



Fresenius Medical Care Deutschland GmbH · 61346 Bad Homburg

To whom it may concern

Fresenius Medical Care

Deutschland GmbH

Marketing Services

Technical Operations

Else-Kröner-Straße 1

61352 Bad Homburg

Germany

www.freseniusmedicalcare.com

Dr. Alla Schmittel

Alla.schmittel@fmc-ag.com

T +49 6172 609-2763

16. March 2020

Handling of postponed disinfection and sampling of water treatment systems due to access restriction to dialysis clinics and intensive care units based on COVID-19 (Coronavirus SARS-CoV-2) outbreak

Dear customer

As the spreading of Coronavirus SARS-CoV-2 (COVID-19) is ongoing, access regulation for external employees in dialysis clinics and intensive care units (ICUs) are tightened. The contact to patients and clinical staff is limited to the most necessary. **Due to this increased restriction, it may not be possible anymore to perform (regularly scheduled) disinfection or sampling of small/single water treatment devices requiring chemical disinfection** (e.g. Aqua UNO, Aqua WTU, etc.) **in intensive care units and dialysis clinics.**

When facing such situation, following recommendations should be followed:

- Country Fluid Quality Responsible or Water Quality Responsible person to review past microbiological analysis data to identify potentially increased risk of delayed disinfection
- In case past microbiological results were below limit values, the disinfection of the WT device can be postponed, due to the exceptional situation
- When HDF is performed, it is recommended to check the lifetime of the Diasafe plus filters and to preventively change the filters if a negative trend of past microbiological analysis results are recognized
- Shifting to HD treatments should be considered and consulted with medical director (or equivalent) of the clinic
- Document the reason why the disinfection was postponed, approve in writing by medical director (or equivalent) of the clinic



- Monitor and document all water quality related data before starting the treatment as per established procedure (measurement of e.g. total chlorine, hardness, etc.)
- Disinfect the surface of small/single place WT system if necessary
- HD device must be disinfected after each treatment (see reference document *Machine Disinfection SARS-CoV-2*)
- Use protective equipment (see reference *SOP Hygiene Measures during technical activities in health care environments C-OI-19-01*)
- If the small/single place WT device was out of use for > 72 h (or according to manufacturer's recommendations) without rinsing or treatment, the WTS should be disinfected prior to next treatment. Decision to not perform disinfection prior to treatment should be based on risk analysis outcome and should be approved by medical director (or equivalent) of the clinic

— **If access to dialysis clinics is generally restricted** and disinfection or sampling of central WTS needs to be performed, adapt the above given recommendations accordingly.

Some **laboratories may postpone chemical and microbiological analysis of the water quality** due to the current situation.

In the given case, following recommendations should be followed:

- Country Fluid Quality Responsible or Water Quality Responsible person to review past microbiological analysis data to identify potentially increased risk of delayed sampling
- Take preventive measures in case chemical data may be out of range
- Monitor and document all water quality related data before starting the treatment as per established procedure (e.g. total chlorine, hardness, etc.)
- Document the reason why the sampling was postponed, approve in writing by medical director (or equivalent) of the clinic

Start of the treatment should be consulted with and approved by medical director (or equivalent) of the clinic, when recognizing that:

- Last microbiological or chemical results were above limit values
- Operational performance values are out of specification, e.g. increased conductivity, hardness, etc.

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

Please don't hesitate to contact us if you have any questions.

Best regards

i. A. Andreas Leclerc
Vice President Technical Operations

i. V. Dr. Alla Schmittel
Sr. Expert Fluid Quality for Dialysis Centres