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To whom it may concern

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Revision 1 - Handling of Fresenius Medical Care devices that have been used to treat patients with COVID-19 (Coronavirus SARS-CoV-2 infection), e.g. 4008S classix, 5008S CorDiax/5008 CorDiax, 6008 CAREsystem, GENIUS®-Therapy System, multiFiltrate, multiFiltrate PRO, sleep.safe, sleep.safe harmony, BCM – Body Composition Monitor, ThermosafePlus, surface of Fresenius R.O. systems, NxStage, or apheresis devices, e.g. Art Universal

Dear customer,

Major risks for cross transmission of Coronavirus SARS-CoV-2 when using dialysis machines for different patients are presented by breaches in hand hygiene or neglect of disinfection of the dialysis machine's surface or patient environment. Consistent application of basic hygiene precautions is therefore the most effective preventive measure, e.g.

- proper hand hygiene and glove changes, especially between patient contacts, before invasive procedures, and after contact with blood and potentially blood-contaminated surfaces/supplies
- proper injectable medication preparation practices following aseptic techniques and in an appropriate clean area, and proper injectable medication administration practice
- thorough cleaning and disinfection of surfaces at the treatment place, especially high-touch surfaces
- adequate separation of clean supplies from contaminated materials and equipment

In addition, all medical devices with direct contact to the patient (e.g. blood pressure cuffs, ECG electrodes, stethoscopes, etc.) must be used patient-related and must be disinfected after use.

The operation and proper disinfection of the device according to the instructions for use and disinfection of the patient environment must be carried out after each treatment - irrespective of the patient's infectious status - with a product approved for this purpose. Thus, the dialysis machine will be rendered safe for use for the next patient, provided that



the dialysis machine is handled and maintained according the instructions for use and fully functional.

SARS-CoV-2 is an enveloped virus, thus disinfectants with an at least **virucidal activity against enveloped viruses** must be used. Apply at the specified concentration and contact time for **prophylaxis against hospital infection** in accordance with locally applicable standards and for at least **virucidal against enveloped viruses**, using a concentration and contact time to cover both. Suitable products are, e.g. surface disinfectants ClearSurf (1% - 15 minutes contact time) or Freka-NOL (undiluted, 1 minute contact time).

As hydraulic disinfectants for 4008S classix, 5008S CorDiax/5008 CorDiax or 6008 CAREsystem, Diasteril, Citrosteril, Puristeril 340 or Puristeril *plus* are suitable. These products are also inactivating SARS-CoV-2. The glass tank of the GENIUS® therapy system is disinfected with Puristeril 340 GENIUS®. Please ensure that the disinfectant used is still within the shelf life. For the GENIUS® therapy system the change intervals (see instructions for use for the preparator) must be observed. The disinfection must be carried out according to the instructions for use of the respective device and disinfectant.

An unscheduled change of Diasafe®*plus* filters is not necessary.

It is not necessary to replace pressure transducers and dialyser couplings as long as there are no blood deposits or leaks in the hydrophobic filters of the tubing systems and the procedure has been followed according to the instructions for use (e.g. replacement or use of a replacement pressure line, disinfection of the dialyser couplings and the short-circuit part after blood contact).

Please note that manual procedures such as surface disinfection are more risky than validated machine-controlled procedures such as hydraulic disinfection due to the possibility of human error.

For apheresis or acute dialysis devices without hydraulic, observe the pressure transducer and surface disinfection procedures described above.

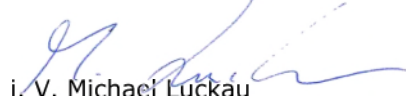
For NxStage please refer to the additional guidance from the US. Please note, that due to the poor availability of disinfectants, the following products with the manufacturer's stated effectiveness against corona viruses can also be used temporarily: PDI Sani-Cloth 70 and Sani-Cloth Active (application solution or wipes).

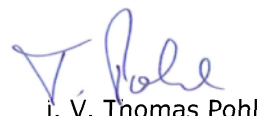
However, if national or regional regulations regarding this topic are available, these must be adhered to.

Please do not hesitate to contact us if you have any questions.

Best regards,

Fresenius Medical Care
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i. V. Michael Luckau


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