

How to handle contaminated and potentially contaminated dialysis machines ?

(Adapted from the "Leitlinie für die Praxis der angewandten Hygiene in Behandlungseinheiten für Dialyse" edited by the "Arbeitskreis für angewandte Hygiene in der Dialyse", – Lengerich; Berlin; Düsseldorf; Leipzig; Riga; Scottsdale (USA); Wien; Zagreb; Pabst Science Publ., 1998; ISBN 3-933151-32-5).

As every dialysis machine returning from a home haemodialysis or any other patient is potentially contaminated (with HCV, HBV, HIV or others) it should be carefully treated as a contaminated device and actions for decontamination should be undertaken. For quite a while it was questionable how to proceed with these "yellow" machines until a group of providers, various dialysis companies and other health care officials sat together and created the "User's guide on applied hygiene in dialysis units" containing recommendations aimed at German dialysis settings. Among others they answered the open question above.

According to this user's guideline you should formally proceed as follows (free translation into English):

§ 3.2.2 Restoration of dialysis machines from patients with infectious diseases transmitted via blood

The members of the work group "Hygiene" assume without special evidence that the transmission of viruses (especially of Hepatitis viruses) can occur with the following priority:

1. through contact with hands
2. through contact with outer surfaces of the devices*
3. through inner surfaces (hydraulic circuit) of dialysis machines.

This means that the danger of i.e. virus transmission through dialysis machines is at lowest priority but however cannot be excluded completely without the execution of proper disinfection procedures.

Validated disinfection procedures avoid this risk in the special case of restoring a dialysis machine which has been in contact with patients suffering from infectious diseases transmittable via blood. Validated disinfection procedures in this context are defined as follows:

- A.** the use of a disinfectant (*the following is true for all recommended FMC disinfectants*)
1. which proved to be effective against hepatitis B virus in suspension tests conducted by two different procedures (MADT- or polymerase- or antigen test)
 2. which was proven to be effective against Bac. subtilis spores in a practise test in the dialysis machine.
- B.** the subsequent use of two different procedures
1. Step: Decalcification and disinfection (acid disinfectant)
 2. Step: Cleaning and disinfection (alkaline disinfectant)

Argumentation

The restoration of a "yellow" machine to a "white" machine should be an exception. Viruses can be covered bei carbonate, proteins or lipid substances and therefore be protected within the machine. To guarantee a proper decalcification and cleaning of an infectious machine the decontamination should be performed by using validated disinfectants as described above.

In the exceptional cases where a so called "yellow" device should be restored so that it can be used in future as a "white" device the procedure mentioned above should be ordered in written form by the clinically responsible of the dialysis unit. Only devices which comply with these procedures can be restored. The whole procedures should be supervised by a responsible nurse and documented in a decontamination protocol. This protocol should be personally signed by two persons (head of medical and head of nursing staff) to make sure that this procedure is not performed routinely and if with great caution.

* As the 2nd highest risk of transmitting infectious diseases is via the surface of medical device these device should be disinfected using validated surface disinfectants with a concentration and contact time which is effective against the assumed virus contamination (e.g. hepatitis B) and which are approved for use with the respective medical device (e.g. ClearSurf).

Notes:

Installed filters Diasafe®/Diasafe® *plus* or Online-HDF should be changed during the restoration, e.g. by making a short-circuit at the place where the filters are mounted before starting the restoration or after the alkaline cleaning step. After mounting the new filters in the restored machine a disinfection has to be executed following the instructions in the manual.

Attention:

There is no guarantee to achieve a successful restored machine if the above steps are executed.