Clinical Bulletin

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Support Document for 'When to HLD' Wall Chart

Ultrasound probe use has expanded across the continuum of clinical care to a growing number of diagnostic and therapeutic procedures. Selecting the level of disinfection required to reprocess an ultrasound probe for a patient examination is essential to mitigate infection risk and comply with accreditation requirements.

The Centers for Disease Control (CDC), the Association for the Advancement of Medical Instrumentation (AAMI) and the American National Standards Institute (ANSI) use the Spaulding classification of the medical device (e.g. ultrasound probe) to determine the level of disinfection that should be applied prior to a procedure.[1,2] Under the Spaulding classification, in general, a device is critical if it will contact sterile tissue or the bloodstream and it should be sterilized. Semi-critical devices will contact mucous membranes or non-intact skin and minimally require high level disinfection (HLD). Non-critical devices will only contact healthy, intact skin and minimally require low level disinfection (LLD). The classification was devised by Earle H. Spaulding based on the risk of infection associated with the use of the device and is adopted globally.[1, 2]

The US Centers for Medicare and Medicaid Services (CMS) surveys critical and semi-critical ultrasound probe disinfection practice during hospital infection control audits to ensure adherence to standards and guidelines.[3] These audits form the basis for accreditation with focus sections on reprocessing semi-critical

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equipment and reusable critical equipment, instruments and devices.[3] Other accreditation providers (e.g. TJC, AAAHC and DNV) apply similar standards.

Critical ultrasound probes contact sterile tissue including all internal body cavities, internal organs, blood and the vasculature. Critical probes include those used in intraoperative procedures, punctures and drainages. These probes should be sterilized under the Spaulding classification. However, ultrasound probes are heat sensitive and cannot be steam sterilized. While ethylene oxide and hydrogen peroxide sterilization is sometimes possible, these methods require the probe be removed from circulation for an extended period of time which is not conducive to high throughput workflows. The CDC guidelines specifically state that if a critical ultrasound probe cannot be sterilized, at a minimum the probe should undergo HLD and be used with a sterile probe cover and sterile gel.[1]

> "Ultrasound probes used during surgical procedures also can contact sterile body sites. These probes can be covered with a sterile sheath to reduce the level of contamination on the probe and reduce the risk for infection. However, because the sheath does not completely protect the probe, the probes should be sterilized between each patient use as with other critical items. If this is not possible, at a minimum the probe should be high-level disinfected and covered with a sterile probe cover."[1; page 19]

Semi-critical ultrasound probes include all intracavity probes as they contact mucous membranes, as well as probes that contact non-intact skin such as wounds, infected skin and rashes. Semi-critical intracavity probes include probes used in transvaginal scans and transrectal scans, and semi-critical surface probes include those used in wound scans, burn graft evaluations and scans on dermatitis affected skin. These probes should minimally undergo HLD and be used with a probe cover.[1]

It is important to note that use of a cover does not change the probe's Spaulding classification and therefore does not negate the requirement for HLD, since probe covers have significant perforation rates that are not always visually detectable:[1]

> "While use of the probe cover could be considered as changing the category, this guideline proposes use of a new condom/probe cover for the probe for each patient, and because condoms/probe covers can fail, the probe also should be high-level disinfected. The relevance of this recommendation is reinforced with the findings that sterile transvaginal ultrasound probe covers have a very high rate of perforations even before use (0%, 25%, and 65% perforations from three suppliers)."[1; page 19]

Non-critical ultrasound probes only include probes used to scan intact, healthy skin and minimally require disinfection with an LLD product prior to the procedure. HLD can still be performed on these probes if desired.

When selecting a disinfection product, it is important to consult the disinfectant manufacturer's instructions for use (IFU) for the list of compatible ultrasound probe models to ensure your probes are compatible with the reprocessing procedure.[2]
It is equally important to consult the ultrasound probe manufacturer's IFU regarding instructions on reprocessing methods and compatible disinfection products. Failure to do so could lead to probe damage:[2]

> "Health care personnel should follow the device manufacturer's written IFU, which should include… b) instructions for compatibility and processing high-level disinfection or sterilization; …d) identification of chemicals or cleaning and disinfectant products known to be compatible or incompatible with the device or its materials."[2; page 39]

> "Health care personnel should follow the LCS/HLD manufacturer's written IFU, which should include… b) identification of materials, devices or soaking or storage trays known to be incompatible with the LCS/HLD."[2; page 39]

> "The LCS/HLD manufacturer's written IFU describe the processing procedures and parameters that have been validated by the manufacturer…Using nonvalidated processing conditions can jeopardize the effectiveness of the liquid chemical sterilization or high-level disinfection process or the performance of the medical device."[2; page 39]

HLD of ultrasound probes will prepare the probe for any subsequent patient procedure in accordance with US guidance and regulation, as long as sterile probe covers and sterile gel are readily available. HLD ensures patient safety by meeting the disinfection requirements for ultrasound probes.

When to HLD with trophon®

WHAT PROCEDURE WILL YOUR PROBE BE USED FOR?

Procedure

Probe may contact sterile tissue or blood

Spaulding Classification

Critical

- intraoperative procedures
- drainages
- biopsies
- needle guidance
- transvaginal oocyte retrieval
- venous catheter placement
- vascular ablation

Disinfection / Sterilization Requirements

Sterilize* or HLD

Probe may contact mucous membranes and non intact skin

Spaulding Classification

Semi-Critical

Intracavity

- transvaginal scans
- transrectal scans

Surface ultrasound (broken skin)

- wound scanning
- burn evaluation

Disinfection / Sterilization Requirements

HLD

Probe may contact healthy, intact skin

Spaulding Classification

Non-Critical

- surface ultrasound (intact skin)

Disinfection / Sterilization Requirements

LLD or HLD

PROBE IS READY FOR PROCEDURE

*Critical probes should be sterilized, or can also be high level disinfected and used with a sterile sheath. Note: The use of a sheath does not negate the need for HLD.[1]

Making the choice simple

For outstanding ultrasound probe HLD compliance.

References: 1. Centers for Disease Control (CDC). Guideline for Disinfection and Sterilization in Healthcare Facilities. CDC; 2008. **2.** American National Standards Institute (ANSI) and Association for the Advancement of Medical Instrumentation (AAMI). ANSI/AAMI ST58:2013. Chemical sterilization and high-level disinfection in health care facilities. **3.** Centers for Medicare and Medicaid Services (CMS). CMS Hospital Infection Control Worksheet 2015, Sections 3A and 3B. Available at: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-15-12-Attachment-1.pdf (Accessed February 2017).

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