# Standardized manual reprocessing of angiographic systems in the hybrid OR

S. Buhl, C. Werner, S. Käs, S. Hentschel, C. Bulitta*

Abstract:

Introduction:

The current FDA guidance requires the validation of cleaning and disinfection protocols for non-sterile medical devices. [1] In this work such a reprocessing manual should be defined based on the recommendations of the guidance itself as well as DIN EN ISO 17664. [2]

Material und methods:

As a test object for the validation of reprocessing of a non-sterile medical device an angiographic system (Artis Zeego / Pheno - Siemens) was used. [3] We focused on the cleaning and disinfection protocols in modern hybrid operating rooms. In the preparation phase of the experiments hygienically critical areas and components of the systems were identified and assessed by means of questionnaires to clinical users (OTA, OR technicians). A hygienic risk assessment was performed with regards to proper infection control. Clinical practice and the cleaning and disinfection protocols used were evaluated by fluorescence testing and microbiological examination with contact plates and swabbing to determine the bacterial contamination at specific risk areas and components of the system. These experiments were done on three different systems in clinical use. On the basis of these results, a reprocessing manual was prepared. Finally the reprocessing manual/protocol was validated.

Results:

We could demonstrate a high contamination on several surfaces of the product studied even after the cleaning and disinfection measures (>10 CFU/25cm²). When using the developed reprocessing protocol these germs could be strongly reduced. Thus the protocol validation was successful. In addition, it could be shown that DIN EN ISO 17664 can in principle be applied and tailored to non-sterile used medical devices. Our findings suggest to standardize cleaning procedures for angiography devices and hybrid ORs. It should be discussed whether this approach should be applied in principle to all medical devices used at the patient or in risk areas according to Krinko / BfArM recommendations. In addition standards for assessing the “cleanliness” of medical device are necessary. Therefore defined procedures and approaches for contamination experiments and assessment of effectiveness of manual reprocessing protocols of non sterile used medical devices need to be developed.

Keywords: cleaning and disinfection; medical products; critical surfaces;

[1] Food and Drug Administration: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling. Guidance for Industry and Food and Drug Administration Staff. Silver Spring, 2015

[2] DIN EN ISO 17664:2004-07

[3]https://www.healthcare.siemens.com/angio/artis-interventional-angiography-systems