Disinfection can be based either on physical or on chemical methods. It is also possible to combine these two methods, a procedure which is often used in treatment machines and dialysis systems.

In dialysis, besides bactericidal efficiency the "limited spectrum of virucidal activity" is of particular interest with regard to disinfection. Hepatitis B, hepatitis C and HIV viruses are enveloped viruses which can be inactivated more easily than non-enveloped viruses (e.g. polioviruses). The German Robert Koch Institute (RKI) recommends that products which are demonstrably able to inactivate surrogate viruses can be considered to have a "limited spectrum of virucidal activity" and therefore to be effective against enveloped viruses.2

**Test viruses to declare "limited spectrum of virucidal activity"**
- Bovine parvovirus (BPaV)
- Human rhinovirus (HRV)
- Poliovirus type 1
- Adenovirus type 5
- Vaccinia virus (Elstree strain)

**Test viruses to declare "virucidal"**
- Adenovirus type 5, adenovirus type 7
- Vaccinia virus (Elstree strain)
- Poliovirus type 1
- Papillomavirus (simian virus 40, SV40, 777 strain)
- Adenovirus (adenovirus type 5, adenoid 75 strain)
- Herpes simplex virus type 1

**Test virus to declare "virucidal" acc. to DIN EN 14476**
- Poliovirus type 1, adenovirus type 5; at disinfection temperatures of more than 40°C: Bovine parvovirus, Haden strain

**Advanced literature**

3. EN 14476:2005: Chemical disinfectants and antiseptics. Virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine. Test method and requirements (phase 2, stage 1).
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Test viruses to declare "limited spectrum of virucidal activity"2
- Bovine serum albumin (BSA)
- Poliovirus type 1, adenovirus type 5, adenovirus type 75

Test viruses to declare "virucidal"2
- Adenovirus (adenovirus type 5, adenovirus type 75 strain)
- Papovavirus (simian virus 40 [SV40], 777 strain)
- Poliovirus (poliomyelitis vaccine strain type I, LSc-2ab strain)
- Vaccinia virus (Elstree strain)

Test virus to declare "virucidal" acc. to DIN EN 14476 3
- Poliovirus type 1, adenovirus type 5; at disinfection temperatures of more than 40°C: Bovine parvovirus, Haden strain

Advanced literature

References
1  ISO 23500 CD (Committee Draft), "Guidance for the preparation and quality management of fluids for haemodialysis and related therapies", 2009.
3  EN 14476:2005: Chemical disinfectants and antiseptics. Virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine. Test method and requirements (phase 2, step 3).

Fig.: Model of a hepatitis B virus
Biofilm – prevention instead of reaction

ISO 23500 CD1 requires regular prophylactic disinfection of the reverse osmosis unit and the permeate ring main to minimize the formation of a biofilm.

Suitable regular disinfection measures are chemical or hot water. Ideally, the measure to be used should already be determined in the planning phase of a dialysis unit.

Quality assurance

To meet the requirements of a quality management system, the chemical and microbiological quality of permeate, dialysis concentrate and dialysate must be monitored regularly.

Cleaning and disinfecting the system hydraulics

In order to prevent microbiological loads, the hydraulics of the dialysis system must be disinfected after each treatment.

In addition, dialysis systems should be subject to a regular cleaning program to remove organic components.

Surface disinfection of medical products

In dialysis, there is a high risk of a transfer of microorganisms, caused by contact with contaminated surfaces. The outside surfaces of a dialysis system may be contaminated, thus requiring disinfection measures.

The modern products and efficient procedures of Fresenius Medical Care support you in achieving a proper hygiene management.

The sections below will give you a summary of the essential hygienic aspects in dialysis and extracorporeal treatment therapies.
Biofilm – prevention instead of reaction
ISO 23500 CD1 requires regular prophylactic disinfection of the reverse osmosis unit and the permeate ring main to minimize the formation of a biofilm. Suitable regular disinfection measures are chemical or hot water. Ideally, the measure to be used should already be determined in the planning phase of a dialysis unit.

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Hygiene Prophylaxis and quality assurance

Hygienic measures are measures to maintain the health of people. The presence of microorganisms can negatively affect the treatment quality and health of dialysis patients. Personnel employed in the public health sector are also exposed to the risk of infection. These facts can only be efficiently counteracted by an appropriate hygiene management.

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ISO 23500 CD1 requires regular prophylactic disinfection of the reverse osmosis unit and the permeate ring main to minimize the formation of a biofilm.

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Test viruses to declare "limited spectrum of virucidal activity":
- Bovine adenovirus type 2 (BADV)
- Vaccinia virus (Elstree strain)

Test viruses to declare "virucidal":
- Adenovirus (adenovirus type 5, adenovirus type 75, adenovirus type 31)
- Papovavirus (simian virus 40 [SV40], 777 strain)
- Poliovirus (poliomyelitis vaccine strain type I, LSc-2ab strain)
- Vaccinia virus (Elstree strain)

Test virus to declare "virucidal" acc. to DIN EN 14476:
- Poliovirus type 1, adenovirus type 5; at disinfection temperatures of more than 40°C: Bovine parvovirus, Haden strain

Advanced Literature:
3. EN 14476:2005: Chemical disinfectants and antiseptics. Virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine. Test method and requirements (phase 2, step 1).


