



MANITOBA RENAL PROGRAM

SUBJECT <ul style="list-style-type: none"> Cleaning and Disinfection of the Fresenius 5008 Hemodialysis System: Internal fluid pathways and External surfaces 	SECTION 30.10 Hemodialysis Equipment Procedures
	CODE 30.10.18
AUTHORIZATION <ul style="list-style-type: none"> Professional Advisory Committee, Manitoba Renal Program Nursing Practice Council, St. Boniface Hospital 	EFFECTIVE DATE April 2018
	REVISION DATE

PURPOSE:

- To provide a standardized procedure for cleaning and disinfecting both the internal fluid pathways and the external surfaces of the Fresenius 5008 hemodialysis delivery system.

POLICY:

- Nurses, Unit Assistants, Nursing Assistants, Health Care Aides and Dialysis Technologists or others identified by the renal educator/renal manager who have received instruction from the Renal Educator or delegate and who have demonstrated competency to the Renal Educator may perform this procedure.
- The external surfaces of the Fresenius 5008 must be disinfected after each patient use and before machine is moved from a patient area to another location.
- The nurse preparing the 5008 for patient treatment is responsible for verifying the appropriate cleaning cycle(s) has (have) been performed on the internal pathways and that the external surfaces have been disinfected prior to use.
- If blood has possibly passed the hydrophobic filter (transducer protector) the device must be checked by a Dialysis Technologist for contamination after completion of the treatment. If the device is contaminated, it must be removed from service. Before the device is returned to operation, all affected parts must be disinfected or replaced in accordance with the manufacturer's specifications.
- The term "cleaning program" refers to all programs selectable in the **CLEANING** menu on the Fresenius 5008. Three options are given. Cleaning programs will be used as follows:

Cleaning Program	Description	Use/Frequency
Rinse	<p>A process ensuring that the hydraulics of the device is free from unwanted deposits resulting from previous processes (eg. disinfectants or dialysate).</p> <p>The hydraulics of the device are rinsed with water from a reverse osmosis unit.</p>	<ul style="list-style-type: none"> Between patients using saline prime. <p>EXCEPTION: Disinfection of the Fresenius 5008 must occur (Heat Disinfection or Cold/Degreasing) following all treatments of a patient with Hepatitis B (regardless of priming method).</p>

**Degreasing/
Cold disinfection**

A disinfection cleaning process which permanently inactivates potentially pathogenic microorganisms and reduces them to a level where they no longer represent a risk of infection.

- Once a week per unit schedule.
- May be required if false positive blood leak alarms do not clear after heat disinfection cleaning cycle.

Degreasing refers to a process using Sodium Hypochlorite (bleach) to remove proteins, lipids and other organic material from the hydraulics of the device.

Heat Disinfection

A disinfection cleaning process which uses thermal means (increased temperature 85°) to permanently inactivate potentially pathogenic microorganisms and reduces them to a level where they no longer represent a risk of infection.

Decalcification is a process using Citric Acid to remove calcium and magnesium deposits from the hydraulics of the device.

Heat Disinfection must be performed:

- Between patients when using ONLINE priming
- Prior to preparing delivery system with ONLINE priming:
 - after the last patient treatment and within 72 hours (24 hours if water testing required)
- After the last treatment of the day
- Minimally every 72 hours if machine not used
- Post treatment of patients with Hepatitis B
- Following blood leak alarm

6. Degreasing/cold disinfection (bleach) and Heat disinfection are both considered disinfection, however, the Manitoba Renal Program has determined that heat disinfection is the program of choice to be performed routinely in the following situations:

- Prior to using ONLINE priming
- After patient with Hepatitis B
- After “Blood Leak” alarm

PROCEDURE:

KEY POINT:

Basic Requirements:

1. The following basic requirements must be fulfilled before the start of a cleaning program:

- Both dialyzer connectors are connected to the shunt interlock
- The shunt interlock flap is closed.
- The concentrate suction tube (red) is connected to the rinse chamber.
- The bicarbonate suction tube (blue) is connected to the rinse chamber.
- The concentrate flap and bicarbonate flap are closed.
- Any failure to comply with the basic requirements will be indicated by a message on the screen.

PROCEDURE:

- The flap (presently unused) is closed (this flap is positioned between the concentrate flap and the bicarbonate flap).
- The optical detector does not detect blood.
- The Online substitute port and the rinse port are closed.

KEY POINT:

Connecting New Disinfectant Containers

EQUIPMENT:

- Container of Sodium Hypochlorite (Bleach)
 - Container of 20% Citric Acid Solution
 - Gloves
1. Perform Hand Hygiene.
 2. Always observe the manufacturer's instructions for use.
 3. Observe the following when connecting the disinfectant canisters:
 - The canisters must be provided with a ventilation opening
 - The disinfectants must be assigned to the appropriate cleaning program
 - Disinfectant canisters must be connected to the disinfectant connectors with the respective coding.
 4. Place the disinfectant canister in its intended position on the rear of the machine.
 5. Secure the disinfectant canister with the strap.
 6. Connect the canister to the port provided.

NOTE:

- Yellow Connector – Citric Acid
- Black Connector – Sodium Hypochlorite (i.e. Bleach)



PROCEDURE:

7. After changing the disinfectant canister, proceed as follows:
 - Select the required cleaning program from the **CLEANING** menu
 - Press the **canister fill level indicator** field
 - Message: *Change container? – Yes - Stop*
 - The canister fill level indicator shows a full canister
8. Press the **Stop** button to cancel the process

Starting a Cleaning Program

1. Perform Hand Hygiene
2. Go to the **CLEANING** menu
3. Select the required cleaning program
4. Press the **Start** button

Stopping a Cleaning Program

1. Perform Hand Hygiene.
2. Go to **CLEANING** menu
3. Press the **Stop** button
4. Message: *Stop cleaning program? – Yes - No*
5. Press the **No** button to continue the program
6. Press the **Yes** button to stop the program

KEY POINT:

KEY POINT:

- Caution: Cleaning programs in progress involve risk of caustic burning and scalding. During cleaning programs:
 - do not open concentrate or bicarbonate flaps;
 - do not disconnect dialysate lines and dialysate connectors;
 - do not open substitute port or rinse port;
 - do not open doors to diasafe filters.
- Risk also exists at the water drain.

- If no button is pressed within approximately 10 seconds, the cleaning program will be continued automatically.
- If the cleaning program is stopped right away you can reselect another program; however if a disinfection program is stopped during the disinfection phase, the complete disinfection program must be performed again.
- If a disinfection program is stopped during the mandatory rinse phase, a mandatory rinse

PROCEDURE:

Cleaning Program Completed

1. Observe the user setup settings

Check for Residual Disinfectant:

EQUIPMENT:

- Chemical residue (Total Chlorine) test strips
- 10 ml syringe (optional)

PROCEDURE:

1. Following a disinfection program with bleach (Degreasing /Cold disinfection), a check for residual disinfectant must be performed.
2. Perform Hand Hygiene.
3. If the automatic message “Manually check for the absence of residual disinfectant!” is displayed on screen, press the “Start” button and follow the prompts on the screen.
4. If the message is not displayed and a Degreasing/Cold disinfection (bleach) program was just performed or you are uncertain if a check is required Go to **CLEANING** menu and look at what is displayed under “Check for residual disinfectant”. If in red letters it indicates that a check for residual disinfectant is required then Press the “**Start**” button and follow the prompts on the screen.
5. Message will read: “**Check now for the absence of residual disinfectant!**” – **OK**
6. Press the “**OK**” button
7. Message: “**Has the absence of residual disinfectant been confirmed?**” – **YES – NO**
8. Wet the indicator strip with fluid from the sample port on the outflow dialysate hose or from the drain port of the hemodialysis system. Follow the manufacturer’s instructions on the test strip bottle to read the indicator strip.
9. Press the **YES** button if the indicator strip shows that there is no residual disinfectant.(.) ppm of Total Chlorine

KEY POINT:

program must be performed.

- If the “Auto off” feature is set the machine will turn off automatically after the preset time if the machine is not touched. e.g. “10 min”
- To stop the machine from turning off, touch the screen anywhere.

KEY POINT:

- Make sure the strips are not expired
- In the “User setup”, under “Cleaning” it is possible to set an automatic screen message “Manually check for the absence of residual disinfectant!” which will be displayed on the screen after performing a disinfection (bleach).
- If “Ignore” is selected the screen prompts will not continue and the machine will not clear the message and in the cleaning menu it will indicate in red letters that the check for residual disinfectant is required.
- If a user touches the **CLEANING** menu before “Start” is selected the message will disappear
- The hemodialysis system rinses the hydraulics for a few seconds when you press start.
- 10 mL syringe may be used to draw a sample from the port on the outlet dialysate hose.

PROCEDURE:

10. Press **NO** if the indicator shows that there is still some residual disinfectant
11. If the check for residual disinfectant could not be performed successfully, a rinse program must be started to rinse out the residual disinfectant. When complete, the manual check for residual disinfectant is repeated.

Surface Cleaning/Surface Disinfection of Fresenius 5008:

EQUIPMENT:

- Manufacturer (Fresenius) approved disinfectants for 5008 machine and screen are:

- Virox Accel Prevention wipes
- Cavi Wipes, Cavi Wipes XL
- Sani-Cloth Plus

1. Perform Hand Hygiene.
2. Always refer to manufacturer's instructions regarding contact time required for disinfectant used.
3. Clean the screen with a disinfectant wipe (damp, not dripping)
4. Clean the top of the machine.
5. Clean the front of the double doors and then the inside of the double doors
6. Clean around the pump heads
7. Clean all components of the external machine including both sides and back.

KEY POINT:

- The program will be exited and the result displayed in the **CLEANING** menu under "**Check for residual disinfectant**"
- If the test for total chlorine is positive after additional rinse, remove machine from operation and notify a Dialysis Technologist

- DO NOT spray detergent solution directly onto machine
- Fresenius suggests prior to wiping machine screen, turn screen lock on by pressing the "Monitor Symbol" located on the Cleaning screen button for approximately 3 seconds. The screen will be "frozen".
- After cleaning the screen, press the "Monitor symbol" for approximately 1 second (normal screen operation is restored).
- **Do Not** clean the operating surfaces of the following with disinfectant wipes (unless blood is visible):
 - BTM – The surface may only be cleaned with a damp cloth.
 - BVM cuvette – The surface may only be cleaned with a damp cloth.
 - Metal components in the EBM
 - Optical detector.

PROCEDURE:

8. Wipe around the shunt interlock and the dialyzer couplings
9. Wipe the sealing area of the bibag® connector.
10. Wipe around both dialysate wands and around the wand seals and rinse chamber covers

KEY POINT:

- The dialyzer connectors and ports must be wiped clean of residue **BEFORE** machine is put into **HEAT DISINFECTION**
- Avoid the bibag sealing O-rings as wiping will remove applied lubricant
- During a cleaning program, pause cleaning cycle before opening covers.
- During the cleaning cycle there is a risk of exposure to heat or chemicals.

REFERENCES:

Instruction Card "Cleaning the 5008 CorDiax"

5008 Hemodialysis System Instructions for Use. Software version: 4.57 Edition: 10B-2015 Part No.: M56 043 1
Developed by Fresenius Medical Care

BC Renal Provincial Standards & Guidelines for Cleaning & Disinfecting Hemodialysis Machines & Stations
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