

	Clinical Practice Standards and Procedures for Dialysis Water Quality: 5: Cleaning and Disinfection of Dialysis Water Equipment
	Section: HD Origin Date: November 2011 Reviewed Date: November 2011

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1.0 PRACTICE STANDARD

1.1. Purpose

The Biomedical Technologist or Renal Dialysis Technician who is trained and has demonstrated competency in dialysis water practices will use the procedure outlined in this document to clean and disinfect the dialysis water equipment as a preventative measure or when microbial counts are high, and to perform the necessary actions should residual cleaners, disinfectants, or sterilants exceed the acceptable limits.

1.2. Standards

Aside from unscheduled cleanings and/or disinfections, and unless otherwise stated by the manufacturer, the schedule must be as follows:

- Dialysis machines must be disinfected **daily** using bleach or heat/citric acid, and disinfected **quarterly** using peracetic acid (e.g., *Minnicare*) as a full flow through the system when the ROs are disinfected using peracetic acid.
- RO systems must be cleaned and disinfected **quarterly** using acid and alkaline cleaners, and peracetic acid (e.g., *Minnicare*).
- Portable RO systems must be disinfected **monthly** using peracetic acid (e.g., *Minnicare*).
- RO distribution loops with heat sanitization capability must be disinfected **nightly** using the heat cycle.

The manufacturer should be consulted for recommended cleaners, disinfectants, or sterilants, and methods for testing residual levels. When the manufacturer does recommend cleaners, disinfectants, or sterilants, means must be provided to restore the equipment and system to a safe condition relative to the residual cleaner, disinfectant, or sterilant prior to the dialysis water being used for dialysis applications.

The following table shows the available recommended tests for residual cleaners, disinfectants, or sterilants, and the maximum allowable amount of residual:

	Test for Residual Cleaner/Disinfectant/Sterilant	Max. Residual Cleaner/Disinfectant/Sterilant
Acid Cleaner	According to manufacturer	As recommended by manufacturer or 0 mg/L
Alkaline Cleaner	According to manufacturer	As recommended by manufacturer or 0 mg/L
Formaldehyde	Hantzsch reaction, Schiff's reagent	3.0 mg/L
Bleach	According to manufacturer	0.1 mg/L
Ozone	According to manufacturer	0.1 mg/L
Peracetic Acid	According to manufacturer	As recommended by manufacturer or 0 mg/L
Heat	-	Approx. 25°C (± 2°C)

If heat sanitization is used, the temperature should exceed 80 °C for a minimum exposure time of 20 minutes for it to be effective.

2.0 DEFINITIONS AND ABBREVIATIONS

<i>Dialysis water</i>	Water that has been treated to meet the requirements of the CSA-ISO standards and which is suitable for use in haemodialysis applications, including the preparation of dialysis fluid, reprocessing of dialysate, preparation of concentrates and preparation of substitution fluid for online convective therapies.
<i>Disinfection</i>	Destruction of pathogenic and other kinds of microorganisms by thermal or chemical means; a less lethal process than sterilization, since it destroys most recognized pathogenic microorganisms, but not necessarily all microbial forms.
<i>Foulant</i>	Any material that causes fouling.
<i>Haemodialysis</i>	Form of renal replacement therapy in which waste solutes are removed primarily by diffusion from blood flowing on one side of a membrane into dialysis fluid flowing on the other side.
<i>Microbial</i>	Referring to microscopic organisms, such as bacteria, fungi, and algae.
<i>Product water</i>	Water produced by a water treatment system or individual component thereof.
<i>RO</i>	Reverse osmosis.
<i>Sterile</i>	Free from all living organisms and viable spores, within the limits of tests for sterility, and maintained in that state by suitable means.
<i>Water treatment system</i>	Collection of water treatment devices and associated piping, pumps, valves, gauges, etc., that together produce treated water for haemodialysis applications and deliver it to the point of use.

Disclaimer: The procedure steps may not depict actual sequence of events. Site-specific considerations may be made when applying the following procedures and protocols.

3.0 EQUIPMENT

- Syringes
- Bleach (*CleanCart-A*)
- Heat/citric acid (*CleanCart-C*)
- Acid cleaner
- Alkaline cleaner
- Peracetic acid (*Minncare* or *Dialox*)
- Gloves
- Eye protection
- Mask
- Test strips (chlorine, peracetic acid, etc.)
- Quarterly RO System Cleaning and Disinfection Log Sheet
- Monthly Portable RO Disinfection Log Sheet

4.0 DAILY DIALYSIS MACHINE DISINFECTION PROCEDURE

- 4.1 Put on eye protection, mask and gloves.

- 4.2 Follow the manufacturer instructions and recommendations accordingly.
- 4.3 Bleach and heat/citric acid cycles are normally alternated on a daily basis.
- 4.4 Using bleach (*CleanCart-A*):
 - 4.4.1 Use bleach as specified by dialysis machine manufacturer.
 - 4.4.2 Run the disinfection cycle as per dialysis machine manufacturer procedure.
 - 4.4.3 Test for residual bleach in the dialysis water after disinfection. Refer to bleach manufacturer instructions for procedure.
 - 4.4.4 If residual bleach is greater than 0.1 mg/L, continue to rinse/flush the dialysis machine.
- 4.5 Using heat/citric acid (*CleanCart-C*):
 - 4.5.1 Connect sterilant line from machine to citric acid solution.
 - 4.5.2 Turn on heat clean process on dialysis machine.
 - 4.5.3 After disinfection, check that the temperature has returned to a safe level.

5.0 QUARTERLY RO SYSTEM CLEANING AND DISINFECTION PROCEDURE

5.1	Record the device name, date, time, and initials on the Quarterly RO System Cleaning and Disinfection Log Sheet, along with the following <i>pre</i> -disinfection RO parameters. It is important to determine whether the overall performance is improved.	
	5.1.1	Measure and record the incoming water temperature.
	5.1.2	Measure and record the pressures before and after the RO membrane.
	5.1.2.1	Calculate and record the pressure change across the membrane. The change in pressure should be less than 10 PSI from baseline.
	5.1.3	Record the product pressure.
	5.1.4	Record the recycle, waste, and permeate flowrates.
	5.1.3	Record the inlet and permeate conductivities.
	5.1.4	Record the percent rejection.
5.2	Put on eye protection, mask and gloves.	
5.3	RO system cleaning.	
	5.3.1	Turn off the RO.
	5.3.2	Prepare the RO for cleaning.
	5.3.2.1	Relieve system pressure as necessary.
	5.3.2.2	Close/open the relevant RO valves.
	5.3.2.3	Connect/secure the relevant RO hoses.
	5.3.3	Perform a low pressure flush with feed or permeate water to remove service concentrate and foulants.
	5.3.3.1	Fill the tank with RO water (to the level marked on the tank).
	5.3.4	Make up the acid cleaning solution to the required concentration as per the manufacturer instructions.
	5.3.5	Check for leaks and security of hoses.
	5.3.6	Add the acid cleaner to the tank. Doing an acid cleaning first will remove any metal buildup on the membrane and prevent membranes from oxidization.
	5.3.7	Run the RO cleaning process for the time recommended by the cleaning agent manufacturer. Adjust cleaning time based on local water quality, time since last cleaning, and/or turbidity of water returning to cleaning tank.
	5.3.7.1	Monitor the temperature of the solution. Make sure it does not exceed 50 °C. If the temperature is in danger of exceeding this level, stop the cleaning process and rinse, and start over as required. High temperatures will

			damage the membranes.
		5.3.7.2	Throttle the flow as necessary to minimize plugging of the feed path with dislodged foulant.
	5.3.8	Turn on the RO system.	
	5.3.9	Rinse and flush the RO system until the pH meter and/or conductivity meters return to normal. (Refer to the Monthly Dialysis Water Equipment Monitoring Log Sheet for trends on the unit's normal conductivity.)	
		5.3.9.1	If the pH meter and/or conductivity readings have not returned to normal, continue to rinse/flush.
	5.3.10	Check that the percent rejection of the RO system is greater than 90%.	
		5.3.10.1	If the percent rejection is less than 90%, continue to rinse/flush.
	5.3.11	Repeat steps 5.3.1 to 5.3.10.1 using alkaline cleaner.	
5.4	Disinfect the system (including RO, loop, and machines) using peracetic acid (i.e., <i>Minnicare</i>).		
	5.4.1	Repeat steps 5.3.1 to 5.3.11.1 using peracetic acid.	
	5.4.2	Create pressure in the RO loop.	
	5.4.3	Allow peracetic acid to circulate through the loop.	
	5.4.4	Turn on the dialysis machines.	
	5.4.5	Put the dialysis machines into rinse cycle until peracetic acid is present in the drain line using the manufacturer recommended test strips.	
	5.4.6	Shut off the machines.	
	5.4.7	Stop the RO and let everything dwell for at least 40 minutes.	
	5.4.8	Rinse and flush the RO until test strips are negative. <i>The system should be flushed with fresh water supply, not circulated from the cleaning tank.</i>	
	5.4.9	Test for residual peracetic acid in the dialysis water from the return product line. Refer to the peracetic acid manufacturer instructions.	
		5.4.9.1	If the residual peracetic acid is not at a safe level, continue to rinse/flush.
	5.4.10	Check that the percent rejection of the RO system is greater than 90%.	
		5.4.10.1	If the percent rejection is less than 90%, continue to rinse/flush.
	5.4.11	Run the RO.	
	5.4.12	Put the dialysis machines into rinse cycle.	
	5.4.13	Upon completion of the rinse cycle, test the machine drain water for residual peracetic acid. Refer to the peracetic acid manufacturer for instructions.	
		5.4.13.1	If the residual peracetic acid is not at a safe level, continue to rinse/flush.
		5.4.13.2	Record the residual on the Quarterly RO System Cleaning and Disinfection Log Sheet.
	5.4.14	Turn off all machines.	
5.5	Check and record the operating parameters of the RO <i>post</i> -disinfection on the Quarterly RO System Cleaning and Disinfection Log Sheet.		
	5.5.1	Measure and record the incoming water temperature.	
	5.5.2	Measure and record the pressures before and after the RO membrane.	
		5.5.2.1	Calculate and record the pressure change across the membrane.
		5.5.2.2	If the change in pressure is greater than 10 PSI from baseline, the membrane module should be replaced.
	5.5.3	Record the product pressure.	
	5.5.4	Record the recycle, waste, and permeate flowrates.	
	5.5.5	Record the inlet and permeate conductivities.	

	5.5.6	Record the percent rejection.
5.6	Turn off the RO.	
5.7	Replace the pre-filters.	
5.8	Perform microbiological testing on cultures after disinfection. This must only be done for new systems until two consecutive tests have met the standards to show that disinfection of the system is effective. The system should be flushed completely before collecting samples.	
	5.8.1	Collect, test, and analyze dialysis water samples for microbial counts and endotoxin levels as per the <i>Microbial Testing of Dialysis Water</i> and <i>Endotoxin Testing of Dialysis Water</i> clinical standards.

Disclaimer: The procedure steps may not depict actual sequence of events. Patient/Client/Resident specifics must be considered in applying Interior Health Clinical Practice Decision Support Tools

6.0 MONTHLY PORTABLE RO DISINFECTION PROCEDURE

6.1	Record the device name, date, time, and initials on the Monthly Portable RO Disinfection Log Sheet, along with the following <i>pre</i> -disinfection RO parameters.	
	6.1.1	Measure and record the incoming water temperature.
	6.1.2	Measure and record the pressures before and after the RO membrane.
	6.1.2.1	Calculate and record the pressure change across the membrane. The change in pressure should be less than 10 PSI from baseline.
	6.1.3	Record the permeate conductivity.
	6.1.4	Record the percent rejection.
6.2	Refer to specific portable RO manufacturer manual (i.e., regular maintenance section) for disinfection instructions and recommendations.	
6.3	Check and record the <i>post</i> -disinfection RO parameters on the Monthly Portable RO Disinfection Log Sheet.	
	6.3.1	Measure and record the incoming water temperature.
	6.3.2	Measure and record the pressures before and after the RO membrane.
	6.3.2.1	Calculate and record the pressure change across the membrane.
	6.3.2.2	If the change in pressure is greater than 10 PSI from baseline, the membrane module should be replaced.
	6.3.3	Record the permeate conductivity.
	6.3.4	Record the percent rejection.
6.4	Use appropriate method to test for residual disinfectant/sterilant.	
	6.4.1	If residual disinfectant/sterilant exceeds the acceptable limit, continue to flush the machine.
	6.4.2	Record the residual on the Monthly Portable RO Disinfection Log Sheet.
6.5	Replace the pre-filters.	
6.6	Replace the carbon filters.	
6.7	Perform microbiological testing on cultures after disinfection. This must only be done for new units until two consecutive tests have met the standards to show that disinfection of the unit is effective. The unit should be flushed completely before collecting samples.	
	6.7.1	Collect, test, and analyze dialysis water samples for microbial counts and endotoxin levels as per the <i>Microbial Testing of Dialysis Water</i> and <i>Endotoxin Testing of Dialysis Water</i> clinical standards.

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7.0 DOCUMENTATION CONSIDERATIONS

All RO system cleaning and disinfection activities must be recorded on the Quarterly RO System Cleaning and Disinfection Log Sheet, and all portable RO disinfection activities must be recorded on the Monthly Portable Disinfection Log Sheet. These results must be reviewed by the Area Renal Manager and Infection Control, and reviewed and signed-off by the Nephrologist on the log sheets **semi-annually**.

8.0 SPECIAL CONSIDERATIONS

- Follow the manufacturer's recommended chemical list, dosage, pH, temperature, and contact time guidelines.
- Use the least harsh chemical for cleaning to optimize the useful life of the equipment.
- Thoroughly rinse each chemical before another chemical is introduced to the equipment.
- Ensure proper disposal of chemicals.
- If cleaning does not provide the expected results, consider contacting off-site services.
- RO cleaning frequency due to fouling will vary by site. A rough rule of thumb is once every 3-12 months. If the RO cleaning frequency is more than once a month, capital expenditures for improved RO pre-treatment should be justifiable, or a redesign of the RO operation should be done. If the RO cleaning frequency is every 1-3 months, it may be necessary to focus on improving the operation of the existing equipment.
- While taking samples for microbiological testing, it is important that no contact is made with the inside of the sampling unit used.
- Sampling for microbiological testing should be done when the system is operating under stable conditions representing normal operation.
- Sampling for microbiological testing should not be done within a 2-hour period following a heat clean procedure as the sample may be too warm.

9.0 REFERENCES

- CAN/CSA-ISO 26722-11 – Water treatment equipment for haemodialysis applications and related therapies (Adopted ISO 26722:2009, First edition, 2009-04-15), *Canadian Standards Association*, 2011.
- Dialysate for hemodialysis (ANSI/AAMI RD52:2004/(R)2010), *Association for the Advancement for Medical Instrumentation*, Arlington (VA), 2009.
- Hemodialysis equipment (ANSI/AAMI RD5:2003), *Association for the Advancement for Medical Instrumentation*, Arlington (VA), 2009.
- Wayne T. Bates, Cleaning Your RO, *Hydronautics* (www.membranes.com)
- Cleaning, Disinfection, and Sterilization of Medical Equipment. [Available Online: http://www.ems.org.eg/esic_home/data/giued_part1/Cleaning.pdf]
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