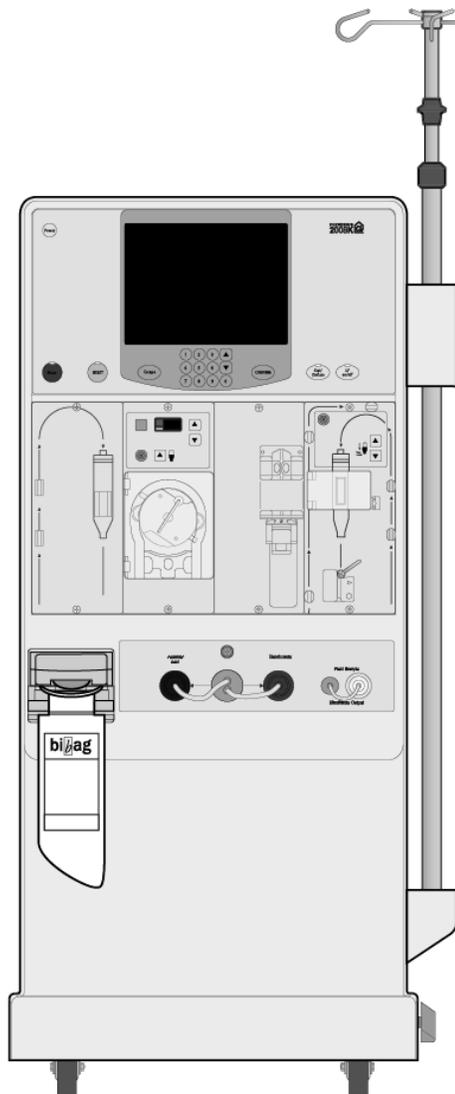




**FRESENIUS
MEDICAL CARE**

bi^obag[®]

2008K@home bi^obag System User's Guide



2008K@home bibag System User's Guide

For software version 4.30 and greater

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Maintenance, calibration and other technical information may be found in the bibag installation kit manual, P/N 490188.

Contact Fresenius Medical Care Technical Support for applicable Field Service Bulletins. The spare parts manual for the 2008K@home hemodialysis machine and other information may be found on our web site at www.fmcna.com

Caution: US Federal 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.

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

bibag Indications for use: the Fresenius Medical Care bibag system is used with Fresenius Medical Care 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.

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Operating Instructions

These instructions are for the *bi*bag hardware option with Functional Board software 4.30 or greater and Actuator/Test Board software 2.16 or greater. The *bi*bag system must only be operated with the 2008K@home hemodialysis machine and according to these instructions and those of the *2008K@home User's Guide* P/N 490180.

For complete instructions on operating the 2008K@home machine, refer to the *2008K@home User's Guide* (P/N 490180).

General Warnings



Warning: The concentrate displayed on the screen must match the labels on the acid container. Make certain there is enough concentrate in the containers to complete the treatment.

Warning: Your doctor must prescribe your entire hemodialysis treatment, including your specific concentrate, sodium, and bicarbonate settings. If you use the wrong values, it may cause serious injury or death. Do not use example values shown in machine pictures.

Warning: Acid concentrate, bicarbonate concentrate, and water must be of the appropriate quality to ensure local regulation regarding safety and performance of the final dialysate is met. Dilute immediately prior to application only. Do not dilute or admix with any other drug solutions.

Warning: Test the conductivity and approximate pH of the final dialysate with an independent device before beginning treatment and when switching from the *bi*bag system to liquid bicarbonate*. Verify that the pH and the conductivity meet the requirements specified in ANSI/AAMI RD52, which are pH within the range of 6.9-7.6 and conductivity within $\pm 5\%$ of the nominal machine value.

*Note: If alternative 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: Replace a leaking bag 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.



Caution: The acid and bicarbonate pressures must not exceed 10 psi when using a Central Delivery System. It may then be necessary to use pressure regulators in order to reach proper conductivity.

Caution: Only the bags manufactured by Fresenius Medical Care North America may be used in the bibag connector.



Note: When the bibag connector is installed, the online pressure holding test becomes mandatory. For more information, see the Online Pressure Holding Test section of the *2008K@home User's Guide*.

Note: The machine will not allow use of 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.

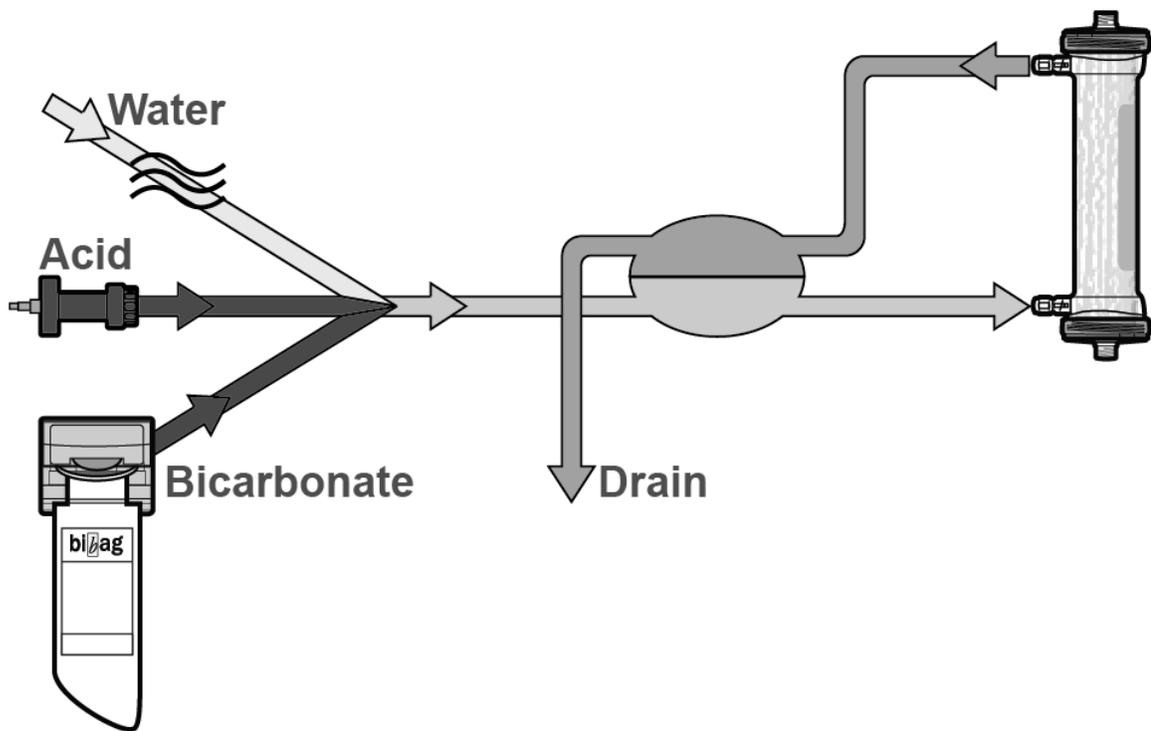
Note: The bibag disposable must hang freely below the bibag connector. Make certain that there are no jugs or other objects obstructing or touching the bibag disposable.

Note: The Diasafe Plus filter is required when the bibag system is in use.

Note: Pressing the **Mute** key will silence an alarm for two minutes. The following alarms are muted for an additional four minutes (for a total of six minutes) upon initiation of dialysis when using the bibag system:

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

The bibag System



Dialysate Path Overview

Your 2008K@home machine is a three-stream hemodialysis machine: acid concentrate, bicarbonate concentrate, and purified water mix together to create dialysate. After your machine heats and degasses the water, it mixes in the concentrates to form 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.

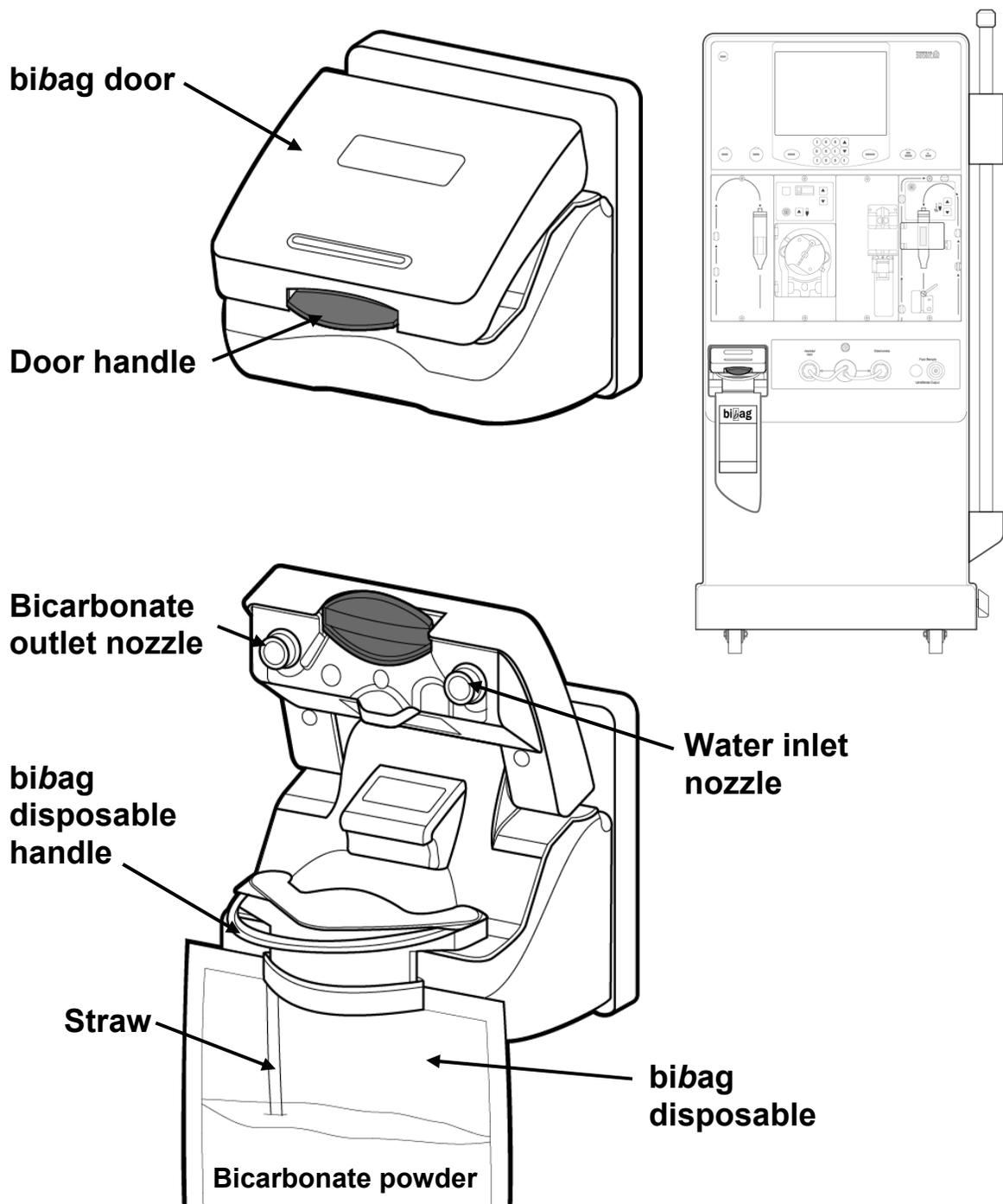
bi*bag* System Overview

The bi*bag* system is a hardware option that allows you to use a dry bicarbonate powder to generate dialysate solution for your 2008K@home hemodialysis machine. The bicarbonate powder is contained in a disposable bag called the bi*bag* disposable which connects to your machine through the bi*bag* connector.



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 32 for estimated run times.

The bibag Connector



bibag Connector

The *bibag* connector is the place where the *bibag* disposable connects to your machine. It connects the bag 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.

Door Handle

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.

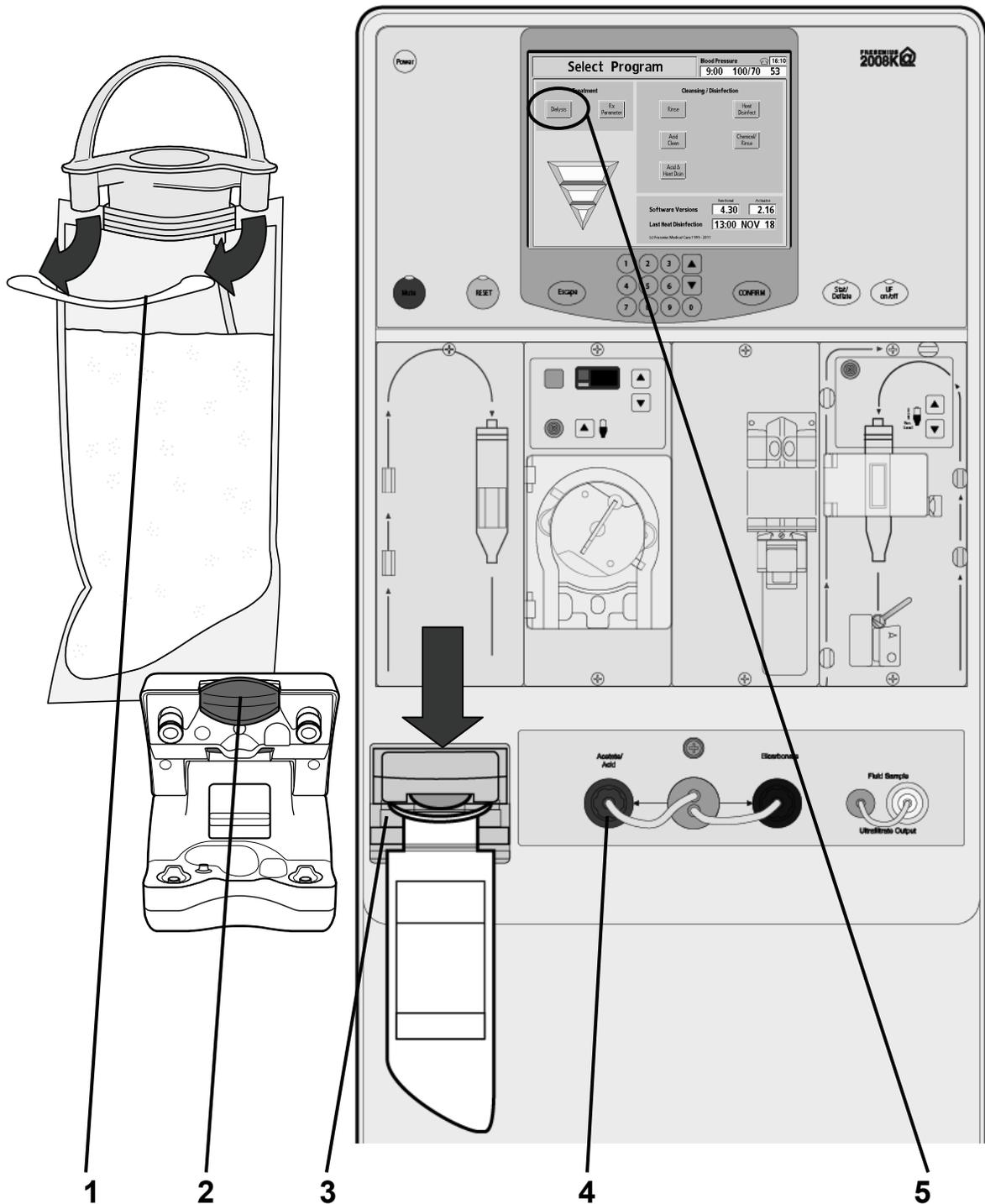
bibag Disposable

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 Bicarbonate Outlet Nozzle and the Water Inlet Nozzle on your machine's *bibag* connector.

The *bibag* disposable's Bicarbonate Outlet Nozzle connects to a straw inside the bag in order to reach the bottom of the bag.

The handle on the bag allows you to easily lift the *bibag* disposable off your machine's *bibag* connector.

Using the bibag for a Dialysis Treatment



Using the *bibag* system for a dialysis treatment

Begin with typical treatment setup (as explained in the *2008K@home User's Guide* P/N 490180), following your clinic's instructions. If the treatment is just beginning, use these instructions before touching the **Dialysis** button on the "Select Program" screen. Follow all warnings listed in the user's guide.



Note: Wait until *bibag* conductivity has stabilized before selecting the **Start Test** button on the "Test" screen.

1 Remove *bibag* disposable's seal

Remove the white plastic seal from underneath the water and bicarbonate nozzles of the *bibag* disposable.

2 Open *bibag* door

Open the *bibag* door on the machine by lifting up on the dark-gray handle.

3 Connect bag and close *bibag* door

With the white *bibag* handle facing outward, hang the bag on the *bibag* connector nozzles. Close the door, making sure it latches firmly in place. An audible click indicates the door is closed.



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

4 Remove red acid concentrate connector

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

5 Touch **Dialysis**

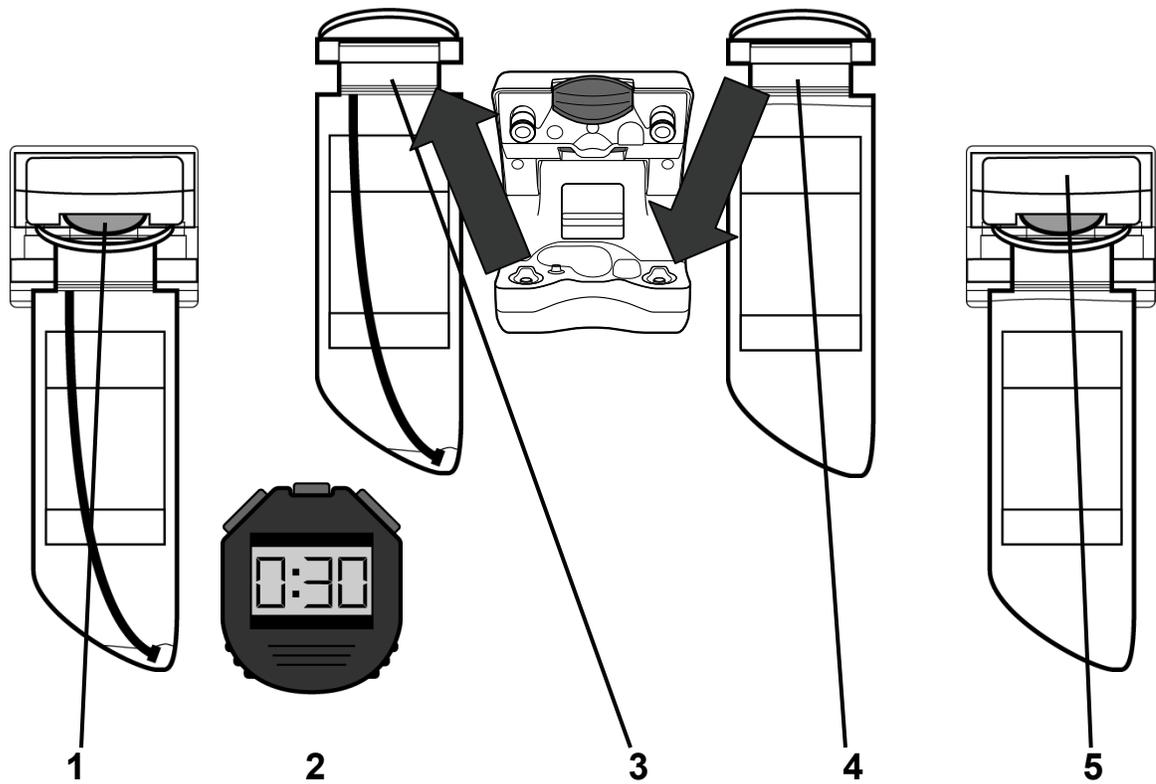
Touch the **Dialysis** screen-button to go to the treatment setup screens. The *bibag* system is now set up. When your machine is ready (water at minimum temperature and no air in the hydraulics), it will fill the *bibag* disposable with heated water and then begin using the bicarbonate concentrate in it for dialysate production. Continue setting up your treatment as directed by your clinic.



Note: Do not pull the blue bicarbonate connector out of your machine's bicarbonate port while using the *bibag* connector for treatment. Doing so will stop the flow to and from the *bibag* disposable.

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

Changing a Bag During Your Treatment



Changing a bag during your treatment

If the *bi*bag disposable needs to be changed during the treatment, use the following steps:



Note: If a bag is changed during treatment, a pause of 6-10 minutes should be expected as the new bag fills. The dialysis machine will automatically go into bypass mode until the new bag is on-line and conductivity comes into the acceptable range.

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

1 Open *bi*bag door

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

2 Wait 30 seconds

Wait 30 seconds to relieve the pressure in the bag.

3 Remove used bag

Lift up the *bi*bag disposable by the handle, remove the used bag, and dispose of it per unit protocol. 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.

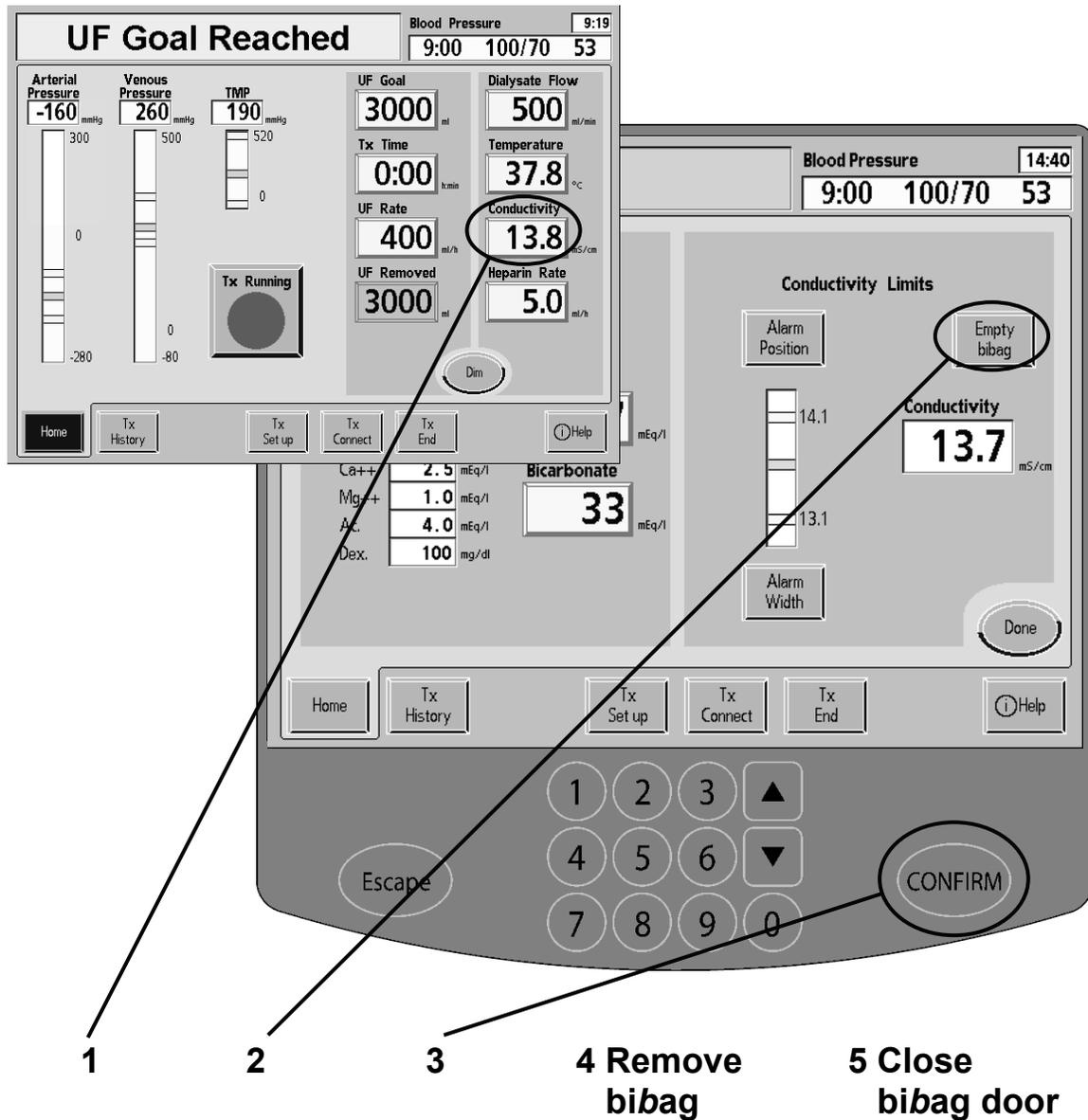
4 Connect new bag

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

5 Close *bi*bag door

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

Emptying the Bag at the End of 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.

Emptying a *bibag*

At the end of your treatment, your *bibag* disposable will still be filled with liquid. 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 at the end of your treatment:



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.

1 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.

2 Touch **Empty *bibag***

3 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.”

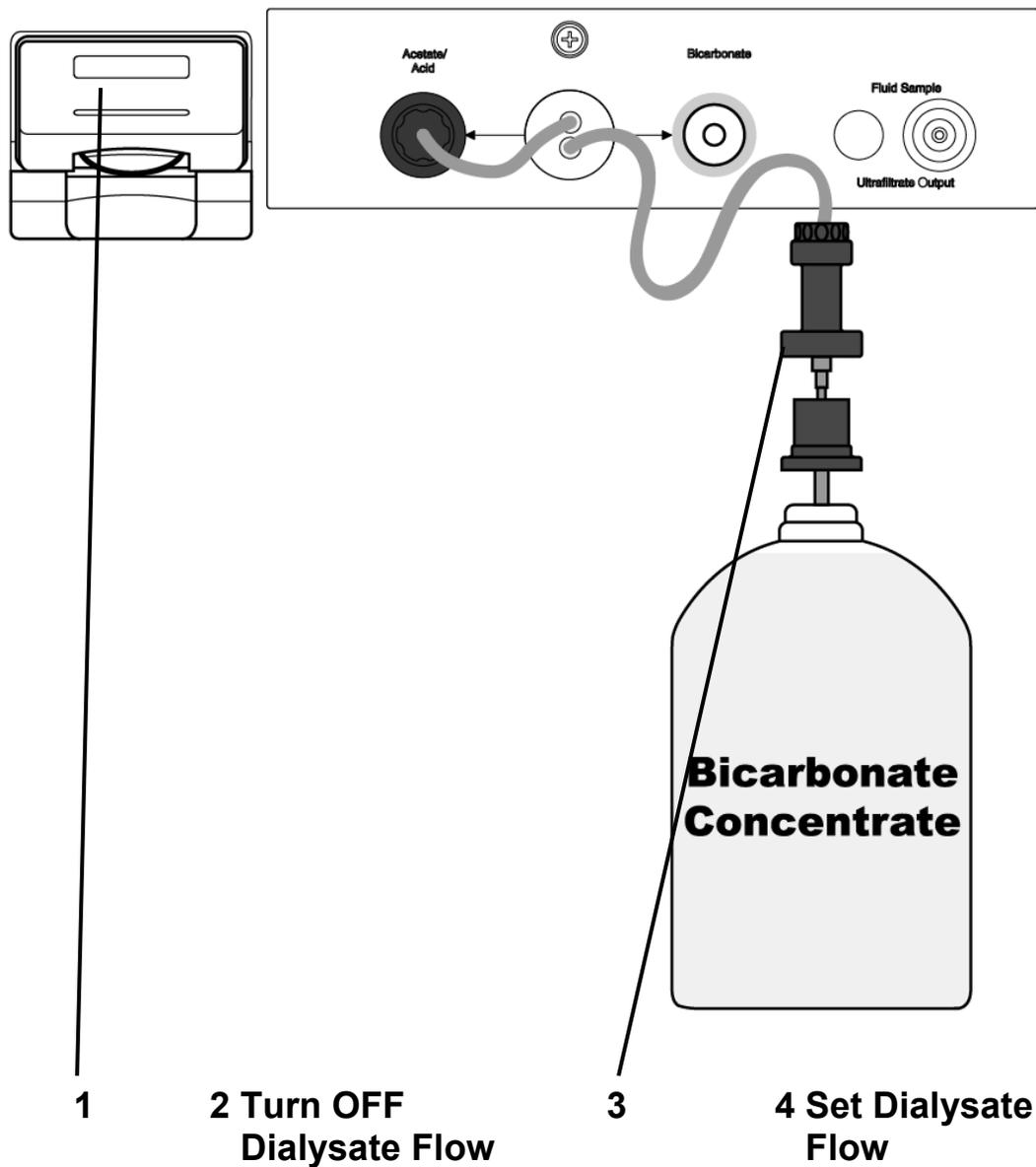
4 Remove bag

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

5 Close *bibag* door

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

Using the Blue Bicarbonate Connector



Using the Blue Bicarbonate Connector

Machines with the *bi*bag system may still be used for liquid bicarbonate-based dialysis when the *bi*bag disposable is not in use. To switch back to liquid bicarbonate-based dialysis:

1 Close *bi*bag door

Make sure that the *bi*bag door is closed without a bag on the *bi*bag connector. If you are closing it at this time, make sure that the door securely latches into place (two clicks should be heard).

2 Turn OFF Dialysate Flow

On the “Home” screen, touch the **Dialysate Flow** button to select it. Use the **Down Arrow (▼)** key on the data entry keypad to set it to OFF and then press the **CONFIRM** key to confirm the change.

3 Connect blue bicarbonate connector

Pull the blue bicarbonate connector from its port and insert it into a central bicarbonate supply or a jug containing sufficient liquid bicarbonate concentrate for an entire treatment.

4 Set Dialysate Flow

On the “Home” screen, touch the **Dialysate Flow** button to select it. Use the **Up Arrow (▲)** key on the data entry keypad to set it back to your prescribed flow rate. Press the **CONFIRM** key to confirm the change.

Your machine will now use the liquid bicarbonate source connected to the blue bicarbonate connector.



Warning: Test the conductivity and approximate pH of the final dialysate before beginning treatment and when switching from the *bi*bag system to liquid bicarbonate*. Verify that the pH and the conductivity meet the requirements specified in ANSI/AAMI RD52, which are pH within the range of 6.9-7.6 and conductivity within $\pm 5\%$ of the nominal machine value.

*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.

Cleaning the *bibag* Connector

The *bibag* connector is connected to the 2008K@home machine's hydraulics so running rinsing or disinfection programs from the "Select Program" screen will also rinse or disinfect the *bibag* system.

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

The exterior of the dialysis machine should be cleaned after every treatment. It can be cleaned with very dilute bleach or other suitable hospital disinfectant. Freshly prepared dilute bleach solution (1:100) is currently recommended by the Center for Disease Control as a suitable disinfectant for the Hepatitis virus. Because surface contamination is the general mode of transmission for this type of virus, thorough cleaning of the 2008K@home exterior is essential.



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.

Warning: A Rinse program must be run after cleaning the sealing area of the *bibag* nozzles on the *bibag* connector to rinse away leftover disinfectant.

Troubleshooting

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

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



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

Note: If you have any questions, please call Fresenius Medical Care Technical Support anytime at **(800) 227-2572**.

Note: There are alarm messages that may be similar. Please take care that you read appropriate message to determine the “Action required” for troubleshooting.

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

- Message Meaning
- Action Required

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

Message	Meaning	Action Required
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.
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.
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.
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.

Message	Meaning	Action Required
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 <i>bibag</i> door and lift the bag off the connector nozzles to vent the air. Hang the bag back on the connector nozzles and close the <i>bibag</i> door to continue.
bibag: Cond Calib Err	Electronic self-test: <i>bibag</i> 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 <i>bibag</i> conductivity has exceeded the high conductivity alarm limit when using the <i>bibag</i> 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.
bibag: Cond Low	The actual or measured <i>bibag</i> conductivity is below the low conductivity alarm limit when using the <i>bibag</i> disposable. The machine is in bypass mode. The bag may also be nearly empty.	Check the <i>bibag</i> 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 <i>bibag</i> door, wait 30 seconds to relieve the pressure, and remove the bag. Place a fresh bag back on the connector and close the door. Wait five minutes for conductivity to stabilize. If conductivity alarm persists: <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 <i>bibag</i> 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. If the appropriate conductivity cannot be reached, connect a new bag. 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. If conductivity alarm still persists, take the machine out of service and call a qualified service technician.

Message	Meaning	Action Required
bibag: Cond Sensor Err	The bibag conductivity sensor is not reading the correct conductivity.	Insert the blue bicarbonate connector into an appropriate liquid bicarbonate source Or To use the bibag 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 bibag door is open. The machine is in bypass mode.	Close the bibag door to continue.
bibag: Emptied	The bibag emptying program has completed. The emptied bag must be removed from the bibag connector.	Open the bibag 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	I2C 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.
bibag: In Bypass	A bibag 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.

Message	Meaning	Action Required
bibag: No Bag	A bag must be on the connector to continue. The machine is in bypass mode.	Place a bag on the bibag connector and close the door to continue.
bibag: No Comm.	The bibag 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 bibag online Pressure Holding Test has failed. The machine is in bypass mode.	<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 bibag door, wait 30 seconds to relieve the pressure, and remove the bag. ○ Place the bag back on the connector and close the door. The bibag online PHT will run again automatically. • If the failure message is repeated on the next test: <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.

Message	Meaning	Action 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.
bibag: Press Too Low	The pressure inside the bibag disposable is below 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
<p>bibag: Select Conc 45x</p>	<p>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.</p> <p>Or</p> <p>The blue bicarbonate connector was not inserted into a liquid bicarbonate source if liquid bicarbonate dialysis is desired.</p>	<p><i>bibag</i> dialysis is compatible only with 45x acid concentrates. Either,</p> <p>Restart the machine and enter Service Mode and select a 45x acid concentrate before beginning dialysis.</p> <p>Or</p> <p>Use liquid bicarbonate for dialysis by inserting the blue bicarbonate connector into an appropriate liquid bicarbonate source.</p>
<p>bibag: Temp Calib Err</p>	<p>Electronic self-test: temperature calibration error.</p>	<p>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.</p>
<p>bibag: Temp Sensor Err</p>	<p>The <i>bibag</i> temperature sensor is not reading the correct temperature.</p>	<p>Insert the blue bicarbonate connector into an appropriate liquid bicarbonate source</p> <p>Or</p> <p>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.</p>
<p>bibag: Val Comm Err</p>	<p>The <i>bibag</i> interface board was unable to communicate with the actuator board.</p>	<p>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.</p>
<p>bibag: Valve 1 Err</p>	<p>Electronic self-test failure.</p>	<p>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.</p>
<p>bibag: Valve 2 Err</p>	<p>Electronic self-test failure.</p>	<p>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.</p>

Message	Meaning	Action Required
bibag: Vent Too Long	The bibag system has been venting longer than ten minutes. The machine is in bypass mode.	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.
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	Bicarbonate conductivity cell is measuring high dialysate bicarbonate conductivity when using the bibag system. The machine is in bypass mode.	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 warning 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.
Bicarb Cond 2 Low	Bicarbonate conductivity cell is measuring low dialysate bicarbonate conductivity when using the bibag system. The machine is in bypass mode.	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 warning 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.
Bicarb: Cond High	The actual or measured sodium bicarbonate conductivity has exceeded the high conductivity alarm limit when using the blue bicarbonate connector for liquid bicarbonate. The machine is in bypass mode.	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.

Message	Meaning	Action Required
Bicarb: Cond Low	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>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>If the 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 alert a qualified service technician.</p>
Bicarb Press Calib Err	Bicarbonate pressure calibration error. The machine is in bypass mode.	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: 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, take the machine out of service and call a qualified service technician.
Bicarb: Vent Too Long	The bibag system has been venting longer than ten minutes when using the blue bicarbonate connector for liquid bicarbonate. The machine is in bypass mode.	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.
Blood Sensed	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.	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.

Message	Meaning	Action Required
Must Calibrate to Run	Electronic self-test failure.	Turn machine power off and back on. If alarm is not cleared, take the machine out of service and alert a qualified service technician.
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.
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 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.
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.

Message	Meaning	Action Required
V104/108 Stuck Closed	Bicarbonate concentrate port valve error or rinse port valve error. The machine is in bypass mode.	<p>Check for a kinked bicarbonate concentrate supply line.</p> <p>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.</p> <p>If the error occurs during a rinse, open the bibag door for at least five seconds (with no bibag attached). Rerun the rinse program.</p> <p>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.</p> <hr/> <p> 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.</p>
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.

Message	Meaning	Action Required
V105 Stuck Closed	The acid concentrate supply line is not pulling in acid concentrate. The machine is in bypass mode.	<p>Check for a kinked acid concentrate supply line.</p> <p>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.</p> <p>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.</p>
		<p> 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.</p>
Valve 104 Err	Bicarbonate concentrate port valve error. The machine is in bypass mode.	<p>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.</p>
Valve 105 Err	Acid concentrate port valve error. The machine is in bypass mode.	<p>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.</p>

Selecting Concentrates in Service Mode

The “45x” concentrate family must be selected in order to use the *bibag* system. When a 45x type concentrate is selected with the *bibag* kit installed, the machine will automatically detect whether or not a *bibag* disposable is connected upon entering Dialysis Mode.



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: In order to easily switch between liquid and *bibag* bicarbonates, liquid bicarbonate options that correspond to the *bibag* 45x concentrates should also be selected.

2008K@home Machine with *bibag* System Specifications

Monitoring	Average Accuracy: $\pm 1.5\%$
Conductivity	Method: Temperature compensated electronic conductivity meter with adjustable alarm limits.

***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 entered in the Dialysate screen at the standard temperature of 25 °C.

Estimated bibag disposable run times (minutes)

The bibag disposable contains a fixed volume of bicarbonate powder. Refer to the tables below to verify that enough run time* (including any set-up time and potential pre-treatment delays) is available to complete your treatment using one bag.

		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)	650g																	
	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	

		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)	900g																	
	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).