

PROVINCIAL STANDARDS & GUIDELINES



Cleaning & Disinfecting Hemodialysis Machines & Stations

Revised July 2019 Approved by the BC Hemodialysis Committee









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Interior Health









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IMPORTANT INFORMATION

This BC Renal guideline/resource was developed to support equitable, best practice care for patients with chronic kidney disease living in BC. The guideline/resource promotes standardized practices and is intended to assist renal programs in providing care that is reflected in quality patient outcome measurements. Based on the best information available at the time of publication, this guideline/resource relies on evidence and avoids opinion-based statements where possible; refer to www.bcrenalagency.ca for the most recent version.

For information about the use and referencing of BC Renal guidelines/resources, refer to <u>http://bit.ly/28SFr4n.</u>



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1.0 Scope of Guideline

This guideline provides a standardized procedure for cleaning and disinfecting hemodialysis (HD): (a) machines; and (b) stations (routine cleaning & disinfection only).

The guideline applies to the provision of hemodialysis (HD) and hemodialfiltration (HDF) in:

- In-centre HD units (both adult and pediatric units).
- Community dialysis units (CDUs).

2.0 Definitions

Rinse:

Flushing the internal hydraulics of the dialysis machine with water that meets CSA dialysis standards.

Descalent:

Removal of calcification / precipitate from within the internal hydraulics of the dialysis machine. i.e., citric acid or acetic acid-based product or removal of calcification.

Heat Disinfection:

Destruction of pathogenic and other kinds of microorganisms by thermal means.

NOTE: Disinfection is a less lethal process than sterilization. It destroys most recognized pathogenic microorganisms but does not necessarily destroy all microbial forms.

Chemical Disinfection:

Destruction of pathogenic and other kinds of microorganisms by chemical means. Chemicals can include: sodium hypochlorite (bleach), sodium carbonate, peracetic acid / hydrogen peroxide blend (i.e., Minncare, Dialox).

Descalent with Heat Disinfection: Combination of descalent and heat disinfection.

Machine Types: Artis = Baxter Gambro Artis Phoenix = Baxter Gambro Phoenix Fresenius = Fresenius 5008 CorDiax

3.0 Recommendations

Recommendation #1: Each HD unit develops a process to identify, update and document the frequency of machine disinfection required for a specific patient based on the frequency tables in recommendation #2.

Suggested mechanisms to identify the frequency of machine disinfection include:

- * Nephrologist/Nurse Practitioner writes an order in the patient record; or
- * Nephrologist/Nurse Practitioner provides education to the HD RNs/renal techs. HD RNs/ renal techs identify the frequency.

Suggested location for documentation of Hepatitis B status and frequency of disinfection: HD log ("run" sheet).

Recommendation #2: Disinfect internal pathways, the external surface of the HD machine and peripheral equipment and accessories as per Tables 1, 2 and 3.

Standards on Tables 1, 2 and 3 are consistent with the Canadian Standards Association (CSA) standards with one exception noted in the footnote.

 Table 1:

 Disinfection of Hemodialysis/HDF Machines & Peripheral Equipment & Accessories¹

	Internal Pa	Blood	Eutomal Curr	Devinhevel		
Recomm- endation	HD, no on-line priming or substitution fluid	HD with on-line priming or HDF sub- stitution fluid	Tubing Transducer Protectors	face of HD Machine	Peripheral Equipment & Accessories	
Hep B: Refer to Table 2 Hep B status unknown	Disinfect after each patient (even if two consecutive runs of Hep B+ patients).	Disinfect after each patient. If using on-line priming or using machine for HDF, machine must be disinfected before each use (i.e., if machine used on previous patient for conventional HD, machine must be disinfected before using on-line priming or using for HDF). If not possible, do not use on-line priming (i.e., use saline) or for HDF.	If blood tubing transducer protector(s) comes in contact with a patient's blood, remove HD machine from clinical care after treatment is completed for biomedical inspection & disinfect machine PRN.	Disinfect after each patient & before machine is moved from a patient area to another location. Refer to recommendation #2 for a description of routine disinfection of the dialysis station.	If single-use, discard. If can't discard, dedicate to single patient where possible (e.g., tape, tourniquet). Disinfect peripheral equipment used with HD machine (e.g., wands, BP cuff) after each patient.	
All other patients	Disinfect at end of day ³ ; AND Disinfect after patient if blood leak occurs outside the blood pathway (i.e., membrane is compromised & blood enters the dialysate pathway). If blood was confirmed in the dialysate effluent, change the dialyzer, complete the run with the same patient, perform a heat or bleach disinfection, and pull the machine for Biomedical Engineering to inspect.	As per above. If not using on-line priming or using for HDF, disinfect as per instructions in column to the left ("HD, no on-line priming or substitution fluid").	As per above.	As per above.	As per above.	

¹ The type of disinfection selected (heat, chemical or heat/descalent combination) will depend on the type of machine and the manufacturer's recommendations for disinfection.

² Refer to Table 3 for specifics.

³ CSA Standards (CSA Z364.2.1-13, 2013) states "the internal path of the HD machine shall be disinfected between each patient use." The rationale deviating from this is:

- Disinfecting at the end of the day (vs after each patient) is standard practice for conventional HD in BC and across Canada. There is no known evidence to suggest an increased risk of infection as a result of not disinfecting between every patient.
- It may not be feasible in some units to disinfect after every patient (lengthens the time between treatments and could mean fewer treatments per day).

Table 2: Hepatitis B Status & Disinfection of Hemodialysis/HDF Machines

Hepatitis B Status			Disinfection Recommendation		
HBsAg	Negative	Susceptible	Routine (as per "all other patients" on Table 1)		
Anti-HBc	Negative				
Anti-HBs	Negative	-			
			D		
HBsAg	Negative	Immune due to natural	Koutine (as per "all other patients" on Table 1)		
Anti-HBc	Positive	meetion			
Anti-HBs	Positive				
HBsAg	Negative	Immune due to hepatitis B	Routine		
Anti-HBc	Negative		(as per all other patients of Table I)		
Anti-HBs	Positive				
HBSAg	Positive	Acutely infected	Disinfect after each patient		
Anti-HBc	Positive				
IgM anti-HBc	Positive				
Anti-HBs	Negative				
HBsAg	Positive	Chronically infected	Disinfect after each patient		
Anti-HBc	Positive				
IgM anti-HBc	Negative	-			
Anti-HBs	Negative	-			
HBsAg	Negative	Interpretation unclear: 4	Disinfect after each patient if:		
Anti-HBc	Positive	 possibilities: 1. Resolved infection (most 	 Confirmed HBV+; and 		
Anti-HBs	Negative	 common) 2. False-positive-anti-HBc, thus susceptible 3. "Low level" chronic infection 4. Resolving acute infection 	• Anti-HBS <10 IU/L		

Source: Columns under "Hepatitis B status": Centers for Disease Control and Prevention (CDC). <u>http://www.cdc.</u> gov/hepatitis/hbv/pdfs/serologicchartv8.pdf.

Table 3:Specifics re: Disinfection of the Internal Pathways

Item	Recommendation
Max time between disinfection and use	24 hours
Max storage time between disinfections, regardless of use	48 hours
	Unless contraindicated by the machine manufacturer, place a low grade disinfectant into the machine if it is expected to sit for more than 48 hours.
	If a machine has sat for more than 48 hours without a low grade disinfectant in it, perform 2 consecutive disinfections prior to patient use.
	If a machine has sat for more than 7 days (regardless of whether it has had a low grade disinfectant in it), follow machine manufacturer's recommendation for long-term storage. Before patient use, refer to Tables 1 & 2 for disinfection requirements if machine used for on-line priming or HDF.
Max frequency for bleach or clean cart A disinfection	Artis: One clean cart A disinfection per week Fresenius: Use bleach a maximum of once/week All other machines: Refer to manufacturer's recommendations
Min frequency for bleach or clean cart A disinfection	All machines: once/week
Descaling frequency	Artis: Daily Phoenix: After every treatment Fresenius: 6 times/wk
Residual check post bleach disinfection	If use bleach, do residual check post-bleach disinfection (Artis does not use bleach)
Residual check post citric disinfection	Not required
Incoming hoses	If possible, conduct integrated heat disinfection of the incoming water hose weekly or monthly chemical disinfection of the hoses.

Recommendation #3: Utilize a standardized process for routine disinfection of the dialysis station, including the exterior surface of the dialysis machine.

Refer to <u>Appendix 1</u> for a checklist of the important steps in Dialysis Station Routine Disinfection.

Disinfectants:

- All disinfectants must have a DIN number from Health Canada and be mixed according to manufacturer's instructions.
- Use of a low level disinfectant is adequate for cleaning the external surface of HD machines.

Selection of disinfectant:

- Each manufacturer provides a list of disinfectants tested and validated for use on specific HD machines (refer to Table 4). Disinfectants not on this list have not been tested.
- HD units may also request approval from the manufacturer to utilize a specific disinfectant on a specific machine.
- If a disinfectant is used that has not been approved by the manufacturer, it could damage the machine and the warranty (if the machine is under warranty) may no longer apply.

Machine	Manufacturer-approve	d Disinfectants				
Machine	Machine	Screen	DO NOT USE PIOUUCIS			
Artis	Ethanol 60% or 70%	Ethanol 60% or 70%	Products containing benzene, toluene,			
	Isopropanol 60%	Isopropanol 60%	xylene, acetone or similar solvents.			
	Sodium hypochlorite 1.5%, except on touch					
	screen, art & ven pumps, air detector, blood					
	sensor, hemoscan sensor, arterial & venous					
	line clamps and automatic pinch valves.					
Phoenix	Ethanol (90%)	Ethanol (90%)	As above.			
	Isopropanol 70%	Isopropanol 70%				
	Sodium hypochlorite (active chlorine from	Sodium hypochlorite (active				
	50,000-60,000ppm; bleach/water ratio	chlorine from 50,000-60,000ppm;				
	1:50). Do not use on the blood pump crank.	bleach/water ratio 1:50). Rinse after				
		appropriate contact time.				
Fresenius	Virox Accel Prevention wipes	Virox Accel Prevention wipes	As above.			
	Cavi Wipes, CaviWipes XL	Cavi Wipes				
	Sani-Cloth Plus	Sani-Cloth Plus				
	Sani-Cloth Plus	Sani-Cloth Plus				

Table 4:Disinfectants Tested & Approved by the Manufacturer(list only includes disinfectants registered in Canada)

Recommendation #4: In the event of a large blood spill, utilize a standardized process for disinfecting the internal pathways of the HD machine and the dialysis station, including the exterior surface of the dialysis machine.

Notes:

- All hemodialysis machine-associated blood spills will be thoroughly cleaned and disinfected at the time of the spill.
- In the event of a hemodialysis machine-related large blood spill, where components of the machine may need to be taken apart for cleaning and disinfecting:
 - Take the machine out of service.
 - Clean the outside surfaces and perform internal disinfection per Appendix 1. NOTE: Visible contaminant on any surfaces should be wiped twice using an approved disinfectant wipe material.
 - Submit a work request to Biomedical Engineering.
 - Print the request and tape it to the machine.
 The request must clearly indicate there was a blood spill.
- If the blood spill was caused by suspected failure of bloodline or dialyzer component, and the renal program / unit has appropriate procedures and facilities in place to store contaminated supplies, the supsplies should be saved for investigation (lot number must be reported).
- If blood spill occurred during the patient treatment and/or before blood was returned to the patient, a PSLS report must be completed by the nurse.
- If blood spill occurred after the patient treatment was completed and blood returned to the patient, a PSLS report must be completed by either the nurse or the renal technician/care aide.

Recommendation #5: Utilize a standardized process for disinfecting small multiple-use items.

Refer to <u>Appendix 2</u> for a checklist of steps for disinfectant solution preparation and disinfection of small multi-use items.

4.0 References

CSA Standards (CSA, 2013)

CSA standard CAN/CSA-Z23500:12 (heat disinfection) CSA standard CAN/CSA-Z23500:12 (chemical disinfection) CSA standard CAN/CSA-Z23500:12 (descalent with heat disinfection)

International Standards

KDIGO, 2018. HCV infections. <u>https://kdigo.org/</u> <u>caring-for-patients-with-hep-c/</u> (guideline 3; Note: there was no change from 2008 guideline)

European Renal Best Practice Guidelines, 2009. HCV infections (response to the 2008 KDIGO guideline) http://ndt.oxfordjournals.org/content/ early/2009/02/08/ndt.gfn608.short

National Kidney Foundation (KDOQI), 2020. HCV management and hemodialysis. <u>https://www.kidney.org/professionals/KDOQI/12-10-1601</u>

UK Renal Association, 2019; HCV, HIV and HBV infections. <u>https://bmcnephrol.biomedcentral.com/</u> <u>articles/10.1186/s12882-019-1529-1</u> (Guidelines 2.1 - 2.4) Canadian Society of Nephrology (CSN), 2005. HCV, HBV and other blood-borne pathogens. <u>https://www.</u> <u>csnscn.ca/images/Docs_Misc/VAWG/The_Prevention_</u> of_Transmission_of_Blood-_Borne_Pathogens_in_ <u>Hemodialysis_Patients.pdf</u> (Recommendations 3,1 - 3.4)

Other

- Centers for Disease Control and Prevention National Center for Emerging and Zoonotic Infectious Diseases. Checklist: Dialysis Station Routine Disinfection.<u>http://www.cdc.gov/dialysis/</u> <u>PDFs/collaborative/Env_checklist-508.pdf</u>.
- Centers for Disease Control and Prevention. Interpretation of Hepatitis B Serologic Test Results. <u>http://www.cdc.gov/hepatitis/hbv/pdfs/</u> <u>serologicchartv8.pdf</u>.
- 3. Fresenius "Cleaning the 5008 CorDiax: General External Cleaning Instructions."

Refer to <u>Appendix 2</u> for a summary of the standards from various professional associations.

5.0 Sponsors

This provincial guideline was developed to support improvements in the quality of hemodialysis care delivered to patients with chronic kidney disease in BC. Based on the best information available at the time it was published, the guideline relies on evidence and avoids opinion-based statements where possible. When used in conjunction with pertinent clinical data, it is a tool health authorities and health professionals can use to develop local guidelines. Developed by two working groups of renal care providers from across BC (biomedical and renal educators groups), the guideline was approved by the BCR Hemodialysis Committee and the BCR Medical Advisory Committee. It has been adopted by BCR as a provincial guideline.

This guideline is based on scientific evidence available at the time of the effective date; refer to www.bcrenalagency.ca for most recent version.

6.0 Appendices

Appendix 1: Checklist for Dialysis Station Routine Disinfection

Appendix 2: Checklist for Disinfecting Small Multi-Use Items

Appendix 3: Recommendations from National/ International Standards

Appendix 1: Checklist for Dialysis Station Routine Disinfection

Preparation for Disinfection of the Dialysis Station

- □ Gather necessary supplies including:
 - Personal protective equipment (PPE): eye goggles, gown and clean gloves.
 - Properly diluted hospital disinfectant (with a DIN number from Health Canada) and wipes/cloths (separate wipe(s)/cloth(s) per machine).
 - Biohazard disposal container(s)
- □ Perform hand hygiene.*
- □ Don gown, eye goggles and clean gloves.
- Disconnect and takedown used blood tubing and dialyzer from the dialysis machine.
- □ Discard tubing and dialyzers in a leak-proof container (container is brought to the dialyzer station or is placed as near to the station as is practical as part of the supply set-up in step 1).
- □ Check that there is no visible soil or blood on surfaces.
- □ If drain bag is still hanging, remove bag and empty in the soiled utility area.
- □ Ensure that the patient has left the dialysis station.
 - Patients should not be removed from the station until they have completed treatment and are clinically stable.
 - If a patient cannot be moved safely, delay routine disinfection of the dialysis station.
 - If patients are moved to a separate seating area prior to removing cannulation needles or while trying to achieve hemostasis, disinfect the chairs and armrests in those areas in between patients.
- Discard all single-use supplies. Move any reusable supplies (e.g., clamps) to an area where they will be cleaned and disinfected before being stored or returned to a dialysis station. This may occur before or after the patient has left the station.
- □ Remove gloves and perform hand hygiene.

Routine Disinfection of the Dialysis Station

- □ Perform hand hygiene* and don clean gloves.
- □ Using a wiping motion (with friction), disinfect all surfaces in the dialysis station in contact with the patient and/or staff. e.g., dialysis chair or bed; tray tables; blood pressure cuffs; countertops; keyboard, etc.
- □ Clean dialysis machine from top to bottom.
 - If visible contaminant on the machine, wipe off using an absorbent material.
 - Clean the machine using wipes/cloths with a disinfectant that is acceptable to the HD machine manufacturer and the HA renal program/infection control.
 - Remove excess fluid from the wipes/cloth(s) prior to using to clean machine.

*Perform hand hygiene at the beginning of this process, at the end and at any point there is a contamination.

- Clean the monitor.
 - If available on machine, activate the wipe screen option (pauses the screen).
 - If any residue remains after cleaning, wipe down screen with a clean, dry cloth.
- Clean the top of the machine.
- If the machine has a door(s), clean the front first, then the insides of the doors.
- Clean all components of the main interface (screen) and the back of the machine* unless recommended otherwise by the manufacturer. e.g., sensors and optical detectors.
- Clean exposed surfaces of dialysate, concentrate, and bicarb connectors.
- Clean each side of machine.
- Clean the area between the main interface (screen) and brakes, including the shelf.
- Clean the brakes.
 - * Frequency of cleaning back of machine is as per HA protocol.
- □ Ensure surfaces are visibly wet with disinfectant but not dripping. Allow surfaces to air-dry. Air-drying is recommended to allow for sufficient contact time with the disinfectant.
- □ Remove gloves, eye goggles and gown.
- □ Perform hand hygiene.

Special Note on Cleaning the Fresenius 5008 CorDiax Hemodialysis Machine

AVOID wiping the following areas (clean the plastic but NOT the sensor/connector):

- □ Venous pressure luer connector (carefully wipe around and do not allow wipe to cover the connector).
- □ Single needle pressure luer connector (carefully wipe around and do not allow wipe to cover the connector).
- □ Blood/air detector.
- □ Temperature sensors.
- □ Blood volume monitor.

Do not bring patient or clean supplies to station until these steps have been completed.

References:

- 1. Checklist: Dialysis Station Routine Disinfection. Centers for Disease Control and Prevention National Center for Emerging and Zoonotic Infectious Diseases. www.cdc.gov/dialysis checklist.
- 2. Fresenius "Cleaning the 5008 CorDiax: General External Cleaning Instructions."

Appendix 2: Checklist for Disinfecting Small Multi-Use Items

Preparation for Disinfection of the Dialysis Station

Applies to facilities that do not use external medical device reprocessing (MDR) providers.

□ Gather necessary supplies including:

- Personal protective equipment (PPE): eye goggles, gown and clean gloves.
- Disinfectant wipes.
- Disinfectant concentrate (accelerated hydrogen peroxide).
- Measuring cup.
- 1-4L water (depending on number of items).
- 1-4L container (clean).
- Drying rack or clean absorbent cloths.

Clean & Disinfect 1-4L (accelerated hydrogen peroxide) DRY

- □ The schematic process of disinfection is shown on the diagram below:
- □ Perform hand hygiene.*
- □ Don gown, eye goggles and clean gloves.
- □ Discard solutions if containers are not empty.
- □ Prepare fresh solutions daily.
- □ Fill clean container with 1-4L of water.
- □ Add 25 mL of accelerated hydrogen peroxide per 1L of water (100mL of concentrate for 4L of water).
- □ Collect dirty small items in soiled utility room until ready to disinfect.
- □ Wipe any soiled items with approved disinfectant wipes.
- □ Soak small items in solution for 5 minutes.
- □ Allow small items to air dry in drying rack or on clean absorbent cloth.
- □ Discard solutions at end of day.

^{*}Perform hand hygiene at the beginning of this process, at the end and at any point there is a contamination.

Appendix 3: National/International Standards (for background)

Standards	Internal Pathways	Blood Tubing Transducer Protectors (Filters)	External Surface of HD Machine	Peripheral Equipment & Accessories
Canadian Standards Association (CSA, 2013) All patients (regardless if patient has BBV)	Disinfect between each patient.	If in contact with patient's blood, remove machine from service & change filter/disinfect machine PRN.	Disinfect between patients & before being moved from a patient area to another location.	Disinfect between each patient.
KDIGO, 2008 Variances for HCV+ patients. Systematic review concluded that most Hep B spread is caused by cross- contamination from supplies and surfaces, not transmission via internal pathways of the HD machine. http://www.kdigo.org/clinical_practic e_guidelines/pdf/KDIGO%20Hepatitis %20C%20Guideline.pdf (guideline 3)	No need to disinfect between patients unless a blood leak has occurred. If blood leak has occurred, disinfect internal pathways and dialysate-to-dialyzer (Hansen) connectors. Dedicated machine not required.	Same as CSA.	Same as CSA. If blood/fluid has seeped into machine, remove from service.	Same as CSA. If can't disinfect easily, dedicate to single patient (e.g., tourniquet). If blood or fluid visible, use bleach to disinfect.
European Renal Best Practice Guidelines, 2009 HCV+ patients (response to KDIGO guidelines) http://ndt.oxfordjournals.org/content /early/2009/02/08/ndt.gfn608.short	Support KDIGO guideline.	Support KDIGO guideline.	Support KDIGO guideline.	Support KDIGO guideline
KDOQI, 2015 HCV+ patients (response to KDIGO guidelines) https://www.kidney.org/professionals /KDOQI/12-10-1601	Support KDIGO guideline.	Support KDIGO guideline.	Support KDIGO guideline.	Support KDIGO guideline.

Standards	Internal Pathways	Blood Tubing Transducer Protectors (Filters)	External Surface of HD Machine	Peripheral Equipment & Accessories
UK Renal Association, 2007 BBV+ http://www.renal.org/guidelines/mod ules/blood-borne-virus- infection#sthash.6azLVUZH.dpbs (Guideline 2.1 - 2.5)	HBV+ & HIV: Dedicated machine not required. Standard disinfection protocol between patients. (standard disinfection protocol not identified). Hep B+: Use separate machine for Hep B+ infected patients. Can use for non-Hep B+ patients if machine decontaminated (including Hansen connectors & pressure transducer ports unless double transducer protectors routinely used).	Same as CSA.	Same as CSA.	Hep B+: Use separate equipment & accessories.
Community & Hospital Infection Control Association (CHICA) - Canada, Dialysis Interest Group, 2007 BBV+ patients http://www.ipac- canada.org/cjic/vol22no4.pdf (page- 220)	HCV+ and HIV+: Routine practices (doesn't identify what routine practices mean). Hep B+: Clean & disinfect between patients.		Hep B+: Clean & disinfect between patients.	Hep B+: Clean & disinfect between patients.
Canadian Society of Nephrology (CSN), 2005 BBV+ patients https://www.csnscn.ca/images/Docs_ Misc/VAWG/The_Prevention_of_Tran smission_of_Blood- _Borne_Pathogens_in_Hemodialysis_ Patients.pdf	Follow manufacturers recommendations for frequency and types of cleaning and disinfection required.	Follow manufacturers recommendations for frequency and types of cleaning and disinfection required.	Follow manufacturers recommendations for frequency and types of cleaning and disinfection required.	Follow manufacturers recommendations for frequency and types of cleaning and disinfection required.
Manufacturer's Guidelines (same for all types of HD machines)	As per CSA Standards	As per CSA Standards		