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Evaluations & Guidance - Guidance

Cleaning and Disinfecting Diagnostic Ultrasound Transducers: Our Recommendations

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EXECUTIVE SUMMARY

The use of diagnostic ultrasound imaging continues to expand beyond the conventional settings of radiology, cardiology, and obstetrics. Point-of-care ultrasound (POCUS) is widely utilized at the bedside throughout hospitals, as well as in physician offices and clinics. Because they are not imaging specialists, POCUS users, especially new ones, may have little experience with cleaning ultrasound transducers. It is essential that all users of ultrasound be familiar with, and utilize, the appropriate methods to clean and reprocess transducers between exams to comply with clinical guidelines and to avoid placing patients and users at risk for cross-contamination.

Ultrasound transducers, also referred to as probes, are classified as noncritical, semicritical, or critical, based on their clinical applications and potential for cross-contamination. Noncritical transducers, such as models used for abdominal, obstetric, and other exams on intact skin, must be cleaned after each use. Semicritical transducers, such as models used for endovaginal and endorectal applications, require high-level disinfection (HLD) after each use. Critical transducers, such as transesophageal echocardiography and laparoscopic transducers, require sterilization.

Automated ultrasound transducer reprocessors are closed systems for HLD that offer several advantages over manual disinfection methods. These devices can be used in many settings where POCUS is practiced, such as an emergency department or private physician office.

Transducers should be stored in a clean environment between uses to protect them from damage or contamination. The storage method should comply with manufacturers' recommendations.

Understanding the Cleaning Requirements of Your Transducers

The use of diagnostic ultrasound imaging has expanded beyond the conventional settings of radiology, cardiology, obstetrics, and vascular imaging. Point-of-care ultrasound (POCUS) is now widely utilized at the bedside throughout hospitals as well as in physician offices and clinics, and it has become an essential tool for aiding diagnoses and guiding interventions in settings such as emergency departments, anesthesia, and orthopedics. Because they are not imaging specialists, POCUS users, especially new ones, may have little experience with cleaning ultrasound transducers, also referred to as probes. It is critical that all users of ultrasound be familiar with, and utilize, the appropriate methods to clean and reprocess transducers between exams to comply with clinical guidelines and to avoid placing patients and users at risk for cross-contamination.

The Spaulding scheme (CDC 2017) is used to classify medical equipment, including ultrasound probes, based on each device's clinical applications and potential for cross-contamination; a device's category determines what level of reprocessing is required. Three categories are defined:

1. Noncritical—Applies to transducers that come in contact only with intact skin. These are sometimes referred

to as external transducers. Examples include transducers used for abdominal, cardiac, obstetric, vascular, and small parts applications when the patient's skin is intact in the region of examination.

2. Semicritical—Applies to transducers that come in contact with internal mucosal surfaces such as the vagina, esophagus, or rectal vault, and any probe that is used to scan patients who have open wounds. Examples include transducers used for endovaginal (EV) obstetrics and gynecology, transesophageal echocardiography (TEE), and endorectal (ER) prostate applications, as well as external probes used to scan patients who have open wounds in the region of examination.

3. Critical—Applies to transducers used in sterile body cavities. Examples include intraoperative hockey-stick-style, laparoscopic, and intravascular ultrasound (IVUS) transducers. Transducers and needle guides used for interventional procedures are also considered critical devices because they may come in contact with needles and other instruments that penetrate sterile tissue.

Recommendations

The table below presents a summary of our recommendations for the different transducer use categories defined above, covering three areas: use of transducer covers during exams, transducer cleaning/disinfection/sterilization, and transducer storage. Following the table is a more detailed discussion of our recommendations.

Summary of Recommendations, by Transducer Use Category

Category	Precautions during Use	Cleaning and Disinfection Recommendations	Storage
Noncritical	No special precautions	Cleaning and low-level disinfection (LLD)	Hung vertically on a covered rack or in a dedicated probe storage cabinet
Semicritical—EV and ER	Probe cover or condom	Cleaning and HLD	Hung vertically on a covered rack or in a dedicated probe storage cabinet
Semicritical—Non-intact skin and TEE	Form-fitting sterile probe cover	Cleaning and HLD	Hung vertically on a covered rack or in a dedicated probe storage cabinet
Critical	Sterile probe cover that extends to the connector	Cleaning and sterilization (chemical sterilization for probes that cannot be steam sterilized)	Stored in a sterile package

Covers

1. Noncritical probes do not require covers during examinations.

2. Semicritical probes

a) Probes used for EV or ER applications should be covered during use with a commercially available, disposable probe cover or a nonlubricated and nonmedicated condom. The cover should not interfere with the use of the biopsy needle guide.

b) A sterile, form-fitting, disposable cover should be used on TEE, intraoperative, and laparoscopic probes, as well as any probes used to scan patients who have open wounds in the region of examination.

3. Critical probes used intraoperatively and for interventional applications, such as transcutaneous biopsies, should be covered during use with a sterile, disposable probe cover that extends over the cable to prevent contamination of the sterile field.

4. The use of probe covers does not replace the need for HLD or sterilization of the probe after each use.

5. At the completion of the exam, the user should remove the probe cover, using caution not to allow the outside of the cover to contaminate the probe or surrounding surfaces, and should discard it as infectious waste.

Cleaning, Disinfection, and Sterilization

General Precautions

1. Consult your infection control specialists regarding their facility's relevant policies and procedures.

2. Employ universal precautions during examinations and throughout probe reprocessing. For example, wear appropriate personal protective equipment (PPE) when working with cleaning solutions and HLD disinfectants.

3. Use only probe-vendor-approved cleaning, HLD, and sterilization products and procedures as can be found in the instructions for use (IFU) or operator manual. The approved products vary between vendors and may also vary between different probe models from the same vendor.

Cleaning and Low-Level Disinfection

All ultrasound probes must be cleaned after each patient. The general cleaning process is as follows:

1. Remove the transducer connector from the scanner, then preclean the probe by rinsing it under running water to remove residual gel and organic matter.

2. Thoroughly clean the probe using a nonabrasive liquid soap on a damp, soft cloth or gauze pad.

a) Use a blotting motion to clean the surface of the probe from which ultrasound is transmitted and received, sometimes referred to as the lens, and do not use a vigorous wiping motion that could damage the surface. ECRI Institute has received a report of damage to ultrasound probes resulting from the use of hospital towels that the vendor considered too abrasive for cleaning probes.

b) If necessary, use a soft-bristle brush to remove gel and debris from within crevices on the probe.

3. If the probe was used for an interventional procedure, clean the needle guide and ensure that there is no residual organic matter or gel.

4. Rinse the probe thoroughly with running water, and then dry the probe with a soft cloth or soft paper towels.

5. Visually inspect the probe and needle channels to confirm they are clean.

6. Wipe the probe with a probe-compatible low-level disinfection (LLD) quaternary ammonium-, hydrogen peroxide-, or bleach-based wipe, or with a soft cloth sprayed with one of those disinfectants.

a) Although LLD products are commonly used as an alternative to cleaning with soap and water, we recommend that they be used in addition to soap and water.

b) Users should follow the LLD product manufacturer's IFU, including the wet time, to ensure effectiveness.

7. Ensure that the probe is dry before storing or using.

High-Level Disinfection

The HLD process can be performed either manually using a commercially available germicidal soak, or automatically with an automated probe reprocessor (for more information on these devices, see About Automated Probe Reprocessors for HLD below). An initial precleaning step, carried out at the point of care to remove gel and contaminants, is recommended if the probe is not going to be reprocessed immediately. Doing this as soon as possible after use will help prevent gel and contaminants from drying on the probe, which can make the device more difficult to clean and reduce the effectiveness of HLD.

Once transported to the reprocessing room, and prior to undergoing HLD, the probe must be properly cleaned and dried, as described in the Cleaning and Low-Level Disinfection discussion above, because:

1. Commonly used chemical disinfectants act more quickly on clean, dry surfaces.
2. Residual gel or organic matter on the probe can create a barrier to the disinfectant and reduces its efficacy.
3. Residual rinse water remaining on the probe can dilute the disinfectant solution.

FDA has a list of approved sterilants and HLD products. The specific steps used for HLD vary depending on the products used and facility policies and procedures. It is imperative that users follow the disinfecting solution IFU, as well as the probe manufacturer's cleaning and HLD instructions. Additionally, users should consider the following aspects of the process:

1. Disinfectant solutions

    a) Disinfectants used for HLD release toxic fumes. The space used for HLD must be properly ventilated to prevent harmful exposure to these fumes by staff and patients. Before selecting an HLD product, users should review its Safety Data Sheet and make sure that their facility can meet the necessary conditions to minimize exposure to potentially toxic solutions and fumes.

    b) Most high-level disinfectants are reusable for a specified period of time. A minimum recommended concentration (MRC) test should be performed prior to use, to confirm that the disinfectant continues to meet the vendor's specifications.

    c) To achieve HLD, soak probes for the period of time and at the temperature recommended by the HLD solution vendor.

    d) After HLD, it is important to thoroughly rinse the probe to ensure that no residual HLD solution remains.

    e) Observe local requirements pertaining to disposal of HLD solutions. Some require facilities to neutralize the solution before disposal.

2. Disinfecting probes

    a) Some probes and their cables can be submerged in HLD solutions up to the connector. However, some vendors allow only the probe or a portion of the probe to be submerged. Whenever possible, the entire

probe, including the handle, should be disinfected. Consult the probe's IFU to determine what parts can be submerged.

b) Do not allow the probe lens to rest against the bottom of the basin during HLD because this can damage the probe surface.

c) If the probe has built-in needle guide channels, thoroughly clean the channels before HLD.

d) After HLD, the portions of the probe that were disinfected should not come in contact with the cable or connector, in order to avoid recontamination. Review handling processes to prevent such contact.

Sterilization

1. Ultrasound probes used for intraoperative and interventional applications should be sterilized after each use. Chemical sterilization can be accomplished using solutions approved for sterilization as listed in the FDA document linked above. However, chemical sterilization typically requires a much longer soak time than HLD and should be done only if the probe IFU include sterilization procedures.

2. Some probes that are designed for intraoperative applications, such as laparoscopic probes, can be steam sterilized. However, most probes are heat sensitive and therefore cannot be sterilized using steam. These probes must be reprocessed using liquid chemical sterilants.

3. Probes that cannot be sterilized using steam or chemicals should undergo HLD and be covered with a form-fitting sterile cover during use.

4. As stated above, it is imperative that users adhere to the probe vendor's IFU in terms of the sterilant and HLD solutions and processes used.

5. Follow the HLD recommendations above regarding disinfecting solutions and probes when performing chemical sterilization.

Storage

Transducers should be stored in a clean environment between uses to protect them from damage or contamination, and the storage method should comply with manufacturers' recommendations (Joint Commission). Probes can be stored in a commercially available enclosed transducer storage cabinet or hung vertically on a covered rack.

1. Ensure that probes are completely dry before storing them, to minimize microbial growth.

2. Do not store probes in plastic bags, or their original shipping case, which can harbor condensation that can lead to microbial growth.

3. After HLD, do not allow portions of the probe that have been disinfected to come in contact with surfaces, including the probe cable or storage rack, that have not been disinfected.

4. Develop policies and procedures regarding tracking HLD or sterilization of probes.

5. Keep sterilized probes in the sealed package to maintain sterility.

About Automated Probe Reprocessors for HLD

Automated ultrasound probe reprocessors are closed systems for HLD that typically do not require special plumbing or ventilation, which makes them attractive for use in many settings where POCUS is practiced, such as an emergency department or private physician office. ECRI Institute has seen an increase in our members' interest

in automated reprocessors (ECRI Institute 2017). We consider these systems to be an acceptable alternative to the manual method for HLD.

Although their cost may be a deterrent, these systems offer several potential advantages over manual HLD, including:

1. They are easier to use.
2. There is no risk of spilling HLD solutions.
3. They eliminate fumes that are toxic to staff and the environment.
4. Disinfecting times are shortened.
5. Disinfection efficacy is improved.

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Information Type

Guidance

UMDNS

Scanning Systems, Ultrasonic, Cardiac [17-422]
Scanning Systems, Ultrasonic, Intravascular [17-746]
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