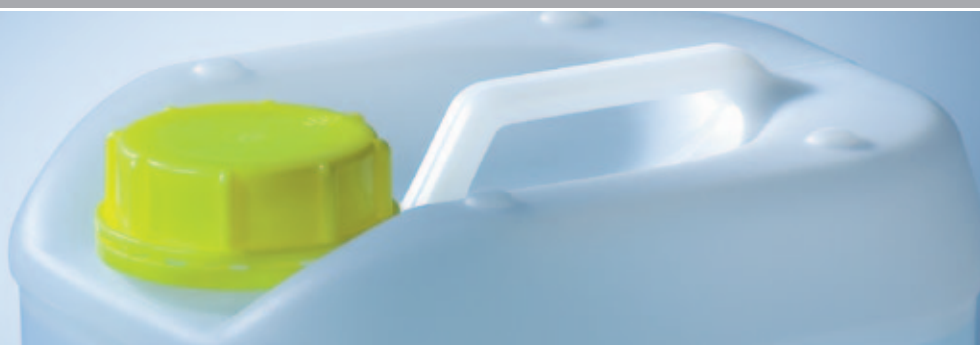


Cleaning and disinfecting the system hydraulics



System processing

Any use of non-approved preparations may cause damage to the system and destroy the structure of applied DIASAFE[®]*plus* filters, resulting in a deterioration of the retention rate. Thus, only those disinfectants and cleaning agents mentioned in the instructions for use of the HD system should be used.

Disinfection

After each treatment, the system hydraulics must be disinfected with a decalcifying disinfectant to remove calcifications and microorganisms. Otherwise, malfunctions may occur depending on the concentrates used and the bicarbonate concentration. We recommend to disinfect dialysis machines again after a downtime of 72 hours.

The GENIUS[®] therapy system is disinfected using the peracetic acid vapour of Puristeril 340 GENIUS[®] and ultraviolet light. In this combination, peracetic acid has a high antimicrobial effect.

Cleaning

To remove potential organic deposits resulting from high-flux dialysis treatments, we recommend a weekly cleaning procedure with the alkaline Sporotal 100. During their operating life, DIASAFE[®]*plus* filters can be treated eleven times with Sporotal 100. Since alkaline preparations do not have any decalcifying effect, it is not possible to omit the decalcifying disinfection with acid disinfectants after the dialysis treatment.

Cleaning and disinfecting the system hydraulics

Disinfection and decalcification of single-station reverse osmosis units (AquaUNO)

Fresenius Medical Care offers easy-to-use small containers for this application. Single station reverse osmosis units are decalcified with Citrosteril. However, Citrosteril cannot develop any disinfecting action if used at room temperature. Therefore small containers with Puristeril^{plus} must be used for disinfecting single station reverse osmosis units.

Mechanism of antimicrobial action¹

Peracetic acid, hydrogen peroxide

Damage of the cell wall through oxidation of membrane proteins, resulting in oxidation of liberated fatty acids, proteins, DNA, etc. Damage of the envelope of enveloped viruses as well as oxidation of the coat proteins.

Organic acids (citric acid, glycolic acid)

Destruction of the phospholipid layers in the cell membrane; disturbance of the intracellular pH balance; formation of Ca/Mg salts or salt complexes in the case of citric acid; activity strongly increased by an increase in temperature.

Sodium hypochlorite

Reaction of the released chlorine with organic substances, e.g. with the cell wall and cell proteins. In aqueous solutions hypochlorous acid (HOCl) is formed which has an oxidizing effect through the release of oxygen.

Properties of the products approved for Fresenius Medical Care dialysis systems

	Citrosteril	Diasteril	Puristeril ^{plus}	Puristeril 340	Sporotal 100
Active ingredients	Citric acid, malic acid, lactic acid	Hydroxyacetic acid (glycolic acid)	Peracetic acid, hydrogen peroxide	Peracetic acid, hydrogen peroxide	Sodium hypochlorite, potassium hydroxide solution
Antimicrobial action	Heat disinfectant (dialysis machine 84 °C)	Heat disinfectant (dialysis machine 84 °C)	Cold disinfectant (dialysis machine 37 °C)	Cold disinfectant (dialysis machine 37 °C)	Cold disinfectant (dialysis machine 37 °C)
Decalcifying	Yes	Yes	Yes	Yes	No
Cleaning	Limited effect	Limited effect	Limited effect	Limited effect	Excellent effect
Material compatibility (4008, 5008, DIASAFE ^{plus})	No restriction	No restriction	No restriction	No restriction	Eleven treatments with DIASAFE ^{plus} during filter life
Storability after manufacture	2 years at 5–25 °C	4 years at 5–30 °C	2 years at 5–30 °C	18 months at 5–25 °C	12 months at 5–25 °C
Odour	Almost odourless	Almost odourless	Faint odour of acetic acid	Acrid	Faint odour of hypochlorite
Testing of residual disinfectant	Not required	With pH-Fix 3.6–6.1 (part no. 6288161)	with potassium-iodide starch paper (part no. 5085211)	with potassium-iodide starch paper (part no. 5085211), not required for GENIUS [®] Therapy System	with potassium-iodide starch paper (part no. 5085211)
Used dilution	1 + 24	1 + 24	1 + 24	1 + 24	1 + 34
Consumption 4008 without/with DIASAFE ^{plus}	Approx. 50/66 mL	Approx. 50/66 mL	Approx. 50/66 mL	Approx. 50/66 mL	Approx. 37/49 mL
Consumption 4008 ONLINE ^{plus} /5008/5008S	Approx. 82/96/90 mL	Approx. 82/96/90 mL	Approx. 82/96/90 mL	Approx. 82/96/90 mL	Approx. 61/72/65 mL

¹ Wallhäußers Praxis der Sterilisation. Edited by: Kramer A, Assadian O. Stuttgart, Germany: Georg Thieme Verlag; 2008