

This guide is a supplement to the **bibag System Operator's Instructions** and **bibag Instructions for Use**. Refer to the **bibag System Operator's Instructions** and **bibag Instructions for Use** for a complete description of error messages, hazards, contraindications, side effects and precautions.

Selecting Concentrates in Service Mode

The "45x" concentrate family must be selected in Service Mode 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.

Using the bibag System for a Dialysis Treatment

Note: The blue bicarbonate connector must be inserted into the machine's bicarbonate port during a bibag-based treatment. Make sure the red acid concentrate connector is connected to the acid concentrate.

1. Remove the white plastic seal from underneath the water and bicarbonate nozzles of the bibag disposable (See Figure 1).
2. Open the bibag door on the machine by lifting up on the dark gray handle (See Figure 2).
3. With the white bibag handle facing outward (the blue labeling should be facing you), hang the bag on the bibag connector nozzles (See Figure 3).
4. Close the door, making sure it latches firmly in place. An audible click indicates the door is closed. After the acid concentrate source and the bibag disposable are connected, resume with "Preparing the Dialysate Delivery System" step 4 of the *2008T Hemodialysis Machine Operator's Manual* (P/N 490122) to put the 2008T hemodialysis machine into Dialysis mode. When the machine is ready (water at minimum temperature and no air in the hydraulics), it will fill the bag with heated water to be used as a bicarbonate concentrate for dialysate production.

Note: Dialysate flow must be ON in order to fill the bibag disposable with heated water.

Note: The bibag disposable contains a fixed volume of bicarbonate powder. Refer to Table I to verify that enough run time (including any setup time and potential pre-treatment delays) is available to complete a treatment using one bag.

Note: Do not remove the blue bicarbonate connector from the machine's bicarbonate port while using the bibag system for treatment. Doing so will stop the flow to and from the bibag disposable.

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.



Figure 1 Remove white plastic seal from bibag disposable



Figure 2 Open the bibag door



Figure 3 Hang bag on the bibag connector nozzles

Changing the bibag Disposable During Treatment

If the bibag disposable needs to be changed during treatment, use the following directions:

1. Lift up on the dark-gray bibag door handle to open the bibag door.
2. Wait 30 seconds to relieve the pressure in the bag.
3. Lift up the bibag 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.
4. For the new bibag disposable, remove the white plastic seal from underneath the water and bicarbonate nozzles. Hang the bag on the machine's bibag connector nozzles.
5. Close the bibag connector door, making sure that the door latches firmly in place. An audible click indicates the door is closed. The treatment will resume after the machine fills the bag with heated water.

Note: When changing the bibag disposable during treatment, the automated empty feature cannot be used so the bag will need to be emptied manually.

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

Table 1: 650 g and 900 g bibag Disposable Estimated Run Time (Minutes)*

650 g		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

900 g		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).

Emptying the bibag Disposable at the End of Treatment

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

Note: The bibag disposable may also be emptied manually.

At the end of the treatment, a blue **Empty bibag** button is displayed in the upper right corner of the “Dialysate” screen (see Figure 4) to empty the bag for easy disposal.

1. Select 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 the machine drain line.

Note: The bibag disposable and the dialyzer cannot be emptied at the same time. To run the Empty bibag program, both dialysate lines must either be on the shunt or on the dialyzer.

2. When the bibag disposable is empty of fluid, the Status Box will display the message “bibag: Emptied.”
3. Lift up on the dark-gray bibag door handle to open the bibag door. Remove the bag and dispose of it per unit protocol.
4. Close the bibag connector door securely, making sure that the door latches into place (two clicks should be heard).

General Tips:

- Before installing a bibag disposable on the machine, ensure the filter is attached to the wand inside the bag.
- 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 with a fresh bag.
- If a “bibag: Cond Low” alarm occurs during dialysis and the bag is not nearly empty, stop dialysate flow, gently massage the bag and then restart dialysate flow.
- In some cases the bicarbonate powder may contain particles that have been slightly discolored after exposure to water. The safety and efficacy of the bibag disposable are not affected by these discolorations.
- To prevent bicarbonate buildup on the bibag connector, the exterior of the sealing area of the bibag nozzles should be cleaned once a day with very dilute bleach solution before running the rinse program.
- If 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.

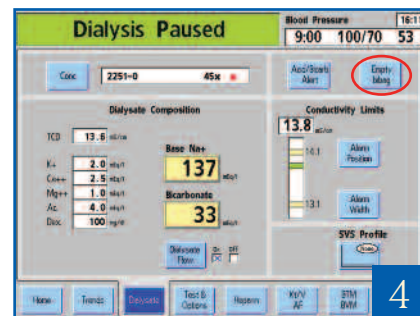


Figure 4 Empty bibag button on the “Dialysate” screen

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 2008T hemodialysis machine and is intended 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. The Fresenius Medical Care 2008T hemodialysis machine is indicated for acute and chronic dialysis therapy.

Caution: Federal (US) law restricts this device to sale by or on the order of a physician or other licensed practitioner. Read the Instructions for Use for safe and proper use of this device. For a complete description of hazards, contraindications, side effects and precautions, see full package labeling available at www.fmcna.com.



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