

EFSUMB

Best Practice recommendations for cleaning and disinfection of ultrasound transducers whilst maintaining transducer integrity

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Introduction

These guidelines give an overview of regulations and procedures for cleaning and disinfecting ultrasound equipment with a specific focus on maintaining the optimal function and condition (integrity) of transducers while reducing the risk of viral and/or bacterial contamination.

In general, users should follow the cleaning and disinfection regulations from their hospital’s hygiene department, but these do not necessarily consider transducer aspects related to cleaning and disinfecting procedures specifically. Transducer housing materials can be changed, or slightly damaged over time due to improper procedures.

Classification of transducers

The purpose of cleaning and disinfection procedures is to eliminate microorganisms and bacterial spores from medical devices. Without correct disinfection the risk of nosocomial transmission of genito-urinary pathogens or cross-infections between patients may exist for e.g. endocavity ultrasound applications [1-2]. Transducers are treated differently to the risk for microbial contamination according to the Spaulding [3] classification system (Fig.1), and this should be tailored to the clinical requirements [4].

Fig.1 : Classification of ultrasound transducers and hygienic requirements

examination	classification (Spaulding)	type of transducer	hygienic requirements	hygiene procedures
intact skin	non-critical	transabdominal others: monitor, console	cleaning and/or low/intermediate level disinfection, potentially: cover	manual (wiping) but automatic methods are preferred.
non-intact skin, mucous membranes, blood contact	semi-critical A semi-critical B	endovaginal, endocavity, endorectal	high-level disinfection + nonsterile cover	automatic methods approved by manufacturers preferred
sterile areas of the body, intra-operative, biopsy, puncture	critical	intraluminal, biopsy-holder	sterilisation + sterile cover	automatic methods approved by manufacturers
		disposable	none (delivered sterile)	none (one use)

The European Centre for Disease Prevention and Control (ECDC), national bodies such as the German Robert Koch Institute, ultrasound societies and the hygiene departments of hospitals have published regulations and policies, that are mandatory, or good practice, guidelines [5-10]. The user should follow these regulations. However, negative interactions with the ultrasound material components that could alter the image performance are not usually addressed. It is important that the biological effectiveness and the material compatibility of the disinfectant are optimal for routine use.

Transducer malfunction related to suboptimal cleaning and disinfection procedures

Ultrasound transducers are sophisticated, sensitive medical products needing specific care during cleaning and disinfection. However, most procedures do not take into account complications arising from material changes, e.g. bleaching, warming-up cycles or yellowing over time. Regular

cleaning and chemical disinfection can expedite ageing of transducer materials in general, and make the transducer electrically unsafe. The image quality can decrease due to micro-fissures and holes produced by repetitive thermal stress during automatic processes or chemical reactions. Using the wrong cleaning cloth (with a rough surface) or wrong disinfectants, may also damage the surface of ultrasound transducers over time. The ultrasound operator needs to consider these aspects.

Best Practice Recommendations

Preparation

- Soft wipes, approved disinfectants and transducer covers must be easily to hand. Special hygienic requirements (such as sterile transducer cover or gels) must be available for specific procedures
 - stay informed about relevant hygienic procedures
 - be sure that dispensing nozzles do not come into contact with patients
 - be sure that the disinfectants in use are approved by the manufacturer of the ultrasound equipment and are in accordance with your hospital regulations. Have the disinfectant name and order numbers easily to hand.

Cleaning

- After removing the cover, the transducer must be wiped with a soft cloth after each examination to remove any residual gel or debris. Water or a low-/intermediate-level disinfectant can be used.
- Do not forget to
 - (1) disconnect the transducer from the equipment if the whole cable needs to be cleaned
 - (2) wipe the monitor and the console, including keyboard panel, transducer holders, hand rest and gel container (to prevent smear-/cross-contamination)
 - (3) respect the time needed to achieve the required efficacy i.e. guaranteed completion of disinfection
 - (4) change gloves after the cleaning process

Disinfection

- All internal transducers (e.g. vaginal, rectal, transesophageal transducers) and intra-operative transducers, require a high-level of disinfection before they can be used in a new patient (Fig.1). Only disposable transducers are delivered in a sterile condition and must be handled adequately. Local regulations from the hygiene department must be followed strictly, and it must be ensured that the disinfectants comply with the manufacturer’s guidance for the transducer.
- Automatic processes such as hydrogen peroxide (H₂O₂, e.g. Nanosonics Trophon EPR) or ultraviolet (UV, e.g. Antigermix) methods are preferred, where approved by the manufacturer to guarantee a reproducible standardised and fast process [11-15], as long as a full documentation of the disinfection process is available (preferably digital).

Sterilisation

- Follow the regulations stipulated by the hospital and the manufacturer for the type of transducer and process if necessary.

It is important to know the appropriate disinfection methods for transducers

It is essential to look for the correct transducer number, because similar housing designs with different covering/plastic materials are used and may react differently with disinfectants. Have a look at the manufacturer’s specific approved disinfectants for optimal transducer / console care.

This can be accessed:

- in the hand book of the ultrasound equipment or transducer user manuals
- on the manufacturer’s website
- by the manufacturer’s service technician

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Definitions

- cleaning** - removal of contamination from a surface or housing
- disinfection** - the process of reducing or eliminating viable microorganisms to a specified level (low-, intermediate- or high-level).

low-level disinfection

- a process that will inactivate most vegetative bacteria, some fungi, and some viruses, but cannot be relied on to inactivate resistant microorganisms (e.g., mycobacteria or bacterial spores; Glossary CDC).

intermediate-level disinfection

- a process that inactivates vegetative bacteria, most fungi, mycobacteria, and most viruses (particularly the enveloped viruses), but not bacterial spores (Glossary CDC).

high-level disinfection

- the destruction of all vegetative microorganisms, mycobacterium, small or nonlipid viruses, medium or lipid viruses, fungal spores, and some bacterial spores (Glossary CDC).

sterilisation

- validated process that eliminates and destroys all viable microorganisms from a transducer surface including bacterial spores.
