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Best Practices in Reprocessing Surface Ultrasound Transducers in Ambulatory Care Settings

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Our accredited ambulatory organizations are always asking how to reprocess medical devices, especially ultrasound transducers.

What level of reprocessing is required? What if the manufacturer's instructions for use (IFU) indicate a level of reprocessing that does not match use of the transducer? What ultrasound transducer reprocessing practices are Joint Commission surveyors looking for?

Spaulding Classifications and Other Guidance Documents

As a first step, we always advise accredited organizations to review and follow this hierarchical approach. The infection prevention hierarchy is a systematic approach which, when followed, will ensure an organization has considered:

- local, state and federal regulations (which may require organizations to follow specific evidence-based guidance)

- The Centers for Medicare and Medicaid Services (CMS) Conditions for Coverage (CfCs)
- manufacturer's IFU for any specific product

Don't forget that ultrasound transducers are medical devices and, as such, regulated by the Food and Drug Administration (FDA). The FDA has published a guidance document specific for diagnostic ultrasound devices, which refers to another guidance document: *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*. This document uses the Spaulding Classification System to guide device manufacturers when developing reprocessing instructions for medical devices based on the intended use of the device. Reprocessing requirements depend on the intended use and that's based on the Spaulding classification, which is outlined below.

- If a transducer is used in a sterile body cavity or sterile tissues, it is considered a critical device and requires sterilization.
- If a transducer is used on non-intact skin or mucous membranes, such as a vaginal, rectal or oral, it is a semi-critical device and should undergo high-level disinfection.
- If a transducer is only used on intact skin, it is considered non-critical and, regardless of whether it is contaminated with blood, the minimum requirement is low-level or intermediate-level disinfection.
- If the transducer manufacturer reprocessing instructions indicate that an instrument should undergo high-level

disinfection if used to assist with percutaneous procedures or if contaminated with blood, the organization must follow the manufacturer's IFU unless they have evidence to negate that instruction from the manufacturer.

The Joint Commission expects all organizations to comply with instructions provided by the manufacturer based on intended use of the device.

Transducer Sheaths

Probe covers or transducer sheaths are also considered medical equipment and must follow FDA regulations. Transducer sheaths cannot be interchanged with items that have not been approved for barrier use (e.g., transparent IV dressings) and are intended to be used during procedures to protect the transducer from body fluids. Sheaths are applied to surface transducers, endocavity transducers or transducer probes used in surgical procedures.

Does using a transducer sheath negate the need to perform the minimum level of disinfection specified in the reprocessing instructions, as required by the manufacturer? This is a hot topic in ambulatory circles. However, the FDA has stated that use of a transducer sheath ***does not*** affect the Spaulding Classification of the transducer (as these sheaths may leak or tear) and therefore ***would not change the minimum level of reprocessing required*** for the transducer based on clinical use, unless otherwise indicated by the manufacturer.

That said, The Joint Commission recognizes there are times that the device manufacturer's instructions may not conform to rules about intended use (Spaulding Classification System) or may not provide enough information for the end user to determine the correct method for reprocessing. We ask that our accredited organizations contact the manufacturer in these instances and refrain from using the device until the situation is rectified.

It's not uncommon for manufacturer's representatives to offer alternative instructions if contacted. If this happens, please obtain those instructions in writing and present them at the time of survey.

Joint Commission Requirements

Even though The Joint Commission is understanding of situations requiring personalized advice from the manufacturer, we do still have specific requirements for ultrasound transducers and related equipment.

If the manufacturer requires a specific product, The Joint Commission surveyor will look for that product at a health care organization or expect the organization to have contacted and resolved any issue related to compatibility of products used. If the manufacturer requires a certain time or temperature for reprocessing,

The Joint Commission will expect the organization to establish a means and process to measure both. Accredited organizations could be cited for failure to:

- produce IFUs of medical equipment and devices reprocessed at the organization
- follow the steps of cleaning and reprocessing described in the IFU (if no steps have been taken to resolve deviation)
- use the products indicated in the IFU (unless compatibility of alternative products has been confirmed)
- provide adequate personal protective equipment to staff (per IFU and hazard assessment) to complete the reprocessing
- train or assess of competence for staff who perform those procedures

We recognize that this is an extremely challenging area for many of our accredited organizations. If you have a question that's not answered above and/or can't be answered by your account representative, please reach out to our Standards Interpretation Group by submitting a question online. Our Joint Commission experts are here to assist and help you prevent infections at your ambulatory care organization.

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