Recommendations by the Quality Task Group (101)

Reprocessing ultrasonic transducers

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1. Introduction

Ultrasonic transducers are indispensable components of the modern medical armamentarium since ultrasound is used to visualize on a screen, and sometimes make audible, several organs and body regions. Often, ultrasonic examination is confined to body surface areas but can also be used to penetrate natural body openings for diagnostic purposes. Ultrasound penetrates deeper into the tissues the lower its frequency. But there are limits since the declining frequency is also accompanied by a reduction in the spatial resolution.

Ultrasonic transducers must be reprocessed after use on a patient so that they can then be reused for another patient. Often, the manufacturer specifies different reprocessing processes for the various components, e.g. connectors, control panel and the parts used for the actual examination, thus rendering reprocessing even more complex.

Whereas cleaning of ultrasonic transducers can generally be easily verified through visual inspection, a product whose efficacy has been demonstrated by appropriate tests and approved by an expert must be used for disinfection. The transducer manufacturers must give precise details of what constitutes an ➜ **EFFECTIVE DISINFECTION PROCESS** for these medical devices (KRINKO/BfArM Recommendation [2], Annex 8/Appendix 7 and 8).

➜ **AN EFFECTIVE DISINFECTION PROCESS** must be specified by the transducer manufactors.

It is imperative to always use protective sheaths, in particular for ultrasound examinations through natural body orifices, since the barrier against pathogens is normally weaker than on healthy skin. However, the use of such protective sheaths should never be misinterpreted as a reason for less rigorous transducer reprocessing [3].

All staff members entrusted with reprocessing must have the required expertise in medical device reprocessing. To ensure problem-free reprocessing, the premises operator must formulate a ➜ **STANDARD OPERATING PROCEDURE (SOP)**.

➜ **A STANDARD OPERATING PROCEDURE (SOP)** must be formulated by the operator.

All staff members entrusted with reprocessing have to receive a documented training (training certificate) to guarantee correct reproccessing according to the manufacturer's instructions. According to the KRINKO-BfArM Recommendation [2] (Section 1, General requirements) the reprocessing process must be validated to reproducibly ensure successful reprocessing at all times.

2. Classification of transducers

Ultrasonic transducers are classified by the KRINKO-BfArM Recommendation [2] (Section 1.2.1 Risk assessment and ➜ **CLASSIFICATION** of medical devices before reprocessing) on the basis of how they are used and the risk this presents. Accordingly, medical devices are assigned to the non-critical, semi-critical or critical medical device risk groups. Reprocessing or the requirements for cleaning, disinfection and sterilization, respectively, must be tailored to the respective risk group and the risk of infection or hazard to patients, users or third parties.

➜ **CLASSIFICATION** of ultrasonic transducers is done according to KRINKO/BfArM Recommendation.

➜ **NON-CRITICAL** devices are e.g. those ultrasonic transducers which for diagnostic purposes only come into contact with intact skin (e.g. standard abdominal sonography, Doppler sonography, echocardiography). Non-critical transducers are generally used without a protective sheath. The ultrasonic gel should be removed immediately after use with a damp single-use wipe, while observing the manufacturer's instructions for precleaning.

➜ **NON-CRITICAL** devices are e.g. ultrasonic transducers which only come into contact with intact skin.

➜ **THE DISINFECTION PROCESS** following cleaning (evidence of cleanliness through visual inspection) must be bactericidal and levoricidal; the instructions of the disinfectant manufacturer must be observed.
To the extent known, the ultrasonic transducers currently on the market are not amenable to automated cleaning and disinfection processes (washer-disinfectors [WDs] pursuant to EN ISO 15883).
Therefore validated manual processes must be used based on standard operating procedures and processing instructions (SOPs). The disinfection step can be performed in suitable automated machines. Often, only the transducer head (distal end) can be disinfected in an automated machine. Manual disinfection of the connecting tube is therefore still required.

➜ **THE DISINFECTION PROCESS OF NON-CRITICAL DEVICES** must be bactericidal and levoricidal.

Ultrasonic transducers belonging to the "semi-critical" group come into contact with the mucosa or with pathologically altered skin. Examples of such devices include e.g. TEE transducers (transesophageal echocardiography), vaginal transducers and rectal transducers which are generally inserted into normal body openings.

The ➜ "**SEMI-CRITICAL A**" group of medical devices are not subject to any special reprocessing requirements, which is why ultrasonic transducers tend to be assigned to the "semi-critical B" group. That the reprocessing process will not negatively impact the application or functional safety of the medical device and its material characteristics cannot be ruled out. In addition to electronic components (ultrasonic heads), transducers are also medical devices that are prone to kinking and whose surfaces are to be classified as sensitive or vulnerable, respectively.

➜ **SEMI-CRITICAL** ultrasonic transducers should be assigned to the semi-critical B group.

➜ **"SEMI-CRITICAL B"** ultrasonic transducers are inserted into natural body openings, thus coming into contact with the mucosa or pathologically altered skin.
➜ **SINGLE-USE PROTECTIVE SHEATHS** should be employed when using these transducers (KRINKO/BfArM Recommendation [2], Annex 8, Appendix 7)
The single-use protective sheath as well as the ultrasonic gel should be removed immediately after use. Adherent soil should be removed using a damp single-use wipe.

➜ **SINGLE-USE PROTECTIVE SHEATHS** should be employed when using these transducers.

➜ **THE DISINFECTION PROCESS** following cleaning (evidence of cleanliness through visual inspection) must be bactericidal, fungicidal and virucidal [1]; the instructions of the tranducer manufacturer and of the disinfectant manufacturer must be observed.
To the extent known, the ultrasonic transducers currently on the market are not fully amenable to automated cleaning and disinfection processes (WDs pursuant to EN ISO 15883).
Therefore validated manual processes must be used based on standard operating procedures and porcessing instructions (SOPs). The disinfection step can be performed in suitable automated machines. Often, only the transducer head (distal end) can be disinfected in an automated machine. Manual disinfection of the connecting tube is therefore still required.

➜ **THE DISINFECTION PROCESS OF SEMI-CRITICAL TRANSDUCERS** must be bactericidal, fungicidal and virucidal.

➜ **CRITICAL C** devices are e.g. ultrasonic transducers used intraoperatively during invasive or minimally invasive procedures on organs and which, accordingly, must be sterile when used or be used with a sterile protective sheath (e.g. puncture ultrasonic transducers with guide channel for a puncture needle or ultrasonic transducers designed for robotic minimally invasive surgical procedures).

➜ **CRITICAL** devices are e.g. ultrasonic transducers used intraoperatively on organs and must be sterile when used.

➜ **THE DISINFECTION PROCESS** following cleaning (evidence of cleanliness through visual inspection) must be bactericidal, fungicidal and virucidal; the instructions of the disinfectant manufacturer must be observed.
Depending on the manufacturer's instructions, these ultrasonic transducers are reprocessed in automated, chemothermal cleaning and disinfection processes (WDs as per EN ISO 15883-4) or are subjected to manual cleaning and disinfection in accordance with the instructions of the device or process chemical manufacturer. In such cases these ultrasonic transducers must be sterilized using a low-temperature sterilization process (e.g. ethylene oxide gas, H_2O_2, LTSF, plasma sterilization).

➜ **THE DISINFECTION PROCESS OF CRITICAL TRANSDUCERS** must be bactericidal, fungicidal and virucidal.

➜ THE KRINKO/BFARM RECOMMENDATION claims the documentation of risk assessment and classification of the medical devices to be reprocessed.

3. Documentary obligations

Pursuant to the **➜ KRINKO/BFARM RECOMMENDATION [2]**, th results of the reprocessing process have to be documented in such a way that traceability is ensured. For Critical C medical devices traceability of the single instrument is required.
For all other risk groups traceability of the set denomination/set code is sufficient. One set can contain several MDs (e.g. in a basic set or tray) or one instrument only (e.g. needle holder in a sterilization pouch) [4]. ■

Table: Overview of reprocessing

	Non-critical	Semi-critical	Critical
Sheath	No	Yes	Yes
Wipe off gel	Yes	Yes	Yes
Manual/automated cleaning	Yes	Yes	Yes
Manual/automated disinfection	Yes	Yes	Yes
Disinfectant spectrum of action	A	AB	AB
Sterilization	No	No	Yes

References

1 according to DVV/RKI and the RKI Recommendation "Testing and declaration of virucidal efficacy of disinfectants for use in human medicine"
2 KRINKO/BfArM Recommendation: Hygiene requirements for processing of medical devices
3 "Since smear infections and cross-infections cannot be ruled out when handling the protective sheath, the transducer must be disinfected after each examination (after removal of the protective sheath) using a disinfectant endowed with bactericidal, fungicidal and virucidal efficacy".
4 Quality Task Group Recommendation No. 100 – Tracking the reprocessing process