Point of care high-level disinfection for ultrasound probes

White paper

More than 140 million ultrasound procedures take place annually in the United States, making it one of the most common and versatile medical technologies[1].

High-level disinfection of ultrasound probes has evolved, with manual processes being replaced by automated systems that require less hands-on time and can be used at point of care.

With the right technology, ultrasound probes can be safely reprocessed without having to leave the room, avoiding the cost and complexities associated with probe transport.

For all point of care reprocessing, there are factors that facilities and healthcare staff should consider to maximize the safety and efficiency of disinfection workflows.

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The evolution of ultrasound probe reprocessing

As ultrasound devices become smaller and more portable, the role of ultrasound as a diagnostic tool at point of care is becoming more established. Point of care ultrasound (PoCUS) is an indispensable tool for triage and management in acute care environments like intensive care units and emergency departments.[2,3] Other specialties including obstetrics and gynecology, vascular surgery and interventional radiology also utilize PoCUS.[4-6]

As ultrasound exams are increasingly performed at the patient bedside, high-level disinfection (HLD) of ultrasound devices is also being performed at point of care.

Prior to the introduction of automated reprocessing technologies, HLD of ultrasound probes was routinely performed in a centralized location away from the patient examination room. The majority of guidelines and standards relating to centralized reprocessing of semi-critical devices are aimed at endoscopes, which are highly complex medical devices with intricate reprocessing requirements. Centralized reprocessing is also common due to the safety limitations of disinfection with bulk liquid disinfectants, requiring staff to wear extensive personal protective equipment (PPE).

Ultrasound probes and endoscopes differ significantly in design, clinical use and levels of contamination. These differences show that while centralized reprocessing is appropriate for endoscopes, ultrasound probes can be effectively processed at point of care. Additionally, automated technologies offer a safer option for point of care HLD that requires minimal PPE.

Applying Spaulding at point of care

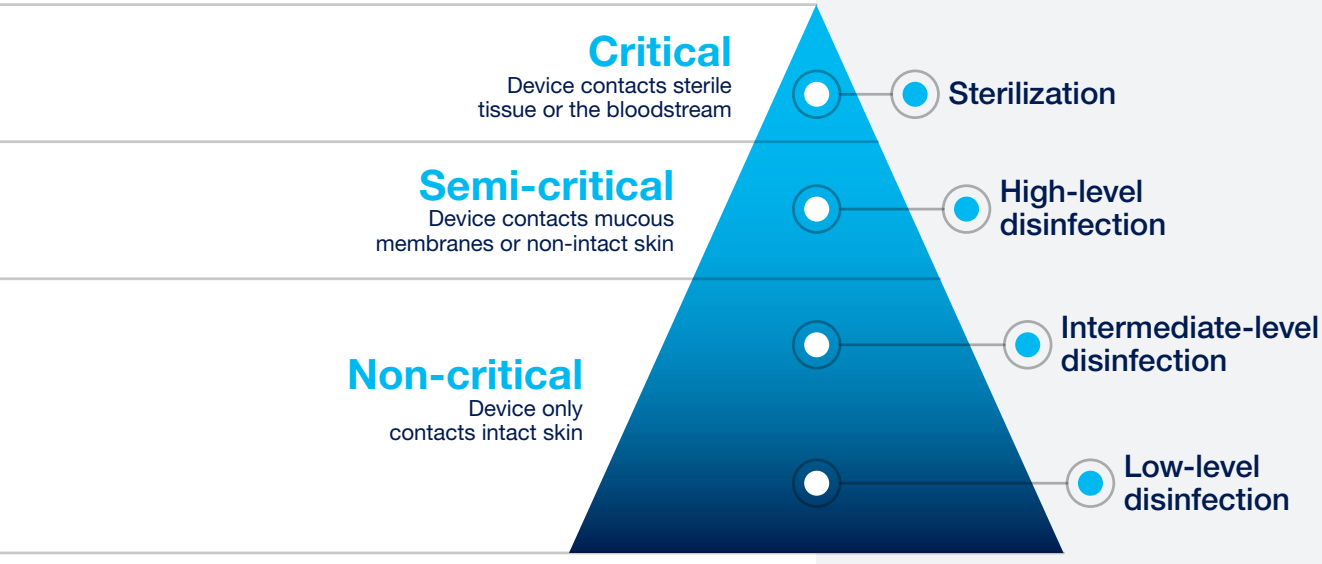
Effective reprocessing at point of care relies on applying the Spaulding classification to each ultrasound probe before use on a patient (Figure 1).

The Spaulding classification system is a clear and rational approach to disinfection and sterilization of medical devices that contact the patient. This universally accepted classification scheme has been retained, refined and successfully implemented in clinical settings for over 50 years. It also forms the basis of national standards and guidelines around medical device reprocessing.[7-12]

Spaulding divides infection transmission risk based on the type of patient tissue the device will contact during use. As advances in technology bring even greater clinical utility and portability to ultrasound probes, consistently applying Spaulding to each use of a probe remains essential. Ultrasound probes used at point of care can be shared between rooms, departments or operators, and used in a range of procedures requiring different levels of disinfection.

For example, the same probe might be used as a non-critical device in a diagnostic scan on intact skin, then later as a critical device during an invasive procedure. In the first scenario, the probe requires only low-level disinfection. But in the second procedure, the probe is classed as critical and requires high-level disinfection and the use of a sterile sheath at a minimum.[7,8]

Figure 1 (below). The Spaulding classification divides infection transmission risk based on the type of patient tissue the device will contact during use, which determines the level of disinfection.[7,8] If sterilization of critical devices is not possible, such as with ultrasound probes, they can minimally undergo HLD and be used with a sterile sheath.[8]



The Spaulding classification

Infection risk from ultrasound

Ultrasound probes contact a range of environmental and biological hazards during use, putting them at high risk of becoming contaminated with pathogens. A study in emergency rooms and intensive care units found that over 50% of ultrasound probes had blood contamination.[13] In other settings, over 90% of transvaginal ultrasound probes have been found to be contaminated with bacteria after use.[14,15] Even after low-level disinfection with wipes and sprays, probes can be contaminated with viruses and bacteria, including pathogens that can cause sexually transmitted infections like human papillomavirus (HPV) and *Chlamydia trachomatis*.[16,17]

A landmark epidemiological study by the Scottish health authority reported an increased risk of infection in the 30 days following an endocavitary ultrasound scan, where low-level disinfection was the practiced standard of care.[18] The study followed almost 1 million patient journeys retrospectively through linked national patient datasets between 2010 and 2016. Following the study, the Scottish government mandated high-level disinfection for semi-critical probes, including endocavitary probes.[10] This infection risk is not confined to endocavitary probes. Surface ultrasound probes are used in medical procedures that span all three categories under the Spaulding classification system (critical, semi-critical and non-critical) depending on the type of tissue that the probe contacts during use.

Consistently applying the Spaulding classification to each use of a surface probe is essential to prevent exposure to pathogens that can lead to infections and outbreaks. In 2021, an intraoperative probe was the source of an outbreak in patients undergoing hepatic surgeries.[19]

Inadequate reprocessing of the probe was identified as one of the contributing factors. Another study found that the use of ultrasound probes was associated with an increased risk of bloodstream infections when guiding central line insertions at the femoral and jugular sites.[20]

To break the chain of infection transmission, every patient must be assumed to be infectious.

Standardization of disinfection processes and workflows is key to ensure compliance with Spaulding and to protect patients from being exposed to infection risk.

Automation enables standardized point of care HLD

HLD of ultrasound probes at point of care should be successful every time to reproducibly protect the next patient from infection transmission. Manual HLD methods can be prone to human error. Automated reprocessing eliminates the variables inherent in manual methods and establishes traceable, reproducible processes. Automated processes are also validated to achieve their expected performance outcomes consistently every time. SDMS guidelines state that automated processes are preferable for ultrasound probe reprocessing because they reduce the risk of operator error.[21]

91% *of respondents from a national survey of infection preventionists preferred automated processes for probe reprocessing.*[22]

Figure 2. Snapshot of US guidelines on semi-critical medical device disinfection, including ultrasound probes.

The importance of traceability

The linking of reprocessing cycle records to a patient record, known as traceability, is an essential component of HLD for semi-critical devices. The keeping of essential documentation, including records of reprocessing and patient procedures, is a key consideration for PoCUS just as it is for centralized reprocessing.

Point of care reprocessing can simplify traceability by housing the examination and reprocessing in a single room. Sterilization and HLD of semi-critical and critical medical devices, including ultrasound probes, must have full traceability to the patient according to AAMI/ANSI ST58 and evidence-based guidelines.[11,23]

The Joint Commission also assesses HLD processes with reference to national standards.[24] Figure 3 shows a suggested minimum dataset to capture for ultrasound probe traceability.

Because of its portability and use at point of care, ultrasound presents unique challenges for traceability. It is essential to have traceability documentation for decision making about device recalls or patient notifications in outbreak settings. In an outbreak of *Serratia marcescens* attributed to an ultrasound probe used in a digestive surgery ward, 8 out of 9 patients who came into contact with the contaminated probe were infected.[19]

Traceability records were instrumental in identifying previously missed cases. An investigation identified several lapses including the absence of terminal disinfection after cleaning, lack of a sterile protective sheath and the use of a damaged probe. Following corrective measures, including the implementation of traceability practices, no further *S. marcescens* infections were reported.[19]

In non-outbreak settings, traceability allows facilities to demonstrate that they have met their duty of care to patients.

Incorporating digitization into traceability is the best way to ensure standardized information across the entire workflow. Digitization can reduce manual administrative burden, the risk of operator error, and incomplete record-keeping.

Figure 3. Traceability involves linking both a reprocessing record and procedure record to a medical device. A suggested dataset to be collected and linked to the patient for every high-level disinfection cycle is presented here. Adapted from AAMI ST58 and AORN guidelines.[11,23]

Safety considerations for ultrasound probe HLD at point of care

The ideal disinfection technology for use at point of care is an automated and fully enclosed system that requires minimal handling of the disinfectant, as this protects both patients and staff from being in contact with the active chemistry. Some chemicals used for HLD soaking, including glutaraldehyde (GTA) and ortho-phthaladehyde (OPA) can have toxic effects from regular exposure.

OPA causes acute inflammation, and case reports of healthcare workers experiencing respiratory problems or skin reactions have been published.[25-29] Regular exposure to GTA has been linked to a 2-fold increased risk of spontaneous abortion in pregnant healthcare workers, prompting a move towards a GTA-free reprocessing environment.[30]

When appropriate risk assessments and safety measures are considered in the design of clinical workflows, automated and enclosed HLD technologies offer point of care disinfection with less hands-on time, without the safety concerns of manual methods.

Streamlining and standardizing HLD workflows

In a centralized HLD workflow, both soiled and disinfected medical devices must be transported between the patient room and central sterile environment. Transport of ultrasound probes is not required with point of care reprocessing, saving time and reducing the risk of probe damage occurring during transport, as well as the risk of cross-contamination from dirty transportation containers.

Point of care reprocessing also minimizes the number of ultrasound probes in circulation, since the probe does not need to leave the patient room. In contrast, centralized workflows have greater time delays associated with probe turnaround, necessitating the need for expanded probe inventories at significant cost. In a point of care workflow, sonographers performing examinations are also able to perform reprocessing during room turnover time. This means there is no need for separate reprocessing staff, easing resource requirements.

One of the most important considerations for point of care HLD is the segregation of clean and dirty processes to prevent recontamination of clean probes. For manual HLD processes, this is often achieved through segregation of clean and dirty areas with physical barriers or demarcation of zones. In the patient room, the same outcome can be achieved by adopting a structured workflow. Under normal circumstances, the patient room becomes “dirty” during a patient stay or procedure and the room must be returned to a “clean” state ready for the next patient.

The use of automated technologies can streamline this segregation of dirty and clean processes. For example, handling of a dirty probe can occur only when the room is “dirty” (i.e. as the patient leaves the room), and handling of the clean probe then only occurs after the room has been turned over and is ready for the next patient (i.e. a “clean” state).

Furthermore, using single-use storage covers protects the probe by providing a barrier to contamination from handling and the environment. Use of these covers completes the clinical workflow for safe HLD at point of care.

Summary

As automated reprocessing solutions replace time-consuming manual processes, point of care HLD of ultrasound probes has become a safe and effective alternative to centralized methods.

When taking into account key considerations around technology, traceability, safety and workflows, point of care HLD can be an efficient and cost-effective way to prevent patients from the risk of infection.

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