treatment.

1 Open *bibag* door

Lift up on the dark-gray *bibag* door handle to open the *bibag* door.

2 Wait 30 seconds

Wait 30 seconds to relieve the pressure in the bag.

3 Remove used bag

Lift up the *bibag* disposable by the handle and lift it off the *bibag* connector. Follow your Home Therapies Nurse’s instructions on how to dispose of the used bag. Since the used bag is not empty of fluid, be careful to prevent spills.



Note: If you are disposing of leftover bicarbonate solution down a drain, be sure to run plenty of hot water down the drain too. This will help prevent bicarbonate buildup in the plumbing.

4 Connect new bag

For the new *bibag* disposable: remove the white plastic seal from underneath the water and bicarbonate nozzles. Then hang the bag on your machine’s *bibag* connector nozzles.

5 Close *bibag* door

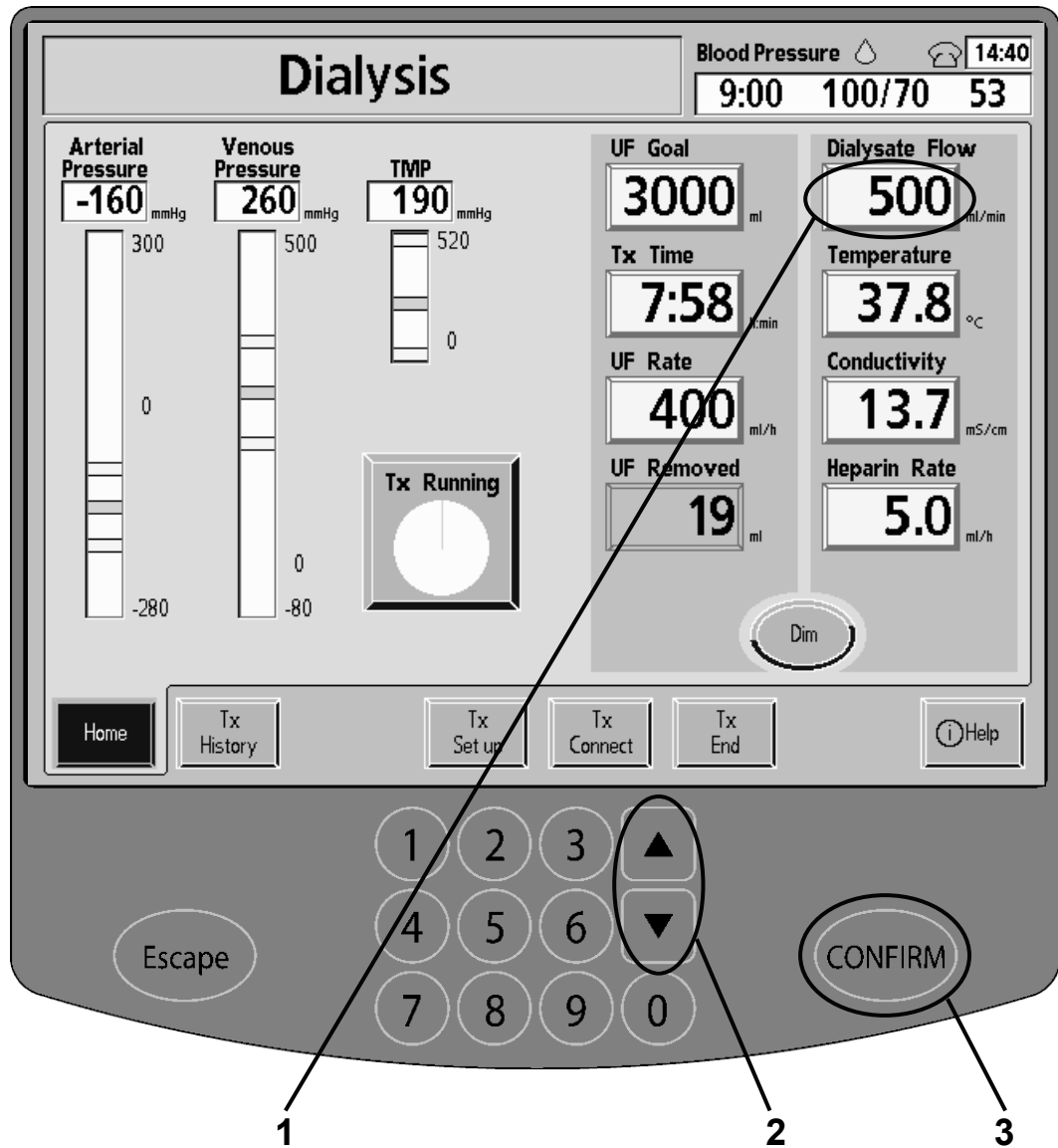
Close the *bibag* door, making sure it latches firmly in place. An audible click means the door is closed. Your treatment will continue after your machine fills the bag with heated water.



Note: You may need to wait 6-10 minutes as the new bag fills. Your machine will automatically go into bypass mode until the new bag is filled and conductivity comes into acceptable range.

During Treatment (continued)

TREATMENT



Warning: The values shown here are for example only. You must use the values prescribed by your doctor. If you use the wrong values, it may cause serious injury or death.

During Treatment (continued)

The Tx Clock will continue to count down until either the “Tx Time” has reached “0:00” or your “UF Removed” is equal to your “UF Goal.”



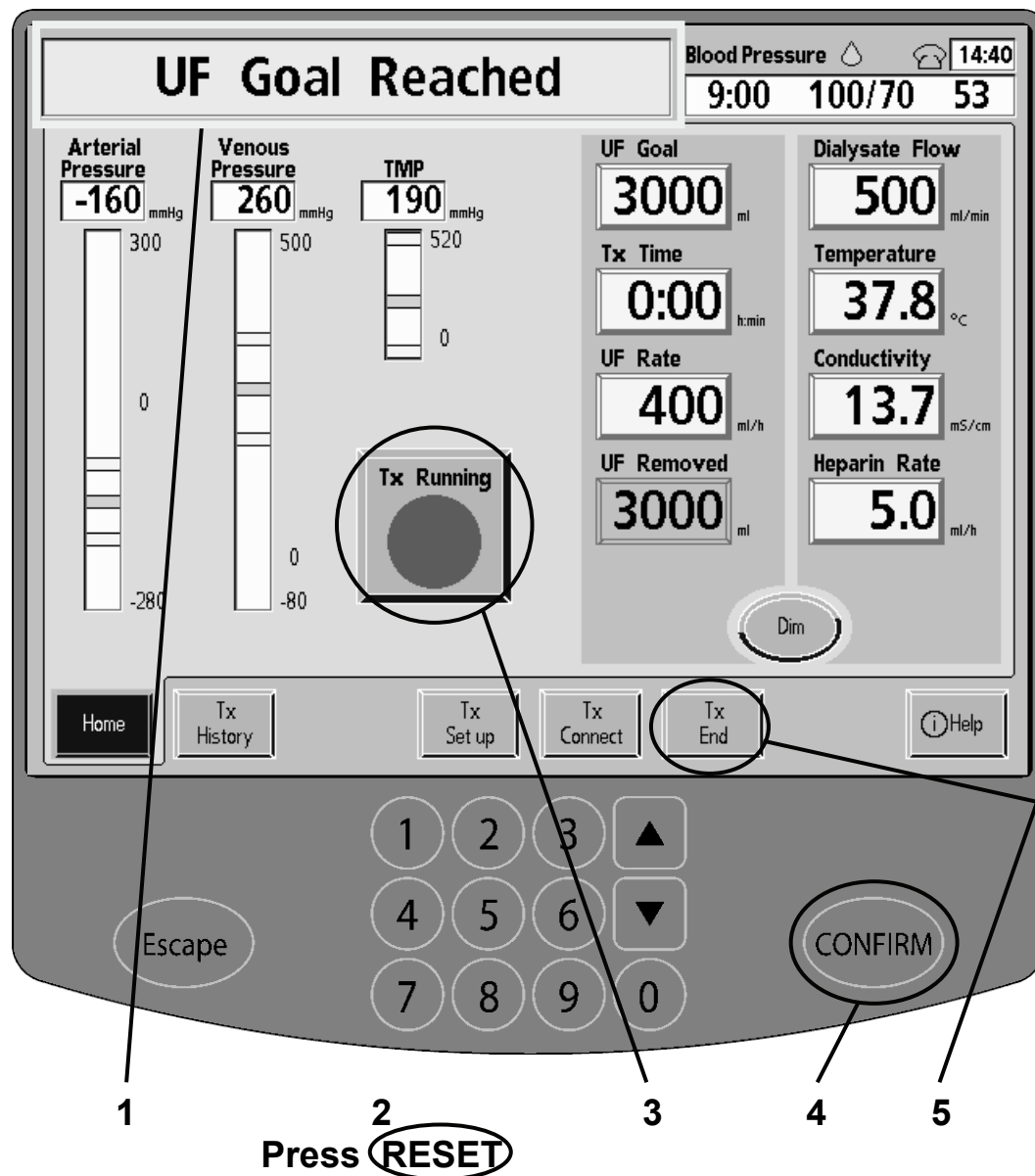
During this time you may choose to review your treatment history. To do so, please see “Reviewing Your Treatment History” on page 286.

If you need to pause your treatment, see “Pausing Your Treatment” on page 298.

Other useful information is listed in Appendix A on page 284.

Ending Your Treatment

TREATMENT



Warning: The values shown here are for example only. You must use the values prescribed by your doctor. If you use the wrong values, it may cause serious injury or death.

1 UF Goal Reached message

At the end of your treatment when the Tx Time has reached “0:00,” a warning will sound. The message, “UF Goal Reached” will appear in the Status Box.



Warning: The “UF Goal Reached” alert is an important feature of your 2008K@home hemodialysis machine. Reaching your prescribed UF Goal is important. If you do not reach your prescribed UF Goal, it may lead to fluid overload, serious injury and death.



Note: When your Tx Time and UF Goal are set to 0, your UF Rate will automatically be set to 10 ml/h.

2 Press **RESET** (see Your K Map: ‘B’)

To reset the alarm, press the **RESET** key in the Machine section of the Control Panel.

3 Touch **Tx Running**

4 Press **CONFIRM**

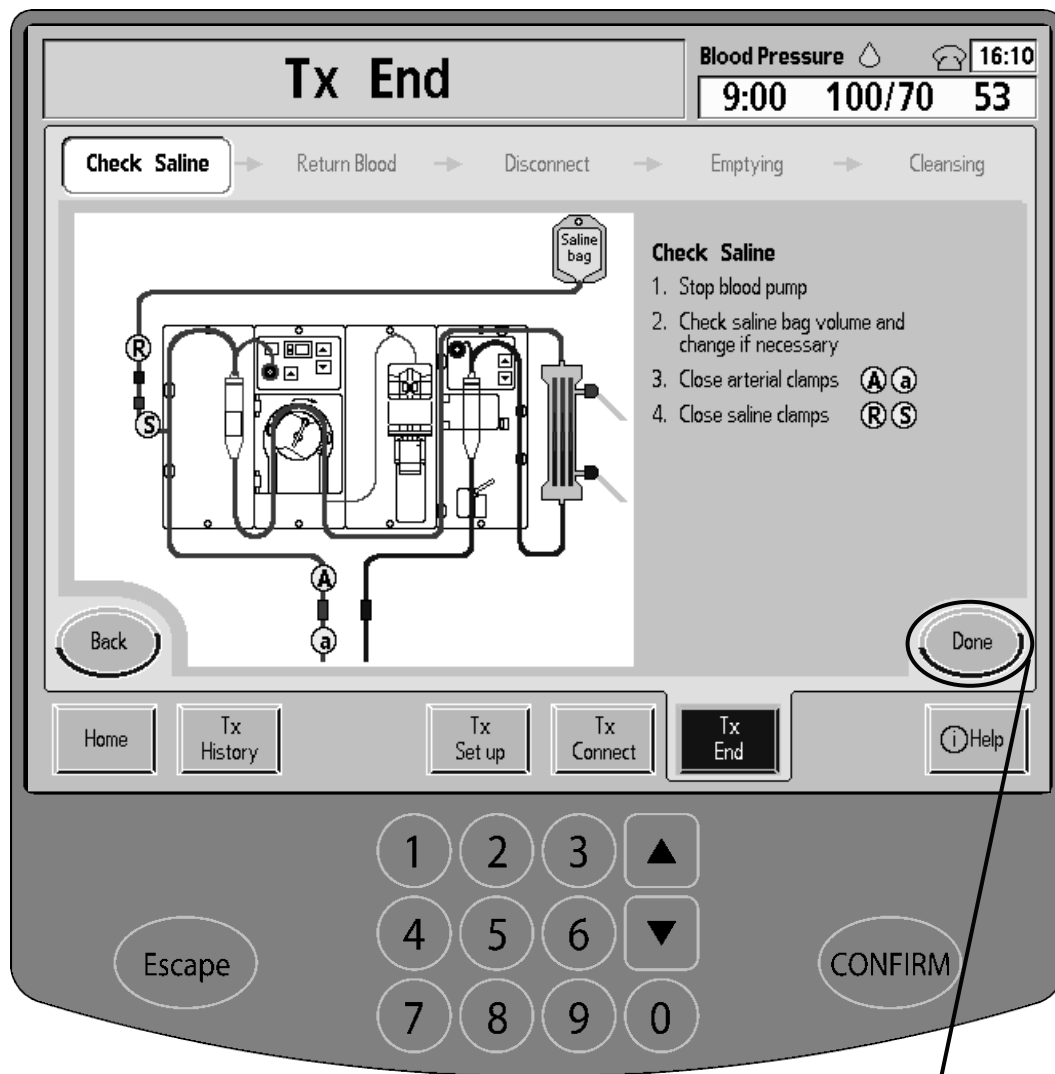
Touch the **Tx Running** button then press the **CONFIRM** key. This will stop the Tx Clock

5 Touch **Tx End**

Touch the **Tx End** screen-button to start the end of treatment procedure.

Checking the Saline

TREATMENT



1 Stop blood pump (see Your K Map: 'D')

Stop the blood pump by pressing the **Start/Stop** key on the Blood Pump module.

2 Check saline bag volume and change if necessary

Check that the saline bag contains enough saline to rinse back your blood. Replace the saline bag with a fresh one, if necessary.

3 Close arterial clamps (A) (a)

4 Close saline clamps (R) (S)

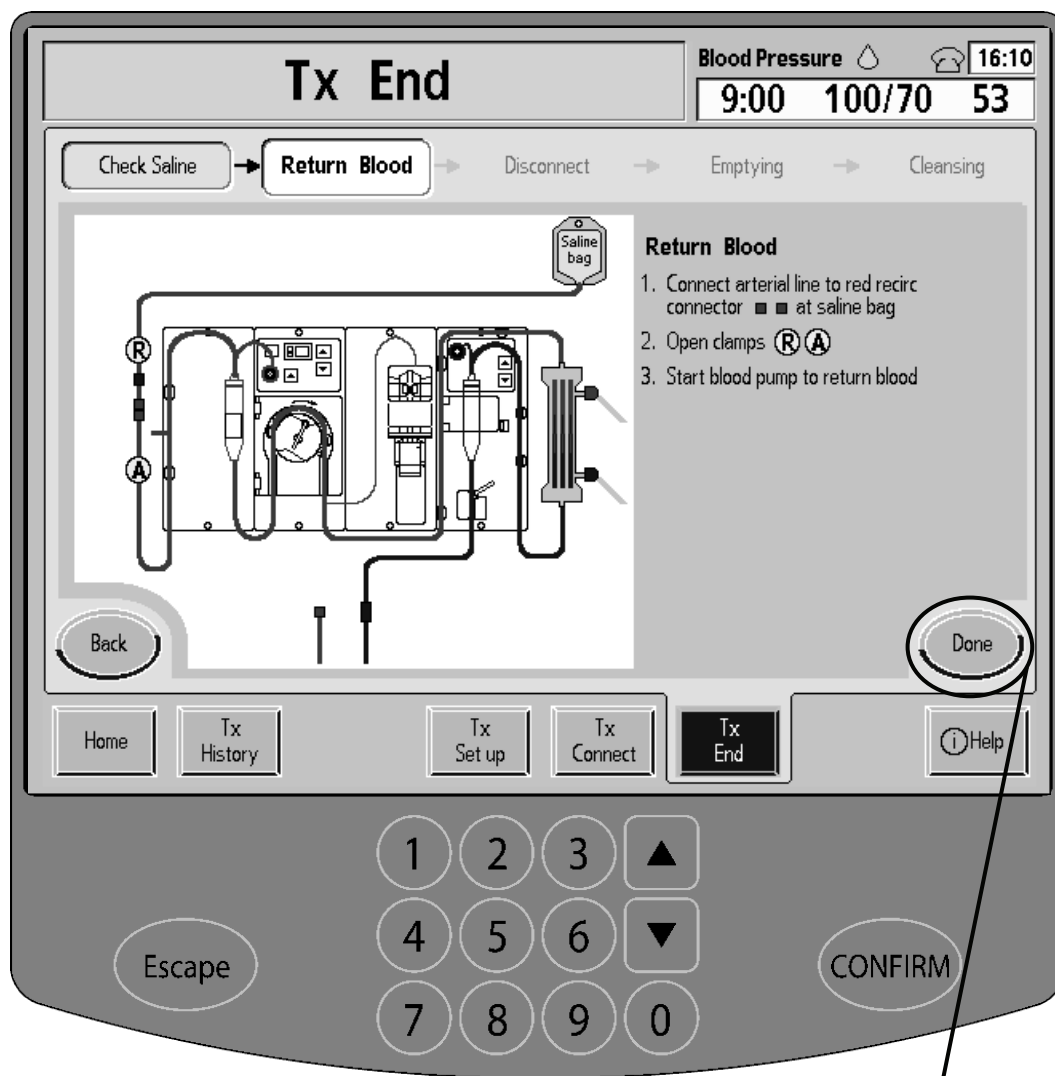
Close both of the saline line clamps.

5 Touch (Done)

When you have completed these steps, touch the **Done** button to go to the next screen.

Returning Your Blood

TREATMENT



4

1 Connect arterial line to red recirc connector

Disconnect the arterial access line. Disconnect the red end of the recirc connector from the saline line. Tightly reconnect the recirc connector to the patient end of the arterial line.



Warning: Check all bloodlines and dialysate lines for leaks. Keep access sites uncovered and monitored. Improper bloodline connections or needle dislodgements can result in excessive blood loss, serious injury and death. Machine alarms may not occur in every blood loss situation.

2 Open clamps

3 Start blood pump to return blood (see your K Map: ‘D’)

Press the **Start/Stop** key on the Blood Pump module to start the blood pump and begin returning your blood. The blood pump will continue to run until the Optical Detector (see your K Map: ‘J’) no longer senses blood.



Note: If you need more saline when rinsing back your blood after the blood pump has automatically stopped, do the following:

1. Make sure all alarms conditions are cleared.
2. Press the **Start/Stop** key on the Blood Pump module to turn off the blood pump.
3. Press the **Start/Stop** key again to turn the blood pump back on. The blood pump will run.
4. When you are finished running the blood pump, press the **Start/Stop** key to turn off the blood pump.

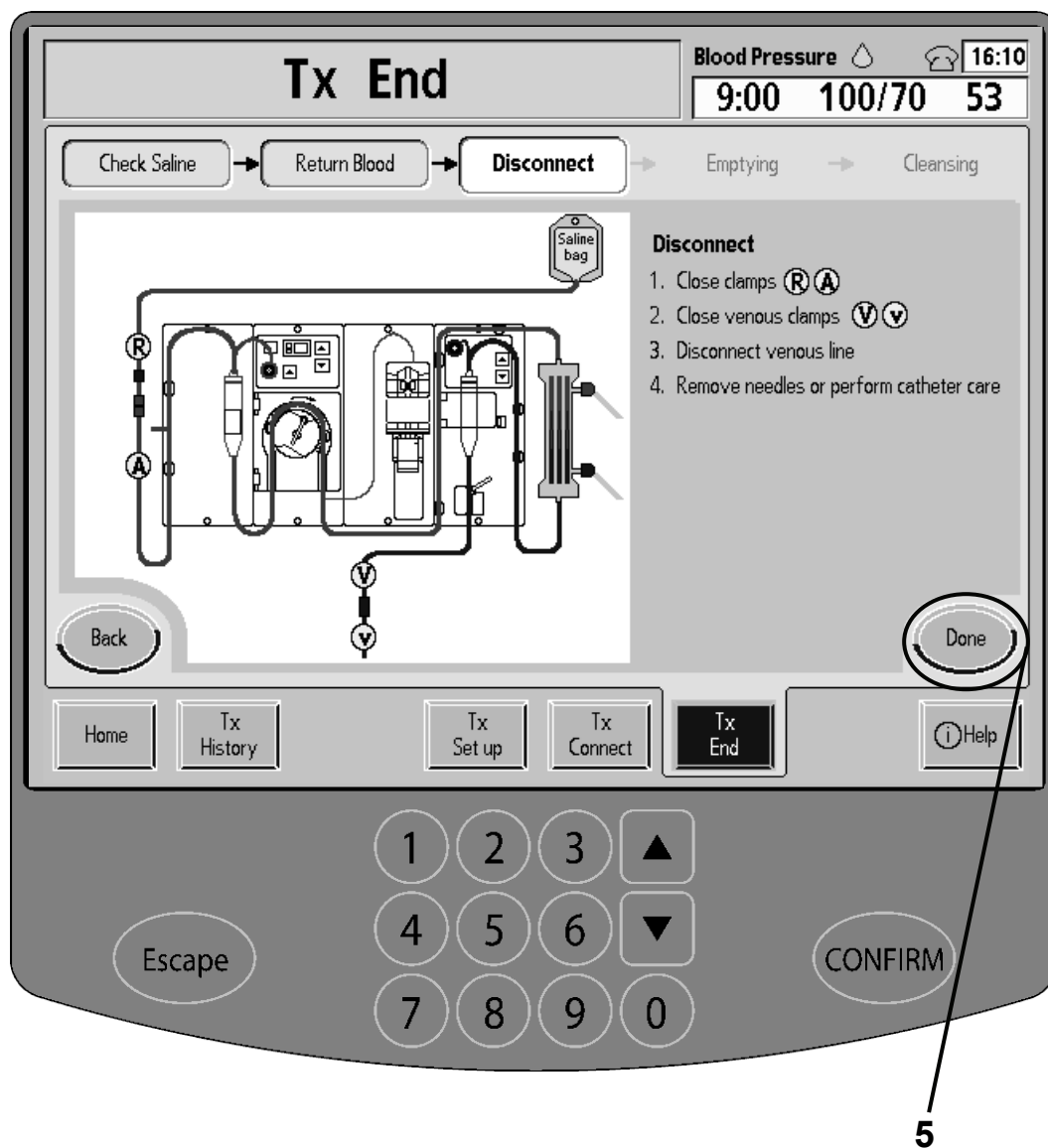
These steps are for Home mode only, please contact your Home Therapies Nurse for more information.

4 Touch

When the blood is returned, touch the **Done** button to go to the next screen.

Disconnecting the Bloodlines

TREATMENT



1 Close clamps **R** **A**



Warning: You must wait until the blood pump has stopped before completing these steps.

2 Close venous patient and access line clamps **V** **v**

3 Disconnect venous access line

Disconnect the patient end of the venous line from the venous access line.



Note: Follow your Home Therapies Nurse's instructions on where to place the patient end of the venous line while you are caring for your access.

4 Remove needles or perform catheter care

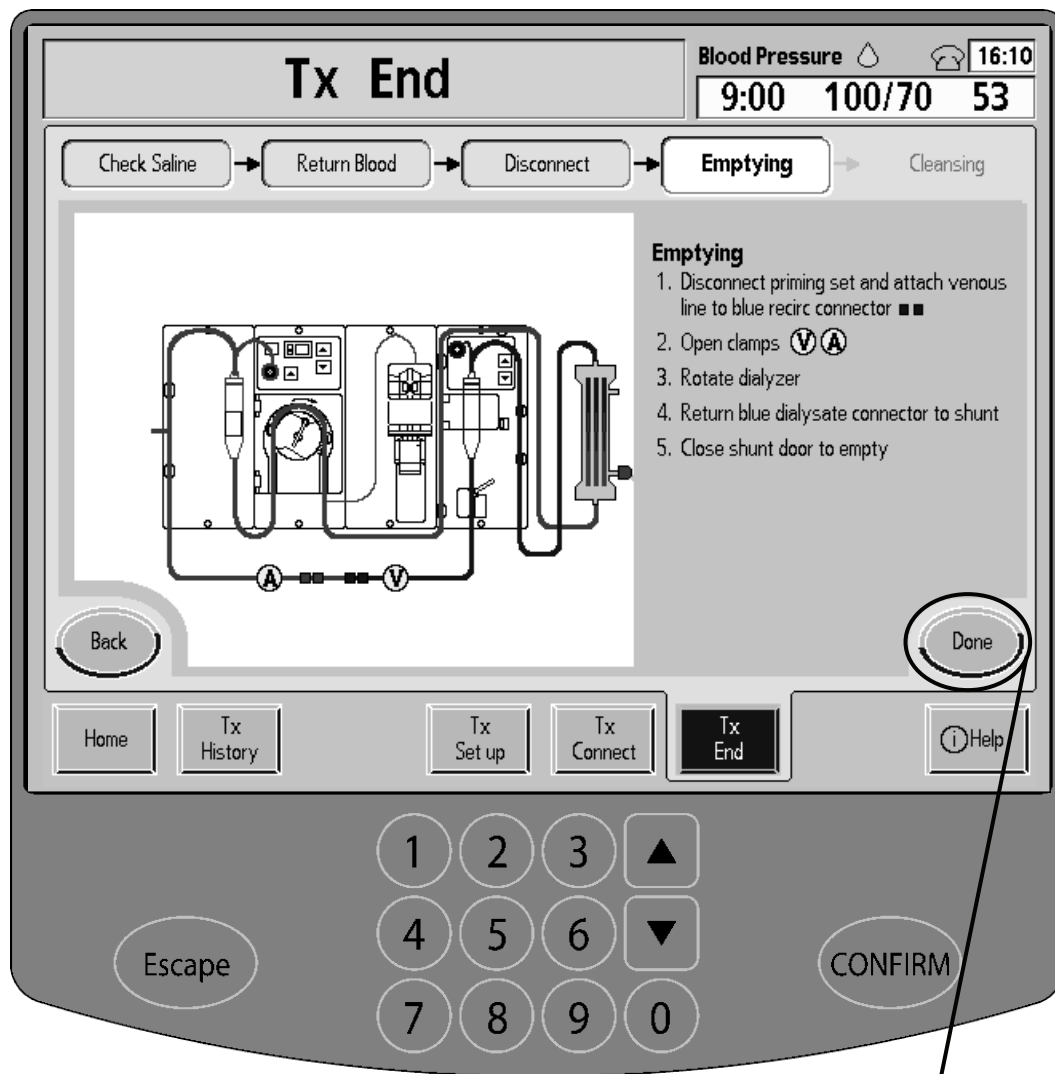
You may now disconnect from your access lines. Use the "My Treatment Procedures" sheet, on page iii, when caring for your access site to prevent infection.

5 Touch **Done**

When you have completed these steps, touch the **Done** button to continue to the next screen.

Preparing for Bloodline Disposal

TREATMENT



6

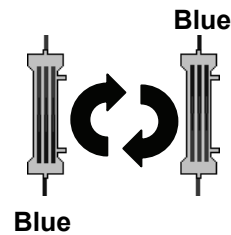
1 Disconnect priming set and attach venous line to blue recirc connector

Disconnect the saline line and bag from the bloodlines. Connect the arterial and venous lines together with the red and blue recirc connector. Make certain that the connections are tight to prevent leaking.

2 Open clamps (V) (A)

3 Rotate Dialyzer

Turn the dialyzer right side up so the venous line is on the top again. Make certain all connections are tight to prevent dialysate or blood leaks.



4 Return the blue dialysate connector to shunt (see your K Map: 'P')

Open the shunt door. Unsnap the blue dialysate connector from the dialyzer. Next, snap the blue connector back onto the shunt interlock.

5 Close shunt door to empty (see your K Map: 'P')

The disposables need to be emptied before being discarded. Close the silver shunt door over the blue dialysate connector line. Your machine will empty the dialyzer, running the dialysate through the drain line.

6 Touch **Done**

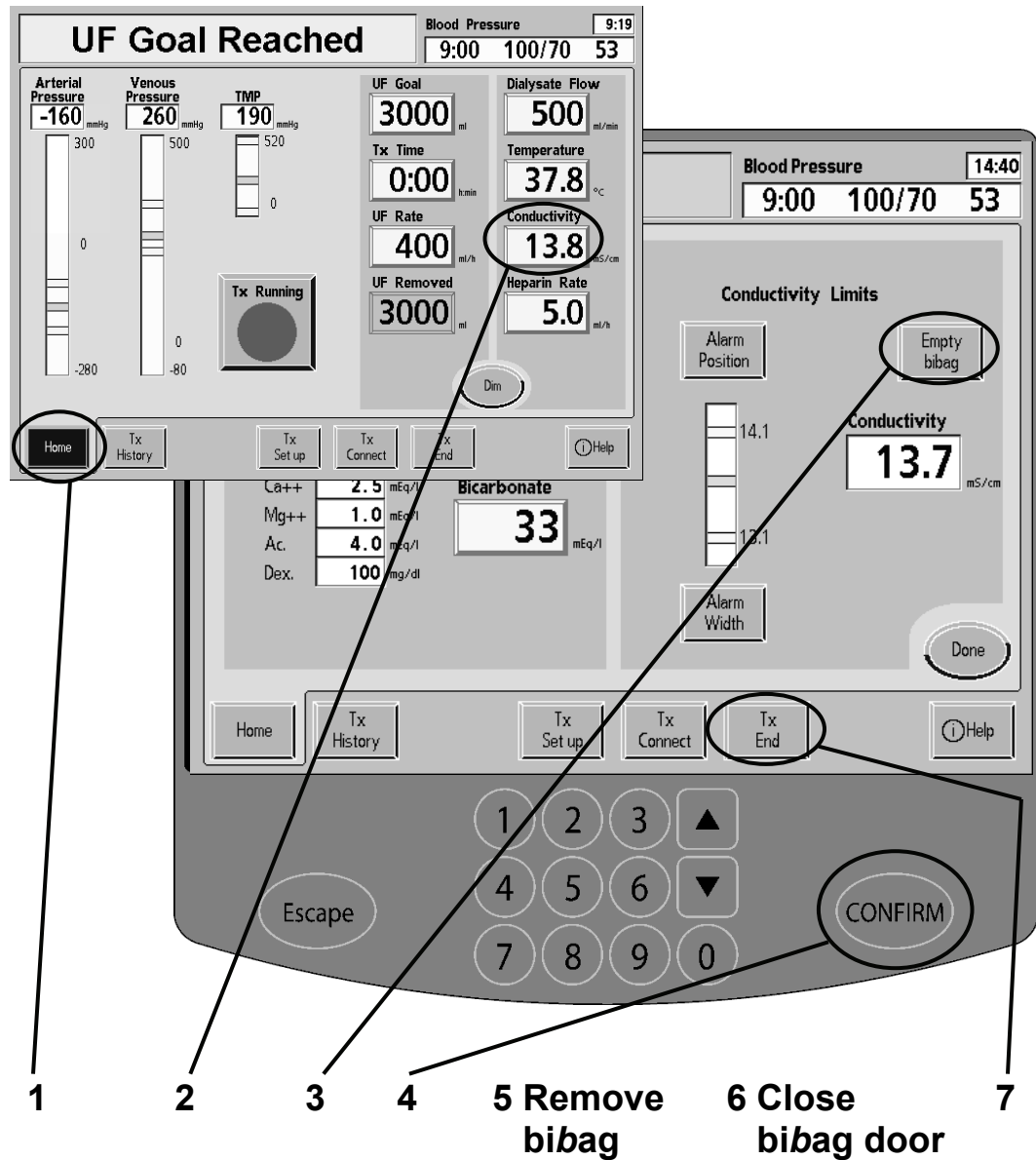
When the dialyzer is drained, the Status Box will display the message "Emptying Stopped."

Your machine can also empty the *bi*bag disposable for you at this time. Turn to the next page for instructions on how to use the 'Empty *bi*bag' feature.

If you are not using the *bi*bag disposable for your bicarbonate source or if you have already emptied the *bi*bag disposable, touch the **Done** button. Then turn to page 150 to continue with the next screen.

Emptying a bibag Disposable

TREATMENT



Warning: The values shown here are for example only. You must use the values prescribed by your doctor. If you use the wrong values, it may cause serious injury or death.

Emptying a *bibag* disposable at the end of treatment

Your 2008K@home machine has a special feature that lets you empty the *bibag* disposable through your machine's drain line. Follow the steps below to empty the *bibag* disposable:



Note: The Empty *bibag* feature cannot be used when blood is sensed or the Tx Clock is running. The **Empty *bibag*** button is disabled during a “*bibag*: Bag Leak” alarm.

Note: The *bibag* disposable may also be emptied manually, see page 134 for more information.

1 Touch **Home**

Touch the **Home** screen-button to go back to the “Home” screen.

2 Touch **Conductivity**

On the “Home” screen, touch the **Conductivity** button to view the “Dialysate” screen. The **Empty *bibag*** button is displayed in the upper right corner of the “Dialysate” screen.

3 Touch **Empty *bibag***

4 Press **CONFIRM**

Touch the **Empty *bibag*** button and press the **CONFIRM** key to begin emptying the *bibag* disposable. Any fluid remaining in the bag will be sent out your machine's drain line. When the *bibag* disposable is empty of fluid, the Status Box will display the message “*bibag*: Emptied.”

5 Remove bag

Lift up on the dark-gray *bibag* door handle to open the *bibag* door. Remove the bag and dispose of it per unit protocol.

6 Close *bibag* door

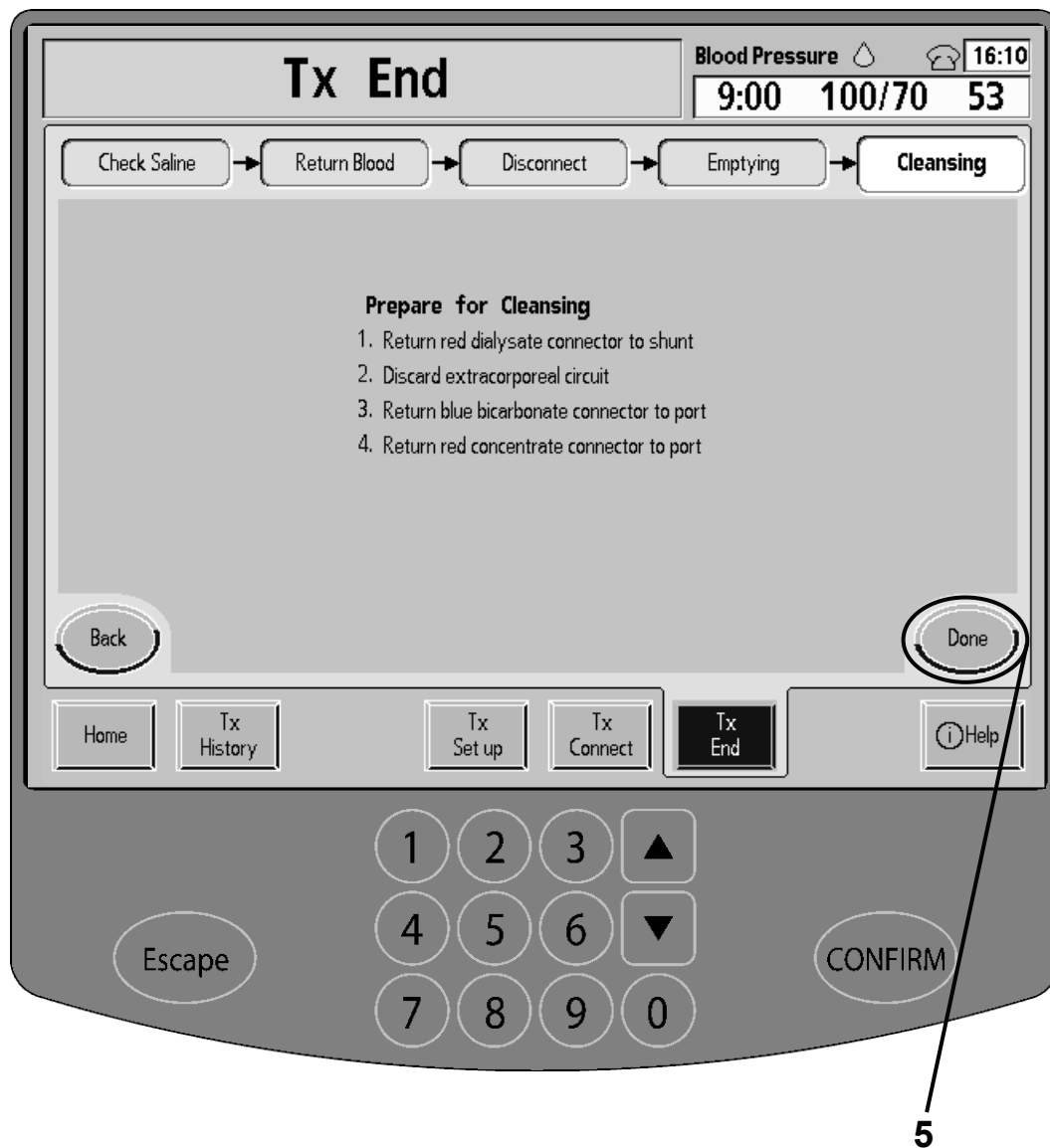
Close the *bibag* door securely, making sure that the door latches into place (two clicks should be heard).

7 Touch **Tx End**

Touch the **Tx End** screen-button to go back to where you left off in the end of treatment procedure. Touch the **Done** button to go to the next screen then turn to the next page.

Cleaning

TREATMENT



1 Return red dialysate connector to shunt (see Your K Map: ‘P’)

Unsnap the red dialysate connector from the dialyzer. Lift up the shunt door and snap the dialysate connector onto the shunt interlock. Close the shunt door again.

2 Discard bloodline circuit

You may now remove the bloodlines from your machine. Cap the ends of the dialyzer and clamp the ends of the bloodlines to prevent fluid spills. Use the “My Cleaning Procedures” sheet, on page iv, for disposal instructions. Discard your needles in the sharps container provided.



Caution: Do not forcefully pull the lines from your machine. Damage to your machine or its sensors may result. Open the pump door and press the **Start/Stop** key on the Blood Pump module (see Your K Map: ‘D’) to re-align the rotor so you can remove the bloodline more easily. Rotate the Optical Detector door open before taking the line from the Venous Clamp.



Warning: Keep fingers clear of the blood pump rotor when it is running. Serious injury may occur.

3 Return blue bicarbonate connector to port (see Your K Map: ‘I’)

4 Return red concentrate connector to port (see Your K Map: ‘H’)

After returning the red concentrate connector to its rinse port, your machine will display the “Select Program” screen. You must now choose from the cleaning and disinfecting programs to clean and disinfect your machine. Use the “My Cleaning Procedures” sheet, on page iv, and continue to chapter 5, “Cleaning and Disinfecting.”

5 Touch **Done**

If you wish to review the dialysis “Home” screen, do not return the red concentrate connector to its port. Instead, touch the **Done** button to exit this screen. Complete step 4 when you are ready to begin disinfection.

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Chapter 5: Cleaning and Disinfecting

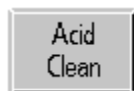
Cleaning



Rinse

Page Number

156



Acid Clean

160



Blood Pressure Cuff

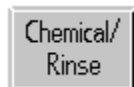
182

Disinfecting



Heat Disinfect

164



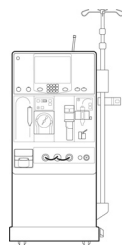
Chemical/Rinse

168



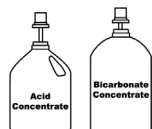
Acid & Heat Disin
(software versions 4.30 or later)

174



Exterior Surface

180

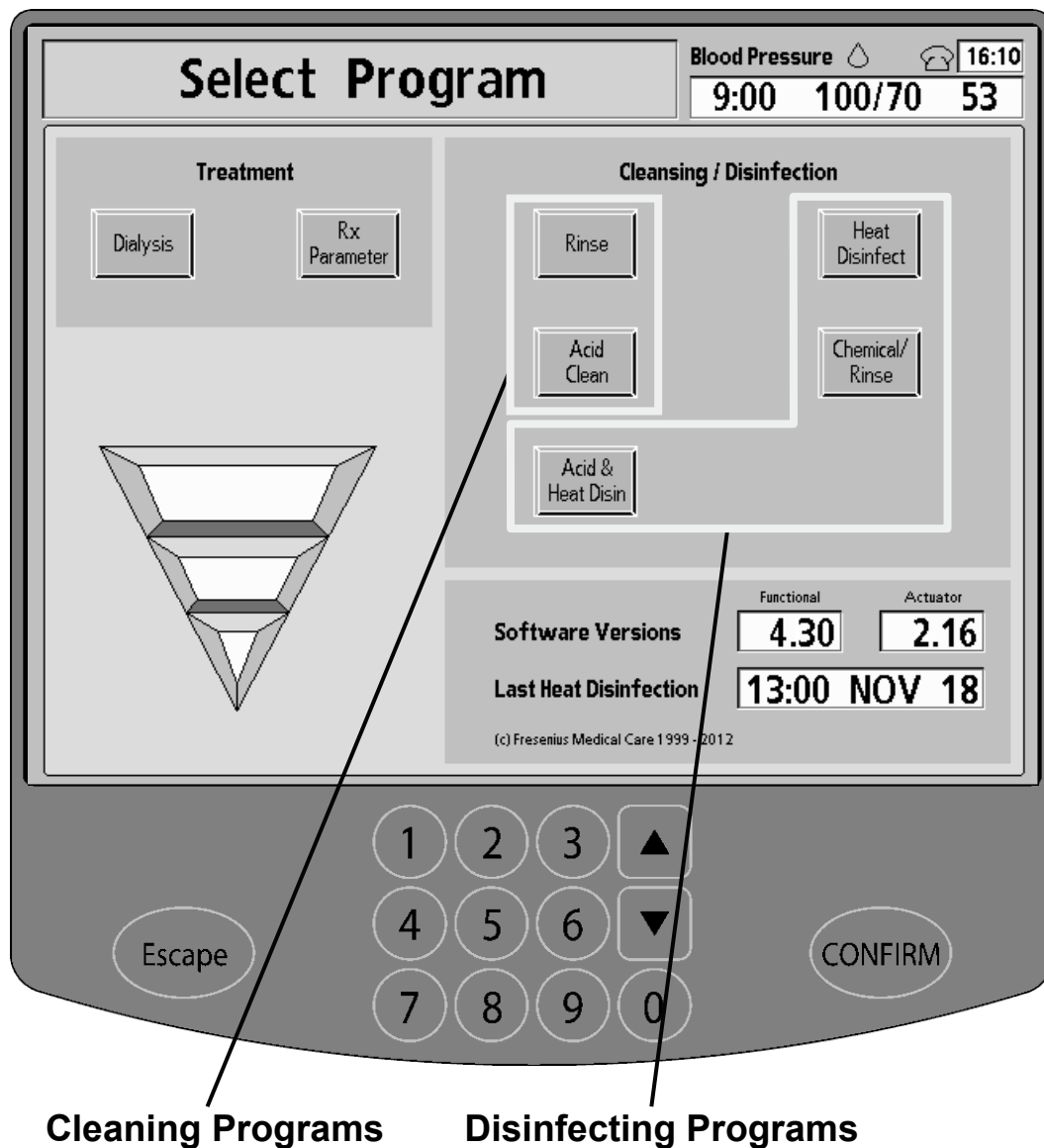


Concentrate Containers

186

CLEANING/
DISINFECTING

Cleansing/Disinfection Programs



Cleansing/Disinfecting Programs

Your 2008K@home hemodialysis machine should be disinfected after every treatment day. Use the “My Cleaning Procedures” sheet, on page iv, for cleaning and disinfecting standards.

The cleaning and disinfection programs are listed on the right side of the “Select Program” screen. The “Select Program” screen appears automatically when the red acid concentrate connector is inserted into its rinse port after a treatment.

The “Rinse” and “Acid Clean” programs clean your machine. The “Heat Disinfect,” “Chemical/Rinse,” and “Acid & Heat Disin” programs disinfect it. To run any of the cleaning and disinfection programs, touch that program’s screen-button.



Warning: Disinfect your machine immediately after your treatment if a blood leak alarm occurs.

Warning: When chemicals are used inside your machine, it must be thoroughly rinsed and tested for remaining disinfectant before your next treatment. Your machine must be labeled with the chemical used and instructions to rinse and test for remaining chemicals.

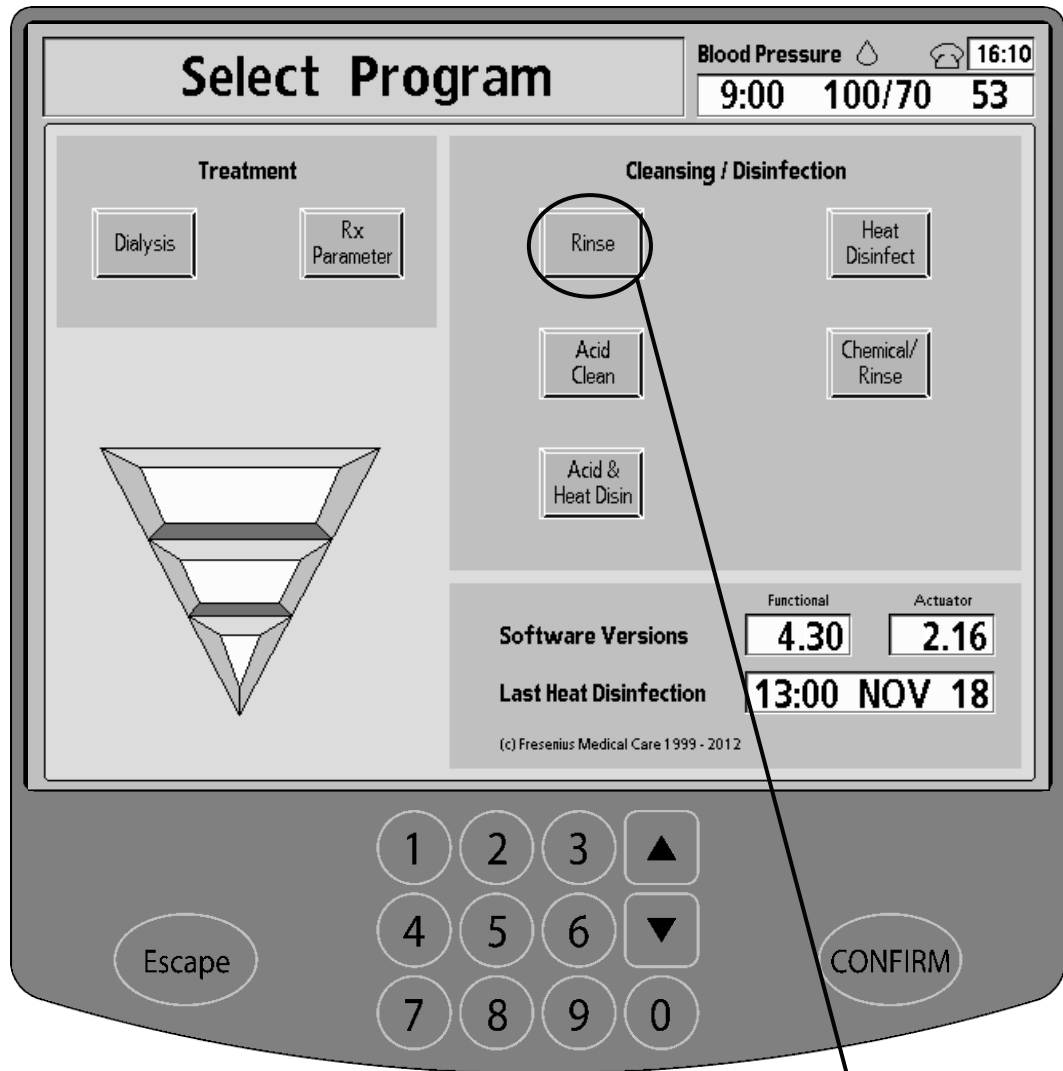


Note: Your machine must be connected to an approved water source, the drain line connected to a drain, the dialysate supply lines on the shunt interlock with the shunt door closed, and the concentrate connectors tightly seated in their rinse ports to run these programs.

Note: If you have missed a scheduled cleaning/disinfecting program, your machine will also remind you with a pop-up message when you touch the **Dialysis** button. You must either press the **CONFIRM** key to continue or press the **Escape** key to cancel and then select the required cleansing/disinfecting program. For more information on the recommended cleaning/disinfection schedule, see “My Treatment Procedures” on page iii.

Rinse

CLEANING/
DISINFECTING



1 Check Shunt

**2 Check Acid/Bicarb
Connectors**

3

Rinse Program

The “Rinse” program may be run before each treatment, but it must be run after an acid clean. See “My Cleaning Procedures” on page iv for how often you should rinse your machine. The program runs a complete water rinsing of the dialysate circuit and concentrate lines. The rinse cycle can be set to run between 10 and 60 minutes (set in Service Mode).



Warning: Rinsing does not disinfect your machine.

1 Check that dialysate lines are on the shunt (see Your K Map: ‘P’)

Both dialysate lines must be tightly connected on the shunt interlock so the rinse cycle can flush them with water.

2 Check that concentrate connectors are in rinse ports

(see Your K Map: ‘H’, ‘I’)

The acid and bicarbonate concentrate connectors must be in their matching rinse ports so the rinse cycle can flush the concentrate lines with water. Make certain the connections are tight.

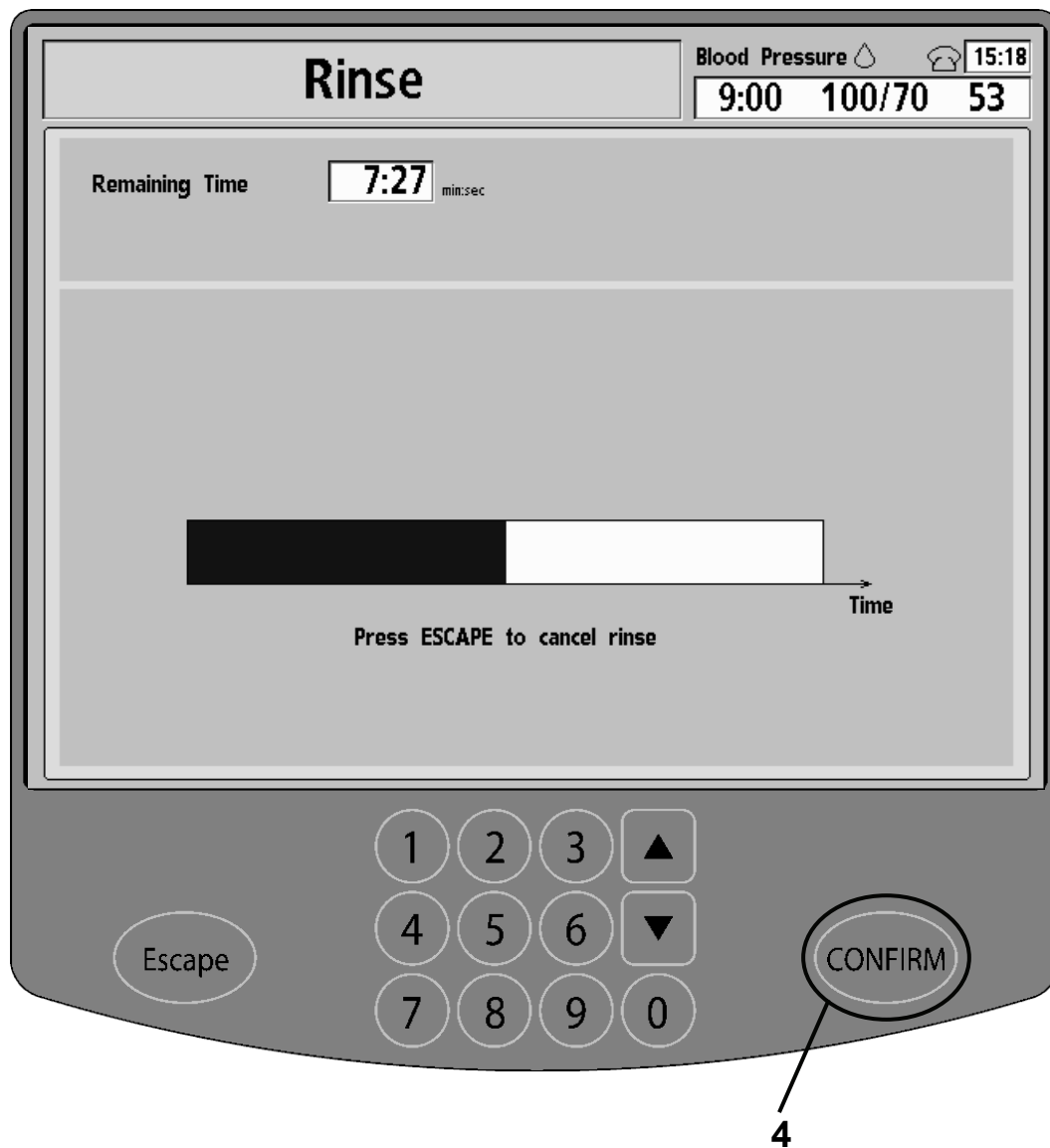
3 Touch **Rinse**

From the “Select Program” screen, touch the **Rinse** screen-button to start the program.

(continued on next page)

Rinse (continued)

CLEANING/
DISINFECTING



(continued)

The “Rinse” screen displays a bar graph showing the rinsing progress. It also shows a timer meter box that counts down the remaining rinse time.

4 Press **CONFIRM**

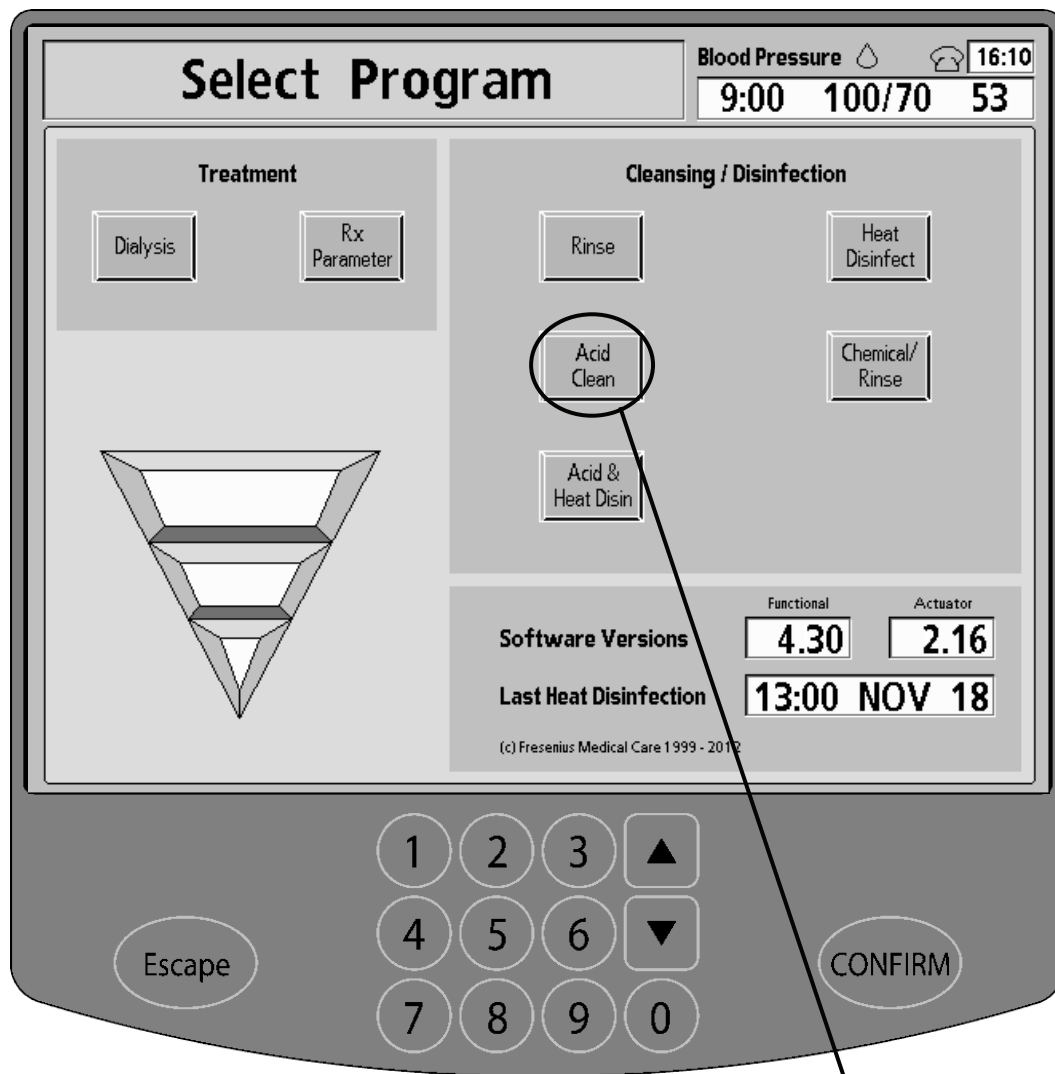
When the timer has reached 0:00 and the Rinse has completed, press the **CONFIRM** key on the data entry keypad to exit.



Warning: Test your machine for remaining disinfectant before starting your treatment after a chemical disinfection. See “My Treatment Procedures,” on page iii.

Acid Clean

CLEANING/
DISINFECTING



1 Check Shunt

**2 Check Acid/Bicarb
Connectors**

3

Acid Clean Program

The “Acid Clean” program flushes your machine with a mild acid (distilled vinegar) to remove bicarbonate build-up. You should run an Acid Clean at the end of every treatment day. See “My Cleaning Procedures” on page iv.



Warning: Acid cleaning does not disinfect your machine.

Warning: Attach a sign to the front of your machine that states the chemical being used to clean your machine.

1 Check that dialysate lines are on the shunt (see Your K Map: ‘P’)

Both dialysate lines must be on the shunt interlock so the rinse cycle can flush them with acid.

2 Check that concentrate connectors are in rinse ports

(see Your K Map: ‘H’, ‘I’)

The concentrate connectors must be in their matching rinse ports so the pre-rinse cycle can flush the concentrate lines with water. Make certain the connections are tight.

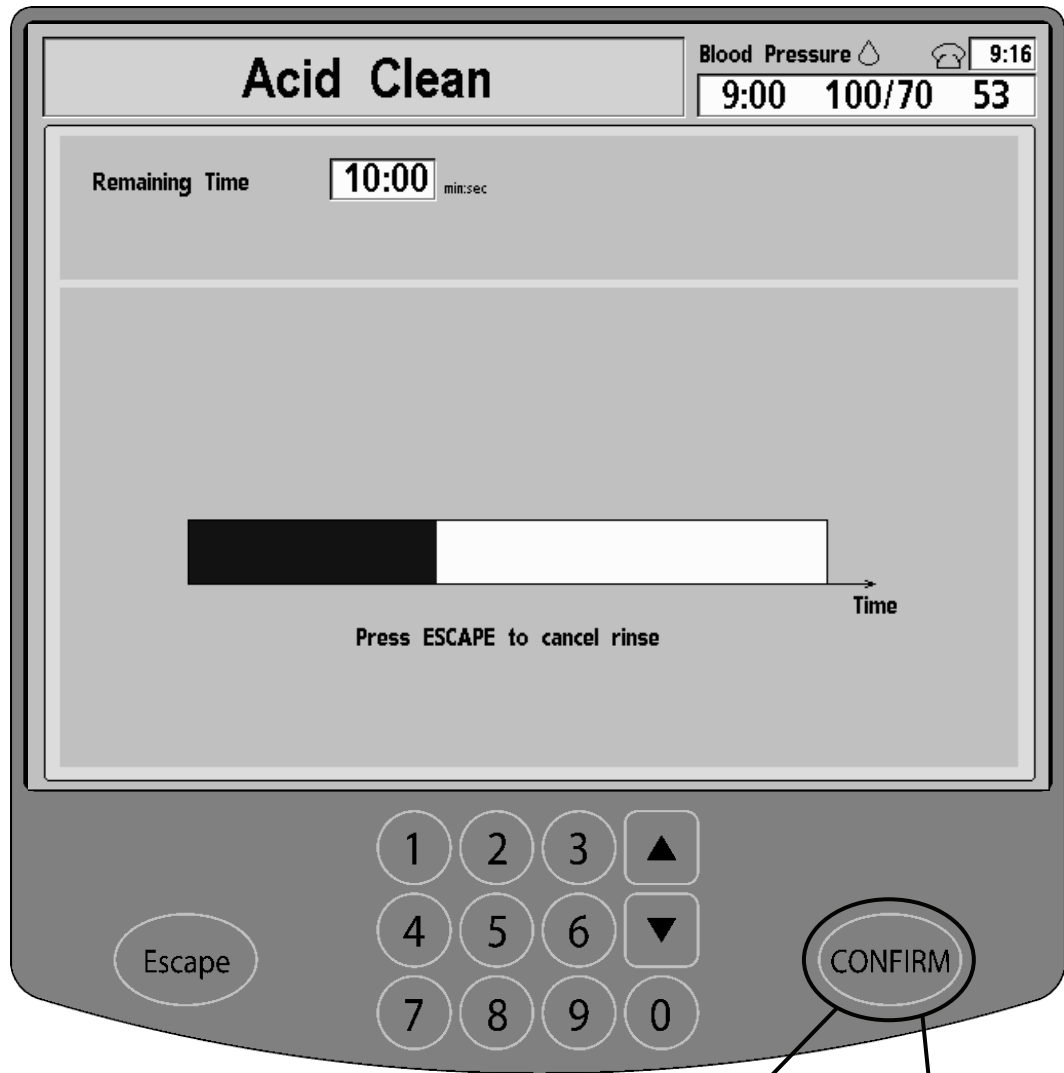
3 Touch **Acid Clean**

From the “Select Program” screen, touch the **Acid Clean** screen-button to start the program.

(continued on next page)

Acid Clean (continued)

CLEANING/
DISINFECTING



4 Connect to Distilled Vinegar

5

6

(continued)

The “Acid Clean” screen’s Status Box displays the message: “Wait: Rinsing Line.”

4 Put connectors in chemical (see Your K Map: ‘H’, ‘I’)

After your machine has finished rinsing the lines, the Status Box instructs you to attach the concentrate connectors to an acid cleaner selected by your clinic. Snap the red acid connector into a full jug of acid cleaner. Snap the blue bicarbonate connector into a full jug of distilled vinegar. Make certain the connections are tight.

5 Press **CONFIRM**

Press the **CONFIRM** key to start the acid cleaning. A bar graph shows the cleaning progress. Also, a timer meter box counts down the remaining time.

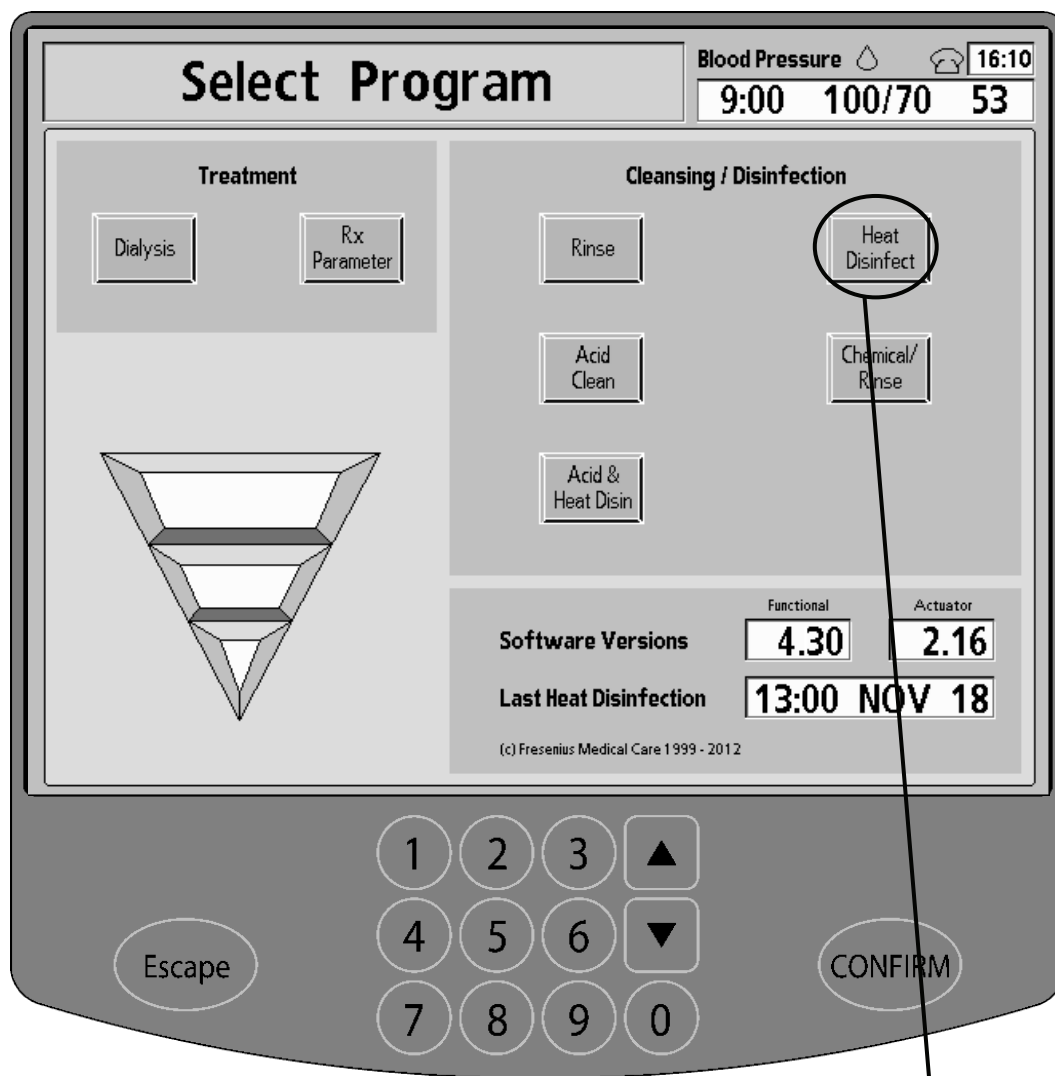
6 Press **CONFIRM**

Return the concentrate connectors to their matching rinse ports when instructed. When the timer has reached 0:00 and the Acid Clean is complete, press the **CONFIRM** key on the data entry keypad to exit.



Warning: Disinfect and rinse your machine before starting treatment after an acid clean.

Heat Disinfection



CLEANING/
DISINFECTING

1 Check Shunt

2 Check Acid/Bicarb
Connectors

3

Heat Disinfect Program

The “Heat Disinfect” program disinfects your machine by running hot water (over 80°C or 176°F) through it. You should run a Heat Disinfect at the end of every treatment day. See “My Cleaning Procedures” on page iv. The program time can be set in Service Mode to run between 10 and 60 minutes.

1 Check that dialysate lines are on the shunt (see Your K Map: ‘P’)

Both dialysate lines must be on the shunt interlock so the rinse cycle can flush them with water.

2 Check that concentrate connectors are in rinse ports

(see Your K Map: ‘H’, ‘I’)

The concentrate connectors must be in their matching rinse ports so the rinse cycle can flush the concentrate lines with water. Make certain the connections are tight.

3 Touch **Heat Disinfect**

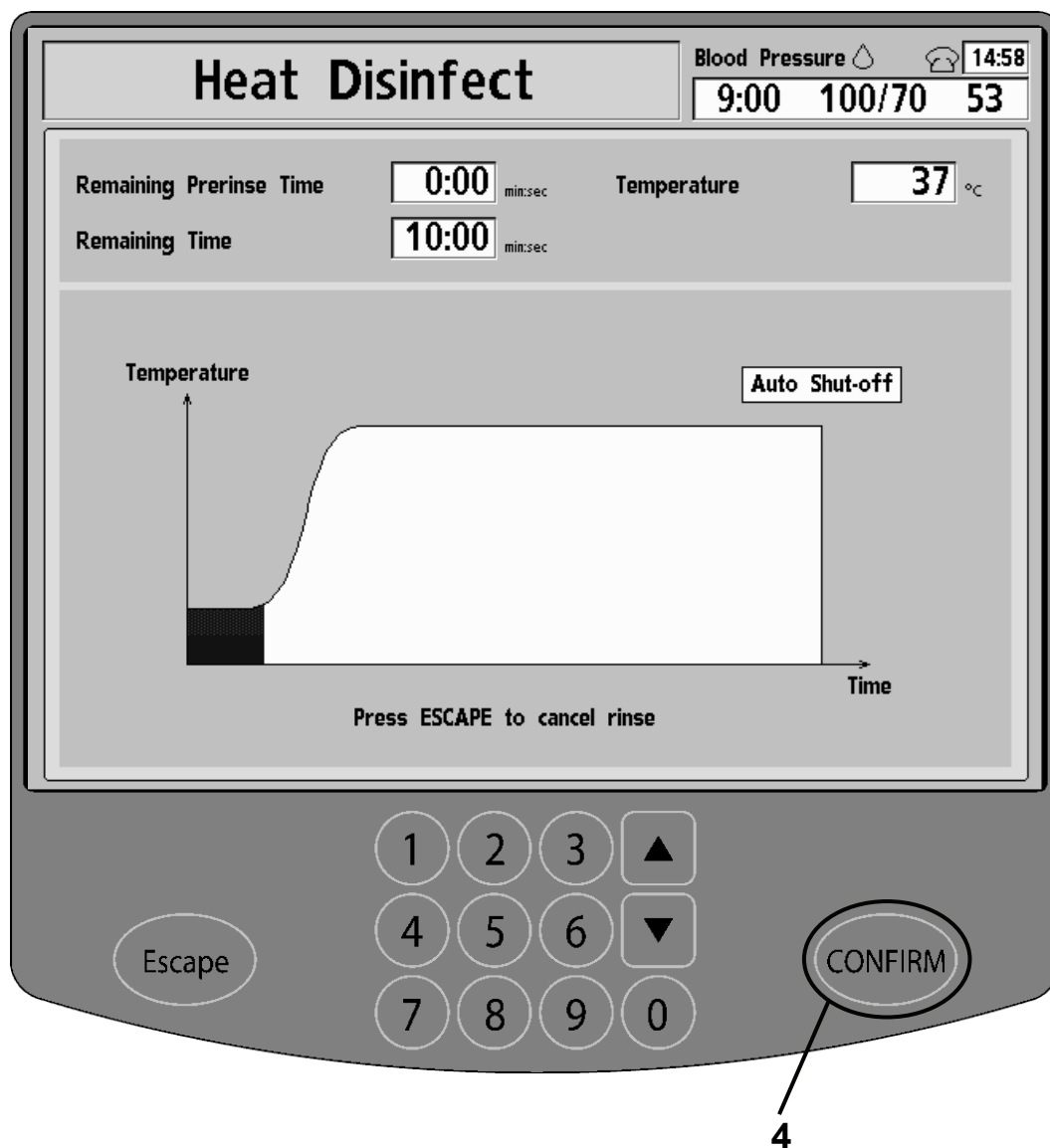
From the “Select Program” screen, touch the **Heat Disinfect** screen-button to start the program.



Note: If your machine was not rinsed prior to this, it will automatically rinse for either 7 or 20 minutes (set in Service Mode).

(continued on next page)

Heat Disinfection (continued)



(continued)

The “Heat Disinfect” screen displays a bar graph that shows the disinfecting progress. It also shows a timer meter box that counts down the remaining time. The timer starts when the water temperature reaches 80°C (176°F).



Warning: Do not come into contact with the steam coming from your machine’s vent during heat disinfection. Steam and machine parts affected by heat-disinfection will be hot and can cause burns.

Warning: Do not open the bibag door during a Heat Disinfection, serious injury may occur. Keep the bibag door closed when running any rinse or disinfection program.

4 Press **CONFIRM**

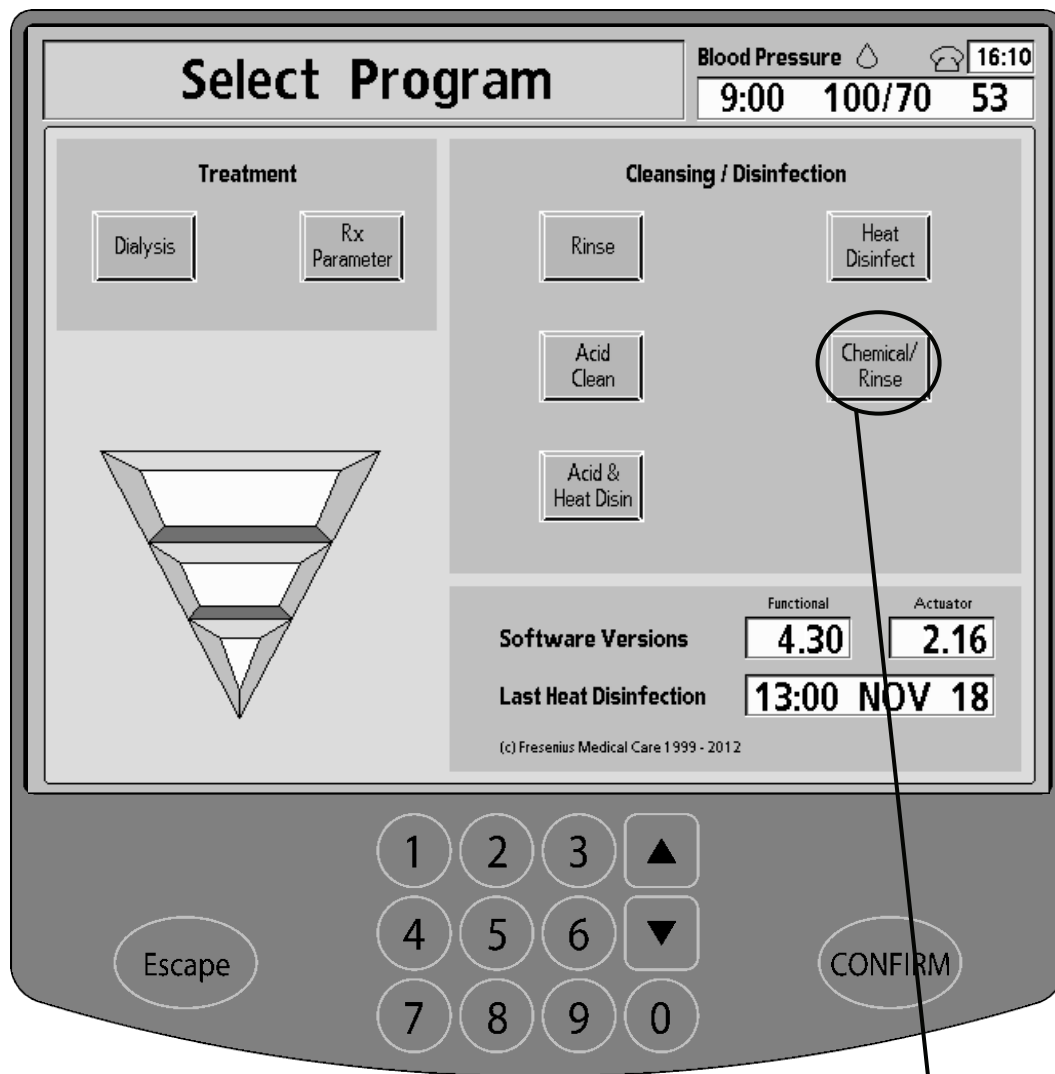
When the Heat Disinfect is complete, press the **CONFIRM** key to exit. You may run your machine through a rinse cycle to cool it down faster, but only for immediate treatment after the rinse is complete.



Note: If the ‘Off after Heat Disinfect’ option is selected in Service Mode, the words ‘Auto Shut-off’ will be displayed above the bar graph. Your machine will automatically power down after the Heat Disinfect is complete.

Chemical/Rinse

CLEANING/
DISINFECTING



1 Check Shunt

2 Check Acid/Bicarb
Connectors

3

Chemical/Rinse Program

The “Chemical/Rinse” program disinfects your machine by rinsing it with water, chemical disinfectant, and water again. You should run a Chemical/Rinse weekly. See “My Cleaning Procedures” on page iv.

1 Check that dialysate lines are on the shunt (see Your K Map: ‘P’)

Both dialysate lines must be on the shunt interlock so the rinse cycle can flush them with water and disinfectant.

2 Check that concentrate connectors are in rinse ports

(see Your K Map: ‘H’, ‘I’)

The concentrate connectors must be in their matching rinse ports so the pre-rinse cycle can flush the concentrate lines with water. Make certain the connections are tight.



Warning: Attach a sign to the front of your machine that states the chemical being used to disinfect your machine.

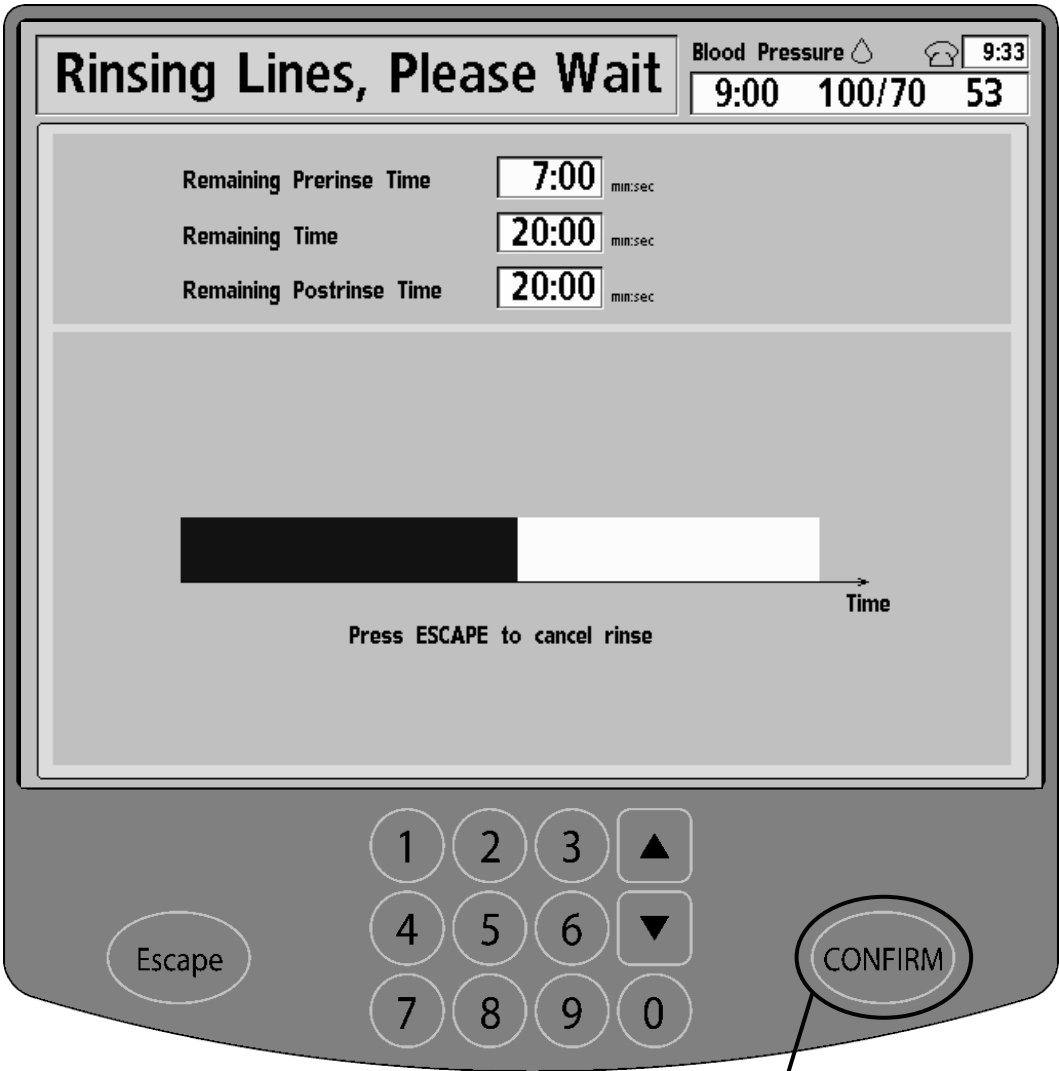
3 Touch **Chemical/Rinse**

From the “Select Program” screen, touch the **Chemical/Rinse** screen-button to start the program.

(continued on next page)

Chemical/Rinse (continued 1)

CLEANING/
DISINFECTING



4 Connect to Disinfectant

5

(continued)

The “Chemical/Rinse” screen’s Status Box displays the message: “Rinsing Lines, Please Wait.” Your machine will run a 45 second pre-rinse.



Note: If the ‘HE Leak Test’ Service Mode option is selected (software versions 4.36 and later), your machine will run a four minute pressure holding test after the 45 second pre-rinse. If the first test fails, a second test will automatically run. If the second test fails, your machine will display a “System Leak, Can’t Run” message, meaning that the Chemical/Rinse program can no longer be run due to a leak detected in the Heat Exchanger. However, your machine will still be able to run Heat Disinfection programs and hemodialysis treatments as directed by your Home Therapies Nurse. Call a qualified service technician.

4 Connect red acid connector to chemical disinfectant (see Your K Map: ‘H’)

After your machine has finished with the previous step, the Status Box will display a new instruction: “Put Red Con in Chemical.” Snap the red acid connector into a chemical disinfectant. You may use bleach, Puristeril 340, or Renalin, for example. Make certain the connection is tight.



Warning: You must test for remaining disinfectant before your next treatment. A sample for testing can be taken from a dialysate line or the drain line.

Bleach – Follow your clinic’s procedures for testing for chlorine levels in the fluid sample.

Puristeril 340 – Test according to manufacturer’s instructions. Use a residual test intended for this product.

Diacide HD – Test according to manufacturer’s instructions. Use Nephrect or another test intended for this product.

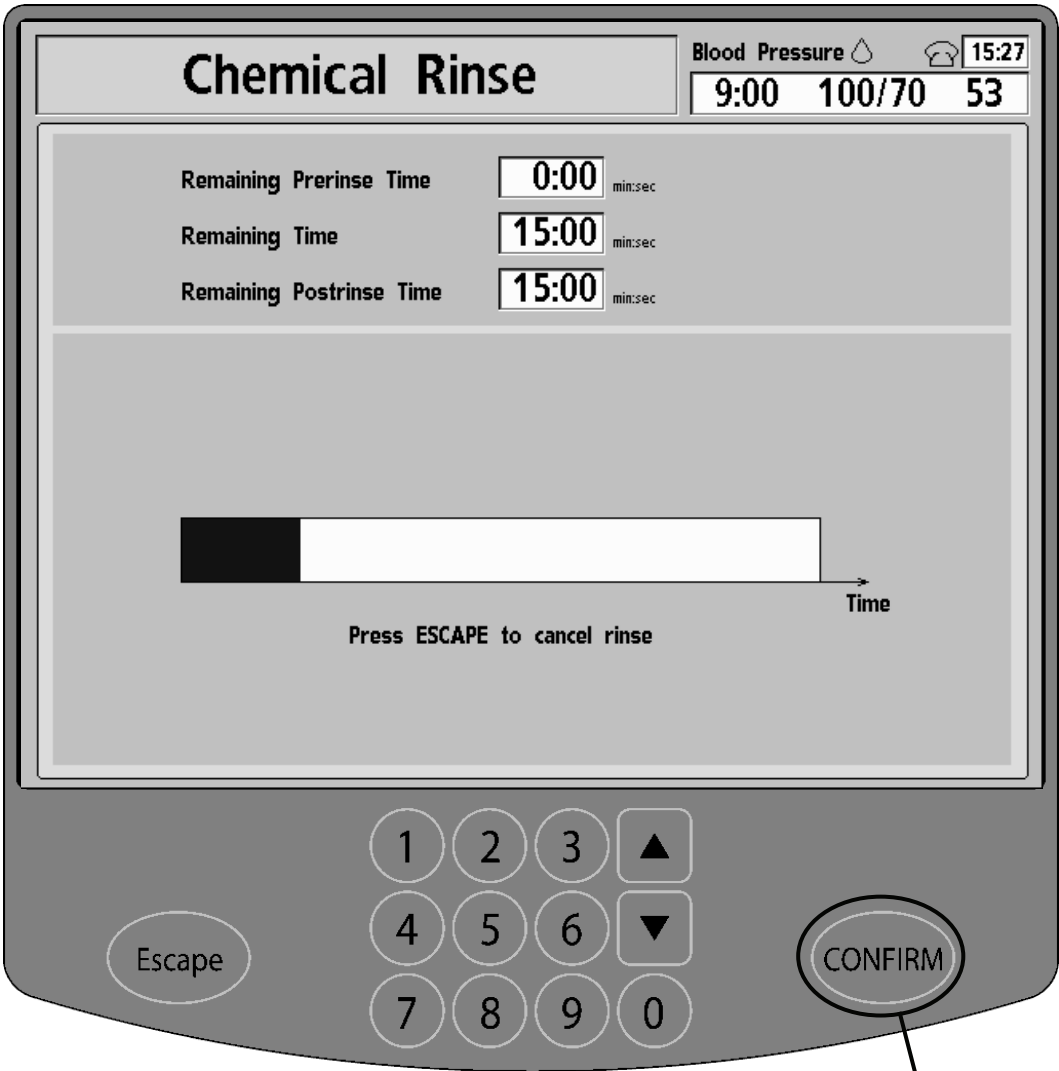
5 Press **CONFIRM**

Press the **CONFIRM** key to start the water pre-rinse. A bar graph shows the disinfecting progress and the “Remaining Prerinse Time” meter box counts down.

(continued on next page)

Chemical/Rinse (continued 2)

CLEANING/
DISINFECTING



6 Check Disinfectant

7 Return Connector

8

(continued)

When the “Remaining Prerinse Time” meter box reads 0:00, the Chemical/Rinse will start after a delay. The “Remaining Time” meter box will start counting down.

6 Check that disinfectant has been pulled into your machine

Visually check the chemical disinfectant jug to make sure the disinfectant has been pulled into your machine. The chemical disinfectant will now run through your machine.

7 Re-insert acid connector in red rinse port (see Your K Map: ‘H’)

When the “Remaining Time” meter box reaches 0:00, the Status Box will display a new instruction: “Put Connector in Port.” Remove the red acid connector and re-insert it into its rinse port. The postrinse will now flush the remaining disinfectant out of your machine. The “Remaining Postrinse Time” meter box will count down.

8 Press **CONFIRM**

When the rinse timer has reached 0:00 and the Chemical/Rinse is complete, press the **CONFIRM** key to exit.



Caution: These chemicals should not remain in contact with your machine for more than about 20 minutes when not rinsing—damage to your machine could result.



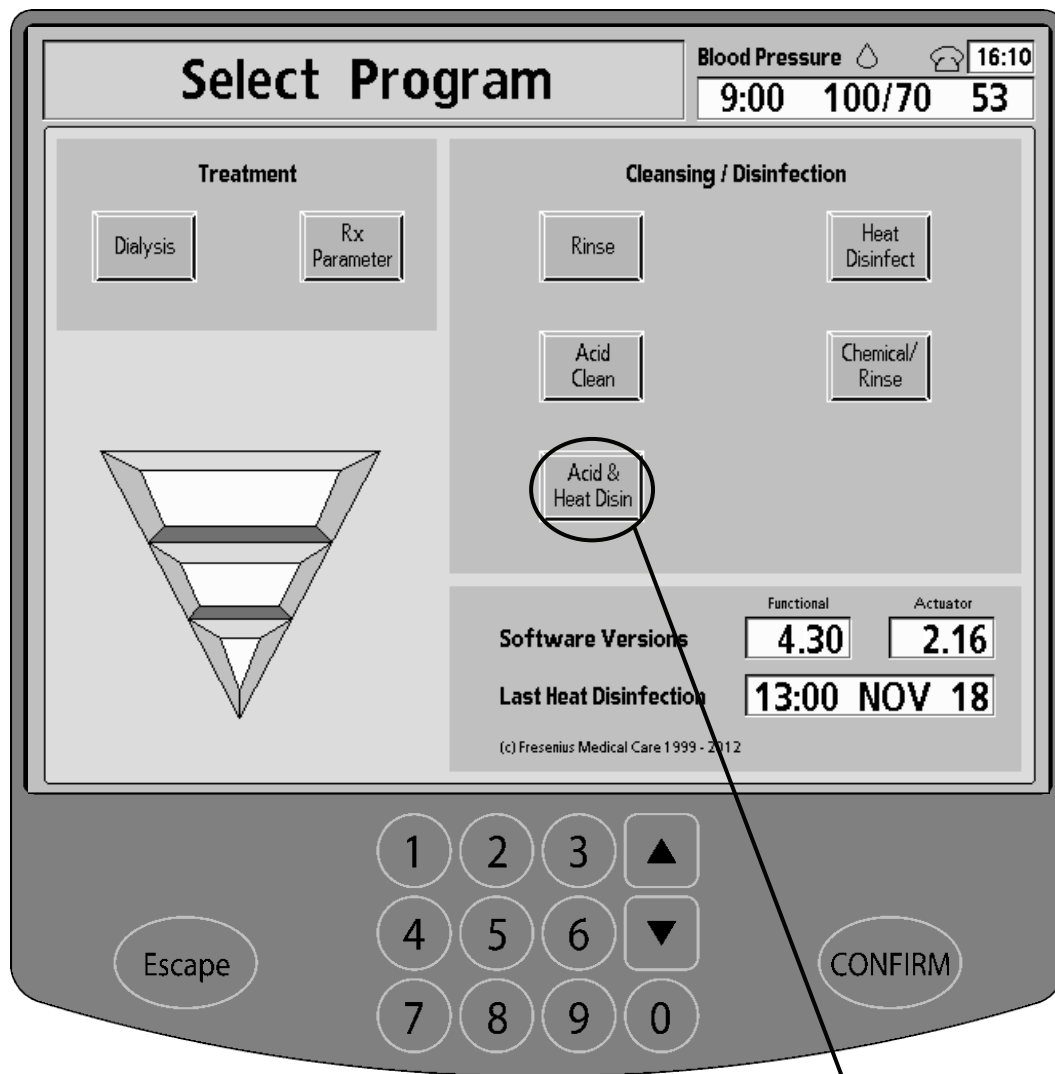
Warning: Test your machine for remaining disinfectant before starting treatment after chemical disinfection. See “My Treatment Procedures” on page iii.



Note: If the Diasafe Auto-Test option is selected in Service Mode, your machine will automatically run a Diasafe test after the Chemical/Rinse is complete. This test will take a few minutes. When the test is complete, press the **RESET** key to clear the message. Then press the **CONFIRM** key to exit.

Acid & Heat Disinfect

CLEANING/
DISINFECTING



1 Check Shunt

2 Check Acid/Bicarb
Connectors

3

Acid & Heat Disinfect Program

The “Acid & Heat Disin (Disinfect)” program (software versions 4.30 or later) is a convenient combination of necessary cleaning and disinfecting programs. Using the Acid & Heat Disinfect program, you can run the Acid Clean and Heat Disinfect programs more quickly together than each separately. You should run the Acid & Heat Disinfect program at the end of every treatment day. See “My Cleaning Procedures” on page iv.

The Acid & Heat Disinfect program first flushes your machine with a mild acid (distilled vinegar) to remove bicarbonate build-up and then disinfects your machine by running hot water (over 80°C or 176°F) through it.



Warning: Acid cleaning does not disinfect your machine alone—the entire Acid & Heat Disinfect program must be run in order to both clean and disinfect your machine.

Warning: Attach a sign to the front of your machine that states the chemical being used to clean your machine.

1 Check that dialysate lines are on the shunt (see Your K Map: ‘P’)

Both dialysate lines must be on the shunt interlock so the rinse cycle can flush them with acid.

2 Check that concentrate connectors are in rinse ports

(see Your K Map: ‘H’, ‘I’)

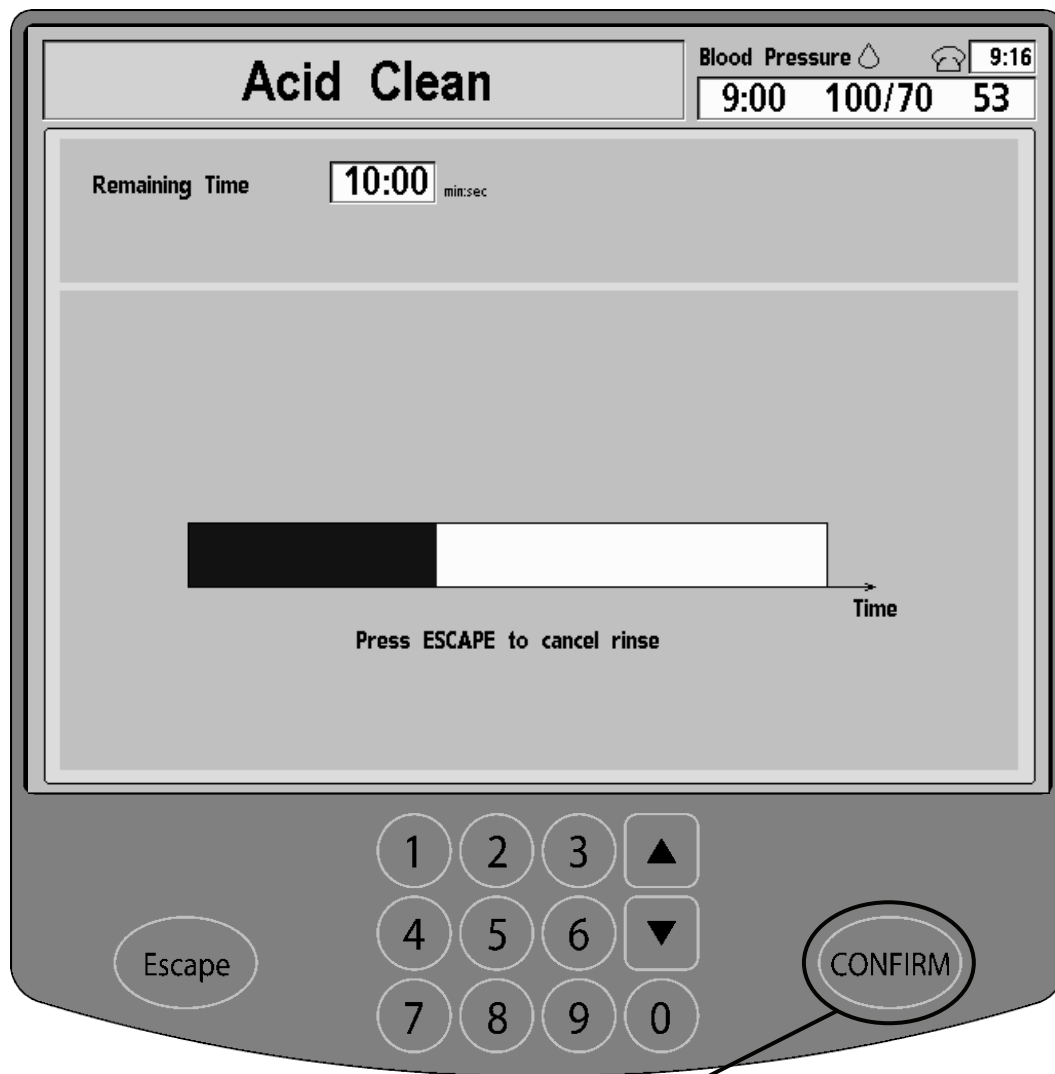
The concentrate connectors must be in their matching rinse ports so the pre-rinse cycle can flush the concentrate lines with water. Make certain the connections are tight.

3 Touch **Acid & Heat Disin**

From the “Select Program” screen, touch the **Acid & Heat Disin** screen-button to start the program.

(continued on next page)

Acid & Heat Disinfect (continued)



4 Connect to Distilled Vinegar 5 6 Return Connectors

CLEANING/
DISINFECTING

(continued)

The “Acid Clean” screen’s Status Box displays the message: “Wait: Rinsing Line.”

4 Put connectors in chemical (see Your K Map: ‘H’, ‘I’)

After your machine has finished rinsing the lines, the Status Box instructs you to attach the concentrate connectors to an acid cleaner selected by your clinic. Snap the red acid connector into a full jug of acid cleaner. Snap the blue bicarbonate connector into a full jug of distilled vinegar. Make certain the connections are tight.

5 Press **CONFIRM**

Press the **CONFIRM** key to start the acid cleaning. A bar graph shows the cleaning progress. Also, a timer meter box counts down the remaining time.

6 Return concentrate connectors to rinse ports

(see Your K Map: ‘H’, ‘I’)

When the timer reaches 0:00, your machine will beep. Return the concentrate connectors to their matching rinse ports when instructed. The concentrate connectors must be in their matching rinse ports so the rinse cycle can flush the concentrate lines with water. Make certain the connections are tight.

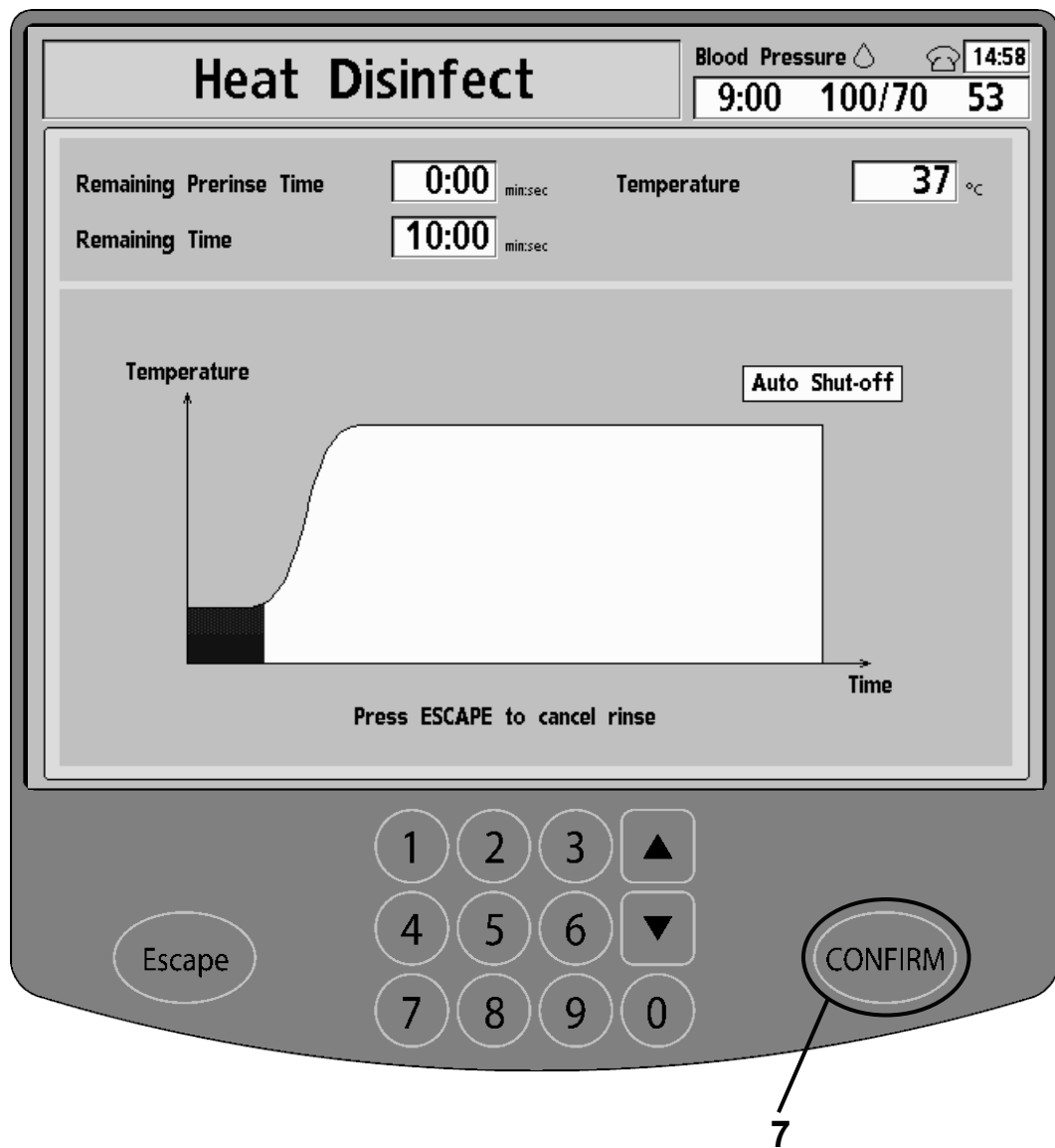


Note: Your machine will beep every 30 seconds until you return the concentrate connectors to their matching rinse ports when instructed.

The Heat Disinfection program will now automatically run, beginning with a pre-rinse. See the next page for more information.

(continued on next page)

Acid & Heat Disinfect (continued)



(continued)

Your machine will run a pre-rinse for seven minutes (or 20 minutes with the extended pre-rinse set in Service Mode).

After the pre-rinse, the “Heat Disinfect” screen displays a bar graph that shows the disinfecting progress. It also shows a timer meter box that counts down the remaining time. The timer starts when the water temperature reaches 80°C (176°F).



Warning: Do not come into contact with the steam coming from your machine’s vent during heat disinfection. Steam and machine parts affected by heat-disinfection will be hot and can cause burns.

Warning: Do not open the bibag door during a Heat Disinfection, serious injury may occur. Keep the bibag door closed when running any rinse or disinfection program.

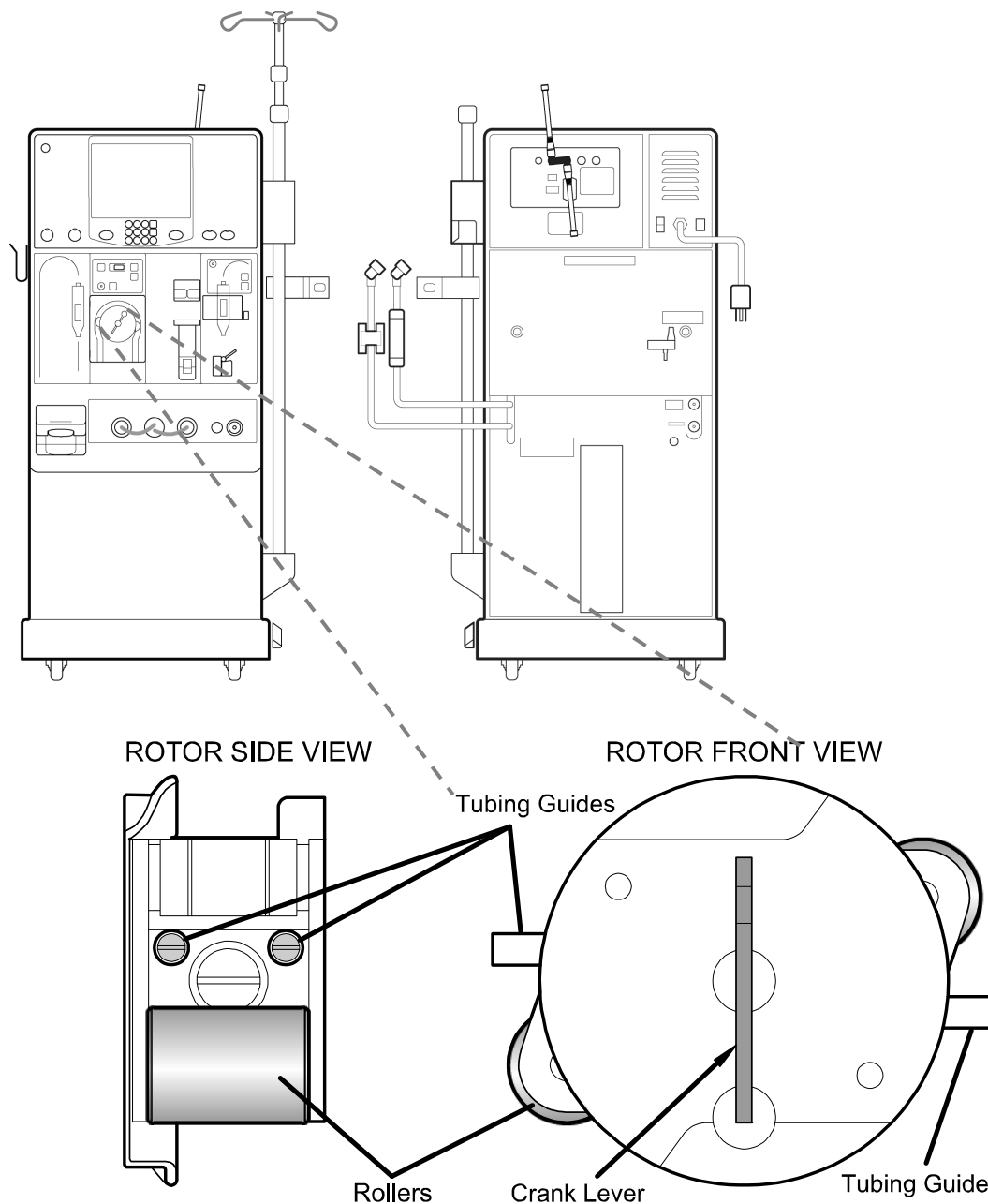
7 Press **CONFIRM**

When the Heat Disinfect portion is complete, press the **CONFIRM** key to exit. You may run your machine through a rinse cycle to cool it down faster, but only for immediate treatment after the rinse is complete.



Note: If the ‘Off after Heat Disinfect’ option is selected in Service Mode, the words ‘Auto Shut-off’ will be displayed above the bar graph. Your machine will automatically power down after the Heat Disinfect is complete.

Disinfecting the Exterior Surface



Warning: Inspect the blood pump rotor for proper operation (tubing guide posts not bent, rollers move freely, crank lever moves freely). Bent or loose tubing guide posts can damage bloodlines. Take your machine out of service and call a qualified technician to replace rotor if necessary.

Disinfecting the Exterior Surface

Thoroughly clean the exterior of your 2008K@home hemodialysis machine after every treatment to prevent the spread of bacteria and viruses like Hepatitis. You can clean it with dilute bleach or other suitable hospital disinfectants. Ask your clinic about other disinfectants you may use.

Use surface cleaners in small amounts to avoid excess cleaner from getting into your machine. Rinse off cleaning solutions with a water-dampened cloth, especially if a corrosive cleaner such as bleach is used.



Caution: Do not use foaming type cleansers or disinfectants containing quaternary ammonium compounds like N-alkyl (C₁₂ – C₁₈) dimethyl benzyl ammonium chloride. These chemicals attack the polycarbonate plastics used in your machine. Read the product labels and follow the instructions. Call Technical Support or your clinic if you have questions.



Note: The Center for Disease Control (CDC) recommends freshly prepared dilute bleach solutions (1:100) as a suitable disinfectant for the Hepatitis virus.

The optional *bibag* connector is connected to your 2008K@home machine's hydraulics so running rinse or disinfection programs from the "Select Program" screen will also rinse or disinfect the *bibag* connector. To prevent bicarbonate buildup on the *bibag* connector:

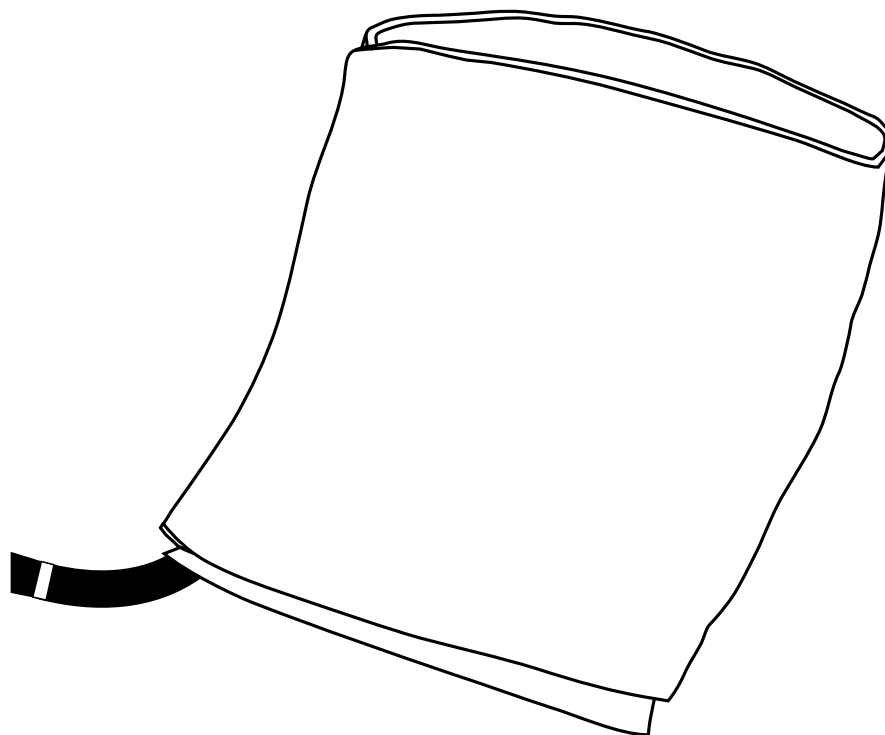
- Clean the exterior of the sealing area of the *bibag* nozzles with very dilute 1:100 bleach every day before running a rinse program.
- Run an Acid Clean program at the end of every treatment day before running a Heat Disinfect program.



Warning: You must run a Rinse program after cleaning the sealing area of the *bibag* nozzles on the *bibag* connector to rinse away any disinfectant.

If a blood leak occurs inside the blood pump module, make sure to clean around the blood pump rotor. Unlatch and remove the rotor during cleaning.

Cleaning the Blood Pressure Cuff



Blood Pressure Cuff

CLEANING/
DISINFECTING

Cleaning the Blood Pressure Cuff

Occasionally the blood pressure cuff may need to be cleaned.

Remove the rubber inflation bag from the Dacron cuff. You may soak both the cuff and inflation bag in commercially available disinfectant soaks. Some disinfectants may cause skin irritation. Follow the manufacturer's instructions. Hand washing will extend the service life of the Calibrated V-Lok cuff.

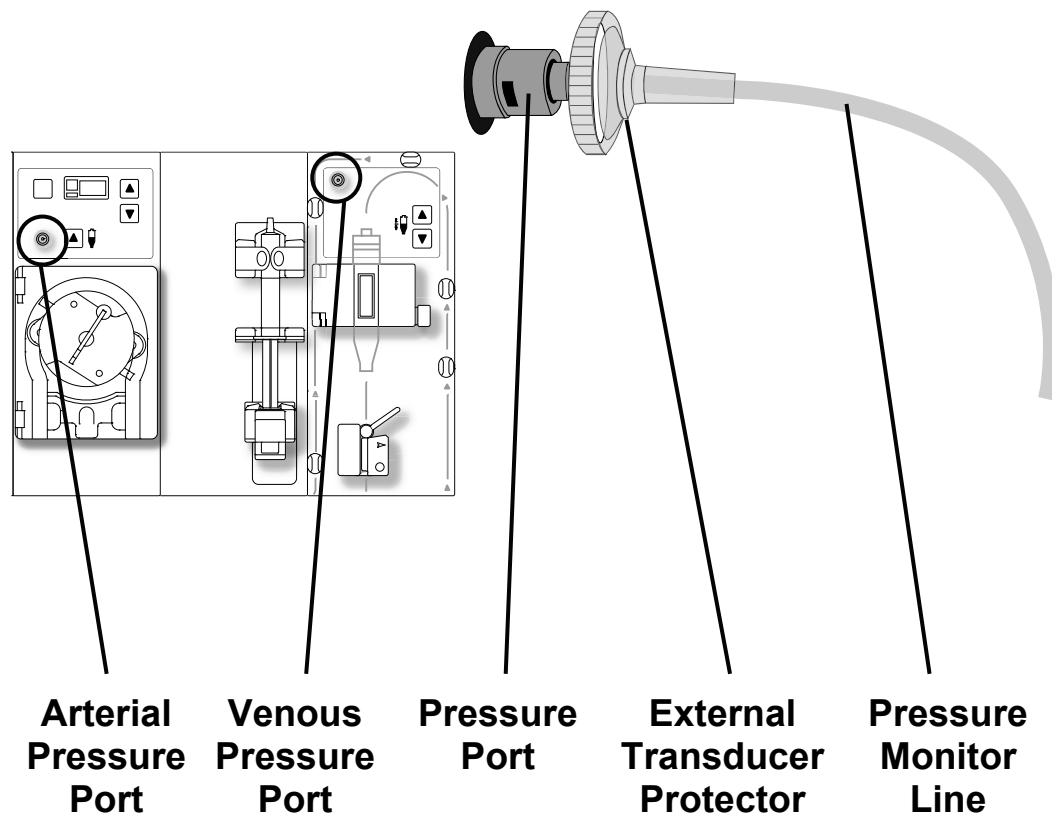
Wash the cuff in warm, soapy water and rinse well. Allow the cuff to air dry then re-insert the inflation bag.



Caution: If you use a chlorine bleach solution to clean the blood pressure cuff, your cuff will wear out faster. Do not use high-temperature steam-cleaners on the cuff. If using a chemical soak, test a small area of the cuff for possible staining. Rinse well to remove any remaining disinfectant. When machine washing, be sure that the hook and loop fasteners are connected so the hooks do not collect lint or other fibers. The fasteners can melt at temperatures above 132°C (325°F), when being ironed or pressed. Follow the manufacturer's instructions.

Disinfecting the Transducer Connection

CLEANING/
DISINFECTING



Disinfecting the Transducer Connection

Your machine monitors bloodline pressures through pressure ports (see Your K Map: ‘F’, ‘M’). Pressure ports, located on both the Blood Pump and Level Detector modules, connect to the bloodlines through pressure monitor lines. Transducer protectors are covers that keep the pressure ports clean and dry. The pressure sensors inside your machine must be kept clean and dry.

If pressure monitor lines become wet:

- Refer to the “Clearing the Pressure Monitor Line” procedure, on page 208

If external transducer protectors become wet:

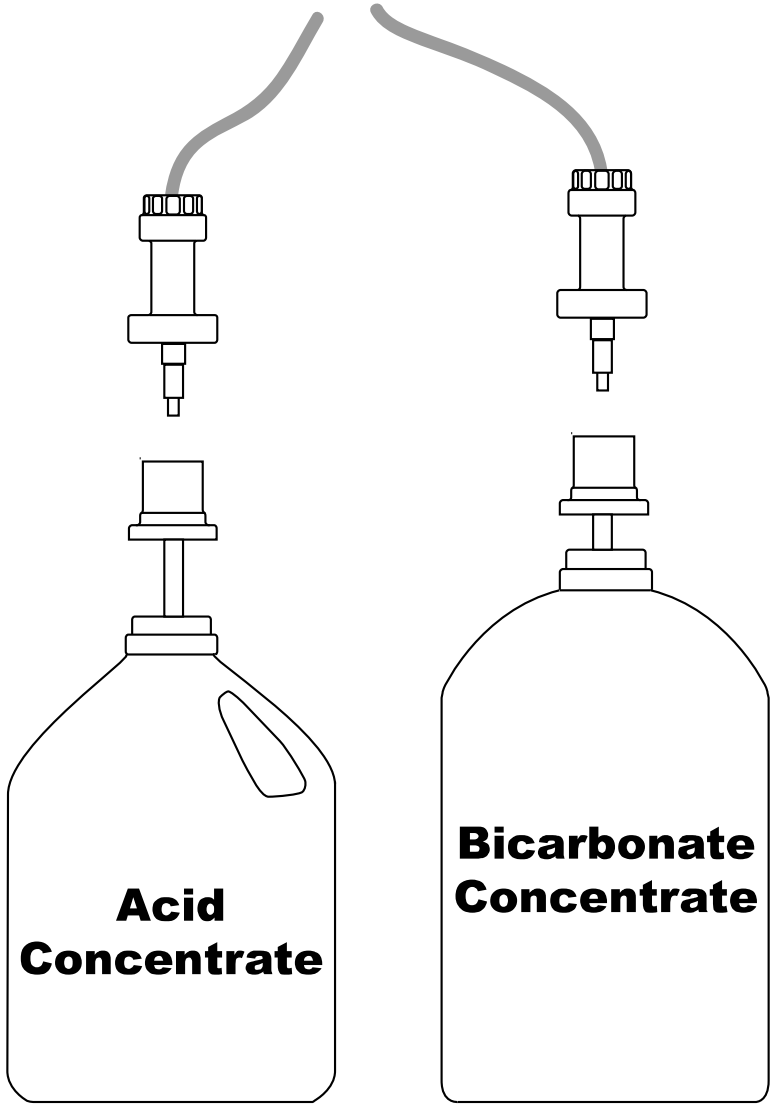
- Replace transducer protector or bloodline

If your machine’s internal parts become contaminated with blood:

- Call a qualified service technician before your next treatment, if necessary
- Replace internal transducer protector
- Disinfect or replace internal lines
- Disinfect all associated parts
- Replace external transducer protector or bloodline

Use the “My Cleaning Procedures” sheet, on page iv, for your clinic’s transducer contamination policy.

Concentrate Container Care



CLEANING/
DISINFECTING

Concentrate Container Care

All concentrate containers should be left empty (shake if necessary) and stored upside-down overnight. The bicarbonate concentrate containers should be disinfected once per week with dilute bleach. Be sure to rinse the containers and test for any residual bleach.

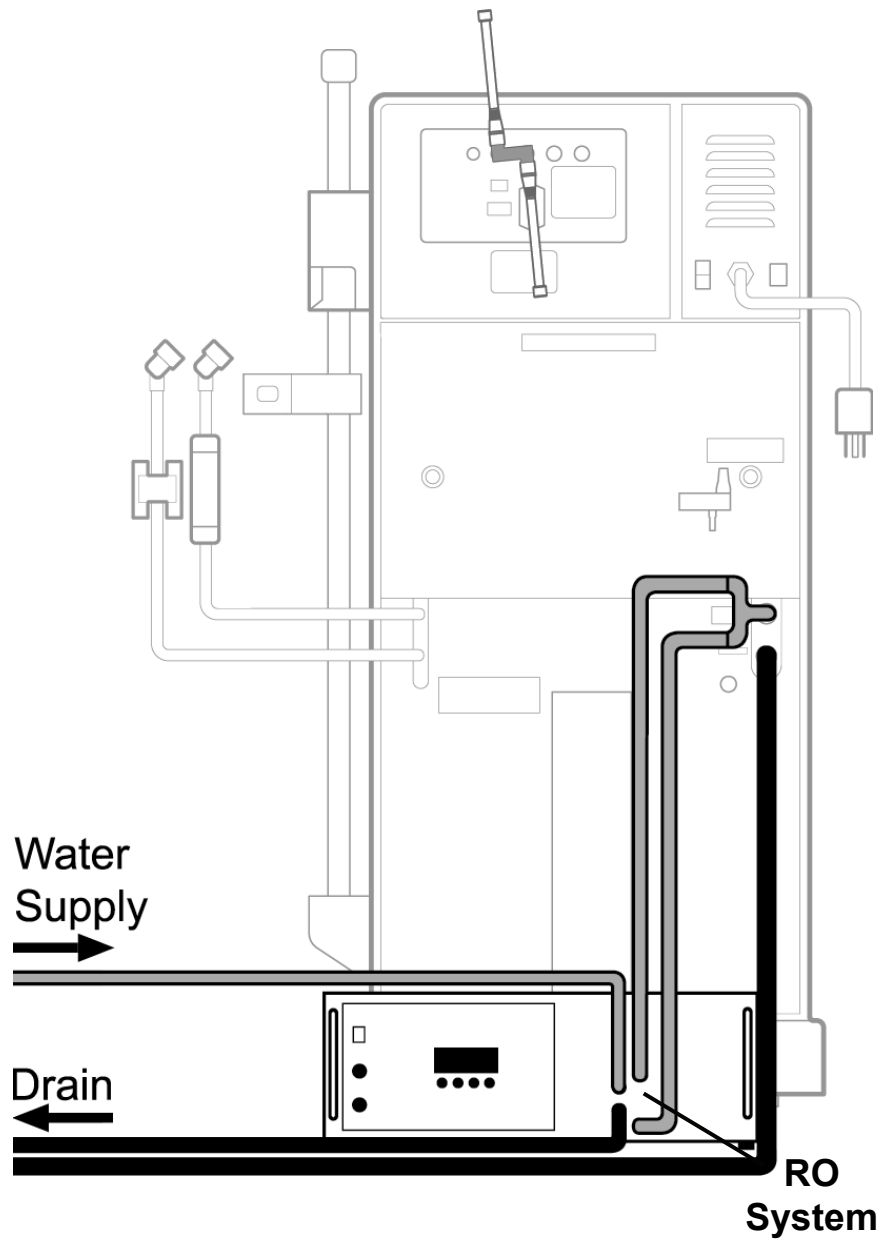
Follow your clinic's instructions on disinfecting the concentrate jug and connector caps; see "My Cleaning Procedures" on page iv.



Warning: Bacteria can grow readily in bicarbonate solutions. Concentrate containers should be cleaned regularly and thoroughly rinsed with treated (RO) water. Test for remaining disinfectant before using the cleaned containers. See "My Treatment Procedures," on page iii. Make a fresh batch of bicarbonate for each treatment according to the manufacturer's instructions.

Water Supply Maintenance

CLEANING/
DISINFECTING



Water Supply Maintenance

Check the dialysate's bacterial quality on a regular basis just before disinfecting the system. Follow the manufacturer's instructions for the operation, cleaning, and storage of your Reverse Osmosis (RO) and water pre-treatment equipment. See also "My Cleaning Procedures" on page iv.

All sections of the treated water feed system and dialysate delivery machine must be disinfected regularly to minimize bacterial levels. Each time the treated water system and distribution piping are disinfected, run the "Rinse" program to allow the disinfectant chemical to flow through the inlet system. If a depth filter is used, it should be changed after the rinse, as it is difficult to completely remove remaining disinfectant from the filter. Test your water supply for disinfectant before every treatment. See "My Treatment Procedures," on page iii.



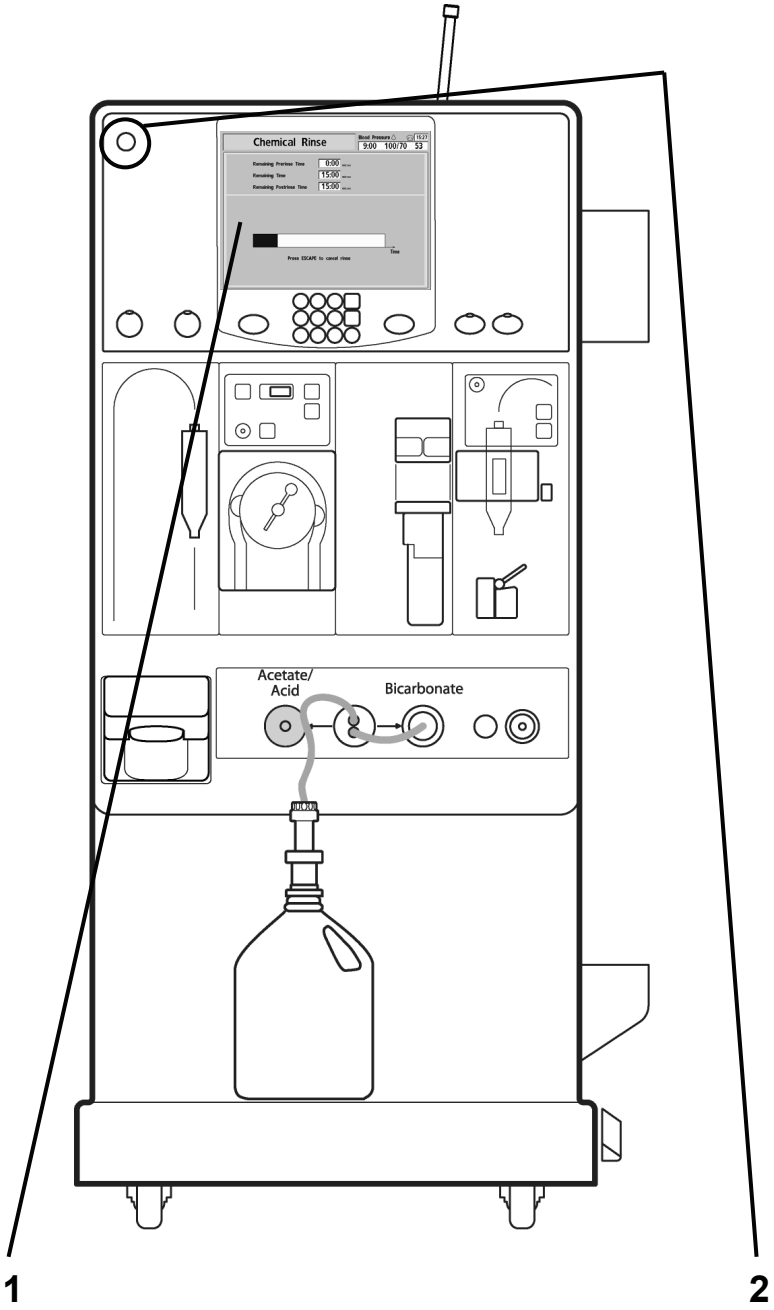
Note: Normal heat disinfection may not completely clean biofilm from the drain line. If biofilm build-up is a problem, have a qualified service technician select the "Extended Pre-rinse" option in Service Mode. If necessary, replace the drain line.



Caution: This is a general guide only; you must follow your RO system manufacturer's instructions.

Storing Your Machine for Extended Times

CLEANING/
DISINFECTING



Storage Preparation

Before storing your 2008K@home hemodialysis machine for an extended time, wipe the external parts of your machine with a surface cleaner; see page 180. You must also disinfect the hydraulics. To disinfect the hydraulics and dwell the disinfectant:



Caution: Use “My Cleaning Procedures” on page iv for storage rules. The table on next page lists commonly used procedures to store equipment and then return it from storage.

1 Run the Chemical/Rinse Program

See page 168 for instructions on running the “Chemical/Rinse” program. After connecting the red acid concentrate connector to a jug of formaldehyde or Diacide, let the chemical recirculate until the “Remaining Time” is down to one minute. Continue to step 2 below.

2 Turn your machine off

When the disinfectant has been pulled into your machine, press and hold the **Power** key (see Your K Map: ‘A’) for two seconds to turn your machine off. Your machine is now ready for storage. You must refill your machine with fresh formaldehyde every 3-4 weeks for the duration of the storage time.



Note: After returning your machine from storage, disinfect your machine’s hydraulics with the Heat Disinfect or standard Chemical/Rinse procedures and test. Continue to disinfect your machine’s hydraulics every 24 hours and retest until your machine is ready for treatment as determined by your clinic.

Storing Your Machine (continued)

Disinfectant	Program	Dwell time	Retest and Repeat
Formaldehyde	Fill Hydraulic (Service mode)	Unlimited	3 – 4 weeks
Bleach	Chemical Disinfection program	<u>Only</u> for time of disinfection program	24 hours
Puristeril 340 Renalin	Chemical Disinfection program	<u>Only</u> for time of disinfection program	24 hours
Heat	Heat Disinfection program	Recirculate and shut machine off	24 hours

Storage Location

Store your machine in a place where it is safe from possible damage. The dedicated storage space should have connections to water and power, and a drain. The room should be well ventilated if disinfectant is used. Depending on the disinfectant and the storage time, frequent flushing of the equipment is important.

Take special care to make sure that the blood pressure, concentrate, and dialysate supply lines are not twisted when in storage. Check for any cracking or kinking.



Warning: Do not use your machine in the presence of flammable substances, like anesthetics, as it may cause explosions which may result in serious injury or death.

See “Moving Your Machine” on page 60 for instructions on how to move your 2008K@home hemodialysis machine.

After prolonged storage, use a bleach disinfectant to clean the exterior of your machine before treatment; see “Cleaning the Exterior Surface” on page 180.



Warning: Use Schiff’s reagent or a commercially available formaldehyde test for remaining disinfectant. Follow the manufacturer’s instructions. The level of formaldehyde should be less than 5 ppm.

Chapter 6: Emergencies and Alarms

Your 2008K@home hemodialysis machine has an advanced system of features that work for your safety. Electronic sensors and diagnostic software constantly monitor your machine's operation. When problems or possible problems are detected, your machine warns you with Status Box messages and, in some cases, audible alarms. Audible alarms are deactivated when dialyzer supply lines are on the shunt interlock and/or the Tx Clock is running, unless blood is sensed.



Warning: All alarms need your immediate attention. Failure to do so may cause serious injury or death.



Note: Your 2008K@home hemodialysis machine may be set to silence all audible alarms until blood is sensed in the venous line. When selected, the audible alarms occur only if the dialysate lines are off the shunt interlock and the optical sensor in the level detector module senses blood. This option is set in Service Mode by a qualified service technician and is selected by your clinic. Otherwise, alarms are always audible when dialysate lines are off the shunt interlock.

Note: If your 2008K@home hemodialysis machine becomes unresponsive (locks-up or 'freezes') or if the display screen unexpectedly turns off, turn off the machine by pressing and holding the **Power** key for two seconds. Press the **Power** key again to restart the machine.

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

During an alarm, the Status Box background turns bright red and an audible alarm sounds. For alarm procedures, use the troubleshooting section of this manual, found on page 224.

Blood Alarms

Blood alarms have the highest priority. When a blood alarm occurs:

- The blood pump stops
- The Venous Clamp on the Level Detector module closes
- The UF pump stops
- The Tx Clock stops

Press and hold the **RESET** key (see your K Map: ‘B’) for two seconds to override a blood leak alarm. Check all bloodline connections if a blood leak alarm sounds—before overriding. Note that your machine may not alarm with all blood loss situations. Your access site must be uncovered, properly secured, and checked regularly throughout the dialysis treatment. Failure to do so may lead to excessive blood loss which can cause serious injury or death. You must correct the condition causing a blood alarm before clearing the alarm. You may then press the **RESET** key to clear a blood alarm.

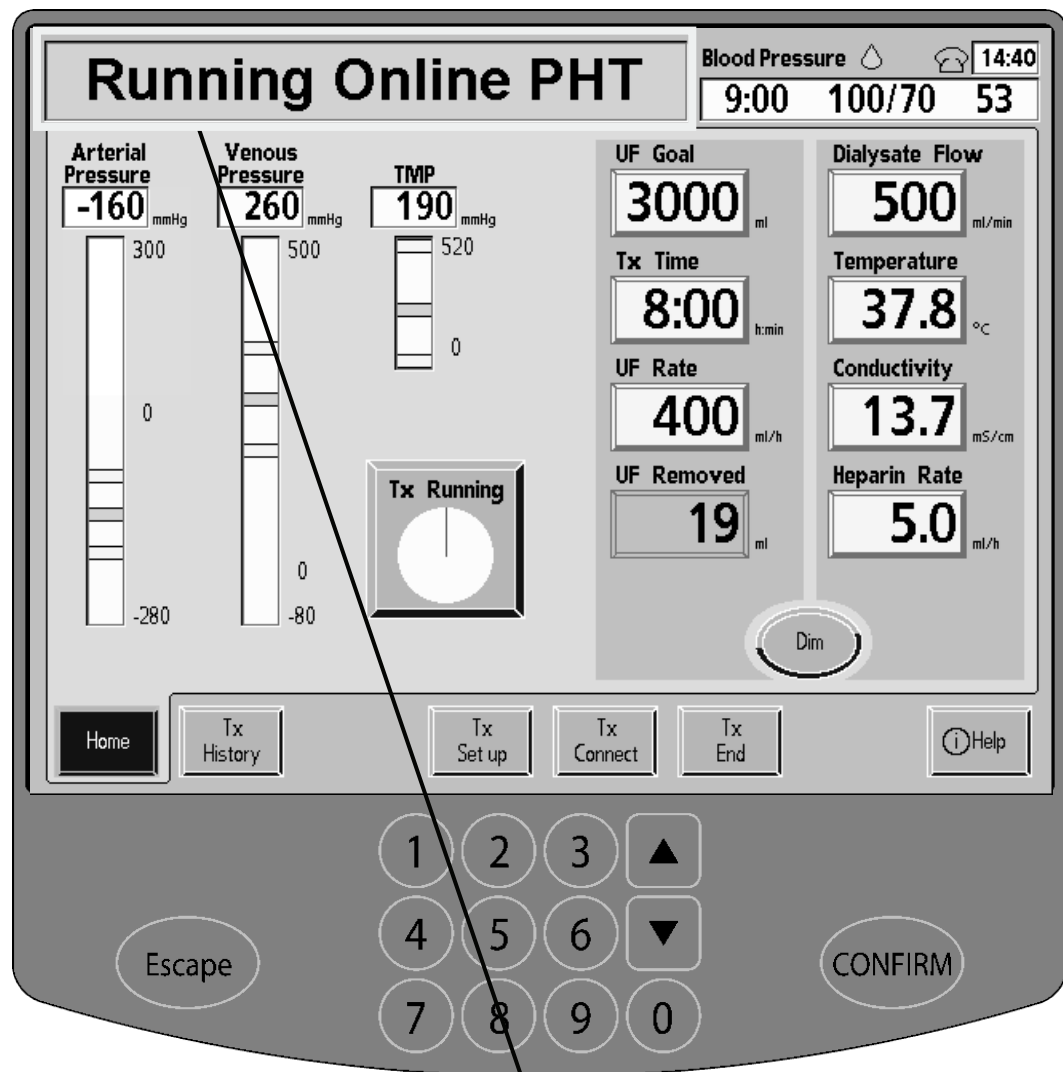
Dialysate Alarms

During a dialysate alarm (temperature or conductivity), the blood system continues to operate, but the dialysate is run through your machine instead of the dialyzer. This is called ‘bypass’ and can be observed by watching the float in the dialyzer supply line. During bypass, the float will remain still at the bottom of the flow indicator. Contrarily, a high or low flow error will not cause your machine to go into bypass. Dialysate alarms are self-resetting when the alarm condition is corrected.

Other Alarms

Other alarms may relate to machine parts like the heparin pump or UF pump.

Online Pressure Holding Test



ALARMS

Online Pressure Holding Test Running Message



Warning: The values shown here are for example only. You must use the values prescribed by your doctor. If you use the wrong values, it may cause serious injury or death.

The online Pressure Holding Test (PHT)

The online Pressure Holding Test (PHT) automatically checks your machine's dialysate balancing system. The PHT runs only during dialysis when the dialyzer is connected.

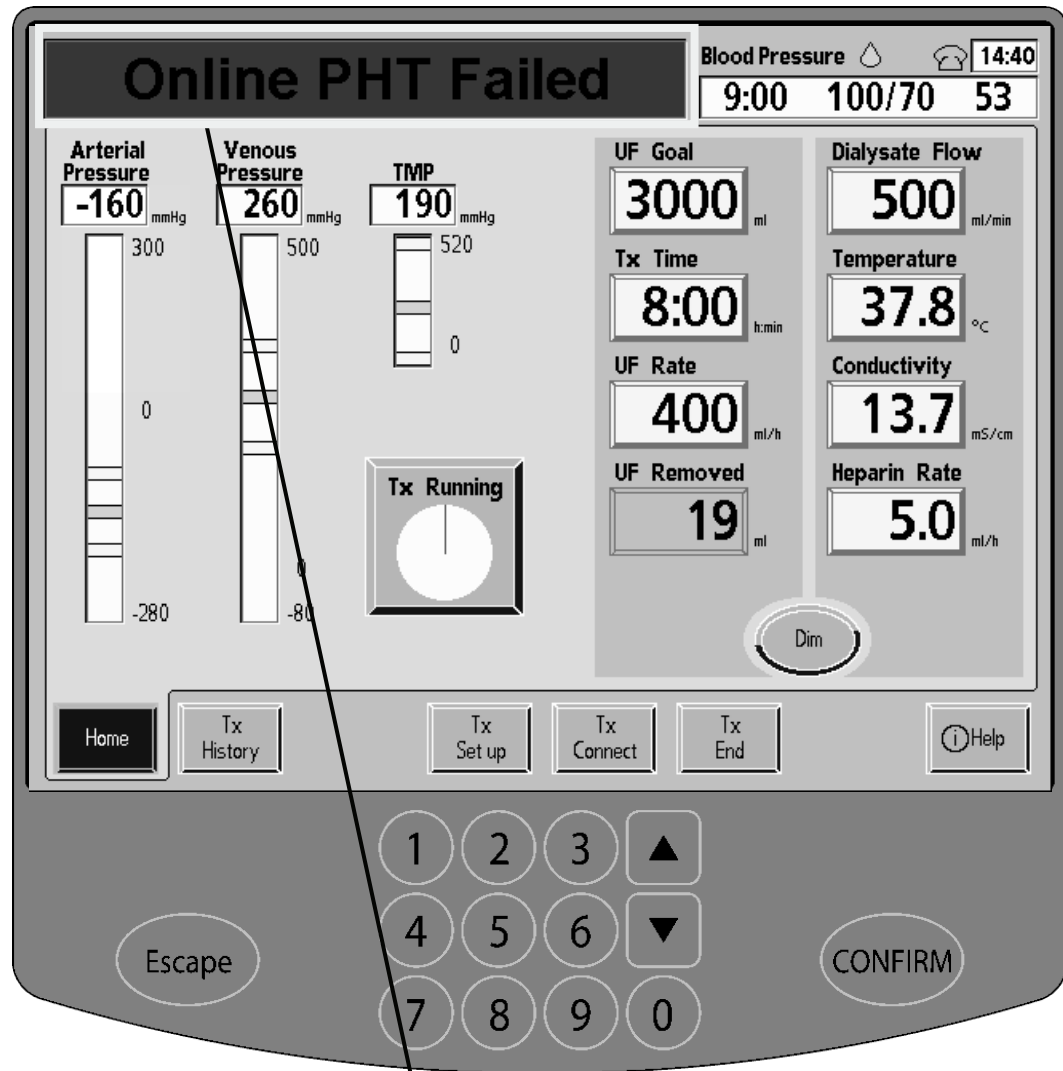
The online PHT runs about every 12 minutes regardless of other alarm conditions. During the test, the Status Box displays the message: "Running Online PHT." The UF light above the **UF on/off** key (see Your K Map: 'N') also flashes. The test will run for about seven seconds as the balancing chamber runs through two cycles. During the test, your machine is in bypass mode and the TMP alarm limits are spread.

If the online PHT fails, see the next page.



Note: The online pressure holding test is not a substitute for the self-test. Do not begin dialysis until the self-test has been run (see page 90).

Online Pressure Holding Test Failure



Failure Message



Warning: The values shown here are for example only. You must use the values prescribed by your doctor. If you use the wrong values, it may cause serious injury or death.

Online PHT Failure

If your machine fails an online PHT (pressure holding test), the Status Box displays the alarm message: “Online PHT Failed.” This alarm does not stop the blood pump.

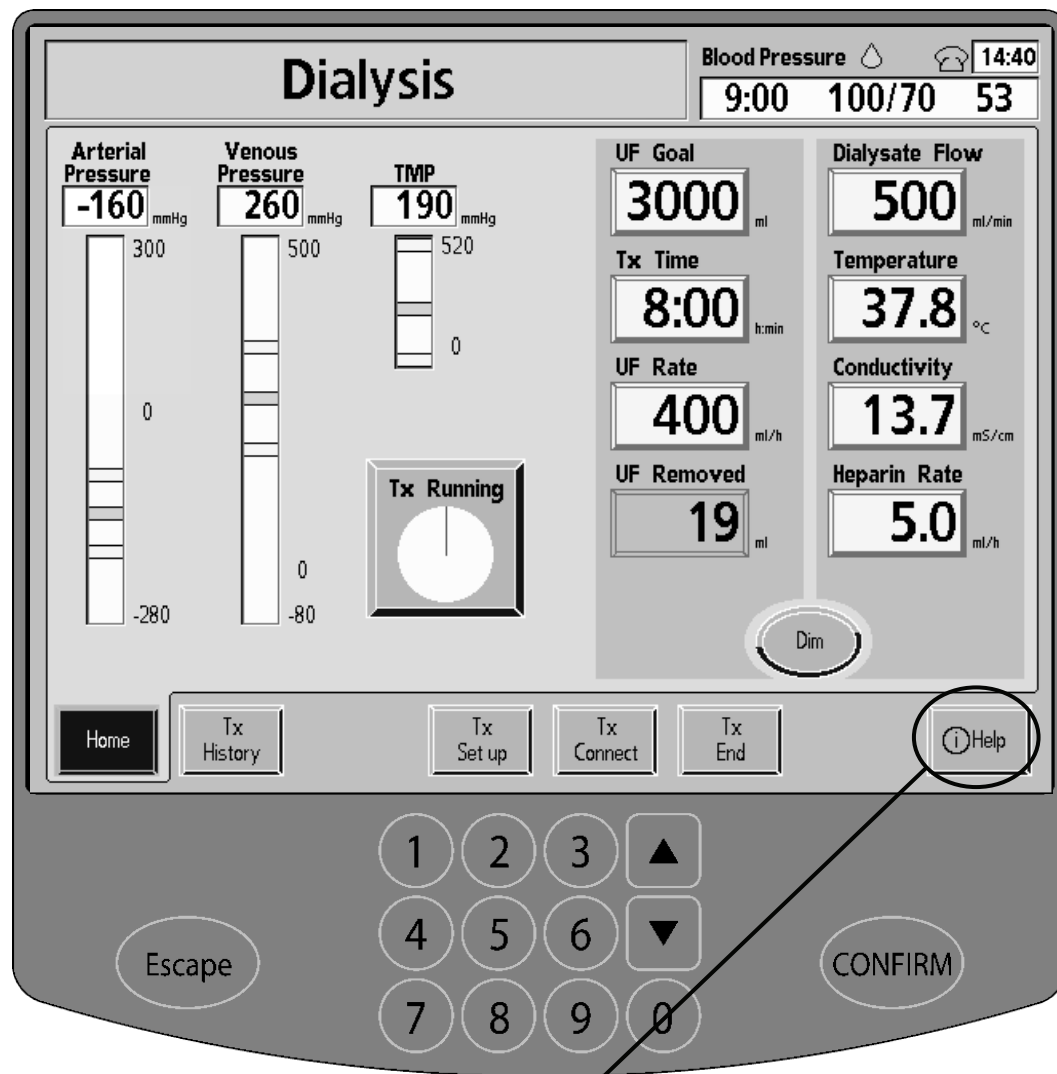
Pressing the **RESET** key (see Your K Map: ‘B’) in the Machine section of the Control Panel will clear the alarm.

If an online PHT fails during your treatment, check tubing connections for any air intake or fluid leaks and use the Troubleshooting section on page 224. Make certain your machine passes the test before your next treatment. To retest the hydraulics, see “The Help Screen” on page 200.



Warning: If an online PHT failure recurs, you must stop your treatment and have a qualified service technician test the hydraulics.

The Help Screen



Help Screen-Button



Warning: The values shown here are for example only. You must use the values prescribed by your doctor. If you use the wrong values, it may cause serious injury or death.

The Help Screen

You may use a built-in help screen to test your machine's systems. The available tests are:

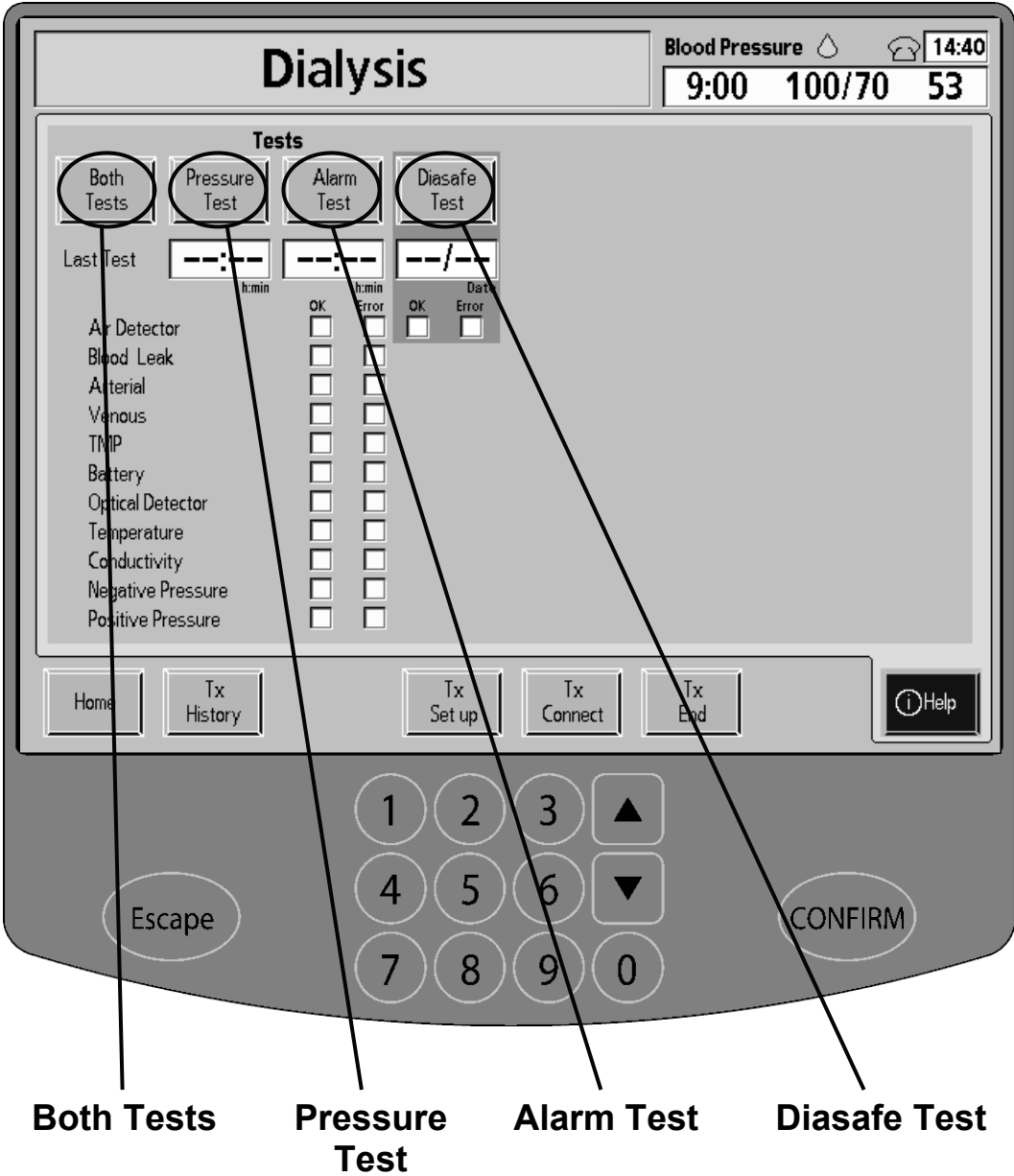
- Pressure
- Alarm
- Both Tests (Pressure and Alarm)
- Diasafe Plus

The “Help” screen is available from any “Dialysis” screen: Press the **Help** screen-button (located on the right side at the bottom of the Touch Screen). See the next page for an in-depth explanation of the tests.



Note: The “Help” screen testing function is not available during a warning or alarm. Instead, during a warning or alarm, the “Help” screen displays step-by-step instructions to correct the problem. See “The Help Screen – Alarms” on page 206 for more details.

Test Buttons



Test Buttons

Touching a test button and pressing the **CONFIRM** key will run its test.



Note: Before running a test, you must place the dialysate lines back on the shunt interlock and close the shunt door. Cap the dialysate connectors on the dialyzer to prevent fluid spills. Clamp and disconnect the pressure monitor lines and transducer protectors from your machine's pressure ports.



Caution: Make sure the pressure ports and transducer protectors remain dry and sterile. Wet transducer protectors must be replaced, as they will cause inaccurate readings and possibly serious injury or death.

Both Tests

“Both Tests” runs a pressure and alarm test on your machine.

Pressure Test

“Pressure Holding Test” runs a test of your machine's hydraulic system under treatment pressures. The time displayed below the **Pressure Test** button shows when these tests were completed.

Alarm Test

“Alarm Test” runs a test of your machine's alarm system. The time displayed below the **Alarm Test** button shows when these tests were completed.

Diasafe Test

“Diasafe Test” tests the Diasafe Plus filter. Replace the filter if it fails the test, see page 308 for more information. The date displayed below the **Diasafe Test** button shows when this test was completed.



Note: You must run a successful Pressure Test before running the Diasafe Test.

Test Buttons (continued)



Test Failed Messages

Test Running

The Status Box displays each test as it runs. As each test passes, a blue “☑” appears in the “OK” column. When all the tests are done, your machine will beep and the Status Box will display the message: “Test Complete.”

Reconnect the dialysate lines and transducer protectors and unclamp the monitor lines before continuing with your treatment.

Test Failed Messages

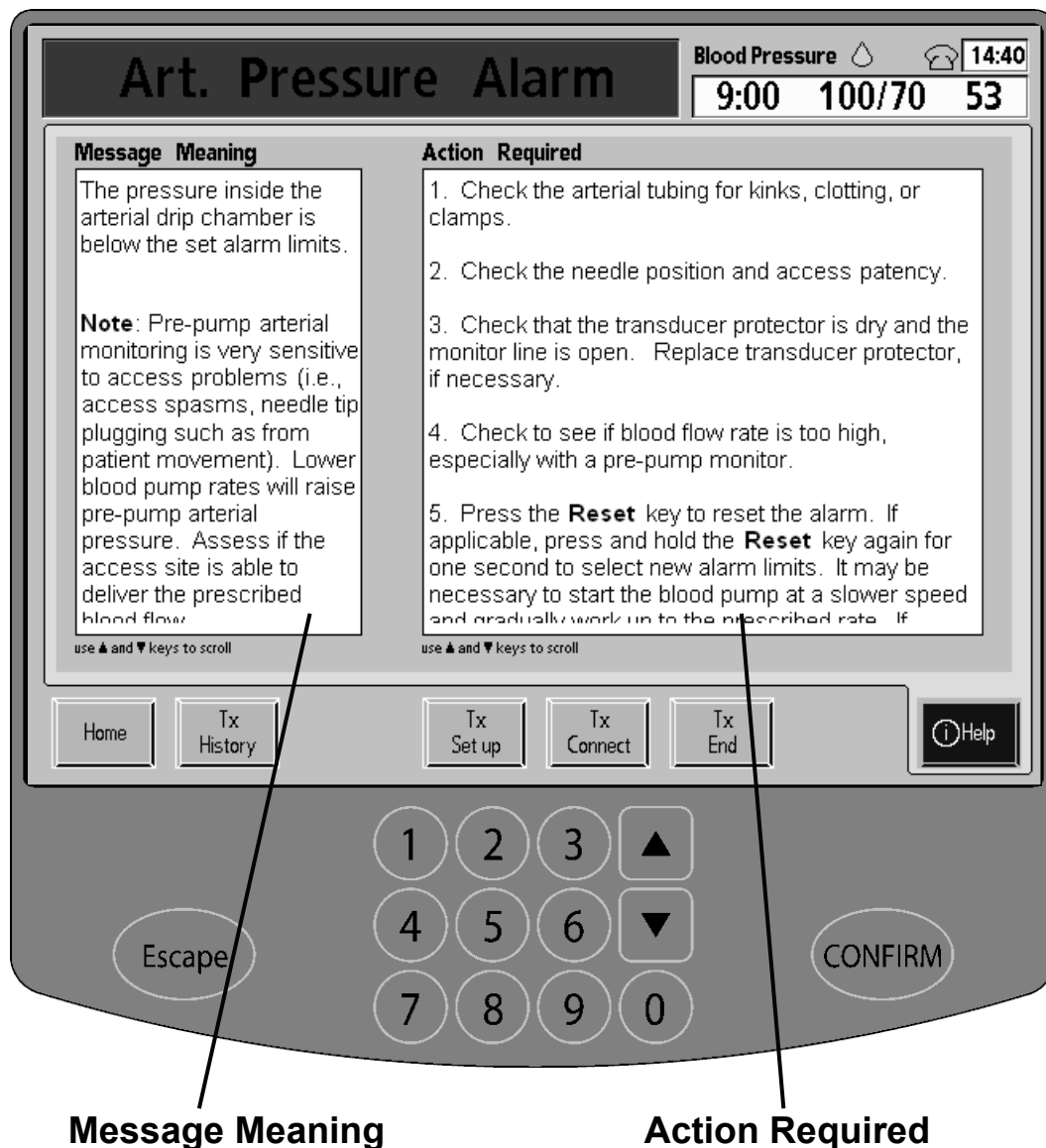
If any part of the test fails, a red “☒” appears in the “Error” column and the Status Box displays the message: “Test Failed.” After running a test, your machine displays the results on the right side of the screen. For a description of errors, see the “Troubleshooting” section on page 224.



Warning: If your machine fails any of the tests and the cause cannot be corrected, or if it fails later tests, it should not be used for treatment. Have your machine checked by a qualified service technician to correct the problem.

To exit the “Help” screen, touch any of the screen-buttons located along the bottom of the Touch Screen. To return to the dialysis “Home” screen, touch the **Home** screen-button.

The Help Screen – Alarms



ALARMS

The Help screen during alarms or warnings

If additional information exists for an alarm or warning, the **Help** screen-button will flash. If you touch the **Help** screen-button, your 2008K@home hemodialysis machine will display the following on the “Help” screen:

- Message Meaning
- Action Required

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.

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.



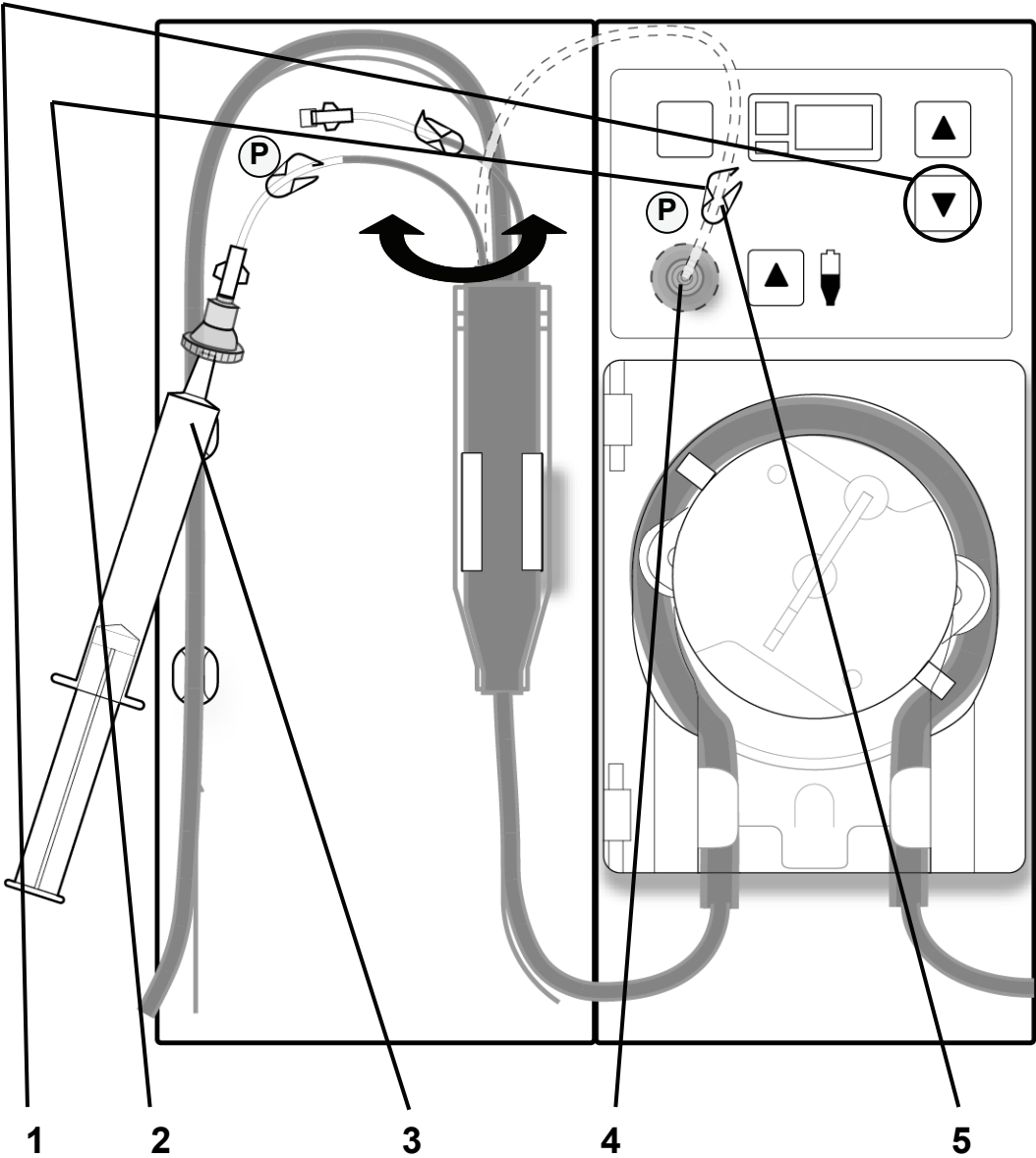
Warning: Doing the recommended action may or may not clear the alarm, warning, or advisory messages displayed. Do not continue your treatment until the conditions causing these messages are corrected and the messages are cleared. Follow your clinic’s instructions.



Note: Refer to the “General Warnings” section, on page 10, for additional warnings.

Note: Machines taken out of service should be tested and repaired by a qualified service technician.

Clearing the Pressure Monitor Line



ALARMS

Clearing the pressure monitor line

If the arterial drip chamber blood or saline level rises too high, you may need to inject pressure to prevent the pressure monitor line from getting wet.



Note: Press and hold the **RESET** key to temporarily widen the arterial and venous pressure alarm windows if needed.

1 Decrease pump speed to 250 ml/min or less (see Your K Map: 'E')

2 Clamp and disconnect the arterial pressure monitor line

Disconnect the transducer protector and the pressure monitor line from the pressure port. Inspect the transducer protector to make sure it is not wet.



Caution: Wet transducer protectors must be replaced, as they will cause inaccurate readings and possibly serious injury or death.

3 Connect a sterile syringe, unclamp, and inject air



Warning: Maintain desired blood level in arterial drip chamber.

Draw air into the sterile syringe before attaching it to the transducer protector at the end of the arterial pressure monitor line. Connect the sterile syringe to the end of the monitor line. Unclamp the line and inject air to push the blood down to a desired level in the arterial drip chamber.

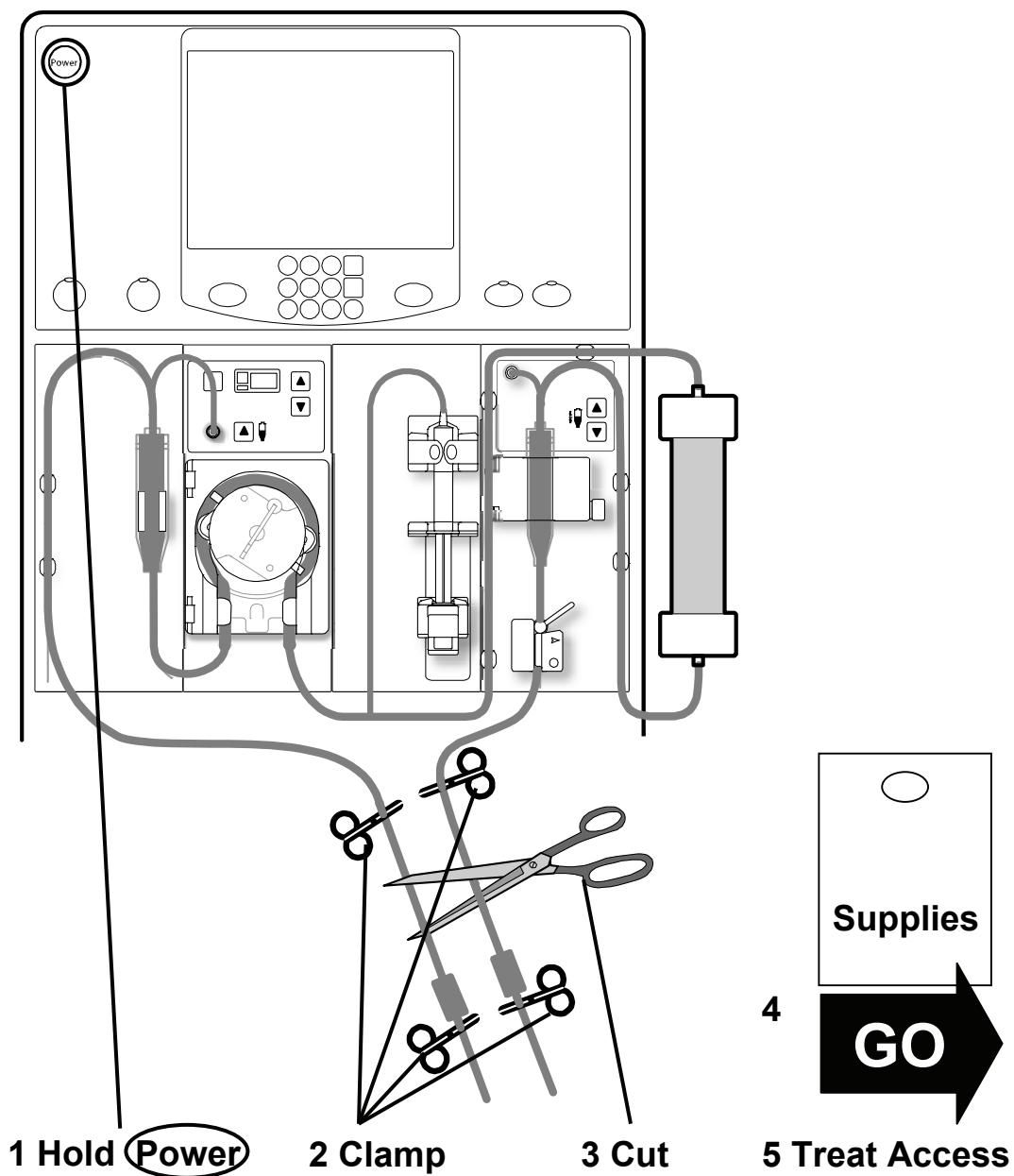
4 Clamp and disconnect line and reconnect to pressure port

Clamp the monitor line and disconnect it from the syringe. Reconnect the line to your machine's arterial pressure port using a sterile transducer protector.

5 Open the pressure monitor line clamp

Unclamp the line. Raise the blood pump back to your prescribed rate using the **Blood Pump Up/Down Arrow** (/) keys (see Your K Map: 'E').

Emergency Disconnection



ALARMS

Emergency Disconnection

In the event of a life-threatening emergency such as a fire, follow these instructions or your clinic's instructions to safely disconnect from your machine:

1 Hold **Power** (see Your K Map: 'A')

Turn your machine off by holding the **Power** key down for two seconds.

2 Clamp arterial and venous access lines

Use the four blue clamps from your emergency bag to clamp the arterial and venous access lines.

3 Cut bloodlines

Cut the bloodlines between the blue clamps with the scissors from your emergency bag.

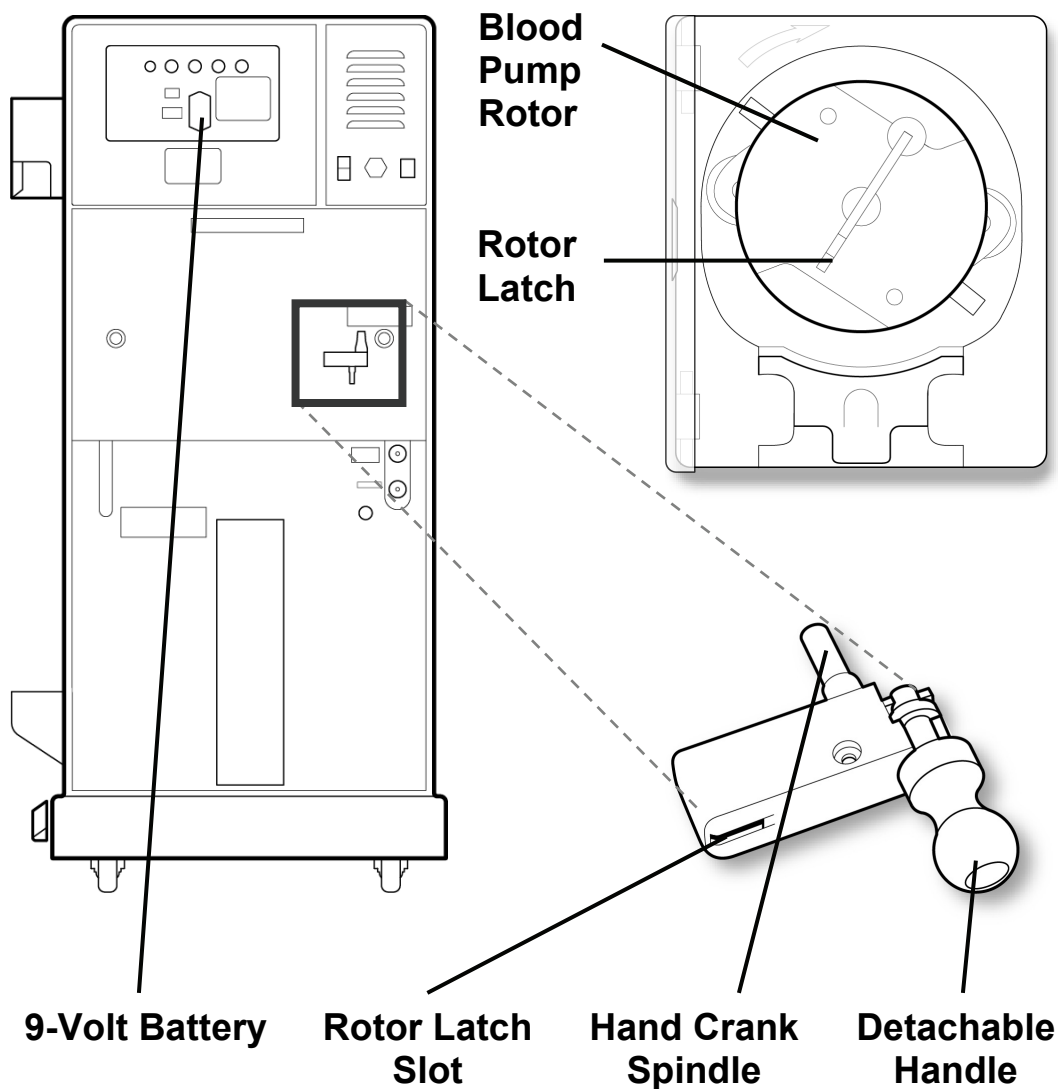
4 Take supplies

Take your emergency bag of supplies and get to safety.

5 Treat access

Care for your access site according to your clinic's procedures. When you return to your machine, you must dispose of your bloodlines and disinfect your machine.

Power Failure during Dialysis



Power Failure during Dialysis

During a power failure the blood pump stops and the venous clamp closes. The dialysate flow pump, heater, blood leak detector, and level detector are non-functional. All machine lights go out and a steady, audible alarm will immediately sound for seven minutes. The alarm cannot be silenced with the **Mute** key.

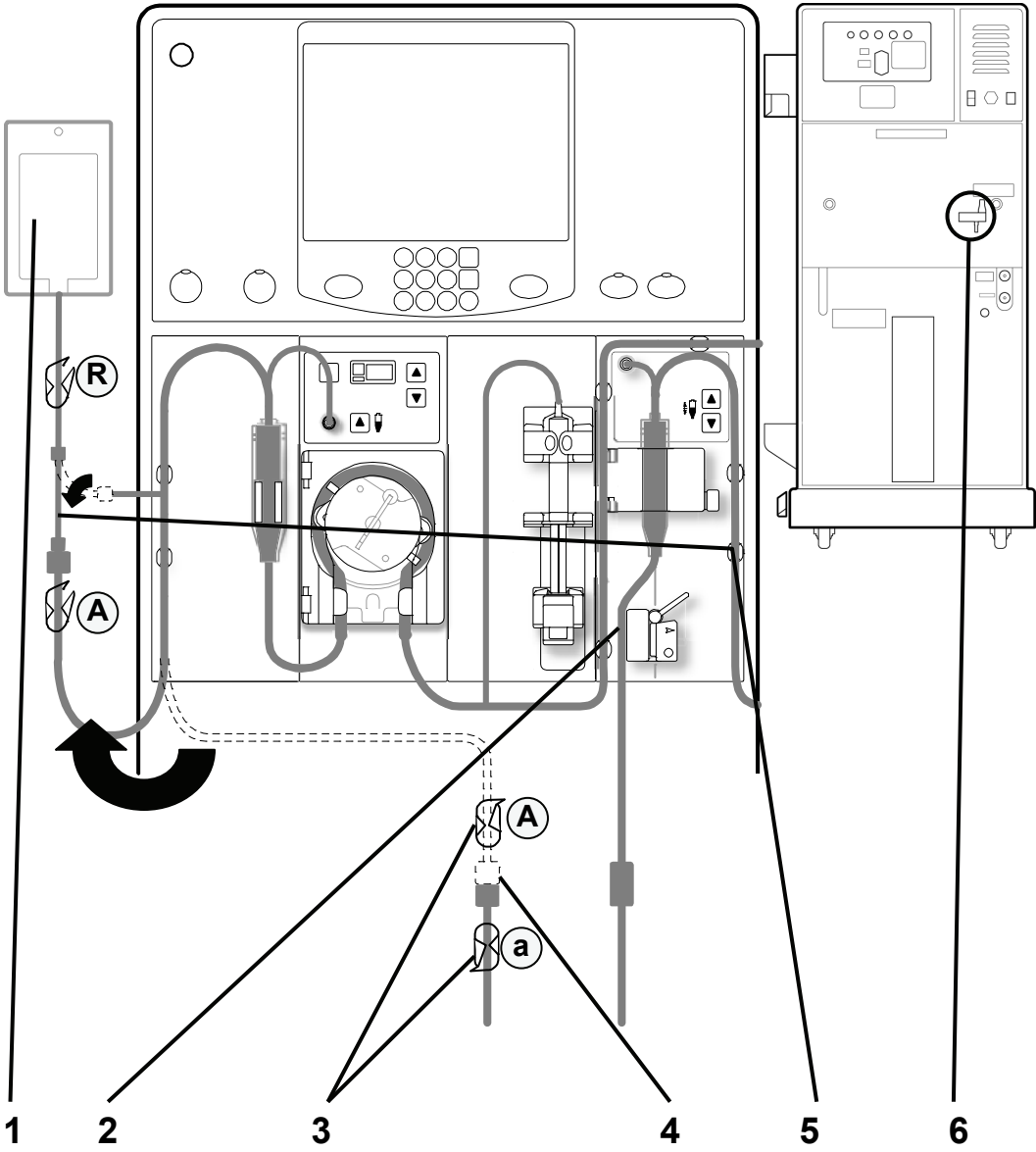
The blood pump can be manually operated to immediately return the blood to the patient, or, if power is expected to return soon, to keep the blood in circulation. Follow the steps on the next page to turn the blood pump using the emergency hand crank.

The emergency hand crank is attached to the back of your machine.



Note: As a precaution, the handle knob will detach from the crank if you try to turn the rotor in the wrong direction. An arrow stamped on the blood pump module, above the rotor, points in the correct direction of rotation (clockwise).

Returning the Blood Manually



ALARMS

1 Check saline bag amount

Check that the saline bag contains enough saline to rinse back your blood. Replace the saline bag with a fresh one if necessary.

2 Remove venous line from Venous Clamp (see Your K Map: 'K')

Remove the bloodline from the Venous Clamp.



Caution: Do not forcefully pull the lines from your machine. Damage to your machine or its sensors may result.

3 Close arterial line clamps (A) (a)

4 Disconnect arterial access bloodline

5 Connect arterial line to saline bag, open clamps (A) (R)

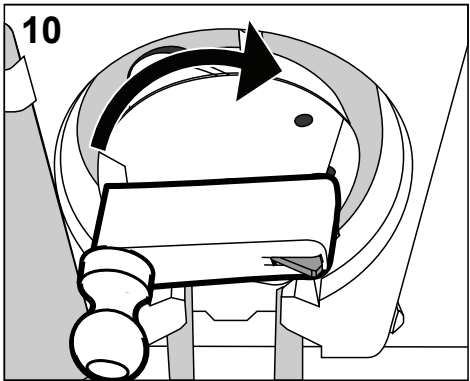
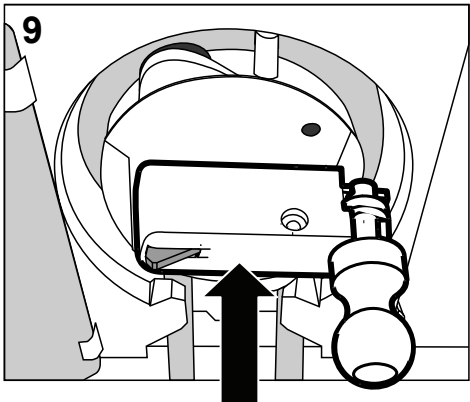
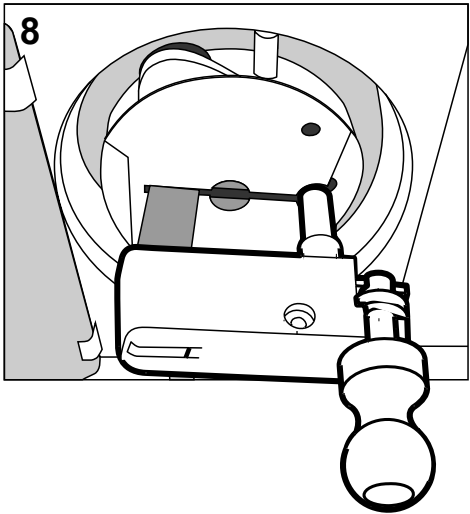
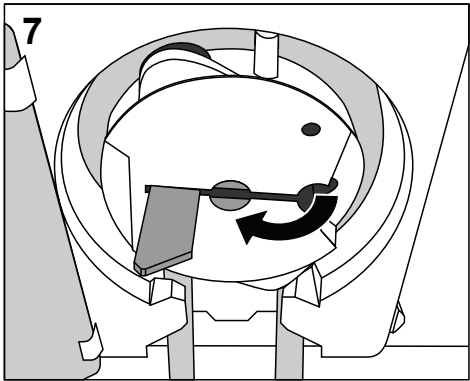
Disconnect the red end of the recirc connector from the saline line. Tightly reconnect it to the patient end of the arterial line. Open the patient arterial line clamp. Open the saline line clamp below the saline bag spike.

6 Retrieve emergency hand crank

The hand crank is located on the back of your machine.

(continued on next page)

Returning the Blood Manually (continued)



11 Disconnect when blood is returned

ALARMS

(continued)

7 Open blood pump door, flip rotor latch outward


8 Line up hand crank with rotor

Line up the crank handle's slot and spindle with the rotor latch and spindle hole.

9 Slide hand crank into place

Slide the crank handle in as far as it will go—the rotor latch will extend slightly beyond the crank handle.

10 Rotate hand crank, rinse back blood with saline

Rotate the crank clockwise . Turn the crank 6 to 10 revolutions per minute for a flow rate of 60 to 100 ml/min. Use the “My Treatment Procedures” sheet, on page iii, for instructions on rinsing back your blood.



Warning: Carefully watch the venous chamber and bloodline for air intakes. Be sure no air enters your access.

Warning: Keep fingers clear of the blood pump rotor when it is turning. Serious injury may occur.

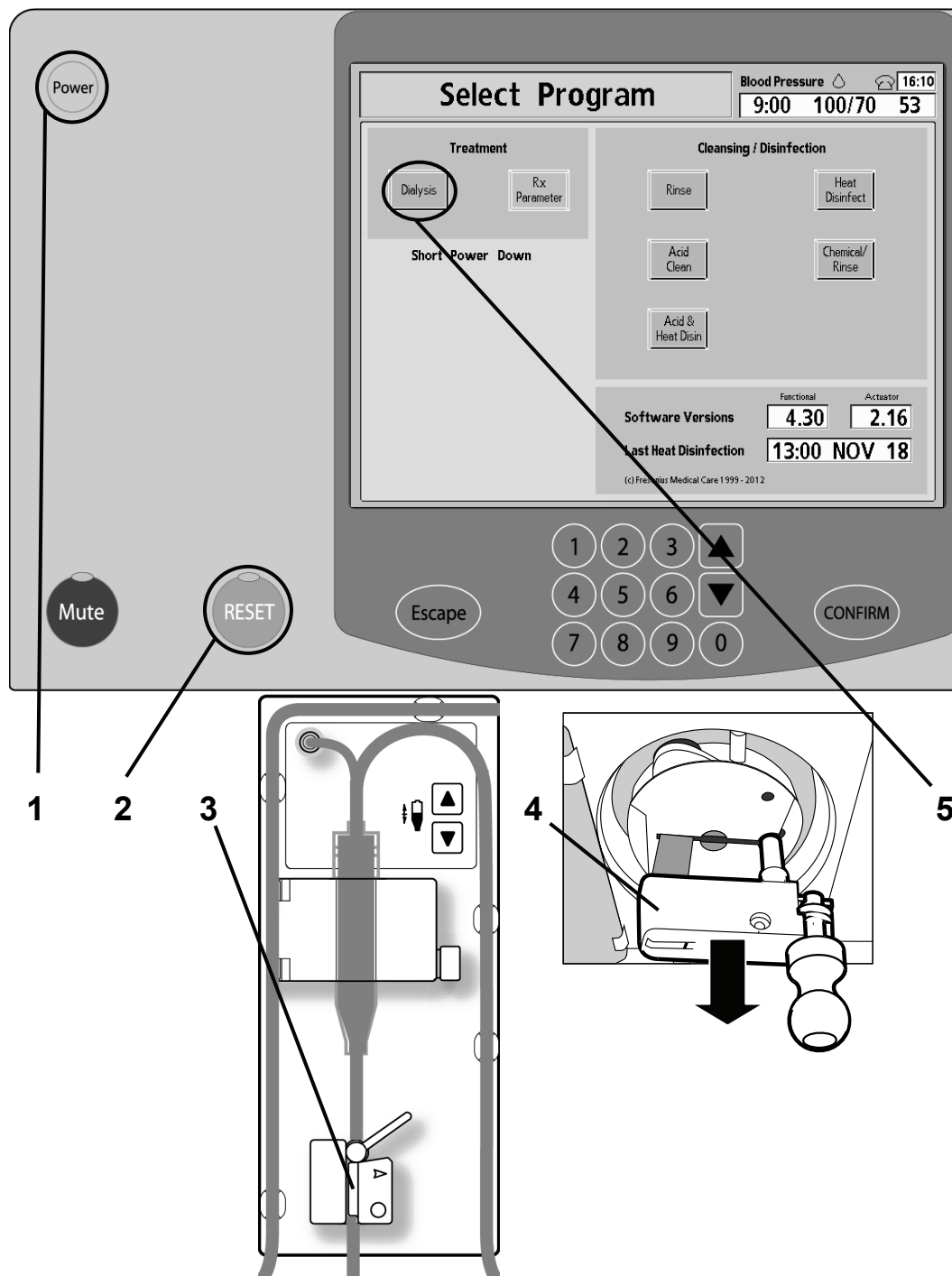


Note: During a power failure, your machine's safety systems are inactive.

11 Disconnect when blood is returned

Clamp and disconnect the venous access line when your blood has returned. You may now perform access care. Use the “My Treatment Procedures” sheet, on page iii, when caring for your access site to prevent infection.

Resuming Dialysis after a Brief Power Failure



ALARMS

1 Press **Power** (see Your K Map: 'A')
Press the **Power** key to turn your machine back on.

2 Press **RESET** (see Your K Map: 'B')
Press the **RESET** key to clear any alarms when your machine has powered up again.



Warning: Do not continue treatment if there is evidence of hemolysis.

Warning: Use aseptic technique.

Warning: Continue turning the emergency hand crank to recirculate the blood. Turn the crank 6 to 10 revolutions per minute for a flow rate of 60 to 100 ml/min.

3 **Insert venous line into Venous Clamp and Optical Detector**
(see Your K Map: 'K', 'J')

Rotate the Optical Detector door open. Insert the venous line back into the Venous Clamp and Optical Detector. Close the Optical Detector door again.

4 **Remove hand crank from blood pump rotor**

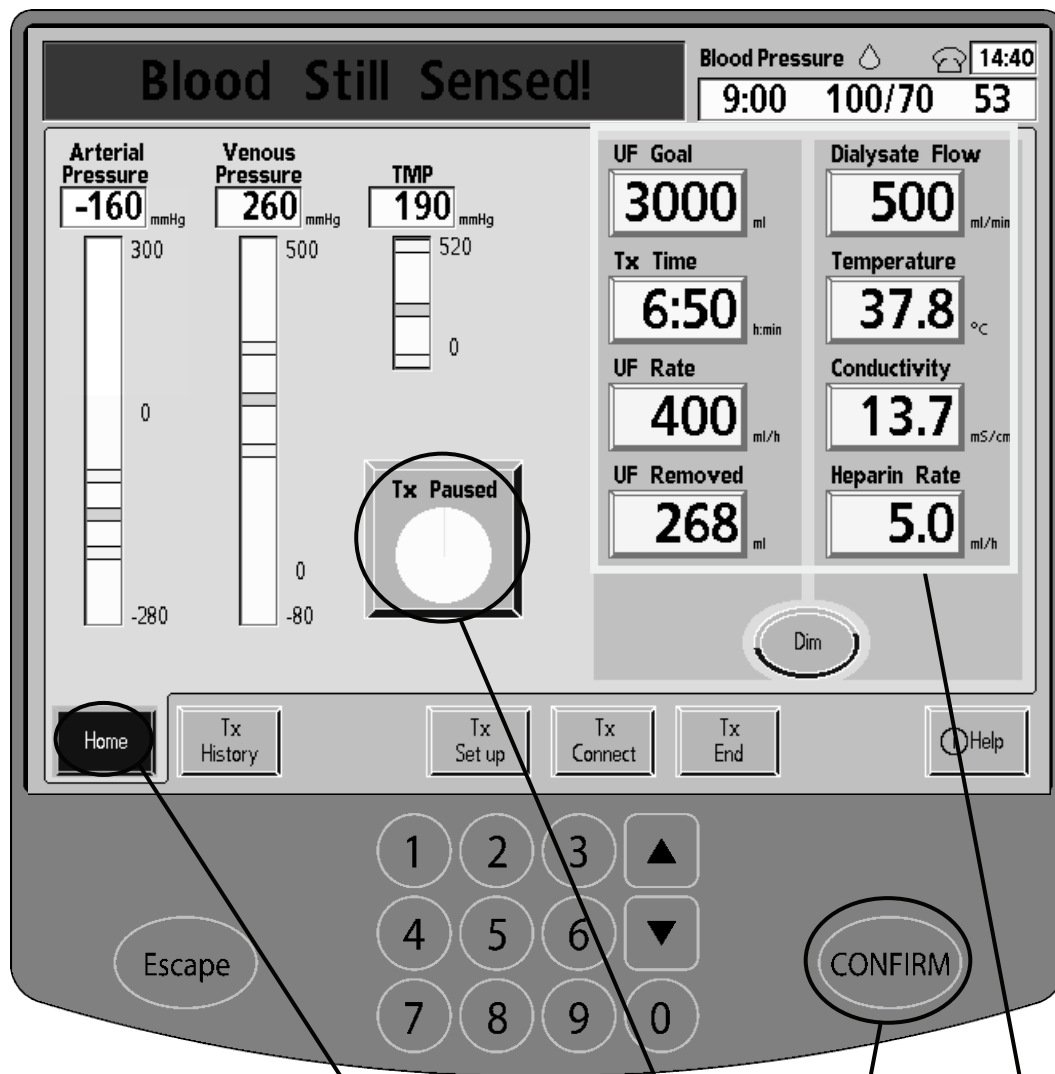
Stop turning the emergency hand crank and remove it from the blood pump rotor. Push the rotor latch back in and close the blood pump door.

5 Touch **Dialysis**

Touch the **Dialysis** screen-button to return to your treatment.

(continued on next page)

After a Brief Power Failure (continued)



ALARMS

- 6 Confirm Concentrate
- 7
- 8
- 9
- 10



Warning: The values shown here are for example only. You must use the values prescribed by your doctor. If you use the wrong values, it may cause serious injury or death.

(continued)

6 Confirm Concentrate

Press the **CONFIRM** key to confirm your concentrate if it is correctly listed. If not, enter your correct concentrate. The blood pump will then restart automatically.

7 Touch **Home**

Touch the **Home** screen-button to go to the dialysis “Home” screen. There you must restart the Tx Clock.

8 Touch **Tx Paused**

9 Press **CONFIRM**

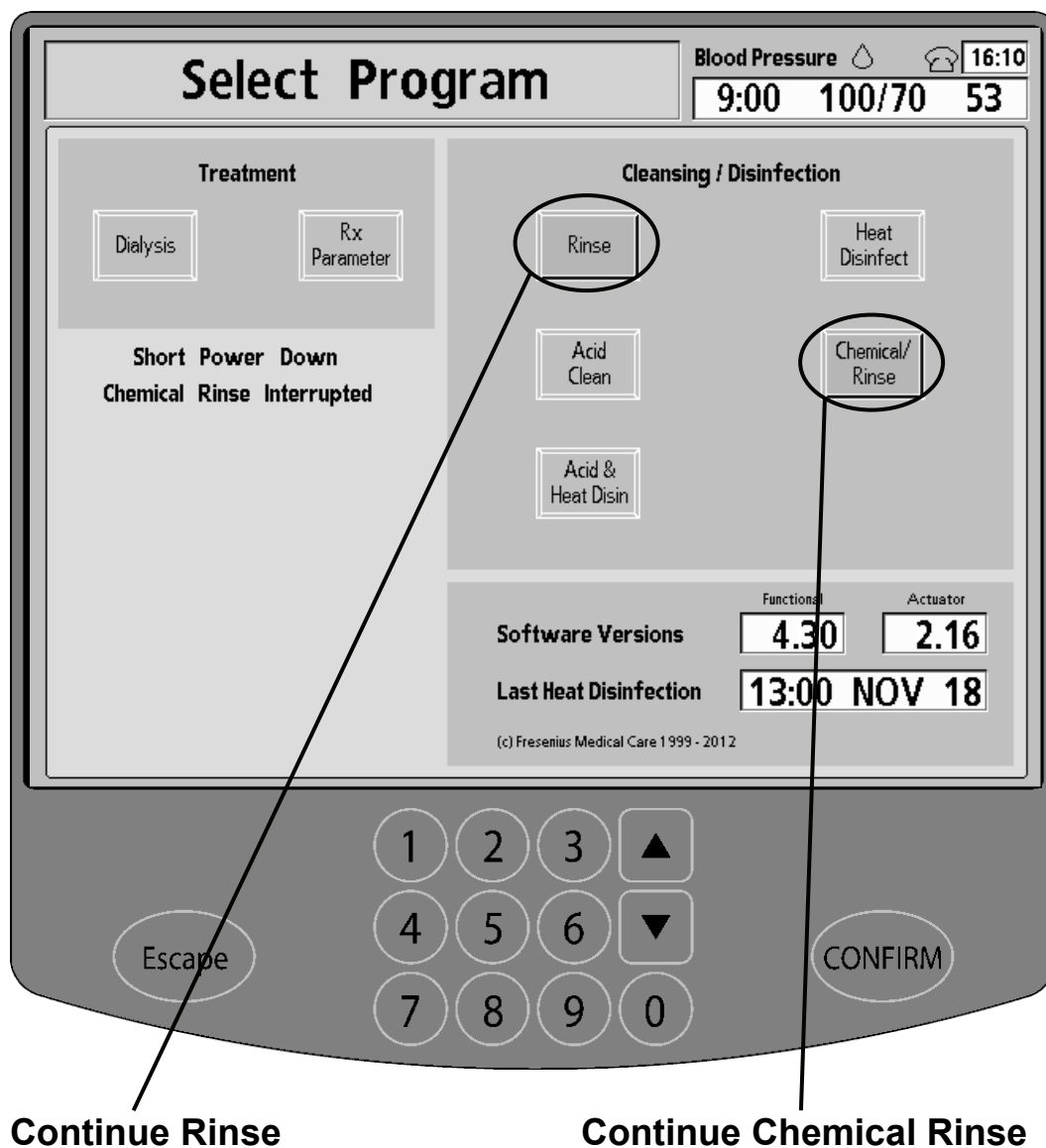
Touch the **Tx Paused** button and then press the **CONFIRM** key start the Tx Clock and resume dialysis. Continue treatment as normal.

10 Check parameters

Your machine saves your UF treatment parameters during a power failure. Check all parameters (UF Goal, Tx Time, UF Rate, UF Removed, etc.) for correct settings and adjust if necessary.

Make sure that the UF pump is running so your treatment can continue. The green light above the UF on/off key is lit when the UF pump is on. If the UF pump is off, press the UF on/off key to turn it back on.

Power Failure during Cleaning or Disinfecting



ALARMS

Power Failure during Cleaning or Disinfecting

If a power failure interrupts a chemical rinse, only the **Rinse** or **Chemical/Rinse** screen-buttons are selectable from the “Select Program” screen. When power is restored, the Status Box displays the message: “Mandatory Rinse.”

If a power failure interrupts a mandatory rinse cycle, only the “Rinse” program is available in the “Select Program” screen. The entire “Rinse” program must be completed before you can begin dialysis.

Depending on which rinse program was running, touch that screen-button and continue as normal.



Note: An interrupted Chemical Rinse or Acid Clean displays a ‘mandatory rinse’ message.

Troubleshooting

The Troubleshooting section is a guide to help you troubleshoot machine alarms, warnings, or advisory messages quickly. Messages shown in the Status Box (see page 30), Dialogue Box (see page 32), and the Blood Pump Display Window (see page 42) 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.



Warning: Doing the recommended action may or may not clear the alarm, warning, or advisory messages displayed. Do not continue your treatment until the conditions causing these messages are corrected and the messages are cleared. If your machine must be taken out of service, you should return the blood to the patient if possible before disconnecting from the machine. Follow your clinic's instructions to rinse back the blood using the blood pump or see "Power Failure during Dialysis" on page 212 for more information on using the hand crank to return the blood.



Note: Refer to the "General Warnings" section, on page 10, for additional warnings.


Note: Machines taken out of service should be tested and repaired by a qualified service technician.

Note: There are alarm messages that may be similar. Please take care that you read the right message to determine the "Action required" for troubleshooting.

Note: Pressing the **Mute** key will silence an alarm for two minutes. The following alarms are muted for an extra four minutes (for a total of six minutes) after the *bibag* disposable is filled with water:

- Conductivity Low and Conductivity High
- *bibag*: Cond Low
- Bicarb Cond 2 Low and Bicarb Cond 2 High
- Low Temperature and High Temperature

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


Message	Meaning	Action Required
*** 5V HIGH ***	Electronic self-test, power supply limits exceeded.	Turn machine power off and back on. If alarm is not cleared, take your machine out of service and call a qualified service technician.
*** 5V LOW ***	Electronic self-test, power supply limits exceeded.	Turn machine power off and back on. If alarm is not cleared, take your machine out of service and call a qualified service technician.
5 Minutes Flow Off	Dialysate flow has been off for five minutes.	Press the RESET key to clear alarm. Turn dialysate flow back on if you intend it to be on.
10 Fill Pgm in 1 hr	<p>Ten fill programs have occurred during a one-hour period.</p> <p> Note: Using a conventional dialyzer at a high UF rate can cause frequent Fill programs because of a high Trans-membrane pressure (TMP). Lowering the UF rate by decreasing the UF Goal may solve the problem. Notify a physician if the UF Goal has changed.</p>	<ol style="list-style-type: none"> 1. Check the dialyzer supply and return lines, especially around the connectors and dialysate filter in the dialyzer return line, for air entering the system and correct the problem. 2. Press the RESET key to clear the alarm. If unable to reset the alarm, return the blood to the patient, take the machine out of service, and call a qualified service technician.
12V POWER FAIL	Electronic self-test, power supply limits exceeded.	Turn machine power off and back on. If alarm is not cleared, take your machine out of service and call a qualified service technician.
*** 24 V HIGH	Electronic self-test, power supply limits exceeded.	Turn machine power off and back on. If alarm is not cleared, take your machine out of service and call a qualified service technician.
*** 24V LOW	Electronic self-test, power supply limits exceeded.	Turn machine power off and back on. If alarm is not cleared, take your machine out of service and call a qualified service technician.


Message	Meaning	Action Required
60 Minutes Flow Off	Dialysate flow has been off for 60 minutes.	<ol style="list-style-type: none"> 1. Press the RESET key to silence the alarm. 2. Raise dialysate flow back to your prescribed rate. Your machine will go into bypass mode until dialysate temperature and conductivity have stabilized (about two minutes).
A.11 (Arterial Blood Pump Message)	Pump is not reaching speed at maximum voltage.	Press the RESET key to clear. If alarm continues, return the blood to the patient if alarm occurs during treatment. Take your machine out of service and call a qualified service technician.
A.13 (Arterial Blood Pump Message)	Pump is turning in the wrong direction.	Press the RESET key to clear. Check that the pump rotor is turning in a clockwise direction. If not, manually return the blood to the patient if alarm occurs during treatment (see page 212 for instructions). Take Blood Pump out of service and call a qualified service technician.
A.16 (Arterial Blood Pump Message)	Key stuck or held in too long.	Press the RESET key to clear. Check that when adjusting settings, you do not hold the key too long. If problem continues, return the blood to the patient if alarm occurs during treatment. Take your machine out of service and call a qualified service technician.
A.20 (Arterial Blood Pump Message)	Set speed-read back analog voltage at X348/14 is out of limits.	Press the RESET key to clear. If alarm continues, return the blood to the patient if alarm occurs during treatment. Take your machine out of service and call a qualified service technician.


Message	Meaning	Action Required
A.21 (Arterial Blood Pump Message)	Actual speed-read back analog voltage at X348/10 is out of limits.	Press the RESET key to clear. If alarm continues, return the blood to the patient if alarm occurs during treatment. Take your machine out of service and call a qualified service technician.
A.22 (Arterial Blood Pump Message)	Arterial pressure-read back analog voltage at X348/7 is out of limits	Press the RESET key to clear. If alarm continues, return the blood to the patient if alarm occurs during treatment. Take your machine out of service and call a qualified service technician.
A.24 (Arterial Blood Pump Message)	Optical tachometer not in range.	Press the RESET key to clear. If alarm continues, return the blood to the patient if alarm occurs during treatment. Take your machine out of service and call a qualified service technician.
A.25 (Arterial Blood Pump Message)	Pressure increase when the Blood Pump module Level Adjust (▲) key is pressed.	Press the RESET key to clear. The level adjust pump might be connected backward so that the level is lowered instead of raised. Check that the level in the arterial chamber rises when the Level Adjust (▲) key (see your K Map: 'G') is pressed. If it does not, return the blood to the patient if alarm occurs during a treatment. Take the machine out of service and call a qualified service technician.
A.26 (Arterial Blood Pump Message)	Pressure was adjusted too much during calibration.	Press the RESET key if this message occurs in Dialysis Mode. If this alarm occurs during a treatment, return the blood to the patient. Take your machine out of service and call a qualified service technician.
A.27 (Arterial Blood Pump Message)	Time out when receiving Intel-Hex-line or overflowed received buffer.	Press the RESET key to clear. If alarm continues, return the blood to the patient if alarm occurs during treatment. Take your machine out of service and call a qualified service technician.

Message	Meaning	Action Required
A.28 (Arterial Blood Pump Message)	Error in received Intel-Hex-line.	Press the RESET key to clear. If this alarm continues, return the blood to the patient if alarm occurs during treatment. Take your machine out of service and call a qualified service technician.
A.29 (Arterial Blood Pump Message)	Pump rotor turning when it should not be.	Press the RESET key to clear. If alarm continues, manually return the blood to the patient if alarm occurs during treatment (see page 212 for instructions). Take your machine out of service and call a qualified service technician.
Acetate Selected!	Acetate concentrate selected and the blue bicarbonate connector is out of its port.	Connect blue bicarbonate connector into the blue rinse port. Be sure the concentrate selection is correct.
Acid Press Calib Err	bibag system pressure calibration error.	Turn machine power off and back on. If message is not cleared, take the machine out of service and alert a qualified service technician.
Acid Pump Alarm	This is a pump failure warning.	A single occurrence is not a problem if your machine automatically resets. If the problem lasts longer than one minute or occurs repeatedly, turn power off and back on. If warning is not cleared, return the blood to the patient if alarm occurs during treatment. Take your machine out of service. Call a qualified service technician.
Acid Pump Always EOS	This is a pump failure warning.	A single occurrence is not a problem if your machine automatically resets. If the problem lasts longer than one minute or occurs repeatedly, turn power off and back on. If warning is not cleared, return the blood to the patient if alarm occurs during treatment. Take your machine out of service. Call a qualified service technician.


Message	Meaning	Action Required
Acid Pump No EOS	This is a pump failure warning.	A single occurrence is not a problem if your machine automatically resets. If the problem lasts longer than one minute or occurs repeatedly, turn power off and back on. If not cleared, return the blood to the patient if alarm occurs during treatment. Take your machine out of service, call a qualified service technician.
Act Blood Pump Failed	Electronic self-test failure.	Turn machine power off and back on. If alarm is not cleared, return the blood to the patient if alarm occurs during treatment. Take your machine out of service and call a qualified service technician.
Act Board CRC Error	Electronic self-test failure.	Turn machine power off and back on. If alarm is not cleared, return the blood to the patient if alarm occurs during treatment. Take your machine out of service and call a qualified service technician.
Act BYP Valve Fail 1	Electronic self-test failure.	Turn machine power off and back on. If alarm is not cleared, return the blood to the patient if alarm occurs during treatment. Take your machine out of service and call a qualified service technician.
Act BYP Valve Fail 2	Electronic self-test failure.	Turn machine power off and back on. If alarm is not cleared, return the blood to the patient if alarm occurs during treatment. Take the machine out of service and call a qualified service technician.
Active Pressure Regulator Uncalibrated	Pressure regulator not calibrated.	Turn machine power off and back on. If alarm is not cleared, take the machine out of service and call a qualified service technician.
Actuator BD no Echo	Functional to Actuator board communication problem.	Turn machine power off and back on. If alarm is not cleared, return the blood to the patient if alarm occurs during treatment. Take your machine out of service and call a qualified service technician.

Message	Meaning	Action Required
Adjusting TMP	The operator has chosen to relieve the TMP after a TMP alarm	No action necessary.
Air Detector Alarm	The level of blood or saline in the venous drip chamber is too low.	<ol style="list-style-type: none"> Check the venous drip chamber and Level Detector module to see if: <ul style="list-style-type: none"> There is an adequate level of blood or saline in chamber. The venous drip chamber is properly mounted in its holder. The venous drip chamber is positioned with the mesh filter below level detector sensors. The sensors are clean (if not, clean with an alcohol pad). The Level Detector door is closed and latched. Check for air intake: Inspect blood and dialysate connections for air intake. Check level of blood or saline in arterial drip chamber. Raise blood level by pressing and holding the Up (▲) key on Level Detector module until the blood or saline reaches acceptable limits. Press the RESET key to reset the alarm. If unable to reset alarm, return the blood to the patient if alarm occurs during treatment. Have a qualified service technician recalibrate for the type of bloodline used.
	 Warning: Make sure that air will not be infused into the patient when the blood flow is reestablished.	
Alarm Test Failed	The Alarm Test section of the Automated Test Sequence has failed.	Press the RESET key once to mute the alarm; pressing it a second time resets the right side of the screen. Retest. If machine retest fails, take it out of service and call a qualified service technician.

Message	Meaning	Action Required
Art. BP No Comm	The blood pump module has lost communication with the machine.	Turn machine power Off and back On. If alarm is not cleared, manually return the blood to the patient if alarm occurs during treatment (see page 212 for instructions). Take the machine out of service and call a qualified service technician.
Art. Pressure Alarm (with the upper Arterial Pressure Alarm limit flashing)	<p>The pressure inside the arterial drip chamber is above the set alarm limits.</p> <p> Note: Pre-pump arterial monitoring is very sensitive to access problems (i.e., access spasms, needle tip plugging such as from patient movement). Lower blood pump rates will raise pre-pump arterial pressure. Assess if the access site is able to deliver the prescribed blood flow.</p>	<ol style="list-style-type: none"> 1. Check access for dislodged needle or disconnection. 2. Check that the saline line is securely clamped. 3. Check arterial/venous lines for kinks, clotting or clamps. 4. Check that the transducer protector is dry and the monitor line is open. Replace transducer protector, if necessary. 5. Check for clotted fibers in the dialyzer. 6. Check to see if blood flow rate is too high, especially with a pre-pump monitor. 7. Press the RESET key to reset alarm. If applicable, press and hold the RESET key again for two seconds to select new alarm limits. 8. If unable to reset the alarm, return the blood to the patient if possible. Do not return clotted blood to the patient. 9. Take the machine out of service and call a qualified service technician.

Message	Meaning	Action Required
Art. Pressure Alarm (with the lower Arterial Pressure Alarm limit flashing)	<p>The pressure inside the arterial drip chamber is below the set alarm limits</p> <p> Note: Pre-pump arterial monitoring is very sensitive to access problems (i.e., access spasms, needle tip plugging such as from patient movement). Lower blood pump rates will raise pre-pump arterial pressure. Assess if the access site is able to deliver the prescribed blood flow.</p>	<ol style="list-style-type: none"> 1. Check the arterial tubing for kinks, clotting, or clamps. 2. Check the needle position and access patency. 3. Check that the transducer protector is dry and the monitor line is open. Replace transducer protector, if necessary. 4. Check to see if blood flow rate is too high, especially with a pre-pump monitor. 5. Press the RESET key to reset the alarm. If needed, press and hold the RESET key again for two seconds to select new alarm limits. It may be necessary to start the blood pump at a slower speed and gradually work up to the prescribed rate. If unable to reset alarm, return the blood to the patient if possible. Do not return clotted blood to the patient. Take the machine out of service and call a qualified service technician.
bibag: +5 V Error	Electronic self-test, power supply limits exceeded.	Turn machine power off and back on. If the alarm is not cleared, take the machine out of service and call a qualified service technician.
bibag: -5 V Error	Electronic self-test, power supply limits exceeded.	Turn machine power off and back on. If the alarm is not cleared, take the machine out of service and call a qualified service technician.
bibag: +12 V Error	Electronic self-test, power supply limits exceeded.	Turn machine power off and back on. If the alarm is not cleared, take the machine out of service and call a qualified service technician.
bibag: Bag Leak	A leak has been detected in the bag.	Open bibag door, wait 30 seconds to relieve the pressure, and remove the bag. Place a new bag on the connector and close the bibag door.

Message	Meaning	Action Required
bibag: Bag On	The bag is on the connector when user is either running a cleansing/disinfecting program or using acetate Or The blue bicarbonate connector was pulled out when a bag is on the connector.	Remove the bag from the bibag connector if using acetate or attempting to run a cleansing/disinfecting program. Or Plug the blue bicarbonate connector back into the bicarbonate port on the machine.
bibag: Bic Pump Locked	The bicarbonate pump has been air locked for over two minutes.	If during treatment, return the blood to the patient and disconnect the patient from the machine. Run a Rinse program to clear the alarm. If the alarm is not cleared, take the machine out of service and call a qualified service technician.
bibag Board Failure	bibag Interface Board cannot boot up.	Turn machine power off and back on. If alarm is not cleared, take the machine out of service and call a qualified service technician.
bibag: Chamber Venting	The system is venting and the machine is in bypass mode.	Advisory only. No action is required. Note: If this message occurs repeatedly, open the bibag door and lift the bag off the connector nozzles to vent the air. Hang the bag back on the connector nozzles and close the bibag door to continue.
bibag: Cond Calib Err	Electronic self-test: bibag conductivity sensor calibration error.	Turn machine power off and back on. If the alarm is not cleared, take the machine out of service and call a qualified service technician.
bibag: Cond High	The actual or measured bibag conductivity has exceeded the high conductivity alarm limit when using the bibag disposable. The machine is in bypass mode.	Wait five minutes for conductivity to stabilize. If the appropriate conductivity cannot be reached, connect a new bag. If the alarm is still not cleared, return the blood to the patient. Take the machine out of service and call a qualified service technician.

Message	Meaning	Action Required
bibag: Cond Low	The actual or measured bibag conductivity is below the low conductivity alarm limit. The machine is in bypass mode. The bag may also be nearly empty.	<p>Check the bibag disposable: if there is only about one inch (2.5 cm) of bicarbonate left at the bottom of the bag, replace the bag. Open the bibag door, wait 30 seconds to relieve the pressure, and remove the bag.</p> <p>Place a fresh bag back on the connector and close the door.</p> <p>Wait five minutes for conductivity to stabilize.</p> <p>If conductivity alarm persists:</p> <ol style="list-style-type: none"> 1. Turn off the dialysate flow by selecting a dialysate flow rate of zero and press CONFIRM. 2. Gently massage the base of the bibag disposable to better mix the bicarbonate powder and remove any trapped air. 3. Turn the dialysate flow back on and set the prescribed dialysate flow rate and press CONFIRM. <p>If the appropriate conductivity cannot be reached, connect a new bag.</p> <p>If conductivity alarm persists, return the blood to the patient and disconnect the patient from the machine. Run an Acid Clean program followed by a complete rinse cycle. Test machine operation.</p> <p>If conductivity alarm still persists, take the machine out of service and call a qualified service technician.</p>
	<p> Note: Pressing the Mute key will silence this alarm for a total of six minutes at a time when using the <i>bibag</i> system.</p>	


Message	Meaning	Action Required
bibag: Cond Sensor Err	The <i>bibag</i> conductivity sensor is not reading the correct conductivity.	Insert the blue bicarbonate connector into an appropriate liquid bicarbonate source Or To use the <i>bibag</i> disposable: If during treatment, return the blood to the patient and disconnect the patient from the machine. Run a Rinse program until message is cleared. If the alarm is not cleared, take the machine out of service and call a qualified service technician.
bibag: Door Error	Sensor error.	Turn machine power off and back on. If the alarm is not cleared, return the blood to the patient if alarm occurs during treatment. Take the machine out of service and call a qualified service technician.
bibag: Door Open	The <i>bibag</i> door is open. The machine is in bypass mode.	Close the <i>bibag</i> door to continue.
bibag: Emptied	The <i>bibag</i> emptying program has completed. The emptied bag must be removed from the <i>bibag</i> connector.	Open the <i>bibag</i> door and remove the bag to continue.
bibag: Empty Too Long	The bag has been emptying longer than five minutes.	Make sure that the blue bicarbonate connector is firmly plugged into the bicarbonate port. If the message is not cleared, remove bag without emptying and call a qualified service technician.
bibag: Emptying	The bag is being emptied by the machine.	No action required, wait until the machine has finished emptying the bag to continue.
bibag: Filling	The bag is filling with water.	Advisory only. No action is required.
bibag: I2C Error	I ² C communication problem.	Turn machine power off and back on. If the alarm is not cleared, return the blood to the patient if alarm occurs during treatment. Take the machine out of service and call a qualified service technician.


Message	Meaning	Action Required
bibag: In Bypass	A <i>bibag</i> alarm or process was occurring when the operator attempted to run recirc saline. The machine is in bypass mode.	Advisory only. No action is required. Wait until the message has cleared before selecting the Recirc Saline button again.
bibag: No Bag	A bag must be on the connector to continue. The machine is in bypass mode.	Place a bag on the <i>bibag</i> connector and close the door to continue.
bibag: No Comm.	The <i>bibag</i> interface board is not communicating with the actuator board.	Turn machine power off and back on. If the alarm is not cleared, take the machine out of service and call a qualified service technician.
bibag PHT Failed	The <i>bibag</i> online Pressure Holding Test has failed.	<p>If the PHT failed <i>on the "Select Program" screen</i>:</p> <ul style="list-style-type: none"> • Turn machine power off and back on to rerun the test. • If the failure message is repeated on the next test, take the machine out of service and alert a qualified service technician. <p>If the PHT failed <i>in Dialysis Mode</i>:</p> <ul style="list-style-type: none"> • Make sure there are no concentrate jugs or other objects obstructing the bag or pressing against it. • Check the machine for leaks. If no leaks are detected: <ul style="list-style-type: none"> ○ Open the <i>bibag</i> door, wait 30 seconds to relieve the pressure, and remove the bag. ○ Place the bag back on the connector and close the door. The <i>bibag</i> online PHT will run again automatically. • If the failure message is repeated on the next test: <p>(continued on next page)</p>

Message	Meaning	Action Required
(continued) bibag PHT Failed		(continued) <ul style="list-style-type: none"> ○ Discontinue use of the bibag system. ○ Insert the blue bicarbonate connector into an appropriate liquid bicarbonate source in order to continue the treatment. ○ Alert a qualified service technician.
bibag: Post Rinse	The machine is rinsing the hydraulics after emptying the bag.	Advisory only. No action is required.
bibag: Press Calib Err	bibag system pressure calibration error.	Turn machine power off and back on. If the alarm is not cleared, take the machine out of service and call a qualified service technician.
bibag: Press Sensor Err	The bibag connector pressure sensor is experiencing an error. The machine is in bypass mode.	Open the bibag door, wait 30 seconds to relieve the pressure, and remove the bag. Place the bag back on the connector and close the door. If the alarm is not cleared, return the blood to the patient if alarm occurs during treatment. Take the machine out of service and call a qualified service technician.
bibag: Press Too High	The pressure inside the bibag disposable is above the set alarm limits. The machine is in bypass mode.	Open the bibag door, wait 30 seconds to relieve the pressure, and remove the bag. Place the bag back on the connector and close the door. If the alarm is not cleared: <ul style="list-style-type: none"> ● Discontinue use of the bibag system. ● Insert the blue bicarbonate connector into an appropriate liquid bicarbonate source in order to continue the treatment. ● Call a qualified service technician.



Message	Meaning	Action Required
bibag: Press Too Low	The pressure inside the <i>bibag</i> disposable is below the set alarm limits. The machine is in bypass mode.	Open the <i>bibag</i> door, wait 30 seconds to relieve the pressure, and remove the bag. Place the bag back on the connector and close the door. If the alarm is not cleared: <ul style="list-style-type: none"> Discontinue use of the <i>bibag</i> system. Insert the blue bicarbonate connector into an appropriate liquid bicarbonate source in order to continue the treatment. Call a qualified service technician.
bibag: Select Conc 45x	The operator has attempted to start dialysis using the <i>bibag</i> system and an acid concentrate other than 45x is selected in Service Mode. Or The blue bicarbonate connector was not inserted into a liquid bicarbonate source if liquid bicarbonate dialysis is desired.	<i>bibag</i> dialysis is compatible only with 45x acid concentrates. Either, Restart the machine and enter Service Mode and select a 45x acid concentrate before beginning dialysis. Or Use liquid bicarbonate for dialysis by inserting the blue bicarbonate connector into an appropriate liquid bicarbonate source.
bibag: Temp Calib Err	Electronic self-test: temperature calibration error.	Turn machine power off and back on. If the alarm is not cleared, take the machine out of service and call a qualified service technician.
bibag: Temp Sensor Err	The <i>bibag</i> temperature sensor is not reading the correct temperature.	Insert the blue bicarbonate connector into an appropriate liquid bicarbonate source Or To use the <i>bibag</i> disposable: If during treatment, return the blood to the patient and disconnect the patient from the machine. Run a Rinse program until message is cleared.

Message	Meaning	Action Required
bibag: Val Comm Err	The <i>bibag</i> interface board was unable to communicate with the actuator board.	Turn machine power off and back on. If the alarm is not cleared, return the blood to the patient if alarm occurs during treatment. Take the machine out of service and call a qualified service technician.
bibag: Valve 1 Err	Electronic self-test failure.	Turn machine power off and back on. If the alarm is not cleared, return the blood to the patient if alarm occurs during treatment. Take the machine out of service and call a qualified service technician.
bibag: Valve 2 Err	Electronic self-test failure.	Turn machine power off and back on. If the alarm is not cleared, return the blood to the patient if alarm occurs during treatment. Take the machine out of service and call a qualified service technician.
bibag: Vent Too Long	The <i>bibag</i> system has been venting longer than ten minutes.	Press the RESET key to clear the message. Pull the blue bicarbonate connector out of its port and then firmly plug it back into its port. If the message persists, return the blood to the patient and disconnect the patient from the machine. Take the machine out of service and call a qualified service technician.
Bic Pump Alarm	This is a pump failure warning.	A single occurrence is not a problem if your machine automatically resets. If alarm lasts longer than one minute or occurs repeatedly, turn power off and back on. If alarm is not cleared, return the blood to the patient if alarm occurs during treatment. Take your machine out of service. Call a qualified service technician.

Message	Meaning	Action Required
Bic Pump Always EOS	This is a pump failure warning.	A single occurrence is not a problem if your machine automatically resets. If alarm lasts longer than one minute or occurs repeatedly, turn power off and back on. If alarm is not cleared, return the blood to the patient if alarm occurs during treatment. Take your machine out of service. Call a qualified service technician.
Bic Pump No EOS	This is a pump failure warning.	A single occurrence is not a problem if your machine automatically resets. If alarm lasts longer than one minute or occurs repeatedly, turn power off and back on. If alarm is not cleared, return the blood to the patient if alarm occurs during treatment. Take your machine out of service. Call a qualified service technician.
Bic Conn Out of Port	The blue bicarbonate connector is out of its port.	Connect blue bicarbonate connector into the blue rinse port. Check the concentrate selection.
Bicarb Cond. Cell Uncalibrated	Bicarbonate cell #117 not calibrated.	Turn machine power off and back on. If alarm is not cleared, take the machine out of service and call a qualified service technician.
Bicarb Cond 2 High	<p>Bicarbonate conductivity cell is measuring high dialysate bicarbonate conductivity when using the <i>bibag</i> system. The machine is in bypass mode.</p> <p> Note: Pressing the Mute key will silence this alarm for a total of six minutes at a time when using the <i>bibag</i> system.</p>	A single occurrence is not a problem if the machine automatically resets. If the problem lasts longer than five minutes or occurs repeatedly, turn power off and back on. If alarm is not cleared, return the blood to the patient if alarm occurs during treatment. Take the machine out of service. Call a qualified service technician.

Message	Meaning	Action Required
Bicarb Cond 2 Low	<p>Bicarbonate conductivity cell is measuring low dialysate bicarbonate conductivity when using the <i>bibag</i> system. The machine is in bypass mode.</p> <p> Note: Pressing the Mute key will silence this alarm for a total of six minutes at a time when using the <i>bibag</i> system.</p>	<p>A single occurrence is not a problem if the machine automatically resets. If the problem lasts longer than five minutes or occurs repeatedly, turn power off and back on. If alarm is not cleared, return the blood to the patient if alarm occurs during treatment. Take the machine out of service. Call a qualified service technician.</p>
Bicarb: Cond High	<p>The actual or measured sodium bicarbonate concentrate conductivity has exceeded the high conductivity alarm limit when using the blue bicarbonate connector for liquid bicarbonate. The machine is in bypass mode.</p>	<p>Wait five minutes for conductivity to stabilize. If the appropriate conductivity cannot be reached, make sure that the correct liquid bicarbonate source is connected. If the alarm is still not cleared, return the blood to the patient and disconnect the patient from the machine. Take the machine out of service and call a qualified service technician.</p>
Bicarb: Cond Low	<p>The actual or measured sodium bicarbonate concentrate conductivity is below the low conductivity alarm limit when using the blue bicarbonate connector for liquid bicarbonate. The machine is in bypass mode.</p>	<p>Make certain the correct liquid bicarbonate is connected to the machine and that there is enough concentrate available. Wait five minutes for conductivity to stabilize. If the appropriate conductivity cannot be reached:</p> <ol style="list-style-type: none"> 1. Plug the blue bicarbonate connector into its port. 2. Wait one minute and then re-connect the bicarbonate connector to the liquid bicarbonate source. 3. Wait five minutes for conductivity to stabilize. <p>(continued on next page)</p>

Message	Meaning	Action Required
(continued) Bicarb: Cond Low		(continued) If conductivity alarm persists, discontinue treatment, return the blood to the patient and disconnect the patient from the machine. Run an Acid Clean program followed by a complete rinse cycle. Test machine operation. If conductivity alarm persists, take the machine out of service and call a qualified service technician.
Bicarb Press Calib Err	Bicarbonate pressure calibration error.	Turn machine power off and back on. If alarm is not cleared, return the blood to the patient if alarm occurs during treatment. Take the machine out of service and call a qualified service technician.
Bicarb: Temp Calib Err	Bicarbonate temperature calibration error. The machine is in bypass mode.	Turn machine power off and back on. If alarm is not cleared, return the blood to the patient if alarm occurs during treatment. Take the machine out of service and call a qualified service technician.
Bicarb: Vent Too Long	The <i>bibag</i> system has been venting longer than ten minutes when using the blue bicarbonate connector for liquid bicarbonate.	Press the RESET key to clear the message. Turn machine power off and back on. If alarm is not cleared, return the blood to the patient if alarm occurs during treatment. Take the machine out of service and call a qualified service technician.
Bicarbonate greater than max. value	Entered Bicarbonate level is higher than allowed.	Your machine has set the Bicarbonate to the highest allowed bicarbonate level. Press CONFIRM to clear message and accept the maximum allowed value. Verify that the value is acceptable.
Bicarbonate has been set to min	The operator has tried to set Bicarbonate level lower than allowed.	The Bicarbonate will be set to the lowest allowed bicarbonate level.
Blood Leak not Calib	The blood leak detector is not in calibration.	Take your machine out of service and call a qualified service technician.


Message	Meaning	Action Required
Blood Leak?	The blood leak detector has detected the presence of blood or air in the dialysate.	<ol style="list-style-type: none"> 1. Press RESET to reset the alarm. Press and hold RESET for three seconds to continue running the blood pump if your machine cannot be reset. 2. Check dialysate fluid for presence of blood with a blood leak test strip. <p>If test is negative, recheck with a new blood leak test strip. If negative after three checks, follow steps below:</p> <p>Press and hold RESET for three seconds to run the blood pump for up to 3 minutes while troubleshooting the alarm.</p> <p>Check the dialysate lines for air leaks, especially at the connectors and the filter.</p> <p>Press the RESET key to clear.</p> <p>If unable to reset the alarm, return the blood according to your clinic's instructions (test positive) and call a qualified service technician.</p> <p>If test is positive, follow your clinic's blood leak policy (see page iv). To return the blood, press the RESET key to reset all other blood flow alarms. Press and hold RESET for three seconds to run the blood pump for up to 3 minutes and allow the blood pump to run and return the blood. Follow your clinic's procedure.</p>
	 Note: Air may cause a false alarm.	
	Note: Pressing and holding the RESET key for three seconds will activate the blood pump for about three minutes while a blood leak alarm exists. Press RESET again if more time is needed to return the patient's blood.	
	 Warning: During an override, the machine's blood leak detector is inactive. You must monitor the treatment.	
Blood Pump +5 V Error		See message E.10
Blood Pump +12 V Error		See message E.07
Blood Pump -12 V Error		See message E.09
Blood Pump +24 V Error		See message E.08
Blood Pump Button Alarm		See message A.16
Blood Pump Calib Alarm		See message A.26
Blood Pump Direction Error		See message A.13


Message	Meaning	Action Required
Blood Pump EEPROM Err		See message E.05
Blood Pump EPROM Error		See message E.01
Blood Pump Erasing Error		See message E.98
Blood Pump Failure	Electronic self-test failure.	Turn machine power off and back on. If alarm does not clear, return the blood to the patient if alarm occurs during treatment. Take your machine out of service and call a qualified service technician.
Blood Pump Flash Error		See message E.97
Blood Pump RAM Error		See message E.03
Blood Pump Rate Alarm		See message A.11
Blood Pump ROM Error		See message E.02
Blood Pump Stop Alarm		See message A.29
Blood Pump Stopped	The blood pump is on and the speed is set, but the blood pump has stopped for longer than its set time limit of either 15 or 30 seconds (time limit is set with dip switch #4 on the blood pump module PCB).	<ol style="list-style-type: none"> 1. Correct other blood alarms that could have triggered the stopped pump message. 2. Check the blood pump module to see if: The blood pump door is closed. The pump tube segment is properly positioned. Correct if necessary. 3. Press the RESET key to reset the alarm. 4. Set blood flow rate to zero and slowly increase flow to the prescribed rate. If unable to resume blood flow rate, manually return the blood to the patient if alarm occurs during treatment. Take your machine out of service and call a qualified service technician.
Blood Pump Tach Alarm		See message A.24
Blood Pump Task Error		See message E.15
Blood Pump Timer Error		See message E.14
Blood Pump Update Error		See message E.99
Blood Pump Volt Error		See message E.04
Blood Pump WD Error		See message E.06

Message	Meaning	Action Required
Blood Sensed	Your machine senses blood and is unable to do the selected action. Or The operator has selected the Empty bibag button when blood is sensed. The bag cannot be emptied using the Empty bibag button when blood is sensed.	<ol style="list-style-type: none"> 1. Check the Optical Detector below the Venous Clamp. 2. Press the RESET key to reset the alarm. 3. If the alarm is not cleared, return the blood to the patient if alarm occurs during treatment. Take your machine out of service and call a qualified service technician. <p>Or</p> <p>If the treatment is not yet finished and the bibag disposable must be changed, lift up on the bibag door, wait 30 seconds to relieve the pressure, and remove the bag. Put a new bag on the connector and close the door again to continue using the bibag system for the treatment.</p>
Blood Still Sensed!	Blood is sensed by the Optical Detector at the "Select Program" screen with the red connector in its port on the front of your machine.	<ol style="list-style-type: none"> 1. Check that there is no longer blood in the patient end of the venous line 2. Check the Optical Detector below the Venous Clamp. 3. Press the RESET key to reset the alarm. 4. If the alarm is not cleared, take your machine out of service and call a qualified service technician.
BP Comm. Timeout		See message A.27
BP Del. Rate Alarm		See message A.21
BP Direction Alarm		See message A.13
BP Feedback Alarm	Arterial rate and the blood pump's arterial setting knob are not synchronized.	If the warning is not cleared, return the blood to the patient if alarm occurs during treatment. Take your machine out of service and call a qualified service technician.
BP Level Up Alarm		See message A.25
BP Pressure Alarm		See message A.22
BP Receive Alarm		See message A.28
BP Rotation Error		See message E.23
BP Set Rate Alarm		See message A.20

Message	Meaning	Action Required
BPM: Cuff Press High	Blood pressure cuff is above 320 mmHg for >25 kg patients or above 220 mmHg for <25 kg patients.	Press the Stat/Deflate key to deflate the cuff. Observe the patient for changes in condition. Alarm indicates a hardware problem. If alarm continues, remove cuff and call a qualified service technician.
BPM: Cuff Press Low	Blood pressure cuff is below 10 mmHg.	Check for loose connection in the inflation system. Indicates a hardware problem. If alarm continues, remove cuff and call a qualified service technician.
BPM: Diastolic High	The diastolic blood pressure reading is above the set Upper Diastolic alarm limit.	Observe the patient for changes in condition. Treat patient according to symptoms.
BPM: Diastolic Low	The diastolic blood pressure reading is below the set Lower Diastolic alarm limit.	Observe the patient for changes in condition. Treat patient according to symptoms.
BPM: Measure > 90 sec	The blood pressure test has been running for more than 90 seconds.	Press the Stat/Deflate key to deflate the pressure cuff. Check the patient for signs for changes in condition. Alarm Indicates a hardware problem. If alarm continues, remove cuff and call a qualified service technician.
BPM Motion Detected	Movement of the patient, cuff tubing, or some other pressure on the detection system.	Observe the patient for changes in condition. Treat patient as symptoms warrant.
BPM: Not Communicating	Blood Pressure module is not communicating with your machine.	If alarm continues, call a qualified service technician.
BPM Not Deflating	Obstruction in inflation system or valve problem in Blood Pressure module.	1. Remove kink in pressure line 2. Alarm may indicate a hardware problem. If alarm continues, remove cuff and call a qualified service technician.
BPM: Oscil Wave Check	Diastolic blood pressure reading is close to or greater than the systolic pressure reading.	Indicates a hardware problem. If alarm continues, remove cuff and call a qualified service technician.

Message	Meaning	Action Required
BPM: Pulse > 100	Patient's heart rate is above 100 beats per minute.	Observe the patient for changes in condition. Treat according to symptoms. May also indicate a hardware problem, call a qualified service technician.
BPM: Pulse Amp Unif	The amplitude of the pressure pulses is inconsistent with an accurate blood pressure profile.	Check pressure cuff for proper fit and alignment. Observe the patient for changes in condition. Treat patient according to symptoms.
BPM: Pulse High	The latest pulse reading is above the Upper Pulse alarm limit.	Observe the patient for changes in condition. Treat patient according to symptoms.
BPM: Pulse Low	The latest pulse reading is below the Lower Pulse alarm limit.	Observe the patient for changes in condition. Treat patient according to symptoms.
BPM: Pump On > 30 sec	The blood pressure cuff pump has been running longer than 30 seconds for a >25 kg patient or longer than 10 seconds for a <25 kg patient.	Cuff is not inflating. Check for loose tubing connections or a leak in the cuff.
BPM: Systolic High	The systolic blood pressure reading is above the set Upper Systolic alarm limit.	Observe the patient for changes in condition. Treat patient according to symptoms.
BPM: Systolic Low	The systolic blood pressure reading is below the set Lower Systolic alarm limit.	Observe the patient for changes in condition. Treat patient according to symptoms.
BPM: Weak Pulse	The pulse pressure is too weak to register an accurate measurement.	Check the cuff for proper fit and inflation. Observe the patient for changes in condition. Treat patient according to symptoms.
BPM: Zero Pressure	The Blood Pressure module is unable to detect any pressure.	Check for a loose connection in the inflation system. Correct as necessary. If no leak found, turn the power off, then back on. If alarm continues, call a qualified service technician.
Chem not Connected?	The red acid connector is still connected to the red rinse port.	Connect the red acid connector into its correct configuration for the operation selected.

Message	Meaning	Action Required
Concentrate Connected?	The red acid connector is not connected to the concentrate container.	Connect the red acid connector to the acid/acetate supply.
Cond Offset Failure	Electronic self-test failure.	Turn machine power off and back on. If alarm is not cleared, take machine out of service and call a qualified service technician.
Cond Ref Failure	Electronic self-test failure.	See “Cond Offset Failure.”
Conductivity High	The actual or measured conductivity has exceeded the high conductivity alarm limit. Your machine is in bypass mode.	<ol style="list-style-type: none"> 1. Check for the prescribed baseline Na⁺ and Bicarbonate values on the “Conductivity” screen and on the “Rx Parameter” screen and re-enter the correct value if incorrectly listed. 2. Check that both the concentrate selected in the “Conductivity” screen and the connected concentrates match your prescribed concentrate. 3. Check that the concentrates are correctly mixed and in proper containers. Remix concentrates as needed. 4. Check that the bicarbonate solution in the jug is completely dissolved. Shake again as needed. <p>Allow five minutes for conductivity to fall back within the alarm window. Adjust the conductivity alarm limit window if necessary (see page 294). Check that there is drain flow.</p> <ol style="list-style-type: none"> 5. Replace the concentrates if it appears that the fluid is being pulled in, but the conductivity is still high. After the prescribed conductivity is reached, test the conductivity and pH using independent testing devices. <p>(continued on next page)</p>
	 Note: Pressing the Mute key will silence this alarm for a total of six minutes at a time when using the <i>bibag</i> system.	

Message	Meaning	Action Required
(continued) Conductivity High		(continued) 6. If actual conductivity matches prescribed value, reposition the conductivity limits as needed. See “Adjusting Conductivity Alarm Limits” on page 294. If unable to attain prescribed conductivity, discontinue treatment and call a qualified service technician.
Conductivity Limits set to default	Conductivity limits were reset after being out of allowed range at power up.	After entering Dialysis, check that the conductivity limits on the “Conductivity” screen are as desired.
Conductivity Low	The actual or measured conductivity has exceeded the low conductivity alarm limit. Your machine is in bypass mode.  Note: Pressing the Mute key will silence this alarm for a total of six minutes at a time when using the bibag system.	1. Check to see if: a. Dialysate flow is on. b. Both the concentrate selected in the “Conductivity” screen and the connected concentrate match the prescribed concentrate. c. The prescribed concentrate, correct base Na ⁺ , and Bicarbonate values are displayed in the “Conductivity” screen. d. The supply jugs contain enough concentrate. e. The bicarbonate solution in the jug is completely dissolved and mixed properly with RO water. Shake again as necessary. f. The heater switch on the back panel is in the ON position. g. If actual conductivity matches prescribed value, reposition the conductivity limits as need. See “Adjusting Conductivity Alarm Limits” on page 294. (continued on next page)

Message	Meaning	Action Required
(continued) Conductivity Low		<p>(continued)</p> <ol style="list-style-type: none"> 2. Check that the concentrate connectors are pulling in concentrate. If not: <ol style="list-style-type: none"> a. Turn off dialysate flow and disconnect concentrate connectors from their jug caps. b. Check for clogged filter screens in the connector handles, especially the bicarbonate connector. Clean if necessary. c. Re-assemble the concentrate connectors. Check that connectors and filter assemblies are tightly screwed together with no air leak. d. Check that the O rings on the tips of the concentrate connectors are not damaged or missing. e. Reconnect the connector to jug caps. Turn on dialysate flow and recheck the connectors for suction. f. If suction is present, allow 5 minutes for conductivity to stabilize. <p>If suction is still not present in both connectors, discontinue treatment and remove yourself from your machine. Run an Acid Clean program followed by a complete rinse cycle. Test machine operation.</p> <p>If conductivity alarm still continues, take your machine out of service and call a qualified service technician.</p>
CONFIRM Concentrate	The user needs to confirm the concentrate selected for use.	Press the CONFIRM key if your concentrate is selected, if not, return to the “Rx Parameter” screen and select your prescribed concentrate.

Message	Meaning	Action Required
Connector(s) Out of Port	The concentrate connectors need to be in their rinse ports.	Insert the concentrate connectors into their matching rinse ports.
Cooling Down	Your machine is cooling down from a heat disinfect.	Advisory message only. No action is required.
** Cover is Open **	The shunt interlock door is open.	To proceed with the selected operation, close the shunt door.
Cuff Pressure = XXX	This is displayed during the blood pressure measurement. The cuff pressure is XXX mmHg	No action is necessary.
Dial Valve Failure 1	Electronic self-test failure.	Turn machine power off and back on. If alarm does not clear, return the blood to the patient if alarm occurs during treatment. Take your machine out of service and call a qualified service technician.
Dial Valve Failure 2	Electronic self-test failure.	See "Dial Valve Failure 1."
Dialysis	Machine is currently in Dialysis Mode.	Advisory message only. No action is required.
Dialysis Paused	In Dialysis Mode, Tx clock is paused.	Advisory message only. No action is required.
Dialyzer Connected?	Dialysate lines are on the shunt but blood is sensed and the blood flow is on or the lines are off the shunt when they should be on.	To proceed, connect the dialysate connectors to the dialyzer or connect them to the shunt as required by the procedure.
Diasafe Test Failed	Diasafe test result.	Press the RESET key to clear the message. Rerun the test. If test fails again return the blood to the patient if alarm occurs during treatment. Take the machine out of service and call a qualified service technician to replace the Diasafe filter if necessary.


Message	Meaning	Action Required
Diasafe Test Passed	Diasafe test result.	Press the RESET key to clear the message.
Diasafe Test Recovery	Diasafe test status.	Advisory message only. No action is required.
E.01 (Arterial Blood Pump Message)	EPROM CRC error.	If this message occurs, take your machine out of service and call a qualified service technician.
E.02 (Arterial Blood Pump Message)	Flash ROM CRC error.	If this message occurs, If this alarm occurs during a treatment, return the blood to the patient. Take your machine out of service and call a qualified service technician.
E.03 (Arterial Blood Pump Message)	RAM check error.	If this message occurs, If this alarm occurs during a treatment, return the blood to the patient. Take your machine out of service and call a qualified service technician.
E.04 (Arterial Blood Pump Message)	Reference Voltage error.	If this message occurs, If this alarm occurs during a treatment, return the blood to the patient. Take your machine out of service and call a qualified service technician.
E.05 (Arterial Blood Pump Message)	EEPROM error.	If this message occurs, If this alarm occurs during a treatment, return the blood to the patient. Take your machine out of service and call a qualified service technician.
E.06 (Arterial Blood Pump Message)	Watchdog timeout.	If this message occurs, If this alarm occurs during a treatment, return the blood to the patient. Take your machine out of service and call a qualified service technician.
E.07 (Arterial Blood Pump Message)	+ 12 Volts is outside the allowable range.	If this message occurs, If this alarm occurs during a treatment, return the blood to the patient. Take your machine out of service and call a qualified service technician.

Message	Meaning	Action Required
E.08 (Arterial Blood Pump Message)	+ 24 Volts is outside the allowable range.	If this message occurs, If this alarm occurs during a treatment, return the blood to the patient. Take your machine out of service and call a qualified service technician.
E.09 (Arterial Blood Pump Message)	- 12 Volts is outside the allowable range.	If this message occurs, If this alarm occurs during a treatment, return the blood to the patient. Take your machine out of service and call a qualified service technician.
E.10 (Arterial Blood Pump Message)	+ 5 Volts is outside the allowable range.	If this message occurs, If this alarm occurs during a treatment, return the blood to the patient. Take your machine out of service and call a qualified service technician.
E.14 (Arterial Blood Pump Message)	50 ms second time period exceeded.	If this message occurs, If this alarm occurs during a treatment, return the blood to the patient. Take your machine out of service and call a qualified service technician.
E.15 (Arterial Blood Pump Message)	Software task was not completed correctly.	If this message occurs, If this alarm occurs during a treatment, return the blood to the patient. Take your machine out of service and call a qualified service technician.
E.23 (Arterial Blood Pump Message)	Pump rotor turning when it should not be for a second time.	If this message occurs, If this alarm occurs during a treatment, return the blood to the patient. Take your machine out of service and call a qualified service technician.
E.97 (Arterial Blood Pump Message)	Error copying data into Flash ROM while in Service Mode.	If this message occurs in Dialysis Mode, If this alarm occurs during a treatment, return the blood to the patient. Take your machine out of service and call a qualified service technician.
E.98 (Arterial Blood Pump Message)	Error erasing Flash ROM while in Service Mode.	If this message occurs in Dialysis Mode, If this alarm occurs during a treatment, return the blood to the patient. Take your machine out of service and call a qualified service technician.

Message	Meaning	Action Required
E.99 (Arterial Blood Pump Message)	Transmit error during Flash update while in Service Mode.	If this message occurs in Dialysis Mode, If this alarm occurs during a treatment, return the blood to the patient. Take your machine out of service and call a qualified service technician.
EEPROM already used, Power Off, Replace EEPROM	Advisory message when uploading hardware key option.	Put in a new hardware key or calibration EEPROM in IC 20 and power up.
EEPROM Missing or Reading Error	During start up, your machine cannot properly read the EEPROM memory chip.	Turn your machine off and try to power up again. If the message repeats, take the machine out of service and call a qualified service technician.
Emptying	The blue dialysate line connector is on the shunt with door closed, the red dialysate line connector remains on the dialyzer in order to drain the dialysate.	If this message occurs when the dialyzer is not being emptied, take your machine out of service and call a qualified service technician.
Emptying Stopped	When air is sensed, emptying will stop.	Connect the red dialyzer return line to the shunt. If the warning is repeated, take your machine out of service.
Emptying too long	The dialyzer empty program has exceeded its maximum limit.	If blood is not sensed, return the dialysate lines to the shunt and close the shunt door to end the program. If your machine was in Dialysis (blood sensed), turn machine power off and back on to clear the program.
Error Reading Flash	Electronic Self Test.	Turn machine power off and back on. If alarm is not cleared, take your machine out of service and call a qualified service technician.
Fail*9 Volt Battery	9V Power Failure Battery test has failed.	Replace 9-Volt battery located on the back of your machine; see page 312.
Fail*Actuator Arterial High Fail*Actuator Arterial Low	Arterial Pressure test has failed.	Rerun test, if failure repeats, take your machine out of service and call a qualified service technician.


Message	Meaning	Action Required
Fail* Actuator Conductivity High Fail* Actuator Conductivity Low	Conductivity test has failed.	Rerun test, if failure repeats, take your machine out of service and call a qualified service technician.
Fail* Actuator Temperature High Fail* Actuator Temperature Low	Temperature test has failed.	Rerun test, if failure repeats, take your machine out of service and call a qualified service technician.
Fail* Actuator TMP High Fail* Actuator TMP Low	Transmembrane Pressure (TMP) test has failed.	Rerun test. If failure repeats, take your machine out of service and call a qualified service technician.
Fail* Actuator Venous High Fail* Actuator Venous Low	Venous Pressure test has failed.	Rerun test, if failure repeats, take your machine out of service and call a qualified service technician.
Fail*Air Detector	Air Detector test has failed.	Check level in venous drip chamber. Reposition venous drip chamber. Rerun Test. If failure repeats, take your machine out of service and call a qualified service technician.
Fail* Arterial High Soft Fail* Arterial Low Soft Fail* Arterial High Hard Fail* Arterial Low Hard	Arterial Pressure test has failed.	Check that arterial pressure reads zero and alarm limits are set properly. Rerun test, if failure repeats, take your machine out of service and call a qualified service technician.





Message	Meaning	Action Required
Fail*Blood Leak 1 Fail*Blood Leak 2	Blood Leak test has failed.	Check for absence of air bubbles in flow indicator and rerun test. If failure repeats, run a Chemical/Rinse with bleach, rerun test. If failure repeats, take your machine out of service and call a qualified service technician.
Fail* Cond High Soft Fail* Cond Low Soft	Conductivity test has failed.	Check that conductivity is in range and stable and the alarm limits are set properly. Rerun test, if failure repeats, take your machine out of service and call a qualified service technician.
Fail*(Get Neg TMP)	Get Neg TMP test has failed.	Rerun test. If failure repeats, take your machine out of service and call a qualified service technician.
Fail*(Get Pos TMP)	Get Pos TMP test has failed.	Rerun test. If failure repeats, take your machine out of service and call a qualified service technician.
Fail*Neg Flow On	Negative flow pressure holding test failed.	Rerun test. If failure repeats, take your machine out of service and call a qualified service technician.
Fail*Neg Stabilize	Negative flow stabilize test failed.	Rerun test. If failure repeats, take your machine out of service and call a qualified service technician.
Fail*Optical Detect	Optical Detector test has failed.	Rerun test, turning off blood pump as test begins. Turn blood pump back on after test. If failure repeats, take your machine out of service and call a qualified service technician.
Fail*Pos Flow Off	Positive flow off pressure holding test failed.	Rerun test. If failure repeats, take your machine out of service and call a qualified service technician.
Fail*Pos Stabilize	Positive flow stabilize test failed.	Rerun test. If failure repeats, take your machine out of service and call a qualified service technician.
Fail* (Remove Air)	Remove air test failed.	Rerun test. If failure repeats, take your machine out of service and call a qualified service technician.
Fail* Temp High Soft Fail* Temp Low Soft	Temperature test has failed.	Check for stable water temperature and rerun test. If failure repeats, take your machine out of service and call a qualified service technician.


Message	Meaning	Action Required
Fail* Temp High Hard Fail* Temp Low Hard	Temperature test has failed.	Check for stable water temperature and rerun test. If failure repeats, take your machine out of service and call a qualified service technician.
Fail* TMP High Soft Fail* TMP Low Soft Fail* TMP High Hard Fail* TMP Low Hard	Transmembrane Pressure (TMP) test has failed.	Rerun test. If failure repeats, take your machine out of service and call a qualified service technician.
Fail* Venous High Soft Fail* Venous Low Soft Fail* Venous High Hard Fail* Venous Low Hard	Venous Pressure test has failed.	Check that venous pressure reads zero and alarm limits are set properly. Rerun test, if failure repeats, take your machine out of service and call a qualified service technician.
** Failed Sending Data to Actuator Board **	Functional to Actuator board communication problem during start up.	Turn machine power off and back on. If alarm is not cleared, take your machine out of service and call a qualified service technician.
Fill for Diasafe test	This message indicates the Diasafe test status.	Advisory only. No action is required.
Fill Program Alarm	A Fill program has occurred for one minute while blood is sensed.	<ol style="list-style-type: none"> 1. Check for air in the system. 2. Correct as required. 3. If the warning is not cleared, return the blood to the patient if alarm occurs during treatment. Take your machine out of service and call a qualified service technician.
Filling Program	A Fill Program is in progress.	Advisory, no action required.
	 Warning: Frequent fill programs may mean air is in the balancing system. Some, but not all, UF errors can be checked by measuring the volumetric accuracy of the UF pump via the fluid sample port using a graduated cylinder. If the cause cannot be corrected quickly, discontinue treatment.	



Message	Meaning	Action Required
Flow Error	General Flow Alarm.	<p>A single occurrence is not a problem if your machine automatically resets. If the problem lasts longer than one minute or occurs repeatedly:</p> <ol style="list-style-type: none"> 1. Check the water supply flow. 2. Check that the dialysate flow is on. 3. Check the dialysate line for kinks. 4. Set Dialysate Flow in the dialysis “Home” screen to 500 ml/min and check that the flow from the drain line is 500 ml/min \pm 50 ml/min. 5. Turn the power off and on. If warning is not cleared, return the blood to the patient if alarm occurs during treatment. Take your machine out of service and call a qualified service technician.
Flow Inlet Error	Float Switch.	<p>A single occurrence is not a problem if your machine automatically resets. If the problem lasts longer than one minute or occurs repeatedly:</p> <ol style="list-style-type: none"> 1. Check the water supply flow to your machine. 2. Check that the dialysate flow is on. 3. Set Dialysate Flow in the dialysis “Home” screen to 500 ml/min and check that the flow from the drain line is 500 ml/min \pm 50 ml/min. 4. Turn the power off and on. If warning is not cleared, return the blood to the patient if alarm occurs during treatment. Take your machine out of service and call a qualified service technician.
Flow is Off	An action requires Dialysate flow to be on.	Turn dialysate flow on.

Message	Meaning	Action Required
Flow Recirc Error 1	Dialysate flow problem.	<p>A single occurrence is not a problem if your machine automatically resets. If the problem lasts longer than one minute or occurs repeatedly:</p> <ol style="list-style-type: none"> 1. Check the water supply flow to your machine. 2. Check that dialysate flow is on. 3. Set Dialysate Flow in the dialysis “Home” screen to 500 ml/min and check that the flow from the drain line is 500 ml/min \pm 50 ml/min. 4. Turn the power off and on. If warning is not cleared, return the blood to the patient if alarm occurs during treatment. Take your machine out of service and call a qualified service technician.
Flow Recirc Error 2	Dialysate flow problem.	<p>A single occurrence is not a problem if your machine automatically resets. If the problem lasts longer than one minute or occurs repeatedly:</p> <ol style="list-style-type: none"> 1. Check the water supply flow to your machine. 2. Check that the dialysate flow is on. 3. Set Dialysate Flow in the dialysis “Home” screen to 500 ml/min and check that the flow from the drain line is 500 ml/min \pm 50 ml/min. 4. Turn the power off and on. If warning is not cleared, return the blood to the patient if alarm occurs during treatment. Take your machine out of service, call a qualified service technician.
Front Panel No Comm	The processor is unable to communicate with the front panel.	Turn machine power off and back on. If failure repeats, take your machine out of service and call a qualified service technician.
Greater than max. value	Entered parameter is larger than allowed.	Check that the maximum value is acceptable. Press the CONFIRM key to clear message and accept the maximum allowed value.



Message	Meaning	Action Required
Heat Relay Test Fail	Electronic self-test failure.	Turn machine power off and back on. If alarm is not cleared, take your machine out of service and call a qualified service technician.
Heparin Pump Alarm	The heparin pump is encountering resistance.	<ol style="list-style-type: none"> 1. Check the heparin line for clamps or kinks and correct. 2. Check the heparin syringe for adequate amount of heparin and correct. 3. Make sure the correct type of syringe is loaded and locked in place properly. 4. Press the RESET key to clear the alarm and restart the heparin pump. 5. If the alarm will not reset or continues intermittently, return the blood to the patient if alarm occurs during treatment. Take your machine out of service and call a qualified service technician.
	 Note: An alarm will sound when the heparin pump has reached the end of its stroke during normal operation.	
High Flow Error	Possible balancing chamber problem.	<p>A single occurrence is not a problem if your machine automatically resets. If the problem lasts longer than one minute or occurs repeatedly:</p> <ol style="list-style-type: none"> 1. Check the water supply flow to machine. 2. Check that the dialysate flow is on. 3. Set Dialysate Flow in the dialysis “Home” screen to 500 ml/min and check that the flow from the drain line is 500 ml/min \pm 50 ml/min. 4. Turn the power off and on. If warning is not cleared, return the blood to the patient if alarm occurs during treatment. Take your machine out of service and call a qualified service technician.

Message	Meaning	Action Required
High Temperature	<p>The actual dialysate temperature has exceeded the high-temperature alarm limit. Machine is in bypass.</p> <p> Warning: Hemolysis of blood in the dialyzer may occur should the dialysate exceed 42°C. Dialysate temperatures must be maintained below this level. Do not return hemolyzed blood to the patient.</p> <p> Note: Pressing the Mute key will silence this alarm for a total of six minutes at a time when using the <i>bi</i>bag system.</p> <p> Note: If the temperature changes between High Temperature and Low Temperature, see “Variable Temperature.”</p>	<ol style="list-style-type: none"> 1. Check that water is flowing to machine when turned on. 2. Check water supply to machine for excess temperature and correct if necessary. 3. If heat disinfection was recently run, place your machine in rinse cycle to decrease temperature. 4. Check the Temperature value in the dialysis “Home” screen. Re-enter it if necessary and allow five minutes for the temperature to stabilize. 5. Check that the dialysate flow at drain line is 500 ml/min ± 50 ml. 6. If unable to reach proper dialysate temperature, return the blood to the patient if alarm occurs during treatment. Take your machine out of service and call a qualified service technician <p> Caution: Do not use the Heat Disinfect cycle until your machine has been repaired.</p>
I2C Read Time Out I2C Bus Read Error I2C Bus Read Too Long I2C Byte Write Error	Functional to I2C EEPROM communication problem.	Turn machine power off and back on. If alarm is not cleared, return the blood to the patient if alarm occurs during treatment. Take your machine out of service and call a qualified service technician.

Message	Meaning	Action Required
In bypass for 8 min	Fluid (dialysate, water, or chemicals) has not been running through the dialysate lines for 8 minutes.	Your machine was in bypass for about eight minutes. This may extend the time necessary to complete the treatment or rinsing of germicide. Press the RESET key to clear the message.  Warning: If this message occurs when rinsing germicide from the dialyzer, additional time will be necessary to fully rinse the germicide from the dialyzer. Always check for residual germicide using the appropriate approved residual test method.
INTERRUPT RINSE? Escape or CONFIRM	Press CONFIRM to interrupt rinse.	Press CONFIRM to accept or press the Escape key to cancel
Interrupted	The selected Rinse program has been interrupted.	Re-insert the dialysate connectors into their rinse ports. To continue rinsing or other program, press the CONFIRM key and then reselect the desired program.
Invalid Data Entry for [item]	Entry value for [item] is out of range.	Set appropriate value for [item].
Invalid UF Rate	Entry value for goal is out of range.	Readjust rate, UF goal, or Tx time.
Invalid UF Time	Entry value for goal is out of range.	Readjust Tx time.
Less than minimum value	Entered parameter is smaller than allowed.	Check that the minimum value is acceptable. Press the CONFIRM key to clear message and accept the minimum allowed value.

Message	Meaning	Action Required
Low Flow Error	Possible balancing chamber problem.	<p>A single occurrence is not a problem if your machine automatically resets. If the problem lasts longer than one minute or occurs repeatedly:</p> <ol style="list-style-type: none"> 1. Check the dialysate lines for kinks. 2. Check the water supply flow to your machine. 3. Check that the dialysate flow is on. 4. Set Dialysate Flow in the dialysis “Home” screen to 500 ml/min and check that the flow from the drain line is 500 ml/min \pm 50 ml/min. <p>Turn the power off and on. If warning does not clear, return the blood to the patient if alarm occurs during treatment. Take your machine out of service and call a qualified service technician.</p>
Low Temperature	The actual dialysate temperature has exceeded the low-temperature alarm limit. Machine is in bypass mode.	<ol style="list-style-type: none"> 1. Check that your machine is in Dialysis Mode and the dialysate flow is on. 2. Check that the heater switch on the back panel is in the ON position. 3. Check water supply to your machine for excessively cold temperature and correct. 4. Check the Temperature value in the dialysis “Home” screen. Re-enter it if necessary and allow five minutes for the temperature to stabilize. 5. If unable to reach the prescribed temperature, return the blood to the patient if alarm occurs during treatment. Take your machine out of service and call a qualified service technician.
	 Note: Pressing the Mute key will silence this alarm for a total of six minutes at a time when using the <i>bi</i> bag system.	
	 Note: If the temperature changes between HIGH TEMPERATURE and LOW TEMPERATURE, see “Variable Temperature.”	
Lost Battery RAM Data	The battery RAM memory has been lost.	Review all treatment settings before using your machine.

Message	Meaning	Action Required
Lower Dia. Has been set to Min [Max]	The operator attempted to set the lower diastolic pressure limit higher or lower than allowed.	Your machine has set the limit to the highest or lowest value allowed. Check that the limit setting is acceptable.
Lower Pulse has been set to Min [Max]	The operator attempted to set the lower pulse rate limit higher or lower than allowed.	Your machine has set the limit to the highest or lowest value allowed. Check that the limit setting is acceptable.
Lower Sys. Has been set to Min [Max]	The operator attempted to set the lower systolic pressure limit higher or lower than allowed.	Your machine has set the limit to the highest or lowest value allowed. Check that the limit setting is acceptable.
Max UF rate reached. Select new Goal or Time	This message informs the operator that the calculated UF rate is higher than the internal selection allows.	In the dialysis "Home" screen, decrease the UF Goal or increase the Tx Time. Contact your clinic for a change in prescription.
Max UF time reached. Select new Goal or Rate	This message informs the operator that the calculated UF time is higher than the maximum allowed.	In the dialysis "Home" screen, decrease the Tx Time.



Message	Meaning	Action Required
Minor Blood Leak?	<p>A minor blood leak (0.35 ml of blood/liter of dialysate) was detected. Air can cause a false alarm.</p> <p> Warning: During an override, the machine's blood leak detector is inactive. You must manually monitor the treatment for evidence of blood leak.</p> <p> Note: "RESET" will activate the blood pump for about three minutes while a blood leak alarm exists. Press RESET again if needed.</p>	<ol style="list-style-type: none"> 1. Press the RESET key to reset the alarm. Press and hold RESET for three seconds to continue to run the blood pump (override) if the alarm cannot be reset. 2. Check dialysate fluid from the red dialyzer return line for presence of blood with a blood leak test strip. <p>If test is negative, recheck with a new blood leak test strip. If negative after three checks, follow steps below:</p> <ol style="list-style-type: none"> 1. Press and hold RESET for three seconds to continue to run the blood pump while troubleshooting the alarm. 2. Check the dialysate lines for air leaks, especially at the connectors and the filter in the dialyzer return line. 3. Press RESET to reset alarm. 4. If unable to reset the alarm, return the patient's blood according to procedure below (test positive), call a qualified service technician. <p>If test is positive, proceed according to the unit's blood-leak policy. If facility policy is to return patient's blood, press RESET to reset all other blood flow alarms and to set the blood pump to run and return patient's blood per your clinic's policy.</p>
Must Calibrate to Run	Electronic self-test failure.	Turn machine power off and back on. If alarm is not cleared, take your machine out of service and call a qualified service technician.
Must Clear UF Removed	An action has been initiated that requires the UF Removed to be cleared to zero.	To proceed with the selected operation, use the data entry keypad to set the UF Removed parameter-button to zero.


Message	Meaning	Action Required
Must Run Test First	The Forced Test is required before proceeding with UF.	To proceed with the selected operation, run the Pressure and Alarm tests.
Need Blood Sensed!	An action has been initiated that requires that blood to be sensed	Check that the venous bloodline is in the Optical Detector.
New Art Limits chosen	This message advises the operator that a new set of arterial limits has been set.	Advisory only. No action is required.
New features loaded, Power Off, Replace EEPROM	Advisory message when uploading hardware key option.	Put the original calibration EEPROM in IC 20 and restart the machine.
New TMP Limits?	This message is an instruction for the operator to set new TMP alarm limits.	Rising TMP may indicate a leak in the balancing system and should be investigated. To set new TMP limits, press and hold the RESET key for two seconds.
New TMP Limits chosen	This message confirms that new TMP limits have been set.	Advisory only. No action is required.
New Ven Limits chosen	New venous alarm limits are set.	Advisory only. No action is required.
No Air Detector Alarm	The Prime button has been selected and confirmed. A level detector alarm must exist for this function to start.	Check the fluid level in the venous drip chamber. Check that the chamber is seated correctly in its holder. Correct if required and then press the RESET key. If message is not cleared, take your machine out of service and call a qualified service technician.
No Chemical Intake	During the “Chemical/Rinse” program, your machine cannot get any chemical through the red acid connector.	Retry Chemical/Rinse and if alarm continues, take your machine out of service and call a qualified service technician.

Message	Meaning	Action Required
No Water	A water inlet valve alarm has occurred. Your machine is not receiving enough water.	Check the treated water source supplying your machine. Correct as required. If the alarm does not clear, return the blood to the patient if alarm occurs during treatment. Take your machine out of service and call a qualified service technician.
Online PHT Failed	The online Pressure Holding Test has failed.	Reset the alarm. Check your machine for liquid leaks. If the failure message is repeated on the next test (12 minutes between tests), return the blood to the patient if alarm occurs during treatment. Take your machine out of service and call a qualified service technician.
Online PHT Too Long	Electronic self-test failure.	Turn machine power off and back on. If alarm is not cleared, return the blood to the patient if alarm occurs during treatment. Take your machine out of service and call a qualified service technician.
Patient Alarm	External alarm.	Clear external alarm. If alarm continues, return the blood to the patient if alarm occurs during treatment. Take your machine out of service and call a qualified service technician.
Plug in Venous Pump	Single Needle option was initiated but the single needle blood pump is not plugged into your machine properly.	To proceed with the selected operation, call a qualified service technician to install the single needle blood pump in your machine.
Power Fail Recovery	Your machine is powering up after power failure; parameters have been recovered.	Check that all your treatment settings are correct before resuming dialysis.


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 the machine. It will not sense wetness until reactivated with a new treatment.
Press CONFIRM to exit	This message instructs the operator to press the CONFIRM key to exit the "Rinse" program.	To proceed with the selected operation, press the CONFIRM key.
Press CONFIRM to Start	This message instructs the operator to press the Confirm key to start the program.	To proceed with the selected operation, press the CONFIRM key.
Press CONFIRM to Load	This message instructs the operator to press the Escape key to cancel the Rinse program.	To proceed with the selected operation, press the Escape key then press the CONFIRM key.
Press ESCAPE To Stop [Item]	This message instructs the operator to press the Escape key to stop loading the heparin syringe or the Rinse program.	To proceed with the selected operation, press the Escape key then press the CONFIRM key.
Pressure Test Failed	The pressure test section (PHT) of the automated Test Sequence has failed.	Reset the alarm. Check the setup to see if the alarm can be corrected and repeat the test. If the failure message is repeated on retest, take your machine out of service and call a qualified service technician.
Prime Complete	The priming process is complete.	Press the RESET key to clear the advisory message.
Priming	The operator has selected and confirmed the Prime button. The priming function has begun.	Advisory only. No action is required.

Message	Meaning	Action Required
Put Connectors in Port	Both acid and bicarbonate connectors are in the chemical jugs.	Connect the red acid and/or blue bicarbonate connectors to their appropriate rinse ports.
Put Lines On Shunt	A selected action requires the dialysate lines to be on the shunt interlock.	To proceed with the selected operation, place dialysate lines on the shunt interlock.
Put Red Con in Chemical	This is a cleaning/disinfectant program instruction for the operator.	Remove the red connector from its rinse port and place it into the wand in the yellow chemical/disinfectant bottle.
RAM Battery Failure	Electronic self-test failure.	Turn machine power off and back on. If alarm is not cleared, take your machine out of service and call a qualified service technician.
RAM Code Corrupted 1	Electronic self-test failure.	Turn machine power off and back on. If alarm is not cleared, return the blood to the patient if alarm occurs during treatment. Take your machine out of service and call a qualified service technician.
RAM Code Corrupted 2	Repeated electronic self-test failure.	Turn machine power off and back on. If alarm is not cleared, return the blood to the patient if alarm occurs during treatment. Take your machine out of service and call a qualified service technician.
Recirc Interrupted	The "Recirculate" program has been interrupted by an alarm condition.	<ol style="list-style-type: none"> 1. Check the blood pump condition. Correct if required. 2. Reset the alarm and turn UF back on, if applicable. 3. If the alarm does not clear, take your machine out of service and call a qualified service technician.
Recirculating	Recirculation is in progress.	Advisory only. No action is required.
Recirculating Done	The recirculation process is done.	Press the RESET key to clear the advisory message.




Message	Meaning	Action Required
Recirculating Stopped	Recirculation has been stopped because blood is sensed or the dialysate lines are on the shunt.	Check the setup of the dialysate lines and bloodlines. Correct any irregularities. If the message is not cleared, take your machine out of service and call a qualified service technician.
Release Wetness Detector	The WetAlert device is being linked to the machine.	Stop touching the selected WetAlert device's sensor on the bottom of the device.
Reset Treatment?	The operator has pressed the Down Arrow key and CONFIRM at the same time.	To reset treatment parameters for a new treatment, press the CONFIRM key. To cancel, press the Escape key.
RESET to adjust TMP	The Transmembrane pressure (TMP) exceeds the hard alarm limits. The operator may relieve the pressure to bring the TMP within limits.	 Warning: Rising TMP may mean a leak in the balancing system and should be investigated.
	 Warning: Repeatedly adjusting the TMP will decrease the UF removed from the patient.	
Resetting, Try Again	Blood Pressure module resetting.	Wait until Blood Pressure module completes resetting and retry blood pressure reading.
Retry > Press = XXX	The cuff pressure is too low to measure the blood pressure. The cuff pressure is XXX mmHg.	No action necessary
Rinse Cond High	The Reverse Osmosis (RO) water inlet conductivity is too high.	Press the RESET key to clear the message. Perform a Rinse cycle. If alarm is not cleared, take the machine out of service and call a qualified service technician.

Message	Meaning	Action Required
RO Water Cond High	The Reverse Osmosis (RO) water inlet conductivity is too high.	Press the RESET key to clear the message. Return the blood to the patient if alarm occurs during treatment. Perform a Rinse cycle. If alarm is not cleared, take the machine out of service and call a qualified service technician.
Running Diasafe Test	Status of the Diasafe test.	Advisory only. No action is required.
Running Online PHT	This message is displayed when the online Pressure Holding Test is in progress.	Advisory only. No action is required. The test will run for about seven seconds.
Sample Bag Connected?	This is a message to remind the patient to remove the dialysate sample bag if dialysate sampling was activated for the current treatment.	Make sure the dialysate sample bag was removed from the back of your machine and capped. Reconnect the "Sample Out" line to the "Sample In" line. Press the CONFIRM key to continue.
Select Concentrate	This message instructs the operator to select a concentrate.	To select a concentrate from the menu, use the Up/Down Arrow (▼/▲) keys to highlight the desired concentrate, and press the CONFIRM key. See "Concentrate Settings," page 66.
Select new goal or rate	UF time is out of range.	Enter a new UF Goal or reduce Tx Time.
Select new Goal or Time	UF rate is out of range.	Enter a new UF Goal or reduce UF Rate.
Select Program	This message instructs the operator to select a program.	To proceed, select the desired program and press the CONFIRM key.
Set Arterial Limits	This is a message to re-center the arterial limits if necessary.	Press and hold the RESET key for two seconds to re-center the limits.
Set TMP Limits?	This is a message to re-center the TMP limits if necessary.	Press and hold the RESET key for two seconds to re-center the limits.  Warning: A rising TMP may indicate a leak in the balancing system and should be investigated.


Message	Meaning	Action Required
Set Venous Limits	This is a message to move the venous limits if necessary.	Press and hold the RESET key for two seconds to adjust the limits. Changes in venous pressure during the treatment should be investigated. See “Venous Pressure Alarm”
Short Power Down	Your machine was switched off for 1 – 2 minutes and turned back on. Setup values have not been set to default values.	Check that the dialysis parameters are as desired.
SN BP +5 V Error		See message E.10
SN BP +12 V Error		See message E.07
SN BP -12 V Error		See message E.09
SN BP +24 V Error		See message E.08
SN BP Button Alarm		See message A.16
SN BP Comm. Timeout		See message A.27
SN BP Del. Rate Alarm		See message A.21
SN BP Direction Alarm		See message A.13
SN BP EEPROM Error		See message E.05
SN BP EPROM Error		See message E.01
SN BP Erasing Error		See message E.98
SN BP Flash Error		See message E.97
SN BP Level Up Alarm		See message A.25
SN BP Pressure Alarm		See message A.22
SN BP RAM Error		See message E.03
SN BP Rate Alarm		See message A.11
SN BP Receiving Alarm		See message A.28
SN BP ROM Error		See message E.02
SN BP Rotation Error		See message E.23
SN BP Set Rate Alarm		See message A.20
SN BP Stop Alarm		See message A.29
SN BP Tach Alarm		See message A.24
SN BP Task Error		See message E.15


Message	Meaning	Action Required
SN BP Timer Error		See message E.14
SN BP Update Error		See message E.99
SN BP Volt Error		See message E.04
SN BP WD Error		See message E.06
Standby for Test	This message is displayed before the start of the Alarms and Pressure test.	Advisory only. No action is required.
Super IO no comm.	Hardware related error message that is displayed on opening screen.	Turn off your machine and try again. If the message is not cleared, call a qualified service technician.
System Leak, Can't Run	A leak was detected in the Heat Exchanger during the Chemical/Rinse program.	Exit the Chemical/Rinse program and return to the "Select Program" screen. Retry the Chemical/Rinse program. If the warning message is still not cleared, take your machine out of service and call a qualified service technician.
		 Note: This message means that the Chemical/Rinse program can no longer be run due to a leak detected in the Heat Exchanger. However, your machine will still be able to run Heat Disinfection programs and hemodialysis treatments as directed by your Home Therapies Nurse.
Take Lines Off Shunt	An action has been initiated that requires the dialysate lines to be off the shunt.	To proceed with the selected operation, dialysate lines must be off the shunt interlock. Connect lines to the dialyzer.
Temp DAC Error	The DAC (Digital/ Analog conversion) for the temperature trim function is outside of its limits.	Press the RESET key to reset alarm. The temperature trim function will be disabled until the temperature sensors are recalibrated.
Temp Over 95 Degrees	Electronic self-test failure.	Turn machine power off and back on. If alarm is not cleared, return the blood to the patient if alarm occurs during treatment. Take your machine out of service and call a qualified service technician.


Message	Meaning	Action Required
Temp Sensors unmatched	When the temperature trim function needs to change DAC by > 1°C, the pre and post sensors are verified against one another; occurs if the two temperature sensors are more than 0.5°C different.	Press the RESET key to reset alarm. The temperature trim function will be disabled until your machine is turned OFF and back ON.
Temperature Control not calibrated	The temperature sensors were not matched when they verified against one another.	Call a qualified service technician to calibrate the temperature control.
Temperature greater than max. value	Entered Temperature value is higher than allowed.	Your machine has set the temperature to the highest allowed level. Press CONFIRM to clear message and accept the maximum allowed value. Check that the value is acceptable or enter a new value.
Temperature has been set to min	The operator has tried to set the temperature lower than allowed.	The temperature will be set to the lowest allowed level. Check that the value is acceptable.
Test Complete	All selected self-tests passed.	Advisory only. No action required.
Test Failed	Both the Alarm and/or PHT sections of the automated test sequence have failed.	Reset alarm. Check the setup to see if alarm can be corrected and retest. If retest fails, turn machine power off and back on. If alarm is not cleared, call a qualified service technician.

Message	Meaning	Action Required
TMP is High (toward 500)	The Transmembrane pressure (TMP) has exceeded the TMP high alarm limit value.	<ol style="list-style-type: none"> 1. Check the dialysate lines for kinks. 2. Check that the dialysate connectors are properly snapped either on the dialyzer or the shunt 3. Clean the dialyzer return line filter 4. Press the RESET key to reset alarm. Press and hold the RESET key again for two seconds to select new alarm limits or for adjusting the TMP. If unable to reset the alarm, call a qualified service technician.
	 Warning: A rising TMP may indicate a leak in the balancing system and should be investigated.	
 Note: In the event of a TMP alarm, the alarm limits spread. Actual limits cannot be seen during this time. Setting or resetting is unnecessary as the alarm width will narrow again after two minutes at that new location which may be out of normal limits.		<p>High UF Goal and low dialyzer KUF coefficient can exceed the maximum TMP of 520 mmHg. The UF Goal may need to be lowered. This in turn will lower the UF Rate and the TMP. Notify a physician if the UF Goal has changed.</p>
TMP is Low (alarm at or below 60)	The Transmembrane pressure (TMP) has exceeded the TMP low alarm limit value.	<ol style="list-style-type: none"> 1. Check that the venous transducer protector is dry and the monitor line is open. Replace the transducer protector, if necessary. 2. Check the dialysate lines for kinks 3. Check the dialyzer return line filter to make sure it is clean. 4. Press the RESET key to reset alarm. Press and hold the RESET key again for two seconds to select new alarm limits or for adjusting the TMP. If unable to reset the alarm, return the blood to the patient if alarm occurs during treatment. Take your machine out of service and call a qualified service technician
	 Note: Increasing the UF Rate can also raise the TMP. Administer saline as prescribed. Notify a physician if the UF Rate has changed.	
	Note: Lowering the venous pressure by reducing the blood flow rate can also be effective, if using a high-permeable dialyzer. Notify a physician if the blood flow rate has changed.	
Touch and Hold Wetness Detector	The machine is searching for a WetAlert device in range so it may link to it.	Touch the metal sensor on the bottom of the WetAlert device so as to cause a wetness signal.

Message	Meaning	Action Required
Touch Wetness Detector	The WetAlert device needs to be activated at this time.	Touch the WetAlert device's metal sensor on the underside then do one of the following: <ul style="list-style-type: none"> For In Center (UF profiles available on the "Home" screen), press the 1 key to continue. For Home mode (no UF Profiles available on the "Home" screen), press the RESET key to continue.
Tx Clock On	The operator has selected the Empty bibag button when the Tx Clock is running. The bag cannot be emptied using the Empty bibag button when the Tx Clock is running.	If the treatment is not yet completed and the bibag disposable must be changed, lift up on the bibag door, wait 30 seconds to relieve the pressure, and remove the bag. Put a new bibag disposable on the connector and close the door again to continue using the bibag system for the treatment.
Tx Clock Paused?	Blood is sensed in Optical Detector while Tx clock is paused.	Start Tx Clock by touching the Tx Paused button and pressing CONFIRM .
UF Goal Reached	The preset ultrafiltration goal has been reached.	Press RESET to reset the alarm. The preset UF Goal has been reached and the UF Rate will drop to the minimum UF Rate. If the patient's prescribed UF Goal has not been reached, you must take further action to follow your prescribed treatment.
UF Is On	An initiated action requires UF to be off.	To proceed with the selected operation, turn the UF pump off.
UF Profile Error	A UF profile calculation error has been detected.	Reset the UF parameters.
UF Pump Alarm	UF pump is not connected or is not pulsing properly.	Press RESET to reset the alarm. If unable to clear the alarm, return the blood to the patient if alarm occurs during treatment. Take your machine out of service and call a qualified service technician.
UF Rate Error	A calculation error has been detected.	Reset the UF parameters.

Message	Meaning	Action Required
Upper Dia. has been set to Min [Max]	The operator has tried to set the upper diastolic pressure limit higher or lower than allowed.	Your machine has set the limit to the highest or lowest value allowed. Check that the limit setting is acceptable.
Upper Pulse has been set to Min [Max]	The operator has tried to set the upper pulse rate limit higher or lower than allowed.	Your machine has set the limit to the highest or lowest value allowed. Check that the limit setting is acceptable.
Upper Sys. has been set to Min [Max]	The operator has tried to set the upper systolic pressure limit higher or lower than allowed.	Your machine has set the limit to the highest or lowest value allowed. Check that the limit setting is acceptable.
V104 Stuck Open	Bicarbonate concentrate port valve error. The machine is in bypass mode.	Turn machine power off and back on. If alarm is not cleared, return the blood to the patient if alarm occurs during treatment. Take the machine out of service and call a qualified service technician.
V104/108 Stuck Closed	Bicarbonate concentrate port valve error or rinse port valve error. The machine is in bypass mode.	Check for a kinked bicarbonate concentrate supply line. Make sure that the bicarbonate concentrate connector is firmly connected. If the bicarbonate concentrate source is a central feed system, make sure that the line is open.
 Note: If this error occurs upon power up or after any of the cleaning/disinfecting programs, make sure the blue bicarbonate connector is firmly plugged into the bicarbonate port then run the cleaning/disinfecting program again. If the alarm is not cleared, turn the machine off and back on and run a Rinse program. If the alarm is still not cleared, take the machine out of service and alert a qualified service technician.		If the error occurs during a rinse, open the bibag door for at least five seconds (with no bibag attached). Rerun the rinse program. If alarm is not cleared, turn machine power off and back on. If alarm is still not cleared, return the blood to the patient if alarm occurs during treatment. Take the machine out of service and call a qualified service technician.

Message	Meaning	Action Required
V105 Stuck Open	Acid concentrate port valve error. The machine is in bypass mode.	Turn machine power off and back on. If alarm is not cleared, return the blood to the patient if alarm occurs during treatment. Take the machine out of service and call a qualified service technician.
V105 Stuck Closed	The acid concentrate supply line is not pulling in acid concentrate. The machine is in bypass mode.	Check for a kinked acid concentrate supply line. Make sure that the acid concentrate connector is firmly connected. If the acid concentrate source is a central feed system, make sure that the line is open.
 Note: If this error occurs after any of the cleaning/ disinfecting programs, make sure the red acid connector is firmly plugged into the acid port then run the cleaning/ disinfecting program again.		If alarm is not cleared, turn machine power off and back on. If alarm is still not cleared, return the blood to the patient if alarm occurs during treatment. Take the machine out of service and call a qualified service technician.
Valve 43 Failure	Valve 43 has remained open too long.	Turn machine power off and back on. Just before restarting the blood pump and Tx Clock again, check that dialysate flow can be turned off and back on (select the Dialysate Flow parameter-button and lower it to 'off' using the Up/Down Arrow (▼/▲) keys on the data entry keypad). Do not begin or continue dialysis if this cannot be done.
Valve 104 Err	Bicarbonate concentrate port valve error. The machine is in bypass mode.	Turn machine power off and back on. If alarm is not cleared, return the blood to the patient if alarm occurs during treatment. Take the machine out of service and call a qualified service technician.
Valve 105 Err	Acid concentrate port valve error. The machine is in bypass mode.	Turn machine power off and back on. If alarm is not cleared, return the blood to the patient if alarm occurs during treatment. Take the machine out of service and call a qualified service technician.

Message	Meaning	Action Required
Variable Temperature	<p>The temperature changes between HIGH TEMPERATURE and LOW TEMPERATURE.</p> <p> Caution: Do not use the Heat Disinfect cycle until your machine is repaired.</p>	<ol style="list-style-type: none"> 1. Check that water to your machine is turned on. 2. Check the temperature in the dialysis “Home” screen. Re-enter it if necessary and allow five minutes for the temperature to stabilize. <p>If unable to reach your prescribed temperature, discontinue treatment and call a qualified service technician.</p>
Ven. Pressure Alarm (with the upper Venous Pressure Alarm limit flashing)	High pressure is detected in the venous drip chamber.	<ol style="list-style-type: none"> 1. Check venous tubing for loose connections, clamps, clotting, or kinks. 2. Check that the transducer protector is dry and the monitor line is open. Replace the transducer protector, if necessary. 3. Check access site for clotting, needle position, or blood leak. 4. Press RESET to reset alarm. Press the RESET key again and hold for one second to select new alarm limits. If alarm continues, reduce the blood flow rate. If the alarm will not reset, return the blood to the patient if alarm occurs during treatment. Take your machine out of service. Call a qualified service technician.
Ven. Pressure Alarm (with the lower Venous Pressure Alarm limit flashing)	Low pressure is detected in the venous drip chamber.	<ol style="list-style-type: none"> 1. Check venous tubing for kinked line, clotting or clamps. 2. Check for dislodged needle or disconnected lines 3. Check that the transducer protector is dry and the monitor line is open. Replace the transducer protector, if necessary 4. Press RESET to reset alarm. Press the RESET key again and hold for two seconds to select new alarm limits. If alarm will not reset, return the blood to the patient if alarm occurs during treatment. Take your machine out of service and call a qualified service technician.

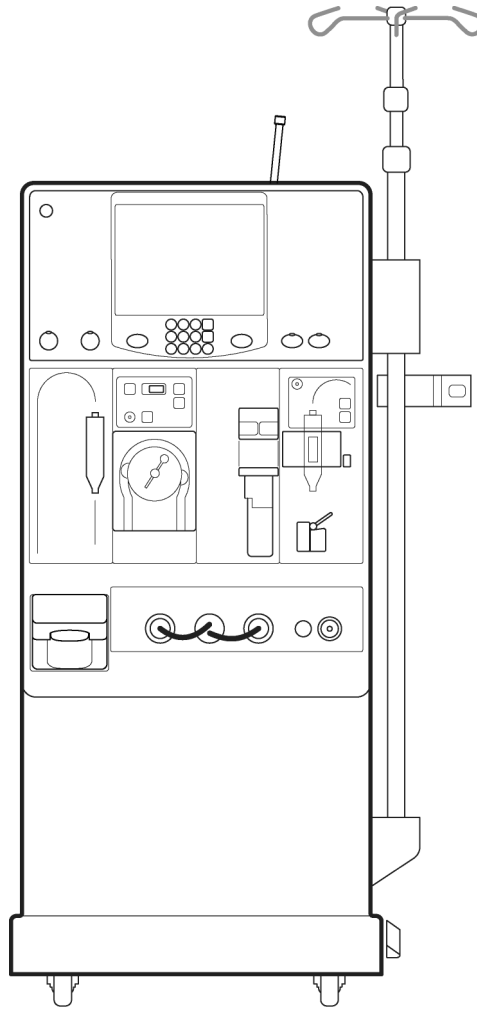
Message	Meaning	Action Required
Verifying temp sensors	Your machine will go into bypass for about 8 minutes while the temperature sensors are verified. The Tx Clock will pause.	Advisory only. No action is required.
Wait: Rinsing Line	Your machine is rinsing the concentrate lines prior to a cleaning or disinfecting program.	Advisory only. No action is required. Line rinsing takes about 45 seconds.
WD: 24v Rcvr Err Long	Electronic self-test failure.	Turn machine power off and back on. If alarm is not cleared, take your machine out of service and call a qualified service technician.
WD: 24v Rcvr Err Short	Electronic self-test failure.	Turn machine power off and back on. If alarm is not cleared, take your machine out of service and call a qualified service technician.
WD: Fail Long Pulse	Electronic self-test failure.	Turn machine power off and back on. If alarm is not cleared, take your machine out of service and call a qualified service technician.
WD: Fail Short Pulse	Electronic self-test failure.	Turn machine power off and back on. If alarm is not cleared, take your machine out of service and call a qualified service technician.
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. 5. Place the WetAlert device back on the vascular access.
Wetness Detected Press 1 to learn	The machine has sensed a WetAlert device as expected.	<p>Press the 1 key to link the alarming WetAlert device to the machine.</p> <p>If you do not want to link this WetAlert device to the machine, press the RESET key.</p>

Message	Meaning	Action Required
Wetness Learn Failed	The selected WetAlert device was not linked to the machine.	Select and confirm the desired Wetness Detector toggle-button again before trying to activate the device.
Wetness Learn Start	The WetAlert device is ready to be linked to the machine.	Follow the prompts in the Status Box to link the WetAlert device to the machine.
Wetness Learn Success	The selected WetAlert device is successfully linked to the machine.	No action is necessary.
Wetness Learned Already	The user is attempting to learn a WetAlert device that is already linked to this machine.	The selected WetAlert device is already linked to this machine.
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 331 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, then press the RESET key. 2. Repeat step 1. <p>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 the machine. It will not sense wetness until reactivated with a new treatment.</p>

Message	Meaning	Action Required
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.
Wetted After Learn	The WetAlert device was touched too late when learning the device.	Select and confirm the desired Wetness Detector toggle-button again. Touch and hold the device when prompted in the Status Box.
Wetted Before Learn	The WetAlert device was touched too soon when learning the device.	Select and confirm the desired Wetness Detector toggle-button again. Touch and hold the device when prompted in the Status Box.

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Appendix A



Appendix A

Appendix A provides instructions on different features or cases that may arise during dialysis:

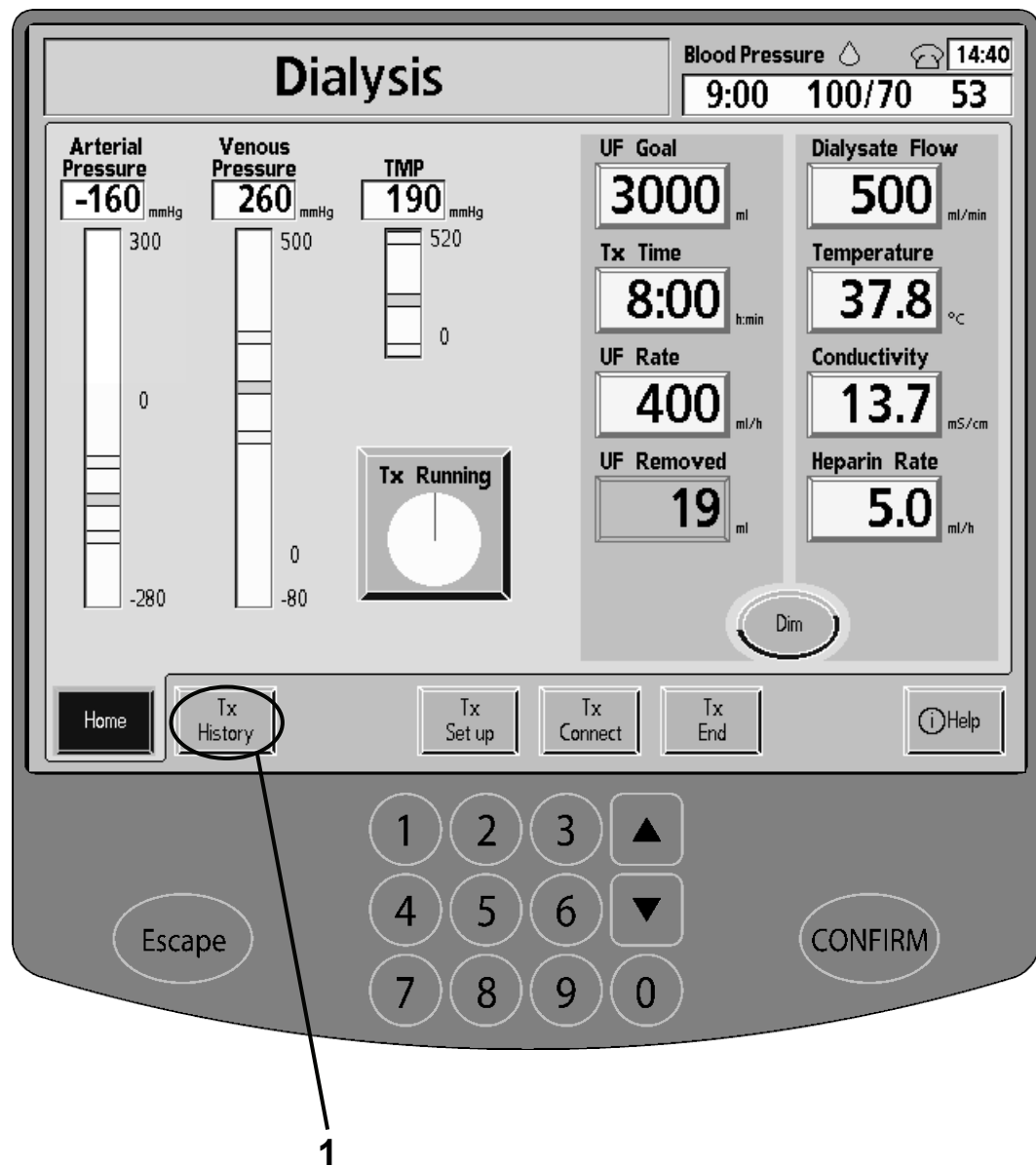
- Reviewing Your Tx History: page 286
- Adjusting Treatment Parameters: page 292
- Adjusting Conductivity Alarm Limits: page 294
- Pausing Your Treatment: page 298
- Resuming Dialysis After Recirculation: page 302
- Replacing the Diasafe Plus Filter: page 308
- Testing the Diasafe Plus Filter: page 310
- Replacing the 9-Volt battery: page 312
- Concentrate Types: page 314
- Hardware & Service Mode Options: page 316

This appendix is a guide only—your clinic must properly instruct you in these procedures.



Warning: Do not attempt these procedures unless your clinic has fully explained them to you. Lack of proper instruction could lead to serious injury. Call your clinic with any questions before using these procedures.

Reviewing Your Treatment History

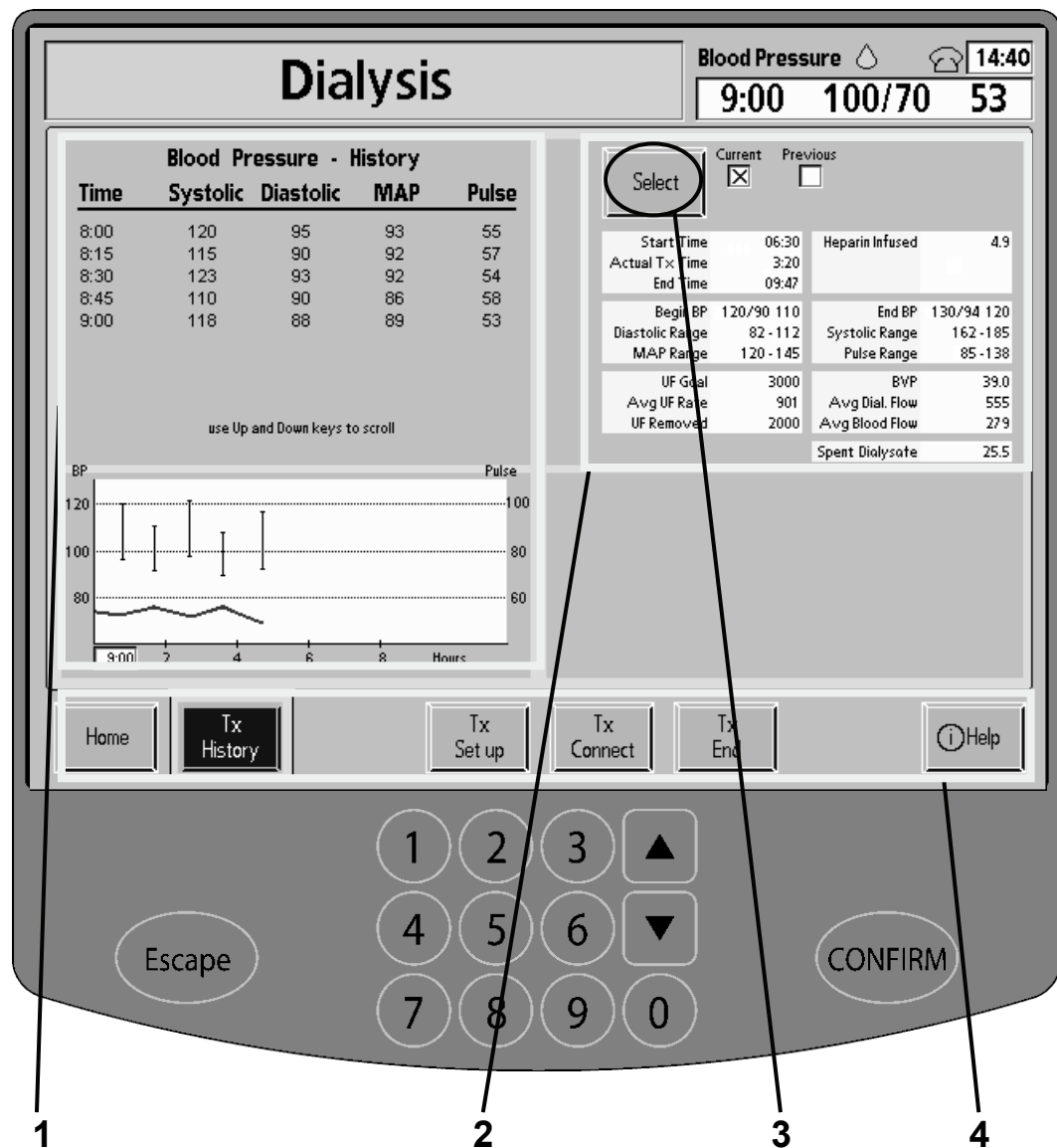


Warning: The values shown here are for example only. You must use the values prescribed by your doctor. If you use the wrong values, it may cause serious injury or death.

1 Touch **Tx History**

Touch the **Tx History** screen-button to monitor your “Treatment History” at any time during your treatment or between Tx End procedures.

The Treatment History Screen



1 Review Blood Pressure – History

Your blood pressure history is on the left side of the screen. It shows a record of blood pressure cuff readings since the start of your treatment. The table displays:

- Systolic pressures (in mmHg)
- Diastolic pressures (in mmHg)
- MAP (Mean Arterial Pressures, in mmHg)
- Pulse (in beats per minute)

The chart below the table shows two different graphs over the length of your treatment: The left side of the chart shows the ranges between your systolic and diastolic pressures, measured at regular times since the Tx Clock began running. The pressure differences appear as vertical lines: systolic is at the top of the line and diastolic is at the bottom. The right side of the chart measures your pulse. It displays your range of pulses as a red line graph.



Note: You may press the **Stat/Deflate** key (see Your K Map: ‘O’) in the Patient section of the Control Panel to take an unscheduled blood pressure reading. Unscheduled blood pressure readings listed in the table have the letter “M” (for ‘manual’) in front of them.

2 Review treatment history

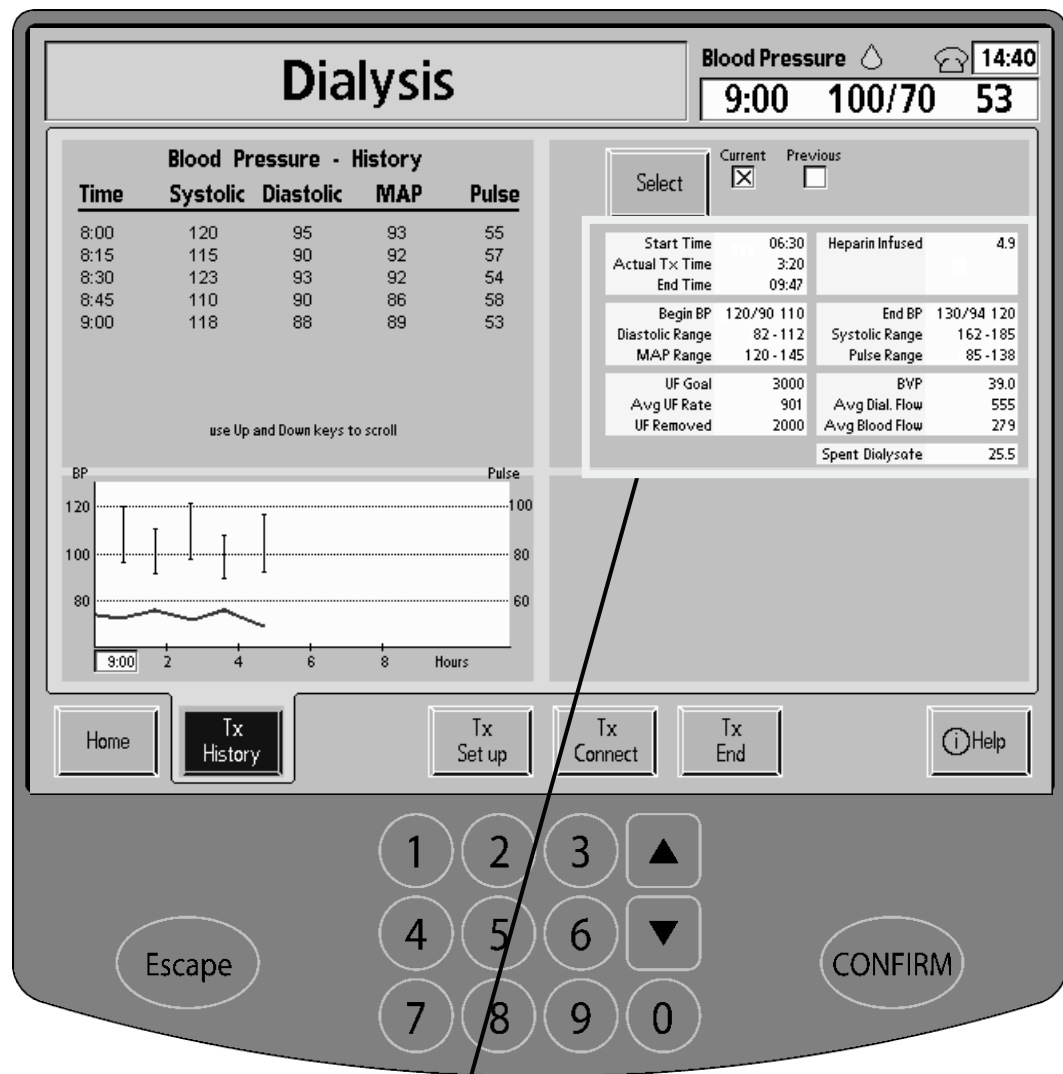
The right side of the screen shows your treatment history in two columns. See the next page for a description of the information listed in these columns.

3 Touch **Select**

To view your Tx History from your last treatment, touch the **Select** toggle-button to change its setting to ‘Previous’. Your machine will display information from your last treatment.

4 Touch any screen-button to exit this screen

The Treatment History Screen (continued)

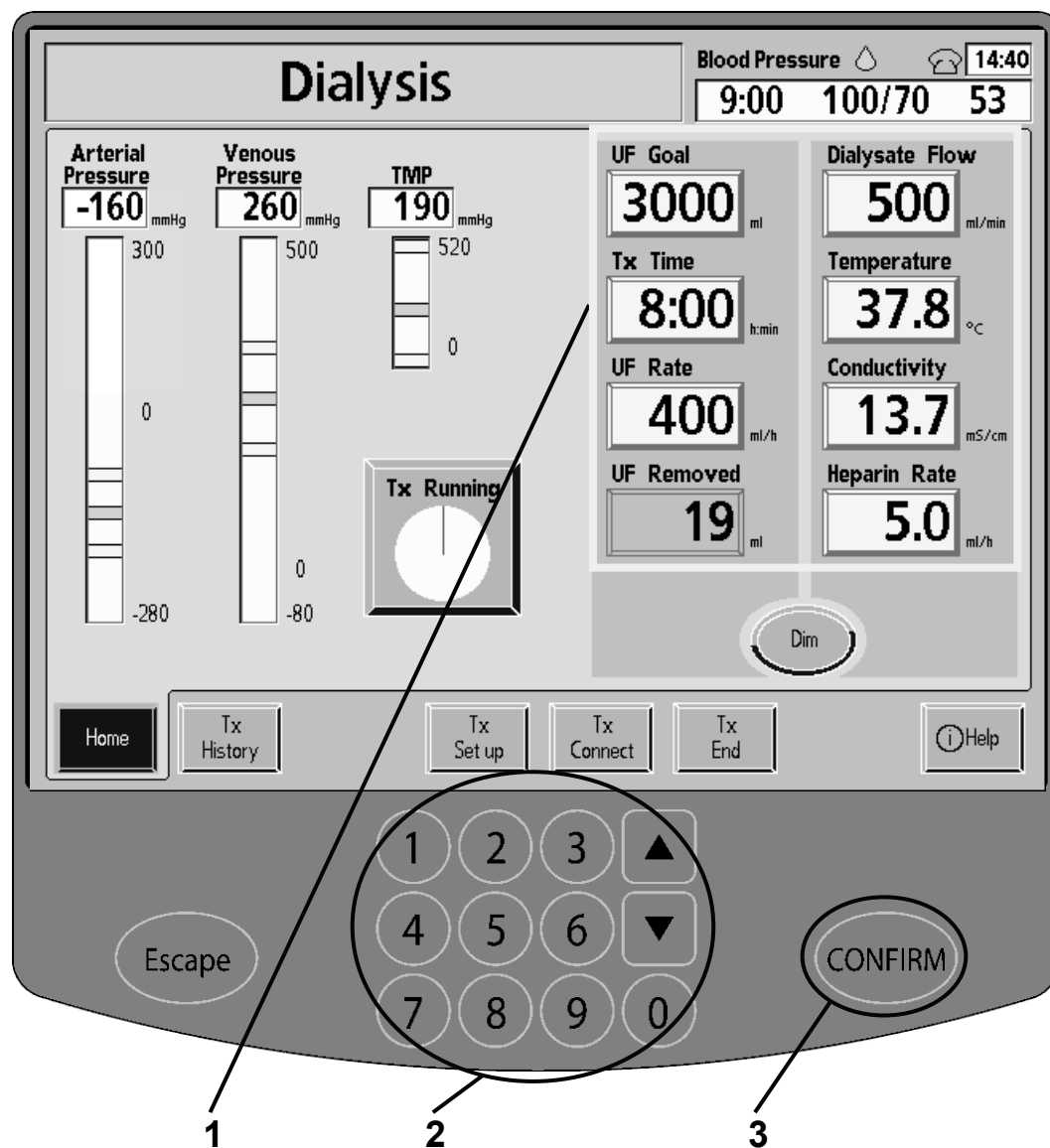


Treatment History

Treatment History

Item	Description
Start Time	This is when your machine has completed recirculation and is ready for you to begin your treatment.
Actual Tx Time	This timer begins at 0:00 and counts up during your treatment as long as UF and dialysate flow are on and blood is sensed. When your treatment is finished, this is the total amount of time in hours and minutes that you received treatment.
End Time	This when you stopped the treatment clock (setting it to 'Tx Paused') at the end of your treatment.
Heparin Infused	This how much heparin the heparin pump module pushes (infuses) into your bloodlines throughout your treatment. It starts at 0.0 ml and counts up.
Begin BP	The first blood pressure and pulse reading.
End BP	The last blood pressure and pulse reading.
Diastolic Range	Your lowest and highest diastolic blood pressure readings.
Systolic Range	Your lowest and highest systolic blood pressure readings.
MAP Range	Your lowest and highest mean arterial blood pressure (MAP) readings.
Pulse Range	Your lowest and highest pulse readings.
UF Goal	This is the value from the "Home" screen that you set with the UF Calculator. It is the amount of excess fluid your machine will remove from you by ultrafiltration (UF).
Avg UF Rate	This is the average rate of fluid removal (ml/hr) during your treatment.
UF Removed	This is the value from the "Home" screen. It shows how much excess fluid was removed from you during your treatment.
BVP	This is your Blood Volume Processed, the number of liters of blood your machine cleaned during your treatment.
Avg Dial. Flow	This is the average dialysate flow in ml/min during your treatment.
Avg Blood Flow	This is the average speed of the blood pump in ml/min during your treatment.
Spent Dialysate	If took a dialysate sample, the Spent Dialysate for your treatment will appear at the bottom of the right column. Contact your Home Therapies Nurse for more information.

Adjusting Treatment Parameters



Warning: The values shown here are for example only. You must use the values prescribed by your doctor. If you use the wrong values, it may cause serious injury or death.

1 Example: Selecting settings

You can change settings from the dialysis “Home” screen such as Dialysate Flow, UF Rate, or Tx Time. Touch any one of the yellow parameter-buttons to highlight it.



Note: The **Conductivity** button does not work like other parameter-buttons; it is also a screen-button. See the next page for more information.

2 Example: Adjusting settings

Next, press the **Up/Down Arrow (▼/▲)** keys or the number keys on the data entry keypad to enter your prescribed values.

If you incorrectly enter a value, press the **Escape** key (located to the left of the number on the data entry keypad) to reset the parameter-button.

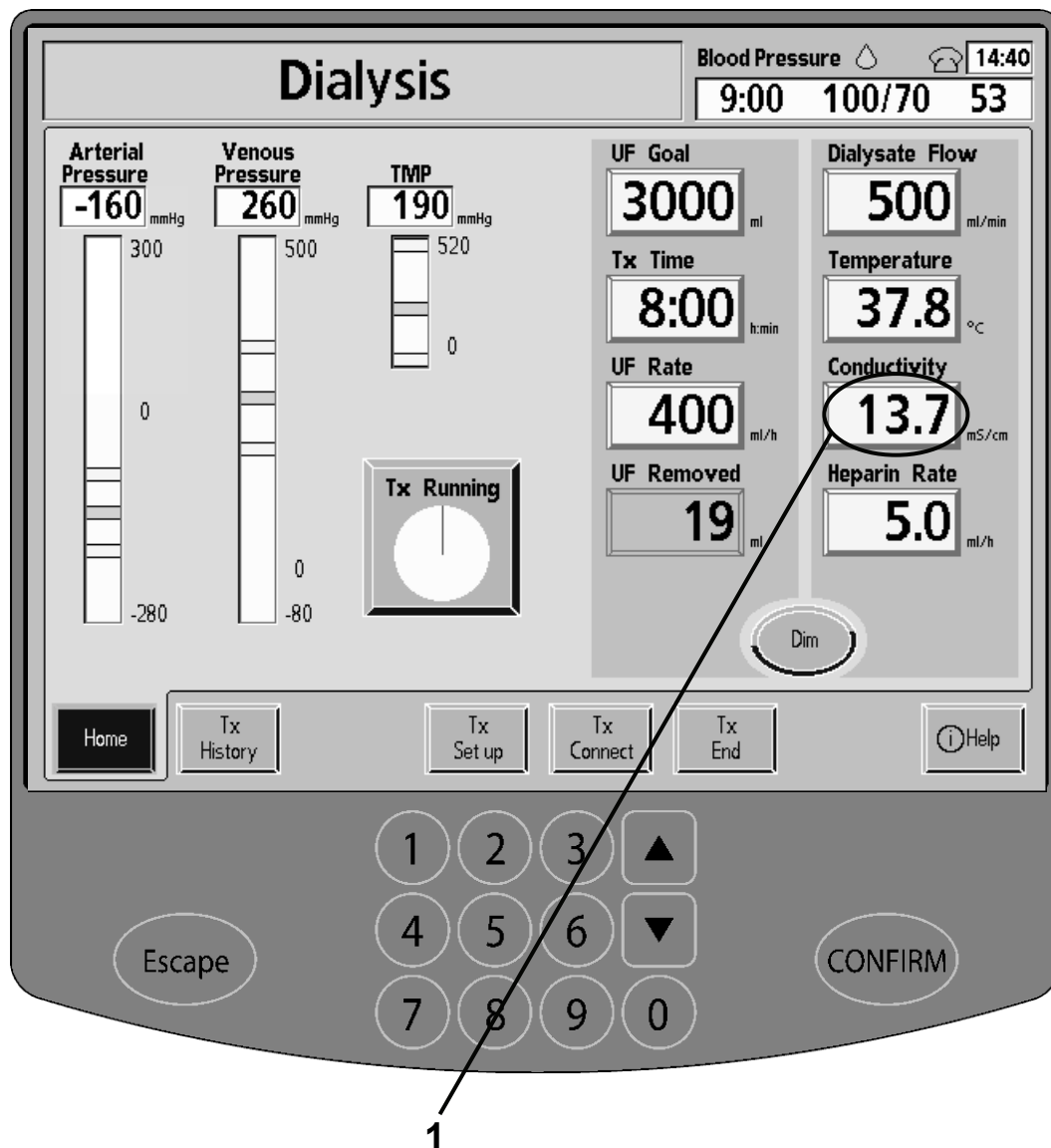
3 Example: Confirming new settings

Press the **CONFIRM** key to confirm the new settings.



Warning: The values shown here are for example only. You must enter the exact values prescribed by your doctor (see “My Treatment Parameters,” on page ii). Incorrectly entered treatment parameters may cause serious injury or death.

Adjusting Conductivity Alarm Limits

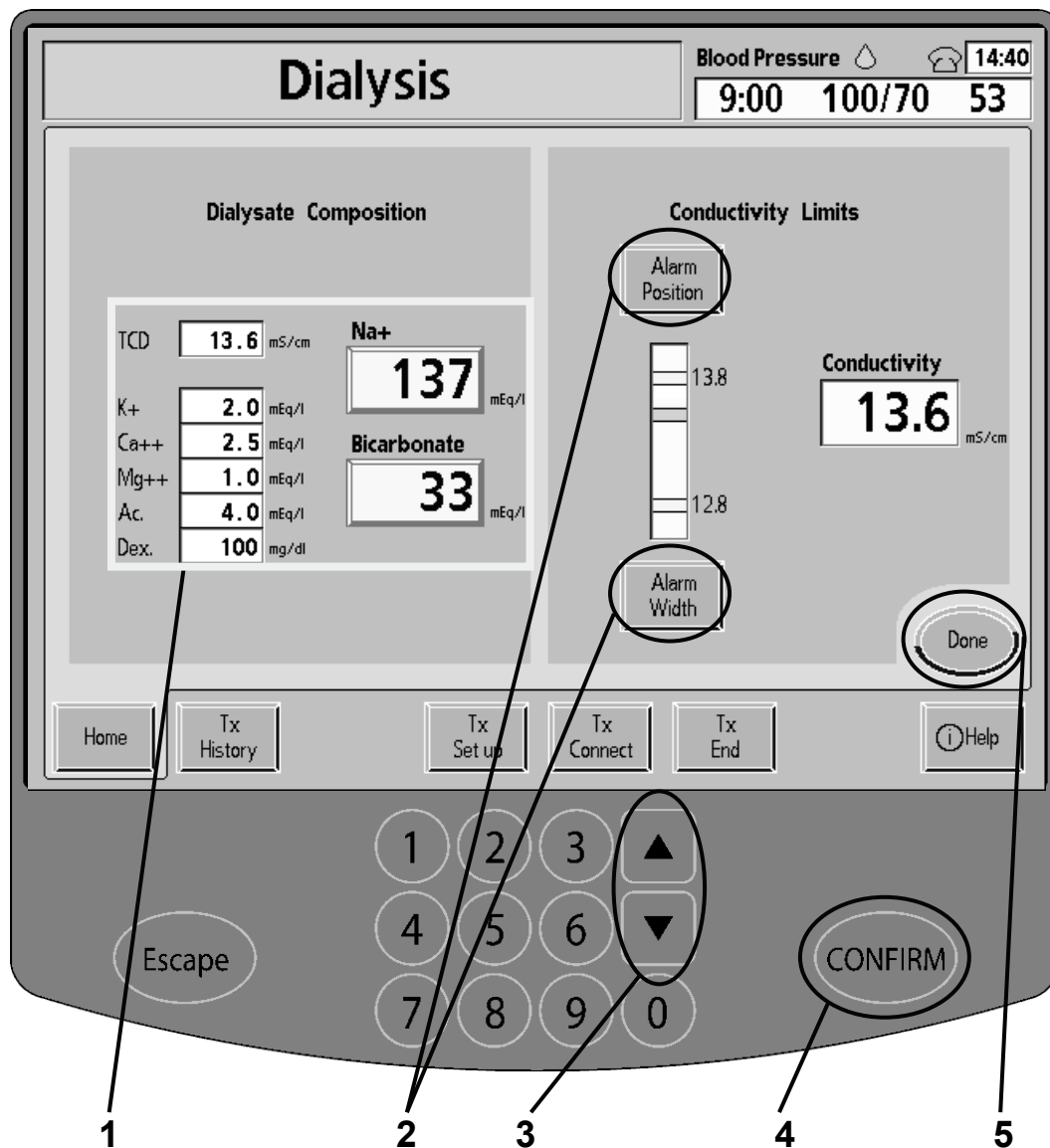


Warning: The values shown here are for example only. You must use the values prescribed by your doctor. If you use the wrong values, it may cause serious injury or death.

1 Touch **Conductivity**

You can adjust the concentrate conductivity and its alarm limits through the dialysis “Home” screen. Touch the **Conductivity** button to go to the “Dialysate Composition and Conductivity Limits” screen.

Setting the Conductivity Limits



Warning: The values shown here are for example only. You must use the values prescribed by your doctor. If you use the wrong values, it may cause serious injury or death.

1 Review dialysate values

Make certain to check the dialysate composition shown on the left side of the screen. The values listed must be those prescribed on your “My Treatment Parameters” sheet, on page ii. The values must also match your concentrate containers. Re-enter the correct composition, if necessary.



Warning: The Dialysate composition must match both your prescription and the acid and bicarbonate jugs. Contact your clinic for more information. The wrong conductivity may cause serious injury or death.

2 Example: Select conductivity limits

Touch the **Alarm Position** button to highlight it. Using the data entry keypad, the alarm window can be moved up or down along the length of the bar graph.

Touch the **Alarm Width** button to highlight it. Using the data entry keypad, the alarm window can be set wider or narrower within the hard limits.

3 Example: Set conductivity limits

After selecting the alarm you wish to change, use the **Up/Down Arrow (▼/▲)** keys on the data entry keypad to adjust it.

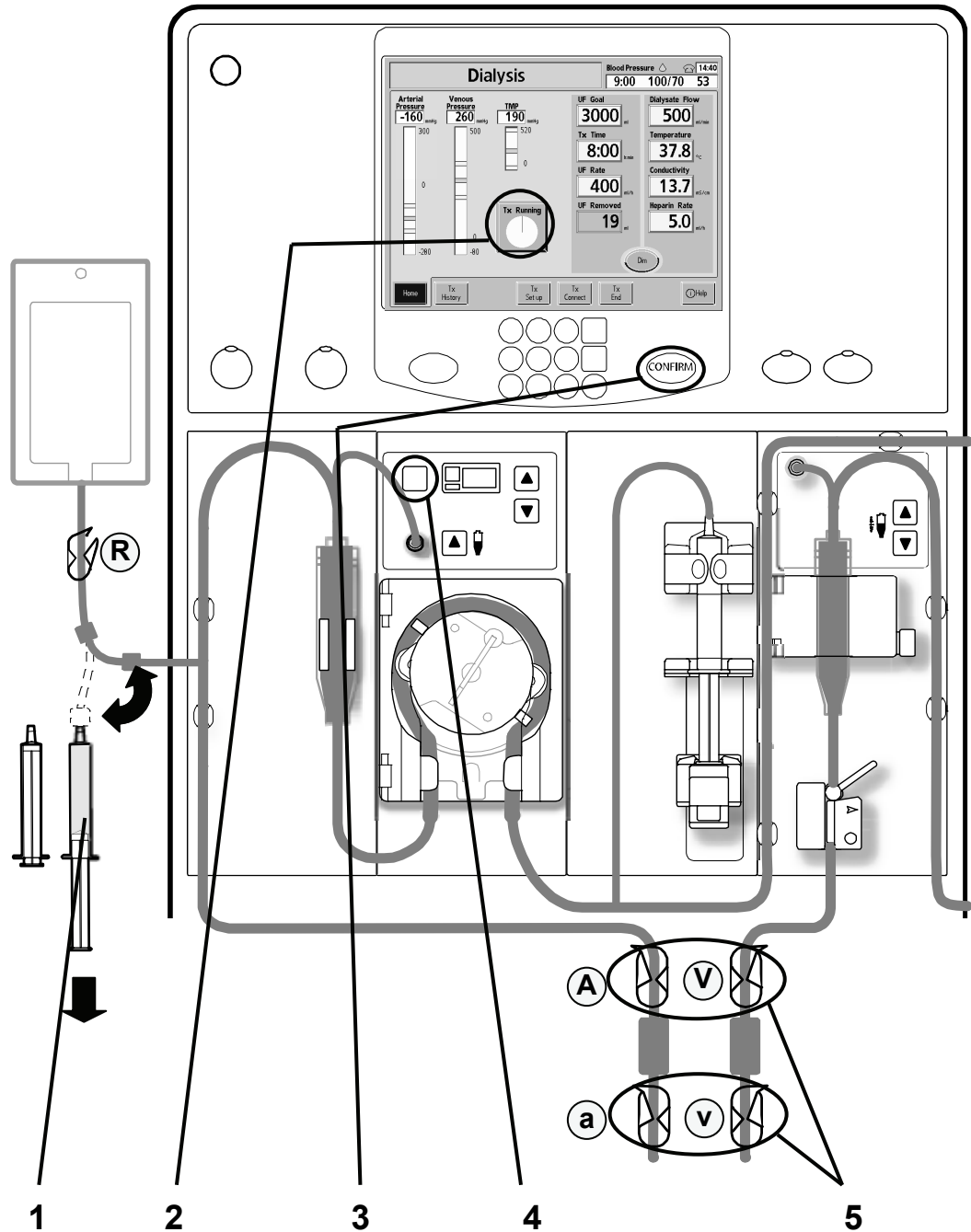
4 Example: Press **CONFIRM**

Next, press the **CONFIRM** key on the data entry keypad to confirm your selection.

5 Touch **Done**

When you are finished, touch the **Done** button to return to the dialysis “Home” screen.

Pausing Your Treatment



Warning: The values shown here are for example only. You must use the values prescribed by your doctor. If you use the wrong values, it may cause serious injury or death.

Pausing your treatment

Sometimes you may find you must briefly pause your 2008K@home hemodialysis machine during your treatment. Such reasons include access problems, high pressures, or air in the system. Follow your clinic's procedures, or the instructions below, to recirculate your blood for no more than 10 minutes.



Warning: Check all bloodlines and dialysate lines for leaks. Keep access sites uncovered and monitored. Improper bloodline connections or needle dislodgements can result in excessive blood loss, serious injury and death. Machine alarms may not occur in every blood loss situation

Warning: Use aseptic technique.

1 Fill two syringes with saline

With clamp **(R)** closed: Disconnect the red end of the recirc connector and connect a sterile syringe. Open clamp **(R)** and draw saline into two syringes. Close the clamp again and reconnect the red end of the recirc connector to the arterial line.

2 Touch **Tx Running**

3 Press **CONFIRM**

Touch the **Tx Running** button and press the **CONFIRM** key on the data entry keypad to **PAUSE** your treatment. The **Tx Running** button will change to **Tx Paused** and the pie chart graph will change from green to yellow.

4 Turn blood pump off (see Your K Map: 'D')

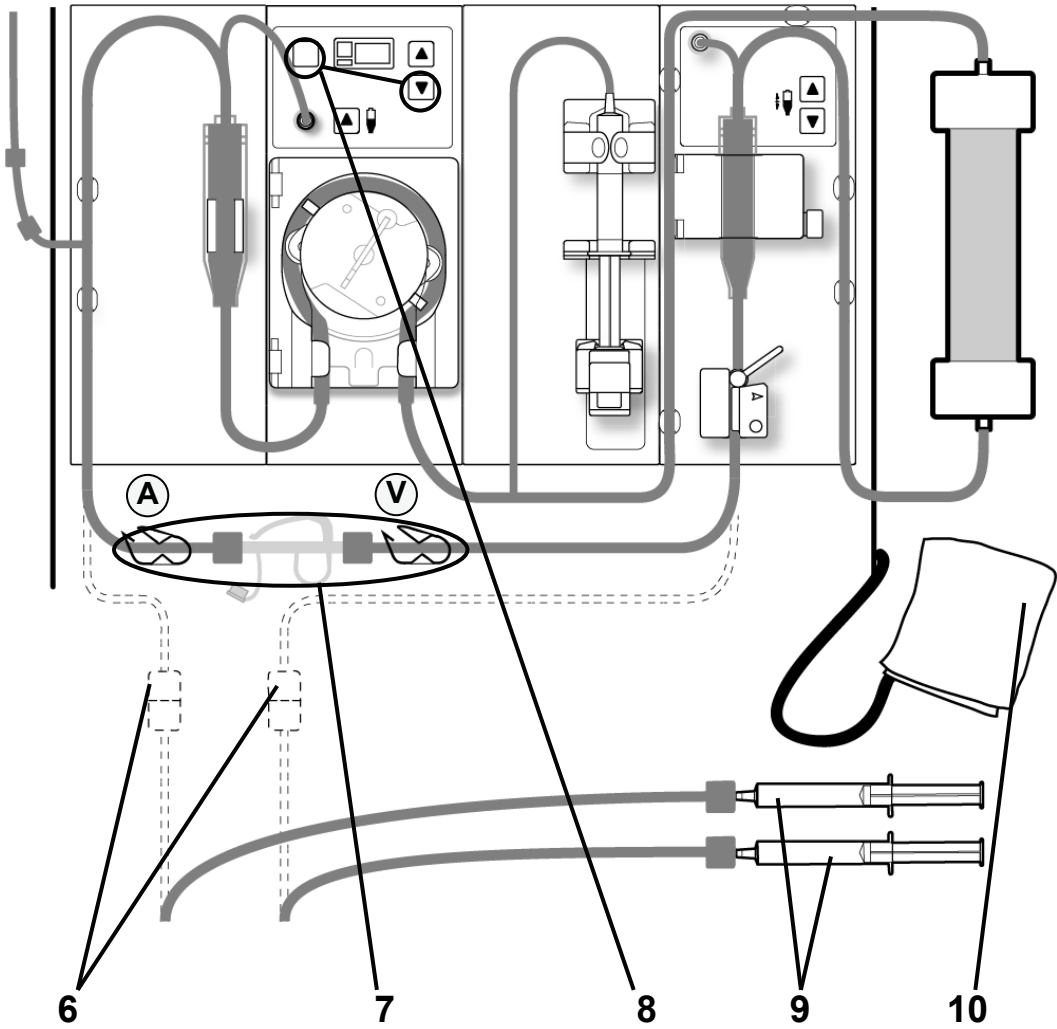
Press the **Start/Stop** key on the Blood Pump module to turn the blood pump off.

5 Close all venous and arterial line clamps **(A)(a)(V)(v)**

Clamp the venous and arterial patient and access lines. Place an underpad beneath your access.

(continued on next page)

Pausing Your Treatment (continued)



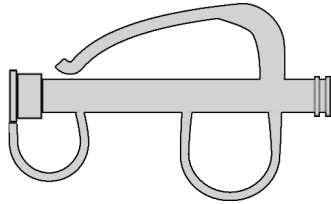
(continued)

6 Disconnect patient lines

Separate the access lines from the patient ends of the venous and arterial lines. Attach the saline filled syringes to the ends of both access lines.

7 Connect recirc connector, open patient arterial and venous clamps **(A)(V)**

Connect the patient ends of the venous and arterial lines together with a new, sterile recirculation connector piece.



Hang the lines on the IV pole. Unclamp the patient end of both the venous and arterial lines.

8 Restart blood pump and lower pump speed (see Your K Map: 'D', 'E')

Press the **Start/Stop** key and then use the **Blood Pump Up/Down Arrow (▼/▲)** keys to set the blood pump speed to 100 ml/min. If the venous pressure drops below 60 mmHg, open the saline bag clamp to maintain pressure.



Note: Do not open the saline line unless venous pressure drops below 60 mmHg. Close the clamp when pressure has returned.

9 Flush patient lines

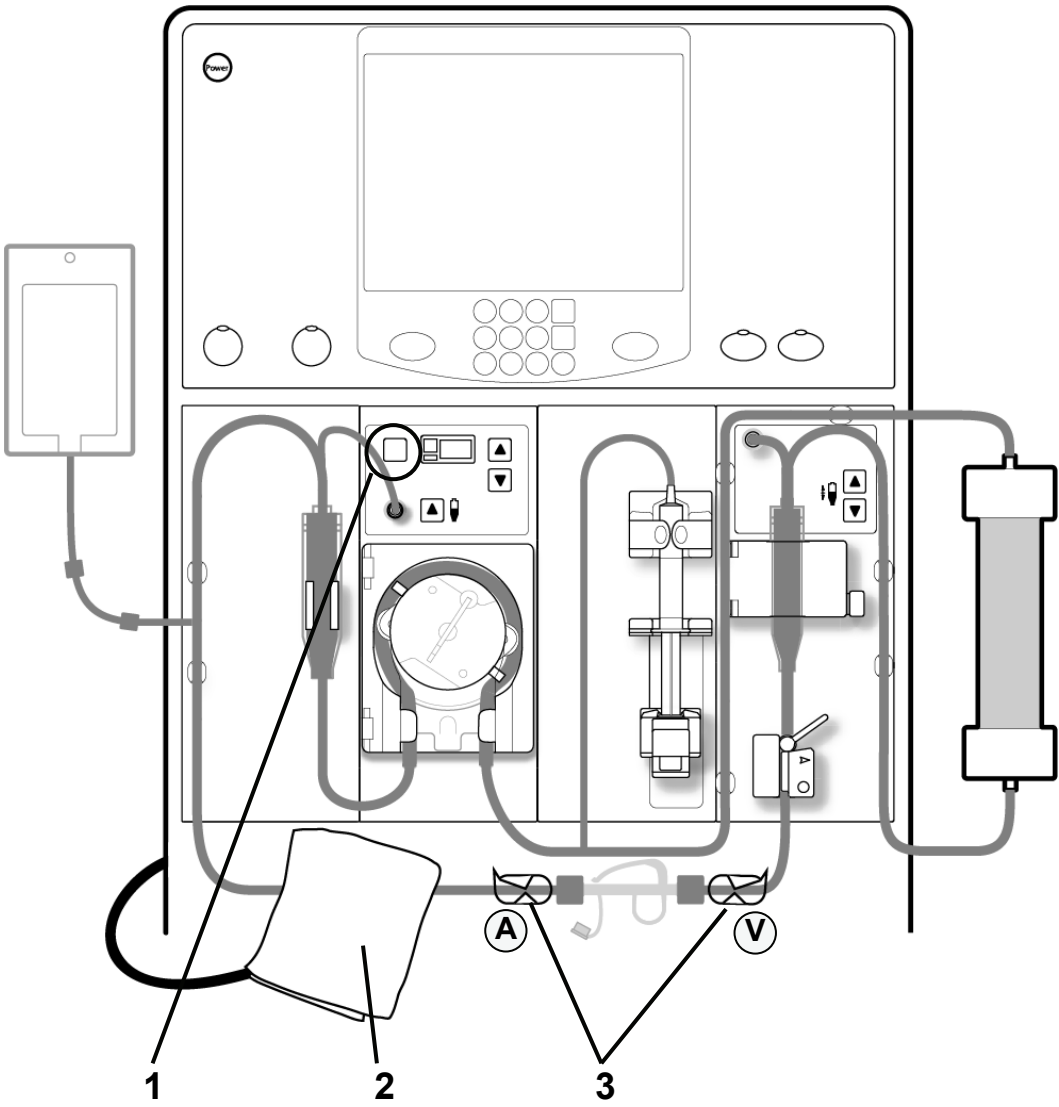
Flush your arterial and venous access lines with saline from the syringes. Leave the syringes attached to prevent air from entering the tubing.

10 Remove blood pressure cuff

Remove the blood pressure cuff. Press the **Stat/Deflate** key to manually deflate the cuff, if necessary. Since blood is sensed while the Tx Clock is paused, an audible alarm will sound every two minutes.

Your blood will recirculate in the bloodlines. You may now leave your machine for no more than 10 minutes.

Resuming Dialysis after Recirculation





Warning: Do not continue your treatment if it looks like your red blood cells are damaged (hemolysis). Contact your clinic for more information.

Warning: Carefully watch the venous chamber and bloodlines for the presence of air. Be sure you will not infuse any air into your bloodlines.

1 Turn blood pump off (see Your K Map: ‘D’)

Press the **Start/Stop** key on the Blood Pump module to turn the blood pump off.

2 Fit blood pressure cuff

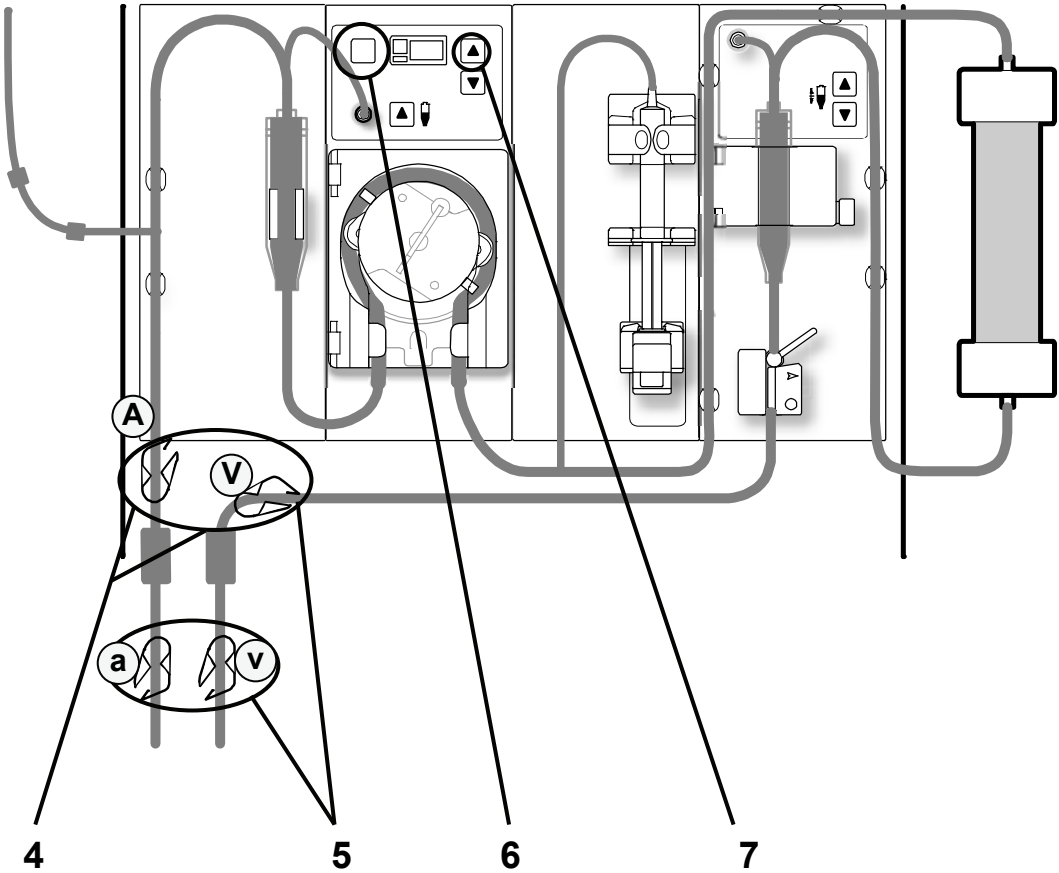
Replace the blood pressure cuff on your arm. For instructions, see “Fitting the Blood Pressure Cuff” on page 120.

3 Close arterial and venous line clamps (A) (V)

Close the arterial and venous line clamps on both sides of the recirc connector.

(continued on next page)

Resuming Dialysis after Recirculation (continued)



(continued)

4 Disconnect recirc connector, connect to access lines

Disconnect the patient end of the arterial line from the recirc connector. Reattach the arterial line to your arterial access line.

Disconnect the patient end of the venous line from the recirc connector. Reattach the venous line to your venous access line.



Warning: Check all bloodlines and dialysate lines for leaks. Keep access sites uncovered and monitored. Improper bloodline connections or needle dislodgements can result in excessive blood loss, serious injury and death. Machine alarms may not occur in every blood loss situation

Warning: Use aseptic technique.

5 Open all arterial and venous line clamps (A) (V) (a) (v)

Open all of the clamps on the venous and arterial lines. Check the lines for any kinking or twisting. Make certain all bloodlines are connected tightly and placed in their tubing guides on the modules.

6 Restart blood pump (see Your K Map: 'D')

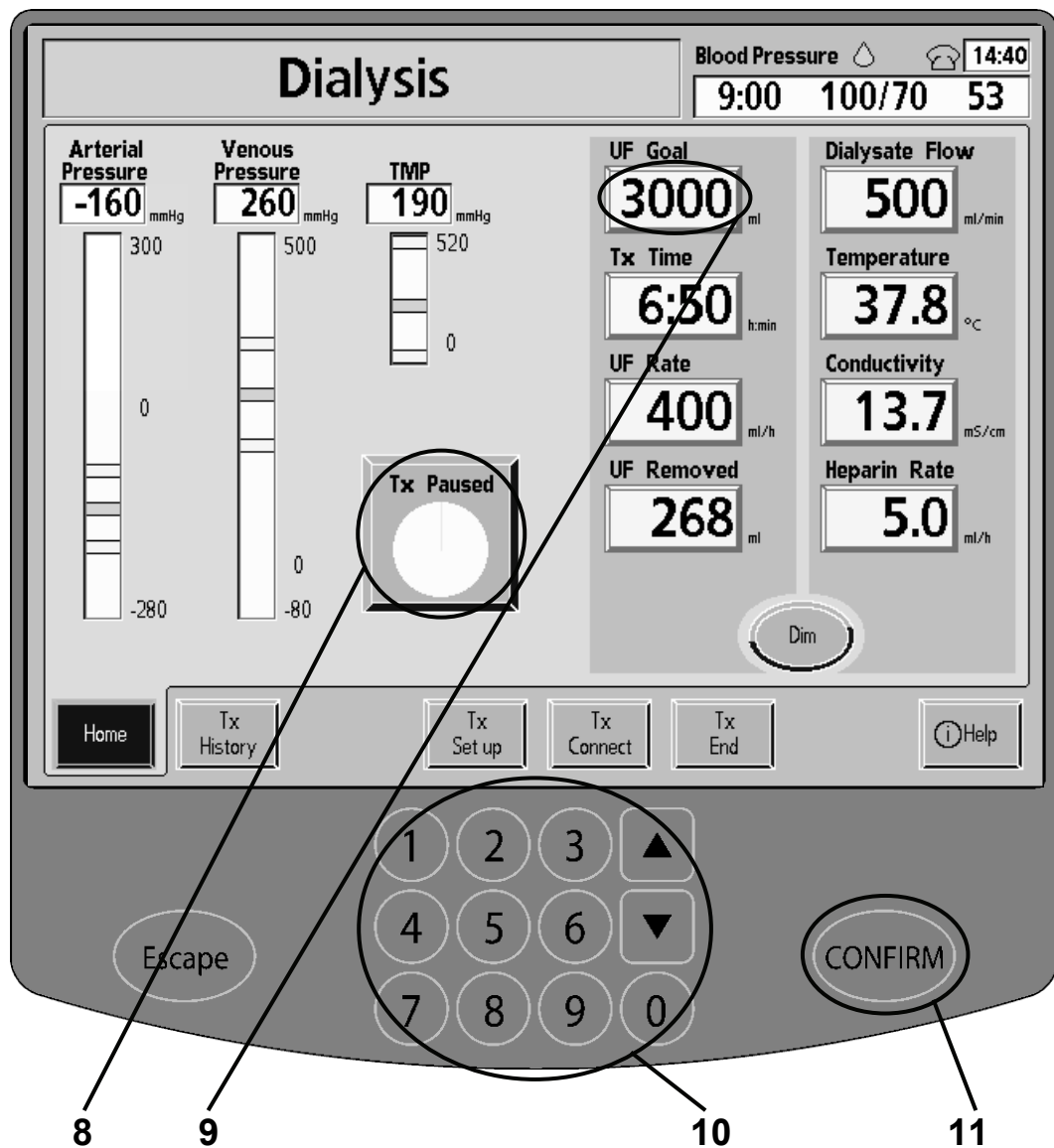
Press the **Start/Stop** key on the Blood Pump module to restart the blood pump.

7 Set blood pump speed (see Your K Map: 'E')

Press the **Up** key of the **Blood Pump Up/Down Arrow** (▼/▲) keys to slowly raise the pump speed back to your prescribed rate. Watch all pressures closely.

(continued on next page)

Resuming Dialysis after Recirculation (continued)



Warning: The values shown here are for example only. You must use the values prescribed by your doctor. If you use the wrong values, it may cause serious injury or death.

(continued)

8 Touch **Tx Paused**

Touch the **Tx Paused** button and press the **CONFIRM** key to start the Tx Clock again.

9 Select UF Goal

For an accurate ultrafiltration, touch the **UF Goal** button to highlight it.

10 Enter new UF Goal

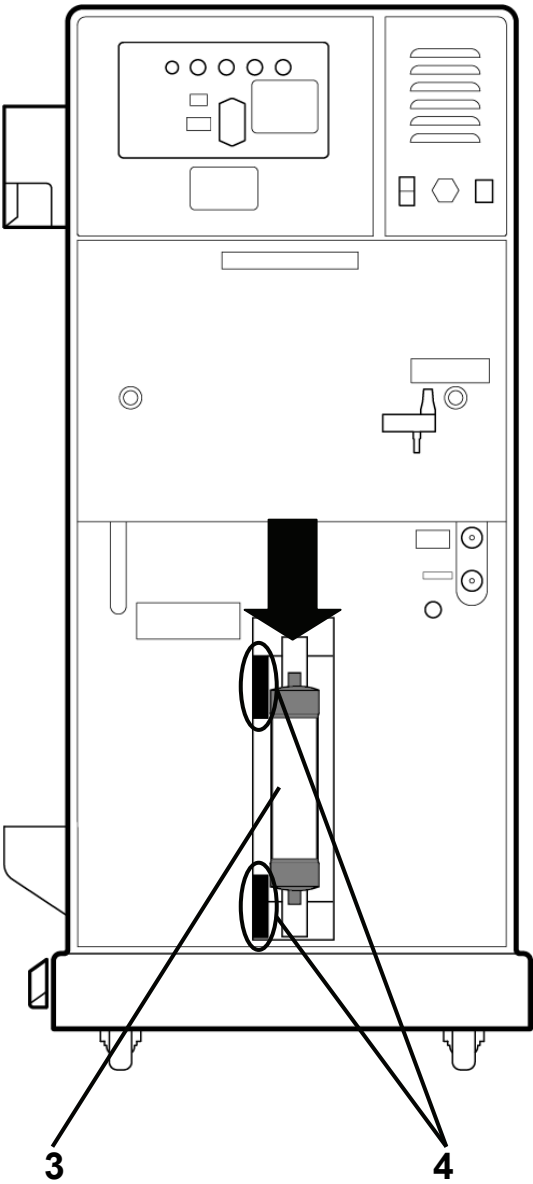
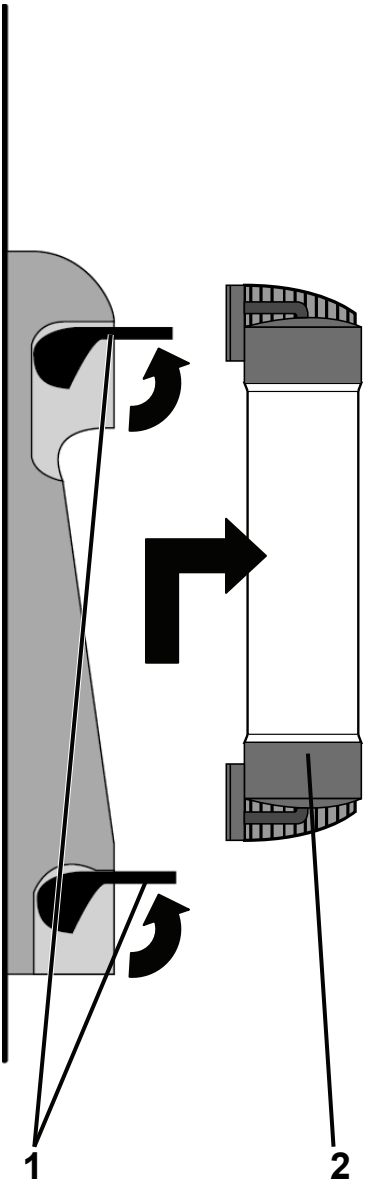
Use the **Up/Down Arrow (▼/▲)** keys on the data entry keypad to raise your UF Goal. Add the volume of the saline that you used to flush your access lines.

11 Press **CONFIRM**

Press the **CONFIRM** key to start the Tx Clock and confirm your new UF Goal. “Tx Paused” will change back to “Tx Running” and your treatment will continue.

You may now resume your treatment.

Replacing the Diasafe Plus Filter



APPENDIX A

Replacing the Diasafe Plus Filter

The Diasafe Plus filter is intended for the preparation of ultra-pure dialysate. If your machine has a Diasafe Plus filter, it should be replaced at least every 90 days (3 months). You must also replace the filter if the Diasafe test fails or shows an external leak. To replace the Diasafe Plus filter:



Warning: The use of the Diasafe Plus filter does not change your disinfection procedure. You must disinfect your machine and RO system just as often without it. You must still monitor the chemical and bacterial water quality.

1 Lift lock levers

Lift up the lock levers on the left side of the filter mount.

2 Remove old Diasafe Plus filter

Slide the old Diasafe Plus filter up and out. Follow your clinic's procedure for filter disposal.

3 Insert new Diasafe Plus filter

Fit the new Diasafe Plus filter into the groove in the top of the mount. Slide the filter down until it snaps into place.



Caution: Before inserting the new filter in your machine, remove the plastic tabs on the Diasafe Plus filter inlet and outlet before inserting the new filter in your machine.

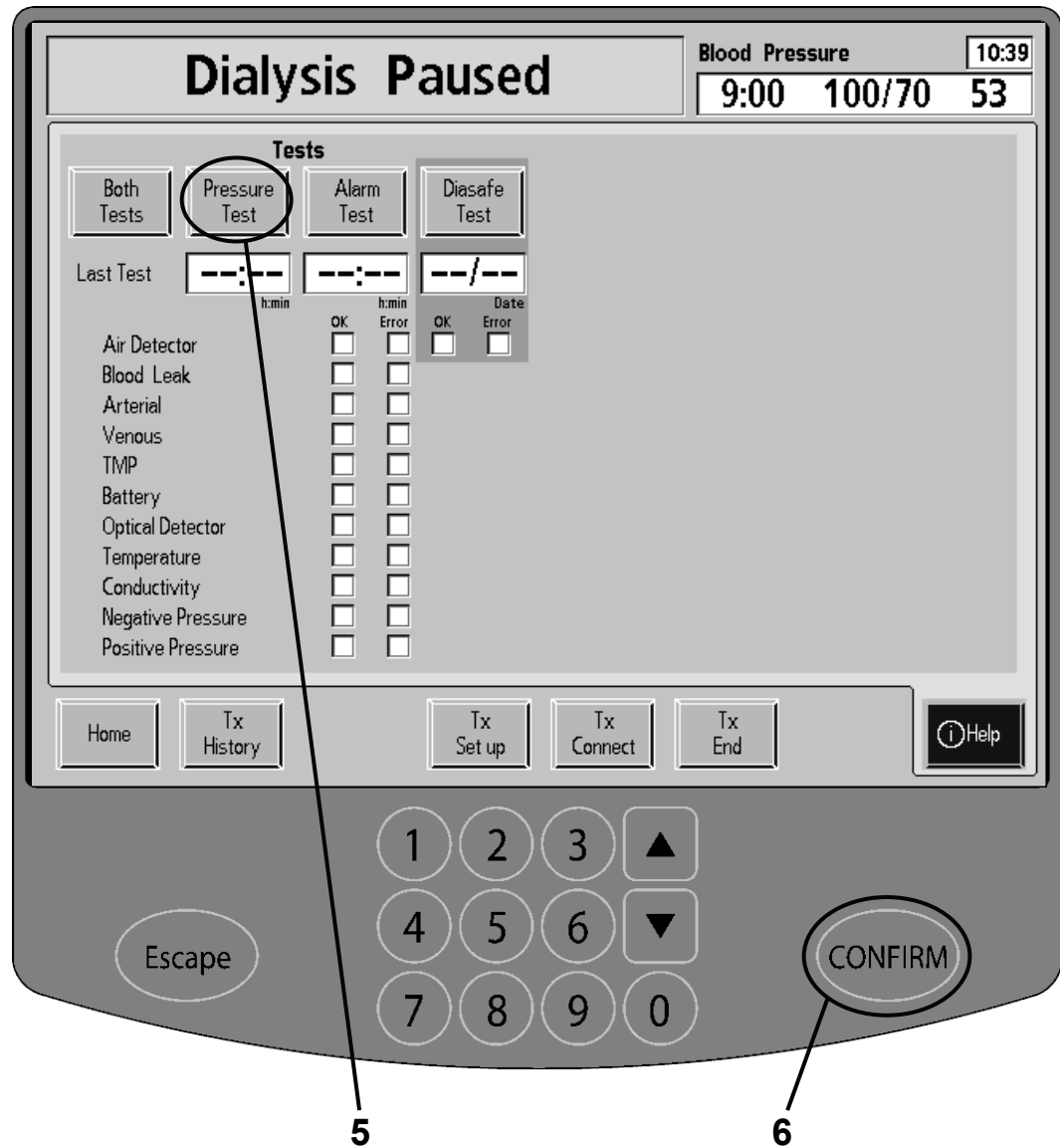
4 Lock levers down

Push the lock levers down to lock the filter into the mount. You must now test your filter; continue to the next page.



Warning: The Diasafe Plus filter can only be used in hemodialysis machines fitted with Diasafe Plus Diafix lock system kits.

Testing the Diasafe Plus Filter



Testing your Diasafe Plus Filter

You must run a Pressure Holding Test (PHT) after replacing your Diasafe Plus filter. You must also run a Diasafe Test every other week. To run the PHT:

5 Touch **Pressure Test**

Pull the red acid concentrate connector from your machine, touch the **Dialysis** screen-button, confirm your concentrate, and touch the **Help** screen-button in the lower right corner of the screen. On the “Help” screen, touch the **Pressure Test** button for your machine’s pressure holding test.

6 Press **CONFIRM**

Press the **CONFIRM** key to confirm your selections. The pressure holding test will begin. The Status Box displays each test as it runs. As each test passes, a blue “☑” appears in the “OK” column. When all the tests are done, your machine will beep and the Status Box will display the message: “Test Complete.”

If any part of the test fails, a red “☒” appears in the “Error” column and the Status Box displays the message: “Test Failed.” For a description of errors, see “Troubleshooting” on page 224.

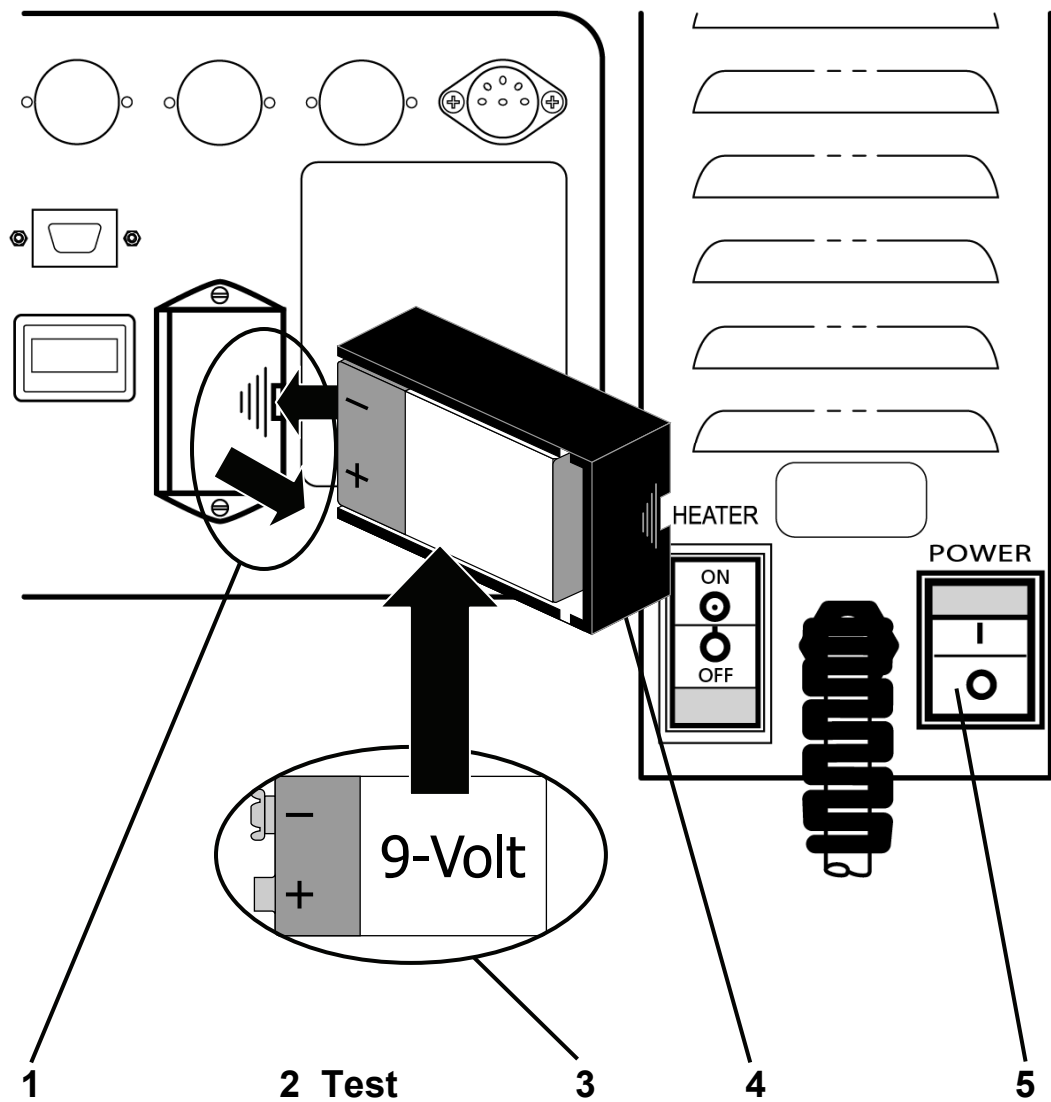


Warning: If your machine fails any of the tests and the cause cannot be corrected, or if it fails later tests, it should not be used for treatment. Have your machine checked by a qualified service technician to correct the problem.

Warning: After replacing the Diasafe Plus filter, run a Heat Disinfect to disinfect your machine.

You must also run the Diasafe Test both after replacing the Diasafe Plus filter and again every other week. See “The Help Screen” on page 200 for more information.

Replacing the 9-Volt Battery



i **Note:** If your machine has the optional WetAlert antenna, you must disconnect it before removing the battery. Locate the locking ring in between the antennae and the machine and rotate each antenna locking ring counter-clockwise. Slide the two antennae off the machine ports.

Replacing the 9-Volt battery

Replace your machine's 9-Volt battery if the battery test fails in the Alarm test. Follow the instructions below:

1 Remove old battery

Turn your machine OFF. Locate the battery on the back of your machine. Push the black battery loading cartridge in and to the left. The battery cartridge will pop forward. Slide the cartridge out.

2 Run Alarm test

Power your machine ON. Run the Alarm test (see page 200) without a battery. Your machine should fail the battery test. If it passes the test, call a qualified service technician.

3 Insert new battery in cartridge

The negative side of the fresh 9-Volt battery should be on top as shown in the picture on the right:



Warning: Do not install the 9-Volt battery backwards in your machine, as it will damage your “No Power” alarm.

4 Re-insert cartridge in your machine

Slide the battery and cartridge back into the battery slot. Push the cartridge to the right and click it into place.

5 Test the No Power alarm

Power your machine ON again. Flip the Main Power switch on the back of your machine to OFF. Listen for the No Power alarm: if the alarm still does not sound, repeat steps 1-5.







Warning: If your machine fails these tests and the cause cannot be corrected, it should not be used for treatment. Have your machine checked by a qualified service technician to correct the problem.



Note: If you removed the WetAlert antenna, re-connect it at this time: Push each antenna back onto its port and rotate the antenna locking rings clockwise.

Note: Periodically check the power cord for damage (fraying, over-heating, cuts, scrapes, etc.)

Concentrate Types

	35X 	36.83X Salt Spiked Bicarbonate 	45X bicarbonate only 	36.1X 	Acetate
Base Mix Ratio Acid: Bicarb: Water: Total	1: 1.23: 32.77: 35	1: 1.83: 34: 36.83	1: 1.72 42.28: 45	1: 1.26: 33.84: 36.1	(Acetate: Water) 1: 34: 35
Na ⁺ @ base mix ratio	138 mEq/l	138 mEq/l	137 mEq/l	138 mEq/l	N/A
Bicarbonate @ base mix ratio after reaction	32 mEq/l (35-3)	35 mEq/l (39-4)	33 mEq/l (37-4)	32 mEq/l (36-4)	N/A
Acid Mix Ratio Acid: Other	1: 34	1: 35.83	1: 44	1: 35.1	1: 34
Bicarbonate Conc. Mix Ratio Bicarbonate: Other	1: 27.46	1: 19.13	1: 25.16 (Bic=81.25 g/L)	1: 27.6	N/A
Sodium Bicarbonate Concentrate Composition	84.0 g/L NaHCO ₃	65.95 g/L NaHCO ₃ + 23.53 g/L NaCl	81.25 g/L, 79.25 g/L, or 72 g/L NaHCO ₃	84.0 g/L NaHCO ₃	None

Concentrate types

Your 2008K@home hemodialysis machine can be set up for many different concentrate types. If a bicarbonate-type concentrate is to be used, both bicarbonate concentrate and acid concentrate must be connected to the machine. The specific bicarbonate type is selected in Service Mode during calibration. The table to the left shows the compatibility of the concentrates and instructions on proper mixture ratios.

Bicarbonate solution is not stable over time. Make a fresh batch for each treatment according to the manufacturer's instructions.



Warning: Your machine must be labeled to indicate the type of concentrate for which it is configured. Check the composition (Na^+ , Cl^- , K , Ca^{++} , Mg^{++} , HCO_3^-) and pH of the dialysate after your machine's concentrate setup has been changed. Check the conductivity and approximate pH of the dialysate with an independent device before starting dialysis. Improper conductivity or pH may cause serious injury or death.

Warning: Acetate concentrates are used individually with your machine without a bicarbonate concentrate. Your 2008K@home hemodialysis machine is a standard 1:34 proportioning machine. Use of a 1:44 acid with a 1:34 acetate machine may cause serious injury or death.

Estimated bibag disposable run times (minutes)

The bibag disposable contains a fixed volume of bicarbonate powder. Refer to the tables below to make sure enough run time* (including any set-up time and potential pre-treatment delays) is available to complete your treatment using one bag.

650g		Bicarbonate Setting (mEq/L or mmol/L)																
		40	39	38	37	36	35	34	33	32	31	30	29	28	27	26	25	24
Dialysate flow QD (mL/min)	800	180	185	189	195	200	206	212	218	225	232	240	248	257	267	277	288	300
	700	206	211	217	222	229	235	242	249	257	265	274	284	294	305	316	329	343
	600	240	246	253	259	267	274	282	291	300	310	320	331	343	356	369	384	400
	500	288	295	303	311	320	329	339	349	360	372	384	397	411	427	443	461	480
	400	360	369	379	389	400	411	424	436	450	465	480	497	514	533	554	576	600
	300	480	492	505	519	533	549	565	582	600	619	640	662	686	711	738	768	800
	200	720	738	758	778	800	823	847	873	900	929	960	993	1029	1067	1108	1152	1200

900g		Bicarbonate Setting (mEq/L or mmol/L)																
		40	39	38	37	36	35	34	33	32	31	30	29	28	27	26	25	24
Dialysate flow QD (mL/min)	800	240	246	253	259	267	274	282	291	300	310	320	331	343	356	369	384	400
	700	274	281	289	297	305	313	323	332	343	354	366	378	392	406	422	439	457
	600	320	328	337	346	356	366	376	388	400	413	427	441	457	474	492	512	533
	500	384	394	404	415	427	439	452	465	480	495	512	530	549	569	591	614	640
	400	480	492	505	519	533	549	565	582	600	619	640	662	686	711	738	768	800
	300	640	656	674	692	711	731	753	776	800	826	853	883	914	948	985	1024	1067
	200	960	985	1011	1038	1067	1097	1129	1164	1200	1239	1280	1324	1371	1422	1477	1536	1600

* Run times are estimates and may vary per unit protocol. Run times include estimated preparation and treatment time. Highlighted run times indicate 10+ hours of treatment time.

** To estimate run times for bicarbonate settings lower than what is listed in the table, use a bicarbonate selection of 24 (mEq/L or mmol/L).

Hardware and Service Mode Options



Warning: Only qualified people from your clinic may use Service Mode. Do not make any changes to your machine in Service Mode. If you enter the wrong options or values, you may cause serious injury or death.

0 Arterial Limit

With this option set to 'Yes', the upper arterial limit cannot be above 0 (with pre-pump arterial monitoring only) when blood is sensed unless the spreading limits function is active.

Allow Slow Flow

Your machine may be set to run dialysate flows as low as 100 or 200 ml/min. This option requires additional calibration.

Arterial and Venous Pressure Limits

The arterial and venous alarm windows may be set to different widths.

Arterial Chamber

This option is used to define whether the arterial chamber is pre-pump or post-pump. The range of display is different depending on the location of the chamber.

Audible Alarms

This option will silence all audible alarms until blood is sensed in the venous line. When selected, the audible alarms occur only if the dialysate lines are off the shunt interlock and the optical sensor in the Level Detector module senses blood.

Auto BP Reading

This option allows you to set the method of taking a blood pressure reading. Select 'Interval' to take a reading at the time interval selected in the "Rx Parameter" screen. Select 'Clock Time' to base the readings off of specific times (for example, every half hour on the hour and half hour).

Clean, Rinse, and Disinfect Times

The specific lengths of time for Cleaning and Disinfecting programs can be set with these buttons by selecting the parameter and changing it with the data entry keypad.

Dialysate Sampling

If this option is selected, the **Dialysate Sampling** button will appear on the "Check Concentrate" screen, allowing you to take a dialysate sample from the back of your machine.

Diasafe Auto-Test

If this option is selected, the **Diasafe Test** button will be displayed on the "Help" screen with the rest of the tests.

Extended Pre-Rinse

With this option set to 'Yes', the pre-rinse time for Heat Disinfect is increased to 20 minutes. There will also be reduced flow and higher fluid temperature throughout the drain line.

Heparin Pump

This option allows you to set the Heparin Pump module for 'none', '10-12 ml', or '20 ml' syringes.

In Center

The In Center option is for 2008K@home hemodialysis machines used in a clinic environment.

HE Leak Test

The HE (Heat Exchanger) Leak Test is available in software versions 4.36 and later. Setting this option to 'Yes' will run a four minute pressure holding test on the Heat Exchanger after the Chemical/Rinse program's 45 second pre-rinse.

Language

The operating screens may be set to either French (Canada), Spanish (Mexico) or English (USA). Service Mode is always in English.

Max. UF Rate

The maximum UF rate may be limited to 1000, 2000, 3000, or 4000 ml/h.

Off After Heat Disinfection

With this option set, your machine will automatically turn off at the end of the Heat Disinfect cycle.

Prime Amount

The prime volume may be set anywhere between 100-1000 ml. The priming process will continue until the selected volume has been delivered (measured by the blood pump speed) or the level detector senses fluid.

Recirculation Options

The Recirc Time and Recirc Goal may both be changed from default values.

Spread Limits

When activated and no blood leak alarm exists, the **RESET** key can be used to spread the arterial and venous limits by 300 mmHg for 30 seconds by pressing and holding the key. The TMP alarm limits will completely open. After 30 seconds the limits will reset around the current pressure readings.

T and C Mode

This is for manufacturing operations only and should never be selected by the facility.

Traffic Light Status Beacon

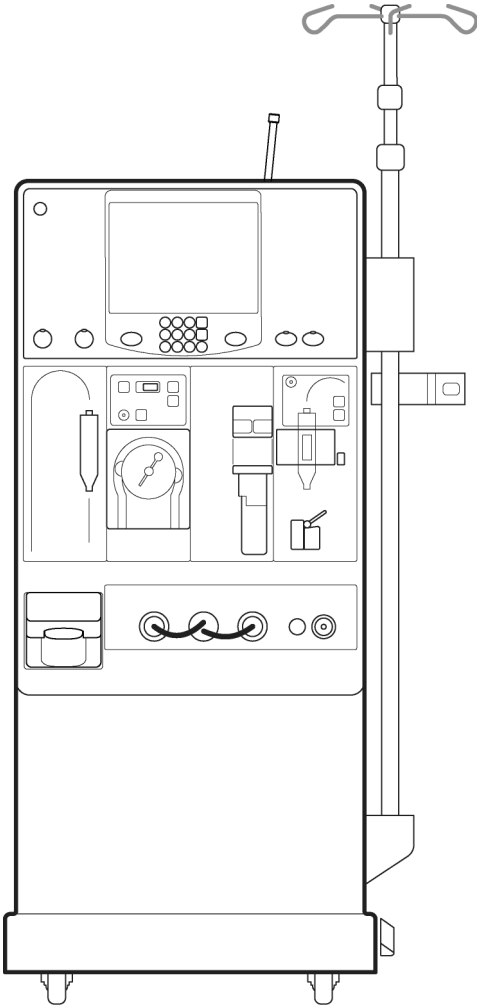
Your 2008K@home hemodialysis machine may be equipped with a 'Traffic Light' beacon to indicate alarm or treatment conditions at the top of the IV pole. You may select from the following options:

- **Alarm** – The red light acts the same as audible alarms. The yellow light shines during warnings. The green light shines when there are no alarms or warnings.
- **FDS08** – The red light acts the same as the audible alarm. The yellow light shines when your machine is set outside of established dialysis FDS08 order limits. The green light shines when the set amount of blood has been processed as required by the FDS08 dialysis order.
- **Status** – The traffic light acts the same as the Red/Yellow/Green Status Box conditions.

Other Options

There are other options in Service Mode that may not be specifically described here. Generally, these are setup options that are based on whether or not certain hardware exists.

Appendix B



Home Evaluation Checklist

This is an example of a checklist your clinic may use to see if your home is a good place for hemodialysis. This checklist lists the following key items:

Note: A qualified person from your clinic must fill out this or a similar form. He or she should come to your home in person to check it over.

Type of Home	Sewage System
<input type="checkbox"/> House <input type="checkbox"/> Apartment <input type="checkbox"/> Mobile Home <input type="checkbox"/> Nursing Home <input type="checkbox"/> Retirement Home <input type="checkbox"/> Other: _____	<input type="checkbox"/> City <input type="checkbox"/> Septic <input type="checkbox"/> Leach Bed <input type="checkbox"/> Trash Service <input type="checkbox"/> Other: _____ <input type="checkbox"/> # of bathrooms: _____ <input type="checkbox"/> Bathroom _____ ft. to bed <input type="checkbox"/> Condition of shower head
Community Environment	Electrical
<input type="checkbox"/> # of occupants: _____ <input type="checkbox"/> Room shared w/ another occupant <input type="checkbox"/> Urban <input type="checkbox"/> Rural <input type="checkbox"/> Local Hospital: <hr/> <input type="checkbox"/> Approximate miles from home to hospital: _____ <input type="checkbox"/> Approximate miles from home to unit: _____	<input type="checkbox"/> 3-Prong outlets (single phase, three-conductor type receptacle and a ground fault interrupter at 120 Volts, 15 Amps, 60 Hz) <input type="checkbox"/> Outlet near bed
Water System	Cooling
<input type="checkbox"/> City <input type="checkbox"/> Well <input type="checkbox"/> Spring <input type="checkbox"/> Water temperature: 10 - 25°C <input type="checkbox"/> Water pressure: 20 -105 psi	<input type="checkbox"/> A/C: Central/Window Units <input type="checkbox"/> Fans: Type _____ <input type="checkbox"/> Duct System: Ceiling/Floor <input type="checkbox"/> Other: _____
	Heating
	<input type="checkbox"/> Electrical <input type="checkbox"/> Gas <input type="checkbox"/> Solar <input type="checkbox"/> Wood stove <input type="checkbox"/> Other: _____

Storage

- Indoor
- Outdoor
- Enclosed w/floor
- Area heated/cooled
- Adequate space
- Supplies grouped together

Conveniences

- Heating pad
- Supplies _____ ft. from work area
- Weight Scales in working order
- Refrigerator for storing Epogen

General Repair of Home

- Plumbing in working order (especially sinks)
- Floor tacked down
- Adequate lighting
- General cleanliness
- Number of pets inside the house _____
- Room inaccessible to pets and children
- Insects/pests absent
- Window screens present
- Doors to rooms able to close
- Type of flooring adequate

Exchange Procedure

- Exchange or treatment observed in home
- Liquid soap available
- Paper towels available
- Appropriate work surface available
- Primary caregiver or backup identified:

- Miles caregiver lives from patient: _____

Safety

- Smoke alarms present
- Fire extinguishers present
- Phone service hooked up
- Long distance service
- 911 available

Comments



Note: This table is for example only. The actual table, filled out by a qualified person from your clinic, should be included in the report to the clinical director.

Machine Specifications

Dimensions

Floor space	Approximately 54 cm wide by 63 cm deep
Height	119 cm
Total weight	Approximately 73 kg
Operating Conditions	15.5 – 38°C (60-100°F)
Storage Conditions	Room temp, 6 months. Do not freeze

Electrical

Power Supply—Main	Single phase AC 117 V \pm 10% 60 Hz \pm 3 Hz must be connected to a circuit which is equipped with a hospital grade receptacle and is protected by circuit breaker and ground fault interrupter (GFI). Resistance from chassis to ground must be < 0.2 ohm.
Power Consumption	Does not exceed 12.5 amps
Fuses	6.3 amp medium blow fuse, 2 each 16 amp double pole rocker switch circuit breaker for heater
External Connections	Spare 1,2: WetAlert antenna connectors Spare 3: Unused Spare 4: External alarm light or traffic light beacon Isolated RS232 port: Leakage current isolation per UL 60601-1 between your machine and external computer
Heat Dissipation to Room	600 to 700 BTU/hr
Electro-magnetic Compatibility	See the Manufacturer's EMC Declaration on page 331

Electrical safety (UL 60601-1)

Protection Against Electric Shock	Type: Safety class I Degree: Type B Type CF: Only BPM Blood Pressure Cuff
Leakage Currents	According to UL 60601-1

Water

Back Flow Prevention	Integral back flow prevention provided by external vent to atmosphere in water inlet circuit.
Water Pressure	Min 20 psi; Max 105 psi
Water Temp.	Min 10°C; max 25°C

Water Quality	<p>Current national (U.S.) Standards for the Quality of Water:</p> <ul style="list-style-type: none"> • ANSI/AAMI 13959:2014, Water for hemodialysis and related therapies • ANSI/AAMI 26722:2014, Water treatment equipment for hemodialysis applications and related therapies <p>Other related standards include:</p> <ul style="list-style-type: none"> • ANSI/AAMI RD62:2006, Water treatment equipment for hemodialysis applications and related therapies
Drain	<p>3 feet max. height. Must meet local codes and must maintain a free fall air gap between drain hose and building drain.</p> <p>10 feet (approximate) maximum drain hose length</p>
Rinsing	<p>Temperature 37°C. Flow rate 620 ml/min. Time between 10 and 60 minutes (internally selectable)</p>

Dialysate

Dialysate Quality	<p>Current national (U.S.) Standards for the Quality of Dialysis Fluid:</p> <ul style="list-style-type: none"> • ANSI/AAMI 11663:2014, Quality of dialysis fluid for hemodialysis and related therapies • ANSI/AAMI 23500:2014, Guidance for the preparation and quality management of fluids for hemodialysis and related therapies
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Other related standards include:

- ANSI/AAMI RD52:2004, Dialysate for hemodialysis

Dialysate Flow Adjustment Range and Accuracy	<p>Accuracy: $\pm 5\%$</p> <p>0/100/200/300/400/500/600/700/800 ml/ min., selectable in the dialysis “Home” screen; additionally: “2x” auto-dialysate flow rate adjusts itself automatically based on your Blood Pump rate (Qb):</p>
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Qb w/2x selected	Dialysate flow rate
< 266	500
266 – 315	600
316 – 365	700
366 and above	800

Note: all flow rates are approximate

Partial Dialysate Collection	<p>From Drain line, intermittent collection using a 3 Liter PD drain bag as a collection device with a Safe-Lock connector (optional).</p>
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Concentrate Supply

Concentrate Quality	<p>Current national (U.S.) Standards for the Quality of Concentrates: ANSI/AAMI 13958:2014, Concentrates for hemodialysis and related therapies</p>
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Concentrate Pressure	<p>Max suction height: 3 feet</p> <p>Max supplied pressure: 2 psi</p> <p>Note: Max supplied pressure is 10 psi with the bibag kit installed.</p>
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Proportional Mixing System

Acid	Volumetric, selectable: 1:34 1:44 1:35.83 1:35.1
Acetate	1:34
Adjustment Range	130 to 155 mEq/L Na ⁺
Bicarbonate	Volumetric, selected with associated acid ratio: 1:27.46, 1:19.13, 1:25.16, 1:27.6
Adjustment Range	20 to 40 mEq/L Bicarbonate
Monitoring Conductivity	Average Accuracy: $\pm 1.5\%$ Method: Temperature compensated electronic conductivity meter with adjustable alarm limits. Temperature compensated conductivity display with automatically set alarm windows ± 0.5 mS/cm around expected conductivity*. User can adjust an additional ± 0.5 mS/cm within this range.
Optional bibag Dry Bicarbonate	Temperature compensated conductivity display with automatically set alarm windows ± 0.5 mS/cm around calculated conductivity*, limited to ± 0.4 mS/cm @ 24 mEq/L bicarbonate or less. With alarm window set at ± 0.5 mS/cm: User can move alarm window up or down an additional ± 0.2 mS/cm @ 40 mEq/L ± 0.1 mS/cm @ 35 mEq/L no adjustment at 29 mEq/L *Conductivity is based on the concentrates' compositional data displayed in the "Rx Parameter" screen at the standard temperature of 25°C.
Range of Display	10.0 to 17.0 mS/cm. At 25°C. Alarm limits will not go below 12.5 or above 16.0 mS/cm.
Dialysate Heating Nominal Value of Temperature	35 to 39°C Accuracy: $\pm 0.3^\circ\text{C}$ (measuring accuracy under calibration conditions for a dialysate flow of 500 ml/min) (selectable in 0.1°C steps)
Temperature Display	Range 35 to 39°C with alarm limit window automatically adjusted to 2°C above and below set point. Alarm window will not go below 30°C or above 41°C. Heater 1.3 kW, electronically controlled.

Heat Disinfection

Temperature	83 ±8°C at NTC 3
Flow Rate	600 ml/min. Pre-rinse either 7 min. @ 600 ml/min or 20 min. @ 300 ml/min (user selectable)
Time	Between 10 and 60 minutes (internally selectable)

Chemical Disinfection

Temperature	37°C (set point applicable)
Flow Rate	620 ml/min
Time	Between 10 and 60 minutes (internally selectable)

Blood Pump

Display of flow rate	8 mm bloodline: 20 – 600 ml/min 6.35 mm bloodline: 20 – 465 ml/min 4.8 mm bloodline: 10 – 274 ml/min 2.6 mm bloodline: 6 – 86 ml/min Accuracy: ±10% tested at -250 mmHg
Internal diameter of pump segment	2.6 to 10 mm (0.1" to 0.4") – listed on package
Tube length	32 cm minimum (12 5/8")
Min. pump segment wall thickness	1.26 mm
Durometer	80 shore A nominal
Level adjust	Up only
Power outage use	The pump can be manually operated with a hand crank.

Heparin Pump

Type of Syringe	10, 12, or 20 ml disposable syringe
Administration Rate	0 to 9.9 ml/hr
Accuracy	±5%
Monitoring	Monitoring end of stroke
Bolus	From 0.1 to 9.9 ml volume

Monitoring Elements: Blood Circuit

Arterial Pressure Monitor	-300 to +500 mmHg with 3 automatically set time-delayed alarm window limit values: ±60, ±80, and ±100 mmHg of actual pressure.
Venous Pressure Monitor	-80 to +500 mmHg with 3 fixed window limit values of ±60, ±80, and ±100 mmHg of actual pressure. There is also an asymmetric range initially set to ±80 mmHg that increases the lower limit after 60 seconds.

Arterial and Venous Pressure Accuracy	± 20 mmHg or $\pm 10\%$ of indicated reading, whichever is greater
TMP Monitor	+60 to -520 mmHg with automatically set time delayed window limit values of ± 60 (conventional dialysis) and ± 40 mmHg (high flux dialysis). Compensation for upward drift.
Level detector	Ultrasonic impulses detect fluid level in the drip chamber.
Optical Sensor	Optical sensor used to detect opaque/ non-opaque presence in the blood tubing.
Clamp	Closes with any blood alarm
Level Adjust	Allows the level in the drip chamber to rise to maintain the desired fluid level in the drip chamber
Blood Leak Detector	Two color light source transmitter / sensor with a resolution of: minor ≥ 0.35 ml/min of blood (hematocrit = 25%) alarm ≥ 0.45 ml/min of blood (hematocrit = 25%)

Ultrafiltration Control

UF Pump Volume Accuracy	$\pm 1\%$ (for $P_{di} > -500$ mbar) where P_{di} = dialysate pressure on the inlet side of the dialyzer
Fluid Removal Rate from Patient	0 – 4000 ml/hr Dialysate flow rate at 100 ml/min: Accuracy (on total volume removed): $\pm(1\%$ UF rate + 18 ml/hr) Dialysate flow rate at 500 ml/min: Accuracy (on total volume removed): $\pm(1\%$ UF rate + 30 ml/hr) Dialysate flow rate at 800 ml/min: Accuracy (on total volume removed): $\pm(1\%$ UF rate + 48 ml/hr)
Adjustment Range of UF Rate	Volumetric Control, 0-4000 ml/hr 1000, 2000, 3000, and 4000 ml/hr. internally maximum rate. Adjusted in 10 ml increments.
UF Goal	Digital Display (0 to 9,990 ml). Selectable in increments of 10 ml
Tx Time	0-9:59 hours auto transfer from UF time, counting down in 1-minute increments. Can adjust manually.
UF Removed Display	Digital display max 9,999 ml counting in 1 ml increments.
Additional Monitoring	Alarm in case of power failure Alarm in case of water shortage

Functional Options

UF and SVS Profiles	In-Center Use Only: Ultrafiltration and Sodium Variation System profiles can be used to vary the rate of ultrafiltration (UF) and the amount of sodium used during treatment. These buttons appear in place of the Dim button on the "Home" screen.
bi <i>bag</i> System	A hardware option to generate dialysate solution online from a dry bicarbonate powder. The bicarbonate powder is contained in a disposable bag called the <i>bi</i> bag disposable which connects to the 2008K@home machine through the <i>bi</i> bag connector.
WetAlert wireless wetness detector	A disposable device that can sense blood leaks when placed at the venous access site. The WetAlert device is for use with the WetAlert device kit (P/N 190442) and requires additional hardware for the 2008K@home machine. Without this kit installed, the machine cannot receive wireless signals from the WetAlert device.

RF Technology Specification

Parameter

Radio Frequency (RF)	433.92Mhz
Power	30 microwatts
Effective Range	Up to six feet
Modulation	Amplitude Shift Keying (ASK)
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 machine monitors for radio signal interference. If the 2008K@Home 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 page 331

User Interface

Language The operating screens may be set to English (USA), Spanish (Mexico), and French (Canada)

Blood Pressure Module

Technique Measures systolic, diastolic pressures, and heart rate (pulse rate) using oscillometric method. MAP measured.

Cuff Deflation Interactive computer controlled. Determination for patients >25 kg requires approximately 25-30 seconds depending on starting point, heart rate and motion artifact.

Cuff Inflation Typically 5-10 seconds from 0-250 mmHg.

Interval Settings Interval times: 5-60 minutes in increments of 5 minutes
Clock Time: 5, 10, 15, 20, 30, 60 minutes

Performance Limits

	<25 kg	≥25 kg
Cuff Pressure Range	5-220 mmHg	10-325 mmHg
Initial Cuff Inflation	125 mmHg or adjusted by host	180 mmHg or adjusted by host
Systolic Determination Range	30-200 mmHg	60-260 mmHg
MAP Determination Range	25-140 mmHg	35-220 mmHg
Diastolic Determination Range	10-180 mmHg	30-200 mmHg
Pulse Rate Determination Range	40-240 BPM	40-180 BPM
Cuff Inflation Rate	5 seconds	5 seconds
Determination Time Normal	Approx. 20 seconds	25-30 seconds
Overpressure Cut Off	220 mmHg	325 mmHg
Transducer Drift	Auto Zeroing	Auto Zeroing
Leakage Rate (Max)	3 mmHg in 3 minutes	3 mmHg in 3 minutes
Pressure Rate Offset	Auto Zeroing	Auto Zeroing

Alarm Preset Values

Internal alarm values preset to provide alarm limits in the event individual values are not entered

	<25 kg	≥25 kg
Systolic	160/80	200/80
MAP	120/70	120/70
Diastolic	100/50	110/50
Pulse	120/50	120/50
Inflation Pressure	Auto	Auto

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.

⁽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
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	<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>
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	<p>$1.2 \sqrt{P}$ 80 MHz to 800 MHz</p> <p>$2.3 \sqrt{P}$ 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 High Frequency Surgical Equipment (such as electrocautery) or other intentional radio frequency emitting equipment typically 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.

Federal Communication Commission Interference Statement

This equipment has been tested and found to comply with Part 15 of the Federal Communication Commission (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 Medical Care could void the user's authority to operate the equipment.

See the Manufacturer's Electromagnetic Compatibility (EMC) declaration on page 331 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 the machine will not alarm.

The 2008K@home hemodialysis machine monitors for radio signal interference. If the 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, See the Manufacturer's Electromagnetic Compatibility (EMC) declaration on page 331 for more information.

Product Improvement Policy

Your 2008K@home hemodialysis machine was designed and built to comply with these product specifications. It is the intention of Fresenius Medical Care to continuously improve products, a process that may result in modifications to specifications or equipment produced in the future. Such product improvements shall not incur any obligation to make similar changes or improvements to equipment previously produced. These changes or improvements may or may not be applicable or usable with previously produced equipment. Where possible, improvements will be made available at reasonable prices. Any such improvement shall not be construed as corrections of any perceived deficiency.

Warranty

SALE of the machine or parts described or referenced herein is expressly conditioned upon the terms and conditions set forth below. Any additional or different terms or conditions set forth by the Purchaser to Fresenius Medical Care North America, (herein called "the Company") shall not be effective or binding, and the terms set forth herein shall not be modified or amended, unless assented to in writing by an authorized official of the Company located in Waltham, Massachusetts.

LIMITED WARRANTY: The Company warrants to the Purchaser that the equipment delivered is free from defects in material or workmanship for the periods specified below, provided the equipment is used and maintained in accordance with the original manufacturer's operating instructions:

A. Mainframe chassis, and electronic components, lamps, etc. shall be warranted for one hundred and eighty (180) days from the date of installation or 2,000 metered hours, whichever occurs first.

B. Consumables are not covered under warranty. Consumables are those parts used in the performance of Preventive Maintenance procedure as described in the Preventive Maintenance Procedures booklet. This includes routine calibrations, electronic and hydraulic, as outlined in the Preventive Maintenance checklist.

The Company will repair or replace, at its option, using new or reconditioned parts and/or assemblies, any parts subject to this warranty, which are proven defective in materials or workmanship. Such repair and replacement will be made without cost to the Purchaser and the Company reserves the right to determine the location at which the repair or replacement will be accomplished. The Warranty does not apply to any equipment which is misused, abused, neglected, tampered with, damaged by accident, flood, fire, or other hazard, subjected to abnormal or unusual electrical or fluid stress, improperly installed or operated, or not maintained in accordance with the routine maintenance schedule set forth in the operating manual for the equipment. **Routine maintenance is not covered under warranty.** Modifications, alterations, installation, and service by other than a FRESINIUS MEDICAL CARE authorized representative may void the warranty.

WARRANTIES APPLICABLE TO EQUIPMENT EXTEND ONLY TO THE PURCHASER, AND ARE NOT ASSIGNABLE OR TRANSFERABLE, AND SHALL NOT APPLY TO AUXILIARY EQUIPMENT, DISPOSABLE ACCESSORIES, OR LIGHT SOURCES. THE FOREGOING WARRANTY SHALL BE IN LIEU OF ANY OTHER WARRANTIES, EXPRESSED IMPLIED OR STATUTORY, RESPECTING THE EQUIPMENT OR ANY PARTS OR COMPONENTS THEREOF, AND THE COMPANY MAKES NO IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. THE PURCHASER'S SOLE AND EXCLUSIVE REMEDY IN CONTRACT, TORT, OR UNDER ANY OTHER THEORY AGAINST THE COMPANY RESPECTING THE EQUIPMENT AND ITS USE SHALL BE THE REPLACEMENT OR REPAIR OF THE EQUIPMENT AND ITS PARTS AS DESCRIBED ABOVE, AND NO OTHER REMEDY (INCLUDING, WITHOUT LIMITATION, CONSEQUENTIAL DAMAGES) SHALL BE AVAILABLE TO THE PURCHASER. The Company

shall have no further obligation or liability with respect to the equipment or its sale, operation and use, and the Company neither assumes, nor authorizes the assumption of, any obligation or liability in connection with such equipment.

For additional servicing and information contact:

Fresenius Medical Care (800) 227-2572

Attention: Service Department
4040 Nelson Avenue
Concord, CA 94520
www.FMCNA.com

Manufactured by

Fresenius USA, Inc. (800) 227-2572

4040 Nelson Avenue
Concord, CA 94520

Glossary

Access—A means to connect to the bloodstream for hemodialysis. Hemodialysis accesses include arteriovenous fistula (AVF), arteriovenous graft (AVG), and central venous catheters.

Alarm Window—The allowable range without activating alarms for the arterial, venous, and transmembrane pressures, and the dialysate temperature and conductivity during treatment. Movement of levels outside the window will trigger an alarm after a short delay. The conductivity alarm window is graphically represented in the “Conductivity” screen (by selecting the **Conductivity** button on the dialysis “Home” screen). It is the area located between the upper and lower alarm limits of the conductivity bar graph. The alarm window can be widened or narrowed, or shifted up or down within the hard limits. The temperature alarm window is $\pm 2^{\circ}\text{C}$ of the set temperature value within the temperature hard limits (30°C to 41°C). The arterial and venous limit window width is also selectable. The position of the window is set automatically.

Aseptic Technique—Ask your clinic for an in-depth explanation of this medical technique.

Back Filtration—The movement of dialysate across the dialyzer membrane and into the patient’s blood. It can be caused by a change in pressure or concentration gradient between the dialysate and the blood.

Balancing Chamber—The hydraulic chambers inside your machine that control the volume of dialysate. The chambers make sure that the amount of fresh dialysate entering the dialysate flow is equal to the amount of used dialysate being drained.

Base Na^{+} —The prescribed sodium level for the dialysate. The default Na^{+} value is carried over from the value displayed in the Na^{+} parameter-button in the “Rx Parameter” screen.

Biofilm—Biological residue from treatment that collects in machine drain lines.

Blood circuit—The blood tubing set (arterial and venous) also including the dialyzer.

Blood Sensed—The venous line runs through an Optical Detector above the Venous Clamp. When the clear bloodline tubing is opaque, your machine uses this “Blood Sensed” information for a number of alarm, informational messages, or warnings.

Bolus—A relatively large, single dose.

Button—Certain identified sites on the Touch Screen that, when touched, will cause a specific action by the software.

Bypass Mode—Bypass mode occurs when the dialysate conductivity or temperature goes outside alarm limits. In bypass mode, valves inside your machine redirect the flow of dialysate to bypass the dialyzer internally until temperature and conductivity are back within acceptable limits.

Clearance—The rate at which waste products in the blood are removed by dialysis.

Conc.—Abbreviation for “concentrate.”

Dialogue Box—Text box in the top right corner of the screen that shows patient information and instructs the operator for certain actions.

Dialysate—Solution used to clear waste from your bloodstream through the dialyzer. It consists of the acid and bicarbonate concentrates mixed together with purified water.

Dialysate Lines—Lines that deliver the fresh dialysate to the dialyzer and return the used dialysate to the drain. The dialysate lines are built into your machine and are located on the

right side, coming from the shunt interlock.

Dialyzer—The device used to filter and diffuse waste from your bloodstream using semi-permeable membranes.

Diasafe Plus—A filter for your dialysis machine that filters the dialysate further, removing even the smallest bacteria, to deliver ultra pure dialysate.

Diastolic Pressure—The lower blood pressure number of the two, it describes the blood’s pressure just before the next heartbeat.

Electrolytes—Ions (like sodium and chloride, for example) in the bloodstream that help cells transfer signals. Healthy kidneys maintain constant, healthy levels despite changes in exercise and diet.

Fill Program—Occurs when the water level in the air separation chamber of the hydraulic system gets too low. To remove excessive air from the hydraulic system, your machine will normally go into a “Fill” program when the dialysate lines are first connected to the dialyzer, and the air within the dialyzer is being evacuated. If the “Fill” program runs repeatedly during operation it could mean a dialysate leak. Call a qualified service technician if this problem occurs.

Flow Indicator—A clear tube in the dialyzer supply line that

allows the operator to monitor dialysate flow. When dialysate flow is on, a small float inside the cylinder moves up and down in rhythm to the dialysate pump. When flow is off, the float sinks to the bottom of the cylinder.

Flushing the Lines—The act of emptying the blood circuit of the recirculated saline solution and replacing it with fresh saline solution. This step is done after recirculation of the saline and before connecting for treatment.

GFI (Ground Fault Interrupter)—Device on special electrical outlets that protects against electrocution by interrupting current. The outlet faceplate has a “Test” and a “Reset” button.

Gravity Flush—Flushing the patient end of the bloodline using gravity.

Hard Limits—Unchangeable limits written in the software that define the maximum and minimum alarm window values for the arterial, venous, and transmembrane pressures, and the dialysate temperature and conductivity. Hard limits are not shown to the user.

Hemodialysis—The procedure carried out by your machine that separates the waste products and excess water artificially from your blood by diffusion and ultrafiltration.

Hemolysis—The premature breakdown of red blood cells.

Ask your clinic for more information on detecting.

Heparin—A chemical naturally found in the liver that prevents blood from clotting.

Keys—Located on the Control Panel and on various modules, keys are used to enter values, make and confirm selections on the Touch Screen, and activate certain machine functions.

Kilogram—Measure of weight, 2.2 lbs. = 1 kg (kilogram).

KUF—An ultrafiltration coefficient that describes how permeable a dialyzer is to water. It is a direct function of surface area and is defined as the number of millimeters of fluid per hour that are transferred across the membrane per mmHg TMP. A dialyzer’s KUF is included with its instructions.

Long Power Down—Turning off your machine for longer than two minutes. Certain information stored in machine memory is lost after two minutes and some treatment parameters are reset to their default settings. Power failures are not the same as long power downs, where treatment information is saved. See also *Short Power Down* and *Power Failure Recovery*.

MAP (Mean Arterial Pressure)—The average pressure your blood vessels experience as your heart beats.

Meter Box—Box that displays screen-specific information like timers and dates.

Optical Detector—Located on the Level Detector module, the Optical Detector can sense whether or not the venous line is filled with blood. See also *Blood Sensed*.

Parameter-Button—A button on the Touch Screen that displays the changeable value it controls through software.

Positive Pressure—Condition that exists when air pressure inside the dialysate lines is greater than outside of the lines. If an opening occurs, air or fluid will flow out of the system.

Power Failure Recovery—When power to your machine is lost, many dialysis parameters are automatically stored. They are recovered when the power is restored to your machine.

Pressure Holding Test (PHT)—Pressure Holding Tests test the integrity of the hydraulic system, which is necessary for accurate fluid balance and UF control. There are two types of pressure holding tests: One is an extensive PHT is activated from the “Test” or “Help” screens. The other is an Online Pressure Holding Test that is run automatically every 12 minutes during treatment. It lasts about seven seconds, depending on the dialysate flow rate (two cycles of the balancing chamber).

Pressure Port—A tubing outlet on both the Blood Pump and Level Detector modules that connects to a pressure transducer and to the drip chambers. Pressure ports allow monitoring of the bloodline pressure.

Puristeril 340—A chemical used to clean and disinfect the hydraulic system.

Recirc (Recirculation) Connector—A special bloodline piece used to link together the arterial and venous bloodlines during recirculation.

Reverse Osmosis (RO)—A method for purifying water by forcing it through a semi-permeable membrane that prevents the passage of ions.

RO—Abbreviation for “Reverse Osmosis.”

Rx—Abbreviation for “Prescription.”

Screen-Button—Any of the buttons located in the row along the bottom of the Touch Screen. Screen-buttons are also on the left side of the “Rx Parameter” screen. Touching one of these buttons will display its screen.

Service Mode—A functional state of your machine that allows technicians to calibrate your machine or program various software features and options not accessible in Dialysis Mode.

Short Power Down—Turning off the power with the Control Panel Power key for less than

two minutes. Certain information stored in memory is only held for up to two minutes—after that, it is erased. See also *Long Power Down* and *Power Failure Recovery*.

Shunt Interlock—Located on the right side of your machine, it is the device that connects the dialysate lines when they are not in use. Audible alarms may be silenced when the dialysate supply lines are on the shunt (unless the Optical Detector senses blood).

Status Box—Top left area of the Display Screen that shows your machine’s operational mode. The Status Box also shows the operator any warnings or alarms.

Systolic Pressure—The higher blood pressure number of the two, it is the blood’s pressure during a heartbeat.

Theoretical Conductivity (TCD)—The approximate conductivity of the dialysate based upon the concentrate type, and sodium and bicarbonate values entered in the dialysis “Home” screen. TCD is measured in milliSiemens per centimeter (mS/cm) and is corrected to 25°C.

TMP (Transmembrane Pressure)—The difference in pressure between the filtrate and permeate sides of the dialyzer membrane. $TMP = \text{Dialysate Pressure} - \text{Venous Pressure}$.

Transducer—An electronic sensor in your machine that reads the pressure inside the arterial and venous drip chambers. Transducers are connected to the drip chambers through pressure monitor lines.

Transducer Protector—A small, disposable, plastic cap containing a hydrophobic paper filter that fits over each pressure port. Inserted between the pressure monitor line and the pressure port connection, it is used to prevent the transducer from becoming wet or contaminated with blood. There are two transducer protectors for each connection: a disposable external TP that is to be replaced with each treatment, and a second, internal TP that comes installed with the module.

Tx—Abbreviation for “treatment.”

Tx Clock—The amount of time remaining until the end of the treatment. The Tx Clock is viewable in the dialysis “Home” screen as a pie chart button.

UF—Abbreviation for “Ultrafiltration.”

Ultrafiltration—Ultrafiltration is the process of drawing off excess fluid from the patient during treatment. Your machine’s hydraulic system is a closed system that uses a separate UF pump for greater measured accuracy.

Urea—Protein waste product.

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