

South Australian Clinical Practice Guideline

Fresenius Dialysis Machine

Disinfection

© Department for Health and Wellbeing, Government of South Australia. All rights reserved.

Note:

This guideline provides advice of a general nature. This statewide clinical practice guideline has been prepared to promote and facilitate standardisation and consistency of practice, using a multidisciplinary approach. The clinical practice guideline is based on a review of published evidence and expert opinion.

Information in this statewide guideline is current at the time of publication.

SA Health does not accept responsibility for the quality or accuracy of material on websites linked from this site and does not sponsor, approve or endorse materials on such links.

Health practitioners in the South Australian public health sector are expected to review specific details of each patient and professionally assess the applicability of the relevant guideline to that clinical situation.

If for good clinical reasons, a decision is made to depart from the guideline, the responsible clinician must document in the patient's medical record, the decision made, by whom, and detailed reasons for the departure from the guideline.

This statewide guideline does not address all the elements of clinical practice and assumes that the individual clinicians are responsible for discussing care with patients in an environment that is culturally appropriate, and which enables respectful confidential discussion. This includes:

- The use of interpreter services where necessary,
- Advising consumers of their choice and ensuring informed consent is obtained,
- Providing care within scope of practice, meeting all legislative requirements and maintaining standards of professional conduct, and
- Documenting all care in accordance with mandatory and local requirements.

Purpose and Scope of Clinical Practice Guideline

This guideline is primarily aimed at all Haemodialysis staff working within their scope of practice and staff working under the direction of haemodialysis competent personnel.

The purpose of this guideline is to provide clinicians with information regarding dialysis machine disinfection to ensure patients safety, reduce risk of blood borne viruses, and reduce the risk of bacterial proliferation in the dialysate pathway.

The principles of disinfection requirements should remain the same and should be used as an adjunct to current machine operating manuals issued by the manufacturer.

Table of Contents

Purpose and Scope of Clinical Practice Guideline	1
Compliance	2
Summary of Practice Recommendations.....	2
Abbreviations	3
Principles.....	3
Cleaning Requirements	4
Regular Cleaning	4
In addition to Regular Cleaning Cycle	5
Safety precautions	5
Documentation	6
Evaluation Criteria	6
Risk factors	6
Education	6
Resources	6
Acknowledgements	6
Document Ownership and History	7

Compliance

- The Nurse Unit Manager of the unit is responsible for ensuring systems are in place to facilitate and monitor compliance.

Summary of Practice Recommendations

- Bacterial and endotoxin water testing is designed to help identify and prevent bacterial proliferation in the water treatment system.
- Monitoring levels of bacteria and endotoxin helps provide evidence that the disinfection program of the reverse osmosis unit is effective in suppressing bacterial growth and endotoxin and aid in maintaining patient safety.

Fresenius Dialysis Machine Disinfection

Abbreviations

BBV	Blood Borne Virus
CaCo3	Calcium carbonate
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
MROs	Multidrug-resistant organisms
OACIS	Open Architecture Clinical Information System
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus 2
TGA	Therapeutic Goods Administration

Principles

Each dialysis machine must be internally disinfected prior to each patient connection.

Fresenius Medical Care Australia Pty Ltd recommends disinfecting the 4008 and 5008 series machines with Citrosteril® in conjunction with a heat disinfection program before each haemodialysis treatment - refer to the manufacturer's instruction for disinfection procedure.

Disinfection is the process that permanently inactivates potentially pathogenic microorganisms and reduces them to a level where they no longer represent a risk of infection.

Hydraulics disinfectant Diasteril®, Citrosteril®, Puristeril340 or Puristeril® plus, are suitable for Fresenius machines (4008 series, 5008/s). These products can inactivate HBV, HCV, HIV, as well as the SARS-CoV-2 virus.

- Machines must be programmed to "Wake Up" in the morning with a heat disinfection cycle.
- Machines that are not currently in use should be heat disinfected at least every 72 hours to prevent bacterial proliferation in the dialysate pathway.
The heat disinfection cycle includes Citrosteril®. This is a potent thermo-chemical disinfectant solution.

Citrosteril® is a CaCo3 product which decalcifies and disinfects the machine in one process.



Fresenius Dialysis Machine Disinfection

Cleaning Requirements

The manufacturer recommends the following cleaning cycles:

Disinfection Cycle - **4008: PGM 2:-F-HDIS-M-/**

5008: Heat Disinfection

Regular Cleaning

In any setting where there is uncertainty about the nature of soiling on the surface (e.g. blood or body fluid contamination versus routine dust or dirt) or the presence of MROs (including *C. difficile*) or other infectious agents requiring transmission-based precautions (e.g. pulmonary tuberculosis) is known or suspected, surfaces should be physically cleaned with a detergent solution, followed or combined with a TGA registered disinfectant with label claims specifying its effectiveness against specific infectious organisms.

This process must involve either:

- a physical clean using detergent followed by a chemical disinfectant (2-step clean) i.e. clean with detergent, then clean with a disinfectant
- OR
- a physical clean using a detergent and chemical disinfectant (2-in-1 clean) i.e. a combined detergent/disinfectant wipe or solution could be used if this process involves mechanical/manual cleaning.

Physical (mechanical or manual) cleaning is the most important step in cleaning.

Sole reliance on a disinfectant without mechanical/manual cleaning is not recommended.”

The following components require regular cleaning:

- the dialyser couplings and the shunt interlock
- the sealing area of the bibag® connector
- the sealing area of the concentrate suction tubes (concentrate / bicarbonate)

A heat disinfection of machine should be performed following the external cleaning of the dialysis machine

This should occur between every patient treatment as part of the surface disinfection of the machine.

Note:

- These components can be cleaned using a detergent wipe that contains a maximum of 45% ethanol. Excess ethanol in wipes causes degradation to plastic components of the dialysis machine
- Use a new, freshly dampened wipe for each component.



Fresenius Dialysis Machine Disinfection

In addition to Regular Cleaning Cycle

(As per Fresenius Medical Care Australia Pty Ltd.)

Where excess biomaterial is present in the machine, additional cleaning cycles must be performed using a non-scented sodium hypochlorite-based solution (bleach).

The recommended strength of the active ingredient is 5% (acceptable range is 1- <20%).

These instances are:

- Blood leak has occurred during the dialysis treatment.
 - If a blood leak into the dialysate has occurred, the machine must have a bleach cycle immediately after the completion of treatment.
 - Blood leaks should be reported via Safety Learning System and documented.
- Bacterial growth or contamination of the dialysate pathway (i.e. maintenance)
 - The machine should be bleached if bacterial growth or contamination of the dialysate pathway has occurred.
- Perform a bleach cycle every week to remove possible biomaterial deposits.

A heat disinfection cycle must be undertaken immediately after a bleach disinfection, which will remove residual bleach from the internal pathway.

The following programs should be used for bleach disinfection cycles. Refer to manufactures instructions for procedure details.

The following disinfection programs are cold water programs:

4008: PGM 5: -F-D(F)-M

5008: degreasing/Cold disinfection

Safety precautions

As per manufacturer's instructions machine disinfection programs in progress involve the following risks:

- Disinfection (risk of caustic burning)
- Heat disinfection (risk of scalding and caustic burning)
- Bleach and hot water - Heat disinfection programs are **NOT** to be used when bleach is used as a disinfectant. When heated there is an increased risk of fumes irritating your eyes and nose. Bleach should only be used in a well-ventilated place.

Personal Protective Equipment – (gowns, gloves, and goggles) must be used at all times when handling chemicals.

Safety Data Sheets (MSDS) must be available and used when handling chemicals.

During the heat disinfection cycle, steam will vent out of the rear of the machine. Staff should be aware and minimise exposure to the back of the machine, during this cycle.



Fresenius Dialysis Machine Disinfection

Accessible machine parts such as suction and Bibag® flap, dialysate line and connectors, substitute and rinse port **should not be accessed** during the disinfection cycle as risk of scalding could occur.

Documentation

Each patient record should include details of types of clean and that an appropriate disinfection cycle has been performed. This should be documented on the running sheet for each treatment, either electronically or manually according to local practices.

Evaluation Criteria

Each haemodialysis Nurse Unit Manager is responsible for ensuring compliance against the guideline.

Risk factors

Some patients who are receiving dialysis treatment have (BBV) such as hepatitis B, hepatitis C and/or HIV present in their blood. Failure to heat disinfect the machine between each patient may result in the risk that these viruses may be transmitted to another patient in the dialysis unit.

Education

Education around the cleaning and disinfection of haemodialysis machines is incorporated into the South Australian haemodialysis education package made available to all new staff.

Resources

1. Instructions for Use – Fresenius Medical Care 5008S Haemodialysis System, Software version: 4.62, Edition:14B-2018.
2. Instructions for Use – Fresenius Medical Care 4008 Haemodialysis System Software version: 12.0, Edition:21D - 2018

Acknowledgements

The South Australian Renal Community of Practice gratefully acknowledges the contribution of clinicians and other stakeholders who participated throughout the guideline development process particularly:

Write Group Leads

- Christopher Kelly
- Linda Thorburn



Fresenius Dialysis Machine Disinfection

Other major contributors

- Members Central Northern Adelaide Renal and Transplantation Service
- Statewide Infection Prevention Control Units
- SA Renal Protocol Working Group Committee Members

Document Ownership and History

Developed by: SA Renal Community of Practice
Contact: health.renalclinicalguidelines@sa.gov.au
Endorsed by: Domain Custodian, Clinical Governance, Safety and Quality
Next review due: 08/06/2027
ISBN number: 978-1-76083-413-5
CGSQ number: CPG01
CPG history: Is this a new clinical practice guideline (V1)? **Y**
 Does this clinical practice guideline amend or update and existing clinical practice guideline? **N**
 If so, which version? **V**
 Does this clinical practice guideline replace another clinical practice guideline with a different title? **N**
 If so, which clinical practice guideline (title)?

Approval Date	Version	Who approved New / Revised Version	Reason for Change
08/06/2022	V1	Domain Custodian, Clinical Governance, Safety and Quality	Original

