

Document Cover Page

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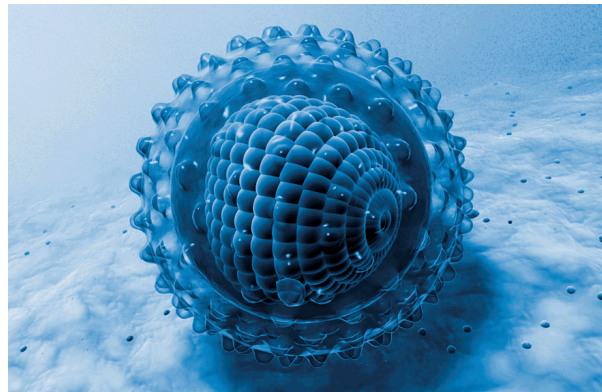
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4. Process and Responsibilities *(see from page 2 onwards)*

Hygiene measures during technical activities in healthcare environments



5. Abbreviations & Related Documents

<p><u>Abbreviations:</u></p> <p>HAV Hepatitis A virus HBV Hepatitis B virus HCV Hepatitis C virus HIV Human Immunodeficiency virus MRSA Methicillin-resistant Staphylococcus aureus MRGN Multidrug-resistant gram-negative pathogens RSSE Russian spring-summer encephalitis virus VRE Vancomycin-resistant enterococci TO Technical operations</p>	<p><u>Related documents:</u></p> <p>N/A</p>
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1. Requirements

- 1.1 Technical processes like service procedures such as repair and servicing (maintenance, technical safety checks, modification, disinfecting, reprocessing, commissioning and recommissioning) of a machine or assembly are subject to more stringent hygiene measures and personal protective equipment requirements because of the potential risk of microbiological contamination.
- 1.2 As it can never be ruled out that service procedures will be performed on dialysis devices which have previously been used to treat patients with a transmissible disease, the measures below must be followed for your own protection as well as to prevent possible spreading of pathogens.
- 1.3 Follow the internal regulations of the dialysis clinic/hospital. Do not eat, drink or smoke at the workstation. Designated areas are usually available for this purpose.
- 1.4 Procedures listed under Item 1 must not normally be performed in a treatment or isolation room next to infectious patients. In **exceptional cases**, the appropriate protective clothing must be worn and more stringent safety and hygiene precautions taken.
- 1.5 Devices on which service procedures are to be performed must be cleaned and disinfected by the user. The cleaning and disinfection procedure should be recorded by the user and shown to the service employee prior to service procedure. The user should also inform the service employee if the device was contaminated by body liquids of patients. If body fluids cannot be completely removed, the affected components must be disposed of. The user has to take into account the local regulations for waste disposal.
- 1.6 Your own protection takes precedence. The service employee commissioned with performing the work is responsible for compliance with the hygiene measures for his or her own protection. These measures include use of the personal protective equipment (protective gowns – single use, disposable gloves, mask and safety glasses) and disinfecting the hands as described below. The personal protective equipment has to be provided by the user or local organisation. Hepatitis B vaccination is recommended.
- 1.7 If it has not been ensured that devices on which infectious patients have been treated have been disinfected, or if the personal protective equipment items or disinfectants listed below are not available, inform your superior to decide the further procedure.
- 1.8 Procedures listed under Item 1 on equipment from special isolation units in treatment centres for highly infectious (contagious) life-threatening diseases may not be carried out before the user of the facility is able to confirm that the necessary disinfection measures have been conducted on these devices in accordance with the manufacturer's instructions and – if applicable - specifications of the responsible surveillance authority. The user should also provide information on the respective serial number. No work must be carried out by the service employee within the infectious treatment area of the special isolation unit.

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2. Personal protective equipment

2.1. Gloves

- Use **disposable gloves** (to be provided by the user or local organisation)
 - for any contact with a possible contaminated surface and/or working environment which has not been disinfected
 - for contact with pathogenic material (visible contamination)
 - when working next to patients
 - when handling disinfectants for surfaces and hydraulic systems.
 - when device needs to be tilted and loaded for transportation e.g. a multiFiltrate device in a car
- Dispose of used gloves in the appropriate container in the room in which the procedure is being carried out.
- After disposal of used gloves, disinfect your hands.

Note: If at all possible, use gloves made of butyl or nitrile rubber which meet the requirements according EN 455-1 to -4 “Medical gloves for single use” resp. if handling with chemicals according EN 374 – “Protective gloves against chemicals and micro-organisms”.

2.2. Protective Gown

- Use long-sleeved protective gown – single use (to be provided by the user or local organisation), required
 - in case of potential contact with pathogenic material (e.g. visible contamination),
 - if described by the clinic/hospital,
 - if splashes from chemicals (e.g. disinfectant in the hydraulic) are likely.
- Dispose of the gown in the appropriate container in accordance with local policy or legal requirements once servicing is complete.

Note: Protective gowns should meet the requirements according EN 14126 “Protective clothing - Performance requirements and test methods for protective clothing against infective agents”

2.3. Safety Glasses

- Wear **safety glasses** (to be provided by the user or local organisation)
 - If prescribed in the instructions for use of the disinfectants / concentrates / chemicals
 - If described by the clinic/hospital
 - If splashes from chemicals (e.g. disinfectant in the hydraulics) are likely.

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2.4. Protective Gown, Mask and Safety Glasses

Wear a **protective gown** and **mask** (Filtering Face Piece (FFP) 2 is recommended) and **safety glasses** or face visor for procedures on the hydraulic system after a blood leakage if it was not possible to disinfect the hydraulic system for technical reasons. The equipment has to be provided by the local organisation.

2.5. Footwear

Wear **footwear** which covers the feet completely for hygienic and work safety reasons to reduce the risk of injury.

3. Disinfecting the Hands

- Use an **alcohol-based hand antiseptic / disinfectant** (locally available product).
- Follow the hand hygiene technique shown below.
- Allow contact time in accordance with the manufacturer's instructions.
 - Always **disinfect hands**
 - following contact with pathogenic material or contaminated surfaces/objects,
 - as well as after changing gloves (e.g. after contact with contaminated material) and after removing gloves,
 - if prescribed by the user, e.g. before leaving an isolation room.
 - When entering and leaving a treatment room (in order to prevent cross-contamination of areas).
- Allow **contact time** for “bactericidal” and “limited virucidal efficacy” (allowing a longer specified time where appropriate).
 - In the case of **Noroviruses** (pathogens causing diarrhea): allow contact time for virucidal efficacy/noroviruses.
 - In the case of **Clostridium difficile** (pathogen causing diarrhea, bacterial spore-former): alcohol-based hand disinfectants are **not** sufficiently effective against bacterial spores, so following disinfecting of the hands (bactericidal), wash hands thoroughly according to the procedure shown below to reduce spores further manually.
- Always follow the instructions for use of the disinfectant !

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4. Surface Disinfection (including internal Parts of the Devices)

- Before commencement of work check if the user has disinfected all exterior surfaces of the device and labelled thereafter.
- If **visible contamination** (e.g. blood, secretions, feces, concentrate deposits etc. in the internal parts of the device)
 - Wear disposable gloves
 - Observing the disinfectant contact time and concentration wipe off contamination using a disposable cloth, cellulose pad or the like soaked in disinfectant and then dispose of the cloth/pad immediately. Then disinfect the surface again.
 - Change gloves, disinfect your hands.
- **Disinfectants**
 - **General disinfection**
 - ClearSurf (standard 1 % dilution, contact time 15 min.) or
 - ClearSurf WIPES (contact time 15 min.) or
 - Freka-NOL (concentrated, contact time 1 min.).
 - Alternatively, the preparation used by the clinic/hospital can be used.
 - Apply at the specified concentration and contact time for **prophylaxis against hospital infection** in accordance with locally applicable standards and for **limited spectrum of virucidal activity / virucidal against enveloped viruses** (using a concentration and contact time to cover both).
 - If the user has informed about an **outbreak situation** of e.g. Noroviruses or Clostridium difficile where standard disinfectants (e.g. ClearSurf, Freka-NOL) are not effective
 - In the case of **Noroviruses** (pathogens causing diarrhea):
apply the preparation* used by the user and prepared at a concentration for "**virucidal efficacy**" or "inactivation of noroviruses" and allow the appropriate contact time!
 - In the case of **Clostridium difficile** (pathogen causing diarrhea, bacterial spore-former):
apply the preparation* used by the user and prepared at a concentration for **sporicidal efficacy** and allow the appropriate contact time!
 - Always follow the safety instructions and instructions for use of the disinfectant and wear appropriate protective clothing!

* e.g. oxygen-based products are effective against bacterial spore-formers and all viruses, e.g.:

- Ultrasol® active, Dr. Schumacher
- Dismozon® plus, Bode
- Use only in case of an outbreak, otherwise material damage is possible.

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5. Disinfection of Tool


Tool and toolbox have to be surface disinfected as described above in case of visible contamination or after contact with pathogenic material or contaminated surfaces/objects. Follow the instructions for use of the tool as appropriate.

6. Skin Protection

On completing the procedures, and after disinfecting and washing your hands with a locally available product (see below), take measures to protect your skin (applying hand cream/lotion). Skin care is necessary because even smallest skin rupture cannot safely be disinfected.

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7. Hand Hygiene Technique



Hand in hand

The programme for safe hand hygiene


Washing with soap and water

Duration of the entire procedure: 40 – 60 sec

1a

1b

Wet hands with water and apply enough soap to cover all hand surfaces.



2

Rub hands palm to palm ...

3

... right palm over left dorsum with interlaced fingers and vice versa ...

4

... palm to palm with fingers interlaced ...

5

... backs of fingers to opposing palms with fingers interlocked ...

6

... rotational rubbing of left thumb clasped in right palm and vice versa ...

7

... rotational rubbing, backwards and forwards with clasped fingers of right hand in left palm and vice versa.

8a

8b

Rinse hands with water ...

9

... dry thoroughly with a single use towel ...

10a

10b

... close tap ...

11

... once dry, your hands are safe.

Rubbing with alcohol-based formulation


Duration of the entire procedure: 40 sec (rubbing time 20 – 30 sec, 10 sec to allow hands to dry)


1

Apply a palmful of the product in a cupped hand and cover all surfaces.

8

Once dry, your hands are safe.





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8. Disinfectant Activities

Disinfectant	Targeted pathogens	Prevalent in dialysis	Further Examples of Pathogens, usually not prevalent in dialysis
Standard surface disinfectants, e.g. <ul style="list-style-type: none"> • ClearSurf • Freka-NOL and standard alcohol-based hand disinfectants	Bacteria including multi-resistant bacteria at bactericidal concentration and contact time	<ul style="list-style-type: none"> • Skin-borne germs, e.g. <ul style="list-style-type: none"> – <i>Staphylococcus aureus</i> • Fecal germs, e.g. <ul style="list-style-type: none"> – <i>Escherichia coli</i> • Water-borne germs, e.g. <ul style="list-style-type: none"> – <i>Pseudomonas aeruginosa</i> • Multi drug resistant pathogens, e.g. <ul style="list-style-type: none"> – MRSA (methicillin-resistant <i>Staphylococcus aureus</i>) • Multidrug-resistant gram-negative pathogens (MRGN), e.g. <ul style="list-style-type: none"> – <i>Escherichia coli</i> – <i>Klebsiella pneumonia</i> – <i>Pseudomonas aeruginosa</i> – <i>Acinetobacter</i> species • VRE (Vancomycin-resistant enterococci) 	
	Yeasts at yeasticidal concentration and contact time		<i>Candida albicans</i> (<i>C. albicans</i>)
	Enveloped viruses at concentration and contact time limited spectrum of virucidal activity ” or “ virucidal against enveloped viruses ”	<ul style="list-style-type: none"> • Hepatitis B/C virus (HBV/HCV) • HIV, Influenza viruses 	<ul style="list-style-type: none"> • Herpes viruses, Rabies virus, Measles, mumps, rubella viruses, • Hemorrhagic fever viruses (e.g. Marburg virus, ebola virus, Lassa fever, hantavirus) • Russian spring-summer encephalitis (RSSE) virus
Aldehyde-based products and oxygen hydrolysis-based products, e.g. <ul style="list-style-type: none"> • Ultrasol® active, Dr. Schumacher • Dismozon® plus, Bode When the products are used, there is a slight risk of material damage. The owner/operator accepts responsibility for use of these products.	Non-enveloped viruses at virucidal concentration and contact time resp. claim to inactivate targeted viruses	<ul style="list-style-type: none"> • Noroviruses (diarrhea) • Rotaviruses (diarrhea) 	<ul style="list-style-type: none"> • Hepatitis A viruses (HAV) • Polio viruses
	Bacterial spore-formers at sporicidal concentration and contact time Note: Alcohol-based products are ineffective!	<ul style="list-style-type: none"> • <i>Clostridium difficile</i> (<i>C. difficile</i>) (diarrhea, usually in conjunction with antibiotic treatment) 	<ul style="list-style-type: none"> • Further Clostridia strains (e.g. <i>C. tetani</i>, <i>C. botulinum</i>, <i>C. perfringens</i>) • Bacilli strains (e.g. <i>Bacillus cereus</i>, <i>Bacillus anthracis</i>)

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9. Informative Part

Reference for further examples of biological agents (e.g. microorganisms) with hazardous potential can be found in Annex III of

DIRECTIVE 2000/54/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work.

Link: <http://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:32000L0054>

The directive is transposed within the European Union into local regulations.